iVue

Model iVue 100

User Manual Domestic

OPTOVUE

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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.

It is the operator's responsibility to use, check, and maintain this device according to the labels of the product, accompanying instruction manuals, and any revisions of the labeling or instructions that may be subsequently issued.

License and use of the iVue 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

iVue 100 and Optovue are trademarks of Optovue, Inc. Other trade names are the property of their respective owners, and are hereby acknowledged.

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1 Introduction

1.1 General

Optovue, Inc. has developed and tested this instrument 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.

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 8.
- **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 Intended Use

The iVue with Normative Database (NDB) is an optical coherence tomography system intended for in vivo imaging, axial cross-sectional, three-dimensional imaging and measurement of anterior and posterior ocular structures.

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.

1.1.3 Indications for Use

The iVue is a non-contact, high resolution tomographic imaging device. It is intended for 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 and anterior chamber of the eye. With the integrated normative database, the iVue is a quantitative tool for the comparison of retina, retinal nerve fiber layer, ganglion cell complex, and optic disc measurements to a database of known normal subjects. The iVue is indicated for use as a device to aid in the diagnosis, documentation, and management of ocular health and diseases in the adult population. Equipment Classification

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

1.2 System Overview

1.2.1 System Components

The iVue 100 system includes the following system components.

- **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, either a laptop or All-in-One (AIO, which includes the computer and monitor in one unit), is approved for medical use. It

supports scanner operation and processes, stores and displays exam data through the application software. The searchable iVue database stores and organizes patient and exam data.

- **Control Box:** The control box supports operation of the scanner and contains the backup hard disk.
- **Footswitch (Optional):** The optional footswitch provides another way to capture scans, including auto-adjustment, capture and saving.
- **Joystick and Chinrest Assembly:** With the patient's chin on the chin rest and head against the forehead rest, the joystick enables you to move the scanner left and right, forward and back, to align it with the patient's eye. Press the joystick button to capture the scan.

1.2.2 Original iVue with Laptop Option

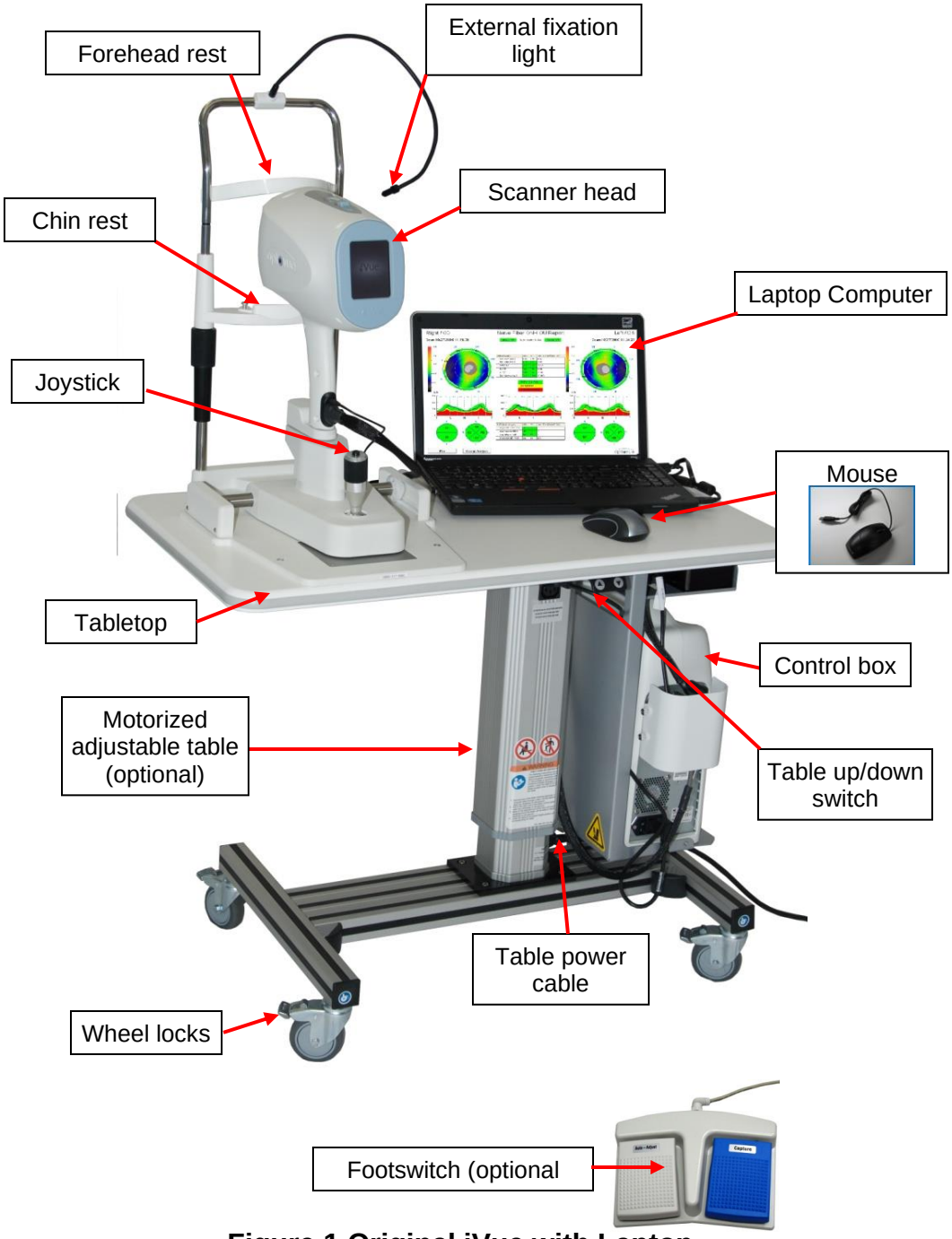


Figure 1 Original iVue with Laptop

1.2.3 Original iVue with All-in-One (AIO) Computer Option

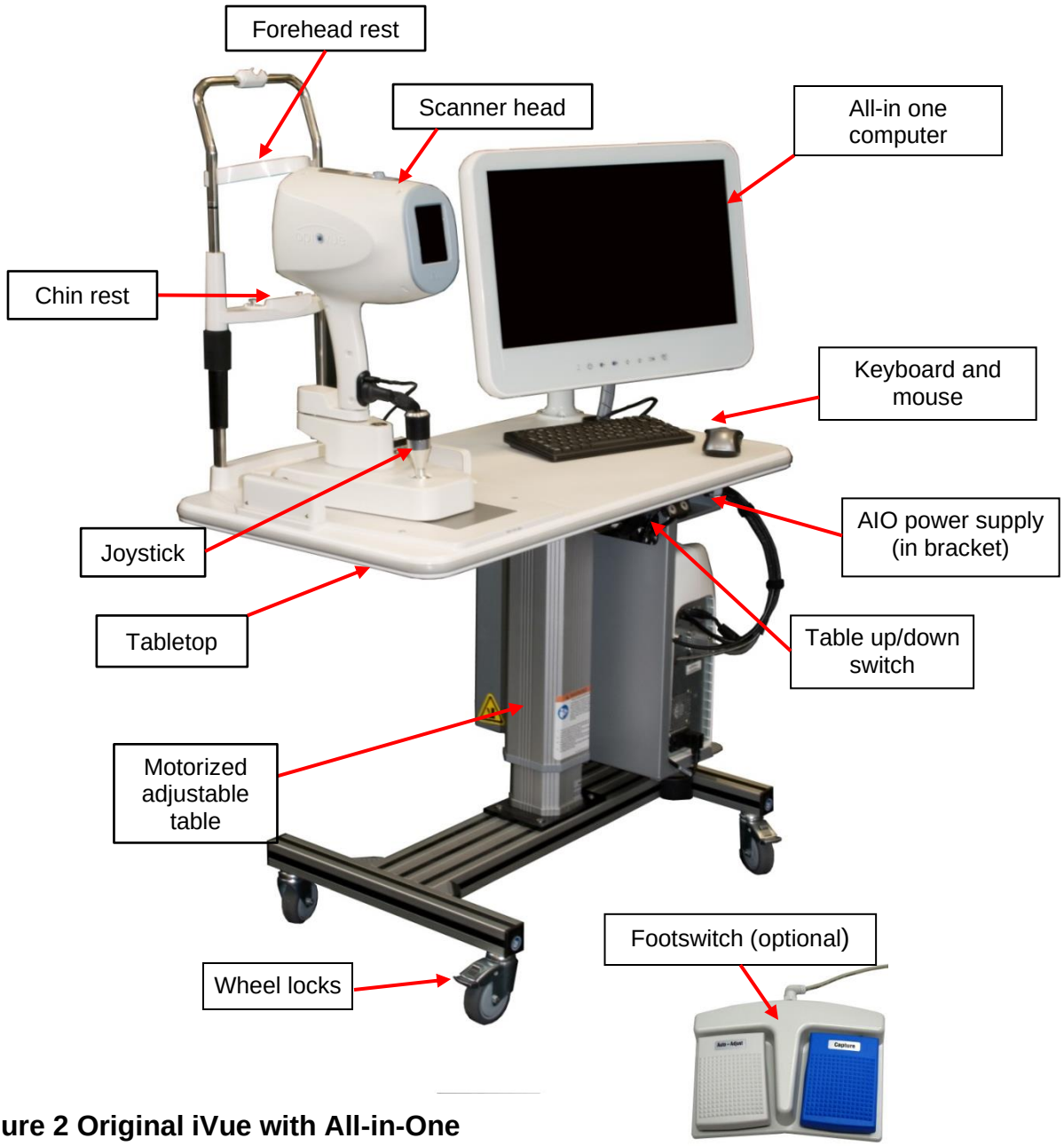


Figure 2 Original iVue with All-in-One

1.2.4 Current iVue with All-in-One (AIO) Computer Option

(Also available with laptop—not shown)

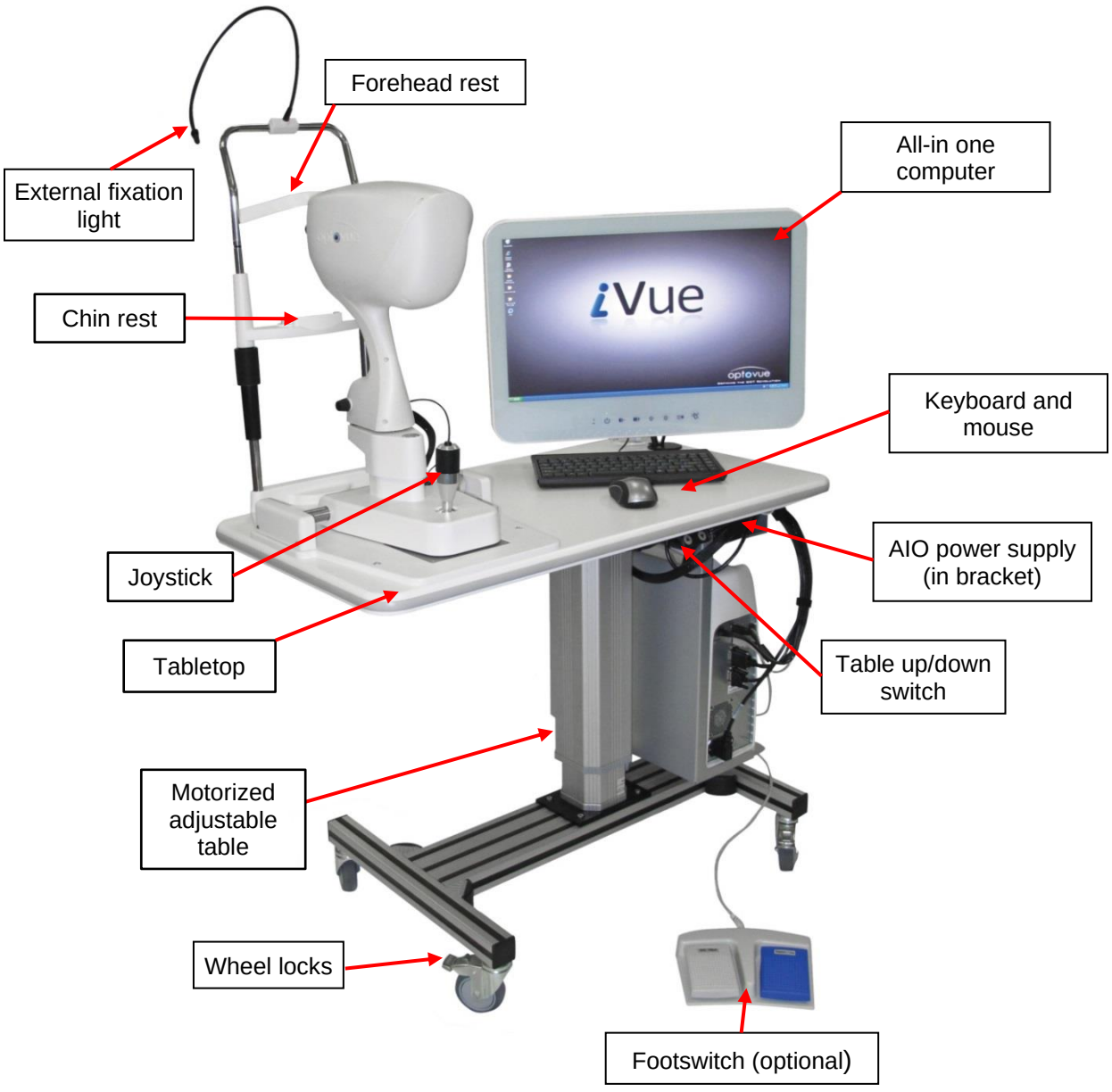


Figure 3 Current iVue with All-in-One

1.2.5 Original vs. Current Scanner Head

Current iVue Scanner Head	Original iVue Scanner Head
	

Figure 4 Original vs. Current Scanner Head

1.2.6 Cornea Adapter Module (CAM) Lens

The CAM lens is required for anterior segment (cornea) scans.


Bottom view


Top view

Current

Current iVue Scanner with CAM Lens	Original iVue Scanner with CAM Lens
	

1.3 System Warnings
Avertissements du Système

WARNING: During normal usage of the iVue 100, 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 iVue 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 iVue 100, 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 iVue 100.

WARNING: Components of the iVue 100 should not be used adjacent to or stacked with other equipment, and, if adjacent or stacked use is necessary, the iVue 100 should be observed to verify normal operation in the configuration in which it will be used.

WARNING: The iVue 100 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 iVue 100 is not intended to be used as the sole diagnostic aid in disease identification, classification or management. The iVue 100 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.

L'instrument iVue 100 OCT 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 iVue 100 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 exclusif du clinicien de soins oculaires qualifié.

