optovue solix™

User Manual

P/N 580-53958-001 D

VISIONIX

INNOVATION TO UNLOCK YOUR POTENTIAL

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Revision Control

Part Number	Revision	Software Version	Description	Release Date
580-53958-001	D	SOLIX 1.0	Reference ECR02952	Aug 2020

Federal (U.S.A.) law restricts this device to sale, distribution and use by or on the order of a physician. Proper procedures and techniques are the responsibility of the medical professional.

License and use of the SOLIX™ System is intended only for trained medical personnel in accordance with the license agreement – all other usage is prohibited – warranty restrictions and possible claim limitations apply.

Standard Warranty Information

See the warranty section of Optovue.com for all product warranty and customer licensing agreements.

Service Policy

Only those service technicians certified by Optovue, Inc. are authorized to service or repair this device. Only those replacement parts approved by Optovue, Inc. may be used in this device. Parts approved by Optovue, Inc. are available only through service technicians certified by Optovue, Inc. Any service or repair by an unauthorized service technician or use of unapproved parts will void the Optovue, Inc. product Warranty, and may increase risk of product failure. For any problem, for technical assistance or to arrange for service, contact: Optovue Technical Support or Optovue Customer Service at the numbers listed below; your local Optovue, Inc. company or authorized distributor.

If the device is to be returned, Optovue or your authorized distributor will provide instructions for returning the device and will issue a Returned Material Authorization (RMA) number. For contaminated devices, request the appropriate Product Return Safety Pack. Returned devices must be packaged with adequate protection against shipping damage. Include a note describing the problem, stating the RMA number, and giving the name, address, and telephone number of a person to contact for additional information.

SOLIX™

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_____End of section_____

1 Introduction

1.1 General

Optovue, Inc. has developed and tested the SOLIX™ 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™ system will be offered with a choice of basic software with 3 software license options, 1. **SOLIX™:** OCT scans only, 2. **SOLIX™** FullRange™: OCT scans plus the FullRange™ anterior and posterior scans 3. **SOLIX™** FullRange™ AngioVue® Essential: OCT, FullRange™ and limited AngioVue® Retina, 4. **SOLIX™** FullRange™ with AngioVue® Expert: OCT, FullRange™ 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™ 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, SOLIX™ 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™ 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.

The non-mydriatic color fundus camera of SOLIX™, is an integrated non-contact, high resolution digital imaging component which is suitable for photographing, displaying and storing images of the retina and external areas of the eye to be evaluated under non-mydriatic conditions. The SOLIX™ fundus camera component is indicated for in-vivo viewing of the posterior and external area of the eye and the images are intended for use as an aid to clinicians in the evaluation, diagnosis and documentation of ocular health.

1.1.2.1 Contraindications

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

☞**Note:** The SOLIX™ 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™ 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™ 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 at www.optovue.com.

1.1.1 Electronic User Manual Access

The SOLIX™ User Manual is provided with the instrument as a USB, on the desktop and Online through Optovue Academy www.OptovueAcademy.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™ User Manual.

☞**Note**: Once opened, you can switch between the user manual and the SOLIX™ 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 photos, 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™ 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

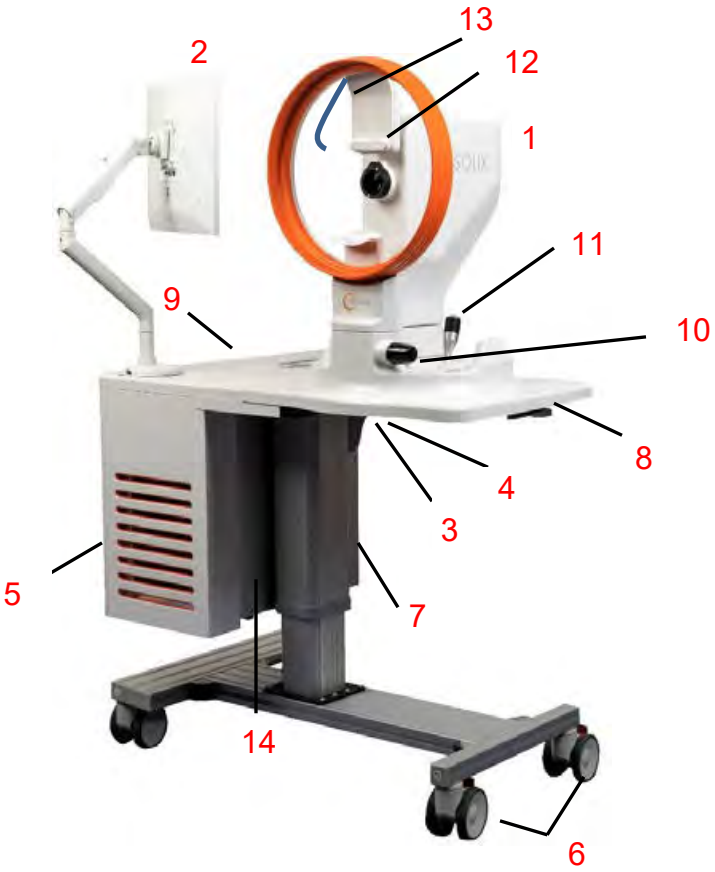


Figure 1 Legend:

1 Scanner

2 Monitor

3 Power switch

4 Table up/down switch

5 Computer

6 Wheels and locks (x4)

7 Warning, SOLIX™, and serial number labels

8 Keyboard and mouse (enclosed in retractable shelf)

9 System table

10 Chin rest up/down knob

11 Joystick

12 Forehead rest

13 External fixation light

14) Control Box

1.2.2 System Configurations (all come complete with table)

- **SOLIX™**: Basic (Fundus Camera and OCT only)
- **SOLIX™** FullRange™: Basic plus the FullRange™ anterior and posterior scans
- **SOLIX™** FullRange™ AngioVue® Essential**:** Basic, FullRange™ and limited AngioVue® Retina
- **SOLIX™** FullRange™ AngioVue® Expert: Basic, FullRange™ and Full AngioVue® capability.

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™** 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™ 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: Equipment is not suitable for use in the presence of a Flammable Anesthetic Mixture with Air, Oxygen, or Nitrous Oxide.

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**

The SOLIX™ 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 <u>VOIDS the warranty completely</u> and can cause SAFETY HAZARDS.

Do not step on surface.

Ne pas marcher sur la surface.

WARNING: Electricity

Avertissement : *Électricité.*

1.5 Power and Electrical Safety

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

	**Pinch Warning Locations** Please observe pinch warnings before raising and lowering the table.
HHHHeavy 	**Footrest Trapping Warning** Do not step on table base when adjusting table height
	**Table Up/Down Label**
	**Heavy Object** Please use proper lifting techniques or ask for help when moving

Figure 2 System labels

WARNING: Possible Pinch Locations

A. Space between bottom of the tabletop and base of column

B. Space between bottom of the PC and the base

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™ 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™ 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: **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.
Harmonics IEC/EN 61000-3-2:2014	Class A Device	Per Clause 5 of the Standard	
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 IMMNITY 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.

<table>
<tr><th colspan="4">GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY</th></tr>
<tr><td>Radiated RF

IEC/EN 61000-4-3</td><td>80 MHz - 2.7 GHz
3 V/m 80% @ 1 kHz

Spot frequencies 385MHz – 5.750 GHz Pulse Modulation</td><td>80 MHz - 2.7 GHz
3 V/m 80% @ 1 kHz

Spot frequencies 385MHz – 5.750 GHz Pulse Modulation</td><td rowspan="2">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)√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.</td></tr>
<tr><td>Proximity field from RF wireless communications equipment

IEC 61000-4-3</td><td>See EN 60601-1-2:2014 Table 9</td><td>See EN 60601-1-2:2014 Table 9</td></tr>
<tr><td>Conducted Immunity
(AC Power)
(I/O Lines)

IEC/EN 61000-4-6</td><td>0.15 - 80 MHz
3 Vrms & 6Vrms in ISM & amateur bands 1 kHz

AC Mains</td><td>0.15 - 80 MHz
3 Vrms & 6Vrms in ISM & amateur bands 1 kHz

AC Mains</td><td>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.</td></tr>
</table>

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_T5 Sec	0% U_T .5 cycle 0% U_T 1 cycle 70% U_T 25 cycles 0% U_T5 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 reglement sur le brouillage radioelectrique 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
Optovue, Inc.
2800 Bayview Drive,
Fremont, CA., USA, 94538

IMPORTADOR:
Emergo Brazil Import Importação e Distribuição de Produtos Médicos Hospitalares Ltda.
Avenida Francisco Matarazzo, 1.752, Salas 502/503, Água Branca, São Paulo- SP, CEP – 05001-200
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

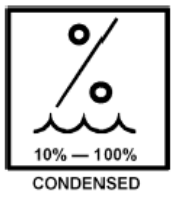
1.9.1 **Protective Packing Symbols**

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

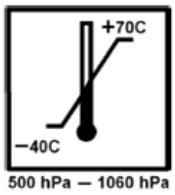
Fragile, handle with care

Keep dry

This side up



Environmental conditions during transport: Relative humidity (10% to 90%, including condensation)



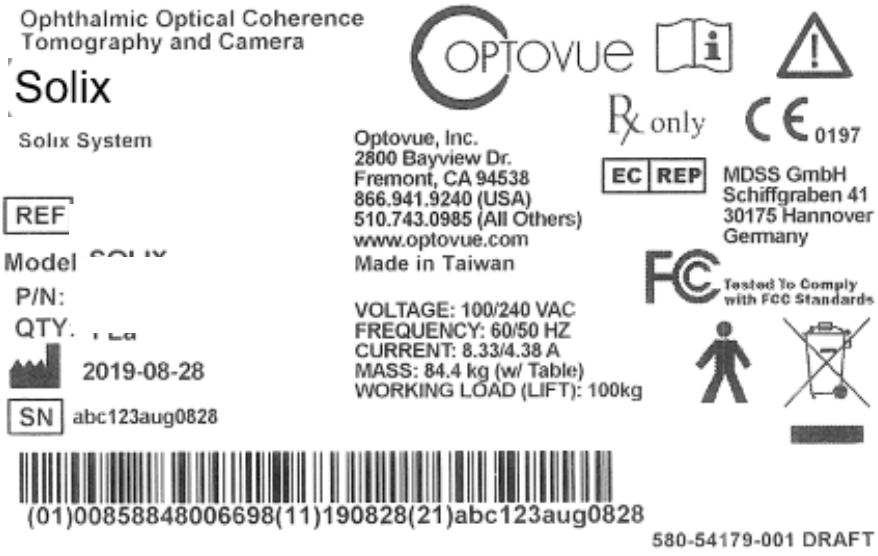
Environmental conditions during transport: Temperature range (10 °C to +55 °C) and atmospheric pressure range (500 hPa to 1060 hPa)

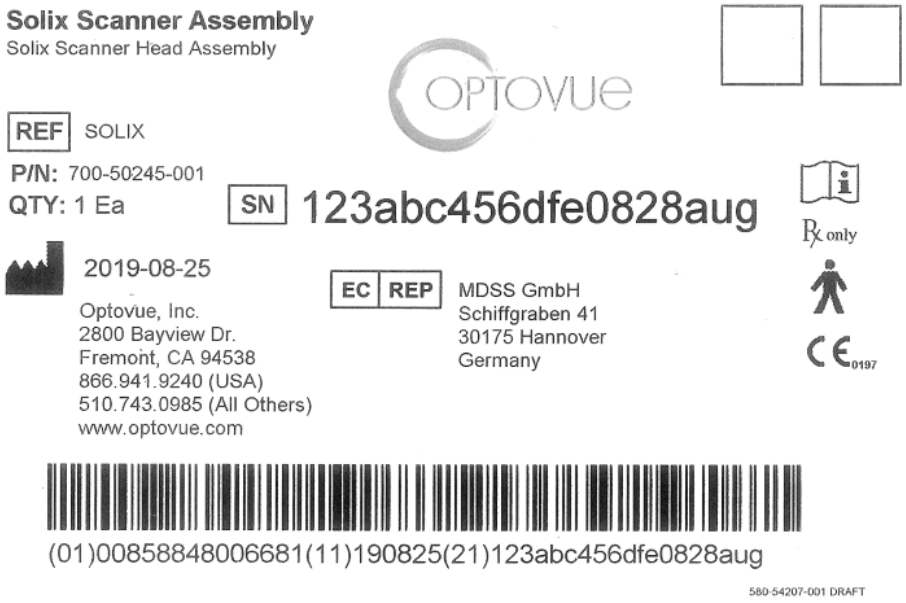
Max stack 2

1.9.2 **Product Labels**

The three SOLIX™ model product labels appear below. These labels are sample drafts only.

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 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.

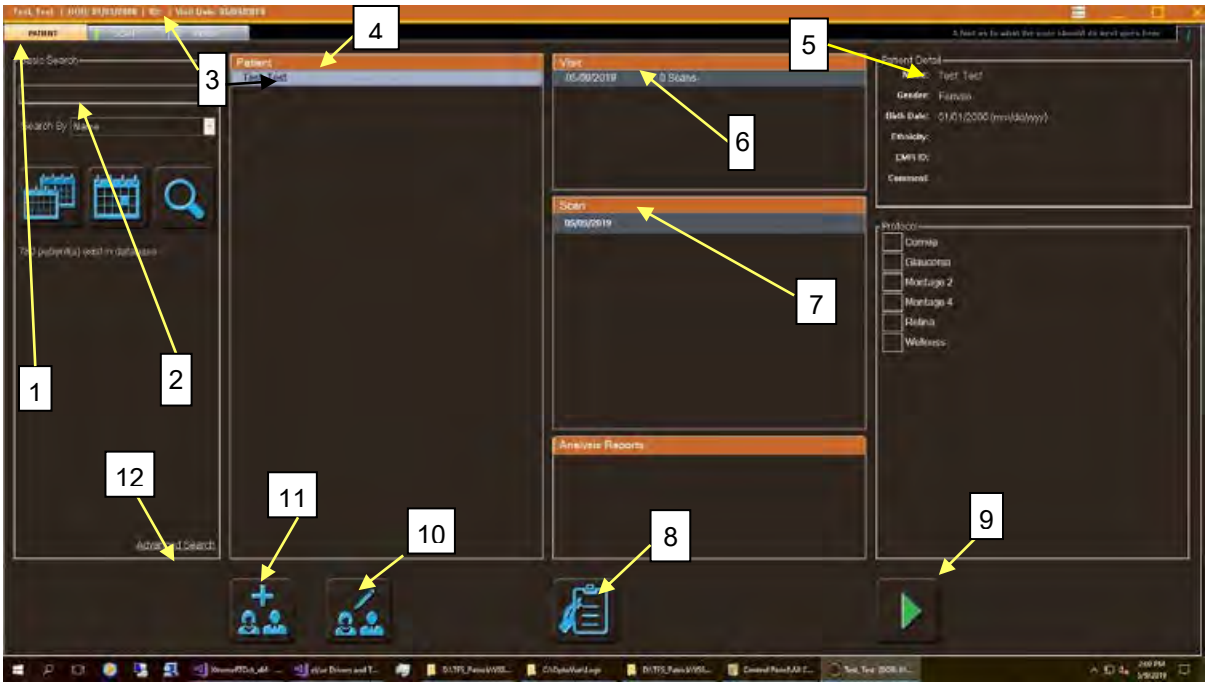


Figure 3 PATIENT Window Items

Legend:

1 PATIENT tab (highlighted)

2 Basic or **Advanced Search** area

3 Selected patient in list and on title bar

4 Patient list

5 Patient Detail area

6 Visit list (for selected patient)

7 Scan list (for selected visit)

8 Review button

9 Scan button

10 Edit button

11 Add Patient button

12 Advanced or **Basic Search** link

☞ **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, 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.

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.

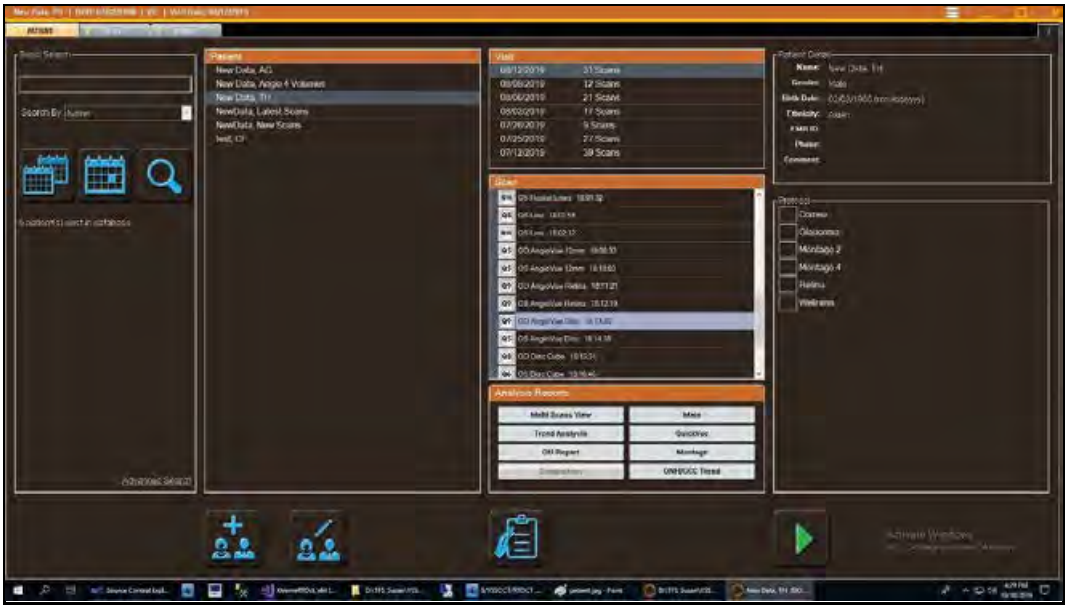


Figure 7 Selections Made in PATIENT Window

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.

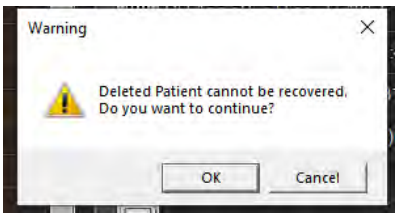


Figure 8 Delete Current Patient Warning

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.

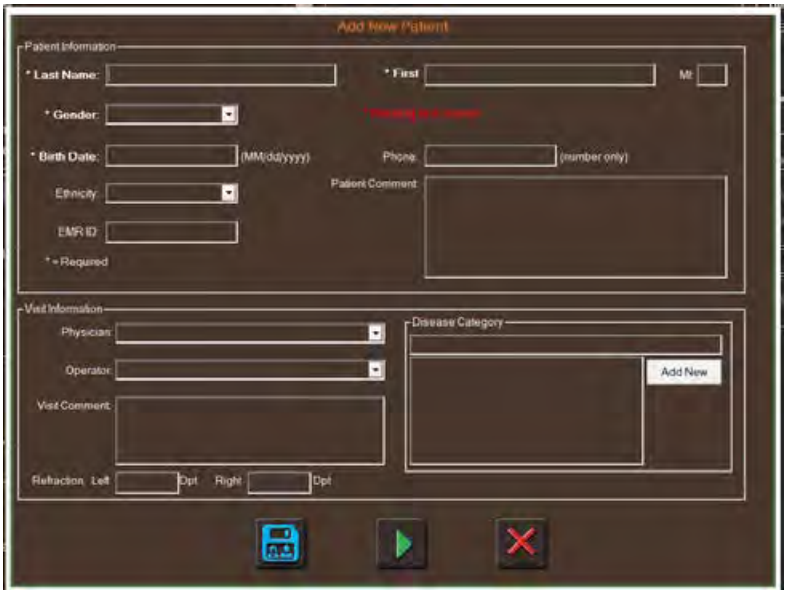


Figure 9 Add New Patient Dialog

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.

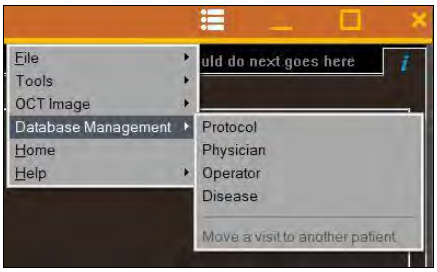


Figure 10 Select Move a visit to another patient

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.

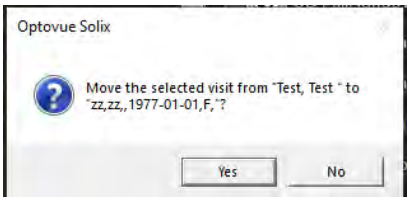


Figure 13 Confirm Move to Selected Patient

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, photo, 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

5. 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 AutoAdjust

7. 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).

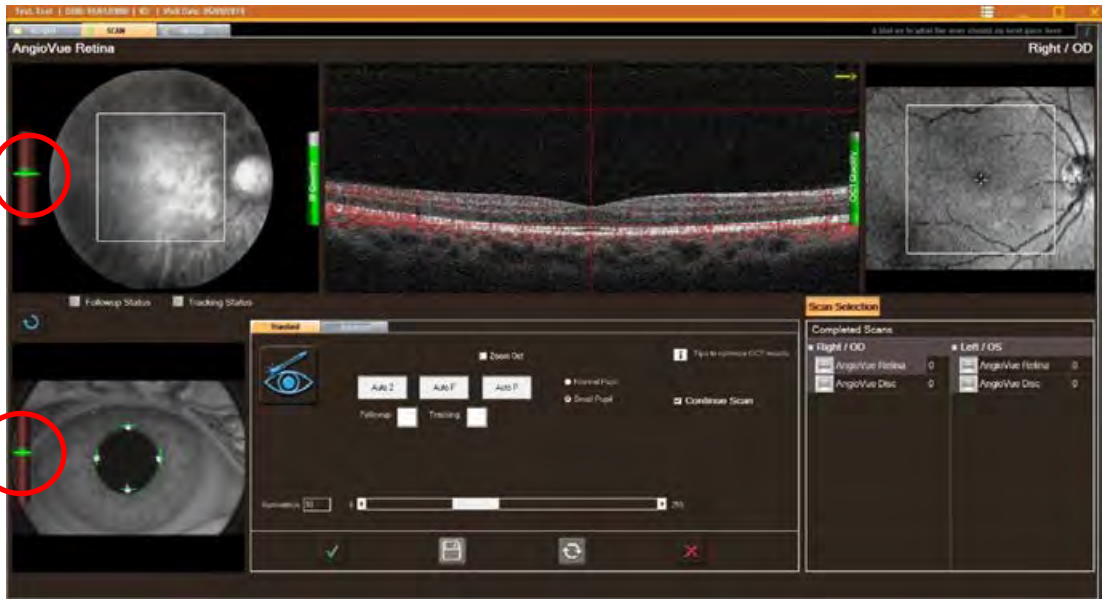


Figure 17 Alignment display after AutoAdjust, no tracking

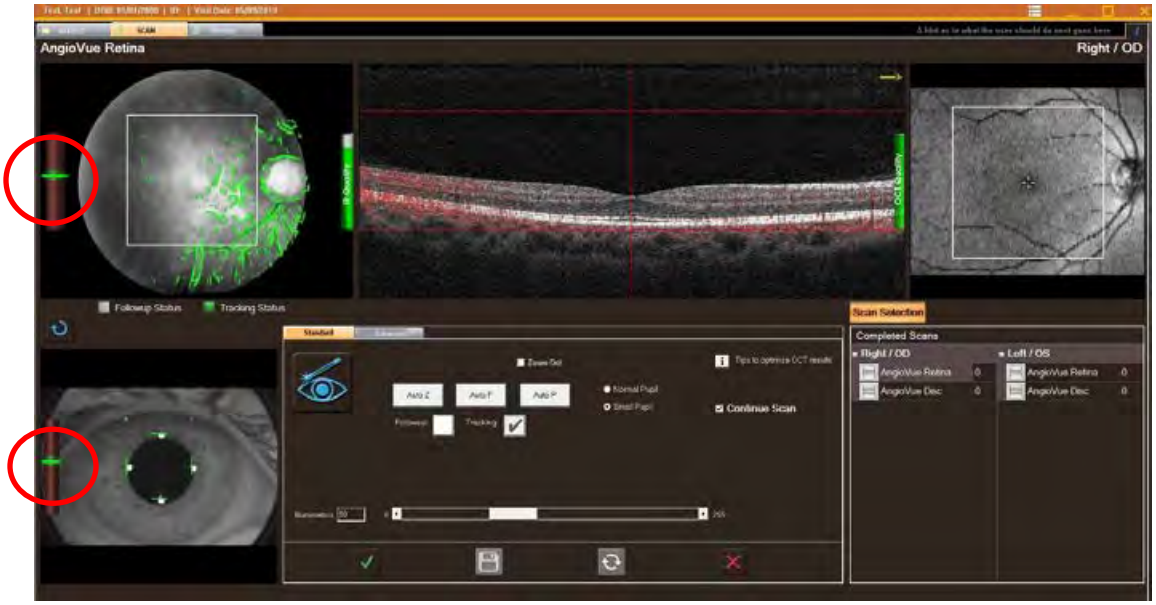


Figure 18 Alignment display with tracking after auto adjust

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.**

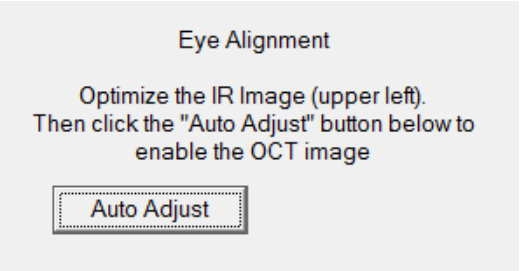


Figure 20 Eye alignment

- 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.

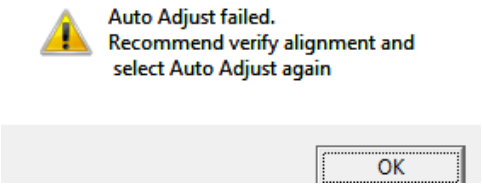


Figure 21 Auto Adjust fail

- 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.

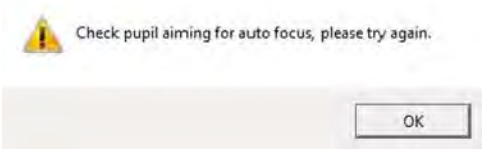


Figure 22 Auto Adjust focus

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.

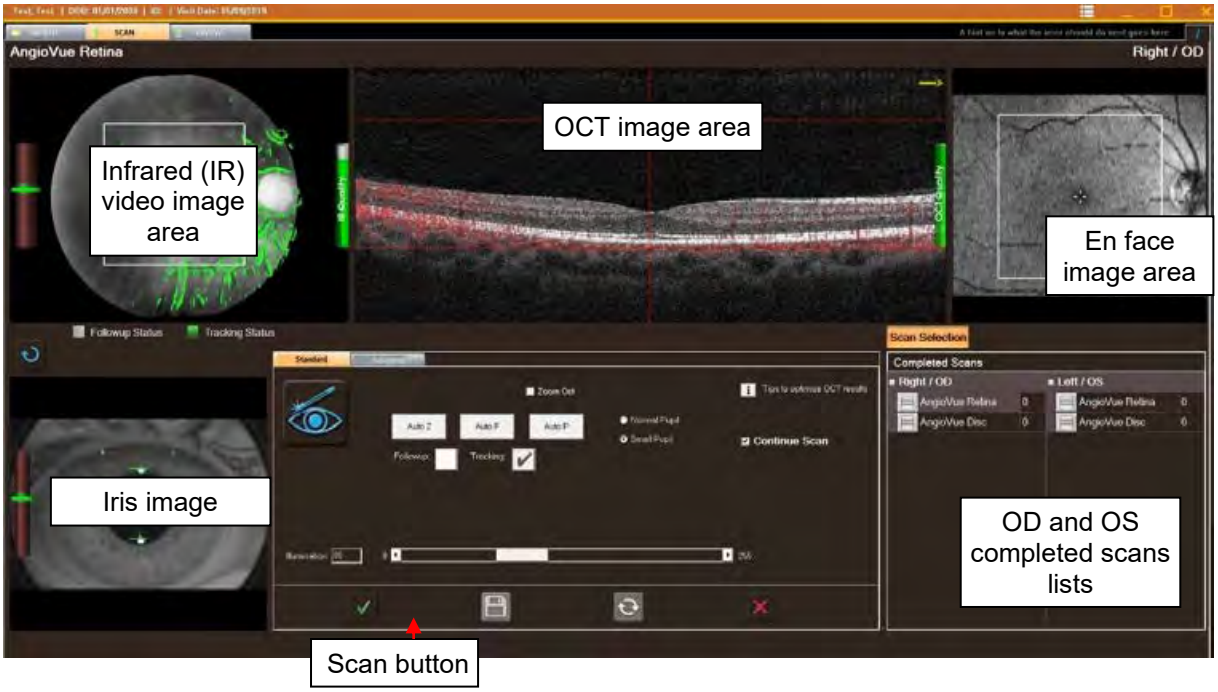


Figure 23 SCAN Window SOLIX™ with AngioVue® tracking on

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.)

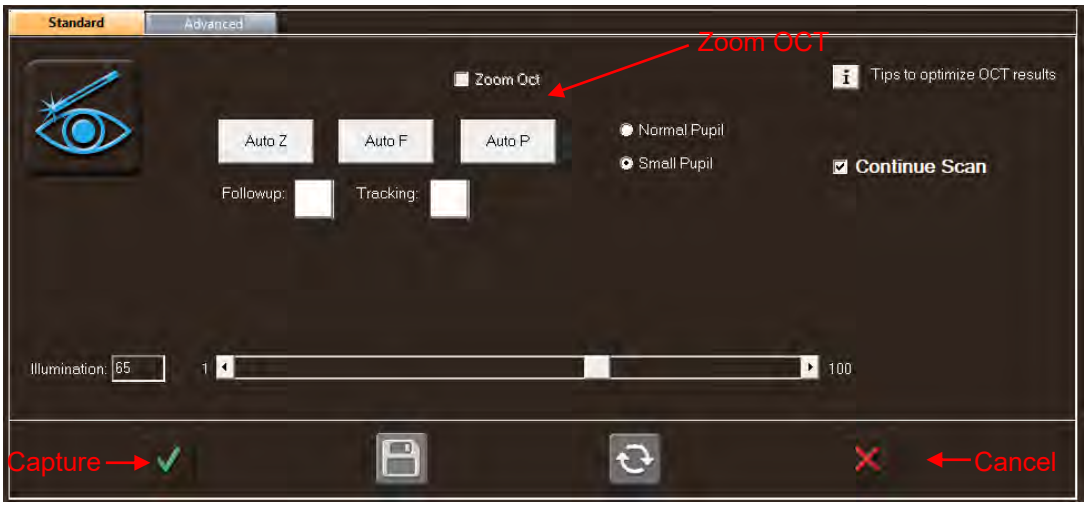


Figure 24 Scan Adjustment Options (Standard Tab)

To customize scan parameters, select the Advanced tab.

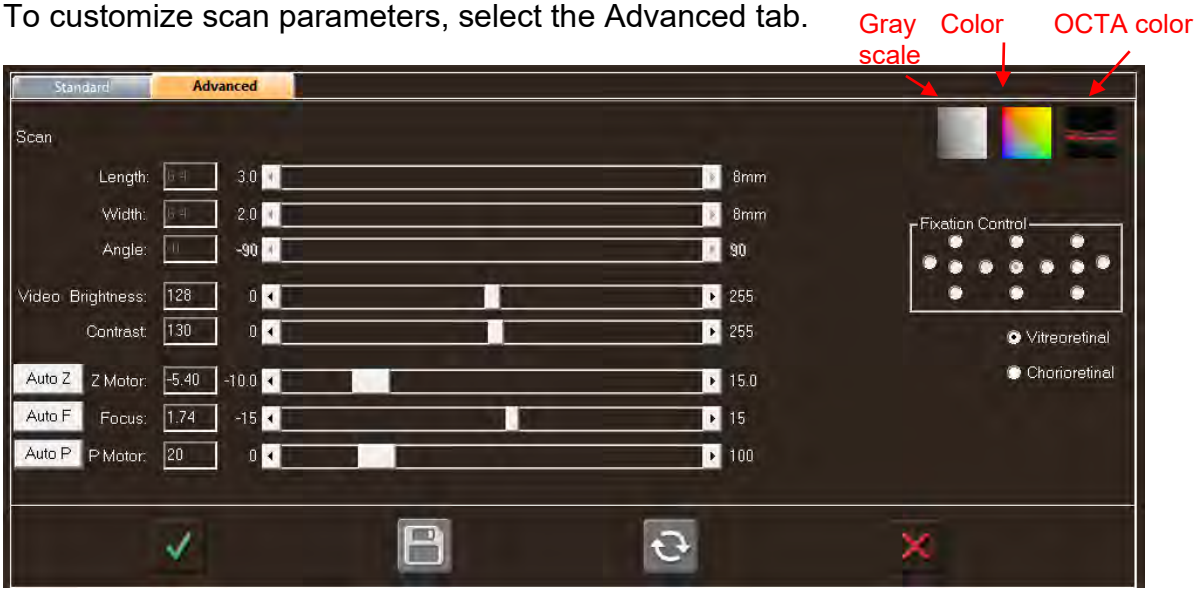


Figure 25 Advanced Tab to Customize Scan

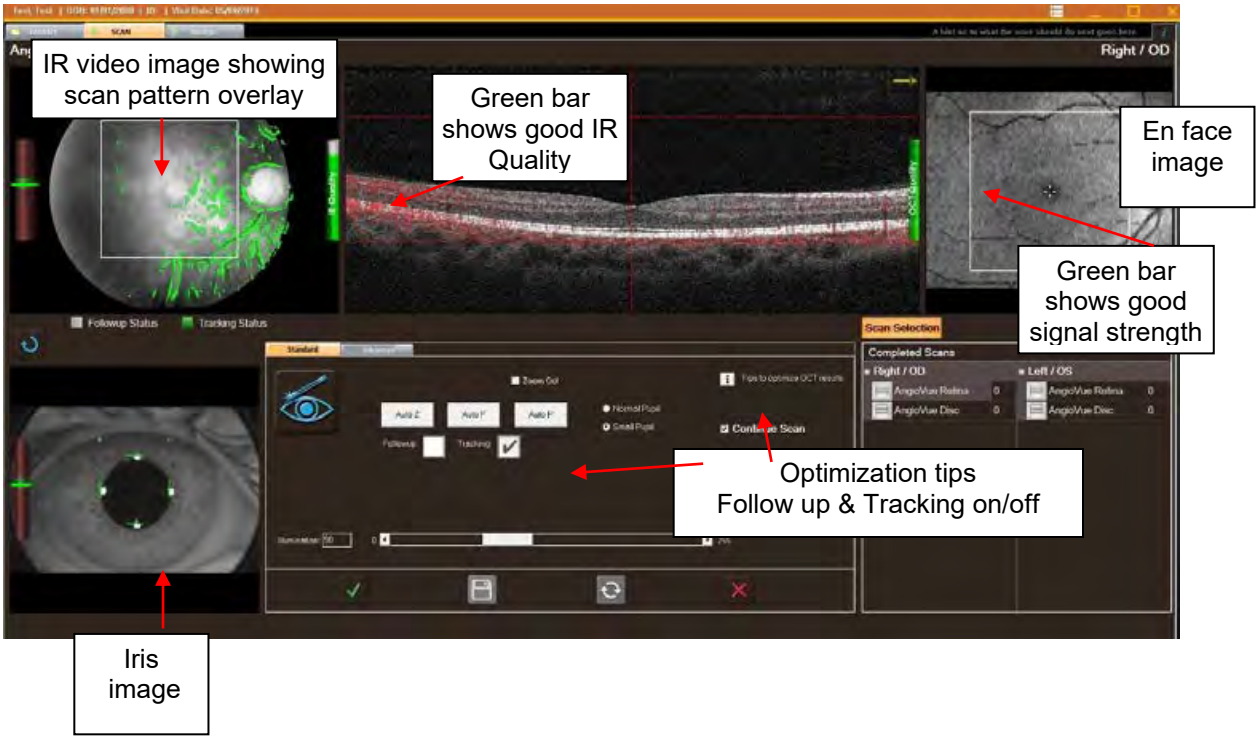


Figure 26 Optimize Working Distance

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.

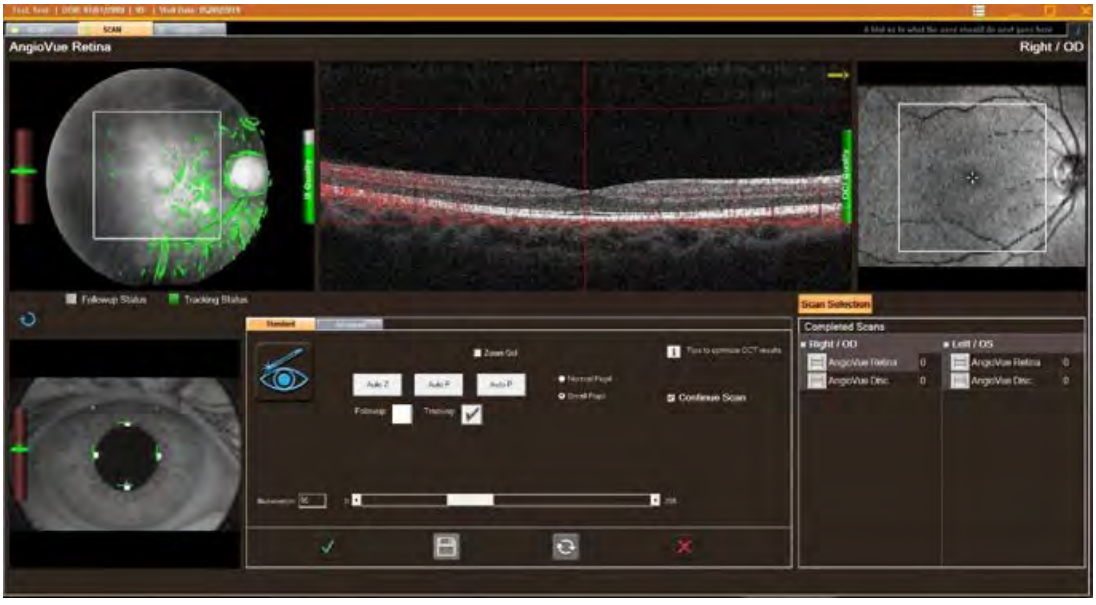


Figure 28 Example of Scan Centered Vertically

☞**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.

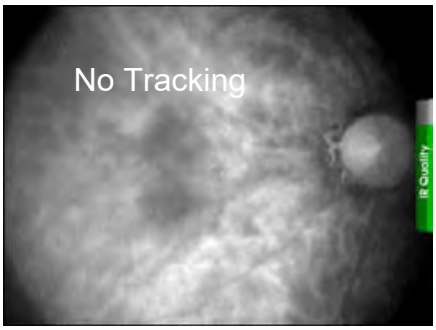
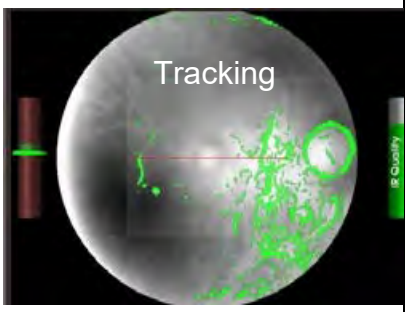
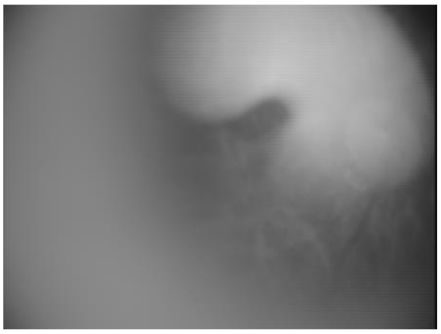
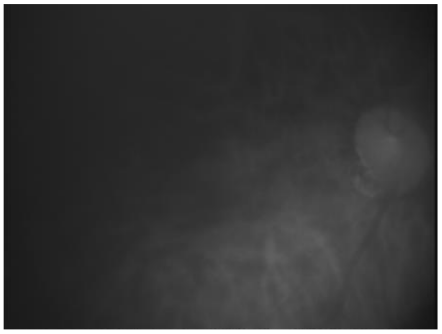
13. If the OCT (SQ) indicator is red, use one or more of the following functions on the **Advanced** tab to manually optimize scan signal strength and image quality.

- 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

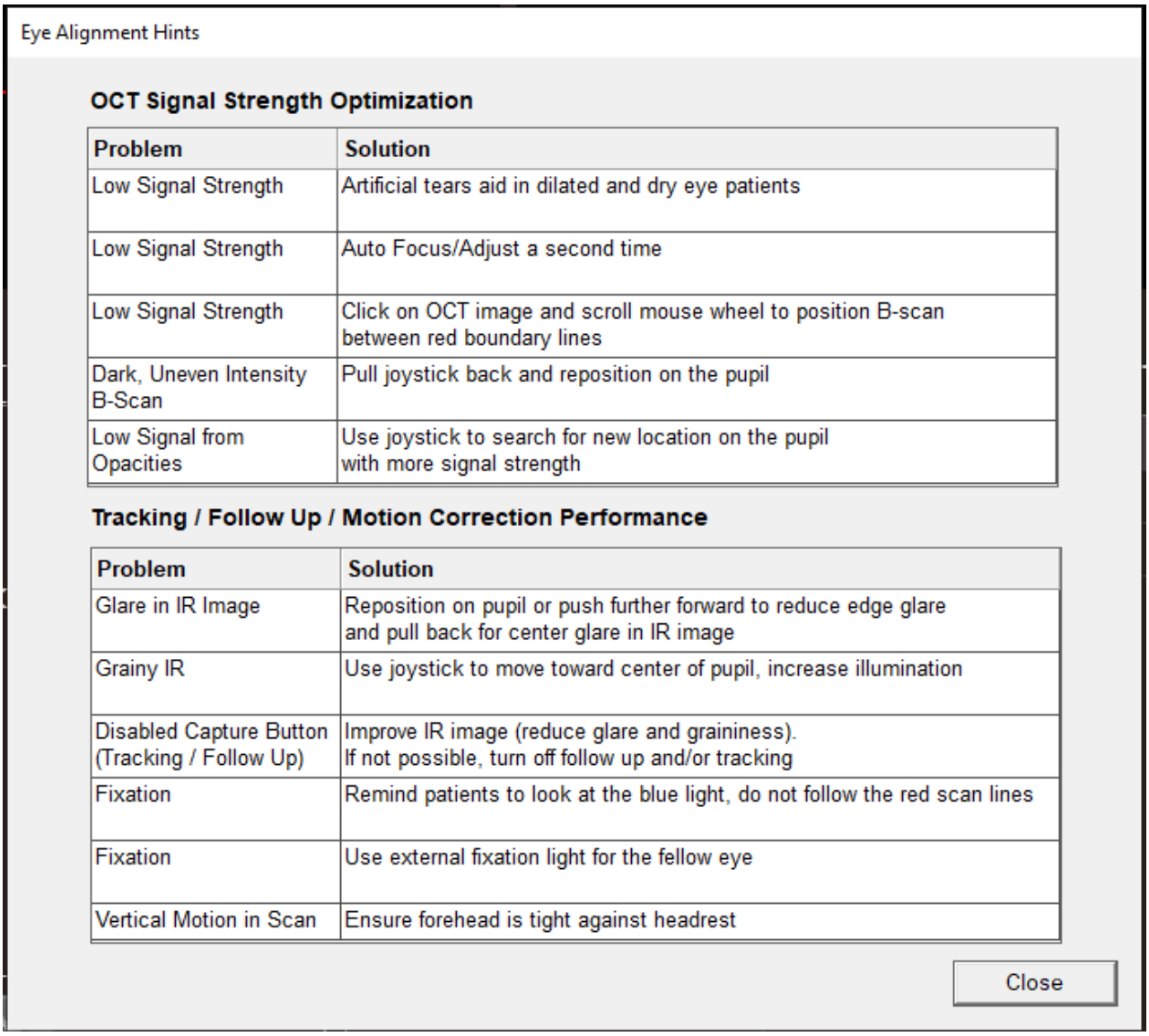


Figure 29 Tips to Optimize OCT results

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

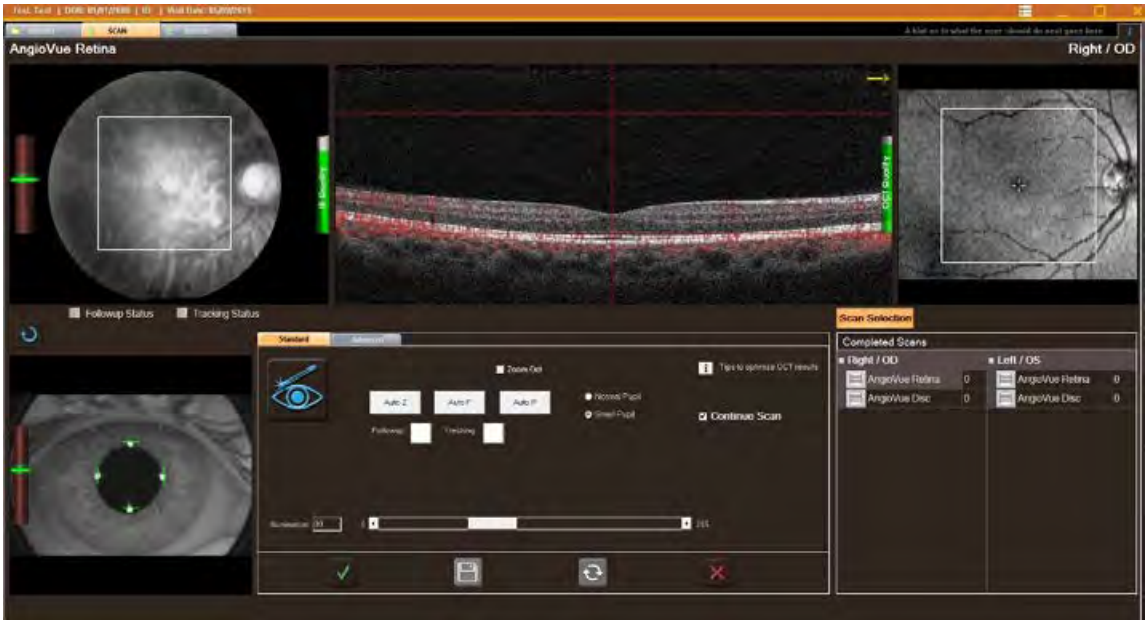
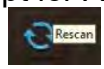


Figure 30 A Captured Scan (Save Button Active)

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:

a. Click the B scans visible over the IR image and scroll.

b. Click the **REVIEW** tab on the left to review the scan just completed.

c. 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.

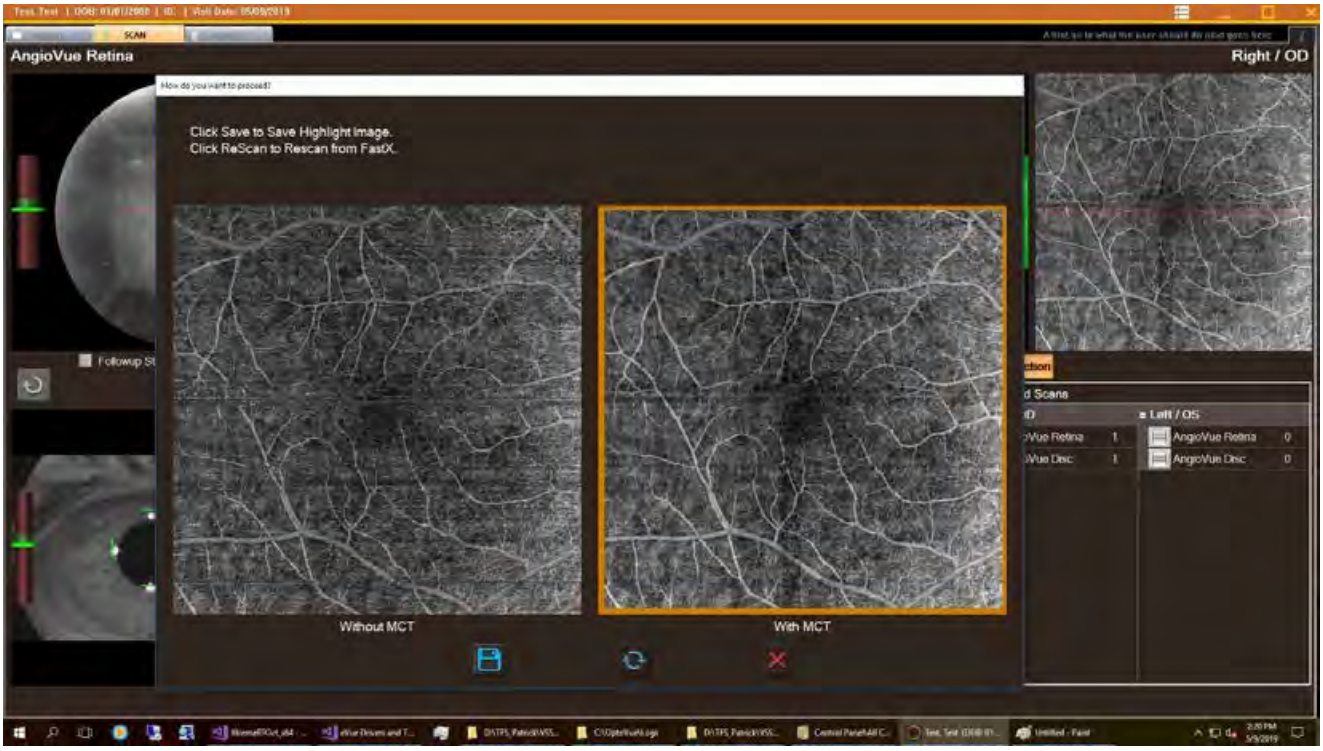


Figure 32 Continuous mode displays Fast-X and combined MCT for operator selection

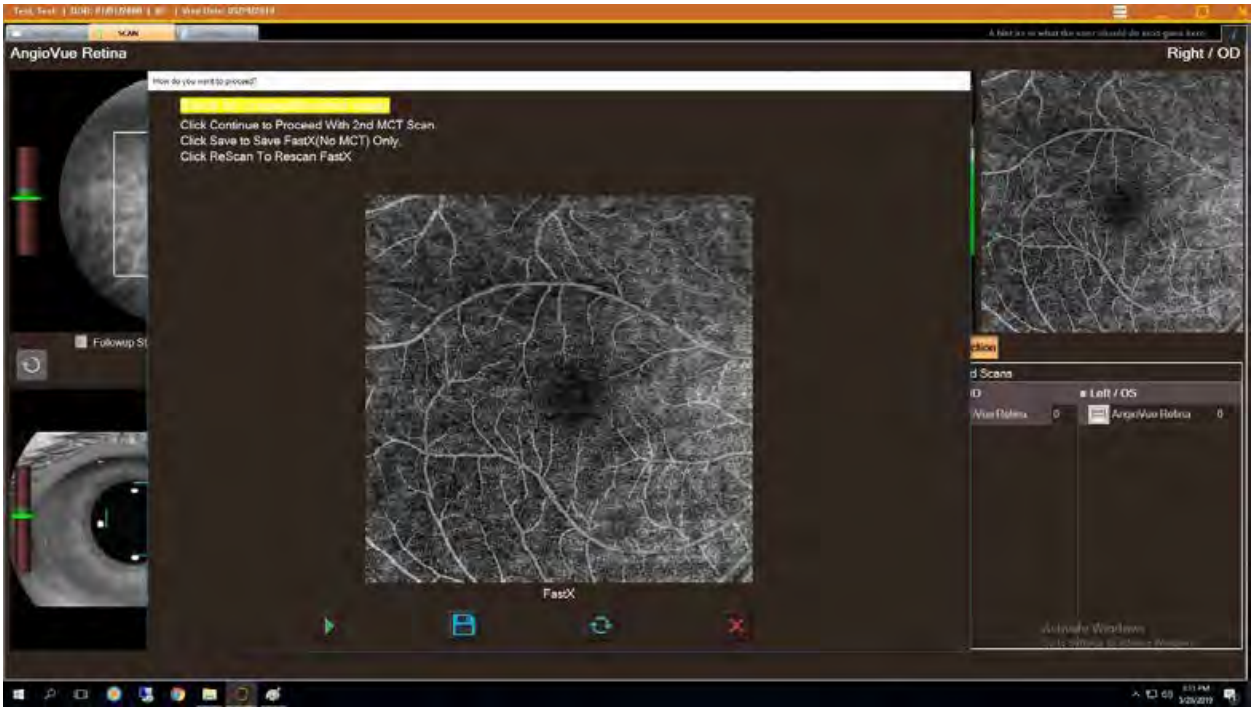


Figure 33 Noncontinuous mode displays a panel after X the user can save and continue or rescan

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.

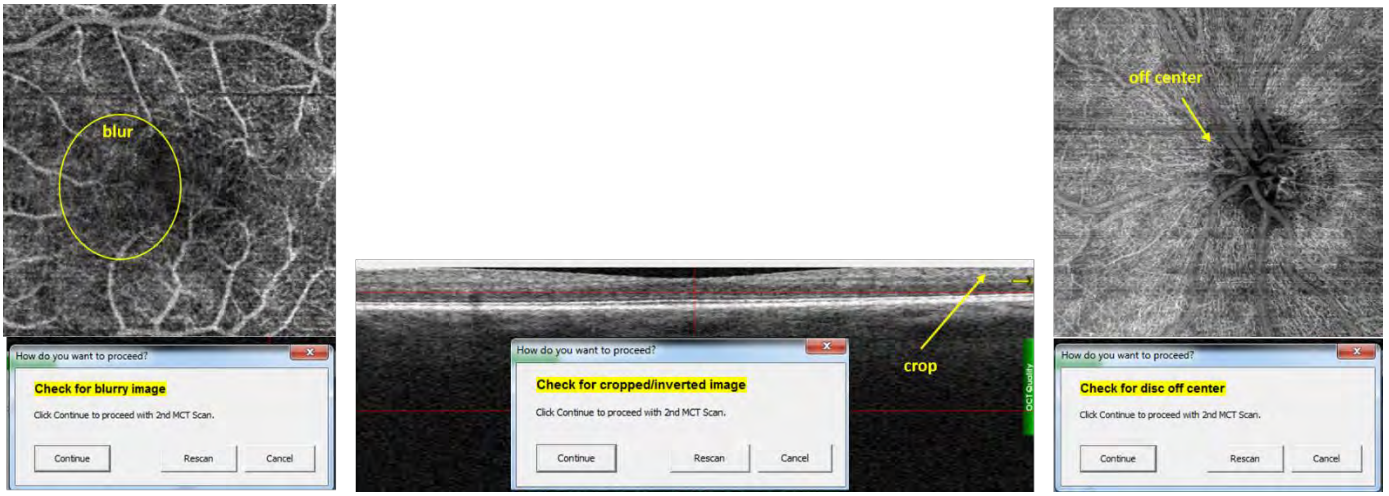


Figure 35 Examples of Scan Quality Alerts During Acquisition

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.

Figure 36 Scan quality indicator

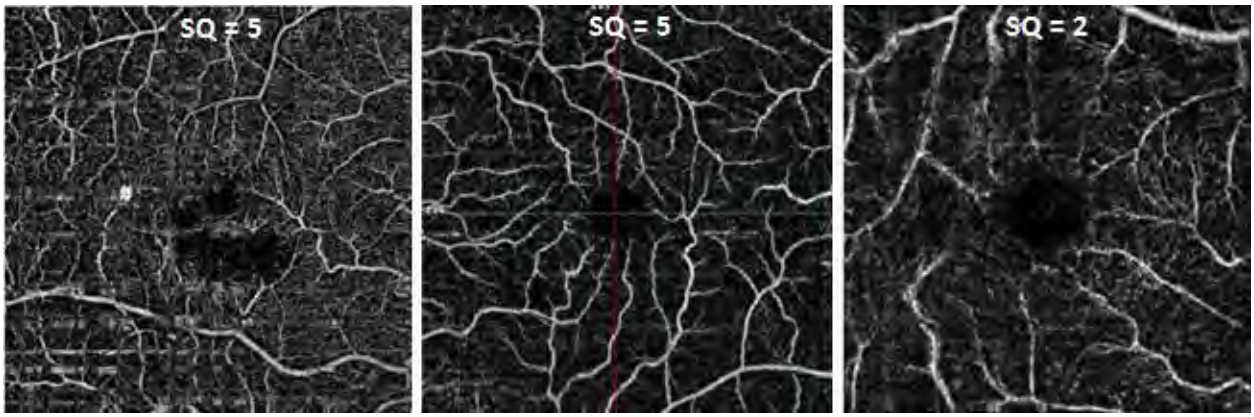


Figure 37 Examples of Scans with SQ<6

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.

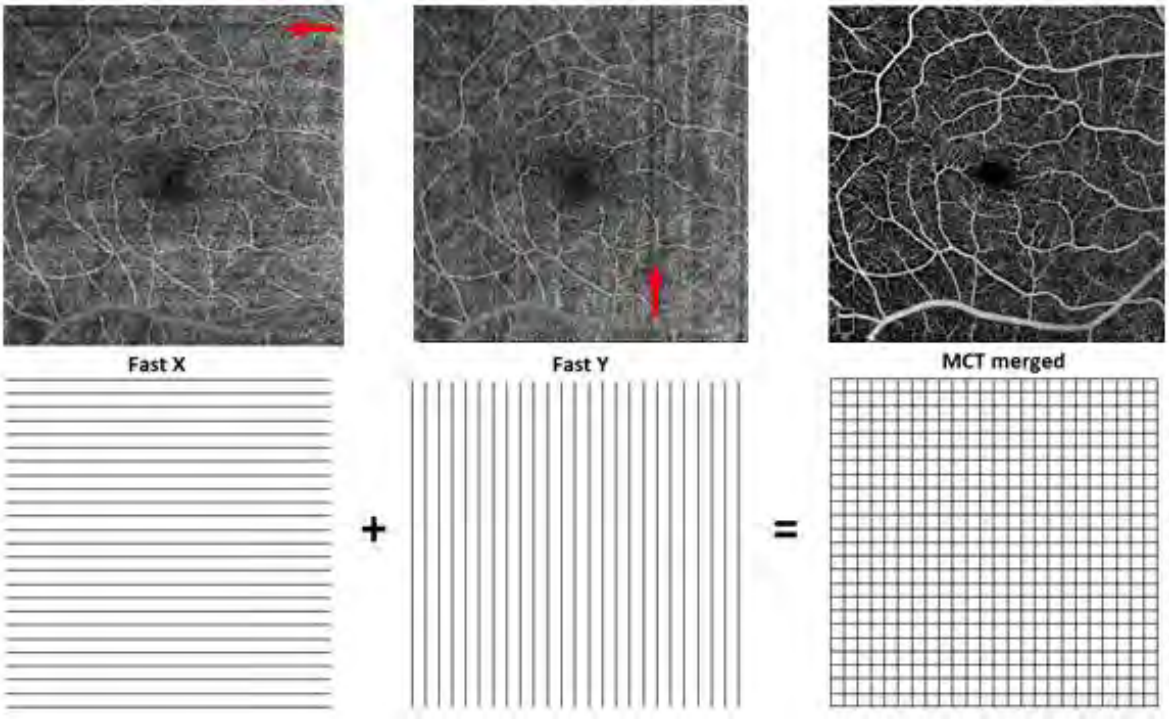


Figure 38 Saccadic Motion Fast-X and Fast-Y saccadic motion corrected on MCT Merged image

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.

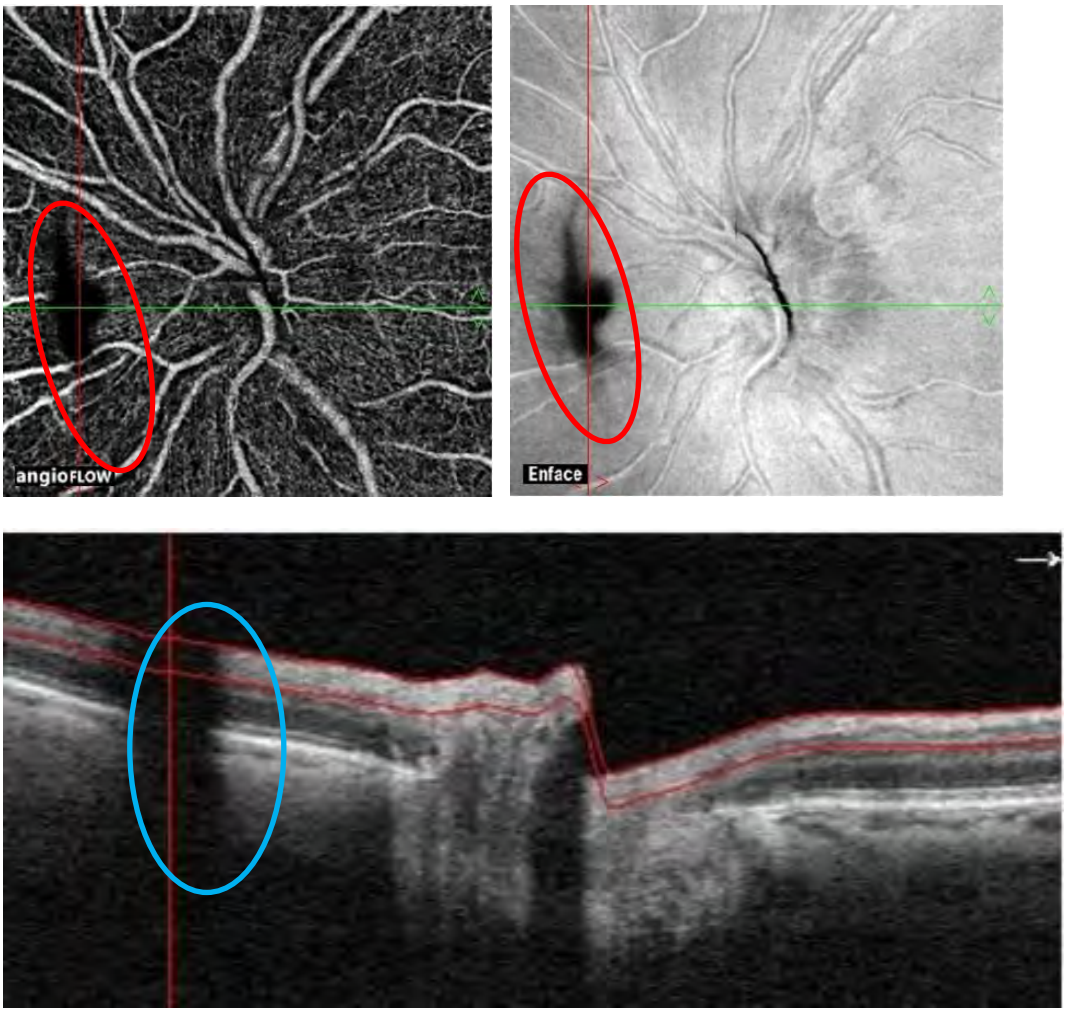


Figure 39 Floaters

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.

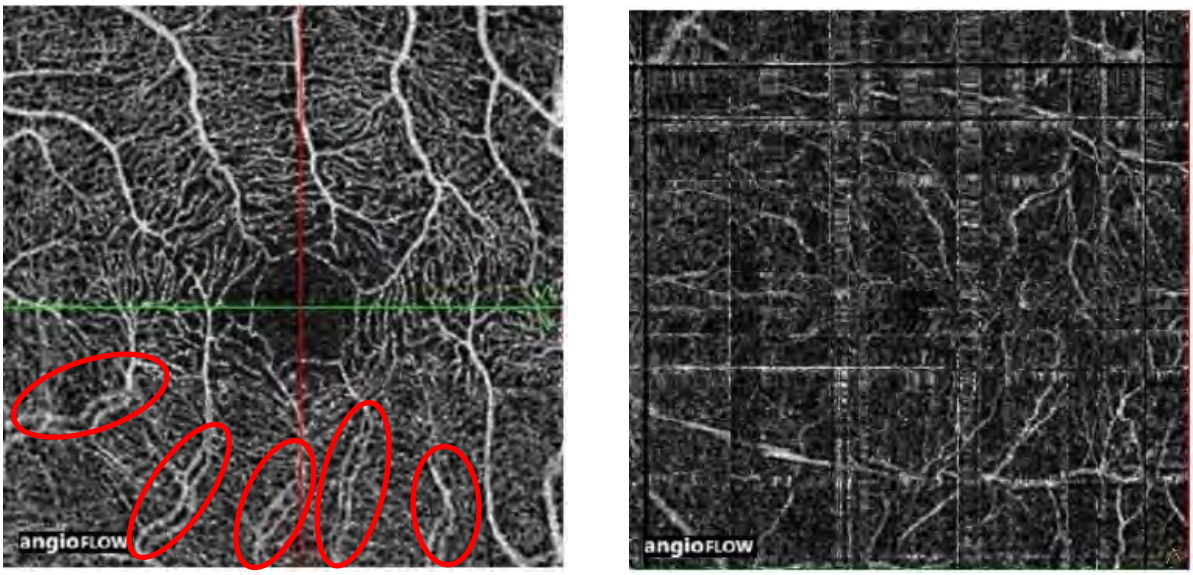


Figure 41 Excessive Motion

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.

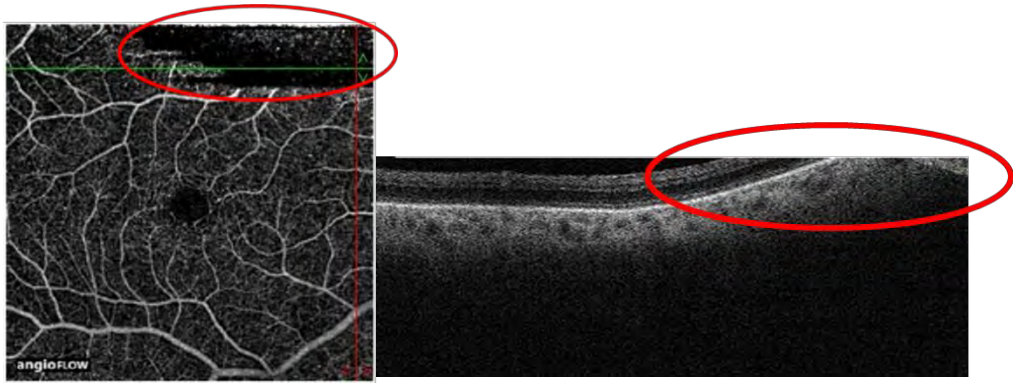


Figure 42 Image Crop

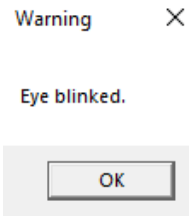
Example of image cropping affecting both the vascular en face image (left**), confirmed in the corresponding B-scan image (**right**)**

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.

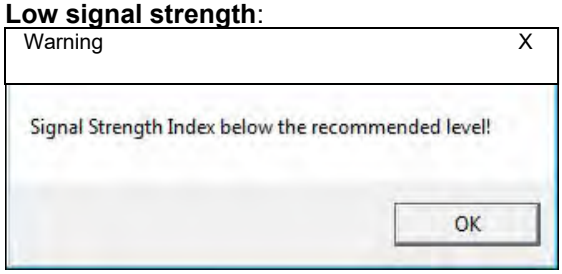
3.1.15 Joystick button Functionality

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:

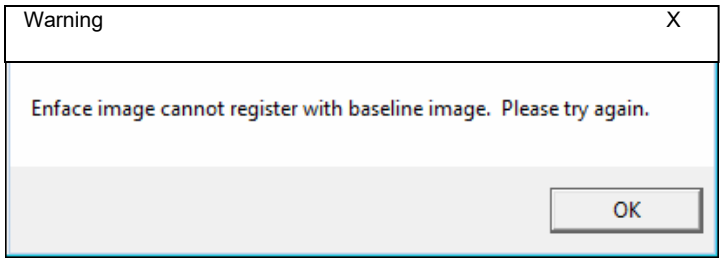
1. **Eye blink**:



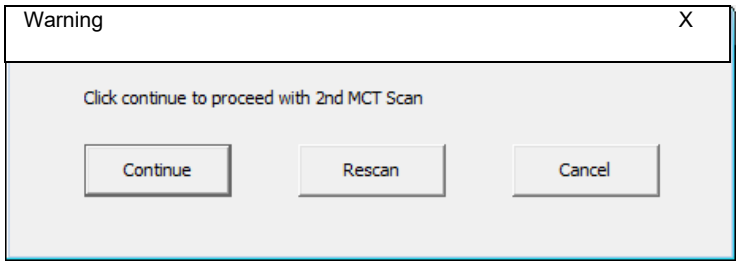
2. **Low signal strength**:

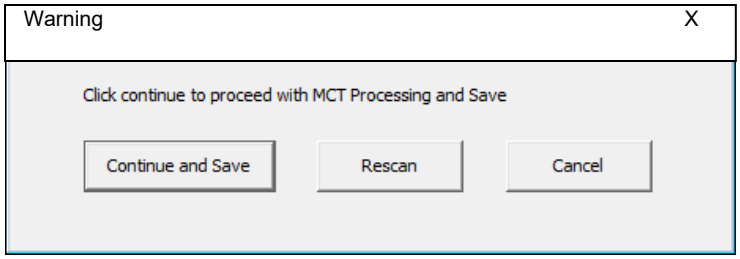


3. **Enface registration failure**:



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



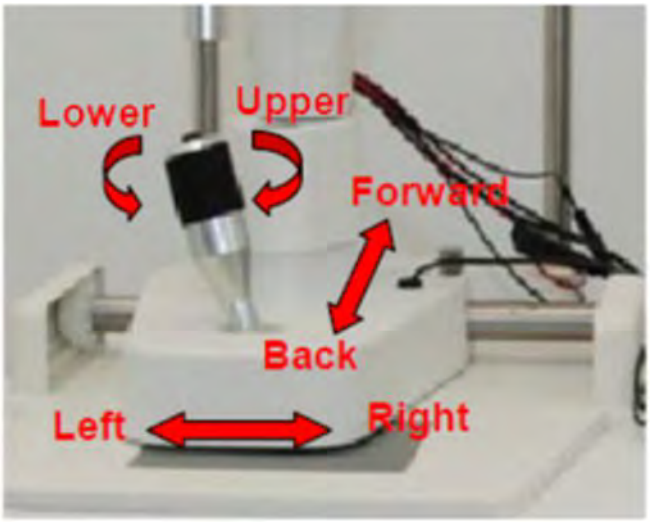


3.1.16 **Fundus image capture**

For non-dilated patients it is recommended to complete all OCT scans prior to capturing fundus photo imaging since the flash will reduce pupil size. In dilated patients, the fundus photo image can be taken at the end of the OCT scans for that eye. See User preference for “Scan navigation order”.

Steps:

1. Check for pupil size Normal 4mm, small 3.3mm
2. Select flash setting based on eye color and pupil size.
3. Center scan head on the pupil and advance the joystick until the working distance indicator reaches the green mark.



4. Ensure there is a good IR image.
5. Click joystick button or Diopter button to autofocus. Focus can also be adjusted manually using the Split bar slider. If only one bar is visible, align to the blue outline on the screen. After finding optimal focus, click split bar out if manually adjusting or click joystick button to return to capture mode, and then the next button click will capture.

Not Aligned

Figure 43 Split bar focused and WDI Aligned

6. Using the joystick to make the two working distance indicators (white dots) as sharp as possible and aligned to the center line and green boxes

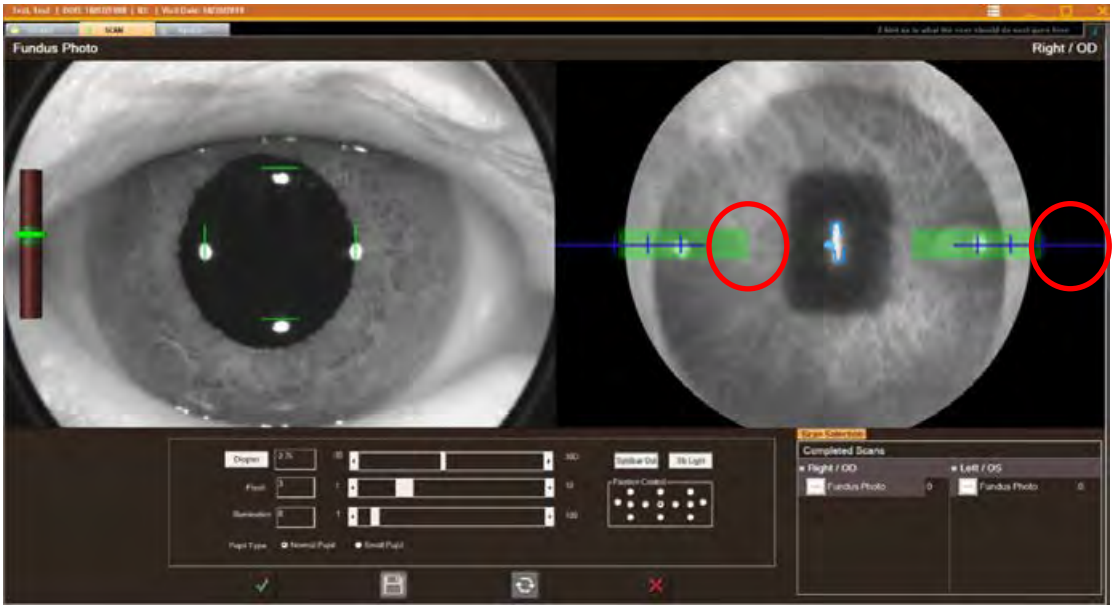


Figure 44 Working distance indicators

7. Capture using the joystick button or mouse

8. Review image. If capturing again, it is recommended to wait approximately 30 seconds until the pupil has time to recover if not dilated.

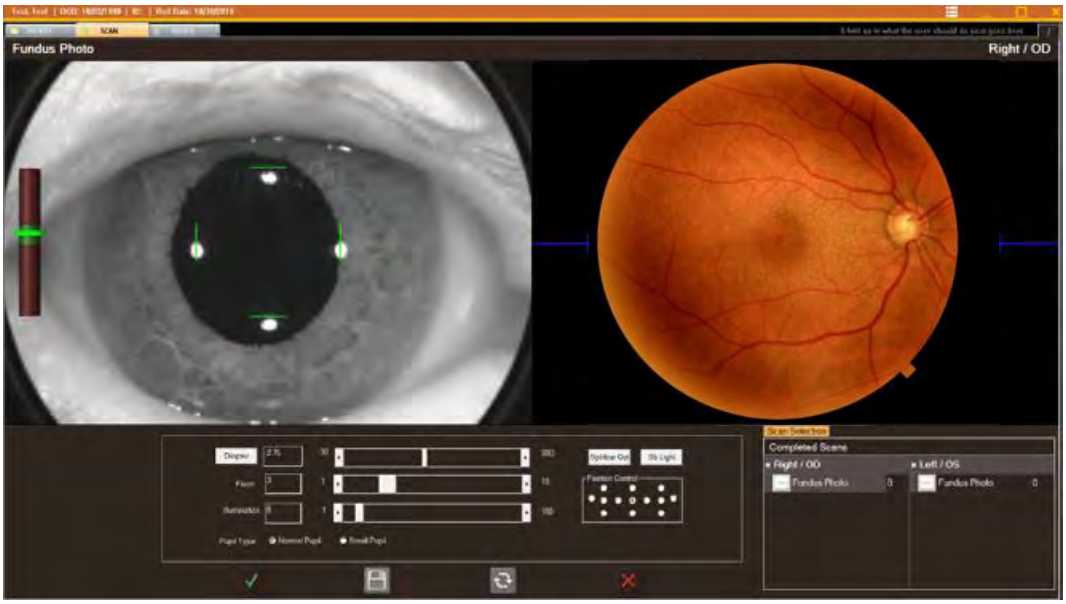


Figure 45 Fundus capture

☞**Note**: The Auto Focus split bar has a range of -10 to +10 Diopters outside of this range manual focus using the slider is required.

