Abbott

APTIVUE™
Offline Review Software
Guide

CONTENTS

AptiVue™ Offline Review Software

INTRODUCTION

The AptiVue™ Offline Review Software (ORS) is designed and intended for retrospective analysis of Optical Coherence Tomography (OCT) images and physiology waveforms for education and research purposes only. It is not intended to be used for the treatment of individual patients, alone or in combination, for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, or alleviation of or compensation for an injury.
- Investigation, replacement, modification, or support of the anatomy or of a physiological process.
- Providing means and suggestions for mitigation of a disease.
- Providing information for determining compatibility, detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.
- Being an aid to diagnosis, screening, monitoring, determination of predisposition; prognosis, prediction, determination of physiological status.

This guide provides:

- Descriptions of the AptiVue™ Offline Review Software
- Procedures for using the AptiVue™ Offline Review Software
- Instructions for using the research option tools, if enabled

Note: Details of the OPTIS™ Imaging Systems are covered in the instructions for use provided with the OPTIS™ Imaging Systems and are not covered in this guide.

Note: Pictures are shown for example only.

SOFTWARE OVERVIEW

AptiVue™ Offline Review Software Features

OCT is an imaging modality that uses fiber-optic technology. The OPTIS™ Imaging Systems use optical imaging catheters that emit near-infrared light to produce high-resolution real-time images.

Fractional Flow Reserve (FFR) is the ratio of distal coronary arterial pressure to aortic pressure, measured during hyperemia. It provides the maximal blood flow in the presence of a stenosis as a fraction of the achievable blood flow that would exist in the hypothetical situation that the stenosis was not present. Pd / Pa at rest is the ratio of distal coronary arterial pressure to aortic pressure measured at resting conditions. Resting Full-Cycle Ratio (RFR) is a moving average ratio of Pd to Pa taken at a point in the cardiac cycle where the Pd / Pa ratio reaches a minimum for the whole cycle. RFR is designed to be used at rest.

These physiological parameters are measured when the AptiVue™ Imaging Software is installed on an OPTIS™ Imaging System and used in conjunction with the manufacturer's wireless distal intracoronary pressure transducer and a proximal aortic pressure transducer.

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

The AptiVue™ Offline Review Software permits users to import, review, measure, and modify OCT raw format images and ILUMIEN™ OPTIS™ System FFR and RFR measurements exported from OPTIS™ Imaging Systems and ILUMIEN™ Systems.

The AptiVue™ Offline Review Software consists of a version of AptiVue™ Imaging Software. All import, export, and review functions that can be performed on the OPTIS™ Imaging System or ILUMIEN™ System can be performed on OCT images imported into the AptiVue™ Offline Review Software. No acquisition functions are supported.

The AptiVue™ Offline Review Software lets you:

- Import, play back, and edit OCT recordings and still images
- Enlarge an area of interest (zoom)
- Add measurements and annotations on OCT images
- Export still images and movies in raw OCT format, or as standard AVI, TIFF, JPEG, BMP, or DICOM formatted images
- Export OCT measurements as a CSV file
- Export FFR measurements as standard TIFF, JPEG, BMP, or DICOM formatted images
- Import and export ILUMIEN™ System FFR raw measurements

- Display Minimum Lumen Area (MLA) of a recording
- Display a three-dimensional (3D) representation of a recording
- Import and review OCT recordings with Angio Co-Registration

Comparison to Image Acquisition Systems

This guide describes the AptiVue™ Offline Review Software and its use. Where appropriate, it indicates how the AptiVue™ Offline Review Software differs from the OPTIS™ Imaging Systems.

Reviewing imported cases on the AptiVue™ Offline Review Software works exactly the same as reviewing cases on the full OPTIS™ Imaging Systems, though no live imaging functions are available on the AptiVue™ Offline Review Software. The live imaging functions, available on the OPTIS™ Imaging System, that are not available on the AptiVue™ Offline Review Software include:

- Scanning functions
- Probe functions
- OCT and FFR recording functions
- Cannot acquire real-time angiography images

However, the AptiVue™ Offline Review Software has some additional research measurement tools. For more information, refer to the Measurements and Annotations section [ ].

Setup Dialog Box

Accessing the Settings on the AptiVue™ Offline Review Software allows for the configuration of various functions on the system: Account, Administration, Database, DICOM, Display, Measurements, Options, Print and Service (see User Interface Reference [ ]).

AptiVue™ Offline Review Software Components

The AptiVue™ Offline Review Software includes the following hardware components:

- USB Flash Drive

Use of the Offline Review Software

The AptiVue™ Offline Review Software is designed and intended for retrospective analysis of OCT images and physiology waveforms for education and research purposes only. It is not intended to be used for the treatment of individual patients, alone or in combination, for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, or alleviation of or compensation for an injury.
- Investigation, replacement, modification, or support of the anatomy or of a physiological process.
- Providing means and suggestions for mitigation of a disease.
- Providing information for determining compatibility, detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.
- Being an aid to diagnosis, screening, monitoring, determination of predisposition; prognosis, prediction, determination of physiological status.

The AptiVue™ Offline Review Software is provided for the import, review, measurement, and modification of raw OCT format images and to analyze ILUMIEN™ System FFR measurements obtained from an OPTIS™ Imaging System. In addition, the system incorporates Angio Co-registration, which allows the user to visualize the position of OCT image data on angiography images, tightening the linkage between anatomical assessment with OCT and subsequent therapeutic actions.

The AptiVue™ ORS is intended to be installed on a laptop or desktop computer that meets the minimum system requirements. The laptop or desktop computer would be set up as a standalone unit for review of OCT cases and FFR / RFR cases offline. Network domain setting and user credentials would be wiped out clean during the AptiVue™ software installation process. Access to Microsoft Windows‡ desktop would be locked out for the user when the AptiVue™ software is installed.

Note: The AptiVue™ ORS is not intended as an upgrade software for the OPTIS™ Offline Review Workstation (ORW) product. Please consult with your sales representative to determine software upgrades available for the OPTIS™ ORW.

Symbol Glossary

Symbol	Definition
(manufacturer symbol)	Manufacturer
(date of manufacture symbol)	Date of manufacture
REF	Catalog number
LOT	Batch code
(WEEE symbol)	Electronic equipment should not be disposed of in the normal waste. Instead it should be recycled in accordance with the Waste Electronics and Electrical Equipment (WEEE) directive 2012 / 19 / EU Return the device to Abbott Medical at the end of its operating life.
SW	Software version
Encryption Recovery Key	Encryption Recover Key

MINIMUM SYSTEM REQUIREMENTS

COMPONENT / ELEMENT	MINIMUM REQUIRED
WINDOWS VERSION:	Windows‡ 10, 1809
WINDOWS EDITION:	Professional‡
VIDEO CARD / GPUS:	Nvidia‡ GTX 1660 Ti or better
SECURITY:	TPM 2.0
RAM MEMORY SIZE:	16 GB
PROCESSOR SPECIFICS:	Intel‡ Core i5, 2.40 GHz
OS ARCHITECTURE:	64-bit
NUMBER OF PROCESSOR CORES:	2
NUMBER LOGICAL PROCESSORS:	4
HARD DRIVE:	1 Hard Drive with > 400 GB free space
DISPLAY RESOLUTION:	1280x1024 pixels (SXGA) **Note:** Recommended display resolution 1920x1080 pixels.

Notes:

- Recommended display resolution 1920x1080 pixels.
- A single 1-TB storage drive is suggested to accommodate the Operating System, Application Software, and Database.
- When the ORS software is installed on the allocated PC or laptop, the software automatically blocks any other third-party software and application from being downloaded.
- It is recommended that any pre-loaded software such as antivirus on the laptop or third-party applications be removed from the system so as not to impact the performance of the ORS software.
- Based on equipment testing, it is strongly recommended to use either a Dell‡ or a Lenovo‡ laptop that meets the minimum system requirements listed above. Software visualization may be suboptimal if using a laptop brand that is not recommended.

SOFTWARE SETUP

POWER ON

1. Press the power button on your laptop.
2. Log in to laptop using account credentials.

The startup screen appears (see figure below).

Figure 1. Startup Screen

Note: Figures of screen images are for reference only. Screen content is correct; however, screen aspect ratio (width and height format) may differ from image shown.

INITIAL SETUP

Note: The first time the software runs in certain geographies, you will be prompted to select a language. This can be changed later. See the Setup - Localization Menu section (page 76).

Note: The first time the software runs, the End User License Agreement (EULA) displays. You must first read and agree to the EULA by checking the "I agree to the terms of the EULA" checkbox in order to proceed.

CREATING A SITE ADMINISTRATOR ACCOUNT

The Site Administrator is responsible for setting up and changing other accounts at the facility.

The Site Administrator must set up their account before the AptiVue™ Offline Review Software can be used.

Note: This step cannot be bypassed.

1. Once the Create Site Administrator Account page loads, enter a new **Username**, **Password** and **Confirm password**.
    Note: The password must meet the following minimum requirements:
    *   Not contain the user's account name or parts of the user's full name that exceed two consecutive characters
    *   Be at least seven characters in length
    *   Contain characters from three of the following four categories:
        – English uppercase characters (A through Z)
        – English lowercase characters (a through z)
        – Base 10 digits (0 through 9)
        – Non-alphabetic characters (for example: !, $, #, %, etc.)

2. After the system accepts the creation of the Site Administrator account, the system may prompt a Select Language dialog box. If required, select the desired language. This can be changed at a later time. Refer to Setup - Localization Menu for more information (page 76).

3. Review the End User License Agreement (EULA) before accepting it.

INACTIVITY TIMEOUT

If the AptiVue™ Offline Review Software is left on the home screen or the select patient screen for 30 minutes, the system will automatically log off.

Note: While reviewing recordings, the timeout period is deactivated and no automatic log off will occur.

EXIT THE APPLICATION

To Exit the AptiVue™ Offline Review Software:
    Click **Exit** located at the top of the screen.
    The Software begins to close. After approximately 10 seconds, the application is closed.

OPENING A PATIENT RECORD

⚠️ **CAUTION: Abbott Medical makes no representation or warranty that use of the AptiVue™ Offline Review Software 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 AptiVue™ Offline Review Software.**

Home Screen

When the system is first started, the Home screen is displayed (figure below). Clicking **Home** from the Select Patient or Patient Summary screen will return to this screen. This screen displays the system platform name and contains the following buttons:

Figure 2. Home Screen
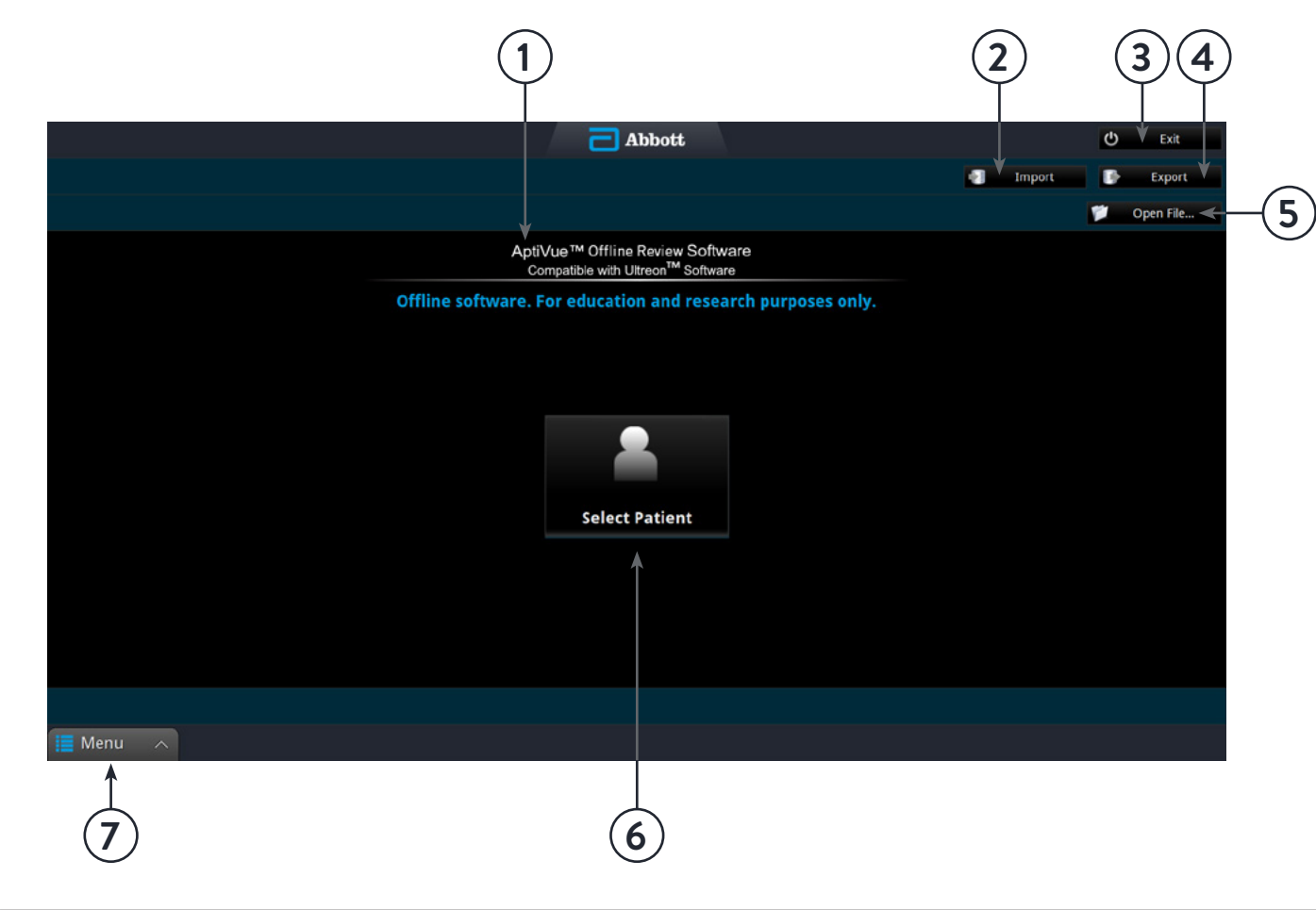
Table 1. Home Screen

1. Platform name	Displays the platform name
2. Import button	Click this button to open the Import menu
3. Exit button	Click this to log off and power down the system
4. Export button	Click this button to open the Export wizard
5. Open file button	Click this button to open file menu
6. Select Patient button	Click this button to display the Select Patient screen
7. Menu button	Display the content-sensitive menu

Select Patient Menu

When the system is first started, the Select Patient menu is displayed (see figure below). From this menu, you can open an existing patient or import a previous patient record.

Figure 3. Select Patient Menu

1. Search field
2. Case filter drop-down menu
3. Import button
4. Export button
5. Open file button
6. List of existing patients
7. Menu button
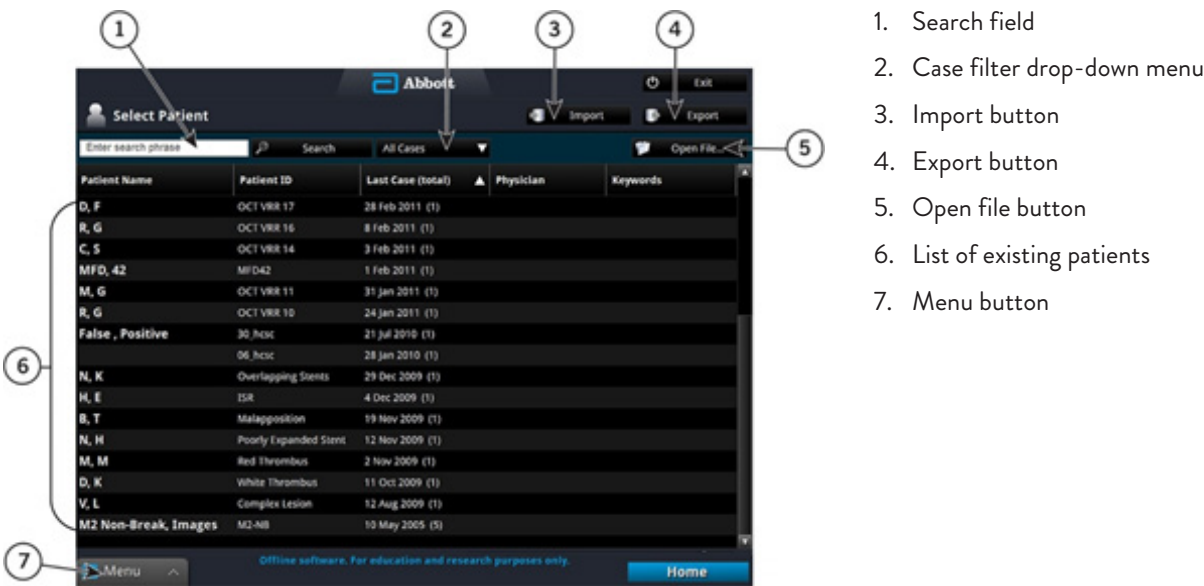
Table 2. Select Patient Menu Functions

Search button	Enter a term then click this button to search the patient database.
Case filter drop-down list	Select ALL Cases, OCT Cases only, OCT w / Angio Cases only, or FFR / RFR Cases only.
Import button	Click this button to open the Import menu.
Export button	Click this button to open the Export Wizard.
Open file button	Click this button to open a raw (native) OCT or FFR from a user-specified folder.
List of all existing patients	Click on a column header to sort the patients according to data in that column.
Menu button	Displays the context-sensitive menu.

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

Patient Summary Menu

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

Figure 4. Patient Summary Menu

1. Patient information bar
2. Case list
3. Gallery of existing recording
4. Menu button
5. Edit Case button
6. Exit button
7. Export button
8. Edit Patient button
9. Home button
10. Delete button
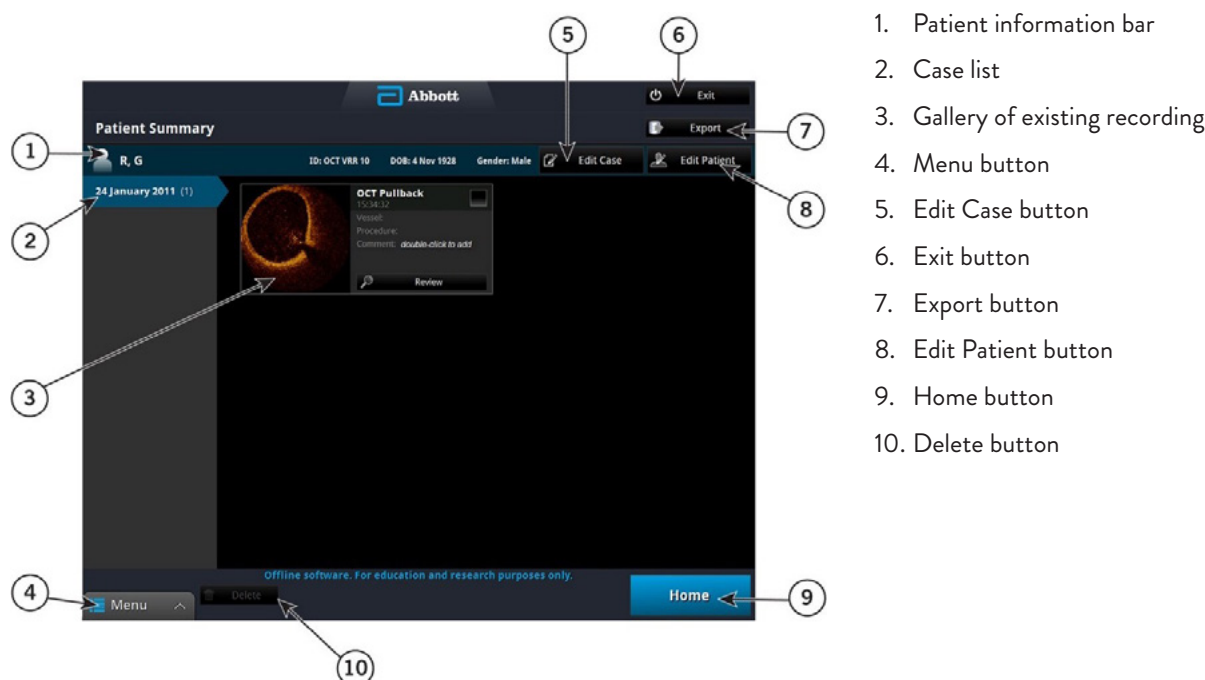
Table 3. Patient Summary Menu functions

Patient information bar	Patient's name, patient ID, date of birth and gender
Case list	The list is sorted by date, with the most recent recordings at the top.
Gallery of existing recording	Existing recordings for this patient on the date highlighted at left. Double-click in the Comment field to add a comment for that recording. Click the Review button under a recording to open it.
Menu button	Displays the context-sensitive menu and provides access to the Setup menu.
Edit case button	Click this button to edit case information.
Exit button	Click this to log off the AptiVue™ Imaging Software and power down the system.
Export button	Click the Checkbox in one or more recordings to select them, then click the Export button to open the Export Wizard. See Exporting, Importing, and Managing Files for more information (page 15).
Edit patient button	Click this button to edit patient information
Home button	Use this button to return the Select Patient menu
Delete button	Check one of more recordings to select them, and click the Delete button to delete them.

