

SOLIX™ Essential



User Manual

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_____End of section_____

1 Introduction

1.1 General

Optovue, Inc has developed and tested the SOLIX™ Essential System with DualTrac™ and AngioVue® software in accordance with Optovue, Inc. applicable quality and safety standards, as well as national and international regulations and guidelines to ensure a high degree of instrument safety. Please observe all labeling related to safety, including information, precautions, warnings and notes in this manual and on the device labels. This device does not produce any waste that needs disposal. This product contains no material that presents a chemical hazard concern.

This manual contains information for all the features of the SOLIX™ System: **SOLIX™ Essential** with AngioVue® OCT, Corneal Map Topography and all OCTA scans.

1.1.1 Proper Instrument Use

- Always enter patient information first.
- Clean patient contact surfaces (forehead and chin rest, according to the cleaning method in this manual in Chapter [10](#)).
- **The power cord is the only way to disconnect the system completely from the power source.** For any emergency, turn the system power **OFF**, then immediately unplug the power cord from the wall or from the system.
- Clean the ocular lens frequently to ensure good image quality as described in Section 10.1.2.
- Adjust power table height properly to ensure patient comfort and safety during the examination.
- Raise or lower the patient's head so the eye aligns with the canthus mark on the chin and forehead rest assembly as described in Section 3.1.
- Dim the room lights to allow natural dilation of the patient's pupil, and to reduce glare and provide comfortable visualization of the fixation target.

 **Note:** Chemically induced pupil dilation is not normally needed.



- Warn others not to sit, lean, support or stand on any part of the table, including the base and the top.



- When lowering the table, make sure that pinch point areas are clear of people and articles; do not store articles around these areas.

1.1.2 Indications for Use

SOLIX™ Essential is an optical coherence tomography system intended for the in vivo imaging, cross-sectional, and the three-dimensional imaging and measurement of anterior and posterior ocular structures, including retina, retinal nerve fiber layer, ganglion cell complex (GCC), optic disc, cornea, corneal epithelium, corneal stroma, pachymetry, and anterior chamber of the eye. With the integrated reference database, is also a quantitative tool for the comparison of the retina, retinal nerve fiber layer, and optic disc measurements in the human eye to a database of known normal subjects. It is indicated for use as a diagnostic device to aid in the detection and management of ocular diseases.

The SOLIX™ Essential with the AngioVue® software feature is indicated as an aid in the visualization of vascular structures of the retina and choroid in normal subjects, and in subjects with glaucoma and retinal diseases. The AngioAnalytics™ software feature of AngioVue® is indicated for the measurement of vascular density, the foveal avascular zone, the thickness of retinal layers, and nerve fiber layer, and measurement of optic disc parameters in normal subjects, and in subjects with glaucoma and retinal diseases.

.

1.1.2.1 Contraindications



This device is not designed, sold or intended for use except as indicated in this manual.

 **Note:** The SOLIX™ Essential System is not intended to be used as the sole diagnostic aid in disease identification, classification or management. The system provides data to be used in conjunction with other information, intended to assist an eye care clinician in determining a diagnosis. Patient diagnosis is the sole domain of a licensed eye care medical practitioner and clinician.

 **Note:** The SOLIX™ Essential System is not intended as a substitute for fluorescein angiography.

1.1.3 Equipment Classification

- Type of protection against electric shock: Class 1
- Degree of protection against harmful ingress of water: IPX0
- Class of operation: Continuous

1.1.4 Certification

To ensure full system quality, the SOLIX™ Essential System has been manufactured in a registered ISO 9001 or 13485 facility. It has been designed and tested to be compliant when used with the laboratory equipment requirements of applicable regulatory agencies. Declarations of conformity and certificates of compliance are available by using the contact options at www.visionix.com.

1.1.1 Electronic User Manual Access

The SOLIX™ Essential User Manual is provided with the instrument as a USB, on the desktop and Online through Visionix Academy www.academy.visionix.com

On the computer desktop: To access the computer desktop without exiting the system software:

- A. Press Ctrl+Esc on the keyboard. Select Windows Systems.
- B. Scroll up to File Explorer, double click Desktop.
- C. Double-click on the folder User Manuals.
- D. Double-click on the SOLIX™ Essential User Manual.

 **Note:** Once opened, you can switch between the user manual and the SOLIX™ Essential application by pressing Alt+Tab.

1.2 System Overview

1.2.1 System Components

The system ships in two palletized boxes, which contains the following hardware.

- **Scanner and control unit:** These are the main components of the System. Along with the joystick, base and head rest they are used to view and scan the patient's eye, collect the OCT signal, and send it to the computer for processing.
- **Head rest, joystick assembly and base plate:** the patient is placed in the head rest and the joystick assembly is moved over the base plate to position the scanner.
- **Computer:** The system computer supports scanner operation, and processes, stores and displays exam data through the application software. The searchable SOLIX™ Essential database stores and organizes patient and exam data.
- **Monitor:** A 24 in. LCD widescreen flat panel monitor provides the graphical user interface (GUI).

 **Note:** The monitor resolution is set at the factory to 1920 X 1080. We recommend you confirm this setting before first use.

- **Keyboard and Mouse:** Standard USB- wireless input devices
- **System Table:** The system table holds all system components. It rests on lockable wheels, making the system portable, and its height is adjustable through a medical grade telescopic lift.

 **Note:** Optovue recommends connecting the system via an uninterruptible power supply (UPS) to the wall outlet.

The system hardware appears below from the patient's perspective. The following legend identifies the callouts.

Figure 1 System Hardware



Figure 1 Legend:

- | | |
|---|--|
| 1 Scanner | 8 Keyboard and mouse (enclosed in retractable shelf) |
| 2 Monitor | 9 System table |
| 3 Power switch | 10 Chin rest |
| 4 Table up/down switch | 11 Joystick |
| 5 Computer | 12 Forehead rest |
| 6 Wheels and locks (x4) | 13 External fixation light |
| 7 Warning, SOLIX™, and serial number labels | 14) Control Box |
| | 15) Chin rest button |

1.2.2 System Configurations (complete with table)

- **SOLIX™ Essential**, AngioVue® :
- **Solix Topography Module** (additional license)

1.2.3 Power On and Launch the System

Follow these steps to power on and launch the system:

1. Turn on the system table using its power switch.
2. Turn on control box (green switch)
3. Turn on the system computer using its power switch.
4. After the computer operating system has fully launched (can take up to a minute), double-click the **SOLIX™ Essential** desktop icon to launch the system software.

1.3 System Warnings



WARNING: During normal use, software periodically polls the system status through the USB. Whenever software detects abnormality in status, it halts operation and flags error messages to warn users. Upon seeing the error messages, please exit the SOLIX™ Essential application and reboot the system.

WARNING: No modification of this equipment is allowed.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

WARNING: Optovue recommends that no accessories other than those specifically called out in this user manual may be connected to the system. Any customer accessory equipment connected to the interface ports must be certified according to the respective IEC standards (for example, IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment) Also, all configurations shall comply with the system standard IEC 60601-1:2005. Any person who connects or installs accessories to the

system has the responsibility to verify the compliance. If in doubt, consult an Optovue representative.

1.4 General Warnings



ESD WARNING: Before assembly, installation or interconnection of the system, Optovue recommends that any staff (that is, biomedical engineers and health care staff) that could touch connectors identified with the ESD warning symbol undergo electrostatic discharge (ESD) training. At minimum, ESD training should include an introduction to the physics of electrostatic charge, the voltage levels that can occur in normal practice and the damage that can be done to electronic components if they are touched by an operator who is electrostatically charged. Furthermore, an explanation should be given of methods to prevent build-up of electrostatic charge, and how and why to discharge one's body to earth or to the frame of the equipment or system, or bond oneself by means of a wrist strap to the equipment or system or to earth, before making a connection. Finally, staff must be made aware that accessible pins of connectors identified with the ESD warning symbol should not be touched with the fingers or with a handheld tool, unless proper precautionary procedures have been followed.

WARNING: The use of accessories, transducers and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.

WARNING: Components of the system should not be used adjacent to or stacked with other equipment, and, if adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

WARNING: The system cannot replace clinical judgment and is intended to be used only in conjunction with other clinical tools considered to be the standard of care for diagnosis of eye health and disease.

The system is not intended to be used as the sole diagnostic aid in disease identification, classification or management. The system provides data to be used in conjunction with other information, intended to assist an eye care

clinician in determining a diagnosis. A patient diagnosis is the sole domain of a licensed eye care clinician.

Warning: The end user should always check the automated segmentation of images to evaluate whether manual adjustments are necessary.

Warning: The RDB comparison results for one scan pattern is not interchangeable with any other scan pattern/size from the same or any other system.

Warning: Measurements of the same parameters from different scan patterns or different products are not interchangeable, including but not limited to RDB or vessel Density values.

Warning: The Density results for one scan pattern are not interchangeable for those for the other scan pattern/size from the same or any other instrument.

WARNING: The system has no special protection against harmful ingress of water or other liquids (classified IPX0). To avoid damage to the instrument and cause a safety hazard, the cleaning solutions, including water, should not be directly applied to the device. Using a dampened cloth (without dripping) is a good method to clean the exterior surface of the enclosure. The table can be cleaned in the same manner as the system. Care should be taken to avoid excess fluid near any of the system components.

WARNING: While being examined, the patient must not touch any part of his or her body to an electrical device that is not powered by the system. In addition, while examining the patient, the system operator must not touch at the same time the patient and any electrical device that is not powered by the system. Failure to observe these warnings could result in electrical shock to the patient and/or operator.

WARNING: Use power cords provided only by Optovue. Do not block access to unplug the power cord.

To remove power from the system, you must disconnect the mains plug from the wall outlet. Do not position the system where plugs are inaccessible during operation.



Caution: The Reference Database and the results displayed based on estimated percentiles should be used only as an aid for making clinical decisions. The results from the Reference database comparison should never be used in isolation, but only as one part of the entire clinical armamentarium. Patients who are not represented by the patients in the Reference database may not be suitable for comparison to the Reference database. In these patients, the Reference database results should be used with caution, if at all. This includes patients outside the age range of the Reference database, that is, outside 18 – 91 years of age; or patients outside the range of refractive error, that is, outside -8 to +3 diopters spherical error or 2 diopters cylindrical error range. Results in patients 80 years of age or older should be interpreted with caution, since only 4 subjects above the age of 80 were included in the Reference database. It should be noted that this Reference database does not have any subject younger than 18 years of age. The color categorization of a pixel presents the percentile with regard to the distribution of thickness at the specific location of a given pixel.

Caution: The color Reference maps provide a way to represent whether a given patient is similar or dissimilar to a “Normal” patient. This information does not provide further diagnostic information beyond representing whether a given patient is similar or dissimilar to a “Normal” patient.

Caution: Reference database comparisons are based on statistical comparisons only, and there are possible normal outliers.

Caution: OCT image is a plot of optical path length. Depending on the optical design and scanning location, the image can be distorted from its actual physical shape. For example, a relatively flat retinal OCT image might not reflect the true curvature of the retina.

Caution: The OCT image can be affected by the optical pathway, that is, by corneal opacity, cataract or eye shape.

Caution: Federal law restricts this device to the sale by or on the order of a Physician or Practitioner (CFR 801.109(b) (1).

1.4.1 WARNING: User Changes to Software or Hardware



Do not step on surface.

Ne pas marcher sur la surface.



WARNING: Electricity

Avertissement : Électricité.



The SOLIX™ Essential System is a medical device. The software and hardware have been designed in accordance with U.S., European and other international medical device design and manufacturing standards and regulations. Unauthorized modification of the system software or hardware, or any addition or deletion of any application in any way, can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data.

Any changes, additions or deletions to factory installed applications, the operating system, or modifications to hardware in any manner VOIDS the warranty completely and can cause SAFETY HAZARDS.

1.5 Power and Electrical Safety



ON/OFF

UP/DOWN

ON/OFF - Even with switch off, there is power to the table column.

Maximum Permissible Load (See socket label. For use by Optovue personnel only.)

Cable Name	Cable Type	Shielded or Unshielded	Cable Max. Length
SOLIX BASE Control Box to PC	USB3.0 (53375)	Shielded	0.5 m
SOLIX BASE Control Box to PC	USB2.0 (53053)	Shielded	1 m
SOLIX Scan Head to PC	USB2.0 (54020)	Shielded	2 m
SOLIX Scan Head to PC	USB2.0 (52724)	Shielded	1.5 m
SOLIX Scan Head to Base	USB2.0 (51404)	Shielded	1.5 m
SOLIX Scan Head to Base	Multi wire (51391)	Shielded	1.5 m
SOLIX Optical	Fiber	Unshielded	2 m
iBase to Solix Base Control Box	Multi wire (46305)	Shielded	1.5 m
Monitor to PC	HDMI Cable	Shielded	1.5 m
Keyboard, Mouse	USB	Shielded	1 m
Column AC to PC	PWR Cord (50847)	Unshielded	1 m
Column AC to Base Control Box	PWR Cord (47706)	Unshielded	1 m
Joystick to SOLIX Scan Head	2 wire	Shielded	0.2 m
From the Wall to table	3 wire (Power Cord)	Unshielded	2.5 m
PWR Cord AC Adapter Monitor	2 wire	Unshielded	1 m
AC/DC Adapter 19V Monitor to Base Control Box	2 wire	Shielded	1 m

1.6 Safety with Moving Parts

Table Handling Instructions

 A rectangular warning label with a yellow background. On the left is a yellow triangle with a black border containing a hand being pinched. To the right of the triangle, the text reads: CAUTION Pinch point hazard. Keep hands clear. ATTENTION Risque de pincement. Garder les mains à l'écart. At the bottom, small text says: ©Cleron Safety Systems, LLC cleronsafety.com 4XXXX Reorder No. C2879-01.	Pinch Warning Locations Please observe pinch warnings before raising and lowering the table.
 A yellow triangular warning label with a black border. Inside the triangle is a black silhouette of a foot being caught between two vertical bars, representing the table base and footrest.	Footrest Trapping Warning Do not step on table base when adjusting table height
 A blue square label with a white border. In the center, the word "UP" is above a white upward-pointing triangle, and the word "DOWN" is below a white downward-pointing triangle.	Table Up/Down Label
 A rectangular warning label with a yellow background. On the left is a yellow triangle with a black border containing a silhouette of a person lifting a heavy box. To the right of the triangle, the text reads: WARNING Heavy object. To avoid muscle strain or back injury, use lifting aids and proper lifting techniques when removing or replacing.	Heavy Object Please use proper lifting techniques or ask for help when moving

How to lock wheels:

Étiquette de blocage de roué:



Locked



Unlocked



Wheel lock label

1.7 Product Compliance

CB Certification: Under IEC 60601-1-2 4th Ed.

This device is classified according to UL/IEC/BS EN 60601-1-2 4th Ed. (2014) as follows:

Mobile, Continuous Operation

With respect to electrical shock, fire and mechanical hazards only in accordance with UL/IEC/BS EN 60601-1-2 4th Ed. (2014) and CAN/CSA C22.2 No. 601.1.



ON for part of the Equipment.



Alternating Current

1.8 EMC and EMI: EN 60601-1-2 4th ED

The SOLIX™ Essential System has been tested to comply with the emission and immunity requirements of IEC 60601-1-2 4th Ed. / BS EN 60601-1-2:2007. The system is intended for use in an electromagnetic environment where radiated RF disturbances are not beyond the standard defined in IEC 60601-1-2 4th Ed. / BS EN60601-1-2:2007.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS			
The system is intended for use in the electromagnetic environment specified below. The system customer or user should ensure that it is used in an appropriate environment.			
Test type	Test level	Compliance	Electromagnetic Environment - Guidance
Conducted Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Class A group 1 150 kHz to 30 MHz	Class A group 1 150 kHz to 30 MHz	The SOLIX™ Essential uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated Emissions EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010	Class A group 1 30 MHz to 1 GHz	Class A group 1 30 MHz to 1 GHz	The system is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following WARNING is heeded:
Harmonics IEC/EN 61000-3-2:2014	Class A Device	Per Clause 5 of the Standard	WARNING: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the system, or shielding the location.
Flicker IEC/EN 61000-3-3:2013	Per Clause 5 of the Standard	Per Clause 5 of the Standard	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±8 kV contact discharge ± 2, 4, 8 & 15kV air discharge	±8 kV contact discharge ± 2, 4, 8 & 15kV air discharge	While the 15 kV ESD air discharge IMMUNITY TEST LEVEL specified in this collateral standard for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT is higher than the ESD air discharge IMMUNITY TEST LEVEL specified in IEC 60601-1-2:2007, MANUFACTURERS should determine if even 15 kV is adequate for the environments of INTENDED USE..
Electrical fast transient/burst IEC/EN 61000-4-4	±2 kV AC Mains ±1 kV I/O Lines 5/50 5kHz & 100 kHz	±2 kV AC Mains ±1 kV I/O Lines 5/50 5kHz & 100 kHz	Mains power quality should be that of a typical commercial or hospital environment.
Surge Line to Line (AC Power) IEC/EN 61000-4-5	±1 kV Line to Line ±2 kV Line to Ground	±1 kV Line to Line ±2 kV Line to Ground	Mains power quality should be that of a typical commercial or hospital environment.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Radiated RF IEC/EN 61000-4-3	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = (6/d)\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m. If the ME EQUIPMENT or ME SYSTEM complies with higher IMMUNITY TEST LEVELS for this test, the 30 cm minimum separation distance in 5.2.1.1 f) may be replaced with minimum separation distances calculated from the higher IMMUNITY TEST LEVELS.
Proximity field from RF wireless communications equipment IEC 61000-4-3	See EN 60601-1-2:2014 Table 9	See EN 60601-1-2:2014 Table 9	IMMUNITY TEST LEVEL in V/m. If the ME EQUIPMENT or ME SYSTEM complies with higher IMMUNITY TEST LEVELS for this test, the 30 cm minimum separation distance in 5.2.1.1 f) may be replaced with minimum separation distances calculated from the higher IMMUNITY TEST LEVELS.
Conducted Immunity (AC Power) (I/O Lines) IEC/EN 61000-4-6	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM & amateur bands 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM & amateur bands 1 kHz AC Mains	The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY

Magnetic Immunity IEC/EN-61000-4-8	30 A/m	30 A/m	This test level assumes a minimum distance between the ME EQUIPMENT or ME SYSTEM and sources of power frequency magnetic field of at least 15 cm. If the RISK ANALYSIS shows that the ME EQUIPMENT or ME SYSTEM will be used closer than 15 cm to sources of power frequency magnetic field, the IMMUNITY TEST LEVEL shall be adjusted as appropriate for the minimum expected distance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	0% U_T .5 cycle 0% U_T 1 cycle 70% U_T 25 cycles 0% U_T 5 Sec	0% U_T .5 cycle 0% U_T 1 cycle 70% U_T 25 cycles 0% U_T 5 Sec	If the user of InZone requires continued operation during power mains interruptions, it is recommended that the InZone be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage before application of the test level.

General Requirements Summary

Standards	Description	Severity Level or Limit	Criteria	Results
IEC 60601-1-2:2014 Clause 4.1	Risk Management Process for ME equipment and ME System	Per Section One, Clause 4	Verification of Electromagnetic Disturbance Risk Management	Complies
IEC 60601-1-2:2014 Clause 5	ME Equipment and ME System Identification, marking and documents	See requirements called out in standard.	Review	Complies

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

Canadian Regulations

This equipment does not exceed the Class A limits for radio noise emissions from digital apparatus as set out in the radio interference regulations of the Canadian Department of Communications.

Le présent appareil numérique n'émet pas de bruits radioélectriques dépassant les limites applicables aux appareils numériques de Classe A prescrites dans le règlement sur le brouillage radioélectrique édicté par le Ministère des Communications du Canada.

1.9 Symbols Explained



Refer to or read user manual first



Electrical shock hazard: Voltage present inside the instrument. Do not remove the instrument cover or parts.



WARNING symbol indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis (does not apply to all products).



Caution symbol indicates a potentially hazardous situation, which, if not avoided, may result in minor or moderate injury. It may also be used to alert against unsafe practices. May be used to indicate the possibility of erroneous data that could result in an incorrect diagnosis (does not apply to all products).



Note: Calls attention to important information for the user.



European Conformity Mark for TUV Rheinland

European Notified Body:

TÜV Rheinland LGA Products GmbH

Tillystrasse 2

90431 Nuremburg Germany



Type B applied part: This instrument complies with the specified requirements to provide protection against electrical shock, particularly regarding allowable patient leakage current.

Anvisa nº: 80117580906

Responsável Técnico: Luiz Levy Cruz Martins / CRF – SP 42415



Manufacturer
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CNPJ: 04.967.408/0001-98

E-MAIL: Brazilvigilance@ul.com



General mandatory action sign



Authorized European Community Representative
Medical Device Safety Services (MDSS) GmbH
Schiffgraben 41
30175 Hannover, Germany



Serial number



Catalog number / part number



Do not sit on



Do not step on



Do not push



WARNING: Hand crush hazard



Consult instructions for use" or "Consult operating instructions



CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician



Tested to comply with FCC standards

Tomógrafo de coerência óptica

Nome comercial: SOLIX

Modelo comercial: SOLIX



1.9.1 Protective Packing Symbols

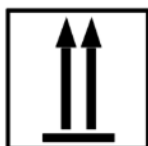
The protective packing symbols specify handling requirements and transport and storage conditions.



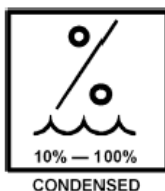
Fragile, handle with care



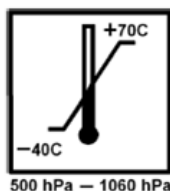
Keep dry



This side up



Environmental conditions during transport: Relative humidity (10% to 100%, including condensation)



Environmental conditions during transport: Temperature range (10 °C to +55 °C) and atmospheric pressure range (500 hPa to 1060 hPa)



Max stack 2

1.9.2 Product Labels

The SOLIX™ Essential model product labels appear below.

Voltage adaptable version.



1.10 Disposal

Dispose of the equipment per local regulations.

1.10.1 Waste Electrical and Electronic Equipment (WEEE) Recycling Instructions



When the device is ready for disposal, it is to be recycled according to local (including institutional and national) policies and procedures. **Do not dispose of the device as general waste.**

Recycling Label



This symbol is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this marking on the product indicates:



The device was put on the European market after August 13, 2005.

The device is not to be disposed of via the municipal waste collection system of any member state of the European Union. It is very important that customers understand and follow all laws regarding the proper decontamination and safe disposal of electrical equipment.

_____End of section_____

2 Manage Patient Information

The system application opens by default to the PATIENT Name or Anonymous window. The application also has a SCAN window (see chapter 3) and a REVIEW window (see chapter 5). The figure below calls out PATIENT window items.

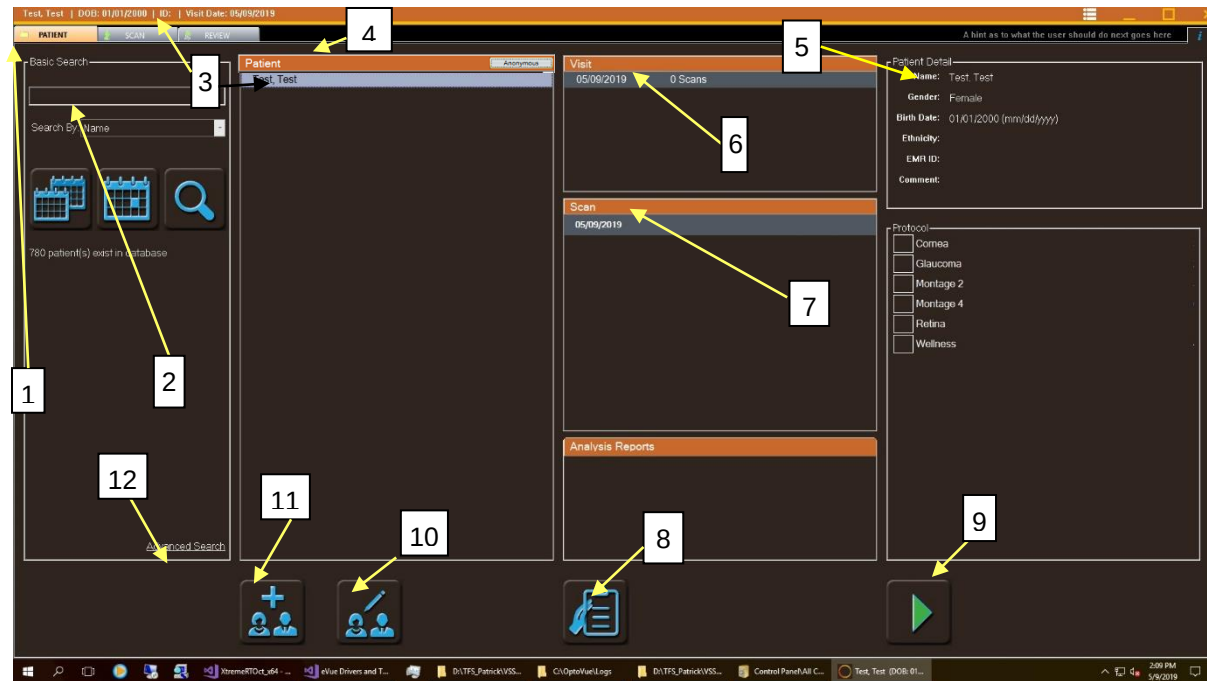


Figure 3 PATIENT Window Items

Legend:

- | | |
|--|--|
| 1 PATIENT tab (highlighted) | 8 Review button |
| 2 Basic or Advanced Search area | 9 Scan button |
| 3 Selected patient in list and on title bar | 10 Edit button |
| 4 Patient list | 11 Add Patient button |
| 5 Patient Detail area | 12 Advanced or Basic Search link |
| 6 Visit list (for selected patient) | |
| 7 Scan list (for selected visit) | |

 **Note:** The selected tab is highlighted as shown for the PATIENT tab in [Figure 3](#).

See chapter [9](#) for information regarding the main menu.

Use the PATIENT window to create, anonymize, find, select, edit and delete patients, visits and scans, and to initiate scanning or scan review. Features of the PATIENT window help you enter patient information in advance, preview today's scheduled patients, and search for patients using a specified date range or other search criteria. The **Patient** list displays search results.

2.1 Patient Search

To find patients in the database, you can perform a **Basic Search** or an **Advanced Search**.

2.1.1 Basic Search

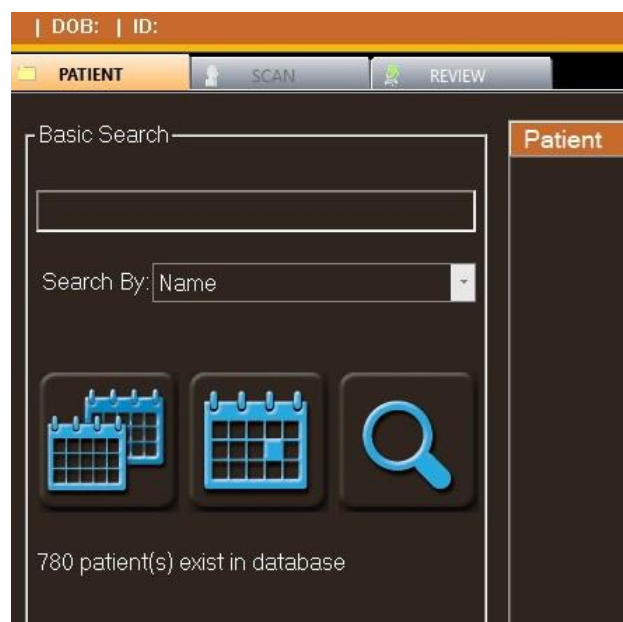
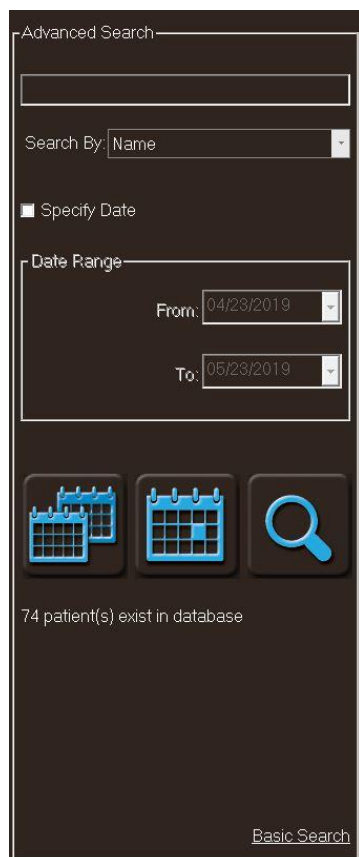


Figure 4 Basic Search Area

- Click **Show Today** to list patients scheduled for today. Click **Show All** to list all patients in the database.
- To search for a patient by name (first or last), enter the name in the Basic Search field and make sure **Name** (default) is selected in the **Search by** field, and click the **Search** button.
- To search by patient ID, enter the ID in the Basic Search field and use the down arrow in the **Search by** field to select **EMR ID** (Electronic Medical Records ID), and then click the **Search** button.

2.1.2 Advanced Search

Click the **Advanced Search** link at lower left to open the Advanced Search area.



Advanced Search

Search By: Name

☐ Specify Date

Date Range

From: 04/23/2019

To: 05/23/2019

74 patient(s) exist in database

[Basic Search](#)

Figure 5 Advanced Search Area

In the **Search By** field, click the down arrow to select one of the following search parameters.

Disease	Name (first or last)
EMR ID	Operator
First Name	Physician
Last Name	Scan Type

Then, in the field at the top, enter the search text for the chosen parameter (for example, name or ID number) and click the **Search** button. If your search returns no patients or not the ones you wish to find, search by another parameter. If you specified

a date range (as described next), searching with no date range, or a broader range, will broaden your search.

To narrow any search by date range, select the **Specify Date** checkbox and click the down arrow next to the **From** and **To** fields to select dates using the calendar that appears. Use the left and right arrows on the month to change the month. You can use the date range to find all patients with visits in the specified date range—if you do not enter text in the field at the top, or to find patients in the specified date range that also match the search text for the chosen search parameter.

2.1.3 Patient, Visit and Scan Lists

The **Patient** list displays results of a search. Before a search, the Patient list says **There are no items to show** and the title bar says **No patient selected**.

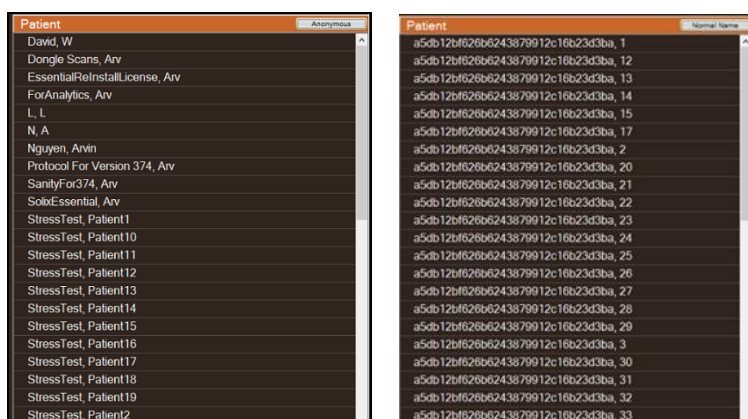
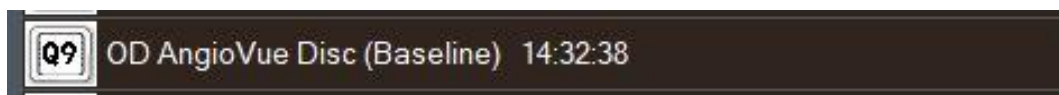


Figure 6 Sample Patient List

Click to select a name in the **Patient** list. When you do:

- The selected name is highlighted in the list and appears in the title bar on top of the window.
- The **Patient Detail** area shows the patient information previously entered for this patient: **Name, Gender, Birth Date, Ethnicity, EMR ID, and Comment**. (To enter or edit patient details, see sections [2.2](#) and [2.3](#).)
- The **Visit** list displays all visits for the selected patient, by date and showing the number of scans on that visit.

Click to select a visit in the **Visit** list. When you do, the **Scans** list displays all scans from that visit by type icon, name, and time of scan. Click to select a scan in the **Scan** list.



When a visit containing a scan is selected, the application enables the **analysis** buttons to display, according to which reports are available.

Figure 7 shows portions of the screen affected by your selections.

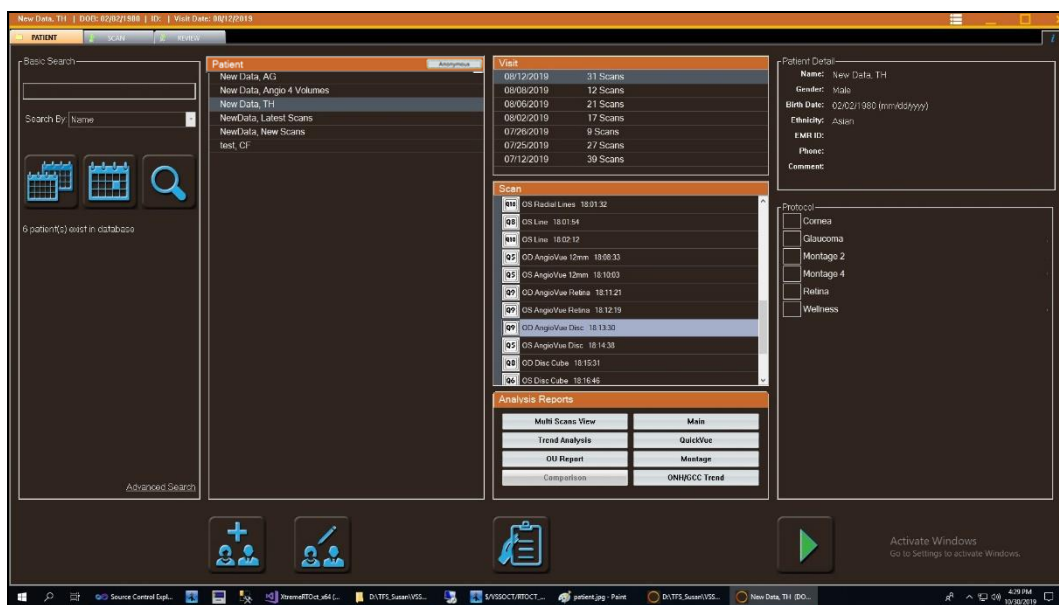


Figure 7 Selections Made in PATIENT Window

2.1.3.1 Patient and Visit Shortcuts

Right-click on a **Patient** name to access the **Delete Patient** option, which is used to permanently delete the selected patient. A warning message appears asking you to confirm deletion.

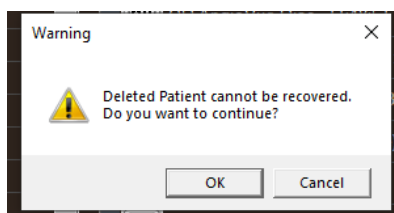


Figure 8 Delete Current Patient Warning

Right-click on a **Visit** date to access these options:

- **Add Visit:** Create a new visit with the current date for the selected patient.
- **Delete Visit:** Permanently delete the selected visit.

To confirm, click **OK**. Click **Cancel** to cancel deletion.

2.2 Add a New Patient

To add a new patient, click the **Add Patient** button. The **Add New Patient** dialog appears, as shown in Figure 9.

Figure 9 Add New Patient Dialog

Required fields are in bold. Enter the required information and enter other information as desired. You must enter the birth date in the indicated format.

 **Note:** You can use symbols in the name fields, but these may interfere with the system's screen capture function.

 **Note:** Enter birth date in the indicated format. You can change the default birth date format in the **User Preferences** dialog (go to **Tools > User Preferences** and choose the format in the **Date Format** field). **However, if you change the birth date format, note that the system computer date format must match it.** Follow the instructions below to change the computer date format:

1. On the computer, select **Start > Control Panel > Region and Language**.
2. Select the matching date format in the **Short date** field.

Use the **Optional** boxes to enter:

- **Physician:** Use the down arrow to select one or more physicians to associate with this patient or select **Add New** to enter a new physician name and associate it with this patient.
- **Operator:** Use the down arrow to select one or more operators to associate with this patient or select **Add New** to enter a new operator name and associate it with this patient.
- **Visit Comment:** Enter desired comments for this patient.

 **Note:** You can also create, edit and delete physicians, operators or diseases by selecting **Physician**, **Operator** or **Disease** from the **Database Management** menu.

Use the **Disease Category** area to associate one or more user-defined diseases with this patient. Once they are created, you can search for patients by disease category. To create disease categories, click **Add New** to display the **Disease Category Editor** dialog, enter a disease name and click **OK**.

When you finish entering information for the new patient, click **Save** to save the new patient and close the dialog, or click **Scan** to initiate scanning for this new patient. Click **Cancel** to discard entered information and close the dialog.

2.3 Edit Patient Information

To edit patient information, select the patient name from the **Patient** list and click the **Edit** button. The **Edit Patient/Visit Info** dialog appears. Edit the fields as desired. Click **Save** to save your changes. Click **Cancel** to discard the edits and close the dialog.

2.4 Correct Visit Linked to the Wrong Patient

Follow these steps to move a visit—a complete visit only, not specific scans—from the wrong patient to the right patient. If the patient you move the visit to already has a visit on that date, the scans will be combined under the one visit date.

 **Note:** To avoid having visits associated with the wrong patient, make sure you have selected or added the name of the patient you are about to scan.

1. From the Patient and Visit lists, select the patient and visit to be moved. Then select **Move a visit to another patient** from the **Database Management** menu.

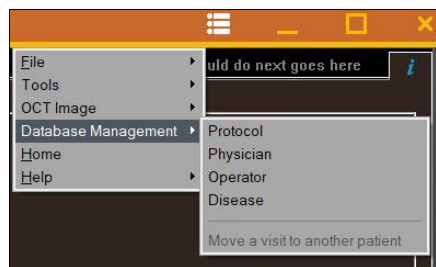


Figure 10 Select Move a visit to another patient

A confirmation dialog appears.

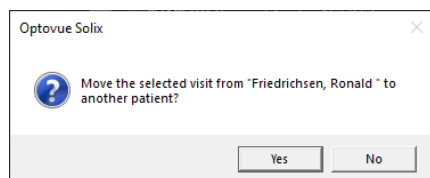


Figure 11 Confirm Intent to Move Selected Visit

2. Select **Yes** to confirm. A list of patients appears.



Figure 12 Select Patient to Move Visit To

3. Select the patient you wish to move the visit to and click **OK**. A second confirmation dialog appears.

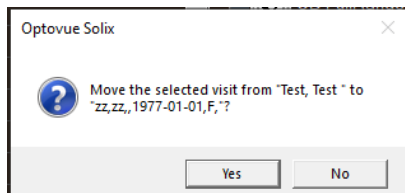


Figure 13 Confirm Move to Selected Patient

4. Select **Yes** to confirm the move to the selected patient.

_____End of section_____

3 Capture Scans

This chapter shows you how to choose and acquire OCT scans. First, it provides all the steps of the general scan acquisition procedure, as a quick guide. Then it provides more detail about available options during the procedure. The basics of all posterior scans are similar.

3.1 Steps to Acquire Scans

 **Note:** We recommend you clean the chinrest and forehead rest between patients with a disinfectant. For example, wipe with an isopropyl alcohol pad or with another approved germicide using a clean cloth.

Use the following procedure to choose and acquire posterior OCT/OCTA scans:

1. From the PATIENT window, select an existing patient (see section [2.1.3](#)) or add a new patient (see section [2.2](#)), then click the **Scan** button to go the SCAN selection page.
 2. Scan selection page select the patient eye to be scanned. **Both / OU** is selected by default. To change, click the **Right / OD** or **Left / OS** button.
 3. Select the desired scan type from the Retina, Nerve Fiber, or Cornea lists, or select a scan protocol from the Protocol list. You can select multiple scans to do the selected scans in succession. When you finish your selections, click the  Scan button to begin scanning or click the joystick button.
- Alternatively, you can repeat any previous scan for a patient by double-clicking on the scan name in the **Scans** list of the PATIENT window.

 **Note:** Scan navigation order is selectable in User preference, **non-dilated** capture order is All OCT then photo, then Cornea. **Dilated** is OCT and photo of one eye then the other eye and then Cornea.

 **Note:** 9x9 Montage 2 and Montage 4 protocols must be selected to enable montage feature, individual 9x9 not in protocol will not montage. At the beginning of the 2nd, 3rd, 4th scan a pop up to optimize focus will appear.

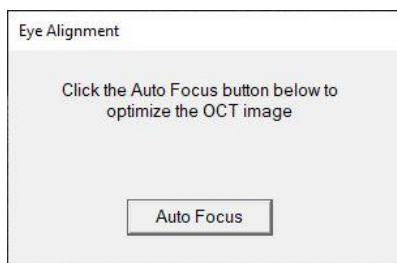


Figure 14 Auto focus box

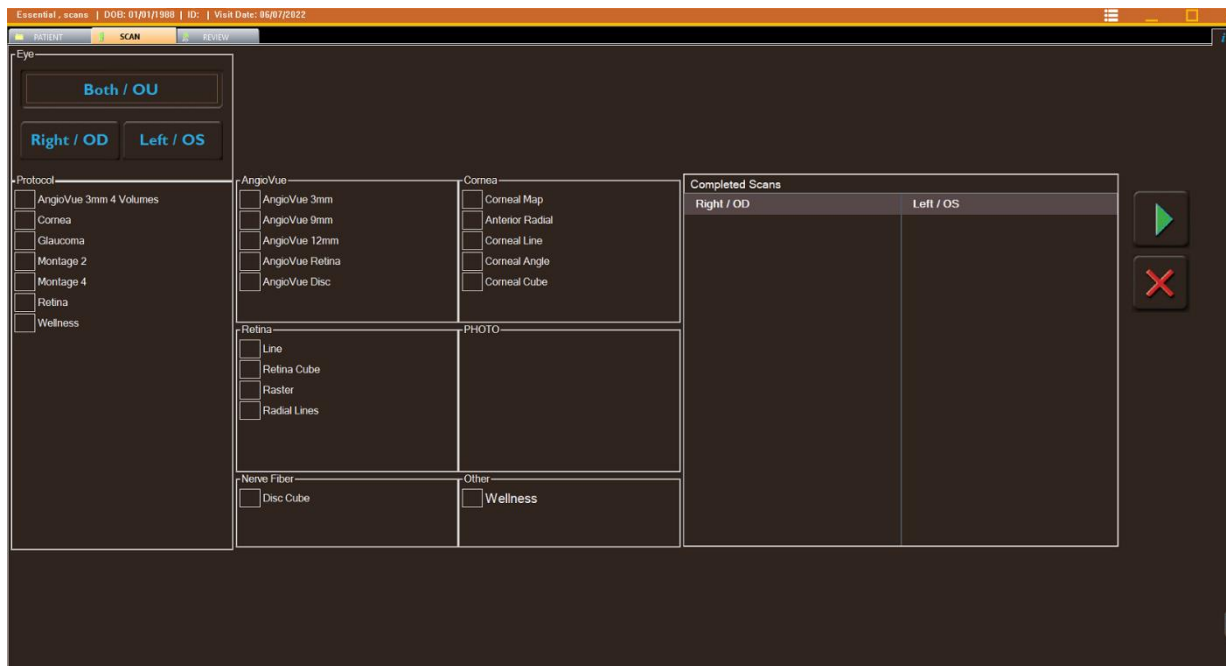


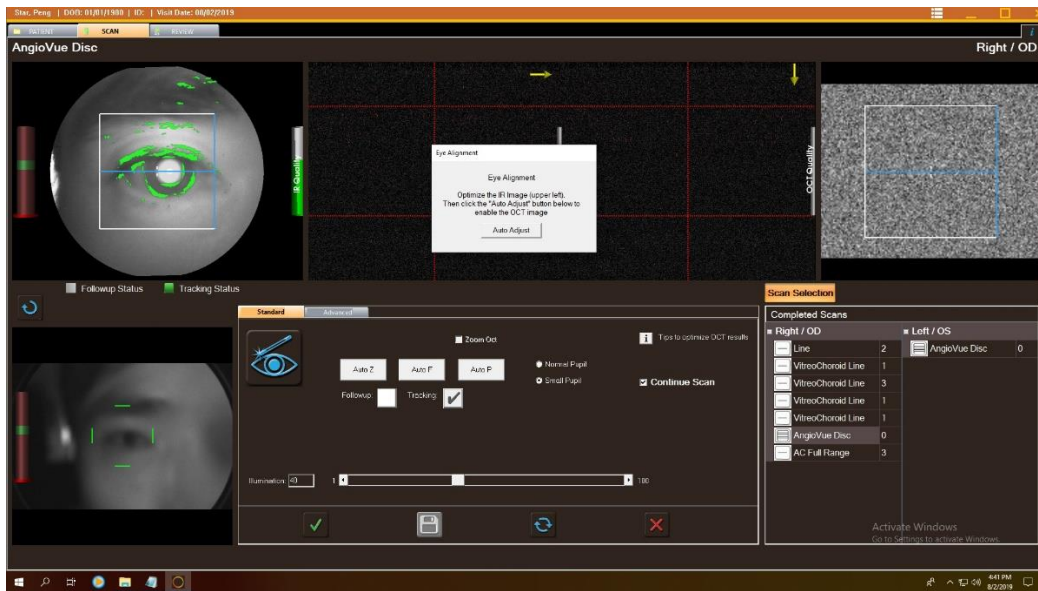
Figure 15 Scan selection page

4. Position the patient correctly as follows:

- **Adjust the table height so the patient is leaning slightly forward**
- **Chin on the system chin rest with teeth together**
- **Forehead against the forehead rest**
- **Eye to be scanned aligned vertically with the canthus mark on the side of the forehead and chin rest assembly.**

Ask the patient to look at (fixate on) the center of the blue fixation in the red field

- Center the eye on the iris image (bottom left) and move forward, moving the scanner head towards the patient, controlling it so that the video image (upper left) passes through the pupil.



6. **Figure 16 Far back no Auto Adjust**

- The slider bar to the left provides an indication as to correct working distance, advance forward when one reaches the green area you should be close to the correct working distance. Carefully advance until the fundus comes into view (for Retina and Disc scans).

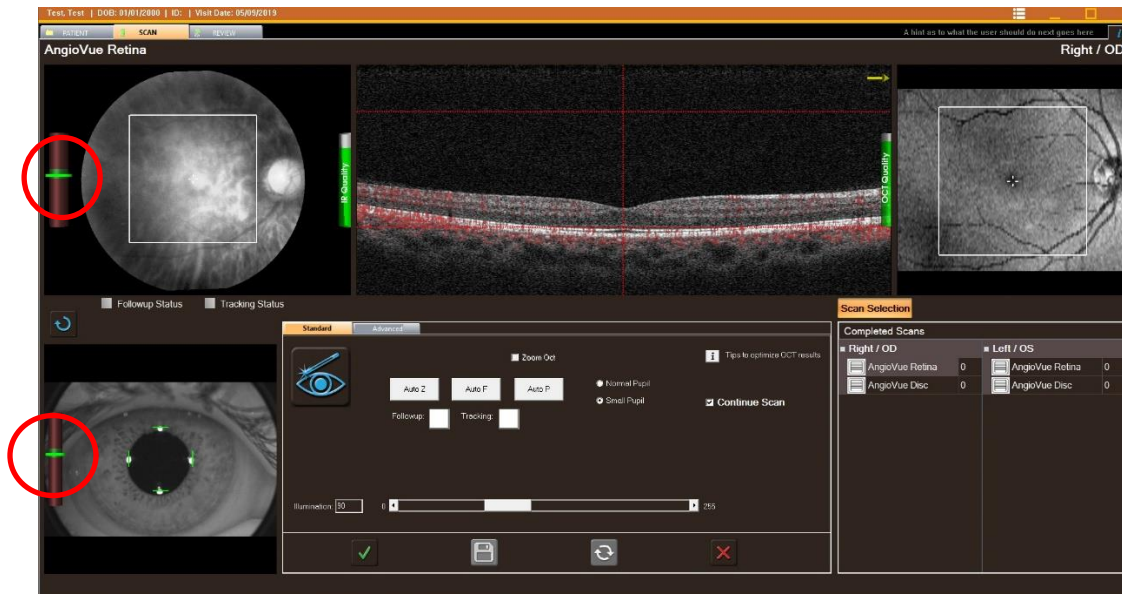


Figure 17 Alignment display after Auto Adjust, no tracking

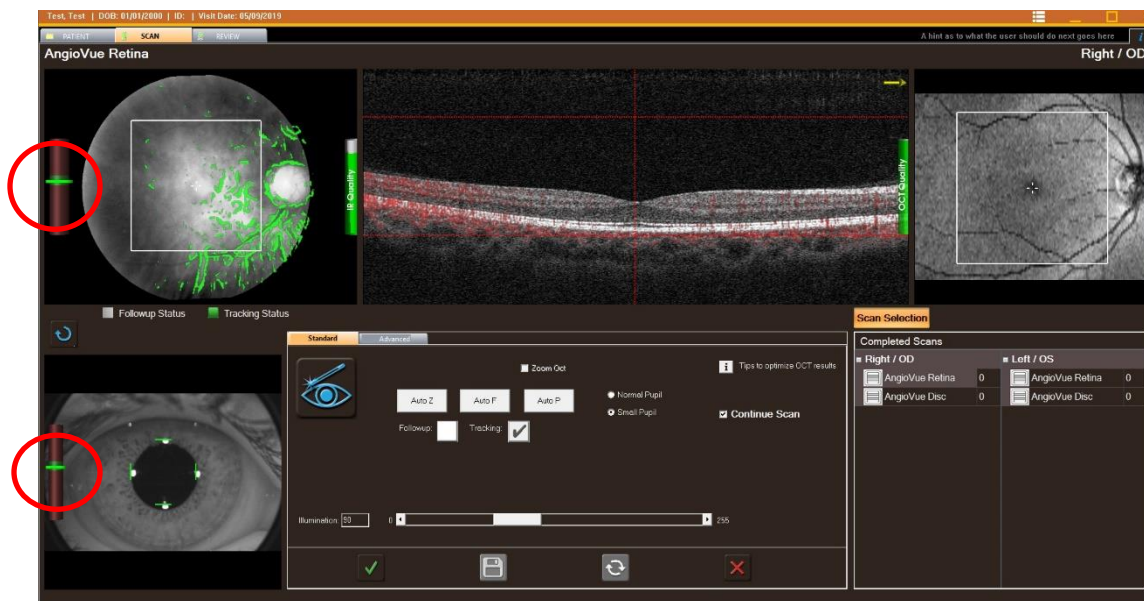


Figure 18 Alignment display with tracking after auto adjust

The figure below shows the progression of views in the IR window (top left) as you move the scan head forward at the correct working distance the image should show the retina and for track scans there will be a green overlay showing the features that the system will track, if this green overlay appears to be predominated by a large area of glare, reposition using the joystick to minimize the glare and have the system track features of the back of the eye.

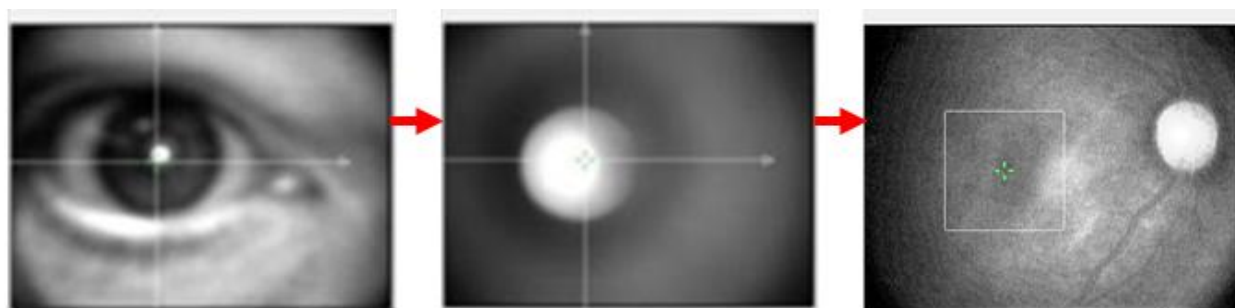


Figure 19 Video Image of IR camera Progression as Scanner Approaches Eye (no tracking)

8. Adjust the working distance between the scan head and patient eye to optimize the IR video image. Optimized fundus images should be illuminated evenly from edge to edge. Optimized optic disc images may contain dark areas on either side. For cornea scans, an optimized video image shows iris detail.

Note: For fundus imaging, make sure to set the working distance first. If a live OCT scan appears in the scan window, do not stop forward movement of the camera until you achieve a good infrared (IR) video image of the fundus. For cornea scans, the OCT image of the cornea in the scan window indicates the correct working distance.

9. When at the right working distance, the auto adjust should be done to complete focus and find and sharpen the retinal image

 **Note:** On each patient, the first scan of each eye, of that day, the auto adjust pop up will appear, the OCT image will not appear until the Auto Adjustment has been performed. A message will appear over the OCT window telling the operator to optimize the IR image then to select auto adjust.

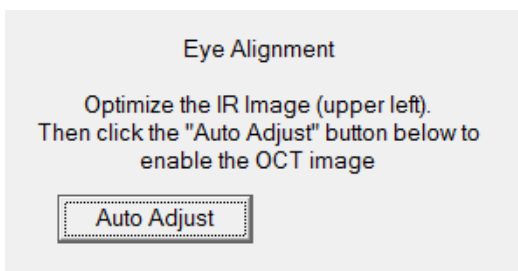


Figure 20 Eye alignment

- If the Auto Adjust fails, the live OCT B-scan window is active but no or poor B scan, then the following message is displayed.

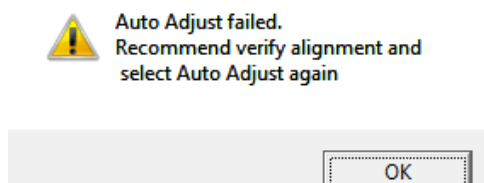


Figure 21 Auto Adjust fail

- The operator should try to optimize the IR image and Auto Adjust again, if the image cannot be improved the operator may decide to capture the image
- If the Auto Focus portion only fails, the following message will be displayed.

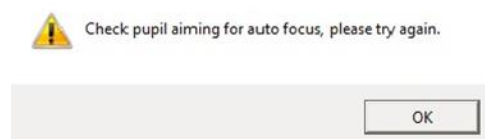


Figure 22 Auto Adjust focus

The operator should try to optimize the IR image and Auto Adjust/focus again, or switch to the Advanced tab and manually adjust Z,F,P or if the image cannot be improved the operator may decide to capture the image.

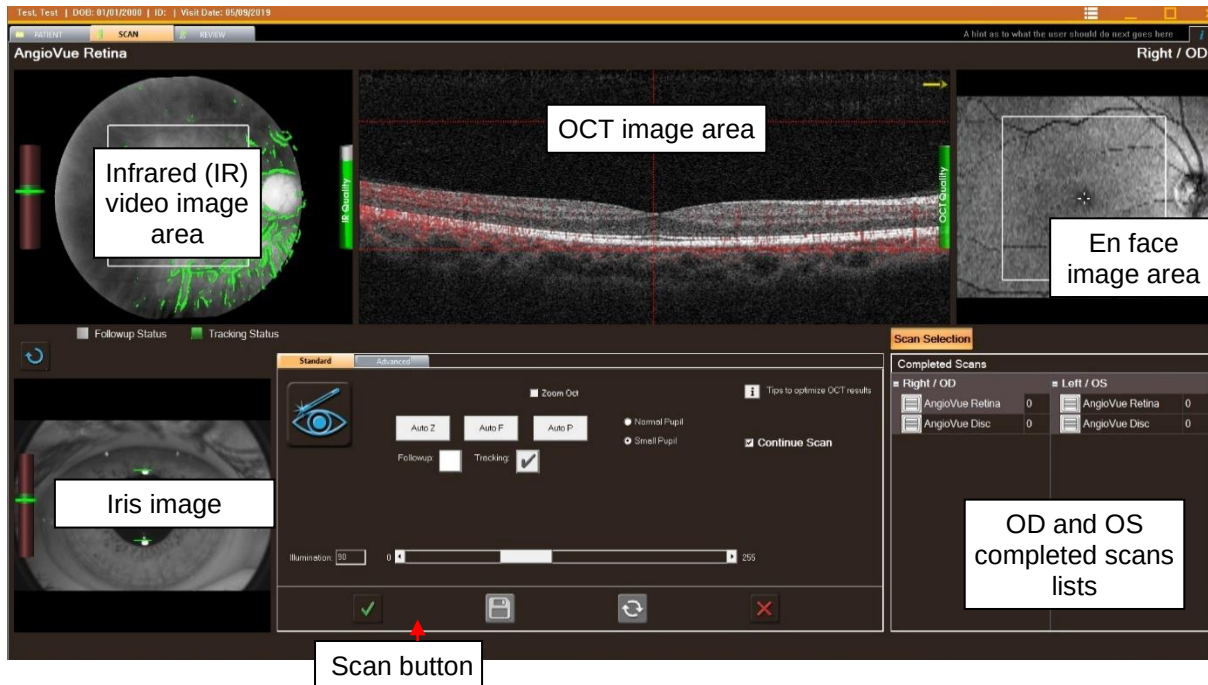


Figure 23 SCAN Window SOLIX™ Essential with AngioVue® tracking on

10. When the image is live, the Scan Selection adjustment options on the **Standard** tab (default) or **Advanced** tab can assist with scan quality. (The available parameters and their ranges depend on the scan type.)

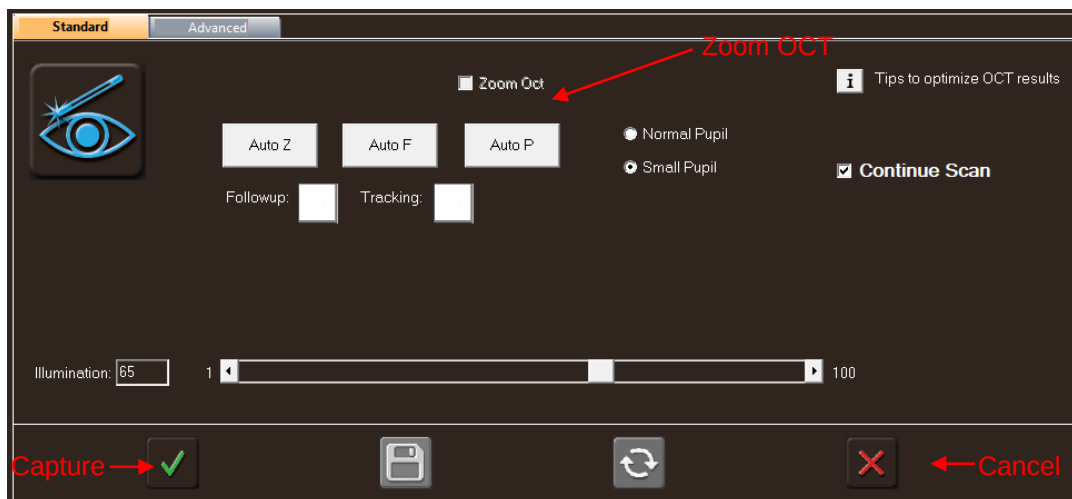


Figure 24 Scan Adjustment Options (Standard Tab)

To customize scan parameters, select the Advanced tab.

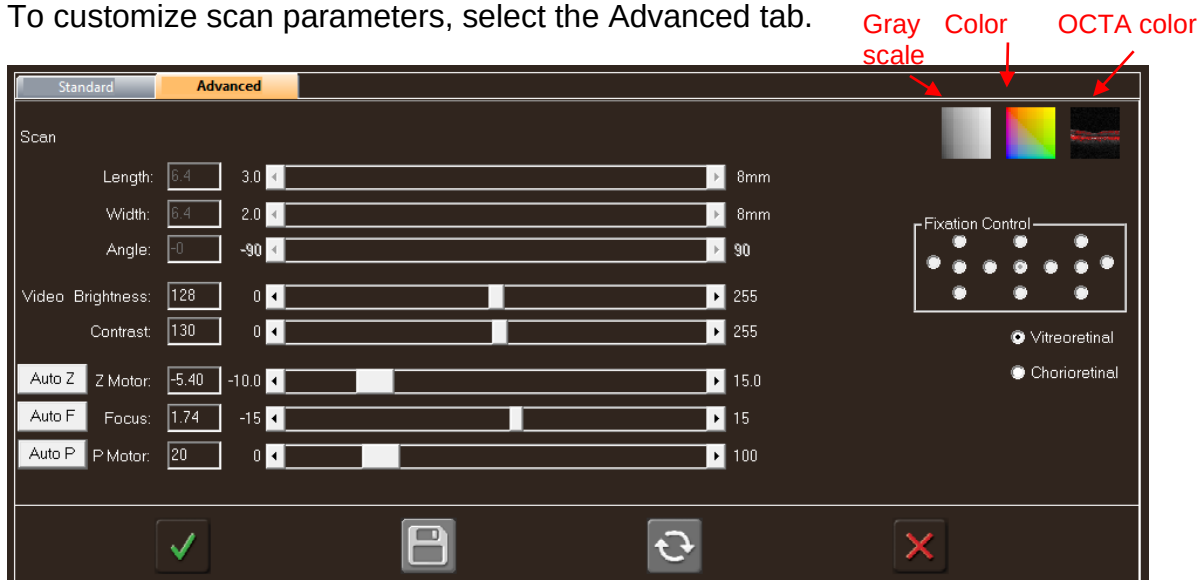


Figure 25 Advanced Tab to Customize Scan

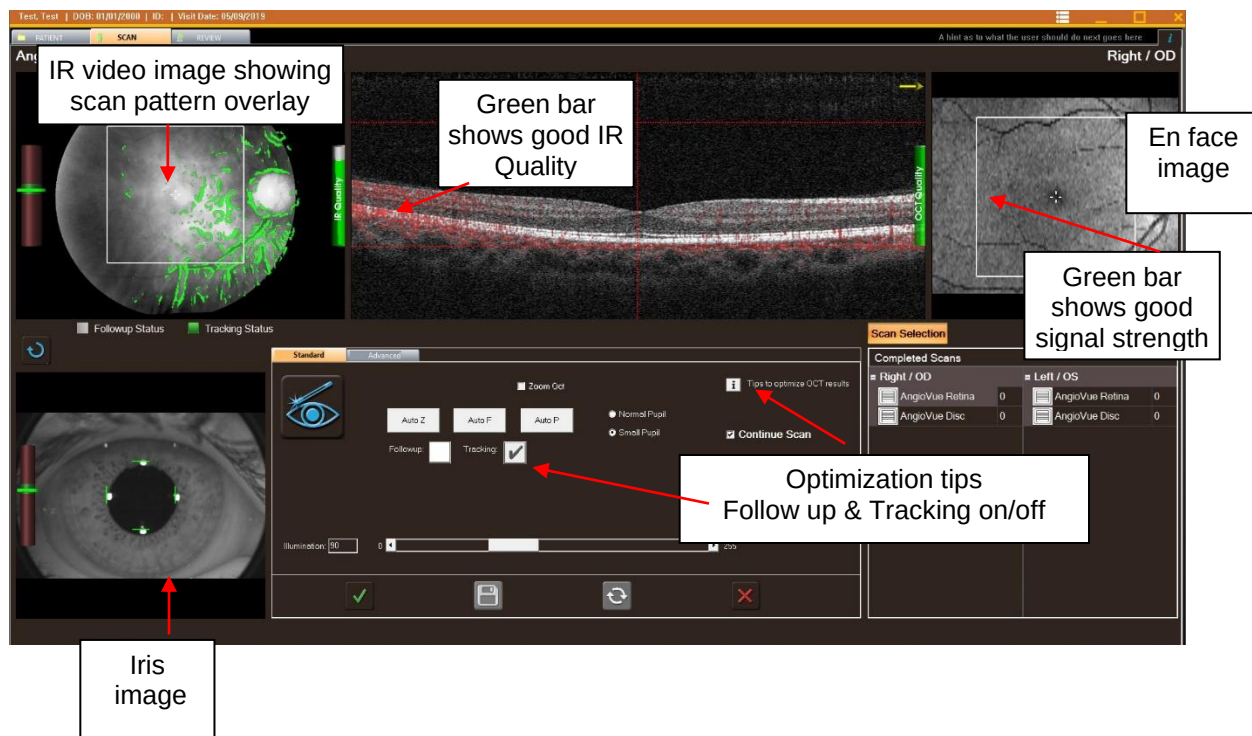


Figure 26 Optimize Working Distance

11. When the IR video image is optimized, use the scan pattern overlay in the live video image to center the scan pattern over the area of interest (fovea or disc). You can either:

- a. Double-click in the video image where you want to position the center of the scan pattern.

OR

- b. Click, hold and drag the scan pattern to the desired location, then release.

To adjust video brightness and contrast, click in the live video, hold and move the cursor up and down for brightness, left and right for contrast.

12. Click **Auto Adjust**—or double-click on the scan image—to optimize scan signal strength and image quality.

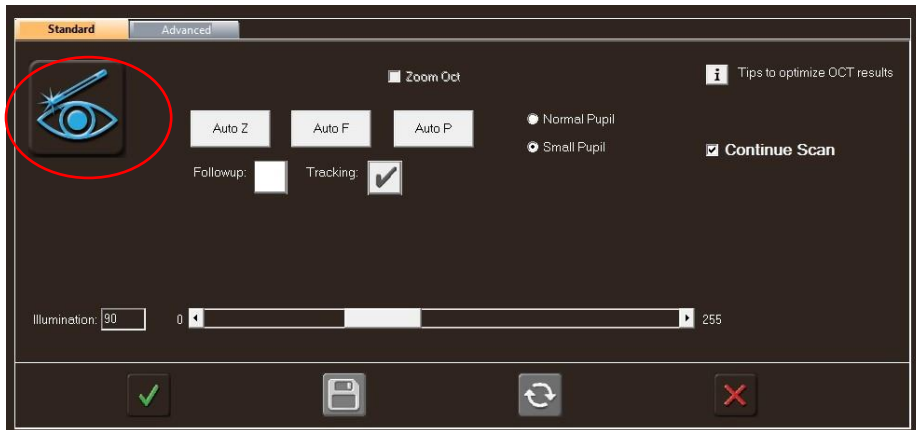


Figure 27 Auto Adjust Combines Auto Z, Auto F and Auto P

Auto Adjust executes **Auto Z**, **Auto F** and **Auto P** in combination. (Only the Auto P option is available for cornea scans.) **Auto Adjust** also tries to place the B-scan image in the target area between the red dashed lines. The image below shows an example of a scan centered vertically. If the scan is not between the red dashed lines but visible in the window, click once in the scan window and scroll the mouse wheel to bring the OCT scan between the red dashed lines.

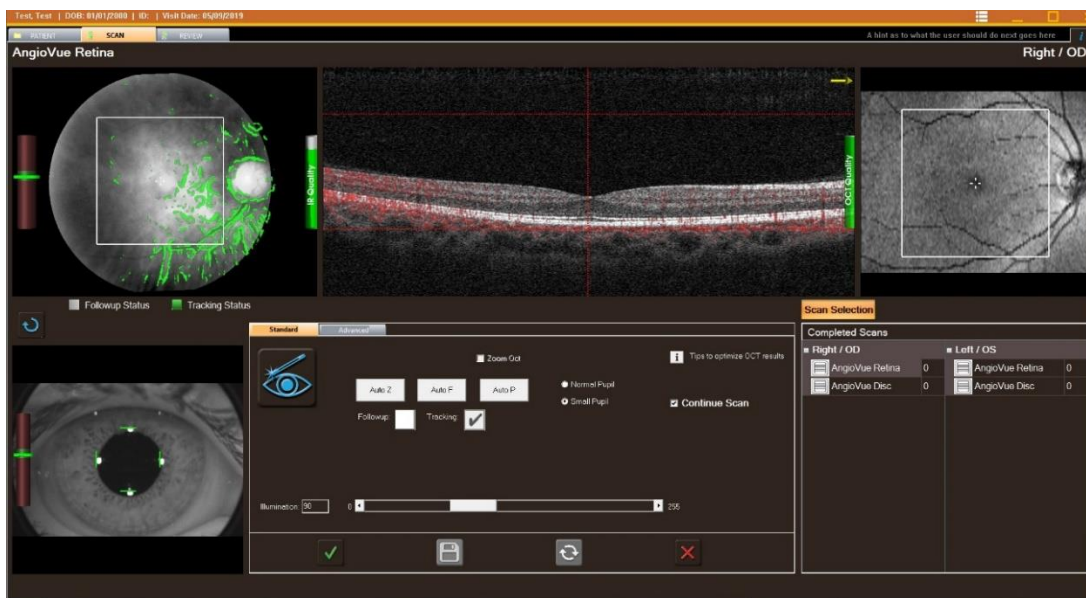


Figure 28 Example of Scan Centered Vertically

 **Note:** For scans that include the optic disc, it is OK-and expected—to have the disc portion of the scan below the lower red line.

On the right side of each live scan, a **green** bar indicates a good signal strength (SQ) value. If the bar is red, you can manually optimize scan signal strength and image quality as instructed in the next step below.

 **Note:** In most normal patients, the OCT (SQ) indicator should be green. However, individual patient variability and the light absorption properties of some pathologies can sometimes make it impossible to achieve a green signal. If the OCT (SQ) indicator is not **green** over a range of patients, including normals, contact Optovue Technical Support for assistance.

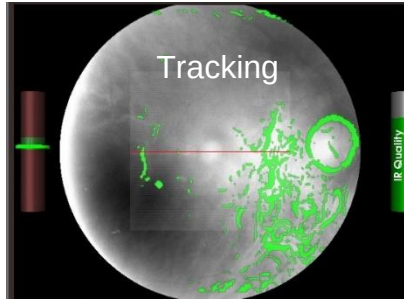
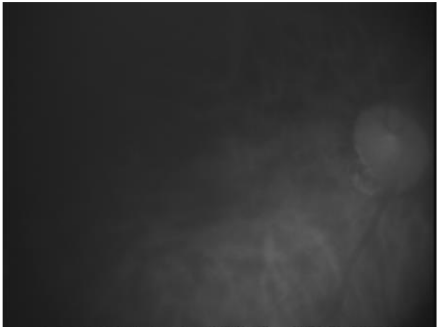
13. If the OCT (SQ) indicator is red, use one or more of the following functions on the **Advanced** tab to manually optimize scan signal strength and image quality.

- Select the **Advanced** tab (at upper left) and adjust the **Z Motor**, **Focus** or **P Motor** settings, or scroll the mouse wheel in the scan image to move the scan image between the red dashed lines.
- Click and hold in the live video image, then drag up or down to adjust video brightness, or left and right to adjust video contrast.

3.1.1 Instructions for Successful Tracking

- **On fundus image**
 - Check bright, homogeneous illumination by alignment to the center of pupil
 - Bring optical disc in the field of view, check the green overlay to ensure the system is tracking features of the retina such as the optic nerve or blood vessels or possibly a pathology
 - Avoid glare by adjusting the scan-head alignment to pupil center
 - In follow-up mode, optimize the IR image to ensure that the “tracking Status indicator” and “good tracking green overlay” shows in the target zone in fundus image.
- **On OCT image**
 - Target tissues should fall between two red lines

- Tracking (green light indicator & overlay) and start scanning

Good Image	 
Poor due to glare	
Blocked or blurry	

3.1.2 Tips for Scanning Difficult Patients

During scanning, if the patient fixation starts to drift, always remind the patient to look at the green fixation before attempting to reposition the camera. Often the patient will return to the correct fixation. AngioVue® scans have two modes, continuous and noncontinuous; and, for problem patients, it may be beneficial to use noncontinuous mode to allow them a break between the X and Y volumes.

Tip: Remind the patient to look at the Blue X and not follow the red lines.

Pupil or fixation drift during scan acquisition may cause tracking to stall.

- Tip: Check the Iris image and re-align the scan by slightly shifting the joystick towards the direction of the drift. This will allow tracking to resume and enable the scan to complete.

Patients with poor vision still need to maintain some level of fixation for tracking to be successful.

- Tip: Use the external fixation light to help keep the eye being scanned in the correct location.
- Tip: If the eye moves outside of the trackable area (no disc in IR image), stop tracking and help the patient fixate properly before resuming the scan or re-scan the patient.

Patients can have excessive up-and-down movement of the B-scan within the scan window

- Tip: This movement will not always affect tracking but will reduce the quality of the scan image. Take action to minimize movement and keep the B-scan in the scan window.
- Tip: Push the joystick slightly towards or away from the patient to keep the B-scan from moving up and down excessively or out of the scan window altogether. Ensure patient forehead is tight against the rest and teeth are together.
- Tip: Take advantage of the stability of the table. Position the table low enough that the patient can lean into the headrest, put their arms on the table and grasp the hand holds at the base of the joystick.

3.1.3 Tips to Optimize OCT results

Eye Alignment Hints

OCT Signal Strength Optimization

Problem	Solution
Low Signal Strength	Artificial tears aid in dilated and dry eye patients
Low Signal Strength	Auto Focus/Adjust a second time
Low Signal Strength	Click on OCT image and scroll mouse wheel to position B-scan between red boundary lines
Dark, Uneven Intensity B-Scan	Pull joystick back and reposition on the pupil
Low Signal from Opacities	Use joystick to search for new location on the pupil with more signal strength

Tracking / Follow Up / Motion Correction Performance

Problem	Solution
Glare in IR Image	Reposition on pupil or push further forward to reduce edge glare and pull back for center glare in IR image
Grainy IR	Use joystick to move toward center of pupil, increase illumination
Disabled Capture Button (Tracking / Follow Up)	Improve IR image (reduce glare and graininess). If not possible, turn off follow up and/or tracking
Fixation	Remind patients to look at the blue light, do not follow the red scan lines
Fixation	Use external fixation light for the fellow eye
Vertical Motion in Scan	Ensure forehead is tight against headrest

Close

Figure 29 Tips to Optimize OCT results

14. To capture the scan, either press the joystick button or click the checkmark button.

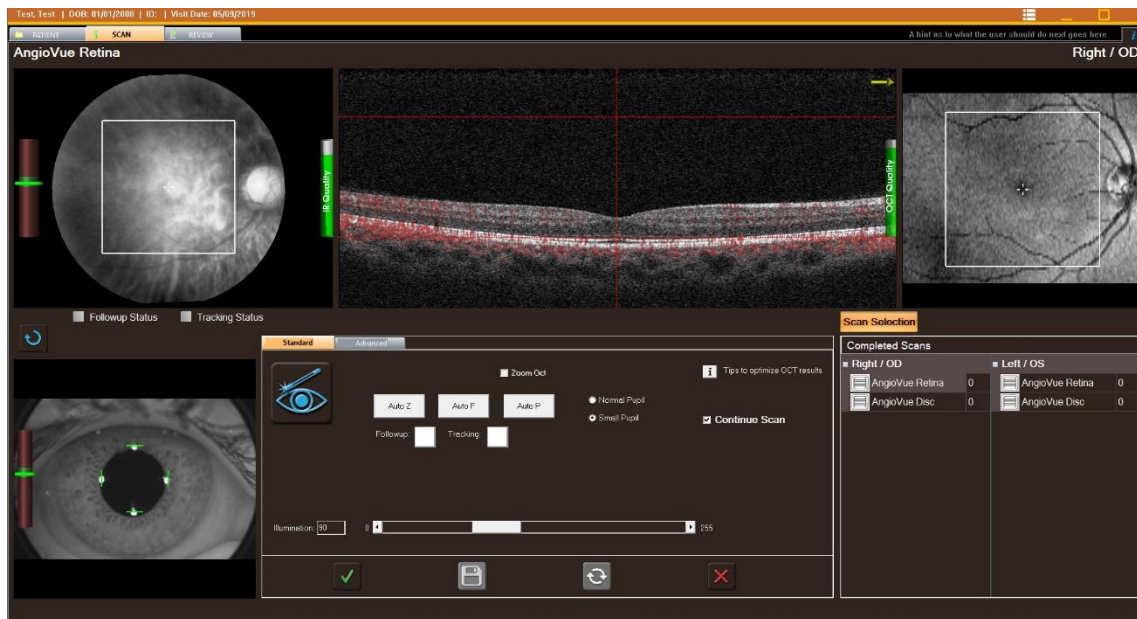


Figure 30 A Captured Scan (Save Button Active)

After scan capture, review the scan images for quality and completeness. The images will auto save except for AngioVue® scan which requires a selection. Selecting the

Scan again button  restarts the same scan.

When you are done scanning, use one of these methods to review scans:

- Click the B scans visible over the IR image and scroll.
- Click the **REVIEW** tab on the left to review the scan just completed.
- Go back to the PATIENT window, select the desired patient, visit and scan, and click the **Review** button or available report.

3.1.4 Disc Scan Capture

Disc scan capture is similar to Retina scan capture except the white dots and green lines in the iris image do not line up with the pupil center due to the offset fixation target; also, the OCT window is split into 2 windows to display one horizontal and one vertical B-scan. Both the Horizontal & vertical B-scans must be within the window, and if the B scan is cropped, the cube will be missing data.

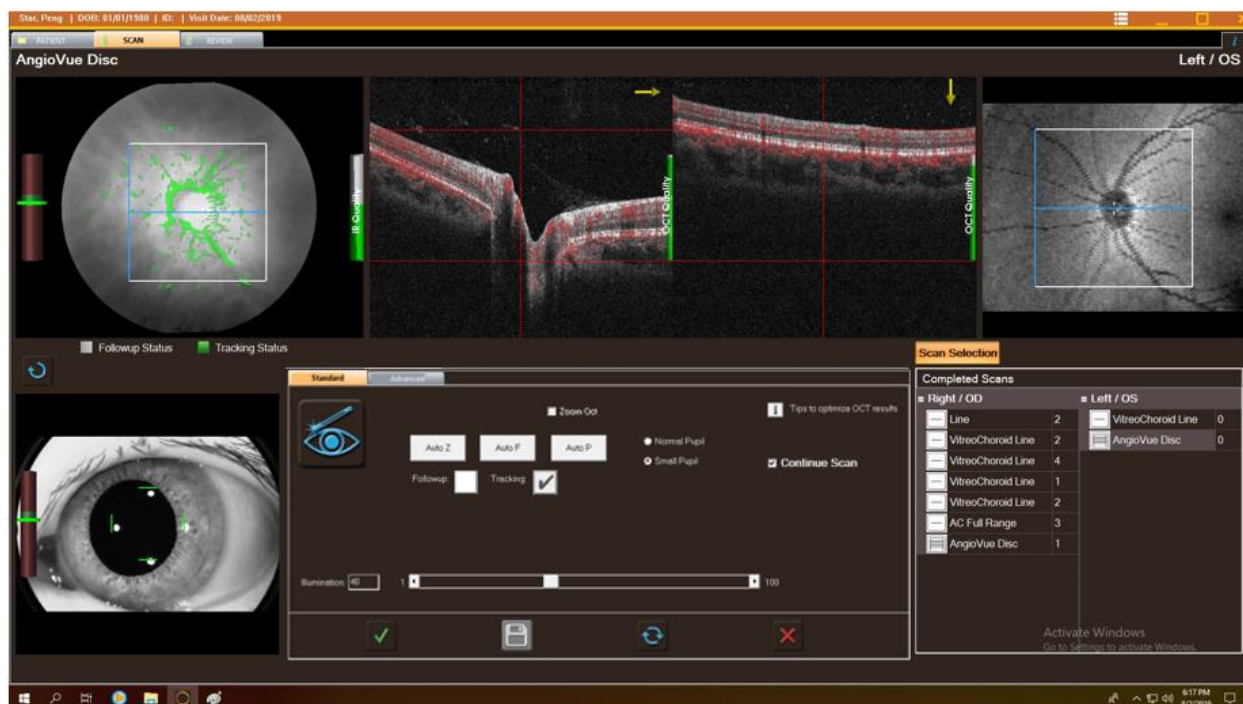


Figure 31 Disc scan capture

3.1.5 AngioVue Scan capture

Note: AngioVue® scans require the acquisition of a Fast-X scan and a Fast-Y scan together (continuous mode) or in consecutive steps (noncontinuous mode). In noncontinuous capture, the system acquires a Fast-X scan. Review the scan for severe eye movement. Then capture the Fast –Y. The user selects continuous or noncontinuous mode prior to starting the scan.

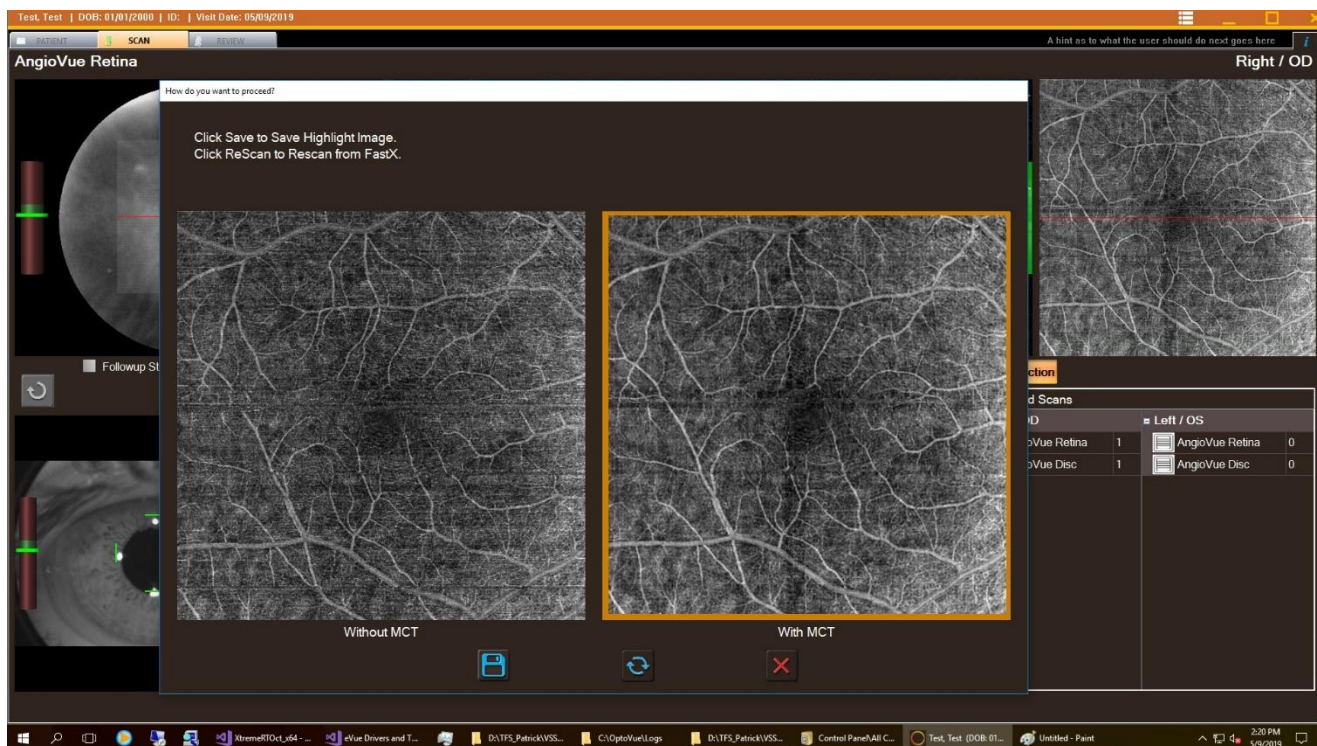


Figure 32 Continuous mode displays Fast-X and combined MCT for operator selection

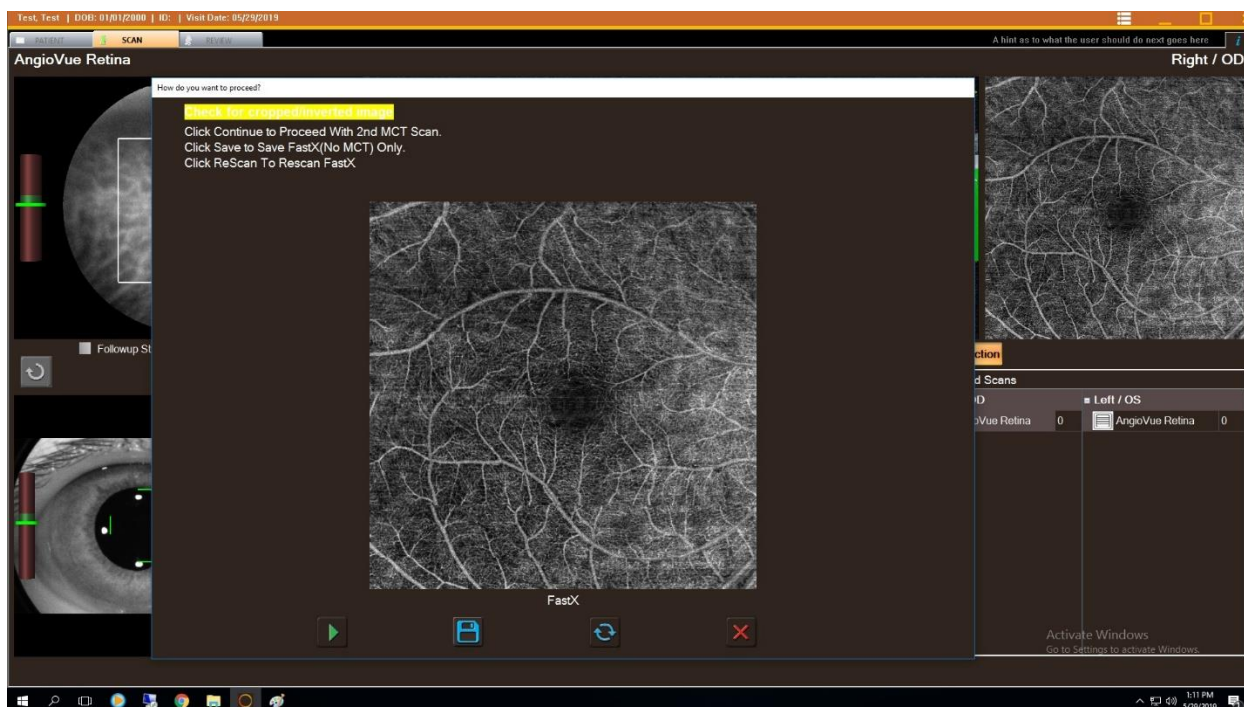


Figure 33 Noncontinuous mode displays a panel after X the user can save and continue or rescan

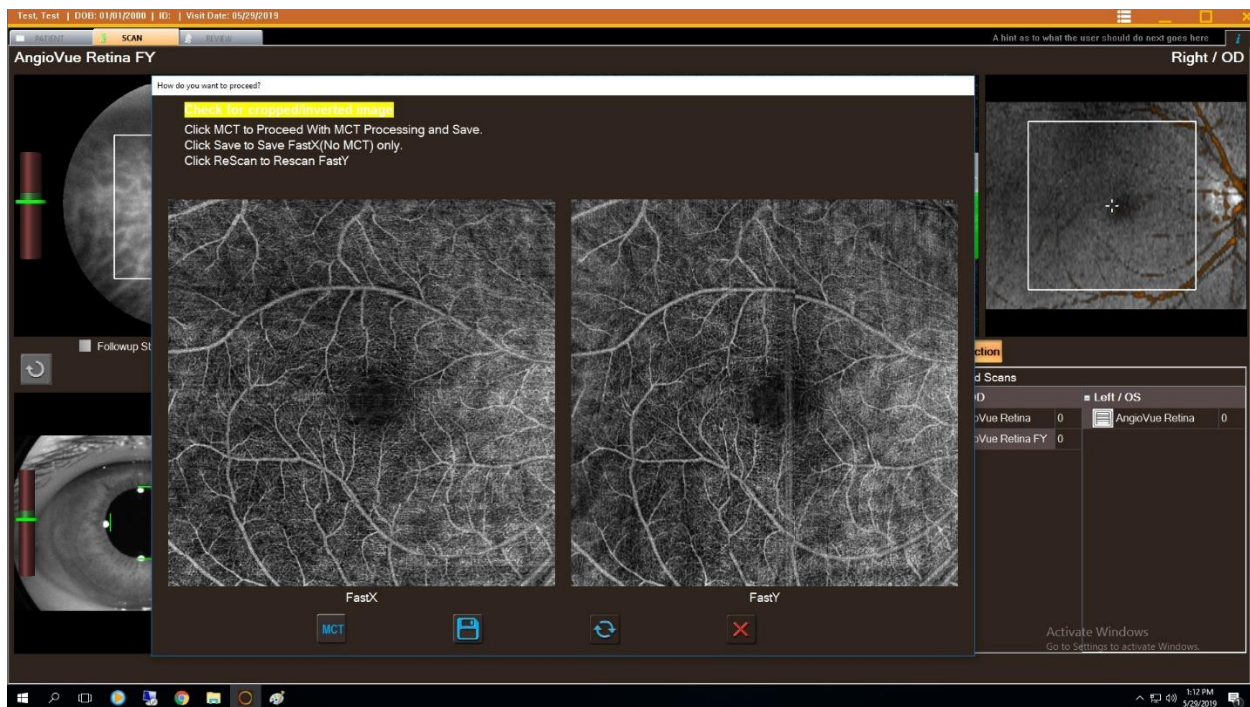


Figure 34 After Fast-X and Fast-Y the user has the option of saving the single Fast-X or merged MCT volume by selecting save button

If you are satisfied with the captured scan, click **Continue** or **joystick button** to proceed. If capturing sequentially (continuous mode), review Fast-X before continuing to the Fast-Y scan. Or Click **Rescan** to retake the Fast-X scan. Click **Cancel** to discard the Fast-X scan and start over.

When you use continuous, the Fast-Y scan begins automatically after Fast-X scan. The orange overlay in the video image (upper left) shows the large vessels from the optic disc as captured in the Fast-X scan, which assists in recognizing whether alignment has been maintained.

15. If necessary, adjust scan placement and optimize scan quality again. It is optimal to capture the second scan with minimal adjustment, so ask the patient not to move between scans. When ready, capture the Fast-Y scan.

3.1.6 OCTA Acquisition Alerts

If the acquired scan is suboptimal, the software may present pop-up alerts, as shown in the figure below. It is the operator's choice whether to rescan the last volume before saving or proceed with acquisition as usual. Alerts are recommendation only.

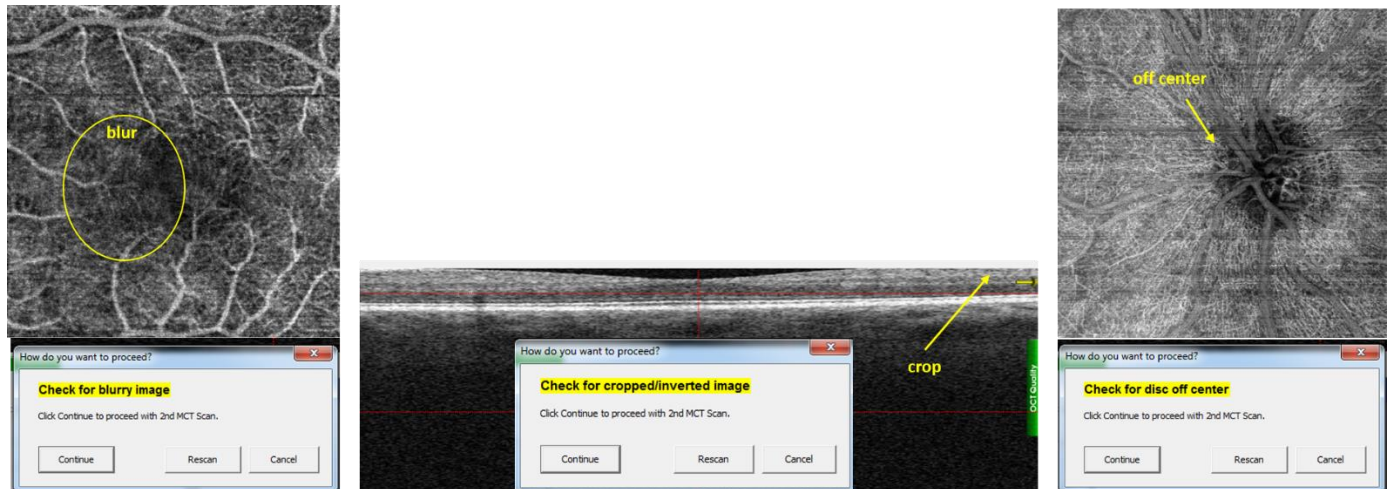


Figure 35 Examples of Scan Quality Alerts During Acquisition

3.1.7 Scan Quality Indicator (SQ)

SQ for OCT is derived from signal to noise ratio (SNR), and it provides an objective image quality index that correlates with qualitative assessment of image quality. The automatic scan quality ranges from 1~10. For AngioAnalytics™ a movement component is applied, and the recommended value is a SQ score of 6 and above. Score of 5 and below should be regarded with more diligence. An SQ number (1-10) will appear in the scan list as the scan saves and is displayed at the top of the AngioVue® reports. The SQ may be used as a quick indicator to determine which scan to open, if there are several of the same area / same scan pattern.

Scan		
02/15/2019		
	OD Retina Cube	14:07:54
	OD AngioVue Retina	14:08:33
	OD Wellness	14:09:12
	OD AngioVue Disc (Baseline)	14:09:47
	OD Disc Cube	14:10:37
	OS Retina Cube	14:11:13
	OS AngioVue Retina	14:11:42
	OS Wellness	14:12:19
	OS AngioVue Disc (Baseline)	14:12:57

Figure 36 Scan quality indicator

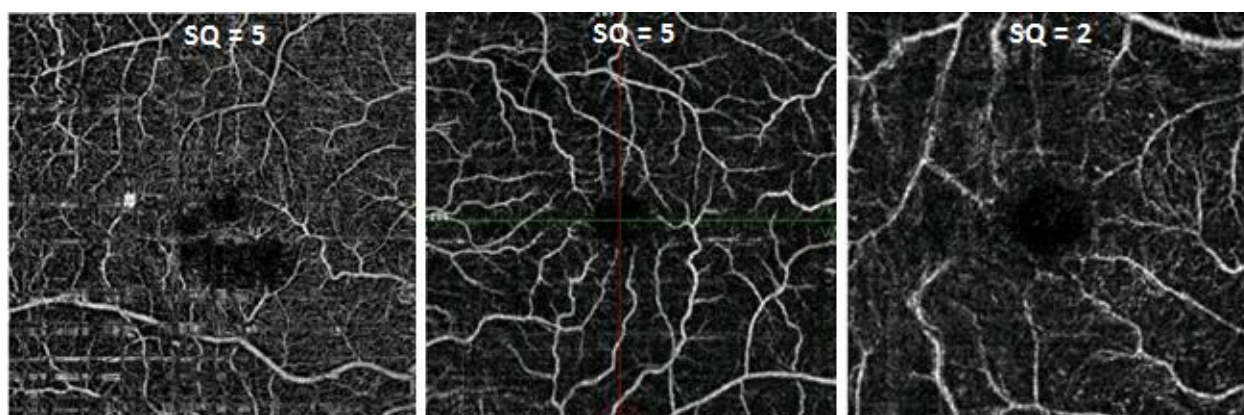


Figure 37 Examples of Scans with SQ<6

From left to right: SQ=5, due to motion, artifact lines (horizontal and vertical) are visible, as well as distortion of blood vessel pattern; SQ=5, due to low SSI, image is dark and lacking details of the smaller blood vessels; SQ=2, due to poor focus, blood vessels appear blurred.

3.1.8 Examples of Artifacts

The following AngioVue® image examples illustrate artifacts that are characteristic of OCTA scans due to movement of the eye during scanning.

 **Note:** In some cases when artifacts are present, it can be useful to select the **No MCT** button to view the Fast-X scan without motion correction, which may show useful anatomical information. Scans should be retaken if artifacts impair adequate visualization of structures.

3.1.9 MCT Motion Artifacts

Saccadic Motion

Saccadic eye motion appears as straight white lines parallel to scan line orientation (horizontal or vertical). Lines due to saccadic motion are easily recognized since they occur in straight lines. Motion Correction Technology (MCT) minimizes artifacts due to involuntary motion. The Fast-X and Fast-Y images below illustrate an amount of saccadic motion that MCT can minimize by integrating data from both scans, as seen in the MCT Merged scan on the right.

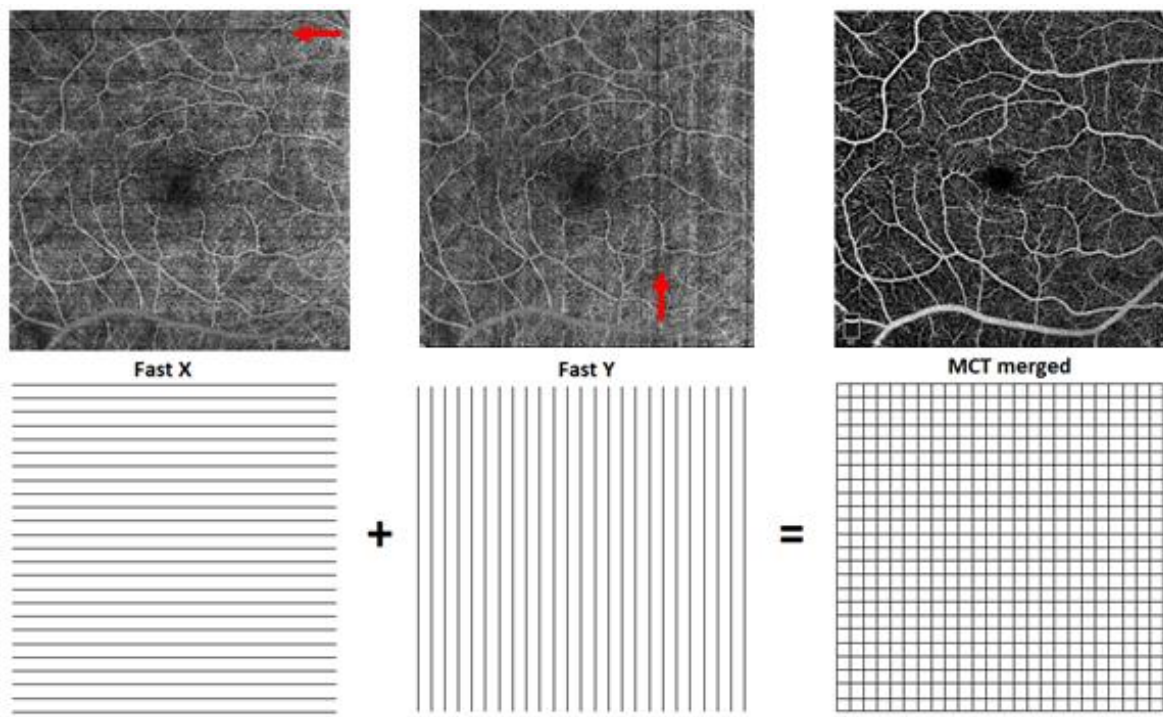


Figure 38 Saccadic Motion Fast-X and Fast-Y saccadic motion corrected on MCT Merged image

3.1.10 Local Weak Signal

Regional drop of the signal, either caused by floaters or by media opacity, can be recognized in the en face images and confirmed in corresponding B-scans.

3.1.11 Floaters

Floaters are a kind of ocular opacity, all of which partially or completely block the OCT scan beam and thereby reduce the signal strength reflected from the tissue beneath the opacity. When a floater has sufficient density and size, the underlying vessels can appear faint or missing, like a shadow, as illustrated below.

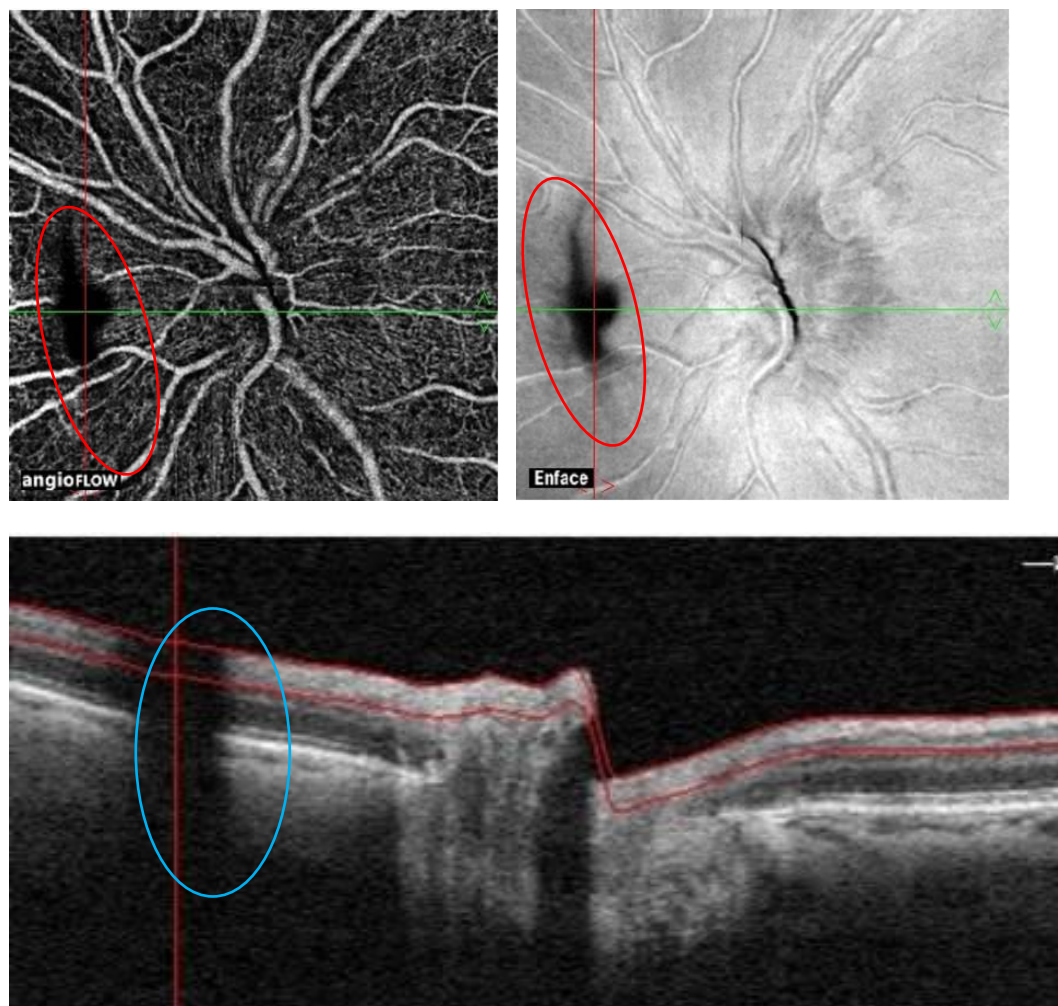


Figure 39 Floaters

You can recognize these “shadows” as floater artifacts by checking for the same pattern of shadows in the en face scan and B-scan. Thus, you can see that the shadow starts in the vitreous and proceeds through the retina, which shows that there was an opacity between the light source and the tissue. Local signal reduction by the floaters is not incorporated in the automated SQ calculations but may significantly affect AngioAnalytics™ data; therefore, metrics of scans with large floaters should be treated with caution.

