RTVue XR Avanti System

User Manual

Optovue, Inc.

2800 Bayview Drive

Fremont, CA 94538, USA

Phone: (510) 623-8868

Fax: (510) 623-8668

www.optovue.com

E-mail: **info@optovue.com**

Telephone: (866) 344-8948

For Customer Service or Technical Support: (510) 623-8868 or (866) 941-9240.

Revision Control

Part Number	Revision	Software Version	Description	Release Date
580-52576-005	A	2018.1	Reference ECR02679	06/2019

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 RTVue XR Avanti 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.

Trademarks

RTVue XR, RTVue XR Avanti, AngioVue, AngioAnalytics, and Optovue are either trademarks or registered trademarks of Optovue, Inc. Other trade names are the property of their respective owners and are hereby acknowledged.


AngioVue™
RETINA


AVANTI™
WIDEFIELD OCT

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_____End of section_____

1 Introduction

1.1 General

Optovue, Inc. has developed and tested the RTVue XR Avanti System (Avanti System) with DualTrac and AngioVue software in accordance with Optovue, Inc. safety standards, as well as national and international regulatory guidelines and all applicable safety standards to ensure a high degree of instrument safety. Please observe all labeling related to safety, including information 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.

Section 10 of this manual contains information for AngioVue Software on the RTVue XR Avanti System. It offers further information on acquisition and review of only the AngioVue scans, which are a subset of the scans available with the Avanti Comprehensive, or the Avanti Retina System.

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 7).
- **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.
- Adjust power table height properly to ensure patient comfort 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.
- 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 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 in these areas.
- To avoid pinching the patient, check the patient's head position before raising the chin rest.

1.1.2 Indications for Use

The Avanti is an optical coherence tomography system indicated for the in vivo imaging, axial cross-sectional, and 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 epithelia, corneal stroma, pachymetry, corneal power, and anterior chamber of the eye. With the integrated normative database, Avanti is also a quantitative tool for the comparison of retina, retinal nerve fiber layer, and optic disc measurements in the human eye to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases.

The Avanti 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 retina 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.

Contraindications
Contre-indications

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

Cet appareil n'est pas conçu ni vendu pour être utilisé de toute autre manière que celle spécifiée.

Note: The RTVue XR Avanti 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 clinician.

☞ ***Remarque** : Le systéme RTVue XR Avanti n'est pas destiné à être utilisé comme seul outil de diagnostic pour l'identification, le classement ou le traitement des maladies. Les données produites par le systéme peuvent être utilisées de pair avec d'autres données destinées à aider le clinicien des soins oculaires à établir un diagnostic. Le diagnostic du patient est le domaine exclusive linicien de soins oculaires qualifié.*

☞ **Note:** The RTVue XR Avanti System with AngioVue software is not intended as a substitute for fluorescein angiography.

☞ ***Remarque** : Le systéme RTVue XR Avanti avec AngioVue logiciel ne vise pas comme un substitut pour angiographie à la fluorescéine.*

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 RTVue XR Avanti 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.

1.2 System Overview

1.2.1 System Components

The system ships in one palletized box, which contains the following hardware.

- **Scanner:** This is the main component of the System. It is used to view and scan the patient's eye, collect the OCT signal, and send it to the computer for processing.

- **Computer:** The system computer supports scanner operation, and processes, stores and displays exam data through the application software. The searchable RTVue database stores and organizes patient and exam data.
- **Monitor:** A 21.5 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-connected input devices
- **System Table:** The system table holds all system components and powers them through a medical grade isolation transformer, which prevents current leakage from main AC power. 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.

☞ Note: The Avanti Comprehensive has Retina, Nerve fiber, Cornea, and AngioVue scans. The Avanti Retina is a simplified version with AngioVue scans for OCTA imaging and only Retina scans for OCT imaging.

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

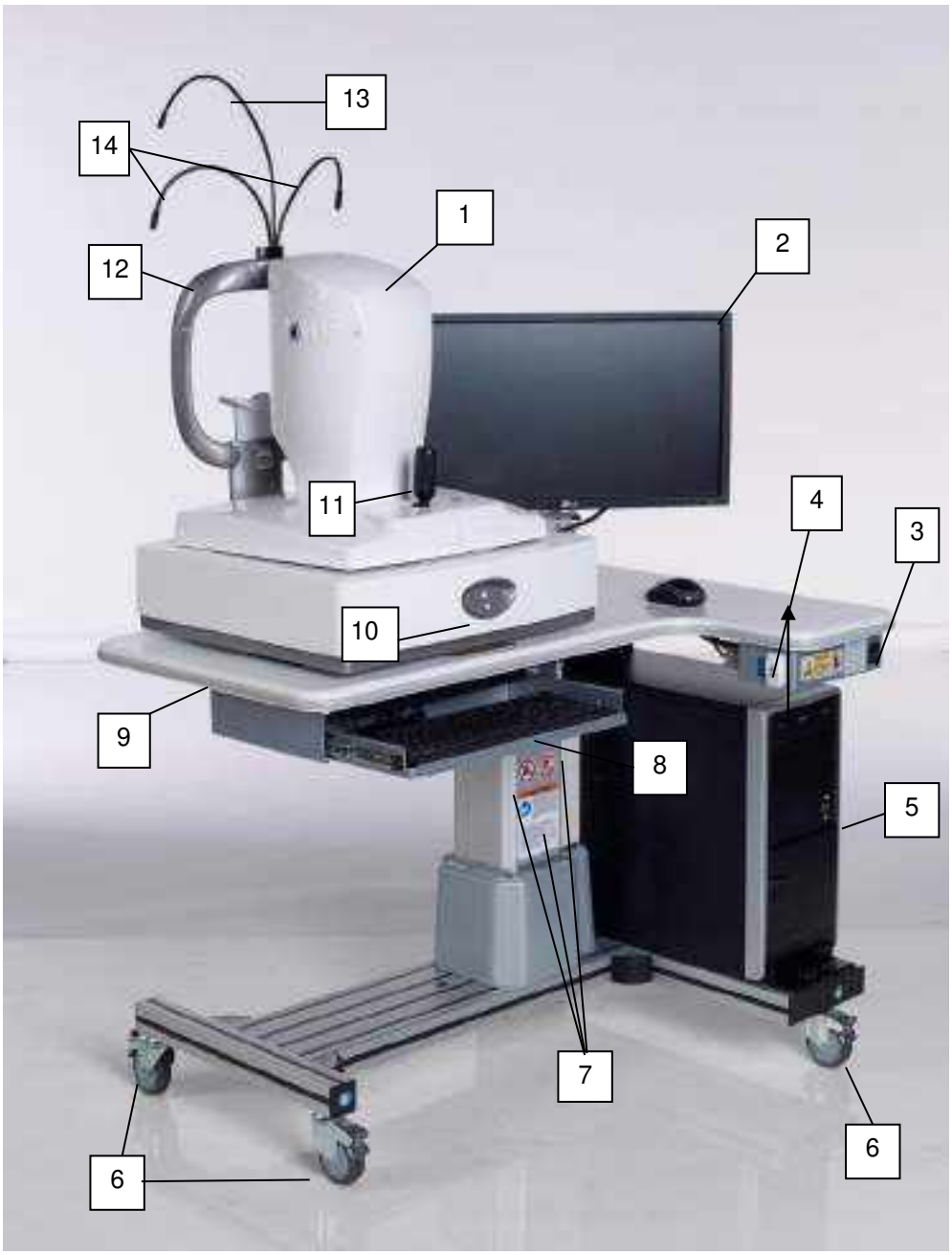


Figure 1 System Hardware

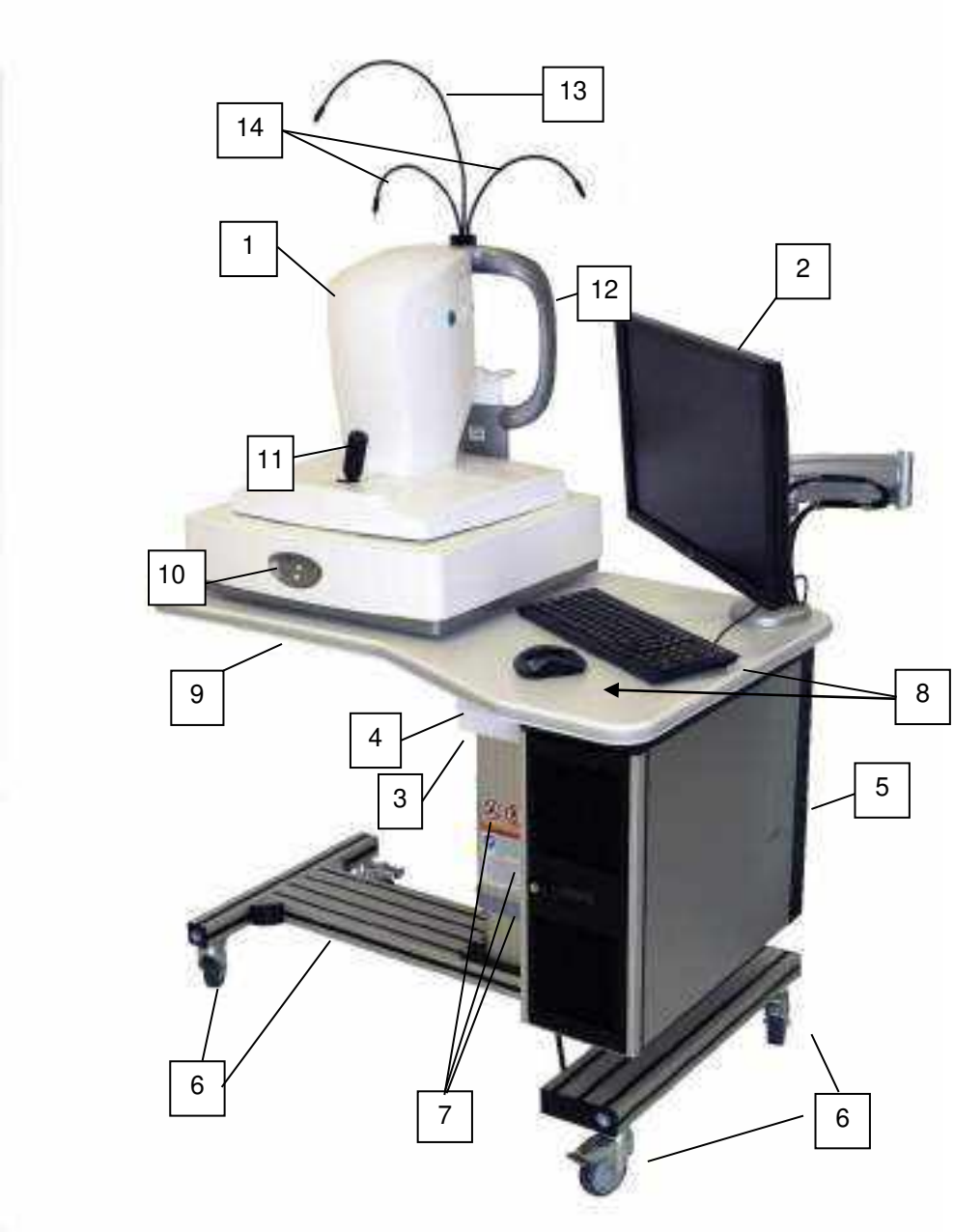


Figure 2 Alternate System Hardware

Figure 1&2 Legend:

1 Scanner

2 Monitor

3 Power switch

4 Table up/down switch

5 Computer

6 Wheels and locks (x4)

7 Warning, RTVue, and serial number labels

8 Keyboard and mouse (enclosed in retractable shelf)

9 System table

10 Chin rest up/down switch

11 Joystick

12 Forehead rest

13 External fixation light

14 Red LED to illuminate eye for CAM (x2)

1.2.2 System Configurations

- Model: RTVue XR-100-1: 110 VAC
- Model: RTVue XR-100-2: 230 VAC
- Model: RTVue XR-100

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 the system computer using its power switch.
3. After the computer operating system has fully launched (can take up to a minute), double-click the **RTVue XR Avanti** desktop icon to launch the system software.

1.3 System Warnings
Avertissements du Système

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 RTVue 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.

Avertissement : *Il est recommandé de ne pas brancher sur l'instrument d'autres accessoires que ceux expressément mentionnés dans ce mode d'emploi. Tout équipement accessoire client branché aux ports d'interface doit être certifié selon les normes CEI respectives (p. ex. la norme CEI 60950 pour le matériel informatique et la norme CEI 60601-1 pour l'équipement médical). En outre, toutes les configurations doivent être conformes à la norme système IEC 60601-1: 2005. Il incombe à toute personne qui branche ou qui installe des accessoires à l'appareil de vérifier la conformité de ces accessoires. En cas de doute, parlez à un représentant d'Optovue.*

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: Do not connect the instrument with anything other than those connections specified. Otherwise, it may result in fire or electric shock. For details of purchasing accessories, please contact an Optovue representative or distributor. To avoid risk of electric shock, this equipment must be connected only to supply mains with protective earthing.

☞ **Note:** Avoid the use of extension cords or a power strip.

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 Normative Database and the results displayed based on estimated percentiles should be used only as an aid for making clinical decisions. The results from the normative 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 normative database may not be suitable for comparison to the normative database. In these patients, the normative database results should be used with caution, if at all. This includes patients outside the age range of the normative database, that is, outside 18 – 82 years of age; or patients outside the range of refractive error, that is, more than 8 diopters spherical error or 2 diopters cylindrical error. Results in patients 30 years of age or younger, and 80 years of age or older, should be interpreted with caution, since only 4 subjects below the age of 30 and three subjects above the age of 80 were included in the normative database. It should be noted that this normative 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 normative 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: Normative 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).

Mise en garde*: La loi fédérale américaine limite la vente de cet appareil directement aux médecins ou praticiens ou sur ordonnance (CFR 801.109 (b) (1)).*

1.4.1 WARNING: User Changes to Software or Hardware

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

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

Avertissement : Modifications apportées par l'utilisateur au logiciel ou au matériel informatique.

Le systéme RTVue XR Avanti est un instrument médical. Le logiciel et le matériel informatique ont été conçus conformément aux normes de conception et de fabrication des appareils médicaux en vigueur aux É.-U., en Europe et ailleurs. Toute modification non autorisée du logiciel ou du matériel informatique du systéme, ou tout ajout ou suppression d'une application de quelque manière que ce soit peut présenter un risque pour la sécurité des opérateurs et des patients, le fonctionnement de l'instrument et l'intégrité des données des patients.

Tout changement, ajout ou suppression aux applications installées en usine et au système d'exploitation et toute modification au matériel informatique, de quelque manière que ce soit, ANNULERONT complètement la garantie et pourraient présenter un DANGER.

1.4.2 WARNING: Phototoxicity

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be prolonged unnecessarily, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures.

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure to the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography.

Avertissement : Phototoxicité

Du fait que l'exposition prolongée à une lumière intense peut endommager la rétine, l'utilisation du dispositif pour l'examen oculaire ne doit pas être inutilement prolongée, et le réglage de la luminosité ne doit pas dépasser l'intensité nécessaire pour obtenir une visualisation claire des structures cibles.

La dose d'exposition rétinienne susceptible de présenter un danger photochimique est le résultat de l'intensité de radiation et de la durée d'exposition. Lorsque la valeur de rayonnement est réduite de moitié, le délai nécessaire pour atteindre la limite d'exposition maximale double.

Même si aucune étude ne montre que les rayonnements optiques des ophtalmoscopes directs ou indirects ont un effet de toxicité aiguë, il est recommandé de réduire l'intensité de la lumière dirigée dans l'œil du patient au niveau strictement nécessaire pour établir le diagnostic. Les nourrissons, les personnes souffrant d'aphakie (absence de cornée) et les personnes souffrant d'une maladie oculaire sont les plus à risque. Le risque peut également augmenter lorsque la personne examinée a été exposée au même instrument ou à tout autre instrument ophtalmique utilisant une source de lumière visible au cours des 24 dernières heures. Cela est particulièrement vrai lorsque les yeux ont été exposés à une photographie rétinienne.

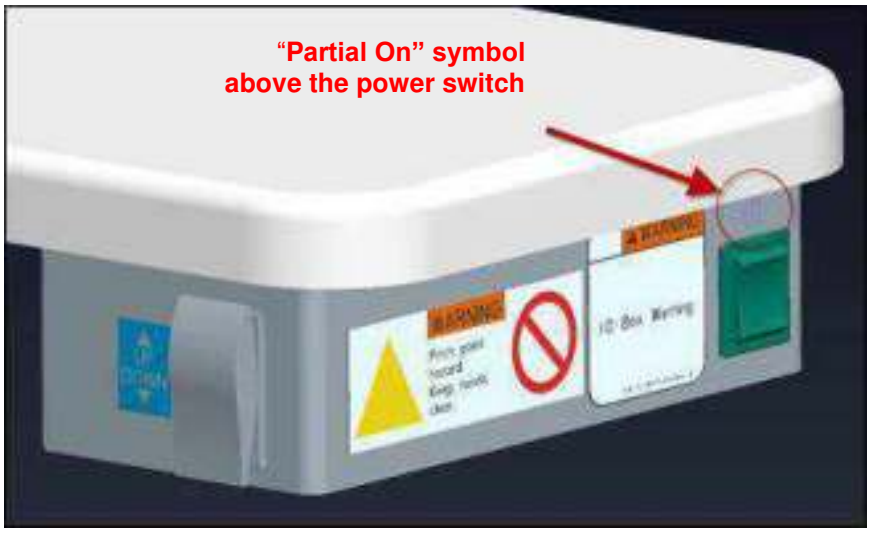
Do not step on surface.

Ne pas marcher sur la surface.

WARNING: Electricity

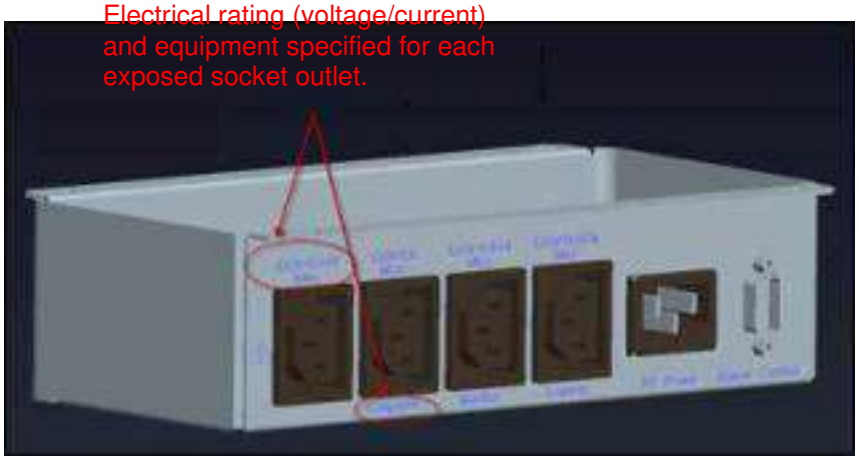
Avertissement : *Électricité.*

1.5 Power and Electrical Safety



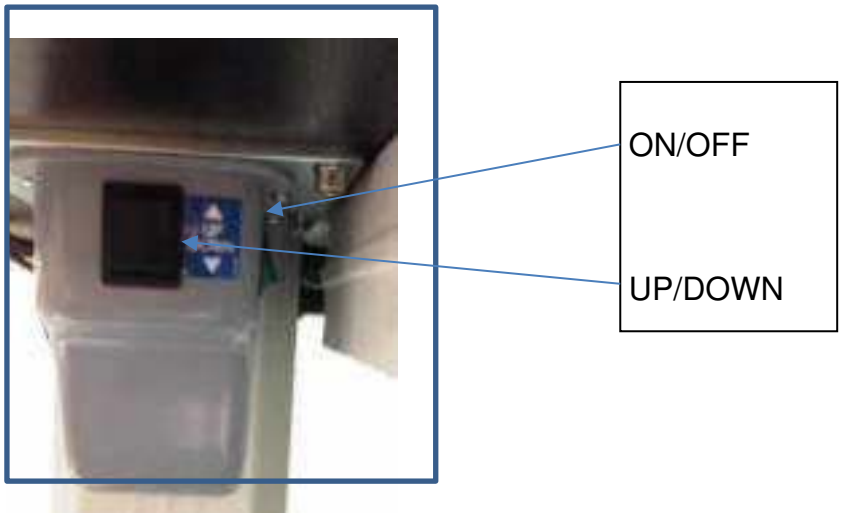
ON/OFF - Even with switch off, there is power to the table column.

ON/OFF - La colonne de la table reste sous tension même lorsque l'instrument est arrêté.



Maximum Permissible Load (See socket label. For use by Optovue personnel only.)
Charge maximale admissible (voir l'étiquette de la prise)

1.6 Alternate Power and Electrical Safety



Maximum Permissible Load (For use by Optovue personnel only.)
Charge maximale admissible

1.7 Safety with Moving Parts

Table Handling Instructions
Directives de manipulation de la table

Read the warning label on the table column for instructions to safely transport the table from room to room. The instructions tell you to lower the table to its lowest height before transport. Observe the pinch point and foot trap warnings before lowering the table, to avoid trapping or pinching a foot, leg, hand or arm.

Pinch Warning Locations

Emplacements pour les avertissements de risque de pincement.

Please observe pinch warnings before raising and lowering the table.

Veuillez lire les avertissements sur le risque de pincement avant de relever ou d'abaisser la table.

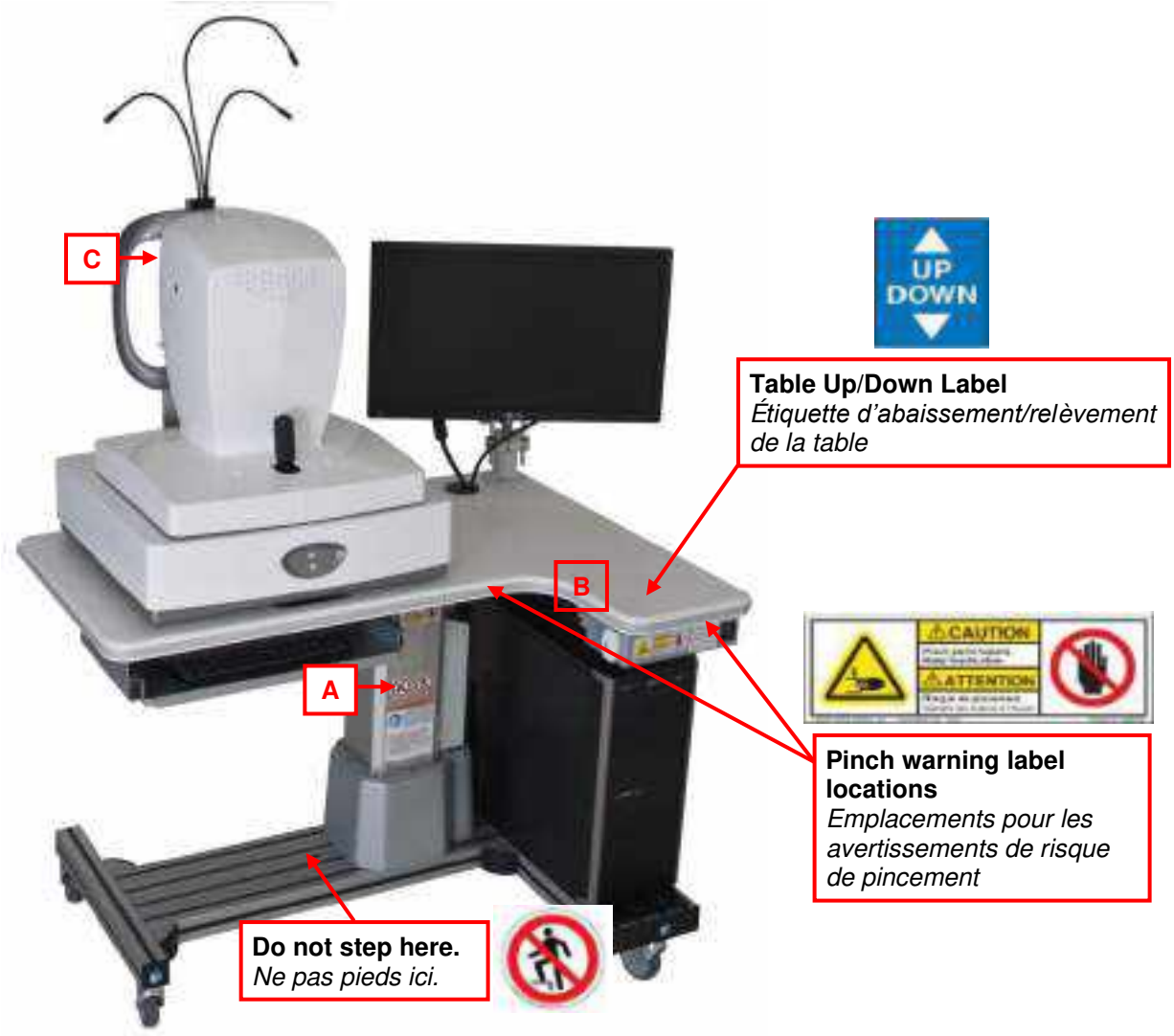
Foot Rest Trapping Warning

Do not step on table base when adjusting table height.

Avertissement de risque de coincement dans le repose-pied

Ne pas poser les pieds sur base de table lors de l'ajustement hauteur de table.

Table Up/Down Label
Étiquette d'abaissement/relèvement de la table



WARNING: Possible Pinch Locations

Avertissement : Zones de risque de pincement

A. Space between bottom of the table top and base of column
Espace entre le dessous de la plateforme de la table et le col de la colonne

B. Space between bottom of the PC and the base
Espace entre le fond de la PC et à la plateforme de la table

C. Space between chin rest and forehead rest
Espace entre la mentonnière et l'appui-tête

How to lock wheels:
Étiquette de blocage de roué:

Locked
Verrouillé

Unlocked
Déverrouillé

Wheel lock label

1.8 Standard Accessories

1.8.1 Standard Accessories

Description	Part No.	Quantity
Installation Manual	810-48858-002	1 pc.
Dust Cover	530-42553	1 pc.
Lock cover Plug, Plastic,, 3/8" OD	620-50389-001	1 pc.
Hardware Kit	500-48112-001	1 pc.
Plug, Plastic Push-in Round 5/8 ID	620-47485-001	3 pc.
Mouse	600-44542	1 pc.
USB Keyboard	600-48557-001	1 pc.

1.8.2 Cabling

System Cabling

Cable Name	Cable Type	Shielded or Unshielded	Cable Max. Length
PC AC	3 wire	Unshielded	1 m
PC DC	2 wire	Unshielded	1 m
Keyboard, Mouse	USB	Shielded	1 m
RTVue AC	3 wire	Unshielded	1 m
RTVue PC	USB	Shielded	1 m
RTVue Scan Head	Multi wire	Shielded	1.5 m
RTVue Optical	Fiber Pair	Unshielded	2 m
RTVue GigE	CAT 6	Unshielded	1 m
RTVue Chinrest	Multi wire	Shielded	1.5 m
RTVue Joystick	2 wire	Shielded	0.2 m
Column AC	3 wire	Unshielded	2 m

1.9 Product Compliance

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

This device is classified according to UL/IEC/BS EN 60601-1-2 4th Ed. (2015) as follows:

Mobile, Continuous Operation, Class 1, Type B.

With respect to electrical shock, fire and mechanical hazards only in accordance with UL/IEC/BS EN 60601-1-2 4th Ed. (2015) and CAN/CSA C22.2 No. 601.1.

ON for part of the Equipment.
*Une partie de l'équipement est en marche **(« ON »)**.*

Alternating Current
Courant alternatif

1.10 Radio Interference

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.

1.10.1 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.

1.10.2 Electromagnetic Compatibility (EMC): EN 60601-1-2 4th Ed.

The RTVue XR Avanti 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.

<table>
<tr><td></td><td colspan="3">GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS</td></tr>
<tr><td></td><td colspan="3">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.</td></tr>
<tr><td>Test type</td><td>Test level</td><td>Compliance</td><td>Electromagnetic Environment - Guidance</td></tr>
<tr><td>Conducted Emissions

EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010</td><td>Class A group 1

150 kHz to 30 MHz</td><td>Class A group 1

150 kHz to 30 MHz</td><td>The RTVue 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.</td></tr>
<tr><td>Radiated Emissions

EN 55011:2009+A1:2010, CISPR 11:2009+A1:2010</td><td>Class A group 1

30 MHz to 1 GHz</td><td>Class A group 1

30 MHz to 1 GHz</td><td rowspan="2">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</td></tr>
<tr><td>Harmonics

IEC/EN 61000-3-2:2014</td><td>Class A Device</td><td>Per Clause 5 of the Standard</td></tr>
</table>

Flicker IEC/EN 61000-3-3:2013	Per Clause 5 of the Standard	Per Clause 5 of the Standard	measures, such as re-orienting or relocating the system, or shielding the location.

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.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
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.
Radiated RF IEC/EN 61000-4-3	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	80 MHz - 2.7 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = (6/d)\sqrt{P}$ Where *P* is the maximum power in W, *d* is the minimum separation distance in m, and *E* is the IMMUNITY TEST LEVEL in V/m. If the ME EQUIPMENT or ME SYSTEM complies with higher IMMUNITY TEST LEVELS for this test, the 30 cm minimum separation distance in 5.2.1.1 f) may be replaced with minimum separation distances calculated from the higher IMMUNITY TEST LEVELS.
Proximity field from RF wireless communications equipment IEC 61000-4-3	See EN 60601-1-2:2014 Table 9	See EN 60601-1-2:2014 Table 9	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
Conducted Immunity (AC Power) (I/O Lines) IEC/EN 61000-4-6	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM & amateur bands 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM & amateur bands 1 kHz AC Mains	The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.
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

1.11 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).

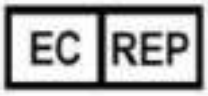
Note: Calls attention to important information for the user.

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.

Manufacturer
Optovue, Inc.
2800 Bayview Drive,
Fremont, CA., USA, 94538

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

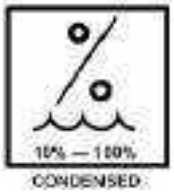
1.11.1 Protective Packing Symbols

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

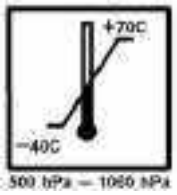
Fragile, handle with care

Keep dry

This side up



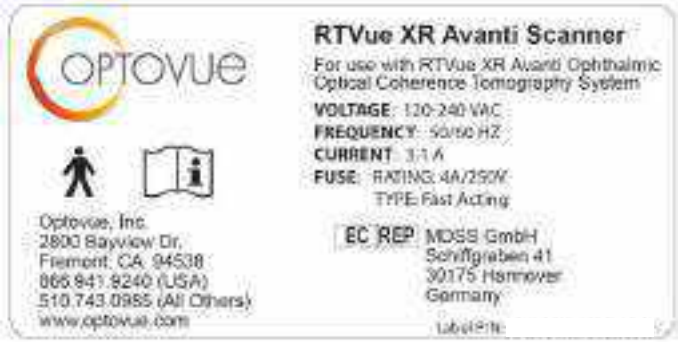
Environmental conditions during transport: Relative humidity (10% to 100%, including condensation)



Environmental conditions during transport: Temperature range (-40 °C to +70 °C) and atmospheric pressure range (500 hPa to 1060 hPa)

1.12 Product Labels

The RTVue XR Avanti model product labels appear below. These labels are examples only.



1.13 Disposal

Dispose of the equipment per local regulations.

1.13.1 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.**

Déchets d'équipements électriques et électroniques (DEEE) Instructions de recyclage

Lorsque l'instrument est considéré prêt à l'envoi au rebut, il doit être recyclé conformément aux politiques et procédures en vigueur dans le pays. ***L'instrument à éliminer ne doit pas être traité comme un déchet ordinaire.***

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.

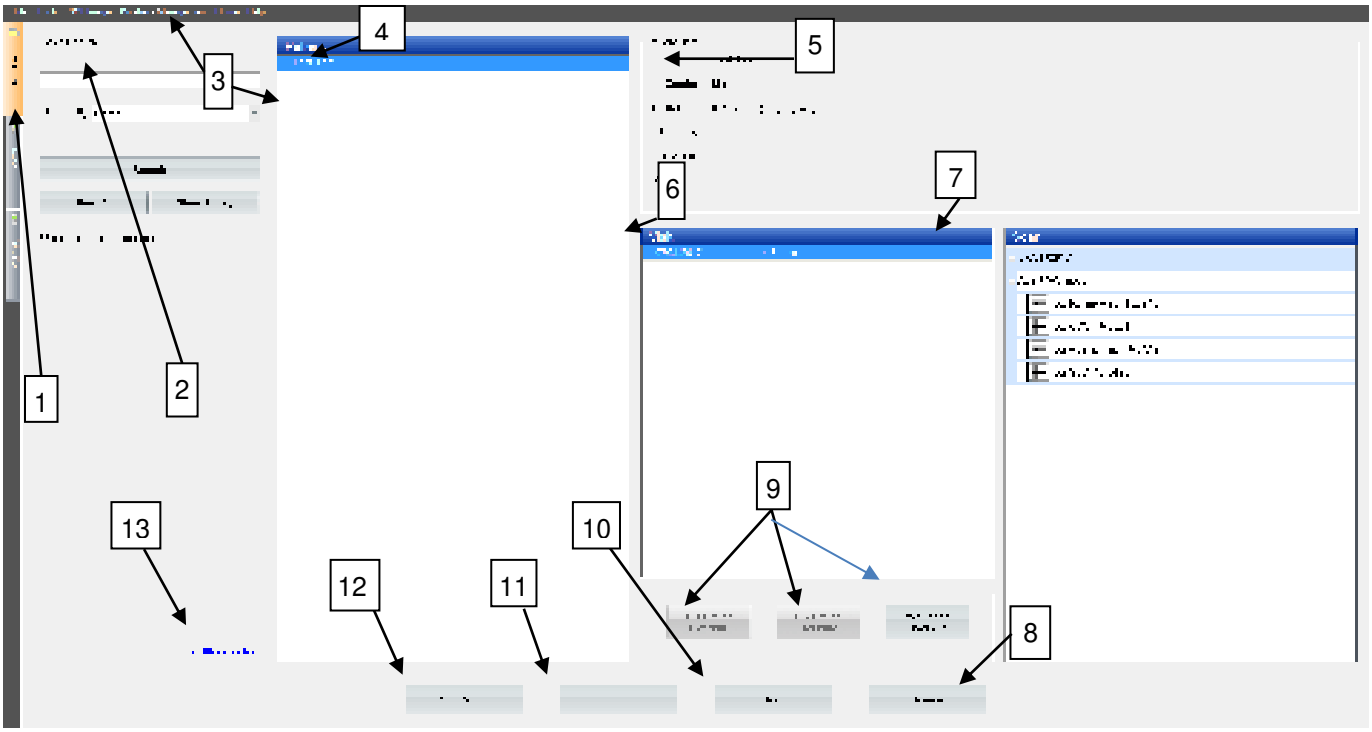


Figure 3 PATIENT Window Items

Figure 3 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 OverVue buttons (Retina Wellness)

10 Scan button

11 Edit button

12 Add Patient button

13Advanced or **Basic Search** link

Note: The selected tab is highlighted as shown for the PATIENT tab in Figure 3.

See chapter 6 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.

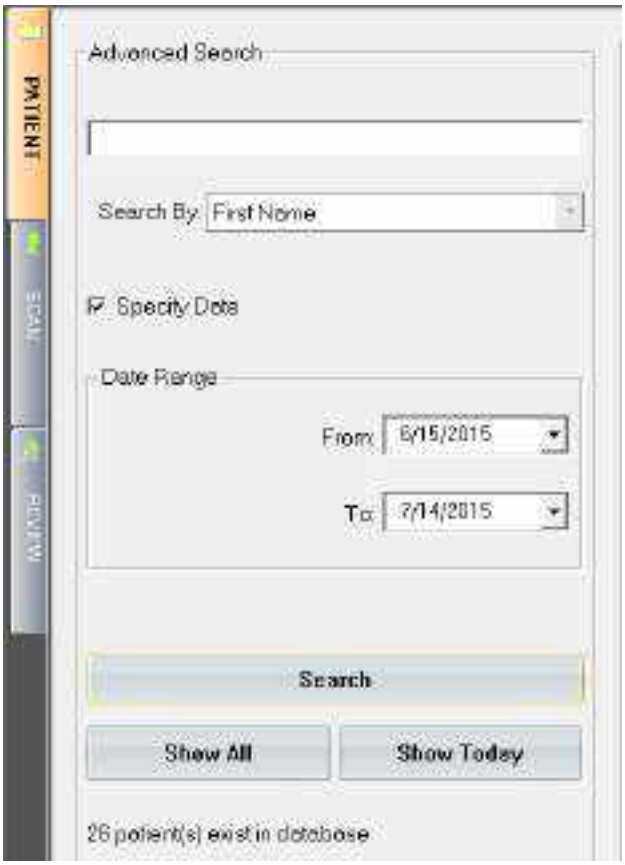


Figure 5 Advanced Search Area

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.**

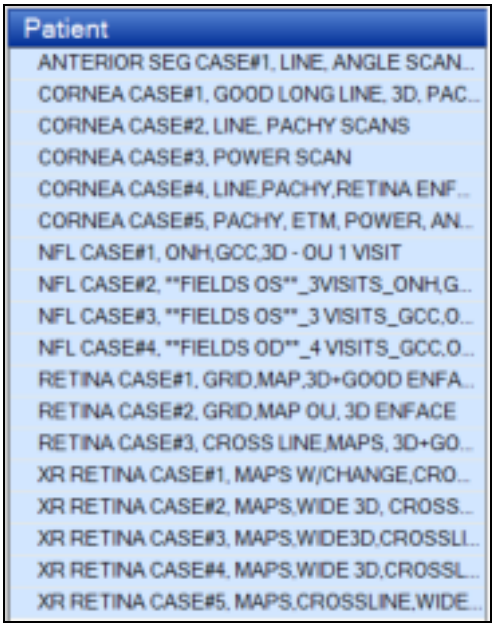


Figure 6 Sample Patient List

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 retinal scan and/or a specific retinal scan is selected, the application enables the **OD Retina OverVue** and/or **OS Retina OverVue** button, according to the eye (left or right, or both with a visit that has both). The Wellness protocol enables the **Wellness OverVue** button

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

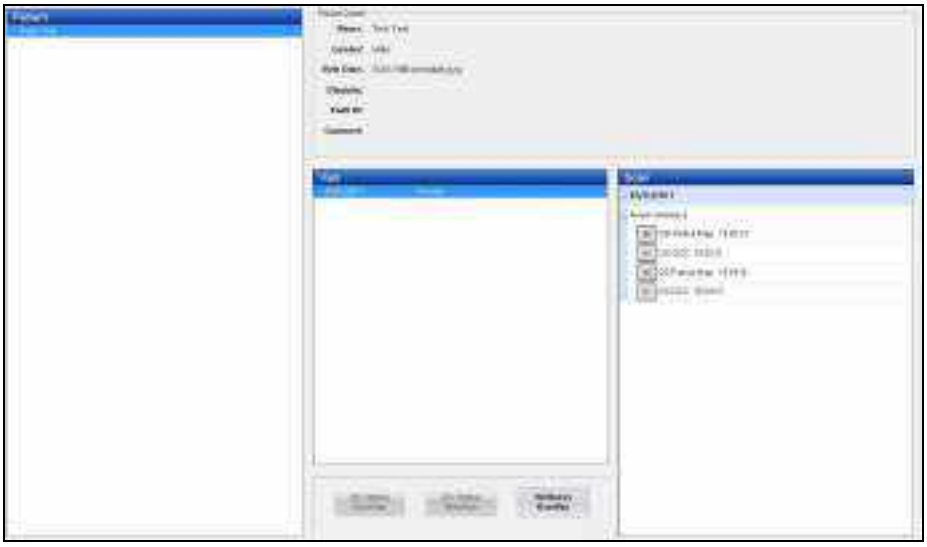


Figure 7 Selections Made in PATIENT Window

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.

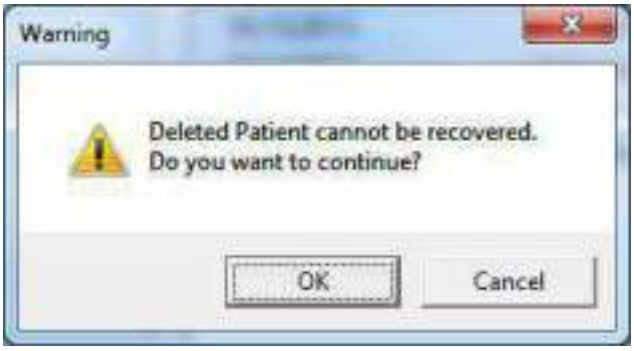


Figure 8 Delete Current Patient Warning

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.

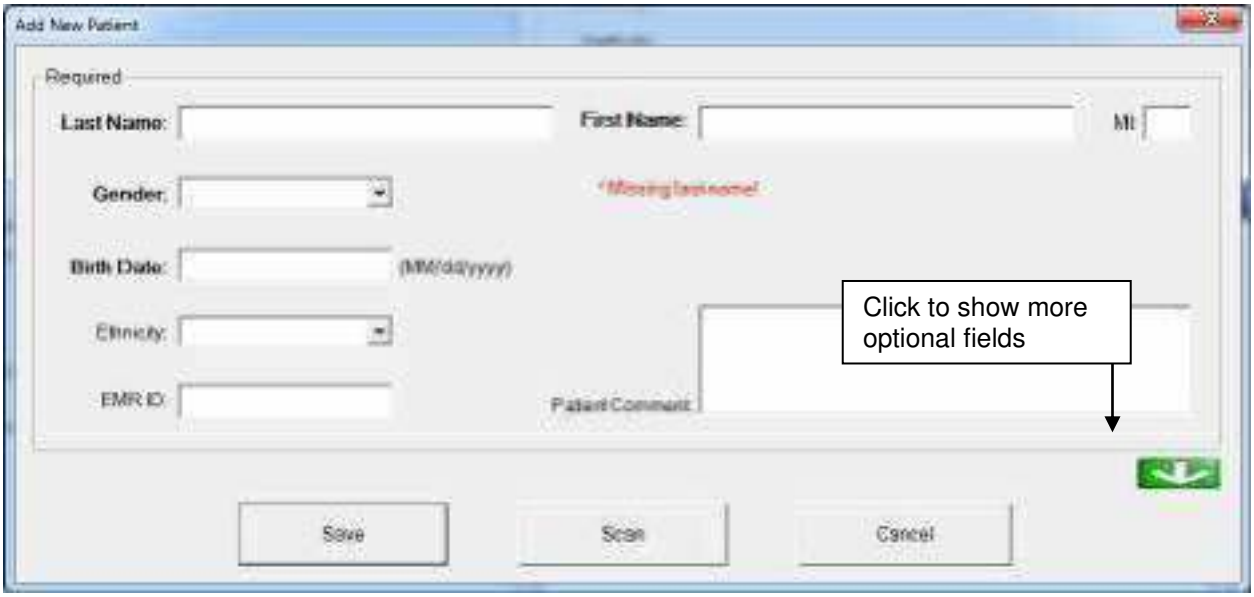


Figure 9 Add New Patient Dialog

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.

   You can enter more optional information for the patient by clicking the green down arrow to expand the dialog.

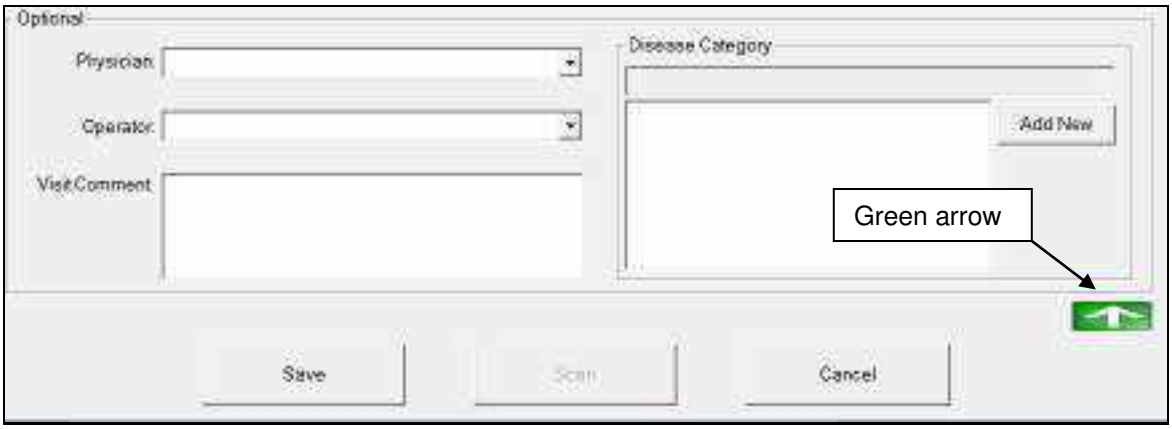


Figure 10 Add New Patient Optional Fields

Use the **Optional** area 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.

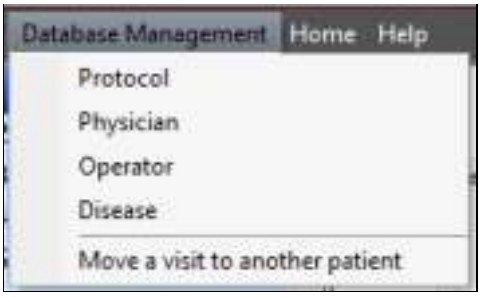


Figure 11 Select Move a visit to another patient

A confirmation dialog appears.

Figure 12 Confirm Intent to Move Selected Visit

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

Figure 13 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.

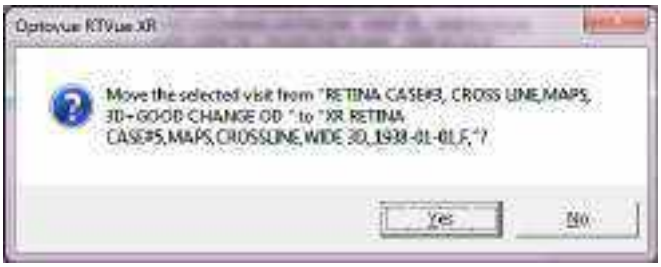


Figure 14 Confirm Move to Selected Patient

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

_____End of section_____

3 Capture Scans

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

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 germicide using a clean cloth.

Use the following procedure to acquire OCT 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 window.

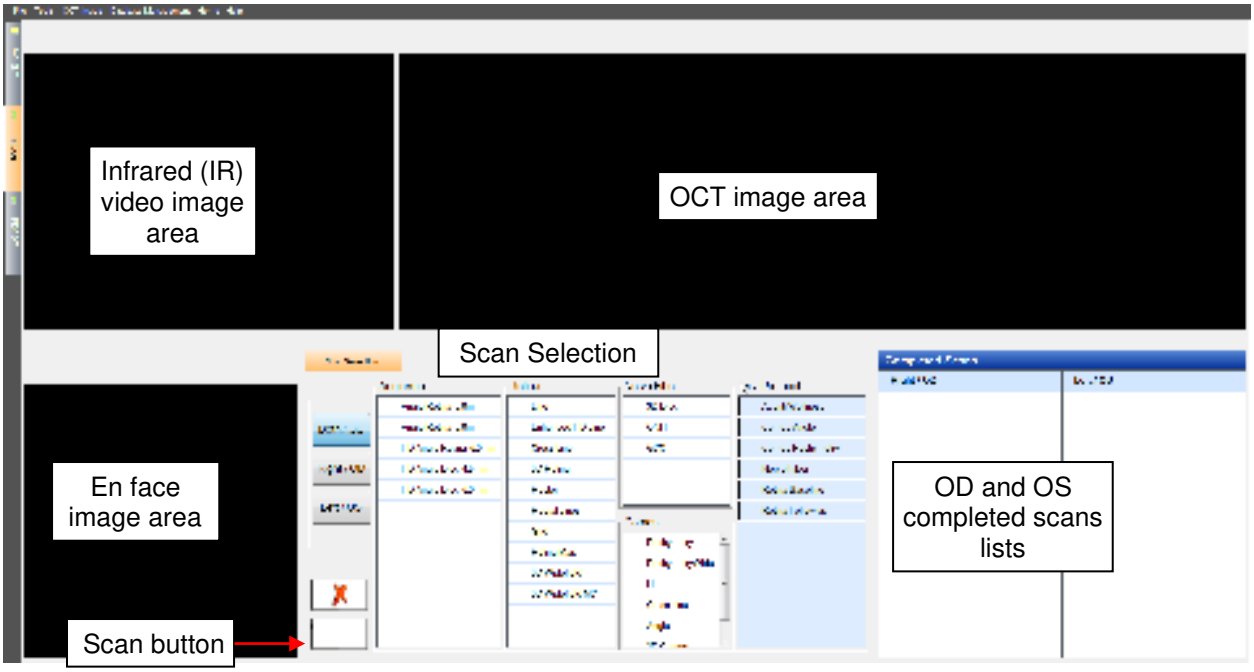


Figure 15 SCAN Window AngioVue Comprehensive

2. In the SCAN window, select the patient eye to be scanned. **Both** / **OU** is selected by default. To change, click the **Right** / **OD** or **Left** / **OS** button.

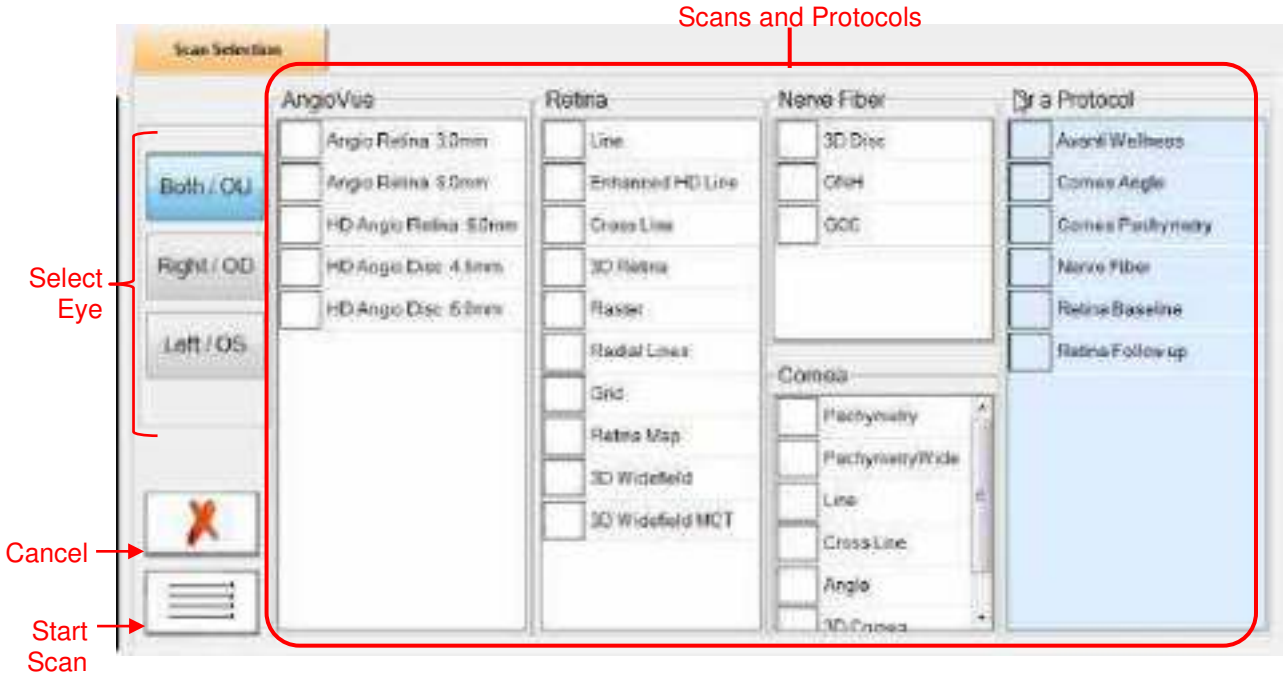


Figure 16 AngioVue Comprehensive scans & protocols

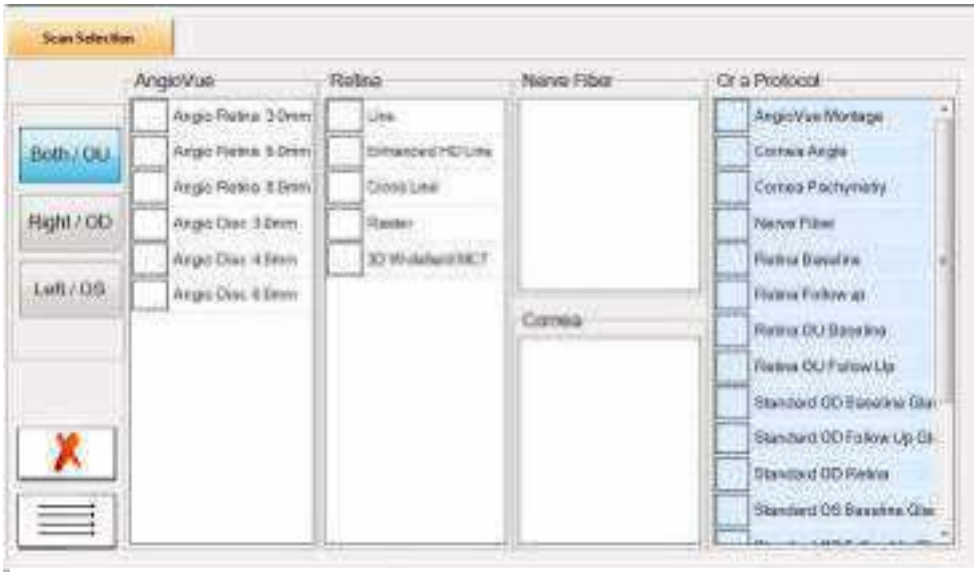


Figure 17 AngioVue Retina Scan Selection Options

3. Select the desired scan type from the Retina, Nerve Fiber, or Cornea lists, or select a scan protocol from the Protocol list. You can select multiple scans to do the selected scans in succession. When you finish your selections, click the Scan button to begin scanning or click the joystick button.

- Alternatively, you can repeat any previous scan for a patient by double-clicking on the scan name in the **Scans** list of the PATIENT window.

When you start scanning, the Scan Selection options are replaced by scan adjustment options on the **Auto** tab (default) or **Manual** tab. (The available parameters and their ranges depend on the scan type.)

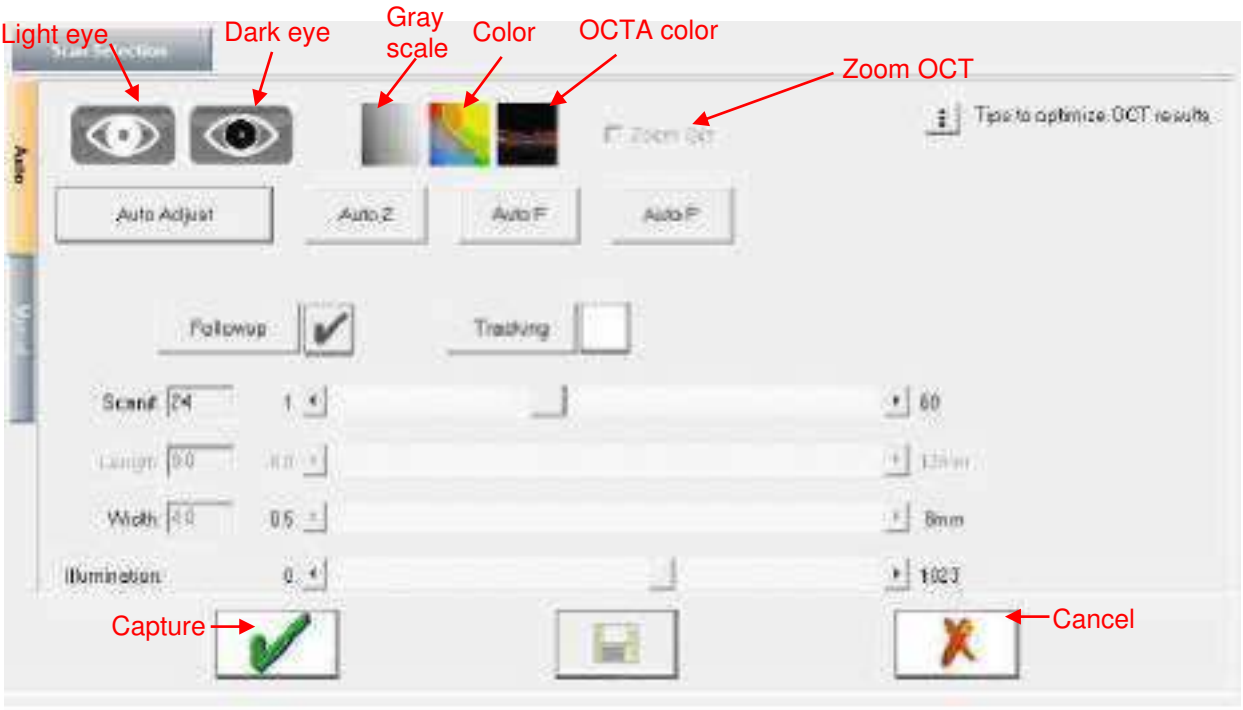


Figure 18 Scan Adjustment Options (Auto Tab)

To customize scan parameters, select the MANUAL tab.

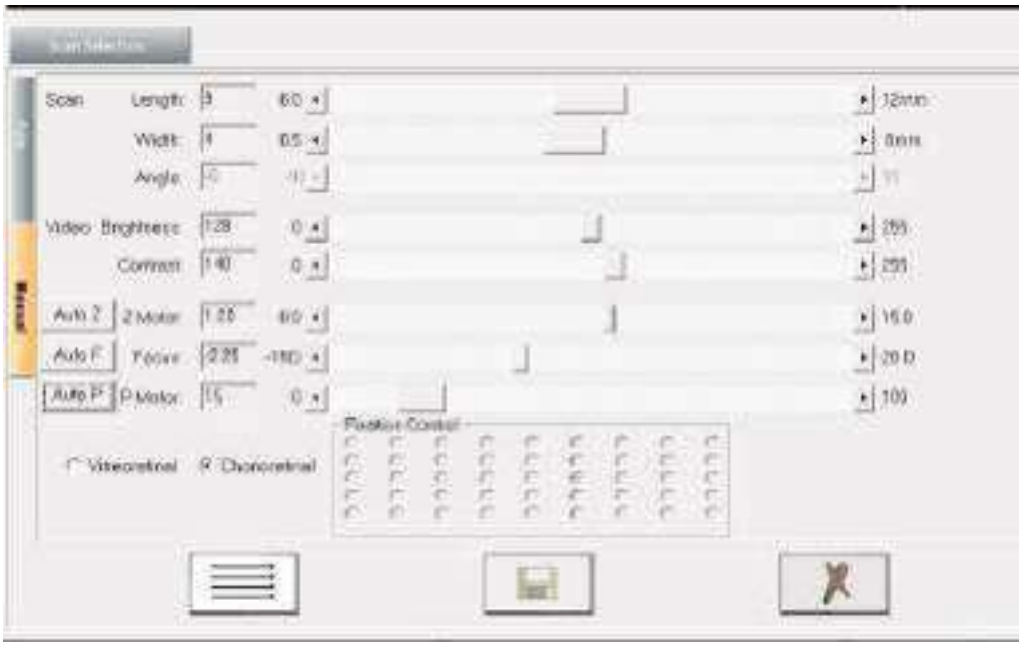


Figure 19 Manual Tab to Customize Scan

4. Position the patient correctly as follows:

- 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 the fixation target, a blue dot in the red field.

5. Center the video image on the pupil and move the scan head towards the patient, controlling it so that the video image passes through the pupil. Carefully advance until

the fundus comes into view (for Retina and Nerve Fiber scans). The figure below shows the progression of views as you move the scan head forward.

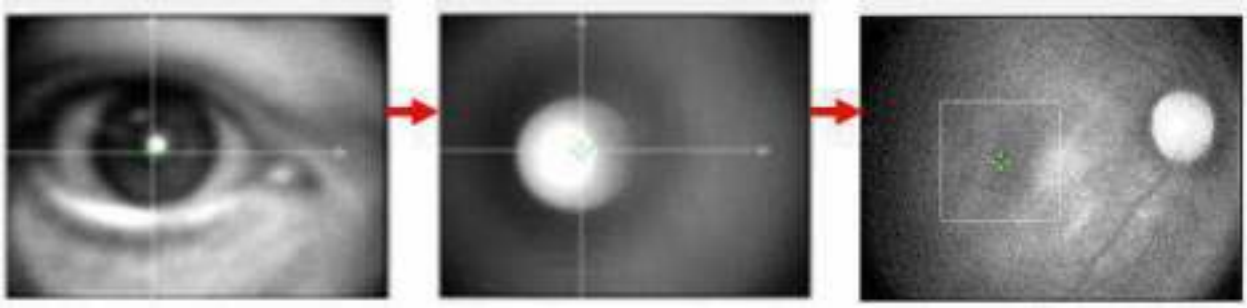


Figure 20 Video Image Progression as Scanner Approaches Eye

6. Adjust the working distance between the scan head and patient eye to optimize the 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 in the scan window indicates the correct working distance.

Note: On each patient, the first scan of each eye, of that day, 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.

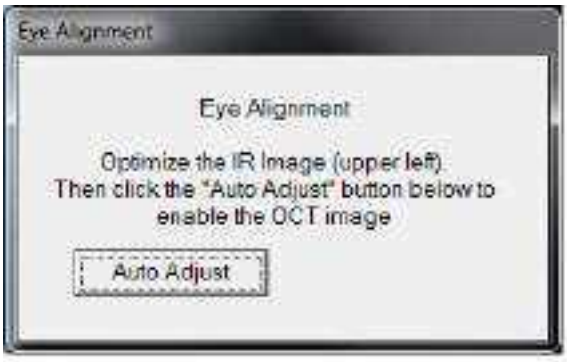


Figure 21 Eye alignment

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 22 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.

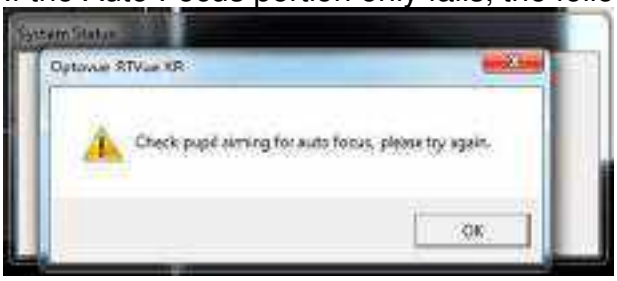


Figure 23 Auto Adjust focus

The operator should try to optimize the IR image and Auto Adjust/focus again, if the image cannot be improved the operator may decide to capture the image

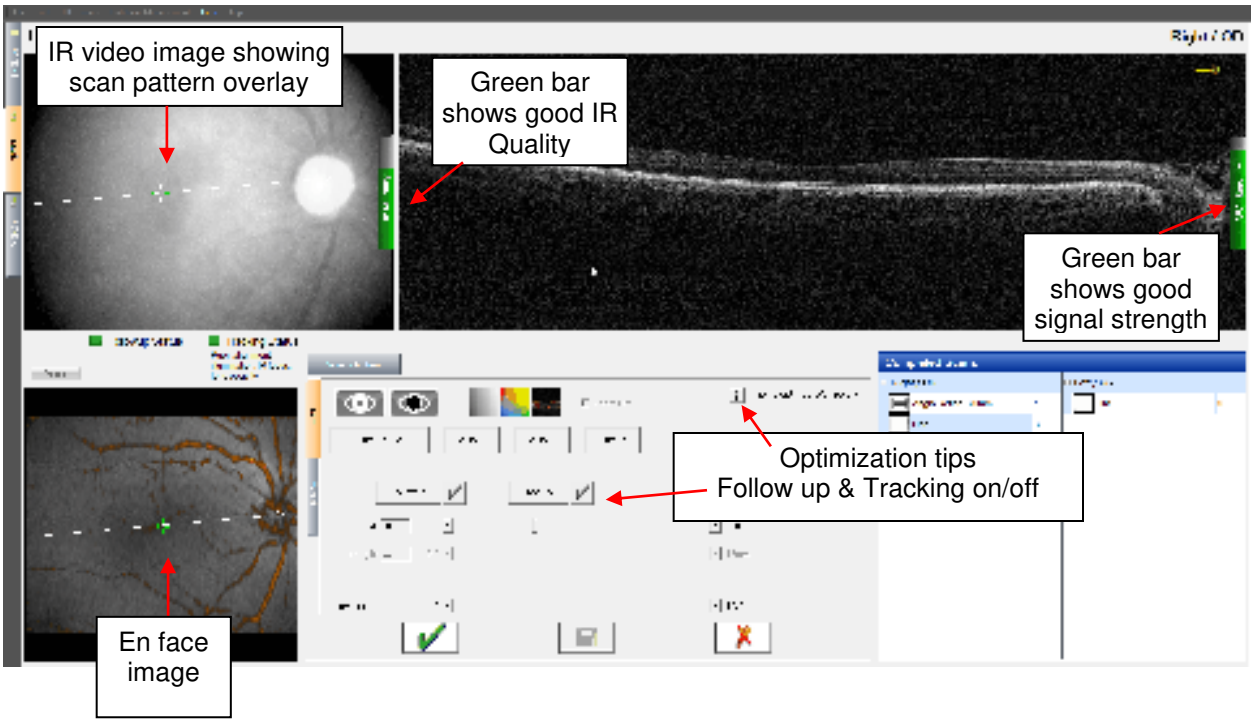


Figure 24 Optimize Working Distance

7. When the 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.

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

Figure 25 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 scan image in the target area between the red dashed lines. Figure 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.

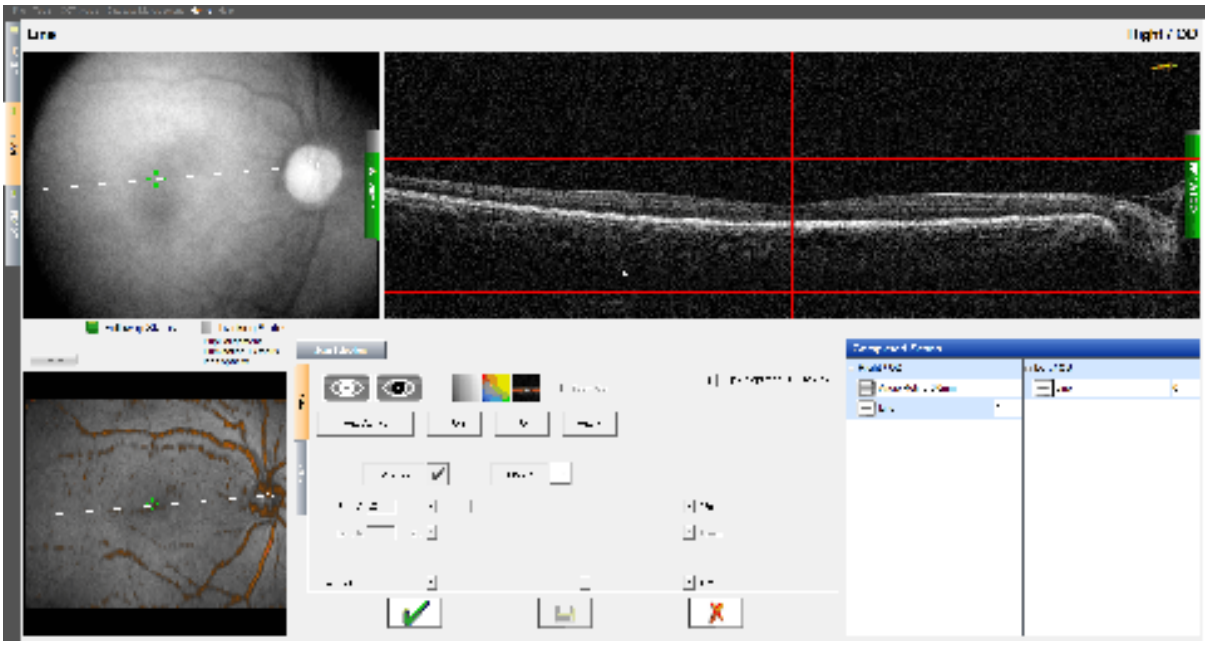


Figure 26 Example of Scan Centered Vertically

Figure 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 index (SSI) 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 (SSI) 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 (SSI) indicator is not **green** over a range of patients, including normals, contact Optovue Technical Support for assistance.

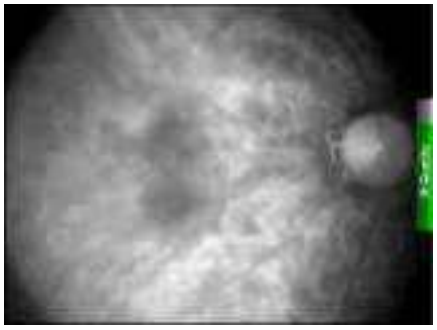
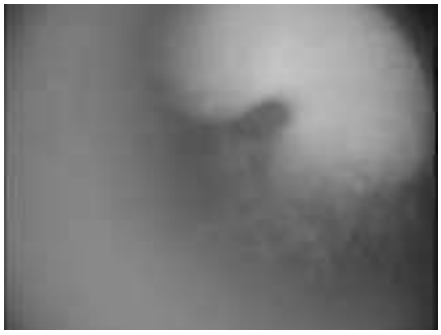
9. If the OCT (SSI) indicator is red, use one or more of the following functions on the **Manual** tab to manually optimize scan signal strength and image quality.

- Select the **Manual** 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 good, homogeneous illumination by alignment to the center of pupil
- Bring optical disc in the field of view
- Avoid glare by adjusting the scan-head alignment to pupil center
- In follow-up mode, adjust the image to ensure green cross (“good tracking”) shows up in the target zone in fundus image.
- **On OCT image**
- Target tissues should fall between two red lines
- **Tracking (green light indicator) and start scanning**

Good Image	
Poor due to glare	

Blocked or blurry	

3.1.2 Tips for Scanning Difficult Patients

Note: After scanning and the patient starts to drift always remind the patient to look at the blue dot before attempting to reposition the camera. Often the patient will return to the correct position.

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

- Tip: 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 before resuming the scan or re-scan the patient.

Nervous 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.
- 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 hug the base of the machine.

3.1.3 Tips to Optimize OCT results

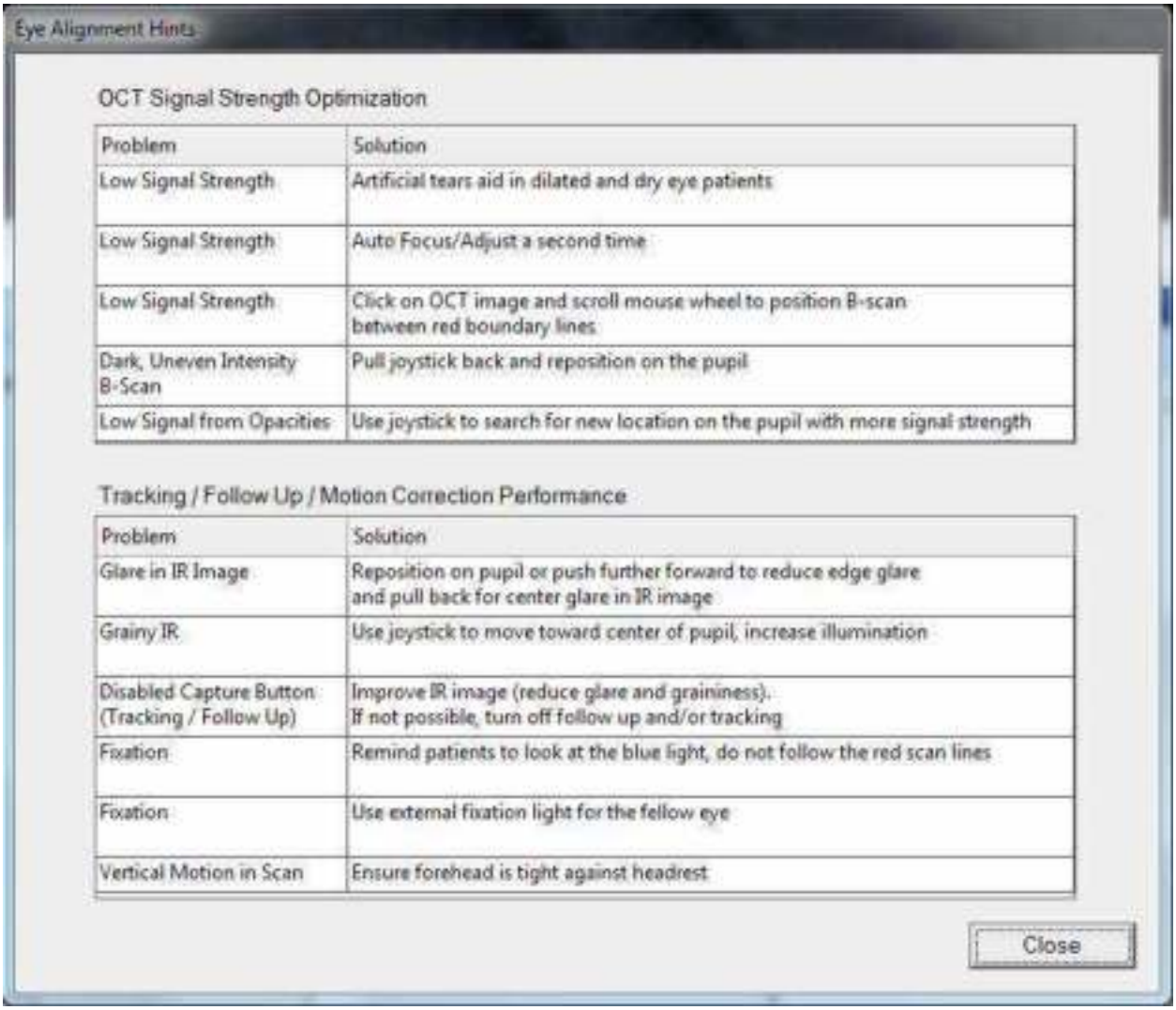


Figure 27 Tips to Optimize OCT results

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

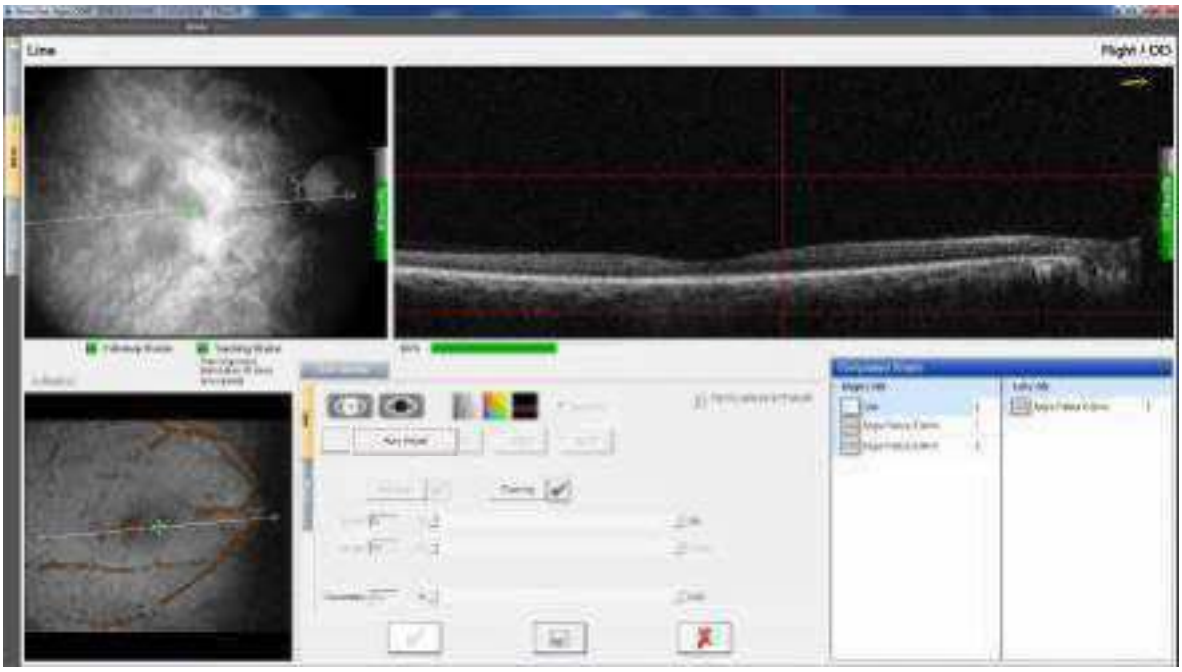


Figure 28 A Captured Scan (Save Button Active)

After scan capture, review the scan images for quality and completeness. If you want to save the images, click the **Save** button  or press the joystick button again. Pressing the **Scan** button  again without saving discards the images and restarts the same scan.

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

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

b. Go back to the PATIENT window, select the desired patient, visit and scan, and click the **Review** button.

Note: Certain scans like the Widefield MCT and AngioVue scans require the acquisition of a Fast-X scan and a Fast-Y scan in consecutive steps. On first capture, the system acquires a Fast-X scan. Review the scan for severe eye movement. Then capture the Fast –Y.

See Chapter 11 on AngioVue for more information on OCTA scan capture.

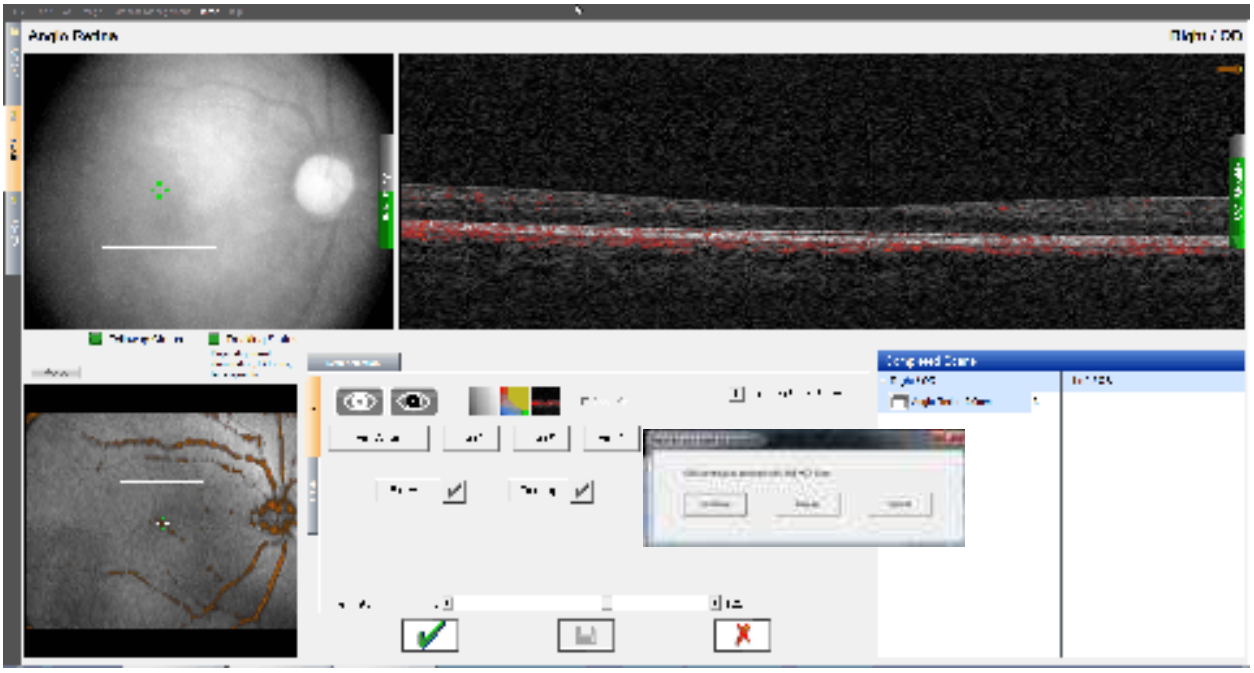


Figure 29 Fast-X Scan Captured

If you are satisfied with the captured scan, click **Continue or joystick button** to proceed 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 continue, the Fast-Y scan begins automatically. 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.

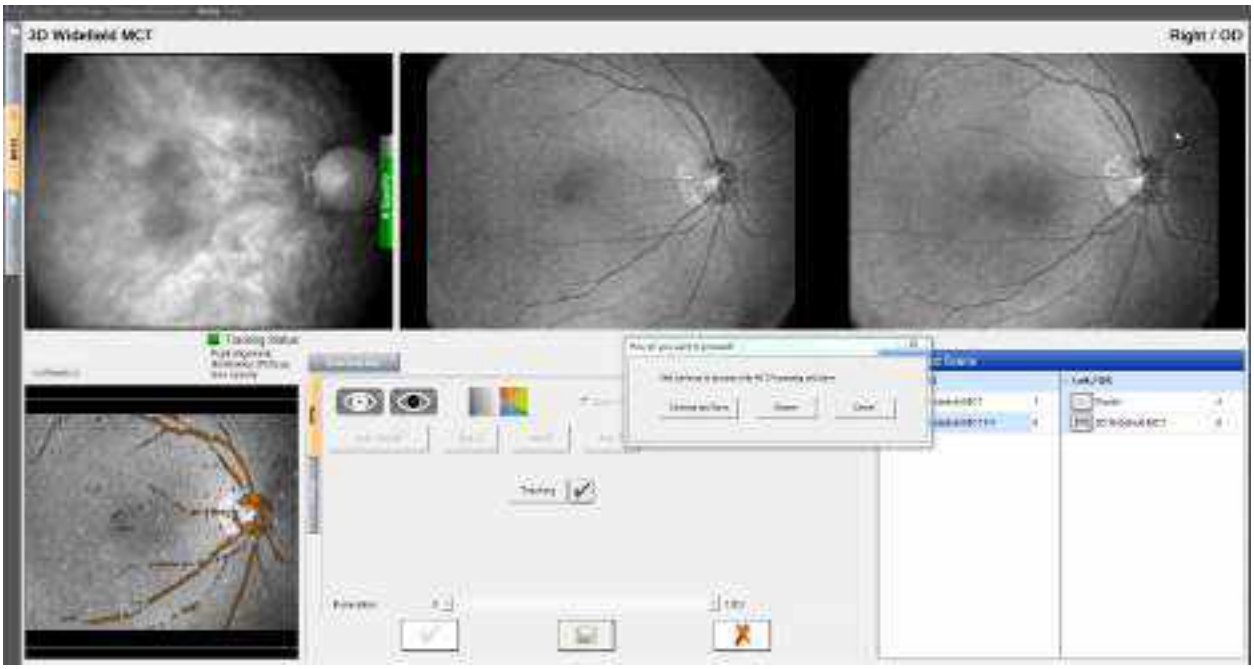


Figure 30 Active Fast-Y Scan

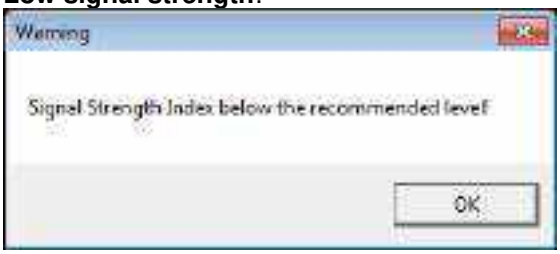
11. If necessary, adjust scan placement and optimize scan quality again. It is optimal to capture the second scan with minimal adjustment, so ask the patient not to move between scans. When ready, capture the Fast-Y scan.

3.1.4 Joystick button Functionality

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

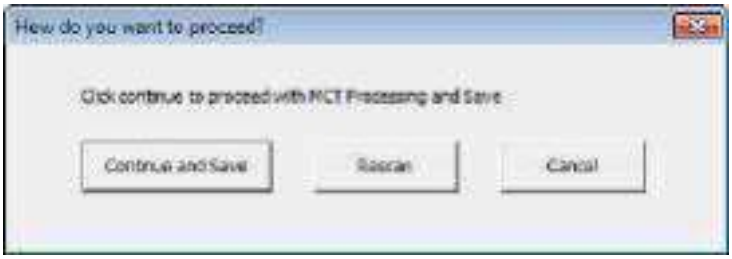
1. **Eye blink**:

2. **Low signal strength**:



3. **Enface registration failure**:

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



3.2 Scanning Options

3.2.1 Scan Types and Protocols

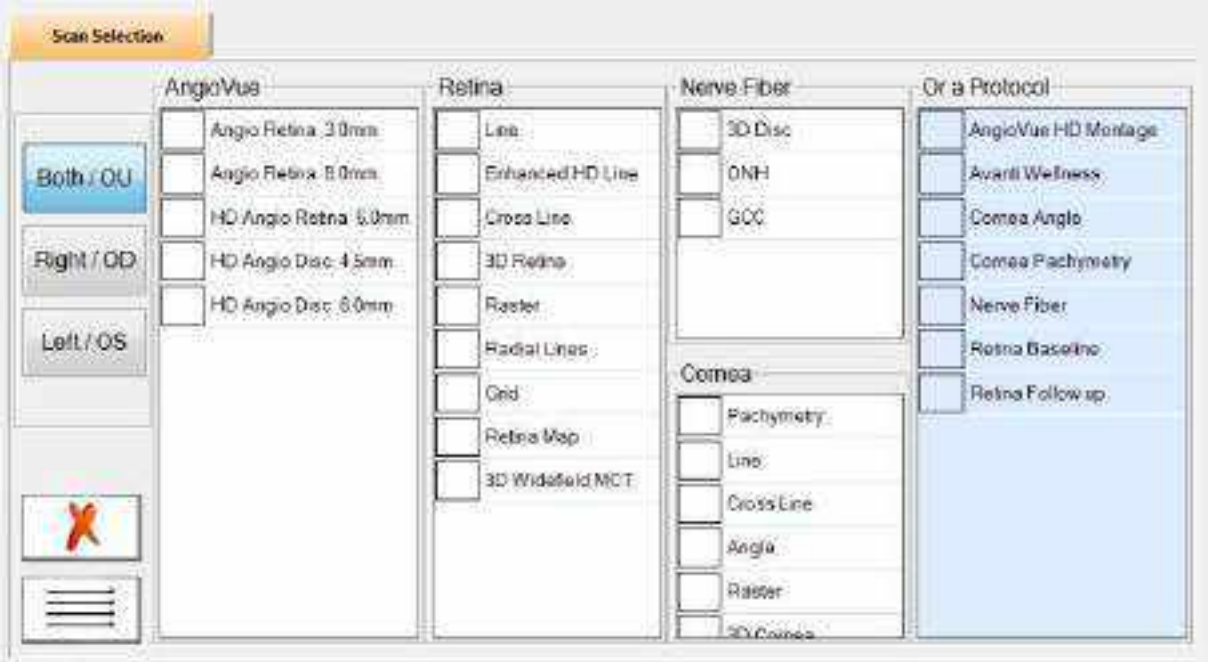


Figure 31 Select Scan Type or Protocol

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

Note: See chapter 8 Scan Pattern Specifications for a description of available OCT scan types.

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 6.4 Database Management Menu for instructions to create, edit or delete scan protocols.

Note: It is recommended to contact Optovue Technical Support before selecting scans or establishing a protocol with the methods described in this manual.

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 6.4 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.

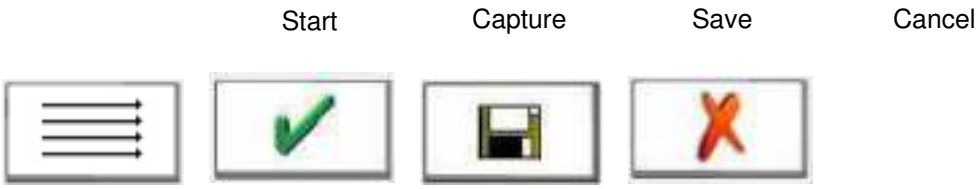


Figure 32 SCAN Window Buttons

Note: To repeat a scan, double-click on the desired scan type in the list of completed scans.

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 three tabs, **RT Scan Pattern**, **Average#** and **Cornea**, to set the default scan settings.

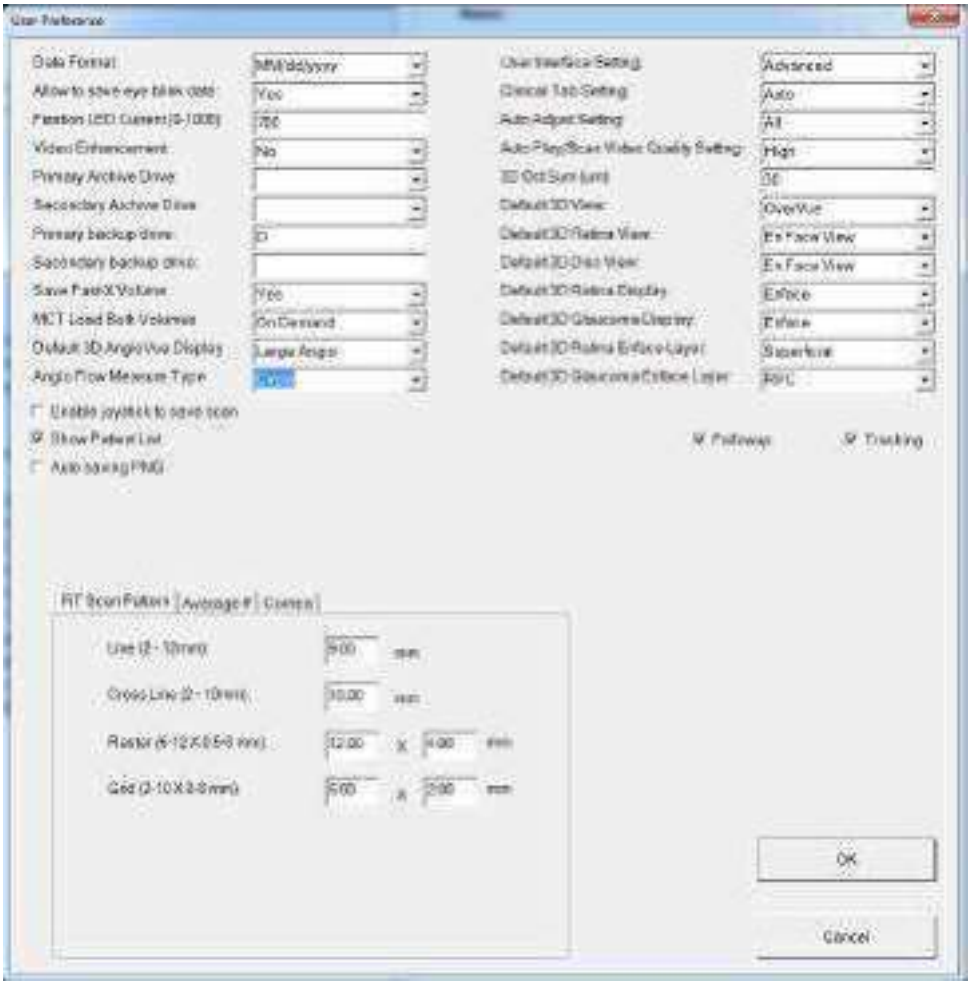


Figure 33 User Preference Dialog

Use the **RT Scan Pattern** 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 6.2.5 User Preference.

3.2.4 Auto Tab: Automated Scan Settings

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

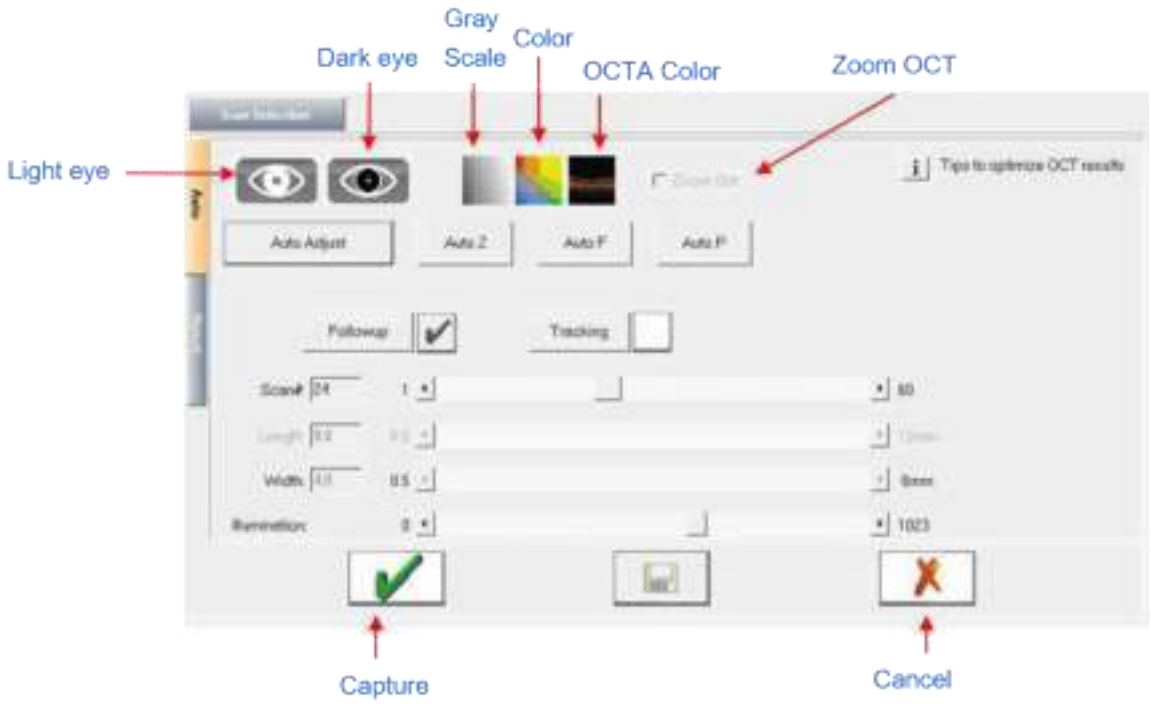


Figure 34 Scan Adjustment Options (Auto Tab)

The **Auto** tab helps you acquire good scans with minimal adjustments. (The **Manual** 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:

- **Eye Color**: According to iris color, click the **light eye** or **dark eye** button, to optimize in one step the video image for illumination, brightness, and contrast. If you click neither button, the system defaults to the average of the dark and light eye settings.
- **Gray Scale** or **Color**: Click one or the other to display the live OCT image in gray scale or color.

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 6.3.4.

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

  For the **Line, Cross Line, Raster, Grid,** and **Enhanced HD Line** 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.

Followup Mode

Figure 35 Follow-up and Tracking Mode Buttons

Followup 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 Followup to repeat the scan location and rotation of the previous scan. Repeat scans using Followup cannot be moved or rotated. Turning Followup off allows you to move or rotate the scan. Followup 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 36 Followup and Tracking status indicators

In Followup mode, the cross-hair on the IR image is red if alignment is not correct, and green when alignment is correct. The capture button turns green when the cross-hair 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 followup mode to allow the scan are to be dragged.

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; red not collecting, or green collecting for. Tracking is available for the following scans: **Line, Cross Line, Raster**, **Grid, Enhanced HD Line** and **Radial Lines and all 3D cubes including AngioVue scans**.

A good IR image of the fundus is important for followup and when tracking is on, because the system tracks image details to maintain scan placement. Image below shows examples of good and poor IR fundus images.

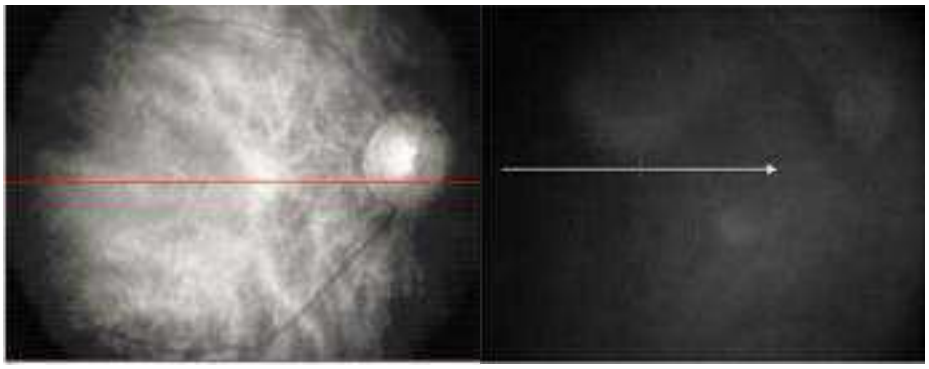


Figure 37 Good IR Image (Left) and Poor IR Image (Right)

The capture button turns green only when a good fundus image is present. A small green cross on the IR image indicates good followup, and a red cross indicates poor followup. The cross will be gray if followup is not active. During scan capture, there are two quality bar 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 Manual Tab: Manually Adjust Scan Settings

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

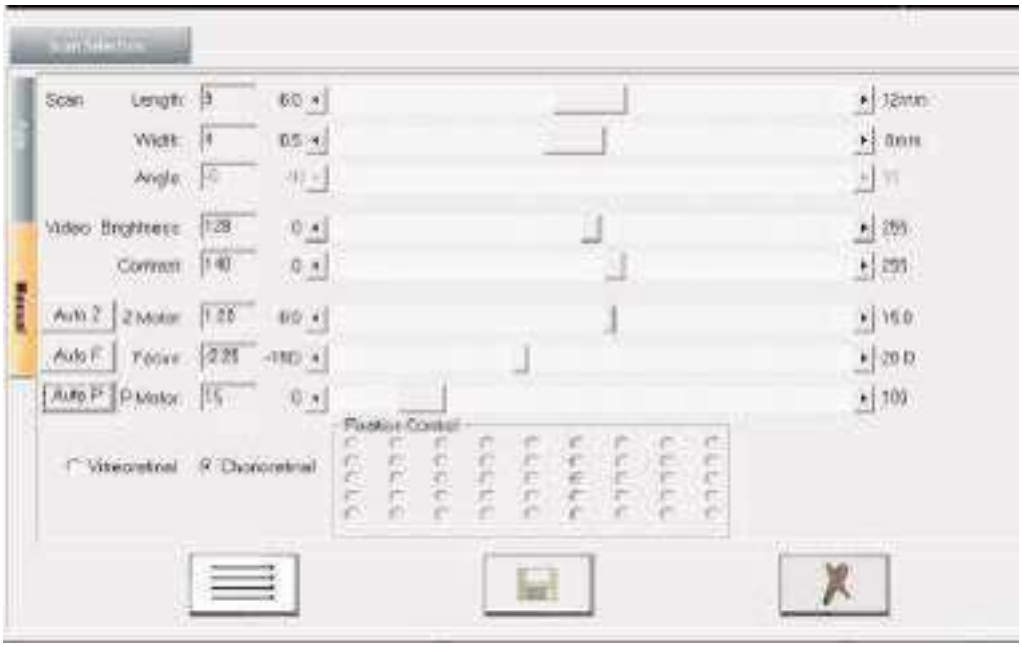


Figure 38 Manual Tab Selected

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.

- **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

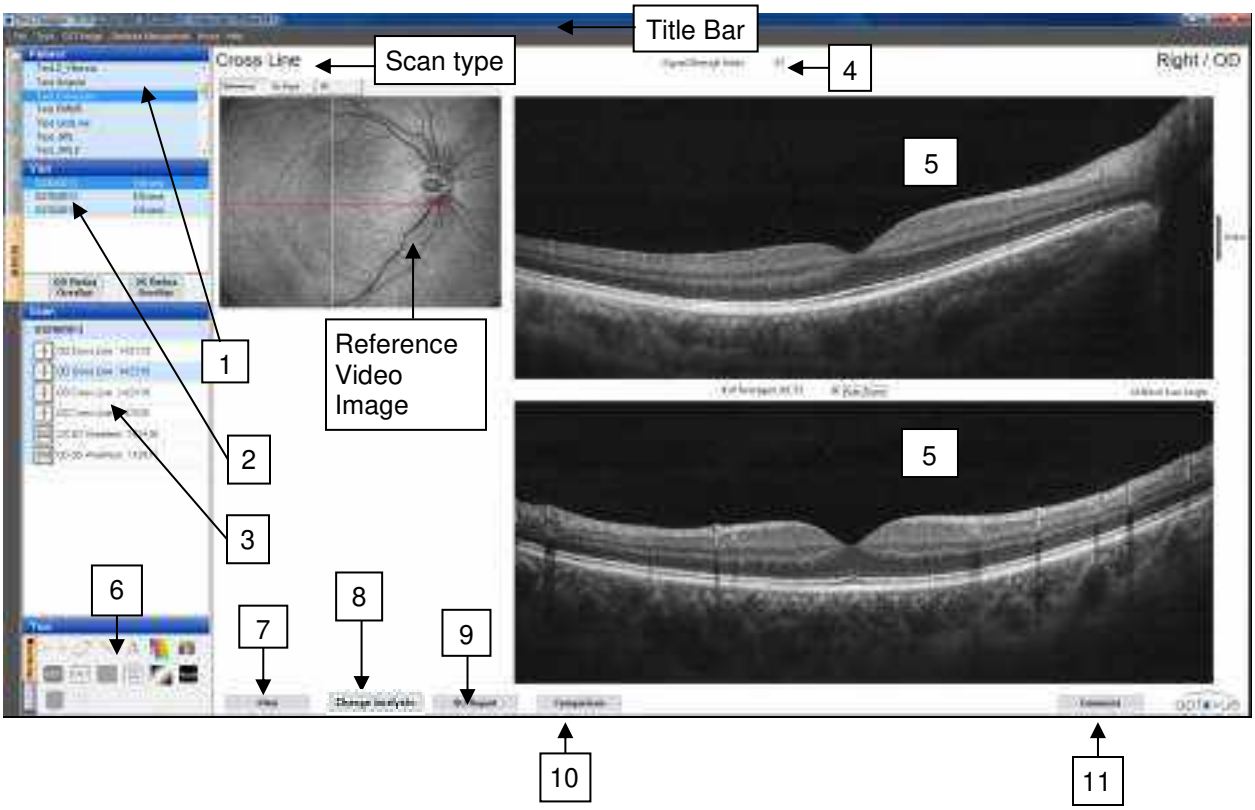


Figure 39 Review Window Components

Legend:

1 -Patient list	**7- Print** button
2- Visit list	**8- Change Analysis** button
3- Scan list	**9- OU Report** button
4- Signal Strength Index value	**10- Comparison** button
5- B-scan windows	**11- Comment** button
6- Tool pane	

Each scan type has its own report that opens in the Review window when you select the scan. Descriptions of the reports for each scan type are in Chapter 5 Scan Reports. (For review of anterior segment scans, see the RTVue XR CAM 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

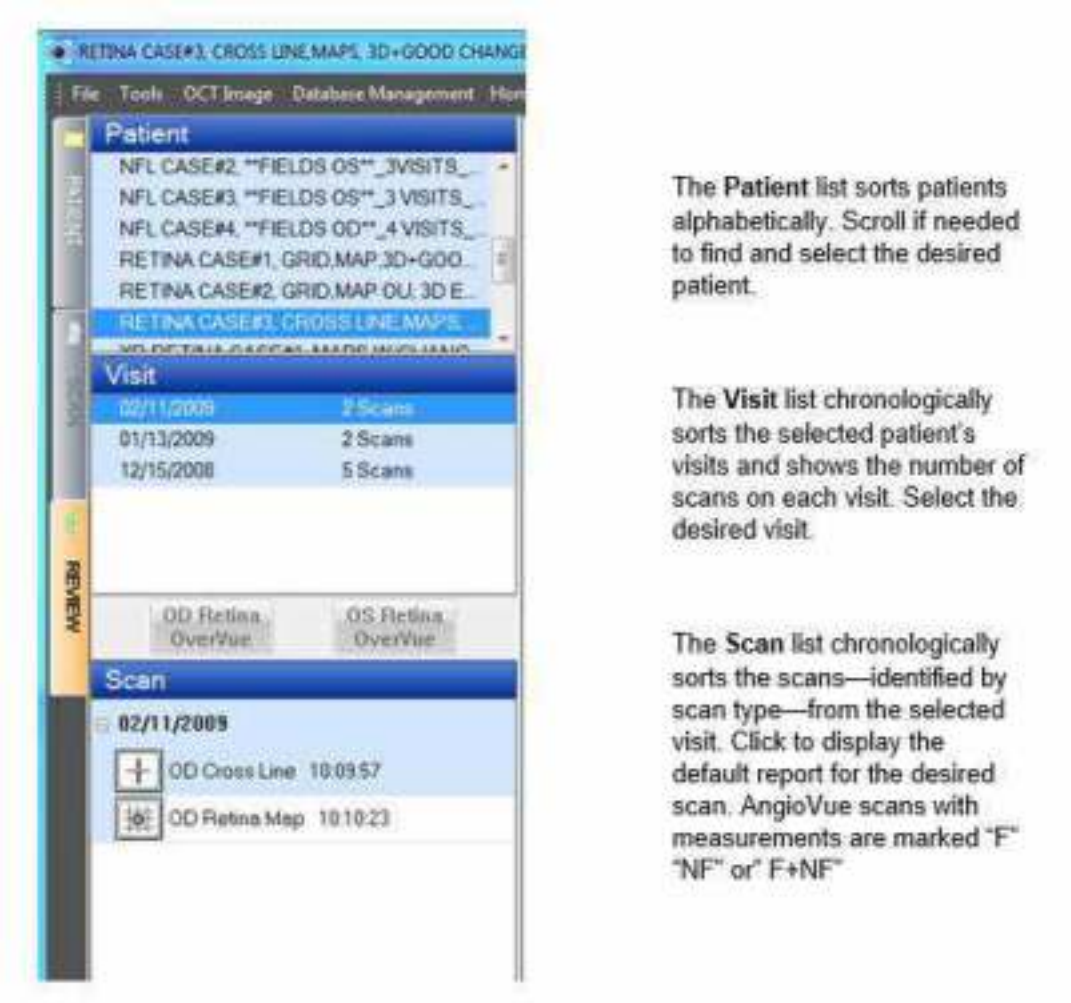


Figure 40 Patient Visit and scan list

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. Patient list can be concealed using user preference selection

4.1.2 Signal Strength Index

The Signal Strength Index (SSI) value appears near top center of each report. It helps you determine whether the scan quality is acceptable or not. The SSI is based on the intensity, or brightness, of reflected light during scanning. Greater intensity corresponds with a higher SSI. The SSI is based on a global average over the entire scan pattern. The SSI is not intended to be used alone to determine image quality. However, when the SSI is lower than the minimum recommended values given in table below, Optovue recommends that you re-take the scan to achieve an SSI value above the minimum recommended, if possible.

Table 1 Minimum Recommended SSI for Each Scan Type

Scan Type	Minimum Recommended SSI
Retina Map	SSI > 39
ONH	SSI > 28
GCC	SSI > 32

See Appendix F: Signal Strength Index (SSI) for further detail on the SSI.

4.1.3 Change Analysis Button

The **Change Analysis** button is available when map scans like Retina Map, GCC and ONH have been taken on two or more visits. Click this button and the system displays up to six visits on the change report that appears.

4.1.4 Comparison Button

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

4.1.5 OU Report Button

The **OU Report** button is available for certain scan types when scans for both eyes have been taken. 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.

4.1.6 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.

4.1.7 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. Image below shows the **Measuring** tools. Callouts identify each icon. Functions not currently available are grayed out.

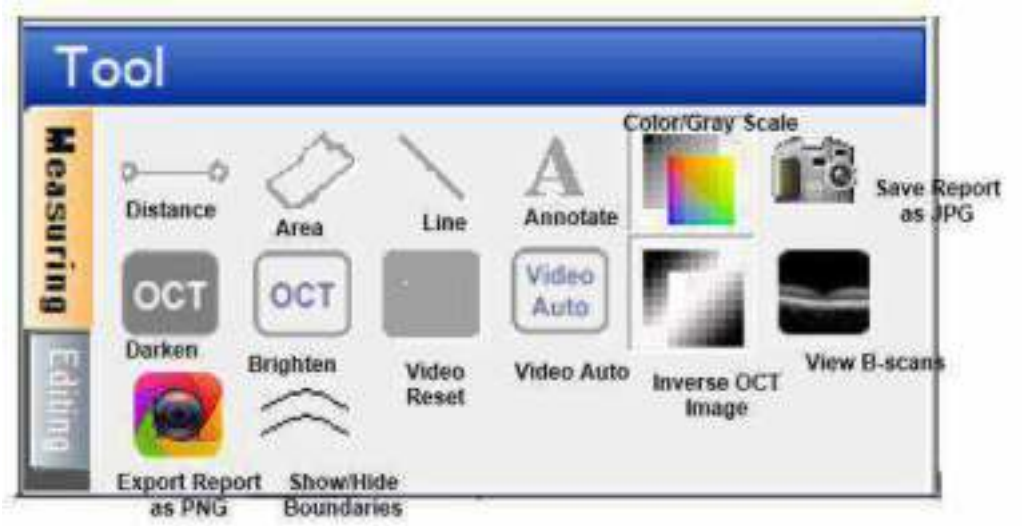


Figure 41 Measuring Tools

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 42 A Sample B-Scan Window

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

Figure 43 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 44 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:

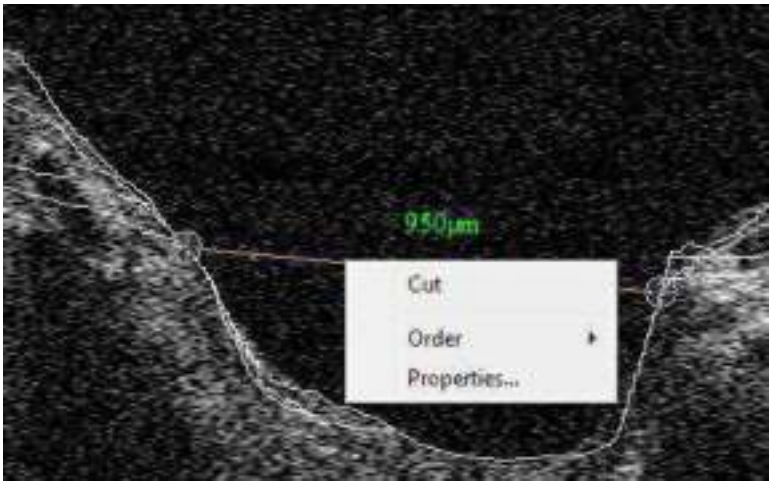


Figure 45 Line Right-Click Options

- **Cut** deletes the line.
- **Order > [selection]** changes the front-back order of overlays.
- **Properties…** gives access to change color, style and width of the line.

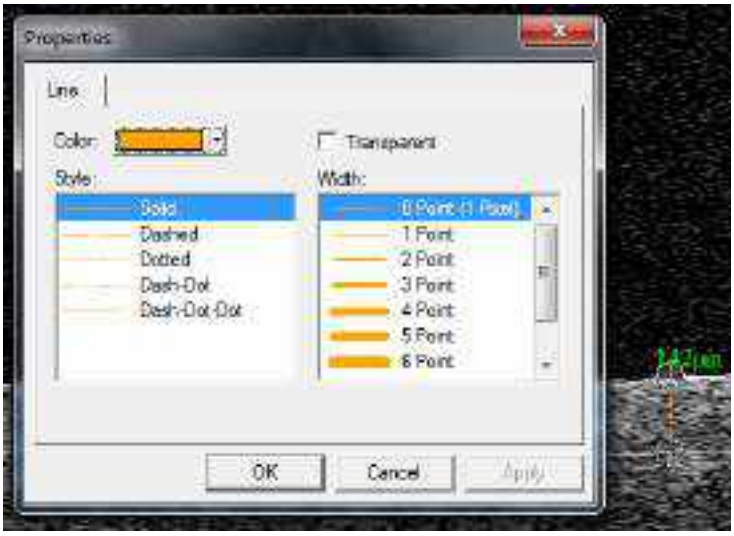


Figure 46 Line Properties Dialog

- **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.

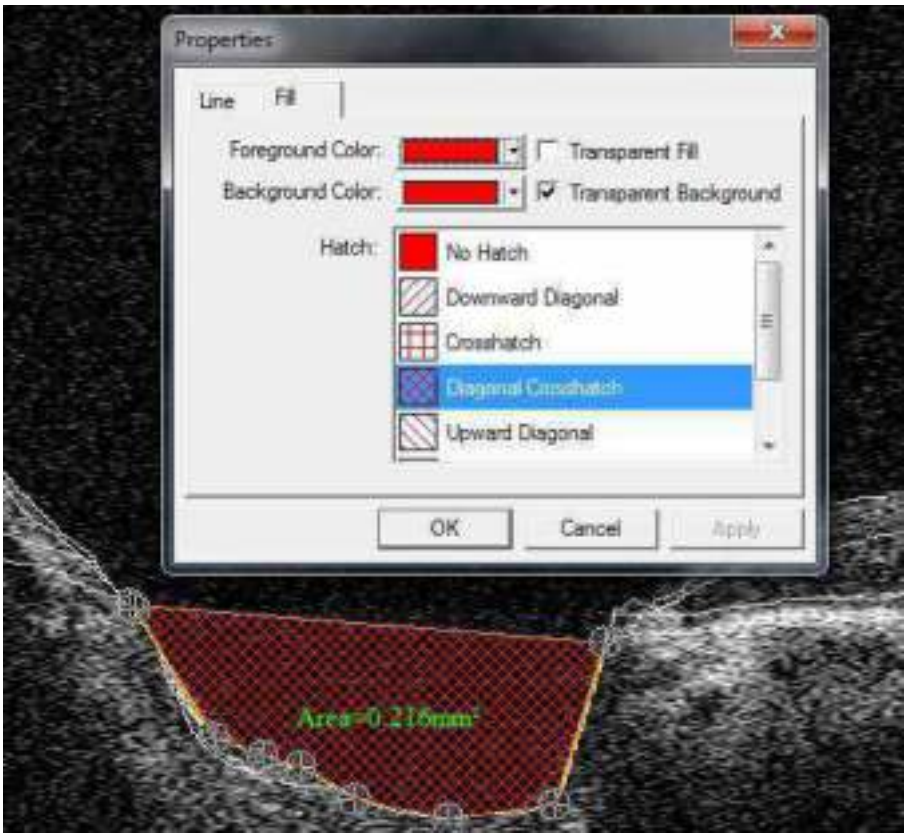


Figure 47 Area Fill Options

- **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.

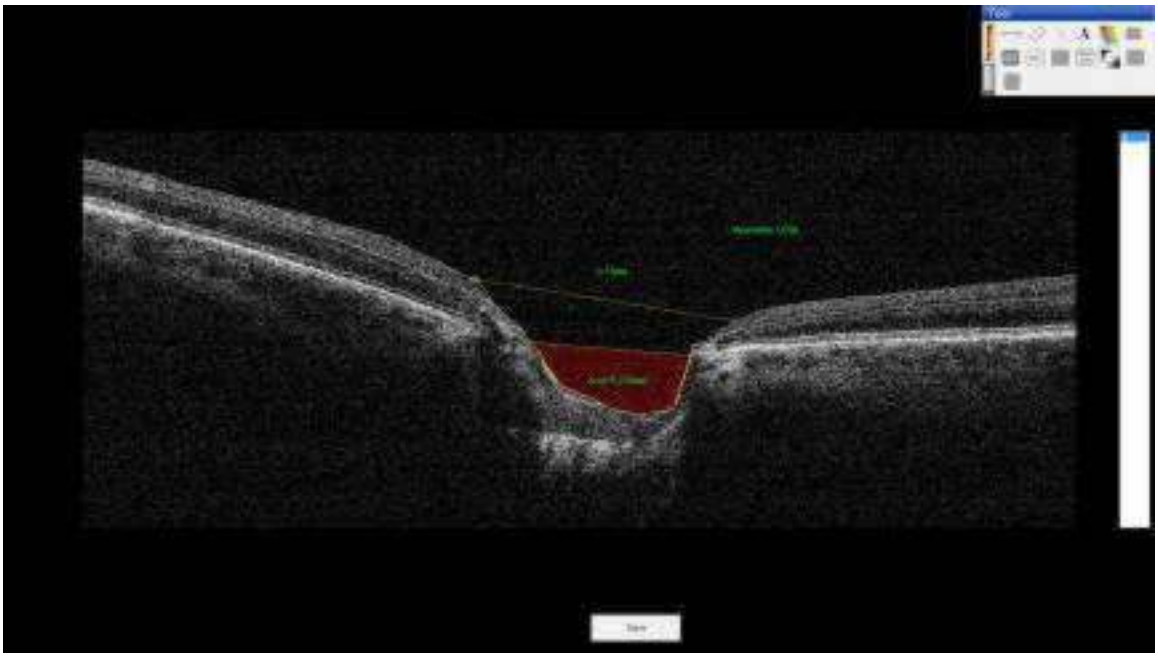


Figure 48 Example B-Scan with Area, Line and Annotation

- **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.

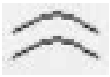
Note: Images made with the **Save Report as JPG** (camera) icon do not include patient and practice information. To include this information, use the **Print** button in the Review window, which prints the report either to an electronic file (PDF) or to hard copy, depending on the printer you choose.

- **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 6.2.5. 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.

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.

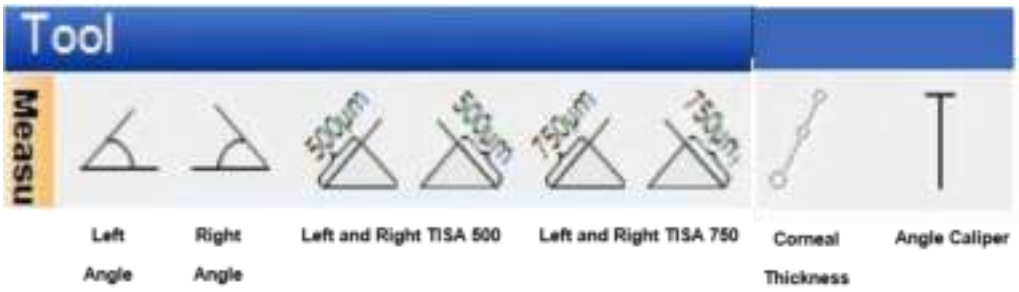


Figure 49 CAM Measuring Tools

- **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 50 Editing Tools

-  **Select**: Click to select a segmentation line for editing or to deselect a zoom tool in use.
- **Edit Segmentation Lines:** 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.

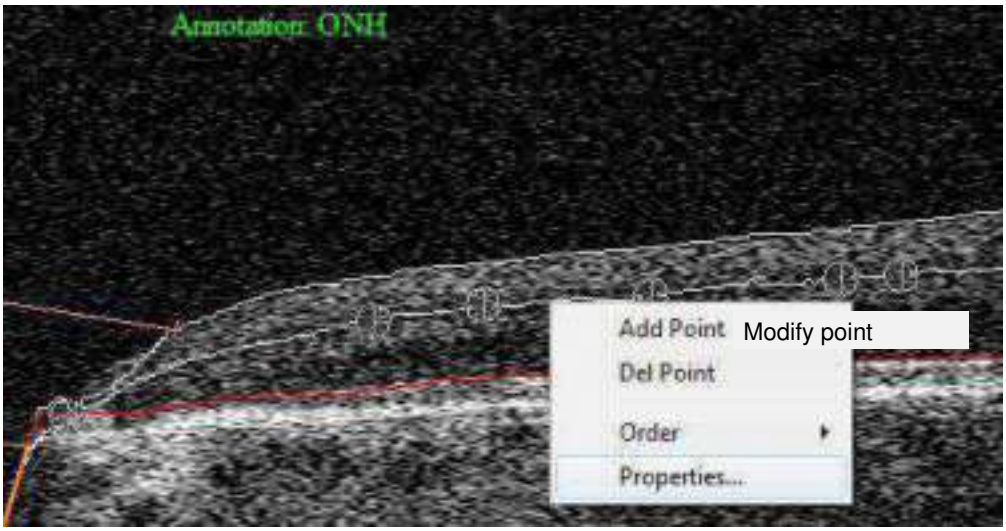


Figure 51 Right-Click Options When Editing Segmentation Lines

- 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 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 or the fovea, in the SLO-like image. The Retina Map scan can overlay on the SLO-like image of the 3D Widefield scan using the fovea for registration. If no widefield scan, the initial Retina map is used as the reference, utilizing the fovea. The ONH scan uses the SLO-like image of the 3D Disc scan as baseline for registration.

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.

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.

5.1.1 3D Widefield Scan for Retina Map Display

The Widefield scan is not required for thickness evaluation of macula or optic nerve. It will affect the scan display but will not change the quantitative analysis and will not impact the change analysis report. If the Widefield scan is available, the Retina Map or the ONH scan will be overlaid on the Widefield scan. The 3D Widefield scan encompasses both the macula and the optic nerve in an approximately 40º view of the fundus. The scan produces a 12 mm x 9 mm SLO-like reference image, which is used for display of scans. Specifically, it uses the fovea for registration. It also produces detailed en face images of the retina surface, and a 3D cube of image data of the entire retina. See section 5.5.5 for information on the 3D Widefield report.

Note; In the event of registration failure the selected scan will not show on top of the Widefield image.

Note: When you repeat a 3D Widefield scan and click the **Save** button, a dialog asks you whether to use the new scan image as the new baseline for registration.

Select **Yes** to use the new image for registration, or **No, use the existing one**. Exit the visit to see “baseline” indicator in scan list change to the new scan.

Figure 52 Widefield registration

5.1.2 3D Disc Scan for ONH Registration

The system uses the SLO-like image of the 3D Disc scan as baseline for registration of ONH scans. Specifically, it uses the disc margin, disc center and vessels for registration. It finds the disc center by first tracing the disc boundary (disc margin) on the 3D Disc scan image. If you acquire an ONH scan before the 3D Disc scan for that eye, the system prompts you to capture the 3D Disc scan in the Baseline Disc Boundary dialog.

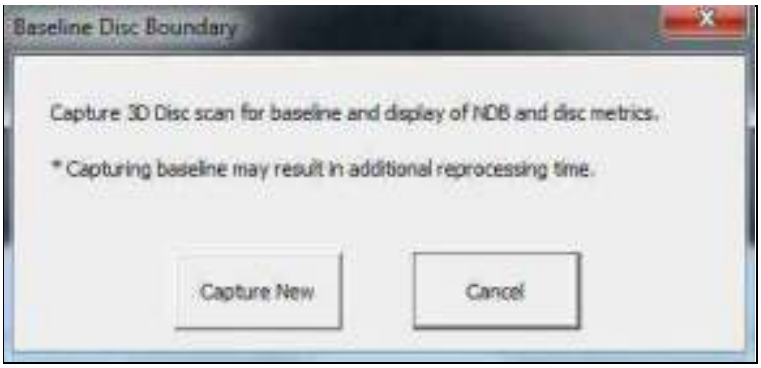


Figure 53 Baseline Disc Boundary Dialog

Click **Capture New** to acquire a baseline 3D Disc scan.

Note: If you do not capture a 3D Disc scan, you must manually draw the disc margin on the ONH scan image. A baseline 3D Disc scan is required to display Normative Database (NDB) comparisons for RNFL measurements, and optic disc metrics for ONH scans.

To show the disc margin on the 3D Disc report, click the **Show** button. Click the **Auto** button for the system to automatically draw the disc margin.

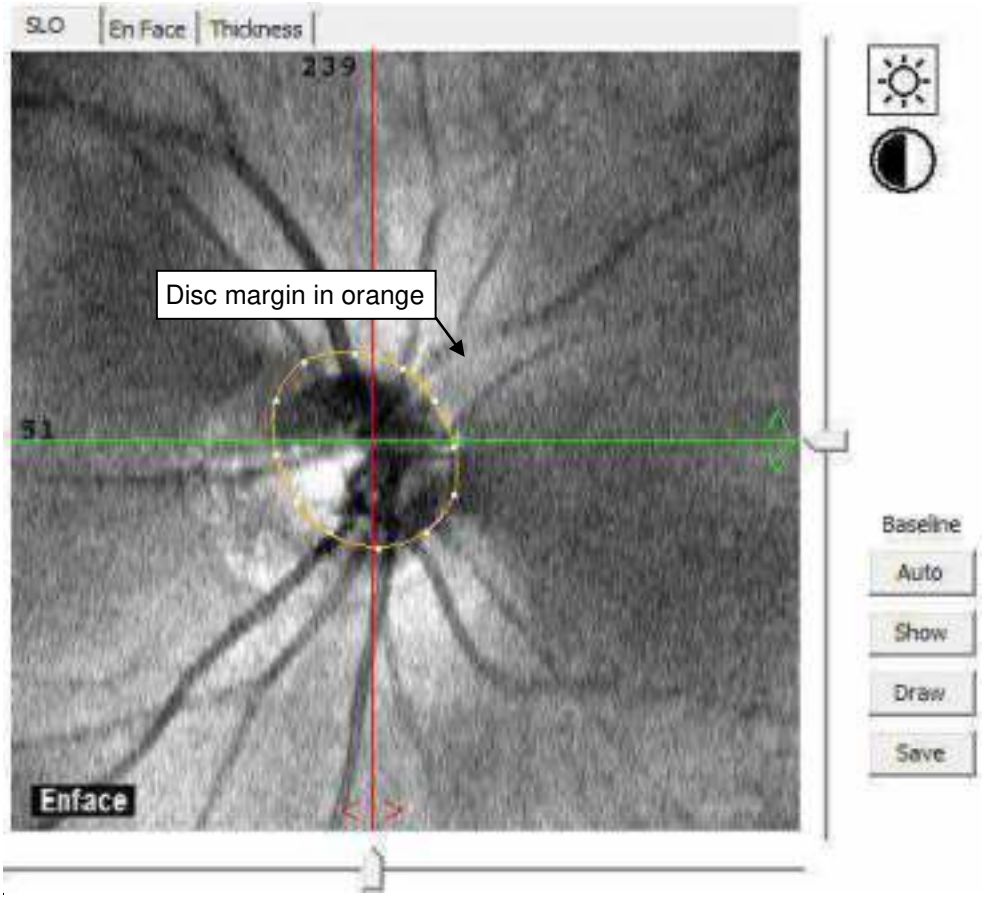


Figure 54 Optic Disc Margin in 3D Disc Report

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

Click **Draw** to draw the disc boundary manually, then click to place anchor points around the disc margin. See section 5.5.7 for information on the 3D Disc report.

5.2 Retina Line Scan Reports

Six scan types designed to scan the retina use line scans (of adjustable length) singly or in combination. These are the Line, Cross Line, Grid, Raster, Radial Line, and Enhanced HD Line scans. As a reference for registration, the system aligns each of these scans to the 3D Widefield scan (see sections 5.1.1 and 5.5.5), when one has been acquired for this eye. The reports for each of these retina line scan types show the 3D Widefield reference scan, when taken, on the default **Reference** tab. (You can also select the **En Face** or **IR** tab to display those images.)

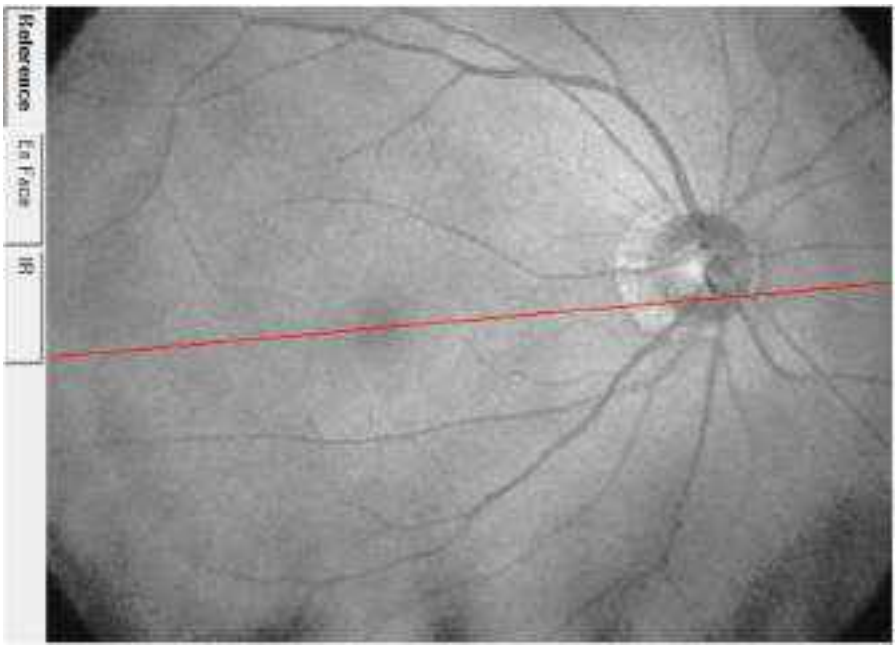


Figure 55 3D Widefield Reference Scan on Reference Tab

Note; In the event of registration failure the selected scan will not show on top of the Widefield image.

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.

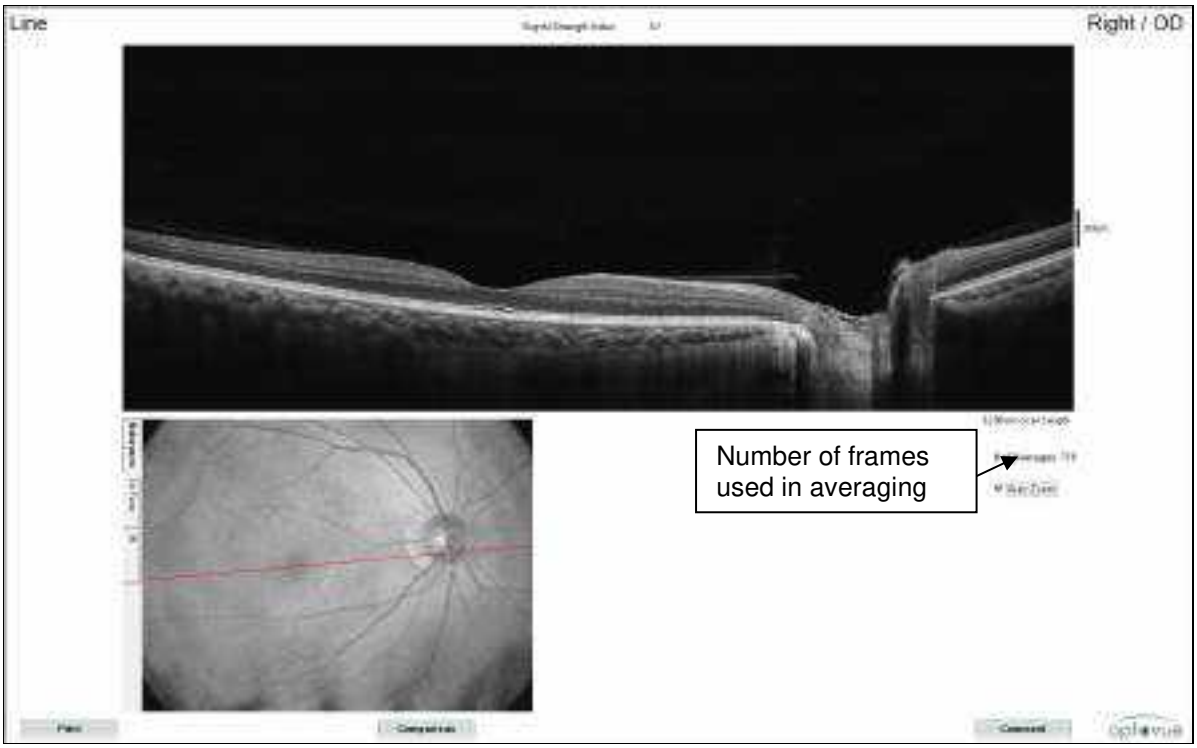


Figure 56 Line Scan Report

Note; In the event of registration failure the selected scan will not show on top of the Widefield image.