Editing Patient Information

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

1. From the Select Patient menu, select the patient.

2. The Patient Summary menu for that patient opens (see Select Patient Menu [page 11]).

3. Click on a case to select it.
   Note: In the AptiVue™ Imaging Software, all recordings and still images from the same date use the same physician and accession number.

4. Click **Edit Case**.

5. The Case Information menu opens.

6. Edit the physician name and accession number as needed.

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

Editing Case Information

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

1. From the Select Patient menu, select the patient. The Patient Summary menu for that patient opens (see Select Patient Menu ([page 11]).

2. Click on a case to select it.
   Note: In the AptiVue™ Imaging Software, all recordings and still images from the same date use the same physician and accession number.

3. Click **Edit Case**. The Case Information menu opens.

4. Edit the physician name and accession number as needed.

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

Importing a Patient Database

OCT, FFR and RFR recordings taken on an OPTIS™ Imaging System can be imported into the system using Import on the Select Patient menu. For more information on importing patient files or information, see the Importing Files from a USB section (page 20).

Opening a Saved Recording or Still Image

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

  A "camera" icon indicates a still frame from an OCT recording.

  A "safe" icon indicates that the file has been archived.

  An "angiographic" icon indicates a recording that has been paired with a cineangiography.

To review a saved recording or still image:

1. Open the Patient Summary menu:
   – From the Select Patient menu, click on a patient's name to select.
   – From an OCT, FFR or RFR recording, click **End Review** at the bottom of the screen. The Patient Summary menu for that patient opens (see figure below).

2. Select the date of the recording from the dates at the left of the menu. All recordings and still images for that patient on that date are displayed.

3. Click on **Review** beneath the recording you want to open. Alternatively, you may click the image thumbnail to open the recording.

Figure 5. Recording as Shown in the Patient Summary Menu
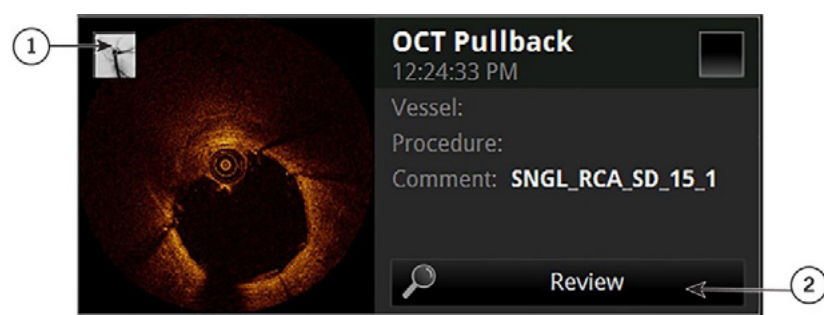
1. Angiographic icon
2. Review button

The recording or still image opens. Recordings play automatically.

Figure 6. OCT Review Screen
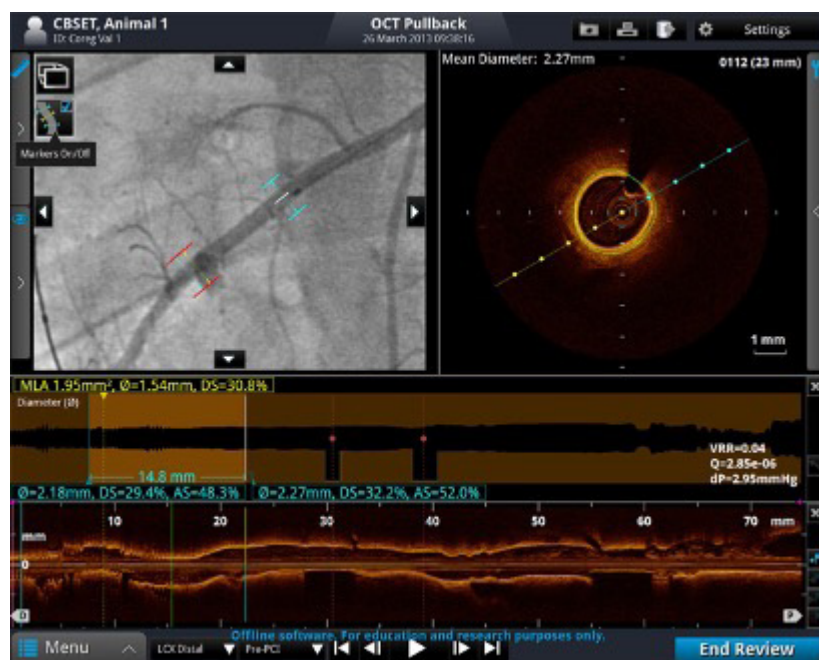
- To navigate an OCT recording, see Playback Controls (page 45); to navigate an FFR recording, see Reviewing an FFR or RFR Procedure (page 63).
- To add measurements and annotations to the OCT recording or still frame, see the Measurements and Annotations section (page 48).
- To export the entire OCT recording or individual frames, see the Exporting, Importing, and Managing Files section (page 15).

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

EXPORTING, IMPORTING, AND MANAGING FILES

⚠️ **CAUTION: Abbott Medical makes no representation or warranty that use of the AptiVue™ Offline Review Software 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 AptiVue™ Offline Review Software.**

Compatible Transfer to USB Devices

If you experience problems with a specific type of USB device, contact Abbott Technical Service for recommendations ( ).

USB CONNECTED MEDIA

The system can export files through the USB port. Any USB hard drive or Flash Drive that meets the USB 2.0 Specification and is supported by Windows may be used.

⚠️ **WARNING: Do not use the AptiVue™ Offline Review Software inside the catheterization lab. Only port-powered USB drives may be connected to the USB port in the catheterization lab. Connecting externally powered devices to the USB port in the patient vicinity may compromise electrical isolation and cause patient injury.**

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

File Formats

Files can be exported in the native file format (raw OCT format), DICOM format, or in a standard format. Exported files can be saved to an external USB device. You can choose whether to delete files after transfer or keep them on the system.

ABOUT NATIVE (RAW OCT) FORMAT

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

Note: Native (raw OCT) files can be reviewed and manipulated only with an ILUMIEN™ System, ILUMIEN™ OPTIS™ Mobile System, OPTIS™ Integrated System, OPTIS™ Mobile System, or AptiVue™ Offline Review Software. They cannot be accessed with any other systems or software.

Note: Native (raw OCT) files are large; exporting to USB flash drive requires large capacity drives (32 GB capacity or higher is recommended).

ABOUT DICOM FORMAT

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

Note: To export files complete with Angio Co-registration data, use native (raw OCT) format. DICOM format does not support Angio Co-registration data.

Note: Exploring Angio Co-registration data is not available on ILUMIEN™ System.

ABOUT STANDARD FORMAT

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

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

Image Format and Size in Standard Formats

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

FILE SIZE

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

STANDARD FILE FORMAT

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

Exporting Files During a Review

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

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

Figure 7. Export Button

1. Export button

EXPORTING FILES IN NATIVE (RAW) FORMAT

1. Click **Export**.
   The Export Wizard opens.

2. Select Native (Raw) and click **Next**.

3. Select the desired export option:
   - Archive - optional password protected export that retains Protected Health Information (PHI)
   - Share - anonymizes the exported data
   - Report a problem - troubleshooting data for Abbott Technical Service

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

5. Click **Next** to approve the settings and open the next page of the Export Wizard.
   Note: Click **Back** to return to the previous page or click Cancel to exit the Export Wizard without exporting files.

6. Select an Export Destination:

   Note: CD / DVD export media is not supported. Only USB device export is supported.
   – Click External Drive to export to an external USB device. If necessary, click the External Drive selection box to select the correct drive location from the drop-down menu.
   – Click the Ellipsis (...) button to the right of the Path selection box to browse for a specific folder on the device.

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

   Note: Verify the free space in the drive capacity section is large enough to save the files that are being exported.

7. Click **Next** to approve the settings and open the next page of the Export Wizard.
   The next page of the Export Wizard opens. The menu shows a summary of Export Information.

8. Click **Export** to complete the export process.
   The export begins. If necessary, click Cancel to stop the export in progress.

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

EXPORTING FILES IN DICOM FORMAT

1. Click **Export**.
   The Export Wizard opens.

2. Select DICOM and click **Next**.

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

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

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

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

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

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

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

8. Click to select an Export Destination:

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

   Note: Check that the Free space in the Drive Capacity section is large enough to save the files that are being exported.
   – Select External Drive to export to an external USB device. If necessary, click the External Drive selection box to select the correct drive location from the drop-down menu.
   – Click the Ellipsis (...) button to the right of the Path selection box to browse for a specific folder on the device.
   – Select Remote Store to export to a network DICOM Server.

   Note: The Remote Store option is enabled only if the DICOM network connection has been configured in the DICOM section of the Setup dialog box (see User Interface Reference for more information on DICOM settings (page 71).

   Note: If one or more pullbacks are selected for export to Remote Store, the Remote Store option on the Export Wizard destination page may add the prompt: Restart Required depending on your AptiVue™ Offline Review Software's operating system requirements.

9. Select a Destination of either External Drive or Remote Store.
   – In the Measurements section, select Show All, Hide Lumen Contour, or Hide All. Drive Capacity is shown.
   – Select the export size by using the slider to choose the Frame Resolution and selecting the Format.

10. Click **Next** to approve the settings and open the next page of the Export Wizard.
    (If a restart is required for your ORS, the Restart Required dialog box appears. Click OK to proceed with the export and restart.) The next page of the Export Wizard opens, showing a summary of Export Information.

11. Click **Export** to export the selected files.
    The export begins. If necessary, click Cancel to stop the export in progress.

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

    Note: If a restart is required for the AptiVue™ Offline Review Software, Restart will appear instead of Done.
    Click Restart to restart.

EXPORTING FILES IN STANDARD FORMATS

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

1. Click **Export**.
   The Export Wizard opens.

2. Select Standard and click **Next**.

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

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

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

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

5. Select the Image Resolution by using the slider.
   – Select the File Format by clicking the desired Still Frame or Pullback radio button.
   – In the Measurements section, select Show All, Hide Lumen Contour, or Hide All.
   – Select the desired Aspect Ratio (Full, Wide, or Square).
   – Select Advanced View, if this option is available.
   – Select Color if color still frames are desired.

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

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

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

9. Select an Export Destination:

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

   Note: Check that the Free space in the Drive Capacity section is large enough to save the files that are being exported.
   – Click External Drive to export to an external USB device. If necessary, click the External Drive selection box to select the correct drive location from the drop-down menu.
   – Click the Ellipsis (...) button to the right of the Path selection box to browse for a specific folder on the device.

10. Click **Next** to approve the settings and open the next page of the Export Wizard.
    The next page of the Export Wizard opens. The menu shows a summary of Export Information.

11. Click **Export** to export the selected files.
    The export begins. If necessary, click **Cancel** to stop the export in progress.

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

    Note: After exporting, the application may require a restart. If the restart dialog box is displayed, click **OK** to complete the export and restart the system.
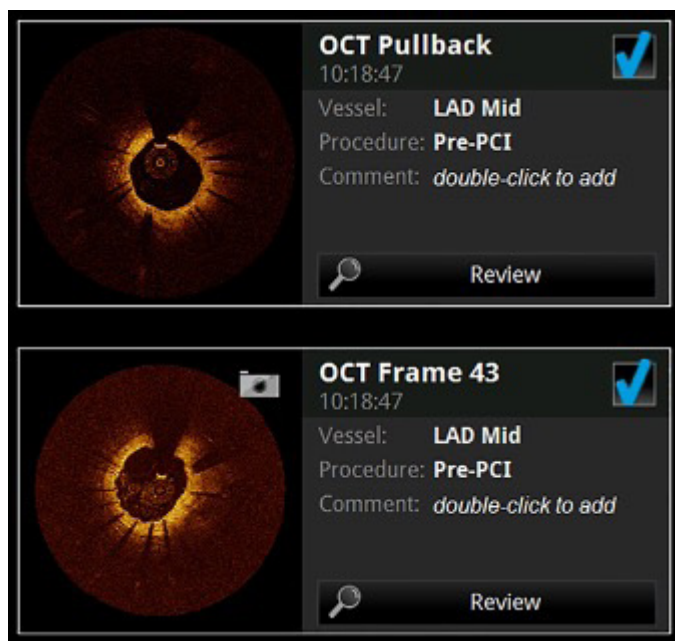
Exporting Files from the Patient Summary Menu

You can export files from the Patient Summary menu.

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

Figure 8. Highlighted Records

A white border appears around each record that is selected.

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

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

2. Click **Export** at the top of the screen. The Export Wizard opens.

3. Click to select an export format and click **Next**.
The next page of the Export Wizard opens.

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

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

6. Click **Next** to approve the list of files for export and open the next page of the Export Wizard.
   – If you are exporting in Native (Raw) format, refer to Step 3 in Exporting Files in Native (Raw) Format to continue the export (page 16).
   – If you are exporting in DICOM format, refer to Step 5 in Exporting Files in DICOM Format to continue the export (page 16).
   – If you are exporting in standard formats, refer to Step 5 in Exporting Files in Standard Formats to continue the export (page 16).

Using Exported Standard Format Recordings

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

Importing Files from a USB

1. Connect an external database to the AptiVue™ Offline Review Software:
    – Insert a USB flash drive containing a database into the system.
    – Connect an external hard drive to the system.

    Note: You can also import from another database on the local drive.

2. In the Select Patient menu, click Import. The Select Database menu opens.

3. Select the database to import and click **OK**.

4. The Import Database menu opens.

Table 4. Import Database Menu Options

Source Database	This is a list of files that will be imported. Each file is displayed in one row, and the patient name, patient ID, image creation date and time, comment, and status are displayed in columns. The list is initially sorted by ascending image creation date and time and can be sorted by any of the columns in ascending or descending order by left-clicking once or twice on the desired column header.

	As each file is imported, its Status message is updated:
	  – Importing - file is currently being imported.
	  – On System - file has been copied to the system.
	  – On Archive Media - file is on the current archive media and has not yet been imported.
	  – Absent - file is not located on the current archive media.
	  – Failed - attempt to import the file failed.

Select New	Select only recordings that are not present in the AptiVue™ Offline Review laptop.
Progress Bar and Message Area	The Progress Bar indicates the status of the file transfer. The Message Area displays information about the file and the transfer.
Import	Import the selected files.
Cancel	Cancel the import.

Deleting Files

You can delete files by any of the following methods:
*   Exporting images with the Remove When Complete function turned on (see Exporting Files in Native (Raw) Format [page 16]).
*   Select and delete files from the Patient Summary menu.
*   Select and delete files from the Database menu.

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

DELETING FILES FROM THE PATIENT SUMMARY MENU

1. In the Patient Summary menu, click the checkbox of each recording that you want to delete. A white border appears around each record that is selected.
   Note: In the Patient Summary menu, you can select multiple files from the same date, but not from different dates.
   Note: To deselect a file, click the checkbox to clear the selection. The check and white border disappear to indicate that the file is no longer selected.

2. Click **Delete** at the bottom of the screen.
   A prompt asks you to confirm that you want to delete the selected recordings.

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

DELETING FILES FROM THE DATABASE MENU

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

2. Click the Database tree item to open the Database menu (see Setup - Database Menu [page 70]).

3. Add a check to the checkbox of any recording to be deleted.
   – Add a check to the checkbox of patient to select all recordings for that patient.
   – Add a check to the checkbox of the first entry in the list to select all recordings.

4. Click **Delete**.
   A prompt asks you to confirm that you want to delete the selected files.

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

Transfer and Import Messages

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

Table 5. Transfer Messages

Error Message	Cause	Action
Transfer failed, the destination drive is full.	The USB drive is full.	Connect a different USB drive.
Transfer failed, the source or destination disk was removed.	The USB drive is disconnected.	Reconnect the USB drive.
Database import not complete.	You have clicked Cancel so the Import operation is not complete.	Click OK to continue system operations. Some of the files may have been partially, but not fully copied into the system. If you try to open one of these files, the system will display an error message.

Duplicate File Name Messages

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

Note: Do not save an image using the same name used for a previous file. Abbott Medical recommends that you label media containing exported files with descriptive information, including the procedure or export date. If the transfer is cancelled, the uncopied files will remain on the hard drive.

Table 6. Duplicate File Name Messages

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

Database Statistics

You can check the size and statistics of your system's database using the Database Maintenance tree item in the Setup dialog box. See Setup - Database / Maintenance Menu for more information ( ).

Exporting a Measurements CSV File

You can save OCT measurements in a standard comma-separated values (CSV) file. With the CSV file, all measurement information may be easily imported into a variety of third-party applications (spreadsheets and databases) for further manipulation.

Figure 9. Sample Measurements CSV file

```
08/11/2009,13:52:39,Administrator
Beta 1,03/22/1937,M,03/16/2009,09:26:00
Frame 138 of 3/16/2009 9:55:28 AM
03/16/2009,09:55:29,1,1,99.2,0.0,20.0

TYPE,FIRSTFRAME,LAST-
FRAME,REGION,LABEL,LABEL1,LABEL2,TEXT,VALUE, VALUE2,VALUE3
Area,1,1,Cross Section,A,,,Area,6.56
Area,1,1,Cross Section,B,,,Area,9.86
%AS,1,1,Cross Section,C,A,B,%AS,33.47
```

Figure 10. Sample Measurements CSV File Imported into a Spreadsheet

Exporting a Measurements CSV File

When the Export Measurements to CSV File option is turned on, a Measurements CSV file is created for each file (recording or still) as part of the standard file export process.

Note: Measurements CSV files are not created when the Export Destination is set to Remote DICOM Store.

File Name and Location

The path and name of the Measurements CSV file matches the path and name of the image file that was exported, with a ".csv" extension appended to the end.

For example, if the exported recording is named "Proximal_RCA.avi", the Measurements CSV file is named "Proximal_RCA.avi.csv" and both files will be exported to the same location.

File Format

The exported measurements file is a CSV (Comma-Separated Values) formatted text file with a header containing general information about the OCT recording and subsequent entries for each measurement in the recording as shown section Exporting a Measurements CSV File (page 22).

Each line of the file will contain one or more data entries delimited by commas. If a comma exists in the data, it will be converted to a semi-colon before being written to the file. Two consecutive commas, a comma at the end of a line, or a blank line, will indicate that the data for a given entry is not available.

MEASUREMENTS CSV FILE FORMAT

Header

The header of the exported measurements file is comprised of the first six lines of the file. Each of these lines is described in this section, except for the fifth and sixth lines that are intended to help make the file more readable. The fifth line will be left blank and the sixth line will contain column headers for the subsequent measurement entries as shown section Exporting a Measurements CSV File (page 22).

File Creation Information

The first line of the file contains general information about the image file and is formatted as follows:

Creation Date, Creation Time, Creator

The data for these entries is generated when the file is created and formatted as described in section Exporting a Measurements CSV File (page 22).

Table 7. Creation Data Format

Entry	Description	Type	Format
Creation Date	Date the CSV file was created.	Text string	mm / dd / yyyy
Creation Time	Time the CSV file was created.	Text string	hh:mm:ss (24 hour)
Creator	User account name.	Text string	free-form text

PATIENT AND STUDY INFORMATION

The second line of the file contains patient and study information and is formatted as follows:
- Patient ID, Patient DOB, Patient Gender, Study Date, Study Time

The data for these entries is retrieved from the OCT database and is formatted as described in the table below.

Table 8. Patient Data Format

Entry	Description	Type	Format
Patient ID	Patient ID in database.	Text string	free-form text
Patient DOB	Patient DOB in database.	Text string	mm / dd / yyyy
Patient Gender	Patient Gender in database.	Text string	M or F (empty if unknown)
Study Date	Date study created in database.	Text string	mm / dd / yyyy
Study Time	Time study created in database.	Text string	hh:mm:ss (24 hour)

RECORDING INFORMATION

The third line of the file contains the comment associated with the image (displayed in the preview image as shown in the Patient Summary menu). This comment is a user-editable, free-form text string that may contain commas to allow for the insertion of user-defined fields and is formatted as follows:
- Comment Text

The fourth line of the file contains recording information and is formatted as follows:
- Acquisition Date, Acquisition Time, Start Frame, End Frame, Frame Rate, Pullback Length, Pullback Speed

The data for each of these entries is derived directly from the OCT image file and is formatted as described in the table below.