3.1.12 Blinks

Blockage of the OCT scan beam during patient blinks results in the absence of data while the eye is closed. Blink artifacts appear as straight black lines, as shown below. These lines are easily recognized due to the loss of data. These artifacts are mitigated if acquisition is performed with tracking.

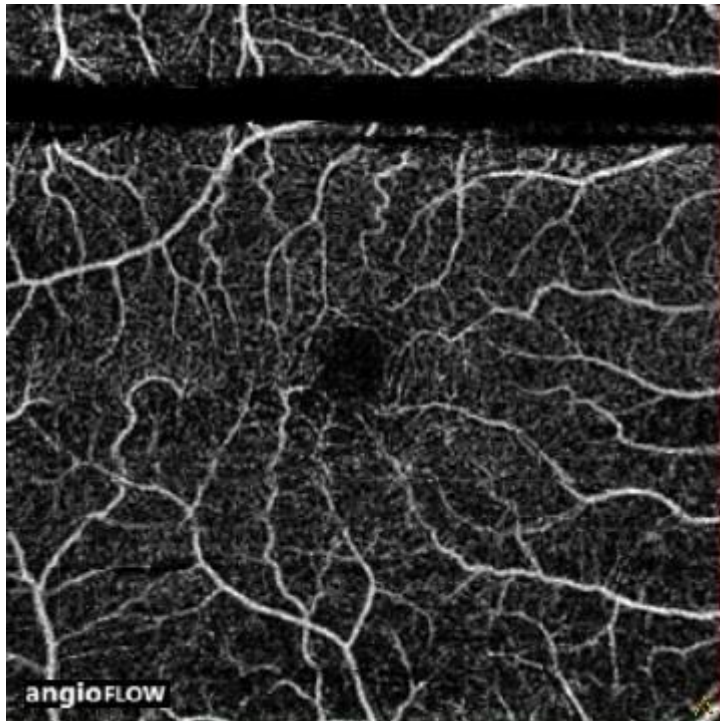


Figure 40 Blink

3.1.13 Excessive Motion Not Correctable by AngioVue® Software

Some eye motion is too great to be corrected by AngioVue® Software. The two images below illustrate artifacts due to excessive motion.

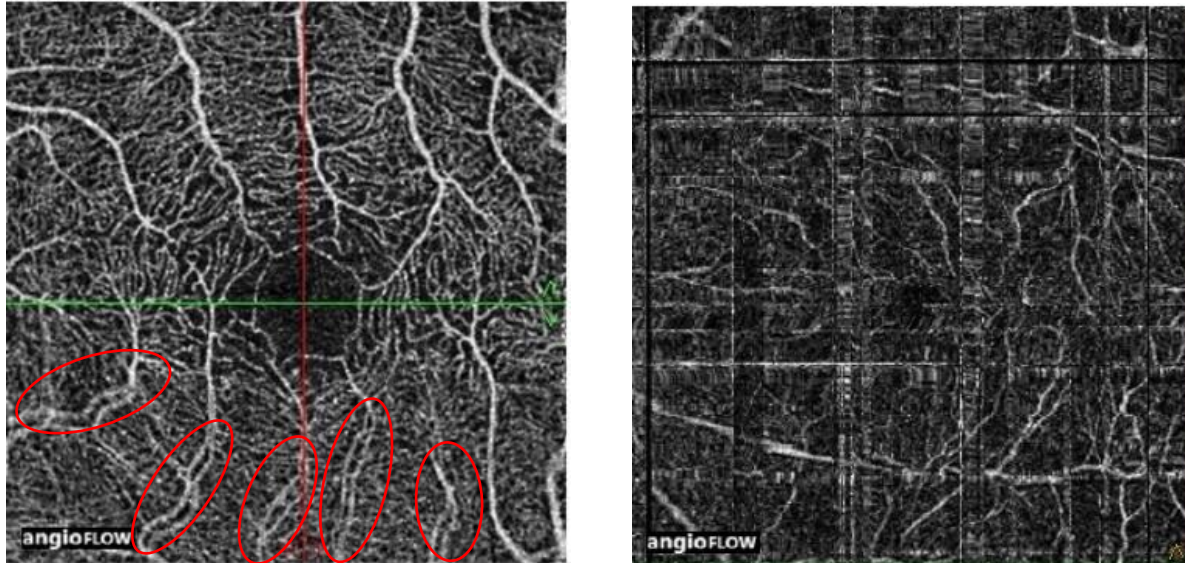


Figure 41 Excessive Motion

Double Vessel Artifact (left), Excessive Motion not Correctable by MCT (right)

Duplication of vasculature (left image) - Double Vessel Artifact

The highlighted areas in the left image above illustrate duplication of vasculature. This happens in cases where the motion correction algorithm is unable to combine the images because the eye motion was too great. Double vessel artifact is not incorporated in the automated SQ calculations but may significantly affect AngioAnalytics™ data; therefore, metrics of scans with double vessel artifacts should be treated with caution.

Muddled image (right image)

The image above on the right illustrates a case where overall eye movement was so great that it resulted in a muddled image lacking comprehensible detail. In such cases the excessive motion is usually captured by the SQ, causing reduction of SQ.

3.1.14 Cropped Image

B-scans placed too high or too low in the OCT window during scan acquisition causes image cropping. Cropped images can be recognized in the en face image and confirmed in the corresponding B-scan image as illustrated below.

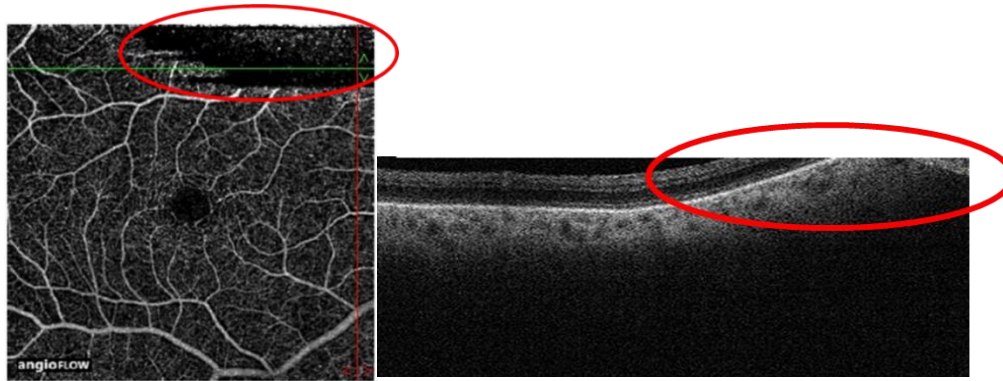


Figure 42 Image Crop

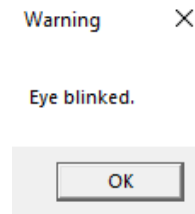
Example of image cropping affecting both the vascular en face image (left), confirmed in the corresponding B-scan image (right)

Cropping artifact is not incorporated in the automated SQ calculations but may significantly affect AngioAnalytics™ data; therefore, metrics of scans with cropping should be treated with caution.

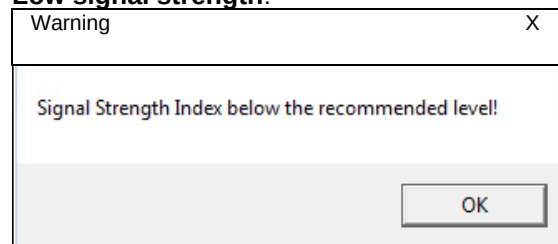
3.1.15 Joystick button Functionality

Joystick button is capable of closing a few message boxes that can appear while capturing scans. These specific message boxes are closable by joystick button:

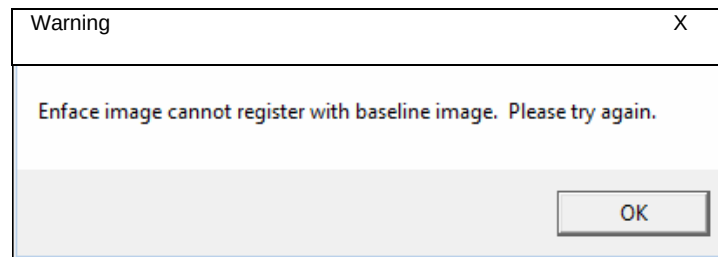
1. **Eye blink:**



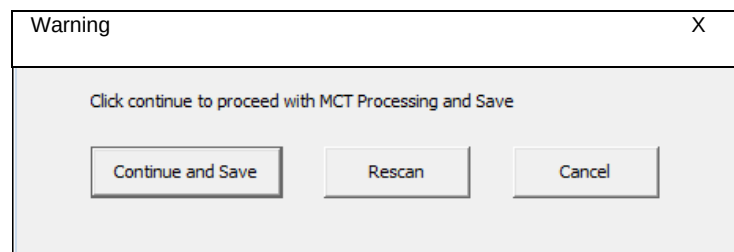
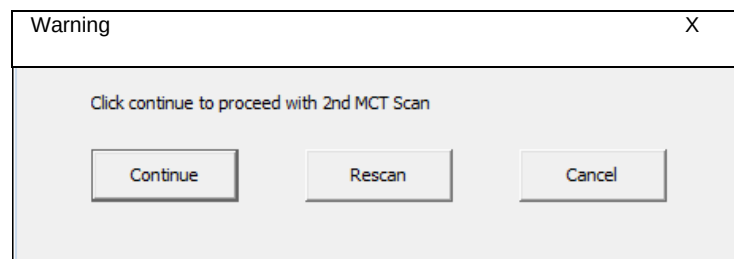
2. **Low signal strength:**



3. **Enface registration failure:**



4. **Continue scan with Fast Y and reduce artifacts** (during MCT scans):



3.2 Scanning Options

3.2.1 Scan Types and Protocols

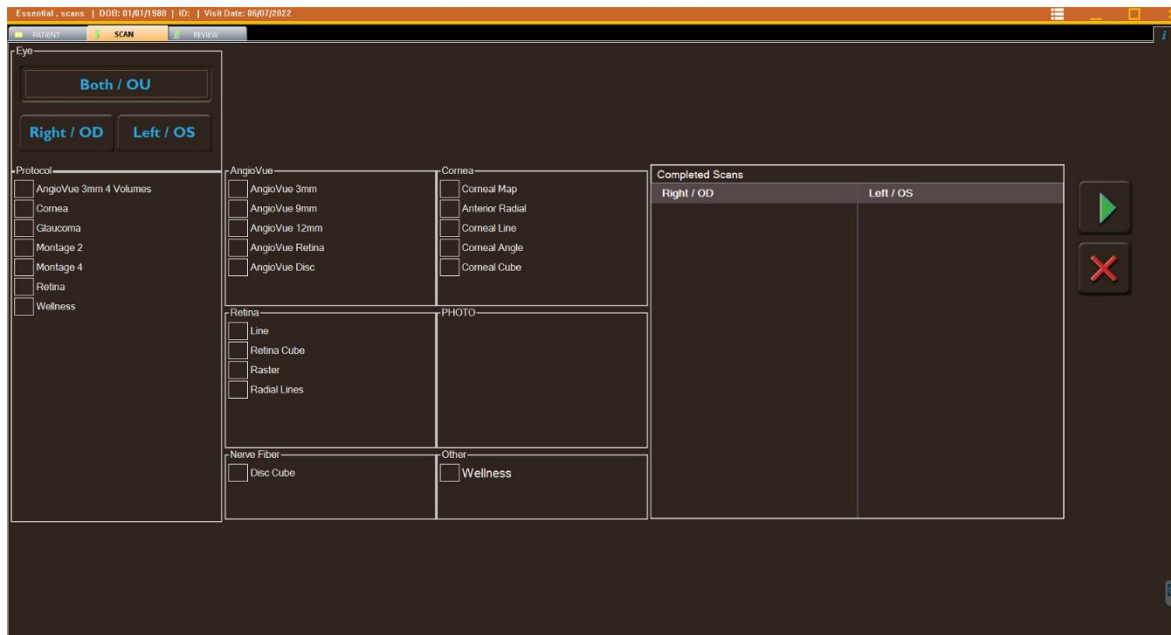


Figure 43 Select Scan Type or Protocol

The initial SCAN window presents scan types grouped in the categories **Retina**, **Nerve Fiber**, **Cornea** and **Protocol**.

 **Note:** See chapter [11 Scan Pattern Specifications](#) for a description of available OCT scan types.

3.2.1.1 Scan Protocols

Scan protocols group a set of scan types for sequential capture with a particular clinical purpose, or to apply a customized scan regimen. See section [9.4 Database Management Menu](#) for instructions to create, edit or delete scan protocols.

 **Note:** Optovue recommends that each practice either use the pre-installed protocols or set up its own protocols based on patient demographics. This enables you to select a protocol to capture all desired scan types sequentially. See section [9.4 Database Management Menu](#) for instructions to create protocols.

3.2.2 Scan Window Buttons

Scan window buttons. The Save button is unavailable until you capture a scan.

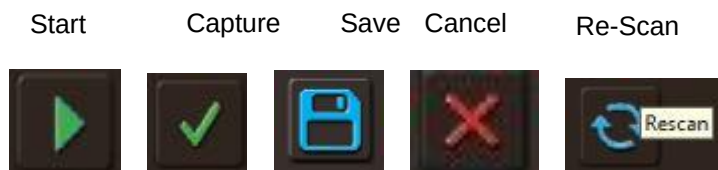


Figure 44 SCAN Window Buttons

 **Note:** To repeat a scan, double-click on the desired scan type in the list of completed scans or select Re-scan button. All non-OCTA scans are auto saved

3.2.3 Change Default Scan Settings

Use the **User Preference** dialog to change the default scan settings (among other things). From the main menu, click **Tools > User Preference** to open the **User Preference** dialog. Values for light & dark eye can be saved, the mean will become the default. Default flash values can also be saved. The lower area of the dialog has two tabs, **Scan Size**, **Average#** to set the default scan settings.

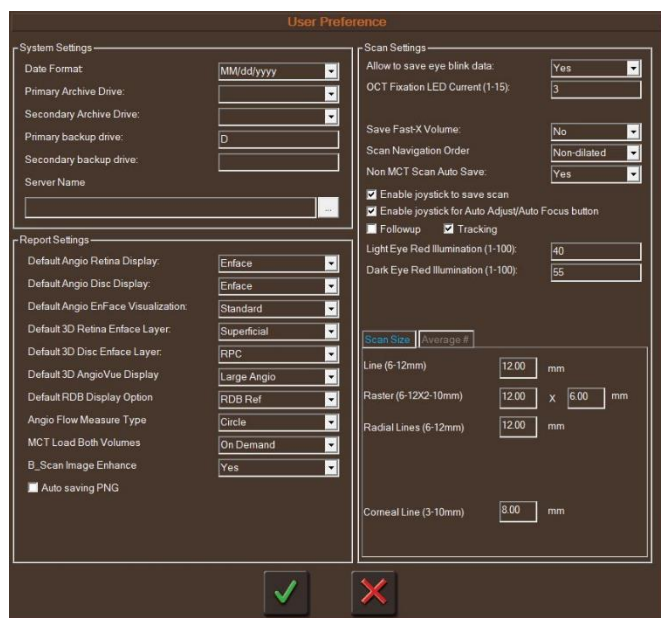


Figure 45 User Preference Dialog

Use the **Scan Size** tab to set the default length (and width for Raster and Grid) for the line scan types. Use the **Average#** tab to adjust the number of averaged scans used when tracking is on during scan acquisition. The values you set here become the

default values in the **Auto** tab of the SCAN window. For more information, see section [9.2.5](#) User Preference.

3.2.4 Standard Tab: Automated Scan Settings

After starting a scan, the **Standard** tab opens. (The available parameters and their ranges can depend on which scan type you are using.)

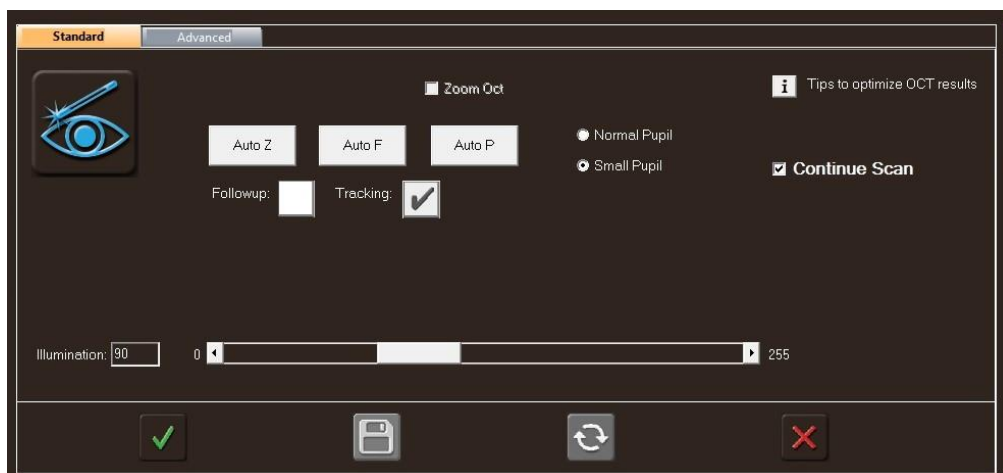


Figure 46 Scan Adjustment Options (Standard)

The **standard** tab helps you acquire good scans with minimal adjustments. (The **advanced** tab, covered in section [3.2.5](#) below, helps you make detailed manual adjustments to many scan and video parameters.) It provides the following functions:

 **Note:** From the main menu bar, select **OCT Image > Scan Parameter Setting** to set the default scan image to either gray scale or color. For details, see section [9.3.4](#).

- **Illumination:** Enter a value in the **Illumination** field or drag the slider to adjust illumination manually.
- **Auto Adjust:** By default, clicking **Auto Adjust** executes **Auto Z**, **Auto F** and **Auto P** in combination. (You can select which functions to execute when you click **Auto Adjust** in the **Auto Adjust Setting** field in the User Preference dialog—see section [9.2.5](#).) You can also execute **Auto Adjust** by double-clicking in the OCT scan window.
- **Auto Z:** Automatically adjusts axial length.
- **Auto F:** Makes automatic spherical adjustments to offset refractive error.
- **Auto P:** Automatically adjusts polarization.
- **Capture:** Use the green checkmark or joystick button to capture the scan.

- **Cancel:** Use the red X button to cancel the scan.

3.2.4.1 Follow-up Mode

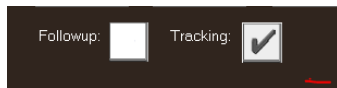


Figure 47 Follow-up and Tracking Mode Buttons

Follow-up mode is selected when the box is checked, and off when it is blank. When you are repeating a scan done on a previous visit for this patient, you can use Follow-up to repeat the scan location and rotation of the previous scan. Repeat scans using Follow-up cannot be moved or rotated. Turning Follow-up off allows you to move or rotate the scan. Follow-up mode does not take into account changes in fixation relative to the previous scan.

 **Note:** You may have to guide the patient's fixation to achieve alignment of the scan to the previous visit.

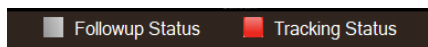


Figure 48 Follow-up and Tracking status indicators

In Follow-up mode, follow up status indicator is red if alignment is not correct, and green when alignment is correct. The capture button turns green when the tracking is green a majority of the time, indicating correct, or close to correct alignment. If the check mark stays red the operators still has the option to capture but with the understanding the location is not confirmed. If you want to scan a different location, turn off follow-up mode to allow the scan reticule to be dragged to a different location.

3.2.4.2 Tracking Mode

Tracking helps to maintain scan placement when the patient blinks or moves their eye. Tracking is selected when its box is checked, and off when it is blank. Check the color of the indicator lights and tracking overlay; red not collecting, or green collecting. Tracking is available for the following scans: **Line, Raster, Radial, and AngioVue® scans.**

A good IR image of the fundus is important for follow-up and tracking because the system tracks image details to maintain scan placement. Image below shows examples of good and poor IR fundus images.

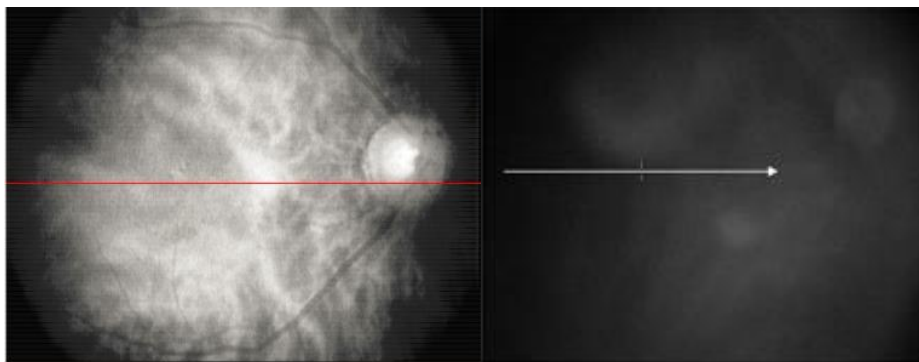


Figure 49 Good IR Image (Left) and Poor IR Image (Right)

The capture button turns green only when a good fundus image is present. The Status indicator light indicates good or bad follow-up. The cross will be gray if follow-up is not active. During scan capture, there are two quality bars one for the IR image and one for the OCT image. Try to maximize the green in both. The progression bar at the bottom shows scan collection progress. If scan capture takes longer than expected because tracking is on, you can turn tracking off during scan capture, and the system captures remaining scans with tracking off.

3.2.5 Advanced Tab: Manually Adjust Scan Settings

The figure below shows the **Advanced** tab.



Figure 50 Advanced Tab Selected

Use the available fields, arrow buttons or sliders to manually adjust scan and video parameters listed below. If a parameter is not available for adjustment, it is because that parameter is not applicable to the current scan type.

- **Gray Scale, Color & OCTA overlay:** Click one or the other to display the live OCT image in gray scale, color or with red OCTA overlay.

For the **Line**, **Raster**, **Radial**, and Retina scans, you can customize the scan using the **Scan#** and **Size** options.

- **Scan #:** Sets the number of scans used for averaging. Averaging reduces the noise in the OCT image and yields a B-scan with reduced speckling. Eye or operator motion can limit the number of frames that are used in this process. Quick eye motion can also smear the OCT image and reduce quality.
- **Size (scan length):** Adjusts B-scan length. For the **Line** scan, radio buttons enable you to select the **Standard** (9 mm) and **Widfield** (12 mm) options.
- **Length (mm):** Adjusts length of scan line(s).
- **Width (mm):** Adjusts the width of applicable scans, spacing the lines of the scan evenly within the selected width.
- **Angle (degrees):** Rotates the scan pattern relative to the center. You can also rotate the scan by clicking on the scan graphic in the video window and scrolling the mouse wheel up or down.
- **Video Brightness:** Adjusts brightness of the video image (not the OCT scan).
- **Contrast:** Adjusts contrast of the video image (not the OCT scan).
- **Z Motor:** Click **Auto Z** or use the slider to vertically center the OCT scan in the scan window (between the dashed red lines). You can also center the scan by clicking in the scan window and scrolling the mouse wheel up or down.
- **Focus (diopters):** Click **Auto F** or use the slider to adjust focus of the OCT scan and thereby improve signal strength.
- **P Motor:** Click **Auto P** or use the slider to adjust scan polarization and thereby improve signal strength.
- **Vitreoretinal** or **Chorioretinal** radio buttons: **Vitreoretinal** presets the scan parameters to achieve highest signal strength above the RPE. **Chorioretinal** presets the scan parameters to achieve highest signal strength below the RPE. **Note** that the red dashed lines in the scan window shift up for a vitreoretinal scan; they shift down for a Chorioretinal scan.

_____End of section_____

4 Review and Edit Scans

This chapter describes review of OCT scans, including editing and measurement functions. Click the **REVIEW** tab to open the Review window.

4.1 Review Window

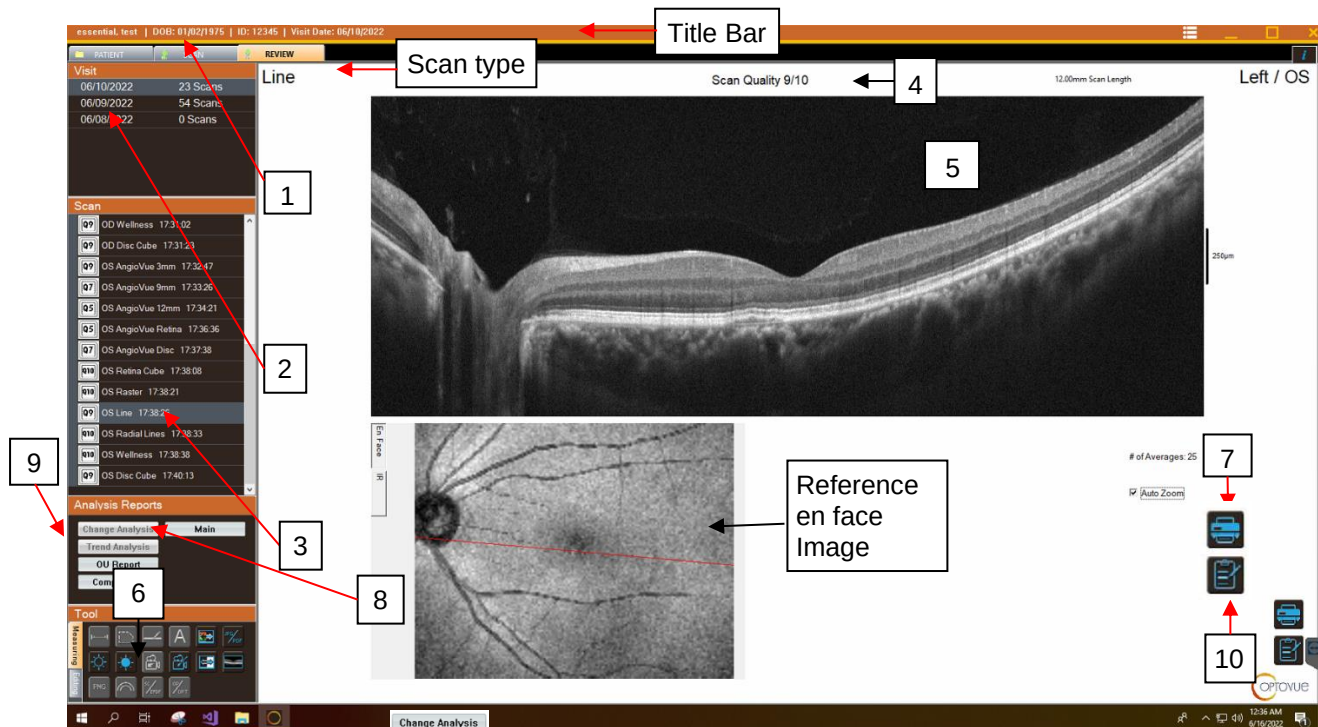
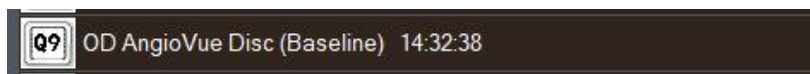


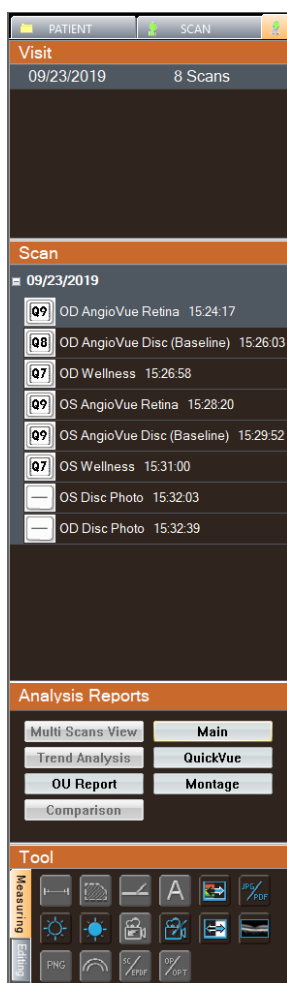
Figure 51 Review Window Components

- | | |
|-------------------------|--|
| 1 -Patient selected | 7- Print button |
| 2- Visit list | 8- Change Analysis button (if data avail.) |
| 3- Scan list | 9- Analysis Report buttons |
| 4- Signal Quality value | 10- Comment button |
| 5- B-scan windows | |
| 6- Tool pane | |

Each scan type has its own report that opens in the Review window when you select the scan. Descriptions of the reports for each scan type are in Chapter 5 OCT Scan Reports. (For review of anterior segment scans, see the CAM section of the User Manual.) This section describes features of the Review window common to many scan types. Other features and options of the Review window are available with reports of specific scan types.



4.1.1 Patient, Visit and Scan



Selected patient shown in banner

The **Visit** list chronologically sorts the selected patient's visits and shows the number of scans on each visit. Select the desired visit.

The **Scan** list chronologically sorts the scans—identified by scan type—from the selected visit. Click to display the default report for the desired scan. AngioVue scans with measurements are marked "F" "NF" or "F+NF"

Shows available reports

Figure 52 Patient Visit and scan list

The left side of the Review window provides a list of patients, visits and scans to choose for display, and a set of tools to use with the currently displayed scan. Signal Quality

The Signal Quality Index (SQ) value appears near top center of each OCT report. It helps you determine whether the scan quality is acceptable or not. The SQ for OCT is based on the signal to noise ratio (SNR), and for AngioVue scans, a motion factor is incorporated. The SQ is not intended to be used alone to determine image quality. However, when the SQ is lower than the minimum recommendation of 6, Optovue recommends that you re-take the scan to achieve an SQ value above the minimum recommended, if possible.

4.1.2 Multi Scan View

Allows display of 2-8 en face and B-scan images of any same type scan patterns.

4.1.3 Trend Analysis

When more than 3 visits are available, the Trend report button allows display of first and last Optic nerve images or last 2 retina images, along with graphs for trend information.

4.1.4 Change Analysis Button

The **Change Analysis** button is available for Cornea Map and Anterior radial.

4.1.5 Comparison Button

The **Comparison** button is available for certain scan types when the same scan type has been acquired on two or more visits. Comparison applies to display of B-scans.

4.1.6 OU Report Button

The **OU Report** button is available for certain scan types when scans for both eyes have been acquired. Click this button and the system automatically displays the most recent scan for each eye, but you can choose a specific scan for each eye. **(The initial scan selected determines if the Retina or ONH /GCC report opens.)**

4.1.7 Comment Field

The **Comment** field is at the bottom of the report. Enter text here and it is saved when you exit the REVIEW window. The information you enter appears only with this specific scan; it does not appear with other scans or visits from this patient. Comments entered do appear on printed and PDF reports of the scan.

4.1.8 Print Button

Click **Print** to print the current report either to an electronic file (PDF) or to hard copy, depending on the printer you choose.

4.2 Tool Pane

The **Tool** pane provides various tools on its **Measuring** and **Editing** tabs. The figure below shows the **Measuring** tools. Callouts identify each icon. Functions not available for a given scan pattern are grayed out.



Figure 53 Measuring Tools

 **Note:** You must click the **View B-scans** icon (right end of second row) to use the first four tools, which are specifically for measurement and annotation of B-scans. Clicking **View B-scans** opens a new window that displays B-scans along with the same **Tool** pane at upper right.



Figure 54 A Sample B-Scan Window

If you right-click on the image, a menu gives you options to adjust its scale and zoom.

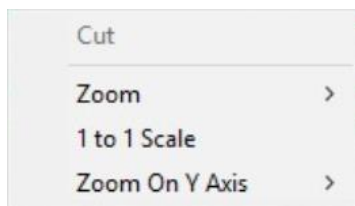


Figure 55 Right-Click Options on B-Scan Image

After you make measurements and annotations as described below, click **Save** to save your changes with the B-scan and return to the report where you started. If you make changes to the segmentation lines, click **Save and Reprocess** to recalculate measurements (such as thickness) based on the revised segmentation. Right click also provides an option to “Undo manual curves”.



Figure 56 Segmentation line correction

4.2.1 Tool Pane Measuring Tab Functions

-  **Distance:** To measure distances in an open B-scan, select this tool, click on the scan at the starting point and drag the endpoints. The distance in mm appears next to the line. Right-click on a line to access these options:

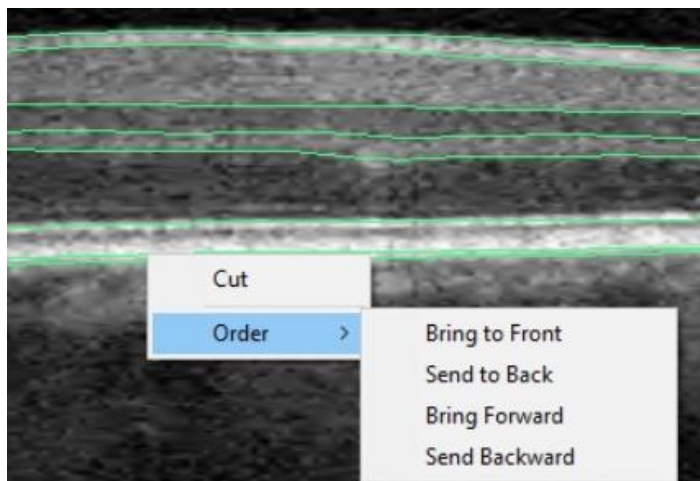


Figure 57 Line Right-Click Options

- **Cut** deletes the line.
- **Order > [selection]** changes the front-back order of overlays.

-  **Area:** Use this tool to draw a polygon and measure its area. To draw the polygon, click once to make each corner point, and double-click to close the shape. The area in mm² appears next to it. The same right-click options are available: **Cut**, **Order > [selection]** and **Properties....** Area has the same **Line** options plus **Fill** options, including Foreground Color, Background Color and Hatch style.

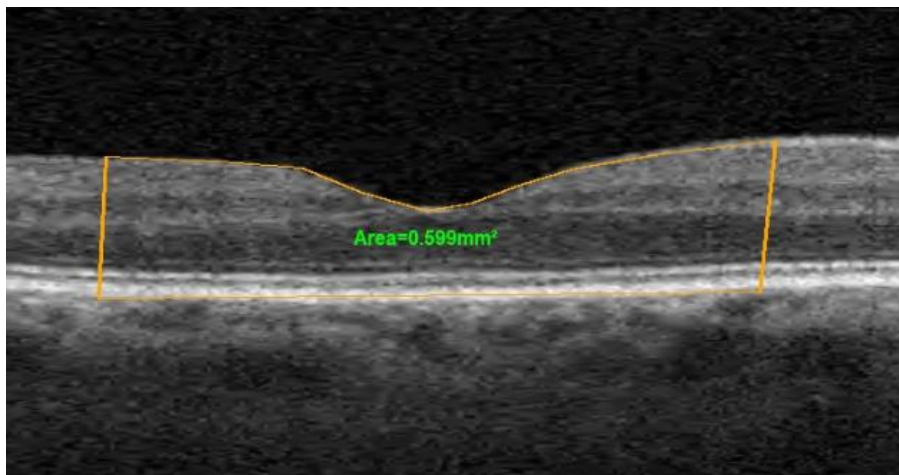


Figure 58 Area Fill Options

-  **Line:** Select this tool to draw a line on the B-scan, but note that this line serves as an annotation or indicator only; no measurement appears.
-  **Text Annotation:** Select this tool, click the image and type to annotate. Right-click on the text to change the font color, style and size.
-  **Color/Gray Scale:** Toggles scan display between pseudo-color and gray scale.
-  **Save Report as JPG:** This option is available in the Review window, but not in the B-scan window. Like a screen capture, click to save an image of the current report in jpg format. You can choose where to save the image and what to name it in the Save As dialog that appears.

 **Note:** Images made with the **Save Report as JPG** (camera) icon do not include patient and practice information. To include this information, use the **Print** button in the Review window, which prints the report either to an electronic file (PDF) or to hard copy, depending on the printer you choose.

-  **Darken:** Darkens OCT images.

-  **Brighten:** Brightens OCT images.
-  **Video Reset:** This option is available in the Review window, but not in the B-scan window. Resets video image brightness and contrast.
-  **Video Auto:** Automatically optimize video image brightness and contrast.
-  **Inverse OCT Image:** Inverts grayscale OCT images.
-  **View B-scans:** This option is available in the Review window, but not in the B-scan window. Displays all B-scans in a new window and enables you to modify the segmentation tracing (lines), and to make measurements and annotations.
-  **Export as PNG:** This option is available in the Review window if you have selected the **Auto saving PNG** checkbox and specified an export destination in the **PNG directory** field of the **User Preference** dialog—see section 9.2.5. This option is never available in the B-scan window. Like a screen capture, click **Export as PNG** to save an image of the current report in .png format. The system exports the report image automatically.
-  **Show/Hide Boundaries:** Toggle to show or hide segmentation lines on the OCT image.

4.2.1.1 Optional Anterior Segment Measuring Tools

Special measuring tools for anterior segment scans are available when the optional corneal anterior module (CAM option) has been installed.

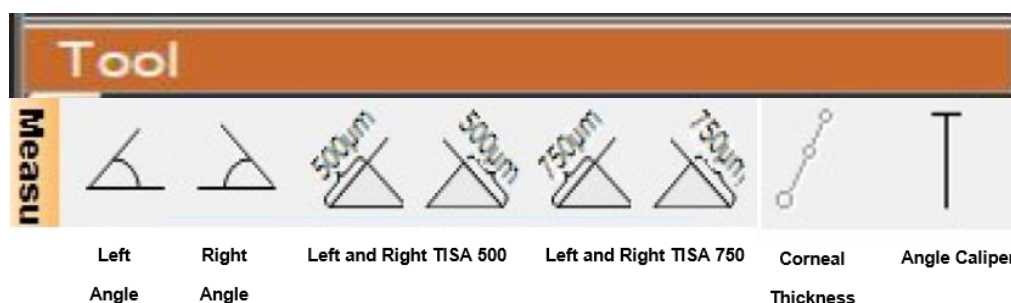


Figure 59 CAM Measuring Tools

- **Left Angle and Right Angle:** Use these tools to measure the angle opening. Click in the angle recess or scleral spur (your preference) to create the angle vertex. Click again to place angle lines along the surfaces of the iris and posterior cornea. The angle measurement appears next to the angle drawn.
- **Left and Right TISA 500 and 750:** Measures the trabecular iris surface area (TISA) at 500 μm or 750 μm from the scleral spur.
- **Angle Caliper:** Draw a line within the angle and measure its length. For example, use it to measure angle opening distance (AOD).
- **Corneal Thickness:** Draws and measures a line between the anterior and posterior cornea surfaces. Drag the line to measure at the point of interest, for example, to make a post-LASIK flap measurement.

4.2.2 Tool Pane Editing Tools

Click the **Editing** tab to display the editing tools. Use these tools on the B-scan images to edit the layer segmentation lines and to zoom the view. Click **Save** or **Save and Reprocess** to save the boundary changes; reprocessing, when applicable, implements the boundary changes into the report measurements.



Figure 60 Tools

-  **Select:** Click to select a segmentation line for editing or to deselect a zoom tool in use.
- **Edit Segmentation Lines:** Select Edit BND, when you select a segmentation line, its anchor points appear. To edit the line, click and drag anchor points. Right-click on the

line to add or delete anchor points using the menu that appears. **Right** click to undo segmentation changes.



Figure 62 Right-Click Options When Editing Segmentation Lines

- When you select **Modify Point**, drag each point where you want it to be.
- When you select **Del Point (Del for delete)**, double click the point you want to delete.
- **Properties...** opens the dialog to change line properties, as shown in the image above. The **Save** button saves any changes you made to the B-scan, but does not recalculate measurements based on segmentation changes.
- Click **Save & Reprocess**—when available—to recalculate measurements based on segmentation changes you made. Once you make segmentation changes, you cannot reprocess scans to revert to the automatic segmentation and measurements. Automatic segmentation and measurements occur only upon first processing after scan capture.

The **Clean Diagnosis Data** function does not affect manually edited segmentation, but it does reset fovea position and previous manual fovea correction will be lost. Please verify fovea location and manually adjust if needed.

-  **Pan:** Select this tool, click and drag to move the OCT image in the window.
-  **Show/Hide Boundaries:** Toggle to show or hide segmentation lines on the OCT image.

-  **Undo** and  **Redo**: Click to undo or redo last edit. Use it repeatedly to make multiple steps back or forward.
-  **Zoom In/Out**: Select this tool and left-click to zoom in, right-click to zoom out, or zoom to the size of the box you draw on the image.
-  **Zoom to Fit**: Zooms out to fit all B-scans in the window.

_____End of section _____

5 OCT Scan Reports

5.1 Scan Registration for Comparison

In some reports, you can compare multiple scans of the same type over time. To enable accurate comparison, these multiple scans must be accurately aligned, or registered, with each other. The system uses a baseline scan, also called a reference scan, for registration of multiple scans. Specifically, it uses for registration particular features, such as blood vessels and/or the fovea, in the SLO-like image.

Registration of multiple scans enables clinicians to compare scans over time and thereby track progression of retinal diseases and glaucoma. When multiple scans of eligible scan types have been acquired, the **Change Analysis** or **Comparison** button is present on the scan report. In the Trend analysis side by side aligned comparison is also available with large B scans.

Retinal morphology can change over time due to disease progression or surgery. In such cases, the clinician can acquire a new baseline scan. Subsequent scans from that point would use the new baseline scan. Scans prior to the new baseline scan continue to be registered against their original baseline scan.

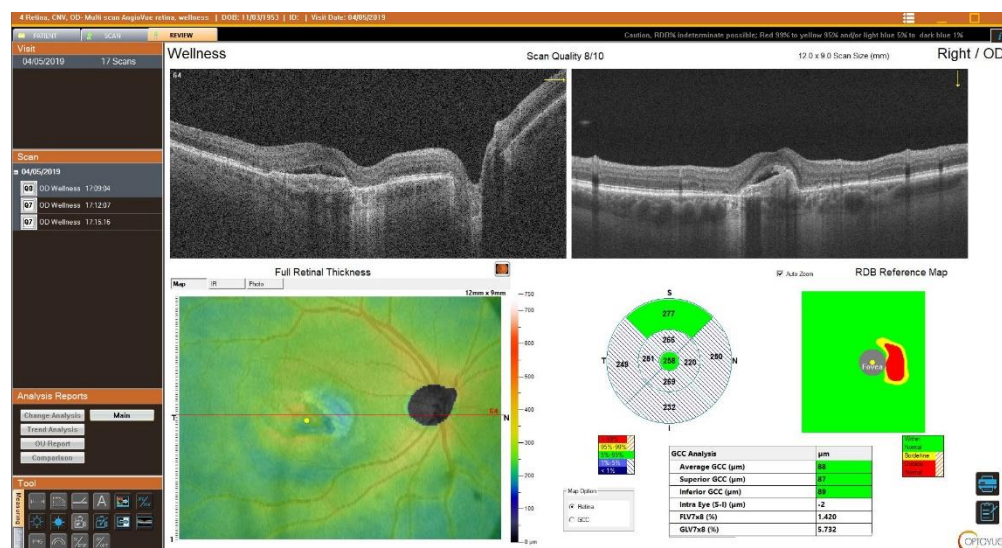


Figure 63 Wellness OCT Report

5.2 Retina Line Scan Reports

Three scan types designed to scan the retina use line scans (of adjustable length) singly or in combination. These are the Line, Raster and Radial Line scans.

5.2.1 Line Scan Report

The Line Scan averages multiple frames of the single line scan in its report, and reports the number of frames used in averaging, as shown in the image below. The scan length in mm, which is adjustable, appears beneath the B-scan image. Click the **Comparison** button to compare any two scans for this eye.

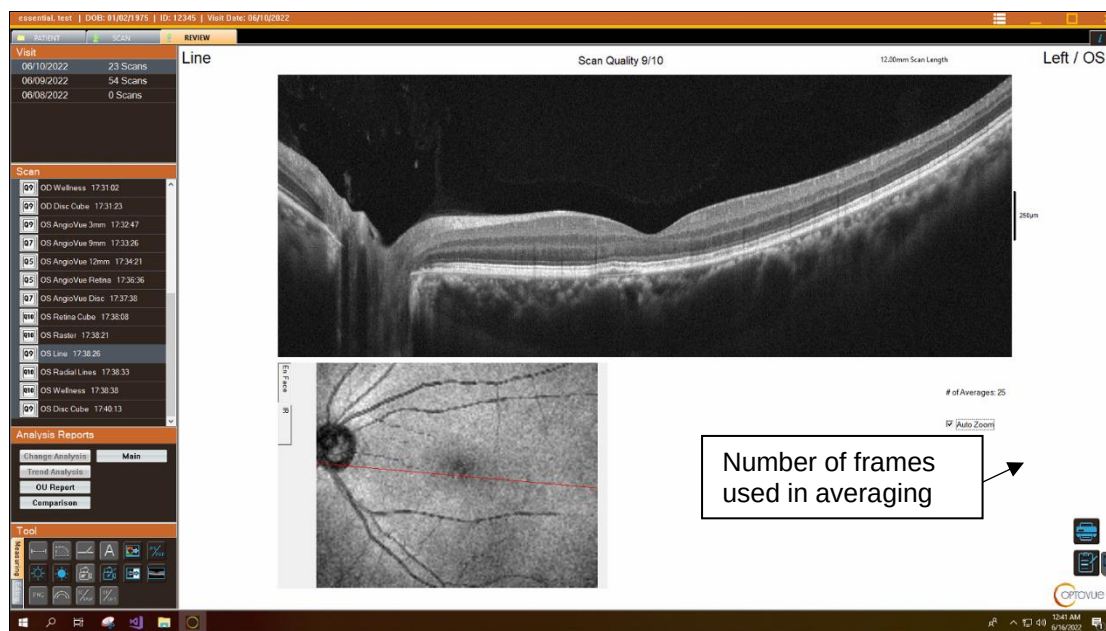


Figure 64 Line Scan Report

5.2.2 Raster Scan Report

The Raster scan report shows a stack of 21 horizontal line scans overlaid on the IR reference image, as shown in the image below. The length and width of the scan pattern are adjustable. The B-scans are for the currently selected line scans, which are highlighted in red on the reference image. Use the mouse wheel or the arrow keys to scroll through each of the scans. The scan size in mm appears between the B-scan images at the right. Select the **1x1**, **1x2** or **2x2** radio button to change the number of B-scans shown on the report. Click the **Comparison** button to compare any two scans for that eye.

A second print page maybe selected and printed to show more scans.

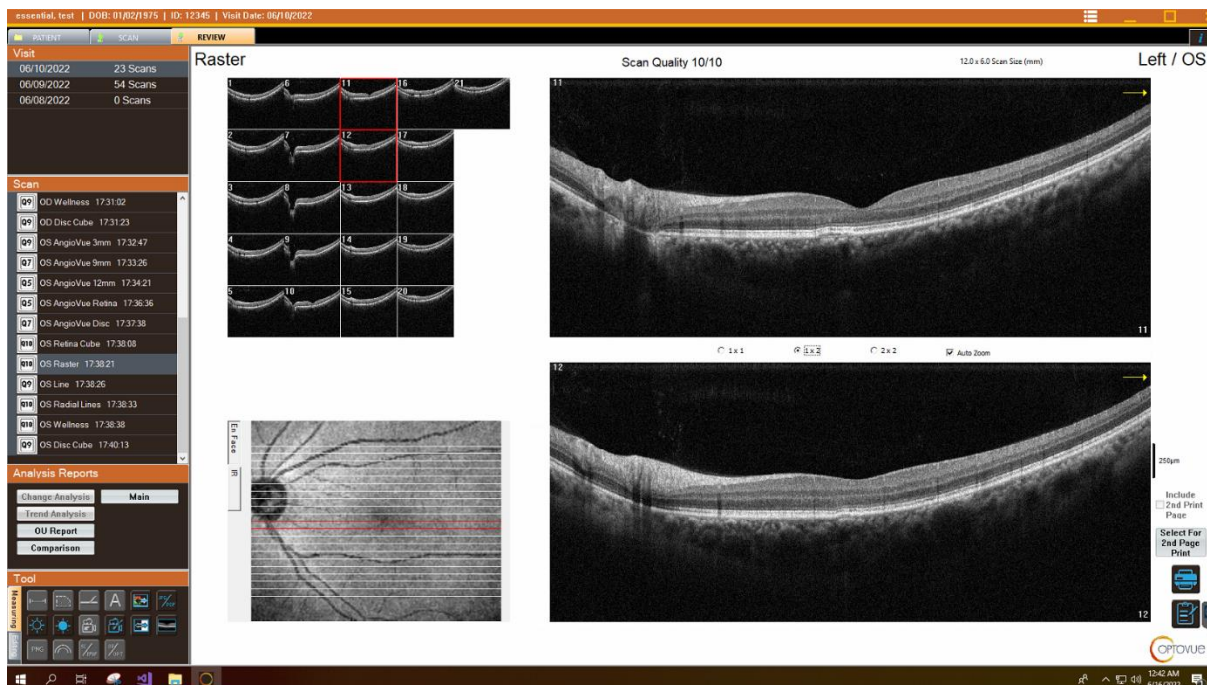


Figure 65 Raster Scan Report

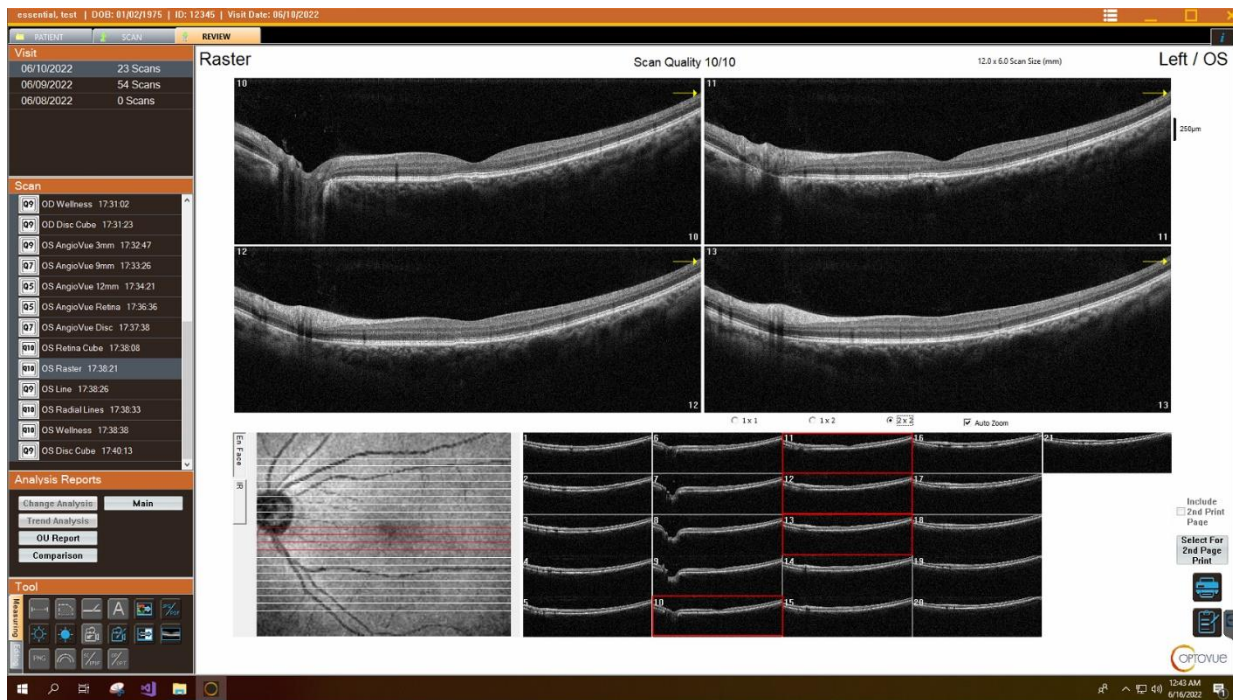


Figure 66 2x2 page of Raster Report.

Select button marked “Back to First page” to return to original page.

Raster Portrait Print page 1

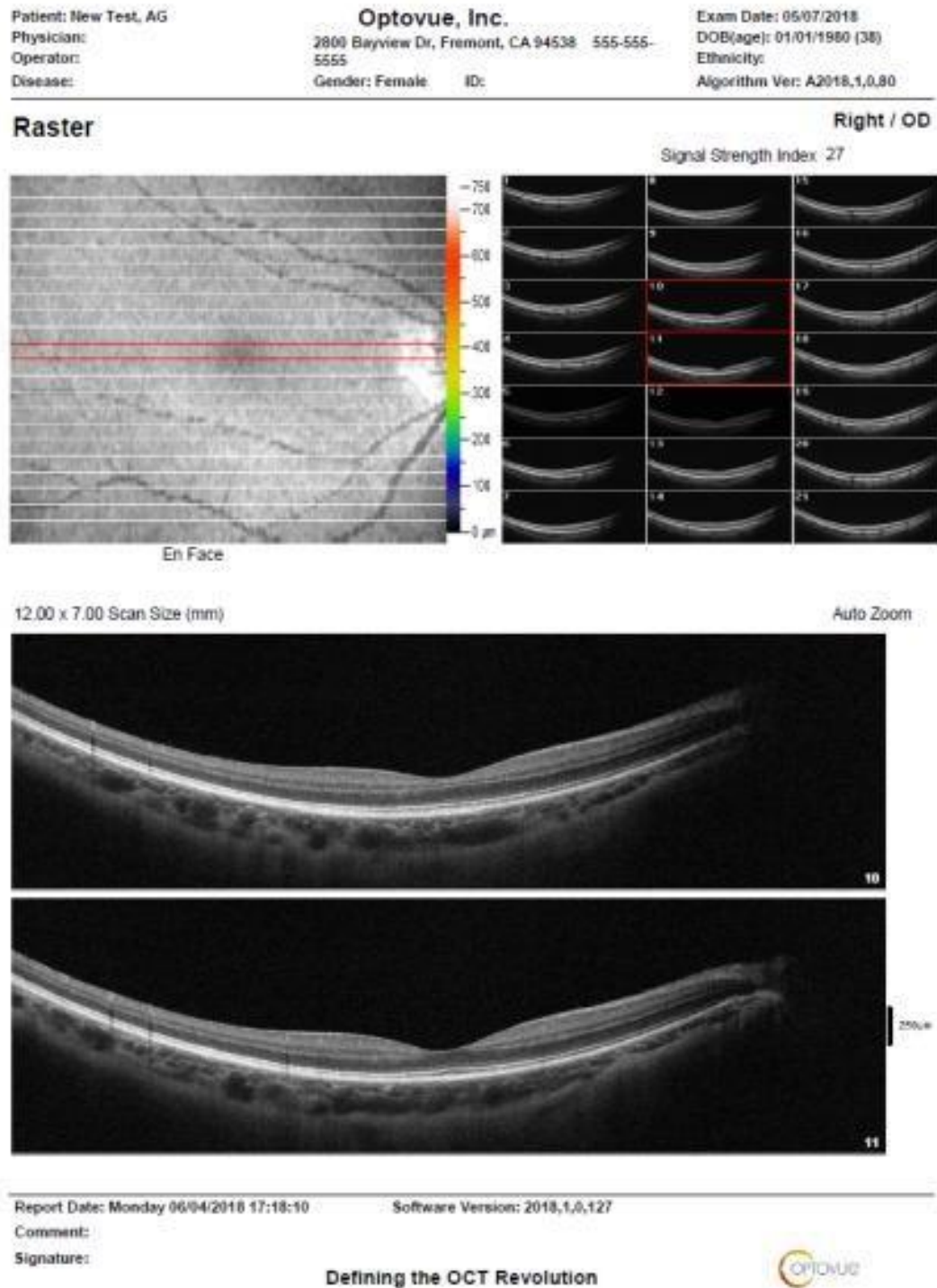


Figure 67 Raster Portrait Print page 1

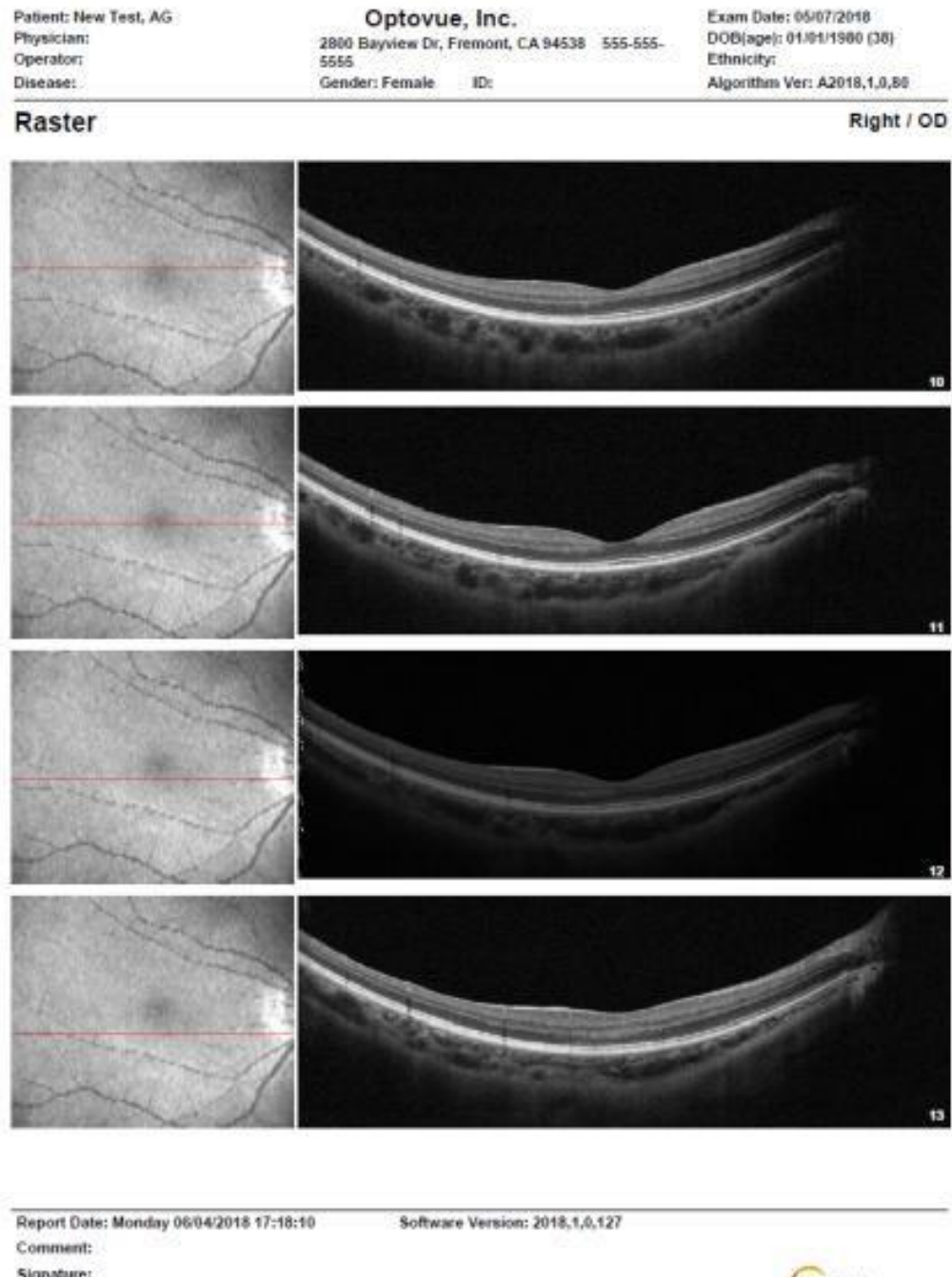


Figure 68 Raster Portrait Print page 2

5.2.3 Radial Lines

The Radial Lines scan report shows line scans arranged like spokes on a wheel overlaid on the reference image, as shown below. The B-scans are for the currently selected line scans, which are highlighted in red on the reference image. Use the mouse wheel or the arrow keys to scroll through each of the scans. The scan size in mm, which is adjustable, appears between the B-scan images at the right. Click the **Comparison** button to compare any two scans for this eye. The software allows you to compare radial line scans of different sizes.

Default report is horizontal and vertical crossline display like a cross line.

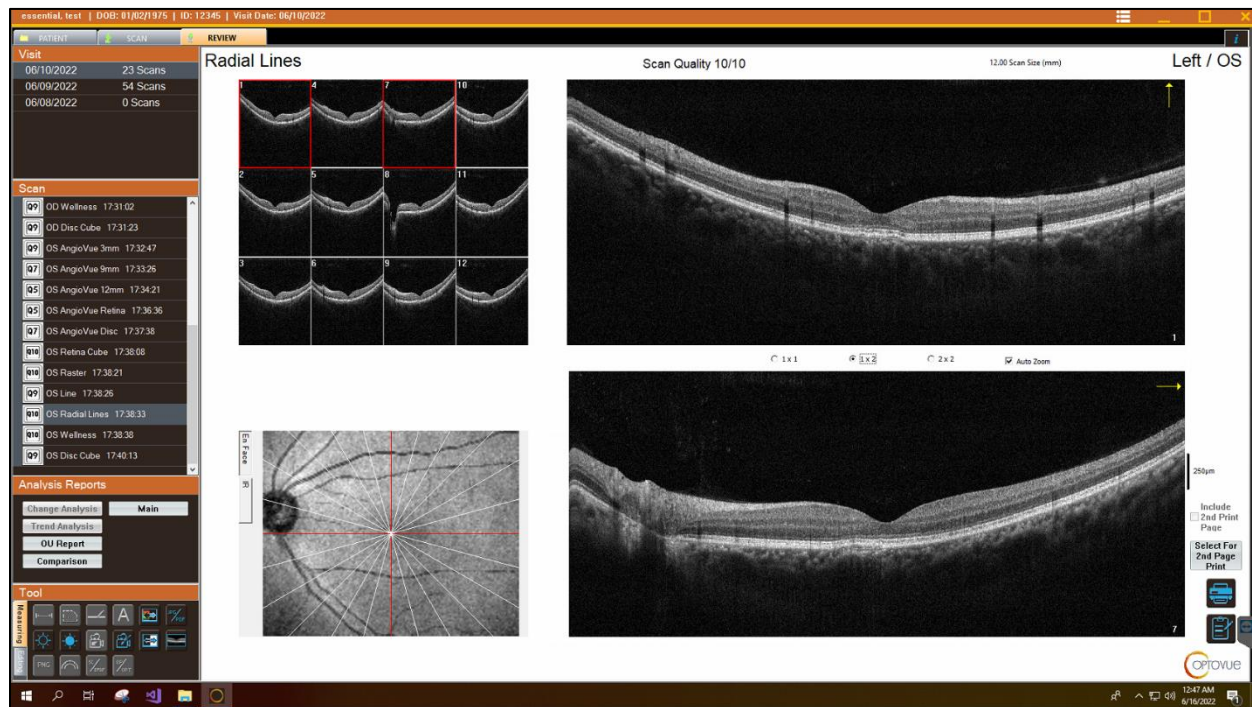


Figure 69 Radial Lines Report

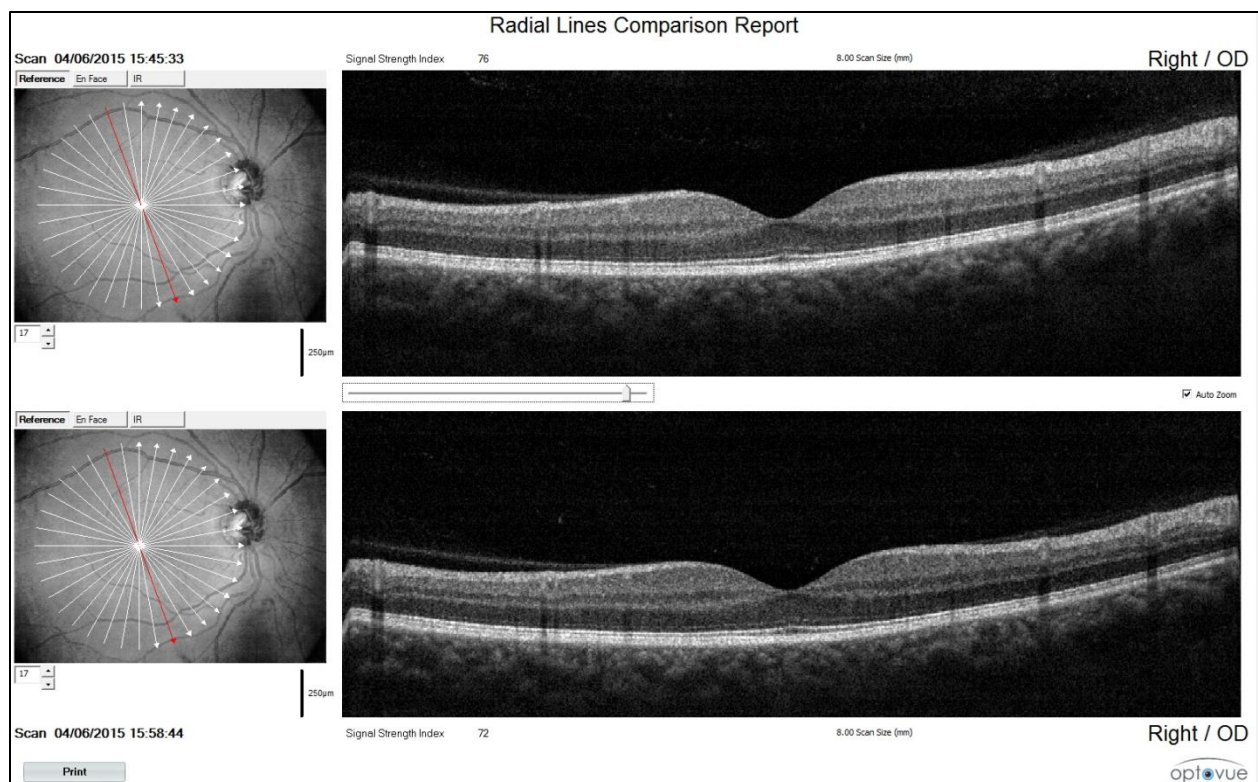


Figure 70 Sample Radial Line Report Comparing B-Scans from Two Visits

5.3 3D OCT Report Options

5.3.1 Retina Cube Report

The 3D Retina report shares a common layout as described below. Each has an image with four display option tabs at upper left, a horizontal B-scan at lower left and vertical B-scan on the right.

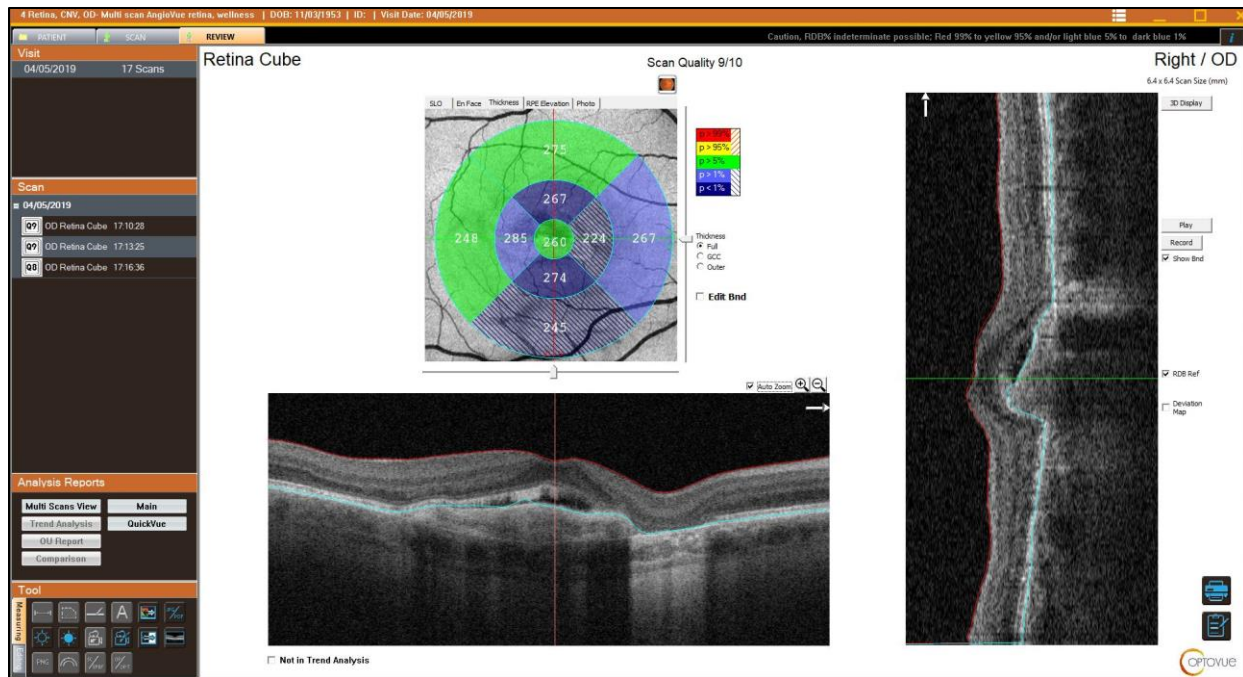


Figure 71 Retina cube Report

The green horizontal line and red vertical line on the upper left image correspond with the horizontal and vertical B-scans currently displayed. Click on the upper left image to select the B-scans where the lines intersect. Drag on the sliders for the green or red line to scroll through the corresponding B-scans.

The upper left image has four tabs to display the following optional images:

- **SLO:** Shows the SLO-like image.
- **En Face:** Shows the en face image. Use the radio buttons to the right to select one of four different layers for display: ILM, IPL, RPE, or RPE Ref. Use the **Upper Offset**, **Thickness** and **Lower Offset** fields (all in μm) to adjust these parameters for the current layer.

- **Thickness** (default): Shows the SLO image overlaid with retinal thickness using a color scale. The color key next to the map explains the thickness values (in μm) associated with the colors. Warmer colors from yellow, orange and red to white represent increasing thickness. Cooler colors from green to blue to black represent decreasing thickness.

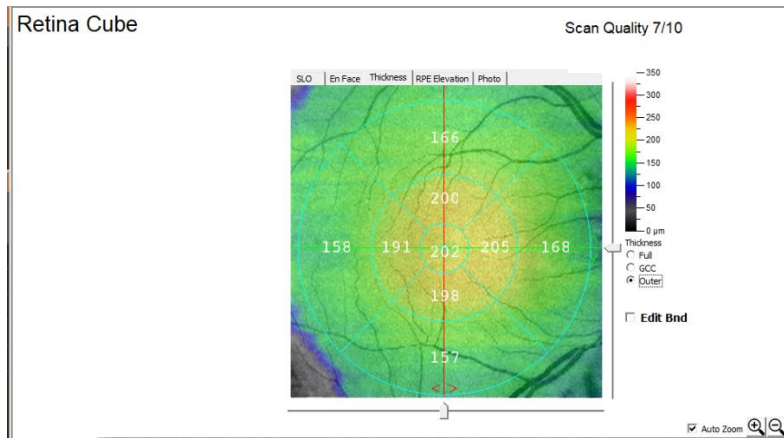


Figure 72 Retina Cube Thickness map

5.3.1.1 Retina measurements;

The reference database for macula scans is adjusted by age, and for Disc scans by age and disk area. If the data is not available due to poor image/calculation error, comparison with the reference database is not performed. If the age of the patient is out of the range of the database there are no RDB colors (range 18- 80 years)

5.3.1.2 Retina RDB

Retina measurements the thicker the layer, the larger the percentile.

If there is no overlap in 95% confidence intervals for the percentiles the color-coded RDB Reference Map shows regions where thickness is as follows:

(0,1) percentile Dark Blue

(1,5) percentile Light Blue

if percentiles overlap a Medium Blue color diagonal cross hatching is used

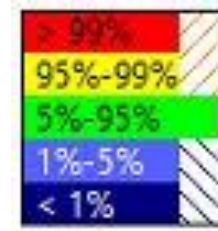
If there is no overlap in 95% confidence intervals for the percentiles the color-coded RDB Reference Map shows regions where thickness is as follows

(5,95) percentile Green,

(95,99) percentile Yellow

(99,100) percentile Red

if the 95st and 99th percentiles overlap an Orange color diagonal cross hatching is used.



- Use the radio buttons to select **Full** (ILM to RPE), **Inner** (ILM to IPL) or **Outer** (IPL to RPE) thickness for display.

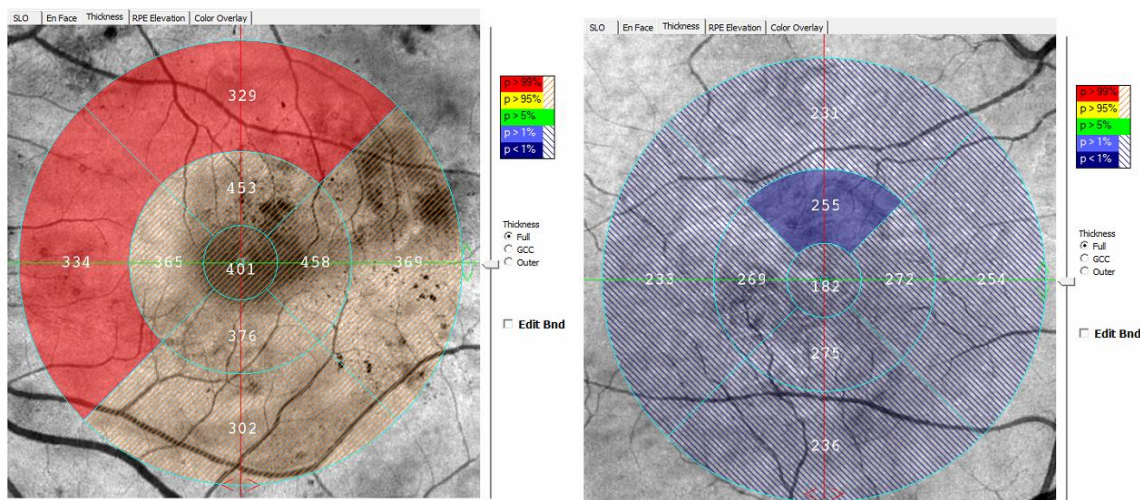


Figure 73 Thickness RDB map & ETDRS



Note: An RDB caution is shown above the report



5.3.1.3 GCC RDB

Ganglion Cell Complex (GCC) the thicker the layer, the larger the percentile.

If there is no overlap in 95% confidence intervals for the percentiles the color-coded RDB Reference Map shows regions where thickness is as follows:

(5,95) percentile Green,

(1,5) percentile Yellow

(0,1) percentile Red

If the 5th and 1st percentiles overlap an Orange color diagonal cross hatching is used.

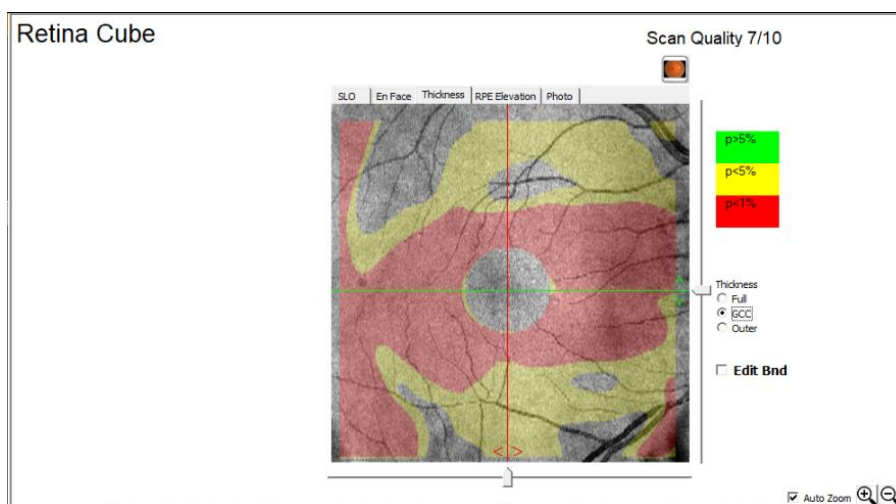
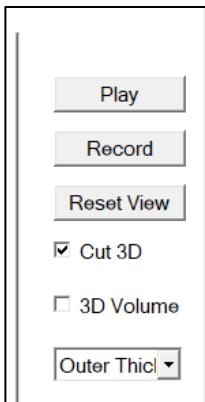


Figure 74 Retina cube GCC Deviation map

- Use the radio buttons to select **Full** (ILM to RPE), **Inner** (ILM to IPL) or **Outer** (IPL to RPE) thickness for display.
- GCC Deviation Map is not stratified by any factor such as age. The cutoffs for each pixel are based on the standard deviation of the Gaussian distribution over the same pixel location in the RDB normal population. It only shows thinning of tissue compared to RDB.

- Select the **Edit Bnd** (Boundaries) checkbox to show and edit the layer boundaries on the horizontal B-scan.
- **RPE Elevation**: Shows elevation of the RPE relative to a normalized plane. The color key next to the map explains the thickness values (in μm) associated with the colors. Warmer colors from yellow, orange and red to white represent increasing thickness. Cooler colors from green to blue to black represent decreasing thickness.

At upper right are the following controls:



3D Display: Opens the 3D Display.

Play: Plays through the horizontal and vertical B-scans.

Record: Records as you play through the B-scans.

Show Bnd (Boundaries): Shows the segmentation boundaries on the B-scans.

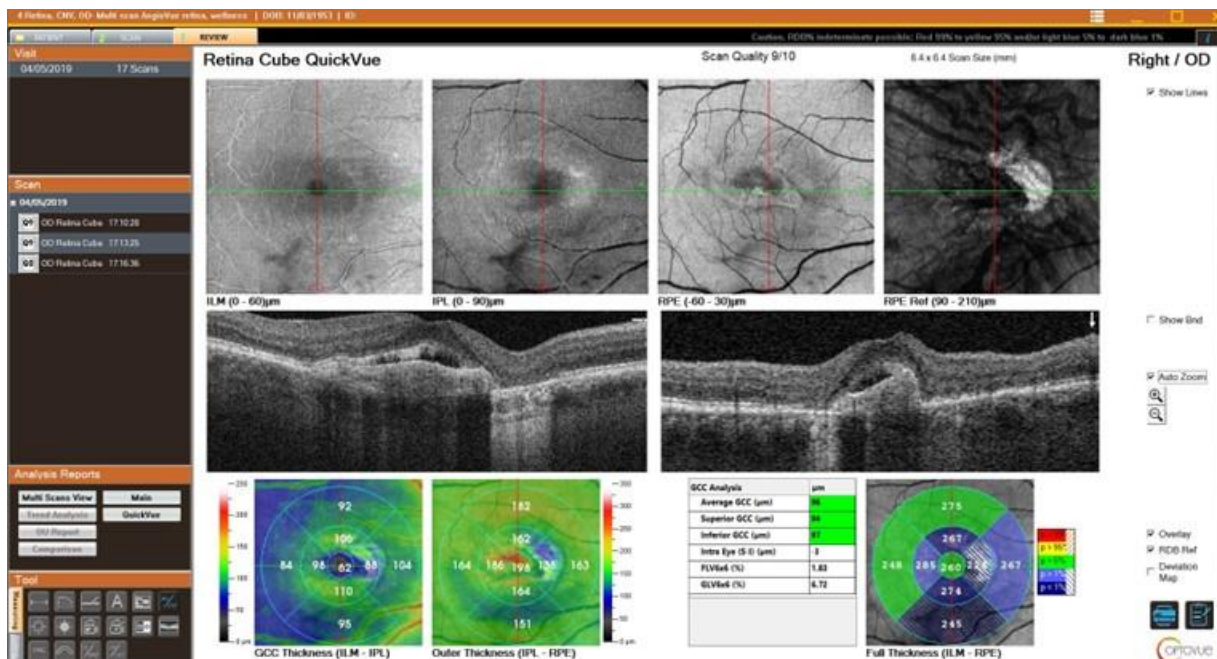


Figure 75 Retina Cube QuickVue with RDB ref

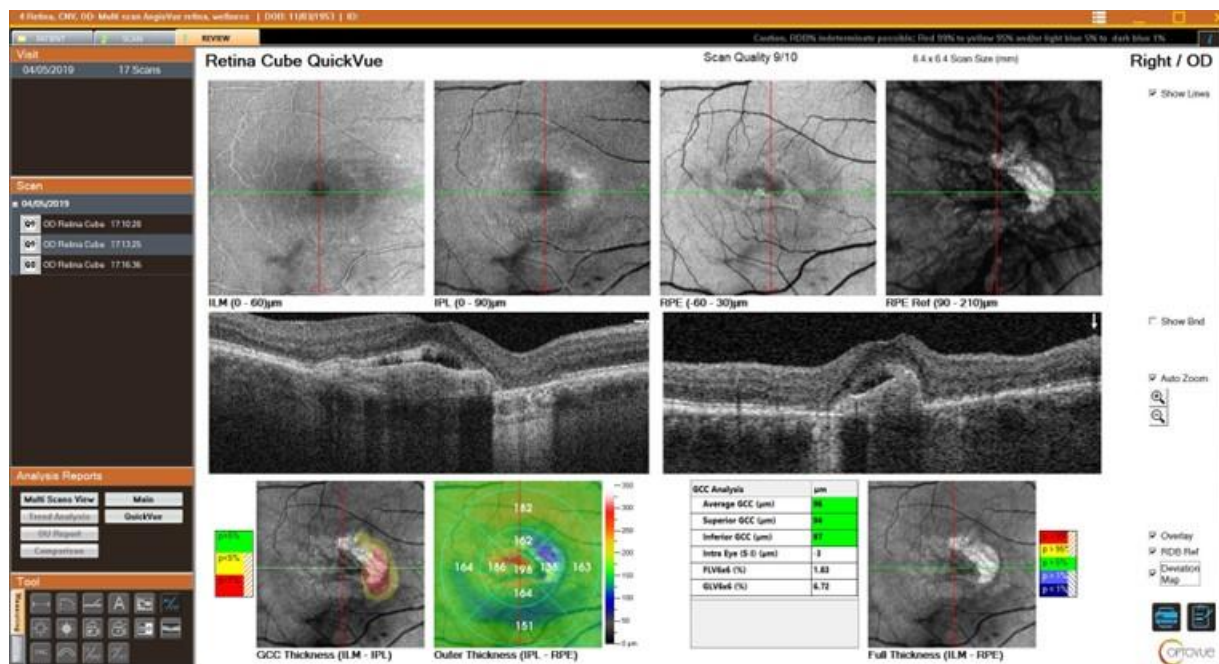


Figure 76 Retina cube with Deviation button selected

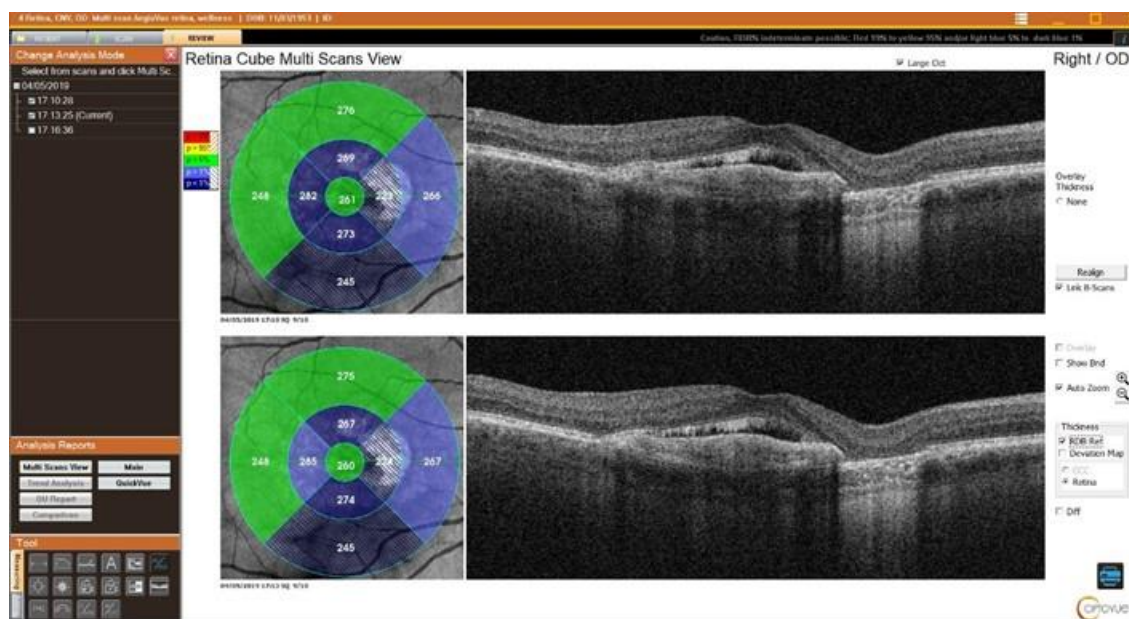


Figure 77 Retina Cube Multi Scan View (2 scans)

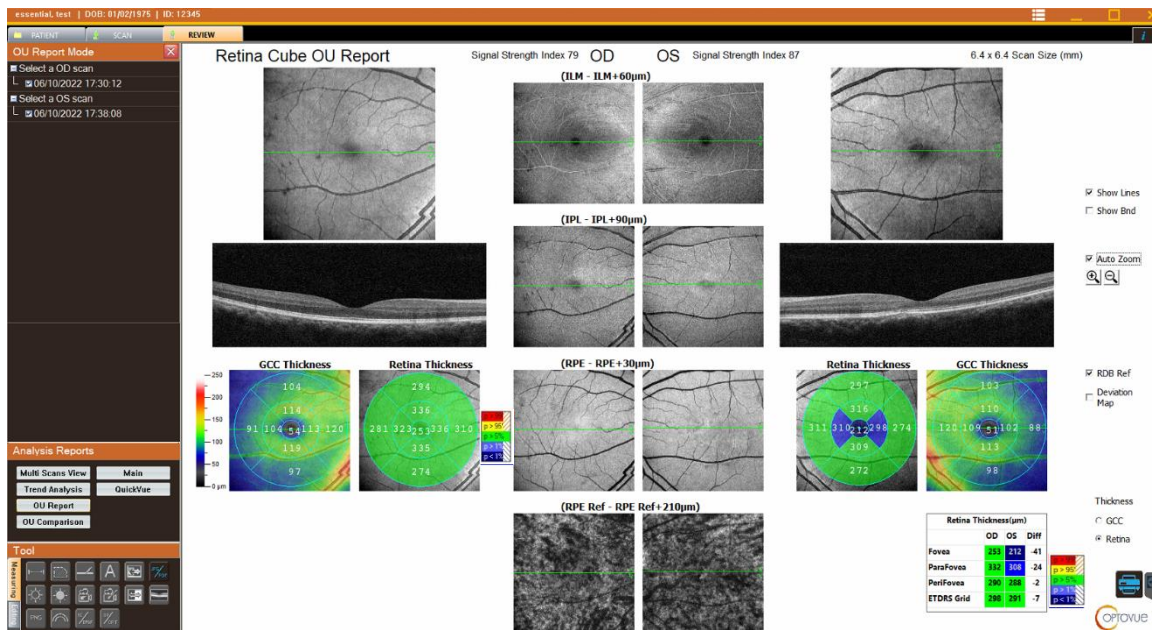


Figure 78 Retina cube OU Report

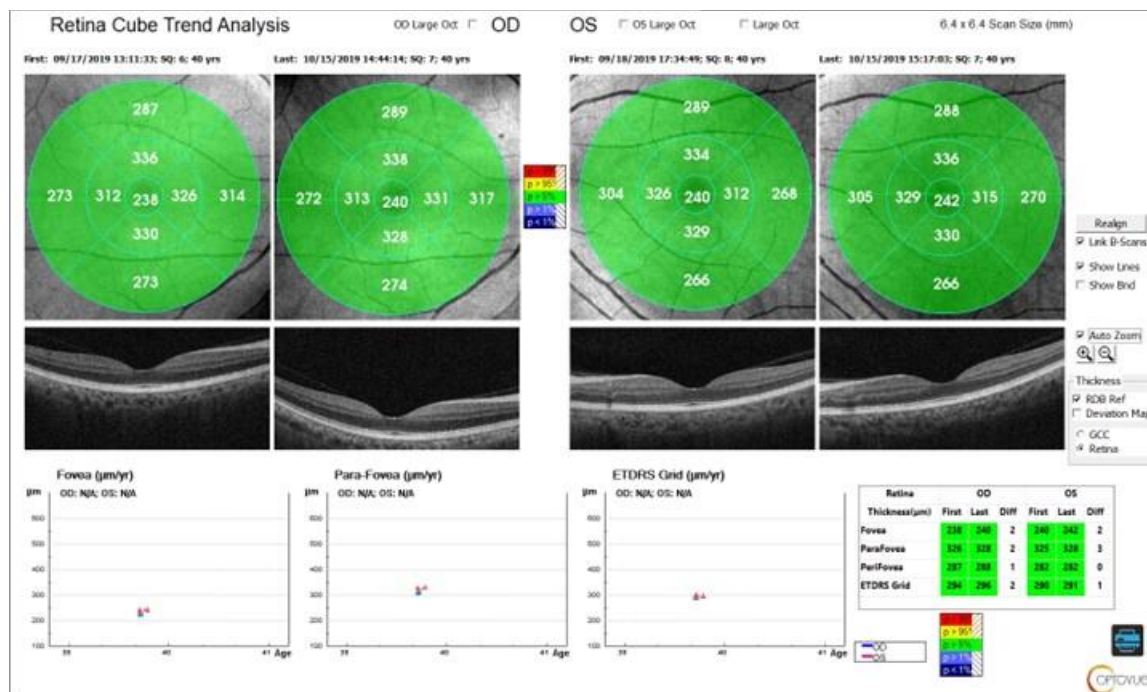


Figure 79 Retina cube Trend analysis, Retinal thickness RDB

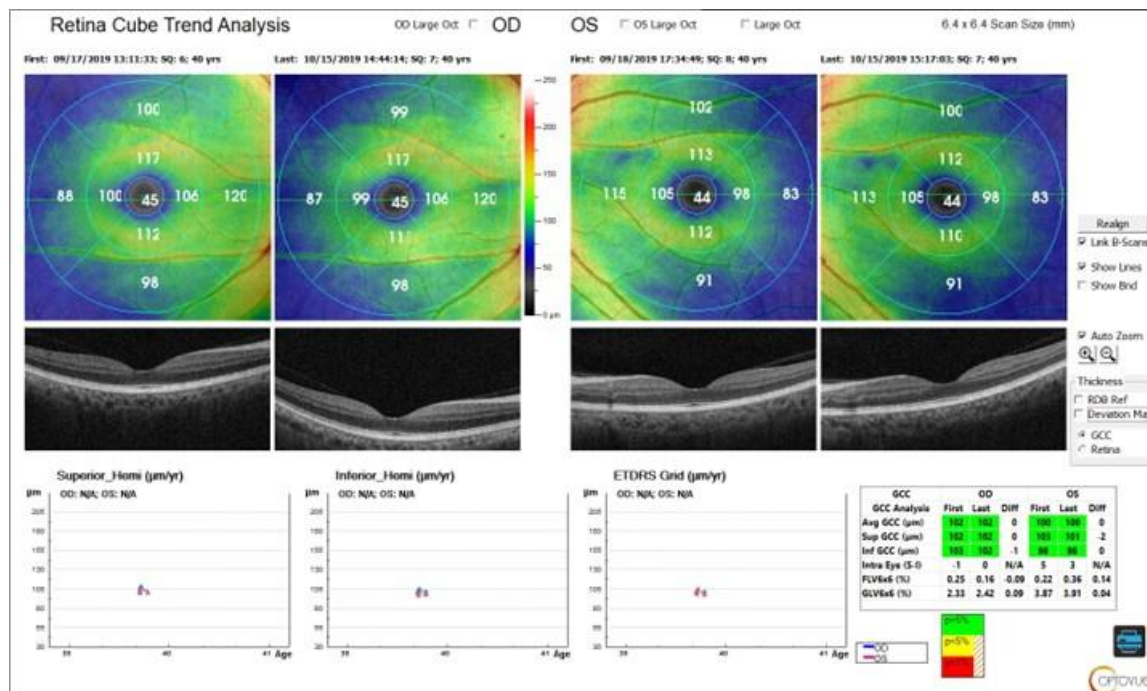


Figure 80 Retina cube Trend analysis GCC Thickness

5.3.2 Disc Report

The 3D Report has an image with three display option tabs at upper left, a horizontal B-scan at lower left and vertical B-scan on the right.

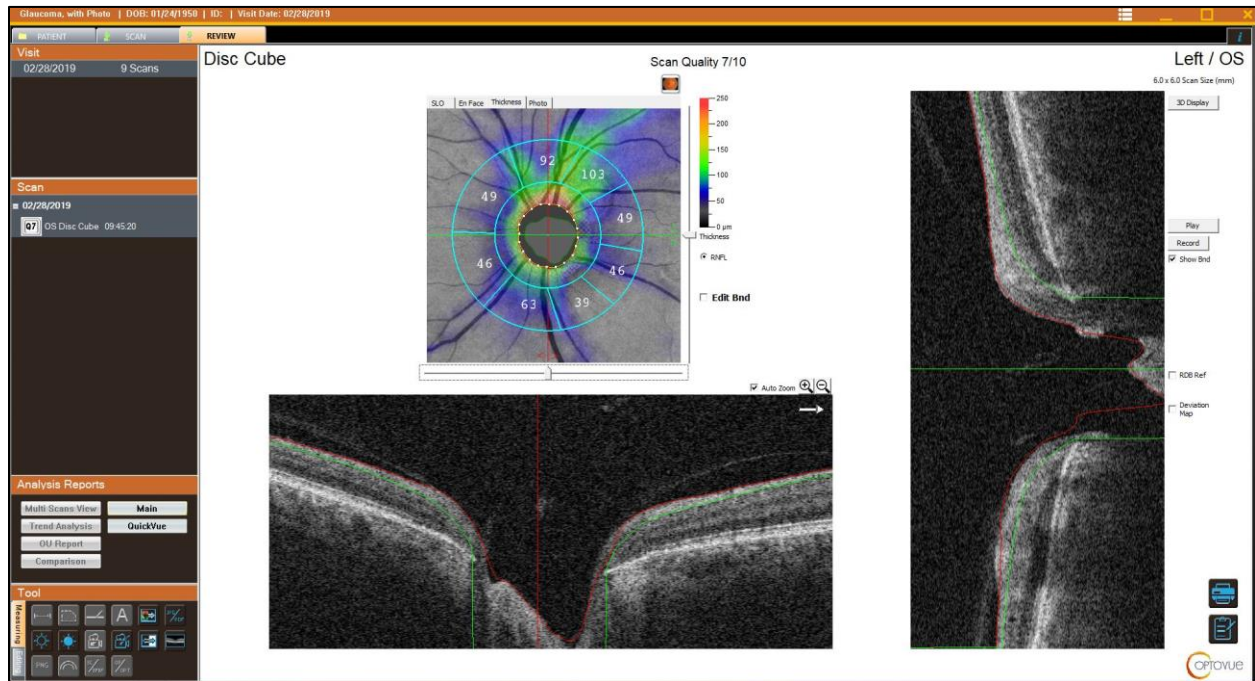


Figure 81 3D Disc Report

5.3.2.1 RNFL RDB

The reference database for Disc scans is adjusted by age and disk area. If the disk area is not available due to calculation error, comparison with the reference database is not performed. If the age or disk area of the patient is out of the range of the reference database, then percentiles are calculated by extrapolation. Age range is 18-80 years and the disk Area range is in the table below.

DiscArea (mm ²)	Solix AngioVue Disc	Solix Disc Cube
Mean (SD)	1.85 (0.35)	1.84 (0.35)
Median	1.82	1.81
Min, Max	[1.06, 3.41]	[1.05, 3.40]

Figure 82 Disc size table

Retinal Nerve Fiber Layer (RNFL) the thicker the layer, the larger the percentile.

If there is no overlap in 95% confidence intervals for the percentiles the color-coded RDB Reference Map shows regions where thickness is as follows:

(5,95) percentile Green,

(1,5) percentile Yellow

(0,1) percentile Red



if the 5th and 1st percentiles overlap an Orange color diagonal cross hatching is used

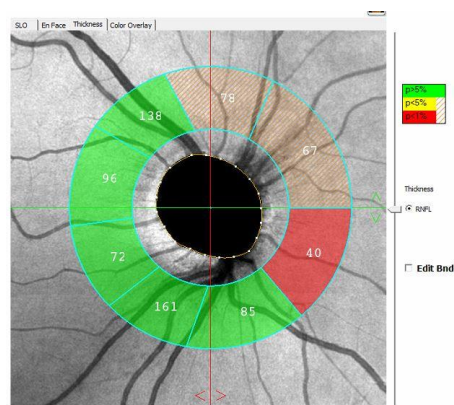


Figure 83 RDB map RNFL

Note: An RDB caution is shown above the report



Caution: RDB interpretation

Clinicians should exercise judgment in the interpretation of the reference data. Measurements in the range of 5% to 95% which are colored green, note 1 out of the 20 normal eyes (approximately 5%) will fall outside the green on either side of the distribution. Caution extrapolating to the general population as only 427 subjects are included in the Reference database.

Confidence Interval Overlap

If adjacent percentiles (for example, the 1st and 5th, or 95th and 99th percentiles) have 95% confidence intervals that are overlapping, then these percentiles cannot be distinguished from each other. In these instances, orange- or blue-colored cross-hatching will be shown for the affected sectors.

To show the disc margin on the 3D Disc report, click the **Show** button.

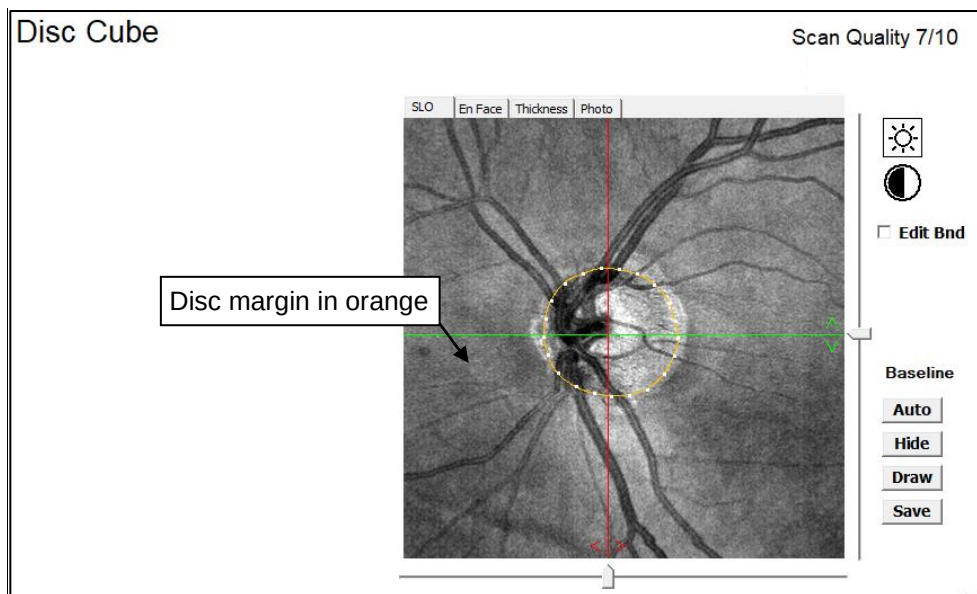
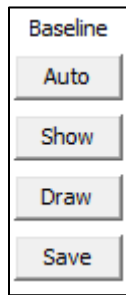


Figure 84 Optic Disc Margin in 3D Disc Report

You can edit the disc margin by clicking and dragging any of the white anchor points to the desired location.

To draw the disc margin manually, select the **Draw** right-click option, then click once to make each anchor point on the margin, and double-click to complete the margin.

Disc Margin Drawing Controls



Auto: Automatically detects the disc margin.

Show: Displays the disc margin.

Draw: Click **Draw** to manually draw the disc margin, then click around the disc margin to place each anchor point.

Save: Saves the disc margin as the ONH baseline.

Excessive eye motion during a 3D Disc scan can cause image registration and disc margin detection to fail. The telltale sign of eye movement during scanning is discontinuity of blood vessels. The image below shows such an example. In these cases, you should retake the scan.

