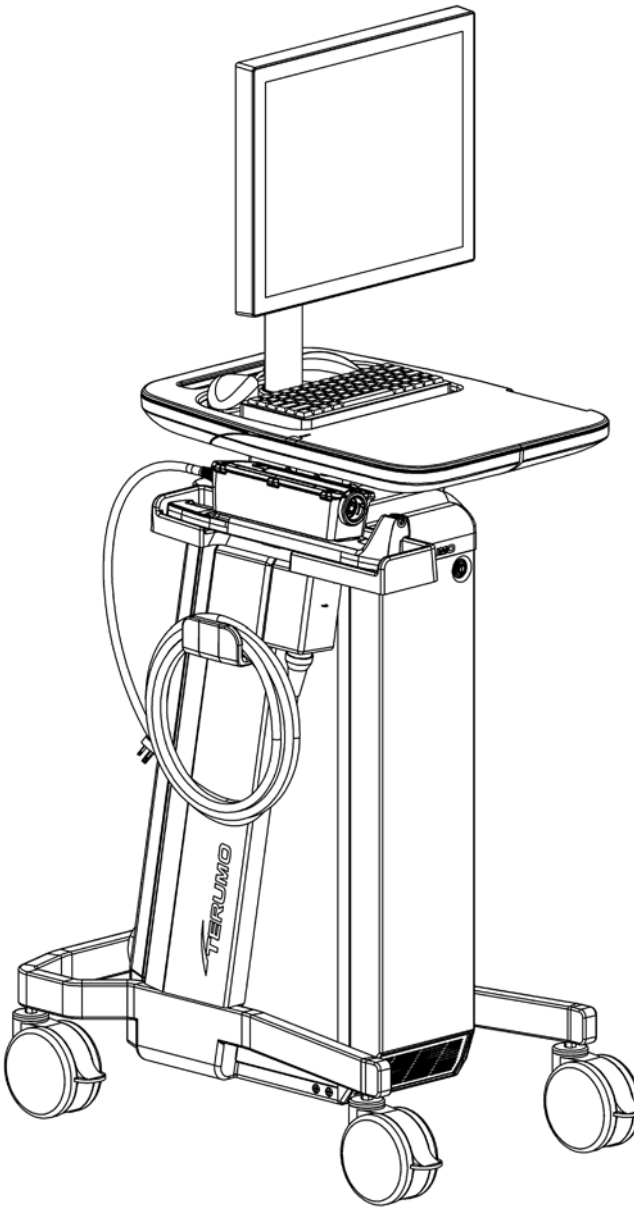
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TERUMO

# Instructions For Use

OPUSWAVE™

Dual Sensor Imaging System




Model 01000-00

# Contact Information

## Service Policy

With the exception of routine cleaning, the replacement of the wireless mouse, and the wireless mouse battery, any servicing of the components of the OPUSWAVE System must be performed by Terumo or an authorized service organization.

If an error message appears on the screen, please follow the instructions on the screen or review the Troubleshooting section of this manual in Section 22," System Safety and Technical Specifications" to determine the possible cause. For additional assistance with any problems or concerns, Terumo troubleshooting hotlines are available during normal business hours.

Should repair be necessary, a technical service or customer administration representative will authorize a replacement instrument. In order to expedite this process, please have the product serial number and a detailed description of the abnormal behavior of the product available when calling. For the most efficient use of the troubleshooting process, the product should be nearby for the execution of some simple tests during the telephone conversation.

**Terumo Cardiovascular Systems Corporation**
Terumo Troubleshooting Hotline
800-521-2818 - Customer Administration
800-441-3220 - Technical Support

**Manufacturer Address:**
Terumo Cardiovascular Systems THI Plant
6190 Jackson Road
Ann Arbor, MI 48103-9300 U.S.A
(734) 663-4145 (800) 521-2818

OPUSWAVE System Instructions For Use Reorder No: **01607-00 Revision E**

## Returned Goods Policy

Should a return be necessary, please initiate by calling Terumo's Customer Administration number. Please be prepared to provide the product description, the quantity of product to be returned, the serial number, and the reason for the return. A Terumo representative will facilitate all product returns.

# Important Instructions

## Using this Manual

This manual provides technical references, descriptions and instructions for frequently used operations and functions of the OPUSWAVE System. It is intended for use by Interventional Cardiologists and catheterization laboratory personnel. The OPUSWAVE System consists of a medical device designed to be managed by medical professionals specially trained in percutaneous coronary interventional imaging procedures and system operation. This IFU should not be considered a substitute for adequate medical training and should always be used in the context of current medical literature and practice.

For the purposes of this Instructions For Use only, all references to the system includes the Console, MDU, MDU Cover, and associated DualView Catheter.

To ensure the safe use of this system:

- Review this manual carefully before using your OPUSWAVE System, especially the information described in Section 3, "Warnings and Cautions" and Section 22 "System Safety & Technical Specifications".
- Perform maintenance to keep this system in safe operating condition.
- Acknowledge all Warning and Caution symbols and statements shown throughout the manual.

This manual contains important symbols for Warnings, Cautions, and Notes:



**WARNING**

A Warning alerts you about a situation which, if not avoided, could result in death or serious injury. You must read these warnings prior to using the OPUSWAVE System.



CAUTION

A Caution alerts you about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or damage to the OPUSWAVE System.

NOTE

A Note contains information that help with the operation of the OPUSWAVE System.

# Important Instructions

## Safety Information:

**WARNING**

- Prior to operating this system, carefully read and review the entire Terumo Cardiovascular Systems OPUSWAVE and DualView™ Instructions For Use.

CAUTION

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

**ETL Listed Mark**

This product has been tested by an accredited third-party testing laboratory and meets the applicable safety standards and minimal requirements for sale or distribution within North America.

**Follow the Instructions For Use (IFU)**

Any user of the OPUSWAVE System must read and understand all the information, including the identification of symbols used on the equipment, in this manual, as well as the instructions for use included with all associated disposables before using the system.

**Laser Radiation**

The OPUSWAVE System complies with 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1, as described in Laser Notice No. 56, dated May 8, 2019.

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# Section 1
# System Overview

**WARNING**

- This device should be used by or under the supervision of medical personnel thoroughly trained in the techniques of percutaneous coronary interventional procedures, specifically, Optical Frequency Domain Imaging [OFDI] and Intravascular Ultrasound [IVUS] techniques and use of this system. Diagnoses based on the images should be done by qualified physicians/doctors. Misuse or misdiagnosis of system and images could cause serious or critical injury to patients.
- The OPUSWAVE System shall only be used in facilities where Cardiac Surgery is available. Failure to do so may result in emergency situations that cannot be addressed if complications arise.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Group 1 Class A). Do not use in residential areas. NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Group 1 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

CAUTION

- Medical personnel who use the OPUSWAVE System must be aware of the system's limitations. Only trained users can determine if use of the OPUSWAVE System is appropriate. Be sure to read Section 22, "System Safety and Technical Specifications" before operating the system for the first time.

# System Overview

## Intended Use/Indications for Use

| Country | Intended Use/Indications for Use |
|---|---|
| USA | • The OPUSWAVE System with DualView is intended for the intravascular imaging of coronary arteries and is indicated in patients who are candidates for transluminal interventional procedures. |

## Complications

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

- Coronary dissection, perforation, rupture, or injury
- Thrombus formation, coronary total occlusion
- Distal emboli, cerebral infarction (with air, tissue, and/or thrombosis)
- Infection
- Renal insufficiency or failure
- Allergic reaction to the contrast media

# System Overview

## System Features

The OPUSWAVE System with the Dual Sensor Catheter is capable of imaging both simultaneously or asynchronously with IVUS and OFDI modalities for tomography images of the coronary arteries.

### Service Life

- The OPUSWAVE system service life, under normal operating conditions, and with periodic preventive maintenance inspections by a Terumo Service Technician, is 8 years.

### Power, Storage, and Environmental Specifications



**WARNING**

- Avoid using this system under rapidly changing temperature cycles even within the operation conditions. Due to the condensation inside of the system, damage and/or degradation may occur and lead to deterioration in function or performance.
- Do not operate or store the system outside specified operating environment conditions. It may cause system malfunction that may lead to patient injury.
- Do not use the system in a flammable environment. It may cause fire or explosion.

#### System Power Requirements

| | |
|---|---|
| Voltage: | 100-240 VAC +/- 10% |
| Frequency: | 50Hz/60Hz |
| Consumption: | 500VA |

#### System Environmental Conditions: Operational:

| | |
|---|---|
| Temperature Range | 10 °C to 35 °C |
| Relative Humidity | 30% to 75% (non-condensing) |
| Atmospheric Pressure | 70 kPa to 106 kPa |

#### System Storage & Transport: Non-operational:

| | |
|---|---|
| Temperature Range | -20 °C to 60 °C |
| Relative Humidity | 10% to 95% (non-condensing) |
| Atmospheric Pressure | 50 kPa to 106 kPa |

#### Catheter Storage:

Refer to DualView Catheter Instructions For Use/labeling for catheter storage information.

# System Overview

## System Configuration

NOTE

- Only use components and accessories provided with the OPUSWAVE System.
- Components described in this manual are subject to change without notice, contact a Terumo representative for component inquiries.

### System Components

**The OPUSWAVE System includes the following components:**

- Main Unit: Wheeled Console with Monitor
- Power Cord
- Wired Keyboard
- Wired Mouse/Wireless Mouse [with Receiver]*
- AA Battery [for Wireless Mouse]
- Optical Disc Drive
- Software User Interface
- Motor Drive Unit [MDU]
- Instruction Manual

**The OPUSWAVE System works with the following Catheter:**

- DualView Catheter

The DualView Catheter package Includes the following components:

- DualView Catheter
- MDU Cover
- Catheter Ancillary Holder [includes Priming and Reservoir Syringes; Connection Tube with 3-way stopcock]

Refer to Page 16, "System Accessories" for additional information on system components and accessories.

* Using the wireless mouse in the sterile field requires placing it in a sterile drape or bag (not provided by Terumo).

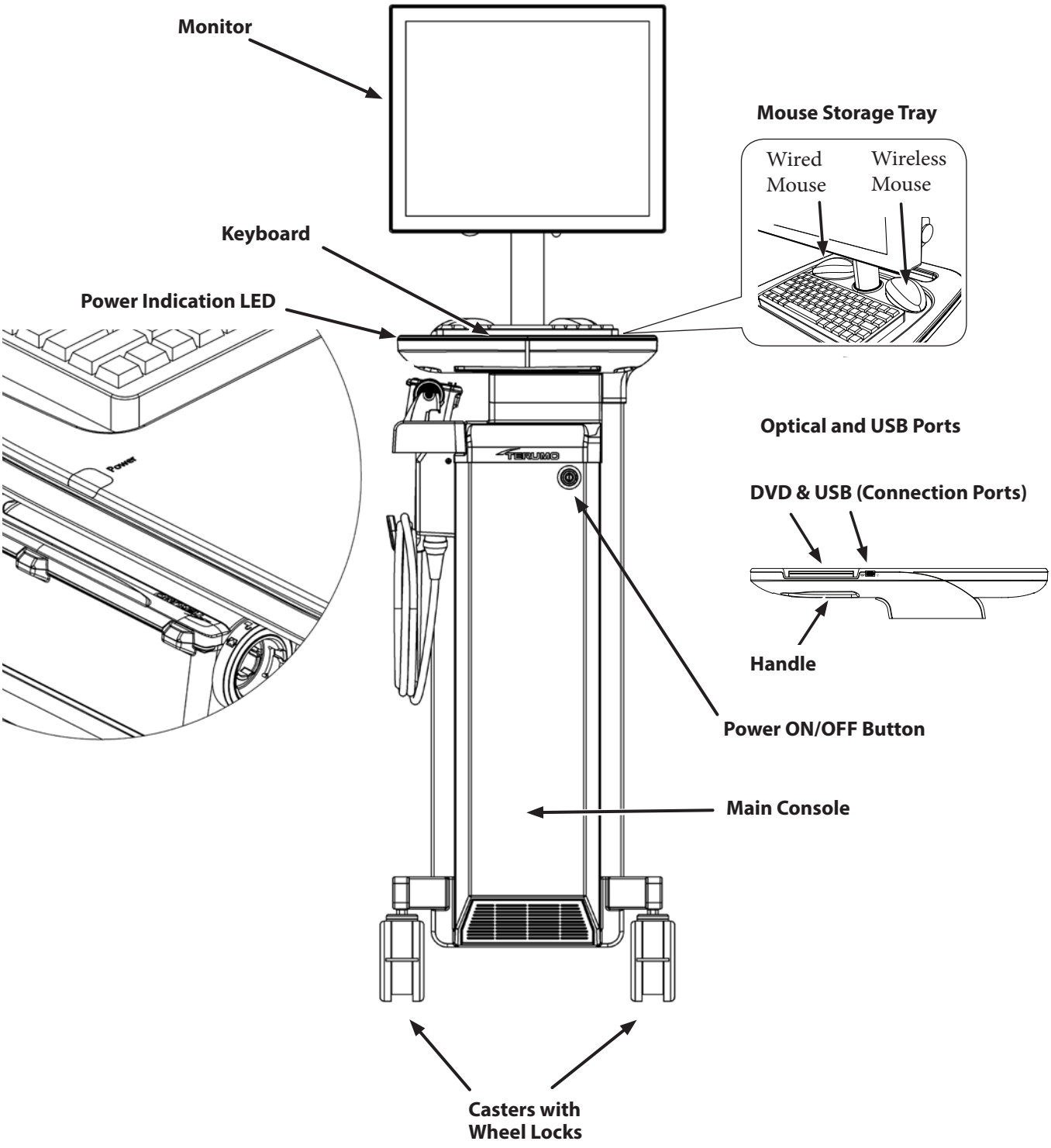
# System Overview

Console Overview [Front View]

NOTE

- Images in this section are schematic representations and are not drawn to scale.
- Detailed component information is found in “Parts Identification" (page 17).

The system is intended for use only with the components specified in this document. These components should never be modified, substituted or replaced. Any parts substituted or used in conjunction with this system, must be evaluated and certified that they conform to applicable safety standards such as IEC 60601-1.

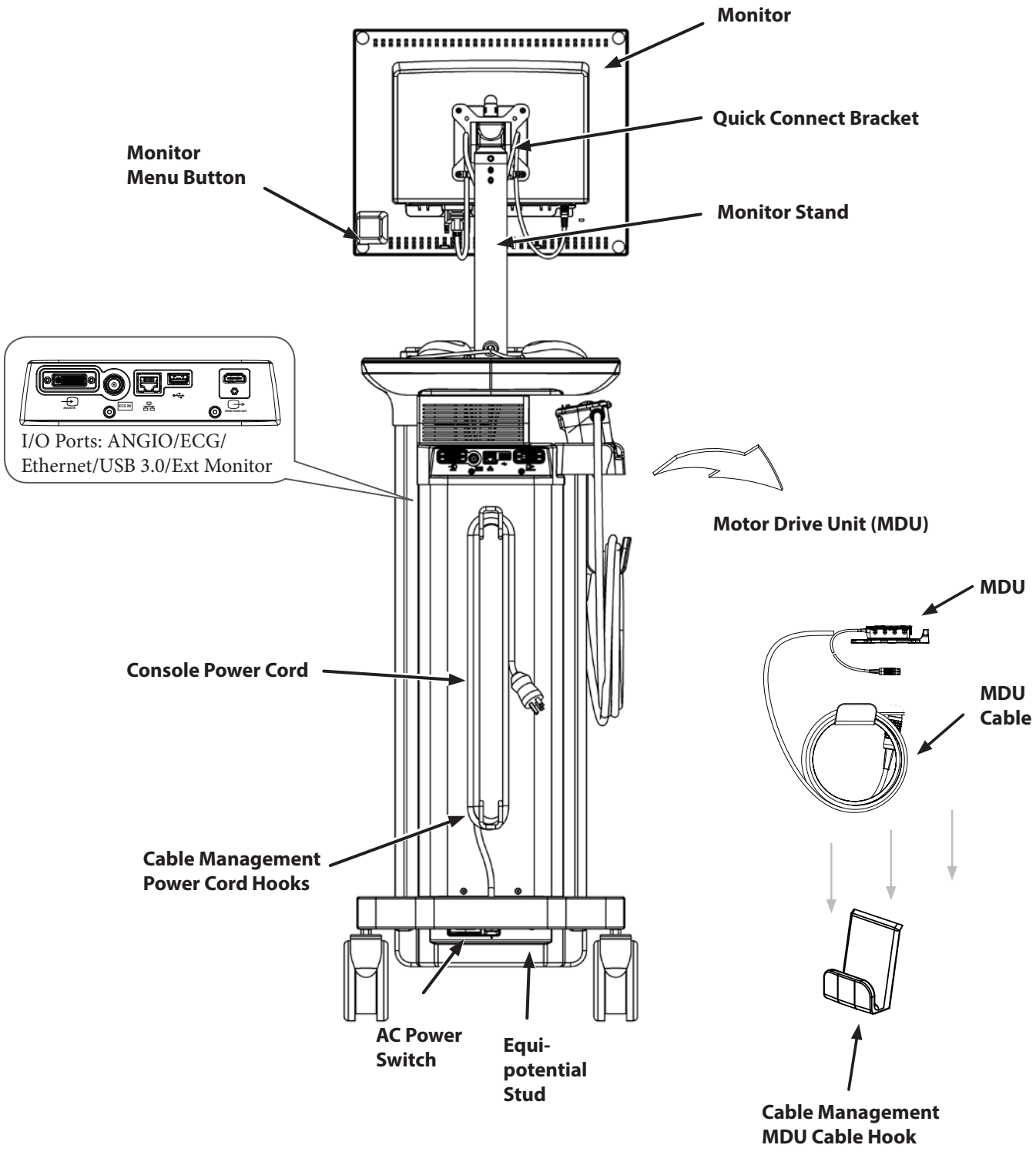


# System Overview

Console Overview [Back View]

NOTE

- The power cord is located at the bottom rear of the system.
- The equipotential stud is used to reduce the difference of electrical potential when the OPUSWAVE device is used simultaneously with another medical equipment or measuring instrument that has a potential different from the Protective Earth of the OPUSWAVE. The operator or patient may receive an electric shock when touching the OPUSWAVE, to prevent this, the metal part of the chassis is connected to the Protective Earth.



## System Accessories

**WARNING**

- Read the Instructions for Use provided with the catheter and MDU Cover prior to use. Misuse of these devices may cause injury to the patient or damage to the System.

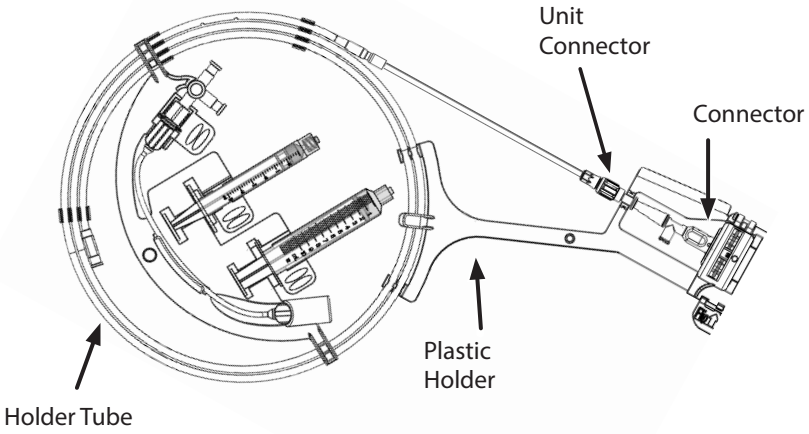
**NOTE**

- Images below are not shown to exact scale.

The OPUSWAVE system is compatible with the following accessories:

Catheter

**DualView Catheter**

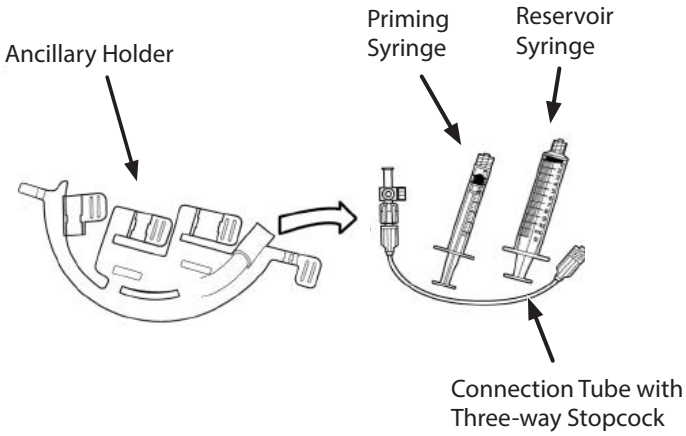


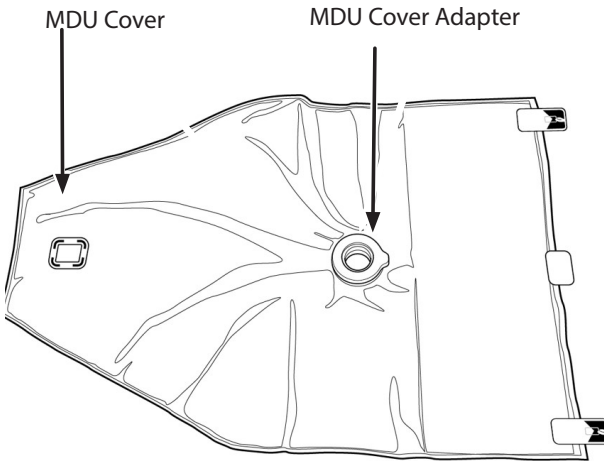

Ancillary Holder/Accessories†

† *Provided with DualView Catheter*

MDU Cover†

† *Provided with DualView Catheter.*



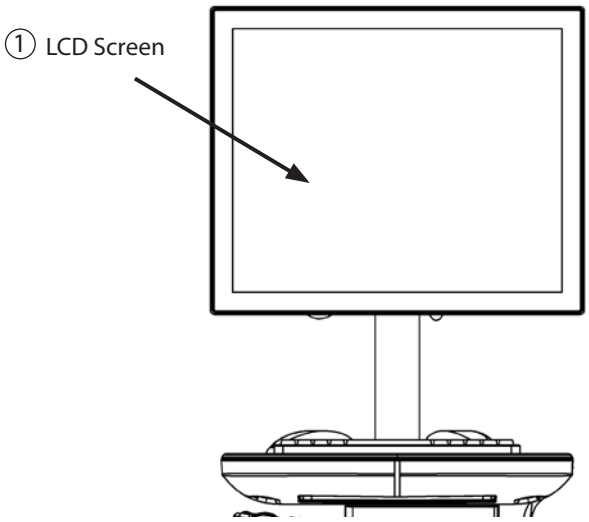



# System Overview

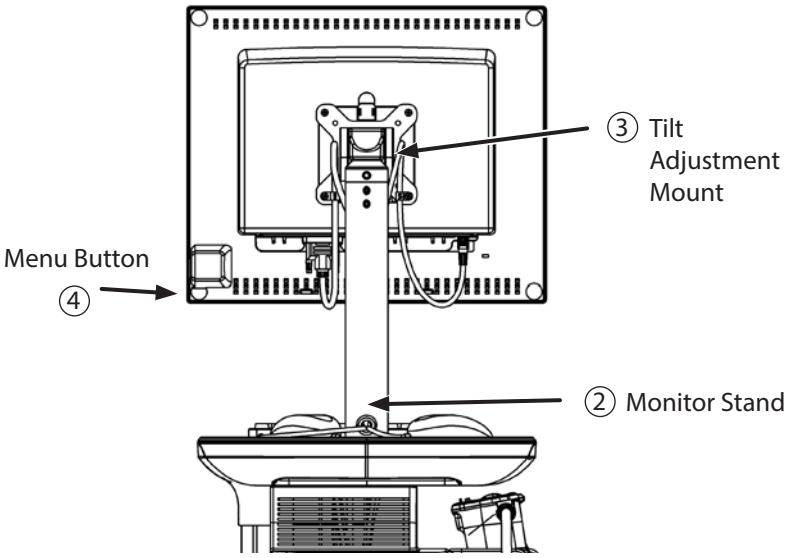
## Parts Identification

LCD Monitor

**LCD Display [Front View]**




**LCD Display [Rear View]**

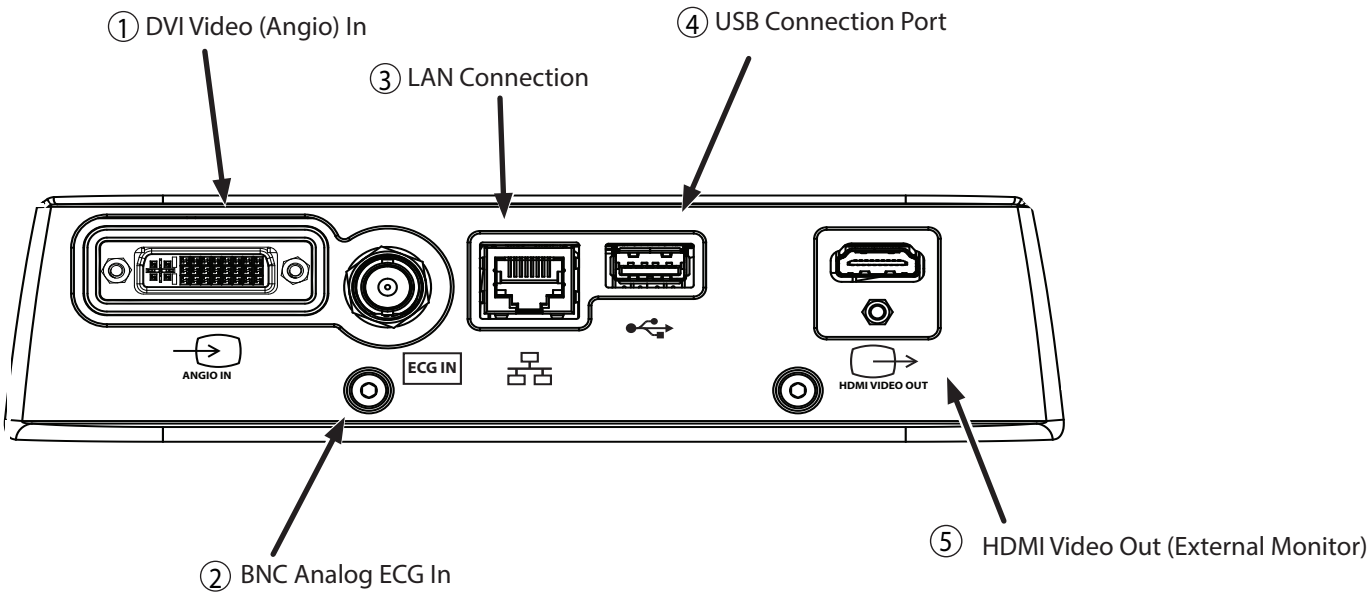



| No. | Name | | Function |
|---|---|---|---|
| ① | **LCD Screen** | | 19-inch LCD High-Definition DisplaySXGA (1280 x 1024) |
| ② | **Monitor Stand** | | Rigid vertical support for the LCD Monitor. |
| ③ | **Monitor Tilt Adjustment Mount** | | Allows the user to adjust the LCD Monitor face position throughout the duration of the procedure:<br>Tilt [Up/Down]: raise 35 degrees and decline 5 degrees.<br>Rotation [Right/Left]: 135 degrees in both directions. |
| ④ | **Menu Button** | | • Adjust Picture Settings - Push button in |
| | | | • Scroll Selection Up - Rotate button clockwise |
| | **Picture Setting Menu** | | |
| | | **Exit** | Exits the menu. |
| | | **Color Mode** | Adjusts color best suited for content |
| | MA | **Management** | Menu of user adjustable settings (see below menu options available) |
| | | **OSD Display** | (On Screen Display) Adjusts horizontal and vertical positioning |
| | | **Language** | Select preferred language to display |
| | | **Source** | Select between video signals connected to the monitor (VGA, DVI, Display Port) |
| | | **Recall** | Resets settings to factory default settings |
| | | **Mute*** | Mutes volume |
| | | **Volume*** | Adjusts volume up and down |

* Functions are deactivated on the OPUSWAVE system monitor.

# System Overview

External Input/Output Connector Panel

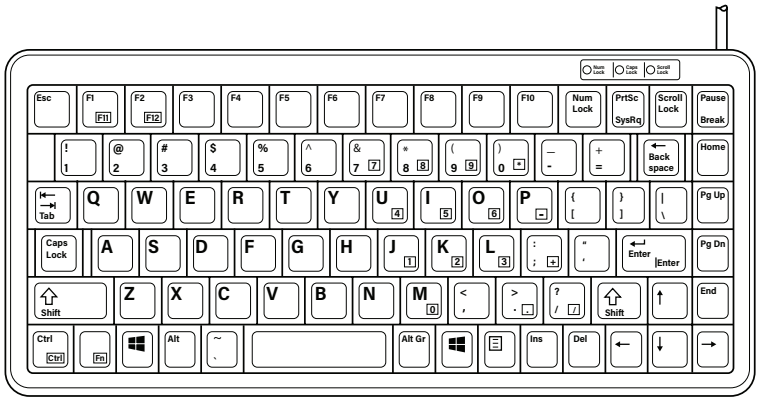



| No. | Description | Function | Marking |
|---|---|---|---|
| ① | DVI (Digital Visual Interface) Input Connector | Angiography Input Connection [ANGIO IN]<br>Receives angio video frame data from a 3rd party angio device from the video digitizer. | ANGIO IN |
| ② | BNC Analog Coaxial Connector | Electrocardiogram Input [ECG] from a 3rd party ECG machine. | ECG IN |
| ③ | LAN [Local Area Connection] Port | Connection to Computer Network [DICOM] | |
| ④ | USB 2.0/3.0 [Universal Serial Bus] Connection Port | Connection for wireless mouse or data export | |
| ⑤ | HDMI (High-Definition Multimedia Interface) Output Connector | Connection to External Monitor [HDMI VIDEO OUT] | HDMI VIDEO OUT |

# System Overview

## Wired Keyboard*

The OPUSWAVE Console uses a standard Windows™ keyboard.



**NOTE**

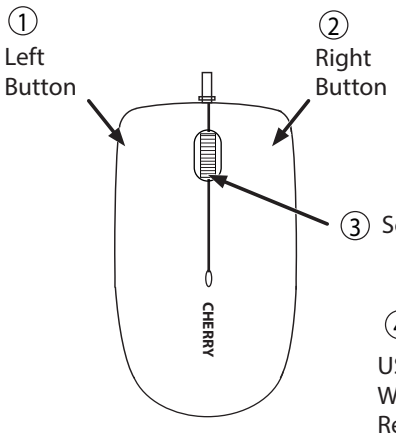
- The keyboard has a mode that will disable the keyboard, this mode can be activated or deactivated by pressing the Fn + Right Shift keys.

## Optical Wired and Wireless Mouse*

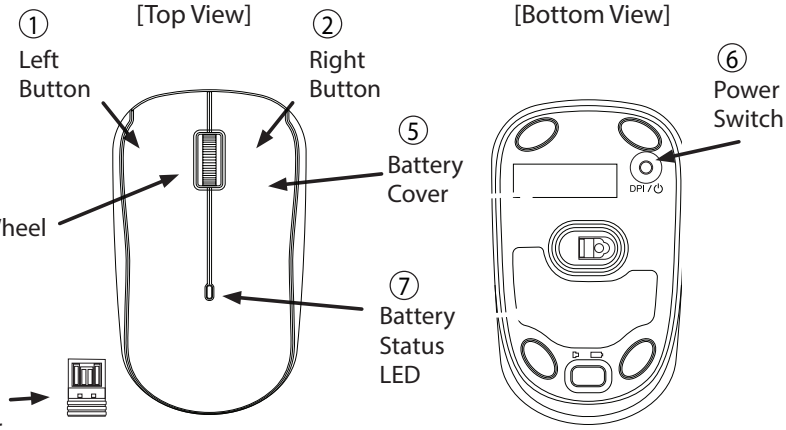
**NOTE**

- The OPUSWAVE Optical Wireless Mouse contains user replaceable AA batteries.
- Read and follow the manufacturer's instructions [provided with each mouse] for safe installation and handling.

**Wired Optical Mouse**




**Wireless Optical Mouse**



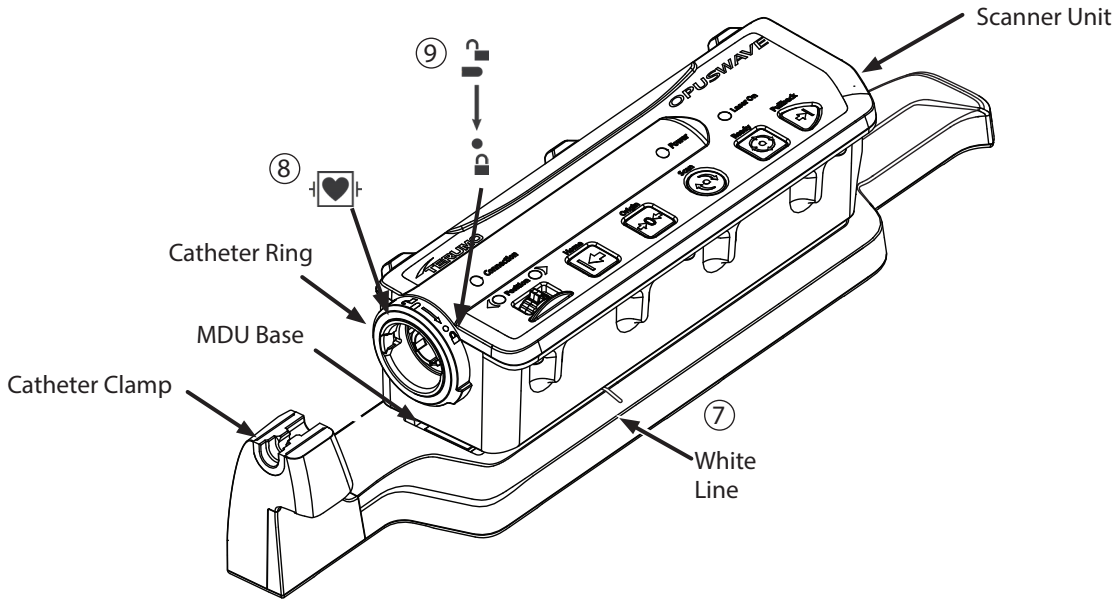

| No. | Description | Function |
|---|---|---|
| ① | Left Mouse Button | Selects objects or tasks by Double-clicking |
| ② | Right Mouse button | Opens Command Menu |
| ③ | Scroll Wheel | Scrolls vertically on computer screen |
| ④ | USB Receiver | Allows wireless mouse to communicate with computer |

| No. | Description | Function |
|---|---|---|
| ⑤ | Battery Cover | Pull open and down to replace batteries |
| ⑥ | Power Switch | Press to turn power to mouse Off and On |
| ⑦ | Battery Status LED | LED color:<br>Solid green: Battery OK<br>Blinking red: replace battery soon |

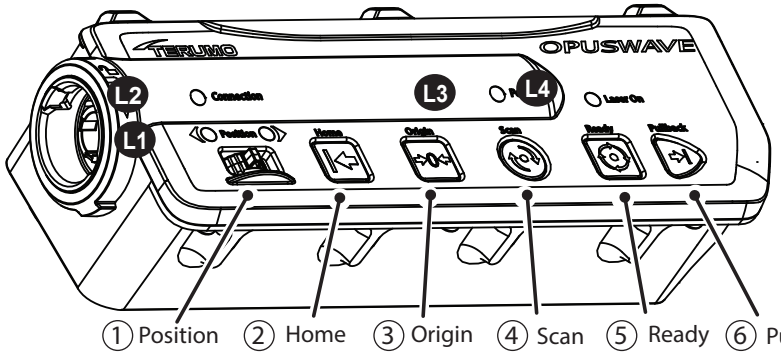
*Mouse and keyboard Images are examples only and subject to change.

# System Overview

Motor Drive Unit [MDU]




Scanner Upper Enclosure (Top View)




| LED Indicators | |
|---|---|
| L1 | Position |
| L2 | Connection |
| L3 | Power |
| L4 | Laser On |

MDU User Control Buttons - Functions and Markings

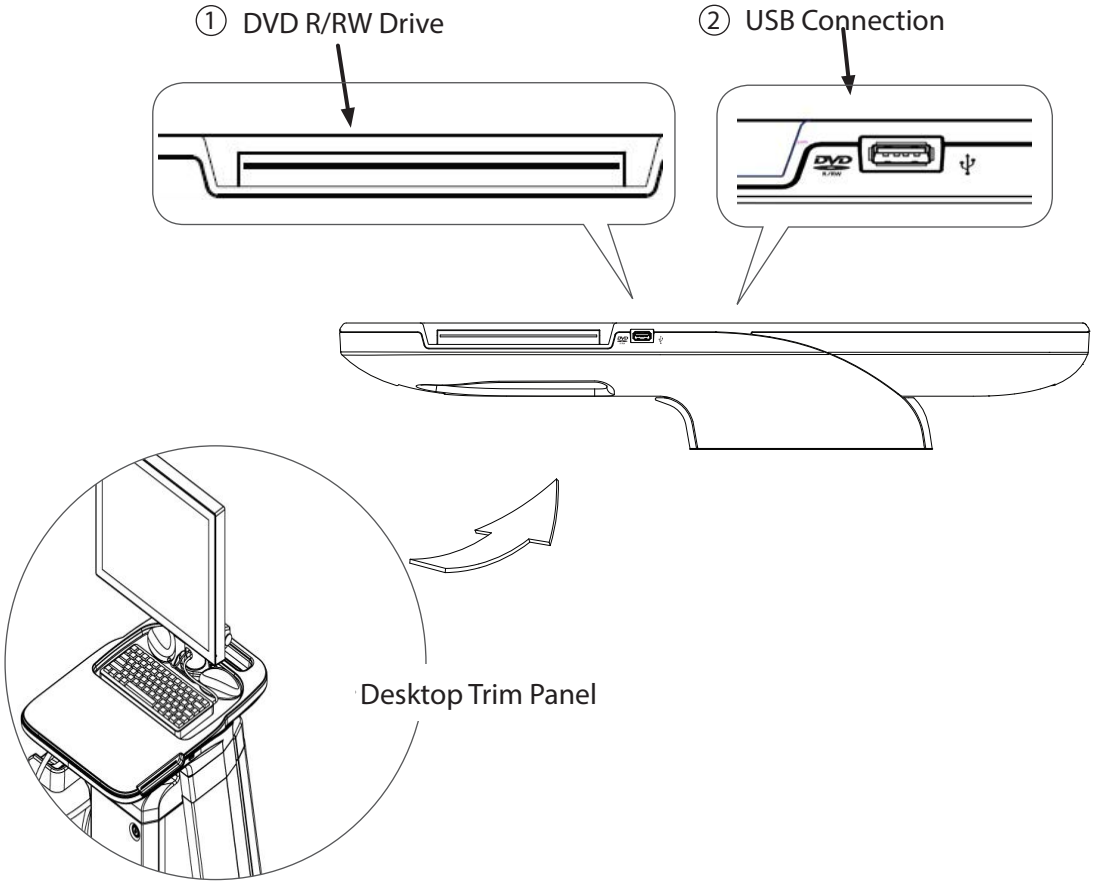
| No. | Description | Function | Marking |
|---|---|---|---|
| ① | Position Switch | Manually moves the MDU Scanner forward/backward. | Position |
| ② | Home Button | Moves the imaging sensor to the most distal position (the end of travel in the forward direction). | |
| ③ | Origin Button-<br>IVUS Mode Only | Places the sensor head at the start point of a ROI. When pressed, it resets the indicator to zero. If the sensor head is moved in any direction, the indicator will display the distance traveled from the start point. | 0 |
| ④ | Scan Button | Initiates MDU/catheter rotation and activates Live mode. | |
| ⑤ | Ready Button | Pressed when the user is ready to bring the MDU up to OFDI scanning speed. This activates the higher RPMs needed for OFDI pullback. | |
| ⑥ | Pullback Button | Initiates pullback of the imaging sensor through the sheath based on the predetermined settings in the Console. | |
| ⑦ | White Line | Visual indication to inform users how much the MDU must be pulled back to properly connect/disconnect the catheter. | [See image.] |
| ⑧ | CF Applied Part Label | Type CF Applied Part (Defibrillation-Proof) connection point for a DualView Catheter only. This connection is suitable for DIRECT CARDIAC APPLICATIONS with regard to LEAKAGE CURRENT. | |

# System Overview

MDU User Control Buttons - Functions and Markings Continued

| No. | Description | Function | Marking |
|---|---|---|---|
| ⑨ | Lock/Unlock Marking | Locks/Unlocks catheter to the MDU. |  |

Optical Disc Drive and USB Ports




| No. | Description | Function | Marking |
|---|---|---|---|
| ① | DVD Writer Drive | An optical drive that reads and/or writes to DVD media (e.g. discs).<br>Drive can write the following media: DVD-R/-RW/ +R/ +RW | DVD R/RW |
| ② | USB [Universal Serial Bus] Connection Port | Connection for wireless mouse or data export. | |

## Frequently Used Functions

- Set-up and connection of system components
- Selecting pullback settings
- Selecting vessel settings
- Operating the MDU
- Performing an OFDI or OFDI + IVUS pullback
- Performing an IVUS only manual recording
- Reviewing a pullback or recording
- Placing bookmarks
- Measurement tools
- Placing annotations
- Reviewing previous cases
- Exporting Files
- Importing Files
- Adding, deleting, or editing a user account

# Section 2
# Symbols Glossary and Definitions

# Symbols Glossary and Definitions

## System Icons and Markings

This section describes the graphical Icons and Markings that are either marked directly, or on adhesive labels, on the OPUSWAVE System MDU and/or as softkeys on the Software GUI.

### MDU Icons and Markings

This table describes the Icons used to operate the OPUSWAVE MDU.

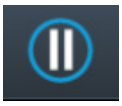
| Icon/Symbol | Description |
|---|---|
|  | HOME. Move the imaging sensor to the most distal position. |
|   | POSITION. Manually positions scanner forward/backward. |
|  | SCAN. Activates and deactivates catheter rotation and LIVE mode. |

| Icon/Symbol | Description |
|---|---|
|  | Ready. OFDI Only spins motor at 9600 RPM and enables the pullback function of the system. |
|  | PULLBACK. Initiates pullback of the imaging sensor. |
|   | ORIGIN. Resets the indicator to zero. |

### Graphical User Interface (GUI) Icons

This table describes the Icons used on the OPUSWAVE System Software GUI.

| Icon | Function | Description |
|---|---|---|
| [Home Screen]: | | |
|  | Adjust System Settings | Accesses the Settings Menu. |
|  | Log Out | Logs user out of the software. |
|  | Shut Down | Shuts down the System software. |
|  | Start a New Case | Opens a new patient information screen. |
|  | View Previous Cases | Opens list of previous patient cases. |

| Icon | Function | Description |
|---|---|---|
| [Calibrate OFDI and Confirm IVUS Screen]: | | |
|  | Pause (w/Circle) | Start image playback in Review screen or thumbnail in Case File Selector. |
|  | Pause (w/o Circle) | Pause updating live image for manual calibration |
|  | Repeat Auto-Calibration | Restart auto-calibration from manual calibration screen |
|  | Resume (w/o Circle) | Resume updating live image for manual calibration |

# Symbols Glossary and Definitions

| Icon | Function | Description |
|---|---|---|
| [Message Box] | | |
|  | Reminder | Reminder message for user to perform a function. |
| [File Search Screen]: | | |
|  | Delete | Delete selected pullback(s) by the user |
|  | Edit | Edit patient information for the selected pullback |
|  | Eject | Eject connected USB storage or inserted DVD media |
|  | Export | Export selected pullback(s) to external storage or PACS server |
|  | Import | Import the selected pullback(s) from external storage to internal storage |
|  | Playback | Display cross-sectional images sequentially for a pullback as thumbnail |
|  | Review | Open Review screen for the selected pullback(s) |
|  | Search | Search pullback(s) which match with the specified conditions |
|  | Resume (w/Circle) | Start image playback in Review screen or thumbnail in Case File Selector |

| Icon | Function | Description |
|---|---|---|
| [New Case Information Screen]: | | |
|  | Import Patient Information | Import patient information from RIS server. |
|  | Start Case | Moves forward to new screen in new case registration |
|  | Cancel | Cancels any entered patient information during new case registration |
| [Review Pullback Settings and Define Vessel Screen]: | | |
|  | Display | Open Display pull-up menu |
| [Ready OFDI Screen]: | | |
|  | Pullback | Begins pullback. |
|  | Stop | Stopping Scan, Ready or Pullback |
| [OFDI-Only or Dual Scan Screen)]: | | |
|  | Ready Pullback | Spins motor at 9600 or 6000 RPM and enables the pullback function of the system. |
|  | Calibrate | Adjust OFDI calibration |
|  | Stop | Stopping Scan, Ready or Pullback |
|  | Scan | Starts spinning at 1800 RPM and acquires live image |

# Symbols Glossary and Definitions

| Icon | Function | Description |
|---|---|---|
| [Adjust System Settings]: | | |
|  | 3D | 3D Image Display Settings for System configuration |
|  | Adjust | Open image adjustment settings for each type of images |
|  | Angio | Angio Image Display Settings for Settings Profile |
|  | Back | Move back to the previous screen. |
|  | Cancel | Cancel or close |
|  | Color Map | Color Map IVUS Display Settings for System configuration |
|  | IVUS | IVUS Image Display for Settings Profile |
|  | OFDI | OFDI Image Display for Settings Profile |
|  | Overlay | Overlay Image Display Settings for System configuration |
|  | Plus | Add new Settings Profile |
|  | Reset Settings | Reset the modified configurations to the original values before changing |
|  | Save | Save the modified configurations to make them effective |

| Icon | Function | Description |
|---|---|---|
| [System Status Bar]: | | |
|  | 0-20% | Indicates the percentage of internal storage that is used.<br><br>NOTE: Always displayed in the top corner of screen when system is in use. |
|  | 20-40% | |
|  | 40-60% | |
|  | 60-80% is used, and remaining capacity is ≥ 200 GB | |
|  | 60-80% is used, and remaining capacity is <200 GB | |
|  | 80-100% is used and remaining capacity is ≥ 100 GB | |
|  | 80-100% is used and remaining capacity is < 100 GB | |
|  | Catheter Connected | Indicates that catheter is connected to MDU. |
|  | Catheter Disconnected | Indicates that catheter is not connected to MDU. |

# Symbols Glossary and Definitions

| Icon | Function | Description |
|---|---|---|
| [IVUS-Only Scan Screen]: | | |
|  | Stop | Stopping Scan, Ready or Pullback |
|  | Bookmark | Creates Bookmark during manually recording |
|  | Record | Starts manually recording |
|  | Stop | Stops manually recording |
| [Compare Mode Screen]: | | |
|  | Bookmark | Places a bookmark on the Image Screen |
|  | Compare Mode | Compares Images |
|  | Desynced | Compared images are played back asynchronously |
|  | Synced | Compared images are played back synchronously |

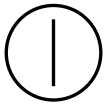
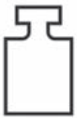
| Icon | Function | Description |
|---|---|---|
| [Review Screen]: | | |
|  | 3D Distal | Indicates distal direction of 3D image |
|  | 3D Proximal | Indicates proximal direction of 3D image |
|  | Bookmark Backward | Moves to the previous bookmarked frame. |
|  | Bookmark Forward | Moves to the next bookmarked frame |
|  | Distal Marker | Drag and drop marker to locate the distal end of the lesion area |
|  | MLA Marker | Indicates the location of the frame with MLA (Minimum Lumen Area) in the lesion area between Distal and Proximal markers |
|  | Proximal Marker | Drag and drop marker to locate the proximal end of lesion area |
|  | Shuttle | Performs shuttle playback for specified frame count |
|  | Close | Close the image modality |
|  | Playback Backward | Moves back to the previous frame |
|  | Playback Forward | Moves forward to the next frame |
|  | Snapshot | Capture screenshot which can be exported as still image file |
|  | Resume (w/Circle) | Start image playback in Review screen or thumbnail in Case File Selector |

# Symbols Glossary and Definitions

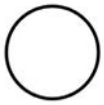
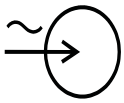
## Safety Symbols and Markings

This section describes the standard Safety Symbols used on the labeling of the OPUSWAVE System. This includes indications, safety warning alerts, graphical icons, and markings that are either marked directly or on adhesive labels, on the OPUSWAVE System MDU and/or as softkeys on the Software GUI.

| Icon/Symbol | Description |
|---|---|
|  | Refer to instruction manual |
|  | Warning |
|  | Caution |
|  | Date of Manufacture |
|  | Manufactured By |
|  | Keep Dry |
|  | Equipotentiality stud connection point marking |
|  | Grounding Stud Identification |
|  | WEEE Waste Electrical and Electronic Equipment |

| Icon/Symbol | Description |
|---|---|
|  | Defibrillation-proof type CF applied part (Cardiac Floating Device) |
|  | Alternating Current |
|   | Catalog Number |
|  | ON/OFF [Power Button] - Located on the top of front of the Console |
|  | Protective Earth |
|  | This Way Up |
|  | USB Connector Terminal |
|  | Consult Instructions For Use |
|  | Mass |

# Symbols Glossary and Definitions

| Icon/Symbol | Description |
|---|---|
|  | ON - Symbol located on the AC Mains power switch on the lower back of the Console |
|  | OFF - Symbol located on the AC Mains power switch on the lower back of the Console |
|  | Rated Power Input, a.c. |
|   | Serial Number |
|  | Temperature Limit |
|  | Humidity Limitation |
|  | Atmospheric Pressure Limitation |
|  | Fragile; Handle with Care |

# Symbols Glossary and Definitions

## Definitions

### The following lists definitions for the terminology that appear throughout this manual.

**A-Line.** The reflected signal of laser or ultrasound processed by FPGA. A-line data is a set of multiple A-lines. Single frame cross- sectional image consists of 512 A-lines.

**Angio/Angiography/Angiogram.** Image captured and input by Fluoroscopy system in catheter laboratory.

**Angle.** Space between two intersecting lines (in degrees) in the cross-sectional view.

**Annotations.** A note, explanation, or comment to describe the cross-sectional or longitudinal image.

**Area/Lumen/% Ratio.** Measurements of a traced closed curve in the cross-sectional or longitudinal image.

**Auto Lumen Detection.** Function for OFDI images which auto-creates a trace of the lumen.

**AVI.** (*"Auto Video Interleave"*) Multimedia file format for video files. Images are converted to AVI format prior to exporting.

**Bookmark.** In review mode, marks an area or frame of interest to facilitate image searching by "skipping" through bookmarked frames.

**Carpet View.** 3D image that is cut lengthwise and expanded/unfolded.

**Color Map.** In review mode, allows adjustment of an image from three options: blue, orange, and gray.

**Contrast.** Adjustment of the Image data display dynamic range from 0-15.

**Contrast Medium.** Substance used to increase the contrast of structures or fluids within the body in medical imaging.

**Cross-Sectional Image.** Tomogram Image of the vessel. Cut plane is perpendicular to the catheter axis. Normal view of intravascular imaging equipment.

**Depth Marker.** Marker that is visible by user and indicates how far the catheter inserted.

**Depth Range.** Predetermined section of the image. Use with STC. For example, change the STC on the depth range.

**Diameter.** Distance (in mm) between two user created points on a straight line in the cross-sectional view.

**DICOM.** (*"Digital Imaging and Communications in Medicine"*). A standard for handling, storing, printing, and transmitting information in medical imaging, including file format definitions and network communications protocols.

**Distal.** The point where the imaging sensor is positioned at the far (distal) end of the catheter.

**Dual Modality.** Display of both IVUS and OFDI image modality on the console screen.

**Dual Sensor Catheter.** Single use imaging catheter that uses both IVUS and OFDI imaging modalities to visualize arteries.

**E-Mode.** IVUS Modality with a longer pulse width.

**Export.** Transferring of the file(s) from the console to a compatible external storage media (DVD or USB).

**External Monitor.** Monitor external to the system that can display a duplicate image through the system connector panel.

**F-Mode.** IVUS Modality with a shorter pulse width.

**Flush.** To remove the blood by injecting the contrast agent, saline or other media into the coronary through guiding catheter.

# Symbols Glossary and Definitions

**FPS/Frames per Second or Frame Rate.** Number of frames or images that are projected, displayed or recorded per second.