☞**Note: The split bar focus is not used for high myopic, hyperopic or external image capture**

3.1.17 **Capturing external images and Red Reflection of the retina**

The red reflection image is dependent on the crystalline lens and cataracts can block the reflection

i. First select External photo, then the eye OD/OS

ii. Diopter slider will automatically go to +25D. Moving the slider in the plus (+) direction for the closest image (Iris) going toward the negative will widen the image (orbit))

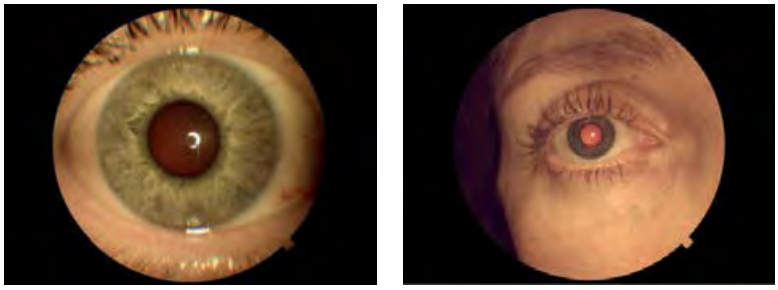


Figure 46 External color images

iii. Push forward until the exterior of the eye comes into focus

iv. Check flash setting “2”, is a good stating value, adjust as necessary

v. For Red Reflex make sure the patient is looking directly into the camera (the IR-image inside the pupil will be brighter when the patient is correctly aligned)

vi. Ask the patient to blink and capture the image

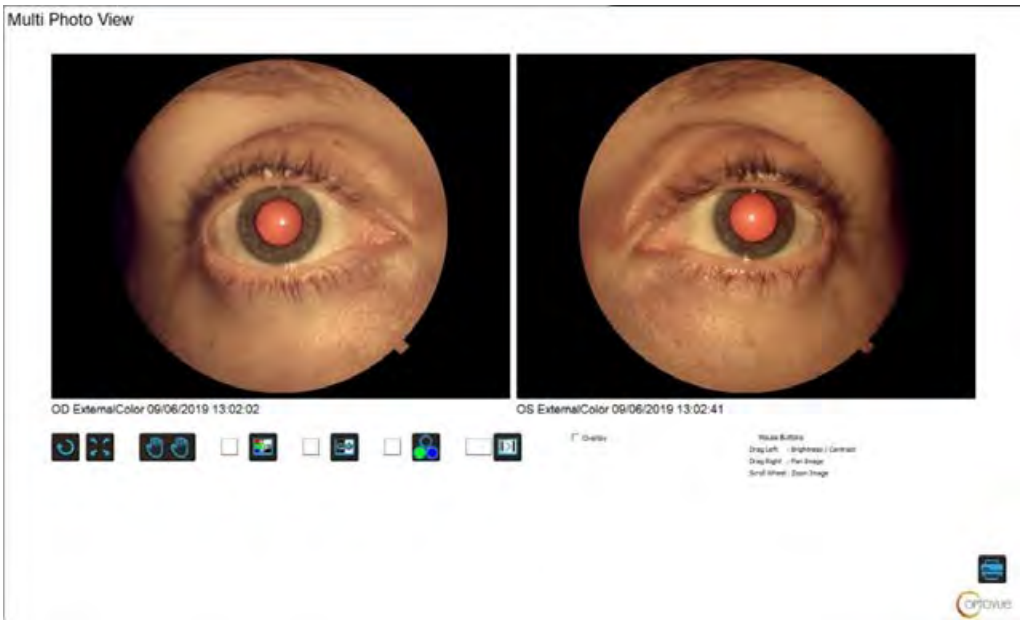


Figure 47 **External color image, Red reflex**

3.1.18 **Exterior IR image**

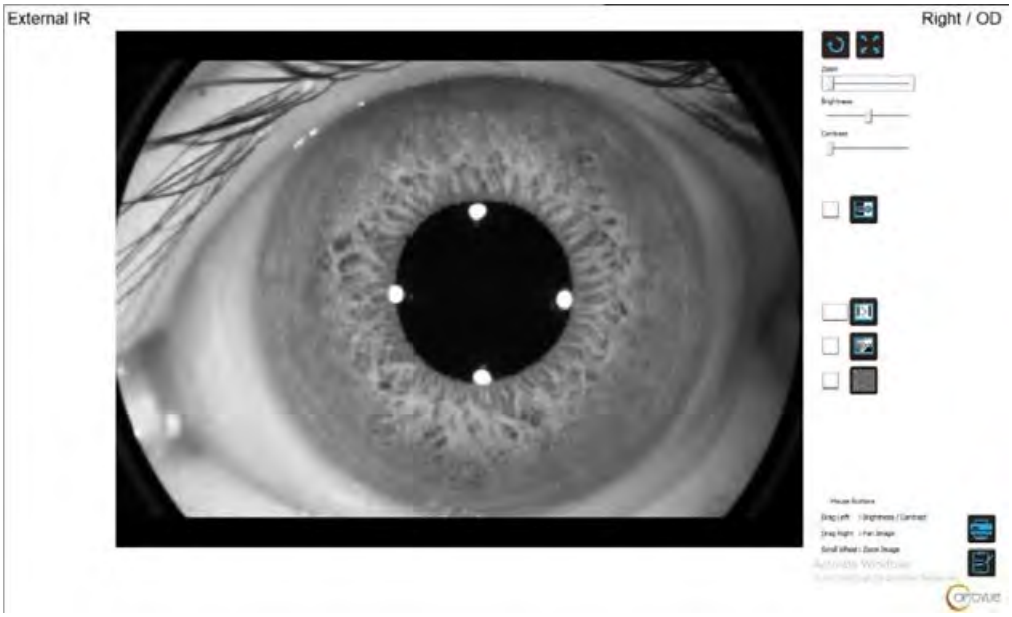


Figure 48 Exterior IR image

For external IR can be used to capture external images without flash, the Focus is achieved by joystick position, Illumination can be adjusted to minimize flares

Figure 49 Multi Photo Report

1.1.2 Review and edit Tools for Photo Image adjustment after capture

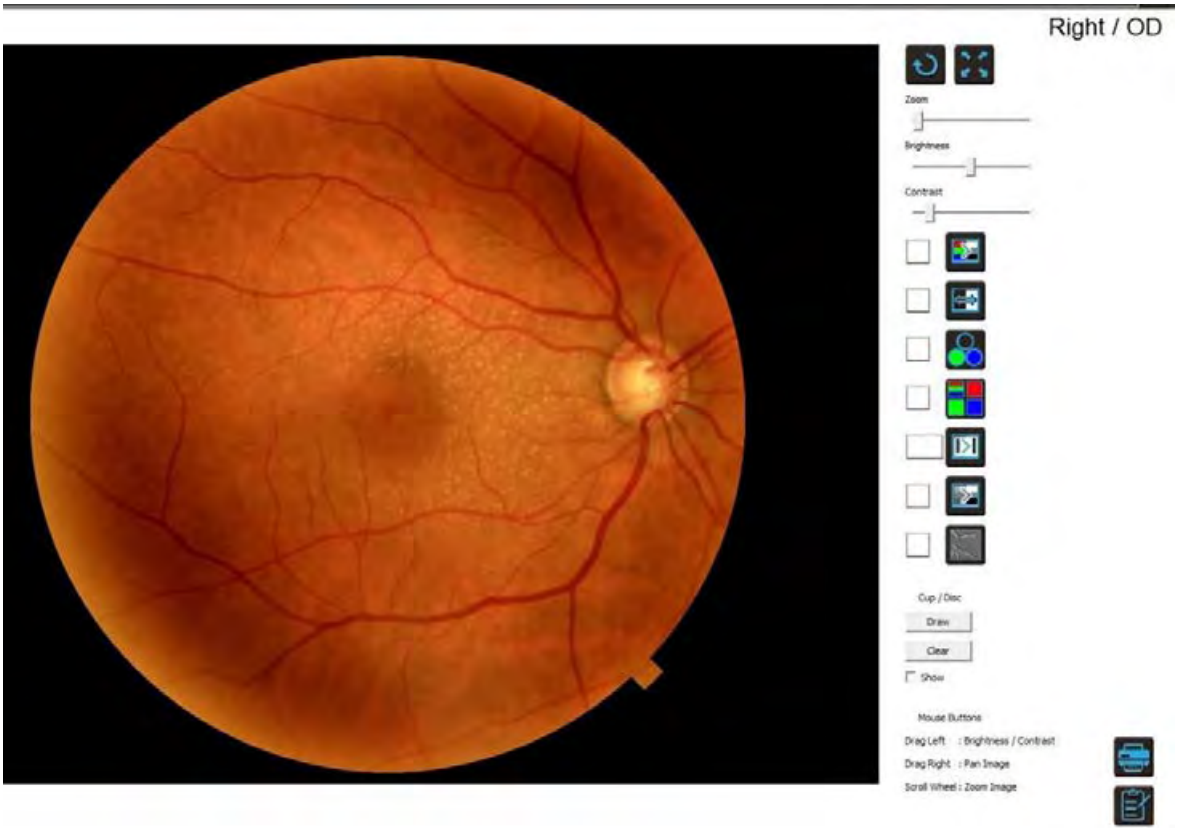


Figure 50 Color Fundus with Drusen

I. To magnify a feature, use zoom slider or click on image and use mouse roller

II. To brighten or darken, use the slider or hold down the left mouse and drag it left or right over the image

III. To add/remove contrast, use the slider or hold down the left mouse and drag it up or down over the image

IV.  Full Gray – color image converted to gray scale

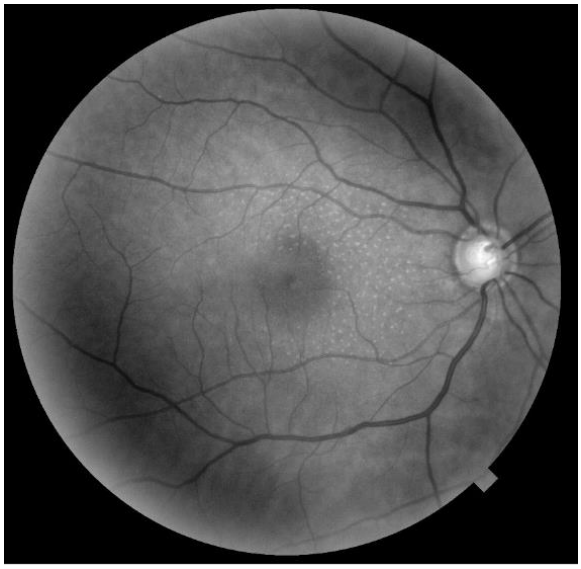


Figure 51 Red free image of image with drusen

V.  Inverse image- either gray scale or color (color inverse produces high contrast blue).

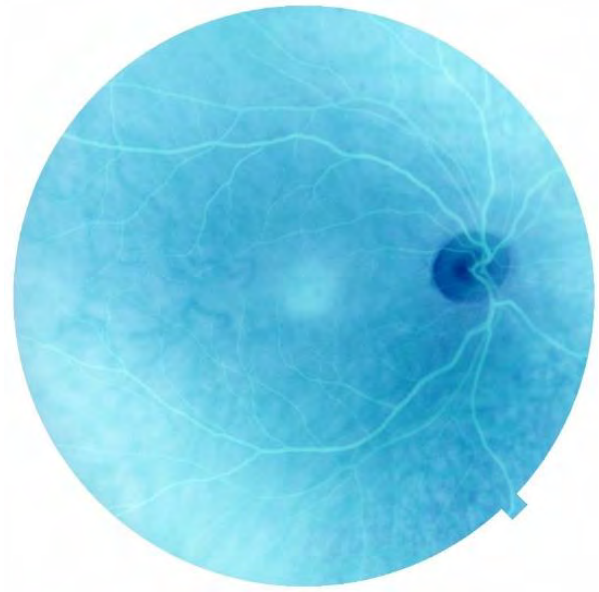


Figure 52 Inverse of color image

VI.  Red free - gray scale without the red channel.

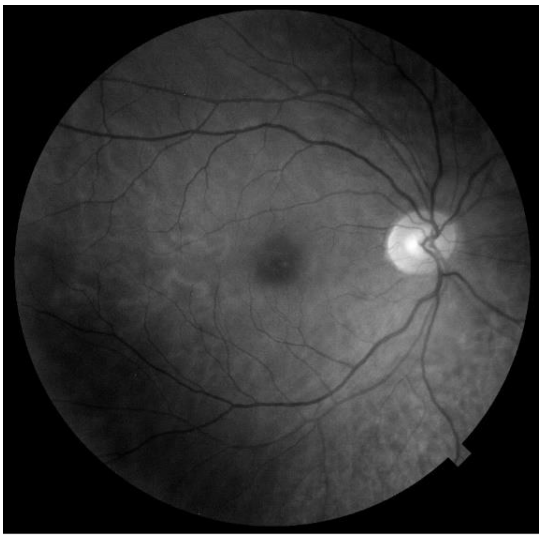
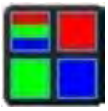


Figure 53 Red free from color image

VII.  3Color display- red, blue, green channels and full color image

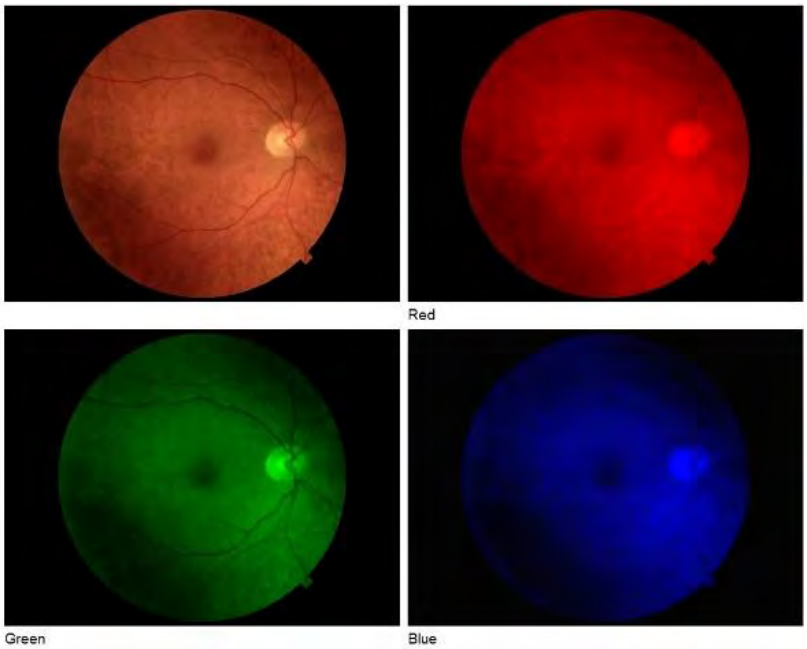


Figure 54 3 color display

VIII.  If more definition is desired click sharpen, it can be clicked 3 times, and 4 clicks resets image to default.

Figure 55 Image with sharpen x3

IX.  Extreme enhance - enhances image

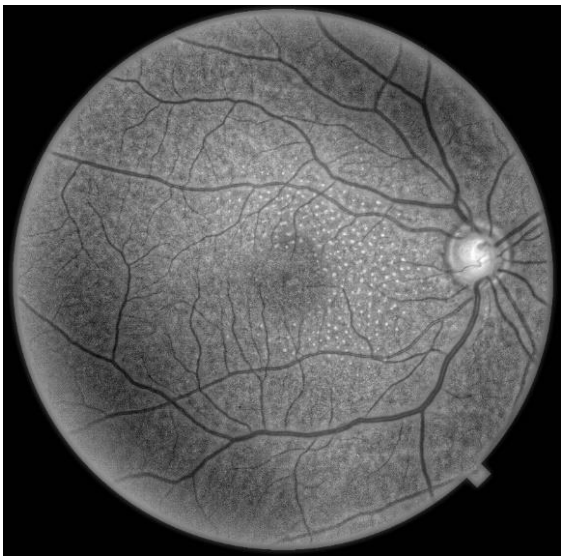


Figure 56 Extreme Enhance

X.  Emboss – produces a 3D-like image

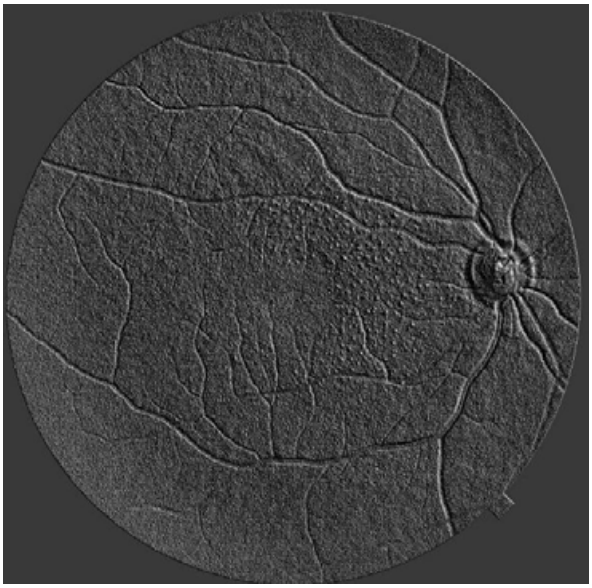


Figure 57 Emboss

XI. Cup/Disc – by selecting draw, the operator can outline the Disc using individual mouse clicks and double click to close circle, and then outline the cup in the same manner to complete the drawing and calculation.

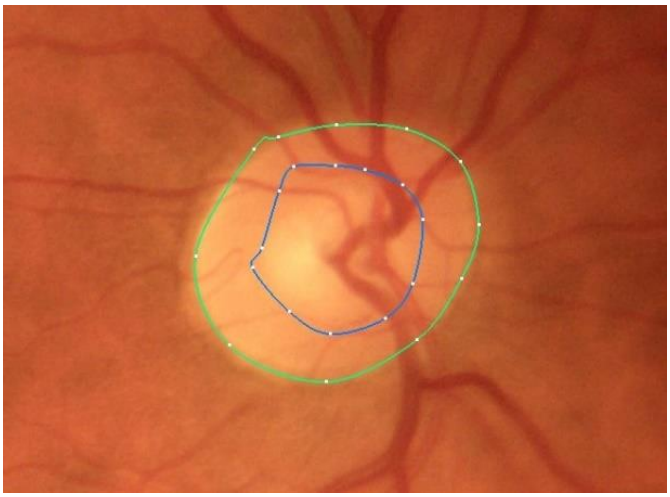


Figure 58 Cup/Disc Draw

XII. Once you have the desired effects, right click on the image and save it.

3.2 Scanning Options

3.2.1 Scan Types and Protocols

Figure 59 Select Scan Type or Protocol

The initial SCAN window presents scan types grouped in the categories **Retina, Nerve Fiber, Photo, 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 60 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. The lower area of the dialog has two tabs, **Scan Size**, **Average#** to set the default scan settings.

Figure 61 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.)

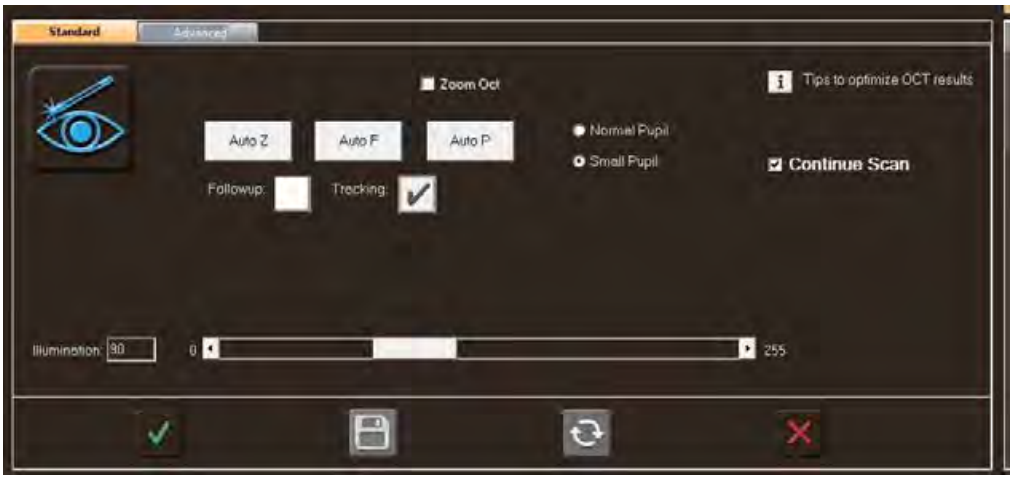


Figure 62 Scan Adjustment Options (Standard)

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 detais, 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 63 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 64 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.

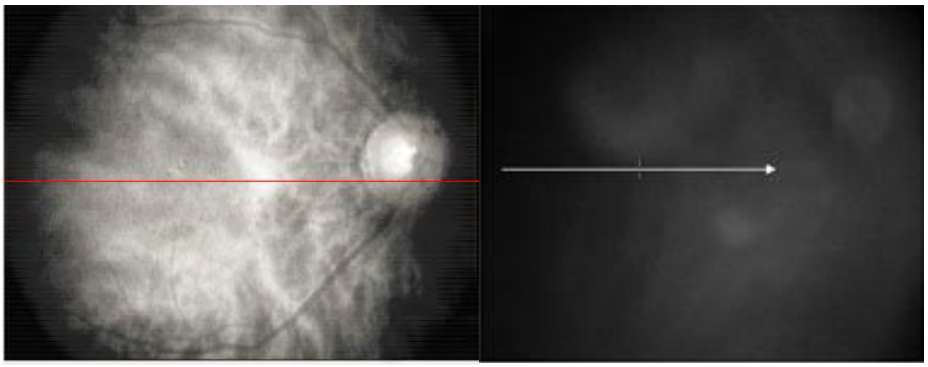


Figure 65 Good IR Image (Left) and Poor IR Image (Right)

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 66 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 **FullRange**™ 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 **Widefield** (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

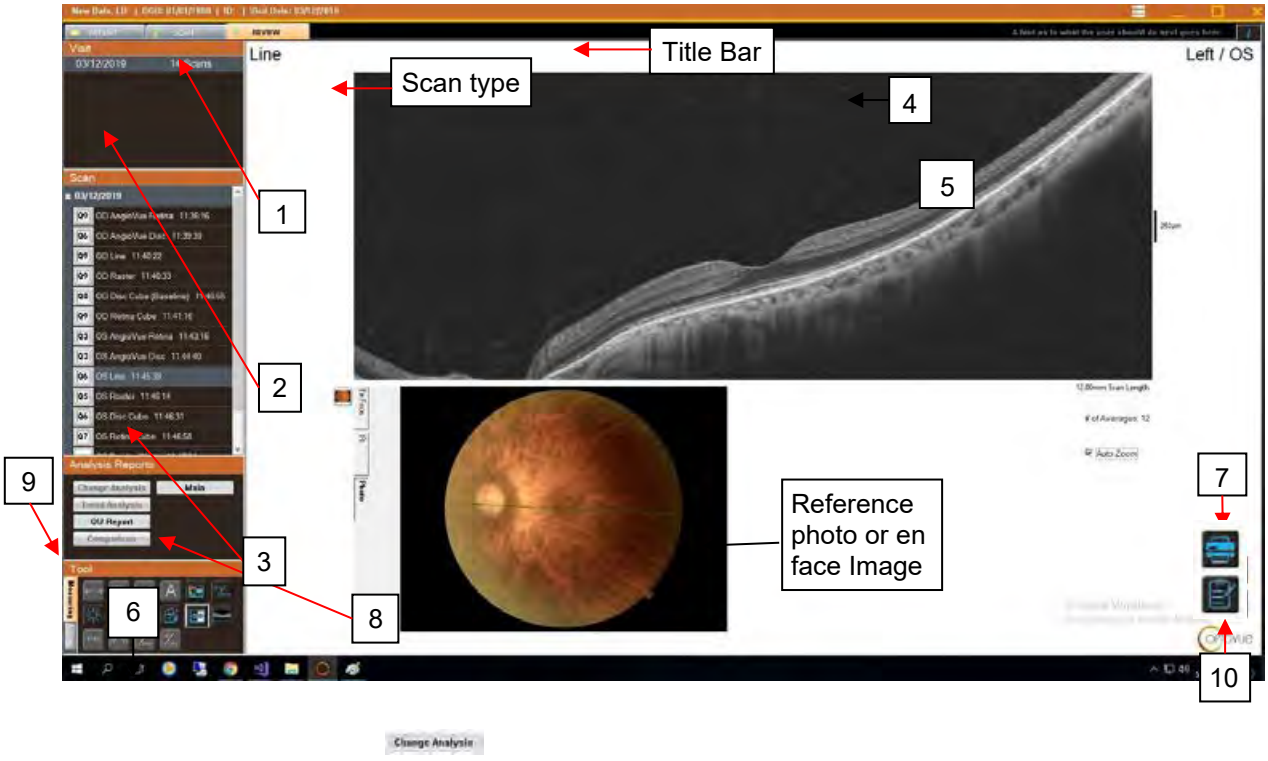


Figure 67 Review Window Components

1 -Patient selected

2- Visit list

3- Scan list

4- Signal Quality value

5- B-scan windows

6- Tool pane

7- Print button

8- Change Analysis button(if data avail.)

9- Analysis Report buttons

10- Comment button

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 68 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 69 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.

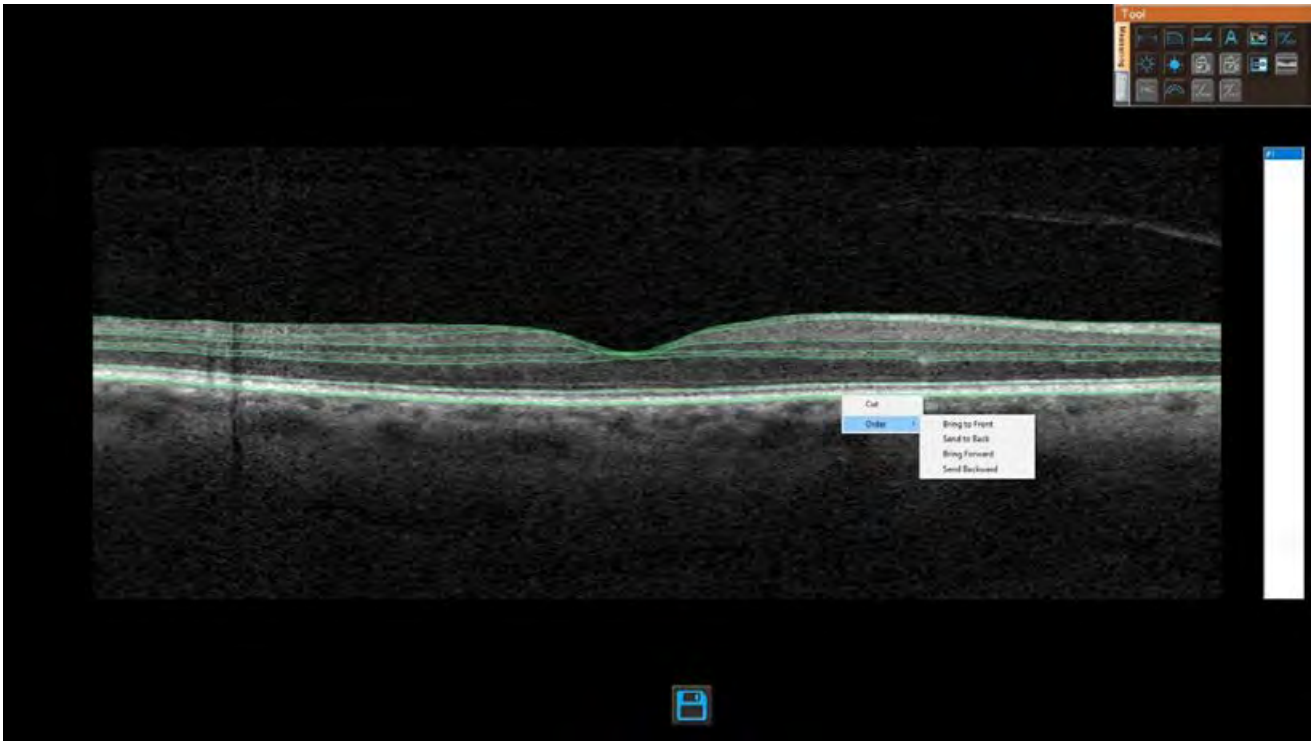


Figure 70 A Sample B-Scan Window

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

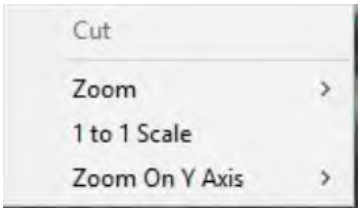


Figure 71 Right-Click Options on B-Scan Image

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 72 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:

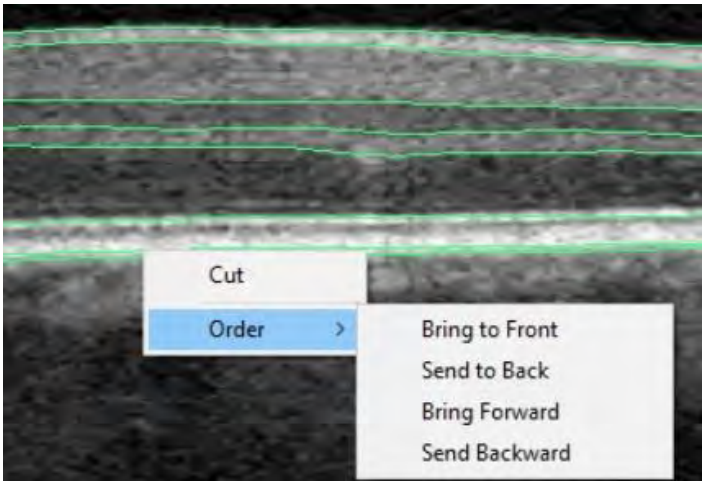


Figure 73 Line Right-Click Options

- **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 mm^2 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.

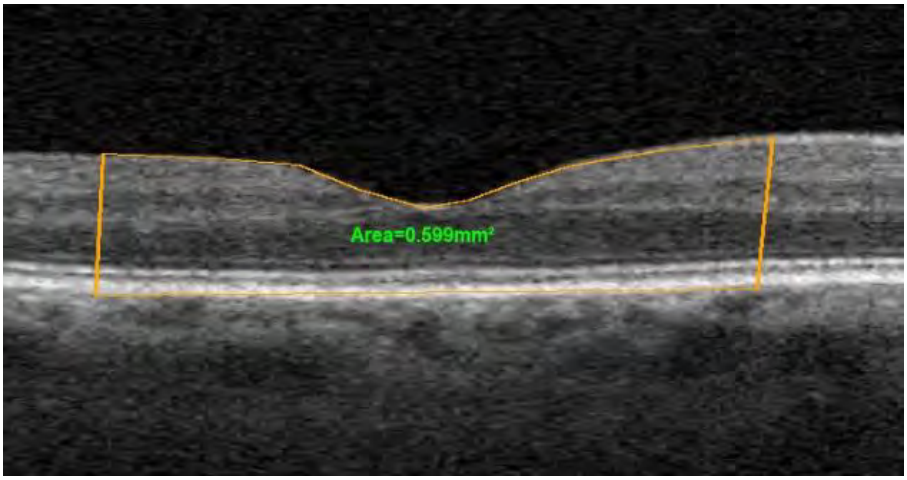


Figure 74 Area Fill Options

- **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.

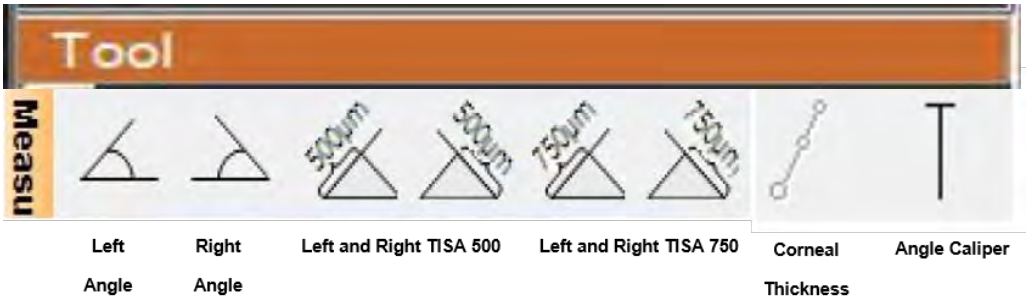


Figure 75 CAM Measuring Tools

- **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 76 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.

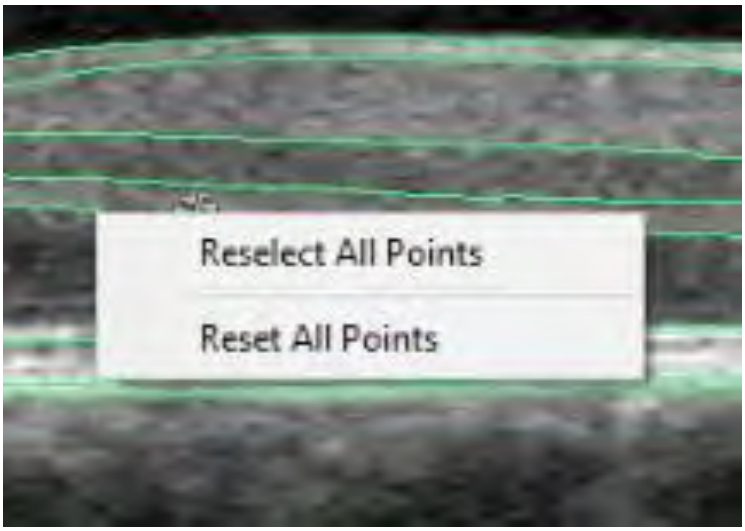


Figure 78 Right-Click Options When Editing Segmentation Lines

- 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. One 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.

To enhance visualization OCT images can be aligned with a Fundus , or Disc photo taken on the same visit. The OCT image uses 3D or fast en Face overlay, matched to the vessels in the photo. Please confirm alignment of all images prior to utilization by right clicking, showing overlay and checking alignment.

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.

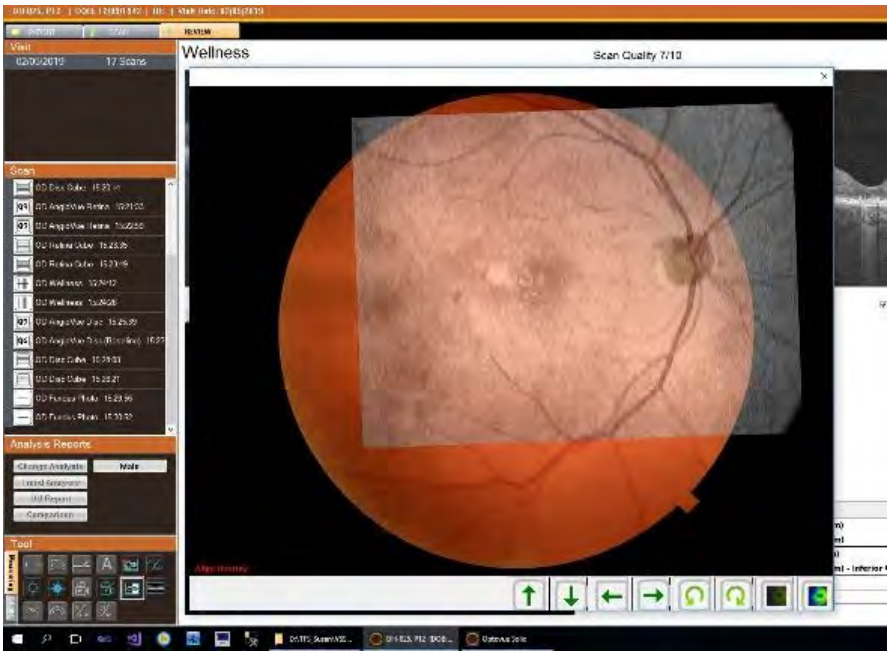


Figure 79 OCT alignment with Fundus photo

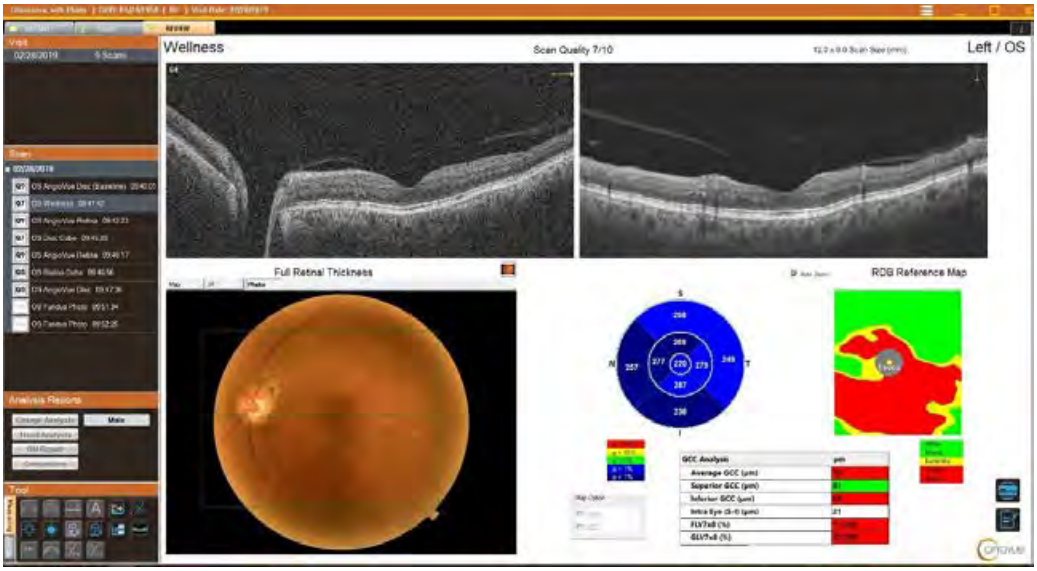


Figure 80 Wellness OCT with B scan overlay on Fundus photo

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. As a reference the system overlays each of these scans to the fundus photo when one has been acquired for this eye.

☞**Note**: In the event of registration failure the selected scan can be manually adjusted and saved.

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.

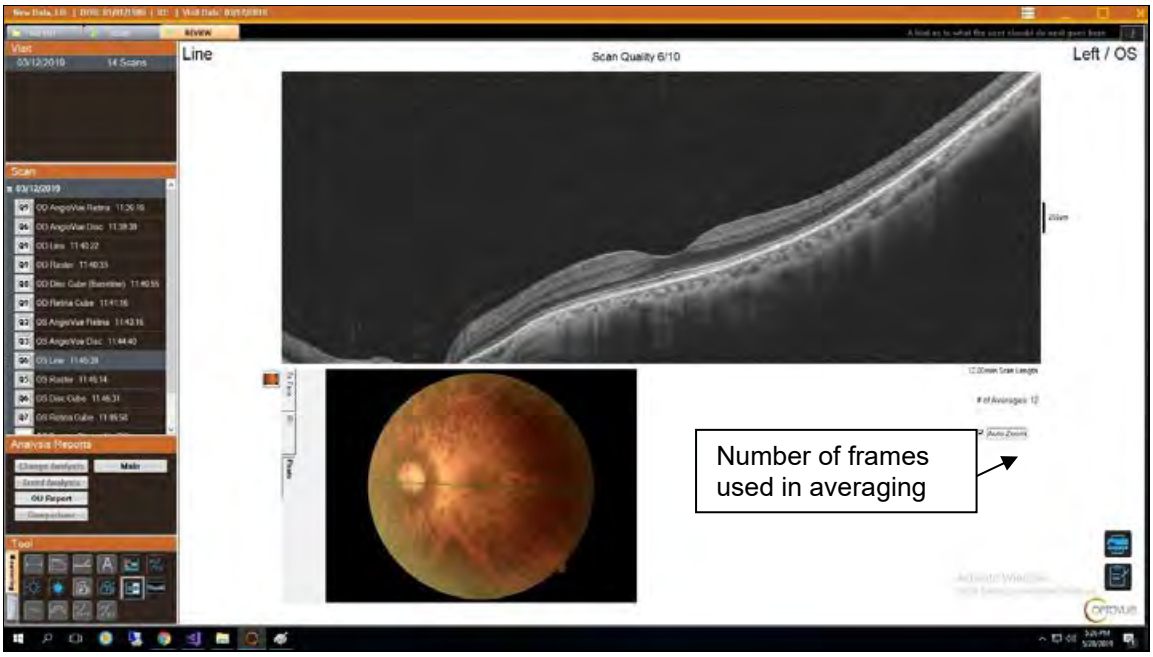


Figure 81 Line Scan Report

☞**Note**: In the event of registration failure the selected scan can be manually adjusted.

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.

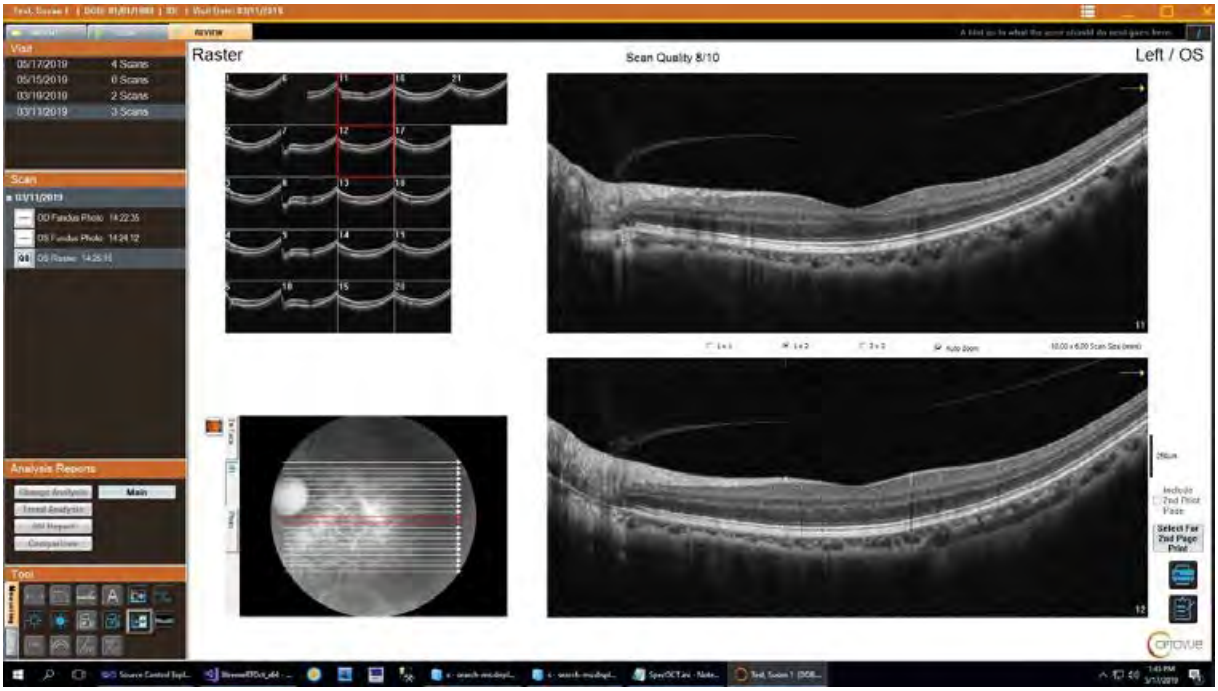


Figure 82 Raster Scan Report

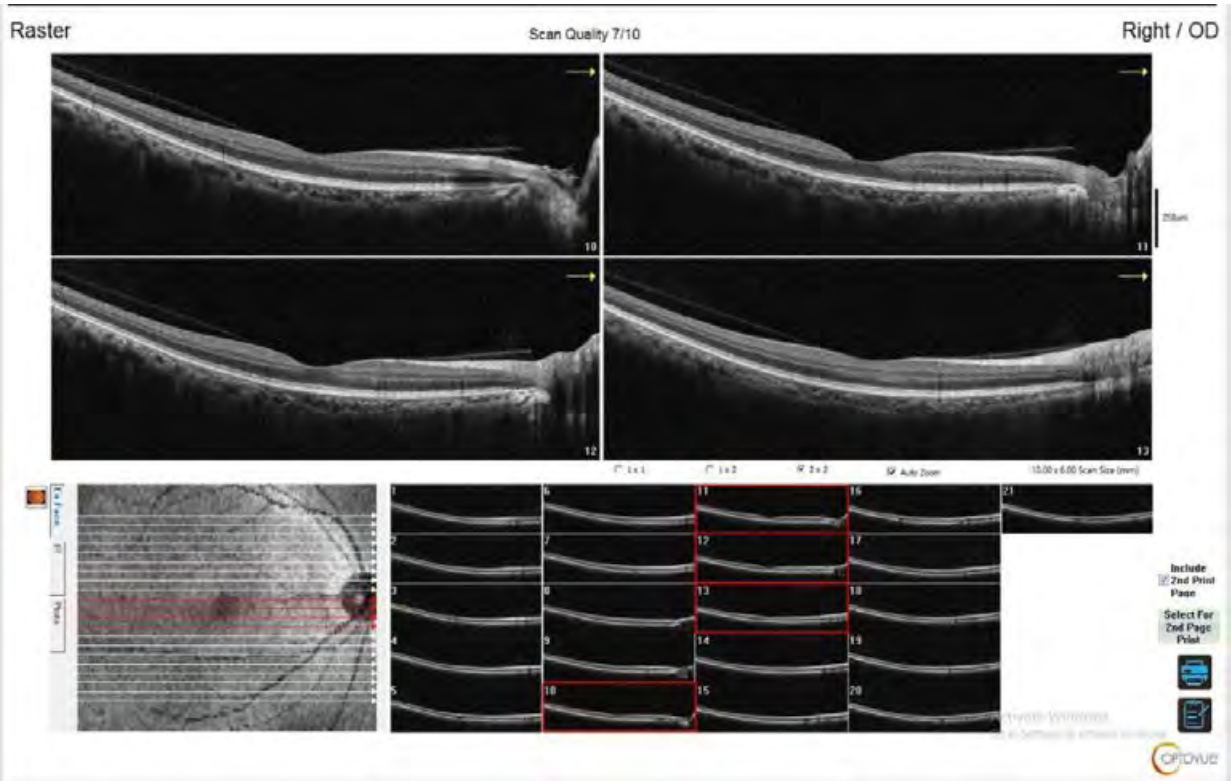


Figure 83 Second page of Raster Report.

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

☞**Note**: In the event of registration failure the selected scan can be manually adjusted.

Raster Portrait Print page 1

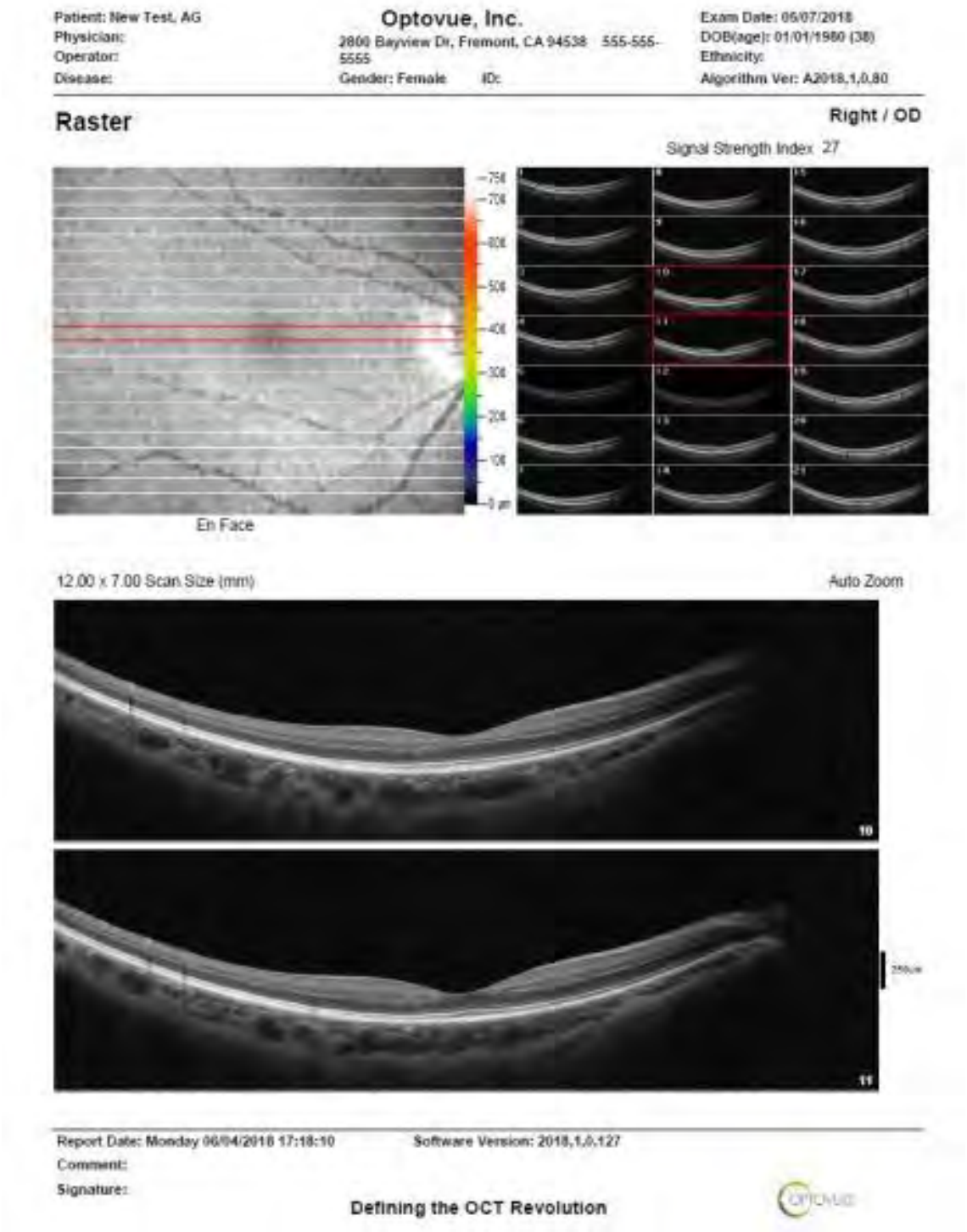


Figure 84 Raster Portrait Print page 1

Raster Portrait Print page 2

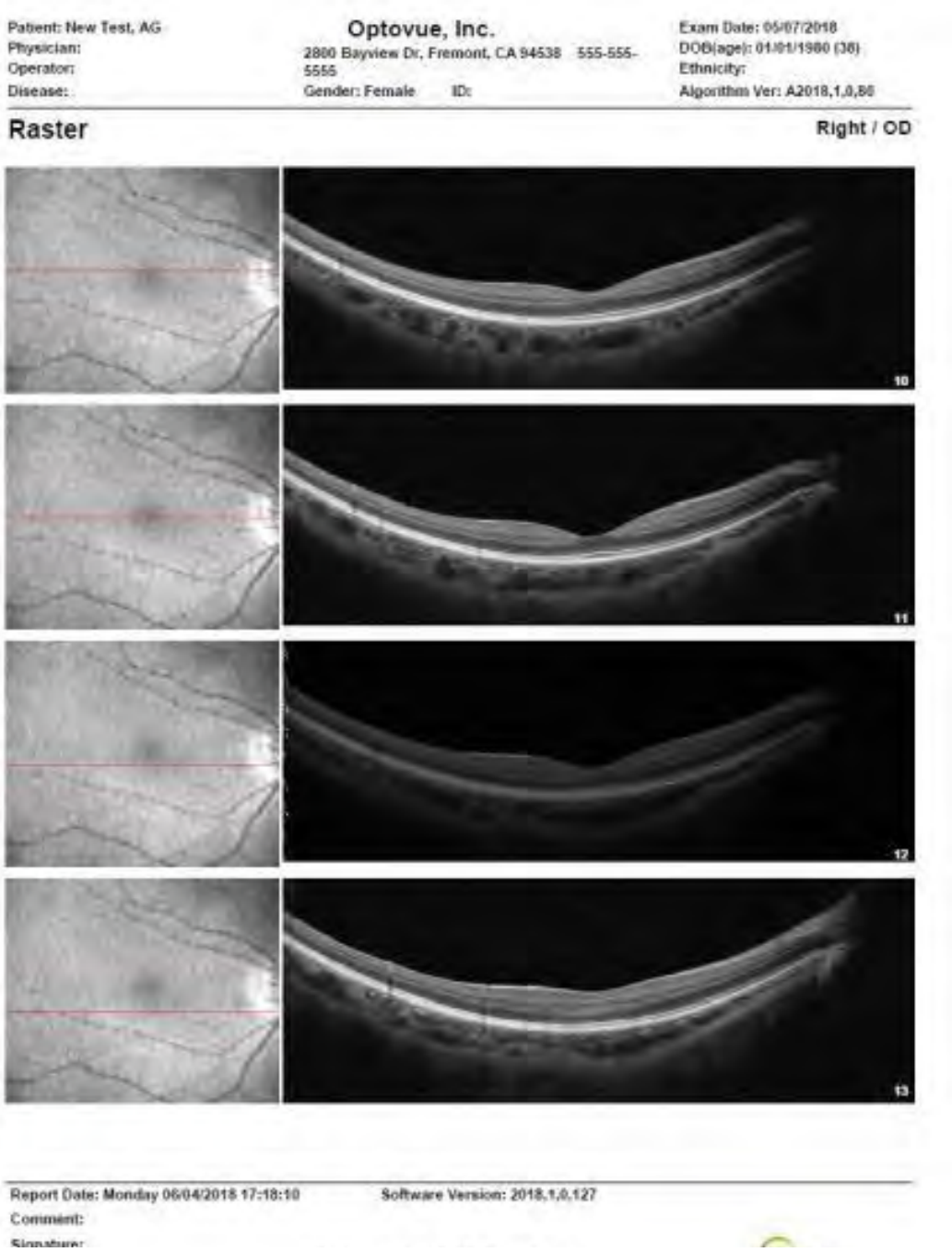


Figure 85 Raster Portrait Print page 2

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.

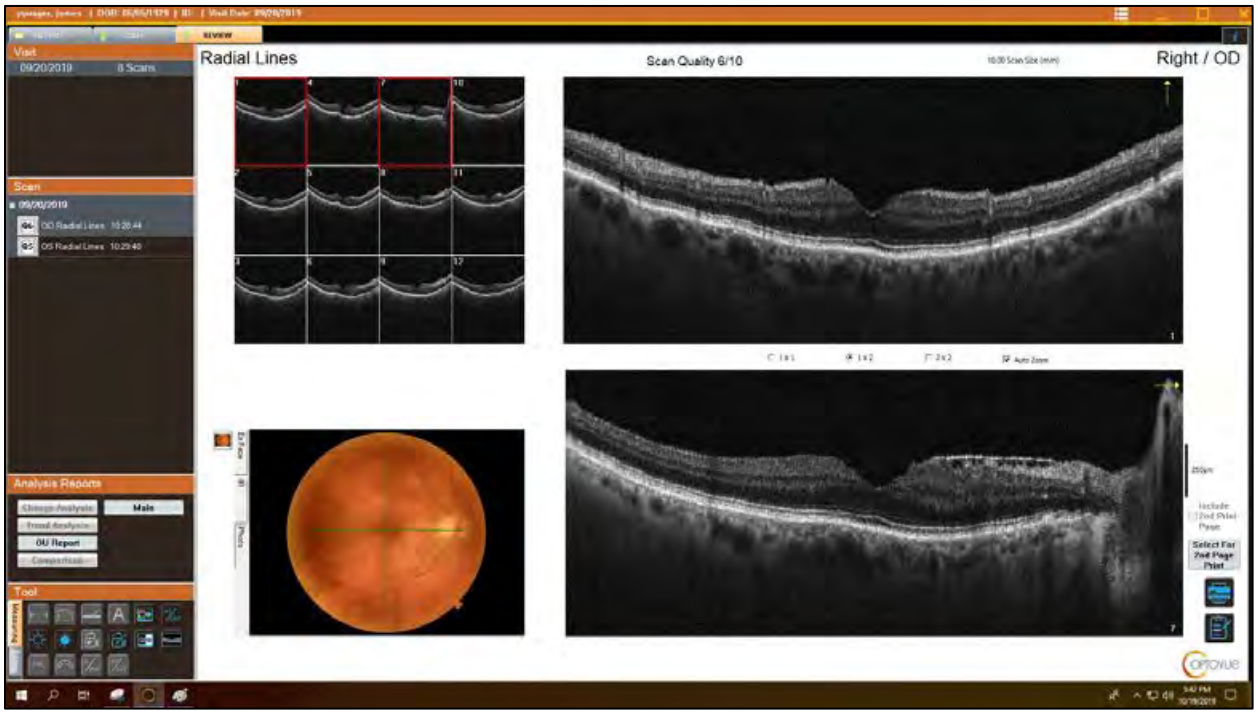


Figure 86 Radial Lines Report

☞ **Note**: In the event of registration failure the selected scan will not show on top of the reference image.

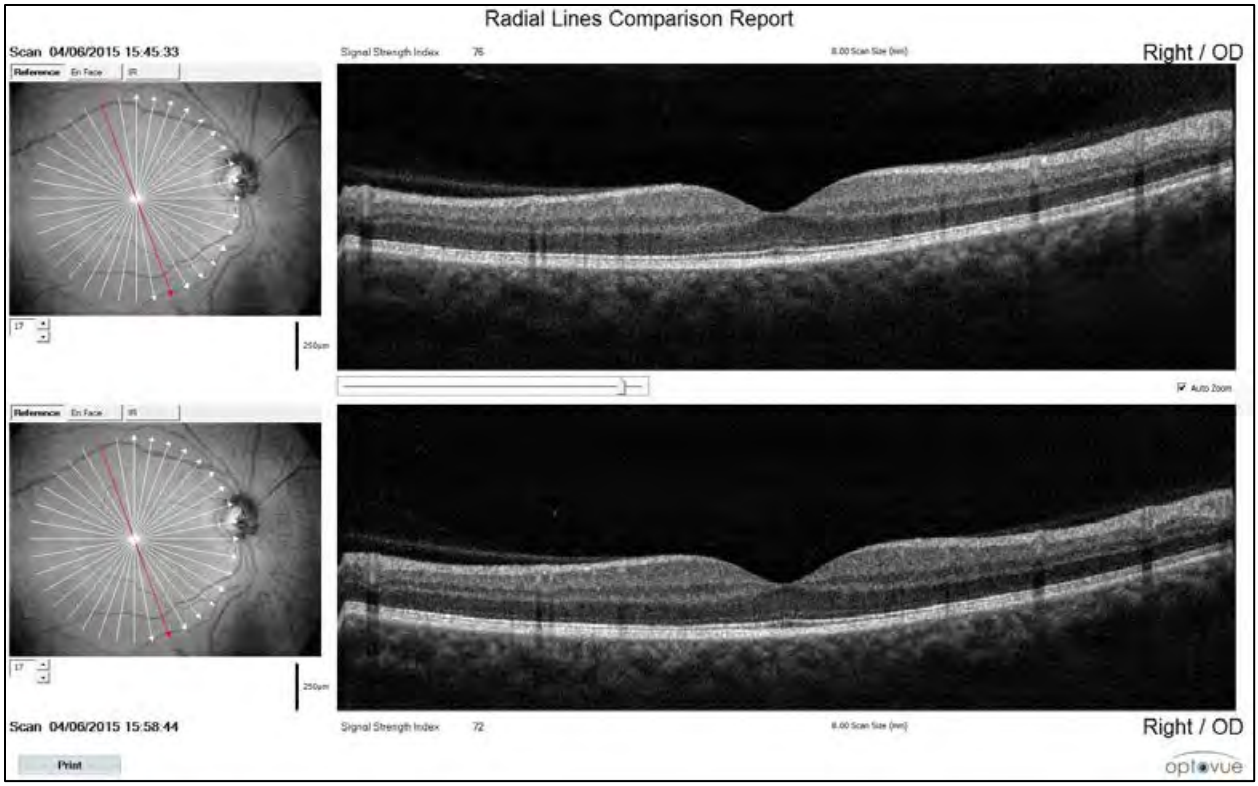


Figure 87 Sample Radial Line Report Comparing B-Scans from Two Visits

☞**Note**: In the event of registration failure the selected scan can be manually adjusted.

5.2.4 **FullRange ™ Retina Line 16mm x 6.25 mm**

The **FullRange ™ Retina Line** scan acquires a single high-definition line, it is a FullRange ™ scan 16mm by 6.25mm deep. Its position shows as an overlay on an IR image. The scan is designed to show detail in the vitreous and the choroid especially in high myope & steep, long eyes.

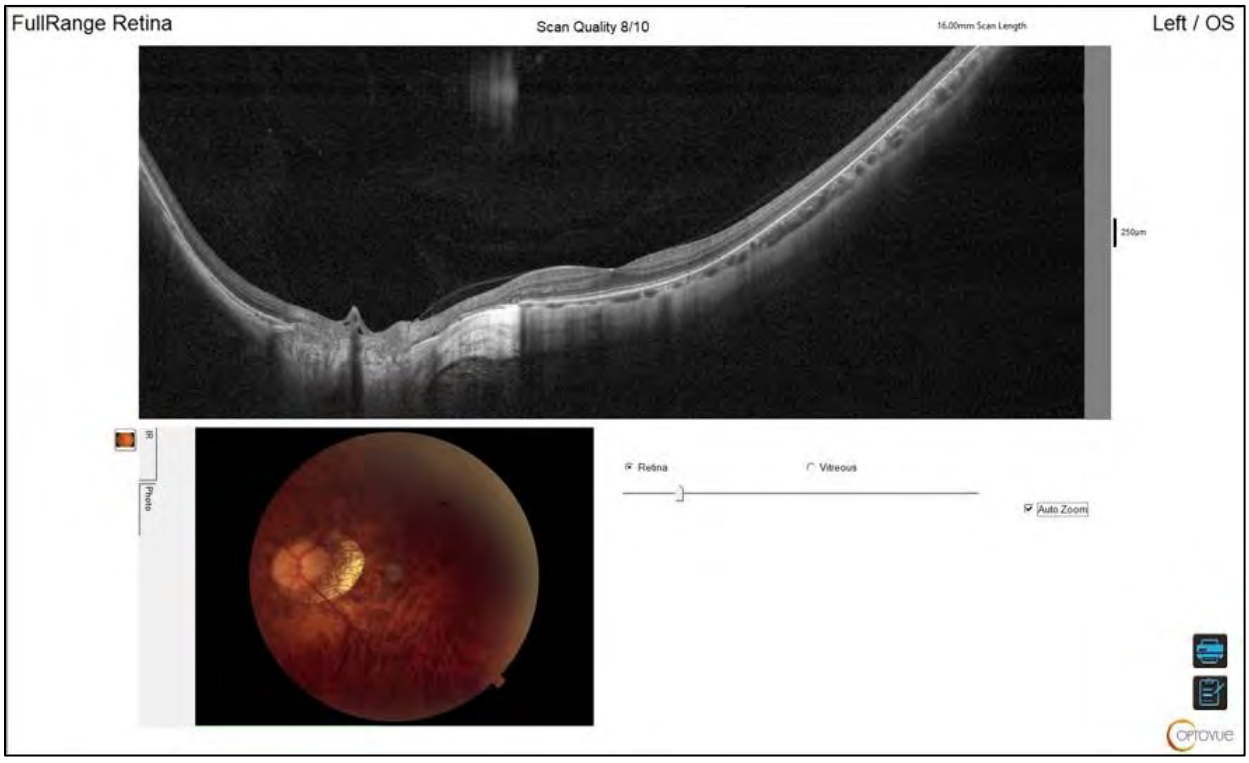


Figure 88 Enhanced Line Report, Vitreous Sample

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.

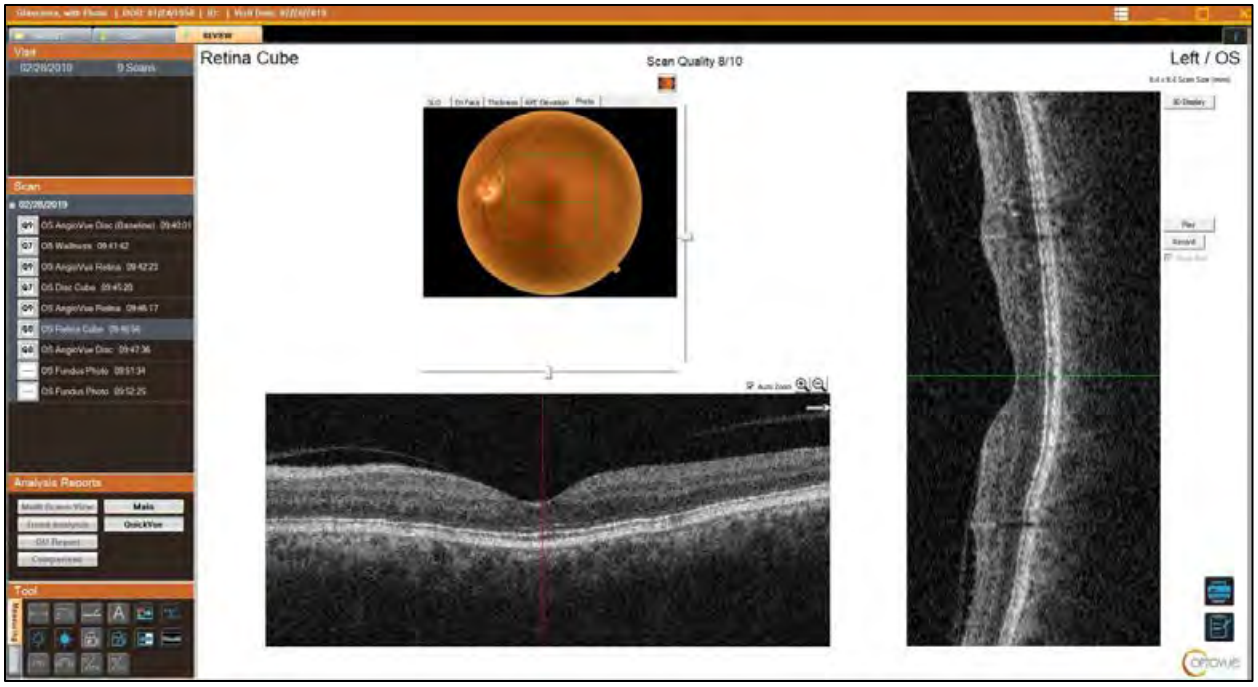


Figure 89 Retina cube Report

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.

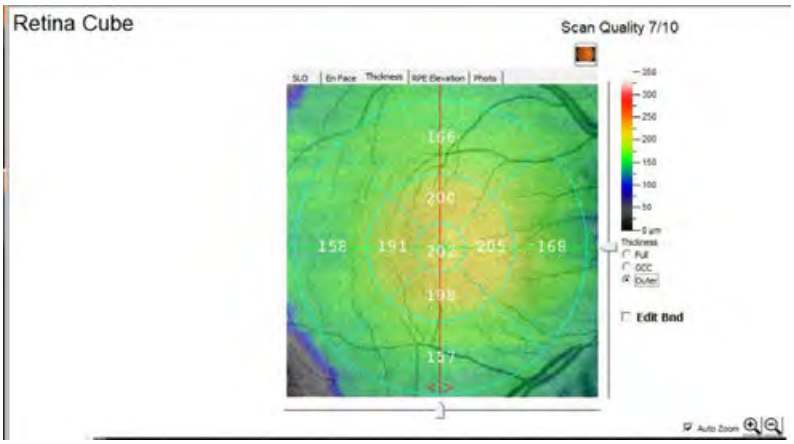


Figure 90Retina Cube Thickness map

5.3.2 **RDB Reference Map Retina & GCC**

- For Retina the 5 color-coded RDB Reference Map shows regions where thickness is thin (Blue, light blue) less than or greater than 1st percentile, within normal range (green, the measurement is between the 5th percentile to 95th percentile of the RDB, borderline (yellow, the measurement is between the 5th percentile to the 1st percentile of the RDB, and outside normal range (red, the measurement is below the 1st percentile of the RDB).

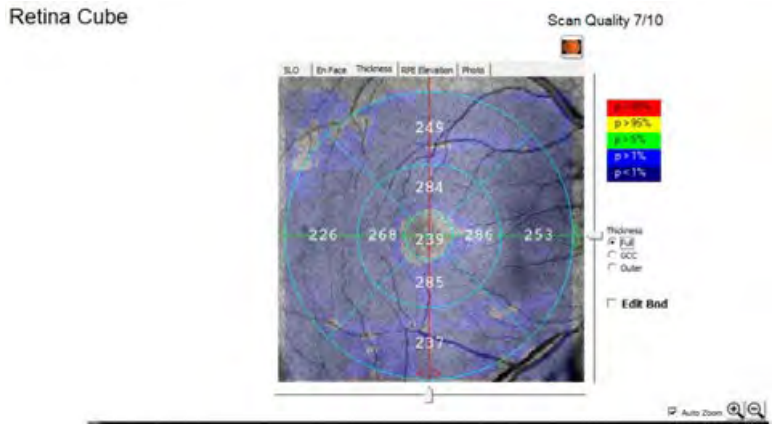


Figure 91 Retina cube Thickness RDB map & ETDRS

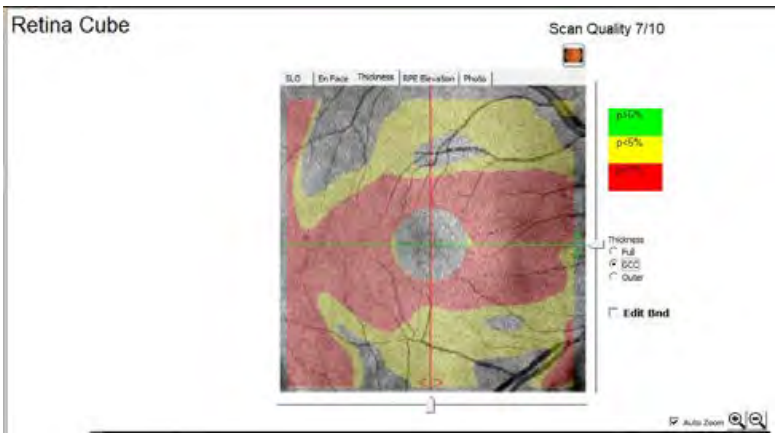
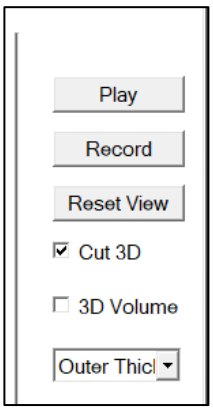


Figure 92 Retina cube GCC Deviation map

- 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.

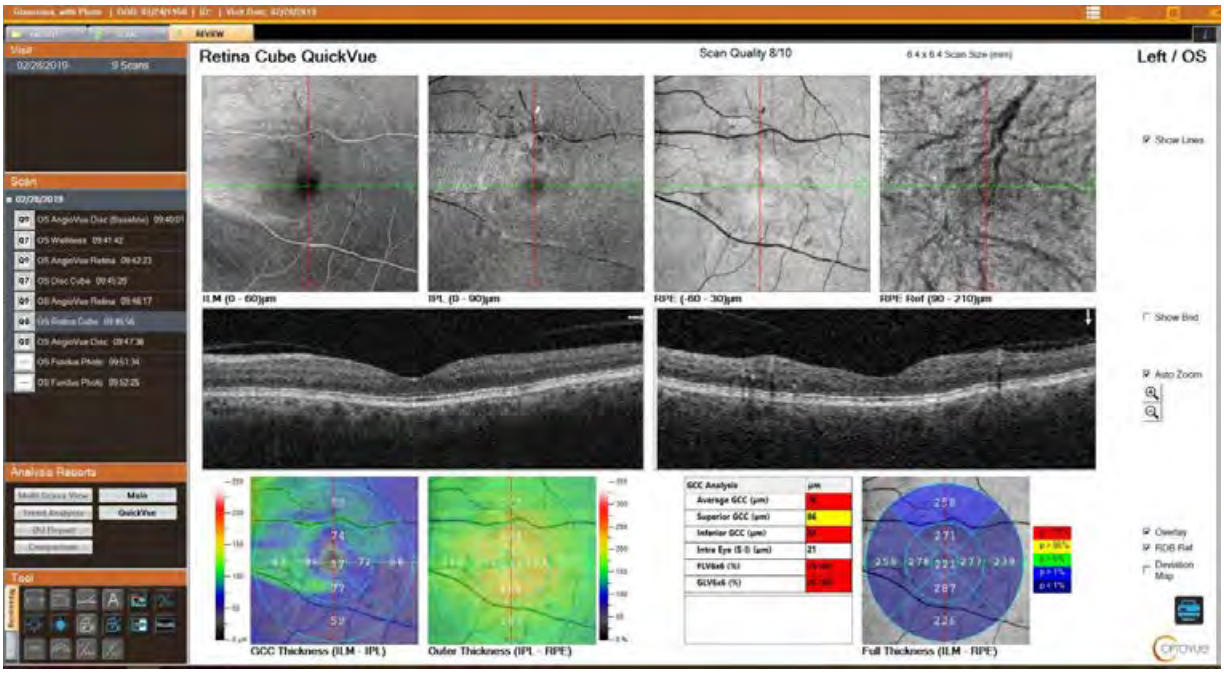


Figure 93 Retina Cube QuickVue with RDB ref

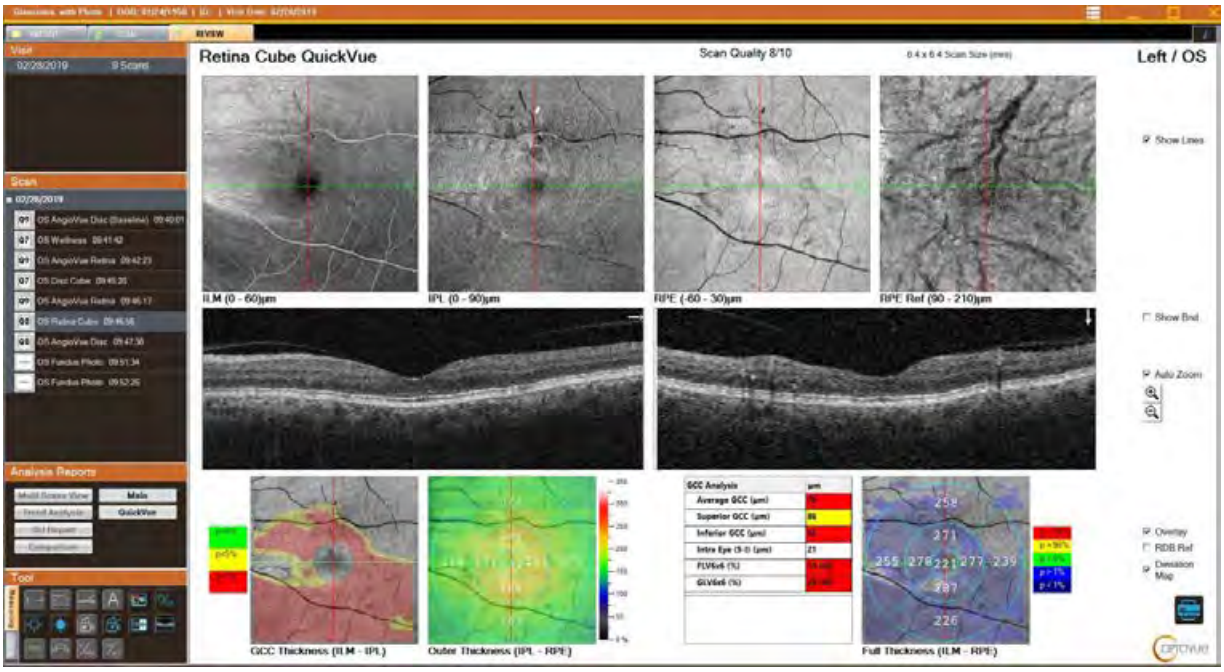


Figure 94 Retina cube with Deviation button selected

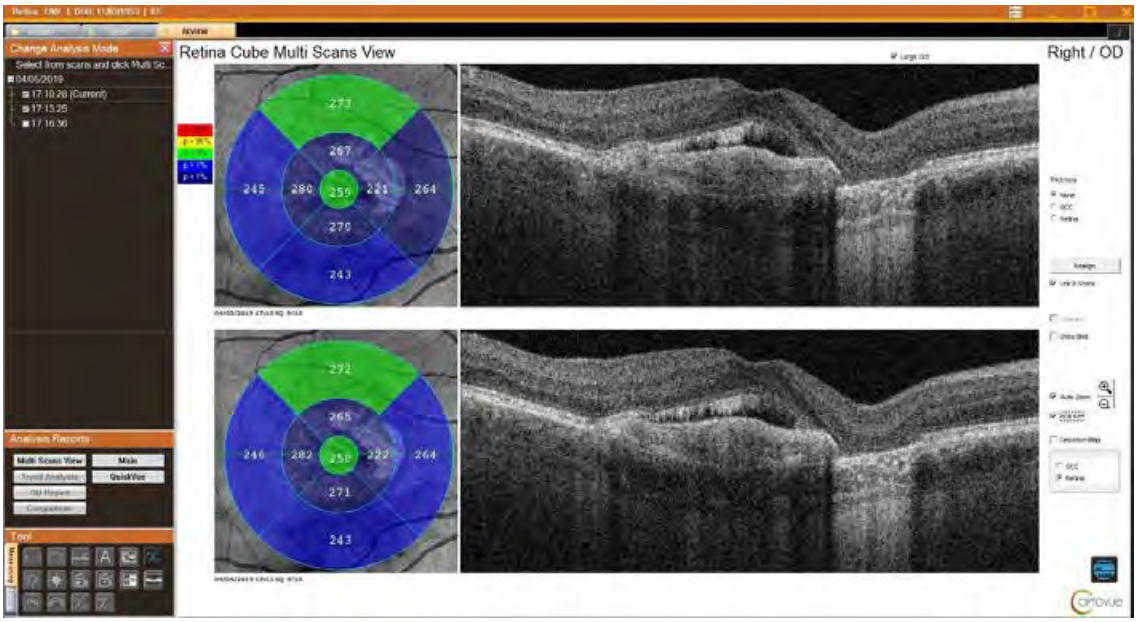


Figure 95 Retina Cube Multi Scan View (2 scans)

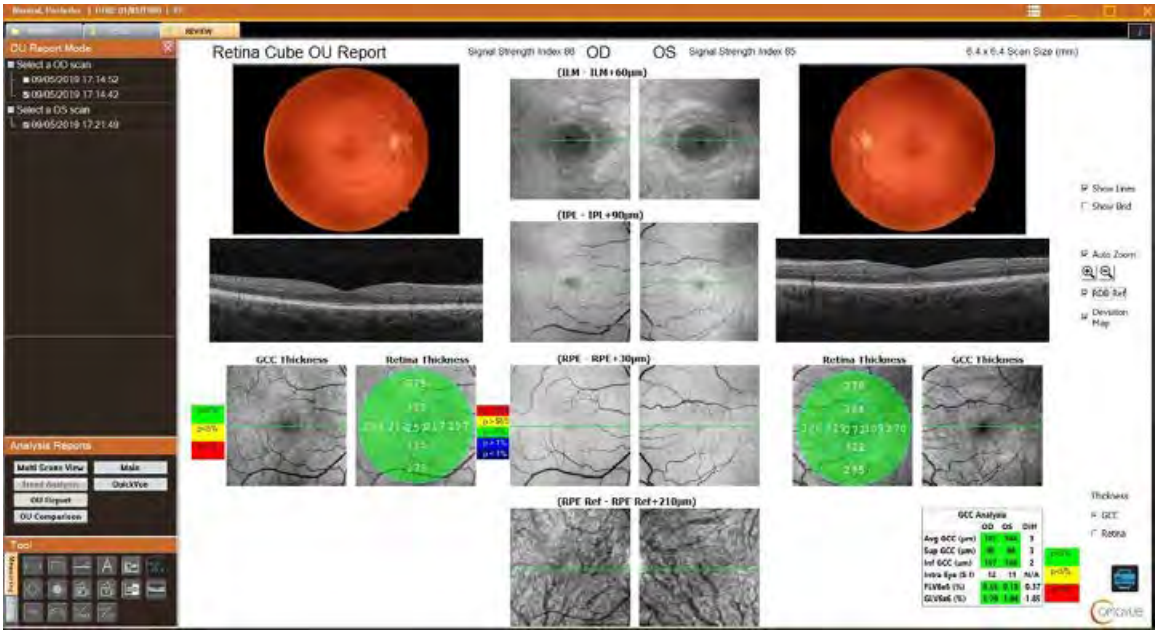


Figure 96 Retina cube OU Report with Fundus photo

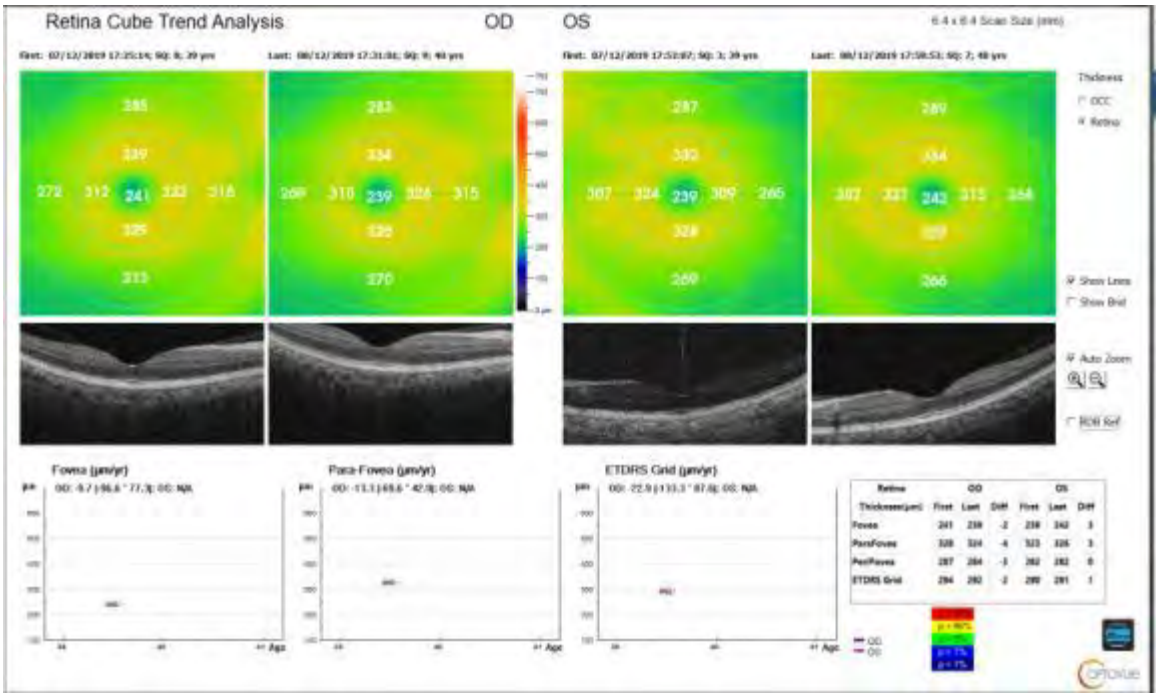


Figure 97 Retina cube Trend analysis, Retinal thickness

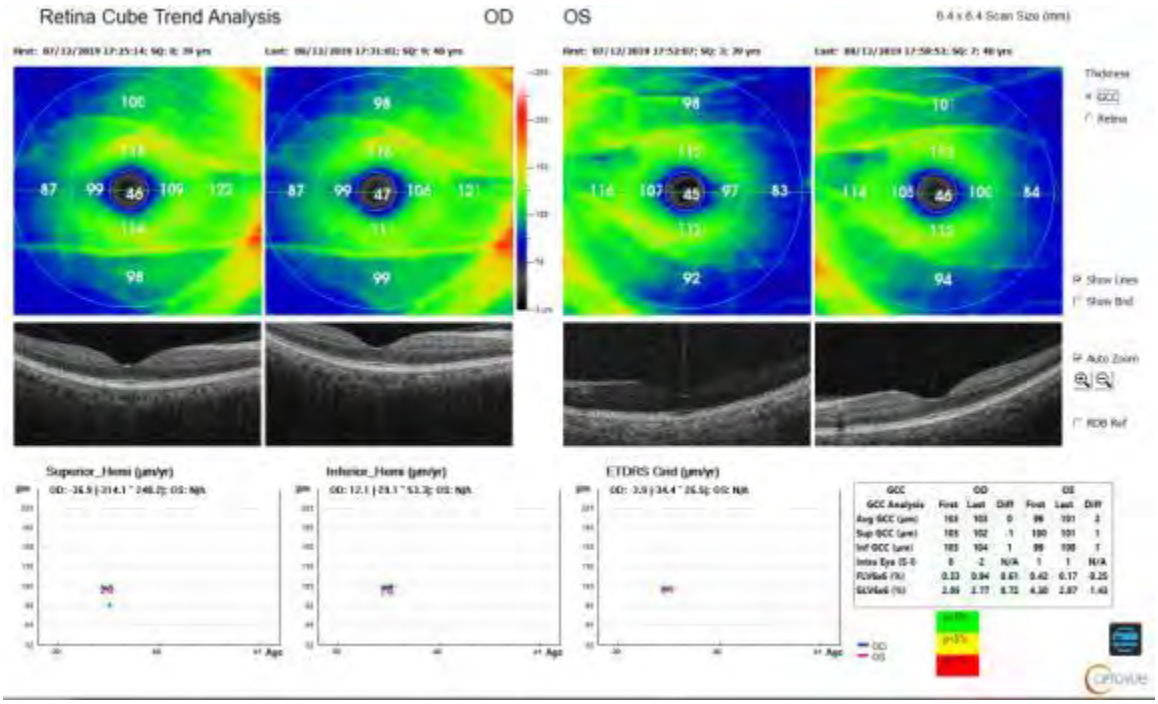


Figure 98 Retina cube Trend analysis GCC Thickness

5.3.3 **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.

