ILUMIEN™ OPTIS™ System
Instructions for Use

ST. JUDE MEDICAL

Information provided within this Document is subject to change without notice and although believed to be accurate, St. Jude Medical, Inc. and its affiliated companies including without limitation, St. Jude Medical System AB (Sweden), assume no responsibility for any errors, omissions or inaccuracies.

ILUMIEN OPTIS systems are subject to US Patent 8,325,419, GB, FR 0883793, DE 69738291. ILUMIEN, OPTIS, ST. JUDE MEDICAL, LIGHTLAB IMAGING, GOLDEN IMAGE and the color gold are registered or unregistered trademarks of St. Jude Medical, Inc. and its related companies.

ILUMIEN OPTIS systems enabled for FFR may also be subject to US Patent 6,565,514.

The ILUMIEN OPTIS system software incorporates third party licensed software as described at the following URL: www.sjmprofessional.com/ilumien-legal-notices

EC REP

St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem Belgium
+32 2 774 68 11

CE 0086

Australian Sponsor:
St. Jude Medical Australia Pty Limited
17 Orion Rd.,
Lane Cove NSW 2066 Australia
+61 2 9936 1200

LightLab Imaging, Inc.
4 Robbins Road
Westford, MA 01886
USA

Phone: +1 800 544 1664 (US)
+1 651 490 4410 (Outside US)

www.sjm.com

Service E-mail: OCTservice@sjm.com

Part Number ARTUS100088927

ENGLISH

Printed in the U.S.A. 3 / 2013

CAUTION: Federal law restricts this device to sale by or on the order of a Physician licensed by law of the state in which he practices to use or order the use of the device.

SAFETY INFORMATION

Please review this manual carefully before using your ILUMIEN OPTIS System, especially the safety information in Chapter 11 “Safety Information”. Also, especially note Warnings and Cautions shown throughout the manual.

WARNINGS

Electrical Shock Hazard

Do not remove ILUMIEN OPTIS System covers. To avoid electrical shock, use only the power cord supplied with the system and connect only to properly grounded wall outlets. See Chapter 2 “System Setup” and Chapter 11 “Safety Information” for electrical safety information.

Explosion Hazard

Do not operate the ILUMIEN OPTIS System in the presence of flammable anesthetics. Doing so could lead to an explosion.

Visible and Invisible Laser Radiation

Do not stare into the beam or view the beam directly with optical instruments. Doing so may cause serious eye damage and hazardous radiation exposure.

Using These Instructions for Use

This manual describes the St. Jude Medical ILUMIEN OPTIS System. In it you will find:

- Descriptions of system components and user interface.
- Procedures for using the system for both Optical Coherence Tomography (OCT) and Fractional Flow Reserve Rate (FFR) procedures.
- System safety and cleaning information.
- System specifications.

Conventions Used in These Instructions for Use

- These abbreviations and shortened expressions are used throughout this manual.

Table Front-1: Instructions for Use Conventions

Dialog Box or Menu	A window that solicits a user response.
Click or Left-click	Click the left mouse button.
Double-click	Click the left mouse button twice in quick succession.
Select	Highlight a menu item with the mouse or the tab or arrow keys.

- Software text, and physical button labels are shown in bold type. Examples: the **Patient Summary** menu, **Settings** button.
- Keyboard keys are shown enclosed in carets. Examples: <Enter>, <Ctrl>, <Tab>.
- Warnings, Cautions, and Notes are set apart from other text and appear as shown below.

WARNING: Warnings alert the user to the possibility of injury, death, or other serious adverse reactions associated with product use or misuse.

CAUTION: Cautions alert the user to the possibility of a problem with the product associated with its use or misuse. Problems can include product malfunctions, product failure, and/or damage to the product or damage to other property, or loss of data.

NOTE: Notes provide additional information.

Other Instructions for Use

Details of the imaging catheter are covered in the *Dragonfly Imaging Catheter Instructions for Use* provided with the catheters and are not covered in this manual.

Details of the PressureWire are covered in the *PressureWire Instructions for Use* and are not covered in this manual.

NOTE: Additionally, this manual does not provide detailed discussion of the system components, except as they are used with the ILUMIEN OPTIS System.

Contents

Figures

Tables

System Overview

System Setup

Opening a Patient Record

Performing an FFR Procedure

Performing an OCT Procedure

Reviewing OCT Recordings

Measurements and Annotations

Exporting, Importing, and Managing Files

Cleaning & Maintenance

User Interface Reference

Safety Information

System Specifications

Index

Figures

Tables

System Overview 1

ILUMIEN OPTIS System Features

Optical Coherence Tomography (OCT) is an imaging modality that uses fiber-optic technology. The ILUMIEN OPTIS System uses optical imaging catheters that emit near-infrared light to produce high-resolution real-time images. The frequency and bandwidth characteristics of the near-infrared light used in these systems result in image resolution that is superior to typical medical ultrasound images..

Fractional Flow Reserve (FFR) is the ratio of distal coronary arterial pressure to aortic pressure, 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. The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated. This functionality is achieved when the ILUMIEN OPTIS System is used in conjunction with the manufacturer's wireless distal intracoronary pressure transducer and a proximal aortic pressure transducer.

NOTE: Fractional Flow Reserve is an optional feature, and must be activated on your system. See your St. Jude Medical service representative for more information.

CAUTION: **Medical personnel who use the ILUMIEN OPTIS System must be aware of the system's limitations. Only trained operators can determine if use of the ILUMIEN OPTIS System is appropriate. Be sure to read Chapter 11 "Safety Information", before operating the ILUMIEN OPTIS System for the first time.**

ILUMIEN OPTIS System Components

The ILUMIEN OPTIS System includes the following components, integrated into a mobile cart:

- An imaging engine.
- Two monitors.
- A Drive-motor and Optical Controller (DOC).
- An isolation transformer.
- Aortic pressure and PressureWire receivers.
- A computer, a keyboard, and a mouse.[1]
- A power cable.

NOTE: Use only the power cable and accessories provided with the system. Use of other cables or accessories may negatively affect EMC performance.

NOTE: FFR procedures require you to have a Wi-Box installed in your cathlab. See your St. Jude Medical service representative for more information.

CAUTION: **The above components are integral parts of the ILUMIEN OPTIS System. 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. See your St. Jude Medical service representative for more information.**

See Chapter 12 “System Specifications” for more information on system components.

1. Brands and models of components may vary from those shown in this manual.

ILUMIEN OPTIS System Accessories

- PressureWire
- Wi-Box
- C7 Dragonfly™ imaging catheter or Dragonfly™ Duo imaging catheter
- Sterile DOC Cover

NOTE: See your sales representative for order numbers of accessories in your market.

ILUMIEN OPTIS System - Physician Side

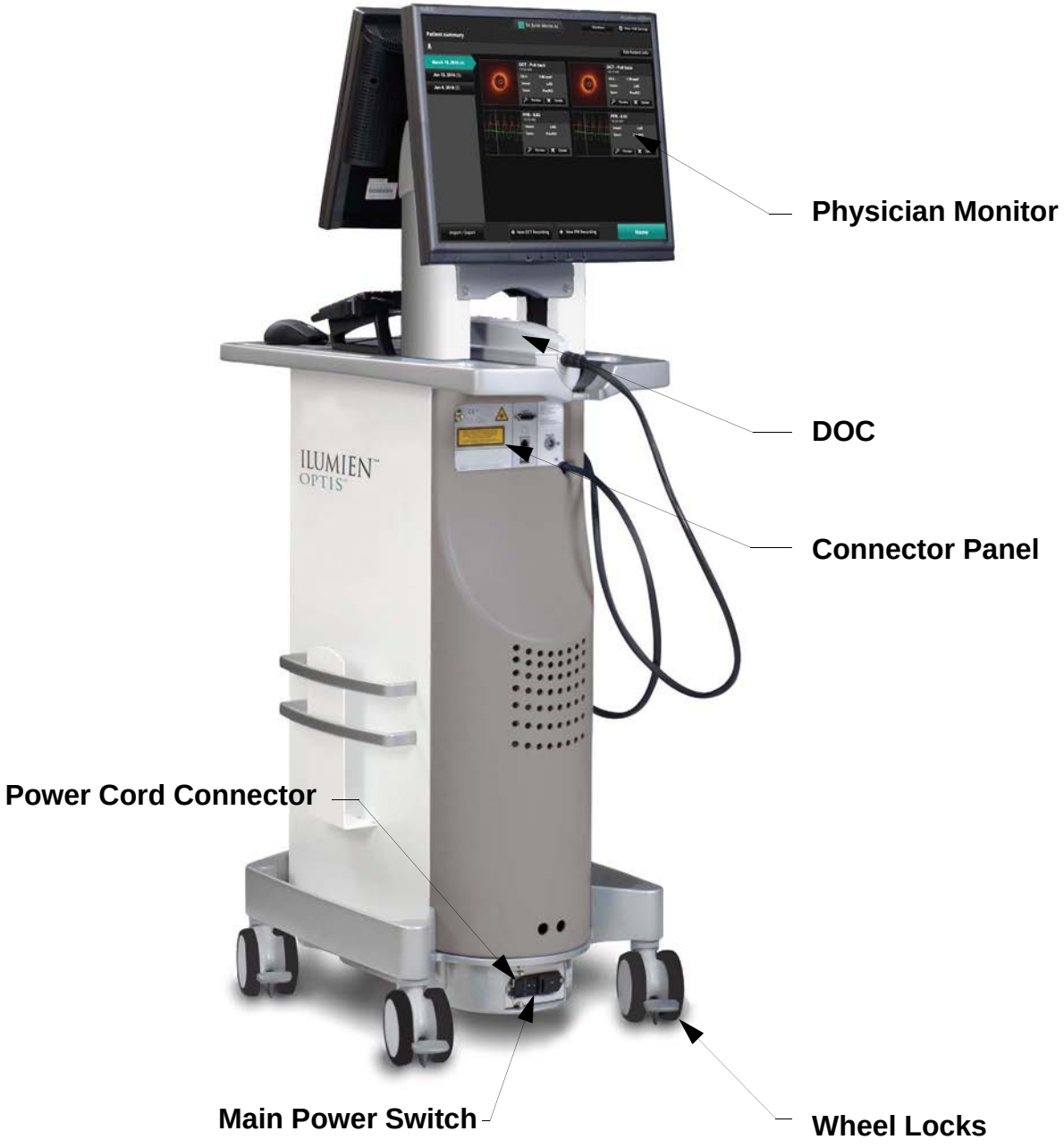


Figure 1-1: ILUMIEN OPTIS System - Physician Side

ILUMIEN OPTIS System - Operator Side

Figure 1-2: ILUMIEN OPTIS System - Operator Side

ILUMIEN OPTIS System - Connector Panel

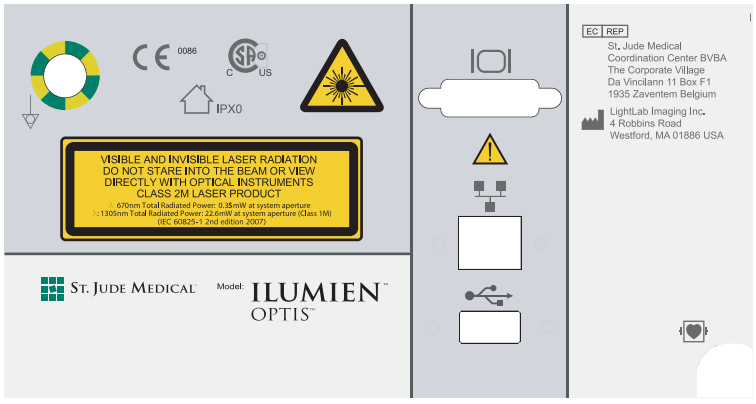


Figure 1-3: ILUMIEN OPTIS System Connector Panel

ILUMIEN OPTIS Symbols

Before using the system, read these Instructions for Use carefully, including the identification of symbols used on the equipment.

Table 1-1: Symbols Description

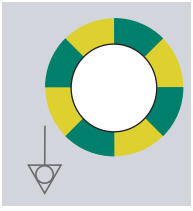
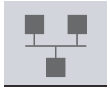
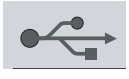
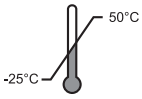
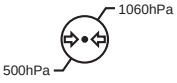
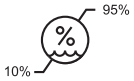
	Equipotential Grounding Post - For a secondary ground connection between equipment.
	European Conformance, BSI Notified Body (British Standards Institution)
	Indoor use only. No protection against ingress of water.
	CSA International testing laboratory
	Laser hazard symbol - marks a device which produces visible and invisible laser radiation.
	**VIDEO:** For connecting an external video monitor. 1280 x 1024 pixel image. Any monitor being connected must be capable of displaying that resolution. If the monitor is not automatically detected, see "Using an External Monitor" on page 2-6 to configure the system. **NOTE:** Only monitors with DVI or VGA inputs and cables are supported. **WARNING: If the 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.**
	**ATTENTION!**: consult accompanying documents.
	**NETWORK:** For connecting to a remote DICOM Store through a network (see the DICOM Setup menus in Chapter 10 "User Interface Reference").
	**USB**: For connection of external storage devices (see "USB Connected Media" on page 8-2). **WARNING: If the USB device is being used in the patient vicinity it must be port powered or it may compromise electrical isolation and cause patient injury.**

Table 1-1: Symbols Description *(continued)*

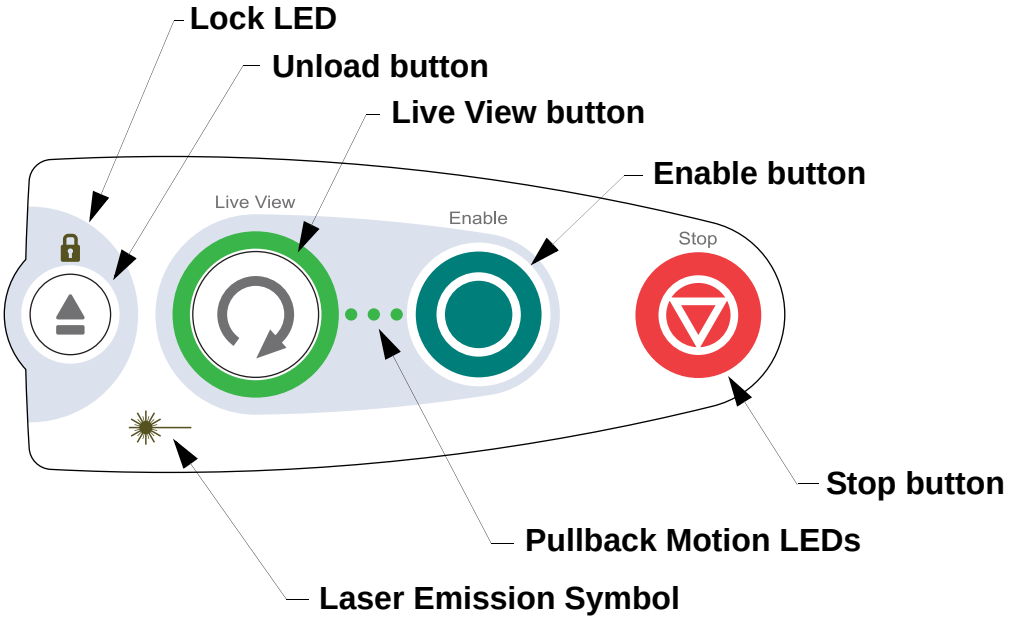
	Type CF, defibrillator-proof. Suitable for all patient applications including direct cardiac applications.
	Do not push the system from the monitors or monitor support mount. See "Moving the System" on page 11-4 for all safety instructions on moving the system.
	Temperature Range (Shipping label)
	Atmospheric Range (Shipping label)
	Humidity Range (Shipping label)

WARNING: All connections to the ILUMIEN OPTIS System 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.

The Drive-motor and Optical Controller (DOC)

The Drive-motor and Optical Controller (DOC) provides bed-side control of the most important OCT imaging functions. Refer to "Preparing to Acquire OCT Recordings" on page 5-6 for Dragonfly Imaging Catheter connection details.

Table 1-2: DOC Controls



Lock LED	• **Off** when the imaging catheter is not loaded. • **Blinking** when loading or unloading the imaging catheter. • **On** when the imaging catheter is loaded.
Unload	Press to unload the imaging catheter.
Live View	Press to switch between Standby View and Live View. When the button is lit in green, the system is in Live View. When the button is blinking, the system is enabled to begin a pullback recording. **NOTE:** If the **Recording Type** is set to **Stationary**, this button does not blink.
Enable	Press to enable recording.
Stop	Press to stop imaging catheter motion and turn off laser output.
Pullback Motion LEDs	• **Off** when the imaging catheter is stationary. • **Blinks** during pullback.
Laser Emission Symbol	Illuminated when laser output is on (whenever the system is in Live scanning mode).

The Wi-Box

The Wi-Box is installed in your cathlab between your Hemodynamic Recording System and the AO Transducer. The position of the Wi-Box in a cathlab is shown in Figure 1-4.

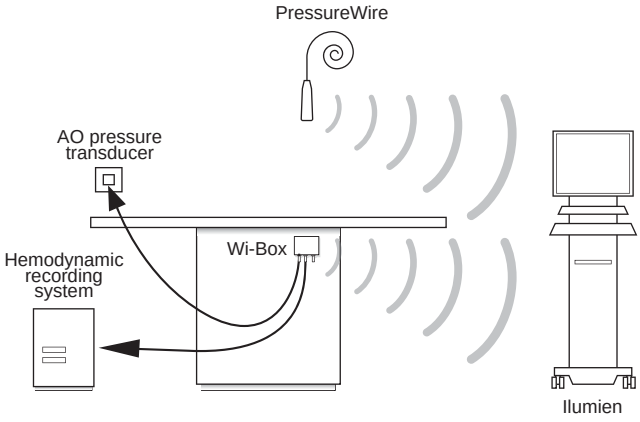


Figure 1-4: Wi-Box in cathlab configuration

The wireless connection to your Wi-Box is made during setup for your procedure. See “Setting up the Wi-Box with the Ilumien Optis System” on page 4-3 for more information.

Indications for Use and Intended Use

The ILUMIEN OPTIS Imaging System with Dragonfly Imaging Catheter is intended for the imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. The Dragonfly Imaging Catheter is intended for use in vessels 2.0 to 3.5 mm in diameter. The Dragonfly 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 ILUMIEN OPTIS Imaging System will further acquire radio frequency signal outputs from both a distal intracoronary pressure transducer and a proximal aortic pressure transducer to determine the physiological parameter, Fractional Flow Reserve (FFR). The physician may use the FFR parameter, along with knowledge of patient history, medical expertise and clinical judgment to determine if therapeutic intervention is indicated.

CAUTION: The ILUMIEN OPTIS System is intended for use by appropriate medical personnel who have received ILUMIEN OPTIS training. St. Jude Medical and its employees cannot give instructions in the interpretation or diagnosis of recordings and makes no attempt to do so.

WARNING: Prior to use, please review the *Instructions for Use* supplied with the Dragonfly Imaging Catheter and with the PressureWire for more information.

Contraindications

Use of the St. Jude Medical ILUMIEN OPTIS System is contraindicated where introduction of any catheter would constitute a threat to patient safety.

Contraindications (listed alphabetically) include:

- Bacteremia or sepsis
- Major coagulation system abnormalities
- Patients diagnosed with coronary artery spasm
- Patients disqualified for CABG surgery
- Patients disqualified for PTCA
- Severe hemodynamic instability or shock
- Total occlusion
- Large thrombus
- Acute renal failure

NOTE: The system has no patient alarm functions. Do not use for cardiac monitoring.

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.
- Leave the guidewire engaged with the catheter at all times during use. Do not withdraw or advance the guidewire prior to withdrawing the catheter.
- 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 catheter and guidewire together.
- The catheter should never be forced into lumens that are narrower than the catheter body or forced through a tight or heavily calcified lesion.
- The catheter should not be advanced through abnormally tortuous anatomy.
- When advancing or retracting a catheter with a minirail tip through a stented vessel, the catheter may engage the stent between the junction of the catheter and guidewire, resulting in entrapment of catheter/guidewire, catheter tip separation, and/or stent dislocation.
- Refer to the contrast media's instructions-for-use for general warnings and precautions relating to use of the contrast media.

CAUTION: Before creating an OCT recording, review Chapter 5 "Performing an OCT Procedure" for additional warnings and cautions.

Precautions (OCT)

- 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.
- All operators must be trained prior to using the ILUMIEN OPTIS System and the Dragonfly Imaging Catheter.
- Only 100% contrast media is approved for human use.
- Store the catheter at ambient temperature in a dry location out of direct sunlight.
- Never attempt to attach or detach a catheter to the DOC while the “lock” LED is lit.
- Do not kink, sharply bend, pinch, or crush the catheter at any time.
- The catheter is for single use only. Do not reuse, re-sterilize, or reprocess.
- The 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.
- After use, the catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.
- The catheter has no user serviceable parts. Do not attempt to repair or alter any part of the catheter assembly as provided.

Complications (OCT)

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

- Acute myocardial infarction or unstable angina
- Allergic reaction to the contrast media
- Arterial dissection, injury, or perforation
- Cardiac arrhythmias
- Coronary artery spasm
- Death
- Embolism
- Thrombus formation

Warnings and Precautions (FFR)

CAUTION: Before beginning an FFR procedure, review the *PressureWire Instructions for Use*. Details of the PressureWire are covered in the *PressureWire Instructions for Use* and are not covered in this manual.

CAUTION: Patients with potential microvascular dysfunction and borderline FFR 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.

Connecting to External Equipment/Accessories

WARNING: When used in the patient environment, all equipment connected to the ILUMIEN OPTIS System 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.
CAUTION: No connections to other systems or components are to be made to the ILUMIEN OPTIS System 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 60601-1-1, Safety requirements for medical electrical systems. Any person who connects external equipment to the ILUMIEN OPTIS system has formed a medical system and is therefore responsible for compliance of the system with the requirements of IEC 60601-1-1. If in doubt contact a qualified technician. Only PressureWire and Wi-Box are intended to be used with the ILUMIEN OPTIS System wireless receivers.

Mechanical Enclosure

WARNING: Do not use the ILUMIEN OPTIS System 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.
CAUTION: Ensure that all ventilation holes are unblocked or else system overheating and false readings may occur.

Electrical

WARNING: The mains 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 ILUMIEN OPTIS System. 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 and the ILUMIEN OPTIS System.

Electronic Interference

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

Aortic Reference Pressure

CAUTION: Check that the monitor cables and AO adapter delivered with the ILUMIEN OPTIS System interface are compatible with the cathlab system to be used. The Aortic Pressure Transducer (AO) should be in accordance with ANSI/AAMI BP22-1994.
Once the lab monitor system has been zeroed, use only the ILUMIEN OPTIS System to calibrate the aortic pressure transducer and PressureWire.

Pressure Averaging (Mean Setting)

CAUTION: Choice of excessively high number of heartbeats may result in insensitive pressure averaging (noticeable when there is a short hyperemic plateau). Choice of excessively low number of heartbeats may result in pressure averaging, which are overly sensitive to arrhythmia and pressure disturbances. An insensitive or overly sensitive mean average of pressure may result in an incorrect FFR value.

Defibrillation

CAUTION: The ILUMIEN OPTIS System is a CF Class I equipment and protected against the effects of a discharge of a defibrillator. PressureWire readings may be affected by defibrillation. Recalibrate PressureWire after defibrillation use.

Recording

CAUTION: The system may place the point of FFR at the wrong location due to abnormal heart beat or artefact in Pa from flushing the guiding catheter. The responsible physician should confirm that the point selected by the system is a valid point of FFR.
CAUTION: If the cursor position has been saved, the FFR value is changed accordingly.

CAUTION: Before creating an FFR recording, review Chapter 4 “Performing an FFR Procedure” for additional warnings and cautions.

CAUTION: After use, the catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

System Setup 2

Positioning the System

WARNING: Failure to position the system as described may lead to a system tipping hazard or a pinching hazard, causing possible patient or operator injury and damage to the system.

- Position the ILUMIEN OPTIS System at the foot of the patient table with the Physician Monitor facing the attending physician.

  The ILUMIEN OPTIS System may be placed at other locations, however care must be taken to ensure the system is clear of any moving equipment, including the angiography system. It is the responsibility of the attending physician to ensure that collisions do not occur.

  NOTE: Whenever the ILUMIEN OPTIS System is used near moving equipment, it is recommended that the wheels remain unlocked to allow the system to roll if it is bumped.

- Ensure the power cord and any other connections to the ILUMIEN OPTIS System are routed to prevent a tripping hazard. Ensure that the main power switch and power plug can be accessed at any time during the procedure.
- Ensure that the ILUMIEN OPTIS System is positioned so the connection between the console and the DOC will not be disturbed during use.

Connecting Your System

System Connections

To connect the system to power, refer to Figure 2-1 for the power connector location:

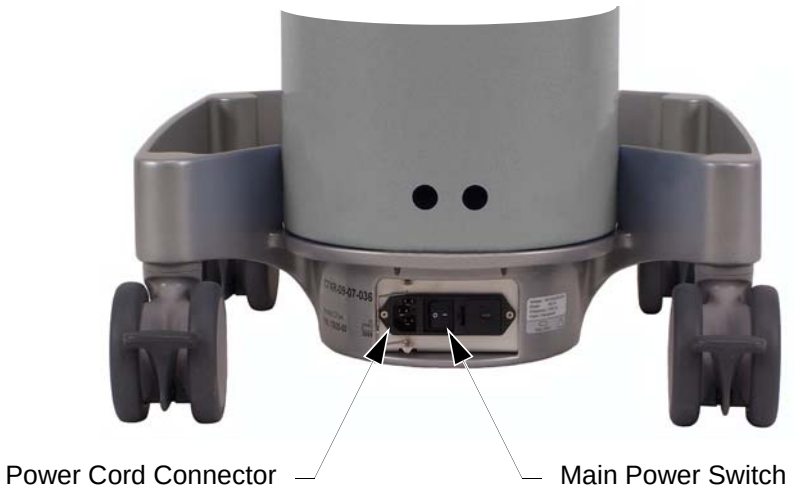


Figure 2-1: ILUMIEN Power Connection

Powering On and Shutting Down Your System

Make sure the power cord is connected to the system and is plugged into a grounded electrical outlet. Secure the power cord using the strain-relief clip on the Power Cord Connector. For detailed information on electrical requirements, see “Making Proper Electrical Connections” on page 11-6.

WARNING: Never use a converter adapter to plug the three-pronged AC plug into a two-pronged, ungrounded wall outlet. Doing so may result in electric shock to the patient or operator and damage to equipment.

Power On

To power on your system:

1. Press the main power switch at the base of the cart to turn on system power (see Figure 1-1 on page 1-4).

2. Confirm that both monitors are powered by observing that the appropriate power indicator is lit. See "Monitor Setup" on page 2-6 for details.

3. Press the On/Standby button located in the upper right corner of the keyboard tray (see Figure 1-2 on page 1-5) to start the system. The system's Startup screen appears (Figure 2-2).

Figure 2-2: Startup Screen

NOTE: Once the system is turned on and the System Display is being shown, you may need to adjust the monitor's brightness and contrast as described in "Monitor Setup" on page 2-6.

Shut Down

CAUTION: **Do not unplug from AC power or turn off main power until the shut-down 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.

To shut down the system:

1. Click the **Shutdown** button located at the top of the screen. The system's **Shutdown** menu appears (Figure 2-3).

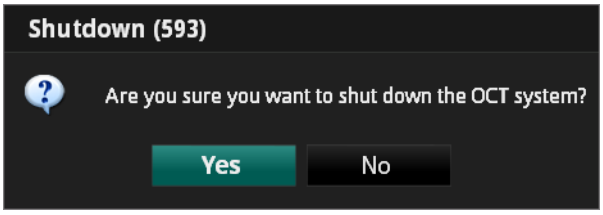


Figure 2-3: Shutdown Menu

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.

FFR Settings

NOTE: To access the full **FFR Settings** menu, you must be in the process of making an FFR recording, and have selected a room for the FFR procedure.

1. Click the **Settings** button at the top of the screen.

   The **FFR Settings** menu opens.

2. Confirm that the FFR settings are correct for this patient.

   - **Pressure Scale**: Changes the vertical scale of the pressure waveform display. The default setting is 0-200 mmHg.
   - **Sweep Speed**: Changes how fast the screen is updated and the level of detail visible to the user. A high number is suitable when a detailed picture of the tracings is required. A low number is suitable when displaying slow changes, for instance during intravenous infusing and pullback. The default setting is **Normal**.
   - **Mean Filter Length (Beats)**: Changes the time over which the mean pressure value is calculated. The adjustments are made by selecting the mean calculation filter length, measured in number of heartbeats. The default setting is 3 heartbeats.

     CAUTION: Choosing a high number of heartbeats makes the pressure averaging slower and less sensitive to artifacts, but may also result in overly insensitive averaging which is noticeable when there is a short hyperaemic plateau. Choosing a low number of heartbeats makes the pressure averaging faster and more sensitive to pressure changes, desirable using a short hyperaemic plateau, but it may also result in an averaging overly sensitive to arrhythmia and pressure disturbances.

     NOTE: An insensitive or overly sensitive averaging of pressure may result in an incorrect FFR value.
     Changes in the **Mean Filter Length** setting are not applied to previous FFR recordings.
     When a new patient is selected, the **Mean Filter Length** setting is reset to 3 heartbeats.

Monitor Setup

The flat panel display monitors provided with the System have controls for brightness, contrast, and other monitor functions. Each monitor's display angle is adjustable.

Setting Monitor Functions

Refer to the Instructions for Use that accompanied your monitor.

Setting Monitor Position

The angle of the flat panel monitor should be set to eliminate or minimize glare from surrounding lighting. To optimize viewing:

1. Grasp the monitor firmly with one hand on each side of the screen.

2. Adjust the viewing angle by tilting the monitor.

Using an External Monitor

An external monitor such as a ceiling mounted display or a projector may be connected to the System through the Video connector on the System Connector Panel. DVI monitors are automatically detected. However, VGA monitors are not detected automatically and must be enabled. For VGA monitors:

1. Click the **Settings** button to open the **Setup** dialog box.

2. Click the **Service** button to open the **Service** menu.

3. Click the **Enable** button in the **External Monitor** section.

   The external monitor shows the System Display within a few seconds.