**Gain.** Adjustment of the image brightness level from 0-20.

**Gamma.** Adjustment of the Gamma Correction Curve from 1-10.

**Graphical User Interface (GUI).** User interface that allows clinicians to view, interact and operate the system.

**Home.** The state of the MDU when the MDU Scanner assembly is in the most distal position on the MDU Base.

**Image Rotation.** The system's ability to allow the user to rotate the cross-sectional image.

**Imaging Depth.** Maximum Depth which corresponding data exists. Determined by sampling number and depth per sampling.

**Import.** Transferring of the file(s) from compatible external storage media (DVD or USB) to the console.

**Injector.** Automated injector which injects contrast agent into the coronary artery.

**IVUS.** (Intravascular Ultrasound). Use of sound waves to visualize or map vasculature.

**Length.** Distance (in millimeters) between two frames in the longitudinal view.

**Lesion.** Any pathological discontinuity of tissue. Such as stenosis, dissection, hematoma, occlusion.

**Live Mode.** (SCAN) The condition that the system rotates the scan motor and outputs laser and/or ultrasound to acquire real-time image.

**Live View.** The state in which the system shows a live image.

**Longitudinal.** Tomogram Image of the vessel. Cut plane is parallel to the catheter axis. Normal view of intravascular imaging equipment.

**Manual Recording.** A feature in the IVUS only modality, which provides the option to conduct a live manual back/forth recording of the vessel.

**MDU Cover.** Sterile drape that wraps the MDU during a procedure inside the sterile field.

**Motor Drive Unit (MDU).** The component responsible for the movement of the catheter during the procedure. It allows users control of the procedure from inside the sterile field.

**OCT.** (Optical Coherence Topography). Use of light waves to visualize or map vasculature.

**OFDI.** (Optical Frequency Domain Imaging. OFDI and OCT are used interchangeably.

**OPUSWAVE System.** Imaging system intended for the intravascular imaging of coronary arteries. It consists of the Dual Sensor Catheter, Motor Drive Unit, and OPUSWAVE Console.

**Origin.** Button that places the catheter sensor at the start point of a region of interest. When pressed, it resets the indicator to zero. If the transducer is moved in any direction, the indicator will display the distance traveled from the start point.

**Overlay.** Image display that places one image over another image to gain clinical information of the anatomy.

**PACS.** (Picture Archiving and Communication System) Hospital server that can store patient data in DICOM format.

**Pan.** A function that allows scrolling horizontally and vertically within the cross-sectional image so that different areas within the image are shown.

# Symbols Glossary and Definitions

**PCI/Percutaneous Coronary Intervention.** A minimally invasive procedure used to treat narrowing (stenosis) of the coronary arteries.

**Penetration Depth.** Distance from surface of tissue to farthest position which could be differentiated from noise. Remind that the difference with Imaging Depth, Display depth, Depth Range.

**Playback.** Control that re-plays the playback frame by frame.

**Position Switch.** Moves the MDU scanner forward and backward.

**Priming.** Process of injecting solution into a catheter to ensure air bubbles are cleared from the catheter prior to the procedure.

**Priming Port.** Luer Lock Connecting Port on the catheter in which fluid can be injected.

**Proximal.** The point where the imaging sensor is positioned at the near (proximal) end of the catheter.

**Pullback.** Withdraw the imaging sensor through the sheath.

**Ready State.** The condition that the system allows the user to inject contrast medium and start pullback in OFDI-only or Dual mode. The scan motor rotates at high speed (9,600 rpm for OFDI-only mode, 9,600 or 6,000 rpm for dual mode). Since IVUS-only mode does not require contrast medium, there is no Ready State in IVUS-only mode.

**Recording.** To store acquired images for review and analysis. Images are stored during each pullback.

**Region of Interest (ROI).** Area within an image that the user identifies and wants to focus on for further analysis.

**Review State.** The condition that the software displays image data acquired during pullback and allow the user to apply any measurements. Since the displayed data is not current, the system stops both scan and pullback motor and turns off laser and ultrasound outputs.

**Safe State.** Condition at which no energy is delivered to the patient to ensure patient safety.

**Scan.** Rotate the sensor of imaging catheter and display the IVUS/OFDI image.

**Shuttle.** Plays back repeatedly within the configured frame counts (1 to 5 frames).

**Snapshot.** Captures still image of the screen.

**STC.** Adjusts brightness of each specified depth range of the image data display area.

**System.** The system consists of the console, MDU, and the catheter.

**Thickness.** Measures the distance (in millimeters) from the specified point to the existing traced lumen in the cross-section view.

**Vessel View.** 3D image of the vessel created by the software from the OFDI data.

**Zoom.** Feature to magnify a section of the image.

# Section 3
# Warnings and Cautions

# Warnings and Cautions



**WARNING**

<General Usage>

- This device should be used by or under the supervision of medical personnel thoroughly trained in the techniques of percutaneous coronary interventional procedures, specifically, Optical Frequency Domain Imaging [OFDI] and Intravascular Ultrasound [IVUS] techniques and use of this system. Diagnoses based on the images should be done by qualified physicians/ doctors. Misuse or misdiagnoses of system and images could cause serious or critical injury to patients.
- The OPUSWAVE System shall only be used in facilities where Cardiac Surgery is available. Failure to do so may result in emergency situations that cannot be addressed if complications arise.
- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Group 1 Class A). Do not use in residential areas. NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Group 1 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Do not attempt to repair, alter, modify, or replace components that are serviceable only by trained technicians. Doing so may result in system malfunction. User replaceable parts are identified in Section 22, "System Safety and Technical Specifications" in the Instructions For Use. Contact your Terumo Representative for service.
- No modification of this equipment is allowed. Doing so may result in system malfunction.
- Do not operate or store the system outside specified operating environment conditions. It may cause system malfunction that may lead to patient injury.
- Do not lean on or apply weight onto the desktop. Other than items supplied with the system, no additional items shall be placed on the desktop. Doing so may cause system damage, malfunction, or tipping risk.
- Do not use the system in a flammable environment. It may cause fire or explosion.
- Avoid handling liquid above or on the console. Otherwise, it could result in ingress of the liquid into the system causing malfunction, fire, or electric shock hazard.
- Do not operate the system with less than two (2) persons, this includes one (1) person in the sterile field and one (1) non-sterile console operator. Failure to do so may interfere with sterile technique.
- Avoid using this system under rapidly changing temperature cycles even within the operation conditions. Due to the condensation inside of the system, damage and/or degradation may occur and lead to deterioration in function or performance.
- Operate controls, keys and buttons with your finger. Using a pen, pencil or other sharp-pointed object for operation may cause damage.
- Refer to the contrast media's Instructions For Use for general warnings and precautions relating to the use of contrast media.

# Warnings and Cautions



**WARNING**

<EMC>

- The OPUSWAVE System is only to be used in a hospital or surgery center within a catheterization lab. Follow standard practices for electronic devices and monitor it closely whenever it is exposed to intense electrical noise and/or fluctuating AC line voltages.

  Strong electromagnetic fields radiated from equipment elsewhere within the lab (particularly defibrillators, HF surgical equipment & electrocautery devices) or fluctuations in AC line voltage may compromise performance or damage the equipment.

  Described in the IFU are the performances determined to have ESSENTIAL PERFORMANCE within the OPUSWAVE system. If this ESSENTIAL PERFORMANCE is lost or degraded, due to EM DISTURBANCES, a description of what the OPERATOR can expect is also provided.

  - Do not use accessories other than those specified. (If accessories other than those specified are used, it may cause malfunction, or adversely affect other equipment.
  - Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
  - Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
  - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the OPUSWAVE System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

# Warnings and Cautions



**WARNING**

<Moving/Installation>

- When the console needs to be repositioned, unlock the casters and carefully move it with at least two people. Failure to do so may result in the system tipping, and/or being displaced, which may cause the System or MDU to fall, leading to patient or user injury.
- Install the console outside the sterile field on a stable, flat surface, and lock casters using your foot. Do not install on a slanted surface. Failure to do so may result in the system tipping, and/or displaced, which may cause the System or MDU to fall, leading to patient or user injury.
- Install the console in a location that allows the screen to be viewed by appropriate users. Failure to do so, may lead to inadequate viewing, resulting in misdiagnoses/ misinterpretation of the data.
- Use handles when the moving the system, otherwise the system may fall, rollover and/or displace, leading to patient/user injury.
- Prior to moving the system, ensure the power cable and MDU cable are stored appropriately to avoid tripping hazards.
- Do not push the system by the monitor or monitor support arm. Doing so may cause the console to tip, resulting in system damage.
- Do not use the System equipment if it has been dropped or damaged. Doing so may result in degraded product performance or malfunction.
- Turn off power to all system components and unplug the AC power cord prior to cleaning or transporting the system. Failure to do so may increase the risk of electrical shock hazard to the user and/or system malfunction.

<Cleaning>

- Thoroughly clean the system and components after use. Failure to do so may result in image readability issues leading to misdiagnoses.
- Do not spray cleaning agents directly on system or its components, instead spray on a cloth to clean the system. Failure to do so may cause system malfunction or damage.
- Thoroughly clean the system and components after use. Failure to do so may result in cross contamination.
- Use only approved cleaning agents when cleaning the system. Failure to do so may cause damage to the system or system not being fully decontaminated.

<Storage>

- Do not store the system in places exposed to vibration, high dust concentration, humidity, corrosive gas, or liquid. Storage in adverse conditions could cause system malfunction and/ or shorten the lifetime of the system.

<Connectivity>

- Use only the power cord supplied with the system that attaches at the bottom rear of the system. Using power cords other than those provided may cause malfunction or electrical shock.
- Do not use externally powered USB devices in this system during the procedure. Use of externally powered USB devices with the system during a procedure may compromise electrical isolation and result in patient injury.

# Warnings and Cautions

CAUTION

<Operations>

- Medical personnel who use the OPUSWAVE System must be aware of the system's limitations. Only trained users can determine if use of the OPUSWAVE System is appropriate. Be sure to read Section 22, "Safety Information", before operating the OPUSWAVE System for the first time.

<Electrical Connectivity>

- Ensure AC Power is disconnected before moving the system. Failure to do so may damage the power cable leading to electrical shock.
- Secure the AC power cable connection to a grounded AC receptacle. If the system is disconnected from power, the system stops its operation.

<Network Connectivity>

- Connect Signal Input (SIP) and Signal Output (SOP) only to equipment compliant with IEC 60950-1 and IEC 62368-1 standards. Connections to non-compliant equipment could de-stabilize the system.
  - Make sure that any devices that connect to the network interface of the OPUSWAVE System comply with the appropriate IEC/national standard and are certified to IEC 60950.
  - Please note: If the OPUSWAVE 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 60601-1requirements for ME system and test the Medical System according to the requirements.
- When setting the IP address, make sure to check with the network administrator and set IP address correctly. Setting the wrong IP address may cause system or other equipment to malfunction.
- Medical electrical equipment shall be installed and used, with special attention to EMC, in accordance with the requirements described below:
  - Following standard practices for electronic devices, monitor this equipment closely when it is exposed to intense electrical noise or fluctuating line voltage. Strong electromagnetic fields radiated from equipment elsewhere in the catheterization lab (particularly defibrillators and electrocautery devices) or fluctuations in AC line voltage may compromise performance or damage the equipment.
  - This system needs special precautions regarding electro-magnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided.
  - Do not use accessories other than those specified. (If accessories other than those specified are used, it may cause malfunction, or adversely affect other equipment.)
  - This system should not be used adjacent to or stacked with other equipment (electro-cautery knives, defibrillators). If adjacent or stacked use is necessary, observe the system closely to verify normal operation in the configuration in which it will be used.
- Do not connect the system to a network environment with the following characteristics:
  - Lack of security management.
  - Suspected vulnerability to malware.
  - Connection to devices which do not provide security management, including appropriate access and control of wireless devices.
  - Connection to the Internet

  Permit USB and LAN connections only to reliable and secure devices.

  It is recommended that physical access control measures are implemented to restrict the entry of personnel to physical spaces where the device is located. This ensures that only authorized individuals can enter these areas and gain access to the device and the data that may be stored therein.

  Failure to follow these guidelines may result in a risk of malware or virus, which will compromise the system and may lead to leakage of patient information or corruption of data or function.

**WARNING**

<Catheter>

- The catheter, MDU cover, and accessories are for single use only. Do not reuse, resterilize, or reprocess. Reprocessing may compromise the sterility, biocompatibility, and functional integrity of the device. Re-using product may result in patient harm/infection.
- Sterile users shall only interact with the catheter and outside the MDU Cover. Non-sterile users shall only interact with the console, MDU, and inside the MDU Cover. Failure to do so may compromise sterility leading to patient harm/infection.
- Sterilization is maintained in an unopened and undamaged individual package. Do not use if individual package or the catheter, catheter disposables, or MDU cover are damaged, soiled, or beyond its expiration date. Doing so may compromise function or sterility.
- Prior to use, check the outer surface of the catheter, intended for insertion into the patient, for rough surfaces, sharp edges or protrusions that could cause harm to the patient.
- Do not attach, detach, manipulate, or prime the catheter while the MDU motor is spinning, or the catheter is in the lock position. Doing so could result in catheter or MDU damage.
- Do not bend or apply excessive force. Do not apply torque or twist. If there is any change in shape, stop the operation. Failure to do so may cause damage to the fiber optics within the catheter or catheter damage.
- Observe insertion and manipulation of the Catheter under fluoroscopy. Failure to observe device movement fluoroscopically or positioning further than intended, may result in damage to the device and/or vessel damage (such as perforation).
- Never leave the catheter inserted in the patient body with the system powered off or during power outage. It may cause injury to the patient.
- While performing assessment of acquired images, OFDI image review should only be relied upon for vessels 2.0 to 3.5 mm in diameter. OFDI images acquired in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure should not be relied upon for image assessment.
- Do not advance the imaging catheter through vessels less than 2 mm in diameter. Doing so could result in catheter and/or vessel damage (such as perforation).

# Warnings and Cautions

**WARNING**

<MDU>

- Keep fingers away from the MDU scanner moving zone while it is in use. There is a risk of damage to the MDU Cover and/or user.
- Carry/hold the MDU while supporting its bottom side during transport or movement. (NOTE: when the catheter is being connected, support the scanner unit with one hand at both flange parts.) Failure to do so may result in the MDU falling, causing catheter and/or vessel damage (such as peroration or dissection).
- Do not move the MDU scanner back while the catheter tip is outside the holder tube. Air bubbles could enter through the catheter tip resulting in an air embolism.
- Do not attach, detach, manipulate, or prime the catheter while the MDU motor is spinning, or catheter is in the lock position. Doing so could result in catheter or MDU damage.
- The MDU must be placed on a stable, flat surface. Fall or sudden movement of the MDU with the catheter inserted into the vessel may cause unintended displacement of the catheter, resulting in vessel damage (such as perforation or dissection). Fall of the MDU may also cause damage to the parts.
- Prior to performing the pullback, make sure that the MDU moving zone is free from obstacles and the MDU Cover is properly set avoiding MDU jam. Failure to do so could result in unintended motion of the catheter leading to vessel damage (such as perforation or dissection). If the system detects that the catheter is not moving smoothly, the operation may be stopped.
- Do not apply excessive force to any part of the MDU during handling and connecting/disconnecting the catheter. Failure to do so may cause system malfunction.
- Ensure that the MDU is properly positioned in preparation for a pullback. It should be located within the sterile field, oriented on a flat, stable surface in a position where the MDU cable allows the normal movement of the MDU during the procedure (DO NOT CLAMP). Failure to properly position may cause the MDU to fall resulting in MDU damage and/or catheter movement causing tissue or vessel damage (such as perforation).
- To minimize the risk of damage to the MDU Cable:
  - NEVER wrap the MDU cable too tight or loose when storing. This could result in damage to the cable or a tripping hazard.
  - Always store the system in a clean, dry, and secure location, consistent with storage guidelines.

CAUTION

<Catheter>

- Do not use catheters other than the Dual View catheter that is designated for use with the system. If catheters other than those designated are used, it may cause patient harm or adversely affect equipment.
- This device should be applied or manipulated carefully when used in patients with:
  - Serious allergies to contrast media or other drugs required for the procedure.
  - Severe thrombosis was found in the target vessel during angiography.

NOTE

<Electrical Connectivity>

- Do not power off this system while saving data. Otherwise, it may result in loss of data.
- Do not unplug the power cord or turn off AC Power switch while saving data. Otherwise, it may result in loss of data.

# Section 4
# System Assembly and Preparation

# System Assembly and Preparation

## System Assembly

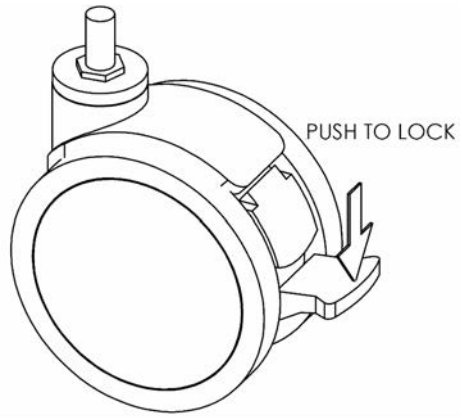
### Unpacking

1. **Unpack the OPUSWAVE System.**
   a. Remove the console, monitor, keyboard, wired/wireless mouse, and MDU from the shipping case.
   b. Remove all the packing material and dispose of according to local recycling and disposal regulations.
2. **Check against "System Components" (pg. 13) to ensure all items are included.**
   • Contact your Terumo service representative if any items are missing.

### Locking the Console Casters

1. **Using your foot, lock the brakes on all four casters by pressing the bottom tab down (to the "locked" position) (Fig. 4.1).**

Fig. 4.1 Lock all Four Caster Brakes

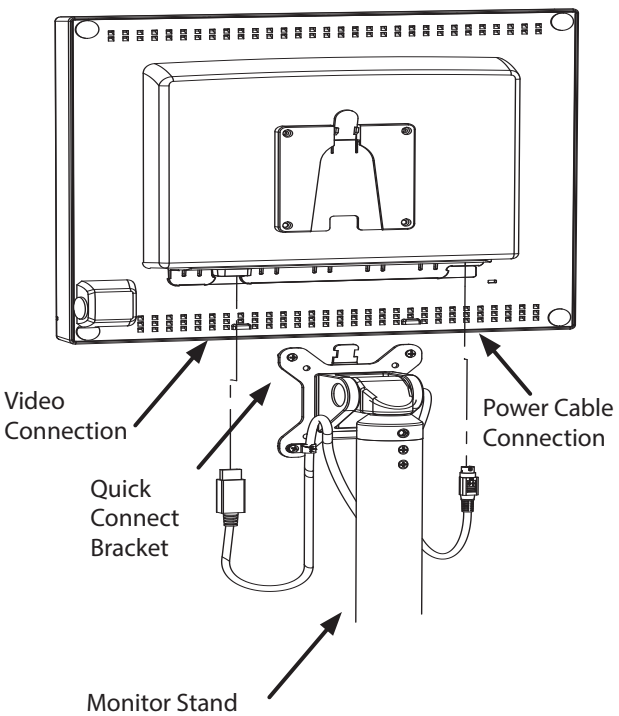



### Attaching the Monitor

Use caution during setup to avoid damaging the Monitor or the System.

1. **Align the monitor bracket with the quick connect bracket (Fig. 4.2).**
2. **Slide the monitor down into the quick connect bracket until it is fully seated.**
3. **Plug the cable into the associated connection point on the monitor.**
4. **Plug the Power Cable into the associated connection point on the monitor.**

Fig. 4.2 Monitor Bracket and Connections



# System Assembly and Preparation

Syncing the Wireless Mouse

1. **Plug in the USB Receiver (packaged within the mouse box) for the Wireless Mouse.**
2. **Switch the Mouse Power Switch to the ON position.**
3. **Ensure that the Battery Status LED illuminates green.**

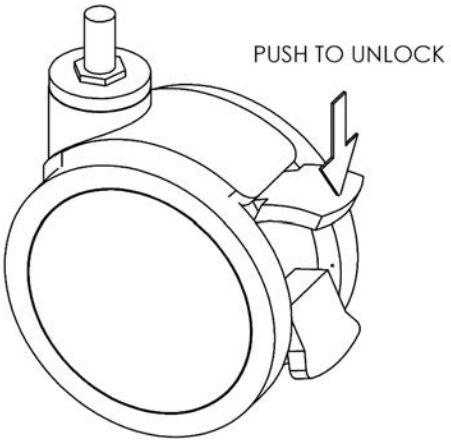
## Positioning the System

**WARNING**

- Use handles when moving the system, otherwise the system may fall, rollover and/or displace, leading to patient/user injury.
- Prior to moving the system, ensure the power cable and MDU cable are stored appropriately to avoid tripping hazards.
- Do not push or pull the system by the monitor or monitor support arm. Doing so may cause the console to tip, resulting in system damage.
- When the console needs to be repositioned, unlock the casters and carefully move it with at least two people. Failure to do so may result in the system tipping, and/or being displaced, which may cause the System or MDU to fall, leading to patient or user injury.
- Install the console outside the sterile field on a stable, flat surface, and lock casters using your foot. Do not install on a slanted surface. Failure to do so may result in the system tipping, and/or displaced, which may cause the System or MDU to fall, leading to patient or user injury.
- Install the console in a location that allows the screen to be viewed by appropriate users. Failure to do so may lead to inadequate viewing, resulting in misdiagnosis/misinterpretation of the data.
- Ensure the power cord and all other connections to the OPUSWAVE System are routed to prevent a tripping hazard. Failure to do so may result in patient or user injury, or equipment damage.

1. **Prepare the System for transport.**
   - Ensure all accessories (e.g., keyboard, MDU, mouse) are housed in their appropriate storage locations on the console.
   - Secure both the MDU and power cables around their designated cable management hooks.
2. **Using your foot, unlock the brakes on all four casters by pressing the top tab down to the "unlocked" position (Fig. 4.4).**
3. **Transport the System.**
   - With a minimum of (2) persons, transport the system by the handle.
   - Position the console on a stable, flat surface, outside the sterile field.
   - Ensure the system monitor is facing the user position.
   - Using your foot, lock all four casters in place by pressing them down toward the floor (**Fig. 4.4**).
4. **Position the system so that:**
   - Cords and cables are not a tripping hazard.
   - The connection between the console and MDU will not be disturbed during use.
   - Access to mains power disconnect on the back base of the console is free and accessible.

Fig. 4.4 Unlock Brakes



## Powering On and Shutting Off the System

**WARNING**

- Before using the system, perform the Pre-Startup Checklist defined in this Instructions For Use. Failure to do so may result in degradation of image quality.

CAUTION

- Secure the AC power cable connection to a grounded AC receptacle. If the system is disconnected from power, the system will stop its operation.

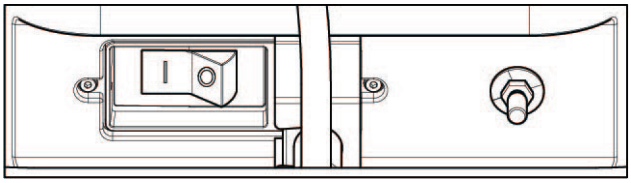
NOTE

- When powering on, the Power indicator on the tabletop will illuminate after pressing the power switch on the front panel of the console. If the Indicator does not illuminate, the system has not been activated.

### Powering on the System

1. **Complete all tasks on the "Pre-Startup Checklist (Section 21).**
2. **Unravel the power cord from the cable management hooks and plug into a grounded AC receptacle.**
3. **Ensure the mains power disconnect on the back base of the console is in the "ON" position to initiate system power, as indicated in the graphic (Fig. 4.5).**
   - The System Fan will initialize and run briefly before turning off.

Fig. 4.5 Mains Power Disconnect [Rear]



**4. Press and release the power button on the front panel of the console (Fig. 4.6) to bring the system to full power.**

- Confirm the power LED light on the left side of the desktop illuminates green.
- The system will boot up and the Splash screen will appear (**Fig. 4.7**).

Fig. 4.6 Console ON/OFF Power Button

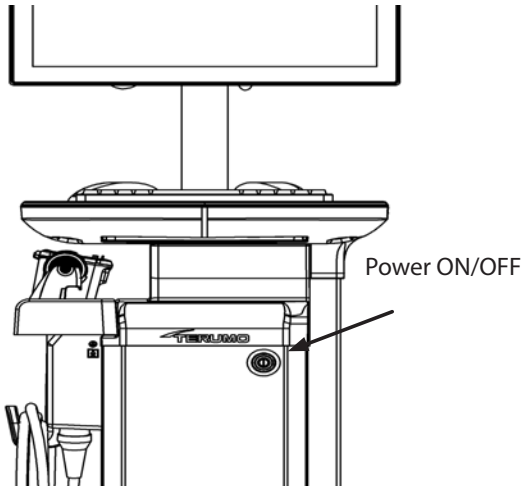
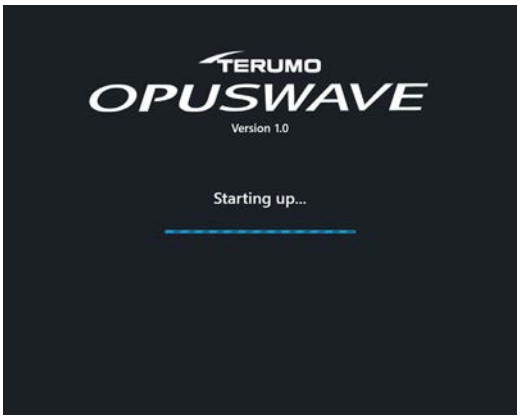



Fig. 4.7 Startup Splash Screen




**5. After start up, the User Login screen will appear (unless login is disabled by the service user).**

a. Enter/select the user and associated password.

b. Select [Login] (**Fig. 4.8**).

- Once successfully logged in, the Home Screen will appear **(Fig. 4.9)**.

Fig. 4.8 User Login Screen




NOTE

- If the login is disabled by the service user, the Home Screen will appear immediately after the Startup Screen.

Fig. 4.9 Home Screen



## Shutting Down the System

**WARNING**

- Ensure AC Power is disconnected before moving the system. Failure to do so may damage the power cable leading to electrical shock.

NOTE

- The power button is not operational while the System is in Scan, Ready, Pullback, or review state.
- Do not power off this system while saving data. Otherwise, it may result in loss of data.
- Do not unplug the power cord or turn off AC Power switch while saving data. Otherwise, it may result in loss of data.

There are two methods to shut down the System:

1. **Click the Shutdown button on the bottom of the OPUSWAVE home screen (Fig. 4.9).**
   - The console will display a confirmation message to acknowledge shutdown.
   - After confirming the shutdown, the screen will turn black, and the LEDs power lights will turn off.
   - The system will shut down within 60 seconds after shutdown confirmation.
2. **If the system needs to be stored or transported, disconnect the power cord from the AC power receptacle.**
   - Store the power cord on the cable management hooks.
   - Always lock the casters after moving the system to its destination or storage.

-OR-

1. **Press and hold the power button on the system console (Fig. 4.6) for a minimum of 3 seconds.**
   - The console will display a confirmation message to acknowledge the shutdown.
   - After confirming the shutdown, the screen will turn black, and the LEDs power lights will turn off.
   - The system will shut down within 60 seconds after shutdown confirmation.
2. **If the system needs to be stored or transported, disconnect the power cord from the AC power receptacle.**
   - Store the power cord on the cable management hooks.
   - Always lock the casters after moving system to its destination or storage.

## Setting Up the Monitor

### Adjusting Monitor Functions

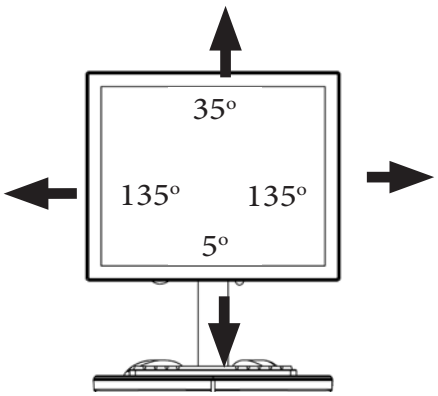
The system monitor can be adjusted from the default settings (e.g., brightness, contrast). See "Parts Identification" (page 17) for a description of the enabled functions on the Monitor's Picture Setting Menu.

### Setting the Monitor Position

The position of the monitor should be adjusted to minimize screen glare and accommodate different viewing positions. To adjust the monitor position **(Fig. 4.10)**:

1. **Place one hand firmly on each side of the monitor screen.**
2. **Tilt the monitor up or down to adjust the viewing angle.**
   - The monitor can raise 35 degrees and lower 5 degrees from the vertical position.
3. **Rotate the monitor left or right to adjust the viewing position.**
   - The monitor can rotate 135 degrees in both directions from the forward-facing centered position.

Fig. 4.10 Adjust the Viewing Angles



## Connecting to External Monitors

**CAUTION**

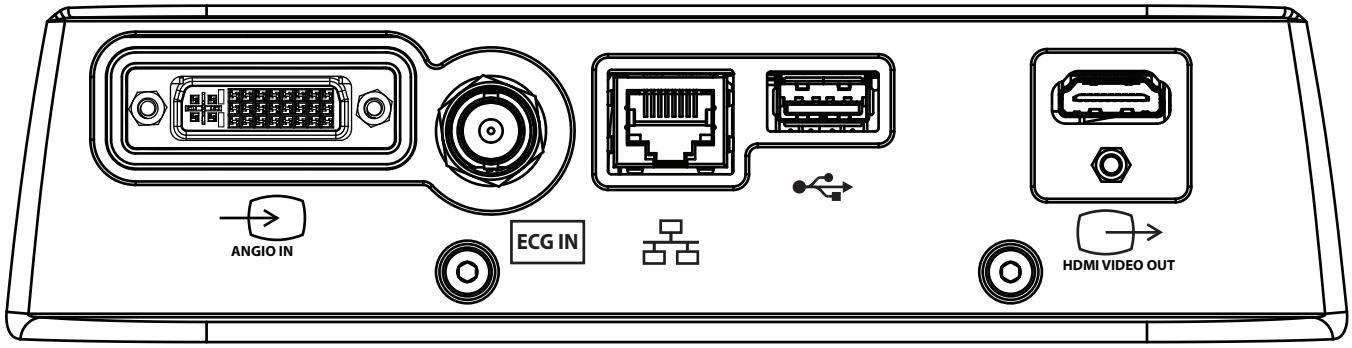
Connect Signal Input (SIP) and Signal Output (SOP) only to equipment compliant with IEC 60950-1 and IEC 62368-1 standards. Connections to non-compliant equipment could de-stabilize system.

- Make sure that any devices that connect to the network interface of the OPUSWAVE System comply with the appropriate IEC/national standard and are certified to IEC 60950.
- Please note: If the OPUSWAVE 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 and test the Medical System according to the requirements.

The OPUSWAVE System can display a current image to an external monitor through the System External Input/Output (I/O) Connector Panel.. To duplicate screens:

1. **Connect an external monitor using a HDMI Cable [not provided] to the corresponding connecter on the I/O Connector Panel (Fig. 4.11). Turn on external monitor.**

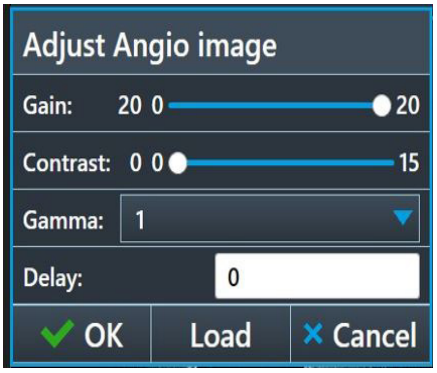
Fig. 4.11 Connecting to I/O Panel




## Adjusting Angio Images

You can adjust the Image data display from the Angio Image adjustment display:

Fig. 4.12 Adjust Angio Images




1. **Open the Angio Image adjustment display (Fig. 4.12).**
   - Refer to Section 13, Review, for detailed information on the available adjustable angio settings.

# Section 5
# Setting Up a New Case

# Setting Up a New Case

NOTE

- It is not required to enter patient information prior to starting a case. This screen can be initially bypassed, and information can be entered when the case is complete.

## Starting a New Case

To start a new case from the Home screen (**Fig. 5.1**):

1. **On the Home screen, select [Start a New Case].**
   - The "New Case: Enter Patient and Case Information" screen comes up.

Fig. 5.1 Start a New Case




2. **Add patient information (Fig. 5.2).**
   - Add patient information as desired, noting that all information in this screen is optional. A patient ID will be automatically generated at the start of each case if the case is started without entering patient ID.
   - Patient information can be edited after saving from the "View Previous Cases" screen.

Fig. 5.2 Add Patient Information



# Setting Up a New Case

## Importing Patient Information from the RIS

Patient information can be imported from the RIS server and loaded on the system when starting a new case.

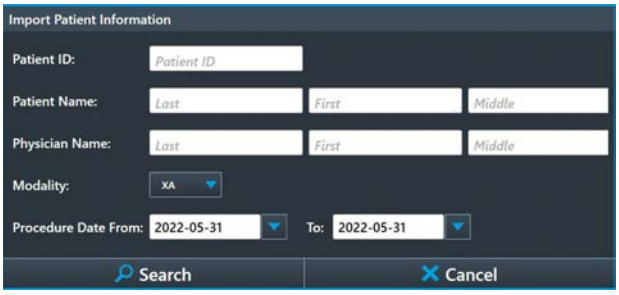
### 1. To search patient information (from RIS):

- Click on [Import Patient Information] button located on the top of the [New Case: Enter Patient and Case Information] screen (**Fig. 5.3**).
- The Import Patient Information display will appear (**Fig. 5.4**).
- Patient information can be searched by entering one or more criteria (Patient ID, Patient Name, Physician Name, Modality, or Procedure Date timeframe. Then click [Search].

Fig. 5.3 Import Patient Information



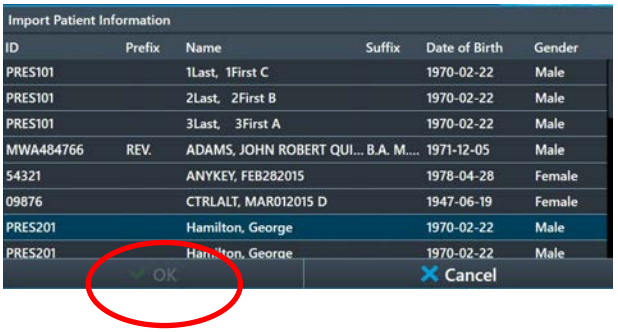

Fig. 5.4 Search Patient Information




### 2. To retrieve patient information (from RIS):

- Patient Information search results will be displayed in a dialog box.
- Select the Patient Information to import from the list and click the [OK] button, then the received information will auto populate the patient information fields (**Fig. 5.5**).

Fig. 5.5 Retrieve Patient Information



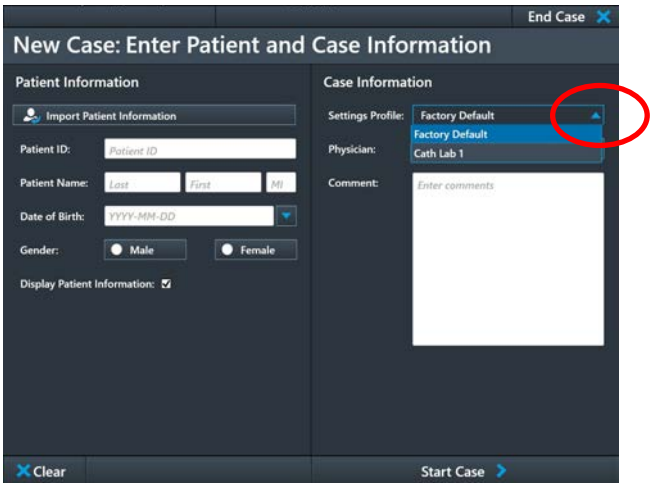
# Setting Up a New Case

## Selecting the Settings Profile

Case settings can be created and loaded onto the system when starting a new case.

1. **To load the desired profile settings:**
   - Click the {Settings Profile} down arrow on the [New Case: Enter Patient and Case Information] screen **(Fig. 5.6)**.

Fig. 5.6 Select Settings Profile




2. **Select the Profile. The selected profile settings are now loaded for the new case.**

3. **Select [Start Case] when ready to begin the case. (Fig. 5.7).**

Fig. 5.7 Start Case



# Section 6
# Setting Up the MDU

# Setting Up the MDU

**WARNING**

- Carry/hold the MDU while supporting its bottom side during transport or movement. (NOTE: when the catheter is being connected, support the scanner unit with one hand at both flange parts.) Failure to do so may result in the MDU falling, causing catheter and/or vessel damage (such as perforation or dissection).
- The MDU must be placed on a stable, flat surface. Fall or sudden movement of the MDU with the catheter inserted into the vessel may cause unintended displacement of the catheter, resulting in vessel damage (such as perforation or dissection). Fall of the MDU may also cause damage to the parts.
- Prior to performing the pullback, make sure that the MDU moving zone is free from obstacles and the MDU Cover is properly set avoiding MDU jam. Failure to do so could result in unintended motion of the catheter leading to vessel damage (such as perforation or dissection). If the system detects that the catheter is not moving smoothly, the operation may be stopped.
- Properly cover the MDU with the provided MDU Cover as indicated in the instructions. Failure to do so may compromise the aseptic barrier resulting in patient harm/infection.
- Do not apply excessive force to any part of the MDU during handling and connecting/ disconnecting the catheter. Failure to do so may cause system malfunction.
- Ensure that the MDU is properly positioned in preparation for a pullback. It should be located within the sterile field, oriented on a flat, stable surface in a position where the MDU cable allows the normal movement of the MDU during the procedure (DO NOT CLAMP). Failure to properly position may cause the MDU to fall resulting in MDU damage and/or catheter movement causing tissue or vessel damage (such as perforation).

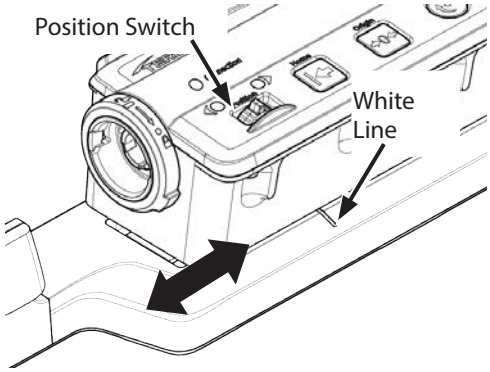
Setting up the OPUSWAVE System MDU requires a user within the sterile field (Sterile User) in cooperation with other personnel outside the sterile field (Non-Sterile User). Before beginning MDU set up, carefully read the Instructions For Use provided with the catheter.

**<Non-Sterile User>**

1. **Using the position switch, move the front edge of the MDU to the white line located on the MDU base (Fig. 6.1).**

   This will allow adequate clearance for the MDU Cover and catheter to connect to the MDU without interference.

6.1 Move MDU Scanner to white line




NOTE

- This step can also be done by the sterile user after the MDU is inside the sterile cover and positioned in the sterile field.

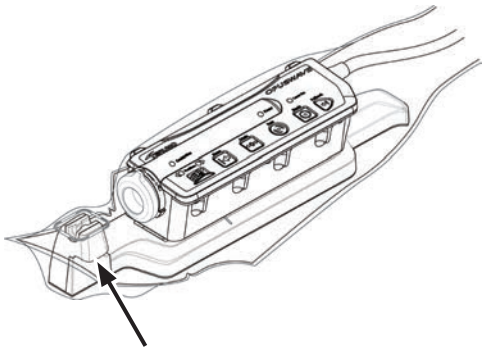
# Setting Up the MDU

**WARNING**

- Sterilization is maintained in an unopened and undamaged individual package. Do not use if individual package or the catheter, catheter disposables, or MDU cover are damaged, soiled, or beyond its expiration date. Doing so may compromise function or sterility.

2. **Inspect the catheter package for damage.**
3. **Confirm that the contents are not beyond its expiration date.**
4. **Following sterile technique, carefully open the catheter package and pass contents into the sterile field to the sterile user.**
5. **Following instructions in the Catheter IFU, Remove the MDU Cover from the package, and unfold.**
6. **With assistance from the sterile user: Place the MDU inside the MDU Cover, extending it over its full cable length (Fig. 6.2).**
   - Align the MDU Cover "clamp label" with the clamp on the MDU base.
   - Ensure the external surfaces remain clean during this process using proper sterile technique.

6.2 Place MDU inside MDU Cover

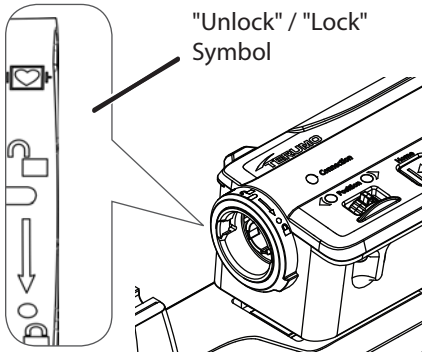


Clamp Label

**<Sterile User>**

1. **Place the covered MDU on a flat stable surface inside the sterile field.**
   - If not done in the prior step, using the position switch, move the front edge of the MDU scanner to the white line located on the MDU base (Fig. 6.1)
   - This will allow adequate clearance for the MDU Cover and catheter to connect to the MDU without interference.
2. **Insert the MDU Cover adapter into the MDU. Align the mark on the MDU Cover adapter to the "unlock" symbol on the MDU (Fig. 6.3).**
   - DO NOT ROTATE THE ADAPTER TO THE "LOCK" SYMBOL AT THIS TIME; this will be done during catheter connection.

6.3 Insert MDU Cover Adapter



# Section 7
# Setting Up the Catheter

# Setting Up the Catheter

**WARNING**

- Read the Instructions for Use provided with the catheter and MDU Cover prior to use. Misuse of these devices may cause injury to the patient or damage to the System.

CAUTION

- Do not use a guiding catheter smaller than 6 Fr. Doing so may result in damage to the catheter.

When setting up the catheter(s), it is recommended to have a user within the sterile field <Sterile User> cooperating with other personnel outside the sterile field <Non-Sterile User>.

However, all interactions with the console interface can be performed by either the Non-Sterile User at the console or the Sterile User using the wired/wireless mouse.

Before beginning catheter set up, carefully read the Instructions For Use provided with the DualView Catheter.

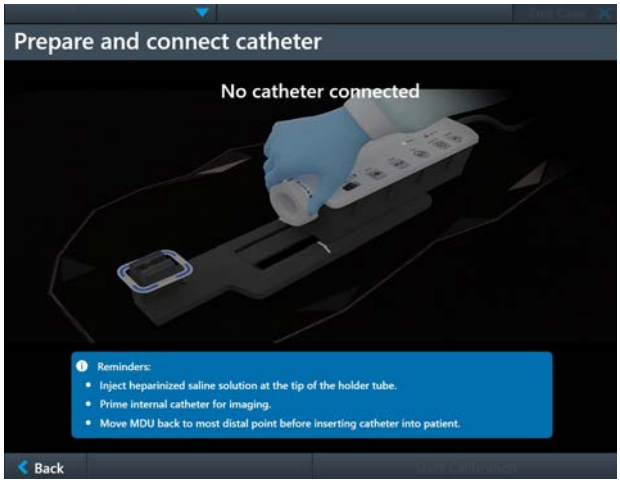
## Preparing the Catheter

**WARNING**

- Do not bend or apply excessive force. Do not apply torque or twist. If there is any change in shape, stop the operation. Failure to do so may cause damage to the fiber optics within the catheter or catheter damage.
- Ensure that all air is removed from the catheter during catheter preparation and insertion. Failure to do so can result in air embolism or image distortion.
- Follow sterile technique when setting up the catheter. Failure to do so may increase the risk of sterile environment contamination or patient infection.
- Sterilization is maintained in an unopened and undamaged individual package. Do not use if individual package or the catheter, catheter disposables, or MDU cover are damaged, soiled, or beyond its expiration date. Doing so may compromise function or sterility.
- Prior to use, check the outer surface of the catheter, intended for insertion into the patient, for rough surfaces, sharp edges or protrusions that could cause harm to the patient.

1. **The OPUSWAVE System screen will display, “Prepare and Connect Catheter” (Fig. 7.1).**

Fig. 7.1 Prepare and Connect Catheter



## Flushing the Holder Tube

**WARNING**

- Flush the holder tube using heparinized saline solution to lubricate the imaging catheter. Failure to do so could result in friction, damaging the catheter coating.

NOTE

- Do not remove the catheter from the holder tube until after initial calibration is completed.

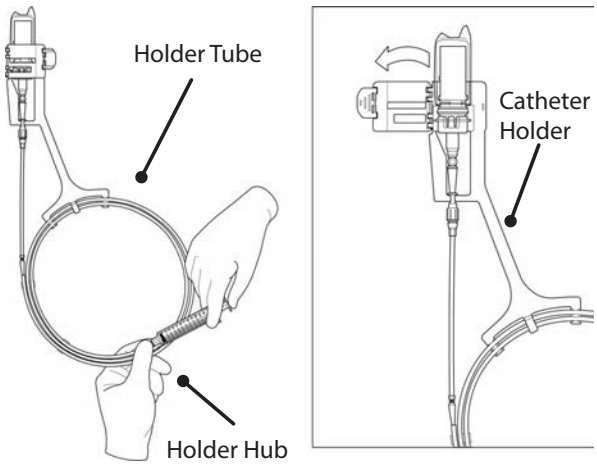
**<Sterile User>**

1. **Inspect the catheter and catheter accessories for damage.**

2. **Flush the holder tube according to the Instructions For Use provided with the DualView Catheter (Fig. 7.2)**
   - Refer to **Fig. 7.2** for catheter flushing configuration.
   - Keep the catheter inside the holder tube for this step.

3. **Extend the catheter telescope.**
   - Unlatch the catheter holder hub and detach the catheter connector cover from the catheter holder.
   - Grasp the connector hub and fully extend the telescope inner tube from the telescope outer tube.

Fig. 7.2 Flush the holder tube



# Setting Up the Catheter

## Priming the Catheter

**WARNING**

- Do not prime with any solution other than heparinized saline solution. Failure to do so may result in low image quality, catheter damage, or embolism due to clot formation.
- Ensure that the three-way stopcock and the connection tube are secured to the priming port before use. Do not allow air bubbles to enter the connection tube or syringe, as air bubbles may enter the catheter. A loose connection could result in an air embolism due to air being introduced into the bloodstream.
- After priming, confirm the IVUS image is clear, and re-prime the catheter if image is not. If a clear image is still not obtained, do not use. Failure to do so may result in low image quality, leading to misdiagnosis.
- Extend the telescope slowly. Do not extend the telescope inner tube with force as it may result in damage to the catheter/connector which could lead to vessel damage (such as dissection).
- Ensure that the catheter telescope is fully extended when priming the catheter. If priming is done with telescope in the halfway position, air bubbles may remain in the catheter resulting in air embolism.
- When priming the catheter, do not use a syringe smaller than the supplied priming syringe or any other device. This may generate excessive pressure, which could result in damage to the catheter or its accessories, or an ingress of heparinized saline solution resulting in failure of the MDU or cardiopulmonary arrest.

**CAUTION**

- Ensure that the stopcock is in the fully open position during priming of catheter. Failure to do so could result in excessive priming forces resulting in catheter damage or patient injury.

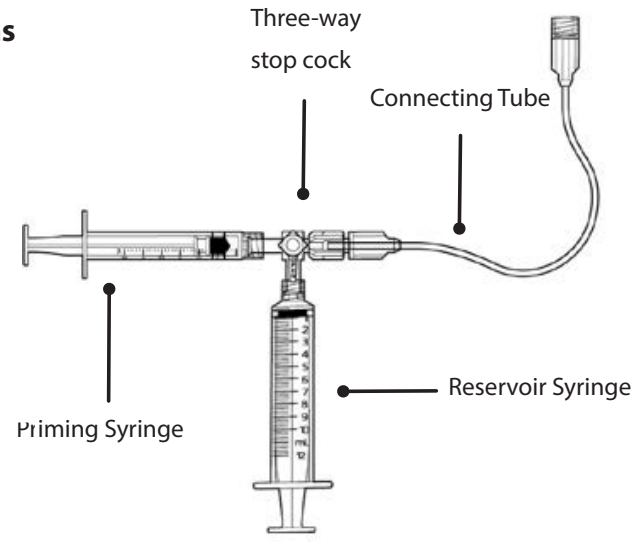
**NOTE**

- Ensure that the syringe has sufficient saline for multiple pullbacks.
- Do not remove the syringes from the catheter after priming.

**<Sterile User>**

1. **Prime the catheter according to the Instructions For Use provided with the DualView Catheter.**
   - Refer to Figure 7.4 for priming syringe configuration.

Fig. 7.4 Priming Syringe Configuration



# Setting Up the Catheter

## Connecting the Catheter to the MDU

**WARNING**

- Do not pinch the Sterile MDU Cover during Catheter connection. Doing so may tear or puncture the Sterile cover compromising sterility.
- Confirm the catheter is clamped in the MDU prior to beginning the procedure. Failure to clamp the catheter may cause unintentional catheter movement resulting in vessel damage (such as perforation or dissection).
- Do not apply excessive force to any part of the MDU during handling and connecting/ disconnecting the catheter. Failure to do so may cause system malfunction.

**CAUTION**

- When moving the MDU scanner, do so only through the position switch located on the scanner. Do not manually move the MDU scanner or catheter. Failure to do so may result in damage to the catheter and/or the MDU.

**<Sterile User>**

1. **Ensure the front edge of the MDU scanner is lined up to the white line located on the MDU base.**
   - If needed, move the MDU scanner to the white line using the position switch (**Fig. 7.5**).
   - This allows adequate clearance for the MDU Cover and catheter to connect to the MDU without interference.

2. **Carefully remove the connector pack on the connector cover.**
   - Keep the catheter inside the holder tube.

3. **Connect the catheter to the MDU.**
   a. Line up the marking on the catheter connector with the corresponding marking on the MDU port.
   b. Insert the catheter connector into the MDU port until it stops.

4. **Lock the catheter in place.**
   a. Grasp the MDU Cover adapter and rotate clockwise to align the mark to the "LOCK" symbol. (**Fig. 7.5**)
   b. Continue to turn the MDU cover adapter until resistance is felt.
      - The MDU connection LED indicator should turn to blue to indicate that it is locked in place.
      - The screen will change from "No catheter connected" to "OFDI + IVUS catheter connected" (**Fig. 7.6**, **Fig. 7.7**).

Fig. 7.5 Connect Catheter

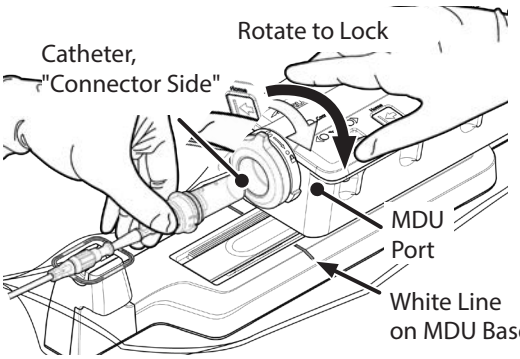



Fig. 7.6 No Catheter Connected

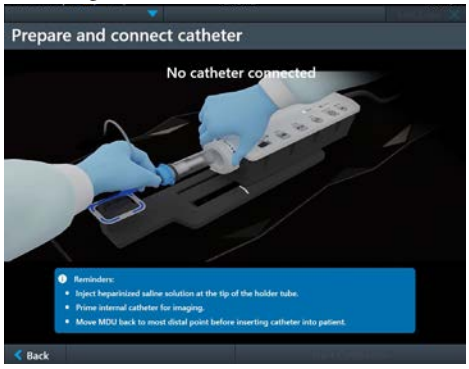
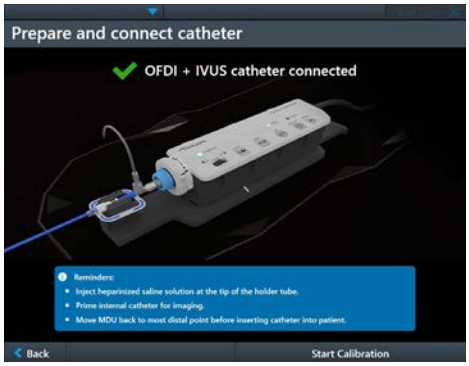



Fig. 7.7 Catheter Connected Check




**NOTE**

- After locking the catheter into the MDU, the screen should change from "No catheter connected" to "OFDI + IVUS catheter connected". If the screen reads "OFDI catheter connected", the catheter function may be compromised. Discontinue use and replace with a new catheter.