Table 9. Recording Data Format

Entry	Description	Type	Format
Acquisition Date	Date data was acquired.	Text string	mm / dd / yyyy
Acquisition Time	Time data was acquired.	Text string	hh:mm:ss (24 hour)
Start Frame	First frame of a recording. 1 if the file is an image.	Integer	frame number
End Frame	Last frame of a recording. 1 if the file is an image.	Integer	frame number
Frame Rate	The acquisition frame rate	Decimal	frames / second
Pullback Length	Distance imaged in the recording. 0 if the file is an image.	Decimal	mm
Pullback Speed	The speed the imaging catheter was pulled back during imaging.	Decimal	mm / second

MEASUREMENTS

The fifth line of the file is left blank. The sixth line of the file contains column headers for the measurement information that is to follow.

All subsequent lines in the file will contain measurement information from the recording. Each line will contain information about one measurement and will be formatted as follows:
- Type, First Frame, Last Frame, Region, Label, Label1, Label2, Text, Value1, Value2, Value3

The data for each of these entries is derived directly from the OCT image file and is formatted as described in the table below.

Table 10. Measurement Data Format

Entry	Description Value (range)	Type	Format
Type	The measurement type. (%AS, %DS, Angle, Area, Chord, Diameter, Length, Ruler, Stent, Thickness)	Text string	free-form text
First Frame	The first frame containing the measurement. The first frame in the recording is the Start Frame from Line 4 of the file.	Integer	frame number
Last Frame	The last frame containing the measurement. If the measurement is in the cross-section view, this value will be equal to the First Frame.	Integer	frame number
Region	The image region containing the measurement. (Cross Section, Longitude, or Longitude-2)	Text string	free-form text
Label	The label assigned to the measurement on the specified frame by the OCT software. (An to Zn)	Text string	free-form text
Label1	The label assigned to the first, or inner, dependent measurement on the specified frame. (An to Zn)	Text string	free-form text
Label2	The label assigned to the second, or outer, dependent measurement on the specified frame. (An to Zn)	Text string	free-form text
Text	The user-defined label text associated with the measurement.	Text string	free-form text
Value	The measurement value, one of the following: Length or area value. Mean value for a diameter or thickness. Angle of an angle of a pie.	Decimal	length units = mm area untis = mm angle units = degree
Value2	One of the following: Minimum value for a diameter or thickness. Chord number for thickness chord. Stent defined length. Thickness ruler angle. Angle of the primary ray for angle measurement.	Decimal	mm
Value3	The apposition value for Stent Area measurements.	Decimal	mm

REVIEWING OCT RECORDINGS

Note: Making measurements, calculations, and text annotations is covered in Measurements and Annotations (page 48).
Exporting images is covered in Exporting, Importing, and Managing Files (page 15).

Measurements Menu

During OCT Review, a Measurements panel (see figure below) is present on the upper, leftmost part of the OCT Review screen. The Measurements panel allows displaying or hiding the automated measurements and the Lumen Contour of each cross-section, as well as unlocking the automated measurements to edit them. When the Advanced Display is turned off, the Measurements panel may be fixed in an open position by clicking the pushpin icon.

Figure 11. Measurements Panel

Any manual measurements created with a cross-sectional image will populate below the automated measurements associated with this location. See Measurements and Annotations for more information (page 48).

Note: Menu items appear darker when they are not available.

View Menu

The View menu (see below) is available when reviewing an OCT pullback. It is a collapsible panel that expands when the mouse cursor is positioned over it or clicked on it when it is collapsed. The settings on this panel may be used to configure the various display options, and are broken out into three distinct functional areas:

1. Advanced Display

2. Longitudinal View

3. Stent Display

   Note: The items displayed in your view menu are dependent on the software configuration as well as the recording being reviewed.

   Note: Menu items appear darker when they are not available.

Figure 12. View Menu

Tools Menu

When the OCT playback is paused, or displaying a still image, the measurement and annotation tools can be accessed on screen by hovering over the Tools menu (wrench symbol). As measurements are added to the image, they are labeled with successive control letters (A, B, C, etc., up to 25 measurements per frame) and listed in the measurements panel.

Note: For more information on the individual tools, refer to Measurement and Annotations ( ).

Figure 13. Tools Menu
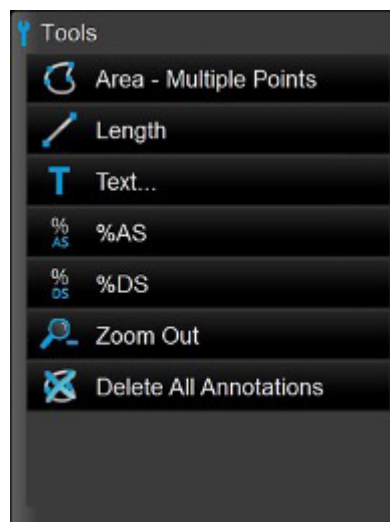
Note: Menu items appear darker when they are not available.

Table 11. Measurement and Annotation Tool Functions

	Area - Multiple Points	Manually place points to trace and measure an area on a frame. This also generates the min., max., and mean diameter measurements for the given area.
	Length	Make a distance measurement on a frame or within the L-Mode.
	Text...	Opens the Enter Note menu to enter text at the cursor position.
	%AS (Percent area stenosis)	Calculates the relative size of two areas drawn in the current frame. **Note:** If there are fewer than two areas on the current frame, this button is disabled.
	%DS (Percent diameter stenosis)	Calculates the relative size of two lengths drawn in the current frame. **Note:** If there are fewer than two lengths on the current frame, this button is disabled.
	Zoom - / Zoom +	Switches between zoom levels. See Quick Zoom for more information (page 55).
	Delete All Annotations	Click to delete all annotations and measurements.

Reviewing with Angio Co-Registration

Only pullback images that contain Angio Co-Registration data can be used for this type of review. Identify the presence of Angio Co- Registration data by locating a black and white angiographic thumbnail image in the upper-left corner of the pullback on the Patient Summary screen.

1. From the Patient Summary screen, identify a pullback that contains a black and white angiographic thumbnail image in the upper- left corner.

Figure 14. Angio Co-registration thumbnail images
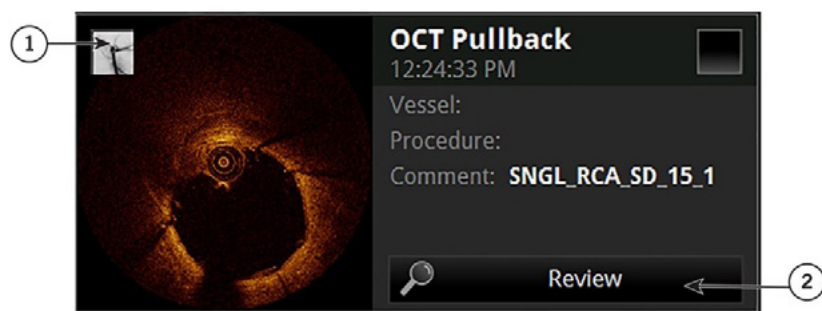
1. Angio-co-registration thumbnail
2. Review button

2. Click the Review button. The OCT review begins to playback.

Figure 15. Image Window Showing Angio Co-registration
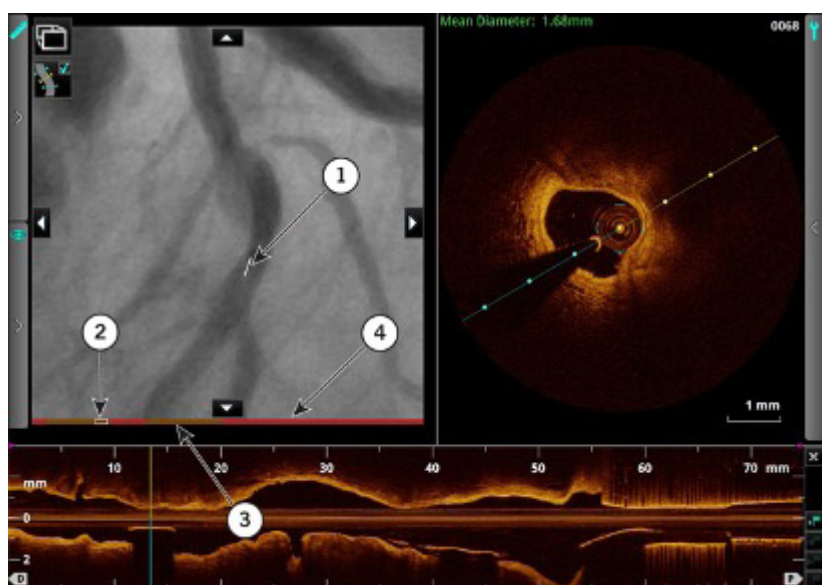
1. OCT Frame Indicator (OFI). The approximate location of the OCT lens associated with the displayed OCT cross section image

2. Current frame position (as represented on the time line bar)

3. High confidence frames (represented in orange on the time line bar)

4. Low confidence frames (represented in red on the time line bar)

Note: The OCT Frame Indicator represents the approximate location of the OCT lens within the co-registered angiography frames. The indicator color corresponds to the confidence of the co-registration result at that location; white is associated with high confidence as red is associated with low confidence. The indicator coloring also aligns with the position on the bar, below the co-registered angiogram.

Note: To verify the Co-Registration result, navigate the Current Frame Indicator to an anatomical landmark in the L-Mode that can be cross-referenced with the OCT Frame Indicator on the Angio Co-Registration view.

Note: The Stent Roadmap represents the approximate location of the Distal, Proximal, MLA markers, and Bookmarks within the co-registered angiography frames. The color of the marker periphery corresponds to the confidence of the co-registration result at that location; red is associated with low confidence.

Note: Areas on the bar marked in red (see red arrow pointing to the bar below the angiographic image in as shown in the figure above) indicate angiography frames where the Angio Co-registration accuracy may be lower, due to poor visibility of the lens marker. Exercise caution when interpreting Angio Co-registration results in these areas.

Note: To use the Quick Zoom feature (see Quick Zoom [page 55]) on the Angiography window, simply click on the angiography image.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of AptiVue™ E Series Software in areas where CE marking is not the regulation in force.

3D Bifurcation and 3D Navigation Views

Note: 3D is not available on all OCT cases.

3D Bifurcation (see 3D Bifurcation Display [page 30]) or 3D Navigation (see 3D Navigation Advanced Display [page 32]) views are accessed from the View menu. A 3D region displays to the left of the Cross Section. 3D Bifurcation or 3D Navigation views are not available in stationary recordings and captured frames. The Cross Section and 3D view can be resized by dragging the vertical line that separates them. While 3D Bifurcation or 3D Navigation is ON, new measurements cannot be added on the Cross Section, and existing measurements cannot be edited on the Cross Section. The 3D Navigation is always available, while 3D Bifurcation is only available when supported by the platform configuration.

The 3D region can be zoomed in or out by clicking and dragging inside the 3D region with the right mouse button. Single-clicking on the 3D volume updates the current frame (3D Navigation view only) and the 3D display is zoomed in by fixed factors, configurable under Setup > Display (see Setup - Display Menu [page 72]).

3D Bifurcation Display

The 3D Bifurcation advanced display, (see the figure below), provides views of detected side branch ostia. When 3D Bifurcation view is first displayed, the closest side branch ostium to the current frame is selected and the 3D cut-plane will be offset by 90° to provide a straight-on view of the side branch (ostium view default shown in the figure below). This orthogonal 3D cut-plane is displayed on the cross-sectional image as a pink cut-plane in the figure below.

Figure 16. 3D Bifurcation Overview (Ostium View)
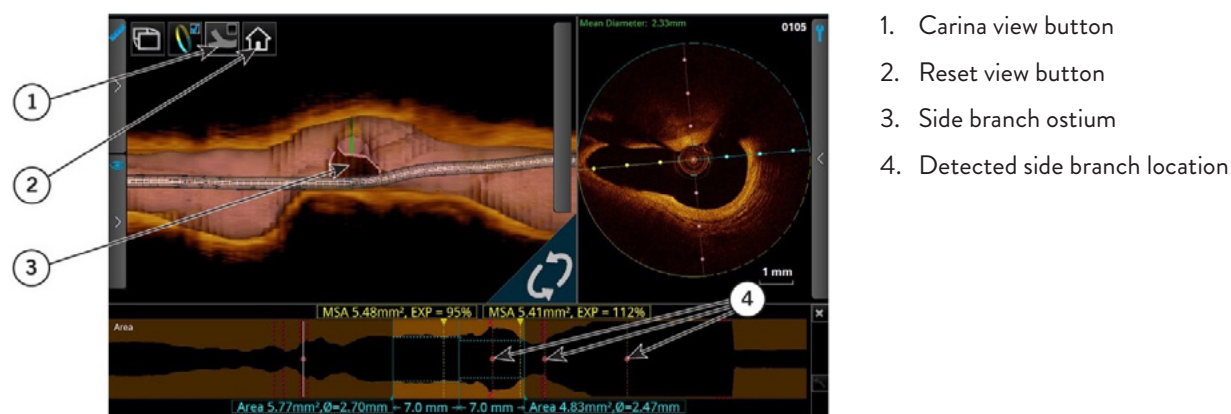
1. Carina view button
2. Reset view button
3. Side branch ostium
4. Detected side branch location

The L-mode cut-plane is adjusted to cut through the side branch (carina view in the figure below).

Figure 17. 3D Bifurcation Overview (Carina View)
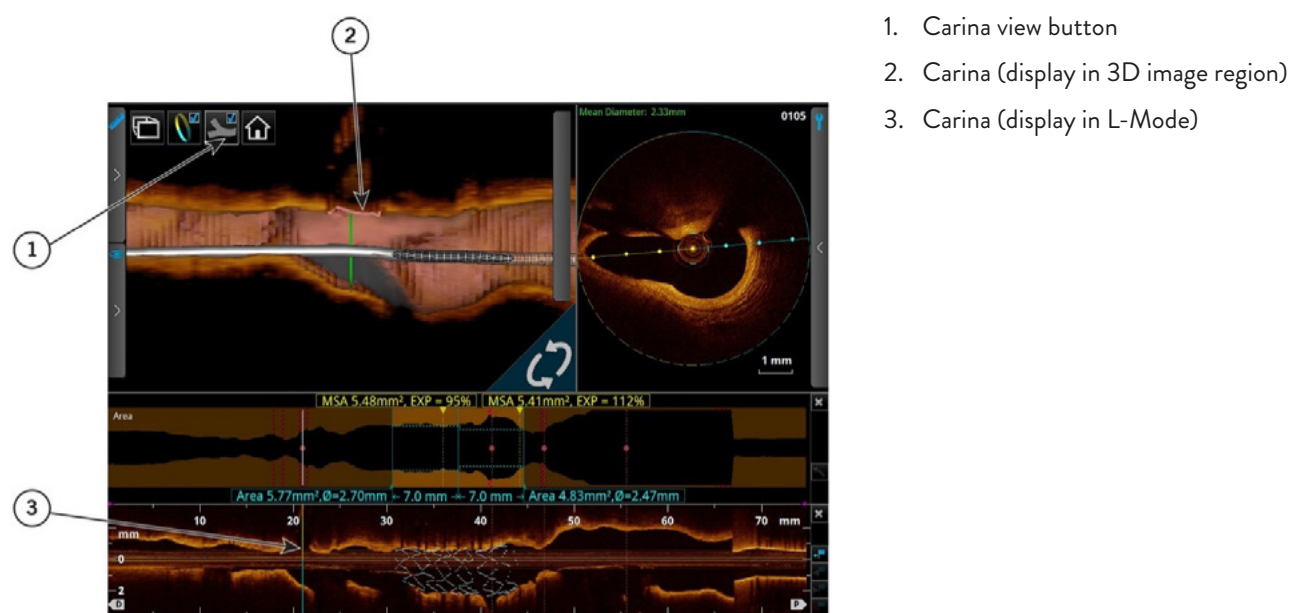

1. Carina view button
2. Carina (display in 3D image region)
3. Carina (display in L-Mode)

Detected side branch ostia are indicated on the lumen profile (or L-mode) view as small dots with vertical dashed lines. Clicking on the Lumen Profile or L-mode image along these vertical dashed lines or dots will navigate the current frame indicator to that side branch ostium and adjust the cut-planes as necessary to view that side branch ostium. If a side branch ostium is located on the same frame as the MLA, distal, or proximal reference frame, the circular side branch ostium marker is enabled for side branch ostium navigation.

Clicking and dragging on the 3D cross section allows the camera to be rotated left and right relative to the vertical axis. The angle is constrained to approximately plus or minus 75 degrees. A Reset View button resets the default camera angle, zoom factor, and resets the current frame to the center of the side branch ostium.

Note: The frame indicators are not drawn over side branch ostia in any 3D advanced display,

Note: The rendering of the side branch ostia must be verified with the cross-sectional and L-mode OCT images.

Note: A side branch ostium may not be rendered completely if there is presence of another OCT artifact near it; e.g., guide wire or metallic stent strut "shadow."

The 3D cut-plane can be synchronized with the L-mode cut-plane by clicking the Carina View button in the 3D image region. In this view, both the L-mode and 3D images show a lateral view of the side branch ostia (see the figure above). This view shows a single cut-plane indicator on the cross-sectional image.

3D Navigation Advanced Display

Figure 18. 3D Navigation (Tissue Option Shown)

1. 3D display
2. Cross-section view
3. Frame indicators
4. Current frame indicator
5. Cut-plane rotation hotspot
6. Rendered half of the vessel image
7. Divider bar
8. Cut-plane indicator
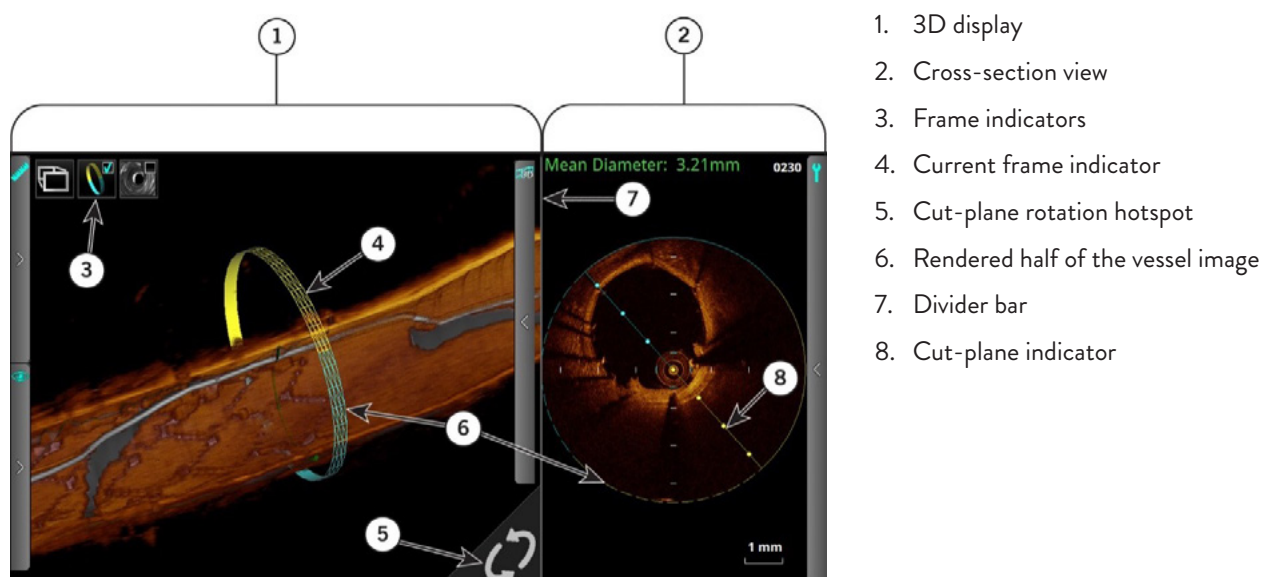
Table 12. 3D Navigation

3D display	
Cross-section view	
Frame indicators	Click to turn on and off the corresponding reference frame markers (Proximal, Distal, MLA, Current Frame Indicator).
Current frame indicator	Current Frame Indicator (3D View): Scroll the mouse wheel to change the cut plane as shown in the L-mode.
Cut-plane rotation hotspot	Place the cursor over the Hotspot and rotate the mouse wheel to change the cut plane as shown in the L-mode and 3D display.
Rendered half of the vessel image	The solid lines in the cross-sectional view represent the rendered half of the vessel image. The dashed lines in the cross-sectional view represent the open, or un-rendered, half of the vessel image. The blue and yellow colors are for location referencing among the views.
Divider bar	Click and drag the divider bar side to side to change the size of 3D display versus cross-section view.
Cut-plane indicator	The cut-plane is shown as a solid line in the cross-sectional view Click and drag this to change the lateral view shown in the L-mode display. **Note:** To zoom you can either left click in the 3D Display window for Quick Zoom factors or right-click and drag up or down, left or right to adjust zoom.