   NOTE: If the **Enable** button in the **External Monitor** section is inactive (dimmed), contact St. Jude Medical to have this option enabled.

Opening a Patient Record 3

CAUTION: Please note St. Jude Medical makes no representation or warranty that use of the ILUMIEN OPTIS System 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 ILUMIEN OPTIS System.

Select Patient Menu (Home Menu)

When the system is first started, the **Select Patient** menu is displayed (Figure 3-1). From this menu, you can enter a new patient in the database, open an existing patient, or import a previous patient record.

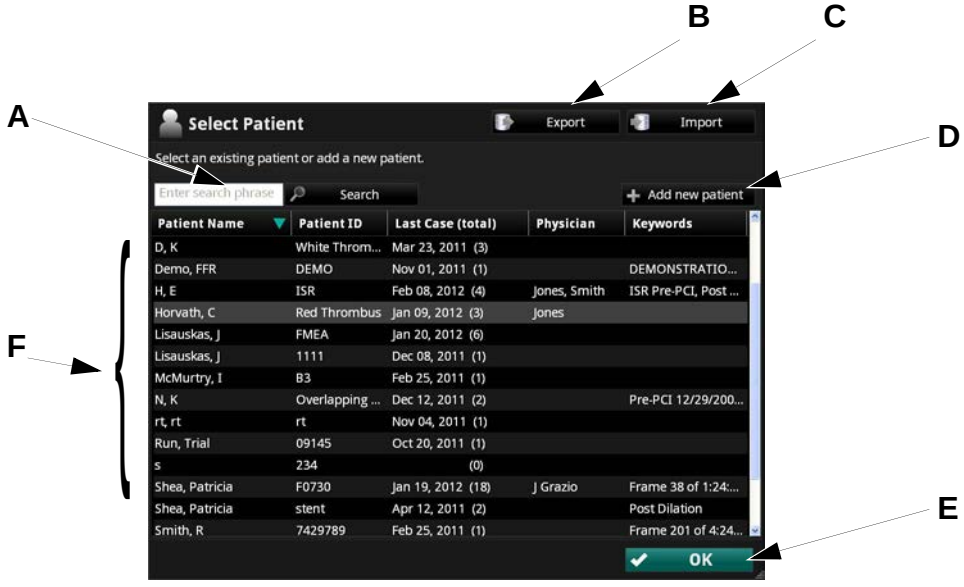


Figure 3-1: Select Patient Menu

Table 3-1: Select Patient Menu functions

A	**Search** button: Enter a term and click this button to search the patient database.
B	**Export** button: Click this button to open the **Export Wizard**.
C	**Import** button: Click this button to open the **Import** menu.
D	**Add New Patient** button: Click this button to enter a new patient into the System database.
E	**OK** button: Select a patient and click this button to open the **Patient Summary** menu for that patient.
F	List of all existing patients in the system database. Click on a column header to sort the patients according to data in that column.

WARNING: If you select the default patient ("Patient, Default" in the patient list), the system displays an alert (Figure 3-2). Do not use the default patient to store patient images. Click OK to continue to use the default patient, or Cancel to return to the Select Patient menu to select another patient.

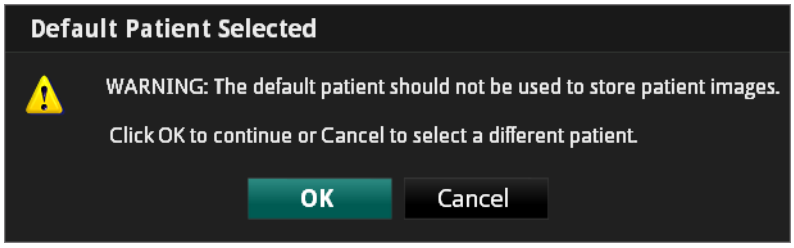


Figure 3-2: Default Patient Alert

Patient Summary Menu

When you click on a patient name, the **Patient Summary** menu for that patient opens (see Figure 3-3). If there are previous recordings for this patient, they are shown here, sorted by date, with the most recent recordings at the top.

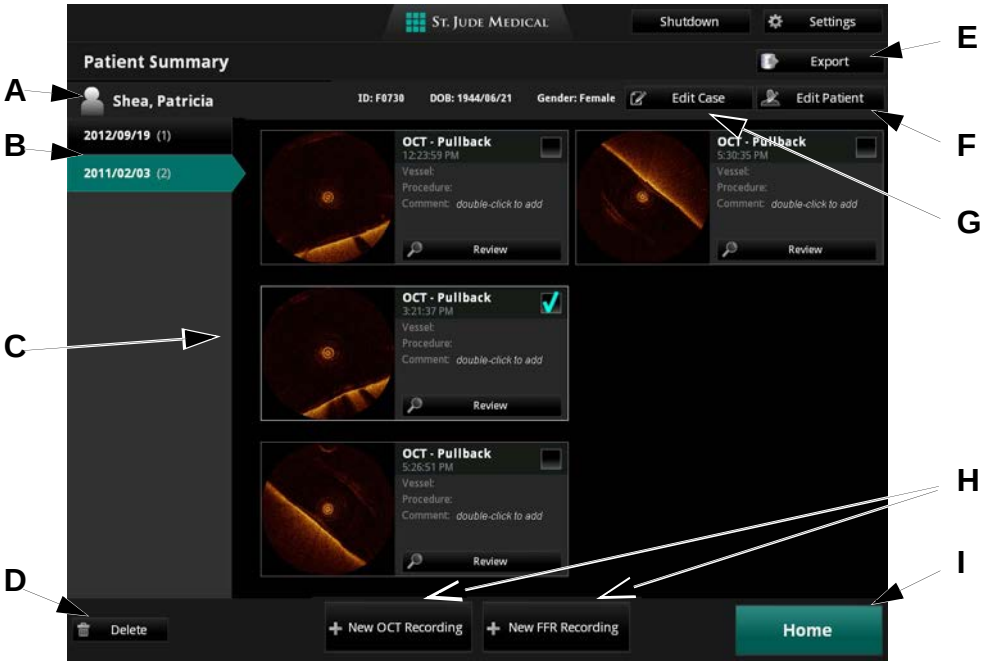


Figure 3-3: Patient Summary Menu

Table 3-2: Patient Summary Menu functions

A	Patient information, including name, ID, date of birth, and gender.
B	Dates of recordings for this patient. The list is sorted by date, with the most recent recordings at the top.
C	Gallery of existing recordings for this patient on the date highlighted at left. Double-click in the **Comment** field to add a comment for that recording. Click the **Review** button under a recording to open it.
D	**Delete** : Check one or more recordings to select them, and click the **Delete** button to delete them.
E	**Export** : Check one or more recordings to select them, and click the **Export** button to open the **Export Wizard**.
F	**Edit Patient** : Click this button to edit patient information.
G	**Edit Case** : Click this button to edit case information.
H	**New OCT Recording** / **New FFR Recording** : Use these buttons to begin a new recording for this patient.
I	**Home** button: Press to return to the **Select Patient** menu.

Entering New Patient Information

You can enter a new patient from the **Select Patient** menu.

1. In the **Select Patient** menu, click the **Add new patient** button.

   The **Add new patient** menu opens (see Figure 3-4).

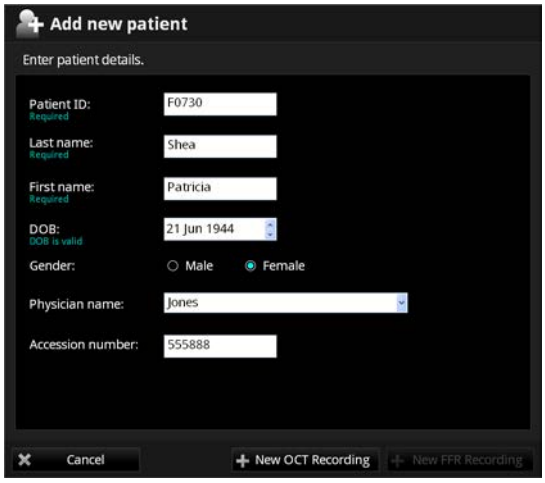


Figure 3-4: Add New Patient Menu

2. Enter the patient information as needed.

   NOTE: You must enter **Patient ID**, **First name**, and **Last name** before you can save the patient information.

3. Click **New OCT Recording** to save the changes and begin a new OCT recording for this patient, click **New FFR Recording** to save changes and begin a new FFR recording for this patient, or **Cancel** to close the menu without saving and return to the **Select Patient** menu.

Editing Patient Information

The patient information can be edited from the **Patient Summary** menu.

1. In the **Select Patient** menu, click on the patient and then click **OK**.

   The **Patient Summary** menu for that patient opens (see Figure 3-3).

2. Click the **Edit Patient** button.

   The **Edit Patient** menu opens (see Figure 3-5).

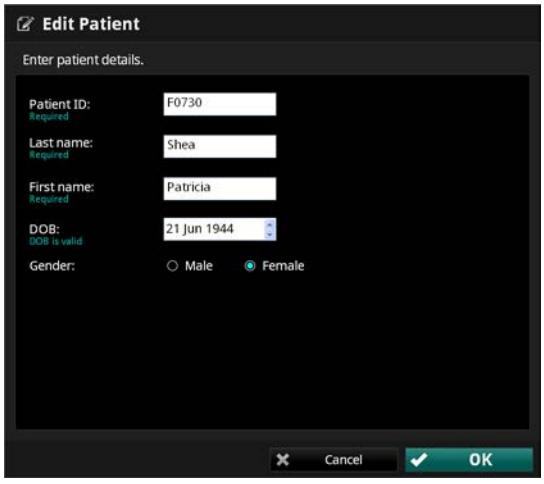


Figure 3-5: Edit Patient Menu

3. Edit the patient information as needed.

   NOTE: You must enter **Patient ID**, **First name**, and **Last name** before you can save the patient information.

4. Click **OK** to save the changes, or **Cancel** to close the menu without saving.

Editing Case Information

The physician name and accession number for a case can be edited from the **Patient Summary** menu.

1. In the **Select Patient** menu, click on the patient and then click **OK**.

   The **Patient Summary** menu for that patient opens (see Figure 3-3).

2. Click on a case to select it.

   NOTE: In the ILUMIEN OPTIS System, all recordings and still images from the same date use the same physician and accession number.

3. Click the **Edit Case** button.

   The **Case Information** menu opens (see Figure 3-6).

Figure 3-6: Case Information Menu

4. Edit the **Physician name** and **Accession Number** as needed.

5. Click **OK** to save the changes, or **Cancel** to close the menu without saving.

Importing a Patient Database

Previous C7 XR, ILUMIEN, and ILUMIEN OPTIS OCT and FFR recordings can be imported into the system using the **Import** button on the **Select Patient** menu. For more information on importing patient files or information, see “Importing Files from a CD/DVD or USB” on page 8-20.

Opening a Saved Recording or Still Image

Each recording or still image has an entry in the **Patient Summary** menu. The entry includes a timestamp and a thumbnail, and can display the **Vessel**, **Procedure**, and a **Comment**, if added. The thumbnail adds icons to represent the status and content of the file:


•A “camera” icon indicates a still frame from an OCT recording.


•A “safe” icon indicates that the file has been archived.

To review a saved recording or still image:

1. Open the **Patient Summary** menu:
   - From the **Select Patient** menu, double-click on a patient’s name, or select a patient name and click **OK**.
   - From an OCT or FFR recording, click on the **Patient Summary** button at the top of the screen.

   The **Patient Summary** menu for that patient opens (Figure 3-3 on page 3-4).

2. Click the date of the recording from the dates at the left of the menu.

   All recordings and still images for that patient on that date are displayed.

3. Click on the **Review** button beneath the recording you want to open.

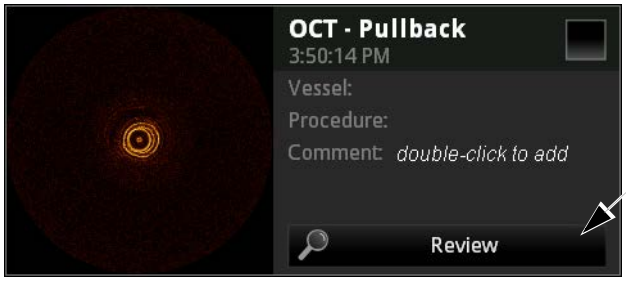


Figure 3-7: Recording as shown in the Patient Summary Menu

The recording or still image opens. Recordings play automatically.

- To navigate an OCT recording, see “Playback Controls” on page 6-6; to navigate an FFR recording, see “Reviewing an FFR Recording” on page 4-12.
- To add measurements and annotations to the OCT recording or still frame, see Chapter 7 “Measurements and Annotations”.
- To export the entire OCT recording or individual frames, see Chapter 8 “Exporting, Importing, and Managing Files”.

4. To end the review and return to the **Patient Summary** menu, click the **End Review** button.

Performing an FFR Procedure 4

Overview

The FFR procedure requires two operators; a sterile operator and a non-sterile operator. All steps requiring contact with the PressureWire must be performed by the sterile operator. All steps performed in direct contact with the ILUMIEN OPTIS System must be performed by the non-sterile operator.

A typical cathlab configured for FFR is shown below.

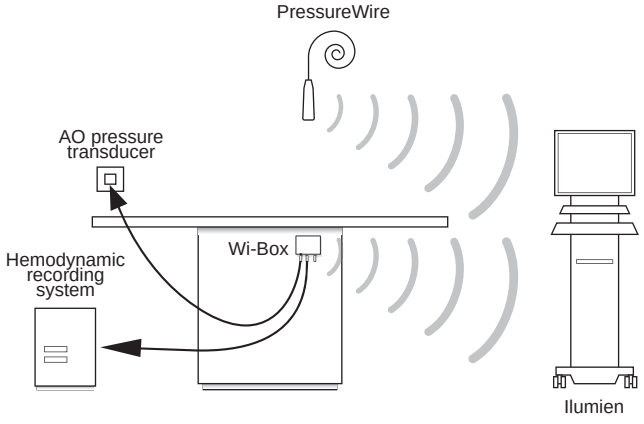


Figure 4-1: Cathlab with FFR

Required Material and Equipment

- ILUMIEN OPTIS System
- PressureWire
- Wi-Box, installed in each room where the ILUMIEN OPTIS System is to be used to measure FFR
- Heparinized, physiologic saline solution, for hydrophilic catheter preparation

Setting up the ILUMIEN OPTIS System

1. Position the system for use. See “Positioning the System” on page 2-1.
2. Turn on the system. See “Power On” on page 2-3.

Setting up the Wi-Box with the ILUMIEN OPTIS System

The Wi-Box should be connected to your facility's Hemodynamic Recording System at installation. The first time the ILUMIEN OPTIS System is connected to a Wi-Box, the room appears as **Unknown**, and must be given a unique name and number. Click on the room and enter a **Room Name** and **Room Number**. Press **OK** when finished.

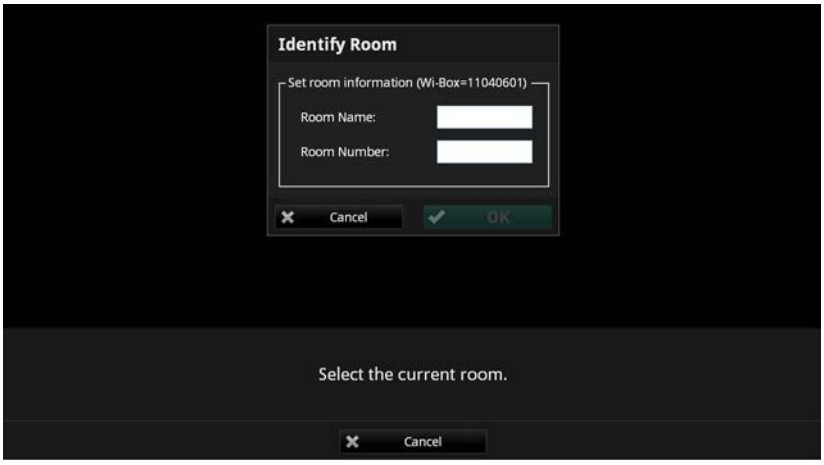


Figure 4-2: Enter Room Information

Refer to the installation instructions that came with your Wi-Box for further information.

Setting up the PressureWire

WARNING: Please review the *Instructions for Use* supplied with the PressureWire for a complete list of warnings, cautions, and setup instructions.

Preparing to Record FFR

WARNING: The heart rate and mean pressure values shown on the ILUMIEN OPTIS System are for reference only and are not intended to be used as the primary display.

Start FFR recordings from the **Patient Summary** menu.

1. If necessary, enter the patient's information. See "Entering New Patient Information" on page 3-5.

   NOTE: Patient information should be entered into the system and selected for use before beginning a recording.
   If you are entering a patient through the **Add New Patient** menu, click the **New FFR Recording** button at the bottom of the menu, and continue with Step 4 in this section.

2. In the **Select Patient** menu, click on a patient name.

   The **Patient Summary** menu for that patient opens (Figure 3-3 on page 3-4).

3. In the **Patient Summary** menu, click the **New FFR Recording** button.

   The screen displays all rooms with an active Wi-Box within range of the system, and the guidance message "*Select the current room.*"

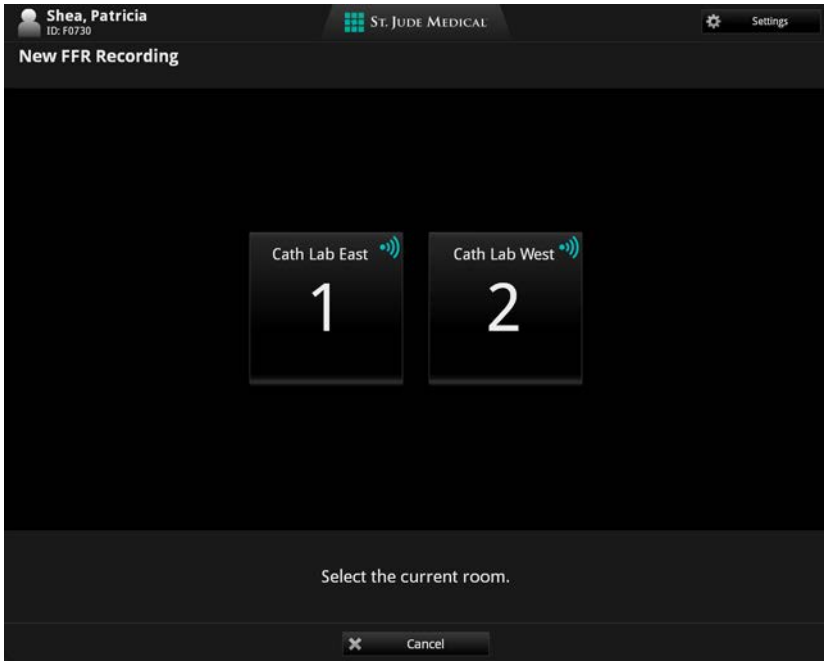


Figure 4-3: Select Current Room message

4. Click on the current room to select it.

CAUTION: **In order to connect to the correct AO source (Wi-Box) 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. See "Setting up the Wi-Box with the Ilumien Optis System" on page 4-3 for more information.

The screen displays the main screen with the guidance message "*Set AO transducer height to heart level, then open AO transducer to air. Click Zero Pa.*"

Figure 4-4: Set AO transducer height and open AO transducer guidance message

5. Position the AO transducer so that it is level with the patient's heart.

NOTE: The AO transducer should remain level with the patient's heart throughout the procedure.

6. Open the AO transducer to air.

7. In the Pa measurement box, click the **Zero** button.

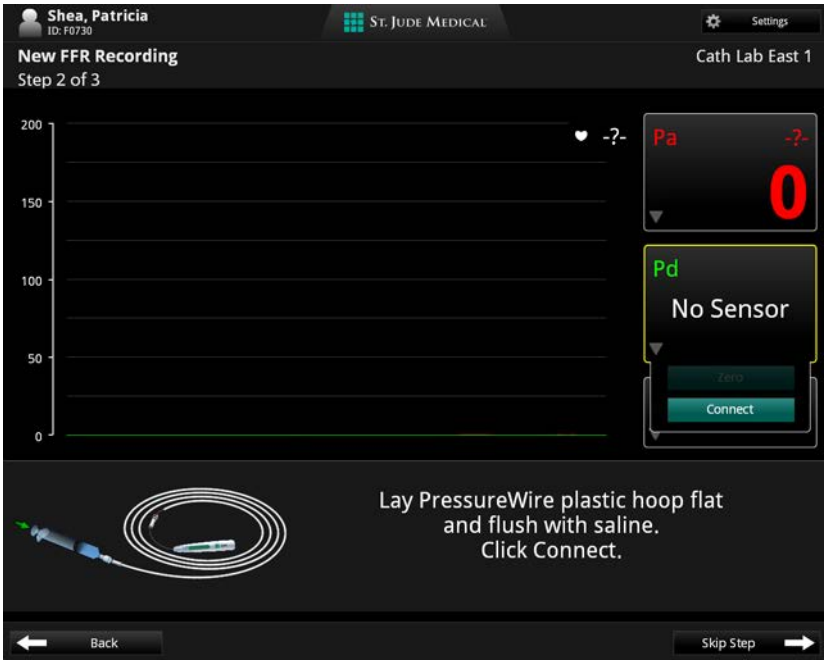


Figure 4-5: Flush PressureWire guidance message

8. Close the AO transducer.

9. Prepare the PressureWire in accordance with the *PressureWire Instructions for Use* and the on screen prompts.

   CAUTION: Do not use the PressureWire if there are any signs of damage.

10. In the Pd measurement box, click the **Connect** button.

    NOTE: You have 60 seconds to make the connection between the PressureWire transmitter and the system.

The system is now looking for a PressureWire. The Pd measurement box shows the message "*Searching*."

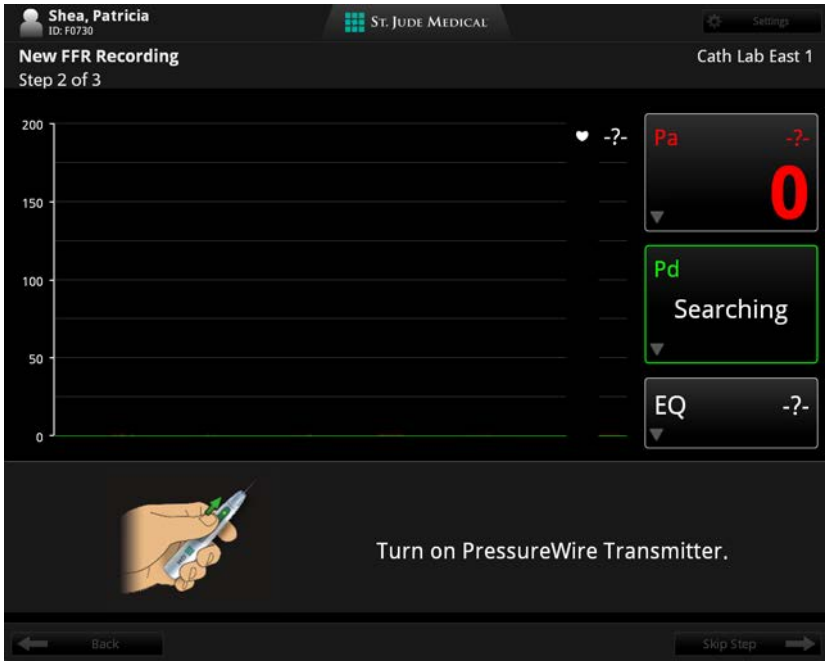


Figure 4-6: Turn on PressureWire guidance message

CAUTION: Do not turn on more than one PressureWire while the system is Searching/Connecting.

11. Turn on the PressureWire transmitter.

    The Pd measurement box shows the message "Connecting" as the PressureWire transmitter and the system make the wireless connection. Once the connection is established, the Pd waveform appears (in green) in the graphical area of the display.

    NOTE: If the system does not find the PressureWire after one minute, the message in the Pd measurement box changes back to "*No Sensor.*" Turn off the PressureWire and return to Step 10.

12. Remove the PressureWire from the plastic hoop.

13. Insert the PressureWire into the patient in accordance with the *PressureWire Instructions for Use*.

The pressure from the AO transducer and PressureWire must now be equalized.

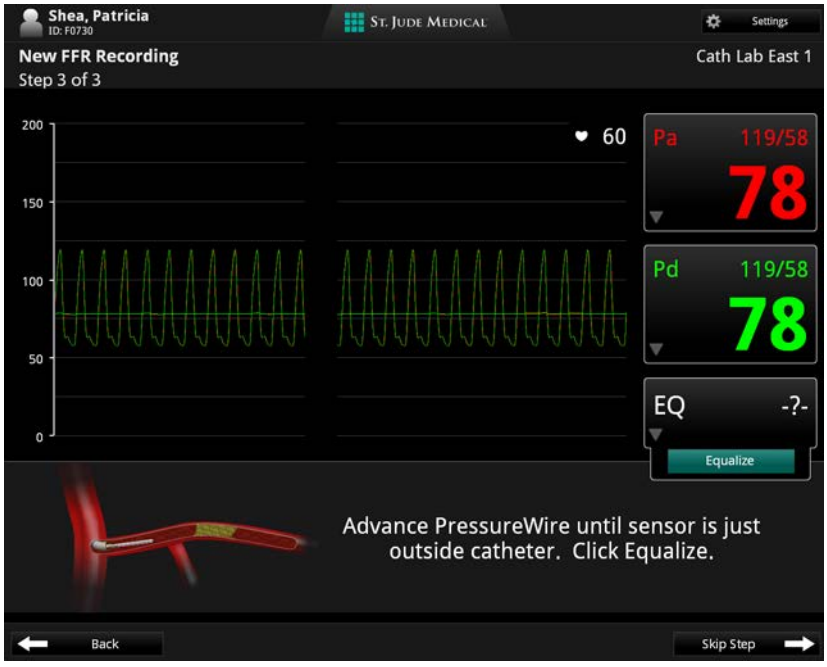


Figure 4-7: Advance PressureWire and Equalize guidance message

CAUTION: If the PressureWire is turned off or loses power at any point after equalization, you must remove it from the patient and re-zero it in its plastic hoop in heparinized saline before continuing. See the PressureWire *Instructions for Use* for more information on troubleshooting the PressureWire.

14. Check the pressures displayed in the Pa and Pd measurement boxes. If the pressures are not equal, click the **Equalize** button to equalize the pressure reading between the AO transducer and the PressureWire.

    The equalization offset value appears in the Equalization measurement box. The offset is applied to the Pd pressure, to match the value of the Pa pressure.

    CAUTION: If the equalization offset value is greater than or equal to 10, or equal to or lower than -10, the system displays an alert icon in the Equalization measurement box. If the system displays this alert icon, try the following to reduce the EQ value:

    - **Confirm the AO transducer is positioned at the same height as the patient's heart and re-equalize.**
    - **If the alert remains, remove the PressureWire from the patient and re-zero it in its plastic hoop in heparinized saline.**

    CAUTION: To prevent incorrect measurement of the aortic pressure by the guiding catheter, causing an incorrect FFR (Pd/Pa) calculation:

    - **Flush any contrast remnants from the guide catheter with heparinized saline.**
    - **The insertion tool must be pulled back out of the hemostatic valve.**
    - **The hemostatic valve must be closed during pressure measurement.**

    NOTE: The equalization value (EQ) is reset when Pa or Pd is zeroed, or when the PressureWire is restarted (turned on/off).

Recording FFR

1. Confirm that the FFR settings are correct for the current procedure. See "FFR Settings" on page 2-5 for more information.

2. With the PressureWire in position and equalized, advance it across the area to be examined.

   The bottom of the graphical area shows the Pd/Pa waveform, along with the Pd/Pa ratio.

Figure 4-8: Pd/Pa waveforms equalizing

3. Induce hyperemia according to standard cathlab procedures.

4. Click the **Record** button.

A recording timer is displayed at the bottom of the screen. Click the **Mark** button to mark an instant on the recording for later review. A mark appears as a vertical white line on the recording.

Figure 4-9: Recording

5. Record pressure until steady state maximum hyperaemic condition is reached, until the hyperaemic effect begins to decrease, or until the physician decides to end the recording. When finished, click the **Stop** button to end the recording.

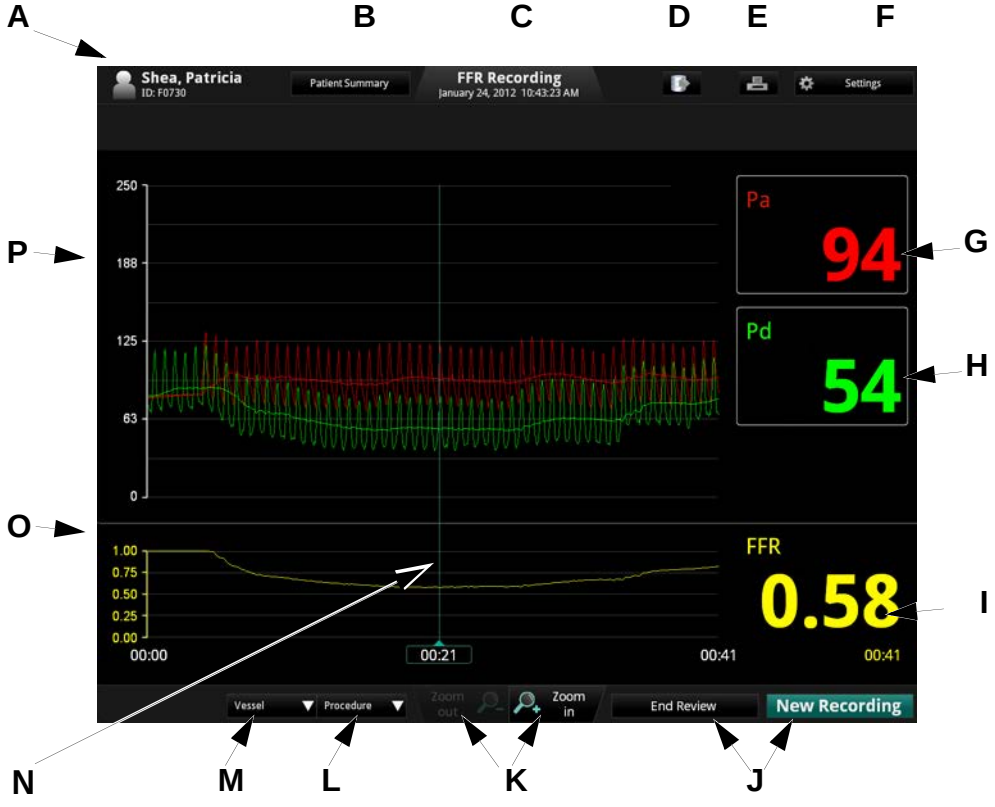
CAUTION: When the procedure is complete, handle the PressureWire and all other disposables used during the procedure as potential biohazards. Dispose of in accordance with accepted medical practice and all applicable laws and regulations.