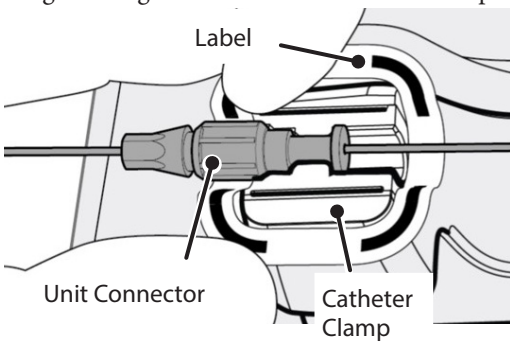
**5. Align and Clamp the catheter. (Fig. 7.8)**

a. Adjust the MDU Cover, lining up the clamp position label with the MDU clamp.

b. Align the unit connector with the catheter clamp and snap in place.

c. Gently pull up on the unit connector to confirm it is clamped in place.

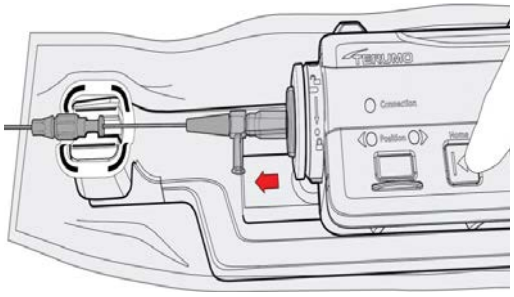
Fig. 7.8 Align Catheter with Catheter Clamp




**6. Home the MDU.**

- Press the [Home] button on the MDU to move the scanner back to the Home position **(Fig. 7.9)**.

Fig. 7.9 MDU Scanner Home Button



## Calibrating OFDI Modality

**WARNING**

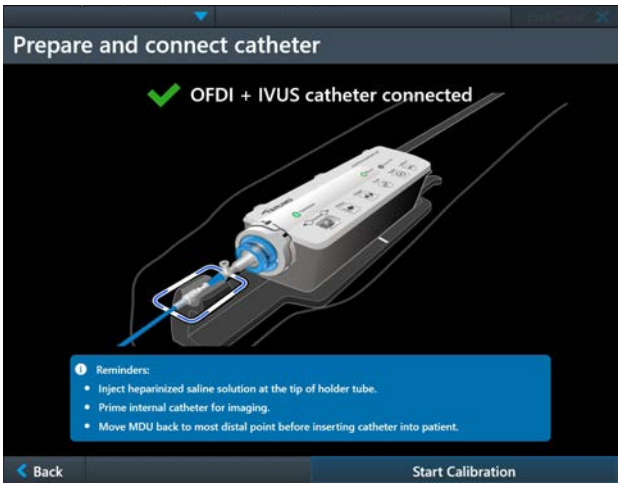
- If auto calibration fails, manually adjust the z-offset. Failure to do so may result in images not properly scaled leading to misdiagnosis and/or vessel damage (such as perforation).

**<Sterile User or Non-Sterile User>**

Automatic (Auto) Calibration

1. **With the catheter in the holder tube properly connected and homed, click on [Start Calibration] to begin auto calibration (Fig. 7.10).**

Fig. 7.10 Select [Start Calibration].

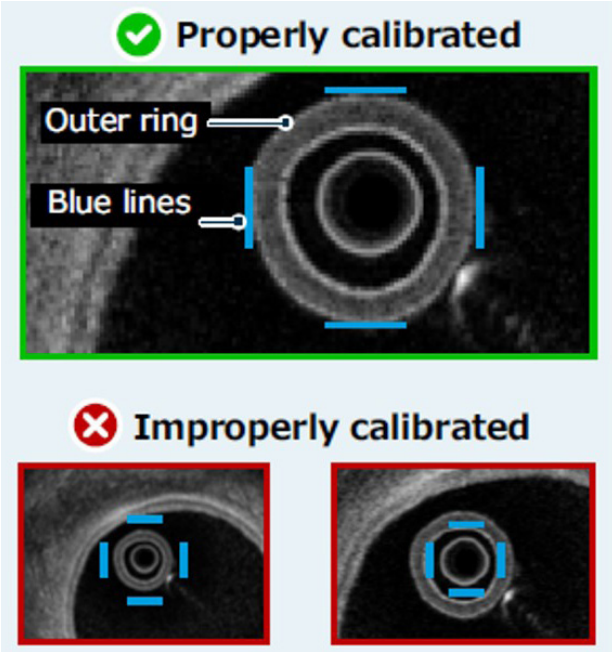


Manual Calibration

**1. Confirm Auto Calibration:**

- After auto calibration is completed, confirm that the blue lines align with the catheter's outer ring (Fig. 7.11)
- If adjustments are needed, proceed to step 2.

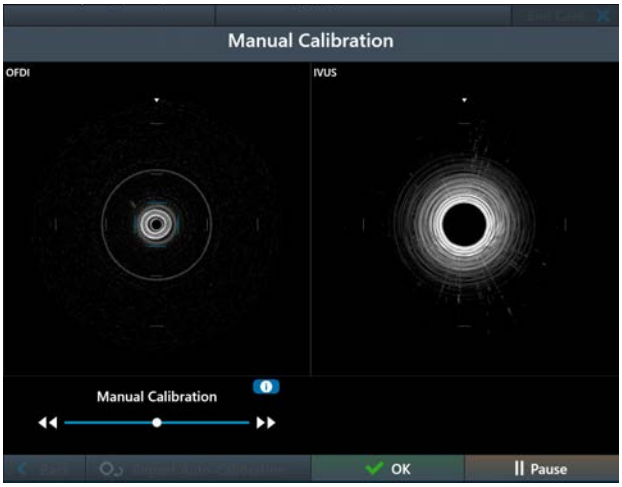
Fig. 7.11 Confirm




**2. To adjust the OFDI image scale (Fig. 7.12):**

- To adjust image scale, move the slider on the system screen, or move the mouse wheel until the outer ring of the catheter sheath aligns to all four blue lines.

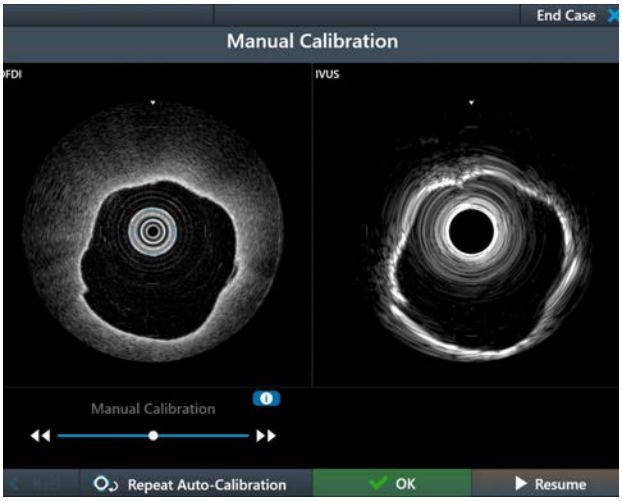
Fig. 7.12 Adjust OFDI image scale




**3. Repeat Auto-Calibration:**

- To repeat auto-calibration click [Pause] and then click [Repeat Auto-Clibration].

Fig. 7.13 Repeat Auto-Calibration



# Setting Up the Catheter

## Confirming Image

**WARNING**

- After priming, confirm the IVUS image is clear, and re-prime the catheter if image is not clear. If a clear image is still not obtained, do not use the catheter. Failure to do so may result in low image quality, leading to misdiagnosis.

1. **If using the IVUS modality on the DualView Catheter, confirm the IVUS image is clear (Fig. 7.14).**
   - If the image is UNCLEAR, click [Pause] to stop scanning, re-prime the catheter, and click [Resume] to restart scanning and confirm the catheter is primed properly.

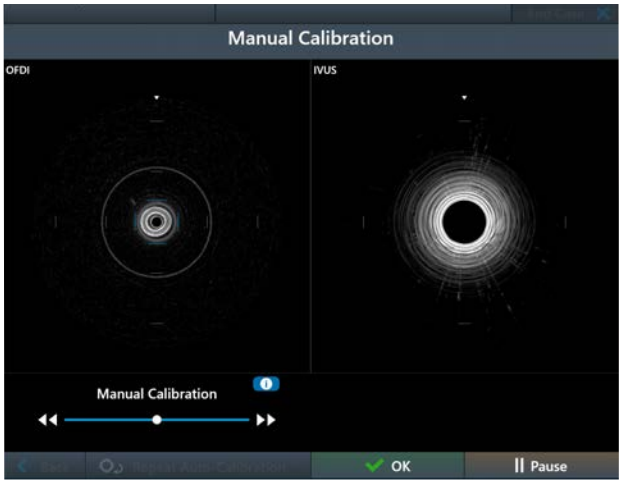
Fig. 7.14 Confirm the IVUS image clarity.




## Complete Calibration

1. **Select [OK] when catheter is properly calibrated and primed (Fig 7.15).**

Fig. 7.15 Select [OK]



# Section 8
# Inserting and Positioning the Catheter

# Inserting and Positioning the Catheter

**WARNING**

- Read the Instructions for Use provided with the catheter and MDU Cover prior to use. Misuse of these devices may cause injury to the patient or damage to the System.
- While performing assessment of acquired images, OFDI image review should only be relied upon for vessels 2.0 to 3.5 mm in diameter. OFDI images acquired in the left main coronary artery or in a target vessel which has undergone a previous bypass procedure should not be relied upon for image assessment.

CAUTION

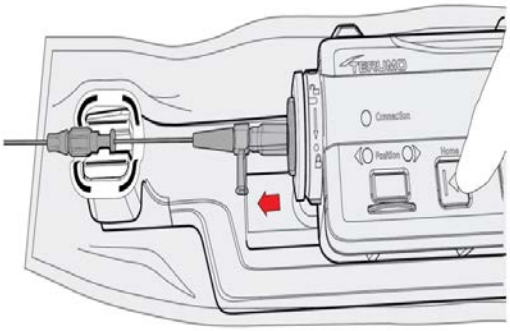
- When positioning the catheter's imaging core, do not move the MDU by hand. Instead use the position switch or the Home button on the MDU. Failure to do so may result in damage to the catheter and/or the MDU.

1. **Prior to use, follow the Instructions For Use provided with the DualView Catheter for inserting and positioning the catheter.**

2. **Home the MDU.**
   - Press the [Home] button on the MDU to move the scanner back to the (Home) position **(Fig. 8.1)**.

3. **Carefully remove the catheter from the holder tube.**

Fig. 8.1 Homing the MDU



**WARNING**

- If a clear image is not obtained, flushing media or blood may have entered the catheter. Inject heparinized saline solution to prime the catheter, according to the appropriate procedure. If a clear image is still not obtained, discontinue use and replace with a new catheter, or it could lead to image distortion or image loss, delaying procedure.
- During insertion, positioning, and removal of the catheter, fully open/close the hemostatic valve. Failure to do so may result in damage to the catheter (if not fully open) or bleeding (if not fully closed).
- Do not advance the imaging catheter through vessels less than 2 mm in diameter. Doing so could result in catheter and/or vessel damage (such as perforation).

NOTE

- Coat the catheter with heparinized physiological saline solution to maintain lubrication.

4. **Thoroughly wipe the guidewire with gauze soaked with heparinized saline solution to remove any blood on the surface of the guidewire. If the catheter is dry, moisten it with gauze soaked in heparinized saline solution to enhance lubrication.**

5. **Insert the guiding catheter and guidewire into the blood vessel as described in the catheter Instructions For Use.**
   - Make sure the scanner motor is not running, the telescope inner tube is inserted into the telescope outer tube, and the imaging sensor is located at the distal end.

**WARNING**

- Observe insertion and manipulation of the Catheter under fluoroscopy. Failure to observe device movement fluoroscopically or positioning further than intended, may result in damage to the device and/or vessel damage (such as perforation).
- Advance the catheter carefully within the artery and, if any resistance is felt, stop manipulating the catheter and determine the cause under fluoroscopy.

6. **Insert the guidewire into the guidewire lumen of the catheter and advance it over the guidewire. 90 cm and 100 cm depth markers can be used as a guide for insertion.**
   - Use the distal radiopaque marker and lens marker as a guide to position the catheter.
   - Verify that the distal radiopaque marker moves as it is manipulated.
7. **Under fluoroscopy, carefully advance the catheter to a position just distal to the lesion, making sure the distal radiopaque marker moves exactly as it is manipulated.**
8. **[OFDI + IVUS or OFDI Modality] If using the auto injector, inject the flushing solution into the injector per the recommended settings in the catheter Instructions For Use.**
9. **[OFDI + IVUS or OFDI Modality] Fill the guide catheter, by the Y-connector, with flushing solution.**
10. **Begin Live mode.**
    - Press the [Scan] button on the MDU, or on system screen **(Fig. 8.2A and 8.2B)**

Fig. 8.2A MDU Scan button

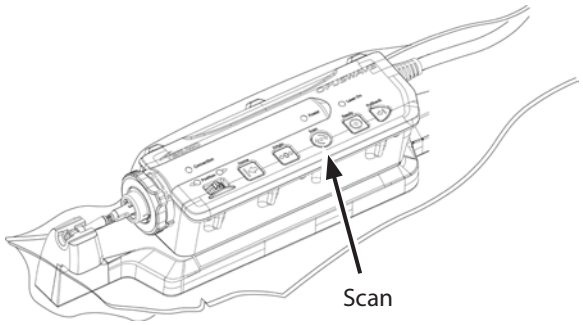
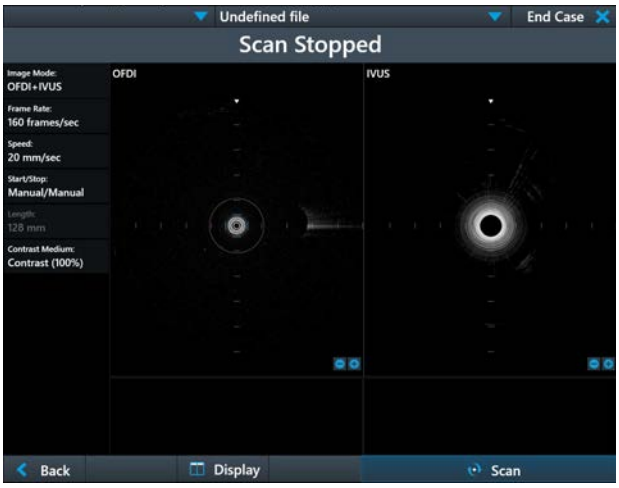


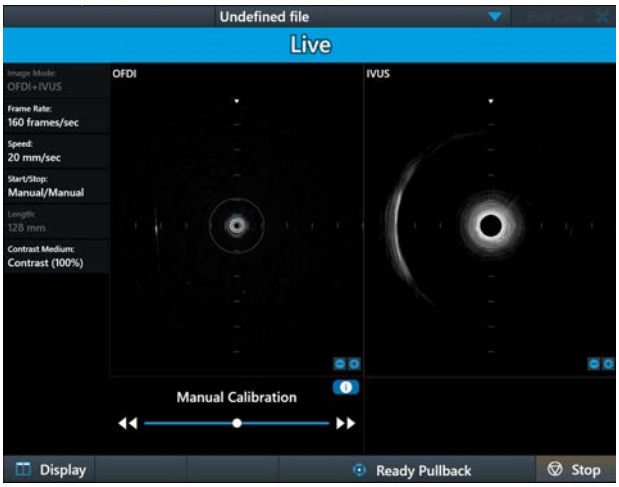

Fig. 8.2B System Screen Scan Button




NOTE

- Adjust the image calibration in Live state at any time by adjusting the OFDI image scale using the slider on the system screen (Fig 8.3).

Fig. 8.3 Live Imaging Calibration



# Section 9
# Preparing for Pullback

# Preparing for Pullback

**CAUTION**

- Prior to pullback, ensure that the MDU and catheter are properly aligned to the catheter insertion point. Failure to do so may result in catheter damage or incomplete pullback.

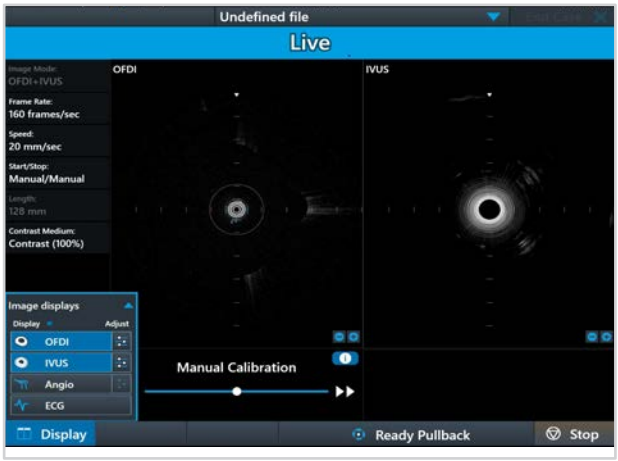
## Displaying Angiography and ECG

- Angiography can be displayed in a sub-screen through an external input by connecting a video signal transmission cable from an external system to the video-in terminal (page 18) on the back panel of the console.
- ECG can be superimposed on both OFDI and IVUS cross-sectional image screen by connecting the ECG cable to the BNC connector (page 18) on the back panel of the console.

**1. Click [Display] at the bottom of the screen.**

- A sub-menu pops up with options for displaying angio or ECG **(Fig. 9.1A).**

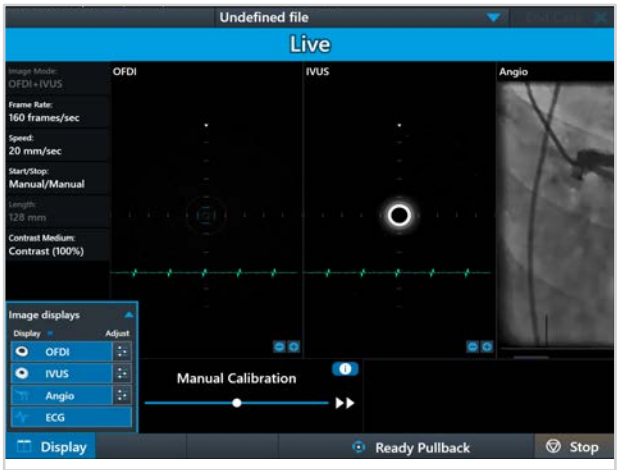
Fig. 9.1A Image Display Options




**2. Click [Angio] and/or [ECG] to highlight screens to be displayed.**

- The selected screens will appear on the console. **(Fig. 9.1B).**

Fig. 9.1B Display Angio and ECG



## Selecting and Confirming Pullback Settings

**WARNING**

- Set the frame rate, pullback speed, pullback length, and the contrast media prior to data acquisition. Failure to do so may cause improper imaging with subsequent incorrect diagnosis.
- Confirm that the selected setting for the contrast media entered is the same as the media in which you are imaging. Failure to do so may result in inaccurate measurements and mistreatment.

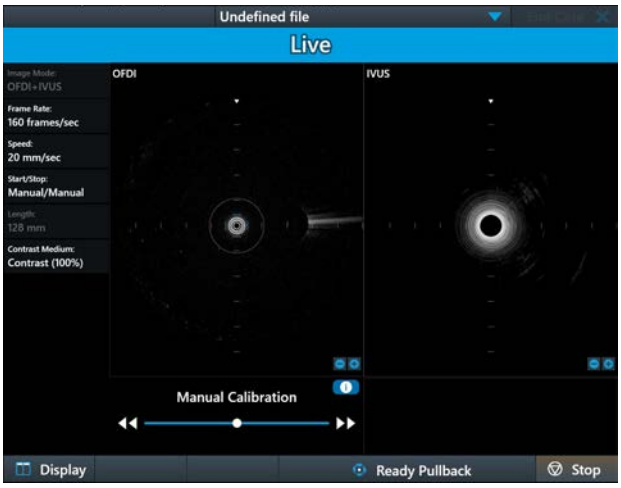
**NOTE**

- Confirm pullback settings prior to starting each subsequent pullback.
- If the incorrect contrast media is selected prior to imaging, it can be changed after the image is taken, and the image will adjust accordingly.

Prior to pullback, select and confirm all pullback settings for accurate imaging (**Fig. 9.2**).

1. **For each setting, selectable values vary based on the catheter and modality selected.**
   - Settings that are not available with the selected catheter/modality will be de-activated and cannot be selected.
   - The editable settings are:
     - Frame Rate
     - Speed
     - Start/Stop
     - Length
     - Contrast Medium (If OFDI or OFDI + IVUS selected)

Fig. 9.2 Pullback Settings




2. **Roll the cursor over setting and click to edit (Fig. 9.3).**
   - A sub-menu will open with editable settings.

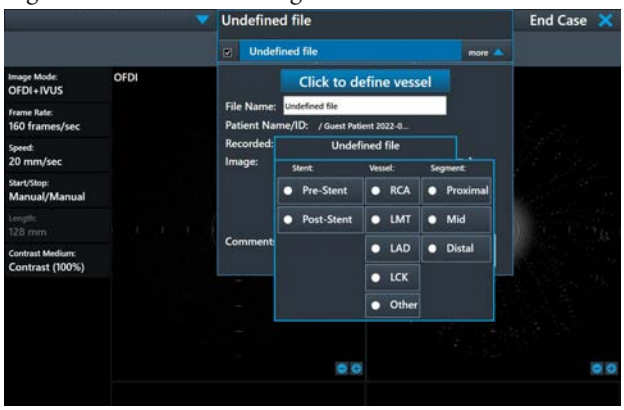
Fig. 9.3 Edit Settings



## Selecting and Confirming File Name

1. **Click [Undefined File] to open a drop-down menu (Fig. 9.4).**
2. **Click [more] drop down menu**
3. **Click [Click to define vessel]**
   - Select options for stent, vessel, and segment.
4. **Pullback name can also be specified by entering a custom name via the keyboard.**

Fig. 9.4 Select Vessel Settings



## Operating the MDU

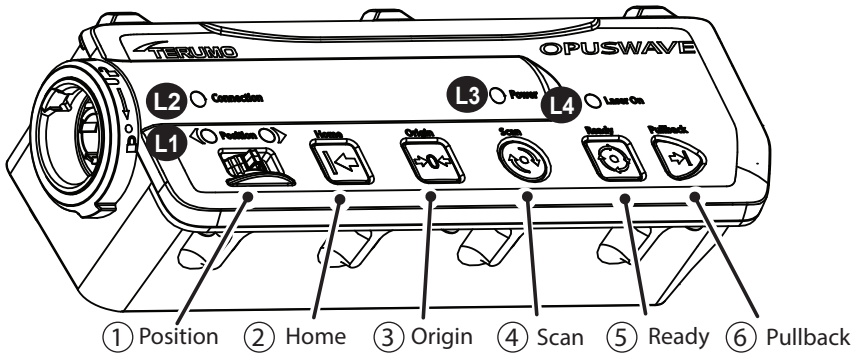
**CAUTION**

- Do not press MDU buttons by mistake. Unexpected or unintended MDU movement could cause damage to the MDU or catheter.

MDU functions can be activated/deactivated by the Sterile User by using the five buttons and position switch illustrated below **(Fig. 9.5)**.

1. **Position Switch-** Manual movement of the MDU scanner:
   - Forward moves the catheter sensors toward the distal end of the catheter at variable speeds.
   - Backward moves the sensors toward the proximal end of the catheter at variable speeds.
2. **Home-** Moves the MDU Scanner to the end of travel in the forward direction; toward the distal end of the catheter.
3. **Origin-** Resets the travel distance indicator to zero. If the user moves the sensor head in any direction, the indicator will display the distance traveled from the start point/origin in IVUS-Only mode. This function can also be activated by the Non-Sterile User at the console.
4. **Scan-** Activates or deactivates the catheter rotation and turns the imaging IVUS and/or the OFDI signals on/off. This is also referred to as "LIVE". If this button is activated while in Ready or Pullback, the system stops both pullback and ready states. This function can also be activated by the Non-Sterile User at the console.
5. **Ready-** Used for OFDI or Dual modalities only. This function increases spinning speed of the MDU to OFDI required speeds of 6000 or 9600 RPM and enables the pullback function of the system. If this button is activated while in Ready or Pullback, the system stops both pullback and scan. This function can also be activated by the Non-Sterile User at the console.
6. **Pullback-** Initiates pullback of the imaging sensor through the sheath based on the predetermined settings. If this button is activated during pullback, the system stops both pullback and scan. This function can also be activated by the Non-Sterile Operator at the console.

Fig. 9.5 Scanner Upper Enclosure [Top View]




| LED Indicators | |
|---|---|
| L1 | **Position-** Indicates manual movement direction while position switch is manipulated. Lights up blue when activated. |
| L2 | **Connection-** Turned on (blue) when a catheter is connected. |
| L3 | **Power-** Turned on (green) when system is powered on. |
| L4 | **Laser On-** Turned on when laser is emitted to catheter tip. Lights up blue when activated. |

# Section 10
# Performing an OFDI or OFDI + IVUS Pullback

# Performing an OFDI or OFDI + IVUS Pullback

**WARNING**

- Refer to the contrast media's Instructions For Use for general warnings and precautions relating to the use of contrast media.

## Overview

The DualView Catheter is capable of simultaneously imaging with both modalities (OFDI + IVUS), as well as switching between the two imaging modalities (OFDI or IVUS) in a single procedure.

This procedure should be performed by a minimum of two users: both a sterile and a non-sterile user:

- The sterile user performs all activities that interact with the catheter or with the MDU outside the MDU Cover. The sterile user can also interact with the OPUSWAVE System Console via the wireless mouse.
- The non-sterile user performs all activities that interact with the OPUSWAVE System Console or with the MDU inside the MDU Cover.
- Some steps can be completed either by the sterile user through the MDU or the Non-Sterile user at the console.

(Refer to sections 7-9 for detailed descriptions on setting up the catheter and preparing for a pullback prior to performing a pullback).

## Required Materials and Equipment

- OPUSWAVE System
- DualView Catheter
- MDU Cover
- 10 ml syringe for flushing (not provided)
- Contrast Medium
- .014" Guidewire
- 6 French Guide Catheter
- Heparinized Saline Solution

# Performing an OFDI or OFDI + IVUS Pullback

## Conducting a Pullback

Starting a Pullback

1. **Home the MDU.**
   - Press the [Home] button on the MDU to move the scanner back to the Home position (Fig. 10.1A).
2. **Select "OFDI + IVUS" or "OFDI Only" Image mode depending on modality desired.**
3. **Confirm all other pullback settings are correct.**
   - (Refer to section 9 for adjusting pullback settings).
4. **Begin Live mode.**
   - Press [Scan] on the MDU or on the system screen (**Fig. 10.1A/10.1B**).

Fig. 10.1A MDU Scan Button

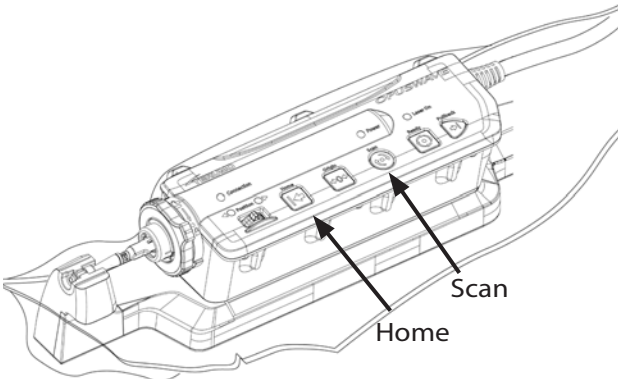



Fig. 10.1B Scan Button- System Screen

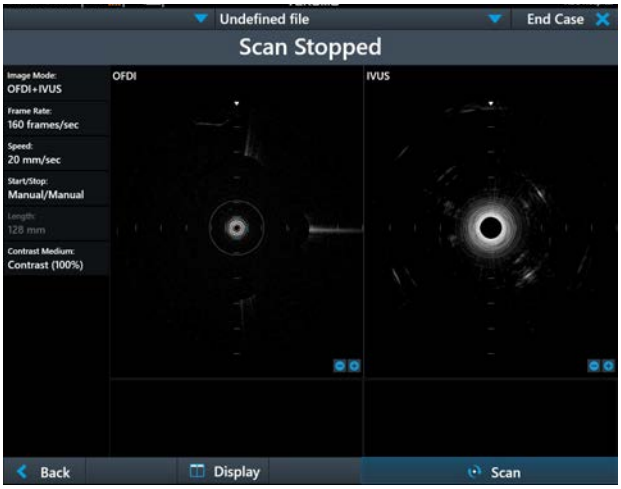
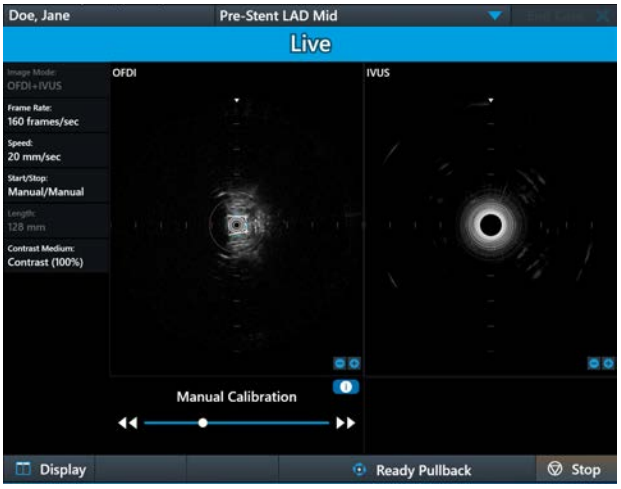



Fig. 10.2 Confirm Clear IVUS Image




5. **If using OFDI + IVUS, confirm that a clear IVUS image appears on the screen (Fig. 10.2).**
   - If the image is UNCLEAR, press [Scan] button on the MDU or click [Stop] on the system screen to stop scanning and re-prime the catheter. Press [Scan] on the MDU or click [Scan] button on the system screen after re-priming the catheter, to resume Live mode and confirm a clear image.
   - If image is CLEAR, proceed to Step 6 below.
   - If CLEAR image is not obtained after re-priming, replace catheter.
6. **Inject a test shot of contrast medium.**
   - Confirm that the blood can be sufficiently removed for OFDI imaging clarity.

### 7. Ready for Pullback

- Press [Ready] on the MDU **(Fig. 10.3A).**
- This step can also be done by the non-sterile user by clicking [Ready Pullback] on the system screen **(Fig. 10.3B)**.

Fig. 10.3A MDU Ready Button

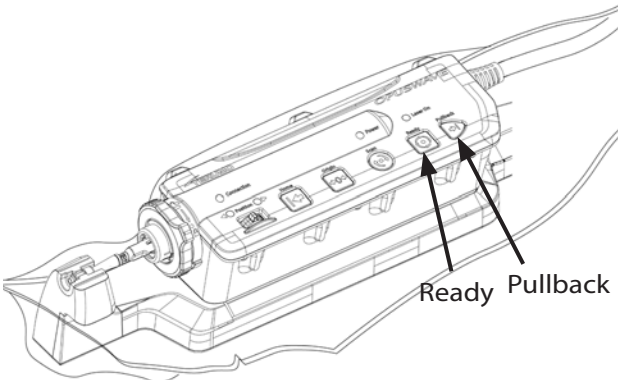
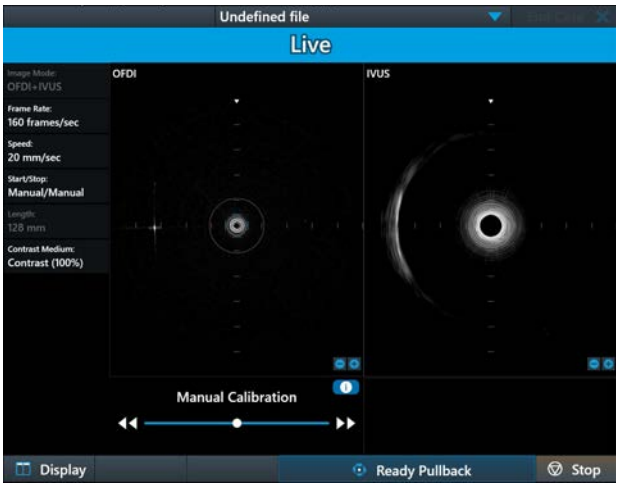



Fig. 10.3B Ready Pullback- System Screen

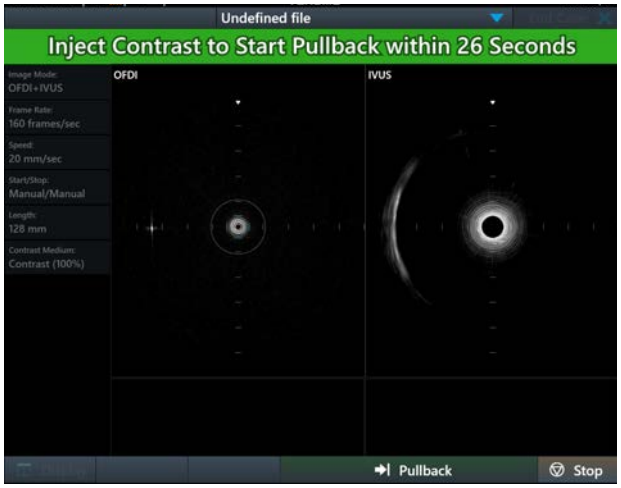



### 8. Inject contrast medium within 30 seconds of activating Ready state (Fig. 10.3C).

### 9. Begin Pullback

- If Auto-start is ON, pullback will start automatically when the software detects a clear image.
- If Manual-start is ON, Press [Pullback] on the MDU **(Fig. 10.3A)**.
  - This step can also be done by the non-sterile user by clicking [Pullback] on the system.
    screen **(Fig. 10.3C)**.

Fig. 10.3C Inject Contrast



# Performing an OFDI or OFDI + IVUS Pullback

**WARNING**

- After completion of a pullback, always return the MDU scanner to the distal (HOME) position prior to re-positioning the catheter. Failure to do so may result in catheter and/or vessel damage (such as perforation or dissection).

## Ending a Pullback

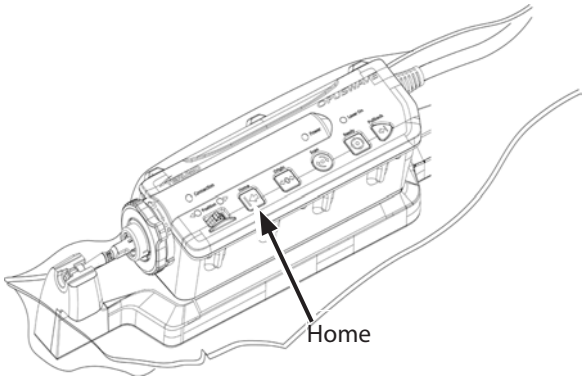
- If [Auto Stop] was selected, the pullback will end when the MDU scanner has traveled the predetermined length, or it can be manually stopped by pressing [Pullback], [Ready], or the [Scan] button on the MDU. This step can also be done by the non-sterile user by clicking [Stop] on the system screen.
- If [Manual Stop] was selected, press the [Pullback], [Ready], or the [Scan] button on the MDU to end the pullback manually. This step can also be done by the non-sterile user by clicking [Stop] on the system screen.

**NOTE**

- Regardless of stop setting, the pullback will end when the MDU scanner reaches the most proximal point (150 mm from the most distal position).

### 1. Home the MDU.

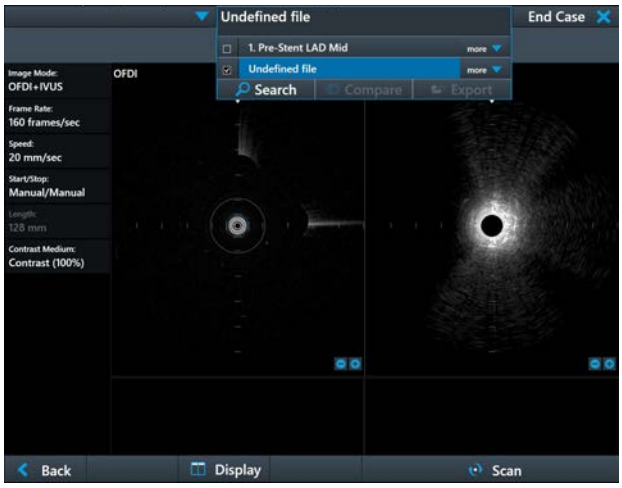
- Press the [Home] button on the MDU to return the MDU scanner to the Home position **(Fig. 10.4).**




### 2. Review the acquired image data and repeat pullback if needed.

- After a pullback has completed, the system will automatically begin reconstructing the image and move to the review screen. This may take up to 5 seconds for a single modality and 10 seconds for dual modalities.
- You can also select from the list of current case files in the file drop down menu (**Fig. 10.5**).

Fig. 10.5 Current Case Files



# Section 11
# Performing an IVUS Only Pullback

# Performing an IVUS Only Pullback

## Overview

The DualView Catheter is capable of simultaneously imaging with both modalities (OFDI + IVUS), as well as switching between the two imaging modalities (OFDI or IVUS). The IVUS only procedure utilizes the IVUS only modality.

This procedure should be performed by a minimum of two users: both a sterile and a non-sterile user:

- The sterile user performs all activities that interact with the catheter or with the MDU outside the MDU Cover. The sterile user can also interact with the OPUSWAVE System Console via the wireless mouse.
- The non-sterile user performs all activities that interact with the OPUSWAVE System console or with the MDU inside the MDU Cover.
- Some steps can be completed either by the sterile user through the MDU or the Non-Sterile user at the console.

(Refer to sections 7-9 for detailed descriptions on setting up the catheter and preparing for a pullback.

## Required Materials and Equipment

- OPUSWAVE System
- DualView Catheter
- MDU Cover
- .014" Guidewire
- 6 French Guide Catheter
- Heparinized Saline Solution

# Performing an IVUS Only Pullback

## Conducting a Pullback

Starting a Pullback

1. **Home the MDU.**
   - Press the [Home] button on the MDU to move the scanner back to the Home position **(Fig. 11.1)**.

2. **Select "IVUS only" imaging mode in pullback settings.**

3. **Confirm all other pullback settings are correct (Fig. 11.2).**
   - (Refer to Section 9 for adjusting pullback settings).

4. **Begin Live mode.**
   - Press [Scan] on the MDU or on the system screen **(Fig. 11.1 and 11.3).**

Fig. 11.1 MDU Scan and Home

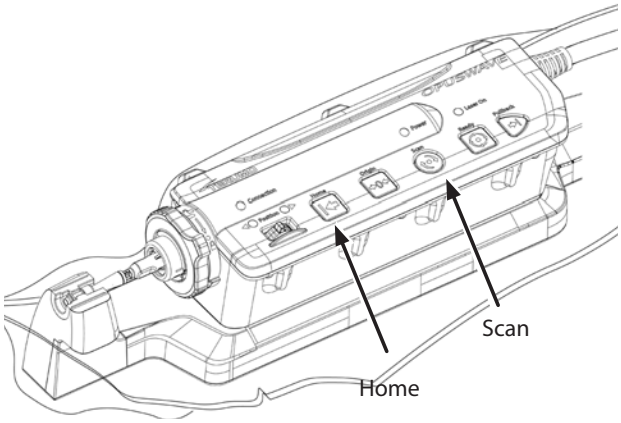



Fig. 11.2 Select IVUS Only Image Mode

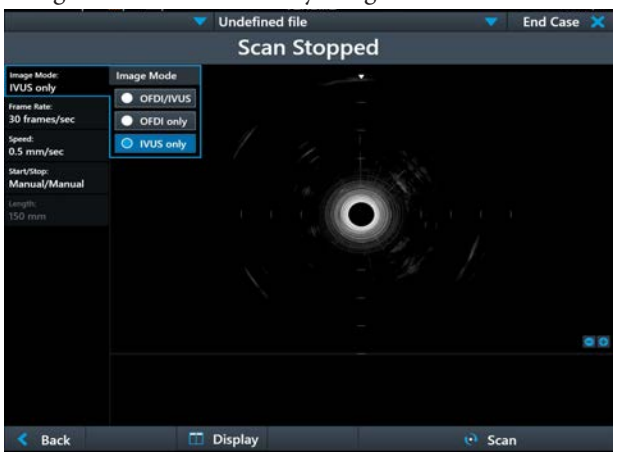
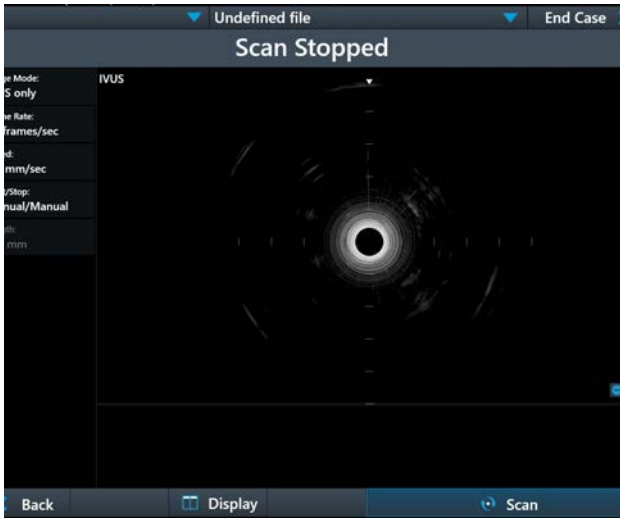



Fig. 11.3 Scan Button- System Screen



**5. Confirm that a clear IVUS image appears on the screen (Fig.11.4).**

- If the image is UNCLEAR, press [Scan] button on the MDU or click [Stop] on the system screen to stop scanning and re-prime the catheter. Press [Scan] on the MDU or click [Scan] button on the system screen after re-priming the catheter, to resume Live mode and confirm a clear image.
- If image is CLEAR, proceed to Step 5 below.
- If CLEAR image is not obtained after re-priming, replace catheter.

**6. Begin Pullback**

- Press [Pullback] on the MDU or on the system screen **(Fig. 11.5A and 11.5B)**.

Fig. 11.4 Confirm Clear Image




Fig. 11.5A MDU Pullback Button

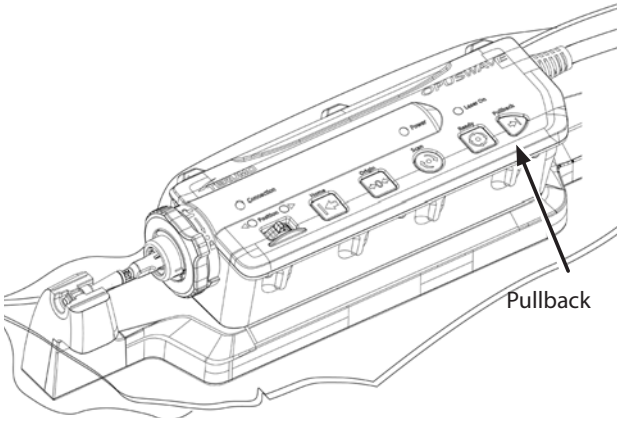
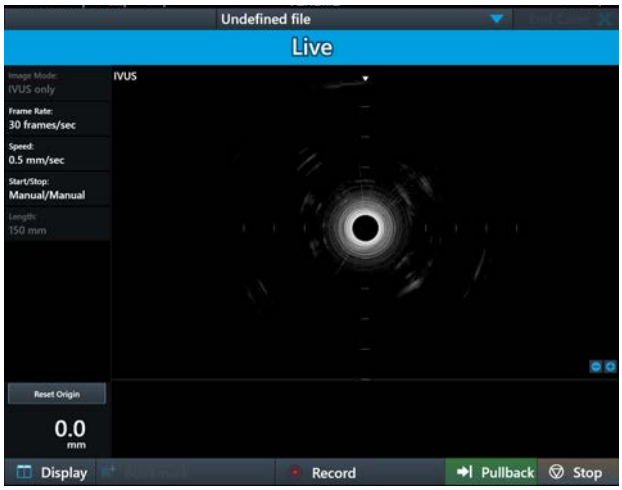



Fig. 11.5B System Screen Pullback Button



# Performing an IVUS Only Pullback

Ending a Pullback

**WARNING**

- After completion of a pullback, always return the MDU scanner to the distal (HOME) position prior to re-positioning the catheter. Failure to do so may result in catheter and/or vessel damage (such as perforation or dissection).

- If [Auto Stop] was selected, the pullback will end when the MDU scanner has traveled the predetermined length or it can be manually stopped by pressing [Pullback], [Ready], or the [Scan] button on the MDU. This step can also be done by the non-sterile user by clicking [Stop] on the system screen.
- If [Manual Stop] was selected, press the [Pullback] or the [Scan] button on the MDU to end the pullback manually. This step can also be done by the non-sterile user by clicking [Stop] on the system screen.

NOTE

- Regardless of stop setting, the pullback will end when the MDU scanner reaches the most proximal point (150 mm from the most distal position).

### 1. Home the MDU

- Press the [Home] button on the MDU to return the MDU scanner to the Home position **(Fig. 11.6)**

### 2. Review the acquired image data and repeat pullback if needed.

- After a pullback has completed, the system will automatically begin reconstructing the image and move to the review screen. This can take up to 5 seconds for a single modality.
- Or select from the list of current case files in the file drop down **(Fig. 11.7).**

Fig. 11.6 MDU return to Home position

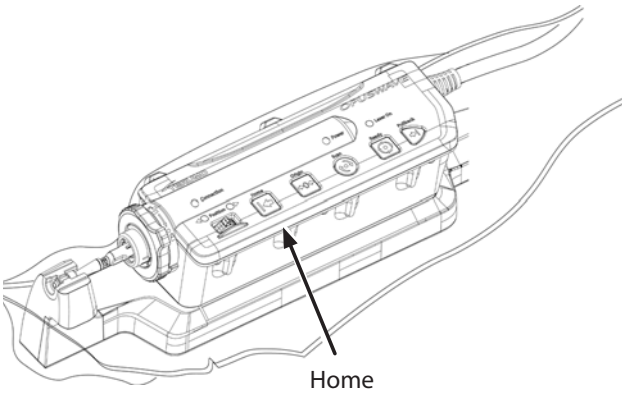
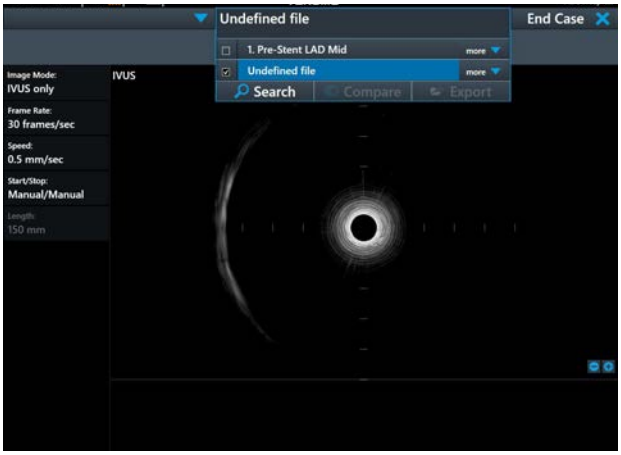



Fig. 11.7 Current Case Files



# Section 12
# Performing an IVUS Only Manual Recording

# Performing an IVUS Only Manual Recording

## Overview

The DualView Catheter is capable of simultaneously imaging with both modalities (OFDI + IVUS), as well as switching between the two imaging modalities (OFDI or IVUS). The IVUS only modality provides the option to conduct a live manual recording of the vessel.

This procedure should be performed by a minimum of two users. Both a sterile and a non-sterile user:

- The sterile user performs all activities that interact with the catheter or with the MDU outside the MDU Cover. The sterile user can also interact with the OPUSWAVE System Console via the wireless mouse.
- The non-sterile user performs all activities that interact with the OPUSWAVE System console or with the MDU inside the MDU Cover.
- Some steps may be completed either by the sterile user through the MDU or the Non-Sterile user at the console.

(Refer to sections 7-9 for detailed descriptions on setting up the catheter and preparing for a pullback).

## Required Materials and Equipment

- OPUSWAVE System
- DualView Catheter
- MDU Cover
- .014" Guidewire
- 6 French Guide Catheter
- Heparinized Saline Solution

# Performing an IVUS Only Manual Recording

## Conducting a Manual Recording

Starting a Manual Recording

### 1. Home the MDU

- Press the [Home] button on the MDU to return the MDU scanner to the Home position**.**

### 2. Select IVUS only imaging mode in pullback settings (Fig. 12.1).

Fig. 12.1 Select IVUS Only Mode




### 3. Begin Live mode.

- Press [Scan] on the MDU or on the system screen (**Fig. 12.2A and 12.2B**).

Fig. 12.2A MDU Home and Scan Button

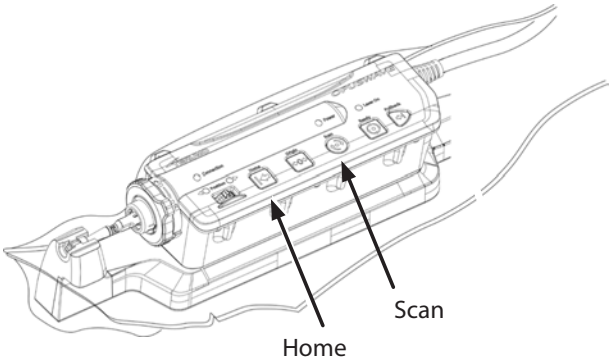



Fig. 12.2B System Screen Scan Button



**4. Confirm that a clear IVUS image appears on the screen (Fig. 12.3).**

- If the image is UNLCEAR, press [Scan] on the MDU or click the [Stop] button on the system screen to stop scanning and re-prime the catheter.
- If image is CLEAR, proceed to Step 5 below.
- If CLEAR image is not obtained after re-priming, replace the catheter.

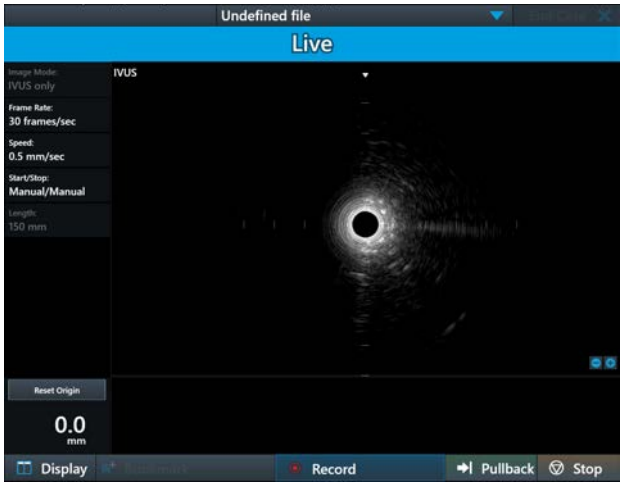
Fig. 12.3 Confirm Clear Image




**5. Begin Recording**

- Press [Record] on the system screen (**Fig. 12.4**).

Fig. 12.4 System Screen [Record] Button




**6. During an IVUS Only manual recording, users can perform the following functions:**

- Use the position switch (**Fig. 12.5**) on the MDU to manually record the vessel moving distal and proximal to record the image data.
- Reset the origin to zero by pressing [Origin] on the MDU or [Reset Origin] the system screen (**Fig. 12.6**)
  - This will re-set the position to 0.0 mm and as the MDU is moved it will re-calculate and display the distance between the current position and the origin.

Fig. 12.5 MDU Position Switch and Origin

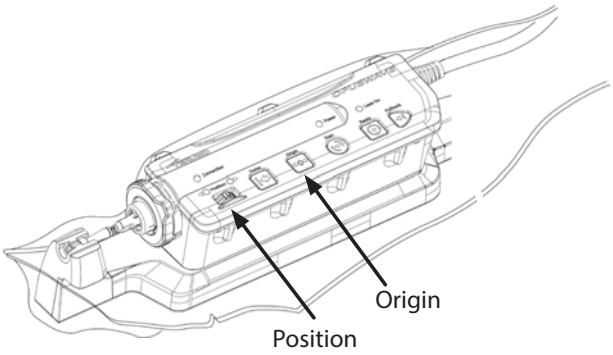
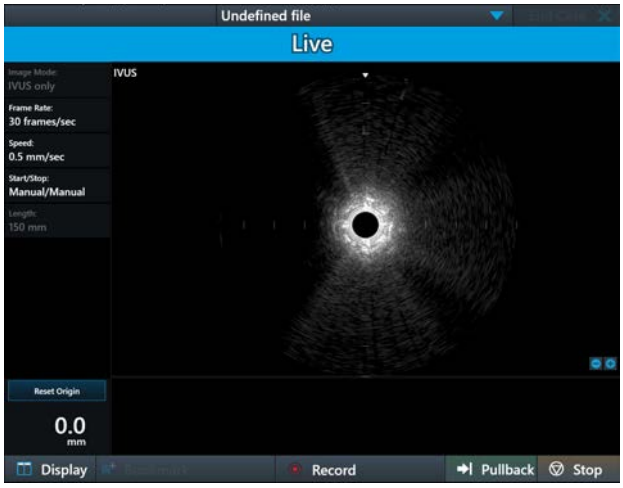



Fig. 12.6 System Screen (Reset Origin) Button




Origin

# Performing an IVUS Only Manual Recording

Ending a Manual Recording

**WARNING**

- After completion of a recording, always return the MDU scanner to the distal start (HOME) position prior to re-positioning the catheter. Failure to do so may result in catheter and/or vessel damage (such as perforation or dissection).