5.2.2 Cross Line Report

The Cross Line scan averages multiple frames of the vertical and horizontal line scans and reports the number of frames used in the averaging for each line—for the B-scan shown above and the one below, in that order, as shown in the image below. The scan length (same for both lines, but adjustable) in mm appears between the B-scans on the right. Click the **Comparison** button to compare any two scans for this eye.

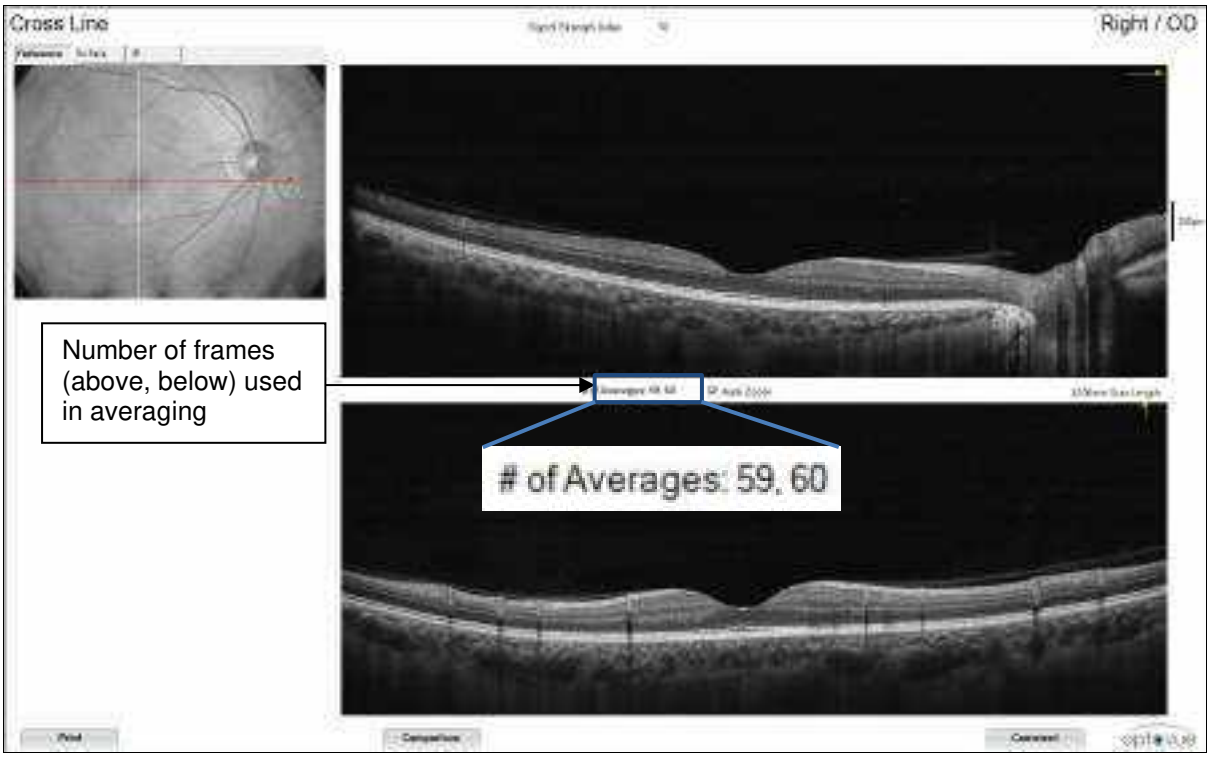


Figure 57 Cross Line Scan Report

Note; In the event of registration failure the selected scan will not show on top of the Widefield image.

5.2.3 Grid Scan Report

The Grid scan report shows the grid of five horizontal and five vertical line scans overlaid on the 3D Widefield reference image, as shown in the image below. The length and width of the scan pattern are adjustable. The B-scans at the top and bottom correspond to the top and bottom line scans highlighted in red on the reference image at upper left. 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 buttons to change the number of B-scans shown on the report. Click the **Comparison** button to compare any two scans for this eye.

Note; In the event of registration failure the selected scan will not show on top of the Widefield image.

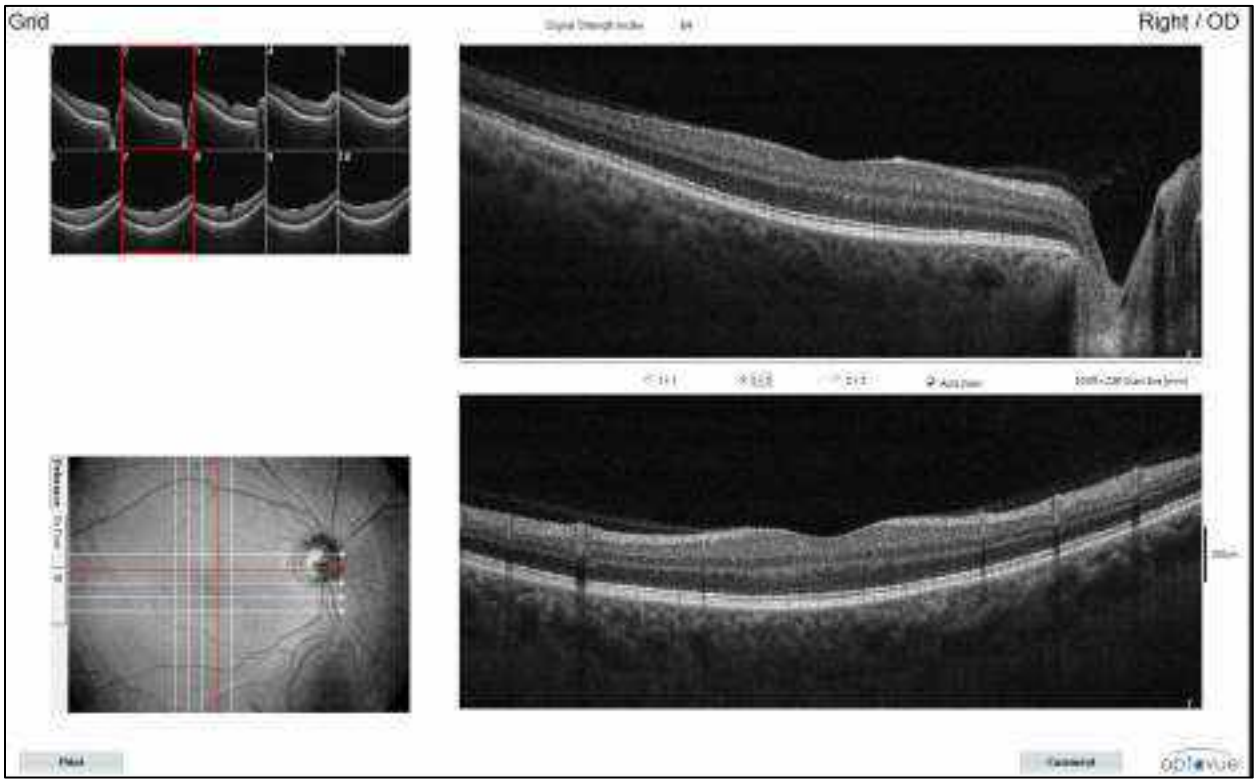


Figure 58 Grid Scan Report

5.2.4 Raster Scan Report

The Raster scan report shows a stack of 21 horizontal line scans overlaid on the 3D Widefield 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 this eye.

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

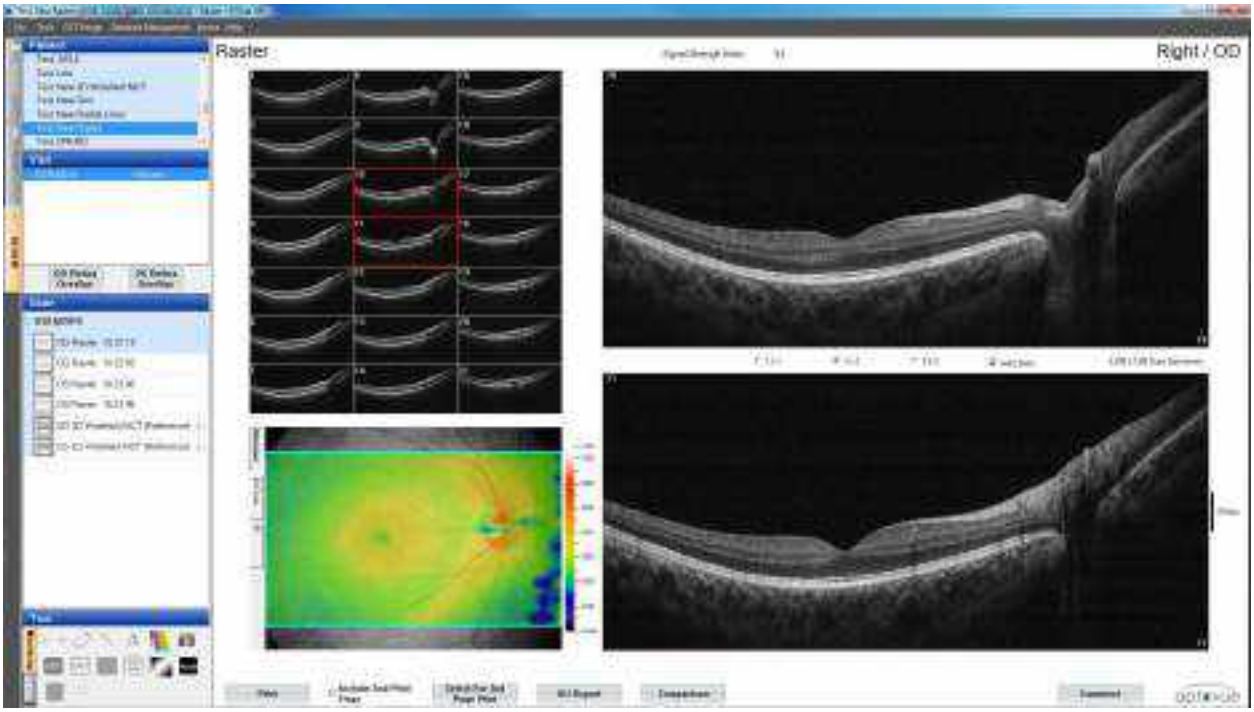


Figure 59 Raster Scan Report

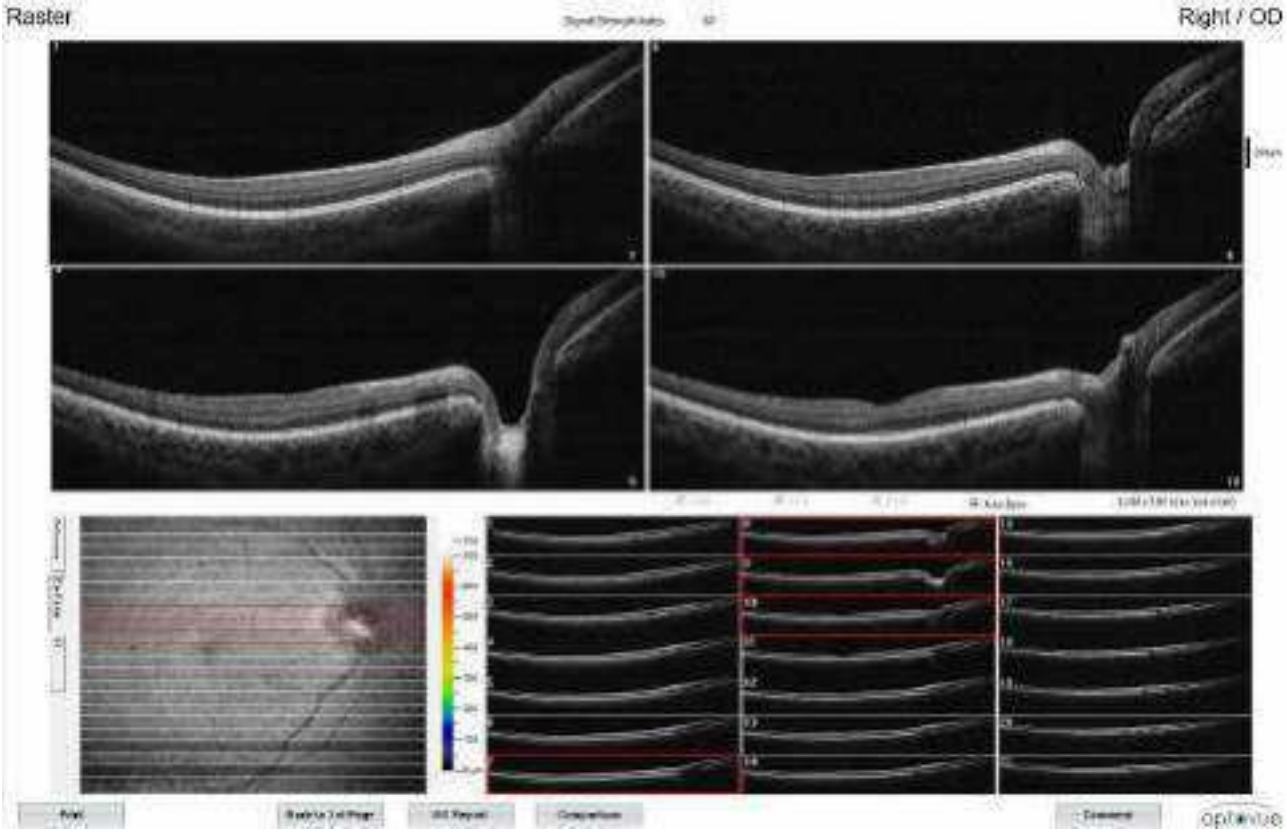


Figure 60 Second page of Raster Report.

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

Note; In the event of registration failure the selected scan will not show on top of the Widefield image.

Raster Portrait Print page 1

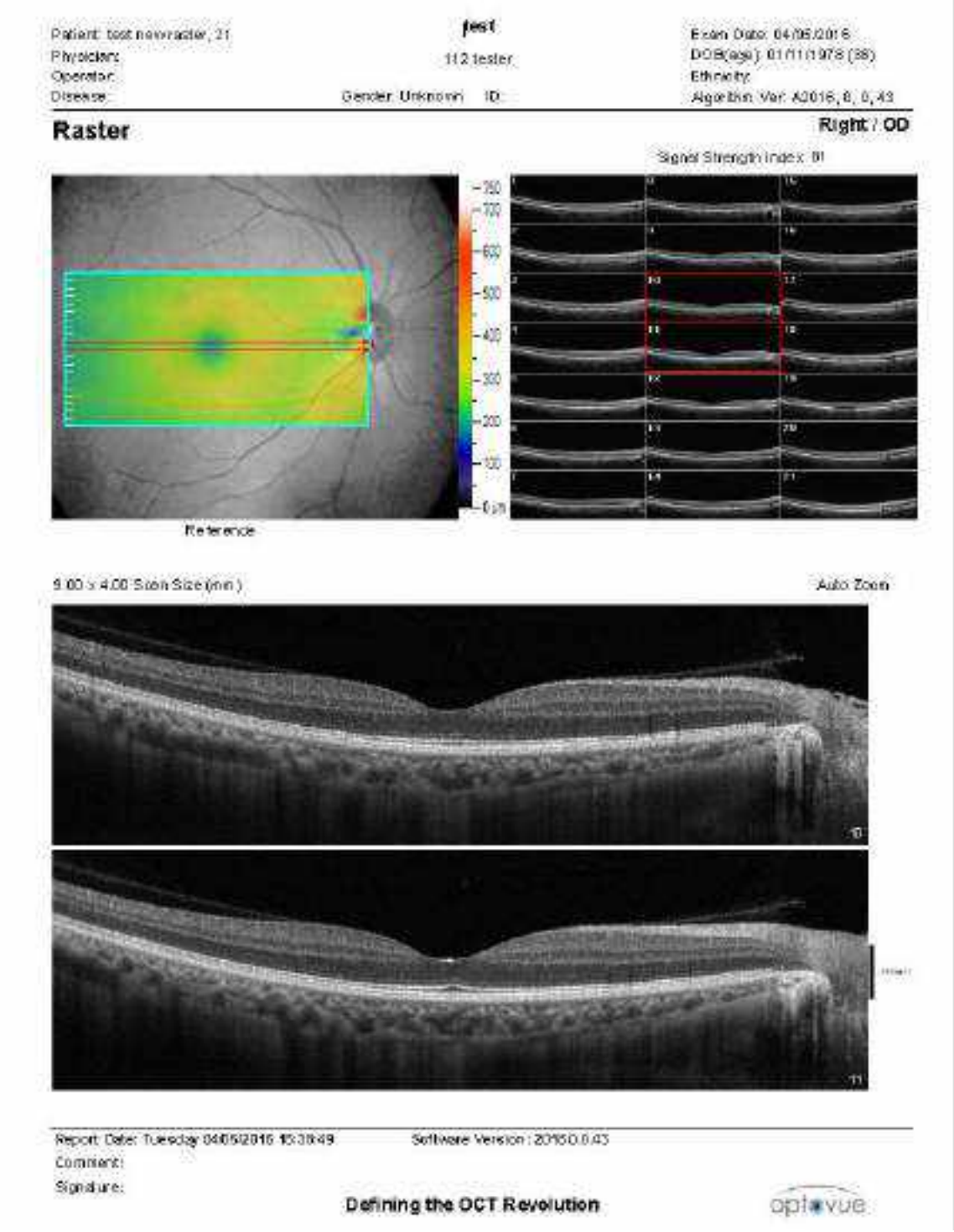


Figure 61 Raster Portrait Print page 1

Raster Portrait Print page 2

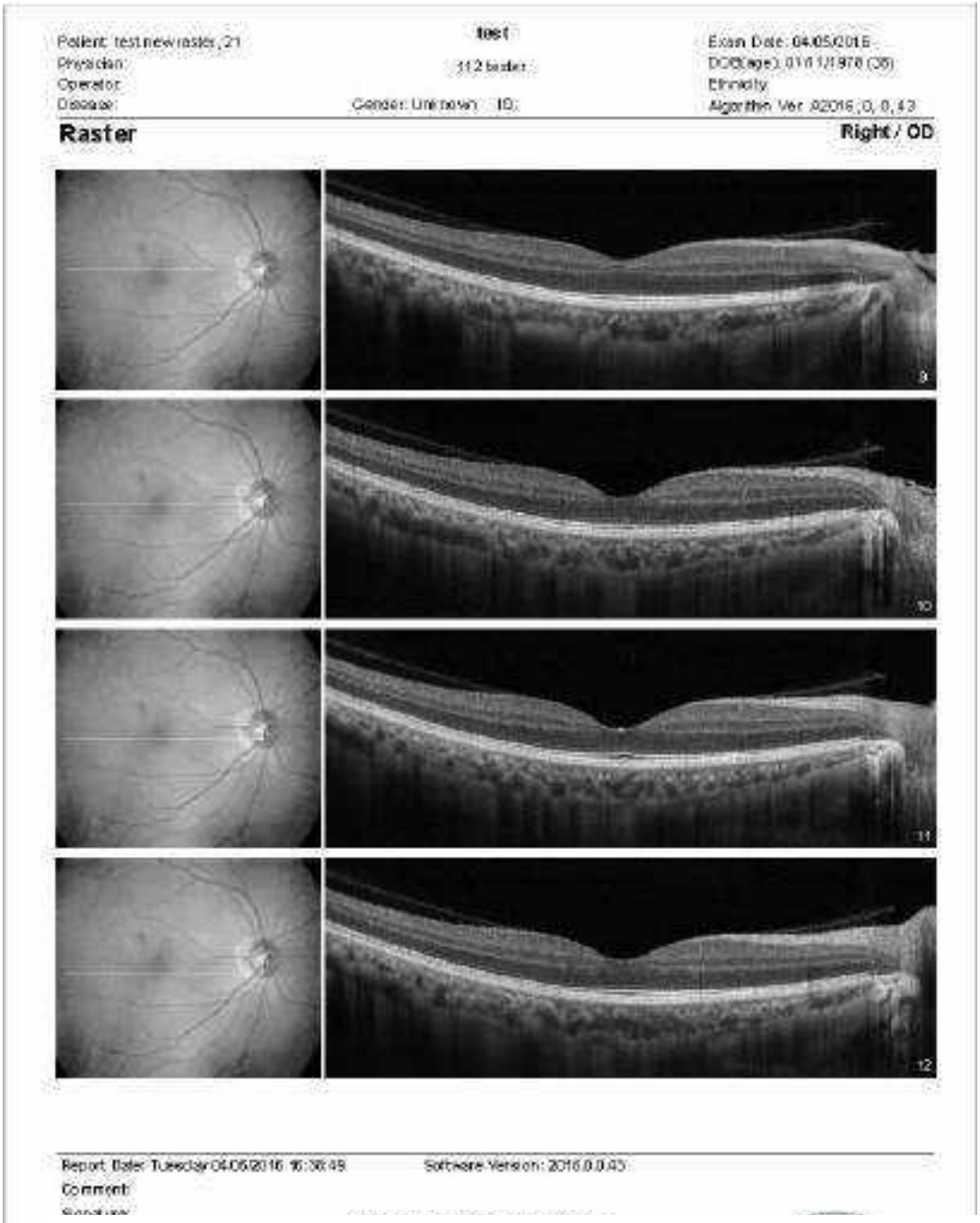


Figure 62 Raster Portrait Print page 2

5.2.5 Radial Lines

The Radial Lines scan report shows line scans arranged like spokes on a wheel overlaid on the 3D Widefield 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.

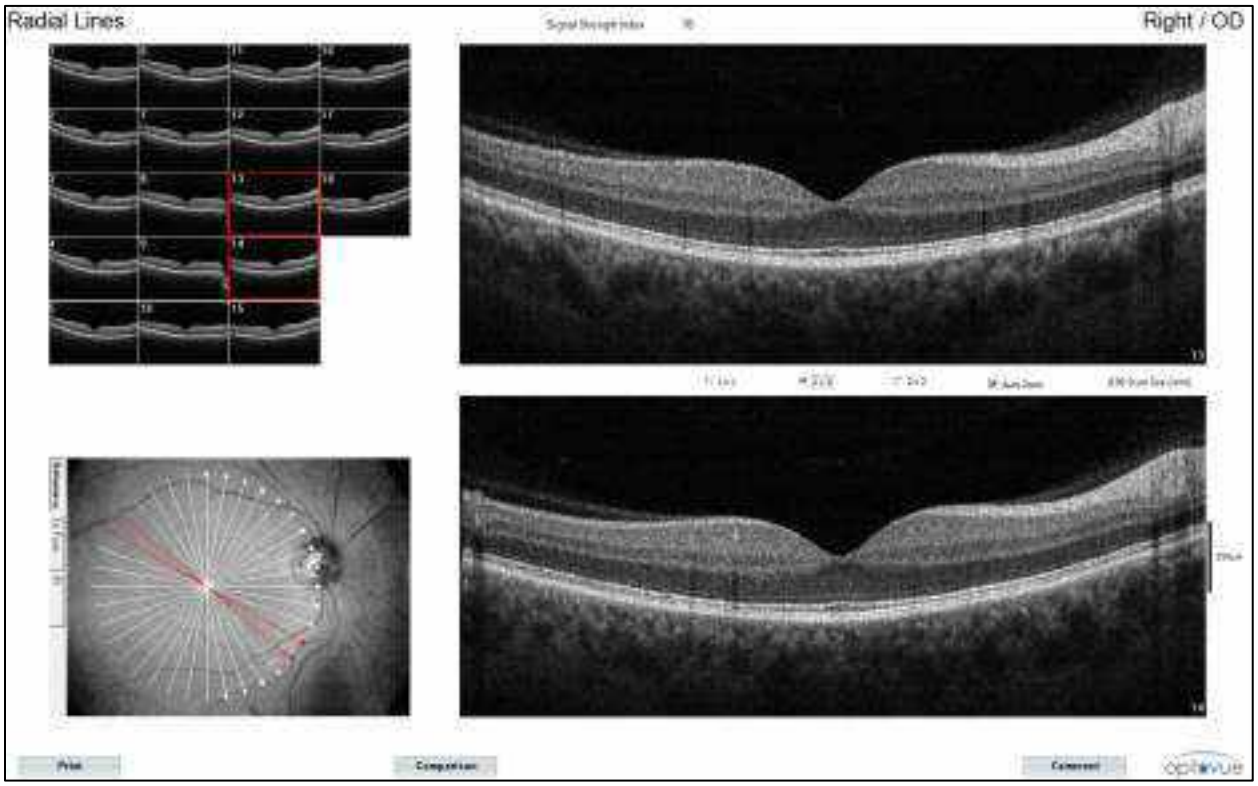


Figure 63 Radial Lines Report

Note; In the event of registration failure the selected scan will not show on top of the Widefield image.

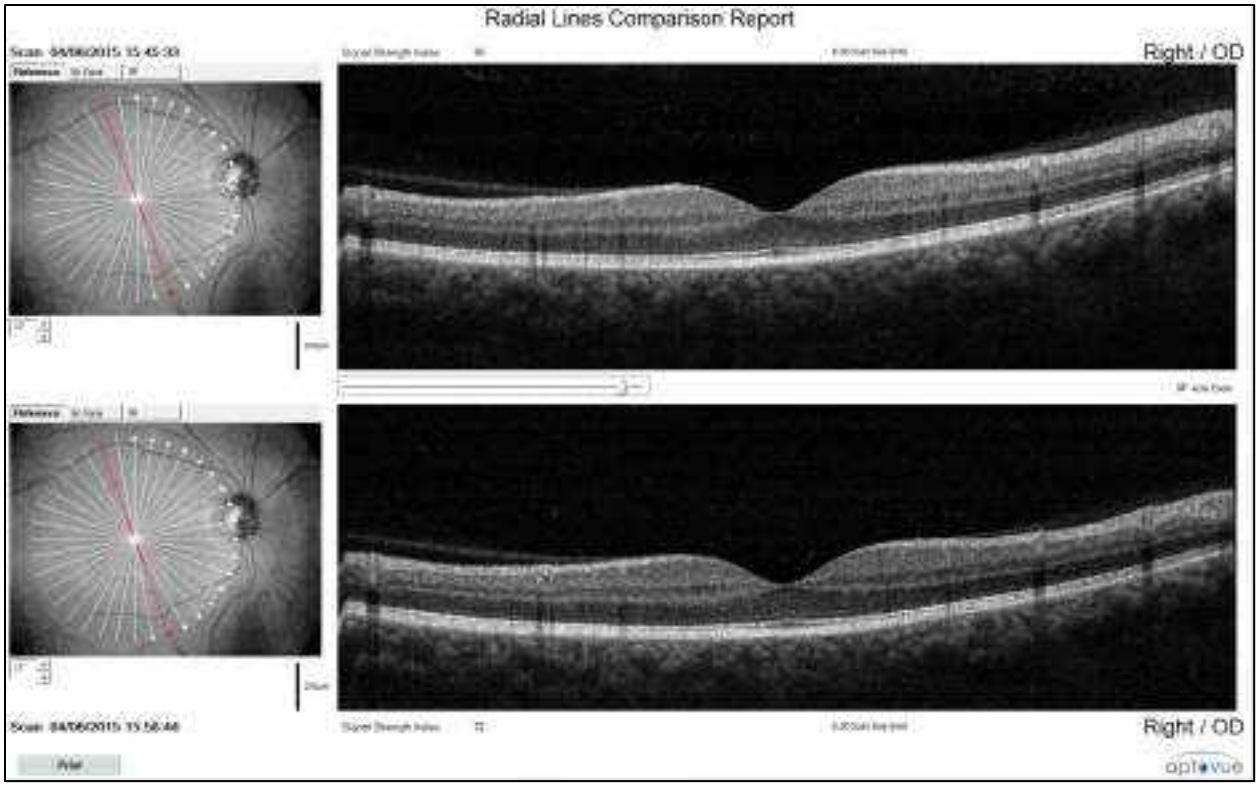


Figure 64 Sample Radial Line Report Comparing B-Scans from Two Visits

Note; In the event of registration failure the selected scan will not show on top of the Widefield image.

5.2.6 Enhanced HD Line

The **Enhanced HD Line** scan acquires a single high-definition line of adjustable length. Its position shows as an overlay on the 3D Widefield reference image. The scan is designed to show detail either in the vitreous or in the choroid; you select which using the corresponding radio button on the AUTO tab before scan acquisition. In addition, the report for Enhanced HD Line enhances detail in the vitreous or the choroid, depending on whether you select the **Vitreous** (default) or **Retina** radio button below the scan image.

The **Vitreous** radio button results in brighter colors with greater color contrast, to more easily see details in the vitreous that would otherwise be subtle. The **Retina** radio button results in less-bright colors with less color contrast, to tone down brightness in the retinal layers and make retinal details more discernible. The slider below the radio buttons also enhances the color intensity as you move it from left to right. The image below shows a sample Enhanced HD Line report captured in Vitreoretinal mode. Click the **Comparison** button to compare up to six scans for this eye.

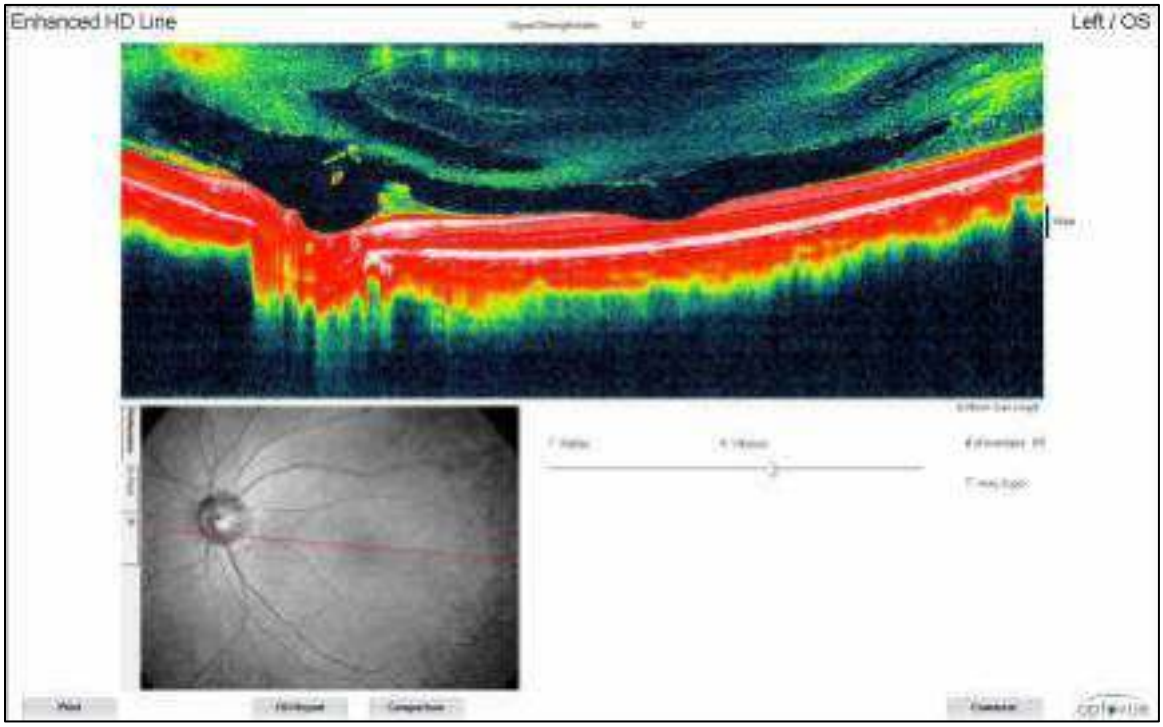


Figure 65 Enhanced HD Line Report, Vitreous Sample

Note; In the event of registration failure the selected scan will not show on top of the Widefield image.

5.3 Retina Map Report

The Retina Map report provides image displays, charts, tables and interactive maps to enable qualitative and quantitative assessment of the retina. The image below and its legend below identify the components of a Retina Map report. The subsections following explain each component. To select editable center B-scans deselect the “Show HR Frames” check box.

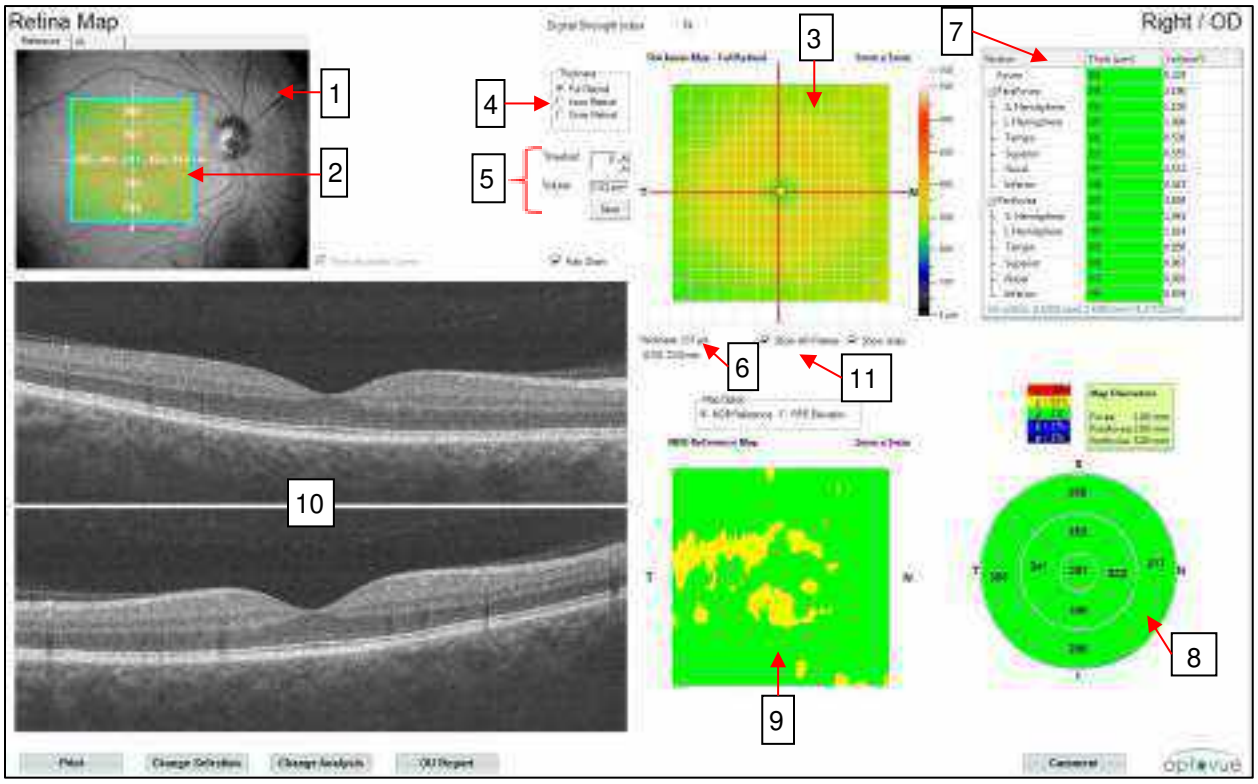


Figure 66 Retina Map Components

Retina Map Components Legend:

1 Reference image

2 Map/chart overlay

3 Thickness map

4 Map display options

5 Volume contouring and threshold selection

6 Thickness at a single point

7 Thickness and volume parameter table

8 ETDRS chart

9 NDB reference map or RPE elevation map

10 B-scan display

11 HR Frames check box

5.3.1 Retina Map Portrait Print Report

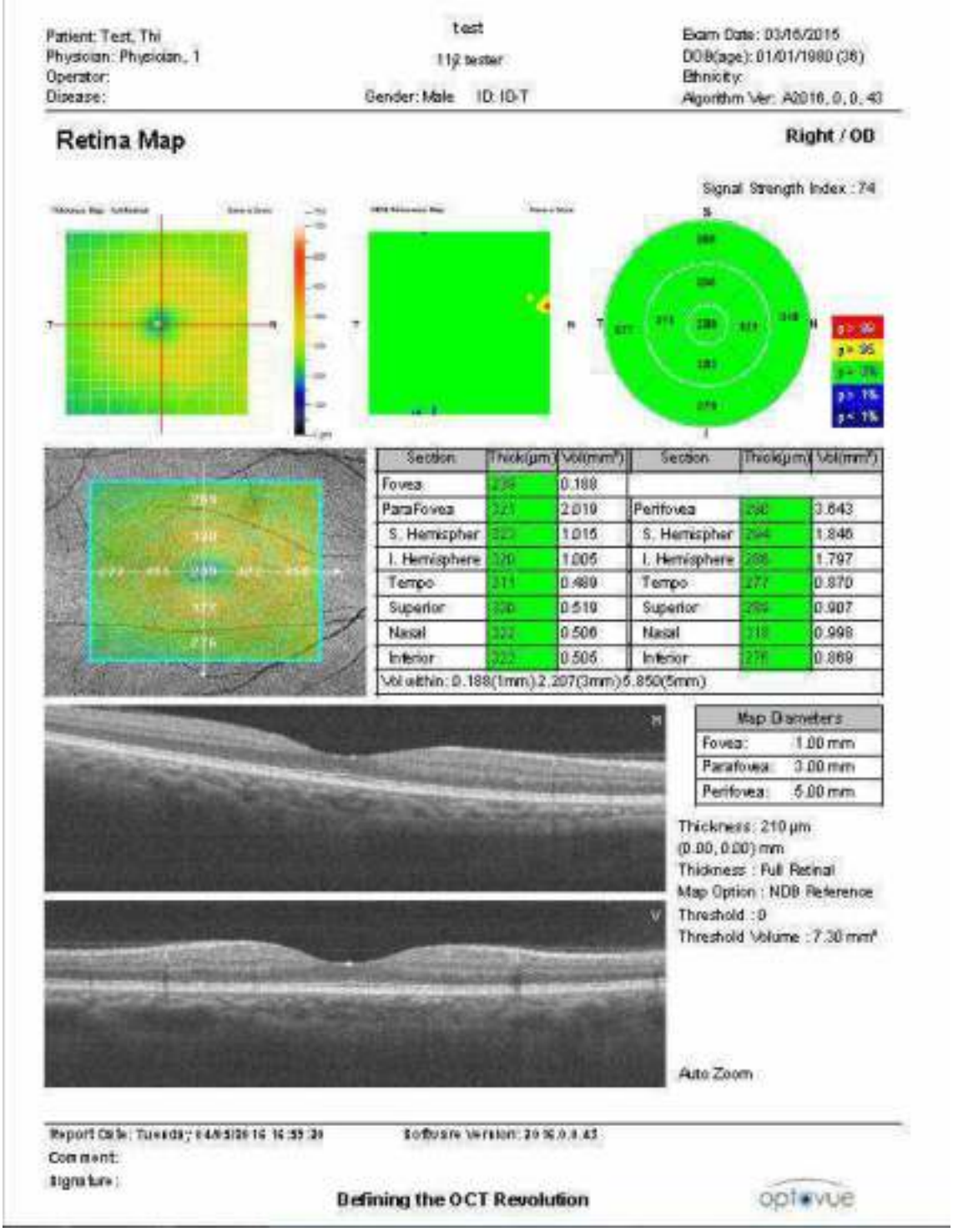


Figure 67 Retina Map Portrait Print Report

5.3.2 NDB References

NDB references are available only for full retinal thickness. The Retina Map report includes three possible presentations of retinal thickness with respect to the normative database, as shown in the image below.

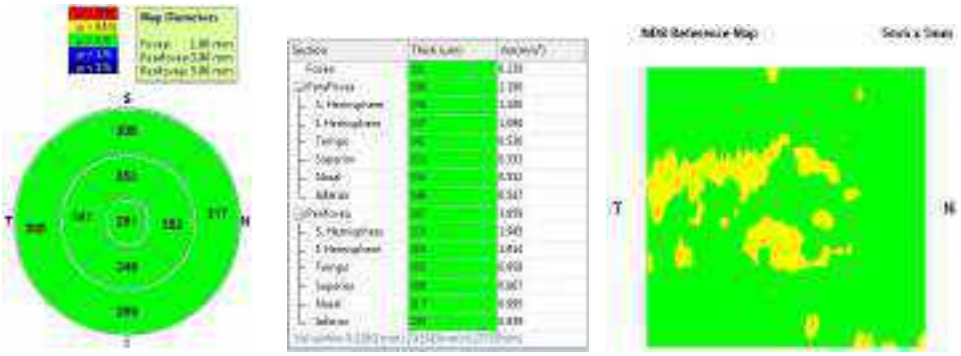


Figure 68 Retina Map Presentations that Include NDB Reference

NDB references can appear in the ETDRS Chart (lower right), the NDB Reference Map (bottom center) and the retinal parameters table (upper right). The NDB color key above the ETDRS chart explains that green indicates “Within normal limits” “ (the measurement is between the 5th percentile to 95th percentile of the NDB); yellow indicates “Borderline” thick (the measurement is between the 95th percentile to the 99th percentile of the NDB); red indicates “Outside normal limits” thick (the measurement is above the 99th percentile of the NDB);—blue indicates “Borderline” thin (the measurement is between the 5th percentile to the 1st percentile of the NDB); and dark blue indicates “Outside normal limits” thin (the measurement is below the 1st percentile of the NDB). See Appendix B for more detail on the Normative Database.

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

5.3.3 Reference Image (Item 1)

The reference image at upper left shows the SLO-like image from the reference scan (by default) on the **Reference** tab, or the video image acquired during scan acquisition on the **IR** tab.

5.3.4 Retinal Thickness Map and Chart Overlay (Item 2)

When the Retina Map report opens, by default the retinal thickness map and ETDRS thickness chart values both overlay the 3D Widefield reference image at upper left. These are the same color-coded maps next to the reference image at upper center (thickness map, item 3) and lower right (ETDRS chart, item 8). Right-click on the overlay to toggle **2D Map Off** and **Chart Off** individually. See below. The right-click options change to turn one or both on again.

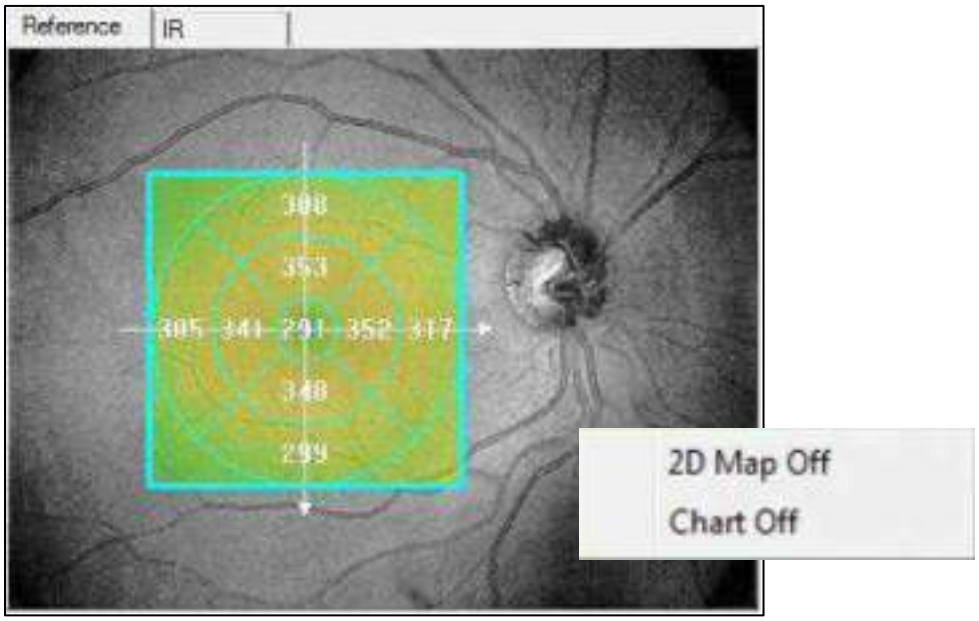


Figure 69 Retina Map Reference Image Options with 2D Map and Chart On)

The 2D Map overlay shows Full Retinal**,** Inner Retinal **or** Outer Retinal **thickness, according to the radio button selected in the Thickness box left of the Thickness Map at top center.**

- When the 2D (Thickness) Map is on, the overlay shows only its colors, which indicate thickness. When the 2D (Thickness) Map is off, the overlay shows the ETDRS chart colors, which are based on the normative database.

Adjust Fovea Location, if Necessary

If the ETDRS chart overlay seems not to be centered on the fovea, check to see if the fovea location indicated by the yellow dot on the Thickness Map (at top center) is accurate. If not, you can move the fovea location in two ways:

- Right-click on the Thickness Map and select **Move Fovea**, then click and drag the yellow dot to where the fovea should be. When you release, the system asks if you want to reprocess the data based on the new foveal location. Click **Yes** and the system saves

the fovea location change and reprocesses the data, which changes the measurements and colors. Click **No** and the fovea location reverts to where it started.

- Open the 3D Widefield (or 3D Widefield MCT) reference image and go to the 3D Widefield report. Right-click on the white space in the report and select **Move Fovea**, then click the location where the fovea should be. Now open the retina map again and confirm the ETDRS map appears in the expected location.

5.3.5 Thickness Map (Item 3)

The Thickness Map at top center reports retinal thickness, using a color code, over the 5 x 5 mm square centered on the fovea. The system finds the fovea location automatically. If the system cannot find the fovea, it places it in the center of the scan. Review the fovea location indicated by the yellow dot in the thickness map, and move it if necessary, as instructed above.

Thickness Map Colors

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.

Show Lines Checkbox

When the Show Lines checkbox is selected (as it is by default), grid lines overlay the map. The grid lines show placement of the scan lines of the Retina Map scan pattern. The grid lines must be on to change the currently selected point and the B-scans shown at lower left.

Thickness Box (Item 4)

The Thickness box next to the map has radio buttons to select display of **Full Retinal**, **Inner Retinal** or **Outer Retinal** thickness on the thickness map, in the thickness and volume parameter table (upper right) and on the ETDRS chart (lower right).

- **Full Retinal Thickness** measures from ILM (inner limiting membrane) to RPE (retinal pigment epithelium).
- **Inner Retinal Thickness** measures from ILM to IPL (inner plexiform layer).
- **Outer Retinal Thickness** measures from IPL to RPE.

Threshold and Volume Fields (Item 5)

Below the Thickness box are the Threshold and Volume fields, which interact to show volume values relative to the currently selected radio button in the Thickness box. (The options are **Full Retinal**, **Inner Retinal** and **Outer Retinal**.) Use the **Threshold** field to set a threshold thickness value: the **Volume** field reports the volume of retinal tissue above the threshold thickness value, for the retinal segment selected in the Thickness box. Only when **Full Retinal** thickness is selected, the map draws contours to indicate areas that exceed the threshold.

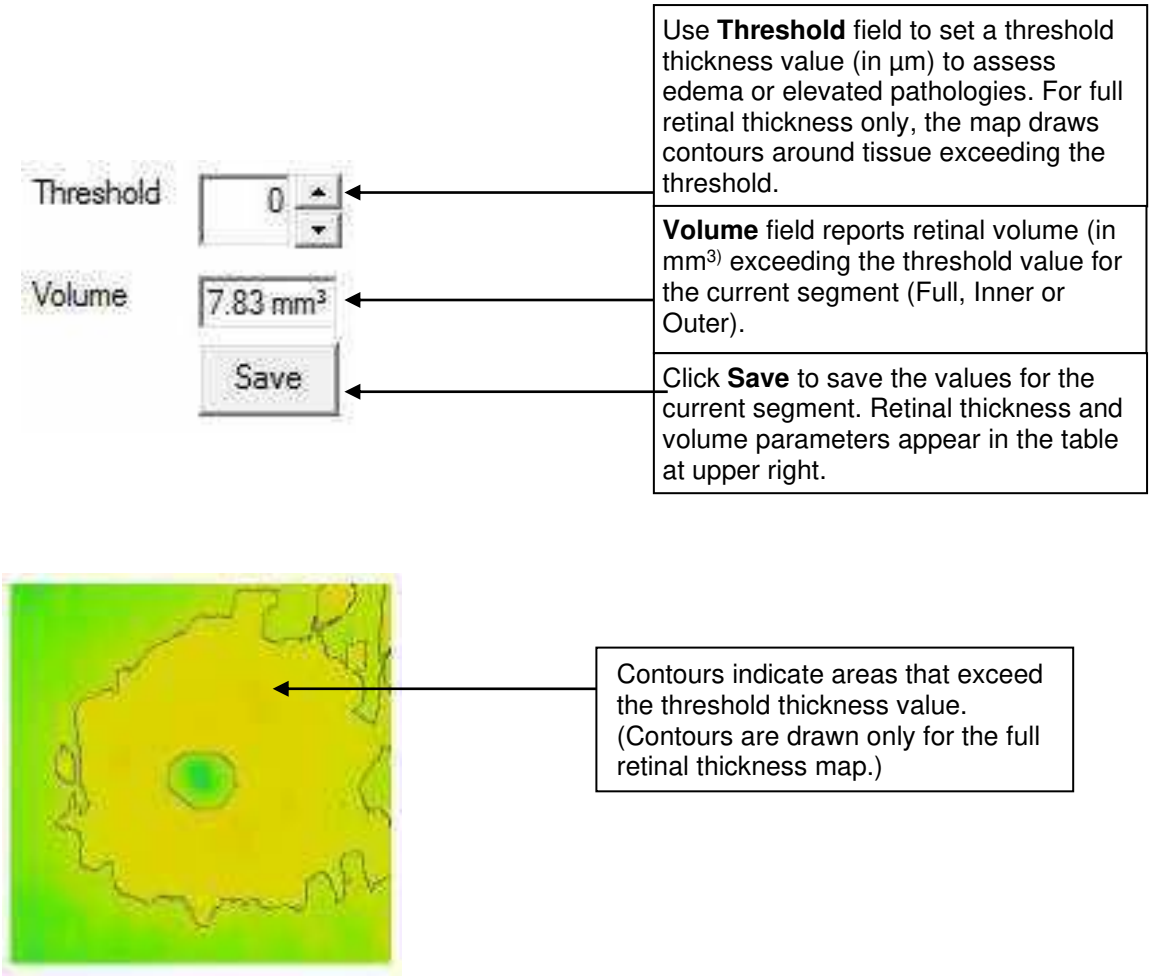


Figure 70 Retina Map with Auto-Drawn Contour

Draw Contours Manually

Manually draw a contour to measure full retinal thickness within the contour. The volume value (in mm^3) appears inside (or next to) the contour as you draw and when complete. Follow these steps to draw a contour:

1. Right-click the Thickness Map and select **Contour > Draw Contour**.

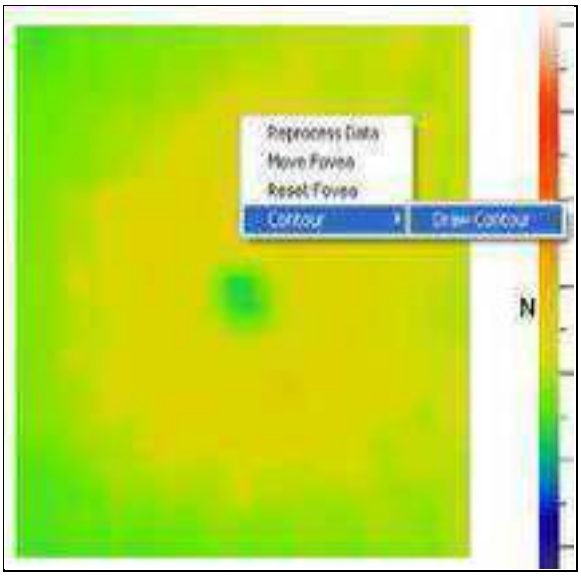


Figure 71 Select Draw Contour

2. Each click you make on the map creates a contour anchor point. The contour line follows the cursor as you move it between clicks. After the third click, the volume value

appears and updates continuously while you draw. The contour line is black while drawing. To complete the contour, double-click. It turns red when complete.

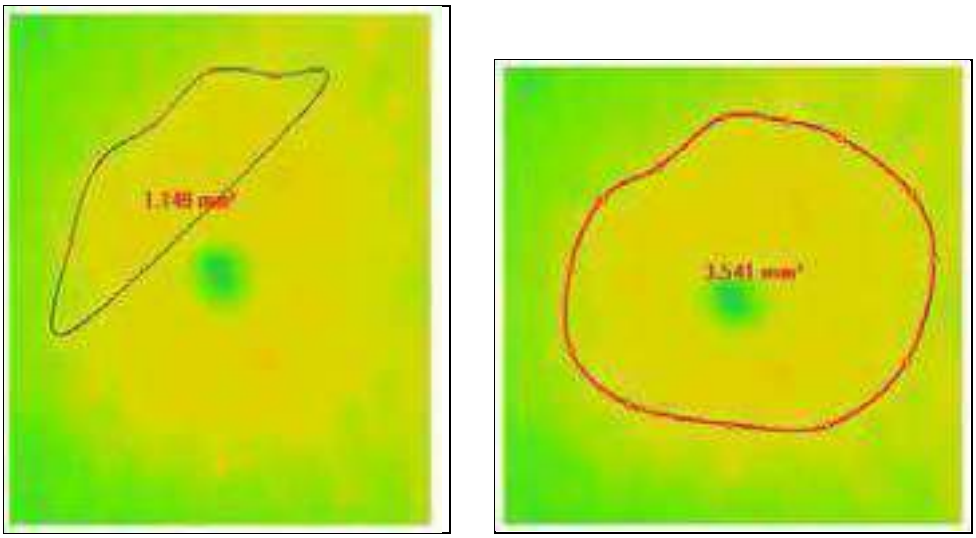


Figure 72 Drawing a Contour Line

Intersecting Red (or Blue) Lines and Single Point Thickness (Item 6)

The red lines on the Thickness Map indicate the currently selected scan lines of the retina map pattern, which correspond to the B-scans shown at lower left (item 10).

- Below the Thickness Map on the left, the software reports Thickness (in µm) at the point of intersection of the red lines. In parentheses below the Thickness value are x-y coordinates (in mm) with respect to the center of the retina map pattern.
- When you click on the Thickness Map, the red lines change to blue and move to intersect where you click. The lines then follow the pointer until you click again, and they turn back to red. When the lines are blue and you move the pointer, the Thickness value updates to show thickness at the exact pointer location. While you move the blue lines, the x-y coordinates update to the nearest point of scan line intersection, and the corresponding B-scans also update.

5.3.6 Thickness and Volume Parameter Table (Item 7)

The table at upper right reports retinal thickness (in µm) and volume (in mm^3) for the superior and inferior hemispheres and for the nine ETDRS-like sectors. The values displayed correspond to the current selection in the Thickness box to the left of the Thickness Map: **Full Retinal**, **Inner Retinal** or **Outer Retinal**. Color-coding with respect to the normative database appears only for full retinal thickness values. (See section 5.3.1 regarding the significance of the colors.)

5.3.7 ETDRS Chart (Item 8)

The ETDRS Chart at lower right reports average thickness in each of nine ETDRS-like sectors, both numerically (in µm) and in color with respect to the normative database. The nine sectors consist of the central 1 mm circle centered on the fovea, and the eight zones defined by the two concentric circles 3 mm and 5 mm from the fovea divided into the four quadrants: superior (S), nasal (N), inferior (I) and temporal (T). (The chart is based on the original four macular regions as defined in Stereoscopic Atlas of Macular Diseases Diagnosis and Treatment, J Donald M. Gass, Mosby, 3rd edition, Volume 1, Page 3).

The NDB color key above the ETDRS chart explains that green indicates "Within normal limits" " (the measurement is between the 5th percentile to 95th percentile of the NDB); yellow indicates "Borderline" thick (the measurement is between the 95th percentile to the 99th percentile of the NDB); red indicates "Outside normal limits" thick (the measurement is above the 99th percentile of the NDB); blue indicates "Borderline" thin (the measurement is between the 5th percentile to the 1st percentile of the NDB); and dark blue indicates "Outside normal limits" thin (the measurement is below the 1st percentile of the NDB). See Appendix B for more detail on the Normative Database.

5.3.8 NDB Reference or RPE Elevation Map (Item 9)

The map at bottom center shows either the **NDB Reference** map (default) or the **RPE Elevation** map, based on the selected radio button in the Map Option box above it.

NDB Reference Map

The NDB Reference map shows retinal thickness relative to the normal distribution.

RPE Elevation Map

The RPE elevation map 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.

The RPE tracing is compared to a normalized RPE ellipse fit. Disruption (D) is based upon +\-80% of the RPE (24 µm), and amplitude of +\- 150% of the RPE thickness (45 µm).

5.3.9 B-Scan Display (Item 10)

The red (or blue) lines on the Thickness Map indicate the currently selected scan lines of the retina map pattern, which correspond to the B-scans shown at lower left.

- **Show Boundary Curves Checkbox:** Select this checkbox above the B-scans to show segmentation lines on the B-scans.
- **Deselect HR frames to edit center cross line**

Retina OU Report

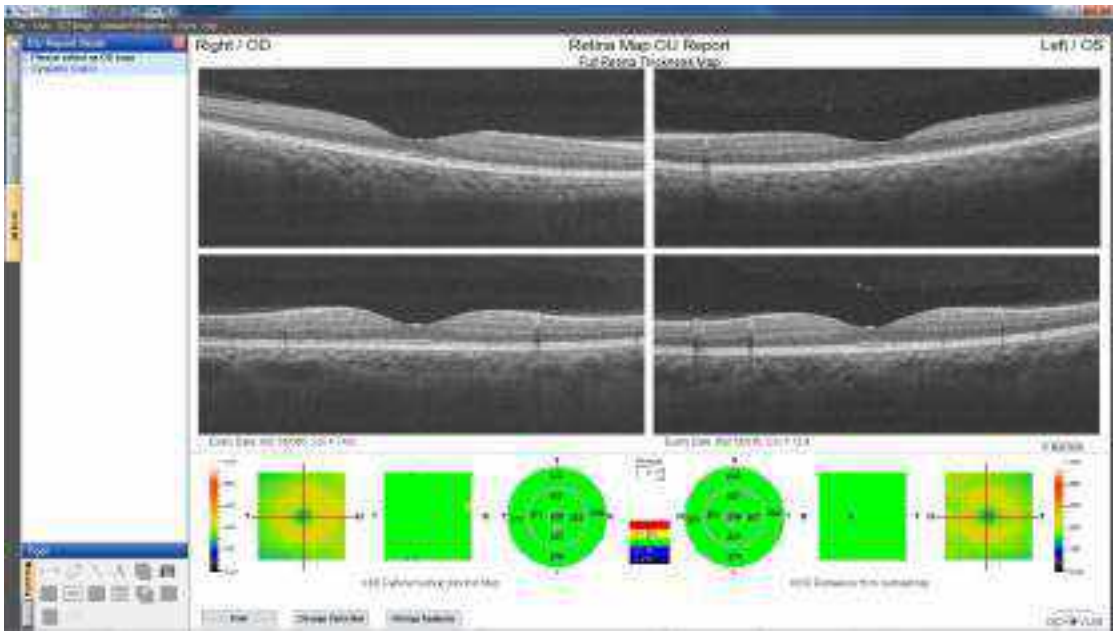


Figure 73 Retina OU Report

5.3.10 OU Retina Map Portrait Print Report

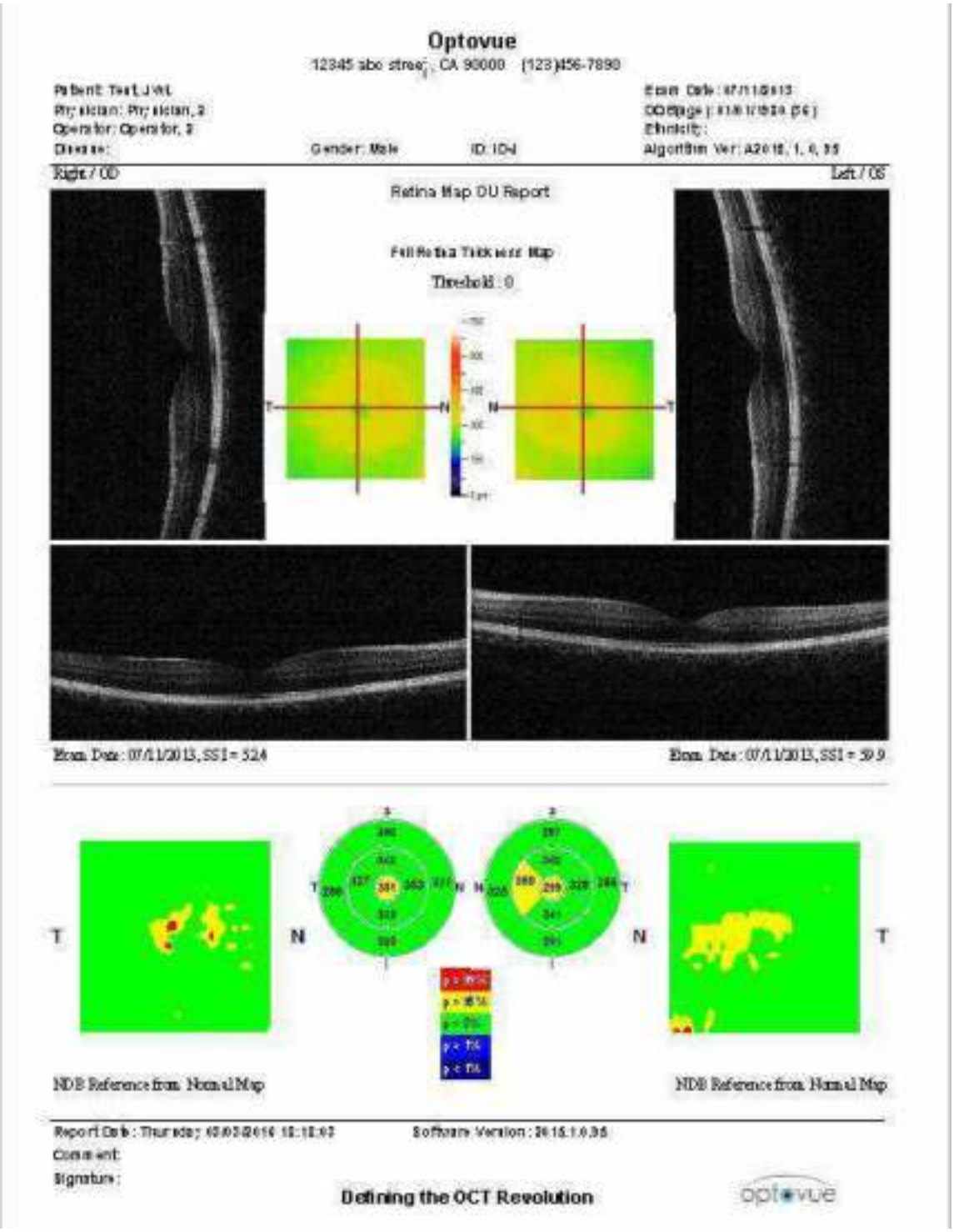


Figure 74 OU Retina Map Portrait Print Report

5.4 Retina Map Change Analysis Report

The **Change Analysis** button is available on the Retina Map report when two or more Retina Map scans have been taken. Click this button and the system displays the Retina Map Change Analysis report; it automatically selects up to six scans (a baseline scan and up to five subsequent scans) for the current patient eye. When a 3D Widefield scan has been acquired, the system uses it as baseline for registration of Retina Map scans. (When no 3D Widefield scan has been acquired, the system uses the first Retina Map scan as baseline.)

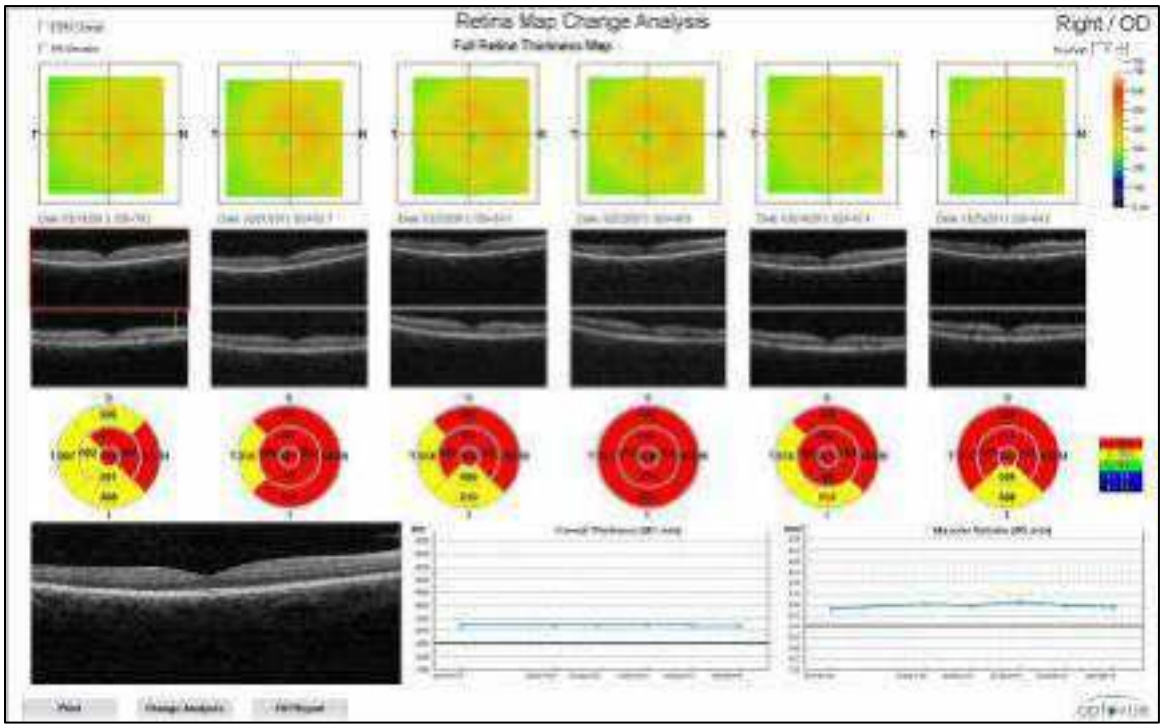


Figure 75 Retina Map Change Analysis Report

The Retina Map scan uses the fovea in the baseline scan (3D Widefield, if available) for registration. (See section 5.1.1 for details.) If the system cannot identify the fovea, it places it in the center of the scan. For a valid comparison, the fovea location on each Retina Map scan must be correct, so it is important that fovea location be reviewed after capture of each scan. Review individual scans as necessary and adjust the fovea location of those with an incorrectly placed fovea. See instructions to adjust the fovea location in section 5.3.4.

Note: If the scans are manually adjusted, make sure the foveal adjustments are consistent. The Clean Diagnosis Data function does not affect manually adjusted segmentation but will reset foveal position.

The Change Analysis report includes:

- Across the top, a full retinal thickness map (default) or an RPE elevation map. Select the **RPE Elevation** checkbox at top left to switch to display of RPE elevation maps.
- When the retinal thickness maps are displayed, you can use the **Threshold** field at upper right to automatically draw contours around areas above the threshold thickness value on all maps. The volume of retinal tissue above the threshold value appears within the contour. This assists in identifying areas of greater thickness that may be due to pathology.
- When the RPE elevation maps are displayed, you can use the **Ref** field at upper right to display elevation (in µm) relative to the reference value you entered, using the color code at upper right. The **Ref** range is from -25 to 25.
- In the second row are horizontal and vertical B-scans that correspond to the indicated scan lines on each map. The currently selected B-scan, highlighted in red around its perimeter, is shown in larger size at bottom left.
- The ETDRS chart for each scan appears in the third row. The chart furthest left, for the baseline scan, always shows full retinal thickness values and includes the normative reference colors. By default, the ETDRS charts after the baseline scan show the change in retinal thickness (in µm) relative to the baseline scan, and do not include normative reference colors.
- When you deselect the **ETDRS Change** checkbox at top left, the ETDRS charts show full retinal thickness for each scan and include the normative reference colors.
- At bottom center and right are graphs that plot Foveal Thickness and Macular Volume, creating a line that traces change from scan to scan.

5.5 3D Report Options

The Avanti System has three types of 3D scan, and provides multiple report options for each scan type, as shown below.

	3D Widefield Scan	3D Retina Scan	3D Disc Scan
Retina OverVue Report	X	X	
En Face Report	X	X	X
3D Display	X	X	X
Scan Specific Report	X	X	X

The system generates all applicable report options when you select a 3D scan for review, and you can move between the report options using buttons on each report. (3D features introduced in this version are intended for the XR PC system. PC systems that do not adhere to the RTVue XR specifications may exhibit reduced performance when using 3D features. 3D Volume views are memory-intensive functions and frequent usage of these features may slow scan processing.)

Note: In the User Preference dialog (see section 6.2.5 User Preference on page 182), you can select which types of 3D report opens by default.

5.5.1 Retina OverVue Report (3D Widefield and 3D Retina)

The system generates a Retina OverVue report only for the 3D Widefield and 3D Retina scans. When you select one of these scans for review, the Retina OverVue report opens first.

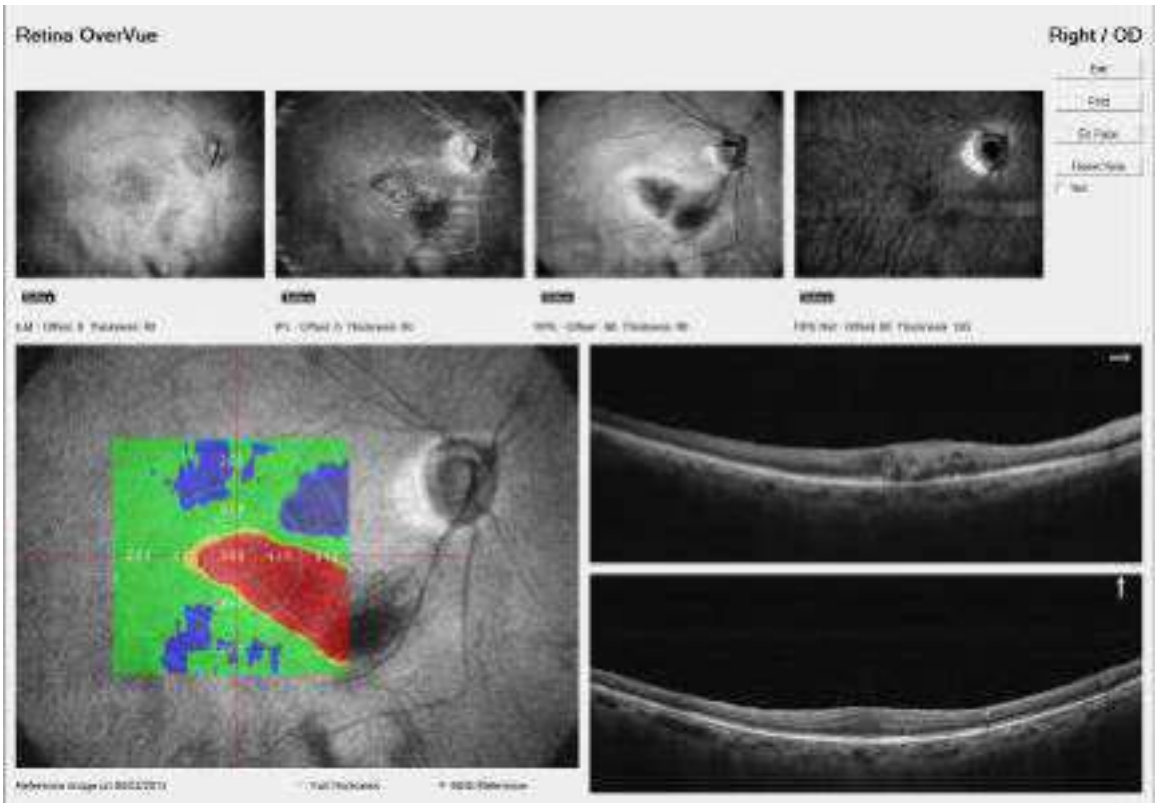


Figure 76 Retina OverVue Report

In addition to the 3D Widefield or 3D Retina scan, the Retina OverVue report uses data from the Retina Map, Cross Line and Grid scans, when they have been acquired. The system constructs the Retina OverVue report as follows:

- Across the top are en face images at four depths taken from the 3D Retina or 3D Widefield scan, in that order of preference
- At lower left is the SLO-like image from the 3D Widefield or 3D Retina scan, in that order of preference.
- Overlying the image is a thickness map from the Retina Map, 3D Widefield, or 3D Retina scan, in that order of preference. The overlay is either an **NDB Reference** map (default) or a **Full Thickness** map, according to the radio button selected beneath it.

- At lower right are horizontal and vertical B-scans from the Cross Line, Grid, 3D Retina, or 3D Widefield scan, in that order of preference.

  When you click the **Exit** button at upper right, the scan specific report opens, (either the 3D Widefield report or the 3D Retina report—see section 5.5.5). When you click the **En Face** button, the En Face report opens.

5.5.2 Retina OverVue Portrait Report

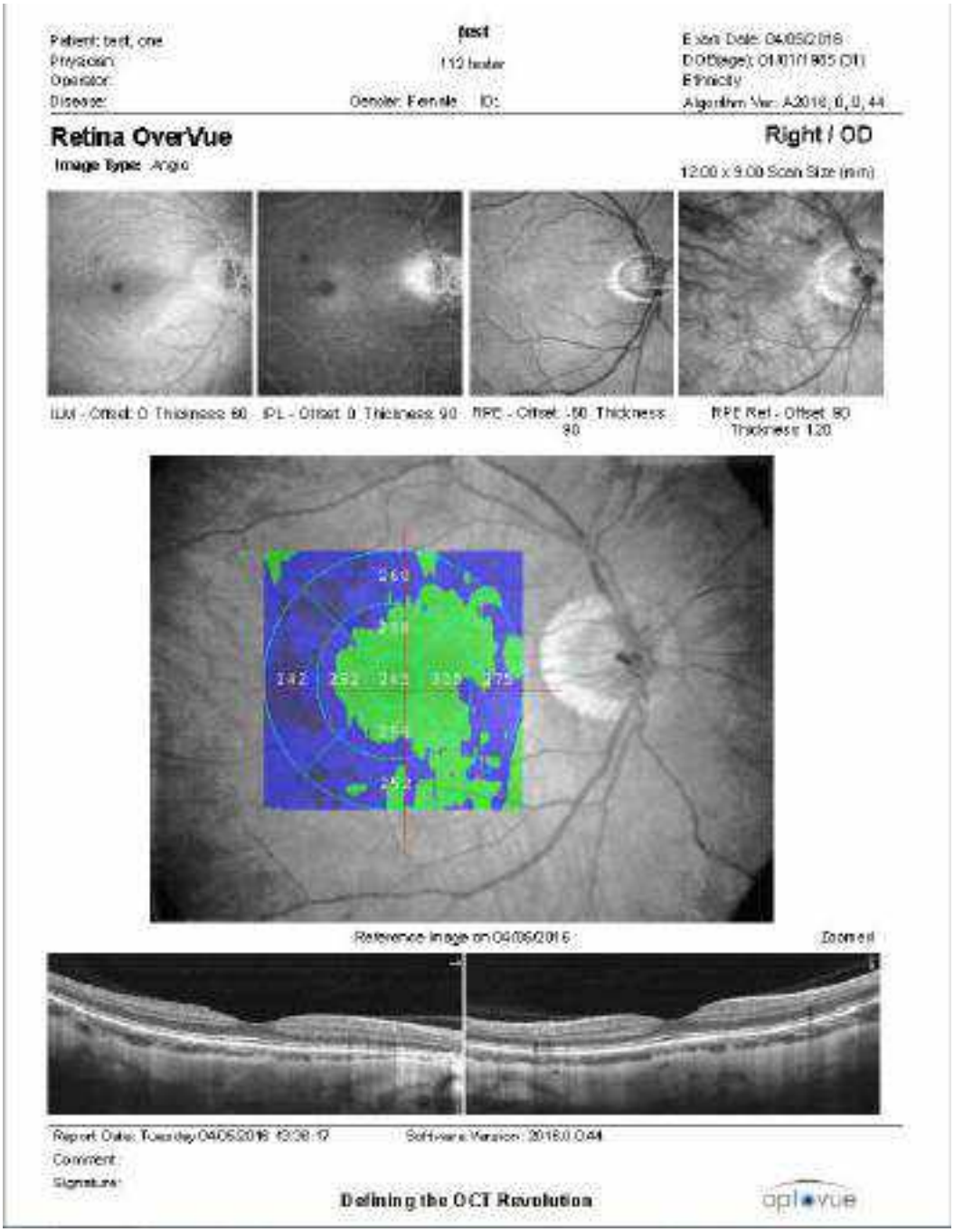


Figure 77 Retina OverVue Portrait Report

5.5.3 En Face Report (All 3D Scans)

The En Face report applies to all 3D scans (Widefield, Retina and Disc). The **En Face** button is available in the Retina OverVue report and in the scan specific reports.

En Face Report with Tint Selected

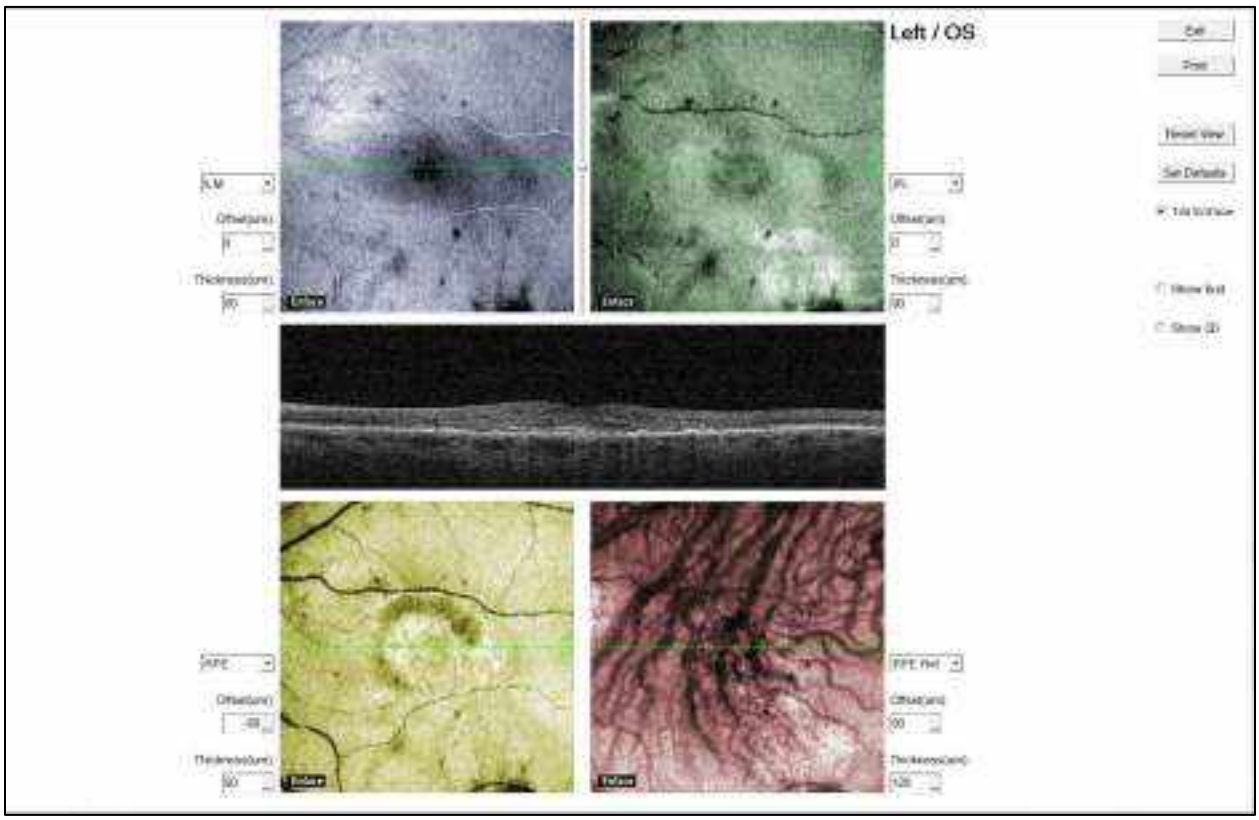


Figure 78 En Face Report with Tint Selected

In the middle appears a single horizontal B-scan that corresponds to the green line across all four en face images. Click and drag the green line to change which B-scan is displayed. By default, this report displays en face images at different depths corresponding to the relevant retinal or disc layers.

- For retina scans, the default layers shown are ILM, IPL, RPE, and RPE Reference.
- For 3D Disc scans, the default layers are ILM, NFL, and RPE.

- You can select the **Show 3D** checkbox at middle right to display the same layers using a 3D image.

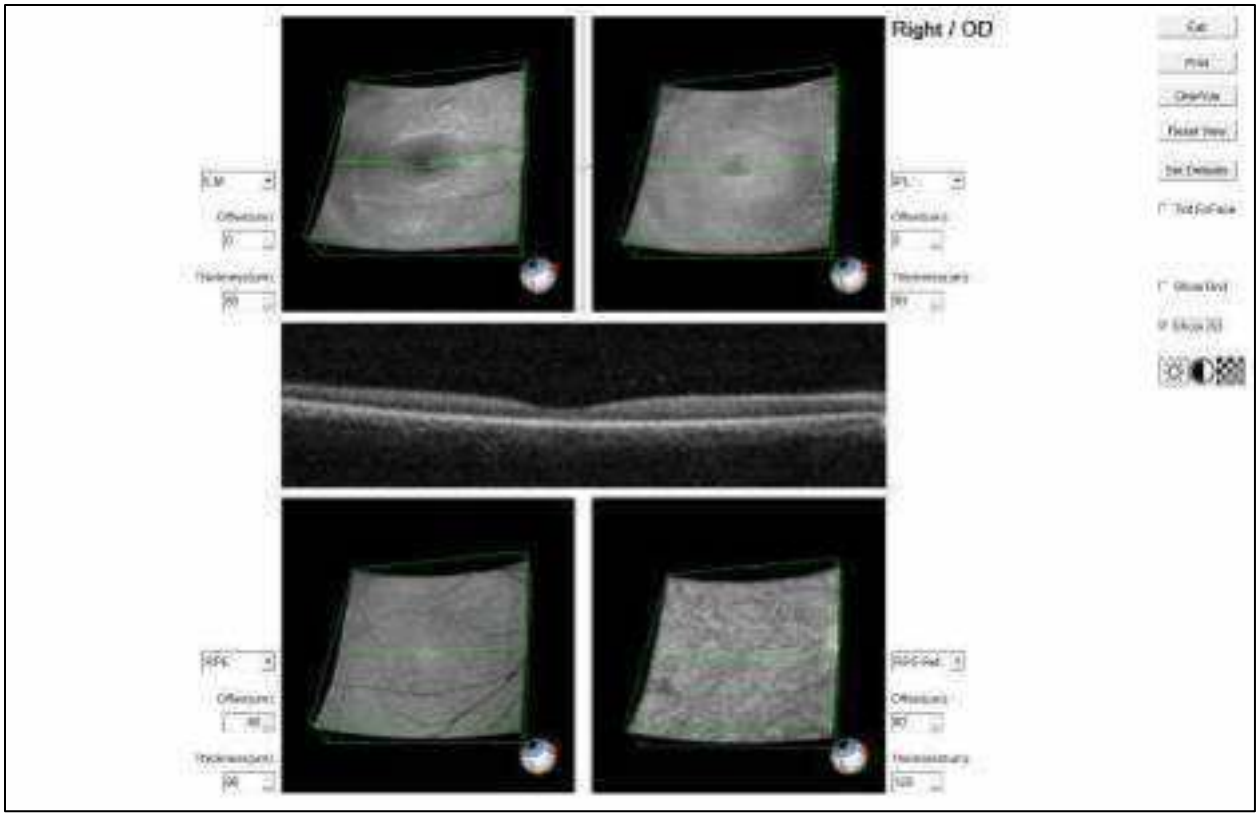


Figure 79 En Face Report, Layers Shown as 3D Images

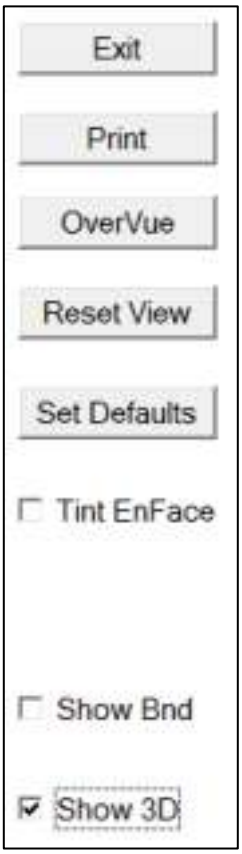
Next to each image are three fields that enable you to change:

- The layer displayed in each image, such as **ILM**, **IPL**, **RPE** and **RPE Ref**
- The **Offset** (in µm) of the layer. To change the offset is to change the layer depth relative to the default layer depth.
- The **Thickness** (in µm) of the given layer.

These options also define the layers displayed in the 3D Volume report (see section 5.5.4).

Click and hold over an image, then drag up or down to adjust video brightness, or left and right to adjust video contrast. Click and scroll over an image to adjust zoom.

At upper right are the following controls:



Exit: Exits the en face report and returns to the scan specific report.

Print: Prints the current report either to an electronic file or to hard copy, depending on the printer you choose.

OverVue: Return to OverVue screen.

Reset View: Resets offset and thickness to standard values.

Set Defaults: Sets the default offset and thickness values to the current values for each image.

Tint EnFace: Tints each en face image for better contrast.

Show Bnd (Boundary): Shows segmentation lines on the B-scan.

Show 3D: Shows en face layers in 3D.

5.5.4 3D Display (All 3D Scans)

The **3D Display** button is available in the scan specific reports of all 3D scans. When you click **3D Display** the system presents a 3D image of the OCT scan.

3D Display, 3D Volume Checkbox Selected

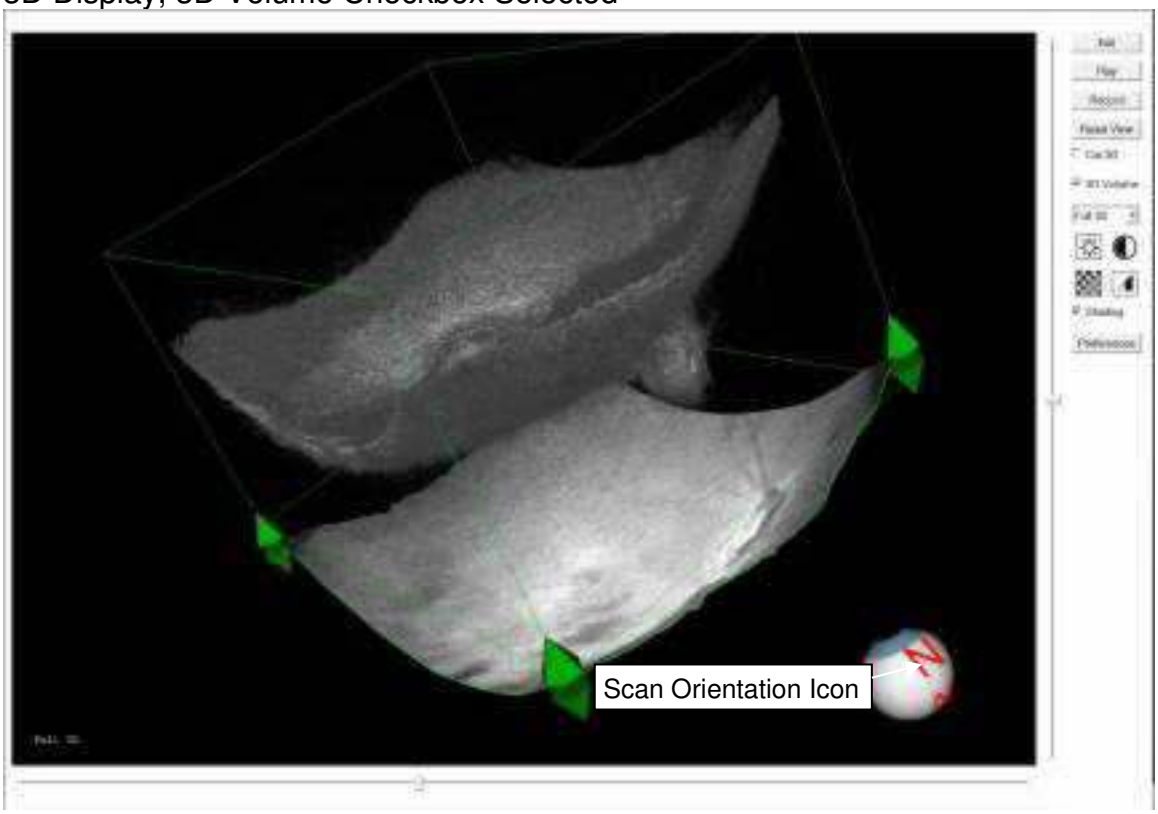
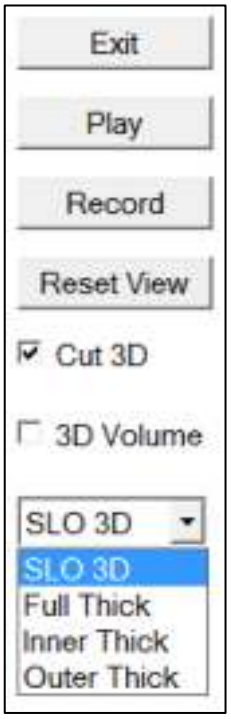


Figure 80 3D Display, 3D Volume Checkbox Selected

- **Scan Orientation Icon**: Shows orientation of the image using TSNI indicators.
- Click and drag on the image to rotate it. Scroll on the image to zoom. Click and drag on the green corner handles to move the SLO image relative to the 3D image.

To the right of the 3D image are the following controls.



Exit: Closes the 3D display window.

Play: Sequentially plays through the B-scans. Click **Pause** to pause.

Record: Click **Record** to save a recording of the sequential display of B-scans: a dialog prompts you to choose a folder where the recording will be saved, in .avi format, and recording begins. To finish recording, click **Stop Recording**.

Reset View: Resets the image to a top-down view.

Cut 3D: Shows the cut 3D image. Click **Play** to change the cut planes and **Pause** to stop.

3D Volume: Presents the entire 3D volume captured, including the vitreous tissue just above the ILM plane.

Layer Selection field: Select to display the chosen layer. When the **3D Volume** checkbox is clear, the options are:

SLO 3D: Entire 3D volume with SLO image on top

Full Thick: Retina from ILM to RPE

Inner Thick: ILM to IPL

Outer Thick: IPL to RPE

3D Volume Checkbox

Select the **3D Volume** checkbox to display the Full 3D volume image (by default) with the SLO image below.

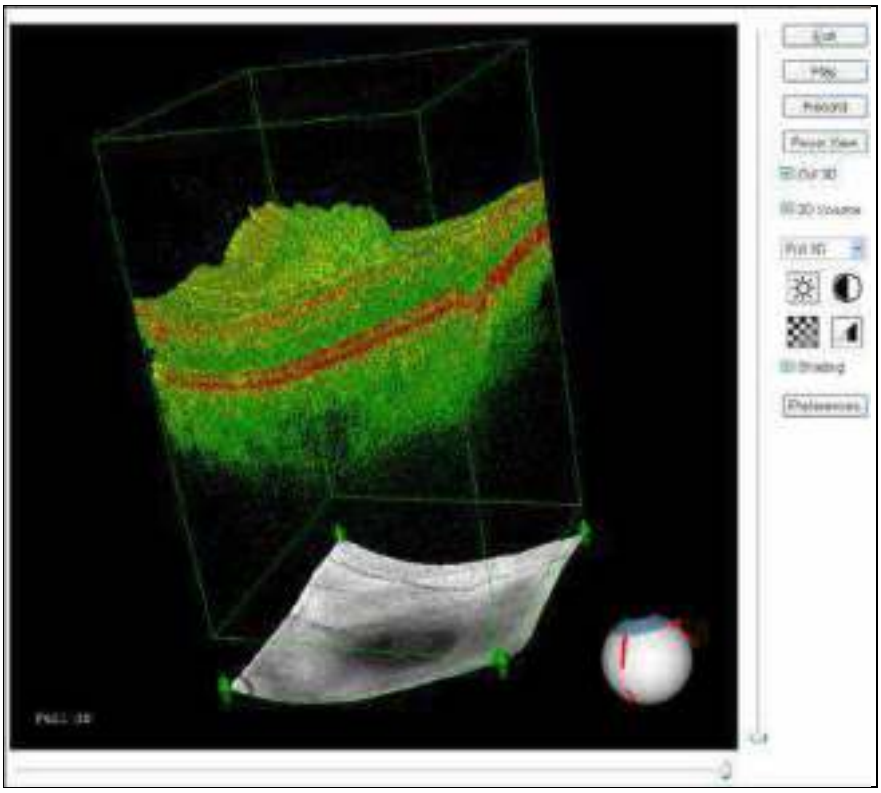
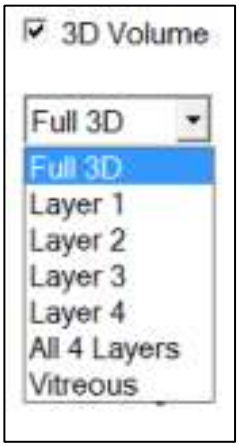


Figure 81 3D Display with 3D Volume Checkbox Selected



When the **3D Volume** checkbox is selected, the layer options are:

Full 3D: Entire 3D volume (default)

Layer 1, Layer 2, Layer 3, Layer 4: Select to display the chosen layer as defined in the En Face report (see section 5.5.3).

All 4 Layers: Displays all 4 layers.

Vitreous: Displays the vitreous and retina.

The following figures give examples of the available 3D Volume display options.

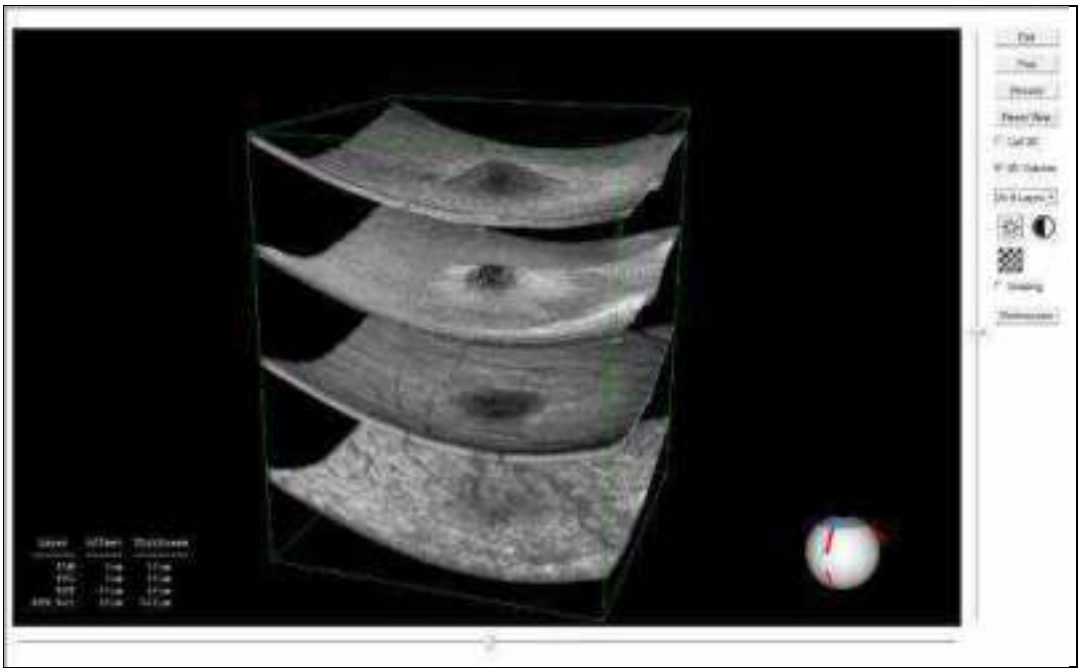


Figure 82 3D Volume, All 4 Layers Selected

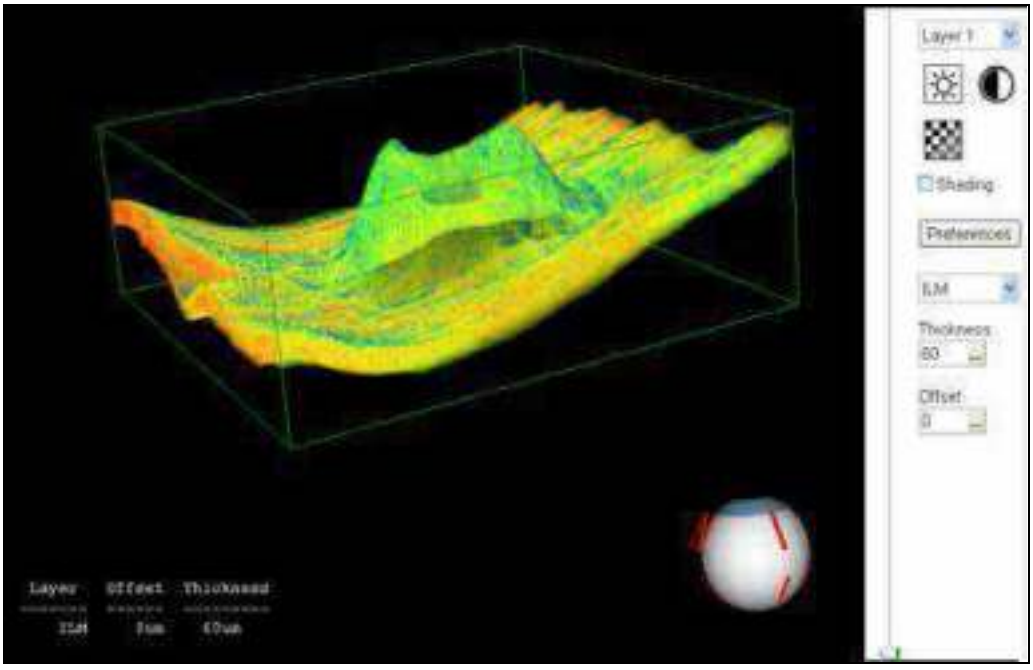


Figure 83 3D Volume, ILM Selected

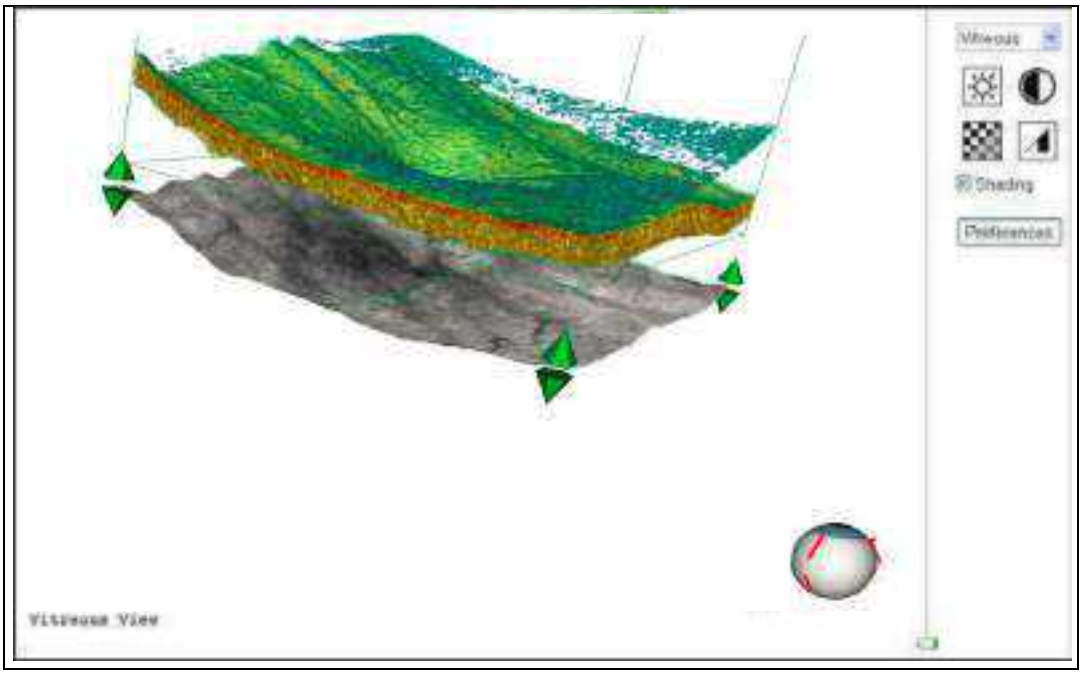


Figure 84 3D Volume with Vitreous Selected

(White Background Used For Better Vitreous Particles View)

3D Volume Image Adjustment

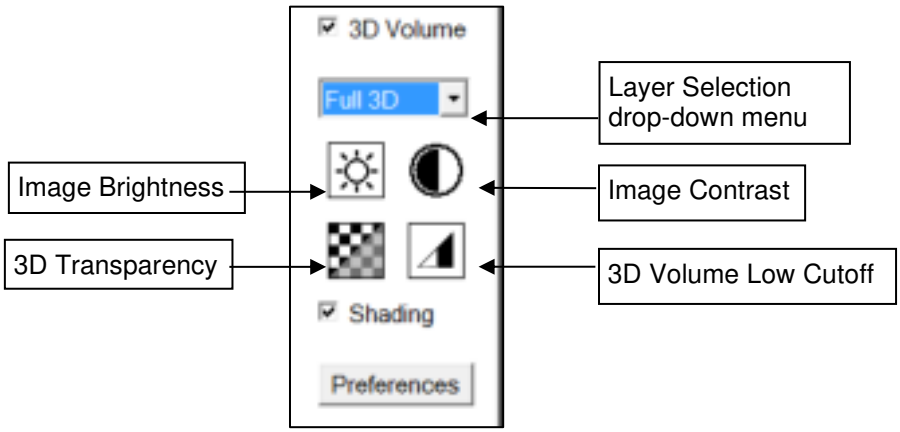


Figure 85 3D Volume Image Options

- **3D Volume Low Cutoff:** Filters additional noise from 3D image.
- **Shading checkbox:** Select to switch shading on/off on the 3D image. When not selected, the SLO image is not present.

- **Preferences button:** Click **Preferences** to open the **3D Preferences** dialog. Use this dialog to adjust the default display of 3D images.

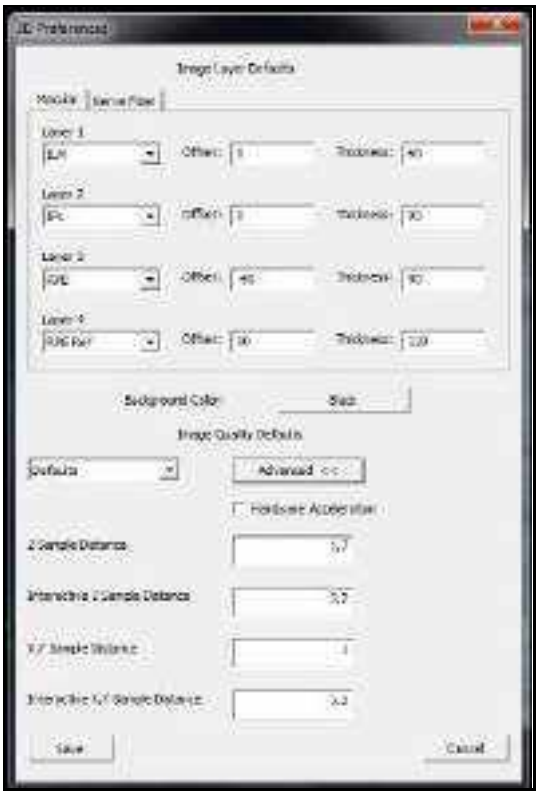


Figure 86 3D Preferences Dialog

Layer 1, 2, 3, 4 Defaults**: Select default layer and set default offset and thickness for each layer.**

- **Background Color**: Click to change the background color of the 3D image. It changes from black to gray to white.

- **Advanced**: Click **Advanced** to adjust **Z Sample Distance, Interactive Z Sample Distance, X,Y Sample Distance** and **Interactive X,Y Sample Distance**. These adjust 3D volume rendering when static (motionless) or dynamic (moving, for example, being dragged or rotated). Higher values yield 3D images of lower resolution, but are processed faster. Lower values yield 3D images of higher resolution, but take longer to process. Optovue sets the factory default values to optimally balance resolution and processing time. Table below shows the range of input values for each parameter.

Table Sample Distance Adjustment Ranges with CPU and GPU

	CPU	GPU (Hardware Acceleration Option Selected)
Z Sample Distance	1.0 < X < 10	0.4 < X < 10
Interactive Z Sample Distance	2.5 < X < 10	2.5 < X < 10
X,Y Sample Distance	0.7 < X < 10	N/A
Interactive Z Sample Distance	0.7 < X < 10	N/A

5.5.5 3D Widefield and 3D Retina Report

The 3D Widefield report and 3D Retina report share a common layout as described below, the difference being the size of the scan pattern. 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.

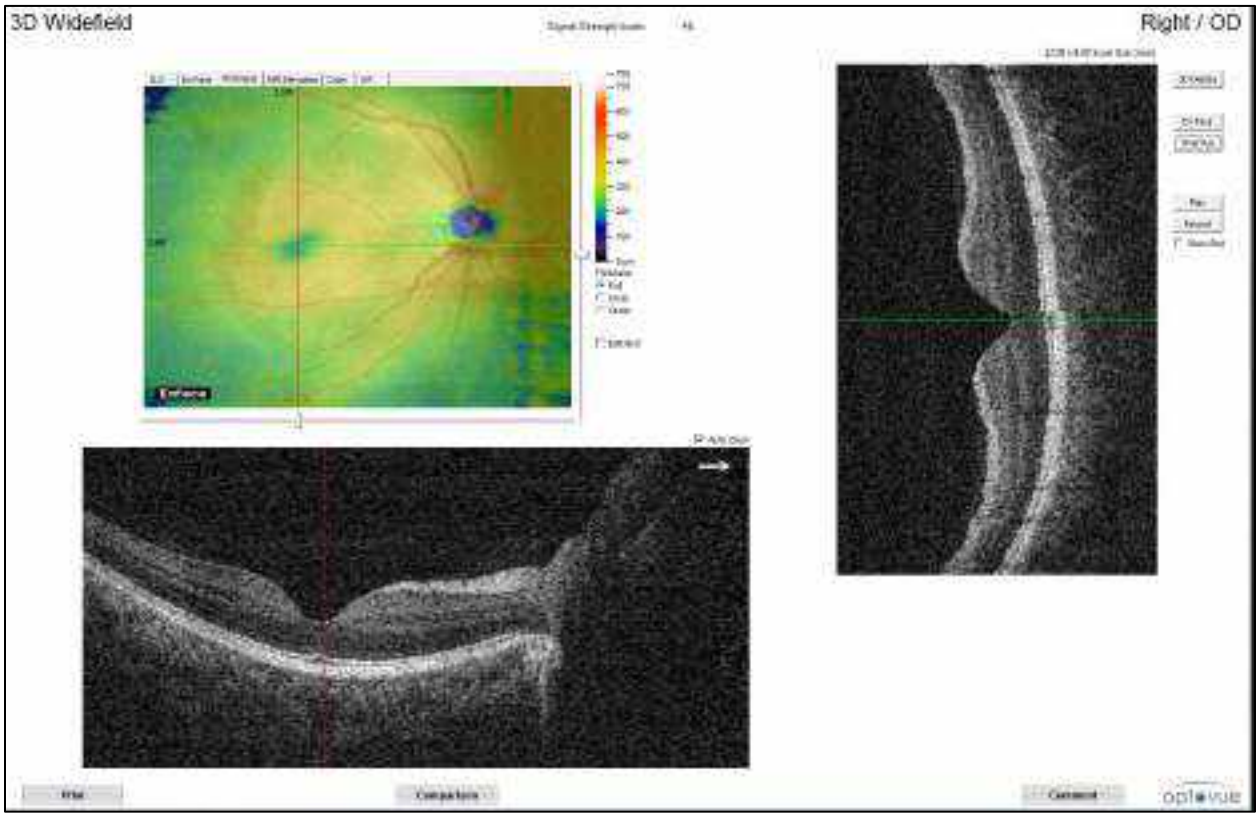


Figure 87 3D Widefield Report

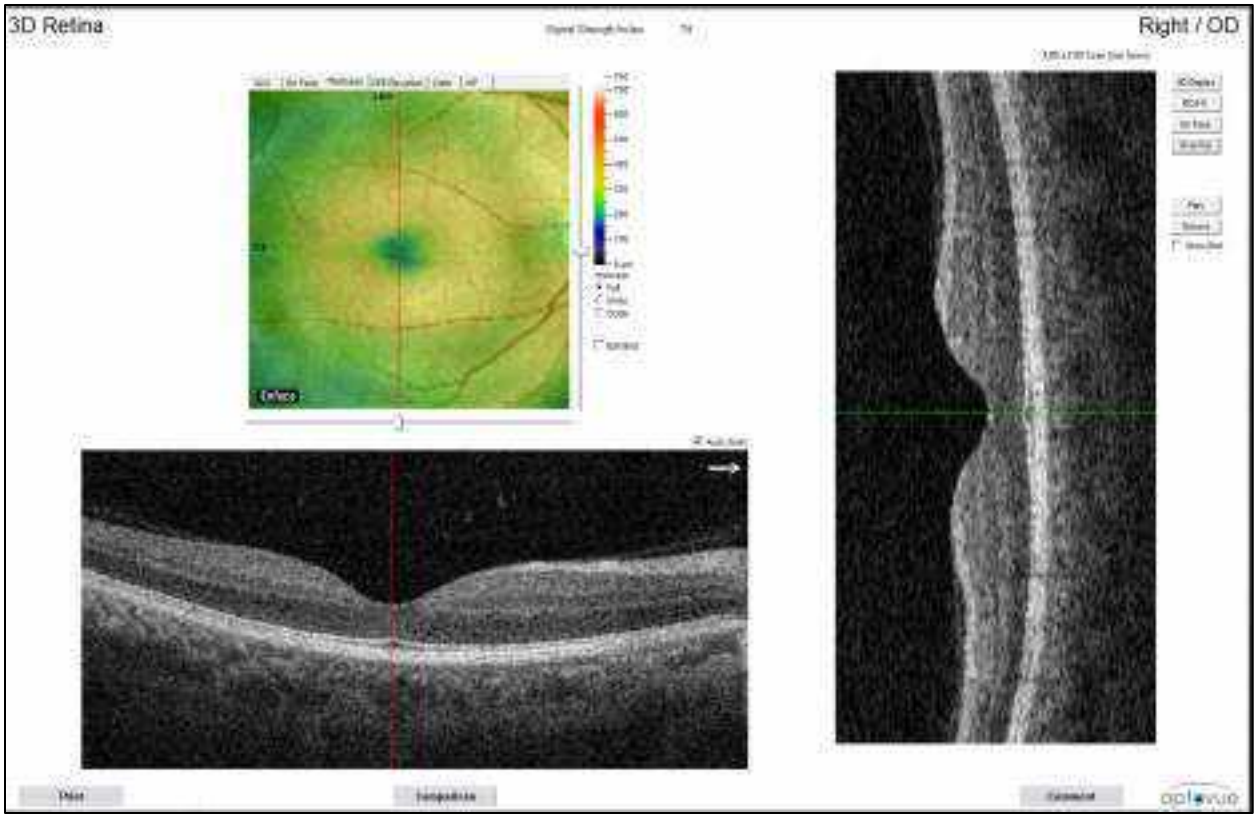


Figure 88 3D Retina Report

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.

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

En Face: Opens the En Face report.

OverVue: Opens the Retina OverVue report.

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.

5.5.6 3D Clinical Scan

The **3D Clinical** scan is a 513 x 101 3D cube covering 6 mm x 6 mm. This scan is designed for use primarily in clinical studies.

5.5.7 3D 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.

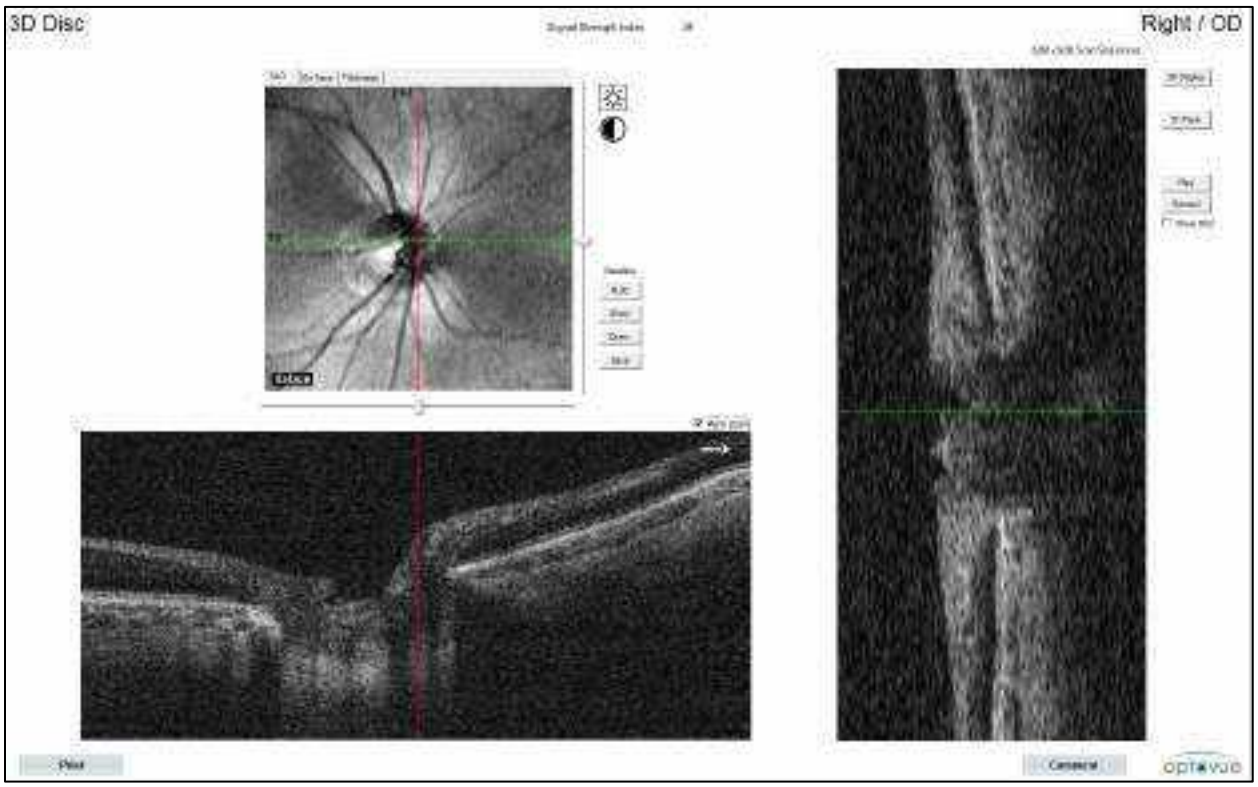


Figure 89 3D Disc Report

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.

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

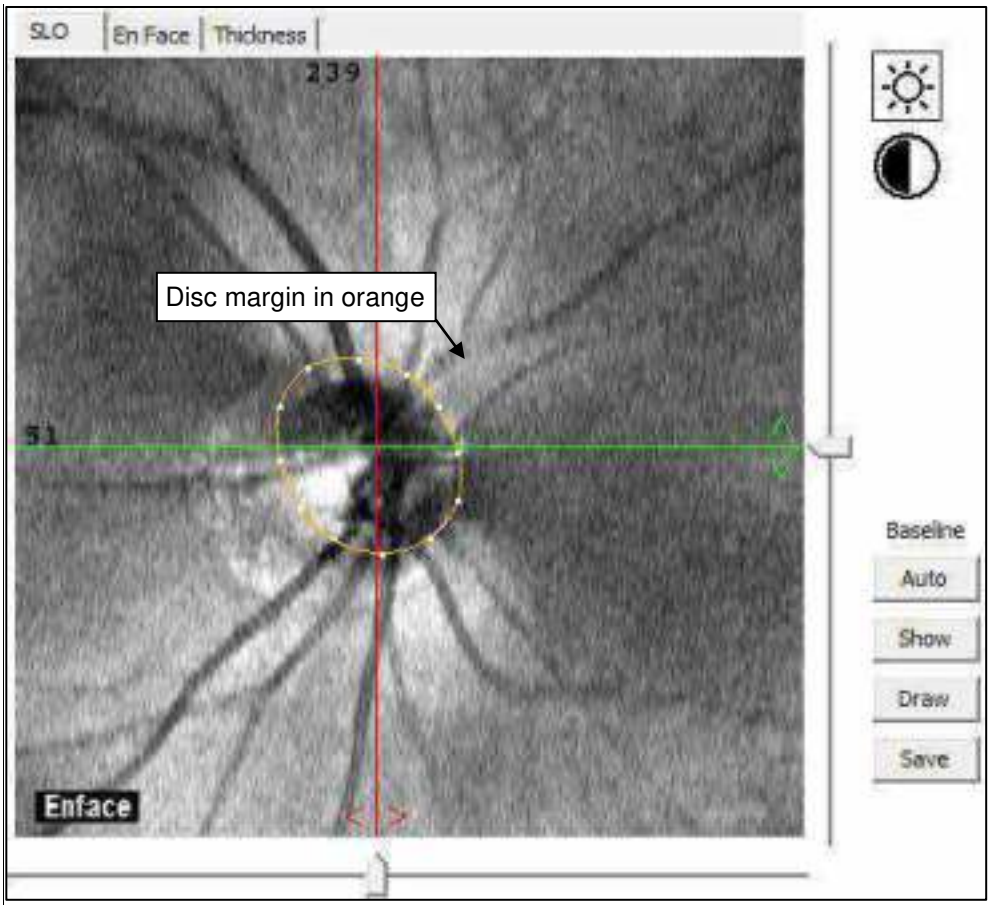


Figure 90 Optic Disc Margin in 3D Disc Report

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.

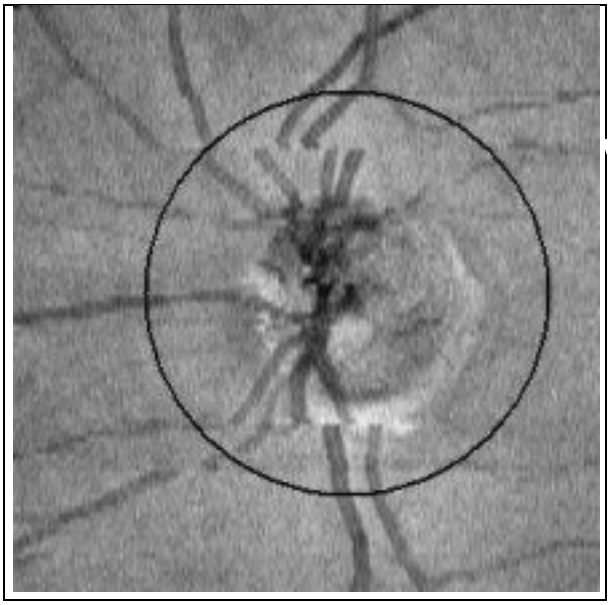


Figure 91 A 3D Disc Scan Showing Eye Motion

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.

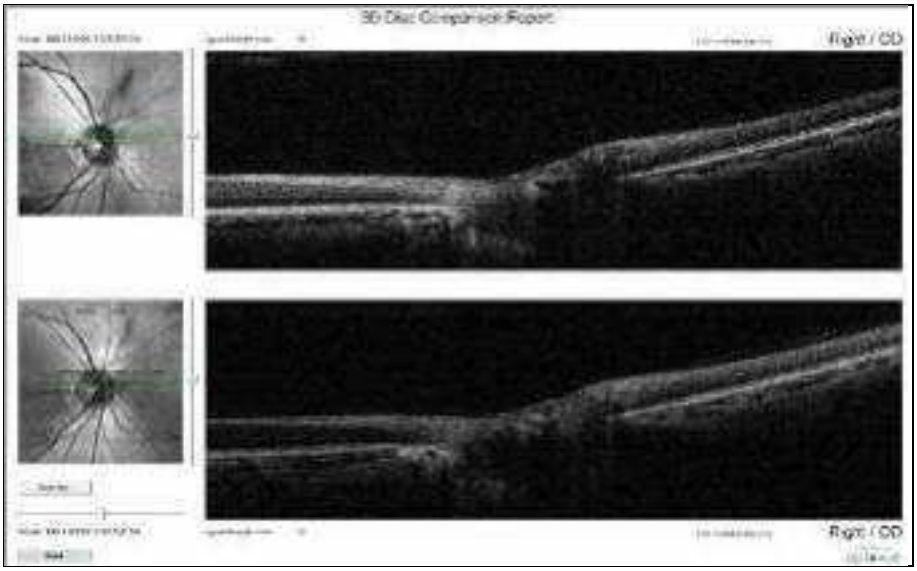


Figure 92 3D Disc Comparison Report

5.6 ONH Report

The ONH report provides images, charts, tables and maps to enable qualitative and quantitative assessment of the retinal nerve fiber layer (RNFL) and the optic disc. The image below and its legend below identify the components of an ONH report. The subsections following explain each component in order.

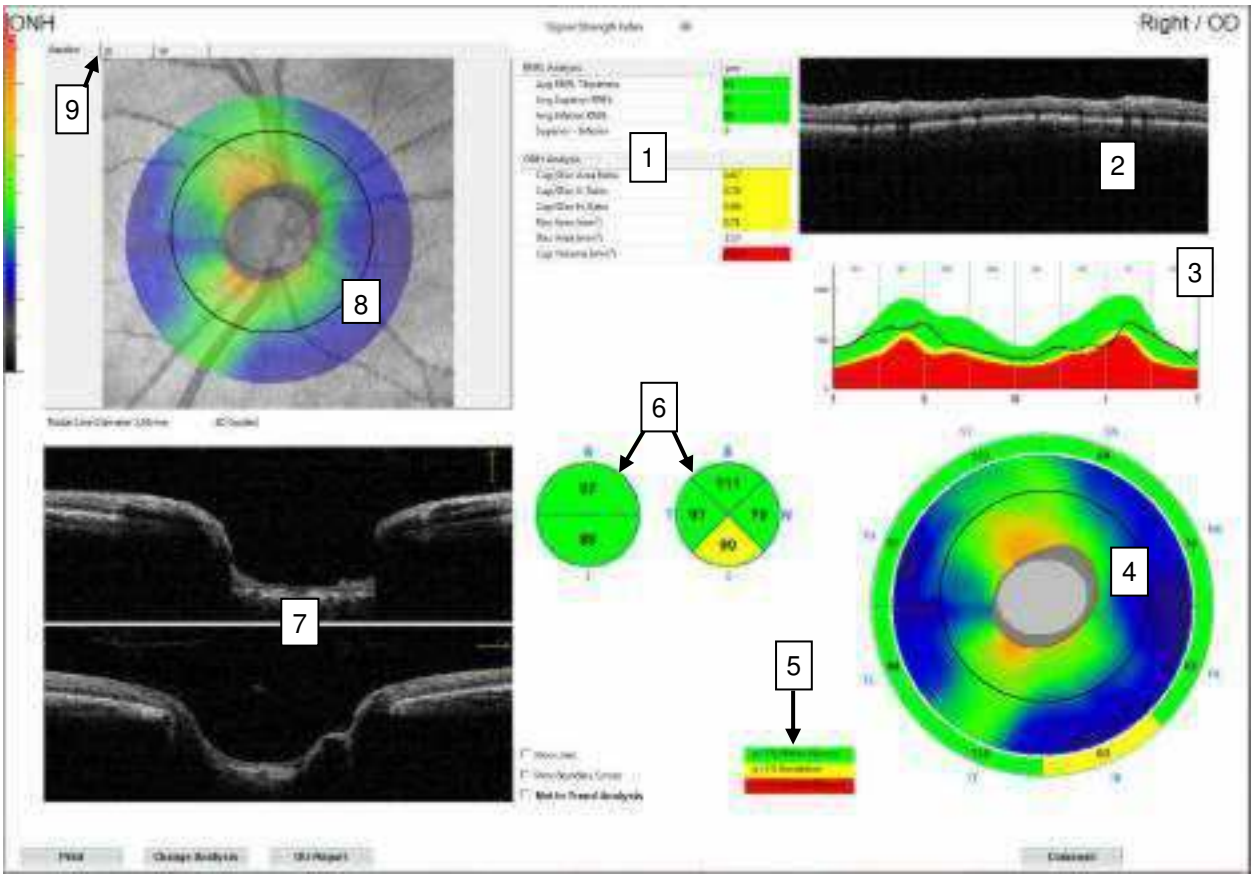


Figure 93 ONH Report Layout

ONH Report Layout Legend:

1 RNFL and ONH Analysis Table

2 RNFL Circle B-scan

3 TSNIT RNFL Thickness Graph

4 RNFL Thickness Map

5 Normative Database legend

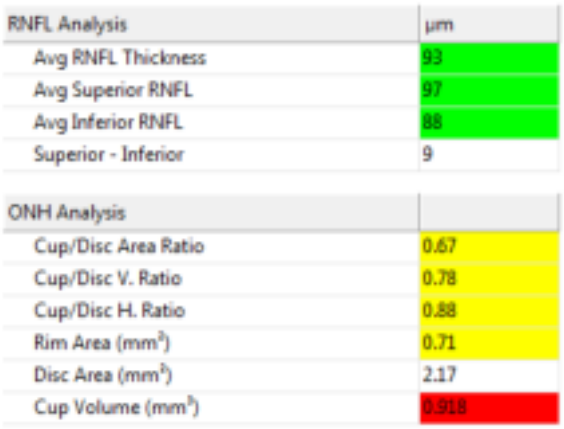
6 Hemisphere and Quadrant Maps

7 Vertical and Horizontal B-scans

8 RNFL Thickness Map Overlay

9 Image Tabs (Baseline default)

5.6.1 RNFL and ONH Analysis Table



RNFL Analysis	µm
Avg RNFL Thickness	93
Avg Superior RNFL	97
Avg Inferior RNFL	88
Superior - Inferior	9

ONH Analysis	
Cup/Disc Area Ratio	0.67
Cup/Disc V. Ratio	0.78
Cup/Disc H. Ratio	0.88
Rim Area (mm^2)	0.71
Disc Area (mm^2)	2.17
Cup Volume (mm^3)	0.918

Figure 94 RNFL and ONH Analysis Table

At top center is the RNFL and ONH Analysis table, which reports the parameters shown above. Cell coloring reflects comparison of each value with the normative database. As the legend at bottom center shows regions where thickness is within normal range (green, the measurement is between the 5th percentile to 95th percentile of the NDB, borderline (yellow, the measurement is between the 5th percentile to the 1st percentile of the NDB, and outside normal range (red, the measurement is below the 1st percentile of the NDB).

5.6.2 RNFL Circle B-Scans

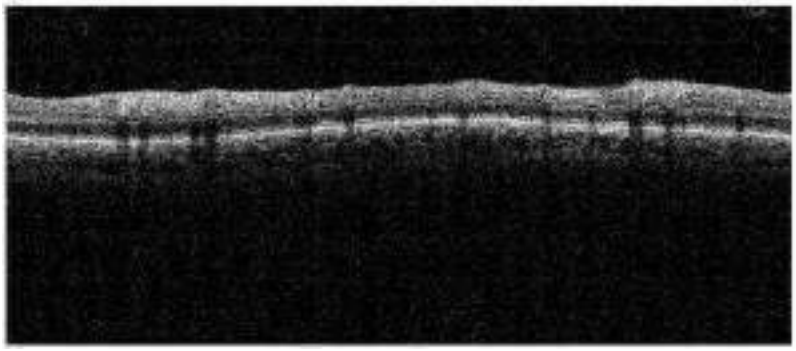


Figure 95 RNFL Circle B-Scan

One of the circle B-scans centered on the optic nerve is shown at top right of the report.

5.6.3 TSNIT RNFL Thickness Graph

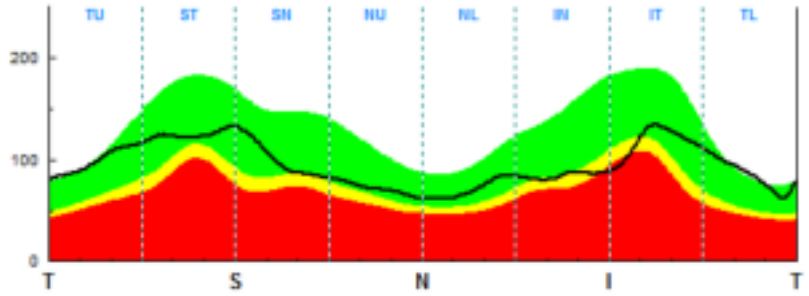


Figure 96 TSNIT RNFL Thickness Graph

At middle right is a graph with the black line depicting RNFL thickness (in µm) along a calculated 3.4 mm diameter circle centered on the optic nerve head. The red, yellow and green background on the graph represents the normative distribution of RNFL thickness, enabling you to see the measured RNFL thickness relative to normal.

5.6.4 RNFL Thickness Map

At lower right is a color-coded RNFL thickness map of 5 mm diameter. Warmer colors from yellow, orange and red to white represent increasing thickness. Cooler colors from green to blue to black represent decreasing thickness. Disc margin (green line) and cup margin (red line) are traced at the center of the map. The space between the cup and disc margins is the rim area.

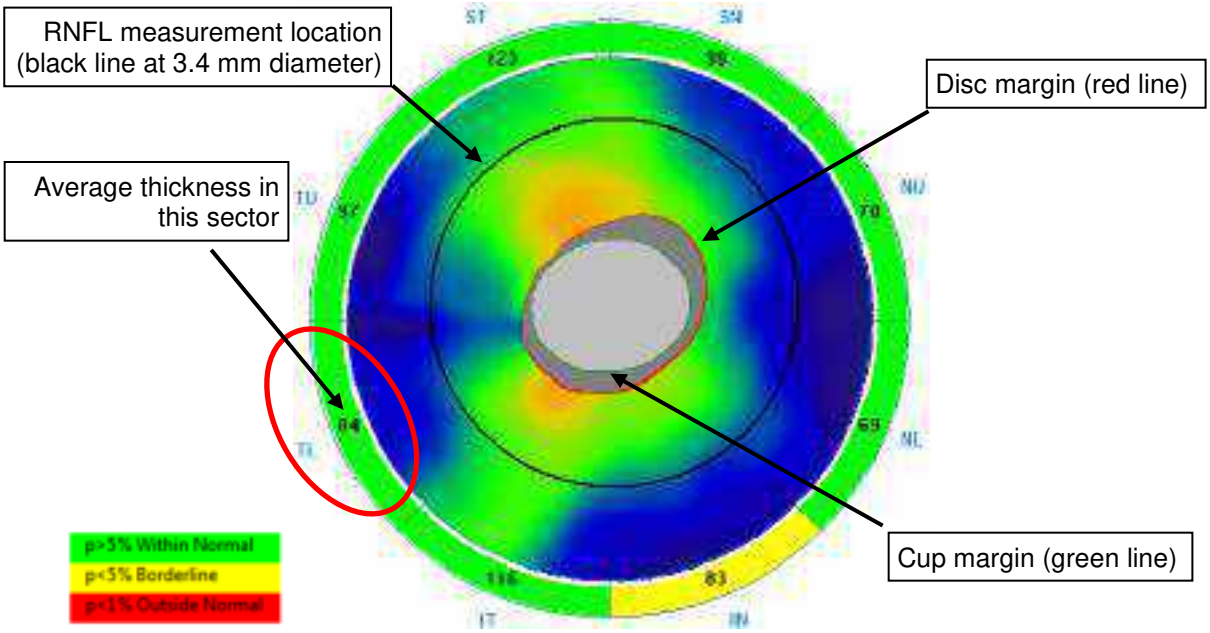


Figure 97 RNFL Thickness Map

Average RNFL thickness for each of eight sectors appears in a ring at the outer edge of the map. Each measurement appears against a green, yellow or red background, indicating whether the measurement is within normal (green), borderline (yellow) or outside normal (red). The RNFL thickness measurement at 3.4 mm diameter is sampled relative to the disc center, not the scan beam center, so minor de-centering of the disc relative to the scan beam does not affect the measurement.