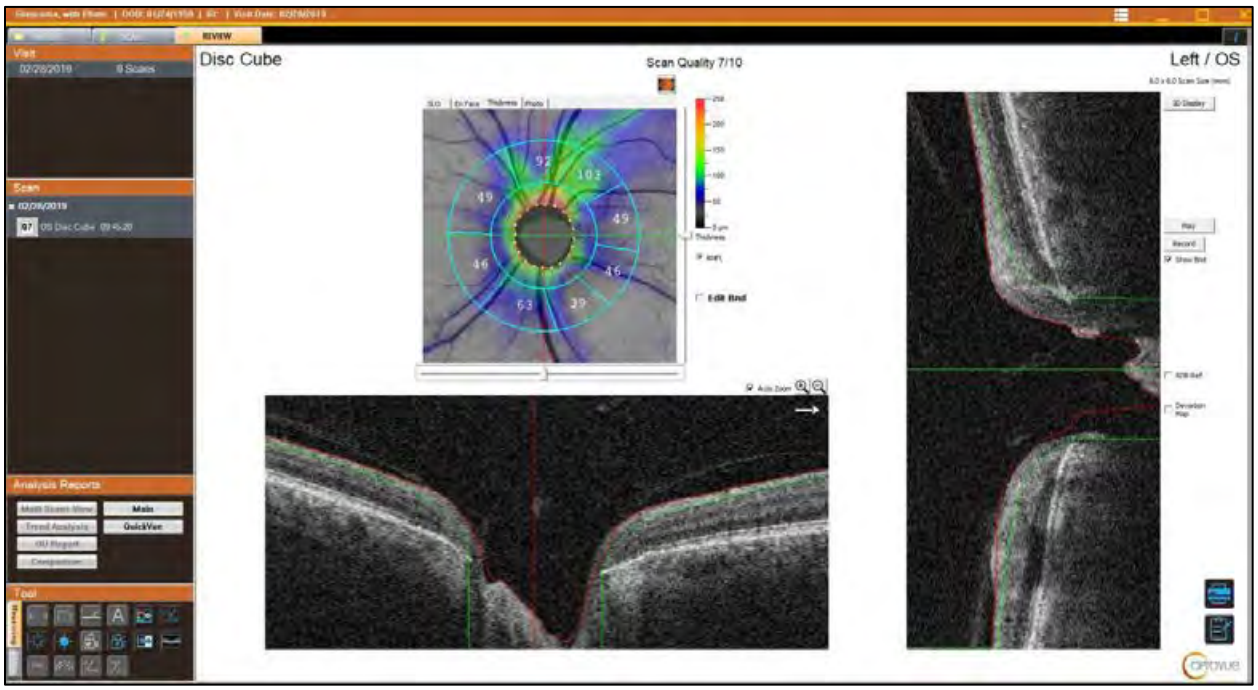


Figure 99 3D Disc Report

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.

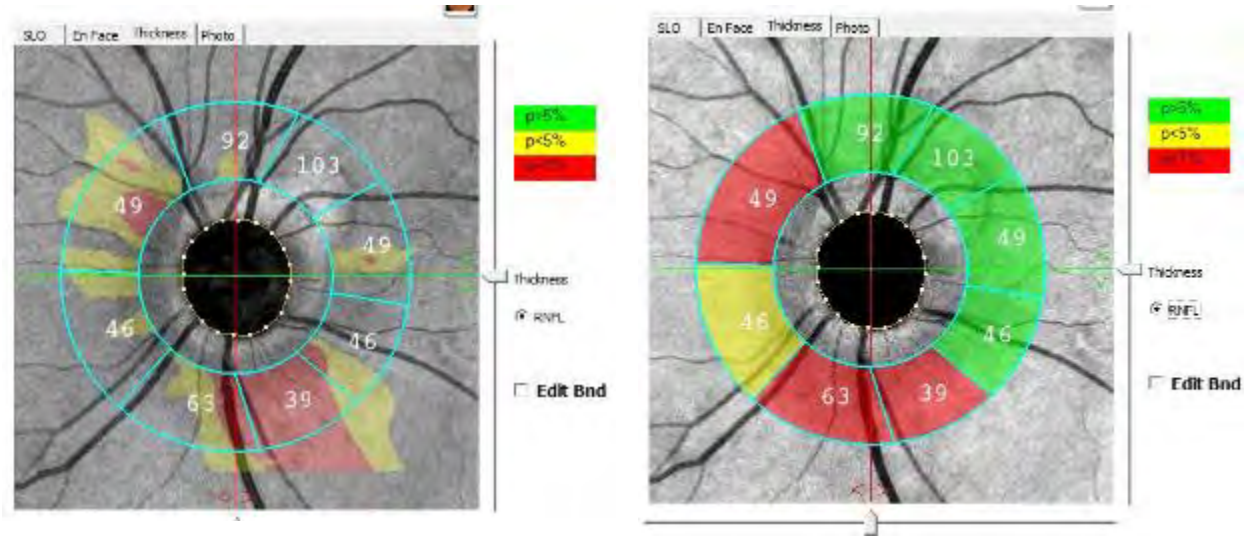


Figure 100 RNFL Deviation map and RDB map RNFL

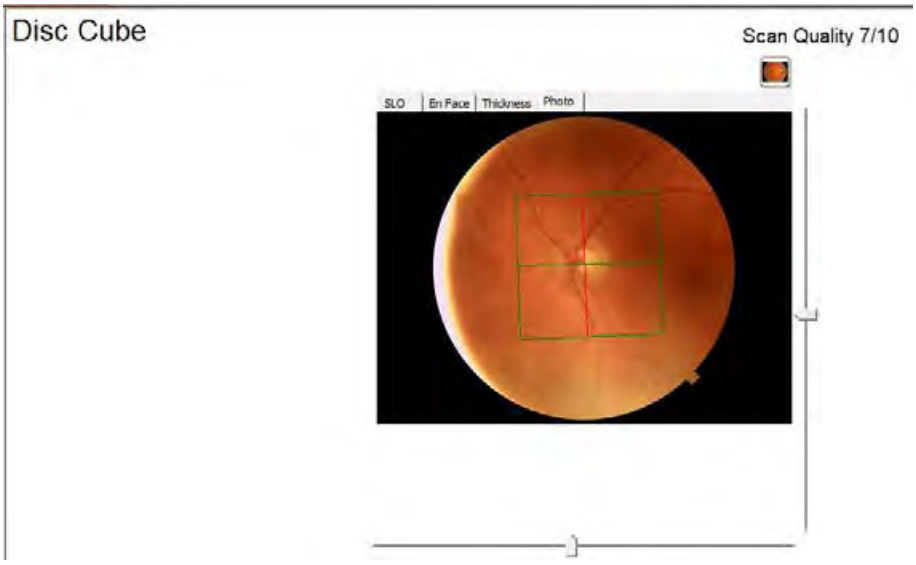


Figure 101 Disc cube overlay on Disc photo

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

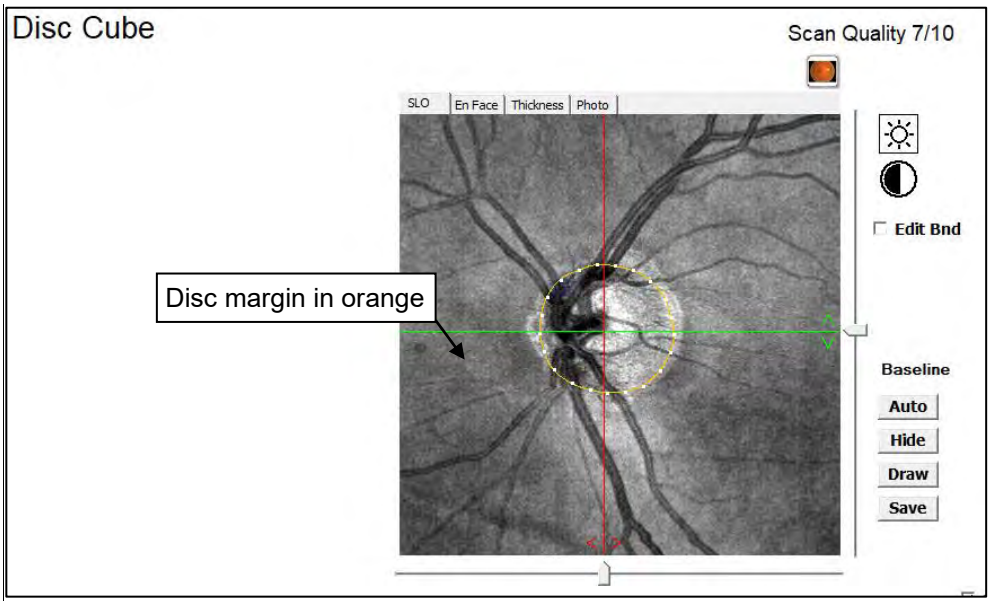
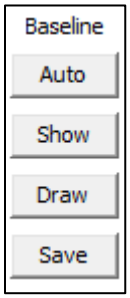


Figure 102 Optic Disc Margin in 3D Disc Report

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.

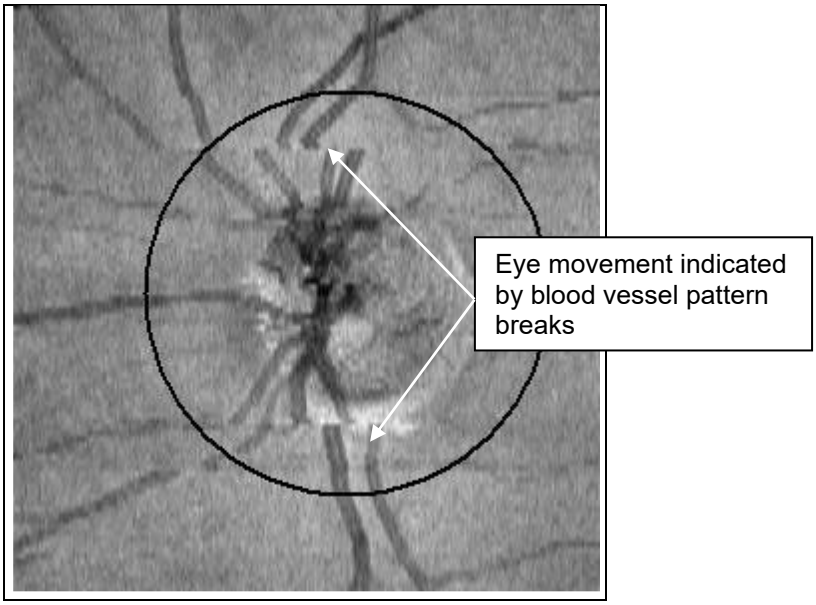


Figure 103 A 3D Disc Scan Showing Eye Motion

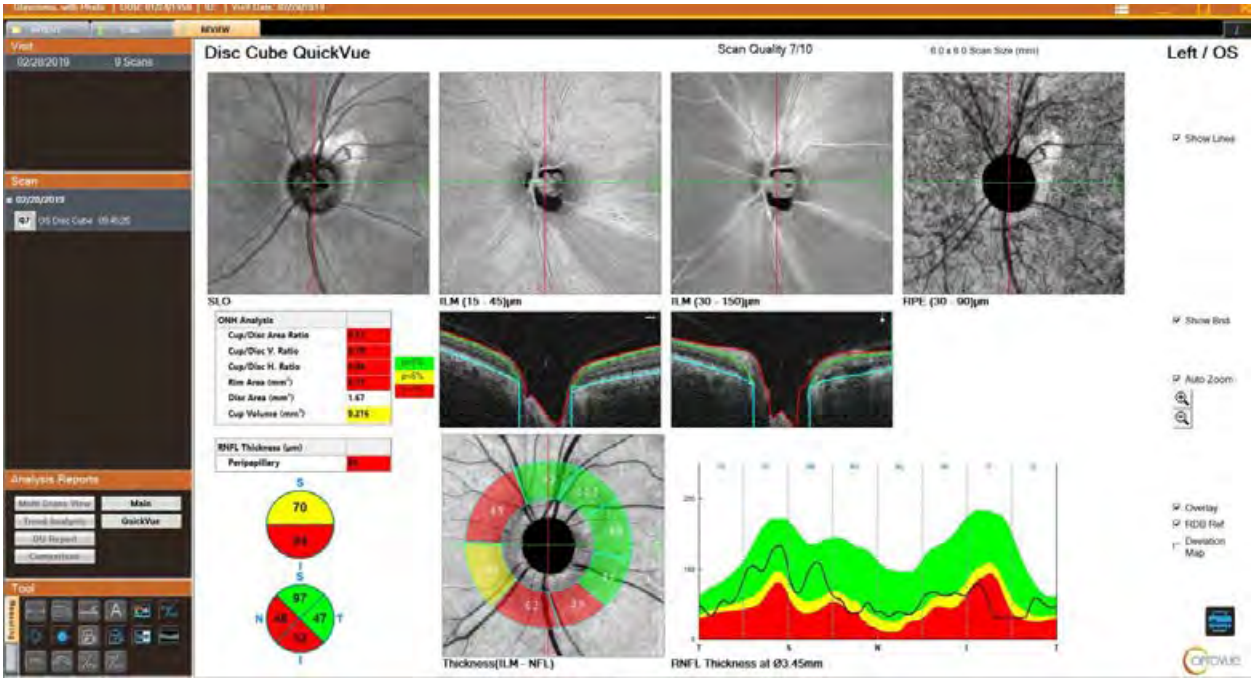


Figure 104 Disc Cube QuickVue with RNFL RDB selected showing TSINT

5.3.3.1 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.

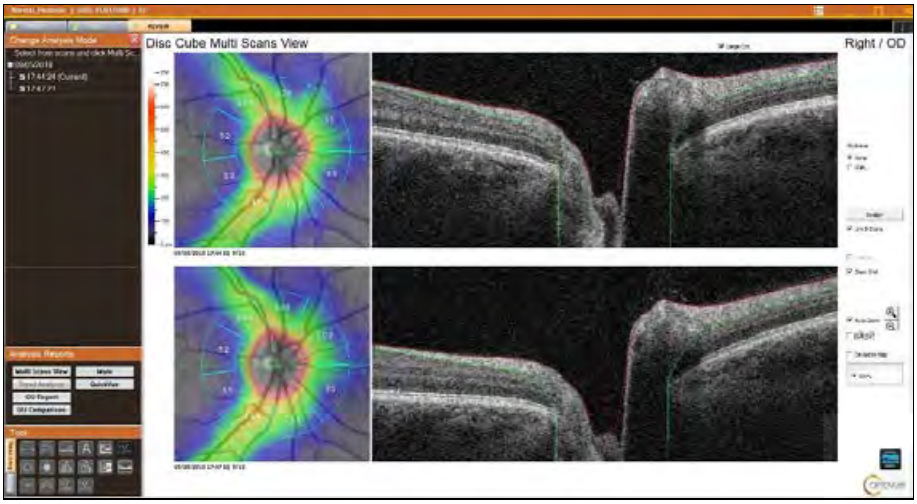


Figure 105 Disc Comparison Report, thickness

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.

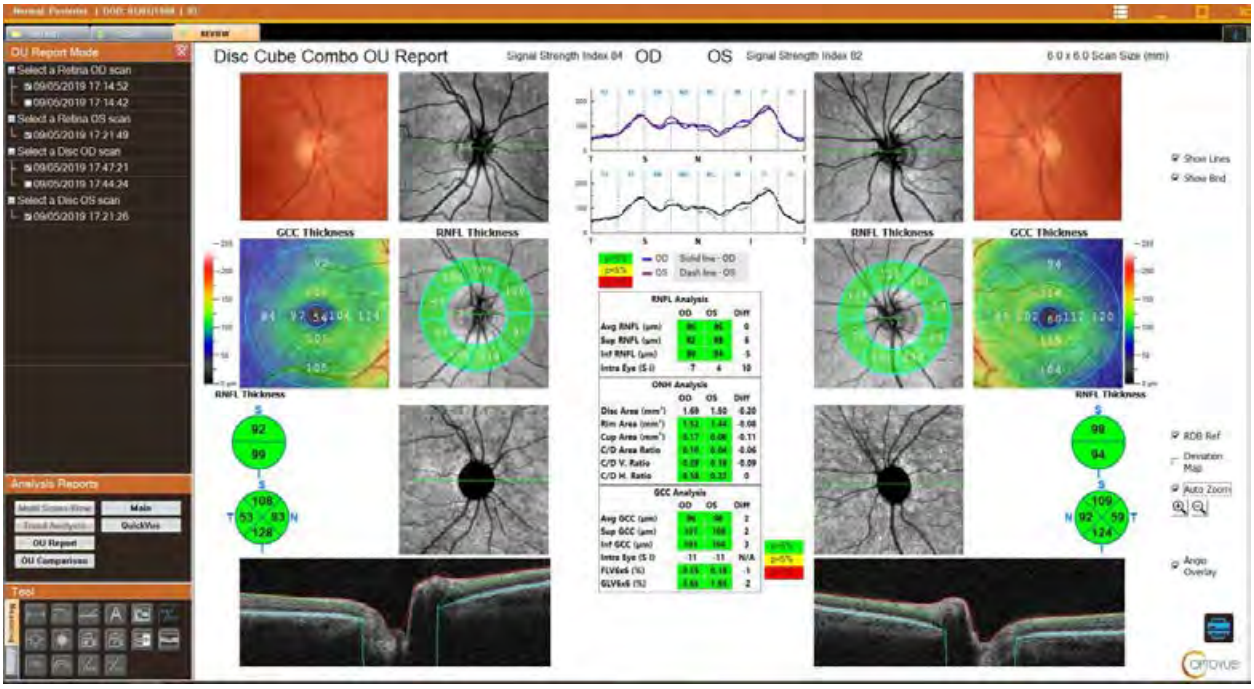


Figure 106 Disc Cube Combo OU From Retina & Disc Cube

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

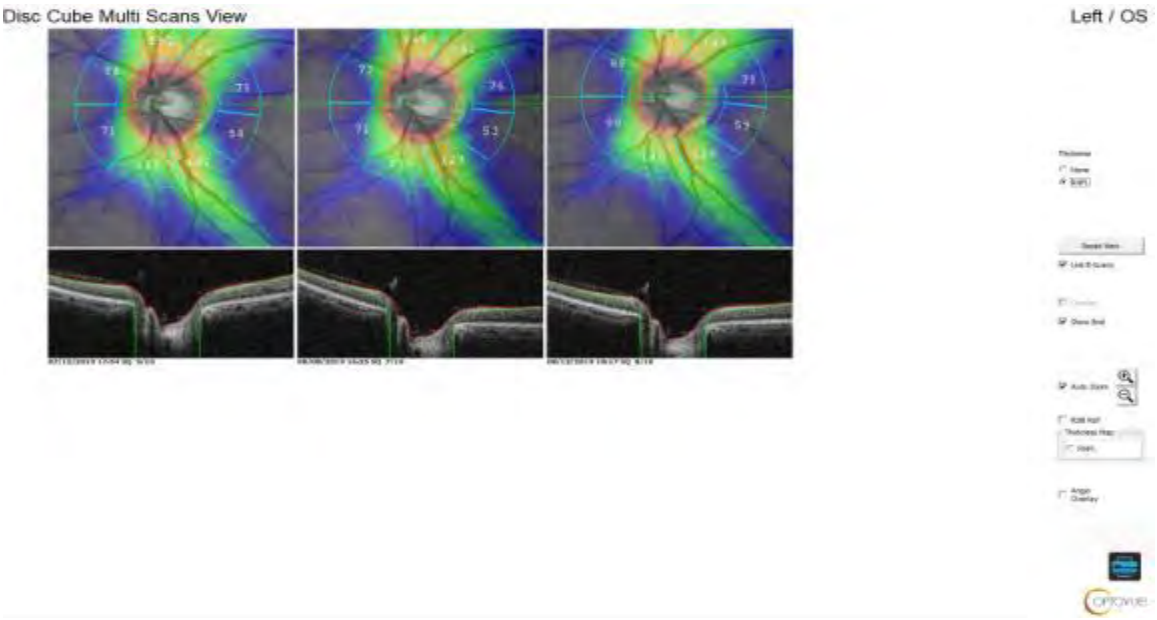


Figure 107 Disc cube Multi Scan Report

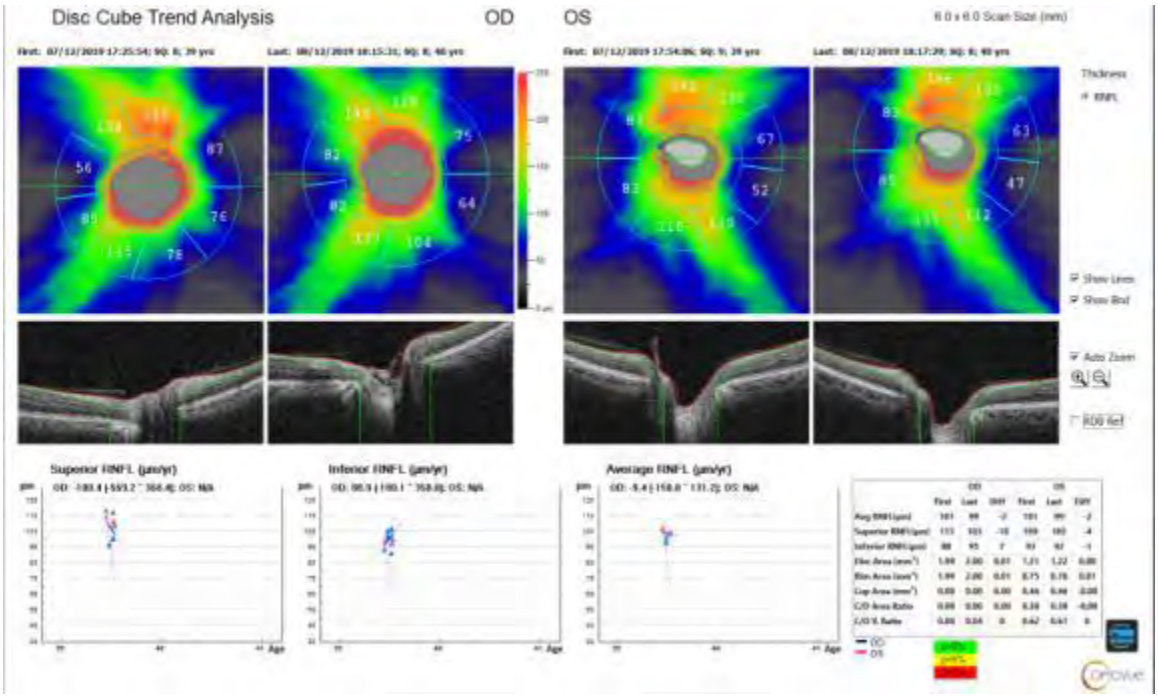


Figure 108 Disc Cube Trend Analysis

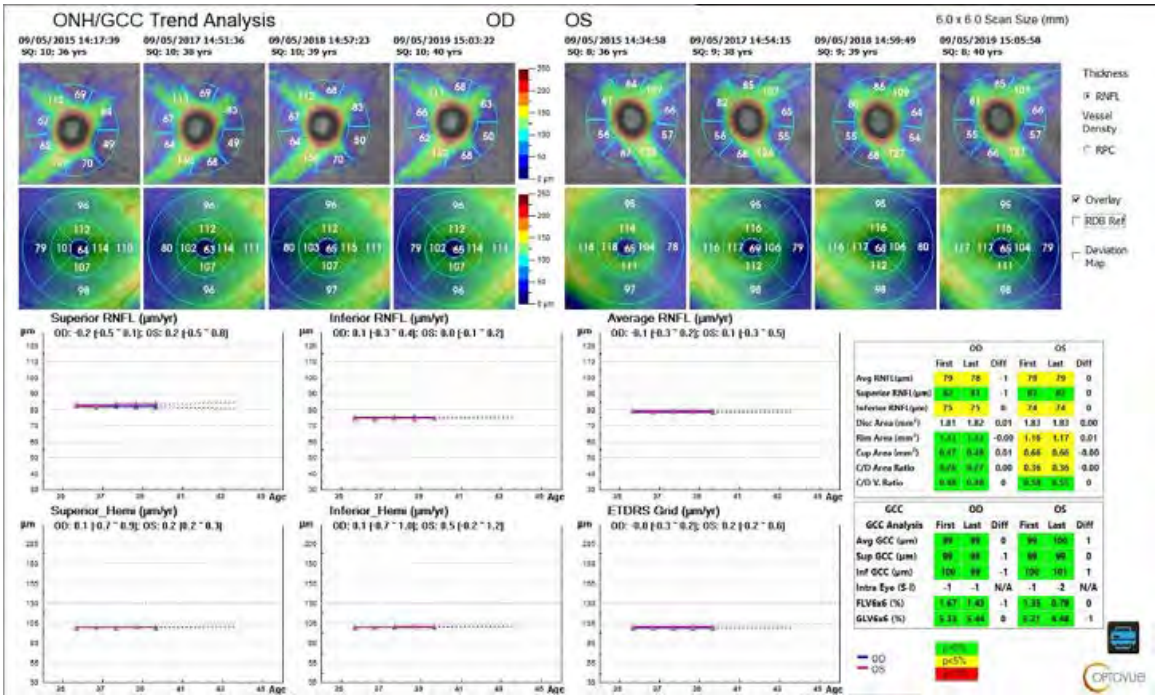


Figure 109 Disc Cube OU Trend Analysis

5.3.4 **Wellness Report 12x9**

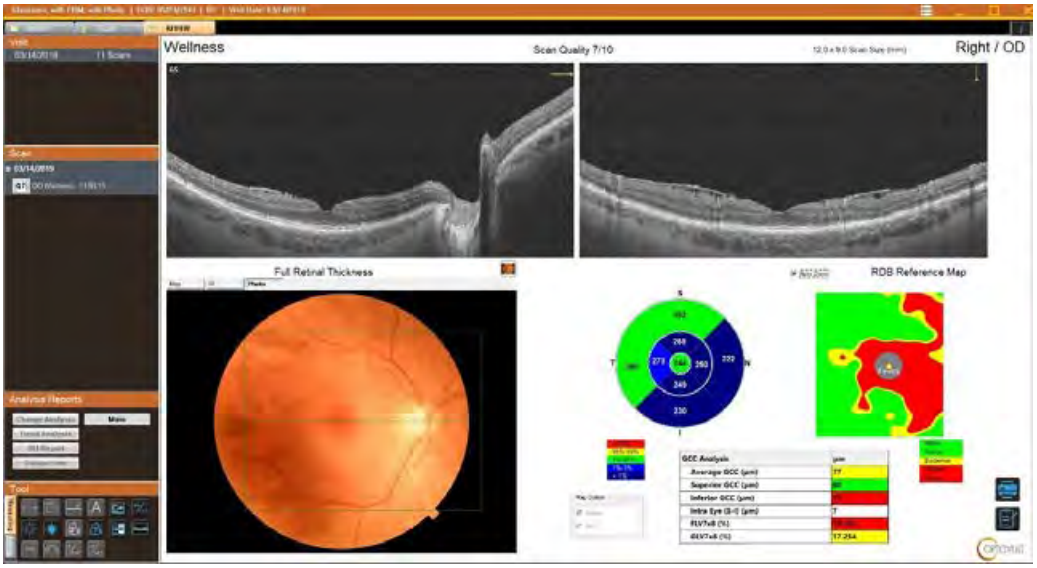


Figure 110 Wellness with map overlay on Fundus photo

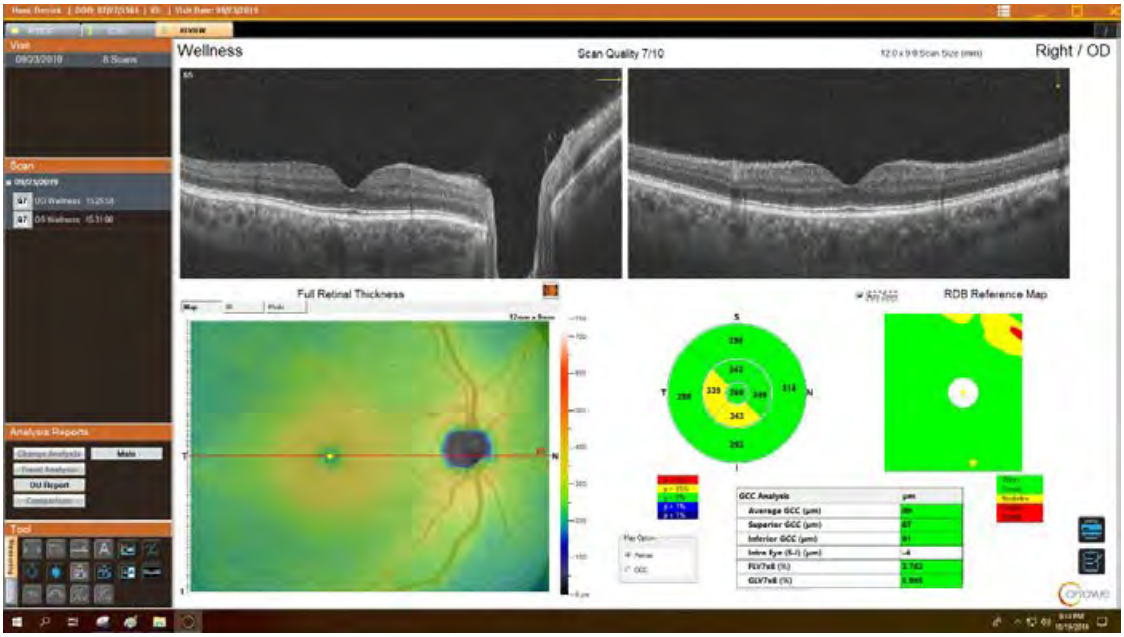


Figure 111 Wellness with thickness map

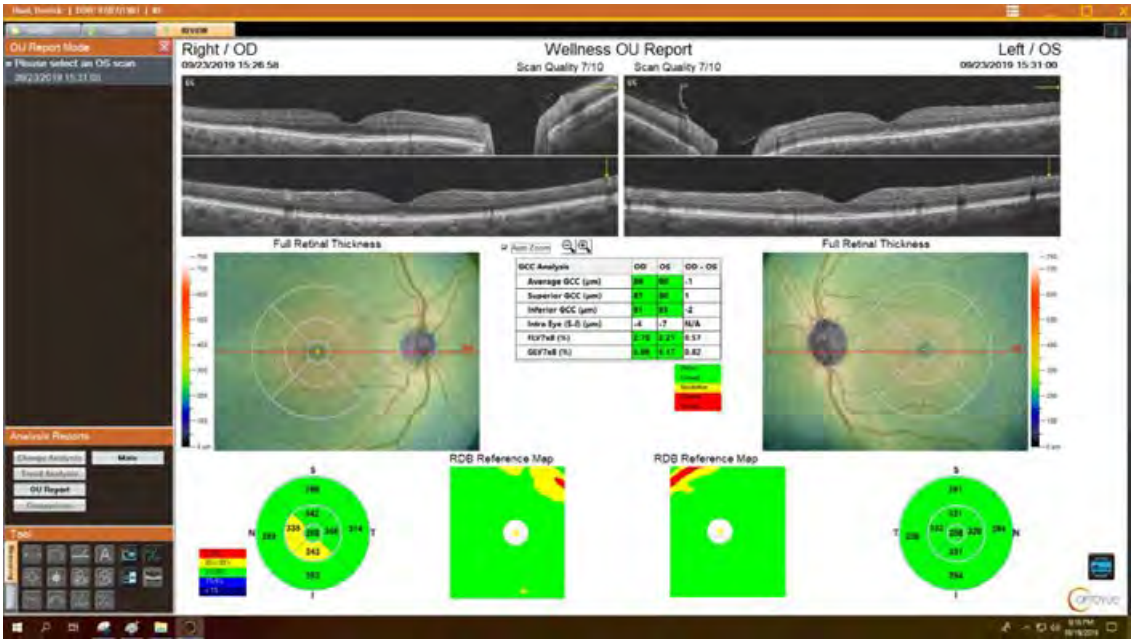


Figure 112 OU Wellness

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.

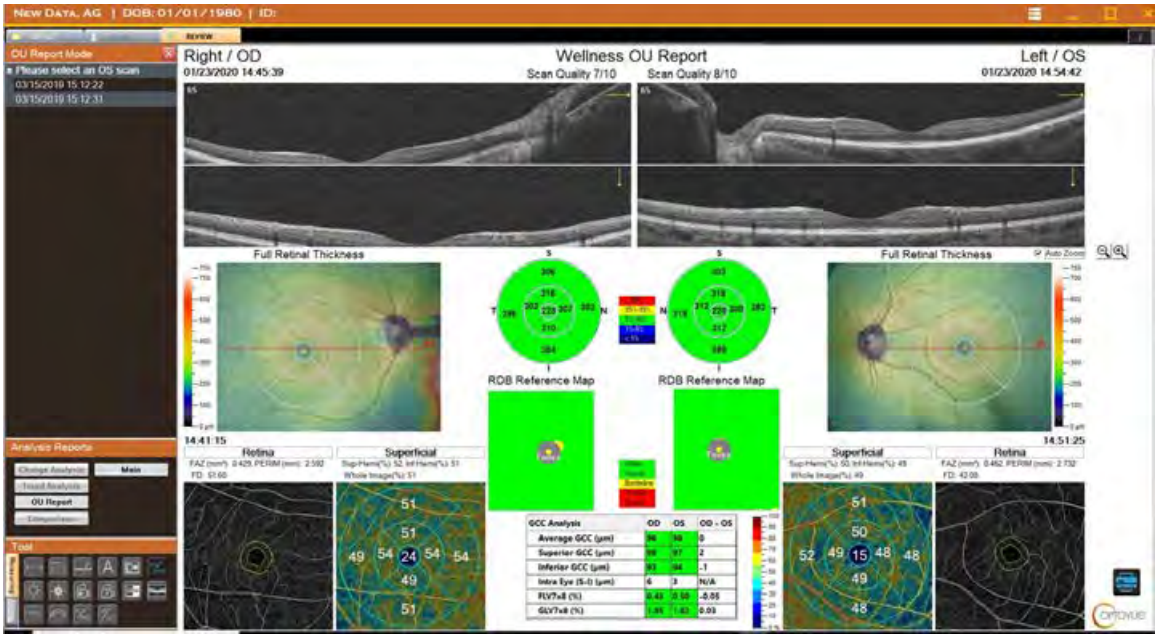


Figure 113 AngioVue Wellness OU Report

6 AngioVue® ® Reports

6.1 Segmentation Retina

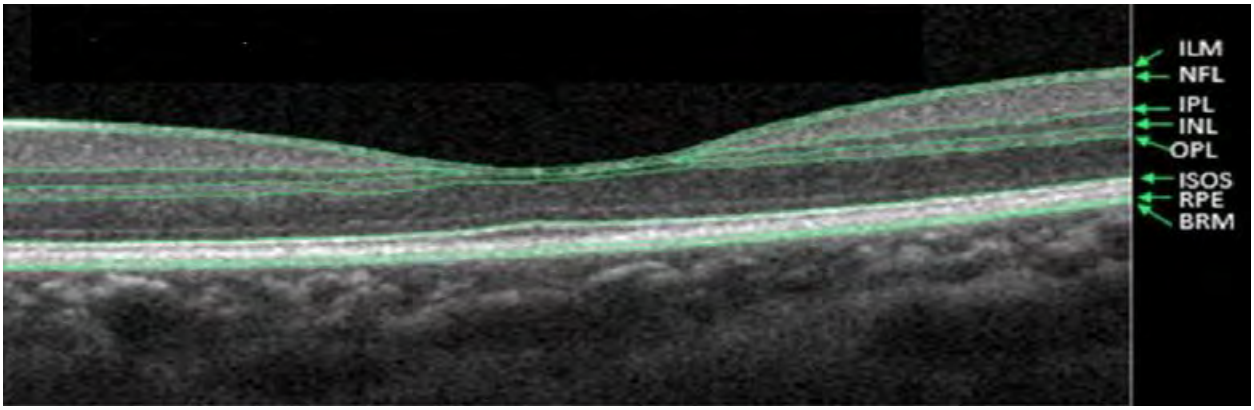


Figure 114 Retina Segmentation Layers

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-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)

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

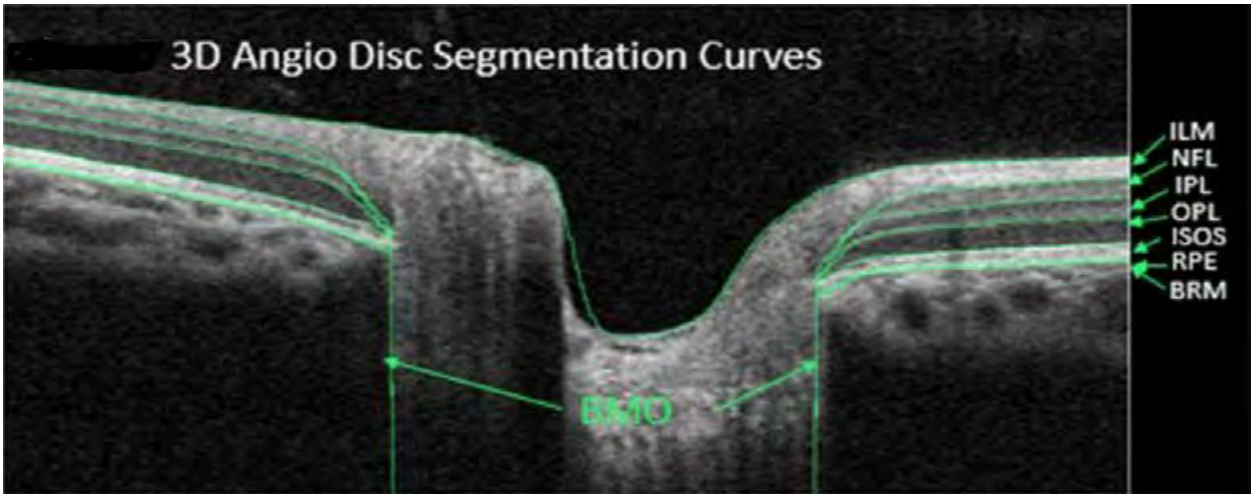


Figure 115 Disc Segmentation Layers

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-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)

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 116 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.

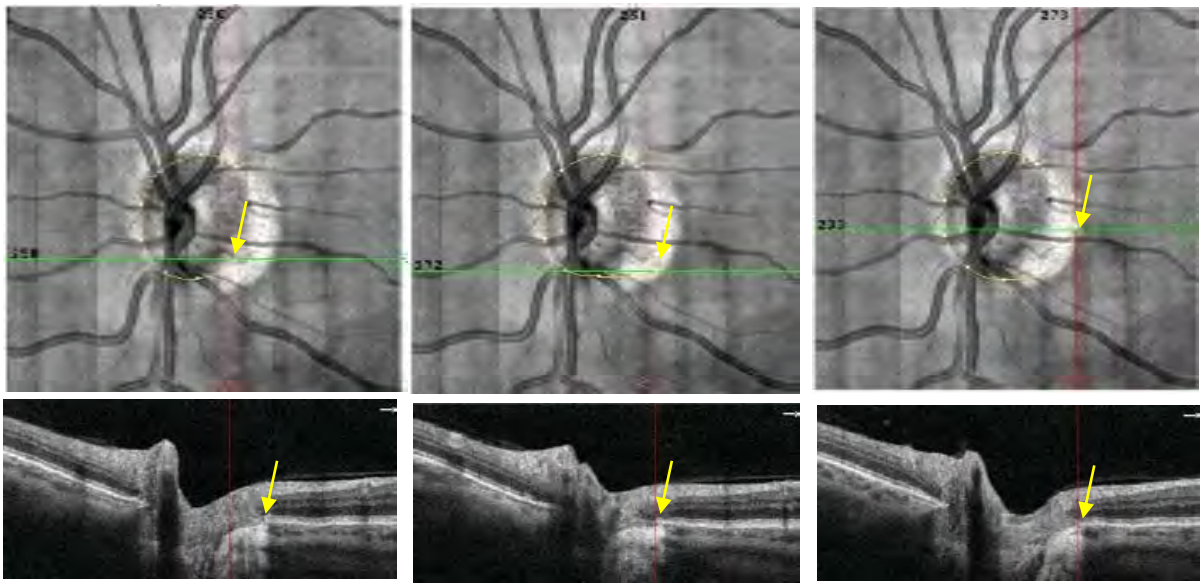


Figure 117 Disc Margin and Margin Correction

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.

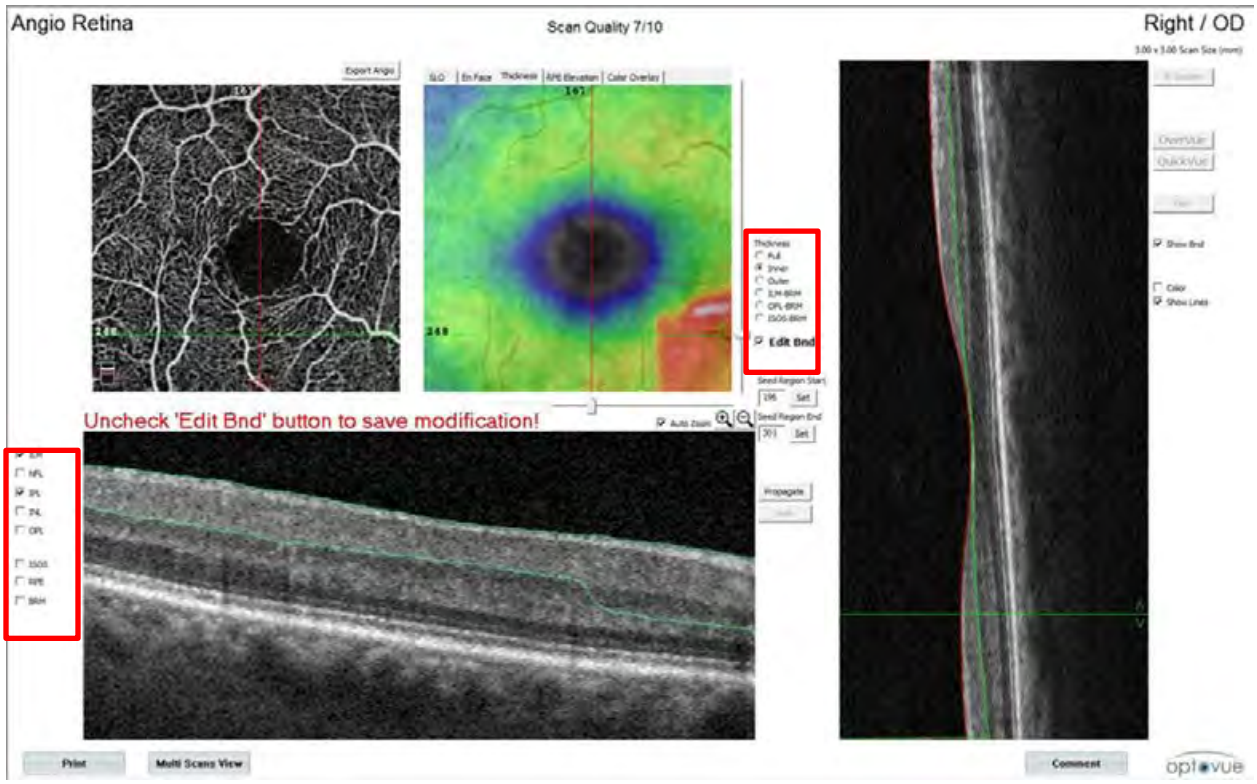


Figure 118 Incorrect IPL segmentation

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.)

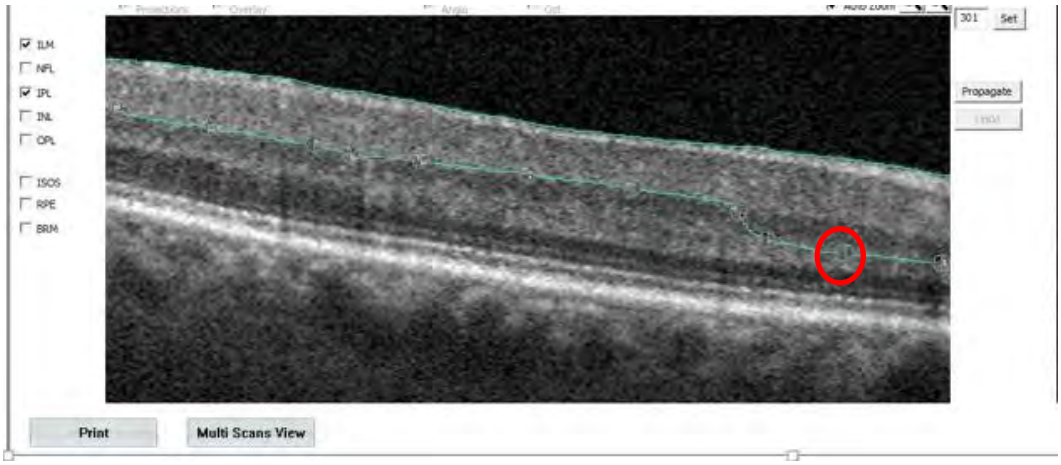


Figure 119 IPL Boundary Selected, Anchor Points Activated

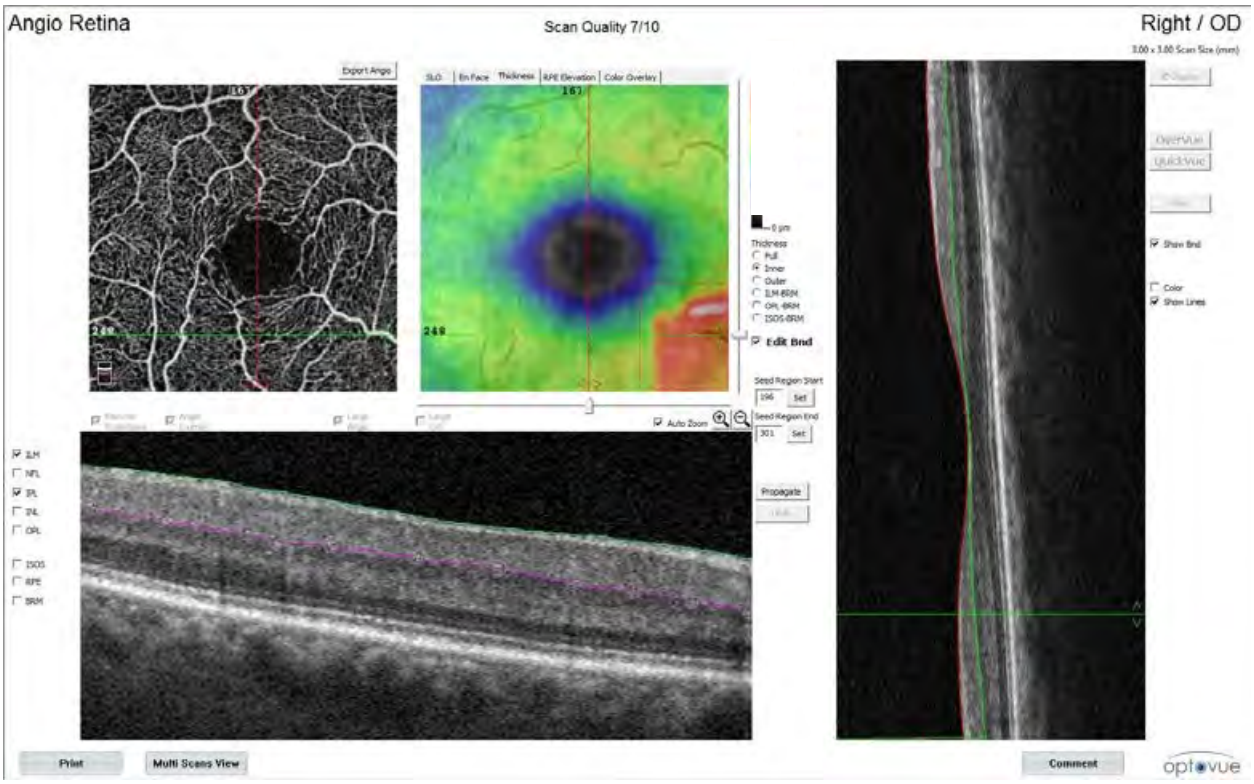


Figure 120 Single B-Scan Corrected (IPL Line Turned Purple), not Propagated

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.

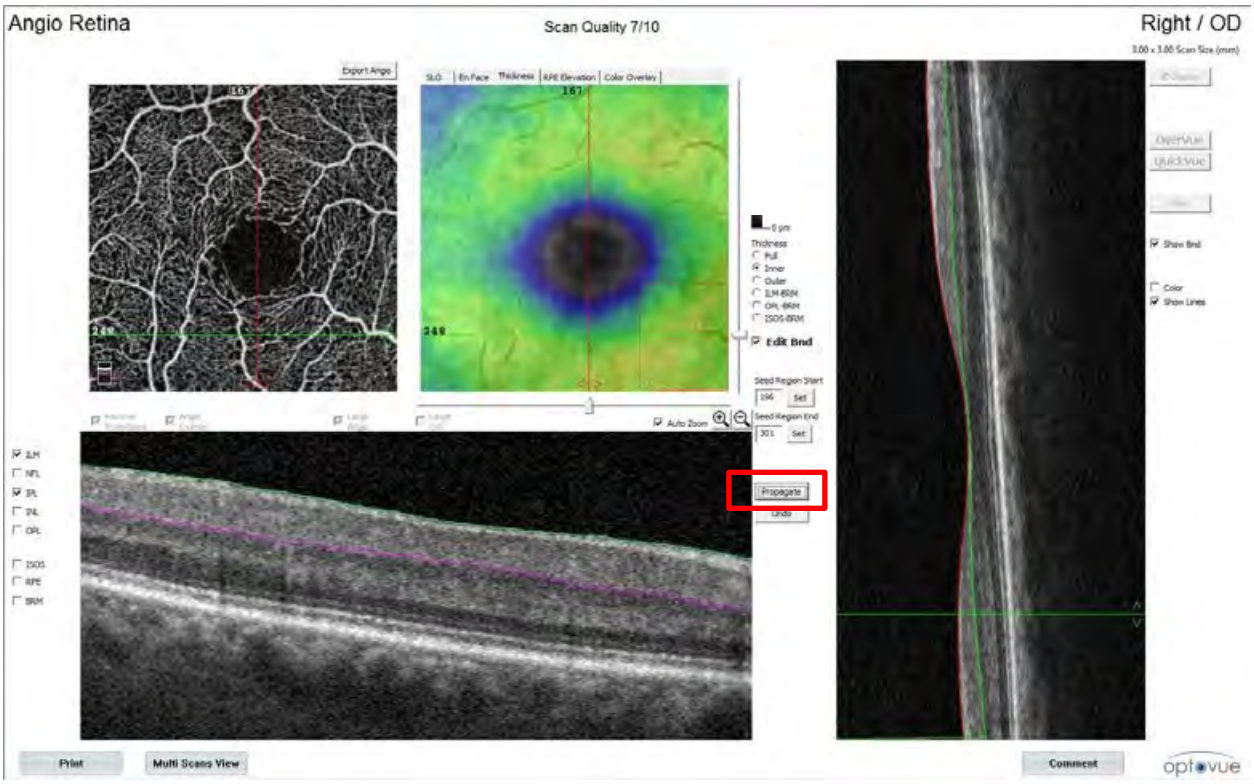


Figure 121 Segmentation Correction and Propagation Applied

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 form 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.

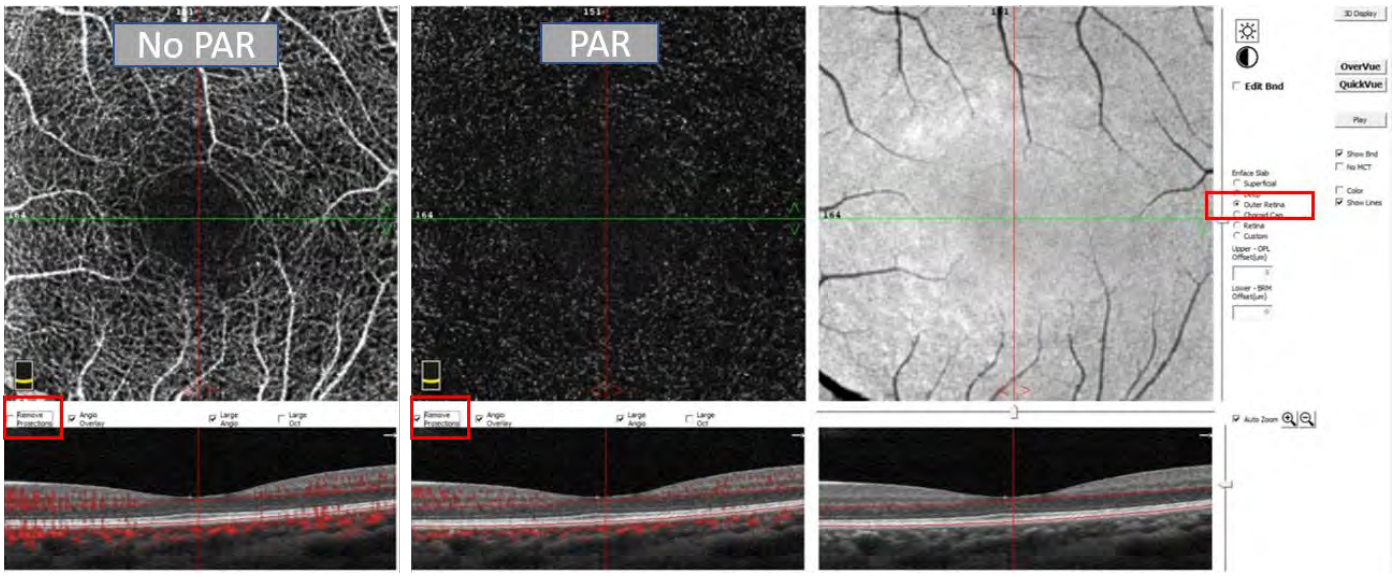


Figure 122 PAR Off and PAR On (same Outer Retina Slab)

☞ **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

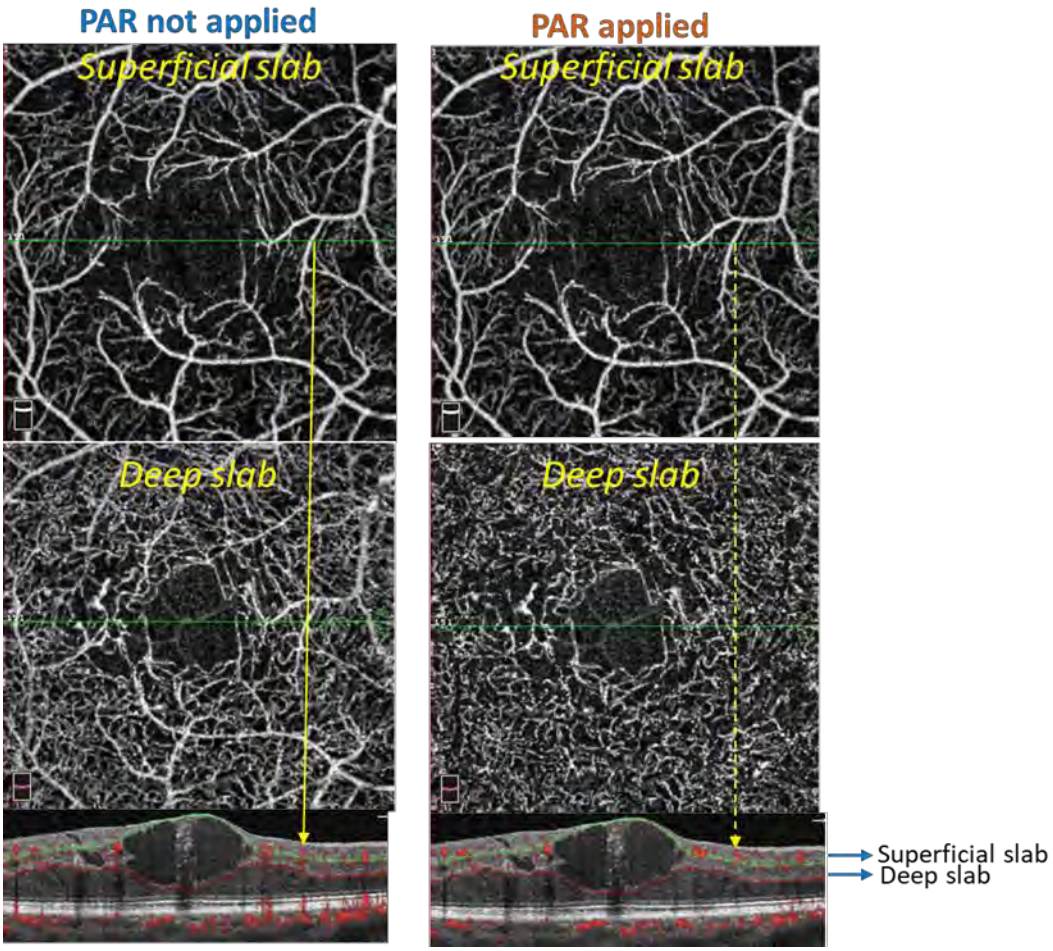


Figure 123 Example: 3 mm AngioVue® retina Scan of Patient with Diabetic Retinopathy, with and without PAR

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.

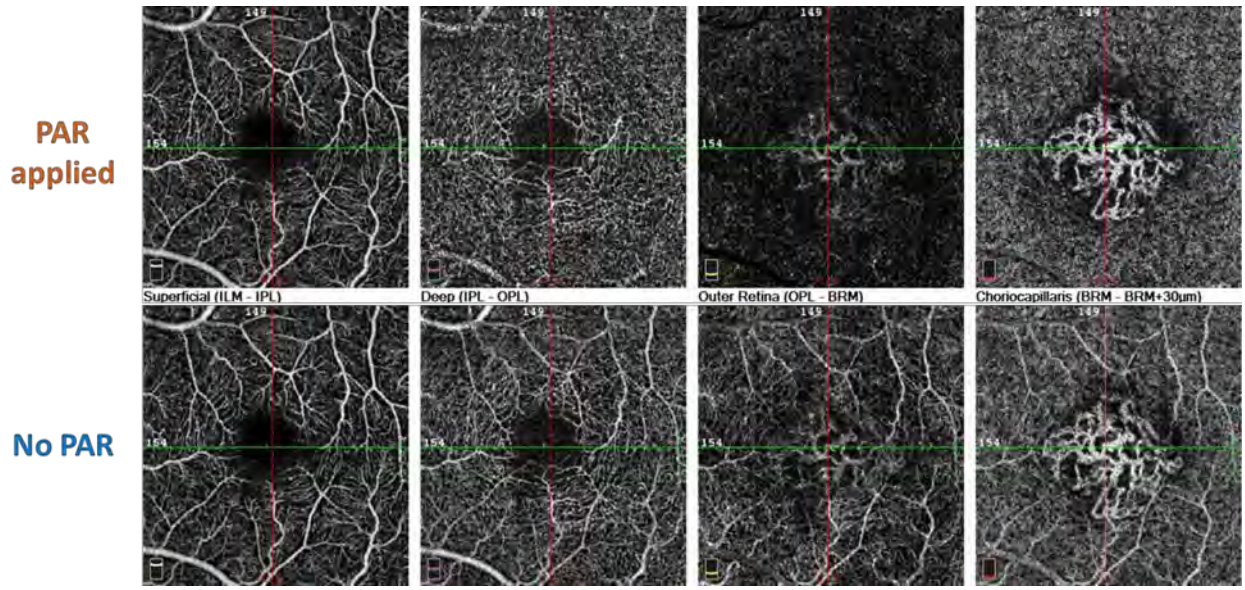


Figure 124 Example: 3 mm AngioVue® retina Scan of Patient with CNV, with and without PAR

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

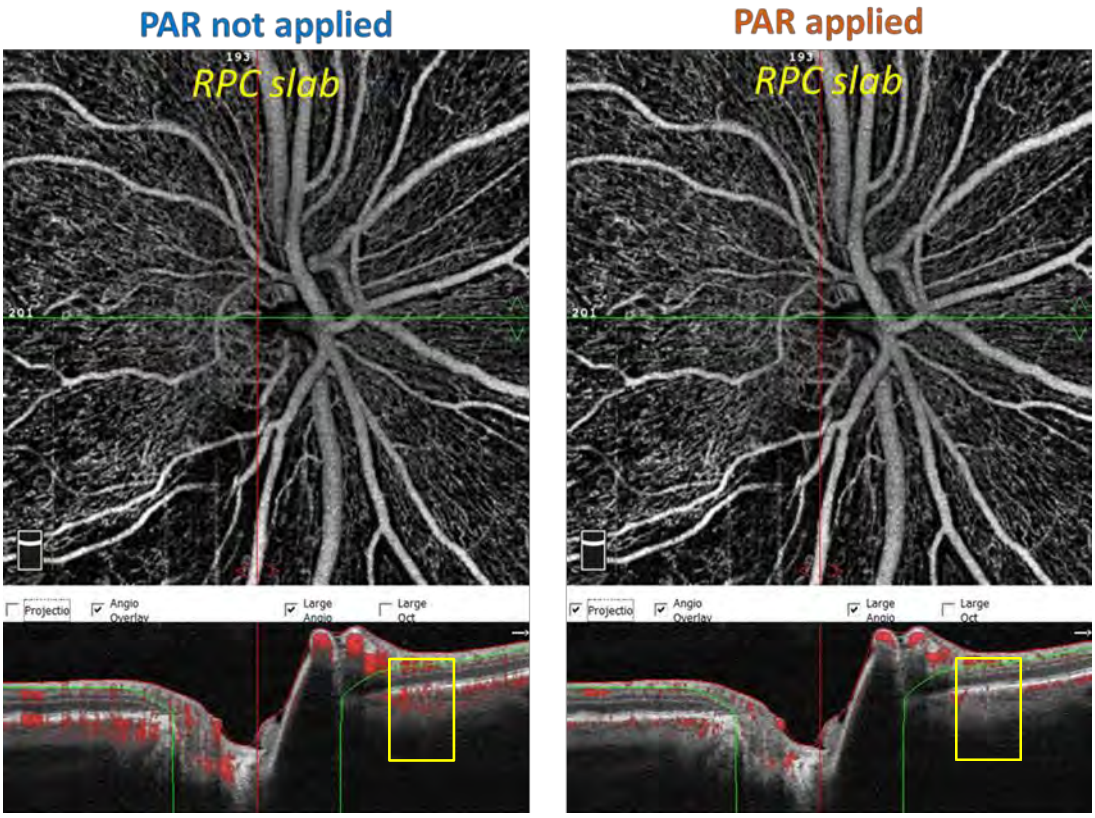


Figure 125 Example:4.5 mm AngioVue® Disc Scan, with and without PAR

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.

6.6.1 AngioVue® Reports List

AngioVue® Retina Reports

- AngioVue® Retinal OverVue (requires Essential license)
- 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 Essential

The Essential Report is a minimal approach to OCTA analysis and requires separate license. The report has the 4-layer en face segmentation presented along the top: Superficial, Deep, Outer Retina and Choriocapillaries. Moveable B-scan indicators are red and green. The upper B-scan is horizontal (green) the lower B-scan is vertical (red). The lower left en face display default is Superficial.

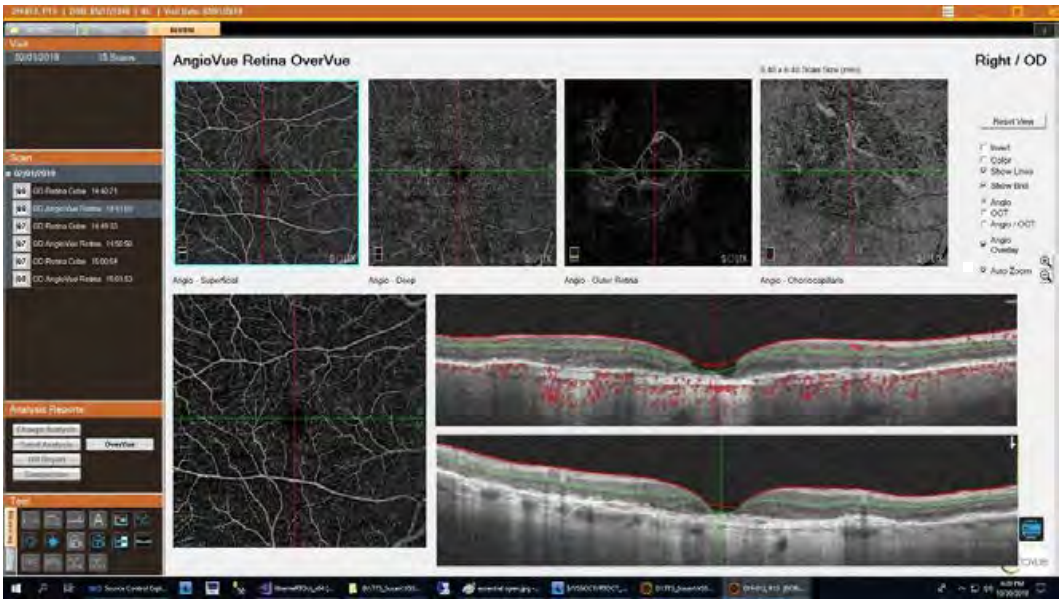


Figure 126 AngioVue® Retina Essential Report Superficial selected

Clicking/selecting on any of the 4 top en face images will change the display in the left lower corner to the selected slab. Selecting the Choroidal Capillary en face enables the choroidal segmentation adjustment slider. The operator can move the segmentation up/down to visualize the vasculature**.**

Figure 127 Essential Report with Choroidal Capillary en face selected

Selecting AngioVue® , OCT or Angio/OCTA button on the right will bring the corresponding en face images to display.

6.6.3 **AngioVue® Retina Main Report**

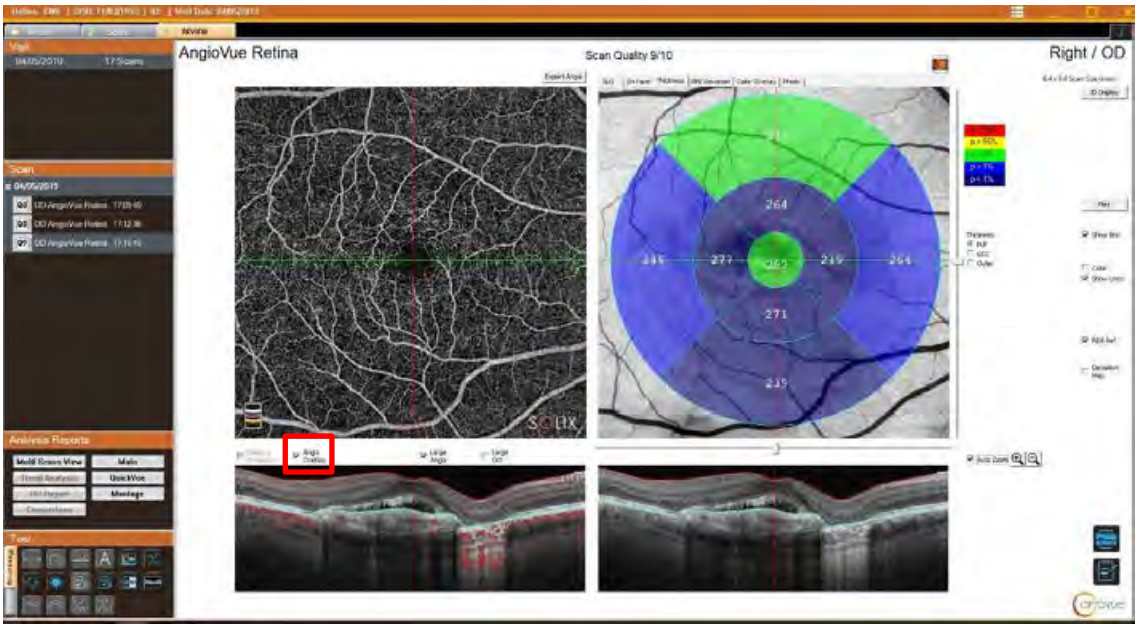


Figure 128 AngioVue® Retina Main Report

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.

6.6.3.1 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.

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.

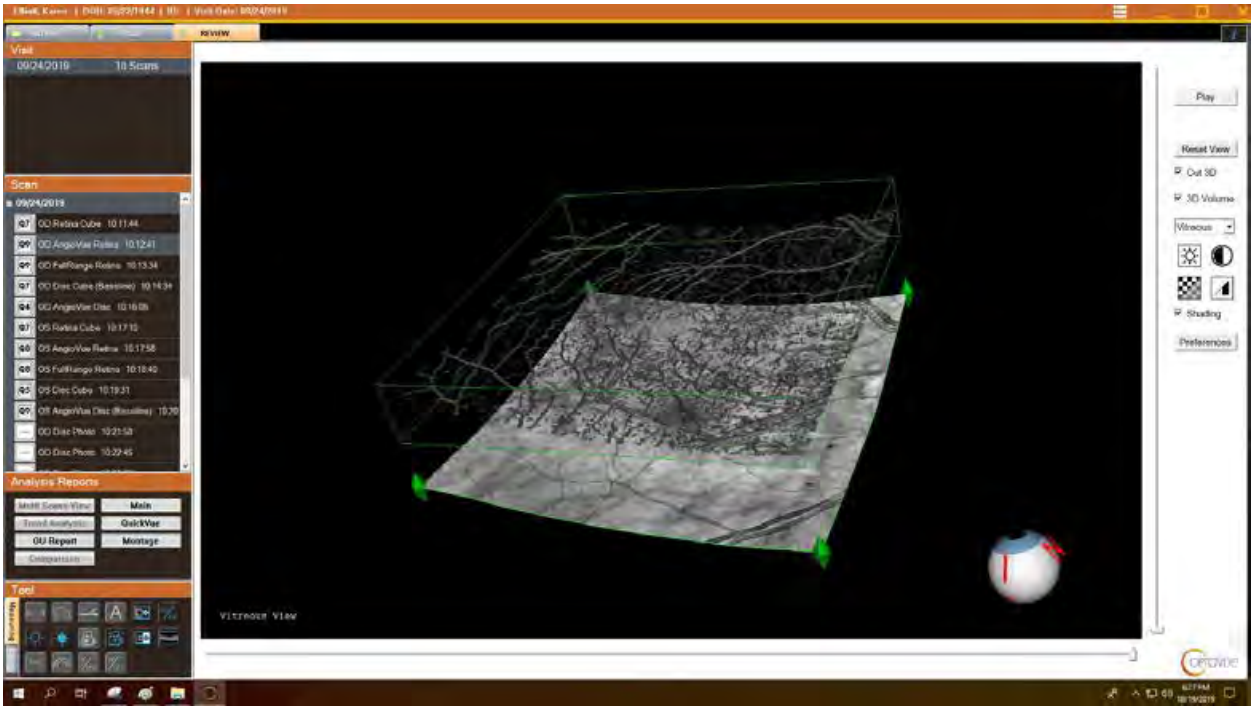


Figure 129 3-D Retina Image

6.6.3.2 Top Center Image Tabs

Thickness Tab

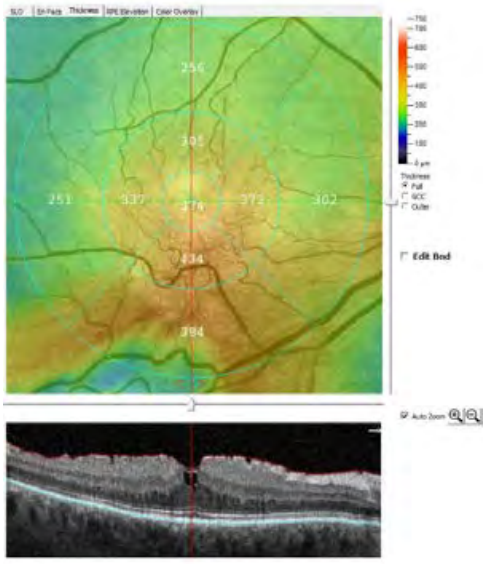


Figure 130 Top Center Image Tabs, Thickness Tab Selected

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

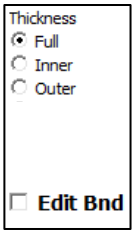
- **SLO:** Shows OCT and AngioVue® images of the full scan thickness.
- **En Face:** Shows the en face OCT image of the retina and the corresponding AngioVue® image to the left.
- **Thickness:** Shows an OCT image overlaid with retinal thickness using a color scale (and ETDRS overlay), and the corresponding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

6.6.4 **RDB Reference Database Map**

- The color-coded RDB Reference Map shows regions where thickness is within normal range (green, the measurement is between the 5th percentile to 95th percentile of the RDB, borderline (yellow, the measurement is between the 5th percentile to the 1st percentile of the RDB, and outside normal range (red, the measurement is below the 1st percentile of the RDB).

- **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.

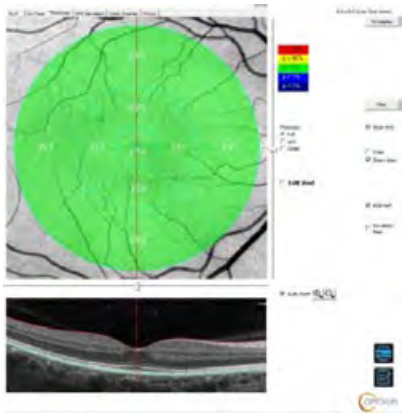


Figure 131 AngioVue Retina Thickness RDB Map

Figure 132 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.