Reviewing an FFR Recording

When the FFR recording opens, the entire recording is shown. By default, when the recording is opened, the cursor is positioned at the point of the lowest Pd/Pa ratio.

WARNING: The system may place the point of FFR at the wrong location due to abnormal heartbeats or 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 FFR.

CAUTION: If you have zoomed in on a section of the recording, portions of the waveform are not displayed (the recording extends off screen). The physician should always review the entire unzoomed recording before selecting the point for the calculation of FFR.



A	Patient name and ID. See "Entering New Patient Information" on page 3-5 for more information.
B	**Patient Summary** button: Click to open a list of all recordings for this patient. See "Patient Summary Menu" on page 3-4 for more information.
C	Recording date and time.
D	**Export** button: Click to open the **Export Wizard**. See Chapter 8 "Exporting, Importing, and Managing Files" for more information.
E	**Print** button: Available when a USB drive is connected. Click to print the FFR recording.
F	**Settings** button: Click to open the FFR Settings menu. See "FFR Settings" on page 2-5 for more information.
G	Pa measurement box. Mean Pa value at the cursor is displayed.
H	Pd measurement box. Mean Pd value at the cursor is displayed.
I	The FFR value at the cursor.
J	**End Review** / **New Recording** : Click the **End Review** button to close this window and return to the **Patient Summary** menu. **NOTE:** While the system is connected to a PressureWire, the button **New Recording** appears here. Click the **New Recording** button to close this review and begin a new FFR recording. **CAUTION: When closing the recording, the current cursor position and corresponding FFR value is saved. When the recording is re-opened, the cursor appears at the saved position. The cursor may then be moved, and the displayed Pa and Pd pressures and FFR value change to reflect the new cursor position.**
K	**Zoom in**/**Zoom out** of the recording, centered on the cursor.
L	**Procedure** list: Click to open a drop-down list of procedures to describe this recording.
M	**Vessel** list: Click to open a drop-down list of vessels to describe this recording.
N	Move the cursor to read the Pa, Pd, and FFR value at any point in the recording.
O	FFR waveform
P	Pa and Pd pressure waveforms

PressureWire Troubleshooting

In case of low power in the PressureWire, the light on the PressureWire unit flashes yellow, and a low battery indicator appears in the Pd measurement box.

If there is a problem with your PressureWire, refer to the *PressureWire Instructions for Use* for details.

Performing an OCT Procedure 5

Overview

The OCT procedure requires two operators; a sterile operator and a non-sterile operator. All steps requiring contact with the Dragonfly Imaging Catheter or the outside of the sterile DOC cover must be performed by the sterile operator. All steps performed within the sterile DOC cover or in direct contact with the ILUMIEN OPTIS System must be performed by the non-sterile operator.

Required Material and Equipment

- ILUMIEN OPTIS System
- C7 Dragonfly Imaging Catheter or Dragonfly Duo Imaging Catheter
- Sterile DOC Cover
- 3 mL purge syringe
- Contrast media indicated for coronary use, for purging and flush (allow 15 mL for each run planned)
- 0.014 inch guidewire (with torque device if desired)
- Guide catheter (6 French, 0.068 inch ID or larger, with no side holes)
- Sheath introducer (to match guide catheter)
- Hemostatic Y-Adapter/Connector
- Heparinized, physiologic saline solution, for hydrophilic catheter preparation
- Power injector pump for coronary angiography or manual syringe (capable of injecting 4.0 mL /sec for a total of 14 mL in 3.5 seconds)

OCT Imaging Overview

1. **Position** - Locate the Dragonfly imaging catheter relative to the target lesion/stent.

2. **Purge** - Clear blood from the catheter lumen, if present, using the attached 3 mL syringe.

3. **Puff** - Inject a small amount (~ 4 mL) of contrast through the guide catheter to evaluate clearance.

   If clarity is marginal, check the orientation of the guide catheter and target vessel.

4. **Pullback** - From Live View, select **Enable** to start the imaging process.

NOTE: In the left coronary system, guide catheter placement and orientation is key to achieving good contrast flow. This is particularly true in the LCX.

OCT Operating Modes

During acquisition, the system is divided into Standby View and Live View.

- **Standby View** - The DOC is not rotating the imaging catheter. The last image viewed through the catheter lens is shown on the display.
- **Live View** - The DOC is rotating the imaging catheter at low-speed, and is transmitting images from the catheter lens to the display.

After the image has been recorded, see Chapter 6 “Reviewing OCT Recordings” for more information on reviewing OCT recordings.

OCT Recording Types

The system can make two types of recordings: **Pullback** and **Stationary**. See “Setup - Acquisition Menu” on page 10-2 for more information.

NOTE: The instructions in this manual are for **Pullback** recordings. Differences for **Stationary** recordings are noted where applicable.

Setting up the ILUMIEN OPTIS System

1. Position the system for use. See “Positioning the System” on page 2-1.
2. Turn on the system. See “Power On” on page 2-3.

Setting up the DOC

The DOC must be readied for use in the sterile environment.

CAUTION: Protect the exposed connector inside the DOC from fluids at all times. Fluid contact can disable the DOC and require service.

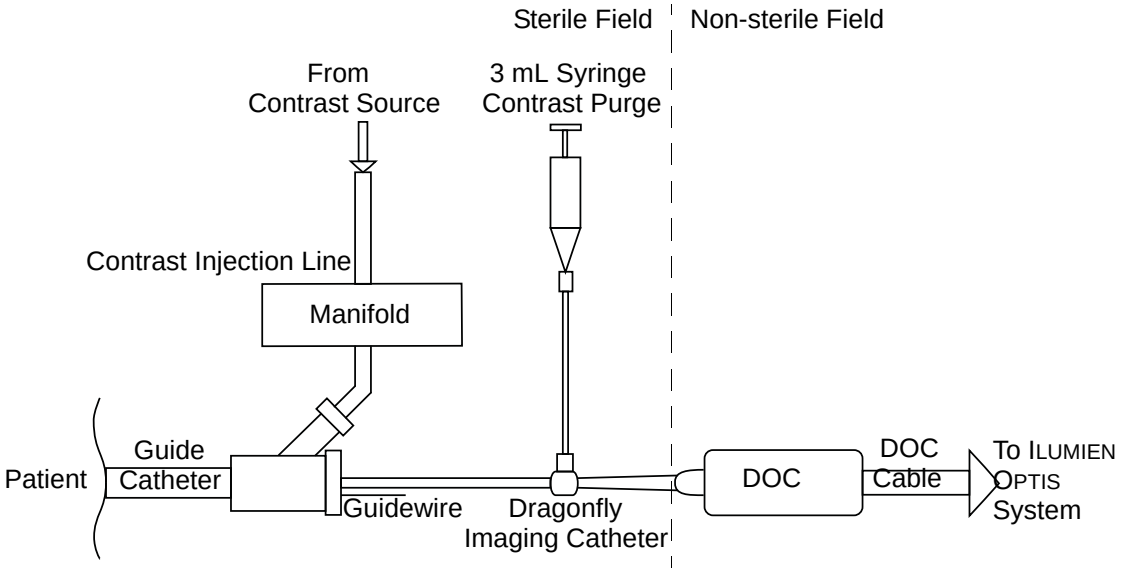


Figure 5-1: DOC Connections

Non-sterile Operator

1. With assistance from the sterile operator, place the DOC inside a sterile DOC cover.

2. Ensure the cover is extended over the DOC cable to its full length.

Sterile Operator

3. Connect the flush media (syringe or automated injector) to one port of the guide catheter manifold (see Figure 5-1).

4. Use the following settings to prepare for flush delivery:
   - 4 ml/sec or less flush rate.
   - 14 ml or less total flush volume.
   - If using an automated injector, pressure limit 300 psi, or the nearest available setting.

5. Purge all air from the tubing and manifold following standard practice.

Setting up the Dragonfly Imaging Catheter

WARNING: Prior to use, please review the *Instructions for Use* supplied with the Dragonfly Imaging Catheter for more information.

1. Inspect the packaging of the catheter for damage.

   CAUTION: Do not use the catheter if the sterile packaging is compromised.

2. Using sterile technique, carefully remove the Dragonfly catheter from its sterile package.

3. Carefully remove the catheter from the plastic hoop and examine it for visible damage or defects.

   CAUTION: Do not use the catheter if there are any signs of damage.

4. Moisten the distal segment of the catheter from the tip to approximately 100 cm proximally using heparinized saline to ensure optimal performance of the hydrophilic coating.

   CAUTION: Use heparinized saline only.

5. Remove the cap from the sidearm luer and attach a 3 ml syringe filled with 100% contrast.

   CAUTION: Take care in handling the Dragonfly to prevent breaking the fiber-optics within the catheter. Kinking and bending of the catheter can cause damage.

Preparing to Acquire OCT Recordings

New OCT recordings are started from the **Patient Summary** menu.

1. If necessary, enter the patient's information. See "Entering New Patient Information" on page 3-5.

   NOTE: Patient information should be entered into the system and selected for use before beginning a recording.
   If you are entering a patient through the **Add New Patient** menu, click the **New OCT Recording** button at the bottom of the menu, and continue with Step 4 below.

2. In the **Select Patient** menu, click on the patient and then click **OK**.

   The **Patient Summary** menu for that patient opens (Figure 3-3 on page 3-4).

3. In the **Patient Summary** menu, click the **New OCT Recording** button.

   NOTE: If necessary, enter **Physician name** and **Accession number** for this case, and click **OK**.

4. If **Flush Medium** was set to anything other than **Contrast** for the previous patient, the setting is changed back to **Contrast** and an alert appears.

   Click **OK** to close the alert. If you need to change the Flush Medium setting, see "Confirm Recording Settings" on page 5-10.

5. The screen displays the guidance message "*Purge catheter with contrast*" (Figure 5-2).

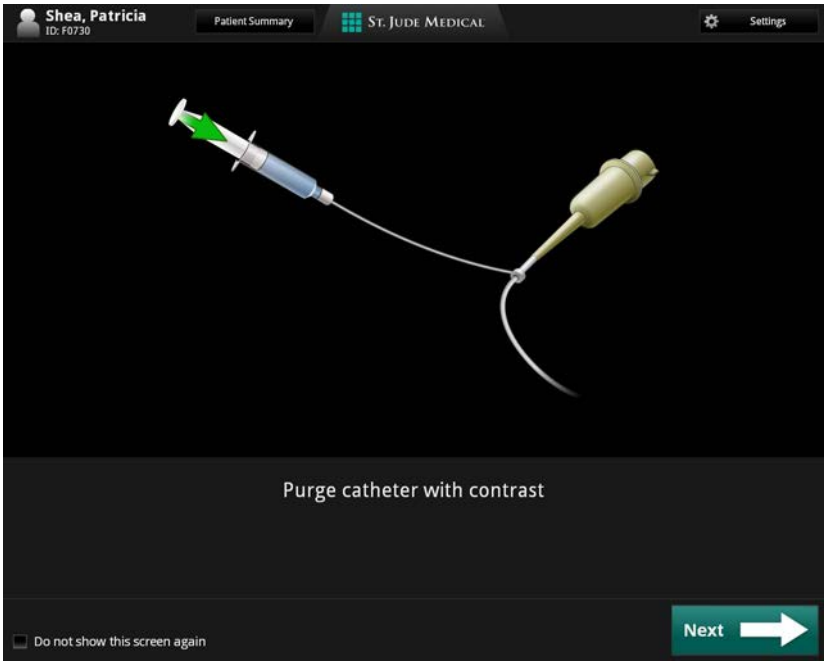


Figure 5-2: Purge Catheter guidance message

NOTE: To prevent this guidance message from appearing, check the box next to the message "*Do not show this screen again*."

6. Purge the Dragonfly Imaging Catheter's lumen with 100% contrast media from the 3 ml syringe to remove all air from the catheter. Flush until 3-5 drops exit from the catheter's distal tip. Do not remove the syringe from the catheter purge port after flushing.

CAUTION: The catheter must be purged prior to connection to the DOC.

7. Once the 100% contrast media has been injected, click the **Next** button.

   The screen displays the guidance message "*Plug catheter into DOC*" (Figure 5-3).

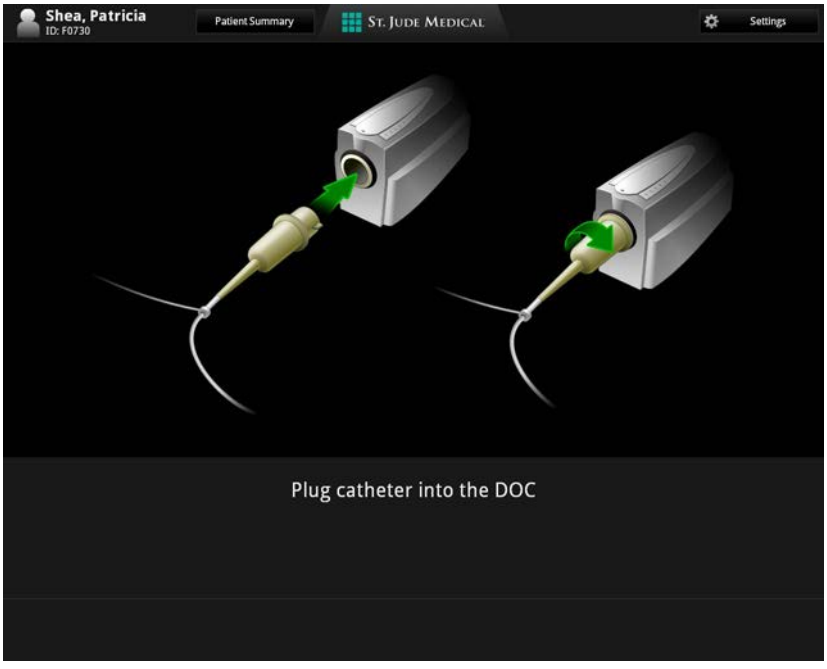


Figure 5-3: Plug Catheter into DOC guidance message

8. Insert the hub of the catheter into the port of the DOC, and twist the hub clockwise until secure ($^1/_8$ turn).

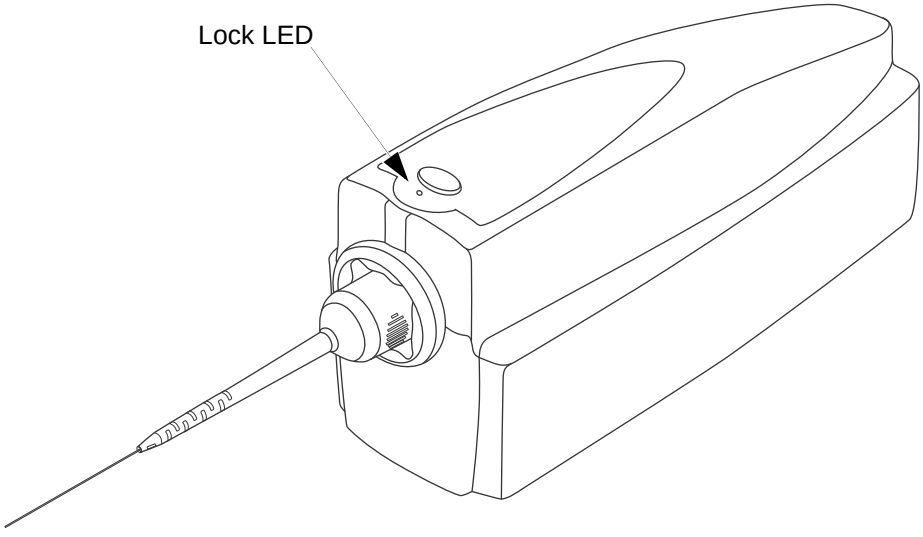


Figure 5-4: Dragonfly Catheter Connected to the DOC

CAUTION: Do not insert or remove the 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.

The DOC's "lock" LED flashes and lights as the DOC automatically makes the internal optical fiber connection, and the green **Connecting imaging catheter** progress bar at the bottom of the screen completes.

NOTE: If the **Connection Failure** alert appears, unload the catheter (press **unload** on the DOC) and try to load the catheter again. If this alert appears again, replace the catheter.

NOTE: If the connection or initial calibration is *stopped*, the **Connection Cancelled** alert is displayed. If this alert appears, unload the catheter (press **unload** on the DOC), click **OK**, and try to load the catheter again.

On screen, the size and position of the outer sheath of the catheter is adjusted with respect to the calibration marks (see Figure 5-5).

When the connection and initial calibration are complete, the confirmation message, **Catheter connected**, appears. The system goes into Standby View.

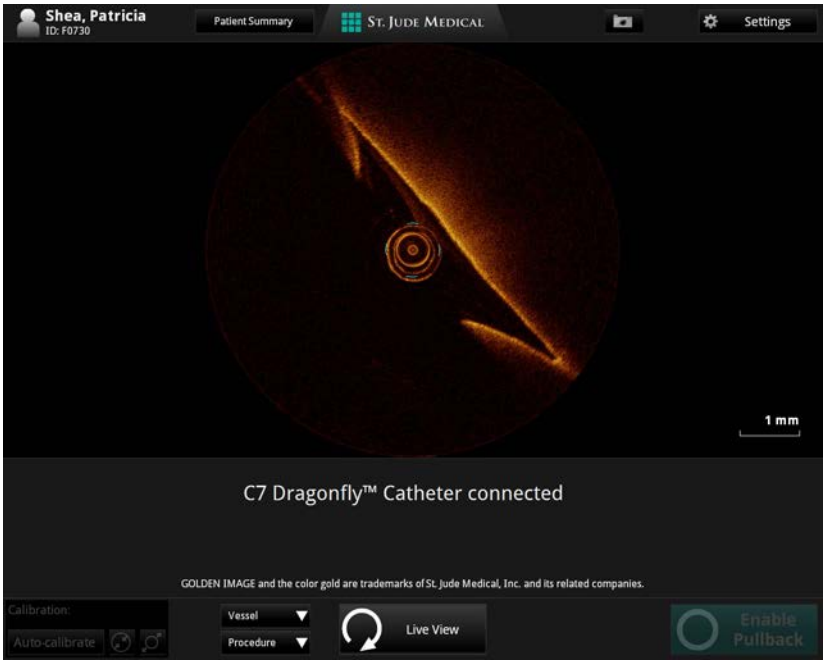


Figure 5-5: Catheter Connected, Initial Calibration done

Confirm Recording Settings

After the catheter has been connected to the DOC, confirm all settings for this recording.

Non-sterile Operator

1. Click the **Settings** button at the top of the screen.

   A context-sensitive menu opens.

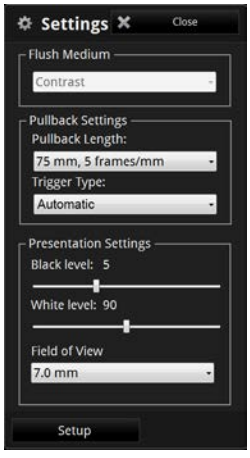


Figure 5-6: OCT Settings Menu (during Recording)

2. Confirm all settings are correct for this recording.

   NOTE: If Flush Medium has been restricted to **Contrast Only**, you cannot change the **Flush Medium** setting. See "Setup - Acquisition/Other Menu" on page 10-4 for more information.
   If Recording Type has been set to **Stationary**, you cannot change the **Pullback Length** setting. See "Setup - Acquisition Menu" on page 10-2 for more information.

   CAUTION: **To obtain accurate measurements, be sure the selection for the Flush Medium is the same as the medium in which you are imaging.**

   NOTE: Only 100% contrast media is approved for human OCT Imaging.

   NOTE: Clicking the **Setup** button at the bottom of the **Settings** menu opens the ILUMIEN OPTIS System **Setup** dialog box. See Chapter 10 "User Interface Reference" for more information.

3. Click **Close** to continue.

Dragonfly Imaging Catheter Insertion and Positioning

The guide catheter and guidewire must be inserted into the patient per normal clinical procedures prior to insertion of the Dragonfly Imaging Catheter. The Dragonfly catheter must be properly inserted into the guide catheter to ensure patient safety and proper operation.

Once the Dragonfly catheter has been inserted, its location, and the position of the guide catheter, may be fine-tuned to ensure optimal imaging.

CAUTION: Ensure that no air is introduced into the system during the imaging catheter insertion.

Non-sterile Operator

1. Ensure that the Dragonfly catheter is not rotating (press **Standby View** if necessary) before the sterile operator begins loading and inserting. If desired, select a **Vessel** and **Procedure** from the fields at the bottom of the screen.

Sterile Operator

2. Back-load the Dragonfly catheter's rapid-exchange lumen onto the indwelling 0.014 inch guidewire.

3. **POSITION** the catheter according to your catheter’s Instructions for Use.

   CAUTION: 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 guidewire after the Dragonfly catheter is in place.

   If resistance is encountered during advancement of the Dragonfly Imaging Catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter and guidewire as a unit from the patient.

   Leave the guidewire engaged with the catheter at all times during use. Do not withdraw or advance the guidewire prior to withdrawing the catheter.

Non-sterile Operator

4. Press the **Live View** button to start live-scan imaging (low-speed rotation of the imaging core).

   The ring around the **Live View** button on the DOC lights in green.

   CAUTION: Monitor the OCT image for indications of catheter optical failure. If optical failure is suspected, return to Standby View (click the Standby View button), remove the catheter, and replace it with a new one.

   NOTE: A pullback can not be started unless the optical fiber is fully advanced.

5. Verify calibration as follows:

   The image is correctly calibrated when the outermost “ring” of the catheter is centered between the 4 calibration marks.

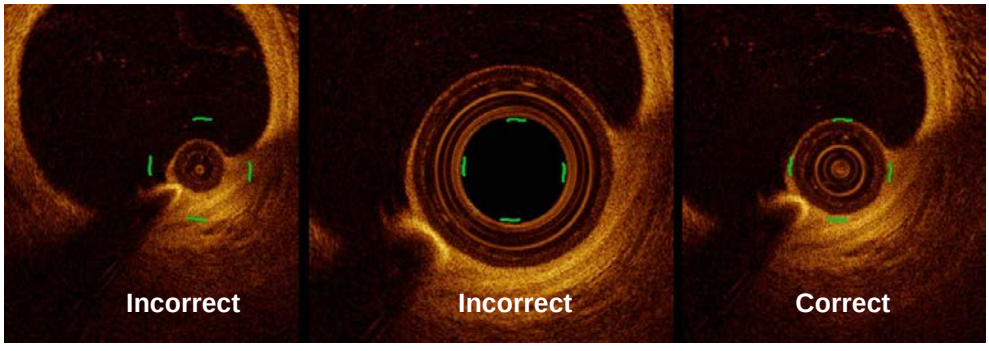


Figure 5-7: Incorrect and Correct Calibration

NOTE: Ensure accurate calibration prior to a recording. Incorrect calibration may cause early pullback initiation and incorrect measurements. You should adjust the calibration to the best approximate size between the outer diameter of the catheter and the 4 calibration marks.

- To calibrate automatically, press the **Auto-calibrate** button. In the Image Window, the position of the catheter outer sheath is adjusted close to its final correct position with respect to the four calibration marks.
- If necessary, click the Increase/Decrease buttons to calibrate manually. 

Sterile Operator

6. **PURGE** the Dragonfly Imaging Catheter by injecting ~0.1 ml contrast using the 3 ml syringe to ensure no blood has diffused into the catheter lumen.

   NOTE: Application of negative pressure to draw blood into the catheter is not recommended. Blood in the catheter lumen will obscure the image and can be difficult to completely purge.

7. Ensure the guide catheter is oriented to preferentially direct contrast flow to the target artery, and verify angiographically that adequate flow of contrast is delivered to the artery.

   NOTE: **PUFF--** Injecting a small "puff" of contrast while reviewing the image on screen to verify that adequate flow of contrast is delivered to the artery.

8. Whether using a syringe or automated injector, verify the following for flush delivery:

   - 4 ml/sec or less flush rate.
   - 14 ml total flush volume.
   - If using an automated injector, pressure limit 300 psi, or the nearest available setting.

9. Verify the stopcock position on the manifold is set to allow flow from the injection pump into the guide catheter.

Acquiring Patient Images

The System Display during image acquisition is shown in Figure 5-8.

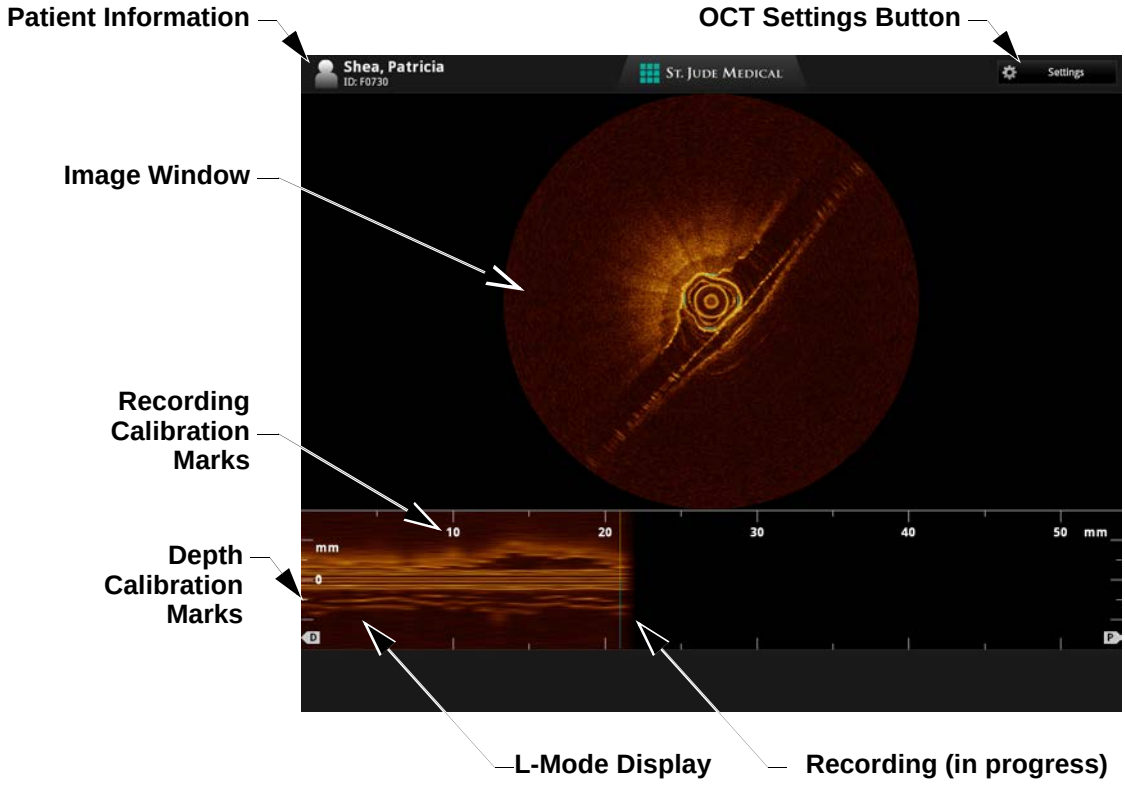


Figure 5-8: System Display - Acquisition

Table 5-1: System Display Description - Acquisition

Patient Information	Displays the Patient name and ID.
OCT Settings button	Opens the **OCT Settings** menu.
Image Window	This display shows the current view by the imaging catheter lens.
Recording Calibration Marks	Recording calibration marks, measured in mm. Note: In a **Stationary** recording, this is a timeline, measured in seconds. See "Setup - Acquisition Menu" on page 10-2 to set the Recording Type to **Stationary**.
Depth Calibration Marks	Depth of the scan in mm.
L-Mode display	This displays the approximate lateral appearance of the vessel being scanned. Note: In a **Stationary** recording, the "L-Mode" is renamed "Timeline."
Recording (in progress)	Displays the recording as it is completed.

Non-sterile Operator

NOTE: If you are performing a **Stationary** recording, the **Enable Pullback** and **Start Pullback** buttons are replaced with a **Start Recording** button. Do not press the **Start Recording** button until you have notified the sterile operator that the system is ready, and that the contrast media has been injected.
Clicking the **Start Recording** button (or pressing the **Enable** button on the DOC) begins the recording immediately; the system does not wait for a clearing from the contrast injection.

1. With the system in **Live View**, click the **Enable Pullback** button to allow the system to detect initiation of the imaging flush. The green ring around the **Live View** button on the DOC begins to flash and the DOC drive motor audibly speeds up.

   The Enabled state lasts for 15 seconds.

2. Notify the Sterile Operator that the system is enabled.

Sterile Operator

3. Begin contrast media injection (using syringe or automated power injector pump).

   The system automatically begins a recording once a brief sequence of clear image frames are detected indicating the area is flushed with contrast media.

   NOTE: If the **Recording Type** is set to **Pullback**, the recording takes approximately 3 seconds. If set to **Stationary**, the recording takes approximately 6 seconds.

   If the **Automatically review recordings** option is enabled, the image file is displayed for review.

Review the recording and repeat it if needed. If the catheter is still connected to the DOC, ask the non-sterile operator to click the **New Recording** button at the bottom of the screen.

Removing the Dragonfly Imaging Catheter

All information obtained during imaging is automatically saved with the recording. Once imaging is completed, the data and images may be reviewed (see Chapter 6 “Reviewing OCT Recordings”) or transferred to removable media for review on a St. Jude Medical Offline Review Workstation (see Chapter 8 “Exporting, Importing, and Managing Files”).

Non-sterile Operator

1. Ensure that the Dragonfly catheter is not rotating (click on the **Standby View** button if necessary) before the sterile operator begins withdrawal and unloading.

Sterile Operator

2. When all OCT imaging is complete, withdraw the Dragonfly catheter into the guide catheter under fluoroscopic observation.

