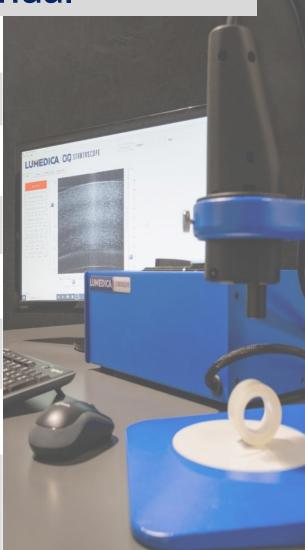
LUXEDICA O STRATASCOPE

User Manual

Optical Coherence Tomography System for Investigative-Use Only



INTRODUCTION2
What is OCT?4
Lumedica Company and Vision5
SAFETY
General Safety6Foreseeable Misuse6Service6Care and Maintenance7Residual Risk7System Disposal7
GETTING STARTED8
OQ StrataScope Contents
SOFTWARE11
Main Tab11Review Tab16Configuration Tab24Measurement Mode Calibration273D Rendering Tab28Advanced Tab27
HARDWARE
Mechanical Drawings
REGULATORY
TROUBLESHOOTING
Customer Support

INTRODUCTION

Thank you for purchasing an OQ StrataScope 3.0 from Lumedica Inc. OCT (Optical Coherence Tomography) is a technology ripe for innovation and improved accessibility. Affordability could be the key to discoveries in research and improvements in healthcare. Our goal is to build high-performance, low-cost, OCT systems for education, research, and industry.

What is the OQ StrataScope 3.0?

The Lumedica OQ StrataScope is an optical coherence tomography (OCT) imaging system for general laboratory, research, and industrial applications. One or more 1310 nm superluminescent diodes (SLD) provide the light source. When combined with an interferometer and high-resolution spectrometer, the system generates optical depth images of samples. Use the scanner either as a handheld device or mounted into a scanner stand. An embedded Windows PC provides the user interface for controlling the system and generating the OCT images. With standard optics, the system has a working distance of 22 mm.

How could we help?

If you experience errors or difficulty with your system, consult the Troubleshooting guide at the end of the user manual. Email <u>support@lumedica.com</u> for additional assistance. The Lumedica team is available to support your work. If you have questions or ideas for further functionality, let us know!

If you are new to OCT refer to the What is OCT? section for a quick overview and a summary of the advantages and limitations of the imaging technique. Doublecheck the Safety section to protect your system and operators. The directions found in Getting Started will guide you from a boxed system to its operational state. Further details concerning the physical system are found in the Hardware section. The **Software** section includes directions on how to operate your system. The **Measurement Mode Calibration** procedure on page 27 provides essential guidance for obtaining accurate measurements based on the optical properties of your sample.

Mail	Email	Call
Lumedica, Inc.	<u>support@lumedica.com</u>	1-919-590-5693
404 Hunt Street, Suite 510	or	
Durham, NC 27701-2275	info@lumedica.com	
USA		

CONTACT



This system is intended for laboratory use only and is NOT cleared or certified for medical applications.



Please read this instruction manual in its entirety before operating the OQ StrataScope. All statements regarding safety and any technical specifications only apply when the system is operated correctly.



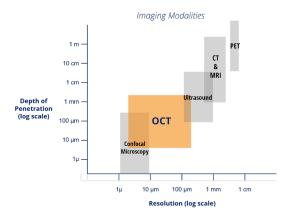
This system contains a superluminescent diode (SLD) which is considered a Class 1 laser device. There is laser emission from the lens at the end of the scanner.

L3 1.1

This manual is version 2.0 for the OQ StrataScope 3.0 hardware version 1.0 with software version 3.0.

What is OCT?

In practice, optical coherence tomography (OC T) shares many similarities to ultrasound. Just as ultrasound systems create an image by measuring how sound returns to a sensor from a sample, OCT measures how light returns to a detector.



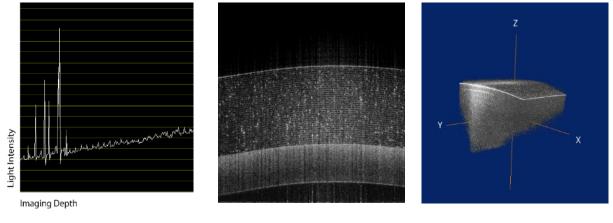
Both are non-invasive imaging techniques used to create both 2D and 3D images of, often biological, samples. However, while ultrasound may resolve centimeters of depth at millimeter resolution, OCT resolves a few millimeters at micron resolution.

OCT uses principles of interference to determine from what depth a photon was reflected inside a sample. OCT images are formed one column or a-scan at a time. A beam is focused to one point on the surface of a sample, and the depths of the photon reflections that occur beneath that point are aggregated into an A-scan. As the beam is scanned sideways, adjacent A- scans are compiled into a 2D image, called a B-scan. If multiple 2D images are acquired as neighboring planes, then this creates a 3D image or a volume scan.

Advantages and Limitations of OCT

Any transparent or translucent sample with critical features on the micron scale may benefit from non-destructive inspection with OCT. As a natural system made to take in light, the human eye has historically been an ideal candidate for OCT imaging. The OQ StrataScope is a research-use system. In approved human studies the longer wavelength passes through the water of the eye and results in a better view of the cornea.

OCT has also proved to be useful in nondestructive testing. The production of contact lenses, microneedles, pill coatings, smartphone components are a



A-scan



Volume Scan

few examples of manufacturing industries that have adopted OCT for quality testing. Imaging depth depends on the material of the sample and how well it returns light to the system. To get accurate measurements your system should be calibrated to the refractive index of your sample. See *Measurement Mode Calibration* for more details.

Lumedica Company and Vision

LUMEDICA Lumedica Inc. was founded in 2014 by Dr.