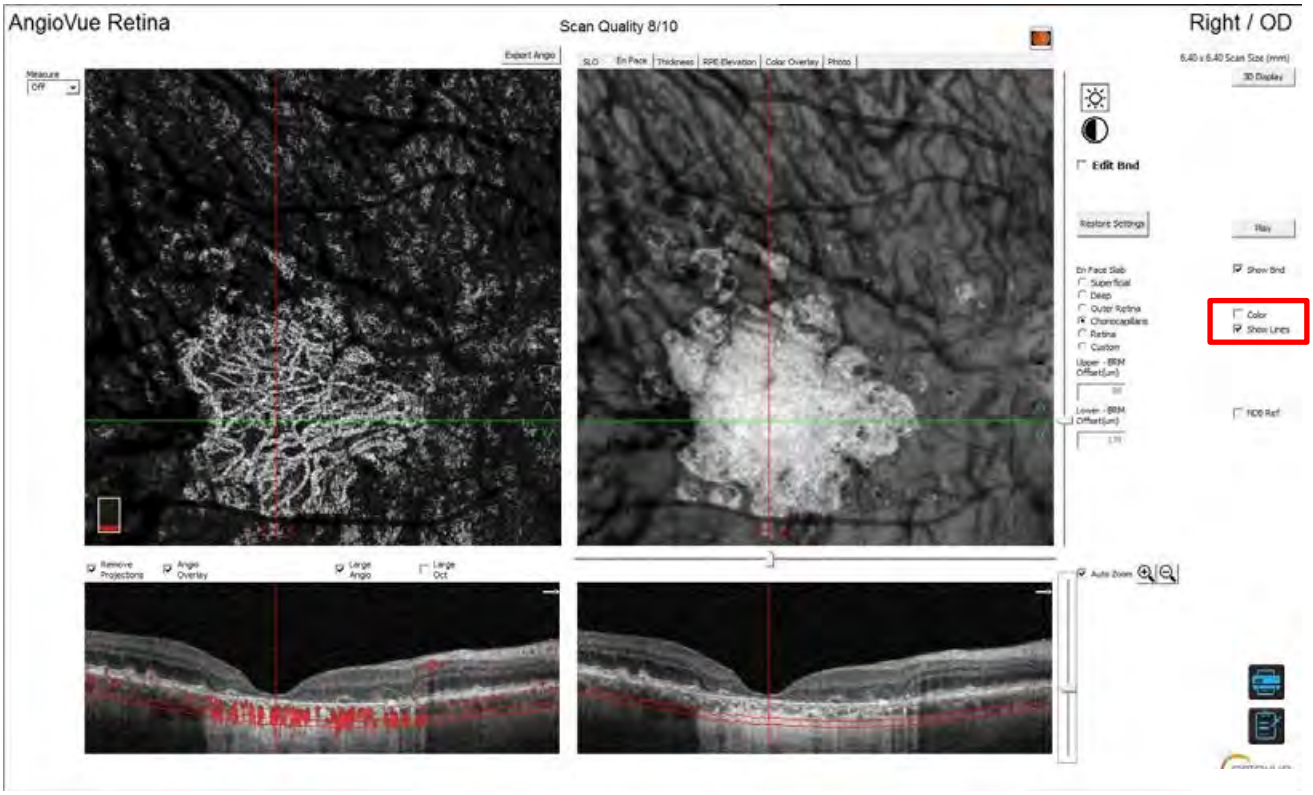
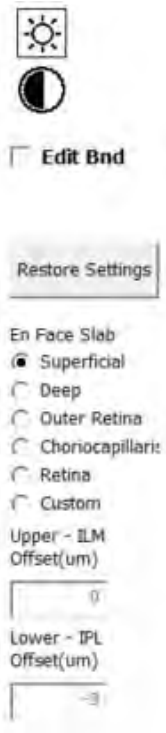


Figure 133 AngioVue® Retina Main Report, En Face Tab Selected

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:** Redirects to segmentation edits screen
- **Restore Settings:** Restores to original settings
- **En Face Slab**
- **Superficial**
- **Deep**
- **Outer Retina**
- **Choriocapillaris**
- **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.

☞**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

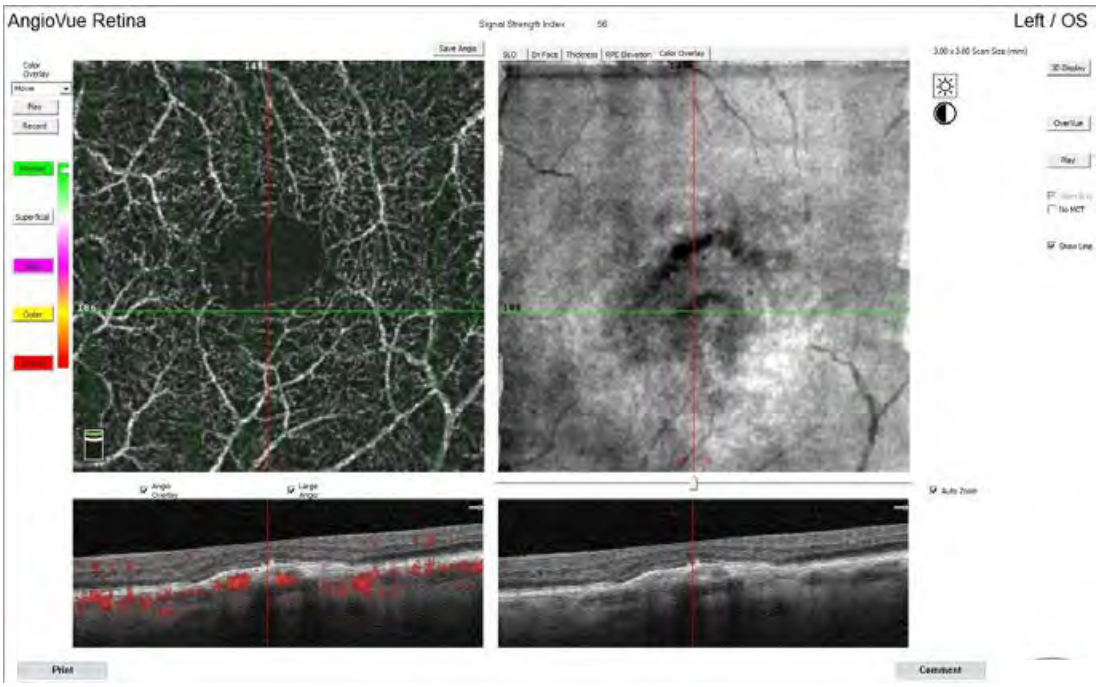
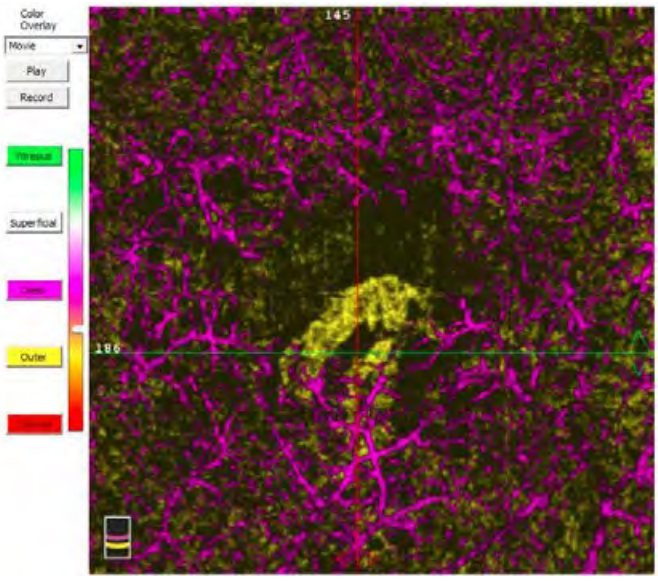


Figure 134 AngioVue® Retina Main Report, Color Overlay Tab Selected (Default to Movie)



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 135 Movie Paused Between Deep and Outer Reina

Movie Layers Boundaries

- 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 (Upper limit = OPL+10µm; Lower limit = BRM-10µm); Color = Yellow
- Choroid (Upper limit = BRM-10µm; Lower limit = BRM+30µm); Color = Red

Color Overlay, Static

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

6.6.5 **AngioVue® Wide (12x12)**

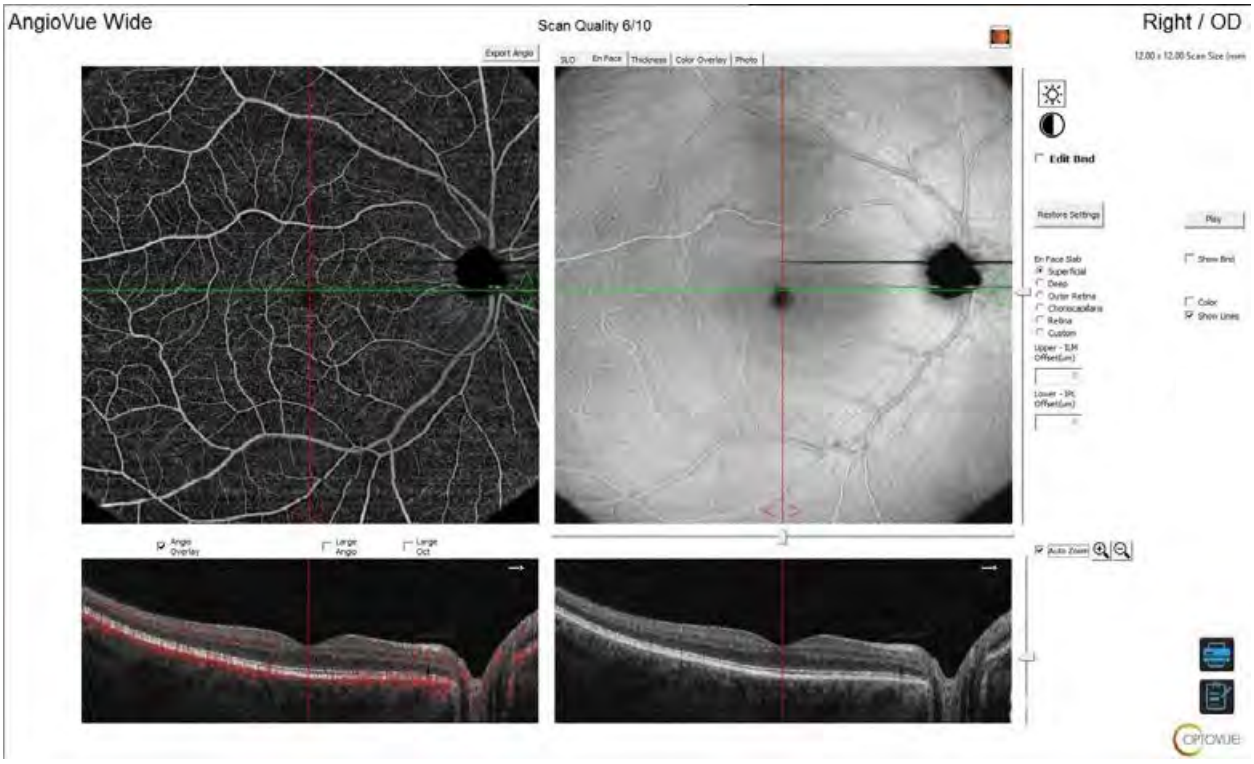


Figure 136 AngioVue® Wide (12x12)

6.6.6 **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.

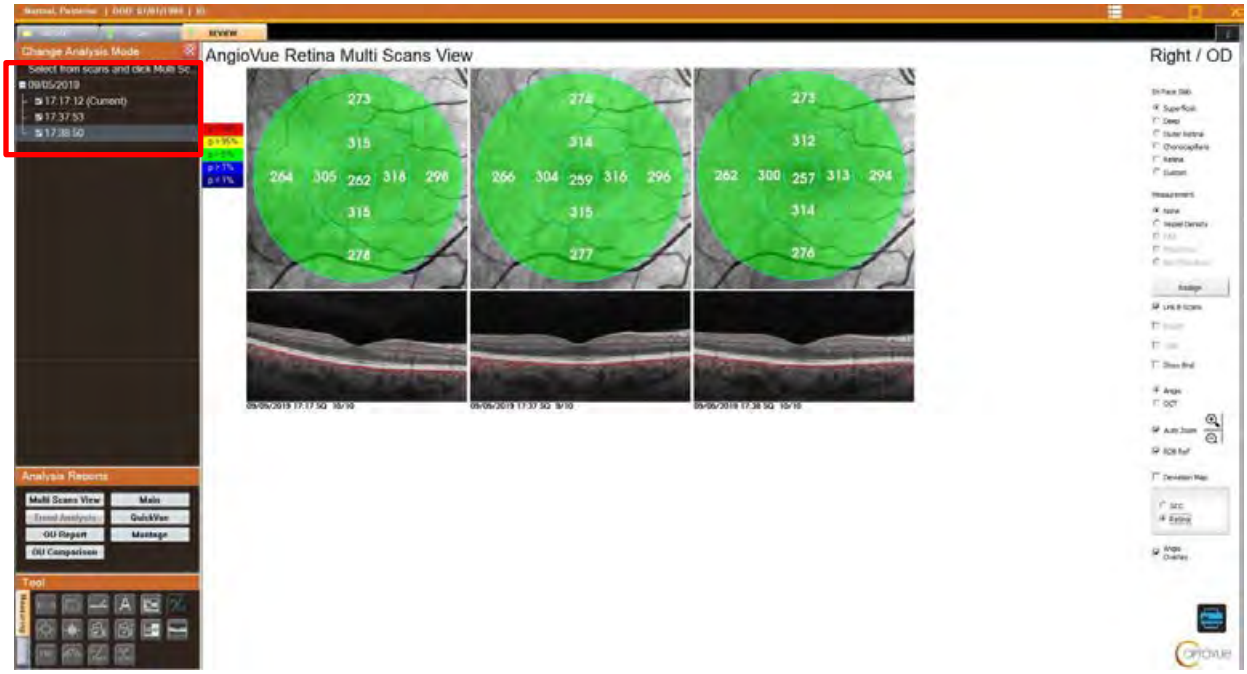
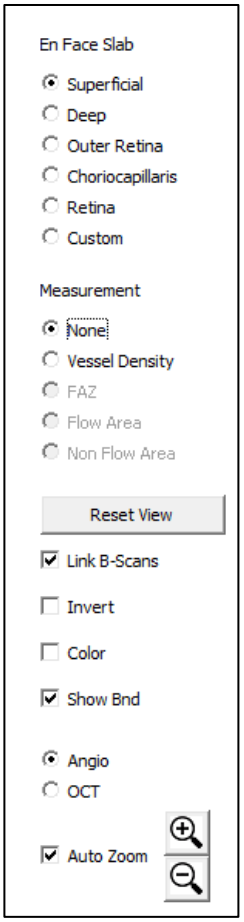


Figure 137 AngioVue® Retina Multiple Visit Report (3 visits)

6.6.6.1 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

6.6.7 **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 138 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

6.6.7.1 Manual Adjustment of Enface Images

Figure 139 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

6.6.7.2 Montage Controls

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

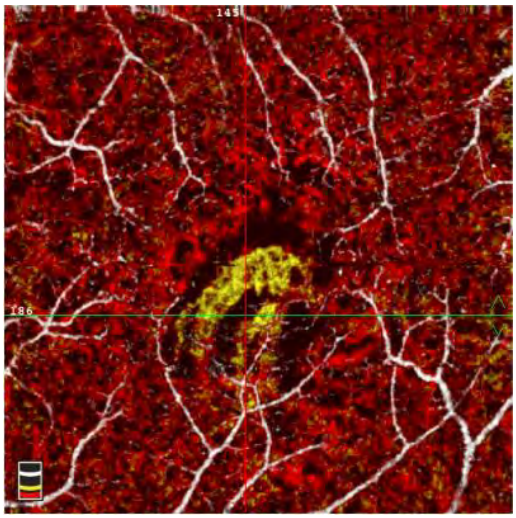
- **Reset View:** Resets view to the default settings.
- **Edit**: Redirects to montage edit screen
- **Vitreous/Retina:** Displays Vitreous/Retina slabs
- **Outer/Choroid:** Displays Outer/Choroid slabs
- **Grayscale:** Presents images in grayscale if checked
- **Print:** Prints the current display.

6.6.7.3 Montage Layers Boundaries and Color Legend

- 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 (Upper limit = OPL+10µm; Lower limit = BRM-10µm); Color = Yellow
- Choroid (Upper limit = BRM-10µm; Lower limit = BRM+30µm); Color = Red

6.6.7.4 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 140 Example of Type 2 CNV

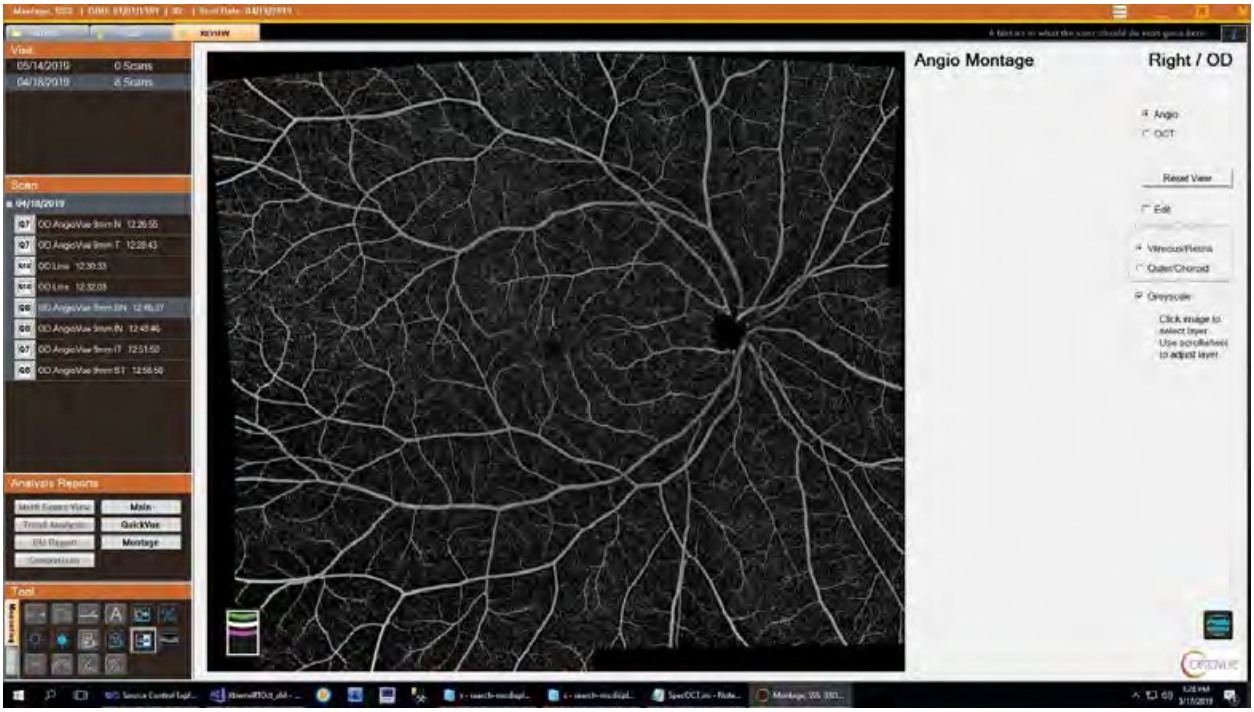


Figure 141 Montage 4 (9x9) Superficial

Figure 142 Montage 4 OCT

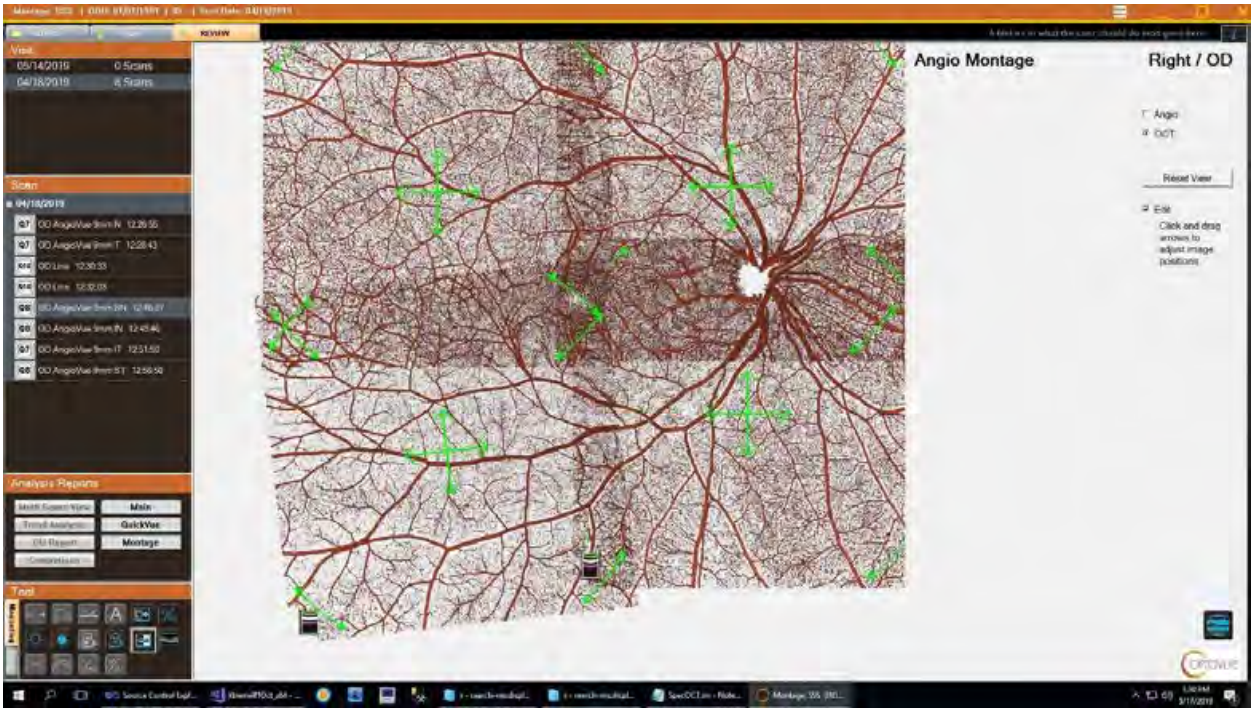


Figure 143 Montage 4 Manual alignment

6.6.8 **AngioVue Disc Main Report**

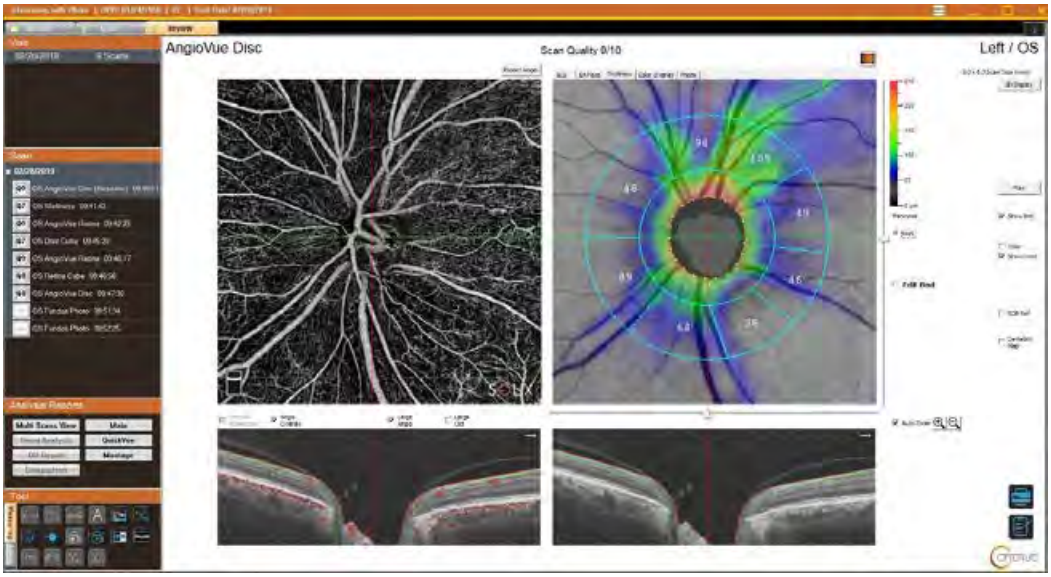


Figure 144 AngioVue® Disc Main Report, Thickness Tab Selected

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.

6.6.9 **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.

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.

6.6.10 **Top Center Image Tabs**

Thickness Tab

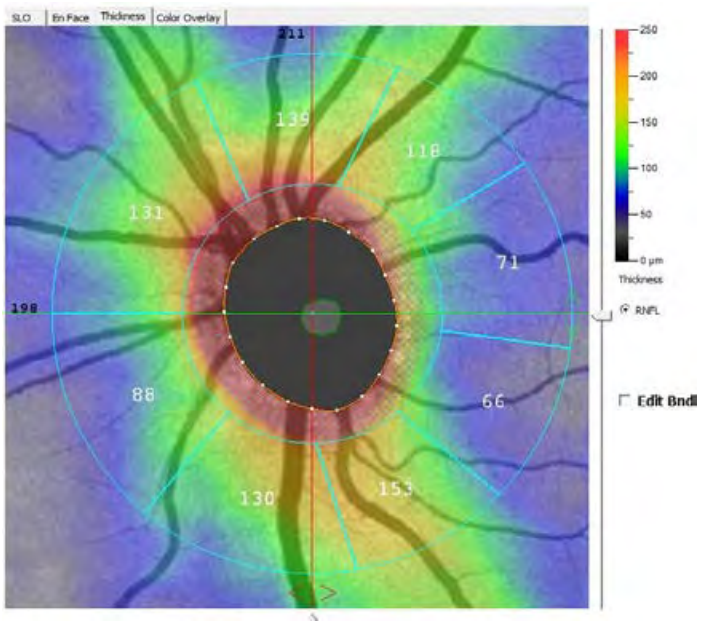


Figure 145 AngioVue® Disc Central Image Tabs

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

6.6.11 **RNFL RDB Map**

- The color-coded RDB Map shows regions where thickness is within normal range (green, the measurement is between the 5th percentile to 95th percentile of the RDB, borderline (yellow, the measurement is between the 5th percentile to the 1st percentile of the RDB, and outside normal range (red, the measurement is below the 1st percentile of the RDB).

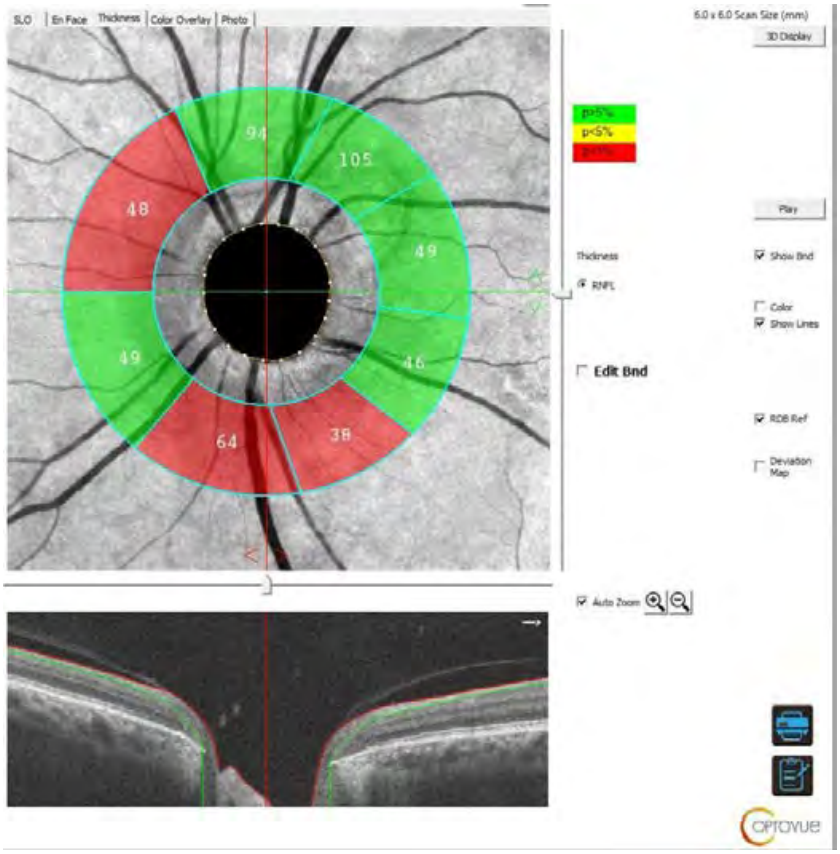
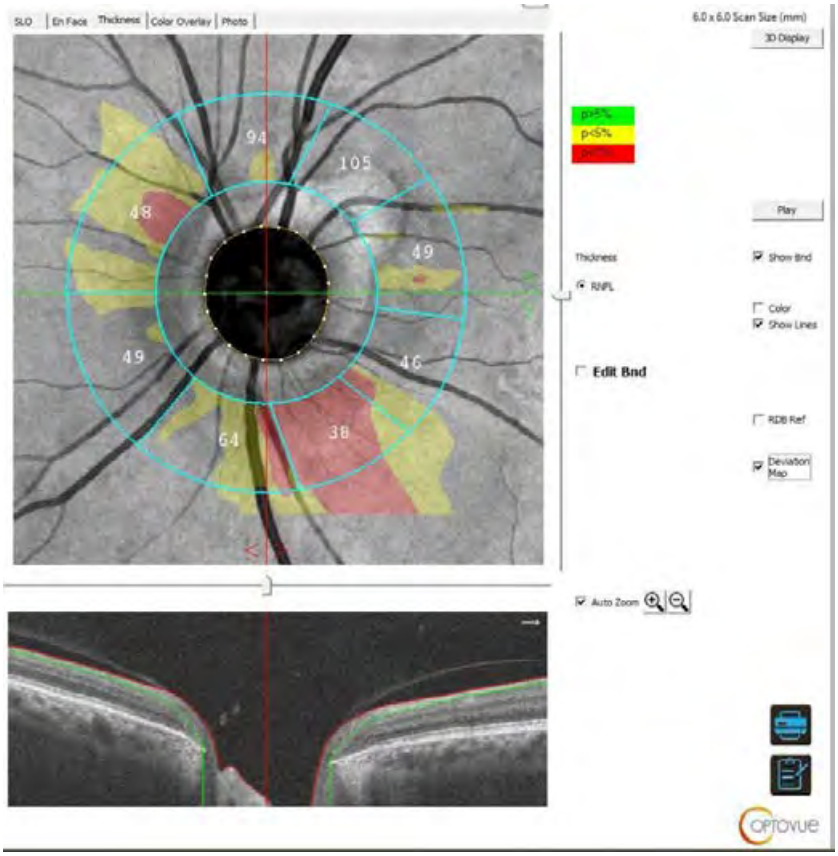


Figure 146 RNFL RDB map

6.6.12 **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.

……



- **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.

6.6.13 **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.

6.6.14 **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.

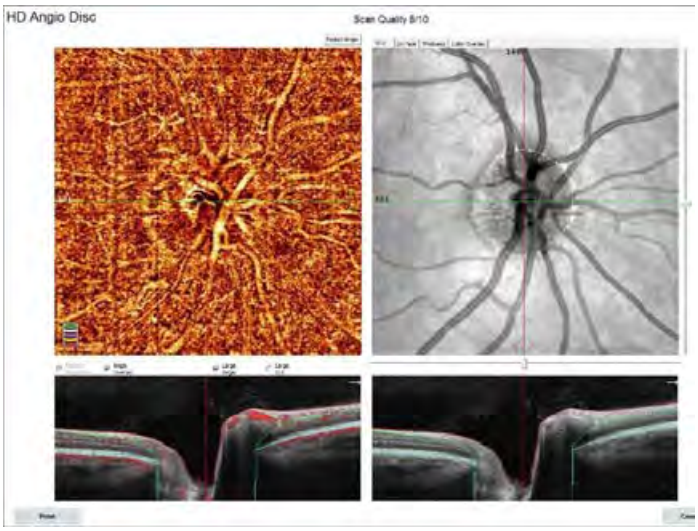


Figure 147 AngioVue® Disc Main Report, SLO Tab with Color Selected

6.6.15 **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.

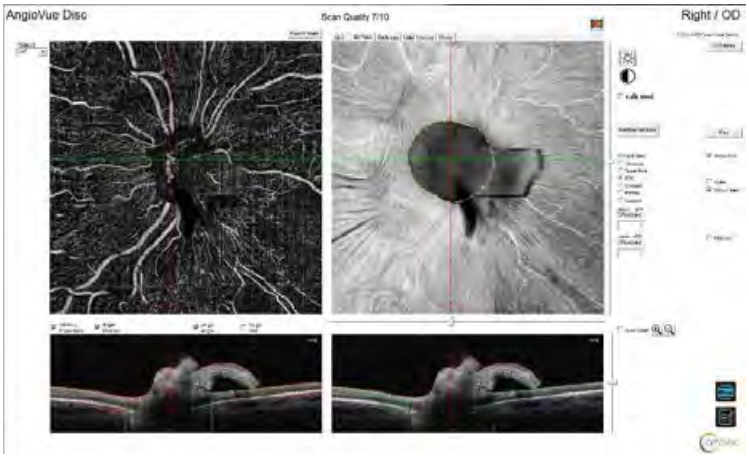
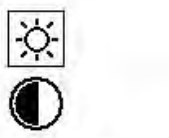


Figure 148 AngioVue® Disc Main Report, En Face Tab Selected

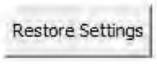
En Face Tab Controls



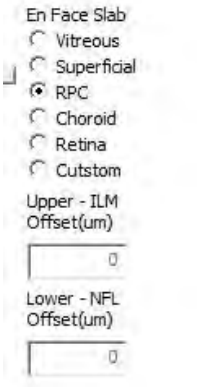
Brightness Icon: Click to adjust.

Contrast Icon: Click to adjust contrast.

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



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.

6.6.16 **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.

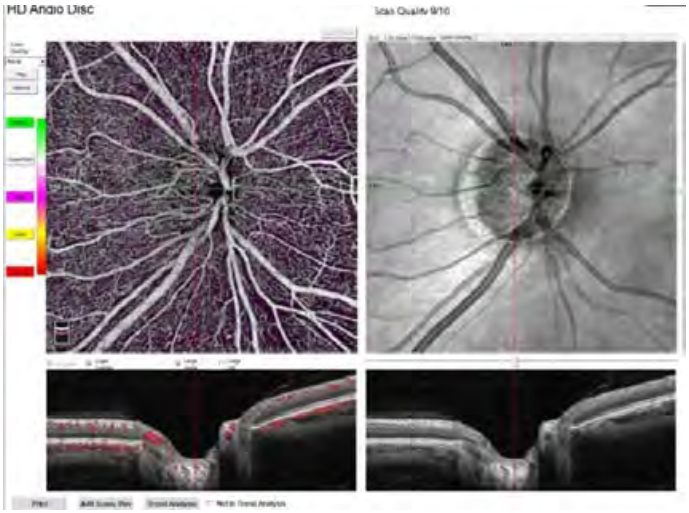


Figure 149 AngioVue® Disc Main Report, Color Overlay Tab with Movie Selected

Movie Layers Boundaries

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

Color Overlay, Static

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

Figure 150 AngioVue® Disc 9x9 mm

6.6.17 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.

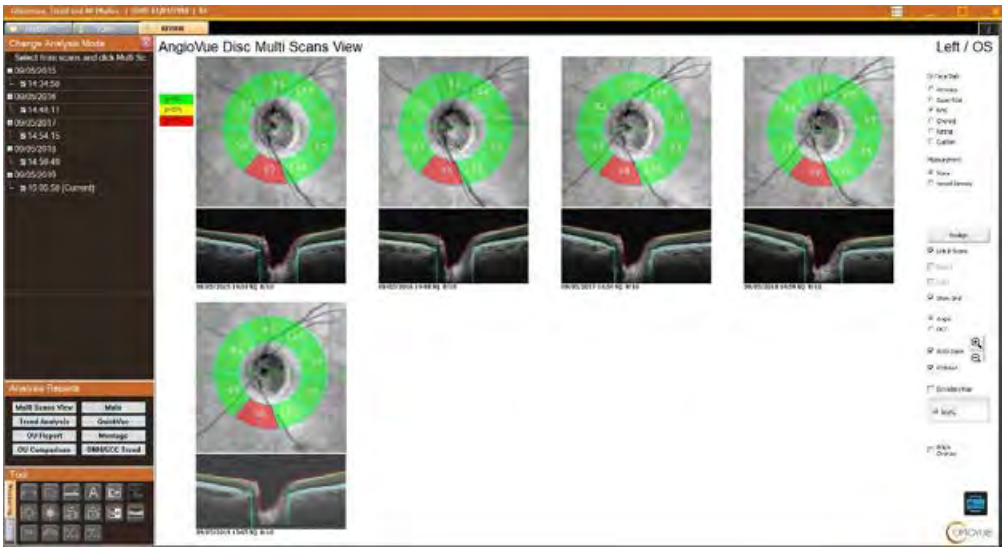
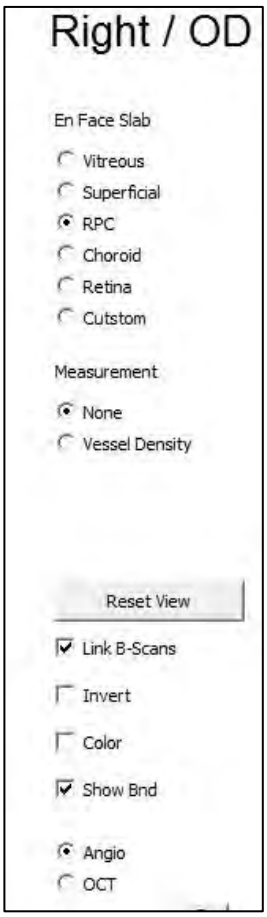


Figure 151 AngioVue® Disc Multiple Visit Report, RNFL RDB

6.6.17.1 AngioVue® Disc Multiple Visits Report Controls



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

Vitreous

Superficial

RPC

Choroid

Retina

Custom

Measurement

None

Vessel Density

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

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.

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.

RDB Map

- The color-coded RDB Map shows regions where thickness is within normal range (green, the measurement is between the 5th percentile to 95th percentile of the RDB, borderline (yellow, the measurement is between the 5th percentile to the 1st percentile of the RDB, and outside normal range (red, the measurement is below the 1st percentile of the RDB).

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 152 RDB scan list

.

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)
- 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)
- 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”

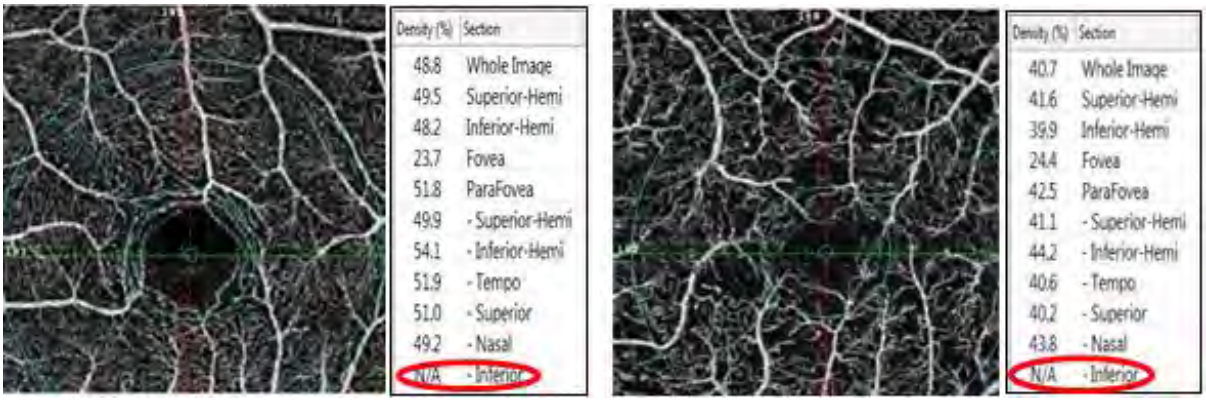


Figure 153 Sector Crop >30% Marked NA

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.

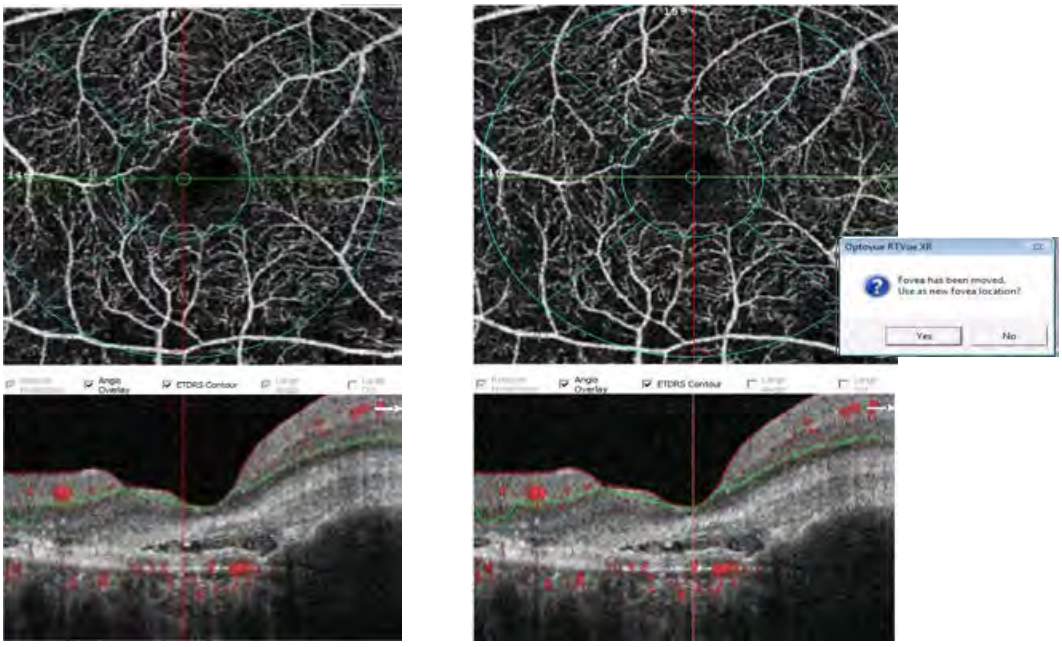


Figure 154 Grid centration

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.

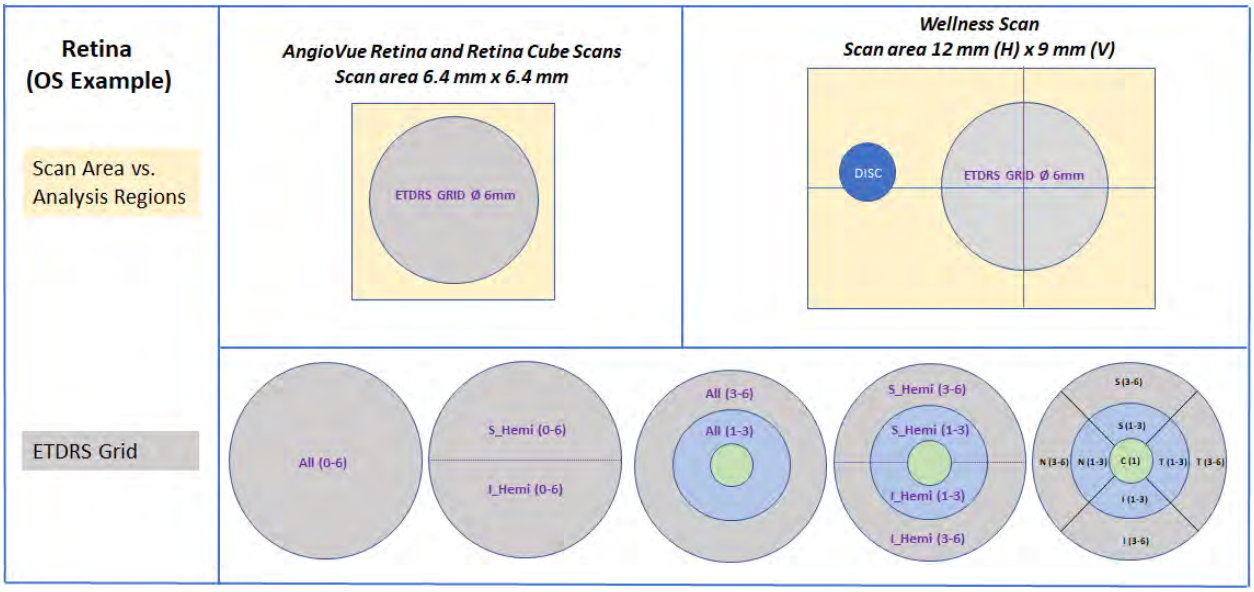


Figure 155 AngioVue® Retina Measurement Zones and Parameters

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**

RDB references are available only for full retinal thickness and GCC. The Retina report includes five 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.

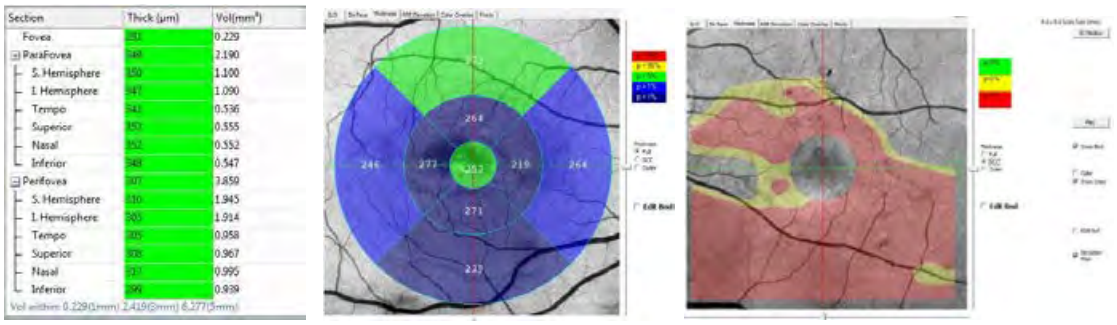


Figure 156 Retina 3D Map with RDB Reference, and Deviation

RDB references can appear in the ETDRS Chart, the RDB Reference Map and the retinal parameters table . The RDB color key chart explains that green indicates “Within normal limits” “ (the measurement is between the 5th percentile to 95th percentile of the RDB); yellow indicates “Borderline” thick (the measurement is between the 95th percentile to the 99th percentile of the RDB); red indicates “Outside normal limits” thick (the measurement is above the 99th percentile of the RDB); blue indicates “Borderline” thin (the measurement is between the 5th percentile to the 1st percentile of the RDB); and dark blue indicates “Outside normal limits” thin (the measurement is below the 1st percentile of the RDB). 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**

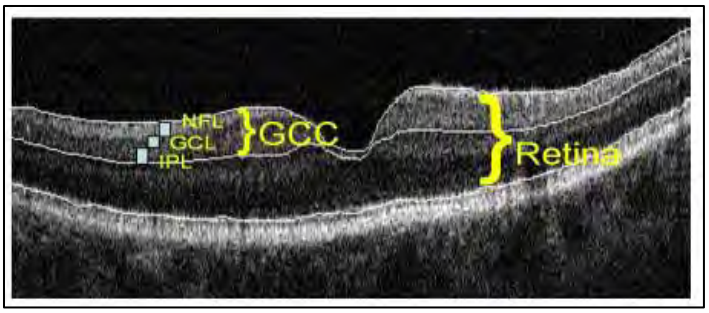


Figure 157 The GCC and Its Layers

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

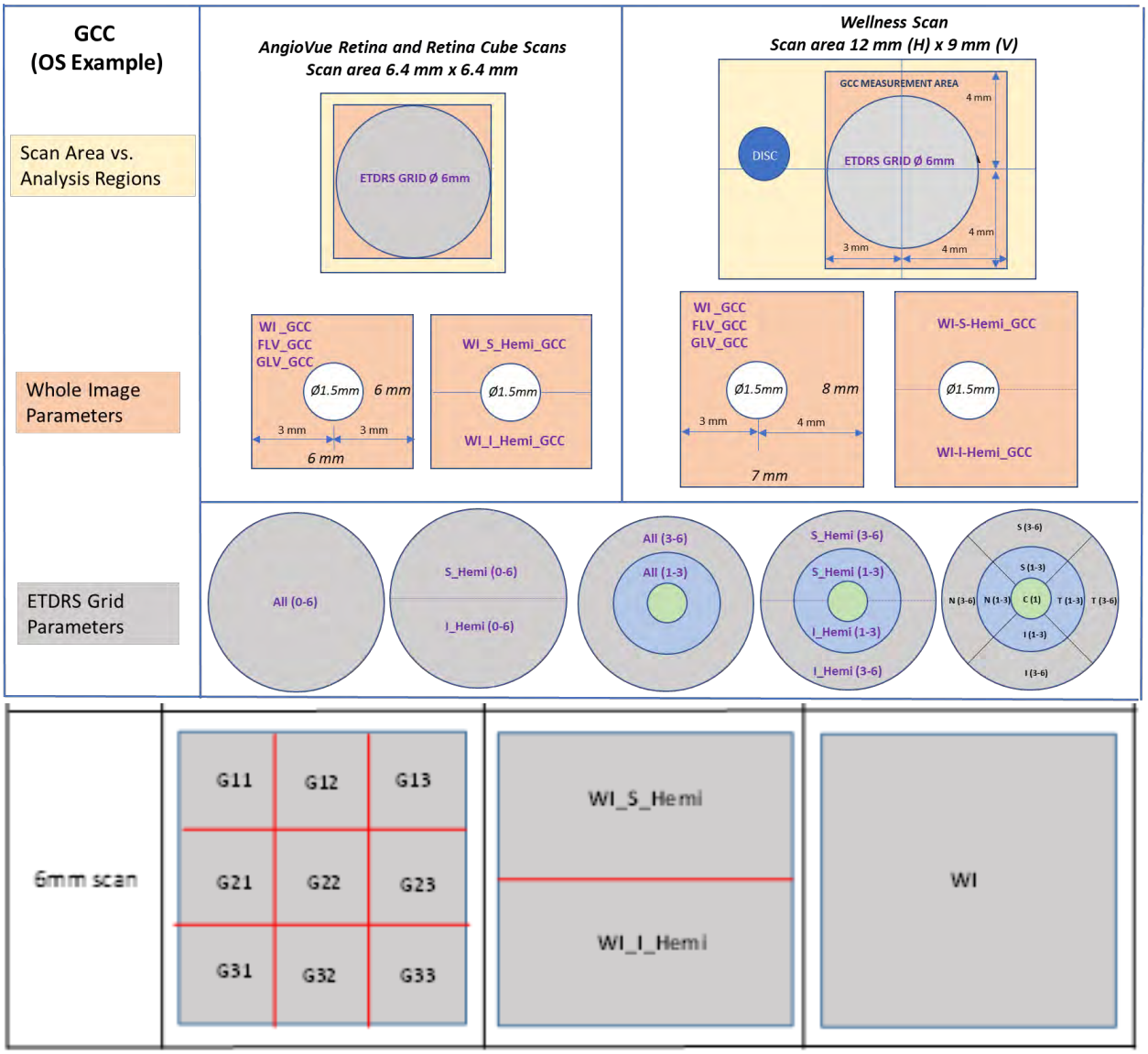


Figure 158 GCC measurement areas

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.

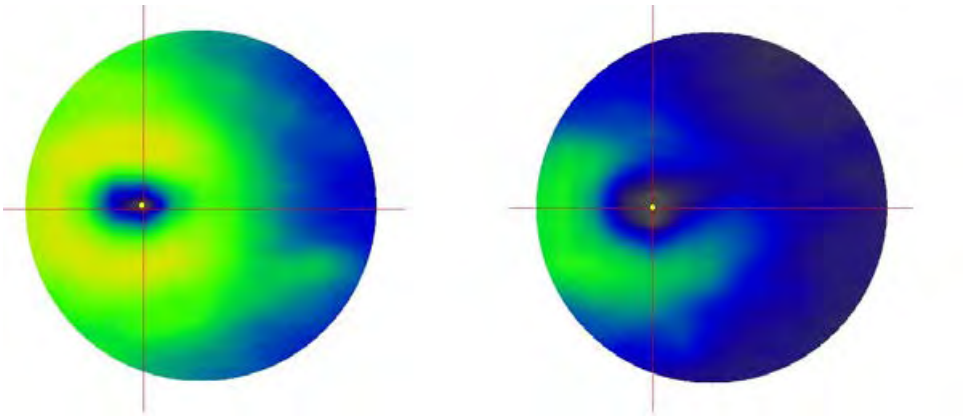


Figure 159 GCC Thickness Maps: Healthy Eye (Left), Glaucoma Eye (Right)

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 RDB Map

The color-coded RDB Map shows regions where thickness is within normal range (green, the measurement is between the 5th percentile to 95th percentile of the RDB, borderline (yellow, the measurement is between the 5th percentile to the 1st percentile of the RDB, and outside normal range (red, the measurement is below the 1st percentile of the RDB). The grey circle around the fovea is to exclude reference to Reference data colors because this region lacks ganglion cells.

7.2.9 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.

7.2.10 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 a100 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.

7.2.11 **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.

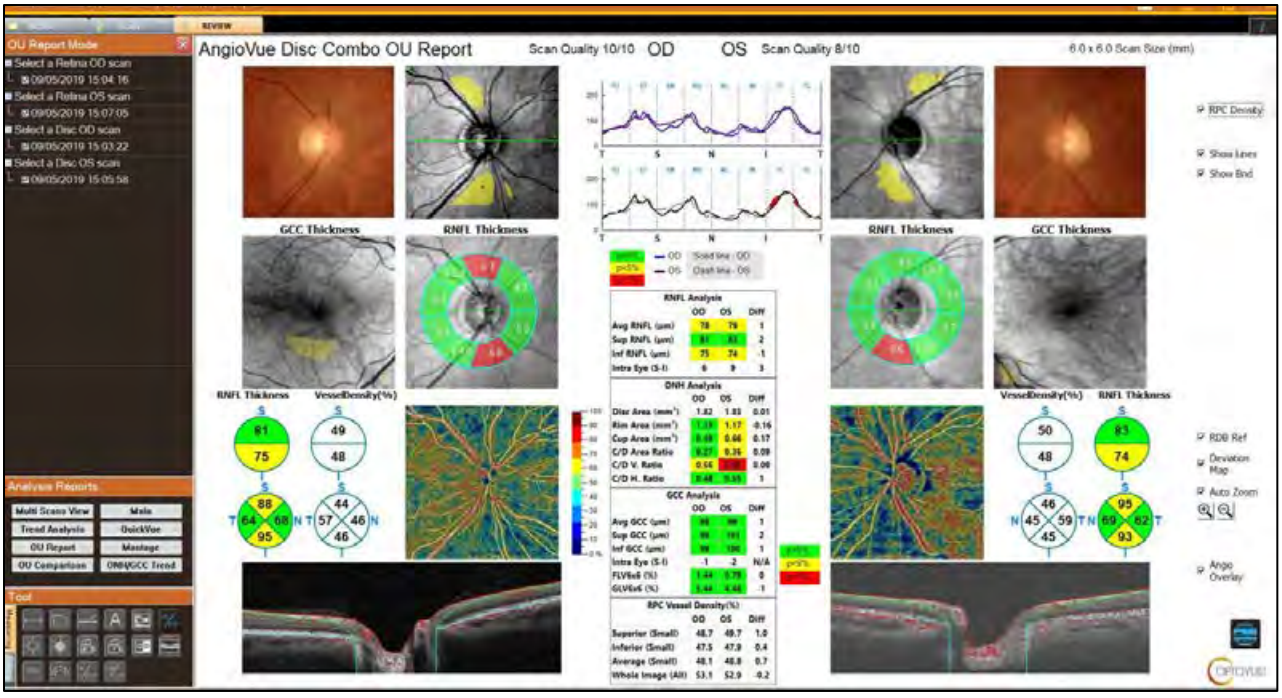


Figure 160 AngioVue® Disc Combo report

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

7.2.12 AngioVue® Retina Vessel Density and Retinal Thickness

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

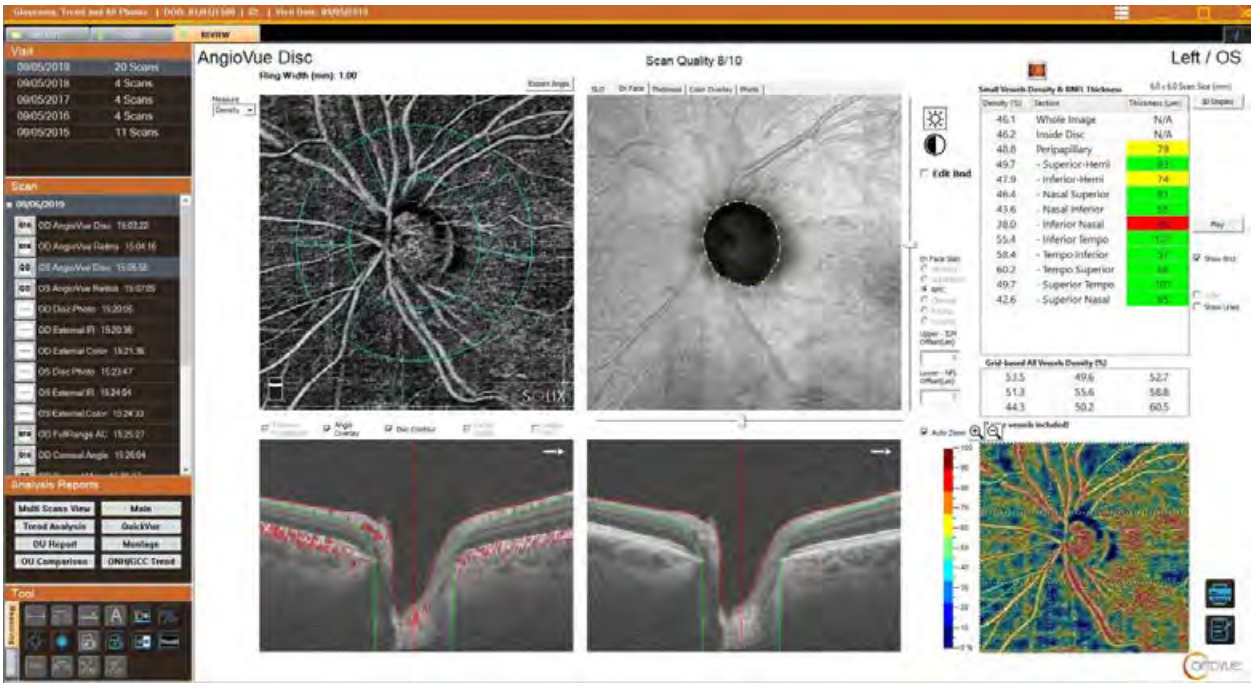


Figure 161 6 mm AngioVue® Retina, Main Report

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.

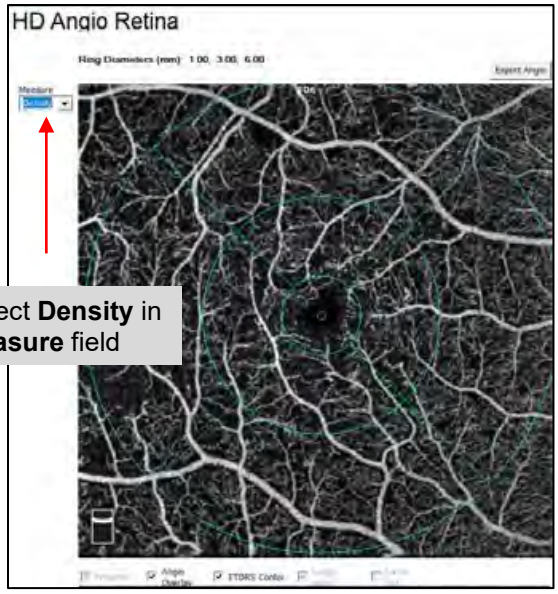


Figure 162 Measurement Window Selection

☞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.

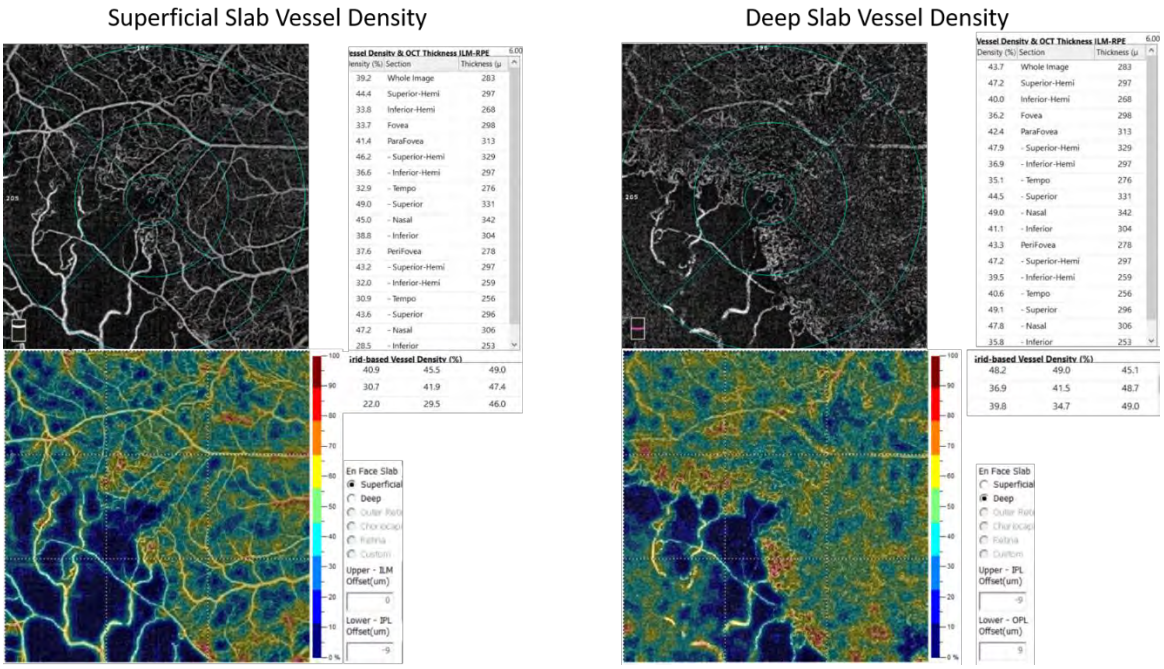


Figure 163 Superficial and Deep Vessel Density Measurements

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.

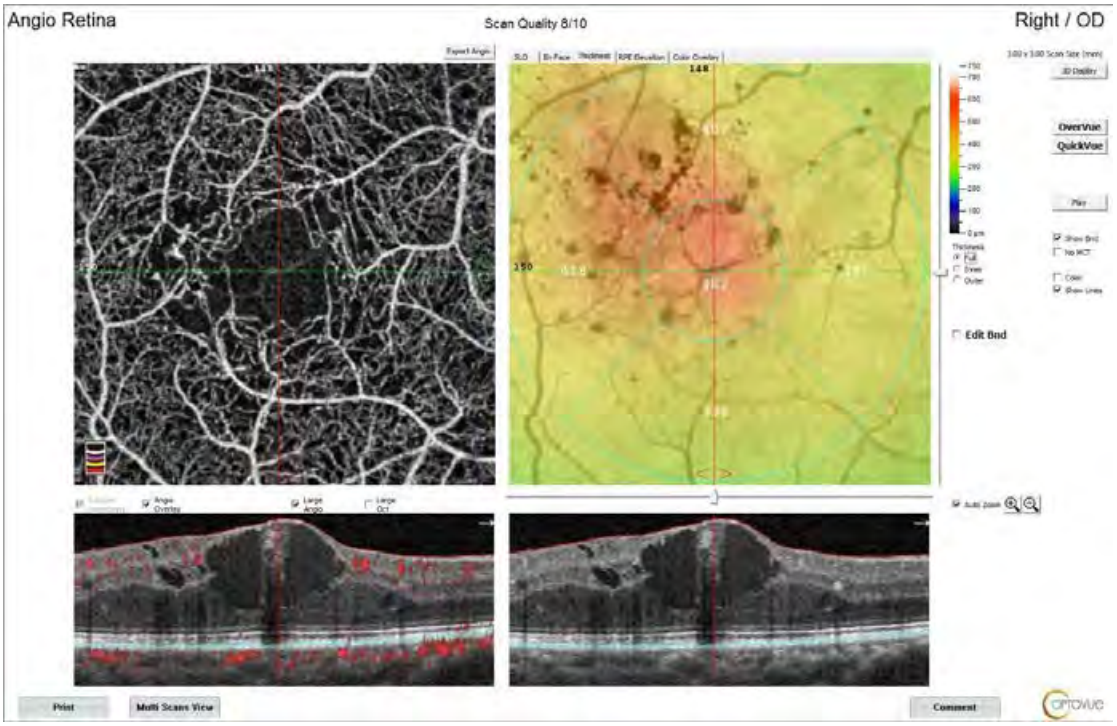


Figure 164 AngioVue® Retina Main Report, Thickness Tab with Full Retina Thickness Selected

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

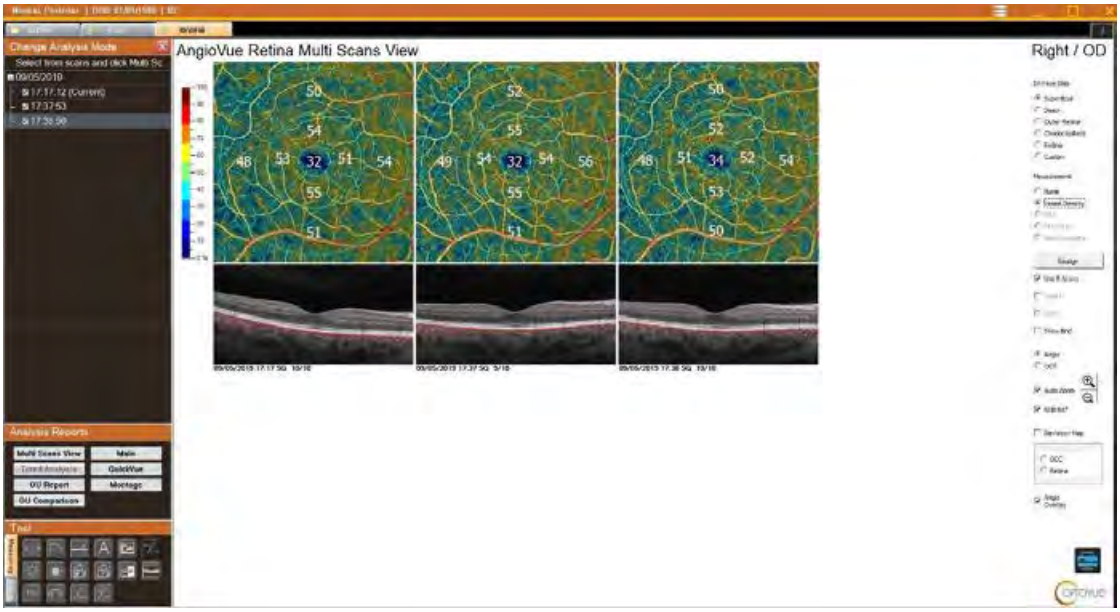


Figure 165 Retina Multi Scan Showing Superficial Density

7.2.13 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 – either 3 mm or 6 mm and are generated based on the Retina slab (ILM to OPL+10µ).

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

- FAZ: FAZ area in mm^2 (3 mm and 6 mm OCTA scans)
- PERIM: FAZ perimeter in mm (3 mm and 6 mm OCTA scans)
- FD: vessel density of the 300µ width ring surrounding the FAZ, in %. (3 mm and 6 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 between 3 mm and 6 mm OCTA scans.

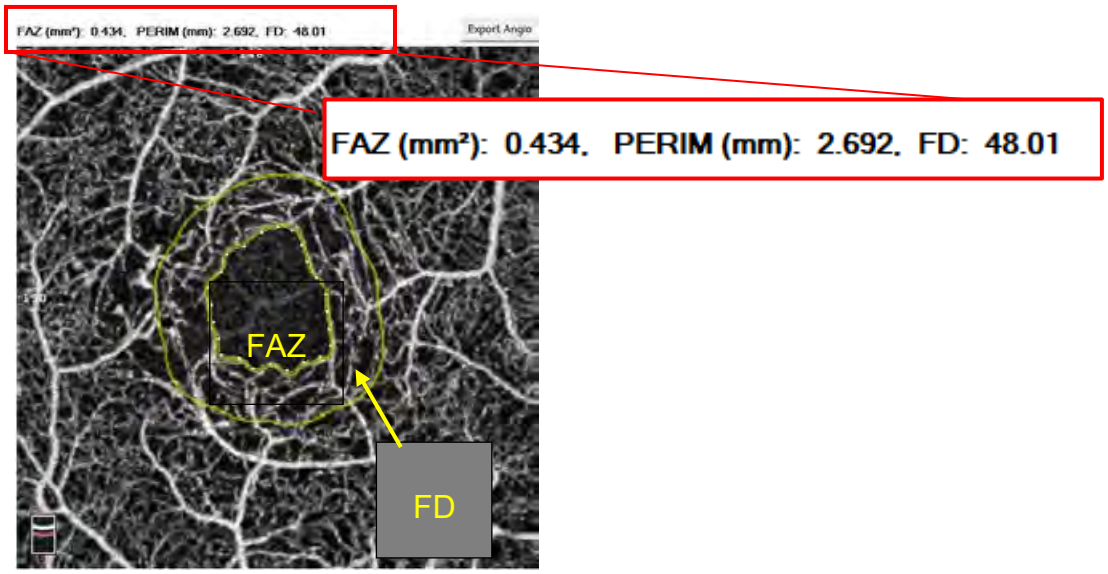


Figure 166 FAZ Parameters

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

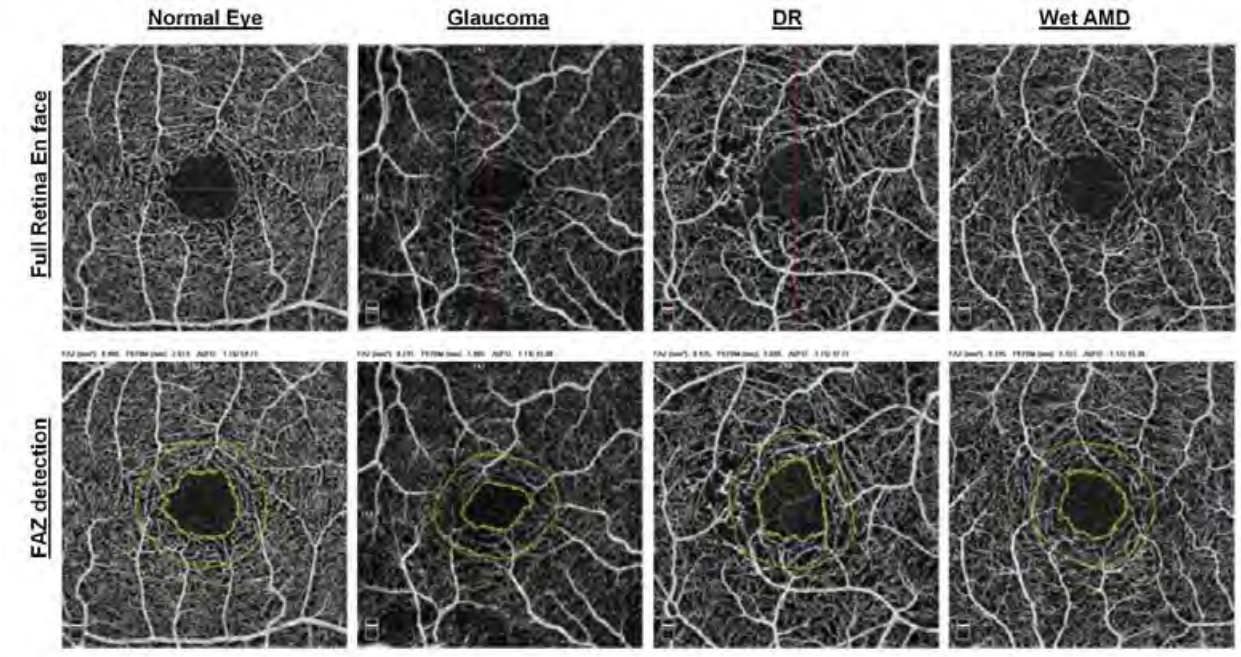


Figure 167 Examples of FAZ Detection based on AngioVue® Retina 3mmx3mm scan.

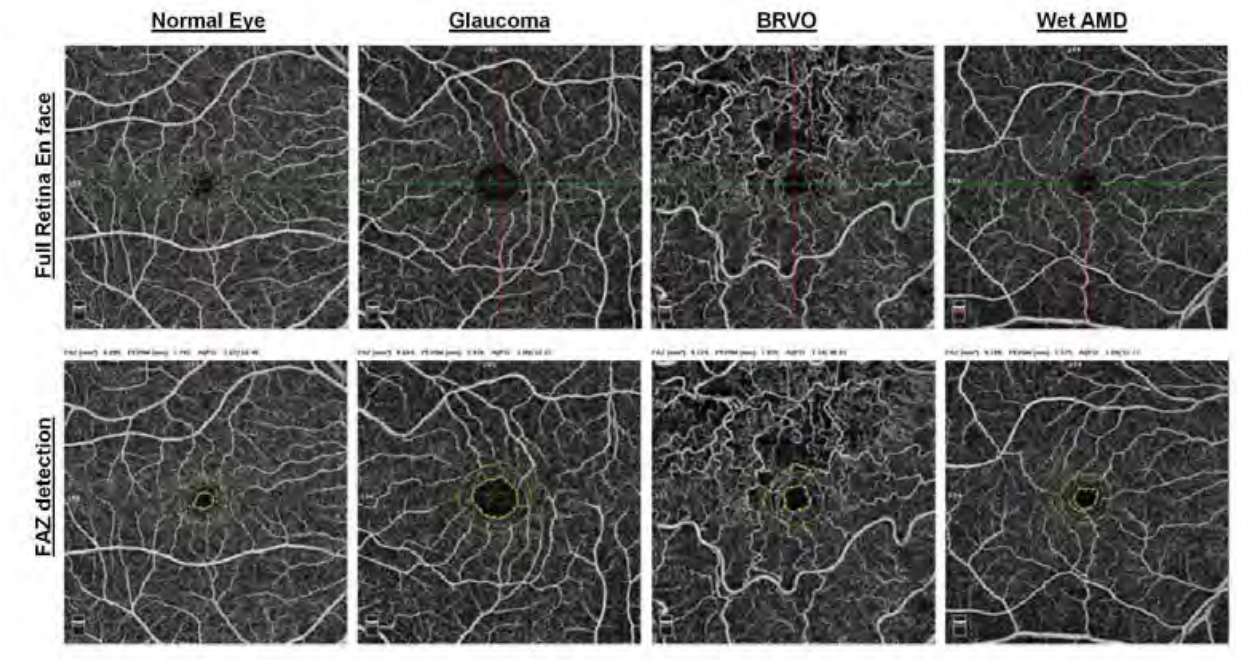


Figure 168 Examples of FAZ Detection based on AngioVue® Retina 6mmx6mm scan.

7.2.13.1 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

7.2.13.2 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 form 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.

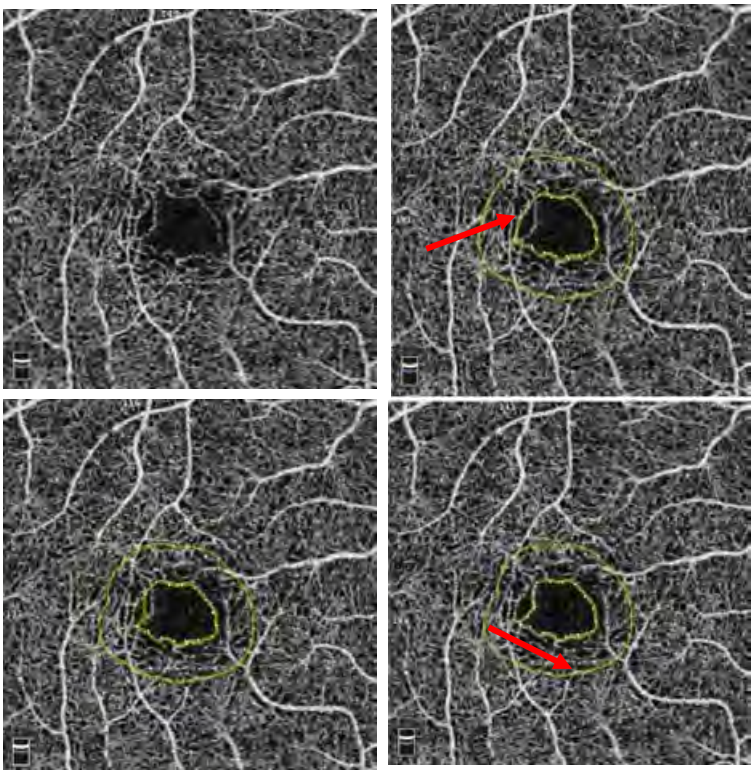


Figure 169 FAZ Editing

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.