   CAUTION: If resistance is encountered during 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 catheter and guidewire as a unit from the patient.

3. Remove the Dragonfly catheter from the guide catheter and guidewire.

4. Disconnect the Dragonfly catheter from the DOC by pressing the **Unload** button. When the “lock” LED stops flashing, the catheter is disconnected internally. Twist the catheter hub counter-clockwise to disengage it from the DOC.

   CAUTION: Handle the Dragonfly Imaging Catheter and all other disposables used during the procedure as potential biohazards. Dispose of in accordance with accepted medical practice and all applicable laws and regulations.

Troubleshooting OCT Acquisition

Immediately Stopping DOC Operation

1. Press the **Stop** button on the DOC at any time to immediately stop operation of the DOC. Pressing this button:
   - Turns off the DOC motors, thereby stopping all optical fiber movement, both rotational and longitudinal.
   - Turns off the Imaging Engine light source.
   - Stops recording and freezes the image. If **Automatically review recordings** is checked in the **Configure** tab of the **Setup** dialog box, it automatically plays back the recording once it has been saved.
   - Prevents the imaging catheter lens from automatically advancing to its original distal position.
2. The system computer remains on and the system is available for new operations.

CAUTION: If the catheter was stopped before returning to its fully advanced position, the system displays an alert: Catheter Must Be Advanced to Continue. Click the Advance Catheter button to advance the optical fiber within the catheter shaft. You must advance the catheter before making another OCT recording.

Catheter Failure

NOTE: These events can only occur if a catheter is connected to the DOC.

In the event of an imaging catheter failure (complete break of the optical fiber) during either pullback or advance, the system stops automatically (and stops pullback/advance) and displays the following message:

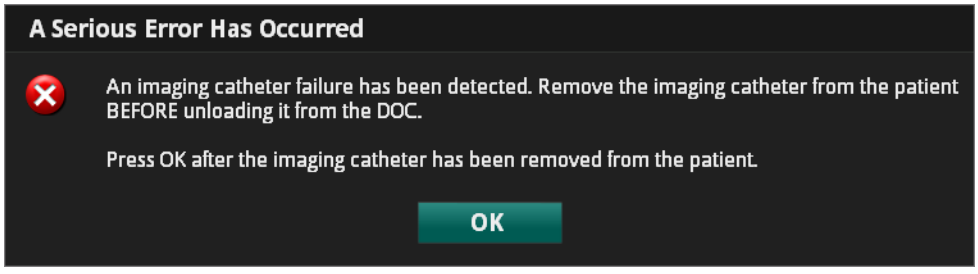


Figure 5-9: Catheter Failure message

CAUTION: Do not click the OK button until after you have removed the Dragonfly Imaging Catheter from the patient.

1. Withdraw the Dragonfly into the guide catheter under fluoroscopic observation.

CAUTION: If resistance is encountered during withdrawal of the Dragonfly catheter, stop manipulation and evaluate under fluoroscopy. If the cause of resistance cannot be determined or mitigated, carefully remove the catheter and guidewire as a unit from the patient.

2. Remove the Dragonfly catheter from the guide catheter and guidewire.

3. Acknowledge the alert by clicking on **OK**.

   After acknowledging the alert, a second alert is displayed as shown below.

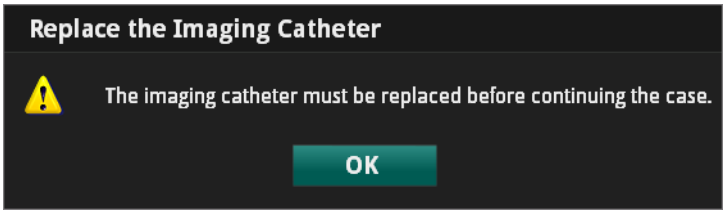


Figure 5-10: Replace Catheter message

4. Acknowledge this message by clicking on **OK**.

5. Advance the optical fiber all the way to its forward position by pressing the **Unload** button on the DOC.

6. Remove the existing Dragonfly Imaging Catheter in the normal manner.

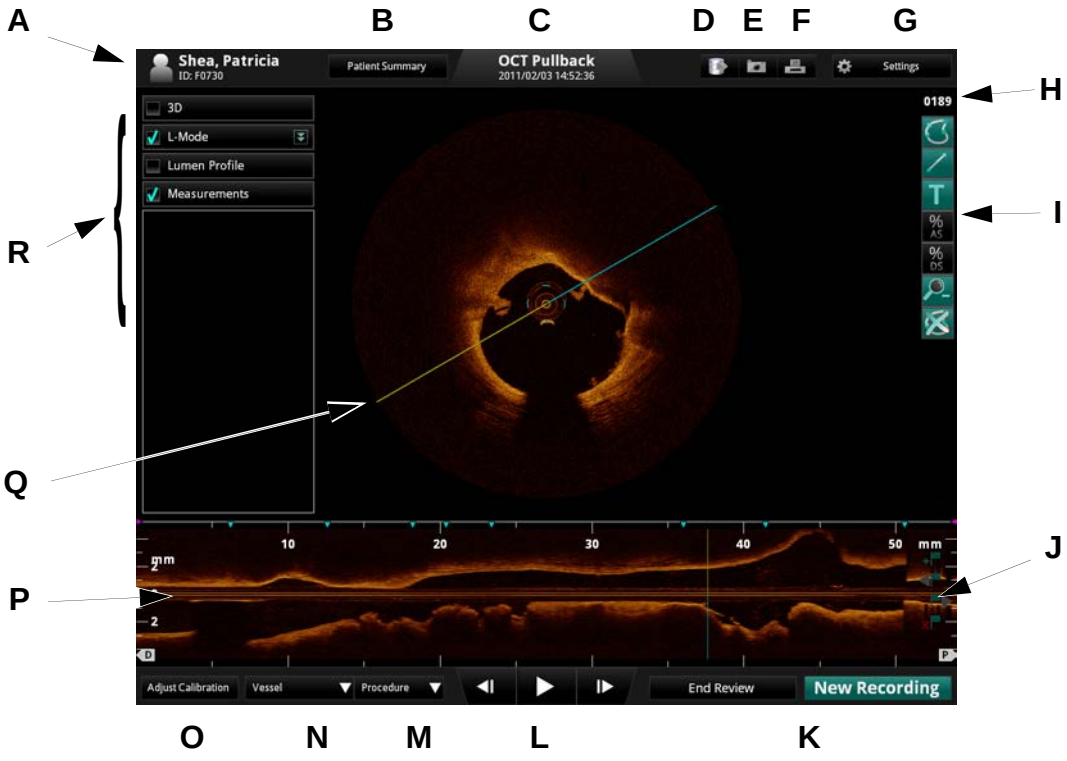
7. Load a new Dragonfly Imaging Catheter in the normal manner.

Reviewing OCT Recordings 6

NOTE: Making measurements, calculations, and text annotations is covered in Chapter 7 “Measurements and Annotations”. Exporting images is covered in Chapter 8 “Exporting, Importing, and Managing Files”.

Image Window

The Image Window shows a cross-section view of the recording or still frame (Table 6-1).
Table 6-1: OCT Display Overview



A Patient name and ID.

See "Entering New Patient Information" on page 3-5 for more information.

B **Patient Summary** button: Click to open a list of all recordings for this patient.

See "Patient Summary Menu" on page 3-4 for more information.

C Recording date and time.

D **Export** button: Click to open the **Export Wizard**.

See Chapter 8 "Exporting, Importing, and Managing Files" for more information.

E **Capture** button: Available on a still frame or paused recording. Click to save the current frame.

F **Print** button: Available when a USB drive is connected and the system is displaying a still frame or paused recording. Click to print the current frame to file.

See "Printing Still Images" on page 6-12 for more information.

G **Settings** button: Click to open the (Playback) **Settings** menu.

See "Adjust Playback Settings" on page 6-8 for more information.

Table 6-1: OCT Display Overview

H	Frame number: Available on a paused recording.
I	Measurement and Annotation tools: Use these to add measurements, calculations, and add text to recordings and still images. See Chapter 7 “Measurements and Annotations” for more information.
J	Bookmark controls: Add bookmarks to the L-Mode view. See “Bookmark Controls” on page 6-9 for more information.
K	**End Review** / **New Recording** : Click the **End Review** button to close this window and return to the **Patient Summary** menu. **NOTE:** While the ILUMIEN OPTIS System is connected to a Dragonfly imaging catheter, the button **New Recording** appears here. Click the **New Recording** button to close this review and begin a new OCT recording.
L	Playback controls: Control the playback of the OCT recording. Not available with still images. See “Playback Controls” on page 6-6 for more information.
M	**Procedure** list: Click to open a drop-down list of procedures to describe this recording.
N	**Vessel** list: Click to open a drop-down list of vessels to describe this recording.
O	**Adjust Calibration** button: Click to open the playback calibration controls. See “Calibration Adjustment” on page 6-7 for more information.
P	L-Mode view: An approximate lateral representation of the vessel for this recording. Not available with still images. See “L-Mode View” on page 6-4 for more information.
Q	Image Window: A cross-section view of the vessel.
R	Annotations Panel: Control display features including L-Mode and optional features such as 3D and Lumen Profile. This section also lists measurements from the current image; click on a measurement to highlight it in the Image Window.

L-Mode View

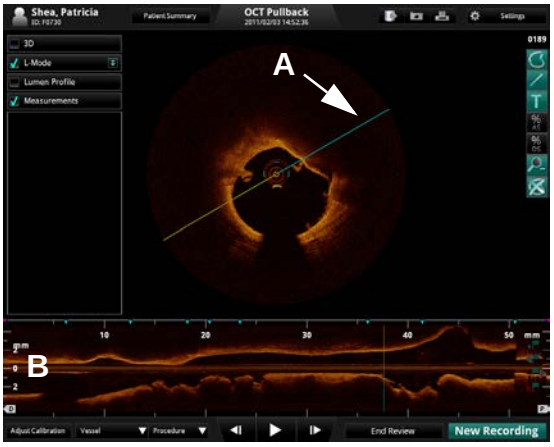
NOTE: If reviewing a **Stationary** recording, the L-Mode display is renamed *Timeline*. The Timeline represents the stationary view of the catheter during the six seconds of recording.

During the OCT pullback recording, the system captures evenly spaced cross-section images and uses them to construct a lateral view of the vessel anatomy. The lateral view is shown in the L-Mode display in the lower portion of the screen; the distal portion of the recording is to the left.

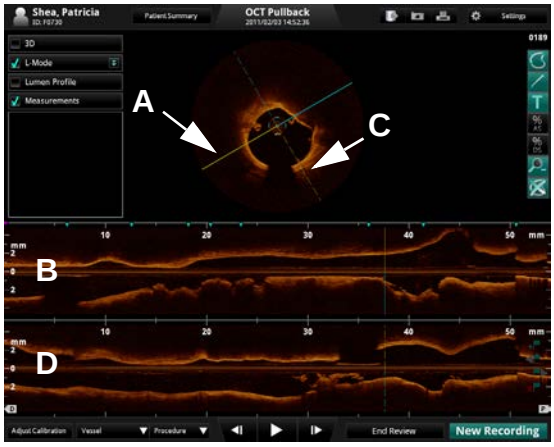
Click an L-Mode to display it. The system can show up to two cut-plane views at a time. If two L-Mode views are shown, the second view is offset from the first view by 90 degrees.

NOTE: If you have the Lumen Profile option, you cannot have the Lumen Profile display and Dual L-Mode displays on screen at the same time.

Table 6-2: L-Mode views



L-Mode: Single



L-Mode: Dual

A Single L-Mode cut-plane indicator. This cut-plane is shown as a solid line in the cross-section view. Click and drag this to change the lateral view shown in the L-Mode display.

B Single L-Mode display.

C Second (Dual) L-Mode cut-plane indicator. This cut-plane is shown as a dashed line in the cross-section view, offset from the first view by 90 degrees. Click and drag either cut-plane indicator to change the lateral views.

D Second (Dual) L-Mode display.

NOTE: The width of the L-Mode window represents the entire range of the recording.

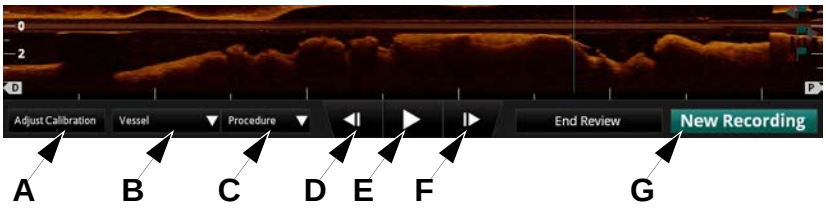
Limitations of L-Mode Data

Please be aware of the following limitations of L-Mode data:

- Due to the catheter's arbitrary position within the vessel, L-Mode data may not be representative of the actual vessel lumen.
- The vessel diameter shown in the L-Mode reconstruction may appear significantly smaller than the actual diameter when the catheter position is off center and close to the vessel wall. To avoid misinterpreting the image when this occurs, rotate the cut-plane to examine all views of the L-Mode.
- Although a vessel may curve, the L-Mode view always appears straight because of the limitations of reconstruction.
- Artifacts caused by the relative motion of the catheter and the vessel often result in a saw-toothed appearance of the reconstruction and can lead to misinterpretation by inexperienced users.
- Shortening or lengthening artifacts in the L-Mode reconstruction may occur due to the relative motion of the Dragonfly catheter with respect to the coronary artery caused by the patient's heart motion.

Playback Controls

Table 6-3: Playback Controls



A **Adjust Calibration**: Press to open the Calibration menu. Only available with a still image or paused recording.

B **Vessel** list: Click to open a drop-down list of vessels to describe this recording.

C **Procedure** list: Click to open a drop-down list of procedures to describe this recording.

D **Step Backward** : Click to move the recording back one frame at a time. Click and hold this button to move back rapidly. Not available with still images.

E **Play/Pause** : Plays or Pauses the recording. If you pause a recording, the frame number is displayed in the upper right corner of the image area. Not available with still images.

F **Step Forward** : Click to move the recording forward one frame at a time. Click and hold this button to move forward rapidly. Not available with still images.

G **End Review** / **New Recording** : Click the **End Review** button to close this window and return to the **Patient Summary** menu.

NOTE: While the system is connected to a Dragonfly Imaging Catheter, the button **New Recording** appears here. Click the **New Recording** button to close this review and begin a new OCT recording.

Calibration Adjustment

Use the **Adjust Calibration** tool to adjust the calibration of the recording.

1. Use the Playback Controls at the bottom of the screen to pause the playback.

2. Click on the **Adjust Calibration** button at the bottom of the screen.

   The Calibration tool opens. The image is zoomed and the calibration circle with two control points is sized approximate to the outside diameter of the catheter.

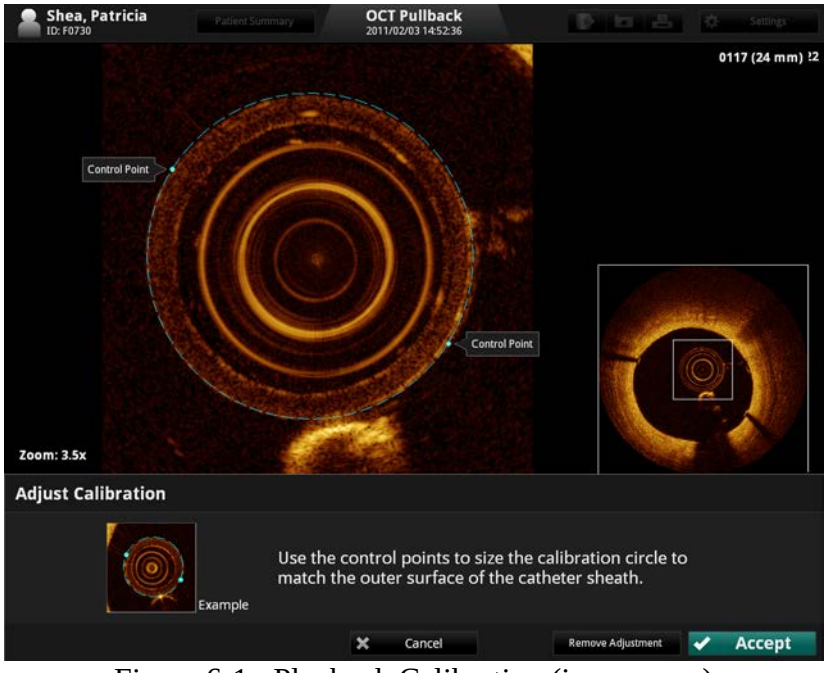


Figure 6-1: Playback Calibration (in progress)

3. Click and drag on the control points until the calibration circle traces the outside diameter of the catheter as shown in the sample picture at the bottom of the screen.

   NOTE: Adjustments made here are for *size*, not *alignment*. The catheter may not appear centered in all frames during playback. This is normal.

4. Click the **Accept** button save the calibration, or click **Cancel** to close the calibration tool without saving the adjustment.

   NOTE: If necessary, you can return the recording to its default calibration by clicking the **Remove Adjustment** button.
   If you remove or change the calibration, any changes that you have made to the automatically-generated Lumen Profile contours are reset. See "Lumen Profile Display Option" on page 7-19 for more information.

Adjust Playback Settings

1. Click the **Settings** button at the top of the screen.

   A context-sensitive menu opens.

2. Click and drag the **Playback Speed** slider bar to set the playback speed.

3. Click and drag the **Rotation** slider bar to rotate the image shown in the cross-section view.

   NOTE: When an image is rotated, the L-Mode cut-plane marker (if visible) and any displayed measurements and annotations are also rotated.

4. Click and drag the **Black level** and **White level** slider bars to set the black and white balance in the image.

5. Click the arrow on the **Field of View** drop-down menu to display the list of diameter sizes.The default setting is **7.0 mm**.

   The **Field of View** setting controls the size of the image displayed on screen. A smaller Field of View setting equals a larger magnification. Click a size to select it.

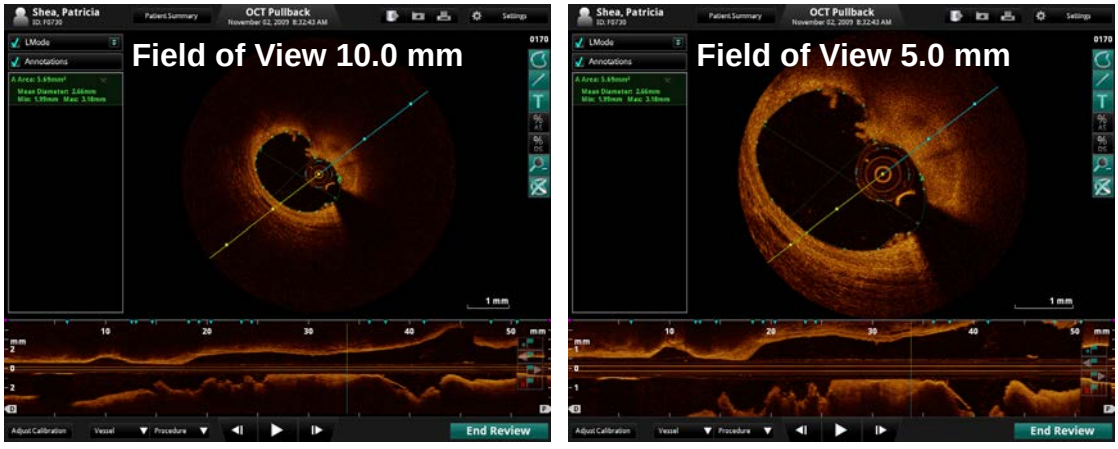


Figure 6-2: Field of View Settings

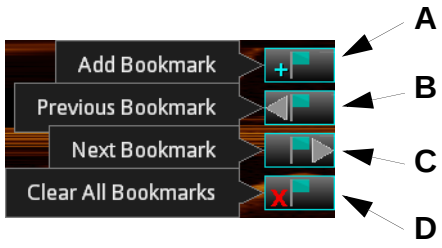
6. Click **Close** to continue.

Bookmark Controls

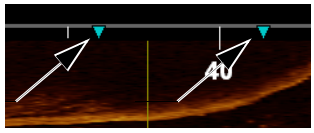
The System allows you to add bookmarks to mark frames for further review.

NOTE: Bookmark controls are only available when an L-Mode view is displayed in a recording.

Table 6-4: Bookmark Controls



A **Add/Remove Bookmark** : Applies or removes a bookmark from the current frame. After a bookmark has been applied to a frame, the position of the bookmark is indicated in the L-Mode view with a green triangle.



Click on a bookmark indicator to jump to the bookmarked frame.

NOTE: Frames with measurements and annotations are bookmarked automatically. See Chapter 7 “Measurements and Annotations” for more information.

B **Previous Bookmark** : Seeks backward to the previous bookmarked frame. If there are no previous bookmarks, it continues seeking from the end of the recording. Unavailable if there are no bookmarks.

C **Next Bookmark** : Seeks forward to the next bookmarked frame. If there are no subsequent bookmarks, it continues seeking from the beginning of the recording. Unavailable if there are no bookmarks.

D **Clear All Bookmarks** : Clears all bookmarks from the current recording. Unavailable if there are no bookmarks.

Setting Playback Range

By default, the system plays the entire length of a pullback during the review. You can shorten the length of the playback by moving the ends of the playback range.

NOTE: Playback range markers are only available on recordings in the L-Mode view. By default, they are at the distal and proximal ends of the recording.

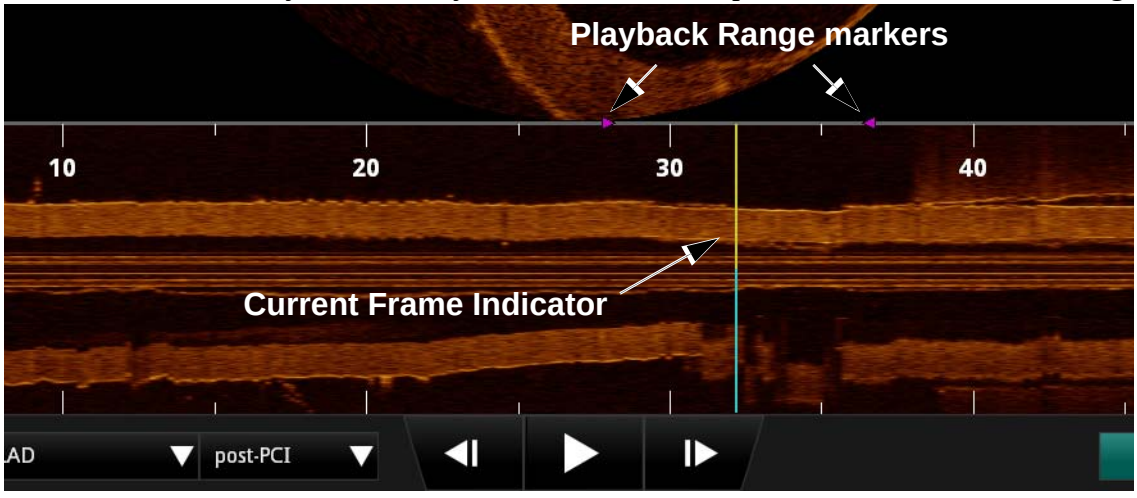


Figure 6-3: Adjusted Playback Range

To change the playback range:

1. Use the Playback Controls at the bottom of the screen to pause the playback.

2. Click on the range markers (purple triangles) and position them before and after the area to be played during review.

NOTE: If the recording is exported as an AVI file, this range determines the length of the exported recording.

NOTE: If the L-Mode view is changed (for example, turned **Off**), the playback range is restored to the full length of the recording.

Exporting a Recording or Still Frame

Refer to Chapter 8 “Exporting, Importing, and Managing Files” for more information on exporting a recording or still frame.

Capturing Still Images

You can use the **Capture** button to save a still image from a recording, or to save a copy of an existing still frame. All measurements and annotations on that screen are saved with the captured image.

NOTE: The **Capture** button is unavailable while a recording is playing. Pause the playback at the frame that you want to capture.

Saving a Still Image

1. Display the frame that you want to capture.

2. Click the **Capture** button.

   A confirmation message appears, and the captured image appears in the **Patient Summary** menu.

   NOTE: The still image is saved with the same date as the source file. It is grouped in the **Patient Summary** menu with other recordings and images of the same date.

   In the **Patient Summary** menu, the system adds the frame number to the title of the captured image (for example, “*OCT Frame 145*”).

Printing Still Images

You can use the **Print** button to print the current screen (including still frame, L-Mode, and any visible annotations) to an attached USB drive. All measurements and annotations on that screen are saved with the captured image.

NOTE: The **Print** button is unavailable while a recording is playing. Pause the playback at the frame that you want to print.

NOTE: If you are printing the file to a USB drive, you can set the file format. See "Setup - Print Menu" on page 10-20 for more information.

Printing a Still Image

1. Display the frame that you want to print.
2. Click the **Print** button.

   A confirmation message appears, and the file is saved on the attached USB drive.

Measurements and Annotations 7

Measurements and Text Callouts in the Image Files

Measurements and text callouts that are added to images do not change the underlying image data. The unannotated image is always preserved and can be reviewed without the measurements and callouts. All measurements and annotations added during the procedure are preserved in the file.

Measurements and text callouts can be modified or deleted, and pen color, line width and point size can be set. In addition, pen color can be set to automatically cycle so that subsequent measurements are displayed in different colors. For information on setting pen color, line width, and point size, see “Setup - Measurements/Labels Menu” on page 10-18.

CAUTION: If you want to make measurements on files which 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.

CAUTION: 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.

NOTE: All measurements and calculations can be made in the cross-section view of the OCT image, but only horizontal length measurements and text annotations can be made in the L-Mode view.

Measurement and Annotation Tools

When the OCT playback is paused, or displaying a still image, the measurement and annotation tools are available on screen. As measurements are added to the image, they are labeled with successive control letters (A, B, C, etc., up to 26 measurements per frame).

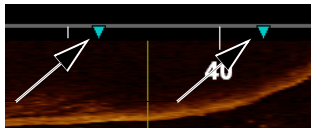
Figure 7-1: Measurement and Annotation Tools

NOTE: Tools have a black background when they are unavailable.

Table 7-1: Measurement and Annotation Tool Functions

	**Area - Multiple Points** : Manually place points to trace and measure an area on a frame. This also generates the min., max., and mean diameter measurements for the given area.
	**Length** : Make a distance measurement on a frame.
	**Text...** : Opens the **Enter Note** menu to enter text at the cursor position.
	**%AS (Percent Area Stenosis)** : Calculates the relative size of two areas drawn in the current frame.
NOTE: If there are fewer than two areas on the current frame, this button is not available.	
	**%DS (Percent Diameter Stenosis)** : Calculates the relative size of two lengths (or diameters) drawn in the current frame.
NOTE: If there are fewer than two lengths on the current frame, this button is not available.	
	**Zoom - / Zoom +** : Switches between zoom levels. See "Adjust Playback Settings" on page 6-8 for more information.
	**Delete All Annotations** : Click to delete all annotations and measurements.

NOTE: After a measurement or text annotation has been applied to a frame, the position of the bookmark is indicated in the L-Mode view with a green triangle.
Click on a bookmark to jump to it.



Verifying Calibration

Before making measurements, you must verify the calibration. If the calibration for this recording or still image has not been adjusted, or if it has been reset, the calibration tool appears when you begin to take a measurement. See “Calibration Adjustment” on page 6-7 for more information.

Once the calibration is accepted, you can begin taking measurements.

Techniques to Improve Measurement Accuracy

Follow these guidelines to improve measurement accuracy:

- Before making measurements, use the Zoom function to zoom into the region of interest until you can clearly see borders and other features you want to measure (see “Field of View” on page 7-14).
- Place the measurement cursor correctly on the image, using the same measurement technique each time you perform the same type of measurement.
- Avoid making measurements in areas that have artifacts that disguise tissue.

Measurements and Annotations in the L-Mode View

All annotations and measurements are typically made in the cross-section view area of the Image Window. Only horizontal measurements, useful for determining pullback distance, are permitted in the L-Mode view.

CAUTION: Artifacts may result in misrepresentation of L-Mode data, so L-Mode is not recommended for quantization of clinical information.

Length Measurements

The system calculates and displays length as the distance in millimeters (mm) between 2 points placed on an image in either the cross-section or L-Mode views.

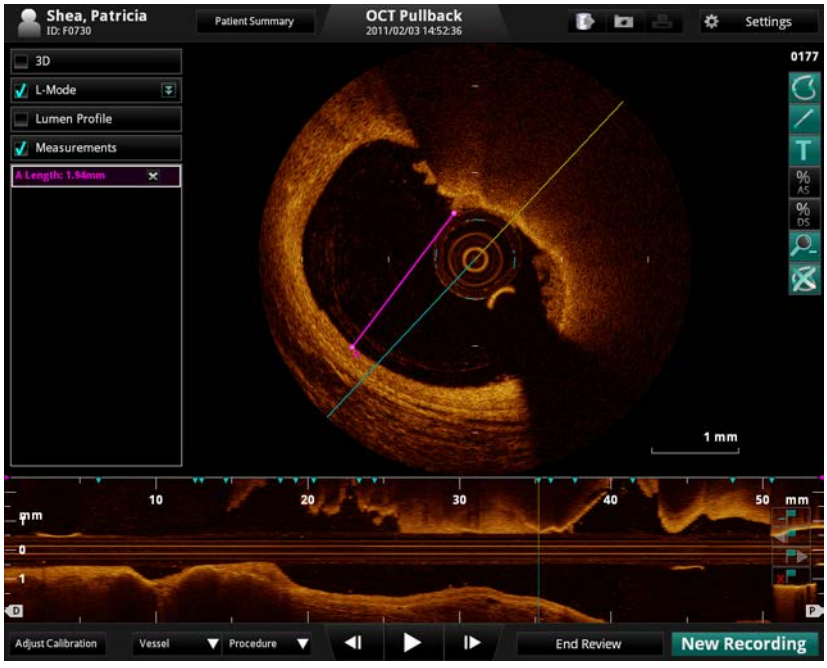


Figure 7-2: Length Measurement

Making a Length (Distance) Measurement

1. Select the still image or paused recording that you want to measure.

2. Click on the **Length** button (Figure 7-1). The cursor changes to a pen.

3. Click anywhere in the Image Window (cross-section view or L-Mode view) to place the starting point for the length measurement.