Adam Wax and Dr. William Brown, who went from university lab partners at Duke University to experienced biomedical imaging business partners. The vision of Lumedica is to design and commercialize low-cost, high-performance, imaging solutions for both clinical and scientific use.



In healthcare, the cost and size of most commercial OCT systems prevent critical diagnosis for rural and underserved populations. Lumedica Vision Inc. envisions a practical device with the resolution and imaging speed necessary to quickly screen patients. The OQ EyeScope 1.0 /X* is expected to launch early 2023. For more details visit lumedicavision.com.

The OQ LabScope, the first commercial OCT system under \$10K, keeps research on track for many scientists and institutions. Research system sales have grown each year as the Lumedica team expanded from 3 to 15 members. In 2019, the company launched the OQ StrataScope with increased imaging depth. The OQ StrataScope 3.0 launched in 2022 with a faster imaging rate to produce video-like scanning and improved volume scans.

*The OQ EyeScope 1.0 /X is not approved for clinical use in the United States by the FDA.

SAFETY

Please read this instruction manual in its entirety before operating the OQ StrataScope 3.0. All statements regarding safety and any technical specifications only apply when the system is operated correctly.

General Safety

- Check the supply voltage and cords before plugging in the system. The system power supply must be plugged into a grounded outlet (100 240 VAC, 50 60 Hz). If the provided cords do not match your outlet, contact Lumedica for a replacement.
- The main unit (or system chassis) requires a supply voltage of 12Vdc and has a maximum power rating of 102W. This power is supplied by a removable 12Vdc mains supply with a power cord.
- If the system has been recently shipped; do not operate until the unit temperature has equilibrated to room temperature.
- Operate the system on a flat, dry, and stable surface.
- There are no user-serviceable parts inside the scanner or the computer. Operators may make adjustments to the reference arm inside the OCT engine. See Polarization Control (page 30) for instruction.
- Do not obstruct the air vents on the bottom or top of the system.
- The safety of any system incorporating this system is the responsibility of the assembler of the combined system.
- If the system is used in a manner not specified by the manufacturer, then the protection provided by the system may be impaired.
- Noise Levels for this equipment were recorded at less than 70 db(A).

Foreseeable Misuse

- Do not use this product outdoors.
- Do not store or operate the system in a damp or closed environment.
- Do not use the equipment in a potentially explosive atmosphere.
- Do not use solvents on or near the equipment.
- Do not use equipment unless trained to do so.
- Do not open any of the sealed electrical enclosures.
- Ensure that the equipment is disconnected from the main power source prior to relocating, any maintenance, and/or cleaning.

Service

Only trained and approved Lumedica personnel should service the OQ StrataScope 3.0. Contact Lumedica for more information.

Care and Maintenance

Handle the system with care during packing, transportation, and installation. Banging or dropping the system can damage the unit or reduce system performance.

- Do not store or operate the system on surfaces that are susceptible to vibrations.
- Keep away from dust, dirt, and air-borne pollutants.
- The system is not designed for outdoor use. Protect the system from rain, snow, and humidity.
- Do not expose the system to mechanical or thermal extremes.
- The system has a degree of ingress protection of IP32.
- The acceptable environment use conditions for this equipment are:
 - Indoor use only.
 - Altitude up to 2000 m.
 - Temperature range of 5C to 40C.
 - Maximum Relative Humidity (RH) at 80% for temperatures up to 31C, decreasing linearly to 50% RH at 40C.
 - Mains supply voltage fluctuations up to +/- 10% of nominal voltage.
 - Transient over-voltages up to the level of overvoltage category II.
 - Temporary over-voltages occurring on the mains supply.
 - The applicable pollution degree of the intended environment is PD2.
- Clean your monitor with an oil-free, lint-free type cloth.
- To clean the system chassis, wipe down the chassis with an oil-free, lint-free cloth. You may need to use a canned air duster to blow the dust off of the main unit.
- To clear the scanner, wipe down the scanner with an oil-free, lint-free cloth. You may need to use a canned air duster to blow the dust off of the scanner and the optics. If optics becomes dirty or smudged, such as with fingerprints, please contact Lumedica customer service.

Residual Risk

Please note the following residual risks associated with this equipment.

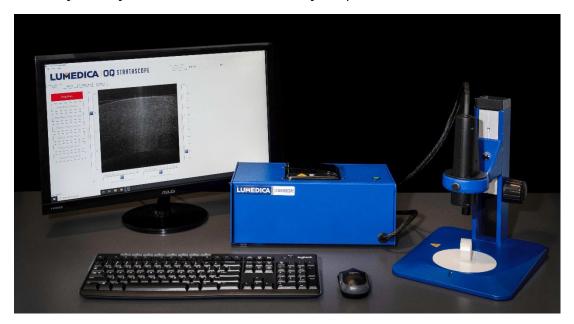
- Possibility of electrical shock if/when working inside electrical enclosures.
- Possibility of ergonomic injury when moving the equipment. The main unit (or system chassis) weighs 4.0 kg, the scanner weighs 0.5 kg, and the optional scanner stand weighs 3.0 kg.

System Disposal

The expected life expectancy for the OQ StrataScope 3.0 is 10,000 hours of use. After the system has reached this point or degraded in functionality, return to Lumedica for disposal.

GETTING STARTED

The following instructions includes the contents shipped with OQ StrataScope 3.0 and the workstation package. The workstation package and scanner stand are an added features that may or may not have been included in your purchase.



OQ StrataScope Contents

The standard OQ StrataScope comes with the following items.

- 1 user manual
- 1 OQ StrataScope base unit (Blue box) with attached handheld scanner
- 1 power supply with 12Vdc cord
- 1 country-specific cord for 12Vdc power supply (ex. US, EU, AU, IN, or UK)
- 1 roll of Scotch[™] tape
- 1 clear plastic ruler (See Measurement Mode Calibration on page 27)

If any items are missing contact support@lumedica.com.