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

WARNING: The iVue 100 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 iVue 100 instrument. 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 iVue 100. In addition, while examining the patient, the operator of the iVue 100 must not touch at the same time the patient and any electrical device that is not powered by the iVue 100. 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 iVue 100, 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 actually 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 iVue 100 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 iVue 100 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 iVue 100 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 iVue 100, 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

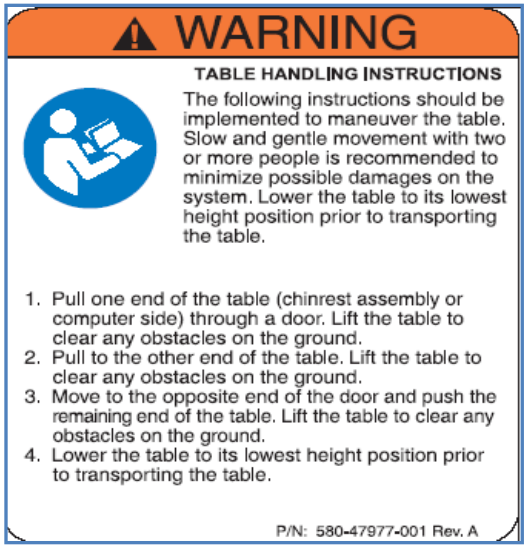
Du fait que l'exposition prolongée à une lumière intense peut endommager la rétine, l'utilisation du dispositif pour l'examen oculaire ne doit pas être inutilement prolongée, et le réglage de la luminosité ne doit pas dépasser l'intensité nécessaire pour obtenir une visualisation claire des structures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

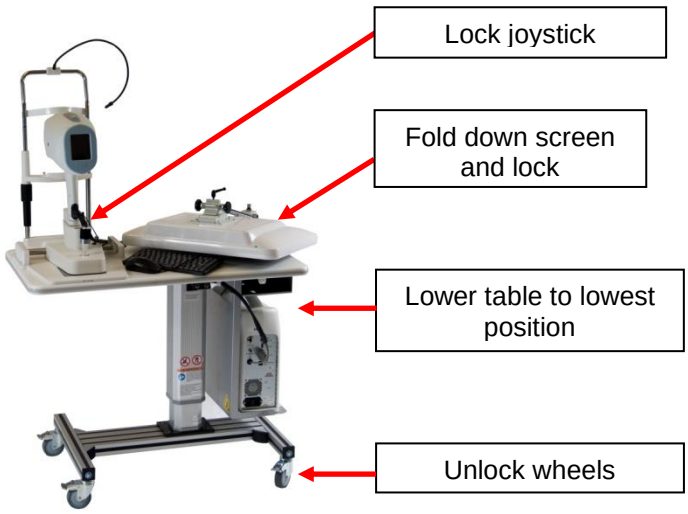
1.5 Safety with Moving Parts

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.

Before moving system



Pinch Warning Locations
Emplacements pour les avertissements de risque de pincement.

WARNING: Possible Pinch Locations

Avertissement : Zones de risque de pincement

- **Space between bottom of the tabletop and base of column**
  Espace entre le dessous de la plateforme de la table et le col de la colonne
- **Space between bottom of the I/O box and top of the PC**
  Espace entre le fond de la boîte d'entrée/sortie et à la partie supérieure de l'ordinateur

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

How to lock wheels:
Étiquette de blocage de roué:

Locked
Verrouillé

Unlocked
Déverrouillé

Wheel lock label

1.6 Standard Accessories

Standard Accessories

Description	Part No.	Quantity
User Manual	580-44960-015	1 pc.
Installation Manual	810-44308-007	1 pc.

1.6.1 Cabling

Cabling

Cable Name	Type of Cable	Shielded or Unshielded	Max. Cable Length
PC AC	3 wire	Unshielded	1m
PC DC	2 wire	Unshielded	1m
Keyboard/Mouse	USB	Shielded	1m
iVue AC	3 wire	Unshielded	1m
iVue PC	USB	Shielded	1m
iVue Scan Head	multi wire	Shielded	1.5m
iVue Optical	Fiber Pair	Unshielded	2m
iVue GigE	CAT 6	Unshielded	1m
iVue Chinrest	multi wire	Shielded	1.5m
iVue Joystick	2 wire	Shielded	0.2m
iVue Foot Switch	USB	Shielded	2m
Column AC	3 wire	Unshielded	2m

1.7 Product Compliance

1.7.1 CB Certification: Under IEC 60601-1

This device is classified according to UL/IEC/BS EN 60601-1 (2005) 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 Third edition (2005) 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

1.8 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.

1.8.1 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.

1.8.2 Electromagnetic Compatibility (EMC): EN 60601-1-2:2007

The iVue 100 has been tested to comply with the emission and Immunity requirements of IEC 60601-1-2 / BS EN 60601-1-2:2007. The iVue 100 is intended for use in an electromagnetic environment where radiated RF disturbances are not beyond the standard defined in IEC 60601-1-2 / BS EN60601-1-2:2007.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS		
The iVue 100 System is intended for use in the electromagnetic environment specified below. The iVue 100 customer or user should ensure that it is used in an appropriate environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11 EN 55011	Group 1	The System 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.
RF emissions CISPR 11 EN 55011	Class A	The iVue 100 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following WARNING is heeded: **WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the iVue 100, or shielding the location.
Harmonics IEC/EN 61000-3-2	Class A	
Flicker IEC/EN 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
The iVue 100 system is intended for use in the electromagnetic environment specified below. The customer or the user of the iVue 100 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	± 2, 4, 6 kV contact ± 2, 4, 8 kV air	± 2, 4, 6 kV contact ± 2, 4, 8 kV air	An ESD warning label adjacent to the rear USB connector and precautionary user manual documentation are required. Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge Line to Line (AC Power) IEC/EN 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Radiated RF IEC/EN 61000-4-3	80 MHz - 2.5 GHz 3 V/m 80% @ 1 kHz	80 MHz - 2.5 GHz 3 V/m 80% @ 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Optical Coherence Tomography System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (3.5 / E1)\sqrt{P}$ 80 MHz to 800 MHz $d = (7 / E1)\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Conducted Immunity: $d = (3.5/V1)\sqrt{P}$ Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 
Conducted RF IEC/EN 61000-4-6	0.15 - 80 MHz 3 Vrms 1 kHz AC Mains 0.15 – 80 MHz 3 Vrms 1 kHz AC Mains	0.15 – 80 MHz 3 Vrms 1 kHz AC Mains	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC/EN 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the iVue 100 system requires continued operation during power mains interruptions, it is recommended that the iVue 100 system 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.			

1.9 Symbols Explained

Refer to or read user manual first

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

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

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

Note: Calls attention to important information.

European Conformity Mark for TUV Rheinland
European Notified Body:
TÜV Rheinland LGA Products GmbH
Tillystrasse 290431 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 stand on

Do not push

WARNING: Hand crush hazard

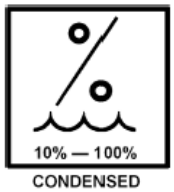
1.9.1 Protective Packing Symbols

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

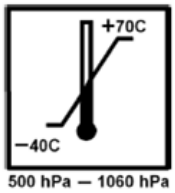
Fragile, handle with care

Keep dry

This side up



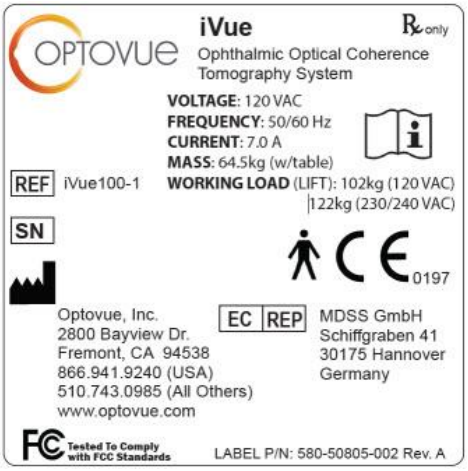
Environmental conditions during transport: Relative humidity (10% to 100%, including condensation)



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

1.10 Product Labels

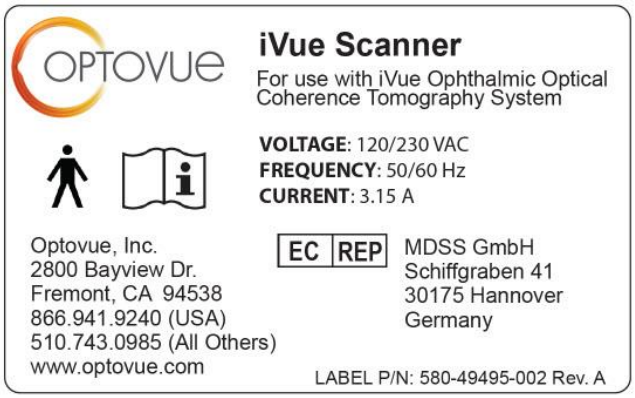
iVue 100-1 label



iVue 100-2

1.11 System Labels

Each iVue 100 system has one of the following labels.



1.12 Disposal

Dispose of the equipment per local regulations.

1.12.1 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:

1. The device was put on the European market after August 13, 2005.
2. 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 System Setup

2.1 Unpack the System

The iVue 100 System ships with the following items:

- Scanner head/control box
- Computer (AIO or laptop)
- Computer carrying case (with laptop only)
- Wired mouse
- CAM (in CAM box)
- Footswitch (optional)
- Joystick and chin rest assembly
- Tabletop
- Cradle for control box
- Motorized table (optional)

2.2 Connect Components

2.2.1 Control Box Connections

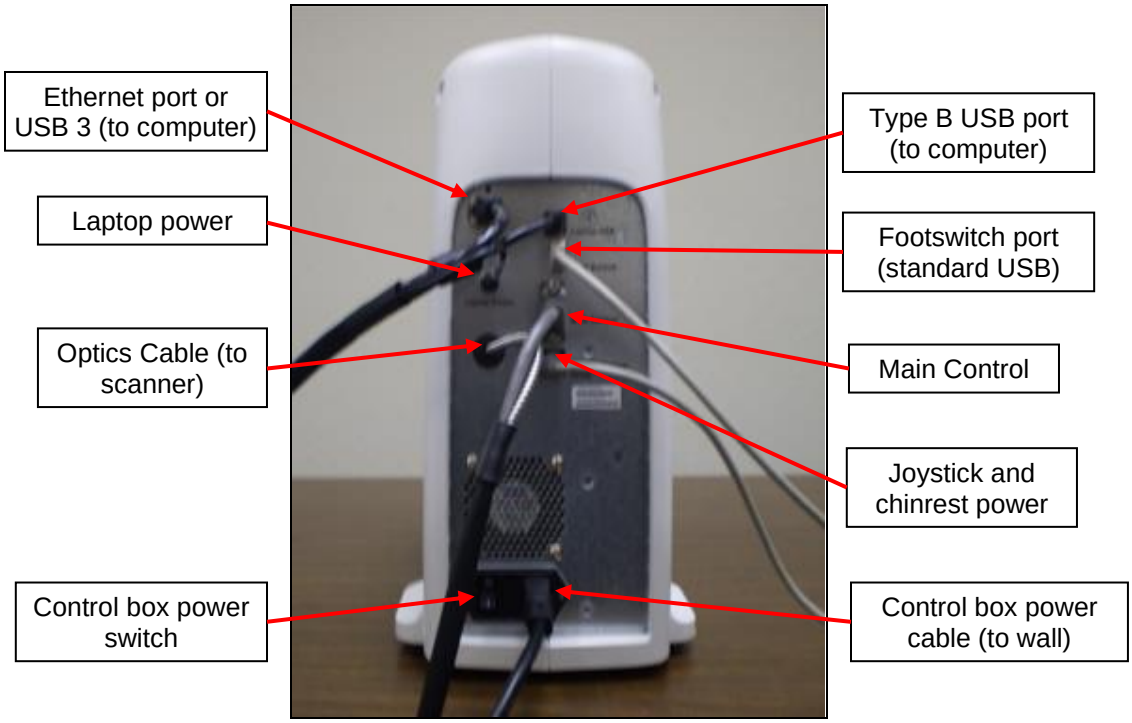


Figure 5 Control Box Cable Connections (Current)

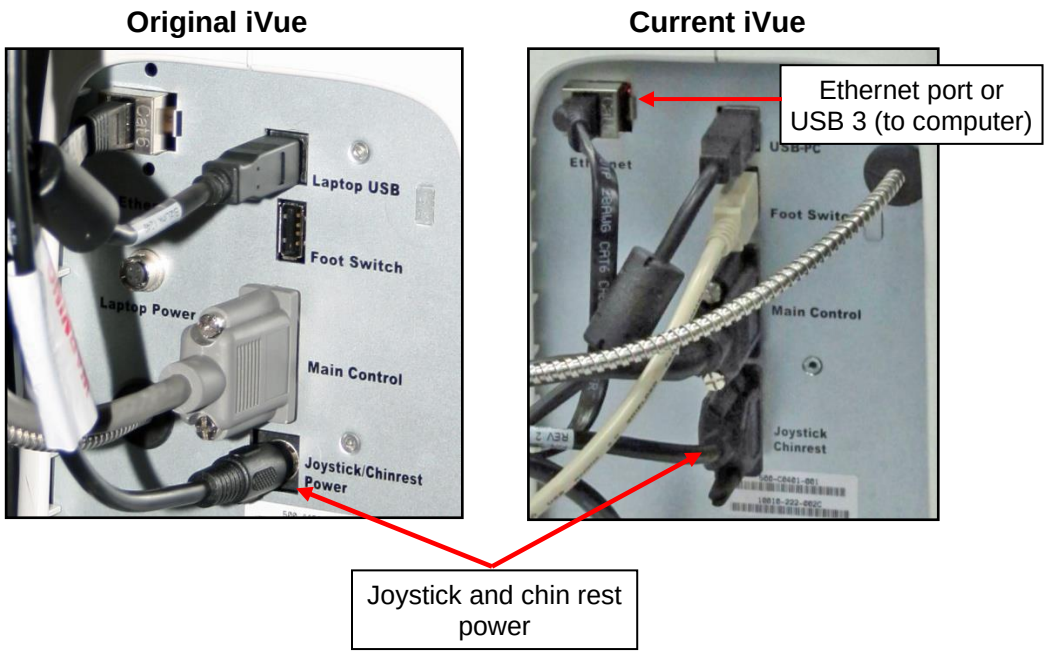


Figure 6 Original vs. Current Connection

2.2.2 Connect Scanner

1. Plug the control box power cable into the back of the control box and into the wall or into the table column socket for power.
2. Mount the scanner head into the joystick/chin rest assembly.
3. Plug the joystick/chin rest power cable into the control box.

2.2.3 Connect Laptop Computer

1. Plug the power supply into the back of the computer and into the control box for power.
2. Plug the Ethernet cable into the computer Ethernet port and the Ethernet port on the back of the control box. Or (USB 3 to USB 3 slot)
3. Plug the USB cable into the computer USB port and plug the Type B USB port in the back of the control box.

2.2.4 Connect All-in-One Computer

1. Plug the power supply into the back of the computer and into the column receptacle for power.
2. Plug the Ethernet cable into the Ethernet port on the computer and the Ethernet port on the back of the control box.

3. Plug the USB cable into the USB computer port and plug the Type B USB port in the back of the control box.

2.2.5 Connect Footswitch (Optional)

The footswitch is an optional accessory on some systems. Plug the footswitch cable into the footswitch USB port on the back of the control box.

☞ **Note**: An AP printer is not provided with iVue.

2.3 System Software Language Options

The system software supports multiple languages. The language is set during software installation.

2.4 Power On and Launch the System

1. **Power the Table:** Plug the table power cable into the column base and the wall socket.
2. **Power the Scanner:** Press the power switch on the back of the control box so it is in the **ON** position. **Wait 30 Seconds** for the scanner to fully power up.
3. **Power the Computer:** Press the power button on the computer. Wait for the computer operating system to fully launch, which can take up to a minute.
4. **Launch the iVue Application:** Double-click the **iVue** desktop icon to launch the system software.

_____End of section_____

3 Manage Patient Information

The system application opens by default to the PATIENT window. The application also has a SCAN window and a REVIEW window (see chapter 5). Figure 7 calls out PATIENT window items.