   NOTE: Both start and end points must be in the same view. For example, if the starting point is placed in the cross-section view, the end point must also be in the cross-section view.
   To cancel the measurement, press the <Esc> key or click the **Cancel** button.

4. Use the mouse to position the pen cursor at the end point and click to set the point.

   The completed, labeled distance measurement result appears in the Annotations Panel. If you position the cursor over the line, the length is shown over the center of the line.

Area Measurements

You can manually create a closed area trace of the lumen contour in the cross-section view. The area is calculated using Green's Theorem, and is displayed in the frame in mm^2 with the minimum and maximum diameter chords.

NOTE: If the Automatic MLA and %DS option is enabled and you are reviewing a pullback recording, your system automatically adds a "Lumen Profile" measurement on each frame.

NOTE: The minimum diameter chord has arrowheads that point inward (toward the diameter chord). The maximum diameter chord has arrowheads that point outward.

Making a Manual Area Measurement

1. Select the still image or paused recording that you want to measure.

2. Click on the **Area - Multiple Points** button (Figure 7-1). The cursor changes to a pen.

3. Use the mouse to position the pen cursor at the desired starting point for the area in the cross-section view and click to set the point.

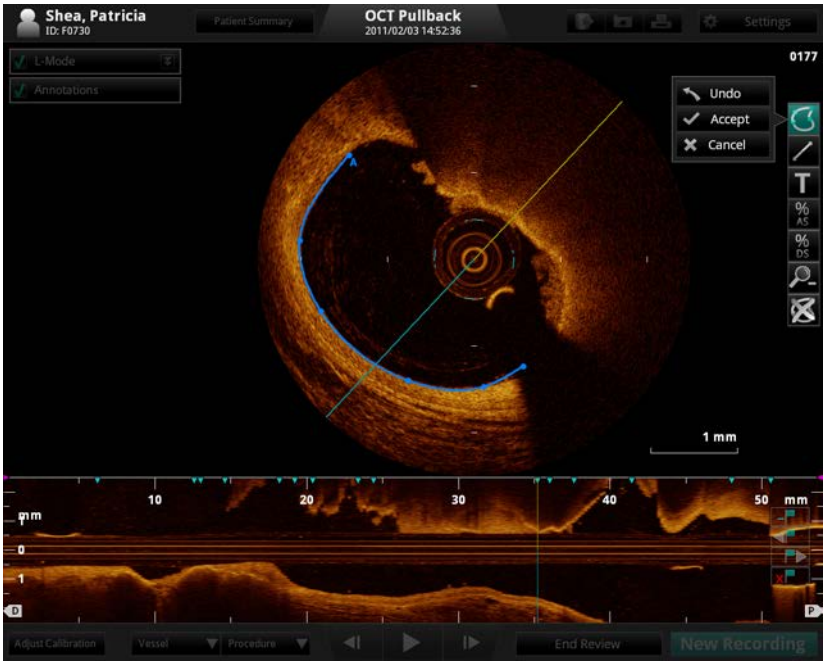


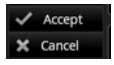
Figure 7-3: Manual Area Measurement (in progress)

NOTE: Click the **Undo** button to the left of the toolbar to delete the most recent point added to the image.

4. Continue to add points with the pen cursor until you have accurately traced the area to be measured. You can place as many points as you like around the border of the desired area. At least three points are required.

   NOTE: The first two points are connected by a straight line. When you place subsequent points, the straight line becomes a smooth curve connecting all points but not closing the area until you click the **Accept** button, or the last point is sufficiently close to the initial point for the system to automatically complete the area. Placing more points increases measurement accuracy.

   NOTE: You must click either **Accept** or **Cancel** to complete the measurement. Click **Cancel** to completely erase the measurement.



5. Click the **Accept** button to the left of the toolbar to save the measurement, or click the **Cancel** button to cancel it.

Adding Text Callouts

You can add text callouts to a single frame or to the entire recording.

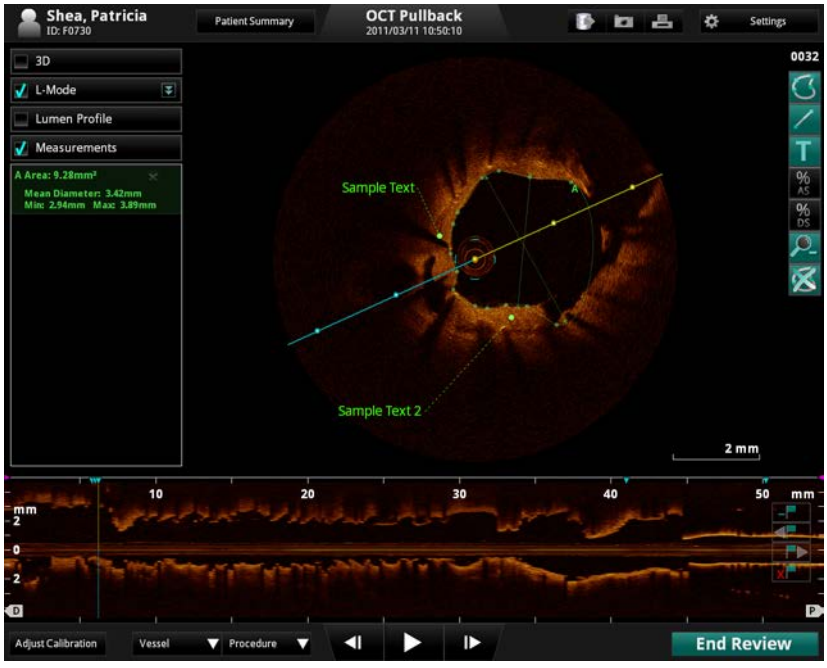


Figure 7-4: Text Callouts

Adding Text Callouts

1. Select the still image or paused recording that you want to annotate with text.

2. Click on the **Text...** button (Figure 7-1).

   The cursor changes to a Text marker (“A”).

3. Place the cursor where you want the text to be displayed.

   The **Enter Note** menu (see Figure 7-5) appears.

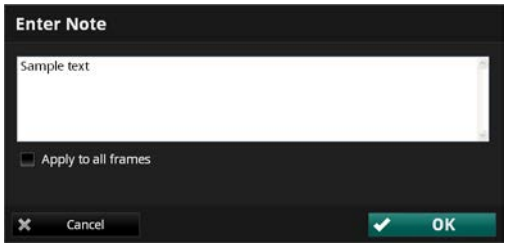


Figure 7-5: Enter Note Dialog Box

4. Type the desired text into the box.

5. If you want to display the text on all frames, click the **Apply to all frames** check-box. (Not applicable for text added in the L-Mode view.)

6. Click **OK** to approve the note or click **Cancel** to cancel the note.

   The text appears, including a callout line beneath the text.

7. To change the position of the text on screen, click and drag the text to the desired position.

8. To change the position of the callout line, click the end of the line and drag it to the desired position.

The %AS Calculation

The %AS (Percent Area Stenosis) calculation calculates the percentage size of a smaller area with relationship to a larger area, typically the area of the inner border of a vessel compared to the area of the outer border.

Formula for %AS Calculation

%AS = (First Area-Second Area)/First Area * 100

To make this calculation, you must have two areas drawn on the current frame.

Make a %AS Calculation

1. Make an area measurement.
2. If necessary, make a second area measurement in the frame.
3. Click on the **%AS** button (Figure 7-1) to display the **Select Area Measurement** dialog box.

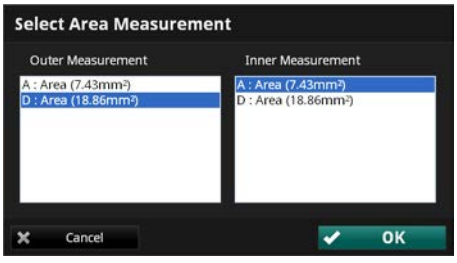


Figure 7-6: Select Area Measurement Dialog Box

4. In the **Outer Measurement** list, click the larger area measurement.
5. In the **Inner Measurement** list, click the smaller area measurement.
6. Click **OK**.

The % Area Stenosis calculation is displayed immediately below the previous calculations in the Annotation Panel as shown in Figure 7-7.

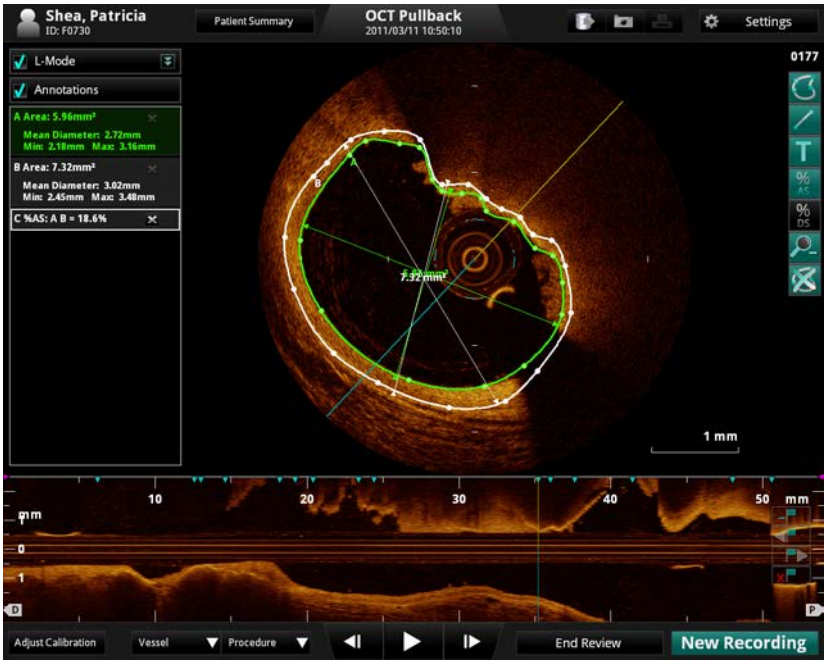


Figure 7-7: %AS Calculation

NOTE: If the second measurement you select is larger than the first measurement, a %AS value will not be displayed. Instead, the Annotation Panel displays an error message, similar to the one shown in Figure 7-8.

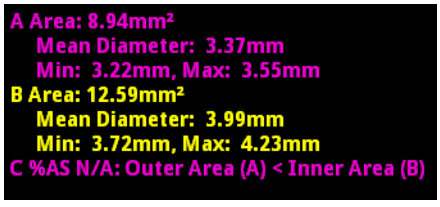


Figure 7-8: %AS Error Message

The %DS Calculation

The %DS (Percent Diameter Stenosis) calculation calculates the percentage size of a smaller length with relationship to a larger one, typically the diameter of the inner border of a vessel compared to the diameter of the outer border.

Formula for %DS Calculation

%DS = (First Length-Second Length)/First Length * 100

To make this calculation you must first draw and specify two lengths, one for the smaller diameter and one for the larger diameter.

Make a %DS Calculation

1. Make two length measurements in the current frame.

2. Click on the **%DS** button (Figure 7-1) to display the **Select Length Measurement** dialog box.

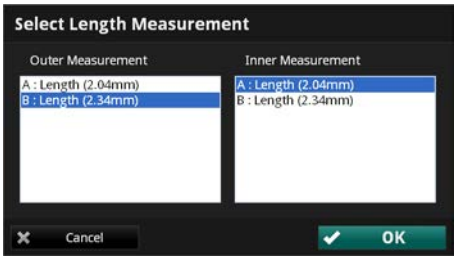


Figure 7-9: Select Length Measurement Dialog Box

3. In the **Outer Measurement** list, click the longer length.

4. In the **Inner Measurement** list, click the shorter length.

5. Click **OK**.

The % Diameter Stenosis calculation is displayed immediately below the previous calculations in the Annotations Panel, as shown in Figure 7-10.

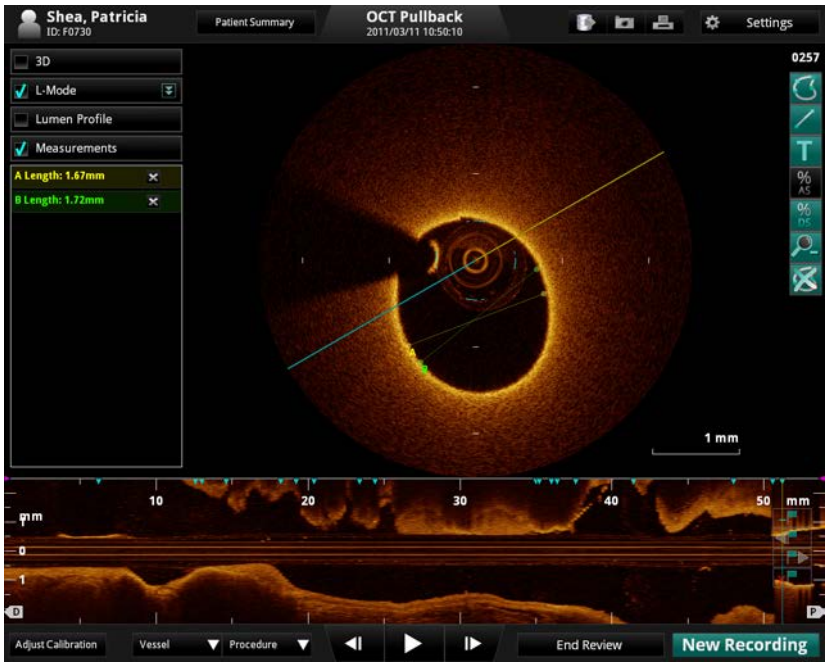


Figure 7-10: %DS Calculation

NOTE: If the second measurement is larger than the first measurement you select, a %DS value will not be displayed. Instead, the Annotation Panel displays an error message, similar to the one shown in Figure 7-8 for %AS.

Field of View

You can zoom out on a recording or still image in order to see the full lumen on a large vessel, centered on the catheter.

NOTE: Using either Zoom function does not change the image data that is saved; it merely changes the portion of the data that is displayed.

Increase/Decrease Field of View

 Click to increase the field of view on the recording or still image. Click again to return to normal image size.

NOTE: Depending on the current Flush Medium, the image may not occupy the entire 10.5 mm diameter.

You can change the magnification of the zoomed field. See "Adjust Playback Settings" on page 6-8 for more information.

Zooming In Manually

You can enlarge any section of the image manually.

NOTE: This magnification function cannot be used in the L-Mode display.

1. Place the cursor over the image area you want to enlarge.

2. Click and drag the mouse across an area to magnify it.

   When you release the mouse, the system zooms in to the selected rectangle, displaying the magnification factor used (ex. **Zoom: 2.5x**, see Figure 7-11).

   The system adds an overall view of the image to the right.

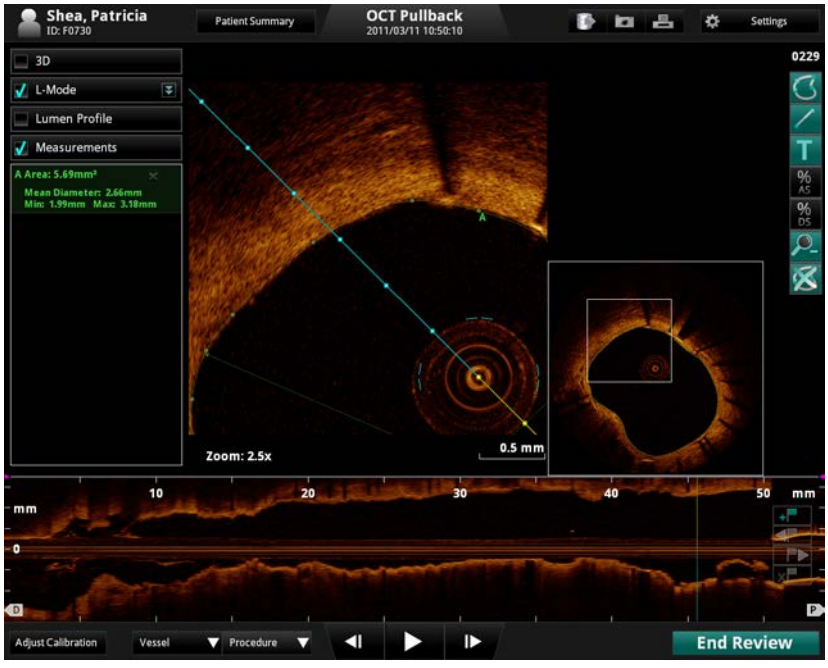


Figure 7-11: Zooming an Image

3. To return to normal imaging, click anywhere in the zoomed image.

Editing Measurements and Annotations

All measurements and annotations can be moved, deleted, or edited.

- Area and length measurements can be adjusted by moving or deleting control points.
- Text annotations can be moved or deleted.

NOTE: When a measurement is changed, calculations that depend on that measurement are updated automatically.

Moving Individual Points

To move an individual point, click on the point and drag it to a new location.

NOTE: When you select a point, the point changes from a circle to a square, indicating that it may now be moved.

NOTE: If you move a point on an automatically-generated Lumen Profile contour, an arrow icon appears in the corner of the measurement listed in the Annotations Panel. Click the arrow to reset the contour on that frame back to the automatically-generated Lumen Profile contour. See "Lumen Profile Display Option" on page 7-19 for more information.

Adding Points to a Multiple Point Area

To add additional points to a multiple point area, click on the curve between two points. A new point will be added where you click.

NOTE: When you position the mouse over a location where a point can be added, the cursor changes from an arrow to a hand.

Deleting Points from a Multiple Point Area

To delete selected points in a multiple point area, click on the desired point and press the <Del> key on the keyboard.

NOTE: When you select a point, it changes from a circle to a square, indicating that it may now be deleted.

Deleting Individual Measurements or Text Callouts

NOTE: If a measurement is in use with a calculation (for example, an area used by **%AS**), the individual measurement cannot be deleted until the calculation is deleted.

To delete a measurement:

- Click on the “x” next to it in the Annotations Panel. The measurement is deleted.

To delete a distance measurement in the L-Mode:

1. Click on a distance measurement in the L-Mode to select it. A white box appears around the label.

2. Press the <Del> key on the keyboard.

   The distance measurement is deleted.

To delete a text callout:

1. Click on a text callout to select it. A white box appears around the text callout.

2. Press the <Del> key on the keyboard.

   The text callout is deleted.

Deleting All Measurements and Text Callouts

Click to delete all measurements, calculations, and text callouts from this recording or still image.

NOTE: Contours generated automatically by the **Lumen Profile** function are not deleted. If you have used the **Lumen Profile** function to calculate the minimum lumen area, that measurement is not deleted.

Lumen Profile Display Option

The system automatically creates a trace of the lumen contour on each frame. Add a check to the **Lumen Profile** checkbox to display a graph of the lumen profile.

NOTE: Lumen Profile is not available with still images or stationary recordings.
A single L-Mode view must be turned on in order to use the Lumen Profile display option. Lumen Profile display cannot be used with Dual L-Mode displays.
Remove the check from the Measurements checkbox to hide the lumen contour trace and corresponding measurements.

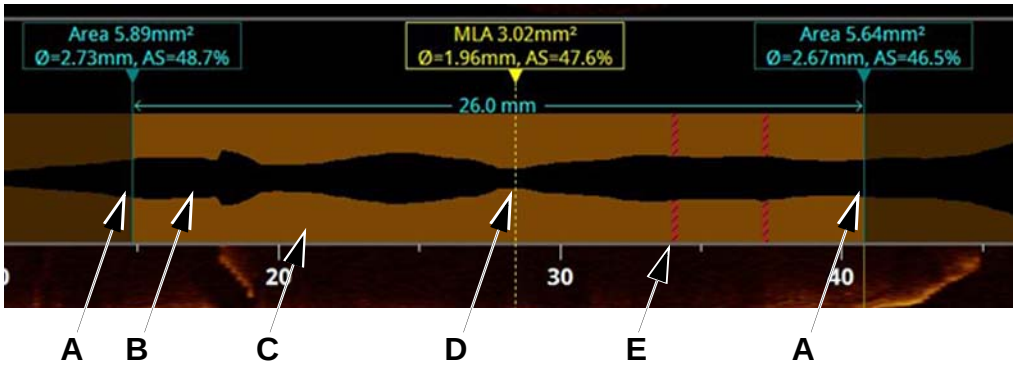
The Lumen Profile display opens with Minimum Lumen Area (**MLA**) and a percent stenosis graph (**%AS** or **%DS**) turned on:

- **MLA** displays the Minimum Lumen Area controls and values for this recording.
- **%DS** shows how the mean diameter changes along the length of the recording.
- **%AS** shows how the lumen area changes along the length of the recording.

Lumen Profile Display With MLA Controls Overview

CAUTION: It is the user's responsibility to confirm the lumen contour on each frame, and to make adjustments if necessary.
Red frames indicate low confidence in the detected contour. If the MLA frame is in the vicinity of a low confidence region, the system displays "?.??" for the MLA values. If the MLA values are "?.??," the contour on the MLA frame must be reviewed, edited if necessary, and accepted before it can be displayed.

Table 7-2: MLA Controls



A **Distal and Proximal Boundaries** : Move these to set the range for MLA calculation. The system's search for a minimum lumen area occurs on frames between the distal and proximal boundaries.

See Table 7-3 on page 7-21 for more information on calculations.

- If **%DS** is selected in the Lumen Profile, the boundaries display the percent diameter stenosis at each end of the range.
- If **%AS** is selected, the boundaries display the percent area stenosis at each end of the range.

B The lumen area is colored black.

C Where the system has high confidence in the contour of the lumen area, or where the contour has been accepted by the user, the section is colored brown.

D **Calculated MLA** : The dashed line indicates the position of the minimum lumen area between the distal and proximal boundaries (**A**).

E Where the system has low confidence in the contour of the lumen area, the section is colored red. These frames are not considered in the MLA search. If these frames are within the range where MLA is calculated, you must go to the MLA frame and confirm the contour.

Table 7-3: Lumen Profile %AS and %DS Calculations

	When Lumen Profile set to %DS...	**When Lumen Profile set to %AS...**
Stenosis calculations of the MLA frame compared to average of distal and proximal references (value listed above the MLA frame):	$\%DS = 100 * (D_{REF} - D_{MLA}) / D_{REF}$ where D_{REF} is the average of the Distal Reference's mean diameter and the Proximal Reference's mean diameter. D_{MLA} is the MLA's mean diameter.	$\%AS = 100 * (A_{REF} - A_{MLA}) / A_{REF}$ where A_{REF} is the average of the Distal Reference's area and the Proximal Reference's area. A_{MLA} is the Minimum Lumen Area.
Stenosis calculations of the MLA frame compared to individual distal and proximal references (values listed above the D or P Boundaries):	$\%DS = 100 * (D_{D\ or\ P} - D_{MLA}) / D_{D\ or\ P}$ where $D_{D\ or\ P}$ is the Distal Reference's mean diameter or the Proximal Reference's mean diameter. D_{MLA} is the MLA's mean diameter.	$\%AS = 100 * (A_{D\ or\ P} - A_{MLA}) / A_{D\ or\ P}$ where $A_{D\ or\ P}$ is the Distal Reference's area or the Proximal Reference's area. A_{MLA} is the Minimum Lumen Area.

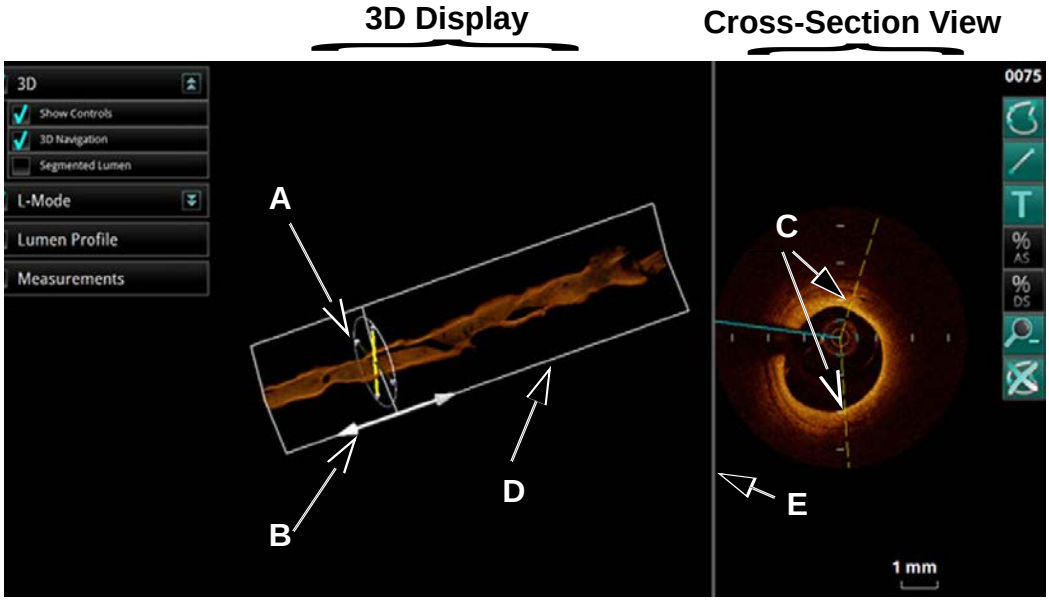
3D Display Option

Click the **3D** button to create a 3D representation of the recording.

NOTE: You cannot add or change measurements or annotations in the cross-section view or 3D Display while 3D Display is on. You can add annotations and distance measurements to the L-Mode view only.
3D Display is not available with still images or stationary recordings.

3D Navigation Controls

Table 7-4: 3D Navigation Controls



A **Cut Plane Angle Indicator** : Click and drag around the vessel to change the cut plane as shown in the L-Mode.

B **Frame Dragger** : Click and drag along the length of the vessel to change the frame shown in the cross-section view.

C **Volume Clip Controls** : Click and drag these to open or close the 3D rendered wall of the vessel shown in the 3D Display. As the Volume Clip is opened, the wall of the vessel is removed in the 3D Display, allowing you to see inside the rendered vessel.

NOTE: The blue line in the cross-section view represents your “line of sight” into the open vessel. The dashed yellow lines represent the edge of the opening into the rendered vessel.

D **Volume Clip Display** : Displays the opening in the rendered vessel as defined by the Volume Clip Controls.

E Click and drag the divider bar side to side to change the size of 3D Display versus cross-section view.

Zooming : Click in the 3D Display area and use the scrollwheel to zoom in or out.

3D Display with Segmented Lumen

NOTE: If the Segmented Lumen setting is turned on, the 3D Navigation setting is turned off, and vice-versa. Selecting one deselects the other.

The **Segmented Lumen** setting adds a 3D representation of the lumen contours drawn on each frame.

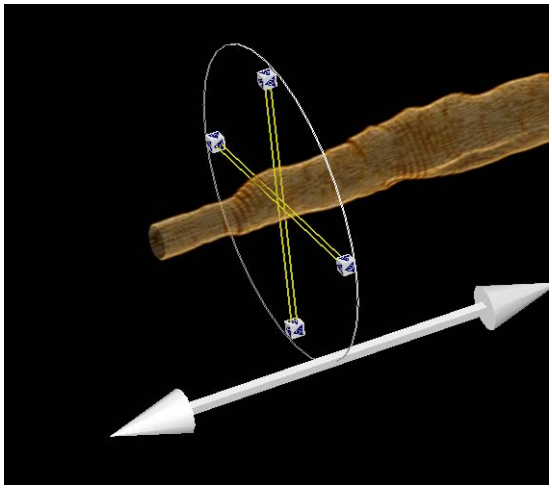


Figure 7-12: 3D Display with Segmented Lumen

NOTE: If you have the **MLA** setting turned on under the **Lumen Profile** display, the distal, proximal, and MLA frames are displayed.

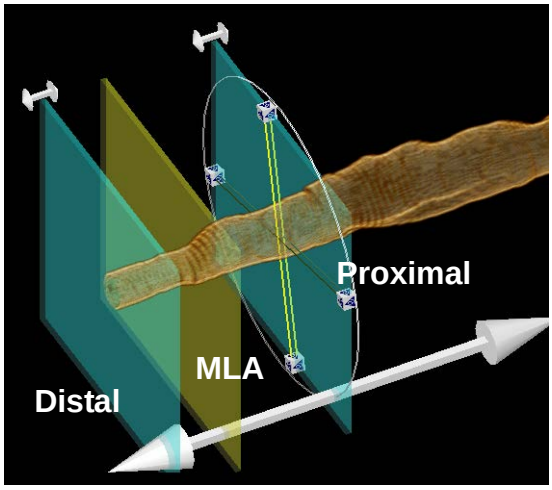


Figure 7-13: MLA Frames in 3D

Limitations of 3D Display

Please be aware of the following limitations of the 3D Display Option:

- Although a vessel may curve, the 3D Display view always appears straight because of the limitations of reconstruction.
- Artifacts caused by the relative motion of the catheter and the vessel often result in a saw-toothed appearance of the reconstruction and can lead to misinterpretation by inexperienced users.
- Shortening or lengthening artifacts in the 3D Display reconstruction may occur due to the relative motion of the imaging catheter with respect to the coronary artery caused by the patient's heart motion.

Exporting, Importing, and Managing Files 8

CAUTION: Please note St. Jude Medical makes no representation or warranty that use of the ILUMIEN OPTIS System 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 ILUMIEN OPTIS System.

Compatible Transfer Media and USB Devices

The following sections list the supported media formats.

If you experience problems with a specific type of CD/DVD or USB device, contact St. Jude Medical for recommendations.

Optical Media

The system can export files through the CD/DVD drive. Table 8-1 lists the supported disc formats and describes whether they can be erased and/or appended.

Table 8-1: Optical Media Characteristics

Media	Capacity	Can Erase	Can Append
CD-R	737 MB		X
CD-RW	737 MB	X	X
DVD+R	4.7 GB		X
DVD+RW	4.7 GB	X	
DVD+R Dual Layered	8.5 GB		X
DVD-R	4.7 GB		X
DVD-RW	4.7 GB	X	
DVD-R Dual Layered	8.5 GB		
DVD-RAM	4.7 GB	X	

If you try to export files to a CD-RW that already has data on it, an alert message appears. Click **Yes** to export your files to this disc, or click **No** to cancel the export.

If you try to export files to a DVD+RW, DVD-RW, or DVD-RAM that already has data on it, an alert message appears. Click **OK** to erase the disc and export your files, or click **Cancel** to cancel the export.