5.6.5 Hemisphere and Quadrant Maps

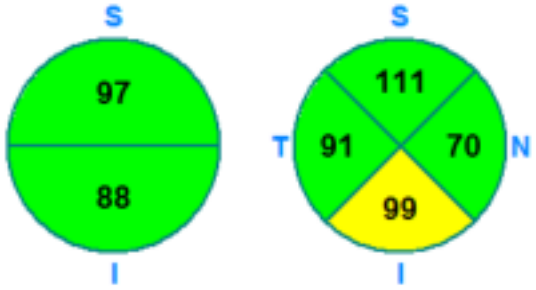


Figure 98 Hemisphere and Quadrant Maps

The hemisphere and quadrant maps show average RNFL thickness in the indicated hemispheres (left) and quadrants (right). Each measurement appears against a green, yellow or red background, indicating whether the measurement is within normal (green), borderline (yellow) or outside normal (red).

5.6.6 Vertical and Horizontal B-Scans

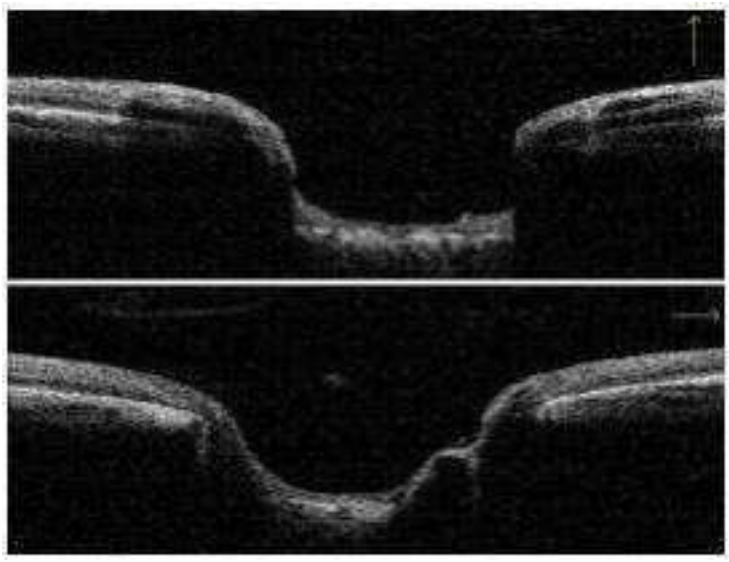


Figure 99 Vertical and Horizontal B-Scans

At lower left are vertical and horizontal B-scans through the optic disc. Click on the IR tab at upper left to see the scan lines on the IR video image.

5.6.7 Baseline Image and RNFL Thickness Map Overlay

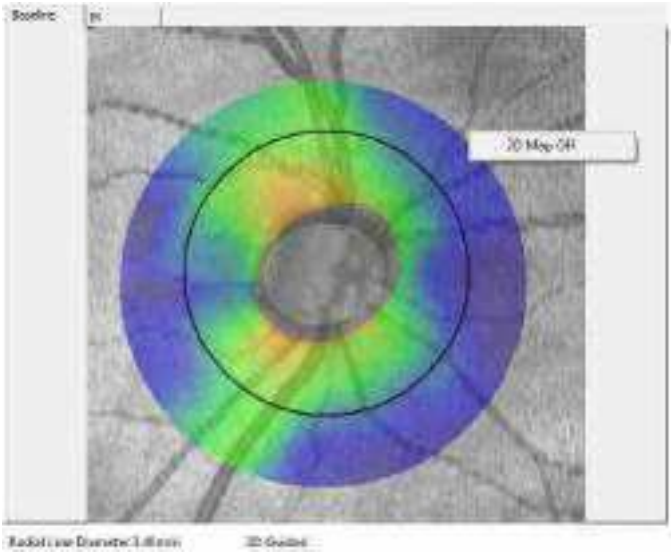


Figure 100 Baseline Image with RNFL Thickness Map Overlay

By default, the RNFL thickness map overlays the Baseline image at upper left. Right-click on the image and select **2D Map Off** to turn off the map overlay. Select the IR tab to display the IR video image with scan pattern lines overlaid.

5.6.8 ONH Change Analysis Report

The **Change Analysis** button is available on the ONH report when ONH scans have been taken on two or more visits. Click this button and the system displays the ONH Change Analysis report; when the patient record includes both ONH and GCC scans, the system displays the Nerve Fiber ONH/GCC Change Analysis Report (see Section 5.9). The system automatically selects up to six scans for the current patient eye. The system uses a 3D Disc scan as baseline for registration of ONH scans.

The Change Analysis report includes most elements of the ONH report side by side for each scan, and adds a plot of RNFL thickness versus age, and reports the resulting RNFL rate of (thickness) change per year, its 95% confidence interval (CI) in brackets, and its p-value.

5.6.9 ONH OU Report

The **OU Report** button is available when the ONH scan has been taken for both eyes. Click this button and the system displays the ONH OU report; when the patient record includes both ONH and GCC scans, the system displays the ONH/GCC OU Report (see section 5.10). OU reports are useful to assess symmetry between eyes.

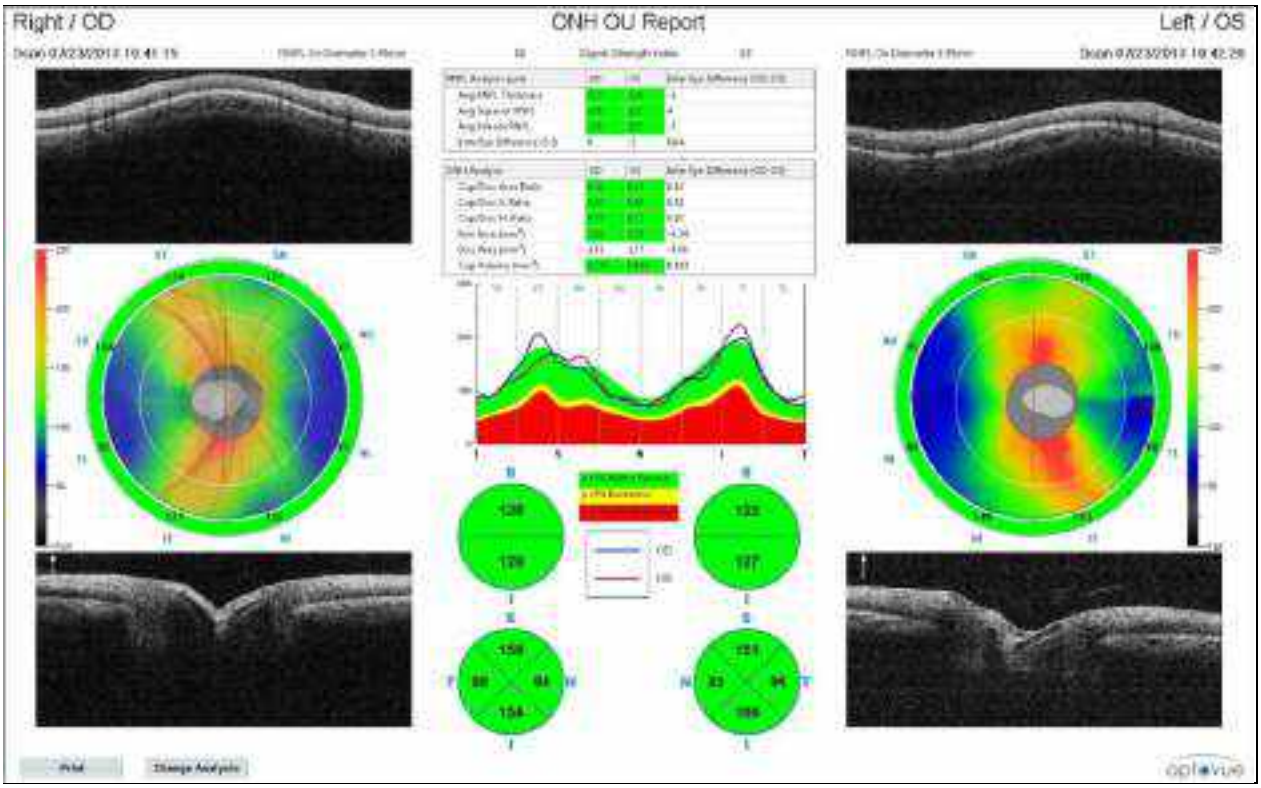


Figure 101 ONH OU Report

5.6.10 Defining the Baseline Optic Disc Margin

The system uses the optic disc margin to calculate measurements of the optic disc, cup and rim. To define the baseline optic disc margin used in the ONH report, the system automatically traces the disc margin using the SLO image from the 3D Disc scan (when it is available). This is called 3D Baseline mode. It is possible to use one of two alternative modes to define the baseline optic disc margin, **though Optovue does not recommend them; you should use an alternative mode only if you cannot capture a useful 3D Disc scan.** The three modes are:

- **3D Baseline mode** (default)**:** The system automatically traces the disc margin using the SLO image of the 3D Disc scan
- **Video Baseline mode:** The user draws the disc margin manually. Right-click and select **Draw Disc**.
- **No Baseline mode:** In this mode, the system does not calculate disc measurements and so reports all metrics as zero.

Caution: Optovue does NOT RECOMMEND using No Baseline mode, for several reasons:

Successful results require great skill to center the scan pattern on the optic disc.

No Baseline mode precludes scan registration between visits, and therefore precludes change analysis.

In this mode, the system does not calculate disc measurements and so reports all metrics as zero.

Modify RPE Anchor Points

RPE tips are relevant in ONH reports only. The system places anchor points on the RPE tips to define the disc and cup, and to center ONH scans on the optic nerve.

1. To verify end point placement on ONH reports, right-click on white space or on the RNFL thickness map and select **Modify RPE Anchor Points**.

2. Drag the yellow dots as desired to adjust placement of one set of RPE anchor points.

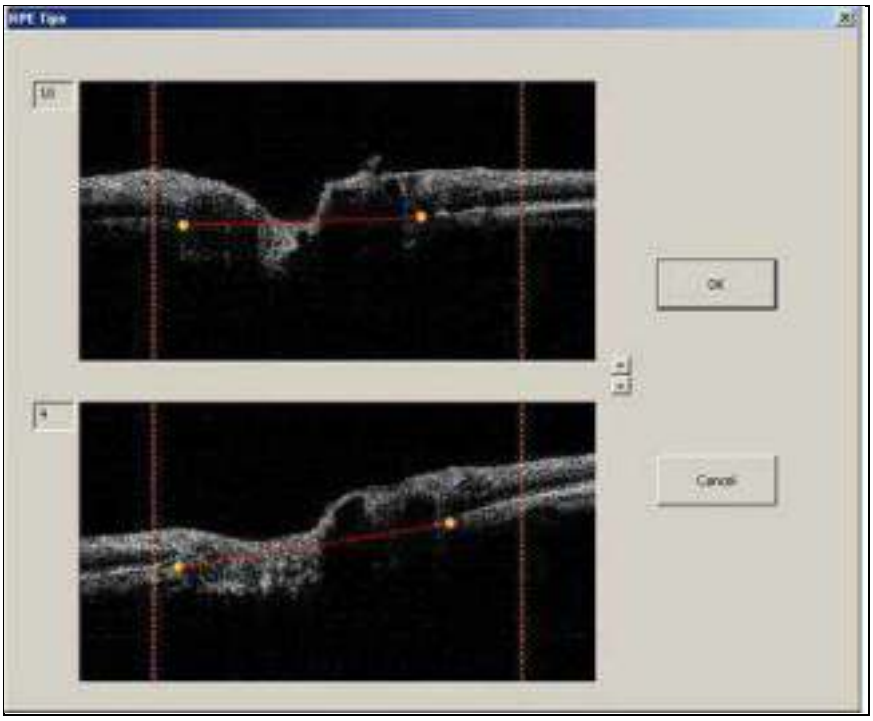


Figure 102 Verify RPE Tips

5.7 Assessing the GCC

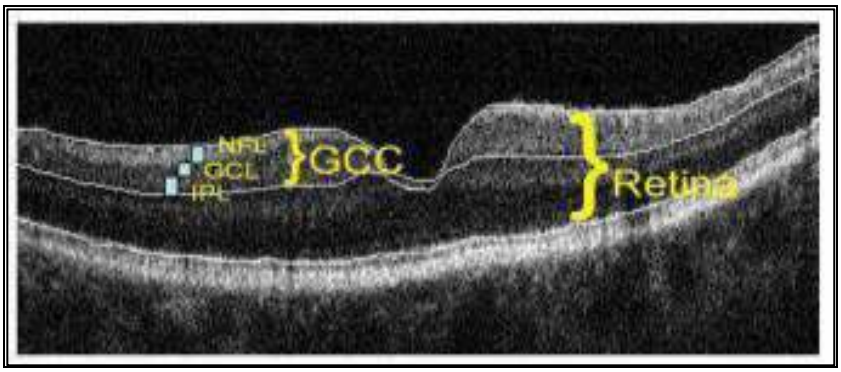


Figure 103 The GCC and Its Layers

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.

5.8 GCC Report

The GCC report provides image displays, charts, tables and interactive maps to enable qualitative and quantitative assessment of the GCC. Figure 104 and its legend below identify the components of a GCC report. The following subsections explain each component in order.

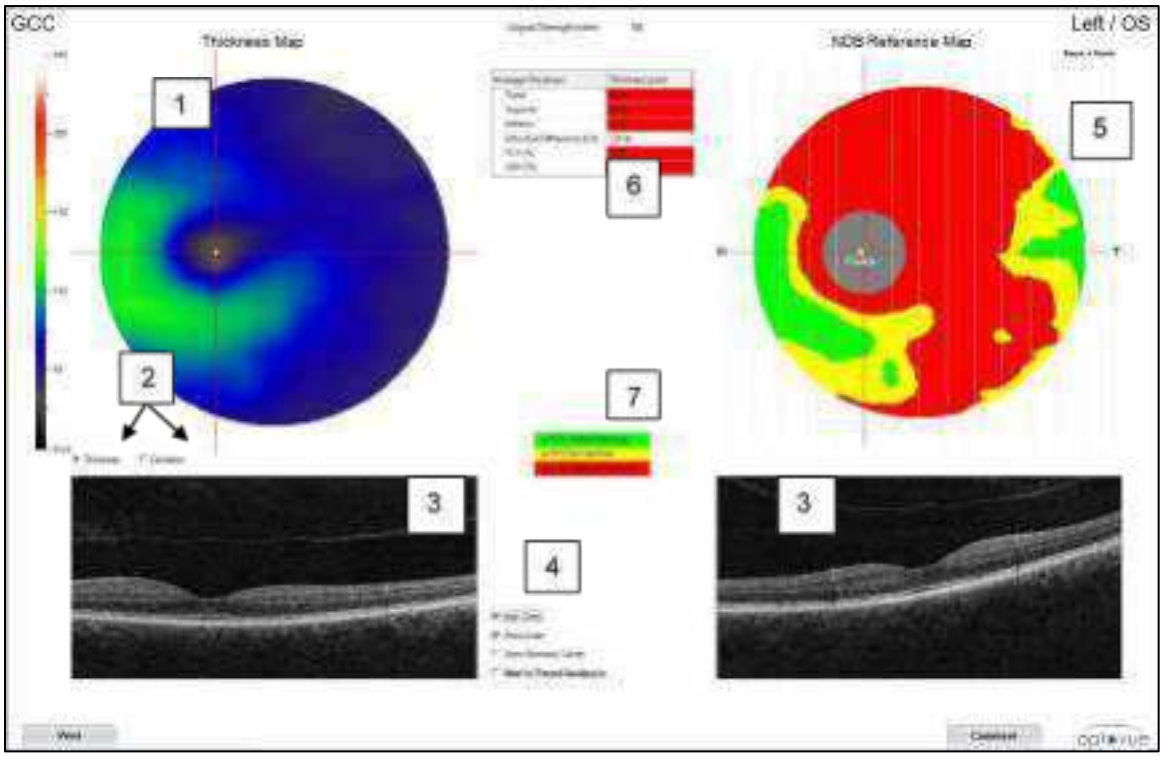


Figure 104 GCC Report Layout

GCC Report Components Legend:

1 Thickness Map

2 Thickness and Deviation radio buttons

3 B-scan display

4 Show Lines and Show Boundary Curves checkboxes

5 NDB Reference Map

6 Table of thickness and volume parameters

7 Normative database legend

5.8.1 Thickness Map or Deviation Map

At upper left appears a GCC Thickness Map by default. The Thickness Map is 6 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 uses a color scale to indicate percent deviation (-50% to +50%) from normal thickness. The color key next to the maps explains the values (in µm) associated with the colors. Warmer colors from yellow, orange and red to white represent greater values. Cooler colors from green to blue to black represent lesser values.

The GCC map for a normal eye shows a broad sweep of bright color around the fovea, indicating a GCC with healthy ganglion cells (healthy eye at left in Figure 105). (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 in Figure 105).

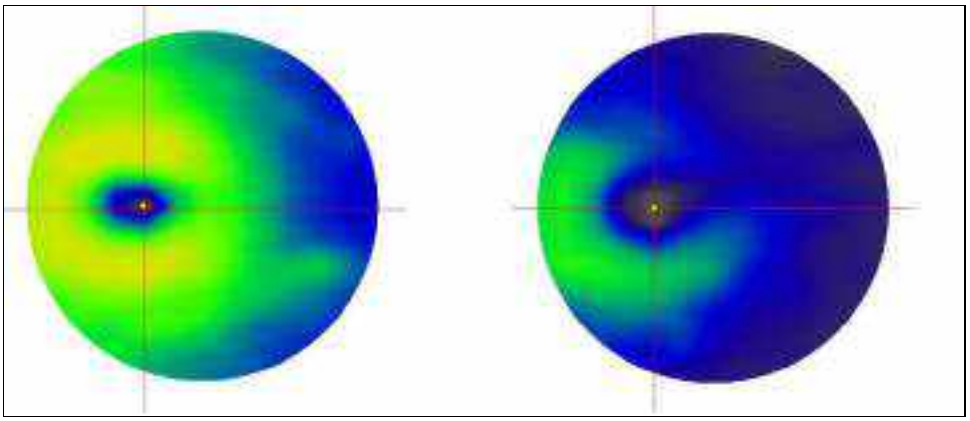


Figure 105 GCC Thickness Maps: Healthy Eye (Left), Glaucoma Eye (Right)

5.8.2 B-Scan Display

The red lines on the NDB Reference 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 NDB reference map. Select **Show Boundary Curves** to show the segmentation lines on the B-scans.

- When you click on the NDB Reference 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.

5.8.3 NDB Reference Map

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

5.8.4 Thickness and Volume Parameters Table

The table at lower right 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.

5.8.5 GCC Change Analysis

The **Change Analysis** button is available on the GCC report when GCC scans have been taken on three or more visits. Click this button and the system displays the GCC Change Analysis report; when the patient record includes both ONH and GCC scans, the system displays the Nerve Fiber ONH/GCC Change Analysis Report (see section 5.9). The system automatically selects up to six visits for the current patient eye.

The GCC Change Analysis report includes most elements of the GCC report side by side for each scan, and adds a plot of RNFL thickness versus age, and reports the resulting RNFL rate of (thickness) change.

5.9 Nerve Fiber ONH/GCC Change Analysis Report

When both ONH and GCC scans were acquired for an eye on three or more visits, the **Change Analysis** button on the ONH and GCC reports generates a Nerve Fiber ONH/GCC Change Analysis report. This report automatically displays ONH and GCC thickness maps (and data for up to six visits for the current patient eye).

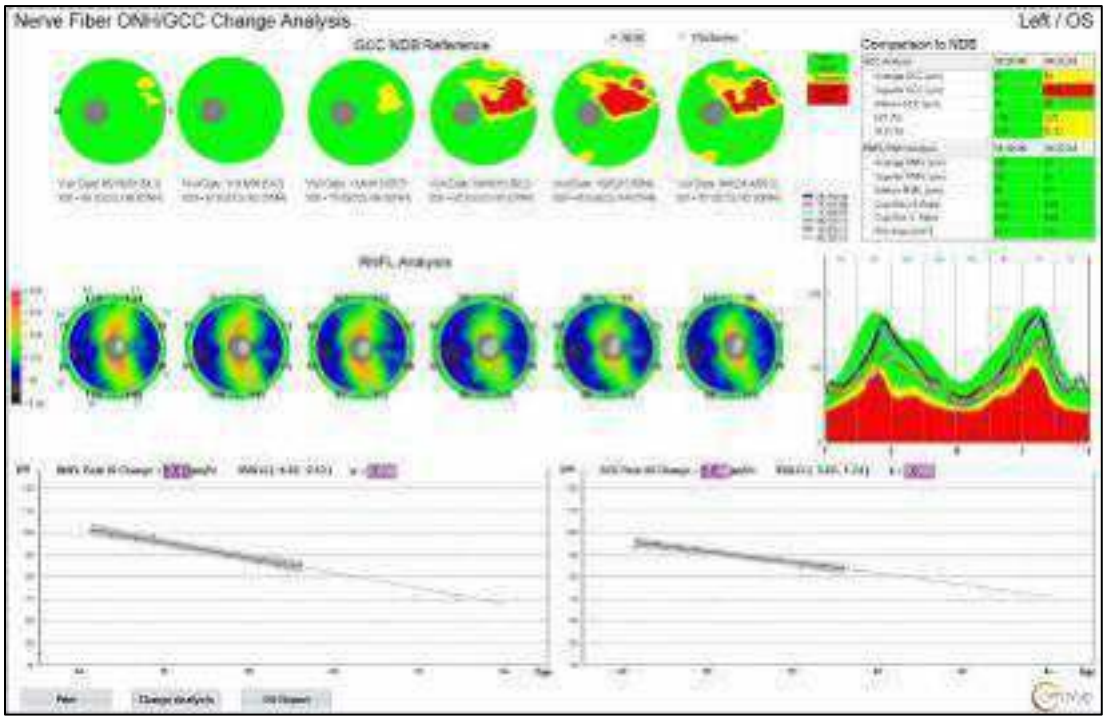


Figure 106 Nerve Fiber ONH/GCC Change Analysis Report

- **Thickness Maps:** At upper left, the report shows thickness maps for up to six GCC scans and six RNFL scans. The software automatically selects for display the earliest two visits and the latest two 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 first two visits should be reasonably consistent with each other and the last two visits should be reasonably consistent with each other, unless a confirmed condition exists to explain rapid change between two adjacent 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, the first two visits should be reasonably consistent with each other and the last two 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 NDB 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 normative database.

- **TSNIT Graph:** At middle right 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.

- **Rate of Change Graphs:** At bottom are graphs that plot RNFL thickness (left) and GCC thickness (right) versus age. Above each graph appears the estimated rate of change (in µm) per year, as well as the range of the 95% confidence interval in brackets, and its p-value. 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.

5.9.1 Interpreting Change Report

- For the estimated rate of thickness change, the report automatically includes thickness measurements from all visits. Including more data with a longer period of follow-up tends to increase the accuracy of the estimate. Optovue recommends that you delete poor quality ONH and GCC scans to exclude them from the analysis.

- The 95% Confidence Interval indicates the range of slope within which the true slope is, with 95% probability. The narrower the range, the more reliable the slope estimate. When the range includes zero, it means the estimated slope is not significantly different from zero statistically. Factors affecting the confidence interval include measurement variability, duration of follow-up, and number of tests performed.

- The p-value indicates whether the estimated slope is statistically different from zero. A smaller p-value means it is less likely the true slope is zero.

When the p-value is between 0.1 and 0.05, the slope and p-value appear with black text against a light purple background, indicating marginal statistical significance.

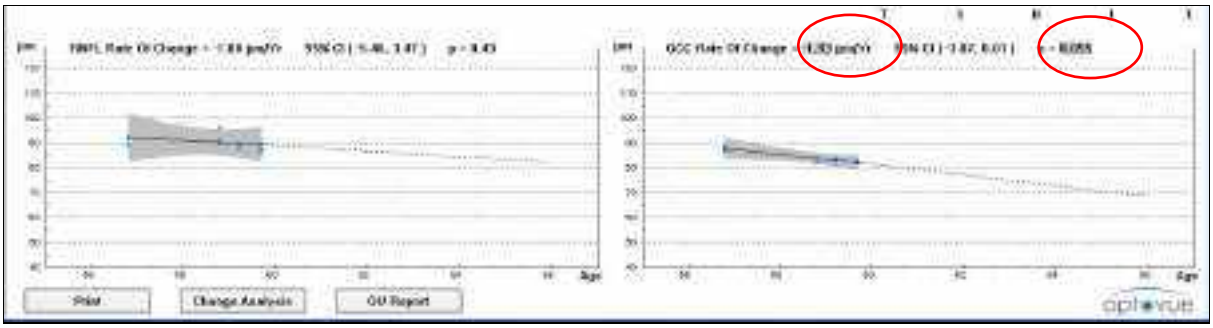


Figure 107 Marginally Significant Change

When the p-value is 0.05 or less, the slope and p-value appear with white text against a dark purple background, indicating statistical significance.

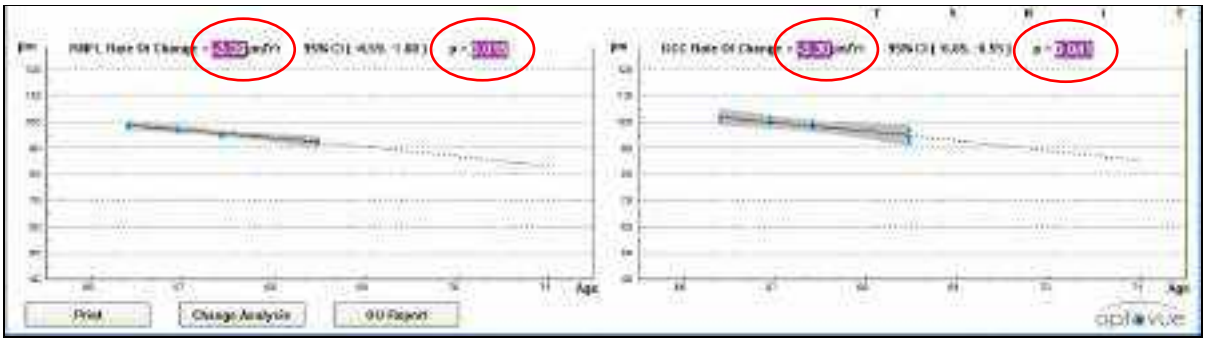


Figure 108 Statistically Significant Change

The rate of change, if estimated with high reliability, could be used to estimate RNFL and GCC thickness measurements in future years. For example, a rate of -3 µm/year could mean loss of 30 µm of thickness in 10 years if it continues at the same rate. For reference, based on the OCT normative database (cross-sectional data set), the estimated age-related loss of average RNFL and average GCC is less than 0.2 µm/year. It is likely that an individual's age-related loss may have a different rate from the average value. However, if a much higher rate of change is detected in an eye, further clinical evaluation may be necessary.

5.10 ONH/GCC OU Report

When the patient record includes both ONH and GCC scans for both eyes, clicking the **OU Report** button generates an ONH/GCC report.

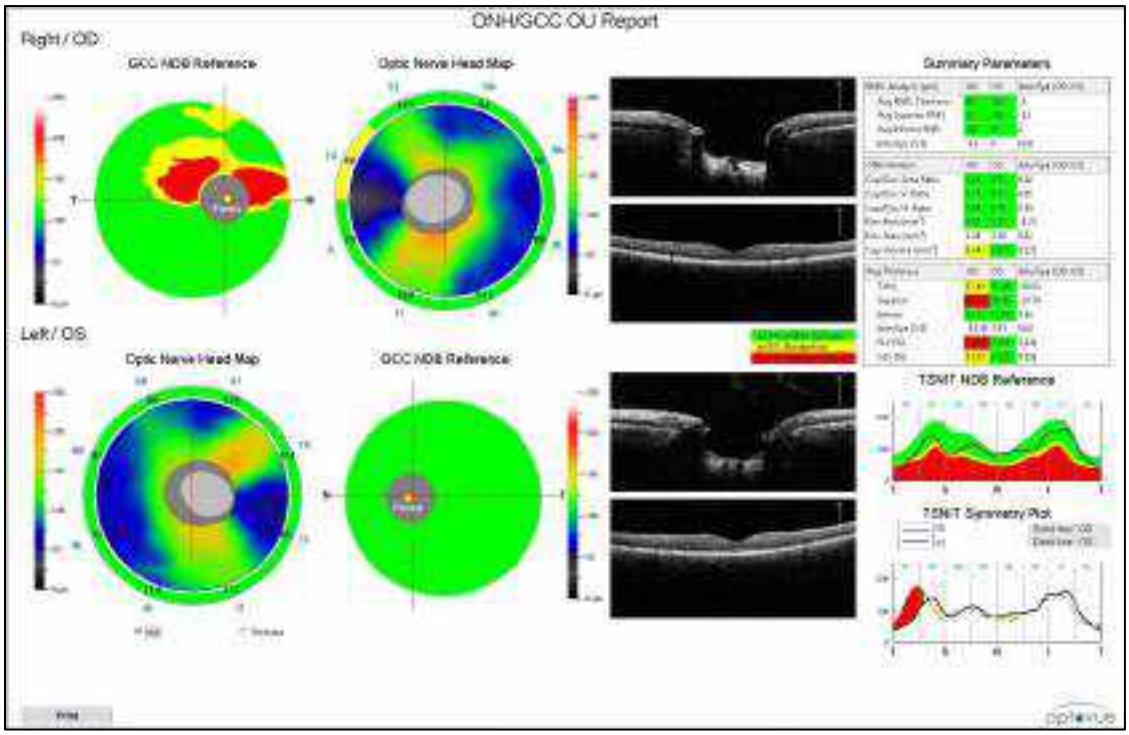


Figure 109 ONH/GCC OU Report

This report includes the elements of the ONH and GCC report for both eyes side by side, for analysis of symmetry. For details, see sections 5.6 ONH Report and 5.8 GCC Report.

ONH/GCC OU Portrait Report

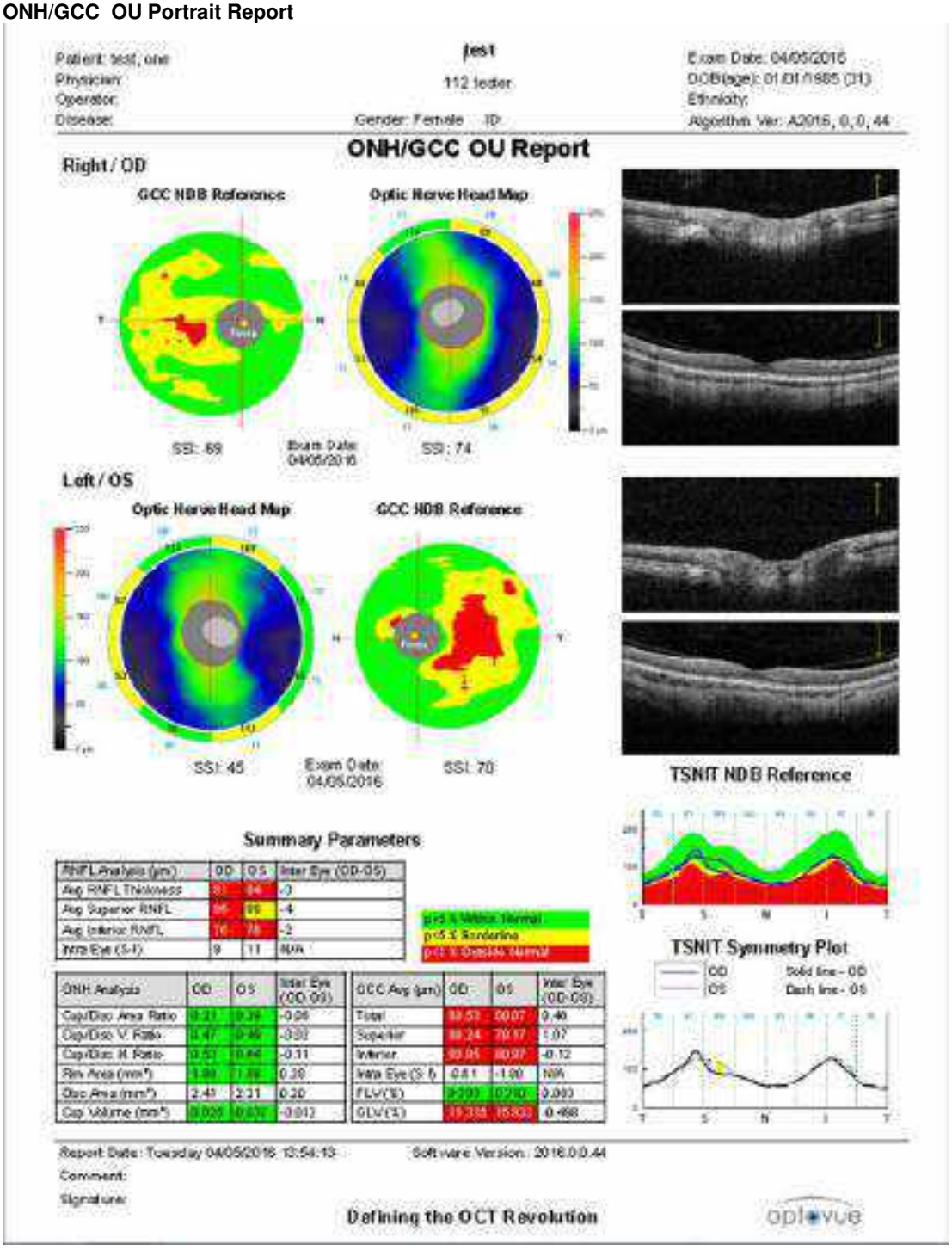


Figure 110 ONH/GCC OU Portrait Report

5.11 Avanti OU Wellness Report

The Avanti OU Wellness report is derived from the Avanti Wellness protocol. It is a combination of the values from the Retina scan and the GCC scan for both eyes. It displays 4 B scans with retina and GCC thickness compared to NDB.

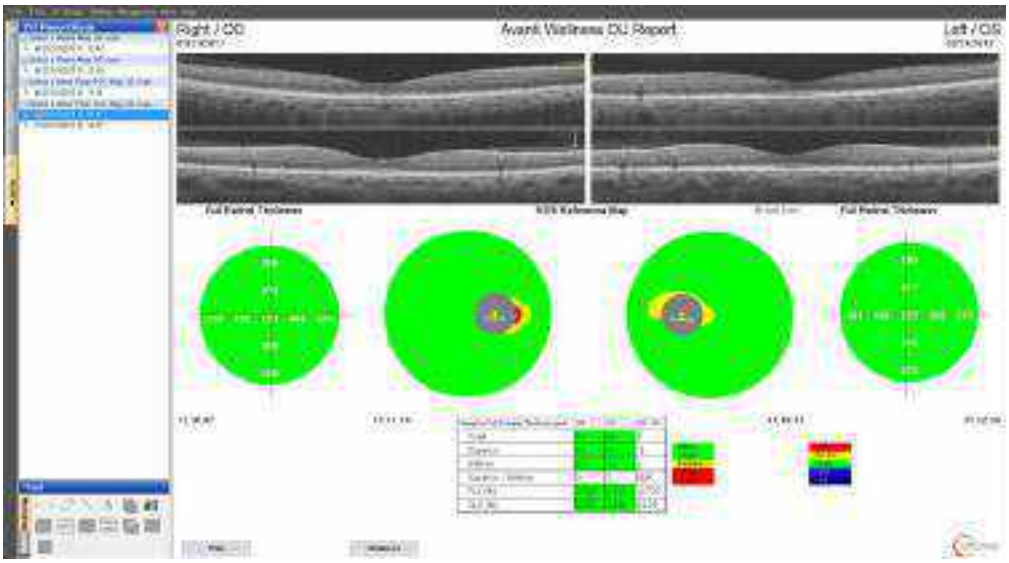


Figure 111 Wellness Report

If the AngioVue Retina scan has been taken in the same visit the Wellness report will also show the Retinal vessel density and FAZ for each eye.

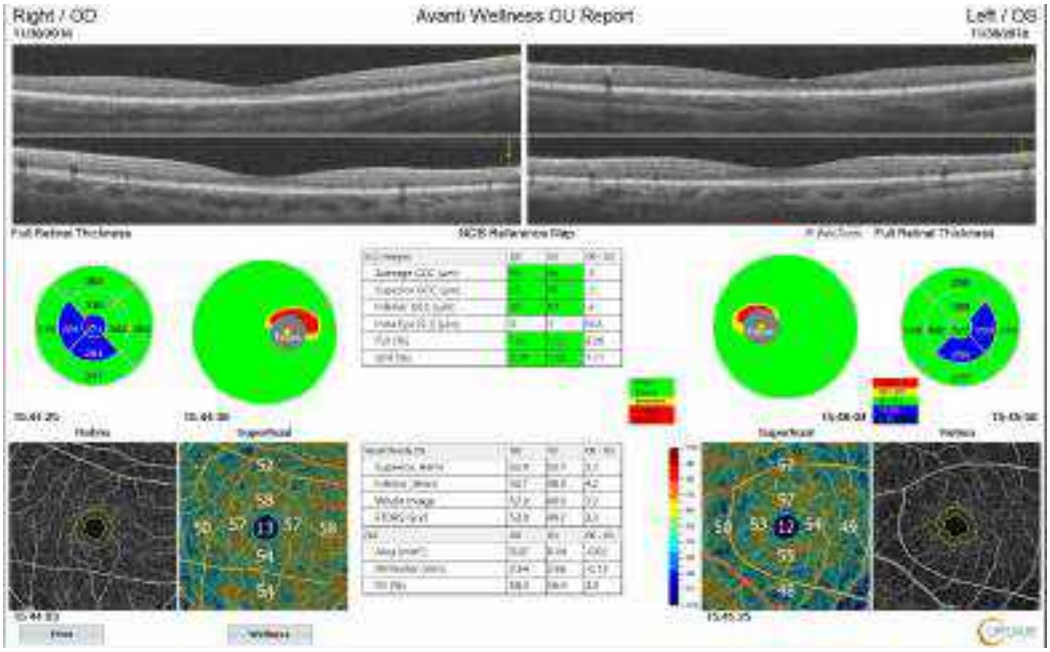


Figure 112 Wellness Report with vessel Density and FAZ

_End of section_____

6 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 (see section 6.2.5). 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.

Figure 113 Main Menu

6.1 File Menu

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

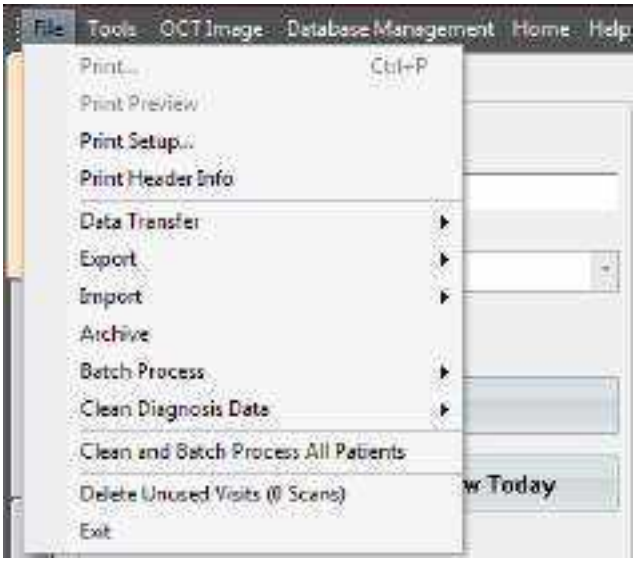


Figure 114 File Menu

6.1.1 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.

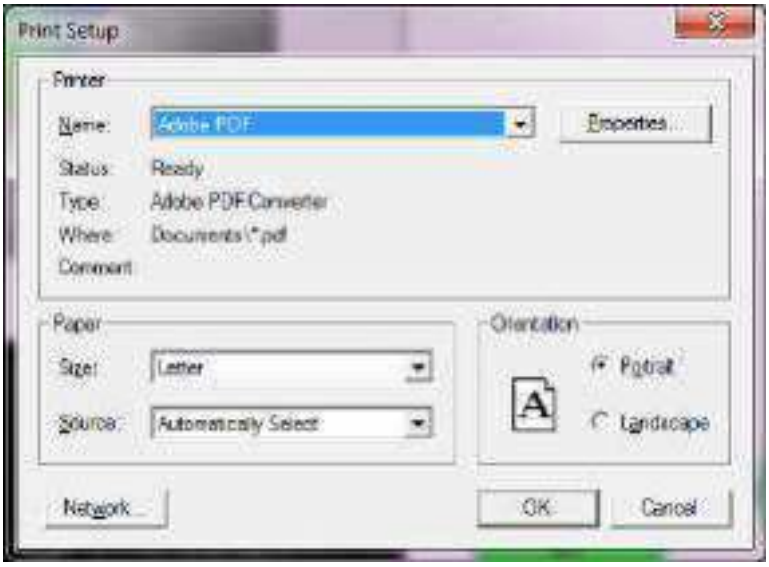


Figure 115 Print Setup Dialog

- **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**.

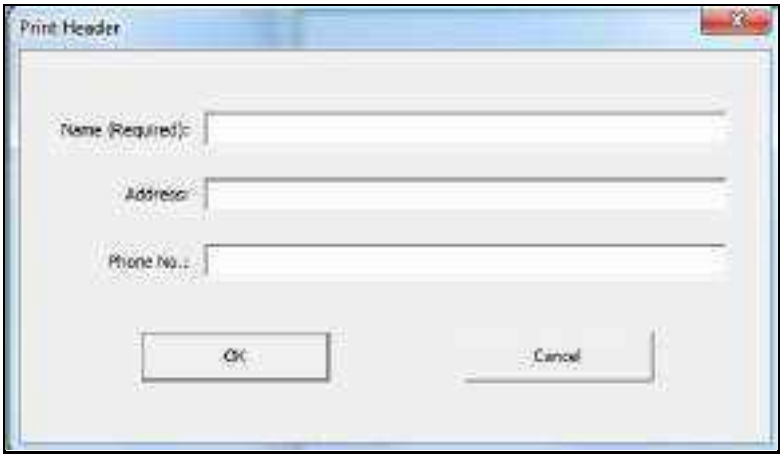
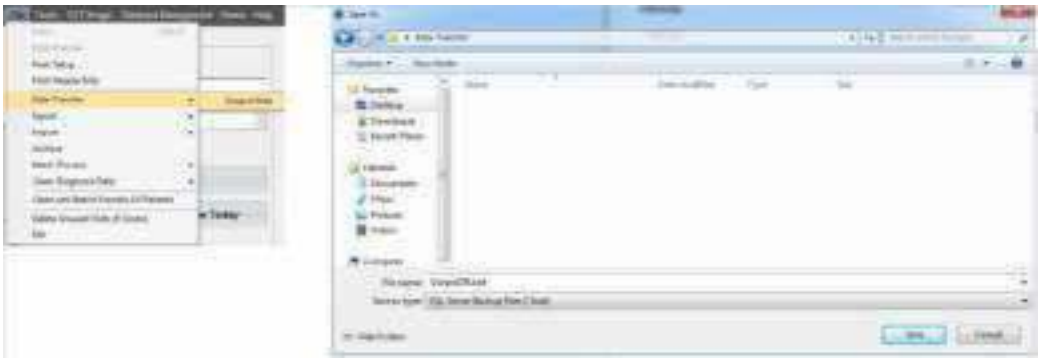


Figure 116 Print Header Dialog

6.1.2 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.

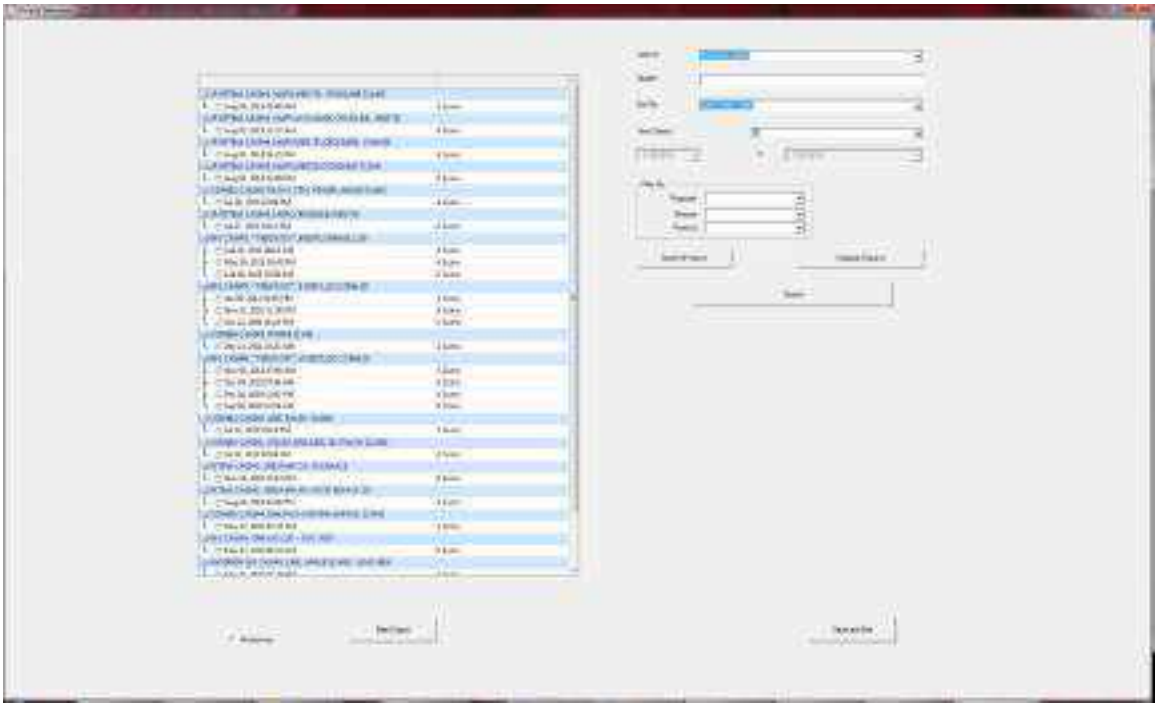
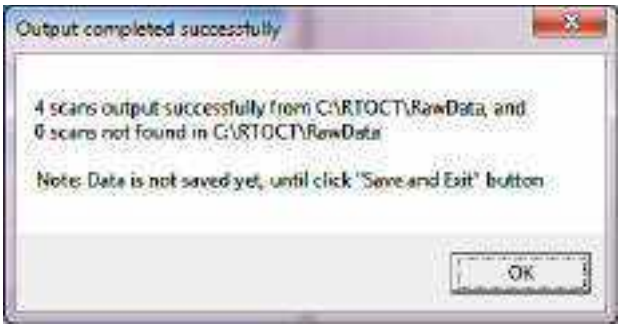


Figure 117 Output Selection Dialog

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.

6.1.3 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.

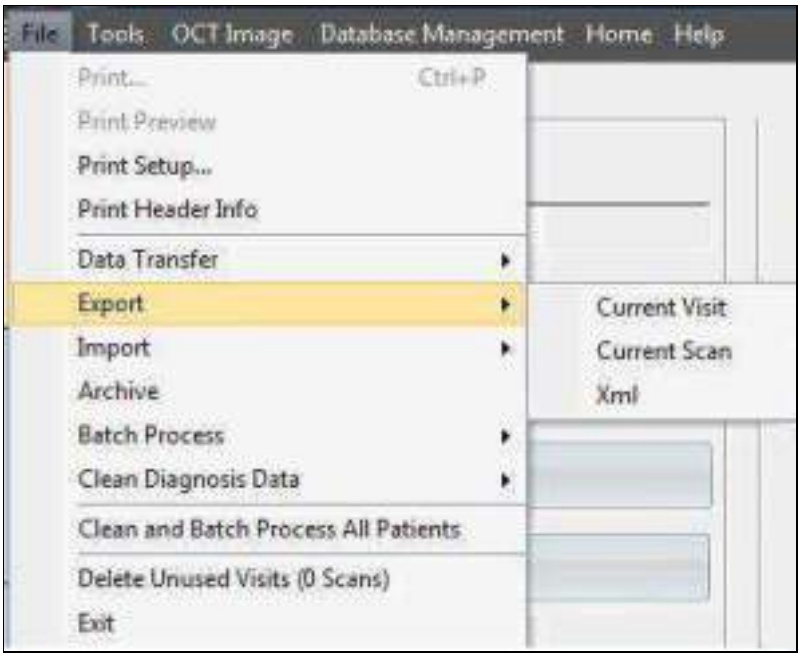


Figure 118 Export Options

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 118.

- 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**.

6.1.4 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 119 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.

6.1.5 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 (see section 6.2.5). 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.

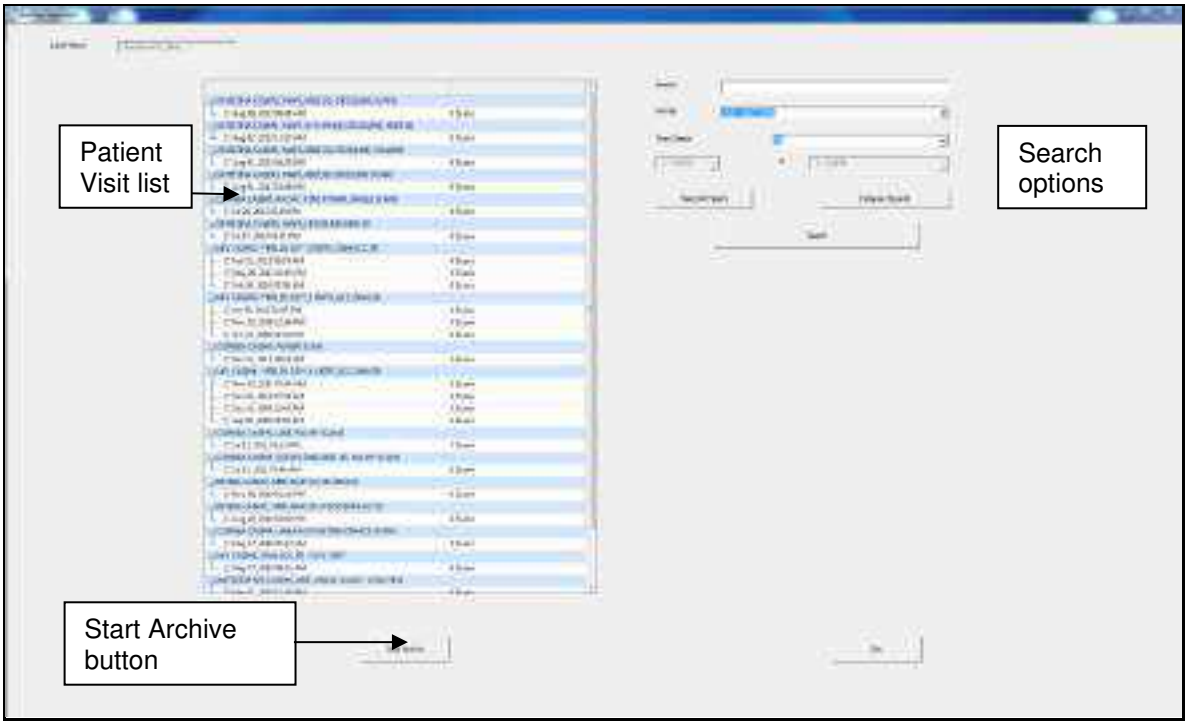


Figure 120 Archive Selection Dialog

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.

6.1.6 Data Backup

Data backup is an automatic background function performed during normal system operation. There are two hard drives supplied in all XR 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.

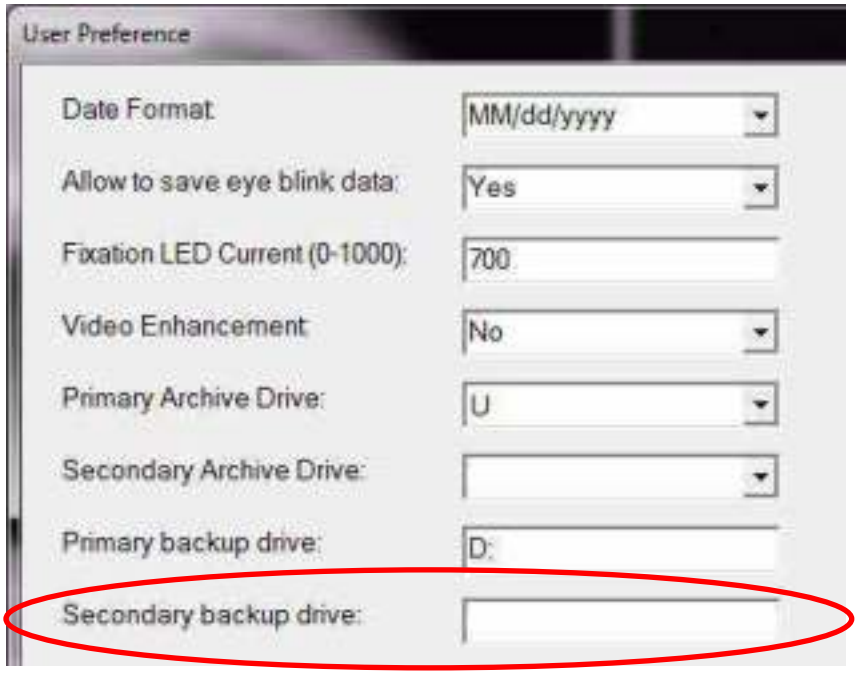


Figure 121 Secondary Backup Drive in User Preference Dialog

6.1.7 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.

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.

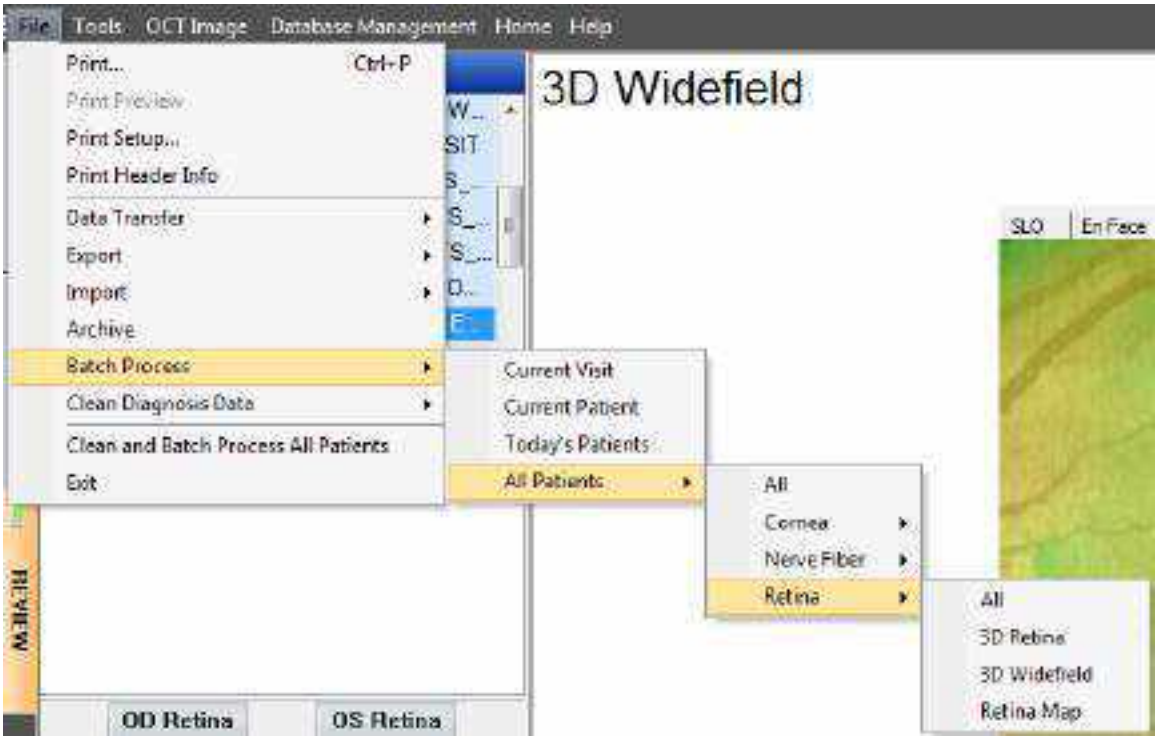


Figure 122 Batch Process Options

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.
- **Cornea:** Further select the option of your choice.
  - **All**: Processes all cornea scans
  - **3D Cornea**: Processes all 3D cornea scans
  - **Pachymetry**: Processes all pachymetry scans
- **Nerve Fiber:** Further select the option of your choice.
  - **All**: Processes all nerve fiber scans
  - **3D Disc**: Processes all 3D Disc scans
  - **GCC**: Processes all GCC scans
  - **ONH:** Processes all ONH scans
- **Retina:** Clicking this option displays these submenu options:
  - **All**: Processes all retina scans
  - **3D Retina**: Processes all 3D retina scans
  - **3D Widefield**: Processes all 3D Widefield scans
  - **Retina Map**: Processes all retina map scans

6.1.8 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 Map foveal position will reset** and previous manual fovea correction will be lost. Please verify fovea location and manually adjust if needed.

Clean Diagnosis Data Options

Select **Clean Diagnosis Data** from the **File** menu. This process has all the same submenu options as the batch process—see section 6.1.7 above for details.

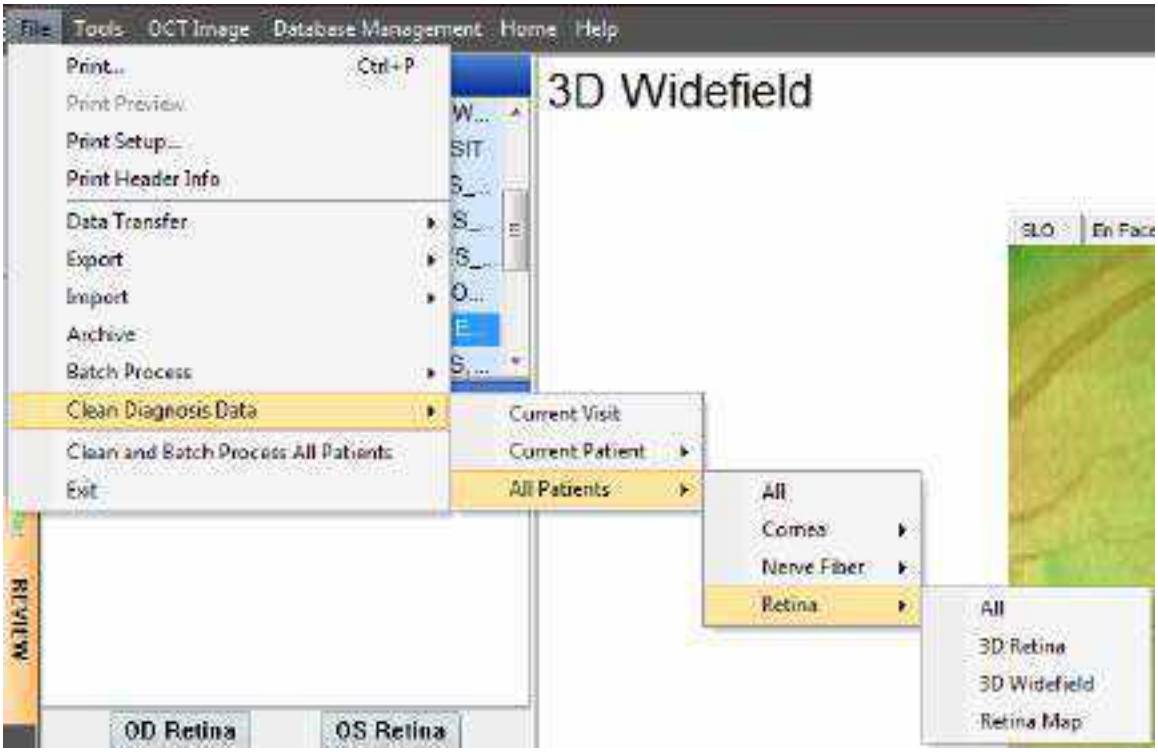


Figure 123 Clean Diagnosis Data Options

6.1.9 Clean and Batch Process All Patients

Note: Manual segmentation edits are preserved when you clean diagnosis data. **Retina 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.

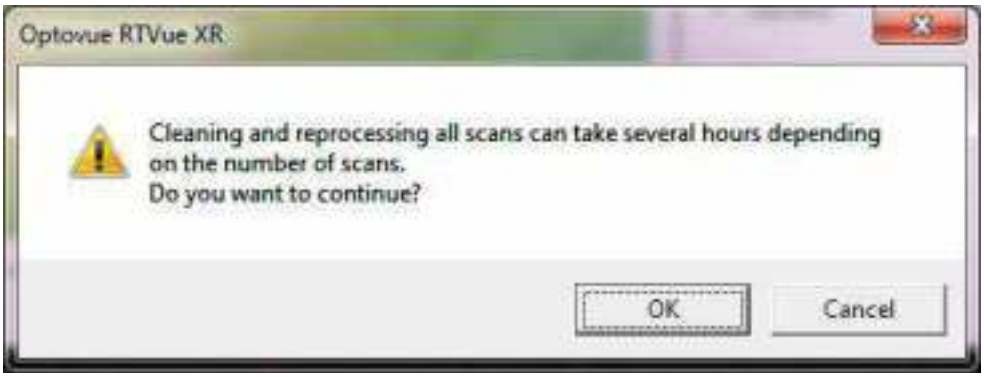


Figure 124 Confirm Cleaning and Reprocessing

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

6.1.10 Delete Unused Visits (0 Scans)

Select this option to delete visits that have no scans.

6.1.11 Exit

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

6.2 Tools Menu

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

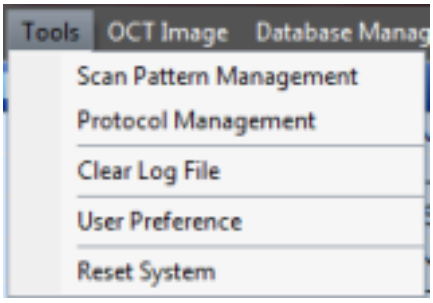


Figure 125 Tools Menu

6.2.1 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 126 Scan Pattern Management Dialog

Click **Done** to implement your selections.

6.2.2 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 (see section 6.4.1).

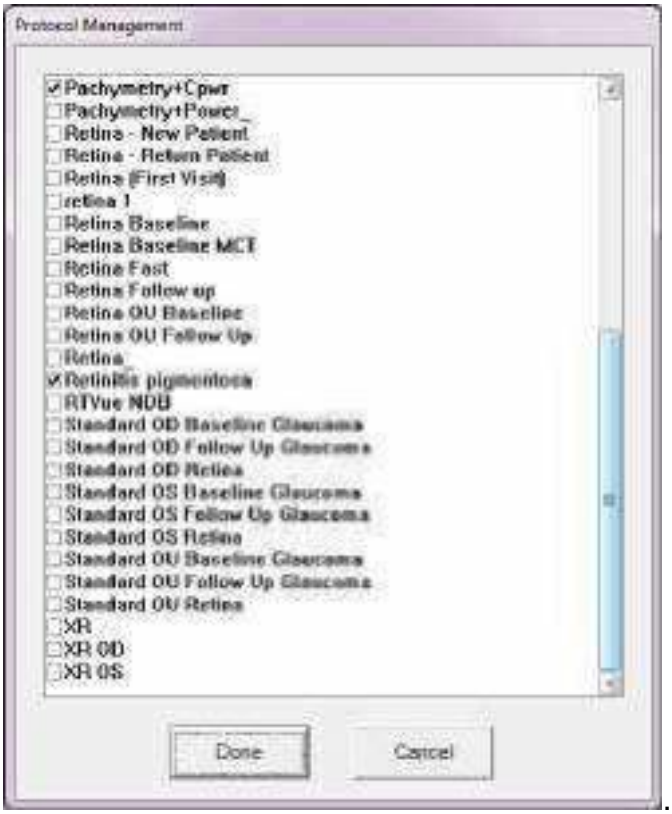


Figure 127 Protocol Management Menu

Click **Done** to implement your selections.

6.2.3 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.

6.2.4 Enter Calibration Password

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

6.2.5 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.

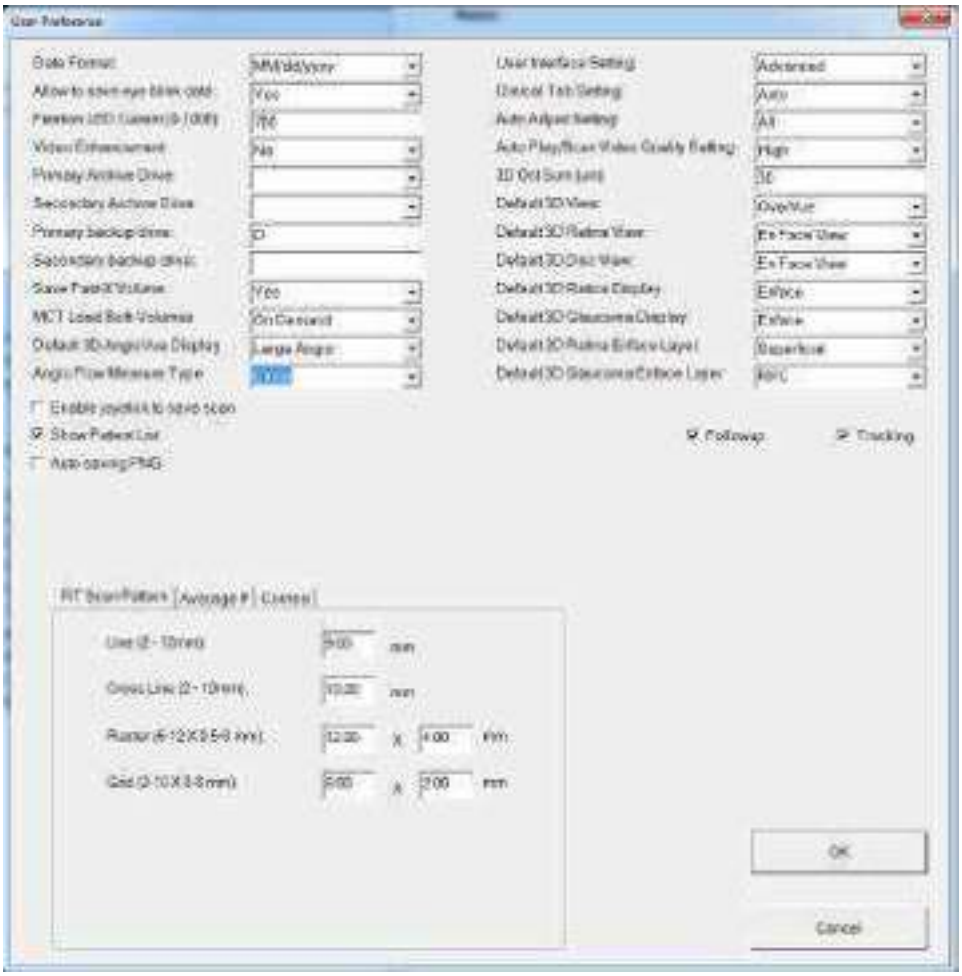


Figure 128 User Preference Dialog

- **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.

- **Fixation LED Current (0-1000)**: Adjusts the LED current—and thus the light intensity—of the fixation target (default is 700).
- **Video Enhancement**: Select **YES** to automatically apply contrast enhancement to the IR video reference image captured with the scan.
- **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.
- **User Interface Setting**: Select the user interface, **Clinical** or **Advanced**.
- **Clinical Tab Setting**: Select **Auto** or **Manual** to set the default layout of scan controls**.**
- **Auto Adjust Setting**: Defines the functions that occur when you press the **Auto Adjust** button or double-click in the live scan area.
- **Auto Play/Scan Video Quality Settings**: Sets the level of quality and the file size of the AVI file created by recording the animation of 3D scans, Range: Low = 25 MB (1 loop/cycle) and High = 125 MB (1 loop/cycle)
- **3D OCT Sum (µm):** Default starting value for en face presentation in 3D analysis display.
- **Default 3D View**: Sets the default report view for 3D Widefield scan and 3D Clinical scan (used at research sites only).
- **Default 3D Retina View**: Sets the default report view for 3D Retina scan.
- **Default 3D Disc View**: Sets the default report view for 3D Disc scan.

- **Default 3D Retina Display**: Sets the default type of image to display in the 3D Retina 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.
- **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.
- **Followup, Tracking and Show Patient list** checkboxes: Select to enable, deselect to disable the tracking, followup, 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.
- **RT Scan Pattern Tab:** Adjust the default length and width of the Line, Cross Line, Raster, and Grid scans.
- **Average # Tab**: Enter for each scan type the number of scans to be averaged.
- **Cornea Tab**: Adjust the default length of each cornea scan type.
- **OK** and **Cancel** buttons: Click the **OK** button to save user preference changes. Click **Cancel** to discard changes and close the dialog.

6.2.6 Reset System (Advanced GUI Only)

Contact Optovue technical support to perform this function.

6.3 OCT Image Menu

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

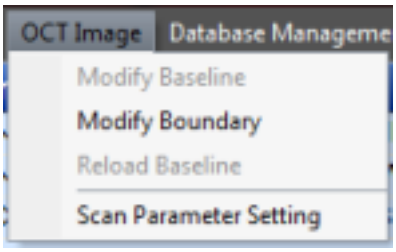


Figure 129 OCT Image Menu

6.3.1 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.

6.3.2 Modify Boundary

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

6.3.3 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.

6.3.4 Scan Parameter Setting

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

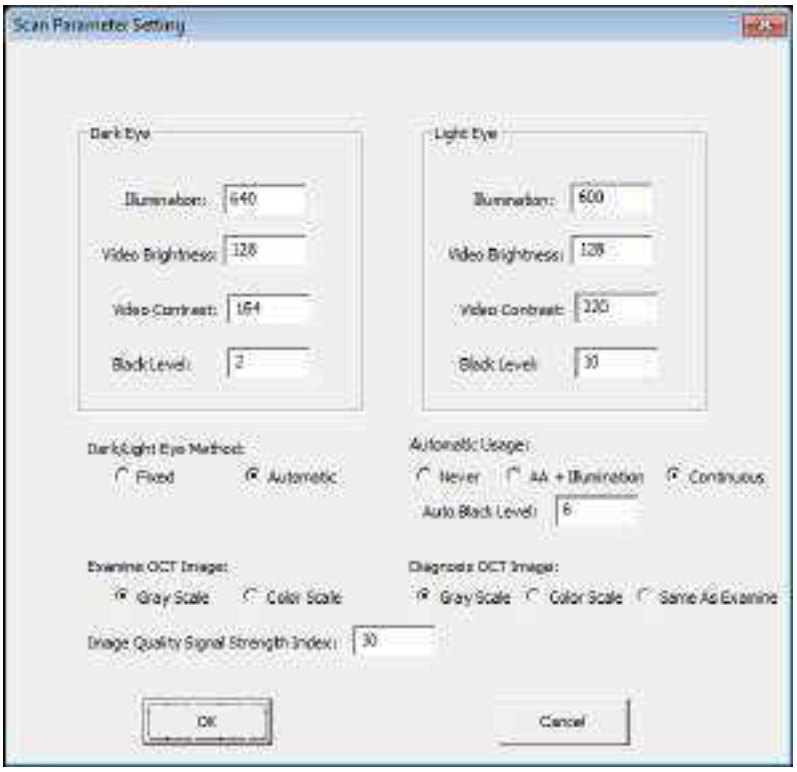


Figure 130 Scan Parameter Setting Dialog

- **Dark Eye** and **Light Eye** field groups: Specify the default IR video settings to be used when you click the **Dark Eye** or **Light Eye** button during scan acquisition. The parameters you can adjust are:
- **Illumination**
- **Video Brightness**
- **Video Contrast**
- **Black Level**
- **Dark/Light Eye Method:** Select **Fixed** or **Black Level** to specify the whether or not to adjust the above video settings based on the black level. **Fixed** means the dark and light eye settings do not adjust based on the black level. **Black Level** means they do adjust based on the black level.

- **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 Strength Index**: Sets the minimum SSI threshold below which the system will not show a green bar during scanning.

6.4 Database Management Menu

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

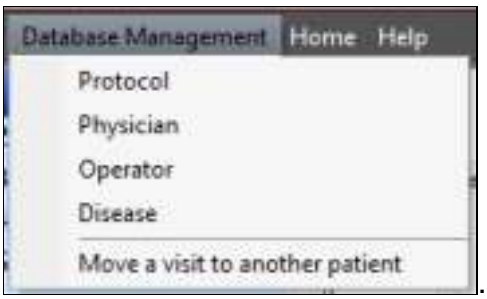


Figure 131 Database Management Menu

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.

6.4.1 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.

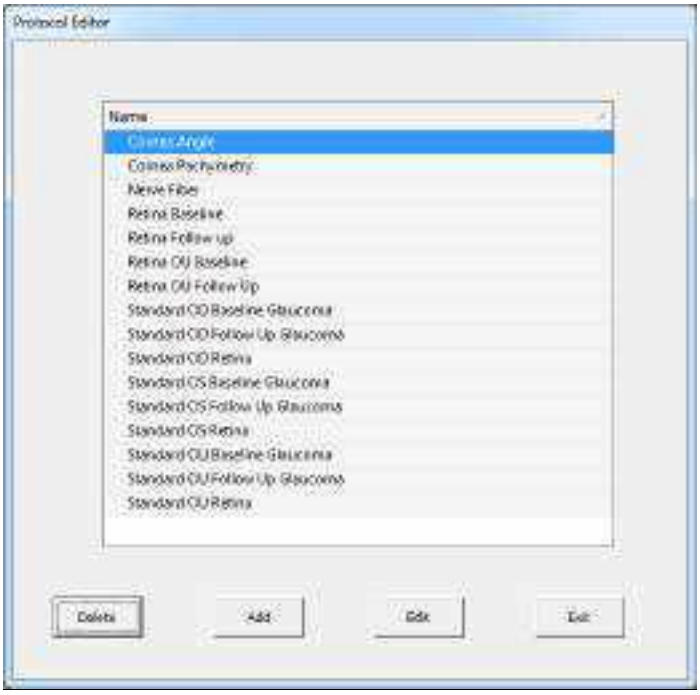


Figure 132 Protocol Editor Dialog

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 (see section 3.2.1).

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.

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.

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.

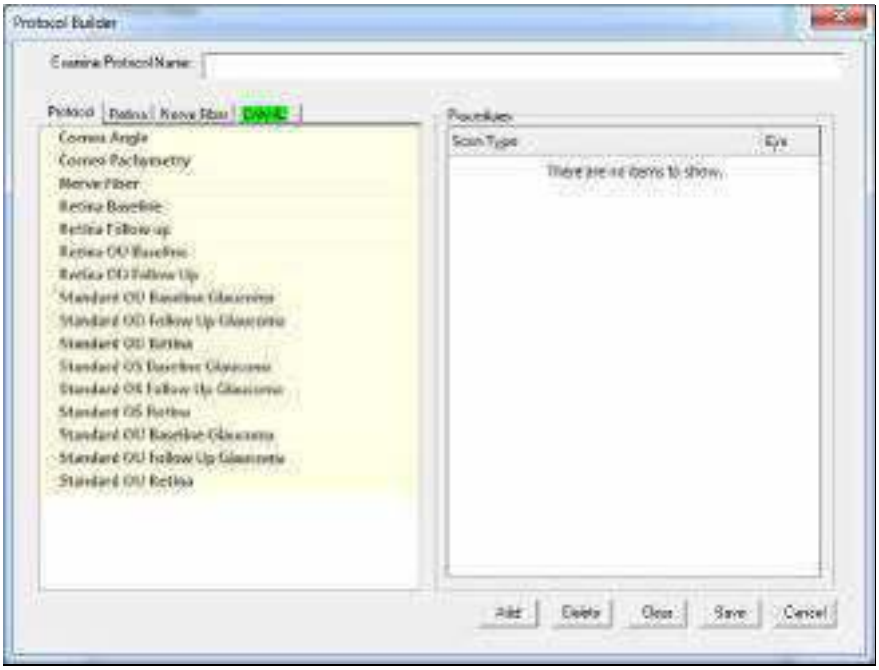


Figure 133 Protocol Builder Dialog

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.

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.

6.4.2 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.

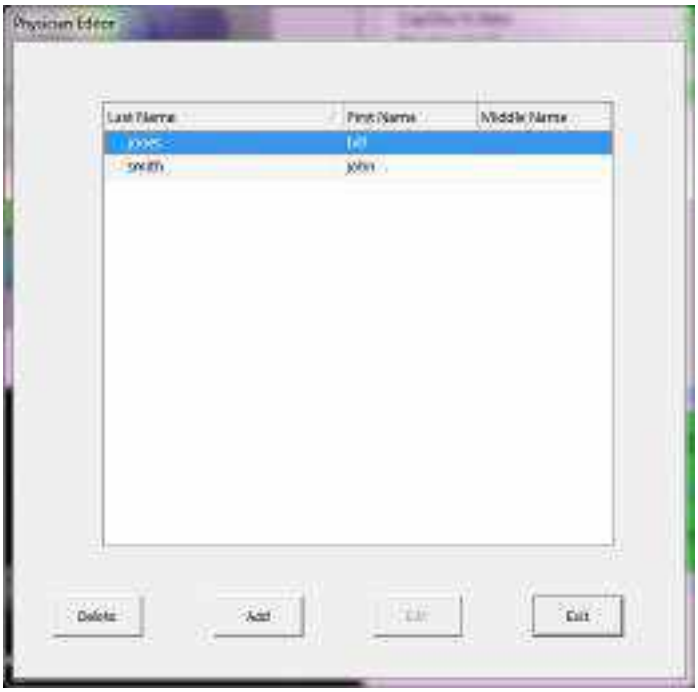


Figure 134 Physician Editor Dialog

- 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.

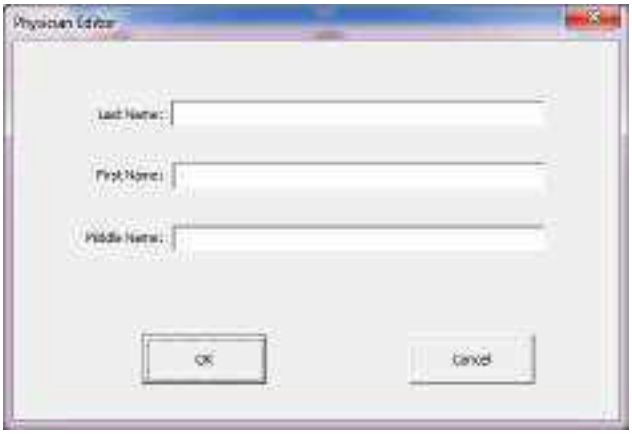


Figure 135 Dialog to Add or Edit Physician Name

- 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.

6.4.3 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.

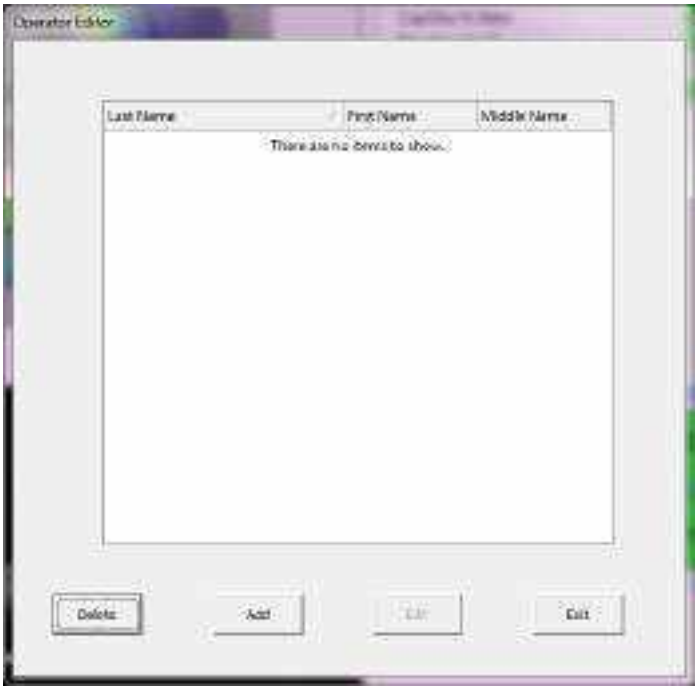


Figure 136 Operator Editor Dialog

- 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.

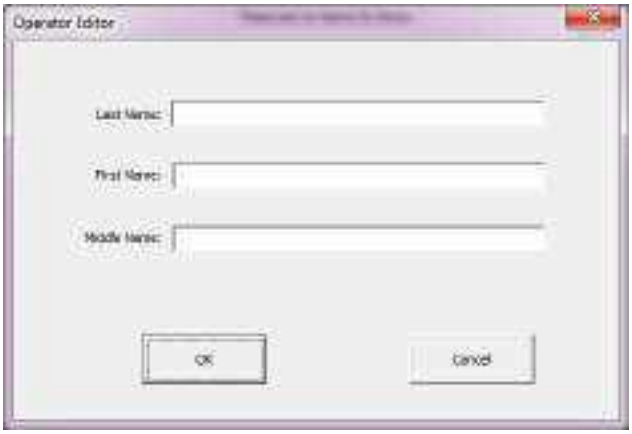


Figure 137 Dialog to Add or Edit Operator Name

- 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.

6.4.4 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.

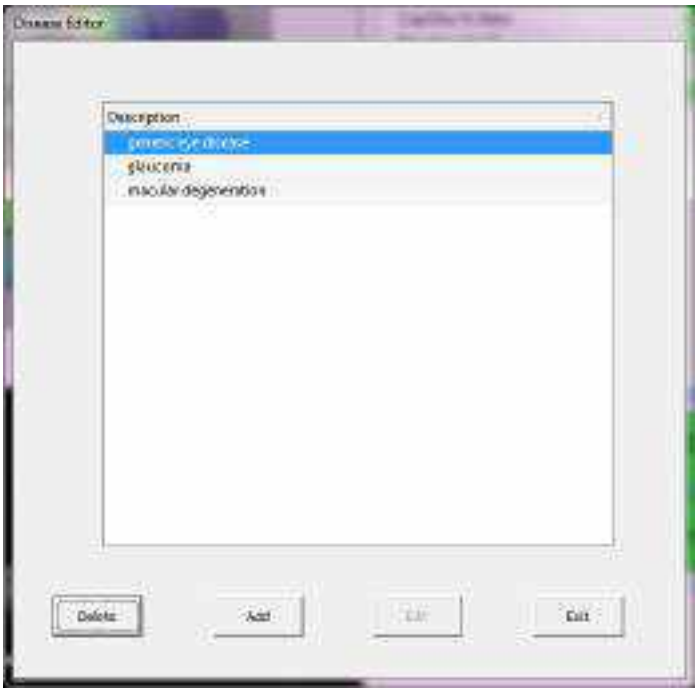


Figure 138 Disease Editor Dialog

- 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.

Figure 139 Dialog to Add or Edit Disease Name

- 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.

6.4.5 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. Follow the steps in section 2.4.

6.5 Home Menu

Select **Home** from the main menu to open the Avanti home screen.

6.6 Help Menu

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

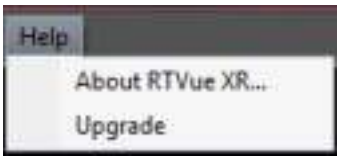


Figure 140 Help Menu

- **About RTVue XR:** Opens the About RTVue XR 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 141 About RTVue XR Dialog

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

_____End of section_____

7 System Maintenance

7.1 Routine Cleaning

7.1.1 Prevent Dust Accumulation

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

7.1.2 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.

7.1.3 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

7.2 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_____

8 Scan Pattern Specifications

Table 2 Scan Pattern Specifications

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
Line	Single line scan with speckle elimination process option	1024 X 1	Transverse: 2-12 mm (0.1 mm increment) Angle: 90 to 90° (1° increment)	12 mm, -5° (monitor screen left to right)
Cross Line	Single line scan with speckle elimination process option	1024 X 2	Transverse: 2-10 mm (0.1 mm increment) Angle: 90 to 90° (1° increment)	10 mm, 0° (monitor screen left to right)
Grid	5 vertical, 5 horizontal lines	1024 X 10	2-12 mm length 0-8 mm width adjustment	10 mm length x 2 mm width
Raster	21 parallel line scans; averaged	1024 X 21	6-12 mm length 1-8 mm zone	12 mm length x 7 mm width

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
Retina Map	13 horizontal lines with 6 mm scan length, 0.5 mm interval; + 8 horizontal lines with 4 mm scan length, 0.5 mm interval; 13 vertical lines with 6 mm scan length, 0.5 mm interval, + 8 vertical lines with 4 mm scan length, 0.5 mm interval, all centered at fovea	(803 x 26) + (535 x 16)	Fixed	6 mm x 6 mm outer region 4 mm x 4 mm inner region 250 µm interval in central 4 mm & 500 µm separation outside 1 mm (each side & top/bottom)
3D Retina	141 B-scans equally spaced to cover 7 mm x 7 mm volume. Center fixation	385 X 141	Fixed	7 mm X 7 mm
3D Widefield	320 B-scans equally spaced to cover 9 mm y-axis (slow transverse axis). Each B-scan has 320 A-scans covering 12 mm x-axis (fast transverse axis).	320 X 320	Fixed	12 mm X 9 mm

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
3D Widefield With MCT	Same as 3D Widefield but with Motion Correction Technology	(320 X 320) X 4	Fixed	12 mm X 9 mm
Radial Lines	18 radial lines	1024 X 18	2 – 12 mm length	12 mm
Enhanced HD Line	Single line scan	1024 X 1	Transverse: 2-12 mm (0.1 mm increment) Angle: 90 to 90°	12 mm, -5° (monitor screen left to right)
GCC	1 horizontal line with 7 mm scan length, followed by 15 vertical lines with 7 mm scan length & 0.5 mm interval, centered 1 mm temporal to fovea	933 x 1 horizontal Line, 933 x 15 vertical lines	Fixed	7 mm X 7 mm
ONH	12 radial line scans 3.4 mm length & 13 concentric rings (1.3-4.9 mm diameter) all centered on disc	965 x 3 ring (4.9, 4.6, 4.3), 775 x 3 ring (4.0, 3.7, 3.4), 587 x 3 (3.1, 2.8. 2.5), 425 x 4 ring (2.2, 1.9, 1.6, 1.3), 12 x 455/radial line	Fixed	4.9 mm diameter centered on optic disc
3D Disc	101 B-Scans equally spaced covering 6 mm y-axis, each with 513 A-scans covering 6 mm x-axis.	513 X 101	Transverse: 3-8 mm (1 mm increment) Width: 3-8 mm (1 mm increment)	6 mm X 6 mm

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
Pachymetry	8 radial lines with 6 mm scan length (1020 A-scans/line), 22.5° interval	1020 X 8	Fixed	6 mm radial scan
Pachymetry Wide	8 radial lines with 9 mm scan length (1020 A-scans/line), 22.5° interval	1020 X 8	Fixed	9 mm radial scan
Pachymetry + Corneal Power	8 radial scans with 6 mm scan length (1020 A-cans/line) & 22.5° interval. 5 repeated sets taken	(1020 x 8) x 5 per 5 repeated sets	Fixed	6 mm radial scan
Cornea Line	1020 A-scans/line with adjustable scan length	1020 X 1	Transverse: 2-8 mm (0.5 mm increment) Angle: 90 to 90° (1° increment)	8 mm, 0°
Cornea Cross Line	2 scan lines each orthogonal with adjustable scan length at 1020 A-scans/line	1020 X 2	Transverse: 2-8 mm (0.5 mm increment) Angle: 90 to 90° (1° increment)	8 mm, 0°
Angle	1 scan line with adjustable scan length (1020 A-scans/line)	1021 X 1	Transverse: 2-6 mm (0.5 mm increment) Angle: 90 to 90° (1° increment)	3 mm, 0°

Scan Pattern	Description	# A-Scan (Without Averaging)	Adjustability	Default
3D Cornea	101 horizontal scan lines, 2-8 mm scan length at 513 A-scans/line & 0-8 mm width	513 X 101	Transverse: 2-8 mm (1 mm increment) Angle: fixed at 0º	4 mm
3D Clinical	101 frames equally spaced B-scans over a square volume. Fixation at center	513 X 101	Transverse: 2-10 mm (0.1 mm increment) Angle: 0 to 180º Width:1-6 mm	6 mm X 6 mm

Notes: Cornea and anterior segment scans are available only with the purchase of the CAM (Cornea and Anterior Module) option.

_____End of section_____

9 Technical Specifications

9.1 Scanner

- OCT Image Acquisition Rate: 70,000 A-scans/second

Axial Resolution (in tissue):

- Depth: 5 µm

Scan Range:

- Depth: 2 mm to 3 mm
- Transverse: 2 mm to 12 mm
- Scan Beam central Wavelength: λ = 840±10 nm
- Exposure Power at pupil: less than or equal to 750 µW

9.2 Fundus Imager

- FOV: 32º (H) x 22º (V)
- Monochrome CCD Camera: WVGA 1/3 in. CCD Format
- NIR Illumination: 735 nm LED

9.3 Patient Interface

- Working Distance: 22 mm
- Motorized Focus Range: -15D to +12D
- Internal Fixation: Center, ±3.5° (Horizontal), and ±18° (Horizontal)
- Motorized Chin-Rest adjustable range: 65 mm
- Joystick controlled X-Y-Z adjustment: X-100 mm, Y-85 mm, Z-25 mm
- Lock mechanism: Electro-magnetic activated

9.4 Computer

- CPU: 3.3 GHz six-core

- Hard Disc: 2 TB
- Back up Hard Disc: 2 TB
- Archive: USB or Network Drive
- RAM: 16 GB
- DAQ: Camera link frame grabber

9.5 Display Unit

- 21.5 inch Flat Panel LCD Monitor

9.6 Power Table

- Power Input: 110 VAC and 230 VAC
- Current: 1.8 A
- Frequency: 50/60 Hz
- Power Rating: 160 W
- Maximum Force: 2500 N
- Motorized adjustment range: 200 mm
- Model: RTVue XR-100-1: 110 VAC
- Model: RTVue XR-100-2: 230 VAC

9.7 Alternate Power & Isolation Box

- Power Input: 110-240 VAC
- Current: 1.8 A
- Frequency: 50/60 Hz
- Auto resettable thermal switch on primary + 2 circuit breaker on input side

9.8 Circuit Breaker and Fuse

- Thermal circuit breaker (main power entry)

- Rating: 10 A, 125-250 VAC
- Dielectric Strength: 2500 VAC/1 minutes
- Operating Temperature: –10 °C to 60 °C
- 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.

9.9 Compliance

- General Medical EN 60601-1
- Medical System EN 60601-1-1
- EMC of Medical System EN 60601-1-2
- ITE (Computer) EN 60950

9.10 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.

9.11 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

9.11.1 Additional Technical Specifications

- Electrical Supply: Class 1
- Installation Category: II
- Pollution degree: 2

9.12 Cybersecurity Information

9.12.1 Objective

The purpose of this section is to summarize the cybersecurity controls for the Avanti system with embedded Windows 10 operating system.

9.12.2 System Overview

The Avanti 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

9.12.3 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.

9.13 Cybersecurity Functions

9.13.1 Limit Access to Trusted Users Only

Authentication of Users

- Avanti 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.

9.13.2 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.

9.13.3 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 Avanti 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 Avanti 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 Avanti 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.

9.13.4 Other implemented mechanisms

Institutional IT Infrastructure

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

Stand Alone Mode

- The Avanti 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 Avanti 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_____

10 AngioVue® Software

10.1 Introduction

AngioVue is a licensed software upgrade for the visualization of vascular structures of the retina and choroid. Once loaded and licensed on the RTVue XR Avanti System, the AngioVue scan patterns and analysis functions are enabled.

10.1.1 General

Optovue, Inc. has developed and tested AngioVue software and the RTVue XR Avanti System in accordance with Optovue, Inc. safety standards, as well as national and international regulatory guidelines and all applicable safety standards to ensure a high degree of instrument safety. Please observe all labeling related to safety, including information 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 chapter contains complete safety and use information for AngioVue Software on the RTVue XR Avanti System. Therefore, this chapter only addresses acquisition and review of AngioVue scans, which are a subset of the scans available with the Avanti System.

10.1.2 Scan Pattern Specifications

Scan Pattern	Description	# A-Scan (Without Averaging)	Default
Angio Retina	304 B-scans equally spaced on X-axis and on Y-axis. Each B-scan has 304 A-scans. 640 pixels in Z-axis	304 X 304	3 X 3 mm 8 X 8 mm (no quantitative analysis)
HD Angio Retina	400 B-scans equally spaced on X-axis and on Y-axis. Each B-scan has 400 A-scans. 640 pixels in Z-axis	400 X 400	6 X 6 mm
HD Angio Disc	400 B-scans equally spaced on X-axis and on Y-axis. Each B-scan has 400 A-scans. 640 pixels in Z-axis	400 X 400	4.5 X 4.5 mm 6 X 6 mm (no quantitative analysis)

Table 3 Scan Pattern Specifications

10.2 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 6 for information regarding the main menu.

10.3 AngioVue Scan Acquisition and Review

Note: AngioVue software is available as part of AngioVue Comprehensive or Essential, as an upgrade to the RTVue XR Avanti System or as part of the Avanti Retina system.

AngioVue Software creates a 3D data set that combines the results of multiple repeated B-scans. Using a motion contrast algorithm, AngioVue Software can aid in the visualization of vascular structures of the retina and choroid.

We recommend that you read the entire RTVue XR Avanti System User Manual and this AngioVue Software User chapter before using the system.

10.3.1 Acquiring AngioVue Scans

The AngioVue scans comprise two back to back, 3D scans, each with aiming, capture and quality review phases in either X (Fx) or Y (Fy) orientation. AngioVue Software combines the Fx and Fy scans and saves them as one MCT-corrected AngioVue scan.

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 germicide using a clean disposable cloth.

Use the following procedure to acquire AngioVue scans. Start from the PATIENT window.

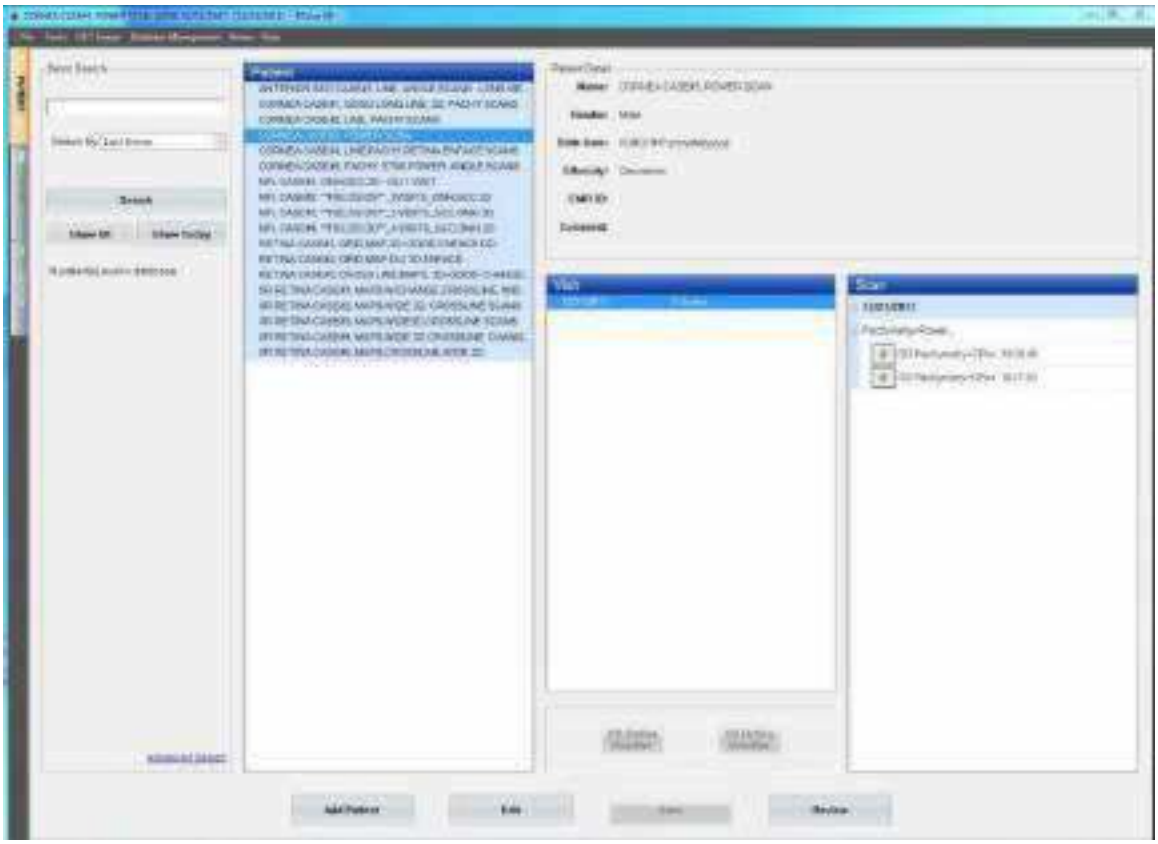


Figure 142 Select or Add Patient

4. 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 window.

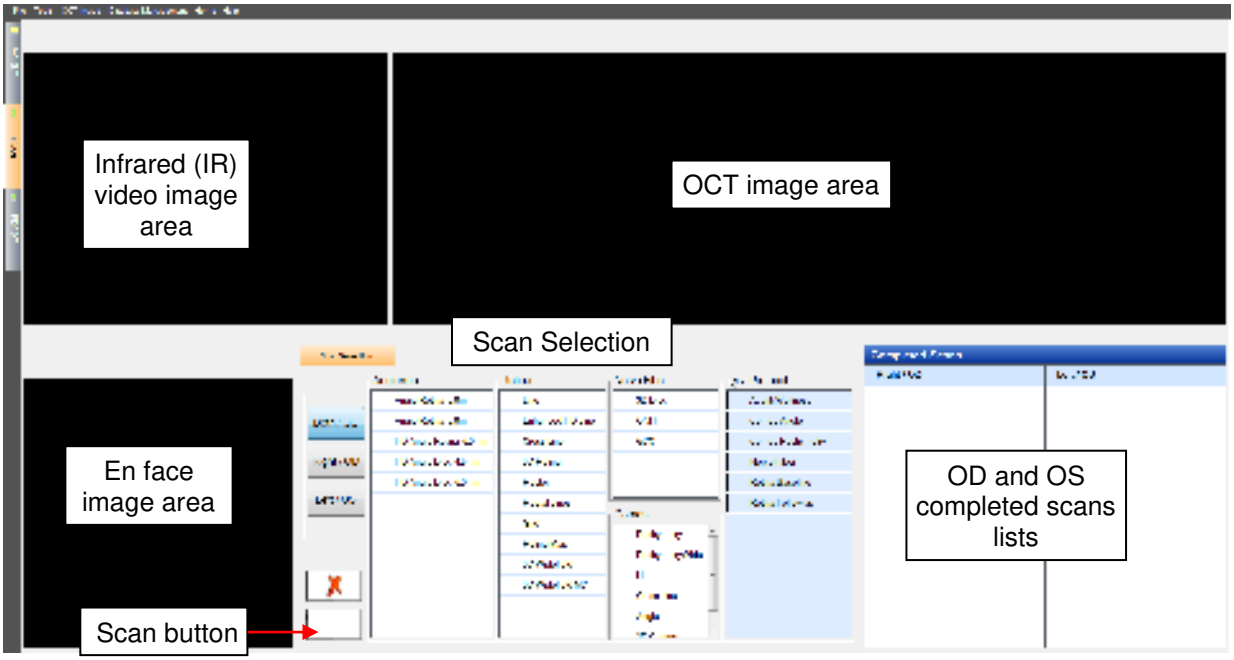


Figure 143 SCAN Window AngioVue Comprehensive

5. In the SCAN window, select the patient eye to be scanned. **Both** / **OU** is selected by default. To change, click the **Right** / **OD** or **Left** / **OS** button.

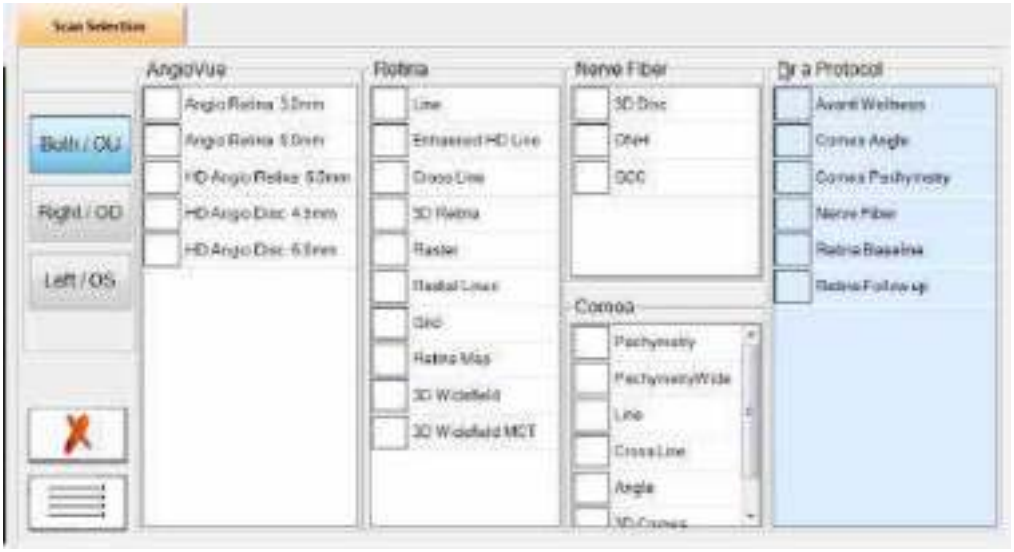


Figure 144 Scan Selection Options AngioVue Comprehensive

6. Select the desired scan type from the AngioVue, Retina, Nerve Fiber, or Cornea lists, or select a scan protocol from the Protocol list. You can select multiple scans to do the selected scans in succession. When you finish your selections, click the Scan button or joystick to begin scanning.

- 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.

  When you start scanning, the Scan Selection options are replaced by scan adjustment options on the **Auto** tab (default) or **Manual** tab. (The available parameters and their ranges depend on the scan type.)

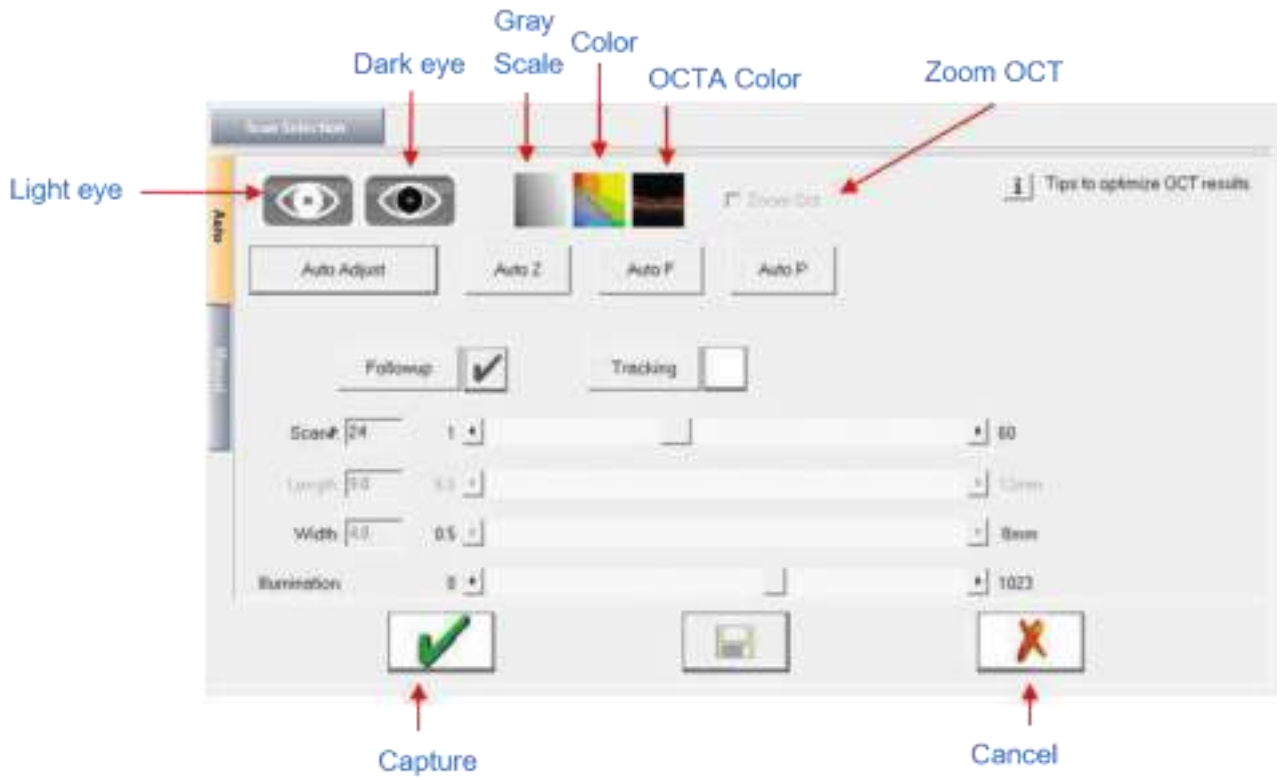


Figure 145 Scan Adjustment Options (Auto Tab)

To customize scan parameters, select the MANUAL tab.

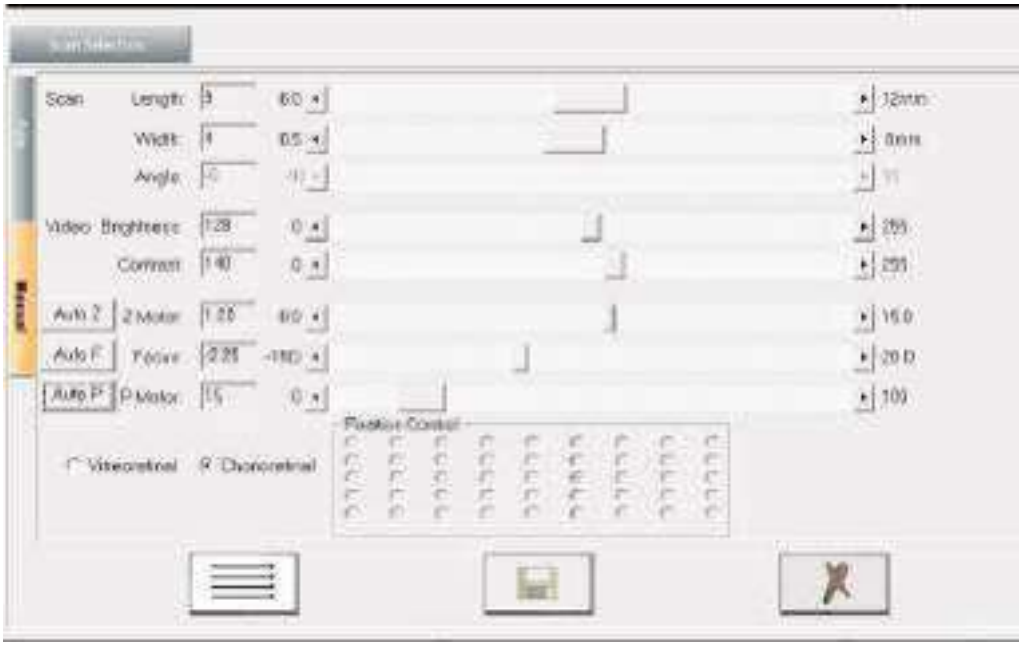


Figure 146 Manual Tab: Customize Scan

7. Position the patient correctly as follows:

- 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 the fixation target, a blue dot in the red field.

8. Center the video image on the pupil and move the scan head towards the patient, controlling it so that the video image passes through the pupil. Carefully advance until the fundus comes into view (for Retina and Nerve Fiber scans). The figure below shows the progression of views as you move the scan head forward.

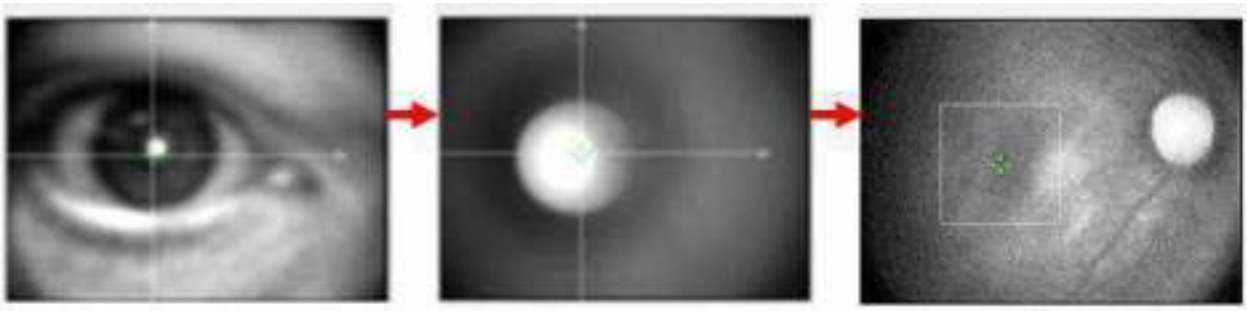


Figure 147 Video Image Progression as Scanner Approaches Eye

9. Adjust the working distance between the scan head and patient eye to optimize the 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 for fundus video image first. If a live OCT scan appears in the OCT image window, do not stop forward movement of the camera until you achieve a **good infrared (IR) video image of the fundus**

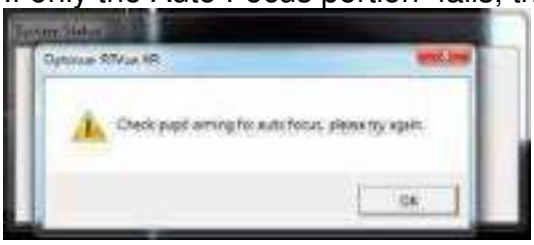
Note: On the first scan of each eye, of that day, the OCT image will not appear until the Auto Adjustment has been performed. A message will appear over the OCT window telling the operator to optimize the IR image then to select auto adjust.

Figure 148 Auto Adjust Fail

If the Auto Adjust fails the live OCT B-scan is now displayed and the following message is displayed.

Figure 149 Auto Focus 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 only the Auto Focus portion fails, the following message will be displayed.



The operator should try to optimize the IR image and Auto Adjust/focus again, if the image cannot be improved the operator may decide to capture the image

10. When the 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:

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

or

d. 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.

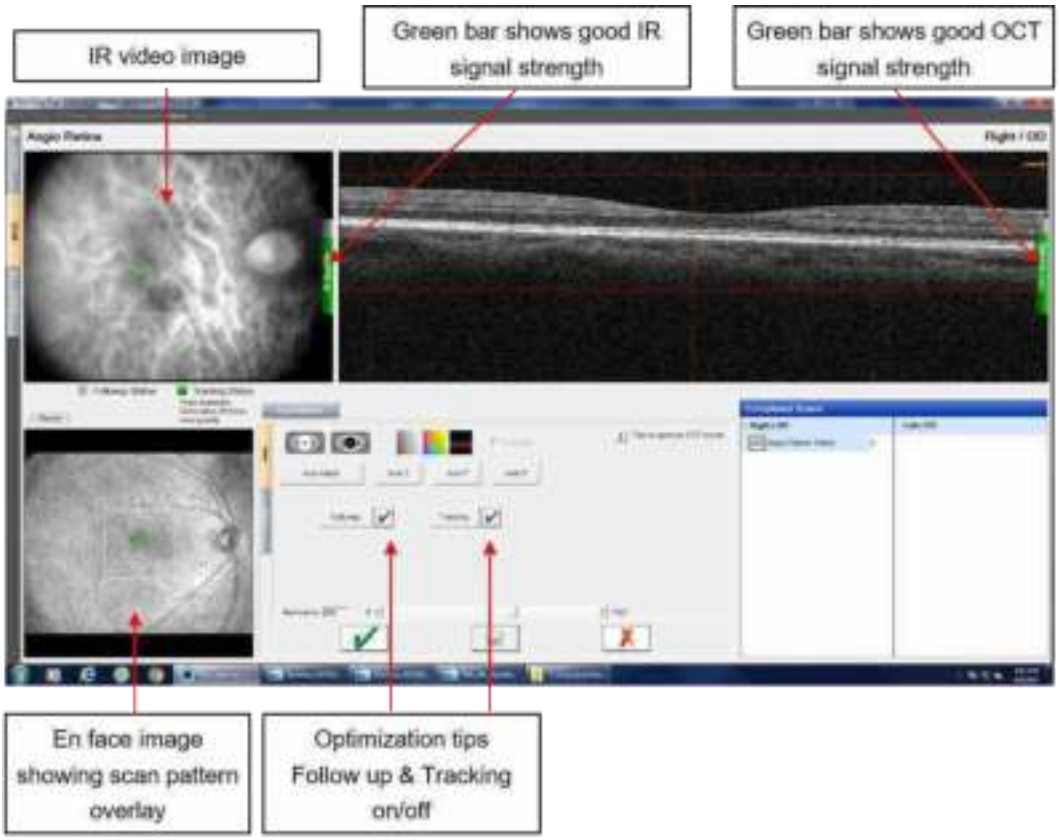


Figure 150 Active AngioVue Scan Window

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

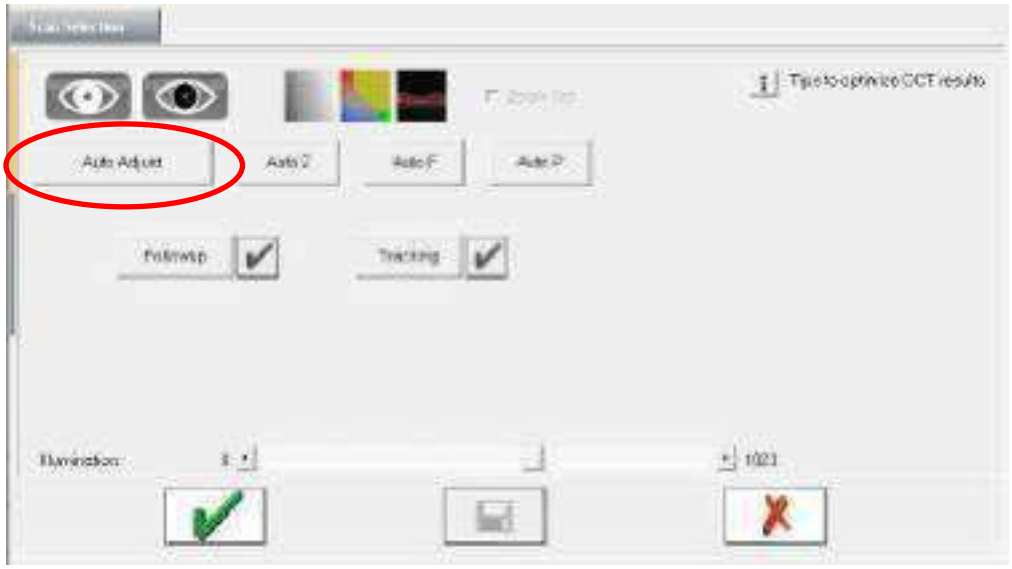


Figure 151 Auto Adjust Combines Auto Z, Auto F and Auto P

Auto Adjust executes **Auto Z, Auto F** and **Auto P** in combination. **Auto Adjust** also tries to place the scan image in the target area between the red dashed lines. If necessary to bring the OCT scan to the target area, click once in the scan window and scroll the mouse wheel to bring the OCT scan between the red dashed lines.

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 OCT signal strength index (SSI) 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 (SSI) 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 (SSI) indicator is not **green** over a range of patients, including normal eyes, contact Optovue Technical Support for assistance.

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

- Select the **Manual** 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.

10.3.2 Instructions for Successful Tracking

- **To improve the fundus image**

- Check good, homogeneous illumination by alignment to the center of pupil, a little darkening of the corners is normal

- Bring optical disc in the field of view

- Avoid glare by adjusting the scan-head alignment to pupil center

- In follow-up mode, adjust the image to ensure green cross (“good tracking”) shows up in the target zone in fundus image.

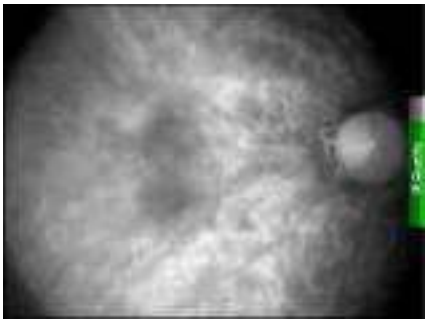
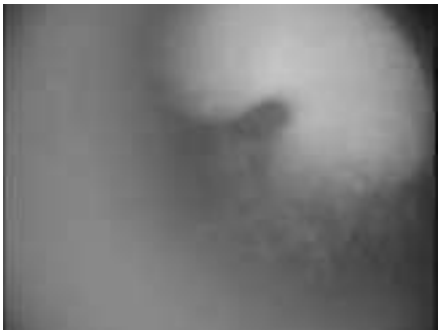
  ! Fundus features detectable on IR video image serve for tracking. Optimized IR video image is a key for successful Angio scan tracking and acquisition.

- **To improve the OCT image**

- Target tissues should fall between two red lines

- Maximize OCT signal as described earlier in chapter 3

- **Tracking (green light indicator) and start scanning**

Good Image	
Poor due to glare	
Blocked or blurry	

10.3.3 Acquisition Alerts

If 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 152 Examples of Scan Quality Alerts During Acquisition

10.3.4 Tips for Scanning Difficult Patients

Note: After scanning starts always remind the patient to look at the blue dot before attempting to reposition the camera. Often the patient will return to the correct position.

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

- Tip- always ask the person to look at the blue dot before moving the joystick
- Tip: 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.
- Tip: use artificial tears when needed.

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

- Tip: Use the external fixation light in front of the fellow eye 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 before resuming the scan or re-scan the patient.

Nervous patients can have excessive up-and-down movement of the B-scan within the scan window from excessive back and forth in the patient chair.

- 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.
- 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 hug the base of the machine.

10.3.5 Tips to Optimize OCT results

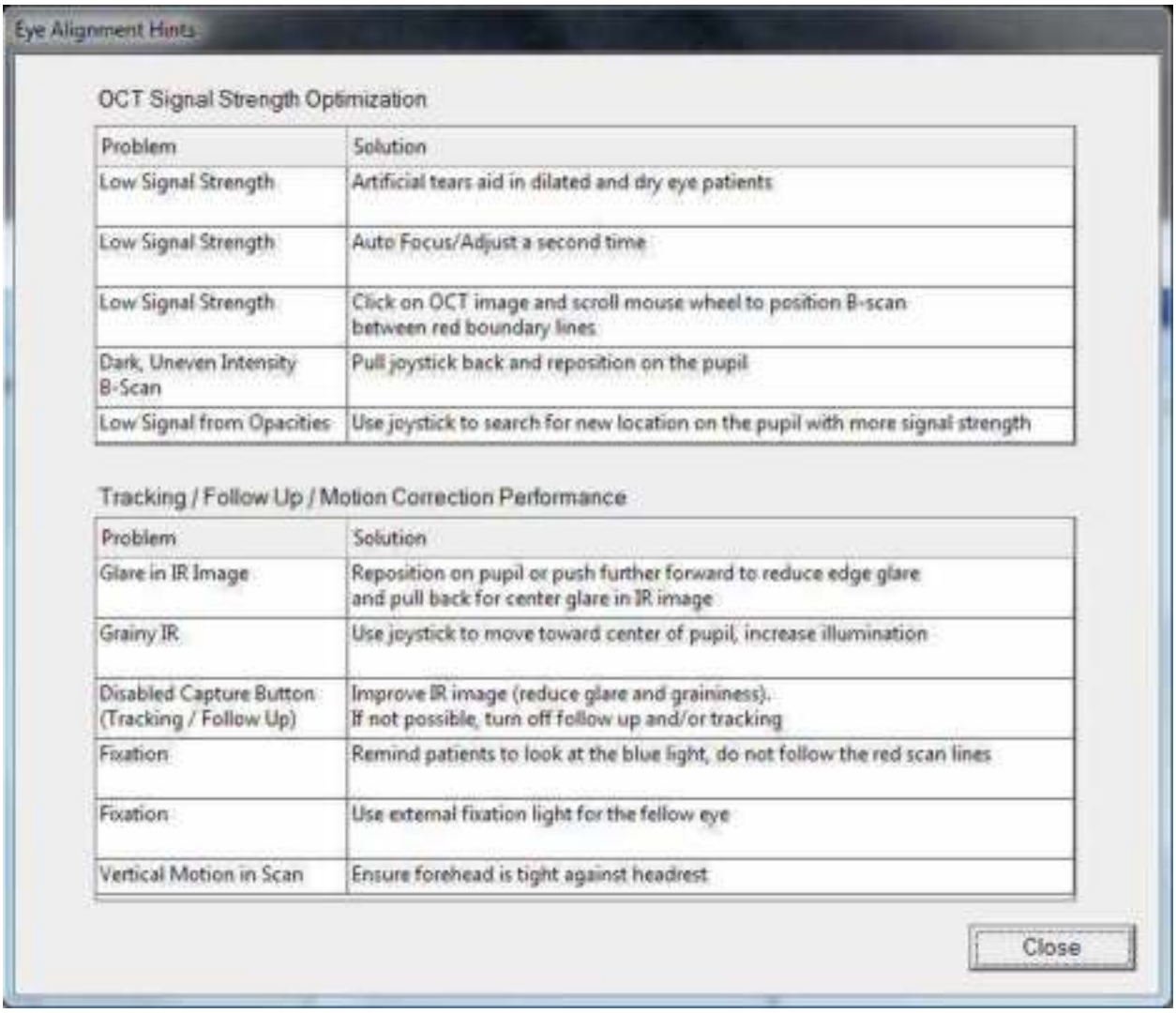


Figure 153 Tips to Optimize OCT results

13. To capture the scan, either press the joystick button or click the checkmark button  . AngioVue scans require acquisition of a Fast-X scan and a Fast-Y scan in consecutive steps. On first capture, the system acquires a Fast-X scan. Review the scan for severe eye movement. (Blinks appear as black bands and saccades appear as bright, thin white lines in the Angio en face image).

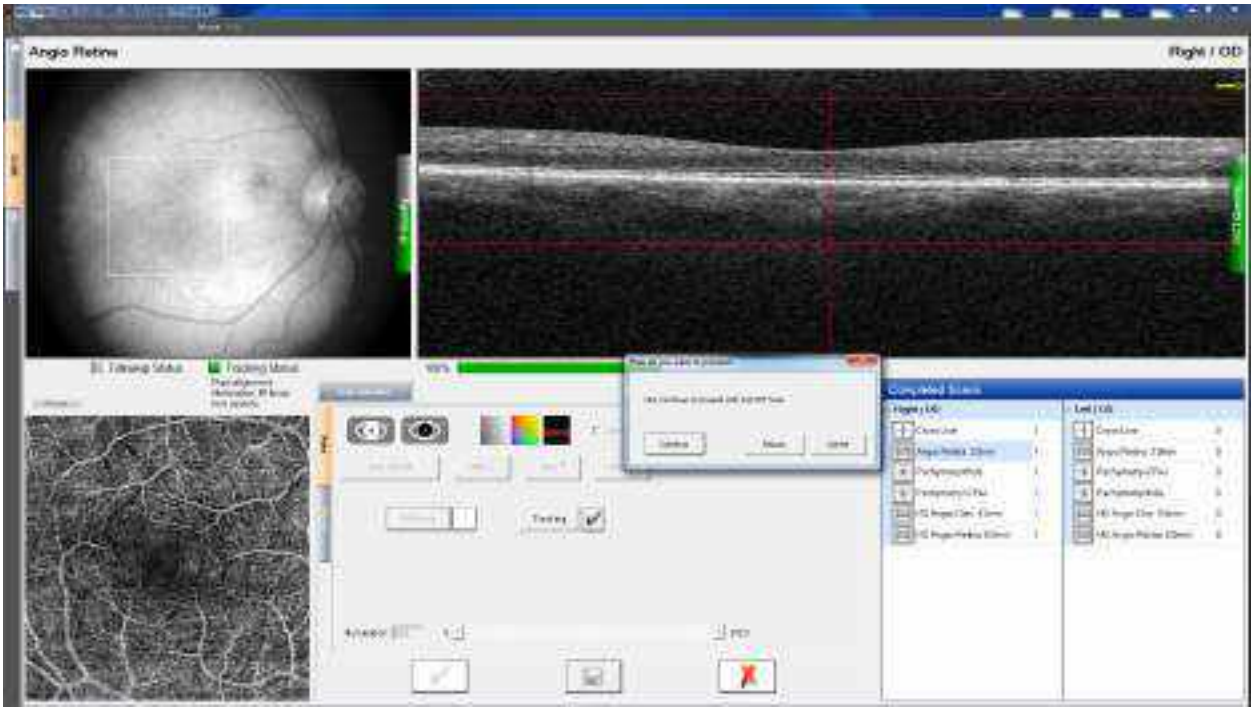


Figure 154 Fast-X Scan Captured

14. If you are satisfied with the captured scan, click **Continue or** click **the joystick button** to proceed to the Fast-Y scan. Click **Rescan** to retake the Fast-X scan. Click **Cancel** to discard the Fast-X scan and start over.

    When you continue, the Fast-Y scan begins automatically. The orange overlay in the video image (lower 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.

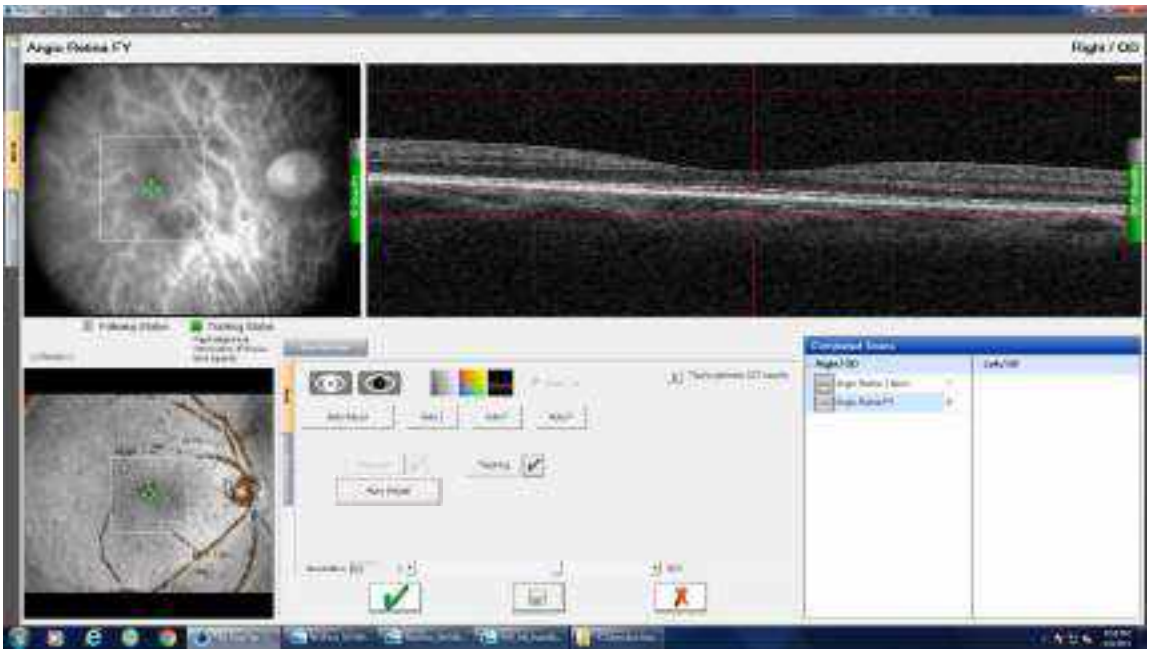


Figure 155 Active Fast-Y Scan

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.

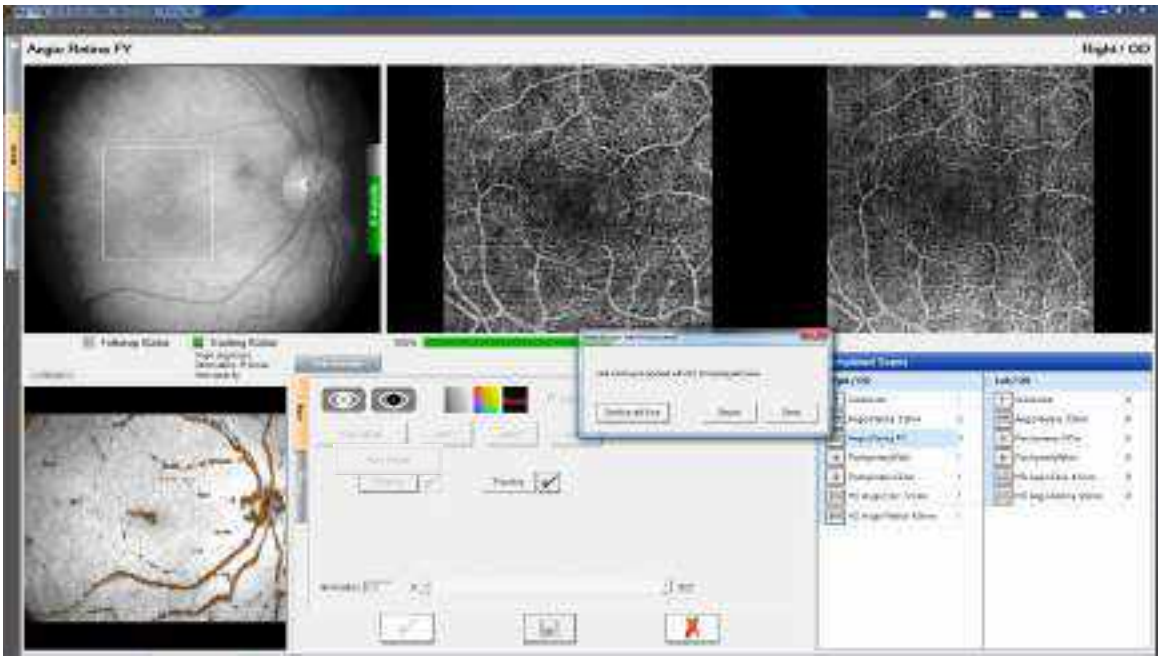


Figure 156 Fast-Y Scan Captured

16. When you capture the Fast-Y scan, the screen shows you both the Fast-X and Fast-Y scans, so you can determine if they align well before processing. If you are satisfied,

click **Continue and Save or click the joystick button** to combine and process the Fast-X and Fast-Y scans, and apply motion correction technology. Click **Rescan** to retake the Fast-Y scan. Click **Cancel** to discard both the Fast-X and Fast-Y scans and start over.