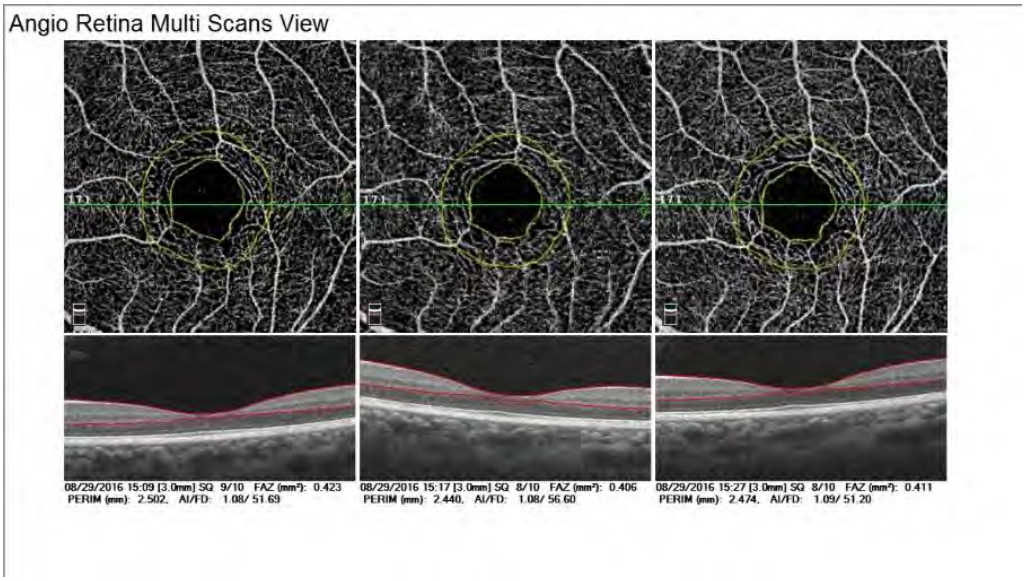
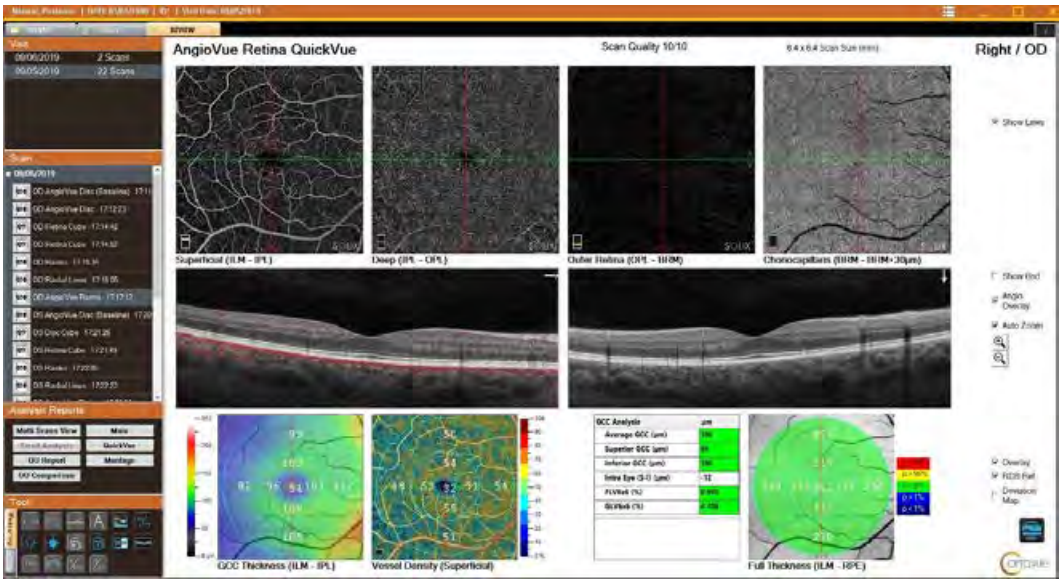


Figure 170 FAZ Multi Scan Report

7.2.14 AngioVue® Retina 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.

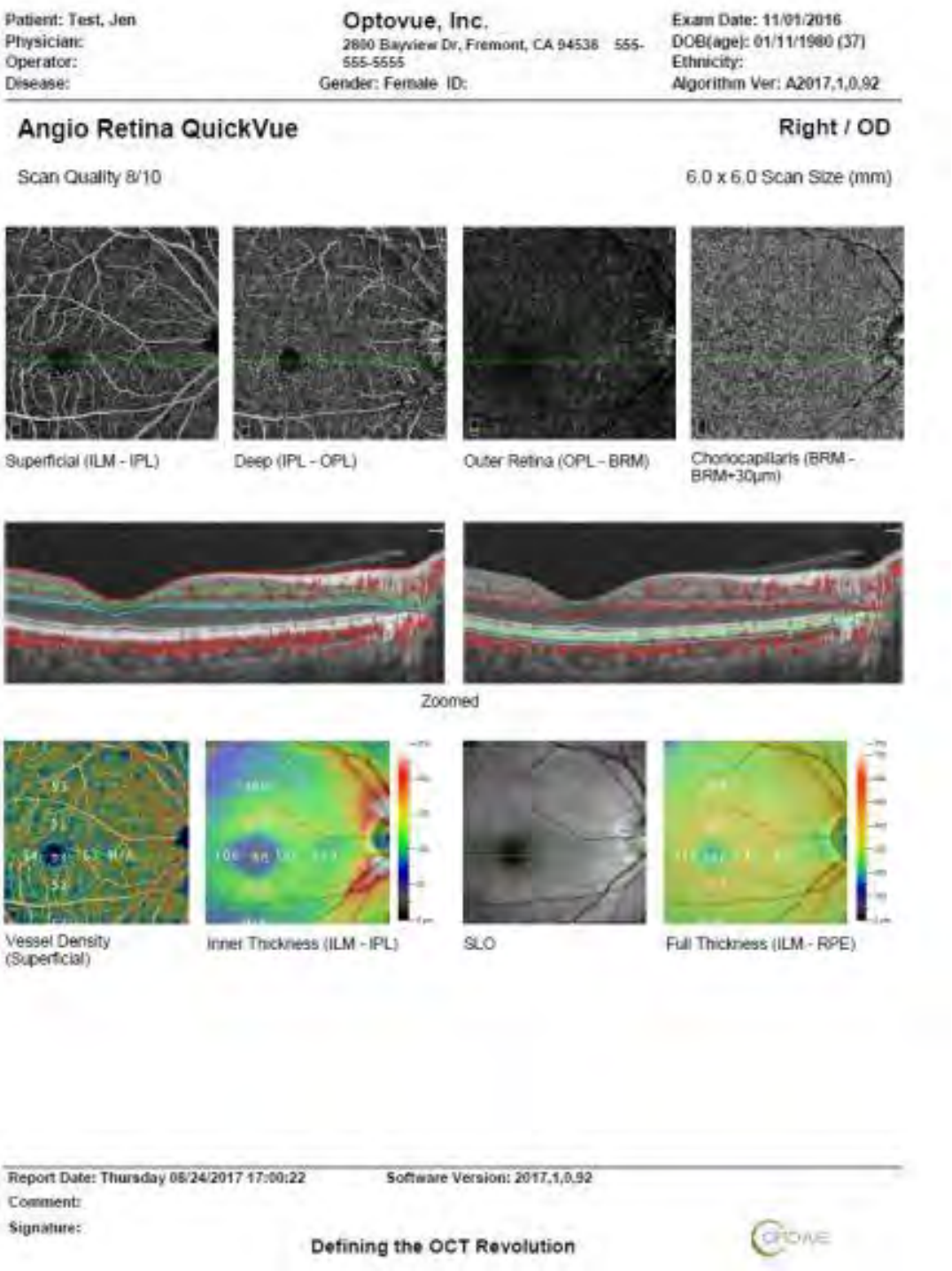


Figure 171 AngioVue Retina QuickVue Portrait

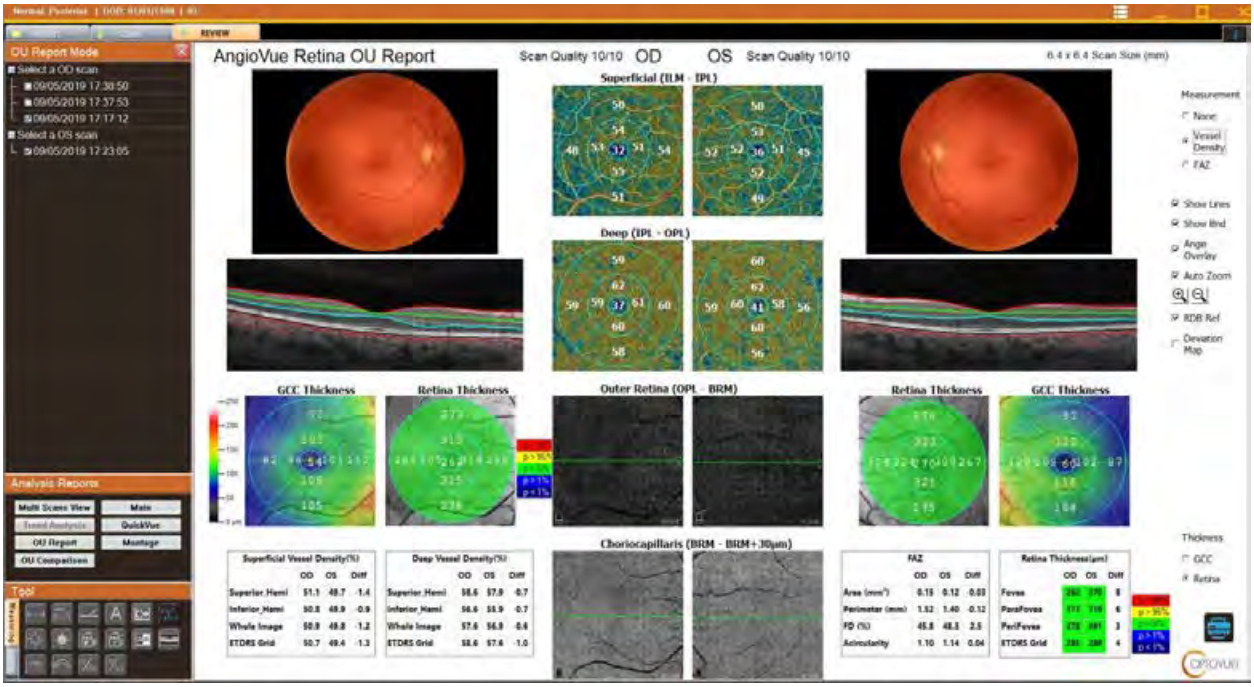


Figure 172 AngioVue Retina OU report

7.2.15 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.

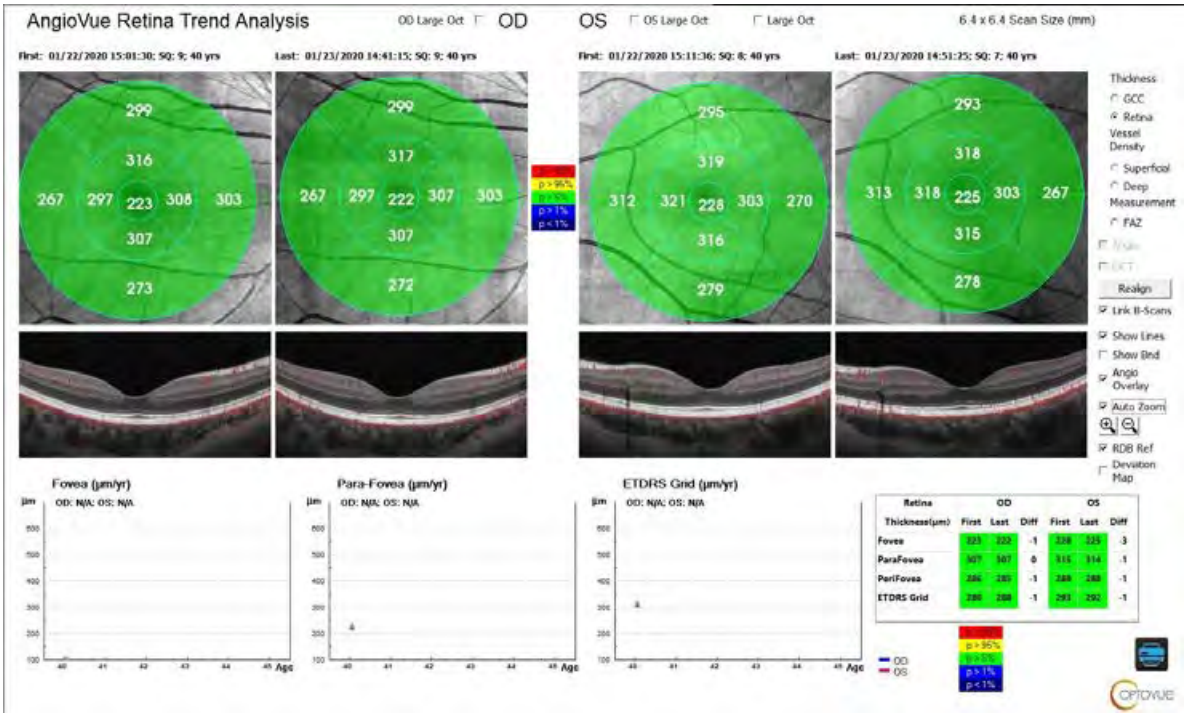


Figure 173 AngioVue® Retina Trend Report, Retina thickness, RDB selected.

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.

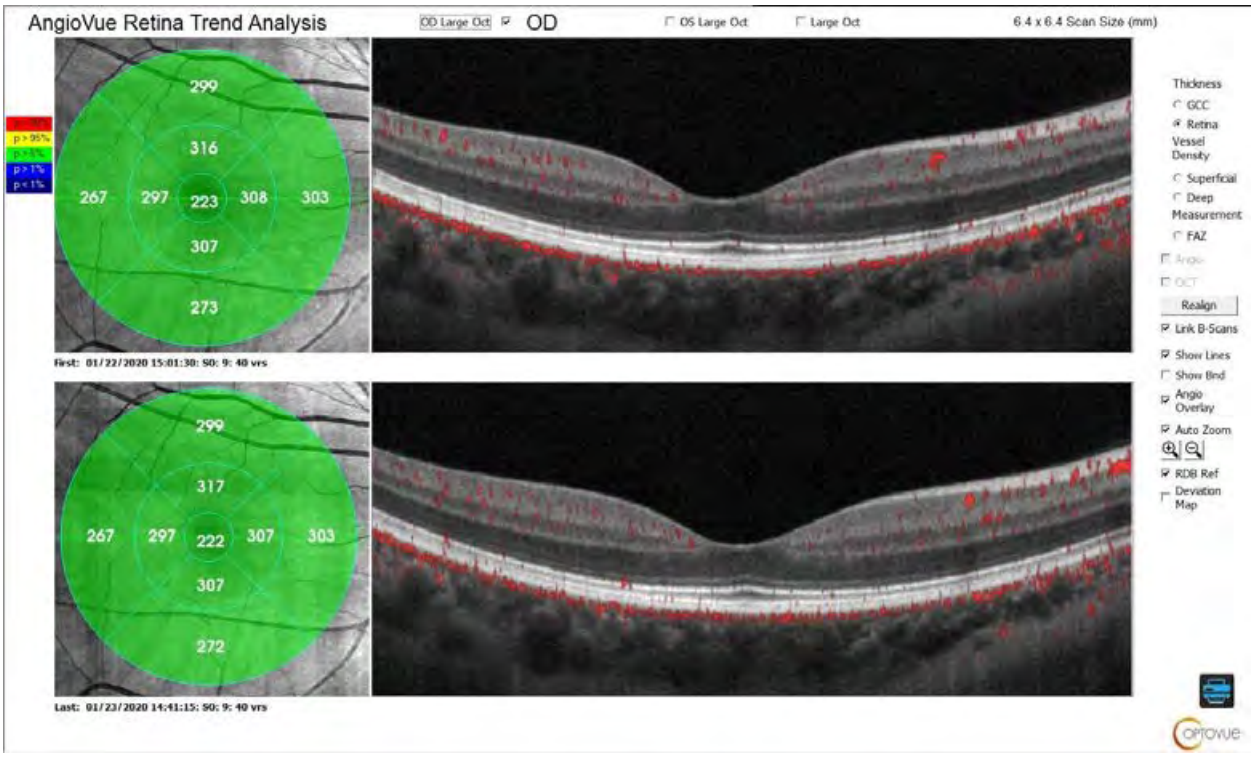


Figure 174 AngioVue Retina Trend Analysis – Aligned 2 scan Comparison

7.2.15.1 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.

7.2.16 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 (mm^2).

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

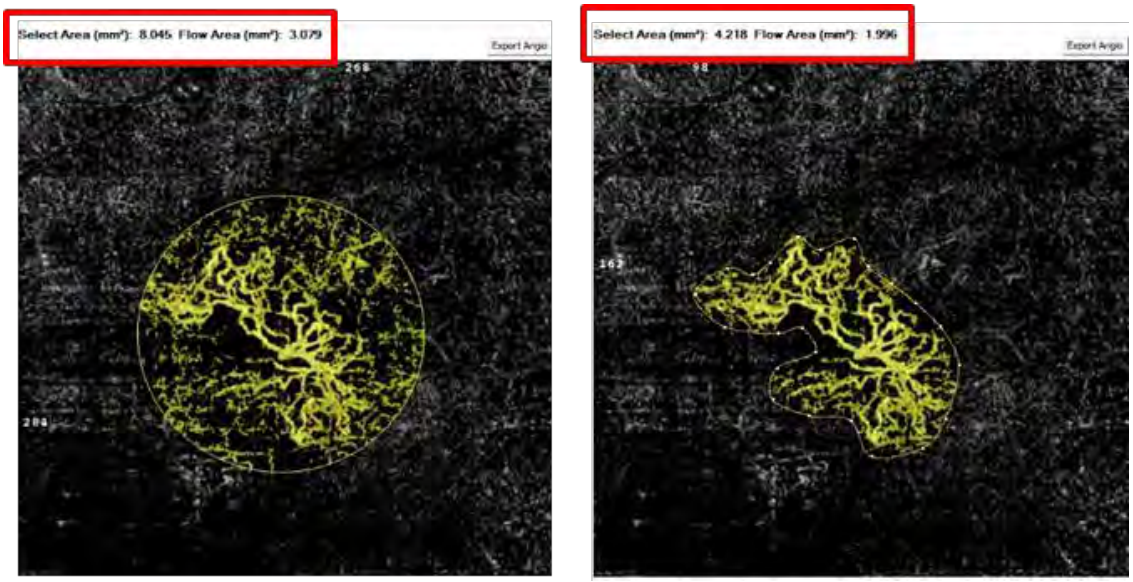


Figure 175 Flow

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

7.2.16.1 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

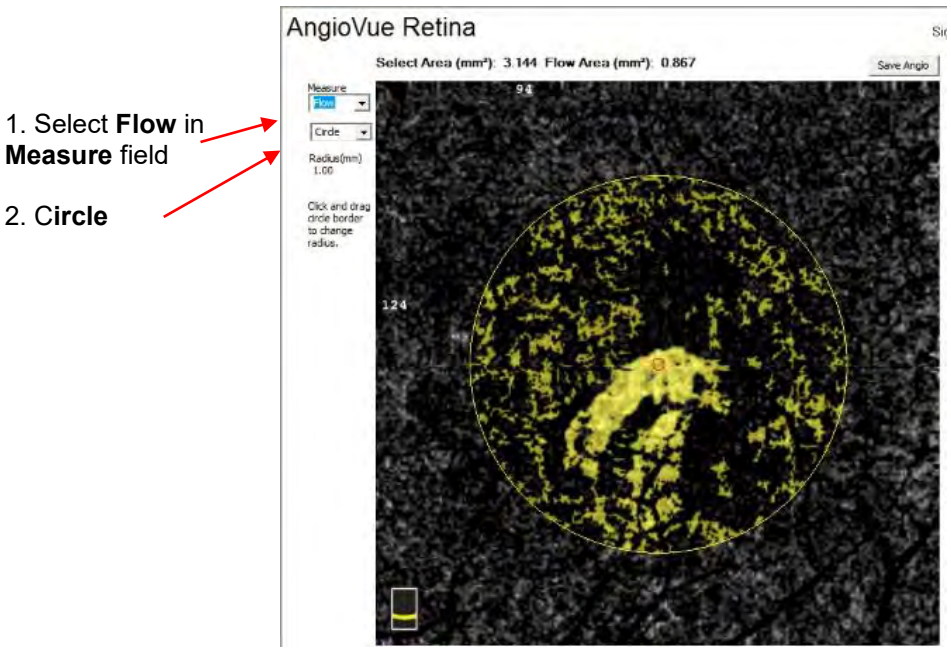


Figure 176 Circle Flow

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.

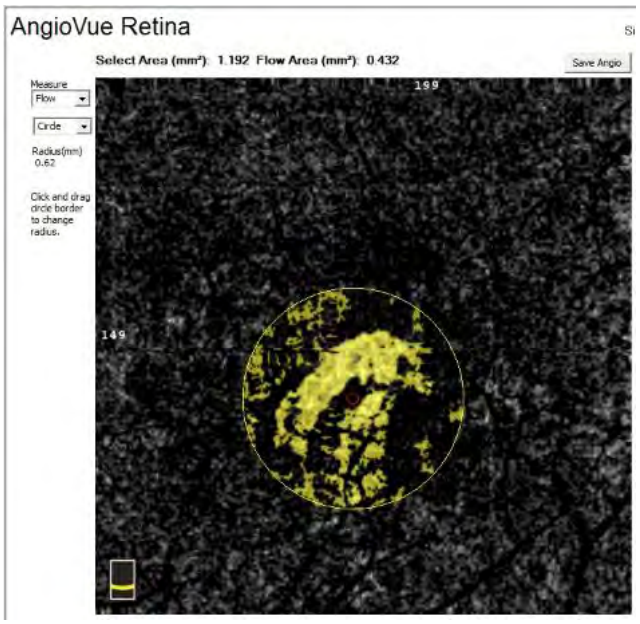


Figure 177 Circle Flow, Moved and Reduced

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.

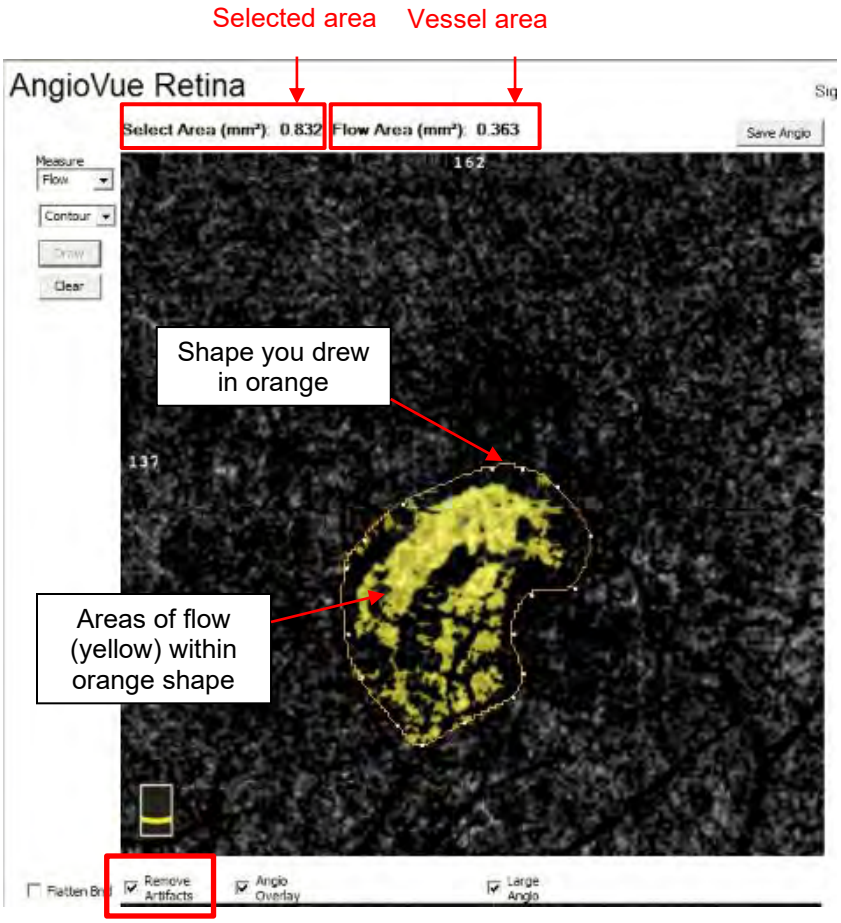
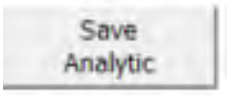


Figure 178 Contour Area of Flow Highlighted Yellow and Measured

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 mm^2) 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 179 AngioVue® Retina Multi scan Report, Outer Retina Slab and Flow Selection

7.2.17 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.

7.2.17.1 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.

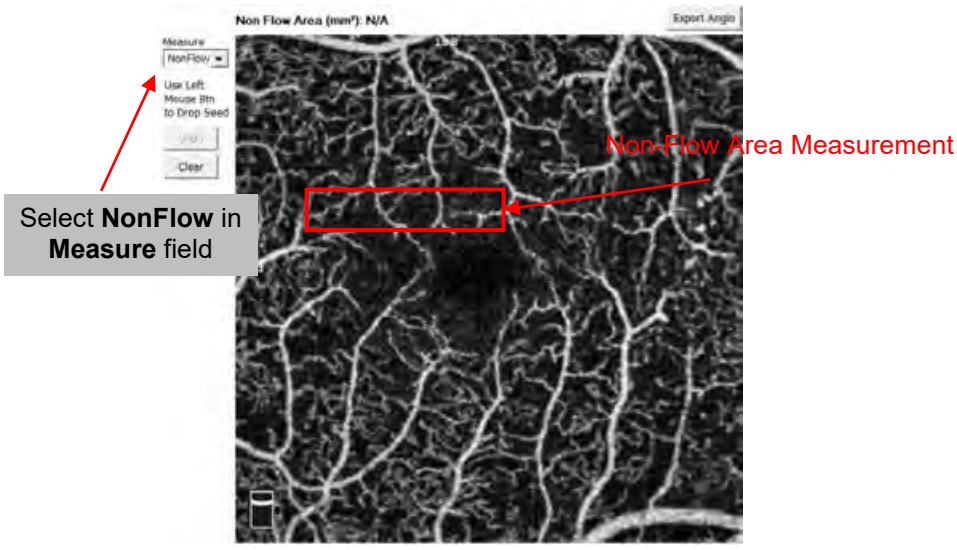


Figure 180 Select NonFlow in Measurement Window

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.

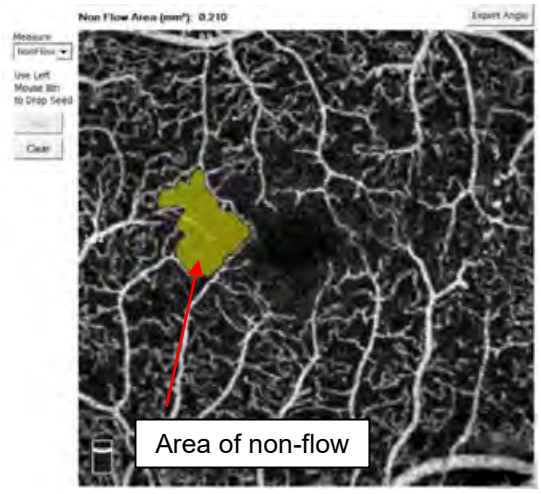


Figure 181 Area of Non-Flow Highlighted Yellow and Measured

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.

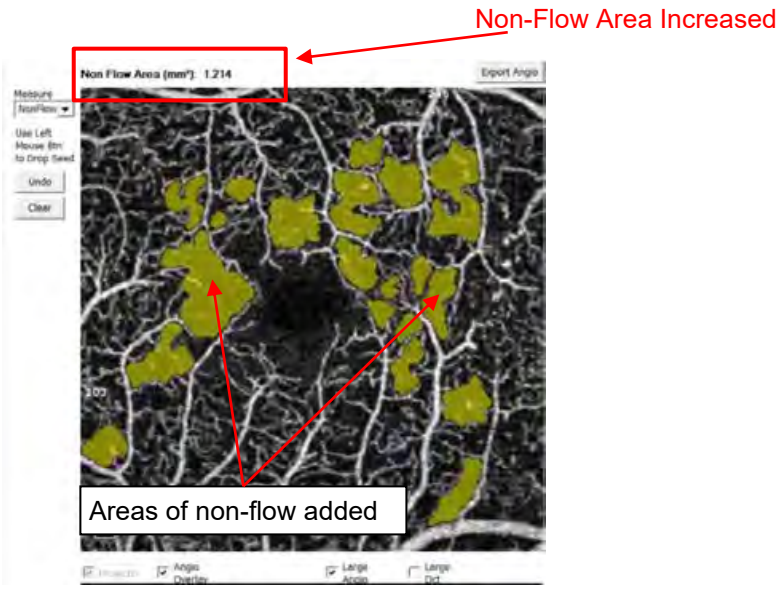
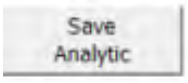


Figure 182 Additional Non-Flow Areas Selected and Measured



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.

7.2.18 **Information Display for Saved Analytics Result**

The Review Scan list shall display information regarding saved Analytics results

F = Flow measurement

NF = Non Flow Measurement

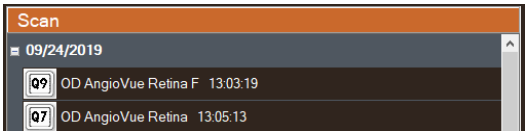


Figure 183 Flow and Non Flow Indicators on the Scan List

7.2.19 **AngioVue® 12x12**

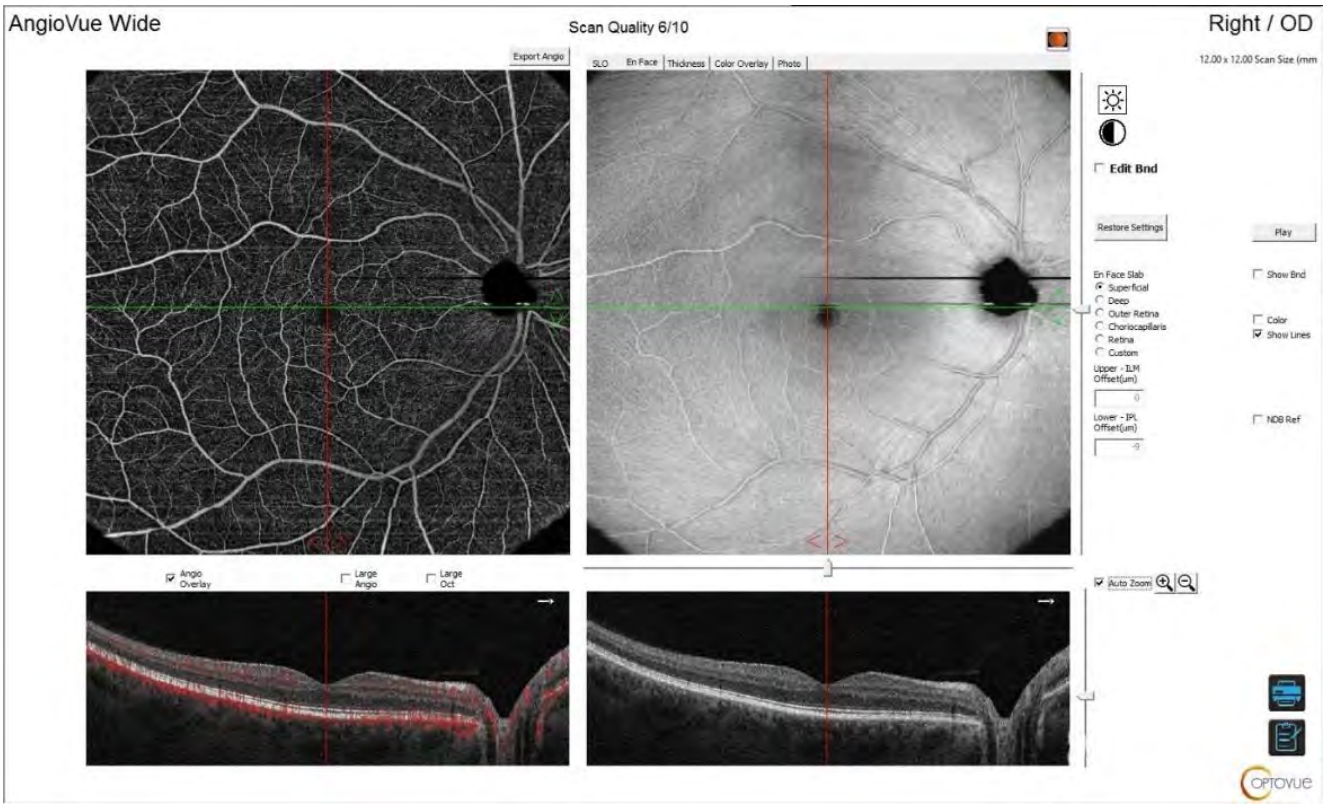


Figure 184 AngioVue® Wide 12x12

7.2.20 **AngioVue® 12x12 OU**

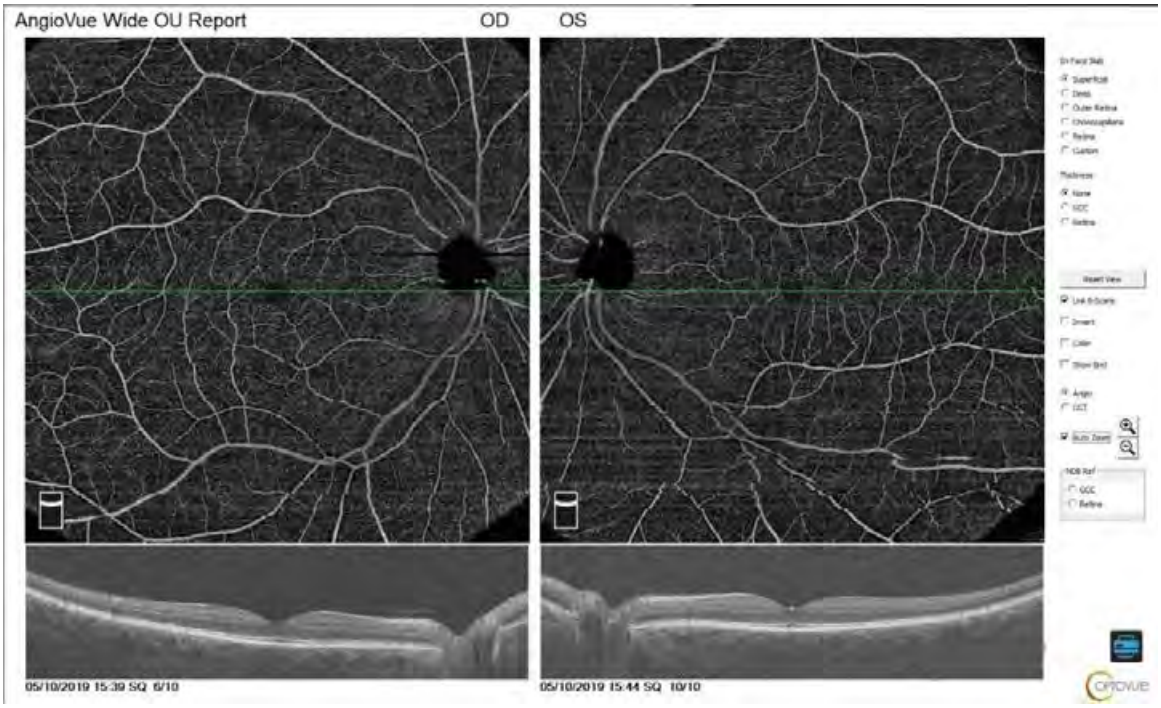


Figure 185 AngioVue® Wide 12x12 OU

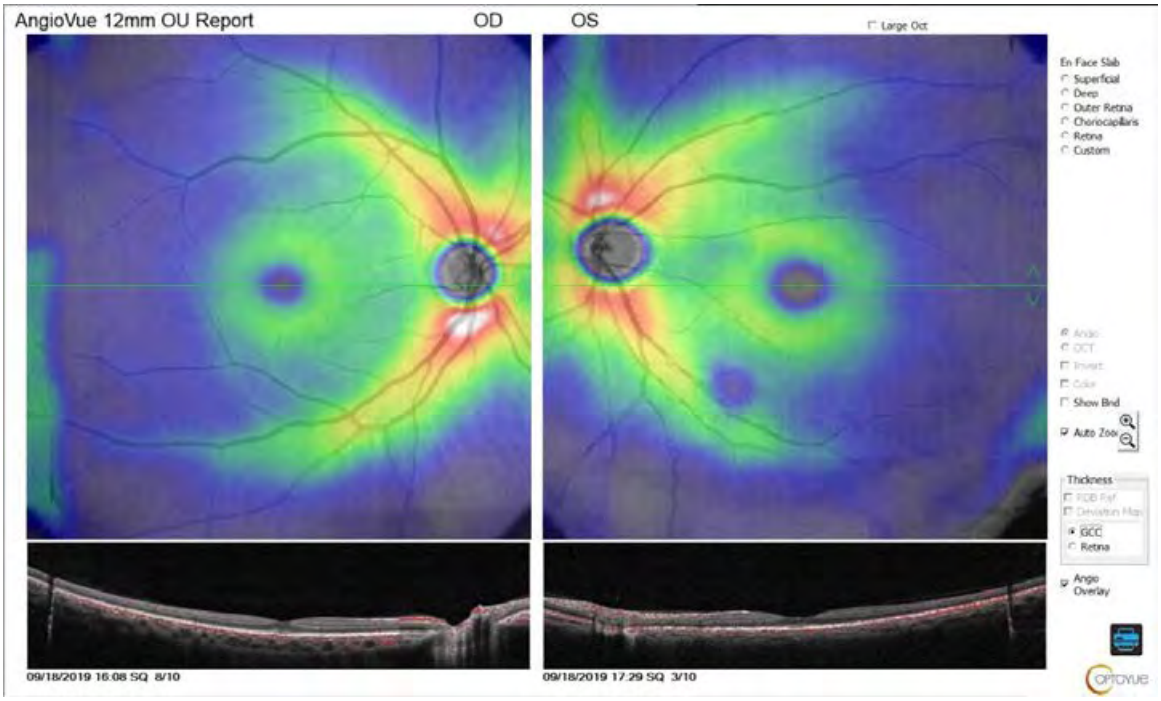


Figure 186 AngioVue 12x12 OU showing GCC Thickness

7.3 AngioVue® Disc Analytics

AngioVue® Disc enables the measurement of RPC density and structural thickness values of RNFL for 4.5 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 25~4.5 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 (mm^2)
- ✓ Disc Area (mm^2)
- ✓ Cup Area (mm^2)
- ✓ Cup Volume (mm^3)

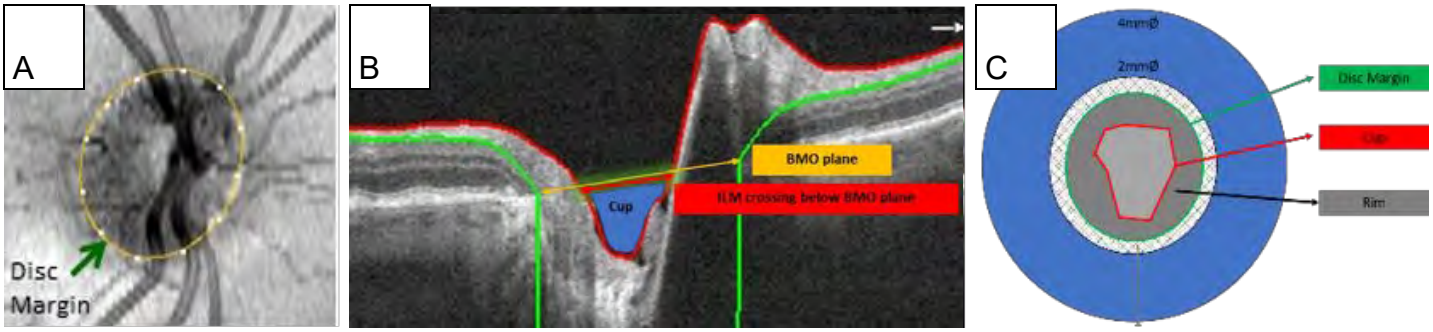


Figure 187 Disc Parameters

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 within the BMO plane: the portion above the BMO 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.

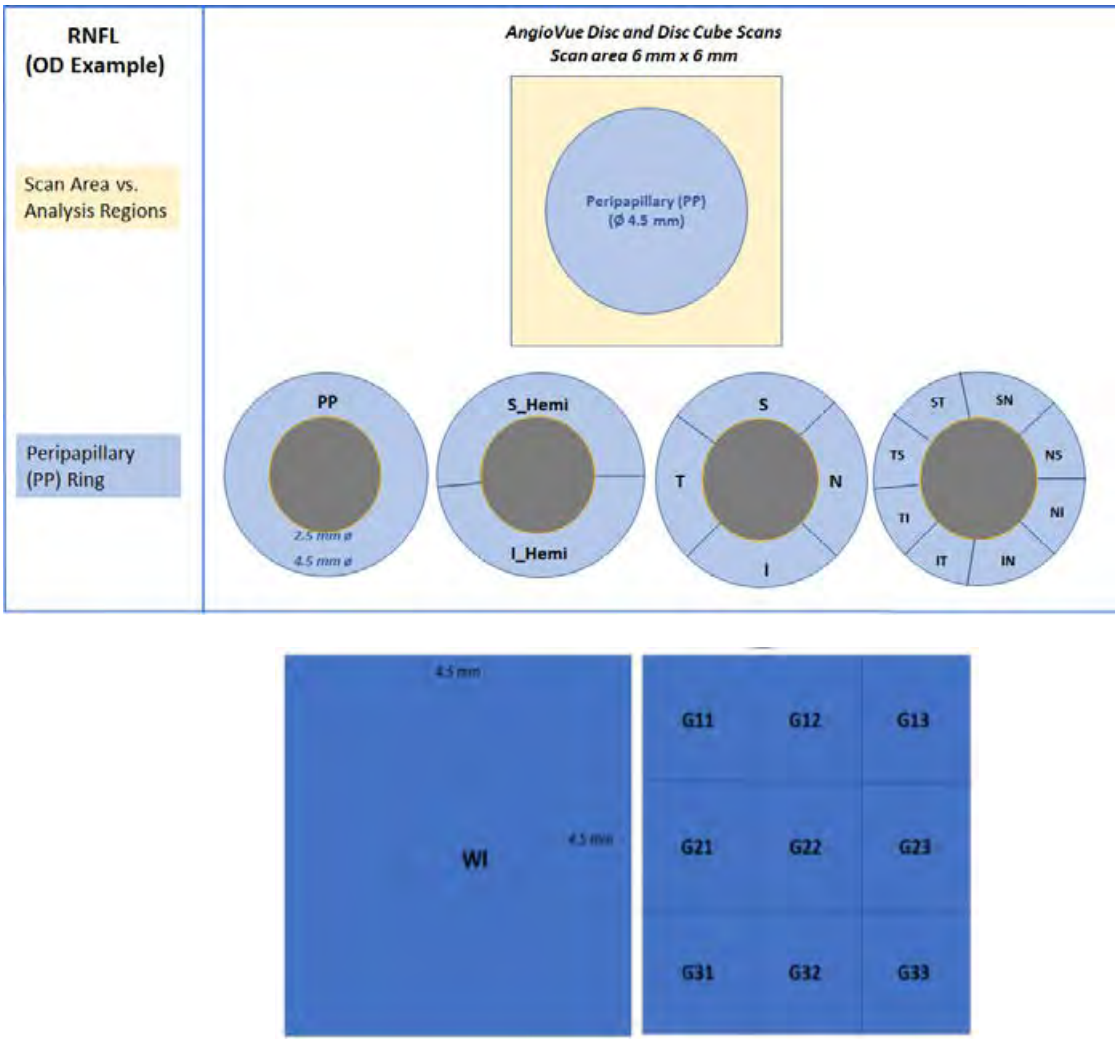


Figure 188 AngioVue® Disc Measurement Zones and Parameters

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 (2-4) grid. Middle - Superior and Inferior Hemi-sectors. Right – Disc and 8 equal sectors. Disc – inside disc (grey area outlined by the yellow boundary) 2mm 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 2mm and 4mm diameter, centered on the center of the optic disc, as determined by BMO fitted circle. The modified grid aims to follow RNFL distribution and sectored to provide easier correlation with visual field testing.

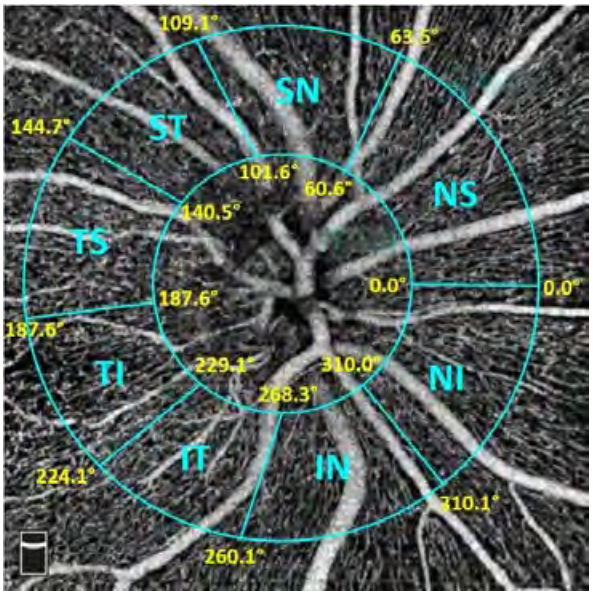


Figure 189 Eight Sector Peripapillary Grid

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.

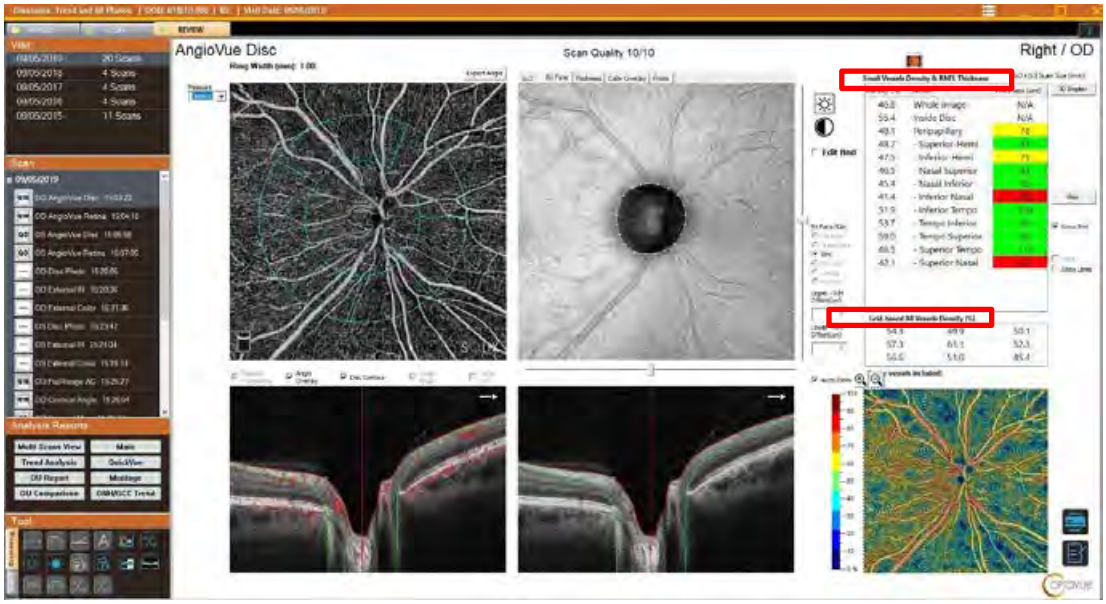


Figure 190 AngioVue® Disc, Main Report with En Face Tab and Density Selected

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 2mm to 4mm 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.

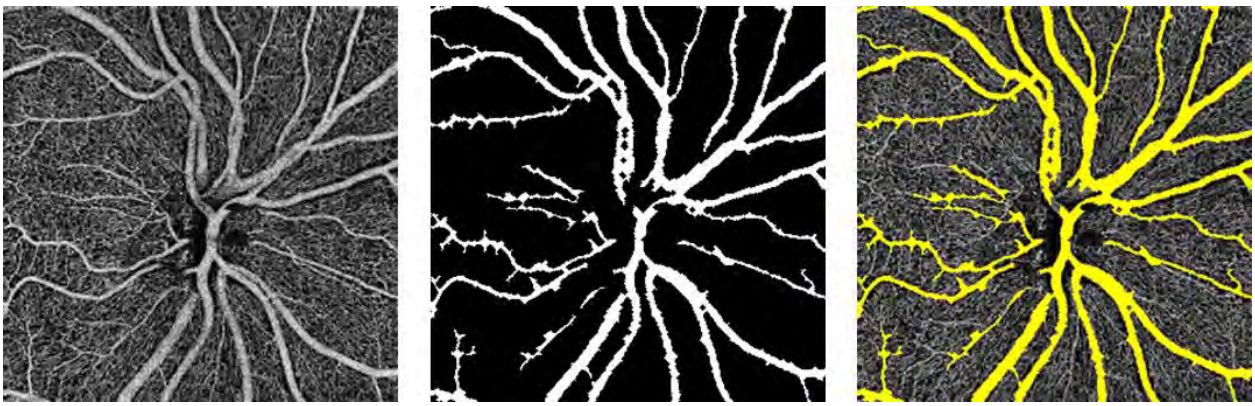


Figure 191 Large Vessels Mask

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 ≥ 35µm 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.

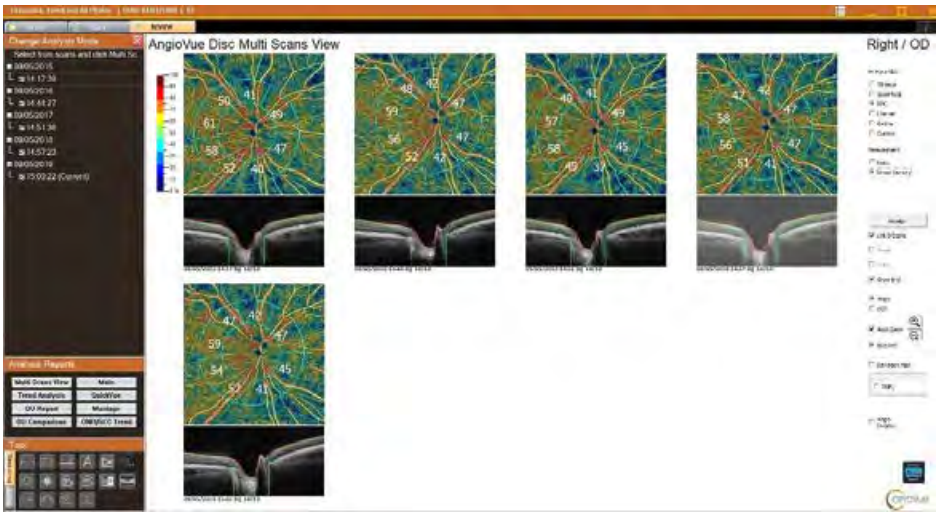


Figure 192 AngioVue® Disc Multi Scan Report

RNFL Thickness is available on Main, QuickVue and Trend reports

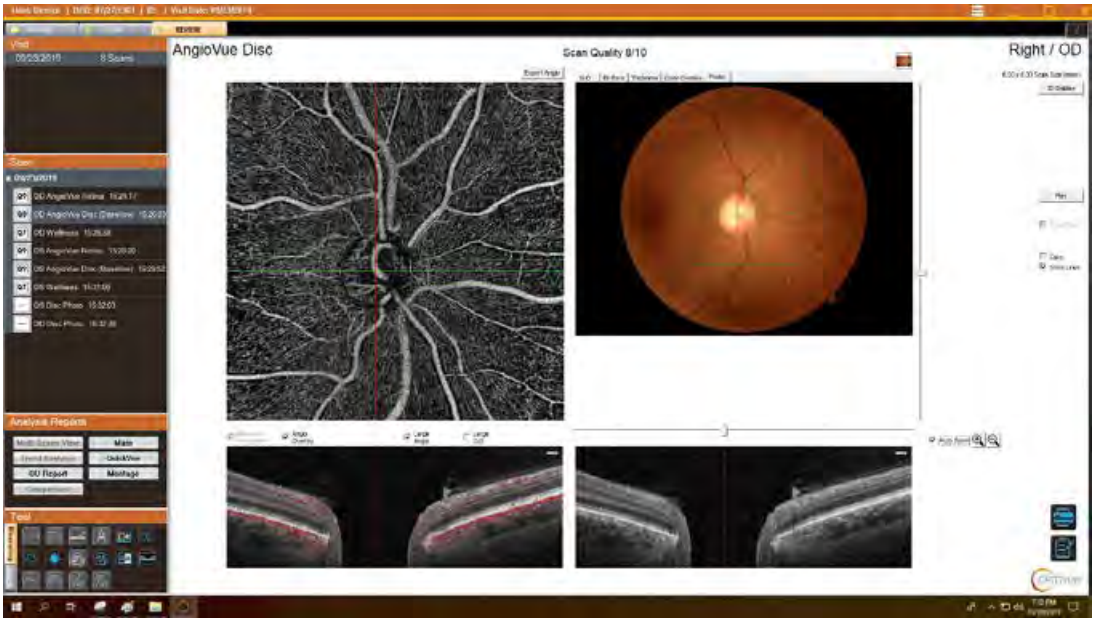


Figure 193 AngioVue® Disc Main Report, Photo Tab Selected

7.3.5 AngioVue® Disc QuickVue Report

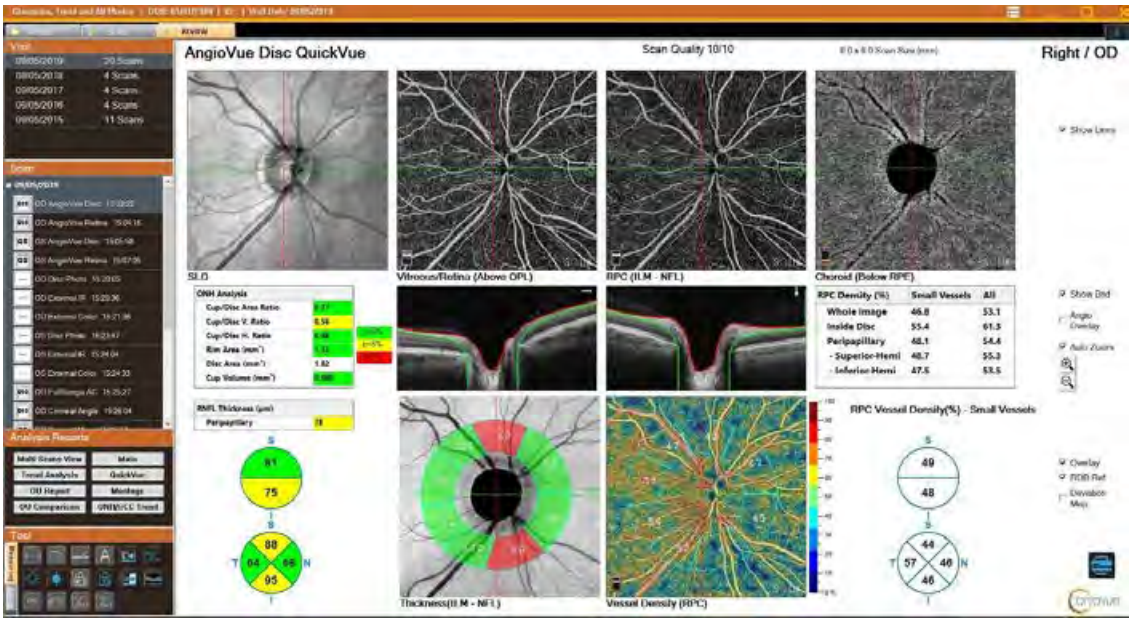


Figure 194 AngioVue® Disc QuickVue Report

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.

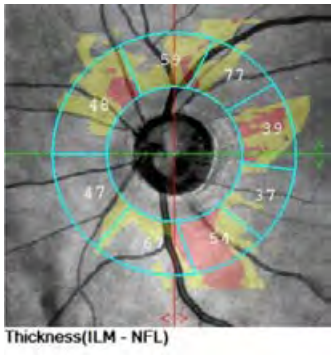


Figure 195, Deviation Map

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.

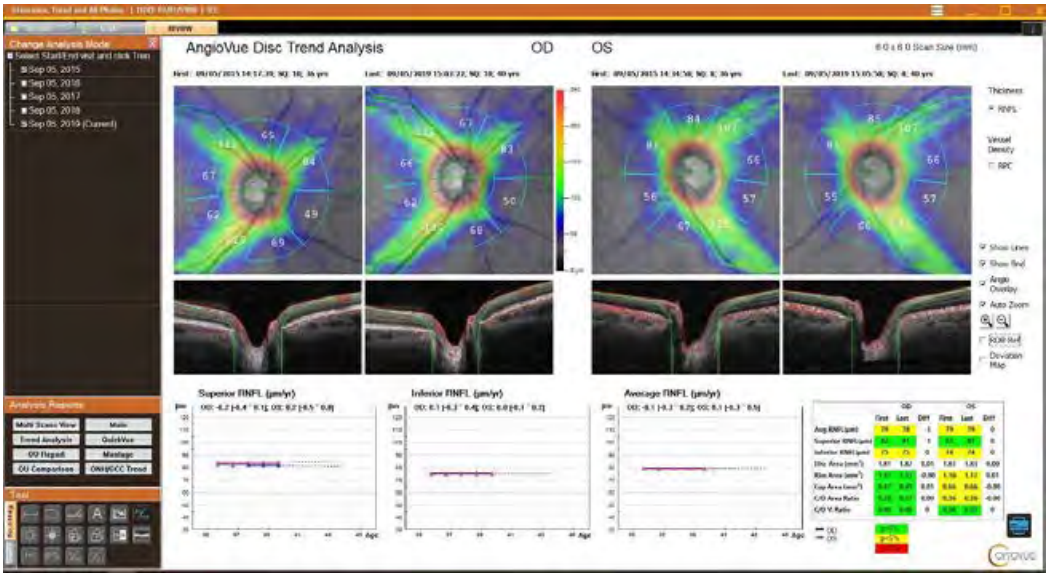


Figure 196 AngioVue® Disc Trend Report

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

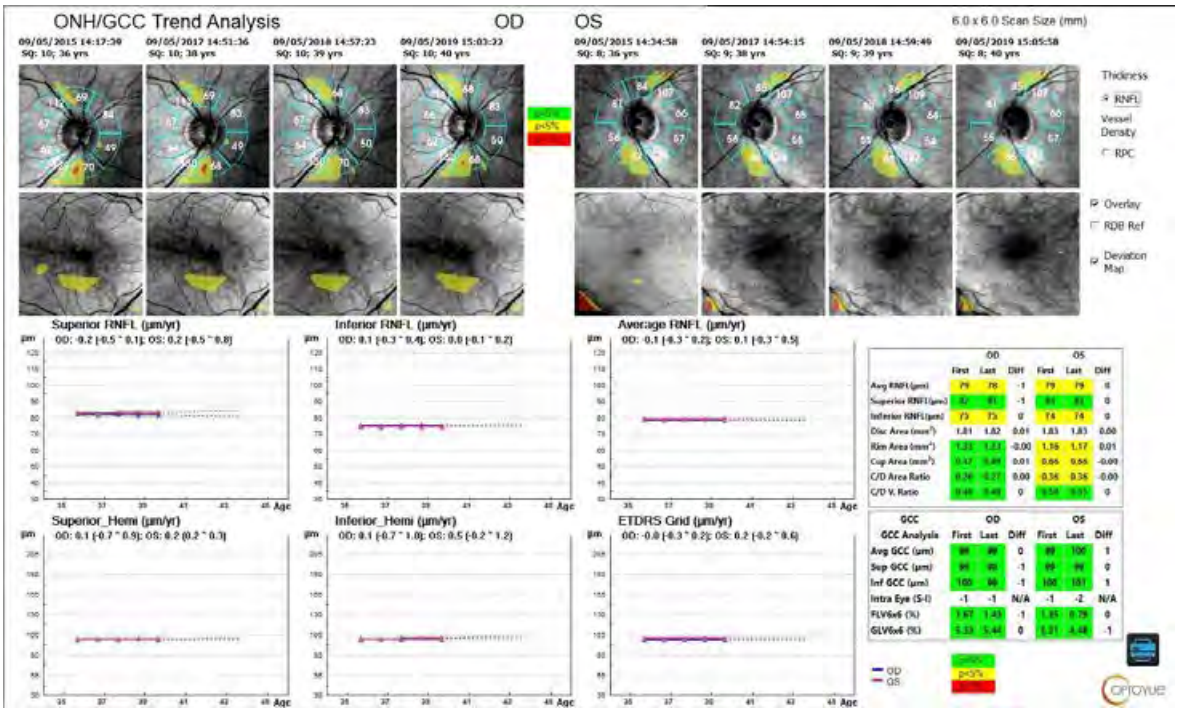


Figure 197 ONH/GCC OU Trend report showing RNFL and GCC Deviation maps

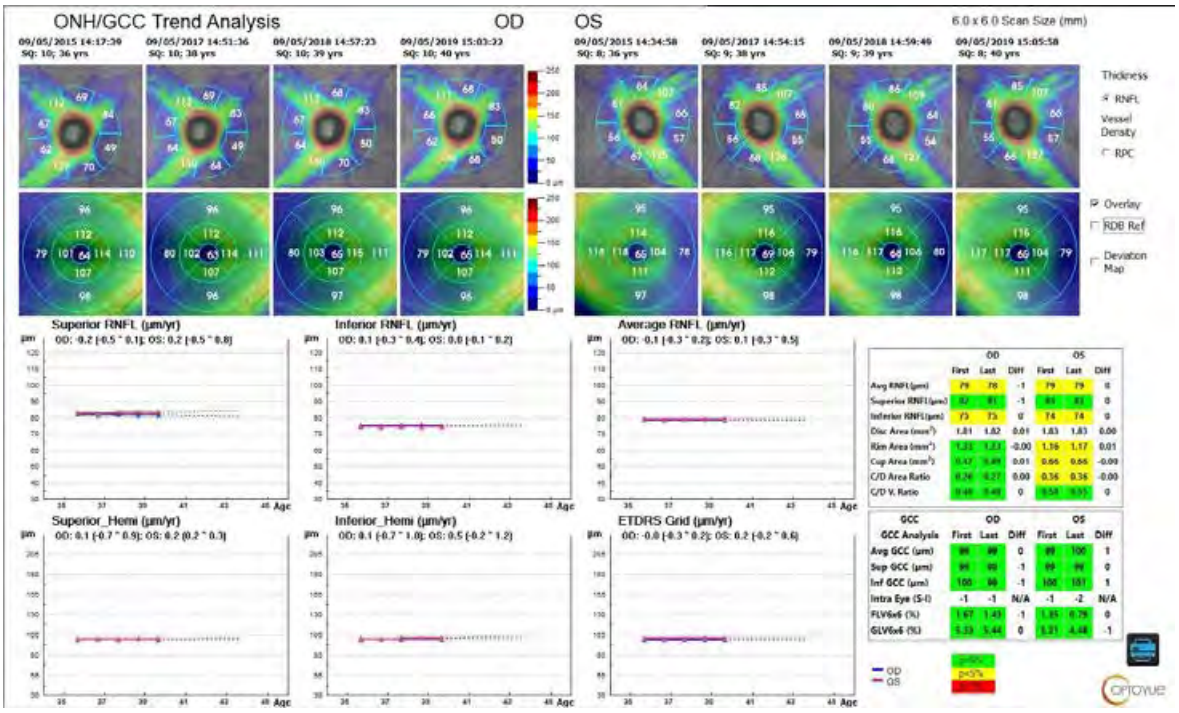


Figure 198 ONH/GCC OU Trend thickness

_____End of section_____

8 Cornea Anterior Module (CAM 16mm, 18mm)

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 both CAM lenses 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 2 auxiliary lens adapters, the16mm Pachymetry, indicated for *in vivo* imaging and measurement of the cornea and other ocular structures of the anterior segment of the eye, including pachymetry and the FullRange 18mm for visualization of the Anterior chamber.

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

8.2 Instrument Description

The SOLIX™ /CAM system is comprised of the system and two CAM options (cornea lens adapter 16mm & 18mm) for use in imaging the cornea and anterior chamber of the eye.

The lens adapters are attached and removed by a trained operator.

8.3 Getting Started

8.3.1 Mounting the Lens Adapters

The lens has a magnet mount system.

☞ **Note: The working distance between both lens adapters and cornea is 20 mm on the CAM model.**

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.)

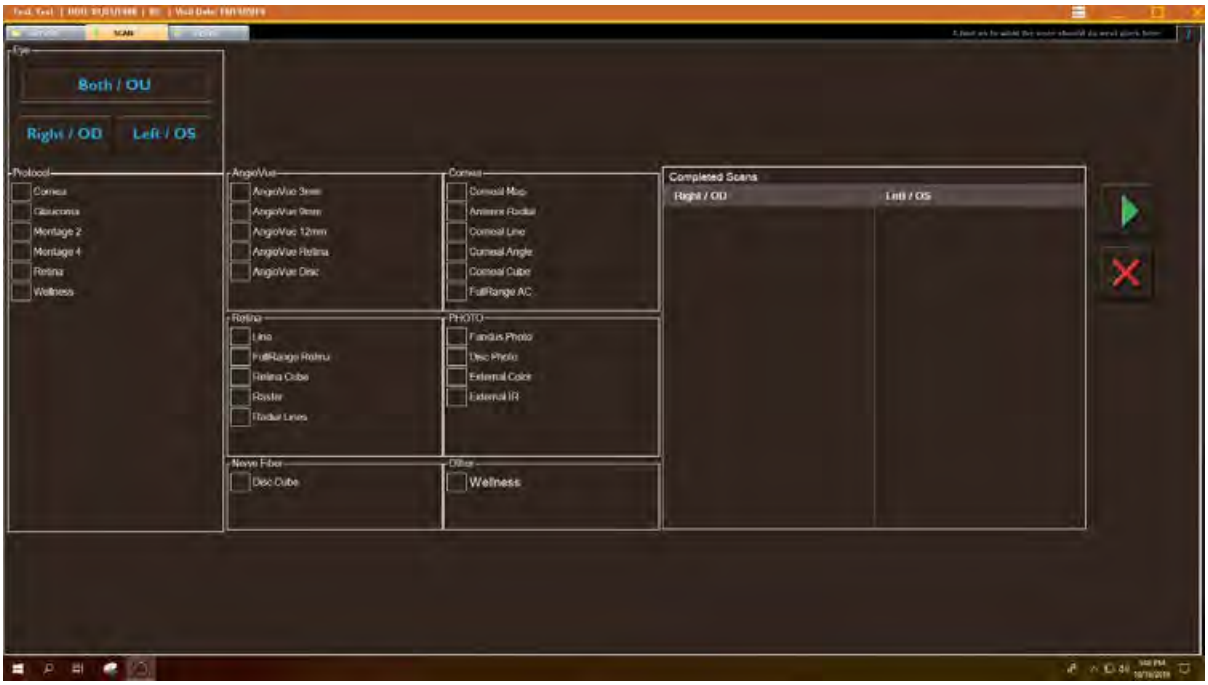


Figure 199 Scan pattern selection

8.4.2 Scan Acquisition:

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

1. Turn off the exam room light (recommended)
2. Attach the CAM lens
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. For corneal power scan, use an internal fixation target
5. Operator should center the scan on the pupil. If the misalignment exceeds 1 mm (pupil center exceeds the boundary of the smallest alignment circle), the scan should be excluded.

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**

OCT scan window: Place the cornea B-scan image in between the two red guidelines to optimize the cornea scan images. Pachymetry, has two OCT windows, one for vertical b- scan, and one for horizontal b- scan.

Figure 200 B scan between red lines

Scan pattern live video window-alignment will depend on scan type chosen.

Pachymetry scan: Align the aiming circle (inner circle is 4mm diameter and outer circle is 6mm diameter) to the center of the pupil.

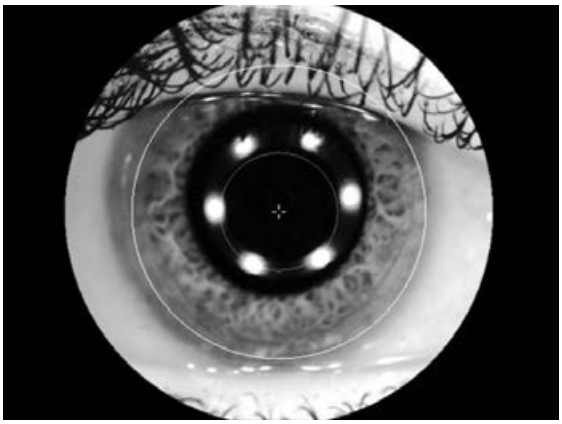


Figure 201 Iris image

Lines,: these scans are centered on the pupil or particular area of interest.

8.4.4 **AC FullRange**

AC FullRange capture follows the same steps as other anterior scans,

- Attach CAM 18mm lens
- center on the pupil
- push forward until the cornea and Iris are balanced in the OCT window
- click Auto P
- Scan line can be rotated by Clicking on the Iris image and using scroll wheel
- Ask the patient to blink, pause , then capture

Figure 202 AC FullRange Capture

8.4.5 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 relative 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 of 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_____

8.5 Review Menu

8.5.1 Cornea Line

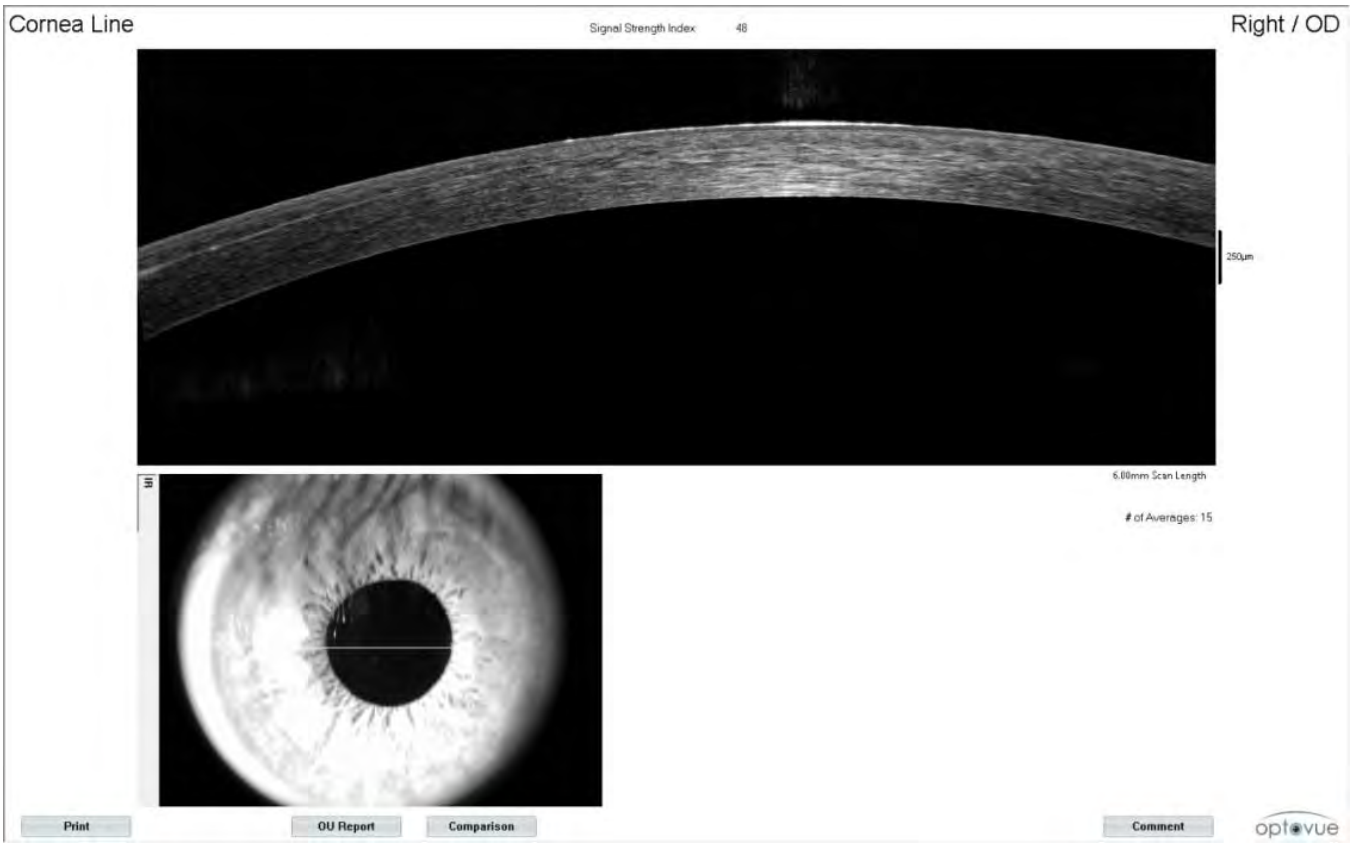


Figure 203 Line scan report

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

8.5.2 AC FullRange 18mm

The scan is 18mm long x 6.25 deep. This line scan is large enough to cover the entire anterior chamber to allow visualization of the anatomy, WTW.

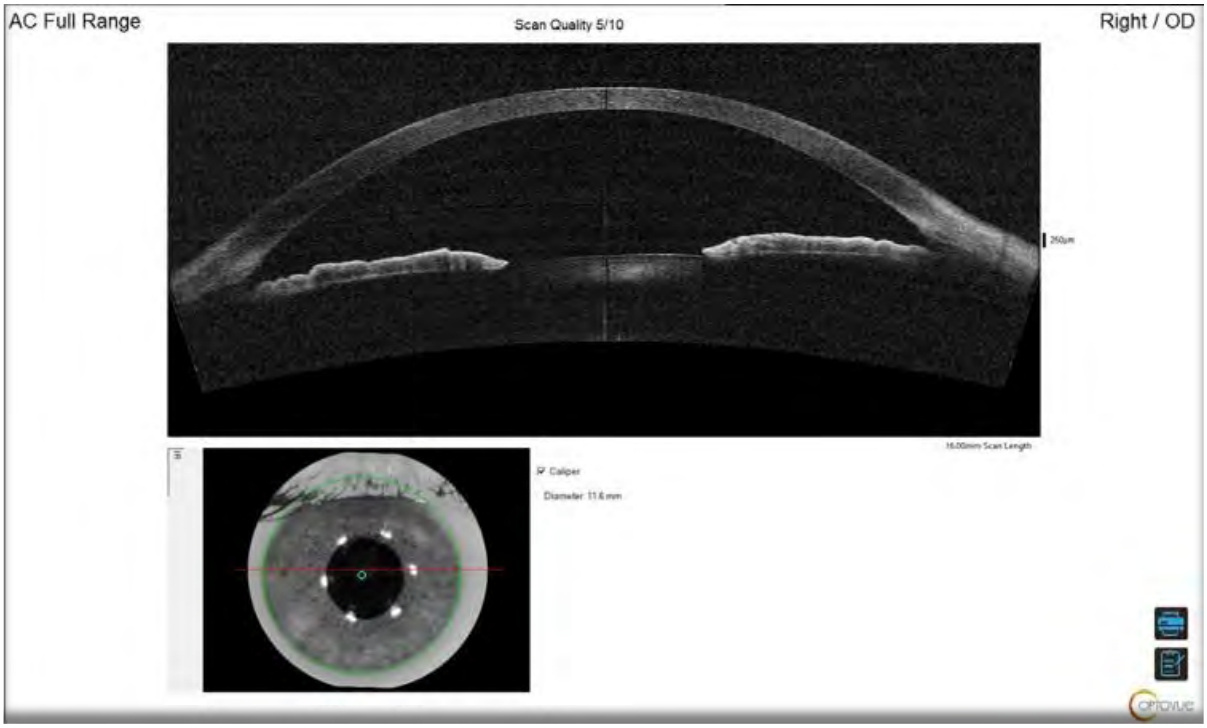


Figure 204 AC FullRange ™ line report with IR image caliper

Center & drag the circle to measure the pupil or iris

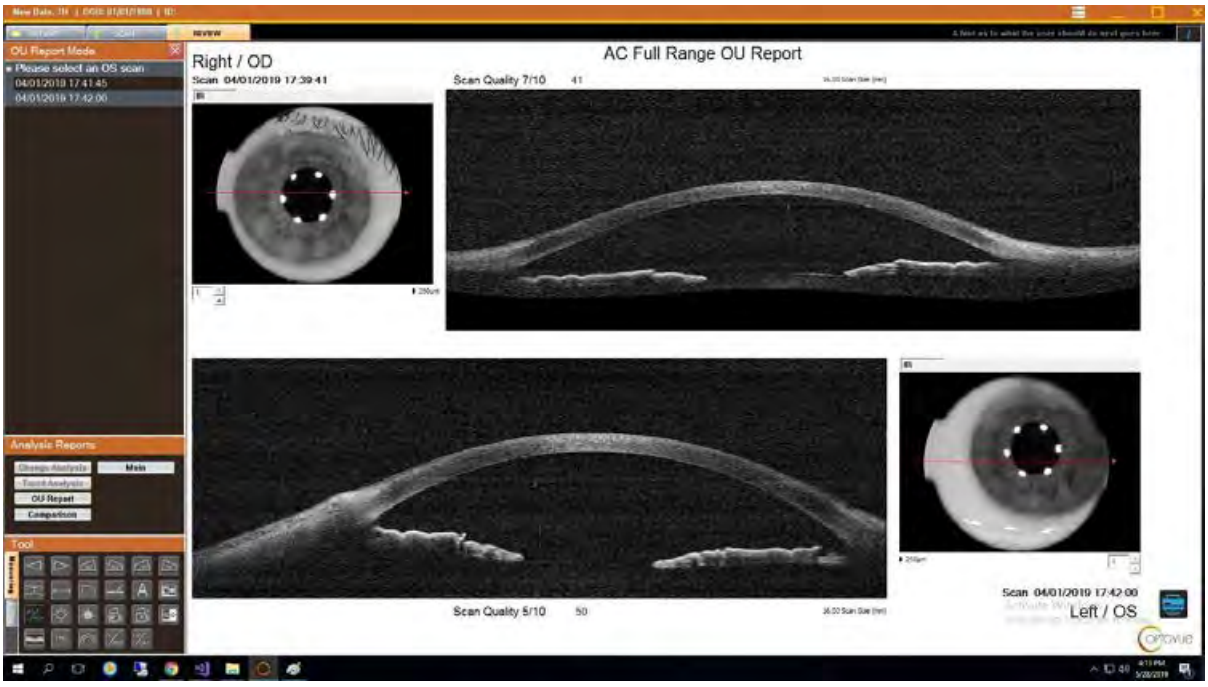


Figure 205 AC FullRange ™ OU

8.5.3 **Anterior Radial 10mm**

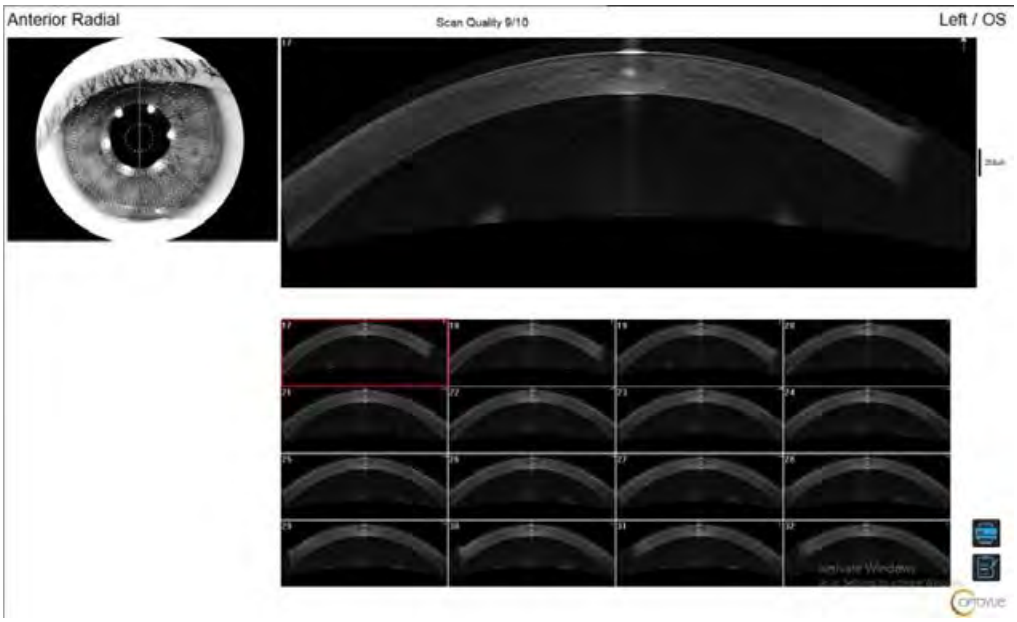


Figure 206 Anterior Radial

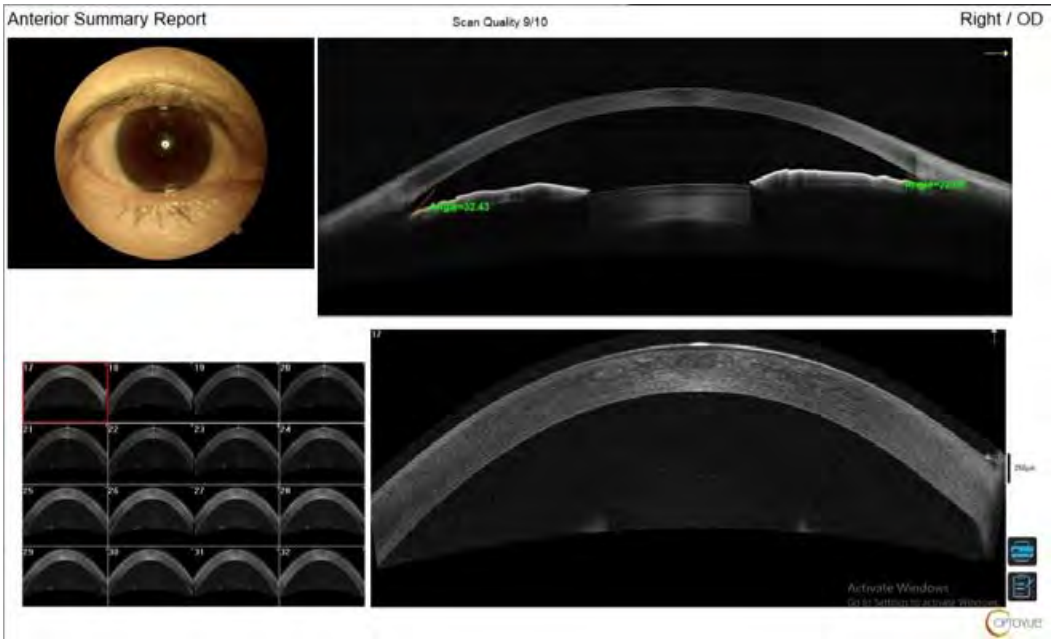


Figure 207 Anterior Summary report

Combination of Ext. Color, FullRange 18mm and Anterior Radial.