If you try to export files to a disc that cannot be formatted or appended (such as DVD+R DL and DVD-R DL), an alert message appears. Insert a new disc to continue, or click **Cancel** to cancel the export.

USB Connected Media

The system can export files through the USB port (see Figure 1-3 on page 1-6). Any USB hard drive or Flash Drive that meets the USB 2.0 Specification and is supported by Windows 7 SP1 may be used.

WARNING: Inside the catheterization lab 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 lab, IEC 60950-compliant, externally powered USB hard drives may be connected to the USB port.

File Formats

Files can be exported in either the native file format (raw OCT format) or in a standard graphic file format (standard format). Exported files can be saved on the system's hard drive, or transferred to a CD/ DVD or external USB device. You can choose whether to delete files after transfer or keep them on the system.

About Native (Raw OCT) Format

If you export in native (raw OCT) file format, every feature of the OCT file will be exported, and the files can be imported into another ILUMIEN or ILUMIEN OPTIS System or an Offline Review Workstation (ORW) and reviewed and manipulated there. An exported OCT file contains exactly the same data as the original file, including any measurements and annotation additions, all patient information associated with each file, and system diagnostic information to help diagnose possible image quality problems.

Note the following:

- Native (raw OCT) files can be reviewed and manipulated only with an ILUMIEN System, an ILUMIEN OPTIS System, or an ORW. They cannot be accessed with any other systems or software.
- Native (raw OCT) files are large; exporting to CD/DVD may require many discs.

About DICOM Format

For a multiple-frame recording using DICOM format stored on a network server, the maximum resolution is 800 x 800.

About Standard Format

If you export in standard file formats (AVI, compressed AVI, or Multi-page TIFF for recordings; JPEG, TIFF, or BMP for images), the images can be used in computer applications outside the system, but cannot be imported into an ILUMIEN System, an ILUMIEN OPTIS System, or an ORW. When exported to formats other than DICOM, only the images, measurements, and annotations are exported, with no system or patient information.

NOTE: For standard format multiple-file exports, the same limitations apply as described in "Image Format and Size in Standard Formats". Just as when exporting a single file, you can choose the size and format.

Image Format and Size in Standard Formats

When exporting files in standard formats, the system gives you several choices of format and file resolution (size). When making these choices, keep in mind the following:

File Size

- File size is dependent on resolution; the lower the resolution, the smaller the file.
    - Decreasing resolution makes the resulting image grainier, but no quantitative data, annotations or measurements are lost.
    - Increasing resolution results in higher image quality in the exported file. For a file that is a single frame (from a captured image, a paused image, or from a recording that has been edited down to only one frame), the maximum resolution for export is 2048 x 2048.
    - For a multiple-frame recording, the maximum resolution is 1024 x 1024.
- It is best to select the resolution that will actually be used in the intended application. When images are enlarged or reduced by the system, the maximum useful information is preserved. External applications may not apply the same diligence when enlarging or reducing an image.

Standard File Format

- The system can export recordings as either AVI, compressed AVI, or Multi-page TIFF format.
    - Most computers include standard players that will play AVI format files.
    - The Compressed AVI and Multi-page TIFF formats require that special players for these formats be installed on the computer you will use to review the files.
- The system can export still images as either JPEG, TIFF, or BMP.
    - TIFF and BMP files are high resolution bit-map files with large file size.
    - JPEG files are compressed image files designed especially for viewing in a computer application. They are significantly smaller than TIFF or BMP files, and are typically the best choice for slide shows or other applications where the files will be viewed on a computer monitor.

Exporting Files During a Review

During review, you can use the **Export** button to export the current recording or still image to Native (Raw) format, DICOM format, or standard file formats.

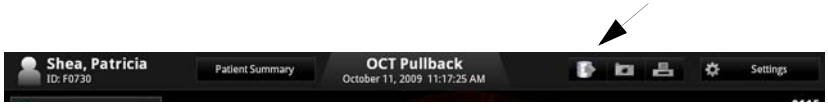


Figure 8-1: Export Button (OCT)

NOTE: The **Export** button is unavailable while a recording is playing. To export from a recording, pause the recording before clicking the **Export** button.

All edits, including measurements, calculations, annotations and zoom, are included with the recording or still image when it is exported (see Chapter 7 “Measurements and Annotations”).

CAUTION: If you are exporting to standard formats, make all measurements BEFORE exporting. Using non-OCT software to measure standard format images will not produce accurate measurements.

CAUTION: 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.

NOTE: Editing images stored on the system does not change the underlying image data in any way. All unedited data taken during the procedure is always preserved and can be reviewed without the changes.

NOTE: If the system displays an error message during export, a restart may be required. If necessary, click **OK** to restart the system. If the error condition persists, export the recording from the Patient Summary menu, or reduce the resolution for the export of the recording. See “Exporting Files from the Patient Summary Menu” on page 8-14 for more information.

Exporting Files in Native (Raw) Format

1. Click the **Export** button.

   The **Export Wizard** opens (see Figure 8-2).

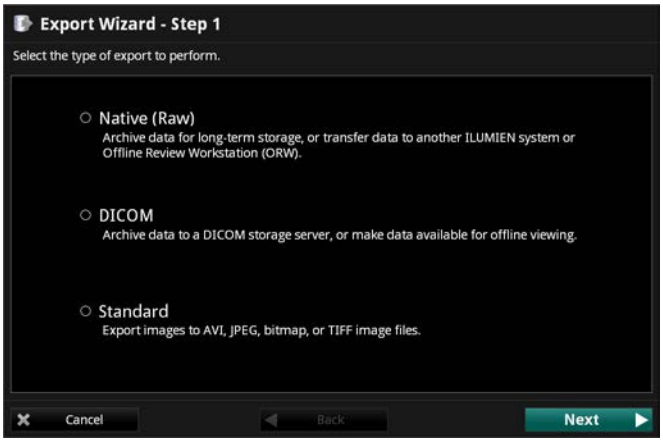


Figure 8-2: The Export Wizard - Step 1

2. Click to select **Native (Raw)**, and click **Next**.

3. If you need to remove patient identifying information from the exported files, add a check to the **Anonymize** checkbox.

   - If you have added a check to the **Anonymize** checkbox, you can also add an alternate means of identifying the patient. Click the **Alternate PIDs...** button to open the **Define Alternate Patient ID** menu:

     - Click in the **Alternate Patient ID** column and type an alternate ID tag for this patient.

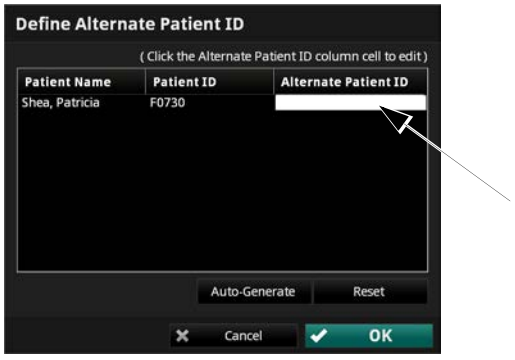


Figure 8-3: Define Alternate Patient ID Menu

     - Click the **Auto-Generate** button to add an alternate ID generated by the system. Click the **Reset** button to clear the ID generated by the system.

- Click **OK** to approve the change and close the menu, or **Cancel** to return to previous settings and close the **Define Alternate Patient ID** menu.

4. Click to set the **System File Options** for the file(s) that you are exporting:
   - **Leave Unchanged** - the files are exported, but the original files in the System are not changed.
   - **Mark as Archived** - the files are exported, and marked as archived.
   - **Remove when Complete** - the files are deleted from the System once the export is complete.

5. Click **Next** to approve the settings and open the next page of the **Export Wizard**.

   NOTE: Click **Back** to return to the previous page, or click **Cancel** to exit the Export Wizard without exporting files.

6. Click to select an **Export Destination**:

   NOTE: If an output device is not available, that option cannot be selected.

   NOTE: Check that the **Free** space in the Drive Capacity section is large enough to save the files that are being exported.

   - Click **CD/DVD** to export to a CD/DVD.

     If the inserted CD/DVD is blank, you can edit the name in the **Volume Label** field.
   - Click **External Drive** to export to an external USB device.

     If necessary, click the **External Drive** selection box to select the correct drive location from the drop-down menu.

     Click the **Ellipsis** (**...**) button to the right of the **Path** selection box to browse for a specific folder on the device.

7. Click **Next** to approve the settings and open the next page of the **Export Wizard**.

   The next page of the **Export Wizard** opens. The menu shows a summary of Export Information.

8. Click **Export** to export the selected files.

   The export begins. If necessary, click **Cancel** to stop the export in progress.

9. When complete, click **Done** to close the **Export Wizard**.

Exporting Files in DICOM Format

1. Click the **Export** button.

   The **Export Wizard** opens (see Figure 8-2).

2. Click to select **DICOM**, and click **Next**.

NOTE: If you are reviewing a single frame instead of a recording, skip to Step 5

3. Click to select the material to be exported:
   - **Pullback**
   - **Current Frame**
   - **Bookmarked Frames** - This choice is unavailable if there are no bookmarked frames in the recording.

4. Click **Next** to approve the settings and open the next page of the **Export Wizard**.

   NOTE: Click **Back** to return to the previous page, or click **Cancel** to exit the Export Wizard without exporting files.

5. If you need to remove patient identifying information from the exported files, add a check to the **Anonymize** checkbox.

6. Click to set the **System File Options** for the file(s) that you are exporting:
   - **Leave Unchanged** - the files are exported, but the original files in the System are not changed.
   - **Mark as Archived** - the files are exported, and marked as archived.

7. Click **Next** to approve the settings and open the next page of the **Export Wizard**.

8. Click to select an **Export Destination**:

   NOTE: If an output device is not available, that option cannot be selected.

   NOTE: Check that the **Free** space in the Drive Capacity section is large enough to save the files that are being exported.

- Click **CD/DVD** to export to a CD/DVD.

  If the inserted CD/DVD is blank, you can edit the name in the **Volume Label** field.

- Click **External Drive** to export to an external USB device.

  If necessary, click the **External Drive** selection box to select the correct drive location from the drop-down menu.

  Click the **Ellipsis** (**...**) button to the right of the **Path** selection box to browse for a specific folder on the device.

- Click **Remote Store** to export to a network DICOM Server.

  NOTE: The **Remote Store** option is enabled only if the DICOM network connection has been configured on the **DICOM** tab of the **Setup** dialog box (see Chapter 10 “User Interface Reference”for more information on DICOM settings).

9. Click **Next** to approve the settings and open the next page of the **Export Wizard**.

   The next page of the **Export Wizard** opens, showing a summary of Export Information.

10. Click **Export** to export the selected files.

    The export begins. If necessary, click **Cancel** to stop the export in progress.

11. When complete, click **Done** to close the **Export Wizard**.

Exporting Files in Standard Formats

NOTE: 3D reconstructions cannot be exported in Standard formats.

1. Click the **Export** button.

   The **Export Wizard** opens (see Figure 8-2).

2. Click to select **Standard**, and click **Next**.

NOTE: If you are reviewing a single frame instead of a recording, skip to Step 5.

3. Click to select the material to be exported:
   - **Pullback**
   - **Current Frame**
   - **Bookmarked Frames** - This choice is unavailable if there are no bookmarked frames in the recording.

4. Click **Next** to approve the settings and open the next page of the **Export Wizard**.

   NOTE: Click **Back** to return to the previous page, or click **Cancel** to exit the Export Wizard without exporting files.

5. Click to set the resolution and file format.

6. Click **Next** to approve the settings and open the next page of the **Export Wizard**.

7. Verify the names of the files that are being exported. If necessary, double-click a filename and edit it using the keyboard.

8. Click **Next** to approve the settings and open the next page of the **Export Wizard**.

9. Click to select an **Export Destination**:

   NOTE: If an output device is not available, that option cannot be selected.

   NOTE: Check that the **Free** space in the Drive Capacity section is large enough to save the files that are being exported.

   - Click **CD/DVD** to export to a CD/DVD.

     If the inserted CD/DVD is blank, you can edit the name in the **Volume Label** field.

- Click **External Drive** to export to an external USB device.

  If necessary, click the **External Drive** selection box to select the correct drive location from the drop-down menu.

  Click the **Ellipsis** (**...**) button to the right of the **Path** selection box to browse for a specific folder on the device.

10. Click **Next** to approve the settings and open the next page of the **Export Wizard**.

    The next page of the **Export Wizard** opens. The menu shows a summary of Export Information.

11. Click **Export** to export the selected files.

    The export begins. If necessary, click **Cancel** to stop the export in progress.

12. When complete, click **Done** to close the **Export Wizard**.

Exporting Files from the Patient Summary Menu

You can export files from the **Patient Summary** menu.

1. In the **Patient Summary** menu, add a check to the checkbox of each file that you want to export.

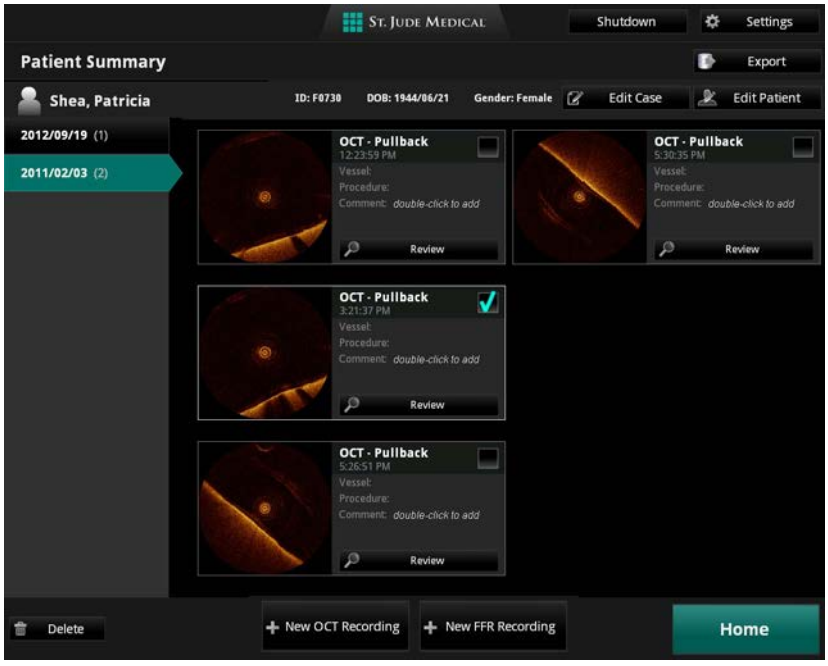


Figure 8-4: Highlighted Records

A white border appears around each record that is selected.

NOTE: In the **Patient Summary** menu, you can select multiple files from the same date, but not from different dates. Within the **Export Wizard**, you can select additional files from different dates and different patients.

NOTE: To deselect a file, clear the check from the checkbox. The check and white border disappear to indicate that the file is no longer selected.

2. Click the **Export** button at the top of the screen.

   The **Export Wizard** opens (see Figure 8-2).

3. Click to select an export format, and click **Next**.

   The next page of the **Export Wizard** opens.

4. To filter the list, click the **All**, **Unarchived**, or **New since last archive** button.

5. If necessary, add a check to the checkbox of any other recording to be exported.
    - Add a check to the checkbox of patient to select all recordings for that patient.
    - Add a check to the checkbox of the first entry in the list to select all recordings.

6. Click **Next** to approve the list of files for export and open the next page of the **Export Wizard**.
    - If you are exporting in Native (Raw) format, refer to Step 3 in "Exporting Files in Native (Raw) Format" on page 8-8 to continue the export.
    - If you are exporting in DICOM format, refer to Step 5 in "Exporting Files in DICOM Format" on page 8-10 to continue the export.
    - If you are exporting in standard formats, refer to Step 5 in "Exporting Files in Standard Formats" on page 8-12 to continue the export.

Using Exported Standard Format Recordings

The system can export recordings as either AVI, compressed AVI, or Multi-page TIFF format. Most computers include standard players that will play AVI format files. However, the Compressed AVI format and the Multi-page TIFF formats require that you have special players installed on your computer to review the files.

St. Jude Medical DICOM Viewer

When an image file is exported to a CD/DVD in the DICOM format, the St. Jude Medical DICOM Viewer (shown in Figure 8-5) is also included on the CD/DVD. This DICOM CD/DVD can then be freely distributed and used with any Microsoft Windows computer (the CD/ DVD is configured to automatically launch the viewer when it is inserted into the drive). The St. Jude Medical DICOM Viewer may only be used to view St. Jude Medical generated DICOM images on a St. Jude Medical DICOM CD/DVD. If this CD/DVD is to be used in a public forum, the Anonymous option should be used when exporting the image using the system.

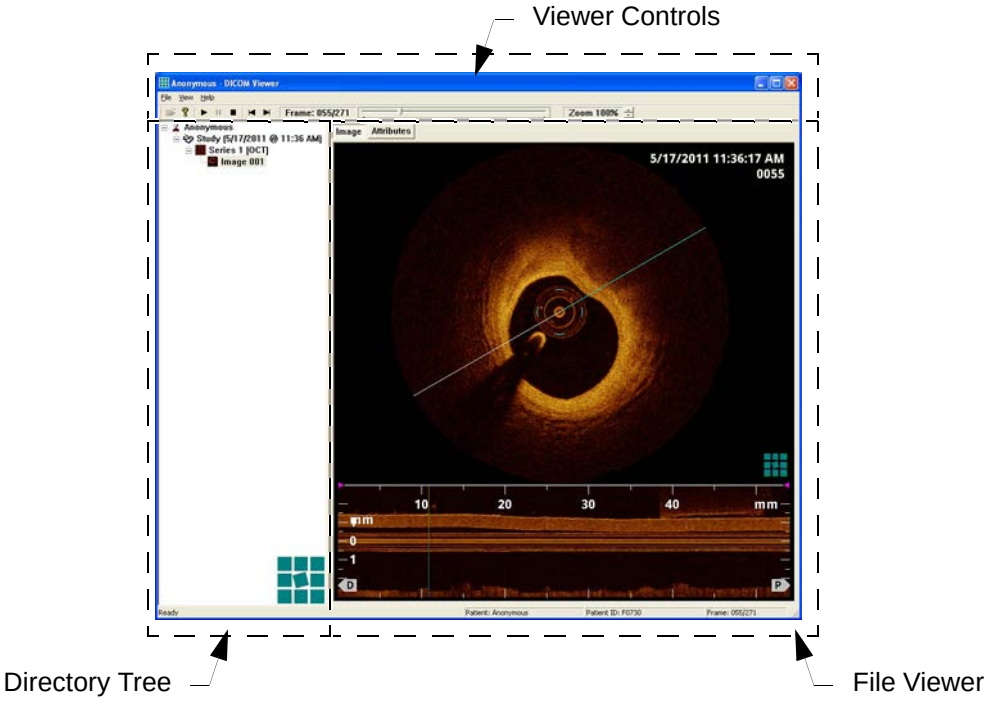


Figure 8-5: St. Jude Medical DICOM Viewer - Image View

The St. Jude Medical DICOM Viewer window contains three different sections:

- **Viewer Controls** - Provides control over the viewer and the active image.
- **Directory Tree** - This tree lists the patient, study, series, and image hierarchy contained in the DICOMDIR file on the CD/DVD. Individual images may be loaded by clicking on the image item in the tree.
- **File Viewer** - Provides two tabs:
  - **Image** tab - Displays the image currently selected in the DICOM Directory Tree (see Figure 8-5). If the image is a recording, playback may be controlled using the playback buttons in the Viewer Controls at the top of the viewer. The image may also be zoomed in or out using the **Zoom** feature in the toolbar.
  - **Attributes** tab - Displays a list of all DICOM modules and attributes contained in the currently selected image (see Figure 8-6).

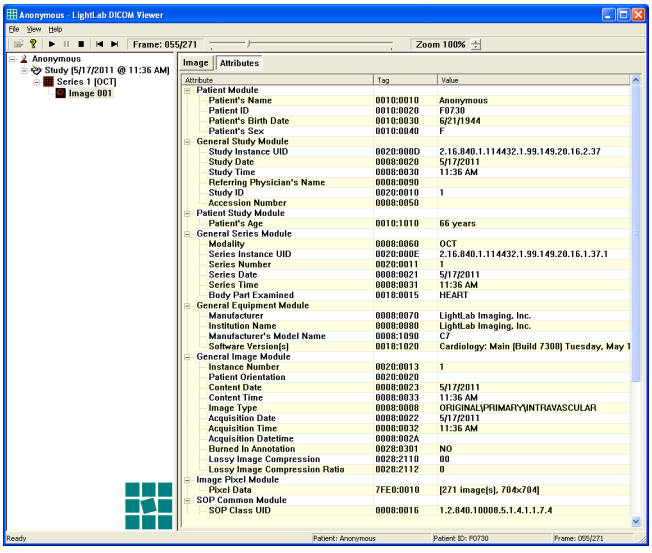


Figure 8-6: St. Jude Medical DICOM Viewer - Attributes View

The St. Jude Medical DICOM files are compliant with the DICOM Standard (PS 3-2008) and use the Secondary Capture Multi-Frame Image Storage IOD (Information Object Definition). The actual attributes contained in the file are listed in Table 8-2.

Table 8-2: DICOM File Attributes

Module	Attribute
Patient	Patient's Name
	Patient ID
	Patient's Birth Date
	Patient's Gender
General Study	Study Instance UID
	Study Date
	Study Time
	Referring Physician's Name
	Study ID
	Accession Number
Patient Study	Patient's Age
General Series	Modality
	Series Instance UID
	Series Number
	Series Date
	Series Time
	Body Part Examined
General Equipment	Manufacturer
	Institution Name
	Manufacturer Model Name
	Software Version(s)
General Image	Instance Number
	Patient Orientation
	Content Date
	Content Time
	Image Type
	Acquisition Date
	Acquisition Time
	Acquisition DateTime
	Burned In Annotation
	Image Comments

Table 8-2: DICOM File Attributes *(continued)*

Module	Attribute
	Lossy Image Compression
	Lossy Image Compression Ratio
Image Pixel	Pixel Data
SOP Common	SOP Class UID
	SOP Instance UID
	Instance Creation Date
	Instance Creation Time
	Timezone Offset from UTC
	Instance Number
Multi-frame[1]	Frame Increment Pointer
Region Calibration	Sequence of Regions
Cine[1]	Frame Time
SC Equipment	Conversion Type
	Modality
	SC Device Manufacturer
	SC Device Model Name
	SC Device Software Version
SC Multi-frame Image[1]	Burned In Annotation
	Frame Increment Pointer

1. Multi-frame files only.

Importing Files from a CD/DVD or USB

1. Connect an external database to the ILUMIEN OPTIS System:
   - Insert a CD/DVD containing a database into the system.
   - Connect an external hard drive to the system.
2. In the **Select Patient** menu, click the Import button.

   The **Select Database** menu opens.
3. Select the database to import, and click OK.
4. The **Import Database** menu opens (Figure 8-7).

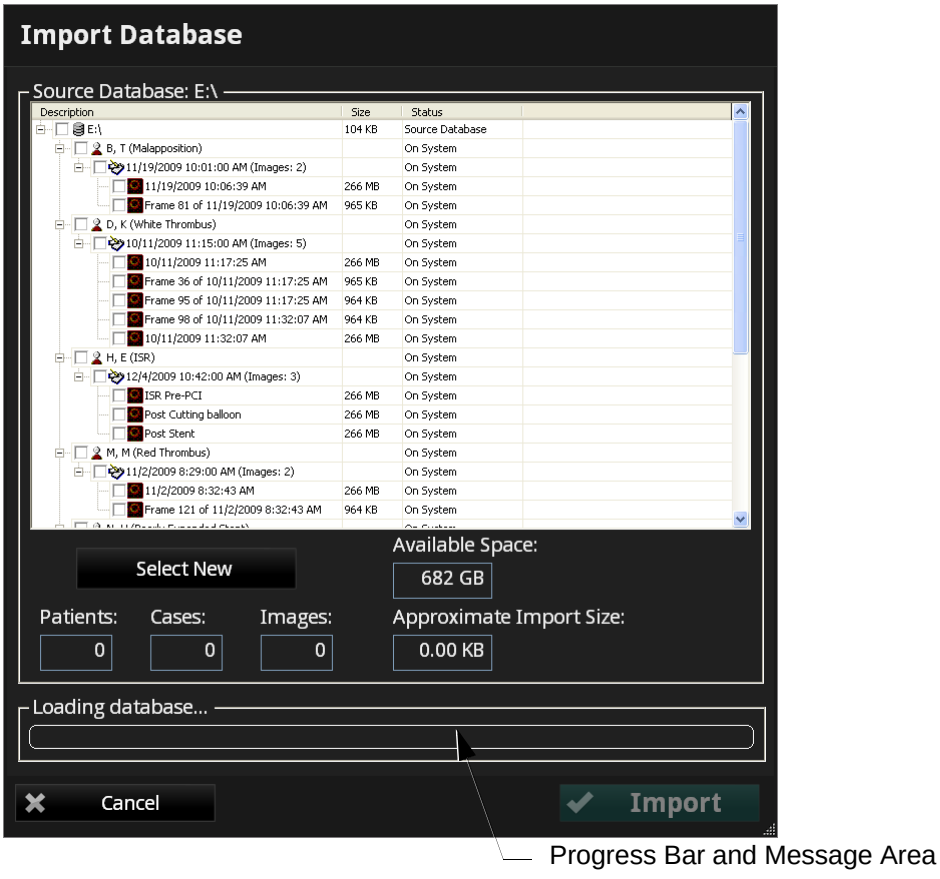


Figure 8-7: Import Database Menu

Table 8-3: Import Database Menu Options

Source Database	List of files which will be imported. Each file is displayed in one row, and the patient name, patient ID, image creation date & time, comment, and status are displayed in columns. The list is initially sorted by ascending image creation date & time and can be sorted by any of the columns in ascending or descending order by left-clicking once or twice on the desired column header. As each file is imported, its **Status** message is updated: • **Importing** - file is currently being imported. • **On System** - file has been copied to the system. • **On Archive Media** - file is on the current archive media and has not yet been imported. • **Absent** - file is not located on the current archive media • **Failed** - attempt to import the file failed.
Select New	Click to select only recordings that are not present in the ILUMIEN OPTIS System.
Progress Bar and Message Area	The Progress Bar indicates the status of the file transfer. The Message Area displays information about the file and the transfer.
Import	Import the selected files.
Cancel	Cancel the import.

An import may require installation of several CD/DVDs. When a new disc is required, the system ejects the current disc and displays a **New Disc Request** alert.

Importing Patient Information from a Remote DICOM Server

NOTE: It is only possible to import patient information from a DICOM server. You can not import and play DICOM images on the system. See the DICOM sections in Chapter 10 "User Interface Reference" for more information on setting up connection to a DICOM server.

1. Click the **Settings** button to open the **Setup** dialog box.

2. Click the **DICOM** button to open the **DICOM** menu.

3. In the **Import Patient Information**, click the **Import** button.

   The **Import from Remote DICOM Store** menu (Figure 8-8) opens.

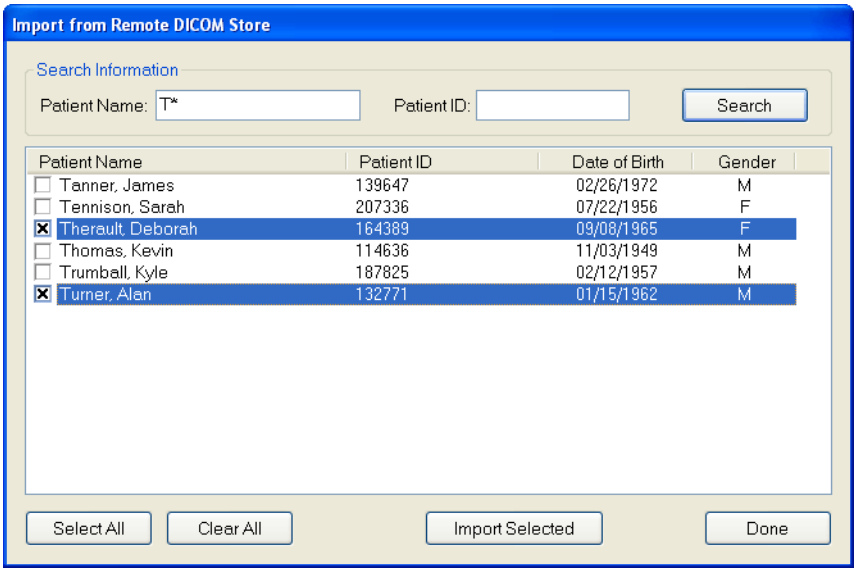


Figure 8-8: Import from Remote DICOM Store Menu

4. Search for the patient whose information you wish to recall to the system.

   - **Patient Name** - Allows you to search by patient name. Patient names are formatted as the last name, comma, space and then the first name. This search string is not case-sensitive. You can use '*' to match any character or multiple characters. A '?' matches any single character. All other characters must be explicitly matched. Leaving the text box empty will display all patients.
   - **Patient ID** - Allows you to search by patient IDs. Patient IDs on the Remote DICOM Store are free-form text fields whose format is defined by the administrators of that system. Use the same special characters above to match unknown characters. Leaving the text box empty will display all patients.

5. Click the **Search** button.

6. Select the patient or patients whose information you wish to import from the **Patient Information List**. You can select multiple patients by holding the <Ctrl> key and clicking the left mouse button. Use the **Select All** button to select all patients listed.

   NOTE: An X in the checkbox next to the patient name indicates that patient information already exists in the system's database.

   NOTE: You can clear all selections in the patient list using the **Clear All** button.

7. Click **Import Selected** to import the patient information for all selected patients into the OCT database. If patient information is to be imported for a patient that already exists in the database, then the information regarding that patient will be verified as being accurate and updated if necessary (the information in the Remote DICOM Store is always assumed to be more accurate).

8. Click **Done** to close the menu.

Deleting Files

You can delete files by any of the following methods:

- Exporting images with the **Remove When Complete** function turned on (see "Exporting Files in Native (Raw) Format" on page 8-8).
- Select and delete files from the **Patient Summary** menu.
- Select and delete files from the **Database** menu.

CAUTION: Once files are deleted, they cannot be restored. After files have been deleted, they can only be imported back to your system from your archived copies.