Workstation Package Contents

The workstation package for the OQ StrataScope 3.0 includes the following.

- 1 monitor with a resolution of 1920 x 1080 px
- 1 HDMI cord
- 1 USB dongle for connecting the keyboard and mouse. The dongle is located inside the mouse battery compartment.
- 1 scanner stand. The scanner stand includes the following:
 - 1 base and base plate
 - 1 vertical stage with travel
 - o 1 set of Allen keys
 - o 1 scanner holder
- Adaptor for integrating the handheld scanner into the scanner stand.

Scanner Stand Set-up Instructions

- 1. Attached the baseplate with two screws.
- 2. Attach the vertical stage to the scanner holder with one screw. Note that holder should be oriented with the arm at the bottom, otherwise the scanner will be too high above the sample.
- 3. Place the baseplate in the base.
- 4. Place the OQ StrataScope scanner into the scanner adaptor. Secure the adaptor with the provided screws.
- 5. Insert scanner into scanner adapter and secure with the provided screws.
- 6. Insert scanner with adapter into holder on scanner stand.

If you have chosen to purchase the standard OQ StrataScope **without a workstation** package, then you will need to supply the following items.

- 1 monitor with a resolution of 1920 x 1080 px and an HDMI interface
 - Lumedica software is designed for this resolution and may not work at other resolutions.
- 1 HDMI cord
- 1 keyboard and mouse
 - Bluetooth or wireless connection recommended.

OQ StrataScope Set-up Instructions

- 1. Inspect the shipped package and contents for evidence that anything has shifted or been tampered with. Make note of anything unusual.
- 2. Carefully remove the OQ StrataScope 3.0 system from the box and place it on a table within a meter of an electrical outlet. Be careful not to twist or kink the scanner cable.
- 3. Plug the country specific cord into the 12Vdc power supply.
- 4. Plug the country-specific end of the power supply into the wall outlet.
- 5. Plug the 12 Vdc power cord into the indicated location on the back of the OQ StrataScope system chassis. Ensure that the input is oriented correctly. The flat side should be facing upward when inserted. Reference diagram below.





If your scanner does not have an inspection camera, then you will receive a scanner stand with a round pillar as shown above. If your scanner was modified to include an inspection camera, then the scanner stand will have a square pillar.

- 6. Connect the monitor to the HDMI port on the back of the system chassis with a HDMI cord.
- 7. Connect the USB dongle in the USB port on the back of the system chassis to operate the keyboard and mouse.
- 8. Ensure that the scanner is secure and will not fall off your work surface.
- 9. Press the circular power button to power up the OQ StrataScope.
- 10. Login to the Windows 10 OS with the following username and password.
 - a. Username: oqStrataScope
 - b. Password: oqStrataScope
- 11. Double click on the Lumedica L software icon to start the OQ StrataScope software.



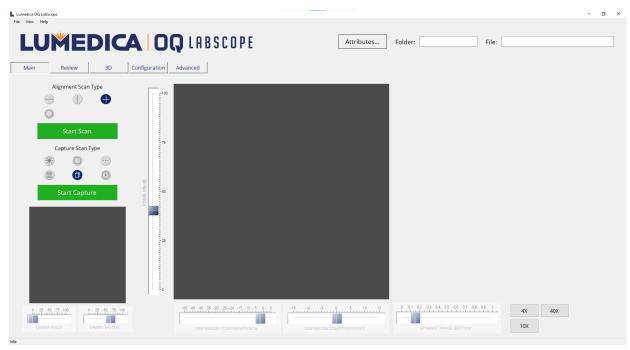
- 12. The OQ StrataScope software will begin on the Main tab.
- 13. To start the OCT scanner, click on the "Start Scan" button.
- 14. OCT image will begin to update.
- 15. Press "Update Background" to minimize the horizontal noise in the OCT image. This step may not be necessary if automatic background subtraction is enabled.
- 16. Lie the handheld scanner flat on your work surface and place the Scotch[™] tape about an inch away from the scanning end.
- 17. If you purchased a workstation package, then you can set the scanner on the stand like a microscope and place the Scotch[™] tape underneath the scanner.
- 18. Slowly move the tape towards the scanner until the tape is near the top of the OCT image.
- 19. Adjust the focus sliders to the left of the image to optimize. Reference the software section for further instructions.
- 20. The OCT image on your screen should look similar to the image below.



SOFTWARE

To open the Lumedica software select the boxed L linked on the desktop.

Main Tab



This is the main tab of the OQ LabScope/StrataScope 3.0. As indicated by the text in the bottom left corner, the scanner is in "idle" which means the scanner was successfully initialized and the system is ready to begin scanning.

Start Scan

If the scan mode is in "idle" (bottom left corner) then your system is ready to start scanning. To start acquiring OCT images use the green "Start Scan" Button. Use the same button to "Stop Scan."

Alignment vs. Capture Scan

Both scan types collect OCT data and start the scanner. Capture scans are typically longer and require a more complicated scan pattern. Therefore, it is best practice to first use an alignment scan to optimize focus and placement. Then, start a capture scan.

Save B-Scan Image

When the scanner is stopped hover over the image to save the last B-scan acquired. The files are saved to directory "Folder" with "File" as the root name. Navigate to the review tab to save raw bscans, a set of b-scans, or a capture scan.

Alignment Scans

Horizontal

Click this button to initiate a single volume (C-Scan) based on the values in the *configuration tab*.

Horizontal

Click this button to initiate a single volume (C-Scan) based on the values in the *configuration tab*.

Capture Radial Scan

Click this button to capture a single set of radial lines where the number of lines is set on the *Configuration tab*.