8.5.4 **Scan with Thickness Measurement Tool**

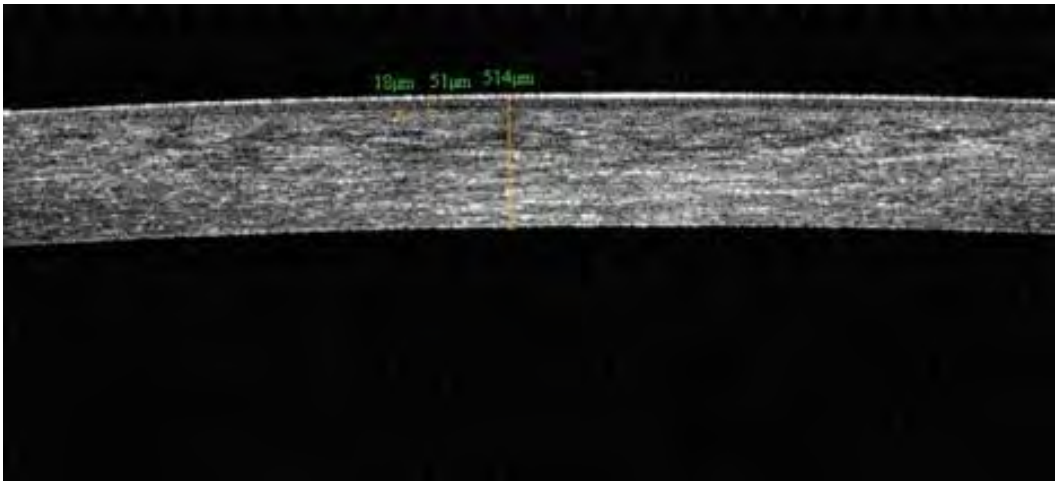


Figure 208 B scan with Measurement tool

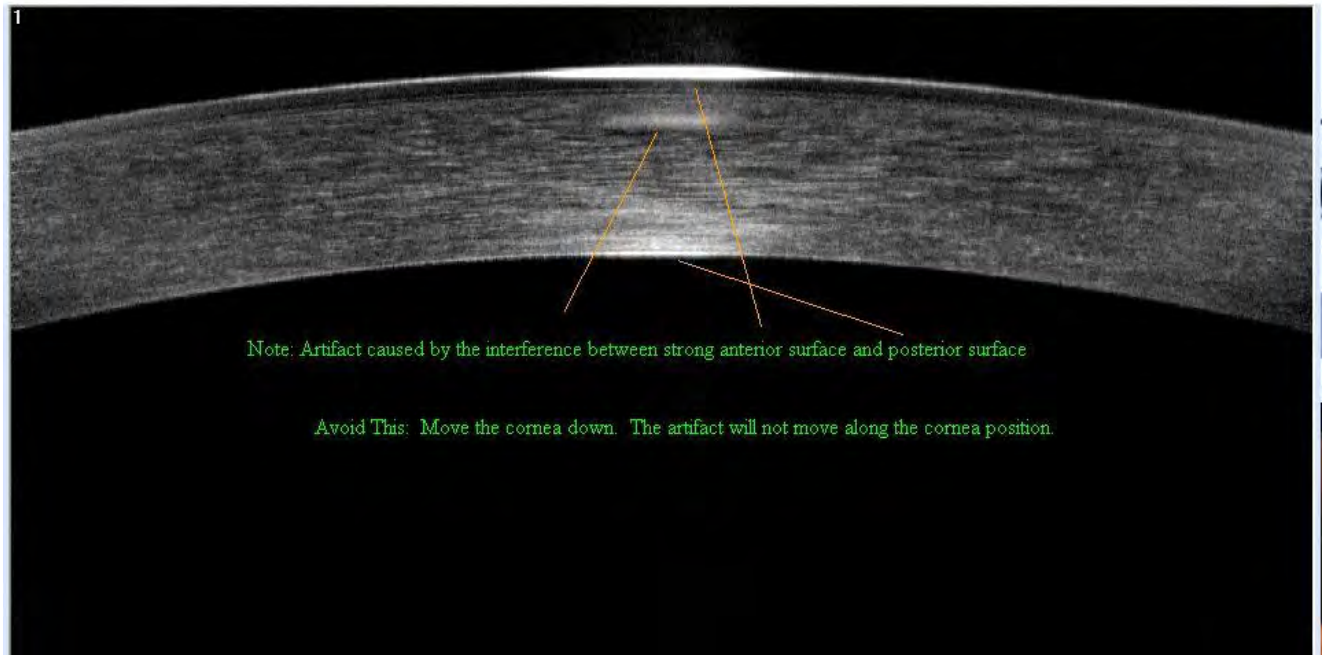
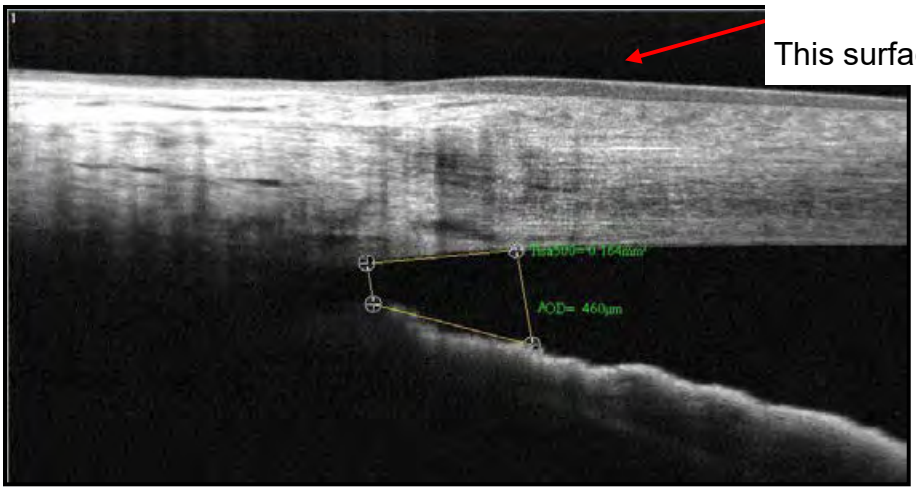


Figure 209 B scan with artifact

☞ 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).

8.5.5 **Angle**

- 

This surface should be parallel or

Figure 210 B scan of angle

8.5.6 **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.

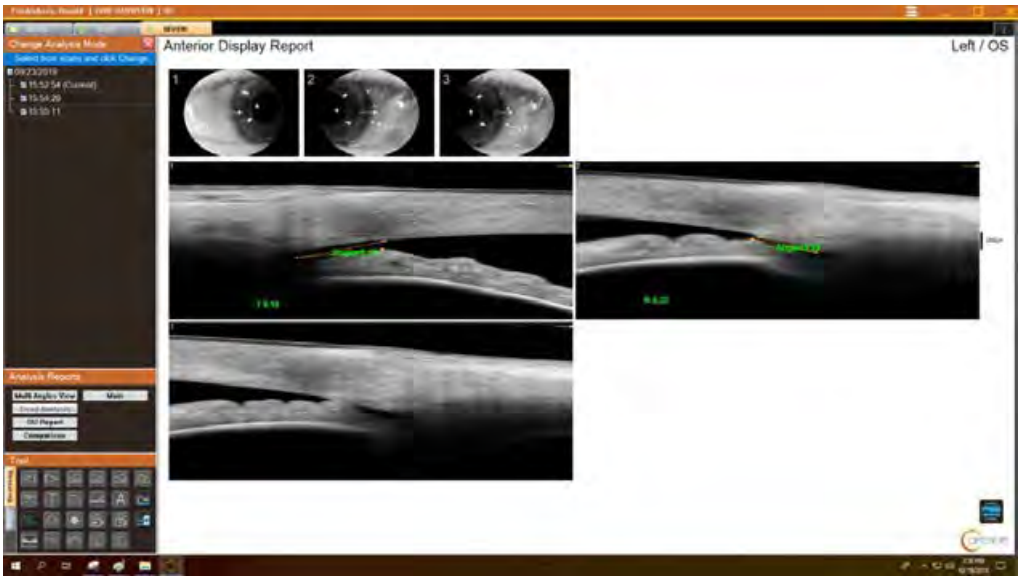


Figure 211 Anterior Display Report showing up to 4 angles

8.5.7 **Cornea 3D**

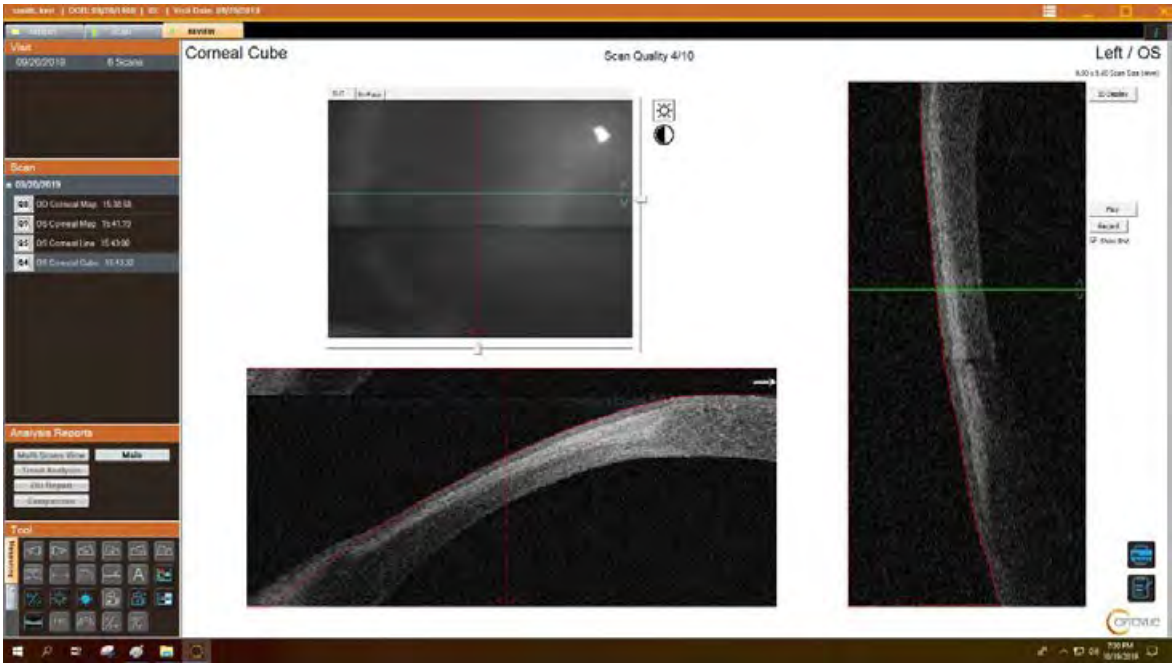


Figure 212 Cornea Cube

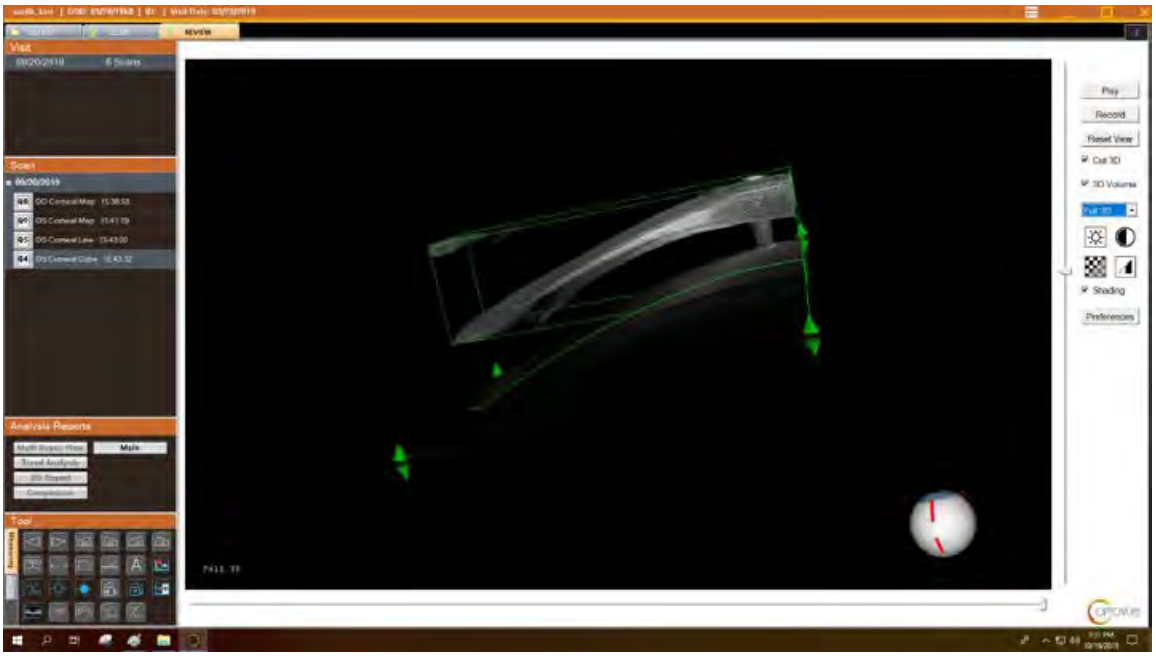


Figure 213 Cornea cube 3D

1.1.3 Corneal Map 10mm

The pachymetry scan is a set of 16 radial meridians 6mm in length and centered on the pupil.

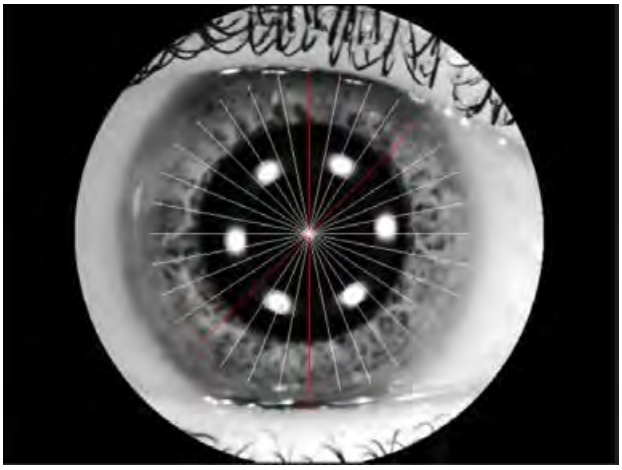


Figure 214 Illustration of Corneal Map scan pattern, 16 meridians, 6mm long

.

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).

8.5.8 **Corneal Map (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

Image Below: Selecting the “Stroma map” will cause the stroma map to replace the epithelial thickness map.

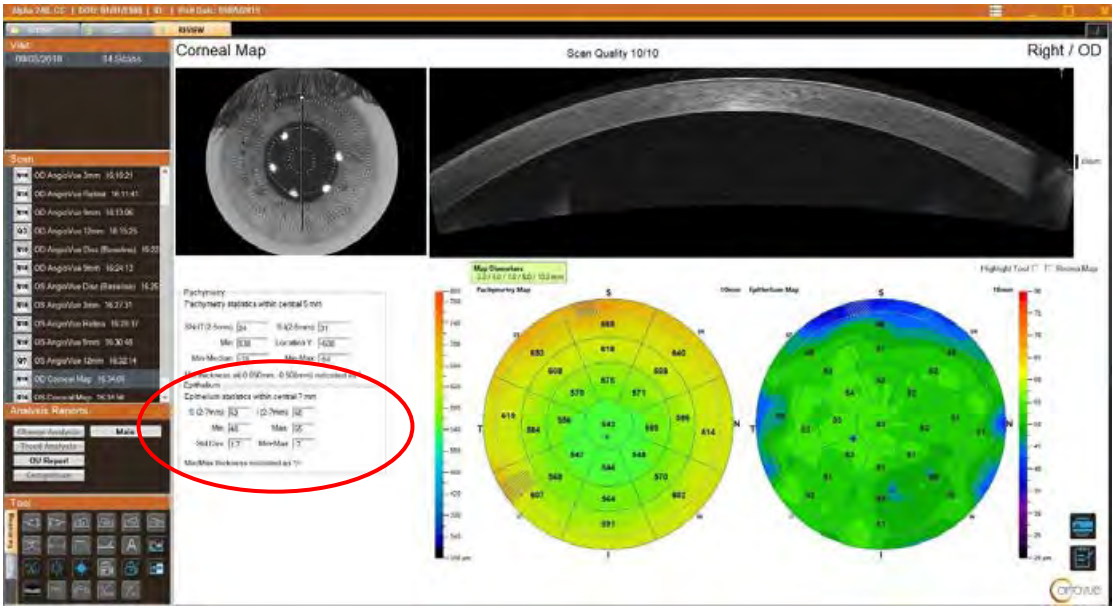


Figure 215 10mm Pachymetry with Epithelial/Stroma thickness

Note: Shaded areas indicate suspect data, the scan should be reviewed to determine accuracy. (Data is often compromised by lid related issues)

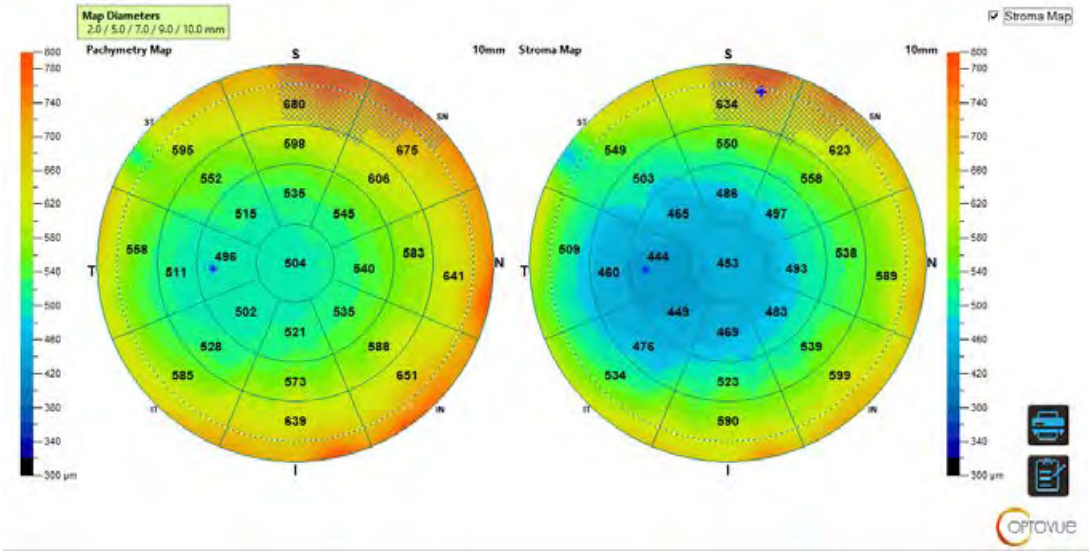


Figure 216 Corneal Stroma map

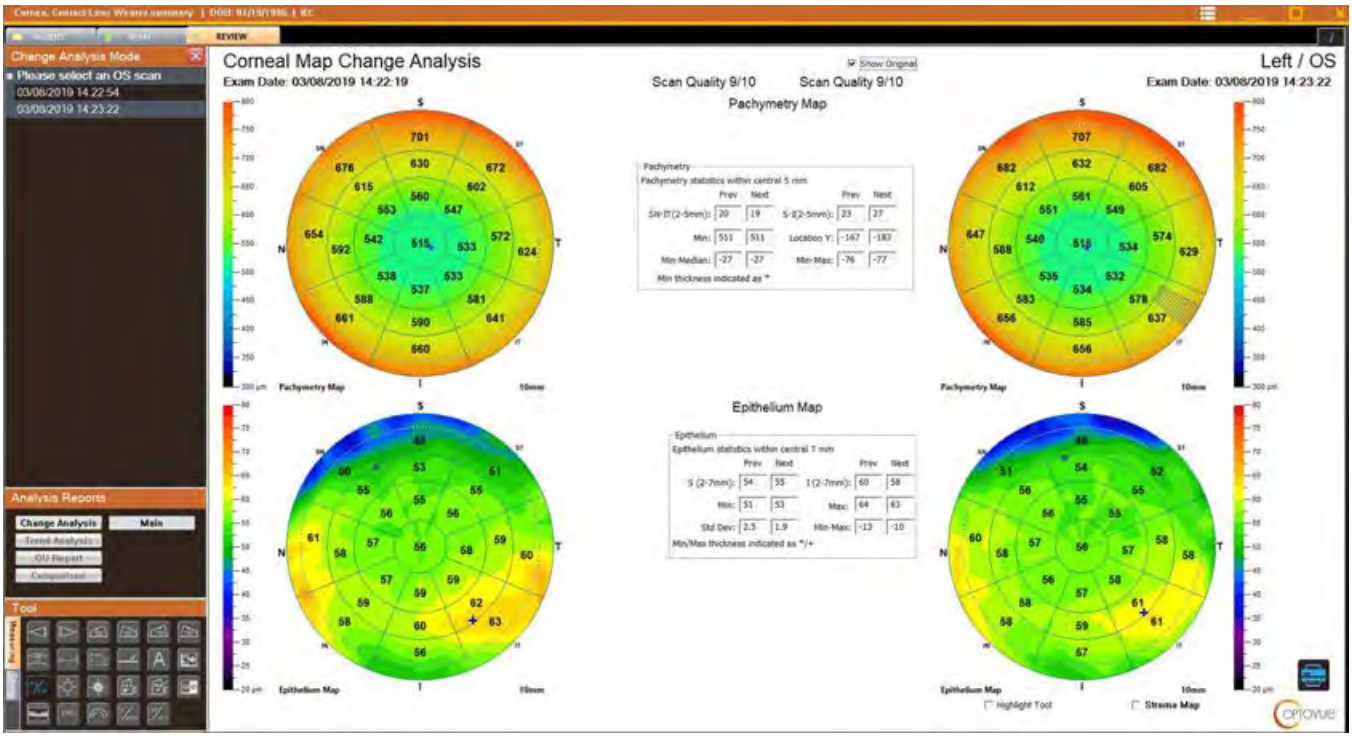


Figure 217 Pachymetry Change Analysis

All Stroma maps are the result of pachymetry (total thickness) minus epithelial thickness.

8.5.9 **Epithelium Thickness Mapping**

The Epithelium Thickness Mapping feature is available to customers who have purchased the Epithelium Thickness Mapping upgrade.

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. The Epithelium Thickness Mapping feature is an upgrade to the pachymetry scan – a sample pachymetry report with epithelium thickness mapping is shown below. Selecting the "Stroma map" will cause the stroma map to replace the epithelial thickness map

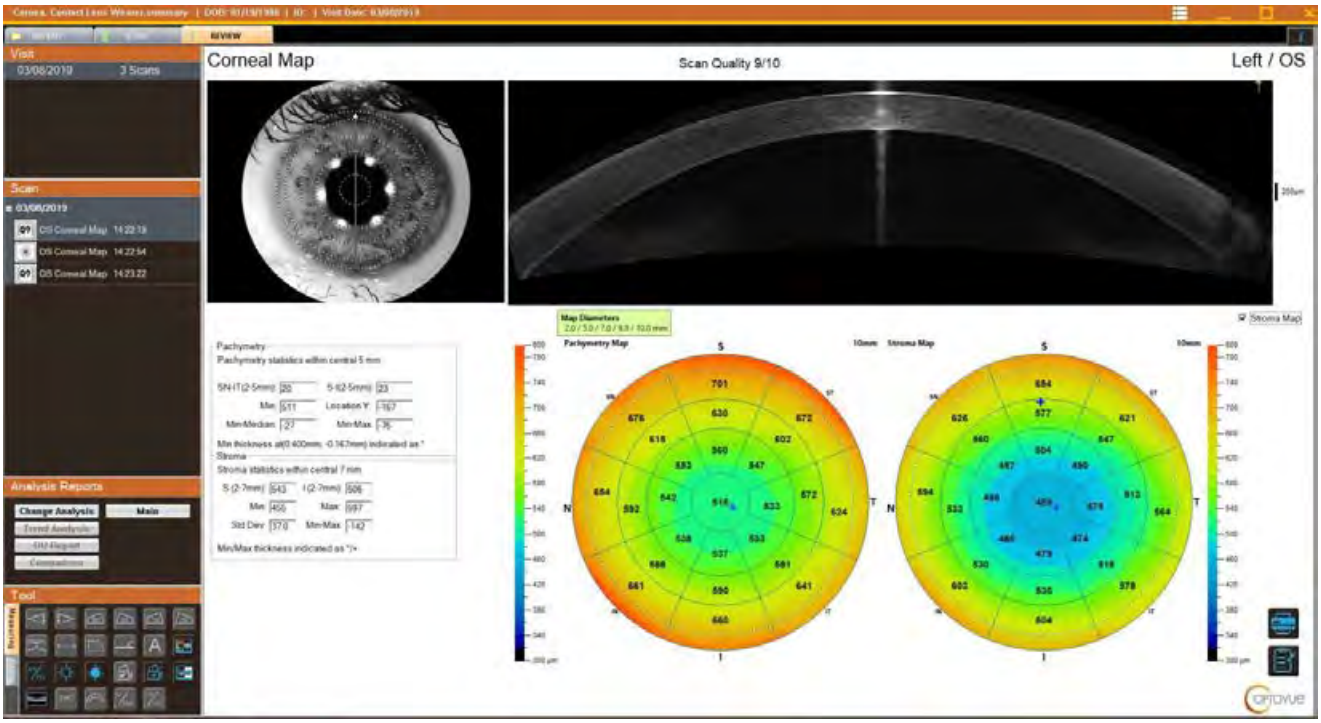


Figure 218 Pachymetry report displaying Stroma thickness map

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.

OU Report

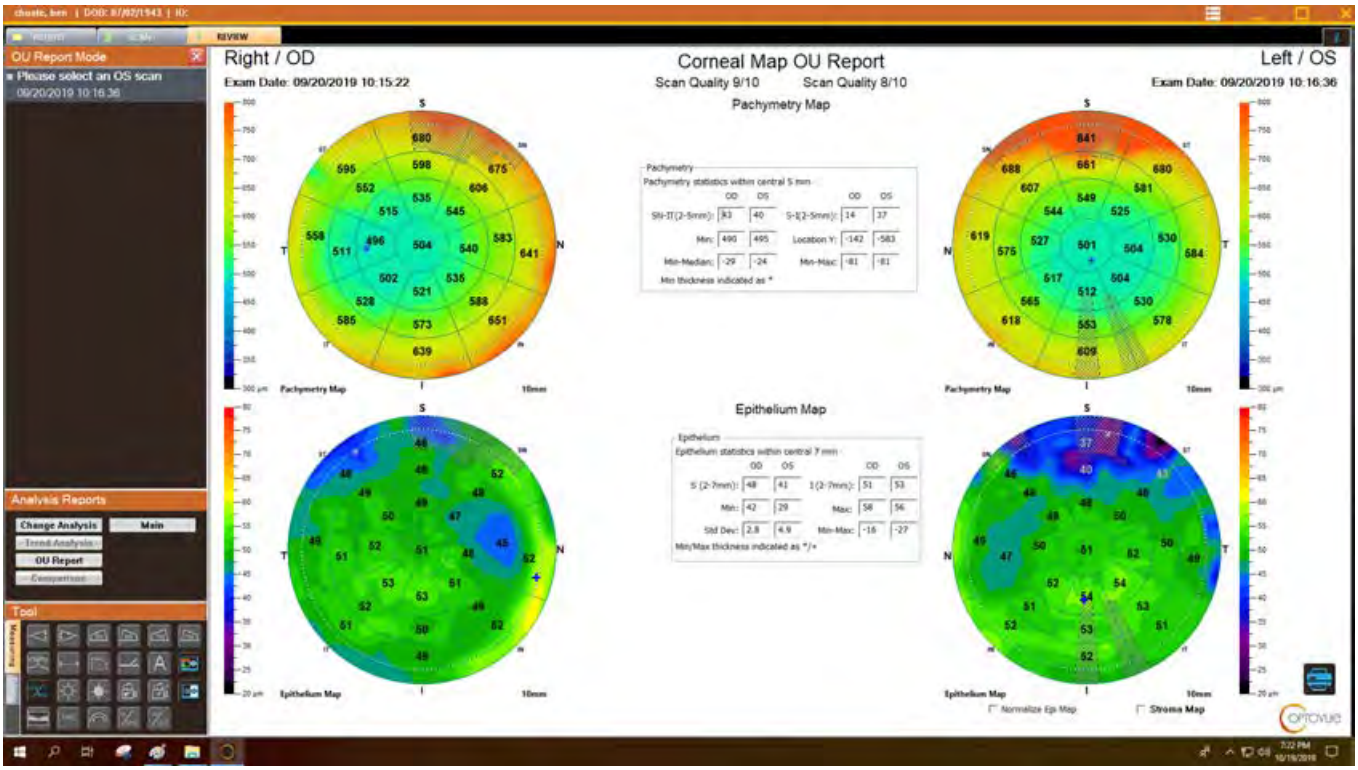


Figure 219 Pachymetry OU Report With Epithelial Mapping

_____End of section_____

8.6 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_____

8.7 Pachymetry & Epithelium Mapping

8.7.1 Zonal parameters

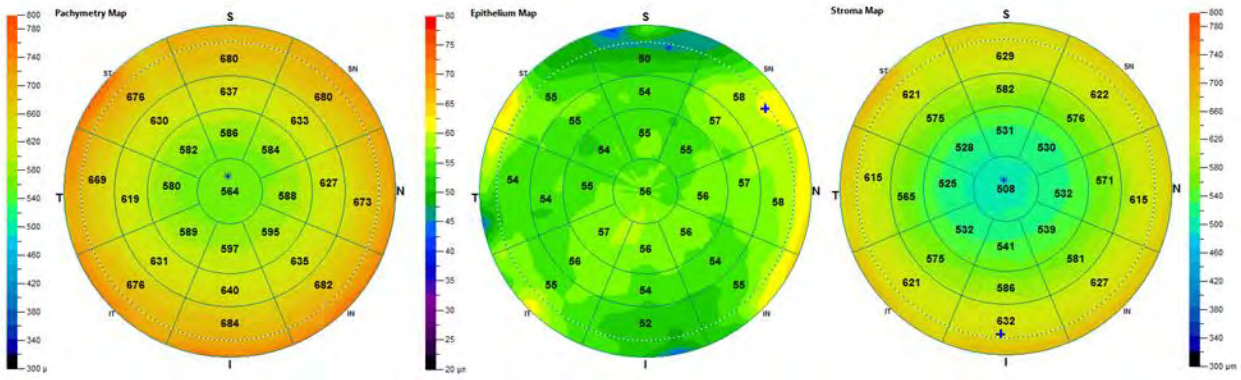


Figure 220 Zonal parameters

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

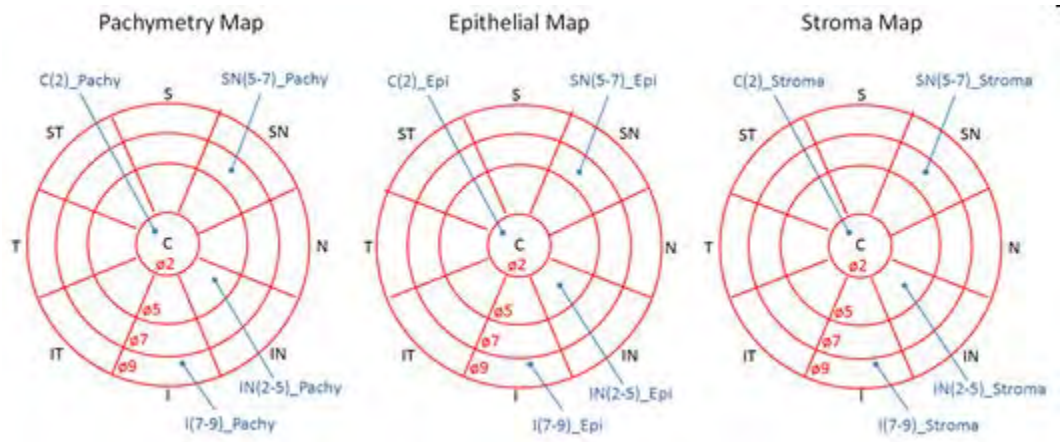


Figure 221 Naming convention of zonal parameters

8.7.2 **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.

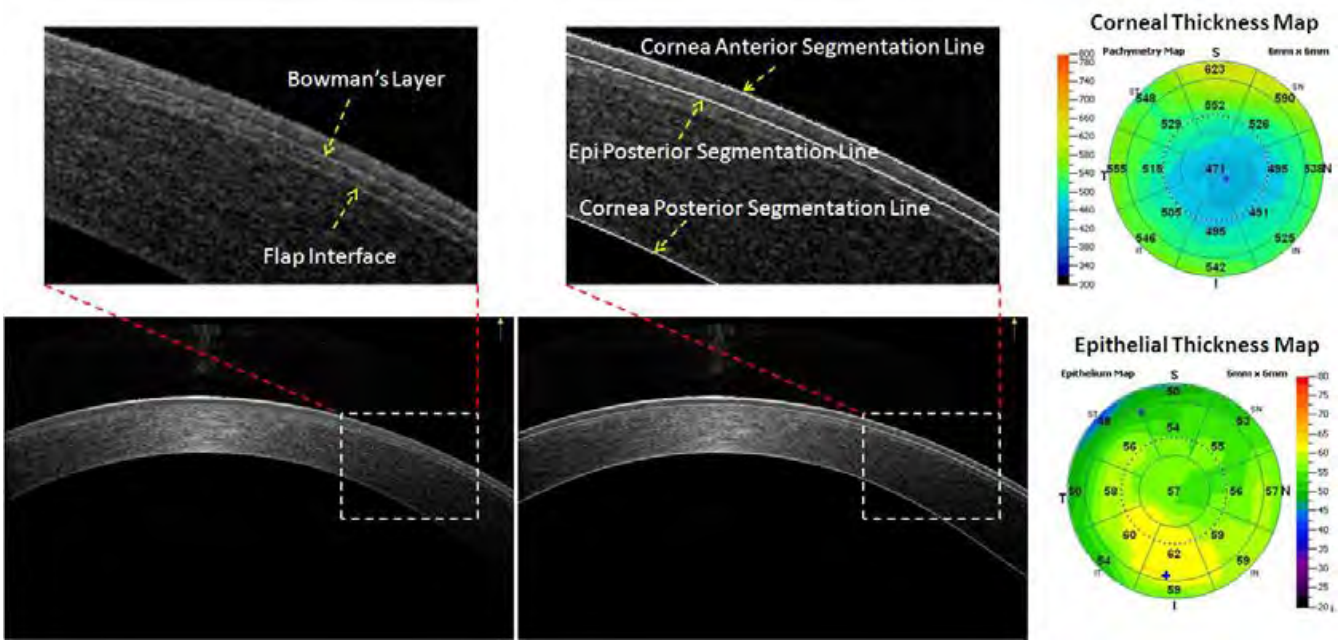


Figure 222 Automatic segmentation boundaries Lasik

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.

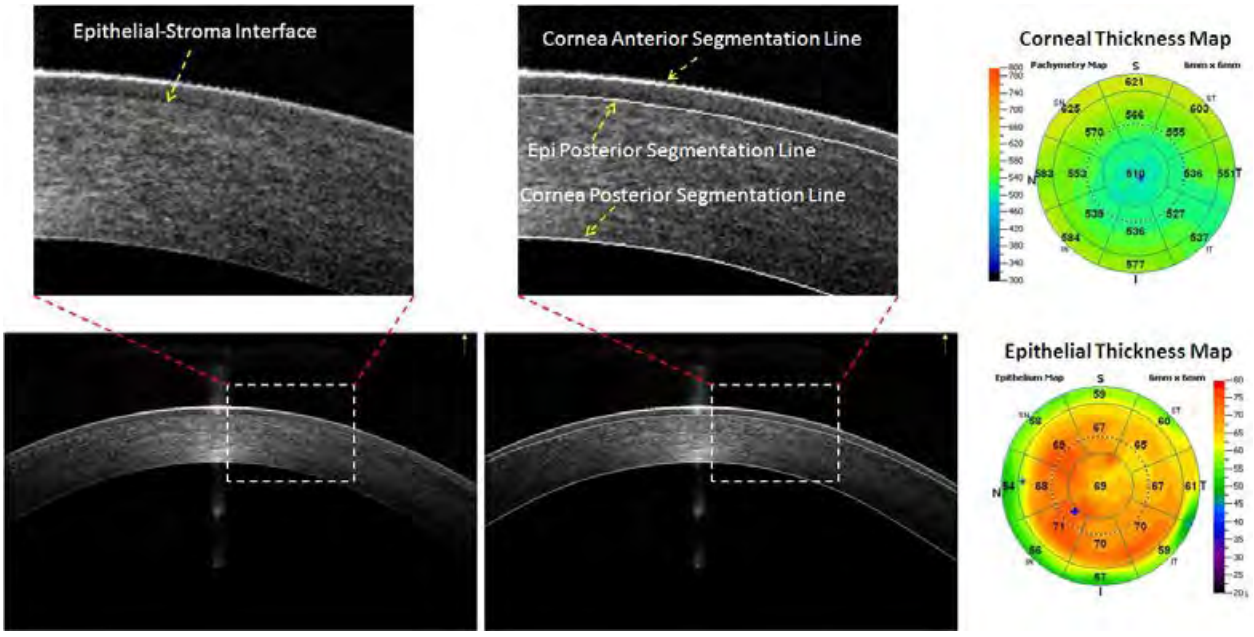


Figure 223 Automatic segmentation boundaries PRK

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.

8.7.3 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.

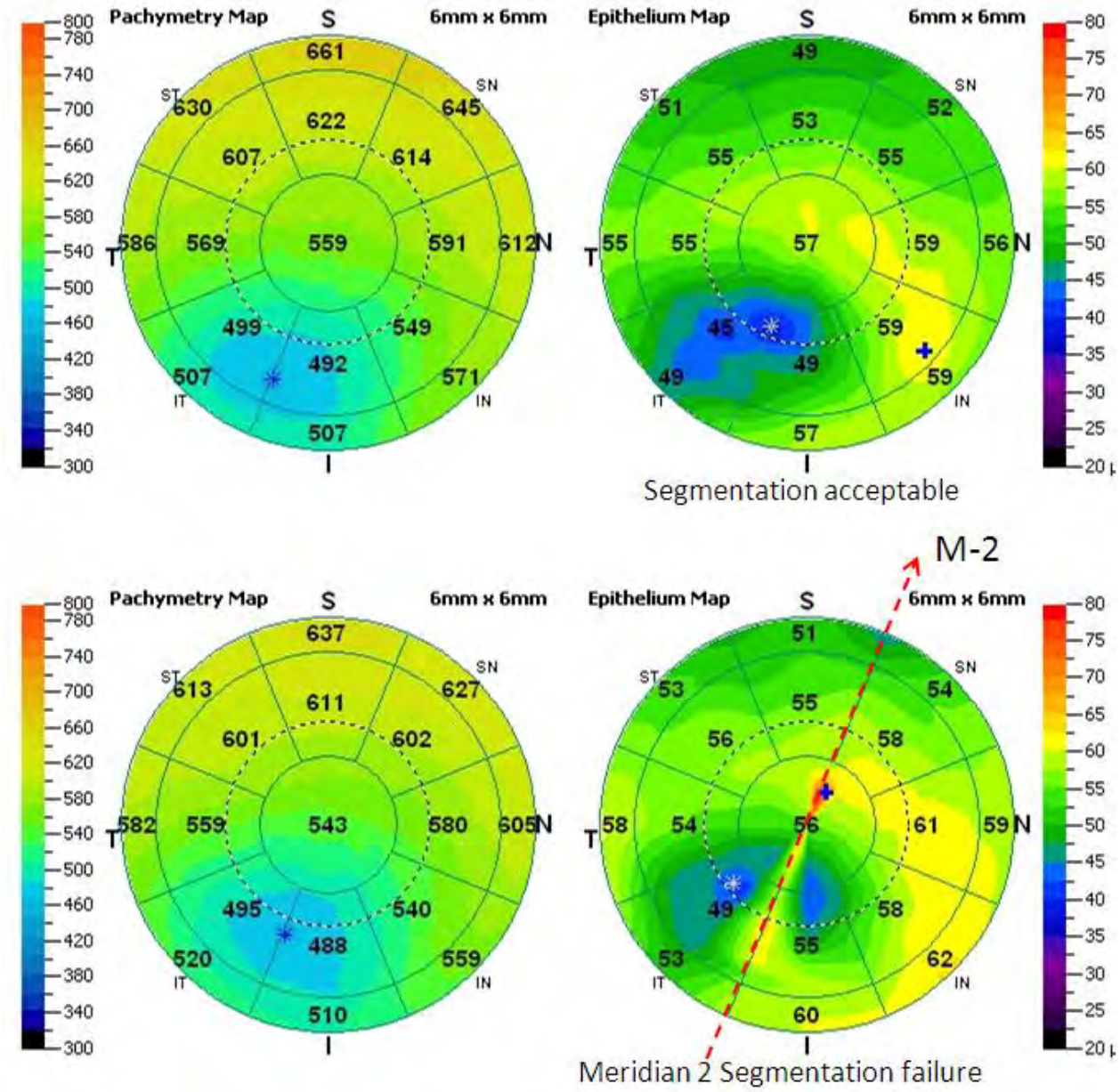


Figure 224 Segmentation error

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.

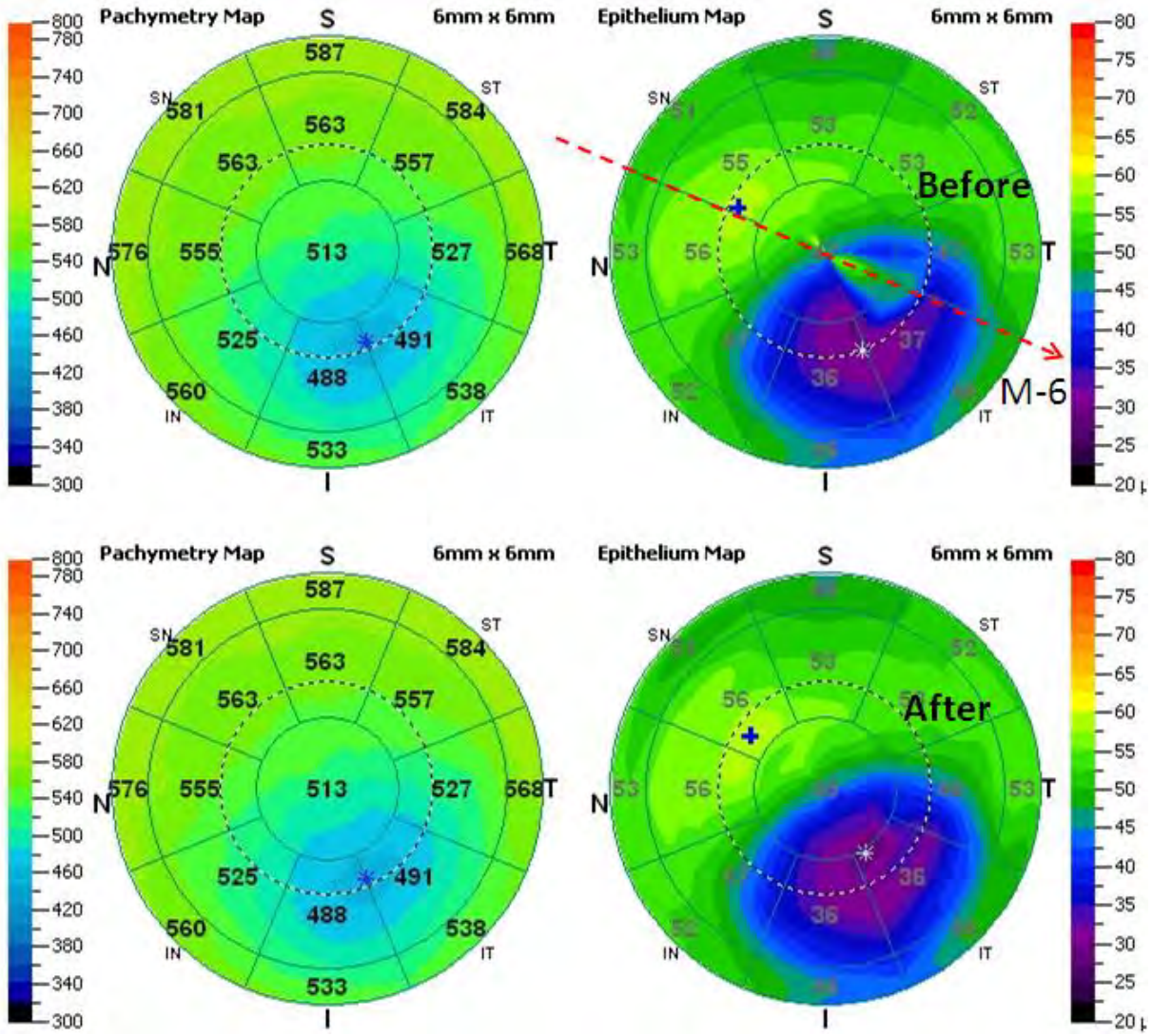


Figure 225 Reprocessed Map

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.

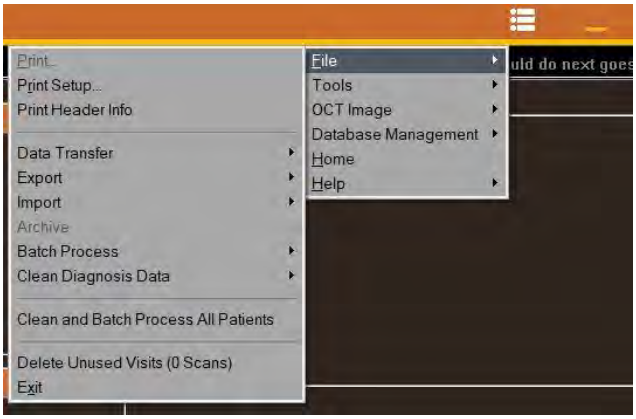


Figure 226 File Menu

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.

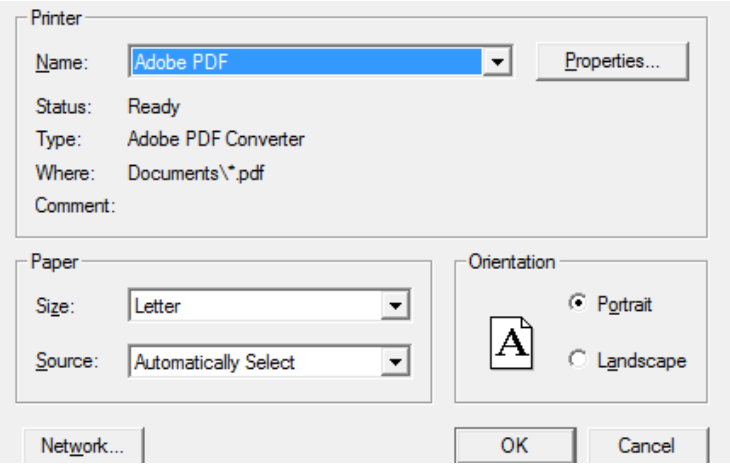


Figure 227 Print Setup Dialog

- **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**.

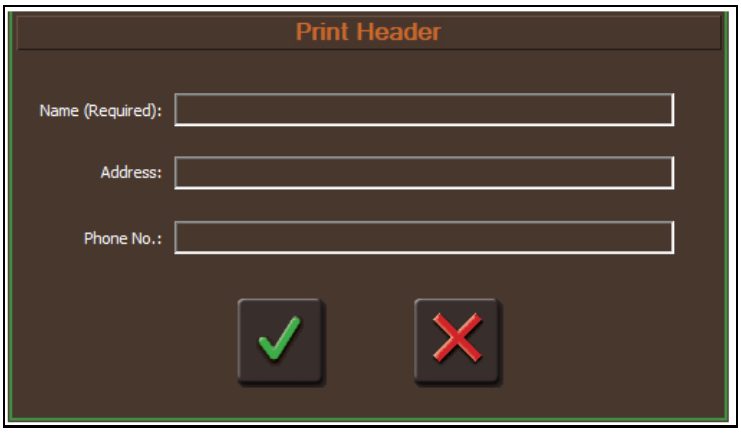
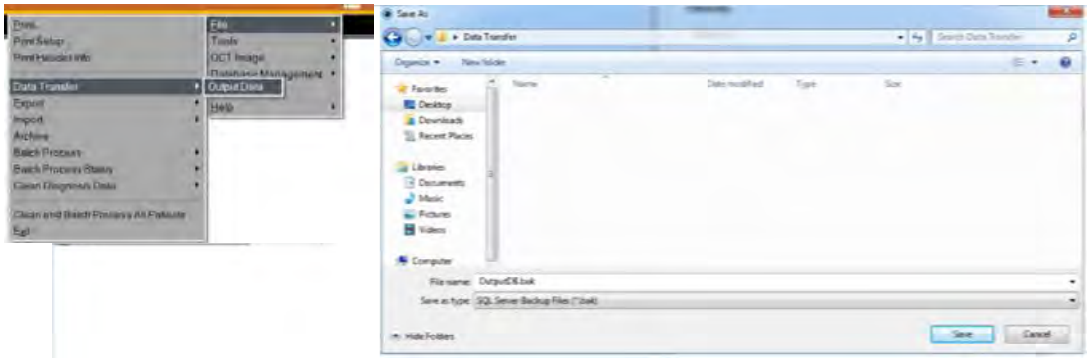


Figure 228 Print Header Dialog

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.

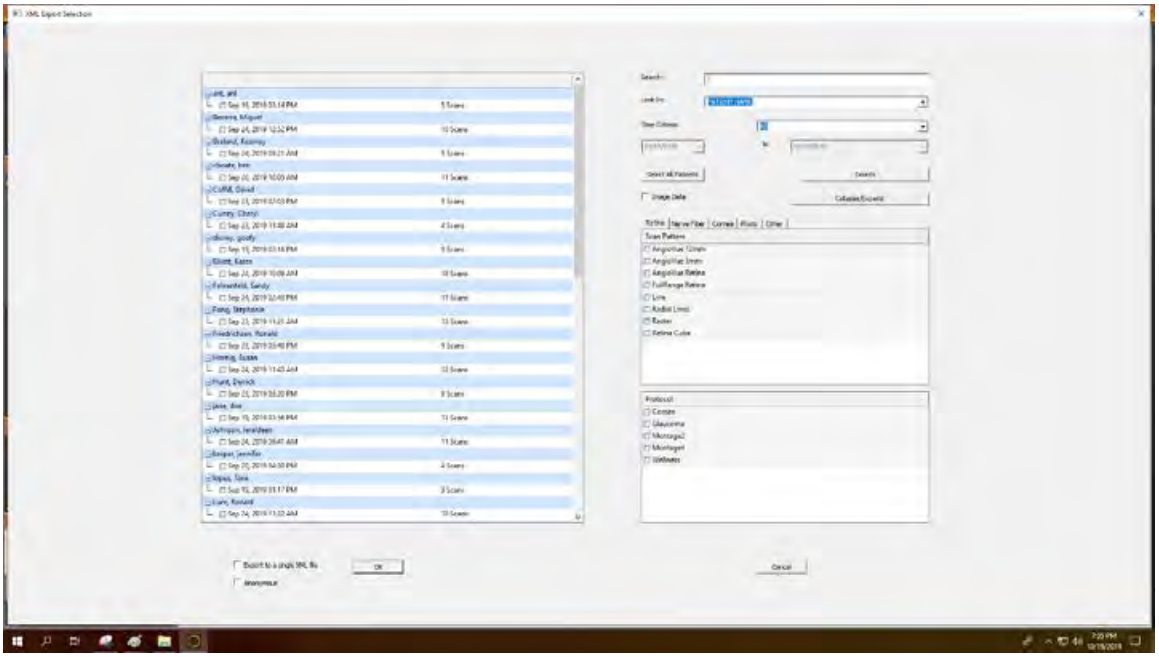


Figure 229 Output Selection Dialog

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 e**nables you to export the current scan or all scans from the current visit.

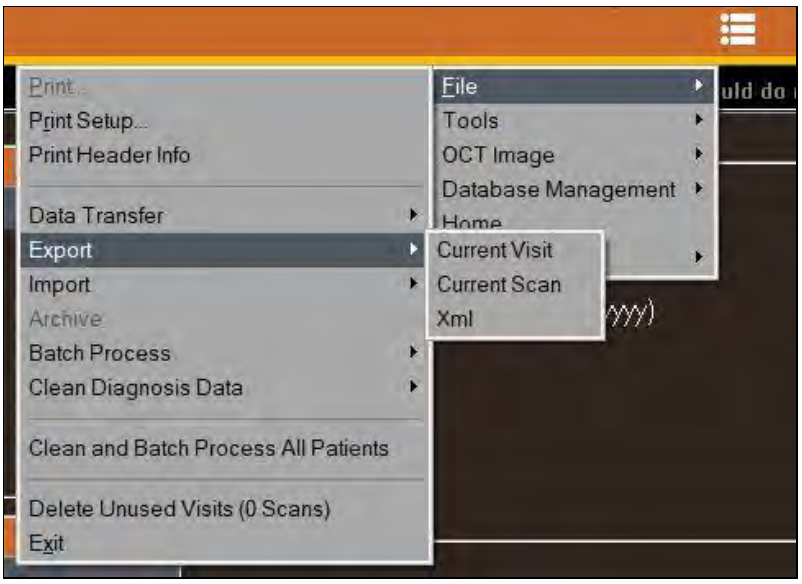


Figure 230 Export Options

☞ **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 230.

- If you select **XML**, the XML Export Selection dialog opens. 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

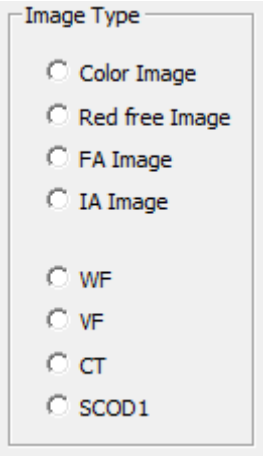
Import enables you to import saved images one at a time from a local or networked directory to the currently selected patient record. You can import any image file, including .bmp, .jpg, .gif, .png and .tif files. Optovue recommends using a common image format for imported and exported images and suggests 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 231 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:



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.

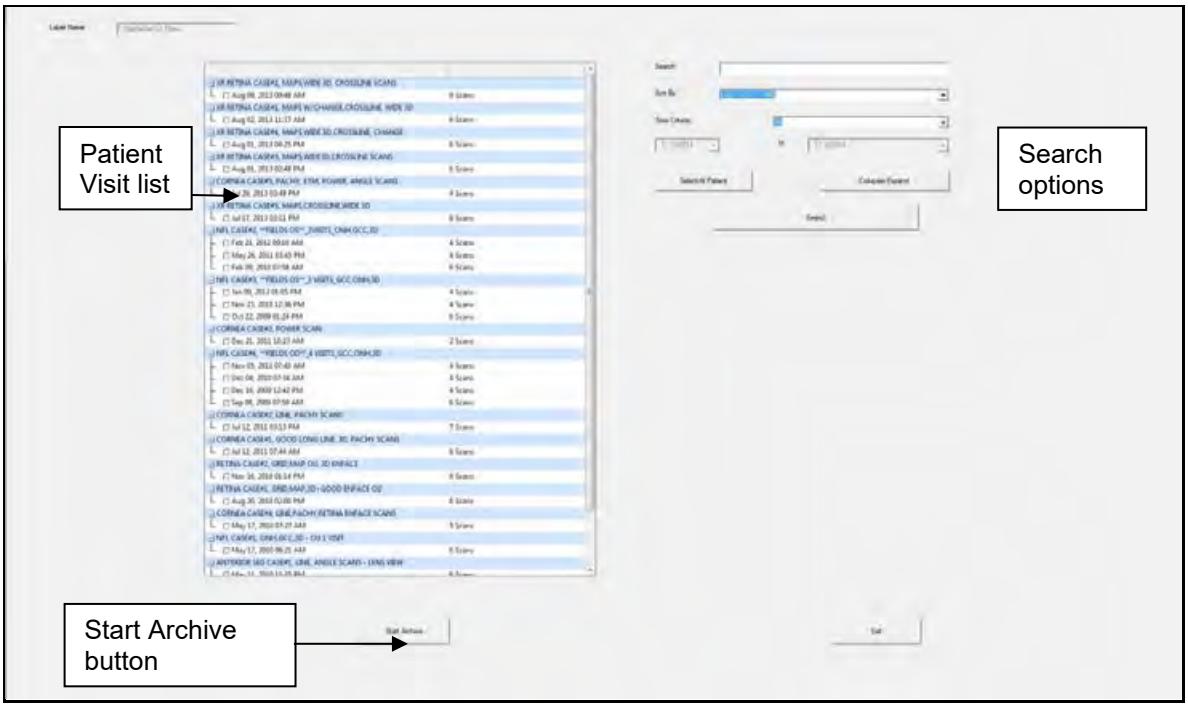


Figure 232 Archive Selection Dialog

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.

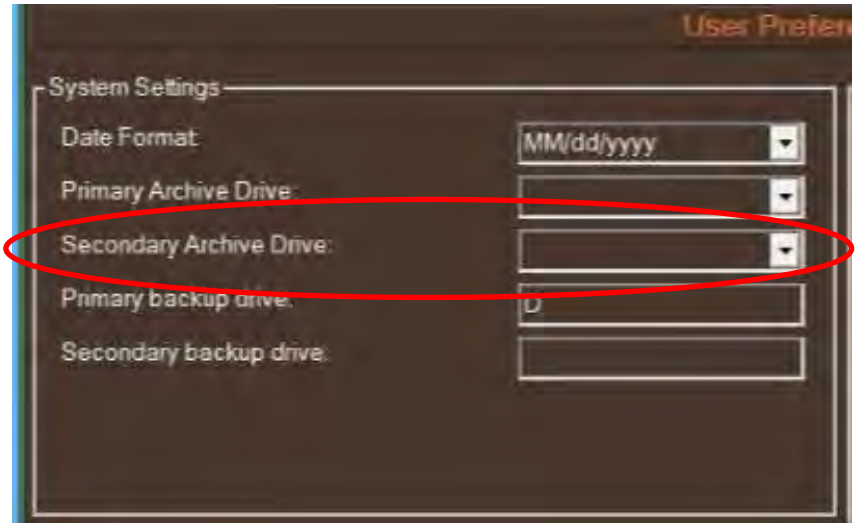


Figure 233 Secondary Backup Drive in User Preference Dialog

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.

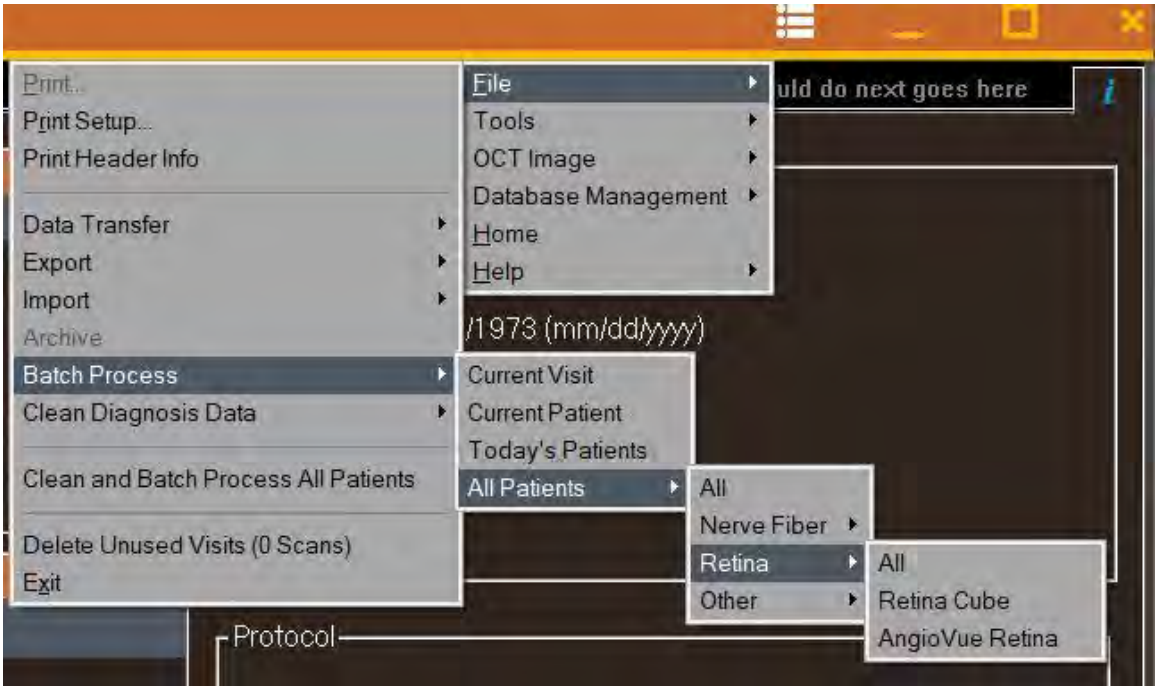


Figure 234 Batch Process Options

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.

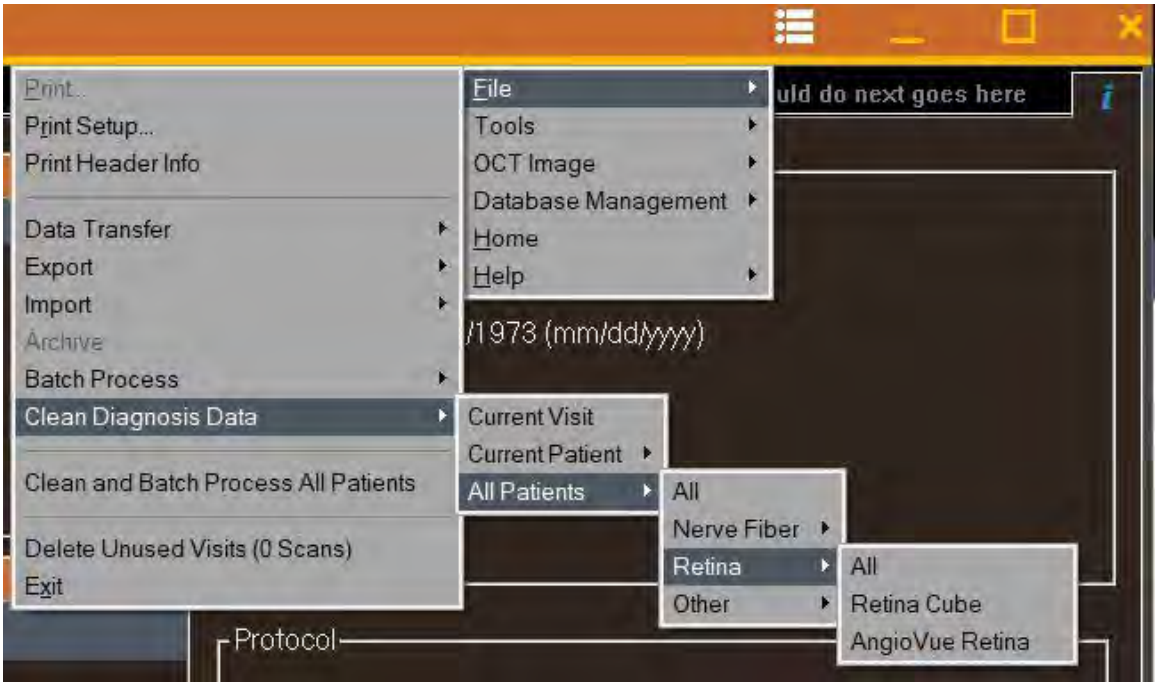


Figure 235 Clean Diagnosis Data Options

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.

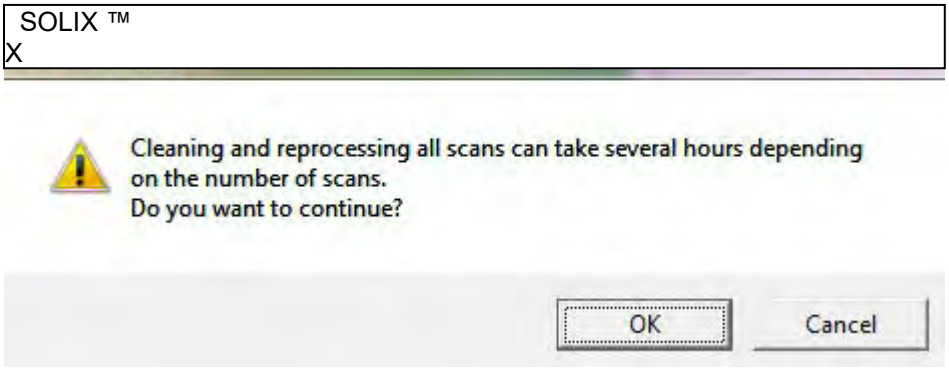


Figure 236 Confirm Cleaning and Reprocessing

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.

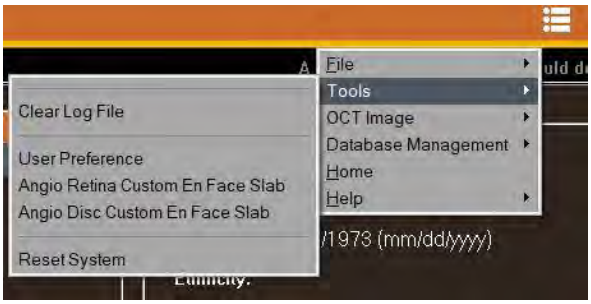


Figure 237 Tools Menu

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 238 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 239 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.

Figure 240 User Preference Dialog

- **Date Format:** Specifies the date format for the system application, which should match the system computer date format.
- **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.
- Scan navigation, either Dilated (photo comes after the last OCT for each eye or non-Dilated photo after all posterior OCT.

- **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
- **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.
- **Non MCT scan Auto save** yes or No
- **Save Fast X & Y volumes** saves both volume
- **Default 3D Retina Display**: Sets the default report view for 3D Retina scan.
- **Default 3D AngioVue® Display**: Sets the default type of image to display in the 3D AngioVue® report.
- **Default 3D Glaucoma Display**: Sets the default type of image to display for the 3D ONH presentation.
- **Default 3D Retina Enface Layer**: Sets the default layer to display in the 3D Retina Enface presentation.
- **Default 3D Glaucoma Enface Layer**: Sets the default layer to display in the 3D ONH Enface presentation.
- **AngioFlow measure type,** 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.

- **Follow-up, Tracking and Show Patient list** checkboxes: Select to enable, deselect to disable the tracking, follow-up, or list features.
- **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.

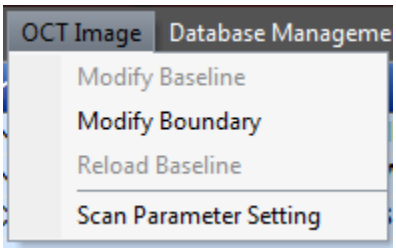


Figure 241 OCT Image Menu

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.

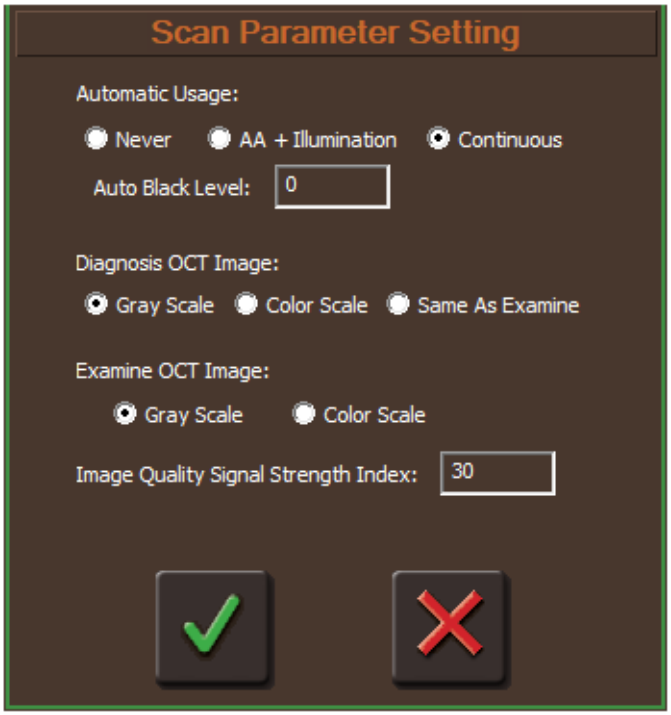


Figure 242 Scan Parameter Setting Dialog

- **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.

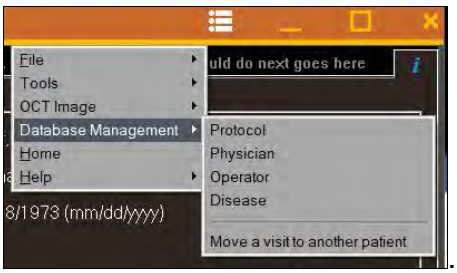


Figure 243 Database Management Menu

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 244 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.

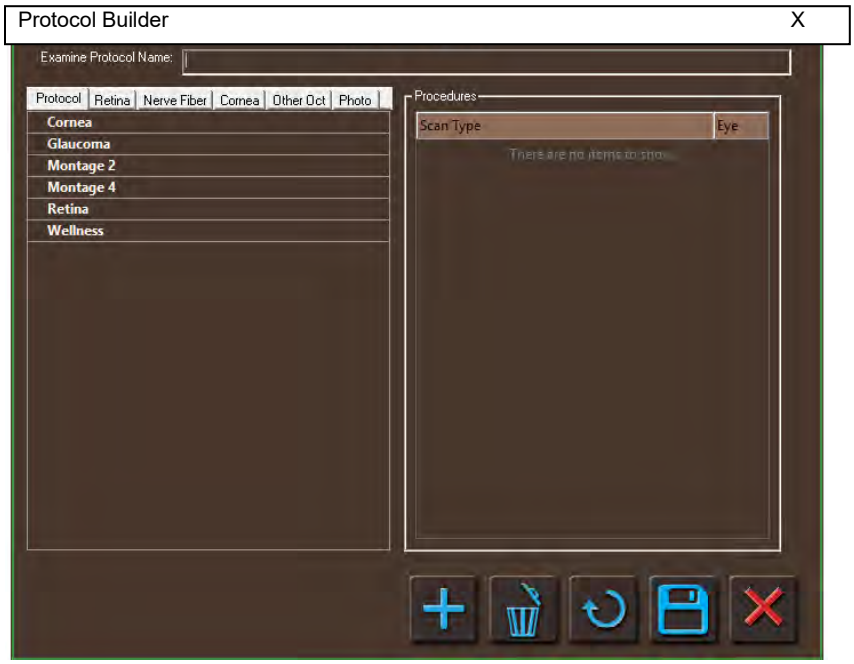


Figure 245 Protocol Builder Dialog

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 246 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 247 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 248 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™ home screen.

9.5 Help Menu

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

Figure 249 Help Menu

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

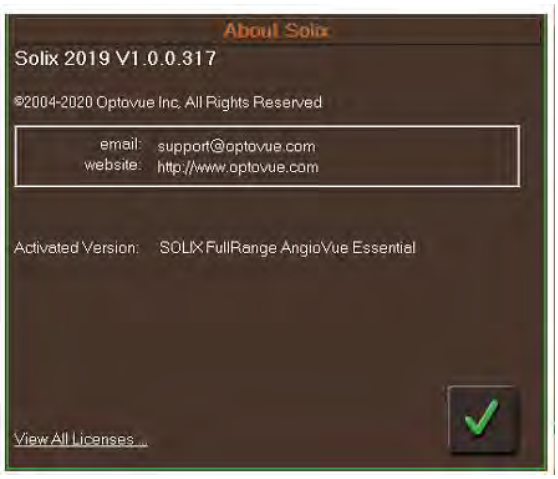


Figure 250 About SOLIX™ Dialog

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

_____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
FullRange ™ Retina line	Single line scan 6.25 x16 mm	1408 X 1	Transverse: 6-16 mm (0.1 mm increment) Angle: 90 to 90°	16 mm, -5° (monitor screen left to right)
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

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
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
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

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
External IR Image	IR photo external			
External Color image	Color photo	5Mp		
Fundus photo	Color photo	5Mp		45 deg
Disc Photo	Color photo	5Mp		45 deg
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
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°

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
Corneal Angle	line	1020	2-6mm	3mm
AC FullRange ™	1 scan line with adjustable scan length	1280 X 1	Length: 14-18mm Angle: -90 to 90 degree18x6.25 mm	18mm, 0 deg

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	Welness	Fovea	

_____End of section_____

12 Technical Specifications

Fundus Imaging		
	Image mode	Color, Red-free*
	Field of view	45° and 35° (small pupil mode)
	Pupil diameter	≥ 4.0 mm; ≥ 3.3 mm (small pupil mode)
	Dioptric Range	-35D to +30D
	Working distance	35mm
	Optical image resolution	Center :60 lines/mm or more Middle (r/2) :40 lines/mm or more Periphery (r) :25 lines/mm or more
	Pixel pitch on fundus	7.4 µm
	Photography magnification	0.295
	LED flash levels	10
External Photography		
	External color	Color (white light flash)
	External IR	IR (940nm illumination)
OCT Imaging (Retina)		
	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) Up to 6.25mm (FullRange™ mode)
	Scan length	3mm - 16mm
	Dioptric Range	-15D to +15D
	Pupil diameter	2.0 mm or more
	AngioVue	SSADA OCTA with MCT Technology and 3D PAR
OCT Imaging (Anterior Segment)		
	Lateral resolution	18 µm (Regular CAM) (in tissue) 36 µm (FullRange™ CAM) (in tissue)
	Working distance	20 mm
	Scan depth	Up to 3 mm (Regular CAM) Up to 6.25mm (FullRange™ CAM)
	Scan length	2mm - 18mm
Patient Interface		
	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
	White LED	420-780nm (single pulse for flash)
	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***
Retina	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)
Nerve Fiber	Disc Cube	6x6x2.34
Cornea	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)
Other	Wellness	12x9x2.93
FullRange™	FullRange Retina	6-16 (L)x6.25(D)
	FullRange AC	14-18(L)x6.25(D)
AngioVue	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
OCT Structure	***Application***	***Image & Analysis***
	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)
	FullRange™ AC Reports	Anterior Summary, Comparison, and OU
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™ system with embedded Windows 10 operating system.

12.5.2 **System Overview**

The SOLIX™ 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™ 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 of 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™ 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™ 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™ 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™ 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™ device will support these site-specific IT systems and this is verified during the installation process by Optovue personnel.

Stand Alone Mode

- The SOLIX™ 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™ 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.

_____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™ 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 251 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 251 below.

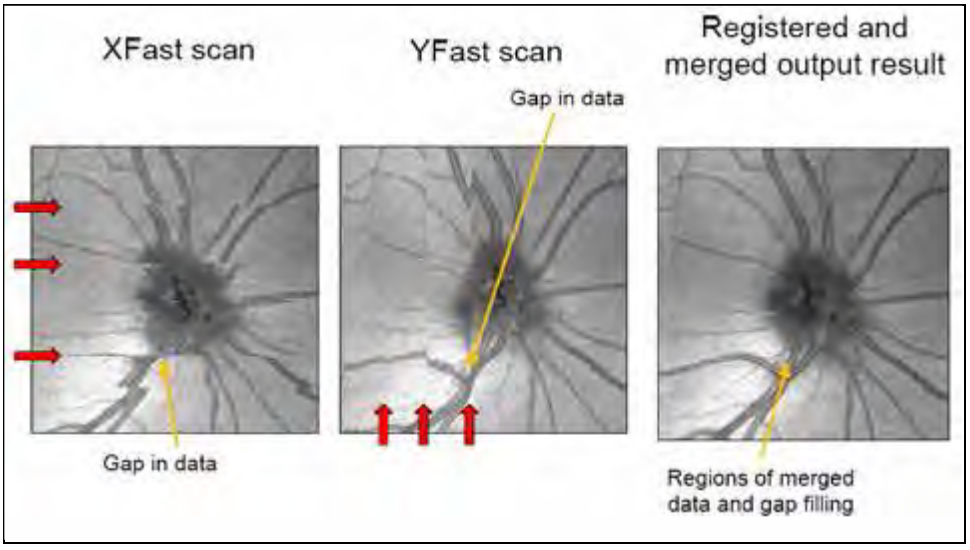


Figure 251 MCT Scan Acquisition and Effect in 3D Volumes, En Face Views

Figure 252 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.