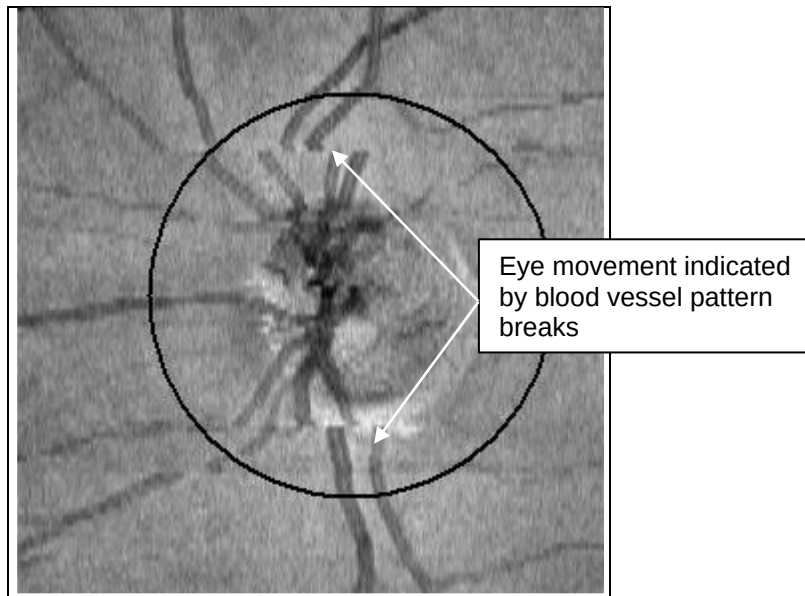


Figure 85 A 3D Disc Scan Showing Eye Motion

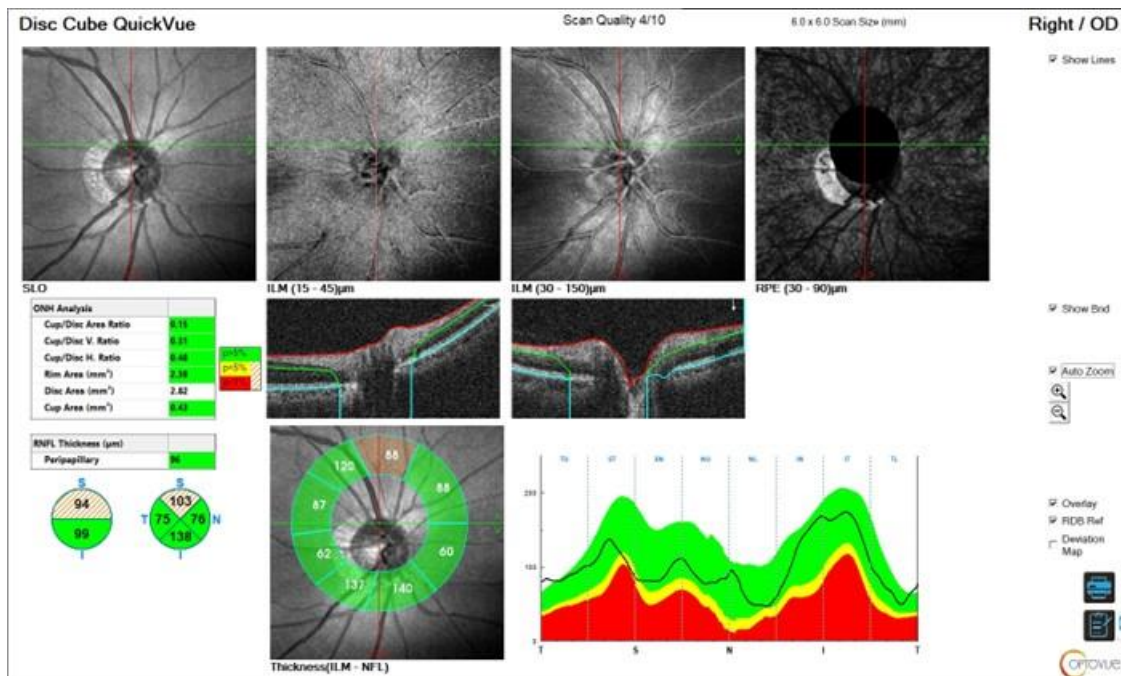


Figure 86 Disc Cube QuickVue with RNFL RDB selected showing TSINT

5.3.2.2 Comparison

If more than one 3D Disc scan has been acquired for this eye, the **Comparison** button will be present on the report. Click **Comparison** and the report shows a reference image and a B-scan window for each compared scan in rows, as shown in the image below. Use the slider next to the reference image to select the B-scans to compare at right.

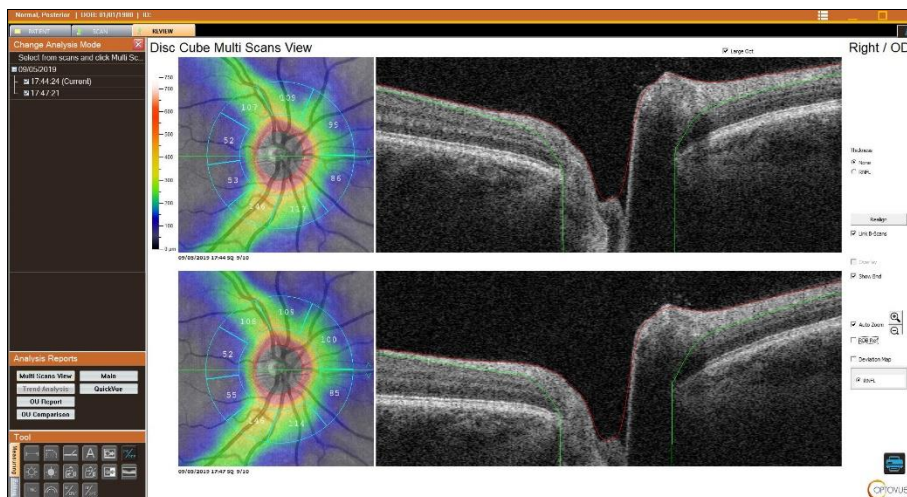


Figure 87 Disc Comparison Report, thickness

The disk cube OU report is made up from 4 exams, OD/OS Disc cube which provides the information on the optic nerve and RNFL as well as the Retina cube OD/OS which provides the GCC information.

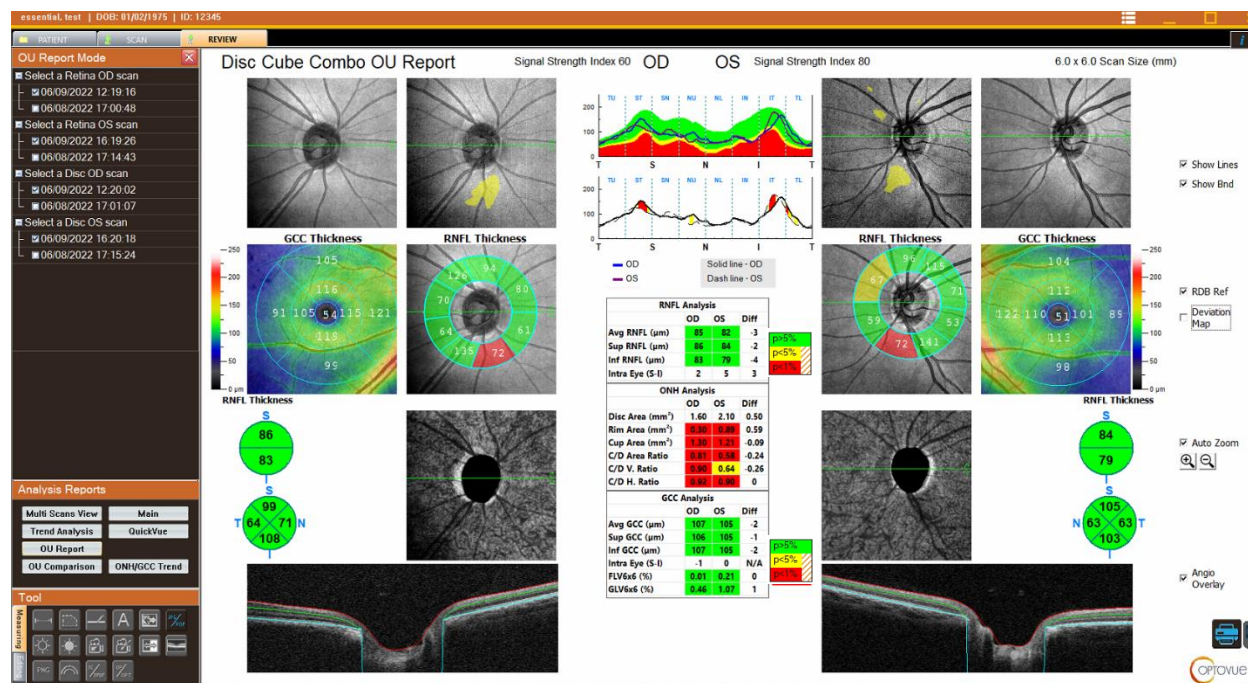


Figure 88 Disc Cube Combo OU From Retina & Disc Cube

Note: Report layout similar to OU AngioVue® Disc without the Density analytics

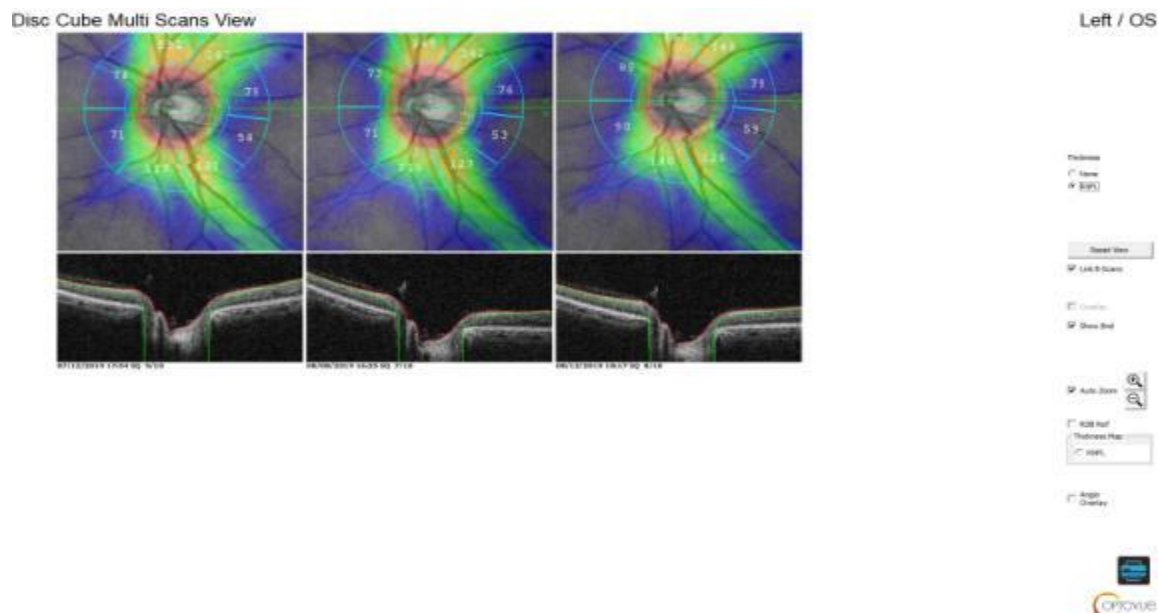


Figure 89 Disc cube Multi Scan Report

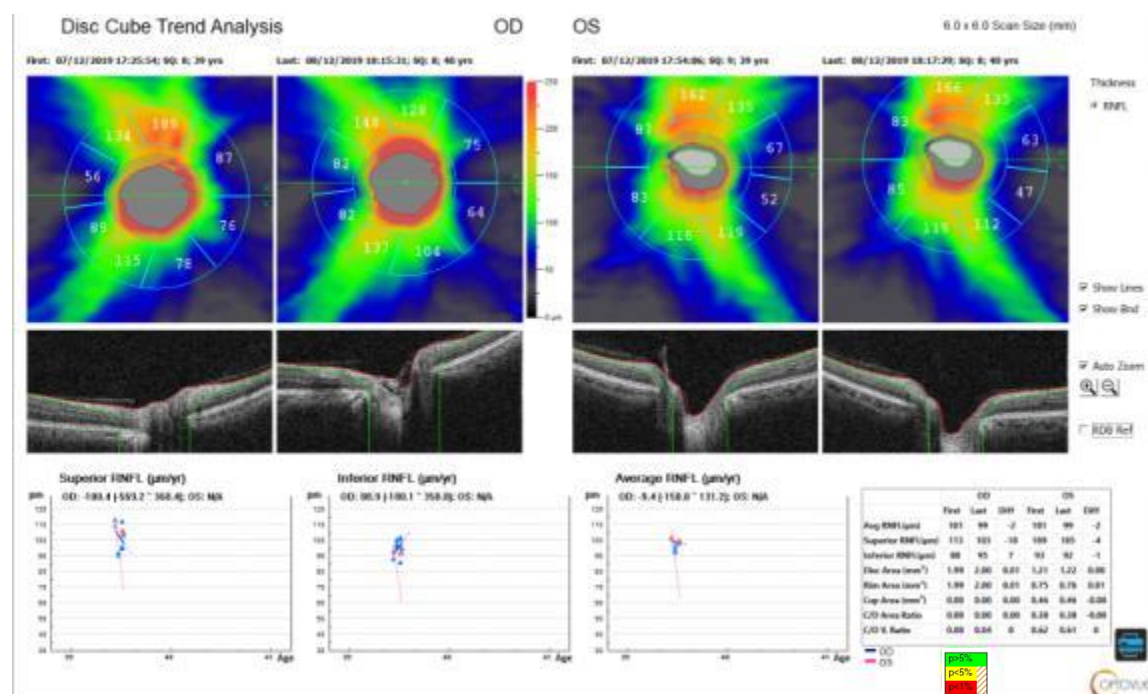


Figure 90 Disc Cube Trend Analysis

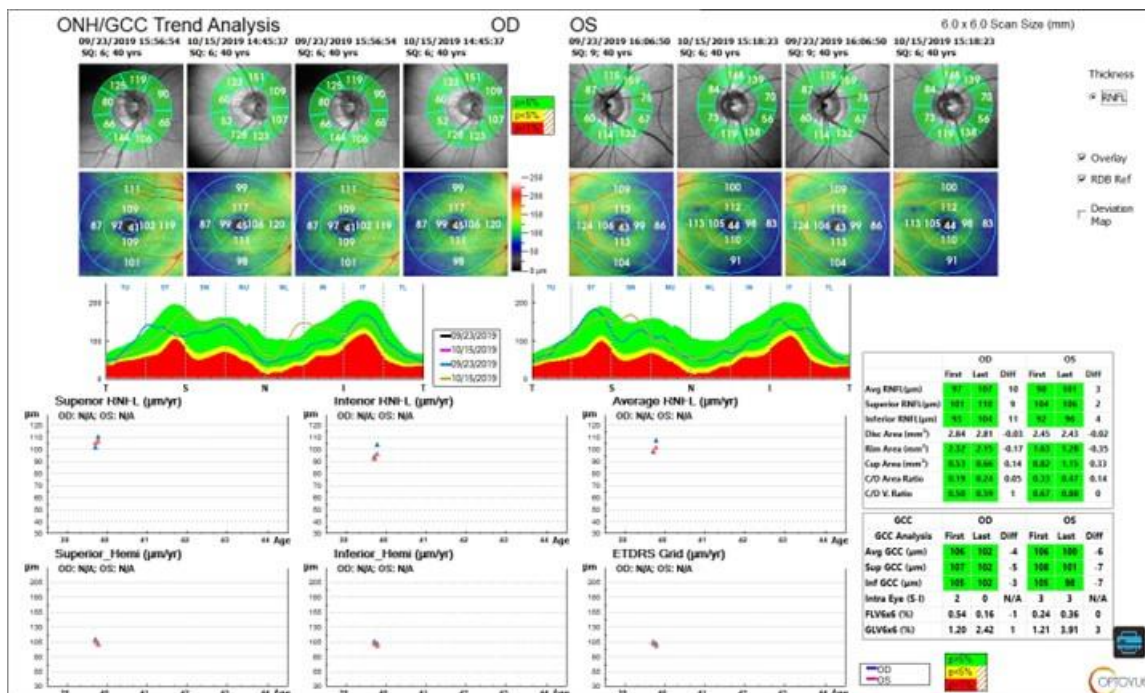


Figure 91 Disc Cube OU Trend Analysis

5.3.3 Wellness Report 12x9

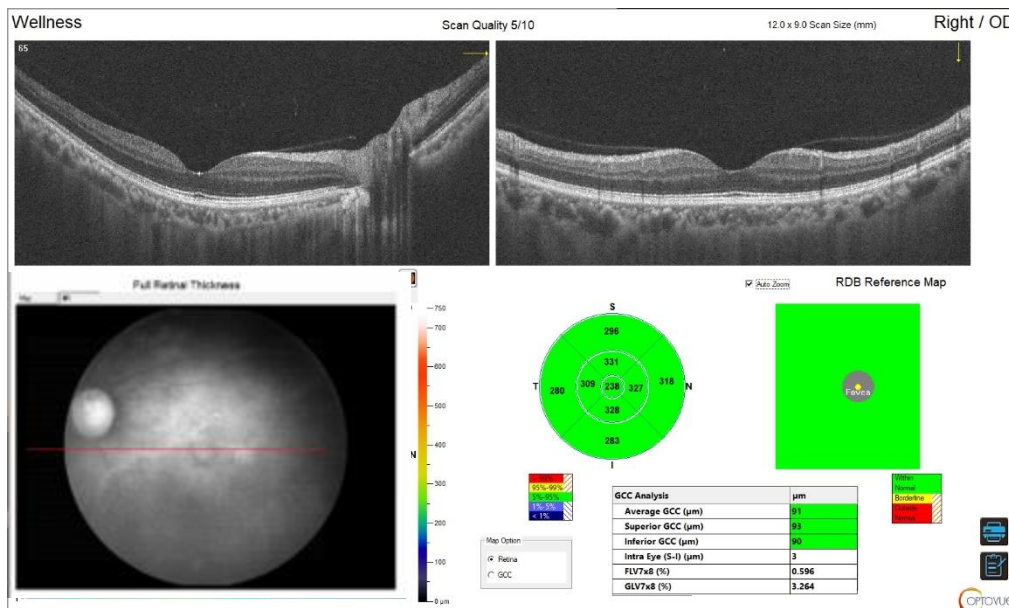


Figure 92 Wellness with IR image

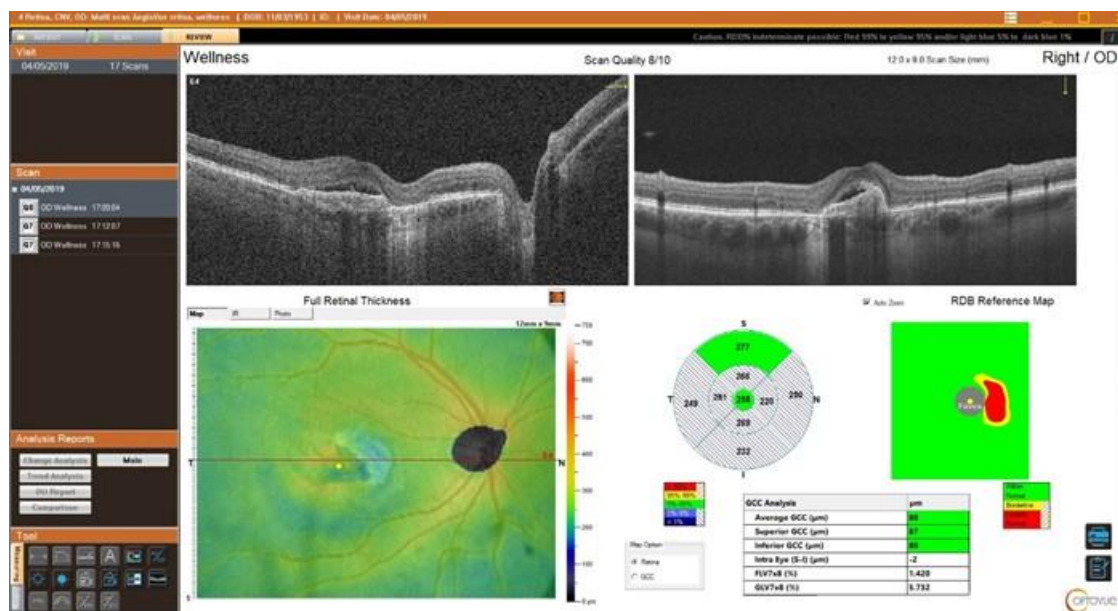


Figure 93 Wellness with thickness map

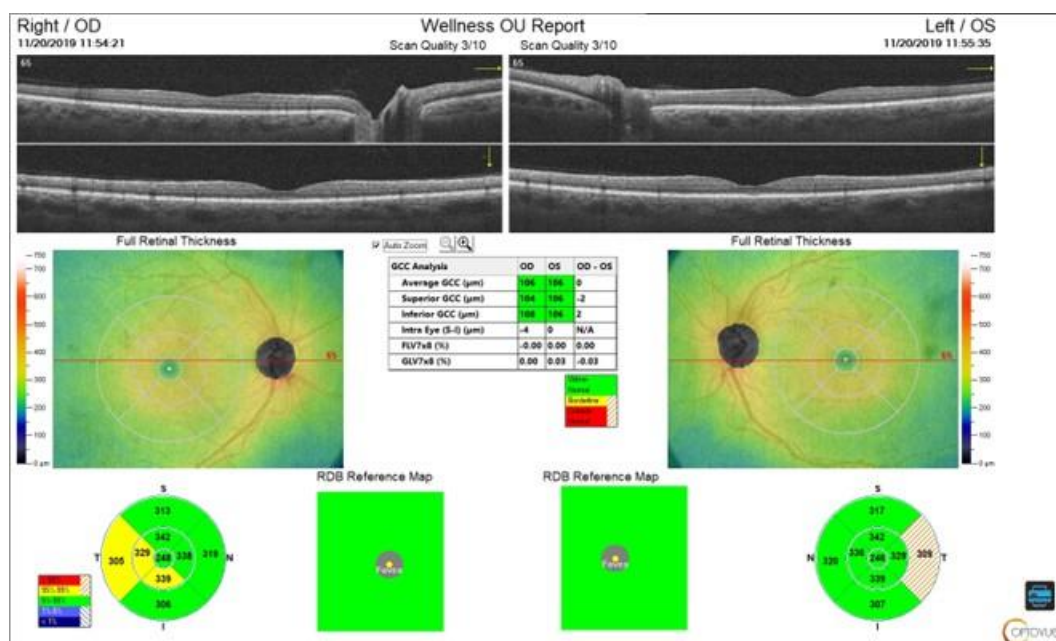


Figure 94 OU Wellness

The OU wellness compares a 12x9 area thickness map from both eyes and displays retinal thickness and GCC with RDB for symmetry of both inter and intra comparison.

If an AngioVue retina scan is also done a combined report is available.

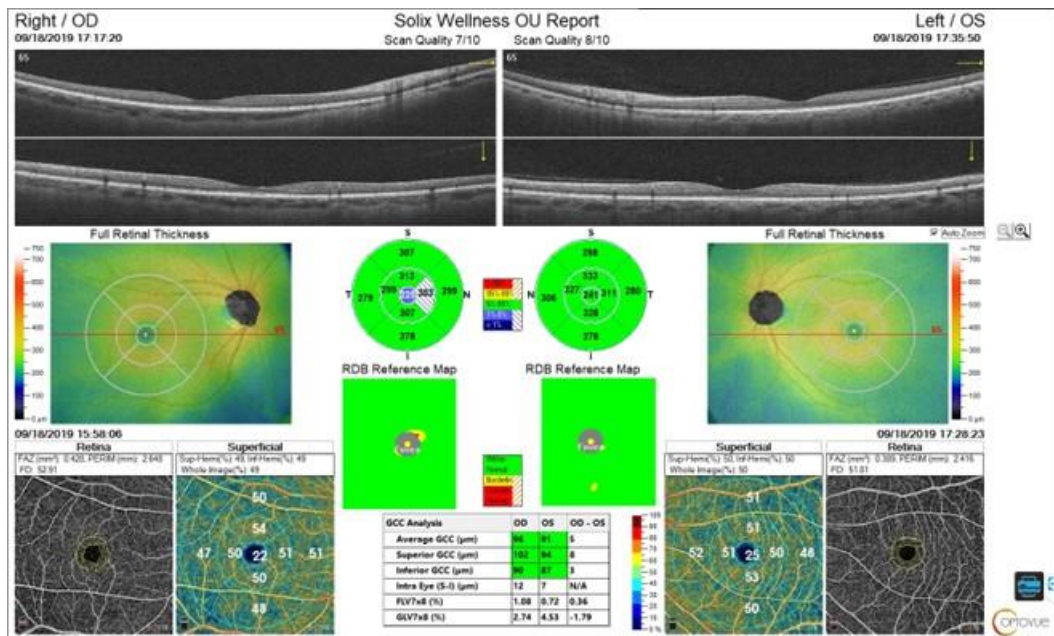


Figure 95 AngioVue Wellness OU Report

6 AngioVue® Reports

6.1 Segmentation Retina

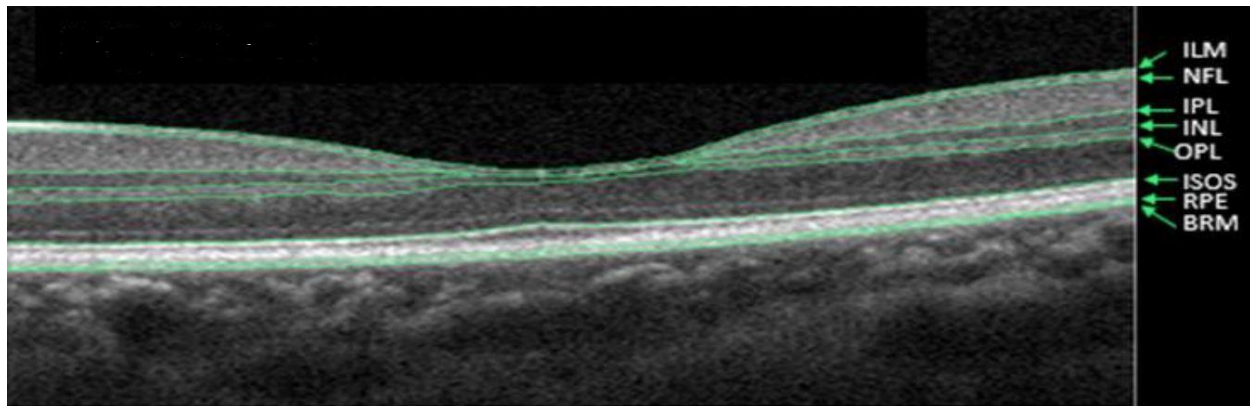


Figure 96 Retina Segmentation Layers

The following segmentation boundaries are available for the AngioVue® retina scans:

ILM, NFL, IPL, INL, OPL, IS/OS, RPE, BRM

6.1.1 Predefined AngioVue® Retina En Face Slabs

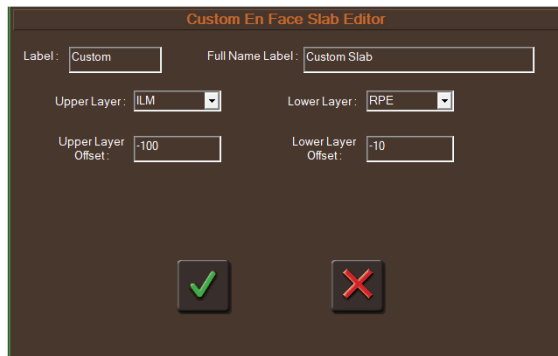
Based on segmentation boundaries as listed above, the following consistent AngioVue® Retina en face slabs are predefined:

- Superficial (Upper limit = ILM; Lower limit = IPL-10 μ m)
- Deep (Upper limit = IPL-10 μ m; Lower Limit = OPL+10 μ m)
- Outer (Upper limit = OPL+10 μ m; Lower limit = BRM-10 μ m)
- Choroid (Upper limit = BRM-10 μ m; Lower limit = BRM+30 μ m)
- Retina (Upper limit = ILM; Lower limit = OPL+10 μ m)

6.1.2 Custom AngioVue® Retina Slab

The custom slab boundaries are user-defined, providing users with the ability to visualize additional retinal slab based on their preferences. The software allows selection of upper layer from available segmentation lines, upper layer offset, lower

layer from available segmentation lines and lower layer offset. The slab can also be renamed



To define custom slab boundaries, go to “Tools”→”AngioVue® Retina Custom En Face Slab” and select the boundaries and offsets.

Figure 106 Custom AngioVue Retina slab setting

6.2 Segmentation Disc

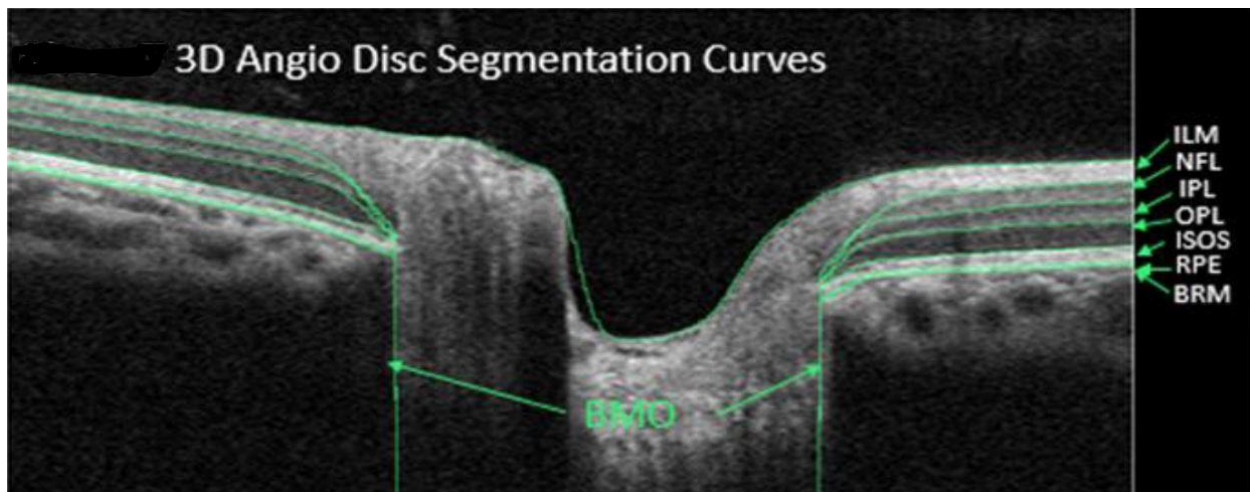


Figure 97 Disc Segmentation Layers

The following segmentation boundaries are available for the AngioVue® Disc scans:

ILM, NFL, IPL, OPL, IS/OS, RPE, BRM

6.2.1 Predefined AngioVue® Disc En Face Slabs

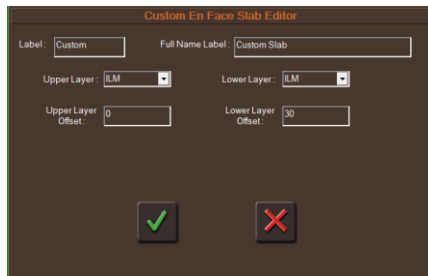
Based on segmentation boundaries as listed above, the following consistent AngioVue® Retina en face slabs are predefined:

- Vitreous (Upper limit = ILM-2000µm; Lower limit = ILM)

- Superficial (Upper limit = ILM; Lower limit = IPL-10 μ m)
- RPC (Upper limit = ILM; Lower Limit = NFL)
- Choroid (Upper limit = BRM-10 μ m; Lower limit = BRM+30 μ m)
- Retina (Upper limit = ILM; Lower limit = OPL+10 μ m)

6.2.2 Custom AngioVue® Disc Slab

The custom slab boundaries are user-defined, providing users with the ability to visualize additional retinal slab based on their preferences. The software allows selection of upper layer from available segmentation lines, upper layer offset, lower layer from available segmentation lines and lower layer offset. The slab can also be renamed.



To define custom slab boundaries, go to “Tools”→”AngioVue® Disc Custom En Face Slab” and select the boundaries and offsets.

Figure 98 Custom slab

6.3 Optic Disc Margin

The optic disc margin detection by the software shall be reviewed in the SLO view screen (Main Report, SLO Tab) Disc margin can be verified by placing cross-hairs on the disc margin outline by the software and verify in the corresponding B-scan that the location is aligned with the Bruch's membrane opening (BMO).

If the location is not aligned with the BMO, the disc margin outline should be manually adjusted until it matches the anatomy. To do that, the mouse is placed on the incorrectly placed “anchor” point, which is then dragged to the correct location where BMO is identified

Automatic segmentation update and recalculation of disc center as well as all peripapillary and disc metrics is performed by the software once modified disc margin boundary is saved by the user.

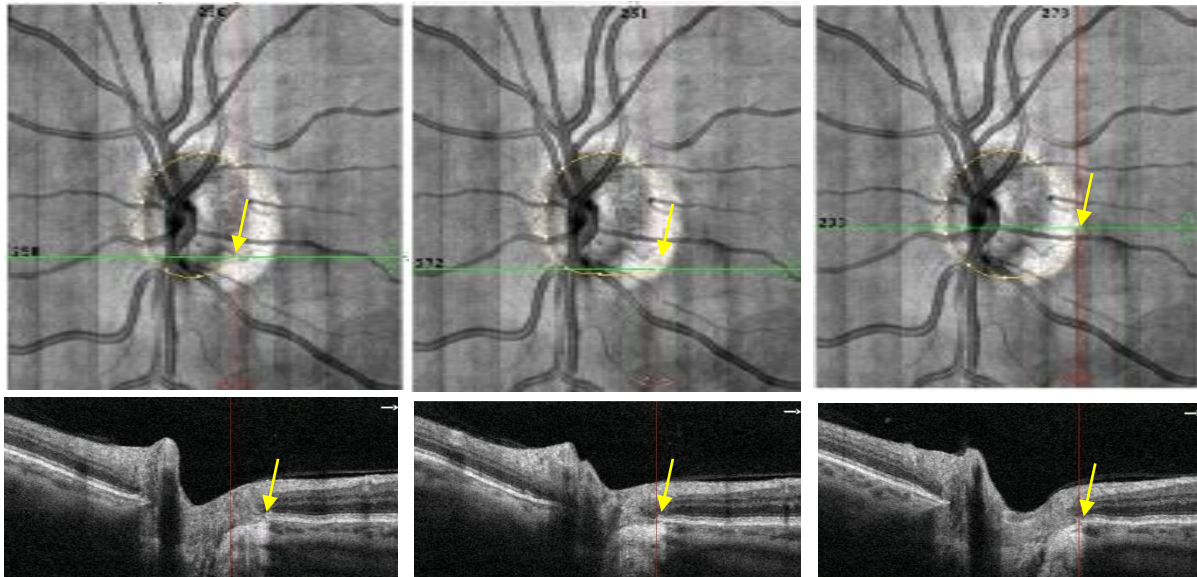


Figure 99 Disc Margin and Margin Correction

Left – Incorrect disc margin detected (red a-scan vertical line through the disc margin point) and confirmed on the corresponding b-scan (yellow arrow points to the correct BMO). Middle – “Anchor” point is dragged to correct location at the BMO, as confirmed by corresponding b-scan. Right – Fully corrected disc margin, as confirmed by selecting additional point of the disc margin and demonstrating its location on the b-scan at the BMO (yellow arrow).

6.4 Segmentation Correction and Propagation Tool

Incorrect segmentation of one or more of the segmentation boundaries can be identified either on OCT or OCTA windows.

In the event of a segmentation error the user can manually correct the segmentation lines on a single b-scan and propagate the change throughout the entire scan or a selected segment (Region of Interest (ROI)).

In the image below a red box has been drawn around the incorrect segmentation area on the OCT Inner Thickness map.

The following steps describe the segmentation editing and propagation process.

1. To access the “segmentation edit” screen, check the **Edit Bnd** checkbox to the right of the screen (inside red rectangle). The screen will appear.
2. To edit specific segmentation line, click the check-box near the line name on the left to the b-scan. The chosen line will appear on the b-scan image,

*(If you would like to visualize your edits on the thickness map, on the right to the OCT window choose the layer that is defined by that line. For example, if you wish to edit IPL, choose **Inner** layer (ILM to IPL) or Outer layer (IPL to RPE). Once the layer defined by IPL line is chosen (Inner layer in Fig.164), only the two segmentation lines defining the Inner layer are displayed (ILM and IPL), and the ILM and IPL lines indicators to the left of the b-scan window become active.)*

3. Define ROI for segmentation correction and propagation. There are several ways to define ROI to propagate the modified curve:
 - a. Use mouse to click on the OCT enface window and continue to drag to the desired Region. There is red dot boundary to indicate the user specified region to be propagated.
 - b. Move the B scan to the start desire location and click “Seed Region Start”→ “Set” button to set the start position. Move the B scan to the end desire location and click “Seed Region End”→ “Set” button to set the end position.
 - c. If no region is specified, start seed should be the first frame and end seed should be the last frame – the curve edit will be propagated thorough the entire scan.

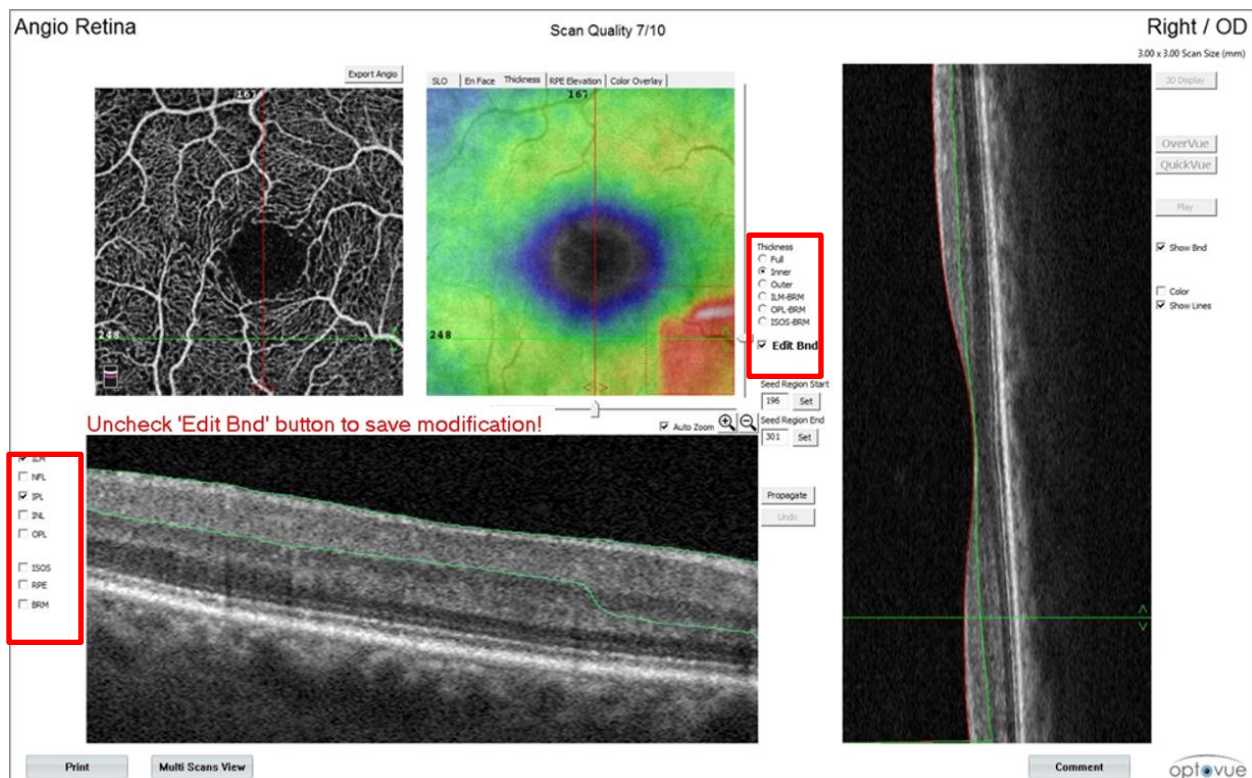


Figure 100 Incorrect IPL segmentation

4. Correct the segmentation of the single selected b-scan **inside the ROI**.

In the b-scan through the incorrectly segmented area is selected. By clicking on the IPL line in the OCT window, the anchor points are activated on the curve, one anchor point is encircled in red).

The segmentation correction of single B-scan can be performed in two ways:

- a. Drag the anchor points to the desired location – the line color will become purple → “edited B-scan”
- b. Right-click and choose to “Reselect All Points”. The green curve will disappear, and by clicking along the correct segmentation location from one side of the B-scan to another **and double-clicking at the end**, the new segmentation line will be created, and will appear purple → “edited B-scan”,

In the example below the IPL layer has dropped below the inner nuclear layer (see green line in B-scan) in the lower right corner of the scan (as illustrated by the red thickness area.)

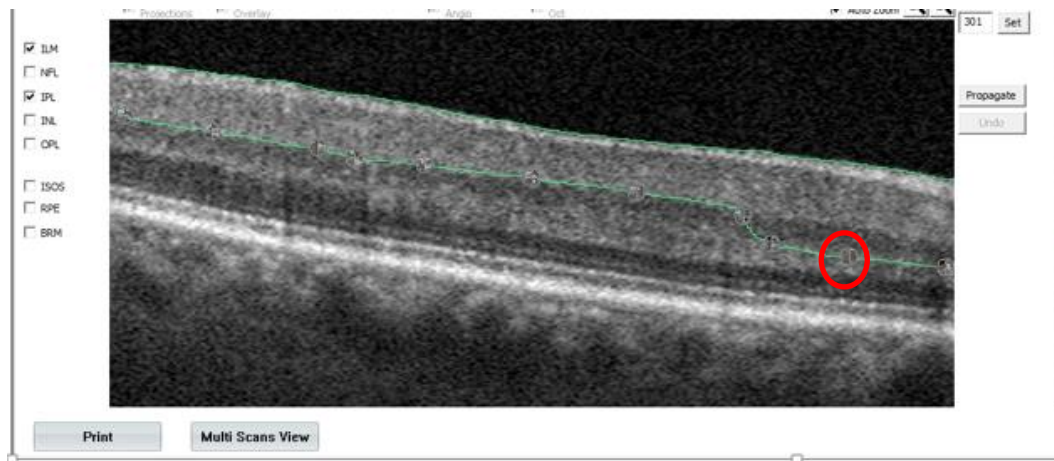


Figure 101 IPL Boundary Selected, Anchor Points Activated

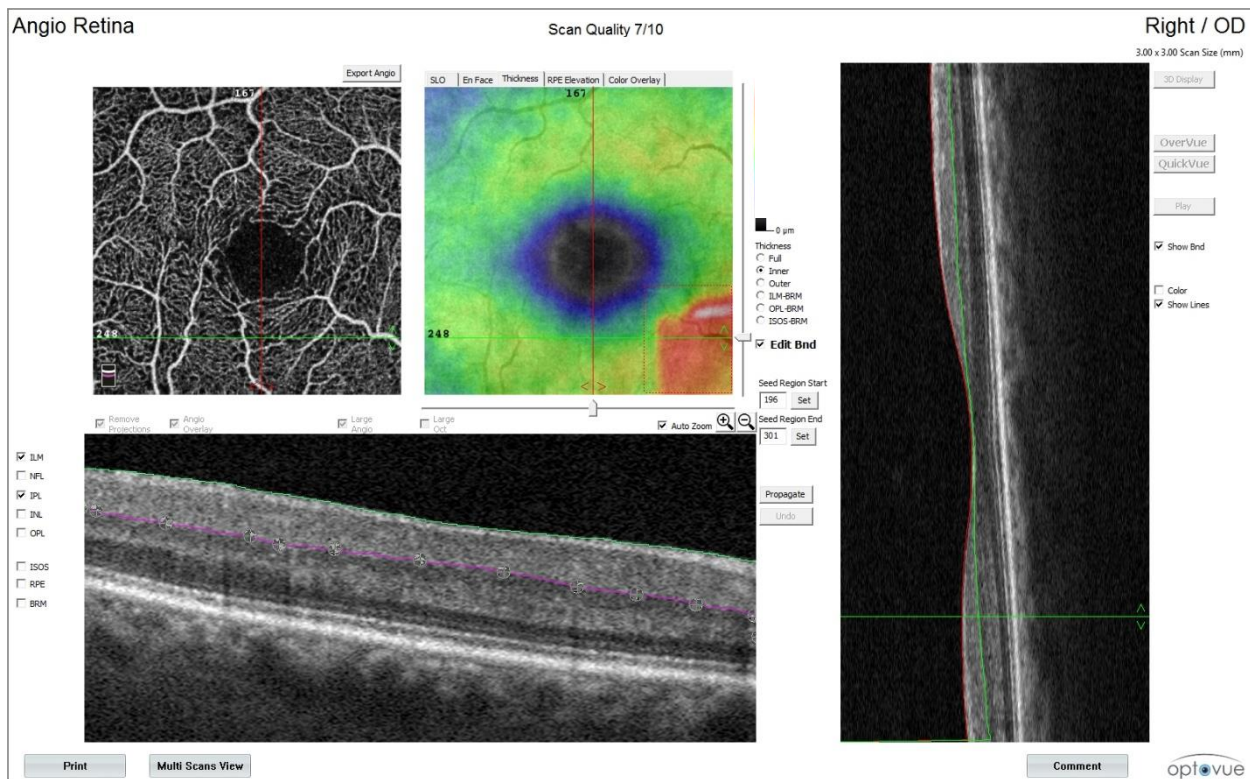


Figure 102 Single B-Scan Corrected (IPL Line Turned Purple), not Propagated

5. Propagation.

Clicking on the **Propagate** button (red rectangle on to the right of the B-scan window will apply the correction to the neighboring b-scans located in the defined ROI, or throughout entire image if no boundary of ROI is drawn. shows the propagated map.

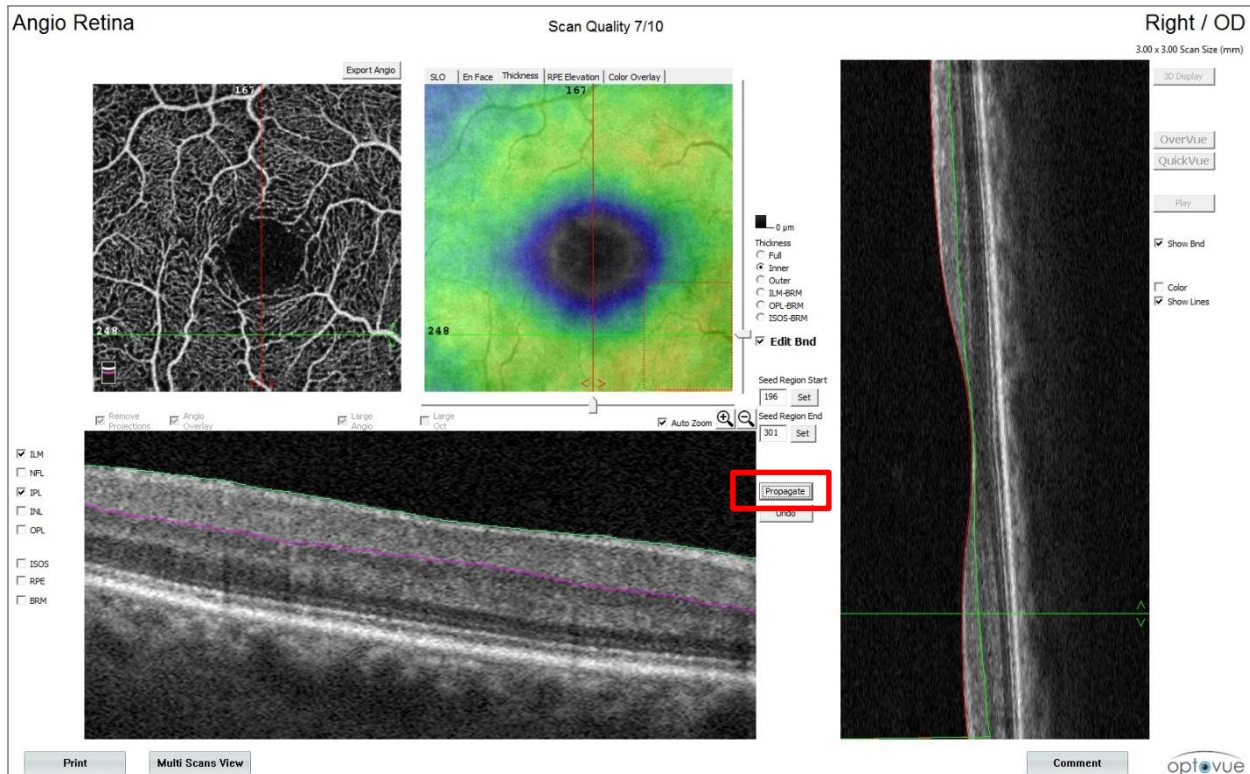


Figure 103 Segmentation Correction and Propagation Applied

The procedure can be performed more than once if needed, and can be either repeated over the same ROI, or different ROI/s. Following segmentation update, software automatically updates all the measurements data.

6.5 Projection Artifact Removal (3D PAR)

OCTA techniques are based on the principle of motion contrast. Visualization of the deeper vascular layers is affected by flow projection artifacts from fluctuating shadows of the flowing blood cells in the more superficial blood vessels that create “false flow” in the deeper layers. This phenomenon is called “projection artifacts”. On cross-sectional OCTA projection artifacts are seen as elongated signal tail. On en face OCTA images the more superficial blood vessels network gets duplicated on the deeper slabs. Without PAR the superficial plexus would project onto the deep plexus, then superficial and deep would project onto Outer and all three would project onto the choroid. PAR suppresses locations of artifacts to the background OCT noise.

PAR algorithm removes projection artifacts from deeper layers. demonstrates outer retinal slab without PAR application – all Superficial and Deep vessels are “imprinted”, and after PAR application - void of vessels projections from the Superficial and Deep vascular plexuses.

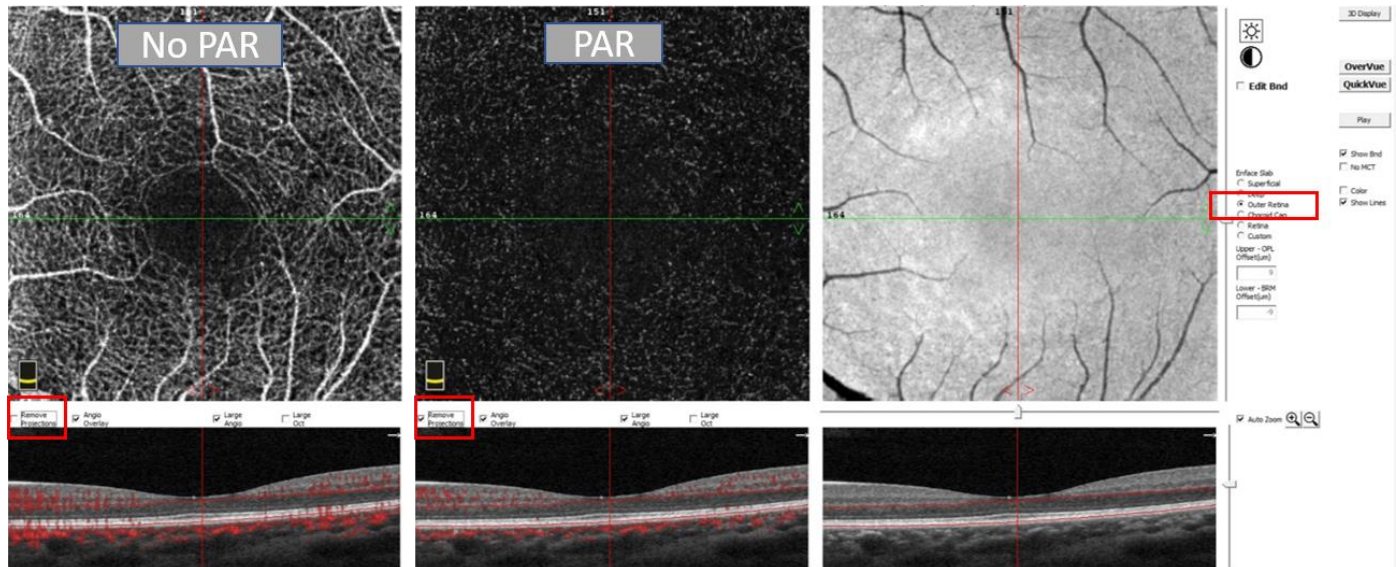


Figure 104 PAR Off and PAR On (same Outer Retina Slab)

-  **Note:** that vessel density measurements are determined only with PAR correction. Therefore, the precision data of vessel density measurements from the AngioAnalytics™ R&R study reflects measurements only with PAR on.
-  **Note:** It is recommended that the PAR-corrected images are inspected and compared to PAR-uncorrected images prior to interpreting vessel density measurement values to determine if there has been extensive removal of non-artifactual signal.
-  **Note** that vessel density measurements are less accurate in locations where there are both projection artifacts and in-situ signal (e.g. deep plexus locations with projection artifacts from the overlying superficial plexus). Examples of PAR vs No-PAR

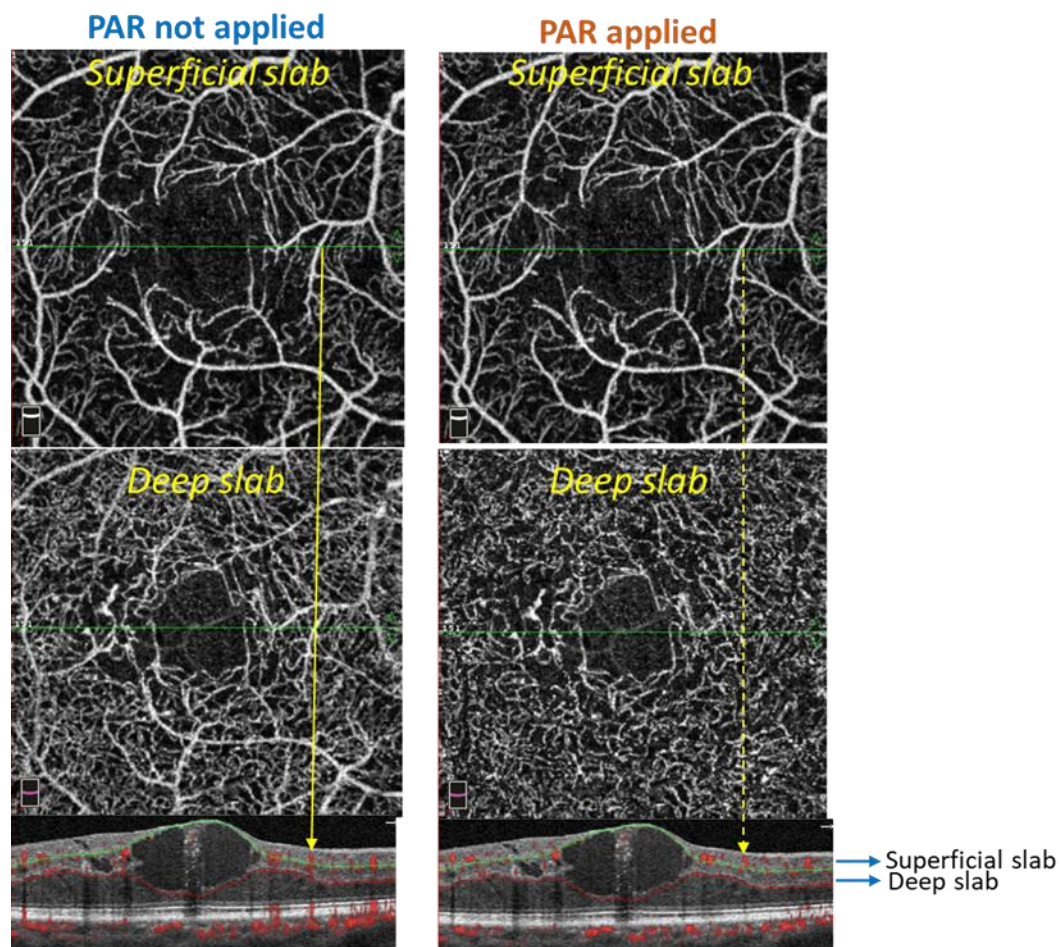


Figure 105 Example: 3 mm AngioVue® retina Scan of Patient with Diabetic Retinopathy, with and without PAR

Superficial and deep en face slabs, and horizontal AngioVue® B-scans of the same scan are presented; without application of PAR (left panel) and following PAR (right panel).

Clear imprint of superficial plexus blood vessels can be seen on the deep plexus en face image with no PAR (left). Following PAR, the projections of the superficial plexus are removed, providing better visualization of the deep plexus vasculature (right). The yellow arrow points to the flow detected in the superficial plexus vessel (the b-scan shows the flow signal appearing in the superficial slab), with the tail projecting into deep slab and beyond if no PAR applied (left b-scan). Following PAR, the flow signal is detected in the superficial slab, however the projection into the deep slab and further is removed.

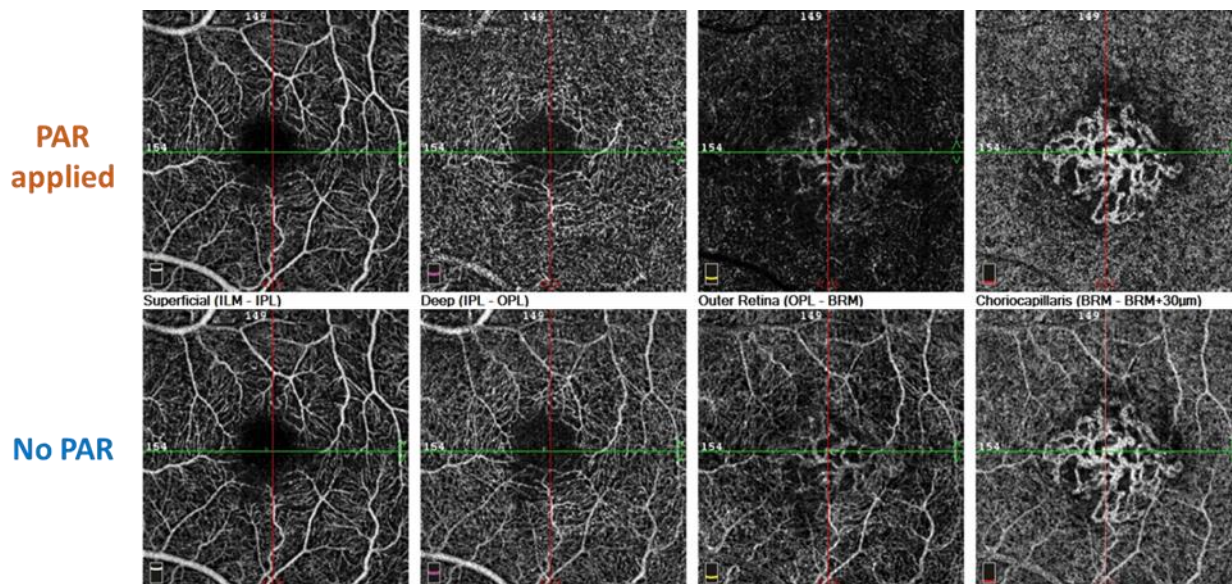


Figure 106 Example: 3 mm AngioVue® retina Scan of Patient with CNV, with and without PAR

Superficial, deep, outer retina and choriocapillaris en face slabs of the same scan are presented; with PAR (upper panel) and without PAR (lower panel).

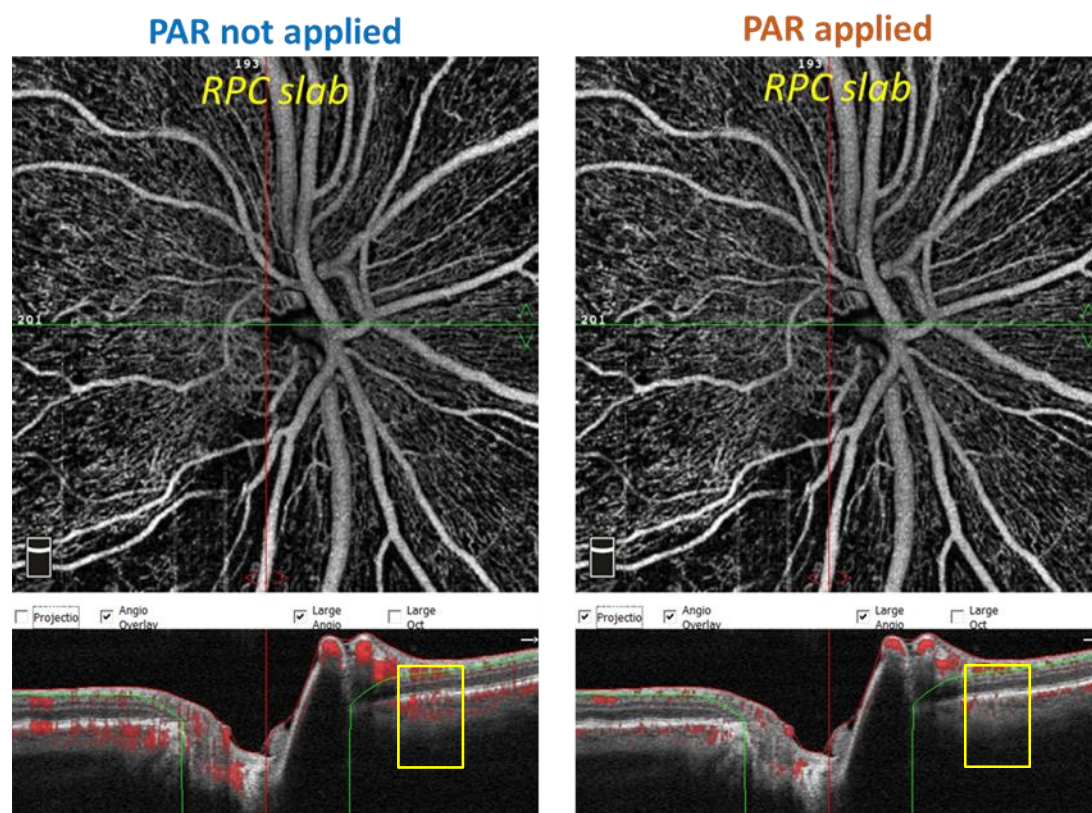


Figure 107 Example: 4.5 mm AngioVue® Disc Scan, with and without PAR

RPC en face slab and horizontal b-scan of the same scan are presented; without application of PAR (left panel) and following PAR (right panel). Vascular plexus of RPC slab is superficial, and therefore is not significantly affected by PAR application, as can be seen on the en face images of RPC slab before and after PAR. Horizontal AngioVue® b-scan demonstrates “projection tails” removal following PAR in the deeper layers of the retina (yellow boxes).

6.6 AngioVue® Reports

AngioVue® integrates the Fast-X and Fast-Y scans in 3D reports that provide many options for presentation. The operator should assess the quality of en face images for excessive motion not correctable by the software. Retake the scans if necessary in order to obtain results without excessive motion. The operator should also assess the images for artifacts. The user should interpret such images with caution.

Note: User Preference allows a choice for “Default Angio EnFace Visualization” standard or Darker option. (more contrast)

6.6.1 AngioVue® Reports List

AngioVue® Retina Reports

- AngioVue® Retina QuickVue report (with AngioAnalytics™)
- AngioVue® Retina Main report 3mm, 6mm, 9mm, 12mm
- AngioVue® Retina Trend report (6mm with AngioAnalytics™)

AngioVue® Disc Reports

- AngioVue® Disc QuickVue report (with AngioAnalytics™)
- AngioVue® Disc Main report
- AngioVue® Disc Trend Report (6mm with AngioAnalytics™)
- AngioVue® Retina Disc OU Report

AngioVue® Montage reports

- 2(6x6) also 2(9x9) and 4(9x9x) montage

6.6.2 AngioVue® Retina Main Report

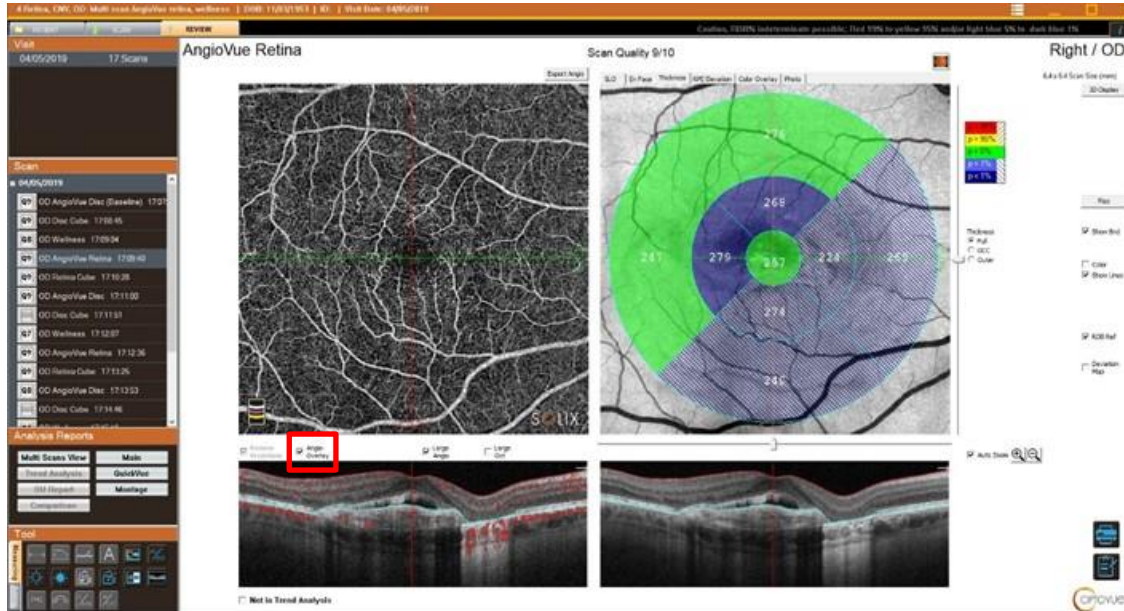


Figure 108 AngioVue® Retina Main Report

The AngioVue® main report is the working report. The default AngioVue® Retina main report includes:

- At top left, an AngioVue® image. Above it is an **Export Angio** button to export the AngioVue® image to a file. You can choose where to save the image and what to name it in the Save As dialog that appears.
- At top center, an OCT image showing retinal thickness using a color scale and ETDRS grid. This image has five tabs to display optional images. It also has sliders to change which B-scans are shown, no matter which tab is selected.

Along the bottom horizontal B-scan are presented, with and without AngioVue® overlay. Unclick **Large Angio** checkbox below the AngioVue® image to enable display of the vertical B-scan on the right side of the screen.

6.6.2.1 AngioVue® Retina Main Report Controls

At upper right, the screen provides the following options, no matter which tab is selected above the top center image.

Right / OD

10 x 3.00 Scan Size (mm)

3D Display

Play

☒ Show Bnd

☐ Color

☒ Show Lines

3D Display: Opens the 3D Display.

QuickVue: en face and measurements display (with AngioAnalytics™ license)

Play: Plays through the B-scans.

Show Bnd: Traces boundaries with colored lines.

Color: Displays images in color

Show Line: Displays horizontal & vertical lines.

At the bottom of the screen are buttons to **Print** and **Comment** on the report.

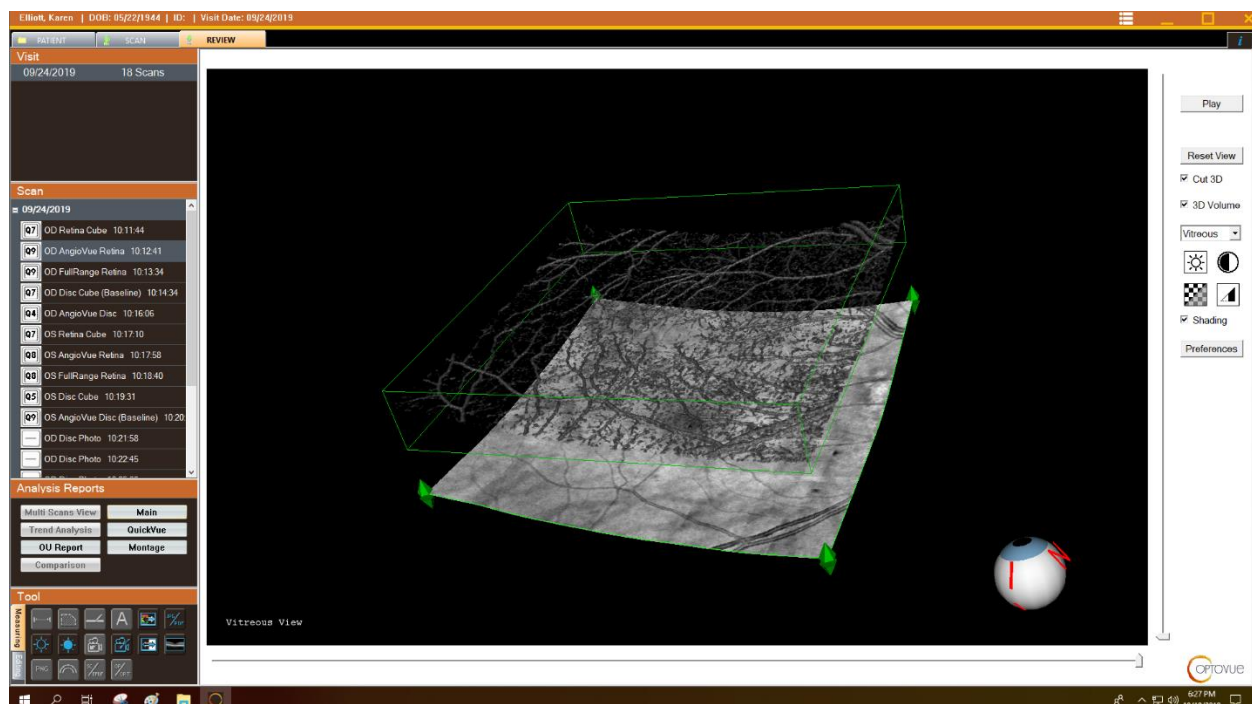


Figure 109 3-D Retina Image

6.6.2.2 Top Center Image Tabs

Thickness Tab

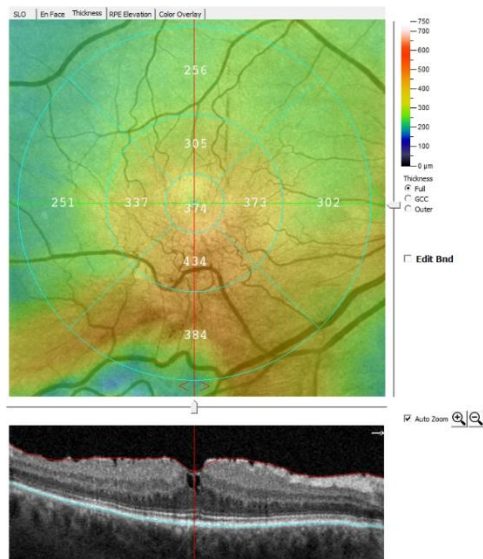


Figure 110 Top Center Image Tabs, Thickness Tab Selected

The top center image has five tabs to display the following optional images:

- **SLO:** Shows OCT and AngioVue® images of the full scan thickness.
- **En Face:** Shows the en face OCT image of the retina and the corresponding AngioVue® image to the left.
- **Thickness:** Shows an OCT image overlaid with retinal thickness using a color scale (and ETDRS overlay), and the corresponding AngioVue® image to the left. (ETDRS is based on fovea center, and is adjustable by user by dragging the mouse; available with AngioAnalytics™)

6.6.3 RDB Reference Database Map

6.6.3.1 Retina Thickness RDB

The reference database for Macula scans is adjusted by age, and for Disc scans by age and disk area. If the data is not available due to poor image/calculation error, comparison with the reference database is not performed. If the age of the patient is out of the range of the database there are no RDB colors (range 18- 80 years)

DiscArea (mm ²)	Solix AngioVue Disc	Solix Disc Cube
Mean (SD)	1.85 (0.35)	1.84 (0.35)
Median	1.82	1.81
Min, Max	[1.06, 3.41]	[1.05, 3.40]

Disc size table

Retina measurements the thicker the layer, the larger the percentile.

If there is no overlap in 95% confidence intervals for the percentiles the color-coded RDB Reference Map shows regions where thickness is as follows:

(0,1) percentile Dark Blue

(1,5) percentile Light Blue

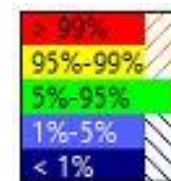
if percentiles overlap a Medium Blue color diagonal cross hatching is used

If there is no overlap in 95% confidence intervals for the percentiles the color-coded RDB Reference Map shows regions where thickness is as follows

(5,95) percentile Green,

(95,99) percentile Yellow

(99,100) percentile Red



if the 95th and 99th percentiles' 95% CIs overlap an Orange color diagonal cross hatching is used.

 Note: An RDB caution is shown above the report



6.6.3.2 GCC RDB

Ganglion Cell Complex (GCC) the thicker the layer, the larger the percentile.

If there is no overlap in 95% confidence intervals for the percentiles the color-coded RDB Reference Map shows regions where thickness is as follows:

(5,95) percentile Green,

(1,5) percentile Yellow

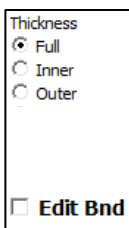
(0,1) percentile Red

if the 5th and 1st percentiles' 95% CIs overlap, an Orange color diagonal cross hatching is used.



- **GCC Deviation Map** is not stratified by any factor such as age. The cutoffs for each pixel are based on the standard deviation of the Gaussian distribution over the same pixel location in the RDB normal population. It only shows thinning of tissue compared to RDB
- **RPE Elevation:** Shows AngioVue® and OCT images of the layers between RPE_Ref and RPE.
- **Color overlay:** allows static or movie color presentation

Thickness Tab Controls



Use the radio buttons to the right to select **Full** (ILM to RPE), **Inner** (ILM to IPL), **Outer** (IPL to RPE), thickness.

Click the **Edit Bnd** checkbox to edit the boundaries shown on the B-scans and thereby adjust the thickness.

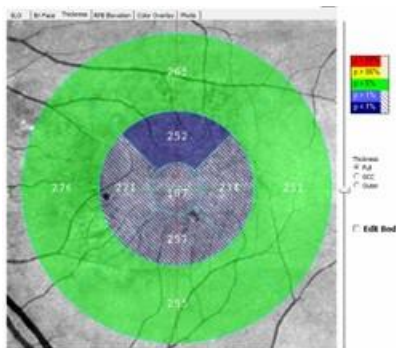


Figure 111 AngioVue Retina Thickness RDB Map

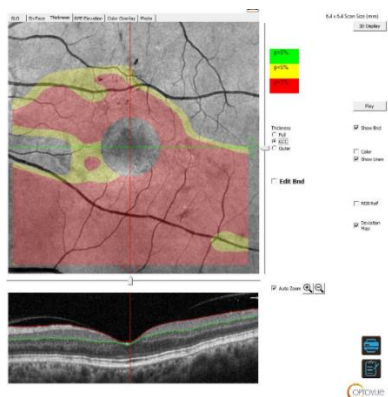


Figure 112 AngioVue Retina GCC, Deviation Map

En Face Tab

The figure below shows the AngioVue® and OCT images when the **En Face** tab is selected. In the example, the **Outer Retina** option is selected as reference, in the controls at right. The following section explains the controls.

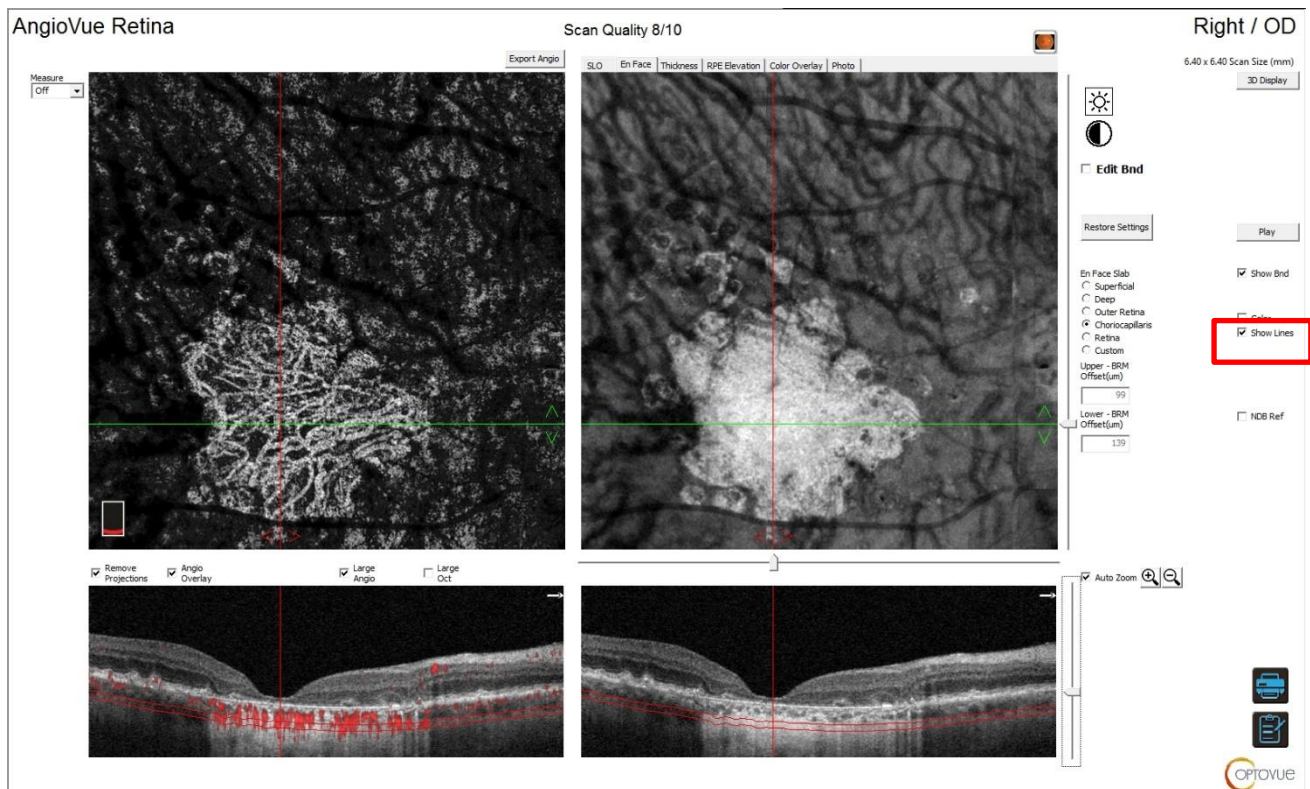


Figure 113 AngioVue® Retina Main Report, En Face Tab Selected

The example shows the AngioVue® image in B&W because the Color checkbox (red rectangle at far right) is not selected.

En Face Tab Controls



- **Brightness Icon:** Click to adjust.



- **Contrast Icon:** Click to adjust contrast.

☐ Edit Bnd

- **Edit Bnd:** Redirects to segmentation edits screen

Restore Settings

- **Restore Settings:** Restores to original settings

En Face Slab

☒ Superficial

- **En Face Slab**

☐ Deep

- **Superficial**

☐ Outer Retina

- **Deep**

☐ Choriocapillaris

- **Outer Retina**

☐ Retina

- **Retina**

☐ Custom

- **Custom**

Upper - ILM
Offset(um)

0

Lower - IPL
Offset(um)

-9

- **Upper – ILM Offset (μm):** Displays the name and offset of upper boundary for the selected slab
- **Lower – IPL Offset (μm):** Displays the name and offset of lower boundary for the selected slab.



Note: for custom slab only, the boundary can be adjusted by user and saved.

Color Overlay Tab

When the Color Overlay tab is selected, the image shows the AngioVue® and OCT images. An overlay pull down selection is available on the left, default is Movie. When play is selected the screen will display the retinal slabs by colors and track the level by the moving indicator to the left. There is also static selection for Vitreous, Superficial, Deep, Outer and Choroid. All static layers have adjustable opacity to enable the user to highlight the pathology.



Note: En face Images show small icon with slab indicator, using the same colors as the movie legend.

Color Overlay, Movie

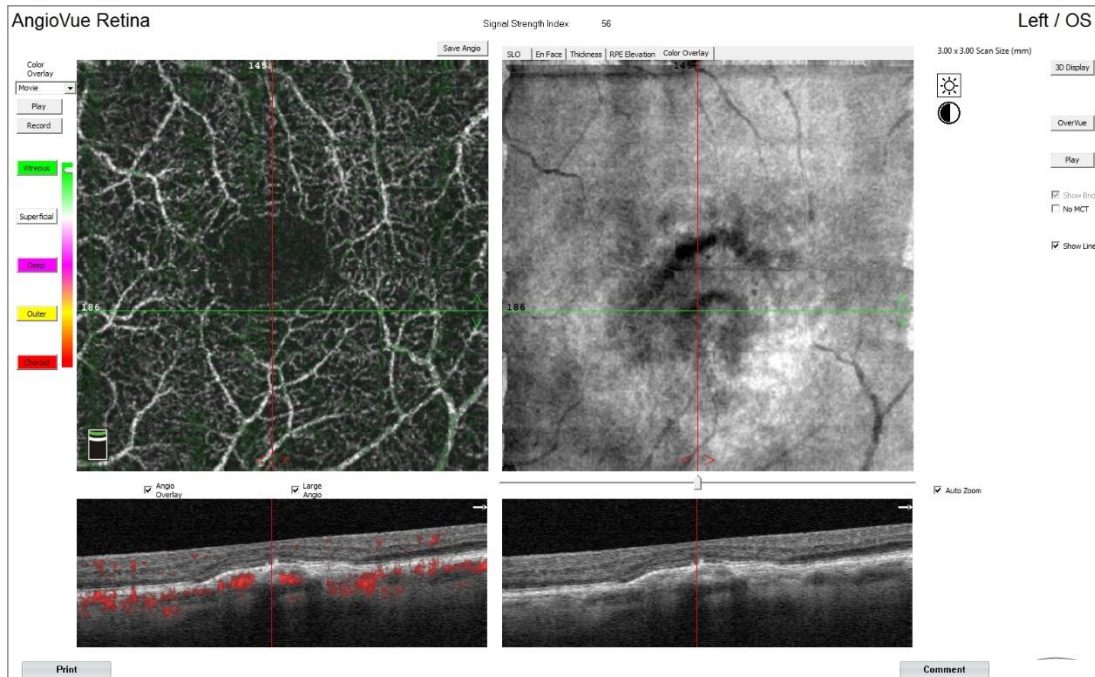
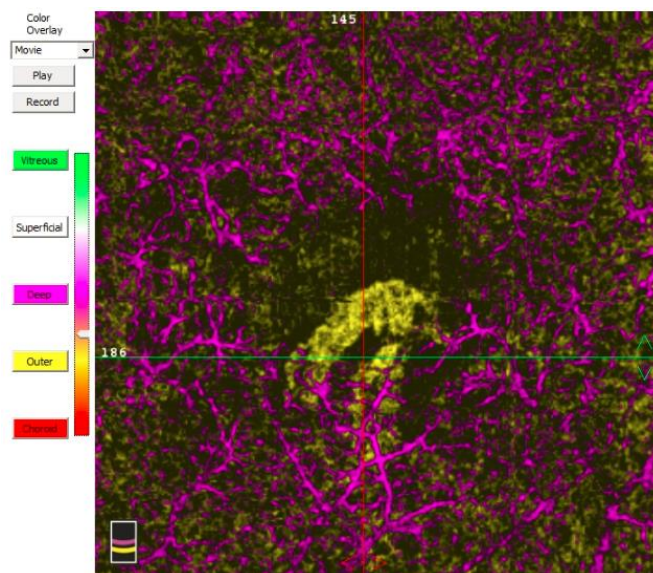


Figure 114 AngioVue® Retina Main Report, Color Overlay Tab Selected (Default to Movie)



This image illustrates the screen as the movie transitions from the Deep layer into the Outer layer showing a Type 2 CNV in yellow.

Figure 115 Movie Paused Between Deep and Outer Retina

Movie Layers Boundaries

- Vitreous (Upper limit: = -2000; Lower Limit = ILM); Color= Green
- Superficial (Upper limit = ILM; Lower limit = IPL-10 μ m); Color= Grayscale
- Deep (Upper limit = IPL-10 μ m; Lower Limit = OPL+10 μ m); Color= Purple
- Outer (Upper limit = OPL+10 μ m; Lower limit = BRM-10 μ m); Color = Yellow
- Choroid (Upper limit = BRM-10 μ m; Lower limit = BRM+30 μ m); Color = Red

Color Overlay, Static

Static images are available for all 5 layers listed above, with corresponding color-coding.

6.6.4 AngioVue® Wide (12x12)

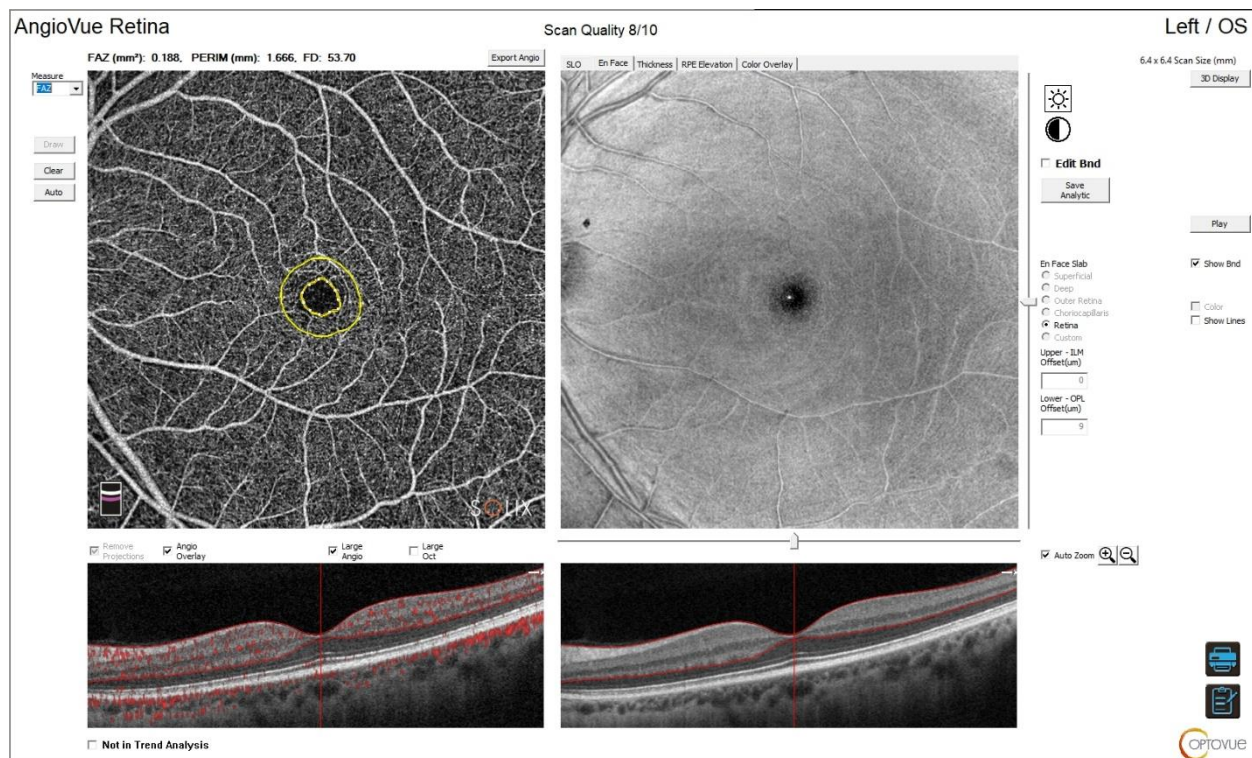


Figure 116 AngioVue® Wide (12x12)

6.6.5 AngioVue® Retina Multiple Visits Report

Use this report to visualize *en face* images and the corresponding B-scans. The B-scans location is “linked” (registered) across visits to display same anatomical location. The system displays scans from up to eight visits, with default display of last two visits. Select or deselect visits to display using the list at upper left. One of the five standard *en face* layers, or custom layer can be selected for display. AngioAnalytics™™ measurement parameters can be displayed as well such as vessel density or FAZ. Utilize the multi-scans view button to refresh the page after reselections.

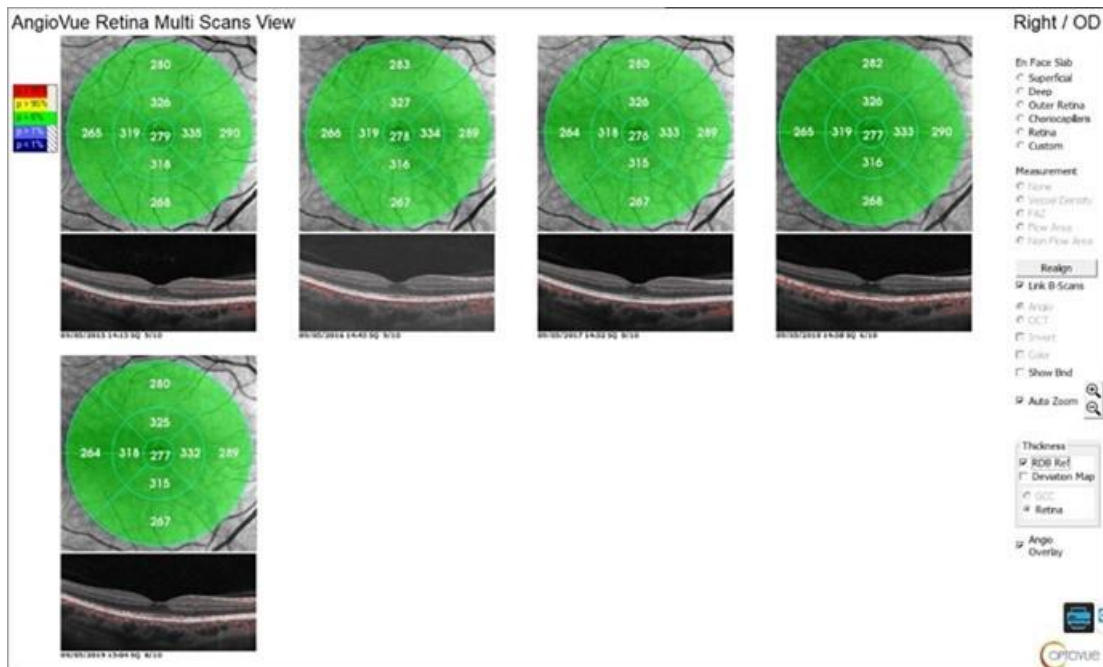
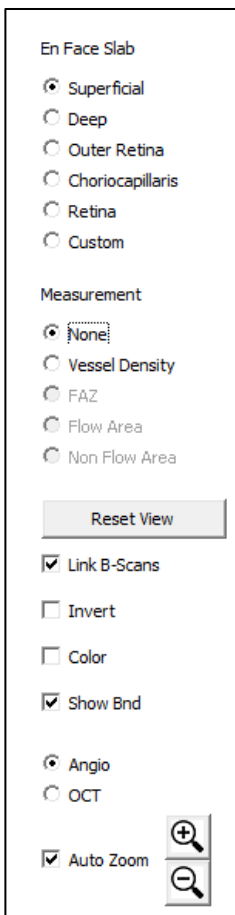


Figure 117 AngioVue® Retina Multiple Visit Report (3 visits)

6.6.5.1 AngioVue® Retina Multiple Visit Report Controls



En Face Slab: Select a radio button to display the desired slab

Superficial

Deep

Outer Retina

Choriocapillaris

Retina

Custom

Measurement: Select a radio button to display the desired measurement

None

Vessel Density

FAZ

Flow Area

Non-Flow Area

Reset View: reverts to original

Link B-scans: links B-scans from multiple images to display same anatomical location

Invert: Select to invert the gray scale shading or color of the images.

Color: Select color image

Show Bnd (Boundaries) in the B-scans.

Use the radio buttons at lower right to show either **AngioVue®** or **OCT** images for comparison.

Auto zoom: for B scans

6.6.6 Retina, Disc 6x6 Montage Report

The Montage radio button is available in the main report screen for both AngioVue® Retina and AngioVue® Disc, if both these scans are available for the visit. When you select the Montage radio button in either the AngioVue® Retina or the AngioVue® Disc, the same AngioVue® montage opens on screen. The montage image combines the aligned and partially overlapping 6 mm AngioVue® Retina and 6 mm AngioVue® Disc images.

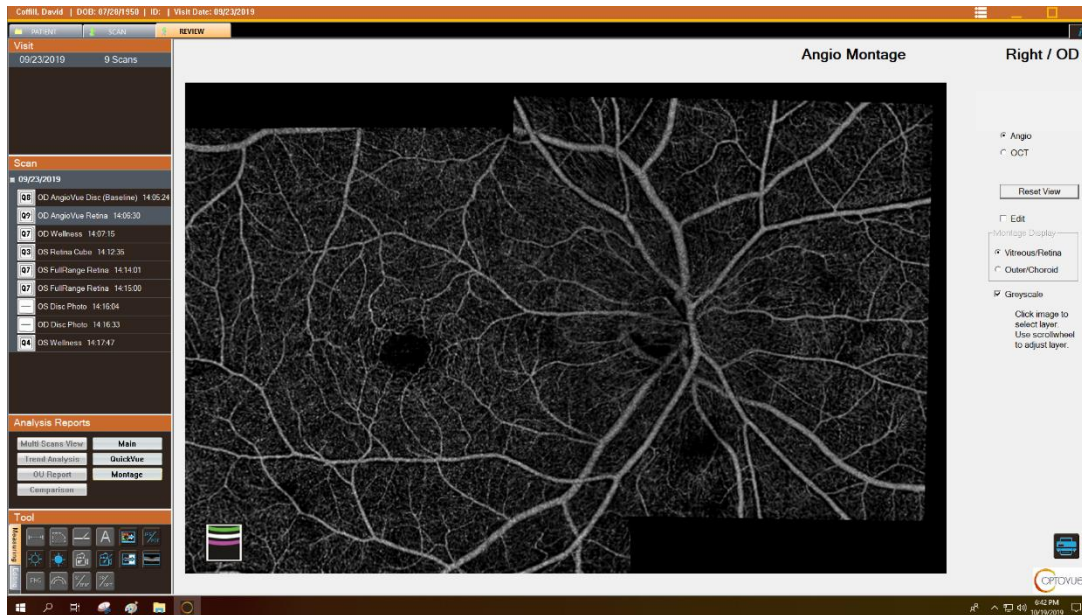


Figure 118 Montage showing Vitreous/Retina layers

Vitreous/Retina Display

- Vitreous (Upper limit: = -2000; Lower Limit = ILM); Color= Green
- Superficial (Upper limit = ILM; Lower limit = IPL-10µm): Color= Grayscale
- Deep (Upper limit = IPL-10µm; Lower limit = OPL+10µm): Color= Purple

Outer/Choroid Display

- Superficial (Upper limit = ILM; Lower limit = OPL+10µm): Color= Grayscale
- Outer (Upper limit = OPL+10µm; Lower limit = BRM-10µm); Color = Yellow
- Choroid (Upper limit = BRM-10µm; Lower limit = BRM+30µm); Color = Red

6.6.6.1 Manual Adjustment of Enface Images

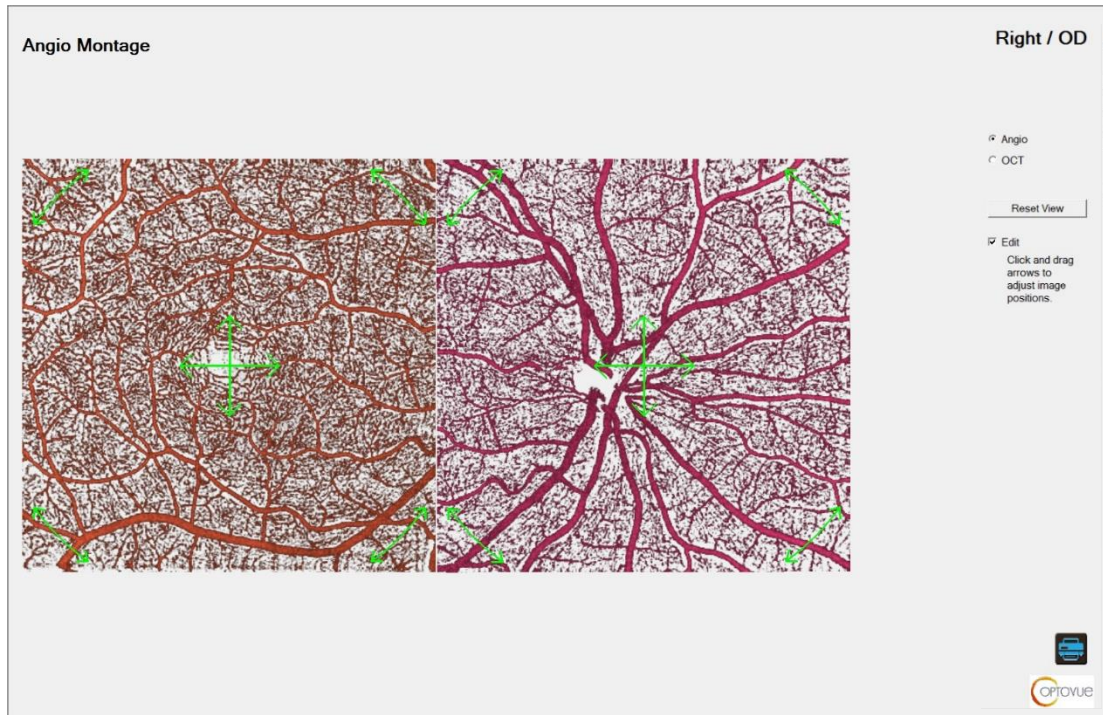
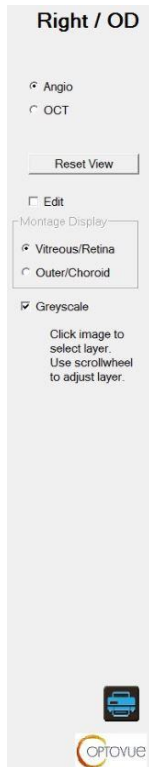


Figure 119 Montage Edit Screen

- Check edit box
- Drag center or corners of each scan to align vessels (holding the shift key slows movement on screen)
- Uncheck edit box to finish
- Reset returns both images to original positions

6.6.6.2 Montage Controls



At right, the Montage Display Mode area assists you to understand what you are viewing in the montage.

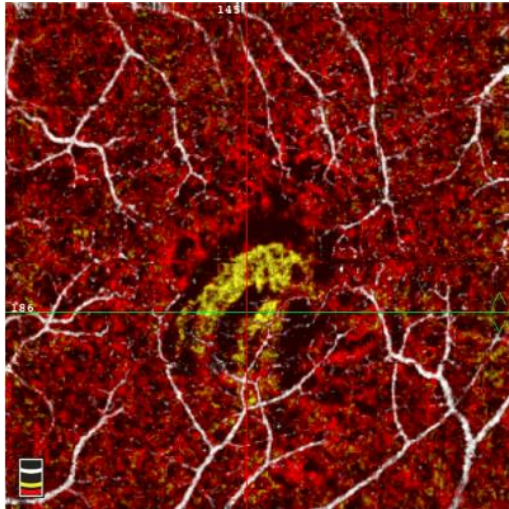
- **Reset View:** Resets view to the default settings.
- **Edit:** Redirects to montage edit screen
- **Vitreous/Retina:** Displays Vitreous/Retina slabs
- **Outer/Choroid:** Displays Outer/Choroid slabs
- **Grayscale:** Presents images in grayscale if checked
- **Print:** Prints the current display.

6.6.6.3 Montage Layers Boundaries and Color Legend

- Vitreous (Upper limit: = -2000; Lower Limit = ILM); Color= Green
- Superficial (Upper limit = ILM; Lower limit = IPL-10 μ m); Color= Grayscale
- Deep (Upper limit = IPL-10 μ m; Lower Limit = OPL+10 μ m); Color= Purple
- Outer (Upper limit = OPL+10 μ m; Lower limit = BRM-10 μ m); Color = Yellow
- Choroid (Upper limit = BRM-10 μ m; Lower limit = BRM+30 μ m); Color = Red

6.6.6.4 Layers Adjustment on Montage Image

AngioVue® images are 3D images. To view every available layer of AngioVue® image data stacked in an image, click on an image → an outer frame color will appear indicating at what depth the screen is currently, then scroll the mouse wheel to change the level of opacity. AngioVue® software assigns colors to the borders of the image data at each depth to enable you to identify the layer in which you are viewing specific anatomy.



Levels adjusted so superficial vessels indicate location of lesion, and the outer color (yellow) indicates CNV above the RPE while red shows choroidal layer.