If you select **Continue and Save or click the joystick button**, the results appear on screen. Check the final image for horizontal and vertical movement lines and vessel duplication. The SQ indicator appear to assist with scan quality evaluation. Repeat the scan if necessary.

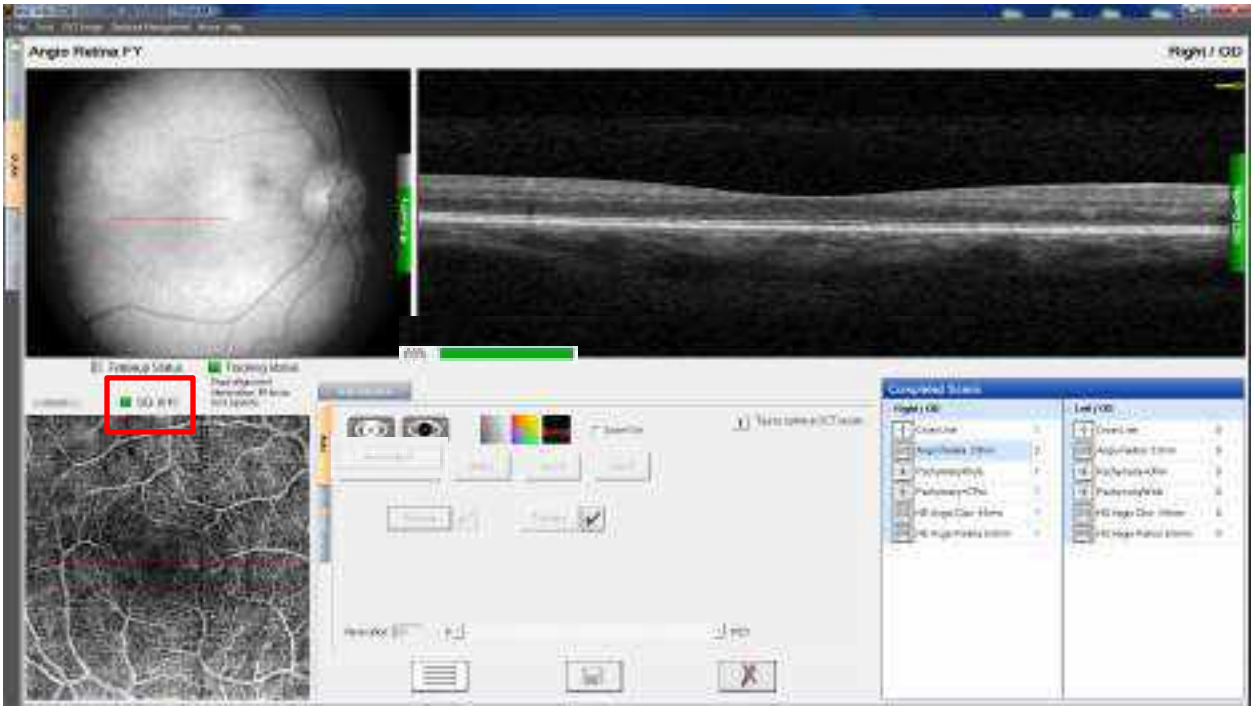


Figure 157 AngioVue Scan Complete

To view the AngioVue and OCT images with color, select the **AUTO** tab and click the **Color** (for Angio image, upper left) and/or the **OCT Color** icons, highlighted below.

Figure 158 Gray Scale and Color Viewing Options

Click the **Gray Scale** icon to return both images to gray scale. To zoom in on the OCT image, select the **Zoom OCT** checkbox.

The only other active button on this screen is the **Start Scanning** button. Use this button to repeat the scan type just completed.

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

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

b. Go back to the PATIENT window, select the desired patient, visit and scan, and click the **Review** button.

10.4 Scan Quality Indicator (SQ)

SQ takes into consideration signal strength, eye motion and focus, providing an objective image quality index that correlates with qualitative assessment of image quality. The automatic scan quality ranges from 1~10. The recommended cut off for AngioAnalytics is a SQ score of 6 and above. Score of 5 and below should be regarded with more diligence. A Scan Quality (SQ) number (1-10) will appear in the scan list as the scan saves and will be 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.

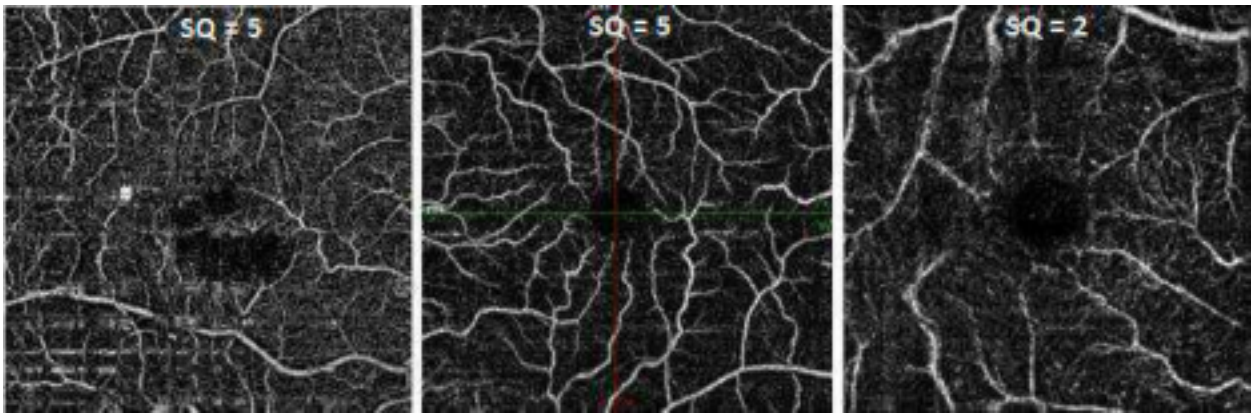


Figure 159 Examples of Scans with SQ<6

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.

10.5 Examples of Artifacts

The following AngioVue image examples illustrate artifacts that are characteristic of OCTA scans due to movement of the human 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.

10.5.1 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.

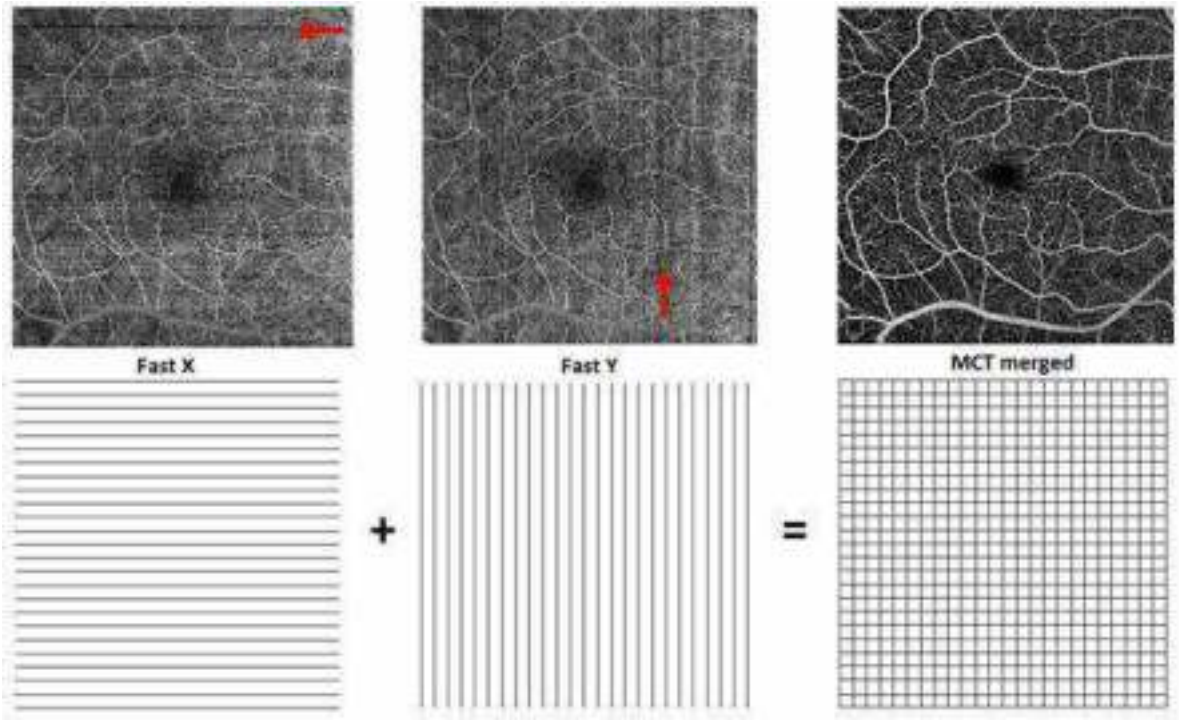


Figure 160 Saccadic Motion

Fx and Fy saccadic motion corrected on MCT Merged image

10.5.2 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.

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.

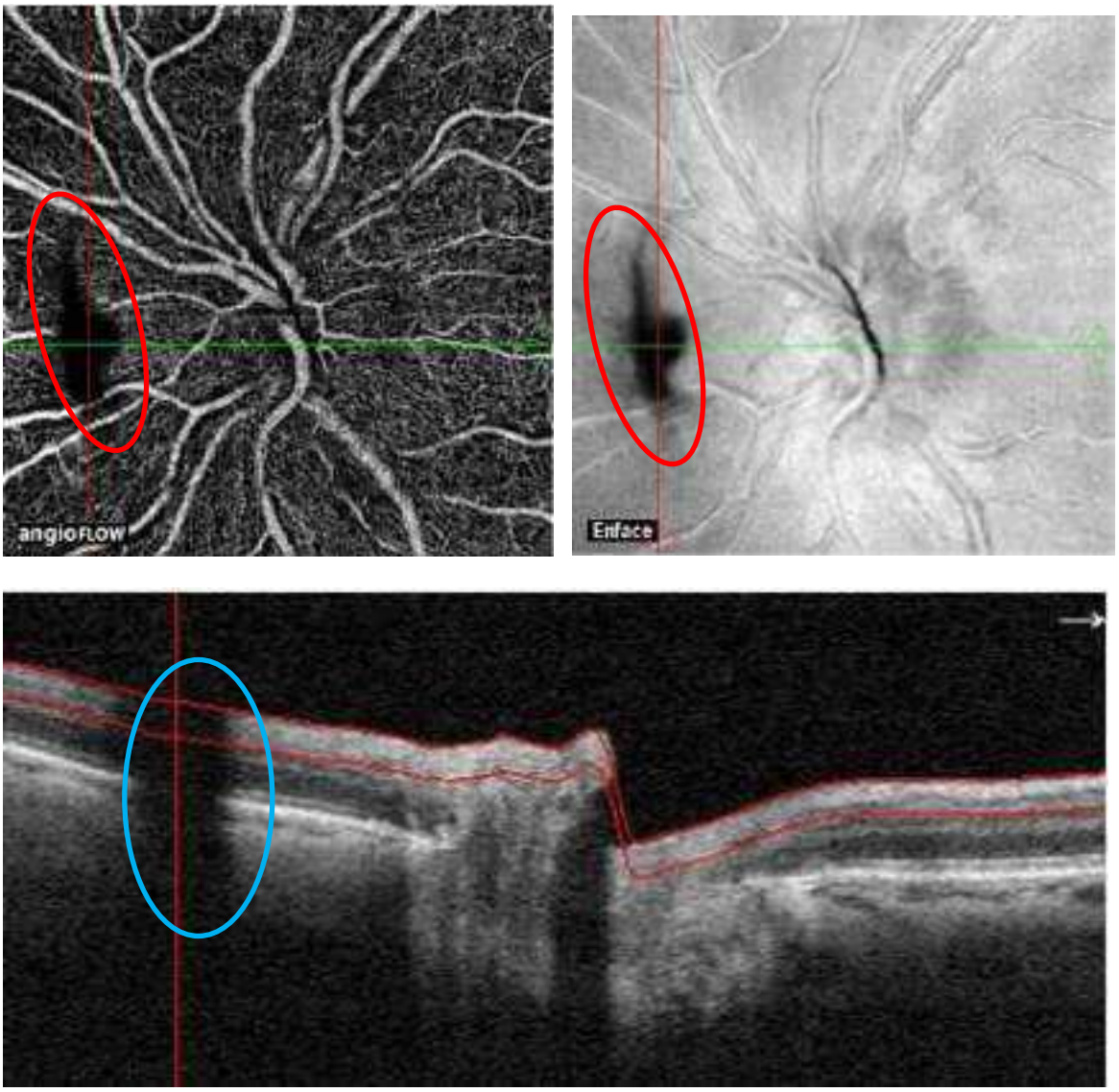


Figure 161 Floaters

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. AngioAnalytics metrics of scans with large floaters should be treated with caution.

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 extremely rare if acquisition is performed with active tracking.

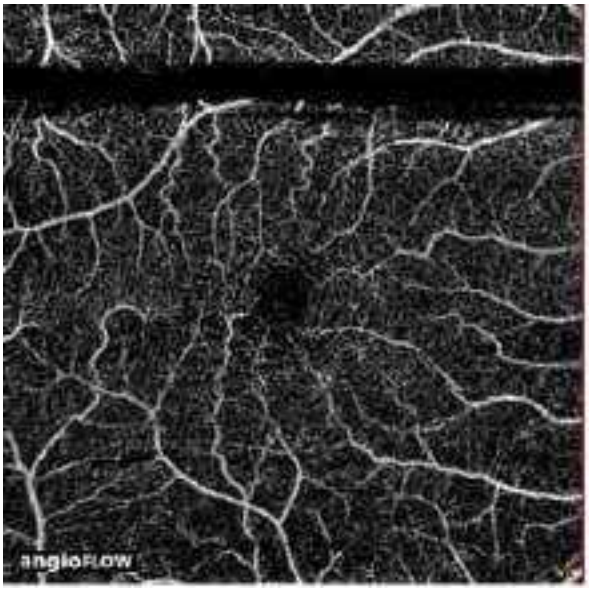


Figure 162 Blink

10.5.3 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.

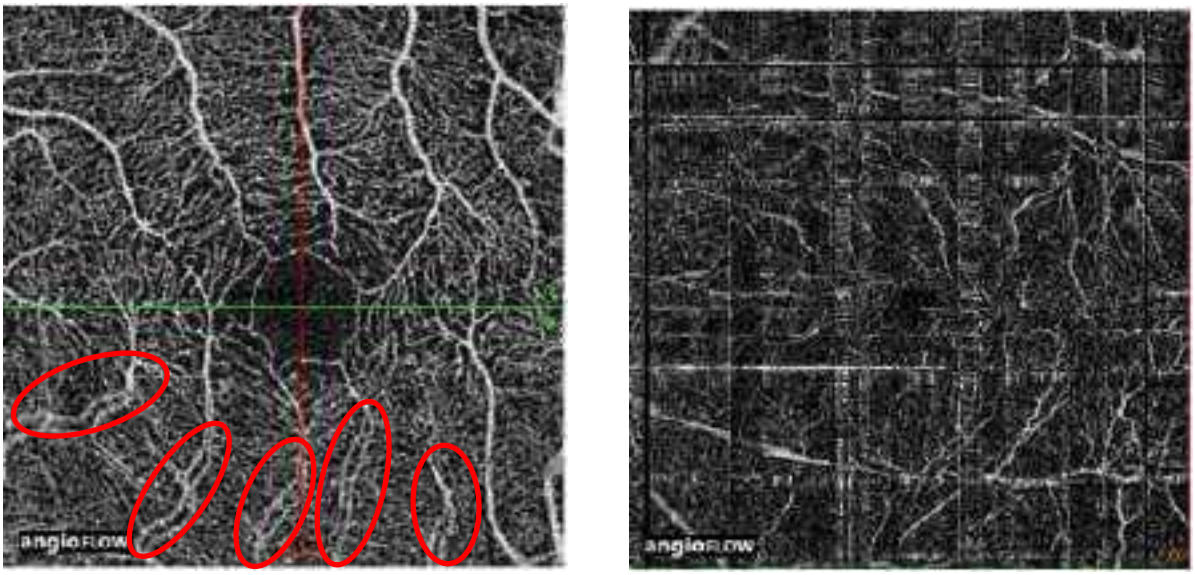


Figure 163 Excessive Motion

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. AngioAnalytics 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 results in a muddled image lacking comprehensible detail. In such cases the excessive motion is usually captured by the SQ, causing reduction of SQ.

10.5.4 Cropped Image

Retina 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 in 160.

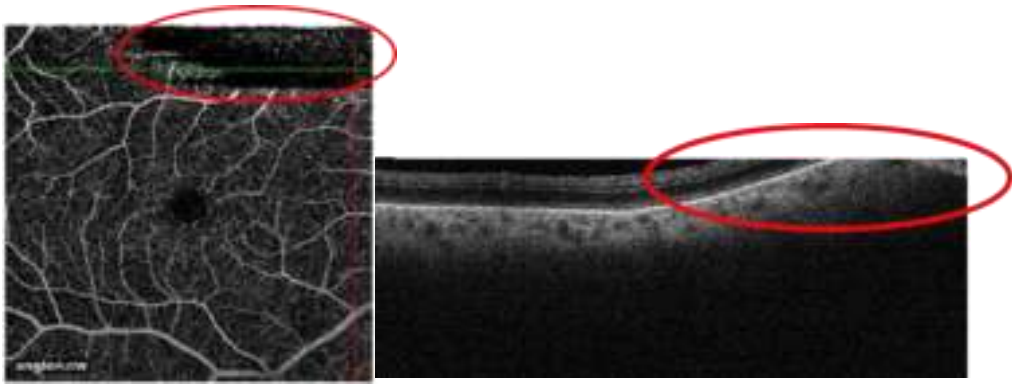


Figure 164 Image Crop

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. AngioAnalytics metrics of scans with cropping should be treated with caution.

10.6 Segmentation Retina

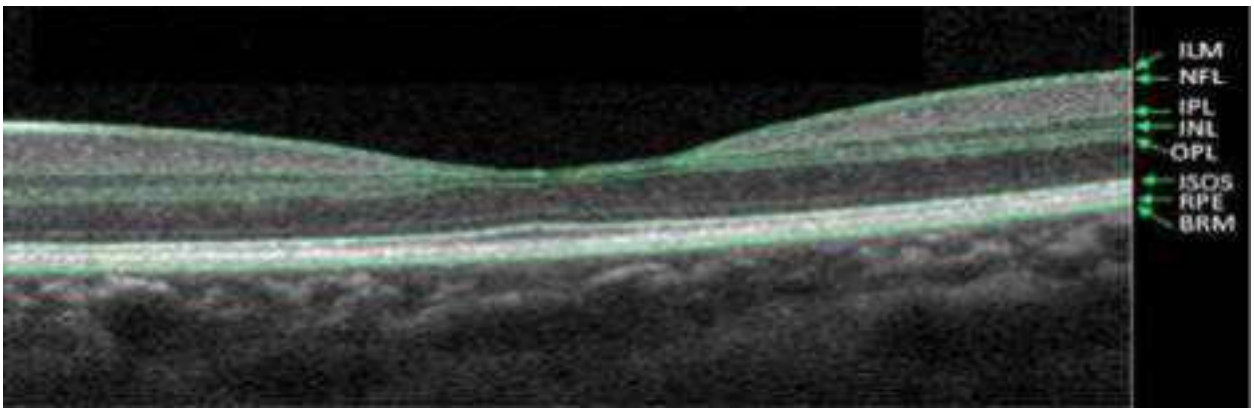


Figure 165 Retina Segmentation Layers

The following segmentation boundaries are available for the AngioRetina scans:

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

10.6.1 Predefined Angio Retina En Face Slabs

Based on segmentation boundaries as listed above, the following consistent Angio 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)

10.6.2 Custom Angio 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"→"Angio Retina Custom En Face Slab" and select the boundaries and offsets.

10.7 Segmentation Disc

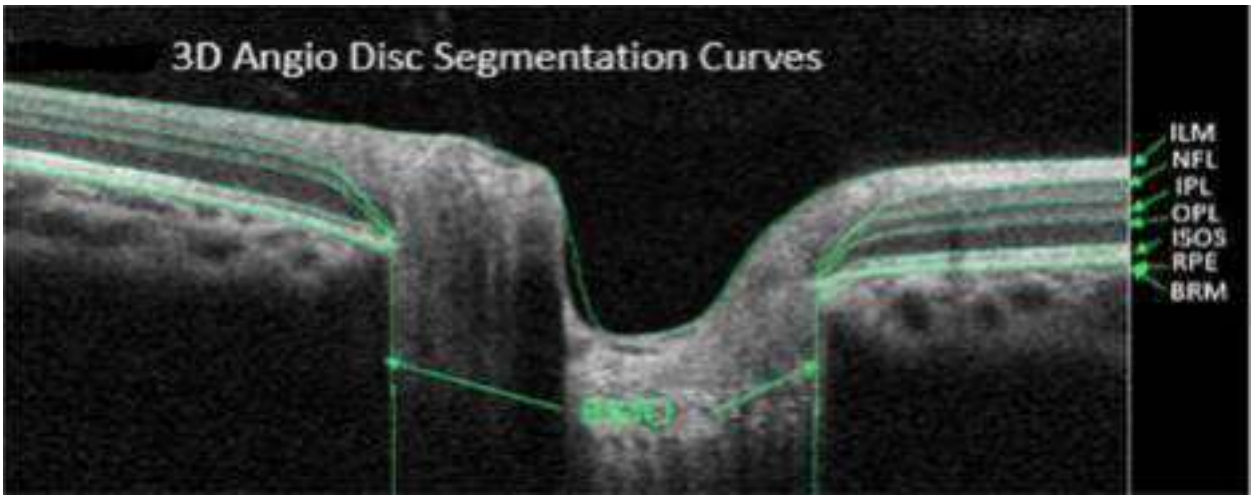


Figure 166 Disc Segmentation Layers

The following segmentation boundaries are available for the AngioDisc scans:

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

10.7.1 Predefined Angio Disc En Face Slabs

Based on segmentation boundaries as listed above, the following consistent Angio 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)

10.7.2 Custom Angio 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”→”Angio Disc Custom En Face Slab” and select the boundaries and offsets.

10.8 Optic Disc Margin

The optic disc margin detection by the software shall be reviewed in the SLO view screen (Main Report, SLO Tab – see Section 10.11.8). 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.

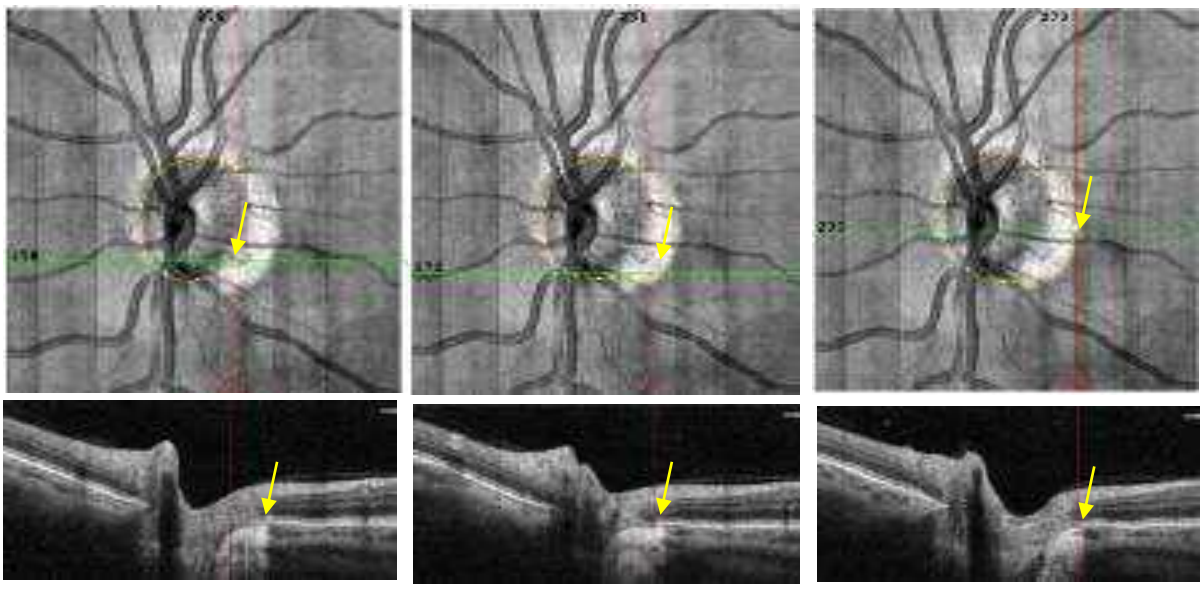


Figure 167 Disc Margin and Margin Correction

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).

10.9 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 (Figure 168) 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 as in Figure 168 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'd 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.

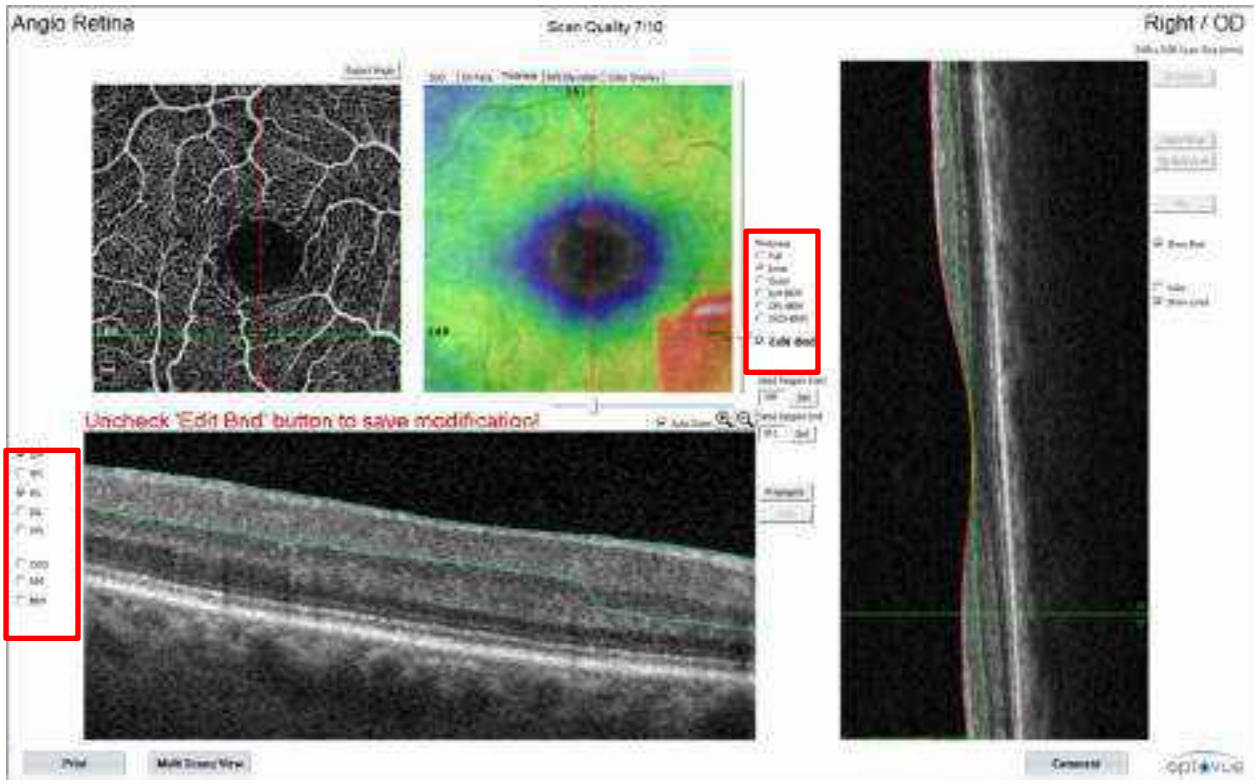


Figure 168 Incorrect IPL segmentation

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

   In Figure 169 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 (Figure 169, 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”, Figure 170

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”, Figure 170

   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.)

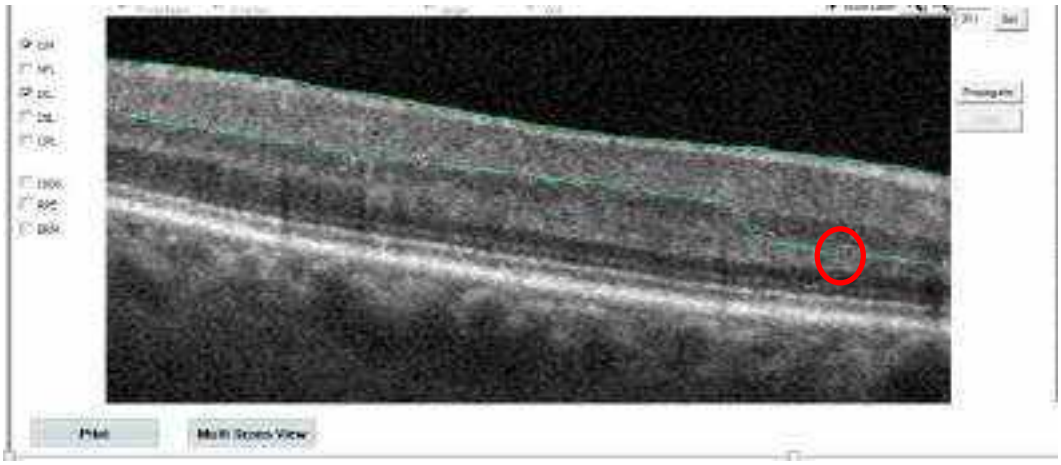


Figure 169 IPL Boundary Selected, Anchor Points Activated

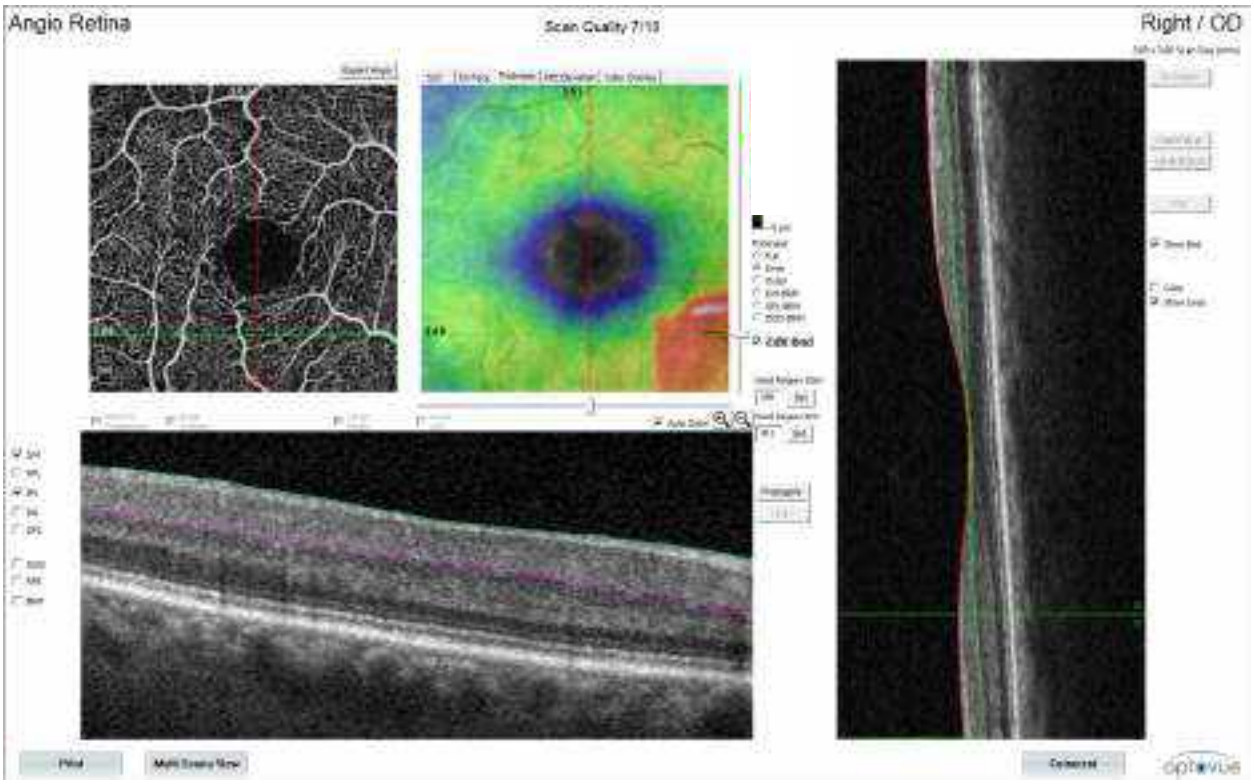


Figure 170 Single B-Scan Corrected (IPL Line Turned Purple), not Propagated

5. Propagation.

   Clicking on the **Propagate** button (red rectangle on Figure 171) 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. Figure 171 shows the propagated map.

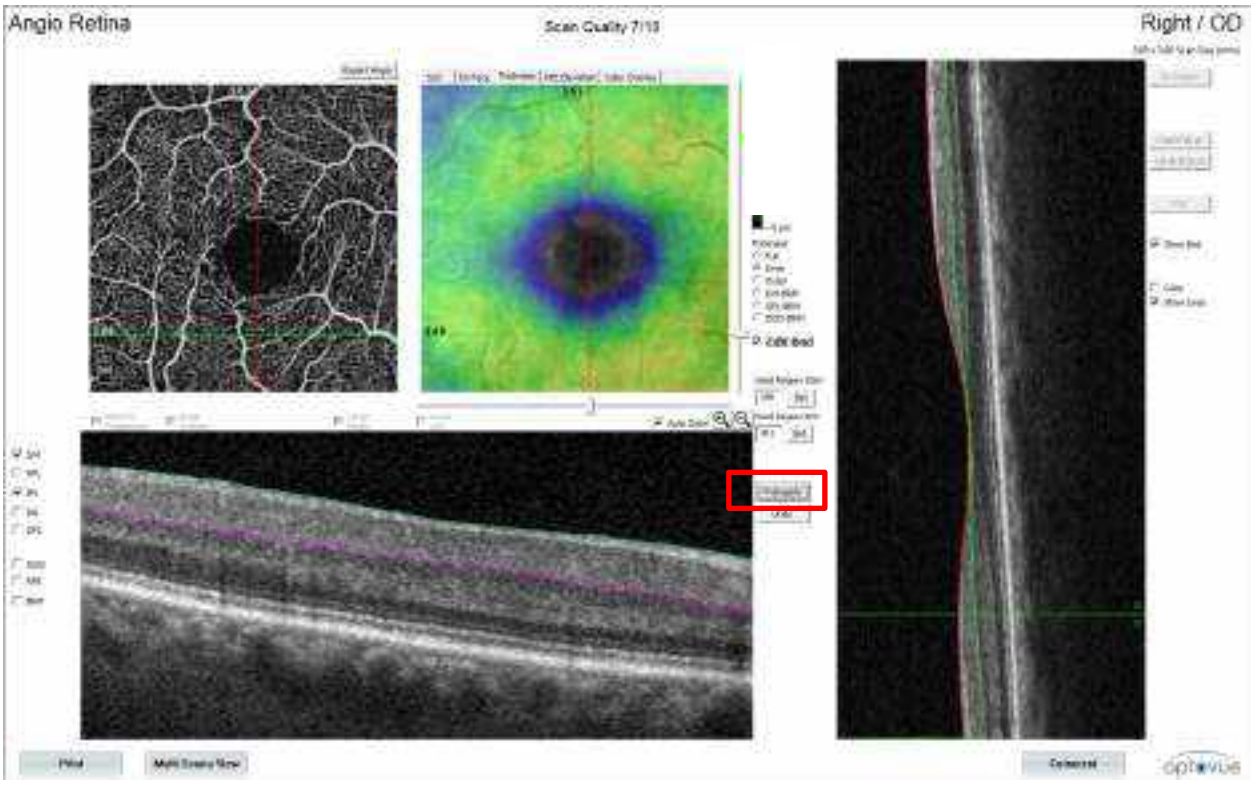


Figure 171 Segmentation Correction and Propagation Applied

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.

10.10 Projection Artifact Removal (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. Figure 172 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.

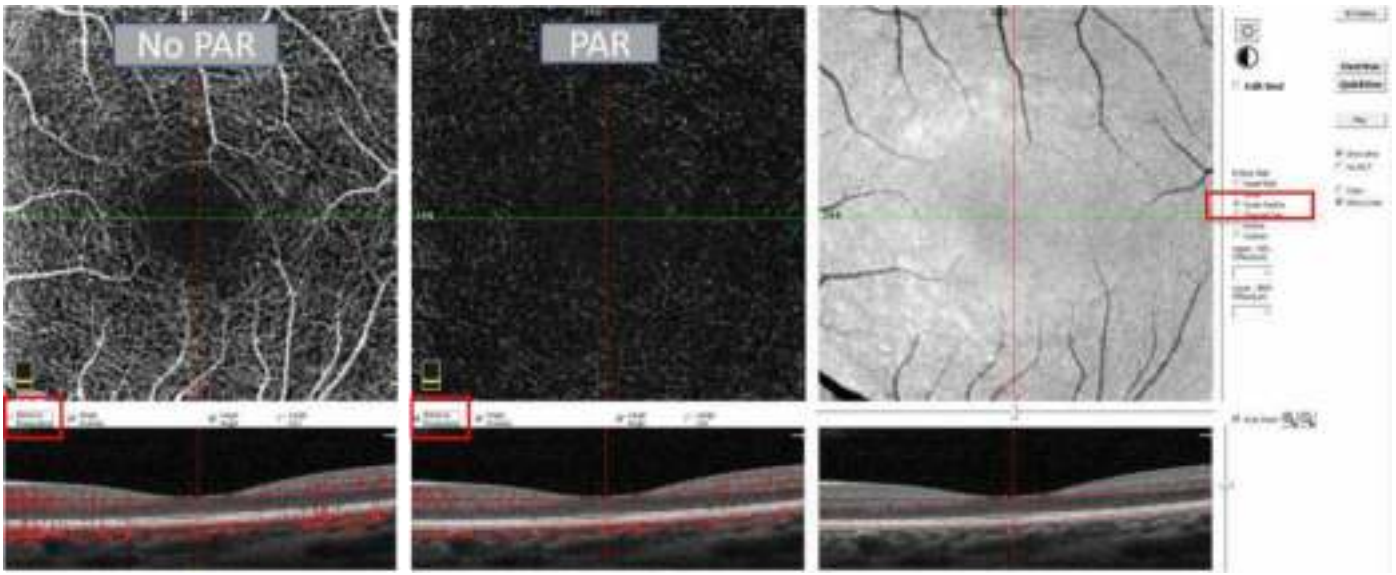


Figure 172 PAR Off and PAR On (same Outer Retina Slab)

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 (Section 16.2) 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). Refer to Section 11.3.4 and 11.4.5 for more information on the vessel density measurement feature.

10.10.1 Examples of PAR vs No-PAR

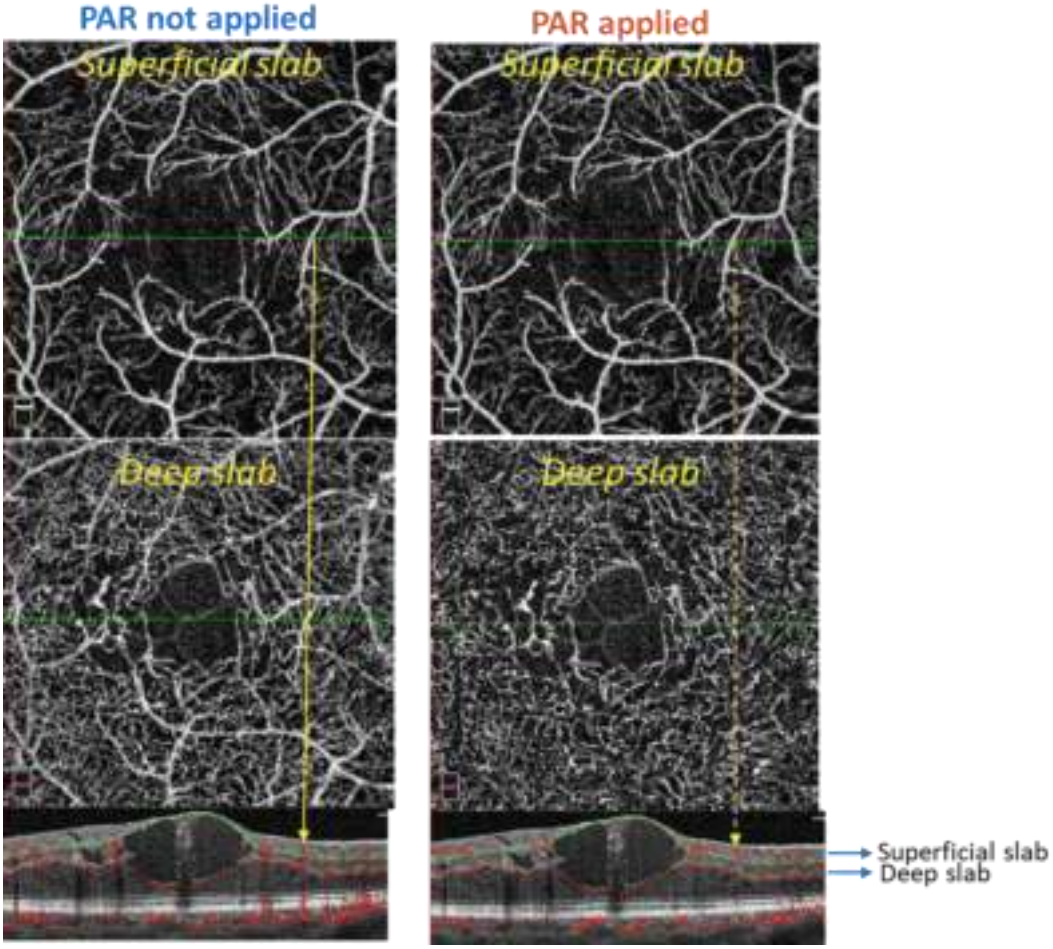


Figure 173 Example: 3 mm AngioRetina Scan of Patient with Diabetic Retinopathy, with and without PAR

Superficial and deep en face slabs, and horizontal angio 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.

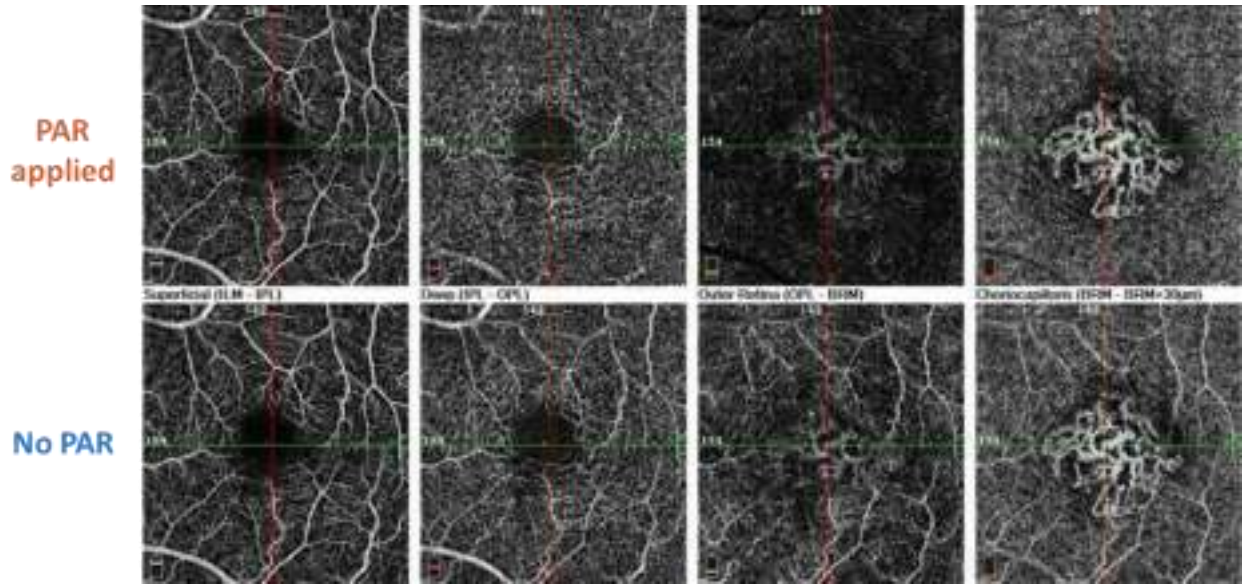


Figure 174 Example: 3 mm AngioRetina Scan of Patient with CNV, with and without PAR

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

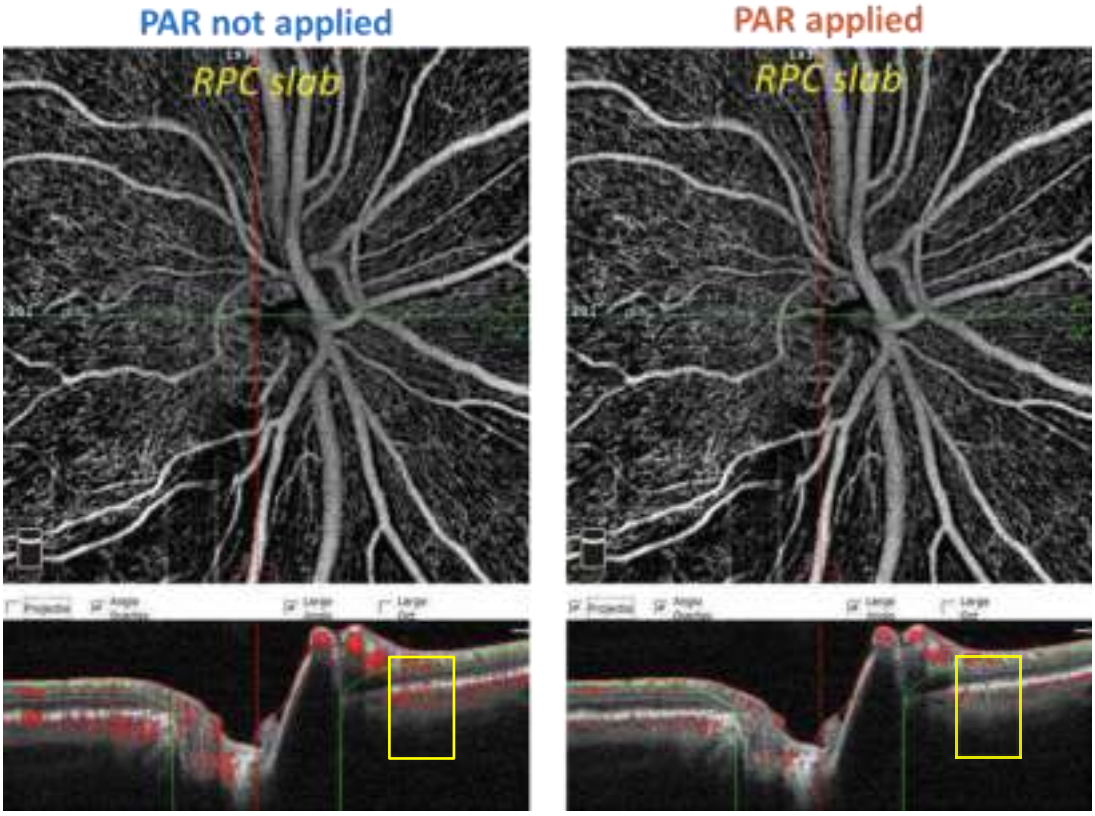


Figure 175 Example:4.5 mm HD AngioDisc Scan, with and without PAR

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 angio b-scan demonstrates "projection tails" removal following PAR in the deeper layers of the retina (yellow boxes).

10.11 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.

10.11.1 AngioVue Reports List

Angio Retina Reports

- Angio Retina Essential (requires Essential license)
- Angio Retina QuickVue report (with AngioAnalytics)
- Angio Retina Main report
- Angio Retina OverVue report
- Angio Retina Trend report (with AngioAnalytics)

Angio Disc Reports

- Angio Disc QuickVue report (with AngioAnalytics)
- Angio Disc Main report
- Angio Disc OverVue report
- Angio Disc Trend Report (with AngioAnalytics)

Angio Montage report

10.11.2 Angio Retina Essential

The Essential Report is a simplified 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.

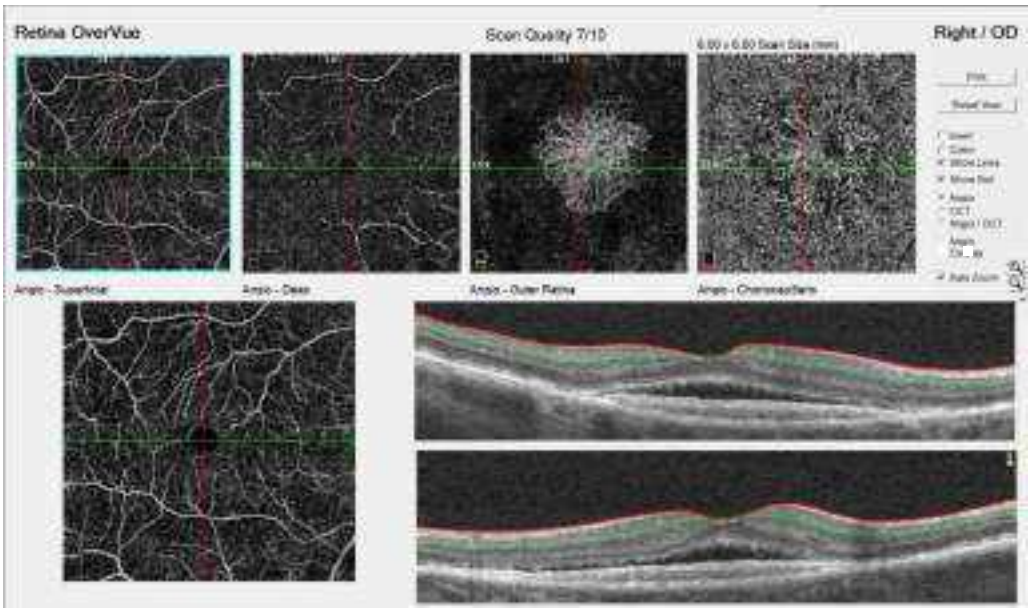


Figure 176 Angio Retina Essential Report

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**.**

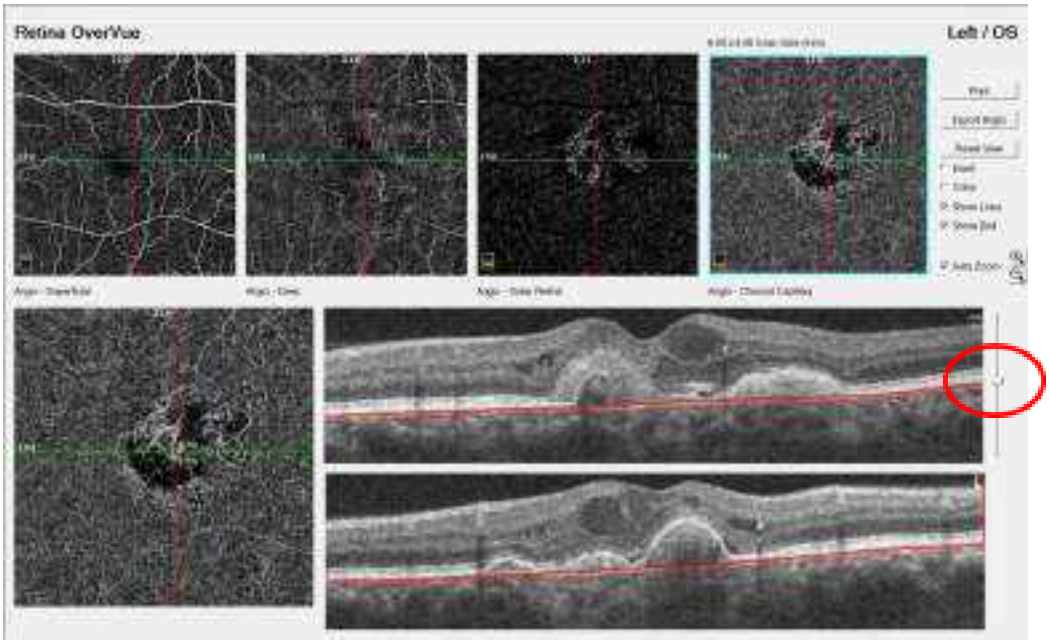


Figure 177 Essential Report with Choroidal Capillary en face selected

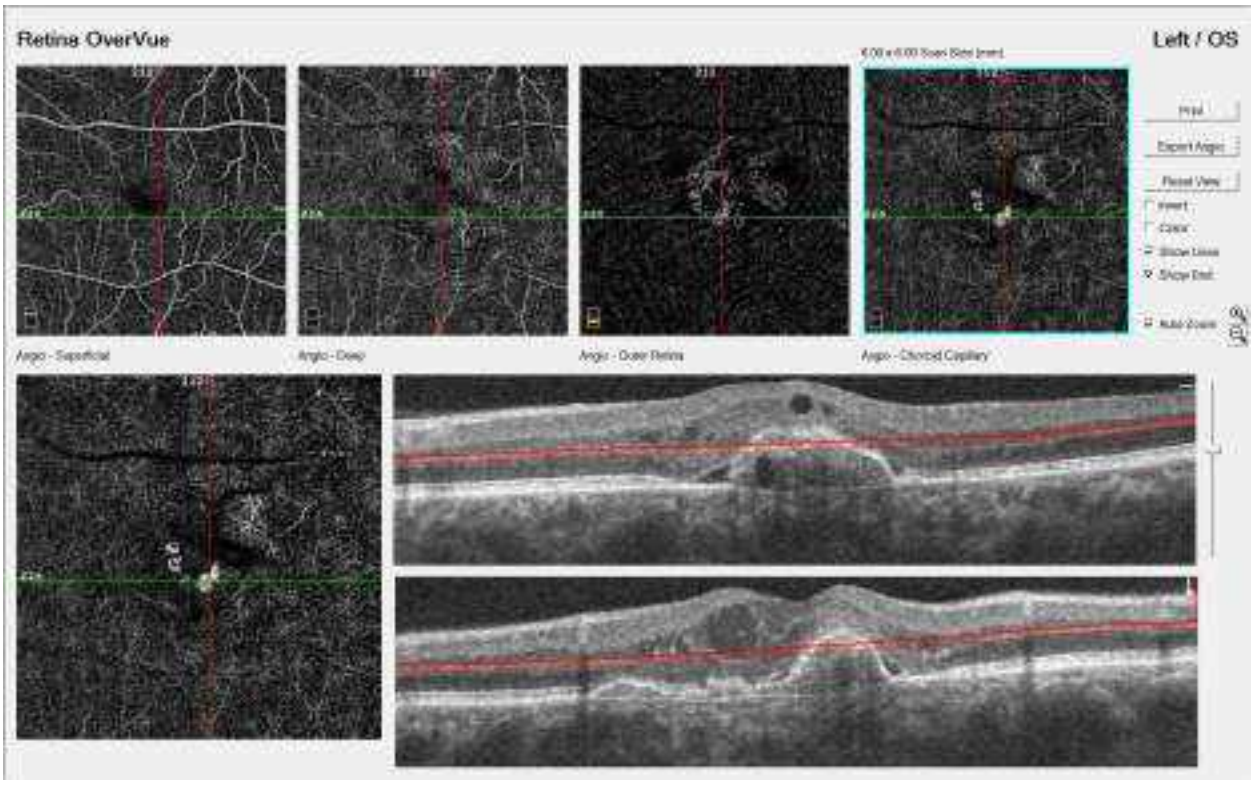


Figure 178 Essentials Report with segmentation raised to evaluate flow

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

Clicking on Angio Overlay will display OCTA overlay on B-scan image.

10.11.3 Angio Retina OverVue Report

Angio Retina OverVue report is presented below with the **Angio** radio button selected (red square). There are two additional radio buttons—**OCT** and **Angio/OCT** —each of which presents different images and associated functionality. (Note: additional Montage button appears only if the scan is 6 mm HD Angio Retina, and there is 6 mm HD AngioDisc scan available from the same visit)

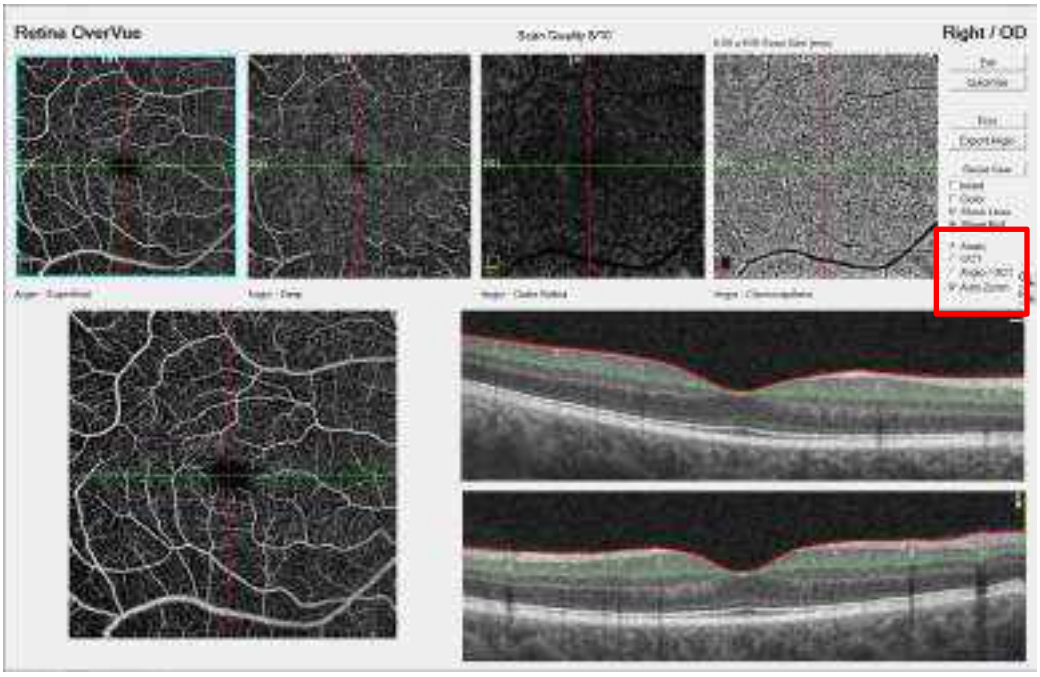


Figure 179 Angio Retina OverVue, Angio Selection

The default Retina OverVue is gray scale and includes:

Across the top, four Angio en face images at different depths shown in gray scale. Click on an image and scroll the mouse wheel to zoom the image.

- The left-most image in the top row is selected by default, which means it is displayed on the lower left image. Click to select one of the other images above and that one becomes the overlay, plus the segmentation lines on the B-scans change to show the layer of the selected image. (If no OCT image larger than the scan area exists for this patient, the currently selected image fills the space at lower left.)
- At lower right, horizontal and vertical B-Scan images. Each Angio en face image has green (horizontal) and red (vertical) lines that indicate the current B-scan location. You can drag these lines to select which horizontal and vertical B-scan displays.

Angio Retina OverVue Controls

At upper right, the screen provides the following options.

Exit: Exits screen and goes to the main report.

QuickVue: redirects to QuickVue report (with AngioAnalytics)

Montage: Displays the AngioVue montage image, which overlays the aligned AngioVue Retina and AngioVue Disc images on the 3D Widefield image.

Print: Prints the current display.

Save Angio: Saves the current AngioVue images in the folder you choose in the Save As dialog that appears.

Reset View: Resets view to the default settings.

Invert: Inverts the gray scale in the images.

Color: Displays images in color.

Show Lines: Displays horizontal (green) and vertical (red) lines that indicate the current B-scan locations.

Show Bnd: Displays segmentation boundaries on B-scans.

Angio: Shows AngioVue images at 4 depths.

OCT: Shows OCT images at 4 depths.

Angio / **OCT**: Shows 4 AngioVue and 4 OCT images

Auto Zoom: Selected by default, auto zoom applies to the B-scans shown. Clear checkbox to turn off auto zoom.

Angio Retina OverVue, Portrait Report

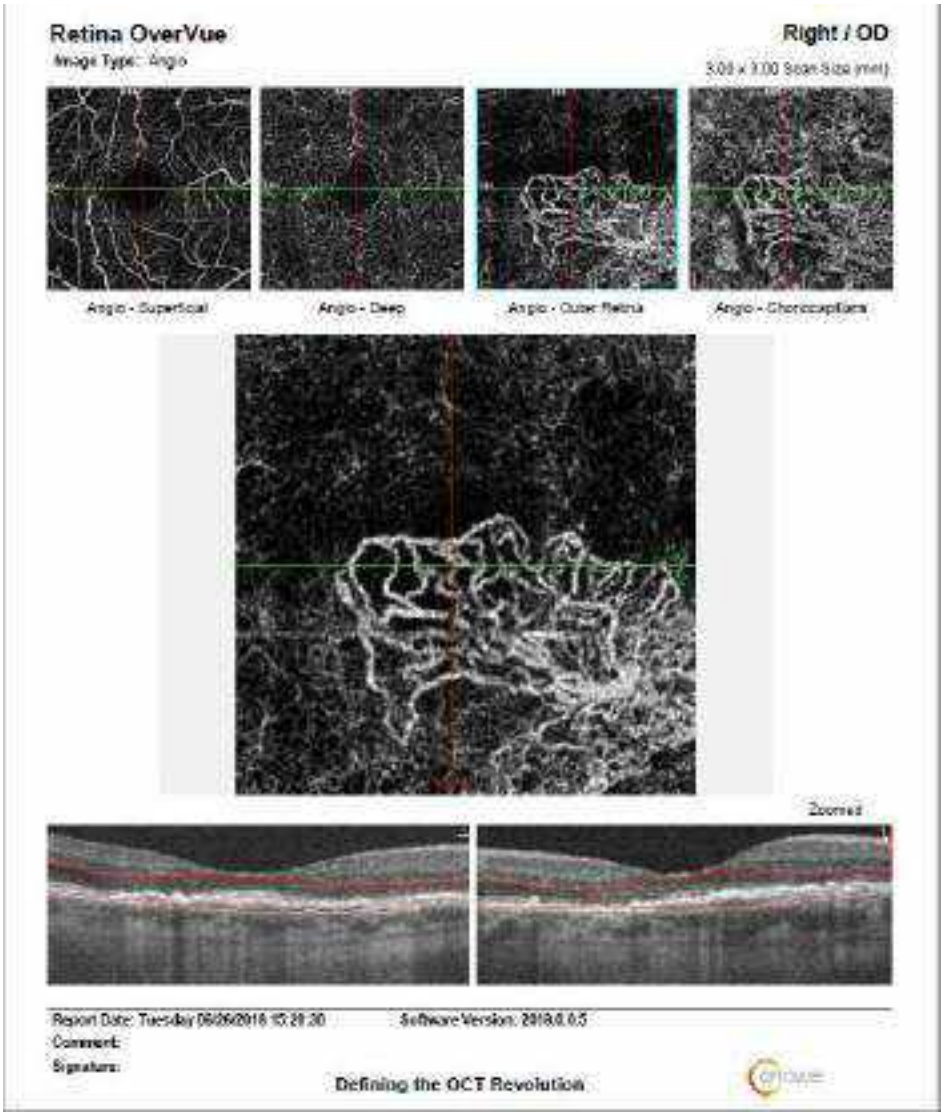


Figure 180 Angio Retina OverVue Portrait Report, Angio Selection

Below is how the report looks when you select the **Angio** / **OCT** radio button. Above are the Angio en face images at different depths, and below are the four corresponding OCT en face images at the same depths. The B-scan shows the Outer Retina slab boundaries, since the outer retina slab was selected (blue frame around the third image in the upper panel)

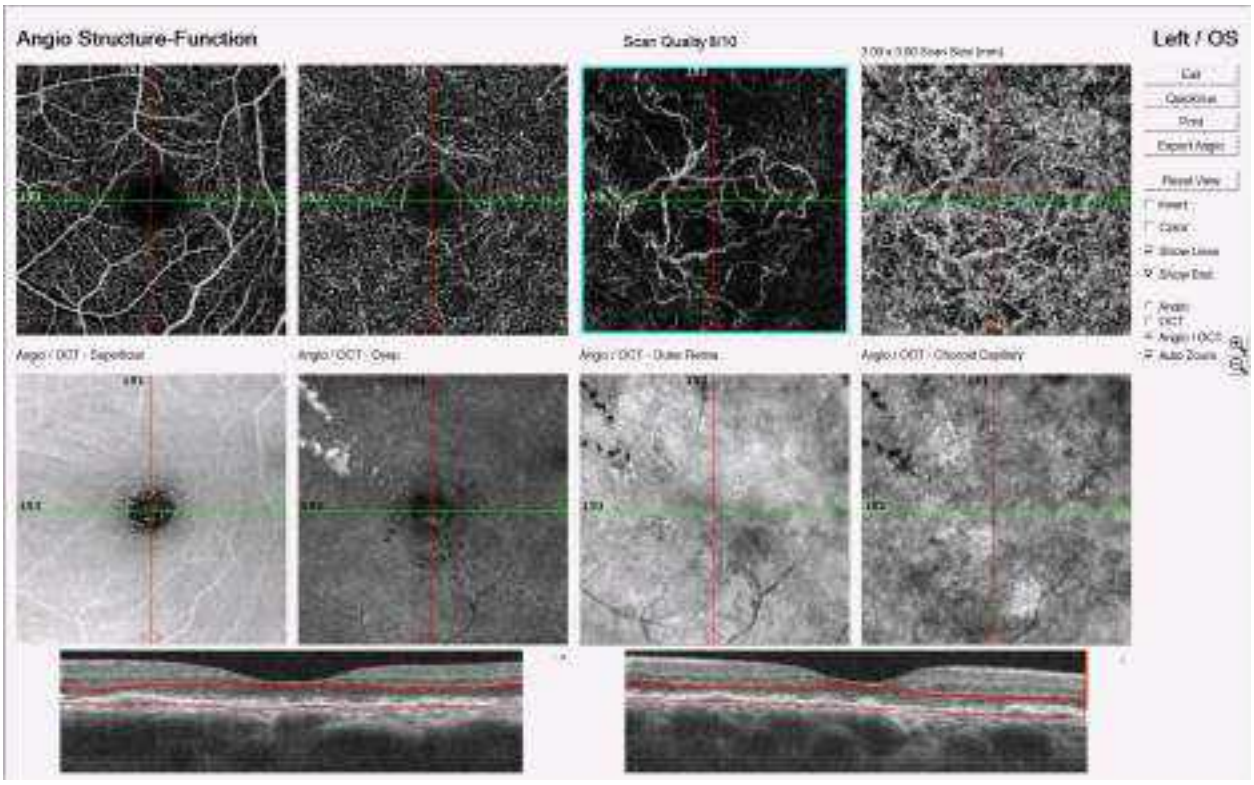


Figure 181 Angio Retina OverVue Report, OCT/OCTA Selection

Angio Retina OverVue. Structure Function Portrait Report

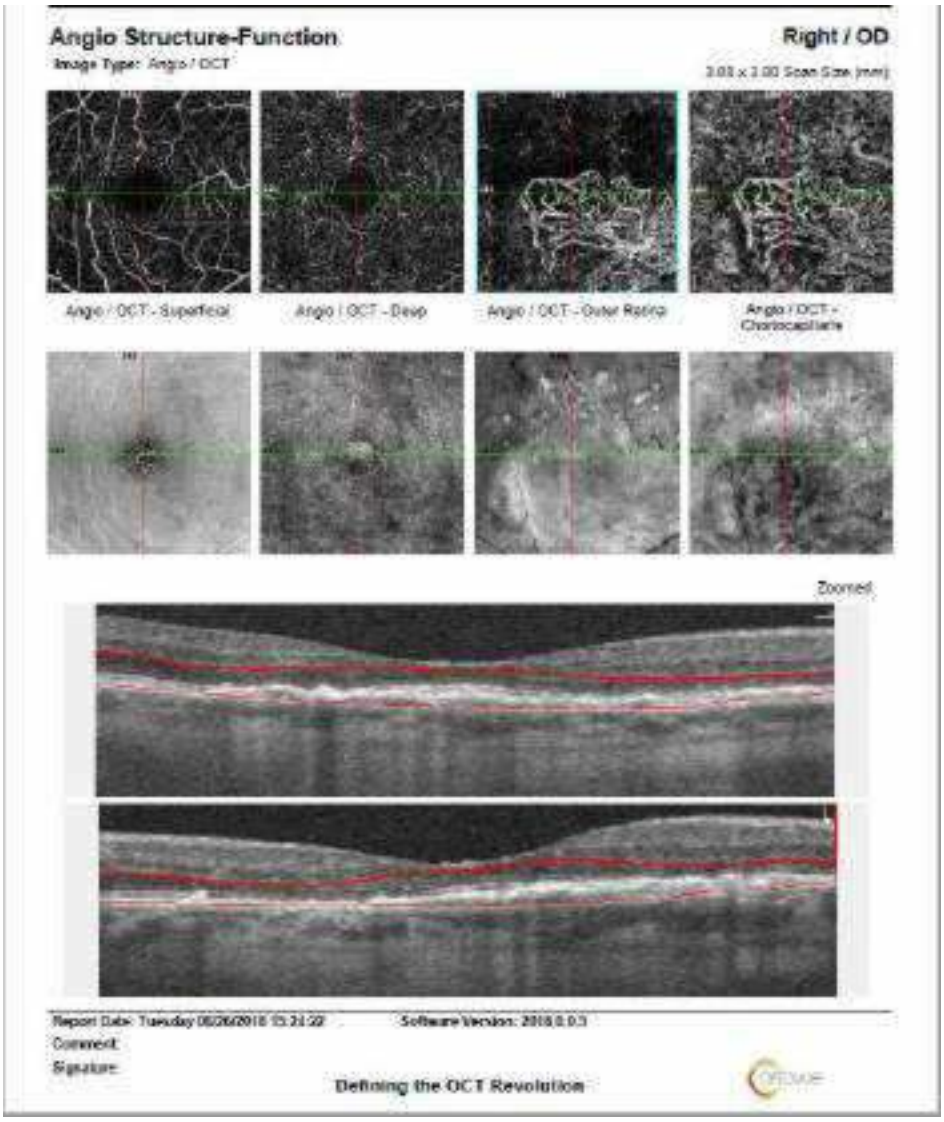


Figure 182 Angio Retina OverVue Report, OCT/OCTA Selection

Report showing corresponding OCT and OCTA en face images.

10.11.4 Angio Retina Main Report

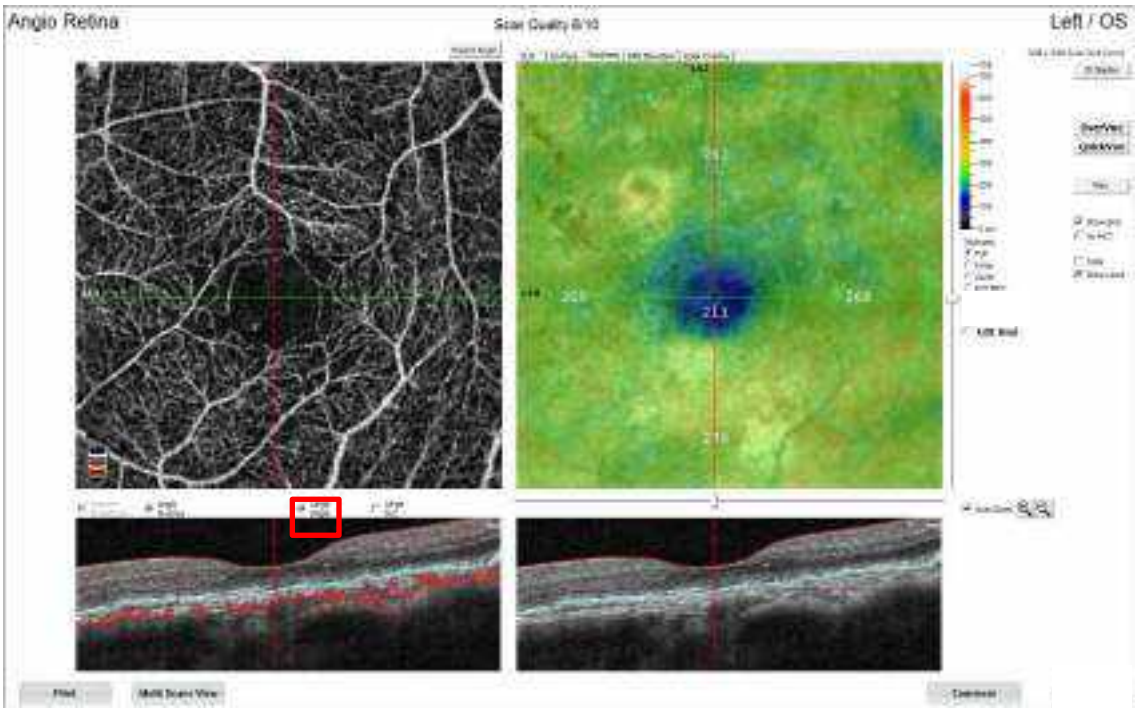


Figure 183 Angio Retina Main Report

The Angio main report is the working report, which means that the options you select here affect display of the OverVue and QuickVue reports. The default Angio 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 Angio overlay . Unclick **Large Angio** checkbox below the AngioVue image to enable display of the vertical B-scan on the right side of the screen.

Angio 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.

OverVue: Return to the OverVue screen.

QuickVue: en face and measurements display display (with AngioAnalytic licence)

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.

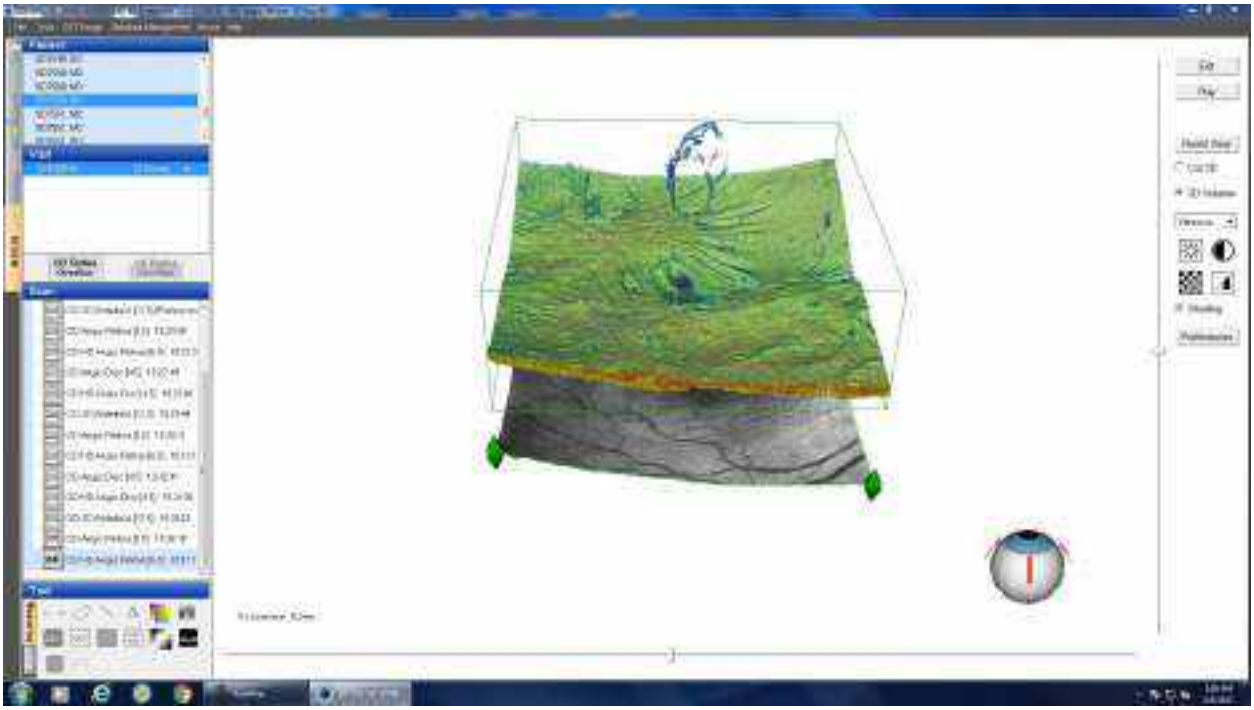


Figure 184 3-D Retina Image

Top Center Image Tabs

Thickness Tab

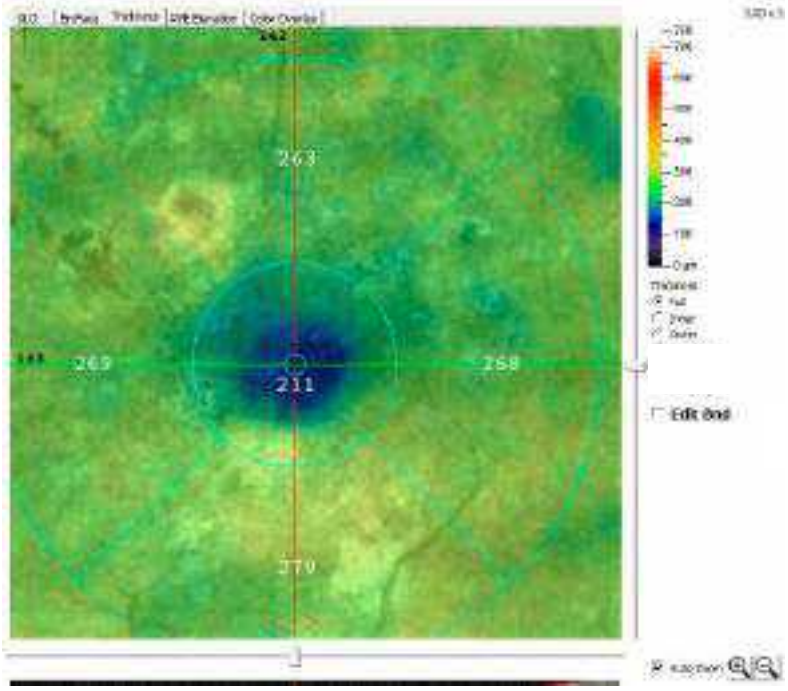
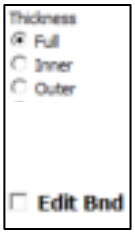


Figure 185 Top Center Image Tabs, Thickness Tab Selected

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)
- **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.

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.

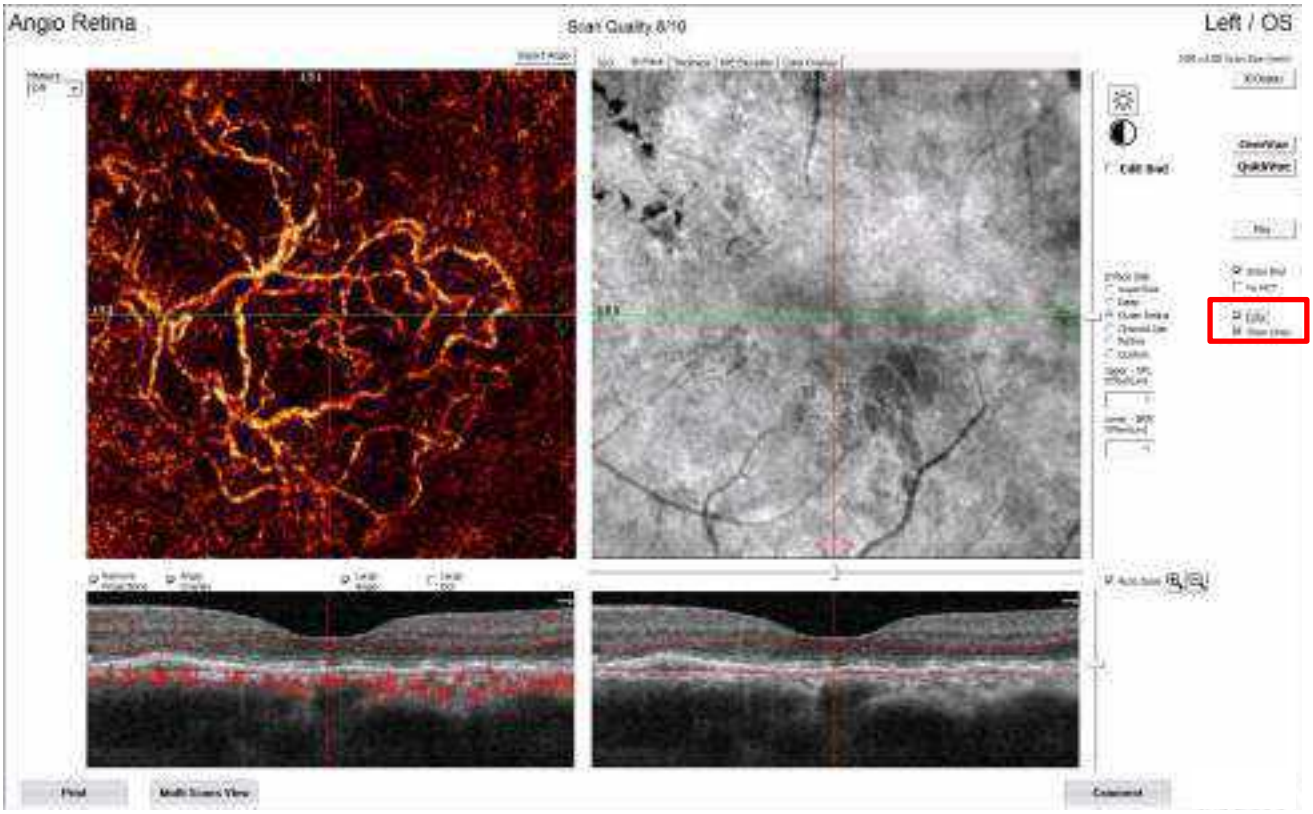


Figure 186 Angio Retina Main Report, En Face Tab Selected

The example shows the AngioVue image in color because the Color checkbox (red rectangle at far right) is 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

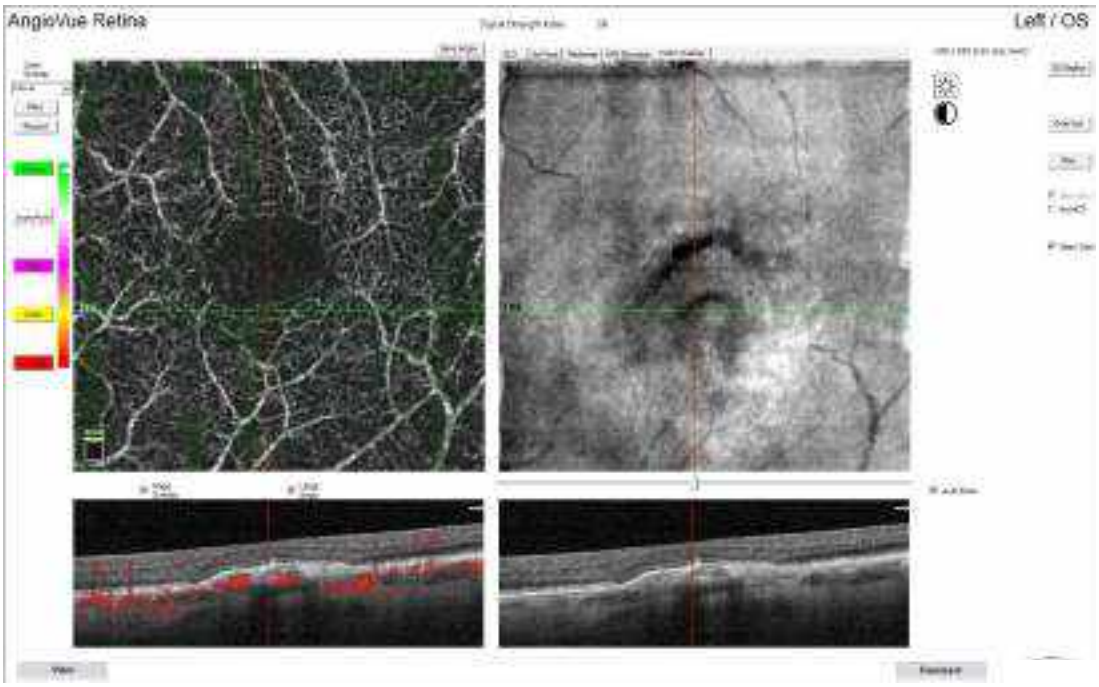
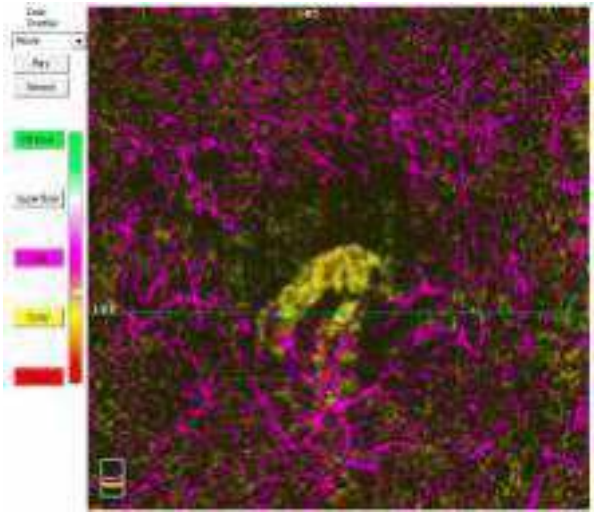


Figure 187 Angio Retina Main Report, Color Overlay Tab Selected (Default to Movie)



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 188 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. Color layer adjustment information available in section 10.11.6.

10.11.5 Angio 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. If AngioAnalytics™ license is activated 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.

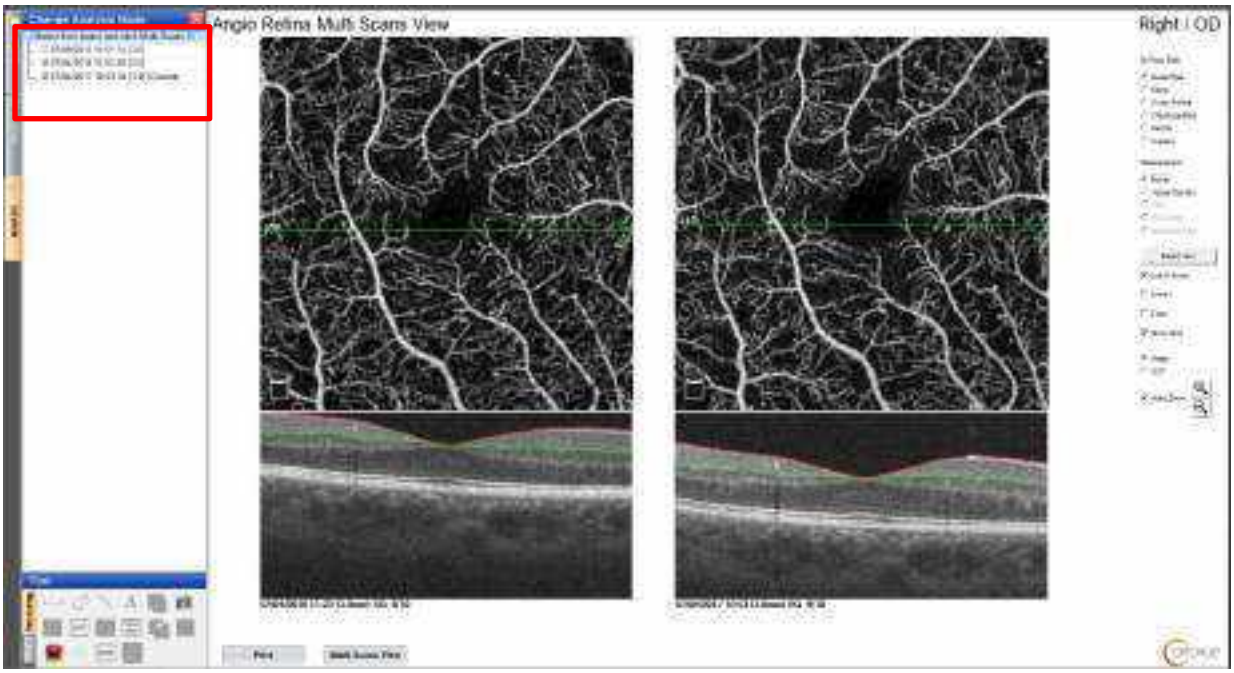


Figure 189 Angio Retina Multiple Visit Report

Angio 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 **Angio** or **OCT** images for comparison.

Auto zoom: for B scans

10.11.6 Angio Montage Report

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

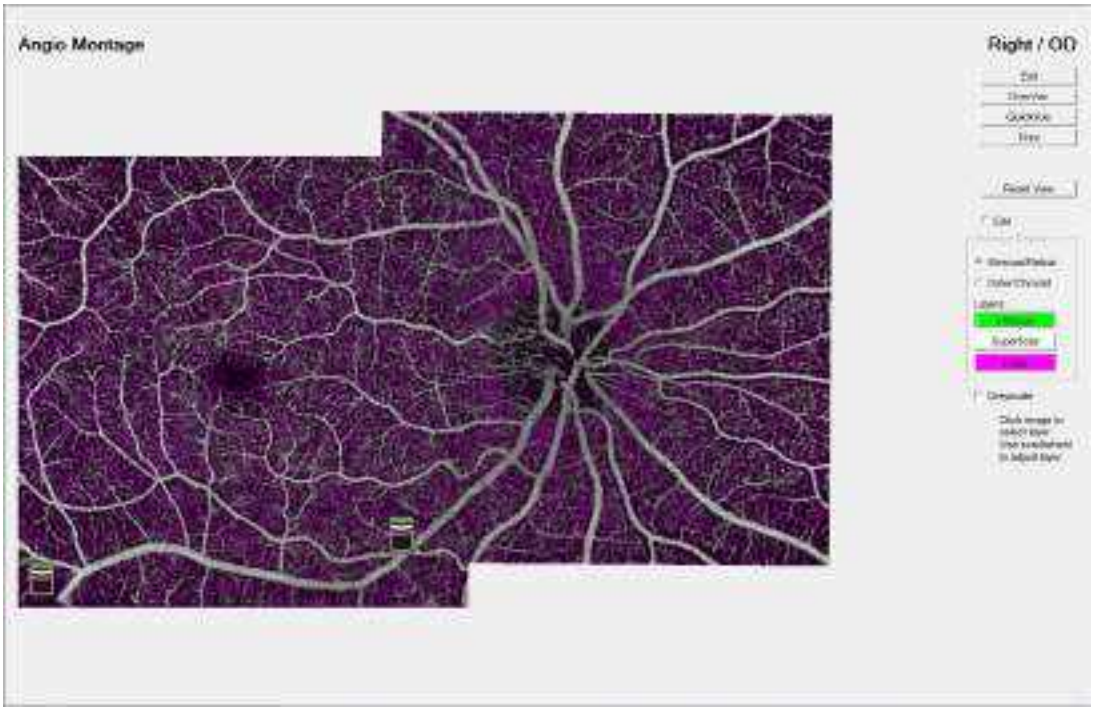


Figure 190 Montage showing Vitreous/Retina layers

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

Manual Adjustment of Enface Images

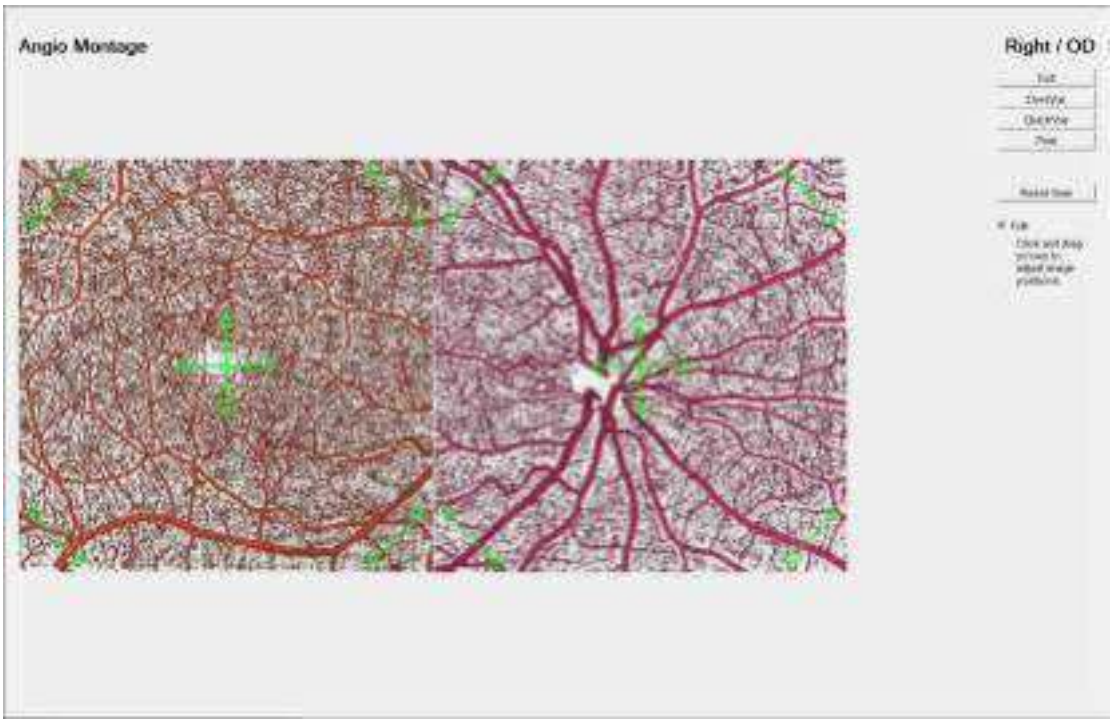


Figure 191 Montage Edit Screen

- **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**

Montage Controls

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

- **Exit:** Exits screen and goes to the main report.
- **OverVue:** Redirects to OverVue report
- **QuickVue**: Redirects to QuickVue report (6mm HD Angio Retina)
- **Print:** Prints the current display.
- **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

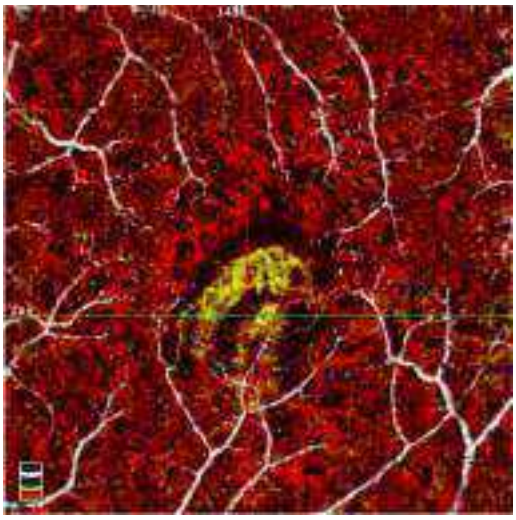
Auto Zoom: Selected by default, auto zoom applies to the B-scans shown. Clear checkbox to turn off auto zoom.

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

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 192 Example of Type 2 CNV

10.11.7 Angio Disc OverVue Report

When you begin review of an AngioDisc scan, the system displays an Angio Disc OverVue report.

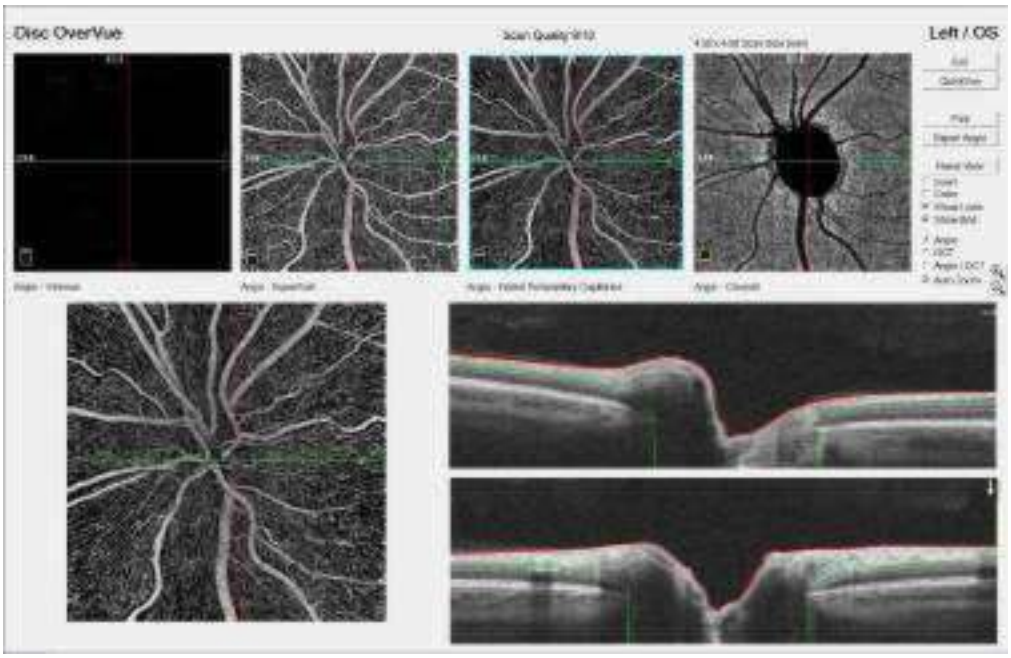


Figure 193 Angio Disc OverVue, Angio Selection

The default Disc OverVue is gray scale and includes:

- Across the top, four en face Angio slabs images at different depths are presented. Click any of the four images to display it at lower left. Click and drag the horizontal (green line) and vertical (red line) to show the corresponding horizontal and vertical B-scan images at lower right.
- At lower left, selected OCTA en face image is presented. If wider field OCT baseline image has been acquired, an OCT en face image overlaid with selected Angio en face image will display.
- At lower right, the currently selected horizontal and vertical B-scan images.

Use the **Patient**, **Visit** and **Scan** lists at left to select AngioDisc scans for review.

Angio Disc OverVue Controls

At upper right, the screen provides the following options.

Exit: Exits screen and goes to the main report.

QuickVue: en face and measurements display

Print: Prints the current display.

Export Angio: Exports the current display settings

Reset View: reverts display to original

Invert: Inverts the gray scale in the images.

Color: Displays images in color

Show Lines: Displays horizontal & vertical lines.

Show Bnd: Traces boundaries with colored lines.

Angio: Shows 4 AngioVue images.

OCT: Shows 4 OCT images.

Angio / **OCT**: Shows 4 AngioVue and 4 OCT images.

Angio Disc OverVue, Portrait Report

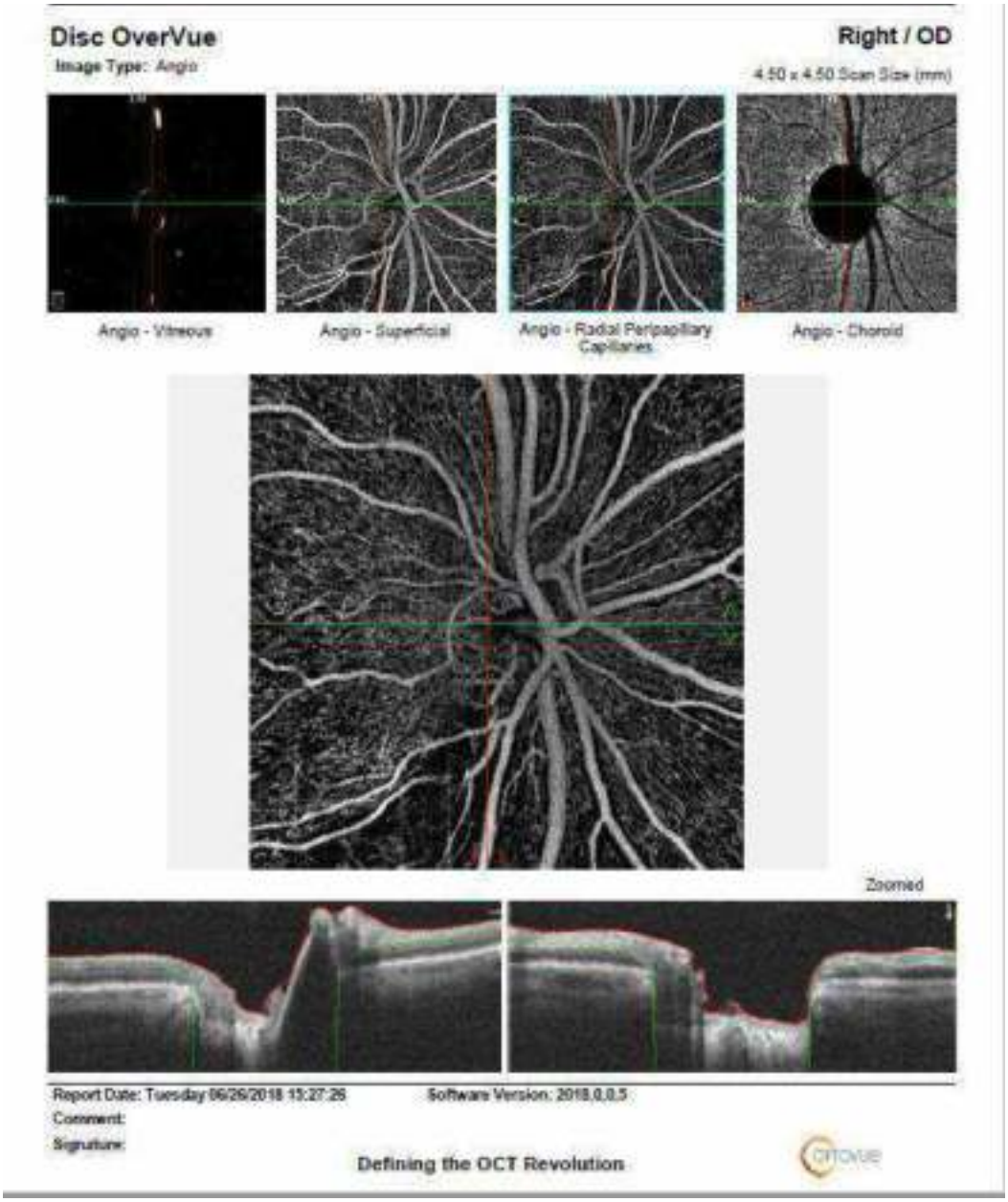


Figure 194 Angio Disc OverVue Report, Angio Selection, Portrait View

If you select the **Angio** / **OCT** radio button, the OverVue report shows four Angio slabs images and four OCT images at each depth, as shown below.

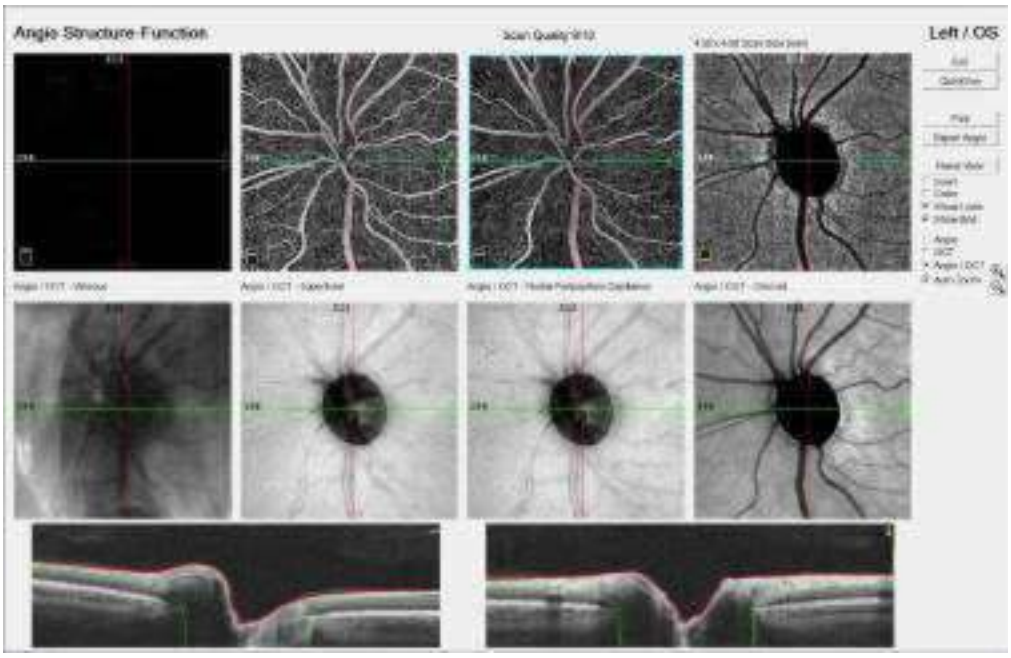


Figure 195 Angio Disc OverVue Report, OCT/OCTA Selection

10.11.8 Angio Disc Main Report

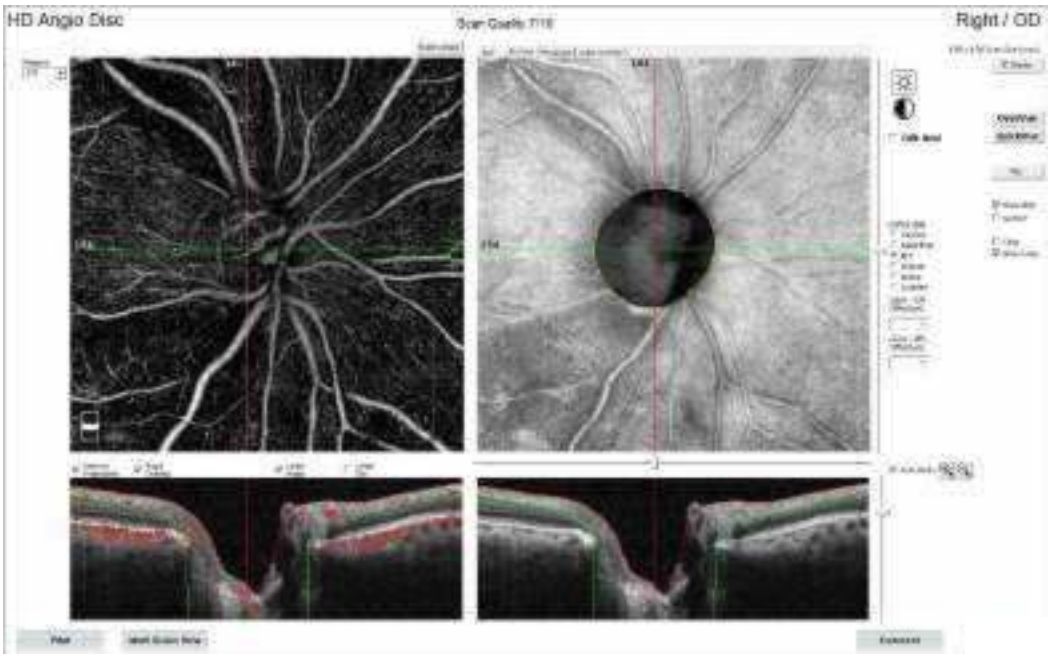


Figure 196 Angio Disc Main Report, En Face Tab Selected

The Angio Disc main report is the working report, which means that the options you select here affect display of the OverVue, QuickVue and other report. The Angio 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.

Angio 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.

OverVue: Return to the OverVue screen.

QuickVue: en face and measurements display (with AngioAnalytic 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.

Top Center Image Tabs

Thickness Tab

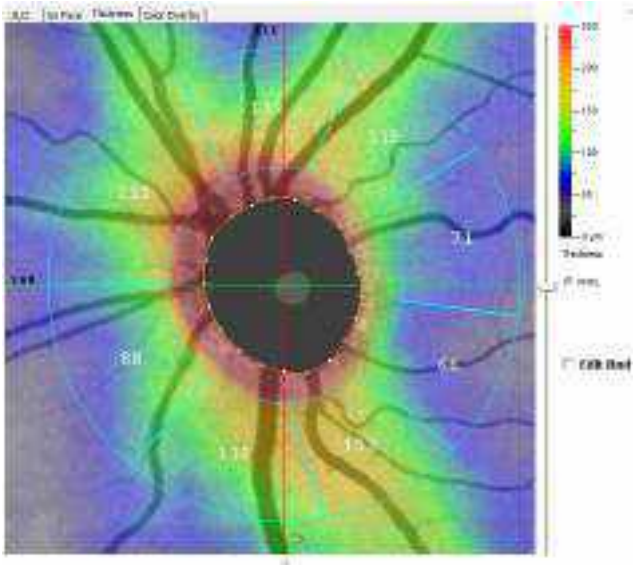


Figure 197 Angio Disc Central Image Tabs

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™ license enabled). There is also an outline of cup/disc. The cup/disc measurement uses Bruch's membrane opening (BMO) as the determining reference plane (see Section 11.4.1).
- **Color Overlay**: allows static or movie color presentation

 Note: This is different than the previous structural only scans which use BMO plus 150µm anterior shift as reference plane. See Section 11.4.2.

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.

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 AngioRetina 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.

SLO Tab

The figure below shows Angio 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 (see Section 10.8)

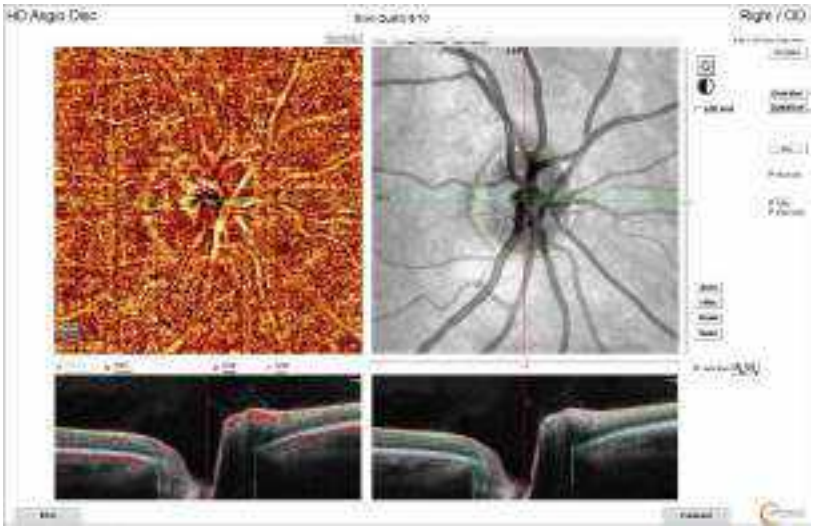


Figure 198 Angio Disc Main Report, SLO Tab with Color Selected

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.

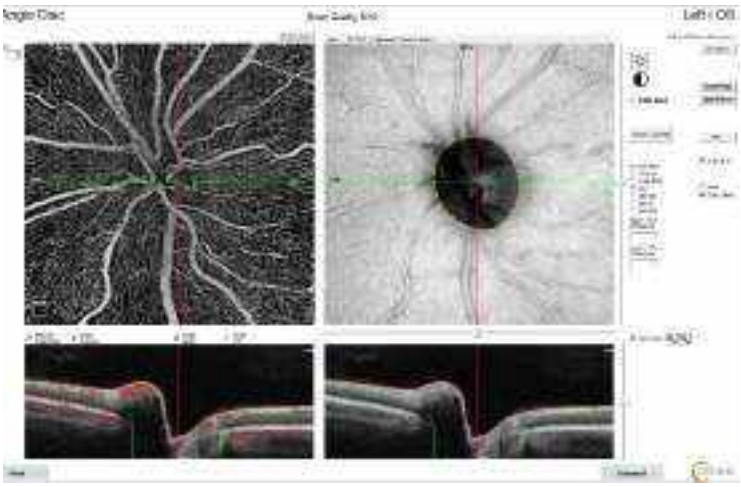


Figure 199 Angio Disc Main Report, En Face Tab Selected

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.

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.

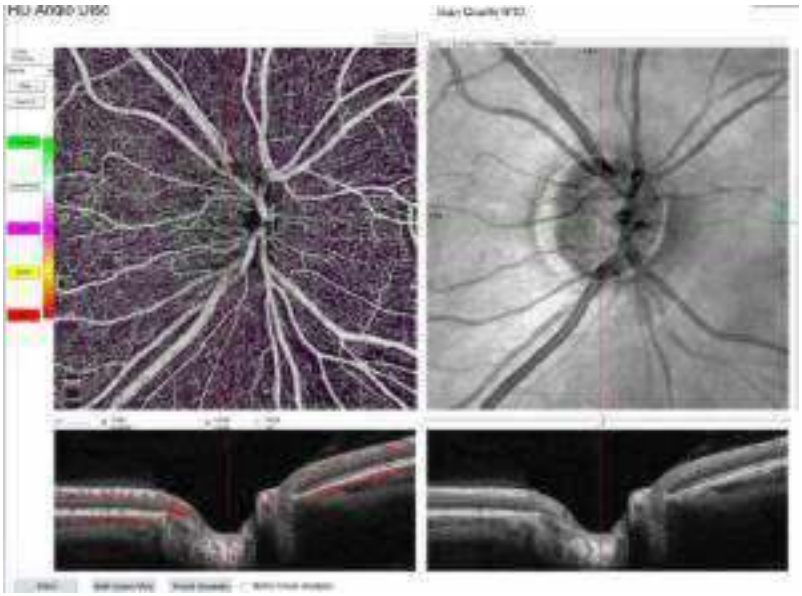


Figure 200 Angio Disc Main Report, Color Overlay Tab with Movie Selected

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.

10.11.9 Angio 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. If AngioAnalytics™ license is activated, vessel density for RPC slab can be displayed.

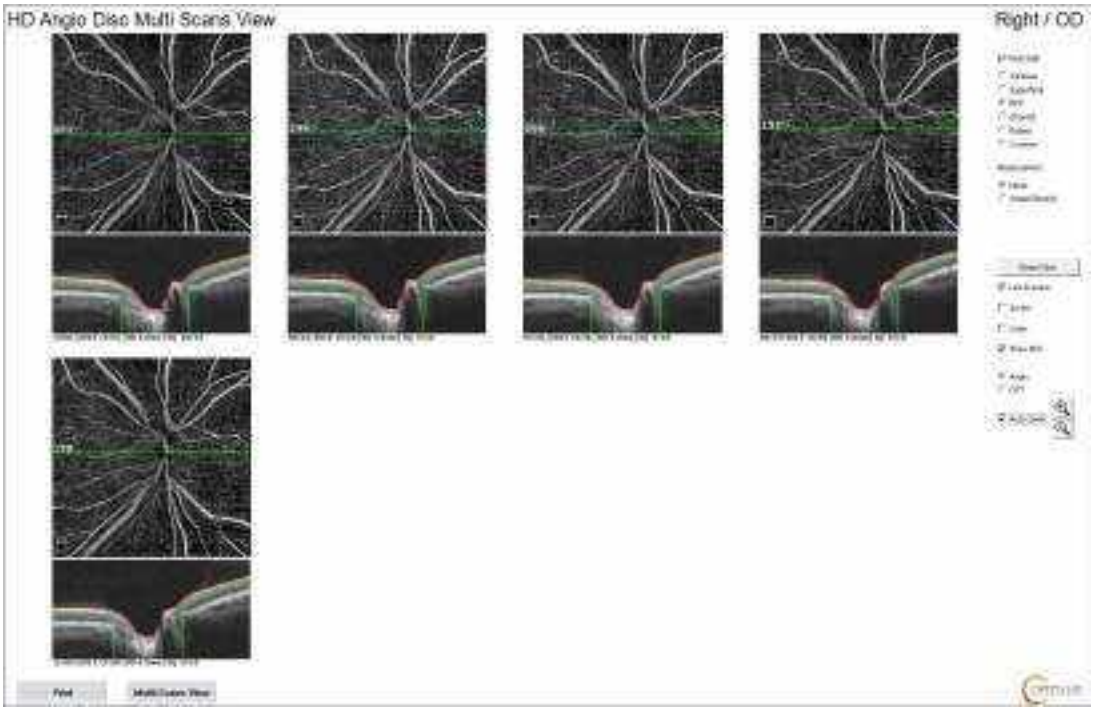
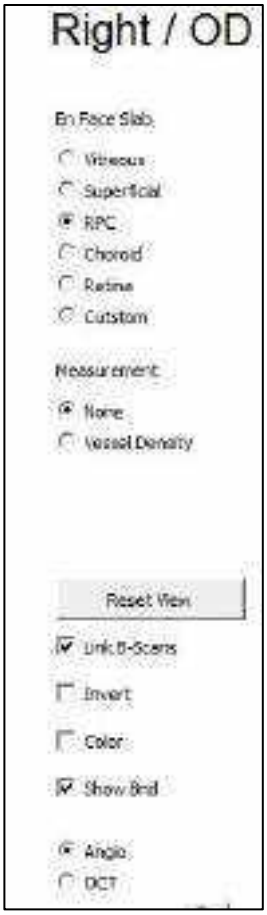


Figure 201 Angio Disc Multiple Visit Report

Angio 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

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 **Angio** or **OCT** images for comparison.

11 AngioAnalytics™

AngioAnalytics™ is a licensed upgrade that enables measurement of retinal vessel density, FAZ, flow area and non-flow area as well as retinal layer thickness to the 3 mm Angio Retina and 6 mm HD AngioRetina scans. It also enables the measurement of RPC density and RNFL thickness and optic disc measurements for 4.5 mm HD AngioDisc scans.

This measurement functionality is available in the Angio Retina and Angio 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 Multiscan 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. Due to the difference in sampling density between the 3 mm AngioRetina scan and the 6 mm HD AngioRetina scan, the vessel density measurements between the 2 scans of the same eye are not interchangeable.

Optic disc parameters (e.g., cup area, cup volume, rim area, rim volume, and cup-to-disc ratio parameters) derived from the 4.5 mm HD AngioDisc scans are based on the BMO plane, while the corresponding measurements derived from the ONH scan are based on BMO plane with 150 µm anterior shift. Therefore, these two sets of measurements are not interchangeable.

The device software also allows for structural measurements from both the 3 mm AngioRetina scan and the 6 mm HD AngioRetina scan. Measurements include Full Retina thickness, Inner Retina thickness, and Outer Retina thickness based on the scan area, with measurements for the central 3 mm available in both scans.

Comparison of the Inner Retinal thickness of the 6 mm HD AngioRetina scan to the GCC thickness of GCC scan, and comparison of the RNFL thickness measurements and optic disc parameters between the 4.5 mm HD AngioDisc scan and the ONH scan are provided in Table 19 of Appendix E.

11.1 Angio Retina vs GCC Scan Thickness

Caution: The analysis region of the GCC scan is offset 1 mm temporally while the analysis region of the AngioRetina scan is centered over the fovea. Therefore, be advised that GCC measurement values (the parameters GCC Average, GCC Inferior Average, and GCC Superior Average) from the AngioRetina scan are not interchangeable with those of the GCC.

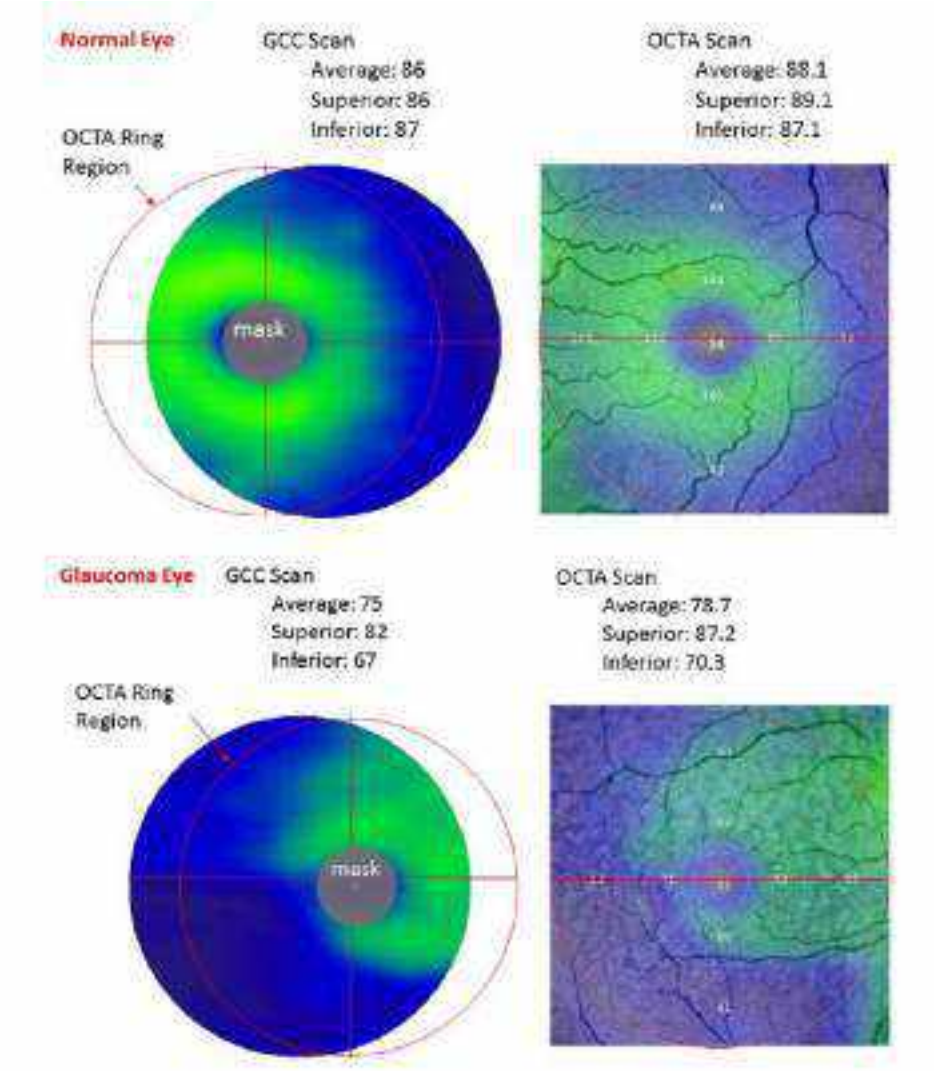


Figure 202 Angio Retina vs GCC Scan Comparison

11.2 AngioAnalytics™ Composition

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

11.2.1 Angio Retina

- AngioRetina scan segmentation (8-layer)
- Automatic fovea center detection.
- Measurements of the vessel density within AngioRetina 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
- Flow and Non-Flow tool

> Note: AngioRetina 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.

11.2.2 Angio Disc

- AngioDisc scan segmentation (7-layer)
- Automatic optic disc margin detection
- Measurements of the vessel density within AngioDisc 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.

11.2.3 Scan Centering and AngioAnalytics Measurements

AngioRetina scans should be centered on the fovea and AngioDisc 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”

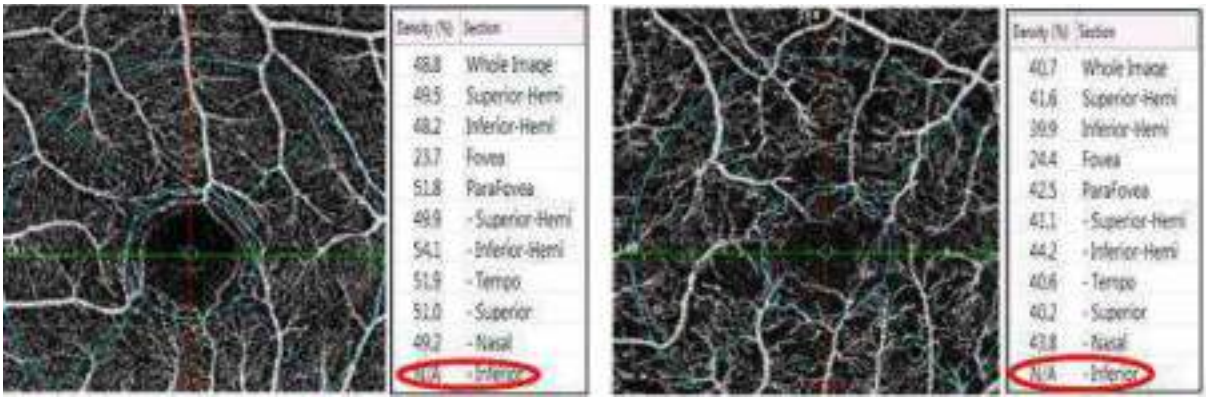


Figure 203 Sector Crop >30% Marked NA

11.3 Angio Retina Analytics

11.3.1 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.

11.3.2 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.

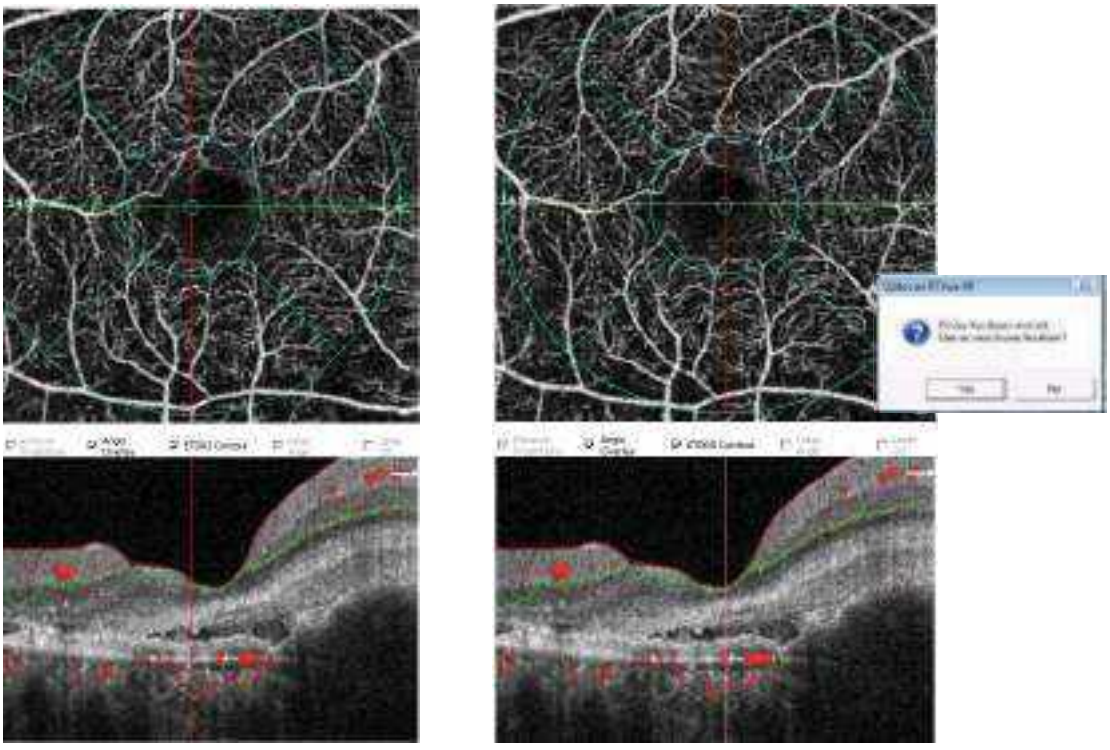


Figure 204 Grid centration

Left - ETDRS grid is not precisely centered on fovea on this 3 mm AngioRetina 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

11.3.3 Angio Retina Measurement Zones and Parameters

Below is schematic presentation of the measurement zones and their report nomenclature for the 3.0mm Angio Retina and 6.0mm HD AngioRetina scans.

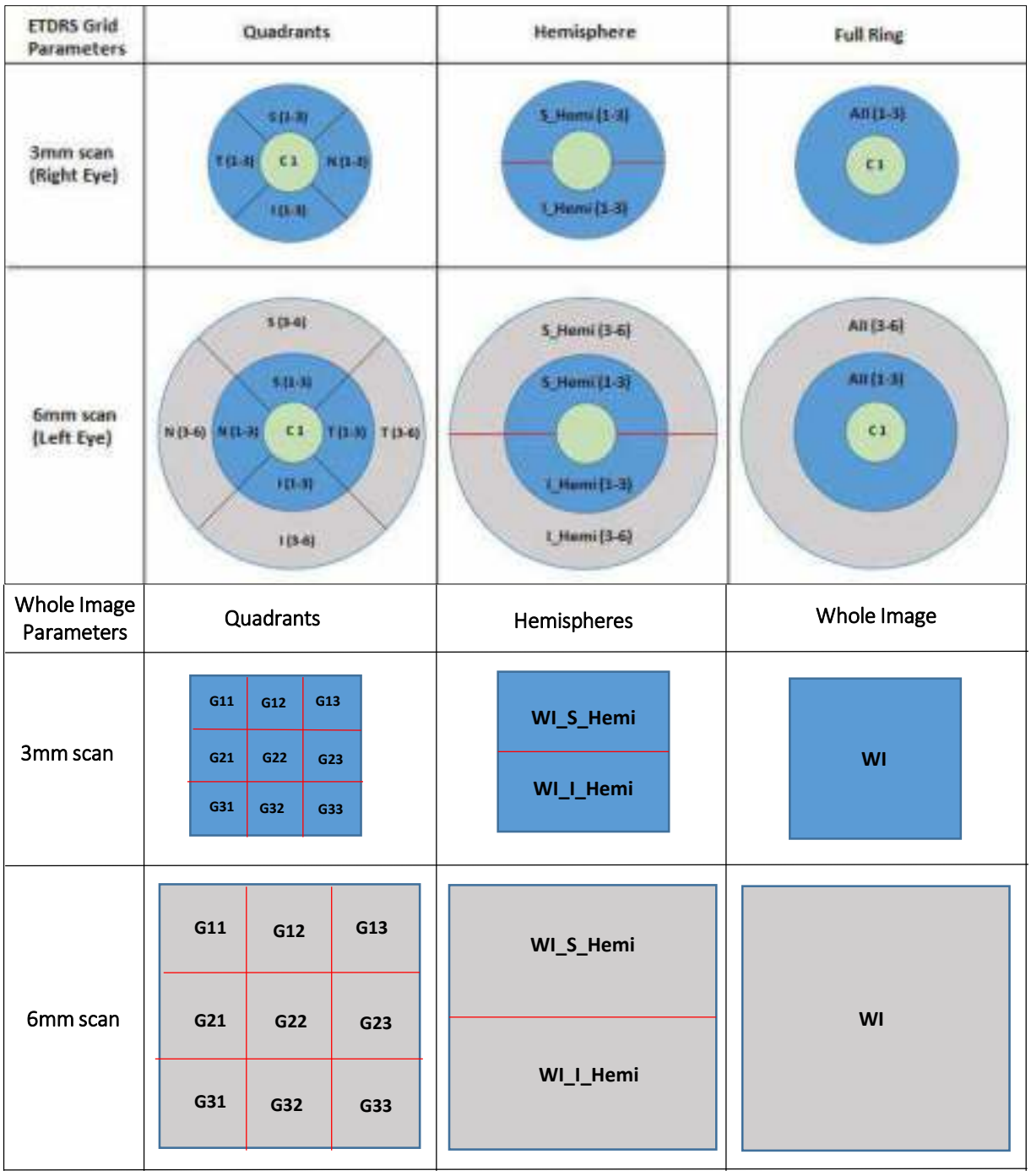


Figure 205 Angio Retina Measurement Zones and Parameters

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. Right (3 mm partial ETDRS grid) and 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.