3D Options Menus

The 3D Options menu allows you to turn on and off the displayed 3D objects while in any of the 3D display views (See figure below).

Figure 19. 3D Options Menu

DISPLAY MODE TISSUE, LUMEN, AND TISSUE + LUMEN

The Tissue + Lumen display will render the image longitudinally bisected. The Lumen display renders the image in its entirety. When the Lumen Profile view is on, the Distal and Proximal markers, along with the MLA frame are also displayed when the Frame Indicators is turned on.

Tissue mode (see figure below) will display the 3D rendering using the raw OCT imaging data.

Figure 20. Tissue Display
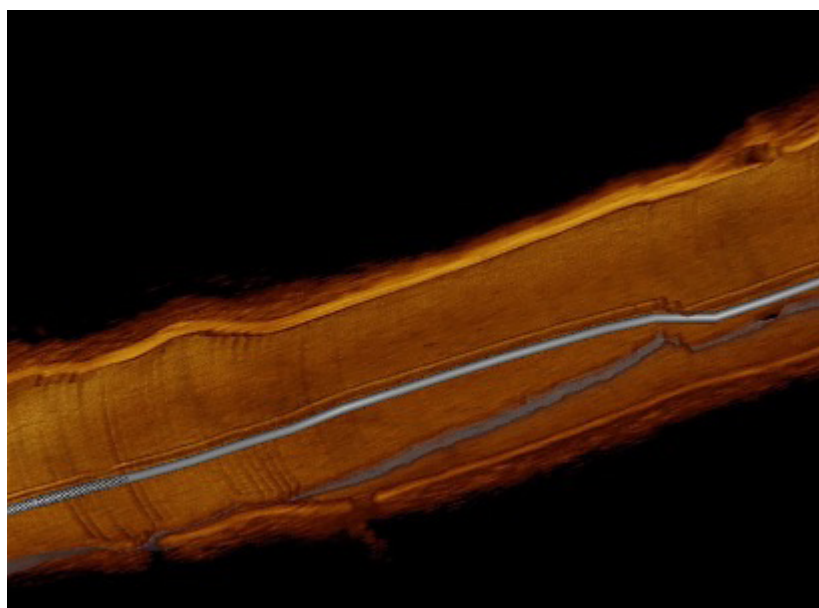
Lumen (see figure below) will display the 3D rendering using the lumen contour.

Figure 21. Lumen Display
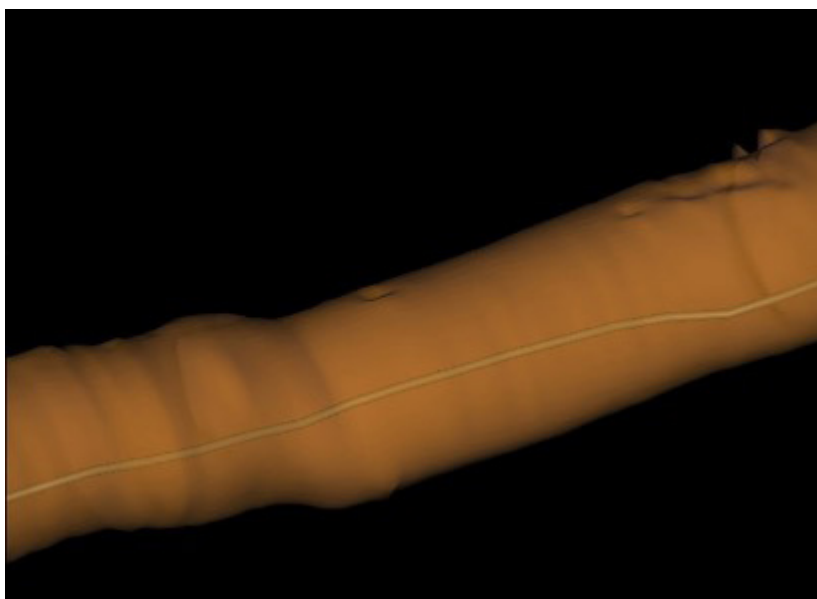
Tissue + Lumen (see figure below) will display the 3D rendering using a hybrid of the two modes.

Figure 22. Tissue + Lumen Display
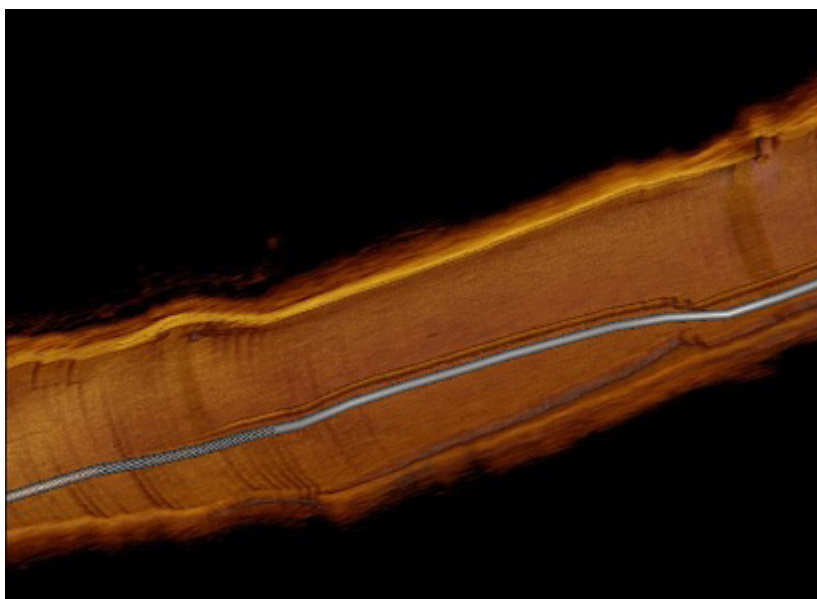
Switching between Tissue + Lumen, and Lumen can be done from the 3D Options panel. (Tissue + Lumen vs. Tissue is configurable through Setup > Display > 3D (see Setup - Display - 3D Menu [page 72]).

3D OPTIONS – STENT ONLY

Detected metallic stents can be displayed in 3D. Individual struts are displayed as faint 3D boxes, and links connecting struts (when available) on neighboring frames are added.

Whenever the image is bisected, only the back half of the stent is visible. (See figure below)

Note: The Stent Only option should only be used for visualizing newly implanted metallic stents.

Note: The rendering may appear incomplete at times, therefore the rendering should always be used in conjunction with the cross-sectional OCT image when assessing metallic stent implantation.

Figure 23. Stent Display: Half Stent

When the entire image is displayed, or when the stent is displayed by itself, then the front half of the stent is brighter than the back half (see figure below).

Figure 24. Stent Display: Full Stent
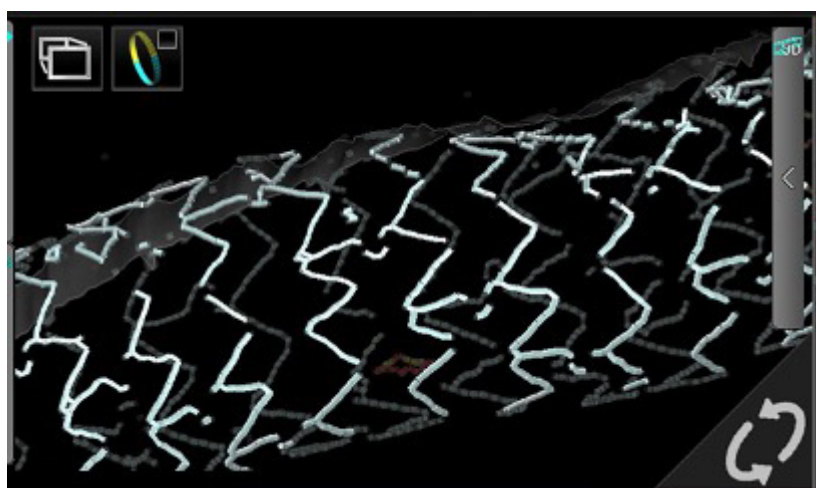
3D OPTIONS – GUIDE WIRE DISPLAY

The guide wire artifact present in the OCT image data presents a penumbra, or shadow, which prevents visualization of any structures beyond it. When rendered in the 3D displays, this shadow may be present as a gray path rendered on the lumen wall that traverses the pullback recording. Up to two detected guide wires can be displayed in 3D mode. The number of guide wire checkboxes matches the number of detected guide wires. They can be turned on or off individually by clicking the Guidewire 1 and Guidewire 2 checkboxes. The position of the cut-plane may affect how the guide wire is displayed as shown in the Guide Wire Partially Rendered / Solid Display figure below. If this is not the case, the guide wires are displayed solid as shown in the Guide Wire Solid Display figure below.

Note: If the guide wire is behind the cut plane, it will appear partially rendered.

Note: The presence of the guide wire artifact or "shadow" will prevent any object covered by it from being rendered.

Note: Location and display of guide wires should be verified with the cross-sectional and L-mode OCT images.

Figure 25. Guide Wire Partially Rendered / Solid Display
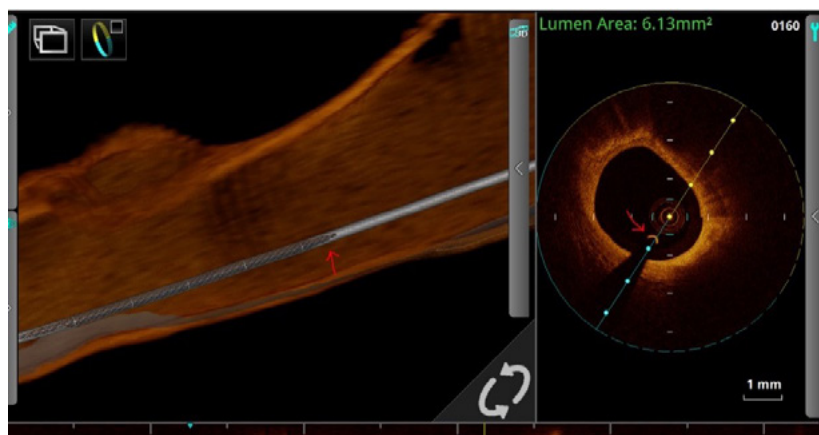
Figure 26. Guide Wire Solid Display

3D OPTIONS – SIDE BRANCH(ES)

The Side Branch(es) option will turn on or off the display of side branch ostia. Side branch ostia can be highlighted in 3D mode by a thick, pink outline and holes in the lumen surface. (See figure 3D Bifurcation Overview (Ostium View) in 3D Bifurcation Display [page 30].) Only side branch ostia that have diameter greater than 1.5 mm are displayed on the L-mode and in 3D mode.

Note: The rendering of the side branch ostia must be verified with the cross-sectional and L-mode OCT images.

Note: A side branch ostium may not be rendered completely if there is presence of another OCT artifact near it; e.g., guide wire or metallic stent "shadow."

3D OPTIONS – FLYTHROUGH

3D Flythrough is accessed via 3D Navigation view.

To enable the 3D flythrough: click the 3D Flythrough button on the upper-left corner of the 3D display.

The 3D flythrough mode allows you to view the vessel from the inside. Clicking and dragging on the 3D display allows you to change the camera direction in the following orientations: up, down, left, and right. The Reset View button allows you to reset the viewing direction of the camera (see figure below). The 3D flythrough view does not rotate when the cut-plane is rotated.

The default flythrough direction is proximal to distal. In this mode, the playback direction is reversed (see figure below). It is possible to change the flythrough direction from distal to proximal from the 3D options panel.

Figure 27. 3D Flythrough Overview

1. 3D flythrough button
2. Reset view button
3. Distal / Proximal 3D flythrough direction indicator
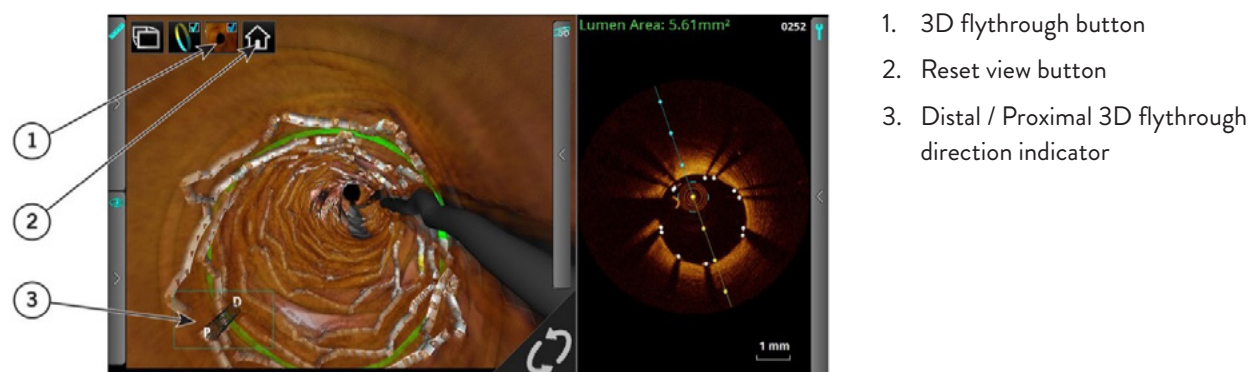
LIMITATIONS OF 3D DISPLAY

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

- The 3D displays are directly dependent on the OCT image data. Therefore, it is important to have good image quality of the OCT images to ensure accurate rendering.
- The 3D displays are approximations that may appear straight and rotationally aligned and have other imaging artifacts due to the method of tomographic reconstruction.
- The presence of red thrombus may degrade the quality of the 3D renderings.
- 3D Display reconstructions that appear "saw-toothed" or appear to have segments that are misaligned can lead to misinterpretation by an inexperienced user.
- Shortening or lengthening artifacts or other degradations in the 3D Display reconstruction may occur due to the relative motion of the imaging catheter with respect to the coronary artery caused by the patient's heart motion.
- Due to the catheter's arbitrary position within the vessel, 3D Display may not be representative of the actual vessel lumen.
- The vessel diameter shown in the 3D Display may appear significantly smaller than the actual diameter when the catheter position is off center and close to the vessel wall. To avoid misinterpreting the image when this occurs, rotate the cut-plane to examine all views of the 3D Display.
- 3D Fullscreen is only available on AptiVue™ Offline Review Software (version E.5 series).

L-Mode Bookmark Controls

The system allows you to add bookmarks to mark frames for further review. Bookmarks will display in the angio co-registration area if this setting is enabled. See Setup - Display - Angio Menu (page 72).

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

Figure 28. Bookmark Controls

1. Add / Remove bookmark
2. Previous bookmark
3. Next bookmark
4. Clear all bookmarks
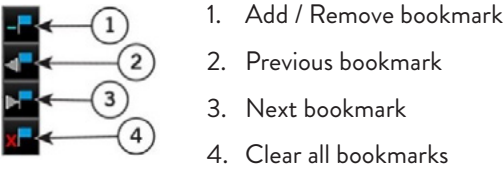
Table 13. Bookmark Controls

Add / Remove bookmark	Applies or removes a bookmark from the current frame. After a bookmark has been applied to a frame, the position of the bookmark is indicated in the L-mode view with a green triangle. Click on a bookmark indicator to jump to the bookmarked frame. **Note:** Frames with measurements and annotations are bookmarked automatically. See Measurements and Annotations for more information (page 48).
Previous bookmark	Seeks backward to the previous bookmarked frame. If there are no previous bookmarks, it continues seeking from the end of the recording. Unavailable if there are no bookmarks.
Next bookmark	Seeks forward to the next bookmarked frame. If there are no subsequent bookmarks, it continues seeking from the beginning of the recording. Unavailable if there are no bookmarks.
Clear all bookmarks	Clears all bookmarks from the current recording. Unavailable if there are no bookmarks.

Setting Playback Range in L-Mode

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

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

Figure 29. Adjusted Playback Range

1. Playback range markers
2. Current frame indicator
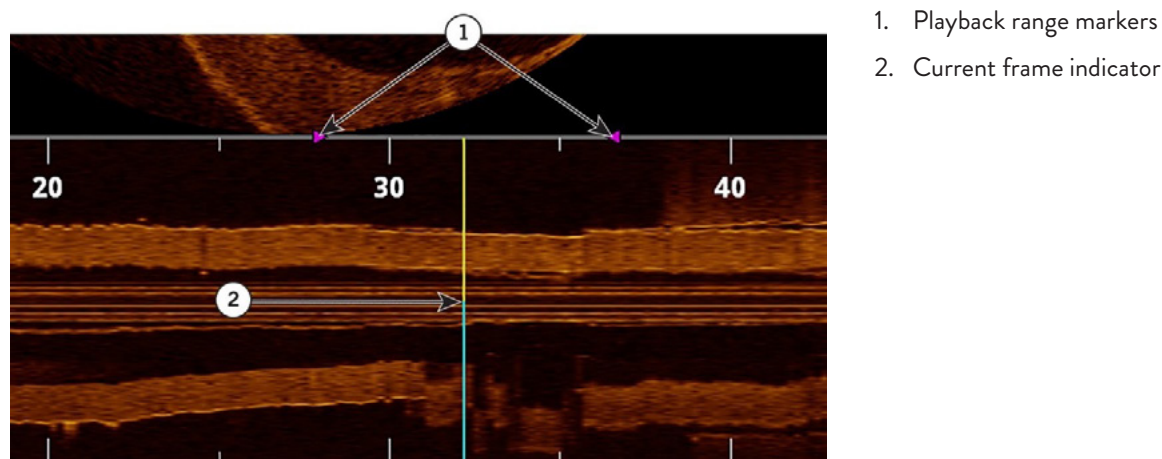
To change the playback range:

1. Use the playback controls at the bottom of the screen to pause the playback.

2. Click on the range markers (purple triangles) and position them before and after the area to be played during review.
   Note: If the recording is exported as an AVI file, this range determines the length of the exported recording.
   Note: If the L-mode view is changed (for example, turned Off), the playback range is restored to the full length of the recording.

LIMITATIONS OF L-MODE DATA

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

- Due to the catheter's arbitrary position within the vessel, L-mode data may not be representative of the actual vessel lumen.
- The presence of red thrombus may degrade the quality of the information derived from OCT imaging.
- The vessel diameter shown in the L-mode reconstruction may appear significantly smaller than the actual diameter when the catheter position is off center and close to the vessel wall. To avoid misinterpreting the image when this occurs, rotate the cut-plane to examine all views of the L-mode.
- The L-mode display may appear straight and rotationally aligned and have other imaging artifacts due to the method of tomographic reconstruction.
- L-mode reconstructions that appear "saw-toothed" or appear to have segments that are misaligned can lead to misinterpretation by an inexperienced user.
- Shortening or lengthening artifacts in the L-mode reconstruction may occur due to the relative motion of the Dragonfly™ Imaging Catheter with respect to the coronary artery caused by the patient's heart motion.

LUMEN PROFILE DISPLAY WITH MINIMUM LUMEN AREA (MLA) CONTROLS OVERVIEW

> ⚠️ **CAUTION: It is the user's responsibility to confirm the lumen contours of all the frames within the reference segment, and to make adjustments if necessary. Red frames indicate low confidence in the detected contours.**

Note: The information derived from the features of the AptiVue™ Imaging Software are directly dependent on the OCT image data. Therefore, it is important to have good image quality of the OCT images to ensure accurate results.

Note: If the system has low confidence in the area measurements, the system displays "?.??" for the area values. If the area values are "?.??," the contours on the relevant frames must be reviewed, edited if necessary, and accepted before they can be displayed.