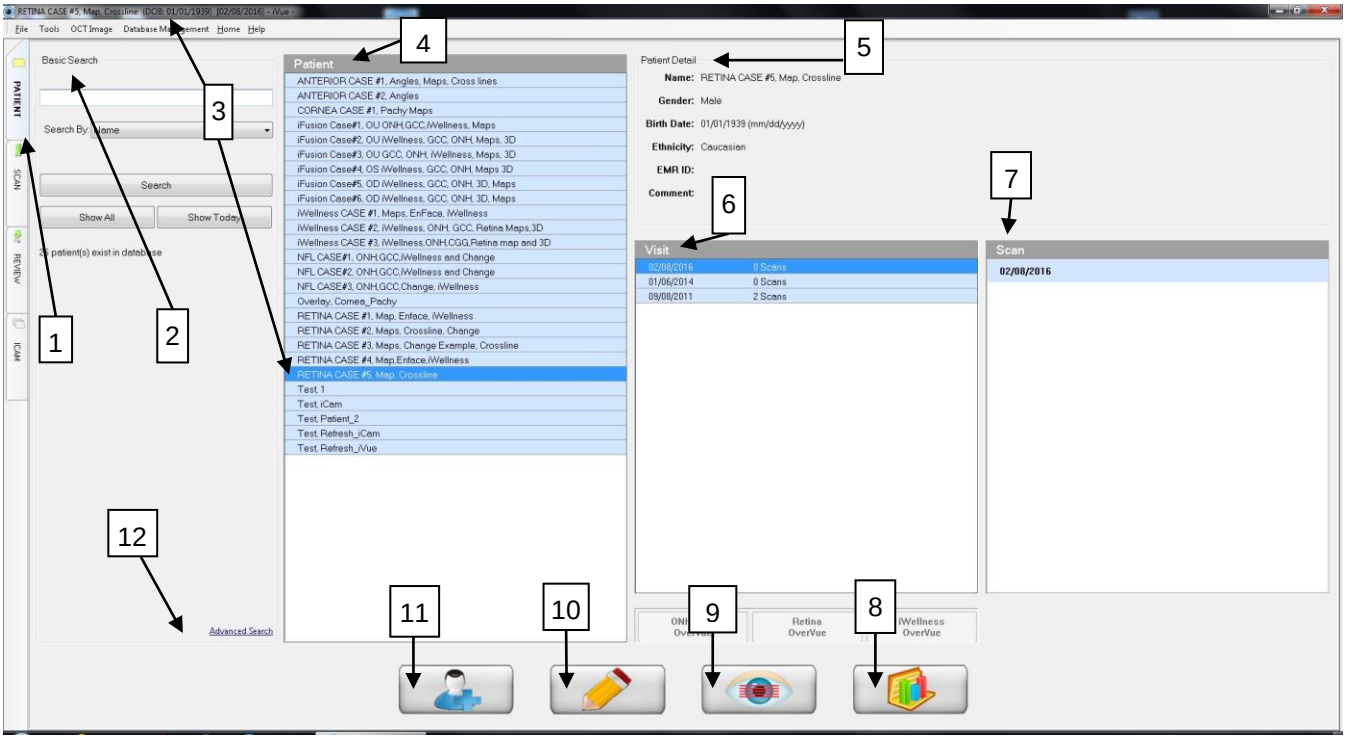


Figure 7 PATIENT Window Items

Legend:

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

Note: The selected tab is highlighted as shown for the PATIENT tab in figure 7.

See chapter 7 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.

3.1 Patient Search

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

3.1.1 Basic Search

- 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 last name, enter the name in the Basic Search field, make sure **Last 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, use the down arrow in the **Search by** field to select **EMR ID** (Electronic Medical Records ID), and click the **Search** button.

3.1.2 Advanced Search

Click **Advanced Search** to open the **Search By** dialog, where you can search by the following parameters.

- Disease
- EMR ID
- First Name
- Last Name
- Operator
- Physician
- Scan Type
- Date Range

Enter text in the fields you wish to search by and click the **Search** button to search with the combination of parameters you used. If your search returns no patients or not the ones you wish to find, reduce the number of parameters used so as to broaden your search.

Select the **Specify Date** checkbox to search by date range using the **From** and **To** fields. 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 use any other parameters, or to find patients in the specified date range that also match the other parameters used.

3.1.3 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.**

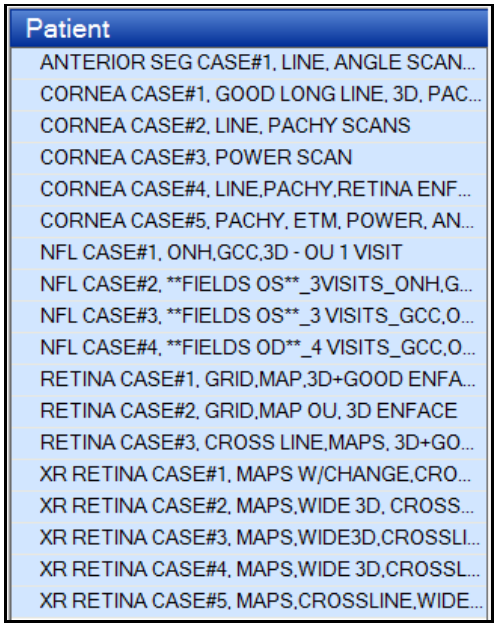


Figure 8 Sample Patient List

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 3.2 and 3.3.)
- 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 you do, the application enables the **OD Retina OverVue** or **OS Retina OverVue** button, according to the eye (left or right) of the selected scan.

Figure 9 shows portions of the screen affected by your selections.

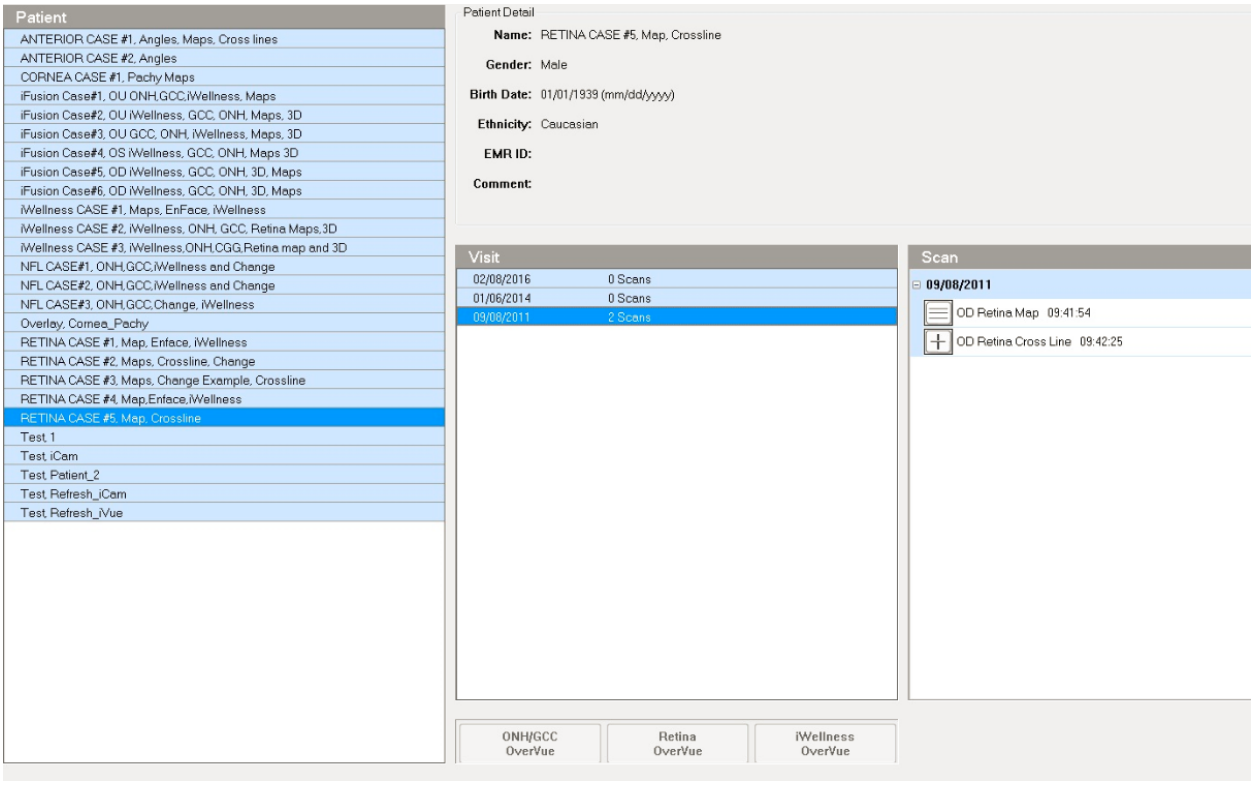


Figure 9 Selections Made in PATIENT Window

Patient and Visit Shortcuts

Right-click on a **Patient** name or **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.
- **Delete Patient**: Permanently deletes the selected patient. A warning message appears asking you to confirm deletion.

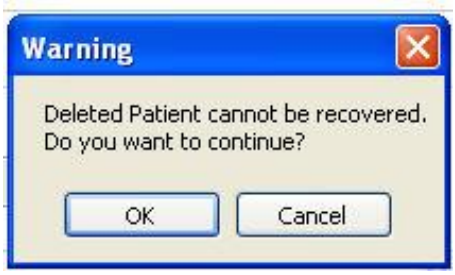


Figure 10 Delete Current Patient Warning

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

3.2 Add a New Patient

To add a new patient, click the **Add Patient** button. The **Add New Patient** dialog appears, as shown in Figure 11.

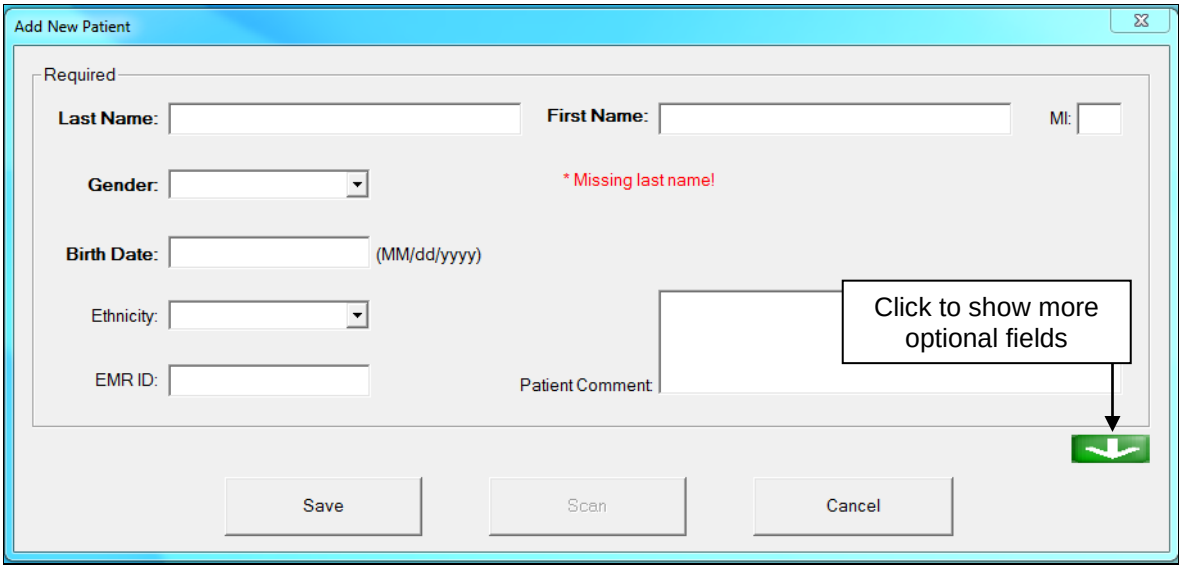


Figure 11 Add New Patient Dialog

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: Optovue recommends following the office convention for capitalization. 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**). ***However, if you change the birth date format, note that the iVue 100 computer date format must match it.*** Follow the instructions below to change the computer date format:

5. On the computer, select Start > Control Panel > **Region and Language**.
6. 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.

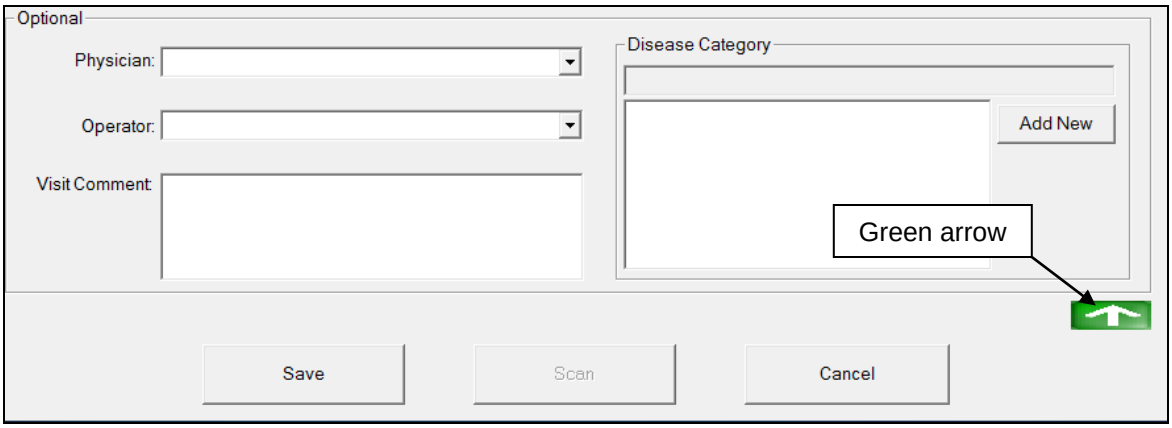


Figure 12 Add New Patient Optional Fields

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.

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.

3.3 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.

3.4 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.

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.

7. 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.

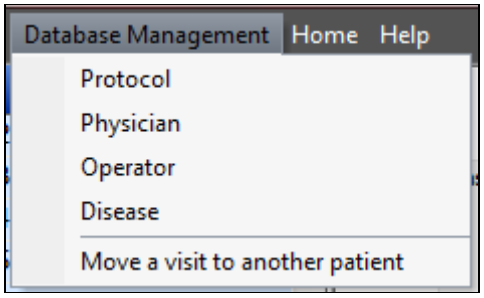


Figure 13 Select Move a visit to another patient

A confirmation dialog appears.

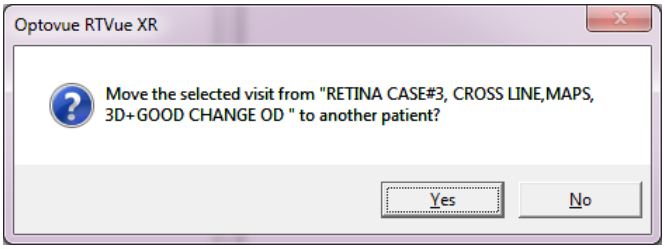


Figure 14 Confirm Intent to Move Selected Visit

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

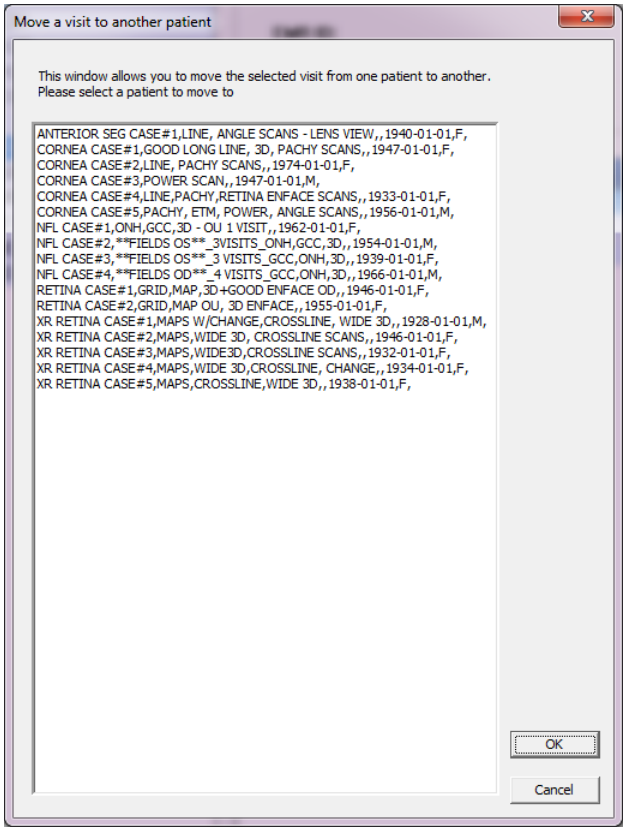


Figure 15 Select Patient to Move Visit To

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

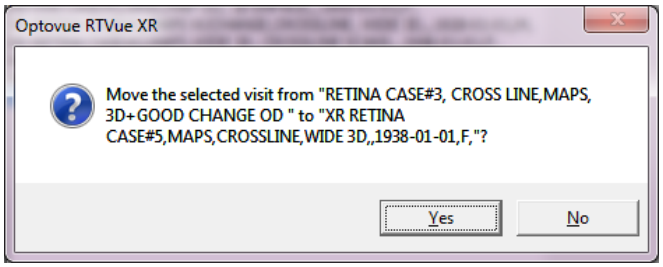


Figure 16 Confirm Move to Selected Patient

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

_____End of section_____

4 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.