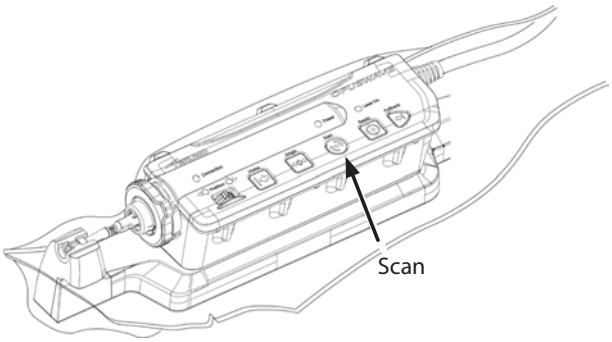
## 1. To end a manual recording:

- Click [Record Stop] on the system screen to end recording and remain in live mode (**Fig. 12.7A**).
  or
- Click [Stop] on the system screen or Press [Scan] on the MDU to end live mode (**Fig. 12.7A and 12.7B**).
- The recording is saved in the pullback list **(Fig. 12.8)**.

Fig. 12.7A End Manual Recording- Screen



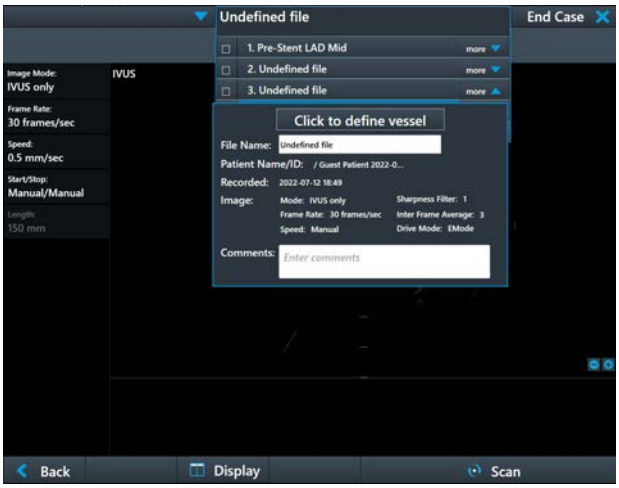

Fig. 12.7B End Manual Recording- MDU




## 2. If additional recording is needed:

- If in live mode, click [Record] on the system screen.
- If not in live mode, Press [Scan] on the MDU or System Screen to enter Live view and then click [Record] on the system screen.
- A new recording will be started and saved in the pullback list under a different file name when recording is ended (**Fig. 12.8**).

Fig. 12.8 Pullback List



# Section 13
# Review

**WARNING**

During review of the pullback, ensure regions of interest are identified and measured. Failure to do so could result in misdiagnosis or patient injury.

## Navigating Recordings

After re-construction, the image window displays the cross-sectional and longitudinal image of the pullback **(Fig. 13.1)**. To review a previous case, refer to section 15, "Reviewing Previous Cases".

Fig. 13.1 Pullback Screen Overview

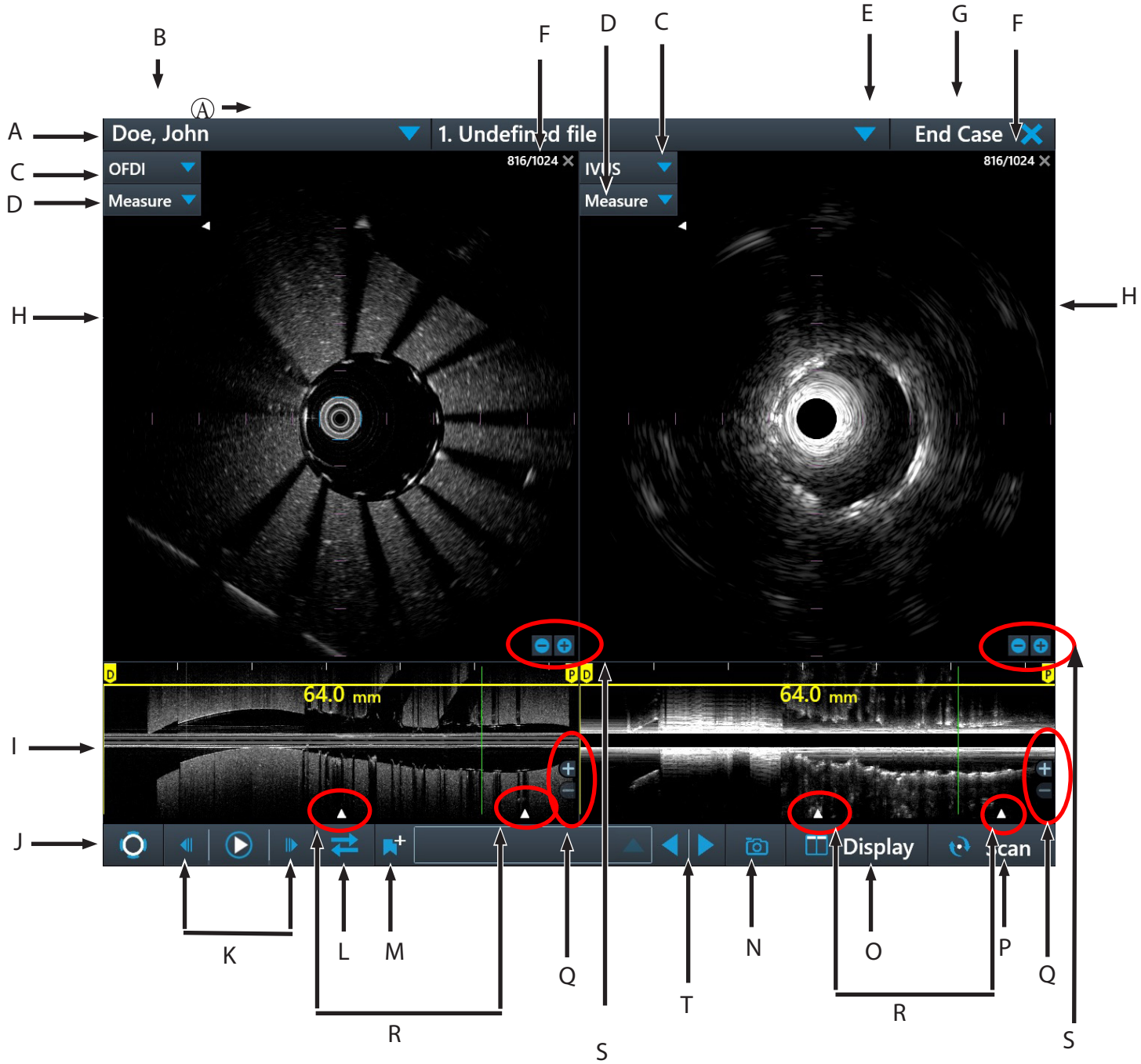


Table 13.1 Pullback Screen Descriptions

| Control | Description | Function |
|---|---|---|
| A | Patient Name | Displays the patient's name |
| B | Time Date Stamp | Displays the current date and time |
| C | Image Adjustment Menu | Opens the pull-down menu to apply image adjustment. It also allows you to apply manual calibration adjustment for OFDI image. |
| D | Measurement Menu | Opens the pull-down menu which lists the tools available for image measurement and image annotation. Refer to Section 14: Measurements and Annotations. |
| E | Pullback Name List | Shows the name of the current displayed pullback. Click to open the pulldown menu to select pullback data to be displayed. |
| F | Frame Number | Displays the current frame number out of the total pullback frame count. |
| G | End Case | Ends the current case and returns to the Home screen. |
| H | Image Window | Displays the selected cross-sectional image. |
| I | Longitudinal Image | Displays Longitudinal image of the pullback. |
| J | Calibration | Applies manual adjustment of OFDI calibration to the image. |
| K | Playback controls | Starts/Stops sequential playback and moves the selected cross-sectional frame forward/backward frame-by-frame. |
| L | Shuttle Playback | Plays back repeatedly within the configured frame counts (1 to 5 frames) |
| M | Bookmark | Pins a placeholder to frames of interest to facilitate image searching by skipping through bookmarked frames. |
| N | Snapshot | Captures still image of the screen. |
| O | Display | Selects screens to review and adjusts the image display settings and provides playback configuration. |
| P | Scan | End the review of the pullback/recording and return to live mode. |
| Q | Longitudinal Zoom | Increases/Decreases longitudinal magnification from the catheter center. |
| R | Playback Range Selection | Sequentially plays back the cross-sectional image of the pullback within these two markers. When "Loop" playback setting is [OFF], the playback stops when it reaches the marker on the right. |
| S | Cross-Sectional Image Depth | Increases/Decreases the image depth within the range from 2.5 mm to 6 mm. |
| T | Bookmark Scroll | Scrolls sequentially through bookmarks by selecting the bookmark forward or bookmark backward arrow. |

## Adjusting Playback Settings

Adjust the playback controls of the OFDI and IVUS pullbacks/recordings by using the buttons on the playback control area of the system screen (refer to Table. 13.1 for Playback Control Menu Functions).

1. **Click on the [Display] button on the system screen (Fig. 13.2).**
2. **Select the [Playback] button.**
3. **Adjust the playback settings on the system screen.**
   - Refer to **Table 13.2** (below) for functions of the adjustable playback controls.
4. **After Adjustments, press [Display] button to close and exit the menu.**

Fig. 13.2 Playback Control Menu on screen.

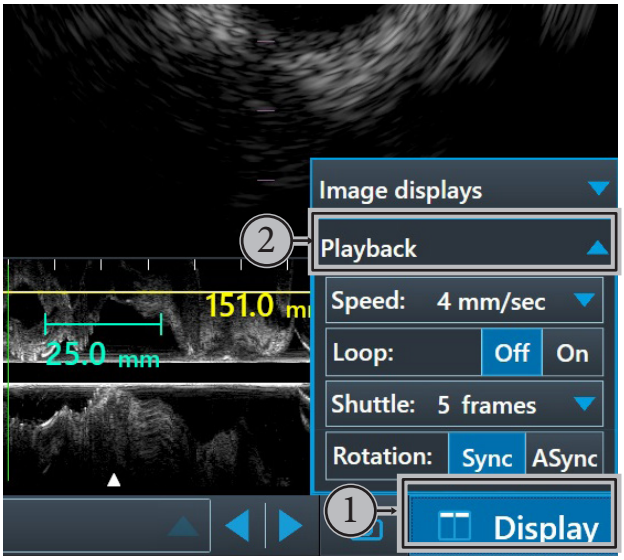



Table. 13.2 Playback Control Menu Functions

| Control | Description | Function |
|---|---|---|
| Speed | Playback Speed | Controls the playback speed. Change the playback speed by selecting speeds from 0.5, 1, 2, 4 and 8 mm/s. |
| Loop | Loop Playback | Loops replay within a defined playback range. Activate/Deactivate loop playback by selecting ON or OFF. |
| Shuttle | Shuttle Playback Frame Count | Loops replay within a smaller playback range. Changes the frame count by selecting the frame count for shuttle playback from 1 to 5 frames. |
| Rotation | synchronous/ asynchronous image rotation | Controls whether the OFDI + IVUS images rotate individually (asynchronously) or together (synchronously). |

## Labeling/Editing Pullback Name

1. **Label/Edit the pullback name and associated information in the review screen by clicking the [Pullback Name] down arrow (Fig. 13.3A).**

2. **Click the [more] down arrow (Fig. 13.3B).**

3. **Enter a custom pullback name in the [File Name] field via the keyboard.**

   OR

4. **Click [Click to Define Vessel] (Fig. 13.3C).**
   - Select options for stent, vessel, and segment.

5. **Close Pullback Name List popup when finished, by clicking on [Pullback Name], to save edited information.**
   - The Pullback Name is automatically created from the parameters selected but it is manually editable after selecting parameters.
   - If any parameters are changed after manually editing the Pullback Name, the edited Pullback Name is discarded and the new Pullback Name is created per the newly selected parameters.

Fig. 13.3A Edit Name- Click Pullback Name

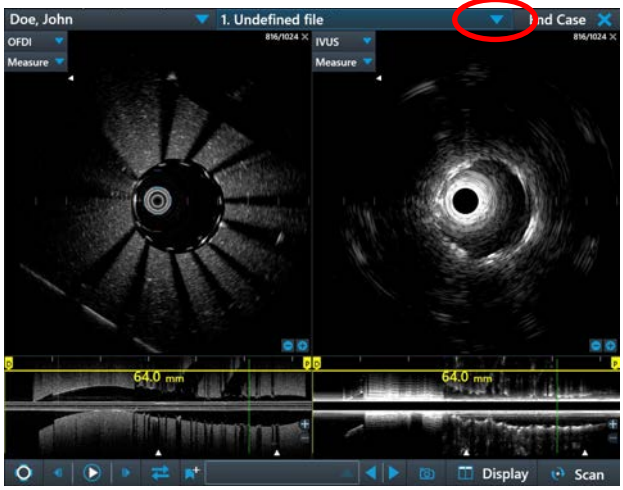



Fig. 13.3B Edit Name- Enter Pullback Information




Fig. 13.3C Edit Name- Click to Define Vessel



## Adjust Images

**WARNING**

- Avoid making image adjustments that may obscure portions of the image. These may cause deterioration of image quality resulting in misdiagnosis or mistreatment.

**METHOD 1:**

1. **Click on the [Display] button on the bottom of the system screen (Fig. 13.4)**
2. **Click on [Image displays] down arrow to open menu.**
3. **Select the adjustment control to the right of the display to open the adjustment menu.**
4. **Adjust the image settings on the image adjustment dialog (Fig. 13.5).**
   - Click the [Load] button to reset to the original image adjustment pre-set display settings.
5. **When finished adjusting, exit the Image Adjustment by selecting either (Fig. 13.5):**
   - the [OK] button to apply the image setting.
     -OR-
   - the [Cancel] button to exit without applying the adjusted settings.

*Images below uses OFDI as an example only. The following pages provides instruction on adjusting each image setting.*

Fig. 13.4 Method 1: Adjust Image Display

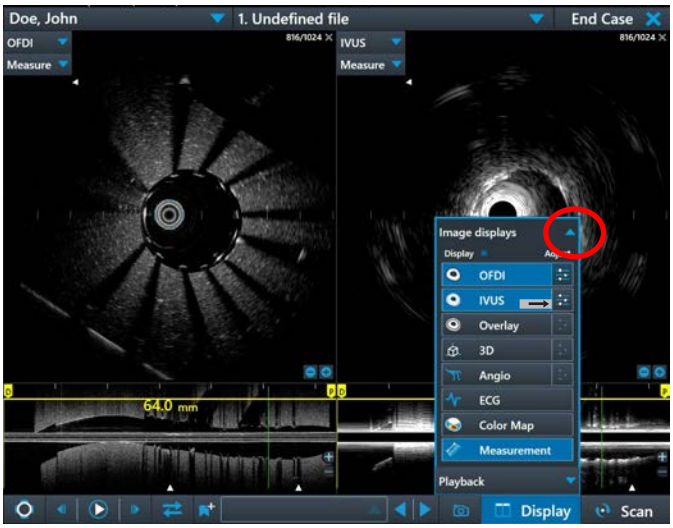



Fig. 13.5 Adjust the OFDI Image



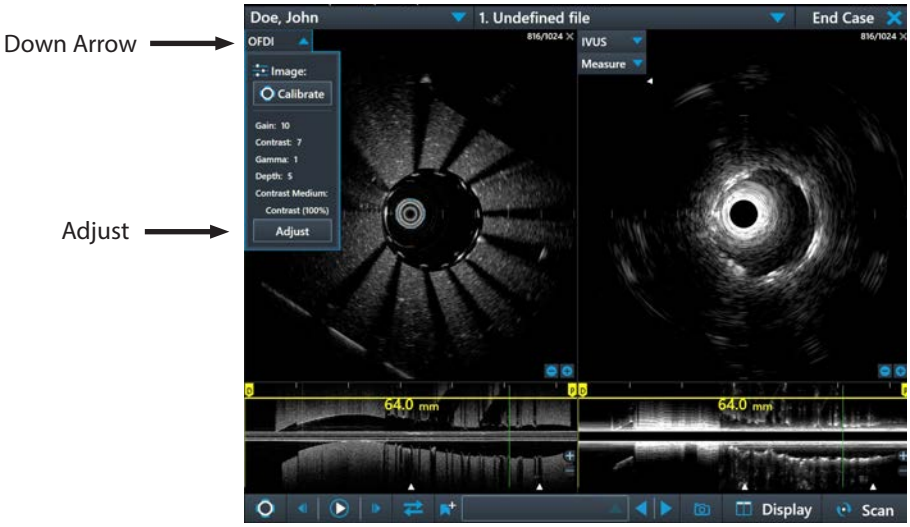
NOTE

- Adjustment is also available by clicking the down arrow next to the image being adjusted and clicking on [Adjust]. Refer to Figure 13.6.

**METHOD 2:**

1. **Click on the down arrow in the top left corner of the modality needing adjusted.**
2. **Click on [Adjust] in the pop-up menu.**
3. **Adjust the image settings on the image adjustment dialog (will be the same display as Fig. 13.6).**
4. **When finished adjusting, exit the Image Adjustment menu by selecting either:**
   - the [OK] button to apply the image setting.
     -OR-
   - the [Cancel] button to exit without applying the adjusted settings.

Fig. 13.6 Method 2: Adjust the Image Display



## Adjust OFDI Images

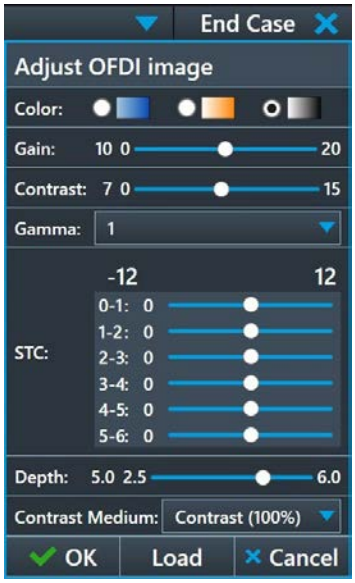
You can adjust the Image data display from the OFDI Image adjustment display (**Fig.13.7**).

1. **Open the OFDI image adjustment display (Fig. 13.7).**
2. **Adjust levels by increasing/decreasing numeric level using the slider or the arrow (for Gamma and contrast medium dropdown menu):**

Table. 13.4 OFDI Adjustment Display Settings

| Setting | Description | Lowest Value (Left) | Highest Value (Right) |
|---|---|---|---|
| Color | Select the type of rendering | • Blue: Specify blue as intermediate between black and white.<br>• Orange: Specify orange as intermediate between black and white.<br>• Gray: Default color map. | |
| Gain | Adjust Brightness | 0 | 20 |
| Contrast | Adjust Dynamic Range | 0 | 15 |
| Gamma | Gamma Correction Curve Adjustment | 1 | 10 |
| STC | Adjust Brightness of each specified depth range of the image data display area | • 0-1: 0 to 0.83mm radius range, centered on 0.43mm radius<br>• 1-2: 0.43 to 1.63mm radius range, centered on 0.83mm radius<br>• 2-3: 0.83 to 2.63mm radius range, centered on 1.63mm radius<br>• 3-4: 1.63 to 3.63mm radius range, centered on 2.63mm radius<br>• 4-5: 2.63 to 4.63mm radius range, centered on 3.63mm radius<br>• 5-6: greater than 3.63mm radius range, centered on 4.63mm radius | |
| Depth | The display depth for OFDI and IVUS is always synchronized. When the display depth is modified for OFDI image, the same display depth is applied to IVUS image. | | |
| | depth of view (8 levels) | 2.5 mm | 6.0 mm |
| Contrast Medium | The contrast medium can be selected in the OFDI image adjustment dialog. The contrast medium setting can be changed after data acquisition. The image will be reconstructed with the refractive index of the selected contrast medium. Select the type of contrast medium from the pull-down menu. | | |
| | Saline/Contrast Mix (5 levels) | | |
| | • Saline (100%): Normal saline solution<br>• Contrast (25%): Flush media of 25% contrast medium / 75% saline solution<br>• Contrast (50%): Flush media of 50% contrast medium / 50% saline solution<br>• Contrast (75%): Flush media of 25% contrast medium / 25% saline solution<br>• Contrast (100%): Flush media of 100% contrast medium | | |

Figure 13.7 Adjust OFDI Images

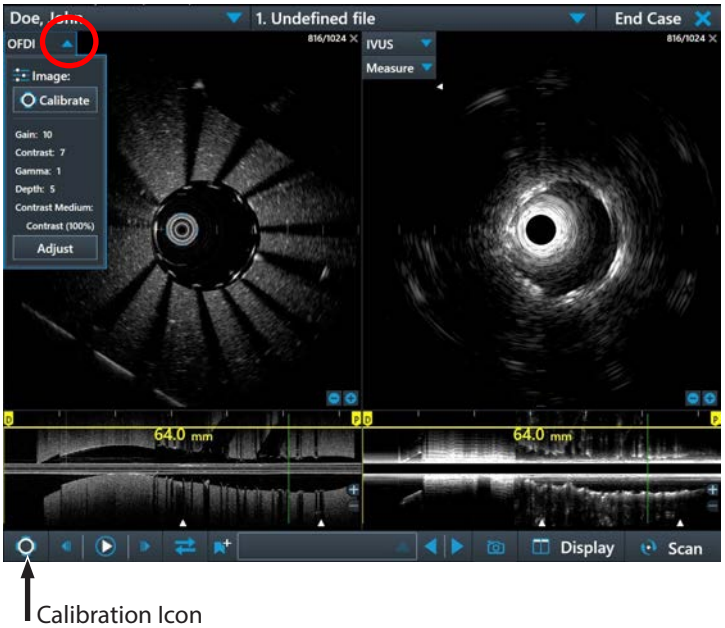


## Manual Calibration after Data Acquisition

Manually re-calibrate (OFDI only option) when the acquired data needs to be corrected (i.e. the blue lines align with the catheter's outer ring).

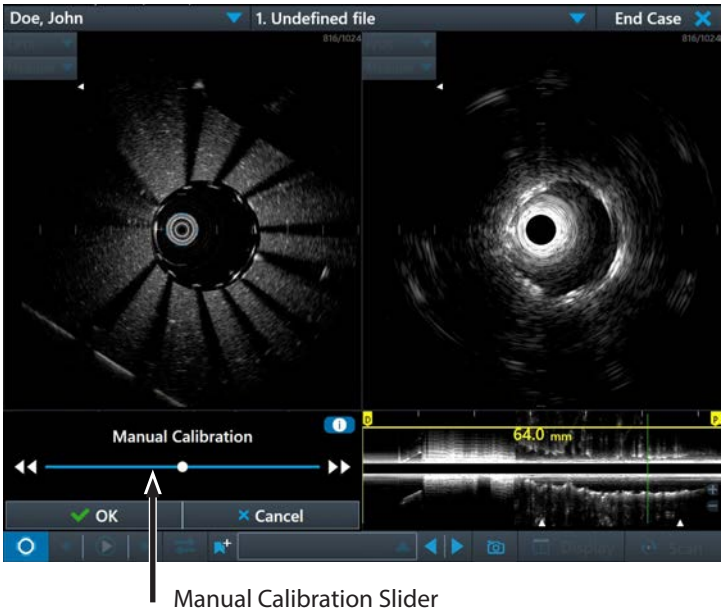
1. **Pull up the manual calibration bar by clicking the down arrow in the top left corner next to the modality and select [Calibrate].**
   **-OR-**
2. **Select the calibration icon in the bottom left corner of the screen (Fig. 13.8).**

Fig. 13.8 Select the calibration icon.




3. **Re-calibrate the displayed frame by using the Manual Calibration slider (Fig.13.9)**
   **-OR-**
   **by using the mouse wheel. For additional details, see "Manual-calibration" (Section 7).**

Fig. 13.9 Calibration slider for re-calibration.



## Adjust IVUS Images

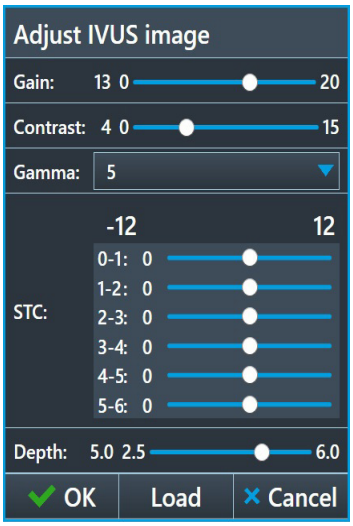
You can adjust the Image data display from the IVUS Image adjustment display:

1. **Open the IVUS image adjustment display (Fig. 13.10).**
2. **Adjust the image display of the IVUS image Adjustment display by increasing/decreasing the numeric level using the slider or the drop-down arrow:**

Table. 13.5 IVUS Adjustment Display Settings

| Setting | Description | Lowest Value (Left) | Highest Value (Right) |
|---|---|---|---|
| Gain | Adjust Brightness | 0 | 20 |
| Contrast | Adjust Dynamic Range | 0 | 15 |
| Gamma | Gamma Correction Curve Adjustment | 1 | 10 |
| STC | Adjust Brightness of each specified depth range of the image data display area | • Sliding the control slider rightward increases the brightness for the corresponding depth range.<br>• Sliding the control slider leftward reduces the brightness for the corresponding depth range.<br>• The following are adjustable depth ranges with each slider:<br>- 0-1: 0 to 0.83mm radius range, centered on 0.43mm radius<br>- 1-2: 0.43 to 1.63mm radius range, centered on 0.83mm radius<br>- 2-3: 0.83 to 2.63mm radius range, centered on 1.63mm radius<br>- 3-4: 1.63 to 3.63mm radius range, centered on 2.63mm radius<br>- 4-5: 2.63 to 4.63mm radius range, centered on 3.63mm radius<br>- 5-6: greater than 3.63mm radius range, centered on 4.63mm radius | |
| Depth* | depth of view (8 levels) | 2.5 mm | 6.0 mm |
| The display depth for OFDI and IVUS is always synchronized. When the display depth is modified for IVUS image, the same display depth is applied to OFDI image. | | | |

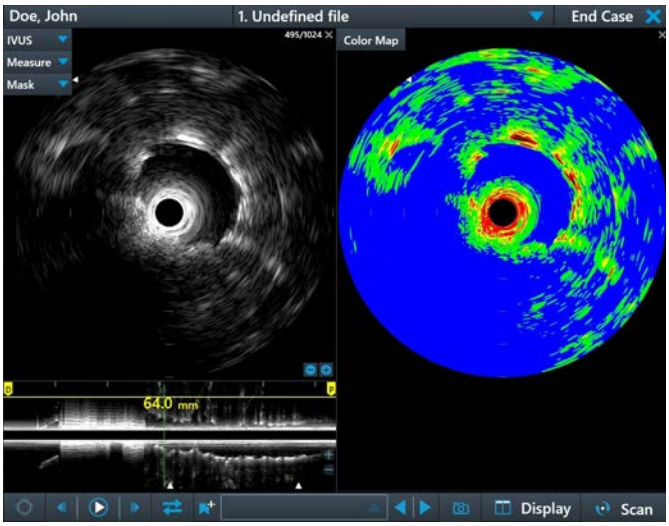
Fig. 13.10 Adjust IVUS Images



## IVUS Color Map

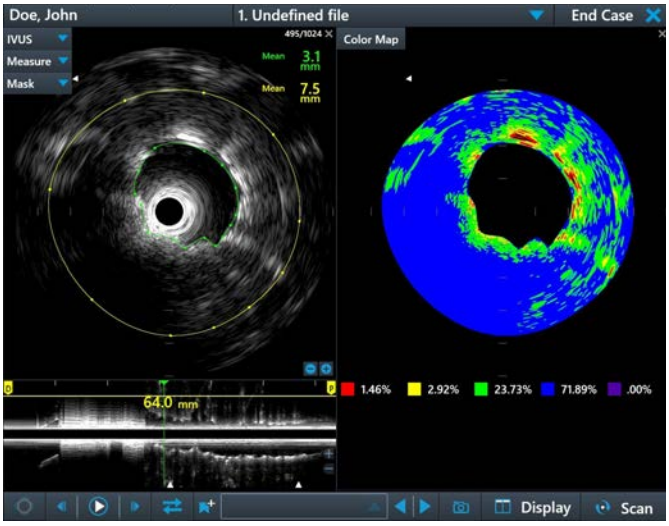
- **IVUS Color Map is available to apply the color code of red, yellow, green, blue, and purple as configured by System Settings (Refer to Section 20). (Fig. 13.11).**

Fig. 13.11 IVUS Color Map without Area Measurements



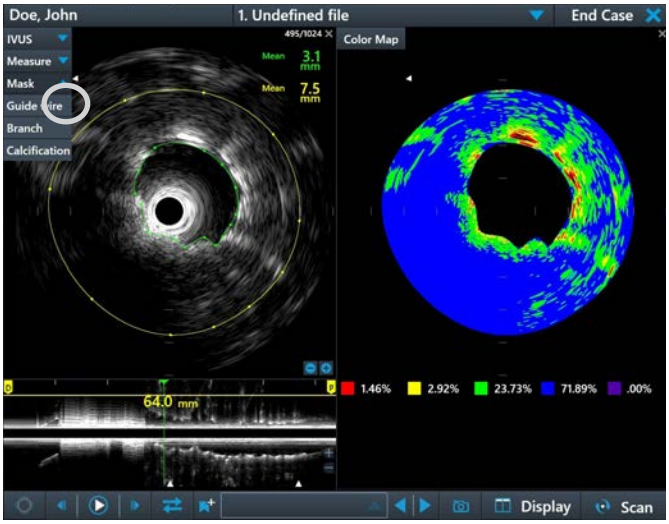

- **When the IVUS image has at least two area measurements, in which the larger one encompasses the other, it shows the percentage values of each color included in the area between the larger area and smaller area (Fig. 13.12).**

Fig. 13.12 IVUS Color Map with Area Measurements



You can exclude unnecessary area from color percentage calculation by applying mask on the IVUS cross-sectional image **(Fig. 13.13).**

Fig. 13.13 Mask Function Menu




1. **Click blue down arrow beside [Mask] to expand the drop-down menu for mask functions. The mask options available are:**
   - Guide Wire
   - Branch
   - Calcification

Guide Wire

1. **Select the [Guide Wire] option from [Mask] menu to draw circular sector by dragging and dropping the mouse pointer and specifying two straight lines ( Fig.13.14A).**

2. **When the circular sector is defined and the [OK] button is clicked, the circular sector for guide wire mask is committed and the masked area is excluded from color percentage calculation (Fig. 13.14B).**
   - Up to two circular sectors can be excluded as Guide Wire Masks.

Fig. 13.14A Guide Wire Mask

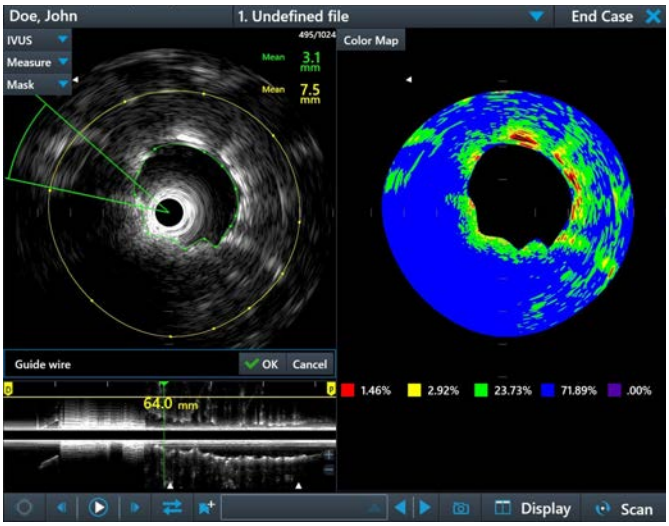
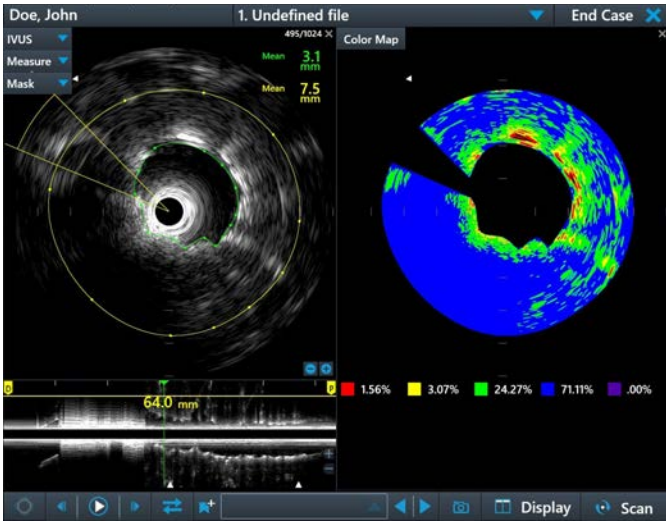



Fig. 13.14B Excluding Guide Wire Mask



Branch

1. **Select [Branch] option from [Mask] menu to draw an area surrounded by an arc and three straight lines. (Fig. 13.15A).**

2. **Click a point within the IVUS cross-sectional image to specify the start point of one of straight lines toward outside of image.**

3. **Click next point to define the first straight line (line #1 in Fig. 13.15A).**

4. **Click third point to define another straight line toward outside of image and the straight line connecting these two lines (line #2 in Fig. 13.15A).**

5. **Click at fourth point to define the line (line #3 in Fig. 13.15A) and the arc is drawn automatically when these three straight lines are defined.**

6. **When the mask area is defined and the [OK] button is clicked, the area for branch mask is committed and the masked area is excluded from color percentage calculation as shown by Fig. 13.15B. Up to two areas can be excluded as Branch Masks.**

Fig. 13.15A Branch Mask

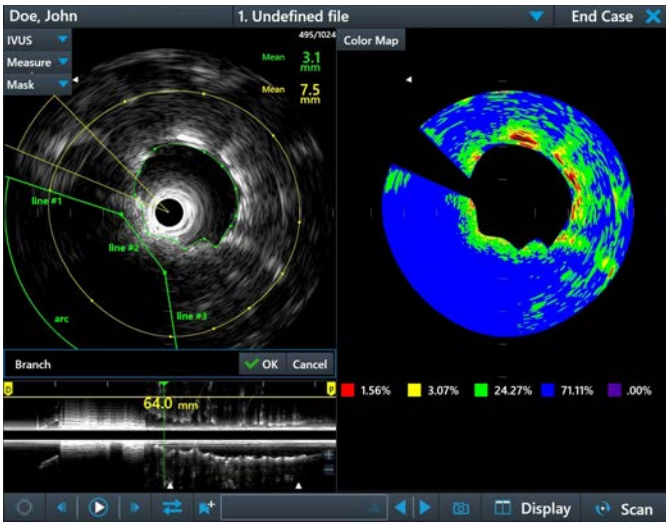
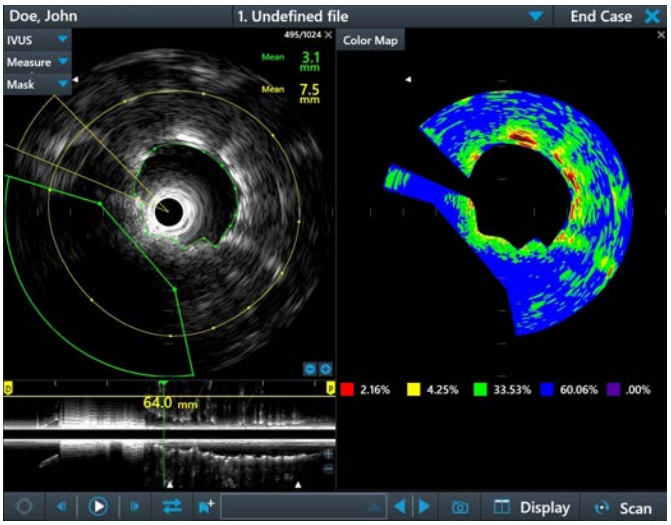



Fig. 13.15B Excluding Branch Mask



Calcification

1. **Select [Calcification] option from [Mask] menu to draw a curve as Fig. 13.16A.**

2. **Click up to 20 points within the IVUS cross-sectional image to specify a curve to locate calcification.**

3. **When the curve is defined and the [OK] button is clicked, the curve is committed and the area behind the curve is excluded from color percentage calculation as shown by Fig. 13.16B.**
   - Up to two areas can be excluded as Calcification Masks.

Fig. 13.16A Calcification Mask Curve

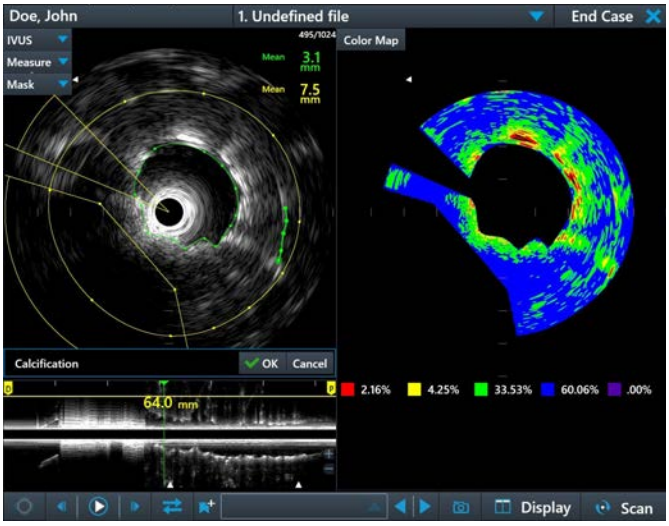
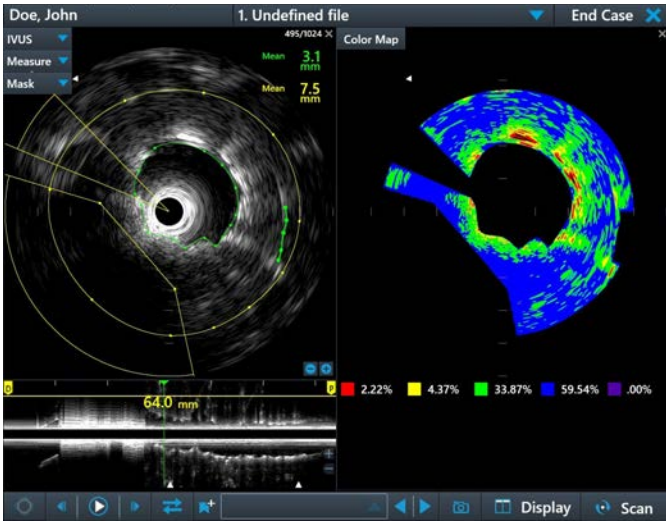



Fig. 13.16B Excluding Calcification Mask Curve



## Adjusting Angio Images

You can adjust the Image data display from the Angio Image adjustment display menu:

**WARNING**

- Adjust Angio delay for the equipment specific to the PCI Lab to ensure accurate co-registration. Failure to do so may result in image mismatches that could lead to uncertainty in the stent selection or placement.

1. **Open the Angio image adjustment display menu (Fig. 13.17).**
2. **Adjust levels by increasing numeric level using the slider or the drop-down arrow:**

Fig. 13.17 Adjust Angio Images

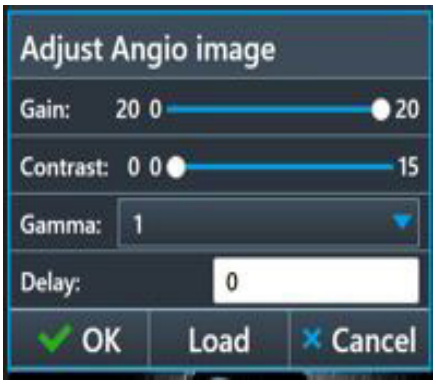



Table. 13.5 Angio Adjustment Display Settings

| Setting | Description | Lowest Value (Left) | Highest Value (Right) |
|---|---|---|---|
| Gain | Adjust Brightness | 0 | 20 |
| Contrast | Dynamic Range | 0 | 15 |
| Gamma | Gamma Correction Curve Adjustment | 1 | 10 |
| Delay | Angio Delay Compensation Value: Configure the best angio delay compensation value to obtain the best co-registration with angio and OFDI + IVUS image | 0 | 1023 |

### Adjusting Angio Delay Setting

1. **You can enter the Angio Delay from the keyboard to shift the co-registration between OFDI + IVUS and Angio images. When the Delay setting becomes larger, the Angio image starts from later frame to adjust the displacement.**

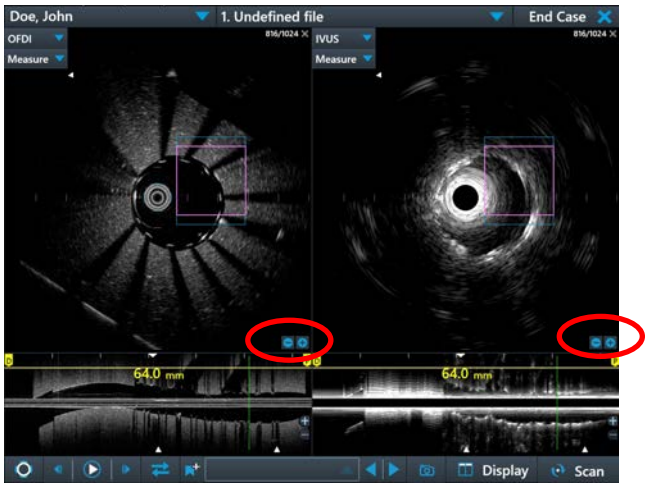
# Image Control

## Cross-Sectional Zoom

To Zoom in the Cross-Sectional View (**Fig.13.18**):

1. **Click and drag in the desired area on the Cross-sectional image to be enlarged. The magenta rectangle indicates the area to be enlarged.**
2. **When the cross-sectional image for one of the Dual Mode images is zoomed in, the other cross-sectional image is synchronously zoomed in to the same size.**
3. **Double click on the cross-sectional view area to return to the original magnification.**

Fig 13.18 Cross-Sectional Zoom

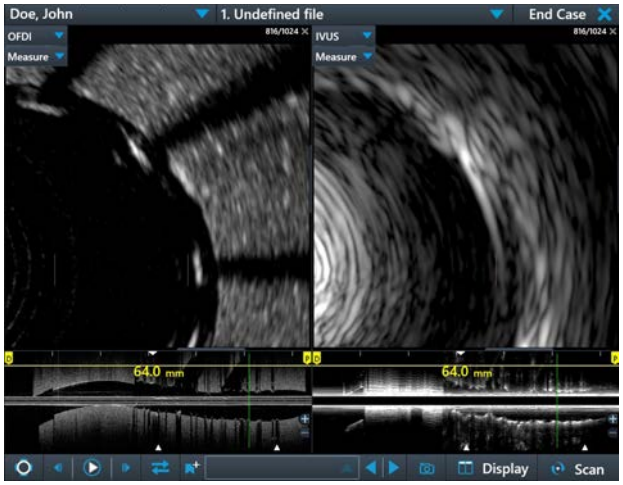



## Image Depth

To change the Cross-Sectional Image Depth **(Fig. 13.19)**:

1. **Click the [+] a button to increase to enlarge.**
2. **When the cross-sectional image for one of the Dual Mode images is zoomed in, the other cross-sectional image is synchronously zoomed in to the same size.**
3. **Click the [-] button to decrease image depth or return to the original magnification.**

Fig 13.19 Cross-Sectional Image Depth

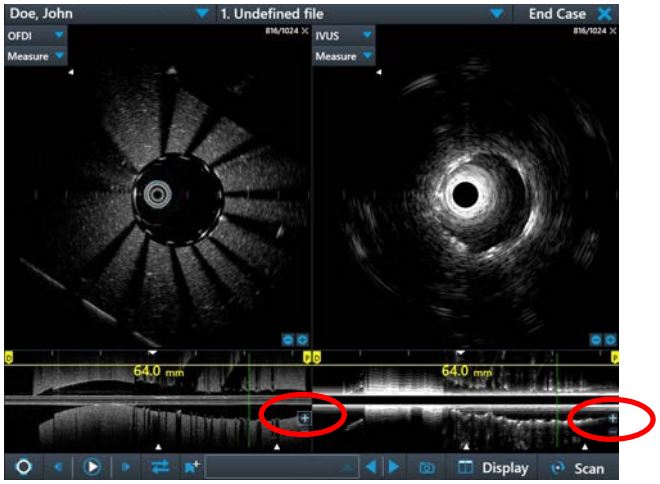



## Longitudinal Zoom

To Zoom in the Longitudinal View **(Fig. 13.20)**:

1. **Click the [- +] buttons to zoom in/out on the longitudinal view area.**
2. **Click on the [+] button to reduce the longitudinal view range by 25 mm increments.**
   - The displayed image section is then enlarged the to the full screen.
   - The minimum longitudinal view range is 50 mm.
3. **Click on the [-] button to increase the longitudinal view range in 25 mm increments up to the entire pullback.**
   - The default value of the longitudinal view range is 150 mm.

Fig. 13.20 Zoom in Longitudinal View



## Panning

When the Cross-sectional image is zoomed in, horizontal and vertical scrollbars are displayed on right and bottom of the cross-sectional image.

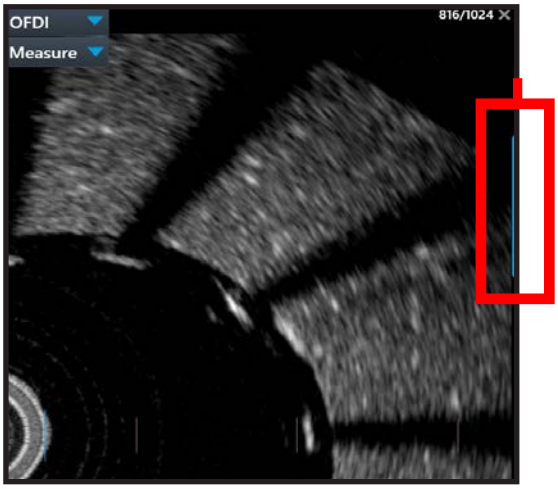
To Pan in the Cross-Sectional View **(Fig.13.21A and Fig. 13.21B):**

1. **Pan horizontally (Left/Right) using the scrollbar at the bottom of the screen (Fig. 13.21A).**
2. **Pan vertically (Up/Down) using the scrollbar at the bottom of the screen.**

Fig. 13.21A Pan horizontally




Fig. 13.21B Pan Vertically

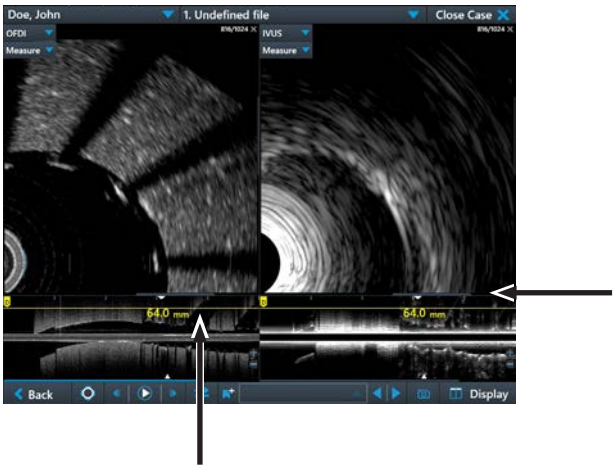



To Pan in the Longitudinal View (**Fig.13.21C):**

When the longitudinal image is zoomed in, a horizontal scrollbar is displayed at the bottom of the screen.

1. **Pan horizontally (Left/Right) using the scrollbar at the bottom of the screen.**

Fig. 13.21C Pan Longitudinal View

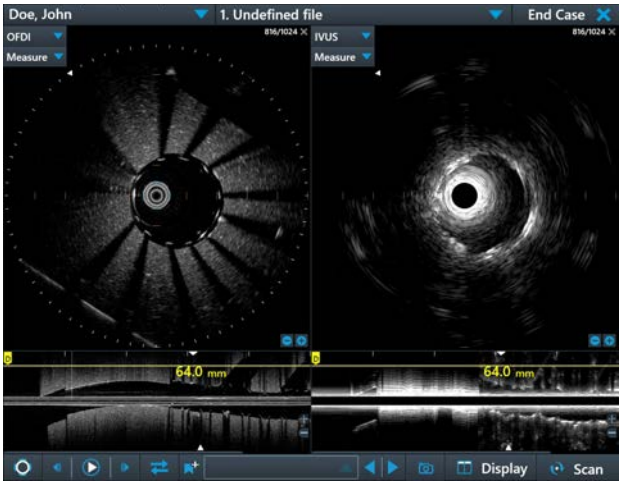


## Cross-Sectional Image Rotation

To change the orientation of the cross-sectional image, rotate the dial around the circumference of the cross-sectional image:

1. **Place the cursor on the outer circumference of the cross-sectional view to show the rotation dial (Fig. 13.22).**
2. **While the rotation dial is displayed, press the left button of the mouse, and drag the mouse to rotate the cross-sectional image.**
3. **Release the left button of the mouse to confirm the image position.**

Fig. 13.22 Image Rotation




NOTE

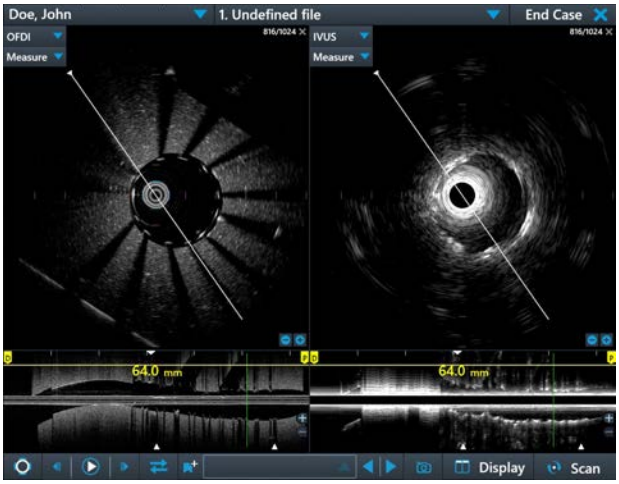
- The image can be rotated 360 degrees either clockwise or counterclockwise.
- If Rotation setting is Sync in Playback menu, OFDI and IVUS cross-sectional images are synchronously rotated for Dual Mode image. If Rotation setting is Async, OFDI and IVUS cross-sectional image can be individually rotated.

## Longitudinal Cut Plane Rotation

To set the angle of the longitudinal cut plane to define the image displayed in the longitudinal view area:

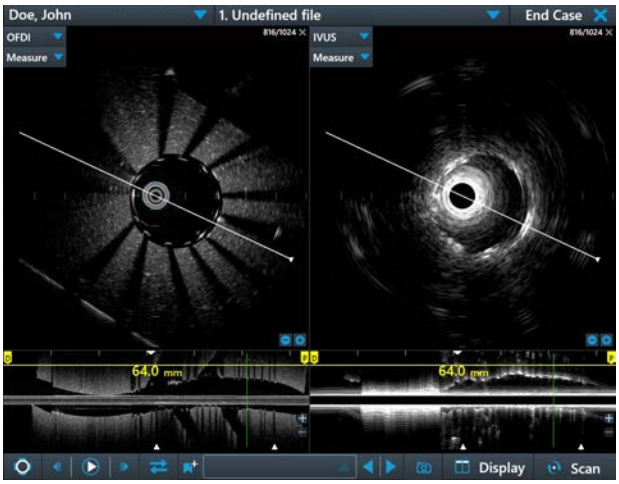
1. **Place the cursor on the cut plane indicator ▼ displayed on the outer circumference of the cross-sectional image and click and hold left mouse button to display the cut plane line (Fig. 13.23).**

Fig. 13.23 Display Cut Plane Line




2. **Drag and drop the cut plane indicator to the desired position to set the cut plane (Fig. 13.24).**

Fig. 13.24 Set Cut Plane Line



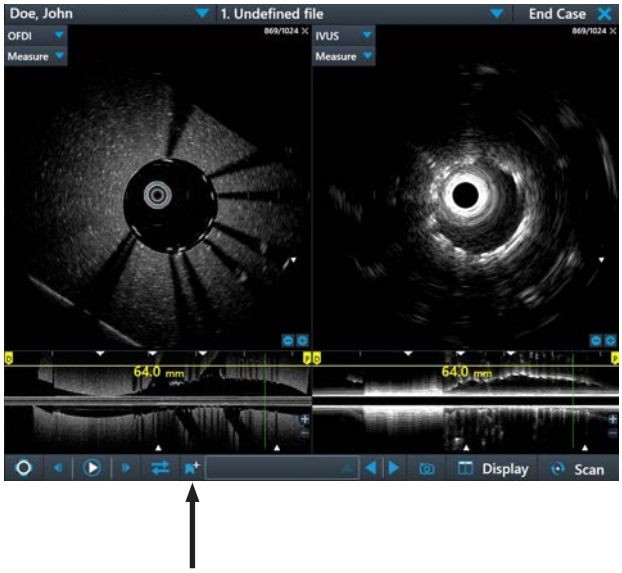
## Placing Bookmarks

In review mode, you can place bookmarks to frames of interest. This feature facilitates image searching by "skipping" through bookmark frames for additional review/analysis.