Deleting Files from the Patient Summary Menu

1. In the **Patient Summary** menu, add a check to the checkbox of each file that you want to delete (see Figure 8-4 on page 8-14).

   A white border appears around each record that is selected.

   NOTE: In the **Patient Summary** menu, you can select multiple files from the same date, but not from different dates.

   NOTE: To deselect a file, clear the check from the checkbox. The check and white border disappear to indicate that the file is no longer selected.

2. Click the **Delete** button at the bottom of the screen.

   A prompt asks you to confirm that you want to delete the selected files.

3. Click **Yes** to delete the files, or click **No** to cancel the deletion and return to the **Patient Summary** menu.

Deleting Files from the Database Menu

1. Click the **Settings** button to open the **Setup** dialog box.
2. Click the **Database** button to open the **Database** menu (see Figure on page 10-6).
3. Add a check to the checkbox of any recording to be deleted.
   - Add a check to the checkbox of patient to select all recordings for that patient.
   - Add a check to the checkbox of the first entry in the list to select all recordings.
4. Click the **Delete** button.

   A prompt asks you to confirm that you want to delete the selected files.

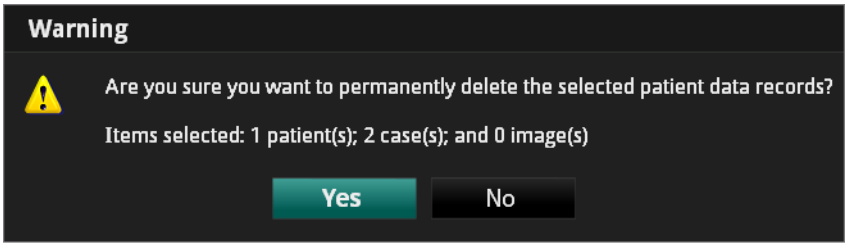


Figure 8-9: Deletion Warning Alert

5. Click **Yes** to delete the files, or click **No** to cancel the deletion and return to the **Database** menu.

Transfer and Import Messages

The system displays a number of different messages to inform you of problems that may arise during transfer and import operations.

Table 8-4: Transfer Messages

Error Message	Cause	Action
The CD/DVD drive is empty. Please insert a writable CD/DVD, or click Cancel to stop the transfer.	No CD/DVD is in the drive, though you have attempted to transfer files.	To continue with the export, insert a blank CD/ DVD or a previously used CD/DVD on which there is sufficient space for the transfer. To stop the transfer, click **Cancel**.
None of the selected files will fit on the disc. Please insert a different CD/DVD, or click Cancel to stop the transfer.	Insufficient space is available on the destination CD/DVD and NONE of the selected files can be transferred to this disc.	Insert a new writable CD/DVD into the drive and close the drive to transfer or click **Cancel** to stop the transfer and file deletion.
Some files did not fit on the disc. Please insert another writable CD/DVD to continue the transfer, or click Cancel to stop the transfer.	Insufficient space is available on the destination CD/ DVD for all of the selected files, but SOME of the files have been transferred.	To continue the transfer on the new disc, insert another writable CD/DVD into the drive and close the drive to continue the transfer. To interrupt the transfer, click **Cancel**. Some files may be on the first disc, some on the second. If you select Cancel, the CD/ DVD will contain the files previously transferred, but the remainder will not be transferred and the uncopied files will remain on the hard drive.
Cancelling the transfer may damage the disc and render previously written files unreadable. Are you sure you want to cancel the transfer?	You have attempted to interrupt a transfer in process by clicking **Cancel**.	Click **No** to continue the transfer. Click **Yes** to stop the transfer and risk losing the files already transferred.
An invalid volume name was specified.	You have typed a character that cannot be used in a volume name.	Retype the name with acceptable characters.
Transfer failed, the destination disk is full.	The USB drive is full.	Connect a different USB drive.

Table 8-4: Transfer Messages *(continued)*

Error Message	Cause	Action
Transfer failed, the destination disc is not blank.	The CD/DVD already contains files and cannot be appended.	Insert a new writable CD/DVD into the drive and close the drive to transfer or click **Cancel** to stop the transfer.
Transfer failed, the source or destination disk was removed.	The USB drive is disconnected.	Reconnect the USB drive.
Please insert the next CD to continue importing the database, or click Cancel to stop importing.	The current disk is full and has been ejected.	Insert another CD/DVD in the series or click **Cancel** to stop the import.
Duplicate CD. Please insert the next CD to continue importing the database, or click Cancel to stop importing.	You have inserted a CD/DVD containing files that have already been imported.	Insert another CD/DVD in the series. or click **Cancel** to stop the import.
Database not found. Please insert the next CD to continue importing the database, or click Cancel to stop importing.	The currently inserted CD/DVD does not include a valid OCT database file.	Insert a CD/DVD which contains a valid OCT database file (OCT.mdb or OCT.dbf) or click **Cancel** to stop the import.
Incorrect database. Please insert the next CD to continue importing the database, or click Cancel to stop importing.	The currently inserted CD/DVD includes a valid OCT database file, but is not in the same series as the previously inserted CD/DVD(s).	Insert a CD/DVD from the same series as the last CD/DVD or click **Cancel** to stop the import.
Database import not complete.	You have clicked **Cancel**, so the Import operation is not complete.	Click **OK** to continue system operations. Some of the files may have been partially, but not fully copied into the system. If you try to open one of these files, the system will display an error message.
Please insert the next CD to continue importing the database, or click Cancel to stop importing.	Additional files exists on another disc.	Insert the next disc. The message is automatically closed and import continues.

Duplicate File Name Messages

Duplicate file name messages warn you when a file has been selected for export with the same name as one already saved. The system does not allow any files to be overwritten.

NOTE: Do not save an image using the same name used for a previous file. St. Jude Medical recommends that you label media containing exported files with descriptive information, including the procedure or export date. To resolve these errors when copying to CD/DVDs, insert another CD/DVD into the drive and close the drive. File transfer resumes automatically. If the transfer is cancelled, the uncopied files will remain on the hard drive.

Table 8-5: Duplicate File Name Messages

Message	Cause	Action
Duplicate files could not be written. Please insert a different CD/DVD to continue the transfer, or click Cancel to stop the transfer	SOME of the file names in an export set are already found on the installed CD/DVD.	Files with non-identical names will be written to the current CD/DVD; files with identical names will not be written. To save the files with the duplicate file names, insert a new CD/DVD and continue with the transfer. To stop the transfer, click **Cancel**.
The disc already contains files with the same names. Please insert a different CD/DVD to continue the transfer, or click Cancel to stop the transfer.	ALL the file names in an export set are already found on the installed CD/DVD.	To save these files with these file names, insert a new CD/DVD and continue with the transfer. To stop the transfer, click **Cancel**. This message may be displayed when the **Delete after transfer** checkbox in the **Manage Exported Files** menu is unchecked, leading to re-exporting the same files.

Database Statistics

You can check the size and statistics of your system's database using the **Database Maintenance** button in the **Setup** dialog box. See "Setup - Database/Maintenance Menu" on page 10-7 for more information.

Cleaning & Maintenance 9

CAUTION: Only a qualified service representative can service components of the system. Any attempt to open the system components by anyone other than a qualified St. Jude Medical service representative will void the warranty.

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

Contacting St. Jude Medical Service

Service can be contacted at:

E-mail: OCTservice@sjm.com
Phone: +1 800 544 1664 (US)
+1 651 490 4410 (Outside US)

Cleaning

Cleaning of the ILUMIEN OPTIS System consists of:

- Cleaning system surfaces.
- Cleaning the DOC and its cable.

Routine Cleaning Procedure

The ILUMIEN OPTIS System should be cleaned following the facilities standard cleaning schedule, or at least every 30 days under normal use.

1. Turn off all system components with accessible power controls and unplug the power cable.

2. Clean system surfaces and the keyboard with a dry cloth, or a dry cloth slightly dampened with water.

3. Clean the monitor's LCD surface with a lint-free, non-abrasive cloth.

   CAUTION: DO NOT clean the LCD surface with detergents or other cleaning solutions.

4. Clean exposed system cables with a soft cloth moistened with water or a mild detergent.

5. Clean the DOC and the DOC optical cable with a disinfectant wipe 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.

6. Clean all other exposed system cables with a soft cloth moistened with water or water and a mild detergent.

7. Clean the air filter on the system as specified in "Air Filter Maintenance Procedure".

Maintenance

Maintenance of the system consists of:

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

Optical Connection Cleaning Procedure

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

CAUTION: This procedure should not be performed during a patient case on a sterile catheter.

NOTE: Before beginning this procedure ensure that you have the St. Jude Medical Optical Fiber Connector Cleaner available.

NOTE: 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. Once the “lock” LED is off, remove the catheter.

2. Click the **Setup** button and select the **Service** menu.

3. In the DOC Service section of the **Service** menu, click the **Enter** button.

   The DOC optical carriage moves all the way to the front and then locks into position for 1 minute. Rotation of the DOC rotary motor is stopped and the laser source is turned off.

4. Remove the sizing cap from the end of the Optical Fiber Connector Cleaner (see Figure 9-1).

5. Insert the cleaner into the center of the Optical Adapter in the DOC, ensuring it seats fully, and press until it clicks.

The cleaning material in the Optical Fiber Connector Cleaner is moved over the optical connection cleaning it.

Figure 9-1: Inserting Cleaner Into Optical Adapter

6. Remove the cleaner from the DOC.

7. In the DOC Service section of the **Service** menu, click the **Exit** button.

   The DOC optical carriage moves all the way to the back and all DOC functions are returned to their normal state.

8. Click on **OK** or **Cancel** to close the **Setup** dialog box.

9. Open the sizing cap and place it on the end of the Optical Fiber Connector Cleaner (see Figure 9-2).

10. Insert the cleaner into the optical connection in the Dragonfly Imaging Catheter, ensuring it seats fully, and press until it clicks.

    The cleaning material in the Optical Fiber Connector Cleaner is moved over the optical connection cleaning it.

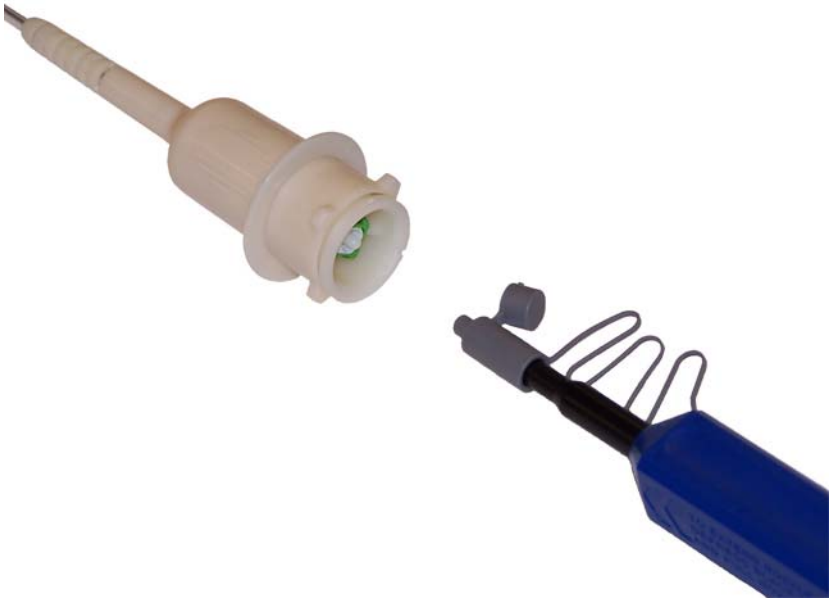


Figure 9-2: Inserting Cleaner Into Catheter

11. Remove the cleaner from the Dragonfly.
12. Reconnect the Dragonfly Imaging Catheter to the DOC.
13. Return the system to normal operation.

Optical Adapter Replacement Procedure

The Optical Adapter should be replaced every 200 cycles or 1 year (which ever comes first), or if cleaning (see "Optical Connection Cleaning Procedure") does not improve the image quality.

CAUTION: This procedure should not be performed during a patient case.

NOTE: Before beginning this procedure ensure that you have a replacement St. Jude Medical Optical Adapter and pliers supplied with it available.

NOTE: 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. Once the "lock" LED is off, remove the catheter.

2. Click the **Setup** button and select the **Service** menu.

3. In the DOC Service section of the **Service** menu, click the **Enter** button.

4. Click on the **Enter DOC Service** button.

   The DOC optical carriage moves all the way to the front and then locks into position for 1 minute. Rotation of the DOC rotary motor is stopped and the laser source is turned off.

5. Use pliers to grip either short surface of the adapter as shown (see Figure 9-3). Ensure the pliers seat over the lip on the end of the adapter.

Figure 9-3: 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 your fingers, align the new adapter with the DOC, ensuring the key is aligned with the slot in the optical carriage, and firmly press it into place.

   There is a small click 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. Once it changes to Enter, click it again. Once the optical carriage is locked into position at the front of the DOC firmly press the adapter into place.

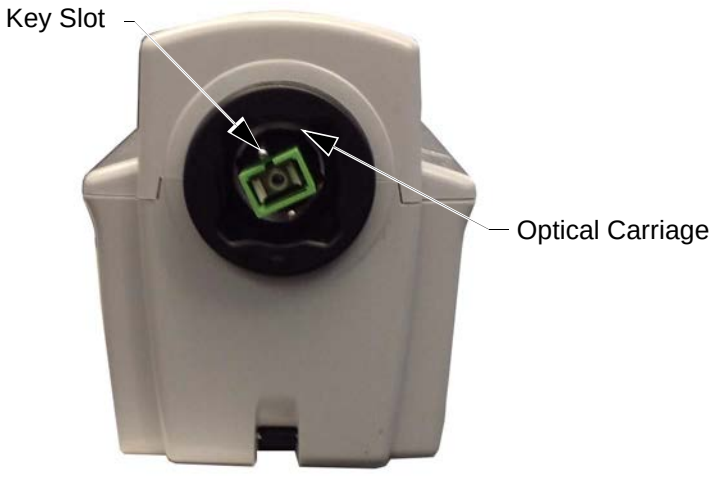


Figure 9-4: Alignment of Optical Adapter with Optical Carriage

9. In the DOC Service section of the **Service** menu, click the **Exit** button.

   The DOC optical carriage moves all the way to the back and restores all DOC functions to their normal state.

10. Click on **OK** or **Cancel** to close the **Setup** dialog box.

11. Return the system to normal operation.

Air Filter Maintenance Procedure

The air filter should be cleaned every 6 months under normal use.

1. Locate the air filter holder at the bottom of the cart (refer to Figure 1-2 on page 1-5).
2. Pull the filter holder out of the cart base.
3. Remove the filter and brush or vacuum off dust (replace if necessary).
4. Place the filter into the filter holder.
5. Push the filter holder back into the cart base.

Cable Connection Inspection Procedure

1. Ensure 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 all other connectors are fully seated and properly secured.

Transferring Log Files

Log files may be transferred to a CD or external USB device so that you can archive them or E-mail them to St. Jude Medical Service.

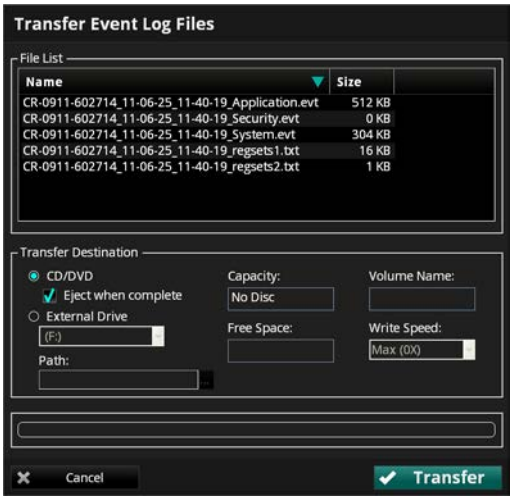


Figure 9-5: Transfer Event Log Files Menu

NOTE: When there are multiple repeated events of the same type the event logs are condensed into two messages. The first message logs the initial event, and the second message logs the event along with a repeat count.

1. Click the **Settings** button to open the **Setup** dialog box.

2. Click the **Service** button to open the **Service** menu.

3. In the Service Log area, click the **Export** button.

   The **Transfer Event Log Files** menu opens (Figure 9-5), which lists all the files to be exported.

4. Click to select a **Transfer Destination**:

   NOTE: If an output device is not available, that option cannot be selected.

   NOTE: Check that the **Free** space in the Drive Capacity section is large enough to save the files that are being exported.

   - Click **CD/DVD** to export to a CD/DVD.

     If the inserted CD/DVD is blank, you can edit the name in the **Volume Label** field.

- Click **External Drive** to export to an external USB device.

  If necessary, click the **External Drive** selection box to select the correct drive location from the drop-down menu.

  Click the **Ellipsis** (**...**) button to the right of the **Path** selection box to browse for a specific folder on the device.

5. Click the **Transfer** button to transfer the files or **Cancel** to cancel the operation.

Identifying the Software Version

The **Startup** window (Figure 9-6) shows the version and copyright information for the system. If the system is running, type <Ctrl-S> to open the Startup window. The software version information might be required when contacting St. Jude Medical Service.

Figure 9-6: System Startup Window

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 Cidex and a soft cloth.

User Troubleshooting

Table 9-1 provides basic guidelines for troubleshooting the ILUMIEN OPTIS System. "Troubleshooting OCT Acquisition" on page 5-18 explains what to do if a catheter fails during pullback.

If your problem is not resolved after attempting the suggested remedies, contact your service representative or E-mail OCTservice@sjm.com.

Table 9-1: 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, located next to the power cord connection.
	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 to 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 your service representative 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 your St. Jude Medical service representative for instructions.
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 7 SP1. Refer to the instructions for use that came with your USB drive to determine if formatting is required.

Table 9-1: User Troubleshooting Tips *(continued)*

Symptom	Possible Causes	Remedy
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 your St. Jude Medical service representative for instructions.
DOC		
Optical fiber does not rotate when **Live View** is pressed.	The **Stop** button on the DOC was pressed.	Check screen for message and follow instructions.
	Imaging catheter defective, optical fiber does not rotate.	Replace imaging catheter.
DOC makes excessive noise without imaging catheter connected.	DOC mechanism failure.	Contact your service representative to obtain a replacement DOC.
Imaging		
OCT image dim, with no background noise visible.	Monitor contrast and brightness set incorrectly.	Set monitor contrast and brightness using monitor controls on the monitor.
	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 9-5 to clean the connection.

System Disposal

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

User Interface Reference 10

Setup Dialog Box and Submenus

The **Setup** dialog box provides access to all of the configuration and service functions for the system. The **Setup** dialog box is accessed through the **Settings** button on the **Select Patient** or **Patient Summary** menus.

NOTE: When creating or reviewing an OCT recording, the **Settings** button opens a context-sensitive OCT **Settings** menu. When creating an FFR recording, the **Settings** button opens the **FFR Settings** menu.

All menus within the **Setup** dialog box share the following common buttons located at the bottom of the dialog box.

Table 10-1: Setup Dialog Box Common Options

Refresh	Click to updates the values displayed in the current tab.
OK	Click to approve any changes and close the **Setup** dialog box.
Cancel	Click to cancel any changes and close the **Setup** dialog box.
Apply	Click to approve any changes and keep the **Setup** dialog box open.

Setup - Acquisition Menu

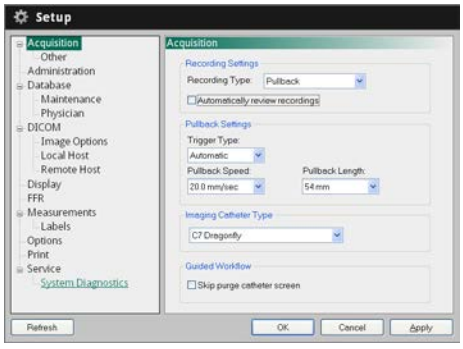


Figure 10-1: Setup - Acquisition Menu

Table 10-2: Setup - Acquisition Menu Settings

Recording Type	Sets the recording type for image acquisition: **Pullback** - Performs a recording while the imaging core of the catheter is pulled back within the catheter sheath. **Stationary** - The system records the live view image for 6 seconds without pulling the imaging core of the catheter back.
Automatically review recordings	Turns on and off automatic review after recording real-time images.
Trigger Type	Sets the Pullback trigger type to use for image acquisition: **Automatic** - The system automatically begins a recording when it detects that the vessel has been cleared by the flush injection.
Pullback Speed	Sets the pullback speed. **NOTE:** When connected to an original C7 Dragonfly imaging catheter, the **Pullback Speed** settings are limited to **10.0 mm/sec**, **20.0 mm/sec**, and **25.0 mm/sec**.
Pullback Length	Sets the length of the pullback. **NOTE:** When connected to an original C7 Dragonfly imaging catheter, the **Pullback Length** setting is limited to **54 mm**.

Table 10-2: Setup - Acquisition Menu Settings *(continued)*

Imaging Catheter Type	**NOTE:** This setting is unavailable if a catheter has already been connected. Sets the type of imaging catheter being used. **NOTE:** Only Dragonfly imaging catheters are approved for use with the ILUMIEN OPTIS System for cardiovascular imaging.
Guided Workflow	Turns on and off the appearance of the purge catheter guidance message.

Setup - Acquisition/Other Menu

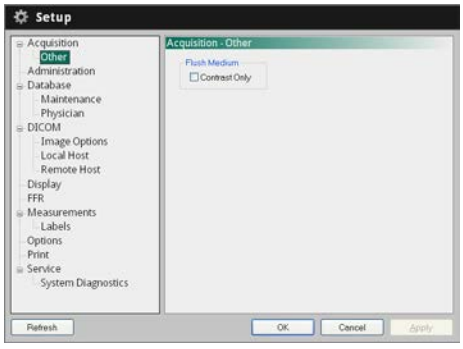


Figure 10-2: Setup - Acquisition/Other Menu

Table 10-3: Setup - Acquisition/Other Menu Settings

Flush Medium	Controls the contrast options available in the **Flush Medium** drop-down box. **Checked** - Only 100% contrast is available, and the **Flush Medium** drop-down box under **Settings** is unavailable. **Unchecked** - All configured contrast options are available for selection in the **Flush Medium** drop-down box. **NOTE:** To change the **Flush Medium** setting before performing an OCT recording, see "Confirm Recording Settings" on page 5-10.

Setup - Administration Menu

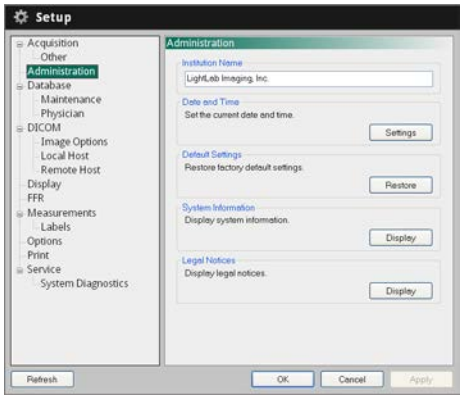


Figure 10-3: Setup - Administration Menu

Table 10-4: Setup - Administration Menu Settings

Institution Name	Click here and enter or clear the institution name.
Date and Time	Opens the system **Date and Time Properties** menu.
Default Settings	Resets all user-entered configuration values except the date and time to the original factory default values. **CAUTION: Restoring factory default settings resets ALL user-entered configuration values except the date and time. This button should be used only by qualified service personnel or under their direction.**
System Information	Displays current date, system name, institution name, and software version
Legal Notices	Displays legal notices of the system.

Setup - Database Menu

The **Database** menu in the **Setup** dialog box shows a list of all files in the database. From this menu, you can select patients or individual recordings for export, delete recordings, or select a patient for editing.

Click on individual recordings to select them, or click on a patient's name to select all recordings for that patient, or click on the database to select all recordings.

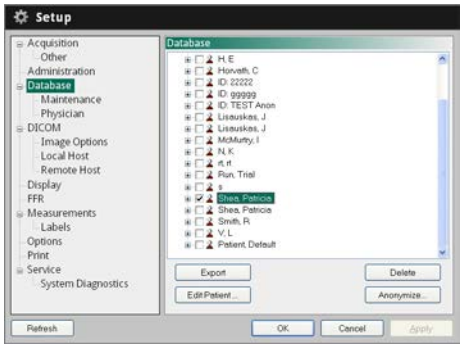


Figure 10-4: Setup - Database Menu

Table 10-5: Setup - Database Menu Settings

Database display	The database display shows all recordings, grouped by patient name, and then by the date of the recordings.
Export	Exports the selected recordings.
Delete	Deletes the selected recordings.
Edit Patient...	Click on a patient's name to edit the patient's information. See "Editing Patient Information" on page 3-6 for more information.
Anonymize...	Click on a patient's name to remove the patient's identifying information from the record. See "Exporting Files in Native (Raw) Format", Step 3, on page 8-8, for an explanation of the anonymization function.

Setup - Database/Maintenance Menu

You can check the status of the system's OCT database using the **Database Maintenance** menu in the **Setup** dialog box. From this menu, you can check the size of the database file, as well as the number of files referenced by the database and the combined size of these files. This menu also warns you of possible issues found with files in the system's database.

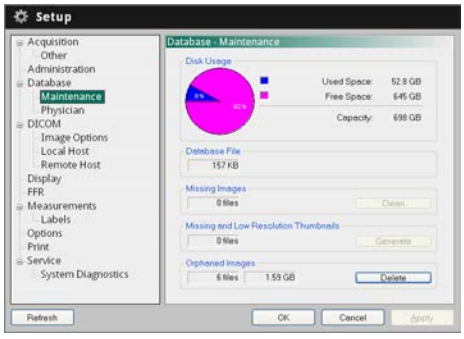


Figure 10-5: Setup - Database/Maintenance Menu

Table 10-6: Setup - Database/Maintenance Menu Settings

Disk Usage	Provides both a graphic and text showing the amount of free and used space on the system's hard disk.
Database File	Indicates the size of the database file.
Missing Images	OCT image files that are referenced by the database but could not be found. Click the **Clean** button to remove references to files that cannot be found.
Missing and Low Resolution Thumbnails	Thumbnail image files that are missing or are low resolution. Click the **Generate** button to generate new thumbnail image files.
Orphaned Images	OCT image files that were found on the system but are not referenced by the database. Click the **Delete** button to delete these orphaned files to free up additional hard disk space.

Setup - Database/Physician Menu

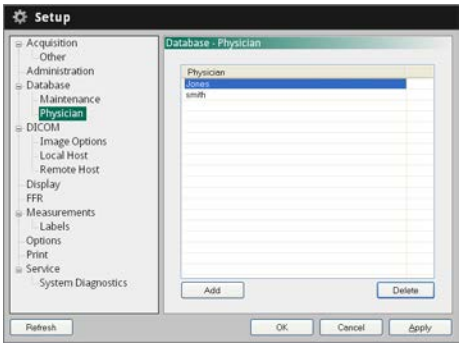


Figure 10-6: Setup - Database/Physician Menu

Table 10-7: Setup - Database/Physician Settings

Physician list	Shows a list of all physician names entered in the system. • Click **Add** to add a new physician name. • Click a name and click **Delete** to remove the name.

Setup - DICOM Menu

The **DICOM** menus in the **Setup** dialog box are used to configure the network settings of the system and the Remote DICOM Store so that the system can initiate a network connection between the two systems. If multiple network adapters exist on the system (not a St. Jude Medical standard configuration) only the primary network adapter can be used.

CAUTION: The ILUMIEN OPTIS System should only be connected to a secure intranet. Direct connection to the Internet may interfere with correct operation and/or result in inappropriate access to patient information, and voids system warranties.
Please note St. Jude Medical makes no representation or warranty that use of the ILUMIEN OPTIS System 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 system.

It is strongly recommended you contact your IT department to set up the system on the DICOM server. Refer to the *St. Jude Medical DICOM Conformance Statement* for more information on configuration.

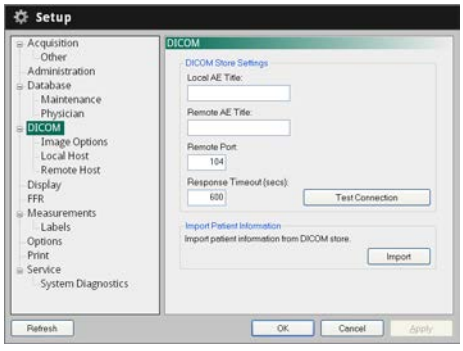


Figure 10-7: Setup - DICOM Menu

Table 10-8: Setup - DICOM Menu Settings

Local AE Title	The AE (Application Entity) title used to configure the Local DICOM Store SCU (Service Class User) used by the ILUM-IEN OPTIS System.
Remote AE Title	The AE title used to configure the Remote DICOM Store SCP (Service Class Provider) to which the system connects.
Remote Port	The port number on which the Remote DICOM Store Host will be listening for connection requests. The default is 104.
Response Timeout (secs)	The maximum time to allow for a response from the Remote DICOM Store after sending a DICOM request. The minimum setting is 15 seconds while the maximum is 1800. The default is 600 seconds. Press the **Test Connection** button to test the connection between the Local DICOM Store SCU and the Remote DICOM Store SCP. For a successful test: • A TCP/IP connection is successfully made from the system to the remote server using the server IP address and port. • A DICOM Associate Connection between the Local SCU and the Remote SCP is accepted by the SCP. • A C-Echo request (Verification class) from the Local SCU results in a successful response from the Remote SCP. **NOTE:** If the DICOM server does not support Multi-Frame True Color Secondary Capture, a warning message appears, telling you to use SC-Image-Storage SOP class instead. If the DICOM server supports neither the Multi-Frame True Color Secondary Capture nor Secondary Capture, a warning message appears: "The presentation syntax supported by the remote server is not compatible. Images cannot be exported to the remote DICOM server." **NOTE:** The **Test Connection** button is unavailable if the **Obtain an IP Address Automatically** checkbox is checked. See "Setup - DICOM/Local Host Menu" on page 10-12.
Import Patient Information from DICOM Store	Click on the **Import** button to import patient information from a Remote DICOM Store into the database.