Figure 30. MLA Controls

1. Distal reference frame
2. Calculated MLA
3. High confidence contour of the lumen area
4. Lumen area
5. Proximal reference frame
6. Low confidence contour of the lumen area

Table 14. MLA Controls

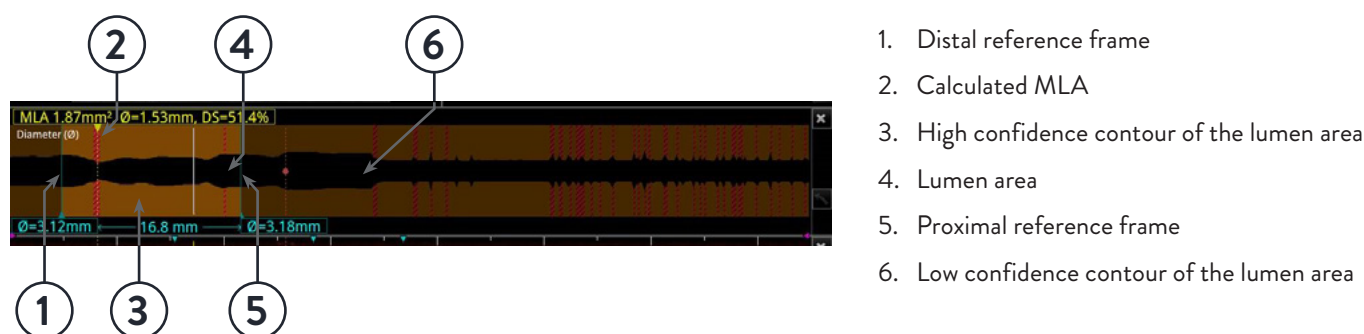|	
Proximal reference frame	Move these to set the range for MLA calculation. The system's search for a minimum lumen area occurs on frames between the distal and proximal reference frames.
Lumen area	The lumen area is colored black.
High confidence contour the lumen area	Where the system has high confidence in the contour of the lumen area, or where the contour has been accepted by the user, the section is colored brown.
Calculated MLA	The dashed line indicates the position of the minimum lumen area between the distal and proximal reference frames (A). – If mean diameter is selected in the Setup > Display > Lumen Profile Measures, the percent diameter stenosis is displayed. – If area is selected in the Setup > Display > Lumen Profile Measures, the percent area stenosis is displayed.
Low confidence contour of the lumen area	Where the system has low confidence in the contour of the lumen area, the section is colored red. These frames are not considered in the MLA search. If these frames are within the range where MLA is calculated, you must go to the MLA frame and confirm the contour.
Distal reference frame	Move these to set the range for MLA calculation. The system's search for a minimum lumen area occurs on frames between the distal and proximal reference frames.

Figure 31. Low Confidence MLA

Click the yellow MLA box to display Accept, then click on Accept to display measurements as the frames currently are. The other option to display measurements is to correct the red frames within the designated reference segment.

The MLA frame computation override feature allows you to click on the MLA frame and drag the frame thereby overriding the automatically computed MLA frame. The MLA frame will change from this:

Figure 32. Automatically Computed MLA Frame
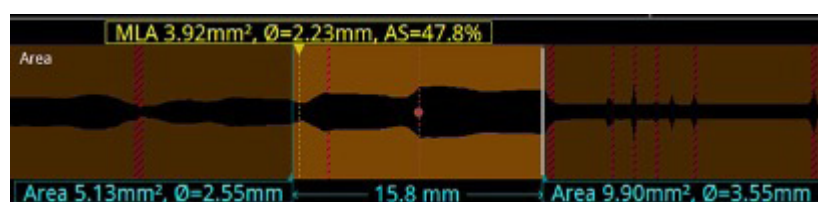
To this:

Figure 33. Overridden MLA Frame

The overridden frame can be restored by going to the overridden frame (click on the yellow text box to jump there) and clicking Restore.

Note: Verify the OCT lumen contours of the distal, proximal, and MLA frames before accepting or overriding the automated data.

Stent Apposition Indicator

When the Apposition Indicator button is clicked, the Stent Apposition Indicator Bar (see figure below) and a similar apposition indicator on the angiography image appears (see Angio Co-Registration / Stent Apposition Integration in Angio Co-Registration View).

Figure 34. Stent Apposition Indicator Bar

1. Stent apposition indicator bar
2. Lumen profile display
3. Stent apposition indicator bar key display
4. L-mode display

The stent apposition indicator bar is displayed between the lumen profile window and the L-mode display window. If no longitudinal view is displayed, then the stent apposition indicator bar will not be displayed. This bar is a representation of the apposition analysis in the stented region of the pullback. The colors used on the apposition indicator represent summary information derived from the individual struts that meet apposition criteria.

Note: Individual strut colors may not match the colors on the apposition indicator bar.

This bar indicates longitudinal regions where stents are detected. These stented regions will be segmented by colors to indicate the apposition of the stent struts in those segments. The meaning of the colors is shown in the key on the right-hand sid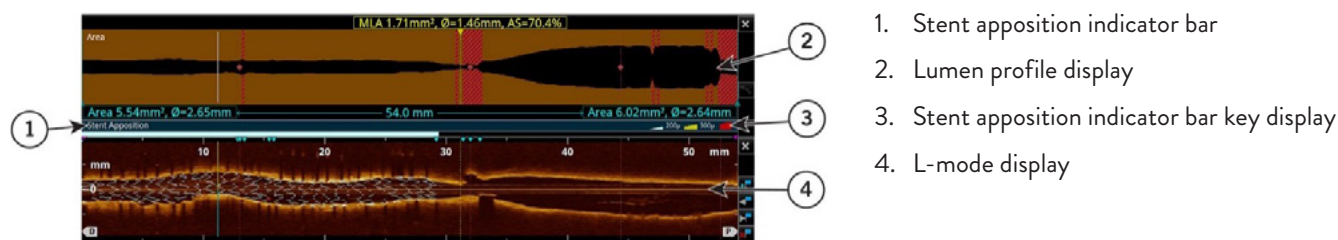e of the stent apposition indicator bar and may be modified by changing the apposition threshold settings in Setup (see Setup - Display - Stent Apposition [page 73]). The apposition indicators displayed along the outside of the vessel on the angio co-registration image are identical in meaning to the stent apposition indicator bar.

Rendered Stent Display

When the Rendered Stent button is clicked, the rendered stent option displays the rendered stent struts on the cross-sectional image, L mode, and 3D image. The rendered stent struts highlight the location where metallic stent struts are detected. They are color coded to indicate the apposition of each strut. If the apposition indicator is displayed, stent struts are color coded to indicate the areas of incomplete apposition.

Note: The information derived from the features of the AptiVue™ Imaging Software are directly dependent on the OCT image data. The stented region may appear longer or shorter due to the quality of the OCT recording. Always verify the location of the stent in the cross-sectional OCT image and L-mode.

Figure 35. L-Mode Rendered Stent Display
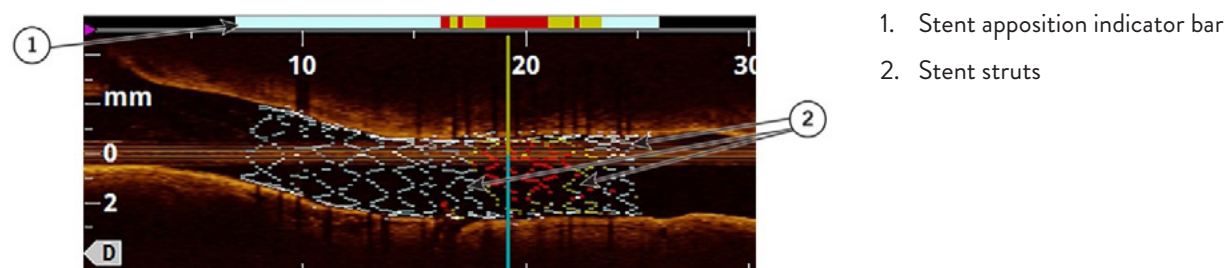
1. Stent apposition indicator bar
2. Stent struts

Note: The rendering may appear incomplete at times, therefore the rendering should always be used in conjunction with the cross-sectional OCT image when assessing metallic stent implantation.

Figure 36. Cross-Sectional View: Rendered Stent Display
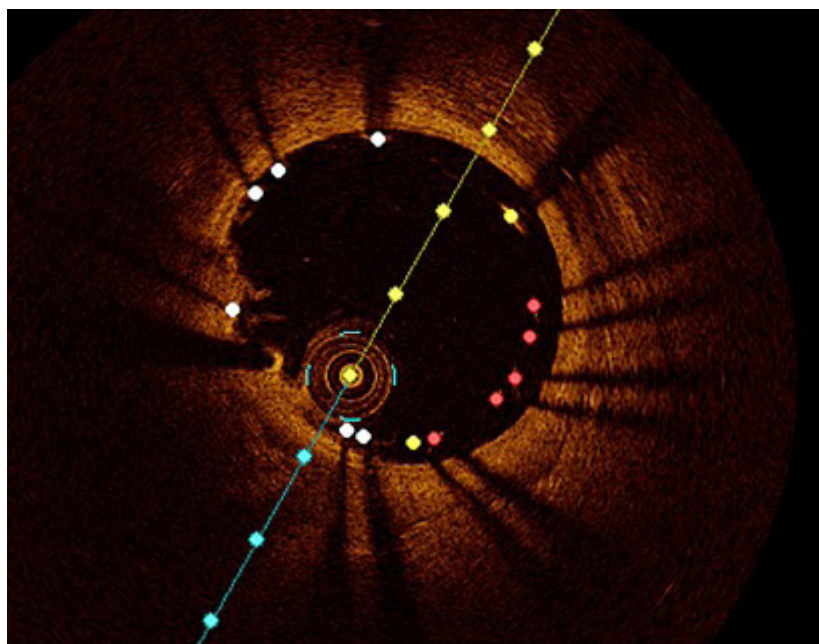
Note: Since the stent apposition indicator bar represents regions along the detected metallic stent, this may be a different color compared to the Rendered Stent at the same location.

Note: Stent displays (apposition indicator and rendered stent) are designed to help the user quickly identify regions of the metallic stent that may need further assessment to determine apposition. Always refer to the cross-sectional OCT image to determine strut element apposition.

EDITING DETECTED STENT STRUTS

Detected stent struts may be edited by the user. To move an individual point, click on the point and drag it to a new location.

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

Note: If you add, move, or delete a point on an automatically generated stent contour, an arrow icon appears in the corner of the measurement listed in the Measurement Panel. Click the arrow to reset the contour on that frame back to the automatically generated stent contour.

STENT EXPANSION DISPLAY

The Stent Expansion display gives a visual representation of the stent expansion on the lumen profile section of the screen using either tapered reference or dual reference method.

Tapered Reference

When the tapered reference is selected, the expansion for each frame is computed relative to an ideal reference area. The expansion thresholds will appear on the angiography window and lumen profile to display the calculated values of stent expansion in the selected pullback. The threshold values can be adjusted in Setup - Display - Stent Expansion.

The AptiVue™ Imaging Software will automatically calculate the minimum stented area.

Figure 37. Stent Expansion Display (Tapered Reference)

1. Stent apposition / Stent expansion toggle
2. Expansion threshold (angiography window)
3. Reference location of the stent (in the lumen profile)
4. Minimum stented area
5. Stent expansion percentage
6. Side branch location
7. Expansion threshold (lumen profile)
8. Expansion indicator / reference profile toggle
9. Reset view
10. Apposition threshold
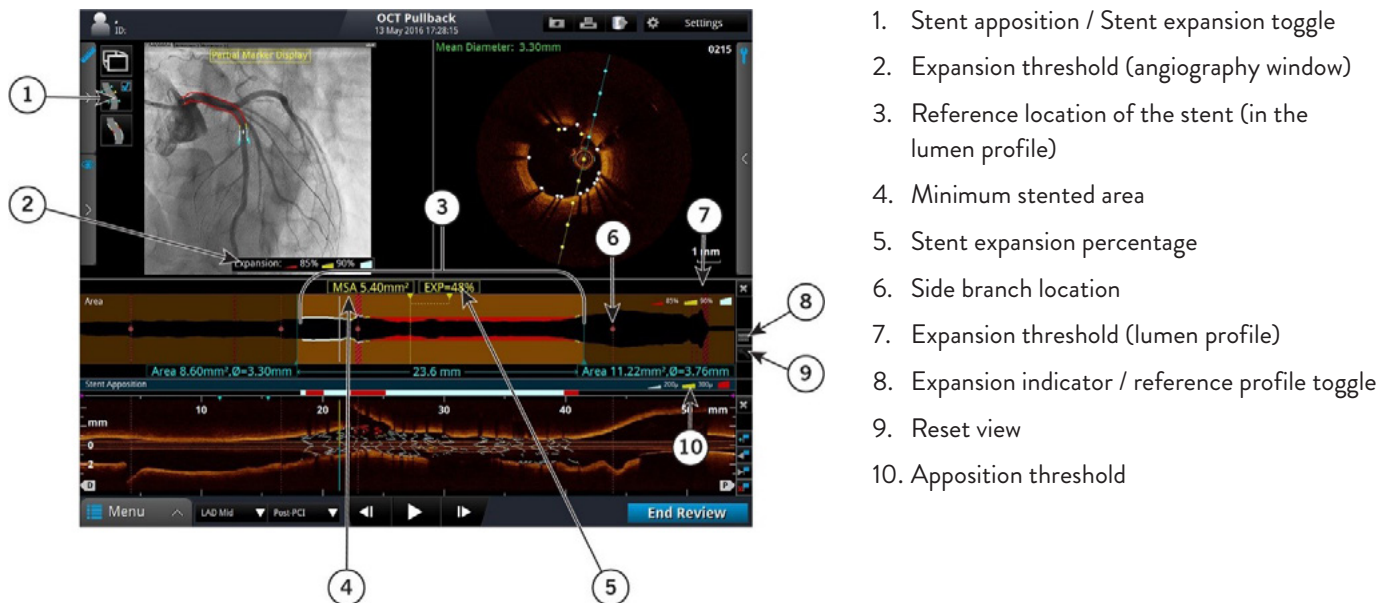
Dual Reference

When the dual reference is selected, the stent is split in half based on the length of the stent with the sections MSA displayed as yellow dotted lines.

Figure 38. Stent Expansion Display (Dual Reference)
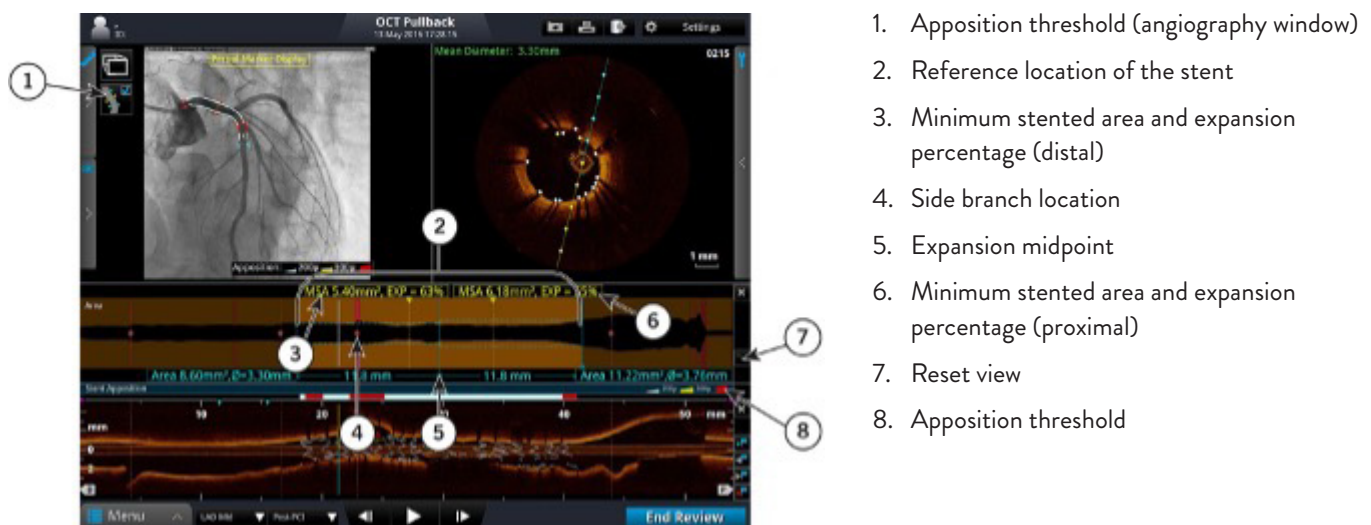
1. Apposition threshold (angiography window)
2. Reference location of the stent
3. Minimum stented area and expansion percentage (distal)
4. Side branch location
5. Expansion midpoint
6. Minimum stented area and expansion percentage (proximal)
7. Reset view
8. Apposition threshold

Playback Controls

Figure 39. Playback Controls

1. Menu button
2. Vessel list
3. Procedure list
4. Step backward
5. Play / Pause
6. Step forward
7. End review / New recording
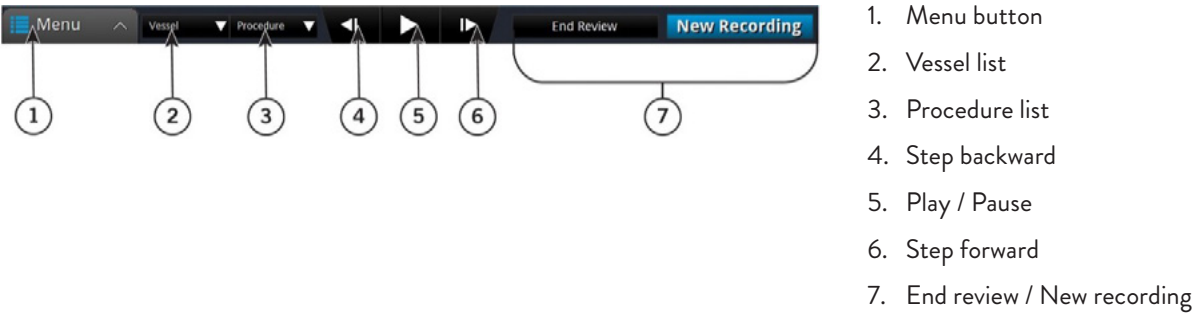
Table 15. Playback Controls

Menu button	Displays the context-sensitive menu. Click to access the Setup and playback Calibration controls. Only available with a still image or paused recording.
Vessel list	Click to open a drop-down list of vessels to describe this recording.
Procedure list	Click to open a drop-down list of procedures to describe this recording.
Step backward	Click to move the recording back one frame at a time. Click and hold this button to move back rapidly. Not available with still images.
Play / Pause	Plays or Pauses the recording. If you pause a recording, the frame number is displayed in the upper right corner of the image area. Not available with still images.
Step forward	Click to move the recording forward one frame at a time. Click and hold this button to move forward rapidly. Not available with still images.
End review / New recording	Click the End Review button to close this window and return to the Patient Summary menu.

CALIBRATION ADJUSTMENT

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

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

2. Click **Adjust Calibration** at the bottom of the screen.
    The Adjust Calibration tool opens. The image is zoomed and the calibration circle with two control points is sized approximate to the outside diameter of the catheter.

Figure 40. Playback Calibration (in progress)

1. Control point
2. Example
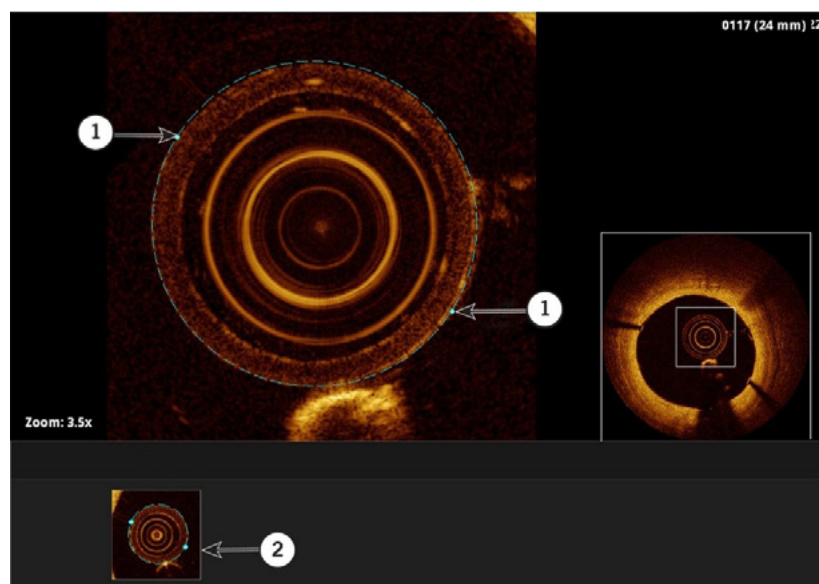
Note: If Playback Calibration is attempted on a successfully calibrated Dragonfly™ OPTIS™ Imaging Catheter pullback, a calibration dialog will display asking to confirm the calibration override.

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

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

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

    Note: If necessary, you can return the recording to its default calibration by clicking Remove Adjustment. If you remove or change the calibration, any changes that you have made to the automatically generated Lumen Profile contours are reset. See Lumen Profile Display with MLA Controls Overview (page 40).

Adjust Playback Settings

1. Click **Settings** at the top of the screen. A context-sensitive menu opens.

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

3. Click and drag the rotation slider bar to rotate the image shown in the cross-section view.
    Note: When an image is rotated, the L-mode cut-plane marker (if visible) and any displayed measurements and annotations are also rotated.