### Adding a Bookmark

1. **While the pullback/recording is being reviewed, press the "Bookmark" icon on the system screen when the frame of interest is displayed (Fig. 13.25).**
   - When the bookmark icon is pressed, a bookmark is pinned to the relevant frame and the position is indicated at the top of the longitudinal view area with a triangle ▼ symbol.
   - In Dual Mode, when a bookmark is added to one modality, it is synchronously added to the corresponding modality.
   - Frames that have measurements are bookmarked automatically.

Fig. 13.25 Bookmark Button

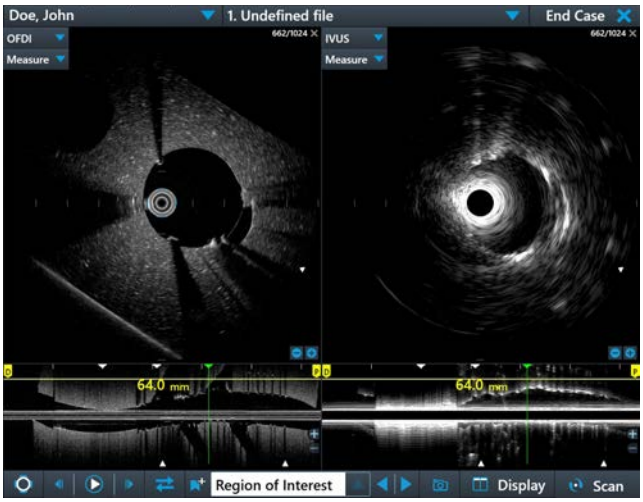


## Labeling a Bookmark

To label a bookmark:

1. **Select the bookmarked frame to be labeled (Fig. 13.26A).**
2. **Click the label field.**
   - The bookmark label edit box is changed to an editable field.
3. **Using the keyboard, enter the text to label the bookmark.**
4. **Press the [Enter] key on the keyboard to create the label.**

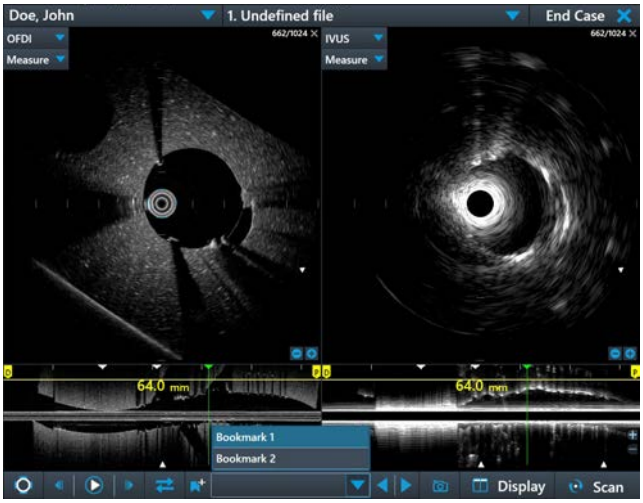
Fig. 13.26A Labeling a Bookmark




Label Field

5. **Press the blue "Up" triangle to expand the list of predetermined bookmarks. Press the down arrow to minimize the list (Fig. 13.26B). Refer to section 20 for bookmark comment list configuration.**

Fig. 13.26B Bookmark List

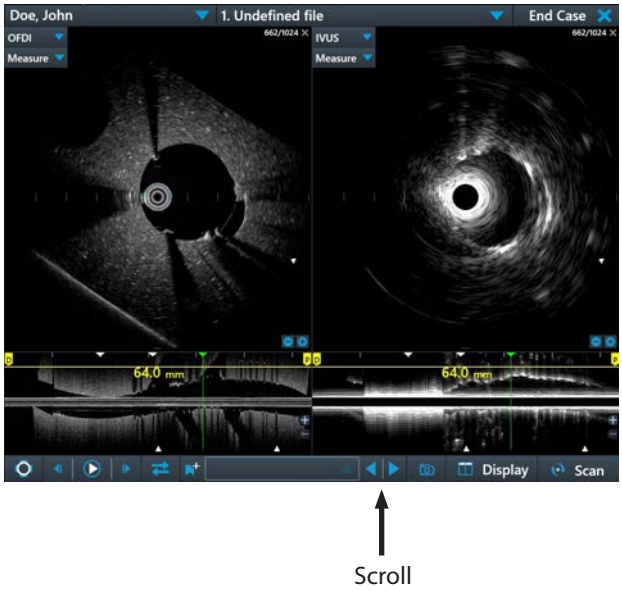



Up/Down Triangle

## Finding Bookmarked Frames

1. **To scroll through bookmarks, click on the Bookmark Forward and Bookmark Backward arrow next to the bookmark label area (Fig. 13.27).**
   - The image will move to the closest bookmark on the left or the right from the image that is currently displayed.
   - Continue to click on the arrow to scroll sequentially through the bookmarks to either the left or right of the displayed image.
   - The displayed bookmark turns green to indicate the bookmark being viewed.

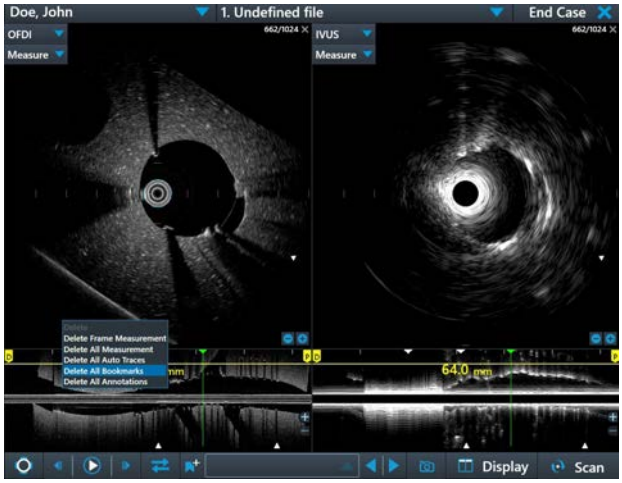
Fig. 13.27 Bookmark Scroll




## Deleting Bookmarks

1. **While playback is paused, click the right or left arrow next to the bookmark icon to scroll to the bookmark to be deleted.**
   - The displayed bookmark position turns green.
2. **To delete the selected bookmark, click Bookmark icon.**
3. **To delete all bookmarks: Right click and select [Delete All Bookmarks] on the popup menu (Fig. 13.28).**
   - Select [OK] to confirm deletion of all bookmarks or press [Cancel] to return to the image without deleting the bookmarks.

Fig. 13.28 Delete All Bookmarks

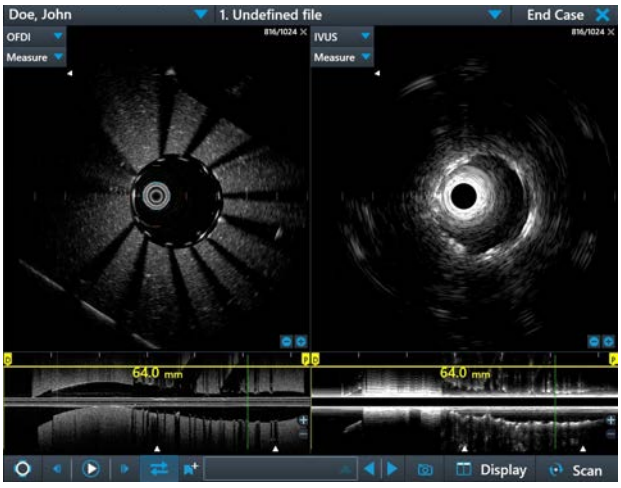


# Review

## Shuttle Playback

In review mode, press Shuttle Playback button **(Fig. 13.29)** to repeat playback for configured frame counts 1-5 frames. Refer to "Adjusting Playback settings" on page 100 for additional information.

Fig. 13.29 Shuttle Playback

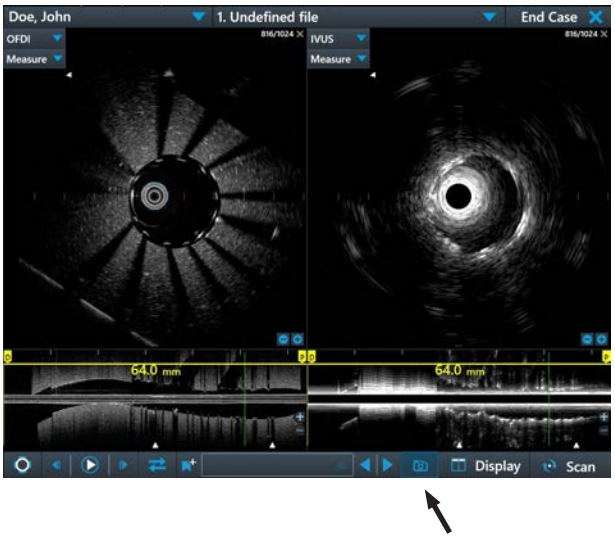



## Image Snapshot

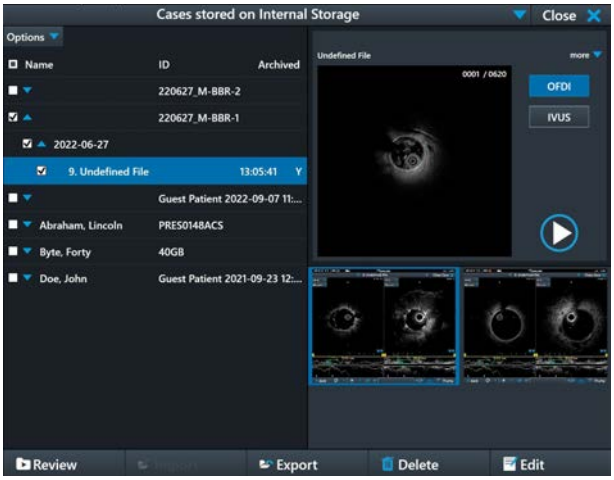
To capture still images in review mode.

1. **Go to the ROI or frame of interest.**
2. **Click the Snapshot Icon on the system screen (Fig. 13.30A).**
   - The image will automatically save in the Pullback List.
3. **To access the saved snapshot images, go to the Home screen and select [View Previous Cases] (Refer to Section 15).**
   - Select the Pullback from the list that contains the snapshot images of interest. All saved snapshot image thumbnails appear when the pullback is selected.
   - Select Snapshot to export **(Fig. 13.30B)**.
   - Select [Export] to export the image to external media, or [Delete] to permanently delete.
   - Click [Close] to close the window.

Fig. 13.30A Snapshot Icon




13.30B Select Snapshot



## Switch Screen Displays

To switch the modalities displayed:

1. **Click on the [Display] button to open the Image Displays menu (Fig.13.31).**
2. **Select/highlight modalities to display on the screen.**
3. **The system displays the modalities selected/ highlighted in the pullup menu to a maximum of three.**

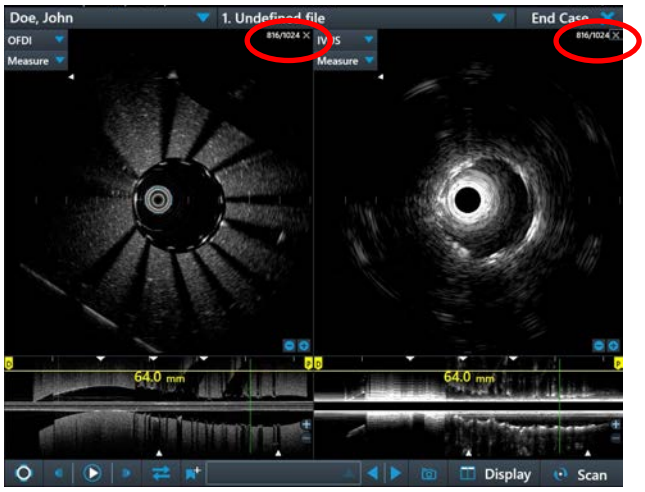
Fig. 13.31 Modalities Display




To switch to a single modality while in dual modality:

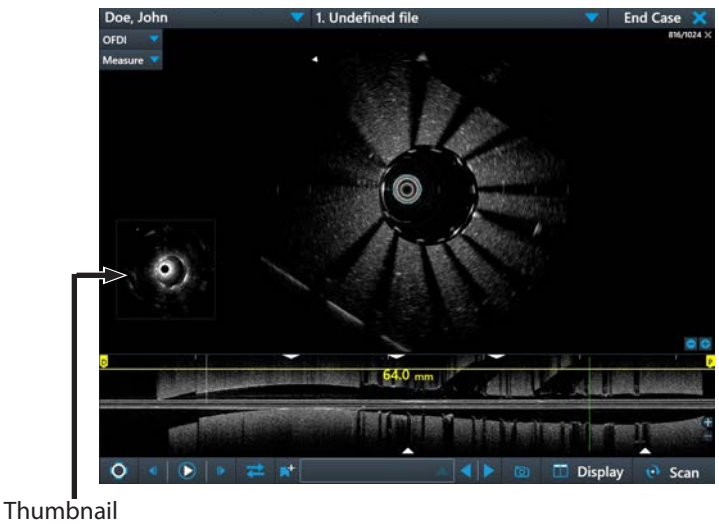
1. **Select the [X] in the top right corner (Fig. 13.32A).**
   - The single modality display in Dual Mode shows the selected modality larger at the center, and thumbnail of another modality on left-bottom corner **(Fig. 13.32B)**.

Fig. 13.32A Dual to Single Display




2. **To switch from single modality back to dual modalities display:**
   - Double-click the thumbnail (**Fig. 13.32B**).

Fig. 13.32B Single to Dual Display



## 3D (3 Dimensional) Images- OFDI Only

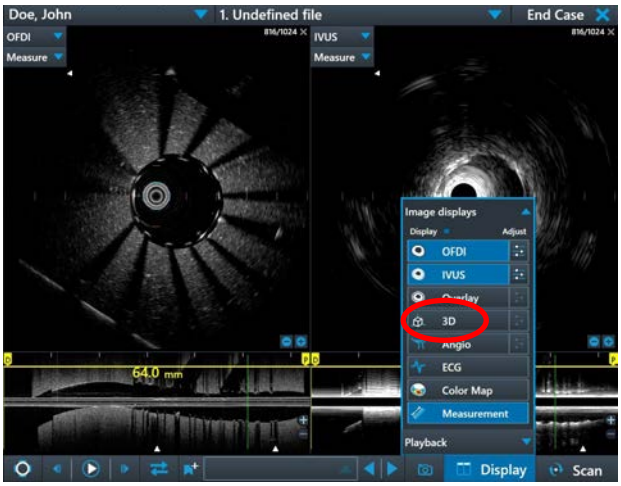
**NOTE**

- 3D Image Display feature is only available for OFDI Images.
- Displaying 3D image requires reconstruction time. Wait until the reconstruction progress indicator dialog closes.

To display the acquired data in 3D (three-dimensional view) during review:

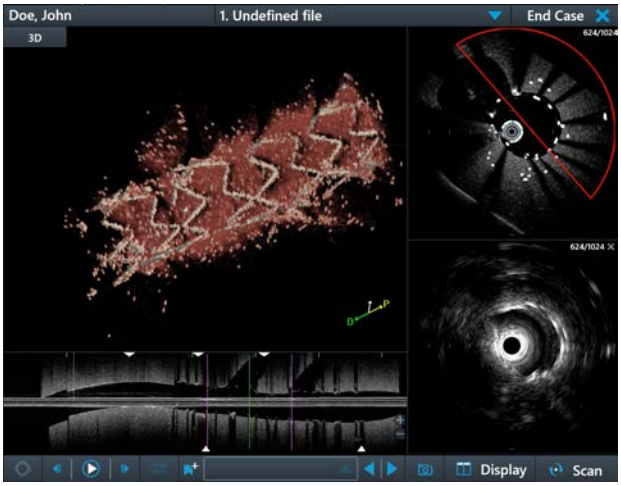
**1. Open the 3D image adjustment display and select [3D] (Fig. 13.33A).**

Fig. 13.33A Image Adjustment Display




**2. The system will display the 3D image (Fig. 13.33B).**

Fig. 13.33B 3D Image Display




**NOTE**

- Fig. 13.33A illustrates the display including OFDI cross-sectional/longitudinal image, IVUS cross sectional image and 3D images. The display layout can be configured without IVUS by de-selecting the IVUS from the display menu.
- Fig. 13.33B shows vessel view of 3D image. If the system setting for 3D is configured to carpet view as default setting, the carpet view is displayed instead of vessel view when 3D reconstruction is completed.
- If the image includes stent located in the vessel, the stent struts are emphasized in the image.

To adjust the 3D Image data display:

1. **Click the Display button on the system screen to open the Display menu and select the adjustment control to the right of the 3D option (Fig. 13.34A)**
   - Refer to Table 13.6 for the 3D Image Display Adjustment Display Settings.

Fig. 13.34A Display Menu

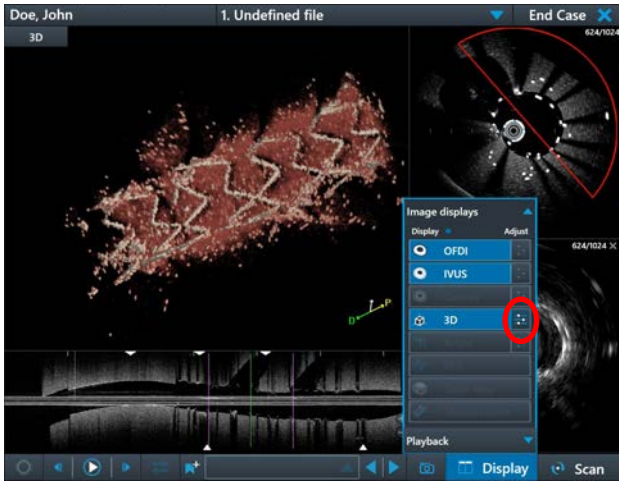



Fig. 13.34B Adjust 3D Image- Vessel View

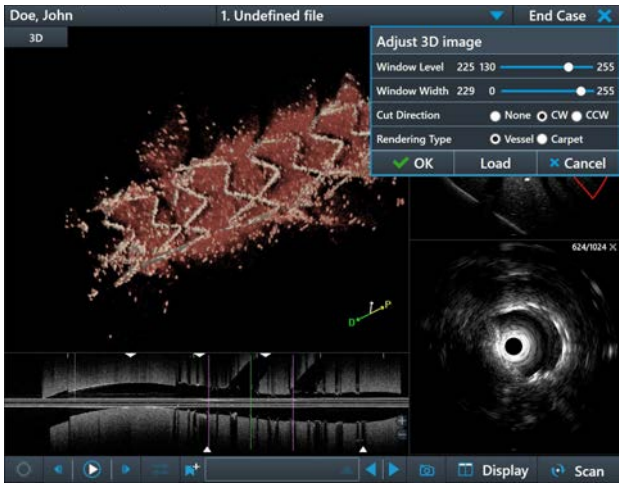
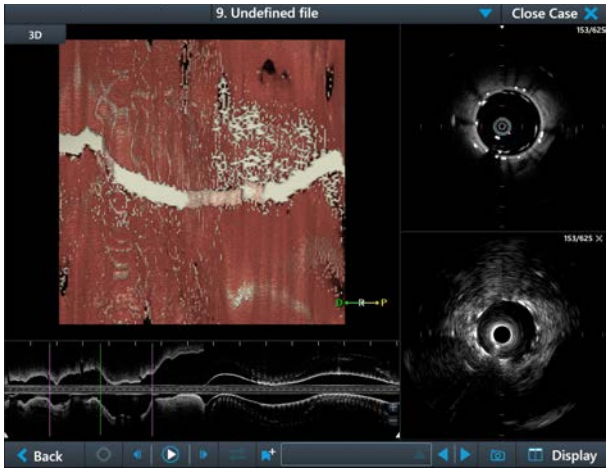



Fig. 13.34C 3D Carpet View



**2. Adjust the image settings on the "Adjust 3D Image" dialog box (Fig. 13.4B).**

- Click the [Load] button to reset to the original image adjustment pre-set display settings.

Table. 13.6 3D Image Display Adjustment Display Settings

| Setting | Description | Lowest Value (Left) | Highest Value (Right) |
|---|---|---|---|
| Window Level | Used for 3D image processing to adjust the opacity and intensity level. | 130 | 255 |
| Window Width | | 0 | 255 |
| Cut Direction | Cut direction of 3D image against the cut plane displayed on OFDI Cross-Sectional image if the configuration is not "None". | Selection from None, CW (Clockwise) or CCW (Counterclockwise).<br>It defines which direction of the 3D image is displayed on the screen against the cut plane when Vessel view is selected for Rendering Type. If "None" is selected, the vessel image model does not have any cut plane and it is viewed from outside of the vessel image.<br>If Carpet view is selected for Rendering Type, this option becomes disabled and grayed out. | |
| Rendering Type | 3D Image Display type | Selection of the 3D image type from Vessel view or Carpet view.<br>If "Vessel" is selected, the 3D image of vessel which is cut at the cut plane location is displayed.<br>If "Carpet" is selected, an image that the vessel wall is cut and unfolded is displayed to see inside the vessel.<br>**(Fig. 13.34B and 13.34C)**. | |

**3. When finished adjusting, exit the Image Adjustment by selecting either**

- **the [OK] button to apply the image setting.**
  **-or-**
- **the [Cancel] button to exit without applying the adjusted settings.**

# Section 14
# Measurements and Annotations

# Measurements and Annotations

**WARNING**

- Refer to instructions on creating measurements and annotations prior to using. Failure to do so may result in inaccurate measurements, leading to misdiagnosis/misinterpretation of the data.
- The user is responsible for diagnosis based on their interpretation and measurement of images during the procedure.
- Compare the measurement results obtained by the OPUSWAVE System with results obtained by angiographic imaging system. Ignoring this recommendation may lead to misdiagnosis.

CAUTION

- Do not perform quantitative evaluations of the image when any artifact is found on the image; the image may not be displayed properly, resulting in inaccurate measurements which could lead to misdiagnosis.

## Using Measurement Tools

The OPUSWAVE System provides measurement tools and calculations that can be applied in the cross-sectional and longitudinal view of the image (**Table 14.1**):

Table 14.1 Measurement Tools and Calculation Descriptions

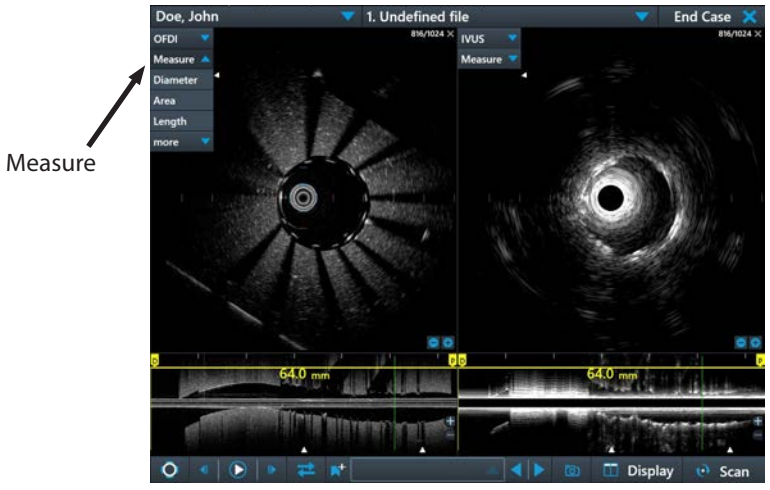
| Measurement Tools | | | Description | Unit |
|---|---|---|---|---|
| Cross-sectional view | Area/ Lumen/% Area Ratio | Area | Area of traced closed curve (three areas per modality, one lumen for OFDI). | $mm^2$ |
| | | Mean Dia. | Mean diameter of a traced closed curve. | mm |
| | | Min. Dia. | Minimum diameter of a traced closed curve. | mm |
| | | Max. Dia. | Maximum diameter of a traced closed curve. | mm |
| | Diameter | | Distance between two points (five measurements per modality). | mm |
| | Angle | | Angle at the corner specified by a pointer (two measurements per modality). | degree |
| | Thickness | | Distance to lumen from a measurement point (eight measurements per modality). | mm |
| Longitudinal view | Length | | Distance between two frames (five measurements per pullback). | mm |

NOTE

- In OFDI images, confirm calibration before making measurements (see "Manual Calibration").
- Cross-sectional measurements are applied to single modality individually but length measurements are applied to both modalities synchronously for Dual Mode image data.
- Whenever a measurement is made, a bookmark is automatically placed on that frame (Fig. 14.1).

**1. Click [Measure] to view the available tools listed in the sub-menu (Fig. 14.1).**

Fig. 14.1 [Measure] Menu

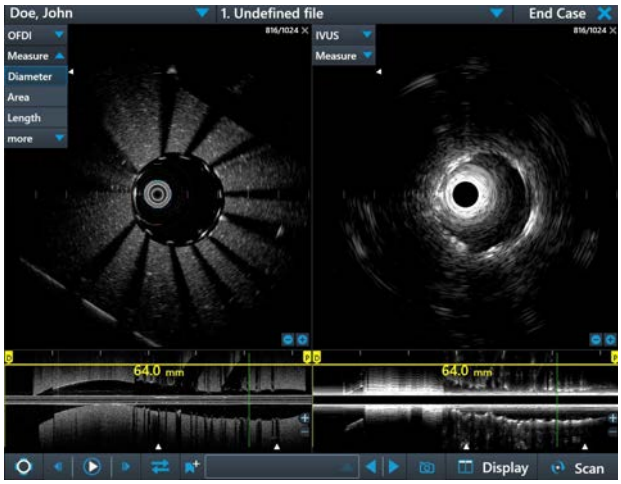


## Diameter

The diameter measurement tool measures the distance (in mm) between two user created points on a straight line in the cross-sectional view. It is intended to allow the user to measure size of the diameter of the Lumen, Vessel, Stent, or other region.

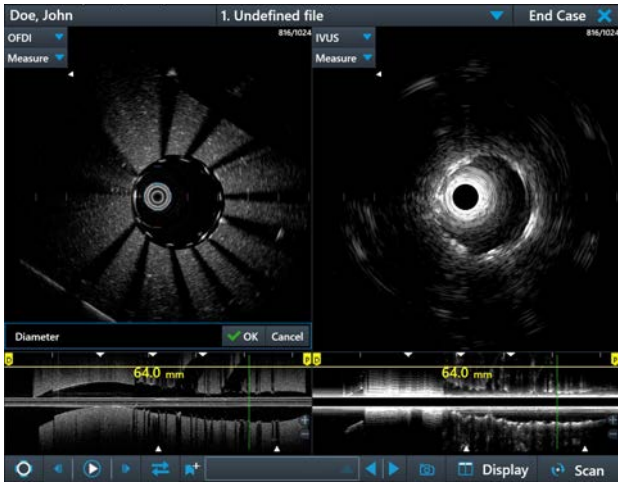
1. **Click on [Diameter] under the Measurement menu (Fig. 14.2).**

Fig. 14.2 Diameter Measurements Menu




2. **Confirm the Diameter measurement tool selected to begin measurement or select cancel to exit (Fig. 14.3).**

Fig. 14.3 Confirm Measurement



3. **Click and hold the left button of the mouse to create the starting point of the measurement.**

4. **Drag the mouse to the end point of the measurement.**

5. **Release the mouse button to set the diameter measurement (Fig. 14. 4A and 14.4B.).**
   - The measurement value will be calculated and placed on the right of the cross-sectional image in the image window in the same color as the measurement line.
   - The measurement is displayed with one decimal place by default. The value can be displayed at two decimal places when the cross-sectional image is zoomed in.
   - Repeat up to five times.

6. **Press OK button to confirm all diameter measurements -or- Press Cancel button to discard all non-confirmed diameter measurements.**

Fig. 14.4A Diameter Measurements

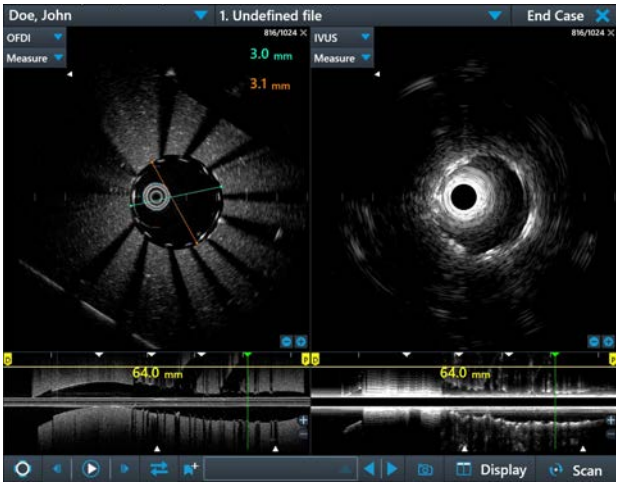
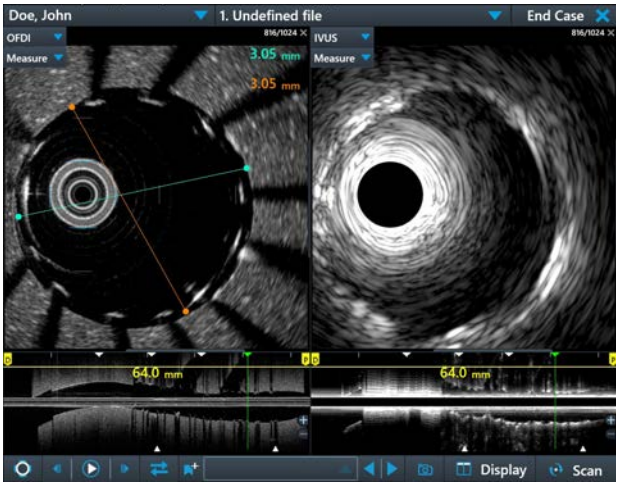



Fig. 14.4B Zoomed Diameter Measurements



## Area

The area measurement tool measures the area of a closed trace in the cross-sectional view.

1. **Click on [Area] under the Measure menu.**
2. **Click the left button of the mouse at the starting point of the area measurement to create the first point.**
3. **Continue to add points by clicking the pointer in the area of interest.**
   - A maximum of thirty-two points can be added around to define a closed curve for area measurement. A minimum of four points are required.
   - The measurement value will be calculated and placed on the right of the cross-sectional image in the image window in the same color with the measurement closed curve.
   - When you manually create the area measurement of a closed curve, the mean diameter for the area is displayed by default **(Fig. 14.5A)**.
4. **Press OK button when all area measurement points are located to commit the area.**
   **-OR-**
   **Press Cancel button to discard all non-confirmed area measurement points.**
5. **Click the mean diameter value to view the measurement display containing:**
   - Mean diameter, minimum diameter, maximum diameter, and area values for the area measurement of the closed curve **(Fig. 14.5B)**.
   - If there are multiple area measurement lines in a frame, the difference between the two areas is calculated as % area ratio and displayed in the detail measurement display dialog.
   - The color of % area ratio indicates the area which was used for the calculation. For example, the green value in **Fig. 14.5C** indicates the ratio between orange lumen and green area, and the yellow value indicates the ratio between orange lumen and yellow area.
6. **Click the measurement display to close and return to the mean diameter display.**

Fig. 14.5A Area Measurement

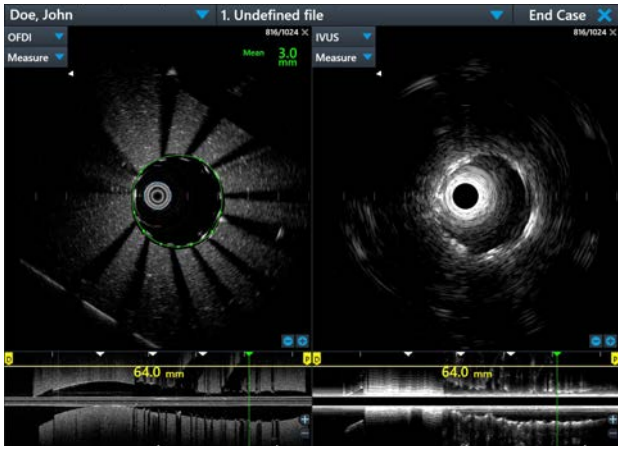



Fig. 14.5B Area Measurement Panel

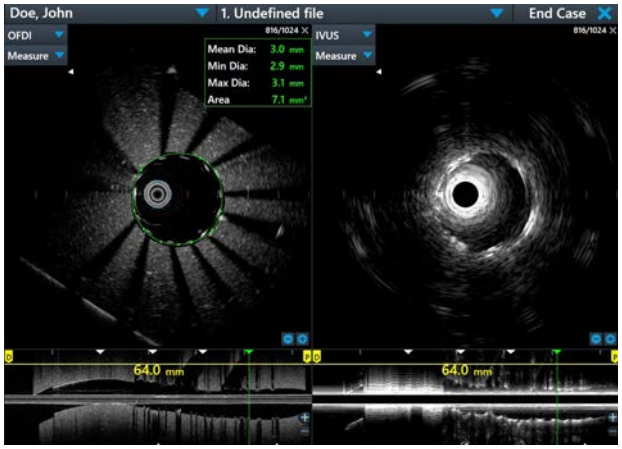
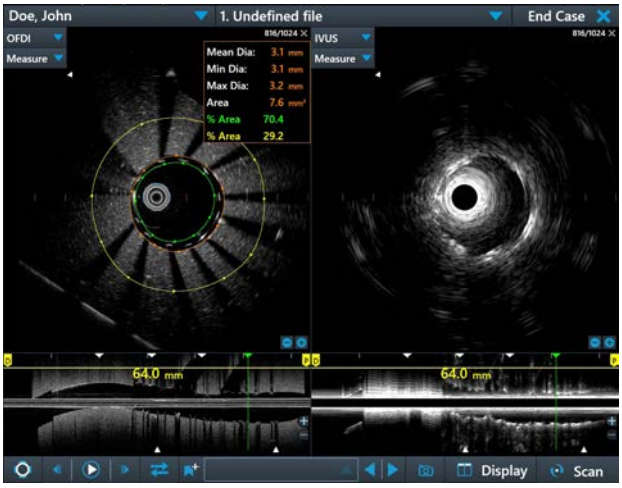



Fig. 14.5C % Area Ration Display

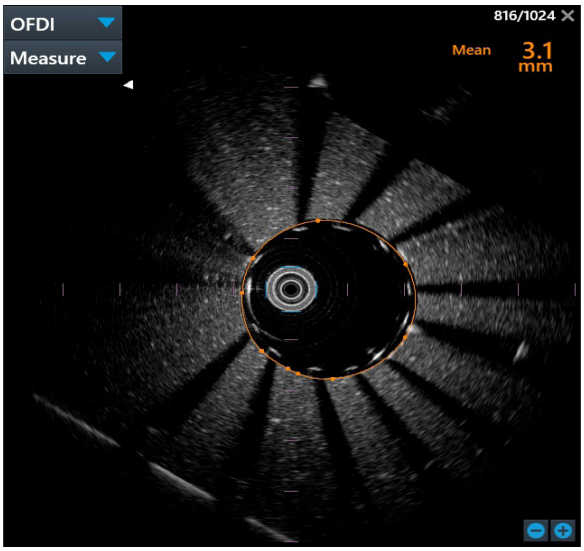


## Single Frame Auto Lumen Detection

Auto Lumen Detection function is provided for OFDI images, which auto-creates a trace of the lumen.

1. **Click on [Area] under the Measure menu.**
2. **Click on [Auto] button to achieve auto lumen detection (Fig 14.6).**
3. **Manually adjust the auto-lumen detection measurement line if adjustments are needed.**

Fig. 14.6 Traced Lumen



## Length

The length tool measures the distance (in millimeters) between two frames in the longitudinal view.

**1. Click on [Length] under the measure menu.**

- If there is any bookmark for the pullback, the length measurement line from the current frame to the closest bookmark is displayed (**Fig. 14.7A**).
- If there is not a bookmark created for the pullback, the length measurement line with 25.0 mm is displayed from the current frame in proximal direction **(Fig. 14.7B)**.
- In Dual Mode, when a length measurement is added to one modality, it is synchronously added to the corresponding modality.

**2. Drag and drop either end point of the length measurement line to the desired location.**

- While moving the length measurement line, the cross-sectional images for both edges of the measurement lines are displayed on the screen.
- The measurement value will be calculated and placed under the length measurement line in the image window in same color as the line.

NOTE

- The length measurement line can move vertically within the longitudinal view.

Fig. 14.7A Length Measurement (with Bookmark)

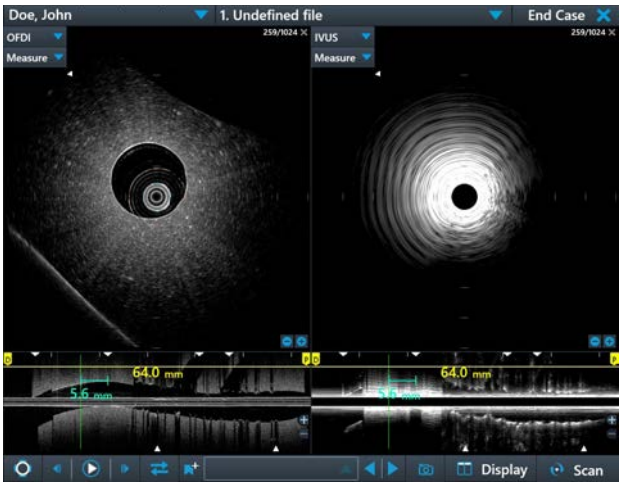
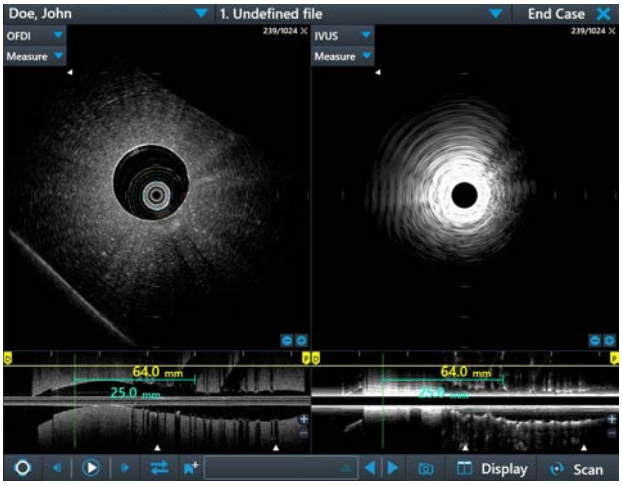



Fig. 14.7B Length Measurement (without Bookmark)



## Thickness

The thickness tool measures the distance (in millimeters) from the specified point to the existing traced lumen in the cross-sectional view.

NOTE

- A traced lumen is required prior to calculating thickness measurements.

1. **Click on [More] to expand the Measure menu (Fig. 14.8A).**
2. **Click on [Thickness] button on the measurement menu.**
3. **Click the point to measure the thickness on the cross-sectional image with the traced lumen. A thickness measurement line will be drawn from the specified point to the lumen line.**
4. **The measurement value will be calculated and placed on the right of the cross-sectional image in the image window in same color with the line. (Fig. 14.8B and Fig. 14.8C).**
5. **Repeat clicking the point up to eight times to make multiple thickness measurements if needed.**
   - After all measurement points are located press the OK button to confirm [Thickness] measurement points or press Cancel to discard all non-confirmed thickness measurement points **(Fig. 14.8B)**.
   - The measurement is displayed with one decimal place by default. The value can be displayed at two decimal places when the cross-sectional image is zoomed in **(Fig. 14.8C)**.

Fig. 14.8A Thickness Measurement Menu

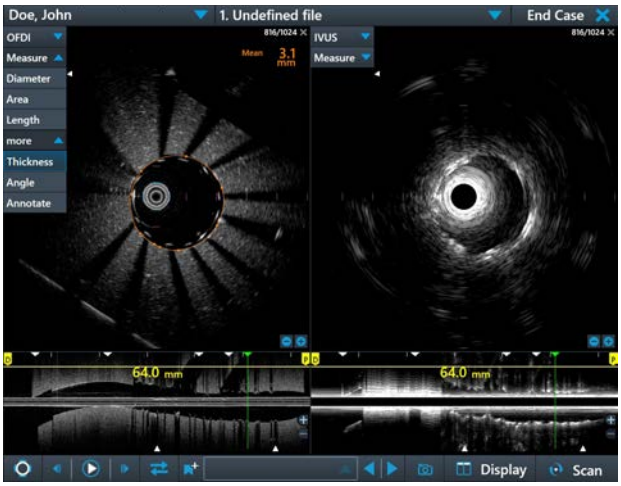



Fig. 14.8B Thickness Measurement

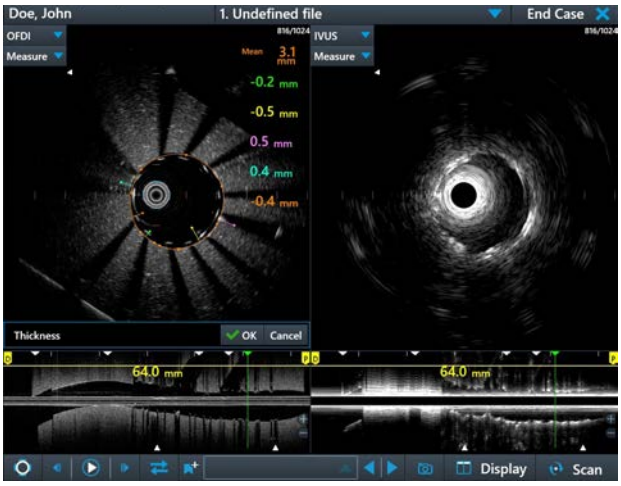
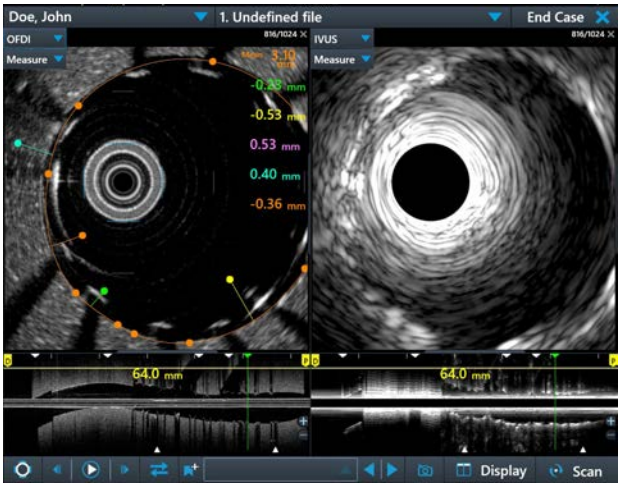



Fig. 14.8C Zoomed Thickness Measurement



## Angle

The angle tool measures the angle between two lines (in degrees) in the cross-sectional view.

1. **Click on [more] to expand the measure menu.**
2. **Click on [Angle] button (Fig. 14.9).**
3. **Press the left button of the mouse at the point where the angle measurement starts.**
4. **Drag and drop the mouse at the point where the angle measurement ends in the cross-sectional view.**
   - The center of the angle measurement is determined based on the following:
     - If there is no auto-traced lumen in OFDI cross-sectional image, or no area which encompasses the catheter center in IVUS cross-sectional image, the catheter center is used for the center of the angle measurement **(Fig. 14.10)**.
     - If there is a lumen traced in the OFDI cross-sectional image, the centroid of the lumen is used for the center of the angle measurement (**Fig. 14.11**).
     - If there is area measurement(s) which encompass the catheter center in the IVUS cross-sectional image, the centroid of the smallest area is used for the center of the angle measurement **(Fig. 14.12)**.
   - The clockwise angle value will be calculated and placed on the right of the cross-sectional image in the image window in the same color as the line.
5. **Repeat the drag and drop of the mouse to draw a second angle measurement line if needed.**
   - A maximum of two angle measurements can be created.
6. **After all measurement points are placed press the OK button to confirm angle measurement points or press the Cancel button to discard all non-confirmed Angle measurement points.**

Fig. 14.9 Angle Measurement Menu

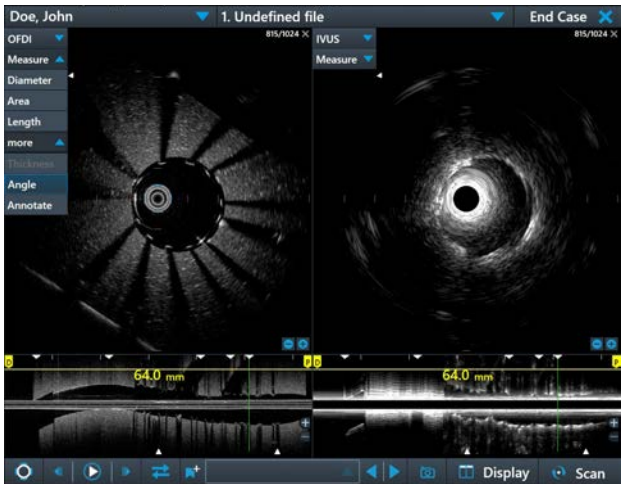



Fig. 14.10 Angle Measurement (without Lumen)

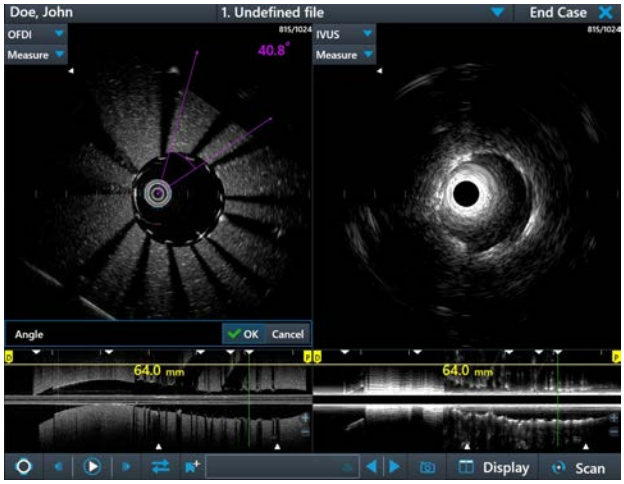



Fig. 14.11 Angle Measurement (with Lumen)

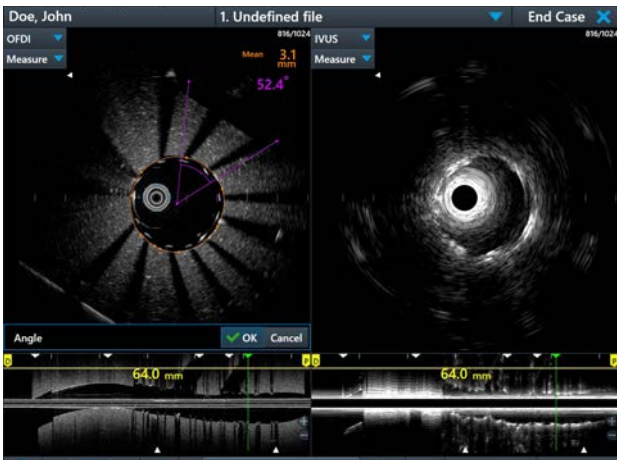
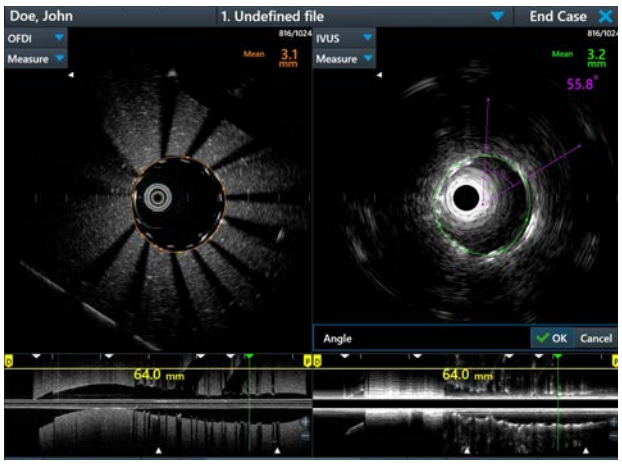



Fig. 14.12 Angle Measurement (with IVUS Area)



## Using the Lesion Tool

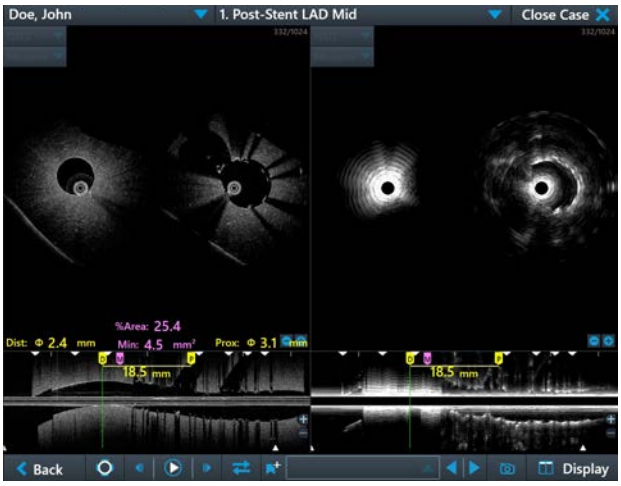
NOTE

- The lesion tool is operated synchronously in both OFDI and IVUS images, when in Dual Mode.

To adjust the distal and proximal points of the lesion:

1. **Drag the [D] and [P] markers left and right.**
   - The length of the lesion (distance between the distal and proximal markers) is always displayed.
   - Once both D and P markers positions are adjusted, auto lumen detection is applied to all frames between these markers (OFDI only). **(Fig. 14.13A)**.
   - When the calculation to apply auto lumen detection is completed, the distal and proximal mean lumen diameters, minimum lumen area, and % area stenosis will update while you drag (OFDI only).
   - While using the 'D' or 'P' marker of Lesion Tool, the cross-sectional images of both edges are displayed on the screen.
   - When one of the edge cross-sectional images is clicked, it jumps to the frame of the clicked edge and display the cross-sectional image larger.
   - The 'M' marker indicates the location of Minimum Lumen Area within the range between the distal and proximal edges of the lesion area. When the 'M' marker is clicked, it jumps to the frame with the minimum lumen area.

Fig. 14.13A Lesion Tool



## Refining Points

To refine an existing measurement:

1. **Hover the mouse pointer over the point to be moved to highlight the point (Fig. 14.14A.**
2. **Click and hold the left button of the mouse on the point to be moved.**
3. **Drag the point to the desired position and drop it to set its position.**
   - The new measurement value is moved and re-calculated per the new location (**Fig. 14.14B**).