Figure 120 Example of Type 2 CNV

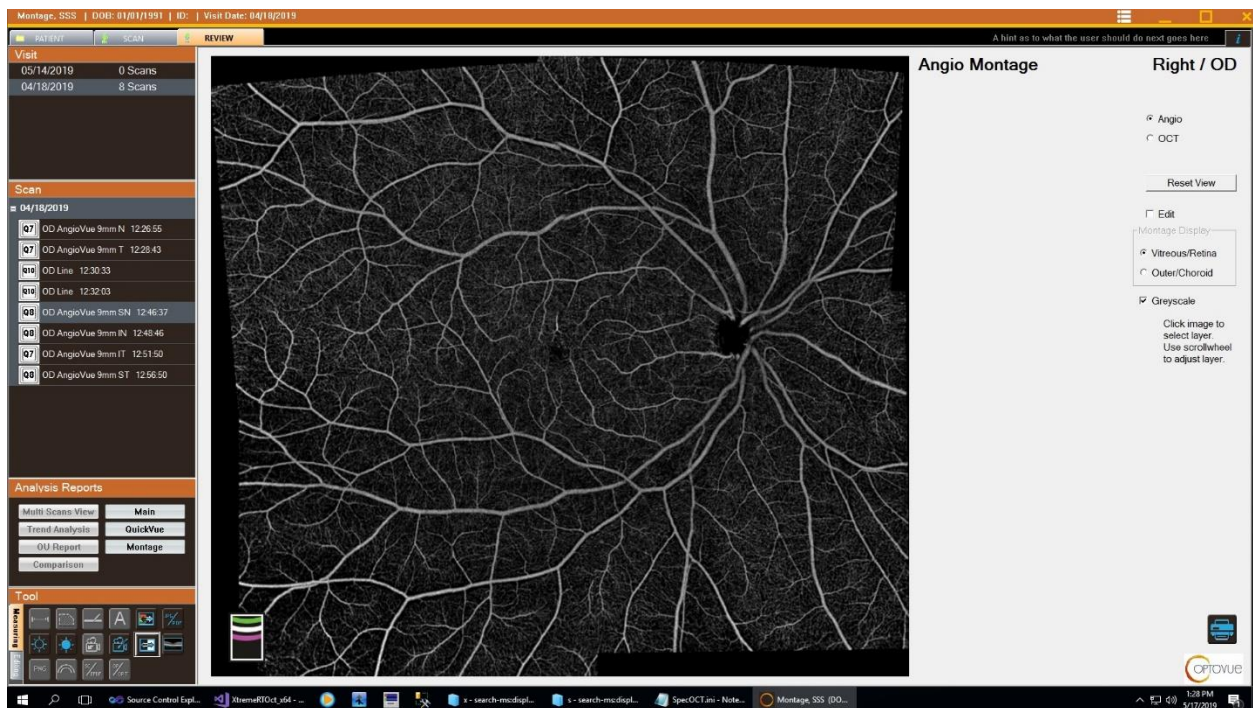


Figure 121 Montage 4 (9x9) Superficial



Figure 122 Montage 4 OCT

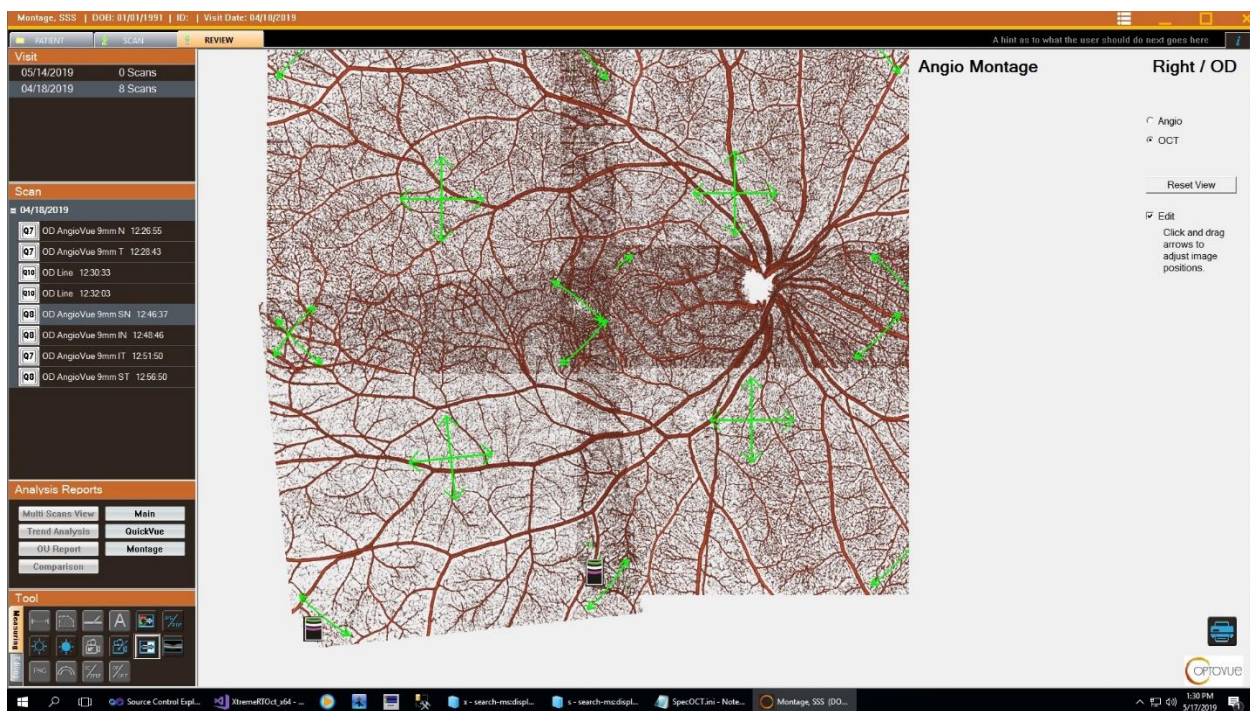


Figure 123 Montage 4 Manual alignment

6.6.7 AngioVue Disc Main Report

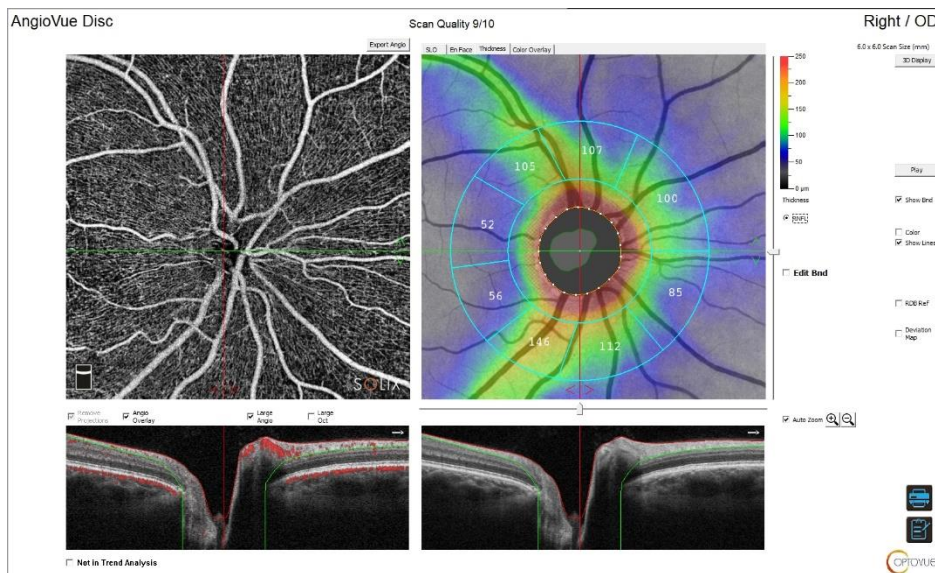


Figure 124 AngioVue® Disc Main Report, Thickness Tab Selected

The AngioVue® Disc main report is the working report, which means that the options you select here affect display of the, QuickVue and other reports. The AngioVue® Disc main report includes:

- At top left, an AngioVue® image. Above it is an **Export Angio** button to export the AngioVue® image to a file. You can choose where to save the image and what to name it in the Save As dialog that appears.
- At top center, an OCT image showing RNFL thickness using a color scale. It also has sliders to change which B-scans are shown, no matter which tab is selected.
- Along the bottom horizontal B-scans are presented, with and without Angio overlay. Unclicking the “Large Angio” button will bring the vertical b-scan along the right side of the screen.

6.6.8 AngioVue® Disc Main Report Controls

At upper right, the screen provides the following options, no matter which tab is selected above the top center image.

Left / OS

4.50 Scan Size (mm)

3D Display

Play

☒ Show Bnd

☐ Color

☒ Show Lines

3D Display: Opens the 3D Display.

Play: Plays through the B-scans.

Show Bnd: Traces boundaries with colored lines.

Color: Displays images in color

Show Line: Displays horizontal & vertical lines.

At the bottom of the screen are buttons to **Print** and **Comment** on the report.

6.6.9 Top Center Image Tabs

Thickness Tab

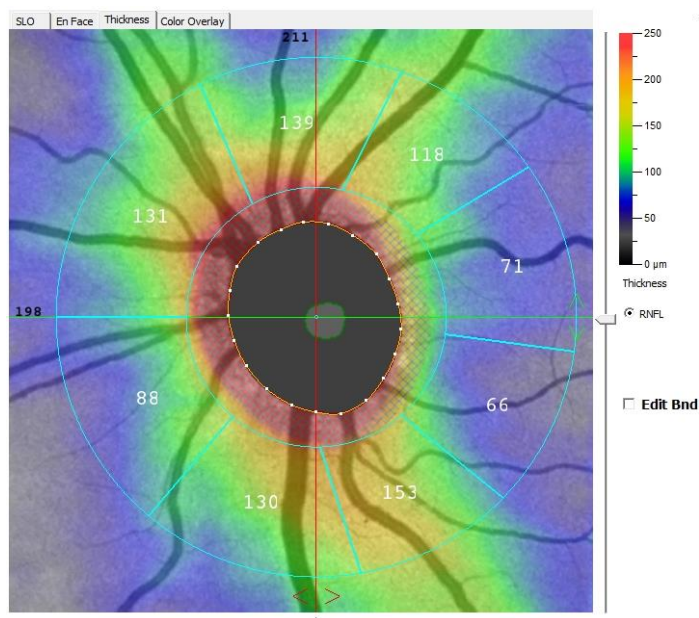


Figure 125 AngioVue® Disc Central Image Tabs

The top center image has four tabs to display the following optional images:

- **SLO:** Shows OCT and AngioVue® images of the full scan thickness
- **En Face:** Shows the en face OCT image of the disc and the corresponding AngioVue® image to the left.
- **Thickness:** Shows an SLO OCT image overlaid with retinal nerve fiber thickness using a color scale (and peripapillary grid if AngioAnalytics™™). There is also an outline of cup/disc. The cup/disc measurement uses Bruch's membrane opening (BMO) as the determining reference plane

6.6.10 RNFL RDB Map

The reference database for Macula scans is adjusted by age, and for Disc scans by age and disk area. If the disc area is not available due to calculation error, comparison with the reference database is not performed. If the age or disk carry the patient is out of the range of the database then percentiles are calculated by extrapolation the age range 18- 80 years. The disc Area range table is below

DiscArea (mm ²)	Solix AngioVue Disc	Solix Disc Cube
Mean (SD)	1.85 (0.35)	1.84 (0.35)
Median	1.82	1.81
Min, Max	[1.06, 3.41]	[1.05, 3.40]

Disc size table

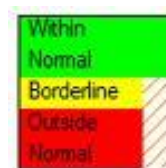
Retinal Nerve Fiber Layer (RNFL) the thicker the layer, the larger the percentile.

If there is no overlap in 95% confidence intervals for the 1st and 5th percentiles the color-coded RDB Reference Map shows regions where thickness is as follows:

(5,95) percentile Green,

(1,5) percentile Yellow

(0,1) percentile Red



if the 5th and 1st percentiles' 95% CIs overlap an Orange color diagonal cross hatching is used

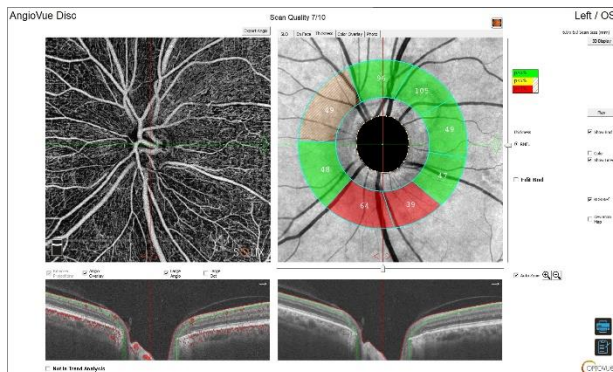


Figure 126 RNFL RDB map

6.6.11 Deviation map RNFL

The deviation map is not stratified by any factor such as age. The cutoffs for each pixel are based on the standard deviation of the Gaussian distribution over the same pixel location in the RDB normal population.

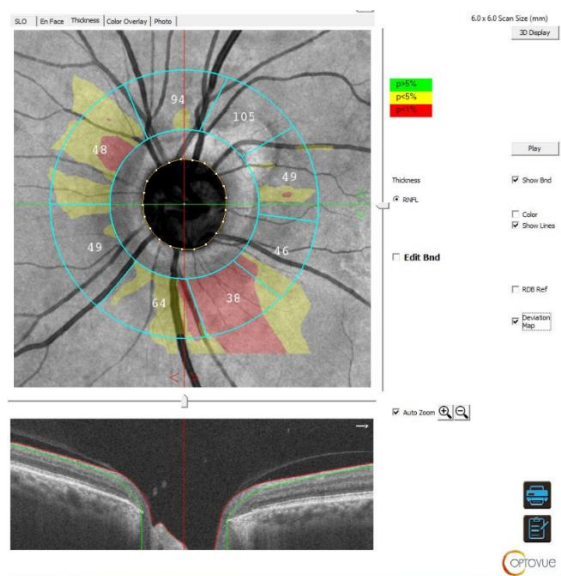
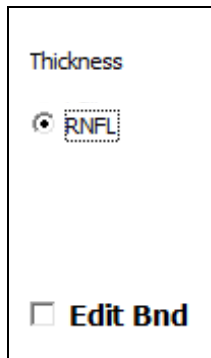


Figure 127 Deviation Map

- **Color Overlay:** allows static or movie color presentation

Note: Peripapillary (adjacent to the disc boundary) 100 µm wide ring region is displayed with mesh pattern to remind the user that no quantitative analysis is performed for this area.

6.6.12 Thickness Tab Controls



Click the **Edit Bnd** checkbox to edit the boundaries shown on the B-scans and thereby adjust the thickness.

 **Note:** segmentation of ILM can be edited similarly to AngioVue® retina scan (section 10.8), however for any other segmentation boundaries the editing of b-scan should avoid disc region. Propagation region should avoid disc region as well.

6.6.13 SLO Tab

The figure below shows AngioVue® Disc main report when the **SLO** tab is selected. The example shows the AngioVue® image in color because the color checkbox is selected at far right. SLO screen is used to edit optic disc boundaries if needed.

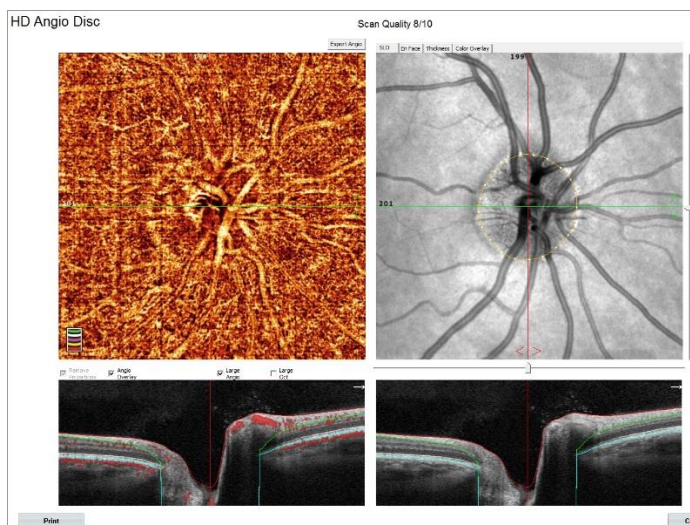


Figure 128 AngioVue® Disc Main Report, SLO Tab with Color Selected

6.6.14 En Face Tab

The figure below shows the AngioVue® and OCT images when the **En Face** tab is selected. In the example, the **RPC** option is selected in the controls at right. The following section explains the controls.

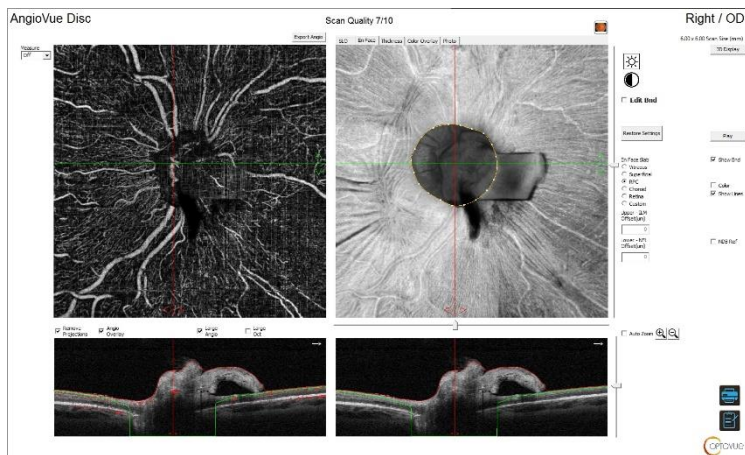


Figure 129 AngioVue® Disc Main Report, En Face Tab Selected

En Face Tab Controls



Brightness Icon: Click to adjust.



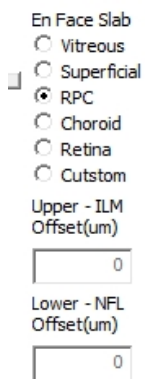
Contrast Icon: Click to adjust contrast.

☐ **Edit Bnd**

Edit Bnd: Clicking this checkbox will take you to the segmentation editing and propagation screen

Restore Settings

En Face Slab: Use the radio buttons to display the retinal segment indicated.



Vitreous

Superficial

RPC

Choroid

Retina

Custom

Upper – ILM Offset (μm): Displays the name and offset of upper boundary for the selected slab

Lower – IPL Offset (μm): Displays the name and offset of lower boundary for the selected slab.

6.6.15 Color Overlay Tab, Movie

When the Color Overlay tab is selected, the image shows the AngioVue® and OCT images. An overlay pull-down selection is available on the left, default is Movie. When play is selected the screen will display the retinal slabs by colors and track the level by the moving indicator to the left. There is also static selection for Vitreous, Superficial, Deep, Outer and Choroid. All static layers have adjustable opacity to enable the user to highlight the pathology.

 **Note:** En face images show a small icon with color slab indicator, using the same colors as the movie legend.

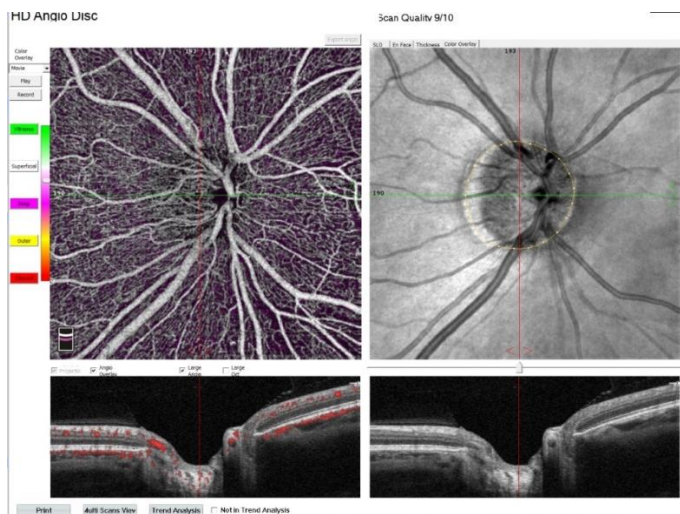


Figure 130 AngioVue® Disc Main Report, Color Overlay Tab with Movie Selected

Movie Layers Boundaries

- Vitreous (Upper limit: = -2000; Lower Limit = ILM); Color= Green
- Superficial (Upper limit = ILM; Lower limit = IPL-10 μ m); Color= Grayscale
- Deep (Upper limit = IPL-10 μ m; Lower Limit = OPL+10 μ m); Color= Purple
- Outer (Upper limit = OPL+10 μ m; Lower limit = BRM-10 μ m); Color = Yellow
- Choroid (Upper limit = BRM-10 μ m; Lower limit = BRM+30 μ m); Color = Red

Color Overlay, Static

Static images are available for all 5 layers listed above, with corresponding color-coding.

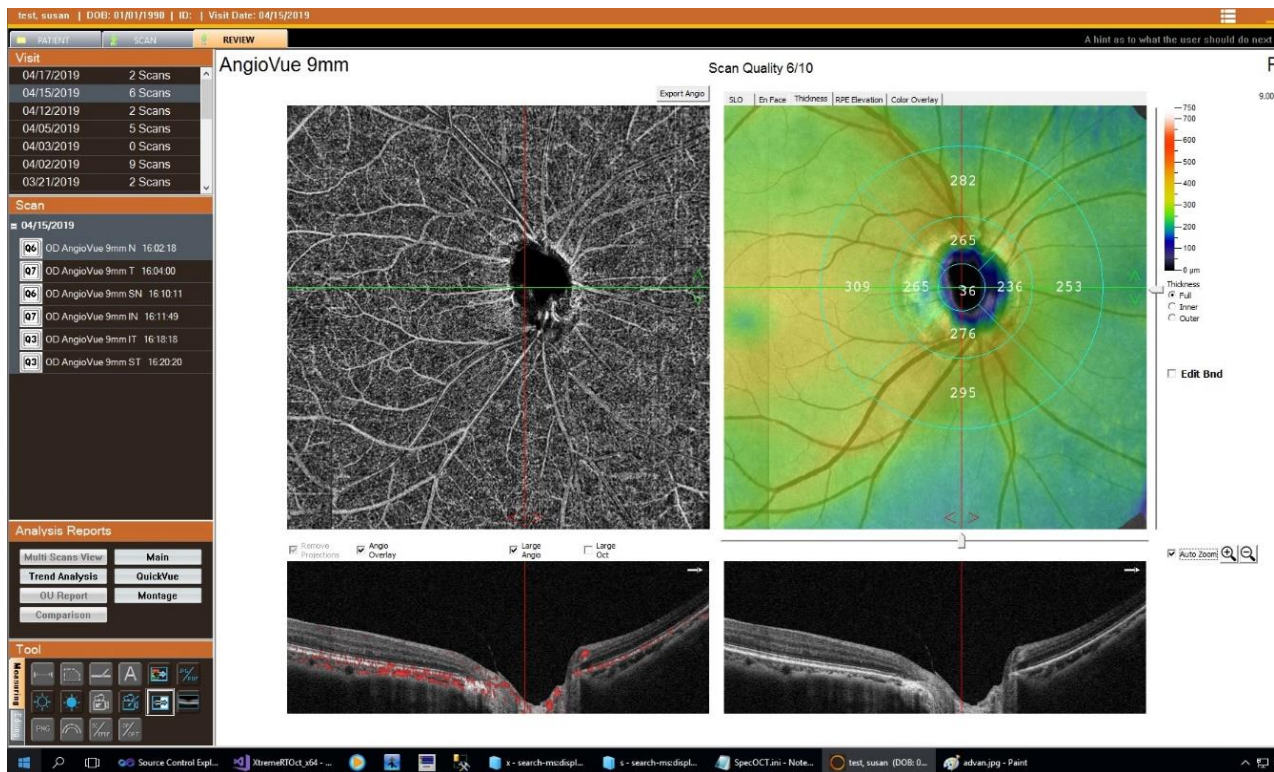


Figure 131 AngioVue® Disc 9x9 mm

6.6.16 AngioVue® Disc Multiple Visits Report

Use this report to visualize en face disc images and the corresponding B-scans. The b-scans location is “linked” (registered) across visits to display same anatomical location. The system displays scans from up to eight visits. Select or deselect visits to display using the list at upper left. Utilize the multi-scans view button to refresh the page after selections. One of the five standard en face layers, or custom layer can be selected for display. AngioAnalytics™™, shows vessel density for RPC slab for AngioVue Retina and AngioVue Disc.



Figure 132 AngioVue® Disc Multiple Visit Report, RNFL RDB

6.6.16.1 AngioVue® Disc Multiple Visits Report Controls

Right / OD

En Face Slab

☐ Vitreous

☐ Superficial

☒ RPC

☐ Choroid

☐ Retina

☐ Custom

Measurement

☒ None

☐ Vessel Density

☒ Link B-Scans

☐ Invert

☐ Color

☒ Show Bnd

☒ Angio

☐ OCT

En Face Slab: Use the radio buttons to display the retinal slab indicated.

Vitreous

Superficial

RPC

Choroid

Retina

Custom

Measurement

None

Vessel Density

Reset View: reverts to original

Link B-scans: links B-scans from multiple images to display same anatomical location

Invert: Select to invert the gray scale shading or color of the images.

Color: Select color image

Show Bnd (Boundaries) in the B-scans.

Use the radio buttons at lower right to show either **AngioVue®** or **OCT** images for comparison.

7 AngioAnalytics™™

AngioAnalytics™™ enables measurement of retinal vessel density, FAZ, flow area and non-flow area as well as retinal layer thickness to the 6.4 mm AngioVue® Retina scans. It also enables the measurement of RPC density and RNFL thickness and optic disc measurements for 6 mm AngioVue® disc scans.

This measurement functionality is available in the AngioVue® Retina and AngioVue® Disc Main Reports. The **Measure** field (next to the AngioVue® image) at upper left is **Off** by default. Use the down arrow to select to measure **Vessel Density, FAZ, Flow** and **Nonflow** parameters. Some functionality is also displayed in the Multi scan and QuickVue reports. These options are described below.

 **Note:** All quantitative analysis for the vasculature are based on en face images after removing projection artifacts. Deselecting artifact removal deactivates the **Measure** field.

Vessel density is quantitation of the proportion of pixels representing vessels) out of total number of pixels for regions in the *en face* images of the Superficial plexus, the Deep plexus, and the RPC respectively.

 **Note:** The Vessel Density and other vessel related parameters of OCTA scans do not have RDB comparison.

7.1 AngioAnalytics™ Composition

AngioAnalytics™ is composed of 3D segmentation and quantitative analysis of posterior ocular structures based on OCTA scans:

7.1.1 AngioVue® Retina

AngioVue® retina scan segmentation (8-layer)

- Retina en face slabs are predefined:
 - Superficial (Upper limit = ILM; Lower limit = IPL-10µm)
 - Deep (Upper limit = IPL-10µm; Lower Limit = OPL+10µm)
 - Outer (Upper limit = OPL+10µm; Lower limit = BRM-10µm)
 - Choroid (Upper limit = BRM-10µm; Lower limit = BRM+30µm)
 - Retina (Upper limit = ILM; Lower limit = OPL+10µm)
- Automatic fovea center detection.
- Measurements of the vessel density within AngioVue® retina scan measurement areas
- Measurement of the thickness of the retina and layers of retina in the macula within measurement areas
- Automatic FAZ margin detection and FAZ parameters calculations t
- Flow and Non-Flow tool

 **Note:** AngioVue® retina scan segmentation (8-layer) supports the thickness measurement of full retina, inner retina, and outer retina, similar to thickness measurements before with OCT scans. The 8-layer segmentation only applies to OCTA scans and have no impact to OCT scans.

7.1.2 AngioVue® Disc

AngioVue® Disc scan segmentation (7-layer)

- Disc en face slabs are predefined:
 - Vitreous (Upper limit = ILM-2000µm; Lower limit = ILM)
 - Superficial (Upper limit = ILM; Lower limit = IPL-10µm)
 - RPC (Upper limit = ILM; Lower Limit = NFL)
 - Choroid (Upper limit = BRM-10µm; Lower limit = BRM+30µm)
 - Retina (Upper limit = ILM; Lower limit = OPL+10µm)
- Automatic optic disc margin detection
 - Measurements of the vessel density within AngioVue® Disc scan measurement areas
 - Measurement of the thickness of the retinal nerve fiber layer (RNFL)
 - Measurement of the optic disc parameters, including disc area, rim area, cup area, cup-to-disc ratio.

7.1.3 Scan Centering and AngioAnalytics™ Measurements

AngioVue® retina scans should be centered on the fovea and AngioVue® Disc scan should be centered on the optic disc to minimize truncation of the measurement areas, such as ETDRS grid and Garway-Heath grid.

If due to scan de-centration one of the measurement sectors is lacking more than 30% of pixels as calculated by the software, the metrics for that sector are marked as “NA”

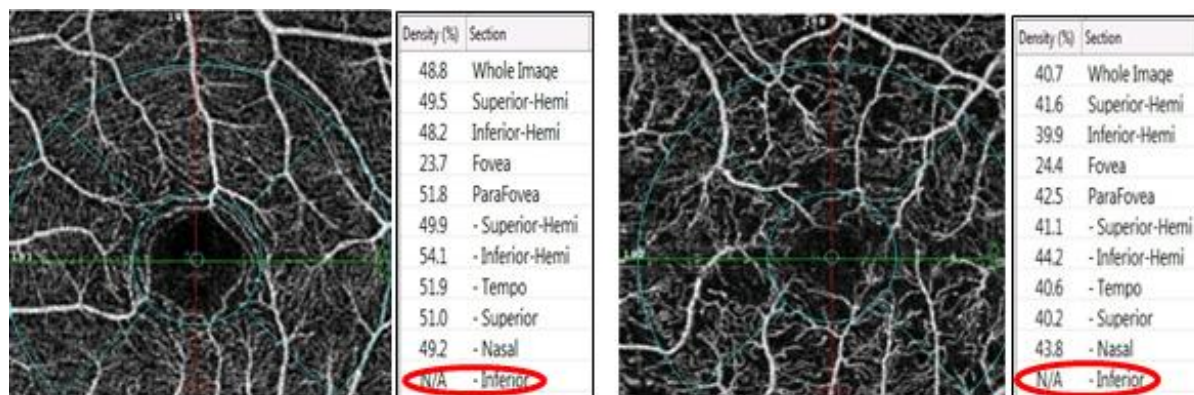


Figure 133 Sector Crop >30% Marked NA

7.2 AngioVue® Retina Analytics

7.2.1 Fovea Center Detection

The fovea center is an important anatomical landmark. Accurate identification of fovea center allows placement of fovea-centered measurement grids such as the early treatment diabetic retinopathy study (ETDRS) grid, as well as registration across multiple visits.

The subject device identifies fovea center automatically by searching for the thinnest part of the inner retina slab (ILM to IPL) generated from the automatic segmentation.

7.2.2 ETDRS Grid Centration

ETDRS grid misplacement can affect vessel density and retinal thickness measurements.

ETDRS grid centration adjustment can be performed by simple dragging of the grid to the required position. All metrics are recalculated by the software following grid replacement.

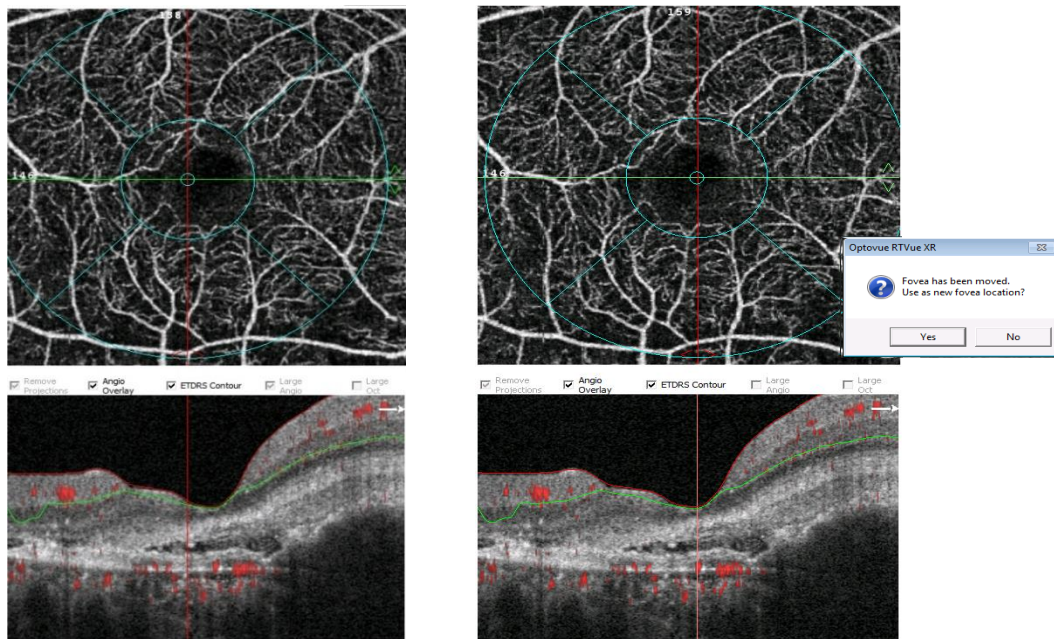


Figure 134 Grid centration

Left - ETDRS grid is not precisely centered on fovea on this 3 mm AngioVue® retina scan. By simple dragging of the grid and dropping it at the desired location, the placement of the grid can be changes, and the action will require confirmation from the operator, by providing response to the pop-up icon – Right

7.2.3 AngioVue® Retina Measurement Zones and Parameters

Schematic presentation of the measurement zones and their report nomenclature for the 6.4mm AngioVue® Retina scans.

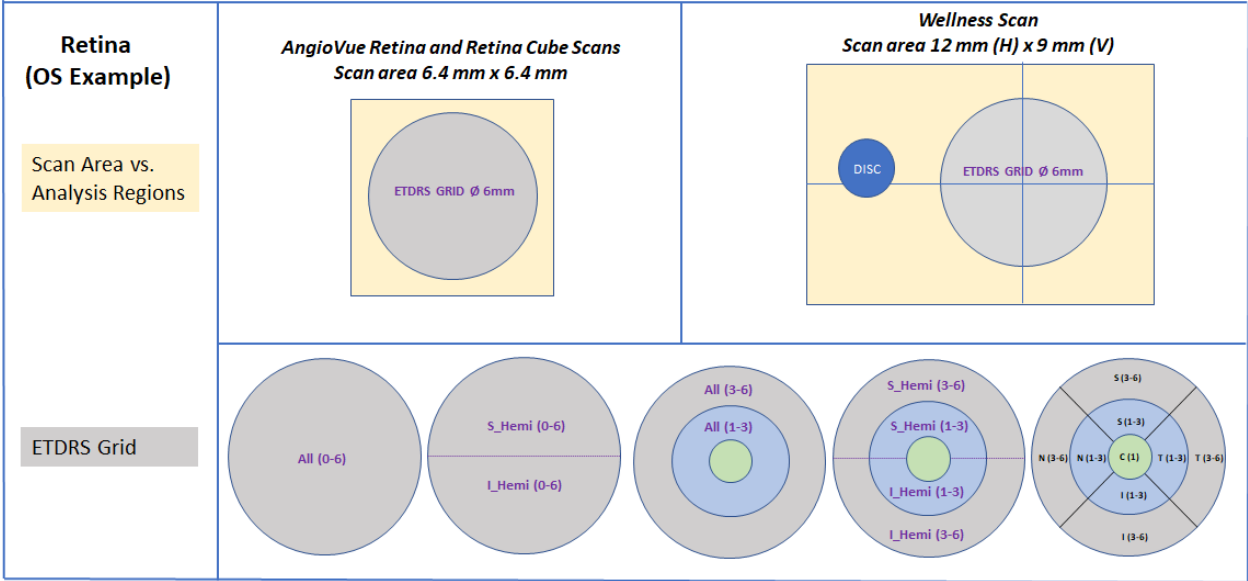


Figure 135 AngioVue® Retina Measurement Zones and Parameters

The ETDRS grid is comprised of 3 concentric rings: 1 mm center (green), 1-3 mm (parafovea, blue), and outer ring of 3-6 mm diameters (perifovea, gray). The outermost rings are further divided into 4 sectors for Quadrant analysis (temporal (T), superior (S), nasal (N) and inferior (I)) or 2 Hemispheres (Superior (S_Hemi) and Inferior (I_Hemi), divided by horizontal line through the foveal center. Left eye (6 mm full ETDRS grid) are illustrated here to show mirrored display of T and N sectors between right and left eyes. The whole image parameters are also subdivided further into Superior and inferior halves and 9 equal squares, however naming of the sectors remains constant in relation to the right /left eye.

7.2.4 RDB Reference Data Base

Reference database scans:

Measurement Region	Measurement Type	Scan Pattern				
		AngioVue Retina (6.4mm x 6.4mm)	Retina Cube (6.4mm x 6.4mm)	Wellness (12mm x 9mm)	AngioVue Disc (6mm x 6mm)	Disc Cube (6mm x 6mm)
Macula	GCC Thickness	✓	✓	✓		
	Full Retinal Thickness	✓	✓	✓		
Peripapillary & Optic Disc	RNFL Thickness				✓	✓
	Rim, Cup, C/D Ratio				✓	✓

Figure 136 RDB scan list

The reference database for Macula scans is adjusted by age and for Disc scans by age and disk area. If the data is not available due to poor image/calculation error, comparison with the reference database is not performed. If the age of the patient is out of the range of the database there are no RDB colors (range 18- 80 years)

DiscArea (mm ²)	Solix AngioVue Disc	Solix Disc Cube
Mean (SD)	1.85 (0.35)	1.84 (0.35)
Median	1.82	1.81
Min, Max	[1.06, 3.41]	[1.05, 3.40]

Disc size table

For Macula scans RDB references are available only for full retinal thickness and GCC.

The Retina report includes multi color display for retinal thickness with respect to the Reference database, GCC is displayed as a Deviation map, (only yellow and red) green is assumed if no color, this allows better visualization of the underlying vessel.

7.2.4.1 Retina RDB

Retina measurements the thicker the layer, the larger the percentile.

If there is no overlap in 95% confidence intervals for the 1st and 5th percentiles the color-coded RDB Reference Map shows regions where thickness is as follows:

(0,1) percentile Dark Blue

(1,5) percentile Light Blue

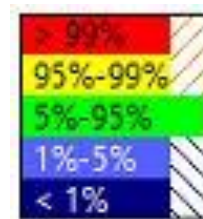
if 1st and 5th percentiles' CIs overlap a Medium Blue color diagonal cross hatching is used

If there is no overlap in 95% confidence intervals for the 95th and 99th percentiles the color-coded RDB Reference Map shows regions where thickness is as follows

(5,95) percentile Green,

(95,99) percentile Yellow

(99,100) percentile Red



if the 95th and 99th percentiles' 95% CIs overlap an Orange color diagonal cross hatching is used.



Note: An RDB caution is shown above the report

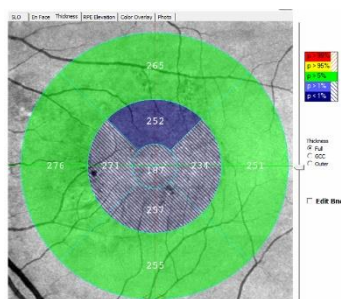


Figure 137 Retina 3D Map with RDB Reference

RDB references can appear in the ETDRS Chart, the RDB Reference Map and the retinal parameters table. See Appendix for more detail on the Reference Database.



Note: The Reference database embedded in system software enables comparison of measured retinal thickness and GCC with that of patients in the normal range. RDB comparison provides an objective metric for a clinician to use in making an overall diagnosis.

7.2.5 Assessing the GCC

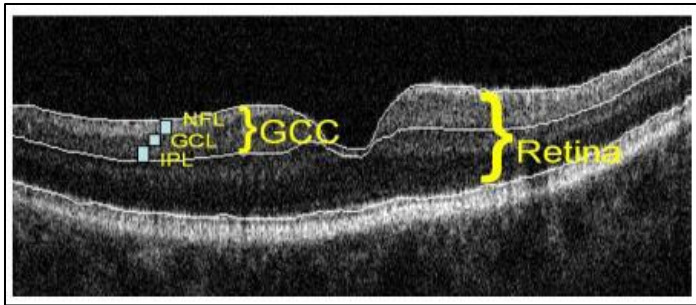


Figure 138 The GCC and Its Layers

The ganglion cell complex (GCC) encompasses three layers of ganglion cells in the retina:

1. The retinal nerve fiber layer (RNFL) is made up of the ganglion cell axons,
2. The ganglion cell layer (GCL) is made up of the ganglion cell bodies,
3. The inner-plexiform layer (IPL) is made up of the ganglion cell dendrites.

The GCC becomes thinner as ganglion cells die from glaucoma. By measuring GCC thickness, the GCC scan supports clinicians who diagnose and track glaucoma and other diseases that affect the GCC layer.

7.2.6 GCC Thickness Map or Deviation Map

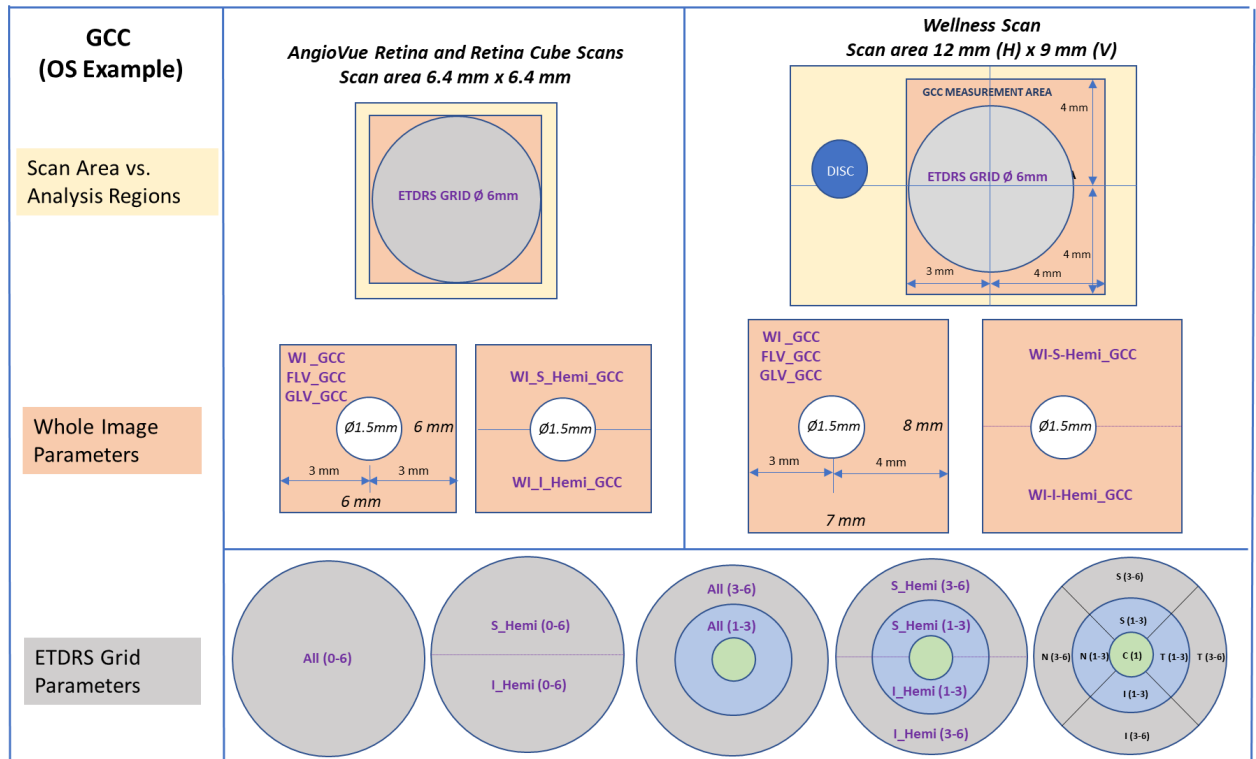


Figure 139 GCC measurement areas

The Thickness Map is 6.4 mm diameter and uses a color scale to indicate thickness (in μm). Use the **Thickness** and **Deviation** radio buttons below the map to choose which type of map to display. The deviation map is not stratified by any factor such as age. The cutoffs for each pixel are based on the standard deviation of the Gaussian distribution over the same pixel location in the RDB normal population. The color key next to the maps explains the values associated with the colors.

The GCC thickness map for a normal eye shows a broad sweep of bright color around the fovea, indicating a GCC with healthy ganglion cells (The fovea has no ganglion cells and therefore shows darker color.) In glaucoma, the GCC thins as ganglion cells are lost; consequently, the extent of bright color around the fovea contracts (glaucoma eye at right). Warmer colors from yellow, orange and red to white represent greater values. Cooler colors from green to blue to black represent lesser values.

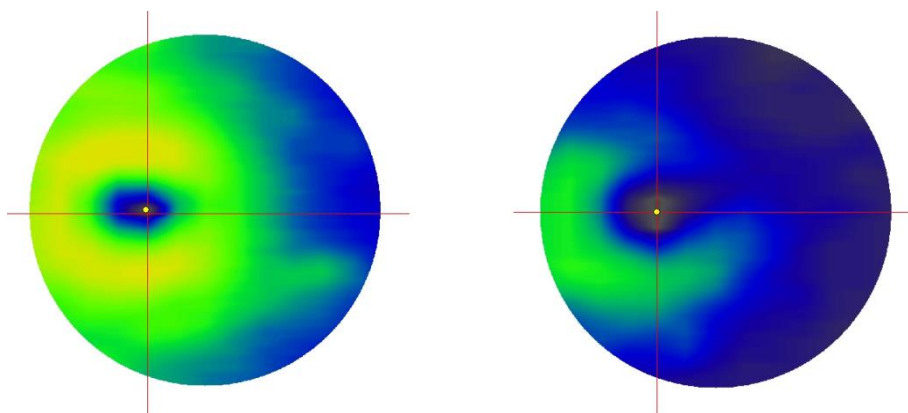


Figure 140 GCC Thickness Maps: Healthy Eye (Left), Glaucoma Eye (Right)

7.2.7 B-Scan Display

The red lines on the RDB Map at upper right indicate the currently selected scan lines of the GCC scan pattern, which correspond to the B-scans shown at lower left and center.

- Select **Show Lines** to show scan pattern lines on the thickness map and RDB map. Select **Show Boundary Curves** to show the segmentation lines on the B-scans.
- When you click on the RDB Map, the red lines change to blue and move to the vertical scan where you click. The vertical line then follows the pointer until you click again, and the lines turn back to red. While you move the blue lines, the corresponding B-scan also updates.

7.2.8 GCC RDB Map

The reference database for Macula scans is adjusted by age, and for Disc scans by age and disk area. If the data is not available due to poor image/calculation error, comparison with the reference database is not performed if the age of the patient is out of the range of the database there are no RDB colors (range 18- 80 years)

DiscArea (mm²)	Solix AngioVue Disc	Solix Disc Cube
Mean (SD)	1.85 (0.35)	1.84 (0.35)
Median	1.82	1.81
Min, Max	[1.06, 3.41]	[1.05, 3.40]

disc size table

Ganglion Cell Complex (GCC) the thicker the layer, the larger the percentile.

If there is no overlap in 95% confidence intervals for the 1st and 5th percentiles the color-coded RDB Reference Map shows regions where thickness is as follows:

(5,95) percentile Green,

(1,5) percentile Yellow

(0,1) percentile Red

if the 5th and 1st percentiles' 95% CIs overlap an Orange color diagonal cross hatching is used.



 Note: An RDB caution is shown above the report



Thickness and Volume Parameters Table

The table reports GCC thickness and volume parameters. Applicable measurements appear against a green, yellow or red background, indicating whether the measurement is within normal (green), borderline (yellow) or outside normal (red). Parameters include:

- **Average GCC thickness** (in μm) overall (Total) and in the superior and inferior hemispheres. GCC thickness is measured from ILM to IPL. Each measurement appears against a green, yellow or red background, indicating whether the measurement is within normal (green), borderline (yellow) or outside normal (red). Intra-eye Difference (S-I) is difference of thickness value between hemispheres.
- **FLV (%) Focal Loss Volume** quantifies the amount of significant GCC loss. FLV is expressed as a percentage of the map area with significant ganglion cell loss (by volume).

- **GLV (%) Global Loss Volume** quantifies the average amount of GCC loss over the entire GCC map. GLV is the sum of the pixels where the fractional deviation map value is < 0 , divided by the total map area to give a percent loss of GCC thickness.

7.2.9 AngioVue ONH GCC OU Trend Report

When both Retina and Disc scans were acquired for an eye on three or more visits, the **OU Report** button on the ONH and GCC reports generates a Nerve Fiber ONH/GCC Trend report. This report automatically displays ONH and GCC thickness/RDB maps for up to 4 visits for both eyes as well as plots for key measurements and a chart for ONH parameters.

- **Thickness Maps:** The report shows thickness maps for up to 4 GCC scans and 4 RNFL scans per eye. The software automatically selects for display the earliest first visit and the latest 3 visits. If desired, you can use the list of visits in the column at left to select which scans to display.
 - **GCC Thickness Maps** support evaluation of GCC thickness distribution (color, pattern, and fovea centering) for consistency, scan quality, and obvious measurement artifacts. Usually, the visits should be reasonably consistent with each other, unless a confirmed condition exists to explain rapid change between visits. Scans with clearly identified image quality problems should be deleted to avoid inclusion in change analysis. Compare images to the GCC trend to rule out contradictory images or those that prompt data quality concerns.
 - **RNFL Thickness Maps** support evaluation of RNFL thickness distribution (color and pattern) and disc/cup shapes for consistency, scan quality, and obvious measurement artifacts. Usually, visits should be reasonably consistent with each other. Scans with clearly identified image quality problems should be deleted to avoid inclusion in change analysis. Compare images to the RNFL trend to rule out contradictory images or those that prompt data quality concerns.
- **Comparison to RDB Table:** At upper right, a table reports GCC and RNFL measurements for the first and last visits. Table cells are color-coded with respect to the Reference database.
- **TSNIT Graph:** In the middle is a TSNIT graph displaying RNFL thickness at each visit. The TSNIT graphs help you visualize regions of change and the shape of the RNFL distribution, and to judge test consistency. The TSNIT graph is based on the 3.45mm diameter ring centered on disc center, with 50 micron to each side, creating a 100 micron width ring.

- **Rate of Change Graphs:** At bottom are graphs that plot RNFL thickness and GCC thickness versus age. Above each graph appears the estimated rate of change (in μm) per year. Different from other threshold-based change detection methods, this change analysis does not apply a fixed threshold for change detection and makes no assumption of test-retest variability. The rate of change estimate uses simple linear regression. It fits a straight line to a graph of thickness data points versus age and calculates the slope of the line to determine whether it indicates a statistically significant change in thickness.

7.2.10 AngioVue Disc Combo OU Report

When the patient visit includes both AngioVue® Disc and AngioVue® Retina scans for both eyes, if the AngioVue Disc is selected then clicking the **OU Report** button generates an AngioVue® Disc Combo report for detailed symmetry evaluation and comparison to RDB.

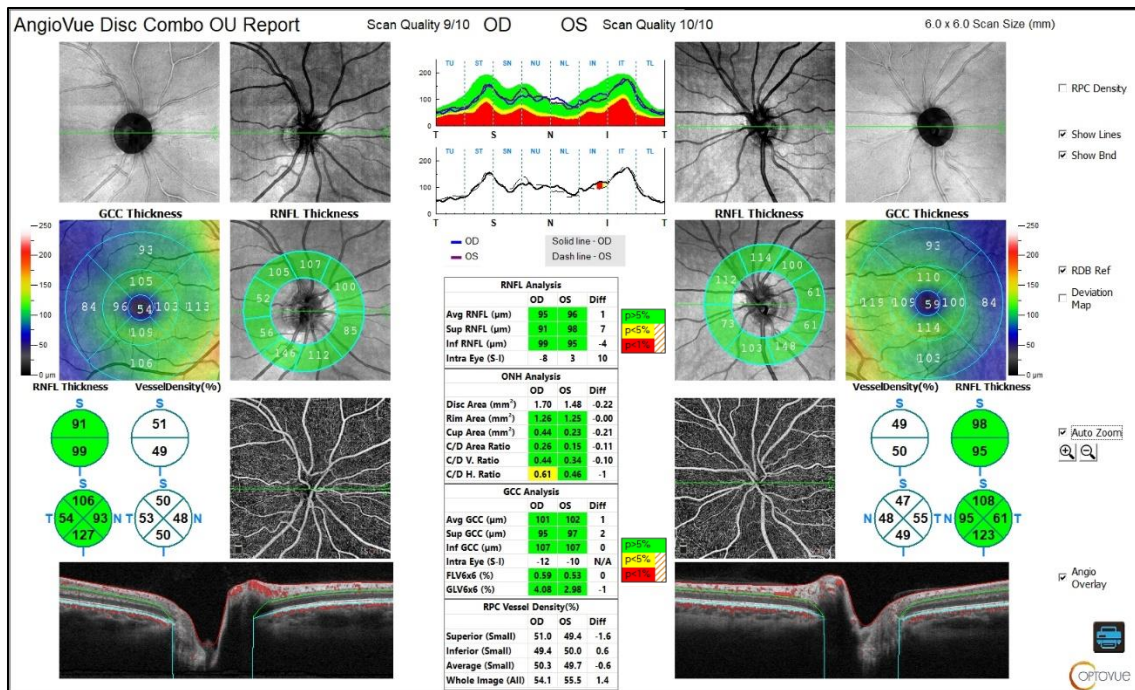


Figure 141 AngioVue® Disc Combo report

This report includes the elements of the ONH, GCC, and disc for both eyes side by side, for analysis of symmetry and RDB.

7.2.11 AngioVue® Retina Vessel Density and Retinal Thickness

Vessel density analysis computes the percentage of area occupied by OCTA detected vasculature.

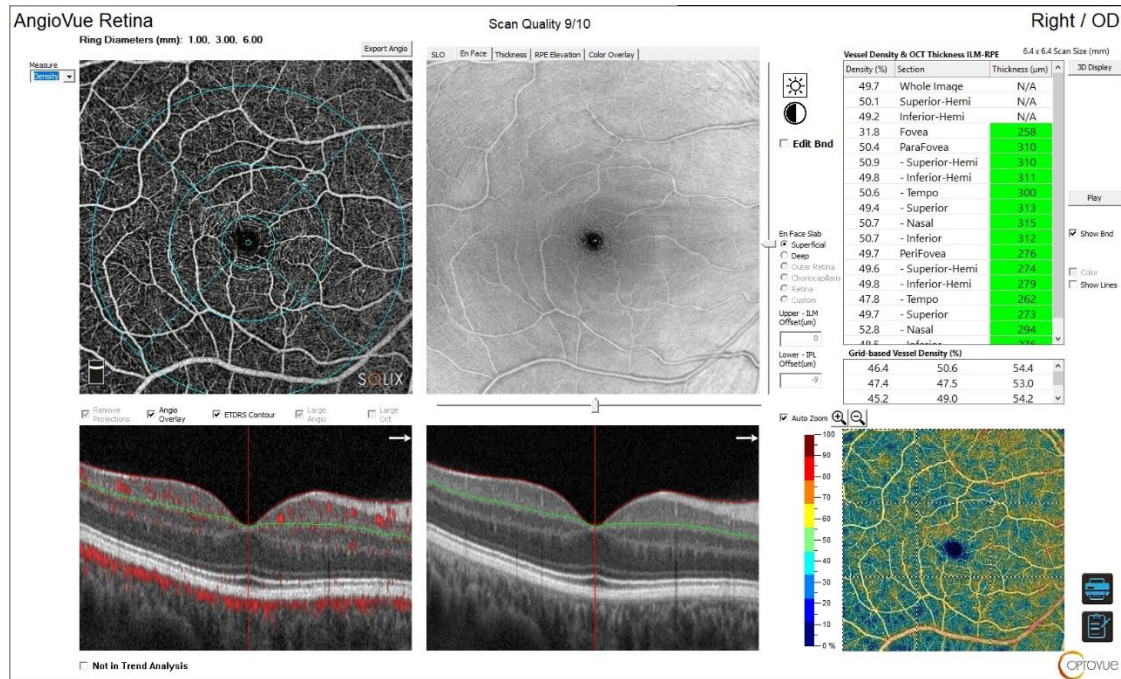


Figure 142 6 mm AngioVue® Retina, Main Report

Select **Density** in the Measure field next to the AngioVue® image at upper left. Concentric blue circles indicating the ETDRS sectors overlay appear on the selected retina slab of the image. The ring diameters appear above the image.

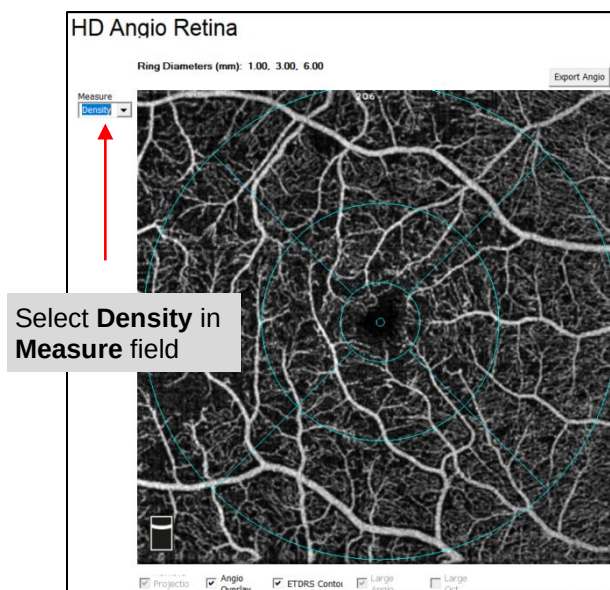


Figure 143 Measurement Window Selection

-  Note: All density measurements are calculated with PAR on. Turning off PAR allows for visualization of vessels with projection artifacts. No quantitative analysis allowed in this mode.
-  Note: It is recommended that the PAR-corrected images are inspected and compared to PAR-uncorrected images prior to interpreting vessel density measurement values to determine if there has been extensive removal of non-artifactual signal.
-  Note: that vessel density measurements are determined only with PAR correction. Therefore, the precision data of vessel density measurements from the AngioAnalytics™ R&R study, reflects measurements only with PAR on.
-  Note that vessel density measurements are less accurate in locations where there are both projection artifacts and in-situ signal (e.g., deep plexus locations with projection artifacts from the overlying superficial plexus).

It is recommended that the PAR-corrected images are inspected and compared to PAR-uncorrected images prior to interpreting vessel density measurement values to determine if there has been extensive removal of non-artifactual signal.

The system measures vessel density of the selected slab (Superficial or Deep) and presents it in tables at upper right, as in the example below.

The blue, concentric ETDRS grid overlay on the AngioVue® image indicates the sections measured.

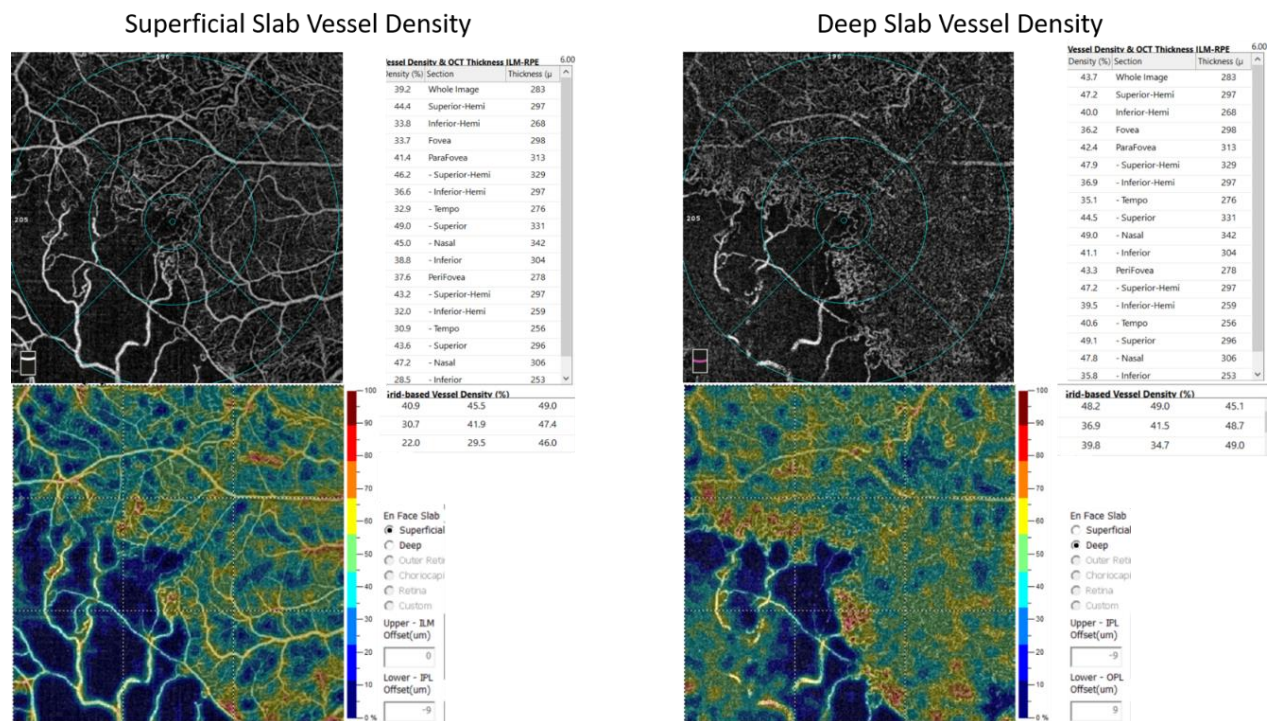


Figure 144 Superficial and Deep Vessel Density Measurements

The large table displays vessel density in % on the left and OCT full retinal thickness on the right for the listed sections of the current layer – superficial on the left, and deep on the right.

The lower table reports the 3x3 grid-based vessel area density in % that matches the color image below.

Under Enface Slab is the radio button showing the displayed and measured layer, “Superficial” or “Deep”.

A color overlay indicates vessel density over the AngioVue® image area. The color scale legend at right associates the colors on the map with percent density in ten percent increments.

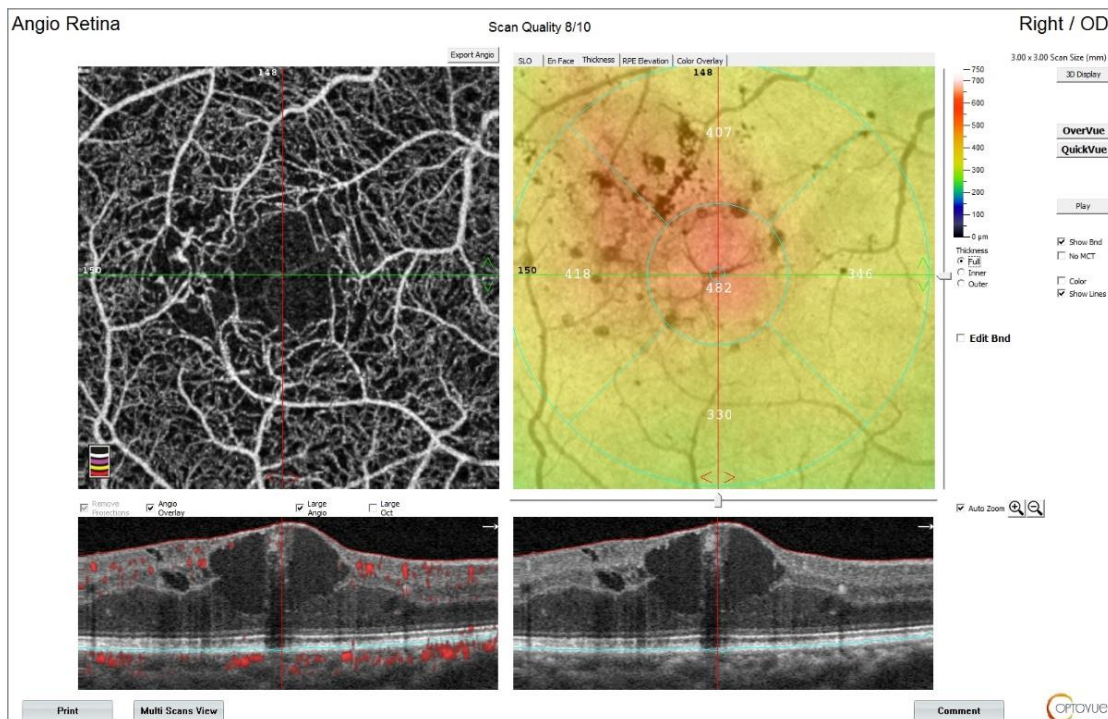


Figure 145 AngioVue® Retina Main Report, Thickness Tab with Full Retina Thickness Selected

→ Vessel density and thickness measurements are available on the Main, Multi scan, Trend and QuickVue reports.

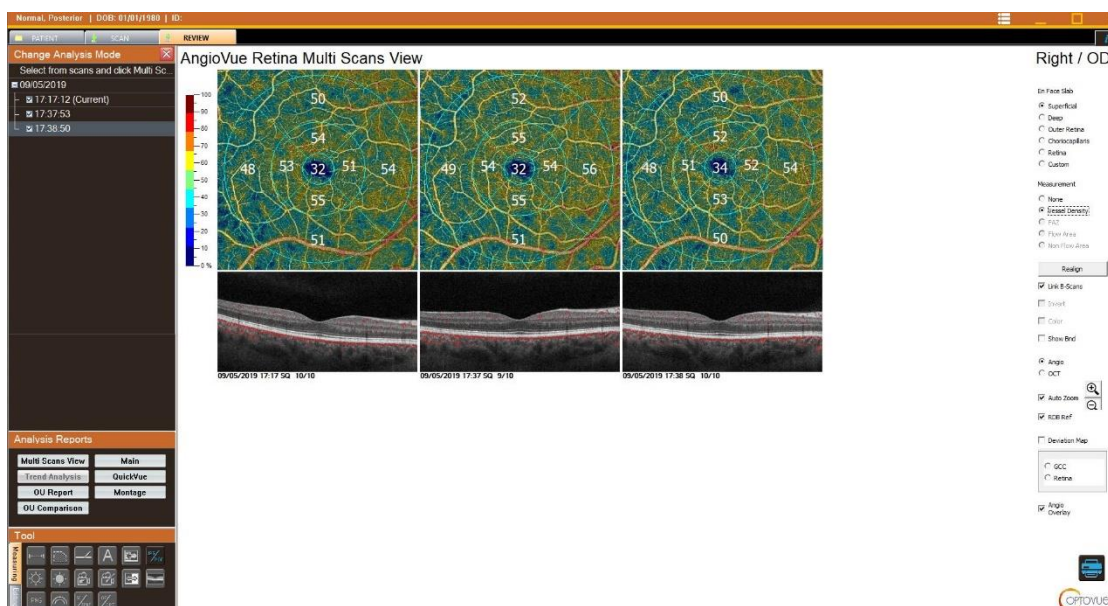


Figure 146 Retina Multi Scan Showing Superficial Density

7.2.12 Foveal Avascular Zone (FAZ)

In fluorescein angiographic analysis of the retina, the center of the macula is generally capillary-free, this area being named the foveal avascular zone (FAZ).

Foveal avascular zone (FAZ) measurements are based on AngioVue® Retina scan – 6.4 mm and are generated based on the Retina slab (ILM to OPL+10 μ).

The following parameters are provided: (Fig. 174):

- FAZ: FAZ area in mm² (6.4 mm OCTA scans)
- PERIM: FAZ perimeter in mm (6.4 mm OCTA scans)
- FD: vessel density of the 300 μ width ring surrounding the FAZ, in %. (6.4 mm OCTA scans). FD is calculated by dividing the number of vessels pixels by the total number of pixels, multiplied by 100%. The foveal vessel density measurement (FD) is not interchangeable with any other system or scan.

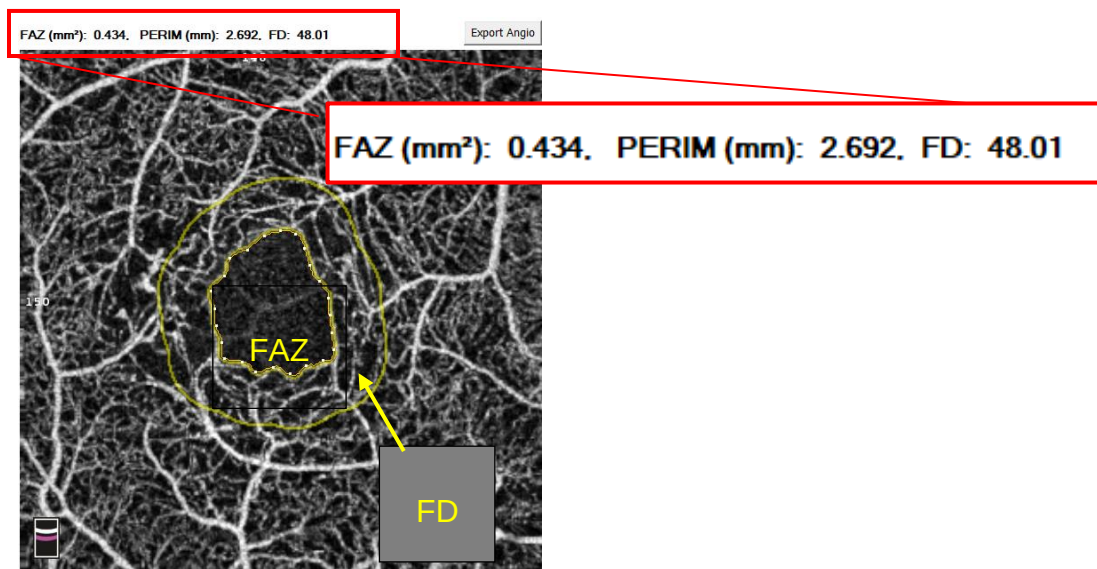


Figure 147 FAZ Parameters

Automated FAZ boundary detection is provided by the AngioVue® software, applied on **Retina** slab (ILM to OPL+10 μ m) and can be reviewed on the En Face screen, under “FAZ” measurement.

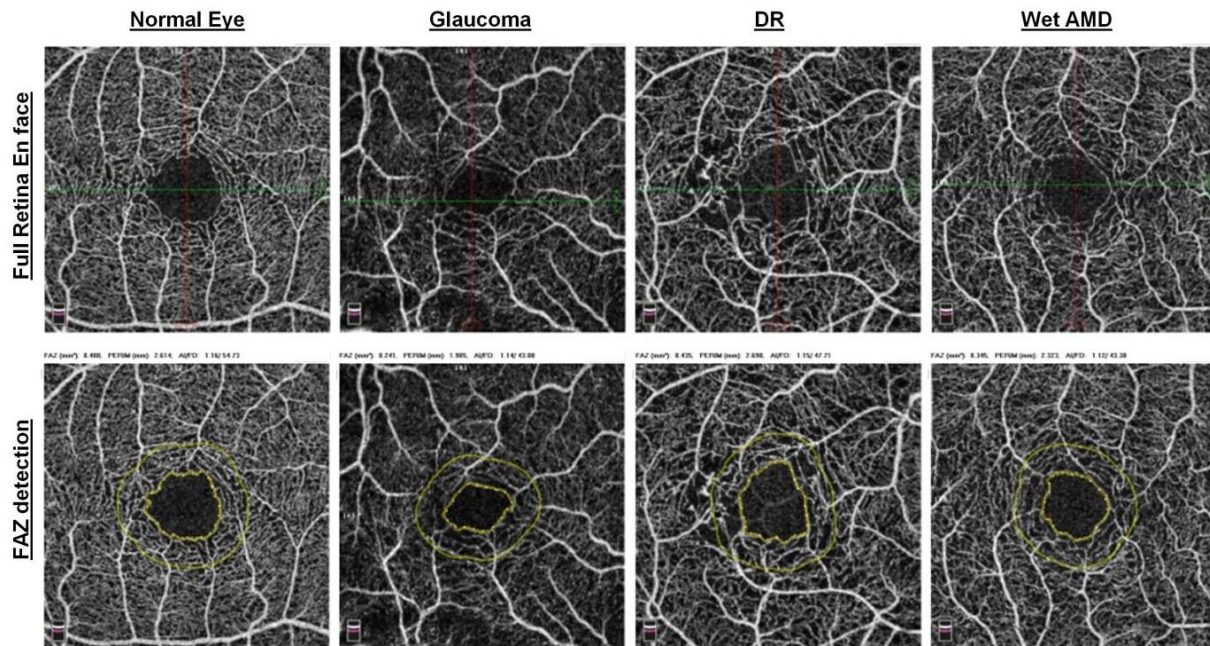


Figure 148 Examples of FAZ Detection based on AngioVue® Retina 3mmx3mm scan.

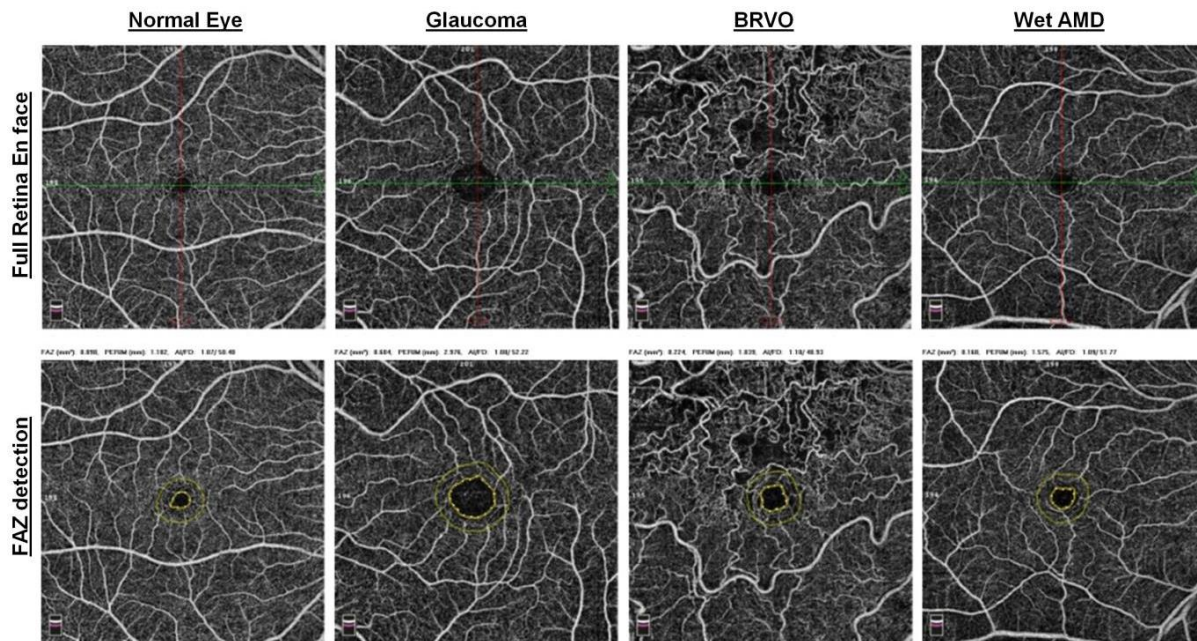


Figure 149 Examples of FAZ Detection based on AngioVue® Retina 6mmx6mm scan.

7.2.12.1 FAZ Controls

- User may change FAZ boundary by dragging the anchor point and the 300µm ring boundary follows automatically.
- Select "Clear" to clear FAZ region
- Select "Draw" to manually select FAZ region
- Select "Auto" to call algorithm to detect FAZ region
- Select "Save Analytics" on the right to save any manual modifications

7.2.12.2 FAZ Edit

Over- or under-detection of the FAZ can be noted following automated FAZ boundary drawing by the software. Correction of FAZ boundary can be performed by dragging the "anchor" point to the correct location of the FAZ boundary as detected from the *Retina* (ILM to OPL+10µ) en face slab.

Automatic recalculation of all FAZ metrics is performed by the software once modified FAZ boundary is saved by the user by clicking on "Save Analytics" button on the right.

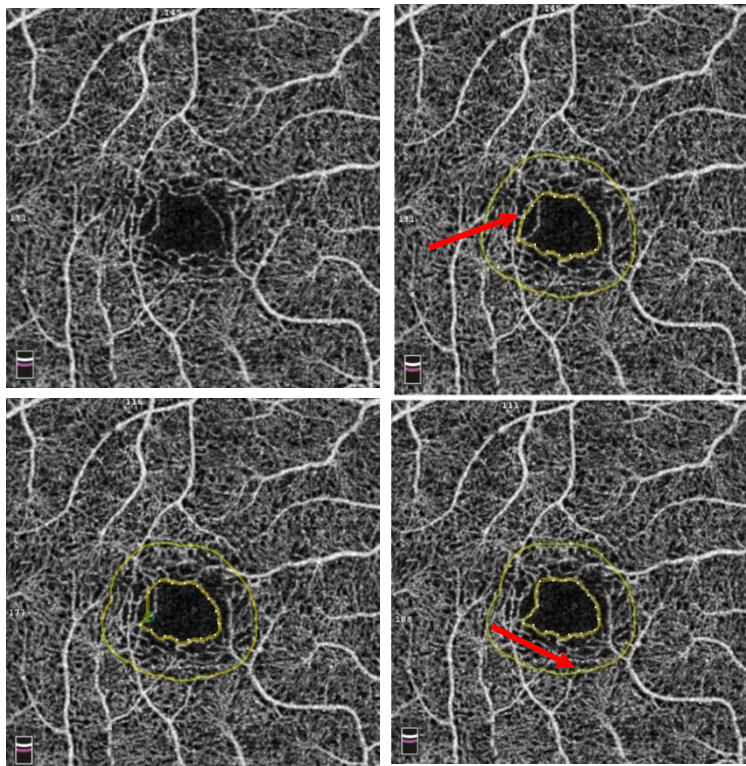


Figure 150 FAZ Editing

Upper left – Retina slab (ILM to OPL+10) of 3 mm AngioVue® retina scan. Upper right – Imprecisely automatically detected FAZ margin (pointed by red arrow). Lower left – FAZ margin correction by dragging the “anchor” point to the correct location (pointed by red arrow). Lower right – Corrected FAZ

→ FAZ measurements are available on Main, Trend and Multi scan reports.

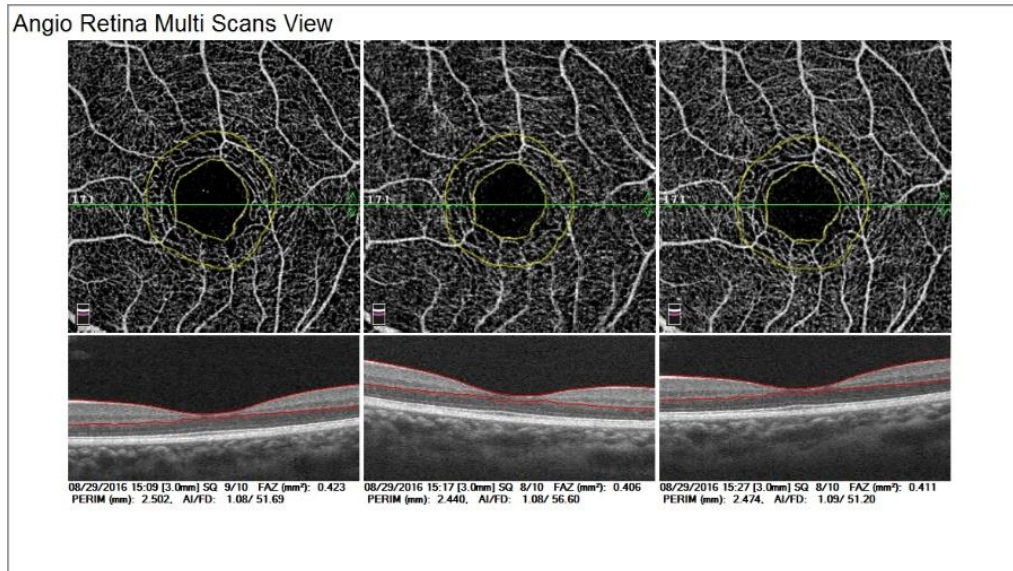


Figure 151 FAZ Multi Scan Report

7.2.13 AngioVue® Retina QuickVue Report

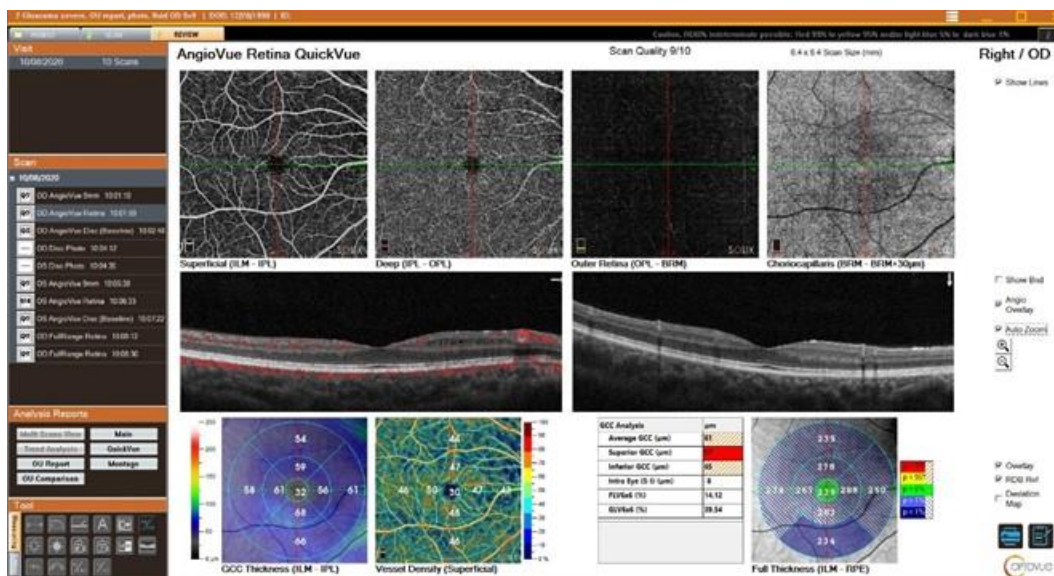


Figure 152 AngioVue QuickVue Report

The Retina QuickVue report shows the 4 default OCTA segmentations along the top. B-scan is fovea centered by default, unless flow is detected in Outer Retina slab – in such case the B-scans will be defaulted to the flow area. The lower 4 displays are RDB, Superficial Vessel Density, GCC Thickness chart, and RDB-Full Retina thickness map. The GCC can be shown as thickness or Deviation Map.

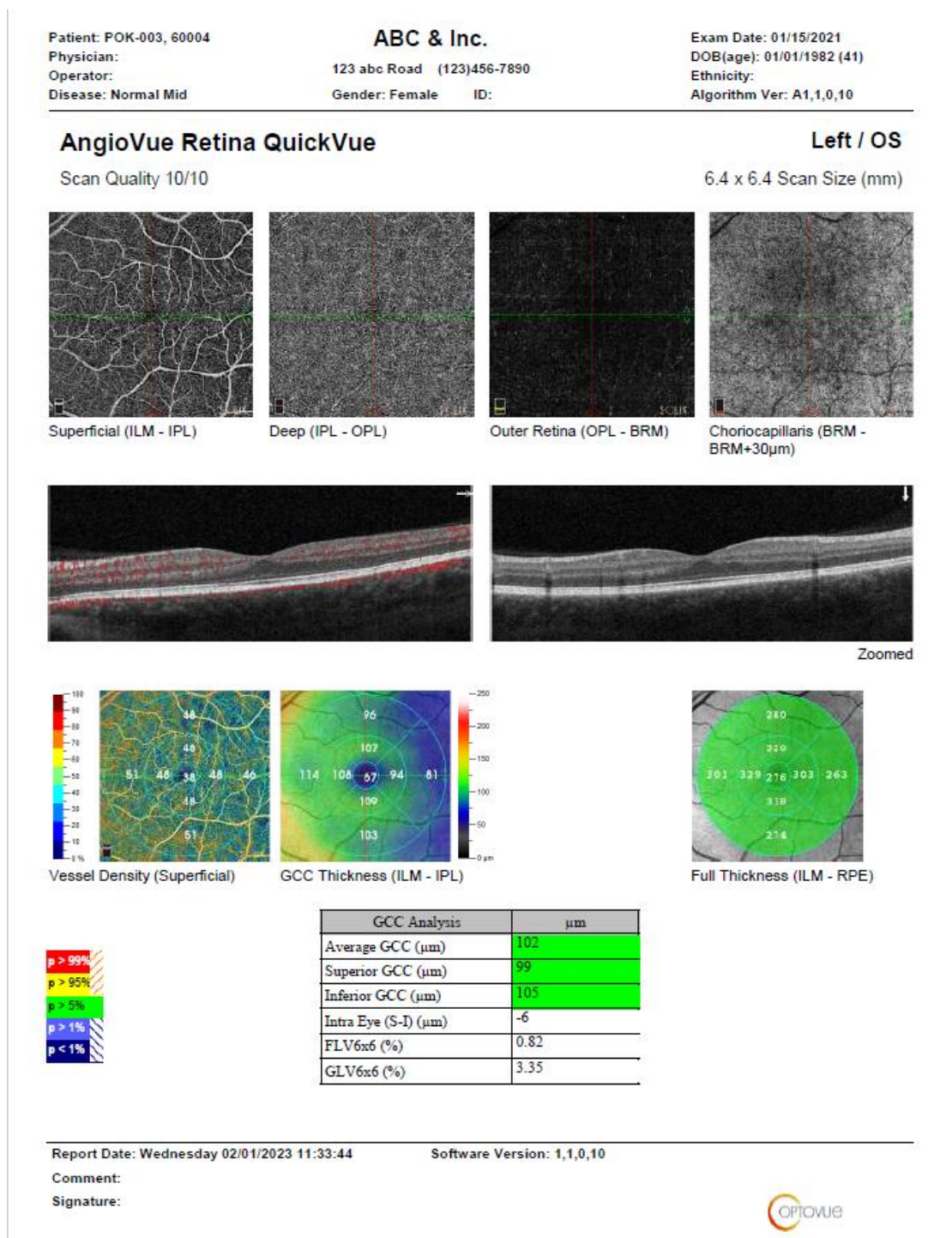


Figure 153 AngioVue Retina QuickVue Portrait

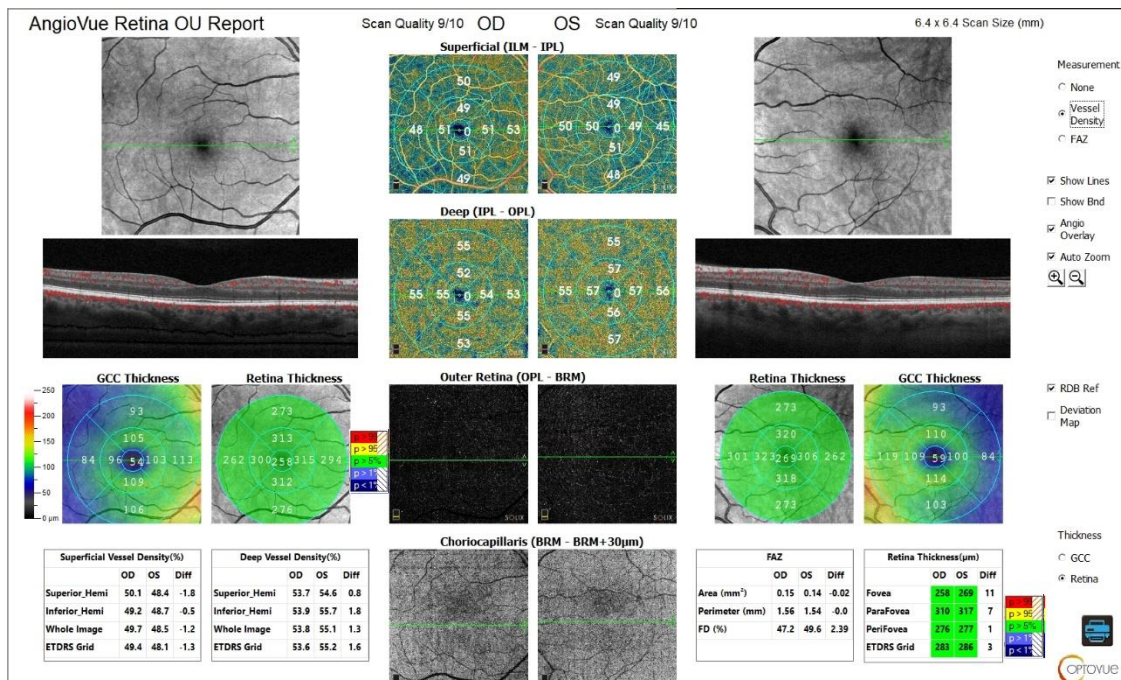


Figure 154 AngioVue Retina OU report

7.2.14 AngioVue® Retina Trend Report

The purpose of AngioVue® Retina Trend report is to provide the user with evaluation of rate of change in AngioAnalytics™ global parameters that are available for AngioVue® retina scans. Trend Report button on Main Report screen becomes available, if there are 3 or more visits of the same scan type available.

Trend report displays parameters of both eyes over time to aid in the assessment of longitudinal change. The trend report requires five visits before a regression line is drawn. A tentative regression line is drawn once three visits are available, and rate of change metrics are marked “NA” if less than five visits are recorded.

The following parameters can be presented on trend report: Retinal Thickness – Inner (GCC) and Full, Vessel Density – Superficial and Deep, and FAZ parameters.

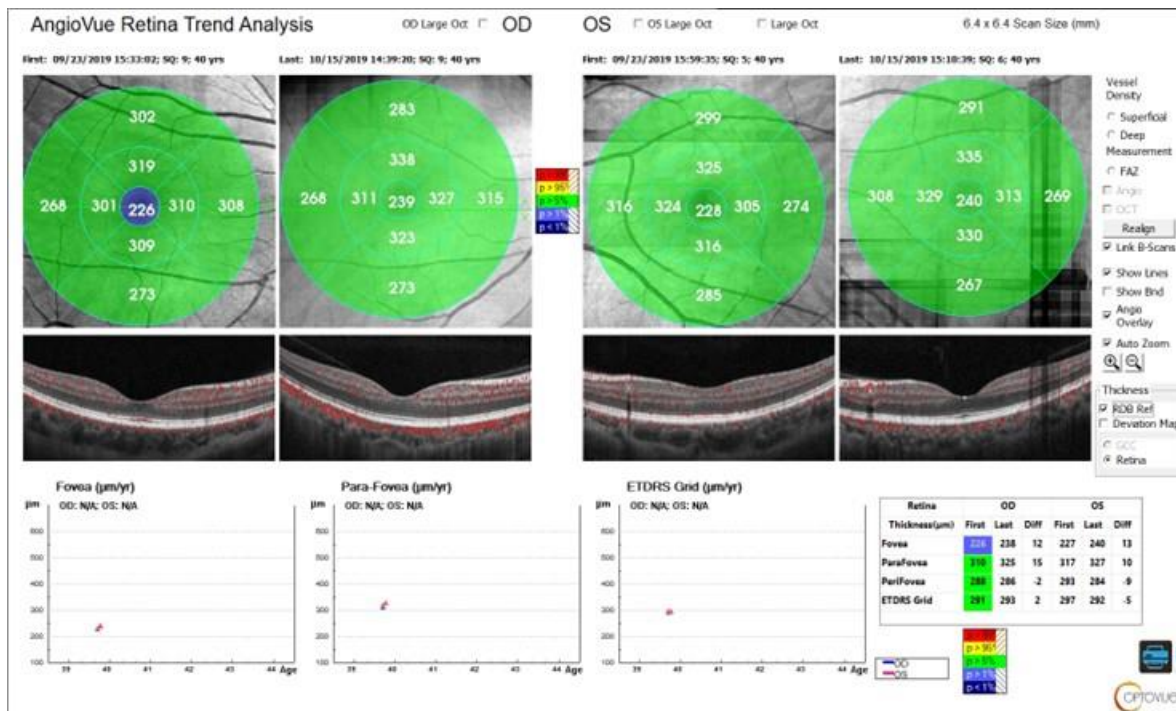


Figure 155 AngioVue® Retina Trend Report, Retina thickness, RDB selected.

The report displays superficial vessel density color-coded map along with the B-scans and ETDRS metrics for the first and the last visit of both eyes (top row). The graphs show Superior Hemifield (of the Whole Image), Inferior Hemifield (of the Whole Image) and ETDRS Grid vessel density over three available visits for each eye, including the tentative trend line. The table on the right provides tabular view of the metrics.

To view different parameter, i.e. FAZ, select FAZ on the right side of the report.

Select one of the “large OCT options OD/OS and the screen changes to a 2 visit aligned comparison.

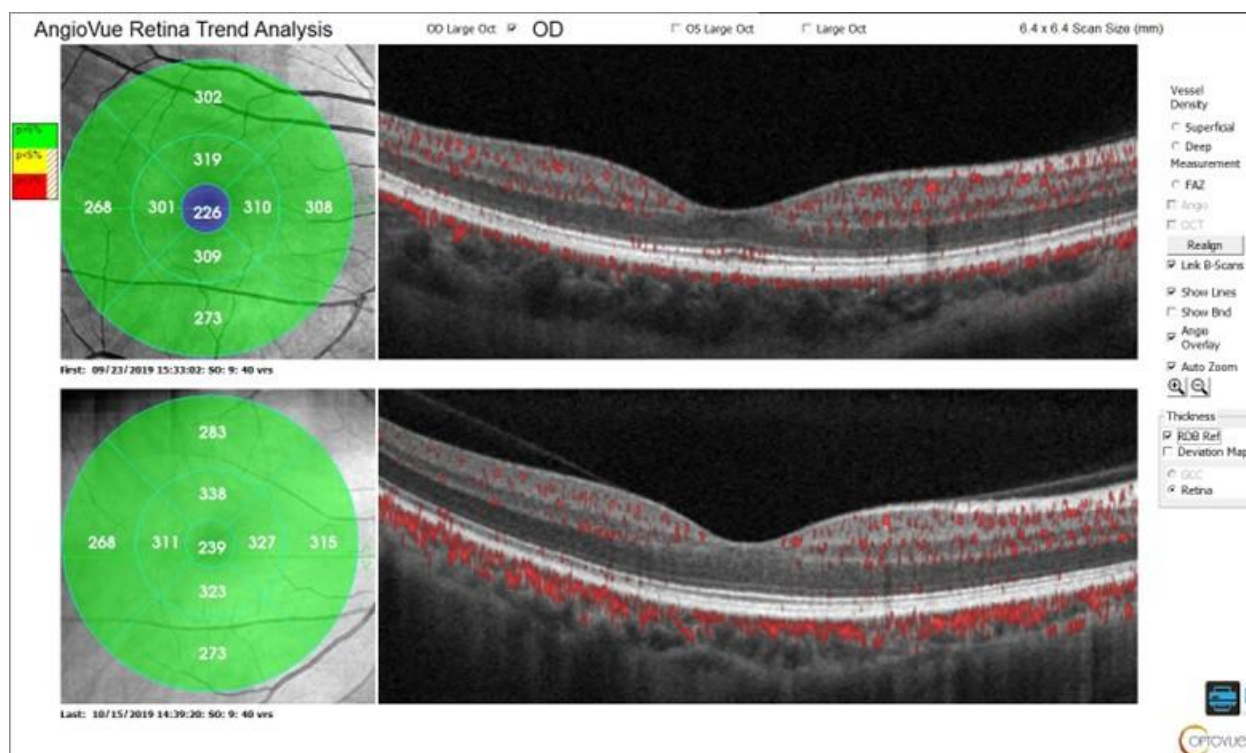


Figure 156 AngioVue Retina Trend Analysis – Aligned 2 scan Comparison

7.2.14.1 Interpreting trend report values

Note: The trend will be graphed as solid line (with rate of change and its confidence interval noted above the graph) if 5 or more scans are available. The trend will be graphed as dotted line (with no metrics available) if at least 3 visits are available.

To interpret the graph:

1. Look at the trend line – horizontal line indicates stable values, positive slope indicates increasing values, negative slope indicates decreasing values.

7.2.15 Flow

Flow area measurement is based on AngioVue® retina scans, detecting the flow in the pre-defined Outer Retina slab (OPL+10µm to BRM-10µm) and Choriocapillaris slab (BRM-10µm to BRM+30µm).

Flow detection can be performed either by using the circle, manually placed on the image slab of the outer retina, or by drawing a closed contour around the region of interest. In such cases selected area and flow area parameters will be provided (mm²).

No quantitative evaluation for these parameters was performed in the AngioAnalytics™ study.

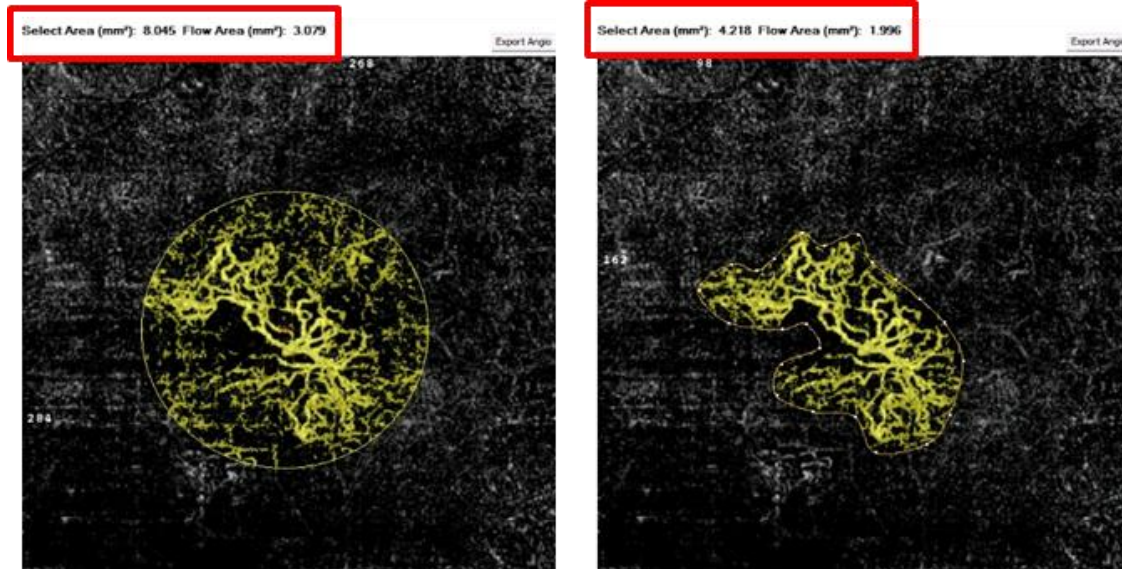


Figure 157 Flow

Left – flow area measured within the circle, right – flow area measured within the delineated contour, measurements are provided at the top of the image.

7.2.15.1 Flow Tool Use

Go to “**En Face**” tab of the OCT, then select **Flow** in the Measure field next to the AngioVue® image at upper left. It is available for the outer retina and choroid layers. When selected, a **pull-down menu** appears below the field. A 2mm diameter circle is placed in the center of the image.

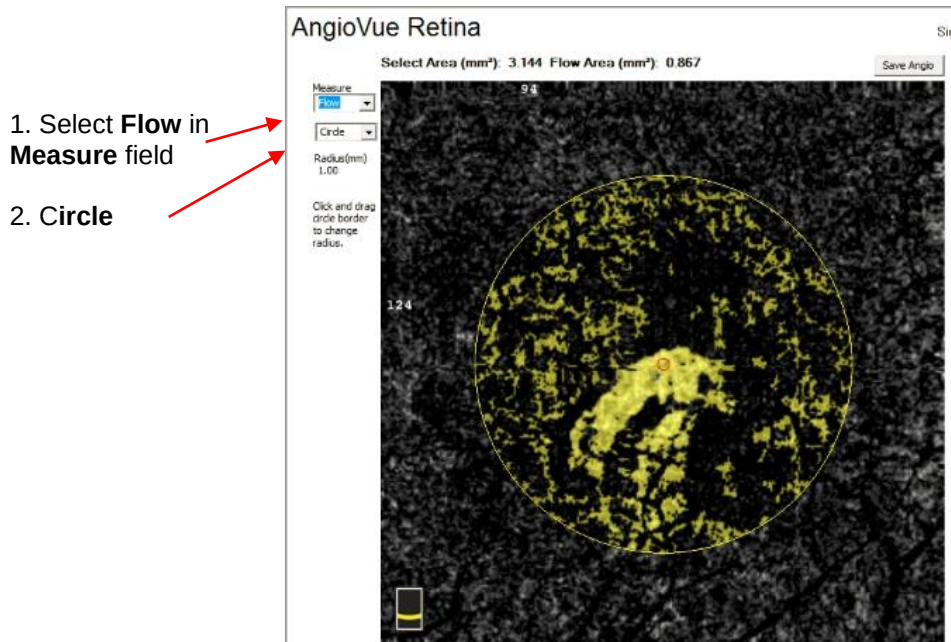


Figure 158 Circle Flow

Using the left mouse key, click in the center to drag the position of the circle, left click on the circle line and adjust the circle size.

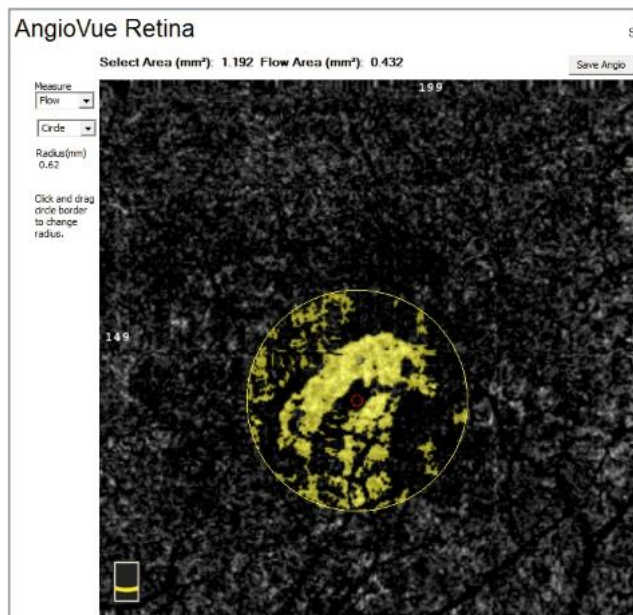


Figure 159 Circle Flow, Moved and Reduced

Click the **Pull down and select Contour**. Then click **Draw**, this allows the operator to outline the area of interest. Each click places an anchor point and the software automatically creates an arch by connecting each anchor point to the last. Close the

area by clicking on the first anchor point again. The yellow-highlighted flow areas and measurements appear automatically when you close the shape.

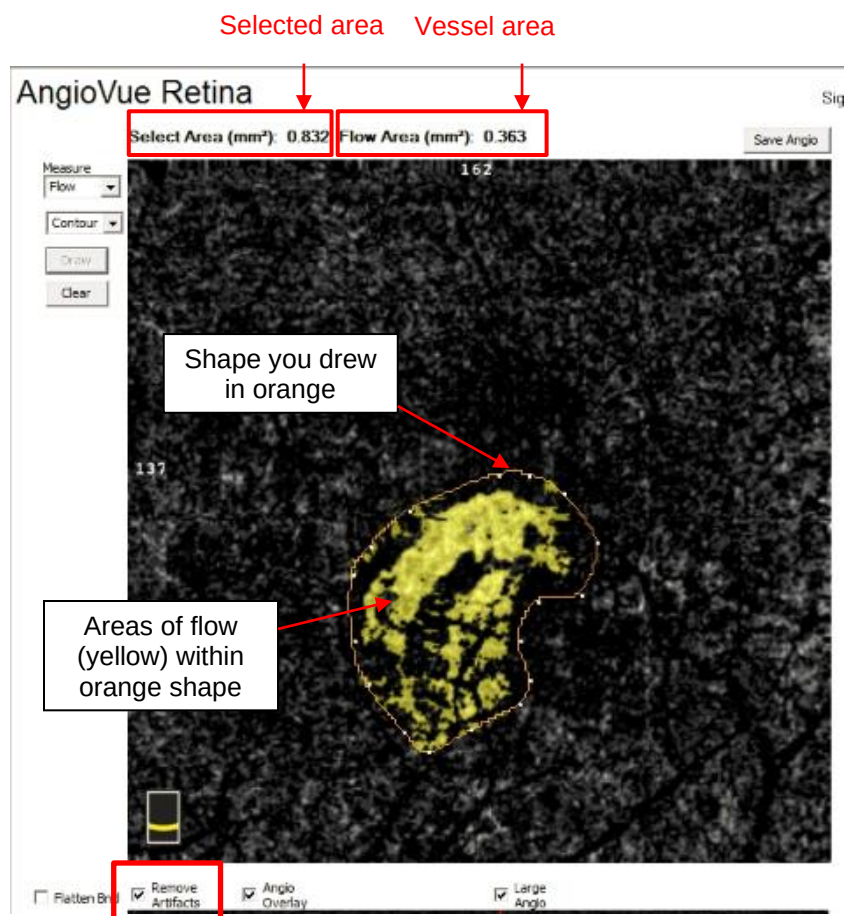
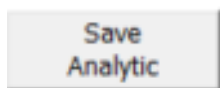


Figure 160 Contour Area of Flow Highlighted Yellow and Measured

To adjust the size and shape of the area, click and drag an anchor point. You can also delete an anchor point by clicking it and pressing the **Delete** key (on your keyboard), and the shape adjusts accordingly. Click **Clear** to clear the shape you drew and start over again by clicking **Draw**.