As shown in Appendix E, tables 21~24, comparing the full retina thickness and inner retina thickness measurements in the fovea and para-fovea zone between the 3 mm AngioRetina scan and 6 mm HD AngioRetina scan, the mean of differences does not exceed 1µm and the Deming regression analysis slope ranges from 0.99 to 1.03.

The retina layers thickness measurements from the OCTA scan are similar to those of the Retina map scan within the ETDRS grid, centered on the fovea. For full retinal thickness, the mean thickness difference between the scans is -1.7 µm for fovea center, 3.8 µm for inner (para fovea) zone, and -4.7 µm for outer (peri fovea) zone. For information relating the Inner retinal thickness of 6 mm HD AngioRetina scan and the GCC scan thickness, and the RNFL thickness measurements and optic disc parameters see reference (Appendix E Tables 19 and 20).

11.3.4 Angio Retina Vessel Density and Retinal Thickness

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

☞ Note: that vessel density measurements from the 6 mm HD AngioRetina scans are not interchangeable with those of the 3 mm AngioRetina scans because of the differences in sampling density between the two scan patterns. Therefore, when assessing for change in measurement values from successive scans over time, the same scan pattern should be used in follow-up.

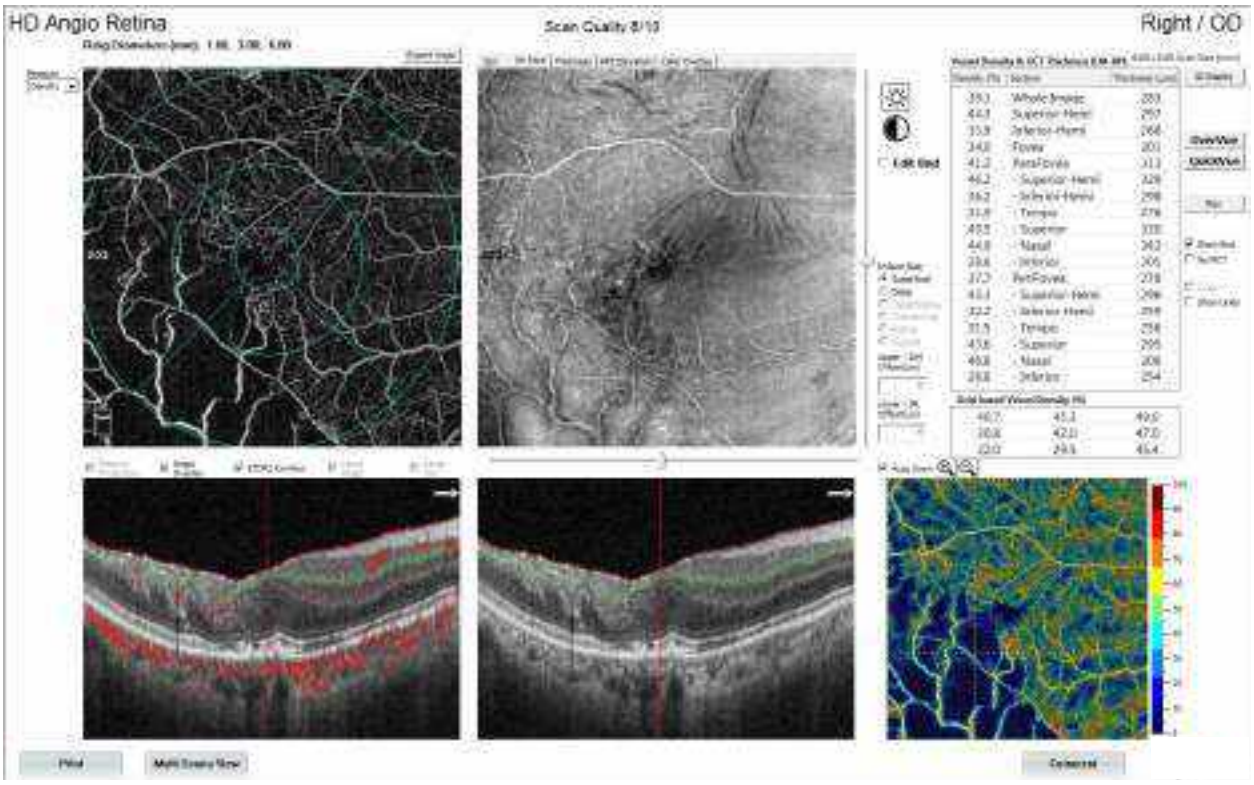


Figure 206 6 mm HD Angio Retina, Main Report

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.

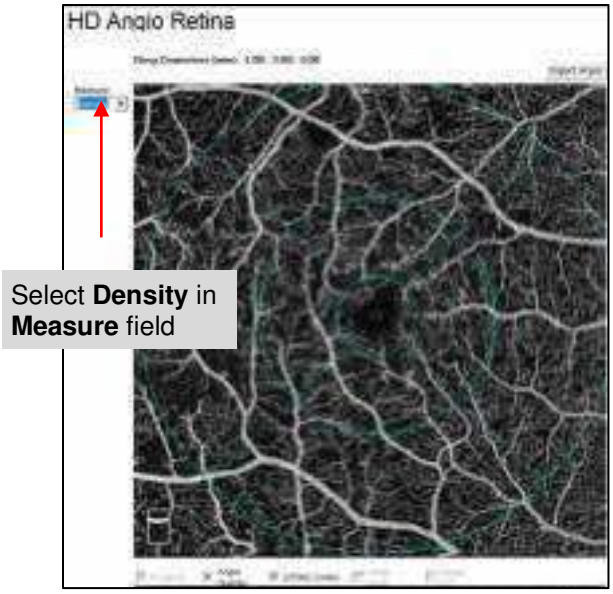


Figure 207 Measurement Window Slection

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 (Section 16.2) 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). Refer to Section 11.3.4 and 11.4.5 for more information on the vessel density measurement feature.

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 Angio image indicates the sections measured.

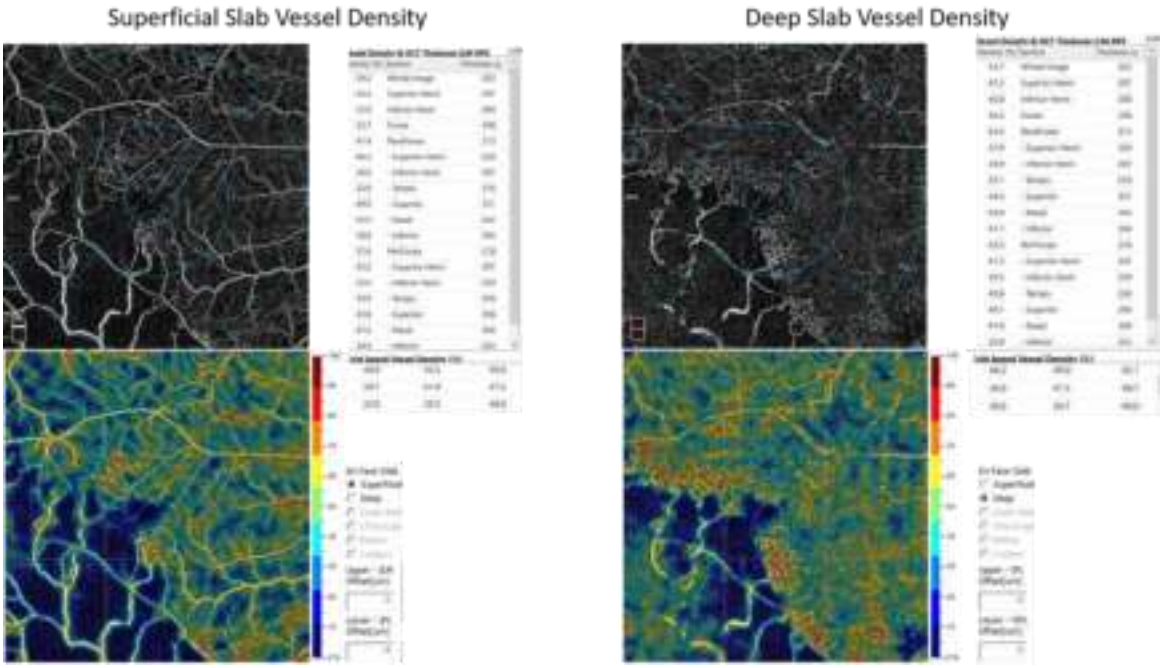


Figure 208 Superficial and Deep Vessel Density Measurements

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.

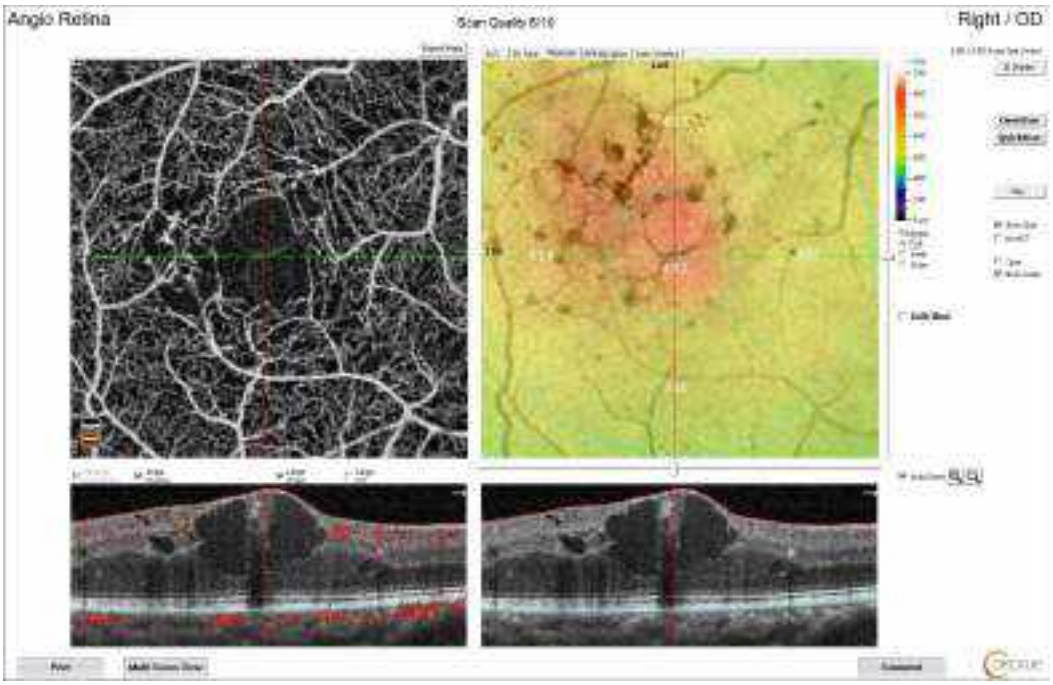


Figure 209 Angio Retina Main Report, Thickness Tab with Full Retina Thickness Selected

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

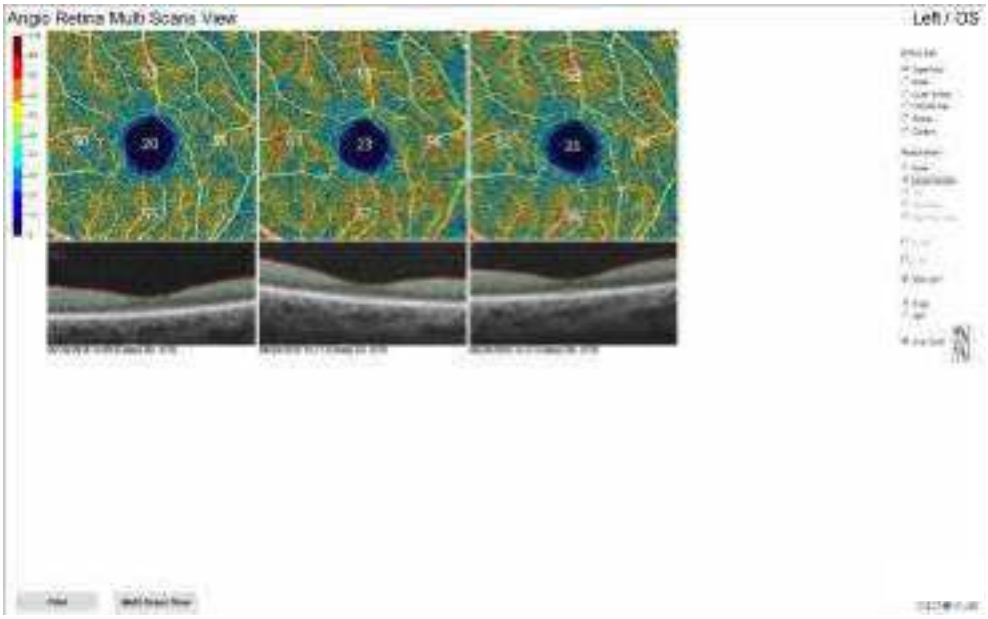


Figure 210 Retina Multi Scan Showing Superficial Density

11.3.5 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 AngioRetina 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.

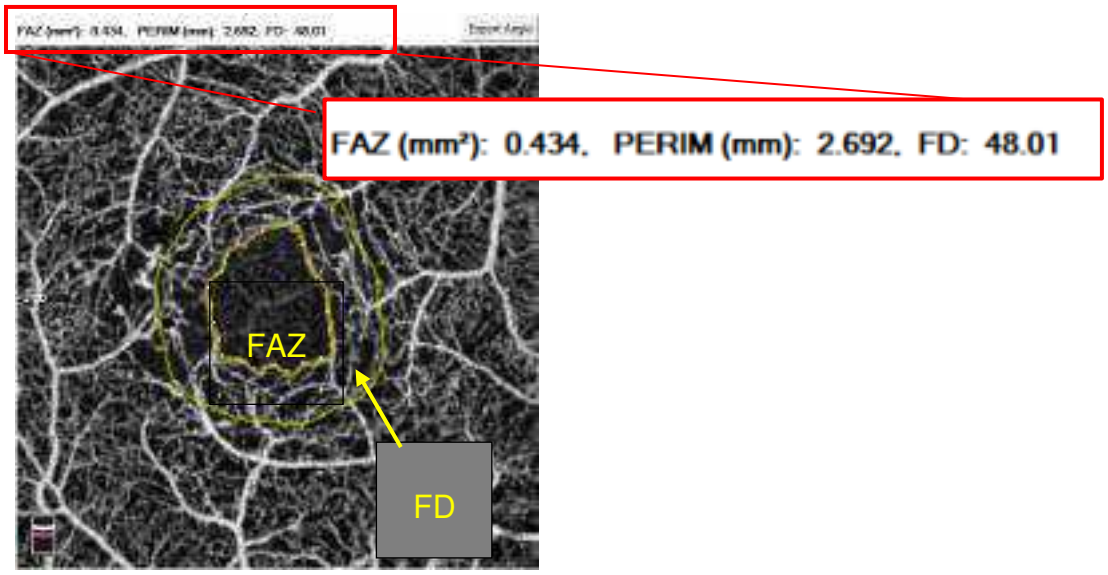


Figure 211 FAZ Parameters

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.

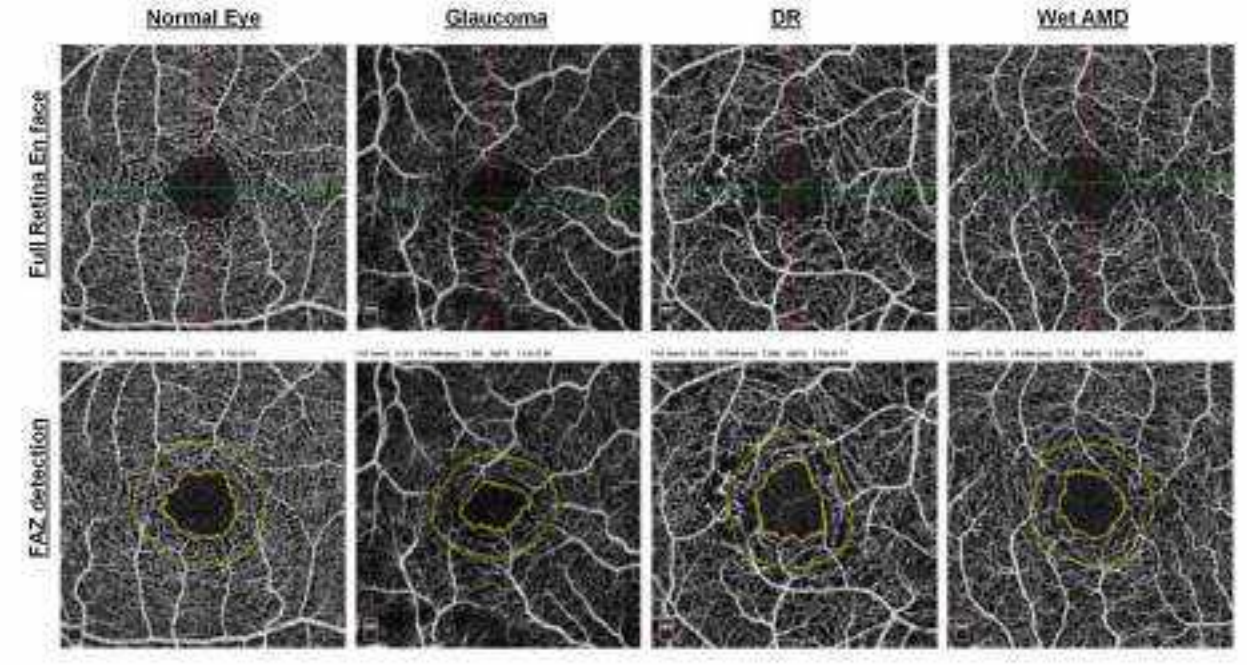


Figure 212 Examples of FAZ Detection based on Angio Retina 3mmx3mm scan.

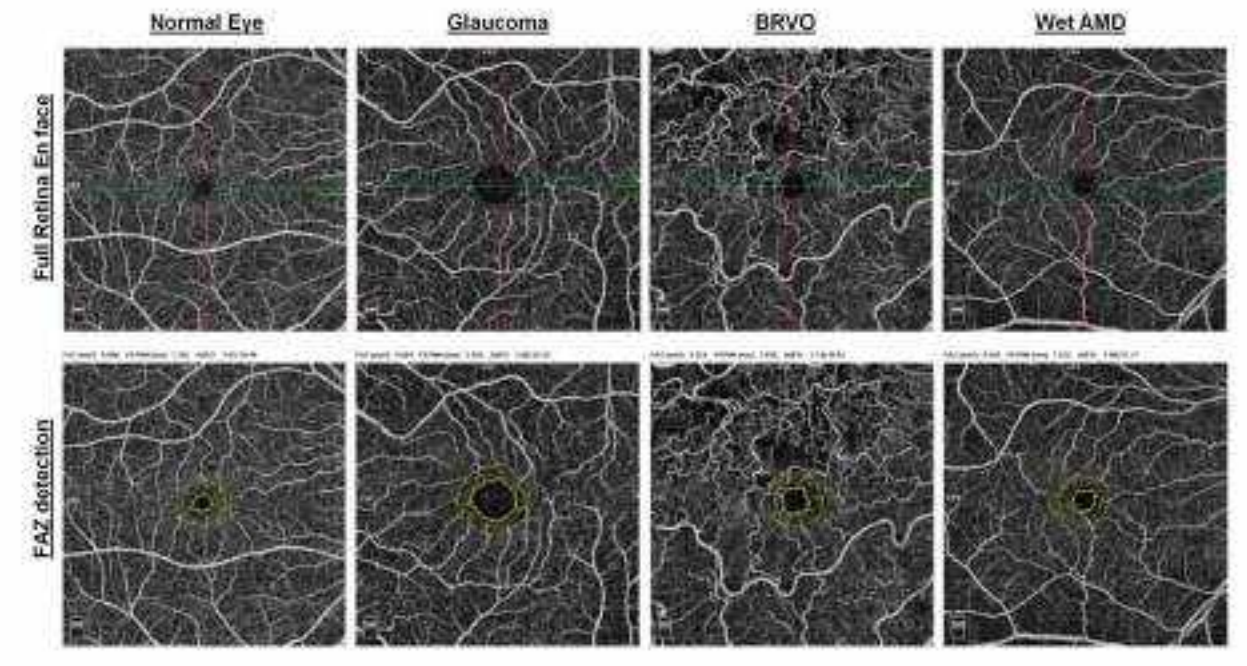


Figure 213 Examples of FAZ Detection based on Angio Retina HD 6mmx6mm scan.

The comparison between the 3 mm AngioRetina scan and the 6 mm HD AngioRetina scan for the FAZ measurements (FAZ area, FAZ Perimeter, and FD-300 vessel density) is provided in Appendix E, Tables 18a and 18b. There is a difference of

approximately 2.5% on average in FD-300 vessel density measurements between the 2 scan patterns.

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

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.

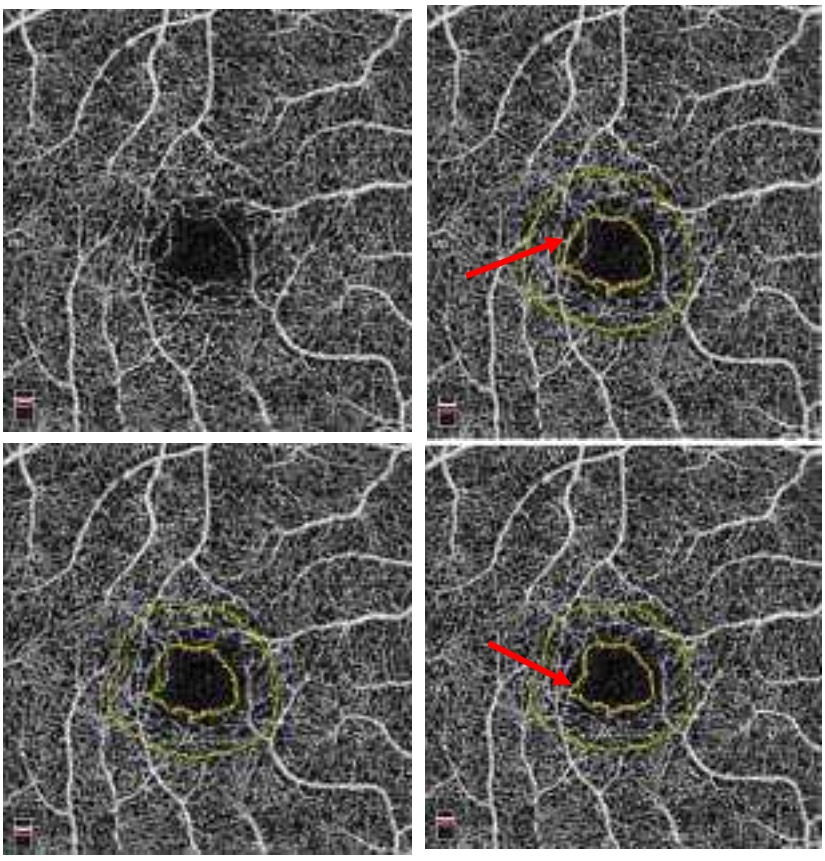


Figure 214 FAZ Editing

Upper left – Retina slab (ILM to OPL+10) of 3 mm AngioRetina 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 Multiscan reports.

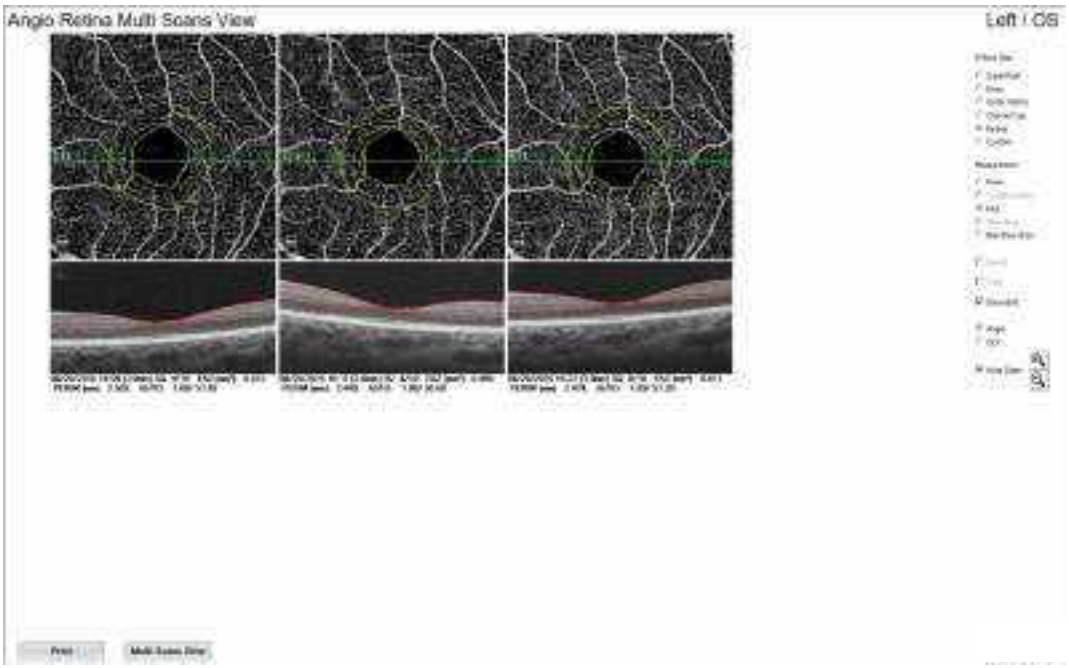


Figure 215 FAZ Multiscan Report

11.3.6 Angio Retina QuickVue Report

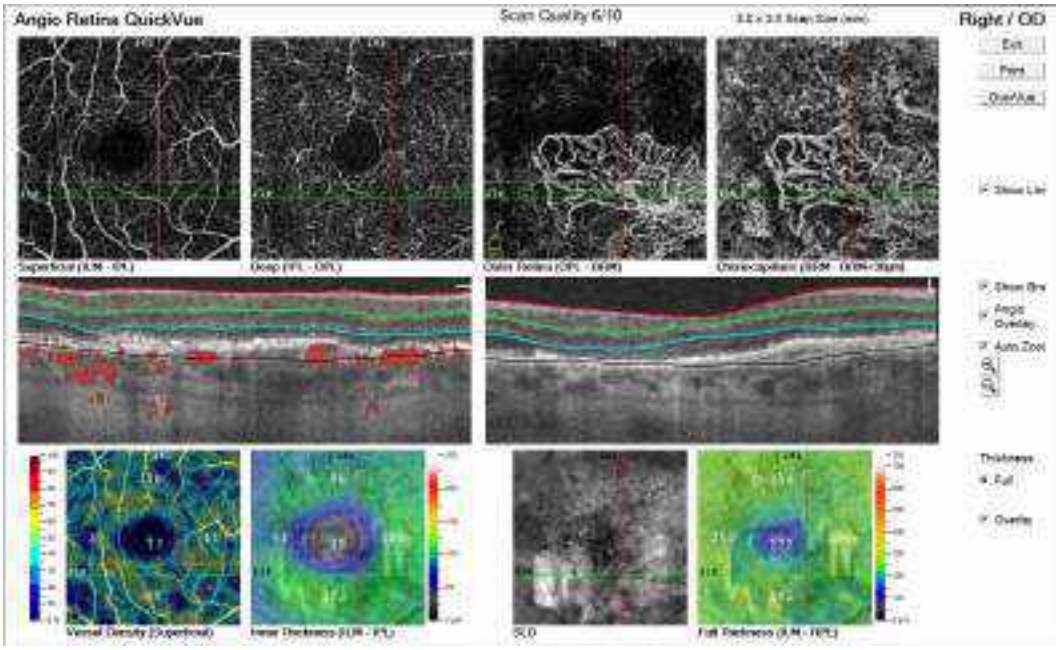


Figure 216 6 mm HD AngioRetina, QuickVue Report

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 Superficial Vessel Density, Inner Retina Thickness, SLO like image and Full Retina thickness map.

11.3.7 Angio Retina Trend Report

The purpose of Angio Retina Trend report is to provide the user with evaluation of rate of change in AngioAnalytics global parameters that are available for AngioRetina 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.

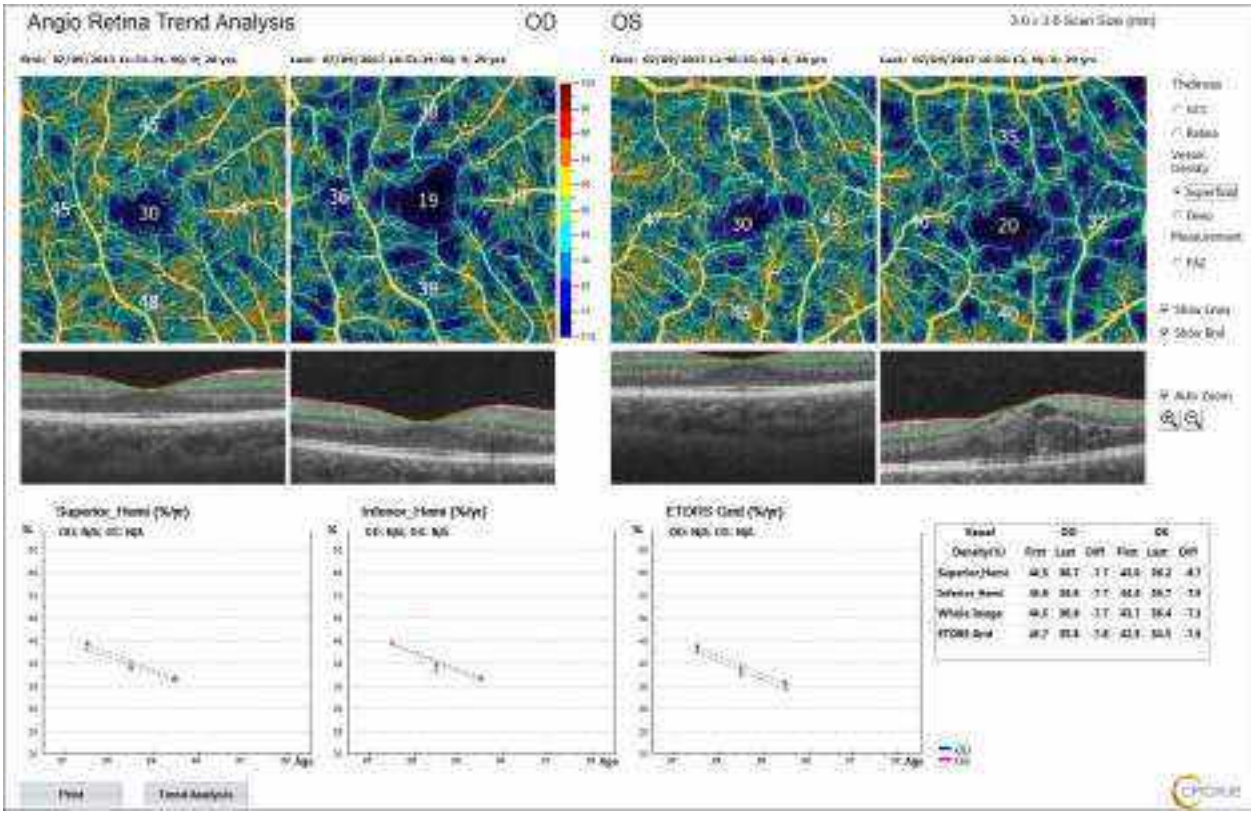


Figure 217 Angio Retina Trend Report, Superficial Vessel Density selected.

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.

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.
2. Look at the confidence interval of the estimated rate between brackets on the report (provided if at least 5 visits are available):
    a. if zero value is included in the confidence intervals, the trend may not be different from zero
    b. if zero value is not included in the confidence intervals, there is likely a change; check the estimated rate of change for clinical significance

11.3.8 Flow

Flow area measurement is based on AngioRetina 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.

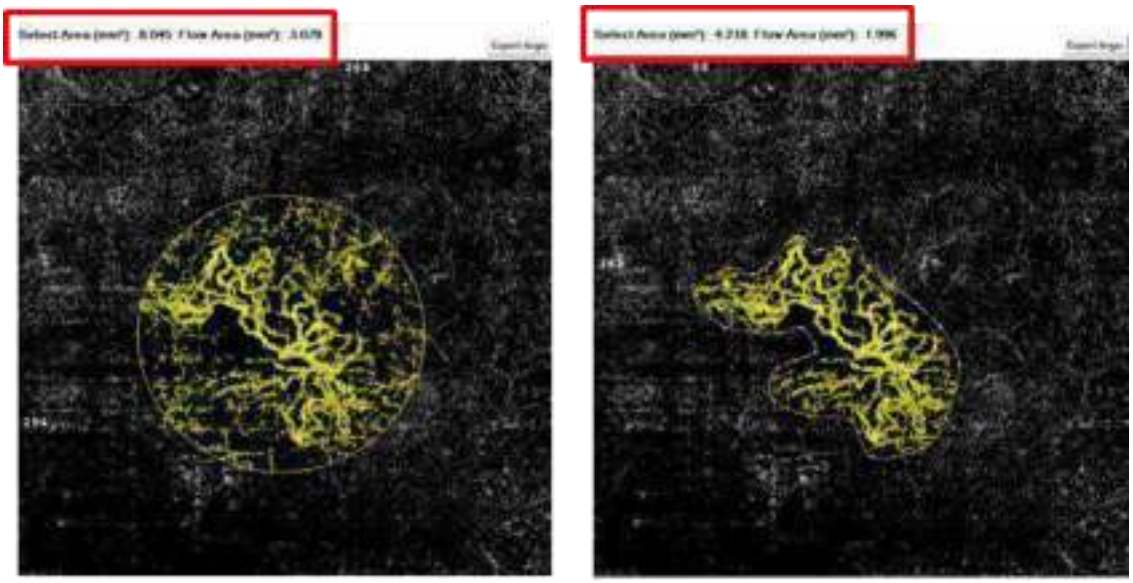


Figure 218 Flow

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

Flow Tool Use

Go to "**EnFace**" 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

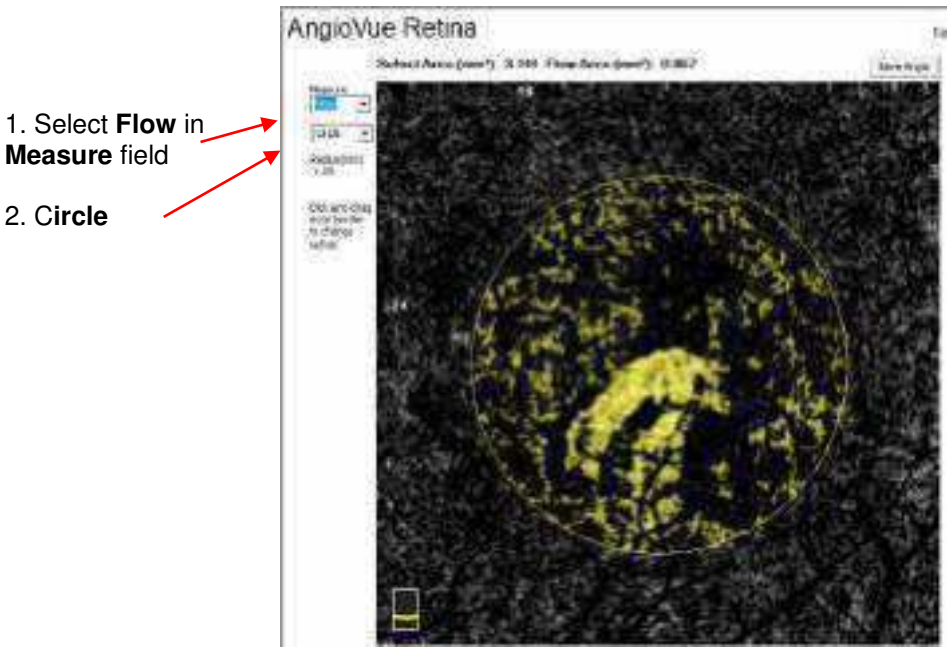


Figure 219 Circle Flow

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.

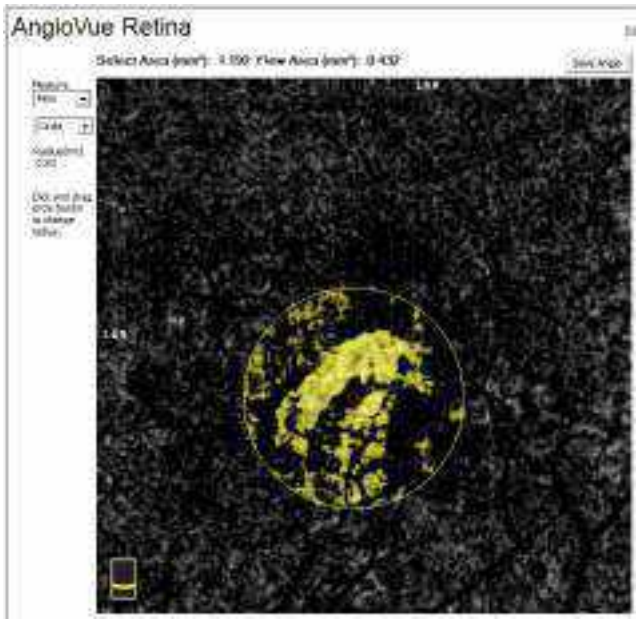


Figure 220 Circle Flow, Moved and Reduced

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.

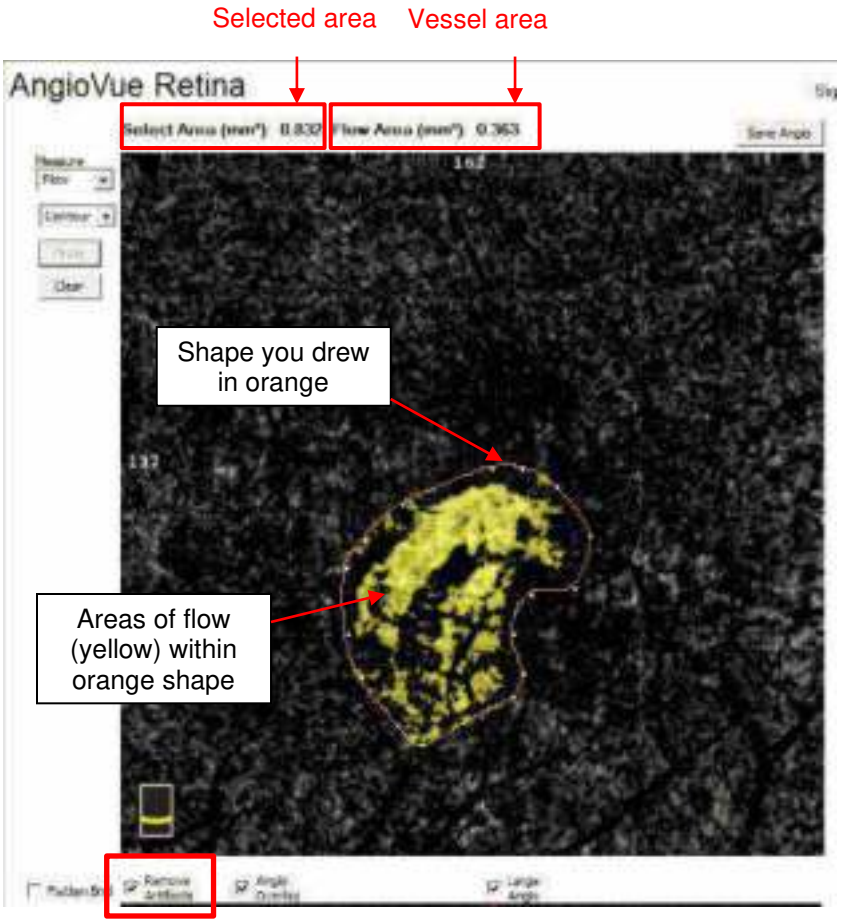
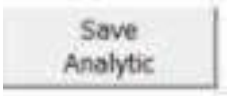


Figure 221 Contour Area of Flow Highlighted Yellow and Measured

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 Multiscan reports review.

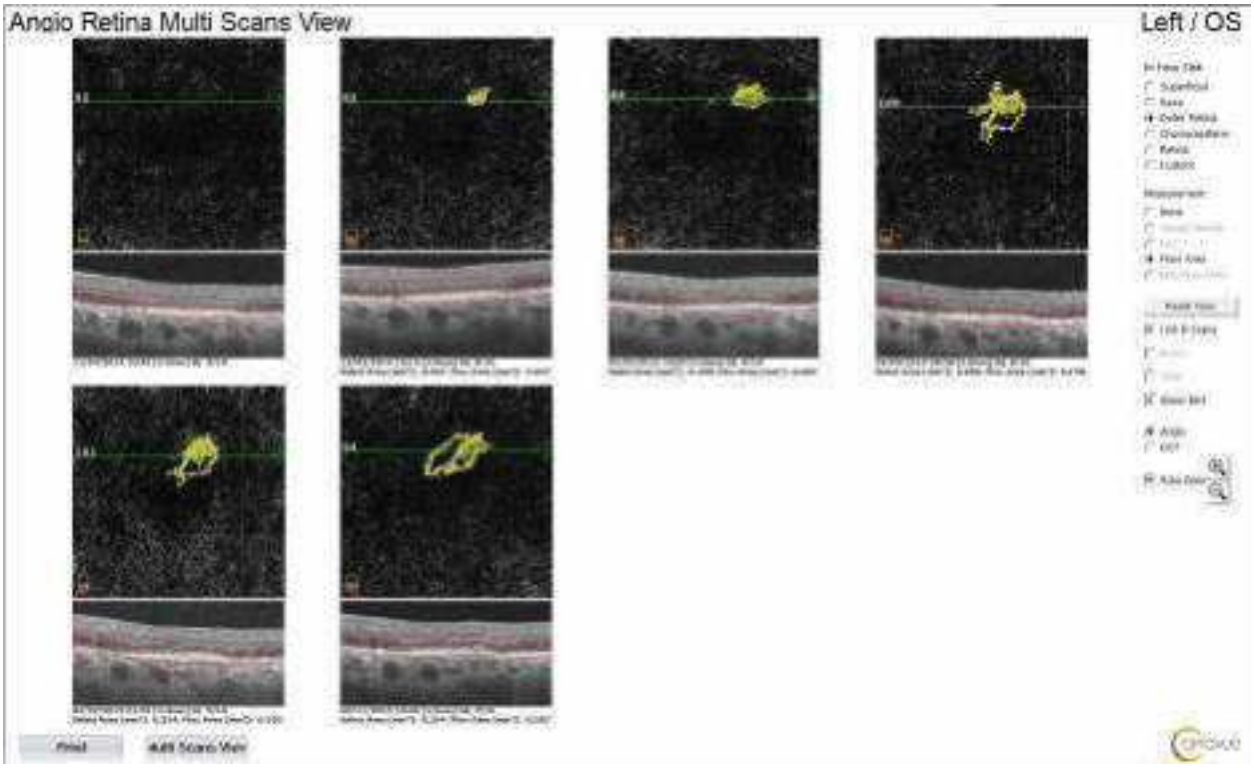


Figure 222 Angio Retina Multiscan Report, Outer Retina Slab and Flow Selection

11.3.9 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.

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.

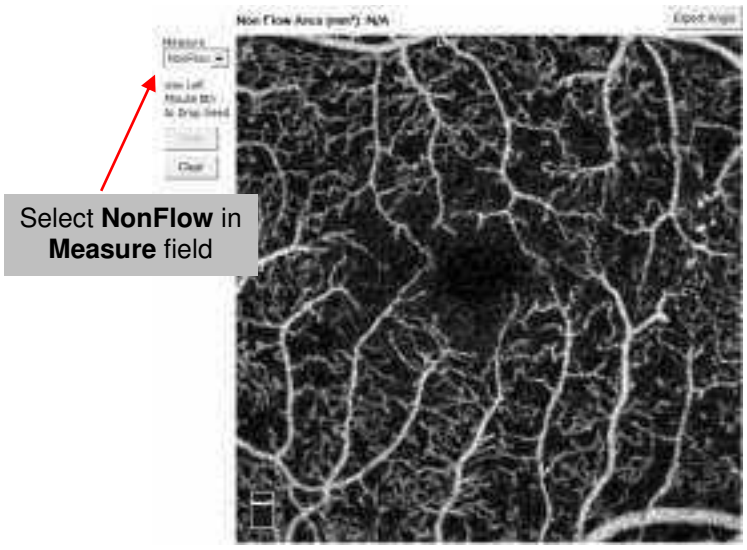


Figure 223 Select NonFlow in Measurement Window

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.

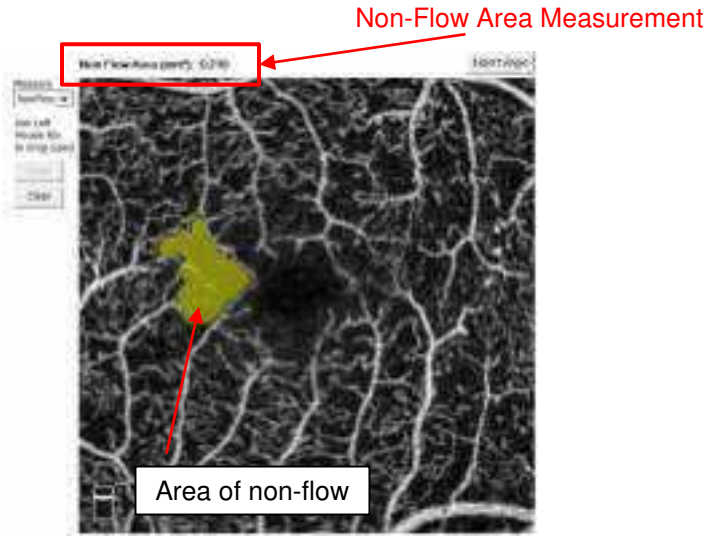


Figure 224 Area of Non-Flow Highlighted Yellow and Measured

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.

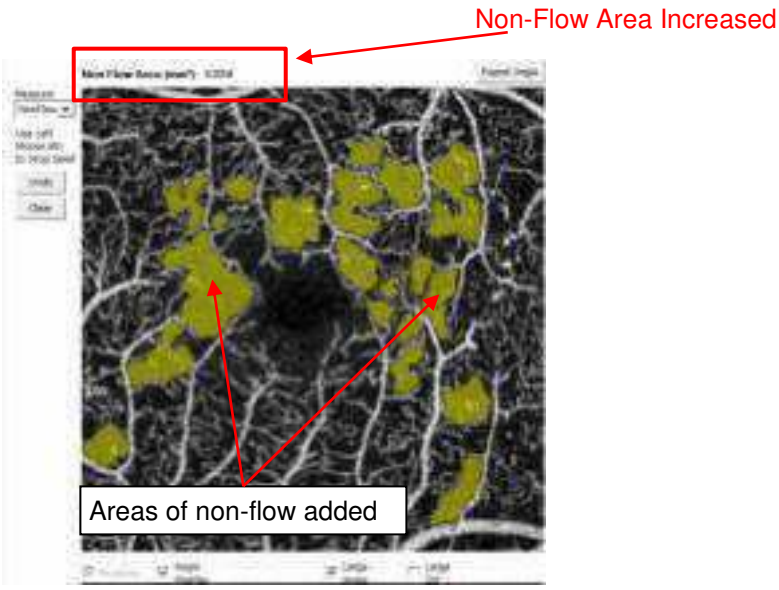


Figure 225 Additional Non-Flow Areas Selected and Measured

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 Multiscan reports review.

11.3.10 Information Display for Saved Analytics Result

The Review Scan list shall display information regarding saved Analytics results

F = Flow measurement

NF = NonFlow Measurement

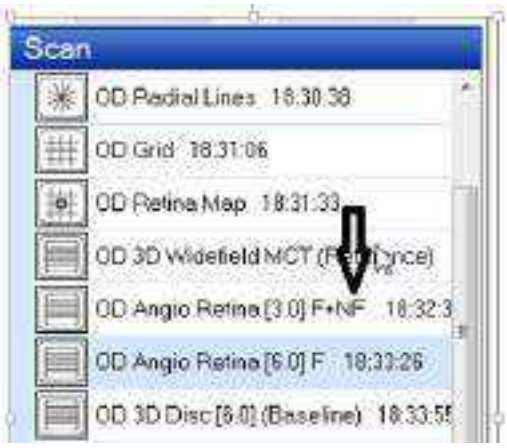


Figure 226 Flow and NonFlow Indicators on the Scan List

11.4 Angio Disc Analytics

Angio Disc enables the measurement of RPC density and structural thickness values of RNFL for 4.5 mm HD Angio Disc.

11.4.1 Optic Disc Parameters

The following parameters are provided based on 3D OCTA intensity images of the disc, derived from RNFL slab of the 2~4 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)
- ✓ CupArea (mm^2)
- ✓ CupVolume (mm^3)

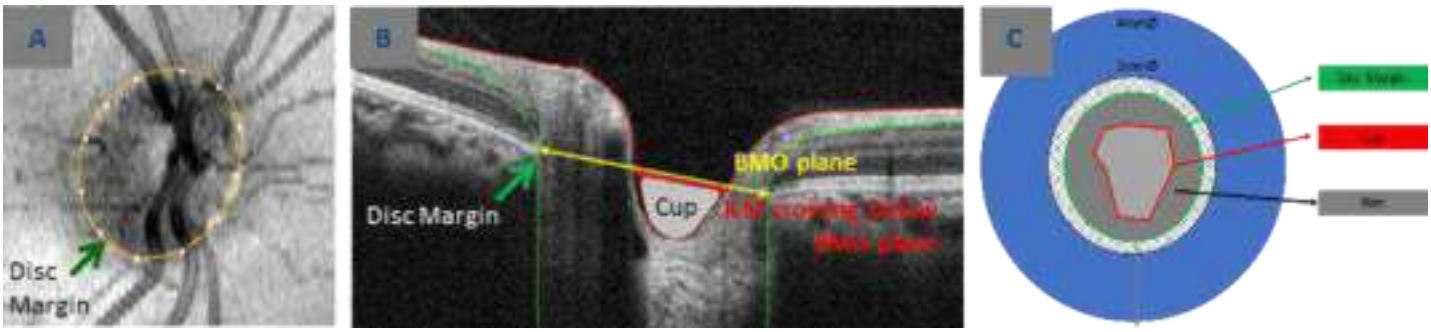


Figure 227 Disc Parameters

For AngioDisc 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.

11.4.2 Comparison of Optic Disc Parameters Between OCT and OCTA Scans.

The differences in optic disc parameters are predominantly due to the shift in the disc analysis plane, as illustrated in the example below. The parameters of the ONH scan are measured from the plane 150 microns anterior to BMO while the parameters of the AngioDisc scan are measured from the BMO plane without any offset, and as expected, the cup will be smaller with the AngioDisc scan.

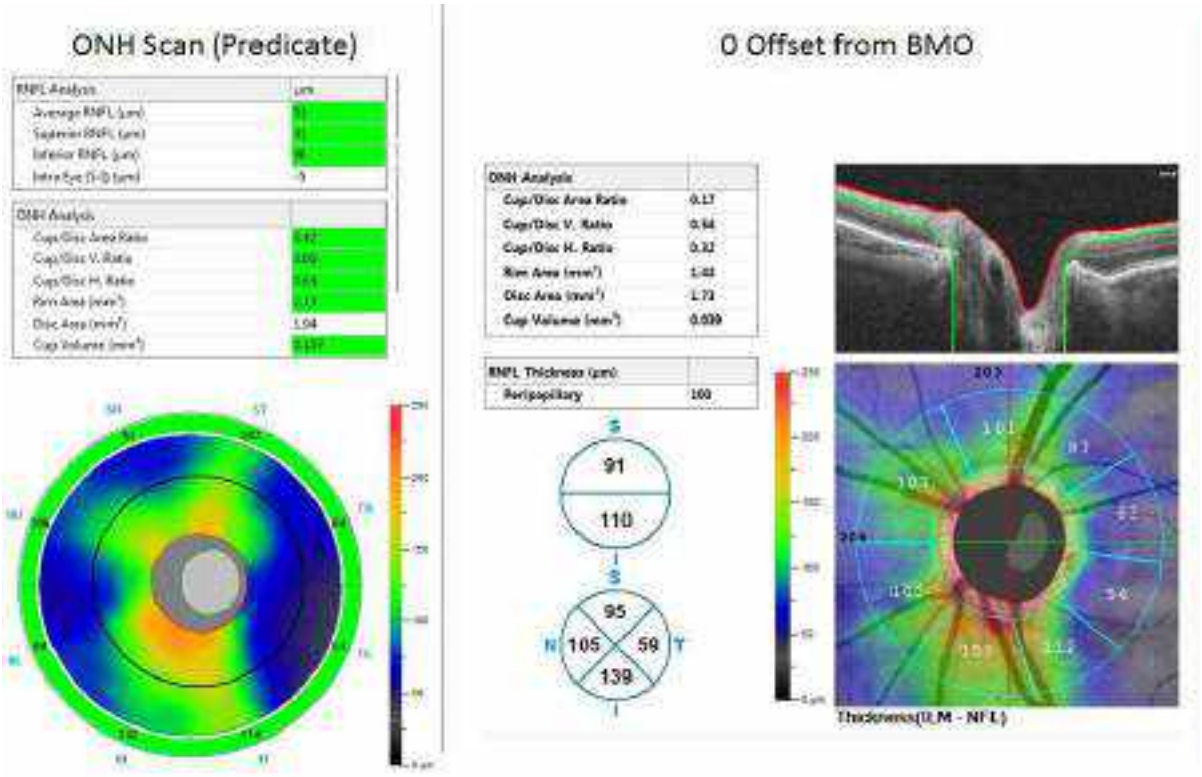


Figure 228 Disc Parameters Comparison between ONH OCT and AngioDisc Scans

11.4.3 Angio 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.

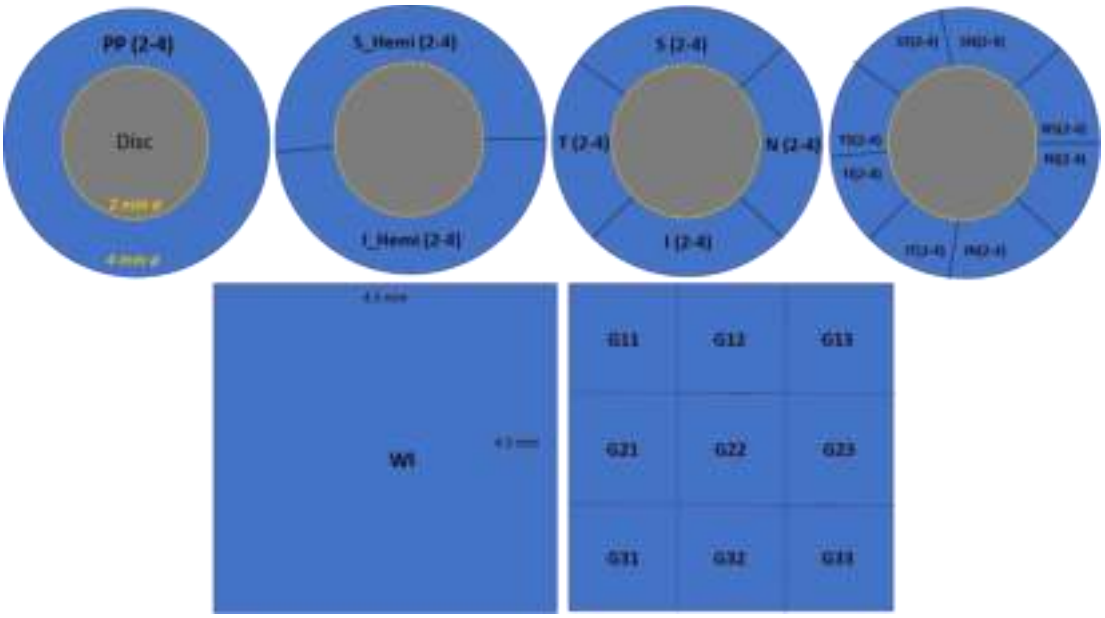


Figure 229 Angio Disc Measurement Zones and Parameters

Schematic presentation of the peripapillary grid and grid sectors naming for the left eye. Peripapillary region is defined by two rings of 2mm and 4mm 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 4.5X4.5 mm of disc scan. Right - 9 sectors grid

11.4.4 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.

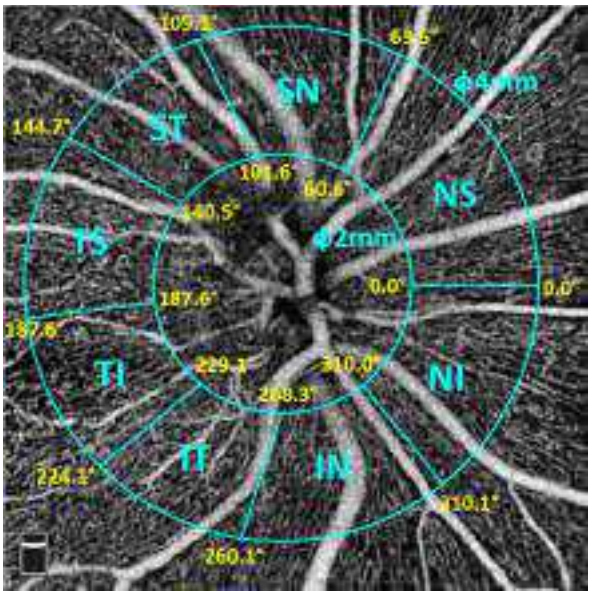


Figure 230 Eight Sector Peripapillary Grid

The eight sectors grid overlaid on and 4.5 mm HD Angio Disc *En Face* RPC Slab.The inner circle has a diameter of 2 mm and the outer circle has a diameter of 4 mm.

11.4.5 Angio 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 HD Angio Disc main report below with **EnFace** tab and **Density** measurement selected shows an OCTA image with peripapillary grid overlayed on RPC slab, a structural image with SLO, EnFace, Thickness, and Color Overlay tabs with EnFace 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.

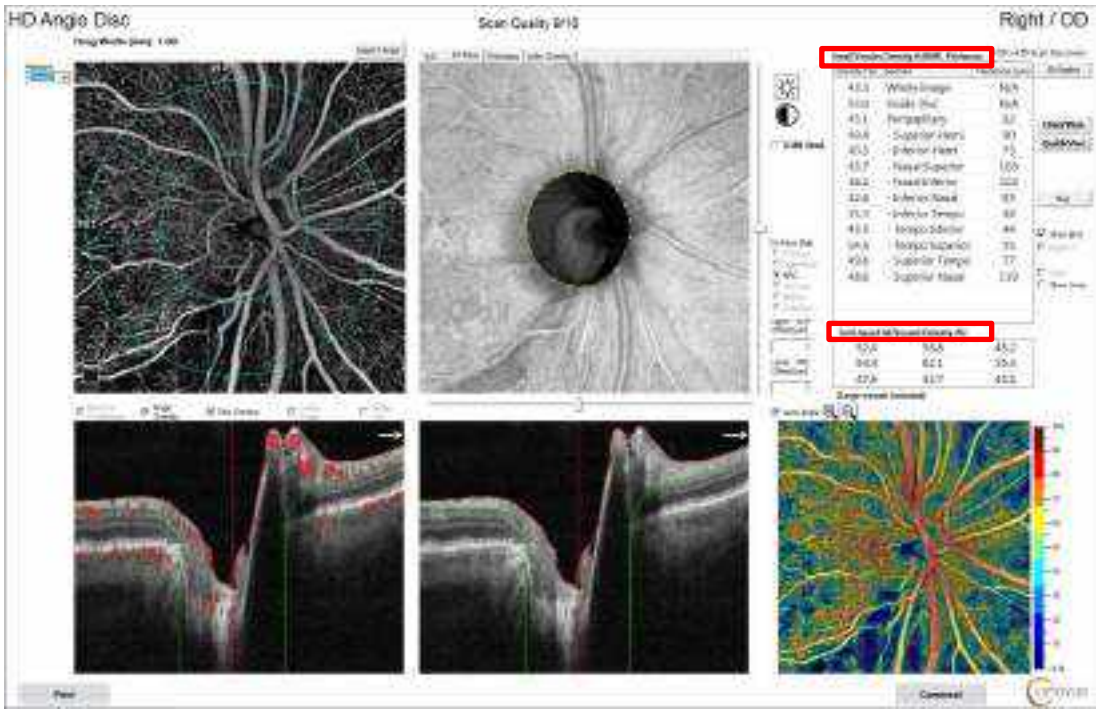


Figure 231 Angio Disc, Main Report with En Face Tab and Density Selected

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”.

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 232 Large Vessels Mask

Example of large vessel mask for 4.5 mm HD AngioDisc 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 ≥ 33µm for the 4.5 mm HD AngioDisc scans). Following mask application, only the “small vessels” density is measured.

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

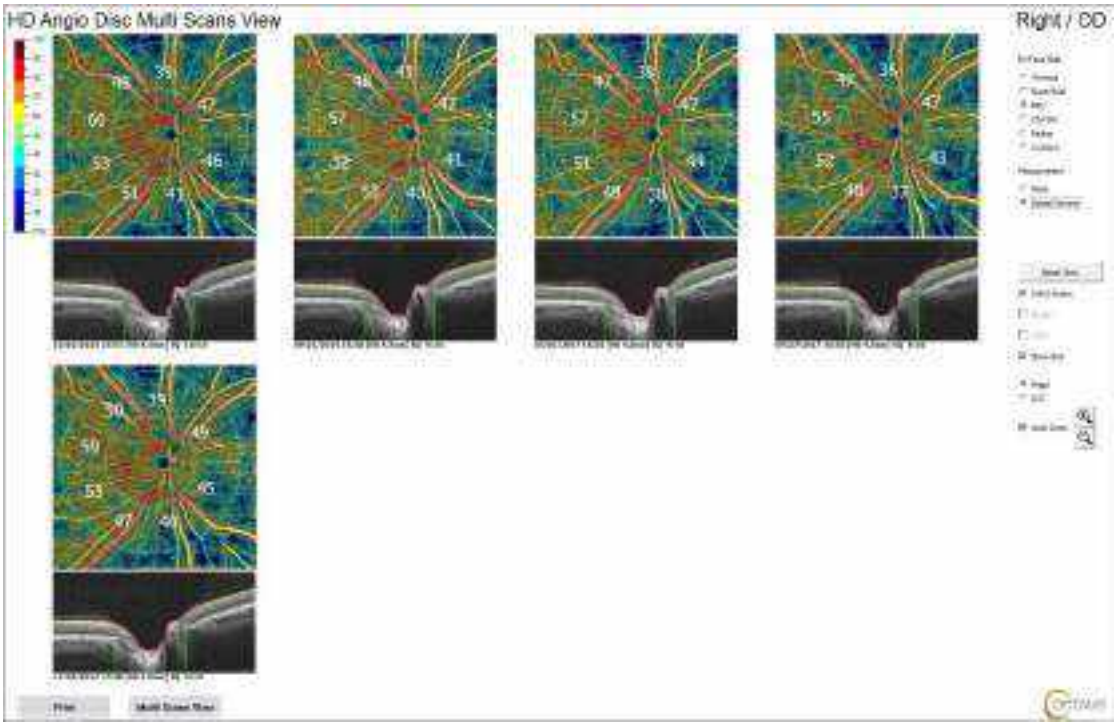


Figure 233 Angio Disc Multi Scan Report, RPC Slab and Vessel Density Selected

→RNFL Thickness is available on Main, QuickVue and Trend reports

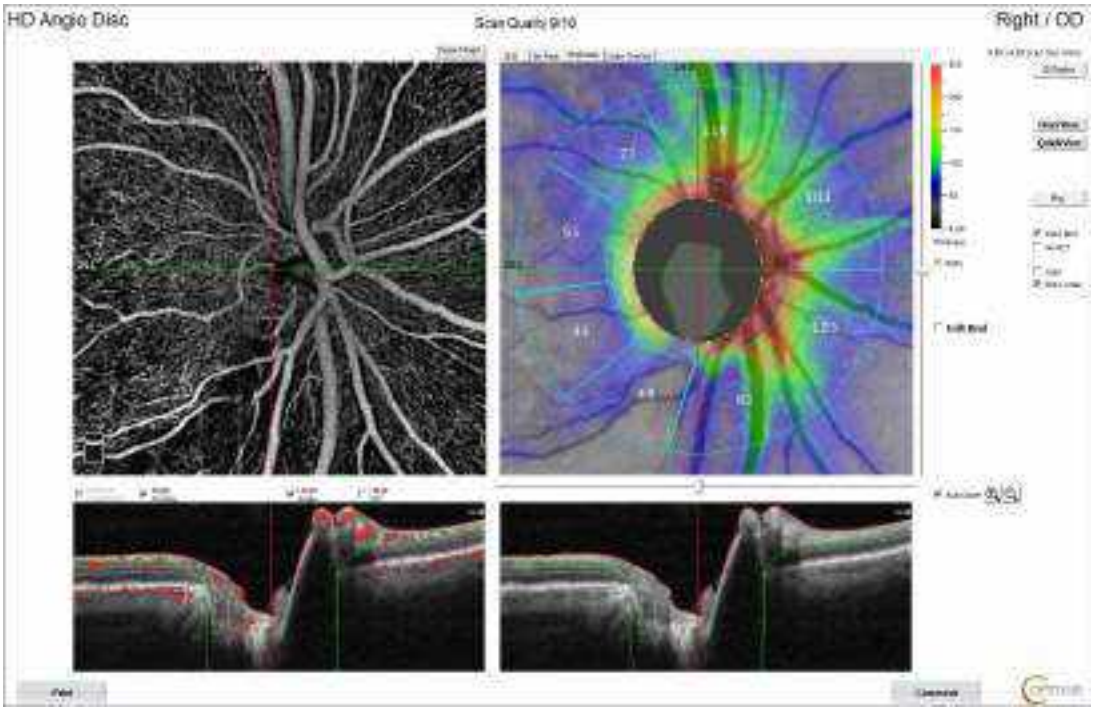


Figure 234 Angio Disc Main Report, Thickness Tab Selected

11.4.6 Angio Disc QuickVue Report

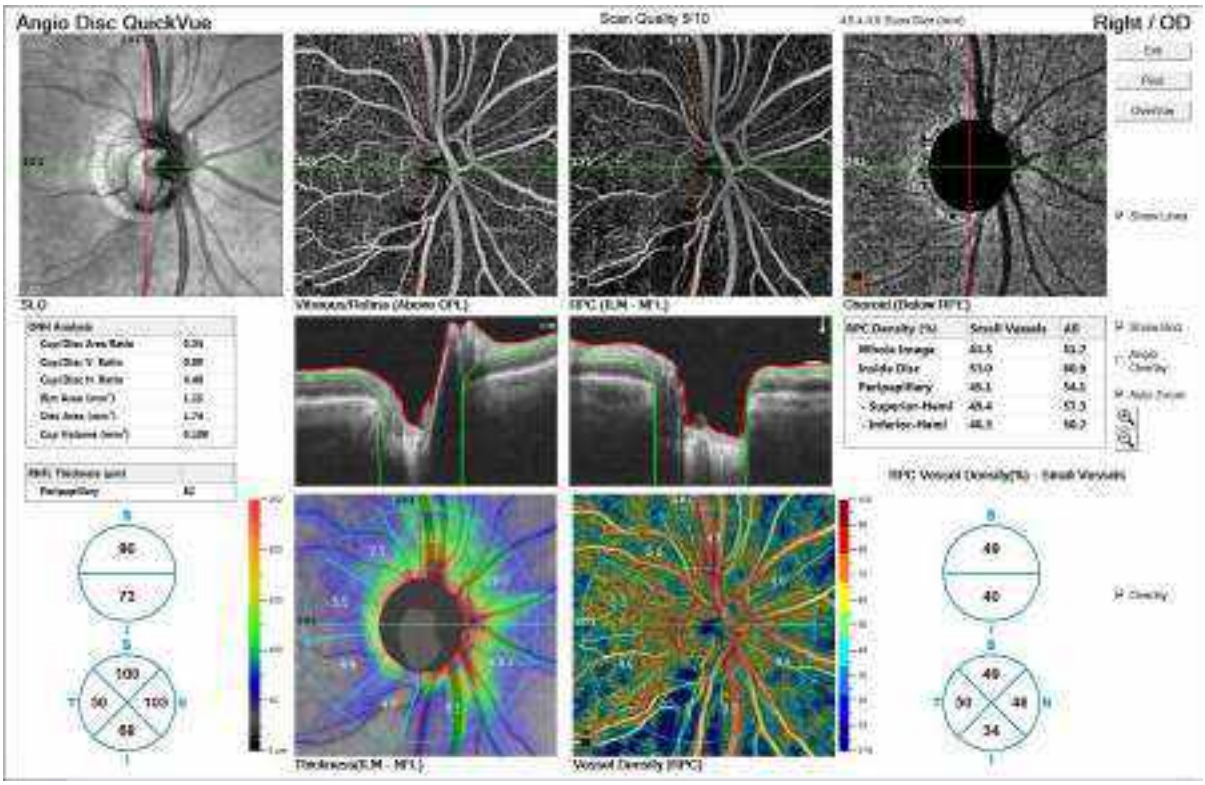


Figure 235 Angio Disc QuickVue Report

The Angio 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.

11.4.7 Angio Disc Trend Report

The purpose of Angio Disc Trend report is to provide the user with evaluation of rate of change in AngioAnalytics global parameters that are available for AngioDisc 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 Angio Disc Trend report: Retinal Nerve Fiber Layer (RNFL) Thickness and Radial Peripapillary Capillaries (RPC) Vessel Density.

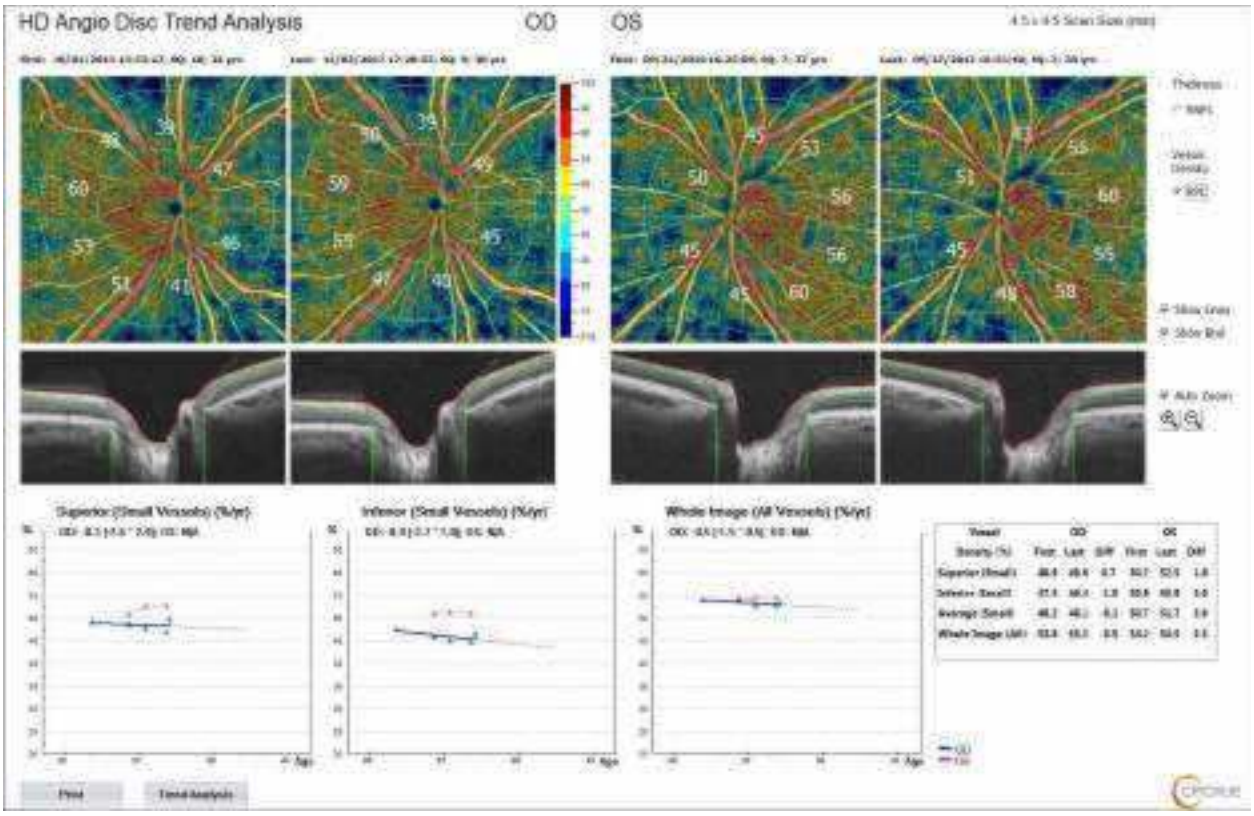


Figure 236 Angio Disc Trend Report, Vessel Density Selected.

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.

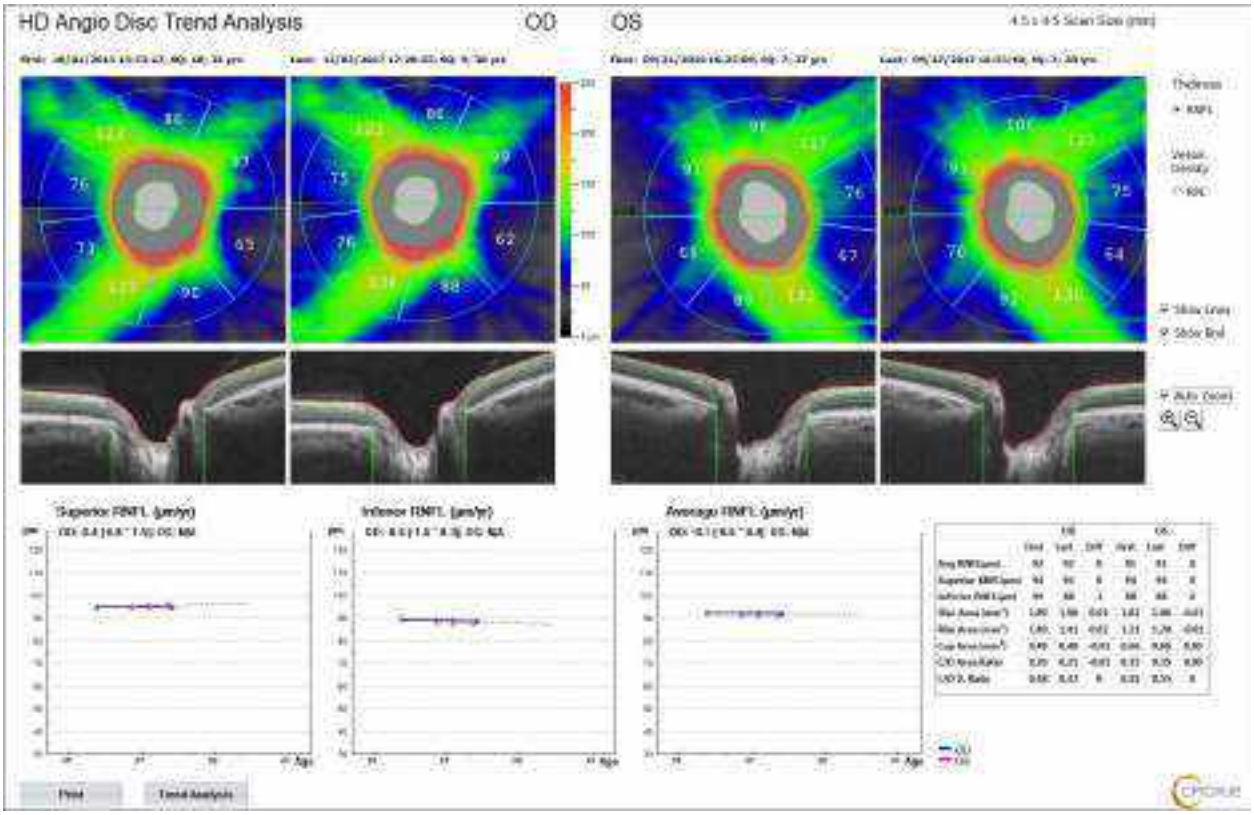


Figure 237 Angio Disc Tren Report, RNFL Thickness Selected

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:

3. Look at the trend line – horizontal line indicates stable values, positive slope indicates increasing values, negative slope indicates decreasing values.
4. Look at the confidence interval of the estimated rate between brackets on the report (provided if at least five visits are available):
    a. if zero value is included in the confidence intervals, the trend may not be different from zero
    b. if zero value is not included in the confidence intervals, there is likely a change; check the estimated rate of change for clinical significance

12 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 RTVue 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.

***AVERTISSEMENT** : Lorsque l'alimentation d'une imprimante USB provient de l'instrument XR, il est recommandé de brancher le cordon d'alimentation de l'imprimante dans la prise de courant conçue à cette fin dans le compartiment PC. Cette prise est isolée de la prise murale (réseau d'alimentation du bâtiment) par le transformateur d'isolement de l'instrument XR. Si l'alimentation de l'imprimante provient d'une autre source que la prise d'alimentation conçue à cette fin, l'imprimante doit être placée à 1,5m au moins du patient, pour éviter tout risque d'électrocution.*

13 Appendix B: Normative Database (NDB)

A normative database (NDB) is an integral part of an imaging device. The RTVue NDB was cleared by the FDA for use on September 15th, 2010 (K101505). It provides a statistical benchmark of normality by comparing an eye to a group of known healthy eyes. The results are labeled as **within normal, borderline**, or **outside normal** depending on where the patient value is relative to the normal distribution. If they are within the 5%~95% range of all normals in the distribution, they are labeled **within normal range**. If they are within the 1%~5% range or the 95%~99% range of all normals in the distribution, they are labeled **borderline**. If they are less than 1% or greater than 99% of all normals in the distribution, they are labeled **outside normal**. The applicable label, based on comparison of the subject eye to the normative database, is not meant to serve as a diagnosis, and should not be used in isolation for clinical decisions. Rather, it is an aid to be taken into consideration, with all other available clinical information, in making an overall diagnosis. It provides an important piece of clinical information to the clinician, by providing a statistical reference for the patient's structural measures compared to a group of known healthy eyes.

Several factors were found to influence the RTVue measurements. Age was found to affect thickness values: older age associated with lesser thickness. Optic disc size was also a significant factor correlated to RNFL thickness: the larger the optic disc, the thicker the RNFL. Furthermore, retinal thickness correlates to gender: retinal thickness in males is greater than in females. Comparisons of thickness measurements of a subject eyes to the RTVue normative database (NDB) automatically take into account these three factors, adjusting for age, gender and optic disc size. This means that the

final label, **within normal, borderline** or **outside normal**, reflects the patient's status relative to NDB adjusted for these factors.

The RTVue normative data was collected at 11 clinical sites following an IRB approved protocol and enrolled known healthy eyes from 480 individuals with a wide age range of age (ages 18-84) from various ethnic backgrounds including African Americans, Asians, Caucasians, Hispanics, Indians, and other.

All data was carefully reviewed for completeness and quality. Subjects not meeting study criteria, and scans not meeting image quality criteria, were excluded. The final RTVue normative database consists of 649 eyes from 366 subjects for the ONH scan, 644 eyes from 364 subjects for the EMM5 scan (that is, the retina map scan), and 656 eyes from 364 subjects for the GCC scan.

13.1.1 Data Collection Sites

Eleven clinical sites worldwide participated in the data collection, all following the approved protocol. These sites were:

US sites:

- Christopher Girkin - University of Alabama at Birmingham, Birmingham, Alabama
- Gadi Wollstein - University of Pittsburgh Medical School, Pittsburgh Pennsylvania
- Rohit Varma - University of Southern California, Los Angeles California
- Jeffrey Liebmann - New York Eye and Ear Infirmary, New York City, New York
- Murray Fingeret - New York VA Hospital, St. Alban's, St. Albans, New York
- David Greenfield - Bascom Palmer Eye Institute, Palm Beach Gardens, Florida

International sites:

- David F. Garway-Heath - Moorfields Eye Hospital, London, England
- Makoto Araie - Tokyo University, Tokyo, Japan
- Yasuo Tanno - Osaka University, Osaka, Japan
- Goji Tomita - Toho University, Tokyo, Japan
- G.S. Sekhar - LV Prasad Eye Institute, Hyderabad, India

13.1.2 Methods:

All subjects enrolled had a complete eye exam and were confirmed to be free of any ocular pathology. All subjects had normal visual fields and normal IOP.

The following inclusion/exclusion criteria were followed in the NDB data collection.

Inclusion Criteria:

a) At least 18 years of age

b) Able and willing to provide consent

c) Able and willing to complete the required examinations and visits

d) Signature on the Informed Consent Form

e) Refractive error within +/- 8 diopters sphere and within +/- 2 diopters cylinder in each eye

f) Best corrected visual acuity of 20/30 or better in each eye

Exclusion Criteria:

a) History of leukemia, AIDS, dementia, or multiple sclerosis

b) Concomitant use of hydroxychloroquine or chloroquine

c) Family history of glaucoma among first degree relatives

d) Intraocular pressure of 22 mm Hg or greater in either eye

e) A visual field test showing one or more of the following:

- An unreliable visual field test result (>30% false negative responses or >30% false positives or >30% fixation losses)
- Pattern Standard Deviation (PSD) of p<5% or worse
- Glaucoma Hemifield Test (GHT) result of **Outside Normal Limits**

f) Active ocular disease including degenerative myopia (for example, AMD, DME)

g) Previously diagnosed with glaucoma or glaucoma suspect

h) Congenital ocular abnormalities

i) Previous intra-ocular surgery or laser treatment (other than refractive surgery

j) or uncomplicated cataract surgery greater than 6 months previously)

k) Anatomical narrow angle

13.1.3 Results

The breakdown of the final normative database by age range and ethnicity group, as well refractive error range, is provided in Table 4. The database covers a wide age range of adults and a wide range of ethnic groups.

Table 4 Normative Database Breakdown by Age and Ethnicity with Refractive Error Range

Age Breakdown	**100%**
18-29	14.50%
30-39	13.10%
40-49	18.90%
50-59	25.40%
60-69	17.50%
70+	10.70%
Ethnicity Breakdown	**100%**
Caucasian	34%
Asian	22%
Hispanic	12%
African Descendant	19%
Indian/Middle East	12%
Pacific Islander	0%
Other	1%
Refraction Error Range	
Sphere (Mean ± SD)	- 0.46 D ± 1.9 D

Range	(- 7.75 D ~ + 5.50 D)

13.1.4 RNFL Thickness

The retinal nerve fiber layer thickness is obtained from the ONH scan. The parameters are derived from a 3.45 diameter circle centered on the optic disc and are shown in Table 5.

Table 5 Normal Subjects Retinal Nerve Fiber Layer Thickness Distribution

ONH Scan – Retinal Nerve Fiber Layer Thickness								
Parameter	**Mean**	**SD**	**Min**	**Q1**	**Median**	**Q3**	**Max**	**N (Subjects)**
Age	49.9	15.6	18.9	37.1	50.8	61.1	83.9	366
SSI	55.3	9.8	31.6	48.2	54.7	62.3	80.3	366
discArea (mm^2)	2.117	0.368	1.330	1.850	2.065	2.328	3.580	366
Avg_RNFL (µm)	101.1	9.0	66.6	95.3	101.3	106.9	126.3	366
Sup_RNFL (µm)	103.3	10.2	65.5	97.0	103.6	110.1	144.8	366
Inf_RNFL (µm)	98.9	9.1	67.7	92.9	99.0	105.0	126.5	366
Tempo (µm)	75.3	9.2	44.4	70.2	74.8	81.1	109.6	366
Superior (µm)	123.8	14.1	73.4	113.2	125.2	132.7	171.3	366
Nasal (µm)	79.3	10.9	48.6	72.6	79.4	86.0	147.4	366

ONH Scan – Retinal Nerve Fiber Layer Thickness								
Parameter	**Mean**	**SD**	**Min**	**Q1**	**Median**	**Q3**	**Max**	**N (Subjects)**
Inferior (µm)	126.1	13.2	85.0	117.7	124.9	135.5	165.2	366
TU (µm)	81.8	11.0	45.6	74.9	81.5	88.7	121.6	366
ST (µm)	135.0	15.9	62.4	124.9	135.9	146.3	176.8	366
SN (µm)	112.7	17.8	66.7	100.5	112.1	123.6	178.2	366
NU (µm)	83.8	13.1	47.0	75.5	83.2	91.3	172.2	366
NL (µm)	74.7	10.5	45.6	67.8	74.7	811	122.6	366
IN (µm)	114.2	17.4	68.1	102.7	114.4	125.5	167.9	366
IT (µm)	137.9	16.7	83.9	126.4	138.7	149.6	188.9	366
TL (µm)	68.9	9.2	43.3	63.6	68.4	73.9	107.0	366

13.1.5 Optic Disc Parameters

Optic disc parameters, including neuro-retinal rim, optic nerve head cup, and cup-to-disc ratio, etc., are also obtained from the ONH scan. ONH disc, rim, and cup measurement parameters are shown in Table 6.

Table 6 Normal Subjects: Distribution of Optic Nerve Head Measurements

ONH Scan – Disc, Rim, & Cup								
Parameter	**Mean**	**SD**	**Min**	**Q1**	**Median**	**Q3**	**Max**	**N (Subjects)**
Age	49.9	15.6	18.9	37.1	50.8	61.1	83.9	366
SSI	55.3	9.8	31.6	48.2	54.7	62.3	80.3	366
discArea (mm^2)	2.117	0.368	1.330	1.850	2.328	2.065	3.580	366
Area_C_D_ratio	0.321	0.172	0.000	0.210	0.320	0.440	0.770	366
H_C_D_ratio	1.413	0.363	0.650	1.190	1.370	1.628	2.680	366
V_C_D_ratio	0.181	0.120	0.016	0.100	0.145	0.228	0.721	366
CupArea (mm^2)	0.704	0.447	0.000	0.393	0.680	0.950	2.200	366
RimArea (mm^2)	0.179	0.195	0.000	0.029	0.120	0.262	1.122	366
RimVolume (mm^3)	0.328	0.186	0.053	0.203	0.269	0.412	1.066	366
Nervehead_Volume (mm^3)	0.584	0.225	0.000	0.480	0.630	0.750	0.990	366
CupVolume (mm^3)	0.521	0.203	0.000	0.430	0.570	0.660	0.910	366

13.1.6 GCC Parameters

The following results are from the GCC™ scan. The GCC scan provides inner retinal thickness values from the ILM to the inner plexiform layer, called the ganglion cell complex (GCC). It is centered 1 mm temporal to the fovea in order to emphasize the temporal retina region, which corresponds to the nasal visual field (area most susceptible to early glaucomatous damage). In addition to the thickness parameters shown in Table 7 below, the GCC also provides two important parameters, the FLV and GLV.

Table 7 Normal Subjects: Distribution of GCC Measurements

GCC Scan – Ganglion Cell Complex								
Parameter	**Mean**	**SD**	**Min**	**Q1**	**Median**	**Q3**	**Max**	**N (Subjects)**
Age	49.8	15.5	18.9	37.4	50.8	61.1	83.9	364
SSI	62.0	8.5	39.3	56.1	61.9	67.9	83.3	364
GCC_Average (µm)	98.8	7.2	78.3	93.9	98.7	103.2	119.6	364
GCC_Superior_Avg (µm)	98.2	7.3	80.6	93.5	97.8	102.4	122.9	364
GCC_Inferior_Avg (µm)	99.4	7.4	75.5	94.1	99.2	104.3	120.8	364
GCC_FLV (%)	0.546	0.693	0.000	0.081	0.324	0.730	4.356	364
GCC_GLV (%)	2.101	2.706	0.000	0.353	1.046	2.856	17.270	364

13.1.7 Retina Thickness

The following results are from the EMM5 scan pattern (that is, Retina Map scan). The EMM5 scan provides full retinal thickness values from the ILM to the RPE layer. It is centered on the fovea. Thickness values for the fovea region and surrounding parafovea and perifovea are provided.

Table 8 Normal Subjects Retinal Thickness Distribution

Retina Map Scan – Retinal Thickness								
Parameter	**Mean**	**SD**	**Min**	**Q1**	**Median**	**Q3**	**Max**	**N (Subjects)**
Age	49.8	15.5	18.9	37.4	50.8	61.1	80.1	364
SSI	63.4	8.3	42.6	58.1	63.2	69.0	85.4	364
Fovea (µm)	255.2	22.0	191.9	239.2	254.9	270.4	320.7	364
ParaFovea (µm)	319.6	16.6	267.0	309.0	320.0	330.2	362.0	364
Para S Hemisphere (µm)	320.7	17.1	269.0	310.0	321.0	332.0	365.0	364
Para I Hemisphere (µm)	318.6	16.6	261.0	307.0	319.0	330.0	362.0	364
Para Tempo (µm)	312.0	17.0	255.0	301.0	313.0	324.0	354.0	364
Para Superior (µm)	323.2	17.3	270.0	312.0	324.0	334.0	373.0	364
Para Nasal (µm)	324.3	17.7	274.0	312.0	326.0	336.0	365.0	364
Para Inferior (µm)	319.0	16.6	259.0	307.8	320.0	330.0	367.0	364

Retina Map Scan – Retinal Thickness								
Parameter	**Mean**	**SD**	**Min**	**Q1**	**Median**	**Q3**	**Max**	**N (Subjects)**
Perifovea (µm)	288.9	14.3	246.0	278.0	288.0	298.2	330.0	364
Peri S Hemisphere (µm)	292.3	14.5	247.0	282.0	291.0	301.2	334.0	364
Peri I Hemisphere (µm)	285.5	14.8	241.0	275.0	284.5	296.0	329.0	364
Peri Tempo (µm)	280.1	15.3	238.0	269.0	279.0	290.0	330.0	364
Peri Superior (µm)	291.5	14.7	243.0	281.0	291.0	302.0	337.0	364
Peri Nasal (µm)	304.2	15.9	258.0	294.0	304.0	315.0	350.0	364
Peri Inferior (µm)	319.6	16.6	267.0	309.0	320.0	330.2	362.0	364

Gender difference was observed with the retinal thickness measurement in the normal subjects. Table 9 provides retinal thickness distribution by gender. On average, male subjects measures approximately 9 µm thicker in central retinal thickness than female subjects.

Table 9 Normal Subjects: Retinal Thickness Distribution by Gender

Male				**Female**		
Parameter (all µm)	**Mean**	**SD**	**N (Subjects)**	**Mean**	**SD**	**N (Subjects)**
Fovea	259.7	21.5	195	250.1	21.6	169
ParaFovea	322.4	16.5	195	316.5	16.2	169
Para S Hemisphere	323.3	16.8	195	317.7	16.9	169
Para I Hemisphere	321.5	16.8	195	315.2	15.9	169
Para Tempo	315.0	16.8	195	308.6	16.6	169
Para Superior	325.6	17.2	195	320.6	17.1	169
Para Nasal	327.2	17.5	195	320.9	17.4	169
Para Inferior	321.8	17.0	195	315.7	15.6	169
Perifovea	289.3	15.1	195	288.5	13.5	169
Peri S Hemisphere	292.5	15.2	195	292.0	13.8	169
Peri I Hemisphere	286.0	15.5	195	284.9	14.0	169
Peri Tempo	281.3	15.8	195	278.7	14.5	169

Male				Female		
Parameter (all µm)	**Mean**	**SD**	**N (Subjects)**	**Mean**	**SD**	**N (Subjects)**
Peri Superior	291.2	15.4	195	291.8	13.9	169
Peri Nasal	304.6	16.8	195	303.8	14.8	169
Peri Inferior	280.0	15.3	195	279.6	14.1	169

Age-related thinning was found with GCC thickness measurements, although the rate of age-related loss is small as shown in Table 10. On average, GCC age-related thinning is approximately -0.1 µm/year, which means 1 µm thinning per decade.

Table 10 Normal Subjects: Age-Related Loss of GCC Thickness

Slope (µm/yr.)	
GCC_Average	-0.093
GCC_Superior_Avg	-0.086
GCC_Inferior_Avg	-0.100

The RNFL thickness measurements were found to be significantly correlated with age and disc size (area). The age-related thinning is small and the RNFL thickness increases with increasing disc size. While the rate of change with age may appear small, but over the wide age range (60~80 years), the impact over the full range is similar to that of disc size which has a much higher rate but small range (1.33 ~ 3.58 mm^2).

Table 11 Normal Subjects: Rate of Change in RNFL Thickness by Age and Disc Area

Parameter	Slope_age (µm/yr)	Slope_discArea (µm/mm²)
Avg_RNFL	-0.118	6.7
Sup_RNFL	-0.125	8.1
Inf_RNFL	-0.111	5.3
Tempo	-0.065	0.3
Superior	-0.138	11.0
Nasal	-0.112	7.0
Inferior	-0.157	7.5
TU	-0.081	1.9
ST	-0.126	9.3
SN	-0.150	12.7
NU	-0.142	8.2
NL	-0.082	5.8
IN	-0.150	9.3
IT	-0.162	5.7
TL	-0.030	0.0

13.1.8 Summary

The OCT measurements of the normal subjects are correlated with age, optic disc size (ONH and RNFL parameters), and gender (retinal thickness parameters). The normative limits were established based on multivariate regression analysis to adjust for the relevant covariant. Therefore, the comparison to the NDB is appropriately accounted for these covariant.

The EMM5 scan in the RTVue has been renamed to Retina Map in the XR.

14 Appendix C: 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 238 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 238 below.

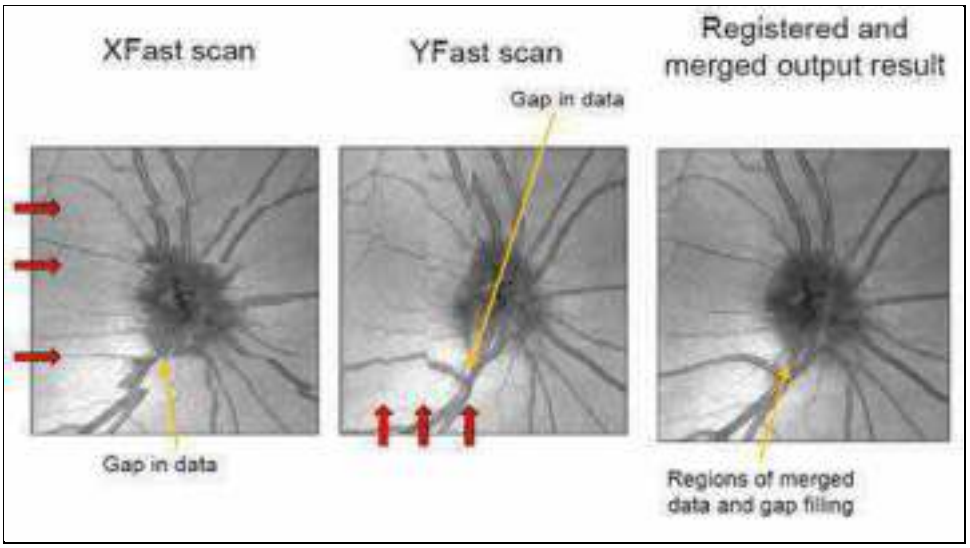


Figure 238 MCT Scan Acquisition and Effect in 3D Volumes, En Face Views

Figure 239 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.

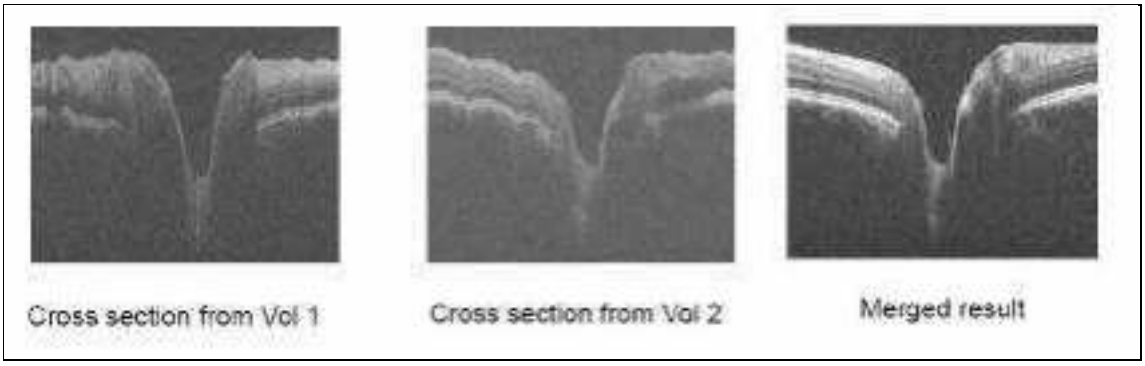


Figure 239 MCT Scan Acquisition and Effect in 3D Volumes, Cross-Sectional Views

The scan shown in Figure 240 covering both macula and optic disc provides image registration reference for other scan types.

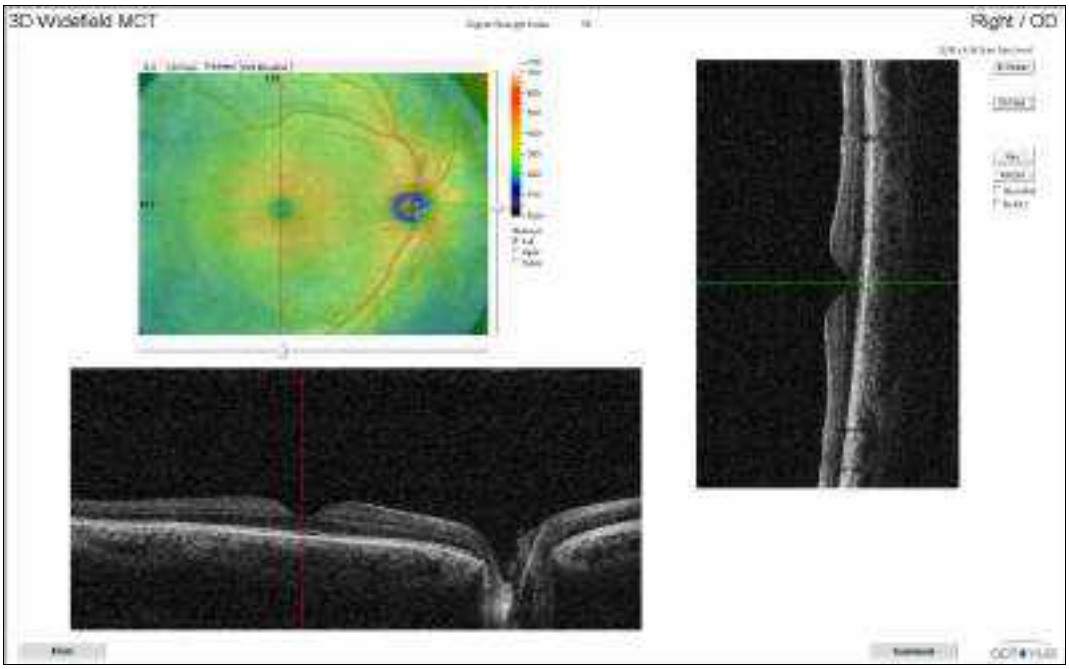


Figure 240 3D Widefield MCT Scan Example Covering Both Macula And Optic Disc

15 Appendix D: Repeatability and Reproducibility

Clinical Data for the repeatability and reproducibility assessment were collected under an IRB approved study protocol. Consenting subjects were enrolled in three study groups, a normal group, a glaucoma group, and a retina group. One eye per qualified subject was included in the data collection and each study eye was imaged repeatedly three times with each of the three RTVue/operator pairs for each of the required OCT scan types.

Inclusion Criteria as Defined in the Data Collection Protocol

All subjects must meet the following criteria:

- At least 18 years of age
- Able and willing to provide consent
- Able and willing to complete the required examinations and visits

In addition, for each respective subject group, the following inclusion criteria were applied:

- Normal subjects must have normal results from the clinical exam and be free of ocular pathology
- Glaucoma patients must have clinical exam results consistent with glaucoma
- They must have visual field defects consistent with glaucoma (for example, PSD < 5% and/or GHT outside normal), and/or structural damage consistent with glaucoma (for example, neuroretinal rim thinning, notching, RNFL defect, etc.)
- Retina patients must have clinical exam results consistent with retina pathology (for example, soft drusen, retinal edema, macula hole, etc.)

Exclusion Criteria as Defined in the Data Collection Protocol

- Normal subjects must be free of any ocular pathology
- Glaucoma patients must be free of any ocular pathology except glaucoma
- Retina patients must be free of any ocular pathology except any type of retina pathology

A total of 16 normal subjects, 19 glaucoma patients, and 17 retinal patients qualified and completed the study. GCC scan and ONH scan were not acquired for retina subjects and EMM5 scan (that is, retina map scan) was not acquired for glaucoma

subjects. All three scan types were acquired for Normal subjects. For each subject, nine scans across three device/operator pairs per required scan type were expected.

Table 12 shows the total number of acquired scans for each scan type. All subjects completed the required number of scans with the exception of one glaucoma subject, who was short of two GCC scans in one instrument; therefore the total number of GCC scans was 169 instead of the expected 171.

Table 12 Number of Scans Acquired by Scan Type and Study Group

Acquired Scans	EMM5	GCC	ONH
Normal (16 subjects)	144	144	144
Glaucoma (19 subjects)		169	171
Retina (17 subjects)	153		
TOTAL	**297**	**313**	**315**

All study scans were reviewed for the following image quality aspects and, if failed any one factor, was marked as poor scan quality for exclusion from further analysis:

- Overall signal strength
- Blink or locally weak signal
- OCT signal clipped
- Fixation errors
- Optic disc off-center
- Eye motion
- Poor quality 3D-Disc reference

The rate of scan exclusion from the quality review is summarized in Table 13. All study groups combined, the image quality based scan exclusion rate was 0.6% (2 out of total 313) for the GCC scan, 2.9% (9 out of total 315) for the ONH scan, and 4.0% (12 out of 297) for the EMM5 scan.

Table 13 Number of Qualified Scans by Scan Type and Study Group

Qualified Scans	**EMM5**	**GCC**	**ONH**
Normal (16 subjects)	142	144	138
Glaucoma (19 subjects)		167	168
Retina (17 subjects)	143		
TOTAL	285	311	306
Disqualified Scans (Rate)	12 (4.0%)	2 (0.6%)	9 (2.9%)

The repeatability and reproducibility were estimated based on the qualified scans and the results are provided in the tables below as follows: repeatability standard deviation (SD), reproducibility SD, coefficient of variation (COV) based on reproducibility (Reproducibility SD/Mean*100), and 95% limits of reproducibility (2.8* Reproducibility SD), along with the Mean values and SD values of the study group.

Table 14 Repeatability and Reproducibility for Retina Thickness (Normal Eyes)

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

Table 15- Repeatability and Reproducibility of Retinal Thickness (Retina Disease Eyes)						
EMM5 (Retina Map) all µm						
Retina Subjects (17 Subjects, 143 Scans)						
Parameter	**Mean**	**SD**	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility COV**	**Reproducibility Limit***
Fovea	266.7	55.1	6.5	6.5	2.4%	18.0
ParaFovea	322.5	30.6	3.5	3.6	1.1%	9.9
Para S Hemisphere	323.7	30.7	4.3	4.5	1.4%	12.3
Para I Hemisphere	321.2	32.8	3.2	3.2	1.0%	8.9
Para Tempo	316.2	38.4	3.8	3.9	1.2%	10.9
Para Superior	330.1	25.2	4.3	4.4	1.3%	12.2
Para Nasal	323.9	17.2	3.2	3.4	1.0%	9.3
Para Inferior	319.0	34.3	3.3	3.3	1.0%	9.1
Perifovea	298.1	29.6	2.5	2.5	0.8%	7.0
Peri S Hemisphere	303.3	29.9	3.0	3.1	1.0%	8.5
Peri I Hemisphere	293.1	30.4	3.5	3.5	1.2%	9.7

Table 15- Repeatability and Reproducibility of Retinal Thickness (Retina Disease Eyes)						
EMM5 (Retina Map) all µm						
Retina Subjects (17 Subjects, 143 Scans)						
Parameter	**Mean**	**SD**	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility COV**	**Reproducibility Limit***
Peri Tempo	294.1	44.6	3.6	3.6	1.2%	10.0
Peri Superior	301.1	31.1	3.2	3.3	1.1%	9.1
Peri Nasal	312.7	20.9	3.7	3.8	1.2%	10.4
Peri Inferior	284.6	32.2	4.2	4.2	1.5%	11.7

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

Table 15 Repeatability and Reproducibility for GCC (Normal Eyes)

GCC						
Normal Subjects (16 Subjects, 144 Scans)						
Parameter	**Mean**	**SD**	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility COV**	**Reproducibility Limit***
GCC_Avg. (µm)	96.2	5.6	1.6	1.6	1.7%	4.5
GCC_Superior Avg. (µm)	95.8	5.5	1.7	1.7	1.8%	4.8
GCC_Inferior Avg. (µm)	96.7	6.1	1.6	1.6	1.7%	4.6
GCC_FLV (%)	0.489	0.507	0.182	0.182	37.2%	0.504
GCC_GLV (%)	2.616	2.417	0.754	0.767	29.3%	2.126

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

The high COV values for GCC_FLV and GCC_GLV is due to the highly skewed distribution near zero values of normal eyes and the denominator for the COV calculation has a low value. COV is not an appropriate measure of test-retest variability for such skewed distributions with a large portion of data at or near zero. Please interpret the data with this information in mind.

Table 16 Repeatability and Reproducibility for GCC (Glaucoma Eyes)

GCC						
Glaucoma Subjects (19 Subjects, 167 Scans)						
Parameter	**Mean**	**SD**	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility COV**	**Reproducibility Limit***
GCC_Avg.(µm)	79.1	10.9	1.3	1.3	1.7%	3.6
GCC_Superior Avg. (µm)	79.5	12.0	1.4	1.4	1.8%	4.0
GCC_Inferior Avg. (µm)	78.7	11.9	1.4	1.4	1.8%	4.0
GCC_FLV (%)	5.525	3.948	0.643	0.643	11.4%	1.783
GCC_GLV (%)	16.856	9.959	1.209	1.209	7.1%	3.352

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

Table 17 Repeatability and Reproducibility for Disc Parameters (Normal Eyes)

ONH						
Normal Subjects (16 Subjects, 138 Scans)						
Parameter	**Mean**	**SD**	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility COV**	**Reproducibility Limit***
discArea (mm^2)	1.963	0.382	0.078	0.078	4.0%	0.216
Area_C_D_ratio	0.274	0.153	0.023	0.023	8.3%	0.063
H_C_D_ratio	0.554	0.191	0.050	0.050	9.1%	0.140
V_C_D_ratio	0.445	0.190	0.043	0.043	9.8%	0.120
CupArea (mm^2)	0.563	0.364	0.042	0.042	7.5%	0.116
RimArea (mm^2)	1.400	0.327	0.081	0.081	5.8%	0.226
RimVolume (mm^2)	0.167	0.058	0.016	0.016	9.2%	0.043
Nervehead_Volume (mm^2)	0.340	0.135	0.044	0.044	12.8%	0.122
CupVolume (mm^2)	0.114	0.141	0.026	0.026	23.8%	0.073

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

Table 18 Repeatability and Reproducibility for Disc Parameters (Glaucoma Eyes)

ONH						
Glaucoma Subjects (19 Subjects, 168 Scans)						
Parameter	**Mean**	**SD**	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility COV**	**Reproducibility Limit***
discArea (mm^2)	2.508	0.427	0.067	0.072	2.8%	0.198
Area_C_D_ratio	0.654	0.144	0.022	0.022	3.4%	0.061
H_C_D_ratio	0.863	0.104	0.046	0.046	5.4%	0.128
V_C_D_ratio	0.817	0.121	0.026	0.026	3.2%	0.073
CupArea (mm^2)	1.647	0.476	0.052	0.055	3.3%	0.153
RimArea (mm^2)	0.861	0.362	0.067	0.067	7.9%	0.186
RimVolume (mm^2)	0.039	0.034	0.008	0.008	21.4%	0.023
Nervehead_Volume (mm^2)	0.109	0.093	0.012	0.012	11.5%	0.034
CupVolume (mm^2)	0.635	0.275	0.053	0.056	8.6%	0.154

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

Table 20- Repeatability and Reproducibility of RNFL Thickness (Normal eyes)						
ONH (all µm)						
Normal Subjects (16 Subjects, 138 Scans)						
Parameter	**Mean**	**SD**	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility COV**	**Reproducibility Limit***
Avg_RNFL	98.6	10.0	1.5	1.5	1.5%	4.1
Sup_RNFL	100.8	12.0	2.1	2.2	2.2%	6.1
Inf_RNFL	96.5	9.3	2.2	2.3	2.3%	6.3
Tempo	77.6	10.9	3.3	3.3	4.2%	9.0
Superior	121.9	16.2	4.0	4.2	3.4%	11.6
Nasal	71.2	12.5	3.6	3.6	5.1%	10.0
Inferior	123.8	11.2	3.4	3.4	2.8%	9.6
TU	85.0	11.9	3.7	3.7	4.4%	10.3
ST	137.8	14.9	5.0	5.1	3.7%	14.2
SN	106.0	19.1	4.6	4.8	4.5%	13.4
NU	74.4	15.4	3.9	3.9	5.3%	10.9
NL	68.0	10.4	3.8	3.9	5.7%	10.7
IN	108.8	15.8	5.2	5.4	5.0%	15.1

IT	138.9	16.6	5.6	5.7	4.1%	15.7
TL	70.2	11.8	4.3	4.3	6.2%	12.0

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

Table 21 Repeatability and Reproducibility of RNFL Thickness (Glaucoma Eyes)						
ONH (all µm)						
Glaucoma Subjects (19 Subjects, 168 Scans)						
Parameter	**Mean**	**SD**	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility COV**	**Reproducibility Limit***
Avg_RNFL	75.3	14.0	1.6	1.6	2.1%	4.5
Sup_RNFL	78.3	16.1	2.2	2.3	2.9%	6.3
Inf_RNFL	72.2	14.4	2.0	2.0	2.8%	5.6
Tempo	61.0	13.4	3.1	3.1	5.1%	8.6
Superior	91.1	20.3	3.7	3.9	4.2%	10.7
Nasal	61.9	12.2	2.8	2.8	4.5%	7.7
Inferior	87.2	19.6	3.2	3.2	3.7%	8.9
TU	65.8	16.7	4.6	4.6	7.0%	12.7
ST	100.4	22.4	4.4	4.4	4.4%	12.3
SN	81.7	21.0	5.3	5.5	6.8%	15.4
NU	65.4	14.1	3.6	3.6	5.5%	10.0
NL	58.5	11.2	2.9	2.9	5.0%	8.2
IN	79.4	17.0	3.3	3.4	4.3%	9.4
IT	94.9	24.4	4.4	4.5	4.7%	12.4
TL	56.2	12.2	4.4	4.6	8.2%	12.7

* Reproducibility Limit is the 95% limit for the difference between measurements under the reproducibility conditions. Reproducibility Limit = 2.8 x Reproducibility SD per ISO 5725-1 and ISO 5725-6.

16 Appendix E: AngioVue Performance Testing

16.1 Non-clinical Performance Testing

A series of 3D phantom models with known ground truth for vessel density measurements was designed to validate the accuracy of the proposed device software for measurement of vessel density from 3 mm Angio Retina, 6 mm HD Angio Retina, and 4.5 mm HD AngioDisc scans. The phantoms were designed to assess the impact of projection artifacts removal (PAR) on vessel density measurements (especially Deep vessel density) and large vessel masking for RPC vessel density.

The 3D phantoms were constructed with the same raw data format as that of an OCTA scan of the eye, containing an OCT volume and an OCTA volume with spatial colocalization. A series of phantoms containing different wireframe densities and/or patterns to cover a range of physiologically relevant vascular densities and pathologies, such as branch occlusions, were designed. Projection artifacts were simulated in the OCTA volume for each phantom throughout the depth. Larger vessels with varying diameters (50µm ~ 180µm) were included in the AngioDisc scan 3D phantom design. Vessel density measurements by the software are based on the RPC en face images for all vessels and for small vessels (applying large vessel mask to mask the regions occupied by large vessels).

Phantoms were processed directly with the device software with all the steps that lead to the generation of vessel density map and associated measurement parameters, including en face slab generation, projection artifacts removal, image processing to generate vessel density map/measurements, and detection of large vessel mask for RPC vessel density analysis.

The agreement between software reported measurements and the expected “vascular” density values computed directly from the model were used to validate the accuracy of the software.

16.1.1 3 mm AngioRetina Scan

To evaluate accuracy of measurements of 3 mm AngioRetina scan, 4 phantoms with various vessel density were used, including one phantom with occlusion (vessel dropout) pattern.

The measurement parameters tested included all software density measurement parameters for Superficial plexus and Deep plexus, as well as the foveal vessel density (FD-300) based on the Retina slab.

The difference between the software reported vessel density value and the expected vessel density value of the phantom were evaluated for each parameter and for each of the 4 phantoms.

The range and accuracy for the 3 mm AngioRetina scan parameters are summarized below, for Superficial and Deep plexuses.

Accuracy for 3 mm AngioRetina scan (pooled results of 4 individual phantoms and all zonal parameters)

Superficial Vessel Density (%)	Expected	SW Reported	Difference
Average	46.5	48.7	2.3
Std Dev	13.0	13.0	1.0
Min	17.2	20.2	-1.0
Max	73.5	75.7	4.3

Deep Vessel Density (%)	Expected	SW Reported	Difference
Average	39.8	39.8	0.0
Std Dev	14.3	13.9	1.2
Min	0.2	0.2	-3.0
Max	50.5	50.9	2.4

FD-300 Vessel Density (%)	Expected	SW Reported	Difference
Average	57.5	55.3	-2.2
Std Dev	2.2	1.5	-0.7
Min	54.7	53.5	-1.2
Max	60.0	57.0	-3.0

Pooling results of the 4 phantoms and both plexuses, the measured vessel density values cover a broad range (from ~ 20% to ~ 75% as measured by the software).

16.1.2 6 mm HD AngioRetina Scan

To evaluate accuracy of measurements of 6 mm HD AngioRetina scan, 3 phantoms with various vessel density were used, including one phantom with occlusion (vessel dropout) pattern.

The measurement parameters tested included all software density measurement parameters for Superficial plexus and Deep plexus, as well as the foveal vessel density (FD-300) based on the Retina slab.

The difference between the software reported vessel density value and the expected vessel density value (i.e., the “known” vessel density value of the phantom) were evaluated for each parameter respectively and for each of the 3 phantoms.

The tables below summarize the measurement range for the 6 mm HD AngioRetina scan parameters, for Superficial and Deep plexuses.

Accuracy for 6 mm HD AngioRetina scan (pooled results of 3 individual phantoms and all zonal parameters)

Superficial Vessel Density (%)	Expected	SW Reported	Difference
Average	49.0	48.7	-0.2
Std Dev	9.8	10.0	1.3
Min	28.6	30.7	-3.7
Max	62.5	62.8	2.3

Deep Vessel Density (%)	Expected	SW Reported	Difference
Average	63.0	63.3	0.3
Std Dev	12.5	12.0	2.5
Min	0.8	1.4	-4.7
Max	68.2	69.2	5.8

FD-300 Vessel Density (%)	Expected	SW Reported	Difference
Average	63.0	62.1	-0.9
Std Dev	3.9	6.1	2.2
Min	60.7	58.5	-1.6
Max	67.5	69.2	2.2

Pooling results of the 3 phantoms and both plexuses, the measured vessel density values cover a broad range (from ~ 31 % to ~ 69% as measured by the software).

16.1.3 4.5 mm HD AngioDisc Scan, with and without Large Vessel Masking

To evaluate accuracy of measurements of 4.5 mm HD AngioDisc scan, 3 phantoms with various vessel density were used, including one phantom with occlusion (vessel dropout) pattern.

The measurement parameters tested included all software density measurement parameters for RPC slab, small vessels only vessel density (with applying large vessel mask) and all vessels density (without large vessel mask), respectively.

The small vessels only vessel density is measured with the application of large vessel mask which has threshold of 3 pixels (approximately 33µm for the 4.5 mm HD AngioDisc scans), therefore representing small vessels in the RPC slab.

The difference between the software reported vessel density value and the expected vessel density value of the phantom were evaluated for each parameter and for each of the 3 phantoms.

The tables below summarize the measurements range for the 4.5 mm AngioDisc scan parameters, RPC plexus; small vessels only vessel density (with applying large vessel mask) and RPC all vessels density, respectively.

Accuracy for 4.5 mm HD AngioDisc scan (pooled results of 3 individual phantoms and all zonal parameters)

Small Vessel Density (%)	Expected	SW Reported	Difference
Average	46.9	47.9	1.0
Std Dev	10.2	10.3	1.1
Min	7.0	6.3	-1.1
Max	56.9	57.1	3.4

All Vessels Density (%)	Expected	SW Reported	Difference
Average	56.1	55.6	-0.5
Std Dev	9.4	8.6	1.7
Min	22.4	23.6	-2.9
Max	68.3	65.5	2.9

Pooling results of the 3 phantoms, the measured vessel density values cover a broad range (from ~ 6.0% to ~ 57% for small vessels only and from ~ 24% to ~ 66% for all vessels as measured by the software).

16.2 Clinical Performance Testing

The repeatability and reproducibility were evaluated for the measurements of vessel density, retinal thickness, retinal sub-layer thicknesses, and optic disc measurements based on the AngioRetina scans and AngioDisc scans. Measurement agreement for structural parameters measured by both devices was also evaluated.

16.2.1 Evaluation of the Repeatability and Reproducibility (“R&R”) of AngioVue in Normal Subjects, Retinal Patients, and Glaucoma Patients

This was a prospective, observational study conducted at a single clinical U.S. 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 of varying severity (with confirmed glaucomatous visual field defect and/or glaucomatous optic nerve changes), and 3) individuals with exudative age-related macular degeneration (AMD), proliferative and non-proliferative diabetic retinopathy (DR), and other retinal vascular conditions. Individuals with media opacity or significant refractive error precluding adequate image quality were excluded. For repeatability/reproducibility and agreement, the study eye is imaged three times using relevant OCTA scan patterns with each of three Avanti instrument-operator pairs. For agreement assessment of retinal thickness and optic nerve head (ONH) parameters, study eyes were also scanned once with each of four predicate (“legacy”) posterior segment scan patterns. All eligible study eyes with at least two acceptable scans were included into final statistical analyses. All scans underwent post-acquisition image quality review. OCTA scans with a SQ score of less than 6 were excluded from analysis; “legacy” scan SSIs of <39 (Retina Map), <32 (GCC), or <28 (ONH scan pattern) were also excluded. Repeatability and reproducibility of the measured parameters (new OCTA parameters and non-OCTA thickness parameters) were calculated using a random-effects analysis of variance (ANOVA)

model. Agreement was evaluated with calculation of 95% limits of agreement (LOAs) and Deming regression analyses.

A total of 70 participants were consented and enrolled, 15 “normals,” 16 with glaucoma (“Glaucoma” sub-group), and 39 with retinal conditions (“Retina” sub-group). Three participants from the Retina sub-group could not complete the required imaging. Therefore, a total of 67 eligible participants completed the study. Of the 36 “Retina” sub-group participants, 12 were assigned to the exudative AMD, DR, and “other” groups each. The age distribution and clinical characteristics of the study cohort are shown in Tables 1 through 5.

Table 1. Age Distribution for All Subjects by Enrollment Category

	Mean	SD	Median	Min	Max
Normal (n=15)	**47**	**21.8**	**41**	**19**	**84**
Glaucoma (n=16)	**72**	**7.4**	**73**	**62**	**87**
Retina (n=36)	**68**	**16.1**	**71**	**21**	**95**
Wet AMD (n=12)	*77*	*9.6*	*74*	*66*	*95*
DR (n=12)	*56*	*12.7*	*57*	*31*	*77*
Retina other (n=12)	*70*	*18.0*	*75*	*21*	*90*

Table 2. Visual Field and Optic Nerve Head Characteristics Distribution in Glaucoma Group

Glaucoma Stage (Total N=16)	VF PSD mean (range) dB	VF MD mean (range) dB	VF GHT outside normal limits (N of eyes)	ONH rim thinning (N of eyes)	RNFL defect (N of eyes)	ONH cupping (N of eyes)
Early N=7	2.69 (1.76 to 3.52)	-1.71 (-2.71 to -0.32)	5	5	0	7
Moderate N=4	4.74 (3.33 to 6.08)	-3.62 (-4.42 to -3.04)	4	4	1	3
Advanced N=5	11.66 (10.72 to 12.23)	-14.06 (-25.79 to -7.84)	5	5	2	5

Table 3. Imaging Findings and Treatment in Retina Wet AMD Sub-group

Subject	Eye	Sub-Group	Type 1 CNV	Type 2 CNV	IRF	SRF	PED	CNV seen on OCTA	Treatment
SD7529	OS	wetAMD	1		1			1	
SD7533	OD	wetAMD		1	1			1	1
SD7549	OS	wetAMD	1		1			1	1
SD7551	OD	wetAMD		1		1	1		
SD7553	OS	wetAMD	1			1			
SD7555	OS	wetAMD		1					1
SD7557	OD	wetAMD		1	1				1
SD7558	OD	wetAMD	1					1	1
SD7561	OD	wetAMD		1				1	1
SD7563	OS	wetAMD	1			1			
SD7564	OD	wetAMD	1			1		1	1
SD7568	OS	wetAMD	1					1	1
Sum			7	5	4	4	1	7	8

Table 4. Clinical and Imaging Findings, and Treatment in Retina DR Sub-group

Subject	Eye	Sub-Group	DR Severity	w/ DME	w/o DME	IRF	Reduced Retinal Vascular Density	Other Vascular Change	Treatment
SD7537	OD	DR	Moderate NPDR	1		1	1		
SD7538	OD	DR	PDR	1		1	1		
SD7539	OS	DR	Moderate NPDR	1		1	1	IRMA	
SD7540	OS	DR	PDR	1		1		dilation, tortuosity	
SD7543	OS	DR	Moderate NPDR	1		1	1	dilation, tortuosity, MA	
SD7547	OS	DR	PDR	1		1	1	FAZ Outpouching	1
SD7554	OD	DR	Moderate NPDR	1		1	1	dilation, tortuosity	
SD 7556	OD	DR	Moderate NPDR			1	1		
SD7560	OS	DR	PDR	1			1	FAZ outpouching	1
SD7565	OS	DR	PDR		1		1	FAZ outpouching	1
SD7566	OS	DR	PDR		1			FAZ outpouching	1
SD7567	OD	DR	Mild NPDR		1		1		
Sum				**8**	**3**	**8**	**10**		**4**

Table 5. Clinical and Imaging Findings, and Treatment in Retina Other Sub-group

Subject	Eye	Sub-Group	Details	IRF	SRF	CNV on OCTA	Reduced Retinal Vascular Density	Other Vascular Change	Treatment
SD7528	OS	Other	ERM						
SD7534	OD	Other	BRVO w/CME				1		1
SD7535	OD	Other	dryAMD						
SD7541	OD	Other	dryAMD						
SD7542	OD	Other	dryAMD						
SD7544	OS	Other	Traumatic CNV			1			
SD7545	OD	Other	PCV		1	1			1
SD7546	OS	Other	BRVO	1			1		1
SD7548	OS	Other							
SD7550	OD	Other	ERM w/ lamellar hole						
SD7559	OD	Other	BRVO	1			1		1
SD7569	OD	Other	BRVO	1			1	dilation, tortuosity	1
Sum				3	1	2	4		5

Results

The frequency of scan exclusion due to insufficient image quality are shown as follows:

- 3 mm AngioRetina scan – 12.9% (77 out of 595 scans)
- 6 mm HD AngioRetina scan – 14.4% (86 out of 598 scans)
- 4.5 mm HD AngioDisc – 3.7% (10 out of 268 scans) (only Normal and Glaucoma groups)

For the 3 mm AngioRetina scan, the edit rates were: IPL 13.3%, BRM 11.6%, OPL 6%, RPE 3.5%, and ILM 0% for segmentation, FAZ boundary 10.8%, and ETDRS grid re-centering 1.5%. For the 6 mm HD AngioRetina scan, the edit rates were: IPL 13.9%, BRM 10.4%, OPL 5.5%, RPE 2.3%, and ILM 0.6% for segmentation, FAZ boundary17.7%, and ETDRS grid re-centering 1.8%.

The results are provided below, organized by scan patterns and measurements.

Vascular Parameters of the 3 mm AngioRetina and 6 mm HD AngioRetina Scans

Tables 6 through **11** summarize the results of the R&R analysis of vascular parameters of 3 mm Angio Retina and 6 mm HD AngioRetina scans.