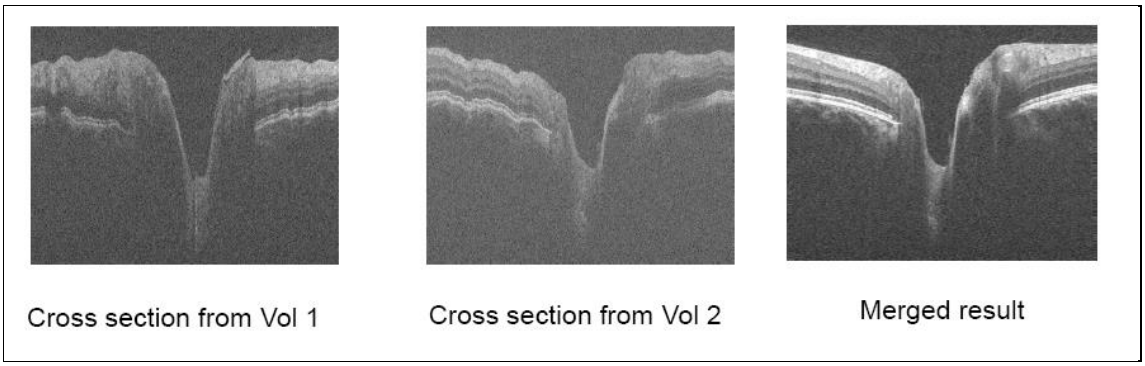


Figure 252 MCT Scan Acquisition and Effect in 3D Volumes, Cross-Sectional Views

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 93 participants were consented and enrolled, including16 normal subjects ("Normal" group) 18 with glaucoma ("Glaucoma" group), and 59 with retinal conditions ("Retina" group). One eye per subject was included in the study. One participant from the Normal group and another from the Retina sub-group could not complete the required imaging. Therefore, a total of 91 eligible participants completed the study. The 58 "Retina" group participants were assigned to the sub-groups as follow: 12 to wetAMD, 14 to DR, 9 to dryAMD-drusen, 9 to dryAMD-GA, and 14 to "other" group. Of the 91 eligible subjects, 55 (60.4%) participants were female and 36 (39.6%) participants were male; the age distribution of the participant was 65.5±15.3 (mean±SD), ranging from 21 to 91; and, 86 (94.5%) participants were Caucasian.

Of the 15 subjects in the Normal group with age ranging from 21 to 70, 1 subject had refractive surgery, and 1 had cataract surgery and IOL implant.

The 18 subjects in the Glaucoma group consisted of 5 subjects in the early stage, 8 subjects in the moderate stage, and 5 subjects in the advanced stage of glaucoma with visual field MD ranging from -27.75 dB to 0.04 dB and PSD ranging from 1.63 dB to 13.42 dB.

Of the 12 wetAMD subjects, 3 subjects had diagnosis of Type-1 CNV, 8 subjects had Type-2 CNV, and 1 subject had mixed type CNV. CNV vessel net was visible in OCTA image in 8 subjects; IRF was observed in OCT image in 6 subjects; 7 subjects had SRF; and 9 subjects had PED. Eleven of the 12 subjects had anti-VEGF injection treatment and 11 subjects had cataract surgery and IOL implant.

The 14 DR subjects consisted of 5 subjects with NPDR without DME, 3 subjects with NPDR with DME, 3 subjects with PDR without DME, and 3 subjects with PDR with DME. In terms of DR severity, 4 subjects had mild NPDR, 4 subjects had moderate NPDR, and 6 subjects with PDR. Based on OCTA image, microaneurysm (MA) was observed in 10 subjects, reduced vessel density was observed in 13 subjects, and FAZ outpouching was observed in 1 subject. Based on OCT image, IRF was observed in 9 subjects and ERM in 5 subjects. Four of the 12 subjects had anti-VEGF injections and 3 subjects had laser/surgery treatment and 6 subjects had cataract surgery with IOL implant.

Of the 18 dryAMD subjects, 9 subjects had drusen without GA, 3 subjects had drusen and non-central GA, and 6 subjects had central GA. PED from confluent drusen was observed in 11 subjects in OCT image. Eight subjects had cataract surgery with IOL implant.

The 14 subjects assigned to the sub-group “other” consisted of 2 BRVO, 1 MacTel, 1 CRVO, 2 CNV but not from AMD, 3 ERM, 1 ocular histoplasmosis, 1 birdshot chorioretinopathy, 1 hypertensive retinopathy, 1 choroidal nevus, and 1 retinitis pigmentosa. Seven subjects had cataract surgery with IOL implant.

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 81.6% to 98%, depending on the scan pattern and structural or vascular analysis:

Solix R&R Study	Normal			Glaucoma			All Retina			Combined		
Qualifying Scans	qualified	acquired	% qualified	qualified	acquired	% qualifie	qualified	acquired	% qualifie	qualified	acquired	% qualified
AngioVue Retina - Structural	135	135	**100.0%**	152	162	**93.8%**	492	517	**95.2%**	779	814	**95.7%**
AngioVue Retina - Vascular	126	135	**93.3%**	132	162	**81.5%**	406	517	**78.5%**	664	814	**81.6%**
Retina Cube	134	135	**99.3%**	152	162	**93.8%**	489	522	**93.7%**	775	819	**94.6%**
Wellness	134	135	**99.3%**	160	162	**98.8%**	504	517	**97.5%**	798	814	**98.0%**
AngioVue Disc - Structural	134	135	**99.3%**	153	162	**94.4%**	469	521	**90.0%**	756	818	**92.4%**
AngioVue Disc - Vascular	134	135	**99.3%**	141	162	**87.0%**	412	521	**79.1%**	687	818	**84.0%**
Disc Cube	123	135	**91.1%**	142	162	**87.7%**	416	521	**79.8%**	681	818	**83.3%**

Table 15.1.1 Rates of qualifying scans per study group per scan pattern.

The main reasons for scan disqualification for structural analysis were motion artifacts for Disc Cube scan at 12.5% and SQ<6 for AngioVue Retina at 3.5%.

The main reasons for scan disqualification for vascular analysis were local weak signal at 10.4% for AngioVue Retina and 5.8% for AngioVue Disc, motion artifacts at 7.4% for AngioVue Retina and 5.8% for AngioVue Disc, SQ<6 at 4.1% for AngioVue Retina.

Across all 5 study scan types and across all study groups, the maximum manual editing rates for segmentation boundaries were 1.1% for ILM, 0.8% for IPL, 0.8% for RPE, 1.7% for BRM, and 0.4% for NFL of qualified scans; the maximum foveal center detection correction rates were 5% (5% for Wellness scan, 4.4% for AngioVue Retina scan, 1.7% for Retina Cube scan) of qualified scans; the FAZ boundary detection manual editing rate was 11.3% of qualified AngioVue Retina scans; the disc margin manual editing was performed for the baseline scan in 10.3% of study eyes per instrument (28 scans of 91 subjects tested in 3 instruments).

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=135 scans)					Retina Cube (n=134 scans)					Wellness (n=134 scans)				
		Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*
GCC		**ETDRS Grid (φ 6mm)**														
C(1)_GCC	µm	57.3	0.8	1.2	2.1%	3.3	58.0	1.0	1.2	2.1%	3.4	64.7	1.4	1.7	2.6%	4.6
T(1-3)_GCC	µm	102.7	0.8	1.2	1.1%	3.3	103.7	0.8	1.1	1.0%	3.0	102.8	0.7	1.0	1.0%	2.8
S(1-3)_GCC	µm	114.1	0.9	1.2	1.1%	3.3	113.7	1.0	1.2	1.1%	3.3	111.3	0.9	0.9	0.8%	2.5
N(1-3)_GCC	µm	111.0	0.7	1.3	1.2%	3.6	111.8	1.1	1.4	1.3%	3.9	110.9	0.8	1.0	0.9%	2.8
I(1-3)_GCC	µm	114.1	0.8	1.2	1.0%	3.3	114.2	1.0	1.2	1.1%	3.5	110.9	0.8	1.0	0.9%	2.7
S-Hemi (1-3)_GCC	µm	110.3	0.7	1.2	1.0%	3.2	110.4	0.8	1.1	1.0%	3.1	109.2	0.7	0.9	0.8%	2.4
I-Hemi (1-3)_GCC	µm	110.7	0.7	1.2	1.1%	3.3	111.2	0.9	1.2	1.0%	3.2	109.5	0.8	0.9	0.8%	2.6
All(1-3)_GCC	µm	110.5	0.7	1.1	1.0%	3.1	110.8	0.7	1.1	1.0%	3.0	109.4	0.7	0.8	0.8%	2.3
T(3-6)_GCC	µm	84.7	0.9	1.0	1.2%	2.8	85.3	0.7	0.8	0.9%	2.2	81.2	0.7	0.7	0.9%	2.1
S(3-6)_GCC	µm	100.2	0.9	1.0	1.0%	2.7	99.0	0.8	0.8	0.8%	2.3	92.1	1.0	1.0	1.1%	2.8
N(3-6)_GCC	µm	116.9	0.7	1.0	0.9%	2.9	116.4	0.7	1.0	0.9%	2.8	113.5	0.8	1.0	0.9%	2.7
I(3-6)_GCC	µm	100.0	0.8	1.0	1.0%	2.7	98.8	0.7	0.9	0.9%	2.6	96.6	0.9	1.0	1.1%	2.9
S-Hemi (3-6)_GCC	µm	99.6	0.8	0.9	0.9%	2.5	99.1	0.6	0.7	0.7%	2.0	93.4	0.7	0.8	0.8%	2.2
I-Hemi (3-6)_GCC	µm	101.2	0.7	0.9	0.9%	2.5	100.7	0.7	0.9	0.9%	2.4	97.7	0.8	0.9	0.9%	2.5
All (3-6)_GCC	µm	100.4	0.6	0.8	0.8%	2.3	99.9	0.6	0.7	0.7%	2.0	95.6	0.6	0.7	0.7%	1.9
S-Hemi (0-6)_GCC	µm	100.8	0.7	0.9	0.9%	2.6	100.5	0.6	0.8	0.8%	2.1	96.1	0.6	0.7	0.8%	2.0
I-Hemi (0-6)_GCC	µm	102.1	0.6	0.9	0.9%	2.6	101.9	0.6	0.9	0.9%	2.5	99.4	0.7	0.8	0.9%	2.4
All (0-6)_GCC	µm	101.5	0.6	0.9	0.9%	2.4	101.2	0.6	0.8	0.8%	2.1	97.8	0.5	0.7	0.7%	1.9
GCC		**6mm x 6mm**										**7mm x 8mm**				
WI_GCC	µm	103.0	0.6	0.9	0.8%	2.4	102.5	0.5	0.7	0.7%	2.0	92.8	0.5	0.6	0.7%	1.8
WI-S-Hemi_GCC	µm	101.7	0.8	0.9	0.9%	2.6	101.2	0.7	0.8	0.8%	2.1	91.4	0.7	0.8	0.8%	2.1
WI-I-Hemi_GCC	µm	104.2	0.6	0.9	0.9%	2.5	103.8	0.6	0.8	0.8%	2.3	94.2	0.7	0.8	0.9%	2.2
FLV_GCC	%	0.187	0.087	0.087	46.6%	0.242	0.161	0.088	0.088	54.9%	0.245	0.216	0.123	0.123	55.9%	0.340
GLV_GCC	%	4.301	0.500	0.619	14.4%	1.715	4.258	0.397	0.463	10.8%	1.284	4.346	0.407	0.466	10.6%	1.291
Retinal Thickness		**ETDRS Grid (φ 6mm)**														
C(1)_R	µm	258.3	1.5	1.9	0.8%	5.4	258.3	1.9	2.3	0.9%	6.5	257.9	2.3	2.5	1.0%	7.0
T(1-3)_R	µm	312.5	1.2	1.6	0.5%	4.3	312.9	1.5	1.9	0.6%	5.3	311.7	1.1	1.5	0.5%	4.1
S(1-3)_R	µm	326.6	1.4	1.6	0.5%	4.4	326.6	1.7	2.0	0.6%	5.6	324.8	1.3	1.6	0.5%	4.5
N(1-3)_R	µm	327.6	1.3	1.7	0.5%	4.8	327.7	1.6	1.9	0.6%	5.4	325.2	1.4	1.6	0.5%	4.5
I(1-3)_R	µm	321.6	1.3	1.7	0.5%	4.8	321.9	1.6	1.9	0.6%	5.3	321.1	1.2	1.6	0.5%	4.3
S-Hemi(1-3)_R	µm	323.4	1.3	1.5	0.5%	4.2	323.5	1.5	1.9	0.6%	5.3	321.4	1.1	1.5	0.5%	4.2
I-Hemi-(1-3)_R	µm	320.7	1.2	1.7	0.5%	4.7	321.1	1.4	1.8	0.6%	5.1	320.0	1.1	1.5	0.5%	4.2
All(1-3)_R	µm	322.1	1.2	1.5	0.5%	4.2	322.3	1.3	1.8	0.5%	4.9	320.7	1.0	1.4	0.4%	3.9
T(3-6)_R	µm	263.5	1.2	1.4	0.5%	3.7	265.0	1.4	1.7	0.6%	4.7	274.8	1.2	1.3	0.5%	3.7
S(3-6)_R	µm	281.3	1.2	1.3	0.5%	3.7	282.4	1.7	2.0	0.7%	5.6	290.0	1.3	1.4	0.5%	3.9
N(3-6)_R	µm	298.0	1.1	1.4	0.5%	3.9	298.6	1.3	1.7	0.6%	4.7	298.9	1.2	1.4	0.5%	3.8
I(3-6)_R	µm	269.0	1.3	1.6	0.6%	4.4	269.5	1.4	1.8	0.7%	4.9	277.4	1.4	1.6	0.6%	4.3
S-Hemi(3-6)_R	µm	281.0	1.1	1.2	0.4%	3.4	282.1	1.4	1.8	0.6%	5.0	288.3	1.1	1.2	0.4%	3.3
I-Hemi(3-6)_R	µm	274.9	1.2	1.5	0.5%	4.1	275.7	1.2	1.6	0.6%	4.5	282.3	1.2	1.4	0.5%	3.8
All(3-6)_R	µm	277.9	1.0	1.2	0.4%	3.4	278.9	1.2	1.6	0.6%	4.4	285.3	0.9	1.1	0.4%	3.1
S-Hemi(0-6)_R	µm	289.8	1.1	1.2	0.4%	3.4	290.6	1.4	1.8	0.6%	4.9	294.8	1.0	1.2	0.4%	3.4
I-Hemi(0-6)_R	µm	284.6	1.2	1.5	0.5%	4.0	285.3	1.2	1.6	0.6%	4.5	290.0	1.1	1.3	0.5%	3.7
All(0-6)_R	µm	287.2	1.0	1.3	0.4%	3.5	287.9	1.2	1.6	0.6%	4.4	292.4	0.9	1.2	0.4%	3.2
All (0-6)_R_Vol	mm^3	8.114	0.039	0.046	0.6%	0.128	8.136	0.039	0.052	0.6%	0.144	-	-	-	-	-
* Reproducibility Limit = 2.8 x SD of Reproducibility																

Table 15.1.1.2. Repeatability and Reproducibility of the Normal group.

Glaucoma Subjects																
GCC	Unit	AngioVue Retina (n=152 scans)					Retina Cube (n=152 scans)					Wellness (n=160 scans)				
		Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*
GCC		**ETDRS Grid (φ 6mm)**														
C(1)_GCC	µm	50.5	0.6	0.9	1.8%	2.5	50.6	1.2	1.4	2.7%	3.9	56.6	1.8	1.9	3.3%	5.2
T(1-3)_GCC	µm	83.3	0.6	0.9	1.1%	2.5	84.0	0.9	1.1	1.3%	3.0	83.2	1.9	2.0	2.4%	5.6
S(1-3)_GCC	µm	96.6	0.7	0.9	1.0%	2.6	95.9	1.2	1.4	1.5%	4.0	94.5	2.2	2.4	2.5%	6.6
N(1-3)_GCC	µm	95.0	0.5	0.8	0.8%	2.1	94.8	1.0	1.2	1.3%	3.4	94.1	1.1	1.3	1.4%	3.5
I(1-3)_GCC	µm	90.4	0.6	0.9	1.0%	2.5	89.1	1.0	1.2	1.3%	3.3	87.6	1.2	1.3	1.5%	3.7
S-Hemi (1-3)_GCC	µm	93.6	0.6	0.8	0.9%	2.3	93.4	0.9	1.2	1.2%	3.2	92.7	1.8	1.9	2.1%	5.4
I-Hemi (1-3)_GCC	µm	89.1	0.5	0.8	0.9%	2.2	88.5	0.7	1.0	1.1%	2.8	87.4	0.8	1.0	1.1%	2.8
All(1-3)_GCC	µm	91.3	0.4	0.8	0.8%	2.1	91.0	0.6	0.9	1.0%	2.6	90.1	1.2	1.4	1.5%	3.8
T(3-6)_GCC	µm	71.5	0.6	0.7	1.0%	1.9	72.0	0.7	0.8	1.1%	2.1	68.4	0.8	0.9	1.4%	2.6
S(3-6)_GCC	µm	88.4	0.7	0.8	0.9%	2.3	86.9	1.0	1.1	1.3%	3.1	77.8	1.3	1.4	1.7%	3.7
N(3-6)_GCC	µm	97.1	0.5	0.7	0.7%	1.9	96.0	0.8	0.9	0.9%	2.5	92.9	3.0	3.0	3.2%	8.3
I(3-6)_GCC	µm	79.8	0.6	0.7	0.8%	1.9	78.4	0.7	0.7	0.9%	2.0	75.0	1.0	1.0	1.4%	2.8
S-Hemi (3-6)_GCC	µm	87.4	0.6	0.7	0.8%	2.0	86.5	0.8	0.9	1.0%	2.4	79.6	1.0	1.1	1.4%	3.1
I-Hemi (3-6)_GCC	µm	81.1	0.5	0.6	0.7%	1.7	80.2	0.6	0.7	0.8%	1.8	76.7	1.3	1.3	1.7%	3.7
All (3-6)_GCC	µm	84.2	0.4	0.6	0.7%	1.6	83.3	0.5	0.6	0.8%	1.7	78.2	0.7	0.8	1.0%	2.2
S-Hemi (0-6)_GCC	µm	87.7	0.6	0.7	0.8%	2.0	87.0	0.7	0.8	0.9%	2.3	81.8	1.1	1.2	1.5%	3.3
I-Hemi (0-6)_GCC	µm	82.0	0.4	0.6	0.7%	1.7	81.2	0.5	0.7	0.8%	1.8	78.5	0.9	1.0	1.3%	2.9
All (0-6)_GCC	µm	84.9	0.4	0.6	0.7%	1.7	84.1	0.5	0.7	0.8%	1.8	80.2	0.6	0.8	1.0%	2.2
GCC		**6mm x 6mm**										**7mm x 8mm**				
WI_GCC	µm	85.2	0.5	0.6	0.7%	1.7	84.4	0.5	0.6	0.7%	1.7	76.3	0.8	0.9	1.2%	2.4
WI-S-Hemi_GCC	µm	87.8	0.6	0.7	0.8%	2.0	86.9	0.7	0.8	0.9%	2.2	77.1	0.9	1.0	1.3%	2.8
WI-I-Hemi_GCC	µm	82.6	0.5	0.7	0.8%	1.8	81.8	0.6	0.6	0.8%	1.8	75.5	1.3	1.3	1.8%	3.7
FLV_GCC	%	6.022	0.349	0.365	6.2%	1.011	5.797	0.393	0.410	7.3%	1.137	5.434	1.269	1.269	23.4%	3.518
GLV_GCC	%	17.759	0.392	0.514	2.9%	1.426	18.013	0.467	0.549	3.1%	1.523	17.581	0.733	0.853	4.8%	2.364
Retinal Thickness		**ETDRS Grid (φ 6mm)**														
C(1)_R	µm	255.8	1.4	1.9	0.7%	5.2	256.4	1.8	2.2	0.9%	6.0	256.7	2.5	2.8	1.1%	7.8
T(1-3)_R	µm	295.4	1.0	1.4	0.5%	3.8	296.8	1.4	1.6	0.5%	4.3	294.4	4.4	4.6	1.6%	12.7
S(1-3)_R	µm	304.4	1.2	1.5	0.5%	4.2	305.3	1.6	1.9	0.6%	5.1	302.1	3.4	3.8	1.2%	10.4
N(1-3)_R	µm	307.9	1.0	1.4	0.5%	3.8	308.8	1.5	1.8	0.6%	4.9	305.9	1.1	1.6	0.5%	4.4
I(1-3)_R	µm	295.8	1.2	1.4	0.5%	3.9	296.7	1.4	1.6	0.5%	4.5	295.2	2.8	3.0	1.0%	8.3
S-Hemi(1-3)_R	µm	303.9	1.0	1.4	0.5%	3.8	304.6	1.4	1.6	0.5%	4.6	301.6	3.0	3.3	1.1%	9.1
I-Hemi-(1-3)_R	µm	297.9	1.0	1.3	0.4%	3.6	299.1	1.3	1.6	0.5%	4.4	297.1	2.5	2.7	0.9%	7.4
All(1-3)_R	µm	300.9	0.9	1.3	0.4%	3.5	301.9	1.2	1.5	0.5%	4.0	299.4	2.6	2.9	1.0%	8.0
T(3-6)_R	µm	247.2	0.9	1.1	0.4%	3.0	249.4	1.5	1.6	0.7%	4.5	256.3	3.1	3.2	1.3%	8.9
S(3-6)_R	µm	265.5	1.2	1.3	0.5%	3.6	266.4	1.8	2.0	0.7%	5.5	271.4	2.8	3.0	1.1%	8.2
N(3-6)_R	µm	271.4	0.9	1.1	0.4%	3.0	272.8	1.5	1.6	0.6%	4.4	274.7	4.9	4.9	1.8%	13.7
I(3-6)_R	µm	245.0	0.9	1.1	0.4%	2.9	246.2	1.4	1.6	0.7%	4.6	253.3	1.5	1.7	0.7%	4.6
S-Hemi(3-6)_R	µm	264.2	1.0	1.2	0.4%	3.2	265.5	1.5	1.6	0.6%	4.4	269.8	1.9	2.2	0.8%	6.0
I-Hemi(3-6)_R	µm	250.3	0.8	0.9	0.4%	2.6	251.9	1.2	1.4	0.6%	3.9	258.1	1.7	1.7	0.7%	4.8
All(3-6)_R	µm	257.3	0.8	0.9	0.4%	2.6	258.7	1.1	1.3	0.5%	3.6	263.9	1.0	1.2	0.5%	3.4
S-Hemi(0-6)_R	µm	272.8	1.0	1.2	0.4%	3.2	274.0	1.3	1.5	0.6%	4.2	276.5	2.0	2.3	0.8%	6.3
I-Hemi(0-6)_R	µm	261.1	0.8	1.0	0.4%	2.7	262.5	1.2	1.4	0.5%	3.9	266.8	1.2	1.4	0.5%	3.8
All(0-6)_R	µm	267.0	0.8	1.0	0.4%	2.7	268.3	1.1	1.3	0.5%	3.6	271.6	1.1	1.4	0.5%	3.9
All (0-6)_R_Vol	mm^3	7.539	0.026	0.031	0.4%	0.085	7.578	0.032	0.038	0.5%	0.104					
* Reproducibility Limit = 2.8 x SD of Reproducibility																

Table 15.1.1.3. Repeatability and Reproducibility of the Glaucoma group.

Retina Subjects																
GCC	Unit	AngioVue Retina (n=492 scans)					Retina Cube (n=489 scans)					Wellness (n=504 scans)				
		Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*
GCC		**ETDRS Grid (φ 6mm)**														
C(1)_GCC	µm	63.7	1.4	1.5	2.4%	4.2	64.6	2.4	2.4	3.8%	6.7	69.5	2.8	2.9	4.2%	8.1
T(1-3)_GCC	µm	100.2	1.1	1.1	1.1%	3.2	99.7	1.2	1.3	1.3%	3.6	98.6	1.3	1.3	1.3%	3.6
S(1-3)_GCC	µm	112.3	1.4	1.5	1.3%	4.1	111.0	1.6	1.7	1.5%	4.7	108.6	2.0	2.0	1.9%	5.7
N(1-3)_GCC	µm	109.6	1.4	1.5	1.4%	4.1	109.1	1.6	1.7	1.6%	4.7	107.5	2.4	2.5	2.3%	6.8
I(1-3)_GCC	µm	113.4	1.3	1.4	1.2%	3.8	112.1	1.5	1.6	1.4%	4.4	110.2	1.6	1.6	1.5%	4.5
S-Hemi (1-3)_GCC	µm	108.2	1.3	1.3	1.2%	3.7	107.2	1.3	1.4	1.3%	3.8	105.9	1.4	1.5	1.4%	4.0
I-Hemi (1-3)_GCC	µm	109.5	1.2	1.3	1.2%	3.5	108.7	1.3	1.4	1.2%	3.7	107.6	1.4	1.5	1.4%	4.0
All(1-3)_GCC	µm	108.9	0.8	0.9	0.8%	2.6	108.0	0.9	1.0	0.9%	2.6	106.8	1.0	1.1	1.0%	3.0
T(3-6)_GCC	µm	85.6	1.0	1.0	1.1%	2.7	86.1	1.2	1.3	1.5%	3.5	82.4	1.4	1.4	1.8%	4.0
S(3-6)_GCC	µm	102.7	1.1	1.1	1.0%	2.9	100.9	1.3	1.3	1.2%	3.5	94.0	2.3	2.3	2.4%	6.4
N(3-6)_GCC	µm	117.9	1.1	1.6	1.3%	4.4	116.7	1.1	1.8	1.5%	4.9	113.4	3.8	3.9	3.4%	10.8
I(3-6)_GCC	µm	103.6	1.2	1.2	1.2%	3.5	102.3	1.6	1.6	1.6%	4.5	97.4	2.6	2.7	2.7%	7.4
S-Hemi (3-6)_GCC	µm	101.4	0.9	0.9	0.9%	2.4	100.3	1.0	1.0	1.0%	2.7	94.9	2.0	2.1	2.2%	5.7
I-Hemi (3-6)_GCC	µm	103.6	1.1	1.2	1.2%	3.4	102.8	1.3	1.3	1.3%	3.7	98.3	2.3	2.3	2.4%	6.5
All (3-6)_GCC	µm	102.5	0.8	0.8	0.8%	2.3	101.5	0.9	1.0	0.9%	2.7	96.6	1.9	1.9	2.0%	5.3
S-Hemi (0-6)_GCC	µm	101.9	0.8	0.8	0.8%	2.3	100.8	0.9	0.9	0.9%	2.5	96.6	1.6	1.6	1.7%	4.5
I-Hemi (0-6)_GCC	µm	103.8	0.9	1.1	1.1%	3.1	103.1	1.0	1.1	1.1%	3.0	99.6	1.8	1.9	1.9%	5.1
All (0-6)_GCC	µm	102.9	0.7	0.8	0.8%	2.2	102.0	0.8	0.8	0.8%	2.4	98.1	1.4	1.5	1.5%	4.2
GCC		**6mm x 6mm**										**7mm x 8mm**				
WI_GCC	µm	104.1	1.0	1.0	1.0%	2.8	103.1	0.9	0.9	0.9%	2.6	93.1	1.5	1.5	1.7%	4.3
WI-S-Hemi_GCC	µm	102.9	1.0	1.1	1.0%	2.9	101.7	1.1	1.1	1.1%	3.0	92.1	2.0	2.0	2.2%	5.6
WI-I-Hemi_GCC	µm	105.4	1.3	1.3	1.2%	3.7	104.5	1.2	1.2	1.2%	3.4	94.2	1.6	1.6	1.7%	4.6
FLV_GCC	%	1.699	0.223	0.226	12.8%	0.626	1.713	0.223	0.225	12.7%	0.624	1.741	0.405	0.405	23.0%	1.123
GLV_GCC	%	5.489	0.364	0.396	7.2%	1.099	5.547	0.442	0.460	8.2%	1.275	5.586	0.619	0.645	11.5%	1.789
Retinal Thickness		**ETDRS Grid (φ 6mm)**														
C(1)_R	µm	260.7	2.3	2.3	0.9%	6.4	265.7	4.6	4.7	1.8%	12.9	263.3	6.0	6.1	2.3%	16.9
T(1-3)_R	µm	297.7	1.8	2.0	0.7%	5.5	299.6	3.1	3.2	1.1%	8.8	298.9	3.1	3.1	1.0%	8.6
S(1-3)_R	µm	302.1	1.7	1.9	0.6%	5.3	305.1	3.0	3.2	1.0%	8.8	302.1	3.5	3.6	1.2%	10.0
N(1-3)_R	µm	306.1	2.1	2.2	0.7%	6.2	308.6	2.9	3.0	1.0%	8.4	305.5	4.8	4.8	1.6%	13.3
I(1-3)_R	µm	304.6	1.9	2.0	0.7%	5.6	306.7	3.0	3.1	1.0%	8.6	305.3	4.5	4.5	1.5%	12.5
S-Hemi(1-3)_R	µm	301.5	1.4	1.6	0.5%	4.5	304.1	2.2	2.4	0.8%	6.5	301.6	3.0	3.1	1.0%	8.5
I-Hemi-(1-3)_R	µm	303.7	1.6	1.7	0.6%	4.7	305.9	2.4	2.5	0.8%	7.0	304.2	3.6	3.6	1.2%	10.1
All(1-3)_R	µm	302.6	1.1	1.3	0.4%	3.6	305.0	1.4	1.7	0.6%	4.7	302.9	2.6	2.6	0.9%	7.3
T(3-6)_R	µm	257.3	1.5	1.6	0.6%	4.5	259.0	2.1	2.2	0.8%	6.1	268.0	3.3	3.4	1.3%	9.3
S(3-6)_R	µm	270.4	1.3	1.4	0.5%	3.8	272.3	1.9	2.0	0.7%	5.4	277.2	2.5	2.7	1.0%	7.4
N(3-6)_R	µm	285.6	1.4	1.6	0.6%	4.5	286.5	1.5	1.7	0.6%	4.6	285.9	2.0	2.1	0.8%	6.0
I(3-6)_R	µm	265.7	1.4	1.5	0.6%	4.1	267.5	1.8	1.9	0.7%	5.3	272.9	3.3	3.3	1.2%	9.2
S-Hemi(3-6)_R	µm	270.7	1.0	1.1	0.4%	3.2	272.1	1.4	1.5	0.5%	4.0	277.0	1.8	2.0	0.7%	5.5
I-Hemi(3-6)_R	µm	268.9	1.2	1.3	0.5%	3.7	270.4	1.4	1.6	0.6%	4.4	275.0	2.5	2.6	0.9%	7.1
All(3-6)_R	µm	269.8	0.9	1.1	0.4%	3.0	271.3	1.1	1.2	0.5%	3.4	276.0	1.6	1.7	0.6%	4.8
S-Hemi(0-6)_R	µm	277.2	1.0	1.1	0.4%	3.1	279.0	1.3	1.4	0.5%	4.0	282.1	1.5	1.7	0.6%	4.6
I-Hemi(0-6)_R	µm	276.5	1.1	1.2	0.4%	3.4	278.2	1.3	1.5	0.5%	4.2	281.1	2.5	2.6	0.9%	7.1
All(0-6)_R	µm	276.9	0.9	1.1	0.4%	2.9	278.6	1.0	1.2	0.4%	3.4	281.6	1.5	1.6	0.6%	4.5
All (0-6)_R_Vol	mm^3	7.794	0.105	0.107	1.4%	0.298	7.860	0.071	0.073	0.9%	0.203					
* 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 Vessel Density	Unit	n=126 scans					Deep Vessel Density	Unit	n=126 scans				
		Mean	Repeatability	Reproducibility					Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*				SD	SD	CV	Limit*
ETDRS Grid (φ 6mm)		Superficial Slab					ETDRS Grid (φ 6mm)		Deep Slab				
C(1)_SVC	%	28.8	2.5	2.7	9.4%	7.5	C(1)_DVC	%	30.3	3.3	3.3	11.0%	9.2
All (1-3)_SVC	%	51.6	2.4	2.5	4.8%	6.8	All (1-3)_DVC	%	58.1	2.2	2.2	3.9%	6.2
S-Hemi (1-3)_SVC	%	51.6	2.3	2.4	4.6%	6.6	S-Hemi (1-3)_DVC	%	57.8	2.5	2.5	4.4%	7.0
I-Hemi (1-3)_SVC	%	51.7	2.6	2.6	5.1%	7.2	I-Hemi (1-3)_DVC	%	58.4	2.3	2.4	4.0%	6.5
T (1-3)_SVC	%	51.7	2.3	2.4	4.6%	6.5	T (1-3)_DVC	%	57.5	2.3	2.3	4.1%	6.4
S (1-3)_SVC	%	51.9	2.4	2.4	4.7%	6.8	S (1-3)_DVC	%	58.5	2.3	2.4	4.2%	6.8
N (1-3)_SVC	%	50.9	2.8	2.8	5.5%	7.7	N (1-3)_DVC	%	57.5	3.4	3.4	6.0%	9.5
I (1-3)_SVC	%	52.0	2.8	2.8	5.5%	7.9	I (1-3)_DVC	%	58.9	2.6	2.6	4.5%	7.3
All (3-6)_SVC	%	51.1	2.1	2.2	4.3%	6.0	All (3-6)_DVC	%	55.7	3.1	3.2	5.8%	8.9
S-Hemi (3-6)_SVC	%	51.2	2.1	2.2	4.3%	6.2	S-Hemi (3-6)_DVC	%	55.9	3.4	3.6	6.5%	10.0
I-Hemi (3-6)_SVC	%	51.0	2.1	2.2	4.3%	6.1	I-Hemi (3-6)_DVC	%	55.6	3.2	3.2	5.8%	8.9
T (3-6)_SVC	%	47.8	2.2	2.3	4.8%	6.3	T (3-6)_DVC	%	56.2	2.8	2.8	5.0%	7.7
S (3-6)_SVC	%	51.3	2.1	2.3	4.4%	6.3	S (3-6)_DVC	%	55.5	3.8	4.1	7.4%	11.4
N (3-6)_SVC	%	54.6	2.2	2.3	4.2%	6.3	N (3-6)_DVC	%	56.2	3.7	3.8	6.8%	10.6
I (3-6)_SVC	%	50.6	2.1	2.2	4.4%	6.2	I (3-6)_DVC	%	55.0	3.6	3.6	6.6%	10.0
WI_SVC	%	51.3	2.0	2.1	4.1%	5.9	WI_DVC	%	54.5	3.1	3.2	5.8%	8.8
WI-S-Hemi_SVC	%	51.3	2.0	2.1	4.2%	5.9	WI-S-Hemi_DVC	%	54.7	3.3	3.5	6.4%	9.6
WI-I-Hemi_SVC	%	51.3	2.1	2.1	4.2%	5.9	WI-I-Hemi_DVC	%	54.4	3.1	3.1	5.8%	8.7
G11_SVC	%	50.2	2.2	2.3	4.6%	6.3	G11_DVC	%	54.1	3.8	4.0	7.4%	11.0
G12_SVC	%	51.9	2.0	2.1	4.1%	5.9	G12_DVC	%	55.9	3.4	3.7	6.7%	10.3
G13_SVC	%	53.8	2.1	2.2	4.1%	6.1	G13_DVC	%	53.3	5.3	5.4	10.2%	15.0
G21_SVC	%	50.2	2.1	2.2	4.4%	6.2	G21_DVC	%	56.4	2.8	2.8	5.0%	7.7
G22_SVC	%	47.8	2.4	2.4	5.1%	6.8	G22_DVC	%	53.4	2.0	2.1	3.9%	5.7
G23_SVC	%	52.8	2.4	2.5	4.7%	6.9	G23_DVC	%	56.5	3.5	3.6	6.4%	10.1
G31_SVC	%	49.9	2.1	2.2	4.5%	6.2	G31_DVC	%	53.5	3.7	3.7	6.9%	10.2
G32_SVC	%	51.5	2.1	2.2	4.2%	6.0	G32_DVC	%	55.2	3.5	3.5	6.4%	9.8
G33_SVC	%	53.4	2.2	2.2	4.2%	6.2	G33_DVC	%	52.5	4.9	5.1	9.8%	14.2
FAZ Parameters		Retina Slab											
FAZ Area	mm^2	0.257	0.010	0.010	3.9%	0.028							
FAZ Perimeter	mm	1.968	0.055	0.056	2.8%	0.155							
FD-300 Density	%	49.828	2.722	2.722	5.5%	7.545							
* Reproducibility Limit = 2.8 x SD of Reproducibility													

Table 15.1.2.1. Repeatability and Reproducibility of the Normal group.

Glaucoma Subjects													
Superficial Vessel Density	Unit	n=132 scans					Deep Vessel Density	Unit	n=132 scans				
		Mean	Repeatability	Reproducibility					Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*				SD	SD	CV	Limit*
ETDRS Grid (φ 6mm)		Superficial Slab					ETDRS Grid (φ 6mm)		Deep Slab				
C(1)_SVC	%	26.1	2.0	2.3	8.9%	6.4	C(1)_DVC	%	28.9	2.2	2.4	8.3%	6.7
All (1-3)_SVC	%	46.4	2.0	2.2	4.7%	6.0	All (1-3)_DVC	%	54.9	1.9	2.0	3.6%	5.5
S-Hemi (1-3)_SVC	%	46.9	2.1	2.3	5.0%	6.5	S-Hemi (1-3)_DVC	%	55.0	2.2	2.3	4.2%	6.4
I-Hemi (1-3)_SVC	%	46.0	2.0	2.2	4.8%	6.1	I-Hemi (1-3)_DVC	%	54.7	2.3	2.3	4.3%	6.4
T (1-3)_SVC	%	45.8	2.1	2.2	4.8%	6.0	T (1-3)_DVC	%	54.0	2.2	2.2	4.1%	6.2
S (1-3)_SVC	%	47.7	2.2	2.6	5.4%	7.1	S (1-3)_DVC	%	55.8	2.6	2.7	4.9%	7.4
N (1-3)_SVC	%	46.7	2.3	2.4	5.2%	6.7	N (1-3)_DVC	%	54.6	2.5	2.5	4.6%	6.9
I (1-3)_SVC	%	45.6	2.3	2.5	5.5%	6.9	I (1-3)_DVC	%	55.1	3.1	3.1	5.7%	8.7
All (3-6)_SVC	%	44.4	1.6	1.8	4.2%	5.1	All (3-6)_DVC	%	52.3	2.8	3.0	5.8%	8.3
S-Hemi (3-6)_SVC	%	45.4	1.7	1.9	4.2%	5.3	S-Hemi (3-6)_DVC	%	53.5	2.9	3.1	5.8%	8.5
I-Hemi (3-6)_SVC	%	43.4	1.6	1.9	4.3%	5.2	I-Hemi (3-6)_DVC	%	51.0	3.2	3.4	6.6%	9.3
T (3-6)_SVC	%	42.2	1.8	2.0	4.7%	5.5	T (3-6)_DVC	%	52.7	2.8	2.8	5.3%	7.7
S (3-6)_SVC	%	45.3	1.6	1.9	4.3%	5.4	S (3-6)_DVC	%	53.3	3.2	3.5	6.6%	9.7
N (3-6)_SVC	%	47.7	1.8	2.0	4.2%	5.6	N (3-6)_DVC	%	53.1	3.4	3.8	7.1%	10.4
I (3-6)_SVC	%	42.5	1.7	1.9	4.5%	5.3	I (3-6)_DVC	%	50.0	3.7	3.9	7.8%	10.8
WI_SVC	%	44.5	1.6	1.8	4.0%	5.0	WI_DVC	%	51.1	2.5	2.8	5.5%	7.7
WI-S-Hemi_SVC	%	45.4	1.6	1.9	4.1%	5.1	WI-S-Hemi_DVC	%	52.0	2.6	3.0	5.7%	8.2
WI-I-Hemi_SVC	%	43.6	1.6	1.8	4.1%	5.0	WI-I-Hemi_DVC	%	50.1	2.8	3.0	5.9%	8.2
G11_SVC	%	45.8	1.7	1.9	4.2%	5.3	G11_DVC	%	50.8	3.4	3.9	7.8%	10.9
G12_SVC	%	45.8	1.7	2.0	4.3%	5.4	G12_DVC	%	53.4	3.3	3.6	6.8%	10.0
G13_SVC	%	44.8	1.6	1.9	4.1%	5.2	G13_DVC	%	50.8	4.0	4.3	8.6%	12.0
G21_SVC	%	45.8	1.9	2.2	4.7%	6.0	G21_DVC	%	53.7	2.9	3.1	5.8%	8.6
G22_SVC	%	43.2	1.9	2.2	5.0%	6.0	G22_DVC	%	50.5	1.8	1.8	3.6%	5.1
G23_SVC	%	45.4	1.8	1.9	4.2%	5.3	G23_DVC	%	52.8	2.9	3.0	5.6%	8.3
G31_SVC	%	44.3	1.8	1.9	4.3%	5.2	G31_DVC	%	48.8	4.3	4.6	9.5%	12.7
G32_SVC	%	43.0	1.8	1.9	4.5%	5.4	G32_DVC	%	50.5	3.7	3.8	7.5%	10.5
G33_SVC	%	42.2	1.7	1.9	4.6%	5.3	G33_DVC	%	48.3	3.7	3.8	8.0%	10.6
FAZ Parameters		Retina Slab											
FAZ Area	mm^2	0.282	0.014	0.014	4.9%	0.039							
FAZ Perimeter	mm	2.057	0.073	0.073	3.5%	0.202							
FD-300 Density	%	47.483	2.618	2.783	5.9%	7.715							
* Reproducibility Limit = 2.8 x SD of Reproducibility													

Table 15.1.2.2. Repeatability and Reproducibility of the Glaucoma group.

Retina Subjects													
Superficial Vessel Density	Unit	n=406 scans					Deep Vessel Density	Unit	n=406 scans				
		Mean	Repeatability	Reproducibility					Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*				SD	SD	CV	Limit*
ETDRS Grid (φ 6mm)		Superficial Slab					ETDRS Grid (φ 6mm)		Deep Slab				
C(1)_SVC	%	30.0	2.2	2.8	9.2%	7.6	C(1)_DVC	%	29.6	2.6	2.7	9.2%	7.5
All (1-3)_SVC	%	47.6	2.0	2.3	4.8%	6.3	All (1-3)_DVC	%	51.6	2.6	2.7	5.2%	7.5
S-Hemi (1-3)_SVC	%	47.5	2.0	2.3	4.8%	6.3	S-Hemi (1-3)_DVC	%	51.2	2.8	2.9	5.8%	8.2
I-Hemi (1-3)_SVC	%	47.7	2.2	2.3	4.9%	6.5	I-Hemi (1-3)_DVC	%	51.9	2.9	3.0	5.8%	8.3
T (1-3)_SVC	%	47.2	2.0	2.2	4.7%	6.1	T (1-3)_DVC	%	51.2	2.8	2.8	5.6%	7.9
S (1-3)_SVC	%	48.0	2.3	2.5	5.2%	6.9	S (1-3)_DVC	%	51.7	3.6	3.7	7.2%	10.2
N (1-3)_SVC	%	47.0	2.5	2.6	5.6%	7.3	N (1-3)_DVC	%	50.9	3.4	3.4	6.7%	9.4
I (1-3)_SVC	%	48.3	2.3	2.6	5.3%	7.1	I (1-3)_DVC	%	52.4	3.4	3.5	6.6%	9.6
All (3-6)_SVC	%	47.9	1.7	1.8	3.9%	5.1	All (3-6)_DVC	%	49.9	3.3	3.5	7.0%	9.6
S-Hemi (3-6)_SVC	%	48.0	1.7	1.9	4.1%	5.4	S-Hemi (3-6)_DVC	%	50.6	3.2	3.5	6.9%	9.6
I-Hemi (3-6)_SVC	%	47.7	1.7	1.8	3.9%	5.1	I-Hemi (3-6)_DVC	%	49.2	3.7	3.8	7.9%	10.7
T (3-6)_SVC	%	44.3	1.9	2.1	4.7%	5.8	T (3-6)_DVC	%	50.8	2.9	2.9	5.8%	8.2
S (3-6)_SVC	%	48.4	1.8	2.0	4.2%	5.6	S (3-6)_DVC	%	50.3	3.6	3.9	7.7%	10.7
N (3-6)_SVC	%	51.2	1.9	2.0	3.9%	5.5	N (3-6)_DVC	%	50.2	4.5	4.7	9.4%	13.0
I (3-6)_SVC	%	47.6	1.7	1.8	3.8%	5.0	I (3-6)_DVC	%	48.4	4.2	4.3	8.9%	11.9
WI_SVC	%	48.1	1.7	1.8	3.9%	5.1	WI_DVC	%	48.8	3.0	3.2	6.7%	9.0
WI-S-Hemi_SVC	%	48.2	1.7	1.9	4.0%	5.3	WI-S-Hemi_DVC	%	49.3	3.1	3.4	7.0%	9.5
WI-I-Hemi_SVC	%	47.9	1.7	1.8	3.8%	5.1	WI-I-Hemi_DVC	%	48.3	3.3	3.4	7.1%	9.4
G11_SVC	%	47.6	1.8	2.0	4.3%	5.6	G11_DVC	%	48.5	4.1	4.6	9.5%	12.7
G12_SVC	%	48.9	1.9	2.1	4.3%	5.7	G12_DVC	%	50.6	3.5	3.9	7.8%	10.8
G13_SVC	%	50.4	1.8	1.9	3.8%	5.3	G13_DVC	%	48.4	4.5	5.5	11.2%	15.2
G21_SVC	%	46.9	2.0	2.2	4.6%	6.0	G21_DVC	%	50.9	3.3	3.4	6.7%	9.4
G22_SVC	%	44.8	2.1	2.4	5.4%	6.7	G22_DVC	%	47.8	2.5	2.6	5.6%	7.3
G23_SVC	%	49.2	2.0	2.1	4.3%	5.8	G23_DVC	%	50.5	3.8	3.8	7.6%	10.5
G31_SVC	%	47.3	1.9	1.9	4.1%	5.3	G31_DVC	%	47.1	4.2	4.4	9.4%	12.1
G32_SVC	%	47.9	1.8	1.9	4.0%	5.2	G32_DVC	%	48.5	4.2	4.3	8.9%	11.9
G33_SVC	%	49.7	1.8	1.9	3.9%	5.3	G33_DVC	%	46.9	4.1	4.3	9.2%	11.8
FAZ Parameters		Retina Slab											
FAZ Area	mm^2	0.288	0.017	0.017	6.0%	0.048							
FAZ Perimeter	mm	2.074	0.114	0.114	5.6%	0.317							
FD-300 Density	%	47.104	2.224	2.391	5.1%	6.627							
* 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=134 scans)					Disc Cube (n=123 scans)				
		Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*
RNFL		φ2.5 ~ φ4.5 mm Ring									
TS_RNFL	μm	62.9	1.3	1.3	2.0%	3.6	63.6	1.6	1.6	2.5%	4.4
ST_RNFL	μm	119.5	1.9	1.9	1.6%	5.3	118.4	2.2	2.2	1.9%	6.0
SN_RNFL	μm	107.8	1.7	1.7	1.5%	4.6	107.2	2.1	2.1	2.0%	5.9
NS_RNFL	μm	94.7	1.3	1.3	1.3%	3.5	94.2	1.5	1.5	1.6%	4.1
NI_RNFL	μm	75.1	1.2	1.4	1.9%	3.9	75.1	1.5	1.7	2.2%	4.7
IN_RNFL	μm	122.3	1.7	1.8	1.5%	5.1	121.6	2.4	2.4	1.9%	6.5
IT_RNFL	μm	134.3	1.6	1.9	1.4%	5.2	133.3	2.0	2.2	1.7%	6.1
TI_RNFL	μm	55.2	1.1	1.2	2.2%	3.4	55.7	1.6	1.6	3.0%	4.5
T_RNFL	μm	59.3	0.8	0.8	1.3%	2.2	60.0	1.1	1.1	1.8%	3.0
S_RNFL	μm	113.1	1.0	1.1	0.9%	2.9	112.3	1.5	1.5	1.3%	4.2
N_RNFL	μm	86.0	0.9	1.0	1.1%	2.7	85.7	1.0	1.1	1.3%	3.1
I_RNFL	μm	127.6	0.9	0.9	0.7%	2.6	126.7	1.4	1.4	1.1%	3.9
S-Hemi_RNFL	μm	95.1	0.6	0.6	0.6%	1.6	94.7	0.9	0.9	0.9%	2.4
I-Hemi_RNFL	μm	96.4	0.7	0.7	0.7%	1.9	96.1	0.9	0.9	0.9%	2.5
PP_RNFL	μm	95.7	0.5	0.5	0.5%	1.4	95.4	0.7	0.7	0.7%	1.9
ONH		Within Disc Margin									
CupArea	mm^2	0.322	0.008	0.009	2.7%	0.024	0.308	0.018	0.020	6.6%	0.056
RimArea	mm^2	1.664	0.032	0.046	2.7%	0.126	1.680	0.041	0.047	2.8%	0.132
CupVolume	mm^3	0.155	0.004	0.004	2.8%	0.012	0.146	0.011	0.011	7.6%	0.031
C/D Area Ratio	mm^2	0.33	0.01	0.01	3.8%	0.03	0.32	0.01	0.01	3.5%	0.03
C/D H Ratio	mm^2	0.34	0.01	0.01	2.6%	0.02	0.31	0.02	0.02	5.3%	0.05
C/D V Ratio	mm^2	0.053	0.002	0.002	3.5%	0.005	0.050	0.004	0.004	8.9%	0.012
* 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=153 scans)					Disc Cube (n=142 scans)				
		Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*
RNFL		φ2.5 ~ φ4.5 mm Ring									
TS_RNFL	μm	54.9	1.0	1.0	1.7%	2.6	55.3	1.5	1.5	2.7%	4.2
ST_RNFL	μm	77.0	1.0	1.0	1.3%	2.8	75.5	2.0	2.0	2.7%	5.6
SN_RNFL	μm	66.8	1.3	1.3	2.0%	3.7	65.7	1.7	1.7	2.6%	4.8
NS_RNFL	μm	59.0	1.2	1.2	2.0%	3.3	59.6	1.4	1.4	2.3%	3.8
NI_RNFL	μm	54.6	1.4	1.5	2.8%	4.2	54.6	1.8	1.9	3.5%	5.3
IN_RNFL	μm	77.4	1.2	1.2	1.6%	3.5	76.2	2.1	2.1	2.8%	5.9
IT_RNFL	μm	77.8	1.6	1.7	2.1%	4.6	77.7	1.9	1.9	2.4%	5.2
TI_RNFL	μm	46.8	1.0	1.0	2.0%	2.7	47.5	1.2	1.2	2.5%	3.3
T_RNFL	μm	51.2	0.8	0.8	1.5%	2.1	51.7	1.1	1.1	2.2%	3.1
S_RNFL	μm	71.5	0.9	0.9	1.3%	2.5	70.2	1.4	1.4	2.0%	3.9
N_RNFL	μm	57.0	1.0	1.0	1.7%	2.8	57.4	1.2	1.3	2.2%	3.5
I_RNFL	μm	77.5	0.7	0.7	0.9%	1.9	76.8	1.3	1.3	1.6%	3.5
S-Hemi_RNFL	μm	63.4	0.7	0.7	1.1%	1.9	63.1	0.9	1.0	1.5%	2.7
I-Hemi_RNFL	μm	64.1	0.5	0.6	0.9%	1.6	63.9	0.9	1.0	1.5%	2.7
PP_RNFL	μm	63.7	0.5	0.5	0.8%	1.4	63.5	0.8	0.8	1.2%	2.2
ONH		Within Disc Margin									
CupArea	mm^2	0.802	0.015	0.018	2.2%	0.049	0.782	0.029	0.031	3.8%	0.085
RimArea	mm^2	0.991	0.044	0.053	5.3%	0.147	1.018	0.055	0.064	6.4%	0.177
CupVolume	mm^3	0.436	0.011	0.012	2.7%	0.033	0.421	0.018	0.019	4.3%	0.051
C/D Area Ratio	mm^2	0.63	0.02	0.02	3.9%	0.07	0.64	0.03	0.03	5.3%	0.10
C/D H Ratio	mm^2	0.69	0.02	0.02	2.4%	0.05	0.66	0.03	0.03	4.6%	0.08
C/D V Ratio	mm^2	0.221	0.006	0.006	2.6%	0.016	0.206	0.011	0.011	5.3%	0.032
* 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=469 scans)					Disc Cube (n=416 scans)				
		Mean	Repeatability	Reproducibility			Mean	Repeatability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*
RNFL		φ2.5 ~ φ4.5 mm Ring									
TS_RNFL	µm	67.1	1.6	1.6	2.4%	4.5	66.6	2.0	2.0	2.9%	5.5
ST_RNFL	µm	116.0	2.1	2.1	1.8%	5.8	112.8	2.7	2.7	2.4%	7.4
SN_RNFL	µm	100.9	2.0	2.0	2.0%	5.6	99.2	2.8	2.8	2.8%	7.7
NS_RNFL	µm	85.2	1.3	1.3	1.6%	3.7	85.0	2.1	2.1	2.5%	5.9
NI_RNFL	µm	70.2	1.5	1.7	2.5%	4.8	69.1	1.8	1.9	2.8%	5.3
IN_RNFL	µm	107.7	2.5	2.6	2.4%	7.1	105.7	3.6	3.6	3.4%	10.1
IT_RNFL	µm	126.4	2.4	2.5	2.0%	7.0	123.5	3.0	3.3	2.7%	9.1
TI_RNFL	µm	64.2	2.2	2.2	3.4%	6.2	63.8	2.1	2.2	3.4%	6.0
T_RNFL	µm	65.8	1.3	1.3	2.0%	3.6	65.3	1.4	1.4	2.2%	4.0
S_RNFL	µm	107.8	1.2	1.3	1.2%	3.5	105.4	2.0	2.0	1.9%	5.5
N_RNFL	µm	78.5	1.0	1.0	1.3%	2.8	77.9	1.5	1.5	1.9%	4.1
I_RNFL	µm	116.0	1.8	1.8	1.5%	4.9	113.5	2.5	2.5	2.2%	7.0
S-Hemi_RNFL	µm	90.6	0.8	0.8	0.9%	2.3	89.4	1.3	1.3	1.4%	3.5
I-Hemi_RNFL	µm	91.3	1.2	1.2	1.3%	3.3	89.7	1.4	1.5	1.6%	4.0
PP_RNFL	µm	90.9	0.8	0.8	0.8%	2.1	89.5	1.0	1.0	1.2%	2.9
ONH		Within Disc Margin									
CupArea	mm^2	0.248	0.010	0.010	3.9%	0.027	0.225	0.017	0.018	7.6%	0.049
RimArea	mm^2	1.491	0.032	0.039	2.6%	0.107	1.495	0.036	0.041	2.7%	0.112
CupVolume	mm^3	0.131	0.005	0.006	4.3%	0.015	0.116	0.011	0.011	9.3%	0.031
C/D Area Ratio	mm^2	0.27	0.01	0.01	4.5%	0.03	0.25	0.04	0.04	15.7%	0.11
C/D H Ratio	mm^2	0.28	0.01	0.01	4.2%	0.03	0.25	0.03	0.03	11.7%	0.08
C/D V Ratio	mm^2	0.049	0.003	0.003	5.7%	0.008	0.042	0.004	0.004	8.9%	0.011
* 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 1.11 summarizes the results of the R&R analysis of the RPC vessel density measurements from the AngioVue Disc scan and the Disc Cube scan.

RPC Vessel Density	Unit	Normal Subjects (n=134 scans)					Glaucoma Subjects (n=141 scans)					Retina Subjects (n=412 scans)				
		Mean	Repeat ability	Reproducibility			Mean	Repeat ability	Reproducibility			Mean	Repeat ability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*
Measurement Region		φ2.5 ~ φ4.5 mm Ring														
PP_RPC_All	%	57.4	1.3	1.3	2.2%	3.6	48.8	1.3	1.3	2.7%	3.6	54.7	1.2	1.2	0.0	3.4
PP_RPC_Sml	%	50.9	1.3	1.4	2.7%	3.7	42.0	1.4	1.4	3.4%	3.9	48.3	1.4	1.4	0.0	3.9
S-Hemi_RPC_All	%	57.7	1.4	1.4	2.4%	3.8	49.0	1.4	1.4	2.9%	4.0	54.8	1.3	1.3	0.0	3.6
I-Hemi_RPC_All	%	57.0	1.3	1.3	2.3%	3.7	48.6	1.4	1.4	2.9%	3.9	54.6	1.3	1.3	0.0	3.7
S-Hemi_RPC_Sml	%	50.8	1.5	1.5	2.9%	4.1	42.0	1.6	1.6	3.8%	4.4	48.1	1.5	1.5	0.0	4.1
I-Hemi_RPC_Sml	%	50.9	1.4	1.4	2.8%	3.9	41.9	1.5	1.5	3.6%	4.2	48.4	1.5	1.5	0.0	4.2
NS_RPC_Sml	%	47.7	1.8	1.8	3.8%	5.0	37.4	1.9	2.0	5.3%	5.5	44.6	1.9	1.9	0.0	5.3
NI_RPC_Sml	%	47.5	1.8	1.8	3.9%	5.1	40.6	2.1	2.2	5.3%	6.0	44.8	2.2	2.2	0.0	6.1
IN_RPC_Sml	%	48.4	2.0	2.1	4.3%	5.8	38.5	2.1	2.1	5.3%	5.7	44.7	2.0	2.1	0.0	5.8
IT_RPC_Sml	%	54.5	1.9	2.0	3.6%	5.5	40.0	2.2	2.2	5.6%	6.1	52.8	2.2	2.2	0.0	6.2
TI_RPC_Sml	%	54.7	1.8	1.8	3.3%	4.9	48.9	2.1	2.1	4.4%	5.9	53.0	2.0	2.0	0.0	5.7
TS_RPC_Sml	%	56.7	1.7	1.8	3.1%	4.9	52.3	2.2	2.2	4.1%	6.0	54.7	1.9	1.9	0.0	5.4
ST_RPC_Sml	%	52.4	2.3	2.3	4.4%	6.4	44.0	2.3	2.3	5.3%	6.4	50.6	2.1	2.1	0.0	5.7
SN_RPC_Sml	%	47.3	2.1	2.3	4.8%	6.2	35.1	2.0	2.0	5.7%	5.6	43.5	2.0	2.0	0.0	5.7
Measurement Region		6mm x 6mm														
WI_RPC_All	%	55.1	1.2	1.3	2.3%	3.6	47.9	1.3	1.3	2.8%	3.7	52.9	1.2	1.2	0.0	3.3
WI_RPC_Sml	%	48.9	1.3	1.3	2.6%	3.5	41.3	1.3	1.4	3.4%	3.8	46.5	1.3	1.3	0.0	3.5
G11_RPC_All	%	55.3	1.8	1.8	3.3%	5.0	46.0	1.7	1.9	4.1%	5.2	53.0	1.7	1.7	0.0	4.6
G12_RPC_All	%	55.5	1.5	1.6	2.8%	4.3	45.4	1.8	2.0	4.4%	5.5	52.0	1.7	1.7	0.0	4.8
G13_RPC_All	%	52.7	1.4	1.5	2.9%	4.3	46.6	1.8	1.9	4.2%	5.4	50.5	1.6	1.6	0.0	4.6
G21_RPC_All	%	54.0	1.6	1.6	2.9%	4.4	49.7	1.6	1.7	3.3%	4.6	53.0	1.8	1.8	0.0	4.9
G22_RPC_All	%	60.5	2.0	2.4	3.9%	6.6	54.3	1.8	2.1	3.8%	5.8	59.1	1.8	1.9	0.0	5.3
G23_RPC_All	%	54.0	1.6	1.6	3.0%	4.5	50.2	1.8	1.9	3.7%	5.2	52.1	1.6	1.7	0.0	4.7
G31_RPC_All	%	54.8	1.7	1.7	3.0%	4.6	44.2	1.8	1.8	4.1%	5.0	52.5	1.7	1.7	0.0	4.6
G32_RPC_All	%	56.4	1.7	1.7	2.9%	4.6	47.4	1.7	1.7	3.7%	4.8	53.6	1.8	1.8	0.0	5.1
G33_RPC_All	%	52.9	1.8	1.9	3.6%	5.3	47.6	1.9	1.9	4.0%	5.3	50.0	1.7	2.4	0.0	6.7
Measurement Region		Inside Disc Margin														
Disc_All	%	59.5	3.2	4.2	7.0%	11.6	55.0	2.6	3.2	5.8%	8.8	57.4	2.4	2.9	0.1	8.0
Disc_Sml	%	48.7	3.3	4.5	9.2%	12.4	44.4	2.8	3.4	7.7%	9.5	45.8	2.6	3.3	0.1	9.1
* Reproducibility Limit = 2.8 x SD of Reproducibility																

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

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. One of the clinical sites was also the R&R study site. Fundus image quality grading was performed at a 3rd party image reading center. Enrollment criteria was the same as that of the R&R study. 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 agreement, the study eye is imaged three times for each relevant OCT and OCTA scan pattern with each of the devices in the comparison set. 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; Agreement was evaluated with calculation of 95% limits of agreement (LOAs) and Deming regression analyses for OCT and OCTA scans; Non-inferiority of 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 126 participants were consented and enrolled, including 33 normal subjects (“Normal” group) 34 with glaucoma (“Glaucoma” group), and 59 with retinal conditions (“Retina” group); the 59 Retina subjects were the same subjects in the R&R study. One participant from the Normal group and another from the Retina group could not complete the required imaging; three subjects enrolled in the Glaucoma group were disqualified due to no signs of visual field damage and no signs of optic nerve damage. Therefore, 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.

For OCT and OCTA scans, up to 3 repeats per scan pattern were acquired per subject (eye) per comparison device. For Solix, the percentage of subjects that qualified (i.e., with at least one qualified scan per scan type) for structural analysis was over 96% (for the 5 OCT and OCTA scan patterns) and at least 92% for vascular analysis (for the 2 OCTA scan types). For Avanti, the percentage of subjects that qualified (i.e., with at least one qualified scan) for structural and vascular analysis (for the 2 OCTA scan patterns) was over 96% and 88%, respectively.

One qualified scan per subject per device was included in the agreement analysis. For Solix, the percentage of subjects for which the *1st scan* was acceptable quality was at least 84% for structural analysis (across all 5 scan types) and at least 81% for vascular analysis (for the 2 OCTA scan types). For Avanti, the percentages of subjects for which the *1st scan* was acceptable quality for structural and vascular analysis (for the 2 OCTA scan types) was at least 76% and 72%, respectively.

Across all 5 study scan types and across all study groups, the maximum manual editing rates for segmentation boundaries were: ILM editing rate was <3.4% for Solix and <2.5% for Avanti, IPL editing rate was <1% for Solix and 22.9% for Avanti, RPE editing rate was 0% for Solix and 8.5% for Avanti, BRM editing rate was 1.7% for Solix and 11% for Avanti, NFL editing rate was <1% for Solix and 10.3% for Avanti. The foveal center detection correction rate was <3.4% for Solix and 5.1% for Avanti. The FAZ boundary manual editing rate was 10.9% for Solix and 7.6% for Avanti. The disc margin manual editing rate was 13.6% for Solix and 22.2% for Avanti.

15.2.1 **Agreement Results - GCC and Retinal Thickness**

Tables 15.2.1.1 through 15.2.1.3 summarize the results of the R&R analysis of the GCC measurements from AngioVue Retina, Retina Cube, and Wellness scans.

AngioVue Retina		Normal (n=32 subjects)						Glaucoma (n=30 subjects)						Retina (n=55 subjects)					
		Solix	Avanti	Difference				Solix	Avanti	Difference				Solix	Avanti	Difference			
		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA	
GCC		φ6 mm ETDRS Grid																	
C(1)_GCC	µm	56.4	57.4	-0.9	2.0	-4.7	2.9	49.3	48.5	0.8	1.7	-2.6	4.1	63.9	63.7	0.3	4.2	-8.1	8.6
T(1-3)_GCC	µm	102.4	103.0	-0.6	1.9	-4.2	3.1	81.5	80.9	0.6	1.6	-2.6	3.8	100.2	101.3	-1.1	3.3	-7.5	5.3
S(1-3)_GCC	µm	114.4	112.6	1.8	1.9	-1.9	5.5	95.4	92.8	2.6	1.6	-0.5	5.6	112.8	110.7	2.2	2.6	-2.9	7.2
N(1-3)_GCC	µm	111.5	111.2	0.4	2.0	-3.6	4.3	93.4	91.8	1.6	2.0	-2.3	5.5	110.0	109.7	0.3	3.1	-5.7	6.2
I(1-3)_GCC	µm	114.0	112.8	1.3	2.3	-3.2	5.7	88.9	85.7	3.1	1.4	0.5	5.8	114.0	112.6	1.4	2.8	-4.1	6.9
T(3-6)_GCC	µm	83.5	84.1	-0.6	1.8	-4.2	2.9	71.5	70.4	1.2	1.7	-2.1	4.5	85.9	86.4	-0.5	2.4	-5.2	4.2
S(3-6)_GCC	µm	99.4	97.8	1.6	1.3	-1.0	4.2	85.5	83.2	2.3	2.0	-1.6	6.1	103.5	101.4	2.1	2.1	-2.2	6.3
N(3-6)_GCC	µm	116.1	115.6	0.4	1.4	-2.3	3.2	95.7	94.9	0.8	1.8	-2.7	4.2	118.1	117.6	0.5	2.5	-4.4	5.3
I(3-6)_GCC	µm	98.5	96.9	1.6	2.7	-3.7	6.8	78.9	75.5	3.5	1.6	0.3	6.6	104.5	103.4	1.1	4.6	-7.9	10.2
All(0-6)_GCC	µm	100.7	100.0	0.7	1.2	-1.7	3.1	83.5	81.6	1.9	0.8	0.3	3.5	103.4	102.4	1.0	1.7	-2.5	4.4
GCC		6mm x 6mm																	
WI_GCC	µm	101.9	100.0	1.9	1.2	-0.5	4.4	83.8	81.2	2.7	1.2	0.3	5.1	104.9	102.4	2.5	4.4	-6.1	11.1
WI-S-Hemi_GCC	µm	101.2	99.2	2.0	1.3	-0.6	4.6	85.9	83.0	2.9	1.4	0.2	5.6	103.6	100.8	2.7	4.4	-6.0	11.4
WI-I-Hemi_GCC	µm	102.6	100.7	1.9	1.7	-1.5	5.3	81.7	79.2	2.5	1.8	-1.0	6.1	106.2	104.1	2.1	4.6	-7.0	11.2
Retinal Thickness		φ6 mm ETDRS Grid																	
C(1)_R	µm	258.7	257.4	1.4	3.1	-4.8	7.5	254.1	256.1	-2.0	5.3	-12.5	8.4	263.0	271.0	-7.9	7.9	-23.5	7.6
T(1-3)_R	µm	314.7	315.7	-1.1	3.2	-7.4	5.3	294.2	297.5	-3.3	3.6	-10.5	3.8	299.4	308.7	-9.3	6.9	-22.7	4.2
S(1-3)_R	µm	328.6	328.3	0.2	2.8	-5.2	5.7	307.0	309.3	-2.3	3.9	-9.9	5.3	303.2	310.9	-7.7	5.8	-19.0	3.6
N(1-3)_R	µm	329.2	329.4	-0.2	2.9	-5.8	5.5	309.4	311.9	-2.4	3.8	-9.8	5.0	306.9	314.8	-7.9	7.8	-23.1	7.4
I(1-3)_R	µm	322.9	324.1	-1.2	2.4	-5.9	3.6	296.8	299.7	-2.9	3.3	-9.4	3.6	304.8	313.1	-8.3	6.2	-20.4	3.9
T(3-6)_R	µm	264.0	267.0	-3.0	3.1	-9.1	3.0	249.7	253.2	-3.6	3.7	-10.7	3.6	258.5	266.3	-7.8	5.0	-17.7	2.0
S(3-6)_R	µm	281.9	283.6	-1.7	2.5	-6.6	3.2	265.4	268.8	-3.4	3.5	-10.2	3.4	271.8	278.9	-7.1	5.4	-17.7	3.4
N(3-6)_R	µm	297.3	299.3	-2.1	3.4	-8.7	4.6	275.3	278.3	-2.9	2.9	-8.7	2.8	286.8	294.2	-7.4	5.3	-17.8	3.0
I(3-6)_R	µm	268.1	271.4	-3.3	2.5	-8.3	1.6	246.8	250.8	-4.1	3.0	-9.9	1.8	266.8	274.7	-7.9	4.3	-16.3	0.5
All(0-6)_R	µm	287.5	289.5	-2.0	2.2	-6.4	2.4	268.6	272.0	-3.3	3.1	-9.4	2.7	278.5	286.3	-7.7	3.8	-15.2	-0.2

Table 15.2.1.1. Agreement between Solix AngioVue Retina scan and Avanti HD AngioRetina scan.

Retina Cube		Normal (n=32 subjects)						Glaucoma (n=30 subjects)						Retina (n=53 subjects)					
		Solix	Avanti	Difference				Solix	Avanti	Difference				Solix	Avanti	Difference			
		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA	
GCC		φ6 mm ETDRS Grid																	
C(1)_GCC	µm	57.1	57.4	-0.3	2.1	-4.5	3.9	49.3	48.5	0.8	2.3	-3.8	5.4	65.1	64.0	1.1	5.9	-10.4	12.7
T(1-3)_GCC	µm	103.5	103.0	0.5	1.7	-2.8	3.9	82.1	80.9	1.2	2.0	-2.8	5.2	99.9	101.4	-1.5	4.3	-10.1	7.0
S(1-3)_GCC	µm	113.8	112.6	1.2	1.9	-2.4	4.9	94.5	92.8	1.7	2.5	-3.3	6.7	111.4	110.5	0.9	4.6	-8.1	9.9
N(1-3)_GCC	µm	111.9	111.2	0.7	1.8	-2.7	4.2	93.6	91.8	1.8	2.6	-3.3	6.8	109.3	109.5	-0.2	5.8	-11.6	11.2
I(1-3)_GCC	µm	113.7	112.8	1.0	2.0	-3.0	5.0	87.9	85.7	2.2	2.0	-1.7	6.1	112.7	112.4	0.3	4.7	-8.9	9.5
T(3-6)_GCC	µm	84.2	84.1	0.1	1.6	-3.0	3.2	71.8	70.4	1.4	1.7	-1.9	4.8	86.7	86.5	0.2	3.4	-6.5	7.0
S(3-6)_GCC	µm	98.6	97.8	0.9	1.6	-2.3	4.1	84.4	83.2	1.1	2.1	-2.9	5.2	101.6	101.4	0.3	3.7	-7.0	7.5
N(3-6)_GCC	µm	115.7	115.6	0.0	1.2	-2.4	2.4	94.7	94.9	-0.2	2.1	-4.3	3.8	116.9	117.7	-0.8	3.5	-7.6	6.0
I(3-6)_GCC	µm	97.5	96.9	0.6	2.7	-4.7	5.9	77.7	75.5	2.2	1.7	-1.1	5.4	103.0	103.3	-0.4	4.6	-9.3	8.6
All(0-6)_GCC	µm	100.4	100.0	0.5	1.2	-1.8	2.8	82.9	81.6	1.3	0.9	-0.5	3.0	102.5	102.5	0.0	2.5	-5.0	5.0
GCC		6mm x 6mm																	
WI_GCC	µm	101.6	100.0	1.7	1.3	-0.8	4.2	83.2	81.2	2.1	1.2	-0.2	4.4	103.6	101.9	1.7	2.6	-3.4	6.8
WI-S-Hemi_GCC	µm	101.0	99.2	1.8	1.4	-1.0	4.6	85.4	83.0	2.3	1.3	-0.3	5.0	102.2	100.2	1.9	2.6	-3.2	7.1
WI-I-Hemi_GCC	µm	102.3	100.7	1.5	1.6	-1.7	4.8	81.1	79.2	1.9	1.6	-1.3	5.1	105.1	103.6	1.5	3.7	-5.8	8.9
Retinal Thickness		φ6 mm ETDRS Grid																	
C(1)_R	µm	257.4	257.4	0.0	3.1	-6.0	6.0	254.6	256.1	-1.5	5.3	-11.9	9.0	271.5	276.2	-4.7	9.0	-22.4	13.0
T(1-3)_R	µm	314.4	315.7	-1.4	3.2	-7.7	5.0	295.7	297.5	-1.9	4.2	-10.1	6.3	301.3	309.5	-8.2	8.9	-25.6	9.1
S(1-3)_R	µm	327.4	328.3	-0.9	2.9	-6.7	4.9	307.7	309.3	-1.5	3.8	-9.0	5.9	307.4	313.9	-6.5	6.4	-19.1	6.2
N(1-3)_R	µm	328.1	329.4	-1.3	2.8	-6.8	4.3	309.8	311.9	-2.1	4.0	-10.0	5.8	311.4	317.4	-6.0	8.5	-22.6	10.6
I(1-3)_R	µm	322.2	324.1	-1.9	2.9	-7.6	3.8	297.5	299.7	-2.2	3.4	-8.9	4.5	308.8	315.0	-6.3	7.9	-21.7	9.2
T(3-6)_R	µm	264.5	267.0	-2.5	3.5	-9.4	4.4	251.6	253.2	-1.6	3.6	-8.6	5.4	260.7	266.3	-5.6	5.9	-17.1	5.9
S(3-6)_R	µm	282.1	283.6	-1.5	2.6	-6.5	3.6	266.4	268.8	-2.4	4.3	-10.9	6.1	273.9	279.7	-5.8	5.3	-16.2	4.6
N(3-6)_R	µm	296.9	299.3	-2.4	2.8	-7.9	3.1	276.0	278.3	-2.3	3.5	-9.0	4.5	288.1	294.6	-6.5	5.5	-17.3	4.3
I(3-6)_R	µm	268.0	271.4	-3.4	2.5	-8.2	1.5	247.2	250.8	-3.6	2.6	-8.7	1.4	269.1	275.3	-6.2	4.1	-14.2	1.8
All(0-6)_R	µm	287.4	289.5	-2.2	2.3	-6.6	2.2	269.6	272.0	-2.4	3.1	-8.4	3.7	280.4	286.6	-6.2	4.1	-14.2	1.8

Table 15.2.1.2. Agreement between Solix Retina Cube scan and Avanti HD AngioRetina scan.

Wellness		Normal (n=32 subjects)						Glaucoma (n=30 subjects)						Retina (n=55 subjects)					
		Solix	Avanti	Difference				Solix	Avanti	Difference				Solix	Avanti	Difference			
		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA	
GCC		φ6 mm ETDRS Grid																	
C(1)_GCC	µm	63.4	57.4	6.0	2.3	1.6	10.5	54.6	48.5	6.1	2.6	1.0	11.2	69.4	63.3	6.1	7.9	-9.4	21.6
T(1-3)_GCC	µm	102.6	103.0	-0.4	1.7	-3.7	2.9	81.6	80.9	0.7	2.1	-3.5	4.9	98.8	100.9	-2.1	5.1	-12.2	7.9
S(1-3)_GCC	µm	111.3	112.6	-1.3	2.7	-6.6	4.0	92.9	92.8	0.1	4.5	-8.8	8.9	109.1	110.1	-1.0	5.9	-12.6	10.6
N(1-3)_GCC	µm	111.1	111.2	-0.1	1.8	-3.6	3.3	92.7	91.8	0.9	2.9	-4.8	6.7	107.3	109.2	-1.9	5.8	-13.3	9.5
I(1-3)_GCC	µm	110.5	112.8	-2.2	2.6	-7.3	2.9	86.3	85.7	0.6	4.8	-8.9	10.1	110.5	111.9	-1.4	6.1	-13.4	10.6
T(3-6)_GCC	µm	80.1	84.1	-4.1	1.4	-6.8	-1.3	68.5	70.4	-1.9	2.3	-6.3	2.6	82.4	86.1	-3.7	3.1	-9.9	2.4
S(3-6)_GCC	µm	91.9	97.8	-5.8	3.9	-13.5	1.9	75.9	83.2	-7.3	4.4	-16.0	1.4	94.1	101.2	-7.1	5.6	-18.1	3.9
N(3-6)_GCC	µm	112.5	115.6	-3.2	1.6	-6.3	0.0	90.8	94.9	-4.1	2.9	-9.7	1.5	113.0	117.3	-4.2	4.5	-13.0	4.5
I(3-6)_GCC	µm	94.6	96.9	-2.3	4.5	-11.1	6.5	74.3	75.5	-1.1	3.7	-8.4	6.1	97.3	102.6	-5.3	7.5	-20.1	9.4
All(0-6)_GCC	µm	96.9	100.0	-3.0	1.7	-6.3	0.2	78.9	81.6	-2.7	2.0	-6.5	1.2	98.2	102.2	-4.0	3.7	-11.3	3.3
GCC		7mm x 8mm																	
WI_GCC	µm	91.8	100.0	-8.2	2.1	-12.3	-4.1	75.4	81.2	-5.8	3.0	-11.7	0.2	93.2	102.1	-8.8	5.2	-19.0	1.3
WI-S-Hemi_GCC	µm	91.1	99.2	-8.1	2.6	-13.1	-3.1	76.2	83.0	-6.8	3.6	-13.9	0.3	92.2	100.7	-8.5	5.6	-19.5	2.4
WI-I-Hemi_GCC	µm	92.5	100.7	-8.3	2.5	-13.2	-3.4	74.5	79.2	-4.7	3.4	-11.3	1.9	94.3	103.4	-9.1	5.8	-20.4	2.2
Retinal Thickness		φ6 mm ETDRS Grid																	
C(1)_R	µm	258.0	257.4	0.7	3.0	-5.3	6.6	253.9	256.1	-2.2	4.5	-10.9	6.6	264.4	271.9	-7.4	9.0	-25.2	10.3
T(1-3)_R	µm	313.6	315.7	-2.1	3.6	-9.2	4.9	293.2	297.5	-4.3	3.4	-11.1	2.4	298.9	307.3	-8.5	6.8	-21.9	4.9
S(1-3)_R	µm	326.2	328.3	-2.1	3.5	-8.9	4.7	304.6	309.3	-4.7	3.5	-11.6	2.2	303.4	311.4	-8.0	5.5	-18.8	2.8
N(1-3)_R	µm	326.2	329.4	-3.2	2.8	-8.7	2.3	307.2	311.9	-4.7	3.4	-11.4	2.0	306.0	315.3	-9.2	7.6	-24.1	5.6
I(1-3)_R	µm	321.9	324.1	-2.2	3.2	-8.5	4.1	296.4	299.7	-3.3	3.6	-10.3	3.6	305.4	313.3	-7.9	7.0	-21.5	5.7
T(3-6)_R	µm	275.8	267.0	8.8	3.8	1.3	16.2	259.3	253.2	6.0	4.5	-2.9	14.9	269.1	266.0	3.1	10.0	-16.6	22.8
S(3-6)_R	µm	290.1	283.6	6.5	3.5	-0.3	13.3	272.8	268.8	4.0	4.8	-5.5	13.4	277.8	278.8	-0.9	9.5	-19.5	17.6
N(3-6)_R	µm	298.7	299.3	-0.7	4.5	-9.5	8.2	278.0	278.3	-0.2	4.4	-8.8	8.3	286.7	293.9	-7.3	9.1	-25.0	10.5
I(3-6)_R	µm	276.4	271.4	5.0	4.0	-2.9	12.8	255.3	250.8	4.4	4.0	-3.4	12.2	273.7	274.1	-0.4	8.0	-16.1	15.3
All(0-6)_R	µm	292.6	289.5	3.1	2.8	-2.4	8.6	273.5	272.0	1.6	3.4	-5.1	8.2	282.2	285.3	-3.2	6.1	-15.1	8.8

Table 15.2.1.3. Agreement between Solix Wellness scan and Avanti HD AngioRetina scan.