4.1 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.

Follow this general procedure to acquire OCT scans:

1. From the PATIENT window, select an existing patient (see section 3.1.3) or add a new patient (see section 3.2), then click the **Scan** button to go the SCAN window.

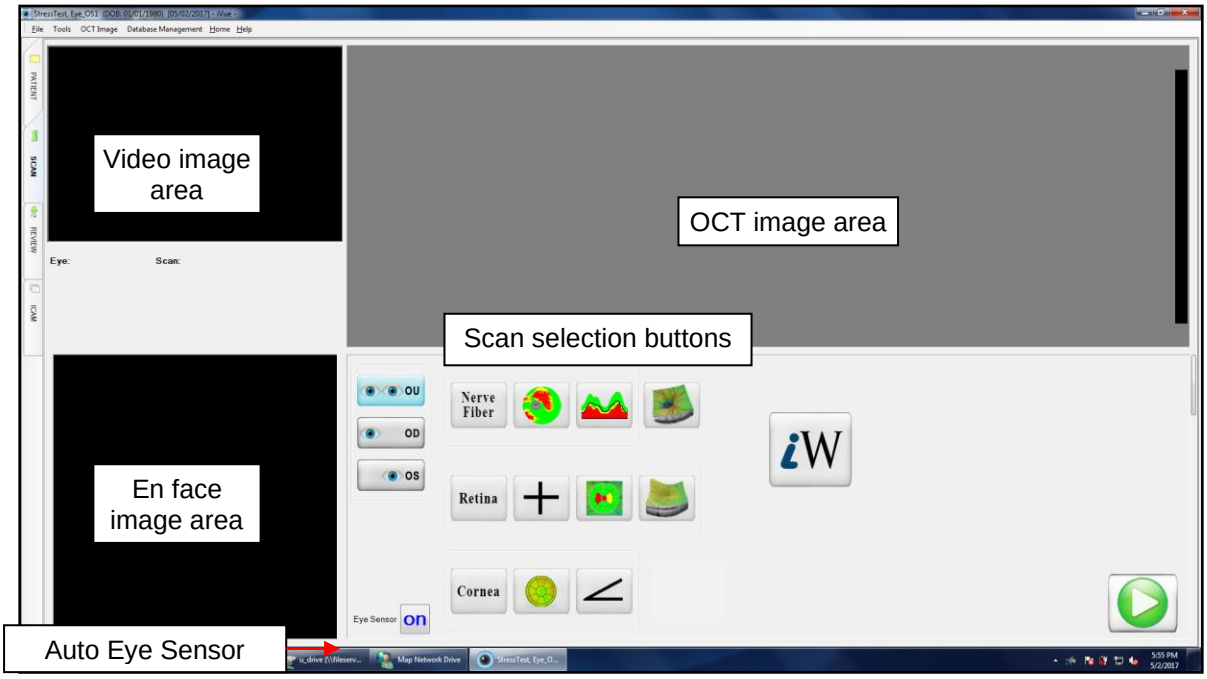


Figure 17 SCAN Window

2. In the SCAN window, select the patient eye to be scanned: click the **Right/OD** or **Left/ OS** button. The default OU button is highlighted.

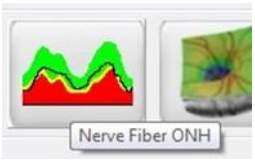
   When the Auto Eye Sensor is on, the system detects which eye is being scanned (based on scanner position) and informs you if your manual eye selection does not match, and notifies you with an incorrect eye error message; “Incorrect Eye” also appears over the en face image area at upper left (and on the small screen of the

scanner head, if you have that original version of hardware). The error message disappears when the scanner is moved in front of the correct eye.

3. Select the desired scan type from the Nerve Fiber, Retina or Cornea lists, or select the iWellness exam. Alternatively, you can repeat any previous scan by double-clicking on the scan name in the **Scans** list to the right.
   - **Nerve Fiber list:** GCC Map*, ONH, (3D Disc*****)
   - **Retina list:** Cross Line, Retina Map, 3D Retina*
   - **Cornea list:** Pachymetry, Angle
   - **iWellness** exam*****

☞ **Note:** Scans with an asterisk (*) are optional upgrades (subject to availability).

☞ Note: Placing the mouse over the icon will display the scan name.



☞ **Note**: If you select a cornea scan, attach the CAM lens before scanning.

When you select a scan, the Step 2 tab opens, which guides you in the next steps.

Figure 18 STEP 2 Tab of the SCAN Window

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.

    At this point, you should be able to see the eye in the video image at upper left, but no en face image nor OCT image yet.

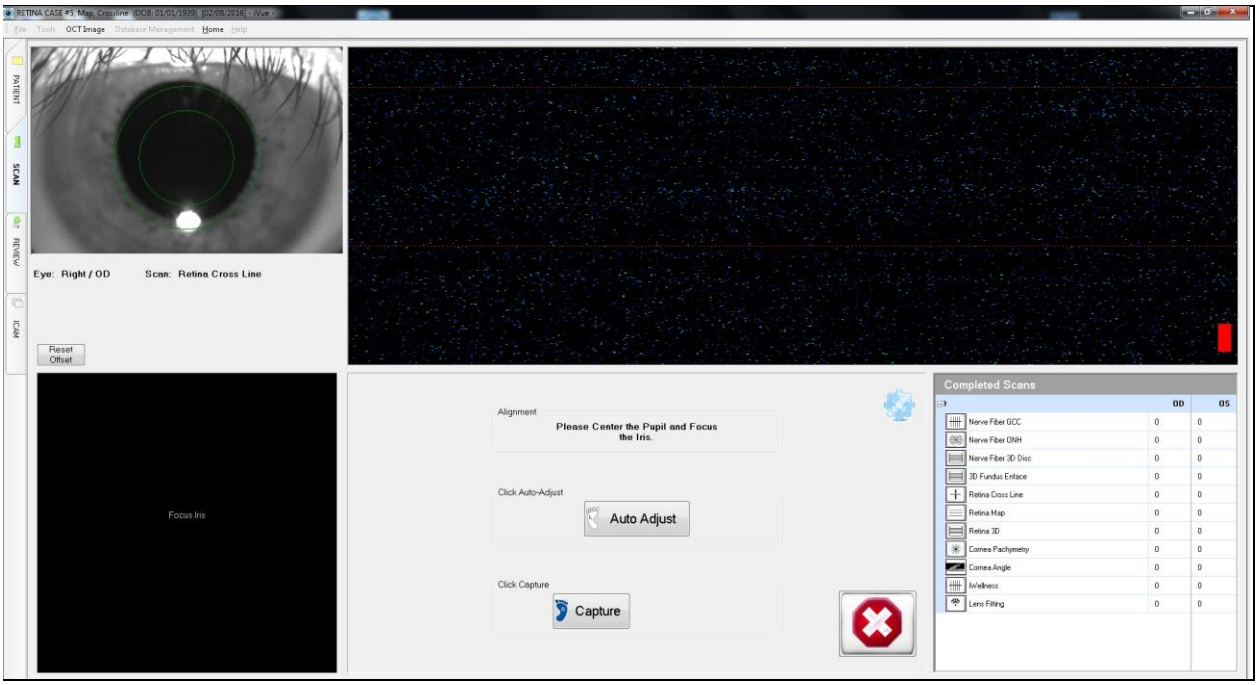


Figure 19 SCAN Window Before Alignment and Focus

5. Use the joystick in this step to properly position the scanner head for capture.
    - **Align:** Start with the scanner head pulled all the way back, then move the scanner head until the pupil is centered in the video image (as indicated by the two concentric green circles overlaying the video image).
    - **Focus:** Move the scanner head forward or back until the iris is in focus. Then select Auto Adjust. The en face image (lower left) and the OCT image (top center) appear when you achieve proper alignment and focus.

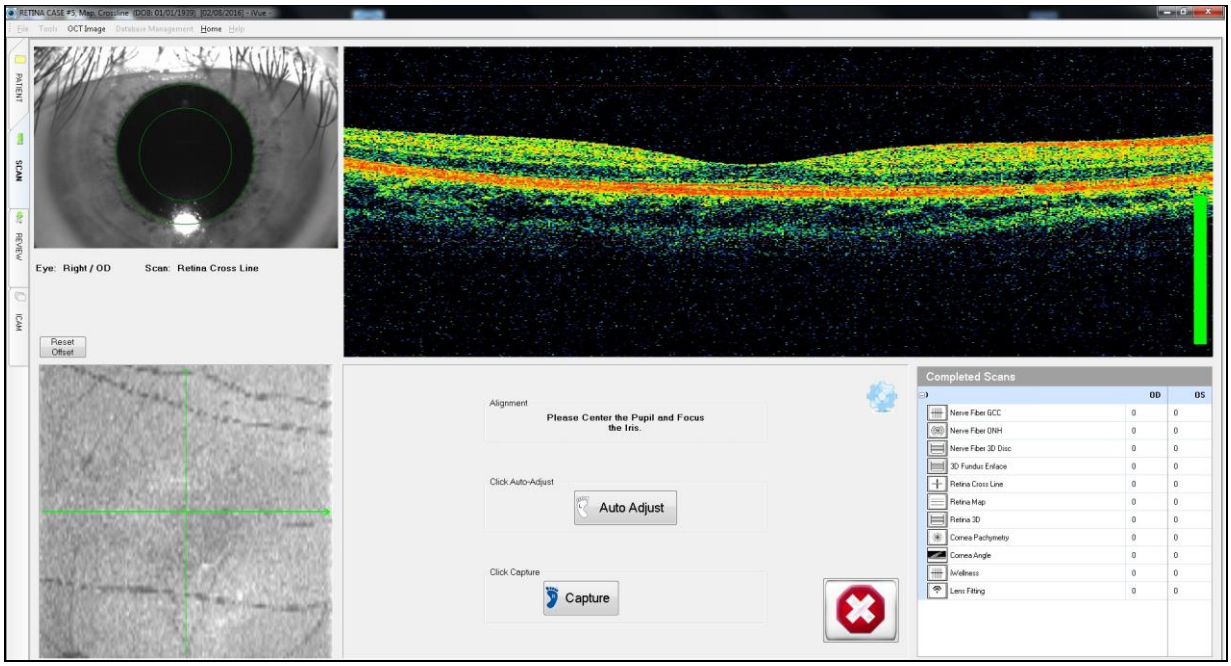
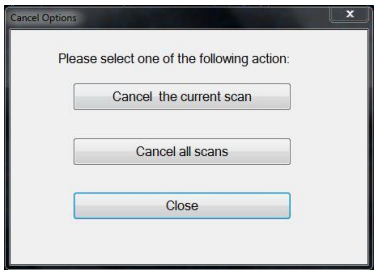


Figure 20 SCAN Window after Alignment and Focus

6. Click **Auto-Adjust** (or press the left pedal) to enhance the OCT image quality. To manually adjust the OCT image, select **Manual Scan Adjustment** from the **OCT Image** menu (see section 7.3.1. for details). A green bar on the right of the OCT image indicates good scan image quality.
7. Click **Capture** (or press the right pedal) to capture the scan. The system automatically saves each captured scan and the Completed Scans list updates.

After capture, you have the following options:

- Click **Scan Again** to take another of the same scan.
- Click next scan
- Double-click a scan in the Completed Scans list to take another of that scan.
- Click the **cancel** button to begin the process again, where you can select a different scan



.

- Click the **Review** tab to view reports of captured scans.

- Click the **Patient** tab to return to the **Patient** window, where you can select a different patient.

4.2 Tips for Particular Scan Types

4.2.1 Optic Nerve Head (ONH) Scan

After auto-adjusting, center the scan pattern by clicking the center of the optic disc on the live en face image (lower left). The optic disc should then be in the center of the circle on the en face image, as shown below. When it is, capture the scan.

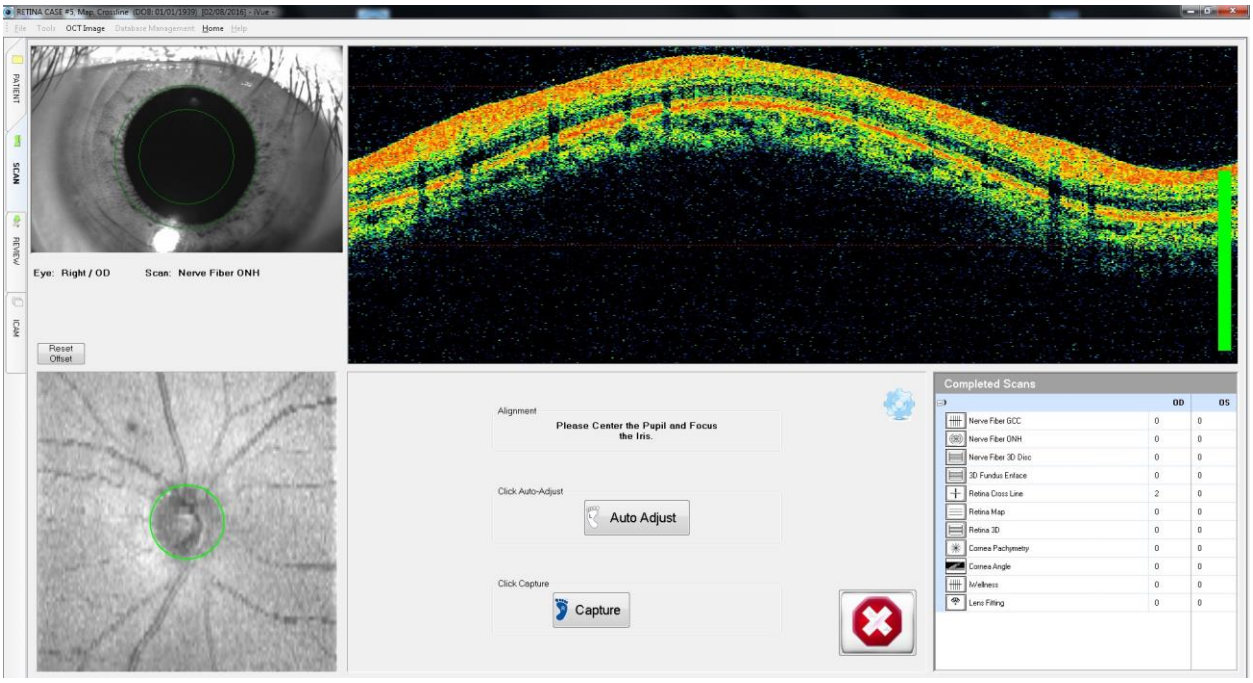


Figure 21 ONH Scan Capture

The first time you capture an ONH scan for a particular patient and eye, the system prompts you to capture a 3D Disc scan as a baseline reference for registration of future ONH scans. Center the optic nerve in the same manner before you capture.