Capture Circle Scan

Click this button to capture a set of circle scans.

Capture Long Scan

Click this button to capture a set of long scans. These scans can have 512, 1024, or 2048 A-Scans per B-Scan set in the *configuration tab*.

Capture Timed Scan

Click this button to capture a timed scan. Time set in the *configuration tab*.

Capture Multi-Line Scan

Click this button to capture a multi-line scan.

How to change scan settings

For each scan type the number of b-scans, diameter of circle scans, and other details can be set on the *configuration tab*.

Acquired images are temporarily stored in the scan buffer. Save images to the disk by selecting the save B-scan button on the main tab or using one of the save options on the *review tab*.

Images in the buffer are not saved automatically. To save, define the folder and file name, then click on a "Save" button in either the *main* or *review* tab.

Navigation



Navigate between the different functions of the OQ LabScope/StrataScope software from the navigation panel under the Lumedica Logo.

File: To exit the software click "File" in the top left and then "Exit."

View: Click "View" to learn the File Attributes of the image most recently acquired. The File attributes include Scan Date, Scan Pattern, and B-Scans per Line. See Configuration tab to set the desired scan pattern and line-rate.

Help: To determine which version of software is installed to your OQ StrataScope click the help tab. This information is very helpful for diagnosing potential software concerns on your system. Email <u>support@lumedica.com</u> for support.



This panel indicates that software version 1.8.67.1 is installed on this OQ LabScope (identical software to the OQ StrataScope).

Data Storage

The software automatically creates folders and files in the "Data" folder.

The subdirectory where your images will be stored is

C:\Users\Public\Documents\Lumedica\OctEngine\Data

For example, the settings in the image above will create a file in the following directory.

C:\Users\Public\Documents\Lumedica\OctEngine\Data\R_tattoo\vol

Attributes	Folder:	R_tattoo	File: vol
This folder input h		The file incur	box will be the file

is where you will label the folder where data is saved. The folder will be created in a subdirectory inside the "Data" folder. You can add multiple images to the same folder. The file input box will be the file name for your image. The software will ensure each file name is unique. The attributes settings determine how the software will choose to append additional information to create a unique file name. ex. vol_1, vol_2, vol_3 etc.

Focal Value

Located to the left of the OCT image, this slider controls the liquid lens in the scanner. Moving the slider up and down sets the focus position of the OCT scanning beam. When the slider is at the top of the screen, the focus is closest to the scanner and when the slider is at the bottom of the screen the focus is farthest away from the scanner.

Dynamic Range Bottom

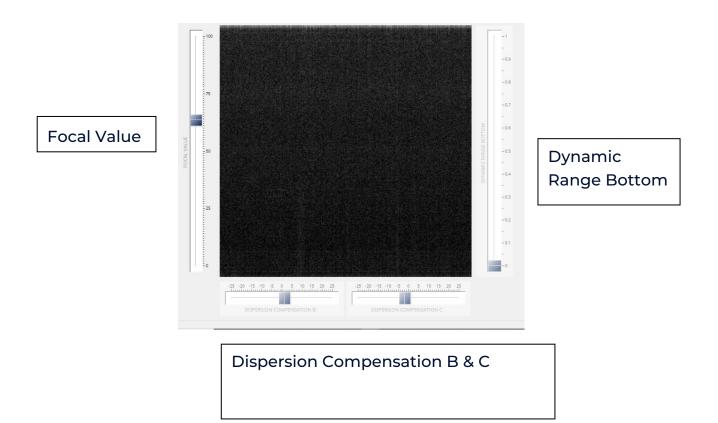
This slider on the right side of the image sets the bottom value of the intensity range of the left-hand image. Sliding this all the way to the bottom will typically make the image look whiter and noisier. Sliding this toward the top will typically make the image look blacker and less noisy but will start to suppress the image signal. As the slider approaches the top of the range, only the most intense areas of the image will still be visible.

Dispersion Compensation B

Sets the second order coefficient in the dispersion compensation. This may be adjusted while the system is running to optimize the image sharpness.

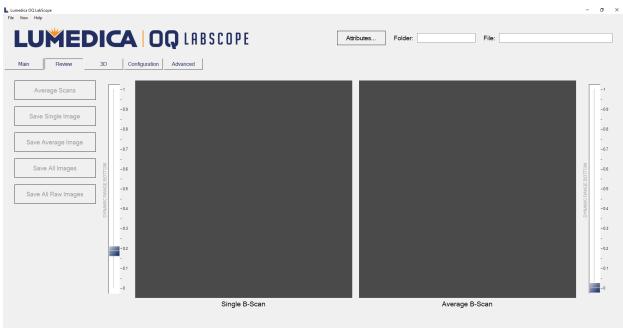
Dispersion Compensation C

Sets the third order coefficient in the dispersion compensation. This may be adjusted while the system is running. Typically, the value of this coefficient is close to zero.



Review Tab

This tab contains the image review controls. This functionality is only enabled when the OCT system is not scanning. The OQ StrataScope 3.0 software maintains buffer images acquired by the system. Review, save, and process these images from the review tab.



Average Scans

Use this button to average all the scans that are in the scan buffer. Averaged image is saved.

Save Single Image

Saves the selected single B-Scan image that is displayed in the left-hand panel to disk. This image is saved in both TIF and JPG formats.

Save Average Image

Saves the average B-Scan image that is displayed in the right-hand panel to disk. This image is saved in both TIF and JPG formats.

Save All Images

Saves all B-Scan images in the scan buffer to disk. These images are saved in JPG format.

Save All Raw Images

Saves a copy of all the raw B-Scan data in the queue from the spectrometer to a set of files. These images are saved in TIF format. The directory is "Folder" with "File" as the root file name with number of the image in the buffer appended. The current background subtraction data is also saved.