Table 6 Vascular Parameters of AngioRetina Scans, Normal Group

Normal																				
		6-mm HD AngioRetina Scan									3-mm AngioRetina Scan									
	Parameter	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility
Superficial (ILM to IPL-10μm) Vessel Density (%)	**WI**	128	50.5	3.2	41.0	56.0	2.3	2.4	4.8%	6.7	129	48.0	3.5	38.3	53.2	1.7	1.9	3.9%	5.2
	WI_S_Hemi	128	50.8	3.3	40.8	56.5	2.3	2.5	4.9%	6.9	129	48.7	3.8	38.0	54.4	1.8	2.1	4.2%	5.7
	WI_I_Hemi	128	50.3	3.3	41.1	55.9	2.4	2.4	4.9%	6.8	129	47.3	3.5	38.5	54.3	2.0	2.1	4.4%	5.8
	All (0-6)	128	50.6	3.3	40.6	56.1	2.3	2.4	4.8%	6.7	129	47.6	3.4	37.9	53.1	1.6	1.8	3.7%	4.9
	C (1)	128	27.4	7.1	8.6	44.3	1.9	2.2	8.2%	6.1	129	24.0	6.5	7.9	39.6	1.4	1.5	6.4%	4.2
	All (1-3)	128	53.0	3.5	42.7	59.2	2.7	2.8	5.4%	7.9	129	50.7	3.3	41.6	55.7	1.8	1.9	3.7%	5.2
	S_Hemi (1-3)	128	53.3	3.4	45.0	60.0	2.4	2.6	4.9%	7.3	129	50.8	3.5	41.3	56.6	1.7	1.9	3.7%	5.2
	I_Hemi (1-3)	128	52.7	4.0	36.2	58.5	3.2	3.3	6.4%	9.2	129	50.5	3.4	41.1	55.9	2.1	2.1	4.3%	6.0
	T (1-3)	128	53.8	3.4	35.8	60.2	2.7	2.8	5.3%	7.9	129	50.2	2.9	42.3	56.0	1.7	1.9	3.8%	5.3
	S (1-3)	128	53.5	3.8	43.6	61.2	2.7	2.9	5.5%	8.1	129	51.5	3.8	40.6	58.2	2.0	2.2	4.2%	6.0
	N (1-3)	128	52.2	4.0	40.5	58.7	3.3	3.3	6.4%	9.3	129	49.9	3.6	38.9	56.7	1.9	2.1	4.2%	5.8
	I (1-3)	128	52.5	4.7	30.6	59.0	3.9	4.0	7.6%	11.0	128	51.1	4.0	40.4	57.4	2.5	2.5	4.9%	7.0
	All (3-6)	128	50.7	3.4	40.7	56.7	2.3	2.4	4.8%	6.8	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	128	50.9	3.5	40.2	56.3	2.4	2.6	5.1%	7.1	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	128	50.5	3.5	41.2	57.2	2.4	2.5	4.9%	6.8	-	-	-	-	-	-	-	-	-
	T (3-6)	128	47.6	3.4	36.7	53.3	2.5	2.7	5.7%	7.5	-	-	-	-	-	-	-	-	-
	S (3-6)	128	51.0	3.8	40.4	57.8	2.6	2.7	5.4%	7.6	-	-	-	-	-	-	-	-	-
	N (3-6)	128	54.1	3.7	44.5	60.3	2.4	2.5	4.6%	6.9	-	-	-	-	-	-	-	-	-
	I (3-6)	128	50.2	3.8	38.3	57.0	2.6	2.6	5.2%	7.3	-	-	-	-	-	-	-	-	-
	G11	128	52.1	6.3	36.8	61.9	2.5	2.5	4.8%	6.9	129	50.7	4.2	37.6	58.9	2.4	2.5	4.9%	6.9
	G12	128	51.6	3.7	41.7	58.6	2.6	2.8	5.4%	7.7	129	52.2	3.6	39.7	58.1	2.0	2.1	4.1%	5.9
	G13	128	48.9	6.4	33.9	61.4	2.9	3.3	6.7%	9.1	129	49.7	4.9	35.3	59.3	2.4	2.9	5.8%	7.9
	G21	128	51.6	4.3	40.1	59.3	2.6	2.6	5.1%	7.3	129	49.7	3.4	38.9	55.8	2.0	2.2	4.4%	6.0
	G22	128	48.3	3.5	37.6	54.9	2.4	2.6	5.4%	7.2	129	29.5	5.7	14.2	42.1	1.8	1.9	6.5%	5.3
	G23	128	50.8	4.3	38.0	59.9	2.4	2.7	5.3%	7.4	129	49.3	3.1	41.2	55.3	1.6	1.8	3.6%	4.9
	G31	128	51.0	6.0	36.1	61.3	2.7	2.7	5.3%	7.4	129	50.5	4.8	30.6	57.4	3.2	3.2	6.4%	8.9
	G32	128	50.7	4.0	35.7	58.2	2.9	2.9	5.7%	8.0	129	50.3	4.1	38.6	57.2	2.6	2.7	5.3%	7.4
	G33	128	49.6	5.6	35.6	61.3	2.8	2.9	5.9%	8.2	129	50.3	4.2	39.1	57.6	2.3	2.5	4.9%	6.9
Deep (IPL-10μ to OPL+10μ) Vessel Density (%)	**WI**	128	50.7	4.8	40.4	64.5	3.9	3.9	7.8%	10.9	129	49.5	3.5	42.0	59.2	2.3	2.5	5.0%	6.8
	WI_S_Hemi	128	50.9	5.0	40.8	64.9	4.1	4.2	8.3%	11.7	129	50.0	3.7	42.2	60.4	2.4	2.7	5.3%	7.4
	WI_I_Hemi	128	50.4	4.9	38.0	64.5	3.8	3.8	7.6%	10.6	129	49.1	3.5	41.6	58.6	2.4	2.4	4.9%	6.7
	All (0-6)	128	52.0	4.7	42.3	64.7	3.7	3.8	7.3%	10.5	129	49.4	3.4	43.0	59.9	2.0	2.1	4.3%	5.9
	C (1)	128	38.2	7.8	16.8	50.9	1.9	2.0	5.2%	5.4	129	33.0	7.4	13.9	46.2	1.3	1.3	4.1%	3.7
	All (1-3)	128	54.0	3.6	46.1	63.5	2.8	2.8	5.2%	7.8	129	51.5	3.5	43.1	62.2	2.2	2.4	4.6%	6.6
	S_Hemi (1-3)	128	54.2	3.6	45.6	62.7	2.9	2.9	5.3%	8.0	129	51.6	3.5	43.3	63.2	2.3	2.4	4.7%	6.7
	I_Hemi (1-3)	128	53.8	3.9	42.6	64.7	3.0	3.2	5.9%	8.8	129	51.5	3.6	43.0	61.3	2.3	2.5	4.8%	6.8
	T (1-3)	128	54.9	3.8	38.9	64.2	2.9	3.0	5.4%	8.2	129	52.1	3.3	45.4	62.2	2.1	2.2	4.3%	6.2
	S (1-3)	128	53.3	4.1	43.1	63.4	3.4	3.5	6.5%	9.6	129	51.2	3.9	39.9	64.0	2.6	2.8	5.5%	7.8
	N (1-3)	128	55.0	3.8	46.3	64.9	3.1	3.1	5.6%	8.6	129	51.9	3.5	42.8	62.5	2.1	2.3	4.5%	6.4
	I (1-3)	128	52.8	4.6	30.0	65.4	3.7	3.9	7.5%	10.9	128	50.8	4.0	41.2	60.2	2.8	2.9	5.6%	7.9
	All (3-6)	128	51.9	5.2	39.9	65.9	4.2	4.2	8.2%	11.7	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	128	52.2	5.3	41.4	66.0	4.3	4.4	8.5%	12.2	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	128	51.6	5.4	36.0	66.5	4.2	4.3	8.3%	11.8	-	-	-	-	-	-	-	-	-
	T (3-6)	128	54.8	4.4	43.6	65.0	3.6	3.7	6.7%	10.1	-	-	-	-	-	-	-	-	-
	S (3-6)	128	51.7	5.8	40.8	67.7	4.7	4.8	9.3%	13.3	-	-	-	-	-	-	-	-	-
	N (3-6)	128	50.4	6.0	36.5	66.6	4.9	5.0	9.9%	13.8	-	-	-	-	-	-	-	-	-
	I (3-6)	128	50.7	5.9	32.9	66.4	4.7	4.7	9.3%	13.0	-	-	-	-	-	-	-	-	-
	G11	128	49.0	6.4	37.7	66.6	5.6	5.7	11.6%	15.8	129	50.2	4.3	39.8	60.7	3.6	3.7	7.4%	10.2
	G12	128	51.2	5.7	40.4	67.2	4.7	4.8	9.3%	13.2	129	51.1	3.9	40.5	62.1	2.7	2.8	5.5%	7.8
	G13	128	49.5	6.7	33.5	65.0	4.9	5.1	10.4%	14.2	129	50.8	4.3	39.2	62.5	3.0	3.4	6.7%	9.5
	G21	128	52.8	4.9	42.3	66.4	4.1	4.1	7.8%	11.4	129	52.2	3.3	44.5	60.8	2.1	2.1	4.1%	5.9
	G22	128	51.8	3.2	45.2	60.4	2.3	2.3	4.4%	6.3	129	37.5	5.8	20.2	48.9	1.8	2.0	5.4%	5.6
	G23	128	53.7	4.8	41.5	64.0	3.8	3.9	7.2%	10.7	129	52.0	3.3	45.0	62.2	2.0	2.1	4.0%	5.8
	G31	128	48.1	6.3	31.6	65.8	4.9	4.9	10.2%	13.6	129	50.3	4.4	39.5	60.3	3.5	3.6	7.1%	9.9
	G32	128	50.9	5.5	34.9	65.8	4.5	4.6	9.0%	12.7	129	51.3	4.2	41.0	61.6	3.0	3.1	6.0%	8.5
	G33	128	49.1	7.3	30.1	64.3	4.6	4.6	9.5%	12.9	129	50.3	4.5	38.7	60.8	3.4	3.6	7.2%	10.0
FAZ	**FAZ (mm^2)**	128	0.270	0.120	0.069	0.585	0.012	0.012	4.2%	0.032	129	0.284	0.127	0.080	0.582	0.008	0.009	3.0%	0.024
	PERIM (mm)	128	1.975	0.456	0.964	3.080	0.085	0.086	4.3%	0.238	129	2.092	0.494	1.127	3.189	0.063	0.066	3.1%	0.182
	FD-300 (%)	128	54.0	4.1	39.6	61.6	2.5	2.6	4.9%	7.3	129	50.7	3.7	41.2	57.7	2.0	2.0	3.8%	5.4

Table 7. Vascular Parameters of AngioRetina Scans, Glaucoma Group

Glaucoma																			
		6-mm HD AngioRetina Scan									3-mm AngioRetina Scan								
	Parameter	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility
Superficial (ILM to IPL-10µm) Vessel Density (%)	**WI**	133	42.6	4.8	30.8	51.2	2.2	2.4	5.7%	6.7	134	42.8	5.3	27.8	53.2	2.1	2.4	5.7%	6.7
	WI_S_Hemi	133	43.5	4.8	31.1	53.0	2.3	2.6	5.9%	7.1	134	43.3	5.1	27.6	52.8	2.3	2.7	6.3%	7.5
	WI_I_Hemi	133	41.7	5.2	30.0	51.1	2.3	2.4	5.7%	6.6	134	42.4	6.0	28.1	54.7	2.2	2.4	5.7%	6.7
	All (0-6)	133	43.0	4.9	30.8	51.4	2.3	2.4	5.7%	6.7	134	43.1	5.3	27.3	53.3	2.0	2.3	5.4%	6.5
	C (1)	133	21.2	6.7	7.5	35.4	2.0	2.2	10.2%	6.0	134	20.3	6.4	6.6	35.9	1.4	1.7	8.7%	4.8
	All (1-3)	133	47.5	5.3	33.5	56.7	2.7	2.9	6.1%	8.0	134	46.0	5.6	29.5	57.1	2.2	2.5	5.4%	6.9
	S_Hemi (1-3)	133	47.7	5.2	33.6	57.6	2.9	3.1	6.5%	8.6	134	46.2	5.5	28.7	57.3	2.3	2.6	5.6%	7.1
	I_Hemi (1-3)	133	47.3	6.0	31.7	56.6	2.8	2.9	6.2%	8.1	134	45.8	6.1	30.2	56.9	2.3	2.6	5.6%	7.1
	T (1-3)	133	47.0	5.2	33.0	57.3	2.6	2.9	6.1%	7.9	134	44.7	5.1	31.7	57.9	2.3	2.6	5.8%	7.2
	S (1-3)	133	48.1	5.6	34.3	58.1	3.4	3.6	7.4%	9.8	134	46.8	5.8	29.6	58.8	2.5	2.8	5.9%	7.7
	N (1-3)	133	47.8	6.3	29.2	59.9	3.3	3.5	7.3%	9.6	134	46.5	6.5	24.4	56.8	2.6	2.8	6.1%	7.9
	I (1-3)	133	47.0	6.6	31.2	57.0	3.3	3.4	7.4%	9.6	133	46.0	6.8	28.7	56.3	2.6	2.8	6.1%	7.8
	All (3-6)	133	42.5	5.0	30.7	51.2	2.3	2.5	5.8%	6.9	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	133	43.5	5.1	30.5	53.4	2.4	2.6	6.1%	7.3	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	133	41.5	5.6	29.3	51.5	2.5	2.5	6.0%	6.9	-	-	-	-	-	-	-	-	-
	T (3-6)	133	39.8	4.7	29.6	50.2	2.4	2.6	6.4%	7.1	-	-	-	-	-	-	-	-	-
	S (3-6)	133	42.7	5.4	30.1	53.2	2.7	2.9	6.8%	8.0	-	-	-	-	-	-	-	-	-
	N (3-6)	133	47.3	5.8	32.4	57.2	2.5	2.7	5.7%	7.5	-	-	-	-	-	-	-	-	-
	I (3-6)	133	40.2	5.9	27.3	52.6	2.7	2.7	6.8%	7.6	-	-	-	-	-	-	-	-	-
	G11	133	43.3	6.3	29.3	56.6	2.6	2.6	6.1%	7.3	134	44.7	6.3	27.5	57.4	3.0	3.2	7.2%	8.9
	G12	133	43.5	5.4	29.4	54.5	3.0	3.2	7.3%	8.8	134	47.2	5.9	28.9	59.6	2.7	2.8	6.0%	7.8
	G13	133	41.5	7.3	27.7	57.2	2.7	3.0	7.2%	8.2	134	43.7	6.3	30.5	58.7	3.2	3.7	8.4%	10.2
	G21	133	45.6	6.4	31.0	57.8	2.4	2.6	5.7%	7.1	134	45.2	6.5	25.2	57.6	2.6	2.9	6.5%	8.1
	G22	133	43.6	4.9	29.1	51.3	2.4	2.6	5.9%	7.1	134	25.8	6.2	11.9	39.3	2.2	2.5	9.7%	6.8
	G23	133	44.0	5.7	31.2	58.2	2.6	2.9	6.6%	8.0	134	46.0	5.0	33.9	56.4	2.6	2.8	6.2%	7.9
	G31	133	41.6	6.8	27.7	52.7	2.3	2.3	5.6%	6.4	134	43.9	7.4	29.2	55.8	2.7	2.8	6.5%	7.9
	G32	133	41.7	5.6	28.7	52.5	2.8	2.9	7.0%	8.0	134	45.3	7.1	24.5	56.3	2.9	3.0	6.7%	8.4
	G33	133	38.5	6.6	24.6	51.7	2.9	3.0	7.9%	8.4	134	43.6	7.0	25.2	55.6	3.0	3.5	8.1%	9.7
Deep (IPL-10µ to OPL+10µ) Vessel Density (%)	**WI**	133	47.9	5.1	36.1	61.3	3.3	3.8	7.9%	10.5	134	48.6	3.3	40.5	55.7	2.4	2.6	5.3%	7.1
	WI_S_Hemi	133	48.1	5.1	35.8	61.1	3.4	4.1	8.5%	11.3	134	48.9	3.5	40.8	56.7	2.4	2.6	5.4%	7.3
	WI_I_Hemi	133	47.7	5.3	35.3	61.5	3.4	3.7	7.7%	10.2	134	48.2	3.3	40.2	55.6	2.5	2.7	5.5%	7.4
	All (0-6)	133	49.3	4.9	37.3	62.6	3.2	3.6	7.4%	10.0	134	48.5	3.0	41.5	56.1	2.2	2.3	4.8%	6.4
	C (1)	133	33.0	9.2	11.3	53.0	2.3	2.3	7.0%	6.3	134	29.9	8.1	12.9	49.4	1.7	1.7	5.7%	4.6
	All (1-3)	133	52.8	3.5	44.1	63.4	2.6	2.9	5.5%	8.1	134	50.9	3.3	43.0	58.8	2.3	2.5	4.9%	6.9
	S_Hemi (1-3)	133	52.9	3.6	44.6	63.6	2.7	3.0	5.6%	8.2	134	51.1	3.3	43.6	58.7	2.3	2.4	4.8%	6.8
	I_Hemi (1-3)	133	52.6	3.7	42.4	63.2	2.9	3.1	6.0%	8.7	134	50.8	3.3	42.0	58.9	2.6	2.7	5.4%	7.6
	T (1-3)	133	53.7	3.6	44.6	62.5	2.6	2.9	5.4%	8.0	134	51.3	3.6	41.3	63.2	2.8	3.0	5.9%	8.4
	S (1-3)	133	52.7	4.1	43.4	64.7	3.3	3.5	6.7%	9.8	134	51.2	3.7	41.2	59.0	2.5	2.7	5.3%	7.5
	N (1-3)	133	52.8	3.7	35.0	62.4	3.2	3.4	6.4%	9.4	134	50.4	3.0	43.9	58.8	2.3	2.4	4.8%	6.7
	I (1-3)	133	51.9	4.3	39.8	64.0	3.5	3.7	7.2%	10.3	133	50.8	3.8	39.8	57.8	2.8	3.0	5.8%	8.2
	All (3-6)	133	48.9	5.6	36.0	63.4	3.6	4.0	8.2%	11.1	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	133	49.3	5.4	36.4	63.4	3.5	4.2	8.5%	11.6	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	133	48.4	5.9	33.1	63.4	3.9	4.1	8.5%	11.4	-	-	-	-	-	-	-	-	-
	T (3-6)	133	51.0	5.0	37.5	62.7	3.2	3.6	7.2%	10.1	-	-	-	-	-	-	-	-	-
	S (3-6)	133	48.5	6.2	32.1	63.3	4.1	4.8	10.0%	13.4	-	-	-	-	-	-	-	-	-
	N (3-6)	133	48.7	5.8	29.9	65.0	4.0	4.4	9.1%	12.3	-	-	-	-	-	-	-	-	-
	I (3-6)	133	47.2	7.0	30.4	62.6	4.4	4.5	9.6%	12.5	-	-	-	-	-	-	-	-	-
	G11	133	46.8	6.2	32.2	59.5	4.4	5.0	10.7%	13.9	134	49.6	4.1	38.8	58.1	3.1	3.3	6.6%	9.1
	G12	133	48.7	5.9	31.1	63.5	4.0	4.7	9.7%	13.1	134	51.2	3.9	41.4	58.9	2.7	2.8	5.5%	7.8
	G13	133	45.2	6.5	28.7	59.3	4.6	5.4	11.9%	14.8	134	49.5	4.6	39.4	57.9	3.5	3.8	7.7%	10.6
	G21	133	50.6	5.4	27.8	64.2	3.6	3.9	7.7%	10.8	134	51.0	3.6	40.1	61.5	2.5	2.7	5.3%	7.5
	G22	133	50.1	3.2	39.7	58.5	2.2	2.3	4.7%	6.5	134	34.9	6.3	20.9	50.6	1.9	2.0	5.7%	5.4
	G23	133	50.7	4.9	40.2	62.5	3.0	3.5	6.9%	9.7	134	51.1	3.6	44.2	67.0	2.6	2.9	5.6%	7.9
	G31	133	46.4	6.0	31.4	62.0	4.2	4.4	9.5%	12.2	134	49.6	4.2	38.8	59.4	3.2	3.4	6.9%	9.4
	G32	133	48.2	6.3	33.1	63.1	4.1	4.2	8.8%	11.7	134	50.9	3.8	38.6	60.2	3.0	3.1	6.2%	8.7
	G33	133	44.6	7.3	26.9	61.3	4.4	4.7	10.7%	13.1	134	49.2	4.5	37.0	58.3	3.4	3.6	7.3%	9.9
FAZ	**FAZ (mm^2)**	124	0.335	0.127	0.151	0.644	0.010	0.010	3.1%	0.029	125	0.334	0.120	0.148	0.611	0.011	0.011	3.3%	0.032
	PERIM (mm)	124	2.217	0.419	1.471	3.184	0.066	0.066	3.0%	0.182	125	2.293	0.411	1.500	3.122	0.062	0.062	2.7%	0.171
	FD-300 (%)	124	50.6	4.9	39.7	63.0	3.1	3.1	6.2%	8.7	125	48.9	4.5	35.3	59.9	2.0	2.1	4.3%	5.9

Table 8. Vascular Parameters of AngioRetina Scans, Retina Group

Retina																			
		6-mm HD AngioRetina Scan									3-mm AngioRetina Scan								
	Parameter	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility
Superficial (ILM to IPL-10µm) Vessel Density (%)	**WI**	251	45.6	3.9	34.2	53.8	1.9	2.0	4.5%	5.6	255	42.1	4.1	33.2	52.8	1.9	2.0	4.9%	5.6
	WI_S_Hemi	251	45.7	3.8	33.9	54.3	2.0	2.2	4.9%	6.1	255	42.4	4.2	33.5	54.5	2.0	2.2	5.3%	6.1
	WI_I_Hemi	251	45.4	4.3	30.5	54.0	2.0	2.1	4.5%	5.7	255	41.7	4.5	31.2	52.9	2.1	2.2	5.3%	6.1
	All (0-6)	251	45.5	4.0	34.6	54.0	2.0	2.1	4.7%	5.9	255	41.8	4.4	31.7	52.9	1.9	2.1	5.0%	5.7
	C (1)	251	26.0	8.2	5.7	43.8	2.9	3.0	11.3%	8.2	255	22.6	7.6	6.2	40.9	1.7	1.9	8.5%	5.3
	All (1-3)	251	46.9	4.4	35.4	57.9	2.5	2.7	5.8%	7.4	255	44.2	4.6	34.4	55.3	2.0	2.2	5.0%	6.1
	S_Hemi (1-3)	251	47.0	4.5	35.2	58.7	2.6	2.8	6.1%	7.8	255	44.3	4.7	34.3	55.5	2.1	2.2	5.1%	6.2
	I_Hemi (1-3)	251	46.9	4.9	33.5	57.2	2.9	3.0	6.5%	8.3	255	44.1	4.9	32.1	56.4	2.2	2.4	5.5%	6.6
	T (1-3)	251	46.3	6.2	26.7	56.7	3.1	3.1	6.8%	8.7	255	42.6	6.1	24.3	54.1	2.3	2.5	5.9%	6.9
	S (1-3)	251	47.7	4.7	32.3	59.0	2.8	3.1	6.6%	8.6	255	45.2	5.2	29.6	57.1	2.3	2.4	5.4%	6.7
	N (1-3)	251	46.4	5.0	26.2	57.9	3.3	3.5	7.7%	9.8	255	44.2	4.5	31.9	54.4	2.4	2.6	5.9%	7.1
	I (1-3)	251	47.4	5.3	32.8	59.5	3.4	3.5	7.3%	9.6	249	45.0	5.3	31.0	57.3	2.5	2.6	5.9%	7.3
	All (3-6)	251	45.8	4.2	33.5	54.6	2.0	2.1	4.7%	5.9	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	251	45.9	4.0	34.6	55.5	2.1	2.2	4.9%	6.2	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	251	45.8	4.8	28.1	54.2	2.1	2.2	4.9%	6.2	-	-	-	-	-	-	-	-	-
	T (3-6)	251	41.7	4.9	25.6	51.7	2.4	2.6	6.2%	7.1	-	-	-	-	-	-	-	-	-
	S (3-6)	251	45.8	4.4	33.2	55.5	2.3	2.5	5.5%	6.9	-	-	-	-	-	-	-	-	-
	N (3-6)	251	50.5	3.7	40.8	58.1	2.1	2.2	4.3%	6.0	-	-	-	-	-	-	-	-	-
	I (3-6)	249	45.2	5.6	24.8	54.6	2.3	2.4	5.2%	6.5	-	-	-	-	-	-	-	-	-
	G11	251	46.7	6.4	31.9	59.1	2.2	2.3	5.0%	6.4	255	44.4	5.3	28.5	57.1	2.7	2.7	6.3%	7.6
	G12	251	46.1	4.5	34.6	56.1	2.5	2.7	6.0%	7.6	255	45.2	5.6	25.3	57.5	2.5	2.7	6.0%	7.4
	G13	251	45.2	7.3	26.9	59.6	2.4	2.5	5.5%	6.9	255	43.8	5.4	26.3	56.7	2.5	2.7	6.2%	7.4
	G21	251	46.0	6.0	25.0	56.3	2.5	2.6	5.7%	7.2	255	42.7	6.0	16.8	55.0	2.6	2.8	6.6%	7.7
	G22	251	43.4	4.4	29.5	55.2	2.4	2.6	6.0%	7.1	255	27.2	6.1	12.7	41.7	2.0	2.1	7.9%	5.9
	G23	251	46.0	5.8	28.4	60.1	2.4	2.6	5.7%	7.3	255	43.3	5.0	30.9	54.0	2.5	2.8	6.5%	7.7
	G31	251	45.6	7.8	20.1	58.1	2.3	2.3	5.1%	6.3	255	43.2	7.3	14.6	56.7	3.0	3.0	7.0%	8.3
	G32	251	45.6	5.3	26.6	56.4	2.5	2.5	5.6%	7.1	255	44.7	5.3	28.0	57.5	2.9	3.0	6.7%	8.2
	G33	251	45.4	6.4	28.5	59.2	2.5	2.5	5.5%	7.0	255	43.9	5.0	32.0	55.9	2.6	2.7	6.3%	7.6
Deep (IPL-10µ to OPL+10µ) Vessel Density (%)	**WI**	251	46.9	4.5	30.1	58.1	3.1	3.2	6.8%	8.8	255	43.0	4.7	30.5	55.6	3.4	3.4	7.8%	9.3
	WI_S_Hemi	251	47.0	4.6	33.4	58.5	3.4	3.5	7.5%	9.7	255	43.4	4.7	30.3	56.2	3.4	3.4	7.9%	9.6
	WI_I_Hemi	251	46.8	4.9	26.8	59.1	3.2	3.2	6.7%	8.7	255	42.7	5.2	30.1	56.3	3.5	3.5	8.1%	9.7
	All (0-6)	251	48.0	4.6	30.7	59.3	3.2	3.2	6.7%	8.9	255	42.8	4.8	30.8	55.5	3.3	3.3	7.6%	9.1
	C (1)	251	35.9	8.0	14.9	52.5	3.5	3.5	9.7%	9.6	255	30.9	7.4	13.4	53.9	2.7	2.7	8.7%	7.5
	All (1-3)	251	49.9	4.6	34.5	62.3	3.5	3.5	6.9%	9.6	255	44.3	5.0	30.9	56.9	3.5	3.5	7.9%	9.8
	S_Hemi (1-3)	251	50.2	4.7	37.6	63.7	3.7	3.7	7.4%	10.2	255	44.7	4.9	31.4	57.6	3.5	3.5	7.8%	9.7
	I_Hemi (1-3)	251	49.6	5.2	31.5	62.1	3.7	3.7	7.4%	10.2	255	44.0	5.6	29.7	57.2	3.8	3.8	8.4%	10.4
	T (1-3)	251	49.9	5.9	29.3	63.0	4.0	4.0	7.9%	11.0	255	44.4	5.6	26.4	58.2	3.3	3.3	7.3%	9.1
	S (1-3)	251	49.5	5.5	29.5	63.1	4.2	4.2	8.5%	11.7	255	44.3	5.7	27.8	59.4	3.8	3.8	8.5%	10.6
	N (1-3)	251	50.9	5.1	33.2	66.9	4.2	4.2	8.3%	11.7	255	44.7	5.2	29.1	59.2	3.8	3.8	8.5%	10.6
	I (1-3)	251	49.1	5.2	34.2	63.2	4.4	4.4	8.9%	12.1	249	44.0	5.5	25.9	58.0	4.1	4.1	9.3%	11.5
	All (3-6)	251	47.9	5.0	29.4	59.3	3.3	3.4	7.1%	9.4	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	251	47.9	5.0	33.0	60.7	3.6	3.7	7.7%	10.2	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	251	47.8	5.5	25.7	61.8	3.4	3.4	7.2%	9.5	-	-	-	-	-	-	-	-	-
	T (3-6)	251	49.5	5.5	26.4	60.2	2.9	3.0	6.2%	8.5	-	-	-	-	-	-	-	-	-
	S (3-6)	251	47.4	5.4	30.9	61.8	3.8	3.9	8.3%	10.9	-	-	-	-	-	-	-	-	-
	N (3-6)	251	47.5	6.0	34.3	62.4	4.4	4.4	9.4%	12.3	-	-	-	-	-	-	-	-	-
	I (3-6)	249	47.0	6.3	22.8	62.8	3.8	3.8	8.2%	10.6	-	-	-	-	-	-	-	-	-
	G11	251	46.5	5.8	23.2	59.6	4.4	4.5	9.6%	12.4	255	44.1	5.5	27.0	59.0	4.3	4.3	9.7%	12.0
	G12	251	47.4	5.3	34.3	61.2	3.9	4.1	8.6%	11.3	255	44.2	6.5	24.0	58.9	3.9	4.0	8.8%	11.0
	G13	251	44.4	6.4	24.3	61.1	4.3	4.6	10.3%	12.6	255	44.0	5.6	26.3	57.3	4.1	4.1	9.3%	11.4
	G21	251	49.2	5.6	28.3	63.8	3.8	3.8	7.7%	10.5	255	44.0	6.5	16.8	62.4	3.6	3.7	8.2%	10.1
	G22	251	47.8	4.4	35.2	59.0	3.1	3.1	6.6%	8.7	255	34.3	5.9	20.3	53.6	3.0	3.0	8.8%	8.4
	G23	251	48.8	5.5	32.4	61.5	3.4	3.5	7.1%	9.6	255	45.5	4.5	32.4	56.6	3.4	3.4	7.5%	9.5
	G31	251	45.5	6.6	18.2	61.0	4.0	4.1	8.9%	11.2	255	42.9	7.6	12.1	58.4	4.5	4.5	10.3%	12.5
	G32	251	47.0	6.0	25.7	62.0	3.9	3.9	8.4%	10.9	255	44.3	5.9	26.5	60.0	4.3	4.3	9.5%	11.8
	G33	251	45.4	5.6	29.3	59.1	4.0	4.0	8.9%	11.2	255	43.9	5.4	29.2	60.7	4.5	4.5	10.1%	12.4
FAZ	**FAZ (mm^2)**	234	0.259	0.117	0.088	0.576	0.017	0.017	6.6%	0.048	237	0.267	0.12	0.102	0.603	0.010	0.010	3.8%	0.029
	PERIM (mm)	234	1.969	0.446	1.130	3.130	0.092	0.093	4.7%	0.257	237	2.075	0.48	1.276	4.182	0.097	0.097	4.6%	0.270
	FD-300 (%)	234	47.1	5.4	18.7	57.9	3.7	3.8	8.1%	10.5	237	43.9	4.8	31.1	54.0	2.1	2.3	5.2%	6.3

Table 9. Vascular Parameters of AngioRetina Scans, Retina Wet AMD Sub-group

Retina: Wet AMD Sub-group																			
		6-mm HD AngioRetina Scan									3-mm AngioRetina Scan								
	Parameter	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility
Superficial (ILM to IPL-10µm) Vessel Density (%)	**WI**	87	46.4	3.2	38.5	53.8	2.2	2.3	5.0%	6.4	89	43.1	2.7	33.2	48.2	1.6	1.7	4.0%	4.8
	WI_S_Hemi	87	46.4	3.5	37.4	54.3	2.3	2.4	5.2%	6.7	89	43.5	2.9	34.3	48.6	1.8	1.9	4.5%	5.3
	WI_I_Hemi	87	46.3	3.1	39.5	54.0	2.2	2.3	5.0%	6.4	89	42.7	3.0	32.1	48.4	1.8	1.9	4.4%	5.2
	All (0-6)	87	46.4	3.3	38.4	54.0	2.3	2.4	5.2%	6.6	89	43.0	2.9	33.0	48.5	1.7	1.8	4.2%	5.0
	C (1)	87	24.4	8.6	5.7	43.8	2.6	2.7	10.5%	7.5	89	21.4	8.5	6.3	40.9	1.8	2.1	9.1%	5.7
	All (1-3)	87	49.0	3.9	37.3	55.7	2.6	2.7	5.5%	7.4	89	45.7	3.1	34.6	50.1	1.8	1.9	4.2%	5.3
	S_Hemi (1-3)	87	48.7	4.1	36.5	55.4	2.8	2.9	6.0%	8.0	89	45.8	3.3	34.6	50.3	1.9	2.0	4.4%	5.6
	I_Hemi (1-3)	87	49.3	4.1	38.1	56.3	2.9	2.9	5.9%	8.0	89	45.6	3.2	34.2	50.6	2.0	2.0	4.5%	5.7
	T (1-3)	87	49.5	4.2	39.8	56.7	2.7	2.7	5.5%	7.5	89	45.5	3.3	33.7	50.3	2.2	2.4	5.3%	6.6
	S (1-3)	87	48.9	4.6	36.5	56.3	3.2	3.3	6.8%	9.2	89	46.5	3.9	32.1	53.7	2.3	2.4	5.1%	6.5
	N (1-3)	87	48.0	4.4	34.8	56.3	3.0	3.1	6.6%	8.7	89	45.0	3.2	36.4	51.3	1.9	2.0	4.5%	5.5
	I (1-3)	87	49.6	4.9	36.5	59.5	3.4	3.4	6.9%	9.3	88	46.0	3.9	32.7	52.1	2.3	2.3	5.1%	6.4
	All (3-6)	87	46.4	3.4	38.4	54.6	2.3	2.4	5.3%	6.8	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	87	46.3	3.8	38.2	55.5	2.4	2.6	5.6%	7.1	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	87	46.5	3.3	38.5	54.0	2.4	2.5	5.4%	6.9	-	-	-	-	-	-	-	-	-
	T (3-6)	87	43.4	3.5	35.3	51.4	2.6	2.7	6.2%	7.4	-	-	-	-	-	-	-	-	-
	S (3-6)	87	45.8	4.1	36.6	55.5	2.7	2.9	6.3%	8.0	-	-	-	-	-	-	-	-	-
	N (3-6)	87	50.4	3.4	42.2	57.9	2.3	2.4	4.7%	6.6	-	-	-	-	-	-	-	-	-
	I (3-6)	87	45.9	3.8	37.9	54.6	2.6	2.7	6.0%	7.6	-	-	-	-	-	-	-	-	-
	G11	87	47.9	5.5	34.3	57.8	2.2	2.3	5.0%	6.5	89	44.9	4.3	29.0	51.4	2.3	2.4	5.4%	6.6
	G12	87	46.4	4.3	37.9	55.6	3.0	3.1	6.7%	8.6	89	47.3	4.1	35.0	53.5	2.3	2.4	5.2%	6.7
	G13	87	44.8	7.5	29.2	58.0	2.7	2.9	6.4%	8.0	89	44.0	3.9	36.3	54.0	2.3	2.5	5.7%	7.0
	G21	87	47.6	3.8	37.4	55.6	2.5	2.6	5.4%	7.1	89	45.2	3.0	35.5	52.4	2.2	2.2	4.9%	6.1
	G22	87	45.0	3.6	33.3	52.6	2.4	2.4	5.4%	6.8	89	26.6	6.1	14.1	41.7	2.2	2.3	8.4%	6.4
	G23	87	46.9	4.6	36.6	57.4	2.5	2.7	5.7%	7.4	89	45.1	3.2	34.7	49.9	2.2	2.4	5.3%	6.5
	G31	87	47.0	5.2	33.8	56.4	2.4	2.4	5.2%	6.7	89	45.0	4.0	33.0	52.1	2.4	2.4	5.4%	6.7
	G32	87	46.7	4.0	38.6	56.4	2.8	2.9	6.2%	7.9	89	45.5	4.8	28.0	53.3	2.8	2.9	6.4%	7.9
	G33	87	45.0	7.1	31.5	59.2	2.7	2.8	6.2%	7.8	89	44.3	3.9	34.8	52.7	2.7	2.7	6.0%	7.3
Deep (IPL-10µ to OPL+10µ) Vessel Density (%)	**WI**	87	47.8	4.1	38.0	58.1	3.1	3.1	6.6%	8.7	89	44.2	4.5	34.3	55.6	3.4	3.4	7.7%	9.5
	WI_S_Hemi	87	47.5	4.6	35.2	58.5	3.3	3.3	6.9%	9.0	89	44.5	4.4	36.7	55.9	3.4	3.4	7.7%	9.6
	WI_I_Hemi	87	48.1	3.9	40.6	59.1	3.2	3.2	6.7%	8.9	89	43.8	4.8	30.3	56.3	3.6	3.6	8.2%	10.1
	All (0-6)	87	49.2	4.0	40.1	59.3	3.1	3.1	6.4%	8.7	89	43.7	4.6	33.0	55.5	3.4	3.4	7.7%	9.4
	C (1)	87	35.3	8.8	16.1	52.5	2.7	2.7	7.4%	7.6	89	30.7	9.4	13.4	53.9	2.4	2.4	7.4%	6.7
	All (1-3)	87	51.3	3.8	41.4	61.8	3.5	3.5	6.8%	9.6	89	45.4	4.5	35.1	56.8	3.7	3.7	8.0%	10.2
	S_Hemi (1-3)	87	51.4	3.8	41.3	61.6	3.6	3.6	7.0%	10.0	89	45.6	4.4	37.6	57.6	3.6	3.6	7.8%	10.0
	I_Hemi (1-3)	87	51.1	4.2	41.3	62.1	3.6	3.7	7.2%	10.2	89	45.2	4.9	31.1	57.2	4.0	4.0	8.8%	11.2
	T (1-3)	87	51.9	3.8	43.4	62.7	3.3	3.3	6.4%	9.2	89	46.1	4.3	32.9	56.8	3.5	3.5	7.5%	9.7
	S (1-3)	87	50.9	4.4	37.2	62.7	4.3	4.3	8.5%	11.9	89	45.8	4.9	36.5	59.4	3.8	3.8	8.1%	10.4
	N (1-3)	87	51.9	4.6	41.9	66.9	4.0	4.0	7.7%	11.1	89	44.7	5.0	33.2	59.2	4.1	4.1	9.2%	11.5
	I (1-3)	87	50.3	4.8	39.2	63.2	4.4	4.4	8.8%	12.3	88	44.9	5.0	34.0	58.0	4.3	4.3	9.5%	11.8
	All (3-6)	87	49.1	4.5	37.1	59.3	3.4	3.4	6.9%	9.3	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	87	48.7	5.1	33.8	60.7	3.6	3.6	7.4%	10.0	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	87	49.5	4.2	40.5	59.8	3.3	3.3	6.8%	9.2	-	-	-	-	-	-	-	-	-
	T (3-6)	87	52.0	3.5	42.5	60.1	2.8	2.8	5.4%	7.8	-	-	-	-	-	-	-	-	-
	S (3-6)	87	47.4	5.9	30.9	61.8	4.0	4.0	8.4%	11.0	-	-	-	-	-	-	-	-	-
	N (3-6)	87	48.3	5.8	35.7	62.4	4.1	4.1	8.6%	11.5	-	-	-	-	-	-	-	-	-
	I (3-6)	87	48.7	4.8	34.2	59.4	3.9	3.9	8.1%	10.9	-	-	-	-	-	-	-	-	-
	G11	87	46.3	6.1	23.2	57.7	4.3	4.3	9.4%	12.0	89	44.8	5.5	31.8	59.0	4.3	4.3	9.5%	12.0
	G12	87	47.9	5.4	34.3	61.2	3.6	3.6	7.6%	10.0	89	46.4	4.8	35.8	58.6	3.8	3.8	8.0%	10.4
	G13	87	44.1	6.5	27.9	58.3	4.0	4.2	9.6%	11.6	89	45.1	5.6	34.4	57.1	4.3	4.3	9.4%	11.9
	G21	87	50.9	4.5	39.7	63.8	3.5	3.6	7.0%	9.9	89	45.4	4.9	34.6	58.4	3.7	3.7	7.9%	10.1
	G22	87	48.7	3.7	41.6	59.0	3.0	3.1	6.3%	8.5	89	34.4	6.9	20.5	53.6	2.9	2.9	8.0%	8.0
	G23	87	50.7	4.9	39.0	61.5	3.2	3.2	6.3%	8.8	89	46.1	4.0	35.6	56.5	3.7	3.7	7.9%	10.2
	G31	87	46.9	5.2	34.3	61.0	4.4	4.4	9.4%	12.2	89	45.3	5.2	29.6	58.4	4.5	4.5	9.8%	12.4
	G32	87	48.7	4.5	37.4	60.2	3.9	3.9	8.1%	10.9	89	44.9	5.3	30.9	60.0	4.1	4.2	9.3%	11.8
	G33	87	45.8	5.4	35.1	58.1	4.1	4.1	8.9%	11.3	89	45.3	5.5	29.2	60.7	4.6	4.6	10.1%	12.8
FAZ	**FAZ (mm^2)**	79	0.300	0.138	0.119	0.576	0.016	0.016	5.5%	0.044	80	0.310	0.153	0.150	0.603	0.011	0.011	3.6%	0.030
	PERIM (mm)	79	2.116	0.510	1.503	3.130	0.083	0.084	4.0%	0.234	80	2.225	0.605	1.496	4.182	0.129	0.129	5.9%	0.358
	FD-300 (%)	79	47.7	4.7	33.8	56.3	3.4	3.4	7.1%	9.3	80	43.7	4.2	31.1	51.6	2.0	2.2	5.1%	6.1

Table 10. Vascular Parameters of AngioRetina Scans, Retina DR Sub-group

Retina: DR Sub-group																				
		6-mm HD AngioRetina Scan									3-mm AngioRetina Scan									
	Parameter	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility
Superficial (ILM to IPL-10µm) Vessel Density (%)	**WI**	76	45.1	2.8	38.2	50.7	1.7	1.7	3.8%	4.8	73	39.3	3.4	33.2	47.1	1.7	1.9	4.83%	5.2
	WI_S_Hemi	76	45.0	2.9	39.2	51.3	1.8	1.9	4.2%	5.3	73	39.4	3.3	33.5	46.3	1.8	2.0	5.07%	5.5
	WI_I_Hemi	76	45.2	3.0	36.9	50.8	1.8	1.8	4.0%	5.0	73	39.1	3.8	31.2	48.0	2.2	2.3	5.81%	6.3
	All (0-6)	76	44.8	2.7	38.0	50.5	1.7	1.8	3.9%	4.9	73	38.6	3.9	31.7	47.6	1.8	1.9	4.92%	5.2
	C (1)	76	26.3	8.0	6.6	40.4	3.4	3.4	13.0%	9.4	73	22.0	6.9	7.0	34.2	1.7	1.8	8.43%	5.0
	All (1-3)	76	44.3	3.0	35.4	50.5	2.3	2.5	5.6%	6.8	73	40.8	3.8	34.4	49.3	1.8	2.0	4.83%	5.4
	S_Hemi (1-3)	76	44.4	3.4	35.2	51.2	2.4	2.8	6.2%	7.6	73	40.8	3.6	34.3	48.3	1.9	2.0	4.83%	5.4
	I_Hemi (1-3)	76	44.2	3.3	33.5	53.2	2.8	2.8	6.3%	7.7	73	40.9	4.4	32.6	51.6	2.0	2.1	5.26%	6.0
	T (1-3)	76	43.4	4.0	30.8	51.5	3.7	3.7	8.5%	10.2	73	38.6	4.4	31.0	48.1	2.3	2.4	6.26%	6.7
	S (1-3)	76	45.4	3.6	36.1	53.3	2.3	2.8	6.2%	7.9	73	41.7	3.3	35.4	49.0	2.0	2.0	4.80%	5.5
	N (1-3)	76	43.7	4.9	26.2	54.5	3.7	4.0	9.2%	11.0	73	41.1	4.7	32.3	51.4	2.1	2.4	5.82%	6.6
	I (1-3)	76	44.7	4.0	32.8	53.6	3.2	3.2	7.1%	8.8	68	41.7	5.0	31.0	53.6	2.3	2.3	5.50%	6.4
	All (3-6)	76	45.7	3.0	39.3	51.4	1.8	1.8	3.9%	5.0	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	76	45.5	3.2	38.7	51.3	1.7	1.7	3.8%	4.8	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	76	46.0	3.1	38.7	51.5	2.0	2.0	4.4%	5.6	-	-	-	-	-	-	-	-	-
	T (3-6)	76	40.3	3.2	32.4	46.4	2.0	2.1	5.3%	6.0	-	-	-	-	-	-	-	-	-
	S (3-6)	76	46.1	3.7	38.0	54.2	2.0	2.0	4.4%	5.6	-	-	-	-	-	-	-	-	-
	N (3-6)	76	50.3	3.3	42.3	56.6	2.2	2.2	4.4%	6.2	-	-	-	-	-	-	-	-	-
	I (3-6)	76	46.2	3.3	38.6	52.9	2.1	2.1	4.6%	5.8	-	-	-	-	-	-	-	-	-
	G11	76	48.5	6.6	34.8	59.1	2.0	2.0	4.1%	5.5	73	42.2	5.5	28.5	52.1	2.6	2.7	6.46%	7.4
	G12	76	45.8	4.1	38.1	54.4	2.3	2.4	5.3%	6.7	73	41.9	3.8	33.4	49.7	2.5	2.5	5.94%	6.9
	G13	76	43.7	6.2	32.2	59.6	2.5	2.5	5.7%	7.0	73	40.8	3.5	30.8	47.9	2.3	2.6	6.45%	7.3
	G21	76	46.0	5.8	29.9	55.7	2.4	2.5	5.4%	6.9	73	39.1	4.9	27.5	49.6	2.5	2.7	6.85%	7.4
	G22	76	40.5	3.7	29.5	47.4	2.4	2.4	6.0%	6.7	73	25.7	5.9	12.7	38.9	1.9	1.9	7.64%	5.4
	G23	76	43.2	4.0	34.3	53.9	2.3	2.5	5.8%	7.0	73	39.4	4.4	30.9	50.2	2.4	2.8	7.23%	7.9
	G31	76	47.6	7.6	32.7	57.5	2.1	2.1	4.5%	5.9	73	42.6	5.6	31.0	56.5	2.6	2.6	6.21%	7.2
	G32	76	45.9	3.4	38.1	52.7	2.3	2.3	5.0%	6.4	73	41.0	4.7	29.2	51.6	2.9	2.9	6.95%	7.9
	G33	76	44.8	5.4	34.5	56.3	2.4	2.4	5.3%	6.6	73	40.4	3.4	32.0	48.3	2.6	2.6	6.51%	7.3
Deep (IPL-10µ to OPL+10µ) Vessel Density (%)	**WI**	76	46.8	3.9	38.7	57.5	3.2	3.4	7.3%	9.4	73	41.8	5.3	30.5	51.4	3.9	4.0	9.49%	11.2
	WI_S_Hemi	76	46.8	4.1	38.9	57.7	3.7	4.0	8.5%	11.0	73	41.9	5.5	30.3	53.3	4.0	4.1	9.66%	11.4
	WI_I_Hemi	76	46.9	4.3	38.5	59.0	3.3	3.3	7.0%	9.2	73	41.7	5.2	30.7	50.9	4.0	4.1	9.64%	11.3
	All (0-6)	76	47.8	4.1	39.4	58.5	3.4	3.5	7.3%	9.7	73	41.6	5.1	30.8	50.9	3.8	3.9	9.22%	10.8
	C (1)	76	35.3	7.8	14.9	50.3	4.3	4.3	12.2%	11.9	73	29.9	5.6	19.1	45.2	2.9	2.9	9.75%	8.1
	All (1-3)	76	49.7	4.4	41.1	62.3	4.0	4.0	8.0%	11.0	73	43.1	5.7	30.9	54.3	4.1	4.2	9.51%	11.6
	S_Hemi (1-3)	76	49.4	4.9	40.3	63.7	4.3	4.4	8.9%	12.3	73	43.3	5.8	31.4	54.6	4.1	4.2	9.53%	11.7
	I_Hemi (1-3)	76	49.9	4.6	41.4	61.0	4.4	4.4	8.7%	12.1	73	43.0	5.8	30.2	54.0	4.3	4.3	9.87%	12.0
	T (1-3)	76	49.1	5.6	29.6	63.0	5.4	5.4	10.9%	14.8	73	42.9	5.0	33.6	55.2	3.8	3.8	8.68%	10.6
	S (1-3)	76	49.3	5.5	38.2	63.1	4.6	4.8	9.8%	13.4	73	43.1	6.2	31.2	56.4	4.4	4.6	10.34%	12.6
	N (1-3)	76	51.0	6.0	33.2	63.3	5.1	5.1	9.9%	14.1	73	43.8	6.4	29.1	58.6	4.3	4.4	9.88%	12.2
	I (1-3)	76	49.4	5.4	34.2	61.0	5.3	5.3	10.7%	14.6	68	43.3	6.2	25.9	54.5	5.0	5.0	11.48%	13.9
	All (3-6)	76	47.7	4.2	39.2	58.7	3.4	3.6	7.5%	10.0	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	76	47.6	4.3	39.9	58.8	3.8	4.0	8.5%	11.2	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	76	47.9	4.8	38.0	61.8	3.6	3.7	7.7%	10.2	-	-	-	-	-	-	-	-	-
	T (3-6)	76	48.7	3.8	38.9	57.8	3.2	3.5	7.1%	9.6	-	-	-	-	-	-	-	-	-
	S (3-6)	76	47.2	4.4	38.9	57.2	4.0	4.2	9.0%	11.7	-	-	-	-	-	-	-	-	-
	N (3-6)	76	47.5	6.3	34.6	61.1	5.0	5.1	10.6%	14.0	-	-	-	-	-	-	-	-	-
	I (3-6)	76	47.5	5.4	34.7	62.8	4.0	4.1	8.6%	11.4	-	-	-	-	-	-	-	-	-
	G11	76	45.9	6.2	33.8	59.6	5.2	5.3	11.5%	14.8	73	42.4	6.3	27.0	56.7	4.9	5.1	11.81%	14.0
	G12	76	47.1	5.0	36.2	58.7	4.5	4.9	10.5%	13.6	73	42.3	7.7	24.0	58.9	4.5	4.6	10.58%	12.8
	G13	76	45.2	5.1	29.6	61.1	4.3	4.6	10.3%	12.7	73	43.6	5.8	30.5	57.3	4.5	4.7	10.60%	12.9
	G21	76	48.7	5.1	38.4	61.2	4.6	4.7	9.5%	12.9	73	42.6	6.4	29.8	62.4	4.1	4.2	9.61%	11.7
	G22	76	47.6	4.6	37.6	58.0	3.9	3.9	8.1%	10.7	73	33.0	4.8	24.6	48.0	3.1	3.2	9.51%	8.8
	G23	76	49.1	4.4	40.0	60.5	3.4	3.5	7.1%	9.7	73	43.8	4.9	32.4	54.9	3.7	3.8	8.57%	10.7
	G31	76	45.1	5.7	33.5	58.0	4.1	4.3	9.5%	11.9	73	42.4	6.5	26.7	53.7	5.1	5.1	11.99%	14.3
	G32	76	47.5	5.3	34.1	62.0	4.3	4.3	9.1%	12.0	73	42.5	7.0	26.5	56.7	5.1	5.2	11.95%	14.4
	G33	76	45.4	5.1	32.5	58.9	3.7	3.8	8.3%	10.4	73	43.4	5.5	29.3	54.4	4.7	4.7	10.73%	13.0
FAZ	**FAZ (mm^2)**	76	0.272	0.090	0.127	0.462	0.020	0.020	7.3%	0.056	73	0.281	0.092	0.145	0.441	0.010	0.010	3.5%	0.028
	PERIM (mm)	76	2.050	0.361	1.374	2.785	0.095	0.095	4.6%	0.263	73	2.168	0.365	1.481	2.780	0.075	0.077	3.5%	0.212
	FD-300 (%)	76	46.8	5.9	18.7	57.9	4.3	4.3	9.3%	12.0	73	43.6	5.1	31.5	54.0	2.2	2.3	5.2%	6.3

Table 11. Vascular parameters of AngioRetina scans, Retina Other Sub-group

Retina: Other Sub-group																			
		6mm HD Angio Retina Scan									3mm Angio Retina Scan								
	Parameter	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility
Superficial (ILM to IPL-10µm) Vessel Density (%)	**WI**	88	45.1	5.0	34.2	53.2	1.7	2.0	4.5%	5.5	93	43.3	4.7	34.8	52.8	2.1	2.4	5.6%	6.6
	WI_S_Hemi	88	45.5	4.6	33.9	53.0	1.8	2.2	4.9%	6.1	93	43.7	4.8	34.1	54.5	2.2	2.6	6.1%	7.2
	WI_I_Hemi	88	44.7	5.9	30.5	53.6	1.9	2.0	4.5%	5.5	93	42.9	5.3	31.7	52.9	2.3	2.4	5.7%	6.7
	All (0-6)	88	45.3	5.2	34.6	52.9	1.9	2.1	4.8%	5.9	93	43.0	4.7	34.5	52.9	2.1	2.4	5.7%	6.7
	C (1)	88	27.4	7.6	12.7	42.1	2.7	2.8	10.5%	7.8	93	24.2	6.9	6.2	37.2	1.6	1.8	7.8%	5.1
	All (1-3)	88	47.2	4.8	38.0	57.9	2.5	2.9	6.2%	8.0	93	45.5	4.9	36.0	55.3	2.3	2.6	5.8%	7.2
	S_Hemi (1-3)	88	47.6	4.7	38.2	58.7	2.4	2.8	6.0%	7.8	93	45.7	5.1	35.0	55.5	2.4	2.6	5.7%	7.1
	I_Hemi (1-3)	88	46.9	5.6	33.8	57.2	3.0	3.3	7.1%	9.1	93	45.2	5.6	32.1	56.4	2.4	2.8	6.3%	7.9
	T (1-3)	88	45.7	7.8	26.7	56.1	2.8	3.0	6.7%	8.4	93	42.9	7.4	24.3	54.1	2.4	2.6	6.1%	7.2
	S (1-3)	88	48.5	4.9	32.3	59.0	2.6	3.1	6.6%	8.7	93	46.6	6.2	29.6	57.1	2.6	2.8	6.0%	7.7
	N (1-3)	88	47.1	4.7	31.0	57.9	3.1	3.5	7.6%	9.8	93	45.9	4.3	31.9	54.4	3.0	3.1	6.9%	8.6
	I (1-3)	88	47.5	5.6	33.3	59.3	3.5	3.8	8.0%	10.5	93	46.3	5.8	33.3	57.3	2.7	3.2	6.9%	8.8
	All (3-6)	88	45.3	5.6	33.5	53.9	1.9	2.1	4.6%	5.7	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	88	45.9	4.9	34.6	53.6	1.9	2.3	5.0%	6.2	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	88	44.8	6.8	28.1	54.2	2.0	2.1	4.7%	5.8	-	-	-	-	-	-	-	-	-
	T (3-6)	88	41.3	6.7	25.6	51.7	2.5	2.8	6.7%	7.6	-	-	-	-	-	-	-	-	-
	S (3-6)	88	45.6	5.1	33.2	55.2	2.1	2.4	5.4%	6.7	-	-	-	-	-	-	-	-	-
	N (3-6)	88	50.7	4.2	40.8	58.1	1.8	1.9	3.8%	5.3	-	-	-	-	-	-	-	-	-
	I (3-6)	86	43.7	7.9	24.8	54.6	2.1	2.1	4.9%	5.9	-	-	-	-	-	-	-	-	-
	G11	88	43.9	6.0	31.9	57.1	2.3	2.5	5.8%	7.0	93	45.6	5.7	33.6	57.1	3.0	3.1	6.8%	8.5
	G12	88	46.2	5.0	34.6	56.1	2.2	2.6	5.7%	7.2	93	45.9	6.7	25.3	57.5	2.7	3.1	6.8%	8.5
	G13	88	46.9	7.6	26.9	56.1	1.8	1.9	4.2%	5.4	93	46.0	6.5	26.3	56.7	2.7	2.9	6.4%	7.9
	G21	88	44.4	7.3	25.0	56.3	2.6	2.7	6.1%	7.5	93	43.2	7.4	16.8	55.0	3.0	3.3	7.7%	9.2
	G22	88	44.2	4.4	34.5	55.2	2.4	2.8	6.5%	7.8	93	28.9	6.0	13.6	41.7	2.1	2.1	7.4%	5.7
	G23	88	47.6	7.1	28.4	60.1	2.2	2.7	5.7%	7.4	93	44.7	5.1	33.2	54.0	2.7	3.1	6.9%	8.5
	G31	88	42.4	9.0	20.1	58.1	2.2	2.3	5.4%	6.3	93	42.1	10.1	14.6	56.7	3.7	3.7	8.9%	10.3
	G32	88	44.2	7.2	26.6	54.2	2.3	2.4	5.5%	6.7	93	46.7	4.9	37.3	57.5	2.7	3.3	7.1%	9.0
	G33	88	46.3	6.5	28.5	55.3	2.3	2.3	5.0%	6.4	93	46.2	5.5	33.2	55.9	2.6	2.9	6.5%	8.1
Deep (IPL-10µ to OPL+10µ) Vessel Density (%)	**WI**	88	46.1	5.2	30.1	56.2	3.0	3.0	6.5%	8.3	93	42.9	4.3	33.5	55.5	2.7	2.7	6.4%	7.6
	WI_S_Hemi	88	46.6	5.0	33.4	55.8	3.2	3.3	7.0%	9.0	93	43.5	4.1	35.4	56.2	2.7	2.9	6.7%	8.0
	WI_I_Hemi	88	45.5	6.0	26.8	57.3	3.0	3.0	6.5%	8.2	93	42.3	5.3	30.1	54.7	2.9	2.9	6.8%	8.0
	All (0-6)	88	46.9	5.4	30.7	57.7	3.0	3.0	6.3%	8.3	93	42.8	4.5	33.4	55.5	2.5	2.6	6.1%	7.2
	C (1)	88	37.0	7.3	21.2	51.6	3.3	3.4	9.3%	9.3	93	31.9	6.4	14.7	44.8	2.8	2.8	9.0%	7.8
	All (1-3)	88	48.6	5.2	34.5	58.9	2.9	2.9	6.0%	8.0	93	44.2	4.6	34.2	56.9	2.7	2.8	6.3%	7.7
	S_Hemi (1-3)	88	49.5	5.0	37.6	60.4	3.0	3.0	6.2%	8.4	93	44.8	4.4	33.8	56.8	2.7	2.8	6.2%	7.8
	I_Hemi (1-3)	88	47.7	6.0	31.5	59.9	3.1	3.1	6.4%	8.5	93	43.6	6.0	29.7	57.0	3.0	3.0	6.9%	8.4
	T (1-3)	88	48.6	7.3	29.3	62.2	3.0	3.0	6.3%	8.4	93	43.9	6.7	26.4	58.2	2.6	2.7	6.1%	7.4
	S (1-3)	88	48.3	6.3	29.5	59.9	3.6	3.6	7.4%	9.9	93	43.8	5.8	27.8	55.8	3.2	3.3	7.5%	9.2
	N (1-3)	88	49.9	4.6	36.8	59.7	3.5	3.5	7.0%	9.7	93	45.5	4.2	36.6	57.3	3.0	3.0	6.7%	8.4
	I (1-3)	88	47.7	5.1	37.2	59.6	3.5	3.5	7.2%	9.6	93	43.7	5.3	34.0	57.8	3.2	3.2	7.4%	9.0
	All (3-6)	88	46.8	5.8	29.4	57.8	3.2	3.2	6.8%	8.9	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	88	47.5	5.5	33.0	57.9	3.3	3.4	7.1%	9.3	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	88	46.0	6.7	25.7	58.0	3.3	3.3	7.1%	9.1	-	-	-	-	-	-	-	-	-
	T (3-6)	88	47.6	7.3	26.4	60.2	2.8	2.9	6.0%	7.9	-	-	-	-	-	-	-	-	-
	S (3-6)	88	47.6	5.6	34.0	58.4	3.5	3.6	7.7%	10.1	-	-	-	-	-	-	-	-	-
	N (3-6)	88	46.8	5.8	34.3	59.9	4.1	4.2	9.0%	11.7	-	-	-	-	-	-	-	-	-
	I (3-6)	86	44.8	7.7	22.8	58.5	3.5	3.5	7.7%	9.7	-	-	-	-	-	-	-	-	-
	G11	88	47.1	5.0	30.6	59.3	3.6	3.7	7.9%	10.3	93	44.8	4.5	34.4	56.0	3.6	3.7	8.4%	10.4
	G12	88	47.3	5.4	34.3	57.6	3.7	3.7	7.9%	10.4	93	43.8	6.5	26.1	58.0	3.6	3.6	8.2%	10.0
	G13	88	44.1	7.3	24.3	56.7	4.7	4.8	10.9%	13.2	93	43.1	5.5	26.3	55.1	3.4	3.4	7.9%	9.5
	G21	88	47.9	6.5	28.3	58.1	3.2	3.2	6.6%	8.8	93	43.7	7.7	16.8	58.9	3.0	3.3	7.5%	9.1
	G22	88	47.1	4.9	35.2	57.8	2.4	2.4	5.2%	6.8	93	35.3	5.4	20.3	46.2	3.1	3.1	8.8%	8.5
	G23	88	46.7	6.2	32.4	60.4	3.7	3.7	7.9%	10.2	93	46.3	4.4	34.9	56.6	2.6	2.9	6.3%	8.1
	G31	88	44.4	8.1	18.2	58.1	3.5	3.5	7.8%	9.7	93	41.1	9.6	12.1	53.6	4.0	4.0	9.7%	11.2
	G32	88	44.8	7.1	25.7	58.3	3.6	3.6	7.9%	9.9	93	45.0	5.1	36.6	58.6	3.4	3.4	7.6%	9.5
	G33	88	45.1	6.2	29.3	59.1	4.2	4.2	9.4%	11.8	93	42.8	5.0	31.6	57.6	4.0	4.1	9.6%	11.4
FAZ	**FAZ (mm^2)**	79	0.205	0.095	0.088	0.510	0.015	0.016	7.2%	0.044	84	0.215	0.089	0.102	0.504	0.010	0.010	4.3%	0.028
	PERIM (mm)	79	1.745	0.361	1.130	2.799	0.098	0.099	5.4%	0.274	84	1.853	0.339	1.276	2.762	0.075	0.075	3.9%	0.209
	FD-300 (%)	79	46.8	5.6	34.5	55.6	3.6	3.6	7.8%	10.1	84	44.5	5.0	32.3	54.0	2.2	2.3	5.1%	6.3

Vessel Density and RNFL Thickness Results within (2-4) mm, and Disc Parameters for 4.5 mm HD AngioDisc Scan

Tables 12 and **13** summarize the results of the R&R analysis of vascular and RNFL thickness parameters of (2-4) mm peripapillary grid, and Disc Parameters of the 4.5 mm HD AngioDisc scan.

Table 12. Vascular and RNFL Thickness Parameters of (2-4) mm Peripapillary Grid, and Disc Parameters of the 4.5 mm HD AngioDisc Scan, Normal Group

Normal										
Parameter		Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_ reproducibility
RNFL Thickness (µm)	PP (2-4)	129	108.3	9.9	94.6	125.8	1.6	1.6	1.5%	4.4
	S_Hemi (2-4)	129	108.3	11.0	89.1	130.7	2.0	2.0	1.9%	5.6
	I_Hemi (2-4)	129	108.3	9.3	87.7	124.6	2.2	2.3	2.1%	6.3
	NS (2-4)	129	101.6	13.5	72.4	133.9	3.9	3.9	3.9%	10.9
	NI (2-4)	129	90.1	12.5	69.6	113.7	3.0	3.0	3.4%	8.4
	IN (2-4)	129	138.5	18.0	92.7	173.1	4.7	4.9	3.5%	13.5
	IT (2-4)	129	144.7	18.4	97.1	173.0	3.5	3.5	2.5%	9.8
	TI (2-4)	129	67.3	11.9	50.1	95.2	2.0	2.0	3.0%	5.6
	TS (2-4)	129	76.1	11.9	55.5	108.4	2.4	2.4	3.1%	6.6
	ST (2-4)	129	135.9	24.6	75.8	174.8	2.8	2.9	2.1%	7.9
	SN (2-4)	129	128.6	19.1	87.3	168.1	3.9	4.0	3.1%	11.1
RPC Vessel Density (%)	WI_All Vessels	129	56.8	2.3	46.5	60.4	1.5	1.5	2.7%	4.2
	WI_Small Vessels	129	49.7	2.0	40.9	53.0	1.5	1.5	2.9%	4.0
	Disc_All Vessels	129	60.0	3.5	44.9	68.0	2.7	2.7	4.5%	7.5
	Disc_Small Vessels	129	50.0	4.2	33.0	61.7	2.9	3.0	5.9%	8.2
	PP (2-4)_All Vessels	129	58.8	2.5	48.2	62.7	1.5	1.5	2.6%	4.2
	PP (2-4)_Small Vessels	129	51.8	2.2	43.1	55.4	1.5	1.5	2.9%	4.1
	S_Hemi (2-4)_All Vessels	129	59.1	2.5	49.0	63.7	1.6	1.6	2.7%	4.5
	I_Hemi (2-4)_All Vessels	129	58.4	2.6	47.4	62.5	1.6	1.6	2.8%	4.6
	S_Hemi (2-4)_Small Vessels	129	51.8	2.2	44.3	55.8	1.6	1.7	3.2%	4.6
	I_Hemi (2-4)_Small Vessels	129	51.7	2.6	41.6	55.8	1.6	1.6	3.2%	4.5
	NS (2-4)_Small Vessels	129	49.1	3.3	36.2	56.5	2.2	2.2	4.4%	6.0
	NI (2-4)_Small Vessels	129	48.3	4.4	32.8	56.4	2.0	2.0	4.1%	5.5
	IN (2-4)_Small Vessels	129	50.9	3.8	39.5	60.8	2.4	2.5	4.9%	6.9
	IT (2-4)_Small Vessels	129	55.4	3.7	39.6	63.0	2.7	2.7	5.0%	7.6
	TI (2-4)_Small Vessels	129	52.9	2.8	46.1	60.2	1.8	1.8	3.4%	5.0
	TS (2-4)_Small Vessels	129	55.7	2.9	48.8	61.6	1.7	1.7	3.1%	4.7
	ST (2-4)_Small Vessels	129	53.6	4.2	43.5	62.4	2.6	2.8	5.1%	7.7
	SN (2-4)_Small Vessels	129	49.1	4.0	36.8	56.9	2.1	2.3	4.7%	6.4
	G11_All Vessels	129	56.4	4.0	39.7	64.1	2.1	2.1	3.7%	5.8
	G12_All Vessels	129	58.9	3.2	45.5	66.2	2.0	2.1	3.5%	5.7
	G13_All Vessels	129	56.2	4.9	44.5	65.4	1.9	2.0	3.6%	5.5
	G21_All Vessels	129	55.1	4.5	34.8	62.1	2.2	2.3	4.3%	6.5
	G22_All Vessels	129	60.3	3.5	45.1	67.4	2.8	2.9	4.8%	8.0
	G23_All Vessels	129	54.5	3.6	43.9	62.2	1.8	1.9	3.4%	5.2
	G31_All Vessels	129	54.5	4.9	35.3	64.0	1.9	2.0	3.7%	5.6
	G32_All Vessels	129	61.5	3.9	48.4	68.6	2.4	2.4	3.9%	6.6
	G33_All Vessels	129	54.2	4.6	41.5	61.9	1.7	1.9	3.4%	5.2
Optic Disc	Disc_H_Size (mm)	129	1.558	0.094	1.347	1.759	0.051	0.051	3.3%	0.142
	Disc_V_Size (mm)	129	1.639	0.134	1.346	1.858	0.054	0.056	3.4%	0.155
	DiscArea (mm^2)	129	2.011	0.248	1.479	2.567	0.051	0.055	2.7%	0.153
	CupArea (mm^2)	129	0.274	0.201	0.000	0.766	0.015	0.018	6.6%	0.049
	RimArea (mm^2)	129	1.737	0.169	1.235	2.014	0.045	0.046	2.7%	0.129
	CupVolume (mm^3)	129	0.040	0.036	0.000	0.129	0.004	0.005	12.1%	0.013
	RimVolume (mm^3)	129	0.505	0.093	0.343	0.676	0.014	0.014	2.7%	0.038
	C_D_Area_Ratio	129	0.130	0.086	0.000	0.305	0.006	0.006	5.1%	0.018
	C_D_H_Ratio	129	0.289	0.164	0.000	0.529	0.006	0.006	2.2%	0.018
	C_D_V_Ratio	129	0.349	0.189	0.000	0.581	0.015	0.016	4.5%	0.043
	DiscElevation (µm)	129	234.6	65.3	102.1	365.8	4.2	4.6	1.9%	12.7
	CupDepth (µm)	129	104.5	69.5	0.0	217.7	7.7	7.8	7.7%	21.7

Table 13. Vascular and RNFL Thickness Parameters of (2-4) mm Peripapillary Grid, and Disc Parameters of the 4.5 mm HD AngioDisc Scan, Glaucoma Group

Glaucoma										
Parameter		Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_ reproducibility
RNFL Thickness (µm)	PP (2-4)	137	74.4	17.1	42.6	111.2	0.9	0.9	1.2%	2.5
	S_Hemi (2-4)	137	77.2	17.8	45.4	111.8	1.1	1.2	1.5%	3.2
	I_Hemi (2-4)	137	71.4	18.5	37.6	111.0	1.1	1.1	1.6%	3.1
	NS (2-4)	137	79.4	20.3	39.4	110.9	2.4	2.4	3.1%	6.8
	NI (2-4)	137	71.3	19.8	34.0	103.7	2.5	2.5	3.5%	6.9
	IN (2-4)	137	87.4	28.1	39.0	166.7	2.8	2.8	3.2%	7.8
	IT (2-4)	137	74.2	30.8	33.7	131.9	2.3	2.3	3.1%	6.4
	TI (2-4)	137	53.9	13.5	34.7	88.4	1.1	1.1	2.1%	3.1
	TS (2-4)	137	59.7	16.1	34.9	96.4	1.3	1.3	2.2%	3.7
	ST (2-4)	137	80.7	29.2	30.8	131.2	2.3	2.3	2.8%	6.3
	SN (2-4)	137	91.0	26.4	54.5	147.6	2.7	2.8	3.0%	7.7
RPC Vessel Density (%)	WI_All Vessels	137	48.7	5.2	35.7	57.0	1.2	1.3	2.7%	3.6
	WI_Small Vessels	137	41.9	5.4	27.8	51.2	1.2	1.3	3.0%	3.5
	Disc_All Vessels	137	55.0	6.5	39.6	64.6	2.0	2.3	4.1%	6.3
	Disc_Small Vessels	137	47.1	7.5	31.3	59.9	2.0	2.3	4.8%	6.3
	PP (2-4)_All Vessels	137	49.8	6.1	33.4	59.1	1.3	1.4	2.8%	3.8
	PP (2-4)_Small Vessels	137	43.1	6.2	25.6	52.8	1.4	1.4	3.2%	3.8
	S_Hemi (2-4)_All Vessels	137	50.8	6.3	35.4	59.9	1.3	1.4	2.8%	3.9
	I_Hemi (2-4)_All Vessels	137	48.8	6.5	31.3	60.2	1.5	1.6	3.3%	4.4
	S_Hemi (2-4)_Small Vessels	137	44.0	6.4	26.8	54.1	1.5	1.5	3.3%	4.1
	I_Hemi (2-4)_Small Vessels	137	42.0	7.0	24.3	55.0	1.6	1.6	3.9%	4.5
	NS (2-4)_Small Vessels	137	42.7	7.7	15.7	52.2	1.9	1.9	4.4%	5.2
	NI (2-4)_Small Vessels	137	40.2	7.0	18.3	51.3	2.3	2.3	5.8%	6.4
	IN (2-4)_Small Vessels	137	39.5	8.2	18.9	60.9	2.1	2.1	5.2%	5.7
	IT (2-4)_Small Vessels	137	39.8	12.1	15.2	60.1	2.3	2.4	6.1%	6.7
	TI (2-4)_Small Vessels	137	47.6	6.9	28.9	60.1	2.3	2.3	4.7%	6.2
	TS (2-4)_Small Vessels	137	50.6	6.1	33.5	59.0	2.2	2.2	4.4%	6.2
	ST (2-4)_Small Vessels	137	41.8	9.6	20.7	57.8	2.1	2.1	4.9%	5.7
	SN (2-4)_Small Vessels	137	39.6	8.3	20.4	53.5	1.9	1.9	4.8%	5.2
	G11_All Vessels	137	47.7	6.1	36.8	59.0	1.6	1.6	3.3%	4.4
	G12_All Vessels	137	49.6	7.6	32.4	62.9	1.8	1.9	3.8%	5.2
	G13_All Vessels	137	45.3	6.5	30.0	57.4	1.9	1.9	4.3%	5.4
	G21_All Vessels	137	49.9	6.4	33.0	61.9	1.8	1.8	3.6%	5.0
	G22_All Vessels	137	55.0	6.8	37.5	66.6	2.0	2.4	4.4%	6.7
	G23_All Vessels	137	50.0	7.2	24.5	60.7	2.0	2.0	4.1%	5.7
	G31_All Vessels	137	44.6	6.6	30.0	60.0	2.1	2.5	5.5%	6.8
	G32_All Vessels	137	50.0	8.6	28.7	67.5	2.1	2.1	4.2%	5.8
	G33_All Vessels	137	46.6	6.8	30.3	57.1	2.0	2.1	4.4%	5.7
Optic Disc	Disc_H_Size (mm)	137	1.534	0.194	1.272	1.993	0.043	0.044	2.9%	0.123
	Disc_V_Size (mm)	137	1.610	0.203	1.312	2.164	0.041	0.041	2.6%	0.114
	DiscArea (mm^2)	137	1.967	0.503	1.413	3.266	0.034	0.035	1.8%	0.098
	CupArea (mm^2)	137	0.721	0.443	0.000	1.674	0.017	0.017	2.4%	0.048
	RimArea (mm^2)	137	1.246	0.308	0.636	1.823	0.029	0.029	2.3%	0.082
	CupVolume (mm^3)	137	0.148	0.170	0.000	0.644	0.013	0.013	8.7%	0.035
	RimVolume (mm^3)	137	0.249	0.098	0.098	0.418	0.008	0.008	3.1%	0.021
	C_D_Area_Ratio	137	0.348	0.171	0.000	0.602	0.007	0.007	2.0%	0.019
	C_D_H_Ratio	137	0.494	0.197	0.000	0.816	0.009	0.009	1.8%	0.024
	C_D_V_Ratio	137	0.639	0.211	0.000	0.916	0.012	0.012	1.9%	0.034
	DiscElevation (µm)	137	64.5	109.8	-184.3	253.8	5.8	5.8	8.8%	15.9
	CupDepth (µm)	137	156.0	95.2	0.0	402.1	6.0	6.0	3.9%	16.7

Retinal Thickness and Volume Parameters of 3 mm AngioRetina and 6 mm HD AngioRetina Scans

Tables 14 through 16 summarize the results of R&R analysis of retinal thickness and volume parameters of 3 mm AngioRetina and 6 mm HD AngioRetina scans for Normal, Glaucoma and Retina groups.

Table 14. Retinal Thickness and Volume of Retinal Layer of AngioRetina Scans, Normal Group

Normal																			
		6 mm HD Angio Retina									3 mm Angio Retina								
	Parameter	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility
ILM ~ IPL Thickness (µm)	**C (1)**	128	43.3	11.5	24.1	71.1	0.8	0.9	2.1%	2.4	129	43.3	11.3	24.7	71.5	1.1	1.2	2.7%	3.3
	T (1-3)	128	102.4	10.3	79.1	123.1	0.7	0.7	0.7%	2.1	129	102.4	10.7	78.5	123.9	0.7	0.8	0.8%	2.2
	S (1-3)	128	113.7	11.9	89.3	135.1	0.9	1.0	0.9%	2.8	129	113.7	12.2	88.6	136.2	1.0	1.0	0.9%	2.8
	N (1-3)	128	109.8	12.5	78.8	132.1	0.7	0.8	0.8%	2.3	129	109.6	12.8	79.2	133.6	1.1	1.1	1.0%	2.9
	I (1-3)	128	114.4	12.3	82.9	133.7	1.0	1.1	0.9%	2.9	128	114.0	12.8	83.0	135.4	1.2	1.2	1.1%	3.4
	S_Hemi (1-3)	128	109.6	11.5	84.4	131.0	0.7	0.8	0.8%	2.3	129	109.5	11.8	83.2	132.0	0.8	0.9	0.8%	2.4
	I_Hemi (1-3)	128	110.6	11.8	81.1	130.9	0.7	0.7	0.7%	2.1	129	110.2	12.2	81.0	132.6	1.0	1.0	0.9%	2.8
	All (1-3)	128	110.1	11.6	82.8	130.5	0.6	0.7	0.6%	1.8	129	109.8	12.0	83.3	132.3	0.7	0.7	0.6%	1.9
	T (3-6)	128	85.7	8.0	69.4	99.1	0.9	0.9	1.1%	2.6	-	-	-	-	-	-	-	-	-
	S (3-6)	128	99.8	10.8	77.6	117.3	1.0	1.1	1.1%	3.0	-	-	-	-	-	-	-	-	-
	N (3-6)	128	116.5	12.9	87.8	141.9	0.9	1.0	0.8%	2.7	-	-	-	-	-	-	-	-	-
	I (3-6)	128	98.5	11.4	69.6	124.1	1.0	1.0	1.1%	2.9	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	128	99.7	9.9	78.4	114.3	0.8	0.8	0.8%	2.3	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	128	100.5	11.1	74.0	124.0	0.7	0.8	0.8%	2.2	-	-	-	-	-	-	-	-	-
	All (3-6)	128	100.1	10.2	76.4	118.7	0.6	0.7	0.7%	2.0	-	-	-	-	-	-	-	-	-
	S_Hemi (0-6)/(0-3)	128	100.4	10.0	78.3	116.2	0.7	0.7	0.7%	2.1	129	102.1	11.4	76.7	123.1	0.8	0.8	0.8%	2.3
	I_Hemi (0-6)/(0-3)	128	101.2	10.9	74.4	122.5	0.6	0.7	0.7%	1.9	129	102.5	11.8	74.7	123.5	1.0	1.0	0.9%	2.7
	All (0-6)/(0-3)	128	100.8	10.3	76.6	118.4	0.5	0.6	0.6%	1.7	129	102.3	11.5	76.8	123.3	0.7	0.7	0.7%	1.9
	WI_S_Hemi	128	99.8	10.2	75.3	117.7	1.6	1.6	1.6%	4.4	129	103.8	11.1	78.9	123.8	1.0	1.1	1.0%	3.0
	WI_I_Hemi	128	101.7	10.5	76.6	121.5	1.1	1.1	1.1%	3.0	129	104.1	11.6	77.0	124.9	1.1	1.1	1.1%	3.2
	WI	128	100.7	10.2	76.8	119.5	1.2	1.2	1.2%	3.2	129	104.1	11.3	78.9	124.5	0.9	0.9	0.8%	2.4
ILM ~ IPL Volume (mm3)	***C (1)***	*128*	*0.034*	*0.009*	*0.019*	*0.056*	*0.001*	*0.001*	*2.3%*	*0.002*	*129*	*0.034*	*0.009*	*0.019*	*0.056*	*0.001*	*0.001*	*2.7%*	*0.003*
	All (0-6)/(0-3)	*128*	*2.831*	*0.286*	*2.114*	*3.307*	*0.017*	*0.018*	*0.6%*	*0.049*	*129*	*0.709*	*0.079*	*0.532*	*0.866*	*0.011*	*0.011*	*1.5%*	*0.030*
	WI	*128*	*3.634*	*0.367*	*2.770*	*4.312*	*0.042*	*0.042*	*1.2%*	*0.117*	*129*	*0.939*	*0.102*	*0.712*	*1.123*	*0.008*	*0.008*	*0.8%*	*0.021*
ILM ~ RPE Thickness (µm)	**C (1)**	128	253.6	21.6	212.9	291.0	1.5	1.8	0.7%	5.0	129	253.3	22.0	212.0	292.4	1.7	1.9	0.8%	5.4
	T (1-3)	128	315.3	16.9	288.9	347.6	1.3	1.4	0.5%	4.0	129	314.9	17.3	288.6	347.5	1.3	1.5	0.5%	4.2
	S (1-3)	128	329.0	18.1	293.2	360.0	1.3	1.7	0.5%	4.7	129	328.8	18.5	292.7	360.5	1.4	1.5	0.5%	4.3
	N (1-3)	128	329.2	17.3	299.0	361.5	1.1	1.5	0.4%	4.0	129	329.0	17.5	298.5	360.5	1.0	1.4	0.4%	3.8
	I (1-3)	128	325.2	16.9	296.0	356.1	1.5	1.6	0.5%	4.4	128	325.2	17.4	296.3	356.8	1.6	1.6	0.5%	4.5
	S_Hemi (1-3)	128	325.7	17.5	293.5	357.0	1.1	1.5	0.5%	4.2	129	325.4	17.9	293.1	356.4	1.1	1.4	0.4%	3.9
	I_Hemi (1-3)	128	323.7	16.7	295.6	354.2	1.2	1.4	0.4%	3.8	129	323.4	17.2	295.6	354.4	1.3	1.4	0.4%	3.9
	All (1-3)	128	324.7	17.0	294.6	355.2	1.1	1.3	0.4%	3.7	129	324.4	17.4	294.6	355.4	1.1	1.3	0.4%	3.6
	T (3-6)	128	271.6	13.8	252.3	303.9	1.6	1.8	0.7%	5.1	-	-	-	-	-	-	-	-	-
	S (3-6)	128	288.5	15.3	260.6	314.5	1.4	1.8	0.6%	5.0	-	-	-	-	-	-	-	-	-
	N (3-6)	128	303.5	16.3	271.3	333.5	1.2	1.5	0.5%	4.1	-	-	-	-	-	-	-	-	-
	I (3-6)	128	275.4	14.1	254.3	311.5	1.5	1.8	0.6%	4.9	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	128	288.3	14.6	261.3	312.7	1.2	1.6	0.6%	4.5	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	128	281.2	14.0	258.6	313.0	1.3	1.5	0.6%	4.3	-	-	-	-	-	-	-	-	-
	All (3-6)	128	284.8	14.0	261.6	312.9	1.1	1.5	0.5%	4.1	-	-	-	-	-	-	-	-	-
	S_Hemi (0-6)/(0-3)	128	295.7	14.9	267.2	321.4	1.1	1.5	0.5%	4.1	129	317.3	17.7	284.2	347.5	1.1	1.4	0.4%	3.8
	I_Hemi (0-6)/(0-3)	128	290.0	14.4	267.2	321.3	1.2	1.4	0.5%	3.9	129	315.4	17.2	285.9	345.3	1.3	1.4	0.4%	3.9
	All (0-6)/(0-3)	128	292.8	14.4	267.7	321.3	1.0	1.4	0.5%	3.8	129	316.3	17.3	285.3	346.4	1.1	1.3	0.4%	3.5
	WI_S_Hemi	128	289.5	14.6	263.9	317.5	2.4	2.4	0.8%	6.6	129	315.9	17.2	282.2	344.6	1.2	1.4	0.4%	3.8
	WI_I_Hemi	128	284.8	13.8	261.3	314.6	1.6	1.9	0.7%	5.2	129	314.0	16.7	284.3	343.2	1.4	1.5	0.5%	4.1
	WI	128	287.2	14.0	263.8	316.2	1.7	1.8	0.6%	4.9	129	315.1	16.8	283.6	344.1	1.1	1.3	0.4%	3.5
ILM ~ RPE Volume (mm3)	***C (1)***	*128*	*0.200*	*0.017*	*0.168*	*0.229*	*0.001*	*0.001*	*0.7%*	*0.004*	*129*	*0.199*	*0.017*	*0.167*	*0.230*	*0.001*	*0.002*	*0.8%*	*0.004*
	All (0-6)/(0-3)	*128*	*8.227*	*0.403*	*7.442*	*8.989*	*0.042*	*0.044*	*0.5%*	*0.122*	*129*	*2.194*	*0.122*	*1.893*	*2.427*	*0.029*	*0.029*	*1.3%*	*0.079*
	WI	*128*	*10.36*	*0.505*	*9.519*	*11.41*	*0.061*	*0.064*	*0.6%*	*0.177*	*129*	*2.844*	*0.152*	*2.560*	*3.106*	*0.010*	*0.011*	*0.4%*	*0.032*
IPL ~ RPE Thickness (µm)	**C (1)**	128	210.2	12.4	181.4	229.9	1.2	1.4	0.6%	3.7	129	209.9	13.0	181.0	230.2	1.5	1.5	0.7%	4.2
	T (1-3)	128	212.9	9.2	198.6	230.4	1.3	1.3	0.6%	3.7	129	212.4	9.3	196.0	230.5	1.3	1.4	0.6%	3.7
	S (1-3)	128	215.3	8.7	198.1	231.5	0.9	1.1	0.5%	3.1	129	215.1	9.0	197.9	233.0	1.2	1.3	0.6%	3.7
	N (1-3)	128	219.5	8.8	203.9	233.6	0.8	1.0	0.5%	2.8	129	219.4	8.9	202.4	234.1	1.0	1.3	0.6%	3.5
	I (1-3)	128	210.8	8.2	198.4	225.0	1.3	1.4	0.6%	3.8	128	211.3	8.2	197.9	226.6	1.3	1.4	0.7%	3.9
	S_Hemi (1-3)	128	216.1	8.7	199.9	231.6	0.8	1.0	0.5%	2.8	129	215.9	8.9	199.4	232.6	1.1	1.2	0.6%	3.3
	I_Hemi (1-3)	128	213.1	8.3	200.5	227.7	1.1	1.2	0.6%	3.4	129	213.2	8.3	200.5	228.8	1.2	1.3	0.6%	3.6
	All (1-3)	128	214.6	8.4	200.5	229.7	0.9	1.0	0.5%	2.9	129	214.6	8.5	200.0	230.0	1.0	1.2	0.5%	3.2
	T (3-6)	128	185.9	8.1	173.0	206.5	1.4	1.6	0.9%	4.5	-	-	-	-	-	-	-	-	-
	S (3-6)	128	188.8	8.6	171.5	204.0	1.0	1.3	0.7%	3.5	-	-	-	-	-	-	-	-	-
	N (3-6)	128	187.1	8.3	166.8	199.8	1.3	1.3	0.7%	3.7	-	-	-	-	-	-	-	-	-
	I (3-6)	128	176.8	6.6	164.4	188.4	1.3	1.4	0.8%	3.8	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	128	188.6	8.3	172.3	203.7	1.0	1.2	0.6%	3.3	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	128	180.7	6.6	168.2	192.0	1.1	1.2	0.7%	3.4	-	-	-	-	-	-	-	-	-
	All (3-6)	128	184.7	7.4	170.7	196.6	0.9	1.1	0.6%	3.1	-	-	-	-	-	-	-	-	-
	S_Hemi (0-6)/(0-3)	128	195.3	8.2	178.8	210.2	0.9	1.1	0.6%	3.0	129	215.2	9.0	197.4	231.4	1.1	1.2	0.5%	3.3
	I_Hemi (0-6)/(0-3)	128	188.8	6.8	176.5	199.1	1.0	1.2	0.6%	3.2	129	212.8	8.4	198.3	228.9	1.1	1.2	0.6%	3.4
	All (0-6)/(0-3)	128	192.1	7.4	178.4	204.1	0.9	1.1	0.6%	2.9	129	214.0	8.6	197.9	230.0	1.0	1.1	0.5%	3.2
	WI_S_Hemi	128	189.7	8.0	174.4	203.6	1.2	1.3	0.7%	3.5	129	212.1	8.9	193.8	229.2	1.2	1.3	0.6%	3.5
	WI_I_Hemi	128	183.1	6.7	169.9	194.2	1.2	1.4	0.7%	3.7	129	209.9	8.0	195.8	225.5	1.3	1.5	0.7%	4.1
	WI	128	186.4	7.2	173.4	198.2	1.2	1.1	0.6%	3.0	129	211.0	8.3	195.1	226.0	1.1	1.2	0.6%	3.3
IPL ~ RPE Volume (mm3)	***C (1)***	*128*	*0.166*	*0.010*	*0.143*	*0.181*	*1.2*	*0.001*	*0.7%*	*0.003*	*129*	*0.165*	*0.010*	*0.142*	*0.181*	*0.001*	*0.001*	*0.8%*	*0.004*
	All (0-6)/(0-3)	*128*	*5.396*	*0.209*	*5.024*	*5.751*	*1.2*	*0.034*	*0.6%*	*0.096*	*129*	*1.484*	*0.065*	*1.310*	*1.604*	*0.019*	*0.019*	*1.3%*	*0.053*
	WI	*128*	*6.730*	*0.262*	*6.260*	*7.153*	*1.2*	*0.039*	*0.6%*	*0.109*	*129*	*1.905*	*0.075*	*1.762*	*2.041*	*0.010*	*0.011*	*0.6%*	*0.030*

Table 15. Retinal Thickness and Volume of Retinal Layer of AngioRetina Scan, Glaucoma Group

Glaucoma																				
		6 mm HD Angio Retina									3 mm Angio Retina									
	Parameter	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility
ILM ~ IPL Thickness (µm)	**C (1)**	133	36.9	10.8	20.2	58.4	0.8	0.8	2.1%	2.2	134	38.0	10.4	21.0	59.2	1.3	1.3	3.6%	3.7
	T (1-3)	133	81.5	16.4	50.1	113.6	0.8	0.8	1.0%	2.2	134	83.2	15.8	51.5	114.9	0.7	0.7	0.9%	2.0
	S (1-3)	133	94.4	18.9	51.6	126.5	0.9	0.9	0.9%	2.4	134	95.7	19.6	52.6	127.7	0.9	0.9	0.9%	2.4
	N (1-3)	133	95.9	17.1	46.3	126.6	1.4	1.4	1.4%	3.7	134	96.7	18.0	46.3	127.2	1.0	1.0	1.0%	2.7
	I (1-3)	133	89.0	21.1	51.6	124.2	0.9	0.9	1.0%	2.5	133	90.2	21.0	54.1	124.6	1.0	1.0	1.1%	2.8
	S_Hemi (1-3)	133	92.0	17.4	53.3	121.6	1.0	1.0	1.1%	2.7	134	93.3	17.7	53.4	122.9	0.8	0.8	0.8%	2.1
	I_Hemi (1-3)	133	88.5	18.8	54.6	121.6	0.7	0.7	0.8%	2.0	134	89.5	18.8	54.3	122.3	0.8	0.8	0.9%	2.3
	All (1-3)	133	90.2	16.8	54.2	121.4	0.7	0.7	0.8%	2.0	134	91.5	16.9	54.3	122.4	0.6	0.6	0.6%	1.6
	T (3-6)	133	65.3	8.8	48.6	86.6	0.6	0.6	0.9%	1.7	-	-	-	-	-	-	-	-	-
	S (3-6)	133	79.5	14.3	55.5	107.2	0.8	0.8	1.0%	2.2	-	-	-	-	-	-	-	-	-
	N (3-6)	133	95.4	14.8	53.0	128.2	2.3	2.3	2.5%	6.5	-	-	-	-	-	-	-	-	-
	I (3-6)	133	72.6	14.0	49.6	104.7	1.4	1.4	1.9%	3.8	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	133	80.9	13.0	57.4	107.6	0.8	0.8	0.9%	2.1	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	133	75.6	12.8	52.7	105.0	1.0	1.1	1.4%	2.9	-	-	-	-	-	-	-	-	-
	All (3-6)	133	78.3	12.0	56.4	106.3	0.7	0.7	0.9%	2.0	-	-	-	-	-	-	-	-	-
	S_Hemi (0-6)/(0-3)	133	82.2	13.6	55.4	109.2	0.6	0.6	0.8%	1.8	134	87.1	16.5	50.2	115.1	0.7	0.7	0.8%	2.0
	I_Hemi (0-6)/(0-3)	133	77.4	13.7	53.3	107.3	0.9	0.9	1.1%	2.4	134	83.7	17.3	50.6	114.4	0.8	0.8	1.0%	2.2
	All (0-6)/(0-3)	133	79.8	12.8	54.9	108.1	0.6	0.6	0.8%	1.7	134	85.4	15.8	50.6	114.6	0.6	0.6	0.7%	1.5
	WI_S_Hemi	133	80.7	13.0	56.2	109.5	1.0	1.0	1.2%	2.7	134	87.9	16.3	53.2	116.3	0.8	0.8	0.9%	2.2
	WI_I_Hemi	133	76.7	12.9	53.4	107.5	1.1	1.1	1.4%	3.0	134	83.7	16.9	52.5	115.4	1.0	1.0	1.3%	2.9
	WI	133	78.8	12.1	55.4	108.5	0.8	0.8	1.0%	2.2	134	86.1	15.3	53.1	115.8	0.8	0.8	0.9%	2.2
ILM ~ IPL Volume (mm3)	***C (1)***	*133*	*0.029*	*0.009*	*0.016*	*0.046*	*0.001*	*0.001*	*2.3%*	*0.002*	*134*	*0.030*	*0.008*	*0.017*	*0.047*	*0.001*	*0.001*	*3.5%*	*0.003*
	All (0-6)/(0-3)	*133*	*2.238*	*0.358*	*1.528*	*3.041*	*0.020*	*0.020*	*0.9%*	*0.056*	*134*	*0.592*	*0.109*	*0.344*	*0.805*	*0.009*	*0.010*	*1.6%*	*0.027*
	WI	*133*	*2.843*	*0.435*	*1.999*	*3.916*	*0.028*	*0.028*	*1.0%*	*0.079*	*134*	*0.774*	*0.146*	*0.170*	*1.045*	*0.028*	*0.028*	*3.7%*	*0.078*
ILM ~ RPE Thickness (µm)	**C (1)**	133	244.4	22.2	208.3	291.3	1.1	1.2	0.5%	3.2	134	246.0	21.6	208.0	292.9	1.4	1.5	0.6%	4.2
	T (1-3)	133	289.9	20.2	257.1	329.6	1.2	1.2	0.4%	3.2	134	290.9	20.4	257.8	331.4	0.8	0.9	0.3%	2.6
	S (1-3)	133	303.0	22.1	262.7	341.9	1.0	1.2	0.4%	3.2	134	304.3	23.3	261.9	343.4	1.1	1.2	0.4%	3.4
	N (1-3)	133	310.1	21.8	253.7	351.9	1.2	1.2	0.4%	3.3	134	311.2	22.9	253.9	354.6	1.0	1.1	0.4%	3.1
	I (1-3)	133	296.5	23.3	250.7	333.3	1.1	1.1	0.4%	3.1	133	298.1	23.3	251.4	333.5	1.0	1.2	0.4%	3.2
	S_Hemi (1-3)	133	301.9	21.2	259.5	339.0	1.0	1.1	0.4%	2.9	134	303.2	22.2	259.9	340.2	0.9	1.0	0.3%	2.9
	I_Hemi (1-3)	133	297.8	21.9	252.9	334.1	1.0	1.0	0.3%	2.8	134	299.0	22.2	253.2	334.7	0.9	1.0	0.3%	2.8
	All (1-3)	133	299.9	20.8	256.2	336.5	0.9	0.9	0.3%	2.6	134	301.1	21.5	256.6	337.2	0.8	0.9	0.3%	2.4
	T (3-6)	133	240.5	12.9	212.9	264.8	1.1	1.1	0.5%	3.0	-	-	-	-	-	-	-	-	-
	S (3-6)	133	256.8	16.9	231.0	282.0	1.1	1.2	0.5%	3.2	-	-	-	-	-	-	-	-	-
	N (3-6)	133	273.0	19.0	228.1	302.7	1.0	1.1	0.4%	2.9	-	-	-	-	-	-	-	-	-
	I (3-6)	133	242.5	16.3	211.0	274.2	1.2	1.2	0.5%	3.3	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	133	258.6	16.2	229.9	283.7	0.9	1.0	0.4%	2.8	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	133	247.9	16.2	214.7	277.0	1.0	1.0	0.4%	2.7	-	-	-	-	-	-	-	-	-
	All (3-6)	133	253.3	15.5	224.6	280.4	0.7	0.7	0.3%	1.9	-	-	-	-	-	-	-	-	-
	S_Hemi (0-6)/(0-3)	133	267.9	16.9	236.5	295.5	0.8	0.9	0.3%	2.5	134	296.7	21.3	256.6	333.2	0.9	1.0	0.3%	2.9
	I_Hemi (0-6)/(0-3)	133	259.0	16.8	226.3	289.3	0.9	0.9	0.3%	2.5	134	293.0	21.3	250.3	328.7	0.9	1.0	0.3%	2.8
	All (0-6)/(0-3)	133	263.5	16.2	231.8	292.4	0.7	0.7	0.3%	1.9	134	294.9	20.7	253.6	331.0	0.8	0.9	0.3%	2.5
	WI_S_Hemi	133	260.7	16.2	230.6	288.7	1.2	1.4	0.5%	3.8	134	293.0	21.1	253.7	330.4	1.3	1.4	0.5%	3.9
	WI_I_Hemi	133	252.6	16.0	221.8	284.5	1.1	1.1	0.4%	3.1	134	289.1	20.4	247.8	324.2	1.5	1.5	0.5%	4.1
	WI	133	256.7	15.4	226.5	286.2	0.9	0.9	0.3%	2.4	134	291.2	20.2	250.9	327.3	1.0	1.1	0.4%	3.0
ILM ~ RPE Volume (mm3)	***C (1)***	*133*	*0.193*	*0.018*	*0.164*	*0.230*	*0.001*	*0.001*	*0.5%*	*0.003*	*134*	*0.193*	*0.017*	*0.163*	*0.230*	*0.001*	*0.001*	*0.6%*	*0.003*
	All (0-6)/(0-3)	*133*	*7.390*	*0.459*	*6.447*	*8.250*	*0.039*	*0.041*	*0.6%*	*0.113*	*134*	*2.045*	*0.144*	*1.725*	*2.324*	*0.028*	*0.029*	*1.4%*	*0.082*
	WI	*133*	*9.267*	*0.554*	*8.175*	*10.329*	*0.031*	*0.031*	*0.3%*	*0.085*	*134*	*2.616*	*0.241*	*0.791*	*2.955*	*0.128*	*0.128*	*4.9%*	*0.355*
IPL ~ RPE Thickness (µm)	**C (1)**	133	207.4	14.0	182.9	234.2	1.1	1.1	0.5%	3.0	134	207.9	14.1	180.5	234.1	1.6	1.7	0.8%	4.6
	T (1-3)	133	208.4	7.7	194.9	223.0	0.9	0.9	0.4%	2.5	134	207.7	8.3	192.7	223.8	1.0	1.0	0.5%	2.8
	S (1-3)	133	208.6	7.1	194.9	218.6	0.8	1.0	0.5%	2.7	134	208.6	7.4	194.4	220.4	1.0	1.1	0.5%	3.1
	N (1-3)	133	214.3	7.8	202.1	232.8	0.9	0.9	0.4%	2.6	134	214.5	8.4	201.5	233.2	1.2	1.3	0.6%	3.6
	I (1-3)	133	207.5	8.1	195.8	227.5	1.0	1.0	0.5%	2.7	133	207.9	8.6	193.8	229.3	1.1	1.2	0.6%	3.2
	S_Hemi (1-3)	133	210.0	6.8	197.1	221.1	0.8	0.9	0.4%	2.4	134	209.9	7.3	196.7	222.2	1.0	1.1	0.5%	3.0
	I_Hemi (1-3)	133	209.4	7.9	197.5	229.4	0.9	0.9	0.4%	2.4	134	209.5	8.5	195.5	230.6	1.0	1.0	0.5%	2.9
	All (1-3)	133	209.7	7.1	198.1	224.3	0.7	0.7	0.3%	2.0	134	209.7	7.7	197.8	225.0	0.8	0.9	0.4%	2.4
	T (3-6)	133	175.2	7.7	159.6	189.0	0.8	0.9	0.5%	2.5	-	-	-	-	-	-	-	-	-
	S (3-6)	133	177.3	6.5	165.6	187.9	0.8	0.8	0.5%	2.3	-	-	-	-	-	-	-	-	-
	N (3-6)	133	177.6	7.8	150.0	192.9	2.3	2.4	1.3%	6.6	-	-	-	-	-	-	-	-	-
	I (3-6)	133	169.8	6.4	152.3	182.6	1.4	1.4	0.8%	3.8	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	133	177.7	6.7	165.4	187.7	0.9	1.0	0.6%	2.8	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	133	172.3	6.7	158.6	184.6	1.1	1.1	0.6%	2.9	-	-	-	-	-	-	-	-	-
	All (3-6)	133	175.0	6.5	162.5	185.8	0.8	0.9	0.5%	2.4	-	-	-	-	-	-	-	-	-
	S_Hemi (0-6)/(0-3)	133	185.7	6.3	174.7	195.5	0.8	0.9	0.5%	2.6	134	209.7	7.7	196.8	223.5	1.0	1.1	0.5%	2.9
	I_Hemi (0-6)/(0-3)	133	181.6	6.4	169.2	194.2	0.9	0.9	0.5%	2.5	134	209.3	8.7	196.2	229.9	1.0	1.0	0.5%	2.9
	All (0-6)/(0-3)	133	183.7	6.2	172.7	194.7	0.7	0.8	0.4%	2.1	134	209.5	8.0	197.9	225.0	0.8	0.9	0.4%	2.5
	WI_S_Hemi	133	180.1	6.0	169.1	190.4	0.9	1.0	0.6%	2.9	134	205.1	7.5	191.5	219.6	1.3	1.4	0.7%	4.0
	WI_I_Hemi	133	175.9	6.2	164.1	188.3	1.1	1.1	0.6%	3.1	134	205.4	8.6	191.8	226.7	1.3	1.3	0.6%	3.6
	WI	133	178.0	5.9	167.6	189.0	0.7	0.7	0.4%	2.0	134	205.1	7.6	193.6	218.9	0.9	1.0	0.5%	2.7
IPL ~ RPE Volume (mm3)	***C (1)***	*133*	*0.164*	*0.011*	*0.144*	*0.185*	*0.001*	*0.001*	*0.5%*	*0.002*	*134*	*0.163*	*0.011*	*0.142*	*0.184*	*0.001*	*0.001*	*0.8%*	*0.004*
	All (0-6)/(0-3)	*133*	*5.152*	*0.176*	*4.755*	*5.474*	*0.031*	*0.033*	*0.6%*	*0.091*	*134*	*1.453*	*0.056*	*1.324*	*1.552*	*0.020*	*0.021*	*1.4%*	*0.058*
	WI	*133*	*6.424*	*0.212*	*6.048*	*6.822*	*0.026*	*0.026*	*0.4%*	*0.073*	*134*	*1.842*	*0.127*	*0.621*	*1.977*	*0.101*	*0.101*	*5.5%*	*0.280*

Table16. Retinal Thickness and Volume of Retinal Layers of AngioRetina Scan, Retina Group

Retina																				
		6 mm HD Angio Retina									3 mm Angio Retina									
	Parameter	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility	Scan #	Mean	SD	min	max	repeatability SD	reproducibility SD	Reproducibility CV	95%_limits_of_reproducibility
ILM ~ IPL Thickness (µm)	**C (1)**	251	51.5	13.3	24.8	87.8	2.1	2.1	4.1%	5.9	255	51.8	13.2	26.3	86.8	1.4	1.4	2.7%	3.9
	T (1-3)	251	103.4	13.6	74.5	141.4	1.2	1.2	1.2%	3.3	255	104.2	14.2	74.9	142.5	1.1	1.1	1.1%	3.0
	S (1-3)	251	116.3	17.3	51.5	170.9	1.7	1.7	1.5%	4.7	255	116.6	17.9	62.5	168.3	1.5	1.5	1.3%	4.1
	N (1-3)	251	114.0	15.3	75.7	156.6	1.9	1.9	1.7%	5.2	255	113.8	15.5	75.6	157.0	1.6	1.6	1.4%	4.3
	I (1-3)	251	116.0	17.6	82.5	173.7	1.7	1.7	1.5%	4.8	249	115.6	16.9	82.8	178.2	1.4	1.4	1.2%	3.9
	S_Hemi (1-3)	251	112.5	14.8	67.7	159.5	1.3	1.3	1.1%	3.5	255	112.9	15.5	73.8	157.7	1.1	1.1	1.0%	3.1
	I_Hemi (1-3)	251	112.3	15.4	83.2	161.8	1.4	1.4	1.2%	3.8	255	112.3	14.9	83.2	165.0	1.2	1.2	1.1%	3.3
	All (1-3)	251	112.4	14.4	86.7	160.1	0.9	0.9	0.8%	2.6	255	112.6	14.5	88.2	161.4	0.8	0.8	0.7%	2.3
	T (3-6)	251	86.1	13.1	56.9	130.5	1.4	1.4	1.7%	4.0	-	-	-	-	-	-	-	-	-
	S (3-6)	251	100.6	14.7	66.2	144.3	1.6	1.6	1.6%	4.4	-	-	-	-	-	-	-	-	-
	N (3-6)	251	120.1	17.0	92.5	157.1	1.4	1.4	1.2%	3.8	-	-	-	-	-	-	-	-	-
	I (3-6)	249	99.5	15.7	65.8	150.4	2.1	2.1	2.1%	5.8	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	251	101.2	13.8	73.3	135.5	1.2	1.3	1.2%	3.5	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	251	102.0	15.6	69.4	152.4	1.4	1.4	1.4%	3.8	-	-	-	-	-	-	-	-	-
	All (3-6)	251	101.6	13.9	71.5	136.6	0.9	0.9	0.9%	2.6	-	-	-	-	-	-	-	-	-
	S_Hemi (0-6)/(0-3)	251	102.3	13.2	71.5	137.7	1.0	1.0	1.0%	2.8	255	106.0	14.6	70.3	147.0	1.1	1.1	1.0%	3.0
	I_Hemi (0-6)/(0-3)	251	102.9	14.5	72.0	150.3	1.1	1.1	1.1%	3.1	255	105.3	14.0	79.2	153.6	1.1	1.1	1.1%	3.1
	All (0-6)/(0-3)	251	102.6	13.1	74.9	135.6	0.8	0.8	0.8%	2.1	255	105.7	13.7	81.4	150.3	0.8	0.8	0.8%	2.2
	WI_S_Hemi	251	101.4	12.8	72.2	137.0	1.3	1.4	1.4%	3.8	255	107.0	14.6	71.8	147.9	1.7	1.7	1.6%	4.8
	WI_I_Hemi	251	103.0	13.7	72.3	141.4	1.5	1.6	1.5%	4.3	254	106.5	14.1	78.4	150.3	1.5	1.5	1.4%	4.1
	WI	251	102.2	12.6	73.8	133.2	1.1	1.1	1.1%	3.1	255	106.9	13.8	83.0	149.3	1.1	1.1	1.1%	3.1
ILM ~ IPL Volume (mm3)	***C (1)***	*251*	*0.041*	*0.010*	*0.020*	*0.069*	*0.002*	*0.002*	*4.1%*	*0.005*	*255*	*0.041*	*0.010*	*0.021*	*0.068*	*0.001*	*0.001*	*2.8%*	*0.003*
	All (0-6)/(0-3)	*251*	*2.878*	*0.367*	*2.103*	*3.768*	*0.028*	*0.028*	*1.0%*	*0.076*	*255*	*0.729*	*0.094*	*0.538*	*1.048*	*0.016*	*0.016*	*2.2%*	*0.044*
	WI	*251*	*3.657*	*0.470*	*2.194*	*4.804*	*0.114*	*0.116*	*3.2%*	*0.323*	*254*	*0.950*	*0.140*	*0.272*	*1.347*	*0.063*	*0.063*	*6.7%*	*0.176*
ILM ~ RPE Thickness (µm)	**C (1)**	251	285.9	87.4	112.6	609.0	5.1	5.1	1.8%	14.2	255	285.5	88.3	116.6	610.3	9.5	9.5	3.3%	26.3
	T (1-3)	251	315.7	49.6	223.6	495.2	3.1	3.2	1.0%	9.0	255	314.5	50.5	222.3	495.3	1.9	2.0	0.6%	5.5
	S (1-3)	251	325.3	55.0	231.6	562.1	1.8	1.9	0.6%	5.1	255	324.9	54.9	233.0	566.4	2.9	2.9	0.9%	8.0
	N (1-3)	251	324.8	46.6	216.6	493.7	3.2	3.3	1.0%	9.0	255	322.9	45.6	218.0	491.1	8.7	8.7	2.7%	24.0
	I (1-3)	251	320.9	48.8	229.4	535.3	4.8	4.8	1.5%	13.4	249	318.8	48.5	220.8	530.7	4.8	4.8	1.5%	13.4
	S_Hemi (1-3)	251	323.2	50.6	232.8	530.6	1.8	1.8	0.6%	5.0	255	322.3	50.6	234.0	531.0	4.4	4.4	1.4%	12.1
	I_Hemi (1-3)	251	320.2	46.1	218.0	503.7	3.4	3.4	1.1%	9.3	255	318.3	45.6	212.6	506.4	3.6	3.6	1.1%	9.9
	All (1-3)	251	321.7	47.5	225.7	516.2	2.1	2.1	0.7%	5.8	255	320.3	47.1	224.0	518.6	3.1	3.1	1.0%	8.7
	T (3-6)	251	273.0	27.9	225.8	374.3	1.8	1.8	0.7%	5.0	-	-	-	-	-	-	-	-	-
	S (3-6)	251	287.0	34.1	219.9	411.0	2.0	2.0	0.7%	5.6	-	-	-	-	-	-	-	-	-
	N (3-6)	251	300.3	31.3	227.4	394.7	1.6	1.6	0.5%	4.4	-	-	-	-	-	-	-	-	-
	I (3-6)	249	277.8	26.2	230.7	355.9	1.6	1.6	0.6%	4.4	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	251	286.6	31.2	222.9	396.2	1.4	1.4	0.5%	4.0	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	251	282.4	26.2	232.0	349.1	1.4	1.4	0.5%	3.9	-	-	-	-	-	-	-	-	-
	All (3-6)	251	284.5	27.4	227.6	365.0	1.0	1.0	0.4%	2.8	-	-	-	-	-	-	-	-	-
	S_Hemi (0-6)/(0-3)	251	294.8	35.2	222.3	432.4	1.4	1.4	0.5%	3.8	255	318.1	54.1	220.9	540.1	4.2	4.2	1.3%	11.6
	I_Hemi (0-6)/(0-3)	251	291.0	29.6	225.4	380.6	1.4	1.5	0.5%	4.0	255	314.5	49.5	201.4	518.2	4.0	4.0	1.3%	11.1
	All (0-6)/(0-3)	251	292.9	31.5	224.0	405.4	1.1	1.1	0.4%	3.1	255	316.3	51.0	211.8	529.1	3.4	3.4	1.1%	9.5
	WI_S_Hemi	251	288.9	32.1	223.2	414.2	1.5	1.5	0.5%	4.2	255	316.0	50.7	223.7	525.7	4.3	4.3	1.4%	11.9
	WI_I_Hemi	251	285.7	26.5	226.0	362.5	1.6	1.8	0.6%	4.9	254	312.0	44.7	204.0	492.1	3.8	3.8	1.2%	10.4
	WI	251	287.3	28.4	224.5	384.1	1.1	1.1	0.4%	3.1	255	314.0	46.5	216.1	506.9	3.1	3.1	1.0%	8.7
ILM ~ RPE Volume (mm3)	***C (1)***	*251*	*0.225*	*0.069*	*0.089*	*0.480*	*0.004*	*0.004*	*1.8%*	*0.011*	*255*	*0.224*	*0.069*	*0.092*	*0.480*	*0.007*	*0.007*	*3.3%*	*0.021*
	All (0-6)/(0-3)	*251*	*8.214*	*0.885*	*6.173*	*11.362*	*0.059*	*0.059*	*0.7%*	*0.165*	*255*	*2.183*	*0.356*	*1.426*	*3.681*	*0.045*	*0.045*	*2.1%*	*0.126*
	WI	*251*	*#####*	*1.089*	*6.409*	*13.865*	*0.320*	*0.322*	*3.1%*	*0.892*	*254*	*2.797*	*0.473*	*0.709*	*4.578*	*0.169*	*0.169*	*6.0%*	*0.469*
IPL ~ RPE Thickness (µm)	**C (1)**	251	234.4	81.8	87.7	551.3	5.3	5.4	2.3%	14.9	255	233.7	83.6	89.4	549.6	9.3	9.3	4.0%	25.8
	T (1-3)	251	212.3	41.9	126.8	353.8	3.1	3.1	1.5%	8.7	255	210.3	42.8	125.5	354.1	2.0	2.0	1.0%	5.6
	S (1-3)	251	208.9	44.0	134.3	395.4	2.0	2.0	1.0%	5.6	255	208.3	44.1	134.0	400.8	2.7	2.8	1.3%	7.6
	N (1-3)	251	210.8	37.4	116.2	338.5	2.9	2.9	1.4%	8.1	255	209.2	37.2	117.0	338.1	8.8	8.8	4.2%	24.3
	I (1-3)	251	205.0	37.6	121.1	362.7	4.8	4.8	2.4%	13.4	249	203.2	38.0	116.4	356.3	4.7	4.7	2.3%	13.2
	S_Hemi (1-3)	251	210.6	41.0	136.7	375.8	1.9	1.9	0.9%	5.4	255	209.4	41.3	136.3	375.7	4.3	4.3	2.0%	11.9
	I_Hemi (1-3)	251	207.9	36.7	113.0	348.1	3.5	3.5	1.7%	9.6	255	206.0	36.9	110.0	343.6	3.6	3.6	1.7%	10.0
	All (1-3)	251	209.3	38.4	124.9	361.9	2.1	2.1	1.0%	5.8	255	207.7	38.4	123.9	359.5	3.1	3.1	1.5%	8.7
	T (3-6)	251	186.9	18.4	152.0	267.7	1.9	2.0	1.1%	5.5	-	-	-	-	-	-	-	-	-
	S (3-6)	251	186.4	24.0	133.7	273.9	2.0	2.0	1.1%	5.6	-	-	-	-	-	-	-	-	-
	N (3-6)	251	180.2	22.4	113.1	244.1	1.8	1.8	1.0%	5.1	-	-	-	-	-	-	-	-	-
	I (3-6)	249	178.2	16.7	139.4	249.9	2.3	2.3	1.3%	6.3	-	-	-	-	-	-	-	-	-
	S_Hemi (3-6)	251	185.4	21.8	134.8	263.8	1.5	1.5	0.8%	4.3	-	-	-	-	-	-	-	-	-
	I_Hemi (3-6)	251	180.4	15.6	139.9	230.7	1.7	1.7	1.0%	4.8	-	-	-	-	-	-	-	-	-
	All (3-6)	251	182.9	18.0	137.9	237.4	1.2	1.2	0.7%	3.3	-	-	-	-	-	-	-	-	-
	S_Hemi (0-6)/(0-3)	251	192.4	26.2	134.2	296.1	1.4	1.4	0.7%	3.9	255	212.1	45.5	131.0	395.7	4.1	4.1	1.9%	11.3
	I_Hemi (0-6)/(0-3)	251	188.1	19.9	132.9	251.9	1.6	1.6	0.9%	4.5	255	209.2	41.4	107.6	367.0	3.9	3.9	1.9%	10.9
	All (0-6)/(0-3)	251	190.3	22.6	133.9	273.3	1.2	1.2	0.6%	3.3	255	210.7	43.0	119.9	381.2	3.4	3.4	1.6%	9.4
	WI_S_Hemi	251	187.5	23.3	135.7	280.5	1.5	1.7	0.9%	4.6	255	209.0	42.0	133.6	383.1	4.0	4.0	1.9%	11.0
	WI_I_Hemi	251	182.7	17.4	133.9	233.8	1.9	1.9	1.1%	5.3	254	205.4	36.5	107.7	344.2	3.7	3.7	1.8%	10.3
	WI	251	185.1	19.8	135.6	255.3	1.2	1.2	0.7%	3.4	255	207.1	38.3	122.9	361.4	3.0	3.0	1.5%	8.4
IPL ~ RPE Volume (mm3)	***C (1)***	*251*	*0.185*	*0.064*	*0.069*	*0.435*	*0.004*	*0.004*	*2.3%*	*0.012*	*255*	*0.184*	*0.066*	*0.070*	*0.432*	*0.007*	*0.007*	*4.0%*	*0.020*
	All (0-6)/(0-3)	*251*	*5.337*	*0.637*	*3.694*	*7.660*	*0.046*	*0.047*	*0.9%*	*0.130*	*255*	*1.454*	*0.300*	*0.808*	*2.644*	*0.034*	*0.034*	*2.3%*	*0.093*
	WI	*251*	*6.626*	*0.754*	*4.215*	*9.221*	*0.214*	*0.214*	*3.2%*	*0.594*	*254*	*1.846*	*0.377*	*0.437*	*3.266*	*0.108*	*0.108*	*5.8%*	*0.299*

16.2.2 FAZ Parameter Validation (for non-vascular FAZ Parameters)

To validate OCTA-based FAZ measurements with the device software, the OCTA derived **FAZ area** and **FAZ perimeter** parameters were compared to manually graded FAZ measurements from fluorescein angiography images.

Study Data

The case series consisted of 30 eyes of 26 subjects (14 males and 12 females) from 3 clinical sites. One early phase FA image with sufficient quality to visualize the FAZ per case was included in the FA grading set, and one 3 mm AngioRetina scan per case with sufficient scan quality was included in the OCTA measurement set. The case series consisted of 4 normal eyes, 3 eyes of wet AMD with CNV, 7 eyes with NPDR, 5 eyes with PDR, 4 eyes with BRVO, and remaining 7 eyes with other retinal pathologies (including dryAMD, CSC, MacTel, and ERM).

Methods

Three readers experienced in FA image grading performed FAZ measurements. Each grader followed a grader-specific randomized grading order, masked to each other's results through the entire grading process, and masked to the OCTA images and measurements. Measurement of Foveal Avascular Zone (FAZ) parameters was done using ImageJ software.

Results

Table 17a. Distribution of FAZ measurements based on FA and OCTA for the case series

	FA (Manual Grading)		OCTA (Device Software)	
	Area (mm^2)	Perimeter (mm)	Area (mm^2)	Perimeter (mm)
Mean	0.399	2.752	0.328	2.547
SD	0.328	1.368	0.306	1.572
Median	0.333	2.497	0.281	2.201
Min	0.120	1.584	0.037	0.860
Max	1.957	9.039	1.801	9.896

Table 17b. Limits of Agreement Analysis for FAZ measurements between OCTA and FA

Difference (FA - OCTA)	mean	mean (%)	SD	min	max	LOA lower bound*	LOA upper bound**	lower 95%CI for LOA lower	upper 95%CI for LOA lower	lower 95%CI for LOA upper	upper 95%CI for LOA upper
Area (mm^2)	0.070	17.7%	0.132	-0.129	0.356	-0.189	0.330	-0.349	-0.029	0.170	0.489
Perimeter (mm)	0.205	7.5%	0.761	-1.480	1.121	-1.287	1.697	-1.697	-0.876	1.287	2.108

* LOA lower bound = mean-1.96xSD

** LOA upper bound = mean+1.96xSD

Table 17c. Deming Regression Analysis for FAZ measurements between OCTA and FA

	n	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper
Area (mm^2)	30	-0.043	-0.123	0.038	0.929	0.721	1.136
Perimeter (mm)	30	-0.655	-1.017	-0.292	1.163	1.031	1.296

16.2.3 FAZ Parameters Agreement between 3 mm AngioRetina and 6 mm HD AngioRetina Scans

The agreement between the 3 mm and 6 mm AngioRetina scan patterns for FAZ parameters (FAZ area, FAZ perimeter, and FD-300 vessel density) was evaluated on the R&R study data set.

Of the 67 subjects enrolled in the R&R study, 5 subjects were excluded for following reasons: no FAZ, indeterminant FAZ, or missing one of the scan type for comparison. The evaluation was then performed for the combined group of 15 Normal, 15 Glaucoma and 32 Retina study eyes (62 subjects/eyes). Agreement (Bland-Altman analysis, Deming regression analysis) between 3 mm AngioRetina and 6 mm HD AngioRetina FAZ measurements are provided based on the first replicate per study eye per scan pattern.

Results

Table 18a. Limits of Agreement Analysis for FAZ measurements between 3 mm AngioRetina and 6 mm HD AngioRetina Scans

Difference (6-mm Scan - 3-mm Scan)	mean	mean (%)	SD	min	max	LOA lower bound*	LOA upper bound**	lower 95%CI for LOA lower	upper 95%CI for LOA lower	lower 95%CI for LOA upper	upper 95%CI for LOA upper
Area (mm^2)	-0.007	-0.3%	0.024	-0.055	0.089	-0.055	0.04	-0.0671	-0.0457	0.0311	0.0524
Perimeter (mm)	-0.107	-5.0%	0.107	-0.304	0.182	-0.317	0.103	-0.3697	-0.2758	0.0619	0.1558
FD-300 (%)	3.195	6.9%	3.695	-5.8	13.89	-4.047	10.436	-5.8568	-2.6223	9.0116	12.2462

* LOA lower bound = mean-1.96xSD

** LOA upper bound = mean+1.96xSD

Table 18b. Deming Regression Analysis for FAZ measurements between 3 mm AngioRetina and 6 mm HD AngioRetina Scans

	n	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper
Area (mm^2)	62	-0.007	-0.022	0.007	1.002	0.952	1.052
Perimeter (mm)	62	0.004	-0.121	0.129	0.948	0.891	1.006
FD-300 (%)	62	-0.464	-13.145	12.218	1.079	0.818	1.340

16.2.4 Retinal Thickness, RNFL Thickness and Disc Measurements Agreement between OCT and OCTA scans

A subset of the R&R study data was used to perform the agreement assessment of structural measurements (Full Retina, Inner Retina or GCC, and RNFL thickness) with the predicate. The agreement was assessed based on the combined group of 67 study eyes of 67 subjects (15 Normal, 16 Glaucoma, and 36 Retina) for evaluation of Full Retina and Inner Retina thickness, and 31 subjects (15 Normal and 16 Glaucoma) for evaluation of RNFL thickness and optic disc measurement. 64 subjects had matched scan pairs for comparison between 3 mm AngioRetina scan and Retina Map scan, 63 subjects had matched scan pairs for comparison between the 6 mm HD AngioRetina scan and Retina Map scan, 62 subjects had matched scan pair for comparison between 6 mm HD AngioRetina scan and GCC scan, and 30 subjects (normal subjects and glaucoma subjects only) with matched scan pair for the comparison between the 4.5 mm HD AngioDisc scan and the ONH scan. Overall scan attrition was low for any given scan type (< 5.0%). A summary of key parameters is shown in the table below for Mean of Differences and standard deviation (STDEV) of differences.

Table 19. Limits of Agreement Analysis for Full Retina, Inner Retina (i.e. GCC), RNFL and Optic Disc Measurements (All Groups Combined)

Difference (6-mm HD AngioRetina Scan vs. Retina Map Scan)									
	Parameter	mean	SD	LOA lower bound*	LOA upper bound**	lower 95%CI for LOA lower	upper 95%CI for LOA lower	lower 95%CI for LOA upper	upper 95%CI for LOA upper
Retina Thickness (µm)	C (1)	-1.7	6.9	-15.3	11.9	-18.2	-12.4	8.9	14.8
	All (1-3)	3.8	5.1	-6.2	13.8	-8.4	-4.0	11.7	16.0
	S_Hemi (1-3)	3.5	5.3	-6.9	13.9	-9.1	-4.6	11.6	16.1
	I_Hemi (1-3)	4.1	6.0	-7.6	15.8	-10.1	-5.1	13.2	18.3
	T (1-3)	4.2	6.8	-9.2	17.6	-12.1	-6.3	14.7	20.5
	S (1-3)	3.3	5.9	-8.2	14.8	-10.6	-5.7	12.3	17.3
	N (1-3)	2.5	6.8	-10.8	15.7	-13.6	-7.9	12.9	18.6
	I (1-3)	5.0	6.3	-7.4	17.5	-10.1	-4.7	14.8	20.2
	All (3-6)	-4.7	4.9	-14.4	4.9	-16.5	-12.3	2.8	7.0
	S_Hemi (3-6)	-5.0	5.3	-15.4	5.5	-17.6	-13.1	3.2	7.7
	I_Hemi (3-6)	-4.7	5.9	-16.3	6.9	-18.8	-13.8	4.4	9.4
	T (3-6)	-7.4	6.4	-20.0	5.1	-22.7	-17.2	2.4	7.8
	S (3-6)	-4.6	6.6	-17.5	8.3	-20.2	-14.7	5.5	11.1
	N (3-6)	-2.9	6.3	-15.2	9.4	-17.8	-12.5	6.8	12.1
	I (3-6)	-4.5	7.7	-19.5	10.5	-22.7	-16.2	7.3	13.8
Difference (6-mm HD AngioRetina Scan vs. GCC Scan)									
	Parameter	mean	SD	LOA lower bound*	LOA upper bound**	lower 95%CI for LOA lower	upper 95%CI for LOA lower	lower 95%CI for LOA upper	upper 95%CI for LOA upper
GCC Thickness (µm)	All (0-6)	4.4	3.9	-3.2	12.1	-4.9	-1.5	10.4	13.7
	S_Hemi (0-6)	4.6	4.3	-3.9	13.0	-5.7	-2.0	11.1	14.8
	I_Hemi (0-6)	4.3	4.3	-4.1	12.7	-5.9	-2.3	10.8	14.5
Difference (4.5-mm HD AngioDisc Scan vs. ONH Scan)									
	Parameter	mean	SD	LOA lower bound*	LOA upper bound**	lower 95%CI for LOA lower	upper 95%CI for LOA lower	lower 95%CI for LOA upper	upper 95%CI for LOA upper
RNFL Thickness (ø3.45)	TS (µm)	-2.9	7.4	-17.4	11.7	-22.0	-12.8	7.1	16.2
	ST (µm)	-11.1	7.3	-25.4	3.3	-29.9	-20.9	-1.2	7.8
	SN (µm)	-3.6	10.3	-23.8	16.6	-30.2	-17.4	10.2	22.9
	NS (µm)	-3.0	8.2	-19.2	13.2	-24.3	-14.1	8.1	18.3
	NI (µm)	-1.7	7.5	-16.3	13.0	-20.9	-11.7	8.4	17.6
	IN (µm)	-3.5	10.3	-23.7	16.7	-30.1	-17.3	10.3	23.0
	IT (µm)	-9.2	7.7	-24.3	6.0	-29.1	-19.5	1.2	10.8
	TI (µm)	-3.4	8.2	-19.4	12.6	-24.5	-14.4	7.5	17.6
	T (µm)	-3.2	7.1	-17.0	10.7	-21.4	-12.6	6.3	15.1
	S (µm)	-7.4	7.1	-21.3	6.5	-25.7	-16.9	2.2	10.9
	N (µm)	-2.3	7.0	-16.1	11.5	-20.5	-11.8	7.1	15.9
	I (µm)	-6.3	7.6	-21.3	8.6	-26.0	-16.6	3.9	13.4
	S_Hemi (µm)	-5.2	4.9	-14.8	4.5	-17.9	-11.8	1.5	7.6
	I_Hemi (µm)	-4.4	4.6	-13.5	4.6	-16.3	-10.6	1.8	7.5
	All (µm)	-4.8	4.2	-13.0	3.5	-15.7	-10.4	0.9	6.1
Optic Disc	DiscArea (mm^2)	-0.130	0.147	-0.418	0.157	-0.508	-0.327	0.066	0.247
	CupArea (mm^2)	-0.450	0.186	-0.816	-0.085	-0.931	-0.700	-0.200	0.031
	RimArea (mm^2)	0.319	0.190	-0.052	0.691	-0.169	0.065	0.574	0.808
	CupVolume (mm^3)	-0.162	0.168	-0.491	0.166	-0.595	-0.387	0.063	0.270
	RimVolume (mm^3)	0.263	0.095	0.076	0.450	0.017	0.135	0.391	0.509
	C_D_Area_Ratio	-0.194	0.075	-0.340	-0.047	-0.386	-0.294	-0.094	-0.001
	C_D_H_Ratio	-0.256	0.090	-0.433	-0.078	-0.489	-0.377	-0.134	-0.022
	C_D_V_Ratio	-0.157	0.124	-0.400	0.085	-0.476	-0.323	0.009	0.162

* LOA lower bound = mean-1.96xSD

** LOA upper bound = mean+1.96xSD

Table 20. Deming Regression Analysis for Full Retina, Inner Retina (i.e. GCC), RNFL and Optic Disc Measurements (All Groups Combined)

6-mm HD AngioRetina Scan vs. Retina Map Scan								
Parameter		n	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper
Retina Thickness (µm)	C (1)	63	-3.3	-9.5	2.9	1.01	0.98	1.03
	All (1-3)	63	2.0	-17.6	21.6	1.01	0.94	1.07
	S_Hemi (1-3)	63	6.0	-4.3	16.3	0.99	0.96	1.02
	I_Hemi (1-3)	63	-1.3	-30.3	27.6	1.02	0.92	1.11
	T (1-3)	63	9.8	-2.9	22.5	0.98	0.94	1.02
	S (1-3)	63	3.5	-8.9	15.9	1.00	0.96	1.04
	N (1-3)	63	9.4	-9.3	28.1	0.98	0.92	1.04
	I (1-3)	63	-2.1	-51.5	47.3	1.02	0.86	1.18
	All (3-6)	63	4.5	-16.4	25.4	0.97	0.89	1.04
	S_Hemi (3-6)	63	10.8	-2.1	23.7	0.94	0.90	0.99
	I_Hemi (3-6)	63	-3.0	-29.5	23.4	0.99	0.90	1.09
	T (3-6)	63	14.0	2.1	25.9	0.92	0.88	0.97
	S (3-6)	63	15.2	-1.2	31.5	0.93	0.87	0.99
	N (3-6)	63	-5.0	-23.8	13.8	1.01	0.94	1.07
	I (3-6)	63	-1.0	-40.5	38.6	0.99	0.84	1.14
6-mm HD AngioRetina Scan vs. GCC Scan								
Parameter		n	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper
GCC Thickness (µm)	All (0-6)	62	-1.2	-7.1	4.8	1.06	1.00	1.12
	S_Hemi (0-6)	62	0.2	-7.0	7.4	1.05	0.97	1.12
	I_Hemi (0-6)	62	-3.3	-9.5	2.9	1.08	1.02	1.15
4.5-mm HD AngioDisc Scan vs. ONH Scan								
Parameter		n	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper
RNFL Thickness (ø3.45)	TS (µm)	30	-4.1	-13.0	4.7	1.02	0.88	1.16
	ST (µm)	30	-29.1	-38.4	-19.8	1.15	1.07	1.24
	SN (µm)	30	-24.7	-35.3	-14.2	1.21	1.10	1.32
	NS (µm)	30	-3.6	-15.6	8.3	1.01	0.84	1.17
	NI (µm)	30	-14.1	-25.3	-2.9	1.18	1.03	1.33
	IN (µm)	30	-19.8	-32.0	-7.7	1.16	1.03	1.29
	IT (µm)	30	-22.3	-31.1	-13.4	1.12	1.04	1.20
	TI (µm)	30	7.5	-9.3	24.3	0.82	0.54	1.09
	T (µm)	30	1.5	-10.5	13.5	0.93	0.74	1.11
	S (µm)	30	-26.1	-34.2	-18.0	1.17	1.09	1.26
	N (µm)	30	-8.4	-18.7	1.8	1.08	0.95	1.22
	I (µm)	30	-20.2	-29.6	-10.7	1.13	1.04	1.23
	S_Hemi (µm)	30	-12.2	-20.0	-4.3	1.08	0.98	1.17
	I_Hemi (µm)	30	-9.9	-16.7	-3.1	1.06	0.98	1.15
	All (µm)	30	-10.3	-16.4	-4.1	1.06	0.99	1.14
Disc	DiscArea (mm^2)	30	-0.148	-0.470	0.173	1.01	0.86	1.15
	CupArea (mm^2)	30	-0.219	-0.325	-0.113	0.75	0.63	0.88
	RimArea (mm^2)	30	0.511	0.243	0.780	0.84	0.63	1.05
	CupVolume (mm^3)	30	-0.024	-0.038	-0.009	0.46	0.40	0.53
	RimVolume (mm^3)	30	0.120	0.063	0.177	2.22	1.62	2.83
	C_D_Area_Ratio	30	-0.122	-0.185	-0.058	0.83	0.69	0.98
	C_D_H_Ratio	30	-0.315	-0.524	-0.105	1.09	0.79	1.40
	C_D_V_Ratio	30	-0.340	-0.580	-0.100	1.28	0.96	1.60

16.2.5 Thickness Measurements Agreement between 3 mm AngioRetina Scan and 6 mm HD AngioRetina Scan

There are several redundant parameters for Full Retina thickness, Inner Retina thickness, and Outer Retina thickness for the central 3 mm macula between 3 mm AngioRetina and 6 mm HD AngioRetina scans. The redundancy is provided to reduce scan acquisition burden and maintain flexibility for user to select preferred scan pattern in clinical use.

The agreement evaluation is based on the study dataset described in the OCTA R&R study for the combined group (67 subjects/study eyes, including 15 Normal, 16 Glaucoma, and 36 Retina subjects).

All qualified scans (up to 9 scans per study eye from 3 repeats per study device and 3 study devices) were included in the limits of agreement analysis and the Deming regression analysis.

Results

Eight thickness measurement parameters were evaluated for Full Retina thickness and Inner Retina thickness. Results provided in Tables 21 through 24.

Full Retina Thickness (ILM to RPE)

Table 21. Limits of agreement for the full retina thickness (ILM to RPE) parameters, 3 mm OCTA scan versus 6 mm HD OCTA scan, based on the combined group (15 Normal, 16 Glaucoma, and 36 Retina subjects).

All (Groups combined)									
	Parameter	mean	SD	LOA_lower_bound*	LOA_upper_bound**	lower_95%CI_for_LOA_lower	upper_95%CI_for_LOA_lower	lower_95%CI_for_LOA_upper	upper_95%CI_for_LOA_upper
Retina Thickness (µm)	C (1)	0.0	8.4	-16.4	16.5	-18.6	-14.3	14.3	18.7
	All (1-3)	-0.4	3.1	-6.4	5.7	-7.3	-5.6	4.9	6.5
	S_Hemi (1-3)	-0.4	3.5	-7.2	6.3	-8.1	-6.4	5.5	7.2
	I_Hemi (1-3)	-0.3	4.3	-8.7	8.1	-9.8	-7.5	6.9	9.3
	T (1-3)	-0.1	3.3	-6.7	6.4	-7.6	-5.8	5.5	7.3
	S (1-3)	-0.9	2.9	-6.7	4.8	-7.4	-5.9	4.1	5.6
	N (1-3)	0.0	7.0	-13.6	13.7	-15.4	-11.9	11.9	15.5
	I (1-3)	-0.5	5.6	-11.5	10.5	-13.0	-10.0	9.0	12.0

* LOA lower bound = mean-1.96xSD

** LOA upper bound = mean+1.96xSD

Table 22. Deming regression analysis for the full retina thickness (ILM to RPE) parameters, 3 mm OCTA scan versus 6 mm HD OCTA scan, based on the combined group (15 Normal, 16 Glaucoma, and 36 Retina subjects).

All (Groups combined)								
Parameter		n	intercept	intercept_ CI_lower	intercept_ CI_upper	slope	slope_ CI_lower	slope_ CI_upper
Retina Thickness (µm)	C (1)	67	0.8	-1.9	3.6	1.00	0.99	1.01
	All (1-3)	67	0.9	-2.9	4.7	1.00	0.98	1.01
	S_Hemi (1-3)	67	1.7	-1.2	4.5	0.99	0.98	1.00
	I_Hemi (1-3)	67	0.8	-6.1	7.7	1.00	0.97	1.02
	T (1-3)	67	2.3	-2.3	6.8	0.99	0.98	1.01
	S (1-3)	67	1.8	-0.7	4.2	0.99	0.98	1.00
	N (1-3)	67	-7.5	-26.3	11.2	1.02	0.96	1.08
	I (1-3)	66	2.1	-4.1	8.3	0.99	0.97	1.01

Inner Retina Thickness (ILM to IPL)

Table 23. Limits of agreement for the inner retina thickness parameters, 3 mm OCTA scan versus 6 mm HD OCTA scan, based on the combined group (15 Normal, 16 Glaucoma, and 36 Retina subjects).

All (Groups combined)									
	Parameter	mean	SD	LOA_lower_ bound*	LOA_upper_ bound**	lower_95%CI_ for_LOA_lower	upper_95%CI_ for_LOA_lower	lower_95%CI_ for_LOA_upper	upper_95%CI_ for_LOA_upper
Inner Retina Thickness (ILM~IPL) (µm)	C (1)	-0.2	2.3	-4.7	4.3	-5.3	-4.1	3.7	4.9
	All (1-3)	-0.6	1.2	-3.1	1.8	-3.4	-2.7	1.4	2.1
	S_Hemi (1-3)	-0.9	1.6	-4.1	2.3	-4.5	-3.6	1.9	2.8
	I_Hemi (1-3)	-0.4	1.9	-4.1	3.3	-4.6	-3.5	2.7	3.8
	T (1-3)	-0.8	1.5	-3.8	2.1	-4.2	-3.4	1.7	2.5
	S (1-3)	-0.9	2.0	-4.9	3.1	-5.5	-4.4	2.6	3.7
	N (1-3)	-0.4	2.1	-4.5	3.7	-5.1	-4.0	3.1	4.2
	I (1-3)	-0.3	2.5	-5.1	4.5	-5.9	-4.4	3.8	5.2

* LOA lower bound = mean-1.96xSD

** LOA upper bound = mean+1.96xSD

Table 24. Deming regression analysis for the inner retina thickness parameters, 3mm OCTA scan versus 6 mm HD OCTA scan, based on the combined group (15 Normal, 16 Glaucoma, and 36 Retina subjects).