When you close the area by clicking on the first anchor point again, the software automatically highlights in yellow the areas of flow within the shape you drew. Above the AngioVue® image, the software reports measurements (in mm²) of the area you selected, the **Select Area**, and the total flow area, the **Vessel Area**.



Click **Save Analytic** on the right side to save the measurement with the report.

 **Note:** The system saves the measurements (including delineated shape and detected vessels area) for each layer if you click **Save Analytic** before exiting the screen. In such case “F” will appear near the scan at the scan list.

- **Remove Artifacts Checkbox:** This checkbox activates Projection artifact removal (PAR) and is selected by default. Its purpose is to remove artifacts from the measured area, thus reducing the area highlighted yellow and corresponding vessel area measurement. If you clear this checkbox, the software restores projection artifacts and removes the option of any measurements, including the **Flow** tool.
- + Once Flow measurements are saved (by clicking Save Analytic button) it will become available on Main and Multi scan reports review.

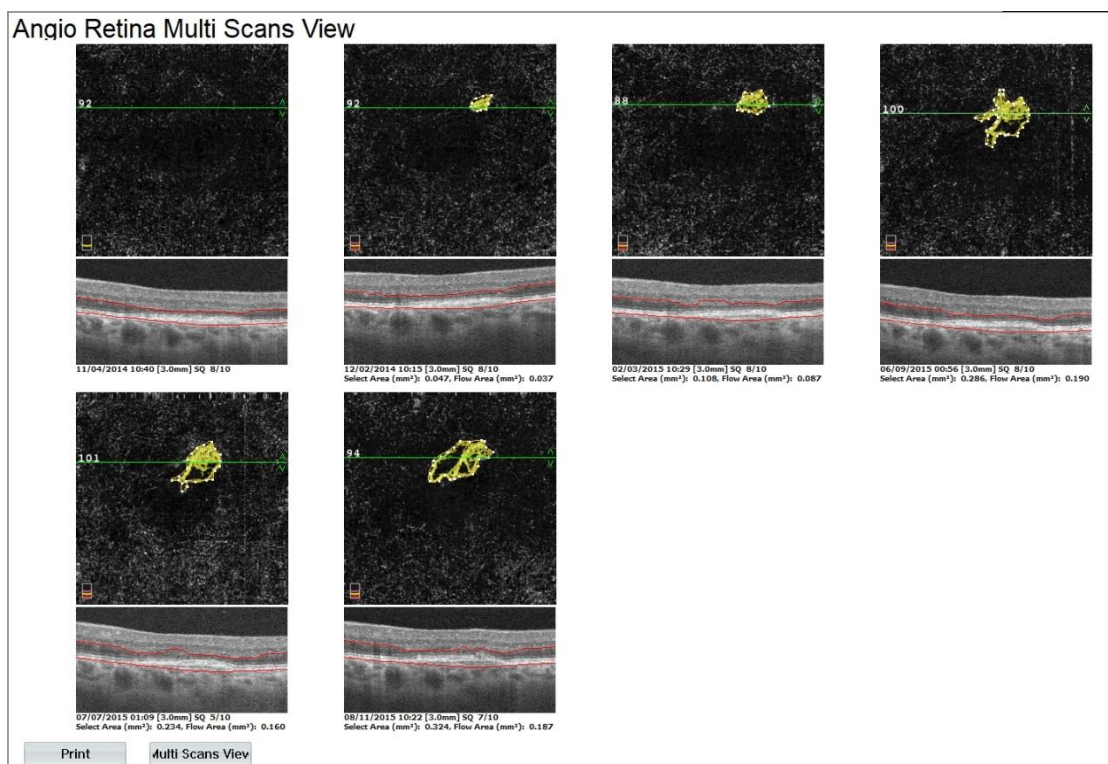


Figure 161 AngioVue® Retina Multi scan Report, Outer Retina Slab and Flow Selection

7.2.16 Non-Flow

The Non-Flow tool is available for application on Superficial retinal slab. It can be used for semi-automatic quantification of non-perfused areas.

No quantitative evaluation for Non-Flow parameters was performed in the AngioAnalytics™ study.

7.2.16.1 Non-Flow Tool Use

Go to En Face OCT tab, then select **NonFlow** in the Measure field next to the AngioVue® image at upper left. When you do, the instruction “**Use Left Mouse Button to Drop Seed**” appears below the field, and **Undo** and **Clear** buttons.

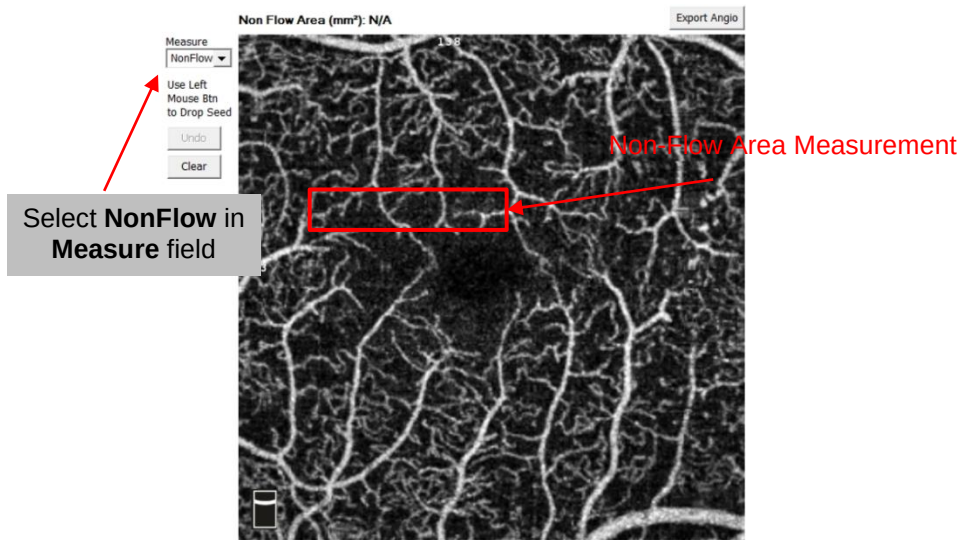


Figure 162 Select NonFlow in Measurement Window

Click inside in a dark area, without vessels, and the software automatically highlights yellow all the contiguous dark area. The yellow-highlighted non-flow area and measurements appear automatically.

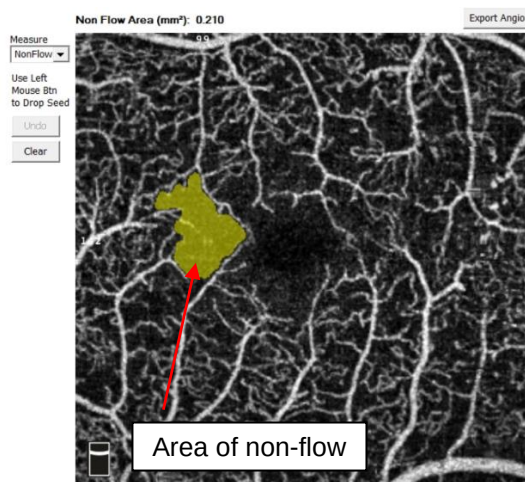


Figure 163 Area of Non-Flow Highlighted Yellow and Measured

You can select additional non-flow areas by clicking in them also, and the additional area is added to the measurement. Click **Undo** to undo your last selection. Click **Clear** to clear the highlighted area and start over again.

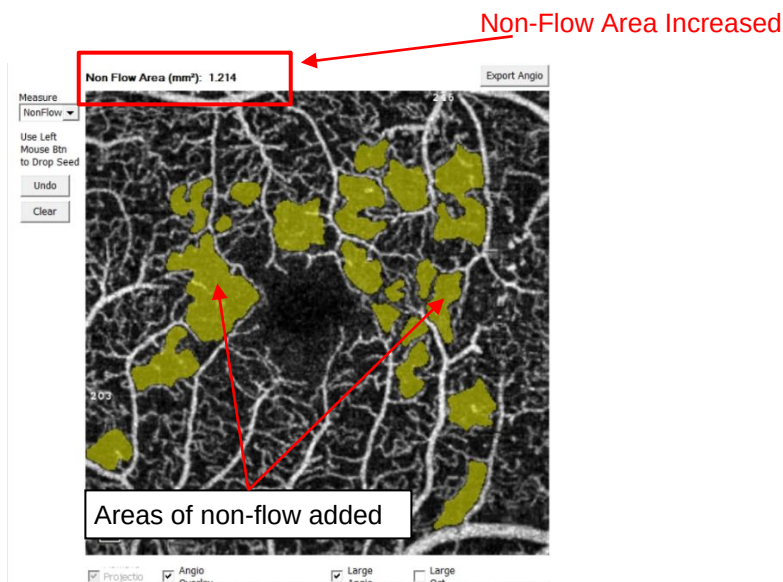
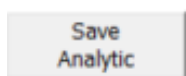


Figure 164 Additional Non-Flow Areas Selected and Measured



Click **Save Analytic** on the right side to save the measurement with the report.

 **Note:** The software automatically clears yellow-highlighted areas and measurements each time you exit the Non-Flow screen. The system saves the measurements (including yellow areas) if you clicked **Save Analytic** before changing the layer. In such case “NF” will appear near the scan at the scan list.

 Once Non-Flow measurements are saved (by clicking Save Analytic button) it will become available on Main and Multi scan reports review.

7.2.17 Information Display for Saved Analytics Result

The Review Scan list shall display information regarding saved Analytics results

F = Flow measurement

NF = Non Flow Measurement

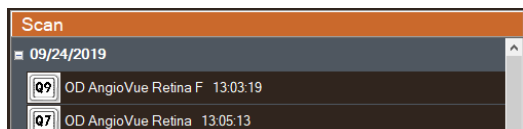


Figure 165 Flow and Non Flow Indicators on the Scan List

7.2.18 AngioVue® 12x12

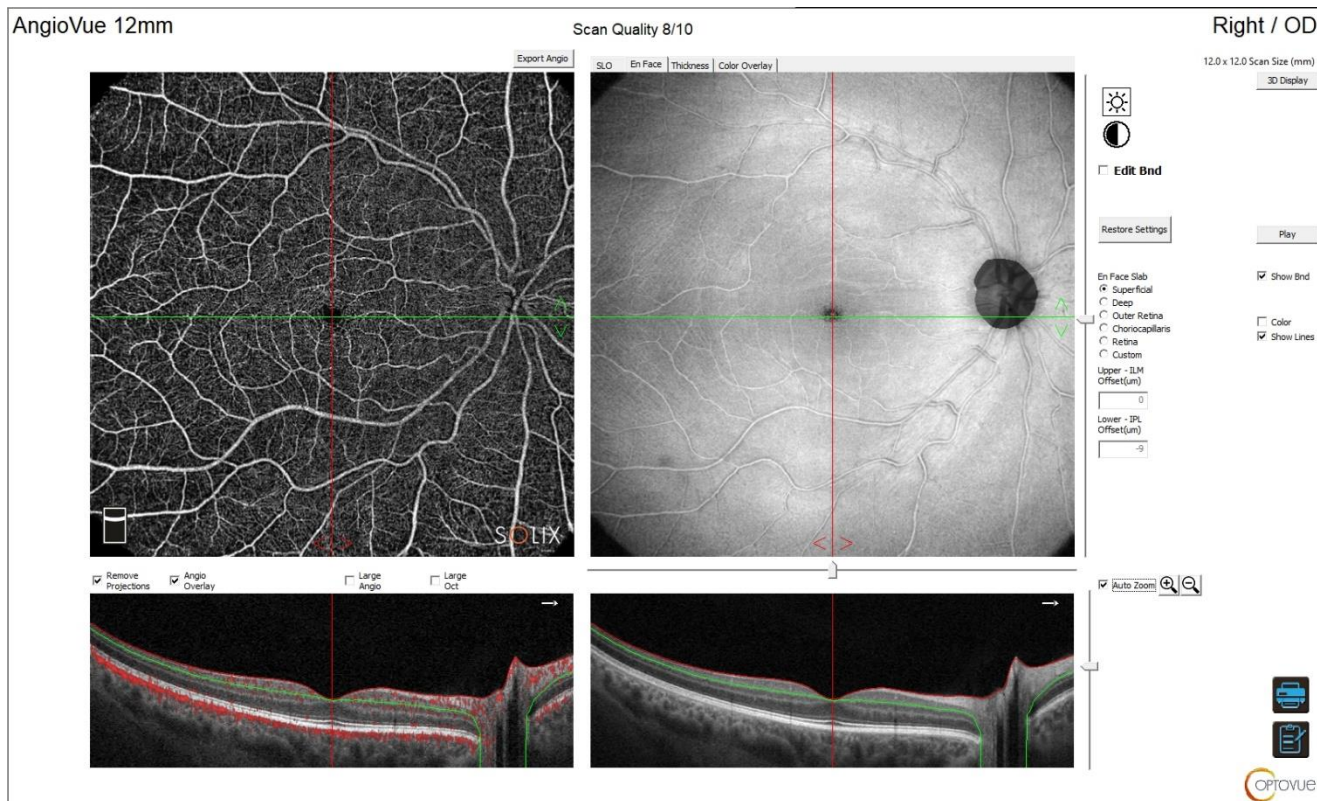


Figure 166 AngioVue® Wide 12x12

7.2.19 AngioVue® 12x12 OU

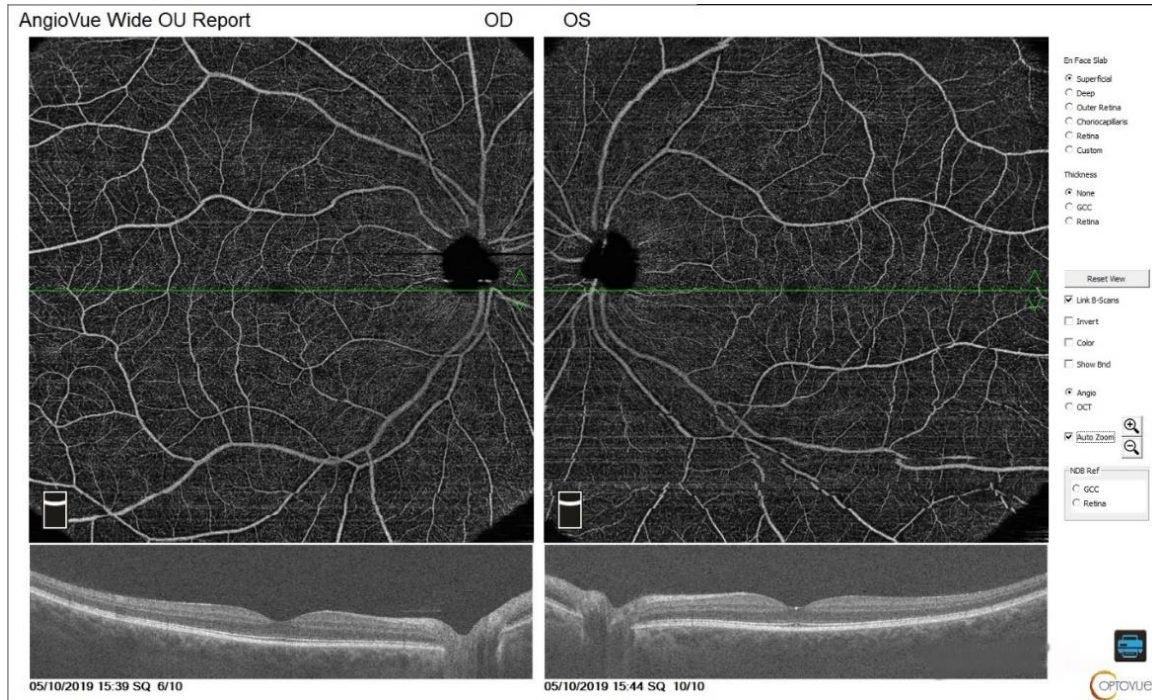


Figure 167 AngioVue® Wide 12x12 OU

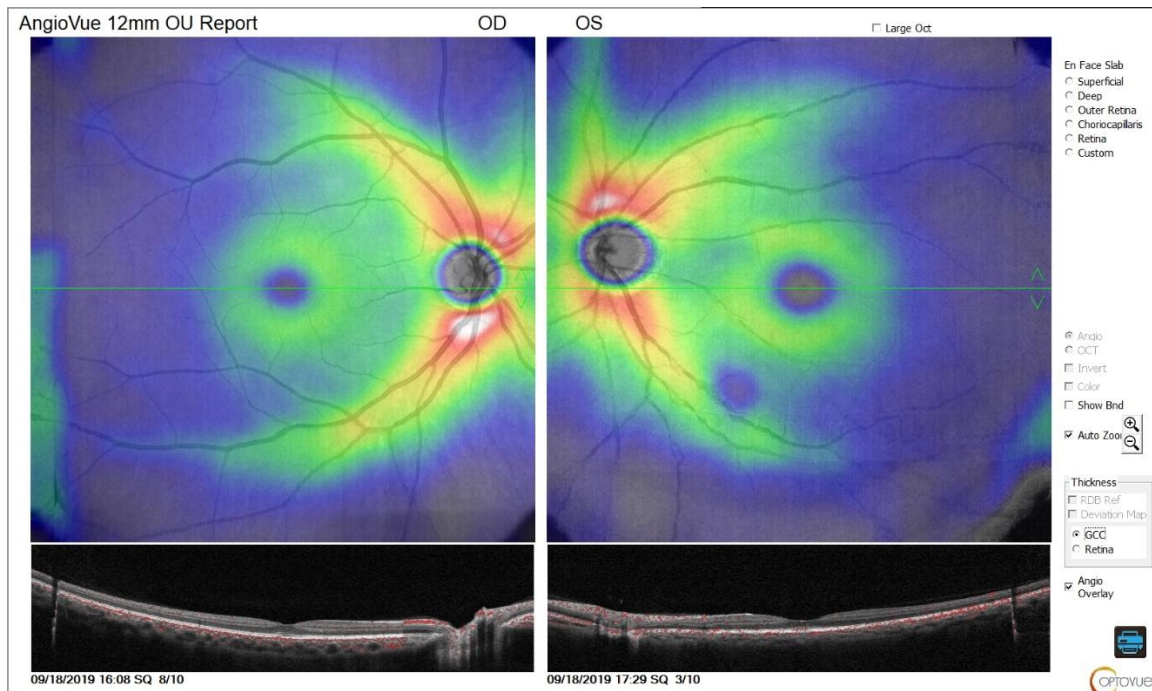


Figure 168 AngioVue 12x12 OU showing GCC Thickness

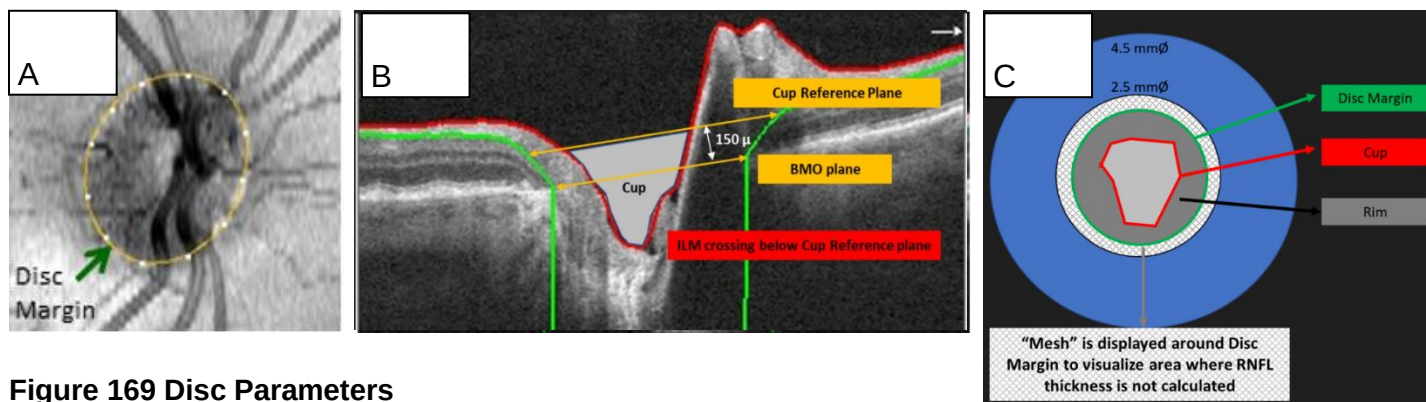
7.3 AngioVue® Disc Analytics

AngioVue® Disc enables the measurement of RPC density and structural thickness values of RNFL for 6 mm AngioVue® Disc.

7.3.1 Optic Disc Parameters

The following parameters are provided based on 3D OCTA intensity images of the disc, derived from RNFL slab of the 2.5~4.5 mm diameter ring.

- ✓ Cup/Disc Area Ratio – cup to disc area ratio
- ✓ Cup/Disc V. Ratio – cup to disc vertical ratio
- ✓ Cup/Disc H. Ratio – cup to disc horizontal ratio
- ✓ Rim Area (mm²)
- ✓ Disc Area (mm²)
- ✓ Cup Area (mm²)
- ✓ Cup Volume (mm³)



For AngioVue® Disc scans the disc margin (A) is automatically detected based at Bruch's Membrane Opening (BMO) (B), and both cup and rim are measured using the BMO+150 plane: the portion above the BMO+150 plane is "rim", while the portion below the plane is a "cup" (C)



Note: Peripapillary (adjacent to the disc boundary) 100 µm wide ring region is displayed with mesh pattern to remind the user that no quantitative analysis is performed for this area.

7.3.2 AngioVue® Disc Measurement Zones and Parameters

The figure below provides schematic presentation of the vessel density and RNFL thickness measurement areas and parameters nomenclature based on whole image and Garway-Heath based peripapillary grid.

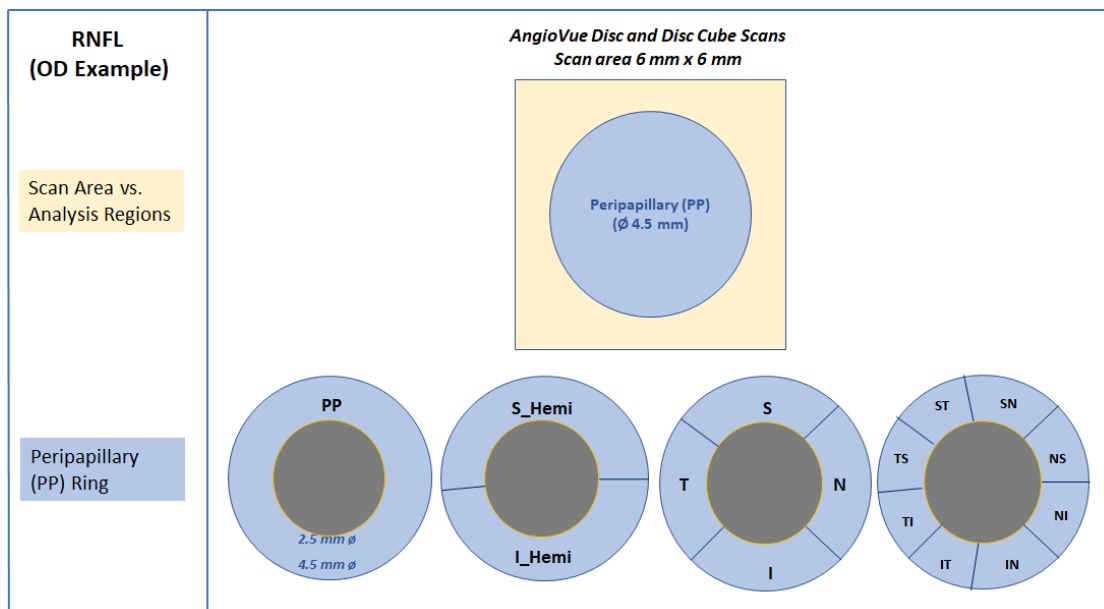


Figure 170 AngioVue® Disc Measurement Zones and Parameters

Schematic presentation of the peripapillary grid and grid sectors naming for the right eye. Peripapillary region is defined by two rings of 2.5mm and 4.5mm centered on disc center (blue area).

Upper panel: Left – Peripapillary (2.5-4.5) grid. Middle - Superior and Inferior Hemi-sectors. Right – Disc and 8 equal sectors. Disc – inside disc (grey area outlined by the yellow boundary) 2.5mm circle centered on disc center; 8 peripapillary sectors - nasal superior (NS), nasal inferior (NI), inferior nasal (IN), inferior temporal (IT), temporal inferior (TI), temporal superior (TS), superior temporal (ST), superior nasal (SN).

Lower panel: Left – whole image of 6 X6 mm of disc scan. Right - 9 sectors grid

7.3.3 Eight Sector Peripapillary Grid

The grid consists of two concentric circles of 2.5mm and 4.5mm diameter, centered on the center of the optic disc, as determined by BMO fitted circle. The modified grid aims to follow RNFL distribution and sectorized to provide easier correlation with visual field testing.

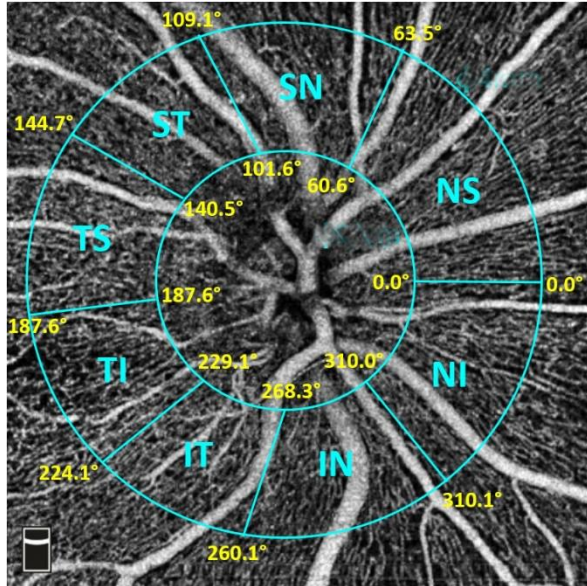


Figure 171 Eight Sector Peripapillary Grid

The eight sectors grid overlaid on and 6 mm AngioVue® Disc *En Face* RPC Slab. The inner circle has a diameter of 2.5 mm and the outer circle has a diameter of 4.5 mm.

7.3.4 AngioVue® Disc RPC Vessel Density and RNFL Thickness

Vessel density analysis computes and displays the percentage of area occupied by OCTA detected vasculature for RPC slab (ILM to NFL). Peripapillary RNFL thickness is calculated for RNFL layer (ILM to NFL).

The AngioVue® Disc main report below with **En Face** tab and **Density** measurement selected shows an OCTA image with peripapillary grid overlaid on RPC slab, a structural image with SLO, En Face, Thickness, and Color Overlay tabs with En Face tab selected; charts for regional RPC vessel density and RNFL thickness parameters; horizontal B scans with/without flow patterns and vessel density 9 square grid chart and color-coded map.

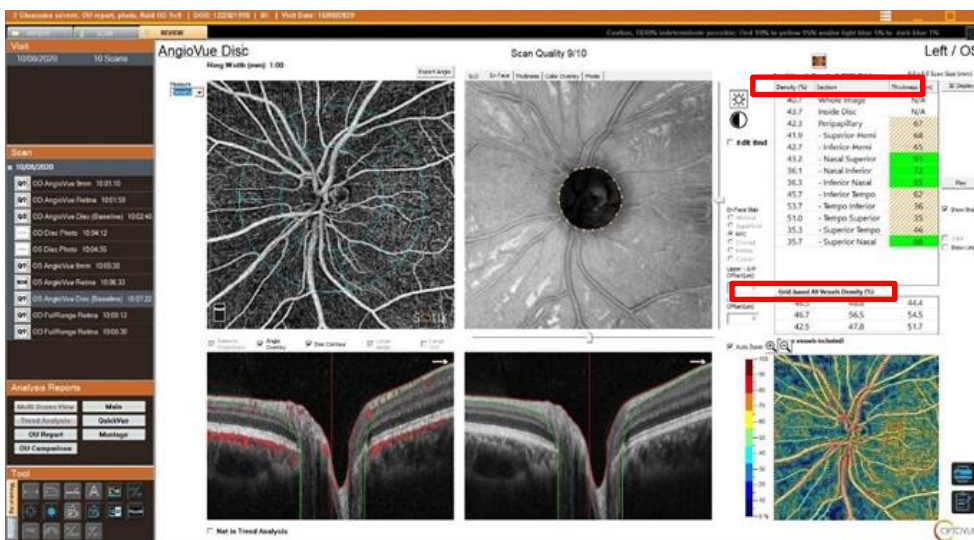


Figure 172 AngioVue® Disc, Main Report with En Face Tab and Density Selected

The vessel density measurements of small vessels (i.e., with large vessel masking) are provided in the table with the header of “Vessel Density & RNFL Thickness” from the peripapillary region (from the 2.5mm to 4.5mm ring region) and inside the optic disc. The vessel density measurements of all vessels (i.e., without large vessel masking) is displayed below with the header of “Grid-based Vessel Density (%)” for parameters derived from the 3x3 square sectors grid of the vessel density map. While end-user may be interested in assessing both small vessel density and all vessels density, the peripapillary ring region centered on the disc center is a clinically more relevant for disc scans.

 **Note:** All density measurements are calculated with projection artifacts removed (PAR applied). RPC is the most superficial plexus and therefore minimally affected by projection artifacts.

Turning off PAR allows for visualization of vessels and projection artifacts. No quantitative analysis is available with “PAR off”.

7.3.4.1 Threshold for Small Vessel

The large-vessel masking is a software-based feature when a pre-determined cutoff is used to distinguish between ‘large vessels’ and ‘small vessels’ (see Figure below). This cutoff is fixed and does not change by *en face* slab or individual scan.

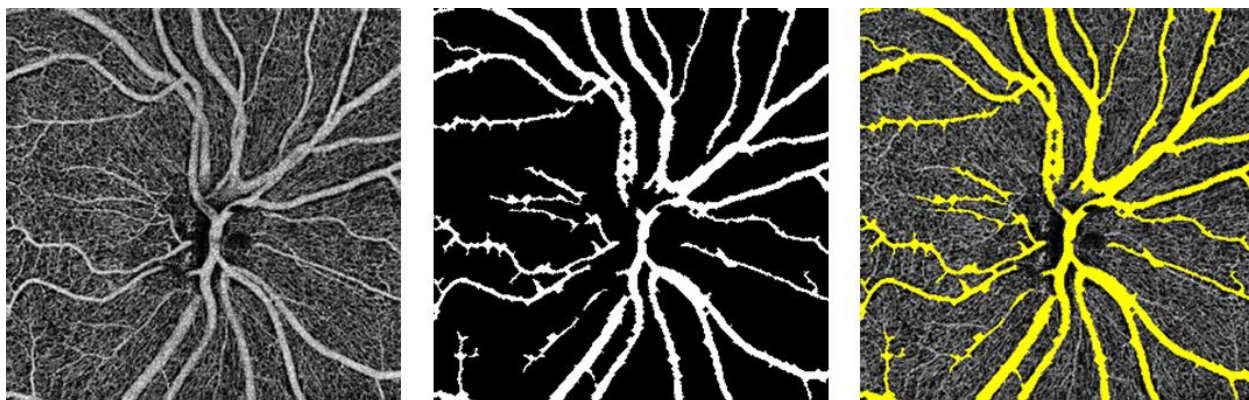


Figure 173 Large Vessels Mask

Example of large vessel mask for AngioVue® Disc scan. (Left) RPC en face image. (Middle) Extracted large vessel mask. (Right) Extracted large vessel mask overlaid on the RPC face image.

The small vessels density is measured with the application of large vessel mask which has threshold of ≥ 3 pixels (approximately $\geq 35\mu\text{m}$ for the 6.0 mm AngioVue® Disc scans). Following mask application, only the “small vessels” density is measured.

Vessel density is also available on Main, QuickVue, Multi Scan and Trend reports.

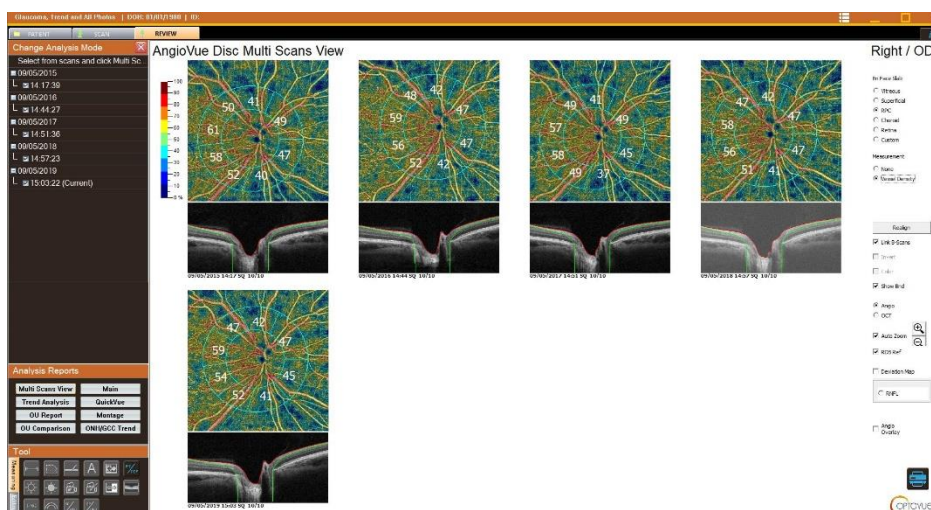


Figure 174 AngioVue® Disc Multi Scan Report

RNFL Thickness is available on Main, QuickVue and Trend reports

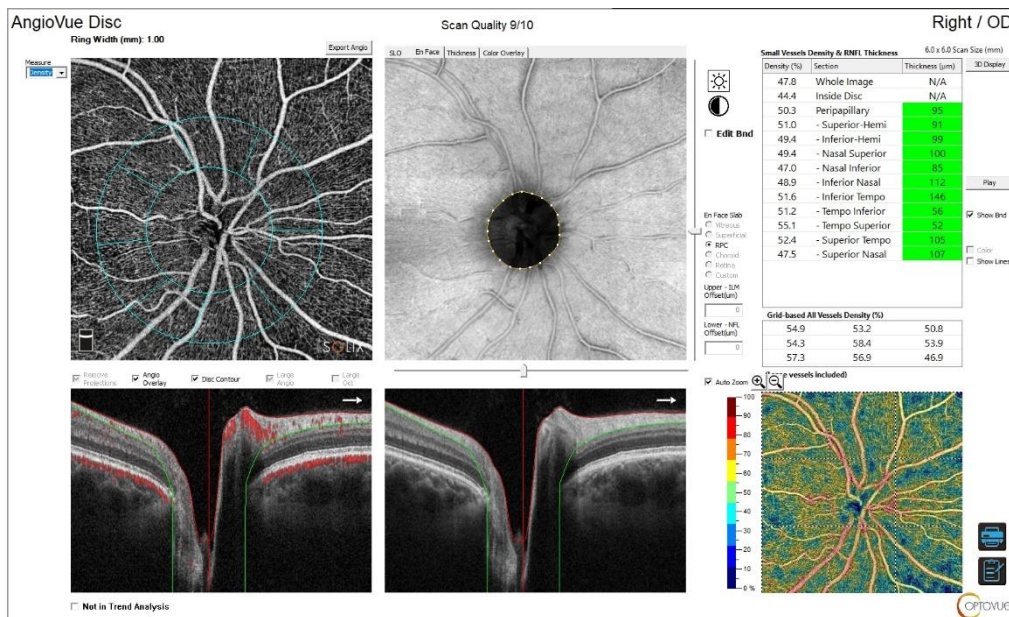


Figure 175 AngioVue® Disc Main Report

7.3.5 AngioVue® Disc QuickVue Report

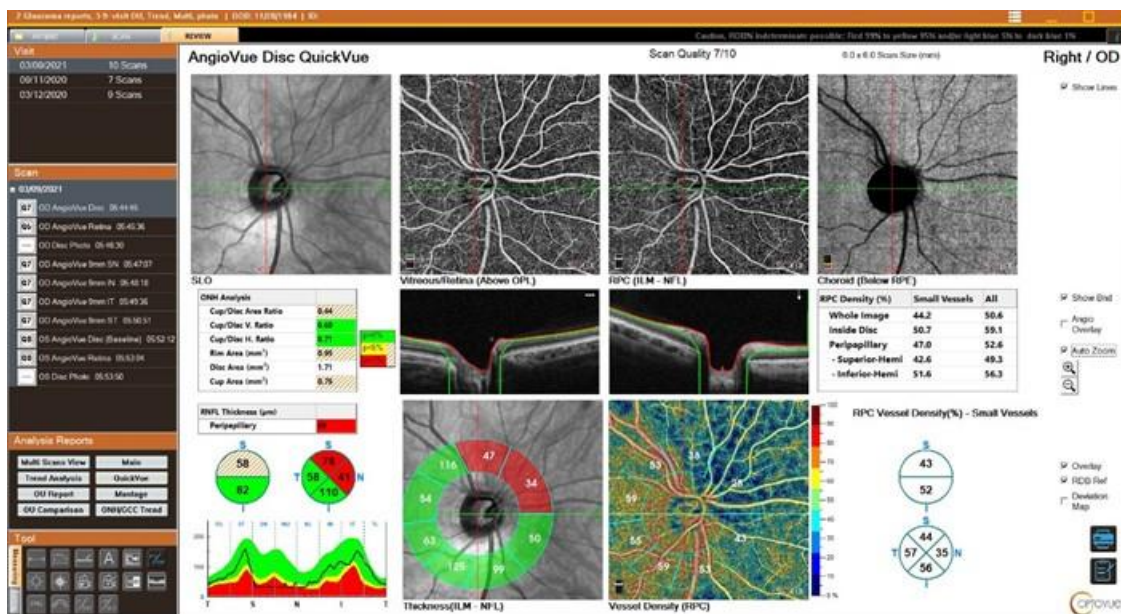


Figure 176 AngioVue® Disc QuickVue Report

The AngioVue® Disc QuickVue Report has the 4 OCTA default segmentations with horizontal and vertical B-scan through the disc. The left lower part displays structural information including Optic Disc parameters, RNFL thickness global parameters and Garway-Heath based grid, well color-coded thickness RNFL thickness map. The right

lower part provides vessels density information including RPC slab global vessel density parameters (small vessels and all vessels) and Garway-Heath based regional vessel density parameters (small vessels only) as well as color-coded vessel density map. There is also an option for a Deviation Map display.

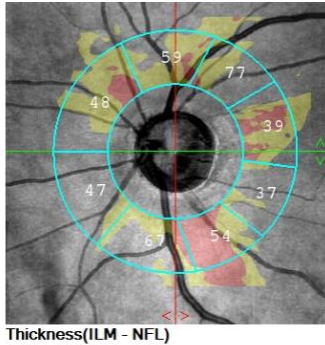


Figure 177, Deviation Map

7.3.6 AngioVue Disc Trend

NFL the purpose of AngioVue® Disc Trend report is to provide the user with evaluation of rate of change in AngioAnalytics™ global parameters that are available for AngioVue® Disc scans. Trend Report button on Main Report screen becomes available, if three or more visits of the same scan type are available.

Trend report displays parameters of both eyes over time to aid in the assessment of symmetry and longitudinal change. The trend report requires five visits before a predictive line is drawn. A tentative predictive projection line is drawn once three visits are available, and rate of change metrics are marked “NA” if less than five visits are recorded.

The following parameters can be presented on AngioVue® Disc Trend report: Retinal Nerve Fiber Layer (RNFL) Thickness and Radial Peripapillary Capillaries (RPC) Vessel Density.

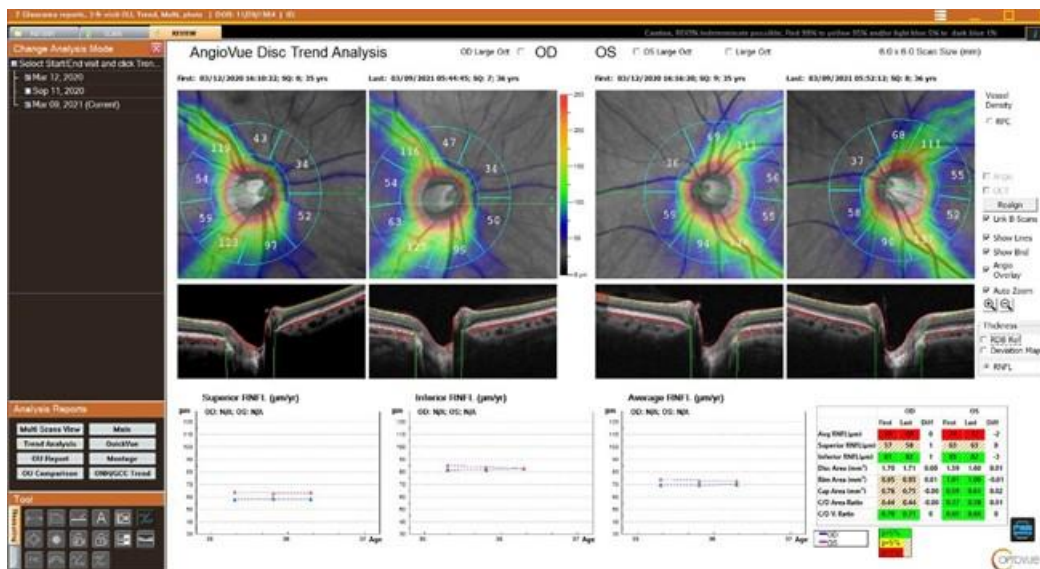


Figure 178 AngioVue® Disc Trend Report

The report displays RNFL thickness color-coded map along with the B-scans and peripapillary grid metrics for the first and the last visit of both eyes (top row). The graphs show Superior (Hemifield) RNFL (of the Whole Image), Inferior (Hemifield) RNFL (of the Whole Image) and Average RNFL thickness (of the Whole Image) over five available visits for right eye, and three visits for left eye, including trend line, rate of change and confidence interval for the right eye, and tentative trend line for the left eye. The table on the right provides tabular view of the metrics. Including optic disc parameters.

To view RNFL Thickness, select RNFL on the right side of the report.

7.3.6.1 Interpreting trend report values

 **Note:** The trend will be graphed as solid line (with rate of change and its confidence interval noted above the graph) if five or more scans are available. The trend will be graphed as dotted line (with no metrics available) if at least three visits are available.

To interpret the graph:

Look at the trend line – horizontal line indicates stable values, positive slope indicates increasing values, negative slope indicates decreasing values.

7.3.7 ONH/GCC OU Trend Report

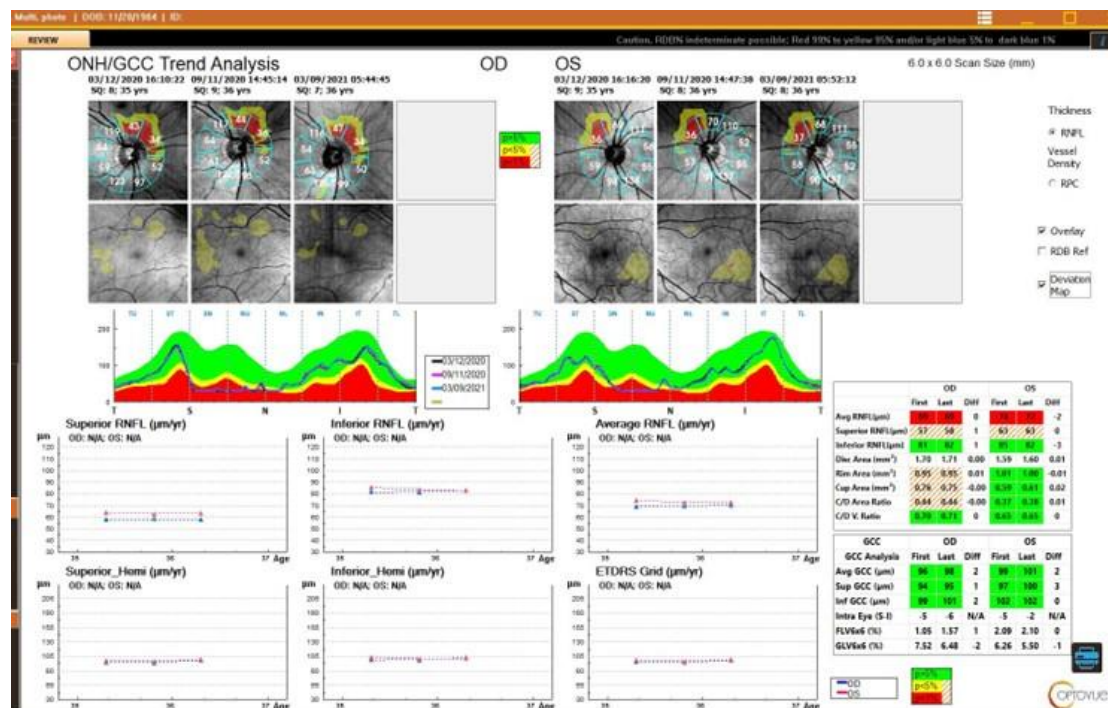


Figure 179 ONH/GCC OU Trend report showing RNFL and GCC Deviation maps

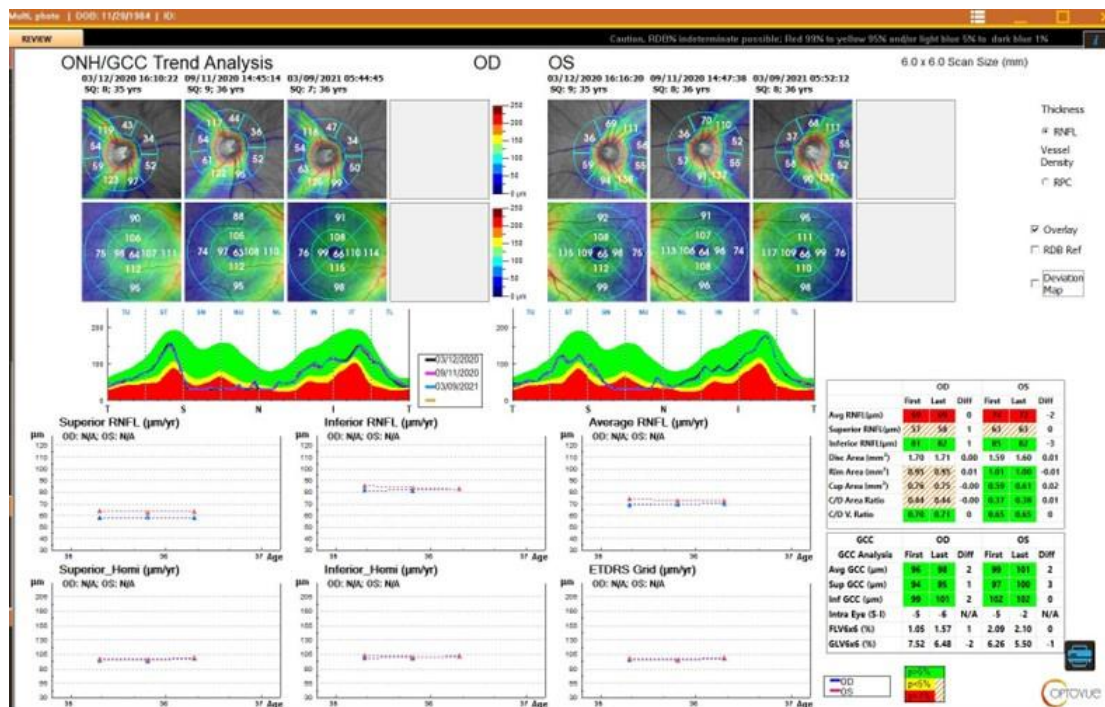


Figure 180 ONH/GCC OU Trend thickness

End of section

8 Cornea Anterior Module (CAM 16mm)

8.1 Safety Notes

General

This system accessory has been developed and tested in accordance with the Optovue safety standards as well as national and international regulatory guidelines. A high degree of instrument safety has been ensured. Observe all safety notes and information in this manual and on the device labels.

Proper Instrument Use

1. Always clean all patient contact surfaces (forehead and chin rest according to the cleaning method in the user manual.
2. Ensure the CAM lens is attached when capturing scans in the **Cornea** category.
3. The working distance to the cornea surface for the CAM lens is 20mm.
4. Align the eye to the proper eye position (canthus) indicator mark on the chin rest.
5. Use the Live IR video image on the LCD monitor and the OCT scan window to monitor distance and focus relative to the patient's eye.

Intended Use

The CAM module, consists of an auxiliary lens adapter, the 16mm Pachymetry, indicated for *in vivo* imaging and measurement of the cornea and other ocular structures of the anterior segment of the eye, including pachymetry.

 **Note:** Neither CAM nor OCT are intended to be used as the sole diagnostic aid in disease identification or classification.

8.2 Instrument Description

The SOLIX™ /CAM system is comprised of the system and CAM option (cornea lens adapter 16mm) for use in imaging the cornea and anterior chamber of the eye.

The lens adapter is attached and removed by a trained operator.

8.3 Getting Started

8.3.1 Mounting the Lens Adapter

The lens has a magnet mount system.

 **Note:** The working distance for the lens adapter and cornea is 20 mm.



Pull the scanner head all the way back, align using the live IR video image of the patient's eye, then gradually move the scanner head forward until OCT scan is in the target area. This will coincide approximately with the patient's iris coming into focus in the live IR video image.

Do not move the instrument head quickly and monitor proximity to patient in order to avoid incidentally hitting the patient's eye with the CAM lens surface.

_____End of section_____

8.4 Examine Menu

8.4.1 Scan Patterns

Click the **Cornea** button and then select a scan pattern from the list that appears, which activates scan acquisition. (See section 9 for a list of scan patterns and specifications.)

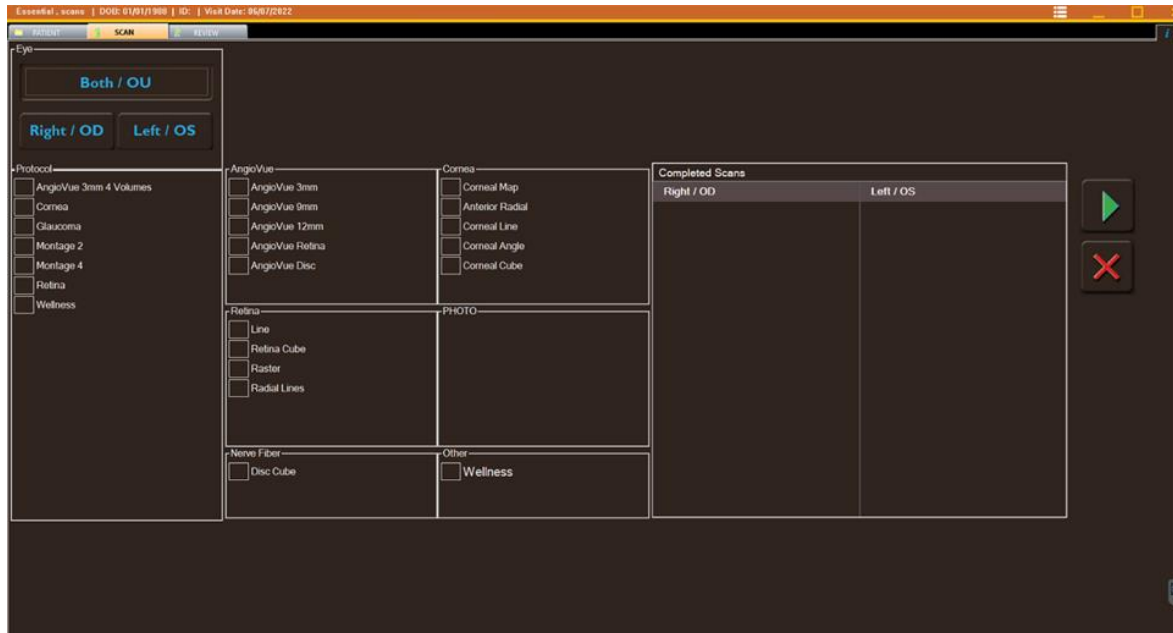


Figure 181 Scan pattern selection

8.4.2 Anterior Scan Acquisition general:

The following is a general procedure to acquire cornea OCT images:

1. Turn off the exam room light (recommended)
2. Attach the CAM lens (Silver for FullRange, black for all other scans)
3. Instruct patient to fixate on the center of light blue internal fixation target.
4. Use the yellow external fixation LED on headrest to guide patient fixation if required.
5. Operator should center the scan on the pupil if there is no other indicator
6. Operator should make sure that the eyelid or eyelashes are not blocking or shadowing a significant portion of the image in vertical meridians concentric circle on the screen. If there is blocking or shadowing, the scan should be excluded.

7. Operator should observe the measurement reliability index status on the report screen (for cornea power). A measurement with poor measurement reliability indicates increased risk of measurement variability. Measurements with poor reliability should be replaced if possible.
8. Align on the desired area to scan.
9. Move forward until the iris is in focus in the live IR image (the image of the desired external scanned region should be within the target zone (two dashed red horizontal lines)).
10. Adjust scan beam to target zone and orientation with joystick.
11. Adjust image quality/scan strength (P-Motor adjustment).
12. If the Iris is in poor focus when the cornea is displayed, click the Auto focus button to reset focus motor
13. Capture scan using joystick button or capture button on screen.
14. Review and process (averaging) the OCT images.

Remember the following key operation points:

15. Use the CAM like a slit lamp in that when the live IR video image is in focus, stop forward motion of the scanning head as the scan should be in the target area (or very close).
16. Auto All and Auto-Z are disabled.
17. Minimal Focus motor adjustment may be used (only available in manual scan control options).
18. Use the P-Motor to optimize scan signal strength.
1. The following items are preset and not adjustable.
19. **Internal Illumination:** Set to **0**
20. **Focus:** default set to cornea (can be adjusted to optimize the image intensity for Line and Angle scans)
21. **Z position:** Set at constant value depends on the system

8.4.3 Scan Alignment Pachymetry (Topography)

- A. For Corneal Map scans using the 16mm CAM lens (Black), move forward until the cornea B-scan is positioned within the two dashed red horizontal lines, with the upper edge of the cornea touching the upper red line. A colored cross will appear as the system approaches the eye. This is to help with centration green for centered red for 500+ microns off apex.
- B. Click joystick to activate auto “P” to improve signal strength.(or GUI button)
- C. Note, the cross is Green when centered and Red, if off center. The outer white ring is 10 mm equal to scan size, the Orange ring is 7 mm; to get Topography there must not be any obstruction inside the Orange ring. The top surface of the cornea should touch the upper red line and be centered to the vertical red marks.

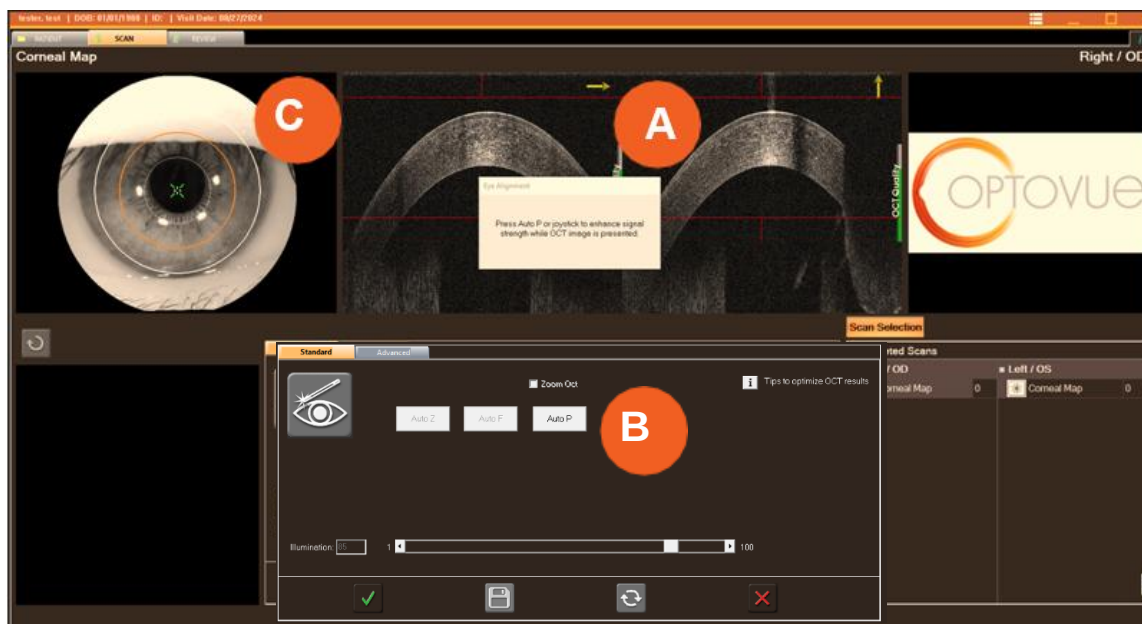


Figure 182 B scan between red lines

A warning will appear if there is Vertex or lid issues. Scan should be repeated.

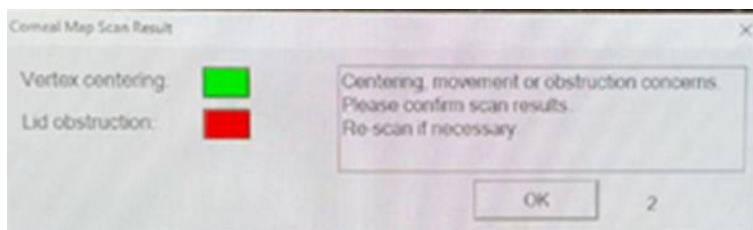


Figure 183 Alignment Obstruction warning

The patient should look at the fixation target. The target Center point together with the center of the ring pattern on the eye defines the Video-Keratoscope axis (VK-axis), the reference axis to which the axial radius/power is calculated. If the patient is fixating on the target, the VK-axis is aligned with the line of sight. When an image is taken with the patient not fixated on the target, results will not be correct or reproducible.

For Topography scanning the operator should focus on the vertex (the center of the six LED lights), to assist with this, there is a floating green/red cross feature that guides vertex centration during scan acquisition. A green cross is displayed when the vertex is correctly targeted, ensuring greater repeatability and reproducibility of topographical maps and metrics. For patients who find it difficult to focus on the vertex, the operator can use the center of the pupil as a backup acquisition method.

If unsure about a scan and patient fixation or due to an error code, re-capture the image and view the difference between the two images. Axial power maps are identical for fixated eyes. The tangential power for both images should have their center in the same position relative to the pupil center.

8.5 Solix Topography Module

Solix Topography Module is an additional license that allows the system to convert Corneal Map scan data to 3D Tomography maps. The topography license comes with an additional validation tool, in user preference the operator can choose a monthly reminder to validate the system or they can choose to do it on their own schedule.

The map data is generated from the 57,600 scanned pixels (16 meridians x 1200 pixels per meridian x 3 surfaces acquired with the Corneal map scan

8.5.1 GUI changes

The addition of the topography license turns on an “Oct/Topo” selection button on the Analysis Report banner for scans taken license activation after which will change the button selection below from Oct reports to topography reports. It adds a similar selector on the report display.

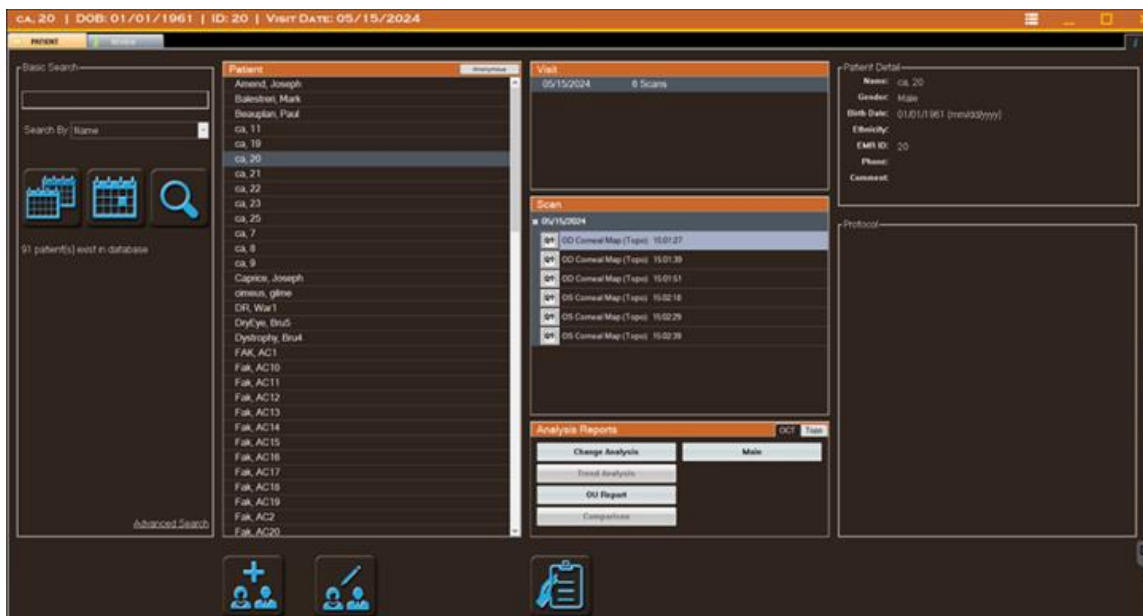


Figure 184 Topography GUI change



Figure 185 Topography Report selection

8.5.1.1 Scan Pattern addition

The scan pattern list will now include “cornea power validation”, this is used in conjunction with the validation tool.

8.5.2 Technical Note Regarding Dewarp

Dewarp is a mathematic calculation (Snell’s Law) used to transfer the OCT image in “optical distance space” to “physical distance space.” A good example of the image in “optical distance space” is when you see a straw in a glass with half water full. The straw in the water seems bent at the interface between water and air, and the portion of the straw in the water looks thicker than the portion of the straw in the air.

There are two aspects to the dewarp calculation:

22. Shape change (like the bending of the straw): This is caused by the cornea surface that is not perpendicular to the scan beam. This cannot be avoided when scanning a length greater than 3mm of the cornea. If you scan on a relatively flat surface of cornea or sclera, the incident beam is relatively perpendicular to the surface. In this instance the beam will not be bent or warped. For example, if you make the straw perpendicular to the water surface, the straw does not look bent or warped at the water and air interface.
23. Distance Change: The straw looks thicker because the index of refraction (n) of water is 1.33 times the air (n=1.33). The cornea (n= 1.38) and aqueous (n=1.34) are very similar but are at a higher index than that of air. To make the physical distance measurement, the tissue thickness needs to be divided by the index of refraction of the media.

A dewarp calculation is used on the cornea Line, and Pachymetry scans to transfer the OCT image into a physical image of the cornea for both shape and distance. For all other scans, the live scan image is placed within the red dashed lines, so the incident beam is relatively perpendicular to the tissue surface. A distance scale factor is only applied in the measurement tool to get accurate distance and area measurements.

_____End of section_____

8.6 Review Menu

8.6.1 Cornea Line

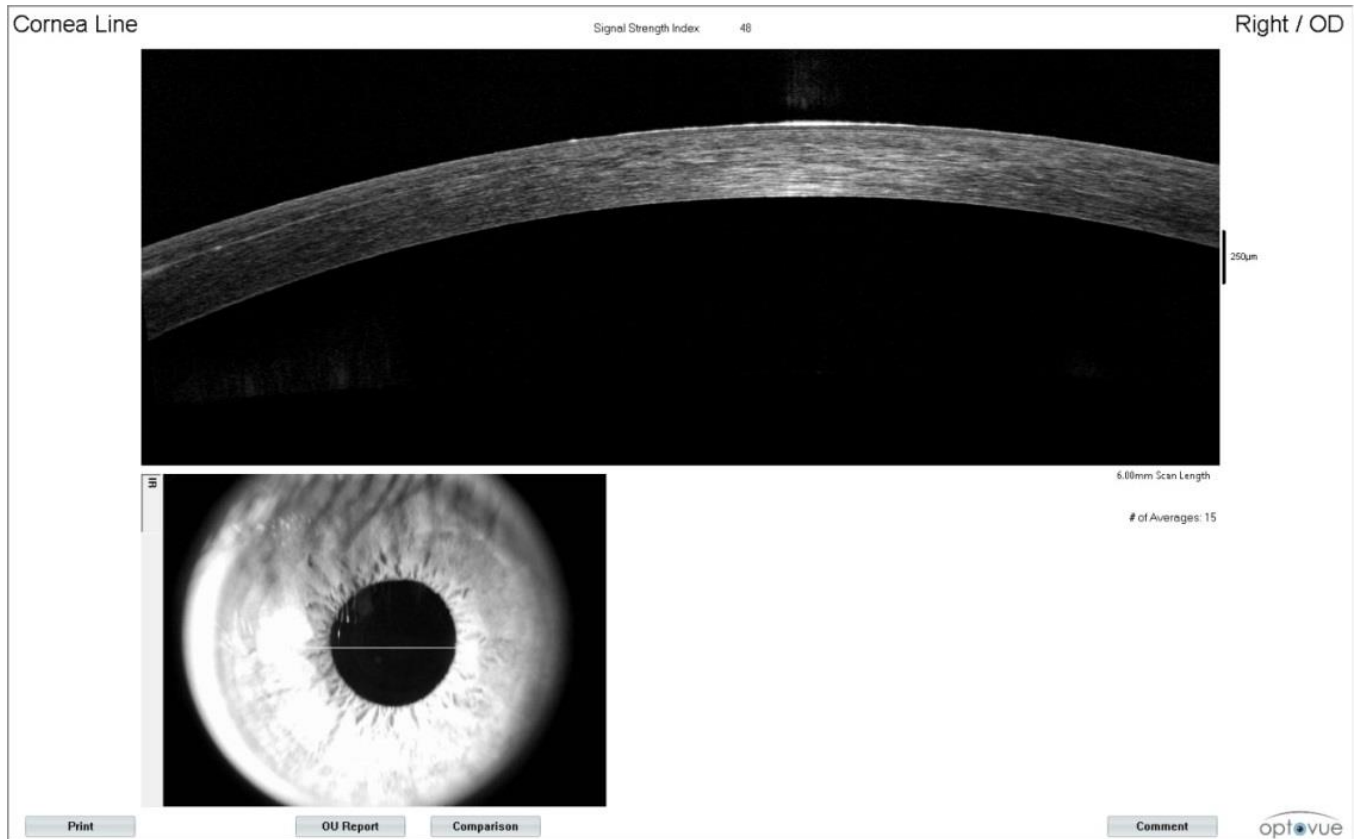


Figure 186 Line scan report

The image saved is an average processed image of cornea scan images.

8.6.2 Anterior Radial 10mm

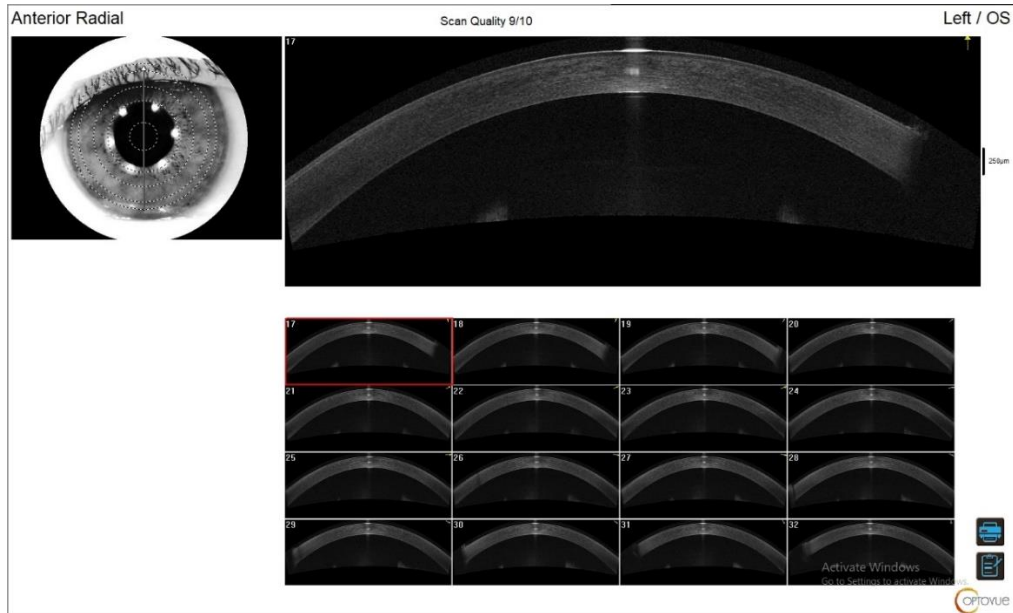


Figure 187 Anterior Radial

8.6.3 Scan with Thickness Measurement Tool

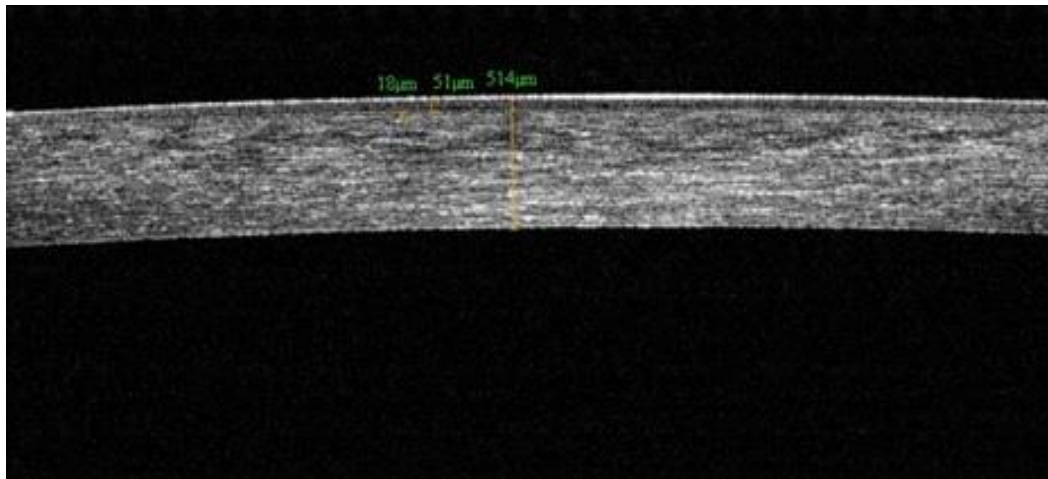


Figure 188 B scan with Measurement tool

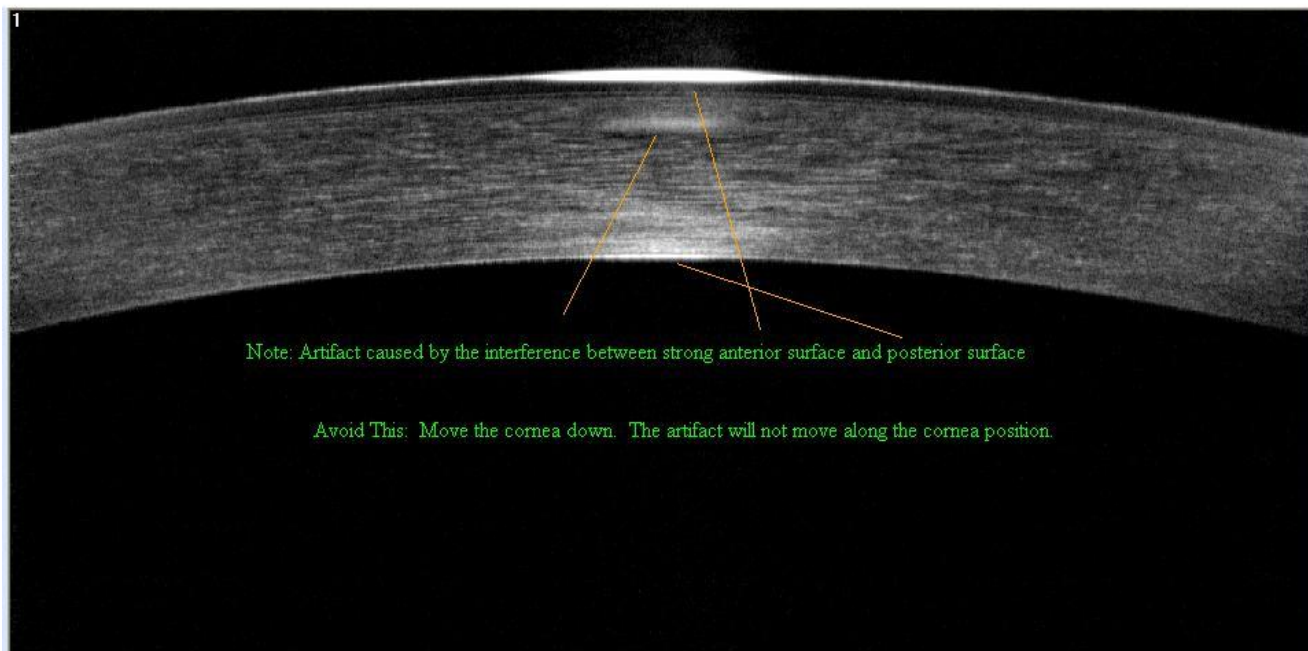


Figure 189 B scan with artifact

 Note: The artifact in the image is from an interference signal caused by the strong signal on both anterior and posterior cornea surface. The artifact is *fixed* at the same location. To avoid or remove the artifact from your scan, use the joystick to move the scan on the eye slightly up/down, left or right. (Use the chinrest elevation control up/down switch for chin adjustment down to avoid the artifact).

8.6.4 Angle

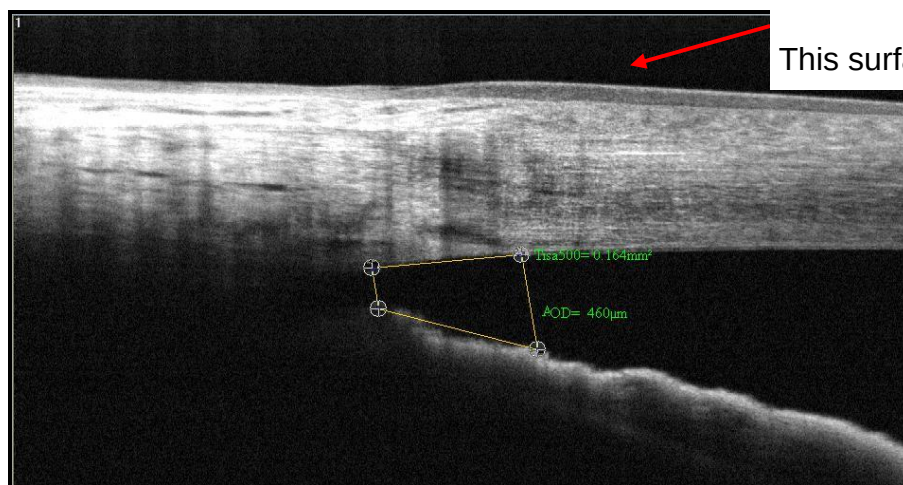


Figure 190 B scan of angle

8.6.5 TISA/AOD Measurement Tool Angle Scan

- TISA (Trabecular Iris Surface Area) Measurement tool is used to measure the angle area and AOD (angle open distance) in the anterior chamber angle. The number 500 or 750 is the distance (in microns) measured between the two upper points along the posterior cornea surface. One of these two upper points shall be located on the sclera spur and the other one on the posterior cornea surface 500 or 750µm away from sclera spur. The AOD is the distance from cornea to iris. The area is measured as the trapezoidal area encompassed by these four points.



Figure 191 Anterior Display Report showing up to 4 angles

8.6.6 Cornea 3D

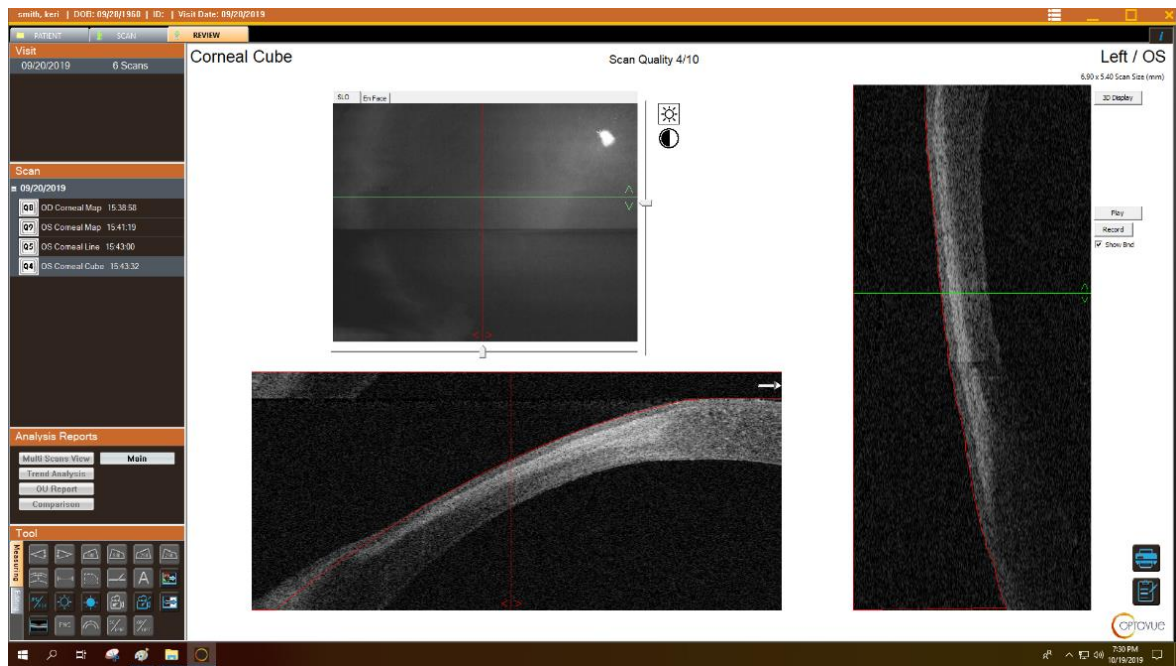


Figure 192 Cornea Cube, with en Face and size adjustment

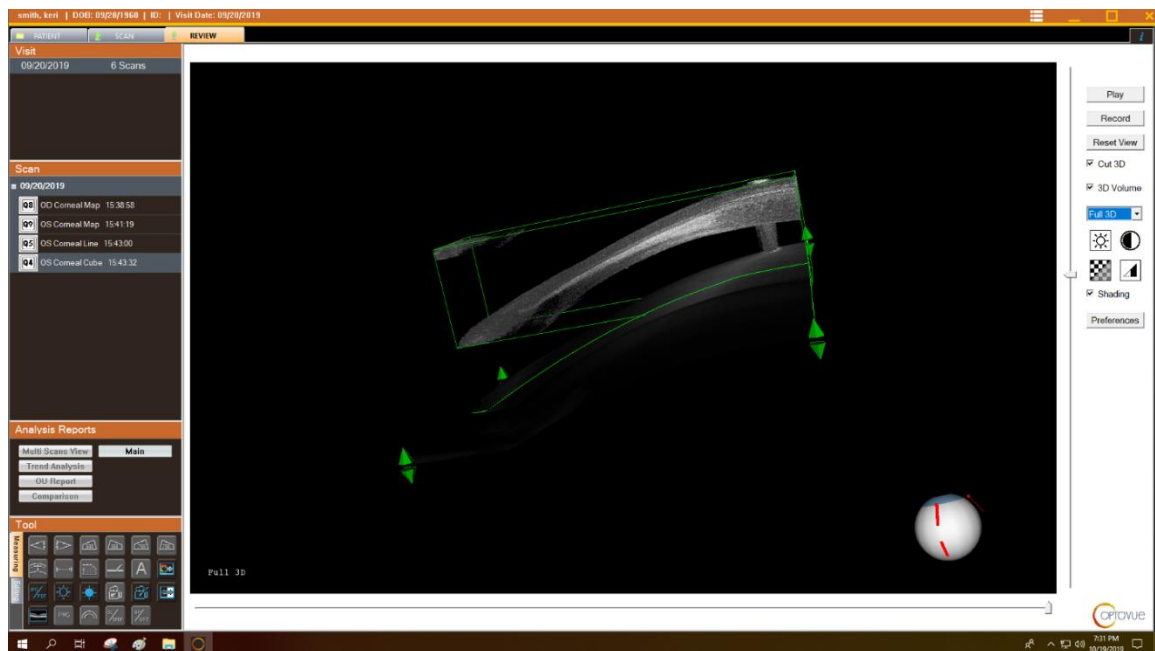


Figure 193 Cornea cube 3D

8.6.7 Corneal Map 10mm

The pachymetry scan is a set of 16 radial meridians 10mm in length and centered on the pupil.

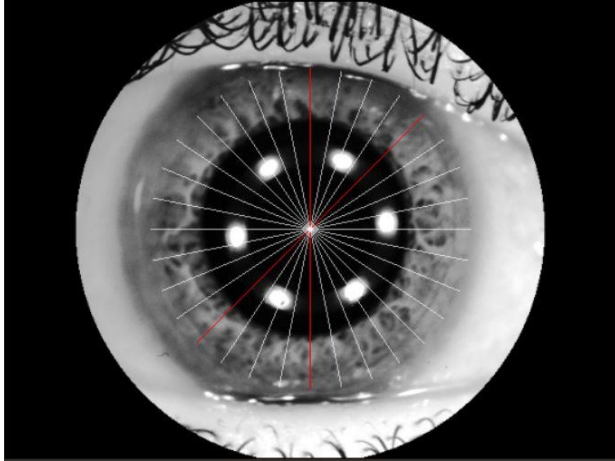


Figure 194 Illustration of Corneal Map scan pattern, 16 meridians, 10mm long

The pachymetry report is a comprehensive collection of maps, tables, and images that provide qualitative and quantitative assessment of the cornea.

Cornea thickness results are presented as a color-coded map (9mm) and a color scale provides reference values for colors. Thicker values are hot colors like red and orange, while thinner values are cool colors like blue and black.

Individual B-scans are displayed in the presentation window above the map. Different B-scans can be displayed by clicking on the thickness map (making it interactive) and moving the cursor around slowly to the white lines (scan location indicators).

8.6.8 Corneal Map Report (10mm)

The Pachymetry analysis provides some key thickness parameters in the table to the left of the Pachymetry report (note the values in the red circle above)

 **Note:** Manual Segmentation of Corneal maps scans is disabled. Rescan poor images.

 **Note:** Pachymetry maps are calculated based on pupil center, Tomography maps are aligned to vertex center. In an eye where pupil center and apex do not align there can be a shift in the alignment of the maps.

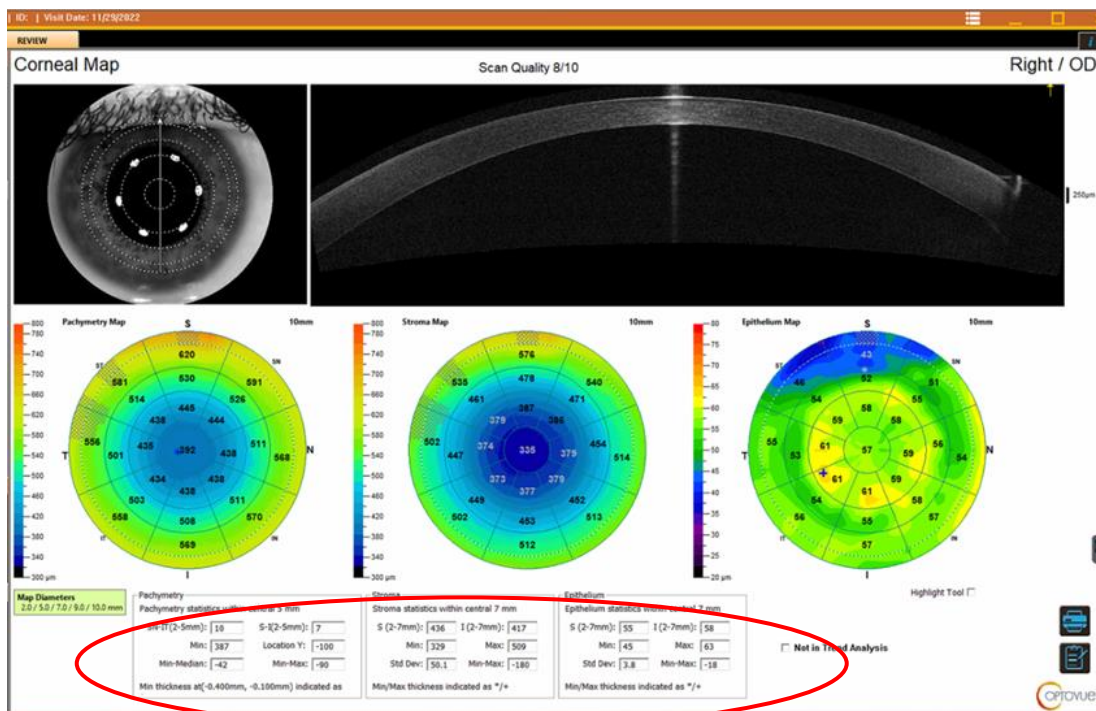


Figure 195 10mm Pachymetry with Epithelial/Stroma and Epi thickness



Note: Shaded areas indicate suspect data, the scan should be reviewed to determine accuracy. (Data is often compromised by lid related issues) All Stroma maps are the result of pachymetry (total thickness) minus epithelial thickness.

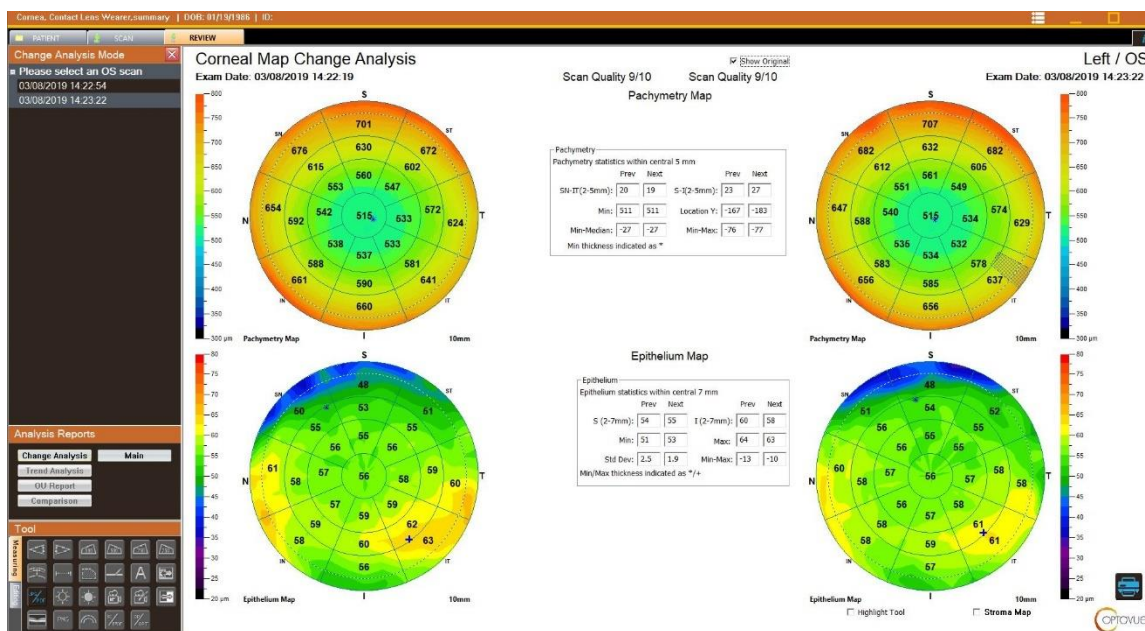


Figure 196 Pachymetry Change Analysis

8.6.9 Epithelium Thickness Mapping

There is a clinical need to measure epithelial cell layer separately from the pachymetry of the cornea. The thickness distribution of the layer is useful in the evaluation and follow up of patients for irregularities and/or changes due to pathologies, contact lens, or refractive surgeries. Epithelium Thickness measures the thickness from the epithelial cell surface to Bowman's membrane.

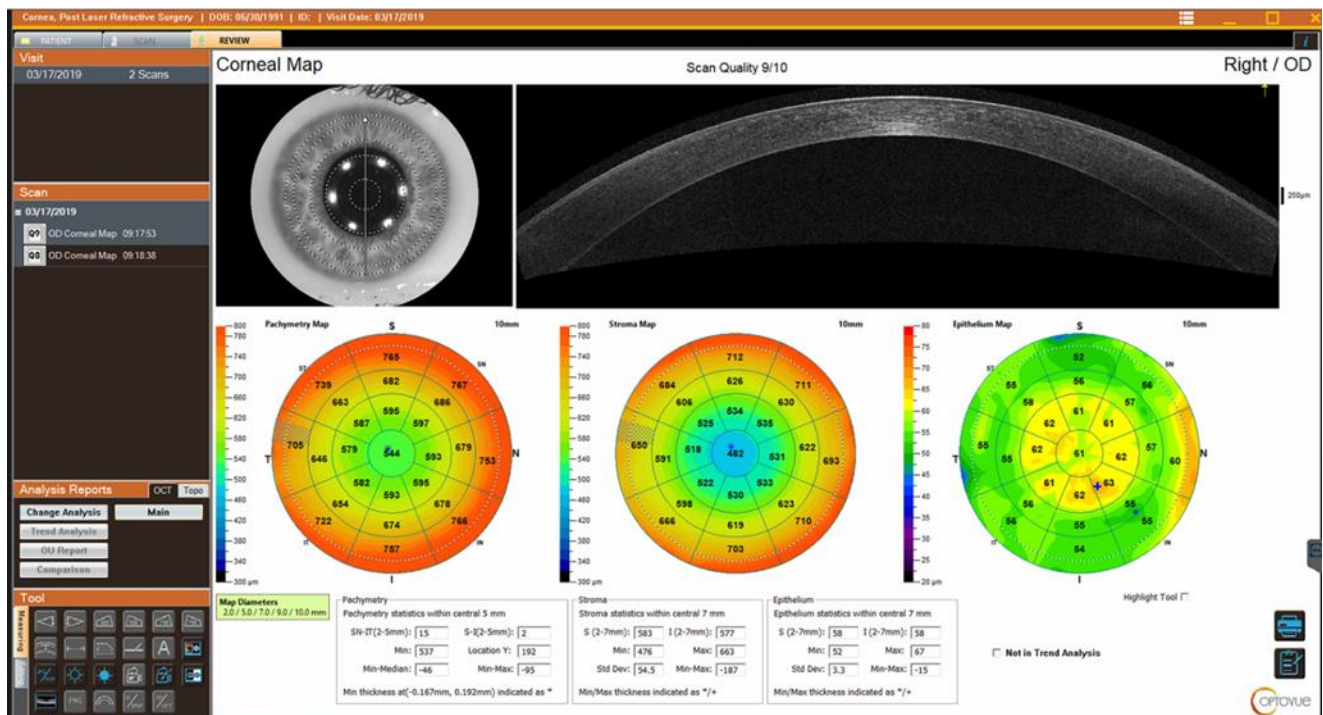


Figure 197 Pachymetry report displaying Stroma/ Epi thickness map

The scan report of epithelium thickness displays an Epithelium/Stroma Map to the right of the pachymetry scan.

 **Note:** The Epithelium Map uses a different color legend than that for the Pachymetry Map. An Epithelium/Stroma Thickness analysis is displayed under the Pachymetry analysis as well.

 **Note:** Keratoconus Risk Score available at Coollabs.org website, example:

Keratoconus Risk Score Table

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Updated: February 19, 2015

Patient Name

Variables (μm)	0	1	2	3	OD	OS
SN-IT	<33	33~42	43~51	>51		
Minimum	>499	499 ~ 476	475 ~ 455	<455		
Minimum-Median	>-21	-21 ~ -25	-26 ~ -29	<-29		
S-I	<30	30~40	41~49	>49		
Ymin	>-734	-734 ~ -1069	-1070 ~ -1353	<-1353		
Keratoconus Risk Score						
					Keratoconus risk:	

Keratoconus risk score 0~3: low risk, ≥4: high risk.

The variables are calculated from the central 5 mm diameter of the pachymetry map. The octant values are averaged in the 2 to 5 mm diameter zone.

S-I = superior-inferior; SN-IT = superonasal-inferotemporal; Ymin = vertical location of the minimum.

Reference: Qin B, Chen S, Brass R, Li Y, Tang M, Zhang X, Wang X, Wang Q, Huang D. Keratoconus diagnosis with an optical coherence tomography-based pachymetric scoring system. J Cataract Refract Surg 2013;39(12):1864-71.

Figure 198 Coollabs Keratoconus risk score

OU Report

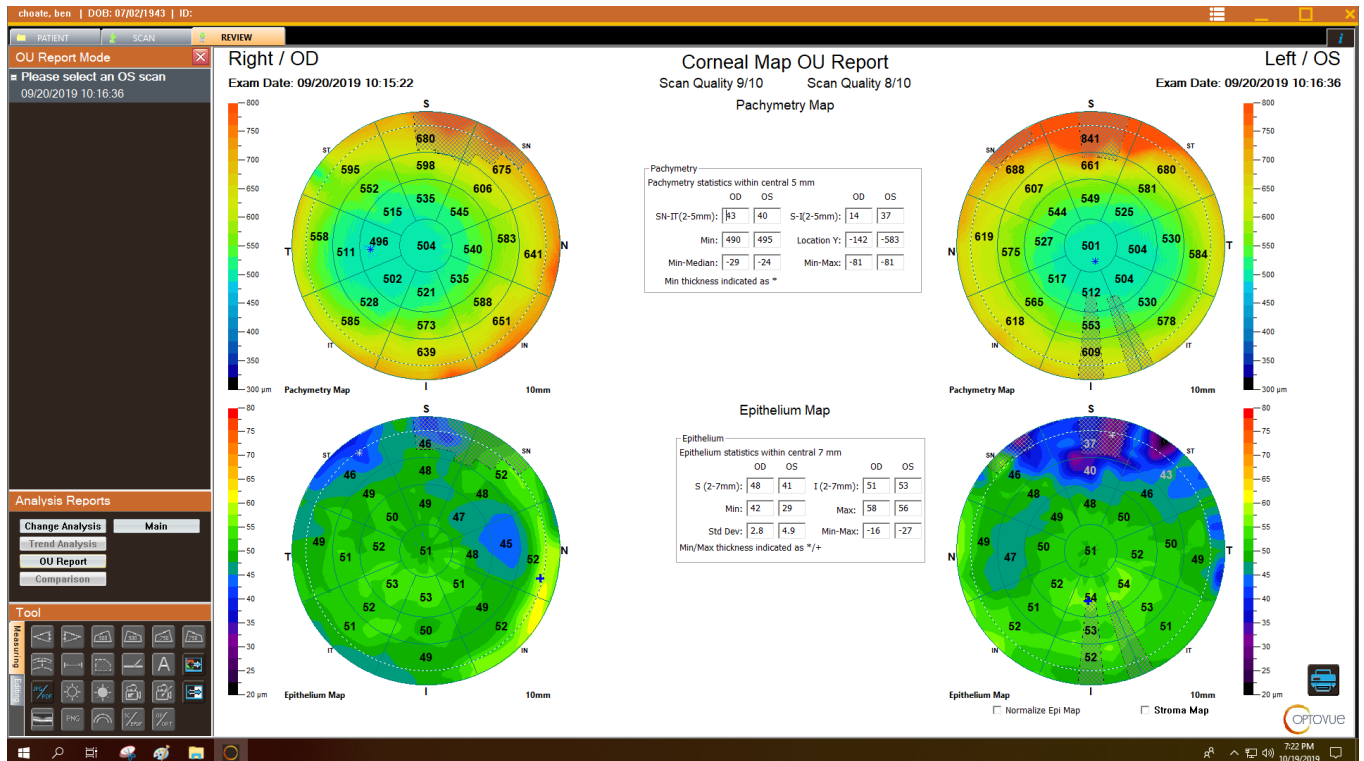


Figure 199 Pachymetry OU Report With Epithelial Mapping

8.6.9.1 OU Pachymetry Trend Analysis

The OU Pachymetry Trend Analysis report can display either pachymetry, stroma or epithelial thickness as well as showing a graph for pachymetry thinnest, epithelial thinnest and superior nasal minus inferior temporal results.