Setup - DICOM/Image Options Menu

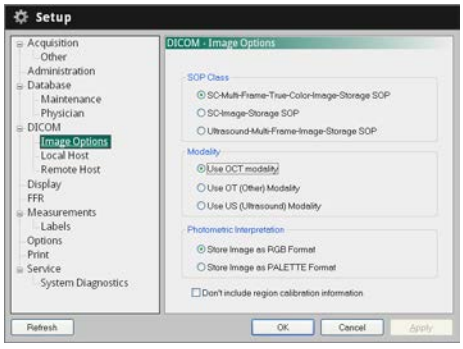


Figure 10-8: Setup - DICOM/Image Options Menu

Table 10-9: Setup - DICOM/Image Options Menu Settings

SOP Class	**SC-Multi-Frame-True- Color-Image-Storage SOP:** When this button is selected, DICOM images are exported as Multi-Frame True Color Secondary Capture. This selection is checked by default. **SC-Image-Storage SOP**: When this button is selected, DICOM images are exported as Single-Frame Secondary Capture. **Ultrasound-Multi-Frame-Image-Storage SOP**: When this button is selected, the images are exported as Ultrasound Multi-Frame DICOM data sets.
Modality	Check to select the image modality: OCT, OT (Other), or US (Ultrasound). The default DICOM export modality is OCT.
Photometric Interpretation	Check to select the export format for DICOM images: RGB or PALETTE. The default format is RGB. PALETTE yields smaller file sizes.
Don't include region calibration information	If this box is checked, region calibration information is not included in the DICOM data.

Setup - DICOM/Local Host Menu

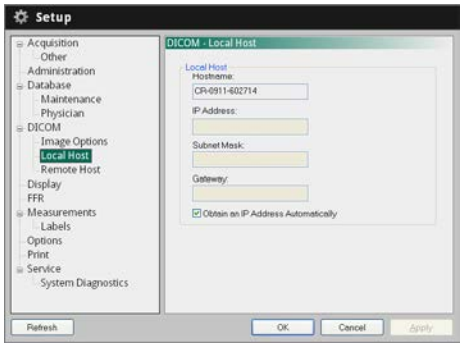


Figure 10-9: Setup - DICOM/Local Host Menu

Table 10-10: Setup - DICOM/Local Host Menu Settings

Hostname	The name used to identify the ILUMIEN OPTIS System on the network. This name is shown for display purposes only and cannot be modified.
IP Address	The IP address of this computer on the network. The default value is determined using DHCP when the network adapter is initialized. **NOTE:** If the **Obtain an IP Address Automatically** option is checked, this is unavailable. **NOTE:** Setting the IP address to an address used by another system on the network may cause network instability.
Subnet Mask	The subnet mask number which is combined with the Local IP Address to identify which network segment this computer is on. The default value is determined using DHCP when the network adapter is initialized. **NOTE:** If the **Obtain an IP Address Automatically** option is checked, this is unavailable.
Gateway	The IP address of the default gateway, IP router, to be used to forward network traffic beyond the local network. The default value is determined using DHCP when the network adapter is initialized. **NOTE:** If the **Obtain an IP Address Automatically** option is checked, this is unavailable.
Obtain an IP Address Automatically	When checked, the **IP Address** of the Local Host, **Subnet Mask**, and **Gateway** are obtained by the system using DHCP, and cannot be edited on the ILUMIEN OPTIS System. Uncheck this option to modify the **IP Address** of the Local Host, **Subnet Mask**, and **Gateway**.

Setup - DICOM/Remote Host Menu

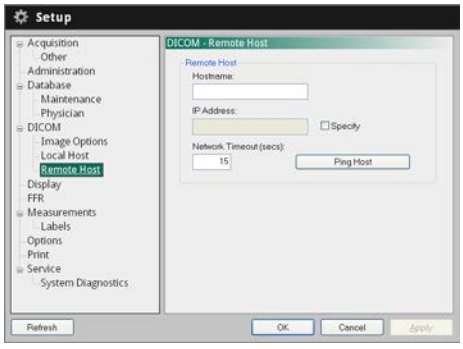


Figure 10-10: Setup - DICOM/Remote Host Menu

Table 10-11: Setup - DICOM/Remote Host Menu Settings

Hostname	The host name of the network server that contains the Remote DICOM Store. Use this option to identify the server if the network supports the Domain Name System (DNS) and the host name is known; otherwise, use the Remote IP Address (see below).
IP Address	The IP address of the network server that contains the Remote DICOM Store. If the Remote Hostname is used to identify the server, this field is automatically filled in if the **Ping Host** button (see below) is successfully used to verify the network connection. Check the **Specify** checkbox to explicitly specify the remote IP address.
Network Timeout	The maximum time to allow for a network ping response from the network server that contains the Remote DICOM Store. The default is 15 seconds.
Ping Host	Use this button to test the network connection between the ILUMIEN OPTIS System and the Remote DICOM Store Host. An ICMP Echo request message is used to verify the connection. **NOTE:** The **Test Connection** button is unavailable if the **Obtain an IP Address Automatically** checkbox is checked. See "Setup - DICOM/Local Host Menu" on page 10-12.

Setup - Display Menu

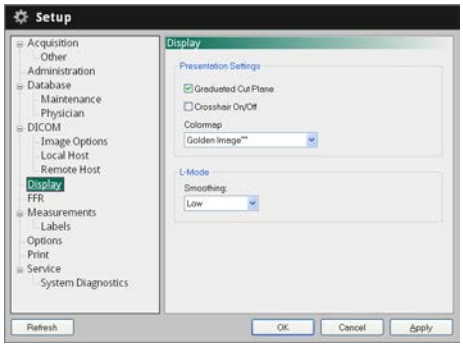
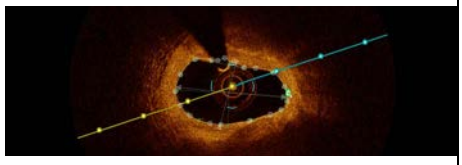
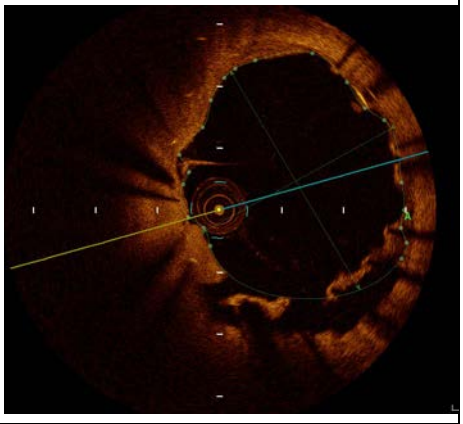


Figure 10-11: Setup - Display Menu

Table 10-12: Setup - Display Menu Settings

Graduated Cut Plane	Check this checkbox to add graduated marks to the cut plane indicators. 
Crosshair On/Off	Check this checkbox to add crosshairs to the cross section view. 
Colormap	Click the arrow on the **Colormap** drop-down menu to display the list of colors. Click a color to select it.
L-Mode (Smoothing)	Click to select the amount of smoothing (averaging) for L-Mode views. The default setting is **Low**.

Setup - Display/3D Option Menu

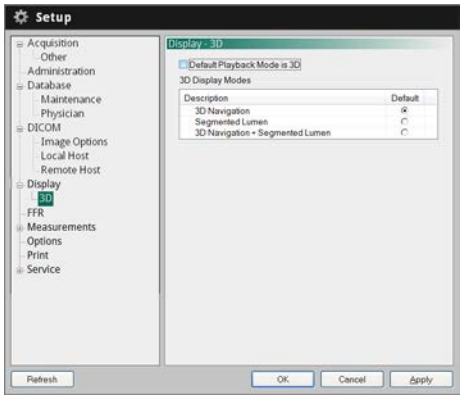


Figure 10-12: Setup - Display/3D Option Menu

Table 10-13: Setup - Display/3D Option Menu Settings

Default Playback Mode is 3D	Turns 3D Display on by default for all pullback recordings.
3D Display Modes	Click to select which display options are available when using 3D. **NOTE:** **Segmented Lumen** is not available when the Automatic MLA and %DS option is disabled.

Setup - FFR

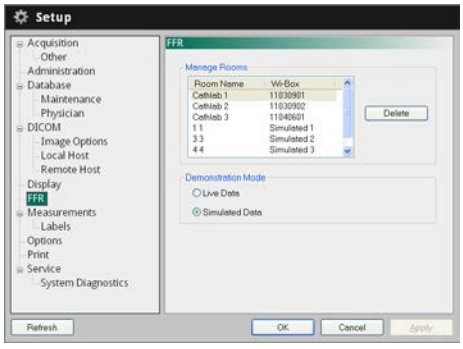


Figure 10-13: Setup - FFR Menu

Table 10-14: Setup - FFR Menu Settings

Manage Rooms	The table lists all Wi-Box receivers that have been added to this ILUMIEN OPTIS System. Click an entry and press **Delete** to remove it from the system.
Demonstration Mode	Click to select the source of data that the system uses when in Demonstration Mode for FFR.

Setup - Measurements Menu

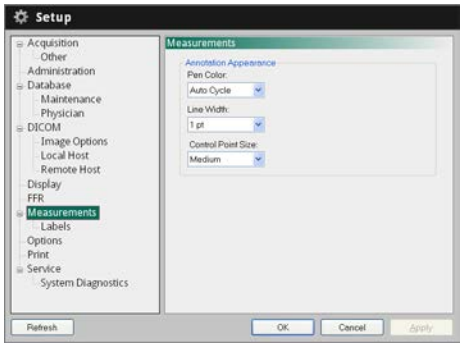


Figure 10-14: Setup - Measurements Menu

Table 10-15: Setup - Measurements Menu Settings

Pen Color	List of pen colors that can be used for subsequent measurements and calculations. If **Auto Cycle** is selected, the pen color used for measurements is automatically changed to the next color after a new measurement is completed.
Line Width	List of line widths that can be used for subsequent measurements and calculations. The default is **1 pt**.
Control Point Size	List of point sizes that can be used for subsequent length and two-point circular area measurements. The default is **Medium**.

Setup - Measurements/Labels Menu

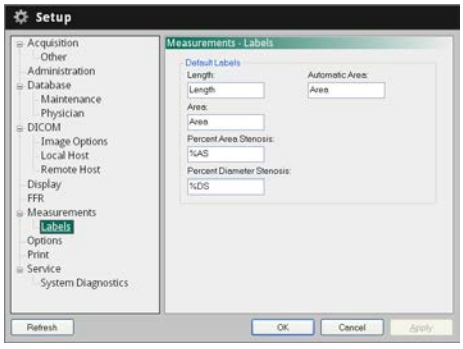


Figure 10-15: Setup - Measurements/Labels Menu

Table 10-16: Setup - Measurements/Labels Menu Settings

Default Labels	Label text that will be used when making the indicated type of measurement. Click and type in any field to change that label.

Setup - Options Menu

The **Options** menu in the **Setup** dialog box is used to enable or disable system options

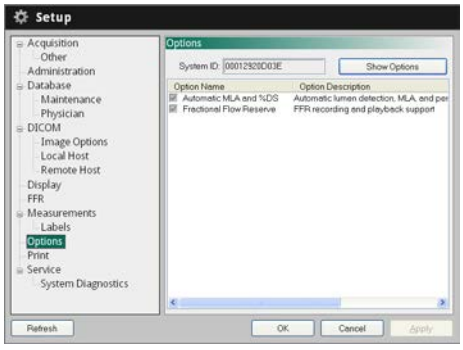


Figure 10-16: Setup - Options Menu

Table 10-17: Setup - Options Menu Settings

System ID	The ID of this system.
Show Options	Click to show the list of available options. A password is required to show the option list.
Option List	System options that may be purchased for this system. A password is required to change option settings.

Setup - Print Menu

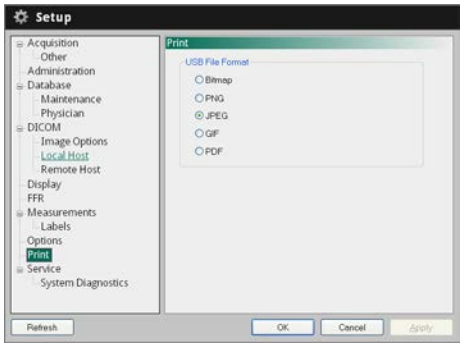


Figure 10-17: Setup - Print Menu

Table 10-18: Setup - Print Menu Settings

USB File Format	Click to choose the format used when printing a file to a USB drive.

Setup - Service Menu

The **Service** menu in the **Setup** dialog box displays service logs to help St. Jude Medical Service analyze problems which may occur during system operation. If you encounter problems while using the system, you may be asked to access and report information from this menu.

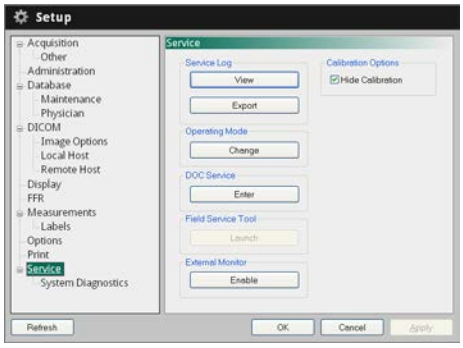


Figure 10-18: Setup - Service Menu

Table 10-19: Setup - Service Menu Settings

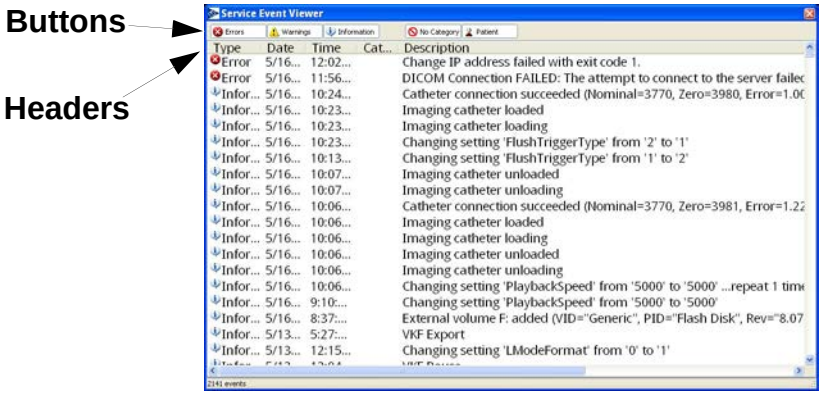
Service Log (View)	Click the **View** button to open the Service Event Viewer.  Click on a column header to sort the patients according to data in that column. Click the buttons at the top to show or hide categories of information: • **Errors** - lists all the operating errors logged by the system. • **Warnings** - lists all the Warning prompts displayed during operation. • **Information** - lists selected system status events which may help diagnose problems. • **No Category** - Displays entries that do not have a Category listed. • **Patient** - lists all changes and import/export of patient data.

Table 10-19: Setup - Service Menu Settings *(continued)*

Service Log (Export)	Click the **Export** button to open the **Transfer Event Log Files** menu, to export the Event Log files to a specified drive. See "Transfer Event Log Files Menu" on page 9-11 for more information.
Operating Mode	Click the **Change** button to open the **System Configuration Utility** window to change the application type and/or operating mode. A password is required to open the configuration utility.
DOC Service	Click **Enter** to perform DOC maintenance, including cleaning or replacing the Optical Adapter.
Field Service Tool	Click **Launch** to start the **Field Service Utility**. **NOTE:** The service utility is for use by trained Field Service Engineers. A password is required to open the service utility.
External Monitor	Click **Enable** to activate the Video connector on the System Connector Panel (see "Ilumien Optis System - Connector Panel" on page 1-6). Once enabled, you can connect an external VGA monitor to the system. Contact St. Jude Medical to have this option enabled.
Calibration Options	The **Hide Calibration** checkbox controls the display of the calibration sequence when a catheter is first connected to the DOC. **Checked** - The calibration sequence is hidden. **Unchecked** - The calibration sequence is displayed on screen.

Setup - Service/System Diagnostics Menu

The **System Diagnostics** menu in the **Setup** dialog box is provided to help St. Jude Medical Service monitor and analyze signal levels in the imaging engine either in real time or at the time a recording was made. When the tab is selected the system immediately displays the detected signal levels while in Acquisition mode or the signal values when the current image was captured when in Playback mode. If you encounter problems while using the system, you may be asked to access and report information from this tab

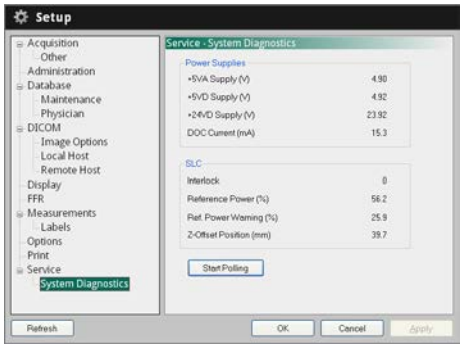


Figure 10-19: Setup - Service/System Diagnostics Menu

Table 10-20: Setup - Service/System Diagnostics Menu Settings

Power Supplies	**+5VA Supply** - The +5 volt AC power supply voltage. **+5VD Supply** - The +5 volt DC power supply voltage. **+24VD Supply** - The +24 volt DC power supply voltage. **DOC Current** - The current being drawn by the DOC in mA.
SLC	**Interlock** - Displays the SLC interlock state. **Reference Power** - Displays the reference power value in %. **Ref. Power Warning** - Reference Power Warning value in %. **Z-Offset Position** - Z-Offset Position value in millimeters.
Start Polling / Stop Polling	Starts/stops automatic update of these values, in real time, every 50 milliseconds. **NOTE:** During playback, the **Polling** button is disabled, and the values represent the signal levels of the imaging engine at the image recording time.

Safety Information 11

Although the ILUMIEN OPTIS System 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 have received ILUMIEN OPTIS System training. Only a trained operator can determine if ILUMIEN OPTIS System use is appropriate. An awareness of the system's limitations is essential to making that determination and assuring safe operation for both operator and patient.

This chapter includes:

- Precautions to assure patient and operator safety.
- How to avoid optical, electrical, explosion, and defibrillator hazards.
- How to make proper electrical connections.
- System imaging limitations.
- How to trace the source of electromagnetic interference.

CAUTION: Before using the ILUMIEN OPTIS System for the first time, be sure to read and understand all of the information in this chapter.

NOTE: The ILUMIEN OPTIS System complies with FDA performance standards for laser products except for deviations pursuant to laser Notice No. 50, dated July 26, 2001.

Patient Safety

The ILUMIEN OPTIS System is intended for use only by medical personnel trained in 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 Dragonfly Imaging catheters with the ILUMIEN OPTIS System. Use of other types of catheters may result in unsafe conditions for the patient and damage the ILUMIEN OPTIS System.

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.

- Only use Dragonfly™ Imaging Catheters. Always use under appropriate imaging guidance (endoscopy, x-ray fluoroscopy, or other appropriate guidance method).
- Only use PressureWire pressure transducers 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 catheter.
- Always use controls, make adjustments and perform procedures as specified in these Instructions for Use.

Techniques to Minimize Patient Exposure

The ILUMIEN OPTIS System 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 ILUMIEN OPTIS System, St. Jude Medical recommends that you carefully read the warning labels on the system (see Figure 11-1) 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 yourself or patients, adhere to the information provided in the safety labels that are located on the system (see Figure 11-1), and observe the precautions outlined in this section.

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

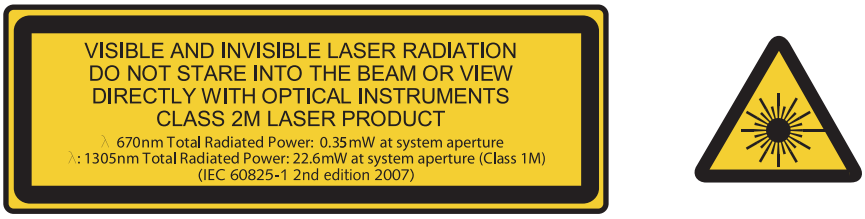


Figure 11-1: Connector Panel Laser Safety Labels

- Avoid eye exposure. Do not look at or stare directly into the beam. Doing so may damage your eyes.
- Never view the laser output with optical instruments (for example, eye loupes, magnifiers, and microscopes). Doing so may damage your eyes.
- 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.

Moving the System

When moving the system, observe these precautions:

WARNING: Failure to follow any of these precautions may lead to a system tipping hazard, causing possible injury to people and damage to the system.

- Be sure to turn off and disconnect the system cord from the wall outlet before beginning a move.
- Position the DOC cable appropriately before moving the system.
- The system weighs up to 95 kg (209 lbs) with all accessories installed, two people are required when moving it.
- Make sure that the system's wheels roll freely before beginning the move. Resolve any wheel problems before you move the system.

  NOTE: Be sure the system brakes are in the up position (unlocked).

- To eliminate the potential danger of the system's tipping over, avoid ramps that are steeper than 5 degrees.
- Do not push the system by the monitors or monitor support mount. 
- If you must move the system up or down ramps with an incline of more than 5 degrees, use two people.
- Do NOT lift a cart bearing the system to move it over uneven elevator entrances or other steps and barriers. Instead, find a route that avoids such problems.

  NOTE: Wheelchair ramps usually have an incline of less than 5 degrees.

- When using a transport vehicle, be sure that it can handle the weight of the system components plus passengers.
- If a lift is used be sure the load capacity of the lift can accommodate the weight of the system components plus passengers.

Avoiding Electrical Hazards

The isolation transformer in the ILUMIEN OPTIS System provides electrically isolated power to components supplied with the system or specified as part of the system.

WARNING: All system components except the isolation transformer itself MUST be powered by, and only by, the isolation transformer in the ILUMIEN OPTIS System.

This electrical isolation separates the system components, and thus the patient, from dangerous leakage currents. If any of the system's components are directly connected to a wall outlet or some power source other than the isolation transformer, the patient and the operator are no longer safely isolated and may be exposed to dangerous electric currents.

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 outlets with the ILUMIEN OPTIS System.

  NOTE: The ILUMIEN OPTIS System's isolation transformer creates an electrically isolated Patient Interface for invasive imaging. This electrically isolated condition must be maintained throughout the procedure or during any contact with the patient.

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

  WARNING: Inside the catheterization lab 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 lab, 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 the electrical connection for the system is properly rated (see Figure 11-2). Carefully follow the safety guidelines described in this section when connecting your system's power cord to the hospital or lab's 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.

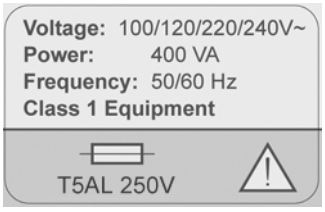


Figure 11-2: Electrical Label

- 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 St. Jude Medical, part number: 11559-02 FUSE
- The power cord is to be used for disconnection from main power.
- Make sure that any devices that connect to the network interface of the ILUMIEN OPTIS System comply with the appropriate IEC/national standard and are certified to IEC 60950.
- Use no electrical peripherals within six feet of a patient unless the peripherals receive power from an isolation transformer that meets medical safety standards.

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

Explosion Hazard

WARNING: Do NOT operate the ILUMIEN OPTIS System in the presence of flammable anesthetics. Doing so could lead to an explosion.

System Imaging Limitations

The ILUMIEN OPTIS System is intended for use by medical personnel who have received training in the use of the system. To determine if system use is appropriate, the trained user must be aware of system imaging limitations.

CAUTION: Use only the Dragonfly™ Imaging catheters with the ILUMIEN OPTIS System. Other types of catheters may break if used.

This section includes information about system capabilities and limitations for both vessel and tissue imaging.

Considerations for Optimal Vessel Imaging

The ILUMIEN OPTIS System can be used to image through vessels or to image the inner surface of certain vessels. Since the Dragonfly 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 eccentrically (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 Compatibility

The ILUMIEN OPTIS System is designed to meet the following electromagnetic compatibility standards:

- IEC 60601-1-2 (International).
- EN 60601-1-2 (Europe).

Electromagnetic Interference

The system produce 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.

In accordance with the standards identified in these Instructions for Use, no interference was observed. However, the trained 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 your service representative. The answers will help a service representative determine if the problem is in the system or in the imaging environment.

Safety Functions Built Into the ILUMIEN OPTIS System

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 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 (see “The Drive-motor and Optical Controller (DOC)” on page 1-9).

System Specifications 12

System - Safety & Regulatory

Table 12-1: System Safety & Regulatory Specifications

Category	Specifications
Regulatory Approvals	CE 0086
Safety standards system meets	EN60601-1: 1990, “Medical Electrical Equipment, Part 1: General Requirements for Safety” including Amendments A1:1993, A2:1995, A13:1996
	EN60601-1-1: 2001, “Medical Electrical Equipment, Part 1: General Requirements for Safety - Section 1.1 Safety Requirements for Medical Electrical Systems”
	EN60601-1-1: 2005, Ed: 3, “Medical Electrical Equipment, Part 1: General Requirements for Basic Safety and Essential Performance”
	EN60601-1-2: 2007, Electromagnetic Radiated Emissions Requirements for Medical Electrical Equipment - Group 1 Equipment, Class B for Non-Life Supporting Equipment
	UL60601-1, “Medical Electrical Equipment, Part 1: General Requirements for Safety” 2nd Edition, including Amendments A1 and A2
	CAN/CSA C22.2 No. 601.1-M90, “Medical Electrical Equipment, Part 1: General Requirements for Safety” including C22.2 No. 601.1S1-94 (IEC 601-1, Amendment 1:1991)
	IEC 60825-1, 2nd Ed., 2007: Safety of Laser Products
Electromagnetic compatibility (EMC)	Refer to Table 12-5, Table 12-6, Table 12-7, and Table 12-8 for detailed specifications.

Table 12-1: System Safety & Regulatory Specifications *(continued)*

Category	Specifications
Classifications	
Type of protection, shock	Class 1
Degree of protection, shock	Type CF • DOC with catheter (CF label at DOC cable exit on Connector Panel)
Degree of protection, ingress	**Console** - IPX0 **DOC** - IPX0, use with Sterile DOC cover for ingress protection
Method of Disinfection	Console 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
Leakage & 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
Software Safety Features	
The computer and software are designed with the following security features. These features do not require any user configuration or action. • Prevents unauthorized access to the operating system. • Prevents installation or execution of unauthorized software • Prevents infiltration via Ethernet connection. • Performs data integrity check when archiving data to external media.	

System - Electrical and Physical

Table 12-2: System Electrical and Physical Specifications

Parameter	Specification
Power Input	
Line voltage	100/120/220/240 VAC ±10%, user selectable
	50/60 Hz ±1 Hz
Power consumption	Active: < 400 VA
	Standby: < 30 VA
Transport and Storage Conditions (Permissible ranges)	
Ambient temp	-25 to +50 degrees C
Relative humidity	10% - 95%, including condensing
Atmospheric pressure	500 to 1060 mBar
Operating Conditions	
Ambient temperature	+10 to +32 degrees C
Relative humidity	30% to 80%, non-condensing
Atmospheric pressure	700 to 1060 mBar
Mechanical Specifications	
Weight	95 kg (209 lbs) max with all accessories
Overall Dimensions	145 cm H x 61 cm W x 71 cm D ±5 mm

Imaging Specifications

Table 12-3: 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 (nominal) (Class 2M Laser Output per IEC 60825-1)
Pullback Parameters	
Pullback Range	75 mm (If connected to a C7 Dragonfly catheter, the range is 54 mm.)
Pullback Speed Settings	18.0 mm/sec, 36.0 mm/sec (If connected to a C7 Dragonfly catheter, the speed settings are 10.0 mm/sec, 20.0 mm/sec, 25.0 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
Lateral Resolution	25 - 60 µm
Optical Sensitivity	90 db minimum
A-Scans per second	90 kHz (nominal)
Frame Rate	180 frames/second (Hz) (If connected to a C7 Dragonfly catheter, the Frame Rate is 100 frames/second (Hz).)

FFR Specifications

Table 12-4: FFR Specifications

Parameter	Specification
AO Pressure (Wi-Box to ILUMIEN OPTIS System)	
Operating pressure	-180 to +450 mmHg
Accuracy	±1 mmHg plus ±1% of reading (-30 to 50 mmHg)
	±3% of reading (50 to 300 mmHg)
AO Pressure (Wi-Box to hemodynamic recording system)	
Direct galvanic connection	
Max pressure shift	<2 mmHg
Radio Specification	
Frequency range	2.4000 - 2.4835 GHz
Type	Frequency hopping spread spectrum (FHSS)
Range	0 - 4 m
Delay time	<20 ms

Electromagnetic Emissions

Table 12-5: Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The ILUMIEN OPTIS System is intended for use in the electromagnetic environment specified below. The customer or user of the ILUMIEN OPTIS System should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The ILUMIEN OPTIS System 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 B	The ILUMIEN OPTIS System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic proposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity

Table 12-6: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The ILUMIEN OPTIS System is intended for use in the electromagnetic environment specified below. The customer or user of the ILUMIEN OPTIS System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV lines(s) to line(s) ± 2 kV lines(s) to earth	± 1 kV lines(s) to line(s) ± 2 kV lines(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (>60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (>60% dip in U_T) for 5 cycles <70% U_T (>30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ILUMIEN OPTIS System requires continued operation during power mains interruptions, it is recommended that the ILUMIEN OPTIS be powered from an uninterruptible power supply or battery.

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

Table 12-6: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The ILUMIEN OPTIS System is intended for use in the electromagnetic environment specified below. The customer or user of the ILUMIEN OPTIS System should assure that it is used in such an environment. *(continued)*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

Table 12-7: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The ILUMIEN OPTIS System is intended for use in the electromagnetic environment specified in this section. The customer or user of the ILUMIEN OPTIS System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ILUMIEN OPTIS System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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 this symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: 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 ILUMIEN OPTIS System is used exceeds the applicable RF compliance level above, the ILUMIEN OPTIS System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ILUMIEN OPTIS System.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Table 12-8: Recommended separation distances between portable and mobile RF communications equipment and the ILUMIEN OPTIS System

The ILUMIEN OPTIS System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ILUMIEN OPTIS System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ILUMIEN OPTIS System 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 2.5 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 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: 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 St. Jude Medical could void the user's authority to operate the equipment.

Essential Performance Defined by Operating Mode

During testing, the OCT Imaging System (MN: C8/ILUMIEN OPTIS) was operating as follows: SSOCT Data Viewer is displaying white noise. The CardioUI Development software is running. The probe is active and displaying an image. Image on screen is stable and without error. Also host PC is pinging the EUT.

Index

Symbols

Numerics

A

B

C

D

E

F

G

H

I

L

M

N

O

P

R

S

T

U

V

W

Z