Fig. 14.14A Highlighted Measurement Point

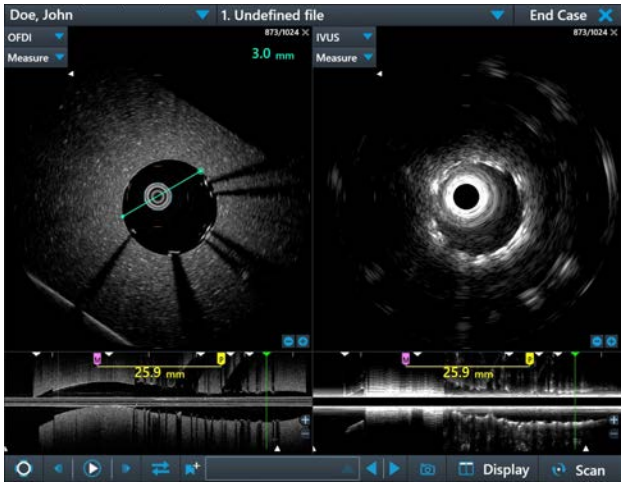
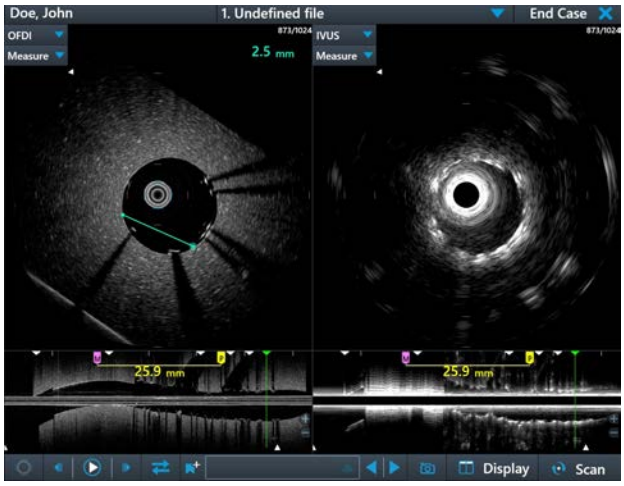



Fig. 14.14B Highlighted Measurement Point



## Deleting Measurements

To delete a measurement: :

1. **Right-click the desired measurement point or line to be deleted to open popup menu to delete the point or line.**

2. **Press "Delete" in the popup menu to delete the point or line, or press anywhere outside of the popup to cancel deletion and close the popup. (Fig. 14.15A).**

   - Press "Delete Frame Measurement" to delete all measurements applied to the pullback data.
   - Press "Delete All Auto Traces" to delete all auto detected lumen traces in the pullback data.

3. **Select "OK" to confirm deletion or "Cancel" to exit the popup menu and keep the current measurement (Fig. 14.15B).**

Fig. 14.15A Popup Menu

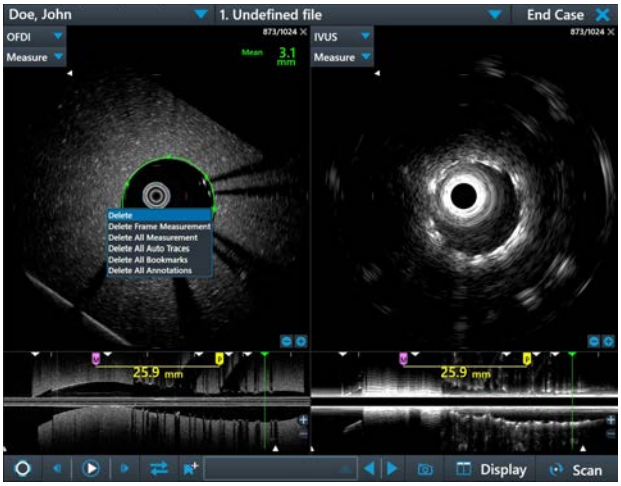
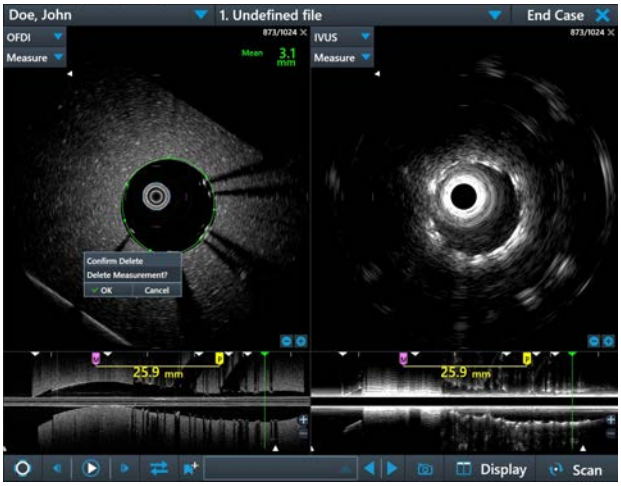



Fig. 14.15B Confirmation Dialog




NOTE

- Area measurement requires at least four points to form the measurement line. If the measurement points become three by deleting a point, all the other points and area measurement lines are deleted accordingly.
- Thickness measurement requires traced lumen. If the lumen measurement line is deleted, all associated thickness measurements are also deleted.

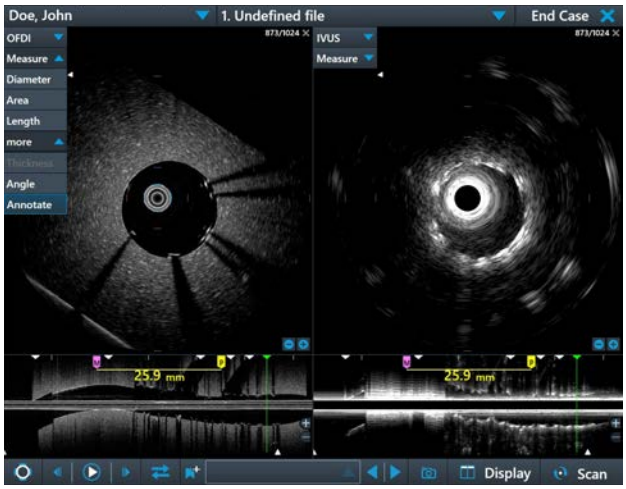
## Entering Annotations

- Text annotations can be added to the cross-sectional and longitudinal image.
- Up to ten annotations per modality for a pullback can be added.

To enter annotations:

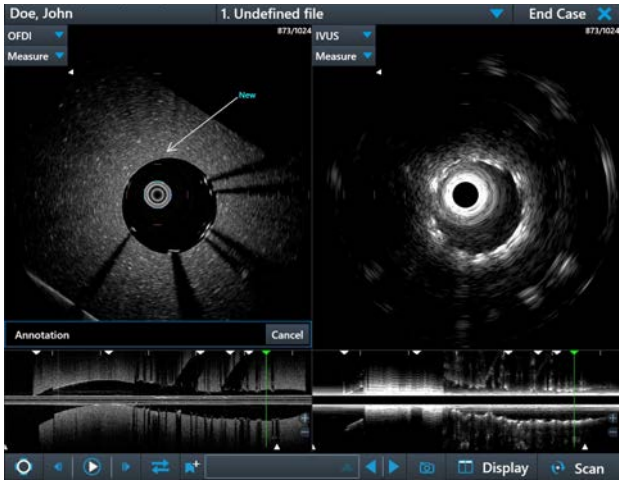
1. **While displaying the image on the screen, click the [Measure] button to drop down the measurement menu.**
   - Click [more] to expand the menu list.
2. **Select [Annotate] from the menu (Fig. 14.16).**

Fig. 14.16 Annotate Menu



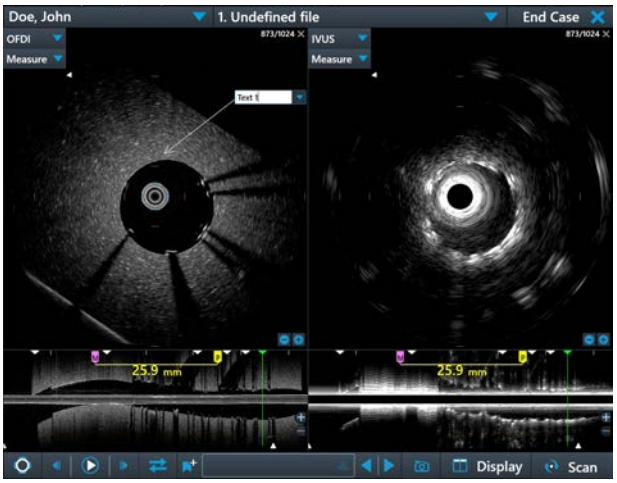

3. **On the image, press the left mouse button where the annotation is to be inserted and drag and drop arrow.**
   - A text box will be displayed with the text "New" as default (**Fig. 14.17**).

Fig. 14.17 Annotation Text Box



4. **Click the text box and enter the desired text into the text box -or- select from predetermined dropdown list (Fig. 14.18 and Fig. 14.19), then commit to text by either:**
   - Pressing enter on the keyboard to display the text,
     -OR-
   - Clicking anywhere outside the text box.

Fig. 14.18 Annotation Manual Entry

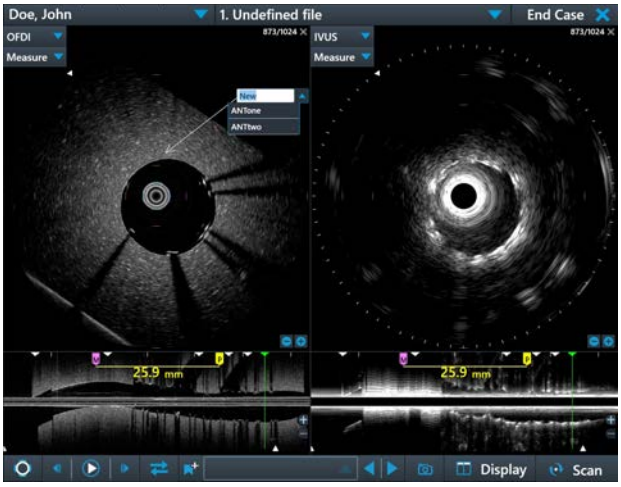



## Editing Annotations

- To edit an annotation:

1. **Click the annotation to be edited.**
2. **Make required edits to the text.**
3. **Approve the edits:**
   - Press the [Enter] key,
     -OR-
   - Click anywhere outside the text box.

Fig. 14.19 Annotation Dropdown List



## Moving Annotations

- To move annotations:

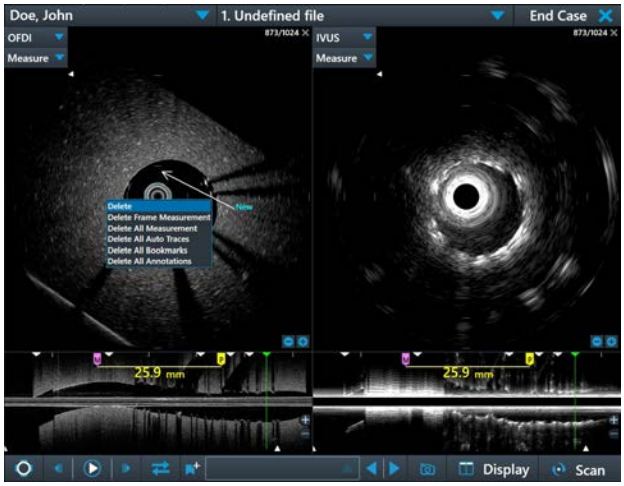
1. **Click and hold (using left mouse button) an edge of the annotation/text box arrows that is to be moved.**
2. **Drag to desired position.**
3. **Release the mouse button to set the position.**

## Deleting Annotations

- To delete annotations:

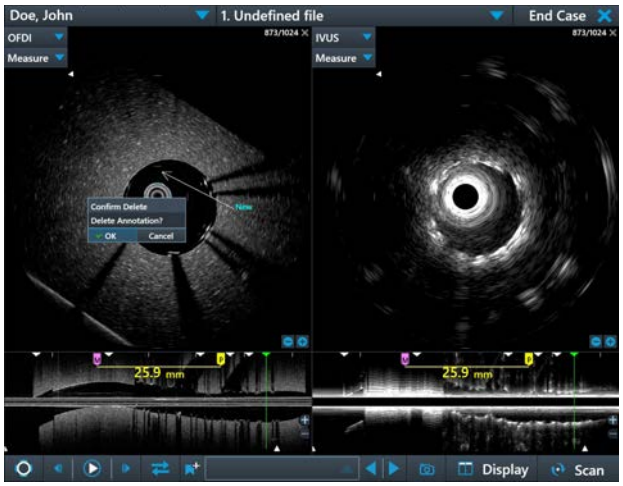
1. **Hover over and highlight the arrow of the annotation to be deleted.**
2. **Delete annotations by right clicking the annotation arrow and selecting [Delete] on the pop-up menu (Fig. 14.20).**
   - There is also an option to [Delete All Annotations] on the pop-up menu which will delete ALL annotations applied to the entire pullback.

Fig. 14.20 Delete Annotation Popup Menu




3. **Confirm deletion on confirmation box or press cancel to exit without deleting (Fig. 14.21).**

Fig. 14.21 Delete Annotation - Confirm



# Section 15
# Reviewing Previous Cases

# Reviewing Previous Cases

Previous Cases/recordings saved on the system console can be retrieved later. To review a saved recording:

1. **On the Home screen, select [View Previous Cases] (Fig. 15.1).**
   - Previous pullbacks will be listed.
   - You can select pullbacks to review from the available list **(Fig. 15.2)**.
     -OR-
   - Click on the [Options] drop down to customize the search by the criteria displayed in menu.

2. **Select pullbacks to review.**
   - Select pullback(s) for review.
   - Selected pullback(s) will be displayed on the right **(Fig. 15.3)**.
   - Selecting the [More] drop down menu in the image display box gives you patient and case, and pullback detailed information **(Fig. 15.3)**.

Fig. 15.1 Home Screen




Fig. 15.2 Select From List

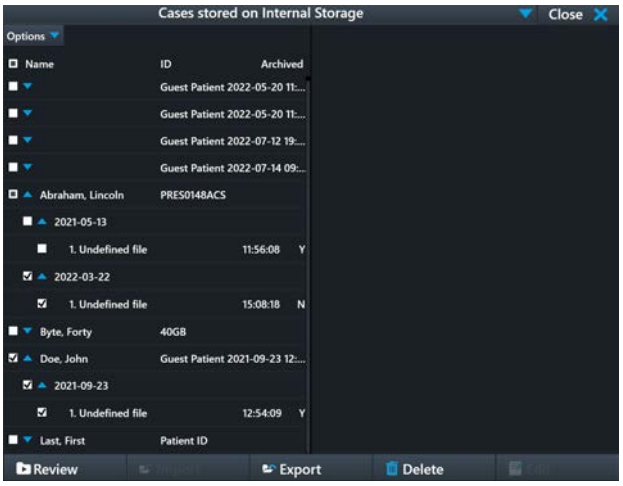
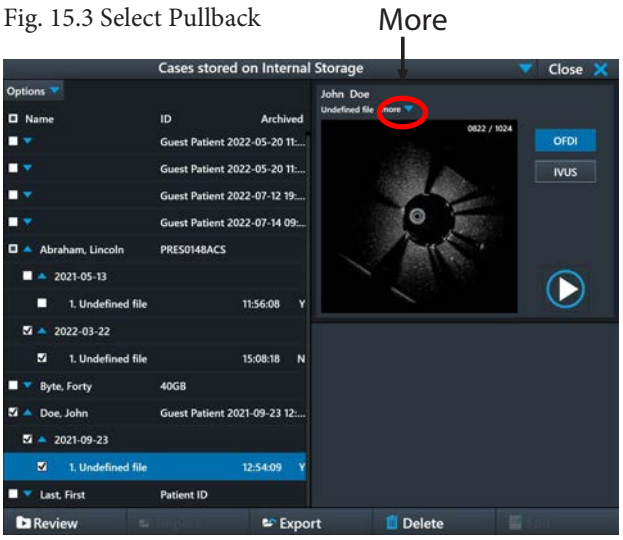
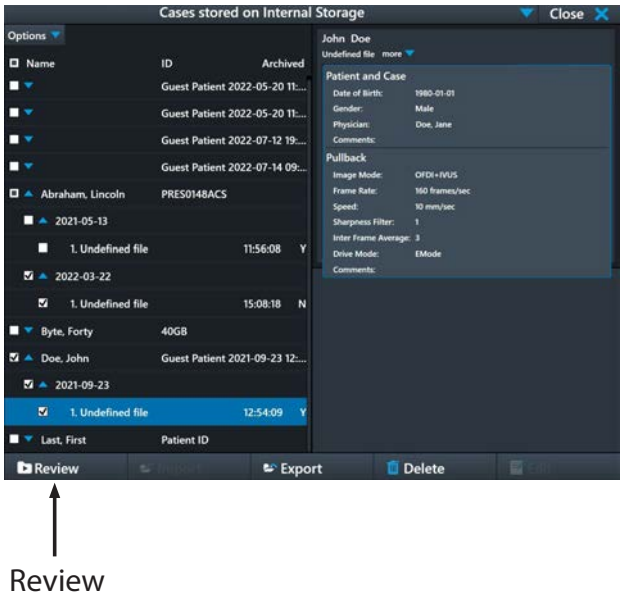



Fig. 15.3 Select Pullback



3. **Click on the "Review" button on the bottom of the screen, to open and review all the selected pullbacks (Fig. 15.4).**
   - Refer to Section 13 "Review" for instruction on navigating pullbacks.
   - Refer to Section 14, "Measurements and Annotations" for instruction on measurements and annotations.
   - Refer to Section 18, "Exporting, Importing & Managing Files" for instruction on exporting files to media or the PACS system.

Fig. 15.4 Detailed Case Data Information Dialog



## Dual Screen Image Comparison

During Review and Measurement, a previously recorded pullback can be displayed simultaneously on the screen as a reference.

1. **Click the down arrow next to the current pullback name being displayed (Fig. 15.5).**
   - This will bring up all pullbacks available for reviewing.
2. **Check the boxes of two files to compare.**
3. **Click on the [Compare] button.**
   - This will bring up a side-by-side image of the selected pullbacks **(Fig. 15.6)**.

> NOTE
>
> - Compare mode function is available between pullbacks of the same modality only (IVUS/IVUS or OFDI/OFDI).

4. **[Desynced] and [Synced] is to play back the two images asynchronously [Desynced]or synchronously [Synced].**
   - Click to toggle between the two options.
   - What is displayed is the current selection.
5. **Select the Playback button on the system screen to play both files.**
   - If two images are Synced: Both play buttons work in the same manner.
   - If two images are Desynced: The left playback button plays back only the left image, and the right playback button plays back only the right image.
   - Click [OFDI <-> IVUS] button to switch between IVUS or OFDI pullback comparison.
6. **Bookmarks can be added to the images (Refer to Section 13, Review), for additional information.**

Fig. 15.5 Select Pullbacks to Compare

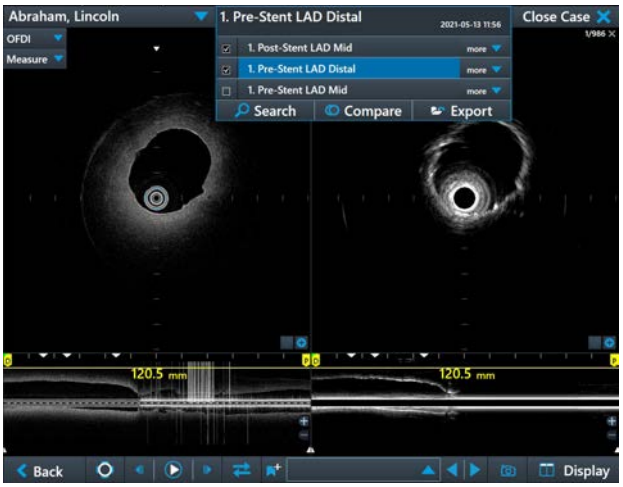
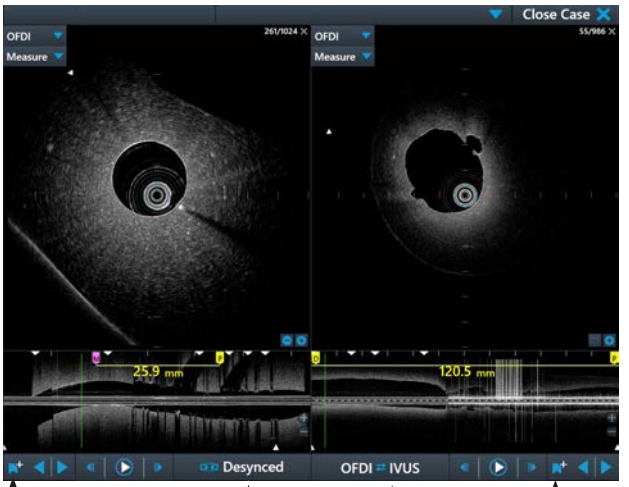



Fig. 15.6 Image Comparison



**7. To exit the dual screen, and return to the single image mode, click [X] button in the upper right corner of the playback you want to close.**

**-OR-**

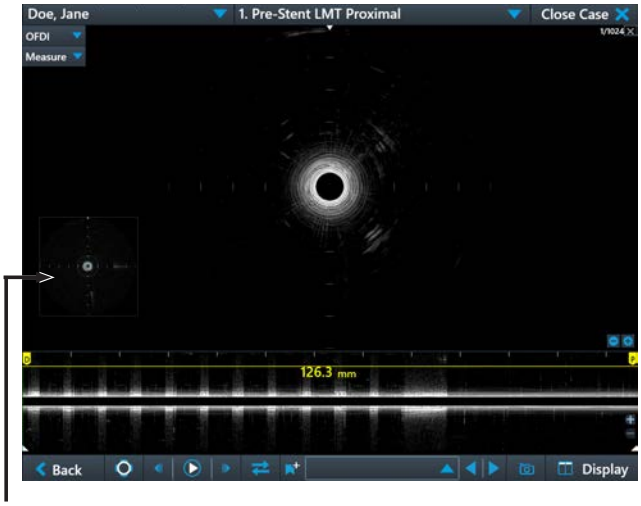
**Click the down arrow on the pullback selection list at the top of the screen and uncheck the pullback you want to close.**

- The single modality displayed shows the selected playback larger at the center, and a thumbnail of the playback that was closed **(Fig. 15.7)**.

**. To switch from single pullback back to dual screen image comparison:**

- Double-click the thumbnail.

Fig. 15.7 Exit Dual Screen



# Section 16
# Removing Imaging Catheter and Detaching from the MDU

# Removing Imaging Catheter and Detaching from the MDU

**WARNING**

- Read the Instructions for Use provided with the catheter and MDU Cover prior to use. Misuse of these devices may cause injury to the patient or damage to the System.
- Remove imaging catheter and MDU Cover following proper sterile technique. Dispose using proper disposal procedures. Failure to do so may increase the risk of sterile environment contamination or patient infection.
- Carefully remove catheter from patient. Failure to do so could result in catheter and/or vessel damage, such as thrombus, perforation, or dissection.
- When removing the catheter from the vessel, observe the movement of the distal guidewire tip under fluoroscopy to ensure that the guidewire is not deflected. If the catheter is removed with a deflected guidewire, the guidewire may break or bend, making it difficult to remove, or result in coronary artery dissection.
- Do not attach, detach, manipulate, or prime the catheter while the MDU motor is spinning or the catheter is in the lock position. Doing so could result in catheter or MDU damage.

## Removing the Catheter from the Patient

1. **If in Live Mode: Press the [Scan] button on the MDU screen or the [Stop] button on the system screen to deactivate scanner and stop showing the live image (Fig. 16.1A and 16.1B).**
   - Ensure the catheter is stationary and the MDU scanner is not running prior to removing the catheter.
2. **Following the instruction manual for the DualView Catheter, withdraw the catheter from the vessel.**
3. **Confirm the MDU cable is not restricted and can move freely.**
4. **Move the MDU and connected catheter away from the patient to an area within the sterile field.**
   - If no further imaging is needed, continue to "Disconnecting the Catheter from the MDU" removing the Imaging Catheter **(page 149).**
   - If the catheter is to be re-inserted into the patient for additional imaging proceed to Step 5.
5. **If the catheter is to be inserted into the patient for additional imaging:**
   - Prime inside of catheter with heparinized saline solution.
   - Wipe the catheter with gauze soaked with heparinized saline solution.
   - Place the catheter inside the heparinized filled holder tube and set aside following proper sterile technique.

Fig 16.1A MDU Scan Button

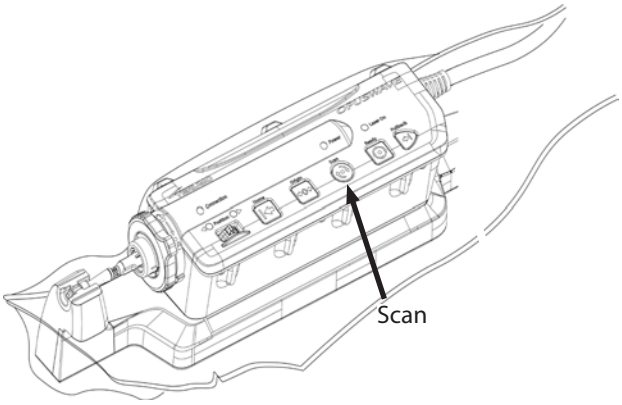
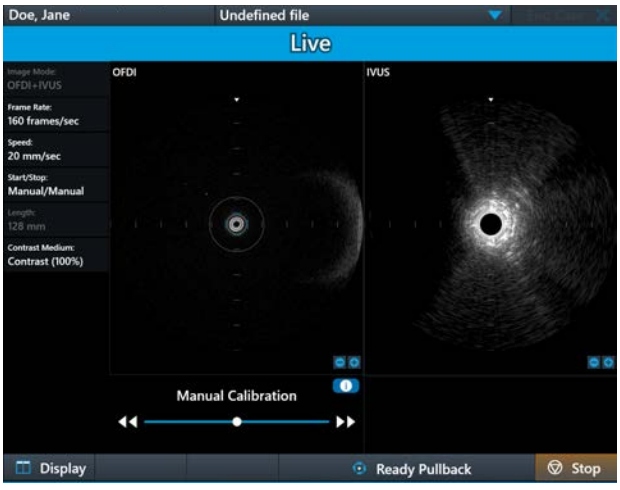



Fig 16.1B System Scan Button



# Removing Imaging Catheter and Detaching from the MDU

## Disconnecting the Catheter from the MDU

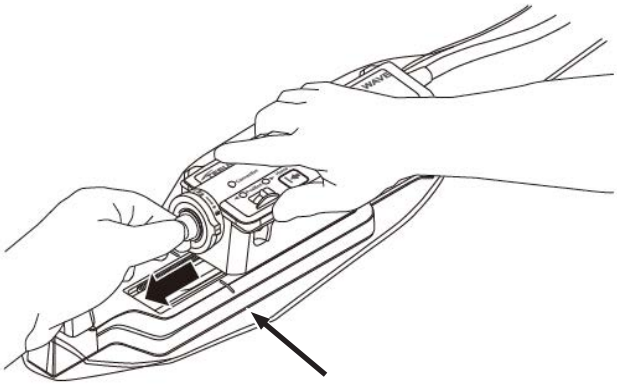
1. **Using the position switch, move the front edge of the MDU scanner to the white line located on the MDU base (Fig. 16.2).**
   - This will allow adequate clearance for the MDU cover and catheter to be disconnected from the MDU without interference.

2. **Grasp the unit connector of the catheter secured in the MDU catheter clamp, and pull up to release.**

3. **Rotate the MDU Cover adapter counterclockwise to unlock the catheter.**
   - The black line on the MDU cover adapter should be aligned with the "unlock" symbol on the MDU.
   - The MDU green connection indicator should turn off to indicate that there is no catheter connected.

4. **Remove the catheter from the MDU Cover adapter.**

Fig. 16.2 Disconnect Catheter

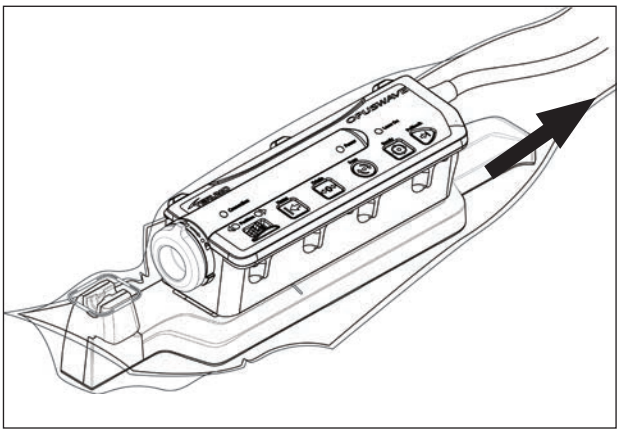


# Removing Imaging Catheter and Detaching from the MDU

Removing the MDU from the Cover

1. **If no additional imaging is needed, remove the MDU Cover from the MDU (Fig. 16.3).**
2. **Dispose of the MDU Cover and disposable materials following proper safety procedures.**
3. **Follow post-imaging cleaning and maintenance procedures (Section 21).**
4. **Place the MDU in the MDU storage location on the console.**
5. **Wrap the MDU cable around MDU cable management feature.**
6. **Return the wireless mouse to the mouse storage tray on the console.**

Fig. 16.3 Remove the MDU Cover from the MDU



# Section 17
# Completing a Case

# Completing a Case

## Closing a Case

When analysis is completed and case is ready to be closed and saved, enter any pullback information (if desired) and confirm that it is accurate.

1. **Click on [End Case] in the top right corner of the system screen (Fig. 17.1).**
2. **Select [Yes} to close the case or [No] to cancel closing the case.**

Fig. 17.1 Close Case

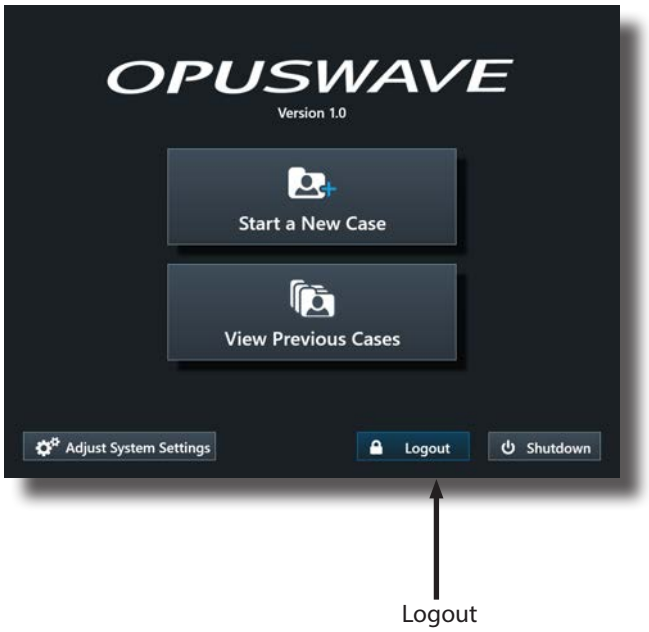



## Logging Out

If no additional pullbacks and/or evaluations are required for the current patient, logout of the system console.

1. **Click [Logout] on the Home Screen (Fig. 17.2).**

Fig. 17.2 Logging Out



# Section 18
# Exporting, Importing and Managing Files

# Exporting, Importing and Managing Files

## Exporting Media

**WARNING**

- Do not use externally powered USB devices in this system during the procedure. Use of externally powered USB devices with the system during a procedure may compromise electrical isolation and result in patient injury

### Exporting Compatible Transfer Media

External transfer media compatible with the OPUSWAVE System are:

- DVD
- USB - Most common and smaller memory USB flash drives are usually Low-power USB devices that operate within 150ma limit that can be connected to USB 2.0 port on the table top or USB 3.0 port on the back panel. These USB flash drives are expected to be identified by OPUSWAVE within few seconds of connecting the device. Larger USB flash drives and external hard drives, especially when USB type-C to USB adapter cables, tend to require higher power and should be connected to the USB 3.0 port on the back panel to avoid any intermittent loss of connection. The compatibility of a USB device with a specific port (2.0 or 3.0) depends on the device's power requirements and its ability to negotiate with the port for sufficient power delivery. Please consult the USB device's manual or specifications to confirm its power requirements.

Table 18.1 DVD Media Type

| MEDIA | CAPACITY | CAN ERASE * | CAN APPEND ** |
|---|---|---|---|
| DVD+R | 4.7 GB | NO | NO |
| DVD+RW | 4.7 GB | NO | YES |
| DVD+R Dual Layered | 8.5 GB | NO | NO |
| DVD-R | 4.7 GB | NO | NO |
| DVD-R W | 4.7 GB | NO | YES |
| DVD-R Dual Layered | 8.5 GB | NO | NO |

***NOTE:***

**OPUSWAVE does not erase the DVD media and does not provide such options to the user to choose from.*

***OPUWAVE always finalizes the disc at the end of export to DVD media and additional export might be possible with DVD+RW and DVD-RW.*

**NOTE**

- Outside of the catheterization laboratory, USB devices with an external power supply in compliance with the IEC 60950 standard can be connected.
- Handle the transfer media with care, ensuring it is inserted in the proper orientation. Do not use excessive force during insertion.

To export a file to the compatible external media, insert or connect the media:

1. **Click [View Previous Cases] button from the home screen. (Fig. 18.1).**
   - A pullback list is displayed.
   - Select pullback(s) to be exported **(Fig. 18.2A)**.

   -OR-

2. **Click the blue triangle next to [Options] to open the options to search for pullback(s) according to the following criteria: (Fig. 18.2B)**
   - Patient ID
   - Patient Name
   - Physician Name
   - Date From/To
   - Time From/To
   - Select pullback(s) to be exported.

3. **Once the intended search is performed and the Search dialog is closed, click the box next to select the case(s)/file(s) for export.**

4. **Click [Export] button to open Export dialog.**

Fig. 18.1 Home Screen




Fig. 18.2A Select Pullback

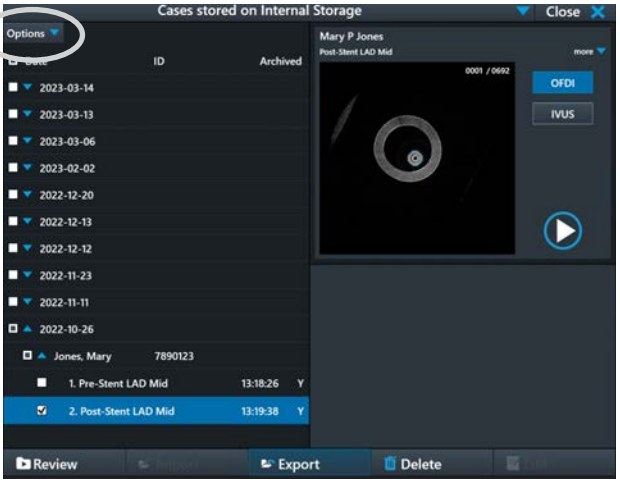
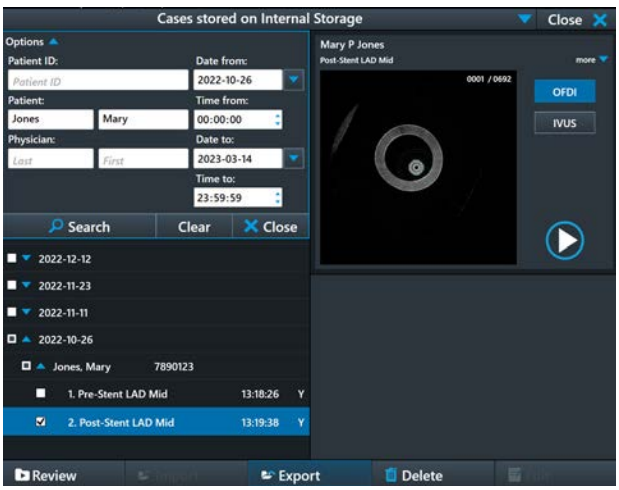



Fig. 18.2B Select Pullback- Options

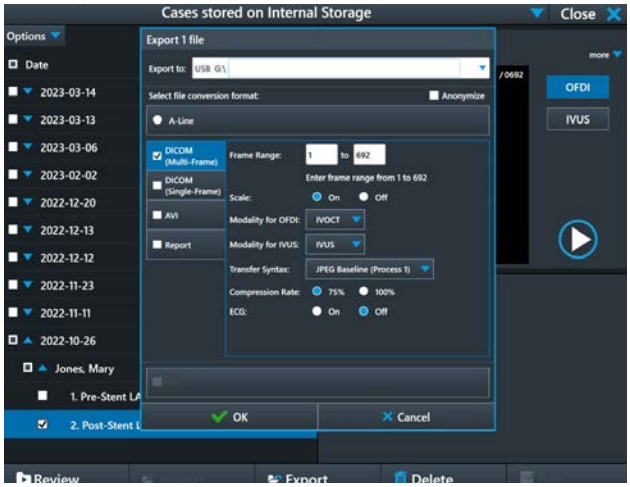


**5. Select a file conversion format. Choices of formats are (Fig. 18.3):**

- A-Line (Native File Format for OPUSWAVE)
- DICOM (Multi-Frame)
- DICOM (Single-Frame)
- AVI
- Report
- Still (Refer to "Exporting Still Images")

**6. Select configuration for the data to be exported if applicable.**

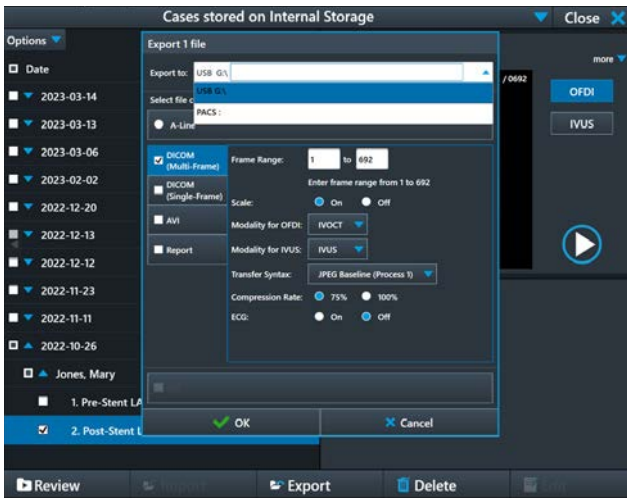
Fig. 18.3 Select File Format




**7. Select the type of external storage device as the file destination (PACS, DVD, USB).**

- If USB storage is selected, select folder name to export the data (not available for A-Line data **(Fig. 18.4)**

Fig. 18.4 Select External Storage Location



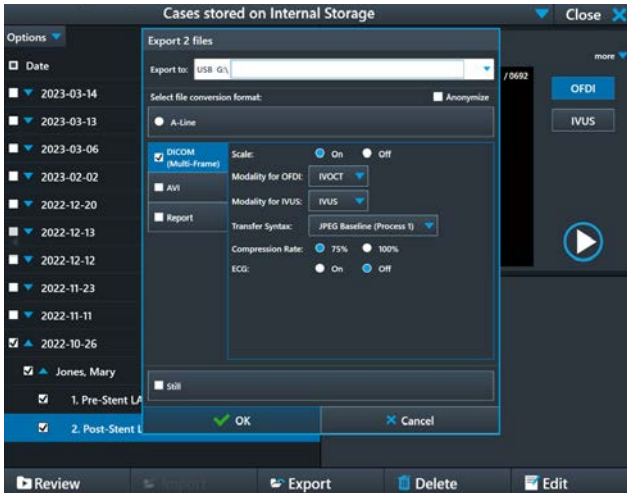

**8. Click [OK] to begin exporting to the designated media or [Cancel] to abort the transfer (Fig. 18.5).**

**9. Click [Yes] to confirm start of export, or [No] to cancel exporting.**

**10. A Progress Dialog box is displayed.**

- Click [Abort] button to abort export.
- Progress Dialog box disappears when export completes.

Fig. 18.5 Export



# Exporting, Importing and Managing Files

## Exporting A-Line Files

The system exports files which can be imported by the OPUSWAVE System. There is no configuration option except for destination and anonymization.

If you export in A-line file format, every feature of the image file will be exported, and the files can be imported into another OPUSWAVE System and reviewed and manipulated there.

**NOTE**

- Native files can be reviewed and manipulated only with an OPUSWAVE System. They cannot be accessed with any other systems or software.

## Exporting DICOM Files (Multi-Frame/Single Frame

The system converts image files to DICOM format file before exporting**.** The following configuration options are available**: (Refer to Fig. 18.5)**

- **Frame Range/Frame Number**
  Specifies which frame(s) will be included in the data to be exported.
- **Scale**
  Specifies whether scale grid is included in the image to be exported.
- **Modality for OFDI**
  Specifies the modality type in DICOM tag for OFDI image from IVUS, US, IVOCT, or OCT.
- **Modality for IVUS**
  Specifies the modality type in DICOM tag for IVUS image from IVUS, US, IVOCT, or OCT.
- **Transfer Syntax**
  Specifies the transfer syntax in DICOM tag from Explicit VR Little Endian, JPEG Baseline (Process 1), or JPEG Lossless.
- **Compression Rate:**

  Specifies the compression rate (75% or 100%).
- ***ECG***
  Specifies whether ECG waveform is included in the image to be exported.

If Anonymize is selected, the Patient ID and Patient Name becomes blank, and the Date of Birth becomes default value 1/1/1.

**NOTE**

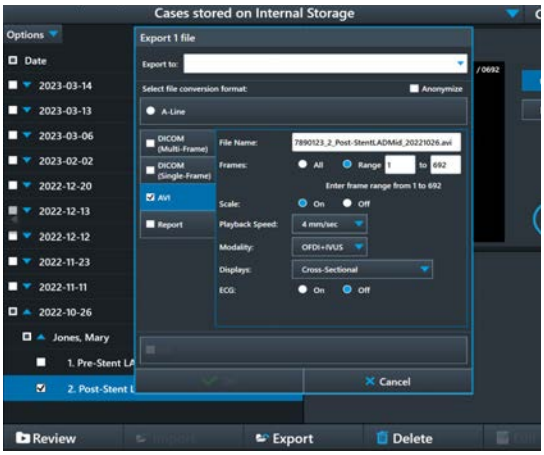
- For a multiple-frame recording using DICOM format stored on a network server, the maximum resolution is 800 x 800.

# Exporting, Importing and Managing Files

## Exporting AVI Files

The system converts image files to AVI format before exporting. The following configuration options are available:

Fig. 18.6 Exporting AVI Files




- **File Name**
  Specifies the file name to be exported. The system shows default file name using Patient ID and date when the data was captured. If Anonymize is selected, the default file name does not have Patient ID information.
- **Frames**
  Specifies frame range to be included to the AVI file. If [All] is selected, the system uses all frames in the image data, otherwise the frame range cannot be defined.
- **Scale**
  Specifies whether scale grids are included in the AVI image.
- **Playback Speed**
  Specifies the playback speed from 0.5 mm/s, 1 mm/s, 2 mm/s, 4 mm/s or 8 mm/s.
- **Modality**
  Specifies modalities to be included in the AVI image. If the selected pullback is IVUS only or OFDI only image, it is the only available selection. If the selected pullback is Dual image, it allows to select from OFDI/IVUS, OFDI only, or IVUS only.
- **Displays**
  Specifies which portion of the image will be included in the AVI image from Cross-Sectional, Cross-Sectional and Longitudinal, or Cross-Sectional, Longitudinal and Angio images.
  - Cross-Sectional
  - Cross-Sectional and Longitudinal
  - Cross-Sectional, Longitudinal and Angiography images
- **ECG**
  Specifies whether ECG waveform is included in the AVI image to be exported.

**NOTE**

- When exporting in standard file formats (AVI for movies; JPEG for still images), the images can be used in computer applications outside the system but cannot be imported into an OPUSWAVE system

## Exporting Report Files

The system exports Report Files which include all measurement information as a CSV file. There is no configuration option except destination and anonymization.

## Exporting Still Images

The system exports selected snapshots as still images in JPEG format.

1. **Click [View Previous Cases] Button on Home screen.**
2. **Select a pullback from the list (Fig. 18.7A).**
   - The system shows thumbnails of available snapshots.
3. **Select snapshot(s) to be exported and click [Export] button to open the Export Dialog.**
4. **Select [Still] in the Export Dialog box (Fig. 18.7B)**
5. **Select [External Storage] as the export destination.**
6. **Click [OK] button to begin exporting.**

Fig. 18.7A Export Snapshot

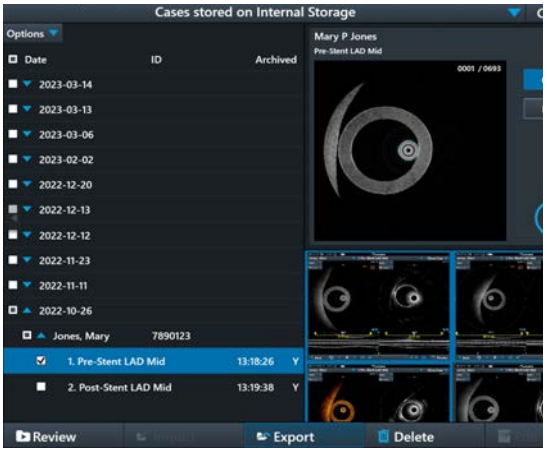
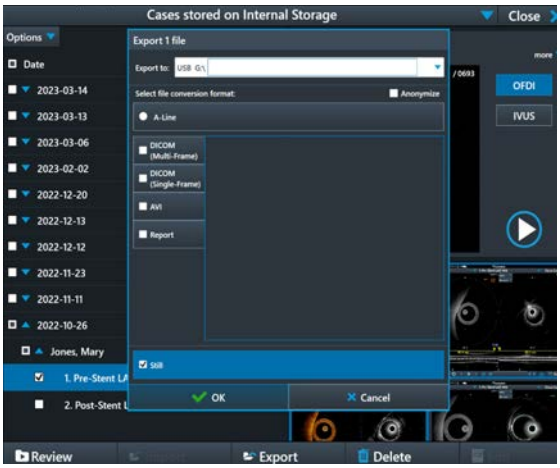



Fig. 18.7B Select Still



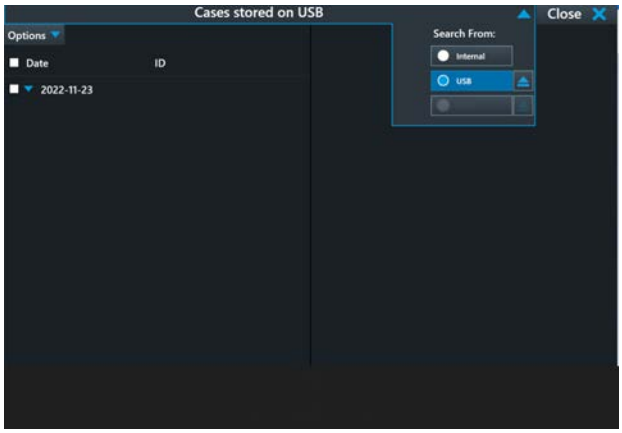
## File Import

A-Line Files can be imported from an external storage device (DVD or USB)

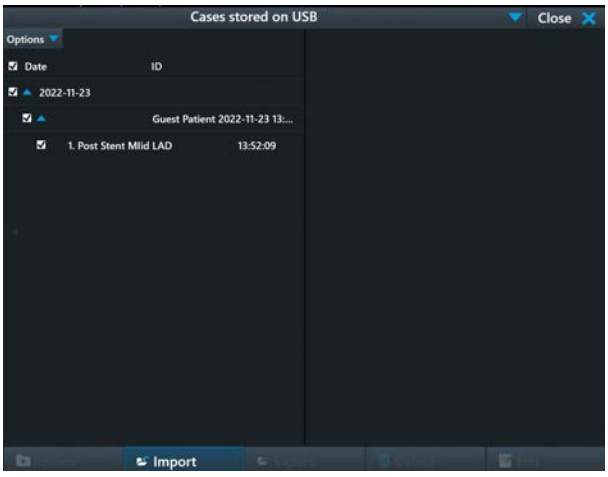
Importing A-Line Files

1. **To import file(s) from an external storage device, insert a DVD or USB into the appropriate drive or port.**
2. **Click [View Previous Cases] button.**
3. **Click the blue triangle on the top of the screen to drop down the list of storage options, and select the source of the external storage device. (Fig. 18.8).**
   - The system will display the pullback files stored in the selected external storage device.
4. **Select the file you want to import by clicking its checkbox (Fig. 18.9).**
5. **Click [Import] button to import the selected file(s).**
6. **Click [Yes] button on the confirmation dialog to start the import, or [No] button to cancel the import.**
   - Imported files will be available in the list to view previous cases.

18.8 Select External Storage Source




18.9 Import




Import

## Managing Files

### Editing Patient Information

1. **Click [View Previous Cases] button on the Home Screen (Fig. 18.10).**
2. **Select the pullback(s) which belongs to a single patient (Fig. 18.11).**
   - [Edit] button becomes enabled.
3. **Click the [Edit] button (Fig. 18.12).**
   - Current Patient information and Editing Patient Information screen is displayed.
4. **Edit patient information On the "Editing Patient information screen", select or enter (Fig. 18.12):**
   - Patient ID (Must select edit to update)
   - Patient Name
   - Date of Birth
   - Gender
5. **Click [Apply] button to apply the edit(s) or [Cancel] button to cancel the edit.**

Fig. 18.10 Home Screen




Fig. 18.11 Select Pullback

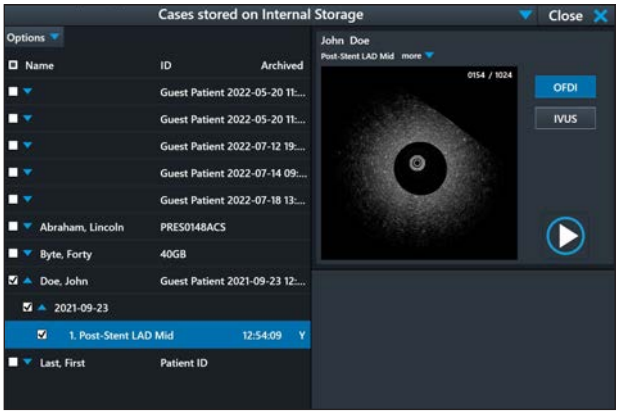
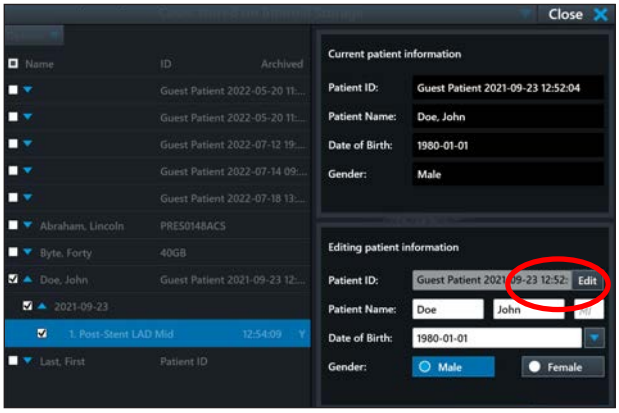



Fig. 18.12 Edit and Apply Changes



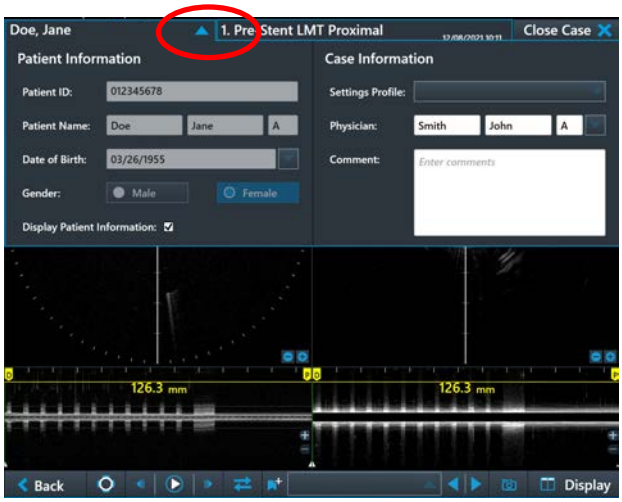

NOTE

- Patient information is not required; case is saved with patient and case ID and can be retrieved later with that information. Refer to Section 6, "Case Set Up" for information on manually entering patient information or importing patient information from RIS.