Single B-Scan Dynamic Range Bottom

Located to the left of the Single B-Scan OCT image, this slider controls the bottom value of the intensity range of this image. Sliding this all the way to the bottom will typically make the image look brighter and noisier. Sliding this toward the top will typically make the image look blacker and less noisy but will start to suppress the image signal. As the slider approaches the top of the range, only the most intense areas of the image will still be visible.

Average B-Scan Dynamic Range Bottom

Located to the right of the Average B-Scan OCT image, this slider controls the bottom value of the intensity range of this image. The effect is similar to the slider on the left, however, the averaged image is typically less noisy, so it may be possible to set the slider to a lower value while still maintaining a good image.

Single B-Scan

This slider at the bottom of the Single B-Scan OCT image selects which image from the image buffer is being displayed. The image buffer contains up to 30 images when capturing B-Scans and all of the B-Scans captured when acquiring a C-Scan.

Measurement Drawing Tools

Calipers

Calipers can be added to the B-Scan images in the *Review tab*. To enable this functionality, navigate to the *Configuration tab* and select the radio button next to "Calipers" under the "Measurement Drawing Mode.

To create a caliper, left click anywhere in the image and draw up or down to create a vertical caliper OR drag left or right to create a horizontal caliper. The length of the caliper will be displayed next to each caliper. The reported measurement is the length of the caliper in pixels times the scaling factor that is set in the *Configuration Tab*.

Right clicking anywhere in the B-Scan image will clear all calipers in the B-Scan.

The calipers will be included in saved JPG files. The calipers will NOT appear in saved TIF files.

Clicking the Start scanning button will override images in the buffer and delete all calipers.

NOTE

As users may wish to measure a variety of samples, with differing refractive indexes, calipers are not calibrated by factory. It is the responsibility of the user to calibrate the calipers for their unique sample. The system measures the optical pathlength, which is the physical pathlength times the index of refraction of the sample. For most substances the refractive index is a known value and readily available on the internet. See *Calibration Instructions*.

Layer Thickness Tool

Lumedica software includes a simple layer thickness tool to measure the thickness of one layer within a selected region of interest. To enable this feature, navigate to the *Configuration tab* and select the radio button next to "Layer Thickness" under the Measurement Drawing Mode.

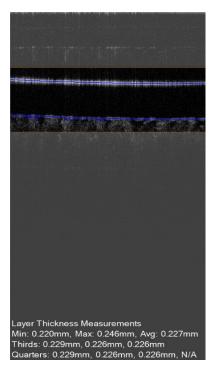
To use the layer thickness tool, select a region of measurement in the image by left clicking the top of the region hold and drag down to include the entire bottom of the region of interest, then release. The software will then locate the two tallest peaks in the region for each A-scan. This will be repeated across the entire B-Scan. The two peaks will be identified in blue.

The software will report the minimum, maximum and average thickness at the bottom of the image. Individual thickness values for each quarter and third of the image are also reported.

Right clicking anywhere will clear the layer thickness measurement.

The layer thickness peaks and reported values will be included in any saved JPG files, but not in TIF files.

Starting a new scan will override the images in the buffer and delete the thickness measurements.



Configuration Tab

Alignment Scan Settings

The configuration section controls the types of scans to best align the sample with the OCT system. The type selected will run continuously once the scan is started. Once stopped, the last few scans are stored in the scan buffer and can be viewed in the *Review* tab.

Main	Review	3D	c	onfiguration	Advan
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-	t Scan Type izontal Line				
	izontal Line ical Line				
O Circ	le				
Alignmen	t Scan Width				
-					_
6		0.5			- E
Alignmen	t Scan Horizontal	Offset			
					-
-1	-0.5			0.5	1
Alignmen	t Scan Vertical Of	fset			
-					-
4	-0.5	0		0.5	1
Imaging M	lode				
4X	10X				
40×					

Horizontal Line

The horizontal scan direction is aligned with the short side of the handheld scanner. When placed in the stand, the horizontal direction is left to right.

Vertical Line

The vertical scan direction is aligned with the long side of the scanner. When placed in the stand, vertical direction is front to back.

Cross

The scanner performs a horizontal scan followed by a vertical scan and then repeats. This pattern is particularly useful for aligning with samples where both the horizontal and vertical locations are critical.

Circle

The scanner repeats a circle scan. Diameter is determined in the Capture scan settings.

Scan Width

Sets the relative length of the B-Scan. The longest scan is "1" and it may be shortened down to "0", at which point the scanner is not moving. This will give a time series at one point, which is referred to as an M-mode scan. A scan length of 1 corresponds to 7 millimeters of scan range. All B-scans have the same number of A-scans, i.e. a shorter scan of a curved surface will make the image appear flatter.

Alignment Scan Horizontal Offset

Sets the horizontal position of the center of the MEMS scan. Slider range is -1 to 1 which corresponds to full range of MEMS mirror.

Alignment Scan Vertical Offset

Sets the vertical position of the center of the MEMS scan. Slider range is -1 to 1 which corresponds to full range of MEMS mirror.

Imaging Mode

If you purchased a microscope objective set, then you can indicate which lens you are using here.

Capture Scan Settings

This configurations section determines the number of A-scans, B-scans and width for each scan pattern.

ABSCOPE				ĺ	At	tribute	es		Folder:
xed								_	
Capture Scan Settin	gs								
Radial Scan									
Lines	12	~							
B-Scans per Line	9	~							
Width	-							_	
	6			0.5				1	ł
Volume Scan									
B-Scans	128	~							
Width	[
	6			0.5				,	i i
Circle Scan									
Circles	16	~							
Width									
	6			0.5					i
Long Scan									
B-Scans	16	\sim							
A-Scans per B-Scan	1024	~							
Width									
	6			0.5					
Multi-Line Scan				0.0					
Lines	5	~							
B-Scans per Line	2	~							
Width			 	 					
widui				0.5					
	0			0.5					1

Radial Scan

Lines

Sets the number of radial scans to acquire. Possible values: 4,6,8,10,12,14,16, 18, 20, 22, 24, 28, 30, 32

Width

Sets the width of the radial scan on a linear scale. The maximum value of "1" has a diameter of approximately 8 mm.