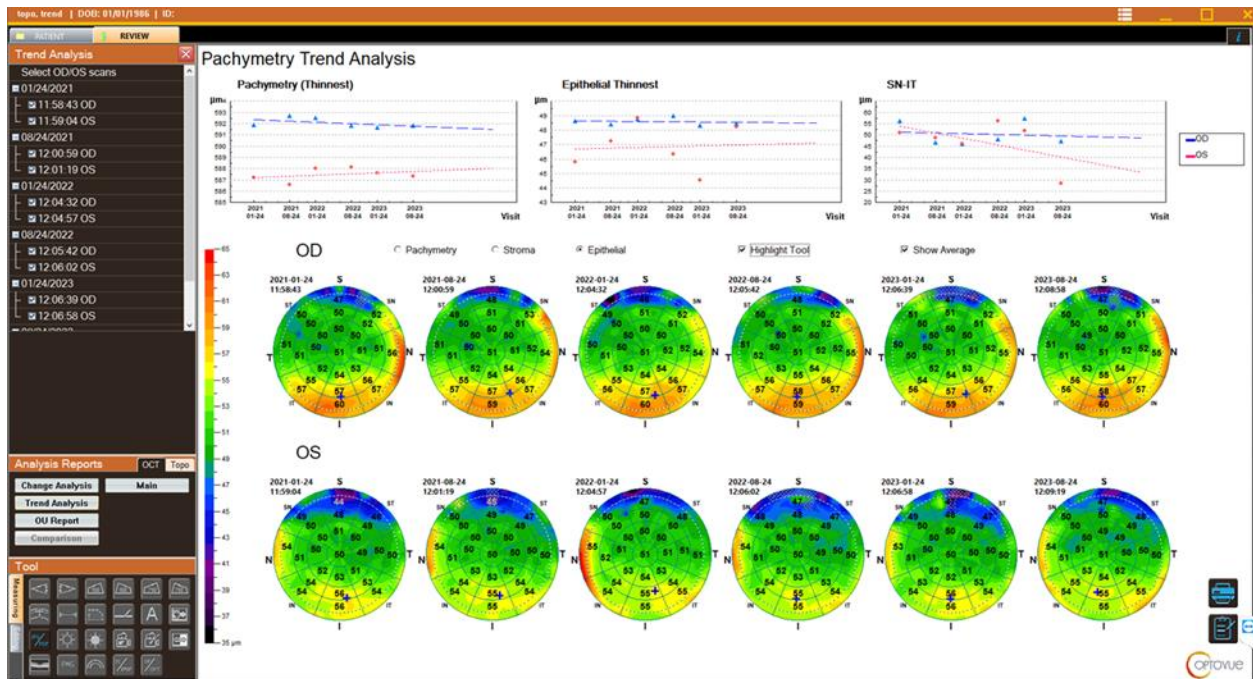


Figure 200 Pachymetry Trend Report

8.7 Topography Reports (with Topography License)

The following topography reports are available:

Main - A six position display with pull downs for each position and a table display

Refractive - same layout as main except maps are selected in user preference

Crystalline lens - five position layout, with additional display for full range anterior and lens

Comparison - Review/subtraction of any 2 scans of the same eye

Trend - multi-scan display of the same eye

OU - two map display with table of OD and OS

Zernike - OU report showing higher order and lower order graph and maps

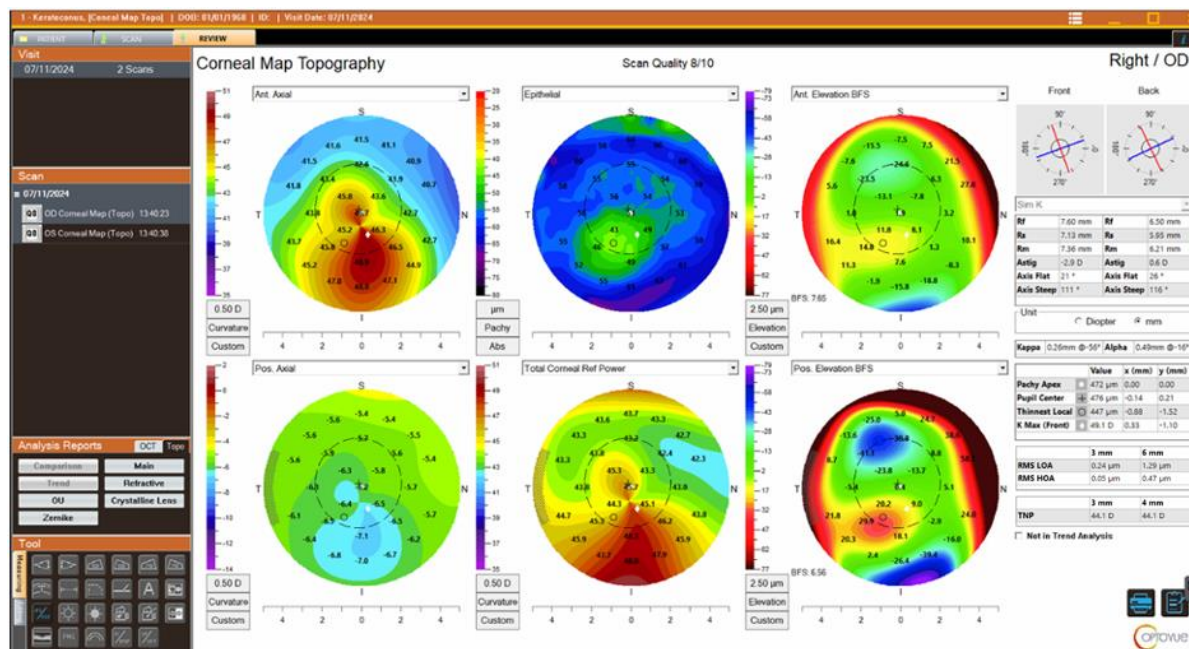


Figure 201 Topography Main Report

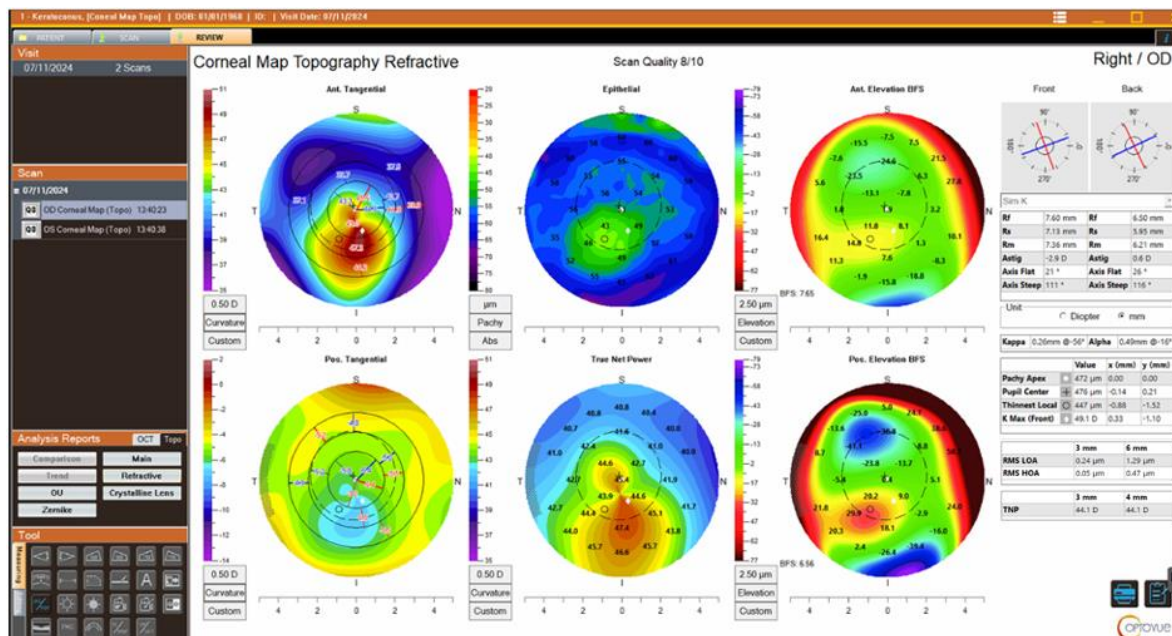


Figure 202 Refractive Report

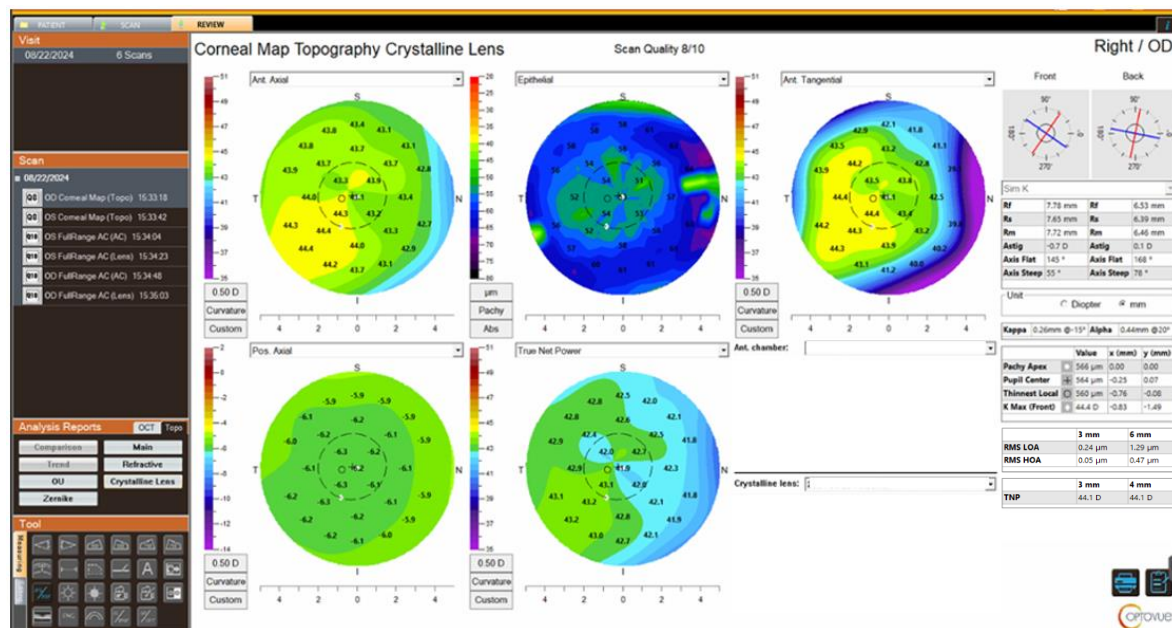


Figure 203 Crystalline lens Report

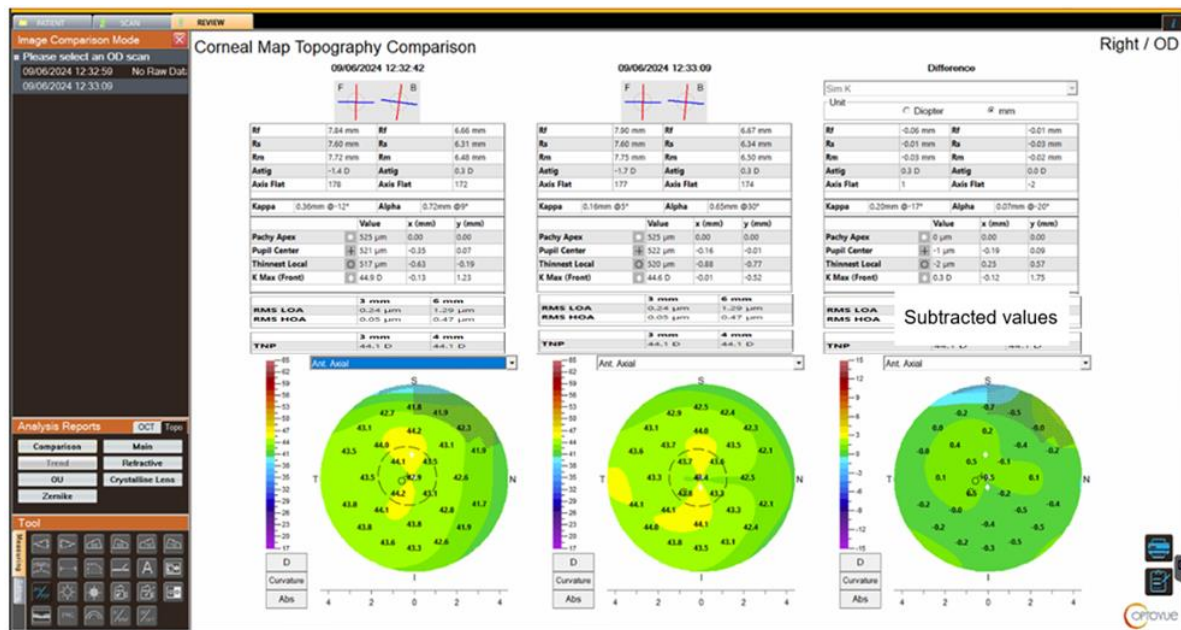


Figure 204 Comparison

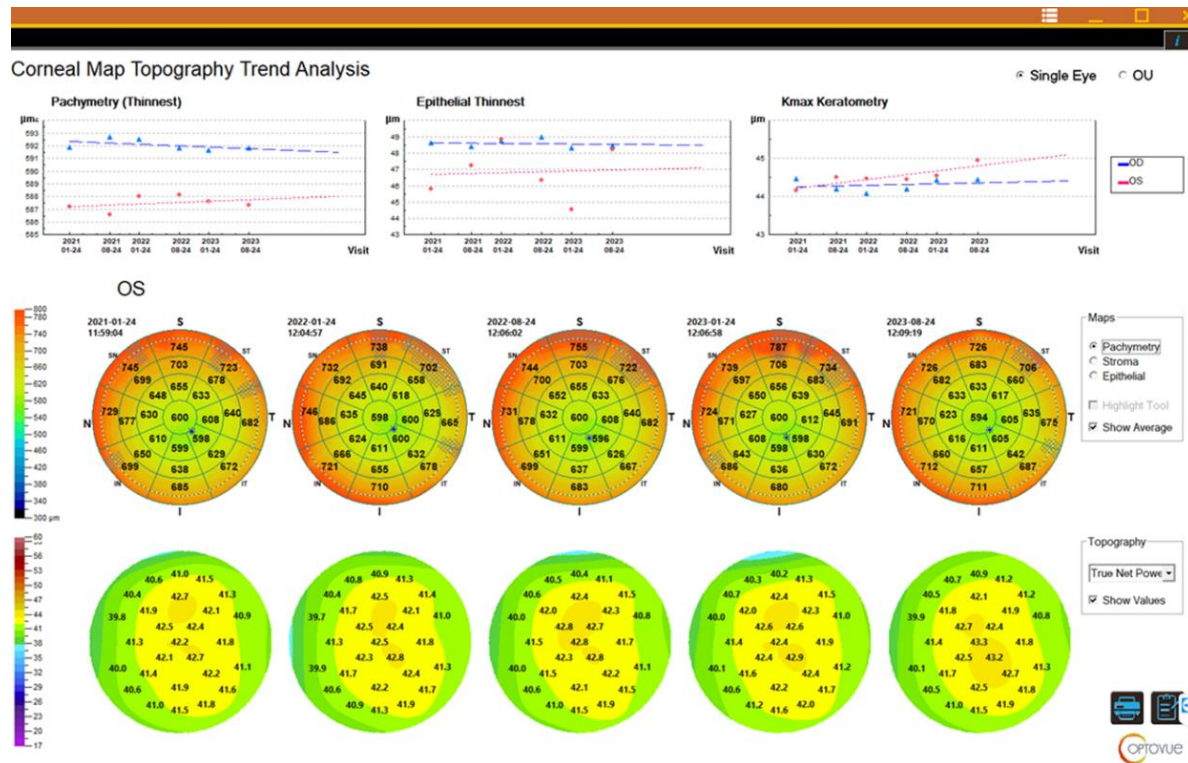


Figure 205 Corneal Map Topography Trend

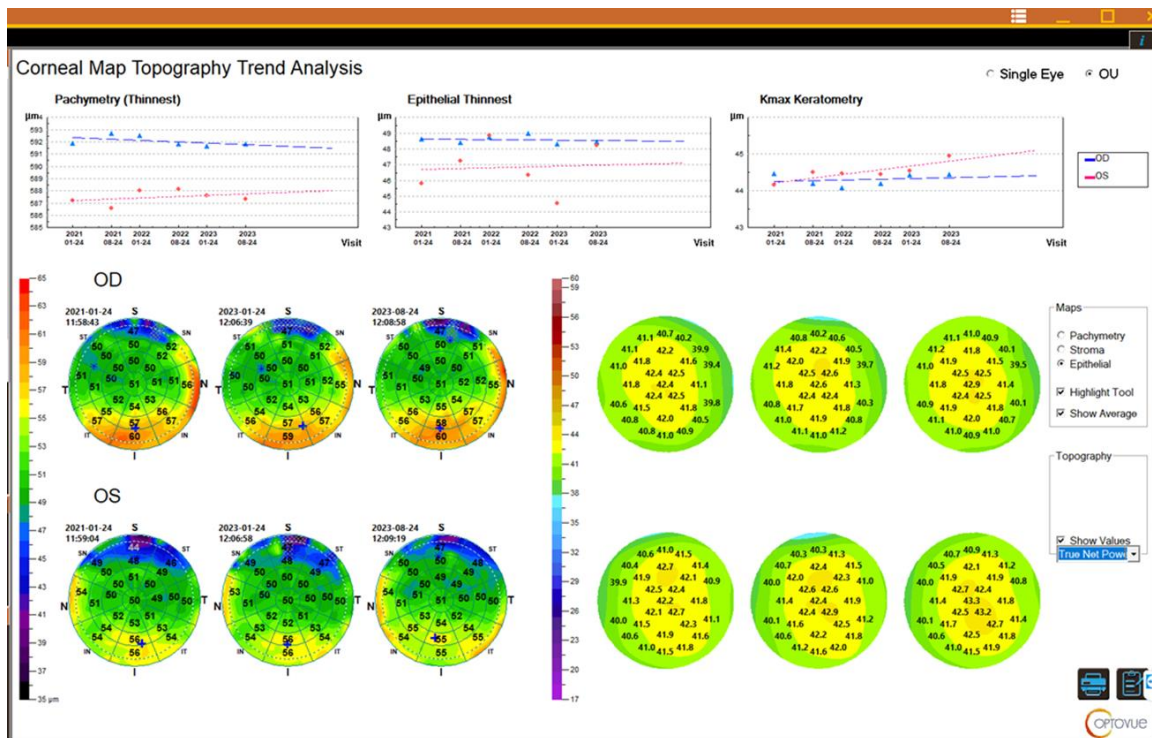


Figure 206 OU Corneal Map Topography Trend

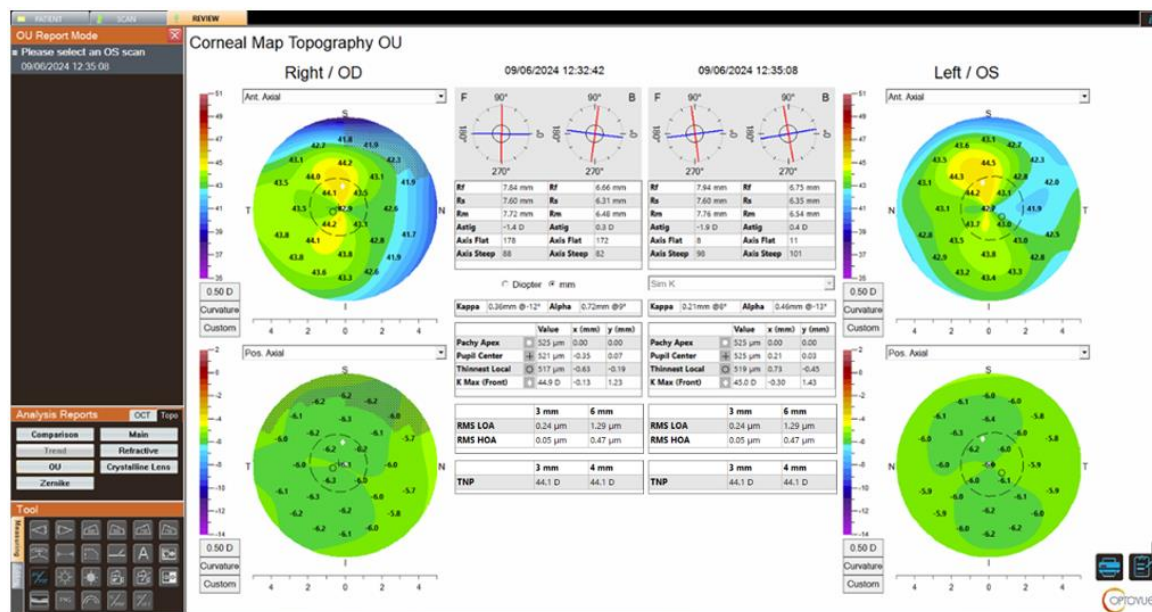


Figure 207 Corneal Map Topography OU



8.7.1 Topography Parameters

K1_ant(D)	flat keratometry calculated using the ring area with a diameter of 2.5mm to 3.5mm, centered on the vertex of the anterior surface
K2_ant(D)	steep keratometry calculated using the ring area with a diameter of 2.5mm to 3.5mm, centered on the vertex of the anterior surface
Astig_ant(D)	astigmatism of the anterior surface, defined as the difference between K1_ant and K2_ant ($K1_ant - K2_ant$).
Kmax_ant(D)	maximal corneal curvature of the anterior surface
Kmean_ant(D)	mean keratometry of the anterior surface, calculated as $(K1_ant + K2_ant)/2$
AxisSteep_ant(degree)	angle of the meridian with the steepest keratometry on the anterior axial map
rBFS_ant	radius of the best-fit sphere within the 8mm diameter area of the anterior surface
K1_pos(D)	flat keratometry calculated using the ring area with a diameter of 2.5mm to 3.5mm, centered on the vertex of the posterior surface
K2_pos(D)	steep keratometry calculated using the ring area with a diameter of 2.5mm to 3.5mm, centered on the vertex of the posterior surface
Astig_pos(D)	astigmatism of the posterior surface, defined as the difference between K1_pos and K2_pos ($K1_pos - K2_pos$).
Kmean_pos(D)	mean keratometry of the posterior surface, calculated as $(K1_pos + K2_pos)/2$
AxisSteep_pos(degree)	angle of the meridian with the steepest keratometry on the posterior surface
rBFS_pos	radius of the best-fit sphere within the 8mm diameter area of the posterior surface

TNP_3mm(D)	True Net power in the central 3mm diameter area derived from both the anterior and posterior surfaces
TNP_4mm(D)	True Net power in the central 4mm diameter area derived from both the anterior and posterior surfaces
RMS LOA_3mm(um)	root-mean-square value of the low-order aberrations within a 3mm diameter area centered on the vertex of the anterior surface
RMS LOA_6mm(um)	root-mean-square value of the low-order aberrations within a 6mm diameter area centered on the vertex of the anterior surface
RMS HOA_3mm(um)	root-mean-square value of the high-order aberrations within a 3mm diameter area centered on the vertex of the anterior surface
RMS HOA_6mm(um)	root-mean-square value of the high-order aberrations within a 6mm diameter area centered on the vertex of the anterior surface

8.8 Topography User Preference Selections

The screenshot shows the 'User Preference' dialog box with three main sections: System Settings, Report Settings, and Scan Settings. The Scan Settings tab is currently selected, showing various parameters for eye scans. At the bottom, there are green and red checkmark buttons for confirmation and cancellation.

Section	Setting	Value
System Settings	Date Format	MM/dd/yyyy
	Primary Archive Drive:	
	Secondary Archive Drive:	
	Primary backup drive:	D
	Secondary backup drive:	
	Use Reminder for Old Validation	☐
Report Settings	Default Angio Retina Display:	Enface
	Default Angio Disc Display:	Enface
	Default Angio EnFace Visualization:	Standard
	Default 3D Retina Enface Layer:	Superficial
	Default 3D Disc Enface Layer:	RPC
	Default 3D AngioVue Display	Large Angio
	Default RDB Display Option	RDB Ref
	Angio Flow Measure Type	Circle
	MCT Load Both Volumes	On Demand
	B_Scan Image Enhance	Yes
Scan Settings	Allow to save eye blink data:	Yes
	OCT Fixation LED Current (1-15):	3
	Fundus Fixation LED Current (1-15):	2
	Save Fast-X Volume:	No
	Scan Navigation Order	Non-dilated
	Non MCT Scan Auto Save:	Yes
	Enable joystick to save scan	☒
	Enable joystick for Auto Adjust/Auto Focus button	☒
	Followup	☐
	Tracking	☒
	Light Eye Red Illumination (1-100):	40
	Dark Eye Red Illumination (1-100):	55
	Internal Fundus Flash Level:	5
	External Photo Flash Level:	2

At the bottom of the Scan Settings tab, there are three tabs: Scan Size, Average #, and Topography. The Scan Size tab is selected, showing the following values:

Parameter	Value	Unit
Line (6-12mm)	12.00	mm
Raster (6-12X2-10mm)	12.00 x 6.00	mm
Radial Lines (6-12mm)	12.00	mm
FullRange Retina (6-16mm)	16.00	mm
FullRange AC (14-18mm)	18.00	mm
Corneal Line (3-10mm)	8.00	mm

Figure 209 Topography User Preference

“Reminder for Validation” if checked this will pop-up a message for the operator to Validate the system every 30 days, if Corneal Map scan is selected.

To set Topography preferences, click the Topography Tab, then click “Topo Settings”

8.8.1 Topography Settings

The tab settings on the upper right determine which maps are displayed on each report. The 3 choice boxes on the left determine how each type of map will appear in terms of the color palette, step scale, etc. for Curvature maps, Pachymetry maps and Elevation maps. The Topo Overlay selection determines the icons and numeric overlays,

Topography Settings

Curvature Color Map

Units:

Color Palette:

Central Value: Diopter

Step Size: Diopter

Scale: ☒ Absolute ☐ Normalized ☐ Custom

Pachymetry Color Map

Units:

Color Palette:

Central Value: Microns

Step Size: Microns

Scale: ☒ Absolute ☐ Normalized ☐ Custom

Elevation Color Map

Units:

Color Palette:

Central Value: Microns

Step Size: Microns

Scale: ☒ Absolute ☐ Normalized ☐ Custom

Best Fit Sphere Diameter: mm

Map Settings

1 2 3
4 5 6

Map 1:

Map 2:

Map 3:

Map 4:

Map 5:

Map 6:

Topo Map Overlay

☒ Apex ☒ KMax

☒ Thinnest ☐ Kerato

☐ Min. Radius Front Sag. ☐ Zones

☐ Min. Radius Back Sag.

☒ Pupil Center ☒ Show Numbers

☒ Pupil radius ☒ Numeric values ☐ Min/Max values

☐ Cross Grid

Table Data Display

☒ Diopter ☐ mm

Figure 210 User Preference Map features

8.8.2 Map Display Options

Scales:

Absolute Scale: uses fixed color-coding that is the same for all patients and exams, allowing for consistent comparison between different exams or different patients.

Normalized (Relative or Adaptive) Scale: matches color coding to a specific patient's measurements, helping to highlight subtle differences in that patient's cornea. However, this scale makes comparisons between patients, and even the same patient, at different time points more difficult.

User-Defined Scale (Custom): some topographers allow users to define their color scale, thus customizing it to specific needs or preferences.

8.8.3 Topography Map Overlays

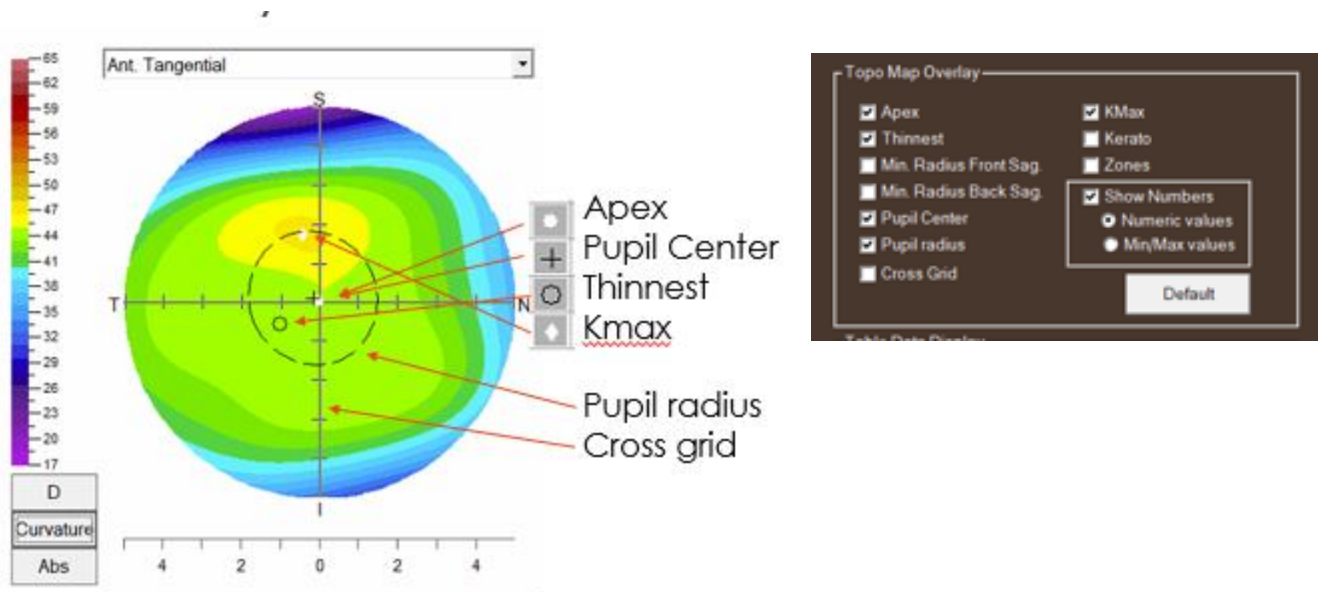


Figure 211 Topography Map Overlays

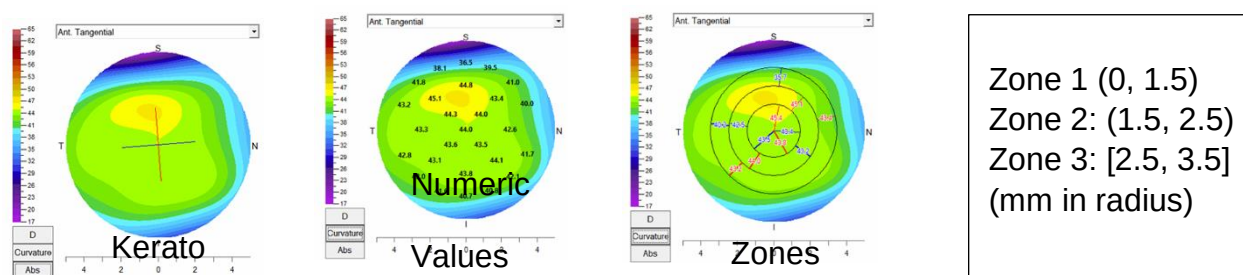


Figure 212 Additional overlays incl. Zones

Zones: There are **4 bars** in each zone:

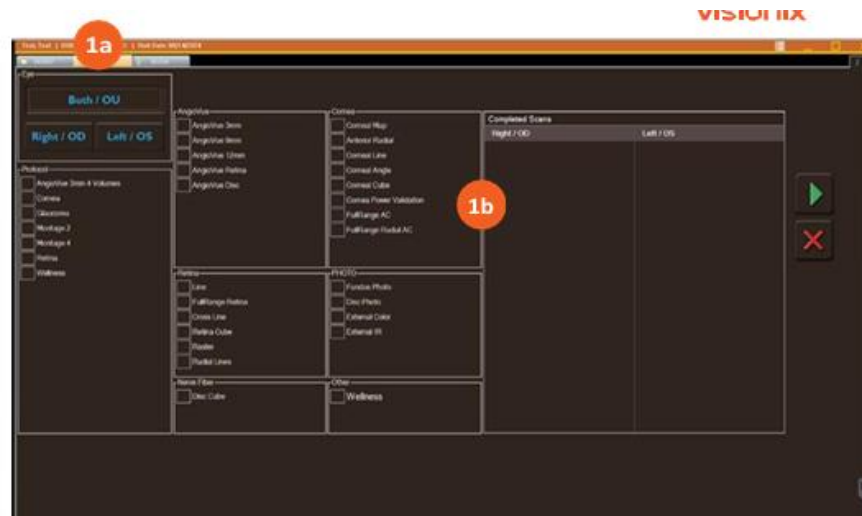
1. Primary K1 (**Thick Red** bar): Represents the steepest angle.
2. Primary K2 (**Thick Blue** bar): Represents the flattest angle.
3. Secondary K1 (Thin Red bar): Represents the second steepest angle outside $\pm 90^\circ$ of the primary K1 angle.
4. Secondary K2 (Thin Blue bar): Represents the second flattest angle outside $\pm 90^\circ$ of the primary K2 angle.

8.9 Topography Validation

1. Use current patient or Test Patient

1a. To use Test patient, enter (Test) or search name for (Test) to search the database.

1b. Select Corneal Power validation Scan & click start



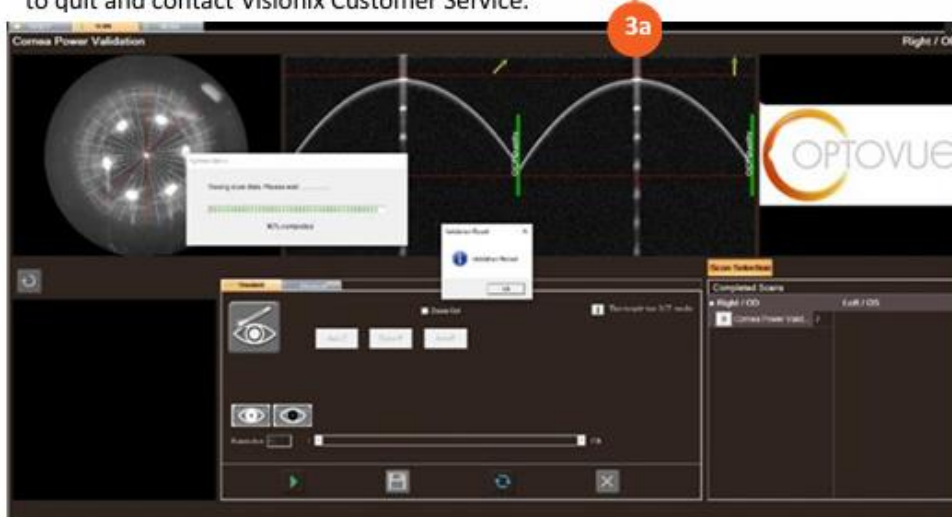
2. Mount Validation Tool on Chinrest

2a. Follow arrows to Slide tool onto chin rest using equal force on each side until snug and doesn't wobble



3. Position Joystick

3a. Start with joystick pulled back, move forward until the “curve” surface is at the red line and then adjust the position up/down, left/right until there is a strong reflection off the vertex. Click Capture. If Validation passes click OK. If Validation fails make several attempts, if it continues to fail, click “continue” to quit and contact Visionix Customer Service.



Important: Always use the lens calibrated for the system, lenses are not interchangeable without recalibration.

Solix is calibrated and validated as per specifications when set up is completed by the Visionix staff. It is not the responsibility of Visionix to guarantee or police the accuracy of this instrument after delivery. Solix Topography comes with a validation tool with which the customer can verify the accuracy of the instrument. User preference can remind the user or the operator may elect to turn off the notification and maintain the system on their own. If the unit fails validation procedure completely it will need to be re-calibrated by Visionix service.

Before using data for surgical determinations always examine the measured data results, compare the difference between measurement values for the left and right eyes, if significant difference or any problem is found check the images & segmentation. If the results are not conclusive, perform the measurement multiple times.

When using data taken by this instrument for diagnosis or determination of treatment, proceed carefully by taking measurements multiple times and/or conducting other examinations.

8.10 Map Types

8.10.1 Curvature Maps

Anterior Axial Map: This map provides the axial radius or power of each point on the anterior cornea surface.

Posterior Axial Map: This map provides the axial radius or power of each point on the posterior cornea surface.

Anterior Tangential Map: This map provides the tangential radius or power of each point on the anterior cornea surface.

Posterior Tangential Map: This map provides the tangential radius or power of each point on the posterior cornea surface

Anterior Mean curvature: This map provides the mean curvature or power of each point on the anterior cornea surface.

Posterior Mean curvature: This map provides the mean curvature or power of each point on the posterior cornea surface.

8.10.2 Mean Curvature maps

Mean curvature is defined as the arithmetic mean of the principle curvatures and Gaussian curvature equals to the geometric mean of the principle curvatures. It is the average curvature of the two principle directions, where the meridional curvature takes

on maximum and minimum values. Mean curvature mapping has the theoretical advantage over conventional representations of corneal topography in detection subtle shape abnormalities in that it is a more faithful description of three-dimensional shape and has the ability to suppress some of non-pathological features while keeping pathological features like keratoconus relatively intact. Because mean curvature mapping is a more faithful three-dimensional description of surface shape than axial and tangential maps and has the unique feature of suppressing the manifestation of regular astigmatism, it could be particularly suitable for the diagnosis of keratoconus, which is characterized by local increase in corneal curvature, and other similar diseases sharing the same feature such as pellucid marginal degeneration and post-LASIK keratectasia.

CORNEAL MEAN CURVATURE MAPPING: APPLICATIONS IN LASER REFRACTIVE SURGERY DISSERTATION
Presented in Partial Fulfillment of the Requirement for the Degree Doctor of Philosophy in the Graduate School of the
Ohio State University By Maolong Tang, M.S.

8.10.3 Elevation Maps

Anterior Float Elevation Map: The difference between the Anterior elevation map and its best fit sphere.

Posterior Float Elevation Map: The difference between the posterior elevation map and its best fit sphere.

Best Fit Sphere – calculated over an 8mm fitting zone. (default and adjustable by research parameter). The best-fit sphere is the one passing through the eye surface defined by the fitting zone minimizing the surface elevations on either side

8.10.4 Pachymetry Maps

Solix shows Full pachymetry, Stroma and Epithelial thickness. In user preference there are two map options, “pachymetry” which displays the corneal thicknesses in the typical Tomographer style where a thin cornea is red and thick is blue, an alternative “OCT Pachymetry” is also offered which displays thickness like an SD-OCT where thin is blue and thick is red.

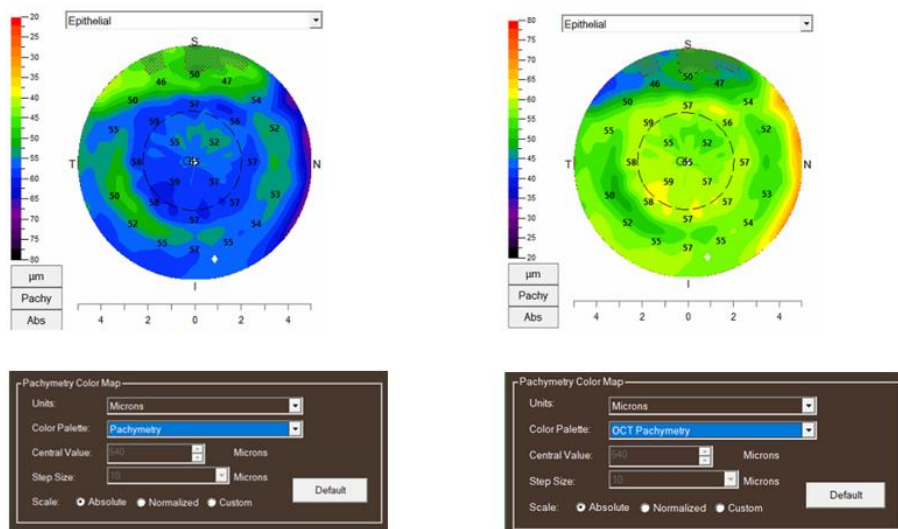


Figure 213 Pachymetry – OCT Pachymetry

8.10.5 Power Maps

True Net Power Map: This map shows the power of the cornea as calculated from the axial curvature values of the anterior and the posterior surface. Anterior sagittal power is calculated using refractive indices of $n=1$ for air and $n=1.376$ for corneal tissue, while posterior sagittal power is calculated using refractive indices of $n=1.376$ for cornea tissue and $n=1.336$ for the aqueous, and the results are then aggregated.

Total corneal Ref Power: The Total Corneal Refractive Power Map uses ray tracing to calculate power. In a simulation parallel light beams are transmitted through the cornea and the focal length resulting from their refraction at the anterior and posterior surface is calculated according to Snell's law of refraction. This refraction is dependent on the true refractive indices of air ($n=1$), corneal tissue ($n=1.376$) and aqueous fluid ($n=1.336$).

Keratometric power Deviation: This map gives the difference between the true net power map and the anterior axial map

Anterior Refractive: Applied Snell's law of refraction to convert curvature values into refractive power values. Due to the phenomenon of spherical aberration parallel light beams incident on a spherical surface do not converge on a single point. Each point corresponds to a focal length, from which a corresponding refractive power can be calculated. (refractive power = n/f , $n=1.3375$, and f is the focal length of each point on the anterior cornea surface).

Posterior Refractive: Applied Snell's law of refraction to convert curvature values into refractive power values. Due to the phenomenon of spherical aberration parallel light beams incident on a spherical surface do not converge on a single point. Each point corresponds to a focal length, from which a corresponding refractive power can be calculated. (refractive power = n/f , $n=1.336$, f is the focal length of each point on the posterior cornea surface).

8.10.6 Zernike

The Zernike report shows higher order and lower order aberrations in map form as well as Zernike polynomials in the form of a bar graph. Also displayed is an eye chart that reflects the RMS HOA, RMS LOA or combinations to illustrate patient vision.

RMS LOA Root Mean Square Lower order aberrations

RMS HOA Root Mean Square Higher order aberrations

8.10.7 Angle Kappa & Angle Alpha (Chord mu values)

Angle Alpha: angle between the pupillary axis and the optical axis

Angle Kappa: angle between the pupillary axis and the visual axis

Pupillary axis- the line through the midpoint of the entrance of the pupil, perpendicular to the corneal surface

Visual axis- the line connecting the fovea to the fixation target

Optical axis- the line connecting the optical center of the cornea and optical center of the crystalline lens

Solix displays the **Alpha and Kappa chord mu** values, denotes two-dimensional displacement of the entrance of the pupil center from the subject-fixated coaxially sighted corneal light reflex. The display shows the distance apart in mm and at which degree the points are separated. i.e. 0.1mm @ 82°



_____End of section_____

8.11 Maintenance

Cleaning the Corneal lens

- Keep the CAM lenses in the case provided when not in use.
- Routinely check the lens for dust, fingerprints, or smudges.
- Use the same Kit and cleaning method as is recommended in chapter 10 on cleaning.

_____End of section_____

8.12 Pachymetry & Epithelium Mapping

8.12.1 Zonal parameters

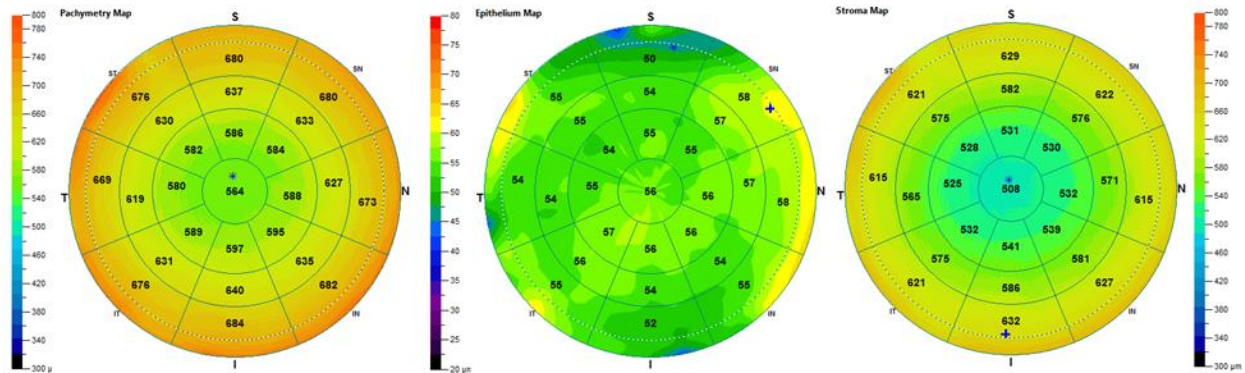


Figure 214 Zonal parameters

25-sector grid overlay on the thickness maps for total corneal (pachymetry), epithelium, and stroma from left to right, respectively.

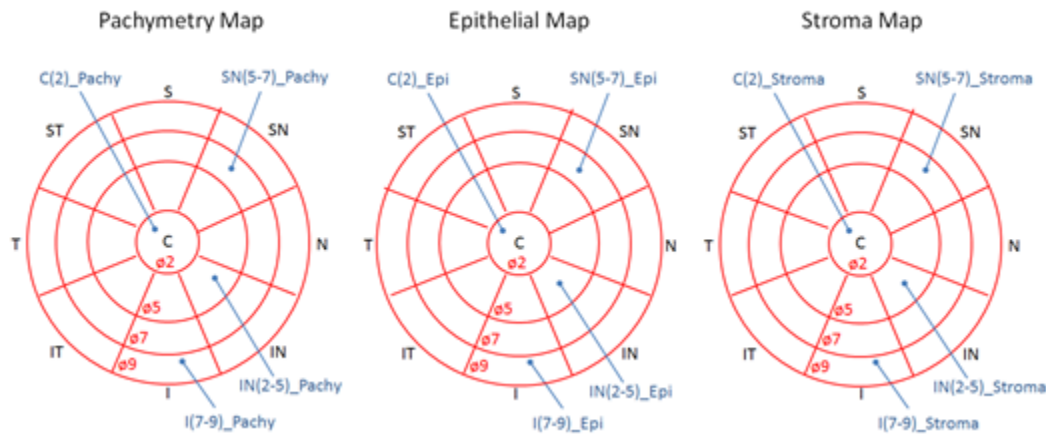


Figure 215 Naming convention of zonal parameters

8.12.2 Detection of Epithelial Boundaries

The automatic algorithm measures epithelial thickness from corneal anterior surface to the posterior boundary of the epithelia. The posterior boundary is defined as the interface of epithelia and Bowman's Layer. When the Bowman's layer is absent as in post-PRK eyes, the posterior boundary is defined as the interface of epithelia and the corneal stroma. There is characteristic reflectivity change at the interfaces which is utilized in the automatic algorithm for boundary detection. The automatic segmentation of the corneal anterior and posterior boundaries and epithelial posterior boundary and

resulting corneal thickness map and epithelial thickness map are illustrated with a post-LASIK eye and with a post-PRK eye as illustrated in the following two images, respectively. Because of the difference in the characteristics in the epithelial posterior boundary in LASIK and PRK eyes, for this validation study, we separated the post-laser refractive surgery eyes into LASIK group and PRK group in the data analysis.

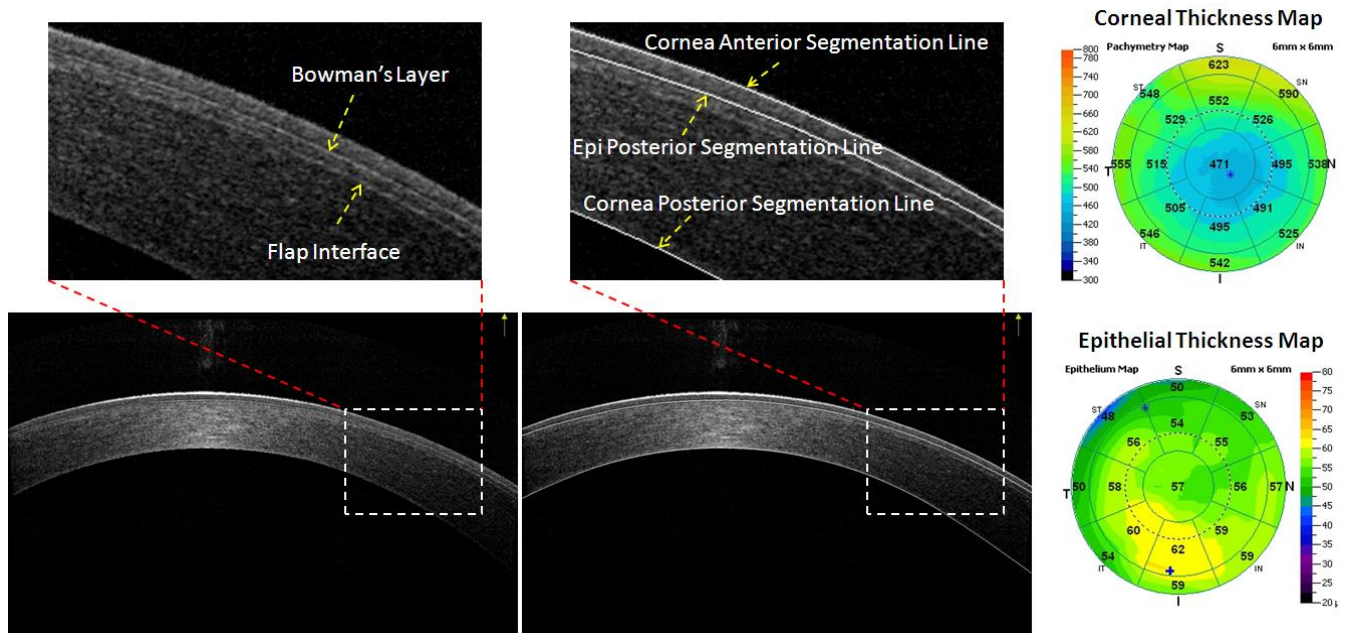


Figure 216 Automatic segmentation boundaries Lasik

Automatic segmentation of corneal and epithelial boundaries in the right eye of a 33 yrs. old male study subject with LASIK previously. The Bowman's layer is clearly visible and in some region, the LASIK flap interface is also visible. The automatic segmentation lines for the corneal and epithelial boundaries are shown in the middle. The resulting thickness maps are shown on the right.

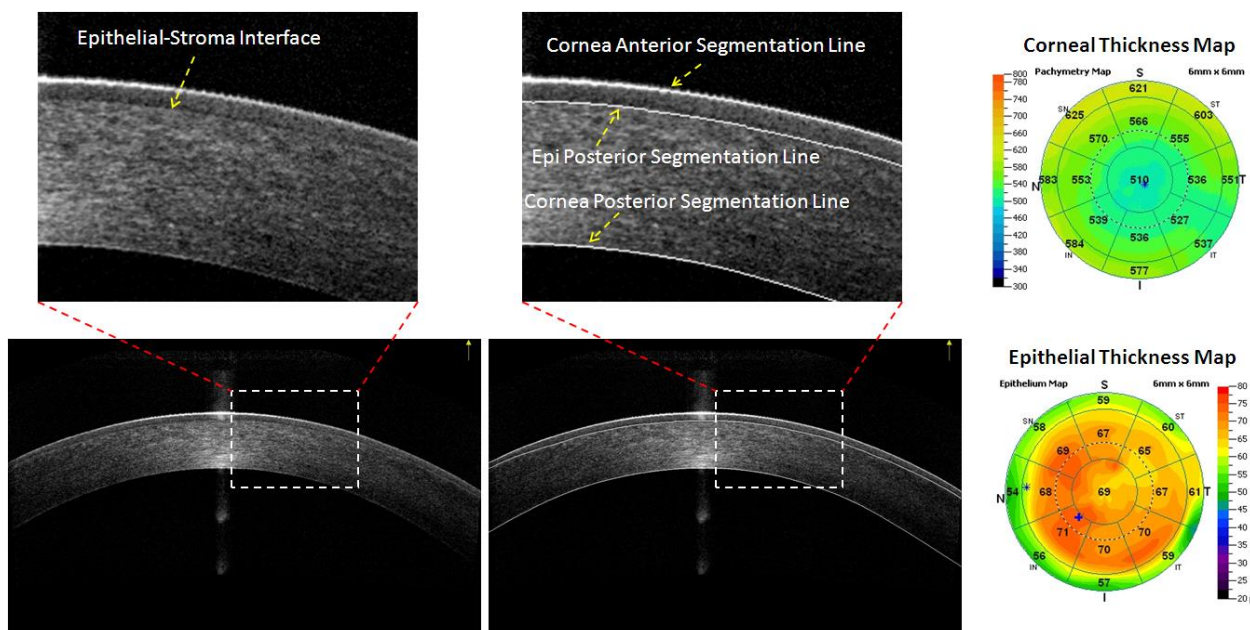


Figure 217 Automatic segmentation boundaries PRK

Automatic segmentation of corneal and epithelial boundaries in the left eye of a 42 yrs. old female study subject with PRK previously. The Bowman's Layer is absent as the result of the PRK procedure. The automatic segmentation lines for the corneal and epithelial boundaries are shown in the middle. The resulting thickness maps are shown on the right.

8.12.3 Identification of Segmentation Error and Manual Correction

Check epithelial map for obvious segmentation error along the eight meridian scan lines. When segmentation error was noted, corresponding cross-sectional OCT image with segmentation line overlay was reviewed for confirmation. Examples of scans from the same eyes with successful segmentation and with obvious segmentation error are shown in the figure below.

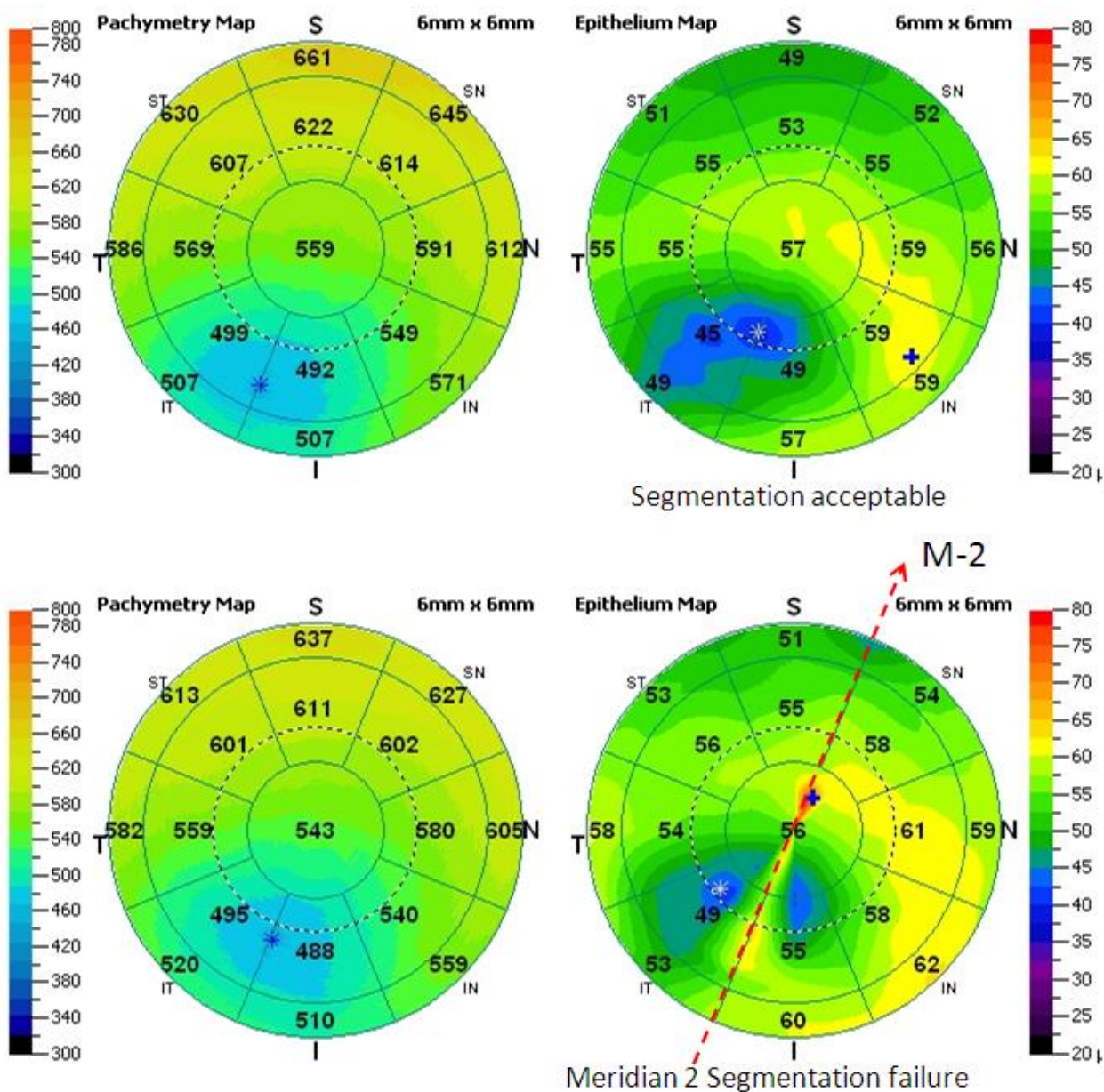


Figure 218 Segmentation error

Pachymetry maps (Left) and epithelial maps (Right) of a 44 yrs. old KCN patient. The epithelial segmentation was acceptable for the 1st scan (Top row) but failed in meridian 2 (M-2) in the 2nd scan (Bottom row). The segmentation error is easily recognized based on sharp color change along the scan lines.

Manual correction is quite feasible when the error is limited to a small number of meridians and could be helpful when imaging difficult eyes. As illustrated in the figure below, the segmentation error in meridian 6 causing a visible artifact in the epithelial map (Top row), and with manual correction of the segmentation error in meridian 6, the

artifact in the epithelial map is much reduced. Note that manual correction of the posterior boundary of the epithelial layer didn't affect the pachymetry map. If a scan has segmentation error in multiple meridians, it is probably more efficient to retake the scan instead of manually correcting each affected meridian.

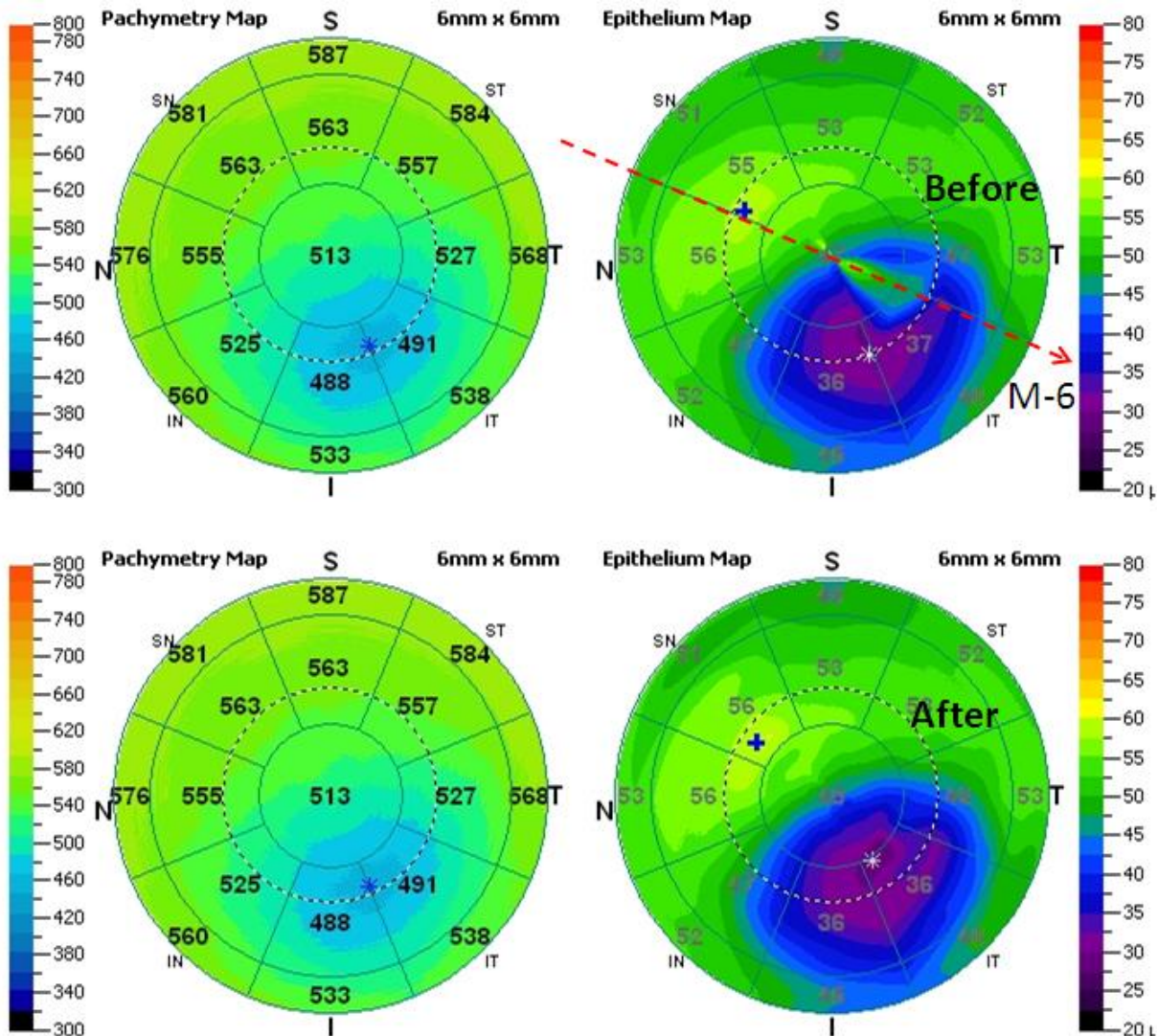


Figure 219 Reprocessed Map

Pachymetry map and epithelial map of the left eye of a 65 yrs. old male KCN patient.

 Note the artifact in the epithelial map in meridian 6 (M-6) in the top row. After manually adjusting the epithelial segmentation line for Meridian 6, the epithelial map was reprocessed with the correction. Note the defect in the epithelial map after is much reduced (bottom row). The pachymetry map remains the same before and after.

9 Main Menu

The options available in the main menu depend on the current user interface setting, which you can select in the User Interface Setting field of the User Preference dialog . The default setting is **Advanced**, which includes all available menu options. Other settings include a subset of the Advanced settings. This chapter addresses the **Advanced** menu options.

9.1 File Menu

Click **File** to open the File menu.

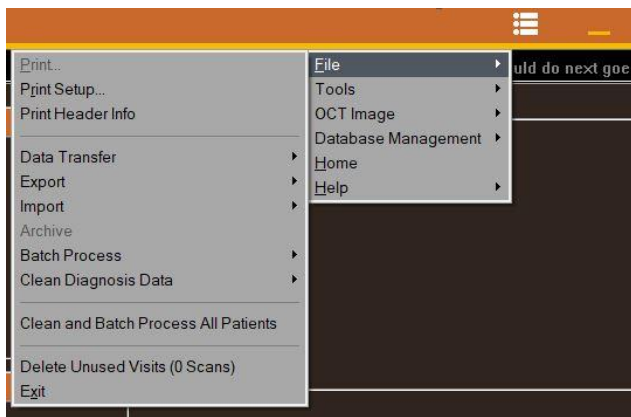


Figure 220 File Menu

9.1.1 Print Options

- **Print:** Prints the current report either to an electronic file or to hard copy, depending on the printer you choose. Make sure the chosen printer is connected and ready to print.
- **Print Preview:** Opens a preview of the printout.

- **Print Setup:** Opens the Print Setup dialog, where you can select the printer and adjust print preferences. ie Portrait or Landscape. If printing to PDF increase the DBI setting to get clearer printouts. The default is usually low resolution.

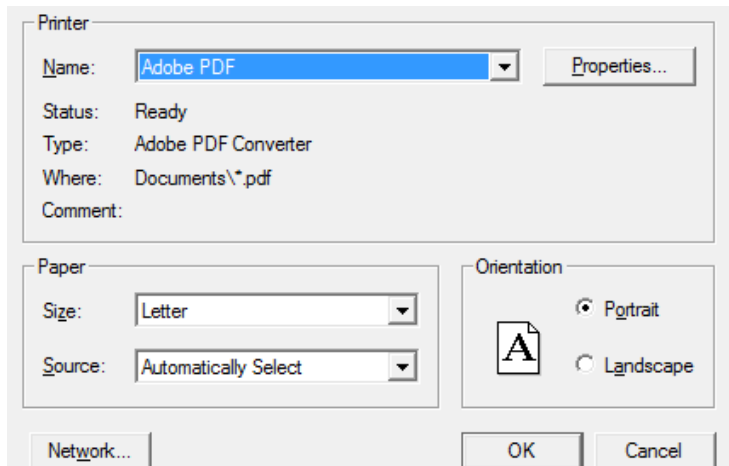


Figure 221 Print Setup Dialog

- **Print Header Info:** Opens the Print Header dialog. Use it enter practice information to be included on all printouts. Name is required, others are optional. If no name has been entered previously, the Print Header dialog also appears when you click **Print**.

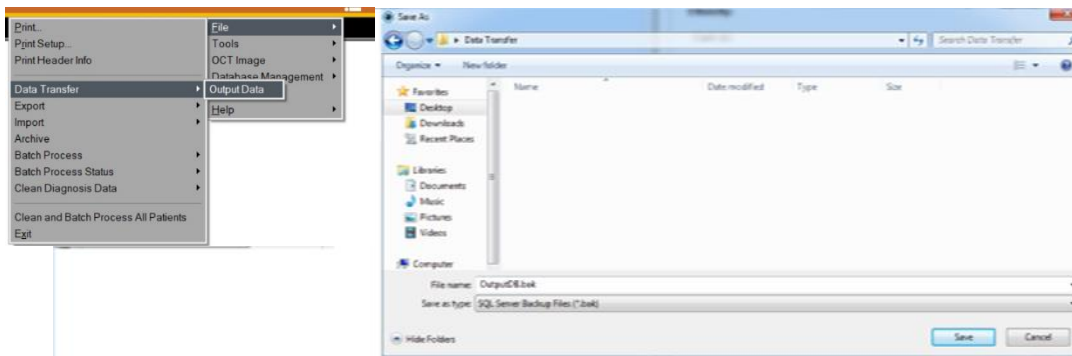


Figure 222 Print Header Dialog

9.1.2 Data Transfer

Data Transfer enables you to transfer scan data from the system database to another local file directory or networked computer. Follow these steps to transfer data:

1. Select **Data Transfer > Output Data**. A Save As dialog opens, enabling you to select the target location.



2. **OutputDB** is the default file name; give the output file a unique name in the **File name** field and click **Save**. The Output Selection dialog appears.

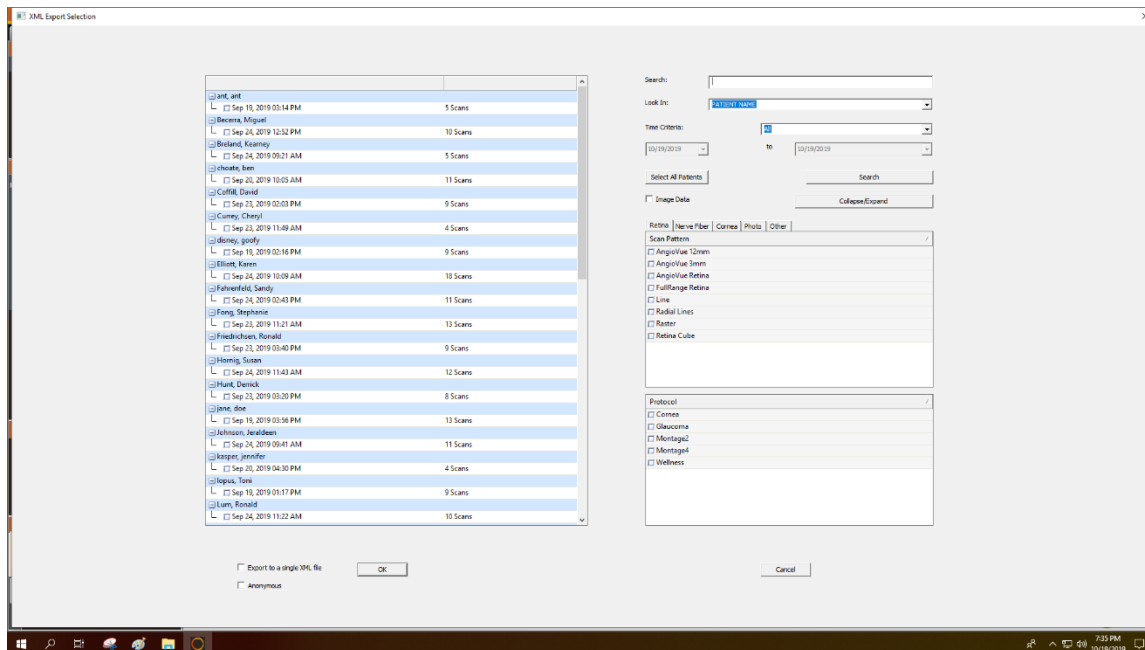
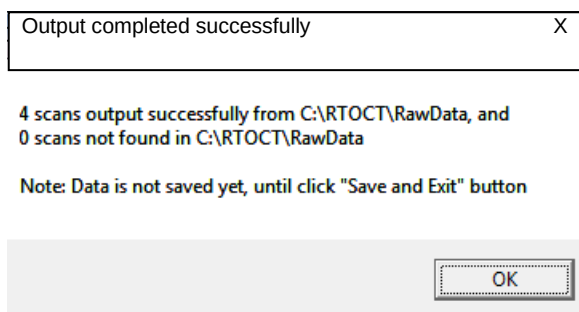


Figure 223 Output Selection Dialog

3. To find specific patients, use the search options at upper right. Select the checkboxes of scans you wish to transfer and click the **Start Output** button. A progress bar shows

output progress. When complete, a dialog informs you and prompts you to do the next step.



4. You must click the **Save and Exit** button to save transferred data. Click **OK** to close the dialog and then click **Save and Exit** back in the Output Selection dialog.

9.1.3 Export (Advanced GUI Only)

Data export is available only when using the Advanced GUI; it is only intended to support research using third party analysis applications. **Export** enables you to export the current scan or all scans from the current visit.

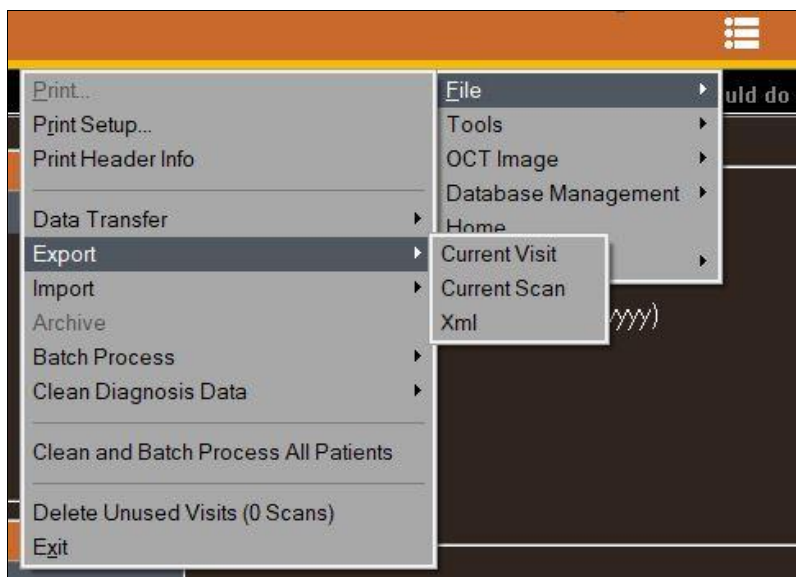


Figure 224 Export Options

 **Note:** The export format is XML. For detailed XML specifications, contact Optovue Technical Support.

1. Select **Export** and then **Current Visit**, **Current Scan**, or **XML**, as shown in Figure 224.
- If you select **XML**, the XML Export Selection dialog opens for normal or or Anonymous XML . Much like the Output Selection dialog, it enables you to search for and to choose scans for export.
 - If you choose **Current Visit** or **Current Scan**, a Browse dialog opens. Select the target directory for export and click **OK**.

9.1.4 Import

Import enables you to import saved images one at a time from a local or networked directory to the currently selected patient record. You can import any image file, including .bmp, .jpg, .gif, .png and .tif files. Optovue recommends using a common image format for imported and exported images and suggests use of .jpg files. Images can be from any system that saves image files, such as fundus photographers, corneal topographers, visual field analyzers, wavefront systems, and OCT, SLO and SLP imaging systems.

Follow these steps to import images:

1. Select **Import > Import Image**. An Open dialog appears.
2. Find and select the desired image for import and click **Open**. A dialog opens showing the selected image. The currently selected patient name, visit, date and the imported image name appear below the image.

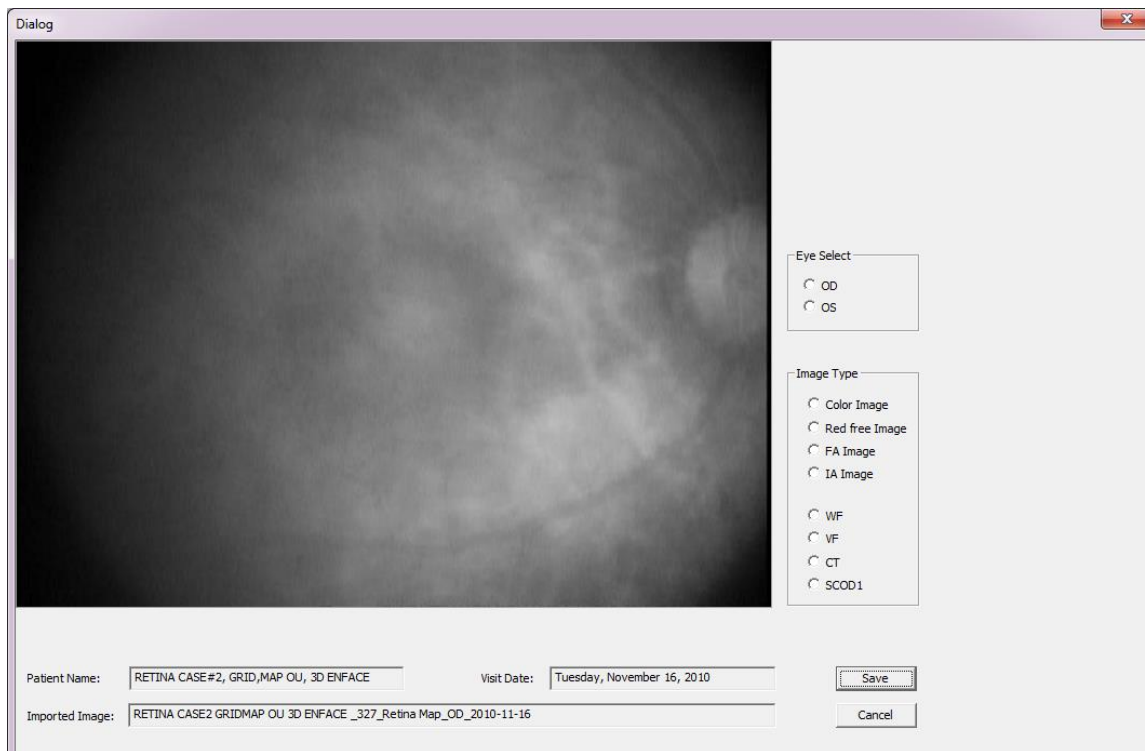
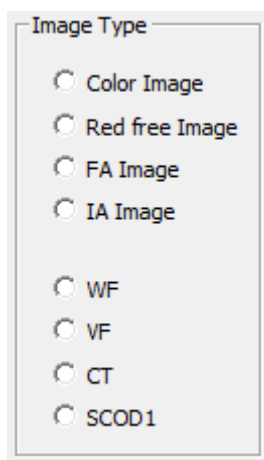


Figure 225 Dialog for Image Import

3. To the right of the image, select the eye (OD or OS) and specify the type of image using the radio buttons and click **Save**. The image is saved with the specified visit and available for viewing on the system. The Image Type radio buttons are:

A screenshot of a software dialog box titled "Image Type". It contains a vertical list of radio buttons, each followed by a label. The labels are: "Color Image", "Red free Image", "FA Image", "IA Image", "WF", "VF", "CT", and "SCOD1". The "Color Image" option is currently selected, indicated by a filled circle in the radio button.

Fundus Image Types

Color Image

Red free Image

FA Image (Fluorescein Angiogram)

IA Image (Indocyanine Green)

Exam Result Types

WF Wavefront

VF Visual Field

CT Corneal Topography

SCODI Scanning Computerized Ophthalmic Diagnostic Instrument (per Medicare nomenclature)

When an imported image is saved to a visit, and you open any scan from that visit, if its report includes an image display with tab options, a new tab will appear named with the image type you specified when importing. Select that tab to view the imported image.

9.1.5 Archive

 **Note:** Always contact Optovue Technical Support department before attempting to archive any patient data. It is a complex procedure requiring technical assistance to perform successfully.

Archiving removes data from the internal hard drive. The purpose of archiving is to free space to save new exams on the internal drive while maintaining access to archived patient records. Archived scans are still displayed in the patient list, but the archive drive must be connected to the system to review archived scans.

 **Note:** Archiving is not a method to back up the database. Archiving **removes** data from the internal hard drives to free space, while backing up **copies** data for recovery in the event of data loss. It is important to maintain a backup of both the internal hard drive and the archive drives in case either is lost or damaged.

Before attempting to archive, you must designate the archive drive in the **User Preference** dialog. Select **User Preference** from the **Tools** menu to open the User Preference dialog; then designate the archive drive in the Primary Archive Drive field.

 **Note:** You must use an **external** USB hard drive or network drive to archive data. Do not archive to the system hard drive. Archive drives must support NTFS format.

Select **Archive** from the **File** menu to start the archive process. The Archive Selection dialog opens.

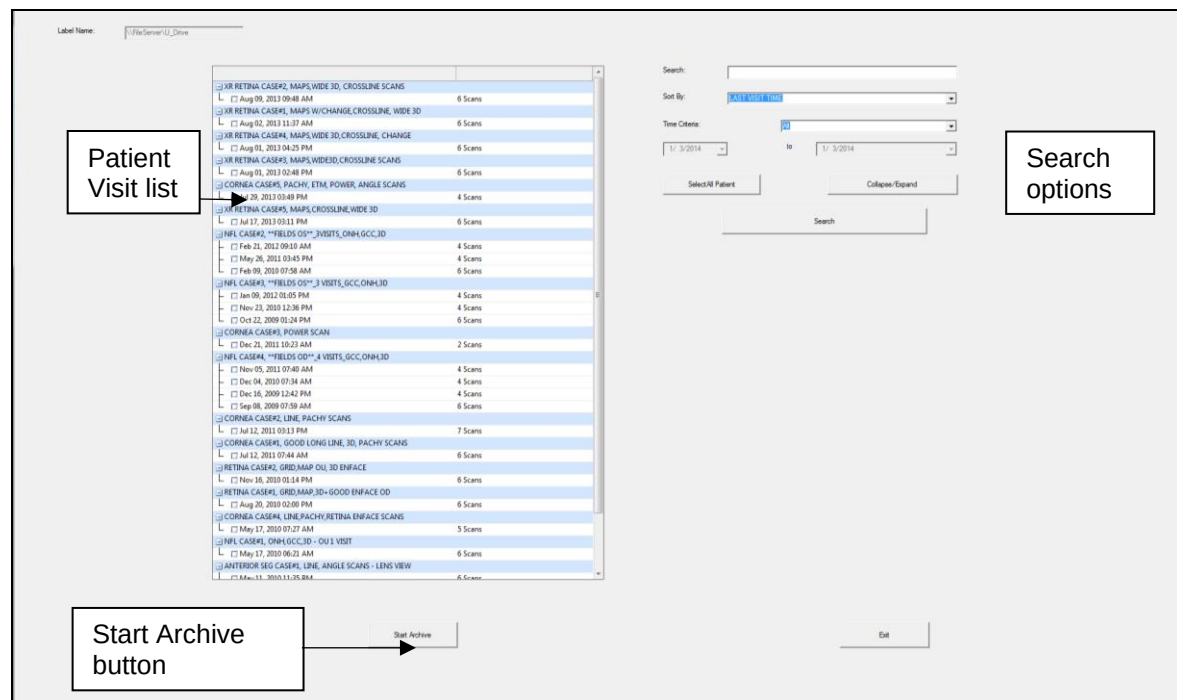


Figure 226 Archive Selection Dialog

To find specific patients, use the search options at upper right. Select the checkboxes of the visits you wish to archive and click the **Start Archive** button. A dialog reports progress until archive is complete. After archiving, the small letter 'a' appears next to the number of scans for that visit date, indicating that the visit is archived. However, when you select a scan from an archived visit for review, the system automatically retrieves the data and opens the scan report as normal, as long as the archive drive is connected.

 **Note:** The archive drive must be connected to the system to review scans from archived visits.

9.1.6 Data Backup

Data backup is an automatic background function performed during normal system operation. There are two hard drives supplied in all systems, the C drive (main) and D drive (primary backup drive). The application automatically copies scan data to both drives as each scan capture session is finished.

 **Note:** The automatic backup does not cover archive drives.

You can add an additional backup target in the form of an external USB drive or a network address (folder, drive, etc.). Simply add the appropriate drive letter (assigned automatically by Windows when connected or determined by an IT person) in the **Secondary backup drive** field in the **User Preference** dialog.

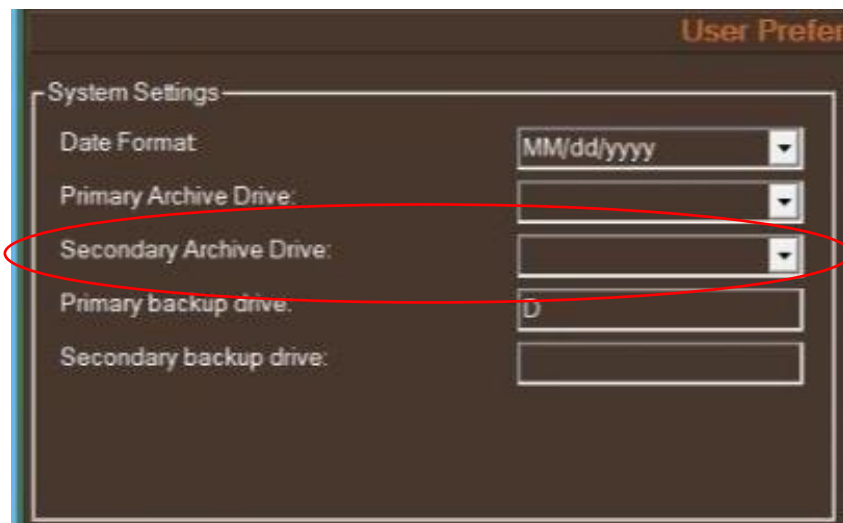


Figure 227 Secondary Backup Drive in User Preference Dialog

9.1.7 Batch Process

To batch process means to process a set of scans you choose in the way they are processed the first time you open the scans in the Review window. In this way, these scans are already processed and open more quickly in the Review window. It is advisable to clean diagnosis data on all scans and then batch process all scans after installing a software update from Optovue. To do this in one step, select **Clean and Batch Process All Patients** from the **File** menu. This can take up to several hours if the database is large.

9.1.7.1 Batch Process Options

Optovue strongly recommends using **Batch Process** only when the system is not otherwise needed. Start it at the end of the day if you choose to batch process all patients, since it can take up to several hours if the database is large.

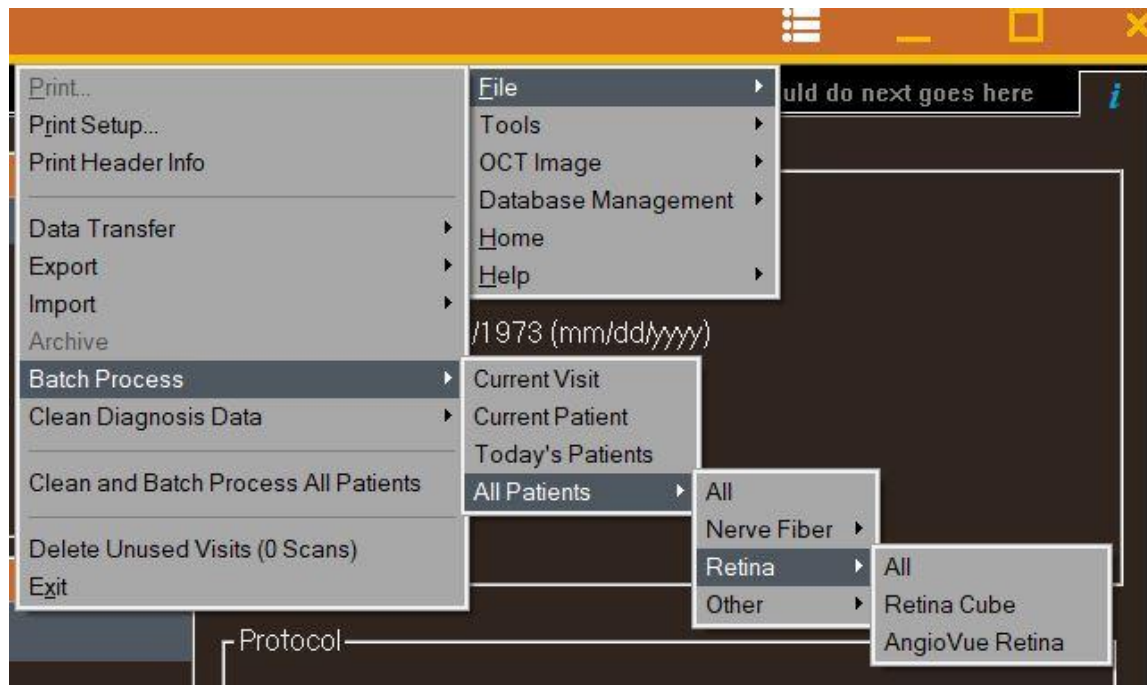


Figure 228 Batch Process Options

Select File > **Batch Process** and then the option of your choice.

- **Current Visit:** Processes all scans of the currently selected visit.
- **Current Patient:** Processes all scans of the currently selected patient.
- **Today's Patients:** Processes all scans acquired today.
- **All Patients:** Further select the option of your choice.
- **All:** Processes all scans in the database. This can take considerable time to complete.

9.1.8 Clean Diagnosis Data

The **Clean Diagnosis Data** process undoes previous scan processing. Scans are then reprocessed as usual when opened in the Review window, or when you run a batch process. If a software update requires reprocessing of certain type of scans, it is advisable to clean diagnosis data on all scans of the scan type and then batch process all scans of the scan type after installing a software update from Optovue. To do this in one step, select **Clean and Batch Process All Patients** and select the scan type from the **File** menu. This can take up to several hours if the database is large.

 **Note:** Manual segmentation edits are preserved when you clean diagnosis data. **Retina foveal position will reset** and previous manual fovea correction will be lost. Please verify fovea location and manually adjust if needed.

9.1.8.1 Clean Diagnosis Data Options

Select **Clean Diagnosis Data** from the **File** menu. This process has all the same submenu options as the batch process.

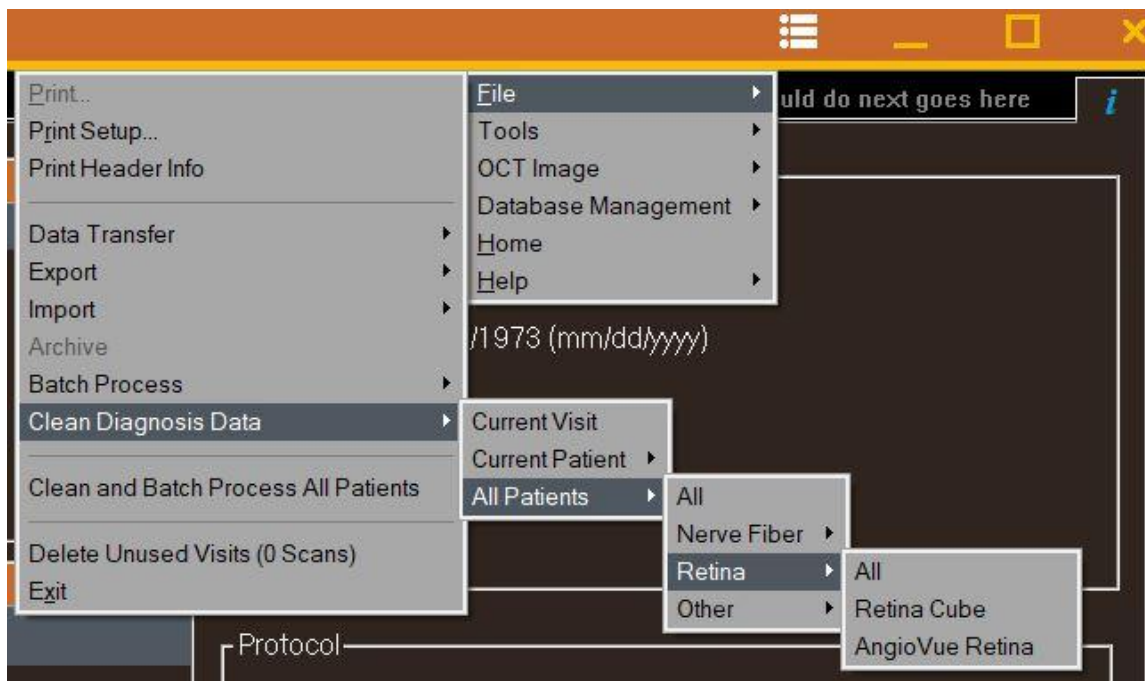


Figure 229 Clean Diagnosis Data Options

9.1.9 Clean and Batch Process All Patients

 **Note:** Manual segmentation edits are preserved when you clean diagnosis data. **Retina 3D Map foveal position will reset**, and previous manual fovea correction will be lost. Please verify fovea location and manually adjust if needed.

This is a one-click solution to clean and reprocess all scans for all patients. Depending on the size of the database, this can require up to several hours. Optovue recommends starting this process only at the end of the day.

1. Select **Clean and Batch Process All Patients** from the **File** menu. A dialog informs you it can take several hours and asks if you want to continue.

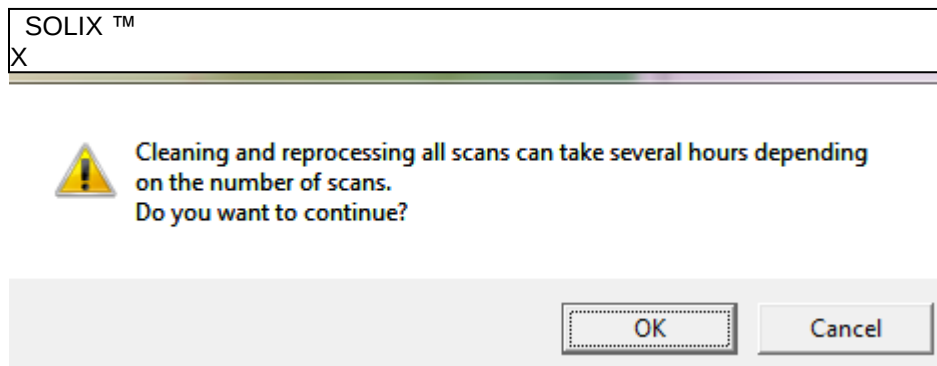


Figure 230 Confirm Cleaning and Reprocessing

2. Click **OK** to proceed. Click **Cancel** to cancel. If you proceed, a dialog shows progress until it completes.

9.1.10 Delete Unused Visits (0 Scans)

Select this option to delete visits that have no scans.

9.1.11 Exit (software)

Exits the software application, like clicking the **X** button in the upper right corner.

9.2 Tools Menu

Click **Tools** to open the Tools menu.

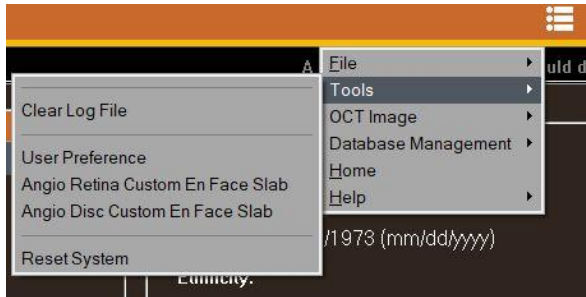


Figure 231 Tools Menu

9.2.1 Scan Pattern Management

Select **Scan Pattern Management** in the **File** menu. The Scan Pattern Management dialog opens; it lists the available scan patterns. Select the checkboxes of those scan patterns you wish to have available during scan acquisition.



Figure 232 Scan Pattern Management Dialog

Click **Done** to implement your selections.

9.2.2 Protocol Management

Select **Protocol Management** in the **File** menu. The Protocol Management dialog opens; it lists the available protocols. Select the checkboxes of those protocols you wish to have available during scan acquisition. Scan protocols group a set of scan types for sequential capture with a particular clinical purpose, or to apply a customized scan regimen. You can create and edit custom protocols by selecting **Protocol** from the **Database Management** menu.

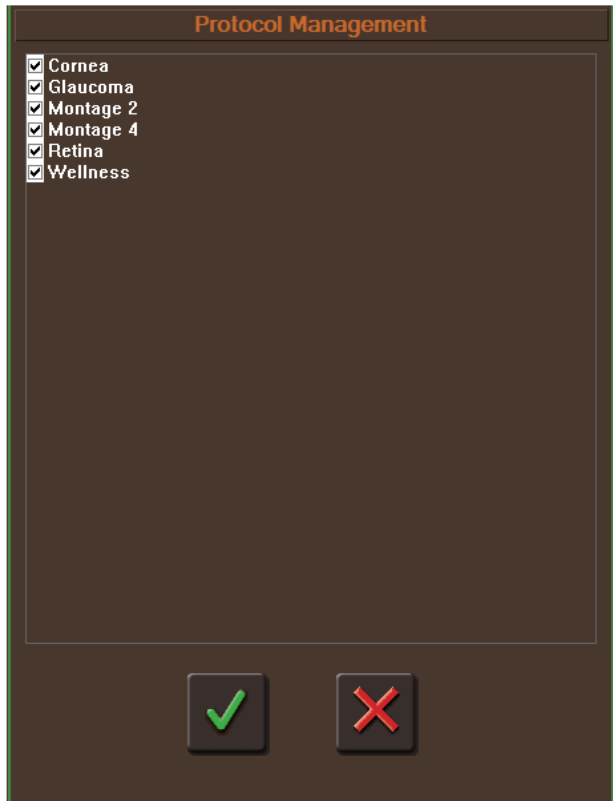


Figure 233 Protocol Management Menu

Click **Done** to implement your selections.

9.2.3 Clear Log File (Advanced GUI only)

 **Note:** Use **Clear Log File** only when so directed by an Optovue representative.

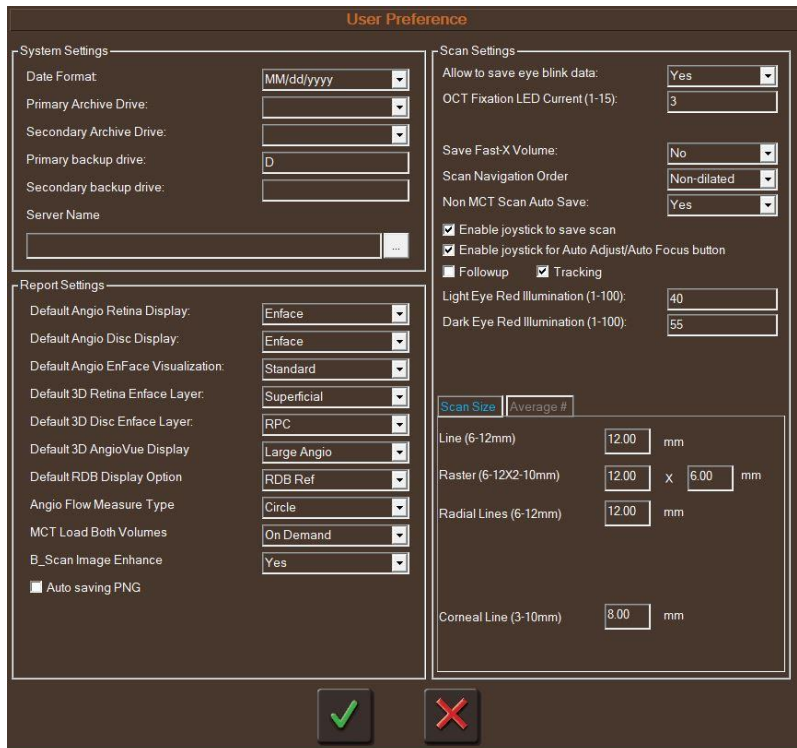
Clear Log File clears the system event log file.

9.2.4 Enter Calibration Password

 **Note:** Only Optovue-trained personnel should use this function.

9.2.5 User Preference

Select **User Preference** from the **Tools** menu to open the **User Preference** dialog. Use it to specify various system settings, default views and scan parameters, as explained below.



The **User Preference** dialog box is divided into three main sections: **System Settings**, **Report Settings**, and **Scan Settings**.

- System Settings:** Includes fields for Date Format (MM/dd/yyyy), Primary Archive Drive, Secondary Archive Drive, Primary backup drive (D), Secondary backup drive, and Server Name.
- Report Settings:** Includes dropdowns for Default Angio Retina Display (Enface), Default Angio Disc Display (Enface), Default Angio EnFace Visualization (Standard), Default 3D Retina Enface Layer (Superficial), Default 3D Disc Enface Layer (RPC), Default 3D AngioVue Display (Large Angio), Default RDB Display Option (RDB Ref), Angio Flow Measure Type (Circle), MCT Load Both Volumes (On Demand), B_Scan Image Enhance (Yes), and an ☒ for Auto saving PNG.
- Scan Settings:** Includes checkboxes for Allow to save eye blink data (Yes), OCT Fixation LED Current (1-15) (3), Save Fast-X Volume (No), Scan Navigation Order (Non-dilated), Non MCT Scan Auto Save (Yes), Enable joystick to save scan, Enable joystick for Auto Adjust/Auto Focus button, Followup, and Tracking. It also has input fields for Light Eye Red Illumination (1-100) (40) and Dark Eye Red Illumination (1-100) (55).

At the bottom, there is a **Scan Size** section with input fields for Line (6-12mm) (12.00 mm), Raster (6-12x2-10mm) (12.00 x 6.00 mm), Radial Lines (6-12mm) (12.00 mm), and Corneal Line (3-10mm) (8.00 mm). The dialog ends with green and red confirmation buttons.

Figure 234 User Preference Dialog

- **Date Format:** Specifies the date format for the system application, which should match the system computer date format.
- **Primary Archive Drive:** Select the drive letter of the primary drive used to save archived data.
- **Secondary Archive Drive:** Select the drive letter of the secondary drive used to save archived data. Using a secondary drive is optional.
- **Primary Backup Drive:** By factory default, the system uses its own second internal hard drive (the D drive) as the primary backup drive used to save an automatic backup copy of scan data. (A backup is used to recover data in the event of damage or loss of the primary internal system drive or an archive drive.) Use this field to specify a different drive as the primary drive.

- **Secondary Backup Drive:** Enables you to specify a second drive to be used for backup, usually an external USB drive or network drive
- **Allow to save eye blink data:** Select **YES** to save scan data even if the system detects patient blinks during scanning. Select **NO** to discard scan data and prompt to rescan when the system detects patient blinks.
- **OCT Fixation LED Current (0-15):** Adjusts the LED current—and thus the light intensity—of the fixation target
- **Fundus photo Fixation LED Current (0-15):** Adjusts the LED current—and thus the light intensity—of the fixation target.
- **Save Fast X & Y volumes:** saves both volume
- **Scan navigation,** either Dilated (photo comes after the last OCT for each eye or non-Dilated photo after all posterior OCT.
- **Non MCT scan Auto save:** yes or No
- **Enable Joystick to Save Scan** checkbox: Selected by default, this means that pressing the joystick button after scan capture saves the scan and the system automatically goes to the next scan (if any). Clear this checkbox to disable this feature, which means you must click the Save button on screen to save.
- **Enable Joystick for Auto Adjust/auto focus:** when selected also allows the joystick button to activate the auto adjust features.
- **Follow-up, Tracking and Show Patient list checkboxes:** Select to enable, deselect to disable the tracking, follow-up, or list features.
- **Light Eye Red illumination:** select light eye IR value appropriate for patient population
- **Dark Eye Red illumination:** select Dark eye IR value appropriate for patient population
Note: the default IR illumination will be the mean between the light and Dark setting
- **Default Angio Retina Display:** Sets the default layer to display in the Retina Enface presentation.
- **Default Angio Disc :** Sets the default layer to display in the Enface presentation.
- **Default Angio Enface Visualization:** option of standard or darker (more contrast)
- **Default 3D Retina enface layer:** Sets the default layer to display in the Enface presentation
- **Default 3D Disc enface layer:** Sets the default layer to display in the Enface presentation

- **Default 3D AngioVue® Display:** Sets the default type of image to display in the AngioVue® report.
- **Default RDB Display Option:** sets the default display type for RDB
- **AngioFlow measure type:** set default for circle or contour
- **MCT Load Both Volumes:** When sending scans over an office network, this option enables you to select whether both source scan data sets are sent when transferring scans that have had MCT (motion correction technology) applied, or only the final MCT scan data. Sending both data sets takes more time and requires sufficiently fast computers to do.
- **B-Scan image enhance:** applies additional averaging to B scans
- **Auto saving PNG checkbox:** Select to enable, deselect to disable the **Export as PNG** button  in the Tool pane of the Review window. Default is disabled (unchecked).
- **PNG directory:** When you select the **Auto saving PNG** checkbox, the **PNG directory** field opens, prompting you to choose where PNG report images will be saved. Click the  button to the right of the field to find and select the target folder, or type in the path. If you do not specify a directory, the system displays an error message when you click the **Export as PNG** button  in the Tool pane of the Review window.
- **Scan Size Tab:** Adjust the default length and width of the Line, Raster, and Grid scans.
- **Average # Tab:** Enter for each scan type the number of scans to be averaged.
- **OK and Cancel buttons:** Click the **OK** button to save user preference changes. Click **Cancel** to discard changes and close the dialog.

9.2.6 Reset System (Advanced GUI Only)

Contact Optovue technical support to perform this function.

9.3 OCT Image Menu

Click **OCT Image** to open the OCT Image menu.

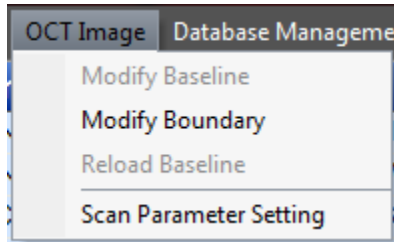


Figure 235 OCT Image Menu

9.3.1 Modify Baseline

Select to modify the disc margin baseline shown on the video (IR) image. This feature applies only to baselines drawn on the video (IR) image. The drawing saved as the baseline may or may not have been drawn on the currently displayed IR image.

9.3.2 Modify Boundary

Opens the B-scan window so you can review and edit segmentation boundaries on individual B-scans.

9.3.3 Reload Baseline

Places the existing baseline disc margin drawing on the video (IR) image in the upper left corner of the review screen for reference (use the **Modify Baseline** function to edit). This feature applies only to baselines drawn on the video (IR) image.

9.3.4 Scan Parameter Setting

Use the **Scan Parameter Setting** dialog to set the default parameters for display of images during scan acquisition.

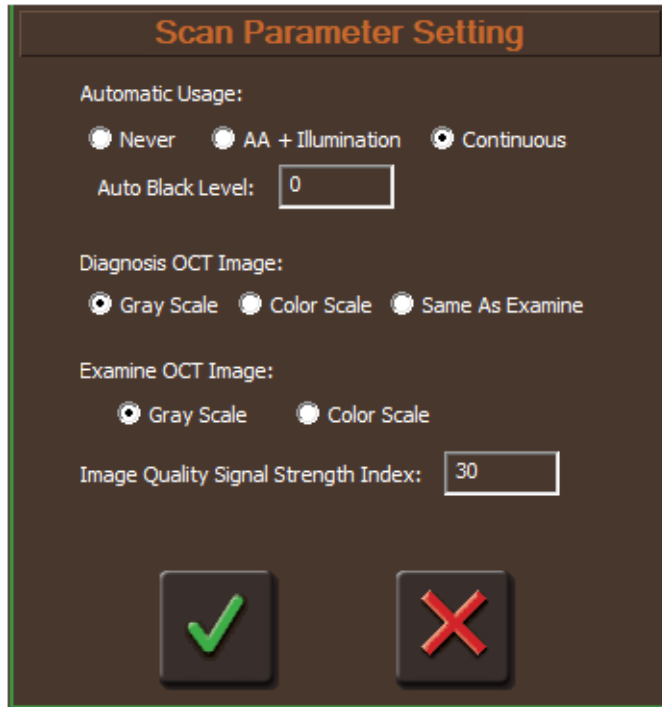


Figure 236 Scan Parameter Setting Dialog

- **Automatic Usage:** Select **Never**, **AA + Illumination** (Auto Adjust plus Illumination), or **Continuous** to specify whether and how the black level automatically adjusts based on the settings reached when you click the **Auto Adjust** button while scanning.
- **Examine OCT Image:** Select **Gray Scale** or **Color Scale** to set the default way to display OCT images during scanning.
- **Diagnosis OCT Image:** Select **Gray Scale**, **Color Scale** or **Same as Examine** to set the default way to display OCT images during review.
- **Image Quality Signal Index:** Sets the minimum SQ threshold below which the system will not show a green bar during scanning.

9.4 Database Management Menu

Click **Database Management** to open the Database Management menu.



Figure 237 Database Management Menu



Note: Once you associate scans with an item (such as physician, protocol, disease, etc.) from the database management menu, you cannot delete that item unless you delete all associated scans first.

9.4.1 Protocol

Click **Protocol** in the **Database Management** menu. The **Protocol Editor** dialog opens. Use this dialog add (create), edit or delete scan protocols. Scan protocols group a set of scan types for sequential capture with a particular clinical purpose, or to apply a customized scan regimen.

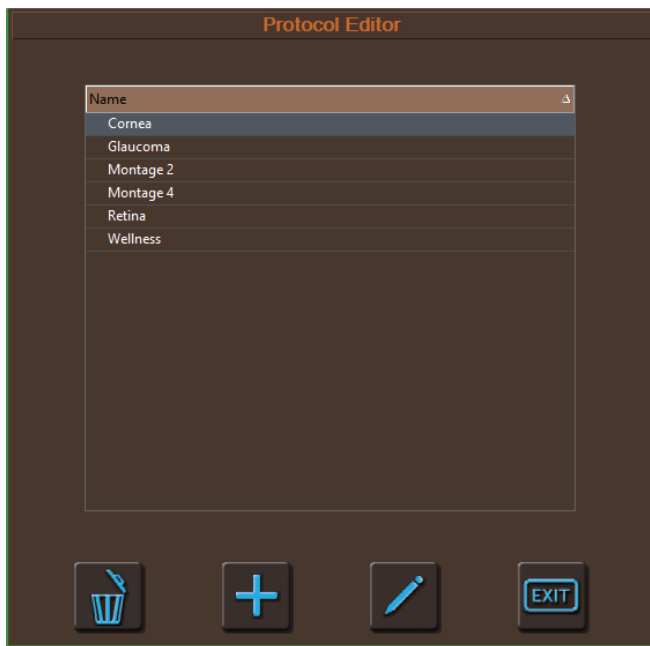


Figure 238 Protocol Editor Dialog

The system provides a preset list of protocols, but you can add, edit or delete any protocol. All protocols appear in the scan window when you click the Protocol button.

 **Note:** Adding protocols at any point adds them to the STEP 1 **Protocols** popup menu discussed in that section and to the list shown in the **Protocol Editor** dialog.

9.4.1.1 Delete Protocols

Select a protocol from the list and click the **Delete** button. A dialog asks **Do you want to delete [selected protocol]?** Click **Yes** to delete, or **No** to retain the protocol. The system does not allow you to delete a protocol that has been used to acquire scans.

9.4.1.2 Add Protocols

Add (create) new protocols by combining scan types or even other protocols using the Protocol Builder dialog. You cannot edit existing protocols, only delete the entire protocol (and make a new one if you wish).