## Editing Case Information

1. **Open a pullback to be edited in the Review screen.**
2. **Click the blue triangle in the Patient Name display on the top, to drop down the Patient/ Case Information Dialog box (Fig. 18.13).**
3. **Enter Physician Name and/or Comment.**
4. **Click the blue triangle to minimize Case Information box and save edits.**

Fig. 18.13 Edit Case Information




## Deleting a File

1. **Click [View Previous Cases] button.**
2. **Select file(s) to be deleted.**
3. **Click [Delete] button (Fig. 18.14A).**
4. **Click [Yes] button on the confirmation dialog to delete the file(s), or [No] button to cancel deletion (Fig. 18.14B).**

Fig. 18.14A Delete File

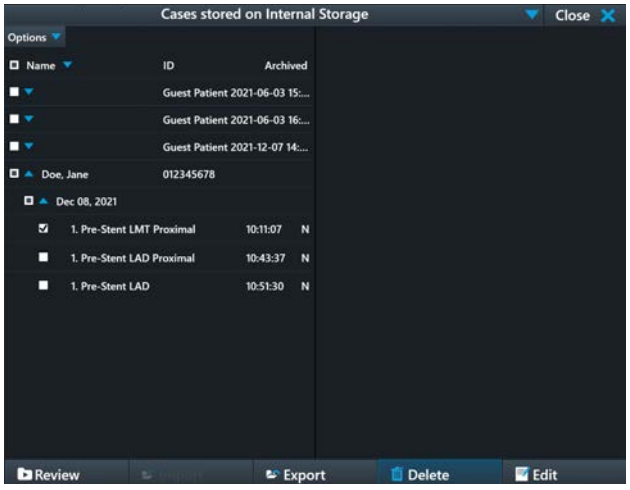
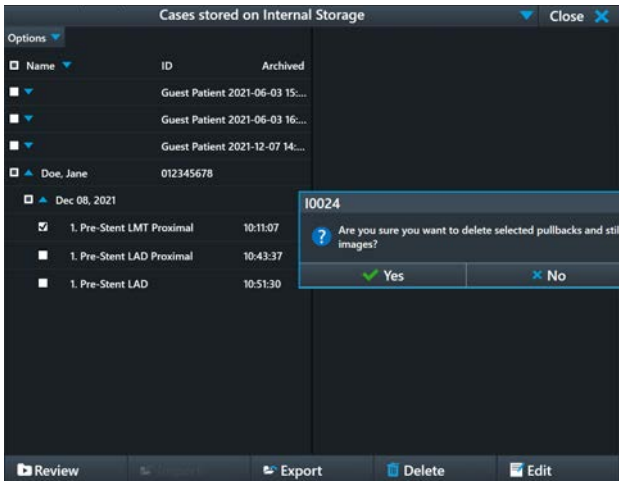



Fig. 18.14B Confirm File Deletion



# Section 19
# User Account Settings

# User Account Settings

## User Privileges

The System provides the following access privileges:

1. Administrator User
2. Clinical User
3. Service User for Terumo Service Representative.

## User Registration

**1. To register a new user, Log into the system as the Administrator User on the Login Screen (Fig. 19.1).**

Fig. 19.1 Login Screen




**2. Click [Adjust System Settings] button (Fig. 19.2).**

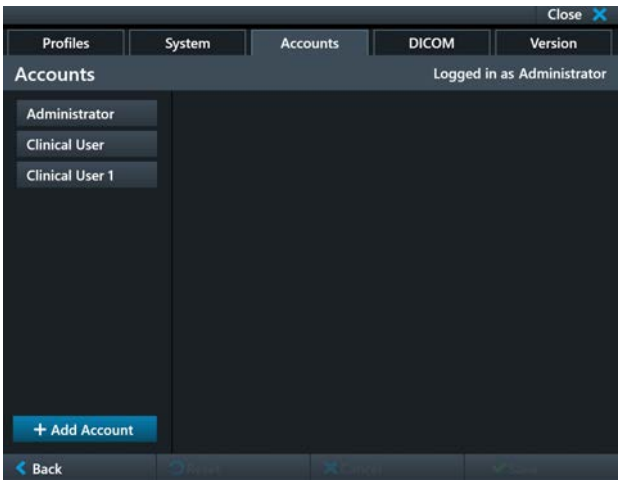
**3. Select [Accounts] tab (Fig. 19.2).**

Fig. 19.2 Adjust System Settings




**4. Click [Add Account] button (Fig. 19.3).**

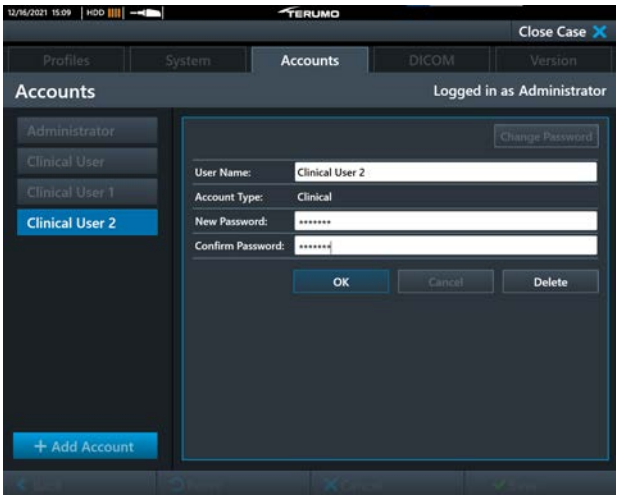
Fig. 19.3 Add Account



5. **Enter the user name, password, and password confirmation (Fig. 19.4).**
   - Password needs to be between 6 and 128 characters long.
   - Password cannot be the same as the user name.

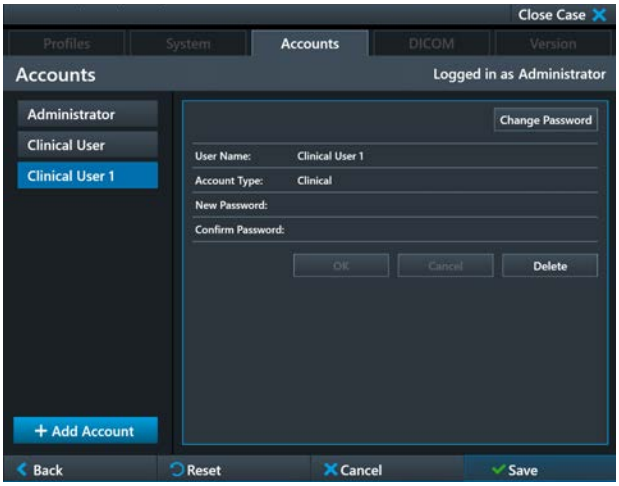
6. **Click the [OK] button to commit the new Clinical User account, or click [Delete] button to cancel adding the account.**

Fig. 19.4 Enter User Credentials



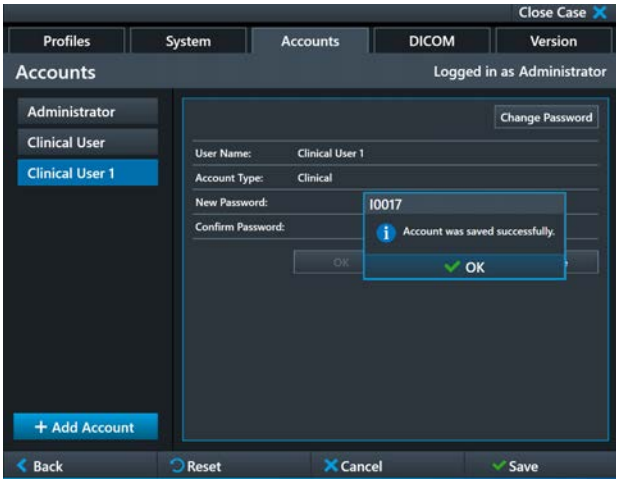

7. **Click [Save] button to save and store the new Clinical User account (Fig. 19.5)**

Fig. 19.5 Save User Account




8. **Confirm new account by selecting [OK] in the confirmation dialog box (Fig. 19.6).**

Fig. 19.6 Confirm New Account



## Deleting a User Account

1. **To delete a user account, log into the system as the Administrator User on the Login Screen (Fig. 19.7).**

Fig. 19.7 Login Screen



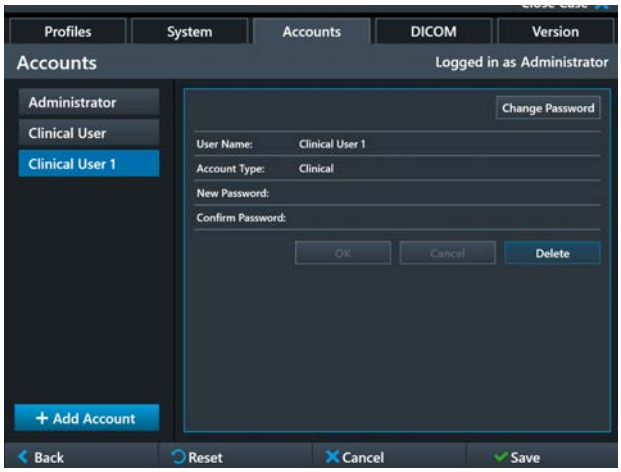

2. **Click [Adjust System Settings] button (Fig. 19.8).**

Fig. 19.8 Adjust System Settings




3. **Select [Accounts] tab. (Fig. 19.9).**
4. **Select the account to be deleted.**
   - Only Clinical User accounts can be deleted.
5. **Click [Delete] button.**

Fig. 19.9 Delete Account



6. **When the confirmation screen appears, click [Yes] button to delete the account, or [No] button to cancel deletion (Fig. 19.10).**

7. **Click [Save] button to save and store the changes.**

Fig. 19.10 Confirm Account Deletion



# User Account Settings

## Changing a Password

The Clinical User can change only their own password.

The Administrator User can change their own password and any Clinical User's password.

1. **To change a password of a user account, log into the system on the Login Screen (Fig. 19.11).**

Fig. 19.11 Login Screen



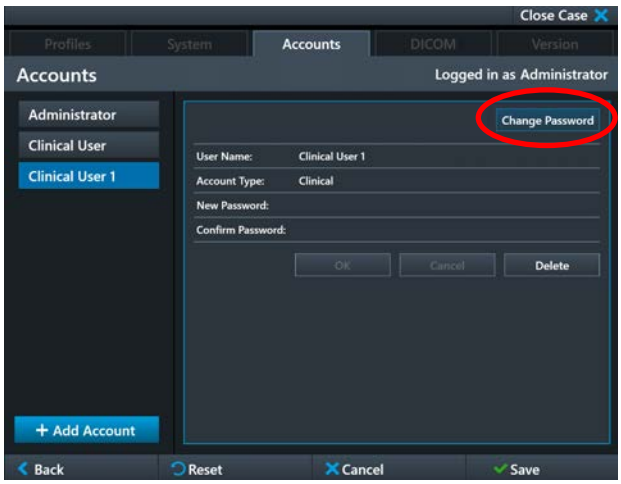

2. **Click [Adjust System Settings] button (Fig. 19.12).**
3. **Select [Accounts] tab.**

Fig. 19.12 Adjust Systems Settings




4. **Select the appropriate user and click [Change Password] (Fig. 19.13).**

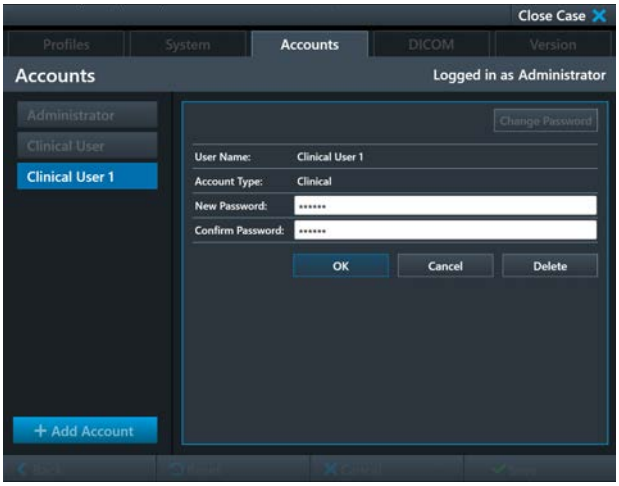
Fig. 19.13 Click Change Password




Select User

5. **Enter a new password and confirm new password (Fig. 19.14).**
6. **Click the [OK] button to commit to the new password, or click the [Cancel] button to cancel changing the password.**
7. **Click [OK] button on the confirmation dialog box.**
8. **Click the [Save] button to save the updated password (or you can reset or cancel).**
9. **Click [OK] button on the confirmation dialog box.**

Fig. 19.14 Update Confirm Password Change



# Section 20
# Settings

## Settings Profiles

- The Settings Profile is used to store setting configurations under a specific profile that can be selected during system setup, prior to the start of a case. Each configuration can be adjusted at any time during the case. However, storing typical configurations as a "Settings Profile" can help with configuring the system prior to using for each case.
- The settings profile can be used for pullback, recording, and image configuration as a default set of configurations.

The Factory Default preset values are initially provided by the system when the user account is registered. When the user logs on, these default settings will be implemented as the user setting parameters.

| **OPUSWAVE SYSTEM SETTINGS PROFILE OF FACTORY DEFAULT VALUES** | | | |
|---|---|---|---|
| **Settings Item** | | | **Factory Default Value** |
| Pullback and Record Settings | IVUS Only | Frame Pullback Stope Rate | 30 fps |
| | | Pullback Speed | 0.5 mm/s |
| | | Pullback Start | Manual |
| | | Pullback Stop | Manual |
| | | Auto Stop Length | 150 mm |
| | | Drive Mode | E |
| | | Sharpness Filter | 1 |
| | | Inter Frame Average | 3 |
| | OFDI Only | Frame Rate | 160 fps |
| | | Pullback Speed | 20 mm/s |
| | | Pullback Start | Manual |
| | | Pullback Stop | Manual |
| | | Auto Stop Length | 128 mm |
| | | Contrast Medium | Contrast (100%) |
| | | Auto Pullback Start Threshold | 90% |
| | OFDI + IVUS | Frame Rate | 160 fps |
| | | Pullback Speed | 20 mm/s |
| | | Pullback Start | Manual |
| | | Pullback Stop | Manual |
| | | Auto Stop Length | 128 mm |
| | | Contrast Medium | Contrast (100%) |
| | | Drive Mode | E |
| | | Sharpness Filter | 1 |
| | | Inter Frame Average | 3 |
| | | Auto Pullback Start Threshold | 90% |

| OPUSWAVE SYSTEM SETTINGS PROFILE OF FACTORY DEFAULT VALUES | | | |
|---|---|---|---|
| **Settings Item Continued** | | | **Factory Default Value** |
| Image Display Settings | IVUS | Gain | 13 |
| | | Contrast | 4 |
| | | Gamma | 5 |
| | | STC | {0,0,0,0,0,0} |
| | OFDI | Color | Gray |
| | | Gain | 10 |
| | | Contrast | 7 |
| | | Gamma | 1 |
| | | STC | {0,0,0,0,0,0} |
| | Angio | Gain | 20 |
| | | Contrast | 0 |
| | | Gamma | 1 |
| | | Delay | 0 |

## Creating a Settings Profile

**WARNING**

- Avoid making image adjustments that may obscure portions of the image. These may cause deterioration of image quality resulting in misdiagnosis or mistreatment.
- Changes from monitor default settings could impact image quality resulting in misinterpretation and/or misdiagnosis.

CAUTION

- When setting the IP address, make sure to check with the network administrator and set IP address correctly. Setting the wrong IP address may cause system or other equipment to malfunction.

**To create a new Settings Profile:**

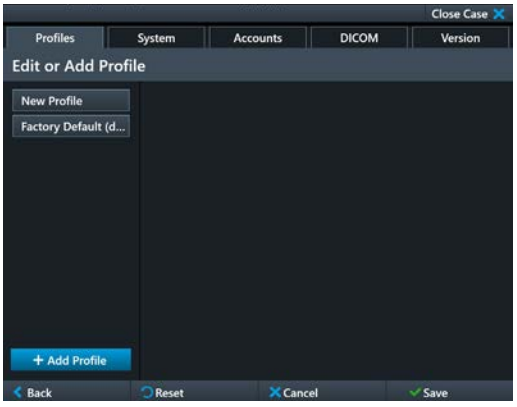
1. **Click [Adjust System Settings] button on the login screen to access system settings (Fig. 20.1).**

Fig. 20.1 Adjust System Settings




2. **Select [Profiles] Tab (Fig. 20.2).**
3. **Click [Add Profile] button.**

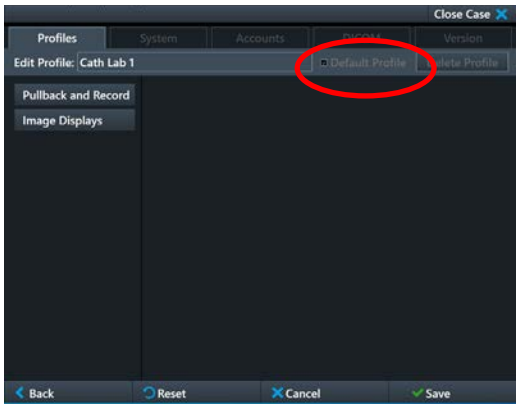
Fig. 20.2 Add Profile




Add Profile

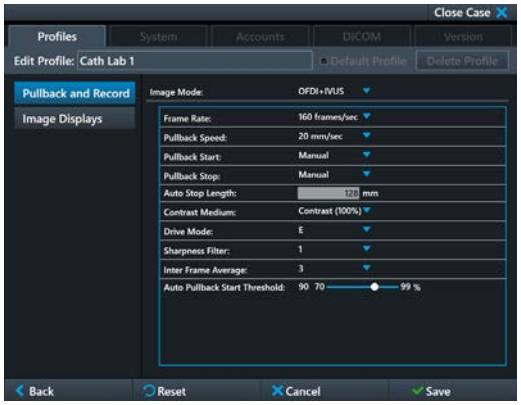
4. **On the Profiles Tab (Fig. 20.3):**
   - Enter Profile Name in "Edit Profile" box.
   - Check the [Default Profile] checkbox to make the Setting Profile being created to be used as the default profile for the user when a new case is started.

Fig. 20.3 Enter Profile Name




5. **Click [Pullback and Record] button to configure the pullback and record settings for the profile (Fig. 20.4).**

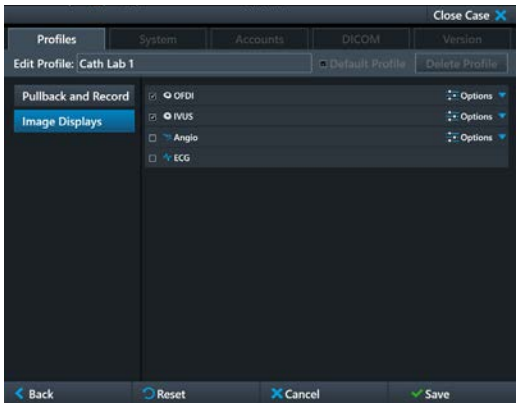
Fig. 20.4 Configure Pullback/Record Settings




6. **Click the blue triangle to edit each setting to the preferred default setting.**
   - "Auto Stop Length" can only be configured if Pullback Start is set to "Auto".
   - Adjust "Auto Pullback Start Threshold" by moving the slider between 70% and 99%.

7. **Click [Image Displays] button to configure the image display settings for the profile (Fig. 20.5).**

Fig. 20.5 Configure Image Display(s)




8. **Click [Reset] button to discard all unsaved modifications in ALL pages.**

9. **Click [Cancel] button to discard all unsaved modifications in the current displayed page.**

10. **Click [Save] button to store configuration to the Settings Profile.**

11. **Click [Back] button to discard all unsaved modifications and return to Profiles tab of System Adjustment screen.**

**E-mode and F-mode are selected as part of the Settings Profile:**

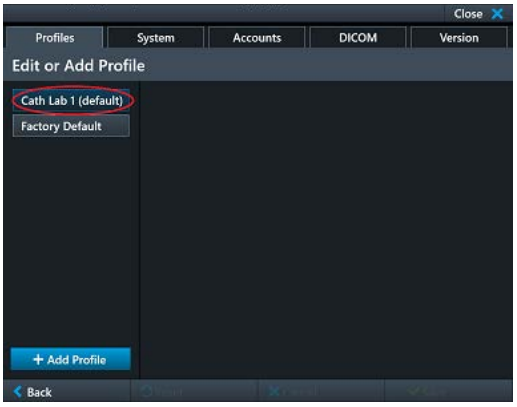
1. **Click [Adjust System Settings] button on the login screen to access system settings (Fig. 20.6).**

Fig. 20.6 Adjust System Settings




2. **Select a settings profile from the [Profiles] Tab (Fig. 20.7).**

Fig. 20.7 Add Profile




3. **Click [Pullback and Record] button (Fig. 20.8).**

Fig. 20.8 Click Pullback and Record

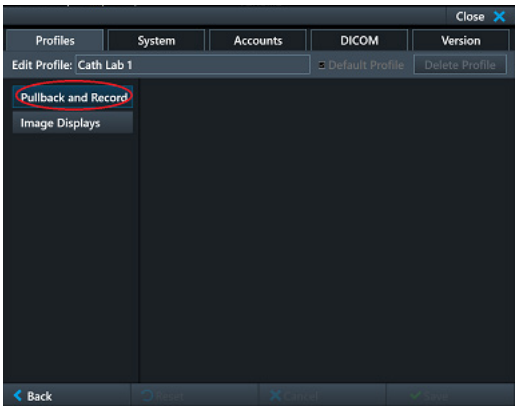
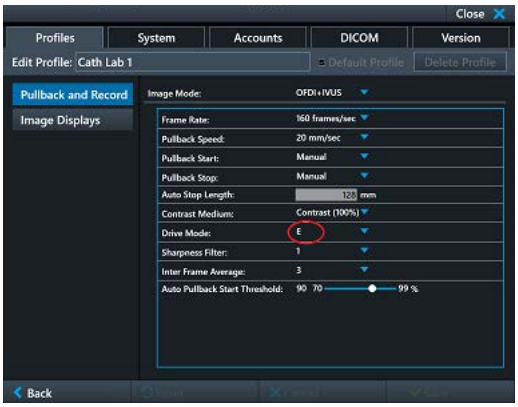
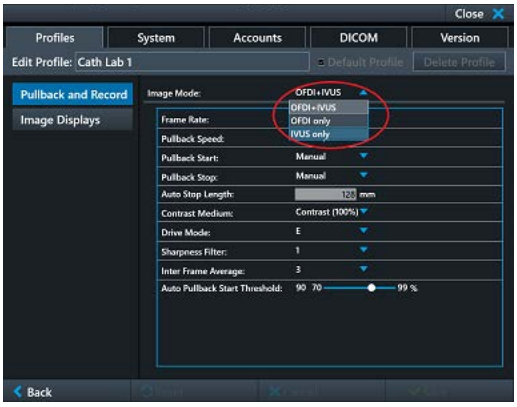


Fig. 20.9 Drive Mode- OFDI/IVUS



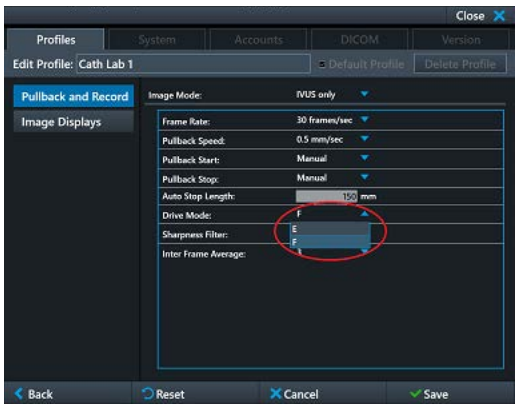

1. **The drive mode for Dual (OFDI/IVUS) can be selected here (Fig. 20.9).**

Fig. 20.10 Image Mode Drop Down



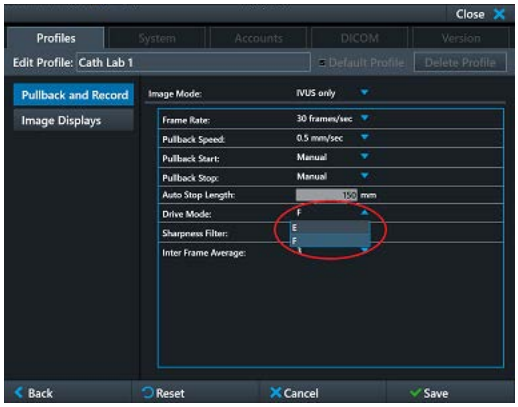

2. **Pullback settings for IVUS only mode can be selected by the "Image Mode" drop down (Fig. 20.10).**

Fig. 20.11 Select Drive Mode- IVUS




3. **The drive mode for IVUS only can be selected here (Fig. 20.11).**

Fig. 20.12 Selected Drive Mode Applied




4. **[The selected drive mode is applied by selecting the Settings Profile when a new case is started (Fig. 20.12).**

# Settings

### Color Map

You can select OFDI Color (Color Map) type from three options: blue, orange, or gray.
For details see "Adjusting Images" in Section 13.

### Gain

You can adjust the brightness setting for the image display area by sliding the bar from 0-20.
For details see "Adjusting Images" in Section 13.

### Contrast

You can adjust the contrast setting for the image display area by sliding the bar from 0-15.
For details see "Adjusting Images" in Section 13.

### Gamma

You can select the gamma correction setting for the image display area from 1-10 using the dropdown list.
For details see "Adjusting Images" in Section 13.

### STC

You can adjust the brightness setting of each specified depth range of the image display area using six STC control sliders.

### Angio Delay

You can enter the Angio Delay from the keyboard to shift the co-registration between OFDI + IVUS and Angio images.
When the Delay setting becomes larger, the Angio image starts from later frame to adjust the displacement.

### Image Display

You can check the checkbox for each image modality to display by default.

## Editing Existing Settings Profiles

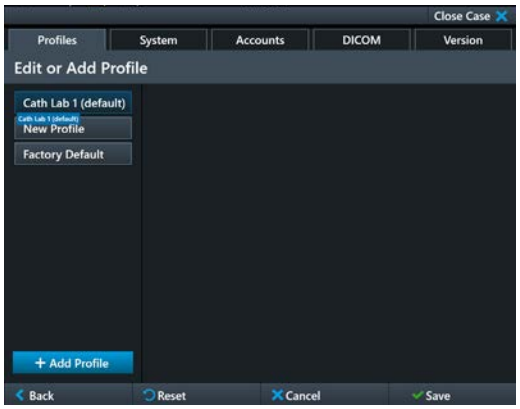
1. **Click [Adjust System Settings] on the HOME screen (Fig. 20.13).**

Fig. 20.13 Adjust System Settings



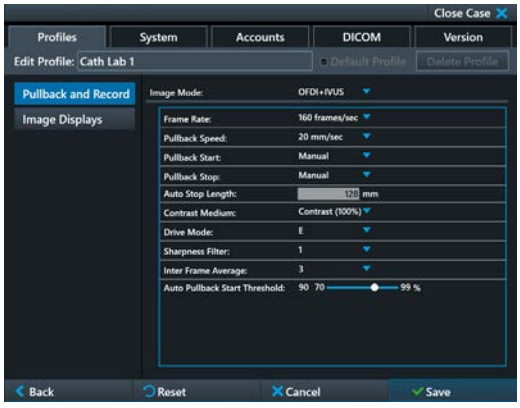

2. **Select the [Profiles] tab (Fig. 20.14).**
3. **Select a Settings Profile to be Edited.**
4. **Refer to "Creating a Settings Profile" in this section and follow same steps for editing settings.**

Fig. 20.14 Select Settings Profile




5. **Click [Reset] button to discard all unsaved modifications in ALL pages (Fig. 20.15).**
6. **Click [Cancel] button to discard all unsaved modifications in the current displayed page.**
7. **Click [Save] button to store edited settings to the Settings Profile.**
8. **Click [Back] button to discard all unsaved modifications and return to Profiles tab of System Adjustment screen.**

Fig. 20.15 Save Changes




NOTE

- Factory Default Settings Profiles cannot be edited.

## Deleting Existing Settings Profiles

1. **Click [Adjust System Settings] on the HOME screen (Fig. 20.16).**

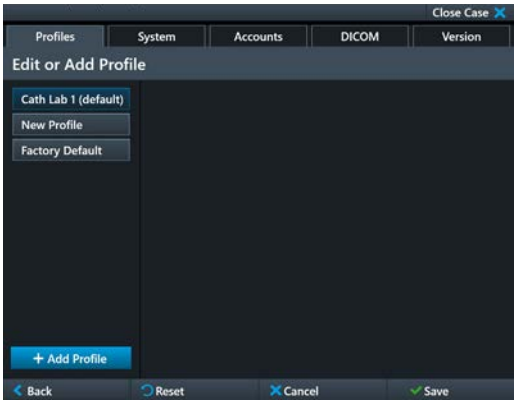
Fig. 20.16 Adjust System Settings




2. **Select the [Profiles] tab (Fig. 20.10).**

3. **Select a Settings Profile to be deleted (Fig. 20.17).**

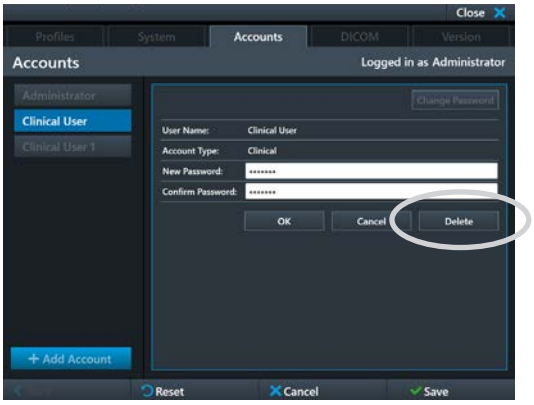
Fig. 20.17 Select Profile




4. **Click [Delete] button (Fig. 20.18).**

5. **Click [Yes] button on the confirmation dialog box to confirm deletion of the selected Settings Profile, or [No] button to cancel the deletion.**

Fig. 20.18 Delete Profile




NOTE

- Factory Default Settings Profiles cannot be deleted.

## System Settings

You can register configurations at the system level to be used for all cases performed on the system.

1. **Click [Adjust System Settings] button on the HOME screen to access system settings (Fig. 20.19).**

Fig. 20.19 Adjust System Settings




2. **Select the [System] tab (Fig. 20.20).**
3. **Select the Item to be configured.**

Fig. 20.20 Select System Tab



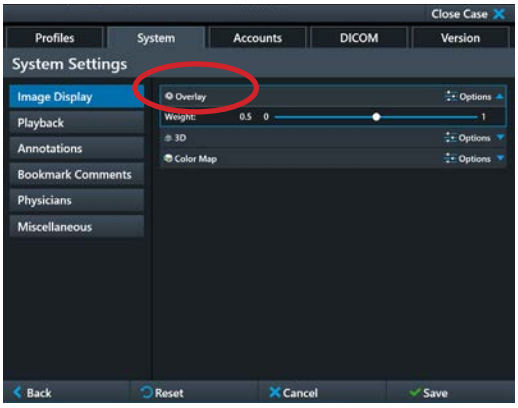
Image Display

Select [Image Display] button to adjust Overlay, 3D, and Color Map.

**Overlay (Fig. 20.21):**

1. **Click [Overlay] field to expand the drop-down.**
2. **Configure weight to create overlay image by adjusting the slider bar. Setting the weight to 0 yields the IVUS image, and setting the weight to 1 yields the OFDI image.**

Fig. 20.21 Overlay




**3D (Fig. 20.22):**

1. **Click [3D] field to expand the drop-down.**
2. **Configure Window Level and Window Width by adjusting the slider bars.**
3. **Select Cut Direction from None, CW (Clockwise) or CCW (Counterclockwise).**
4. **Select Rendering Type from Vessel or Carpet.**

Fig. 20.22 3D




**Color Map (Fig. 20.23):**

1. **Click [Color Map] field to expand the drop-down.**
2. **Configure thresholds between each color for IVUS drive mode E and F by adjusting the slider bars.**

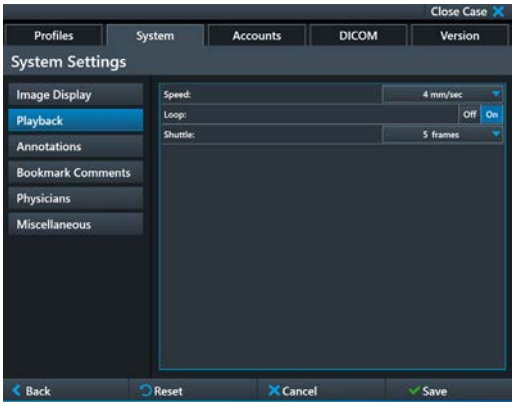
Fig. 20.23 Color Map



Playback

Select [Playback] button to adjust playback speed, loop, and shuttle **(Fig. 20.24)**.

Fig. 20.24 Speed, Loop, and Shuttle




### Speed:

1. **Select speed for playback in the Review screen from 0.5, 1, 2, 4, or 8 mm/s.**

### Loop:

1. **Select [On] or [Off].**
   - Selecting [On] will do a continuous play of the playback. When the playback reaches the end, it moves back to the beginning and repeats playback.
   - Selecting [Off] will do a single playback of the recording. When the playback reaches the end, it will not automatically replay from the beginning.

### Shuttle:

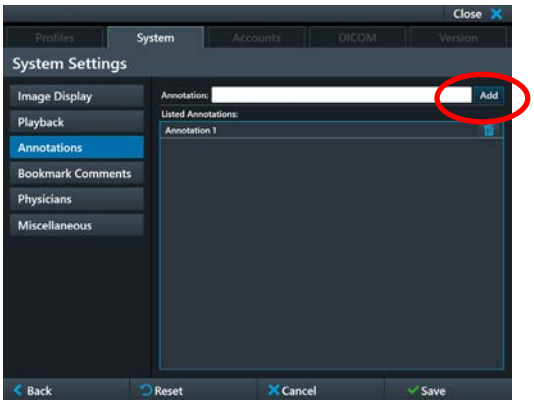
1. **Select frame counts for shuttle payback from 1, 2, 3, 4, or 5 frames.**

## Annotations

Select [Annotations] button to register up to 20 predetermined annotations **(Fig. 20.25)**.

1. **Enter text strings to be registered as a predetermined annotation.**
2. **Click [Add] button to register the text to the list.**
3. **Click the trash can icon next to the entered annotation to delete the predetermined annotation item from the list.**

Fig. 20.25 Annotations

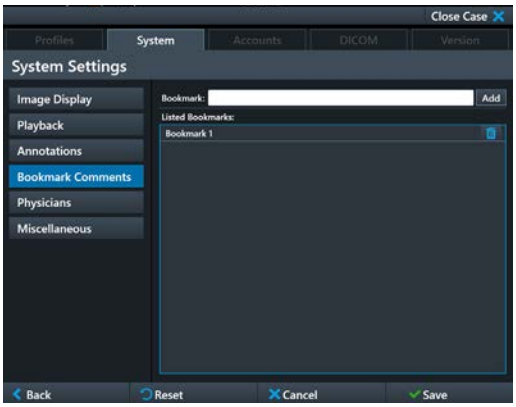



## Bookmark Comments

Select [Bookmark] button to register up to 20 predetermined bookmark labels **(Fig. 20.26)**.

1. **Enter text strings to be registered as a predetermined bookmark label.**
2. **Click [Add] button to register the text to the list.**
3. **Click the trash can icon next to the entered bookmark to delete the predetermined bookmark label item from the list.**

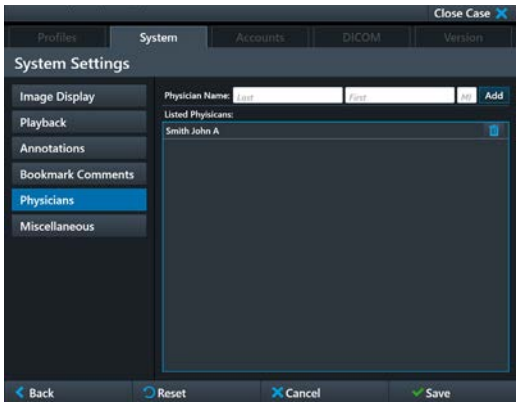
Fig. 20.26 Bookmark Comments



## Physicians

Select [Physicians] button to register up to 20 predetermined physician names **(Fig. 20.27)**.

Fig. 20.27 Register Physicians Names

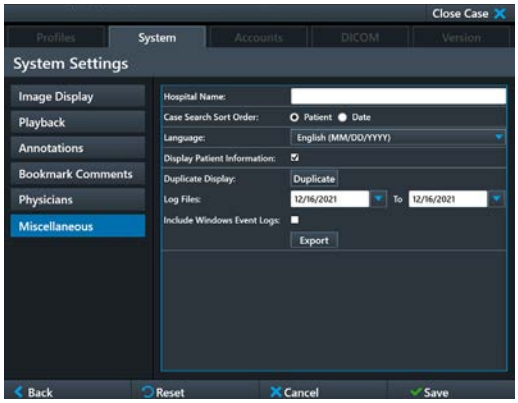



1. **Enter text strings to be registered as a predetermined physician name.**
   - The system requires either last name or first name. Middle Initial is not required.
2. **Click [Add] button to register the name to the list.**
3. **Click the trash can icon next to the entered physician name to delete the predetermined physician name from the list.**

## Miscellaneous

Select [Miscellaneous] button to update the following fields **(Fig. 20.28)**:

Fig. 20.28 Miscellaneous Fields




1. **Hospital Name**
   - Enter the name of the hospital that is displayed on the top right corner of the screen.
2. **Case Search Sort Order**
   - Select whether the case data list is sorted by Patient ID or Case Date.
3. **Language**
   - Select screen display language and date format from English (MM/DD/YYYY), Europe (DD/MM/YYYY) or Japanese (YYYY/MM/DD).
4. **Display Patient Information**
   - Check the box to display patient information on the screen. When this box is unchecked, the system screen does not display patient information.
5. **Duplicate Display**
   - Click [Duplicate] button to output the screen image to the external monitor.
6. **Log Files**
   - Select the date range and click the [Export] button to export the log file to the connected USB storage device.

## DICOM Settings

You can set the network communications for the OPUSWAVE System.

1. **Click [Adjust System Settings] button on the HOME screen to access system settings (Fig. 20.29).**

Fig. 20.29 Adjust System Settings




2. **Select the [DICOM] tab (Fig. 20.30).**
   - The DICOM tab shows the DICOM settings menu. DICOM configurations should be set when transferring data to the PACS server and/or receiving patient information from the RIS server on the hospital network.
3. **Select the Item to be configured.**

Fig. 20.30 Set Network Communications



## DICOM Local

Click the [DICOM (local)] button to set the network communications for OPUSWAVE System **(Fig. 20.31)**:

Fig. 20.31 DICOM Local




### 1. Local AE Title

- Enter a text string up to 16 alphanumeric characters as the name of the unit in DICOM network.

### 2. Local Station Name

- Enter a text string to specify the name of the computer in the DICOM network.

### 3. Local IP Address

- Enter the IP address assigned to the OPUSWAVE System.

### 4. Local Subnet Mask

- Enter the subnet mask of the OPUSWAVE System.

### 5. Local Default Gateway

- Enter the default gateway for the OPUSWAVE system.

### 6. IVUS DICOM Modality

- Select a DICOM modality for IVUS images from IVUS (Intravascular Ultrasound), US (Ultrasound), IVOCT (Intravascular Optical Coherence Tomography), or OCT (Optical Coherence Tomography).

### 7. OFDI DICOM Modality

- Select a DICOM modality for OFDI images from IVUS (Intravascular Ultrasound), US (Ultrasound), IVOCT (Intravascular Optical Coherence Tomography), or OCT (Optical Coherence Tomography).

### 8. Transfer Syntax

- Select disk transfer syntax from Explicit VR Little Endian, JPEG Baseline (Process 1), or JPEG Lossless.

### 9. Click [Save] button to store all changes.

DICOM (PACS)

Click the [DICOM (PACS)] button to enter the network communication information for the PACS System **(Fig. 20.32)**:

Fig. 20.32 DICOM PACS- TLS Disabled




**1. PACS AE Title**

- Enter the name of the PACS server unit in DICOM network.

**2. PACS Station Name**

- Enter the name of the PACS server computer in the DICOM network.

**3. PACS IP Address**

- Enter the IP address assigned to the PACS server.

**4. PACS Port**

- Enter the port number of the PACS server.

**5. Ping Test**

This function checks the accessibility between the OPUSWAVE System and PACS server in the network.

**1.Click the [Check] button.**

- Check has been completed when a message is displayed saying the check was successful.

**6. C-Echo Test**

This function checks the communication status between the OPUSWAVE System and DICOM AE of the PACS server at application level.

- **Click the [Check] button.**
  - Check has been completed when a message is displayed saying the check was successful.

**7. Click the [Save] button to store all changes.**

DICOM (RIS)

Click the [DICOM (RIS)] button to enter the network communication information for the RIS System **(Fig. 20.33)**:

Fig. 20.33 DICOM RIS-TLS Disabled




1. **RIS AE Title**
   - Enter the name of the RIS server unit in the DICOM network.
2. **RIS Station Name**
   - Enter the name of the RIS server computer in the DICOM network.
3. **RIS AP Address**
   - Enter the IP address assigned to the RIS server.
4. **RIS Port**
   - Enter the port number of the RIS server.
5. **Ping Test**
   - This function checks the accessibility between the OPUSWAVE System and RIS server in the network.
   - **Click [Check] button.**
     - Check has been completed when a message is displayed saying the check was successful.
6. **C-Echo Test**
   - This function checks the communication status between the OPUSWAVE System and DICOM AE of the RIS server at application level.
   - **Click the [Check] button.**
     - Check has been completed when a message is displayed saying the check was successful.
7. **Click the [Save] button to store all changes.**

Setting up Secure DICOM Communications using TLS

**1. For DICOM encryption using Transport Layer Security (TLS) for PACS or RIS, OPUSWAVE requires Privacy Enhanced Mail (PEM) files with certificate information. The PEM files are container files for the generated PACS or RIS certificate, private key without any encryption and the common root certificate from 'Certificate Authority'.**

**Open SSL may be used to generate a new root trusted certificate authority file, private key, and certificate pair each for the PACS or RIS DICOM Server and for the OPUSWAVE application. The PACS or RIS DICOM servers itself might need a separate private key (.key) and certificate (.cert) pair along with a copy of the generated PEM file (.pem) for the OPUSWAVE.**

**Below is a PEM file format required for reference without any encrypted private key that is created by combining a private certificate, private key with the common root certificate:**

**------- BEGIN CERTIFICATE -----------**

**xxx**

**------- END CERTIFICATE --------------**

**------- BEGIN PRIVATE KEY --------**

**yyy**

**------- END PRIVATE KEY -----------**

**------- BEGIN CERTIFICATE -----------**

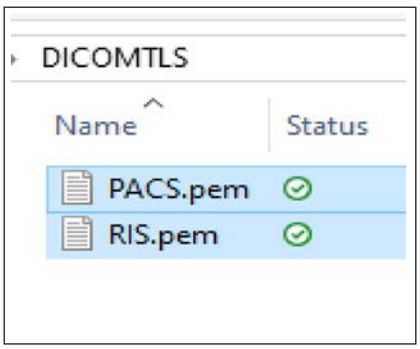
**zzz**

**------- END CERTIFICATE --------------**

NOTE

- "xxx", "yyy", "zzz" are any strings.

Fig. 20.34 PEM Files




2. **OPUSWAVE requires separate PEM files for PACS and RIS servers. If the PACS and RIS server are combined as part of the same DICOM server, the same PEM file may be copied and renamed separately for PACS and RIS servers (Fig. 20.34).**

3. **The PEM files can be imported onto the OPUSWAVE by copying the files to an USB drive 'DicomTls' folder as shown below with names 'PACS.pem' and 'RIS. pem' and selecting OPUSWAVE PACS or RIS settings 'TLS Import Certificate' 'Import' button (Fig. 20.35).**

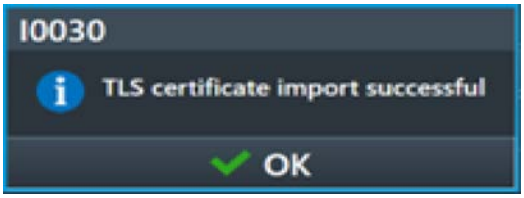
   - The [Import] button is enabled only for the 'Administrator' user account and disabled for 'Service' and other local inical' user accounts.

Fig. 20.35 Import




4. **Once the TLS certificate import is successful, a confirmation message box is displayed to the user . Click [OK] to confirm. (Fig. 20.36).**

Fig. 20.36 Confirmation Box



**5. OPUSWAVE is limited to four TLS 1.2 Cipher suites (Fig. 20.37).**

- The preferred TLS 1.2 cipher suite can be chosen by selecting the checkbox next to the cipher suite. If more than one TLS 1.2 cipher suite is chosen, the most secure cipher suite among the ones selected might be used for secure DICOM communications.

Fig. 20.37 Cipher Suites




Configure OPUSWAVE to commuincate with PACS/RIS server

**1. Click [Adjust System Settings] button on the HOME screen to access system settings (Fig. 20.38).**

Fig. 20.38 Adjust System Settings




**2. Select the [DICOM] tab (Fig. 20.39).**

- Confirm the 'DICOM (local) settings' are appropriate.
- Update settings as needed and select the "Save" button.

**3. Select DICOM (PACS) or DICOM (RIS) button to display options for PACS or RIS settings.**

**4. Set PACS or RIS AE Title, Station Name, IP Address, and Port Number.**

Fig. 20.39 DICOM Settings



**With DICOM Encryption disabled:**

5. **Confirm that the TLS Enable checkbox is deselected to disable secure DICOM communications.**
6. **Verify "Ping" and "C-Echo" are successful and click [Save].**
7. **Refer to Fig. 20.40 and Fig. 20.41 for sample settings with DICOM TLS Encryption disabled.**

**With DICOM Encryption enabled:**

5. **Login as 'Administrator' to enable TLS Import Certificate 'Import' button and click the [Import] button to import the TLS Certificate.**
6. **Confirm that the 'TLS Enable' checkbox is selected to enable secure DICOM communications.**
7. **Select any preferred TLS 1.2 ciphers for secure DICOM communications.**
8. **Verify 'Ping' and 'C-Echo' are successful and click [Save].**
9. **Refer to Fig. 20.42 and Fig. 20.43 for sample settings with DICOM Encryption enabled.**

Fig. 20.40 DICOM PACS- TLS Disabled




Fig. 20.41 DICOM RIS- TLS Disabled




Fig. 20.42 DICOM PACS- TLS Enabled




Fig. 20.43 DICOM RIS- TLS Enabled



## Version Information

You can view the current software version on the system:

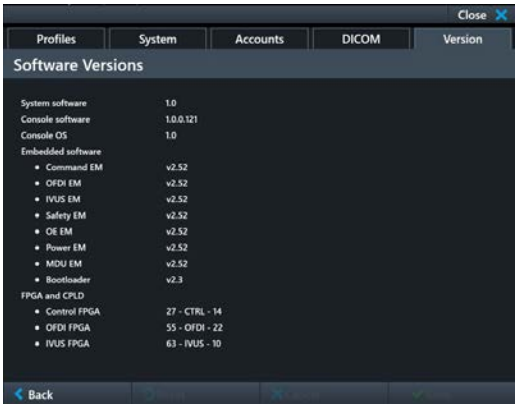
1. **Click [Adjust System Settings] button on the HOME screen to access system settings (Fig. 20.44).**

Fig. 20.44 Adjust System Settings




2. **Select the [Version] tab (Fig. 20.45).**

Fig. 20.45 Version Information




3. **The following versions can be viewed:**
   - System Software
   - Console Software
   - Embedded Software
     - Command EM
     - OFDI EM
     - IVUS EM
     - Safety EM
     - OE EM
     - Power EM
     - MDU EM
     - Bootloader
     - FPGA
     - Control FPGA
     - OFDI FPGA
     - IVUS FPGA

# Section 21
# Cleaning and Maintenance

# Cleaning and Maintenance

## Routine Cleaning of the System

### Preparation For Cleaning

The OPUSWAVE System should be cleaned every 30 days, under normal use, following your facilities cleaning procedures. In preparation for cleaning, perform the following:

1. **Properly shut down power to the system. Refer to "Shutting down the system" in Section 4.**
2. **Unplug the power cable from the outlet.**
3. **Disconnect cables from external screen ports and the back of the console.**



**WARNING**

- Properly clean the system and components after use. Failure to do so may result in image readability issues leading to misdiagnosis.
- Do not spray cleaning agents directly on system or its components, instead spray on a cloth to clean the system. Failure to do so may cause system malfunction or damage.
- Properly clean the system and components after use. Failure to do so may result in cross contamination.
- Use only approved cleaning agents when cleaning the system. Failure to do so may cause damage to the system or system not being properly decontaminated.
- Turn off power to all system components and unplug the AC power cord prior to cleaning or transporting the system. Failure to do so may increase the risk of electrical shock hazard to the user and/or system malfunction.

# Cleaning and Maintenance

## Cleaning the OPUSWAVE Monitor

1. **Wipe the monitor's surface using a lint-free, non-abrasive cloth dampened with Isopropyl Alcohol (70%).**

## Cleaning the OPUSWAVE Console

1. **Refer to the below table for disinfection solutions approved for cleaning and disinfecting the OPUSWAVE System Console/MDU/Mouse. For dilution rates of the solution, refer to the instruction manual of the antiseptic being used. Using solutions other than below, may cause damage to the system or system not being fully decontaminated.**

| Cleaner |
|---|
| Sani-Cloth Germicidal Disposable Wipes |
| Clorox Bleach Germicidal Wipes |
| Chlorhexidine Gluconate diluted by water to 0.1-0. 5% |
| Benzalkonium Chloride diluted by water to 0.1% |

2. **Clean the system surfaces and power cord with an approved disinfection solution and a soft cloth.**
3. **Clean the keyboard with a damp cloth and mild cleaning agent (e.g., dishwashing liquid). Prevent liquids from entering the keyboard.**
4. **System Console Intake: Remove dust on the intake in front of the console by vacuuming or other appropriate means.**
5. **System Casters: Periodically check the casters to ensure that they are clean and free of debris that could prevent them from moving freely.**
6. **Inspect the OPUSWAVE console after cleaning to ensure that there is no visible damage.**

## Cleaning the OPUSWAVE MDU

1. **Clean the MDU and MDU cable with an approved disinfection solution and a soft cloth. Be careful when handling the cable as to not stress or bend. Gently wipe any contamination of chemicals or blood on the openings.**
2. **Inspect the OPUSWAVE MDU and MDU cable after cleaning to ensure that there is no visible damage.**

## Cleaning the OPUSWAVE Mouse

1. **Periodically clean the exterior surface of the mouse with an approved disinfection solution and a soft cloth to maximize smooth use of the mouse.**

# Cleaning and Maintenance

## Maintenance

**WARNING**

- Do not attempt to repair, alter, modify, or replace components that are serviceable only by trained technicians. Doing so may result in system malfunction. User replaceable parts are identified in Section 22, "System Safety and Technical Specifications". Contact your Terumo Representative for service.

CAUTION

- Replace batteries on the wireless mouse per the recommended manufacturers suggestions. Refer to the wireless mouse instruction manual provided. Failure to do so may result in loss of mouse function.
- The power cord supplied with the system is non-detachable and should be replaced only by a trained technician. Failure to follow this caution may result in system malfunction. User replaceable parts are identified in Section 22, "System Safety and Technical Specifications".

NOTE

- User-replaceable components in the OPUSWAVE System can be found in Section 22, User Replaceable Parts Table.
- There are no User-Serviceable batteries or fuses in the OPUSWAVE System.
- To ensure safe operation of the system, perform regular maintenance. If any abnormality is detected, immediately discontinue using the system and contact your Terumo service representative.

### System Service Life

- The OPUSWAVE system service life, under normal operating conditions, and with periodic preventive maintenance inspections by a Terumo Service Technician, is 8 years.

### System Inspection and Service

**Servicing the OPUSWAVE System:**

- Service of the OPUSWAVE should only be performed by qualified Terumo personnel.
- Only Authorized Terumo Service Representatives shall perform System Software updates and/ or Upgrades.
- Contact your Terumo Service Representative for the annual inspection.
- Disassembly, repair, or modification by unauthorized or non-commissioned personnel from Terumo may cause further serious failures, for which Terumo shall not be responsible for.
- Only Terumo, Inc. certified parts and components shall be used for replacement by a Terumo Representative.
- User-replaceable parts can be found in Section 22, "System Safety and Technical Specifications", User Replaceable Parts Table.
- Contact Terumo Field Service for instructions and issuance of a Return Material Authorization (RMA) if claims under this warranty become necessary and if the System or components of the System are to be returned.
- The System or components will not be accepted for warranty purposes unless the return has been authorized by Terumo.
- For further information contact your Terumo Service Representative.

# Cleaning and Maintenance

## Routine and Service Maintenance

**WARNING**

- Before using the system, perform the Pre-Startup Checklist defined in this Instructions For Use. Failure to do so may result in degradation of image quality.

## Pre-Startup Checklist

### PRIOR TO EVERY USE

[See APPENDIX A - PRE-STARTUP CHECKLIST FORM FOR RECORD-KEEPING PROPOSES.]

| Pre-Startup Checklist - Use prior to every system start-up. |
|---|
| **Visual Inspection** |
| • No damage in physical appearance of the system. |
| • No abnormalities are detected on the MDU, Monitor unit, or Console. |
| • No contamination of blood or chemicals. |
| • No contamination of particles, blood or chemicals at the imaging window and the connecting section of the Catheter.<br>*Remove all contamination that exists.* |
| • If any contamination and/or smear is found, follow the instructions for cleaning in Section 21 of the Instructions For Use. |

# Cleaning and Maintenance

## System Disposal



"To discard the system and/or batteries at its end of life, be sure to follow your local, state, and federal hazardous material disposal regulations.