Volume Scans A-Scans per B-Scan Sets the number of A-scans in each B-Scan. Possible values: 16, 32, 64, 128, 256, 512

B-Scans per C-Scan (Volume Scan)

Sets the number of B-scans in each C-Scan

Width

Sets the size of the volume scan on a linear scale. The maximum value of "1" corresponds to approximately 5 mm. The length and the width of the volume scan are the same.

Circle Scan

This scan type captures circle scans centered at the location of the alignment scan

Circles

Sets the number of circle scans to acquire. Possible values: 4, 6, 8, 10, 12, 14, 16.

Width

Sets the diameter of the circle scans on a linear scale. The maximum value of "1" has a diameter of approximately 8 mm.

Review Settings

This configuration section determines the measurement options available in the *Review tab.*

r: File: Fi
Review Settings Measurements
Measurements
Measurements
Measurements
Measurements
Depth Per Pixel 100
popul of the roo put
Width Per Pixel 1.00 🜩 µm
Measurement Drawing Mode
O Calipers
Layer Thickness

Measurements Depth Per Pixel

Sets the scaling value used to report vertical lengths. This value is not calibrated by factor as it is dependent on the index of refraction of the sample. The system measures optical depth, the physical depth times the index of refraction of the sample.

Width Per Pixel

Sets the scaling value used to report the horizontal widths. This value is not calibrated by the factory and depend on the type and size of scan being used.

Measurement Drawing Mode Caliper

If selected (radio button filled) then the measurement calipers are available in the review tab. Horizontal and vertical calipers are available.

Layer Thickness

If selected, then the layer thickness tool is available in the review tab. The layer thickness tool uses a peak detection algorithm to measure the thickness of one layer in the user selected region of interest. Algorithm reports the maximum, minimum, and average thickness of the entire selected area and values at each quarter of the image and each third of the image.

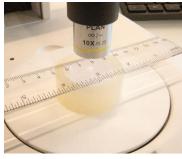
Measurement Mode Calibration

Your Lumedica OQ StrataScope or OQ StrataScope provides depth and width measurements of your sample in the review tab. However, these tools are not calibrated upon arrival because *depth measurements are dependent on the optical properties of your sample.* Use the provided plastic ruler and procedure below to calibrate the measurement tools.

OCT measures optical pathlength. The optical pathlength is equal to the physical pathlength divided by the index of refraction. For this procedure, you can also use anything with a known thickness and refractive index, like a glass slide. You will need the refractive index of your sample. For many materials the refractive index is a known value available on the internet.

Depth per Pixel Calibration

- 1. Place the ruler on top of the provided roll of tape under the scanner (Figure 1).
- 2. Start the scan and position the scanner so that the top and bottom edges of the ruler are visible on the OCT image.
- 3. Adjust the "Dynamic Range Bottom" slider up to increase the contrast of the image. The top and bottom edge should be visible as two bright lines (Figure 2).
- 4. Stop Scan.
- 5. From the configuration tab, set the Depth per Pixel to 1. Select "Layer Thickness" under Measurement Drawing Mode.
- 6. From the review tab, click above the top edge of the ruler on the image, drag below the bottom edge, and release (Figure 3). This will provide the layer measurements in mm. Use the average thickness.
 - a. Depth per pixel is in μ m so multiple the average thickness by 1000. This is the number of pixels shown for the thickness of the ruler.
- 7. Divide the actual physical thickness of the ruler, 1.59+/-0.01 mm, by the number of pixels measured in step 6. Multiply by the index of refraction of the ruler, 1.566. This is the depth per pixel in air.





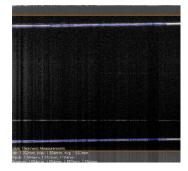


Figure 3*

Figure 3

Figure 3

- 8. Divide the depth per pixel in air by the index of refraction of your sample. This is the depth per pixel in your sample.
- From the configuration tab, adjust the depth per pixel to the value calculated in step 8. The layer analysis and calipers tools are now calibrated to display the actual physical depth of your sample according to its index of refraction.

Width Per Pixel Calibration

- 1. Move the ruler on the role of tape so that the metric edge is visible under the scanner. The ruler must be flat (Figure 4).
- 2. Start the scan. Adjust so that the edge of the ruler is visible. The image should appear as a dashed line with long bright dashes and short dark dashes (Figure 5).
- 3. For the most accurate measurements, the displayed line must be horizontal. If there is an angle, then the ruler is not perpendicular to the scanner or parallel to the role of tape. Adjust the role of tape until the displayed line is horizontal on the screen.
- 4. Stop Scan.
- 5. From the configuration tab, set the Width per Pixel to 1. Select "Calipers" under the Measurement Drawing Mode.
- 6. From the review tab, click and drag horizontally from the left edge of one dark dash to the left edge of the adjacent dark dash (Figure 6)
- 7. The physical distance between dashes is 1 mm or 1000 μ m. The width per pixel calibration is not dependent on the index of refraction of your sample.
 - a. From the configuration tab adjust the width per pixel until the measurement from the right of one dark dash to the left of the next dark dash equals 1000 μ m.