4.2.2 Cross Line Scan

The bold line on the en face image corresponds to the current OCT image. You can rotate this scan in 5º intervals up to 90º clockwise or counterclockwise. To do so, move the pointer over the video image (upper left) and scroll the mouse wheel.

To adjust placement of the scan pattern, click on the video image to center the scan pattern where you click. In this way, you can scan the desired location on the retina. Click **Reset** to reset the scan to its original location.

4.2.3 Pachymetry Scan

Attach the CAM lens before scanning. Center the video image (upper left) on the pupil and move the scanner forward slowly. As you move forward, the iris comes into focus and the top of the cornea appears in the OCT image. Continue forward until the top and bottom surfaces of the cornea are between the red lines in the OCT image. Auto-adjust and capture.

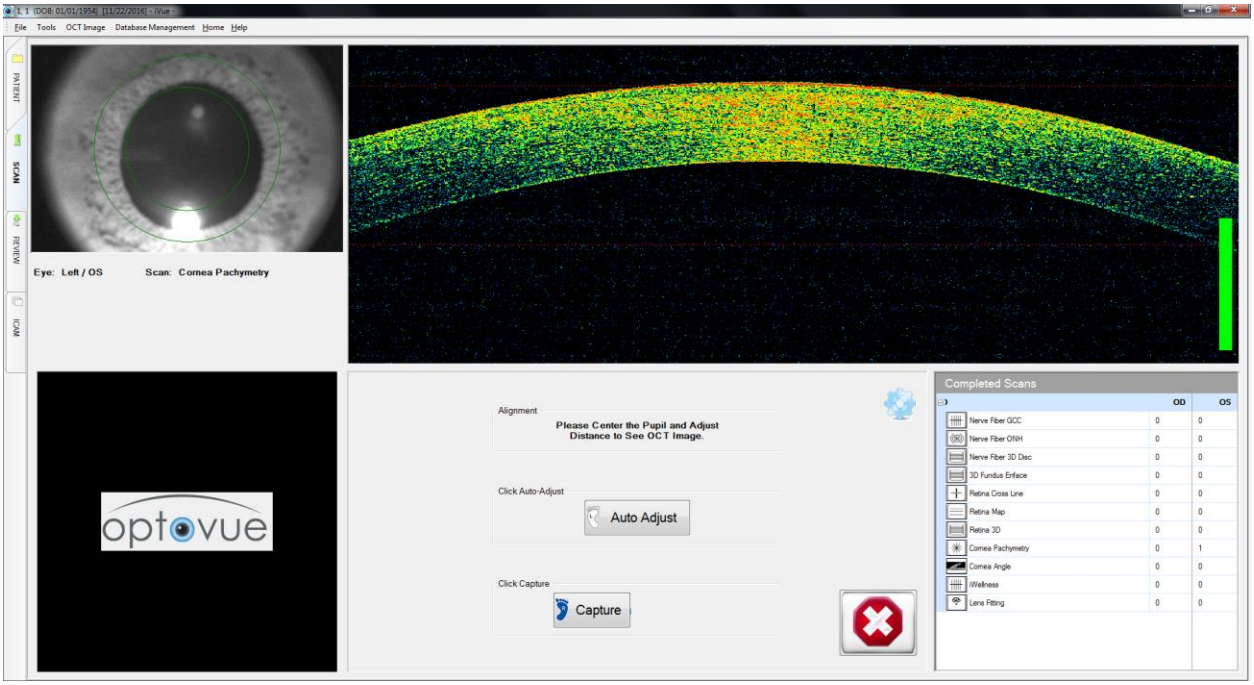


Figure 22 Pachymetry Scan

4.2.4 Cornea Angle Scan

Attach the CAM lens before scanning. Use an external fixation light to guide the patient's fixation. You can rotate this scan in 5º intervals up to 90º clockwise or counterclockwise. To do so, move the pointer over the video image (upper left) and scroll the mouse wheel.

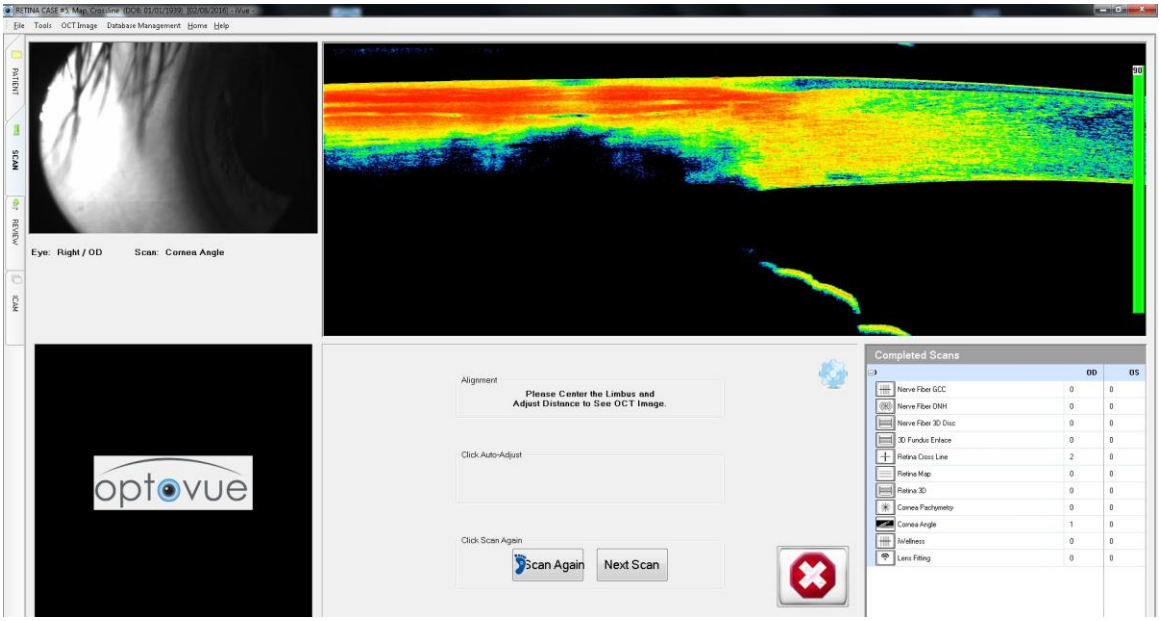


Figure 23 Cornea Angle Scan

The arrow on the video image shows the location and orientation of the scan. Place the scan line across the limbus with the arrow pointing to the center of the pupil. The scan line should be perpendicular to the plane where it intersects the limbus, which yields a nearly horizontal OCT image.

_____End of section_____

5 Review and Edit Scans

This chapter describes review of OCT scans, including editing and measurement functions. The REVIEW window opens when you double-click on any saved scan, or when you click the **REVIEW** tab.

5.1 Review Window

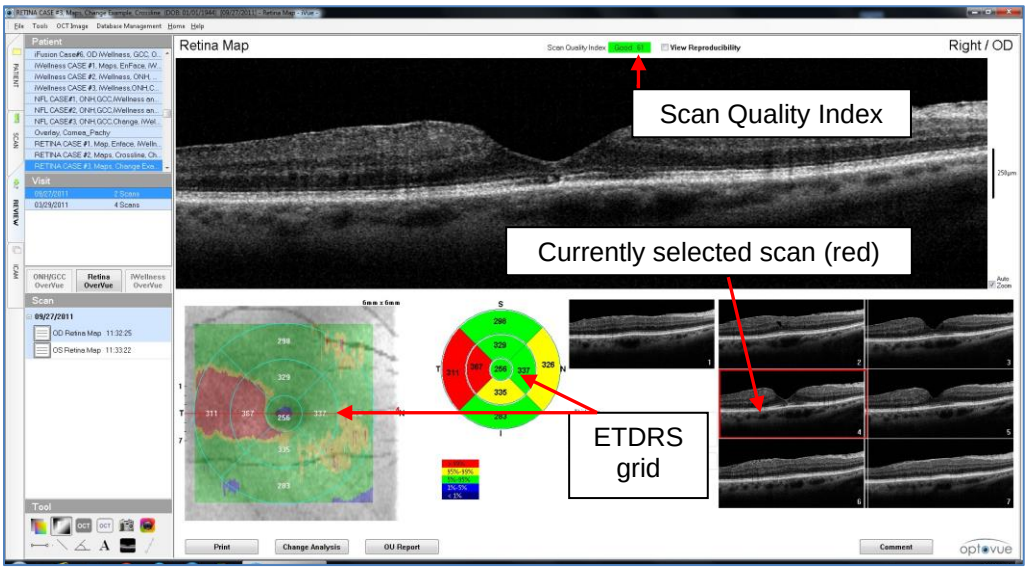
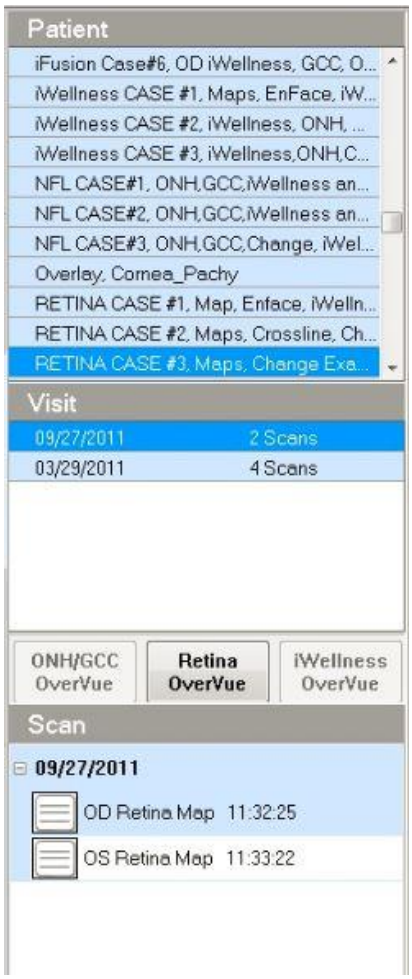


Figure 24 Example Review Window—Retina Map Scan

Each scan type has its own report that opens in the REVIEW window when you select the scan. See chapter 6 Scan Reports for details on specific reports. 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.

5.1.1 Select Patient, Visit and Scan

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.



The **Patient** list sorts patients alphabetically. Scroll if needed to find and select the desired patient.

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

OverVue buttons open OU reports

The **Scan** list chronologically sorts the scans—identified by scan type—from the selected visit. Click to display the default report for the desired scan.

Figure 25 Patient, Visit and Scan Lists

5.2 Scan Quality Index

The Scan Quality Index (SQI) appears near top center of each report. The SQI is either **Good** and highlighted green, or **Poor** and highlighted red. It includes a numeric value from 1 to 100 that quantifies the average intensity of reflected light over the whole scan pattern. Greater intensity (brightness) corresponds with a higher SQI. The SQI is not intended to be used alone to determine image quality. However, when the SQI is lower than the minimum recommended values given in the table below, Optovue recommends that you re-take the scan to achieve an SSI value above the minimum recommended, if possible. If you cannot, use caution in interpreting the results.

Minimum Recommended SQI for Each Scan Type

SQI	Minimum Recommended SQI
Retina scans	40
ONH scans	27
GCC scans	32
Cornea scans	27
iWellness scan	40

SQI is **Good** for most patients in normal use. However, the light absorption properties of pathologies can make it difficult to achieve a **Good** SQI. If SQI is not **Good** over a series of patients including those without pathologies, contact Optovue Technical Support for assistance. See APPENDIX – Scan Quality Index for further detail on the SQI.

5.2.1 Factors Affecting Scan Image Quality

In addition to the SQI, other factors can affect scan image quality. Consider all factors; do not rely on any one factor when judging image quality.

8. **SQI**: The system quantifies the average intensity of reflected light over the whole scan pattern to determine the SQI from 1 to 100: the greater the intensity (brightness), the higher the SQI. When the SQI is at or above the cutoff value, it is labeled **Good**, and you can continue. When the SQI is below the cutoff value, it is labeled **Poor,** and you should retake the scan. If the scan does not improve to **Good**, for example due to media opacity, we recommend caution in interpreting its results.

9. **Locally weak signal**: An area of locally weak signal in an OCT image is a place where you cannot see retinal layers. Such areas may be due to blinks, eye lid occlusion, poor alignment, or other reasons. Since the software does not measure thickness at the right and left edges of the OCT image, locally weak signal at the edges can be disregarded and measurement results are not affected. When areas of weak signal are within the measurement area, that is, not near the right or left edges of the OCT image, measurements in these areas may not be accurate and you should retake the scan. Keep in mind that a scan can have a **Good** SQI while having

areas of weak signal, and still should be retaken because weak signal areas are within the measurement area.

10. **OCT data out of bounds**: For some scans, the OCT data might be out of the OCT window boundary (that is, data is clipped off because the OCT data is either too high or too low in the OCT window). If this happens at the edge of the scan region, it is not likely to have a negative effect on the final measurements. However, if it exists inside the measurement area, the results can be affected and the scan should be retaken.

5.3 Tool Pane

The icons in the Tool pane at bottom left provide tools for measuring, annotation and scan presentation.

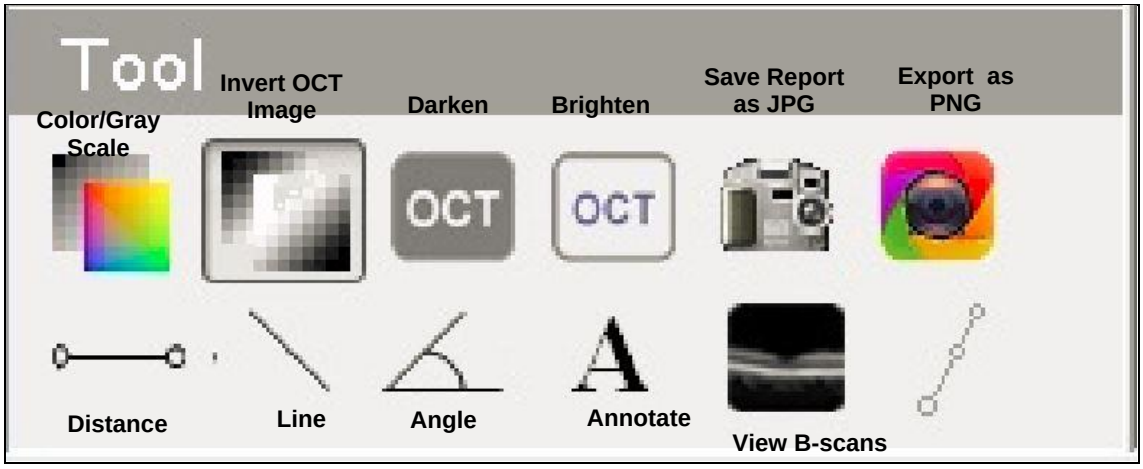


Figure 26 Review Screen Tools

Figure 26 Legend:

1. **Distance**: Measures the distance between two points.
2. **Point Line**: Draws a line between two points.
3. **Angle** tool: Measures the angle between two lines.
4. **Annotate**: Annotate images.
5. **Gray/Color**: Toggles scan display from grayscale and pseudo-color.
6. **Invert:** Inverts black and white in a grayscale image.
7. **OCT noise**: Increase (white) and reduce (gray) OCT noise level.

8. **Snapshot JPEG**: Saves the report page in .jpg format. The filename has a default combination of patient information, but you can edit it. You can select the destination folder.
9. **Export as PNG**: Saves the report page in .PNG format. The filename has a default combination of patient information, but you can edit it. You can select the destination folder
10. **View B-scans**: Displays all scans from selected pattern for review and enables you to modify or correct the segmentation tracing (lines). See the **Modify Boundary** section.