1. In the Protocol Editor dialog, click the **Add** button. The **Protocol Builder** dialog opens.

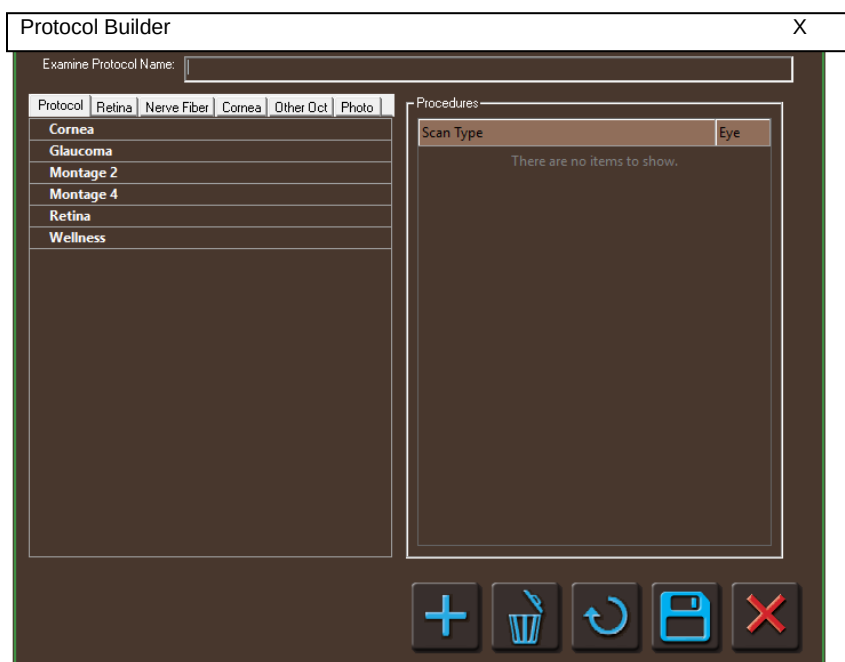


Figure 239 Protocol Builder Dialog

2. Enter a name in the **Examine Protocol Name** field.
3. From the tabbed lists for **Protocol**, **Retina**, **Nerve Fiber** and **CAM-L** on the left, select a scan type or protocol and click **Add** to add it to the list on the right.
 - To delete a scan type or protocol from the new protocol before saving, select it and click **Delete**.
 - Click **Clear** to delete all the scan types and protocols added so far and start over. Click **Save** to save the new protocol.
 - Click **Cancel** to exit the Protocol Builder; changes you have already saved will be retained.



Note that when you add a scan type, it is added for both eyes. If you wish to make a protocol for OD or OS only, delete each OD or OS version separately.

9.4.1.3 Edit Protocol Name

You cannot edit existing protocols, only delete the entire protocol (and make a new one if you wish). The **Edit** button in the Protocol Editor enables you to edit only the name of the protocol.

In the Protocol Editor dialog, select a protocol and click the **Edit** button. Edit the name in the **Edit Protocol Name** dialog that opens, then click **Save** to save the name.

9.4.2 Physician

Select **Physician** from the **Database Management** menu. The Physician Editor dialog opens. Use this dialog to create or edit a list of physicians. You can select a physician from the list you create to associate with his or her patients.

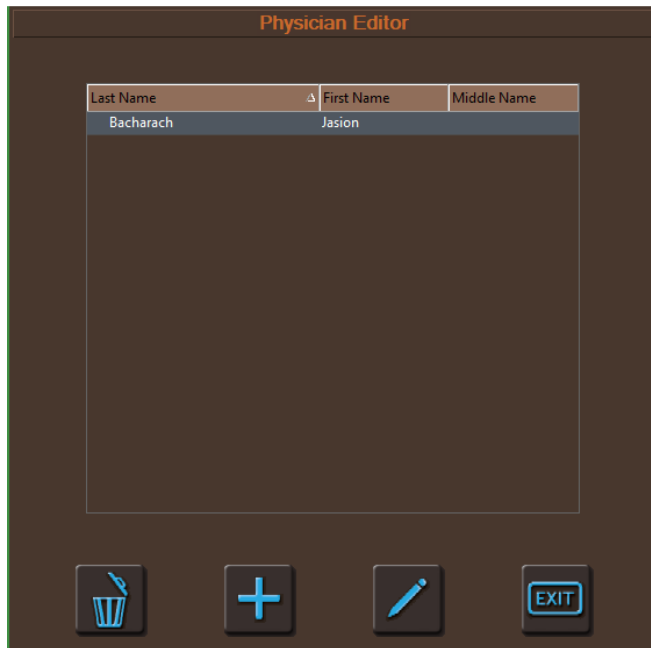


Figure 240 Physician Editor Dialog

- Select a physician from the list and click **Delete** to delete a physician. The system does not allow you to delete a name that is associated with any visit or scan.
- Click **Add** to open a dialog where you can enter the name of a physician, then click **OK** to save.
- Select a physician from the list and click **Edit** to open the same dialog where you can edit the name, then click **OK** to save.

9.4.3 Operator

Select **Operator** from the **Database Management** menu. The Operator Editor dialog opens. Use this dialog to create or edit a list of system operators. You can select an operator from the list you create to associate with patients.

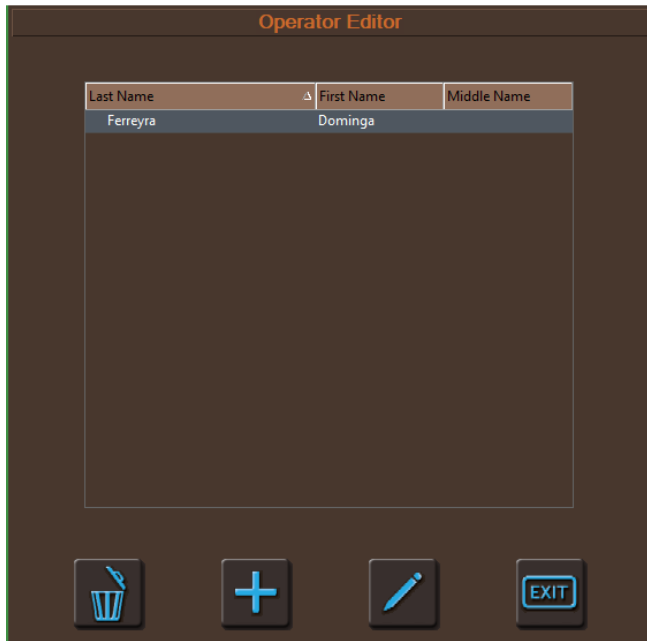


Figure 241 Operator Editor Dialog

- Select an operator from the list and click **Delete** to delete an operator. The system does not allow you to delete a name that is associated with scan data.
- Click **Add** to open a dialog where you can enter the name of a physician, then click **OK** to save.
- Select an operator from the list and click **Edit** to open the same dialog where you can edit the name, then click **OK** to save.

9.4.4 Disease

Select **Disease** from the **Database Management** menu. The Disease Editor dialog opens. Use this dialog to create or edit a list of diseases. You can select a disease from the list you create to associate with his or her patients.

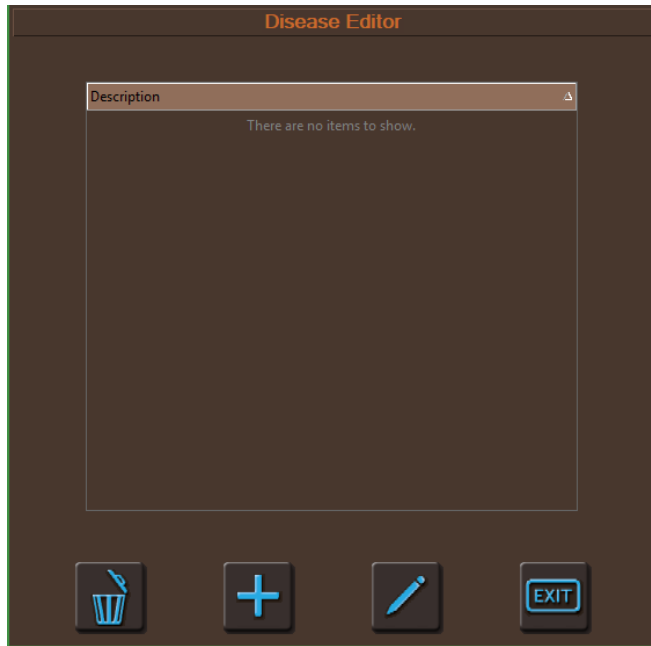


Figure 242 Disease Editor Dialog

- Select a disease from the list and click **Delete** to delete a disease. The system does not allow you to delete a disease that is associated with scan data.
- Click **Add** to open a dialog where you can enter the name of a disease, then click **OK** to save.
- Select a disease from the list and click **Edit** to open the same dialog where you can edit the name, then click **OK** to save.

9.4.5 Move a visit to another patient

If a visit was erroneously created under the incorrect patient, this feature enables you to correct the error. Select the patient and visit you wish to move, and then select **Move a visit to another patient** from the **Database Management** menu. Home Menu

Select **Home** from the main menu to open the SOLIX™ Essential home screen.

9.5 Help Menu

Select **Help** to open the Help menu.



Figure 243 Help Menu

- **About SOLIX™ Essential** : Opens the About SOLIX™ Essential dialog, which shows the current software version, the Optovue support email address service@visionix.com, the Optovue website redirects to www.visionix.com, and has a link to **View All Licenses**.

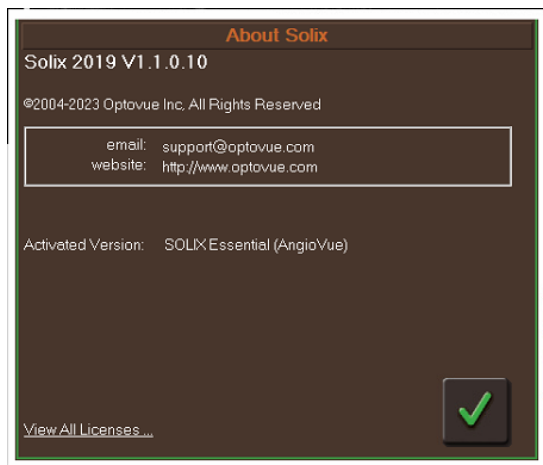


Figure 244 About SOLIX™ Essential Dialog

- **Upgrade**: Select to perform a software upgrade.

9.6 About Solix ReVue

Solix ReVue License available for exam lanes and offices has Full, Medium and Lite levels which are determined by the specifications of the computer the software is loaded on. If the computer meets the system specifications of processor, GPU and memory the Full ReVue is loaded. If the software determines there is no GPU available but sufficient memory (Swap included) then Medium is loaded and if the computer only meets the minimum processor and memory then Light version is loaded.

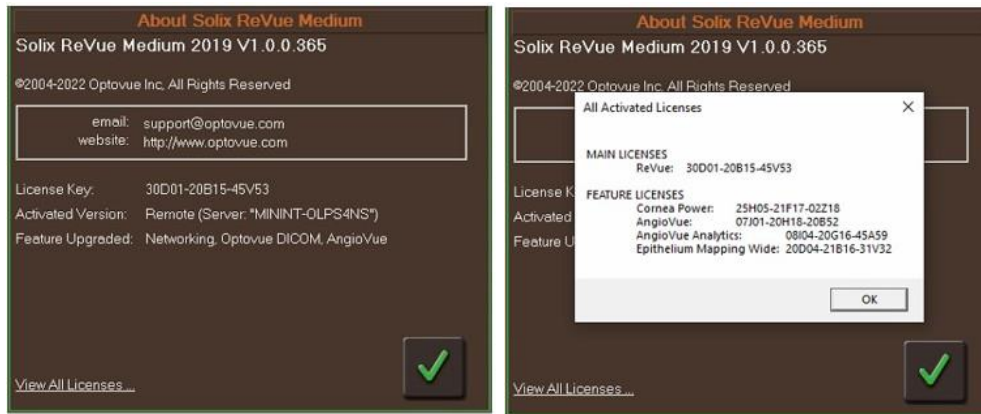


Figure 245 ReVue Medium License

Medium and Lite versions will allow the user to review the data but there are limitations, without a GPU the system cannot reprocess the entire cube so reprocessing PAR and Editing the boundaries of cubes is not possible so it is grayed out. In addition, if there is insufficient memory (Lite) the various 3D Main report is not available.

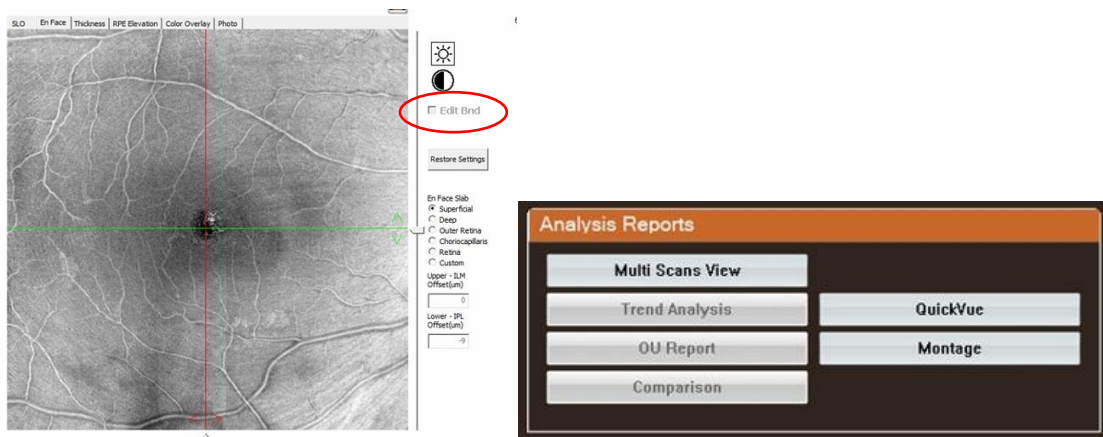
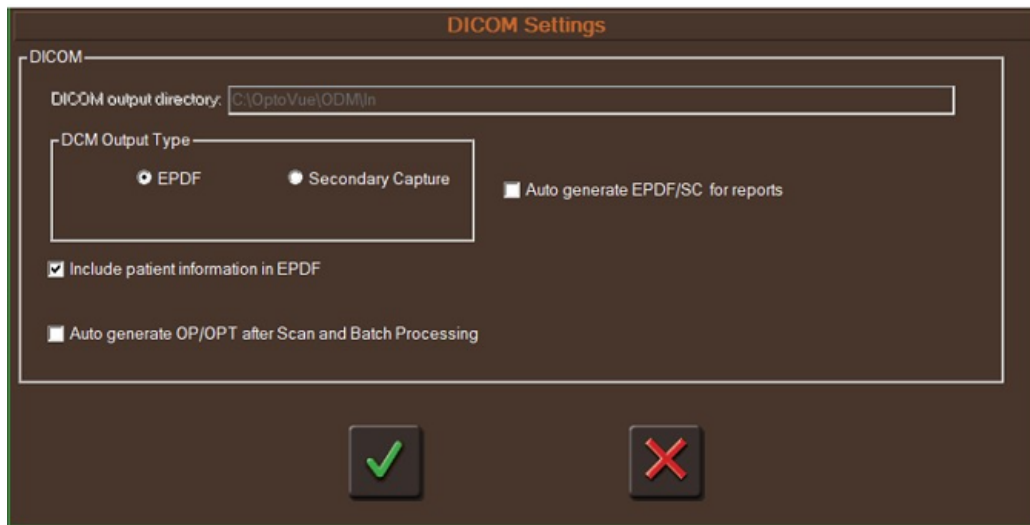


Figure 246 Grayed out “Edit Bnd” and hidden Main report button



Note: System Software version and ReVue versions must be the same.

9.7 Dicom Settings



The image shows a 'DICOM Settings' dialog box with a dark blue background. At the top, the title 'DICOM Settings' is displayed in orange. Below the title, the 'DICOM' section is enclosed in a white border. Inside this section, there is a text field for 'DICOM output directory:' containing the path 'C:\OptoVue\ODM\In'. Below this, the 'DCM Output Type' section is also enclosed in a white border and contains two radio buttons: 'EPDF' (which is selected) and 'Secondary Capture'. To the right of these radio buttons is a checkbox labeled 'Auto generate EPDF/SC for reports'. Below the 'DCM Output Type' section, there are two more checkboxes: 'Include patient information in EPDF' (which is checked) and 'Auto generate OP/OPT after Scan and Batch Processing' (which is unchecked). At the bottom of the dialog box, there are two buttons: a green checkmark button on the left and a red 'X' button on the right.

Figure 247 Dicom Settings

Choice of output, auto features and patient information

_____End of section_____

10 System Maintenance

10.1 Routine Cleaning

10.1.1 Prevent Dust Accumulation

To prevent accumulation of dust, place the dust cover over the system when not in use.

10.1.2 Clean the Ocular (Front Objective) Lens



Caution: Make sure the front lens is clean before scanning. An unclean lens can cause a weak OCT image or a blurry video image and may skew scanning data. The ocular lens can be unclean due to smudges from contact with eyelashes, the nose or fingers, or excessive dust or dirt from the environment.

Optovue recommends cleaning the ocular lens regularly using lens cleaning solution and lens cleaning paper. Wet the lens paper with cleaning solution and wipe the ocular lens with one pass in one direction. Discard the used lens paper. Use a new sheet for each wipe until the lens is clean.

A lens cleaning kit is provided with each system. New kits can be purchased from Optovue.

10.1.3 Clean the Head and Chin Rest

Optovue recommends cleaning the head and chin rest between patients using either a disinfecting agent, such as an anti-germicide or isopropyl alcohol, on a clean, lint-free cloth or an isopropyl alcohol wipe

10.2 System Computer Maintenance

To maintain computer performance, Optovue recommends regular use of the Disk Cleanup and Disk Defragmenter tools. To access these tools, from the computer desktop select  **Start > All Programs > Accessories > System Tools > Disk Cleanup** or **Disk Defragmenter**. We suggest disk defragmentation monthly, or more frequently if the system is used heavily.

Optovue suggests major maintenance, including calibration verification, be done once a year. We further suggest to close the system application when the system has not been in use for a long period of time, and to shut down the system at the end of each business day. _____ End of section _____

11 Scan Pattern Specifications

Table 1 Scan Pattern Specifications

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
Line	Single line scan with speckle elimination process option	1600 X 1	Transverse: 6-12 mm (0.1 mm increment) Angle: 90 to 90° (1° increment)	12 mm, -5° (monitor screen left to right)
Radial Lines	12 radial lines	1024 X 12	6 – 12 mm length	12 mm, fovea
Raster	21 parallel line scans; averaged	1024 X 21	6-12 mm length 2-10 mm zone	9 mm length x 6 mm, fovea
Retina Cube	200 B-scans equally. Center fixation	200 x 512	Fixed	6.4 x 6.4 mm, fovea
Disc Cube	350 B-Scans equally spaced covering 6 mm y-axis, each with 350 A-scans covering 6 mm x-axis.	320 x 320	Fixed	6 mm X 6 mm, optic nerve
AngioVue® Retina	512 B-scans equally spaced on X-axis and on Y-axis. Each B-scan has 512 A-scans. Fovea fixation 640 pixels in Z-axis	512 X 512	Fixed	6.4 X 6.4 mm, fovea

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
AngioVue® Disc	512 B-scans equally spaced on X-axis and on Y-axis. Each B-scan has 6512 A-scans. Fovea fixation 640 pixels in Z-axis	512 X 512	fixed	6 x 6 mm, optic nerve
AngioVue® 3mm	400 B-scans equally spaced on X-axis and on Y-axis. Each B-scan has 400 A-scans. Fovea fixation	400 x 400	Fixed size, moveable fixation	Fovea 3x3mm
AngioVue® 9mm	600 B-scans equally spaced on X-axis and on Y-axis. Each B-scan has 600 A-scans. Fovea fixation	600x600	Fixed	9mmx9mm, fovea
AngioVue® Disc 9 mm	600 B-scans equally spaced on X-axis and on Y-axis. Each B-scan has 600 A-scans. Disc fixation	600x600	Fixed	9mmx9mm, optic nerve
AngioVue® 12mm	600 B-scans equally spaced on X-axis and on Y-axis. Each B-scan has 600 A-scans. Disc fixation	600x600	fixed	12x12mm, fovea
Wellness	600 x 5 vertical raster + 600 x 130 cube + 1014 x2 x 8 (repeats per B-scan) cross-line scans	600x130 +1014x2	Fixed	12 x 9, fovea
Corneal map	16 radial lines with 10 mm scan length (1200 A-scans/line), 22.5 ° interval	1200x16 5 (repeats)	Fixed	10 mm radial scan

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
Corneal cube	256 evenly spaced B scans	513x256	Length: 2-8mm; Width:2-8mm ; Angle: -90 to 90 degree	4mmx4mm
Anterior Radial	16 radial lines with 9 mm scan length 1200 A-scans/line), 22.5 ° interval	1200x16 5 (repeats)	Fixed	10 mm radial scan
Corneal Line	1700 A-scans/line with adjustable scan length	1700 X 1	Transverse: 3-10 mm (0.5 mm increment) Angle: 90 to 90° (1° increment)	8 mm, 0 °
Corneal Angle	line	1020	2-6mm	3mm

Protocol	scans	Fixation	Result
AngioVue® 3mm 4 Volume	4 AngioVue® 3mm Scans	Fixation adjustable	4 volumes merged into 1 3mmx3mm OCTA by MCT
Cornea	Cornea Map	None	
Glaucoma	AngioVue® Retina AngioDisc	Fovea, Disc	
Montage 2	AngioVue® 9mm scans (T) AngioVue® 9mm (N)	Fixtion at Fovea (T) and Disc (N)	Montage 16x9mm
Montage 4	AngioVue® 9mm scans (SN) AngioVue® 9mm scans (IN) AngioVue® 9mm scans (IT) AngioVue® 9mm scans (ST)	Fixation at four corners (SN, IN, IT, & ST)	Montage 16x16mm
Retina	AngioRetina Raster	Fovea	
Wellness	Wellness	Fovea	

End of section

12 Technical Specifications

<i>OCT Imaging (Retina)</i>		
	Scan speed	120,000 A lines per second
	Axial resolution	5µm (in tissue)
	Lateral resolution	15µm (in tissue)
	Working distance	35mm
	Scan depth	Up to 3 mm (Regular mode)
	Scan length	3mm - 12mm
	Dioptric Range	-15D to +15D
	Pupil diameter	2.0 mm or more
	AngioVue	SSADA OCTA with MCT Technology and 3D PAR
<i>OCT Imaging (Anterior Segment)</i>		
	Lateral resolution	18 µm (Regular CAM) (in tissue)
	Working distance	20 mm
	Scan depth	Up to 3 mm (Regular CAM)
	Scan length	2mm - 10mm
<i>Patient Interface</i>		
	Fixation targets	External and (13-point) internal

	Chin-Rest adjustable range	~77mm
	Joystick controlled X-Y-Z adjustment	X-90mm, Y-80 mm, Z-30 mm
	Display unit	24 inch Flat Panel LCD Monitor
Computer/Networking		
	Operating system	Windows 10
	CPU	Intel Core i7-8700 Processor or above
	RAM	32GB DDR4 or more
	Hard drive	Solid State Disk 256GB for Operating system Main Disc 4 TB Back-up Disc 4 TB
	Power supply	600W PSU Medical Grade
	Interfaces	USB ports and network connectors, HDMI/DP port
	Archive	USB or Network Drive
	DICOM	DICOM MWL, DICOM storage
	Review SW	NetVue™ image management software
Light sources		
	OCT SLD	840 nm with FWHM 50nm
	NIR LED (Retina)	750nm

	NIR LED (Cornea)	735nm
	IR LED for Iris Viewer	940nm
	Fixation LED	460nm
Power Table		
	Power Input	AC 100V~240V
	Frequency	50/60 Hz
	Power Rating	100 W
	Motorized adjustment range	200 mm
Dimensions		
	Main unit	1000mm X 800mm x 1500mm (W 39.4 x D 31.5 x H 59 inches)
	Weight (main unit)	95 kg (210 lbs)
	Rated voltage	AC 100V~240V
	Frequency	50/60 Hz
	Power consumption	800 W (w/o power table)
OCT Scan Sizes	Scan Name	Size (LxWxD)mm unless specified otherwise
<i>Retina</i>	Line	6-12(L) x 2.93(D)
	Retina Cube	6.4x6.4x1.95
	Raster	6-12(L)x2-10(W)x2.93(D)

	Radial Lines	6-12 (Ø)x2.93(D)
<i>Nerve Fiber</i>	Disc Cube	6x6x2.34
<i>Cornea</i>	Corneal Map	10(Ø)x2.34(D)
	Anterior Radial	10(Ø)x2.34(D)
	Corneal Line	3-10(L)x2.34(D)
	Corneal Angle	2-6(L)x2.34(D)
	Corneal Cube	2-8(L)x2-8(W)x1.95(D)
<i>Other</i>	Wellness	12x9x2.93
<i>AngioVue</i>	AngioVue 3mm	3x3x1.95
	AngioVue Retina	6.4x6.4x1.95
	AngioVue 9mm	9x9x2.34
	AngioVue 12mm	12x12x2.93
	AngioVue Disc	6x6x2.34
	AngioVue 3mm (4-volume MCT Merged)	3x3x1.95
<i>OCT Structure</i>	<i>Application</i>	<i>Image & Analysis</i>
	Retina	Retina Thickness Map; GCC Thickness Map; Outer Retina Thickness Map
	Glaucoma	RNFL; GCC; FLV, GLV; ONH parameters
	Cornea	Pachymetry, ETM, Stroma Maps, and Angles

	Reports	RDB, OU report, Trend Analysis, ONH/GCC OU trend report, Comparison, Multi- Scan view, Enface, Color Fundus Overlay, QuickVue, Main 3D report, Wellness report, AC Multi-Angles Report, and Cornea Map report (OU and change)
AngioVue & AngioAnalytics	Application	Image & Analysis
	Retina	SCP, DVC, Outer, & Choroidal Capillary Plexus, Custom layer Vessel Density: SCP & DVC, FAZ, Flow and Non-Flow Zone area
	Disc	RPC Vessel Density
	Montage protocols	Montage 2 (16mmx9mm); Montage 4 (16mmx16mm); Montage 2(10mmx6mm)
	Multi-volume merged	4-volume MCT merged AngioVue 3x3mm
	Reports	Same as OCT structural reports with additional Vessel Density measurements

12.1 Compliance

- General Medical IEC 60601-1
- EMC of Medical System IEC 60601-1-2 4th Ed:2014
- ITE (Computer) EN 60950
- Ophthalmic Instruments ISO 15004-1:2006
- Light hazard protection ISO 15004-2:2007 and ANSI Z80.36:2016
- Fundus Camera ISO 10940:2009
- Ophthalmic Instruments – OCT ISO 16971:2015

12.2 Circuit Breaker and Fuse

- Fuse (Power supply in Scanner)
- Rating: 4 A/250 V
- Package: 5 mm x 20 mm



- Type: Fast Acting, Short Time Lag
- **WARNING:** Do not use fuses that are not approved by Optovue. Optovue provides approved fuses.

12.3 Operating Environment

Operating Conditions:

- Temperature: 10 °C to 35 °C
- Relative Humidity: 30% to 90%
- Atmospheric pressure: 800 – 1060 hPa

Storage Conditions:

- Temperature: –10 °C to 55 °C
- Relative Humidity: 10% to 95%
- Atmospheric pressure: 700 to 1060 hPa

- Altitude: < 3000 m

Transport Conditions:

- Temperature: -40 °C to 70 °C
- Relative Humidity: 10% to 95%
- Atmospheric pressure: 500 hPa to 1060 hPa
- Vibration, Sinusoidal: 10 Hz to 500 Hz, 0.5 g
- Shock: 30 g, duration 6 ms
- Bump: 10 g, duration 6 ms

12.4 Additional Technical Specifications

- Electrical Supply: Class 1
- Installation Category: II
- Pollution degree: 2

12.5 Cybersecurity Information

12.5.1 Objective

The purpose of this section is to summarize the cybersecurity controls for the SOLIX™ Essential system with embedded Windows 10 operating system.

12.5.2 System Overview

The SOLIX™ Essential device has the following interfaces that are critical for cybersecurity:

- ETHERNET port for DICOM/PACS interface and Optovue Remote Service
- USB ports for connecting to various USB devices

12.5.3 General Principles

Cybersecurity risk management is a shared responsibility among stakeholders including the medical device manufacturer, the user, and the health care facility. Failure to

maintain cybersecurity can result in compromised device functionality, loss of data availability or integrity, or expose other connected devices or networks to security threats.

12.6 Cybersecurity Functions

12.6.1 Limit Access to Trusted Users Only

Authentication of Users

- SOLIX™ Essential device uses Microsoft Windows 10 as the main operating system. The operating system itself allows the end user to establish and configure “User Accounts” (example: standard users, power users, administrators) and “User Passwords” so that authentication is performed by password.

Auto-Logoff

- The operating system has the ability to prevent access and misuse by unauthorized users if the device is left idle for a period of time. The length of inactivity time before auto-logoff/screen lock is user/administrator configurable.
- The auto-logoff/screen lock can be manually invoked by the user.

Layered Authorization Based on User Role

- Users can be assigned different privilege levels within an application based on ‘roles.’

Appropriate Authentication

- “IT Admin” and “Optovue Service” require password authentication.

User Authentication for Software or Firmware Updates

- Software and firmware updates require Privileged account access.

12.6.2 Ensure Trusted Content

Restrict Software or Firmware Updates to Authenticated Code

- Software and firmware updates are performed by Optovue Field Service or Customer Service personnel from a protected source.
- All updates require a Privileged account.

12.6.3 Detect, Respond, Recover

Features that allow for security compromises to be detected, recognized, logged, timed, and acted upon during normal use.

- System, security and anti-virus logs are implemented.
- Log files can be accessed by or exported to Optovue Service.

Provide information to the end user concerning appropriate actions to take upon detection of a cybersecurity event.

- Disconnect the SOLIX™ Essential device from any network
- Contact the IT Administrator at the user facility for on-site evaluation
- Run a scan using the anti-virus software
- Quarantine and delete any identified threats using the anti-virus software
- Restore the database
- Reconnect to the network
- Contact Optovue Technical Services if additional assistance is required

Device features that protect critical functionality, even when the device's cybersecurity has been compromised.

- The SOLIX™ Essential safety circuit for light hazard exposure is designed in the device hardware and will continue to operate during a power surge even when the device's cybersecurity has been compromised.

Methods for retention and recovery of device configuration by an authenticated privileged user.

- The SOLIX™ Essential device comes with a built-in primary backup hard-drive and all data are backed up to this hard-drive.
- The device also provides an option for a secondary data backup.
- The device provides for archiving of old data to external storage.
- The device configuration data is backed up automatically at each launch of the application.

- Optovue Clinical Applications, Field Service, or Technical Services personnel can restore to a previous backup.

12.6.4 Other implemented mechanisms

Institutional IT Infrastructure

- The SOLIX™ Essential device uses the Windows 10 operating system and supports integration into the IT infrastructure and domain at the institution or facility where the device is installed. Some facilities/institutions will have their own cybersecurity infrastructure, such as remote control of User Accounts, firewalls, encryption, and so forth. The SOLIX™ Essential device will support these site-specific IT systems and this is verified during the installation process by Optovue personnel.

Stand Alone Mode

- The SOLIX™ Essential system can be run completely without internet connection. There is no specific requirement to be connected to the internet for the device to operate properly.

Cybersecurity and Data Back-up Configurations

- The device is manufactured with anti-virus protection provided by “Microsoft Security Essentials”
- The device is manufactured the device with “Windows Firewall” enabled
- Data encryption can be added by a third-party tool
- The SOLIX™ Essential device comes with a built-in primary backup hard-drive and all data are backed up to this hard-drive.
- The device also provides an option for a secondary data backup.
 - The device provides for archiving of old data to external storage.

12.6.5 Password Structure

Visionix Solix OCT Systems are password protected, on two levels; “Administrator” and “User” at startup.

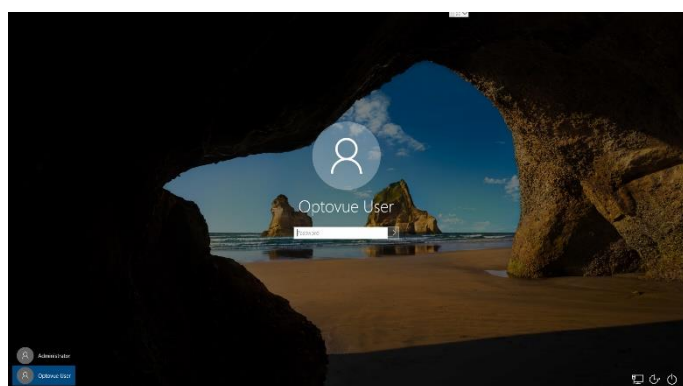
The current Administrator account will be named “Administrator” with the password “Visionix#123” and a new sample user account will be created and named “Optovue User” with the password “Optovue#123”

At install the **Administer** and **User** passwords should be changed according to the requirements below and documented by the purchaser.

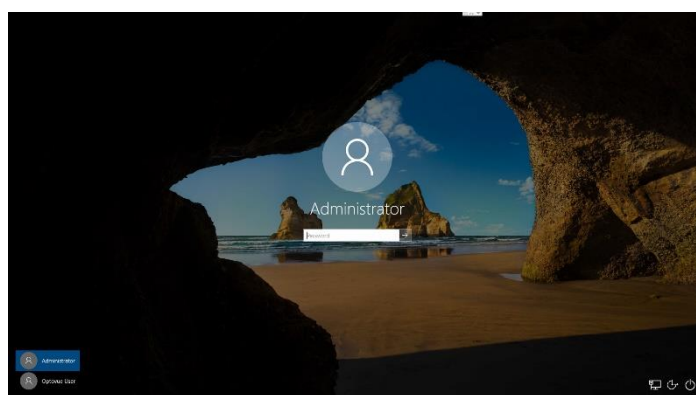
Password complexity requirements:

- Minimum eight (8) characters long
- Contain a combination of at least three (3) of the following characters: uppercase letters, lowercase letters, numbers, symbols (punctuation marks)
- Must Not contain the user’s username or screen name
- User cannot use the same password as the previous 2 passwords.

User



Administrator



End of section

13 Appendix A: Printer Installation



WARNING: When using a printer connected directly to the system via USB, Optovue recommends that you plug the printer into the designated power outlet in the system PC compartment. This outlet is isolated from the wall plug (building power) through the SOLIX™ Essential isolation transformer. If you plug the printer into any other power outlet, place the printer at least 1.5 meters away from the patient to avoid electric shock.

14 Appendix B: Motion Correction Technology (MCT)

It is commonly understood that it takes at least a couple of seconds to acquire a 3D data volume at reasonable density with typical SD-OCT devices. As a result, the 3D data volume is susceptible to artifacts caused by blinks and eye motion during scan acquisition. Such artifacts appear as distortion in the retinal blood vessel pattern and/or dark bands, as viewed in the en face image; they appear as a rippling retinal surface and/or dark sections, as viewed in the cross-sectional image.

When the two 3D volumes are acquired in orthogonal directions as illustrated in Figure 248 below, the system applies a proprietary software-based motion correction technology (MCT) to assess and correct motion in each volume. The system performs motion correction based on minimization of the overall difference between the two corrected volumes. The system generates the final 3D volume of an MCT scan based on the weighted average of the horizontal and vertical motion corrected volumes, as shown in Figure 248 below.

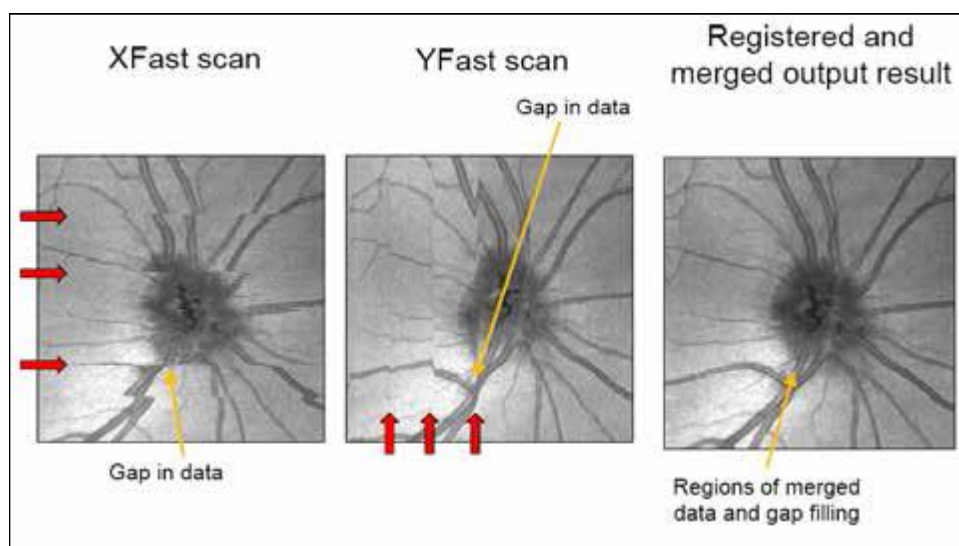


Figure 248 MCT Scan Acquisition and Effect in 3D Volumes, En Face Views

Figure 249 shows scans before and after motion correction:

- **Left:** 3D volume acquired in horizontal direction with noticeable motion artifacts.
- **Middle:** 3D volume acquired in vertical direction with noticeable motion artifacts.
- **Right:** Merged 3D volume with reduced motion artifacts using MCT.

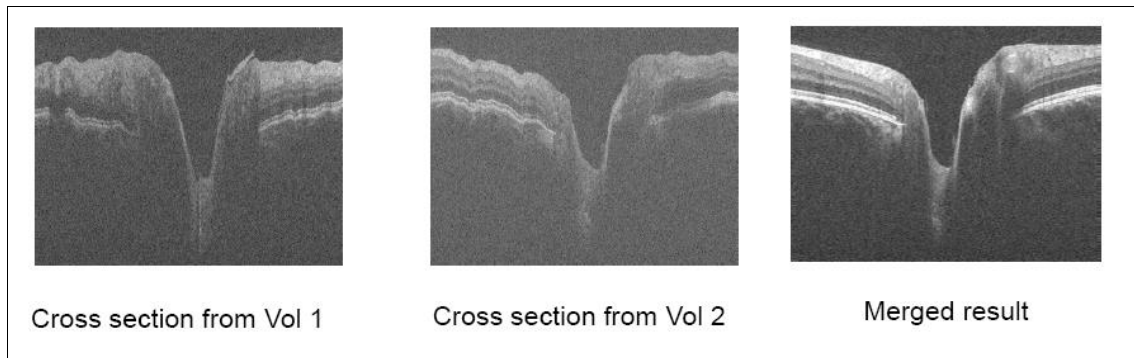


Figure 249 MCT Scan Acquisition and Effect in 3D Volumes, Cross-Sectional Views

15 Appendix C: Solix Clinical Summary

15.1 Evaluation of the Repeatability and Reproducibility (“R&R”) of Solix in Normal Subjects, Retinal Patients, and Glaucoma Patients for Posterior Segment Measurements

This was a prospective, cross-sectional study conducted at a single U.S. clinical site. Eligible participants age 18 or older were enrolled and assigned to one of three study groups: 1) individuals with no ocular disease; 2) individuals with glaucoma (with confirmed glaucomatous visual field defect and/or glaucomatous optic nerve changes) of varying severity, and 3) individuals with exudative age-related macular degeneration (wetAMD), proliferative and non-proliferative diabetic retinopathy (DR), non-neovascular age-related macular degeneration (dryAMD) of varying stages from drusen load (drusen) to non-foveal or foveal geographic atrophy (GA), and other retinal conditions. Individuals with media opacity or poor fixation precluding adequate image quality were excluded. For repeatability and reproducibility, the study eye is imaged three times using relevant OCT and OCTA scan patterns with each of three Solix instrument-operator pairs. All scans underwent post-acquisition image quality review. OCT and OCTA scans with a SQ score of less than 6, local weak signal affecting regional structure and/or vasculature visibility, motion artifacts, blink, and cropped B-scan images etc. were excluded from analysis; Repeatability and reproducibility of the measured parameters (structural measurements from OCT and OCTA scans and vascular measurements OCTA scans) were calculated using a random-effects analysis of variance (ANOVA) model.

A total of 83 participants were qualified, including 30 normal subjects (“Normal” group) 25 with glaucoma (“Glaucoma” group), and 28 with retinal conditions (“Retina” group). One eye per subject was included in the study. The 28 “Retina” group participants were assigned to the sub-groups as follows: 8 to wet AMD, 8 to DR, 6 to dry AMD-drusen, 3 to dry AMD-GA, and 3 to “other” group. Of the 83 eligible subjects, 44 (53%) participants were female and 39 (47%) participants were male; the age distribution of the participant was 65.5 ± 15.3 (mean $\pm$ SD), ranging from 21 to 91; and 86 (94.5%) participants were Caucasian.

Of the 30 subjects in the Normal group with age ranging from 24 to 72, 2 subject had refractive surgery, and 2 had cataract surgery and IOL implant.

The 25 subjects in the Glaucoma group consisted of 10 subjects in the early stage, 7 subjects in the moderate stage, and 8 subjects in the advanced stage of glaucoma with visual field MD ranging from -13.84 dB to -0.72 dB and PSD ranging from 1.76 dB to 13.65 dB.

Of the 8 wet AMD subjects, 7 subjects had diagnosis of Type-1 CNV, and 1 subject had mixed type CNV. CNV vessel net was visible in OCTA image in 5 subjects; IRF was observed in OCT image in 1 subject; 2 subjects had SRF; and 5 subjects had PED; 8 subjects had anti-VEGF injection treatment and 5 subjects had cataract surgery and IOL implant.

The 8 DR subjects consisted of 6 subjects with NPDR without DME, 1 subject with NPDR with DME, 1 subject with PDR without DME, and 1 subject with PDR with DME. In terms of DR severity, 4 subjects had mild NPDR, 2 subjects had moderate NPDR, and 2 subjects with PDR. Based on OCTA image, microaneurysm (MA) was observed in 6 subjects, reduced vessel density was observed in 6 subjects. Based on OCT image, IRF was observed in 1 subject.

Of the 9 dry AMD subjects, 6 subjects had drusen without GA, 2 subjects had drusen and non-central GA, and 1 subject had central GA. PED from confluent drusen was observed in 5 subjects in OCT image..

The 3 subjects assigned to the sub-group “other” consisted of 1 Adult Vitelliform Dystrophy and 2 retinitis pigmentosa..

Each study subject (i.e., study eye) was imaged on all 3 device/operator pairs with 3 repeats per pair per scan pattern. The rates of scans qualified from image quality review for the R&R study are shown in the table below, ranging from 93.7% to 100%, depending on the scan pattern and subgroup:

Solix R&R Study	Normal			Glaucoma			Retina			Combined		
Qualifying Scans	qualified	acquired	% qualified	qualified	acquired	% qualified	qualified	acquired	% qualified	qualified	acquired	% qualified
AngioVue Retina	269	277	97.1%	224	234	95.7%	252	267	94.4%	745	778	95.8%
Retina Cube	269	271	99.3%	225	226	99.6%	251	254	98.8%	745	751	99.2%
Wellness	270	272	99.3%	225	225	100.0%	250	254	98.4%	745	751	99.2%
AngioVue Disc	270	271	99.6%	225	229	98.3%	252	255	98.8%	747	755	98.9%
Disc Cube	270	274	98.5%	225	235	95.7%	252	269	93.7%	747	778	96.0%

Table 15.1.1 Rates of qualifying scans per study group per scan pattern.

The main reasons for scan disqualification were motion artifacts for Disc Cube scan and local weak signal for AngioVue Retina.

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Across all 5 study scan types and across all study groups, the maximum manual editing rates for segmentation boundaries were 4.3% for ILM, 5.2% for IPL, 0.1% for RPE, and 3.9% for NFL; the maximum foveal center detection correction rates were 0.5% for Wellness scan, 0.7% for AngioVue Retina scan and 0.7% for Retina Cube scan; the FAZ boundary detection manual editing rate was 19.7% for AngioVue Retina scans; the disc margin manual editing was performed for the baseline scan in 1.5% of study eyes per instrument.

15.1.1 R&R Results - GCC and Retinal Thickness

Tables 15.1.1.1 through 15.1.1.4 summarize the R&R analysis results of the GCC measurements and retinal thickness measurements from the AngioVue Retina scan, the Retina Cube scan, and Wellness scan.

Normal Subjects																
Measurement	Unit	AngioVue Retina (N = 269)					Retina Cube (N=269)					Wellness (N=270)				
		Mean (SD)	Repeatability SD	Reproducibility			Mean (SD)	Repeatability SD	Reproducibility			Mean (SD)	Repeatability SD	Reproducibility		
				SD	CV	Limit*			SD	CV	Limit*			SD	CV	Limit*
GCC																
ETDRS Grid (Ø 6mm)																
C(1)_GCC	µm	60.7 (9.6)	0.7	1.0	1.6%	2.7	61.3 (9.4)	1.1	1.4	2.2%	3.8	67.9 (9.1)	1.3	1.4	2.0%	3.8
T(1-3)_GCC	µm	102.2 (6.6)	0.7	0.9	0.9%	2.6	103.1 (6.5)	0.7	1.0	0.9%	2.7	102.0 (6.4)	0.7	1.0	1.0%	2.7
S(1-3)_GCC	µm	114.5 (7.4)	0.7	1.1	0.9%	3.0	114.2 (7.3)	0.9	1.2	1.1%	3.4	111.6 (7.9)	1.0	1.2	1.1%	3.5
N(1-3)_GCC	µm	112.6 (6.9)	0.8	1.0	0.9%	2.8	112.9 (6.8)	1.0	1.2	1.1%	3.3	112.3 (6.6)	0.9	1.2	1.1%	3.4
I(1-3)_GCC	µm	114.9 (7.0)	0.7	1.1	1.0%	3.1	114.3 (7.0)	0.9	1.2	1.0%	3.3	111.1 (7.3)	0.9	1.3	1.1%	3.5
S-Hemi(1-3)_GCC	µm	110.7 (6.9)	0.6	0.9	0.8%	2.6	110.9 (6.8)	0.7	1.0	0.9%	2.9	109.6 (7.1)	0.8	1.0	0.9%	2.9
I-Hemi(1-3)_GCC	µm	111.4 (6.7)	0.6	0.9	0.8%	2.6	111.4 (6.6)	0.7	1.0	0.9%	2.8	109.6 (6.6)	0.8	1.1	1.0%	3.0
All(1-3)_GCC	µm	111.1 (6.7)	0.5	0.9	0.8%	2.4	111.1 (6.6)	0.6	0.9	0.8%	2.6	109.6 (6.8)	0.7	1.0	0.9%	2.7
T(3-6)_GCC	µm	84.2 (7.2)	0.8	1.1	1.3%	3.0	84.7 (7.1)	0.8	1.0	1.2%	2.7	80.1 (6.6)	0.8	1.0	1.3%	2.8
S(3-6)_GCC	µm	100.7 (8.2)	0.8	1.0	1.0%	2.8	99.3 (8.2)	0.9	1.1	1.1%	3.0	91.2 (7.8)	1.0	1.3	1.5%	3.8
N(3-6)_GCC	µm	119.3 (8.8)	0.6	0.9	0.8%	2.6	118.6 (8.6)	0.8	1.1	0.9%	3.1	115.4 (9.5)	1.1	1.5	1.3%	4.3
I(3-6)_GCC	µm	100.2 (8.4)	0.7	1.1	1.1%	3.0	99.0 (8.3)	0.9	1.2	1.2%	3.4	95.4 (8.3)	1.3	2.0	2.1%	5.7
S-Hemi(3-6)_GCC	µm	100.7 (7.6)	0.6	0.9	0.9%	2.4	100.0 (7.5)	0.7	0.9	0.9%	2.5	93.4 (7.4)	0.9	1.2	1.2%	3.2
I-Hemi(3-6)_GCC	µm	101.5 (8.1)	0.6	0.9	0.9%	2.6	100.8 (8.0)	0.8	1.0	1.0%	2.9	96.8 (7.9)	1.0	1.6	1.7%	4.5
All(3-6)_GCC	µm	101.1 (7.6)	0.5	0.8	0.8%	2.3	100.4 (7.5)	0.6	0.9	0.9%	2.4	95.1 (7.3)	0.8	1.2	1.3%	3.5
S-Hemi(0-6)_GCC	µm	101.8 (7.0)	0.6	0.8	0.8%	2.3	101.3 (6.9)	0.6	0.8	0.8%	2.3	96.3 (6.8)	0.8	1.0	1.1%	2.8
I-Hemi(0-6)_GCC	µm	102.6 (7.2)	0.6	0.9	0.9%	2.5	102.0 (7.2)	0.7	0.9	0.9%	2.6	98.9 (7.2)	0.9	1.4	1.4%	3.8
All(0-6)_GCC	µm	102.2 (6.9)	0.5	0.8	0.8%	2.2	101.7 (6.8)	0.6	0.8	0.8%	2.2	97.6 (6.8)	0.7	1.1	1.1%	3.0
GCC																
ETDRS Grid (Ø 6mm)																
WI_GCC	µm	103.3 (7.0)	0.5	0.8	0.7%	2.2	102.7 (6.9)	0.6	0.8	0.8%	2.3	92.1 (6.2)	0.7	1.1	1.2%	3.2
WI-S-Hemi_GCC	µm	102.2 (7.1)	0.6	0.8	0.8%	2.3	101.6 (7.0)	0.7	0.9	0.8%	2.4	91.1 (6.4)	0.8	1.0	1.1%	2.9
WI-I-Hemi_GCC	µm	104.4 (7.4)	0.6	0.9	0.8%	2.5	103.7 (7.4)	0.7	1.0	1.0%	2.8	93.0 (6.7)	0.9	1.5	1.6%	4.2
FLV_GCC	%	0.57 (0.92)	0.1	0.2	29.5%	0.5	0.54 (0.91)	0.2	0.2	32.2%	0.5					
GLV_GCC	%	3.6 (3.7)	0.3	0.5	12.3%	1.3	3.6 (3.7)	0.3	0.5	13.8%	1.4					
Retina Thickness																
ETDRS Grid (Ø 6mm)																
C(1)_R	µm	269.6 (21.0)	1.0	1.6	0.6%	4.4	270.4 (21.0)	1.6	2.3	0.9%	6.5	269.1 (21.0)	1.4	2.1	0.8%	5.9
T(1-3)_R	µm	312.3 (13.9)	1.0	1.5	0.5%	4.2	313.5 (14.1)	1.3	1.9	0.6%	5.3	311.7 (14.1)	1.0	1.6	0.5%	4.5
S(1-3)_R	µm	327.2 (14.6)	1.0	1.8	0.5%	5.0	328.0 (14.6)	1.4	2.3	0.7%	6.3	325.6 (14.5)	1.2	1.9	0.6%	5.3
N(1-3)_R	µm	329.9 (13.9)	1.0	1.6	0.5%	4.5	330.9 (14.1)	1.4	2.1	0.6%	5.8	328.0 (14.3)	1.2	1.8	0.5%	4.9
I(1-3)_R	µm	322.2 (13.6)	1.0	1.6	0.5%	4.5	323.2 (14.0)	1.6	2.0	0.6%	5.5	322.3 (13.9)	1.1	1.6	0.5%	4.4
S-Hemi(1-3)_R	µm	324.3 (14.2)	0.9	1.6	0.5%	4.5	325.2 (14.2)	1.2	2.0	0.6%	5.7	322.6 (14.2)	1.1	1.7	0.5%	4.9
I-Hemi(1-3)_R	µm	321.4 (13.3)	0.9	1.5	0.5%	4.1	322.6 (13.7)	1.4	1.8	0.6%	5.1	321.1 (13.7)	1.0	1.5	0.5%	4.1
All(1-3)_R	µm	322.9 (13.7)	0.8	1.5	0.4%	4.1	323.9 (13.8)	1.1	1.8	0.6%	5.1	321.9 (13.8)	0.9	1.5	0.5%	4.3
T(3-6)_R	µm	262.7 (14.5)	1.1	1.4	0.5%	4.0	264.8 (14.5)	1.4	1.8	0.7%	5.1	274.0 (15.4)	1.0	1.6	0.6%	4.4
S(3-6)_R	µm	282.5 (14.6)	1.0	1.7	0.6%	4.7	283.5 (14.5)	1.5	2.0	0.7%	5.6	290.4 (15.1)	1.2	1.7	0.6%	4.8
N(3-6)_R	µm	300.9 (15.5)	0.9	1.4	0.5%	3.9	302.3 (15.6)	1.1	1.7	0.6%	4.8	302.7 (16.2)	1.1	1.6	0.5%	4.6
I(3-6)_R	µm	269.7 (13.5)	1.0	1.4	0.5%	4.0	270.7 (13.8)	1.4	1.7	0.6%	4.8	278.9 (15.1)	1.3	1.8	0.6%	5.0
S-Hemi(3-6)_R	µm	282.7 (14.6)	0.8	1.4	0.5%	4.0	284.0 (14.5)	1.2	1.7	0.6%	4.8	289.6 (15.1)	1.0	1.5	0.5%	4.2
I-Hemi(3-6)_R	µm	275.2 (13.8)	0.9	1.3	0.5%	3.7	276.7 (14.0)	1.2	1.6	0.6%	4.5	283.3 (15.0)	1.0	1.5	0.5%	4.3
All(3-6)_R	µm	279.0 (14.0)	0.8	1.3	0.5%	3.5	280.3 (14.0)	1.0	1.5	0.5%	4.3	286.5 (14.9)	0.9	1.4	0.5%	3.9
S-Hemi(0-6)_R	µm	291.6 (13.9)	0.8	1.4	0.5%	3.9	292.8 (13.9)	1.1	1.7	0.6%	4.8	296.4 (14.4)	1.0	1.5	0.5%	4.2
I-Hemi(0-6)_R	µm	285.3 (13.2)	0.9	1.3	0.4%	3.6	286.7 (13.4)	1.2	1.6	0.6%	4.5	291.4 (14.1)	0.9	1.5	0.5%	4.1
All(0-6)_R	µm	288.5 (13.4)	0.7	1.3	0.4%	3.5	289.8 (13.5)	1.0	1.6	0.5%	4.4	293.9 (14.1)	0.8	1.4	0.5%	3.9
All(0-6)_R_Vol	mm ³	8.2 (0.38)	0.02	0.04	0.5%	0.10	8.2 (0.38)	0.03	0.05	0.6%	0.13					
*Reproducibility Limit = 2.8 x SD of Reproducibility																

Table 15.1.1.2. Repeatability and Reproducibility of the Normal group.

Glaucoma Subjects																	
Measurement	Unit	AngioVue Retina (N = 224)						Retina Cube (N=225)					Wellness (N=225)				
		Mean (SD)	Repeatability	Reproducibility			Mean (SD)	Repeatability	Reproducibility			Mean (SD)	Repeatability	Reproducibility			
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*	
GCC																	
ETDRS Grid (Ø 6mm)																	
C(1)_GCC	µm	51.9 (10.7)	0.8	1.0	2.0%	2.9	52.1 (11.0)	1.3	1.6	3.0%	4.4	58.1 (11.0)	1.3	1.6	2.7%	4.4	
T(1-3)_GCC	µm	82.6 (11.6)	0.7	0.8	1.0%	2.4	83.2 (11.6)	0.9	1.0	1.2%	2.8	82.2 (11.0)	1.0	1.1	1.3%	3.1	
S(1-3)_GCC	µm	95.6 (13.0)	0.9	1.0	1.0%	2.7	94.6 (12.6)	0.9	1.0	1.1%	2.9	91.6 (12.0)	1.0	1.3	1.4%	3.1	
N(1-3)_GCC	µm	96.1 (12.1)	0.8	1.0	1.0%	2.7	96.3 (11.8)	1.0	1.0	1.0%	2.8	95.4 (11.7)	0.9	1.0	1.1%	2.9	
I(1-3)_GCC	µm	92.1 (13.2)	0.7	0.9	0.9%	2.4	91.1 (12.7)	0.9	1.0	1.1%	2.9	87.1 (11.8)	0.9	1.1	1.2%	3.0	
S-Hemi (1-3)_GCC	µm	92.7 (12.2)	0.7	0.8	0.9%	2.3	92.5 (11.9)	0.8	0.9	1.0%	2.5	90.8 (11.4)	0.8	1.0	1.1%	2.8	
I-Hemi (1-3)_GCC	µm	90.4 (12.4)	0.6	0.8	0.9%	2.3	90.1 (12.1)	0.7	0.9	1.0%	2.4	87.5 (11.3)	0.8	0.9	1.1%	2.6	
All(1-3)_GCC	µm	91.6 (11.5)	0.5	0.7	0.7%	1.9	91.3 (11.3)	0.6	0.7	0.8%	2.0	89.1 (10.5)	0.6	0.8	0.9%	2.3	
T(3-6)_GCC	µm	69.4 (8.4)	0.7	0.9	1.3%	2.5	69.5 (8.3)	0.8	1.0	1.4%	2.8	66.1 (7.8)	0.8	0.9	1.4%	2.5	
S(3-6)_GCC	µm	81.5 (12.7)	0.7	0.8	1.0%	2.2	80.0 (12.3)	0.9	1.1	1.4%	3.1	72.2 (12.3)	1.1	1.4	1.9%	3.8	
N(3-6)_GCC	µm	97.4 (11.8)	0.6	0.8	0.8%	2.1	96.2 (11.5)	1.0	1.3	1.4%	3.7	90.9 (12.0)	1.0	1.4	1.6%	4.0	
I(3-6)_GCC	µm	76.5 (12.1)	0.7	0.8	1.0%	2.2	75.2 (11.5)	0.8	1.1	1.5%	3.2	70.6 (12.1)	1.1	1.5	2.1%	4.1	
S-Hemi (3-6)_GCC	µm	83.2 (11.1)	0.6	0.7	0.8%	1.8	82.2 (10.8)	0.7	0.9	1.1%	2.6	75.4 (10.9)	0.8	1.1	1.5%	3.1	
I-Hemi (3-6)_GCC	µm	79.2 (11.0)	0.6	0.7	0.9%	1.9	78.3 (10.6)	0.7	1.0	1.2%	2.7	73.2 (11.0)	0.9	1.1	1.5%	3.2	
All (3-6)_GCC	µm	81.2 (9.7)	0.5	0.6	0.7%	1.5	80.2 (9.4)	0.6	0.8	1.0%	2.2	74.3 (9.7)	0.7	0.9	1.2%	2.6	
S-Hemi (0-6)_GCC	µm	84.5 (10.9)	0.5	0.6	0.7%	1.7	83.6 (10.6)	0.6	0.8	0.9%	2.2	78.3 (10.6)	0.7	1.0	1.3%	2.8	
I-Hemi (0-6)_GCC	µm	81.0 (10.7)	0.5	0.6	0.8%	1.8	80.2 (10.3)	0.6	0.8	1.0%	2.3	76.0 (10.4)	0.8	1.0	1.3%	2.7	
All (0-6)_GCC	µm	82.7 (9.7)	0.4	0.5	0.7%	1.5	81.9 (9.4)	0.6	0.7	0.9%	2.0	77.1 (9.4)	0.6	0.8	1.0%	2.3	
GCC																	
ETDRS Grid (Ø 6mm)																	
												7mm x 8mm					
WL_GCC	µm	82.5 (10.3)	0.4	0.5	0.6%	1.4	81.7 (9.9)	0.6	0.7	0.9%	2.1	73.4 (8.9)	0.7	0.8	1.1%	2.3	
WI-S-Hemi_GCC	µm	84.1 (11.6)	0.5	0.6	0.8%	1.8	83.2 (11.3)	0.7	0.9	1.0%	2.4	74.6 (10.2)	0.8	1.0	1.3%	2.8	
WI-I-Hemi_GCC	µm	80.9 (11.5)	0.5	0.7	0.8%	1.8	80.1 (11.1)	0.7	0.9	1.1%	2.5	72.1 (9.7)	0.9	1.0	1.4%	2.9	
FLV_GCC	%	5.7 (3.5)	0.4	0.4	6.9%	1.1	5.5 (3.3)	0.4	0.5	8.6%	1.3						
GLV_GCC	%	19.8 (9.4)	0.4	0.5	2.5%	1.4	20.1 (9.1)	0.5	0.7	3.4%	1.9						
Retina Thickness																	
ETDRS Grid (Ø 6mm)																	
C(1)_R	µm	252.2 (18.9)	1.0	1.7	0.7%	4.8	253.4 (19.3)	1.7	2.4	0.9%	6.7	252.1 (18.7)	1.6	2.1	0.8%	6.0	
T(1-3)_R	µm	287.3 (17.4)	1.1	1.5	0.5%	4.3	288.9 (17.8)	1.4	2.0	0.7%	5.7	286.6 (17.6)	1.3	1.8	0.6%	5.0	
S(1-3)_R	µm	300.7 (18.1)	1.1	1.6	0.5%	4.4	302.2 (18.3)	1.7	2.2	0.7%	6.1	299.5 (18.1)	1.4	1.9	0.6%	5.4	
N(1-3)_R	µm	307.6 (16.9)	1.1	1.7	0.5%	4.7	309.6 (17.3)	1.4	1.9	0.6%	5.3	306.4 (17.2)	1.2	1.8	0.6%	4.9	
I(1-3)_R	µm	293.6 (16.7)	1.3	1.8	0.6%	5.2	295.2 (17.1)	1.5	2.0	0.7%	5.6	293.9 (17.1)	1.2	1.7	0.6%	4.7	
S-Hemi(1-3)_R	µm	299.6 (17.4)	1.0	1.5	0.5%	4.2	301.2 (17.8)	1.5	1.9	0.6%	5.4	298.4 (17.4)	1.2	1.8	0.6%	5.0	
I-Hemi(1-3)_R	µm	294.9 (16.6)	1.0	1.6	0.5%	4.5	296.7 (17.0)	1.2	1.9	0.6%	5.2	294.8 (17.0)	1.0	1.6	0.5%	4.4	
All(1-3)_R	µm	297.3 (16.5)	0.9	1.4	0.5%	4.0	299.0 (16.9)	1.1	1.7	0.6%	4.8	296.6 (16.8)	1.0	1.6	0.5%	4.4	
T(3-6)_R	µm	241.9 (17.1)	1.1	1.5	0.6%	4.2	244.2 (17.7)	1.4	1.9	0.8%	5.2	250.9 (18.3)	1.3	1.7	0.7%	4.9	
S(3-6)_R	µm	255.5 (20.0)	1.0	1.5	0.6%	4.3	257.3 (20.6)	1.7	2.2	0.8%	6.1	262.9 (20.5)	1.5	1.9	0.7%	5.4	
N(3-6)_R	µm	273.3 (16.6)	1.0	1.4	0.5%	4.0	275.4 (16.9)	1.2	1.7	0.6%	4.9	276.6 (17.5)	1.2	1.6	0.6%	4.3	
I(3-6)_R	µm	239.8 (16.5)	1.1	1.5	0.6%	4.3	241.3 (17.1)	1.5	1.8	0.7%	5.0	248.5 (17.9)	1.2	1.6	0.6%	4.5	
S-Hemi(3-6)_R	µm	258.2 (18.1)	0.8	1.3	0.5%	3.7	260.2 (18.7)	1.3	1.8	0.7%	5.1	264.5 (18.8)	1.2	1.7	0.7%	4.8	
I-Hemi(3-6)_R	µm	247.1 (16.2)	1.0	1.4	0.6%	3.9	248.9 (16.9)	1.3	1.7	0.7%	4.8	255.0 (17.5)	1.0	1.4	0.6%	4.0	
All(3-6)_R	µm	252.7 (16.5)	0.7	1.2	0.5%	3.4	254.5 (17.0)	1.0	1.5	0.6%	4.3	259.7 (17.5)	0.9	1.4	0.5%	3.9	
S-Hemi(0-6)_R	µm	267.3 (17.3)	0.8	1.3	0.5%	3.7	269.1 (17.7)	1.3	1.8	0.7%	4.9	271.7 (17.8)	1.2	1.7	0.6%	4.7	
I-Hemi(0-6)_R	µm	257.8 (15.6)	0.9	1.4	0.5%	3.8	259.7 (16.2)	1.2	1.7	0.6%	4.7	263.8 (16.7)	1.0	1.4	0.5%	3.9	
All(0-6)_R	µm	262.6 (15.9)	0.7	1.2	0.5%	3.4	264.4 (16.4)	1.0	1.5	0.6%	4.3	267.7 (16.6)	0.9	1.4	0.5%	3.9	
All (0-6)_R_Vol	mm ³	7.4 (0.45)	0.02	0.04	0.5%	0.10	7.5 (0.46)	0.03	0.05	0.6%	0.13						
*Reproducibility Limit = 2.8 x SD of Reproducibility																	

*Reproducibility Limit = 2.8 x SD of Reproducibility

Table 15.1.1.3. Repeatability and Reproducibility of the Glaucoma group.

Retina Subjects																
Measurement	Unit	AngioVue Retina (N = 252)					Retina Cube (N=251)					Wellness (N=250)				
		Mean (SD)	Repeatability SD	Reproducibility			Mean (SD)	Repeatability SD	Reproducibility			Mean (SD)	Repeatability SD	Reproducibility		
				SD	CV	Limit*			SD	CV	Limit*			SD	CV	Limit*
GCC		ETDRS Grid (Ø 6mm)														
C(1)_GCC	µm	55.4 (11.5)	0.9	1.0	1.8%	2.8	55.3 (11.6)	1.3	1.6	2.9%	4.4	59.8 (12.7)	2.4	3.2	5.3%	8.8
T(1-3)_GCC	µm	95.2 (11.2)	1.0	1.1	1.2%	3.1	95.3 (11.5)	0.9	1.0	1.1%	2.8	92.9 (12.5)	1.4	2.3	2.5%	6.5
S(1-3)_GCC	µm	107.7 (13.1)	0.9	1.0	0.9%	2.7	106.6 (12.7)	1.1	1.2	1.1%	3.3	102.9 (15.4)	1.5	5.0	4.9%	14.0
N(1-3)_GCC	µm	106.8 (13.7)	0.9	1.0	1.0%	2.9	106.8 (13.8)	1.1	1.2	1.1%	3.2	104.8 (15.1)	2.6	4.3	4.1%	12.2
I(1-3)_GCC	µm	107.7 (12.3)	0.8	1.0	0.9%	2.8	106.5 (12.6)	1.1	1.2	1.1%	3.4	103.2 (13.3)	1.7	1.8	1.7%	5.0
S-Hemi(1-3)_GCC	µm	103.7 (12.4)	0.9	0.9	0.9%	2.5	103.3 (12.2)	0.9	0.9	0.9%	2.5	100.8 (14.4)	1.3	4.5	4.5%	12.6
I-Hemi(1-3)_GCC	µm	104.9 (12.0)	0.7	0.9	0.8%	2.4	104.3 (12.2)	0.9	1.0	0.9%	2.7	101.9 (12.9)	1.6	1.8	1.7%	5.0
All(1-3)_GCC	µm	104.3 (12.1)	0.7	0.7	0.7%	2.1	103.8 (12.1)	0.7	0.7	0.7%	2.0	101.3 (13.3)	1.3	2.8	2.8%	8.0
T(3-6)_GCC	µm	84.6 (11.4)	0.6	0.8	0.9%	2.2	84.5 (11.4)	0.7	0.9	1.0%	2.4	78.9 (10.6)	1.0	1.3	1.7%	3.7
S(3-6)_GCC	µm	99.2 (12.1)	0.7	1.1	1.1%	3.1	97.6 (12.1)	1.1	1.2	1.2%	3.3	88.0 (13.7)	1.3	2.6	2.9%	7.2
N(3-6)_GCC	µm	114.9 (12.9)	0.5	0.7	0.6%	1.9	113.7 (13.1)	0.9	1.1	0.9%	3.0	108.3 (13.1)	1.5	2.9	2.7%	8.1
I(3-6)_GCC	µm	98.7 (12.3)	0.7	1.0	1.0%	2.8	96.9 (12.4)	1.2	1.6	1.7%	4.5	91.3 (11.9)	1.7	2.3	2.5%	6.5
S-Hemi(3-6)_GCC	µm	98.9 (11.0)	0.5	0.8	0.8%	2.2	97.8 (11.1)	0.8	0.9	0.9%	2.6	89.7 (12.2)	1.0	2.3	2.6%	6.5
I-Hemi(3-6)_GCC	µm	99.9 (11.7)	0.5	0.8	0.8%	2.2	98.5 (11.7)	1.0	1.2	1.2%	3.4	92.8 (11.5)	1.3	1.8	2.0%	5.1
All(3-6)_GCC	µm	99.4 (11.1)	0.4	0.6	0.6%	1.6	98.2 (11.1)	0.7	0.9	0.9%	2.5	91.3 (11.4)	0.9	1.7	1.9%	4.9
S-Hemi(0-6)_GCC	µm	98.8 (10.4)	0.5	0.7	0.7%	2.0	97.8 (10.4)	0.7	0.8	0.8%	2.2	91.3 (11.7)	0.8	2.6	2.9%	7.4
I-Hemi(0-6)_GCC	µm	99.7 (11.1)	0.5	0.7	0.7%	2.0	98.6 (11.1)	0.8	1.0	1.0%	2.8	93.9 (11.1)	1.2	1.6	1.7%	4.5
All(0-6)_GCC	µm	99.3 (10.5)	0.4	0.6	0.6%	1.5	98.2 (10.6)	0.6	0.8	0.8%	2.1	92.6 (11.1)	0.8	1.8	2.0%	5.2
GCC		ETDRS Grid (Ø 6mm)										7mm x 8mm				
WL_GCC	µm	100.8 (10.7)	0.4	0.7	0.6%	1.8	99.6 (10.7)	0.7	0.9	0.9%	2.5	88.7 (10.0)	0.7	1.6	1.8%	4.4
WI-S-Hemi_GCC	µm	99.7 (10.9)	0.5	0.8	0.8%	2.2	98.6 (10.9)	0.8	0.9	0.9%	2.6	87.6 (10.8)	0.9	2.1	2.4%	6.0
WI-I-Hemi_GCC	µm	101.9 (11.1)	0.6	0.9	0.9%	2.6	100.5 (11.1)	1.0	1.3	1.3%	3.5	89.7 (10.1)	1.1	1.7	1.9%	4.7
FLV_GCC	%	1.7 (2.2)	0.3	0.3	15.8%	0.8	1.8 (2.3)	0.3	0.3	18.3%	0.9					
GLV_GCC	%	6.4 (6.3)	0.3	0.5	7.9%	1.4	6.7 (6.6)	0.4	0.6	8.7%	1.6					
Retina Thickness		ETDRS Grid (Ø 6mm)														
C(1)_R	µm	232.1 (40.0)	1.2	1.7	0.7%	4.7	233.1 (40.0)	2.0	2.3	1.0%	6.6	231.4 (39.8)	1.9	2.9	1.3%	8.1
T(1-3)_R	µm	283.1 (35.8)	1.2	1.6	0.6%	4.5	284.2 (36.2)	1.4	1.8	0.6%	5.1	282.5 (34.9)	1.6	2.1	0.8%	5.9
S(1-3)_R	µm	292.3 (36.4)	1.3	1.6	0.6%	4.6	293.8 (36.8)	1.8	2.2	0.8%	6.2	291.4 (35.9)	1.6	2.3	0.8%	6.3
N(1-3)_R	µm	300.0 (36.6)	1.3	1.5	0.5%	4.3	301.6 (37.0)	1.5	1.9	0.6%	5.2	298.3 (36.0)	1.3	2.0	0.7%	5.5
I(1-3)_R	µm	292.7 (35.3)	1.1	1.3	0.5%	3.7	293.5 (35.7)	1.4	1.6	0.5%	4.4	291.8 (34.9)	1.6	2.6	0.9%	7.2
S-Hemi(1-3)_R	µm	291.0 (35.6)	0.9	1.3	0.4%	3.5	292.4 (36.0)	1.3	1.7	0.6%	4.9	289.9 (35.0)	1.4	2.0	0.7%	5.5
I-Hemi(1-3)_R	µm	293.1 (35.3)	1.0	1.2	0.4%	3.4	294.1 (35.7)	1.2	1.5	0.5%	4.1	292.1 (34.7)	1.3	2.1	0.7%	5.8
All(1-3)_R	µm	292.0 (35.2)	0.8	1.1	0.4%	3.0	293.3 (35.6)	1.0	1.4	0.5%	3.9	291.0 (34.6)	1.1	1.8	0.6%	5.2
T(3-6)_R	µm	250.2 (30.4)	1.0	1.3	0.5%	3.7	251.5 (30.8)	1.2	1.7	0.7%	4.6	258.7 (31.9)	1.2	1.8	0.7%	5.1
S(3-6)_R	µm	261.8 (30.8)	0.9	1.2	0.5%	3.3	263.1 (31.2)	1.5	1.8	0.7%	5.0	267.3 (31.9)	1.5	2.1	0.8%	5.9
N(3-6)_R	µm	277.7 (30.2)	0.9	1.2	0.4%	3.5	278.8 (30.2)	1.2	1.5	0.5%	4.1	279.6 (30.5)	1.3	1.7	0.6%	4.8
I(3-6)_R	µm	254.2 (25.2)	0.9	1.4	0.6%	3.9	255.5 (25.6)	1.4	1.8	0.7%	5.0	261.0 (28.4)	1.5	1.9	0.7%	5.4
S-Hemi(3-6)_R	µm	262.8 (29.2)	0.7	1.0	0.4%	2.8	264.0 (29.6)	1.1	1.4	0.5%	4.1	268.1 (29.8)	1.3	1.8	0.7%	5.2
I-Hemi(3-6)_R	µm	259.2 (26.8)	0.8	1.2	0.5%	3.3	260.4 (27.1)	1.1	1.4	0.6%	4.0	265.3 (29.3)	1.2	1.6	0.6%	4.6
All(3-6)_R	µm	261.0 (27.7)	0.6	0.9	0.4%	2.6	262.2 (28.1)	0.9	1.2	0.5%	3.5	266.7 (29.2)	1.0	1.5	0.6%	4.3
S-Hemi(0-6)_R	µm	268.2 (29.4)	0.6	0.9	0.3%	2.6	269.5 (29.8)	1.0	1.4	0.5%	3.9	271.9 (29.9)	1.2	1.8	0.7%	5.0
I-Hemi(0-6)_R	µm	266.0 (27.7)	0.7	1.1	0.4%	3.1	267.2 (28.1)	1.0	1.3	0.5%	3.7	270.3 (29.6)	1.1	1.6	0.6%	4.6
All(0-6)_R	µm	267.1 (28.3)	0.6	0.9	0.3%	2.5	268.3 (28.7)	0.9	1.2	0.4%	3.4	271.1 (29.5)	1.0	1.6	0.6%	4.4
All(0-6)_R_Vol	mm³	7.5 (0.81)	0.02	0.04	0.5%	0.11	7.6 (0.83)	0.04	0.06	0.8%	0.16					
*Reproducibility Limit = 2.8 x SD of Reproducibility																

*Reproducibility Limit = 2.8 x SD of Reproducibility

Table 15.1.1.4. Repeatability and Reproducibility of the Retina group.

15.1.2 R&R Results – Superficial & Deep Vessel Density and FAZ Parameters

Tables 15.1.2.1 through 15.1.2.3 summarize the R&R analysis results of the Superficial (SVC) vessel density measurements, Deep (DVC) vessel density measurements, and FAZ measurements from the AngioVue Retina scan.

Normal Subjects													
Superficial Vascular Complex (SVC)	Unit	N = 269					Deep Vascular Complex (DVC)	Unit	N = 269				
		Mean (SD)	Repeatability	Reproducibility					Mean (SD)	Repeatability	Reproducibility		
			SD	SD	CV	Limit*				SD	SD	CV	Limit*
SVC		ETDRS Grid (Ø 6mm)					DVC		ETDRS Grid (Ø 6mm)				
C(1)_SVC	%	29.7 (5.4)	2.1	2.6	8.7%	7.3	C(1)_DVC	%	33.0 (6.0)	2.2	2.8	8.6%	7.9
T(1-3)_SVC	%	47.5 (2.7)	1.9	2.5	5.3%	7.0	T(1-3)_DVC	%	53.6 (1.9)	1.7	2.0	3.7%	5.5
S(1-3)_SVC	%	48.3 (2.8)	2.1	2.6	5.4%	7.3	S(1-3)_DVC	%	53.3 (2.0)	1.8	2.0	3.7%	5.5
N(1-3)_SVC	%	47.2 (3.3)	2.3	2.8	6.0%	8.0	N(1-3)_DVC	%	53.3 (2.2)	1.9	2.2	4.0%	6.0
I(1-3)_SVC	%	48.3 (2.9)	2.0	2.7	5.5%	7.5	I(1-3)_DVC	%	53.4 (1.9)	1.7	1.8	3.5%	5.2
S-Hemi(1-3)_SVC	%	47.8 (2.6)	1.9	2.4	5.1%	6.8	S-Hemi(1-3)_DVC	%	53.5 (1.5)	1.2	1.6	2.9%	4.4
I-Hemi(1-3)_SVC	%	47.8 (2.7)	1.9	2.6	5.4%	7.2	I-Hemi(1-3)_DVC	%	53.4 (1.7)	1.4	1.7	3.2%	4.7
All(1-3)_SVC	%	47.8 (2.6)	1.8	2.4	5.1%	6.8	All(1-3)_DVC	%	53.4 (1.4)	1.1	1.4	2.6%	3.9
T(3-6)_SVC	%	44.0 (2.4)	1.5	2.2	4.9%	6.1	T(3-6)_DVC	%	53.2 (1.9)	1.7	1.9	3.7%	5.4
S(3-6)_SVC	%	47.5 (2.2)	1.4	1.7	3.7%	4.9	S(3-6)_DVC	%	52.5 (2.3)	1.9	2.3	4.4%	6.4
N(3-6)_SVC	%	50.9 (1.8)	1.3	1.5	3.0%	4.3	N(3-6)_DVC	%	52.4 (2.3)	1.9	2.3	4.3%	6.3
I(3-6)_SVC	%	47.4 (2.2)	1.3	1.7	3.7%	4.9	I(3-6)_DVC	%	52.3 (2.4)	1.9	2.4	4.6%	6.8
S-Hemi(3-6)_SVC	%	47.4 (2.0)	1.3	1.7	3.5%	4.7	S-Hemi(3-6)_DVC	%	52.7 (1.8)	1.4	1.8	3.4%	5.1
I-Hemi(3-6)_SVC	%	47.5 (1.9)	1.2	1.7	3.5%	4.7	I-Hemi(3-6)_DVC	%	52.5 (1.9)	1.3	1.9	3.6%	5.3
All(3-6)_SVC	%	47.5 (1.8)	1.2	1.6	3.4%	4.5	All(3-6)_DVC	%	52.6 (1.6)	1.1	1.6	3.1%	4.5
All(0-6)_SVC	%	47.1 (1.9)	1.3	1.7	3.7%	4.9	All(0-6)_DVC	%	52.3 (1.4)	1.0	1.4	2.7%	3.9
SVC		6 mm x 6 mm					DVC		6 mm x 6 mm				
WI_SVC	%	47.5 (1.8)	1.2	1.6	3.4%	4.5	WI_DVC	%	51.8 (1.7)	1.0	1.7	3.2%	4.7
WI-S-Hemi_SVC	%	47.5 (1.8)	1.3	1.6	3.4%	4.5	WI-S-Hemi_DVC	%	51.9 (1.8)	1.2	1.8	3.4%	4.9
WI-I-Hemi_SVC	%	47.5 (1.8)	1.2	1.7	3.5%	4.6	WI-I-Hemi_DVC	%	51.7 (2.0)	1.2	1.9	3.7%	5.4
FAZ Parameters (N=233)		Retina Slab											
FAZ Area	mm ²	0.23 (0.089)	0.01	0.01	4.6%	0.03							
FAZ Perimeter	mm	1.8 (0.38)	0.1	0.1	3.4%	0.2							
FD-300 Vessel Density	%	48.4 (4.6)	2.9	3.9	8.0%	10.9							
*Reproducibility Limit = 2.8 x SD of Reproducibility													

*Reproducibility Limit = 2.8 x SD of Reproducibility

Table 15.1.2.1. Repeatability and Reproducibility of the Normal group.

Glaucoma Subjects													
Superficial Vascular Complex (SVC)	Unit	N = 224					Deep Vascular Complex (DVC)	Unit	N = 224				
		Mean (SD)	Repeatability	Reproducibility					Mean (SD)	Repeatability	Reproducibility		
			SD	SD	CV	Limit*				SD	SD	CV	Limit*
SVC		ETDRS Grid (Ø 6mm)					DVC		ETDRS Grid (Ø 6mm)				
C(1)_SVC	%	27.3 (6.0)	2.4	2.7	10.0%	7.7	C(1)_DVC	%	31.6 (7.0)	3.2	3.6	11.2%	9.9
T(1-3)_SVC	%	46.3 (3.2)	2.3	2.9	6.2%	8.1	T(1-3)_DVC	%	53.0 (1.9)	1.8	1.9	3.5%	5.2
S(1-3)_SVC	%	47.4 (3.3)	2.2	2.6	5.5%	7.3	S(1-3)_DVC	%	52.7 (2.4)	2.3	2.4	4.5%	6.6
N(1-3)_SVC	%	46.5 (3.3)	2.3	2.8	5.9%	7.7	N(1-3)_DVC	%	52.7 (2.6)	2.4	2.5	4.7%	6.9
I(1-3)_SVC	%	47.4 (3.4)	2.1	2.6	5.5%	7.3	I(1-3)_DVC	%	52.7 (2.1)	1.9	2.0	3.8%	5.6
S-Hemi(1-3)_SVC	%	46.9 (2.9)	1.9	2.4	5.1%	6.7	S-Hemi(1-3)_DVC	%	52.9 (2.0)	1.9	1.9	3.7%	5.5
I-Hemi(1-3)_SVC	%	47.0 (2.8)	1.8	2.3	4.8%	6.3	I-Hemi(1-3)_DVC	%	52.7 (1.7)	1.6	1.7	3.1%	4.6
All(1-3)_SVC	%	46.9 (2.7)	1.6	2.2	4.6%	6.0	All(1-3)_DVC	%	52.8 (1.4)	1.2	1.3	2.5%	3.8
T(3-6)_SVC	%	42.7 (2.7)	1.6	2.1	4.9%	5.9	T(3-6)_DVC	%	52.2 (2.2)	2.0	2.1	4.1%	6.0
S(3-6)_SVC	%	45.9 (2.7)	1.4	1.7	3.7%	4.7	S(3-6)_DVC	%	51.2 (2.6)	2.2	2.4	4.7%	6.7
N(3-6)_SVC	%	49.4 (2.5)	1.3	1.7	3.4%	4.8	N(3-6)_DVC	%	51.0 (3.0)	2.4	2.6	5.2%	7.4
I(3-6)_SVC	%	43.6 (3.8)	1.4	1.7	4.0%	4.9	I(3-6)_DVC	%	51.1 (3.2)	2.5	2.9	5.7%	8.2
S-Hemi(3-6)_SVC	%	46.2 (2.3)	1.3	1.7	3.6%	4.7	S-Hemi(3-6)_DVC	%	51.5 (2.2)	1.7	1.9	3.7%	5.4
I-Hemi(3-6)_SVC	%	44.6 (2.9)	1.2	1.6	3.5%	4.4	I-Hemi(3-6)_DVC	%	51.3 (2.5)	1.9	2.3	4.4%	6.4
All(3-6)_SVC	%	45.4 (2.1)	1.2	1.5	3.4%	4.3	All(3-6)_DVC	%	51.4 (2.0)	1.3	1.7	3.4%	4.8
All(0-6)_SVC	%	45.2 (2.0)	1.2	1.6	3.5%	4.4	All(0-6)_DVC	%	51.2 (1.6)	1.1	1.4	2.8%	3.9
SVC		6 mm x 6 mm					DVC		6 mm x 6 mm				
WI_SVC	%	45.3 (2.1)	1.1	1.5	3.4%	4.3	WI_DVC	%	50.6 (1.9)	1.1	1.5	3.0%	4.3
WI-S-Hemi_SVC	%	46.0 (2.1)	1.2	1.6	3.6%	4.6	WI-S-Hemi_DVC	%	50.8 (2.0)	1.3	1.7	3.3%	4.7
WI-I-Hemi_SVC	%	44.6 (2.8)	1.1	1.6	3.5%	4.4	WI-I-Hemi_DVC	%	50.5 (2.2)	1.5	1.9	3.8%	5.3
FAZ Parameters (N=215)		Retina Slab											
FAZ Area	mm ²	0.26 (0.12)	0.01	0.01	4.5%	0.03							
FAZ Perimeter	mm	2.0 (0.51)	0.1	0.1	5.4%	0.3							
FD-300 Vessel Density	%	44.8 (5.4)	3.2	3.7	8.2%	10.3							
*Reproducibility Limit = 2.8 x SD of Reproducibility													

*Reproducibility Limit = 2.8 x SD of Reproducibility

Table 15.1.2.2. Repeatability and Reproducibility of the Glaucoma group.

Retina Subjects													
Superficial Vascular Complex (SVC)	Unit	N = 252					Deep Vascular Complex (DVC)	Unit	N = 252				
		Mean (SD)	Repeatability	Reproducibility					Mean (SD)	Repeatability	Reproducibility		
			SD	SD	CV	Limit*				SD	SD	CV	Limit*
SVC		ETDRS Grid (Ø 6mm)					DVC		ETDRS Grid (Ø 6mm)				
C(1)_SVC	%	26.8 (5.2)	2.3	3.0	11.1%	8.4	C(1)_DVC	%	29.7 (6.1)	3.2	3.8	12.8%	10.6
T(1-3)_SVC	%	45.6 (3.0)	1.7	2.2	4.8%	6.2	T(1-3)_DVC	%	52.7 (2.2)	1.7	2.0	3.8%	5.6
S(1-3)_SVC	%	46.3 (3.2)	1.9	2.5	5.4%	6.9	S(1-3)_DVC	%	52.8 (2.7)	2.3	2.5	4.7%	6.9
N(1-3)_SVC	%	45.2 (3.4)	2.0	2.6	5.7%	7.1	N(1-3)_DVC	%	52.4 (3.0)	2.2	2.6	5.0%	7.4
I(1-3)_SVC	%	46.5 (3.1)	1.8	2.4	5.1%	6.6	I(1-3)_DVC	%	52.9 (2.0)	1.8	1.9	3.5%	5.2
S-Hemi(1-3)_SVC	%	45.8 (2.8)	1.6	2.2	4.8%	6.1	S-Hemi(1-3)_DVC	%	52.6 (2.3)	1.6	1.9	3.5%	5.2
I-Hemi(1-3)_SVC	%	46.0 (2.9)	1.5	2.0	4.4%	5.7	I-Hemi(1-3)_DVC	%	52.8 (1.8)	1.4	1.6	3.1%	4.6
All(1-3)_SVC	%	45.9 (2.7)	1.4	2.0	4.3%	5.5	All(1-3)_DVC	%	52.7 (1.7)	1.2	1.4	2.7%	4.0
T(3-6)_SVC	%	43.1 (2.4)	1.4	2.0	4.7%	5.7	T(3-6)_DVC	%	52.5 (2.3)	1.8	2.1	3.9%	5.8
S(3-6)_SVC	%	46.4 (2.3)	1.4	1.6	3.4%	4.4	S(3-6)_DVC	%	51.9 (2.5)	1.9	2.1	4.0%	5.9
N(3-6)_SVC	%	49.6 (2.1)	1.5	1.6	3.3%	4.6	N(3-6)_DVC	%	51.4 (2.5)	2.0	2.2	4.2%	6.1
I(3-6)_SVC	%	45.9 (2.7)	1.3	1.6	3.4%	4.4	I(3-6)_DVC	%	51.0 (3.3)	2.2	2.4	4.7%	6.8
S-Hemi(3-6)_SVC	%	46.3 (1.9)	1.3	1.6	3.4%	4.3	S-Hemi(3-6)_DVC	%	52.1 (2.0)	1.4	1.7	3.2%	4.6
I-Hemi(3-6)_SVC	%	46.3 (2.3)	1.2	1.5	3.2%	4.2	I-Hemi(3-6)_DVC	%	51.2 (2.7)	1.7	1.9	3.7%	5.4
All(3-6)_SVC	%	46.3 (1.9)	1.2	1.5	3.1%	4.1	All(3-6)_DVC	%	51.7 (1.9)	1.2	1.4	2.8%	4.0
All(0-6)_SVC	%	45.6 (1.8)	1.2	1.5	3.2%	4.1	All(0-6)_DVC	%	51.3 (1.6)	1.0	1.2	2.3%	3.4
SVC		6 mm x 6 mm					DVC		6 mm x 6 mm				
WI_SVC	%	46.3 (1.9)	1.1	1.4	3.0%	3.9	WI_DVC	%	50.7 (1.9)	1.0	1.5	2.9%	4.1
WI-S-Hemi_SVC	%	46.3 (1.9)	1.2	1.5	3.1%	4.1	WI-S-Hemi_DVC	%	51.1 (1.9)	1.2	1.6	3.2%	4.6
WI-I-Hemi_SVC	%	46.2 (2.0)	1.1	1.4	3.0%	3.9	WI-I-Hemi_DVC	%	50.3 (2.5)	1.4	1.8	3.5%	4.9
FAZ Parameters (N=252)		Retina Slab											
FAZ Area	mm ²	0.35 (0.22)	0.01	0.02	5.2%	0.05							
FAZ Perimeter	mm	2.4 (1.1)	0.1	0.1	5.3%	0.4							
FD-300 Vessel Density	%	45.3 (5.3)	2.7	4.0	8.7%	11.1							
*Reproducibility Limit = 2.8 x SD of Reproducibility													

*Reproducibility Limit = 2.8 x SD of Reproducibility

Table 15.1.2.3. Repeatability and Reproducibility of the Retina group.

15.1.3 R&R Results - RNFL Thickness and ONH Parameters

Tables 15.1.3.1 through 15.1.3.3 summarize the results of the R&R analysis of the RNFL thickness measurements and ONH parameters from the AngioVue Disc scan and the Disc Cube scan.

Normal Subjects											
Measurement	Unit	AngioVue Disc (N=270)					Disc Cube (N=270)				
		Mean (SD)	Repeatability	Reproducibility			Mean (SD)	Repeatability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*
RNFL		Ø2.5 ~ Ø4.5 mm Ring									
TS_RNFL	µm	62.5 (8.1)	1.0	1.9	3.1%	5.4	62.8 (8.0)	1.2	1.9	3.0%	5.3
ST_RNFL	µm	114.5 (17.2)	1.3	2.7	2.4%	7.6	111.8 (16.3)	1.5	2.7	2.4%	7.5
SN_RNFL	µm	109.8 (25.5)	1.1	1.9	1.8%	5.4	109.8 (25.0)	1.7	2.3	2.1%	6.6
NS_RNFL	µm	90.4 (15.8)	0.7	1.7	1.9%	4.8	90.3 (15.7)	1.4	2.1	2.3%	5.9
NI_RNFL	µm	70.9 (12.0)	0.9	2.0	2.9%	5.7	71.3 (12.3)	1.3	2.2	3.1%	6.2
IN_RNFL	µm	111.4 (19.5)	1.0	2.1	1.9%	5.9	111.0 (19.4)	1.6	2.6	2.3%	7.2
IT_RNFL	µm	132.7 (16.2)	1.1	2.6	2.0%	7.3	129.5 (15.5)	1.7	3.0	2.3%	8.4
TI_RNFL	µm	56.0 (7.5)	0.8	1.8	3.1%	4.9	56.6 (8.0)	1.3	2.3	4.0%	6.4
T_RNFL	µm	59.5 (7.1)	0.8	1.5	2.5%	4.2	59.9 (7.3)	1.0	1.6	2.6%	4.4
S_RNFL	µm	111.9 (16.2)	0.9	1.6	1.4%	4.3	110.7 (16.4)	1.2	1.8	1.6%	5.1
N_RNFL	µm	81.7 (12.9)	0.6	1.6	2.0%	4.5	81.8 (13.1)	1.0	1.7	2.0%	4.6
I_RNFL	µm	120.8 (14.0)	0.8	1.3	1.1%	3.7	119.1 (14.2)	1.2	1.7	1.5%	4.8
S-Hemi_RNFL	µm	93.0 (11.3)	0.5	1.0	1.1%	2.9	92.5 (11.4)	0.8	1.1	1.2%	3.0
I-Hemi_RNFL	µm	92.0 (10.2)	0.5	0.9	1.0%	2.6	91.4 (10.4)	0.8	1.1	1.3%	3.2
PP_RNFL	µm	92.5 (9.9)	0.4	0.9	0.9%	2.4	92.0 (10.1)	0.6	0.9	1.0%	2.5
ONH Parameters		Within Disc Margin									
Cup Area	mm ²	0.36 (0.28)	0.010	0.015	4.2%	0.042	0.33 (0.28)	0.018	0.024	7.1%	0.067
Rim Area	mm ²	1.4 (0.27)	0.012	0.064	4.7%	0.180	1.4 (0.28)	0.019	0.065	4.7%	0.180
C-D_Area_Ratio		0.20 (0.14)	0.006	0.011	5.8%	0.032	0.19 (0.14)	0.010	0.014	7.8%	0.040
C-D_H_Ratio		0.41 (0.22)	0.015	0.024	5.9%	0.068	0.39 (0.23)	0.020	0.024	6.3%	0.068
C-D_V_Ratio		0.39 (0.21)	0.011	0.021	5.3%	0.058	0.37 (0.22)	0.018	0.023	6.1%	0.063
CupVolume	mm ³	0.073 (0.085)	0.004	0.005	6.8%	0.014	0.065 (0.084)	0.007	0.012	18.5%	0.034
DiscArea	mm ²	1.7 (0.32)	0.003	0.064	3.8%	0.180	1.7 (0.32)	0.002	0.064	3.8%	0.180
*Reproducibility Limit = 2.8 x SD of Reproducibility											

*Reproducibility Limit = 2.8 x SD of Reproducibility

Table 15.1.3.1. Repeatability and Reproducibility of the Normal group.

Glaucoma Subjects											
Measurement	Unit	AngioVue Disc (N=225)					Disc Cube (N=225)				
		Mean (SD)	Repeatability	Reproducibility			Mean (SD)	Repeatability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*
RNFL		Ø2.5 ~ Ø4.5 mm Ring									
TS_RNFL	µm	54.3 (13.2)	1.0	1.5	2.7%	4.1	54.0 (13.1)	1.2	1.5	2.8%	4.3
ST_RNFL	µm	76.1 (31.0)	1.2	2.1	2.8%	6.0	73.4 (29.5)	1.3	2.4	3.2%	6.6
SN_RNFL	µm	71.1 (22.1)	1.0	1.7	2.3%	4.7	70.4 (22.1)	1.7	2.5	3.6%	7.1
NS_RNFL	µm	58.4 (17.5)	1.2	1.7	2.9%	4.8	58.5 (17.0)	1.8	2.1	3.7%	6.0
NI_RNFL	µm	49.7 (12.6)	1.1	1.4	2.8%	3.9	49.9 (12.6)	1.7	1.9	3.7%	5.2
IN_RNFL	µm	73.4 (23.4)	1.1	1.9	2.6%	5.4	72.4 (24.0)	1.8	2.2	3.1%	6.2
IT_RNFL	µm	76.7 (31.7)	0.9	2.0	2.6%	5.7	74.3 (30.5)	1.5	2.1	2.8%	5.8
TI_RNFL	µm	46.7 (9.6)	0.8	1.3	2.8%	3.7	46.5 (9.9)	1.7	2.0	4.3%	5.5
T_RNFL	µm	50.8 (10.6)	0.8	1.2	2.3%	3.3	50.5 (10.7)	1.2	1.4	2.9%	4.0
S_RNFL	µm	73.3 (23.1)	0.9	1.2	1.6%	3.3	71.8 (23.0)	1.1	1.9	2.6%	5.2
N_RNFL	µm	54.5 (14.5)	1.0	1.3	2.3%	3.5	54.7 (14.3)	1.5	1.7	3.0%	4.6
I_RNFL	µm	74.8 (25.7)	0.9	1.7	2.2%	4.7	73.2 (25.7)	1.4	1.7	2.3%	4.8
S-Hemi_RNFL	µm	63.9 (16.3)	0.7	0.8	1.3%	2.3	63.1 (16.4)	0.9	1.2	1.9%	3.4
I-Hemi_RNFL	µm	61.3 (16.4)	0.7	0.9	1.5%	2.6	60.5 (16.5)	0.9	1.1	1.8%	3.0
PP_RNFL	µm	62.6 (14.5)	0.6	0.7	1.2%	2.0	61.9 (14.7)	0.8	1.0	1.6%	2.7
ONH Parameters		Within Disc Margin									
Cup Area	mm ²	1.1 (0.53)	0.043	0.043	3.8%	0.120	1.1 (0.54)	0.035	0.048	4.2%	0.130
Rim Area	mm ²	0.69 (0.32)	0.047	0.071	10.3%	0.200	0.67 (0.32)	0.037	0.079	11.7%	0.220
C-D_Area_Ratio		0.60 (0.21)	0.021	0.026	4.4%	0.074	0.61 (0.21)	0.019	0.031	5.1%	0.087
C-D_H_Ratio		0.77 (0.21)	0.016	0.024	3.2%	0.068	0.78 (0.21)	0.029	0.037	4.7%	0.100
C-D_V_Ratio		0.77 (0.20)	0.019	0.024	3.2%	0.068	0.76 (0.21)	0.026	0.036	4.7%	0.100
CupVolume	mm ³	0.29 (0.17)	0.013	0.016	5.4%	0.043	0.28 (0.17)	0.020	0.025	8.7%	0.069
DiscArea	mm ²	1.8 (0.40)	0.004	0.069	3.8%	0.190	1.8 (0.40)	0.003	0.069	3.8%	0.190
*Reproducibility Limit = 2.8 x SD of Reproducibility											

Table 15.1.3.2. Repeatability and Reproducibility of the Glaucoma group.

Retina Subjects											
Measurement	Unit	AngioVue Disc (N=252)					Disc Cube (N=252)				
		Mean (SD)	Repeatability SD	Reproducibility			Mean (SD)	Repeatability SD	Reproducibility		
				SD	CV	Limit*			SD	CV	Limit*
RNFL		Ø2.5 ~ Ø4.5 mm Ring									
TS_RNFL	µm	64.1 (14.4)	1.4	2.2	3.5%	6.3	64.1 (14.1)	1.4	2.0	3.1%	5.5
ST_RNFL	µm	106.8 (27.8)	1.5	2.8	2.6%	7.9	104.2 (27.1)	2.1	3.3	3.1%	9.1
SN_RNFL	µm	101.5 (27.3)	1.3	2.7	2.6%	7.5	100.0 (26.7)	2.3	3.0	3.0%	8.5
NS_RNFL	µm	84.9 (19.9)	1.4	2.2	2.6%	6.2	85.1 (19.7)	2.1	2.4	2.8%	6.7
NI_RNFL	µm	69.0 (15.8)	1.2	2.1	3.1%	5.9	69.0 (15.9)	1.9	2.3	3.3%	6.4
IN_RNFL	µm	107.7 (24.7)	1.6	2.7	2.5%	7.5	106.7 (25.1)	2.2	2.9	2.7%	8.1
IT_RNFL	µm	123.6 (22.1)	2.0	3.2	2.6%	8.9	119.6 (22.3)	2.3	3.7	3.1%	10.5
TI_RNFL	µm	58.4 (11.9)	1.0	1.9	3.3%	5.3	58.4 (11.5)	1.2	2.1	3.6%	5.8
T_RNFL	µm	61.5 (12.7)	1.1	1.6	2.6%	4.4	61.5 (12.3)	1.1	1.4	2.3%	3.9
S_RNFL	µm	103.9 (23.0)	1.0	2.2	2.1%	6.2	101.9 (22.8)	1.8	2.7	2.6%	7.5
N_RNFL	µm	77.8 (17.2)	1.1	1.7	2.2%	4.8	77.9 (17.1)	1.5	1.8	2.3%	5.0
I_RNFL	µm	114.7 (20.2)	1.2	1.7	1.5%	4.8	112.4 (20.9)	1.7	2.1	1.8%	5.8
S-Hemi_RNFL	µm	88.2 (15.8)	0.8	1.5	1.7%	4.3	87.3 (15.7)	1.3	1.6	1.9%	4.6
I-Hemi_RNFL	µm	89.0 (14.2)	0.7	1.1	1.3%	3.2	87.9 (14.4)	1.0	1.3	1.5%	3.6
PP_RNFL	µm	88.6 (14.3)	0.7	1.2	1.4%	3.4	87.6 (14.4)	0.9	1.3	1.4%	3.5
ONH Parameters		Within Disc Margin									
Cup Area	mm ²	0.38 (0.30)	0.013	0.018	4.7%	0.051	0.37 (0.30)	0.016	0.020	5.5%	0.057
Rim Area	mm ²	1.4 (0.41)	0.014	0.072	5.2%	0.200	1.4 (0.41)	0.018	0.074	5.3%	0.210
C-D_Area_Ratio		0.22 (0.17)	0.008	0.014	6.4%	0.039	0.21 (0.17)	0.009	0.015	7.1%	0.042
C-D_H_Ratio		0.41 (0.24)	0.014	0.022	5.4%	0.062	0.39 (0.25)	0.022	0.027	7.0%	0.077
C-D_V_Ratio		0.41 (0.27)	0.011	0.017	4.2%	0.049	0.41 (0.27)	0.023	0.027	6.5%	0.074
CupVolume	mm ³	0.065 (0.075)	0.003	0.004	6.3%	0.011	0.060 (0.068)	0.012	0.012	19.7%	0.033
DiscArea	mm ²	1.8 (0.30)	0.003	0.069	3.9%	0.190	1.8 (0.30)	0.002	0.069	3.9%	0.190
*Reproducibility Limit = 2.8 x SD of Reproducibility											

Table 15.1.3.3. Repeatability and Reproducibility of the Retina group.

15.1.4 R&R Results – RPC Vessel Density

Table 15.1.3.2 summarizes the results of the R&R analysis of the RPC vessel density measurements from the AngioVue Disc scan and the Disc Cube scan.