Figure 6*

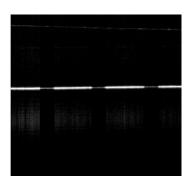
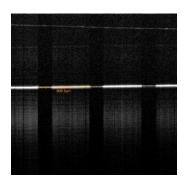


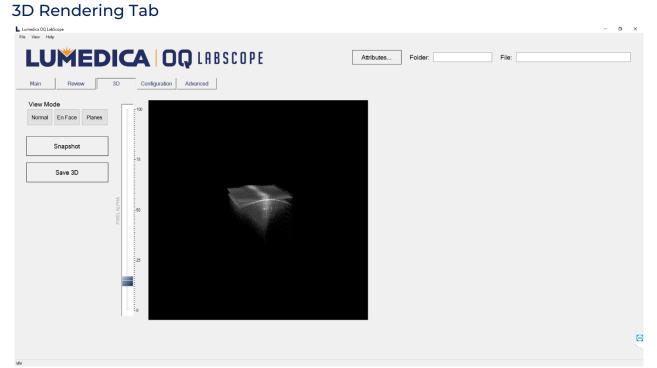
Figure 6





* The microscope objective shown is an optional feature that is not included in the standard model. Microscope objectives increase the lateral resolution of a system.

OQ STRATASCOPE 3.0



After a volume scan has been captured, the rendering will be available to save from the 3D tab. Rotate the rendering by clicking and dragging across the image. Use the mouse scroll wheel to zoom in and out of the image.

Pixel Alpha

Adjust this slider to filter out voxels based on brightness. With the slider set to 0, all voxels will be visible. With the slider set to 100, no voxels will be visible.

Normal

Snapshot – Saves a png image of the current volume scan rendered at its current orientation.

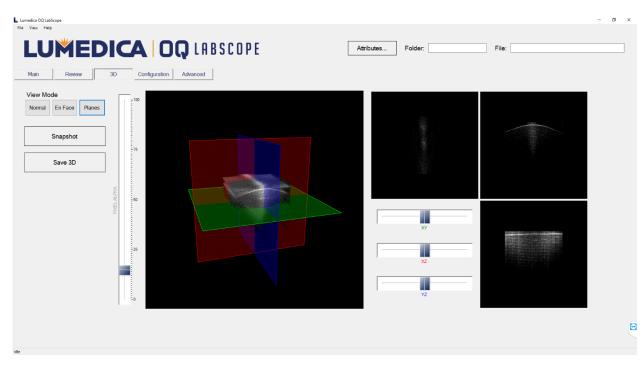
Save 3D – Saves a DICOM file containing the B-scans used to construct the rendered volume scan in the data folder or indicated folder and file at the top right of the screen.

En Face

Rotates the volume rendering 90° about the X axis as if the camera is placed on the Y axis, directly viewing one face of the volume.

Planes

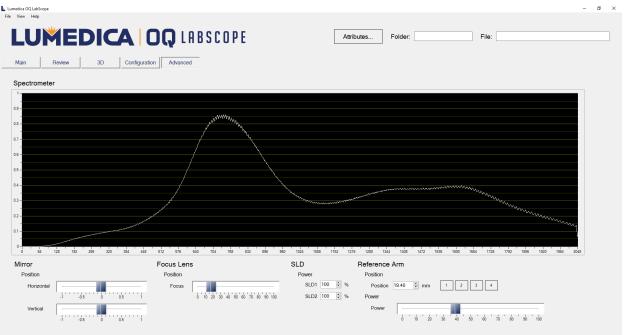
If selected, three translucent planes will appear, intersecting the volume. Three image controls and sliders will appear. Each image control displays a cross section of the volume intersected by one of the three planes. Adjust the color-coded sliders marked XY, XZ, and YZ to move each plane.



Planes View Mode

OQ STRATASCOPE 3.0

Advanced Tab



Spectrometer

The graph on the spectrometer shows the raw output of the high-resolution spectrometer inside the OCT engine. This information is not needed for typical operation. It may be used to diagnose issues with the OCT system.

Mirror

Position – Horizontal

Sets the horizontal position of the MEMS mirror. This slider is enabled only when the scanner is stopped. The value is not stored. They system will revert to factory settings when the scan starts again.

Position – Vertical

Sets the vertical position of the MEMS mirror. This slider is enabled only when the scanner is stopped. The value is not stored. They system will revert to factory settings when the scan starts again.

Focus Lens Focus

Sets the focus of the liquid lens. This slider is enabled only when the scanner is stopped.

SLD

Power

Adjusts the percentage of power that is output by the SLD. For dual SLD systems, two power adjustment controls are available.

Reference Arm Position

Sets the path length of the reference arm. Smaller values correspond to a shorter path length and larger values to a longer path length. The value can be changed by using the up and down arrows or by typing in a new value. Minimum value is 0.0 (zero) and maximum value is 30.0.

1, 2, 3, 4

Preset values for the reference arm. These are set in the configuration file and typically are used when there is multiple reference arm pathlengths that are used, for example different magnification lenses on a microscope turret.

Power

This slider ranges from 0 to 100 and controls the amount of light reflected form the reference arm by using a liquid lens. For optimum performance, the highest peak in the spectrum should be between 0.7 and 0.8 (scale on the left side).

Reference arm manual control

Controls the power level from the reference arm via the focus of a liquid lens. Left end of the slide is lower power and right end is higher power.

Some systems may be configured with a manual reference arm. In this case

pathlength and power adjustments can be made mechanically and are located inside of the OCT engine. Please contact Lumedica for details on how to adjust a manual reference arm.