The OPUSWAVE System must be disposed of in accordance with hospital policy regarding electrical and electronic equipment waste. Contact your Terumo Representative for information concerning the decommissioning of your equipment.

Refer to Chapter 16 for disposal of the catheter, MDU cover, and disposable accessories.

# Cleaning and Maintenance

## Troubleshooting

**NOTE**

- For basic guidelines on troubleshooting the OPUSWAVE System, please reference this section. If your problem is not resolved by the stated solution immediately discontinue use and contact your Terumo service representative.

This chapter can help the user solve problems that might occur with the Terumo Cardiovascular Systems OPUSWAVE System. If an error message appears on the screen or you are having a problem with the system, consult this chapter to determine the possible cause. If you cannot solve a problem you are having with the system, or if you cannot determine the cause of a problem, you can call the Terumo troubleshooting hotline during normal business hours.

**Terumo Cardiovascular Systems Corporation**

Terumo troubleshooting hotline

800-521-2818 — Customer Administration

800-441-3220 — Technical Support



**CAUTION**

- Users should never leave the device unattended. After a procedure or completing file transfer, users should log out of the system and disconnect the ethernet cable from the HDO network to ensure the system cannot be accessed by unauthorized individuals. Failure to do so could result in leakage of patient information.

# Cleaning and Maintenance

Power On Issues

| Function | Condition | Possible Cause | Suggested Solutions |
|---|---|---|---|
| Power On | System does not turn on. | Main Power Switch on the Console base is in the "OFF" position. | Ensure the main power switch on the back base of the console is in the "ON" position. |
| | | System power button was not pressed. | Press and release the power button on the front panel of the console. |
| | | AC power cord not plugged in or secure at either the system end or wall connection. | Ensure plug is securely connected to both the system and to the wall outlet. |
| | | System malfunction. | Contact Terumo Service Representative. |
| Login | Freeze up at Login Screen: After startup, software does not show login screen. | System Error | Shut down and re-start the system. |
| | | Data loading problem. Damage to internal SSD. | Contact Terumo Service Representative. |
| | Unable to type in logon password. | Mouse pointer is not within password dialog box. | Move mouse pointer to dialog box and click button on mouse to place cursor. |
| | | Keyboard failure. | Contact Terumo Service Representative. |
| Power Off | Unable to turn off power to the console. | The system is writing the data to external media or DICOM Server. | Wait until the system completes the export. |
| | | System power button was not held for a minimum of 3 seconds. | Hold power button down for a minimum of 3 seconds. |
| Basic Performance | Slowed or sluggish performance, or complete lack of performance (denial of service). | Suspected malicious cyber- attack, "hacking" | Log off and restart the system, removing it from the local network (Restarting the system returns it to a controlled state and may resolve the issue). If no resolution, contact your IT department for incident response. |

## Catheter Connection

| Function | Condition | Possible Cause | Suggested Solutions |
|---|---|---|---|
| Connect MDU Cover | MDU cover adapter not seating in MDU port. | Wrong orientation of the adapter in relation to the MDU port. | Attach the MDU cover adaptor by aligning mark o the adapter to the "unlock" symbol on the MDU |
| | | Foreign material in the MDU port. | Clean MDU using approved cleaning agents. |
| Catheter Connect | Catheter cannot be inserted into the MDU. | Wrong orientation of the catheter connector in relation to the MDU. | Line up the marking on the catheter connector with the corresponding marking on the MDU port. Insert until it stops. |
| | | Foreign material in the MDU. | Clean the MDU using approved cleaning agents. |
| | | Defect on catheter. | Replace catheter. |
| | | Defect on MDU. | Contact Terumo Service Representative. |
| Catheter Disconnect | Catheter cannot be disconnected from the MDU | Marking on MDU cover adapter not aligned to the [UNLOCK] symbol on the MDU. | Align the MDU cover adapter marking to the [UNLOCK] symbol on the MDU. Pull catheter and catheter adaptor out from MDU port.<br>Refer to Section 16. |

## Pullback

| Function | Condition | Possible Cause | Suggested Solutions |
|---|---|---|---|
| [Scan] | [Scan] button is pressed but does not scan for pullback. | Patient information was not input. | Input patient information on the system screen. |
| | | Catheter disconnected. | Confirm catheter is connected to the MDU. |
| | | Catheter calibration was not done. | Complete catheter calibration. |
| [Ready Pullback] | [Ready Pullback] button is pressed but does not ready for pullback. | MDU failure. | Contact a Terumo Service Representative. |
| [Pullback] | [Pullback] button is pressed but does not activate MDU. | Catheter disconnection. | Confirm catheter connection. |
| | | MDU failure. | Contact a Terumo Service Representative. |
| Record | Clicking [RECORD] on System Screen does not start recording. | Internal storage is full. | Check storage capacity. Delete or export image data to free up space. |
| Playback | Unable to playback a pullback. | Data load failure or data corruption on the built in storage. | Try to play pullback again. If not successful, contact your Terumo Service Representative. |
| | | Loop playback range was set on unexpected location. | Correct loop playback range. |
| MDU Noise | Excessive noise from the MDU. | MDU failure. | Contact a Terumo Service Representative. |

Image Viewing

| Function | Condition | Possible Cause | Suggested Solutions |
|---|---|---|---|
| Activate "SCAN" Function | When the Scan button is pressed, abnormal vibration or noise occurs. | The catheter is not securely connected to the MDU. | Remove catheter from MDU. Attach catheter per instructions in Section 7, "Setting Up The Catheter" |
| View Live Image | Noise is imposed on a live image. | The catheter is not securely connected to the MDU. | Remove catheter from MDU. Attach catheter per instructions in Section 7, "Setting Up The Catheter" |
| | | A source of high-frequency noise (mobile phone, electrosurgical knife, or defibrillator) is in the vicinity. | Keep the noise source away from the OPUSWAVE System. |
| | | Defective catheter. | Disconnect and re-connect catheter. If problem repeats, replace catheter. |
| Display Angio and ECG | [Angio], [ECG], etc. screen is not displayed when display box is checked. | Monitor cable connection not connected. | Ensure cable is connected. Refer to Section 4, "System Assembly and Preparation" |
| | | The signal does not meet with OPUSWAVE required specification. | Ensure ECG device is good. |
| Poor or no image displayed | Low brightness level on the Cross-sectional viewing area. | Settings for [Gain] and [STC] are too low. | Adjust image parameters per instructions in Section 13, Review. |
| | LCD screen blank, dark, or disturbed. | Monitor is disconnected or not connected properly. | Secure the connection.<br>Refer to Section 4. |
| | | MDU cover adapter and/or catheter not connected to MDU. | Turn off console and secure connection.<br>Refer to Section 6 and 7. |
| | | Insufficient priming (IVUS) | Prime the catheter.<br>Refer to catheter IFU. |
| | | Defective catheter. | Disconnect and re-connect catheter. If problem repeats, replace catheter. |
| | | Monitor failure. | Contact Terumo Representative. |
| Keyboard text | Keyboard input does not appear on the screen. | Cursor is displaced from the field. | Move the mouse pointer to the empty field and click the mouse button to place cursor. |
| | | Keyboard is disconnected from the console. | Contact a Terumo Representative. |
| | | Keyboard failure. | Contact a Terumo Representative. |

# Cleaning and Maintenance

Transportation

| Function | Condition | Possible Cause | Suggested Solutions |
|---|---|---|---|
| Transport | Cannot move console. | Casters are locked. | Unlock casters. Refer to Section 4. |

External Devices

| Function | Condition | Possible Cause | Suggested Solutions |
|---|---|---|---|
| External Monitor Image Quality | Image on the External Monitor is distorted. | External monitor does not meet the output signal specification. | Replace with an external monitor that meets specifications. |
| | | Unstable connection. | Reconnect cable and adjust screw to tighten. |
| External Monitor Image Display | External monitor does not display images. | Monitor cable not connected. | Confirm cable is securely connected and re-start. |
| | | AC power cable to the external monitor is not securely connected. | Secure connection of the AC power cable. |
| USB Recognition | System does not recognize the USB device. | USB memory device failure. | Replace USB. If problem repeats, contact a Terumo Representative. |
| | | Connected USB is not compatible with the system. | System supports USB 3.0. Any USB Hard Drive or Flash Drive that meets the USB 2.0 Specification may be used. |
| DVD Recognition | System does not recognize the DVD | DVD failure. | Replace DVD. If problem repeats, contact a Terumo Representative. |
| Network Connection | System does not connect to the PACS and/or RIS. | Incomplete Network Connection | Confirm DICOM(PACS) and DICOM(RIS) settings are correct. Refer to Section 20. |
| File Export | Unable to export file(s) | The file system of the USB external storage is FAT32 when exporting data includes file with a size exceeding 4GB. | Use exFAT or NTFS file system USB storage. Or reformat your FAT32 USB storage with exFAT file system. NOTE: If you reformat your device, all stored data on your device will be removed. |
| | | LAN cable is disconnected. | Secure connection of LAN cable to LAN port on the back of console. |
| | | LAN cable is damaged. | Replace LAN cable. |
| File Import | Unable to Import File(s) | File with the same name exists in the system. | Delete image file on the system, and re-import. |
| | | Internal storage is full. | Check capacity of internal storage. Export image data from system and delete from system. Re-import. |

Error Messages

| Code | Message | Possible Cause | Suggested Solutions |
|---|---|---|---|
| E1001 | Internal Storage Hardware Failure. Contact Terumo's service representative. Select OK to shut down. | System Malfunction. | Stop use and contact a Terumo Service Representative. |
| E1002 | PCIe Device(s) not found. | IVUS, OFDI or Control PCIe device(s) is not connected or not recognized by the device. | Shutdown and powerup the system to check if that helps. If issue does not resolve contact a Terumo Service Representative. |
| E1003 | Media eject failed. | System still importing/ exporting or accessing files. | Confirm nothing is in process and if error persists, re-boot. If issue does not resolve, contact a Terumo Service Representative. |
| E2001 | DICOM settings could not be applied. | Software error. | Confirm Settings with the network administrator, refer to Section 20.<br>Re-boot system. |
| E2002 | Local Network settings could not be applied. | Inaccurate settings. | Confirm Settings with the network administrator, refer to Section 20.<br>Re-boot system. |
| E2003 | Export not possible- PACS unavailable. | Inaccurate PACS Settings. | Confirm PACS setting on the DICOM screen with network administrator. Refer to Section 20. |
| | | LAN cable is disconnected. | Secure connection of LAN cable to LAN port on back of console. . |
| | | PACS Network down. | Try again a few minutes later and/or contact your internal IT Department. |
| E2004 | Export not possible- PACS storage failed. | PACS Network down | Try again a few minutes later and/or contact your internal IT Department |
| | | Data corruption | Contact your internal IT Department. |
| E2005 | DICOM Local IP settings could not be applied. | Ethernet cable is not connected to the network or the entered local network settings could not be applied. | Verify the ethernet cable is connected to the hospital network and the entered static IP address information is valid. |
| E2006 | Invalid startup settings. Contact Terumo's service representative. Select OK to shut down. | Startup settings is incorrectly formatted or possibly corrupted. Indicates that the StartupSettings.config could not be loaded. | Shutdown and powerup the system to check if that helps. If issue does not resolve contact a Terumo Service Representative. |
| E2007 | TLS Certificate not found at USB:\DicomTls\ Pacs.Pem | TLS certificate is not found on the connected USB drive at DicomTls\Pacs.pem | Verify the TLS certificate path on the USB drive is as expected at DicomTls\Pacs. pem |

Error Messages Continued

| Code | Message | Possible Cause | Suggested Solutions |
|---|---|---|---|
| E2008 | TLS Certificate not found at USB:\DicomTls\Ris.Pem | TLS certificate is not found on the connected USB drive at DicomTls\Pacs.pem | Verify the TLS certificate path on the USB drive is as expected at DicomTls\Ris.pem |
| E3001 | Error occurred during startup. Cannot start a new case. | System malfunction. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E3002 | Error occurred during data acquisition or saving. Select OK to continue. | Software detected error during data acquisition, updating database, or creating new image files on the storage. | If error occurs again, re-boot system. If the problem persists after re-boot, contact a Terumo Service Representative. |
| E3003 | Error occurred during image data validation. Select OK to continue. | Software detected error during data acquisition. | If possible, try pullback again. If error repeats, contact Terumo Service Representative. |
| E3004 | Error occurred during data acquisition. Aborting data acquisition. | Software detected error during data acquisition | If possible, try pullback again. If error repeats, contact Terumo Service Representative. |
| E3005 | Error occurred during startup, cannot start a new case. | System malfunction. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E4001 | No communication with hardware. | Loss of communication with Embedded Managers detected. Indicates that the software could not receive the Heartbeat message from Embedded Manager. | If issue does not resolve contact a Terumo Service Representative. |
| E4002 | Error occurred during startup. Cannot start a new case. | System malfunction. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E4003 | System Startup Failure detected. Start New Case is disabled but you can review previous data. Do you want to shut down the system? | System Malfunction. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E4004 | System unrecoverable Fault detected. Only review of previous data is available. Shut down to restart. Do you want to shut down? | System malfunction. | Re-boot system. if error repeats, contact a Terumo Service Representative. |
| E4005 | No communication with hardware. Select [OK] to shut down. | Software communication error. | Re-boot system. If error repeats, contact a Terumo Service Representative. |

Error Messages Continued

| Code | Message | Possible Cause | Suggested Solutions |
|---|---|---|---|
| E4006 | System recoverable Fault detected.<br>Only review of pervious data is available. If recovery attempts are unsuccessful, shut down.<br>Do you want to attempt recovery? | Software detects recoverable Fault. | Click [YES] to attempt recovery. If error repeats, re-boot. Contact a Terumo Service Representative if re-boot does not correct error. |
| E4007 | Error occurred during startup. Cannot start a new case. | System malfunction. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E4008 | Error occurred during startup. Cannot start a new case. | System malfunction. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E5001 | Unknown error, System is shutting down. | Software error. | Re-boot system. If the error repeats, contact a Terumo Service Representative. |
| E5002 | 3D construction failure. | Time exceeded maximum time allowed for 3D construction. | Redo 3D construction. If error repeats, contact a Terumo Service Representative. |
| E5003 | Error occurred during 3D image update. | 3D construction failure. | Redo 3D construction. If error repeats, contact a Terumo Service Representative. |
| E5004 | There are some error(s) during case move for cases. | Error while editing patient information. | Try to edit patient information again. If error repeats, contact a Terumo Service Representative. |
| E5005 | Error occurred during patient information edit. | Error while editing patient information. | Try to edit patient information again. If error repeats, contact a Terumo Service Representative. |
| E5006 | Fatal error occurred for Auto Lumen Detection. | Error while using Auto Lumen Detect. | If error continues, manually trace lumen and contact a Terumo Service Representative. |
| E5007 | Error occurred during startup. Cannot start a new case. | System malfunction. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E5008 | Timeout occurred during image processing. Cannot export data. | Time exceeded maximum time allowed for making video data. | Try to export again. If error repeats, contact a Terumo Service Representative. |

Error Messages Continued

| Code | Message | Possible Cause | Suggested Solutions |
|---|---|---|---|
| E5009 | Auto-Calibration Failed. | Failure to complete auto-calibration. | Repeat auto-calibration or adjust calibration manually by using manual calibration.<br>If you cannot adjust calibration properly, replace the catheter. |
| E5011 | Some pullback(s) have invalid data: | Image data file does not exist in the internal storage. | Contact a Terumo Service Representative. |
| E5012 | Error in exporting logs. | SSD failure or file corruption. | Try exporting again. If error repeats, contact a Terumo Service Representative. |
| E5013 | There are some issues with the database. Shutting down. | Error in database. | Contact a Terumo Service Representative. |
| E5014 | Error occurred during startup. Cannot start a new case. | Software error. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E5018 | Error occurred during startup. Cannot start a new case. | Software error. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E5019 | Error occurred during startup. Cannot start a new case. | System malfunction. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E5020 | Error occurred during startup. Cannot start a new case. | Optical Engine performance validation failed. | Re-boot system. If error repeats, contact a Terumo Service Representative. |

Error Messages Continued

| Code | Message | Possible Cause | Suggested Solutions |
|---|---|---|---|
| E5021 | Error occurred during RIS patient search. | Network Server Error. | Confirm system is connected to server. |
| | | | Check DICOM conformance statement of both RIS and this device to check the compatibility. |
| | | The specification of the RIS does not meet our specification. | Confirm RIS specification. |
| E5022 | Export Failed! | Corrupt external device. | If error repeats, try new media. |
| | | Software error. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E5023 | Import Failed! | Corrupt external device. | If error repeats, try new media. |
| | | Insufficient memory. | Confirm storage capacity. Delete files if reached maximum storage. |
| | | Software error. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| E5024 | No Linearity Map files available to export! | Indicates that the application could not export linearity map files because no such files are available. | Linearity map files are generated at shutdown if the DSS uptime is more than 1 hour. Leave DSS up and running for more than one hour and check if that helps. |
| E5025 | TLS Certificate Import failed from USB. | Unknown exception during importing TLS certificate for PACS or RIS servers. It is possible that a previously imported TLS certificate is marked read-only. | Verify the TLS certificate is included on the USB drive in the expected folder path.<br>If issue does not resolve contact a Terumo Service Representative. |

Warning Messages

| Code | Message | Possible Cause | Suggested Solutions |
|---|---|---|---|
| W0001 | Pullback data confliction detected. Some pullbacks could not be imported. | Importing data already exist in internal storage. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| | | Database error. | Try importing again. If error repeats, contact a Terumo Service Representative. |
| W0002 | Profile with same name already exists. Rename to save it. | Profile name already exists. | Rename with naming convention not previously used. |
| W0003 | New password and confirmation password do not match. | Inaccurate password. | Re-try. Password and password confirmation text must match. |
| W0004 | Account with same name already exist. Rename to save it. | Account name already exists. | Rename account with a naming convention not previously used. |
| W0005 | Passwords cannot be empty. | No password entered. | Enter a password adhering to the password rules. |
| W0006 | Passwords must be at least 6 characters. | Password selected does not adhere to password rules. | Re-enter a password with a minimum of 6 characters. |
| W0007 | USB storage is not detected. Connect USB storage and retry to export data. | No USB connected. | Connect a USB. |

Warning Messages Continued

| Code | Message | Possible Cause | Suggested Solutions |
|---|---|---|---|
| W0008 | Password must be different from User Name. | Password selected does not adhere to password rules. | Re-enter a password that is different from user name. |
| W0009 | The format of the USB storage does not support the file size of the selected data. Connect a USB storage in exFAT format and export data. | Insufficient USB storage format. | Connect a USB that has sufficient storage and re-export. |
| W0010 | Internal storage space is not sufficient to Import selected data. | Insufficient storage space on system. | Export pullbacks for backup and delete pullbacks from console. |
| W0011 | Entered Patient ID already exists. Same ID cannot be used for different patient. | Patient ID already exists. | Patient IDs are unique to patient. Confirm patient ID and re-enter. |
| W0012 | OPUSWAVE folder is reserved by the system. Rename the folder to export data. | OPUSWAVE Folder name cannot be selected for export. | Select or create new folder to export. |
| W0013 | Start New Case is disabled due to insufficient storage space. Please delete data to free up storage space before acquiring new data. | Available internal storage space is less than 100 GB. | Delete or Export cases to free up storage capacity. Available space should be >100 GB. |
| W0014 | Start New Case is disabled due to insufficient storage space. Please delete data to free up storage space before acquiring new data. | Available internal storage space is less than 100 GB. | Delete or Export cases to free up storage capacity to >40 GB. |
| W0015 | Storage space is Low. Please delete data to free up the storage. | Available internal storage space on system is less than 100 GB. | Delete or Export cases to free up internal storage capacity. Available space should be >100 GB. |
| W0016 | Temporary file drive does not have enough free space to perform the requested export. | Temporary file drive available storage is less than file size. | Try export again. If warning repeats, reduce selected pullbacks count and try export. |
| | | Storage device has error. | Try export again. If warning repeats, reduce selected pullbacks count and try export. |
| W0017 | Please insert a new or valid media. | Current inserted media is not writable. | Insert writable media. |
| W0018 | Multiple USB storage devices are detected. Please connect only one USB storage device and retry to export. | More than one USB devices connected to the system. | Disconnect all but one USB. |
| W0019 | The dates are invalid or out of order. The 'From' date should be earlier than or the same as the 'To' date. | Entered "To" date that is earlier than the "From" date or entered invalid date format. | Correct date range. |
| W0020 | System date is invalid or out of range. | Invalid format or date range. | Correct date range. |
| | | Data corruption. | Try to set date again. |
| W0021 | Patient DOB is invalid or out of range. | Invalid format or range. | Correct DOB range. |
| | | Data corruption. | Try to set DOB again. |
| W0022 | User Name cannot be empty. | Indicates that the entered account User Name is empty. | Use a non-empty account user name. |

Warning Messages Continued

| Code | Message | Possible Cause | Suggested Solutions |
|---|---|---|---|
| W0023 | The Log Export dates must be between '2017-01-01' and the current date. | The dates specified for log file export are outside expected range. | The dates entered for log file export must be between '2017-01-01' and the current date. |
| W0024 | There are no log files for the specified dates. | No log files exist for the specified date range. | Verify the current system date and time is accurate. Adjust the date range for log file export and check if that helps. |
| W1001 | Export Failed!<br>(Additional information may be provided in the warning box) | Insufficient storage space on USB storage. | Delete or export cases to free up storage capacity. |
| W2001 | Ping Test for PACS Server Failed. Confirm Network Configuration and PACS Settings. | PACS Communication Error. | Confirm Settings with the network administrator, refer to Section 20.<br>Re-boot system. |
| | | Bad cable connection. | Replace network cable. |
| W2002 | Ping Test for RIS Server Failed. Confirm Network Configuration and RIS Settings. | RIS Communication Error. | Confirm Settings with the network administrator, refer to Section 20.<br>Re-boot system. |
| | | Bad cable connection. | Replace network cable. |
| W2003 | C-ECHO Test for PACS Server Failed. Confirm Network Configuration and PACS Setting. | PACS Communication Error. | Confirm Settings with the network administrator, refer to Section 20.<br>Re-boot system. |
| W2004 | C-ECHO Test for RIS Server Failed. Confirm Network Configuration and RIS Settings. | Inaccurate RIS Settings. | Confirm RIS Settings with the network administrator, refer to Section 20.<br>Re-boot system. |
| W2005 | Cannot capture Angio image due to out of spec input signal. | Inaccurate Angio Settings. | Confirm Angio Settings with the network administrator, refer to Section 20.<br>Re-boot system. |
| | | Wrong cable used. | Confirm/replace cable. |
| W3001 | Routine processing failed. If you see this message more than once, please stop using the device and contact Terumo's service representative. | Processing failure. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| W4001 | Hardware is not responding. Aborting the process. | Communication timeout. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| W4002 | Unexpected communication detected. Aborting the process. | Communication error. | Re-boot system. If error repeats, contact a Terumo Service Representative. |
| W5002 | A database operation failed. Contact Terumo's service representative. | Database error. | If issue does not resolve contact a Terumo Service Representative. |

Information Messages

| Code | Message | Message Description |
|---|---|---|
| I0001 | Ping Test for PACS Server Passed. | PACS Communication Successful. |
| I0002 | Ping Test for RIS Server Passed. | RIS Communication Successful. |

Information Messages

| Code | Message | Message Description |
|---|---|---|
| I0003 | C-ECHO Test for PACS Server Passed. | PACS Communication Successful. Settings are accurate. |
| I0004 | C-ECHO Test for RIS Server Passed. | RIS Communication Successful.<br>Settings are accurate. |
| I0005 | Are you sure you want to export data? | Information message to user to confirm export of data. |
| I0006 | The same pullback exists in the external storage. Overwrite? | Information message to user to confirm overwrite of pullback data.<br>If "Yes" is selected, the software exports all pullbacks data by overwriting duplicated items. If "No" is selected, the software exports only not-duplicated pullbacks to the destination. |
| I0007 | Are you sure you want to import data? | Information message to user to confirm importing of selected pullbacks from external storage. |
| I0008 | Contrast Medium was changed. Measurements need to be recalculated. Select 'Yes' to recalculate measurements for all frames or select 'No' to abort the change. | Information message to user to confirm recalculating all measurements by changing the contrast medium selection for obtained data |
| I0009 | Calibration value was changed. Measurements need to be recalculated. Select 'Yes' to recalculate measurements for all frames or select 'No' to abort the change. | Information message to user to confirm recalculating all measurements by adjusting calibration for obtained data. |
| I0010 | Patient ID was edited for this data. There is no data stored for the previous patient. Do you want to delete the previous patient? | Information message to ask the user to confirm deletion of the selected patient from the database when the case data was moved to another patient and there is no pullback data associated with the patient anymore. |
| I0011 | The same pullback exists in the external storage. Overwrite with anonymized pullback? | Information message to ask the user for confirmation to overwrite the same data in the destination when the user tries to export pullback data with anonymization.<br>The message dialog has Yes/No buttons. If "Yes" is selected, the software exports all pullbacks data by overwriting duplicated items with anonymized data. If "No" is selected, the software exports only not-duplicated pullbacks to the destination. |
| I0012 | Are you sure you want to delete this profile? | Information message to ask the user for confirmation to delete settings profile. |
| I0013 | There is unsaved data, if you want to save these changes, please press 'Yes'. | Information message to ask the user for confirmation to save the unsaved update for settings profile when the user tries to exit from setting profile edit. |
| I0014 | Profile update was saved successfully. | Information message to indicate that the software succeeded saving updated settings profile to database. |
| I0015 | There is unsaved data. If you want to save these changes, please press 'Yes'. | Information message to ask the user to confirm whether to save the unsaved update for system settings, account settings or DICOM settings when the user tries to exit from the setting being edited. |
| I0016 | System Setting(s) was saved successfully. | Information message to indicate that the software successfully saved the updated system settings to database. |

Information Messages Continued

| Code | Message | Message Description |
|---|---|---|
| I0017 | Account was saved successfully. | Information message to indicate to the user that the software successfully saved the updated account settings to database. |
| I0018 | Are you sure you want to delete the account? | Information message to ask the user to confirm deletion of selected account. |
| I0019 | DICOM setting(s) was saved successfully. | Information message to the user to indicate that the software succeeded saving updated DICOM settings to database. |
| I0020 | Are you sure you want to shut down the system? | Information message to the user to confirm whether to shut down the system. |
| I0021 | Ejected successfully. Please remove media. | Information message to the user to indicate that the software successfully ejected the selected external storage (USB or DVD). |
| I0022 | Recovered from System fault. | Information message to the user to indicate that the EM succeeded recovering from safe state. |
| I0023 | Are you sure you want to delete Linearity Map files from internal storage? | Information message to the user to confirm deletion of Linearity Map files. |
| I0024 | Are you sure you want to delete selected pullbacks and still images? | Information message to the user to confirm deletion of selected pullback data. |
| I0025 | Are you sure you want to delete patient information? | Information message to the user to confirm deletion of the patient information from database in the following conditions:<br>• The user selects patient without having pullback and tries to delete<br>• The user selects all pullbacks for a patient and tries to delete |
| I0026 | Available storage space is low. Please back up the data and then delete the data to free up storage. | Information message to the user to indicate that the remaining capacity of internal storage is less than 200 GB. |
| I0027 | Storage space is very low on import and new data acquisition might be restricted. Are you sure you want to import data? | Information message to the user to indicate that the remaining capacity of internal storage will become between 40 and 100 GB after importing the selected pullback(s). |
| I0028 | Are you sure you want to log out of Windows? | Information message to the user to confirm whether to log out of the current logged on Windows when the user clicked Logout button on Service Menu of System Settings screen. |
| I0029 | Calibration value and Contrast Agent was changed. Measurements need to be recalculated. Select 'Yes' to recalculate measurements for all frames or select 'No' to abort the change. | Information message for I0029 to confirm the user whether recalculating all measurements by adjusting calibration and Contrast Agent for obtained data. |
| I0030 | TLS certificate import successful. | Information message displayed to the user to confirm that the TLS certificate Import is successful. |
| I0031 | Do you want to save the language changes? | Information message displayed to the user to confirm that they would like to change the language. |

# Section 22
# System Safety and Technical Specifications

# System Safety and Technical Specifications

## Overview

The technical specification is intended for the Biomedical department of Surgical Centers and Hospitals and their trained SERVICE PERSONNEL.

All service of the OPUSWAVE should not be performed by the user and must only be performed by qualified Terumo personnel.



**WARNING**

- Use this system within the rated voltage range. Using the system outside of the specified rated voltage range may cause system malfunction.
- If the USB device is being used inside the catheterization laboratory, it must be port powered. Connecting USB devices with an external power supply to the USB connector may compromise electrical isolation resulting in patient injury.
- Do not use externally powered USB devices in this system during the procedure. Use of externally powered USB devices with the system during a procedure may compromise electrical isolation and result in patient injury.

PERIODIC SYSTEM INSPECTION

To use the system safely for an extended time, please have your system fully inspected and documented at least once a year.

# System Safety and Technical Specifications

## System Safety

To ensure safe operation of the system, perform regular maintenance. If any abnormality is detected, immediately discontinue using the system and contact your Terumo service representative.

### User Replaceable Parts

The following are equipment and or consumables that the user may need to replace or replenish over the lifetime of the console. The use of non-approved spare parts is prohibited.

| **Part Name** | **Description** |
|---|---|
| Equipment | |
| Wireless Mouse | Cherry MW 2400 |
| Consumables | |
| Wireless Mouse Battery | Type AA Battery (Qty. 1) |

### Periodic Replacement Parts- Service

The console has parts that require periodic maintenance/replacement. These frequency of replacement of these parts is dependent on the systems usage and environment. The table below is an approximate timeline for replacement of the parts. Service agreements with Terumo may supersede these recommended durations. For replacement or service of these parts, please contact Terumo directly.

| **Part Name** | **Duration** | **Reason For Replacement** |
|---|---|---|
| Replace | | |
| Processor BIOS Battery | Approximately two (2) years | BIOS Battery maintains clock time for the system |
| Clean/Replace | | |
| Card Rack Fan Filter | Approximately one (1) year | Optimize cooling performance |
| Power Shelf Fan Filter | Approximately one (1) year | Optimize cooling performance |
| 0 dB Attenuator | Approximately one (1) year | Optimize image quality |

# System Safety and Technical Specifications

Product Dimensions

| Console (With MDU Installed) | |
|---|---|
| **Dimension** | **Measurement** |
| Weight (with MDU) | 69 kg |
| Width (Casters inline) | 467.5 mm |
| Length (Caster inline) | 830.8 mm |
| Height (including monitor) | 1553 mm |

| MDU (With Cable Attached) | |
|---|---|
| **Dimension** | **Measurement** |
| Weight | 2.68 kg |
| Width | 90 mm |
| Length (Compressed) | 430 mm |
| Length (Extended without Cable) | 493 mm |
| Height | 97 mm |
| MDU Cable Length | 4,700 mm |

# System Safety and Technical Specifications

## Measurement Accuracy

| Measurement Tool | Measurement Accuracy |
|---|---|
| Diameter | 10% (greater than 1 mm) |
| Length | 10% (greater than 5 mm) |

## Accessories

| Accessories | |
|---|---|
| **Accessories Provided** | **Re-order Number** |
| Priming Syringe (3 ml) | n/a |
| Reservoir Syringe (10 ml) | n/a |
| Connection tube with 3-way stopcock. | n/a |
| Wireless Mouse | 00402-00 |
| Wired Mouse | 00322-00 |
| Wired Keyboard | 00323-00 |
| US Power Cord (3M) | 01790-00 |
| Japan Power Cord (3M) | 01791-00 |

## Accessories Recommended (Sold Separately)

| Accessories |
|---|
| Heparinized Saline |
| 10 mL Syringe |
| 0.014" guidewire |
| Introducer Sheath |

# System Safety and Technical Specifications

**Medical device connection capability to OPUSWAVE®**

The OPUSWAVE is a medical electrical device compliant to IEC 60601-1 with 4000 Vac (2 x MOPP) isolation from the AC wall supply mains to the DC outputs (24VDC & 5VDC) used to operate the device.

See the SIP/SOP Back panel & Tabletop connections section for each specific connection's isolation specification and operating requirements.

The system is designed and required to have a Protective Earth (PE) connection through the system's AC power cord when operated. Through the PE ground connection of the appliance coupler, all exposed metal and the system's chassis are connected at less the 100 milli-ohms resistance.



**WARNING**

- No modification of this equipment is allowed. Doing so may result in system malfunction.

Terumo Cardiovascular will make available on request for their customer circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist qualified SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

Input/Output

| System Input/System Output (SIP/SOP) Back Panel Requirements | |
|---|---|
| **Port** | **Compliance** |
| Angiography | DVI-I Isolated Input / ESD protected –<br>SXGA (1280 x 1024) @ 60 / 72 / 75 Hz<br>Bit Depth: 8 Bit (Gray Scale) |
| ECG | BNC Isolated Input / ESD protected |
| Ethernet (Network)<br>RIS/PACS | LAN Magnetically Isolated Input & Output / ESD protected<br>LAN connector type @ 50 Mbps or higher |
| USB 3.0 | USB 3.0 Import & Export w/ Repeater / ESD protected –<br>Import Only - Case data to console.<br><br>Export Only - Case data to media.<br>Device connection and use only before and after procedures. |
| External Monitor | HDMI isolated Output / ESD protected – SXGA |

# System Safety and Technical Specifications

## Storage and Environmental Conditions

| System Environmental Conditions: Usage-Operational | |
|---|---|
| Ambient Operation Temperature | 10 °C to 35 °C |
| Relative Humidity | 30% to 75% (non-condensing) |
| Atmospheric Pressure | 70 - 106 kPa |

| System Storage and Transport: Non-Operational | |
|---|---|
| Temperature | -20 °C to 60 °C |
| Relative humidity | 10% to 95% (non-condensing) |
| Atmospheric pressure | 50-106 kPa |

| Catheter Storage |
|---|
| Refer to DualView Catheter Instructions For Use /labeling for catheter storage information. |

| Disposal Environment |
|---|
| Dispose of system components in compliance to all applicable Local, State, and Federal Regulations  |

# System Safety and Technical Specifications

System Safety and Regulatory

| Standards | |
|---|---|
| **Category** | **Standards** |
| Safety Standards | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020<br>AAMI ES60601-1:2005/AMD1:2012, AAMI ES60601-1:2005/AMD2:2021<br>JIS T 0601-1:2023 |
| Laser | IEC 60825-1: 2007 (2nd Edition)<br>IEC 60825-1: 2014 Ed. 3 |
| Ultrasonic | IEC 60601-2-37 (Ed 2.0), AMD1 |
| Endoscopic | IEC 60601-2-18:2009 |
| Usability | IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020<br>IEC 62366-1:2015, AMD1:2020 |
| Software | IEC 62304:2006+AMD1:2005 |
| EMC | IEC 60601-1-1-2 ed 4.1 (2020-09)<br>IEC 60601-2-18:2009<br>IEC 60601-2-37: 2007 + AMD1: 2015<br>Group 1 Class A |

| Power Supply to the System | |
|---|---|
| Frequency | 50/60 Hz |
| OPUSWAVE System Power Consumption | 500 VA |

# System Safety and Technical Specifications

| Class I ME Equipment |
|---|
| CF (Defibrillation Proof) Applied Part |

| IEC 60601-1 (3rd Edition) Classifications for Medical Electrical Equipment | | |
|---|---|---|
| **Subclause** | **Classification** | **OPUSWAVE Dual Sensor Imaging System Classification** |
| 6.2 | Protection against electric shock | Class I<br>Defibrillator-proof type CF applied part (Catheter)<br>BF Applied part (MDU) |
| 6.3 | Protection against harmful ingress of water or particulate matter. | IPX1 operational ability is achieved for the MDU's operation only when the catheter's components (Catheter and Sterile Bag) are correctly installed on the MDU and operated as instructed in the IFU. |
| 6.4 | Suitability for use in an OXYGEN RICH ENVIRONMENT | Not for use in oxygen rich environments. |
| 6.5 | Mode of operation | CONTINUOUS OPERATION |

| IEC 60825-1 Safety of Laser Products- Part 1: Equipment classification and requirements | | |
|---|---|---|
| **Subclause** | **Classification** | **OPUSWAVE System Classification** |
| 5.2 | Safety of Laser Product | The laser in the OPUSWAVE Dual Sensor Imaging System is classified as a Class 1 Laser Product. |

| Essential Performance Table |
|---|
| The system displays an image that is free from distortion or artifacts and incorrect measurements which may indirectly alter treatment decisions during a PCI case, including the selection or placement of a stent. |
| The system is free from the display of incorrect safety related indications. |
| The system does not produce unintended or excessive temperature of 41 C or above from the catheter or MDU. |
| The system does not cause unintended or uncontrolled motion of the catheter during intra-corporeal use. |

## Electromagnetic Compatibility (EMC) Tables For Emissions



**WARNING**

- The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Group 1 Class A). Do not use in residential areas. NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Group 1 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- The OPUSWAVE System is intended for use in the electromagnetic environment at emission levels for Class A Group 1 and immunity levels that comply with the Professional Healthcare Facility.

  **No deviations from the standard or allowances are required.**

| Guidance and Manufacturer's Declaration - Electromagnetic Emissions | | |
|---|---|---|
| The OPUSWAVE System is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the OPUSWAVE System should ensure that it is used in such an environment. | | |
| Emissions Tests | Compliance | Electromagnetic Environment- Guidance |
| RF Emissions CISPR 11 | Group 1 | The OPUSWAVE System uses RF energy only for its internal function. Therefore, its RF emissions are very low and is not likely to cause any interference in nearby electronic equipment. |
| RF Emissions CISPR 11 | Class A | The OPUSWAVE System may emit unintentional electromagnetic energy during normal operation up to permissible limits suitable for use in professional healthcare establishments. |
| Harmonic emissions IEC 61000-3-2 | Class A | The OPUSWAVE System is suitable for use in a typical commercial or hospital environment. |
| Voltage fluctuations IEC 61000-3-3 | Complies | |

| Guidance and Manufacturer's Declaration - Electromagnetic Immunity | | | |
|---|---|---|---|
| The OPUSWAVE System is intended for use in the electromagnetic environment specified below. The customer or the user of the OPUSWAVE System should ensure 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 | ±2 kV, ±4 kV & ± 8 kV for Contact Discharge<br><br>±2 kV, ±4 kV, ±8 kV and± 15kV for Air Discharge | ±2 kV, ±4 kV & ± 8 kV for Contact Discharge<br><br>±2 kV, ±4 kV, ±8 kV and± 15kV for Air Discharge | 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 | ±2kV AC port<br><br>±1kV SIP/SOP port | ±2kV AC port<br><br>±1kV SIP/SOP port | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | Line to Ground ±0.5kV, ±1kV and ±2kV<br><br>Line to Line ±0.5kV and ±1kV | Line to Ground ±0.5kV, ±1kV and ±2kV<br><br>Line to Line ±0.5kV and ±1kV | Mains power quality should be that of a typical commercial or hospital environment. |
| Power frequency (50/60Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | 0 % UT; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % UT; 1 cycle and 70 % UT; 25/30 cycles<br>Single phase: at 0°<br><br>0 % UT; 250/300 cycle | 0 % UT; 0,5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br><br>0 % UT; 1 cycle and 70 % UT; 25/30 cycles<br>Single phase: at 0°<br><br>0 % UT; 250/300 cycle | Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterrupted power supply or a battery. |
| * NOTE: UT is the a.c mains voltage prior to application of the test level. | | | |

<table>
<tr><th colspan="4">Guidance and Manufacturer's Declaration - Electromagnetic Immunity<br>Non-Life supporting ME Equipment</th></tr>
<tr><td colspan="4">The OPUSWAVE System is intended for use in the electromagnetic environment specified below. The customer or the user of the OPUSWAVE System should ensure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 Test Level</td><td>Compliance Level</td><td>Electromagnetic Environment - Guidance</td></tr>
<tr><td>Conducted RF<br>IEC 61000-4-6</td><td>AC port & SIP/ SOP port<br>3V<br>6V in ISM bands<br>80% AM at 1 kHz<br>150 kHz – 80 MHz</td><td>AC port & SIP/ SOP port<br>3V<br>6V in ISM bands<br>80% AM at 1 kHz<br>150 kHz – 80 MHz</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance:<br><br>d=1.2√P @80MHz to 800 MHZ<br>d=2.3√P @800MHz to 2.7 GHz<br><br>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 metres (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya should be less than the compliance level in each frequency range.</td></tr>
<tr><td>Radiated RF<br>IEC 61000-4-3</td><td>3V/m,<br>80% AM at 1 kHz<br>80 MHz – 2700 MHz</td><td>3V/m,<br>80% AM at 1 kHz<br>80 MHz - 2700 MHz</td></tr>
<tr><td colspan="4">*NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.<br>*NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">a Field strength 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 system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.<br><br>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.</td></tr>
</table>

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|---|---|---|
| Proximity magnetic fields<br>IEC 61000-4-39 | 134.2 kHz<br>Pulse modulation:<br>2.1 kHz<br>65 A/m<br><br>13.56 kHz<br>Pulse modulation:<br>50 kHz<br>7.5 A/m | 134.2 kHz<br>Pulse modulation:<br>2.1 kHz<br>65 A/m<br><br>13.56 kHz<br>Pulse modulation:<br>50 kHz<br>7.5 A/m | No special precautions for magnetic fields. |
| NOTE: 30kHz not tested as this system is not used for Home Healthcare. | | | |

| Test specifications for Immunity to RF Wireless Communication | |
|---|---|
| Test Frequency (MHz) | Immunity Test Level (V/m) |
| 385 | 27 |
| 450 | 28 |
| 710 | 9 |
| 745 | 9 |
| 780 | 9 |
| 810 | 28 |
| 870 | 28 |
| 930 | 28 |
| 1720 | 28 |
| 1845 | 28 |
| 1970 | 28 |
| 2450 | 28 |
| 5240 | 9 |
| 5500 | 9 |
| 5785 | 9 |

# System Safety and Technical Specifications

## Diagnostic Ultrasound Systems and Transducers

The OPUSWAVE System and Catheters conform to applicable acoustic output information as described in the Output Display Standard, International Electrotechnical Commission (IEC) 60601-2-37.

Acoustic Output Parameters : IVUS Only

| | Index Label | | MI | TIS | |
|---|---|---|---|---|---|
| | | | | At Surface | Below Surface |
| Maximum Index Value | | | 0.16 | 1.49 E-02 | 1.49 E-02 |
| Index Component Value | | | | 1.49 E-02 | 1.49 E-02 |
| Acoustic Parameters | $\rho_{r,\alpha}$ at $Z_{MI}$ | (MPa) | 1.02 | | |
| | P | (mW) | | 0.16 | 0.16 |
| | $P_{1 X 1}$ | (mW) | | 8.01 E -02 | 8.01 E -02 |
| | $Z_s$ | (cm) | | | N/A |
| | $Z_{MI}$ | (cm) | 1.00 E -01 | | |
| | $Z_{pii,\alpha}$ | (cm) | 1.00 E -01 | | |
| | $f_{awf}$ | (MHz) | 39.09 | 39.09 | 39.09 |
| Other Information | prr | (Hz) | 61440.0 | | |
| | srr | (Hz) | 30.0 | | |
| | $n_{pps}$ | | 1 | | |
| | $I_{pa,\alpha}$ at $z_{pii,\alpha}$ | (W/cm2) | 27 | | |
| | $I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$ | (mW/cm2) | 5.85 | | |
| | $I_{spta}$ at $z_{pii}$ or $z_{sii}$ | (mW/cm2) | 7.66 | | |
| | $p_r$ at $z_{pii}$ | (MPa) | 1.17 | | |
| | | | | | |
| Operating Control Conditions | 40MHz-D999 F-Mode with Sheath | | | | |

Acoustic Output Terminology

| Symbol | Definition |
|---|---|
| $f_{awf}$ | Acoustic Working Frequency |
| $I_{\rho a,\alpha}$ | Attenuated Pulse-Average Intensity |
| $I_{spta}$ | Spatial-Peak, Temporal-Average Intensity (In Water) |
| $I_{spta,\alpha}$ | Attenuated Spatial-Peak Temporal-Average Intensity |
| MI | Mechanical Index |
| P | Output Power (In Water) |
| $P_{1X1}$ | Bounded-Square Output Power (In Water Per 1 cm X1 cm) |
| $pr,_{\alpha}$ | Attenuated Peak-Rarefactional Acoustic Pressure |
| $p_r$ | Peak-Rarefactional Acoustic Pressure (In Water) |
| $n_{pps}$ | Number Of Pulses Per Ultrasonic Scan Line |
| prr | Pulse Repetition Rate |
| $S_{rr}$ | Scan Repetition Rate |
| TIS | Soft-Tissue Thermal Index |
| sc | Scanning Mode |
| ns | Non-Scanning Mode |
| $Z_{pii}$ | Depth For Peak Pulse-Intensity Integral |
| $Z_{MI}$ | Depth For Mechanical Index |
| $Z_{pii,\alpha}$ | Depth For Peak Attenuated Pulse Intensity Integral |
| $Z_s$ | Depth For TIS |
| $Z_{sii}$ | Position of maximum Spatial-Peak Temporal-Average Intensity for Scanning Mode components, determined beyond the Break-Point Depth, $Z_{bp}$, on the Beam-Axis |
| $Z_{sii,\alpha}$ | Position of maximum Attenuated Spatial-Peak Temporal-Average Intensity for Scanning Mode components, determined beyond the Break-Point Depth, $z_{bp}$, on the Beam-Axis |

# System Safety and Technical Specifications

## System Component Specifications

**WARNING**

- To avoid risk of electrical shock, this equipment must only be connected to a supply main with a protective earth connection. This device conforms to the Protective Earth (PE) labeling requirements of IEC 60601-1 (7.3.5) including the PE impedance & current carrying capacity requirements of IEC 60601-1 (8.6.4).

| Trade Name | OPUSWAVE System |
|---|---|
| Scan Type | Mechanical Radial Scan |
| Imaging Mode | B Mode |
| Depth of View | 5 mm OFDI, 6 mm IVUS |
| Applicable Catheters | DualView |
| Usage Classifications | |
| ME Class I;<br>Suitable for Continuous Operation<br>IEC 60601-1 (6.6)<br>IEC 60601-1 (7.2.11)<br>IEC 60601-1 (7.9.2.1) | OPUSWAVE SYSTEM |
| Class 1<br>IEC 60601-1 (7.9.2.2)<br><br>WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.<br>IEC 60601-1 (7.3.5)<br>IEC 60601-1 (7.9.2.2)<br>IEC 60601-1 (8.6.4) | CF Defibrillation Proof (Cardiac Floating device).<br>IEC 60601-1 (7.9.2.1)<br>A.P.-Catheter (Applied Part is the Catheter).<br>IEC 60601-1 (7.2.10)<br>The MDU is a BF Isolated Part.<br>IEC 60601-1 (7.9.2.1) |

## The Importance of Device Security

This medical device, in its intended use environment, uses and stores both Patient Identifying Information (PII) and Patient Health Information (PHI). As such, regulations apply that protect both users and patients from the loss of confidential information, which can be damaging in various ways.

The OPUSWAVE system is designed to interface directly with a Local Area Network (LAN) to manage patient files and information within the user's file system. This interface presents a risk of vulnerability to remote attacks to both the OPUSWAVE system and the network. Your network administrator should be involved in securing this interface.

Cybersecurity is an emerging and evolving threat in the healthcare sector. Terumo is committed to supporting a safe environment for the use of this device.



**CAUTION**

- Please note Terumo Cardiovascular makes no representation or warranty that use of the OPUSWAVE 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 OPUSWAVE System.

**NOTE**

- OPUSWAVE supports secure DICOM communications using TLS 1.2 cipher suites. If the PACS or RIS servers do not support TLS 1.2, secure DICOM communications might be disabled as described in Section 20 (Settings).

**Physical Environment**

Many threats to the security of this device and patient data are not "cyber" in nature; rather, they look for vulnerabilities in the physical device and in the users' responses. Phishing is one example of the type of "social engineering" threats that can exist.

Care should be taken to limit physical access to qualified personnel. Accounts should be secured using strong passwords and, where possible, layered security (keyed entries, etc.). This includes access by service personnel and administrators using the corresponding accounts on the DS System.

Removable media, including DVD/CDs and USB memory devices, should be secured and protected when PII or PHI is contained on them. The OPUSWAVE system prohibits executable software from running from an inserted disc or USB device; however, use care when inserting any removable media.

**Virtual Environment**

The local network (intranet) to which the OPUSWAVE system may be connected should be secured; direct connection to the Internet may cause security risks. Proper architecture should limit the local network's access to and from any outside systems. Although Terumo offers advice and insight, this is the responsibility of the user, to ensure that patient data is kept confidential and system integrity is maintained. Appropriate firewalls and anti-virus and -malware tools are also strongly recommended.

Transferring files from the OPUSWAVE System to the RIS and PACS servers is done by establishing LAN connection. Disconnect LAN connection upon completion of file transfer. The local network (intranet) to which the OPUSWAVE System may be connected should be secured; direct connection to the Internet may cause security risks. Proper architecture should limit the local network's access to and from any outside systems.

The OPUSWAVE system includes a firewall; configuration of this firewall is restricted to authorized users. Note that the OPUSWAVE system does not contain the capability to access the World Wide Web.

Communications with the PACS and RIS servers utilize DICOM. The OPUSWAVE System provides TLS 1.2 or later DICOM encryption to secure patient data. It is strongly recommended that this encryption is used on the servers as well. Older versions of TLS encryption are not recommended and not supported.



CAUTION

- Users should never leave the device unattended. After a procedure or completing file transfer, users should log out of the system and disconnect the ethernet cable from the HDO network to ensure the system cannot be accessed by unauthorized individuals. Failure to do so could result in leakage of patient information.

**Accounts and Security**

The OPUSWAVE system allows three levels of user accounts:

1. Clinical User – Configures the system for a case, manage patient information
2. Administrator User – Manages User accounts, configure system
3. Service User – Performs system upgrades and maintenance

The appropriate access should be given to each user, and no more, to protect both the OPUSWAVE system and the user. Refer to sections 19 and 20 for further information.

Users should never leave the device unattended. After a procedure, users should log out of the system and disconnect the ethernet cable from the HDO network to ensure the system cannot be accessed by unauthorized individuals.

**Response to Potential Threats**

Despite the best intentions and practices, there is always the possibility that a threat could exploit a vulnerability. Some system vulnerabilities are not recognized at the time the device or system is created but are discovered later by creative hackers. These "zero-day vulnerabilities" can result in significant problems for the security of the device, network and data.

If a malicious attack is suspected, including slowed performance or denial of service, immediately log off and restart the system and remove it from the local network. Restarting the system may resolve the issue. If the issue is not resolved, stop using the system and contact your IT department for incident response.

Only Authorized Terumo Service Representatives shall perform System Software updates and/or upgrades.

# Appendices

## Appendix A

OPUSWAVE SYSTEM MAINTENANCE INSPECTION CHECKLIST FORM:

1. **Checkmark each item noted on the maintenance inspection checklist form that is confirmed satisfactory, prior to every use.**

2. **Sign and date the completed Checklist form record.**

3. **File the completed record with the facility maintenance records.**

NOTE

- For the periodic inspection, contact your Terumo Service Representative.
- Only Authorized Terumo Service Representatives shall perform System Software updates and/or upgrades.
- Checklist can be laminated for re-use and kept near console as a record, or printed as needed.

PRIOR TO EVERY USE- PRE-STARTUP INSPECTION CHECKLIST FORM FOR RECORD-KEEPING PROPOSES.

| **Pre-Startup Checklist - Use prior to every system start-up.** | **Pass, Fail, or N/A** | **Initials** |
|---|---|---|
| **Visual Inspection** | | |
| • No damage in physical appearance of the system. | | |
| • No abnormalities are detected on the MDU, Monitor unit, OR Console casters. | | |
| • No contamination of blood or chemicals. | | |
| • No contamination of particles, blood or chemicals at the imaging window and the connecting section of the Catheter. *Remove all contamination that exists.* | | |
| • If any contamination and/or smear is found, follow the instructions for cleaning in Section 21 of the Instructions For Use. | | |

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*** For inquiries or system performance problems, contact the nearest Terumo location.**

**Manufacturer**
Terumo Cardiovascular Systems THI Plant
6190 Jackson Road
Ann Arbor, MI 48103-9300