5.3.1 Distance Measurement or Pointer Line

To make a manual measurement or draw a pointer line: select the desired tool, click on the OCT image to make an initial anchor point. A line follows the pointer until you click to make the endpoint. Measurements appear next to the line.

5.3.2 Angle Measurement

To make an angle measurement: Select the desired angle tool and click on the OCT image to place the angle vertex. A line follows the pointer until you click to make the endpoints of the two lines that form the angle. The measurement appears inside.

_____End of section_____

6 Scan Reports

6.1 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 uses the fovea of the scan for registration. 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.

6.1.1 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.

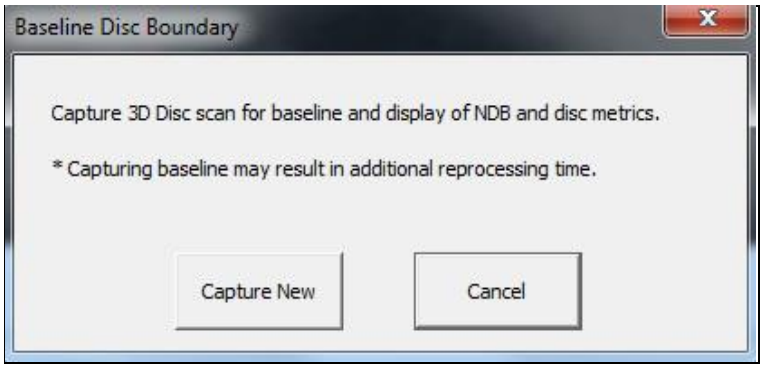


Figure 27 Baseline Disc Boundary Dialog

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 **Auto** button or right-click on the SLO-like image and select **Show Disc**.

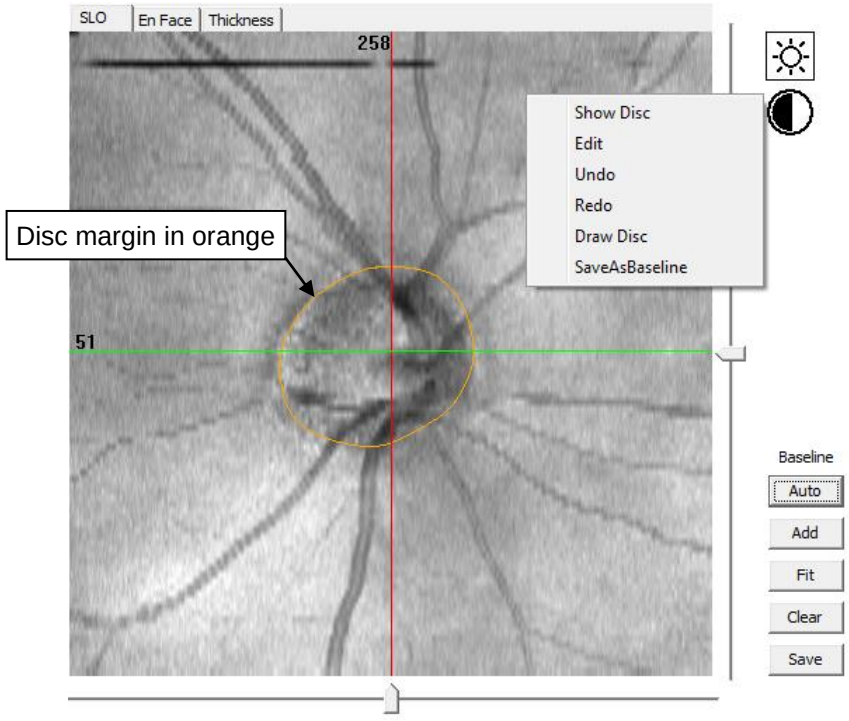


Figure 28 Optic Disc Margin in 3D Disc Report

Use the **Edit** right-click option to edit the disc boundary, or **Draw Disc** to draw the disc boundary manually

6.2 Normative Database

A normative database was established using the iVue 100 for the retinal thickness, the GCC thickness, the RNFL thickness, and the optic nerve measurements from a study population deemed representative of the normal population. The normative database contained 458 qualified normal subjects from initial enrollment of 521 subjects. At least 442 normal subjects with one or more qualified scans per subject were included in the final database for the four scan types, that is, the nerve fiber ONH scan (449 normal subjects), the GCC map scan (451 normal subjects), the retina map scan (452 normal subjects), and the iWellness scan (442 normal subjects).

The iVue 100 normative database consists of:

- 46.9% Caucasian descent
- 18.6% Asian
- 10.0% African
- 15.3% Hispanic
- 7.9% Indian
- 1.4% Other

The iVue 100 NDB covers age range from 18 to 82, refractive error (spherical equivalent) range from -8.63D to +6.00D, IOP range from 8.0 to 21.0 mmHg, and CCT range from 350 µm ~ 666 µm. The gender ratio of the database is 39.5% to 60.5% (male to female).

The retina thickness measurements, the RNFL thickness measurements, the GCC thickness measurement, and the optic nerve head parameters of the normal subjects from the iVue 100 NDB study are similar to the normal values reported before with OCT devices. The mean ± SD from the iVue 100 NDB study for the central fovea retinal thickness was 261.4µm ±19.3µm, for the average RNFL thickness was 99.1µm ± 9.5µm, and for the average GCC thickness was 93.9µm ± 6.8µm.

The iVue 100 NDB study found that age was significantly associated with most study parameters, but the effect of age was small. The iVue 100 NDB study found that SQI was significantly associated with most study parameters; the effect was small and at similar level to the age effect. The RNFL and ONH parameters were found to have strong association with disc area.

The standard deviation values of repeatability and reproducibility of selected iVue 100 measurement parameters based on the normative database study.

The normative database includes data for both **retina** and **nerve fiber** *(***Optic Disc, RNFL**, and **GCC***).*

The NDB parameters were adjusted by the following factors:

Age (retina and nerve fiber maps)

Optic Disc size (only in conjunction with the ONH scan)

Gender (Retina Only)

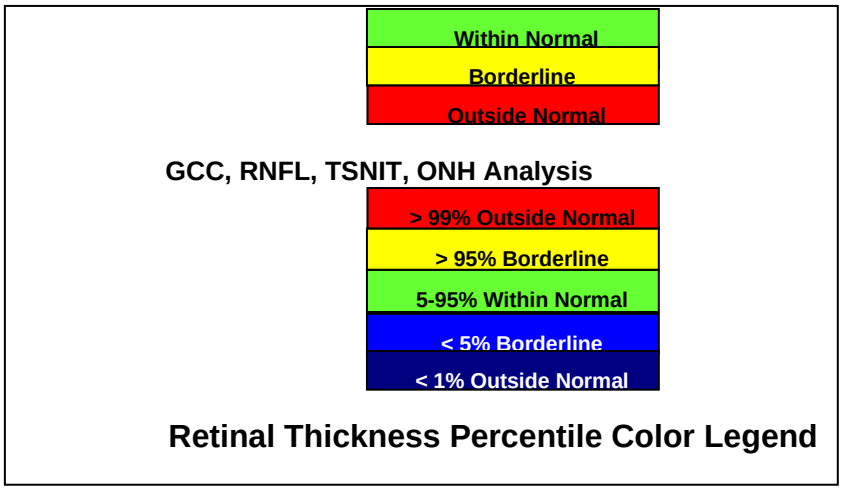
The NDB is used to provide a relative comparison of where a particular patient's results fall within the parameters of the "normal" population range for their age group.

The color coding for the normative display uses a Green (within normal range), Yellow (borderline normal range) and Red (outside normal range). See the figure below.

☞ Note: The ETDRS thickness and NDB results are affected by the positioning of the foveal indicator (yellow dot on Retina Map thickness display). For more information see section 6.4.1.

6.2.1 Color Legend for NDB Reference

For GCC, ONH Analysis, TSNIT, and RNFL Thickness, the Percentile Color Legend represents: >5% for within normal, <5% borderline and is <1% for Outside normal. For GLV, FLV, Optic disc C/D and Cup, the Percentile Color Legend represents: <95% is within normal, >95% borderline, and >99% for outside normal.



NDB Color Legend

6.2.2 Nerve Fiber-GCC Normative Database Explained

Retinal ganglion cells encompass three layers in the retina:

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

All three layers, collectively known as the **ganglion cell complex**, become thinner as the ganglion cells die from glaucoma. The system directly measures the thickness of these three layers and provides a unique percentile analysis of these layers compared to an extensive normative database. The color categorization of a pixel presents the percentile with regard to the distribution of thickness at the specific location of a given pixel. The results are presented as color coded percentile categories relative to the normative distribution to aid in the clinical interpretation.

The figure below shows a cross sectional B-scan from the iVue in the macula region. Because of the high depth resolution available in the technology, the GCC can be separated from other retinal layers.

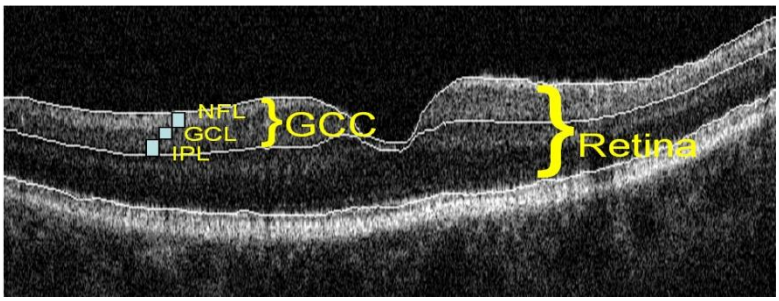


Figure 29 NFL, GCL, and IPL: GCC Layers

This figure illustrates the GCC layer segmentation. This is comprised of the NFL, GCL, and IPL compared to the entire retina segmentation. The high depth resolution of 5 microns helps enable this type of
inner-retina segmentation that is not possible in older time domain OCT devices with worse depth resolution.

The GCC scan data is displayed as a thickness map of the GCC layer as shown in the two figures below. The thickness map is color coded where thicker regions are displayed in hot colors (yellow and orange), and thinner areas are displayed in cooler colors (blue and green).

The GCC map for a normal eye shows a bright circular band surrounding the macula representing a thick GCC from healthy ganglion cells (see the left figure). The center of the macula is thinner because there are no ganglion cells in this area. In glaucoma, as the ganglion cells are lost, the GCC complex becomes thinner (the right figure).

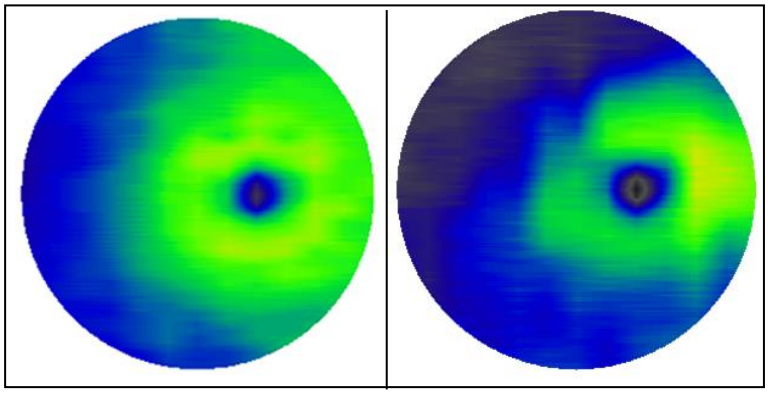


Figure 30 Healthy Eye GCC Thickness Map (Left) Compared With Glaucoma Patient Eye (Right)

In the left figure above the GCC thickness map for a healthy eye is shown. Note the thick band surrounding the macula. The right figure shows the GCC thickness map for a glaucoma patient. Note a decreased in the thickness of this band around the macula.

The GCC thickness values are analyzed and compared to an extensive normative database. This normative database contains approximately 450 healthy adult eyes from various ethnicities and ages. The results are presented in a map and a parameter table.

6.2.3 NDB References Maps for GCC

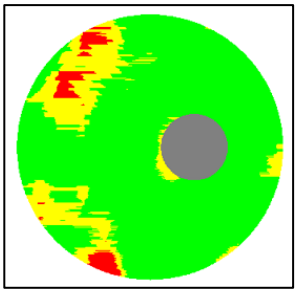


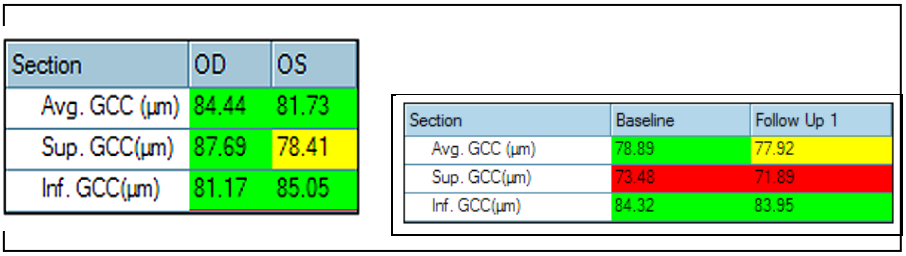
Figure 31 NDB Reference Map Showing Normal, Borderline And Outside Borderline Areas

NDB References Maps for GCC have a circular mask (1mm diameter) in the center of the macula where the analysis is not possible due to an absence of ganglion cells in this region.

An NDB Reference Map shows the regions where the thickness *is borderline or outside the range of the normative distribution*. The **NDB Reference Map** shows normal areas as green and borderline areas as yellow. Outside normal areas are shown as red as in the figure above. These are based on percentile values of < 5% for borderline, and < 1% for outside normal.

A parameter table is also provided for the GCC analysis. The table(s) consists of the average GCC thickness, Superior GCC thickness , Inferior GCC thickness, FLV and GLV are color coded relative to the percentile value. The color categorization of a pixel presents the percentile with regard to the distribution of thickness at the specific location of a given pixel.

The table also provides a symmetry parameter for the difference between superior and inferior hemispheres, and this parameter is not compared to the NDB.



Percentile Value Color-Coded GCC Parameters Review Layout

6.2.4 Retina Analysis Presentation

Retina Map Analysis Presentation

The 6mm x 6mm retina map is displayed with the ETDRS grid and associated values, along with the en face image from the scanning session. The seven center raster scans (each the result of five scans averaged) are displayed to the right of the screen with the selected scan at the top of the report. Use the mouse pointer or scroll-wheel to select designated raster scan to view in the top window.

For user convenience, Retina Map scan presentation optimizes the OCT image window by occupying a majority of space to display the
B-scan and by reducing the amount of *black space* shown in the window. Note that the default Retina Map report screen is shown in the figure below, and the **View Reproducibility** checkbox is unchecked.

Note: RPE reference button is not available in USA version software.