15.2.2 Agreement Results – Superficial & Deep Vessel Density and FAZ

Table 15.2.2 summarizes the results of the agreement analysis of the superficial (SVC) vessel density, Deep (DVC) vessel density, and FAZ measurements from AngioVue Retina scan.

AngioVue Retina		Normal (n=32 subjects)						Glaucoma (n=27 subjects)						Retina (n=43 subjects)					
		Solix	Avanti	Difference				Solix	Avanti	Difference				Solix	Avanti	Difference			
		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA	
Superficial Vessel Density		Superficial Slab (φ6 mm ETDRS Grid)																	
C(1)_SVC	%	29.5	21.7	**7.8**	3.9	0.2	15.4	26.4	17.6	**8.8**	4.1	0.7	16.8	30.5	22.0	**8.4**	4.4	-0.2	17.1
T (1-3)_SVC	%	51.8	53.0	-1.2	2.8	-6.7	4.3	45.4	44.8	0.6	3.9	-7.1	8.3	47.5	46.9	0.6	4.4	-8.1	9.3
S (1-3)_SVC	%	53.0	53.5	-0.5	3.0	-6.4	5.3	47.5	47.5	0.0	3.5	-6.9	6.9	48.6	48.1	0.6	4.5	-8.3	9.4
N (1-3)_SVC	%	51.7	52.3	-0.6	3.2	-6.8	5.5	46.4	46.6	-0.2	3.4	-6.9	6.4	47.8	47.2	0.6	4.5	-8.2	9.4
I (1-3)_SVC	%	53.1	53.8	-0.7	4.1	-8.6	7.3	45.8	45.4	0.4	3.8	-7.0	7.9	49.0	49.0	-0.1	4.1	-8.0	7.9
T (3-6)_SVC	%	48.0	46.8	1.2	2.8	-4.3	6.7	42.1	40.1	2.0	3.4	-4.6	8.7	44.8	42.5	2.3	3.4	-4.3	9.0
S (3-6)_SVC	%	51.9	51.0	0.9	2.8	-4.5	6.4	45.0	43.5	1.5	3.1	-4.6	7.6	48.9	47.0	1.9	3.8	-5.6	9.3
N (3-6)_SVC	%	55.5	55.3	0.2	3.0	-5.7	6.1	47.6	46.9	0.6	3.0	-5.2	6.5	51.5	51.4	0.1	3.6	-6.9	7.2
I (3-6)_SVC		51.2	51.1	0.1	3.2	-6.1	6.3	42.9	41.8	1.1	3.3	-5.2	7.5	48.0	47.3	0.7	3.1	-5.3	6.6
All (0-6)_SVC	%	51.2	50.7	0.5	2.6	-4.7	5.7	44.3	43.0	1.3	2.8	-4.2	6.8	47.8	46.5	1.3	3.3	-5.0	7.7
Superficial Vessel Density		Superficial Slab, Solix (6.4mm x 6.4mm), Avanti (6mm x 6mm)																	
WI_SVC	%	51.8	50.6	1.2	2.5	-3.7	6.1	44.5	42.8	1.7	2.8	-3.9	7.3	48.7	46.7	2.0	3.2	-4.2	8.2
WI-S-Hemi_SVC	%	51.8	50.5	1.3	2.5	-3.6	6.2	45.2	43.4	1.8	2.9	-3.9	7.5	48.9	46.6	2.3	3.4	-4.4	9.0
WI-I-Hemi_SVC	%	51.8	50.6	1.2	2.7	-4.1	6.4	43.8	42.1	1.6	2.9	-4.1	7.4	48.4	46.8	1.6	3.0	-4.1	7.4
Deep Vessel Density		Deep Slab (φ6 mm ETDRS Grid)																	
C(1)_DVC	%	30.5	39.5	**-9.0**	4.9	-18.5	0.5	29.7	35.7	**-5.9**	4.2	-14.2	2.4	29.9	36.5	**-6.6**	5.0	-16.4	3.3
T (1-3)_DVC	%	57.4	57.1	0.2	4.0	-7.6	8.0	53.8	54.5	-0.7	5.6	-11.7	10.3	52.1	51.8	0.3	5.0	-9.5	10.0
S (1-3)_DVC	%	59.8	54.6	5.1	5.2	-5.1	15.4	55.8	54.6	1.3	3.7	-6.0	8.6	52.4	50.8	1.6	5.8	-9.7	12.9
N (1-3)_DVC	%	57.9	57.3	0.7	4.6	-8.3	9.6	54.8	55.1	-0.3	4.1	-8.4	7.7	52.1	52.2	-0.1	5.0	-9.9	9.8
I (1-3)_DVC	%	60.0	54.9	5.1	5.4	-5.5	15.8	55.6	54.0	1.6	5.9	-9.9	13.2	53.2	50.8	2.3	5.3	-8.1	12.8
T (3-6)_DVC	%	56.6	55.7	0.9	5.5	-9.9	11.6	52.2	53.1	-0.8	5.2	-11.0	9.3	51.5	51.2	0.3	5.0	-9.4	10.0
S (3-6)_DVC	%	56.7	52.2	4.5	6.3	-7.9	16.9	53.3	51.7	1.6	3.6	-5.5	8.6	51.8	47.6	4.2	7.7	-10.9	19.3
N (3-6)_DVC	%	57.7	51.4	6.3	6.9	-7.3	19.8	54.3	51.8	2.5	4.5	-6.4	11.4	52.3	47.5	4.8	6.9	-8.7	18.3
I (3-6)_DVC	%	56.1	52.1	4.0	6.9	-9.6	17.6	51.5	50.4	1.1	5.1	-8.8	11.1	49.6	48.2	1.5	6.2	-10.8	13.7
All (0-6)_DVC	%	56.5	53.2	3.3	5.3	-7.0	13.6	52.7	51.9	0.8	3.5	-6.2	7.7	50.9	48.9	2.1	5.1	-8.0	12.1
Deep Vessel Density		Deep Slab, Solix (6.4mm x 6.4mm), Avanti (6mm x 6mm)																	
WI_DVC	%	55.8	51.7	4.1	5.2	-6.1	14.3	51.5	50.7	0.8	3.4	-6.0	7.5	50.2	47.9	2.4	5.0	-7.4	12.2
WI-S-Hemi_DVC	%	55.9	51.7	4.2	5.4	-6.4	14.8	52.1	51.1	1.0	3.2	-5.2	7.2	50.9	47.8	3.0	5.4	-7.6	13.7
WI-I-Hemi_DVC	%	55.8	51.8	4.0	5.5	-6.9	14.8	51.0	50.4	0.6	4.4	-8.1	9.2	49.5	48.0	1.6	5.1	-8.5	11.6
FAZ		Retina Slab																	
FAZ Area	mm^2	0.26	0.25	0.01	0.01	-0.02	0.04	0.29	0.28	0.01	0.02	-0.03	0.05	0.29	0.28	0.01	0.03	-0.04	0.06
FAZ Perimeter	mm	1.96	1.91	0.05	0.09	-0.12	0.22	2.05	2.03	0.02	0.12	-0.21	0.26	2.06	2.05	0.01	0.16	-0.31	0.33
FD-300 Density	%	50.6	54.6	-4.1	3.4	-10.7	2.5	48.2	51.6	-3.4	3.6	-10.5	3.6	47.8	49.3	-1.6	3.8	-9.0	5.9

Table 15.2.2. Agreement between Solix AngioVue Retina scan and Avanti HD AngioRetina scan.

Difference was noted for the foveal vessel density C(1)_SVC and C(1)_DVC, with Solix measured higher than Avanti for SVC, and Solix measured lower than Avanti for DVC. Due to the converging of SVC and DVC towards fovea, small difference in ILM and IPL segmentation boundaries could affect noise characteristics inside FAZ; also, the enhanced 3D-PAR in Solix further reduces the projection tail which could lead to less OCTA signal in the Deep slab near the FAZ where the slabs converge. In some of the Solix cases, due to higher signal strength as compared to their Avanti counterpart, more

small vessels were visible in Solix image which also contributed to the higher C(1)_SVC measurement.

15.2.3 **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=32 subjects)						Glaucoma (n=31 subjects)						Retina (n=54 subjects)					
		Solix	Avanti	Difference				Solix	Avanti	Difference				Solix	Avanti	Difference			
		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA	
RNFL		Peripapillary Ring, Solix (φ2.5 ~ φ4.5 mm), Avanti (φ2.0 ~ φ4.0 mm)																	
TS_RNFL	µm	68.9	78.1	-9.2	4.7	-18.5	0.0	52.8	62.7	-9.9	4.8	-19.3	-0.6	67.3	76.3	-9.0	5.7	-20.1	2.2
ST_RNFL	µm	124.5	131.5	-7.0	4.5	-15.8	1.8	75.7	85.4	-9.7	5.3	-20.1	0.7	116.0	123.9	-8.0	7.8	-23.3	7.4
SN_RNFL	µm	103.9	120.2	-16.3	6.8	-29.7	-2.9	69.9	78.9	-9.0	6.1	-21.1	3.0	101.3	116.9	-15.5	7.0	-29.3	-1.8
NS_RNFL	µm	87.7	103.6	-15.9	6.5	-28.7	-3.0	62.8	72.4	-9.6	7.0	-23.4	4.1	85.3	99.6	-14.3	8.0	-30.0	1.5
NI_RNFL	µm	67.1	85.3	-18.1	7.2	-32.3	-3.9	55.3	68.7	-13.3	10.2	-33.3	6.7	70.3	86.1	-15.8	8.3	-32.0	0.5
IN_RNFL	µm	113.3	136.8	**-23.5**	7.7	-38.7	-8.4	76.7	90.5	**-13.8**	6.8	-27.2	-0.4	106.7	128.9	**-22.2**	9.2	-40.3	-4.1
IT_RNFL	µm	134.1	143.0	-8.9	6.4	-21.4	3.6	77.4	83.2	-5.9	5.4	-16.5	4.8	126.8	132.4	-5.6	8.1	-21.5	10.4
TI_RNFL	µm	61.2	71.0	-9.8	5.7	-20.9	1.3	44.9	54.8	-9.9	5.4	-20.4	0.7	64.0	71.9	-7.8	6.0	-19.6	4.0
T_RNFL	µm	65.4	74.8	-9.5	2.8	-14.9	-4.0	49.2	59.0	-9.9	4.3	-18.2	-1.5	65.8	74.2	-8.4	5.0	-18.3	1.4
S_RNFL	µm	113.2	125.3	-12.1	3.9	-19.8	-4.4	72.5	81.9	-9.4	4.9	-18.9	0.2	108.0	120.1	-12.1	6.1	-24.0	-0.2
N_RNFL	µm	78.6	95.4	-16.9	6.2	-29.0	-4.8	59.5	70.8	-11.3	7.6	-26.3	3.7	78.7	93.6	-14.9	7.5	-29.7	-0.2
I_RNFL	µm	122.5	139.5	-17.0	5.3	-27.4	-6.6	77.0	87.3	-10.3	4.6	-19.3	-1.3	115.6	130.4	-14.8	6.5	-27.7	-2.0
S-Hemi_RNFL	µm	94.2	106.9	-12.7	3.1	-18.8	-6.6	64.6	74.2	-9.6	3.8	-17.0	-2.1	90.8	102.9	-12.1	4.5	-21.0	-3.3
I-Hemi_RNFL	µm	92.9	108.7	-15.7	4.2	-24.1	-7.4	63.6	74.7	-11.1	4.5	-19.8	-2.3	91.1	104.7	-13.6	5.0	-23.3	-3.9
PP_RNFL	µm	93.6	107.8	**-14.2**	3.3	-20.6	-7.7	64.1	74.5	**-10.3**	3.4	-17.0	-3.6	90.9	103.8	**-12.8**	4.2	-21.0	-4.7
ONH		Within Disc Margin																	
DiscArea	mm^2	1.92	1.85	0.07	0.12	-0.16	0.30	1.98	1.88	0.10	0.14	-0.18	0.38	1.74	1.72	0.01	0.08	-0.14	0.17
CupArea	mm^2	0.28	0.25	0.03	0.05	-0.07	0.13	0.91	0.81	0.10	0.07	-0.03	0.22	0.25	0.22	0.02	0.05	-0.07	0.12
RimArea	mm^2	1.64	1.61	0.04	0.12	-0.20	0.27	1.08	1.07	0.01	0.12	-0.22	0.23	1.49	1.50	-0.01	0.09	-0.19	0.17
C/D-Area-Ratio	-	0.14	0.13	0.01	0.03	-0.04	0.06	0.44	0.41	0.03	0.02	-0.02	0.07	0.13	0.12	0.01	0.03	-0.05	0.07
C/D-H-Ratio	-	0.32	0.29	0.03	0.08	-0.12	0.18	0.62	0.59	0.03	0.04	-0.04	0.10	0.27	0.24	0.02	0.05	-0.07	0.12
C/D-V-Ratio	-	0.33	0.32	0.01	0.06	-0.10	0.12	0.67	0.63	0.03	0.08	-0.12	0.19	0.28	0.27	0.02	0.05	-0.07	0.11
CupVolume	mm^3	0.05	0.04	0.01	0.02	-0.03	0.04	0.25	0.21	0.04	0.04	-0.04	0.12	0.05	0.04	0.01	0.02	-0.02	0.04

Table 15.2.3.1. Agreement between Solix AngioVue Disc scan and Avanti HD AngioDisc scan.

Disc Cube		Normal (n=32 subjects)						Glaucoma (n=31 subjects)						Retina (n=53 subjects)					
		Solix	Avanti	Difference				Solix	Avanti	Difference				Solix	Avanti	Difference			
		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA	
RNFL		Peripapillary Ring, Solix (φ2.5 ~ φ4.5 mm), Avanti (φ2.0 ~ φ4.0 mm)																	
TS_RNFL	µm	69.5	78.1	-8.6	4.5	-17.4	0.1	53.3	62.7	-9.4	5.3	-19.8	1.0	66.5	75.9	-9.4	5.8	-20.7	1.9
ST_RNFL	µm	122.0	131.5	-9.4	4.6	-18.5	-0.4	74.5	85.4	-10.9	4.8	-20.4	-1.4	112.5	123.6	-11.1	7.0	-24.9	2.7
SN_RNFL	µm	104.4	120.2	-15.8	6.6	-28.7	-2.8	69.0	78.9	-9.9	6.1	-21.8	1.9	99.7	115.7	-16.0	7.1	-30.0	-2.0
NS_RNFL	µm	88.9	103.6	-14.7	8.1	-30.5	1.1	63.0	72.4	-9.5	6.4	-22.1	3.1	84.8	99.2	-14.4	7.9	-30.0	1.1
NI_RNFL	µm	67.8	85.3	-17.5	6.7	-30.6	-4.4	55.0	68.7	-13.6	9.5	-32.3	5.0	69.5	85.6	-16.2	8.5	-32.8	0.5
IN_RNFL	µm	112.8	136.8	**-24.0**	7.1	-37.8	-10.1	75.2	90.5	**-15.4**	8.9	-32.9	2.1	105.7	128.7	**-23.0**	10.7	-43.9	-2.0
IT_RNFL	µm	132.0	143.0	-11.0	6.1	-23.0	1.0	74.8	83.2	-8.4	5.4	-19.1	2.2	122.8	132.3	-9.5	8.4	-26.0	6.9
TI_RNFL	µm	62.2	71.0	-8.9	5.7	-20.0	2.3	45.1	54.8	-9.7	5.5	-20.4	1.0	63.8	71.8	-8.0	6.6	-21.0	5.0
T_RNFL	µm	66.1	74.8	-8.7	2.6	-13.9	-3.5	49.5	59.0	-9.5	4.5	-18.4	-0.6	65.2	74.0	-8.8	5.2	-18.9	1.4
S_RNFL	µm	112.4	125.3	-12.9	4.5	-21.7	-4.1	71.5	81.9	-10.4	4.9	-20.1	-0.7	105.5	119.3	-13.8	6.0	-25.5	-2.1
N_RNFL	µm	79.5	95.4	-15.9	6.8	-29.3	-2.5	59.4	70.8	-11.3	6.8	-24.7	2.1	78.0	93.2	-15.2	7.5	-29.9	-0.5
I_RNFL	µm	121.3	139.5	-18.2	5.1	-28.2	-8.3	75.0	87.3	-12.3	5.2	-22.5	-2.2	113.2	130.2	-17.0	7.1	-30.9	-3.2
S-Hemi_RNFL	µm	94.4	106.9	-12.5	4.1	-20.5	-4.6	64.3	74.2	-9.9	3.7	-17.2	-2.5	89.4	102.4	-13.0	4.5	-21.8	-4.3
I-Hemi_RNFL	µm	92.7	108.7	-16.0	3.7	-23.4	-8.7	62.6	74.7	-12.1	4.6	-21.3	-3.0	89.6	104.4	-14.8	5.3	-25.2	-4.5
PP_RNFL	µm	93.6	107.8	**-14.2**	3.3	-20.7	-7.7	63.5	74.5	**-11.0**	3.3	-17.5	-4.4	89.5	103.4	**-13.9**	4.2	-22.1	-5.7
ONH		Within Disc Margin																	
DiscArea	mm^2	1.91	1.85	0.05	0.11	-0.16	0.26	1.97	1.88	0.09	0.14	-0.18	0.37	1.72	1.71	0.01	0.08	-0.15	0.17
CupArea	mm^2	0.27	0.25	0.02	0.05	-0.08	0.12	0.90	0.81	0.09	0.08	-0.06	0.25	0.23	0.23	0.01	0.03	-0.05	0.07
RimArea	mm^2	1.64	1.61	0.03	0.11	-0.17	0.24	1.07	1.07	0.00	0.11	-0.21	0.21	1.48	1.48	0.00	0.09	-0.17	0.18
C/D-Area-Ratio	-	0.14	0.13	0.01	0.03	-0.05	0.06	0.44	0.41	0.03	0.03	-0.03	0.09	0.12	0.12	0.00	0.02	-0.03	0.04
C/D-H-Ratio	-	0.32	0.29	0.03	0.08	-0.13	0.19	0.64	0.59	0.05	0.05	-0.05	0.14	0.26	0.24	0.01	0.05	-0.08	0.11
C/D-V-Ratio	-	0.31	0.32	-0.01	0.06	-0.13	0.11	0.65	0.63	0.02	0.08	-0.13	0.17	0.26	0.27	-0.01	0.04	-0.09	0.08
CupVolume	mm^3	0.04	0.04	0.00	0.02	-0.03	0.04	0.24	0.21	0.03	0.04	-0.05	0.12	0.05	0.04	0.00	0.01	-0.02	0.02

Table 15.2.3.2. Agreement between Solix Disc Cube scan and Avanti HD AngioDisc 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.

15.2.4 **Agreement Results – RPC Vessel Density**

Table 15.2.4 summarizes the agreement results for RPC vessel density measurements for the AngioVue Disc scan.

AngioVue Disc		Normal (n=32 subjects)						Glaucoma (n=30 subjects)						Retina (n=48 subjects)					
		Solix	Avanti	Difference				Solix	Avanti	Difference				Solix	Avanti	Difference			
		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA	
RPC Vessel Density		RPC Slab, Peripapillary Ring, Solix (φ2.5 ~ φ4.5 mm), Avanti (φ2.0 ~ φ4.0 mm)																	
PP_RPC_All	%	56.3	57.8	**-1.5**	2.6	-6.5	3.5	48.7	46.6	**2.1**	3.0	-3.9	8.1	54.5	55.5	**-1.0**	2.0	-4.9	3.0
PP_RPC_Sml	%	49.6	51.5	-1.9	2.7	-7.2	3.4	41.6	40.1	1.5	3.0	-4.5	7.5	47.9	49.3	-1.4	2.2	-5.8	3.0
S-Hemi_RPC_All	%	56.7	58.4	-1.7	2.6	-6.8	3.4	49.0	47.2	1.8	3.3	-4.8	8.3	54.7	55.8	-1.1	2.1	-5.1	2.9
I-Hemi_RPC_All	%	55.9	57.2	-1.2	2.8	-6.7	4.2	48.4	45.9	2.5	3.1	-3.6	8.6	54.3	55.2	-0.8	2.3	-5.3	3.6
S-Hemi_RPC_Sml	%	49.6	51.8	-2.3	2.7	-7.6	3.1	41.6	40.4	1.2	3.4	-5.5	7.9	47.8	49.4	-1.7	2.3	-6.1	2.8
I-Hemi_RPC_Sml	%	49.5	51.0	-1.5	3.0	-7.5	4.4	41.5	39.7	1.9	3.3	-4.7	8.4	48.1	49.2	-1.1	2.6	-6.2	3.9
NS_RPC_Sml	%	46.4	48.8	-2.4	3.3	-8.9	4.1	37.7	37.9	-0.3	3.6	-7.3	6.8	44.2	46.5	-2.3	3.4	-9.0	4.4
NI_RPC_Sml	%	46.0	45.6	0.3	3.5	-6.6	7.3	40.7	37.3	3.5	3.7	-3.8	10.7	44.2	44.1	0.1	3.8	-7.3	7.6
IN_RPC_Sml	%	46.7	50.9	**-4.1**	4.7	-13.4	5.1	37.4	38.2	**-0.7**	5.4	-11.4	9.9	44.4	48.8	**-4.5**	3.8	-11.9	2.9
IT_RPC_Sml	%	53.2	57.6	-4.4	4.2	-12.6	3.8	39.4	39.6	-0.2	4.4	-8.8	8.3	52.8	55.9	-3.1	4.3	-11.5	5.4
TI_RPC_Sml	%	53.7	52.2	1.5	3.4	-5.1	8.2	48.7	44.2	4.5	5.0	-5.3	14.2	52.8	50.2	2.6	3.4	-4.0	9.2
TS_RPC_Sml	%	56.0	56.1	-0.2	3.7	-7.4	7.1	50.8	48.8	2.0	4.6	-7.0	11.0	54.4	53.3	1.0	3.2	-5.2	7.2
ST_RPC_Sml	%	50.7	54.9	-4.2	3.3	-10.6	2.3	42.1	41.0	1.1	4.8	-8.3	10.6	50.7	53.3	-2.6	3.8	-10.1	4.9
SN_RPC_Sml	%	46.0	48.8	-2.8	3.5	-9.7	4.0	36.4	34.0	2.4	4.2	-5.8	10.6	43.0	45.9	-2.9	3.7	-10.1	4.4
RPC Vessel Density		RPC Slab, Solix (6 mm x 6 mm), Avanti (4.5mm x 4.5mm)																	
WI_RPC_All	%	54.6	56.0	-1.3	2.2	-5.6	3.0	48.0	45.9	2.1	2.8	-3.4	7.7	52.7	53.8	-1.1	1.9	-4.9	2.7
WI_RPC_Sml	%	48.1	49.5	-1.4	2.4	-6.0	3.3	41.2	39.4	1.8	2.8	-3.7	7.2	46.3	47.5	-1.2	2.0	-5.1	2.6
Disc Vessel Density		RPC Slab, Within Disc Margin																	
Disc_All	%	62.1	60.3	1.8	3.4	-4.9	8.4	56.1	54.7	1.5	4.3	-7.0	9.9	57.9	58.5	-0.6	3.8	-8.1	6.9
Disc_Sml	%	51.9	50.9	1.0	3.6	-6.0	8.0	45.9	47.0	-1.2	4.9	-10.7	8.4	46.3	49.3	-3.0	4.7	-12.1	6.1

Table 15.2.4. Agreement between Solix AngioVue Disc scan and Avanti HD AngioDisc scan.

15.2.5 **Fundus Image Quality Non-Inferiority Evaluation**

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 (all 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 73 participants were consented and enrolled (16 Normal, 12 Contact Lens, 14 Dry Eye, 13 post-LRS, 18 KCN). A total of 8 subjects were excluded as follows: 3 in the normal group due to pathology or cataract surgery, and 5 subjects due to prior cataract surgery consisting of 1 in dry eye subgroup, 1 in post_LRS subgroup, and 3 in KCN subgroup. Therefore, a total of 65 subjects qualified and completed the study, and analysis was based on all groups combined (13 Normal subjects and 52 Cornea subjects consisting of, 12 Contact Lens, 13 Dry Eye, 12 Post-LRS, 15 KCN.

Of the 65 eligible subjects, 34 (52%) participants were female and 31 (48%) participants were male; the age distribution was 48.8±18.3 (mean±SD), ranging from 18 to 78; and, 61 (94%) participants were Caucasian.

Of the 12 Contact Lens subjects, the average duration of contact lens wear was 21.75 years, ranging from 10 to 53 years, and the average length of daily wear was 14.17 hours, ranging from 9 to 18 hours.

The 13 subjects with dry eye consisted of 4 mild, 6 moderate, and 3 severe cases. The distribution of OSDI score was 40.6±20.0 (mean±SD), ranging from 10.4 to 85.4; and, the distribution of TBUT was 4.5±3.2 sec. (mean±SD), ranging from 1.5 sec. to 10 sec.

Of the 12 Post-LRS subjects, 5 had LASIK procedure and 7 had PRK procedure. All 12 subjects had myopic correction.

The 15 KCN subjects consisted of 4 mild, 5 moderate, and 6 severe cases. The distribution of steep K was 49.14±5.98 D (mean±SD), ranging from 41.38D to 64.95D.

Of 581 scans acquired, 45 scans (9.1%) were excluded from R&R analysis due to scan quality issues. Out of 532 scans qualified for final R&R analysis, 54 (10.2%) required manual edits for segmentation boundaries.

15.3.1 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=109 scans)																
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	SD	CV	Limit*
C_2	µm	54.4	0.9	1.0	1.8%	2.8	538.1	1.9	3.1	0.6%	8.5	483.6	1.7	2.6	0.5%	7.3
T_2_5	µm	54.1	0.9	1.1	2.0%	3.0	545.5	2.7	3.5	0.6%	9.7	491.3	2.9	3.3	0.7%	9.1
ST_2_5	µm	53.0	1.1	1.3	2.4%	3.5	559.6	4.7	5.1	0.9%	14.1	506.5	5.1	5.2	1.0%	14.4
S_2_5	µm	52.7	1.2	1.3	2.5%	3.6	574.1	5.7	6.6	1.1%	18.2	521.4	5.9	6.5	1.3%	18.1
SN_2_5	µm	54.0	1.0	1.1	2.1%	3.1	575.5	5.2	6.5	1.1%	18.1	521.4	5.2	6.2	1.2%	17.2
N_2_5	µm	54.8	1.0	1.1	2.0%	3.0	567.0	4.5	5.6	1.0%	15.4	512.1	4.3	5.3	1.0%	14.6
IN_2_5	µm	55.6	0.9	1.1	1.9%	2.9	560.7	4.7	5.4	1.0%	15.1	505.0	4.5	5.0	1.0%	13.9
I_2_5	µm	56.0	0.9	1.0	1.8%	2.7	554.4	4.3	5.1	0.9%	14.0	498.4	4.1	4.6	0.9%	12.8
IT_2_5	µm	55.4	0.9	1.0	1.9%	2.9	545.7	3.1	4.3	0.8%	12.0	490.3	2.8	3.8	0.8%	10.4
T_5_7	µm	53.8	1.0	1.2	2.2%	3.2	575.4	4.8	5.5	1.0%	15.3	521.5	5.0	5.5	1.1%	15.3
ST_5_7	µm	51.5	1.3	1.5	2.8%	4.1	601.3	6.7	7.2	1.2%	19.9	549.7	7.3	7.5	1.4%	20.7
S_5_7	µm	50.7	1.5	1.7	3.3%	4.7	625.8	7.1	8.2	1.3%	22.7	575.0	7.5	8.2	1.4%	22.9
SN_5_7	µm	53.3	1.4	1.4	2.7%	4.0	625.3	6.6	7.5	1.2%	20.7	571.9	6.5	7.2	1.3%	19.9
N_5_7	µm	54.6	0.9	1.0	1.8%	2.7	608.9	5.9	6.8	1.1%	18.8	554.3	5.7	6.4	1.2%	17.8
IN_5_7	µm	55.1	0.8	0.9	1.6%	2.5	601.9	6.2	6.9	1.1%	19.1	546.7	6.0	6.5	1.2%	18.1
I_5_7	µm	55.5	0.7	0.8	1.5%	2.2	594.5	6.2	6.9	1.2%	19.1	538.9	6.1	6.7	1.2%	18.5
IT_5_7	µm	55.4	0.8	0.9	1.6%	2.5	578.4	5.5	6.9	1.2%	19.1	522.9	5.4	6.6	1.3%	18.4
T_7_9	µm	53.6	1.1	1.2	2.2%	3.3	614.6	7.3	8.0	1.3%	22.1	561.0	7.7	8.2	1.5%	22.7
ST_7_9	µm	49.5	1.4	1.5	3.0%	4.1	649.0	9.1	9.5	1.5%	26.3	599.5	9.8	10.0	1.7%	27.7
S_7_9	µm	47.9	1.9	1.9	3.9%	5.2	680.6	14.5	14.7	2.2%	40.7	632.6	14.7	14.8	2.3%	41.1
SN_7_9	µm	51.8	1.5	1.5	2.9%	4.2	669.6	8.8	9.2	1.4%	25.5	617.8	8.9	9.2	1.5%	25.4
N_7_9	µm	56.1	1.1	1.2	2.1%	3.3	653.5	7.7	8.4	1.3%	23.2	597.3	7.2	7.8	1.3%	21.5
IN_7_9	µm	55.4	0.8	1.0	1.8%	2.7	648.4	8.7	9.3	1.4%	25.7	593.0	8.3	8.7	1.5%	24.2
I_7_9	µm	54.0	0.8	0.9	1.6%	2.5	638.9	8.2	8.9	1.4%	24.7	584.9	8.3	8.9	1.5%	24.8
IT_7_9	µm	55.2	0.8	0.9	1.6%	2.4	618.4	7.4	8.2	1.3%	22.7	563.2	7.4	8.1	1.4%	22.5
* Reproducibility Limit = 2.8 x SD of Reproducibility																

Table 15.3.1.1. Repeatability and Reproducibility of the normal group.

Four Corneal Conditions Combined (n=423 scans)																
Parameter (φ9 mm)	Unit	Epithelia (Epi)					Cornea (Pachy)					Stroma				
		Mean	Repeat ability	Reproducibility			Mean	Repeat ability	Reproducibility			Mean	Repeat ability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*
C_2	µm	54.3	1.1	1.6	3.0%	4.5	518.0	4.1	4.5	0.9%	12.5	463.6	3.5	3.9	0.8%	10.9
T_2_5	µm	53.2	1.4	1.4	2.6%	3.8	531.5	6.3	6.8	1.3%	19.0	478.2	6.0	6.5	1.4%	17.9
ST_2_5	µm	54.2	1.4	1.4	2.6%	3.9	550.6	7.1	7.5	1.4%	20.8	496.3	7.0	7.4	1.5%	20.4
S_2_5	µm	54.6	1.5	1.5	2.7%	4.1	564.6	8.1	8.5	1.5%	23.6	510.0	8.3	8.7	1.7%	24.0
SN_2_5	µm	55.3	1.3	1.3	2.5%	3.7	563.7	7.9	8.2	1.5%	22.8	508.4	7.8	8.2	1.6%	22.7
N_2_5	µm	55.5	1.0	1.8	3.2%	4.9	553.6	6.9	7.2	1.3%	20.0	498.1	6.8	7.2	1.4%	19.9
IN_2_5	µm	55.3	1.1	1.2	2.1%	3.2	543.5	7.4	7.7	1.4%	21.4	488.2	7.1	7.4	1.5%	20.4
I_2_5	µm	54.3	1.1	1.1	2.1%	3.2	530.9	7.1	7.3	1.4%	20.4	476.5	6.8	6.9	1.5%	19.2
IT_2_5	µm	53.3	1.2	1.2	2.2%	3.2	524.0	5.9	6.2	1.2%	17.2	470.6	5.6	5.9	1.3%	16.3
T_5_7	µm	53.1	1.2	1.2	2.3%	3.4	568.7	7.5	8.1	1.4%	22.6	515.6	7.5	8.0	1.6%	22.3
ST_5_7	µm	52.1	1.5	1.5	2.9%	4.2	598.3	8.6	9.3	1.6%	25.7	546.1	9.2	9.9	1.8%	27.4
S_5_7	µm	51.7	1.8	2.3	4.4%	6.4	621.8	9.8	10.4	1.7%	28.9	570.1	10.3	11.0	1.9%	30.4
SN_5_7	µm	53.7	1.3	1.9	3.4%	5.1	617.1	9.2	9.7	1.6%	27.0	563.3	9.6	10.1	1.8%	28.0
N_5_7	µm	54.6	1.1	1.1	2.1%	3.2	600.6	8.5	8.8	1.5%	24.4	545.9	8.5	8.8	1.6%	24.5
IN_5_7	µm	54.9	1.0	1.0	1.9%	2.9	592.3	9.0	9.3	1.6%	25.7	537.4	9.0	9.3	1.7%	25.7
I_5_7	µm	54.3	1.2	1.2	2.2%	3.2	579.7	9.5	9.7	1.7%	27.0	525.4	9.4	9.6	1.8%	26.6
IT_5_7	µm	54.0	1.1	1.1	2.1%	3.1	565.6	8.6	8.9	1.6%	24.7	511.5	8.2	8.6	1.7%	23.7
T_7_9	µm	52.9	1.3	1.3	2.4%	3.5	610.6	9.3	9.6	1.6%	26.7	557.6	9.5	9.8	1.8%	27.2
ST_7_9	µm	50.0	1.6	1.6	3.1%	4.3	647.2	12.3	13.0	2.0%	35.9	597.1	12.5	13.1	2.2%	36.4
S_7_9	µm	49.5	2.3	2.3	4.7%	6.4	679.8	16.9	17.4	2.6%	48.1	630.2	17.0	17.5	2.8%	48.4
SN_7_9	µm	52.8	1.7	1.7	3.2%	4.7	667.8	12.3	12.9	1.9%	35.7	614.9	12.5	13.0	2.1%	36.0
N_7_9	µm	56.4	1.5	1.5	2.7%	4.1	650.6	10.2	10.7	1.6%	29.5	594.1	9.8	10.2	1.7%	28.1
IN_7_9	µm	54.6	1.2	1.2	2.2%	3.4	645.9	11.9	12.2	1.9%	33.8	591.3	11.7	12.1	2.0%	33.4
I_7_9	µm	53.0	1.6	1.6	3.1%	4.5	634.7	13.3	13.3	2.1%	36.9	581.7	13.1	13.2	2.3%	36.5
IT_7_9	µm	55.0	1.1	1.1	2.1%	3.2	613.1	11.3	11.4	1.9%	31.6	558.1	11.1	11.2	2.0%	31.0
* Reproducibility Limit = 2.8 x SD of Reproducibility																

Table 15.3.1.2. Repeatability and Reproducibility of the combined group of all four corneal conditions.

Contact Lens (n=106 scans)																
Parameter (φ9 mm)	Unit	Epithelia (Epi)					Cornea (Pachy)					Stroma				
		Mean	Repeat ability	Reproducibility			Mean	Repeat ability	Reproducibility			Mean	Repeat ability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*
C_2	µm	52.8	0.9	0.9	1.8%	2.6	531.7	2.4	3.1	0.6%	8.7	478.9	2.0	2.8	0.6%	7.8
T_2_5	µm	52.3	1.2	1.2	2.3%	3.3	543.0	4.8	5.2	1.0%	14.4	490.7	4.6	5.1	1.0%	14.0
ST_2_5	µm	51.7	1.3	1.4	2.7%	3.8	555.8	5.8	6.5	1.2%	18.1	504.0	5.6	6.4	1.3%	17.8
S_2_5	µm	51.8	1.4	1.4	2.7%	3.9	566.9	6.8	7.9	1.4%	22.0	515.0	6.6	7.8	1.5%	21.6
SN_2_5	µm	52.3	1.2	1.3	2.4%	3.5	564.2	6.5	7.4	1.3%	20.5	511.8	6.2	7.0	1.4%	19.4
N_2_5	µm	52.8	0.9	0.9	1.8%	2.6	555.4	5.4	5.9	1.1%	16.3	502.6	5.2	5.7	1.1%	15.7
IN_2_5	µm	53.3	0.8	0.8	1.5%	2.3	550.2	4.6	4.7	0.9%	13.1	496.8	4.4	4.6	0.9%	12.6
I_2_5	µm	53.4	1.0	1.0	1.8%	2.7	545.4	4.0	4.1	0.8%	11.4	491.9	4.0	4.0	0.8%	11.1
IT_2_5	µm	53.2	1.1	1.1	2.0%	2.9	540.8	3.8	4.1	0.7%	11.2	487.6	3.7	4.0	0.8%	11.1
T_5_7	µm	52.6	1.1	1.1	2.2%	3.1	572.8	6.6	7.0	1.2%	19.4	520.2	6.4	6.8	1.3%	18.9
ST_5_7	µm	50.9	1.5	1.5	3.0%	4.2	597.9	7.4	8.4	1.4%	23.3	547.0	7.4	8.6	1.6%	23.7
S_5_7	µm	50.8	1.6	1.6	3.2%	4.5	620.1	7.7	9.3	1.5%	25.7	569.2	7.8	9.4	1.7%	26.1
SN_5_7	µm	52.3	1.4	1.4	2.7%	3.9	613.1	8.1	9.2	1.5%	25.4	560.7	8.1	9.1	1.6%	25.4
N_5_7	µm	53.3	1.0	1.1	2.0%	3.0	595.6	8.3	8.6	1.4%	23.9	542.2	8.0	8.3	1.5%	23.1
IN_5_7	µm	53.5	0.8	0.8	1.5%	2.3	588.9	7.2	7.2	1.2%	20.1	535.4	7.1	7.1	1.3%	19.7
I_5_7	µm	53.5	0.9	1.0	1.8%	2.7	582.9	6.0	6.0	1.0%	16.7	529.3	6.0	6.0	1.1%	16.5
IT_5_7	µm	54.0	0.9	0.9	1.8%	2.6	572.9	5.8	6.1	1.1%	16.8	518.9	5.5	5.9	1.1%	16.4
T_7_9	µm	52.3	1.4	1.4	2.7%	4.0	611.6	10.3	10.3	1.7%	28.6	559.3	10.4	10.4	1.9%	28.8
ST_7_9	µm	49.6	1.6	1.6	3.2%	4.4	650.4	11.0	12.0	1.8%	33.1	600.8	11.2	12.1	2.0%	33.6
S_7_9	µm	48.6	1.8	1.8	3.7%	5.0	678.1	11.6	13.2	1.9%	36.6	629.5	11.9	13.6	2.2%	37.8
SN_7_9	µm	51.5	1.7	1.7	3.3%	4.8	664.7	10.1	11.3	1.7%	31.4	613.2	10.5	11.8	1.9%	32.7
N_7_9	µm	55.5	1.9	1.9	3.4%	5.2	645.9	10.9	11.4	1.8%	31.5	590.4	10.9	11.4	1.9%	31.6
IN_7_9	µm	53.5	1.3	1.3	2.4%	3.6	639.6	10.0	10.0	1.6%	27.8	586.0	10.2	10.2	1.7%	28.3
I_7_9	µm	52.3	1.1	1.1	2.1%	3.1	630.9	8.6	8.6	1.4%	23.8	578.5	8.7	8.7	1.5%	24.0
IT_7_9	µm	54.5	1.0	1.0	1.9%	2.9	614.2	9.0	9.3	1.5%	25.8	559.7	8.9	9.2	1.6%	25.6
* Reproducibility Limit = 2.8 x SD of Reproducibility																

Table 15.3.1.3. Repeatability and Reproducibility of the contact lens group.

Dry Eye (n=106 scans)																
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	SD	CV	Limit*
C_2	µm	53.3	1.0	1.1	2.1%	3.1	539.1	1.8	2.6	0.5%	7.3	485.8	1.6	2.1	0.4%	5.7
T_2_5	µm	52.4	0.9	0.9	1.8%	2.6	546.7	3.1	3.4	0.6%	9.4	494.3	3.2	3.4	0.7%	9.4
ST_2_5	µm	52.5	1.2	1.2	2.3%	3.4	561.5	5.3	5.4	1.0%	15.1	509.0	5.5	5.7	1.1%	15.7
S_2_5	µm	52.7	1.3	1.4	2.6%	3.8	575.9	7.4	7.4	1.3%	20.5	523.2	7.5	7.5	1.4%	20.7
SN_2_5	µm	53.7	1.2	1.3	2.4%	3.5	576.8	7.1	7.3	1.3%	20.2	523.0	7.0	7.1	1.4%	19.6
N_2_5	µm	54.1	1.1	1.2	2.2%	3.2	567.9	5.5	6.0	1.1%	16.6	513.8	5.3	5.7	1.1%	15.8
IN_2_5	µm	54.3	1.1	1.2	2.2%	3.3	560.4	5.1	6.1	1.1%	16.8	506.1	5.0	5.8	1.1%	16.2
I_2_5	µm	54.1	1.1	1.2	2.2%	3.2	552.9	5.2	6.0	1.1%	16.7	498.7	5.1	5.9	1.2%	16.5
IT_2_5	µm	53.3	0.9	1.0	1.8%	2.7	545.2	4.1	4.6	0.8%	12.6	491.9	4.0	4.4	0.9%	12.2
T_5_7	µm	52.4	0.7	0.7	1.4%	2.1	577.0	5.4	5.7	1.0%	15.8	524.6	5.4	5.6	1.1%	15.6
ST_5_7	µm	51.1	1.2	1.2	2.5%	3.5	604.3	7.6	8.0	1.3%	22.1	553.1	8.1	8.4	1.5%	23.4
S_5_7	µm	51.1	1.6	1.6	3.2%	4.6	629.3	9.4	9.6	1.5%	26.5	578.1	9.7	9.8	1.7%	27.3
SN_5_7	µm	53.8	1.2	1.3	2.4%	3.5	628.5	9.4	9.6	1.5%	26.6	574.6	9.5	9.6	1.7%	26.7
N_5_7	µm	55.0	1.2	1.2	2.3%	3.5	612.0	7.7	8.2	1.3%	22.7	557.0	7.4	7.8	1.4%	21.5
IN_5_7	µm	54.5	1.3	1.3	2.4%	3.7	603.2	7.8	9.1	1.5%	25.1	548.6	7.6	8.9	1.6%	24.7
I_5_7	µm	53.9	1.0	1.1	2.0%	2.9	593.3	8.2	9.3	1.6%	25.8	539.4	8.3	9.5	1.8%	26.3
IT_5_7	µm	53.9	0.8	0.8	1.4%	2.1	577.9	7.3	7.9	1.4%	21.8	523.9	7.0	7.7	1.5%	21.2
T_7_9	µm	52.6	0.9	1.0	1.8%	2.7	616.3	8.1	8.1	1.3%	22.6	563.6	8.2	8.2	1.5%	22.7
ST_7_9	µm	49.6	1.4	1.5	3.1%	4.2	655.2	11.5	12.1	1.8%	33.5	605.5	11.9	12.4	2.0%	34.2
S_7_9	µm	49.7	2.6	2.6	5.3%	7.3	689.7	15.6	16.7	2.4%	46.4	639.9	16.2	17.0	2.7%	47.2
SN_7_9	µm	53.5	1.7	1.8	3.3%	4.9	679.8	13.4	14.0	2.1%	38.8	626.2	13.8	14.2	2.3%	39.4
N_7_9	µm	57.1	1.2	1.2	2.2%	3.4	660.4	9.6	10.0	1.5%	27.8	603.3	9.0	9.4	1.6%	26.1
IN_7_9	µm	54.7	1.3	1.3	2.5%	3.7	654.6	10.9	12.3	1.9%	34.0	599.9	11.0	12.4	2.1%	34.2
I_7_9	µm	53.2	1.3	1.4	2.6%	3.8	644.6	13.2	14.1	2.2%	39.2	591.4	13.5	14.4	2.4%	40.0
IT_7_9	µm	54.6	0.8	0.8	1.6%	2.4	618.5	10.3	10.9	1.8%	30.2	563.9	10.3	10.9	1.9%	30.2
* Reproducibility Limit = 2.8 x SD of Reproducibility																

Table 15.3.1.4. Repeatability and Reproducibility of the Dry Eye group.

Post-Laser Refractive Surgery (n=93 scans)																
Parameter (φ9 mm)	Unit	Epithelia (Epi)					Cornea (Pachy)					Stroma				
		Mean	Repeat ability	Reproducibility			Mean	Repeat ability	Reproducibility			Mean	Repeat ability	Reproducibility		
			SD	SD	CV	Limit*		SD	SD	CV	Limit*		SD	SD	CV	Limit*
C_2	µm	58.1	0.9	1.0	1.7%	2.7	503.7	2.1	2.5	0.5%	6.9	445.5	1.9	2.3	0.5%	6.3
T_2_5	µm	57.5	1.4	1.4	2.4%	3.8	525.8	5.4	6.2	1.2%	17.1	468.3	6.0	6.8	1.4%	18.8
ST_2_5	µm	56.6	1.5	1.5	2.6%	4.1	539.7	6.9	7.7	1.4%	21.3	483.0	7.5	8.3	1.7%	22.9
S_2_5	µm	56.3	1.4	1.4	2.5%	3.9	552.7	8.6	9.5	1.7%	26.4	496.4	9.2	10.2	2.0%	28.1
SN_2_5	µm	56.8	1.4	1.4	2.5%	4.0	551.9	9.0	9.7	1.7%	27.0	495.0	9.2	10.0	2.0%	27.8
N_2_5	µm	57.0	1.1	1.1	1.9%	3.1	543.0	7.8	8.2	1.5%	22.8	486.0	8.0	8.5	1.7%	23.5
IN_2_5	µm	57.6	0.9	1.0	1.7%	2.7	537.9	7.2	7.2	1.3%	19.9	480.2	7.2	7.3	1.5%	20.2
I_2_5	µm	57.9	0.8	0.8	1.5%	2.3	532.8	7.3	7.3	1.4%	20.3	474.8	7.4	7.4	1.5%	20.5
IT_2_5	µm	57.7	1.1	1.1	2.0%	3.1	524.7	6.6	7.1	1.3%	19.7	466.9	6.7	7.2	1.5%	19.9
T_5_7	µm	52.8	1.5	1.5	2.9%	4.2	572.2	7.6	8.8	1.5%	24.5	519.4	8.5	9.7	1.9%	26.9
ST_5_7	µm	50.5	1.7	1.7	3.4%	4.7	597.0	9.2	10.6	1.8%	29.4	546.5	10.2	11.6	2.1%	32.0
S_5_7	µm	50.7	1.9	2.0	3.9%	5.5	620.9	11.2	12.2	2.0%	33.9	570.1	12.0	13.2	2.3%	36.5
SN_5_7	µm	53.2	1.4	1.5	2.8%	4.1	616.0	10.6	11.1	1.8%	30.8	562.7	11.4	11.9	2.1%	32.9
N_5_7	µm	53.2	1.1	1.1	2.1%	3.1	601.6	9.9	10.1	1.7%	27.9	548.4	10.2	10.3	1.9%	28.6
IN_5_7	µm	52.8	0.9	0.9	1.8%	2.6	598.9	9.0	9.0	1.5%	24.9	546.1	9.2	9.2	1.7%	25.6
I_5_7	µm	53.1	1.3	1.3	2.5%	3.6	593.1	9.6	9.7	1.6%	26.8	539.9	9.8	10.0	1.8%	27.7
IT_5_7	µm	53.9	1.0	1.0	1.8%	2.7	575.5	9.3	10.3	1.8%	28.5	521.5	9.6	10.7	2.0%	29.6
T_7_9	µm	52.1	1.2	1.2	2.4%	3.4	617.7	8.7	9.8	1.6%	27.3	565.6	8.7	9.8	1.7%	27.1
ST_7_9	µm	48.2	1.4	1.5	3.0%	4.1	652.6	12.2	14.2	2.2%	39.5	604.3	12.1	14.3	2.4%	39.5
S_7_9	µm	48.2	2.6	2.6	5.5%	7.3	685.4	21.1	21.3	3.1%	59.1	637.2	20.3	20.7	3.2%	57.3
SN_7_9	µm	52.0	1.7	1.7	3.4%	4.8	672.9	12.9	13.2	1.9%	36.5	620.8	12.4	12.7	2.0%	35.1
N_7_9	µm	56.0	1.4	1.4	2.5%	3.9	655.7	9.3	9.4	1.4%	26.2	599.7	8.5	8.6	1.4%	23.8
IN_7_9	µm	53.5	1.2	1.2	2.2%	3.3	656.9	10.9	11.2	1.7%	31.2	603.4	10.4	10.7	1.8%	29.7
I_7_9	µm	50.9	2.5	2.6	5.1%	7.1	650.3	14.1	14.1	2.2%	39.2	599.4	12.5	12.6	2.1%	34.8
IT_7_9	µm	53.4	1.2	1.2	2.2%	3.2	624.9	11.0	11.2	1.8%	31.1	571.4	10.5	10.8	1.9%	29.9
* Reproducibility Limit = 2.8 x SD of Reproducibility																

Table 15.3.1.5. Repeatability and Reproducibility of the post-LRS group.

Keratoconus (n=118 scans)																
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	SD	CV	Limit*
C_2	µm	53.5	1.4	1.9	3.5%	5.2	498.0	6.9	7.4	1.5%	20.4	444.5	5.9	6.3	1.4%	17.3
T_2_5	µm	51.3	1.6	2.0	3.9%	5.6	511.9	8.9	10.3	2.1%	28.4	460.6	8.1	9.0	2.0%	25.1
ST_2_5	µm	56.1	1.4	1.8	3.3%	5.1	544.7	8.9	9.7	1.8%	26.9	488.5	8.2	8.8	1.8%	24.5
S_2_5	µm	57.4	1.7	1.7	3.0%	4.8	561.7	8.9	9.3	1.7%	25.7	504.3	9.0	9.3	1.9%	25.8
SN_2_5	µm	58.1	1.4	1.4	2.5%	4.0	560.8	8.4	8.6	1.6%	23.8	502.7	8.4	8.6	1.7%	23.8
N_2_5	µm	57.9	1.0	1.8	3.1%	4.9	547.6	8.1	8.5	1.6%	23.5	489.6	8.0	8.4	1.8%	23.3
IN_2_5	µm	56.0	1.3	1.4	2.6%	4.0	526.8	10.2	11.1	2.1%	30.7	470.8	9.5	10.3	2.2%	28.5
I_2_5	µm	52.4	1.3	1.5	2.8%	4.1	496.9	9.4	10.3	2.1%	28.5	444.4	8.5	9.2	2.1%	25.6
IT_2_5	µm	50.0	1.4	1.4	2.9%	4.0	489.5	7.9	8.0	1.7%	22.2	439.5	7.1	7.2	1.7%	20.0
T_5_7	µm	54.3	1.2	1.5	2.7%	4.0	555.0	9.3	10.3	1.9%	28.5	500.7	8.7	9.5	1.9%	26.3
ST_5_7	µm	55.3	1.5	1.6	2.9%	4.5	594.3	9.2	10.3	1.8%	28.6	538.9	10.0	11.0	2.1%	30.6
S_5_7	µm	53.7	1.8	2.3	4.2%	6.3	617.4	9.6	11.0	1.8%	30.4	563.7	10.4	11.7	2.1%	32.4
SN_5_7	µm	55.3	1.2	1.9	3.4%	5.2	611.3	8.7	9.3	1.5%	25.9	555.9	9.3	9.9	1.8%	27.4
N_5_7	µm	56.6	1.2	1.2	2.1%	3.3	594.0	8.0	8.5	1.4%	23.5	537.3	8.4	8.9	1.7%	24.6
IN_5_7	µm	58.0	0.9	1.0	1.8%	2.8	580.6	10.4	11.2	2.0%	31.1	522.5	10.5	11.3	2.2%	31.4
I_5_7	µm	56.2	1.2	1.3	2.3%	3.6	554.3	11.8	12.7	2.3%	35.1	498.0	11.2	12.0	2.5%	33.2
IT_5_7	µm	54.3	1.5	1.5	2.8%	4.2	540.5	10.7	10.7	2.0%	29.6	486.1	9.6	9.6	2.0%	26.5
T_7_9	µm	54.4	1.4	1.4	2.6%	3.9	599.1	9.8	10.1	1.7%	28.0	544.7	10.3	10.6	2.0%	29.3
ST_7_9	µm	52.2	1.7	1.7	3.2%	4.6	633.0	13.5	13.9	2.2%	38.6	580.8	13.7	14.1	2.4%	39.1
S_7_9	µm	51.2	2.2	2.2	4.3%	6.1	668.1	17.3	18.1	2.7%	50.1	616.9	17.8	18.4	3.0%	51.1
SN_7_9	µm	54.0	1.7	1.7	3.1%	4.6	655.9	12.1	12.8	2.0%	35.4	601.8	12.4	13.1	2.2%	36.3
N_7_9	µm	57.0	1.3	1.4	2.4%	3.8	641.9	10.9	11.4	1.8%	31.5	584.9	10.3	10.6	1.8%	29.4
IN_7_9	µm	56.2	1.0	1.0	1.9%	2.9	635.1	13.5	14.7	2.3%	40.7	578.8	13.2	14.4	2.5%	39.8
I_7_9	µm	55.1	1.3	1.3	2.4%	3.7	617.2	14.8	15.6	2.6%	43.1	562.0	15.1	15.9	2.9%	44.0
IT_7_9	µm	56.9	1.4	1.4	2.5%	3.9	598.2	13.6	13.6	2.3%	37.8	541.3	13.3	13.3	2.5%	36.9
* Reproducibility Limit = 2.8 x SD of Reproducibility																

Table 15.3.1.6. Repeatability and Reproducibility of the KCN group.

15.4 Evaluation of the Agreement of Solix to Avanti in Normal Subjects and Corneal Patients for Anterior Segment Measurements

This was a multi-center, prospective, cross-sectional study conducted at 2 U.S. clinical sites equipped with 3 pairs of devices (1 Solix and 1 Avanti per device pair) for data collection. One of the clinical sites participated in the anterior segment “R&R” study and 2 device pairs were placed at this site. Eligible participants age 18 or older were enrolled and assigned to one of two study groups: 1) individuals with no corneal pathology or conditions in qualifying for the Cornea sub-groups; 2) those with four specified corneal conditions (contact lens wearers, post-refractive surgery (post-LRS), dry eye, keratoconus (KCN)), jointly referred to as the Cornea group. Each study eye was imaged 3 times using the Cornea Map scan pattern with Solix and using the

PachymetryWide scan pattern with Avanti. Post-acquisition image review of scan quality score, signal strength, pupil alignment, eyelid artifact, scan range, and motion artifact were conducted for all scans. Agreement between Solix and Avanti of all 25 zonal thicknesses parameters for 3 map types (corneal, epithelial, and stromal thickness) was evaluated with 95% limits of agreement (LOAs) and Deming regression analyses.

A total of 104 participants were consented and enrolled, (23 Normals, 18 Contact Lens, 21 Dry Eye, 19 Post-LRS, 23 KCN. A total of 10 subjects were excluded, majority due to prior cataract surgery, a few due to additional pathology not consistent with the enrolled condition. Therefore, a total of 94 subjects qualified and completed the study, and analysis was based on all 94 eyes of 94 subjects for all groups combined (20 Normal subjects and 74 Cornea subjects consisting of, 18 Contact Lens, 18 Dry Eye, 18 post-LRS, 20 KCN), combining into a cornea group of 74 subjects.

Of the 94 eligible subjects, 53 (56.4%) participants were female and 41 (43.6%) participants were male; the age distribution was 46.0±18.6 (mean±SD), ranging from 18 to 88; and, 72 (76.6%) participants were Caucasian.

Of the 18 Contact Lens subjects, the average duration of contact lens wear was 16.9 years, ranging from 1 to 53 years, the average length of daily wear was 13.3 hours, ranging from 6 to 18 hours.

The 18 Dry Eye subjects consisted of 6 mild, 7 moderate, and 5 severe cases. The distribution of OSDI score was 42.9±25.7 (mean±SD), ranging from 4.2 to 93.0; and, the distribution of TBUT was 5.0±3.0 sec. (mean±SD), ranging from 1.5 sec. to 10 sec.

Of the 18 Post-LRS subjects, 8 had LASIK procedure, 10 had PRK procedure, and all had myopic correction.

The 20 KCN subjects consisted of 6 mild, 8 moderate, and 6 severe cases. The distribution of steep K was 52.49±12.06 D (mean±SD), ranging from 41.30D to 90.00D.

One qualified scan per subject per device was included in the agreement analysis. For Solix, the percentage of subjects for which the *1st scan* was acceptable quality was 87.2%. For Avanti, the percentages of subjects for which the *1st scan* was acceptable quality was at 88.2%.

Of 94 qualified subjects, an additional 5 subjects were lost to image quality issue or missing paired data for comparison; therefore, the final data set for analysis included 20 normal subject and 69 combined cornea conditions subjects.

Manual edit of segmentation boundaries was performed in 5.6% of Solix scans and 11.1% 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		Normal (n=20 subjects)						Cornea (n=69 subjects)					
		Solix	Avanti	Difference				Solix	Avanti	Difference			
		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA	
C.2._Epi	µm	53	54	-0.9	1.1	-3.1	1.2	55	55	-0.4	2.3	-4.9	4.1
T.2.5._Epi	µm	52	54	-1.0	1.2	-3.4	1.3	54	55	-0.8	2.8	-6.2	4.6
ST.2.5._Epi	µm	52	53	-1.0	1.2	-3.3	1.4	55	55	-0.7	2.3	-5.2	3.7
S.2.5._Epi	µm	51	52	-0.9	1.2	-3.3	1.5	55	56	-0.7	2.0	-4.7	3.3
SN.2.5._Epi	µm	53	53	-0.9	1.0	-3.0	1.1	56	57	-0.4	2.0	-4.3	3.4
N.2.5._Epi	µm	53	54	-1.0	0.7	-2.5	0.4	56	57	-0.5	1.8	-3.9	3.0
IN.2.5._Epi	µm	54	55	-1.0	0.7	-2.4	0.4	55	56	-0.8	1.8	-4.4	2.8
I.2.5._Epi	µm	54	55	-1.1	0.9	-2.9	0.6	55	56	-0.8	1.9	-4.5	3.0
IT.2.5._Epi	µm	54	55	-0.8	1.1	-2.9	1.3	54	55	-0.5	1.9	-4.2	3.2
T.5.7._Epi	µm	53	53	-0.3	1.1	-2.4	1.7	53	53	0.3	3.2	-5.9	6.5
ST.5.7._Epi	µm	51	51	-0.2	1.3	-2.7	2.3	52	52	0.2	2.7	-5.1	5.4
S.5.7._Epi	µm	50	50	-0.5	1.7	-4.0	2.9	52	52	-0.2	1.9	-3.9	3.6
SN.5.7._Epi	µm	52	53	-0.7	1.0	-2.8	1.3	54	54	-0.2	2.0	-4.1	3.7
N.5.7._Epi	µm	54	54	-0.8	0.7	-2.2	0.6	55	55	-0.2	1.9	-4.0	3.6
IN.5.7._Epi	µm	54	55	-0.9	0.7	-2.2	0.4	55	55	-0.4	1.5	-3.4	2.6
I.5.7._Epi	µm	54	55	-0.9	1.0	-2.9	1.1	54	54	0.1	2.7	-5.3	5.5
IT.5.7._Epi	µm	54	55	-0.7	0.9	-2.4	1.1	54	54	0.4	2.5	-4.4	5.3
T.7.9._Epi	µm	54	53	0.8	1.3	-1.7	3.2	54	52	1.2	2.8	-4.2	6.7
ST.7.9._Epi	µm	49	49	0.1	2.1	-4.0	4.3	50	49	0.4	2.5	-4.5	5.3
S.7.9._Epi	µm	46	47	-0.9	3.1	-7.0	5.2	49	49	-0.2	2.8	-5.7	5.4
SN.7.9._Epi	µm	52	51	0.1	2.2	-4.3	4.5	52	52	0.4	2.2	-4.0	4.8
N.7.9._Epi	µm	57	56	0.6	1.3	-1.8	3.1	57	56	0.9	2.2	-3.5	5.2
IN.7.9._Epi	µm	55	55	-0.2	1.2	-2.5	2.1	55	54	0.4	2.0	-3.4	4.3
I.7.9._Epi	µm	53	54	-0.8	1.6	-3.9	2.2	53	53	0.2	2.2	-4.1	4.6
IT.7.9._Epi	µm	55	55	0.0	1.0	-1.9	2.0	55	54	0.9	1.9	-2.8	4.7

Table 15.4.1.1. Agreement between Solix Cornea Map scan and Avanti PachymetryWide scan for epithelial thickness.

Cornea		Normal (n=20 subjects)						Cornea (n=69 subjects)					
		Solix	Avanti	Difference				Solix	Avanti	Difference			
		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA	
C.2._Pachy	µm	536	541	-4.9	2.7	-10.2	0.4	510	516	-5.6	8.8	-22.8	11.5
T.2.5._Pachy	µm	541	551	-9.5	5.2	-19.8	0.8	524	533	-9.5	9.9	-28.9	9.9
ST.2.5._Pachy	µm	556	566	-9.1	9.5	-27.6	9.5	543	552	-8.8	9.2	-26.8	9.1
S.2.5._Pachy	µm	571	579	-8.1	11.9	-31.5	15.3	558	565	-6.9	9.3	-25.1	11.3
SN.2.5._Pachy	µm	573	579	-6.7	10.7	-27.7	14.4	558	563	-4.6	9.6	-23.4	14.2
N.2.5._Pachy	µm	563	570	-6.2	8.2	-22.3	9.8	550	554	-4.5	9.8	-23.7	14.8
IN.2.5._Pachy	µm	557	563	-5.4	7.8	-20.7	9.8	538	543	-5.1	10.5	-25.6	15.4
I.2.5._Pachy	µm	549	556	-7.1	7.8	-22.4	8.2	524	531	-6.7	9.3	-24.8	11.5
IT.2.5._Pachy	µm	540	549	-8.6	7.2	-22.7	5.4	517	525	-8.4	7.0	-22.1	5.3
T.5.7._Pachy	µm	578	583	-5.4	10.1	-25.2	14.3	564	567	-3.6	9.9	-23.0	15.8
ST.5.7._Pachy	µm	604	609	-5.2	15.1	-34.8	24.4	591	595	-3.6	10.8	-24.8	17.7
S.5.7._Pachy	µm	628	631	-3.0	15.2	-32.7	26.7	614	614	-0.6	12.5	-25.0	23.8
SN.5.7._Pachy	µm	629	630	-0.8	14.3	-28.8	27.1	612	610	1.8	13.2	-24.1	27.7
N.5.7._Pachy	µm	611	612	-1.4	12.4	-25.7	22.8	598	596	2.2	12.3	-21.9	26.3
IN.5.7._Pachy	µm	604	604	0.1	11.9	-23.2	23.3	588	587	1.9	12.6	-22.8	26.7
I.5.7._Pachy	µm	596	597	-1.0	12.7	-25.9	23.9	574	573	0.9	14.7	-27.9	29.7
IT.5.7._Pachy	µm	579	583	-4.3	12.2	-28.2	19.7	562	562	-0.8	14.3	-28.8	27.3
T.7.9._Pachy	µm	632	625	6.3	12.1	-17.4	29.9	609	602	7.4	14.0	-19.9	34.8
ST.7.9._Pachy	µm	656	657	-1.0	16.7	-33.8	31.7	640	635	5.9	16.2	-25.8	37.5
S.7.9._Pachy	µm	693	688	4.7	20.2	-34.8	44.3	668	661	7.0	19.1	-30.3	44.4
SN.7.9._Pachy	µm	680	677	2.3	17.6	-32.2	36.7	659	656	3.6	20.8	-37.1	44.4
N.7.9._Pachy	µm	669	661	8.4	13.9	-18.8	35.7	648	638	9.5	14.8	-19.6	38.5
IN.7.9._Pachy	µm	663	654	8.7	13.9	-18.5	35.9	642	632	9.7	16.3	-22.3	41.7
I.7.9._Pachy	µm	653	644	9.6	19.4	-28.4	47.5	631	617	13.6	22.4	-30.2	57.5
IT.7.9._Pachy	µm	631	625	5.6	14.9	-23.7	34.8	611	604	6.9	20.6	-33.4	47.2

Table 15.4.1.2. Agreement between Solix Cornea Map scan and Avanti PachymetryWide scan for corneal thickness.

Stroma		Normal (n=20 subjects)						Cornea (n=69 subjects)					
		Solix	Avanti	Difference				Solix	Avanti	Difference			
		Mean	Mean	Mean	SD	95% LOA		Mean	Mean	Mean	SD	95% LOA	
C.2._Stroma	µm	487	491	-4.0	2.6	-9.2	1.1	456	461	-5.2	7.6	-20.1	9.7
T.2.5._Stroma	µm	497	506	-8.5	5.0	-18.4	1.4	470	479	-8.8	9.0	-26.5	9.0
ST.2.5._Stroma	µm	513	521	-8.2	9.7	-27.1	10.8	488	497	-8.2	9.3	-26.3	10.0
S.2.5._Stroma	µm	527	534	-7.3	12.2	-31.1	16.6	502	509	-6.3	10.2	-26.2	13.7
SN.2.5._Stroma	µm	526	531	-5.8	10.9	-27.1	15.6	502	507	-4.3	10.3	-24.5	16.0
N.2.5._Stroma	µm	515	521	-5.3	8.0	-21.0	10.5	493	497	-4.0	10.4	-24.5	16.4
IN.2.5._Stroma	µm	508	512	-4.5	7.7	-19.5	10.5	483	487	-4.3	10.1	-24.1	15.4
I.2.5._Stroma	µm	501	507	-6.0	7.8	-21.2	9.2	470	476	-6.0	8.7	-23.0	11.0
IT.2.5._Stroma	µm	494	502	-7.9	6.7	-21.1	5.3	462	470	-7.9	7.1	-21.8	5.9
T.5.7._Stroma	µm	530	535	-5.2	9.9	-24.6	14.2	510	514	-3.9	11.1	-25.6	17.8
ST.5.7._Stroma	µm	558	563	-5.1	15.0	-34.4	24.3	539	542	-3.8	12.2	-27.6	20.1
S.5.7._Stroma	µm	581	583	-2.5	15.7	-33.2	28.2	562	562	-0.5	13.3	-26.5	25.5
SN.5.7._Stroma	µm	577	578	-0.2	14.4	-28.4	28.1	558	556	2.0	14.3	-26.0	30.0
N.5.7._Stroma	µm	558	558	-0.7	12.5	-25.2	23.8	543	541	2.4	13.0	-23.1	27.8
IN.5.7._Stroma	µm	550	549	0.9	12.0	-22.7	24.5	534	531	2.3	12.7	-22.6	27.1
I.5.7._Stroma	µm	542	542	-0.2	13.2	-26.1	25.8	520	519	0.7	14.7	-28.1	29.5
IT.5.7._Stroma	µm	528	532	-3.7	12.2	-27.7	20.3	507	508	-1.3	13.9	-28.6	26.0
T.7.9._Stroma	µm	572	567	5.5	11.8	-17.7	28.6	556	550	6.2	14.7	-22.7	35.0
ST.7.9._Stroma	µm	608	609	-1.2	17.1	-34.7	32.3	590	585	5.4	16.6	-27.2	38.0
S.7.9._Stroma	µm	641	635	5.6	21.6	-36.6	47.9	619	612	7.2	20.1	-32.3	46.6
SN.7.9._Stroma	µm	626	624	2.1	17.8	-32.8	37.1	607	604	3.1	21.4	-38.9	45.1
N.7.9._Stroma	µm	604	596	7.8	13.2	-18.1	33.6	591	582	8.6	14.4	-19.7	36.8
IN.7.9._Stroma	µm	598	590	8.9	13.7	-17.9	35.6	587	578	9.2	15.9	-22.0	40.4
I.7.9._Stroma	µm	589	579	10.4	20.2	-29.2	49.9	578	564	13.4	22.4	-30.6	57.3
IT.7.9._Stroma	µm	570	565	5.5	14.9	-23.7	34.6	556	550	5.9	19.9	-33.1	44.9

Table 15.4.1.3. Agreement between Solix Cornea Map scan and Avanti PachymetryWide scan for stroma 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 worth than 20/40, IOP>21mmHg, 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 the 3 macular scan patterns, the study eyes were selected for the RDB based on randomization for over 99% of the qualified subjects, and the percentage of subjects for which the 1st scan of the study eye was qualified for the final RDB analysis dataset was over 88.7%. For the 2 peripapillary/optic disc scan patterns, the study eyes were selected for the RDB based on randomization for over 99% of the qualified subjects, and the percentage of subjects for which the 1st scan of the study eye was qualified for the final RDB analysis dataset was over 85%.

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 (BMO edit) was performed for the baseline scan for each qualified eye, and the BMO edit rate is approximately 23%.

15.5.1 **Measurement Summary – GCC and Retinal Thickness**

The 1st, 5th, 95th, and 99th percentile were established for macular measurements by regression analysis. Age and gender were used as regression covariates for these measurements.

GCC Thickness		AngioVue Retina (n=427)			Retina Cube (n= 427 Sujects)			Wellness (n= 425 Sujects)		
Parameters	Unit	mean	SD	median	mean	SD	median	mean	SD	median
SQ		8.5	1.0	9	9.0	0.9	9	8.5	0.8	9
Measurement Region		ETDRS Grid (ϕ 6mm)								
C(1)_GCC	µm	56.2	10.2	55.1	56.5	10.4	55.6	63.1	10.5	62.2
T(1-3)_GCC	µm	102.6	7.7	102.3	103.5	7.7	103.2	102.6	7.5	102.1
S(1-3)_GCC	µm	114.6	8.4	114.3	113.7	8.5	113.3	111.8	8.5	111.5
N(1-3)_GCC	µm	111.4	8.8	111.1	111.7	8.9	111.5	111.1	8.7	110.9
I(1-3)_GCC	µm	114.8	8.3	114.8	114.5	8.5	114.7	111.8	8.4	111.4
S-Hemi(1-3)_GCC	µm	110.5	8.2	110.0	110.2	8.2	109.9	109.5	8.0	108.9
I-Hemi(1-3)_GCC	µm	111.2	8.0	111.1	111.5	8.2	111.1	110.0	7.9	110.0
All(1-3)_GCC	µm	110.9	8.0	110.5	110.9	8.1	110.5	109.8	7.8	109.2
T(3-6)_GCC	µm	85.6	6.6	85.4	86.1	6.6	85.8	81.6	6.4	81.2
S(3-6)_GCC	µm	100.7	8.2	100.2	99.5	8.3	99.4	92.0	8.6	91.6
N(3-6)_GCC	µm	117.3	9.6	117.4	116.6	9.8	116.7	113.1	10.2	113.2
I(3-6)_GCC	µm	100.5	8.4	100.2	99.1	8.4	98.6	95.0	9.3	95.1
S-Hemi(3-6)_GCC	µm	100.4	7.7	99.9	99.9	7.8	99.6	93.6	7.8	93.2
I-Hemi(3-6)_GCC	µm	101.6	7.9	101.5	100.8	8.0	100.8	96.6	8.5	96.5
All(3-6)_GCC	µm	101.0	7.5	100.8	100.3	7.6	100.2	95.1	7.7	94.9
S-Hemi(0-6)_GCC	µm	101.5	7.3	100.9	101.0	7.4	100.4	96.3	7.4	96.0
I-Hemi(0-6)_GCC	µm	102.5	7.4	102.3	102.0	7.5	102.1	98.6	7.8	98.8
All(0-6)_GCC	µm	102.0	7.1	101.5	101.5	7.2	101.0	97.5	7.3	96.9
Measurement Region		6mm x 6mm Area						7mm x 8mm Area		
WI_GCC	µm	103.1	7.4	102.8	102.5	7.5	102.4	92.4	6.8	92.0
WI-S-Hemi_GCC	µm	102.0	7.6	101.1	101.5	7.6	100.9	91.5	7.0	91.1
WI-I-Hemi_GCC	µm	104.2	7.8	104.2	103.6	7.8	103.8	93.3	7.2	93.3
FLV_GCC	%	0.51	0.78	0.20	0.52	0.76	0.20	0.55	0.76	0.30
GLV_GCC	%	3.77	3.91	2.80	3.80	3.96	2.80	4.14	3.89	3.10

Table 15.5.5. GCC measurements summary.

Retinal Thickness		AngioVue Retina (n=427)			Retina Cube (n= 427 Sujects)			Wellness (n= 425 Sujects)		
Parameters	Unit	mean	SD	median	mean	SD	median	mean	SD	median
SQ		8.5	1.0	9	9.0	0.9	9	8.5	0.8	9
Measurement Region		ETDRS Grid (ϕ 6mm)								
C(1)_R	µm	258.9	21.7	258.6	259.0	21.9	258.5	258.6	21.9	258.3
T(1-3)_R	µm	315.3	14.3	314.9	315.9	14.4	316.1	314.4	14.6	313.7
S(1-3)_R	µm	328.8	14.5	328.2	329.0	14.5	328.3	326.8	14.9	326.4
N(1-3)_R	µm	329.5	14.8	329.7	329.8	14.9	329.8	327.0	15.0	327.2
I(1-3)_R	µm	324.3	14.1	324.3	324.6	14.1	324.4	323.7	14.3	324.1
S-Hemi(1-3)_R	µm	325.6	14.3	325.4	325.9	14.4	326.0	323.5	14.6	323.1
I-Hemi-(1-3)_R	µm	323.3	14.0	322.9	323.8	14.1	323.6	322.5	14.2	322.2
All(1-3)_R	µm	324.4	14.1	324.1	324.9	14.1	324.8	323.0	14.3	322.9
T(3-6)_R	µm	266.9	13.1	266.8	268.4	13.3	268.5	279.1	14.2	279.3
S(3-6)_R	µm	284.0	13.3	283.2	285.2	13.4	285.1	292.7	14.3	291.9
N(3-6)_R	µm	299.9	14.9	300.0	300.7	14.9	300.7	302.1	15.5	302.9
I(3-6)_R	µm	271.5	13.2	271.6	271.5	13.3	271.6	280.8	14.5	281.4
S-Hemi(3-6)_R	µm	284.1	13.3	283.9	285.3	13.4	285.0	291.8	14.1	291.5
I-Hemi(3-6)_R	µm	277.1	13.1	277.1	277.5	13.2	277.9	285.6	14.2	286.1
All(3-6)_R	µm	280.6	13.0	280.6	281.4	13.1	281.2	288.7	13.9	288.9
S-Hemi(0-6)_R	µm	292.6	12.9	292.4	293.6	12.9	293.1	297.9	13.6	297.4
I-Hemi(0-6)_R	µm	286.9	12.6	286.9	287.3	12.8	287.0	293.0	13.5	293.2
All(0-6)_R	µm	289.7	12.6	289.3	290.5	12.7	290.4	295.5	13.4	295.3
All(0-6)_R_Vol	mm^3	8.19	0.36	8.18	8.21	0.36	8.20	-	-	-

Table 15.5.6. Retina measurements summary.

15.5.2 **Measurement Summary – RNFL Thickness and ONH Parameters**

The 1st, 5th, 95th, and 99th percentile were established for RNFL and ONH measurements by regression analysis. Age and discArea were used as regression covariates for these measurements.

RNFL Thickness		AngioVue Disc (n=426)			Disc Cube (n= 421)		
Parameters	Unit	mean	SD	median	mean	SD	median
Scan Quality		8.0	1.0	8	8.3	1.0	8
Disc Area	mm^2	1.867	0.365	1.821	1.855	0.359	1.811
Measurement Region		Peripapillary Ring (ϕ2.5 mm ~ ϕ4.5mm)					
TS_RNFL	µm	56.2	10.2	55.1	56.5	10.4	55.6
ST_RNFL	µm	102.6	7.7	102.3	103.5	7.7	103.2
SN_RNFL	µm	114.6	8.4	114.3	113.7	8.5	113.3
NS_RNFL	µm	111.4	8.8	111.1	111.7	8.9	111.5
NI_RNFL	µm	114.8	8.3	114.8	114.5	8.5	114.7
IN_RNFL	µm	110.5	8.2	110.0	110.2	8.2	109.9
IT_RNFL	µm	111.2	8.0	111.1	111.5	8.2	111.1
TI_RNFL	µm	110.9	8.0	110.5	110.9	8.1	110.5
T_RNFL	µm	85.6	6.6	85.4	86.1	6.6	85.8
S_RNFL	µm	100.7	8.2	100.2	99.5	8.3	99.4
N_RNFL	µm	117.3	9.6	117.4	116.6	9.8	116.7
I_RNFL	µm	100.5	8.4	100.2	99.1	8.4	98.6
S-Hemi_RNFL	µm	100.4	7.7	99.9	99.9	7.8	99.6
I-Hemi_RNFL	µm	101.6	7.9	101.5	100.8	8.0	100.8
PP_RNFL	µm	101.0	7.5	100.8	100.3	7.6	100.2

Table 5.7. RNFL measurements summary.

Cup, Rim, C/D Ratio		AngioVue Disc (n=426)			Disc Cube (n= 421)		
Parameters	Unit	mean	SD	median	mean	SD	median
Scan Quality		8.0	1.0	8	8.3	1.0	8
Disc Area	mm^2	1.867	0.365	1.821	1.855	0.359	1.811
Measurement Region		Inside Disc Margin					
CupArea	mm^2	0.278	0.262	0.221	0.260	0.253	0.201
RimArea	mm^2	1.589	0.304	1.551	1.595	0.301	1.566
CupVolume	mm^3	0.047	0.068	0.023	0.043	0.064	0.019
C/D Area Ratio	mm^2	0.140	0.116	0.123	0.131	0.115	0.110
C/D H Ratio	mm^2	0.334	0.205	0.353	0.321	0.211	0.339
C/D V Ratio	mm^2	0.325	0.191	0.362	0.304	0.191	0.338

Table 5.8. ONH measurements summary.

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™ System

SOLIX™ (SOLIX™ System) The brand name of this OCT system

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

RPE tips Ends of the RPE at the optic disc, which are used to define the optic disc margin

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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