AngioVue Disc	Unit	Normal Subjects (N=270)					Glaucoma Subjects (N=225)					Retina Subjects (N=252)				
		Mean (SD)	Repeat ability	Reproducibility			Mean (SD)	Repeat ability	Reproducibility			Mean (SD)	Repeat ability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*
RPC Vessel Density		Ø2.5 ~ Ø4.5 mm Ring														
TS_RPC_Sml	%	56.2 (3.9)	1.6	2.0	3.6%	5.6	53.8 (6.4)	1.9	2.5	4.7%	7.1	56.0 (4.3)	2.1	2.3	4.2%	6.5
ST_RPC_Sml	%	52.5 (4.4)	1.9	2.1	4.1%	6.0	42.1 (10.4)	2.2	2.8	6.6%	7.8	49.0 (6.3)	2.3	2.5	5.2%	7.1
SN_RPC_Sml	%	46.1 (4.2)	1.8	2.3	5.0%	6.4	38.6 (7.8)	2.2	2.6	6.6%	7.2	43.4 (5.7)	2.2	2.5	5.7%	6.9
NS_RPC_Sml	%	46.5 (4.0)	1.5	1.9	4.1%	5.3	37.2 (5.6)	2.0	2.8	7.6%	7.9	44.7 (4.8)	1.9	2.4	5.3%	6.6
NI_RPC_Sml	%	46.2 (3.8)	1.7	2.0	4.3%	5.5	39.8 (6.1)	2.9	3.2	8.0%	8.9	44.8 (5.4)	2.1	2.2	4.8%	6.1
IN_RPC_Sml	%	46.0 (4.5)	1.6	2.0	4.3%	5.5	37.7 (8.5)	2.4	3.2	8.5%	9.0	44.7 (5.5)	2.6	3.2	7.2%	9.0
IT_RPC_Sml	%	55.0 (3.2)	1.7	2.2	3.9%	6.0	44.1 (9.9)	2.2	2.7	6.0%	7.4	52.5 (4.8)	2.5	2.8	5.4%	7.9
TI_RPC_Sml	%	53.3 (4.1)	1.7	1.9	3.6%	5.4	49.7 (5.4)	2.0	2.5	5.1%	7.0	53.4 (3.9)	2.2	2.4	4.5%	6.7
S-Hemi_RPC_Sml	%	50.1 (3.1)	1.3	1.5	2.9%	4.1	42.7 (5.9)	1.4	2.0	4.8%	5.7	48.1 (3.9)	1.6	1.8	3.8%	5.1
I-Hemi_RPC_Sml	%	49.7 (3.1)	1.1	1.3	2.7%	3.8	42.5 (5.8)	1.8	2.1	5.0%	5.9	48.5 (3.6)	1.6	1.8	3.7%	5.0
PP_RPC_Sml	%	49.9 (2.9)	1.1	1.3	2.6%	3.6	42.6 (5.2)	1.5	1.9	4.5%	5.4	48.3 (3.5)	1.5	1.7	3.4%	4.7
S-Hemi_RPC_All	%	56.5 (3.0)	1.1	1.2	2.1%	3.3	49.7 (5.5)	1.2	1.7	3.3%	4.6	54.5 (3.7)	1.3	1.5	2.7%	4.1
I-Hemi_RPC_All	%	55.9 (3.0)	1.0	1.1	1.9%	3.0	49.0 (5.2)	1.6	1.8	3.7%	5.1	54.3 (3.6)	1.4	1.5	2.8%	4.2
PP_RPC_All	%	56.2 (2.8)	1.0	1.0	1.9%	2.9	49.3 (4.8)	1.3	1.6	3.2%	4.5	54.4 (3.5)	1.3	1.4	2.5%	3.8
RPC Vessel Density		6 mm x 6 mm														
WI_RPC_Sml	%	47.5 (2.7)	0.9	1.2	2.5%	3.3	41.6 (4.1)	1.3	1.8	4.3%	5.0	46.6 (2.9)	1.1	1.4	3.0%	4.0
WI_RPC_All	%	53.7 (2.6)	0.9	1.2	2.2%	3.4	48.2 (3.7)	1.2	1.6	3.3%	4.4	52.7 (2.8)	1.0	1.3	2.5%	3.6

Table 15.1.3.2. Repeatability and Reproducibility of the Normal, Glaucoma, and Retina groups.

15.2 Evaluation of the Agreement of Solix to Avanti for Posterior Segment Measurements and to iCam for Fundus Photo Quality in Normal Subjects, Retinal Patients, and Glaucoma Patients

Same study cohort as for R&R study above was used for agreement analysis of Solix vs Avanti XR. First qualifying scans per subject (eye) and per scan pattern were compared.

15.2.1 Agreement Results - GCC and Retinal Thickness

Tables 15.2.1.1 through 15.2.1.3 summarize the results of the agreement analysis of the GCC measurements from AngioVue Retina, Retina Cube, and Wellness scans.

AngioVue Retina		Normal (n=30 subjects)			Glaucoma (n=25 subjects)			Retina (n=28 subjects)		
		Difference			Difference			Difference		
		Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]
GCC		ø6 mm ETDRS Grid								
C(1)_GCC	µm	0.00 (1.80)	-3.5 [-4.7, -2.4]	3.5 [2.4, 4.7]	-0.61 (1.53)	-3.6 [-4.7, -2.5]	2.4 [1.3, 3.5]	-1.33 (2.47)	-6.2 [-7.9, -4.5]	3.5 [1.8, 5.2]
T(1-3)_GCC	µm	0.39 (1.61)	-2.8 [-3.8, -1.7]	3.5 [2.5, 4.6]	-1.94 (1.42)	-4.7 [-5.7, -3.7]	0.8 [-0.2, 1.9]	-0.74 (2.36)	-5.4 [-7.0, -3.7]	3.9 [2.3, 5.5]
S(1-3)_GCC	µm	-1.63 (2.03)	-5.6 [-6.9, -4.3]	2.3 [1.0, 3.7]	-2.54 (2.45)	-7.4 [-9.1, -5.6]	2.3 [0.5, 4.0]	-2.80 (2.20)	-7.1 [-8.6, -5.6]	1.5 [0.0, 3.0]
N(1-3)_GCC	µm	-0.75 (1.76)	-4.2 [-5.3, -3.1]	2.7 [1.6, 3.8]	-2.06 (1.77)	-5.5 [-6.8, -4.3]	1.4 [0.1, 2.7]	-1.40 (2.20)	-5.7 [-7.2, -4.2]	2.9 [1.4, 4.4]
I(1-3)_GCC	µm	-2.26 (1.85)	-5.9 [-7.1, -4.7]	1.4 [0.2, 2.6]	-3.31 (1.52)	-6.3 [-7.4, -5.2]	-0.3 [-1.4, 0.8]	-2.57 (2.33)	-7.1 [-8.7, -5.5]	2.0 [0.4, 3.6]
T(3-6)_GCC	µm	0.39 (1.74)	-3.0 [-4.1, -1.9]	3.8 [2.7, 4.9]	-1.59 (1.11)	-3.8 [-4.6, -3.0]	0.6 [-0.2, 1.4]	-0.97 (1.82)	-4.5 [-5.8, -3.3]	2.6 [1.4, 3.9]
S(3-6)_GCC	µm	-1.87 (1.78)	-5.4 [-6.5, -4.2]	1.6 [0.5, 2.8]	-3.27 (1.67)	-6.5 [-7.7, -5.3]	-0.0 [-1.2, 1.2]	-2.87 (1.93)	-6.7 [-8.0, -5.3]	0.9 [-0.4, 2.2]
N(3-6)_GCC	µm	-0.85 (1.61)	-4.0 [-5.1, -3.0]	2.3 [1.3, 3.4]	-1.06 (1.45)	-3.9 [-4.9, -2.9]	1.8 [0.7, 2.8]	-1.69 (2.02)	-5.6 [-7.0, -4.3]	2.3 [0.9, 3.6]
I(3-6)_GCC	µm	-1.97 (1.87)	-5.6 [-6.8, -4.4]	1.7 [0.5, 2.9]	-2.63 (1.58)	-5.7 [-6.9, -4.6]	0.5 [-0.7, 1.6]	-2.21 (1.97)	-6.1 [-7.4, -4.7]	1.7 [0.3, 3.0]
S-Hemi(0-6)_GCC	µm	-0.96 (1.50)	-3.9 [-4.9, -2.9]	2.0 [1.0, 2.9]	-2.32 (1.24)	-4.8 [-5.7, -3.9]	0.1 [-0.8, 1.0]	-2.10 (1.71)	-5.5 [-6.6, -4.3]	1.3 [0.1, 2.4]
I-Hemi(0-6)_GCC	µm	-1.17 (1.43)	-4.0 [-4.9, -3.1]	1.6 [0.7, 2.6]	-2.08 (0.96)	-4.0 [-4.7, -3.3]	-0.2 [-0.9, 0.5]	-1.80 (1.61)	-4.9 [-6.0, -3.8]	1.4 [0.3, 2.4]
All(0-6)_GCC	µm	-1.06 (1.34)	-3.7 [-4.6, -2.8]	1.6 [0.7, 2.4]	-2.20 (0.74)	-3.7 [-4.2, -3.1]	-0.7 [-1.3, -0.2]	-1.96 (1.35)	-4.6 [-5.5, -3.7]	0.7 [-0.2, 1.6]
GCC		6mm x 6mm								
WI_GCC	µm	-2.58 (1.60)	-5.7 [-6.7, -4.7]	0.6 [-0.5, 1.6]	-2.71 (1.20)	-5.1 [-5.9, -4.2]	-0.4 [-1.2, 0.5]	-3.41 (2.00)	-7.3 [-8.7, -6.0]	0.5 [-0.9, 1.9]
WI-S-Hemi_GCC	µm	-2.61 (1.81)	-6.2 [-7.3, -5.0]	0.9 [-0.2, 2.1]	-3.21 (1.50)	-6.2 [-7.2, -5.1]	-0.3 [-1.3, 0.8]	-3.43 (2.27)	-7.9 [-9.4, -6.3]	1.0 [-0.5, 2.6]
WI-I-Hemi_GCC	µm	-2.56 (1.65)	-5.8 [-6.9, -4.7]	0.7 [-0.4, 1.7]	-2.26 (1.75)	-5.7 [-6.9, -4.4]	1.2 [-0.1, 2.4]	-3.44 (2.34)	-8.0 [-9.6, -6.4]	1.2 [-0.5, 2.8]
Retinal Thickness		ø6 mm ETDRS Grid								
C(1)_R	µm	-3.80 (2.80)	-9.3 [-11.1, -7.5]	1.7 [-0.1, 3.5]	-1.80 (3.92)	-9.5 [-12.3, -6.7]	5.9 [3.1, 8.7]	2.42 (7.89)	-13.1 [-18.5, -7.6]	17.9 [12.5, 23.3]
T(1-3)_R	µm	0.39 (2.58)	-4.7 [-6.3, -3.0]	5.4 [3.8, 7.1]	-0.14 (3.81)	-7.6 [-10.3, -4.9]	7.3 [4.6, 10.0]	4.70 (5.99)	-7.0 [-11.1, -2.9]	16.4 [12.3, 20.5]
S(1-3)_R	µm	-0.07 (3.10)	-6.1 [-8.1, -4.1]	6.0 [4.0, 8.0]	0.79 (3.40)	-5.9 [-8.3, -3.4]	7.5 [5.0, 9.9]	3.40 (4.74)	-5.9 [-9.1, -2.6]	12.7 [9.4, 15.9]
N(1-3)_R	µm	-0.58 (2.54)	-5.6 [-7.2, -3.9]	4.4 [2.8, 6.1]	-0.01 (3.20)	-6.3 [-8.6, -4.0]	6.3 [4.0, 8.6]	3.59 (5.31)	-6.8 [-10.5, -3.2]	14.0 [10.4, 17.6]
I(1-3)_R	µm	0.66 (3.01)	-5.2 [-7.2, -3.3]	6.5 [4.6, 8.5]	0.38 (3.15)	-5.8 [-8.0, -3.5]	6.6 [4.3, 8.8]	3.72 (4.17)	-4.5 [-7.3, -1.6]	11.9 [9.0, 14.7]
T(3-6)_R	µm	2.02 (3.95)	-5.7 [-8.3, -3.2]	9.8 [7.2, 12.3]	1.59 (3.93)	-6.1 [-8.9, -3.3]	9.3 [6.5, 12.1]	4.05 (4.57)	-4.9 [-8.0, -1.8]	13.0 [9.9, 16.1]
S(3-6)_R	µm	0.78 (3.41)	-5.9 [-8.1, -3.7]	7.5 [5.3, 9.7]	1.10 (3.36)	-5.5 [-7.9, -3.1]	7.7 [5.3, 10.1]	3.69 (3.52)	-3.2 [-5.6, -0.8]	10.6 [8.2, 13.0]
N(3-6)_R	µm	1.05 (4.01)	-6.8 [-9.4, -4.2]	8.9 [6.3, 11.5]	0.96 (3.83)	-4.6 [-6.6, -2.6]	6.5 [4.5, 8.5]	4.06 (3.45)	-2.7 [-5.1, -0.3]	10.8 [8.5, 13.2]
I(3-6)_R	µm	2.91 (3.30)	-3.6 [-5.7, -1.4]	9.4 [7.2, 11.5]	2.32 (2.51)	-2.6 [-4.4, -0.8]	7.2 [5.4, 9.0]	4.60 (3.14)	-1.6 [-3.7, 0.6]	10.8 [8.6, 12.9]
S-Hemi(0-6)_R	µm	0.70 (3.02)	-5.2 [-7.2, -3.3]	6.6 [4.7, 8.6]	0.91 (3.10)	-5.2 [-7.4, -2.9]	7.0 [4.8, 9.2]	4.03 (3.80)	-3.4 [-6.0, -0.8]	11.5 [8.9, 14.1]
I-Hemi(0-6)_R	µm	1.72 (3.16)	-4.5 [-6.5, -2.4]	7.9 [5.9, 9.9]	1.34 (2.67)	-3.9 [-5.8, -2.0]	6.6 [4.7, 8.5]	3.97 (3.42)	-2.7 [-5.1, -0.4]	10.7 [8.3, 13.0]
All(0-6)_R	µm	1.21 (3.03)	-4.7 [-6.7, -2.8]	7.1 [5.2, 9.1]	1.14 (2.80)	-4.4 [-6.4, -2.3]	6.6 [4.6, 8.6]	4.00 (3.40)	-2.7 [-5.0, -0.3]	10.7 [8.3, 13.0]

Table 15.2.1.1. Agreement between Avanti HD AngioRetina scan and Solix AngioVue Retina scan .

Retina Cube		Normal (n=30 subjects)			Glaucoma (n=25 subjects)			Retina (n=28 subjects)		
		Difference			Difference			Difference		
		Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]
GCC		ø6 mm ETDRS Grid								
C(1)_GCC	µm	-0.27 (1.79)	-3.8 [-4.9, -2.6]	3.2 [2.1, 4.4]	-0.70 (2.19)	-5.0 [-6.6, -3.4]	3.6 [2.0, 5.2]	-1.00 (2.96)	-6.8 [-8.8, -4.8]	4.8 [2.8, 6.8]
T(1-3)_GCC	µm	-0.57 (1.35)	-3.2 [-4.1, -2.3]	2.1 [1.2, 3.0]	-2.28 (1.61)	-5.4 [-6.6, -4.3]	0.9 [-0.3, 2.0]	-0.53 (2.04)	-4.5 [-5.9, -3.2]	3.5 [2.1, 4.9]
S(1-3)_GCC	µm	-1.55 (1.95)	-5.4 [-6.6, -4.1]	2.3 [1.0, 3.5]	-1.70 (2.09)	-5.8 [-7.3, -4.3]	2.4 [0.9, 3.9]	-1.45 (2.26)	-5.9 [-7.4, -4.4]	3.0 [1.5, 4.5]
N(1-3)_GCC	µm	-1.12 (2.10)	-5.2 [-6.6, -3.9]	3.0 [1.6, 4.3]	-2.16 (1.70)	-5.5 [-6.7, -4.3]	1.2 [-0.0, 2.4]	-1.55 (2.20)	-5.9 [-7.3, -4.4]	2.8 [1.3, 4.2]
I(1-3)_GCC	µm	-1.71 (1.99)	-5.6 [-6.9, -4.3]	2.2 [0.9, 3.5]	-2.56 (1.87)	-6.2 [-7.6, -4.9]	1.1 [-0.2, 2.4]	-1.43 (1.91)	-5.2 [-6.5, -3.9]	2.3 [1.0, 3.6]
T(3-6)_GCC	µm	-0.28 (1.65)	-3.5 [-4.6, -2.5]	3.0 [1.9, 4.0]	-1.55 (1.30)	-4.1 [-5.0, -3.2]	1.0 [0.1, 1.9]	-0.86 (1.74)	-4.3 [-5.4, -3.1]	2.6 [1.4, 3.7]
S(3-6)_GCC	µm	-0.83 (1.65)	-4.1 [-5.1, -3.0]	2.4 [1.3, 3.5]	-1.74 (1.71)	-5.1 [-6.3, -3.9]	1.6 [0.4, 2.8]	-1.17 (1.95)	-5.0 [-6.3, -3.7]	2.6 [1.3, 4.0]
N(3-6)_GCC	µm	-0.29 (1.58)	-3.4 [-4.4, -2.4]	2.8 [1.8, 3.8]	0.06 (1.34)	-2.6 [-3.5, -1.6]	2.7 [1.7, 3.6]	-0.47 (2.27)	-4.9 [-6.4, -3.4]	4.0 [2.5, 5.5]
I(3-6)_GCC	µm	-1.02 (1.83)	-4.6 [-5.8, -3.4]	2.6 [1.4, 3.7]	-1.10 (2.07)	-5.2 [-6.6, -3.7]	3.0 [1.5, 4.4]	-0.80 (2.05)	-4.8 [-6.2, -3.4]	3.2 [1.8, 4.6]
S-Hemi(0-6)_GCC	µm	-0.71 (1.32)	-3.3 [-4.2, -2.4]	1.9 [1.0, 2.7]	-1.49 (1.39)	-4.2 [-5.2, -3.2]	1.2 [0.2, 2.2]	-1.05 (1.54)	-4.1 [-5.1, -3.0]	2.0 [0.9, 3.0]
I-Hemi(0-6)_GCC	µm	-0.80 (1.34)	-3.4 [-4.3, -2.6]	1.8 [1.0, 2.7]	-1.20 (1.08)	-3.3 [-4.1, -2.5]	0.9 [0.2, 1.7]	-0.83 (1.52)	-3.8 [-4.8, -2.8]	2.1 [1.1, 3.2]
All(0-6)_GCC	µm	-0.76 (1.20)	-3.1 [-3.9, -2.3]	1.6 [0.8, 2.4]	-1.34 (1.00)	-3.3 [-4.0, -2.6]	0.6 [-0.1, 1.3]	-0.96 (1.29)	-3.5 [-4.4, -2.6]	1.6 [0.7, 2.4]
GCC		6mm x 6mm								
WI_GCC	µm	-2.14? (1.50)	-5.1 [-6.1, -4.1]	0.8 [-0.2, 1.8]	-1.78 (1.08)	-3.9 [-4.7, -3.1]	0.3 [-0.4, 1.1]	-2.36 (2.09)	-6.5 [-7.9, -5.1]	1.7 [0.3, 3.1]
WI-S-Hemi_GCC	µm	-2.24? (1.66)	-5.5 [-6.6, -4.4]	1.0 [-0.0, 2.1]	-2.30 (1.65)	-5.5 [-6.7, -4.4]	0.9 [-0.2, 2.1]	-2.33 (2.22)	-6.7 [-8.2, -5.2]	2.0 [0.5, 3.5]
WI-I-Hemi_GCC	µm	-2.08? (1.60)	-5.2 [-6.2, -4.2]	1.0 [0.0, 2.1]	-1.28 (1.25)	-3.7 [-4.6, -2.8]	1.2 [0.3, 2.1]	-2.50 (2.39)	-7.2 [-8.8, -5.6]	2.2 [0.6, 3.8]
Retinal Thickness		ø6 mm ETDRS Grid								
C(1)_R	µm	-4.30 (3.74)	-11.6 [-14.1, -9.2]	3.0 [0.6, 5.5]	-2.94 (3.45)	-9.7 [-12.2, -7.2]	3.8 [1.3, 6.3]	1.32? (7.84)	-14.0 [-19.3, -8.8]	16.7 [11.4, 21.9]
T(1-3)_R	µm	-1.06 (3.33)	-7.6 [-9.7, -5.4]	5.5 [3.3, 7.6]	-1.98 (3.91)	-9.6 [-12.4, -6.9]	5.7 [2.9, 8.5]	3.45? (5.95)	-8.2 [-12.2, -4.2]	15.1 [11.1, 19.1]
S(1-3)_R	µm	-1.00 (3.59)	-8.0 [-10.4, -5.7]	6.0 [3.7, 8.4]	-0.86 (2.83)	-6.4 [-8.4, -4.4]	4.7 [2.7, 6.7]	2.17? (5.08)	-7.8 [-11.2, -4.4]	12.1 [8.7, 15.5]
N(1-3)_R	µm	-1.77 (3.23)	-8.1 [-10.2, -6.0]	4.6 [2.5, 6.6]	-2.34 (3.21)	-8.6 [-10.9, -6.3]	4.0 [1.7, 6.3]	1.74? (5.46)	-8.9 [-12.6, -5.3]	12.4 [8.8, 16.1]
I(1-3)_R	µm	-0.68 (3.17)	-6.9 [-8.9, -4.8]	5.5 [3.5, 7.6]	-1.31 (3.61)	-8.4 [-11.0, -5.8]	5.8 [3.2, 8.4]	2.29? (4.56)	-6.6 [-9.7, -3.6]	11.2 [8.2, 14.3]
T(3-6)_R	µm	-0.56 (4.03)	-8.5 [-11.1, -5.9]	7.4 [4.7, 10.0]	-0.98 (4.23)	-9.3 [-12.3, -6.2]	7.3 [4.3, 10.3]	2.19? (4.72)	-7.1 [-10.2, -3.9]	11.4 [8.3, 14.6]
S(3-6)_R	µm	-0.56 (3.58)	-7.7 [-9.9, -5.3]	6.4 [4.1, 8.8]	-1.02 (3.43)	-7.7 [-10.2, -5.3]	5.7 [3.2, 8.1]	2.57? (4.04)	-5.3 [-8.1, -2.6]	10.5 [7.8, 13.2]
N(3-6)_R	µm	-0.48 (4.40)	-9.1 [-12.0, -6.3]	8.2 [5.3, 11.0]	-1.38 (3.18)	-7.6 [-9.9, -5.3]	4.8 [2.6, 7.1]	2.78? (4.36)	-5.8 [-8.7, -2.8]	11.3 [8.4, 14.2]
I(3-6)_R	µm	1.46 (3.54)	-5.5 [-7.8, -3.2]	8.4 [6.1, 10.7]	0.98 (3.08)	-5.1 [-7.3, -2.9]	7.0 [4.8, 9.2]	3.02? (3.09)	-3.0 [-5.1, -1.0]	9.1 [7.0, 11.2]
S-Hemi(0-6)_R	µm	-0.73 (3.34)	-7.3 [-9.4, -5.1]	5.8 [3.7, 8.0]	-1.25 (2.96)	-7.0 [-9.2, -4.9]	4.6 [2.4, 6.7]	2.66? (4.33)	-5.8 [-8.7, -2.9]	11.1 [8.2, 14.1]
I-Hemi(0-6)_R	µm	-0.01 (3.32)	-6.5 [-8.7, -4.4]	6.5 [4.4, 8.6]	-0.53 (3.25)	-6.9 [-9.2, -4.6]	5.8 [3.5, 8.2]	2.47? (3.54)	-4.5 [-6.8, -2.1]	9.4 [7.0, 11.8]
All(0-6)_R	µm	-0.37 (3.23)	-6.7 [-8.8, -4.6]	6.0 [3.9, 8.0]	-0.90 (3.00)	-6.8 [-8.9, -4.6]	5.0 [2.8, 7.1]	2.56? (3.78)	-4.8 [-7.4, -2.3]	10.0 [7.4, 12.5]

Table 15.2.1.2. Agreement between Avanti HD AngioRetina and Solix Retina Cube scan .

Wellness		Normal (n=30 subjects)			Glaucoma (n=25 subjects)			Retina (n=28 subjects)		
		Difference			Difference			Difference		
		Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]
GCC		ø6 mm ETDRS Grid								
C(1)_GCC	µm	-6.99 (3.08)	-13.0 [-15.0, -11.0]	-1.0 [-2.9, 1.0]	-7.14 (1.88)	-10.8 [-12.2, -9.5]	-3.5 [-4.8, -2.1]	-5.80 (6.50)	-18.5 [-22.9, -14.2]	6.9 [2.6, 11.3]
T(1-3)_GCC	µm	0.38 (1.68)	-2.9 [-4.0, -1.8]	3.7 [2.6, 4.8]	-1.23 (2.12)	-5.4 [-6.9, -3.9]	2.9 [1.4, 4.4]	1.32 (6.52)	-11.5 [-15.8, -7.1]	14.1 [9.7, 18.5]
S(1-3)_GCC	µm	1.46 (3.01)	-4.4 [-6.4, -2.5]	7.4 [5.4, 9.3]	1.14 (3.97)	-6.6 [-9.5, -3.8]	8.9 [6.1, 11.7]	1.77 (8.21)	-14.3 [-19.8, -8.8]	17.9 [12.4, 23.4]
N(1-3)_GCC	µm	-0.17 (1.87)	-3.8 [-5.0, -2.6]	3.5 [2.3, 4.7]	-1.43 (2.38)	-6.1 [-7.8, -4.4]	3.2 [1.5, 4.9]	1.22 (6.93)	-12.4 [-17.0, -7.7]	14.8 [10.2, 19.5]
I(1-3)_GCC	µm	2.01 (3.06)	-4.0 [-6.0, -2.0]	8.0 [6.0, 10.0]	1.81 (3.95)	-5.9 [-8.8, -3.1]	9.6 [6.7, 12.4]	1.95 (6.70)	-11.2 [-15.7, -6.7]	15.1 [10.6, 19.6]
T(3-6)_GCC	µm	4.36 (1.90)	0.6 [-0.6, 1.9]	8.1 [6.9, 9.3]	1.72 (1.80)	-1.8 [-3.1, -0.5]	5.2 [4.0, 6.5]	4.38 (6.26)	-7.9 [-12.1, -3.7]	16.6 [12.4, 20.8]
S(3-6)_GCC	µm	8.02 (3.71)	0.8 [-1.6, 3.1]	15.3 [12.9, 17.7]	5.82 (3.86)	-1.7 [-4.5, 1.0]	13.4 [10.6, 16.1]	8.60 (7.03)	-5.2 [-9.9, -0.5]	22.4 [17.7, 27.1]
N(3-6)_GCC	µm	3.33 (2.26)	-1.1 [-2.6, 0.4]	7.8 [6.3, 9.2]	5.56 (2.25)	1.1 [-0.5, 2.8]	10.0 [8.4, 11.6]	5.40 (4.26)	-3.0 [-5.8, -0.1]	13.8 [10.9, 16.6]
I(3-6)_GCC	µm	3.08 (4.07)	-4.9 [-7.5, -2.3]	11.1 [8.4, 13.7]	3.62 (5.30)	-6.8 [-10.6, -3.0]	14.0 [10.2, 17.8]	4.92 (6.85)	-8.5 [-13.1, -3.9]	18.3 [13.8, 22.9]
S-Hemi(0-6)_GCC	µm	4.79 (2.04)	0.8 [-0.5, 2.1]	8.8 [7.5, 10.1]	3.68 (2.37)	-1.0 [-2.7, 0.7]	8.3 [6.6, 10.0]	5.39 (5.28)	-5.0 [-8.5, -1.4]	15.7 [12.2, 19.3]
I-Hemi(0-6)_GCC	µm	2.70 (2.31)	-1.8 [-3.3, -0.3]	7.2 [5.7, 8.7]	3.14 (3.08)	-2.9 [-5.1, -0.7]	9.2 [7.0, 11.4]	4.00 (5.16)	-6.1 [-9.6, -2.7]	14.1 [10.7, 17.6]
All(0-6)_GCC	µm	3.75 (1.96)	-0.1 [-1.4, 1.2]	7.6 [6.3, 8.8]	3.40 (2.40)	-1.3 [-3.0, 0.4]	8.1 [6.4, 9.8]	4.70 (4.75)	-4.6 [-7.8, -1.4]	14.0 [10.8, 17.2]
GCC		6mm x 6mm								
WI_GCC	µm	8.83 (2.40)	4.1 [2.6, 5.7]	13.5 [12.0, 15.1]	6.53 (2.71)	1.2 [-0.7, 3.2]	11.8 [9.9, 13.8]	8.70 (5.20)	-1.5 [-5.0, 2.0]	18.9 [15.4, 22.4]
WI-S-Hemi_GCC	µm	8.67 (2.60)	3.6 [1.9, 5.2]	13.8 [12.1, 15.5]	6.24 (3.13)	0.1 [-2.1, 2.3]	12.4 [10.1, 14.6]	8.81 (5.10)	-1.2 [-4.6, 2.2]	18.8 [15.4, 22.2]
WI-I-Hemi_GCC	µm	9.00 (2.65)	3.8 [2.1, 5.5]	14.2 [12.5, 15.9]	6.79 (3.18)	0.5 [-1.7, 2.8]	13.0 [10.8, 15.3]	8.50 (6.06)	-3.4 [-7.4, 0.7]	20.4 [16.3, 24.4]
Retinal Thickness		ø6 mm ETDRS Grid								
C(1)_R	µm	-3.44 (3.98)	-11.2 [-13.8, -8.7]	4.4 [1.8, 6.9]	-1.33 (3.18)	-7.6 [-9.8, -5.3]	4.9 [2.6, 7.2]	3.46 (7.81)	-11.8 [-17.1, -6.6]	18.8 [13.5, 24.0]
T(1-3)_R	µm	0.28 (3.04)	-5.7 [-7.6, -3.7]	6.2 [4.3, 8.2]	0.60 (3.68)	-6.6 [-9.3, -4.0]	7.8 [5.2, 10.5]	5.01 (5.70)	-6.2 [-10.0, -2.3]	16.2 [12.4, 20.0]
S(1-3)_R	µm	1.24 (3.74)	-6.1 [-8.5, -3.7]	8.6 [6.2, 11.0]	1.57 (4.03)	-6.3 [-9.2, -3.4]	9.5 [6.6, 12.3]	4.50 (5.22)	-5.7 [-9.2, -2.2]	14.7 [11.2, 18.2]
N(1-3)_R	µm	1.33 (2.82)	-4.2 [-6.0, -2.4]	6.9 [5.0, 8.7]	1.17 (3.31)	-5.3 [-7.7, -3.0]	7.7 [5.3, 10.0]	5.19 (5.40)	-5.4 [-9.0, -1.8]	15.8 [12.1, 19.4]
I(1-3)_R	µm	0.44 (3.00)	-5.4 [-7.4, -3.5]	6.3 [4.4, 8.3]	0.03 (3.11)	-6.1 [-8.3, -3.8]	6.1 [3.9, 8.3]	4.17 (4.78)	-5.2 [-8.4, -2.0]	13.5 [10.3, 16.7]
T(3-6)_R	µm	-9.75 (4.07)	-17.7 [-20.3, -15.1]	-1.8 [-4.4, 0.8]	-7.72 (4.23)	-16.0 [-19.0, -13.0]	0.6 [-2.5, 3.6]	-4.79 (6.72)	-18.0 [-22.5, -13.5]	8.4 [3.9, 12.9]
S(3-6)_R	µm	-6.85 (3.98)	-14.7 [-17.2, -12.1]	1.0 [-1.6, 3.5]	-6.48 (4.68)	-15.6 [-19.0, -12.3]	2.7 [-0.7, 6.0]	-1.56 (6.62)	-14.5 [-19.0, -10.1]	11.4 [7.0, 15.9]
N(3-6)_R	µm	-0.70 (5.90)	-12.3 [-16.1, -8.4]	10.9 [7.1, 14.7]	-2.24 (4.67)	-11.4 [-14.7, -8.1]	6.9 [3.6, 10.2]	1.83 (7.15)	-12.2 [-17.0, -7.4]	15.8 [11.1, 20.6]
I(3-6)_R	µm	-6.73 (4.29)	-15.1 [-17.9, -12.4]	1.7 [-1.1, 4.5]	-6.48 (3.92)	-14.2 [-17.0, -11.4]	1.2 [-1.6, 4.0]	-2.63 (6.55)	-15.5 [-19.9, -11.1]	10.2 [5.8, 14.6]
S-Hemi(0-6)_R	µm	-4.16 (3.65)	-11.3 [-13.7, -9.0]	3.0 [0.6, 5.3]	-3.63 (3.88)	-11.2 [-14.0, -8.5]	4.0 [1.2, 6.7]	0.37 (5.49)	-10.4 [-14.1, -6.7]	11.1 [7.4, 14.8]
I-Hemi(0-6)_R	µm	-4.63 (3.86)	-12.2 [-14.7, -9.7]	2.9 [0.4, 5.4]	-4.67 (3.38)	-11.3 [-13.7, -8.9]	2.0 [-0.5, 4.4]	-0.73 (5.51)	-11.5 [-15.2, -7.8]	10.1 [6.4, 13.8]
All(0-6)_R	µm	-4.38 (3.67)	-11.6 [-13.9, -9.2]	2.8 [0.4, 5.2]	-4.13 (3.45)	-10.9 [-13.4, -8.4]	2.6 [0.2, 5.1]	-0.16 (5.34)	-10.6 [-14.2, -7.0]	10.3 [6.7, 13.9]

Table 15.2.1.3. Agreement between Avanti HD AngioRetina and Solix Wellness scan .

15.2.2 Agreement Results – RNFL Thickness and ONH Parameters

Tables 15.2.3.1 and 15.2.3.2 summarize the results of the agreement results for RNFL thickness and ONH parameters for AngioVue Disc and Disc Cube scans.

AngioVue Disc		Normal (n=30 subjects)			Glaucoma (n=25 subjects)			Retina (n=28 subjects)		
		Difference			Difference			Difference		
		Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]
RNFL										
Ø2.5 ~ Ø4.5 mm Ring for Solix vs Ø2.0 ~ Ø4.0 mm Ring for Avanti XR										
TS_RNFL	µm	9.88 (3.54)	2.9 [0.6, 5.2]	16.8 [14.5, 19.1]	7.55 (4.12)	-0.5 [-3.5, 2.4]	15.6 [12.7, 18.6]	6.51 (6.85)	-6.9 [-11.6, -2.2]	19.9 [15.2, 24.6]
ST_RNFL	µm	8.57 (4.88)	-1.0 [-4.1, 2.2]	18.1 [15.0, 21.3]	4.70 (4.20)	-3.5 [-6.5, -0.5]	12.9 [9.9, 15.9]	9.32 (7.00)	-4.4 [-9.1, 0.3]	23.0 [18.4, 27.7]
SN_RNFL	µm	20.14 (6.91)	6.6 [2.1, 11.1]	33.7 [29.2, 38.1]	10.87 (5.80)	-0.5 [-4.6, 3.6]	22.2 [18.1, 26.4]	17.18 (10.15)	-2.7 [-9.5, 4.1]	37.1 [30.3, 43.9]
NS_RNFL	µm	18.82 (5.83)	7.4 [3.6, 11.1]	30.3 [26.5, 34.0]	11.07 (7.90)	-4.4 [-10.1, 1.2]	26.5 [20.9, 32.2]	13.77 (7.99)	-1.9 [-7.2, 3.5]	29.4 [24.1, 34.8]
NI_RNFL	µm	17.37 (6.15)	5.3 [1.3, 9.3]	29.4 [25.5, 33.4]	11.79 (7.45)	-2.8 [-8.1, 2.5]	26.4 [21.1, 31.7]	16.19 (5.75)	4.9 [1.1, 8.8]	27.5 [23.6, 31.3]
IN_RNFL	µm	22.96 (6.82)	9.6 [5.2, 14.0]	36.3 [31.9, 40.7]	11.83 (6.69)	-1.3 [-6.1, 3.5]	24.9 [20.2, 29.7]	21.12 (7.81)	5.8 [0.6, 11.1]	36.4 [31.2, 41.7]
IT_RNFL	µm	8.05 (5.67)	-3.1 [-6.7, 0.6]	19.2 [15.5, 22.8]	4.37 (4.21)	-3.9 [-6.9, -0.9]	12.6 [9.6, 15.6]	7.23 (8.25)	-8.9 [-14.5, -3.4]	23.4 [17.9, 28.9]
TI_RNFL	µm	9.82 (3.48)	3.0 [0.8, 5.2]	16.6 [14.4, 18.9]	7.66 (3.93)	-0.1 [-2.9, 2.8]	15.4 [12.5, 18.2]	6.85 (3.17)	0.6 [-1.5, 2.8]	13.1 [10.9, 15.2]
T_RNFL	µm	9.84 (3.09)	3.8 [1.8, 5.8]	15.9 [13.9, 17.9]	7.58 (3.14)	1.4 [-0.8, 3.7]	13.7 [11.5, 16.0]	6.86 (4.52)	-2.0 [-5.0, 1.0]	15.7 [12.7, 18.7]
S_RNFL	µm	14.89 (4.47)	6.1 [3.2, 9.0]	23.7 [20.8, 26.5]	8.06 (4.04)	0.1 [-2.8, 3.0]	16.0 [13.1, 18.9]	13.60 (6.52)	0.8 [-3.6, 5.2]	26.4 [22.0, 30.8]
N_RNFL	µm	18.17 (5.46)	7.5 [3.9, 11.0]	28.9 [25.4, 32.4]	11.39 (6.80)	-1.9 [-6.8, 2.9]	24.7 [19.9, 29.6]	14.87 (5.62)	3.9 [0.1, 7.6]	25.9 [22.1, 29.6]
I_RNFL	µm	16.34 (4.52)	7.5 [4.6, 10.4]	25.2 [22.3, 28.1]	8.54 (4.39)	-0.1 [-3.2, 3.1]	17.2 [14.0, 20.3]	14.98 (6.29)	2.7 [-1.6, 6.9]	27.3 [23.1, 31.5]
S-Hemi_RNFL	µm	15.09 (3.50)	8.2 [6.0, 10.5]	22.0 [19.7, 24.2]	8.96 (3.56)	2.0 [-0.5, 4.5]	15.9 [13.4, 18.5]	12.15 (4.31)	3.7 [0.8, 6.6]	20.6 [17.7, 23.5]
I-Hemi_RNFL	µm	15.22 (3.46)	8.4 [6.2, 10.7]	22.0 [19.8, 24.2]	9.25 (3.29)	2.8 [0.5, 5.2]	15.7 [13.3, 18.1]	13.59 (4.17)	5.4 [2.6, 8.2]	21.8 [19.0, 24.6]
PP_RNFL	µm	15.15 (3.16)	9.0 [6.9, 11.0]	21.3 [19.3, 23.4]	9.11 (3.19)	2.9 [0.6, 5.1]	15.3 [13.1, 17.6]	12.84 (3.66)	5.7 [3.2, 8.1]	20.0 [17.6, 22.5]
ONH Parameters										
Within Disc Margin (BMO reference plane has 150µ elevation in Solix, and is at BMO plane in Avanti XR)										
Cup Area	mm ²	-0.20 (0.13)	-0.5 [-0.5, -0.4]	0.1 [-0.0, 0.1]	-0.52 (0.27)	-1.1 [-1.2, -0.9]	0.0 [-0.2, 0.2]	-0.24 (0.17)	-0.6 [-0.7, -0.5]	0.1 [-0.0, 0.2]
Rim Area	mm ²	0.13 (0.14)	-0.1 [-0.2, -0.1]	0.4 [0.3, 0.5]	0.44 (0.32)	-0.2 [-0.4, 0.0]	1.1 [0.8, 1.3]	0.20 (0.17)	-0.1 [-0.3, -0.0]	0.5 [0.4, 0.7]
C-D_Area_Ratio		-0.11 (0.06)	-0.2 [-0.3, -0.2]	0.0 [-0.0, 0.1]	-0.27 (0.11)	-0.5 [-0.6, -0.4]	-0.0 [-0.1, 0.0]	-0.14 (0.11)	-0.3 [-0.4, -0.3]	0.1 [0.0, 0.1]
C-D_H_Ratio		-0.20 (0.13)	-0.4 [-0.5, -0.4]	0.1 [-0.0, 0.1]	-0.26 (0.12)	-0.5 [-0.6, -0.4]	-0.0 [-0.1, 0.1]	-0.22 (0.15)	-0.5 [-0.6, -0.4]	0.1 [-0.0, 0.2]
C-D_V_Ratio		-0.17 (0.15)	-0.5 [-0.6, -0.4]	0.1 [0.0, 0.2]	-0.17 (0.14)	-0.5 [-0.6, -0.3]	0.1 [0.0, 0.2]	-0.19 (0.18)	-0.5 [-0.7, -0.4]	0.2 [0.0, 0.3]
CupVolume	mm ³	-0.04 (0.04)	-0.1 [-0.1, -0.1]	0.0 [0.0, 0.1]	-0.16 (0.09)	-0.3 [-0.4, -0.3]	0.0 [-0.1, 0.1]	-0.04 (0.04)	-0.1 [-0.2, -0.1]	0.0 [0.0, 0.1]
DiscArea	mm ²	-0.06 (0.07)	-0.2 [-0.2, -0.2]	0.1 [0.0, 0.1]	-0.08 (0.11)	-0.3 [-0.4, -0.2]	0.1 [0.1, 0.2]	-0.04 (0.07)	-0.2 [-0.2, -0.1]	0.1 [0.0, 0.1]

Table 15.2.3.1. Agreement between Avanti HD AngioDisc scan. And Solix AngioVue Disc scan

Disc Cube		Normal (n=30 subjects)			Glaucoma (n=25 subjects)			Retina (n=28 subjects)		
		Difference			Difference			Difference		
		Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]
RNFL										
Ø2.5 ~ Ø4.5 mm Ring for Solix vs Ø2.0 ~ Ø4.0 mm Ring for Avanti XR										
TS_RNFL	µm	9.58 (3.24)	3.2 [1.1, 5.3]	15.9 [13.8, 18.0]	7.82 (4.35)	-0.7 [-3.8, 2.4]	16.3 [13.2, 19.5]	6.51 (5.93)	-5.1 [-9.3, -1.0]	18.1 [14.0, 22.3]
ST_RNFL	µm	11.11 (4.46)	2.4 [-0.5, 5.3]	19.9 [17.0, 22.7]	6.82 (4.17)	-1.4 [-4.3, 1.6]	15.0 [12.0, 18.0]	11.93 (6.36)	-0.5 [-4.9, 3.8]	24.4 [20.0, 28.7]
SN_RNFL	µm	20.26 (6.85)	6.8 [2.4, 11.3]	33.7 [29.3, 38.1]	12.04 (4.83)	2.6 [-0.9, 6.0]	21.5 [18.1, 25.0]	19.15 (10.60)	-1.6 [-8.9, 5.6]	39.9 [32.7, 47.2]
NS_RNFL	µm	18.52 (6.23)	6.3 [2.3, 10.3]	30.7 [26.7, 34.8]	11.02 (7.65)	-4.0 [-9.4, 1.5]	26.0 [20.5, 31.5]	13.49 (7.71)	-1.6 [-6.9, 3.7]	28.6 [23.3, 33.9]
NI_RNFL	µm	16.56 (6.01)	4.8 [0.9, 8.7]	28.3 [24.5, 32.2]	11.65 (7.28)	-2.6 [-7.8, 2.6]	25.9 [20.7, 31.1]	15.64 (6.02)	3.8 [-0.3, 8.0]	27.4 [23.3, 31.6]
IN_RNFL	µm	23.00 (7.13)	9.0 [4.4, 13.6]	37.0 [32.4, 41.6]	12.70 (6.36)	0.2 [-4.3, 4.8]	25.2 [20.6, 29.7]	21.22 (8.04)	5.5 [-0.0, 11.0]	37.0 [31.5, 42.5]
IT_RNFL	µm	11.22 (6.47)	-1.5 [-5.6, 2.7]	23.9 [19.7, 28.1]	7.53 (5.16)	-2.6 [-6.3, 1.1]	17.6 [14.0, 21.3]	11.68 (7.84)	-3.7 [-9.0, 1.7]	27.0 [21.7, 32.4]
TI_RNFL	µm	9.56 (3.54)	2.6 [0.3, 4.9]	16.5 [14.2, 18.8]	7.95 (3.85)	0.4 [-2.3, 3.2]	15.5 [12.7, 18.2]	6.83 (3.02)	0.9 [-1.2, 3.0]	12.8 [10.7, 14.8]
T_RNFL	µm	9.57 (2.93)	3.8 [1.9, 5.7]	15.3 [13.4, 17.2]	7.88 (3.22)	1.6 [-0.7, 3.9]	14.2 [11.9, 16.5]	6.85 (3.75)	-0.5 [-3.1, 2.1]	14.2 [11.6, 16.8]
S_RNFL	µm	16.12 (4.46)	7.4 [4.5, 10.3]	24.9 [22.0, 27.7]	9.68 (3.53)	2.8 [0.2, 5.3]	16.6 [14.1, 19.1]	15.87 (7.38)	1.4 [-3.7, 6.5]	30.3 [25.3, 35.4]
N_RNFL	µm	17.63 (5.64)	6.6 [2.9, 10.2]	28.7 [25.0, 32.3]	11.30 (6.57)	-1.6 [-6.3, 3.1]	24.2 [19.5, 28.9]	14.46 (5.58)	3.5 [-0.3, 7.3]	25.4 [21.6, 29.2]
I_RNFL	µm	17.79 (4.45)	9.1 [6.2, 11.9]	26.5 [23.6, 29.4]	10.42 (4.53)	1.5 [-1.7, 4.8]	19.3 [16.1, 22.5]	17.04 (6.51)	4.3 [-0.2, 8.7]	29.8 [25.3, 34.3]
S-Hemi_RNFL	µm	15.46 (3.41)	8.8 [6.6, 11.0]	22.2 [20.0, 24.4]	9.72 (3.54)	2.8 [0.3, 5.3]	16.6 [14.1, 19.2]	13.05 (4.46)	4.3 [1.3, 7.4]	21.8 [18.7, 24.8]
I-Hemi_RNFL	µm	15.65 (3.27)	9.2 [7.1, 11.4]	22.1 [19.9, 24.2]	10.22 (3.72)	2.9 [0.3, 5.6]	17.5 [14.8, 20.2]	14.45 (4.25)	6.1 [3.2, 9.0]	22.8 [19.9, 25.7]
PP_RNFL	µm	15.55 (3.09)	9.5 [7.5, 11.5]	21.6 [19.6, 23.6]	9.96 (3.33)	3.4 [1.1, 5.8]	16.5 [14.1, 18.9]	13.72 (3.91)	6.1 [3.4, 8.7]	21.4 [18.7, 24.1]
ONH Parameters										
Within Disc Margin (BMO reference plane has 150µ elevation in Solix, and is at BMO plane in Avanti XR)										
Cup Area	mm ²	-0.18 (0.13)	-0.4 [-0.5, -0.3]	0.1 [-0.0, 0.2]	-0.51 (0.27)	-1.0 [-1.2, -0.8]	0.0 [-0.2, 0.2]	-0.22 (0.16)	-0.5 [-0.6, -0.4]	0.1 [-0.0, 0.2]
Rim Area (mm2)	mm ²	0.12 (0.14)	-0.2 [-0.3, -0.1]	0.4 [0.3, 0.5]	0.43 (0.30)	-0.2 [-0.4, 0.1]	1.0 [0.8, 1.2]	0.18 (0.17)	-0.1 [-0.3, -0.0]	0.5 [0.4, 0.6]
C-D_Area_Ratio		-0.10 (0.06)	-0.2 [-0.3, -0.2]	0.0 [-0.0, 0.1]	-0.26 (0.12)	-0.5 [-0.6, -0.4]	-0.0 [-0.1, 0.1]	-0.12 (0.10)	-0.3 [-0.4, -0.3]	0.1 [0.0, 0.1]
C-D_H_Ratio		-0.17 (0.12)	-0.4 [-0.5, -0.3]	0.1 [-0.0, 0.2]	-0.26 (0.12)	-0.5 [-0.6, -0.4]	-0.0 [-0.1, 0.1]	-0.19 (0.14)	-0.5 [-0.6, -0.4]	0.1 [-0.0, 0.2]
C-D_V_Ratio		-0.15 (0.16)	-0.5 [-0.6, -0.4]	0.2 [0.1, 0.3]	-0.16 (0.15)	-0.5 [-0.6, -0.3]	0.1 [0.0, 0.2]	-0.18 (0.17)	-0.5 [-0.6, -0.4]	0.2 [0.0, 0.3]
CupVolume (mm3)	mm ³	-0.04 (0.04)	-0.1 [-0.1, -0.1]	0.0 [0.0, 0.1]	-0.16 (0.11)	-0.4 [-0.4, -0.3]	0.0 [-0.0, 0.1]	-0.04 (0.04)	-0.1 [-0.1, -0.1]	0.0 [0.0, 0.1]
DiscArea (mm2)	mm ²	-0.06 (0.07)	-0.2 [-0.2, -0.2]	0.1 [0.0, 0.1]	-0.08 (0.12)	-0.3 [-0.4, -0.2]	0.1 [0.1, 0.2]	-0.03 (0.07)	-0.2 [-0.2, -0.1]	0.1 [0.1, 0.2]

Table 15.2.3.2. Agreement between Avanti HD AngioDisc scan and Solix Disc Cube scan .

Difference was noted for the RNFL measurements with Solix measured lower than Avanti. The main explanation for the difference is the measurement ring size change with Solix measuring further out from disc margin where RNFL is thinner. This change of measurement ring in Solix was implemented to ensure no invalid RNFL measurement between the disc margin and the inner ring diameter is included in the measurement area.

OCTA vessel density measurements – agreement with the Avanti XR predicate device

For both the superficial and deep vascular complexes imaged with the macular AngioVue scans, the vessel density values from SOLIX tended to be within a smaller range than the vessel density values from Avanti XR (e.g., absolute values of SOLIX vs. Avanti XR Deming regression slopes are less than 1). For the radial peripapillary capillaries imaged with disc scans, vessel density measurement agreement between SOLIX and Avanti XR was closer than what was observed with macular AngioVue scans. Differences between SOLIX and Avanti XR vessel density measurements are associated with the increased scan density (due to smaller OCTA image pixel size) with SOLIX and updates to the vessel density software algorithm in SOLIX.

15.2.3 Fundus Image Quality Non-Inferiority Evaluation

This was a multi-center, prospective, cross-sectional study conducted at 2 U.S. clinical sites equipped with 3 sets of devices (1 Solix, 1 Avanti, and 1 iCam per set) for data collection. Fundus image quality grading was performed at a 3rd party image reading center. Eligible participants age 18 or older were enrolled in 3 study groups: 1) individuals with no ocular disease; 2) individuals with glaucoma (with confirmed glaucomatous visual field defect and/or glaucomatous optic nerve changes) of varying severity, and 3) individuals with exudative age-related macular degeneration (wetAMD), proliferative and non-proliferative diabetic retinopathy (DR), non-neovascular age-related macular degeneration (dryAMD) of varying stages from drusen load (drusen) to non-foveal or foveal geographic atrophy (GA), and other retinal conditions. Individuals with media opacity or poor fixation precluding adequate image quality were excluded. The study eye was imaged twice with Solix and iCam, and fundus image quality was tested based on image quality scores by 3 graders, each grading the images independently, and the final usable image rate determined based on 2-out-of-3 graders in agreement rule for Solix and iCam respectively.

A total of 121 eligible participants completed the study, 32 in the Normal group, 31 in the Glaucoma group, and 58 in the Retina group. The 58 “Retina” group participants were the same subjects enrolled in the R&R study.

Of the 121 eligible subjects, 75 (62%) participants were female and 46 (38%) participants were male; the age distribution was 61.7±17.5 (mean±SD), ranging from 21 to 95; and, 100 (82.6%) participants were Caucasian.

Of the 32 subjects in the Normal group with age ranging from 21 to 70, 4 subjects had refractive surgery, and 2 subjects had cataract surgery and IOL implant.

The 31 subjects in the Glaucoma group consisted of 9 subjects in the early stage, 11 subjects in the moderate stage, and 11 subjects in the advanced stage of glaucoma with visual field MD ranging from -27.75 dB to 0.04 dB and PSD ranging from 1.29 dB to 13.99 dB.

The 58 subjects in the Retina group consisted of 12 Wet AMD, 18 Dry AMD, 14 DR and 14 with other type of retinal pathology (1 birdshot chorioretinopathy, 1 inactive CNV, 1 hypertensive retinopathy, 1 choroidal nevus, 2 ERM with CME, 1 ERM with pseudo macular hole, 1 Mac Tel Type 2, 1 ocular histoplasmosis, 1 panuveitis, 1 retinitis pigmentosa, 1 BRVO, 1 CRVO and 1 CNV secondary to histoplasmosis).

Of the 121 qualified subjects for the agreement study, there were 9 subjects (7.4%) excluded from agreement analysis due to missing photos on either Solix or iCam device that resulted in unpaired data. The final fundus image quality grading data set consisting of 112 subjects, including 31 Normal subjects, 26 Glaucoma subjects, and 55 Retina subjects.

Only 1 photo per subject per device were selected for image quality grading. Image quality grading was performed by 3 graders independently and masked to each other's results during the grading process. The percentage of subjects for which the 1st photo of 2 repeats was selected as best quality for grading was 52.7% for Solix and 34.8% for iCam.

The overall sample proportion of clinically useful images (grade ≥ 3 based on a 5-point quality scale) was 97.3% for both Solix and iCam and similar for all 3 study group.

Photo Grading Results by 3	Photo Pairs Available	Total		Normal		Glaucoma		Retina	
		112		31		26		55	
Passing rate	Solix	109	97.3%	30	96.8%	25	96.2%	54	98.2%
	iCAM	109	97.3%	31	100.0%	26	100.0%	52	94.5%
Failing rate	Solix	3	2.7%	1	3.2%	1	3.8%	1	1.8%
	iCAM	3	2.7%	0	0.0%	0	0.0%	3	5.5%

Table 15.2.5. Percentages of photos graded as clinically useful (passing rate) versus not clinically useful (failing rate).

15.3 Evaluation of the Repeatability and Reproducibility (“R&R”) of Solix in Normal Subjects and Corneal for Anterior Segment Measurements

This was a prospective, cross-sectional study conducted at a single U.S. clinical site equipped with 3 Solix devices. Eligible participants age 18 or older were enrolled and assigned to one of two study groups: 1) individuals with no corneal pathology or conditions qualifying for the Cornea sub-groups; 2) those with four specified corneal conditions (contact lens wearers, post-refractive surgery, dry eye, keratoconus). Each study eye was imaged at least 3 times using the Cornea Map scan pattern with each of 3 Solix device/operator pairs. Post-acquisition image review of scan quality score, signal strength, pupil alignment, eyelid artifact, scan range, and motion artifact were conducted for all scans. Repeatability and reproducibility of the study parameters (25 zonal thickness parameters for 3 map types: corneal, epithelial, and stromal thickness), and “summary statistics” parameters were calculated using a crossed, random-effects ANOVA model.

A total of 63 participants were consented and enrolled (30 Normal, 7 Contact Lens, 7 Dry Eye, 8 post-LRS, 11 KCN). A total of 2 subjects were excluded in KCN subgroup. Therefore, a total of 61 subjects qualified and completed the study, and analysis was based 2 groups (30 Normal subjects and 31 Cornea subjects consisting of, 7 Contact Lens, 7 Dry Eye, 8 Post-LRS, 9 KCN).

Of the 61 eligible subjects, 32 (52%) participants were female and 29 (48%) participants were male; the age distribution was 43 ± 16.1 (mean $\pm$ SD), ranging from 22 to 74; 42 (69%) participants were Caucasian and 19 (31%) were American Indian.

Of the 7 Contact Lens subjects, the average duration of contact lens wear was 12 years, ranging from 2 to 25 years, and the average length of daily wear was 12 hours, ranging from 8 to 15 hours.

The 7 subjects with dry eye consisted of 2 mild, 3 moderate, and 2 severe cases. The distribution of OSDI score was 41.2 ± 20.0 (mean $\pm$ SD), ranging from 12.5 to 72.9; and, the distribution of TBUT was 5 ± 2.1 sec. (mean $\pm$ SD), ranging from 2 sec. to 8 sec.

Of the 8 Post-LRS subjects, 1 had LASIK procedure and 7 had PRK procedure. All 12 subjects had myopic correction.

The 9 KCN subjects consisted of 2 mild, 3 moderate, and 4 severe cases..

Of 556 scans acquired, 7 scans (1.3%) were excluded from R&R analysis due to scan quality issues. Out of 549 scans qualified for final R&R analysis, 55 (10.0%) required manual edits for segmentation boundaries.

15.3.1.1 R&R Results – Corneal Thickness, Epithelial Thickness, and Stromal Thickness

Tables 15.3.1.1 through 15.3.1.6 summarize the results of the R&R analysis of the Epithelial (Epi), the corneal thickness (Pachy), and the stroma parameters for the Solix Cornea Map scan.

Normal (N=269 scans)																
Parameter (φ9 mm)	Unit	Epithelia (Epi)					Cornea (Pachy)					Stroma				
		Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility		
				SD	SD	CV			SD	SD	CV			SD	SD	CV
						Limit*					Limit*					Limit*
C(2)	μm	53.6	0.7	0.9	1.6%	2.4	527.1	1.3	1.9	0.4%	5.3	473.4	1.0	1.8	0.4%	5.0
T(2-5)	μm	52.8	0.8	0.9	1.6%	2.4	537.1	2.4	3.1	0.6%	8.6	484.2	2.4	3.0	0.6%	8.3
ST(2-5)	μm	52.7	0.8	1.0	2.0%	2.9	552.9	4.3	5.8	1.0%	16.2	500.2	4.2	5.6	1.1%	15.6
S(2-5)	μm	53.0	0.9	1.2	2.2%	3.2	565.7	5.4	7.5	1.3%	21.0	512.7	5.4	7.4	1.4%	20.6
SN(2-5)	μm	53.9	0.9	1.1	2.0%	3.1	563.5	4.9	6.6	1.2%	18.6	509.5	4.7	6.4	1.3%	17.9
N(2-5)	μm	54.1	0.7	0.9	1.7%	2.5	553.5	3.8	4.9	0.9%	13.8	499.4	3.7	4.8	1.0%	13.3
IN(2-5)	μm	54.7	0.7	0.8	1.5%	2.3	546.6	3.7	4.5	0.8%	12.7	491.9	3.6	4.4	0.9%	12.3
I(2-5)	μm	54.9	0.8	0.9	1.6%	2.5	541.0	3.6	4.6	0.9%	12.9	486.0	3.5	4.5	0.9%	12.5
IT(2-5)	μm	54.0	0.8	0.9	1.7%	2.5	534.6	2.8	3.4	0.6%	9.5	480.6	2.7	3.3	0.7%	9.3
T(5-7)	μm	53.3	0.6	0.8	1.5%	2.2	569.0	3.8	5.1	0.9%	14.3	515.7	3.8	4.9	0.9%	13.7
ST(5-7)	μm	52.0	0.7	1.0	1.9%	2.8	597.3	6.0	8.1	1.4%	22.8	545.3	6.2	8.1	1.5%	22.7
S(5-7)	μm	51.7	1.0	1.3	2.5%	3.6	618.0	6.7	10.2	1.7%	28.7	566.3	6.9	10.5	1.8%	29.3
SN(5-7)	μm	54.8	1.0	1.2	2.2%	3.4	614.7	6.4	8.5	1.4%	23.8	559.8	6.4	8.4	1.5%	23.5
N(5-7)	μm	54.8	0.8	1.0	1.8%	2.7	596.4	5.5	7.2	1.2%	20.0	541.6	5.2	6.8	1.3%	19.1
IN(5-7)	μm	54.9	0.7	0.8	1.4%	2.2	587.7	5.6	7.0	1.2%	19.7	532.8	5.5	7.0	1.3%	19.6
I(5-7)	μm	55.1	0.6	0.8	1.4%	2.1	580.5	5.7	7.1	1.2%	19.9	525.4	5.7	7.2	1.4%	20.1
IT(5-7)	μm	54.8	0.6	0.7	1.3%	2.0	567.7	4.8	5.9	1.0%	16.4	512.9	4.7	5.8	1.1%	16.1
T(7-9)	μm	53.3	0.9	1.2	2.2%	3.3	610.0	7.0	8.9	1.5%	24.8	556.7	7.2	8.8	1.6%	24.6
ST(7-9)	μm	49.6	1.1	1.2	2.5%	3.5	648.9	8.7	11.4	1.8%	32.0	599.2	9.1	11.9	2.0%	33.2
S(7-9)	μm	48.2	1.2	1.5	3.1%	4.2	668.8	8.8	13.8	2.1%	38.7	620.6	9.1	14.1	2.3%	39.6
SN(7-9)	μm	53.1	1.2	1.8	3.3%	5.0	663.4	7.1	9.7	1.5%	27.3	610.2	7.4	10.0	1.6%	28.0
N(7-9)	μm	56.8	0.8	0.9	1.6%	2.6	644.9	6.9	9.1	1.4%	25.4	588.1	6.6	8.6	1.5%	24.1
IN(7-9)	μm	54.9	0.8	1.0	1.7%	2.6	637.1	7.9	9.9	1.6%	27.7	582.2	7.9	9.9	1.7%	27.7
I(7-9)	μm	54.0	0.8	1.2	2.1%	3.2	628.3	8.1	10.2	1.6%	28.6	574.2	8.3	10.6	1.8%	29.7
IT(7-9)	μm	55.1	0.9	1.1	1.9%	3.0	609.9	7.5	8.7	1.4%	24.4	554.8	7.6	8.7	1.6%	24.5
*Reproducibility Limit = 2.8 x SD of Reproducibility																

Table 15.3.1.1. Repeatability and Reproducibility of the normal group.

Cornea (N=279scans)																
Parameter (φ9 mm)	Unit	Epithelia (Epi)					Cornea (Pachy)					Stroma				
		Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility		
				SD	SD	CV			Limit*	SD	SD			CV	Limit*	SD
C(2)	μm	54.3	0.8	1.0	1.8%	2.8	508.5	2.3	3.1	0.6%	8.6	454.1	2.1	3.0	0.7%	8.5
T(2-5)	μm	53.6	1.1	1.4	2.5%	3.8	524.5	4.5	6.5	1.2%	18.2	470.9	4.7	6.7	1.4%	18.9
ST(2-5)	μm	53.4	1.3	1.6	3.0%	4.5	543.1	5.0	7.1	1.3%	19.9	489.7	4.9	6.9	1.4%	19.3
S(2-5)	μm	53.9	1.1	1.3	2.4%	3.6	556.5	5.5	7.3	1.3%	20.4	502.6	5.6	7.5	1.5%	20.9
SN(2-5)	μm	55.0	0.9	1.1	2.1%	3.2	553.8	5.4	6.4	1.2%	18.0	498.7	5.4	6.6	1.3%	18.4
N(2-5)	μm	56.0	0.9	1.1	1.9%	3.0	542.2	4.7	5.6	1.0%	15.7	486.2	4.6	5.5	1.1%	15.5
IN(2-5)	μm	55.9	1.0	1.3	2.3%	3.6	531.1	4.5	6.2	1.2%	17.4	475.1	4.5	5.9	1.2%	16.6
I(2-5)	μm	55.0	1.2	1.5	2.8%	4.3	518.9	4.5	6.6	1.3%	18.6	463.8	4.7	7.0	1.5%	19.7
IT(2-5)	μm	54.6	1.2	1.5	2.7%	4.2	513.8	3.6	4.2	0.8%	11.8	459.2	3.9	4.3	0.9%	12.1
T(5-7)	μm	52.5	1.0	1.6	3.1%	4.6	563.0	5.5	7.4	1.3%	20.8	510.5	5.6	7.0	1.4%	19.7
ST(5-7)	μm	51.5	1.2	1.5	2.8%	4.1	592.3	6.5	8.9	1.5%	24.9	540.8	6.8	9.2	1.7%	25.9
S(5-7)	μm	51.2	1.4	1.8	3.5%	5.0	614.2	6.9	9.2	1.5%	25.8	563.0	7.0	9.5	1.7%	26.6
SN(5-7)	μm	53.2	1.0	1.4	2.6%	3.9	608.6	6.4	8.2	1.3%	23.0	555.4	6.5	8.4	1.5%	23.6
N(5-7)	μm	54.7	0.9	1.2	2.1%	3.2	588.2	6.0	7.4	1.3%	20.7	533.4	6.0	7.4	1.4%	20.7
IN(5-7)	μm	54.6	1.0	1.2	2.1%	3.2	575.2	6.0	8.0	1.4%	22.4	520.5	6.1	8.1	1.6%	22.6
I(5-7)	μm	53.7	1.1	1.2	2.3%	3.4	563.1	6.0	8.1	1.4%	22.6	509.3	6.3	8.1	1.6%	22.6
IT(5-7)	μm	53.4	1.0	1.2	2.2%	3.3	554.7	5.5	6.3	1.1%	17.5	501.3	5.6	6.2	1.2%	17.3
T(7-9)	μm	52.3	1.2	1.4	2.7%	4.0	607.9	7.3	9.3	1.5%	25.9	555.6	7.3	9.3	1.7%	25.9
ST(7-9)	μm	49.5	1.3	1.7	3.3%	4.6	644.7	8.9	12.2	1.9%	34.2	595.2	8.9	12.3	2.1%	34.4
S(7-9)	μm	49.5	1.6	2.2	4.4%	6.2	669.9	9.4	13.2	2.0%	37.0	620.4	9.6	13.3	2.1%	37.1
SN(7-9)	μm	52.1	1.3	1.6	3.0%	4.4	658.3	6.5	8.9	1.4%	25.0	606.2	6.8	9.2	1.5%	25.9
N(7-9)	μm	55.6	1.0	1.2	2.1%	3.3	635.2	6.7	8.2	1.3%	23.0	579.6	6.5	7.8	1.3%	21.8
IN(7-9)	μm	54.2	0.9	1.0	1.9%	2.9	624.5	7.4	9.9	1.6%	27.7	570.3	7.4	9.6	1.7%	26.9
I(7-9)	μm	52.9	0.8	1.0	2.0%	2.9	612.4	8.2	10.6	1.7%	29.6	559.5	8.4	10.8	1.9%	30.3
IT(7-9)	μm	54.0	0.9	1.1	2.1%	3.2	600.3	7.4	9.2	1.5%	25.7	546.3	7.1	9.0	1.6%	25.1
*Reproducibility Limit = 2.8 x SD of Reproducibility																

*Reproducibility Limit = 2.8 x SD of Reproducibility

Table 15.3.1.2. Repeatability and Reproducibility of the group of corneal conditions.

15.4 Evaluation of the Agreement of Solix to Avanti in Normal Subjects and Corneal Patients for Anterior Segment Measurements

All R&R subjects (Section 15.3) were also imaged 3 times each on the Avanti device..

The first qualified scan per subject per device modality was included in the agreement analysis.

Of the 556 Solix scans acquired, 549 (98.7%) scans qualified and of 555 Avanti scans acquired, 547 (98.6%) scans qualified.

Manual edit of segmentation boundaries was performed in 10.0% of Solix scans and 14.8% of Avanti scans.

15.4.1 Agreement Results – Corneal Thickness, Epithelial Thickness, and Stromal Thickness

Tables 15.4.1.1 to 15.4.1.3 summarize the agreement results for corneal, epithelial, and stromal thickness between Solix Cornea Map scan and Avanti PachymetryWide scan for the Normal group and the combined Cornea group.

Epithelial (Epi)		Normal (n=30 subjects)			Cornea (n=31 subjects)		
		Difference			Difference		
		Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]
C(2)_Epi	µm	0.39 (1.10)	-1.8 [-2.5, -1.1]	2.5 [1.8, 3.3]	0.08 (1.50)	-2.9 [-3.8, -1.9]	3.0 [2.1, 4.0]
T(2-5)_Epi	µm	0.55 (1.36)	-2.1 [-3.0, -1.2]	3.2 [2.3, 4.1]	0.39 (1.92)	-3.4 [-4.6, -2.2]	4.2 [2.9, 5.4]
ST(2-5)_Epi	µm	0.71 (1.61)	-2.4 [-3.5, -1.4]	3.9 [2.8, 4.9]	0.58 (1.95)	-3.2 [-4.5, -2.0]	4.4 [3.2, 5.6]
S(2-5)_Epi	µm	0.37 (1.83)	-3.2 [-4.4, -2.0]	4.0 [2.8, 5.1]	0.67 (1.87)	-3.0 [-4.2, -1.8]	4.3 [3.2, 5.5]
SN(2-5)_Epi	µm	0.41 (1.81)	-3.2 [-4.3, -2.0]	4.0 [2.8, 5.1]	0.36 (1.74)	-3.1 [-4.2, -2.0]	3.8 [2.7, 4.9]
N(2-5)_Epi	µm	0.21 (1.54)	-2.8 [-3.8, -1.8]	3.2 [2.2, 4.2]	0.44 (2.35)	-4.2 [-5.7, -2.7]	5.0 [3.6, 6.5]
IN(2-5)_Epi	µm	0.19 (1.45)	-2.6 [-3.6, -1.7]	3.0 [2.1, 4.0]	0.75 (2.23)	-3.6 [-5.0, -2.2]	5.1 [3.7, 6.5]
I(2-5)_Epi	µm	0.19 (1.27)	-2.3 [-3.1, -1.5]	2.7 [1.9, 3.5]	1.15 (2.46)	-3.7 [-5.2, -2.1]	6.0 [4.4, 7.5]
IT(2-5)_Epi	µm	0.23 (1.13)	-2.0 [-2.7, -1.3]	2.4 [1.7, 3.2]	0.63 (1.62)	-2.5 [-3.6, -1.5]	3.8 [2.8, 4.8]
T(5-7)_Epi	µm	0.13 (1.35)	-2.5 [-3.4, -1.6]	2.8 [1.9, 3.6]	0.09 (1.96)	-3.7 [-5.0, -2.5]	3.9 [2.7, 5.2]
ST(5-7)_Epi	µm	0.45 (1.63)	-2.7 [-3.8, -1.7]	3.7 [2.6, 4.7]	-0.04 (2.15)	-4.3 [-5.6, -2.9]	4.2 [2.8, 5.5]
S(5-7)_Epi	µm	-0.09 (2.05)	-4.1 [-5.4, -2.8]	3.9 [2.6, 5.2]	0.15 (2.15)	-4.1 [-5.4, -2.7]	4.4 [3.0, 5.7]
SN(5-7)_Epi	µm	-0.10 (2.37)	-4.7 [-6.3, -3.2]	4.5 [3.0, 6.1]	0.19 (2.17)	-4.1 [-5.4, -2.7]	4.4 [3.1, 5.8]
N(5-7)_Epi	µm	0.30 (1.57)	-2.8 [-3.8, -1.8]	3.4 [2.4, 4.4]	0.72 (1.74)	-2.7 [-3.8, -1.6]	4.1 [3.0, 5.2]
IN(5-7)_Epi	µm	0.29 (1.09)	-1.9 [-2.6, -1.2]	2.4 [1.7, 3.1]	0.80 (2.00)	-3.1 [-4.4, -1.9]	4.7 [3.5, 6.0]
I(5-7)_Epi	µm	0.40 (0.99)	-1.5 [-2.2, -0.9]	2.3 [1.7, 3.0]	0.76 (1.66)	-2.5 [-3.5, -1.4]	4.0 [3.0, 5.1]
IT(5-7)_Epi	µm	0.03 (1.08)	-2.1 [-2.8, -1.4]	2.2 [1.5, 2.9]	0.48 (1.67)	-2.8 [-3.9, -1.7]	3.8 [2.7, 4.8]
T(7-9)_Epi	µm	-0.16 (1.48)	-3.1 [-4.0, -2.1]	2.7 [1.8, 3.7]	0.17 (2.47)	-4.7 [-6.2, -3.1]	5.0 [3.4, 6.6]
ST(7-9)_Epi	µm	-0.31 (2.31)	-4.8 [-6.3, -3.3]	4.2 [2.7, 5.7]	0.37 (2.42)	-4.4 [-5.9, -2.8]	5.1 [3.6, 6.6]
S(7-9)_Epi	µm	-0.44 (1.97)	-4.3 [-5.6, -3.0]	3.4 [2.2, 4.7]	0.65 (4.78)	-8.7 [-11.7, -5.7]	10.0 [7.0, 13.0]
SN(7-9)_Epi	µm	-0.78 (1.90)	-4.5 [-5.7, -3.3]	2.9 [1.7, 4.2]	-0.38 (3.01)	-6.3 [-8.2, -4.4]	5.5 [3.6, 7.4]
N(7-9)_Epi	µm	-0.30 (1.59)	-3.4 [-4.5, -2.4]	2.8 [1.8, 3.8]	-0.50 (1.59)	-3.6 [-4.6, -2.6]	2.6 [1.6, 3.6]
IN(7-9)_Epi	µm	0.47 (1.47)	-2.4 [-3.4, -1.5]	3.4 [2.4, 4.3]	-0.01 (1.90)	-3.7 [-4.9, -2.5]	3.7 [2.5, 4.9]
I(7-9)_Epi	µm	0.84 (1.74)	-2.6 [-3.7, -1.5]	4.3 [3.1, 5.4]	0.43 (1.44)	-2.4 [-3.3, -1.5]	3.3 [2.3, 4.2]
IT(7-9)_Epi	µm	-0.02 (1.47)	-2.9 [-3.9, -2.0]	2.9 [1.9, 3.8]	-0.30 (1.99)	-4.2 [-5.5, -2.9]	3.6 [2.3, 4.9]

Table 15.4.1.1. Agreement between Solix Cornea Map scan and Avanti PachymetryWide scan for

Corneal (Pachy)		Normal (n=30 subjects)			Cornea (n=31 subjects)		
		Difference			Difference		
		Mean (SD)	LOA low [95%CI]	LOA high [95%CI]	Mean (SD)	LOA low [95%CI]	LOA high [95%CI]
C(2)_Pachy	µm	2.30 (3.09)	-3.8 [-5.8, -1.8]	8.4 [6.4, 10.4]	2.14 (4.08)	-5.9 [-8.5, -3.3]	10.1 [7.6, 12.7]
T(2-5)_Pachy	µm	3.82 (4.56)	-5.1 [-8.1, -2.2]	12.8 [9.8, 15.7]	2.08 (6.39)	-10.4 [-14.5, -6.4]	14.6 [10.5, 18.6]
ST(2-5)_Pachy	µm	5.72 (7.27)	-8.5 [-13.2, -3.8]	20.0 [15.3, 24.7]	4.48 (6.68)	-8.6 [-12.8, -4.4]	17.6 [13.3, 21.8]
S(2-5)_Pachy	µm	7.46 (9.33)	-10.8 [-16.8, -4.8]	25.8 [19.7, 31.8]	5.67 (6.99)	-8.0 [-12.5, -3.6]	19.4 [14.9, 23.8]
SN(2-5)_Pachy	µm	7.35 (8.60)	-9.5 [-15.1, -4.0]	24.2 [18.7, 29.8]	6.40 (7.78)	-8.8 [-13.8, -3.9]	21.7 [16.7, 26.6]
N(2-5)_Pachy	µm	5.71 (5.64)	-5.3 [-9.0, -1.7]	16.8 [13.1, 20.4]	6.16 (7.67)	-8.9 [-13.7, -4.0]	21.2 [16.3, 26.1]
IN(2-5)_Pachy	µm	3.31 (5.29)	-7.1 [-10.5, -3.6]	13.7 [10.3, 17.1]	4.13 (8.40)	-12.3 [-17.7, -7.0]	20.6 [15.3, 25.9]
I(2-5)_Pachy	µm	1.28 (6.11)	-10.7 [-14.6, -6.8]	13.3 [9.3, 17.2]	2.50 (7.13)	-11.5 [-16.0, -7.0]	16.5 [12.0, 21.0]
IT(2-5)_Pachy	µm	1.69 (4.72)	-7.6 [-10.6, -4.5]	10.9 [7.9, 14.0]	1.80 (7.13)	-12.2 [-16.7, -7.7]	15.8 [11.3, 20.3]
T(5-7)_Pachy	µm	-1.36 (6.92)	-14.9 [-19.4, -10.5]	12.2 [7.7, 16.7]	-4.75 (8.72)	-21.8 [-27.4, -16.3]	12.3 [6.8, 17.9]
ST(5-7)_Pachy	µm	2.44 (10.61)	-18.4 [-25.2, -11.5]	23.2 [16.4, 30.1]	0.98 (9.01)	-16.7 [-22.4, -11.0]	18.6 [12.9, 24.4]
S(5-7)_Pachy	µm	5.75 (13.71)	-21.1 [-30.0, -12.3]	32.6 [23.8, 41.5]	3.08 (9.36)	-15.3 [-21.2, -9.3]	21.4 [15.5, 27.4]
SN(5-7)_Pachy	µm	3.45 (13.17)	-22.4 [-30.9, -13.9]	29.3 [20.8, 37.8]	2.05 (9.25)	-16.1 [-21.9, -10.2]	20.2 [14.3, 26.1]
N(5-7)_Pachy	µm	0.75 (8.28)	-15.5 [-20.8, -10.1]	17.0 [11.6, 22.3]	1.57 (8.21)	-14.5 [-19.7, -9.3]	17.7 [12.5, 22.9]
IN(5-7)_Pachy	µm	-3.12 (7.86)	-18.5 [-23.6, -13.5]	12.3 [7.2, 17.3]	-2.34 (10.05)	-22.0 [-28.4, -15.7]	17.4 [11.0, 23.7]
I(5-7)_Pachy	µm	-5.96 (9.46)	-24.5 [-30.6, -18.4]	12.6 [6.5, 18.7]	-6.04 (10.50)	-26.6 [-33.3, -20.0]	14.5 [7.9, 21.2]
IT(5-7)_Pachy	µm	-5.67 (7.73)	-20.8 [-25.8, -15.8]	9.5 [4.5, 14.5]	-7.00 (10.26)	-27.1 [-33.6, -20.6]	13.1 [6.6, 19.6]
T(7-9)_Pachy	µm	-10.88 (10.94)	-32.3 [-39.4, -25.3]	10.6 [3.5, 17.6]	-12.37 (14.00)	-39.8 [-48.7, -30.9]	15.1 [6.2, 23.9]
ST(7-9)_Pachy	µm	-4.19 (14.67)	-32.9 [-42.4, -23.5]	24.6 [15.1, 34.0]	-4.31 (15.38)	-34.5 [-44.2, -24.7]	25.8 [16.1, 35.6]
S(7-9)_Pachy	µm	0.22 (17.66)	-34.4 [-45.8, -23.0]	34.8 [23.4, 46.2]	1.64 (15.92)	-29.6 [-39.7, -19.5]	32.8 [22.8, 42.9]
SN(7-9)_Pachy	µm	4.32 (15.03)	-25.1 [-34.8, -15.4]	33.8 [24.1, 43.5]	0.54 (15.17)	-29.2 [-38.8, -19.6]	30.3 [20.7, 39.9]
N(7-9)_Pachy	µm	-4.24 (11.89)	-27.6 [-35.2, -19.9]	19.1 [11.4, 26.7]	-4.45 (12.58)	-29.1 [-37.1, -21.1]	20.2 [12.2, 28.2]
IN(7-9)_Pachy	µm	-10.12 (11.90)	-33.5 [-41.1, -25.8]	13.2 [5.5, 20.9]	-9.64 (13.73)	-36.5 [-45.2, -27.8]	17.3 [8.6, 26.0]
I(7-9)_Pachy	µm	-17.55 (12.73)	-42.5 [-50.7, -34.3]	7.4 [-0.8, 15.6]	-12.56 (14.26)	-40.5 [-49.5, -31.5]	15.4 [6.4, 24.4]

Table 15.4.1.2. Agreement between Solix Cornea Map scan and Avanti PachymetryWide scan for corneal thickness.

15.5 Solix Reference Database

Optovue conducted a multi-center, prospective, cross-sectional study to collect a reference database of normal eyes for Solix posterior segment OCT and OCTA scans so that structural measurements derived from these scans of a future test subject can be compared to the database to aid in the clinical interpretation of the test results. The study was conducted at five U.S. sites located in the states of California (CA), Florida (FL), New Jersey (NJ), Ohio (OH), and Oklahoma (OK). Data collected from the study were analyzed to establish reference limits (i.e. the 1st percentile, the 5th percentile, the 95th percentile, and the 99th percentile) for the structural measurements of the eye, including the ganglion cell complex (GCC) thickness, full retinal (R) thickness, the retinal nerve fiber layer (RNFL) thickness, and optic nerve head (ONH) parameters (rim, cup, and cup-to-disc ratios).

The key eligibility criteria included participants age ≥ 18 presenting at the site with no history of ocular pathology and no signs of ocular pathology based on clinical examination, fundus photography, and visual field testing. Retinal pathologies except hard drusen, glaucomatous optic nerve damage or significant visual field PSD or GHT outside normal limits, BCVA worse than 20/40, IOP > 21 mmHg, and unreliable visual field test were all exclusion criteria.

Five posterior OCT and OCTA scan patterns were included in the study. For each scan pattern, 2 repeat scans were acquired per eye for both eyes of a subject. The structural measurements for the 5 Solix scan patterns included in the study are listed in the table below.

Scan Region	Measurement Type	Scan Pattern				
		AngioVue Retina (6.4mm x 6.4mm)	Retina Cube (6.4mm x 6.4mm)	Wellness (12mm x 9mm)	AngioVue Disc (6mm x 6mm)	Disc Cube (6mm x 6mm)
Macula	GCC Thickness	✓	✓	✓		
	Full Retinal Thickness	✓	✓	✓		
Peripapillary & Optic Disc	RNFL Thickness				✓	✓
	Disc, Rim, Cup				✓	✓

Table 15.5.1. Scan Patterns included in the RDB study.

Total 482 subjects were consented and enrolled in the study with 55 subjects disqualified for either failing the enrollment criteria or did not complete the study scans. Total 427 subjects were qualified for the Solix RDB. Only one eye per qualified subject was included in the RDB dataset. If both eyes qualified, then one eye was randomly selected as the study eye for RDB inclusion. Total 427 eyes of 427 qualified subjects were included in the RDB.

The number of qualified subjects in each age bin met the enrollment targets and maintained the distribution proportions set in the study protocol. The gender distribution

is within the range set in the RDB study protocol. Majority of the subjects were Caucasian and Non-Hispanic.

Age	Subject #	%
18-29	86	20.1%
30-39	68	15.9%
40-49	68	15.9%
50-59	68	15.9%
60-69	81	19.0%
70+	56	13.1%
Total	427	
Gender	Subject #	%
F	242	56.7%
M	185	43.3%
Total	427	
Eye	Subject #	%
OD	209	48.9%
OS	218	51.1%
Total	427	

Table 15.5.2 Age, Gender, Eye

Race		Subject #	%
African American	AA	56	13.1%
Asian	A	49	11.5%
Caucasian	C	272	63.7%
Pacific Islander	PI	0	0.0%
American Indian	AI	31	7.3%
Multiracial	MR	5	1.2%
Other	O	5	1.2%
Not Disclosed	ND	9	2.1%
Total		427	
Ethnicity		Subject #	%
Hispanic	H	65	15.2%
Non-Hispanic	N	359	84.1%
Not Disclosed	ND	3	0.7%
Total		427	

Table 15.5.3 Race and Ethnicity.

Of the 427 subjects qualified Solix RDB, the distribution of Age, IOP, CCT, AL, BCVA, Refraction (Spherical Equivalent and Cylinder), and VF (MD and PSD) values are summarized in the Table 15.5.4.

	Age	IOP (mmHg)	CCT (μm)	Axial Length (mm)	BCVA	Spherical Equivalent (D)	Cylinder (D)	VF MD (dB)	VF PSD (dB)
mean	48.3	14.1	538.1	23.97	-	-0.87	-0.37	-0.31	1.44
std. dev.	17.1	2.7	40.2	1.20	-	1.91	0.78	1.39	0.74
minimum	18	8.0	345.0	20.11	20/40	-7.75	-2.00	-5.03	0.89
1st quartile	33	12.0	515.0	23.13	20/20	-1.88	-0.75	-1.01	1.26
median	49	14.0	539.0	23.83	20/20	-0.28	-0.25	0.00	1.40
3rd quartile	62	16.0	563.0	24.66	20/20	0.25	0.00	0.50	1.63
maximum	89	21.0	637.0	28.30	20/13	3.00	2.00	3.15	1.98

Table 15.5.4 Characteristics of the qualified RDB subjects.

Scans from all qualified subjects underwent post-acquisition image quality review. OCT and OCTA scans with a SQ score of less than 6, local weak signal affecting regional structure and/or vasculature visibility, motion artifacts, blink, and cropped B-scan images etc. were excluded from analysis.

For all scan patterns, the study eyes were selected for the RDB based on randomization or as the only qualified eye of the two eyes of an enrolled subject, and the 1st scan of the study eye was qualified for the final RDB analysis dataset in over 95.6% of the qualified subjects for macula scans, and in over 85% for disc scans

There was no segmentation boundary editing for any of the qualified scans included in the RDB data set for any of the 5 scan patterns. There was no manual adjustment of fovea center for ETDRS grid placement. Automatic fovea detection by software was correct for all qualified scans included in the final RDB data set for all of the 3 macular scan patterns. Disc margin manual correction was performed for the baseline scan per qualified subject per eye. The BMO editing rate is about 8%.

15.5.1 Measurement Summary – GCC and Retinal Thickness, Macula Scans

Factor	Level	Solix AngioVue Retina	Solix Retina Cube	Solix Wellness
N (subjects)		426	424	423
C(1)_GCC				
Mean(SD)		56.3 (10.2)	56.5 (10.4)	62.6 (10.3)
Median		55.4	55.7	61.9
Min, Max		[30.8, 85.7]	[31.5, 86.9]	[36.8, 89.7]
T(1-3)_GCC				
Mean(SD)		102.6 (7.7)	103.5 (7.7)	102.5 (7.5)
Median		102.4	103.2	102.0
Min, Max		[78.3, 126.5]	[78.0, 127.9]	[77.8, 126.3]
S(1-3)_GCC				
Mean(SD)		114.2 (8.4)	113.7 (8.5)	111.8 (8.5)
Median		113.6	113.3	111.4
Min, Max		[85.9, 138.7]	[85.9, 137.5]	[85.0, 135.1]
N(1-3)_GCC				
Mean(SD)		111.4 (8.8)	111.8 (8.9)	111.0 (8.7)
Median		111.2	111.6	110.7
Min, Max		[81.5, 138.0]	[81.1, 140.1]	[81.1, 137.8]
I(1-3)_GCC				
Mean(SD)		115.2 (8.3)	114.5 (8.5)	111.8 (8.4)
Median		115.1	114.7	111.3
Min, Max		[86.5, 138.5]	[84.1, 138.3]	[81.7, 136.8]
S-Hemi(1-3)_GCC				
Mean(SD)		110.1 (8.2)	110.2 (8.2)	109.5 (8.0)

Median	109.7	109.9	108.8
Min, Max	[82.4, 134.5]	[82.7, 134.3]	[82.6, 130.8]
I-Hemi(1-3)_GCC			
Mean(SD)	111.5 (8.1)	111.5 (8.2)	110.0 (7.9)
Median	111.4	111.2	109.8
Min, Max	[83.7, 133.1]	[81.8, 133.4]	[81.0, 132.1]
All(1-3)_GCC			
Mean(SD)	110.8 (8.0)	110.9 (8.1)	109.7 (7.8)
Median	110.5	110.5	109.1
Min, Max	[83.0, 132.9]	[82.3, 133.3]	[81.8, 130.4]
T(3-6)_GCC			
Mean(SD)	85.6 (6.6)	86.1 (6.6)	81.6 (6.4)
Median	85.5	85.8	81.2
Min, Max	[63.4, 105.4]	[63.8, 106.1]	[59.3, 100.9]
S(3-6)_GCC			
Mean(SD)	100.8 (8.3)	99.6 (8.3)	91.9 (8.6)
Median	100.3	99.3	91.5
Min, Max	[73.7, 125.3]	[71.8, 123.2]	[64.7, 120.2]
N(3-6)_GCC			
Mean(SD)	117.3 (9.7)	116.6 (9.8)	113.1 (10.2)
Median	117.5	116.8	113.3
Min, Max	[83.2, 147.4]	[83.6, 148.3]	[78.8, 146.7]
I(3-6)_GCC			
Mean(SD)	100.3 (8.4)	99.1 (8.4)	95.0 (9.4)
Median	100.0	98.6	95.0
Min, Max	[70.7, 126.9]	[69.4, 125.6]	[65.2, 123.2]
S-Hemi(3-6)_GCC			
Mean(SD)	100.5 (7.7)	99.9 (7.8)	93.6 (7.8)
Median	100.1	99.5	93.2
Min, Max	[74.0, 123.0]	[73.1, 121.5]	[67.2, 119.5]
I-Hemi(3-6)_GCC			

Mean(SD)	101.5 (8.0)	100.8 (8.0)	96.6 (8.5)
Median	101.5	100.8	96.5
Min, Max	[72.6, 126.5]	[72.1, 126.1]	[67.4, 122.9]

All(3-6)_GCC			
Mean(SD)	101.0 (7.6)	100.4 (7.6)	95.1 (7.8)
Median	100.7	100.2	94.9
Min, Max	[75.8, 122.4]	[75.1, 122.1]	[69.4, 116.2]
S-Hemi(0-6)_GCC			
Mean(SD)	101.4 (7.3)	101.0 (7.4)	96.2 (7.4)
Median	100.9	100.3	95.9
Min, Max	[75.9, 124.3]	[75.2, 123.1]	[70.5, 121.1]
I-Hemi(0-6)_GCC			
Mean(SD)	102.5 (7.5)	102.0 (7.5)	98.6 (7.9)
Median	102.5	102.1	98.8
Min, Max	[75.7, 124.2]	[74.8, 123.9]	[70.1, 122.3]
All(0-6)_GCC			
Mean(SD)	101.9 (7.2)	101.5 (7.2)	97.4 (7.4)
Median	101.5	101.0	96.9
Min, Max	[77.5, 122.3]	[76.6, 122.1]	[71.3, 118.0]
C(1)_R			
Mean(SD)	259.2 (21.7)	259.1 (21.9)	257.8 (21.9)
Median	258.9	258.9	257.8
Min, Max	[201.0, 325.5]	[202.6, 325.6]	[194.5, 327.5]
T(1-3)_R			
Mean(SD)	315.3 (14.4)	316.0 (14.3)	314.3 (14.5)
Median	315.2	316.1	313.5
Min, Max	[278.5, 372.1]	[281.8, 370.8]	[276.3, 371.8]
S(1-3)_R			
Mean(SD)	328.6 (14.6)	329.1 (14.4)	326.7 (14.9)

Median	327.9	328.3	326.3
Min, Max	[287.7, 377.5]	[287.4, 378.2]	[281.7, 377.3]
N(1-3)_R			
Mean(SD)	329.5 (14.8)	329.9 (14.9)	326.9 (15.0)
Median	329.5	329.9	327.2
Min, Max	[289.6, 376.1]	[290.3, 374.8]	[283.7, 375.9]
I(1-3)_R			
Mean(SD)	324.2 (14.1)	324.6 (14.1)	323.7 (14.4)
Median	324.1	324.4	324.1
Min, Max	[286.5, 368.9]	[289.5, 368.1]	[281.3, 369.1]
S-Hemi(1-3)_R			
Mean(SD)	325.4 (14.4)	325.9 (14.3)	323.4 (14.6)
Median	325.2	326.0	323.1
Min, Max	[285.2, 375.6]	[286.7, 375.6]	[280.3, 375.0]
I-Hemi(1-3)_R			
Mean(SD)	323.4 (14.0)	323.8 (14.1)	322.4 (14.2)
Median	323.2	323.6	322.1
Min, Max	[285.9, 370.3]	[289.0, 370.2]	[281.3, 370.1]
All(1-3)_R			
Mean(SD)	324.4 (14.1)	324.9 (14.0)	322.9 (14.3)
Median	324.4	324.8	322.9
Min, Max	[285.6, 372.9]	[287.9, 372.9]	[280.8, 372.6]
T(3-6)_R			
Mean(SD)	266.9 (13.1)	268.4 (13.3)	279.0 (14.1)
Median	267.0	268.4	279.3
Min, Max	[227.1, 310.2]	[229.4, 310.6]	[240.9, 325.1]
S(3-6)_R			
Mean(SD)	284.4 (13.5)	285.2 (13.4)	292.5 (14.3)
Median	283.7	284.9	291.8
Min, Max	[244.5, 322.8]	[245.7, 320.5]	[249.7, 336.3]
N(3-6)_R			

Mean(SD)	299.8 (14.9)	300.7 (14.9)	302.1 (15.6)
Median	299.8	300.7	302.9
Min, Max	[257.5, 336.8]	[259.2, 338.7]	[257.5, 341.7]
I(3-6)_R			
Mean(SD)	270.9 (13.1)	271.4 (13.3)	281.0 (14.5)
Median	270.9	271.6	281.7
Min, Max	[234.4, 311.0]	[232.9, 312.9]	[239.5, 325.9]
S-Hemi(3-6)_R			
Mean(SD)	284.3 (13.3)	285.3 (13.3)	291.7 (14.1)
Median	284.1	285.1	291.2
Min, Max	[243.8, 321.8]	[245.1, 321.6]	[250.3, 331.5]
I-Hemi(3-6)_R			
Mean(SD)	276.7 (13.1)	277.5 (13.2)	285.6 (14.2)
Median	276.7	277.9	286.2
Min, Max	[238.0, 314.8]	[238.5, 316.7]	[243.5, 328.7]
All(3-6)_R			
Mean(SD)	280.5 (13.0)	281.4 (13.0)	288.6 (13.9)
Median	280.6	281.2	288.7
Min, Max	[240.9, 318.2]	[241.8, 317.7]	[246.9, 329.1]
S-Hemi(0-6)_R			
Mean(SD)	292.8 (12.9)	293.6 (12.9)	297.8 (13.6)
Median	292.5	293.1	297.2
Min, Max	[251.8, 332.7]	[253.2, 333.1]	[255.4, 339.1]
I-Hemi(0-6)_R			
Mean(SD)	286.6 (12.6)	287.3 (12.7)	293.0 (13.5)
Median	286.5	286.9	293.1
Min, Max	[247.6, 322.3]	[248.7, 322.5]	[250.6, 331.7]
All(0-6)_R			
Mean(SD)	289.7 (12.6)	290.5 (12.6)	295.4 (13.4)
Median	289.1	290.4	295.1
Min, Max	[249.7, 327.5]	[251.0, 327.7]	[253.0, 335.4]

All(0-6)_R_Vol			
Mean(SD)	8.2 (0.4)	8.2 (0.4)	NA
Median	8.2	8.2	NA
Min, Max	[7.1, 9.3]	[7.1, 9.3]	
WI_GCC			
Mean(SD)	103.1 (7.4)	102.5 (7.5)	92.3 (6.8)
Median	102.8	102.2	92.0
Min, Max	[78.4, 124.7]	[77.4, 123.9]	[68.7, 109.7]
WI-S-Hemi_GCC			
Mean(SD)	102.0 (7.6)	101.5 (7.7)	91.4 (7.0)
Median	101.1	100.8	91.0
Min, Max	[76.6, 128.3]	[75.6, 126.9]	[67.5, 112.6]
WI-I-Hemi_GCC			
Mean(SD)	104.1 (7.8)	103.6 (7.9)	93.3 (7.2)
Median	104.3	103.7	93.3
Min, Max	[75.6, 126.5]	[75.4, 125.9]	[68.2, 116.3]
FLV			
Mean(SD)	0.5 (0.7)	0.5 (0.8)	0.6 (0.8)
Median	0.2	0.2	0.3
Min, Max	[0.0, 6.6]	[0.0, 6.9]	[0.0, 7.1]
GLV			
Mean(SD)	3.7 (3.9)	3.7 (3.9)	4.2 (3.9)
Median	2.7	2.7	3.1
Min, Max	[0.0, 23.9]	[0.0, 24.1]	[0.0, 24.7]

15.5.2 Measurement Summary – RNFL Thickness and ONH Parameters, Disc Scans

Factor	Level	Solix AngioVue Disc	Solix Disc Cube
N (subjects)		423	416
TS_RNFL			
Mean(SD)		64.59 (10.22)	64.75 (10.04)
Median		63.90	64.50
Min, Max		[40.30, 112.70]	[39.40, 105.90]
ST_RNFL			
Mean(SD)		120.23 (20.41)	117.43 (19.50)
Median		119.80	116.75
Min, Max		[58.90, 169.20]	[59.30, 174.20]
SN_RNFL			
Mean(SD)		110.39 (21.10)	110.42 (20.55)
Median		109.10	108.80
Min, Max		[58.40, 174.30]	[59.80, 167.50]
NS_RNFL			
Mean(SD)		90.91 (14.88)	91.27 (14.57)
Median		91.40	92.15
Min, Max		[43.40, 136.40]	[49.80, 137.20]
NI_RNFL			
Mean(SD)		69.54 (13.76)	69.77 (13.73)
Median		69.90	69.50
Min, Max		[33.40, 127.20]	[35.80, 129.20]
IN_RNFL			
Mean(SD)		115.90 (23.12)	115.39 (22.76)
Median		114.30	114.00
Min, Max		[61.40, 193.80]	[61.30, 189.80]
IT_RNFL			
Mean(SD)		134.63 (19.99)	131.79 (19.67)
Median		134.70	132.60
Min, Max		[63.70, 194.00]	[64.60, 201.60]

TI_RNFL		
Mean(SD)	58.98 (11.98)	59.26 (11.82)
Median	57.70	57.90
Min, Max	[35.90, 140.50]	[35.70, 134.40]
T_RNFL		
Mean(SD)	62.01 (9.98)	62.21 (9.72)
Median	61.70	61.70
Min, Max	[39.20, 125.50]	[39.10, 114.80]
S_RNFL		
Mean(SD)	114.86 (13.88)	113.59 (13.94)
Median	115.70	113.95
Min, Max	[79.50, 155.60]	[77.90, 156.40]
N_RNFL		
Mean(SD)	81.40 (13.33)	81.71 (13.15)
Median	81.80	81.85
Min, Max	[38.90, 130.20]	[45.00, 130.90]
I_RNFL		
Mean(SD)	124.18 (16.03)	122.61 (16.10)
Median	123.60	121.65
Min, Max	[84.60, 176.20]	[82.30, 173.80]
S-Hemi_RNFL		
Mean(SD)	94.97 (9.86)	94.58 (9.87)
Median	95.30	95.25
Min, Max	[66.20, 118.30]	[67.30, 117.70]
I-Hemi_RNFL		
Mean(SD)	93.94 (10.67)	93.26 (10.77)
Median	94.10	93.40
Min, Max	[63.40, 122.80]	[62.70, 122.00]
PP_RNFL		
Mean(SD)	94.48 (9.73)	93.95 (9.78)
Median	94.60	94.10

Min, Max	[64.90, 118.40]	[65.20, 117.90]
DiscArea(mm2)		
Mean(SD)	1.85 (0.35)	1.84 (0.35)
Median	1.82	1.81
Min, Max	[1.06, 3.41]	[1.05, 3.40]
CupArea(mm2)		
Mean(SD)	0.51 (0.35)	0.49 (0.35)
Median	0.46	0.43
Min, Max	[0.00, 2.24]	[0.00, 2.38]
RimArea(mm2)		
Mean(SD)	1.34 (0.30)	1.35 (0.31)
Median	1.32	1.32
Min, Max	[0.57, 2.33]	[0.46, 2.49]
CupVolume(mm3)		
Mean(SD)	0.11 (0.11)	0.10 (0.11)
Median	0.07	0.07
Min, Max	[0.00, 0.88]	[0.00, 0.81]
C/DAreaRatio		
Mean(SD)	0.26 (0.15)	0.26 (0.16)
Median	0.26	0.25
Min, Max	[0.00, 0.71]	[0.00, 0.76]
C/DHRatio		
Mean(SD)	0.52 (0.21)	0.51 (0.22)
Median	0.54	0.53
Min, Max	[0.00, 0.97]	[0.00, 0.97]
C/DVRatio		
Mean(SD)	0.46 (0.17)	0.45 (0.18)
Median	0.49	0.48
Min, Max	[0.00, 0.83]	[0.00, 0.82]

15.5.3 Summary

The SOLIX has the same intended use as the legally marketed predicate devices identified in this 510(k) notification. The IFU statement differs from those for the predicate devices, but these differences do not change the intended use of the device. The technological characteristics of the SOLIX differ from those of the predicate devices, however, the differences do not raise new or different questions of safety or effectiveness. Results of the non-clinical performance testing demonstrate that the SOLIX functions as intended. Results of clinical performance testing demonstrate a favorable clinical performance profile that supports a determination of substantial equivalence. The non-clinical and clinical performance testing demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicates.

16 Glossary

A Amperes (amps)

AMD Age-Related Macular Degeneration

AngioFlow The brand name given to OCT angiography en face images

AngioVue® OCT angiography software for the SOLIX™ Essential System

Colour scale: A set of colors used to map data values to colors a representation of a surface.

SOLIX™ Essential (SOLIX™ Essential System) The brand name of this OCT system

Elevation: The difference between the height and either a best-fit or user specified sphere

En face Face-on visualization of OCT data between defined boundaries

ETDRS Early Treatment Diabetic Retinopathy Study

FLV Focal loss volume

Fundus The bottom or base of the eye (the retina)

GCC Ganglion Cell Complex (RNFL, ganglion cell and inner plexiform layer)

GCL Ganglion cell layer

GLV Global loss volume

GUI Graphical User Interface, the means by which the user and a computer system interact, in particular the visual interface of the system software

ILM Inner Limiting Membrane

IPL Inner-plexiform layer

MCT Motion Correction Technology

RDB Reference Database

OCT Optical Coherence Tomography, an optical signal acquisition and processing method that captures micrometer-resolution, three-dimensional images from within optical scattering media.

OCTA OCT Angiography

OD Oculus dexter, right eye

ONH Optic nerve head

OS Oculus sinister left eye

RNFL Retinal nerve fiber layer

RPE Retinal pigmented epithelium

RNFL scan Retinal Nerve Fiber Layer scan

RT Real-time

Scanner Main component used to scan the patient's eye, collect the OCT signal and send it to the computer for processing

SLO Scanning laser ophthalmoscope

SSI Signal strength index

TSNIT Temporal-superior nasal-inferior-temporal

UI User interface, the means by which the user and a computer system interact, in particular the use of input devices and software

µm Micrometers

V Volts

VAC Volts - Alternating Current

VF Visual fields.

_____End of section_____

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