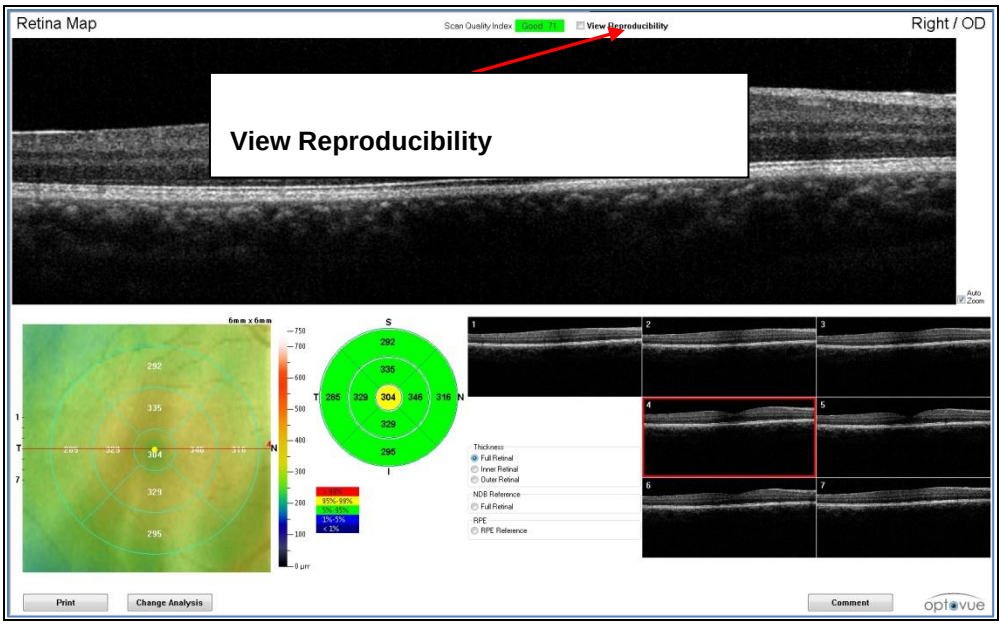


Figure 32 Retina Map

1. Retina Map Without Reproducibility SD Values

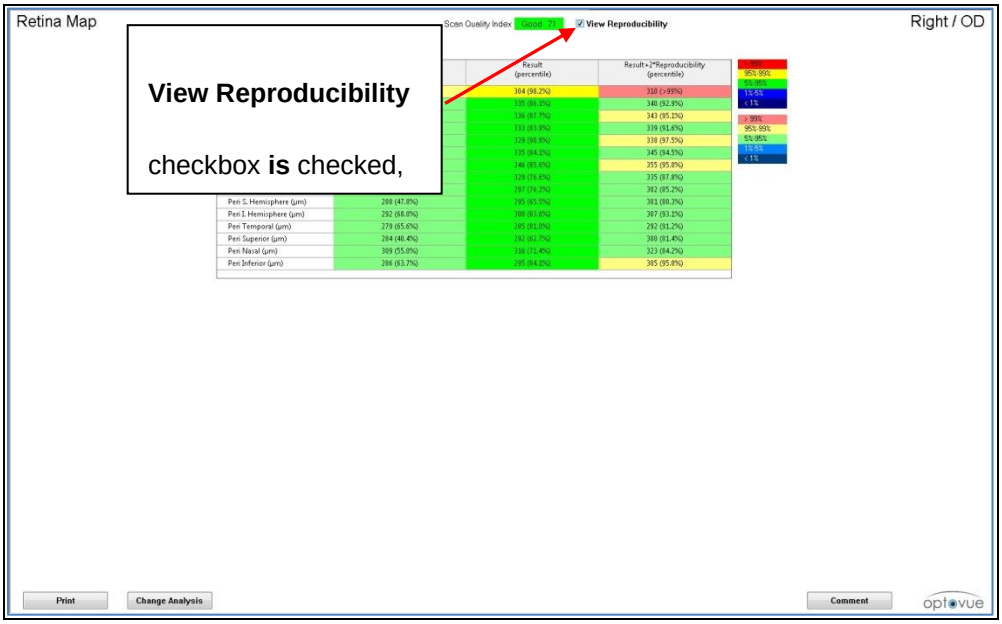


Figure 33 Retina Map With Reproducibility SD Values Table

The pooled reproducibility SD values to calculate the range of measurement reproducibility that accompany the measured result as illustrated in the example above are applied in the software when the **View Reproducibility** button is checked with reproducibility range table shown.

The report bottom left displays either a Thickness or NDB Reference Map. The Thickness Map has three different presentations **– Full Retinal, Inner Retinal**, and **Outer Retinal**. The NDB Reference Map has Full Retinal. When viewing the NDB Reference Maps, values are colored based on percentiles against the Retina Normative Database. NDB reference is shown by default.

☞ **Note**: The ETDRS chart in the iVue 100 reports reflect 1, 3, and 5mm diameter zones instead of the 1, 3, and 6mm diameter zones in the traditional ETDRS chart.

The OCT image displayed has the default **Auto Zoom** function applied when viewing scans. Uncheck the **Auto Zoom** checkbox in order to not use the **Auto Zoom** feature.

Manual Boundary Adjustment : This feature allows the operator to verify any segmentation performed by the software and allows for manual adjustment. To manually adjust the boundary lines, click the View B-scans button on the Tool menu or click OCT Image on the menu bar. Then select **Modify Boundary** from the dropdown menu. Make any segmentation related adjustments and click **Save**. Any manual boundary adjustments will result in measurement recalculations after the **Save** button is clicked.

☞ **Note**: All modifications to the segmentation lines will erase any prior annotations on the report. Add any annotations after modifying the segmentation.

☞ **Note**: The Clean Diagnosis Data function does not affect manually edited scans.

Thickness and NDB Reference : This feature selects the designated retina map display. Thickness metrics of the selected layers or the percentile relating to the Normative Database (Full Thickness) and other measurements are:

- **Full Retinal** – Segmentation from ILM (Inner Limiting Membrane) to RPE (Retinal Pigment Epithelium)
- **Inner Retinal** – Segmentation from ILM to outer limit of IPL (Inner Plexiform Layer)
- **Outer Retinal** – Segmentation from IPL to RPE

Factors that can affect the segmentation or thickness map results:

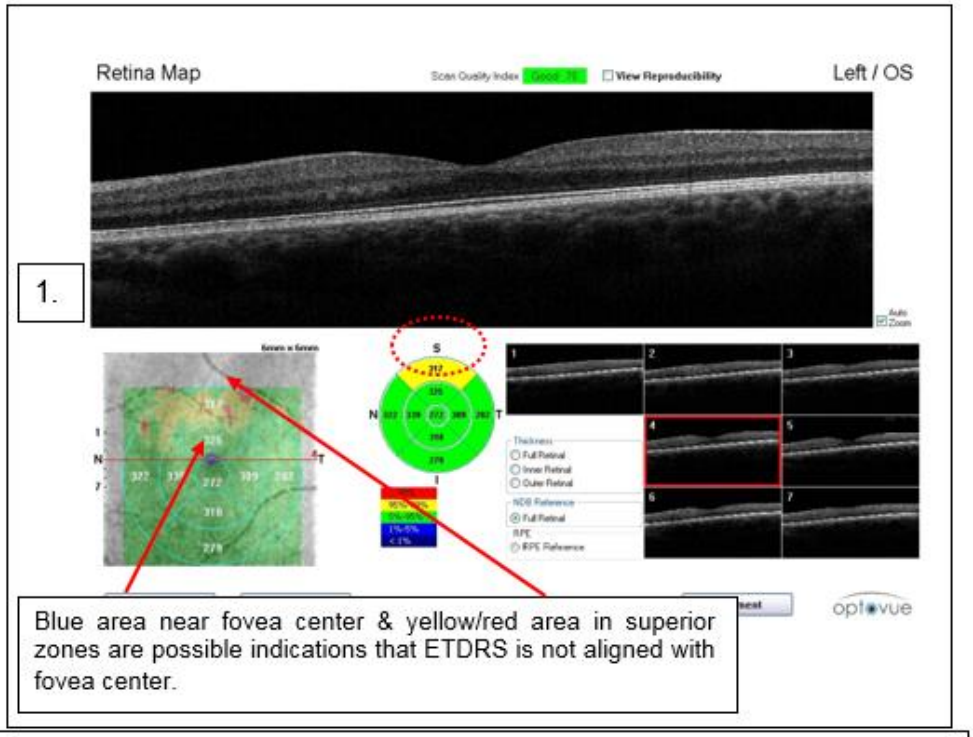
Check the layer segmentation accuracy of the retina scan: The segmented layers for retina scans are the ILM, IPL, and RPE. Check the segmentation lines for accuracy, and make adjustments as necessary. The ILM segmentation line should be at the retinal surface at the ILM. The IPL segmentation line should be at the outer limit of the IPL layer. The RPE segmentation line should be in the middle of the RPE layer. If the

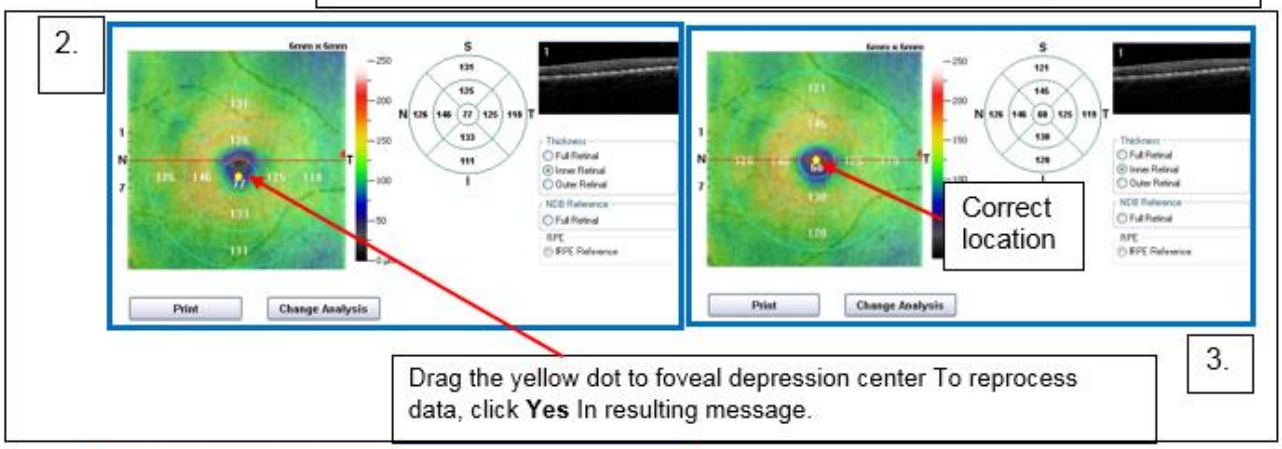
segmentation lines are not accurately placed, the thickness measurements will be affected. If the user performs any manual correction, the results will be valid and the scan can be used.

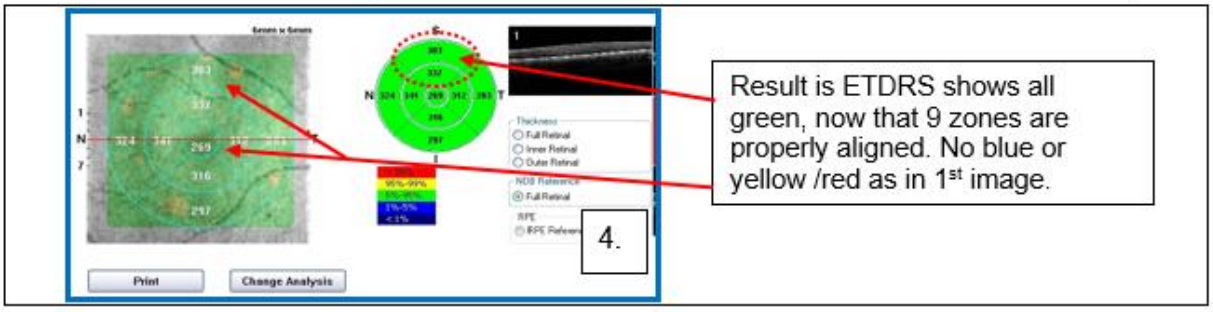
Fovea Locator: Software automatically identifies fovea location for Retina Map, primarily based on detecting the thinnest location of the inner retinal thickness. To compare Retina Map from different visits, the software uses the fovea location as the basis for registration. The fovea location detection should be verified by user for individual Retina Map scans; it is easiest to verify the fovea location by switching to the inner retinal thickness map display. If the fovea is off center to a large degree relative to the ETDRS grid, it should be manually corrected. The automatic fovea find may be affected by retinal pathologies and fixation error. If a patient failed to fixate on the fixation target or near the target, the actual fovea could be outside the software search range and thus result in an incorrect fovea location.

Retina scan pattern not centered on the fovea: During the retina scan, if the patient does not maintain good fixation, the fovea may not be in the center of the scan pattern. All measurements assume the fovea is in the center of the scan within 500 microns. If it is not, then the measurements will be affected.

If the fovea is not in the center of the scan, it can be moved by the user manually. This will ensure the measurements come from the expected locations. If the repositioned fovea causes some measurement areas to be outside the scan pattern, these measurements should not be used. Select either full retina or inner retina thickness button to further visualize the foveal depression. The fovea position marker (yellow dot) can be moved on the scan by simply dragging and dropping the yellow dot, and selecting **Yes** at the prompt to reprocess. The reproducibility chart will change to reflect the new values.


Retina Map
Left / OS
1.
Blue area near fovea center & yellow/red area in superior zones are possible indications that ETDRS is not aligned with fovea center.


2.
Print
Change Analysis
Correct location
3.
Drag the yellow dot to foveal depression center To reprocess data, click **Yes** In resulting message.


Print
Change Analysis
4.
Result is ETDRS shows all green, now that 9 zones are properly aligned. No blue or yellow /red as in 1st image.

Retina Map OU Report

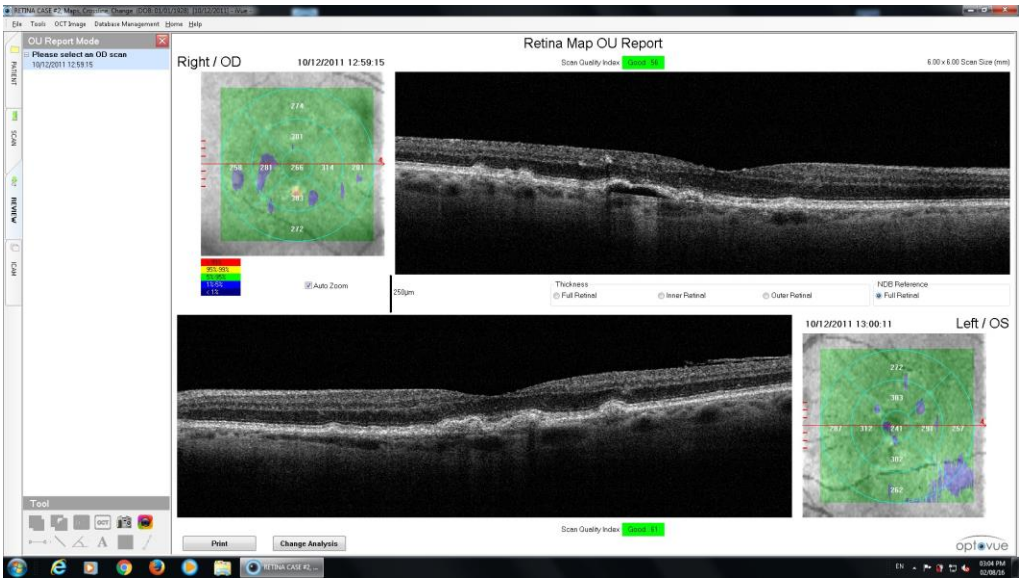


Figure 34 Retina OU Report

Retina OU report shows a Bscan and either Thickness or NDB Map from each eye. Map layer is selectable, Full, Inner, Outer

Retina Map Change Analysis Report

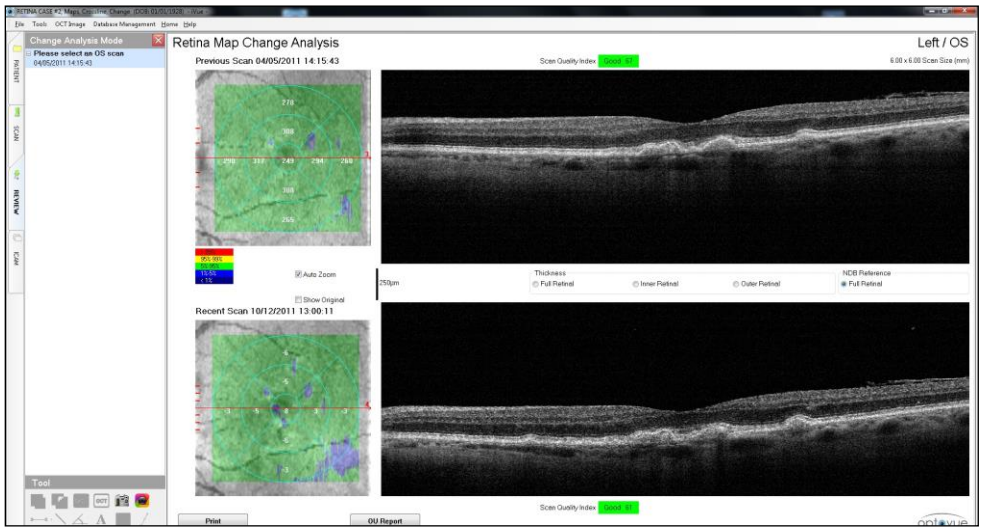


Figure 35 Retina Map Change Analysis Report

Retina Map Change Analysis reports display the previous map at the top, and the most current at the bottom. The en face image also includes a thickness map. The current map can display the change from a previous scan, or the actual thickness values of the

scan result. Retina scans from different scan times are aligned according the location of the fovea which can be manually adjusted.