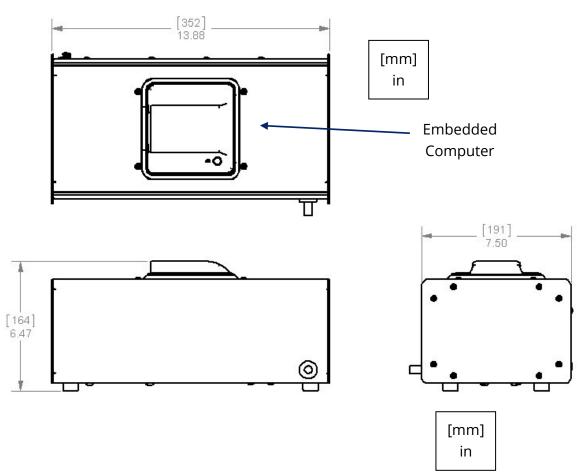
HARDWARE

These are your OQ StrataScope 3.0 system hardware components.

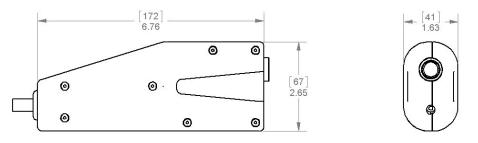
- System Chassis
- Embedded Computer
- Power Cord
 - Including one 12Vdc cord and one country-specific cord.
- Scanner Cable
 - This is the permanent connection between the system engine and the scanner. Do not modify or remove this cable. Modifications to the scanner cable will void your warranty.
 - The Scanner Cable is approximately 2 meters long. Excessive bending or stretching of this cord will negatively impact the performance of your system.
- Scanner

Mechanical Drawings

System Chassis



Scanner*



If you purchased a scanner with an integrated camera, then the dimensions of your scanner are difference than shown above. Email <u>support@lumedica.com</u> for more information.

WARNING

Do not attempt to adjust the scanner or parts within the scanner. Contact Lumedica if there seems to be a problem with the hardware within the scanner. Making adjustments to the scanner or to the parts within the scanner will void your warranty.

Polarization Control

Lumedica OCT systems are generally insensitive to the polarization alignment between the scanner and the reference arm. However, if the two polarizations end up orthogonal, then there will be a significant reduction in the signal strength in the OCT image.

If this happens, first check the scanner arm. Make sure that the scanner cord is not looped across itself and that the cord does not have a twist in it. Either of these conditions may affect the polarization and thus the OCT image.

Alternatively, you could adjust the polarization paddles inside the OCT engine. There are two sets of polarization paddles; the set at the back of the box is in the sample arm and the set closer to the front is in the reference arm. The amount of polarization rotation is set by the position of each of the two paddles in the two arms.

Open the top by unscrewing the two screws on each end and then lifting the top from the front side. Be careful since the computer is mounted to the top and there are several USB cables running from the computer to other parts of the system. You may need assistance holding the top open while making adjustments inside the box.

The polarization alignment can be adjusted by rotating the front set of paddles to optimize the OCT image. We recommend having a known sample to image while making the adjustment, such as the roll of ScotchTM tape supplied with the system.

REGULATORY

As required by WEEE (Waste Electrical and Electronic Equipment Directive) of the European Community and the corresponding national laws, Lumedica offers all end users in the EC the possibility to return end of life systems without incurring disposal charges.

Systems must be:

- Sold to a company or institute within the EC
- Currently owned by a company or institute within the EC
- A complete system not disassembled and not contaminated.

This service does not cover:

- OEM products that are integrated into other systems
- Components
- Mechanics and optics
- Leftover parts of disassembled systems

Please contact Lumedica for details on how to return end-of-life systems.

If you do not return an end-of-life system to Lumedica, you must deliver it to a company that specializes in waste recovery. Do NOT dispose of the system in a litter bin or at a public waste disposal site.

TROUBLESHOOTING

If you encounter a software error, there are a few simple steps you may be able to try to quickly solve the issue.

Complete a full power cycle by shutting down the NUC (Windows > Power > Shut Down), unplug the 12v power supply, wait a few seconds, then plug the power supply back into the OQ StrataScope and turn it back on.

Customer Support

If a full power cycle does not solve the concern, then contact Lumedica for further support. Email <u>support@lumedica.com</u> with your system's serial number and a short description of the problem.

TeamViewer

To facilitate customer support, TeamViewer has been installed on the computer inside of the OQ EyeScope. TeamViewer is only activated with your participation and permission. Provided that the system has an internet connection, TeamViewer allows our team to remotely control the OQ StrataScope 3.0 and assist with any issues.

Using TeamViewer requires the following steps:

- 1. Contact us by phone or email to discuss any issues and to set up a meeting time and contact phone number.
- 2. At the meeting time, start TeamViewer from the icon on the desktop.
- 3. Start a Meeting within TeamViewer and send us the provided meeting ID and access code over email or a phone call.
- 4. With this information, we will remote in from our machine and assist with the issues discussed.
- 5. Once completed, you will shut down the TeamViewer application on the OQ StrataScope.
- 6. Note: once the meeting is closed our team cannot access your system without a new meeting ID and access code. We do not collect any information beyond what is needed to troubleshoot issues for which you have requested help.

Warranty

Standard Warranty

Lumedica offers a standard 90-day warranty on all OCT imaging systems.

Extended Warranty

Extended warranties may be purchased from Lumedica, Inc. Please contact Lumedica to determine if your system already has an extended warranty or to receive a quote for further warranty coverage.

Non-Warranty Repairs

Systems returned for repair that are not covered by warranty will incur repair charges in addition to all shipping expenses. Any repair charges will be quoted to the customer and accepted by the customer before any work is performed.

Warranty Exclusions

Warranty does not apply to systems that are

- 1. Custom, modified, or otherwise nonstandard
- 2. ESD sensitive items whose static protection has been opened or compromised, repaired, modified, or altered by any party other than Lumedica,
- 3. Used in conjunction with equipment not provided by or acknowledged as compatible by Lumedica.
- 4. Subjected to unusual physical, thermal, or electrical stress
- 5. Damaged due to improper installation, misuse, abuse, or storage
- 6. Damaged due to accident or negligence in use, storage, transportation, or handling.

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