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

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

6. The Field of View setting controls the size of the image displayed on screen. A smaller Field of View setting equals a larger magnification. Click a size to select it.
    Note: Clicking on the image will also change the zoom level. See Quick Zoom (page 55).

Exporting a Recording or Still Frame

Refer to Exporting, Importing, and Managing Files for more information on exporting a recording or still frame ( ).

Capturing Still Images

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

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

SAVING A STILL IMAGE

1. Display the frame that you want to capture.
2. Click **Capture**.
    A confirmation message appears, and the captured image appears in the Patient Summary menu.
    Note: The still image is saved with the same date as the source file. It is grouped in the Patient Summary menu with other recordings and images of the same date.

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

Printing Still Images

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

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

Note: If you are printing the file to a USB drive, you can set the file format. See Setup - Print Menu for more information ( ).

PRINTING STILL IMAGES

1. Display the frame that you want to print.
2. Click **Print**.
    A confirmation message appears, and the file is saved on the attached USB drive.

MEASUREMENTS AND ANNOTATIONS

Measurements and Text Callouts in the Image Files

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

Measurements and text callouts can be modified or deleted, and pen color, line width and point size can be set. In addition, pen color can be set to automatically cycle so that subsequent measurements are displayed in different colors. For information on setting pen color, line width, and point size, see Setup - Measurements / Labels Menu (page 75).

> ⚠️ **CAUTION: If you want to make measurements on files that will be exported to standard formats, you must make the measurements BEFORE exporting the images. Using non-OCT software to measure standard format images will not produce accurate measurements.**

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

Measurement and Annotation Tools

When the OCT playback is paused, or displaying a still image, the measurement and annotation tools are enabled on screen. As measurements are added to the image, they are labeled with successive control letters (A, B, C, etc., up to 25 measurements per frame).

Figure 41. Measurement and Annotation Tools
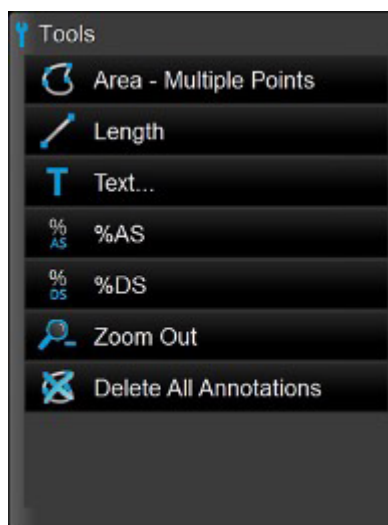
Note: Tools have a black background when they are not enabled.

Note: Refer to Setup - Measurements / Research Menu for instructions on turning on the research tools (page 75).

Table 16. Measurement and Annotation Tool Functions

|	
	Area - Multiple Points: Manually place points to trace and measure an area on a frame. This also generates the min., max., and mean diameter measurements for the given area.
	Length: Make a distance measurement on a frame or within the L-Mode.
	Text...: Opens the Enter Note menu to enter text at the cursor position.
	%AS (Percent Area Stenosis): Calculates the relative size of two areas drawn in the current frame. **Note:** If there are fewer than two areas on the current frame, this button is disabled.
	%DS (Percent Diameter Stenosis): Calculates the relative size of two lengths drawn in the current frame. **Note:** If there are fewer than two lengths on the current frame, this button is disabled.
	Zoom - / Zoom +: Switches between zoom levels. See Quick Zoom for more information (page 48).
	Delete All Annotations: Click to delete all annotations and measurements.
	Stent: Use this button to mark the location of stents within the L-Mode view.
	Angle: Use this button to measure the angle between two points on the contour of an area measurement. This button is not enabled if there is no area measurement on the current frame.
	Pie Tool: Use this button to determine if there is sufficient clearing or sufficient lumen detection within a minimum contiguous area of the image. This button is not enabled if there is no area measurement on the current frame.
	Thickness Ruler: Use this button to measure the thickness from a specific point to the edge of an area contour. This button is not enabled if there is no area measurement on the current frame.
	Neointimal Thickness: Use this button to determine the minimum, maximum, and mean thickness between two area measurement contours. This button is not enabled if there are fewer than two area measurements on the current frame.
	Copy Measurement: Use this button to copy a selected measurement.
	Paste Measurement: Use this button to paste a previously copied measurement to the current image or frame. This button is not enabled if no measurement has been copied.

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

Note: Measurements may be locked to help prevent unintentional changes. (Lock or unlock items by clicking on the padlock icon.)

Verifying Calibration

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

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

Note: Calibration before making measurements should not be necessary when images were captured using the Dragonfly™ OPTIS™ or Dragonfly OpStar™ Imaging Catheter. The AptiVue™ Imaging Software in conjunction with the Dragonfly™ OPTIS™ or Dragonfly OpStar™ Imaging Catheter uses automatic continuous calibration technology to eliminate the need for this step in the workflow.

Techniques to Improve Measurement Accuracy

Follow these guidelines to improve measurement accuracy:
- Before making measurements, use the Zoom function to zoom into the region of interest until you can clearly see borders and other features you want to measure (see Field of View [page 55]).
- Place the measurement cursor correctly on the image, using the same measurement technique each time you perform the same type of measurement.
- Avoid making measurements in areas that have artifacts that disguise tissue.

MEASUREMENTS AND ANNOTATIONS IN THE L-MODE VIEW

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

Area Measurements

 You can manually create a closed area trace of the lumen contour in the cross-section view. The area is calculated using Green's Theorem and is displayed in the frame in mm2 with the minimum and maximum diameter chords.

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

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

MAKING A MANUAL AREA MEASUREMENT

1. Select the still image or paused recording that you want to measure.
2. Click **Area - Multiple Points**. The cursor changes to a pen.
3. Use the mouse to position the pen cursor at the desired starting point for the area in the cross-section view and click to set the point.

Figure 42. Manual Area Measurement (in Progress)
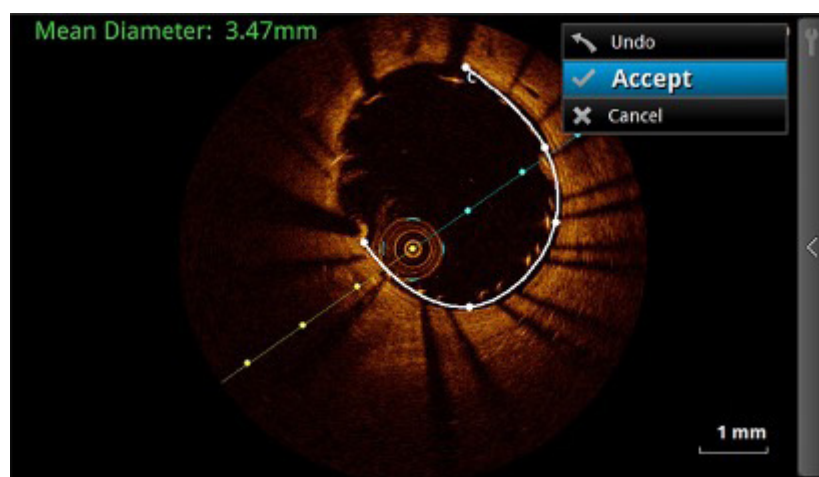
> **Note:** Click **Undo** to the left of the toolbar to delete the most recent point added to the image.

4. Continue to add points with the pen cursor until you have accurately traced the area to be measured. You can place as many points as you like around the border of the desired area. At least three points are required.
   Note: The first two points are connected by a straight line. When you place subsequent points, the straight line becomes a smooth curve connecting all points but not closing the area until you click the Accept button, or the last point is sufficiently close to the initial point for the system to automatically complete the area. Placing more points increases measurement accuracy.
   Note: You must click either **Accept** or **Cancel** to complete the measurement. Click **Cancel** to completely erase the measurement.

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

Length Measurements

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

Figure 43. Length Measurement
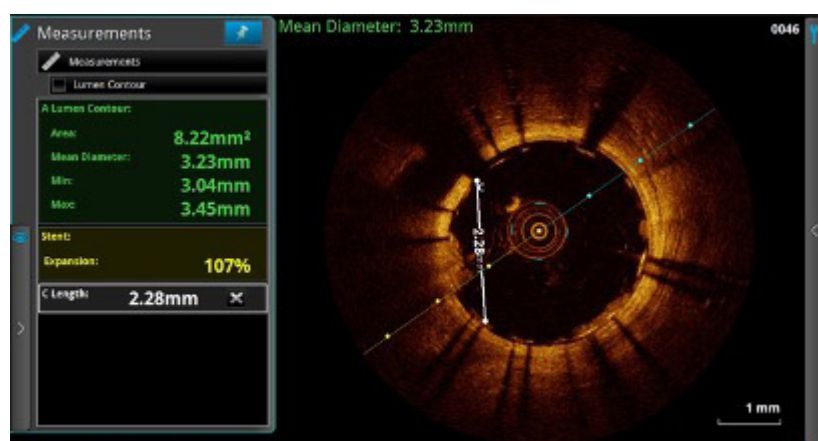
MAKING A LENGTH (DISTANCE) MEASUREMENT

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

2. Click **Length**. The cursor changes to a pen.

3. Click anywhere in the Image Window (cross-section view or L-mode view) to place the starting point for the length measurement.
   Note: Both start and end points must be in the same view. For example, if the starting point is placed in the cross-section view, the end point must also be in the cross-section view.
   To cancel the measurement, press the <Esc> key or click the Cancel button.

4. Use the mouse to position the pen cursor at the end point and click to set the point.
   The completed, labeled distance measurement result appears in the Measurement panel. If you position the cursor over the line, the length is shown over the center of the line.

Adding Text Callouts

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

Figure 44. Text Callouts
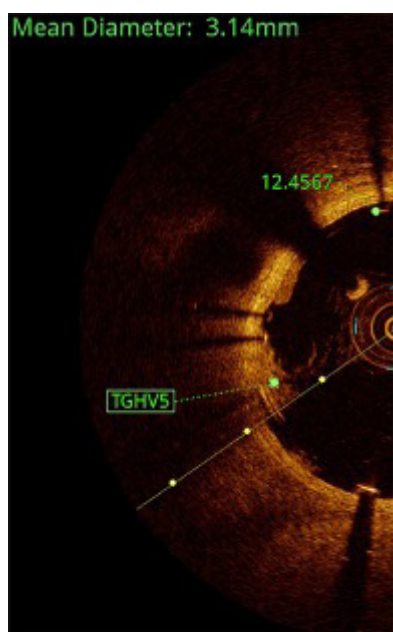
%AS Calculation

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

MAKE A %AS CALCULATION

1. Make an area measurement.

2. If necessary, make a second area measurement in the frame.

3. Click on **%AS** to display the Select Area Measurement dialog box.

4. In the Outer Measurement list, click the larger area measurement.

5. In the Inner Measurement list, click the smaller area measurement.

6. Click **OK**.
   The % Area Stenosis calculation is displayed immediately below the previous calculations in the Measurement panel as shown in the figure below.

Figure 45. % Area Stenosis Calculation
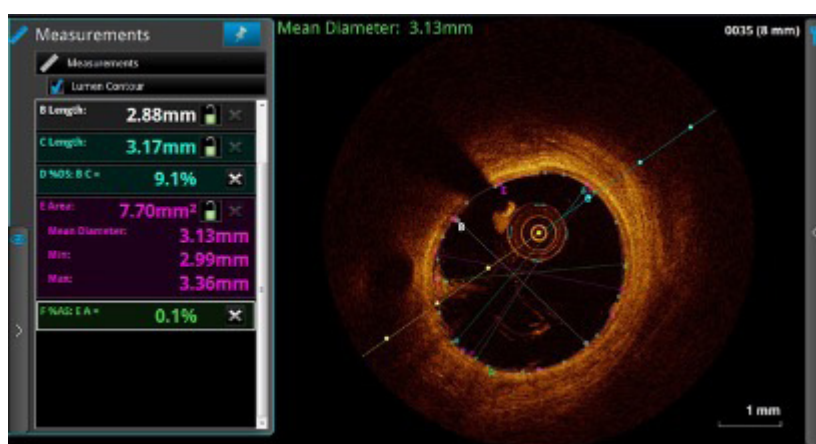
Note: If the second measurement you select is larger than the first measurement, a %AS value will not be displayed. Instead, the Measurement panel displays an error message, similar to the one shown in the figure below.

Figure 46. % Area Stenosis Error Message

FORMULA FOR %AS CALCULATION

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

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

Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of AptiVue™ E Series Software in areas where CE marking is not the regulation in force.

©2021 Abbott. All rights reserved. MAT-2113323 v1.0

%DS Calculation

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

FORMULA FOR %DS CALCULATION

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

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

MAKE A %DS CALCULATION

1. Make two length measurements in the current frame.
2. Click on **%DS** to display the Select Length Measurement dialog box.
3. In the Outer Measurement list, click the longer length.
4. In the Inner Measurement list, click the shorter length.
5. Click **OK**.
   The % Diameter Stenosis calculation is displayed immediately below the previous calculations in the Measurement panel shown in the figure below.

Figure 47. % Diameter Stenosis Calculation
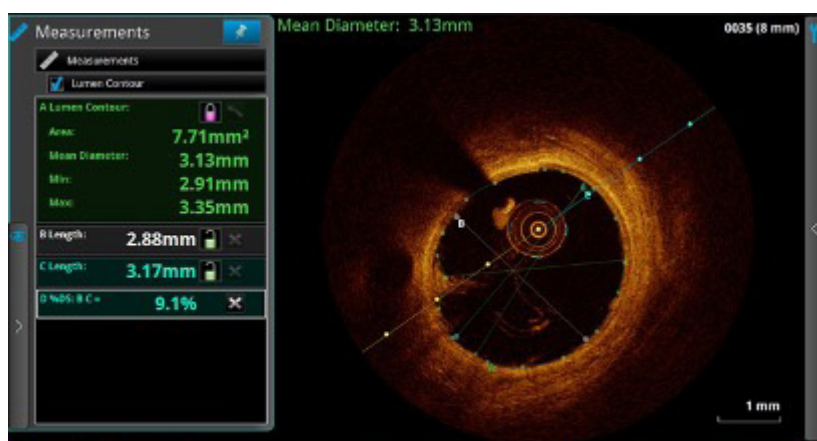
Note: If the second measurement is larger than the first measurement you select, a %DS value will not be displayed. Instead, the Measurement panel displays an error message, similar to the one shown in Make a %AS Calculation ( ).

Field of View

- Zoom out sets the image field of view to the maximum setting (10 mm).
- Zoom in sets the image field of view to the user setting ("field of view" in the settings dialog menu).

Note: If the field of view setting is set to 10 mm, this option is disabled.

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

You can change the magnification of the zoomed field. See Adjust Playback Settings for more information (page 46).

ZOOMING IN MANUALLY

You can enlarge any section of the image manually.

Note: This magnification function cannot be used in the L-mode or lumen profile display.

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

2. Click and drag the mouse across an area to magnify it.
   In the cross-sectional view, when you release the mouse, the system zooms in to the selected rectangle, displaying the magnification factor used (ex. Zoom: 8.4x, see the figure below).
   The system adds an overall view of the image to the right.

Figure 48. Zooming an Image
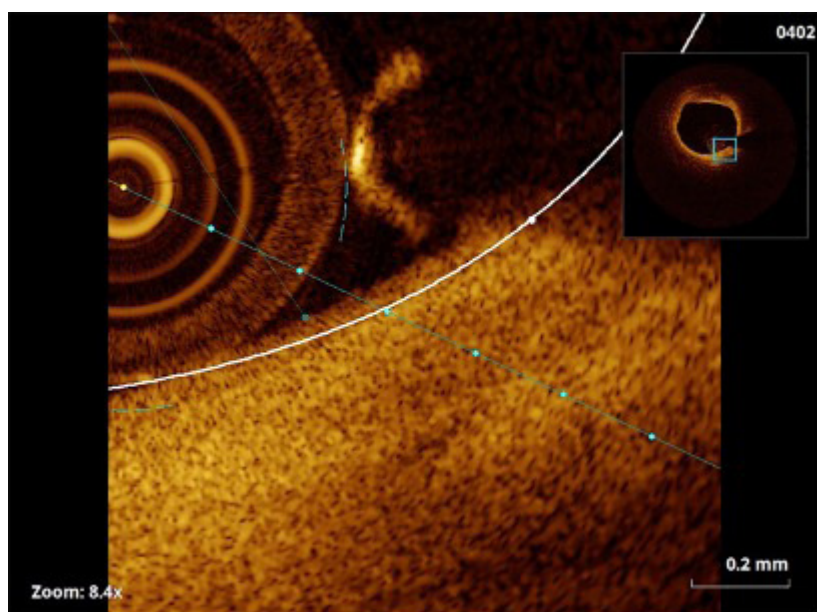
3. To return to normal imaging, click anywhere in the zoomed image.

Quick Zoom

The Quick Zoom feature provides two pre-set levels of magnification by simply clicking on the image with the left mouse button. Hover over the cross-sectional view so your cursor changes into a magnifying glass icon. Click once to zoom in to the first level; click a second time to zoom in to the second level; and then click again to return to normal magnification (1.0X).

The pre-set Quick Zoom Factors can be customized in the Settings menu Display option. By default, the First Click is set to 2.0X. The Second Click is set to 4.0X.

Adding Stent Annotations

The Stent tool is used to create, modify, and delete stent annotations in the L-Mode view (single trace or upper trace of a dual trace). Predefined stent lengths can be selected, and the distal and proximal edges of the stent can be identified. The stent length can be changed until the first stent edge is defined. Once a stent edge has been defined, the only way to change the stent length is to delete the stent annotation and start over.

Table 17. Stent Submenu Options

Set Stent Length or Stent Length xx mm	Provides a list of predefined Stent lengths. Once a Stent length is selected, this option displays the selected length.
Set Distal Edge	Sets the location of the Distal edge of the Stent at the Current Frame Indicator location.
Set Proximal Edge	Sets the location of the Proximal edge of the Stent at the Current Frame Indicator location.
Delete Stent	Removes the Stent information from the recording.

ADDING A STENT IDENTIFICATION

The stent may be identified in the image in the L-mode view (the upper trace if Dual Trace is selected) of a recording.

Note: Only one stent annotation can be added per recording.

1. Select and display the paused recording that you want to measure.

2. Click **Stent** to display the Stent submenu.

3. Select Set Stent Length and click on the appropriate length.

4. Click and drag the Current Frame Indicator to the first frame of the pullback containing a sufficient number of visible stent struts in the L-mode view (refer to your research guidelines for a definition of sufficient stent struts).
   Note: If the distal edge of the stent is not visible, define the proximal edge first (see Step 6) and then select the Distal Edge Not Visible option from the Stent submenu.

5. Click **Stent** to display the Stent submenu, then select Set Distal Edge.
   The Distal Edge indicator is displayed at the Current Frame Indicator in the L-mode view.
   Click and drag the Current Frame Indicator to the last frame of the pullback containing a sufficient number of visible stent struts in the L-mode view (refer to your research guidelines for a definition of sufficient stent struts).
   Note: If the proximal edge of the stent is not visible, define the distal edge first (see Step 4) and then select the Proximal Edge Not Visible option from the Stent submenu.

6. Click **Stent** to display the Stent submenu, then select Set Proximal Edge.
   The Proximal Edge indicator is displayed at the Current Frame Indicator in the L-mode view with a line connecting it to the Distal Edge indicator.

DELETING A STENT IDENTIFICATION FROM AN L-MODE VIEW

After at least one edge of the stent annotation has been defined the Delete Stent option of the Stent menu becomes enabled. Selecting this option at any time will remove the stent annotation from the recording.

Angle Measurement

 The Angle measurement can be used to measure the angle between two points on the contour of an area measurement.

Figure 49. Angle Measurement
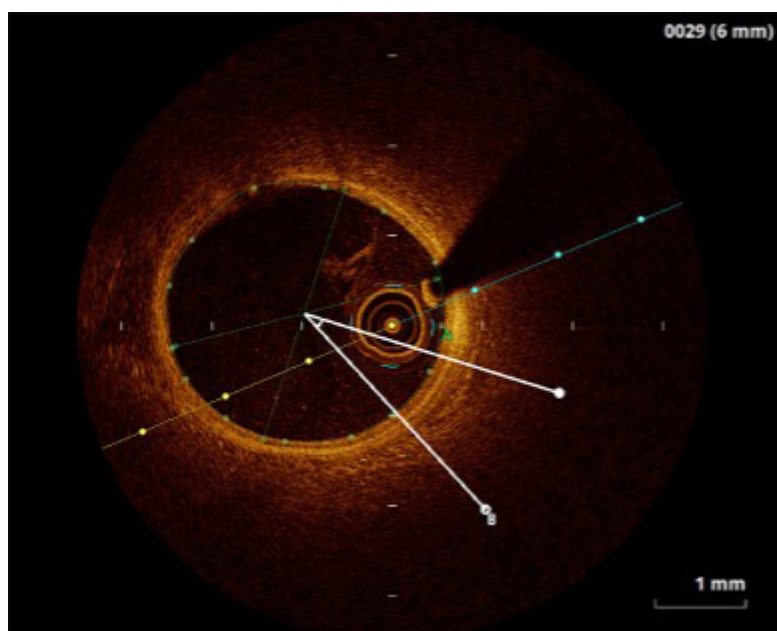
THE ANGLE CALCULATION

The angle value is determined by locating the vertex of the angle at the centroid of an area measurement then projecting two rays from the vertex and calculating the angle between them.