All (Groups combined)								
Parameter		n	intercept	intercept_ CI_lower	intercept_ CI_upper	slope	slope_ CI_lower	slope_ CI_upper
Inner Retina Thickness (ILM~IPL) (µm)	C (1)	67	-1.8	-2.9	-0.7	1.03	1.01	1.06
	All (1-3)	67	-1.9	-3.3	-0.4	1.01	1	1.02
	S_Hemi (1-3)	67	-1.9	-4.1	0.2	1.01	0.99	1.03
	I_Hemi (1-3)	67	-2	-5.1	1.1	1.02	0.98	1.05
	T (1-3)	67	-0.5	-2.1	1.2	1	0.98	1.01
	S (1-3)	67	-2.6	-5.6	0.4	1.02	0.99	1.04
	N (1-3)	67	-1.3	-3.9	1.3	1.01	0.98	1.03
	I (1-3)	66	-1.8	-4.9	1.3	1.01	0.98	1.04

17 Appendix F: Signal Strength Index (SSI)

The system provides a Signal Strength Index (SSI) to help you determine if the scan quality is acceptable or not. The Signal Strength Index (SSI) is based on the intensity, or brightness, of reflected light during scanning. Greater intensity corresponds with a higher SSI. SSI is based on a global average over the entire scan pattern. The SSI appears after each scan.

The SSI is a quantitative measure of signal strength, a major component of image quality, but is not intended to be used alone to determine image quality. However, when SSI is lower than the minimum recommended values given in Table below, Optovue recommends that you re-take the scan to achieve an SSI value above the minimum recommended, if possible.

Table Minimum Recommended SSI for Each Scan Type

Scan Type	Minimum Recommended SSI
Retina Map	SSI > 39
ONH	SSI > 28
GCC	SSI > 32

Minimum recommended values for SSI are different for Retina Map, ONH and GCC scan types, because these scans address anatomical features that vary in their general reflectivity. For example, GCC and Retina Map scans address the inner-plexiform layer (IPL), which is generally less reflective, and thus darker when scanned, than other layers. The system therefore requires greater intensity of reflected light to enable recognition of the IPL. The minimum recommended SSI is lower for the ONH, because the RNFL layer is highly reflective, allowing recognition of its layers even if the intensity of reflected light is lower.

Characteristics of certain patients' eyes can prevent the system from achieving an SSI value above the recommended minimum, even after you retake the scan. One example is ocular opacity from a cataract. In such cases, the clinician can choose to use the scan, but should interpret it with more caution, compared to a scan with a high SSI.

Optovue established the SSI cutoff values for RTVue based on review of a large data set of RTVue scans. The data set comprises approximately 100 scans with a wide range of SSI values. It includes EMM5, ONH, and GCC scan types. These three scan

types are the same in RTVue XR. (The EMM5 in RTVue is equivalent to Retina Map in XR.) The criteria to establish the minimum recommended SSI was whether or not visualization of the relevant retinal layers was possible. The relevant layers include the ILM for all scan types; the RNFL for glaucoma scans; the IPL for GCC and retina scans; and the RPE for retina scans. The minimum recommended SSI value was the value where the relevant retinal layers could no longer be reliably visualized in the B scans. Such scans cannot be segmented accurately, because the retinal layers cannot be reliably visualized with low variability. The SSI values associated with this point (where retinal layers cannot be reliably visualized) were determined to be the minimum recommended values given in the table above.

To validate the minimum recommended SSI, which differentiates scans of acceptable and unacceptable quality, Optovue evaluated all three scan patterns scans at different SSI levels. To do this, we gathered SSI data from repeat scans performed on six normal subjects with clear ocular media, which we used to establish a normal baseline. We repeated each scan three times to calculate repeatability, defined as the standard deviation of the thickness values for each measurement. We manipulated image quality by defocusing the OCT image during scan acquisition. The defocusing and resulting lower image quality mimics the clinical situation that occurs with media opacity and small pupils. Analysis of all measurements results in the values presented in the following tables. (Numerical values represent the standard deviation of the three scans averaged across all six subjects.) The average standard deviation of thickness values indicates the amount of measurement variability present when the SSI is above and below the recommended minimum value; the higher the standard deviation, the greater the measurement variability.

Table EMM5 Scan: Thickness Standard Deviation when SSI Is Above and Below Recommended Cutoff

Measurements		Above Cutoff	Below Cutoff
Full Retina	Fovea	9.58	54.57
	Tempo	7.27	62.04
	Superior	10.77	43.42
	Nasal	6.91	52.72
	Inferior	10.90	60.97
	Tempo2	5.33	38.96
	Superior2	2.90	33.91
	Nasal2	5.59	42.38
	Inferior2	9.91	52.25
Average		7.68	49.02

Table shows the standard deviation of thickness for the three scans averaged over all subjects for each EMM5 thickness parameter. The first column of data is the result when the image quality is above the recommended cutoff (equal to or above the ROC cutoff 39) and the scans are deemed acceptable and usable. The second column of data is the result when the image quality is below the recommended cutoff (below the ROC cutoff 39) and the scans are deemed unacceptable and not usable. Observe that the standard deviations are very good (small) when the image quality is usable, and then get much worse (large) when the image quality is unusable. Due to the high variability and poor image quality of such unusable scans, Optovue recommends that these scans not be used for clinical decision making.

Table below shows ONH scan variability when SSI values are above and below the recommended cutoff.

ONH scan Thickness Standard Deviation when SSI Is Above and Below Recommended Cutoff		
ONH		
Measurements	**Above Cutoff**	**Below Cutoff**
Avg RNFL	2.01	5.88
Sup RNFL	2.56	4.31
Inf RNFL	2.76	8.82
Tempo	6.21	11.52
Superior	3.96	10.46
Nasal	4.55	12.68
Inferior	3.68	8.36
TU	5.68	14.16
ST	5.29	13.37
SN	5.92	15.63
NU	5.82	15.79
NL	4.52	10.99

ONH scan Thickness Standard Deviation when SSI Is Above and Below Recommended Cutoff		
ONH		
Measurements	**Above Cutoff**	**Below Cutoff**
IN	5.40	14.56
IT	4.29	13.93
TL	7.76	19.08
Average	4.69	11.97

Note: The EMM5 scan in the RTVue has been renamed to Retina Map in the RTVue 100 XR.

Table shows the standard deviation values of three scans averaged over all subjects for each ONH thickness parameter. The first column of data is the result when the image quality is above the recommended cutoff (equal to or above the ROC cutoff 28). The second column of data is the result when the image quality is below the recommended cutoff (below the ROC cutoff 28). Observe that the standard deviations are very good (small) when the image quality is usable, and then get much worse (large) when the image quality is unusable. Due to the high variability and poor image quality of such unusable scans, Optovue recommends that these scans not be used for clinical decision making.

Table GCC Scan: Thickness Standard Deviation when SSI Is Above and Below Recommended Cutoff

GCC		
Measurements	**Above Cutoff**	**Below Cutoff**
Inner Retina Average	1.88	12.25
Superior Average	2.13	14.06
Inferior Average	3.25	14.02
S-I Average	4.13	12.43
GCC-FLV	0.98	3.59
GCC-GLV	1.47	4.85
Average	2.31	10.20

Table shows the standard deviation values of three scans averaged over all subjects for each GCC thickness parameter. The first column of data is the result when the image quality is listed as above the cutoff (equal to or above the ROC cutoff 32) and the scans are deemed acceptable and usable. The second column of data is the result when the image quality is below the cutoff (below the ROC cutoff 32). Observe that the standard deviations are very good (small) when the image quality is usable, and then get much worse (large) when the image quality is unusable. Due to the high variability and poor image quality of such unusable scans, Optovue recommends that these scans not be used for clinical decision making.

When scanning, the Signal Strength Index (SSI) should be green. However, due to individual patient variability and the light absorption properties of pathologies, it is not always possible to achieve a green signal. If signal strength is not in the green over a range of patients including normals, contact Optovue Technical Support for assistance.

_____End of section_____

18 Appendix G Cornea Anterior Module (CAM)

18.1 Safety Notes

General

This XR 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 XR user manual.
2. Ensure the CAM lens is attached when capturing scans in the **Cornea** category.
3. Note the working distance to the cornea surface for CAM lens (13mm for the CAM-L)
4. Align the eye to the proper eye position (canthus) indicator mark on the chin rest.
5. Illuminate the external eye structures using the Red LED illumination lights
6. 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, an auxiliary lens adapter, when used in conjunction with XR, is indicated for *in vivo* imaging and measurement of the cornea and other ocular structures of the anterior segment of the eye, including pachymetry and corneal power.

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

Warning: Corneal Power Feature

The Net Corneal Power value determined by the TCP function is NOT INTERCHANGEABLE with the corneal power value determined by any other device. The Net Corneal Power determined by the TCP function of the CAM option for XR is not intended to be used in lieu of, or replace a value from another device into your standard IOL calculation formula.

Warning: User Changes to Software or Hardware

The XR and XR with CAM Option are medical devices. The software and hardware is designed in accordance with U.S., European and other international medical device design and manufacturing standards. Unauthorized modification of RTVue XR100 or RTVue XR with CAM Option software or hardware in any way can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data. Modification of either of these in any way also voids the instrument warranty in its entirety.

Warning: Phototoxicity

The CAM Option is an accessory only for the Avanti system and has no function whatsoever as an independent product. As such, the CAM option may not be used independently of the Avanti system, and should be kept in the storage (wooden) box when not in use.

There is no increase in the risk of phototoxicity from the Avanti system when used in conjunction with the CAM option. Refer to the Avanti user manual for all Safety Notes pertaining to the use of the system.

Product Compliance

European Conformity

CE 0197 2007/47/EC Medical Device Directive

European Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nuremberg Germany

EC REP **European Representative**

Medical Device Safety Services (MDSS) GMbH
Schiffgraben 41
30175 Hannover, Germany

Lens Identification and Serial Number Location:

CAM-L Lens (also referred to as CAM Lens)

_____End of section_____

18.2 Instrument Description

The Avanti/CAM system is comprised of the XR system and the CAM option (cornea lens adapter) for use in imaging the cornea and anterior chamber of the eye.

The lens adapter is attached and removed by a trained operator. The cornea scan patterns and analysis functions are enabled only after the XR/CAM license is purchased.

18.3 XR/CAM System Configuration:

The lens adapter with low magnifications (CAM-L) is not included in the standard XR systems:

1. XR Scanner
2. Computer
3. System Table
4. Monitor (Computer Display)
5. Keyboard and Mouse
6. Printer
7. Cornea lens adapter (CAM)

Refer to the XR user manual for detailed descriptions of all sub-systems.

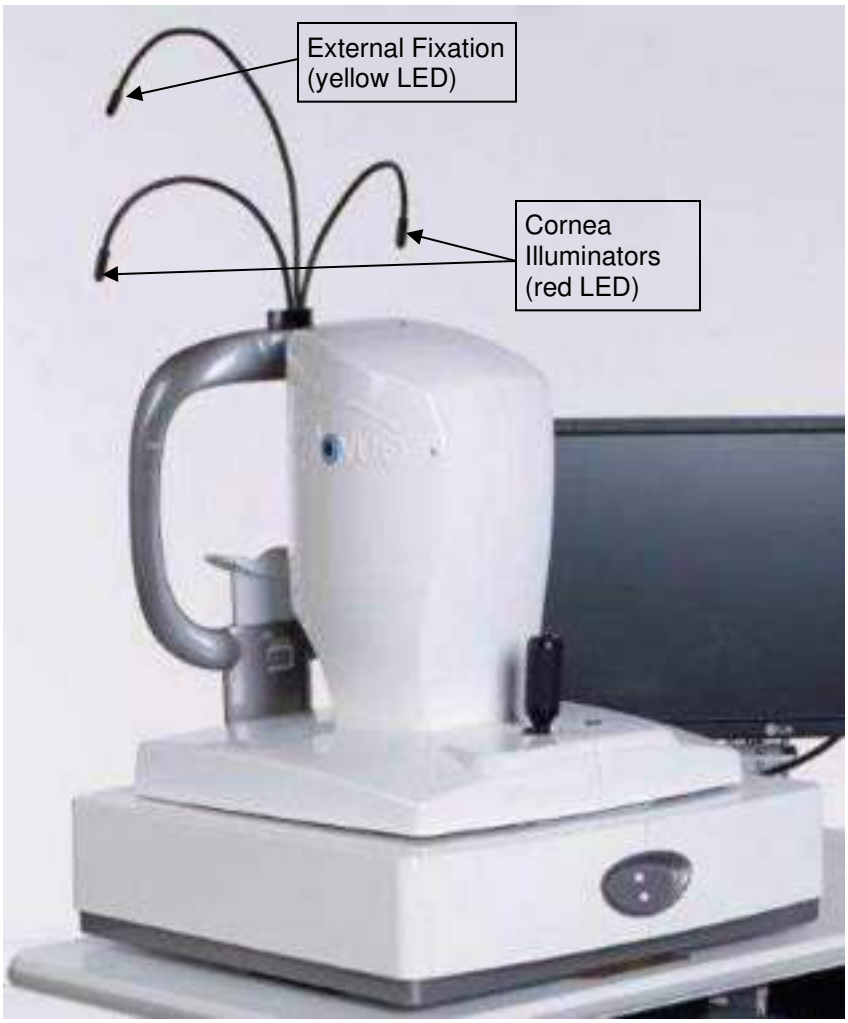


Figure 241 Scanner head with fixation and cornea illumination lights

_____End of section_____

18.4 Getting Started

Refer to the XR Installation Manual for system unpacking and installation instructions.

18.4.1 Mounting the Lens Adapters

The lens has a bayonet mount system.

Note: The working distance between the lens adapter and cornea is 13 mm on the CAM-L 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_____

18.5 Patient Menu

Refer to the XR User Manual for this section.

_____End of section_____

18.6 Examine Menu

18.6.1 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.)

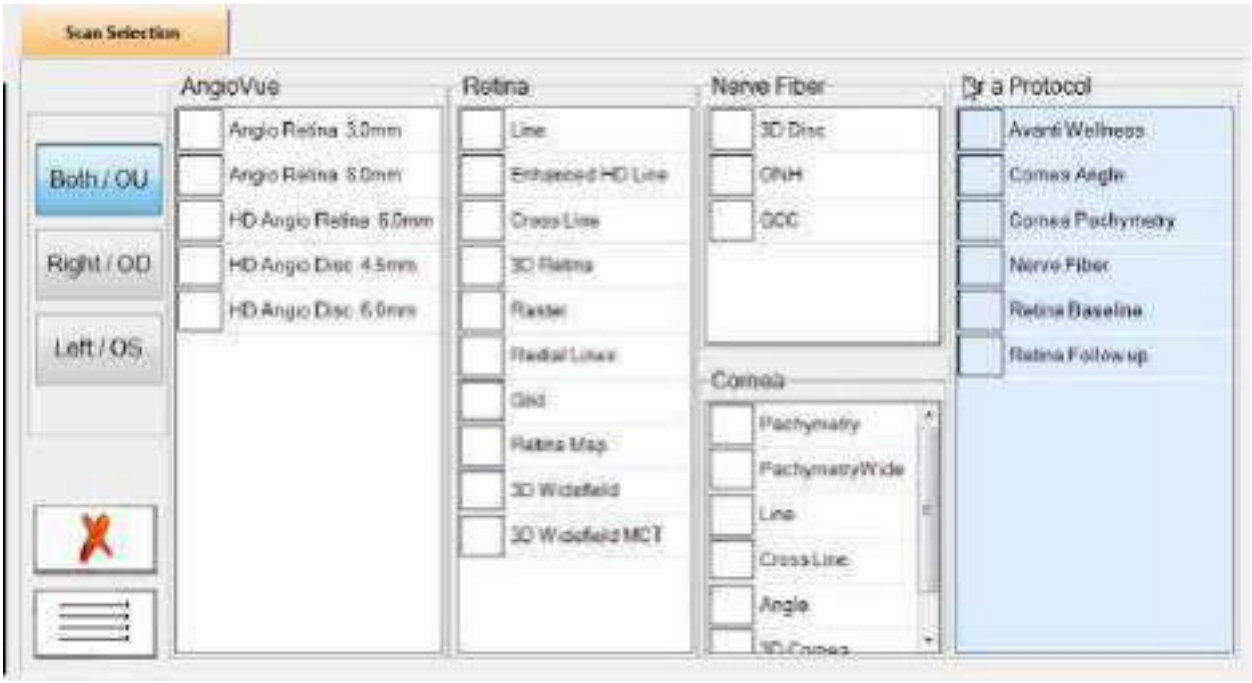


Figure 242 Scan pattern selection

18.6.2 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. Use the two red external illumination LEDs on headrest to illuminate the cornea (one for each eye).
4. Instruct patient to fixate on the center of light blue internal fixation target.
5. Use the yellow external fixation LED on headrest to guide patient fixation if required. For corneal power scan, use an internal fixation target
6. 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.

7. 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.
8. 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.

Note: Corneal power measurements are not displayed for poor quality scans in which an algorithm failed. In this case, the scan should be repeated.

9. Align on the desired area to scan.
10. 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).
11. Adjust scan beam to target zone and orientation with joystick.
12. Adjust image quality/scan strength (P-Motor adjustment).
13. Capture scan using joystick button or capture button on screen.
14. Review and process (averaging) the OCT images.
15. Save the scan.

Remember the following key operation points:

1. Use the XR with CAM like a Photo 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).
2. Auto All and Auto-Z are disabled.
3. Minimal Focus motor adjustment may be used (only available in manual scan control options).
4. Use the P-Motor to optimize scan signal strength.

The following items are preset and not adjustable.

1. **Internal Illumination**: Set to **0**
2. **Focus**: default set to cornea (can be adjusted to optimize the image intensity for Line, Cross Line and Angle scans)
3. **Z position**: Set at constant value depends on the system

18.6.3 Scan Alignment

OCT scan window: Place the cornea B-scan image in between the two red guide lines to optimize the cornea scan images. Pachymetry, PachymetryWide and cross line scans will have two OCT windows, one for vertical b- scan, and one for horizontal b-scan.

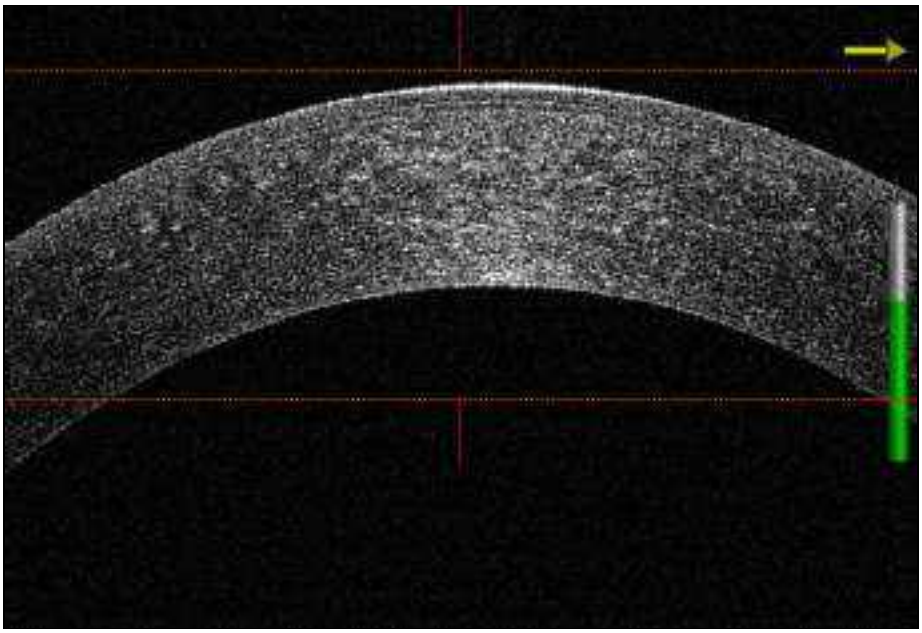


Figure 243 B scan between red lines

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

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

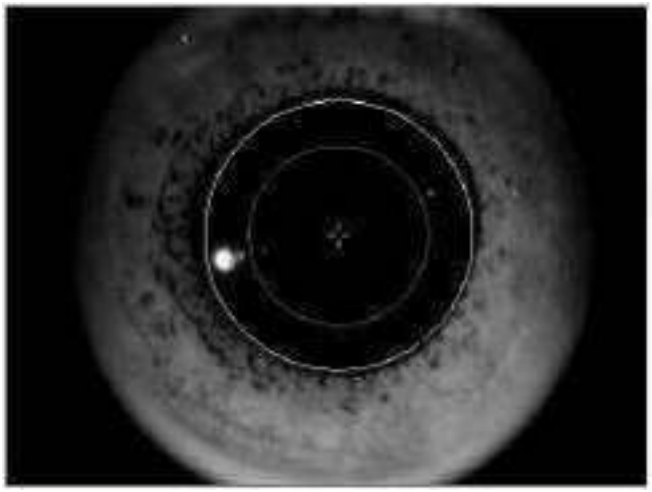


Figure 244 Iris image

2. **Angle scan**: Use the external fixation (yellow light on gooseneck cable) to guide the patients fixation until the cornea/sclera edge is **parallel and located in the red guided lines region**. Place center of scan line pattern on the limbus and cornea/scleral OCT image parallel to the red horizontal guidelines.

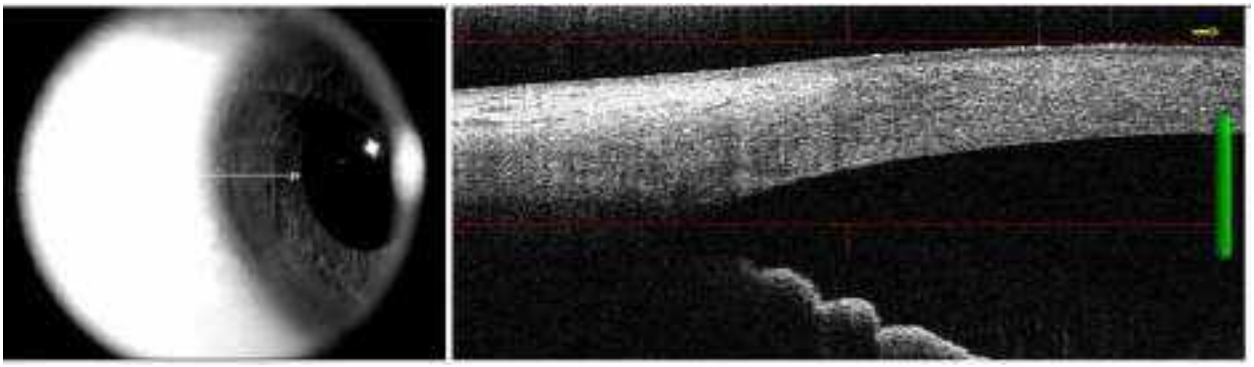


Figure 245 Iris and B scan image for Angle

Note: Only when the posterior cornea/sclera tissue is parallel or contained inside the red lines (from left to right edge of scan) are the AOD/TISA measurements accurate.

3. **Line, cross line, 3-D cornea:** these scans are centered on the pupil or particular area of interest.

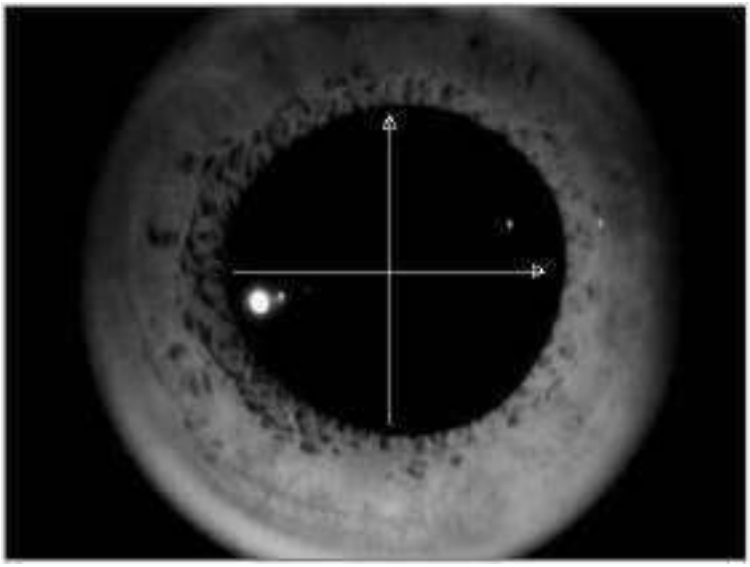


Figure 246 Cross line centering

18.6.4 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:

1. 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.
2. 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, Cross 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_____

18.7 Review Menu

18.7.1 Review Layout

Refer to the XR user manual.

18.7.2 Measurement

Refer to the XR user manual.

18.7.3 Review Result Layout

18.7.4 Line

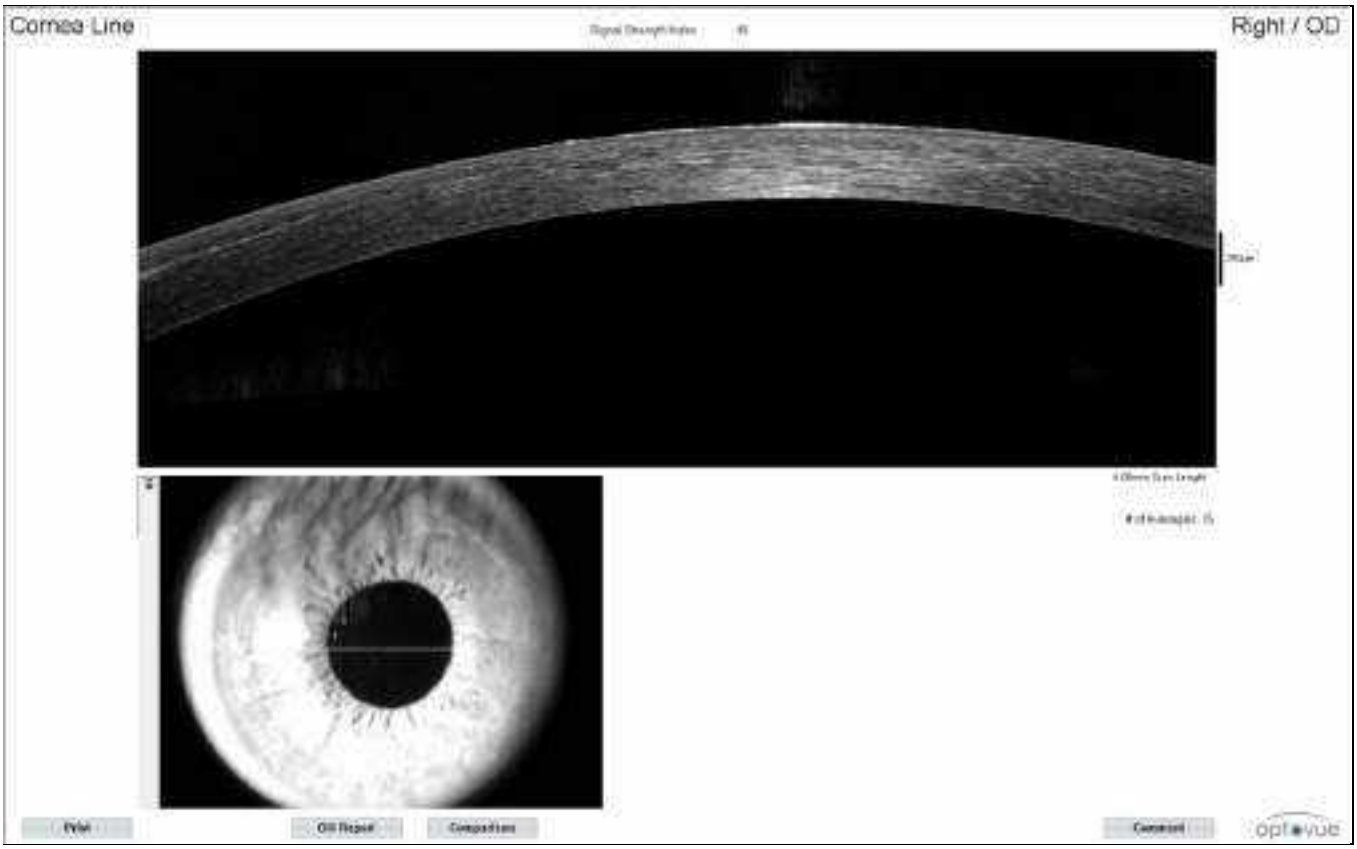


Figure 247 Line scan report

If the image saved is an average processed image on both Line and Cross line scans, both the averaged and single frame image will be saved.

18.7.5 Cross Line Scan

The illustration below shows both vertical and horizontal cornea scan images.

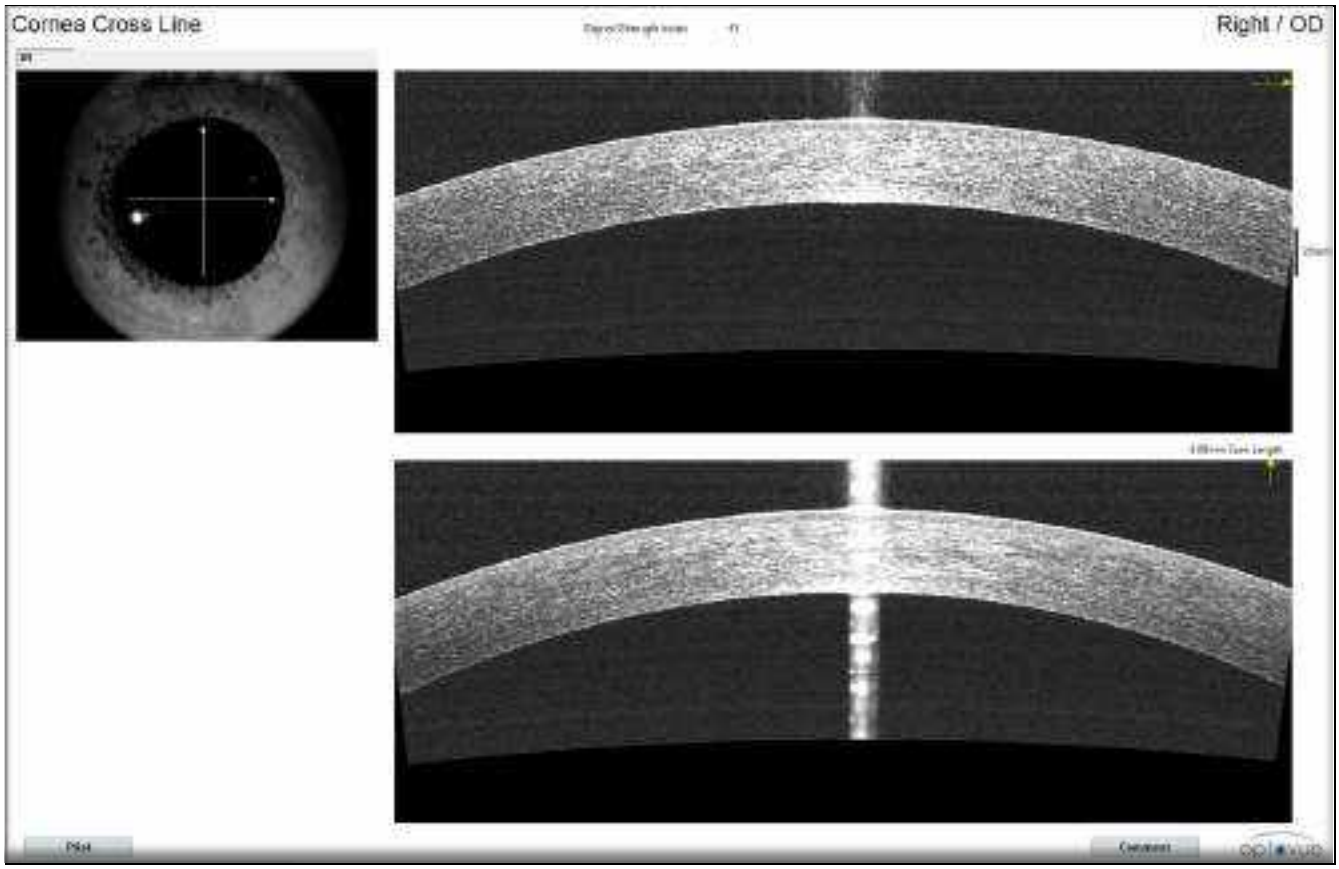


Figure 248 Cross line report

18.7.6 Scan with Thickness Measurement Tool

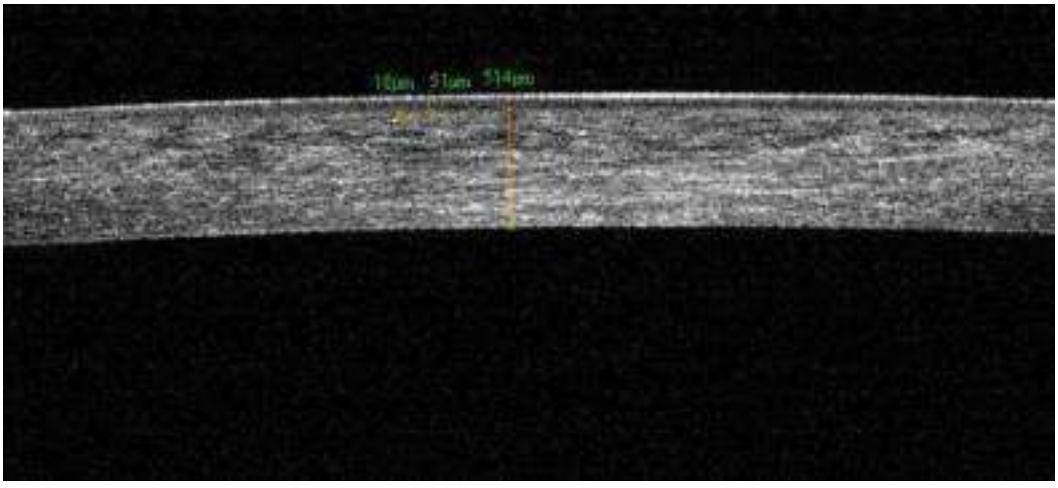


Figure 249 B scan with Measurement tool

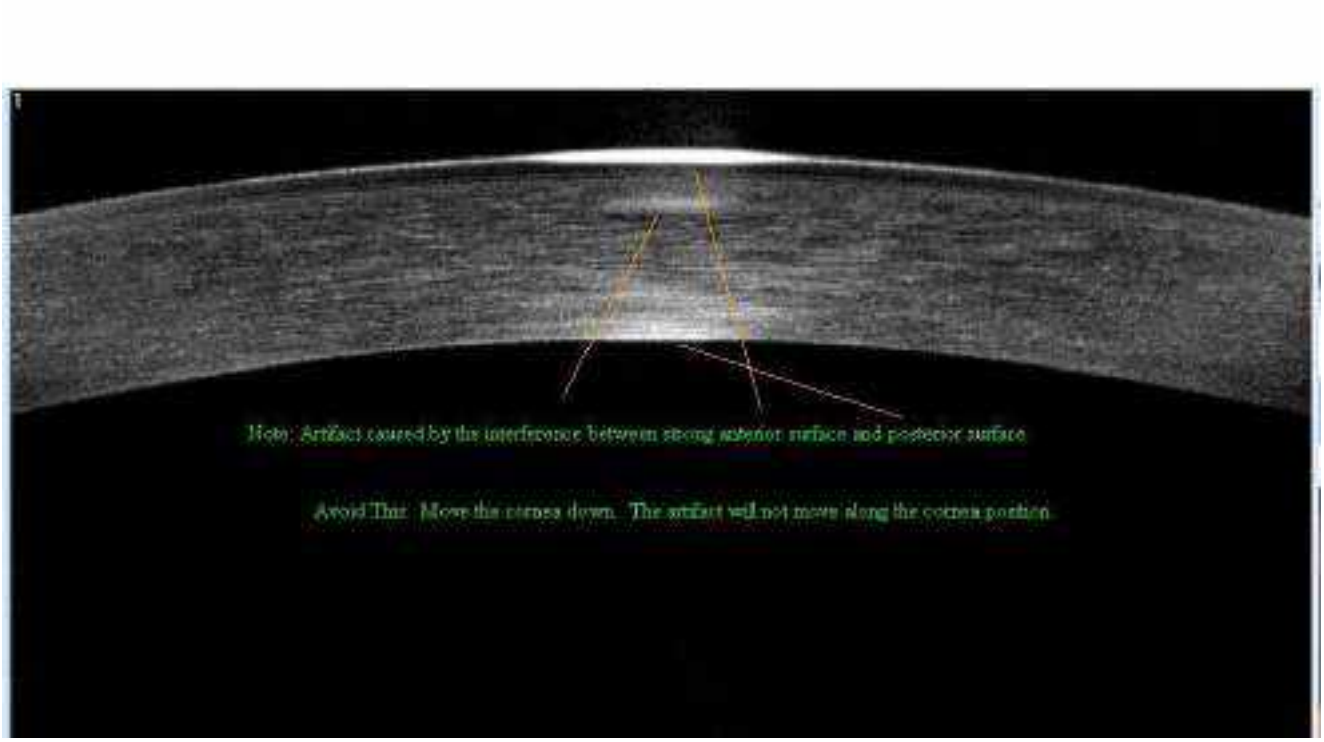


Figure 250 B scan with artifact

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).

18.7.7 Angle

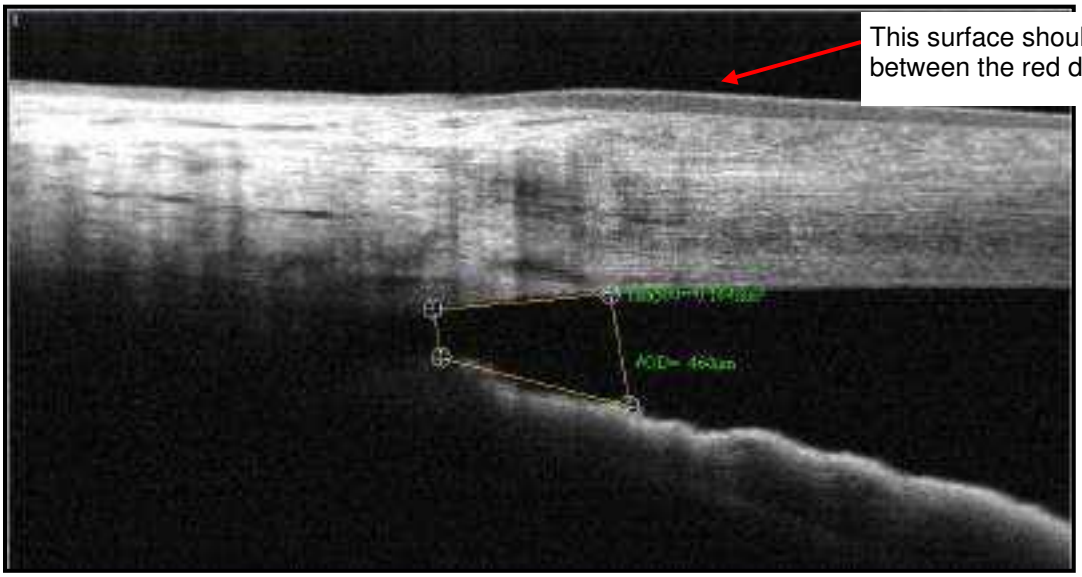


Figure 251 B scan of angle

18.7.8 TISA/AOD Measurement Tool

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.

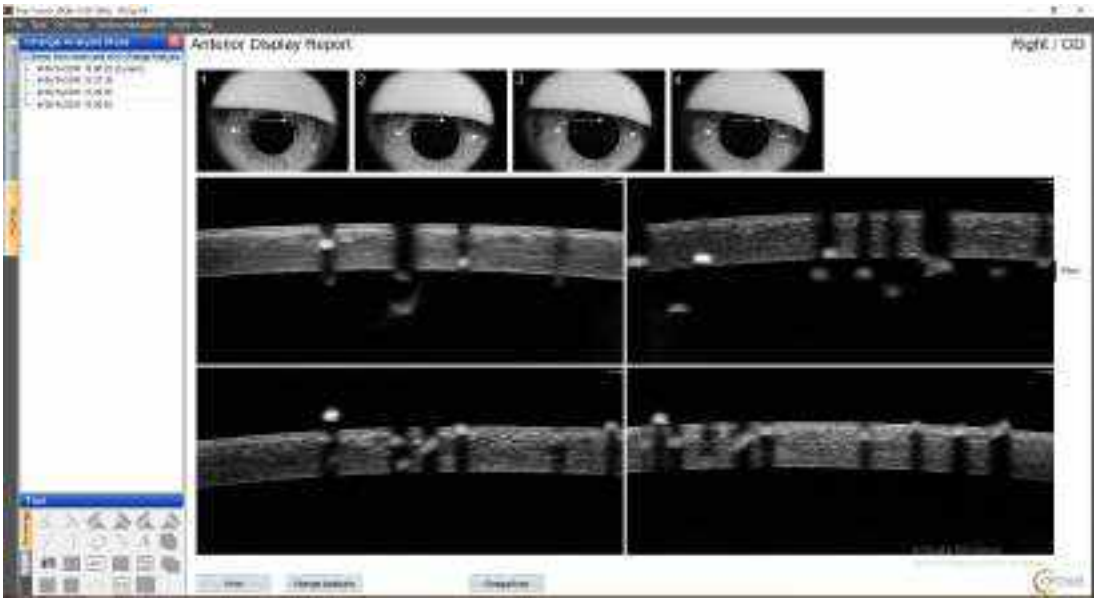


Figure 252 Four scan display page

18.7.9 3D Cornea

The Cornea 3D scan has scan density of 513 A-scans and 101 B-scans.

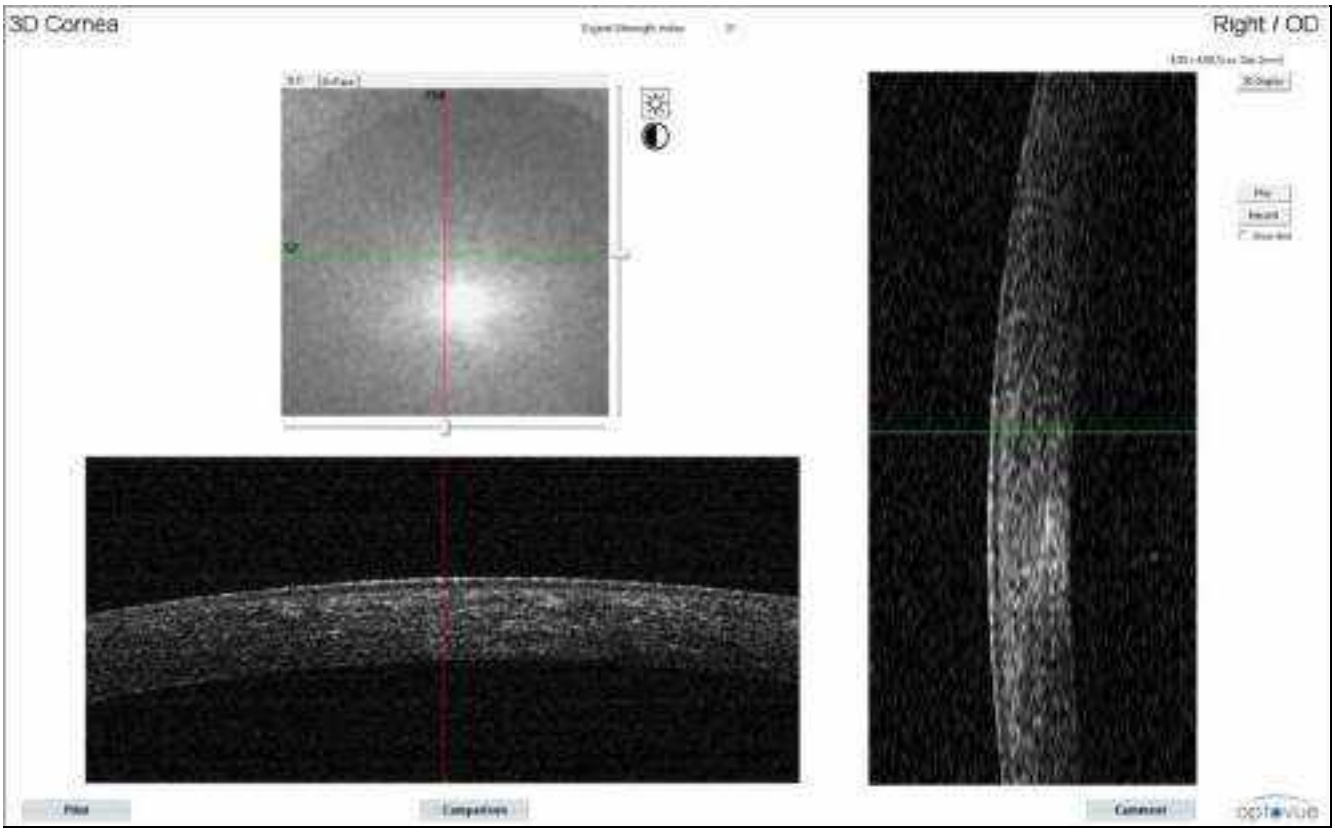


Figure 253 3D Cornea report

See the Avanti user manual for more information on the 3D scan presentations. The 3D Cornea presentation is similar to that for the retinal 3D presentations (without retinal features). Below is a sample presentation created by clicking on 3D Display.

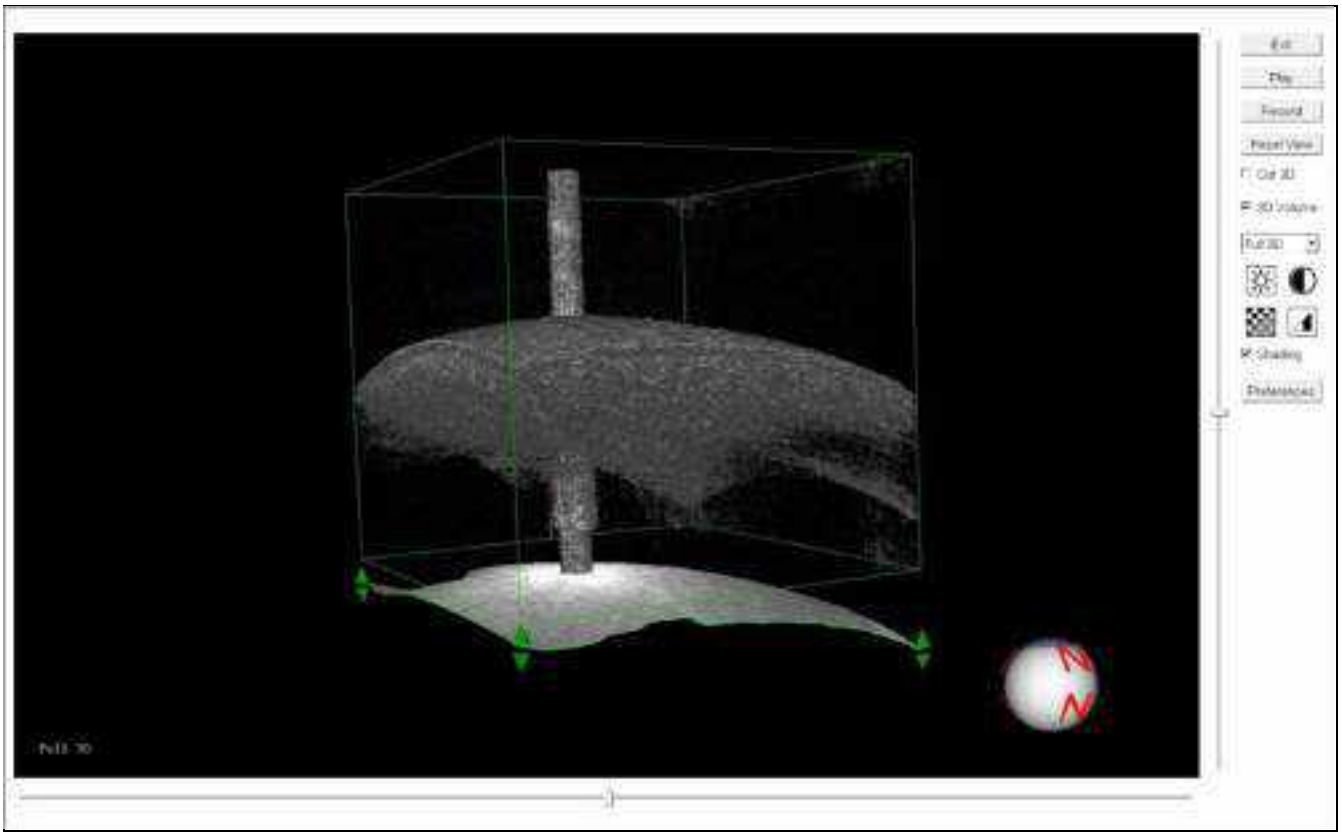


Figure 254 3D Cornea Volume presentation

18.7.10 Pachymetry

The pachymetry scan is a set of 8 radial meridians 6mm in length and centered on the pupil.

Figure 255 Illustration of Pachymetry scan pattern, 8 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 (6mm) 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).

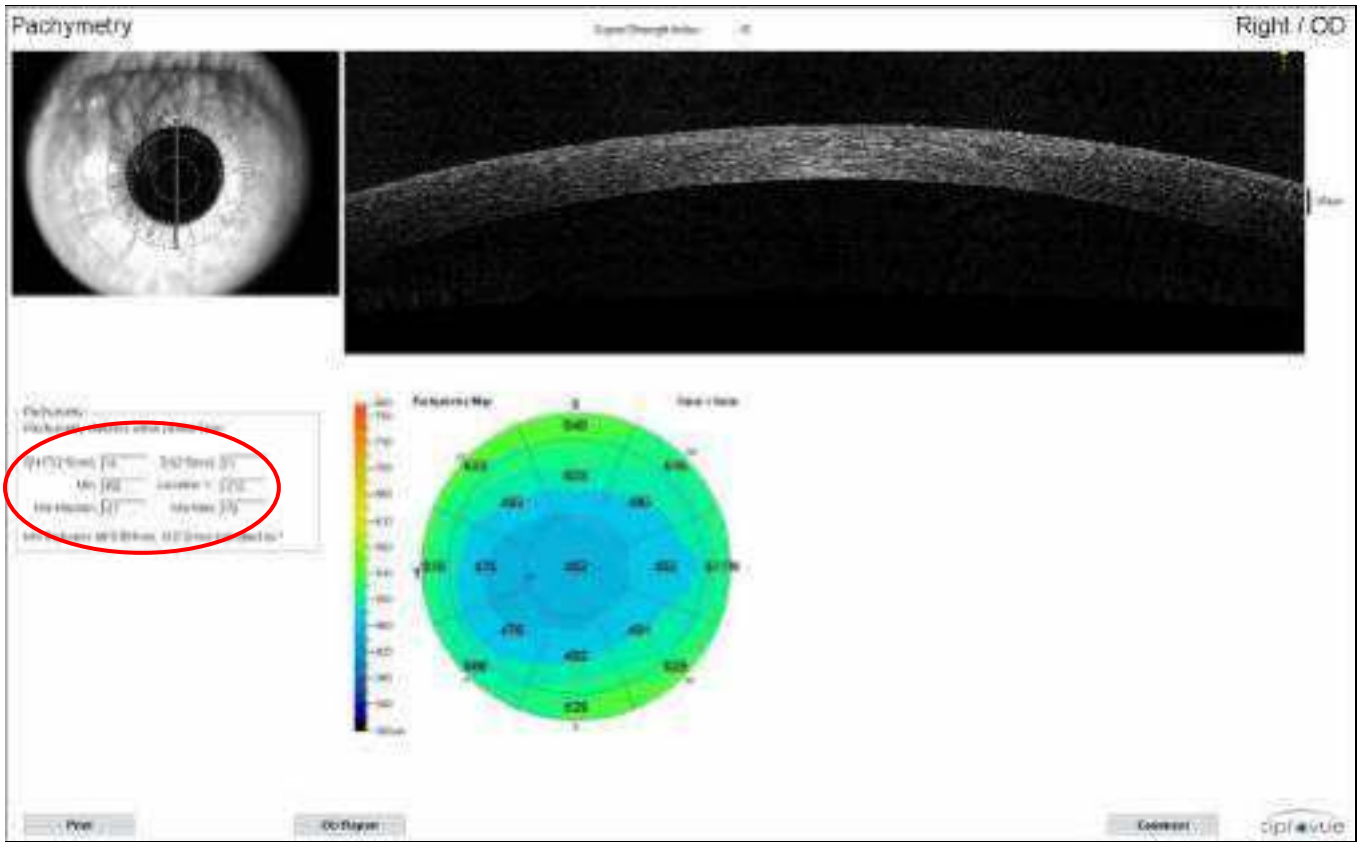


Figure 256 Pachymetry report

18.7.11 Pachymetry Assessment

The Pachymetry analysis provides some key thickness parameters in the table to the left of the Pachymetry report. The Epithelial map also has a normalized mode to highlight thickness variation.

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

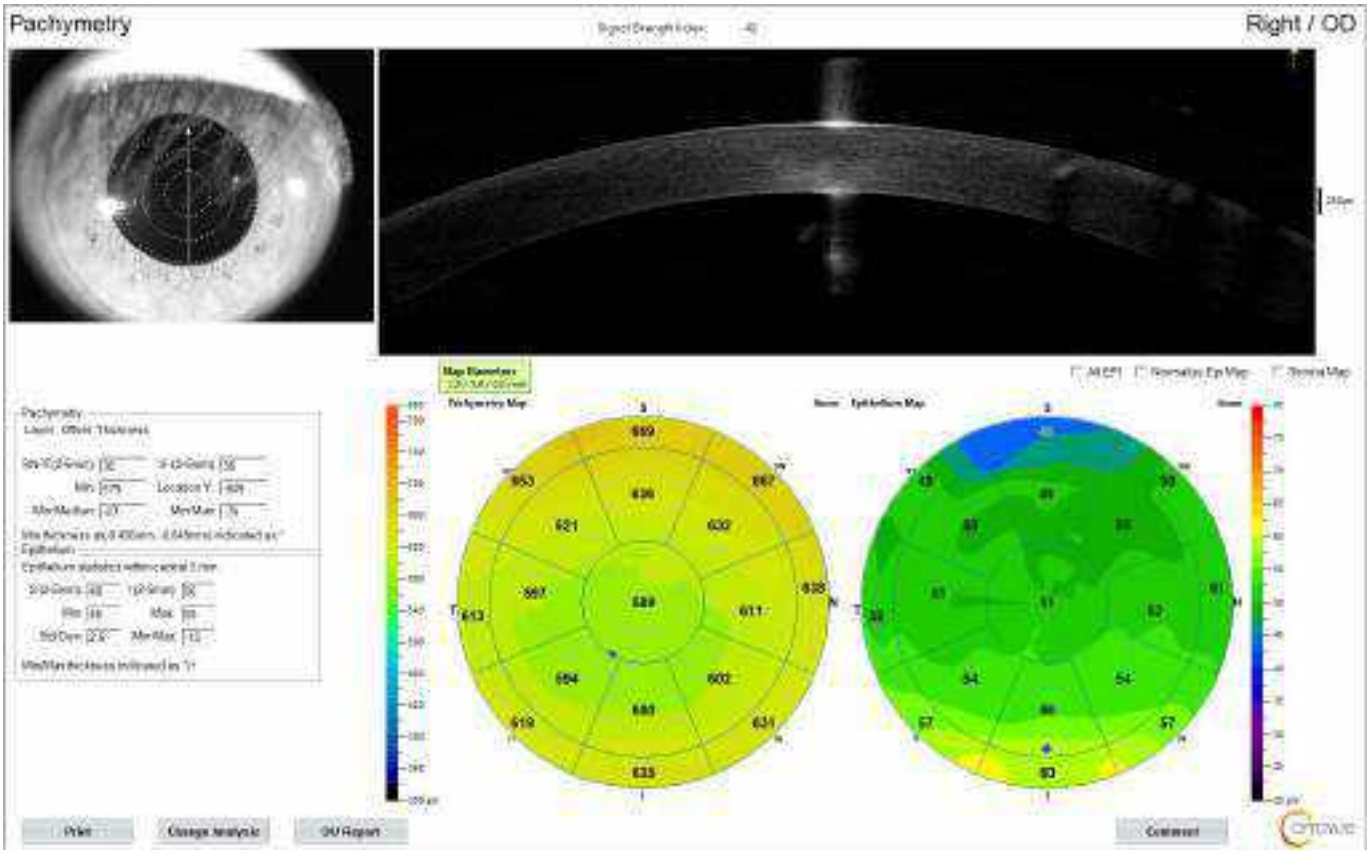


Figure 257 Pachymetry report with epithelial thickness/Stroma map

18.7.12 Symmetry and Change Analysis

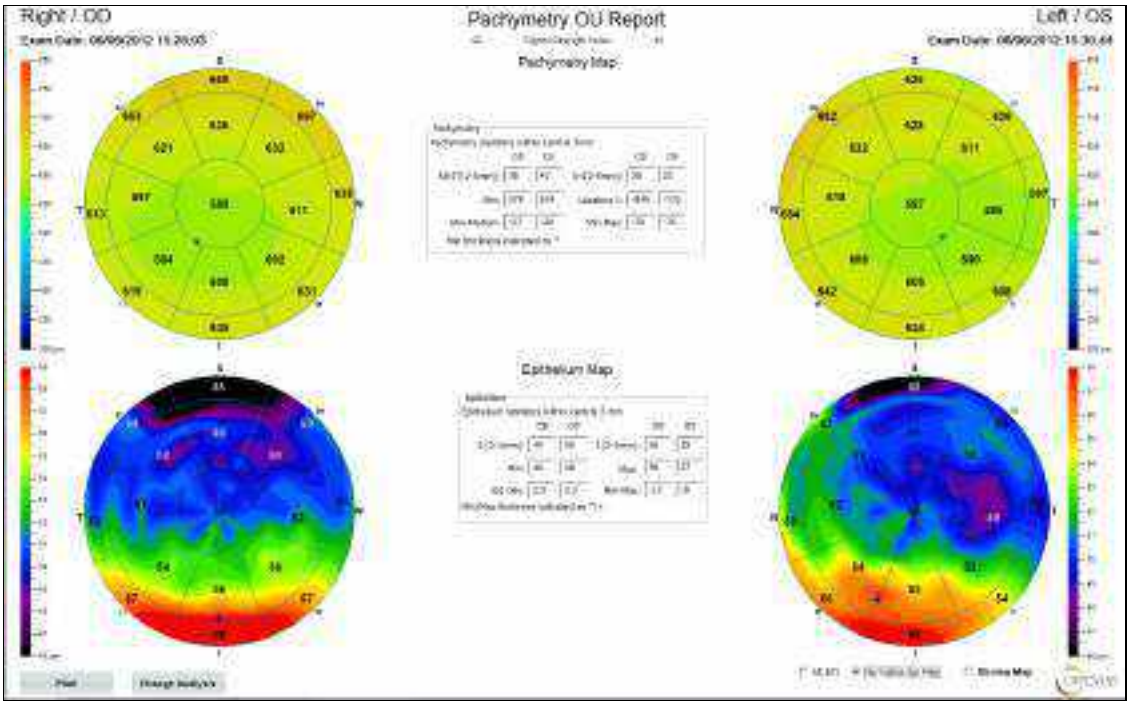


Figure 258 Symmetry Analysis for Pachymetry Results (Normalized)

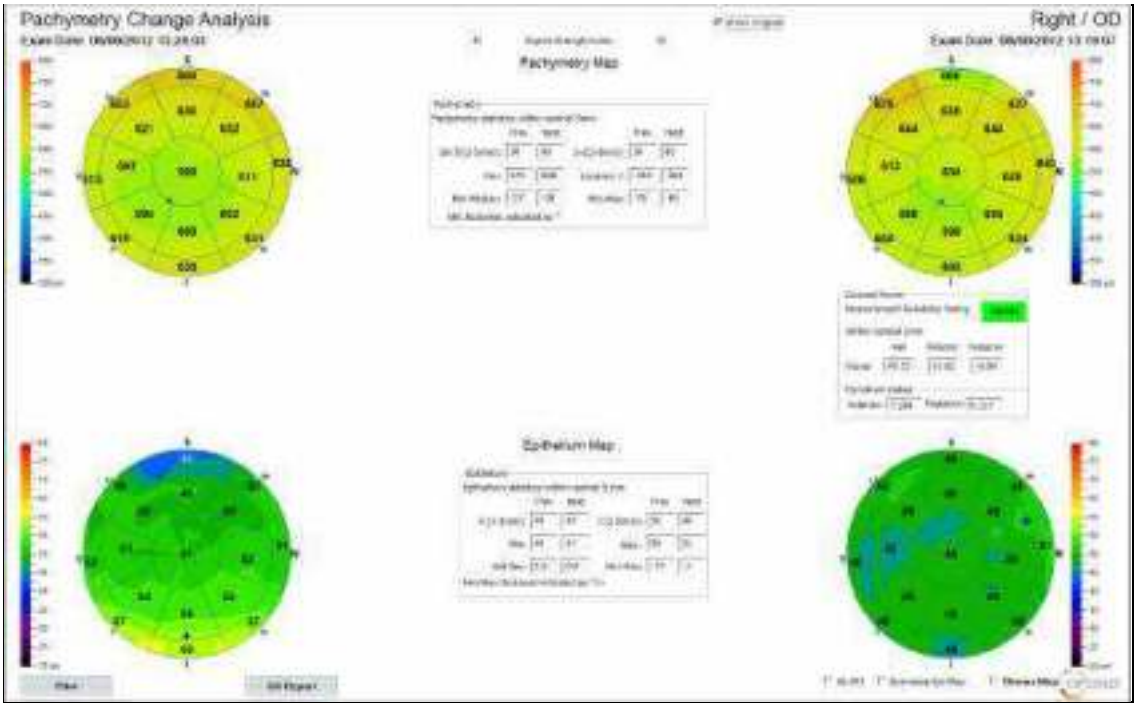


Figure 259 Change Analysis Results for Pachymetry, Cornea Power and Epithelial/Stroma Map

18.7.13 Wide Field Pachymetry (9mm)

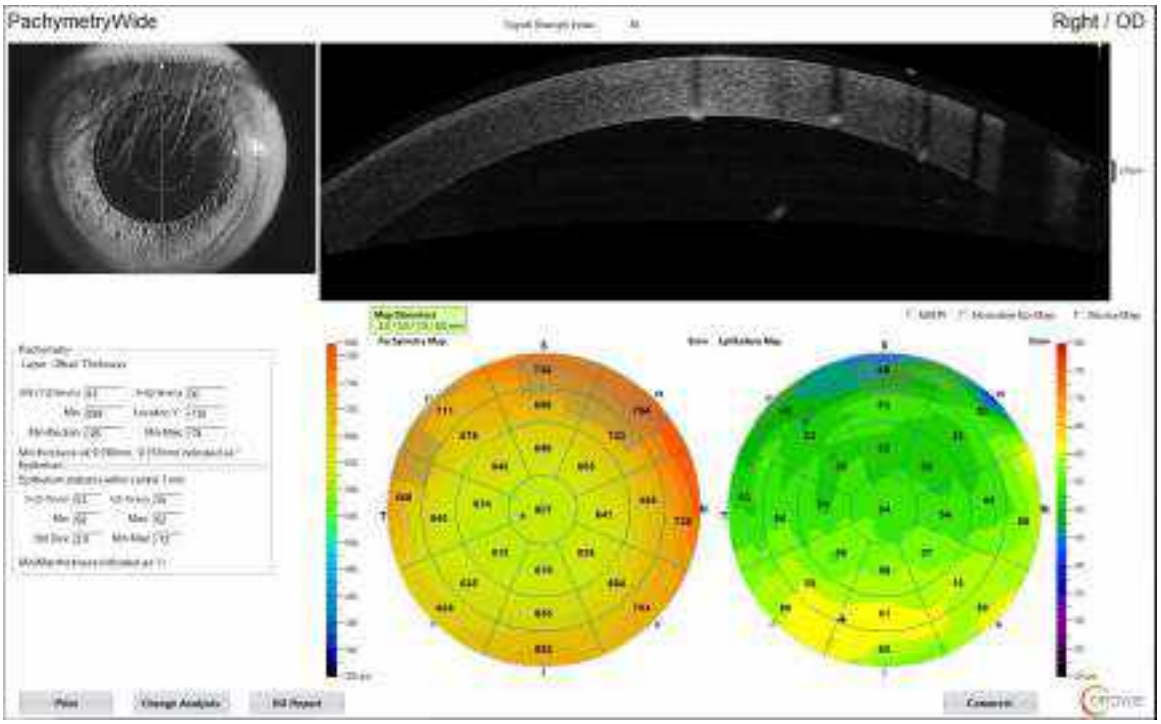


Figure 260 9mm Widefield Pachymetry with Epithelial/Stroma thickness

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

The Epithelial scale can be displayed with the locked scale 35-65 microns or for more enhanced visualization with a normalized scale.

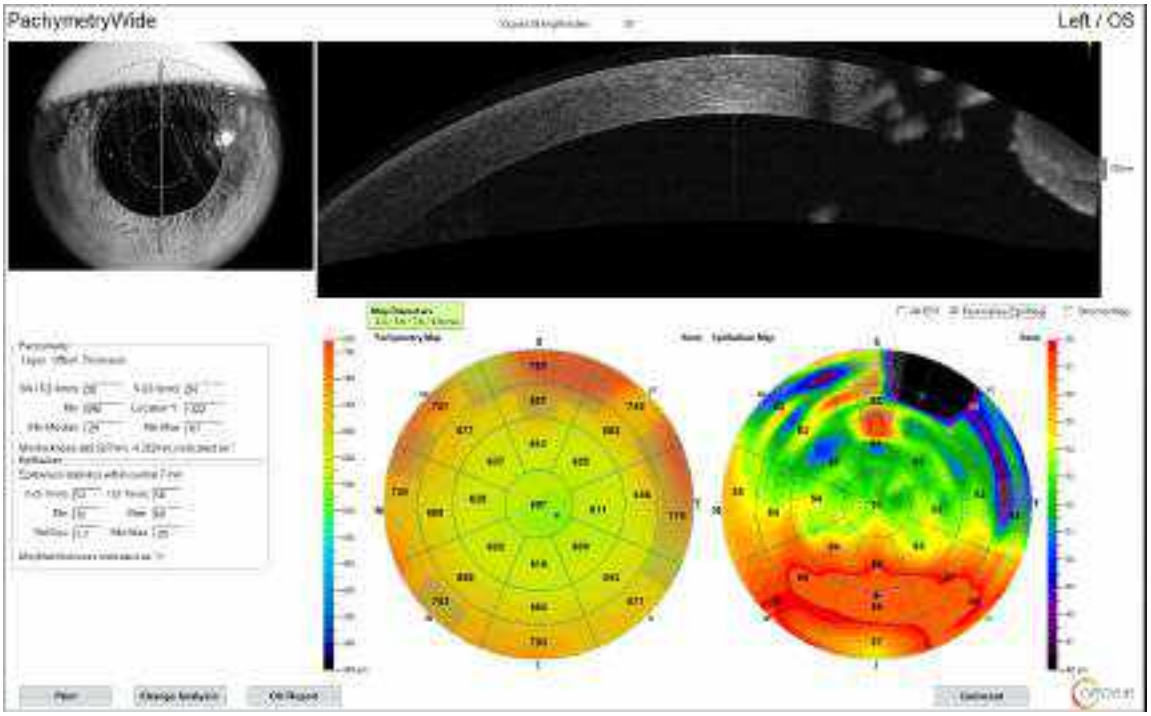


Figure 261 Widefiled Pachymetry with normalized Epithelial scale

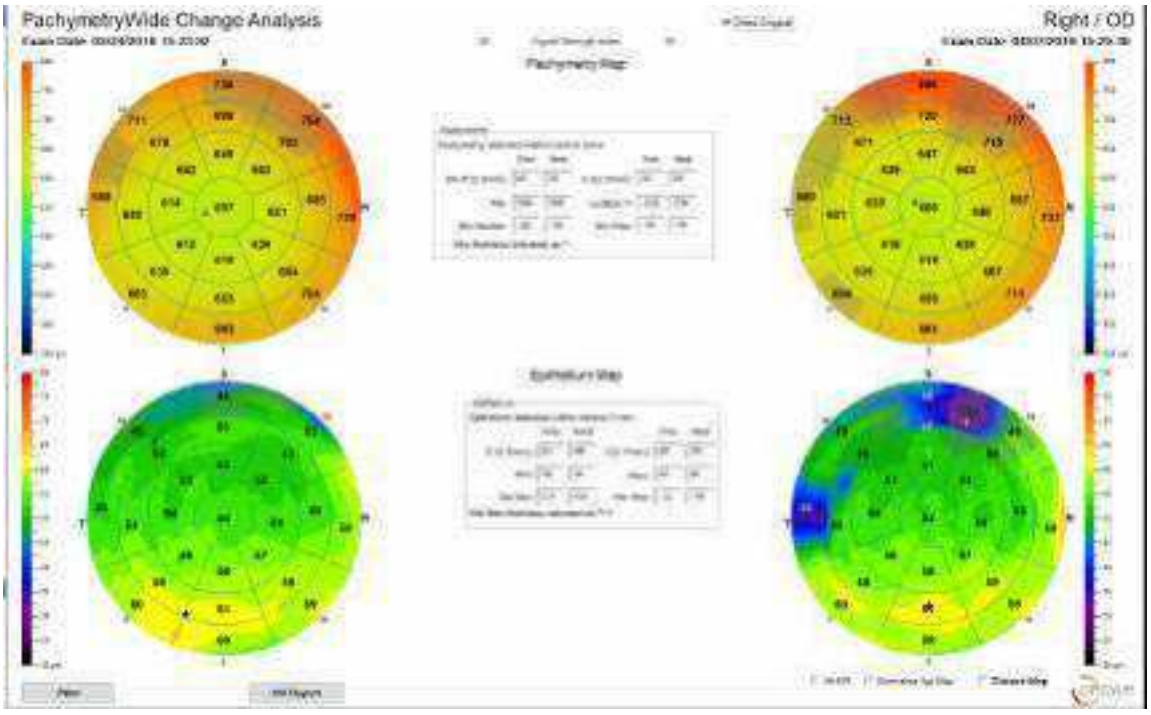


Figure 262 Widefield Pachymetry Change Analysis

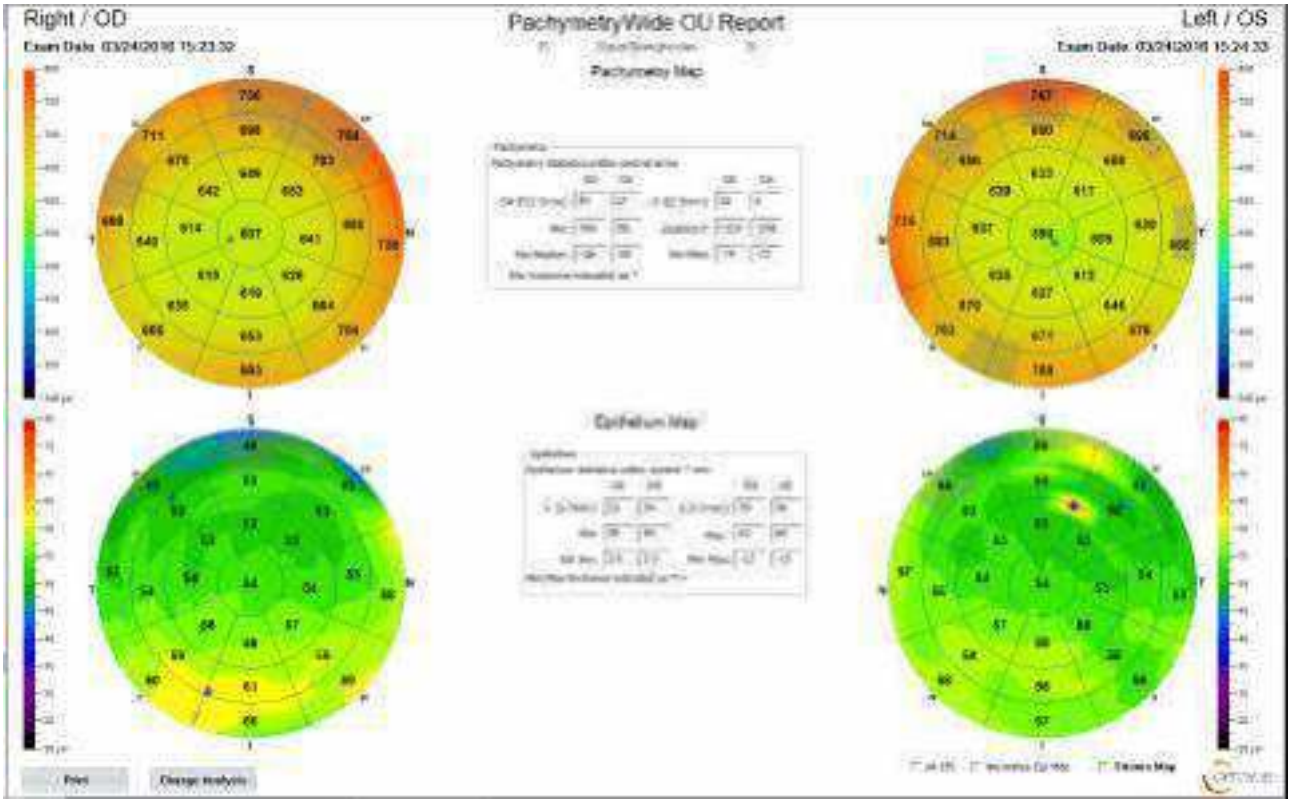


Figure 263 Widefield Pachymetry OU report with Epithelial/Stroma maps

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

18.7.14 Corneal Power

The Corneal Power feature is available to customers who have purchased the Corneal Power upgrade. For information on how to install and validate the cornea power tool, refer to the installation manual.

The Net Corneal Power value determined by the TCP function is NOT INTERCHANGEABLE with the corneal power value determined by any other device. The Net Corneal Power determined by the TCP function of the CAM option for Avanti is not intended to be used in lieu of, or replace a value from another device into your standard IOL calculation formula.

18.7.15 Summary Description

Corneal power is one of the key input parameters for IOL power calculation in cataract surgery. In clinical practice, corneal power is commonly measured by manual or automated keratometry or by simulated keratometry (Sim-K) from Placido-ring corneal topographers. Corneal power provided by keratometry or topography is based on measuring the anterior surface curvature of the cornea and assuming a fixed ratio of 0.883 between posterior and anterior curvature to compute the total corneal power.[3] Corneal power measurement with keratometer or topographer works well enough in normal eyes, but the assumption of fixed ratio between anterior and posterior curvature could lead to erroneous corneal power assessment in eyes with corneal pathology or eyes with prior refractive surgery for obvious reasons.[1,2,3] Therefore, direct measurement of both anterior and posterior corneal curvatures to assess corneal refractive power as implemented in XR CAM could be advantageous.

The XR CAM net corneal power is not clinically interchangeable with keratometric corneal power measurements or Pentacam net corneal power measurement for IOL Power calculation. In other words, the XR CAM corneal power measurements cannot be directly applied in existing IOL power formulas developed based on measurements provided by other devices, such as keratometer or Pentacam

XR corneal power scan is performed with CAM adaptor and with the “Pachymetry” scan protocol which consists of 5 sets of pachymetry scan. Each set of pachymetry scan consists of 8 evenly spaced meridian scans (6 mm in length each) centered on the pupil.

The corneal curvature radii are derived based on best fit sphere to the central 3 mm for anterior and posterior surfaces. The anterior and posterior corneal power is calculated based on refractive indices of 1.376 for the cornea and 1.336 for the aqueous. The net corneal power is calculated using a thick lens formula based on anterior corneal power, posterior corneal power, taking into account the central thickness of the cornea.

18.7.16 Summary Report

The results of the Corneal Power scan provides Net, Anterior, and Posterior power measurements, representing the net corneal power, anterior corneal power, and posterior corneal power respectively, in measurement unit of diopter (D). The radius of curvature measurements are also provided, in measurement unit of mm. A measurement reliability index for the corneal power measurement is also provided on the analysis report. Selecting the “Stroma map” will cause the stroma map to replace the epithelial thickness map

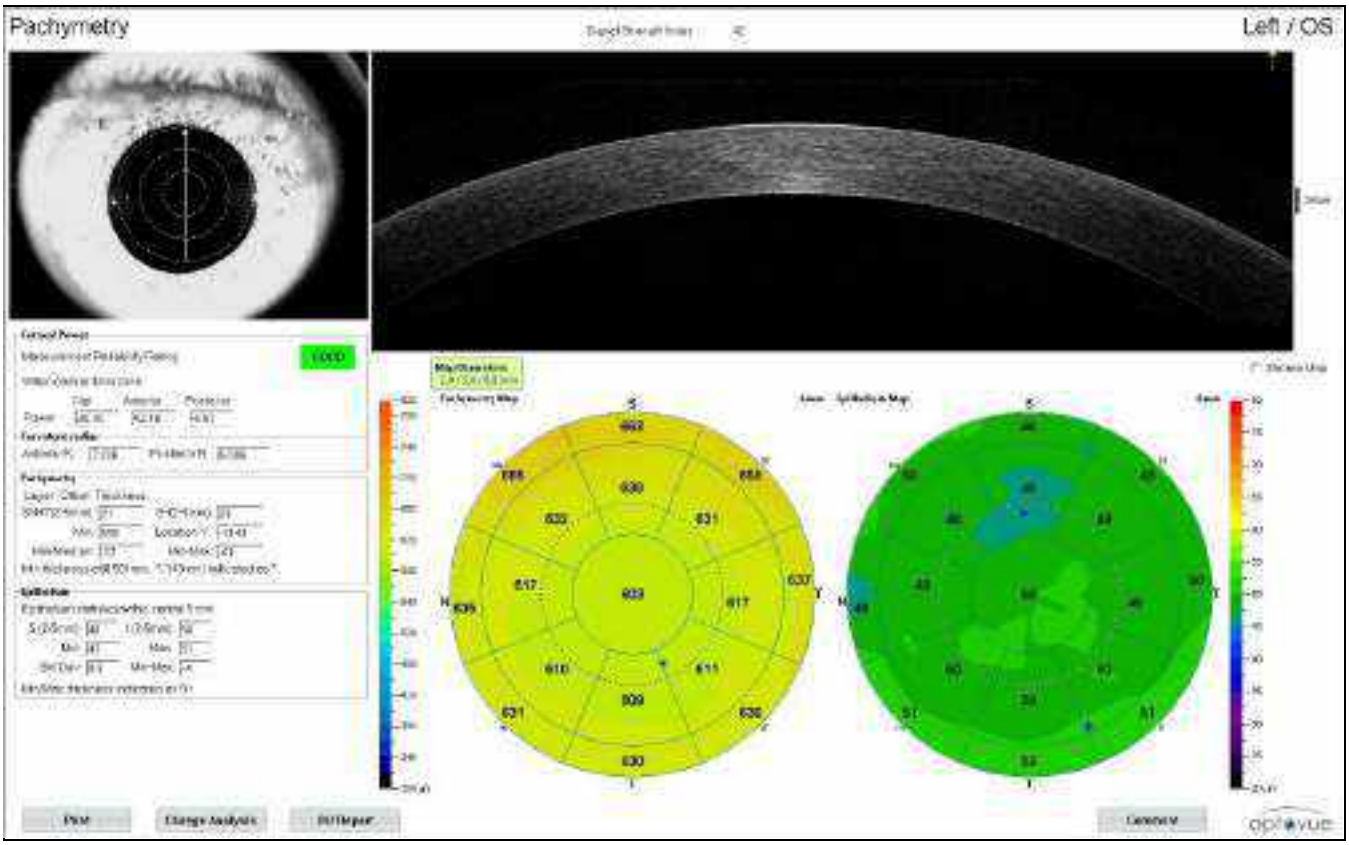


Figure 264 Pachymetry report with Corneal power values

When acquiring Corneal Power scan, the following steps should be observed.

1. Patient must be instructed to fixate on the center of light-blue internal fixation target with the test eye.
2. Operator should center the scan on the pupil. If the misalignment exceeds 1 mm (pupil center exceeds the boundary of the smallest concentric circle on the screen), the scan should be excluded.
3. Operator should set the working distance properly by placing the corneal cross-sectional images within the range defined by the two horizontal red lines to avoid image cropping.

4. Operator should make sure that the lids of the eye are not blocking or shadowing a significant portion of the image in vertical meridians.
5. Operator should observe the measurement reliability index status on the report screen. A measurement with poor measurement reliability indicates increased risk of measurement variability. Measurements with poor reliability should be replaced if possible.
6. Corneal power measurements are not displayed for poor quality scans in which an algorithm failed. In this case, the scan should be repeated.

Correct patient fixation and alignment centered on pupil are both critical to produce consistent corneal power measurement.

Examples of corneal power scan quality problems to watch for are provided in Appendix A

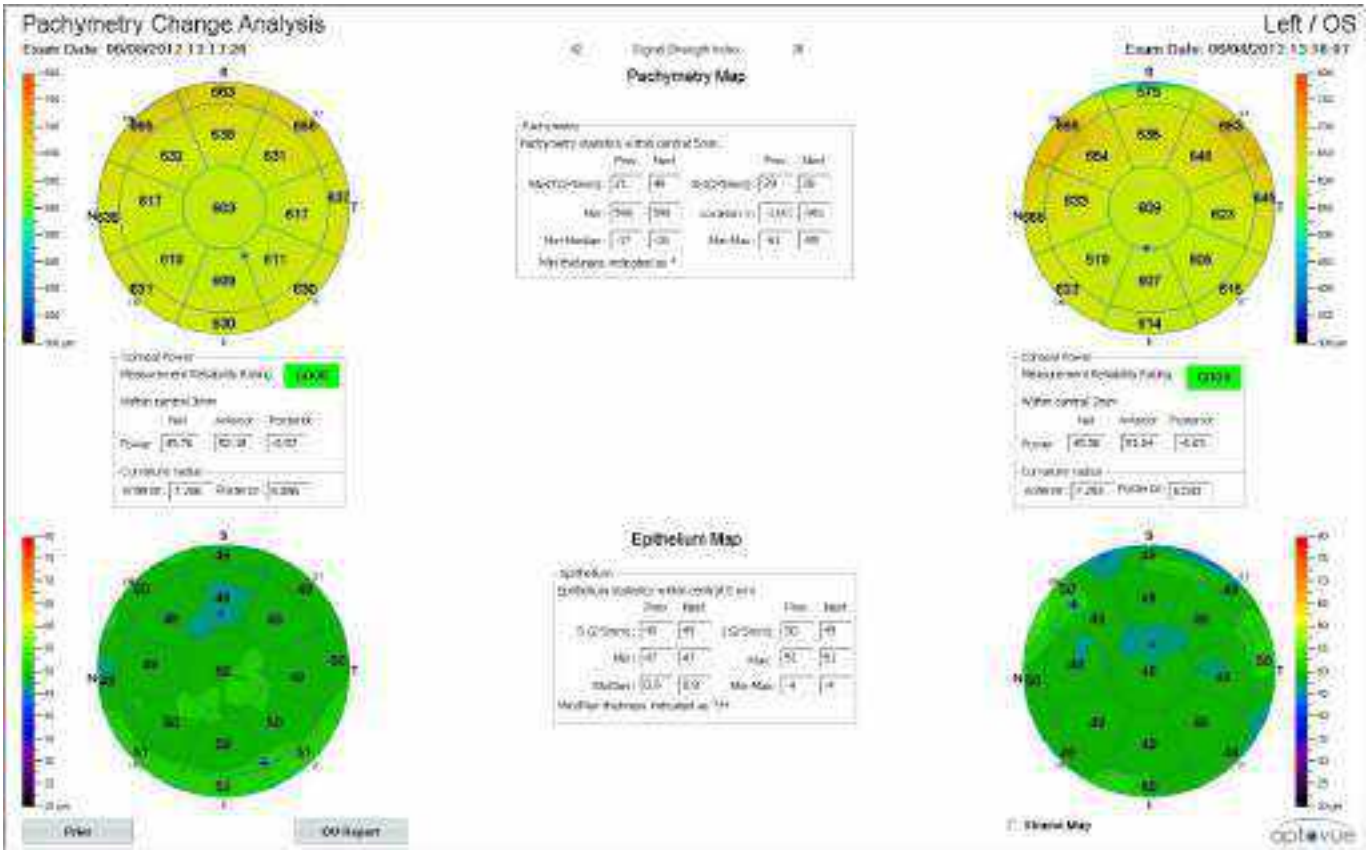


Figure 265 Pachymetry & Epithelial change analysis with Corneal Power values

18.7.17 Repeatability

The repeatability (standard deviation) of the corneal power scan with XR CAM is summarized in the table below. The repeatability of corneal power parameters is better

than 0.25D for a single scan in the normal eye and the post-laser refractive surgery eyes. For clinical use, it is recommended that a user takes at least three corneal power scans and calculate mean corneal power to further reduce measurement variability.

	Normal	Post-Laser Refractive Surgery	Pathological or Post-Incisional Surgery
Net Corneal Power (D)	0.21	0.17	0.35
Anterior Corneal Power (n=1.3375) (D)	0.20	0.16	0.39
Posterior Corneal Power (D)	0.05	0.05	0.16
Anterior Radius of Curvature (mm)	0.034	0.030	0.064
Posterior Radius of Curvature (mm)	0.050	0.048	0.172
Central Corneal Thickness (µm)	2.1	1.9	3.8
Thinnest Corneal Thickness (µm)	3.8	1.3	18.0

Figure 266 repeatability (standard deviation) of the corneal power scan

18.7.18 Validation

To ensure system stability overtime, the corneal power software automatically prompts for a weekly validation test. The validation test is performed with the corneal power validation tool stored with the instrument. The result of the validation test is compared with the stored value obtained during the initial corneal power calibration to verify system stability. The limit of acceptable difference is ±0.25D; if exceeded, the software will not allow acquisition of corneal power scan. A warning message is displayed on screen with instructions for further actions. See section 18.12 A for instructions to perform the Validation Test.

If the weekly validation test is not performed on schedule, the corneal power feature will be automatically disabled and only pachymetry measurement will be produced. To reactivate corneal power measurement, select the validation test and perform the test according to instruction.

18.7.19 References:

1. Seitz B, Langenbucher A, Nguyen NX, Kus MM, Ku¨chle M. Underestimation of intraocular lens power for cataract surgery after myopic photorefractive keratectomy. Ophthalmology 1999; 106:6936–702.
2. Wang L, Hill WE, Koch DD. Evaluation of intraocular lens power prediction methods using the American Society of Cataract and Refractive Surgeons Post-Keratorefractive Intraocular Lens Power Calculator. J Cataract Refract Surg 2010; 36:1466–1473.

3. Tang M, Li Y, Avila M, Huang D. Measuring total corneal power before and after laser in situ keratomileusis with high-speed optical coherence tomography. J Cataract Refract Surg. 2006; 32:1843-50.

18.7.20 Epithelium Thickness Mapping

The Epithelium Thickness Mapping feature is available to customers who have purchased the Epithelium Thickness Mapping upgrade, USA 9mm ETM and international 6mm & 9mm ETM are available..

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

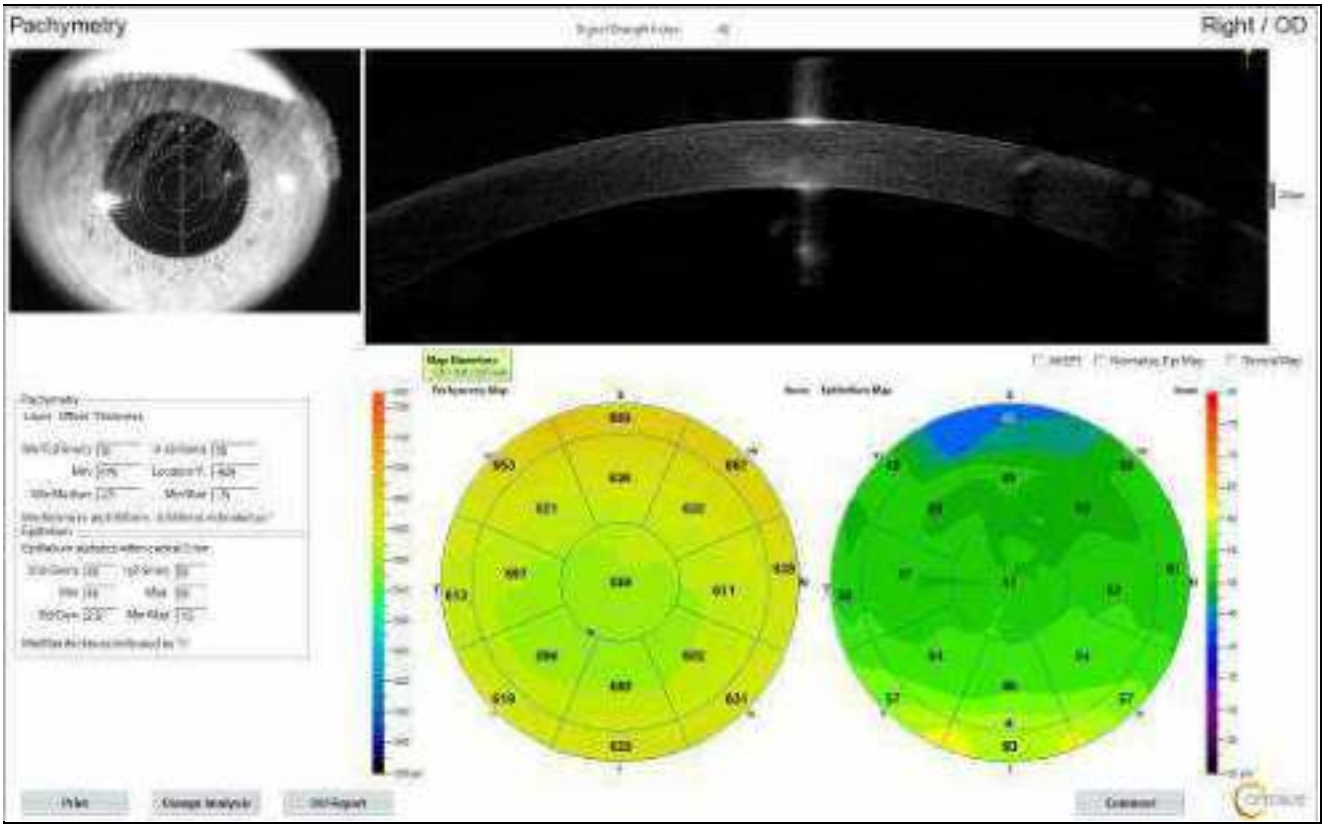


Figure 267 Pachymetry report displaying Epithelial thickness map

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.

Symmetry Analysis

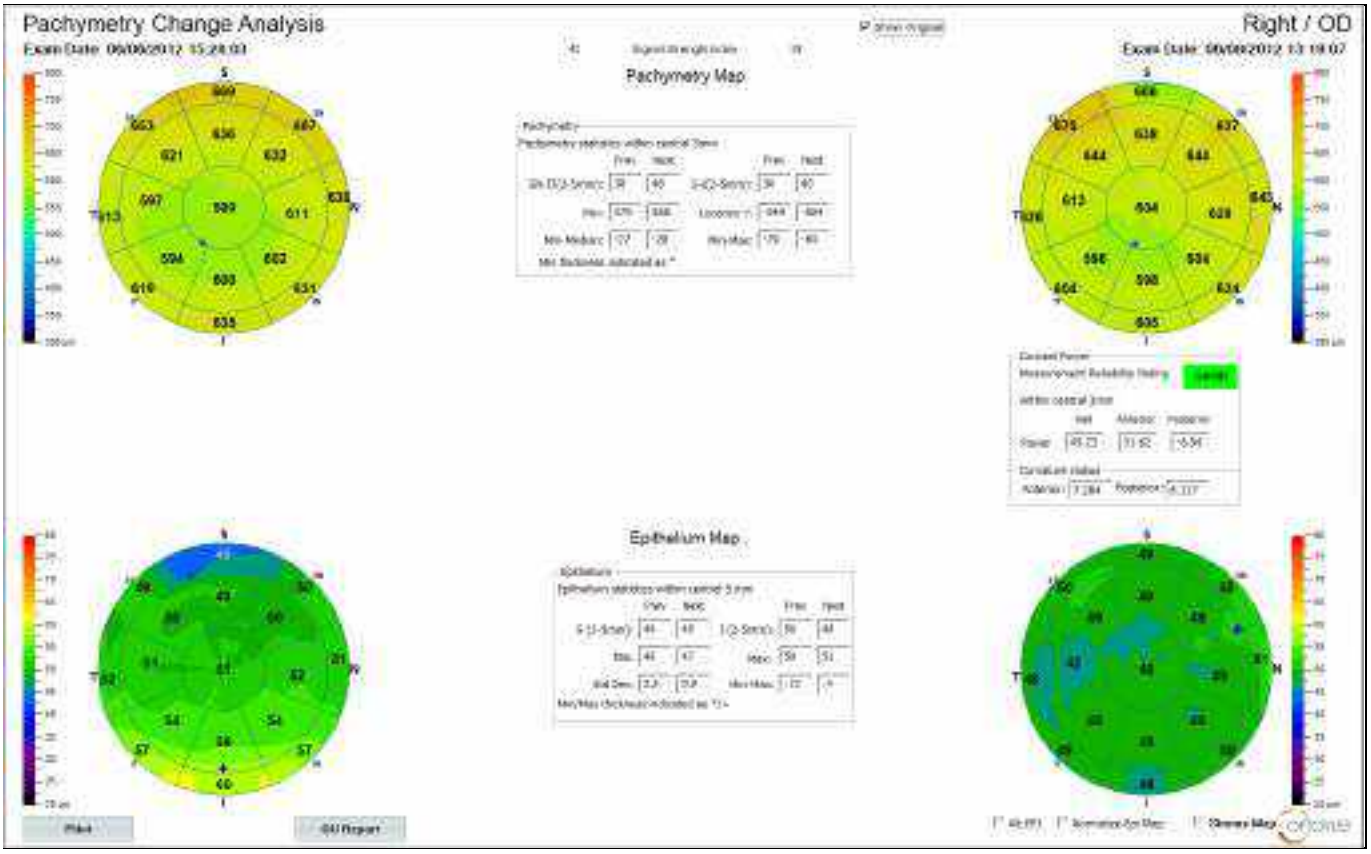


Figure 268 Pachymetry Change Analysis with Epithelial Thickness/Stroma and Corneal Power

OU Report

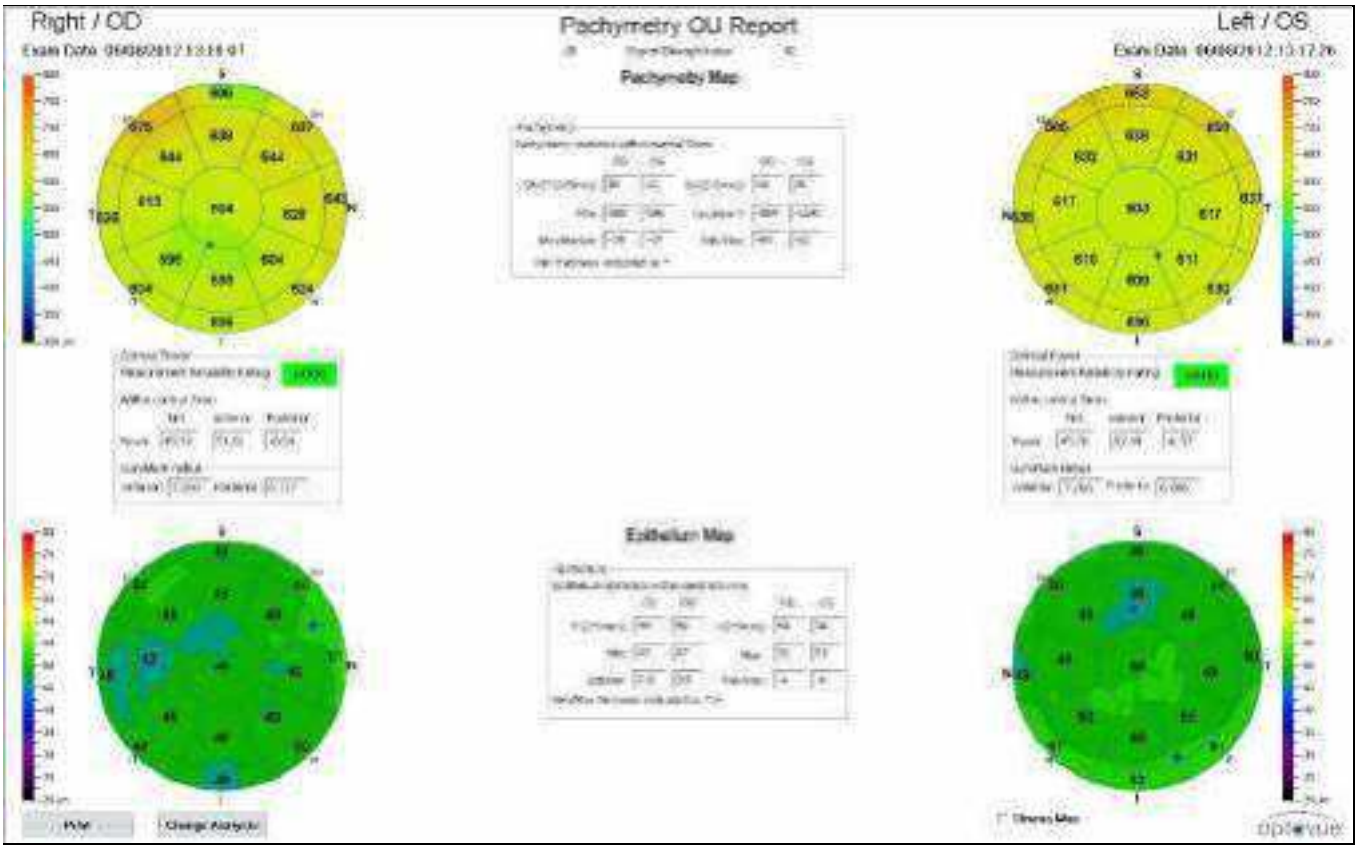


Figure 269 Pachymetry OU Report With Epithelial Mapping/Stroma and Corneal Power

_____End of section_____

18.8 File Management Menu

Refer to the XR manual for this section.

_____End of section_____

18.9 Maintenance and Troubleshooting

Refer to the XR user manual for this entire section plus additional CAM lens care.

Cleaning the Corneal Power Validation Tool

1. Keep the CAM lenses and the Corneal Power Validation Tool in the wooden case provided when not in use.
2. Routinely check the lens for dust, fingerprints, or smudges.
3. Use the same cleaning method as is recommended in the XR User Manual to use to clean the front ocular lens of the XR.

_____End of section_____

18.10 Scan Pattern Specifications

See the table below for scan pattern specification information.

Scan Pattern Name	Description	# A-Scan (without averaging)	Adjustability	Default
Pachymetry	8 radial lines with 6mm scan length (1020 A-scans/line) and 22.5 degree interval. B scan 4 frame avg.	1020 x 8	Fixed	6mm radial scan
Pachymetry + Corneal Power	8 radial scans with 6mm scan length (1020 A-scans/line) and 22.5 degree interval. 5 repeated sets are taken.	1020 x 8 x 5 (due to 5 repeated sets)	Fixed	6mm radial scan
PachymetryWide	8 radial scans with 9mm scan length (1536 A-scans/line) and 22.5 degree interval. B scan 4 frame avg.	1536 x 8	Fixed	9 mm radial scan
Cornea Line	1020 A-scans/line with adjustable scan length	1020 x 1	Transverse: 2 -8 mm (0.5 mm increment) Angle: -90° - 90° (1° increment)	8mm, 0 degree
Cornea Cross Line	Two scan lines orthogonal to each other with adjustable scan length (1020 A-scans/line)	1020 x 2	Transverse: 2 -8 mm (0.5 mm increment) Angle: -90° - 90° (1° increment)	8mm, 0 degree
Angle	1 scan line with adjustable scan length (1020 A-scans/line)	1020 x 1	Transverse: 2 -6 mm (0.5 mm increment) Angle: -90°- 90° (1° increment)	3mm, 0 degree
3D Cornea	101 horizontal scan lines with 6mm scan length (513 A-scans/line) and 60 µm interval between each horizontal scan.	513 x 101	Transverse: 4mm - 6mm (1mm increment) Angle: fixed at 0°	6 mm

_____End of section_____

18.11 Technical Data

18.11.1 System Specifications

Performance Specifications Summary:

1. OCT Image Resolution: 5 µm (in tissue)
2. OCT Image Scan Rate: 70,000 A-Scan/Second
3. Scan Depth: Maximum of 2.3 mm
4. Scan Length (CAM-L): 2-8 mm
5. Cornea Image FOV: 12mm x 8mm

Cornea Imager:

- Monochrome CCD Camera: 811x 508 pixel 1/3” CCD Format
- NIR Illumination: 735nm LED

Patient Interface:

- Working distance:
    - CAM-L: 13 mm
- Motorized Chin-Rest adjustable range: 65mm
- Joystick controlled X-Y-Z adjustment: X-100m, Y-85mm, Z-25mm
- Lock-mechanism: Manual

Measurement Features:

Cornea Analysis:

- CAM-L:
    a. Pachymetry map
        i. Cornea thickness map
        ii. Flap/Stroma thickness Measurement
        iii. Pachymetry Assessment
        iv. Corneal Power Assessment
    b. Line: Flap/Stroma, Distance/Area measurement
    c. Cross line : Flap/Stroma, Distance, Area measurement

d. Angle Scan (3mm scan length, 2.3mm depth)
    i. AOD 500/750 measurement
    ii. TISA 500/750 measurement
    iii. Angle in degrees

_____End of section_____

18.12 Corneal Power

Note: This feature is a license controlled revenue product and payment for the license is only in advance.

Follow the activation instructions provided with the license key in the document titled **Corneal Power License Key – Activation Instructions.**

18.12.1 Validating Corneal Power Calibration Tool

Corneal Power (Calibration) Validation

The Cornea Power scan must be re-calibrated every seven days. Clinical staff should be trained to perform the below calibration validation steps every 7 days. Before using the calibration tool, please make sure tool is clean. Refer to section 18.9 for steps to clean the calibration tool.

- Attach the CAM lens onto the Avanti machine and slip the calibration tool on the end of the lens until it stops. Tighten the white lock nut as shown in the figure below.

Figure 270 Mounting of Corneal power validation tool

- Select Test Patient
- Click **Examine** and select the Pachymetry scan. A warning window will pop-up as shown in the below image. Click the **Yes button**.

Figure 271 Validation message

- Start the scan.
- Check that the two images are between the red parallel lines. The two images are in the X and Y axis planes.

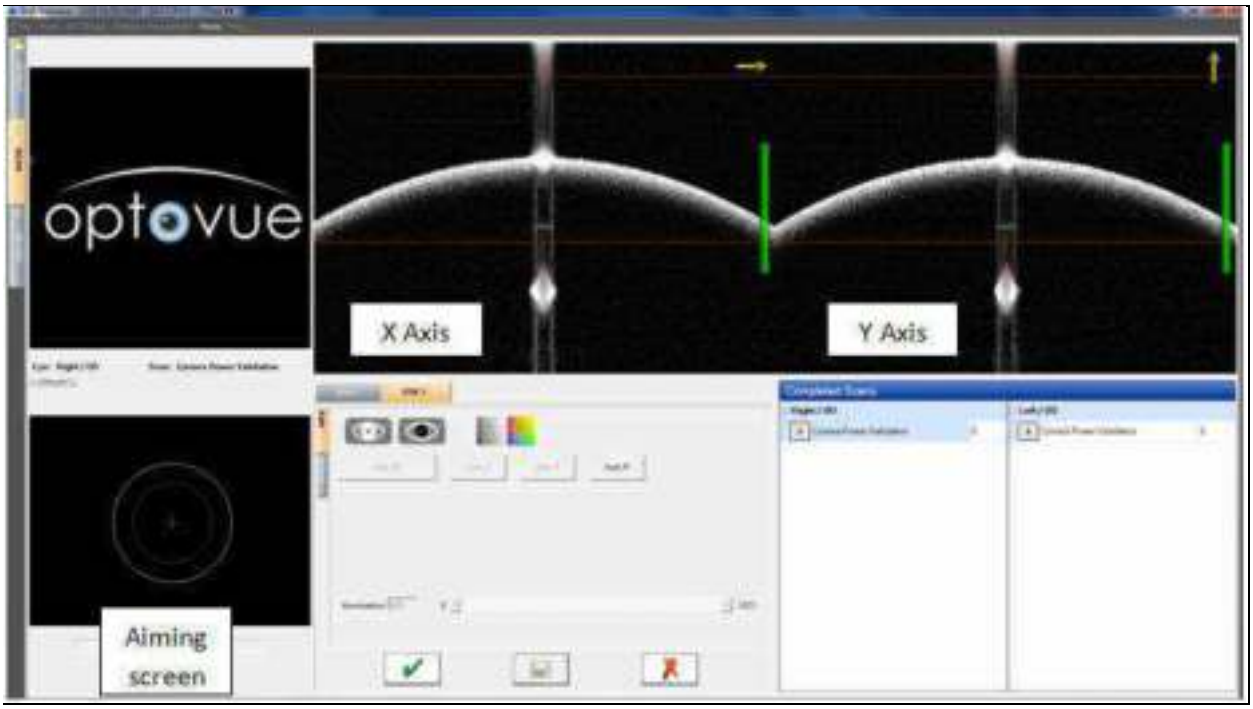


Figure 272 Validation screen

- Using the mouse, click and hold the target on the aiming screen and move the aim LEFT or RIGHT to get a wide reflection on the image and to align the center of the reflection to the center guideline on the X Axis plane.
- Using the mouse, click and hold the target on the aiming screen and move the aim UP or DOWN to get a wide reflection on the image and to align the center of the reflection to the center guideline on the Y Axis plane.

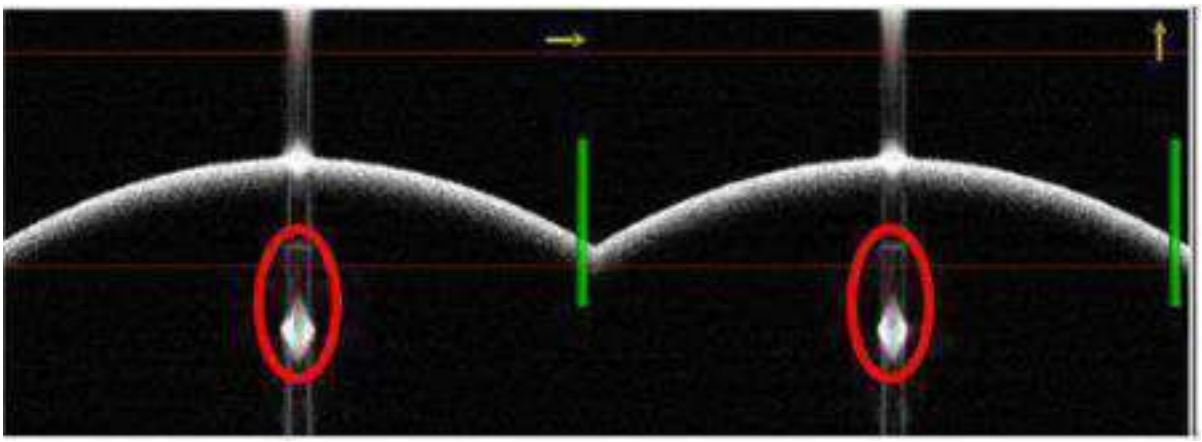


Figure 273 OCT Reflection signal

- Press Auto P to optimize the signal.
- Once the OCT reflection and red dotted line are aligned, click the green check mark, and save the scan. The machine will confirm calibration of cornea power.
- The device is now ready.

Note: The calibration procedure will need to be repeated every 7 days.

- If validation fails and error message similar to the one below appears, remove and clean the Validation tool.

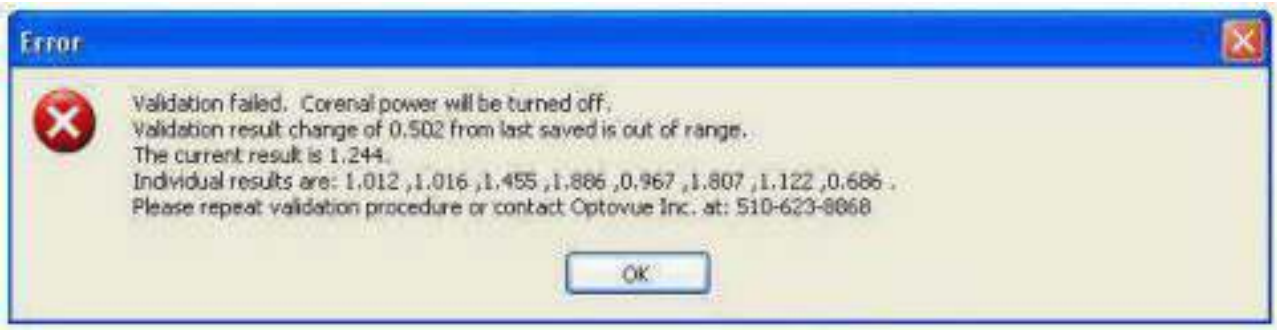


Figure 274 Validation failure message

- Re-install the Validation tool over the CAM lens until it stops, tighten the white lock screw and retry validation.
- If error message continues to appear when attempting the Validation, the TCP requires a re-installation. Contact your Optovue service department for assistance.

18.12.2 Corneal Power Scan and Calculations

The corneal power scan consists of 5 sets of pachymetry scans in rapid succession. Each set of pachymetry scan consists of 8 meridian scans of 6mm in length centered on the pupil.

As illustrated in the figure below, the anterior and posterior corneal curvature radii are calculated from 8 meridian corneal cross-sectional images based on the central 3 mm zone. The corneal anterior power (K_a) and posterior power (K_p) are calculated based on the anterior radius (R_a) and the posterior radius (R_p) as follow:

$$K_a = \frac{n_1 - n_0}{R_a}, \; K_p = \frac{n_2 - n_1}{R_p}$$

where n_0 = 1, n_1 = 1.376 and n_2 = 1.336.

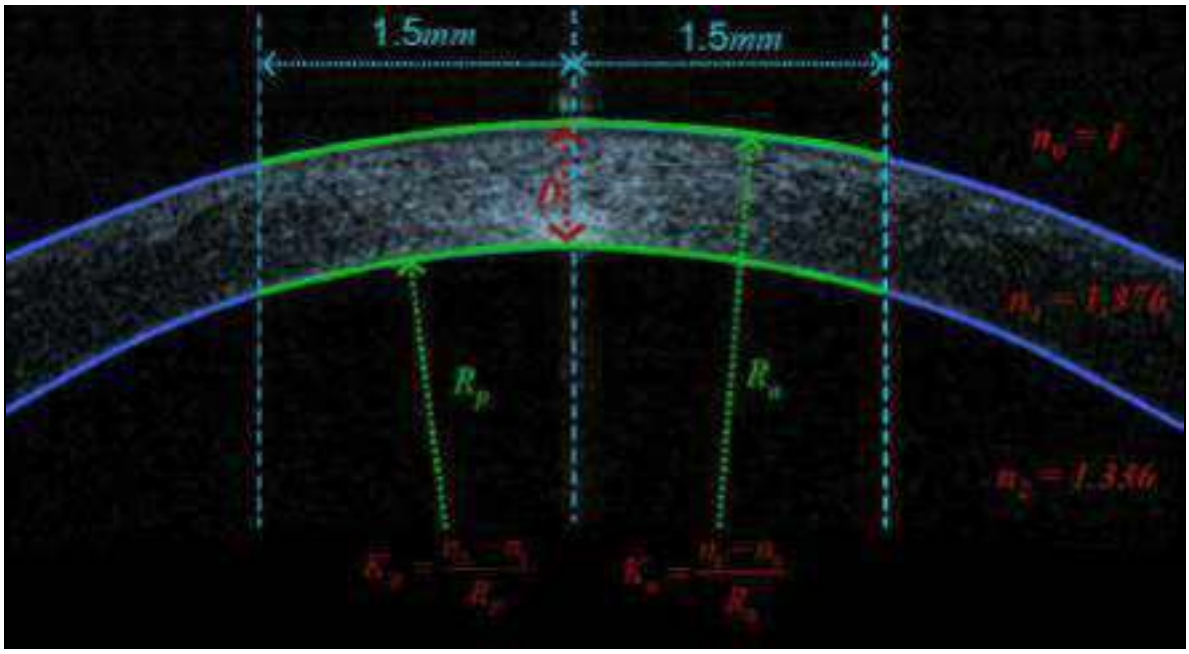


Figure 275 Curvature illustration

The net corneal power is computed using thick lens formula:

$$K = K_a + K_p - \frac{D}{n_1} * K_a * K_p$$

where D is the central corneal thickness.

18.12.3 Samples of Poor or Borderline Quality Corneal Power Scan

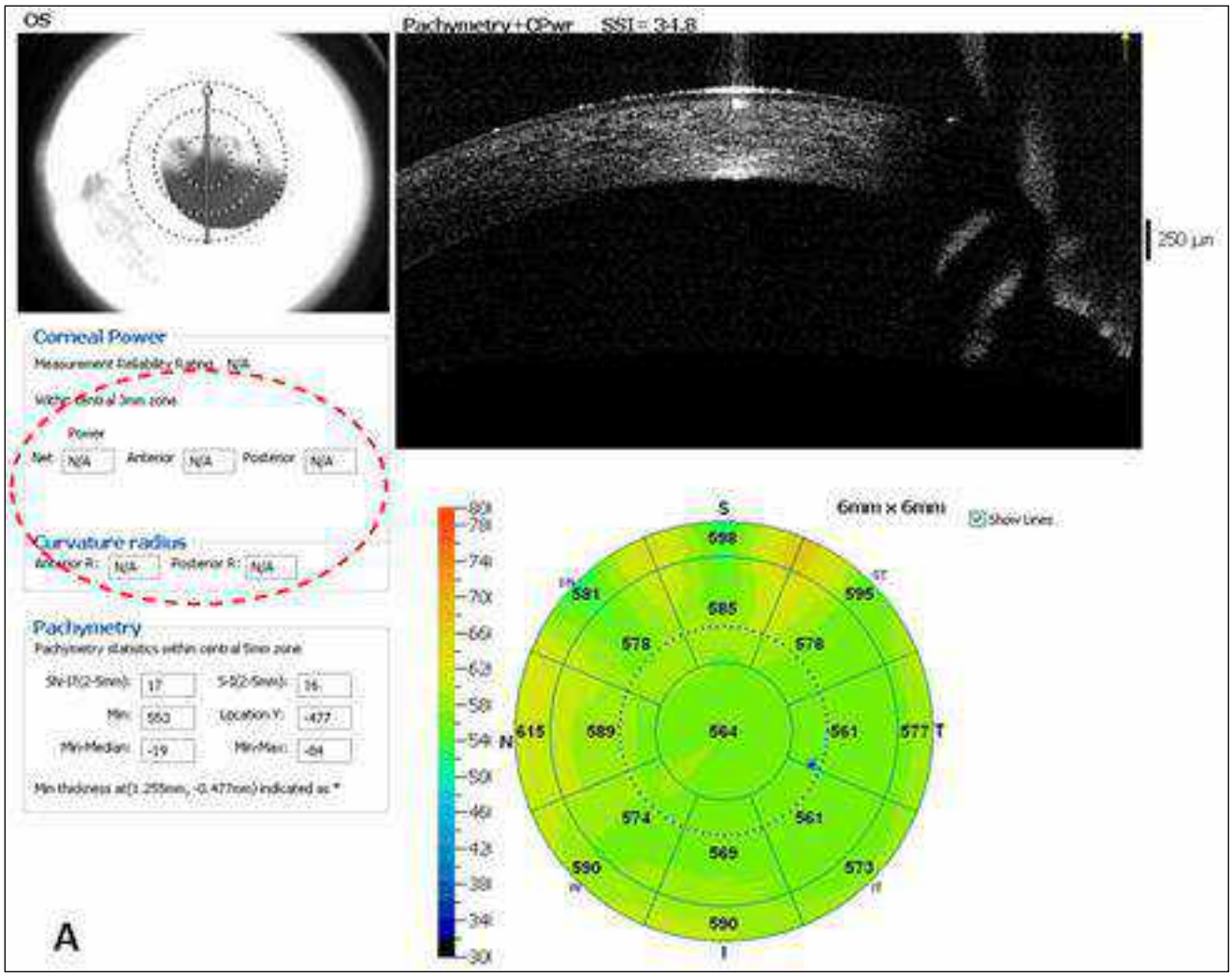


Figure 276 Invalid scan. No corneal power measurements are calculated

.

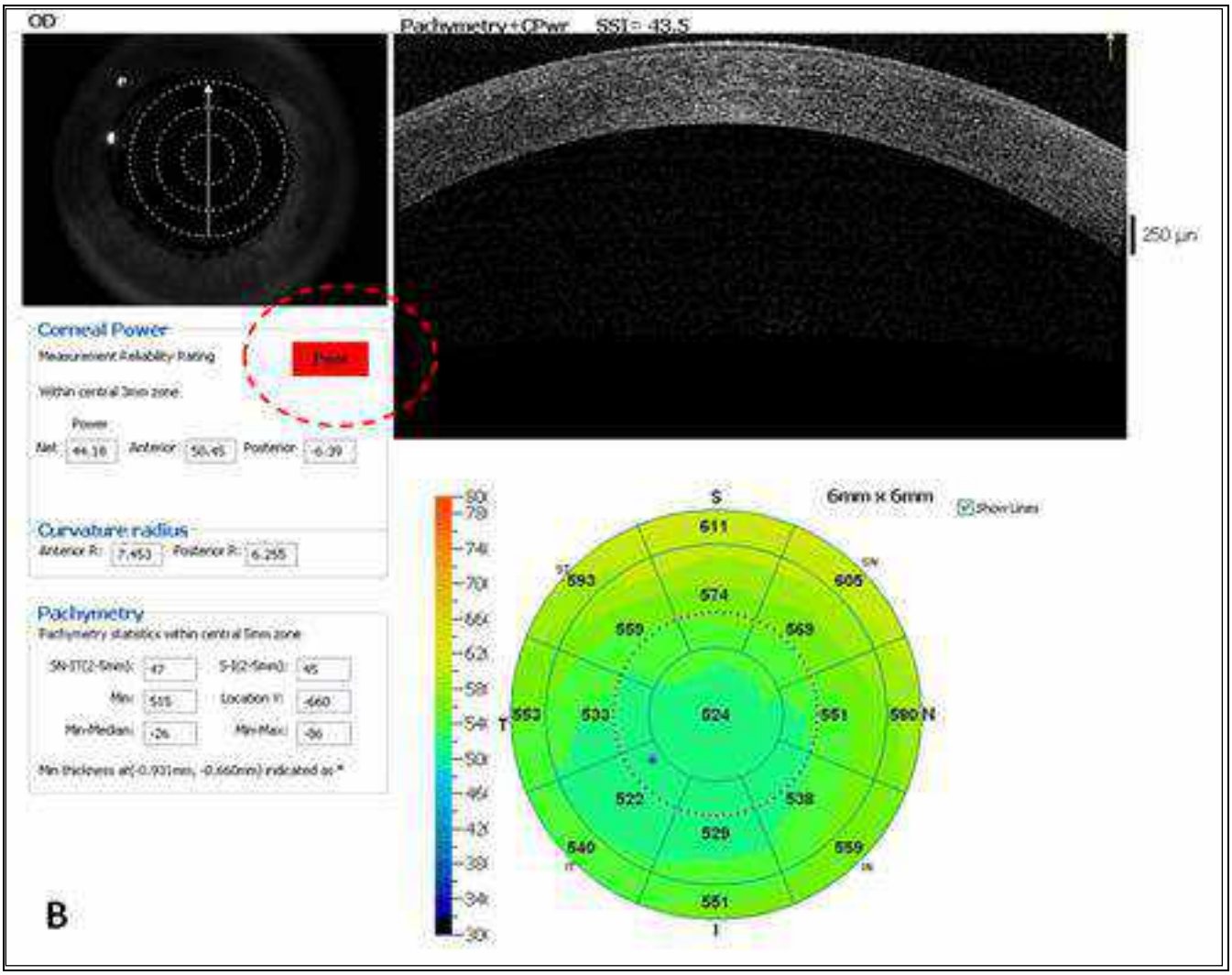


Figure 277 Poor reliability index.

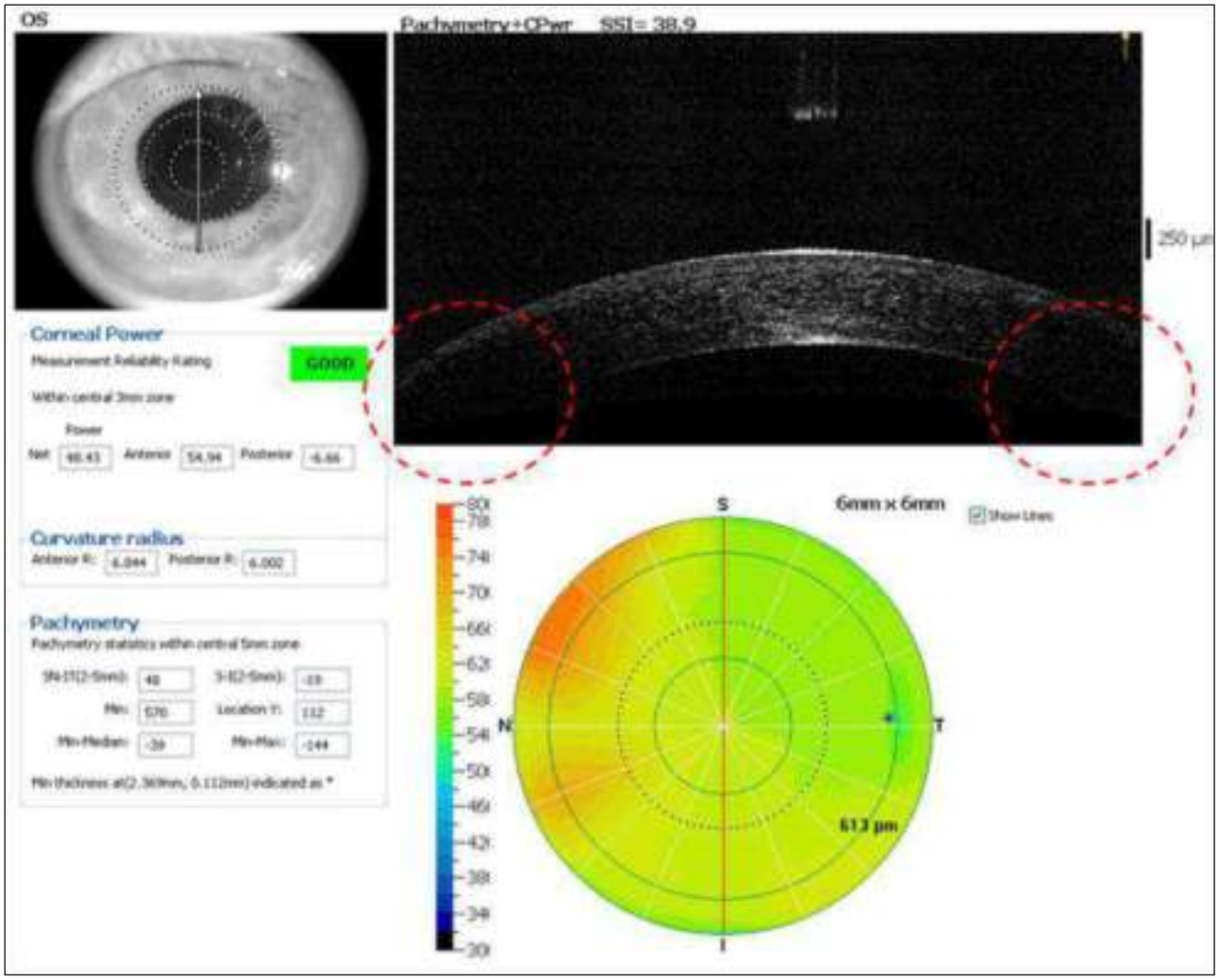


Figure 278 Scan out of range

Scan out of range, placed too low in the window that part of the corneal cross-sectional OCT image is cropped.

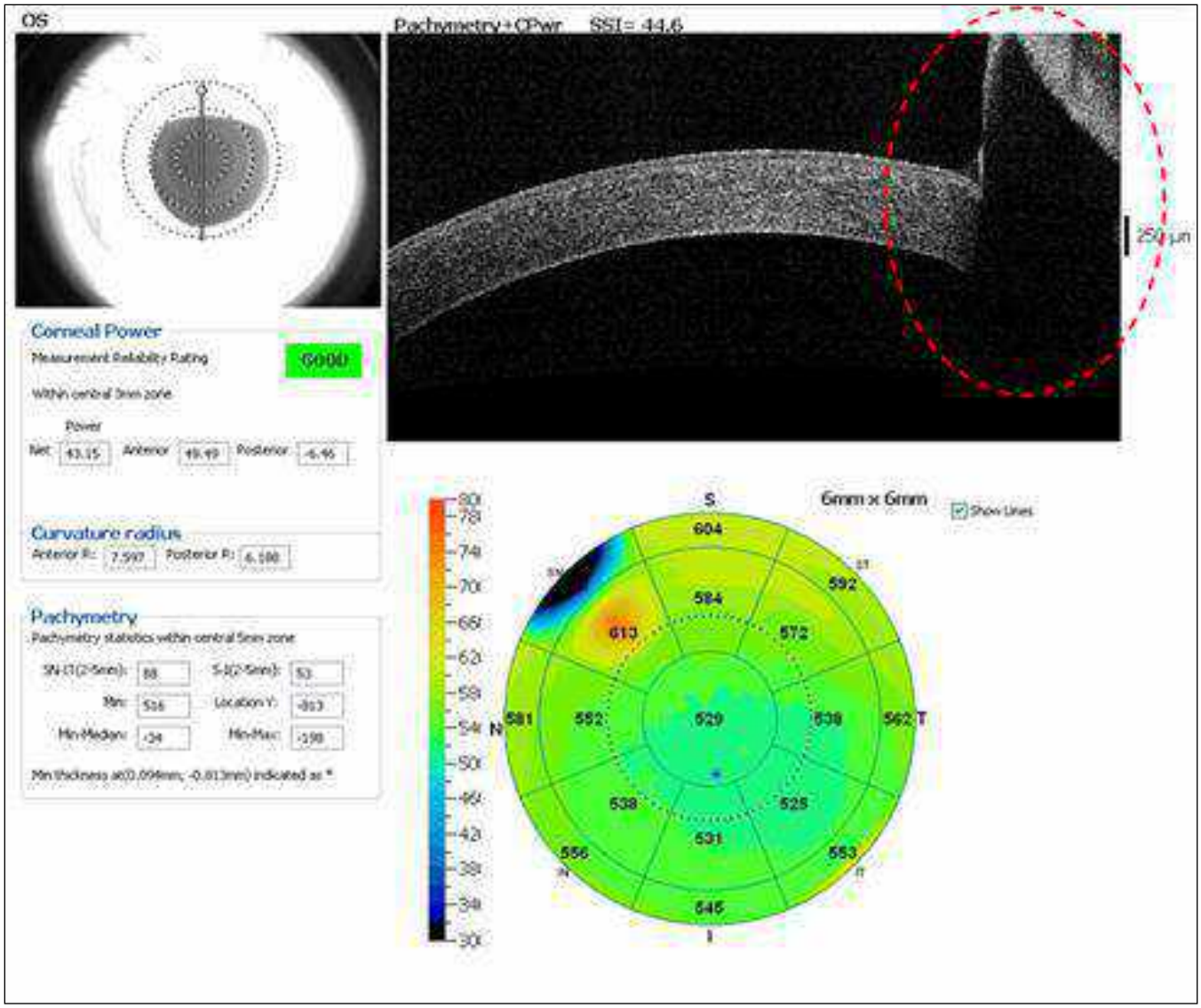


Figure 279 Eyelid blocking more than 1 mm of the image.

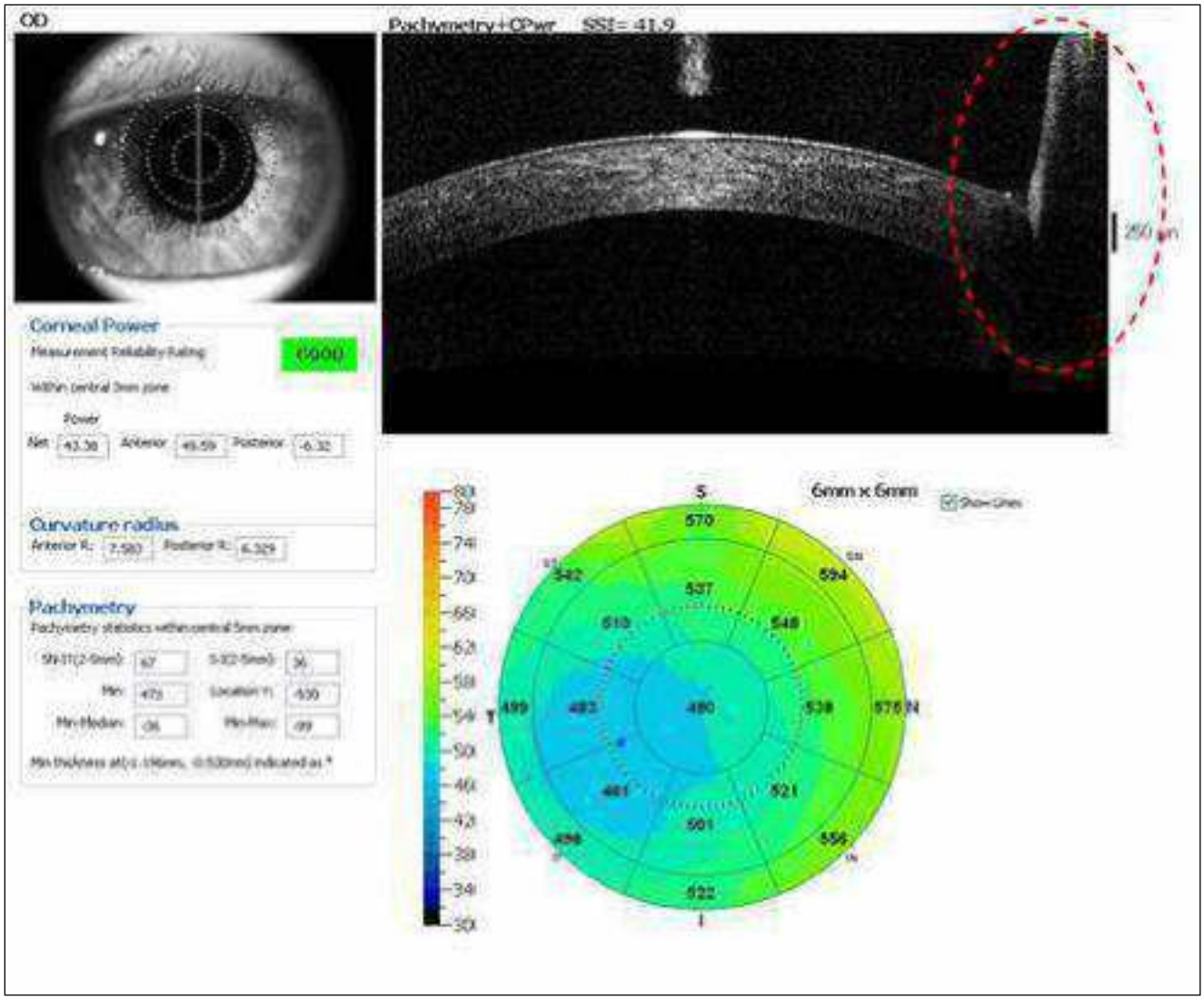


Figure 280 Eyelid blocking between 0.5 mm ~ 1 mm of the image.