MAKE AN ANGLE CALCULATION

1. Make an area measurement.

2. Click **Angle** to start the measurement process. The cursor turns into a pen.
   Note: If there is more than one area measurement, the Select Measurement dialog box is displayed. In this case, select the letter that identifies the desired area and click **OK**.

3. Place the pen on the location to be used to identify the first ray and click to select that location.
   The initial position of the Angle measurement is drawn on the image with the primary ray terminated in a hollow circle and the secondary ray terminated in a filled circle. The result of the Angle calculation is displayed immediately below the previous calculations in the upper left corner of the Image Window.
   – Rotate the Angle measurement as desired without changing the angle value by dragging the control point (hollow circle) on the primary ray.
   – Change the value of the angle and / or the length of the rays by dragging the control point (filled circle) on the secondary ray.
   – An arc is drawn between the two lines near the centroid to indicate the inside of the angle.
   – The value of the angle is always calculated from the initial line to the second line in a counter-clockwise direction.

INITIAL ANGLE VALUE

This setting in the Measurements / Research menu of the Setup dialog box is used to change the angle that is initially displayed when creating an Angle measurement. Modifying this setting does not affect any existing Angle measurements. The default setting is 30 degrees.

Pie Tool

The Pie Tool can be used to determine if there is sufficient clearing or sufficient lumen detection within a minimum contiguous area of the image. For instance, this tool could be used to answer the question: Is the lumen visible and clear for a contiguous 270°?

This measurement is similar to the Angle measurement (see Angle Measurement [page 57]), except that the angle value is fixed. The fixed angle value used for this measurement is determined by the Fixed Pie Angle setting in the Measurements / Research menu of the Setup dialog box, which has a default value of 270°.

Figure 50. Pie Tool
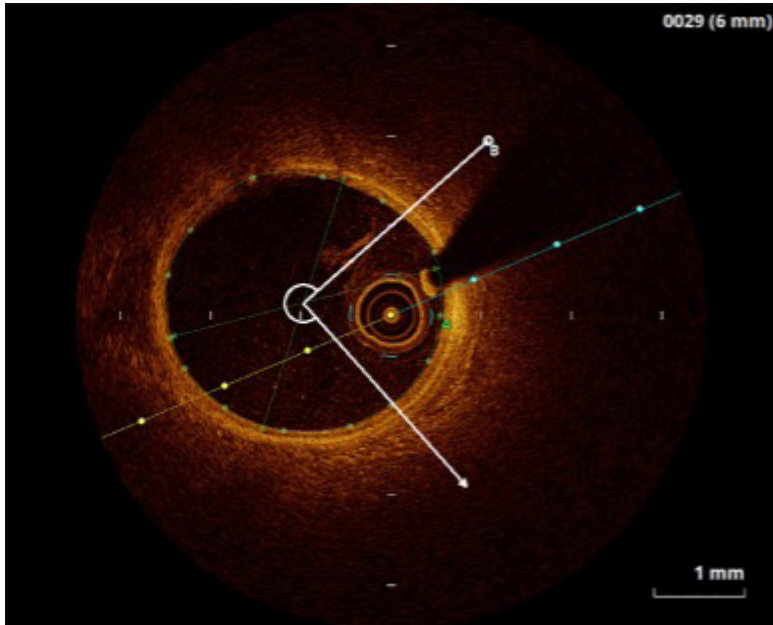
MAKE A PIE TOOL CALCULATION

1. Make an area measurement.

2. Click **Pie Tool** to start the measurement process. The cursor turns into a pen.
   Note: If there is more than one area measurement, the Select Measurement dialog box is displayed. Select the letter that identifies the desired area and click **OK**.

3. Place the pen on the location to be used to identify the first ray and click to select that location.

4. The initial position of the Angle measurement is drawn on the image with the primary ray terminated in a hollow circle and the secondary ray terminated in an arrow point. The result of the Angle calculation is displayed immediately below the previous calculations in the upper left corner of the Image window.
   – Rotate the Pie Tool as desired by dragging the control point (hollow circle) on the primary ray.
   – Change the length of the rays by dragging the control point (arrowhead) on the secondary ray.
   – An arc is drawn between the two lines near the centroid to indicate the inside of the angle.

CHANGING THE FIXED PIE ANGLE

This setting in the Measurements / Research menu of the Setup dialog box is used to change the angle used in a Pie Tool measurement. The angle used in a Pie Tool measurement is set on the Measurements / Research menu and cannot be changed when the tool is being used. Modifying this setting does not affect any existing Pie Tool measurements. The default setting is 270 degrees.

Thickness Ruler Measurement

This Thickness Ruler measurement can be used to measure the thickness from a specific point to the edge of an area contour on the image in the cross-section view. It may be more useful than the Neointimal Thickness measurement when measuring thickness in situations where the thickness of the growth is more distributed and regionalized. One such situation could be the need to measure the thickness of growth over drug-eluting stents.

The Thickness Ruler example (the figure below) shows a zoomed-in image with a Thickness Ruler measurement (B) being used to measure the thickness from a stent strut to a lumen contour (A).

Figure 51. Thickness Measurement
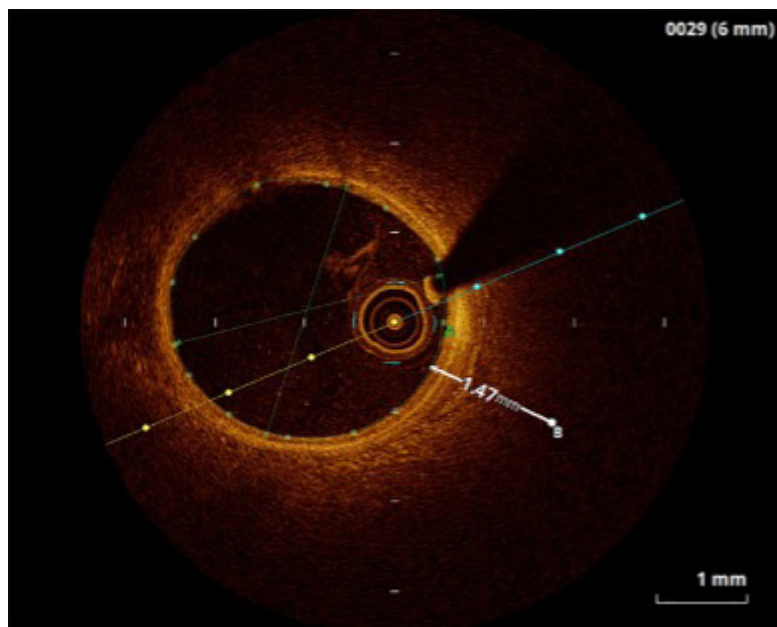
THE THICKNESS RULER CALCULATION

To make this calculation, you must first draw at least one area contour, typically the lumen. Once you have specified the point to be measured (P0) the end point for the length measurement (P1) must be determined. This end point is determined as follows:

1. The centroid of the area measurement is determined.

2. A line segment from the initial point (P0) to the area centroid is created.

3. The end point (P1) is determined as the point at which the line segment intersects with the area contour.

MAKE A THICKNESS RULER CALCULATION

1. Make at least one area measurement in the cross-section view by either of the area methods.

2. Click Thickness Ruler to start the measurement process.
   The cursor will turn into a pen to allow selection of the point to be measured to.
   Note: If there is more than one area measurement, the Select Measurement dialog box is displayed. In this case, select the letter that identifies the desired area and click OK.

3. Place the tip of the pen cursor on the location to be measured and click the mouse button.
   A line is drawn from the specified point to the point on the specified area contour between the point and the center of the area, and the result of the Thickness Ruler calculation is displayed immediately below the previous calculations in the upper left corner of the Image window.

Neointimal Thickness Measurement

The Neointimal Thickness measurement can be used to determine the minimum, maximum, and mean thickness between two area measurement contours.

Figure 52. Neointimal Thickness Measurement

THE NEOINTIMAL THICKNESS CALCULATION

To make this calculation you must first draw at least two area contours on the image in the cross-section view, typically the inner and outer surfaces of the neointima. The thickness chords are each defined by two points, one on each area contour, which are determined as follows:

1. The area centroid for the inner area measurement is determined. If this centroid is found to be outside either the inner area contour or the outer area contour, then the thickness chords are indeterminate, and no further calculation will be performed.

2. The number of chords used is determined by the Thickness Chord Count.

3. The initial point (P0) for each chord is on the outer area contour. It is determined by calculating the circumference increment (total outer area circumference divided by the number of chords) and getting the point on the outer area contour at each circumference increment starting at 12 o'clock.

4. The end point (P1) for each chord is on the inner area contour. It is determined by projecting a line segment from the initial point (P0) to the inner area centroid and finding the point at which it intersects with the inner area contour. If the line segment does not intersect, then the inner area contour is assumed to be outside the outer area contour and the line segment is projected in the opposite direction. If the new line segment intersects with the inner area contour, the resulting thickness chord is flagged as inverted.

MAKE A NEOINTIMAL THICKNESS CALCULATION

1. Make two area measurements: an inner area and an outer area.

2. Click **Neointimal Thickness** to display the Select Measurement dialog box.

3. In the Outer Measurement list, click the letter that identifies the larger area.

4. In the Inner Measurement list, click the letter that identifies the smaller area.

5. Click **OK**.
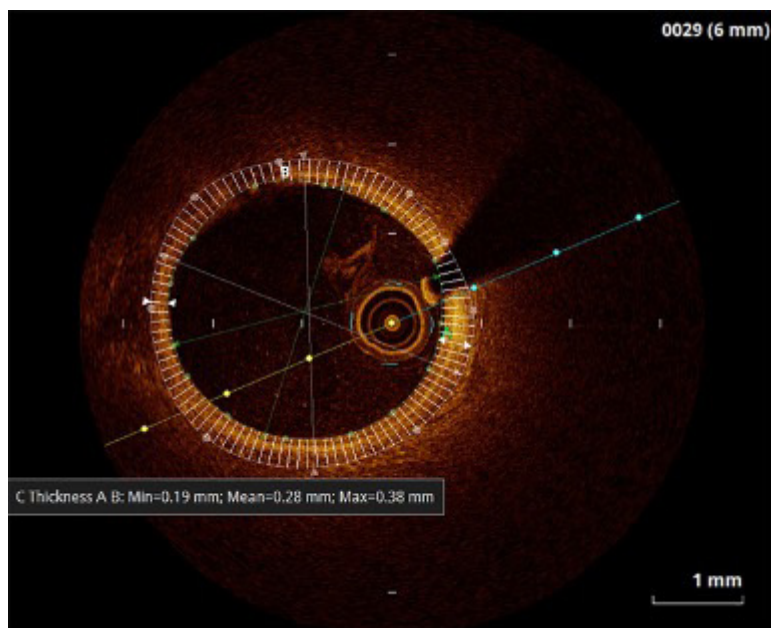   The results of the Neointimal Thickness calculation are displayed immediately below the previous calculations in the upper-left corner of the Image window. If Show Thickness Chords is selected on the Measurements / Research menu of the Setup dialog box the chords, including the minimum and maximum thickness chords, will be shown between the selected areas.
   Note: If the second measurement is larger than the first measurement you select, the thickness values will not be displayed. Instead, the Image window will display an error message in the upper left corner.

Thickness Chords

Enabling the Show Thickness Chords option (disabled by default) on the Measurements / Research menu of the Setup dialog box causes all chords used in a Neointimal Thickness measurement to be displayed when the measurement is drawn on the image. The Minimum and Maximum chords will be identified by arrowheads that will not exist on the other chords. When the thickness chords are displayed, the following additional functions are available.

- Chord Tool-tip - Hovering the cursor over a chord endpoint (on the inner or outer area contour) will display a tool-tip containing the chord number and length of the chord in millimeters (mm).
- Exported Chord Information - When measurement information is exported to a CSV file, information about each chord will also be included. This information will include the chord number and length of the chord.

In all cases, a negative chord length value indicates a location in the thickness measurement where the outer area contour crosses over and goes inside the inner area contour.

Thickness Chord Count

This setting in the Measurements / Research menu of the Setup dialog box is used to change the number of chords used when determining the minimum, maximum, and mean values for a Neointimal Thickness measurement. Modifying this setting does not affect any existing thickness measurements; only newly created measurements will use the new setting. The minimum setting is 4 chords, the maximum is 720 chords. The default is 100 chords.

Copy

The Copy Measurement button can be used to copy an area or length measurement from one frame to another in the cross-section view. The measurement can then be pasted using the Paste Measurement button in the Measurement Tools menu. See Copying and Pasting a Measurement for more information on this button (page 61).

Paste Measurement

The Paste Measurement button can be used to paste an area or length measurement from one frame to another in the cross-section view. A measurement can be copied using the Copy Measurement button in the Measurement Tools menu. A pasted measurement is a newly created measurement on the current frame, and it is assigned the next available letter label by the system. This button is only available in paused Playback mode, and only if a measurement from the same still image or recording has been copied.

COPYING AND PASTING A MEASUREMENT

1. Make at least one area or length measurement in the cross-section view. The measurement appears in the Measurements panel.

2. Select the measurement to be copied.

3. Click **Copy**.
   If you are in a recording, move to the frame where you want to paste the measurement.

4. Click **Paste** to paste the measurement.
   The pasted measurement appears in the frame in the same position relative to the center as it had in its original frame.

Editing Measurements and Annotations

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

- Area and length measurements can be adjusted by moving or deleting control points.
- Text annotations can be moved or deleted.
  Note: Measurements may be locked or unlocked by clicking on the padlock icon. (Lock items to help prevent unintentionally modifying them.)
  Note: When a measurement is changed, calculations that depend on that measurement are updated automatically.

MOVING INDIVIDUAL POINTS

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

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

Note: When you edit an automatically generated Lumen Profile contour, an Accept / Cancel toolbar displays. Click **Cancel** to cancel editing or click **Accept** to accept the changes. Next, an arrow icon appears in the corner of the measurement listed in the Measurement panel. Click the arrow to reset the contour on that frame back to the automatically generated Lumen Profile contour.

ADDING POINTS TO A MULTIPLE POINT AREA

To add additional points to a multiple point area, click on the curve between two points. A new point will be added where you click.
Note: When you position the mouse over a location where a point can be added, the cursor changes from an arrow to a hand.

DELETING POINTS FROM A MULTIPLE POINT AREA

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

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

DELETING INDIVIDUAL MEASUREMENTS OR TEXT CALLOUTS

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

To delete a measurement:
- Click on the "x" next to it in the Measurement panel. The measurement is deleted. To delete a distance measurement in the L-mode:

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

  2. Press the <Del> key on the keyboard. The distance measurement is deleted.

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

  2. Press the <Del> key on the keyboard. The text callout is deleted.

DELETING ALL MEASUREMENTS AND TEXT CALLOUTS

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

REVIEWING AN FFR OR RFR RECORDING

The Review window displays the recording with a primary cursor line (colored) indicating the index value. An additional secondary cursor in white can be added. The primary cursor is automatically set to the recording cycle minima upon entering Review mode.

Making adjustments:
- Review the recording and place the index cursor by moving the cursor. If necessary, reposition the cursor at a new position to calculate a new index value. The recording will be updated with the adjusted index value.
- Reviewing other recordings in the study:
- All recordings in a study are listed on the Study Summary menu with procedure time, the index of primary cursor, and a shortened version of the added annotations. The primary cursor is displayed on top.
- Click the Study Summary menu to expand the list of all the recordings in the study. Select the recording of interest for review.

Review Window

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

> ⚠️ **WARNING: The system may place the point of FFR / RFR at an incorrect location due to abnormal heartbeats or artifacts in the AO (Pa) caused by flushing of the guiding catheter or value opening / closing. The physician should always confirm the point selected by the system is a valid point for the calculation of the index value.**

> ⚠️ **CAUTION: If you have zoomed in a section of the recording, portions of the waveform are not displayed (the recording extends off screen). The physician should always review the entire un-zoomed recording before selecting the point for the calculation of the index value.**

Figure 53. Review Window

1. Primary cursor
2. Optional secondary cursor
3. Recording type
4. Main function button
5. End Review button
6. Zoom in / Zoom out buttons
7. Recording display options

Note: Functions not described in the table below are found in the section, Live Window.

Table 18. Review Window

Primary cursor Yellow for FFR and blue for RFR	Indicates the position where the pressure values and index value are taken from. Hold cursor to select and move. Click the label to change type or remove.
Secondary cursor White	Location of a mark placed during recording or review.
Recording type	Display the type of recording
End Review button	Return to Patient Summary window
Main function button	Return to Live window
Zoom in / Zoom out buttons	Zooms in or out in the current recording
Recording display options	Drop-down menu to select FFR recording, FFR and Pd / Pa, Pd / Pa recording or RFR pullback

Note: When there is a decrease in the RFR value during a pullback, the raw value will not be displayed. A different color in the graphic will indicate the graph will indicate the previous highest recorded value. See figure below.

Figure 54. RFR Review Window

1. Change in color

Reviewing an FFR or RFR Recording

The Review window displays the recording with a primary cursor line (colored) indicating the index value. An additional secondary cursor in white can be added. The primary cursor is automatically set to the recording cycle minima upon entering Review mode.

Making adjustments:
- Review the recording and place the index cursor by moving the cursor. If necessary, reposition the cursor at a new position to calculate a new index value. The recording will be updated with the adjusted index value.

Reviewing other recordings in the study:
- All recordings in a study are listed on the Study Summary menu with procedure time, the index of primary cursor, and a shortened version of the added annotations. The primary cursor is displayed on top.
- Click the Study Summary menu to expand the list of all the recordings in the study. Select the recording of interest for review.

MAINTENANCE

Contacting Abbott Technical Service

Service can be contacted at:

E-mail: avcapitaltechsupportapj@abbott.com

Phone:

China: 010 84447110

Malaysia and Singapore: (+)6048101116

Japan: 0800-123-4171

Thailand: (+)6627966506

Australia: (+)61390551604

Korea: DG-Korea-GCS@abbott.com

New Zealand: (+)61390551605

Hong Kong and Taiwan: DG-HKTW-GCS@abbott.com

India: (+)914044600104

Web: https://www.cardiovascular.abbott/int/en/customer-service/hcp/technical-services.html

Transferring Log Files:

Log files may be transferred to an external USB device so that you can archive them or E-mail them to Abbott Technical Service.

Figure 55. Transfer Event Log Files Menu
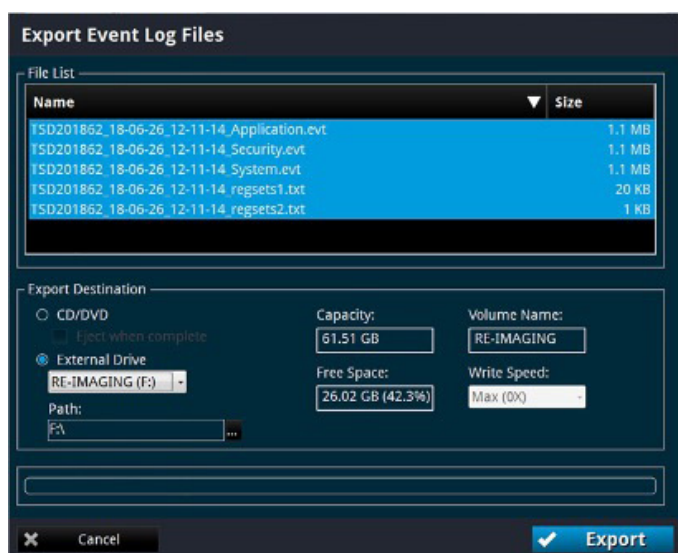
Note: When there are multiple repeated events of the same type the event logs are condensed into two messages. The first message logs the initial event, and the second message logs the event along with a repeat count.

1. Click **Menu** and select the Setup option. The Setup dialog box displays.

2. Click **Service**. The Service menu displays.

3. In the Service Log area, click **Export**.
   The Transfer Event Log Files menu opens, which lists all the files to be exported.