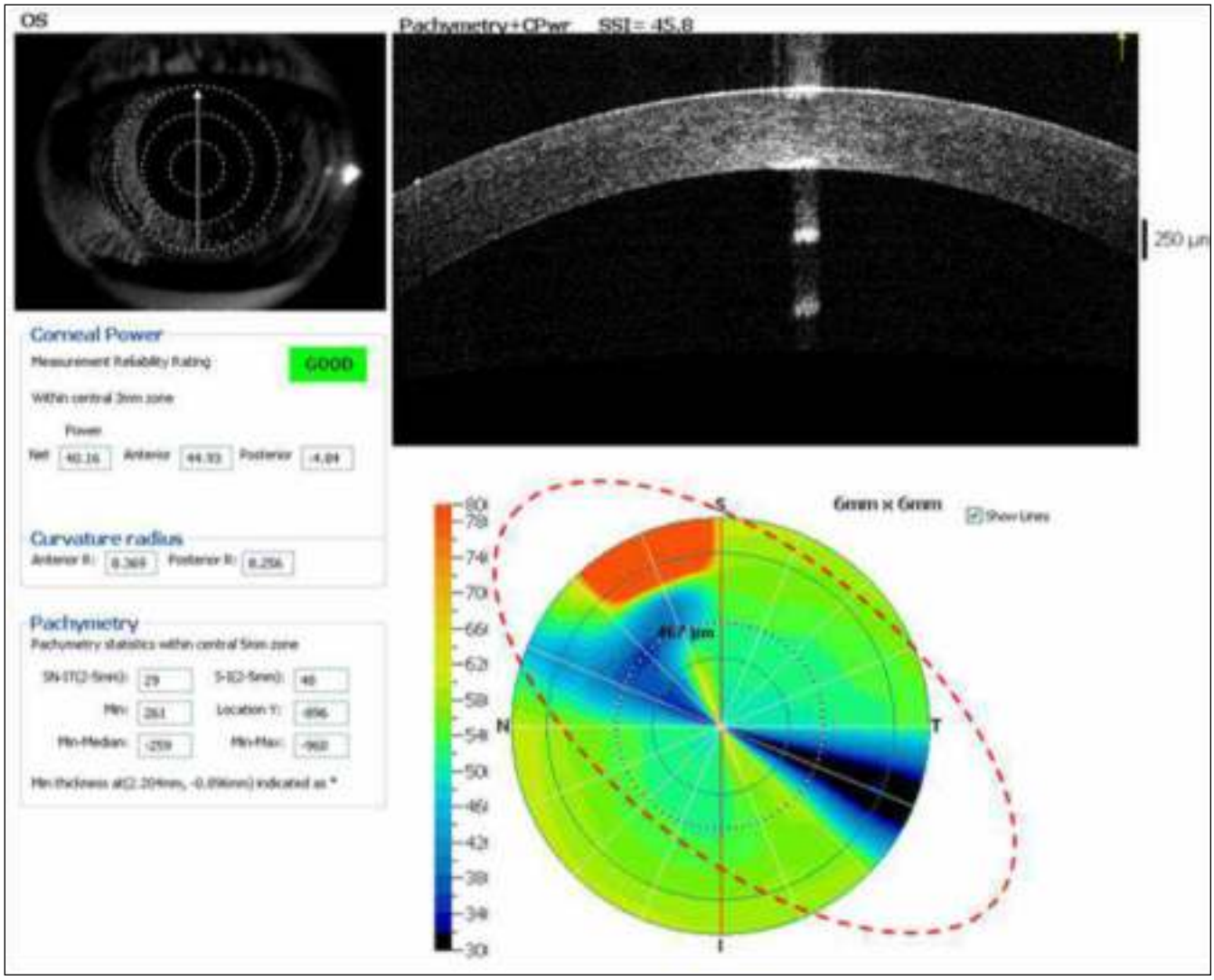


Figure 281 Eyelid / Eyelash artifact

Occasionally, eyelid or eyelash artifact in meridians other than the vertical one (due to blinking) could cause obvious artifact in the pachymetry map but no obvious impact on CCP_{Net} measurement quality.

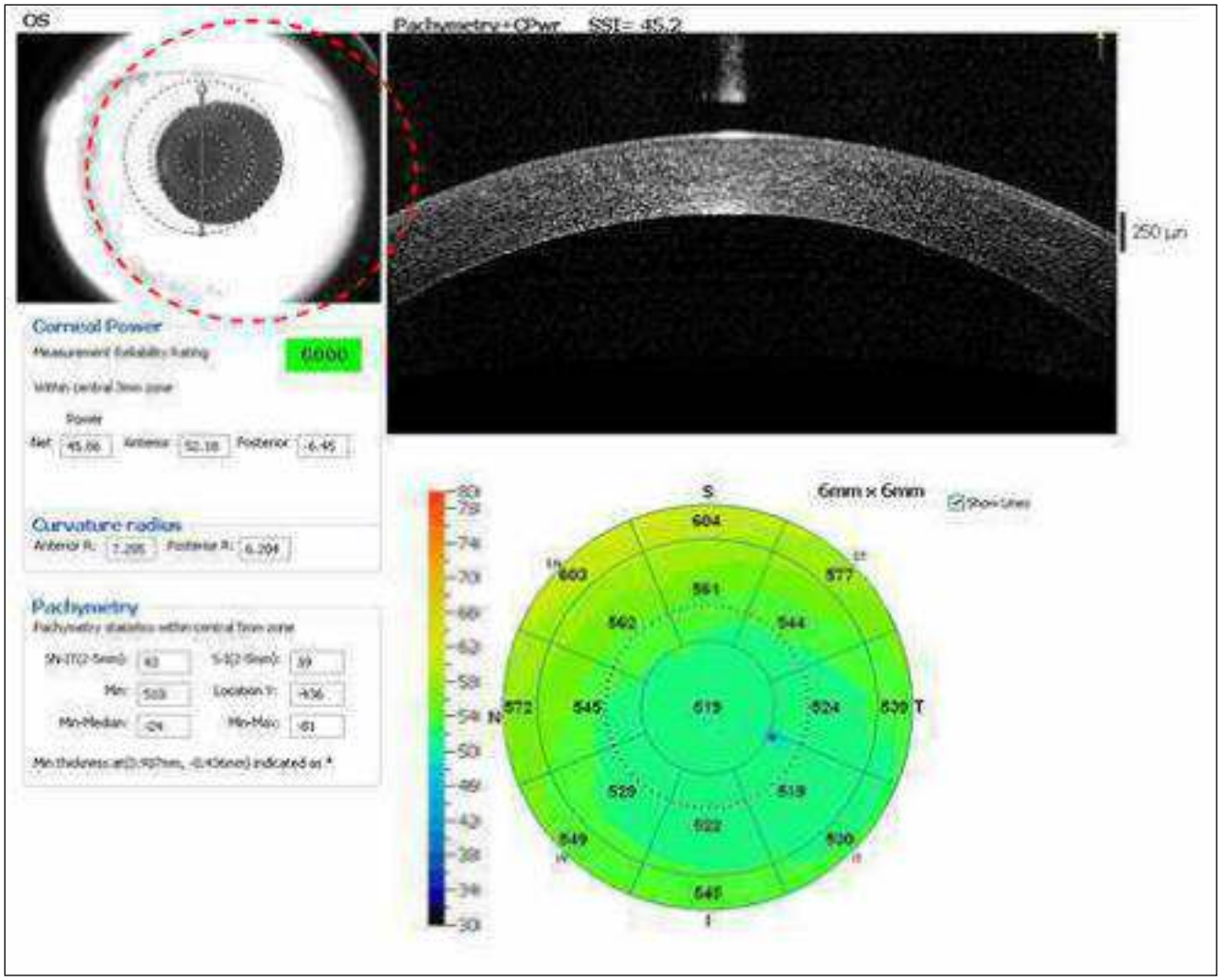


Figure 282 Misalignment on pupil between 0.5 mm ~ 1 mm.

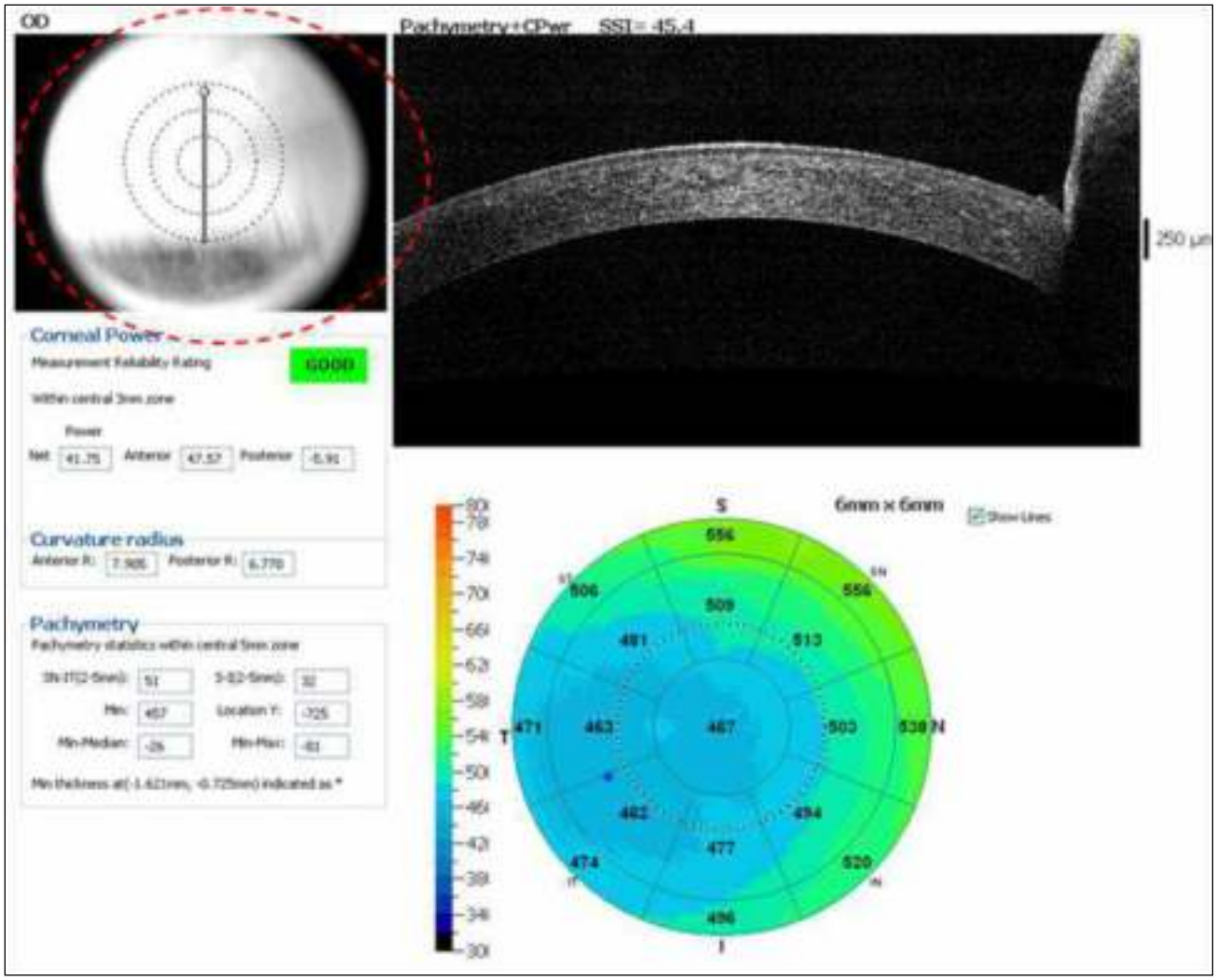


Figure 283 Pupil blocked by eyelid in the video image and alignment cannot be assessed.

_____End of section_____

18.13 Pachymetry & Epithelium Mapping

Note: This ETM is a license controlled revenue product and payment for the license is only in advance.

Follow the activation instructions provided with the license key in the document titled **Epithelium Mapping License Key – Activation Instructions**.

1.1 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.

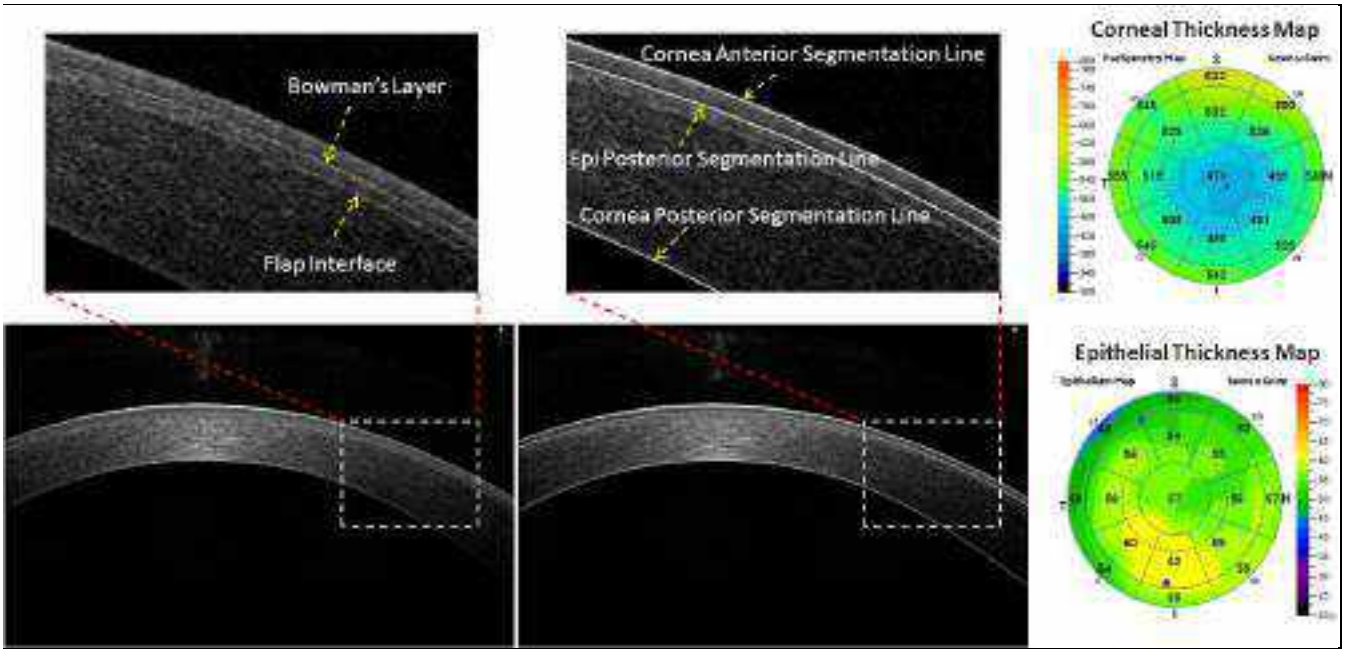


Figure 284 Automatic segmentation boundaries Lasik

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.

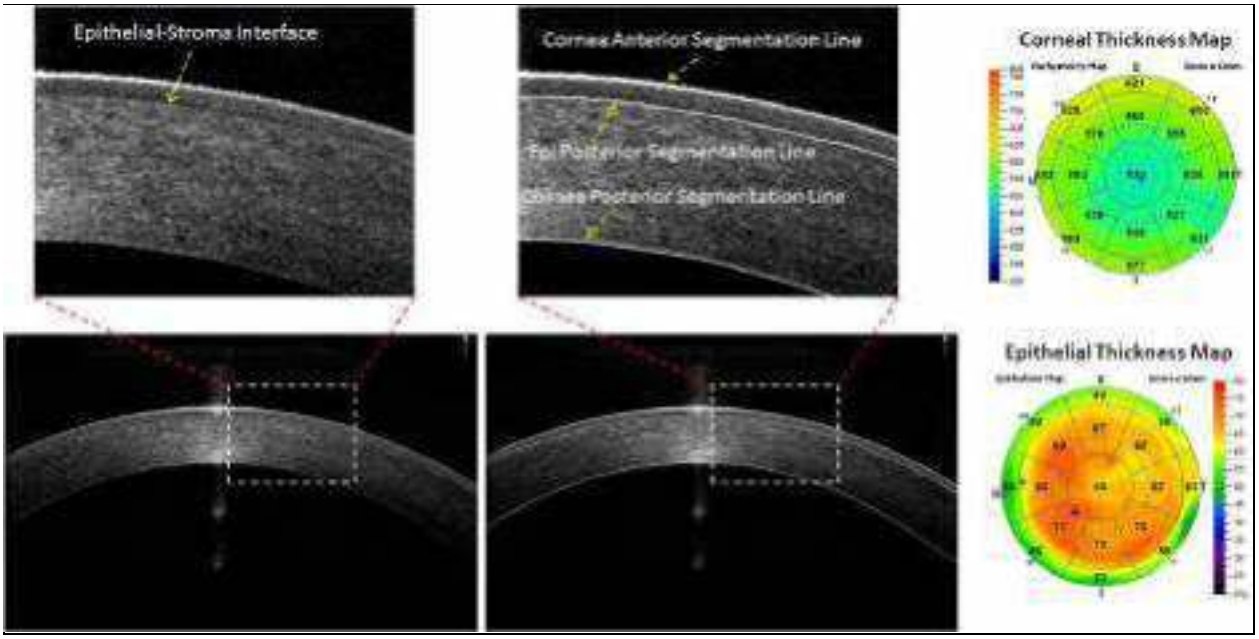


Figure 285 Automatic segmentation boundaries PRK

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.

18.13.1 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.

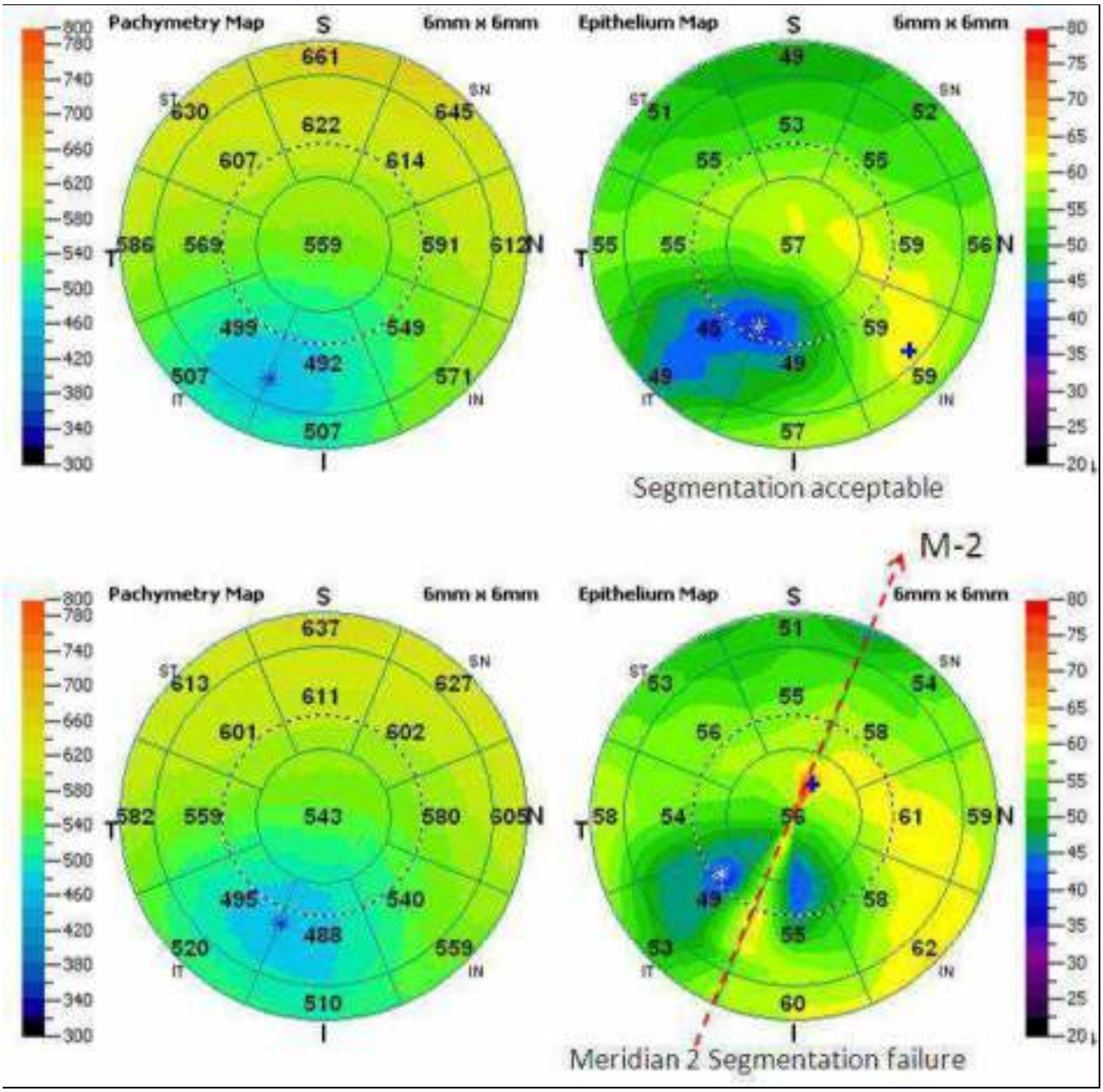


Figure 286 Segmentation error

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.

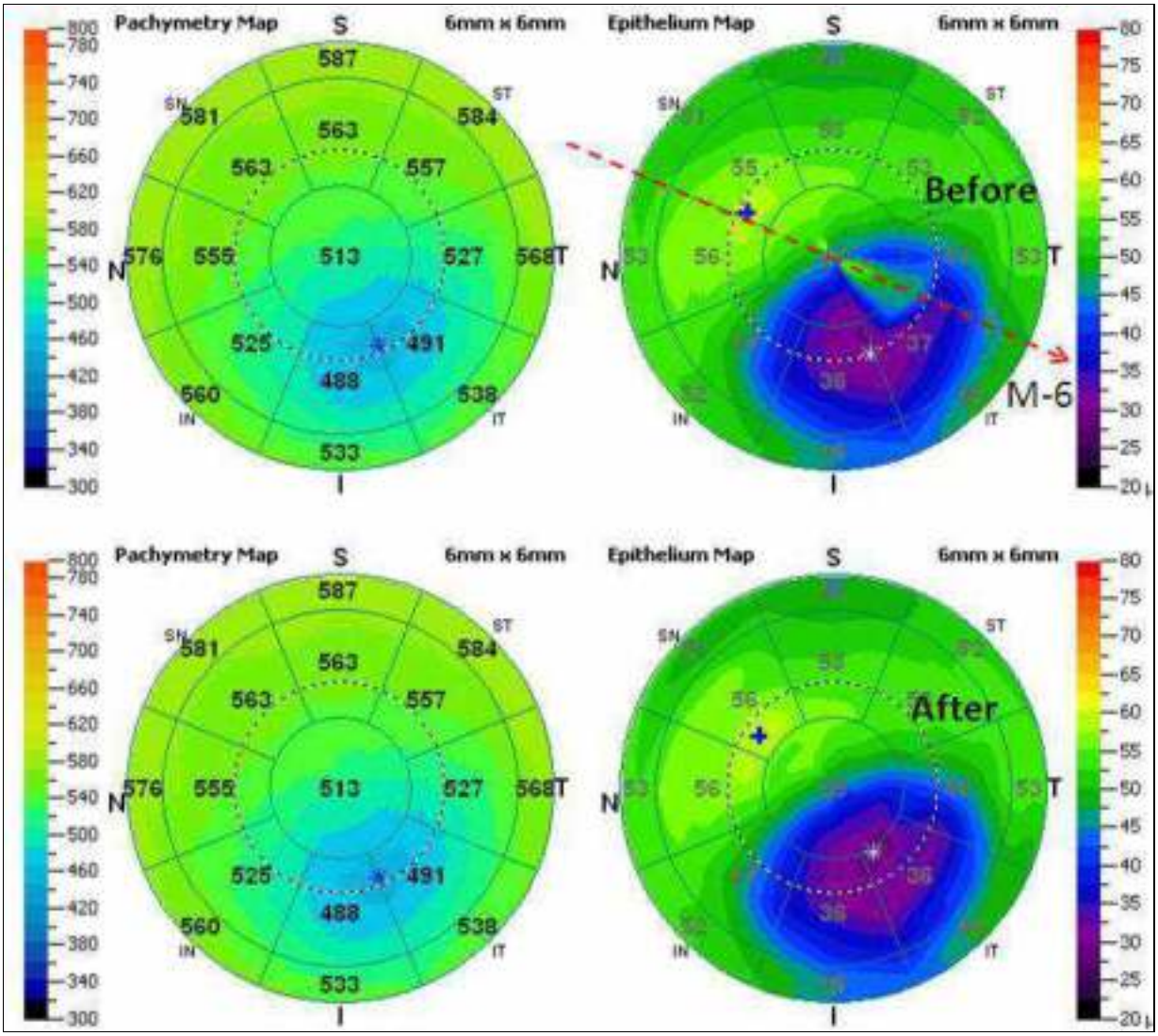


Figure 287 Reprocessed Map

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.

18.14 Clinical Validation Study 6mm Pachymetry scan

Clinical validation of the software was performed based on the following study groups

1. Normal cornea with no contact lens wearing history (Normal)
2. Normal cornea with regular contact lens wearing history (CL)
3. Post-laser refractive surgery cornea (Post-LRS), which was further separated into two sub groups in the analysis: post-LASIK group (LASIK) and post-PRK group (PRK)
4. Keratoconus cornea (KCN)

While we do not expect the dry eye syndrome group to pose extra difficulty in the epithelial thickness automatic measurement algorithm as compared to the KCN group or the LASIK and PRK groups, **the performance data for the dry eye syndrome group has not been established and extra caution is recommended when using the device for the measurement of the dry eye subject group**.

18.14.1 Enrollment Criteria

18.14.2 Normal

Subjects were recruited from staff volunteers, patients seeking refractive surgery consultation, and patients seeking cataract surgery consultation according to the following criteria.

1. 18 years of age or older
2. No corneal pathology
3. Not a contact lens wearer
4. No prior ocular surgery and no prior laser refractive surgery
5. No history and no current diagnosis of dry eye

18.14.3 CL

Subjects were recruited from staff volunteers, patients seeking refractive surgery consultation, and patients seeking cataract surgery consultation according to the following criteria.

1. 18 years of age or older
2. A regular contact lens wearer

3. No corneal pathology
4. No prior ocular surgery and no prior laser refractive surgery

18.14.4 LASIK

Subjects were recruited from the pool of post-LASIK patients according to the following criteria.

1. 18 years of age or older
2. No corneal pathology
3. No prior ocular surgery except laser refractive surgery
4. At least 1 week post laser refractive surgery without complication

18.14.5 PRK

Subjects were recruited from the pool of post-PRK patients according to the following criteria.

1. 18 years of age or older
2. No corneal pathology
3. No prior ocular surgery except laser refractive surgery
4. At least 1 week post laser refractive surgery without complication

18.14.6 KCN

Subjects were recruited from the pool of patients with keratoconus diagnosis according to the following criteria.

1. 18 years of age or older
2. Clinical diagnosis of keratoconus
3. No prior laser refractive surgery

Epithelial measurement parameters evaluated:

1. Min: Minimum epithelial thickness of the map
2. Max: Maximum epithelial thickness of the map
3. Std Dev: Standard deviation of the epithelial thickness of the map
4. Superior: Average epithelial thickness of the superior region of the map between 2mm to 5mm in diameter
5. Inferior: Average epithelial thickness of the inferior region of the map between 2mm to 5mm in diameter.

6. Central: Average epithelial thickness of the central 2mm diameter region

18.14.7 Study Subject Demographics and Characteristics

17 normal subjects, 10 CL subjects, 12 LASIK subjects, 9 PRK subjects, and 13 KCN patients were included in the validation study.

Age distribution by study group.

Analysis Variable : Age							
Group	**N Obs**	**N**	**Mean**	**Std Dev**	**Range**	**Minimum**	**Maximum**
CL	10	10	34.500	12.748	38.000	18.000	56.000
KCN	13	13	48.538	12.306	42.000	27.000	69.000
LASIK	12	12	50.583	12.937	39.000	26.000	65.000
Normal	17	17	46.294	15.280	46.000	19.000	65.000
PRK	9	9	41.778	12.969	41.000	23.000	64.000

Signal strength distribution by study group.

Analysis Variable : SSI							
Group	**N Obs**	**N**	**Mean**	**Std Dev**	**Range**	**Minimum**	**Maximum**
CL	10	10	40.913	3.548	12.590	36.097	48.686
KCN	13	13	42.135	8.810	29.304	33.072	62.376
LASIK	12	12	39.238	3.921	12.453	32.500	44.953
Normal	17	17	39.785	3.029	12.410	32.090	44.500
PRK	9	9	42.019	4.545	11.828	36.199	48.027

Central corneal thickness distribution by study group.

Analysis Variable : CCT							
Group	**N Obs**	**N**	**Mean**	**Std Dev**	**Range**	**Minimum**	**Maximum**
CL	10	10	525.709	16.174	58.267	497.644	555.911
KCN	13	13	486.507	54.382	182.265	367.665	549.930
LASIK	12	12	530.350	34.791	122.611	467.318	589.930
Normal	17	17	541.930	46.227	159.123	468.417	627.540
PRK	9	9	464.734	57.486	173.957	361.434	535.391

Thinnest corneal thickness distribution by study group.

Analysis Variable : Thinnest_CT							
Group	**N Obs**	**N**	**Mean**	**Std Dev**	**Range**	**Minimum**	**Maximum**
CL	10	10	515.257	23.813	83.673	465.889	549.562
KCN	13	13	427.430	79.515	273.886	239.691	513.578
LASIK	12	12	522.215	35.396	126.346	457.260	583.606
Normal	17	17	534.254	46.444	164.254	457.860	622.114
PRK	9	9	455.636	57.296	170.372	353.674	524.047

18.15 Evaluation of the Repeatability and Reproducibility of PachymetryWide 9mm Corneal Epithelial Thickness Mapping with SD-OCT

18.15.1 Clinical Performance Testing

Two anterior segment clinical studies were conducted to demonstrate substantial equivalence of the subject device to the predicate RTVue XR with CAM for pachymetry, corneal epithelial thickness, and corneal stromal thickness measurements with PachymetryWide scan. One study evaluated the repeatability and reproducibility of the cornea measurements, and the second study evaluated agreement with manual measurements based on the PachymetryWide scan software results.

18.15.2 Evaluation of the Repeatability and Reproducibility of Corneal Epithelial Thickness Mapping with SD-OCT

This was a prospective, observational study conducted at a single clinical U.S. site. Eligible participants age 18 or older were enrolled and assigned to one of two study groups: 1) individuals with no corneal pathology, eyelid margin disease, or conditions in qualifying for the other sub-group; 2) those with four specified corneal conditions (soft and hard contact lens wearers, post-refractive surgery, dry eye, keratoconus). Each study eye was imaged at least three times using the PachymetryWide scan pattern with each of three Avanti instrument/operator pairs. Post-acquisition image review of signal strength, pupil alignment, eyelid artifact, scan range, and motion artifact was conducted on all scans. Repeatability and reproducibility of the parameters (all zonal thicknesses [epithelial and stromal thickness], “summary statistics” parameters) were calculated using a crossed, random-effects ANOVA model.

Results

A total of 62 participants were consented and enrolled, 12 “normals,” 12 contact lens wearers, 12 with dry eye, 12 post-laser refractive surgery (post-LRS), and 14 with keratoconus (KCN). Analysis was conducted on scans from 60 participants. The age distribution and clinical characteristics of the study cohort are shown in Tables 21 through 26.

64 of 581 total acquired scans (11%) were excluded from R&R analysis due to scan quality issues. Out of 517 scans qualified for final R&R analysis, 60 (12%) required manual edits of the segmentation lines.

Table 21. Age Distribution for All Subjects by Enrollment Group

Age by Category (n=60)	Min	Median	Mean	Max	SD
Normal (n=12)	21	45.5	46.3	72	15.68
Contact Lens (n=12)	31	40.5	46.7	67	14.43
Dry Eye (n=11)	39	66.0	63.0	75	9.79
Post Laser Refractive Surgery (n=12)	19	47.5	44.7	73	16.34
Keratoconus (n=13)	18	38.0	39.4	71	16.31

All subjects in the Contact Lens group wore soft contact lens regularly for eight or more hours per day, and for at least three months at the time of enrollment.

Table 22. Contact Lens Wear Data for the Contact Lens Study Group

Contact Lens Wear	Min	Median	Mean	Max	SD
Duration (yr.)	2	15.5	22.5	45	14.77
Hours/Day	10	14.5	13.7	16	1.84

The severity of dry eye condition was documented using Ocular Surface Disease Index (OSDI) score with a scale from 0 to 100 (mild to severe) in the table below.

Table 23. OSDI Score Distribution of the Dry Eye Study Group

Dry Eye Assessment	Min	Median	Mean	Max	SD
ODSI Score	14.58	33.33	42.8	75	21.42

Table 24. Post-LRS Group Clinical Data Summary

Procedure	Total	% Total
LASIK	9	75.0%
PRK	3	25.0%
Correction		
Myopic	10	83.3%
Hyperopic	1	8.3%
Astigmatism	1	8.3%
Duration since procedure		
> 1yr	10	83.3%
> 3mo	1	8.3%
> 1mo	1	8.3%

The subjects in the KCN group all had a clinical diagnosis of keratoconus. None of the KCN subjects had any prior surgical treatment.

Table 25. KCN Group Distribution by Clinical Signs and Severity

Clinical Signs	**Total**	**% Total**
Slit lamp exam	8	57.1%
Topographic patterns	2	14.3%
Slit lamp exam & Topographic patterns	4	28.6%
Retinoscope reflex	0	0.0%
Severity (clinically established by PI)	**Total**	**% Total**
Mild	6	42.9%
Moderate	5	35.7%
Severe	3	21.4%

Table 26. Distribution of Steep K and Delta K (difference between Steep K and Flat K) in KCN Group

Corneal Curvature	**Min**	**Median**	**Mean**	**Max**	**SD**
Steep K	45.73	52.36	52.27	62.72	5.098
Delta K	1.02	3.23	4.75	21.95*	5.154

18.15.3 Normal Group R&R

Table 27a. Zonal Parameters

Normal Group (n = 105 scans)																								
	Pachymetry								*Epithelium*								*Stroma*							
	Mean	SD	Min	Max	Repeatability	Reproducibility			Mean	SD	Min	Max	Repeatability	Reproducibility			Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	95% Limits					SD	SD	COV	95% Limit					SD	SD	COV	95% Limits
C_2	551.3	23.2	518.4	608.1	1.4	1.5	0.3%	4.3	54.5	5.9	45.3	69.1	0.7	0.8	1.4%	2.1	496.7	23.2	467.2	546.6	1.2	1.2	0.3%	3.5
T_2_5	564.7	23.9	527.5	615.0	2.3	2.3	0.4%	6.3	53.8	5.1	44.5	66.1	0.8	0.8	1.5%	2.2	510.9	23.4	476.9	555.3	2.1	2.1	0.4%	5.9
ST_2_5	580.9	22.4	547.8	625.7	3.4	3.5	0.6%	9.6	53.9	4.5	46.0	63.9	0.9	0.9	1.7%	2.6	527.0	22.0	494.1	569.4	3.3	3.4	0.7%	9.6
S_2_5	593.9	20.7	561.7	639.1	4.0	4.0	0.7%	11.0	54.2	4.3	46.1	63.9	1.2	1.2	2.2%	3.3	539.7	20.8	507.5	581.8	3.9	4.0	0.7%	11.0
SN_2_5	590.5	19.8	554.1	639.9	4.1	4.1	0.7%	11.5	54.5	4.5	46.3	65.7	1.2	1.2	2.2%	3.3	536.0	20.1	500.9	580.6	4.0	4.1	0.8%	11.3
N_2_5	579.2	20.3	545.6	631.2	3.3	3.3	0.6%	9.1	54.9	4.9	46.2	67.3	0.9	1.0	1.8%	2.7	524.3	20.5	493.0	570.9	3.1	3.1	0.6%	8.7
IN_2_5	571.2	21.8	542.0	625.9	2.7	2.7	0.5%	7.5	56.0	5.6	48.3	69.1	0.7	0.7	1.3%	2.1	515.2	21.5	488.6	564.1	2.5	2.5	0.5%	6.9
I_2_5	565.4	23.2	530.1	623.9	2.1	2.2	0.4%	6.1	56.2	6.6	46.9	71.7	0.8	0.8	1.5%	2.3	509.2	22.4	482.3	559.7	2.1	2.1	0.4%	5.8
IT_2_5	560.3	23.9	523.2	617.7	1.8	1.8	0.3%	4.9	54.8	6.0	45.7	70.1	0.9	0.9	1.7%	2.6	505.5	23.3	474.2	555.5	1.9	1.9	0.4%	5.1
T_5_7	592.9	23.6	544.7	634.7	3.8	3.8	0.6%	10.4	53.2	4.1	42.0	61.0	0.9	0.9	1.6%	2.4	539.7	22.8	500.3	578.8	3.8	3.8	0.7%	10.7
ST_5_7	621.0	20.9	584.5	661.5	4.8	5.0	0.8%	13.8	52.0	3.5	45.2	61.1	1.1	1.1	2.2%	3.1	569.0	20.7	533.7	609.8	5.0	5.2	0.9%	14.4
S_5_7	641.9	19.2	609.0	683.7	5.1	5.2	0.8%	14.4	52.3	3.4	45.8	65.0	1.4	1.5	2.9%	4.1	589.6	20.1	555.1	630.4	5.2	5.4	0.9%	14.9
SN_5_7	634.5	18.9	600.1	675.2	5.9	6.0	1.0%	16.7	54.2	3.1	47.9	62.1	1.2	1.3	2.3%	3.5	580.3	19.2	544.8	618.5	5.7	5.9	1.0%	16.4
N_5_7	615.2	18.2	584.0	654.9	4.9	4.9	0.8%	13.6	55.2	4.1	48.5	65.0	0.9	1.0	1.8%	2.7	560.1	18.2	529.9	596.5	4.6	4.6	0.8%	12.8
IN_5_7	604.3	20.3	569.9	652.9	4.7	4.7	0.8%	13.1	56.3	5.2	47.9	68.7	0.8	0.8	1.3%	2.1	548.0	19.9	521.9	598.3	4.5	4.5	0.8%	12.5
I_5_7	597.6	22.7	553.3	646.6	4.1	4.2	0.7%	11.6	56.7	6.7	45.1	71.1	0.8	0.8	1.4%	2.1	540.9	21.6	508.2	592.1	4.1	4.2	0.8%	11.6
IT_5_7	588.1	23.2	540.4	636.7	3.9	3.9	0.7%	10.7	55.1	5.6	45.1	66.8	1.0	1.0	1.8%	2.7	533.0	22.5	493.2	575.1	4.0	4.0	0.7%	11.1
T_7_9	628.0	24.6	569.6	674.7	6.8	7.0	1.1%	19.5	52.2	3.6	42.9	58.4	0.9	0.9	1.7%	2.5	575.8	23.9	525.6	623.0	6.8	7.1	1.2%	19.7
ST_7_9	666.2	22.1	616.6	703.4	7.9	8.3	1.2%	22.9	49.3	3.3	41.5	57.1	1.1	1.2	2.3%	3.2	616.9	22.3	571.6	655.8	8.1	8.5	1.4%	23.7
S_7_9	688.2	19.6	641.0	724.0	8.1	8.2	1.2%	22.7	49.7	3.4	41.3	56.5	1.5	1.5	3.0%	4.1	638.4	21.1	588.6	676.4	8.1	8.3	1.3%	23.0
SN_7_9	681.9	19.7	635.0	724.9	8.2	8.2	1.2%	22.7	53.4	3.0	48.0	61.0	1.5	1.5	2.9%	4.3	628.5	20.6	578.2	672.3	8.1	8.1	1.3%	22.5
N_7_9	658.0	20.3	619.7	697.4	6.8	6.8	1.0%	18.8	56.4	4.1	49.7	66.8	1.4	1.4	2.5%	4.0	601.6	20.4	567.5	643.3	6.4	6.4	1.1%	17.9
IN_7_9	646.2	23.0	598.0	713.3	7.3	7.3	1.1%	20.2	56.5	5.3	49.2	69.9	0.9	0.9	1.6%	2.6	589.7	23.4	548.0	658.2	7.1	7.1	1.2%	19.8
I_7_9	635.7	25.4	578.6	701.0	6.7	6.8	1.1%	18.9	56.4	6.6	46.9	71.0	0.7	0.7	1.2%	1.9	579.3	25.2	531.4	646.3	6.8	6.9	1.2%	19.2
IT_7_9	623.8	24.0	563.5	663.1	6.5	6.5	1.0%	18.1	55.2	5.8	44.2	68.0	0.8	0.9	1.5%	2.4	568.6	23.8	518.0	610.9	6.5	6.6	1.2%	18.2

Table 27b. Summary Parameters

Normal Group (n = 105 scans)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	95% Limit
Pachymetry								
SN-IT (2-5mm)__Pachy	30.2	10.7	8.4	52.0	5.3	5.4	18.1%	15.0
S-I (2-5mm)__Pachy	28.5	10.8	6.7	51.5	5.6	5.6	20.0%	15.6
Min_Pachy	544.8	24.0	512.8	603.7	1.2	1.2	0.2%	3.4
Location_Y_Pachy	-0.4	0.2	-0.8	0.3	0.1	0.1	-31.7%	0.3
Min-Median_Pachy	-25.7	3.3	-32.4	-16.5	1.4	1.4	-5.5%	3.9
Min-Max_Pachy	-69.4	10.8	-91.2	-46.7	4.8	4.8	-7.0%	13.3
Epithelium								
Min_Epi	48.3	3.2	38.6	54.3	1.2	1.2	2.6%	3.4
Max_Epi	59.5	5.9	50.4	72.9	1.0	1.0	1.7%	2.7
Min-Max_Epi	-11.2	4.7	-24.8	-4.9	1.4	1.4	-12.5%	4.0
STD Dev_Epi	2.5	1.2	1.0	6.1	0.3	0.3	11.5%	0.8
S (2-7)__Epi	53.2	3.4	46.3	62.0	1.2	1.3	2.4%	3.5
I (2-7)__Epi	56.5	6.5	46.0	71.4	0.7	0.7	1.3%	2.1
Stroma								
Min_Stroma	490.2	23.8	462.2	541.9	0.8	0.9	0.2%	2.4
Max_Stroma	607.1	20.5	571.1	649.5	6.1	6.2	1.0%	17.3
Min-Max_Stroma	-116.8	12.8	-148.6	-87.2	5.8	5.8	-5.0%	16.1
STD Dev_Stroma	29.4	3.4	22.6	36.2	1.3	1.3	4.5%	3.6
S (2-7)__Stroma	566.3	20.3	532.9	607.7	4.6	4.7	0.8%	13.0
I (2-7)__Stroma	526.1	21.8	496.5	574.2	3.1	3.2	0.6%	8.8

18.15.4 Contact Lens Group R&R

Table 28a. Zonal Parameters

Contact Lens Group (n = 101 scans)																								
	Pachymetry								*Epithelium*								*Stroma*							
	Mean	SD	Min	Max	Repeatability	Reproducibility			Mean	SD	Min	Max	Repeatability	Reproducibility			Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	95% Limits					SD	SD	COV	95% Limits					SD	SD	COV	95% Limits
C_2	555.4	46.1	454.7	662.6	2.3	2.6	0.5%	7.1	51.1	4.2	40.3	63.0	2.0	2.1	4.0%	5.7	504.3	46.5	400.5	610.5	1.2	1.5	0.3%	4.2
T_2_5	569.2	47.2	465.1	679.2	3.3	3.4	0.6%	9.4	50.4	3.8	41.1	60.3	2.0	2.0	3.9%	5.5	518.9	47.9	412.3	630.4	2.6	2.6	0.5%	7.3
ST_2_5	587.6	45.8	474.0	699.0	4.6	4.7	0.8%	12.9	51.0	3.9	42.7	61.0	1.9	1.9	3.8%	5.3	536.5	47.0	420.6	651.6	4.3	4.4	0.8%	12.3
S_2_5	602.6	45.8	482.3	712.2	4.6	4.9	0.8%	13.5	51.4	3.7	41.8	60.7	1.7	1.7	3.4%	4.8	551.2	46.9	427.7	663.8	4.4	4.8	0.9%	13.4
SN_2_5	598.1	45.1	482.6	704.9	4.2	4.5	0.8%	12.4	51.8	3.9	40.3	61.2	1.7	1.8	3.4%	4.9	546.3	46.2	426.5	655.3	4.0	4.4	0.8%	12.1
N_2_5	584.1	46.1	477.3	690.4	3.3	3.6	0.6%	9.9	51.5	3.7	42.4	58.9	1.7	1.7	3.3%	4.7	532.6	46.7	420.2	637.9	3.3	3.5	0.7%	9.6
IN_2_5	574.3	48.2	476.9	686.0	3.0	3.1	0.5%	8.5	51.6	3.5	43.9	58.9	1.0	1.0	2.0%	2.8	522.7	47.9	418.9	631.1	2.9	2.9	0.6%	8.1
I_2_5	568.3	49.7	472.9	685.4	2.6	2.6	0.5%	7.1	51.8	3.6	44.9	59.4	1.3	1.3	2.5%	3.5	516.5	49.0	416.7	629.1	2.2	2.2	0.4%	6.0
IT_2_5	564.0	49.4	466.8	678.6	2.7	2.7	0.5%	7.5	50.8	3.7	42.8	61.0	1.8	1.8	3.6%	5.1	513.2	49.0	412.3	624.6	1.8	1.8	0.3%	4.9
T_5_7	598.2	49.7	487.5	712.9	4.8	4.8	0.8%	13.4	50.3	2.8	43.1	57.2	1.5	1.5	3.0%	4.2	547.9	49.8	434.7	665.2	4.5	4.5	0.8%	12.4
ST_5_7	630.5	47.7	508.4	745.1	6.4	6.4	1.0%	17.9	49.9	3.7	39.5	59.0	1.9	2.1	4.1%	5.7	580.7	48.2	453.6	698.9	6.5	6.6	1.1%	18.3
S_5_7	655.5	46.1	526.8	756.6	5.9	6.1	0.9%	16.8	50.1	3.3	43.8	59.2	1.9	2.0	4.0%	5.6	605.4	47.0	471.0	709.8	5.8	6.1	1.0%	16.9
SN_5_7	645.1	45.4	518.2	747.3	6.0	6.4	1.0%	17.7	51.8	3.3	41.4	61.4	1.8	1.8	3.5%	5.0	593.3	46.2	463.7	698.1	5.9	6.3	1.1%	17.4
N_5_7	620.0	45.4	504.8	721.4	5.0	5.2	0.8%	14.4	52.0	3.4	42.3	59.6	1.4	1.4	2.7%	3.9	568.0	45.8	450.6	669.4	5.0	5.1	0.9%	14.2
IN_5_7	608.1	47.9	502.9	714.1	5.1	5.1	0.8%	14.2	52.3	2.7	46.8	58.8	1.0	1.0	1.9%	2.8	555.9	47.8	447.8	661.5	4.9	4.9	0.9%	13.5
I_5_7	601.8	50.4	500.9	716.8	4.3	4.3	0.7%	11.8	52.6	3.0	47.0	60.6	1.3	1.3	2.5%	3.7	549.2	50.0	443.9	662.0	4.2	4.2	0.8%	11.7
IT_5_7	592.9	51.5	490.3	710.2	4.4	4.4	0.7%	12.1	51.6	2.6	45.5	60.0	1.4	1.4	2.7%	3.8	541.3	51.1	435.6	657.0	3.9	3.9	0.7%	10.9
T_7_9	633.6	51.4	521.0	755.4	9.4	9.4	1.5%	26.0	50.2	3.3	44.2	59.9	1.7	1.8	3.5%	4.9	583.4	51.0	469.8	709.2	8.8	8.8	1.5%	24.5
ST_7_9	677.7	48.4	549.7	790.1	12.0	12.1	1.8%	33.6	48.9	5.2	34.5	64.6	2.1	2.2	4.5%	6.1	628.8	48.9	499.5	747.7	12.1	12.2	2.0%	33.9
S_7_9	706.0	45.6	571.7	797.4	9.6	9.6	1.4%	26.6	47.7	5.1	38.2	64.9	2.6	2.6	5.5%	7.3	658.3	46.1	523.7	759.2	10.2	10.2	1.6%	28.3
SN_7_9	695.2	44.5	566.3	780.6	7.3	7.8	1.1%	21.7	50.8	4.7	39.7	62.6	1.9	1.9	3.7%	5.2	644.4	45.3	516.7	736.7	7.7	8.2	1.3%	22.7
N_7_9	662.3	43.9	550.3	759.2	6.0	6.2	0.9%	17.1	53.8	3.7	41.8	62.6	1.4	1.4	2.6%	3.8	608.5	44.7	497.4	708.2	5.5	5.6	0.9%	15.5
IN_7_9	649.5	47.0	544.1	750.7	7.7	7.7	1.2%	21.4	53.2	3.7	44.9	62.7	1.1	1.1	2.1%	3.1	596.3	47.5	489.4	702.1	7.3	7.3	1.2%	20.2
I_7_9	640.2	49.8	537.5	753.6	6.6	6.6	1.0%	18.3	53.0	3.2	45.7	60.9	1.2	1.3	2.4%	3.5	587.3	50.7	480.6	703.0	6.7	6.8	1.2%	18.8
IT_7_9	628.0	52.5	524.0	747.3	7.7	7.7	1.2%	21.2	52.7	2.7	45.2	62.1	1.3	1.3	2.5%	3.7	575.4	52.5	470.6	695.9	7.3	7.3	1.3%	20.3

Table 28b. Summary Parameters

Contact Lens Group (n = 101 scans)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	95% Limits
Pachymetry								
SN-IT (2-5mm)__Pachy	34.1	15.2	11.8	77.9	6.0	6.1	18.3%	17.0
S-I (2-5mm)__Pachy	34.3	16.3	5.5	76.6	6.6	6.7	20.2%	18.6
Min_Pachy	548.0	47.1	451.0	657.2	1.9	2.0	0.4%	5.5
Location_Y_Pachy	-0.4	0.3	-1.7	0.1	0.2	0.2	-35.9%	0.4
Min-Median_Pachy	-27.5	4.4	-41.4	-17.7	1.7	1.7	-6.2%	4.7
Min-Max_Pachy	-76.6	16.1	-118.8	-46.5	5.6	5.7	-7.6%	15.9
Epithelium								
Min_Epi	46.1	3.6	35.9	52.0	1.5	1.5	3.2%	4.1
Max_Epi	56.8	3.0	51.5	67.7	2.3	2.3	4.1%	6.4
Min-Max_Epi	-10.7	3.8	-25.9	-4.0	2.1	2.1	-19.5%	5.8
STD Dev_Epi	2.2	0.9	1.0	5.6	0.5	0.5	21.8%	1.4
S (2-7)__Epi	50.7	3.2	43.9	59.0	1.6	1.7	3.4%	4.7
I (2-7)__Epi	52.2	3.1	46.1	59.9	1.2	1.2	2.3%	3.3
Stroma								
Min_Stroma	497.3	47.1	396.9	603.3	0.9	1.2	0.2%	3.2
Max_Stroma	623.8	46.6	486.3	723.7	6.4	6.6	1.1%	18.4
Min-Max_Stroma	-126.5	20.1	-172.9	-89.4	6.1	6.2	-4.9%	17.0
STD Dev_Stroma	31.4	5.2	22.3	44.8	1.5	1.6	5.0%	4.4
S (2-7)__Stroma	580.1	46.8	450.8	688.3	5.1	5.5	0.9%	15.1
I (2-7)__Stroma	533.9	49.5	431.2	646.6	3.2	3.2	0.6%	8.8

18.15.5 Dry Eye Group R&R

Table 29a. Zonal Parameters

Dry Eye Group (n = 89 scans)																								
	Pachymetry								*Epithelium*								*Stroma*							
	Mean	SD	Min	Max	Repeat ability	Reproducibility			Mean	SD	Min	Max	Repeat ability	Reproducibility			Mean	SD	Min	Max	Repeat ability	Reproducibility		
					SD	SD	COV	95% Limits					SD	SD	COV	95% Limits					SD	SD	COV	95% Limits
C_2	536.1	29.0	485.0	588.5	1.6	2.0	0.4%	5.5	54.0	2.8	48.8	59.8	1.1	1.3	2.3%	3.5	482.1	28.9	428.6	529.2	1.4	1.5	0.3%	4.2
T_2_5	549.7	29.1	493.0	598.5	2.9	2.9	0.5%	8.1	53.4	2.6	47.9	59.4	0.9	1.0	1.9%	2.8	496.3	29.3	436.5	541.3	2.7	2.7	0.5%	7.5
ST_2_5	565.9	27.7	507.4	609.7	4.0	4.0	0.7%	11.1	52.1	2.6	45.6	59.5	1.3	1.3	2.5%	3.6	513.8	28.0	453.6	553.1	3.9	3.9	0.8%	10.8
S_2_5	578.7	26.8	527.1	619.4	4.3	4.4	0.8%	12.2	52.0	2.7	45.3	59.2	1.4	1.4	2.8%	4.0	526.7	27.2	473.7	566.3	4.5	4.5	0.9%	12.6
SN_2_5	574.8	26.4	525.1	621.4	4.1	4.3	0.7%	11.9	52.8	2.8	46.6	59.9	1.5	1.5	2.9%	4.2	522.0	26.8	470.8	561.8	4.2	4.4	0.8%	12.1
N_2_5	562.3	27.4	510.1	614.7	3.3	3.7	0.7%	10.2	53.8	2.8	48.6	62.3	1.3	1.4	2.6%	3.8	508.6	27.5	454.3	555.4	3.3	3.6	0.7%	10.0
IN_2_5	554.7	28.5	506.3	606.2	2.5	2.8	0.5%	7.7	54.6	2.8	48.6	63.5	1.2	1.2	2.3%	3.4	500.1	28.8	449.5	546.6	2.4	2.5	0.5%	7.0
I_2_5	550.4	29.2	502.6	598.1	2.3	2.6	0.5%	7.2	55.1	2.8	49.7	60.9	1.1	1.2	2.1%	3.2	495.3	29.4	444.2	543.1	2.0	2.2	0.4%	6.0
IT_2_5	545.2	30.1	491.2	596.1	2.0	2.3	0.4%	6.3	54.3	2.8	48.1	60.7	0.9	1.0	1.8%	2.7	490.9	30.0	433.6	537.0	1.7	1.9	0.4%	5.2
T_5_7	576.6	28.7	513.3	621.6	4.6	4.6	0.8%	12.9	52.3	2.6	46.1	59.2	1.0	1.1	2.0%	2.9	524.3	29.1	458.4	563.7	4.7	4.7	0.9%	12.9
ST_5_7	605.3	28.1	542.2	657.2	5.6	5.6	0.9%	15.6	49.2	3.1	41.4	57.2	1.3	1.3	2.7%	3.7	556.2	28.8	492.3	608.6	5.8	5.8	1.0%	16.1
S_5_7	627.1	27.4	581.3	682.8	5.9	6.0	1.0%	16.7	48.5	4.0	35.2	57.1	1.7	1.7	3.6%	4.8	578.6	28.2	528.1	634.0	6.3	6.3	1.1%	17.6
SN_5_7	616.9	26.1	566.3	654.1	5.6	6.0	1.0%	16.6	51.5	3.5	43.0	59.8	1.5	1.5	3.0%	4.2	565.4	27.2	511.7	603.0	5.9	6.2	1.1%	17.3
N_5_7	594.6	26.9	538.5	641.3	5.1	5.4	0.9%	14.9	53.3	2.6	49.4	63.8	1.3	1.4	2.6%	3.8	541.3	27.4	484.0	582.3	4.9	5.2	1.0%	14.4
IN_5_7	584.6	27.8	536.6	630.4	3.9	4.0	0.7%	11.2	54.1	3.1	49.0	63.7	1.3	1.4	2.6%	4.0	530.5	28.6	480.5	578.5	3.8	3.9	0.7%	10.7
I_5_7	580.1	28.7	533.6	634.5	3.8	4.1	0.7%	11.3	54.4	3.3	48.7	60.8	1.2	1.4	2.5%	3.8	525.7	29.9	476.1	584.4	3.5	3.7	0.7%	10.1
IT_5_7	571.6	29.9	516.6	622.1	4.0	4.1	0.7%	11.4	54.3	2.7	49.9	60.7	1.2	1.2	2.3%	3.4	517.3	29.9	459.6	568.1	3.7	3.8	0.7%	10.6
T_7_9	607.4	30.3	538.3	656.0	7.6	7.6	1.3%	21.1	50.0	3.2	41.1	56.1	1.2	1.2	2.4%	3.4	557.4	31.4	485.3	607.6	7.9	7.9	1.4%	21.8
ST_7_9	645.1	31.7	586.2	730.9	8.2	8.2	1.3%	22.8	46.2	4.0	37.6	53.7	1.2	1.3	2.9%	3.7	598.9	32.9	534.8	679.9	8.2	8.3	1.4%	23.0
S_7_9	675.3	34.3	614.5	790.9	13.5	14.2	2.1%	39.4	46.4	4.9	27.3	55.9	2.0	2.0	4.3%	5.5	628.9	34.6	566.9	742.3	14.0	14.7	2.3%	40.7
SN_7_9	658.8	33.0	604.2	733.1	8.6	9.1	1.4%	25.1	49.5	4.4	37.8	56.6	1.6	1.7	3.4%	4.6	609.3	34.2	548.7	680.6	9.0	9.4	1.5%	26.1
N_7_9	626.4	30.8	562.0	670.3	7.0	7.3	1.2%	20.3	53.2	3.2	46.3	64.8	1.7	1.8	3.4%	5.0	573.2	31.4	506.0	619.9	6.5	7.0	1.2%	19.5
IN_7_9	615.4	29.2	563.4	663.8	6.9	6.9	1.1%	19.2	53.3	5.3	44.2	63.6	1.8	1.9	3.6%	5.4	562.1	31.6	506.7	618.6	6.8	6.8	1.2%	18.8
I_7_9	611.1	31.7	557.5	667.8	5.7	5.7	0.9%	15.8	53.2	5.2	40.3	62.0	1.2	1.3	2.5%	3.7	557.9	34.1	502.7	627.6	6.1	6.1	1.1%	16.9
IT_7_9	603.7	31.7	540.9	659.5	6.0	6.2	1.0%	17.2	53.5	3.1	48.2	59.6	1.0	1.0	1.9%	2.8	550.2	32.6	483.6	608.6	6.1	6.2	1.1%	17.2

Table 29b. Summary Parameters

Dry Eye Group (n = 89 scans)								
	Mean	SD	Min	Max	Repeat ability	Reproducibility		
					SD	SD	COV	95% Limits
Pachymetry								
SN-IT (2-5mm)__Pachy	29.6	10.8	3.3	55.7	5.4	5.6	19.0%	15.6
S-I (2-5mm)__Pachy	28.3	12.9	-5.2	60.3	6.1	6.2	21.8%	17.1
Min_Pachy	529.4	30.1	478.3	583.3	1.4	1.8	0.3%	5.0
Location_Y_Pachy	-0.3	0.2	-0.7	0.3	0.1	0.1	-41.7%	0.4
Min-Median_Pachy	-25.4	4.8	-35.3	-16.0	1.1	1.1	-4.4%	3.1
Min-Max_Pachy	-69.6	15.4	-110.9	-43.2	4.5	4.7	-6.7%	13.0
Epithelium								
Min_Epi	45.1	5.5	24.8	53.6	1.7	1.7	3.7%	4.7
Max_Epi	57.8	3.1	52.3	65.8	1.3	1.4	2.4%	3.8
Min-Max_Epi	-12.7	5.5	-30.9	-5.8	2.0	2.1	-16.1%	5.7
STD Dev_Epi	2.6	1.1	1.1	5.7	0.5	0.5	19.0%	1.3
S (2-7)__Epi	50.1	3.0	42.9	58.1	1.4	1.4	2.8%	4.0
I (2-7)__Epi	54.7	3.0	49.8	60.4	1.1	1.2	2.2%	3.3
Stroma								
Min_Stroma	475.0	30.2	421.4	524.1	1.0	1.2	0.2%	3.2
Max_Stroma	596.0	28.9	546.6	656.2	7.4	7.6	1.3%	21.0
Min-Max_Stroma	-121.1	20.4	-177.4	-87.1	7.0	7.3	-6.0%	20.1
STD Dev_Stroma	29.6	5.4	20.4	43.9	1.6	1.7	5.7%	4.7
S (2-7)__Stroma	554.4	27.4	502.7	598.7	5.3	5.4	1.0%	14.9
I (2-7)__Stroma	511.5	29.4	461.2	565.1	2.8	2.9	0.6%	8.0

18.15.6 Post-LRS Group R&R

Table 30a. Zonal Parameters

Post-LRS Group (n = 112 scans)																								
	Pachymetry								*Epithelium*								*Stroma*							
	Mean	SD	Min	Max	Repeatability	Reproducibility			Mean	SD	Min	Max	Repeatability	Reproducibility			Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	95% Limits					SD	SD	COV	95% Limits					SD	SD	COV	95% Limits
C_2	504.6	44.6	418.3	573.5	1.3	1.6	0.3%	4.4	57.4	4.3	46.9	64.1	0.7	0.8	1.4%	2.3	447.2	46.4	359.2	519.2	1.2	1.4	0.3%	3.8
T_2_5	531.2	35.5	459.4	594.2	4.2	4.2	0.8%	11.7	58.2	3.4	50.7	66.5	1.0	1.1	1.8%	3.0	473.1	37.5	396.3	539.3	4.3	4.3	0.9%	12.0
ST_2_5	548.2	39.1	461.7	611.9	5.9	6.0	1.1%	16.5	57.4	4.3	48.5	65.4	1.0	1.1	1.8%	2.9	490.7	41.1	399.5	555.9	6.0	6.0	1.2%	16.6
S_2_5	562.3	40.4	474.6	630.0	7.0	7.1	1.3%	19.7	56.9	4.7	44.3	65.7	1.1	1.2	2.1%	3.3	505.4	42.7	412.2	575.7	7.0	7.1	1.4%	19.8
SN_2_5	556.6	40.4	466.2	633.8	6.8	7.0	1.3%	19.4	58.0	4.0	49.1	66.4	1.1	1.2	2.1%	3.3	498.6	42.4	403.1	577.1	7.0	7.2	1.4%	20.0
N_2_5	544.1	38.1	460.5	617.8	5.1	5.4	1.0%	14.9	58.5	3.1	52.1	64.6	0.9	1.0	1.8%	2.9	485.7	39.7	398.4	560.9	5.3	5.7	1.2%	15.7
IN_2_5	539.1	35.3	465.5	599.8	4.5	4.5	0.8%	12.6	58.0	3.2	50.9	63.3	0.8	0.9	1.6%	2.6	481.1	37.0	405.1	546.1	4.9	4.9	1.0%	13.5
I_2_5	535.7	34.7	463.2	595.8	4.7	4.7	0.9%	13.1	58.3	3.5	50.7	63.7	0.8	0.8	1.3%	2.1	477.3	36.9	400.4	542.9	4.9	4.9	1.0%	13.5
IT_2_5	528.9	34.1	454.6	586.9	4.7	4.7	0.9%	13.0	58.3	3.0	50.4	63.7	0.9	0.9	1.5%	2.4	470.6	36.0	390.8	530.4	4.9	4.9	1.0%	13.6
T_5_7	575.3	27.9	515.1	634.2	5.1	5.2	0.9%	14.4	54.7	3.5	47.6	65.1	1.2	1.2	2.3%	3.4	520.5	29.6	457.3	582.1	5.6	5.6	1.1%	15.5
ST_5_7	606.6	30.1	541.1	669.7	7.7	7.7	1.3%	21.4	53.6	4.2	40.3	61.7	1.6	1.7	3.2%	4.7	553.1	31.2	481.8	616.9	8.5	8.5	1.5%	23.6
S_5_7	631.8	30.0	562.8	700.7	8.1	8.1	1.3%	22.5	52.0	4.0	39.5	58.6	1.8	1.9	3.6%	5.2	579.8	30.4	506.4	647.1	8.7	8.8	1.5%	24.4
SN_5_7	620.1	31.5	547.4	699.1	8.3	8.4	1.4%	23.3	54.3	3.8	41.3	60.7	1.4	1.6	3.0%	4.5	565.8	31.7	492.0	645.7	8.8	9.0	1.6%	25.0
N_5_7	598.0	31.0	537.3	680.8	6.2	6.4	1.1%	17.7	55.5	4.0	46.1	65.1	1.1	1.2	2.2%	3.4	542.6	31.6	484.5	625.4	6.6	6.8	1.3%	18.9
IN_5_7	591.5	28.9	534.6	662.4	5.4	5.4	0.9%	14.9	54.8	3.3	47.7	61.4	0.8	0.8	1.4%	2.2	536.7	29.6	474.4	606.7	5.7	5.7	1.1%	15.8
I_5_7	588.3	27.2	538.0	658.3	6.1	6.2	1.0%	17.1	55.4	2.6	49.4	59.9	0.9	0.9	1.7%	2.6	532.9	27.8	479.7	604.1	6.3	6.4	1.2%	17.7
IT_5_7	574.1	26.0	520.3	639.6	6.4	6.4	1.1%	17.8	55.8	3.4	49.5	64.5	1.1	1.2	2.1%	3.3	518.3	27.1	463.4	585.6	6.8	6.8	1.3%	18.9
T_7_9	616.6	23.3	564.0	679.7	6.2	6.4	1.0%	17.7	51.4	2.6	44.4	55.7	1.1	1.2	2.3%	3.3	565.2	23.7	510.5	627.8	6.5	6.7	1.2%	18.7
ST_7_9	653.7	23.8	608.0	712.3	8.5	8.5	1.3%	23.6	50.3	3.8	41.0	59.6	1.5	1.5	3.1%	4.2	603.4	22.6	558.2	659.7	8.9	8.9	1.5%	24.6
S_7_9	682.2	26.6	622.0	739.1	12.6	13.6	2.0%	37.8	48.7	4.2	36.5	57.5	2.5	2.5	5.2%	7.0	633.5	25.2	576.2	690.0	12.8	13.9	2.2%	38.4
SN_7_9	673.9	24.9	613.8	730.7	7.9	7.9	1.2%	21.9	52.1	5.3	41.5	66.6	1.4	1.4	2.7%	3.9	621.7	22.5	566.5	676.7	7.8	7.8	1.2%	21.5
N_7_9	647.5	25.4	604.7	717.3	5.9	6.2	1.0%	17.2	54.6	3.6	47.8	65.1	1.3	1.3	2.3%	3.5	592.9	24.7	552.8	661.4	5.7	6.1	1.0%	16.9
IN_7_9	638.1	26.6	575.3	704.7	7.6	7.6	1.2%	21.1	53.8	2.6	47.0	60.3	0.9	0.9	1.6%	2.5	584.3	25.8	524.6	648.7	7.6	7.6	1.3%	21.2
I_7_9	633.1	24.8	595.2	699.4	6.1	6.1	1.0%	16.9	53.8	2.6	47.3	58.0	1.0	1.1	2.0%	2.9	579.4	25.1	541.7	646.1	6.3	6.3	1.1%	17.5
IT_7_9	618.1	23.7	575.7	683.9	7.5	7.5	1.2%	20.9	53.7	2.5	47.4	59.2	1.2	1.3	2.3%	3.5	564.4	24.3	524.3	631.0	7.6	7.6	1.3%	21.0

Table 30b. Summary Parameters

Post-LRS Group (n = 112 scans)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	95% Limits
Pachymetry								
SN-IT (2-5mm)__Pachy	27.7	14.5	-20.3	71.3	11.3	11.5	41.7%	31.8
S-I (2-5mm)__Pachy	26.7	14.2	-17.3	52.7	11.5	11.6	43.4%	32.1
Min_Pachy	496.7	44.8	409.1	567.8	1.0	1.2	0.2%	3.3
Location_Y_Pachy	-0.2	0.2	-0.8	0.3	0.1	0.1	-50.7%	0.3
Min-Median_Pachy	-38.8	10.0	-59.4	-22.6	1.5	1.5	-4.0%	4.3
Min-Max_Pachy	-95.5	15.6	-135.1	-60.6	7.5	7.9	-8.2%	21.8
Epithelium								
Min_Epi	47.8	3.6	36.1	55.7	1.4	1.5	3.1%	4.1
Max_Epi	64.3	3.5	57.4	69.8	1.0	1.1	1.7%	3.0
Min-Max_Epi	-16.4	5.7	-27.1	-6.7	1.5	1.5	-9.2%	4.2
STD Dev_Epi	3.9	1.6	1.5	6.5	0.3	0.3	7.4%	0.8
S (2-7)__Epi	54.3	3.8	43.5	60.5	1.3	1.4	2.7%	4.0
I (2-7)__Epi	56.8	2.5	51.7	60.6	0.7	0.7	1.3%	2.1
Stroma								
Min_Stroma	439.1	45.9	353.0	513.8	0.7	0.8	0.2%	2.3
Max_Stroma	602.7	26.6	540.9	666.8	8.1	8.4	1.4%	23.2
Min-Max_Stroma	-163.6	27.3	-225.5	-113.9	7.9	8.2	-5.0%	22.6
STD Dev_Stroma	42.6	9.3	28.6	61.8	1.7	1.8	4.2%	4.9
S (2-7)__Stroma	545.1	35.6	462.4	613.8	7.8	7.9	1.5%	22.0
I (2-7)__Stroma	506.9	31.1	442.7	575.5	5.6	5.6	1.1%	15.5

18.15.7 KCN Group R&R

Table 31a. Zonal Parameters

Keratoconus Group (n = 110 scans)																								
	Pachymetry								*Epithelium*								*Stroma*							
	Mean	SD	Min	Max	Repeat ability	Reproducibility			Mean	SD	Min	Max	Repeat ability	Reproducibility			Mean	SD	Min	Max	Repeat ability	Reproducibility		
					SD	SD	COV	95% Limits					SD	SD	COV	95% Limits					SD	SD	COV	95% Limits
C_2	487.0	28.1	403.4	523.7	7.0	7.0	1.4%	19.4	50.9	4.8	40.6	65.5	1.9	1.9	3.7%	5.2	436.0	26.9	358.3	473.1	6.4	6.4	1.5%	17.8
T_2_5	503.5	29.4	411.4	553.5	8.0	8.0	1.6%	22.2	47.3	5.3	36.6	59.0	2.1	2.1	4.4%	5.7	456.1	28.4	366.3	502.7	6.9	7.0	1.5%	19.3
ST_2_5	540.3	29.4	458.6	595.9	7.3	7.5	1.4%	20.8	52.4	4.7	39.8	66.0	2.1	2.1	3.9%	5.7	488.0	29.7	406.5	537.4	6.2	6.5	1.3%	18.0
S_2_5	559.4	32.6	473.2	617.9	7.9	8.1	1.4%	22.4	54.4	3.4	45.4	62.6	2.1	2.2	3.9%	6.0	505.0	32.5	413.9	561.0	6.9	7.2	1.4%	19.9
SN_2_5	555.8	32.1	466.2	615.7	7.5	7.5	1.4%	20.9	54.8	4.6	41.9	63.9	1.8	1.9	3.4%	5.2	501.0	32.2	405.4	556.7	6.9	7.0	1.4%	19.5
N_2_5	537.5	31.9	454.7	596.2	8.7	8.7	1.6%	24.0	54.6	5.1	43.2	67.5	1.6	1.6	3.0%	4.5	482.9	31.0	395.9	536.1	7.9	7.9	1.6%	22.0
IN_2_5	509.9	34.0	431.0	557.9	9.5	9.5	1.9%	26.2	53.9	4.7	44.5	71.6	2.1	2.1	3.9%	5.8	456.1	32.4	380.2	502.7	9.3	9.3	2.0%	25.8
I_2_5	480.0	36.3	397.4	533.1	7.2	7.3	1.5%	20.2	50.9	4.8	40.9	63.9	2.3	2.3	4.6%	6.4	429.1	36.2	341.1	478.5	7.6	7.7	1.8%	21.3
IT_2_5	477.7	29.2	392.0	529.9	8.0	8.1	1.7%	22.4	47.0	4.7	37.4	56.9	1.9	1.9	4.0%	5.3	430.8	27.6	346.1	476.4	7.6	7.7	1.8%	21.3
T_5_7	539.0	42.4	402.1	600.5	9.2	9.2	1.7%	25.5	50.5	5.4	37.0	60.4	1.6	1.6	3.2%	4.5	488.5	42.2	347.7	546.7	8.7	8.8	1.8%	24.5
ST_5_7	586.4	45.8	460.1	675.8	7.5	7.8	1.3%	21.6	52.4	4.3	43.0	63.0	1.8	1.9	3.6%	5.2	534.0	43.9	413.9	619.4	7.4	7.8	1.5%	21.5
S_5_7	610.1	49.3	474.5	689.3	6.9	7.1	1.2%	19.5	51.7	3.7	45.0	60.6	1.8	1.8	3.5%	5.0	558.4	46.9	426.7	633.8	7.0	7.2	1.3%	20.1
SN_5_7	604.0	42.7	486.2	684.7	8.5	8.6	1.4%	24.0	52.7	3.7	43.0	63.0	1.9	2.0	3.8%	5.6	551.3	41.3	431.4	628.2	8.7	9.0	1.6%	25.0
N_5_7	580.5	39.3	479.2	667.1	8.4	8.4	1.4%	23.3	53.6	4.3	44.4	63.1	1.4	1.4	2.6%	3.8	527.0	37.3	424.2	605.9	8.5	8.5	1.6%	23.6
IN_5_7	553.8	34.9	463.6	608.2	9.1	9.1	1.6%	25.3	54.1	5.5	44.4	68.5	1.6	1.6	3.0%	4.4	499.7	31.0	414.6	550.5	9.0	9.0	1.8%	25.0
I_5_7	520.5	40.3	413.6	571.2	8.0	8.3	1.6%	23.0	52.0	8.3	36.8	69.5	2.0	2.0	3.8%	5.5	468.5	36.7	374.1	516.6	7.8	8.0	1.7%	22.3
IT_5_7	514.4	39.4	380.4	583.0	9.9	9.9	1.9%	27.5	50.3	5.6	36.8	59.6	2.3	2.3	4.6%	6.4	464.1	38.5	331.9	526.0	9.0	9.0	1.9%	24.8
T_7_9	587.0	42.0	463.1	663.5	12.4	12.6	2.1%	35.0	51.0	3.7	42.8	58.2	1.1	1.1	2.2%	3.1	536.0	40.8	414.5	615.5	12.1	12.4	2.3%	34.5
ST_7_9	613.2	51.0	474.3	730.7	15.4	15.4	2.5%	42.8	49.6	3.0	43.1	58.3	1.6	1.7	3.4%	4.6	563.6	50.7	427.2	683.5	15.6	15.6	2.8%	43.2
S_7_9	638.6	53.8	479.1	745.7	18.3	18.3	2.9%	50.6	47.5	4.1	35.8	56.1	2.2	2.2	4.5%	6.0	591.1	52.9	437.3	693.9	18.3	18.3	3.1%	50.7
SN_7_9	635.8	42.6	505.4	704.1	13.6	13.7	2.1%	37.8	50.8	4.3	39.0	61.4	1.7	1.7	3.4%	4.8	585.0	40.3	459.4	655.7	13.6	13.6	2.3%	37.8
N_7_9	617.0	36.9	522.4	688.1	9.9	9.9	1.6%	27.5	52.8	4.6	43.4	66.7	1.2	1.2	2.3%	3.4	564.2	33.5	474.5	629.6	9.7	9.7	1.7%	26.8
IN_7_9	602.9	41.3	491.8	698.0	13.6	13.6	2.2%	37.7	53.2	5.5	41.3	63.0	1.3	1.3	2.5%	3.6	549.7	36.8	447.8	638.0	13.6	13.6	2.5%	37.7
I_7_9	579.7	50.9	438.8	692.4	16.3	17.0	2.9%	47.2	52.6	7.9	31.1	67.0	2.1	2.1	4.0%	5.9	527.0	45.3	400.0	628.1	15.9	16.7	3.2%	46.2
IT_7_9	572.5	47.8	413.0	663.5	14.8	14.9	2.6%	41.2	52.2	5.3	37.8	61.2	1.7	1.7	3.3%	4.8	520.3	44.3	367.5	604.6	14.4	14.5	2.8%	40.1

Table 31b. Summary Parameters

Keratoconus Group (n = 110 scans)								
	Mean	SD	Min	Max	Repeat ability	Reproducibility		
					SD	SD	COV	95% Limits
Pachymetry								
SN-IT (2-5mm)__Pachy	78.1	31.7	10.4	166.1	13.3	13.3	16.8%	36.9
S-I (2-5mm)__Pachy	79.4	44.3	7.2	202.3	13.4	13.8	16.9%	38.2
Min_Pachy	447.0	41.7	350.3	513.7	5.2	5.2	1.2%	14.5
Location_Y_Pachy	-1.0	0.4	-2.2	-0.2	0.2	0.2	-20.6%	0.6
Min-Median_Pachy	-66.6	31.4	-145.3	-17.2	4.3	4.4	-6.4%	12.1
Min-Max_Pachy	-136.5	60.1	-283.4	-42.4	7.4	7.6	-5.5%	21.1
Epithelium								
Min_Epi	40.4	5.1	31.4	50.5	1.6	1.6	3.8%	4.3
Max_Epi	63.3	5.4	52.3	75.6	1.7	1.7	2.6%	4.6
Min-Max_Epi	-22.9	7.7	-35.3	-8.4	1.6	1.6	-7.2%	4.5
STD Dev_Epi	5.1	1.8	1.8	8.1	0.3	0.3	6.3%	0.9
S (2-7)__Epi	53.0	2.8	47.7	59.5	1.6	1.7	3.2%	4.7
I (2-7)__Epi	51.5	5.9	40.2	65.1	1.9	1.9	3.7%	5.3
Stroma								
Min_Stroma	396.2	46.3	289.9	462.1	5.4	5.4	1.4%	14.9
Max_Stroma	579.4	46.2	451.1	653.5	8.9	9.1	1.6%	25.2
Min-Max_Stroma	-183.3	67.3	-348.9	-81.6	10.0	10.1	-5.5%	28.0
STD Dev_Stroma	45.3	16.2	19.8	85.9	2.2	2.2	4.9%	6.2
S (2-7)__Stroma	533.4	39.9	420.7	599.0	6.5	6.8	1.3%	19.0
I (2-7)__Stroma	450.1	34.8	373.4	493.5	7.2	7.3	1.6%	20.3

18.16 Evaluation of the Agreement of the Corneal Epithelial Thickness Mapping with SD-OCT

This was a prospective, observational study conducted at three study sites to evaluate the agreement of the Avanti 9mm ETM software with manual measurements performed by three qualified graders. Eligible participants age 18 or older were enrolled and assigned to one of two groups as described under #5 above. The manual measurements were performed at 15 locations along each of the eight meridians in the PachymetryWide scan pattern in a randomized order with a 2-section caliper tool that was available in the previously cleared RTVue XR with CAM device. One eye per study subject was included in the study. One scan of sufficient image quality was required per study eye. Agreement was evaluated with calculation of 95% limits of agreement (LOAs) and Deming regression analyses.

A total of 89 subjects were enrolled. Scans from a total of 85 (17 "normal," 15 contact lens wearers, 18 with dry eye, 19 post-laser refractive surgery, and 16 with keratoconus) were included in analyses. The age distribution and clinical characteristics of the study cohort are shown in Tables 32 through 38.

Table 32. Age Distribution by Entire Study Group and by Sub-Groups

Age Distribution	Min	Median	Mean	Max	SD
Entire Group	**23**	**34**	**38.6**	**73**	**12.6**
Normal	25	32	33.5	66	10.4
Contact Lens	25	30	35.2	58	11.1
Dry Eye	24	51	46.5	73	15.3
Post Laser Refractive Surgery	23	38	38.8	56	8.9
Keratoconus	25	34	38.0	62	11.7

Of the 16 subjects enrolled in the Contact Lens group, 15 wore soft contact lens and one wore hard contact lens. Subjects wore contact lenses for eight or more hours each day for at least one year prior to testing.

Table 33. Contact Lens Wear Data for the Contact Lens Sub-Group

Contact Lens Wear	Min	Median	Mean	Max	SD
Duration (yr)	1	10	11	20	6.07
Hours/Day	8	12	12.6	16	2.06

For the subjects in the Dry Eye group, the severity of the dry eye condition for each study subject was documented using Ocular Surface Disease Index (OSDI) score with a scale from 0 to 100 (mild to severe) and Tear Break Up Time (TBUT).

Table 34. OSDI Score and Tear Break Up Time (TBUT) Distribution of the Dry Eye Sub-Group

Dry Eye	Min	Median	Mean	Max	SD
OSDI score	6.3	20.8	22.2	40.9	5.28
TBUT	1	4.8	4.6	7	1.83

For the subjects in the Post-LRS group, the majority (75%) had had a LASIK procedure versus the PRK procedure (25%), mainly for myopic vision correction (83.3%) and most had the procedure done at least one year or more prior to testing (83.3%).

Table 35. Summary of the Post LRS Sub-Group

Procedure	Total	% Total (n=20)
LASIK	15	75.0%
PRK	5	25.0%
Correction		
Myopic	13	65.0%
Hyperopic	4	20.0%
Astigmatism	0	0.0%
Mixed*	3	15.0%
Duration since procedure		
> 1yr	16	80.0%
> 3mo	4	20.0%
> 1mo	0	0.0%

****Mixed represented procedures either combining myopic correction with astigmatism correction or hyperopic correction with astigmatism correction.***

The 16 subjects in the KCN sub-group all had a clinical diagnosis of keratoconus. None of the subjects in the KCN sub-group underwent any surgical treatment for KCN. The clinical signs of KCN diagnosis for the study subjects, severity of keratoconus for the KCN subjects, and details on corneal curvature are summarized in the table below.

Table 36. KCN Subjects Diagnosis by Clinical Signs

Subject ID	Severity	slit lamp thinning	slit lamp protrusion	slit lamp munson	slit lamp vogt	slit lamp fleisher	slit lamp rizutti	topo bow-tie	topo steep	topo claw
DS-10	moderate	1								1
DS-12	mild	1								1
DS-21	moderate	1			1				1	
DS-29	moderate	1	1						1	1
DS-31	severe	1							1	1
DS-32	moderate	1							1	1
DS-34	severe	1	1						1	
DS-36	moderate	1						1	1	
DS-37	mild	1							1	
MP-08	severe								1	
MP-14	moderate							1	1	
MP-19	moderate	1	1							
MP-25	mild								1	
MP-28	severe									1
MP-31	moderate							1		
K1, SH	moderate									1

Table 37. KCN Group Distribution by Severity

Severity	Total	% Total (n=16)
Mild	3	18.8%
Moderate	9	56.3%
Severe	4	25.0%

Table 38. Distribution of Steep K and Delta K (difference between Steep K and Flat K) of the KCN Sub-Group

Corneal Curvature	Min	Median	Mean	Max	SD
Steep K	41.80	47.76	49.65	70.80	6.47
Delta K	0.36	2.67	3.30	8.33	2.17

12 of the 85 total study scans required manual segmentation editing (five from the keratoconus sub-group, three from the post-laser refractive surgery group, three from the contact lens groups, and one from the normal group).

Manual image grading was performed by three qualified graders. Each grader was assigned one randomized grading order to follow. The graders were masked to each other's results.

18.16.1 Results

Normal Group Agreement

Table 39a. Limits of Agreement Analysis between Software and Manual Measurements

Difference (Software vs. Manual), Normal Group (n= 17)												
Parameter	Epithelial Thickness				Stromal Thickness				Corneal Thickness			
	mean	SD	LOA lower bound*	LOA upper bound**	mean	SD	LOA lower bound*	LOA upper bound**	mean	SD	LOA lower bound*	LOA upper bound**
C_2	-0.4	1.3	-3.1	2.2	-2.5	1.6	-5.6	0.6	-2.9	0.8	-4.4	-1.4
T_2_5	-0.2	2.0	-4.1	3.7	1.0	1.9	-2.8	4.8	0.8	0.9	-1.0	2.6
ST_2_5	-0.3	2.0	-4.1	3.6	2.1	2.0	-1.8	6.1	1.9	1.0	-0.1	3.8
S_2_5	0.4	1.8	-3.2	4.0	2.9	1.8	-0.5	6.4	3.3	0.9	1.6	5.0
SN_2_5	0.3	1.7	-3.0	3.6	2.6	1.6	-0.6	5.8	2.9	1.1	0.7	5.0
N_2_5	0.5	1.4	-2.3	3.3	1.6	1.7	-1.7	4.8	2.1	0.9	0.3	3.9
IN_2_5	0.7	1.7	-2.7	4.1	1.1	2.0	-2.8	4.9	1.8	1.0	-0.1	3.7
I_2_5	0.3	1.8	-3.3	3.9	1.1	2.1	-3.1	5.2	1.4	1.0	-0.5	3.3
IT_2_5	-0.1	1.8	-3.6	3.4	1.0	2.0	-2.9	5.0	1.0	1.0	-1.1	3.0
T_5_7	0.5	2.3	-4.1	5.0	-1.1	2.2	-5.4	3.2	-0.7	0.9	-2.5	1.2
ST_5_7	-0.2	2.4	-4.8	4.4	1.0	2.7	-4.3	6.3	0.8	1.9	-2.9	4.5
S_5_7	0.0	1.9	-3.8	3.7	2.1	3.2	-4.1	8.3	2.0	2.5	-2.9	6.9
SN_5_7	1.2	1.9	-2.6	5.0	-0.2	2.1	-4.3	3.9	1.0	1.2	-1.3	3.3
N_5_7	1.6	2.0	-2.3	5.6	-1.7	2.2	-6.0	2.7	0.0	1.2	-2.4	2.4
IN_5_7	1.5	2.1	-2.6	5.6	-1.2	2.3	-5.7	3.3	0.3	0.9	-1.5	2.2
I_5_7	0.9	2.1	-3.1	4.9	0.1	2.8	-5.5	5.7	1.0	1.8	-2.5	4.5
IT_5_7	0.6	2.3	-3.9	5.1	0.3	4.3	-8.1	8.7	0.9	3.9	-6.7	8.5
T_7_9	-0.5	2.9	-6.3	5.3	0.6	4.7	-8.5	9.8	0.1	3.1	-5.9	6.1
ST_7_9	-1.8	3.5	-8.7	5.0	6.6	8.5	-10.1	23.3	4.8	7.7	-10.2	19.8
S_7_9	-1.9	2.9	-7.5	3.7	11.3	11.4	-11.2	33.7	9.4	10.6	-11.4	30.2
SN_7_9	-0.8	2.9	-6.5	4.9	7.1	8.3	-9.2	23.4	6.3	6.9	-7.2	19.9
N_7_9	1.3	3.0	-4.6	7.1	-0.4	5.4	-11.0	10.2	0.9	4.4	-7.8	9.5
IN_7_9	0.8	2.6	-4.3	6.0	0.7	4.8	-8.7	10.0	1.5	3.9	-6.2	9.2
I_7_9	-0.3	3.1	-6.4	5.9	2.4	5.7	-8.9	13.7	2.1	4.5	-6.6	10.9
IT_7_9	0.1	3.1	-5.9	6.2	2.5	7.4	-12.0	16.9	2.6	7.0	-11.1	16.3

* LOA lower bound = mean-1.96xSD
** LOA upper bound = mean+1.96xSD

Table 39b. Deming Regression Analysis between Software and Manual Measurements

Normal Group (n= 17)																		
Parameter	Epithelial Thickness						Stromal Thickness						Corneal Thickness					
	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper
C_2	-10.1	-22.4	2.3	1.18	0.95	1.41	3.0	-5.5	11.6	0.99	0.97	1.01	-1.8	-5.1	1.4	1.00	0.99	1.00
T_2_5	-20.6	-42.1	0.9	1.38	0.97	1.78	3.1	-11.7	18.0	1.00	0.97	1.03	-1.2	-8.3	5.9	1.00	0.99	1.02
ST_2_5	-8.7	-19.6	2.1	1.16	0.95	1.36	3.8	-5.2	12.8	1.00	0.98	1.01	-0.2	-7.6	7.2	1.00	0.99	1.02
S_2_5	-8.2	-19.9	3.5	1.16	0.94	1.38	4.6	-4.8	14.0	1.00	0.98	1.01	-1.8	-4.0	0.3	1.01	1.01	1.01
SN_2_5	-11.0	-22.7	0.8	1.21	1.00	1.42	3.6	-6.5	13.6	1.00	0.98	1.02	-3.1	-11.8	5.5	1.01	1.00	1.03
N_2_5	-7.4	-19.7	5.0	1.15	0.92	1.38	1.6	-3.8	7.1	1.00	0.99	1.01	1.7	-3.1	6.5	1.00	0.99	1.01
IN_2_5	-10.3	-21.8	1.2	1.20	0.99	1.42	5.3	-2.8	13.4	0.99	0.98	1.01	2.4	-5.0	9.9	1.00	0.99	1.01
I_2_5	-11.4	-23.4	0.7	1.21	0.99	1.43	5.7	-6.1	17.5	0.99	0.97	1.01	1.6	-3.9	7.1	1.00	0.99	1.01
IT_2_5	-18.8	-32.9	-4.7	1.34	1.08	1.60	0.9	-10.5	12.2	1.00	0.98	1.02	-2.6	-8.1	3.0	1.01	1.00	1.02
T_5_7	-14.9	-45.6	15.8	1.29	0.71	1.87	4.9	-8.7	18.6	0.99	0.96	1.01	0.9	-11.3	13.1	1.00	0.98	1.02
ST_5_7	-10.9	-20.1	-1.7	1.20	1.03	1.37	9.5	-0.8	19.8	0.98	0.97	1.00	8.4	0.6	16.2	0.99	0.98	1.00
S_5_7	-8.3	-15.9	-0.6	1.16	1.02	1.29	18.0	9.5	26.5	0.97	0.96	0.99	15.8	5.8	25.9	0.98	0.96	0.99
SN_5_7	-8.4	-21.5	4.6	1.18	0.93	1.42	4.9	-6.3	16.1	0.99	0.97	1.01	-0.6	-7.4	6.1	1.00	0.99	1.01
N_5_7	-2.3	-17.8	13.3	1.07	0.79	1.36	7.0	-11.5	25.5	0.98	0.95	1.02	3.4	-11.3	18.1	0.99	0.97	1.02
IN_5_7	-4.3	-13.6	5.0	1.11	0.94	1.28	-3.1	-10.5	4.3	1.00	0.99	1.02	-3.8	-9.8	2.3	1.01	1.00	1.02
I_5_7	-8.2	-16.7	0.3	1.17	1.01	1.32	3.1	-12.1	18.3	0.99	0.96	1.02	-0.8	-11.7	10.0	1.00	0.98	1.02
IT_5_7	-12.0	-29.4	5.5	1.23	0.90	1.56	-5.4	-26.8	16.1	1.01	0.97	1.05	-13.1	-35.2	9.0	1.02	0.98	1.07
T_7_9	-8.0	-54.7	38.7	1.14	0.26	2.02	20.3	-5.7	46.4	0.96	0.92	1.01	13.7	-13.9	41.4	0.98	0.93	1.02
ST_7_9	-8.1	-49.6	33.4	1.12	0.33	1.92	16.8	-28.3	62.0	0.98	0.91	1.06	12.0	-50.1	74.2	0.99	0.89	1.08
S_7_9	-1.8	-18.0	14.4	1.00	0.68	1.31	5.6	-109.4	120.6	1.01	0.83	1.19	11.0	-98.8	120.9	1.00	0.84	1.16
SN_7_9	-0.6	-11.3	10.1	1.00	0.80	1.19	-16.8	-89.0	55.4	1.04	0.92	1.16	-21.4	-91.7	48.9	1.04	0.93	1.15
N_7_9	7.4	-6.2	21.0	0.89	0.64	1.13	10.9	-33.3	55.1	0.98	0.90	1.06	3.5	-41.0	47.9	1.00	0.93	1.07
IN_7_9	-0.6	-9.7	8.5	1.03	0.85	1.20	7.5	-12.7	27.8	0.99	0.95	1.02	5.6	-13.4	24.7	0.99	0.96	1.02
I_7_9	-14.3	-27.4	-1.2	1.26	1.02	1.50	8.4	-39.7	56.4	0.99	0.90	1.08	1.4	-45.3	48.2	1.00	0.92	1.08
IT_7_9	-8.8	-26.6	9.0	1.16	0.83	1.49	-13.9	-60.8	33.0	1.03	0.94	1.12	-23.8	-78.7	31.0	1.04	0.95	1.14

Contact Lens Group Agreement

Table 40a. Limits of Agreement Analysis between Software and Manual Measurements

Difference (Software vs. Manual), Contact Lens Group (n= 15)												
Parameter	Epithelial Thickness				Stromal Thickness				Corneal Thickness			
	mean	SD	LOA lower bound*	LOA upper bound**	mean	SD	LOA lower bound*	LOA upper bound**	mean	SD	LOA lower bound*	LOA upper bound**
C_2	-0.4	1.3	-2.9	2.1	-1.7	2.0	-5.6	2.3	-2.1	1.6	-5.2	1.0
T_2_5	-0.2	1.7	-3.6	3.1	1.5	1.5	-1.4	4.5	1.3	1.0	-0.6	3.2
ST_2_5	-0.1	1.8	-3.6	3.4	2.4	1.4	-0.4	5.3	2.3	1.1	0.3	4.4
S_2_5	0.3	1.3	-2.2	2.8	3.0	1.5	0.1	5.8	3.3	1.4	0.6	5.9
SN_2_5	0.2	1.4	-2.6	2.9	2.8	1.4	0.1	5.6	3.0	0.9	1.1	4.8
N_2_5	0.4	1.5	-2.7	3.4	1.7	1.3	-0.9	4.3	2.1	0.8	0.6	3.6
IN_2_5	0.4	1.6	-2.7	3.5	1.2	1.6	-2.0	4.3	1.6	0.9	-0.1	3.3
I_2_5	0.0	1.3	-2.4	2.5	1.2	1.2	-1.2	3.6	1.2	0.7	-0.2	2.6
IT_2_5	0.0	1.8	-3.6	3.6	1.1	1.6	-2.1	4.2	1.1	1.0	-0.9	3.1
T_5_7	0.1	2.2	-4.1	4.4	-0.1	2.5	-5.1	4.9	0.0	1.4	-2.7	2.8
ST_5_7	-0.1	2.3	-4.6	4.4	0.6	2.3	-3.9	5.1	0.5	1.0	-1.4	2.4
S_5_7	0.1	1.9	-3.6	3.7	1.4	2.0	-2.4	5.3	1.5	1.0	-0.5	3.4
SN_5_7	0.2	1.8	-3.4	3.8	0.8	2.0	-3.2	4.8	1.0	0.9	-0.9	2.8
N_5_7	1.0	1.7	-2.3	4.3	-0.8	1.9	-4.5	2.9	0.1	1.0	-1.8	2.1
IN_5_7	1.2	1.8	-2.2	4.7	-0.8	1.9	-4.5	2.9	0.5	0.9	-1.4	2.3
I_5_7	0.3	1.7	-2.9	3.6	-0.3	1.7	-3.6	3.1	0.1	0.9	-1.8	1.9
IT_5_7	0.7	2.6	-4.3	5.8	-0.5	4.4	-9.2	8.2	0.2	3.3	-6.4	6.8
T_7_9	0.1	3.0	-5.7	5.8	1.5	4.3	-6.9	10.0	1.6	3.5	-5.3	8.5
ST_7_9	-1.7	3.4	-8.4	5.0	4.1	7.2	-10.0	18.2	2.4	5.8	-9.0	13.8
S_7_9	-1.7	3.1	-7.8	4.3	6.8	7.8	-8.5	22.2	5.1	6.3	-7.2	17.4
SN_7_9	-1.3	2.7	-6.5	4.0	3.3	7.5	-11.5	18.0	2.0	6.0	-9.8	13.9
N_7_9	0.4	2.2	-4.0	4.7	0.0	4.2	-8.3	8.3	0.4	3.0	-5.5	6.3
IN_7_9	1.2	2.3	-3.2	5.6	-0.6	3.6	-7.7	6.6	0.6	2.7	-4.6	5.9
I_7_9	0.0	2.7	-5.3	5.3	0.9	4.4	-7.7	9.4	0.9	2.7	-4.4	6.2
IT_7_9	0.5	3.4	-6.0	7.1	-1.0	11.9	-24.3	22.4	-0.4	11.2	-22.3	21.5

* LOA lower bound = mean-1.96xSD

** LOA upper bound = mean+1.96xSD

Table 40b. Deming Regression Analysis between Software and Manual Measurements

Contact Lens Group (n= 15)																		
Parameter	Epithelial Thickness						Stromal Thickness						Corneal Thickness					
	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper
C_2	-2.3	-12.7	8.2	1.04	0.83	1.25	0.4	-20.4	21.3	1.00	0.95	1.04	6.5	-10.1	23.1	0.98	0.95	1.01
T_2_5	5.4	-3.7	14.6	0.89	0.71	1.06	6.2	-18.4	30.7	0.99	0.94	1.04	-1.4	-21.3	18.6	1.01	0.97	1.04
ST_2_5	5.3	-2.3	12.9	0.89	0.75	1.04	-1.4	-28.9	26.1	1.01	0.95	1.06	-11.5	-25.5	2.6	1.03	1.00	1.05
S_2_5	2.8	-0.5	6.0	0.95	0.89	1.01	-10.7	-27.1	5.6	1.03	0.99	1.06	-14.3	-32.6	4.0	1.03	1.00	1.06
SN_2_5	3.3	-0.8	7.4	0.94	0.86	1.02	-6.7	-21.6	8.3	1.02	0.99	1.05	-6.3	-15.2	2.5	1.02	1.00	1.03
N_2_5	5.2	2.9	7.6	0.91	0.86	0.95	-0.4	-7.9	7.1	1.00	0.99	1.02	-5.7	-16.6	5.2	1.01	0.99	1.03
IN_2_5	2.7	-5.4	10.9	0.96	0.79	1.12	-10.1	-23.4	3.1	1.02	1.00	1.05	-8.7	-16.5	-0.9	1.02	1.00	1.03
I_2_5	1.7	-6.1	9.5	0.97	0.81	1.12	-4.3	-15.0	6.4	1.01	0.99	1.03	-4.3	-13.0	4.3	1.01	0.99	1.03
IT_2_5	3.8	-6.3	13.9	0.93	0.74	1.12	3.6	-5.7	12.8	0.99	0.98	1.01	-4.1	-18.0	9.7	1.01	0.98	1.04
T_5_7	6.4	-10.9	23.8	0.88	0.54	1.21	9.0	-9.7	27.7	0.98	0.95	1.02	-5.9	-16.2	4.5	1.01	0.99	1.03
ST_5_7	1.6	-12.9	16.0	0.97	0.68	1.25	4.2	-28.1	36.4	0.99	0.93	1.05	-10.4	-33.5	12.6	1.02	0.98	1.06
S_5_7	2.7	-5.7	11.1	0.95	0.78	1.11	10.6	-23.5	44.7	0.98	0.92	1.05	6.2	-23.9	36.4	0.99	0.94	1.04
SN_5_7	0.3	-6.2	6.9	1.00	0.87	1.13	1.4	-8.3	11.1	1.00	0.98	1.02	-6.7	-30.7	17.3	1.01	0.97	1.05
N_5_7	7.5	3.1	12.0	0.87	0.78	0.96	-5.1	-11.2	1.1	1.01	1.00	1.02	-10.3	-20.5	-0.2	1.02	1.00	1.04
IN_5_7	5.6	-0.8	11.9	0.92	0.80	1.04	-9.3	-18.3	-0.3	1.02	1.00	1.03	-7.0	-23.7	9.7	1.01	0.98	1.04
I_5_7	-5.7	-11.5	0.1	1.11	1.01	1.22	4.0	-9.1	17.2	0.99	0.97	1.02	4.1	-8.4	16.6	0.99	0.97	1.02
IT_5_7	6.1	-27.0	39.2	0.90	0.26	1.53	32.5	-42.0	106.9	0.94	0.79	1.08	21.4	-43.9	86.7	0.96	0.84	1.08
T_7_9	2.3	-13.1	17.7	0.96	0.65	1.26	-5.6	-22.0	10.8	1.01	0.98	1.04	-26.6	-38.2	-14.9	1.05	1.03	1.07
ST_7_9	1.6	-22.1	25.4	0.93	0.46	1.40	13.0	-42.6	68.6	0.98	0.89	1.08	-12.8	-51.0	25.4	1.02	0.96	1.09
S_7_9	-6.3	-22.9	10.2	1.10	0.77	1.43	-31.8	-51.7	-11.9	1.06	1.03	1.09	-36.3	-80.2	7.5	1.06	1.00	1.13
SN_7_9	-2.5	-12.1	7.1	1.02	0.84	1.21	-12.1	-117.9	93.7	1.03	0.85	1.20	-4.7	-121.1	111.6	1.01	0.83	1.19
N_7_9	6.3	0.2	12.5	0.88	0.77	1.00	20.6	-1.9	43.0	0.96	0.93	1.00	20.5	-11.4	52.4	0.97	0.92	1.02
IN_7_9	-0.8	-8.9	7.3	1.04	0.88	1.19	11.2	-31.5	53.9	0.98	0.90	1.06	16.5	-26.4	59.3	0.97	0.90	1.05
I_7_9	-9.6	-24.8	5.5	1.18	0.90	1.47	-3.4	-17.2	10.4	1.01	0.98	1.03	15.7	5.4	26.0	0.98	0.96	0.99
IT_7_9	10.5	-16.9	37.8	0.81	0.28	1.34	69.9	-86.7	226.5	0.87	0.58	1.16	59.2	-128.8	247.2	0.90	0.58	1.22

Dry Eye Group Agreement

Table 41a. Limits of Agreement Analysis between Software and Manual Measurements

Difference (Software vs. Manual), Dry Eye Group (n= 18)												
Parameter	Epithelial Thickness				Stromal Thickness				Corneal Thickness			
	mean	SD	LOA lower bound*	LOA upper bound**	mean	SD	LOA lower bound*	LOA upper bound**	mean	SD	LOA lower bound*	LOA upper bound**
C_2	-0.3	1.0	-2.3	1.7	-2.4	1.1	-4.5	-0.3	-2.7	0.7	-4.1	-1.3
T_2_5	-0.2	1.6	-3.3	2.8	1.1	1.8	-2.4	4.5	0.8	0.8	-0.6	2.3
ST_2_5	-0.3	1.8	-3.9	3.2	2.2	1.7	-1.1	5.5	1.9	1.0	-0.1	3.8
S_2_5	0.3	1.5	-2.5	3.2	2.8	1.6	-0.4	6.0	3.1	1.3	0.6	5.6
SN_2_5	-0.1	1.8	-3.7	3.4	2.8	2.1	-1.4	7.0	2.7	1.1	0.6	4.7
N_2_5	-0.1	1.5	-3.1	2.8	1.9	1.5	-1.1	4.9	1.7	0.7	0.3	3.2
IN_2_5	0.1	1.6	-3.1	3.2	1.6	1.8	-1.9	5.0	1.6	0.9	-0.1	3.3
I_2_5	0.2	1.8	-3.3	3.7	1.2	1.9	-2.6	5.0	1.4	1.0	-0.6	3.5
IT_2_5	0.1	1.5	-2.8	3.0	0.5	1.4	-2.3	3.3	0.6	0.8	-1.0	2.2
T_5_7	0.7	2.9	-5.1	6.5	-1.4	4.8	-10.9	8.0	-0.7	4.3	-9.1	7.6
ST_5_7	0.4	2.7	-4.8	5.6	0.9	4.6	-8.2	10.0	1.3	3.6	-5.8	8.4
S_5_7	0.5	2.3	-4.0	5.0	1.8	4.6	-7.2	10.7	2.3	4.2	-6.0	10.6
SN_5_7	0.8	2.2	-3.6	5.1	0.0	2.3	-4.4	4.5	0.8	1.5	-2.2	3.8
N_5_7	0.6	1.8	-3.0	4.1	-0.3	2.0	-4.2	3.7	0.3	1.1	-1.8	2.4
IN_5_7	1.1	1.8	-2.4	4.5	-0.7	1.8	-4.3	2.8	0.3	0.9	-1.4	2.0
I_5_7	0.6	1.9	-3.0	4.3	0.2	1.8	-3.3	3.7	0.8	0.9	-1.0	2.5
IT_5_7	0.9	2.6	-4.2	6.0	-0.5	2.4	-5.3	4.2	0.3	2.1	-3.7	4.4
T_7_9	-0.2	4.0	-8.0	7.6	1.6	8.2	-14.5	17.8	1.4	7.4	-13.1	16.0
ST_7_9	-1.5	3.4	-8.2	5.2	4.9	5.6	-6.2	15.9	3.4	5.5	-7.4	14.2
S_7_9	-2.1	3.0	-7.9	3.7	7.4	9.2	-10.7	25.5	5.3	8.3	-11.0	21.6
SN_7_9	-0.6	2.8	-6.0	4.9	5.3	11.1	-16.5	27.1	4.7	10.0	-15.0	24.4
N_7_9	0.5	3.2	-5.7	6.7	0.1	4.9	-9.6	9.8	0.6	4.2	-7.6	8.8
IN_7_9	0.4	3.0	-5.4	6.3	0.3	4.1	-7.7	8.4	0.8	3.1	-5.3	6.8
I_7_9	-0.4	3.1	-6.6	5.7	1.6	3.4	-5.1	8.2	1.1	1.8	-2.5	4.7
IT_7_9	0.4	3.2	-5.9	6.7	1.3	5.6	-9.6	12.2	1.7	4.2	-6.6	10.0

* LOA lower bound = mean-1.96xSD

** LOA upper bound = mean+1.96xSD

Table 41b. Deming Regression Analysis between Software and Manual Measurements

Dry Eye Group (n= 18)																		
Parameter	Epithelial Thickness						Stromal Thickness						Corneal Thickness					
	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper
C_2	-1.6	-6.6	3.3	1.02	0.93	1.12	0.6	-3.3	4.4	0.99	0.99	1.00	-0.8	-13.4	11.8	1.00	0.97	1.02
T_2_5	5.3	0.3	10.3	0.89	0.80	0.99	-5.2	-22.0	11.5	1.01	0.98	1.05	-4.0	-8.1	0.2	1.01	1.00	1.02
ST_2_5	-0.2	-9.7	9.4	1.00	0.81	1.18	-0.2	-7.8	7.4	1.00	0.99	1.02	0.0	-4.9	5.0	1.00	0.99	1.01
S_2_5	-4.1	-11.0	2.8	1.08	0.95	1.22	2.4	-7.4	12.3	1.00	0.98	1.02	1.2	-9.1	11.5	1.00	0.99	1.02
SN_2_5	-8.6	-23.8	6.6	1.16	0.88	1.44	8.0	-3.3	19.3	0.99	0.97	1.01	2.6	-5.2	10.3	1.00	0.99	1.01
N_2_5	-10.6	-17.7	-3.5	1.20	1.06	1.33	5.8	-7.0	18.6	0.99	0.97	1.02	0.4	-4.0	4.8	1.00	0.99	1.01
IN_2_5	-2.6	-11.7	6.5	1.05	0.88	1.22	2.0	-14.0	17.9	1.00	0.97	1.03	-4.6	-11.6	2.5	1.01	1.00	1.02
I_2_5	-3.4	-8.9	2.0	1.07	0.96	1.17	-5.7	-17.9	6.4	1.01	0.99	1.04	-4.5	-10.5	1.4	1.01	1.00	1.02
IT_2_5	-2.1	-7.3	3.0	1.04	0.95	1.14	-7.1	-11.3	-2.8	1.02	1.01	1.02	-6.1	-14.3	2.1	1.01	1.00	1.03
T_5_7	4.0	-14.3	22.2	0.94	0.58	1.29	5.5	-83.5	94.5	0.99	0.81	1.16	30.1	-35.8	95.9	0.95	0.83	1.06
ST_5_7	-8.4	-38.2	21.5	1.17	0.60	1.73	-34.9	-112.6	42.8	1.07	0.92	1.21	-21.3	-86.9	44.3	1.04	0.92	1.15
S_5_7	-6.0	-22.0	9.9	1.13	0.82	1.43	-25.7	-95.0	43.6	1.05	0.92	1.17	-30.0	-99.5	39.4	1.05	0.94	1.17
SN_5_7	0.6	-14.6	15.8	1.00	0.72	1.29	5.0	-6.0	16.1	0.99	0.97	1.01	-1.7	-15.8	12.4	1.00	0.98	1.03
N_5_7	-1.9	-13.1	9.3	1.05	0.84	1.25	-2.4	-20.7	16.0	1.00	0.97	1.04	-7.3	-21.3	6.8	1.01	0.99	1.04
IN_5_7	-0.4	-11.0	10.1	1.03	0.83	1.22	6.2	-2.3	14.6	0.99	0.97	1.00	-3.5	-11.4	4.3	1.01	0.99	1.02
I_5_7	0.0	-11.7	11.7	1.01	0.79	1.23	-6.7	-13.6	0.3	1.01	1.00	1.03	-0.2	-6.6	6.2	1.00	0.99	1.01
IT_5_7	-1.0	-22.2	20.2	1.03	0.64	1.43	-10.8	-25.8	4.2	1.02	0.99	1.05	1.3	-9.3	11.9	1.00	0.98	1.02
T_7_9	-1.5	-22.6	19.5	1.03	0.62	1.43	-8.8	-99.3	81.6	1.02	0.85	1.19	26.7	-25.6	79.0	0.96	0.87	1.05
ST_7_9	4.8	-8.2	17.8	0.88	0.64	1.12	13.4	-16.9	43.8	0.99	0.93	1.04	33.6	-9.3	76.4	0.95	0.89	1.02
S_7_9	-4.4	-21.3	12.5	1.05	0.73	1.37	24.4	-30.3	79.2	0.97	0.89	1.06	10.2	-29.7	50.1	0.99	0.94	1.05
SN_7_9	2.4	-6.4	11.2	0.94	0.78	1.11	-37.8	-131.4	55.9	1.07	0.92	1.23	-56.7	-157.6	44.2	1.09	0.94	1.25
N_7_9	-8.3	-23.3	6.7	1.16	0.89	1.44	-14.3	-46.9	18.4	1.02	0.97	1.08	-34.9	-61.5	-8.2	1.06	1.01	1.10
IN_7_9	-7.6	-27.1	11.9	1.15	0.78	1.52	3.2	-13.1	19.5	0.99	0.97	1.02	-13.2	-28.7	2.3	1.02	1.00	1.05
I_7_9	-7.6	-25.3	10.1	1.13	0.81	1.45	2.4	-10.4	15.1	1.00	0.98	1.02	-1.3	-8.6	6.0	1.00	0.99	1.02
IT_7_9	3.1	-30.3	36.5	0.95	0.33	1.57	-15.1	-42.4	12.2	1.03	0.98	1.08	-1.3	-17.1	14.4	1.01	0.98	1.03

Post-LRS Group Agreement

Table 42a. Limits of Agreement Analysis between Software and Manual Measurements

Difference (Software vs. Manual), Post-Laser Refractive Surgery Group (n= 19)												
Parameter	Epithelial Thickness				Stromal Thickness				Corneal Thickness			
	mean	SD	LOA lower bound*	LOA upper bound**	mean	SD	LOA lower bound*	LOA upper bound**	mean	SD	LOA lower bound*	LOA upper bound**
C_2	0.4	1.2	-2.1	2.8	-3.9	1.8	-7.4	-0.5	-3.5	1.0	-5.5	-1.5
T_2_5	1.4	2.1	-2.7	5.6	0.3	2.3	-4.2	4.8	1.7	1.4	-1.1	4.6
ST_2_5	1.1	2.2	-3.3	5.5	1.8	2.4	-2.9	6.5	2.9	1.6	-0.1	6.0
S_2_5	1.1	2.0	-2.8	5.0	3.1	2.1	-0.9	7.2	4.2	1.9	0.5	7.9
SN_2_5	0.8	2.1	-3.3	4.9	3.1	2.0	-0.8	6.9	3.9	1.4	1.1	6.7
N_2_5	0.7	1.9	-3.1	4.5	2.2	1.9	-1.4	5.9	2.9	1.6	-0.3	6.2
IN_2_5	1.0	1.8	-2.6	4.6	1.6	2.0	-2.4	5.6	2.6	1.6	-0.6	5.8
I_2_5	1.3	1.7	-2.1	4.7	1.2	1.8	-2.4	4.7	2.5	1.4	-0.3	5.3
IT_2_5	1.6	1.8	-1.9	5.0	0.2	2.0	-3.8	4.1	1.7	1.5	-1.1	4.6
T_5_7	1.1	4.0	-6.6	8.9	-1.2	4.5	-10.1	7.8	0.0	1.5	-3.0	2.9
ST_5_7	0.4	3.1	-5.7	6.5	1.1	4.1	-7.1	9.2	1.5	2.1	-2.7	5.7
S_5_7	1.3	3.6	-5.8	8.4	1.2	4.2	-7.0	9.4	2.5	2.0	-1.3	6.4
SN_5_7	1.4	2.9	-4.3	7.1	-0.6	3.2	-6.9	5.8	0.8	2.7	-4.5	6.1
N_5_7	1.4	2.7	-3.8	6.6	-0.4	2.7	-5.7	5.0	1.1	1.4	-1.6	3.7
IN_5_7	1.5	2.5	-3.3	6.3	-0.3	2.9	-6.0	5.4	1.2	1.5	-1.8	4.2
I_5_7	1.0	2.9	-4.7	6.7	1.1	3.8	-6.4	8.7	2.1	1.7	-1.2	5.5
IT_5_7	0.9	2.7	-4.3	6.2	-0.4	3.4	-7.0	6.3	0.6	1.4	-2.3	3.4
T_7_9	-1.3	4.2	-9.4	6.9	1.8	7.5	-12.9	16.5	0.5	5.2	-9.7	10.7
ST_7_9	-1.0	4.5	-9.9	7.9	3.6	9.5	-15.1	22.3	2.6	7.4	-11.9	17.1
S_7_9	-0.5	5.1	-10.4	9.4	4.2	13.7	-22.7	31.1	3.7	12.6	-20.9	28.3
SN_7_9	-0.3	4.2	-8.5	7.9	2.5	7.5	-12.2	17.2	2.2	6.7	-10.9	15.3
N_7_9	1.1	3.3	-5.5	7.6	0.7	5.4	-9.9	11.2	1.8	4.3	-6.7	10.2
IN_7_9	0.3	3.7	-7.0	7.6	1.0	5.9	-10.6	12.6	1.3	4.6	-7.6	10.3
I_7_9	-0.2	3.4	-6.7	6.4	2.0	5.4	-8.5	12.6	1.9	3.8	-5.6	9.3
IT_7_9	-0.3	4.0	-8.2	7.5	1.9	5.6	-9.1	12.8	1.6	3.7	-5.8	8.9

* LOA lower bound = mean-1.96xSD

** LOA upper bound = mean+1.96xSD

Table 42b. Deming Regression Analysis between Software and Manual Measurements

Post-Laser Refractive Surgery Group (n= 19)																		
Parameter	Epithelial Thickness						Stromal Thickness						Corneal Thickness					
	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper
C_2	-4.5	-8.1	-0.9	1.09	1.02	1.15	-10.1	-17.0	-3.2	1.02	1.00	1.03	-6.8	-11.1	-2.5	1.01	1.00	1.02
T_2_5	-5.6	-14.8	3.6	1.12	0.96	1.29	-2.9	-17.1	11.3	1.01	0.98	1.04	1.1	-7.7	9.9	1.00	0.98	1.02
ST_2_5	-5.1	-12.1	1.8	1.11	0.98	1.24	-1.6	-9.2	5.9	1.01	0.99	1.03	5.1	-2.0	12.1	1.00	0.98	1.01
S_2_5	-4.3	-12.1	3.4	1.10	0.95	1.25	-2.7	-22.6	17.2	1.02	0.97	1.06	10.3	0.3	20.3	0.99	0.97	1.01
SN_2_5	-5.2	-12.6	2.1	1.11	0.97	1.25	4.9	-22.8	32.7	1.00	0.94	1.05	13.3	6.3	20.4	0.98	0.97	1.00
N_2_5	-4.6	-14.2	5.0	1.10	0.92	1.27	4.8	-16.5	26.1	1.00	0.95	1.04	11.6	3.5	19.8	0.98	0.97	1.00
IN_2_5	-2.1	-11.3	7.2	1.05	0.89	1.21	24.6	-4.3	53.6	0.96	0.89	1.02	2.5	-4.4	9.4	1.00	0.99	1.01
I_2_5	-4.5	-9.5	0.6	1.10	1.01	1.19	11.0	-36.2	58.2	0.98	0.88	1.08	5.6	-2.0	13.2	0.99	0.98	1.01
IT_2_5	-2.6	-8.6	3.4	1.07	0.96	1.18	-21.1	-75.8	33.6	1.05	0.93	1.16	1.8	-6.4	9.9	1.00	0.98	1.02
T_5_7	-24.2	-54.4	6.0	1.47	0.91	2.03	-14.8	-62.2	32.6	1.03	0.93	1.12	2.0	-9.2	13.2	1.00	0.98	1.02
ST_5_7	-11.6	-25.9	2.6	1.22	0.97	1.48	-0.4	-22.7	22.0	1.00	0.96	1.04	0.7	-8.5	10.0	1.00	0.99	1.02
S_5_7	-9.3	-17.1	-1.4	1.20	1.07	1.34	-30.0	-67.0	7.0	1.06	0.99	1.13	2.9	-8.1	13.8	1.00	0.98	1.02
SN_5_7	4.0	-8.8	16.8	0.95	0.71	1.19	-26.9	-53.1	-0.7	1.05	1.00	1.10	2.1	-26.1	30.3	1.00	0.95	1.04
N_5_7	-6.3	-22.9	10.3	1.14	0.83	1.46	-15.7	-49.8	18.5	1.03	0.97	1.09	-0.3	-10.3	9.7	1.00	0.99	1.02
IN_5_7	-1.7	-12.3	8.9	1.06	0.86	1.25	-8.4	-68.0	51.2	1.01	0.91	1.12	0.8	-8.5	10.0	1.00	0.98	1.02
I_5_7	-14.7	-32.4	3.0	1.28	0.96	1.60	-17.8	-43.7	8.0	1.03	0.98	1.08	5.8	-4.3	16.0	0.99	0.98	1.01
IT_5_7	-17.2	-40.8	6.3	1.33	0.90	1.76	-57.4	-155.1	40.3	1.11	0.91	1.30	1.4	-11.6	14.4	1.00	0.98	1.02
T_7_9	-1.5	-59.9	57.0	1.00	-0.13	2.14	-10.5	-55.9	34.9	1.03	0.95	1.11	-13.7	-44.0	16.6	1.02	0.97	1.07
ST_7_9	-5.1	-49.0	38.8	1.08	0.21	1.95	-9.6	-55.7	36.5	1.02	0.94	1.10	-7.5	-44.7	29.7	1.02	0.96	1.08
S_7_9	-32.2	-86.2	21.8	1.64	0.52	2.75	16.0	-60.6	92.6	0.97	0.83	1.11	-9.2	-95.1	76.8	1.02	0.89	1.15
SN_7_9	1.5	-14.3	17.4	0.96	0.65	1.28	3.4	-58.2	65.1	1.00	0.89	1.11	-31.4	-70.0	7.2	1.05	0.99	1.11
N_7_9	-10.6	-26.6	5.4	1.22	0.92	1.51	26.6	-15.3	68.4	0.95	0.88	1.03	-32.8	-71.1	5.6	1.05	0.99	1.11
IN_7_9	1.4	-15.4	18.3	0.98	0.67	1.29	45.4	-29.8	120.6	0.92	0.78	1.05	-14.5	-32.0	3.0	1.03	1.00	1.05
I_7_9	10.6	-4.7	25.8	0.80	0.52	1.08	-31.0	-74.8	12.9	1.07	0.98	1.15	14.5	-2.7	31.7	0.98	0.95	1.01
IT_7_9	13.6	-17.3	44.5	0.73	0.14	1.32	-49.6	-116.0	16.9	1.10	0.97	1.22	-6.8	-23.9	10.2	1.01	0.99	1.04

Keratoconus Group Agreement

Table 43a. Limits of Agreement Analysis between Software and Manual Measurements

Difference (Software vs. Manual), Keratoconus Group (n= 16)												
Parameter	Epithelial Thickness				Stromal Thickness				Corneal Thickness			
	mean	SD	LOA lower bound*	LOA upper bound**	mean	SD	LOA lower bound*	LOA upper bound**	mean	SD	LOA lower bound*	LOA upper bound**
C_2	-0.4	1.9	-4.2	3.4	-3.4	1.9	-7.2	0.5	-3.8	2.2	-8.1	0.6
T_2_5	-0.2	3.9	-7.9	7.5	1.3	3.3	-5.2	7.8	1.1	2.6	-4.0	6.2
ST_2_5	1.0	3.0	-4.9	6.8	3.4	2.9	-2.3	9.2	4.4	3.3	-2.1	10.9
S_2_5	1.0	2.4	-3.7	5.8	4.8	3.1	-1.4	10.9	5.8	4.2	-2.4	14.1
SN_2_5	0.7	2.6	-4.4	5.7	4.5	3.1	-1.6	10.6	5.2	4.1	-2.8	13.1
N_2_5	0.8	2.4	-3.9	5.6	3.7	2.9	-2.0	9.3	4.5	3.9	-3.2	12.2
IN_2_5	0.3	3.8	-7.3	7.8	4.0	4.8	-5.4	13.5	4.3	3.4	-2.4	11.0
I_2_5	-0.5	4.6	-9.5	8.6	1.5	7.6	-13.3	16.3	1.0	5.7	-10.2	12.3
IT_2_5	-0.6	4.3	-8.9	7.8	-1.5	9.7	-20.4	17.4	-2.1	10.5	-22.6	18.4
T_5_7	0.5	4.4	-8.1	9.1	-2.1	5.8	-13.5	9.2	-1.6	5.8	-13.0	9.7
ST_5_7	1.2	3.5	-5.7	8.2	1.5	4.1	-6.5	9.5	2.8	3.7	-4.6	10.1
S_5_7	1.1	3.1	-5.0	7.2	3.6	7.2	-10.4	17.7	4.8	6.8	-8.5	18.0
SN_5_7	1.3	3.2	-4.9	7.6	1.8	6.5	-10.9	14.5	3.2	5.4	-7.4	13.8
N_5_7	1.3	2.8	-4.1	6.7	-0.8	5.2	-11.0	9.4	0.5	5.3	-9.8	10.8
IN_5_7	1.5	2.7	-3.7	6.7	-0.9	9.3	-19.2	17.4	0.6	10.0	-19.1	20.2
I_5_7	1.0	3.8	-6.4	8.4	-2.1	5.8	-13.4	9.3	-1.1	6.2	-13.3	11.1
IT_5_7	0.7	4.9	-9.0	10.4	-6.5	12.2	-30.5	17.5	-5.8	11.6	-28.5	16.8
T_7_9	0.6	3.6	-6.5	7.7	4.9	14.2	-22.9	32.6	5.5	13.7	-21.4	32.3
ST_7_9	0.2	4.0	-7.7	8.0	1.9	11.4	-20.4	24.2	2.1	11.3	-20.0	24.2
S_7_9	0.0	4.0	-7.8	7.8	-1.0	16.0	-32.3	30.3	-1.0	14.5	-29.5	27.5
SN_7_9	0.9	4.7	-8.2	10.0	2.3	11.0	-19.3	23.9	3.2	9.8	-16.0	22.3
N_7_9	0.8	4.3	-7.7	9.2	-0.1	6.1	-12.0	11.8	0.7	4.5	-8.1	9.5
IN_7_9	0.3	3.8	-7.1	7.7	0.0	12.1	-23.8	23.7	0.3	10.9	-21.2	21.7
I_7_9	0.5	4.2	-7.6	8.7	5.5	13.2	-20.4	31.4	6.0	12.3	-18.1	30.2
IT_7_9	0.8	4.5	-8.0	9.6	2.3	18.8	-34.6	39.1	3.1	16.8	-29.9	36.1

* LOA lower bound = mean-1.96xSD
** LOA upper bound = mean+1.96xSD

Table 43b. Deming Regression Analysis between Software and Manual Measurements

	Keratoconus Group (n= 16)																	
Parameter	Epithelial Thickness						Stromal Thickness						Corneal Thickness					
	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper	intercept	intercept CI lower	intercept CI upper	slope	slope CI lower	slope CI upper
C_2	-5.2	-8.8	-1.7	1.09	1.02	1.16	-12.4	-16.6	-8.1	1.02	1.01	1.03	-16.2	-27.8	-4.7	1.03	1.00	1.05
T_2_5	-8.7	-26.2	8.7	1.17	0.85	1.48	-5.1	-13.5	3.3	1.01	0.99	1.03	-12.3	-29.2	4.5	1.03	0.99	1.06
ST_2_5	-5.0	-15.2	5.1	1.11	0.94	1.28	-3.2	-10.7	4.4	1.01	0.99	1.03	-8.5	-25.1	8.2	1.02	0.99	1.06
S_2_5	-0.5	-12.9	11.9	1.03	0.79	1.26	1.5	-5.8	8.9	1.00	0.99	1.02	-6.4	-33.6	20.9	1.02	0.97	1.07
SN_2_5	-5.8	-27.3	15.6	1.12	0.74	1.49	2.0	-4.1	8.1	1.00	0.99	1.01	-0.4	-36.8	35.9	1.01	0.95	1.07
N_2_5	-4.2	-19.2	10.8	1.09	0.83	1.35	4.1	-3.7	12.0	1.00	0.98	1.01	-2.4	-43.7	39.0	1.01	0.94	1.09
IN_2_5	-3.3	-10.1	3.5	1.06	0.93	1.20	-0.9	-8.9	7.2	1.01	0.99	1.02	15.1	-14.4	44.6	0.98	0.92	1.03
I_2_5	1.1	-36.1	38.2	0.97	0.26	1.69	-0.9	-8.1	6.3	1.00	0.99	1.02	8.1	-27.1	43.3	0.99	0.92	1.05
IT_2_5	-0.3	-27.6	27.0	1.00	0.45	1.54	-2.9	-10.5	4.7	1.01	0.99	1.02	-32.2	-96.4	32.0	1.06	0.94	1.18
T_5_7	-7.1	-35.6	21.3	1.14	0.61	1.68	-0.7	-22.1	20.8	1.00	0.96	1.04	-21.0	-62.7	20.6	1.04	0.96	1.11
ST_5_7	-17.8	-43.0	7.4	1.36	0.88	1.83	-4.7	-19.0	9.6	1.01	0.98	1.04	-3.1	-27.7	21.6	1.01	0.97	1.05
S_5_7	-8.1	-50.2	34.0	1.17	0.39	1.96	-20.8	-45.5	3.8	1.04	1.00	1.08	-28.5	-74.4	17.4	1.05	0.98	1.13
SN_5_7	0.8	-92.9	94.5	1.01	-0.69	2.71	-11.2	-28.9	6.4	1.02	0.99	1.05	-26.3	-62.8	10.3	1.05	0.99	1.11
N_5_7	0.4	-20.5	21.2	1.02	0.65	1.39	-5.3	-23.7	13.0	1.01	0.98	1.04	-15.9	-58.7	27.0	1.03	0.96	1.10
IN_5_7	4.5	-8.0	17.1	0.95	0.73	1.16	-0.4	-16.2	15.4	1.00	0.97	1.03	-8.9	-80.4	62.5	1.02	0.90	1.13
I_5_7	-7.4	-28.1	13.3	1.15	0.79	1.51	11.4	-15.1	37.8	0.98	0.93	1.03	-14.0	-36.7	8.7	1.02	0.99	1.06
IT_5_7	3.7	-37.0	44.3	0.94	0.19	1.70	6.5	-14.4	27.4	0.99	0.94	1.03	-57.1	-152.3	38.0	1.10	0.93	1.26
T_7_9	5.0	-14.0	23.9	0.92	0.57	1.27	-19.8	-69.7	30.1	1.04	0.95	1.13	4.7	-61.8	71.3	1.00	0.89	1.11
ST_7_9	5.0	-34.2	44.2	0.91	0.13	1.68	-22.5	-63.7	18.8	1.04	0.97	1.12	4.7	-54.5	63.8	1.00	0.90	1.09
S_7_9	-56.6	-115.7	2.5	2.13	0.94	3.32	-47.3	-113.1	18.6	1.08	0.97	1.19	35.2	-42.6	113.0	0.94	0.82	1.07
SN_7_9	13.0	-72.3	98.3	0.77	-0.80	2.35	-5.1	-61.4	51.1	1.01	0.92	1.10	15.9	-48.4	80.2	0.98	0.88	1.08
N_7_9	20.8	2.5	39.2	0.64	0.32	0.96	-31.6	-78.2	15.0	1.06	0.98	1.13	25.8	-4.6	56.2	0.96	0.91	1.01
IN_7_9	8.3	-30.3	46.9	0.86	0.18	1.53	-21.6	-38.3	-4.9	1.04	1.01	1.07	52.4	-21.7	126.6	0.92	0.79	1.04
I_7_9	-1.8	-18.4	14.8	1.04	0.76	1.32	10.8	-13.1	34.8	0.98	0.94	1.03	-35.6	-88.6	17.3	1.07	0.98	1.16
IT_7_9	-3.9	-32.6	24.7	1.09	0.58	1.59	-11.8	-44.0	20.3	1.02	0.97	1.08	-50.2	-102.9	2.6	1.09	1.00	1.18

19 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 Avanti System

Avanti (RTVue XR Avanti 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

NDB Normative 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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