4. Select a transfer destination:
   – Click External Drive to export to an external USB device.
     If necessary, click the External Drive selection box to select the correct drive location from the drop-down menu. Click the Ellipsis (...) button to the right of the Path selection box to browse for a specific folder on the device.
     Note: If an output device is not available, that option cannot be selected.
     Note: Check that the Free space in the Drive Capacity section is large enough to save the files that are being exported.

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

Identifying the Software Version

The Startup window (see figure below) shows the version and copyright information for the system. If the system is running, type **Ctrl + S** to open the Startup window. The software version information might be required when contacting Abbott Technical Service.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of AptiVue™ E Series Software in areas where CE marking is not the regulation in force.

Figure 56. System Startup window
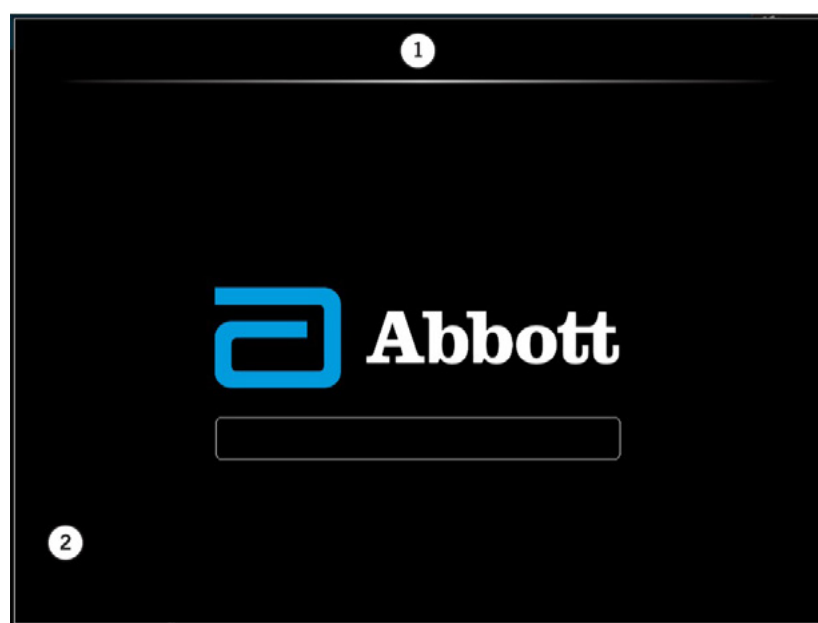
1. Platform name
2. Software version

USER TROUBLESHOOTING

The table below provides basic guidelines for troubleshooting the AptiVue™ Offline Review Software. If your problem is not resolved after attempting the suggested remedies, contact your service representative or E-mail avcapitaltechsupportapj@abbott.com.

Table 19. User Troubleshooting Tips

Symptom	Possible Causes	Remedy
During data export, the system does not list the USB drive plugged into the USB port.	The connected USB drive is not compatible with the laptop, or the USB drive requires formatting.	Connect only a USB drive supported by Windows. Refer to the instructions for use that came with your USB drive to determine if formatting is required.
OCT image is too light or too dark.	Image contrast levels set incorrectly.	Check the Presentation Settings in the Settings section of the OCT Settings menu. (Default settings are: Black level = 5%, White level = 90%.)
Pullback frames do not match those displayed in Ultreon™ Software.	Ultreon™ Software displays the pullback oriented from proximal to distal, while AptiVue™ displays it oriented from distal to proximal.	The AptiVue™ frame numbers will be the inverse of the Ultreon™ Software frame numbers. The first frame in the pullback in AptiVue™ is the last frame in the pullback in Ultreon™ Software.
The stent apposition and / or stent expansion results do not match the results from Ultreon™ Software.	Ultreon™ Software uses the stent apposition and stent expansion settings from the physician preferences, while ApitVue uses system-wide settings.	To see the same results in AptiVue™ as were seen in Ultreon™ Software, set the system-wide settings for stent apposition and stent expansion to match the Physician Preferences used in Ultreon™ Software.

Note: AptiVue™ Offline Review Software does not display augmented data and values such as Calcium (thickness, angle, location) and External Elastic Lamina (EEL; diameter, location) for an imported Ultreon™ Software case.

Information contained herein for DISTRIBUTION outside of the U.S. ONLY. Check the regulatory status of AptiVue™ E Series Software in areas where CE marking is not the regulation in force.

USER INTERFACE REFERENCE

Setup Dialog Box and Submenus

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

Note: When reviewing an OCT recording, the Settings button opens a context-sensitive OCT Settings menu. When reviewing an FFR recording, the Settings button opens the FFR Settings menu.

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

Table 20. Setup Dialog Box Common Options

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

Setup - Administration Menu

Table 21. Setup - Administration Menu Settings

Institution Name	Click here and enter or clear the institution name.
Date and Time	Opens the system Date and Time Properties menu.
Default Settings	Resets all user-entered configuration values except the date and time to the original factory default values.
⚠️	**CAUTION: Restoring factory default settings resets ALL user-entered configuration values except the date and time. This button should be used only by qualified service personnel or under their direction.**
System Information	Displays current date, system name, institution name, and software version
End User License Agreement	Displays EULA. Resets EULA. The EULA must be accepted upon first operation after reset in order to access the system.
Data Volume Encryption	**Status:** – Not Encrypted – Fully Encrypted – Encrypting (XX%) **Note:** XX is the percent complete. **Turn On:** Click to turn encryption on. **Note:** Only available when status is "Not Encrypted". **Save Key:** Click to save a copy of the encryption recovery key to removable media. **Revoke Key:** Click to create a new encryption recovery key and revoke the previous version.

Setup - Administration - Account Manager

Setup - Administration - Security Policy

User Settings

Table 22. User Classification

User Type	Functions
Site administrator	– Creates and modifies user profiles on the system – Able to review FFR / RFR and OCT procedures
Standard user	– Able to review FFR / RFR and OCT procedures
Domain user	– Standard user account using the facility's network authentication
Local user	– Standard user account using the OCT system's authentication

Note: Abbott Medical recommends that any Site Administrator or Standard User account be disabled as soon as possible after their termination.

Add New User

To add a new domain user:

1. Click on **New User...**
2. Enter their user name in the appropriate field.
3. Check the "Use domain account" checkbox.
4. Enter the fully qualified domain name.
5. Click Ok.

To add a new local user:

1. Click on **New User...**
2. Enter their user name in the appropriate field.
3. Ensure the "Use domain account" is not checked.
4. Enter and confirm a password for the user.
   Note: The user must change the password when they log in for the first time.

Modifying Users

The available tasks on the "Select a task..." list depend on the user status:

- If the selected user is enabled:
    - Local user: reset password
    - Domain user: no reset password option
    - Site administrator: Clear as site administrator instead of set as site administrator
- If the selected user is disabled:
    - Enable or Delete
- If the selected user is locked:
    - Unlock or Delete
- If the selected user is currently logged on, there is no task.

The Account Manager menu allows a site administrator to add users or modify users' roles.

Table 23a. Setup - Administration - Security Policy

Policy	Description	Range	Default
Password policy			
Enforce password history	The number of unique new passwords that have to be associated with a user account before an old password can be reused.	0-24	24
Maximum password age (day)	The period of time in days that a password can be used before the system requires the user to change it. If the value is 0, the password never expires.	0-999	42

Table 23b. Setup - Administration - Security Policy

Policy	Description	Range	Default
Password expire warning	The number of days in advance users are warned that their passwords are about to expire.	5-20	5
Minimum password length (characters)	The minimum number of characters that a password must contain.	3-14	7
Password must meet complexity requirements	If this policy is enabled, passwords must meet the minimum requirements: – English uppercase characters (A through Z) – English lowercase characters (a through z) – Base 10 digits (0 through 9) – Non-alphabetic characters (for example: !, $, #, %, etc.)	N / A	Enabled
Account lockout policy			
Account lockout threshold	The number of failed logon attempts that causes a user account to be locked out. If the value is set to 0, the account will be locked out until an administrator explicitly unlocks it.	0-10	3
Account lockout duration (minutes)	The number of minutes a locked-out account remains locked out before automatically becoming unlocked.	1-100	30
Inactivity Timeout			
Timeout period (minutes)	The timeout period of inactivity in minutes after which the system will automatically log off. While acquiring or reviewing patient data this timeout period is deactivated and no automatic log off will occur.	1-60	30

Setup - Account Profile

Allows the currently logged in user to change their password.

Refer to Setup - Administration - Account Manager for more information ( ).

Setup - Database Menu

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

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

Table 24. Setup - Database Menu Settings

Database display	The database display shows all recordings, grouped by patient name, and then by the date of the recordings.
Export	Exports the selected recordings.
Delete	Deletes the selected recordings.
Edit Patient...	Click on a patient's name to edit the patient's information. See Editing Patient Information (page 13) for more information.
Anonymize...	Click on a patient's name to remove the patient's identifying information from the record. See Exporting Files in Native (Raw) Format, Step 3, for an explanation of the anonymization function (page 16).

Setup - Database / Maintenance Menu

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

Table 26. Setup - Database / Maintenance Menu Settings

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

Setup - Database / Physician Menu

Table 27. Setup - Database / Physician Settings

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

Setup - DICOM Menu

The DICOM menus in the Setup dialog box are used to configure the network settings of the system and the Remote DICOM Store so that the system can initiate a network connection between the two systems.

⚠️ **CAUTION: The AptiVue™ Offline Review Software should only be connected to a secure intranet. Direct connection to the Internet may interfere with correct operation and / or result in inappropriate access to patient information, and voids system warranties.**

Abbott Medical makes no representation or warranty that use of the AptiVue™ Offline Review Software complies with applicable privacy, security and confidentiality laws, but encourages you to assess your own risk as you use, disclose, control, process or transfer patient health information with the system.

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

Table 28. Setup - DICOM Menu Settings

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

Setup - DICOM / Local Host Menu

Table 29. Setup - DICOM / Local Host Menu Settings

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

Setup - Display Menu

Table 30. Setup - Display Menu Settings

Graduated Cut Plane	Check this checkbox to add graduated marks to the cut plane indicators.
Crosshair On / Off	Check this checkbox to add crosshairs to the cross-section view.
Colormap	Click the arrow on the Colormap drop-down menu to display the list of colors. Click a color to select it.
L-Mode (Smoothing)	Click to select the amount of smoothing (averaging) for L-Mode views. The default setting is Low.
Quick Zoom Factors	Select the first click and second click zoom factor for the 2D, 3D, and Angio displays. Available choices for the first click setting are: 2.0x; 3.0x; 4.0x; 5.0x; 6.0x; and 7.0x. The second click setting can be set to a zoom factor greater than or equal to the first click setting, or None. If the first click and second click settings are set to the same value, then the first click will zoom in and the second click will zoom out. If the two settings are different, then the first and second clicks will zoom in to their zoom factor, and the third click will zoom out. The default values are 2.0x and 4.0x respectively.
Show Vessel / Procedure	Check this box to present the Vessel and Procedure value on the exported DICOM image. The default is unchecked.

Setup - Display - 3D Menu

This menu may be used to configure the 3D tissue mode as to whether it will be combined with the 3D Lumen. The default setting is checked.

Setup - Display - Angio Menu

This menu may be used to display the L-mode bookmarks on the Angio Co-Registration view. The default setting is unchecked.

Setup - Display - Stent Apposition

The Setup - Display - Stent Apposition page is shown in the figure below. This menu may be used to change the apposition thresholds (microns) settings that are used to color the rendered stent struts and indicate the strut apposition. There are two apposition threshold settings, a low apposition threshold (default: 200 microns) and a high apposition threshold (default: 300 microns). Strut apposition will fall into one of three ranges and be colored as follows:
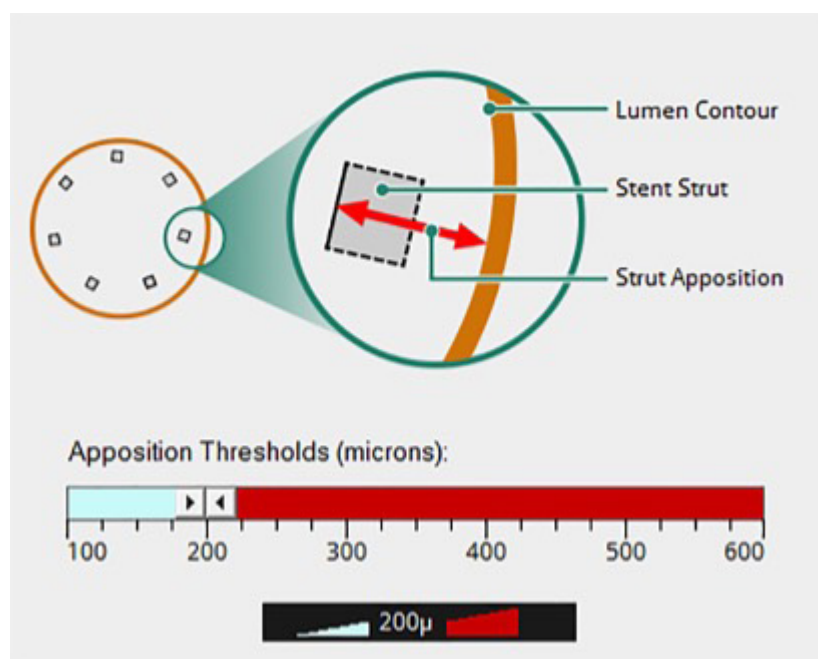
- Silver: Struts with an apposition value less than the low threshold.
- Yellow: Struts with an apposition value greater than or equal to the low threshold AND less than the high threshold.
- Red: Struts with an apposition value greater than or equal to the high threshold.

Figure 57. Setup – Stent Apposition
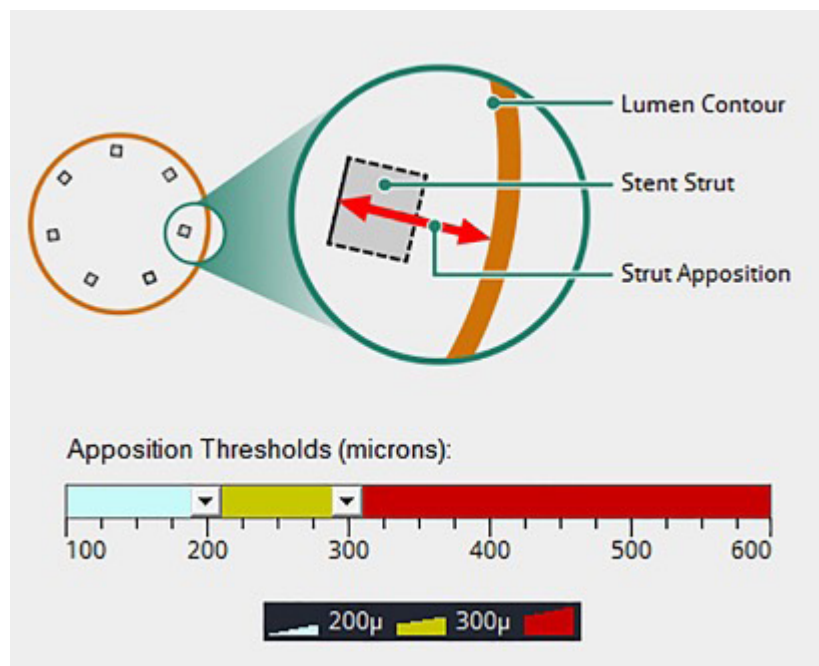
The apposition thresholds (microns) values may be changed using the range slider control. Drag the left slider to change the low threshold. Drag the right slider to change the high threshold. The two thresholds may be changed together, maintaining the same range, by dragging the yellow section between the sliders. To set a single threshold value, drag the two sliders together where the threshold is desired. See the figure below for an example of a single threshold setting.

Figure 58. Single Apposition Threshold Setting

Setup - Lumen Profile

Table 31. Setup - Lumen Profile Settings

Percent Stenosis Preferences	Customize which percent stenosis values are displayed with the distal and proximal frames and which percent stenosis values are displayed with the MLA frame. The default is None for the distal and proximal frames and Automatic for the MLA frame. The distal and proximal frames and MLA frame pulldown menus allow for the following selections: – None - No %AS or %DS is displayed – %AS - %AS is displayed always, regardless of the Lumen Profile units preference (Area or Diameter) – %DS - %DS is displayed always, regardless of the Lumen Profile units preference (Area or Diameter) – %AS and %DS - Both %AS and %DS values are displayed. – Automatic (based on Units) - %AS or %DS is displayed, according to the Lumen Profile units preference (Area or diameter).
Lumen Profile Units	Set the units represented in the Lumen Profile view. Available choices are Mean Diameter (mm) and Area (mm2). The default is Mean Diameter. Changing this setting requires confirmation.
Automatically Display Lumen Profile	When checked, the Lumen Profile view will automatically be displayed when a calibrated pullback is loaded for review. This option is checked by default

Note: AptiVue™ Offline Review Software does not display augmented data and values such as Calcium (thickness, angle, location) and External Elastic Lamina (EEL; diameter, location) for an imported Ultreon case.

Setup - Measurements Menu

Table 32. Setup - Measurements Menu Settings

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

Setup - Measurements / Labels Menu

Table 33. Setup - Measurements / Labels Menu Settings

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

Setup - Measurements / Research Menu

Table 34. Setup - Measurements / Research Menu Settings

Default Labels	Label text that will be used when making the indicated type of measurement (Research option tools). Click and type in any field to change that label.
Predefined Labels	A set of labels that can be used with the Edit Label function during review of OCT recordings. The default list is Lumen, Stent, and Strut. Click the Add button to create a custom predefined label.
Export Measurements to CSV File	Check this box to Export Measurements to a comma-separated values (CSV) file. Creates a Measurements CSV file for each image that is exported to a standard file format. See Exporting a Measurements CSV File for a complete description of this feature and the CSV file format ([page 23](#)).
Show Thickness Chords	Causes all chords used in a Neointimal Thickness measurement to be displayed when selected.
Thickness Chord Count	Specifies the number of chords used when determining the minimum, maximum, and mean values for a Neointimal Thickness measurement.
Initial Angle Value	Specifies the angle that is initially used when creating an Angle measurement.
Playback Page Size	Used with the Page forward / Page backward buttons. Specifies the length of a playback page in millimeters.
Fixed Pie Angle	Specifies the angle used when creating a Pie Tool measurement.

Setup - Print Menu

Table 35. Setup - Print Menu Settings

USB File Format	Click to choose the format used when printing a file to a USB drive. Color is the default export setting. Uncheck the Color box to export a black and white image.

Setup - Service Menu

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

Table 36. Setup - Service Menu Settings

Service Log (View)	Click the View button to open the Service Event Viewer. Click on a column header to sort the patients according to data in that column. Click the buttons at the top to show or hide categories of information: – Errors - lists all the operating errors logged by the system. – Warnings - lists all the Warning prompts displayed during operation. – Information - lists selected system status events that may help diagnose problems. – No Category - displays entries that do not have a Category listed. – Patient - lists all changes and import / export of patient data.
Service Log (Export)	Click the Export button to open the Transfer Event Log Files menu, to export the Event Log files to a specified drive. See Transferring Log Files for more information (page 65).
Operating Mode	Click the Change button to open the System Configuration Utility window to change the application type and / or operating mode. A password is required to open the configuration utility.

Setup - Localization Menu

The Localization menu in the Setup dialog box is provided to allow for custom date / time settings.

Table 37. Localization Menu Settings

Date and Time Formats	Short Date - allows for custom short date settings. Long Date - allows for custom long date settings. Time - allows for custom time format settings.

General

The AptiVue™ Offline Review Software is designed and intended for retrospective analysis of OCT images and physiology waveforms for education and research purposes only. It is not intended to be used for the treatment of individual patients, alone or in combination, for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, or alleviation of or compensation for an injury.
- Investigation, replacement, modification, or support of the anatomy or of a physiological process.
- Providing means and suggestions for mitigation of a disease.
- Providing information for determining compatibility, detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.
- Being an aid to diagnosis, screening, monitoring, determination of predisposition; prognosis, prediction, determination of physiological status.

Always use controls, make adjustments, and perform analysis as specified in this Product Guide..

Only USB hard drives or Flash drives supported by Windows may be used.

Reference Abbott website for patent markings: www.abbott.com/patents

For Guide and Symbol Glossary

International Customers   www.AbbottOCT.com/INT/ORSGuide

CAUTION: The AptiVue™ E Series Software is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *vascular.eifu.abbott* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events. This material is intended for use by healthcare professionals only.

The AptiVue™ Offline Review Software is designed for education and research purposes only. This material is intended for use by healthcare professionals only.

Check the regulatory status of the product in areas where CE marking is not the regulation in force.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Data on file at Abbott.