☞ Each of the seven current raster scans is displayed with the same scan of the previous retina map scan. (User selected if more than one previous visit or scan.) Scroll the mouse wheel to move through the available seven raster scans.

☞ **Notes:** The **Clean Diagnosis Data** function does not affect manually edited scans.

Change analysis is a simple difference map without any statistical adjustments. The values are simple differences and may not be statistically or clinically significant.

If the scans in multiple visits are manually adjusted please ensure the foveal adjustments are consistent.

Retina Cross Line Report

Retina Cross Line review default screen is displayed with one OCT image (option **Both** selected as shown in the image). An arrow is displayed on the top right corner of the OCT images indicating the scan direction. Furthermore, arrows are displayed on the en face image showing the direction and location of the scan.

☞

Note: The user can choose the default display from User Preferences (See section 7.2.1 for more information).

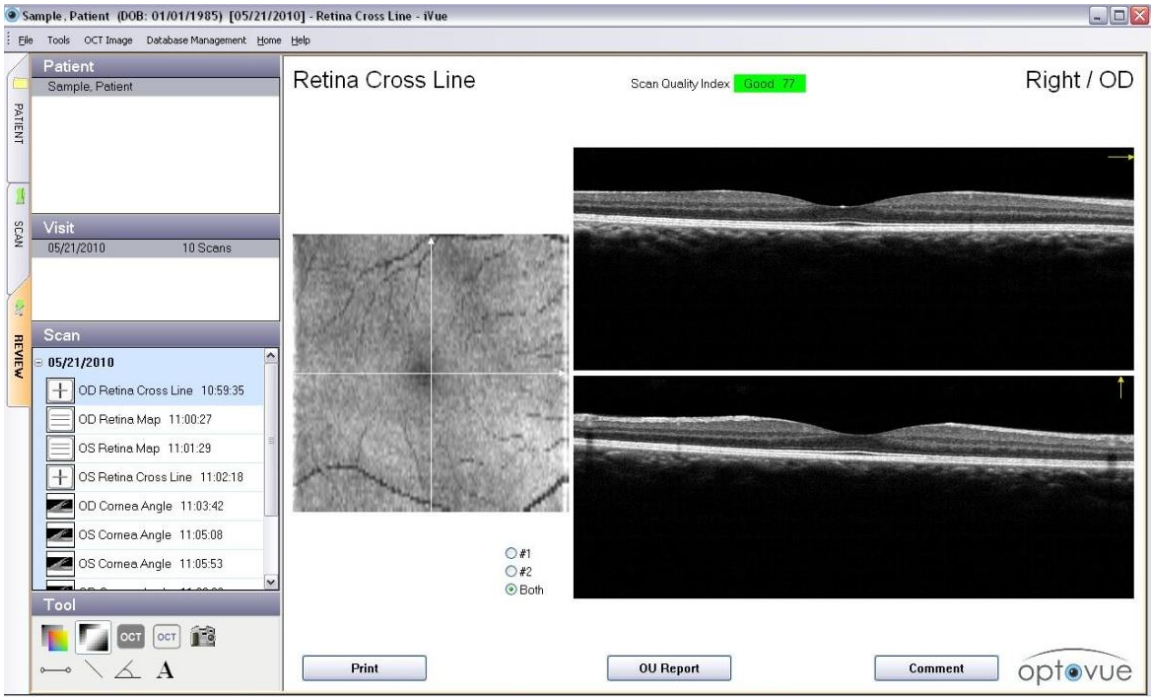
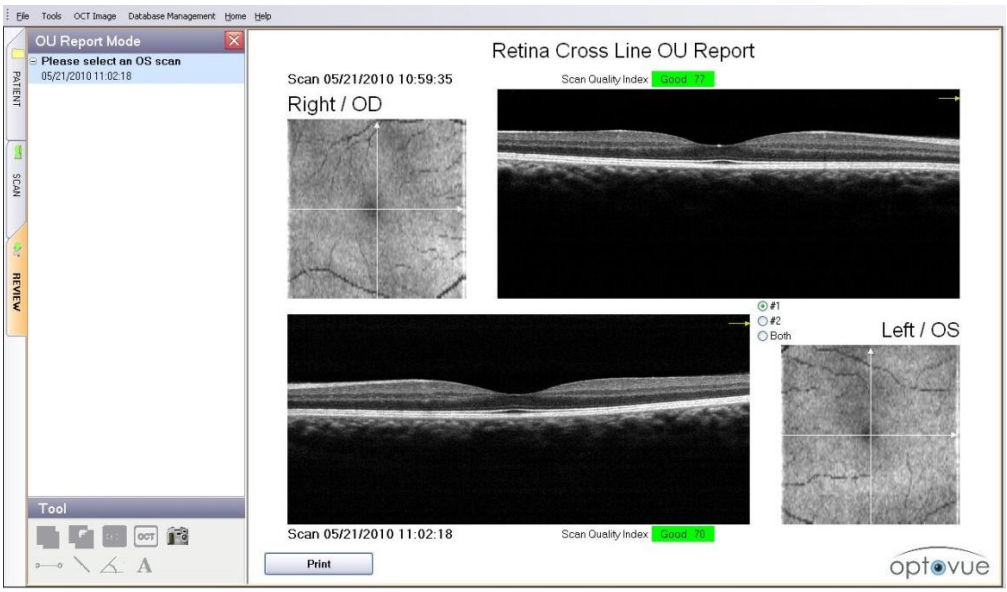


Figure 36 Retina Cross Line Analysis With Both Selected

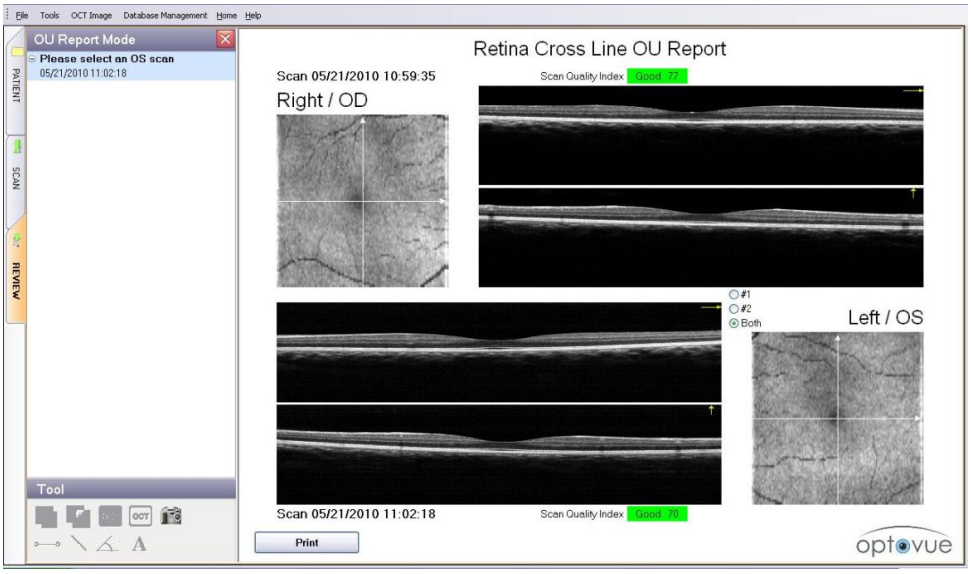
Selecting option **#1** or **#2** by clicking the radio button shows one image in a larger display area, as shown in the image below. Again, the scan direction is shown in the top right corner in order to show its correlation with the arrow on the en face image.

Figure 37 Retina Cross Line OU Report With # 1 Selected

Retina Cross line OU report by default (option **Both** selected) shows both scans for each eye. Similar to the Retina Cross Line report when option **#1** or **#2** is selected the corresponding scan is shown in a larger display. See the OU Cross Line report images below.



OU Cross Line Report With Option #1 Selected



OU Cross Line Report With Both Option Selected

3D Retina Report

Note: The 3D Retina scan is a payable upgradable feature.

The 3D Retina report is shown below. There are three different viewing options which can be selected from the three tabs on the top left panel: **SLO, EnFace**, and **Thickness**. The top right panel and lower panel are the respective vertical and horizontal B-scans. The position of the vertical and horizontal B-scans correlate to the red and green line marked on the tab presentation window.

Tab Presentation Window

SLO: This view shows a SLO-style image created by the sum of all C-scans, producing a high contrast en face image.

En Face: This view presents the sum of c-scan planes indicated in the thickness value field. This view has the option to see three different reference planes: ILM, IPL, and RPE.

Thickness: Presents the thickness with a log scale of user selectable segmentations for Full, Inner, and Outer retina.

Note: The color scale for the 3D map is not present in the USA software version.

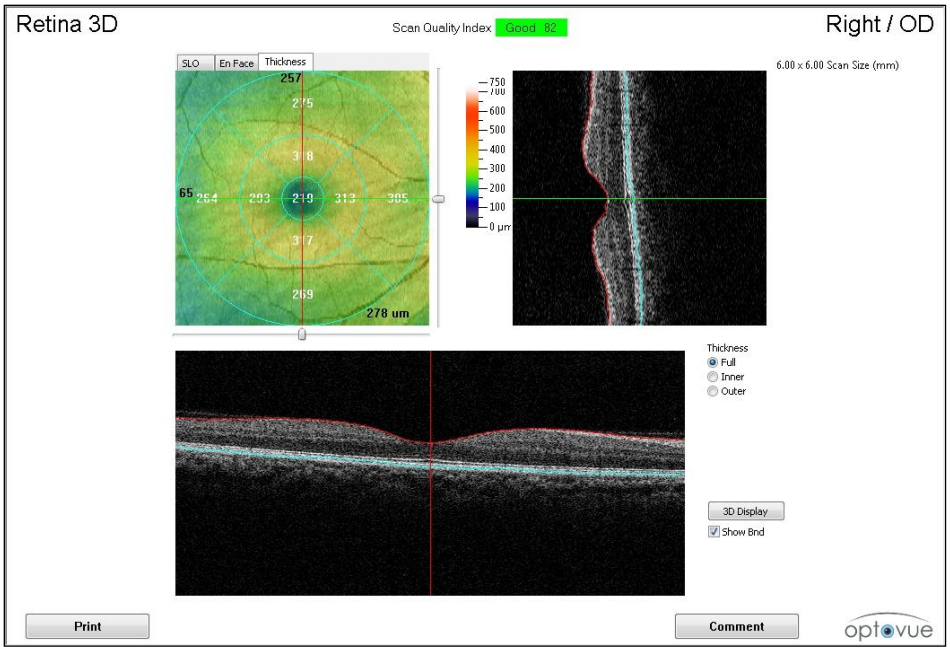


Figure 38 3D Retina Report, Thickness Tab Selected

Clicking the **3D Display** button on the 3D Retina presentation displays a separate 3D window, as shown below.

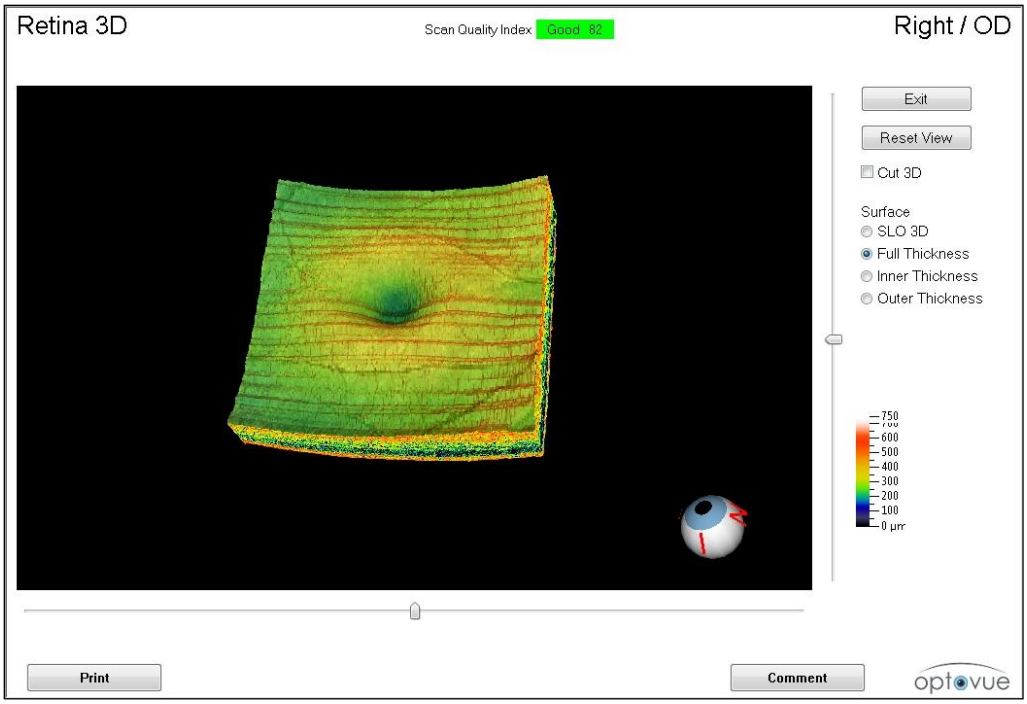


Figure 39 3D Retina Display

The 3D display has four different options:

SLO 3D,

Full Thickness

Inner Thickness, and

Outer Thickness.

The 3D model can be rotated by clicking the model and dragging the model to the designated orientation. The eyeball on the bottom serves as an orientation indicator based on temporal (**T**), superior (**S**), nasal (**N**) and Inferior (**I**) positions. To zoom in on the 3D image, click the 3D image and scroll using the mouse wheel.

Click **Reset View** to return to the default position.

6.2.5 Nerve Fiber Report

Nerve Fiber ONH Report

The nerve fiber scan produces the **RNFL Thickness (at Diameter 3.45mm) TSNIT** graph and NFL thickness map from disc margin to 4.93 mm radius from disc center. All NDB software includes the basic 3D optic nerve scan for ONH scan registration. The full featured scan is available as an upgrade. The disc margin is automatically detected in the 3D scan by the software but can be modified if the glaucoma specialist draws it differently. Nerve head parameters now displayed are: cup area, rim area, rim volume, nerve head volume, cup volume, cup/disc area ratio, cup/disc horizontal ratio, and cup/disc vertical ratio. The cup's shape was also drawn inside the optic disc in the map representation. A sample scan report is shown below.

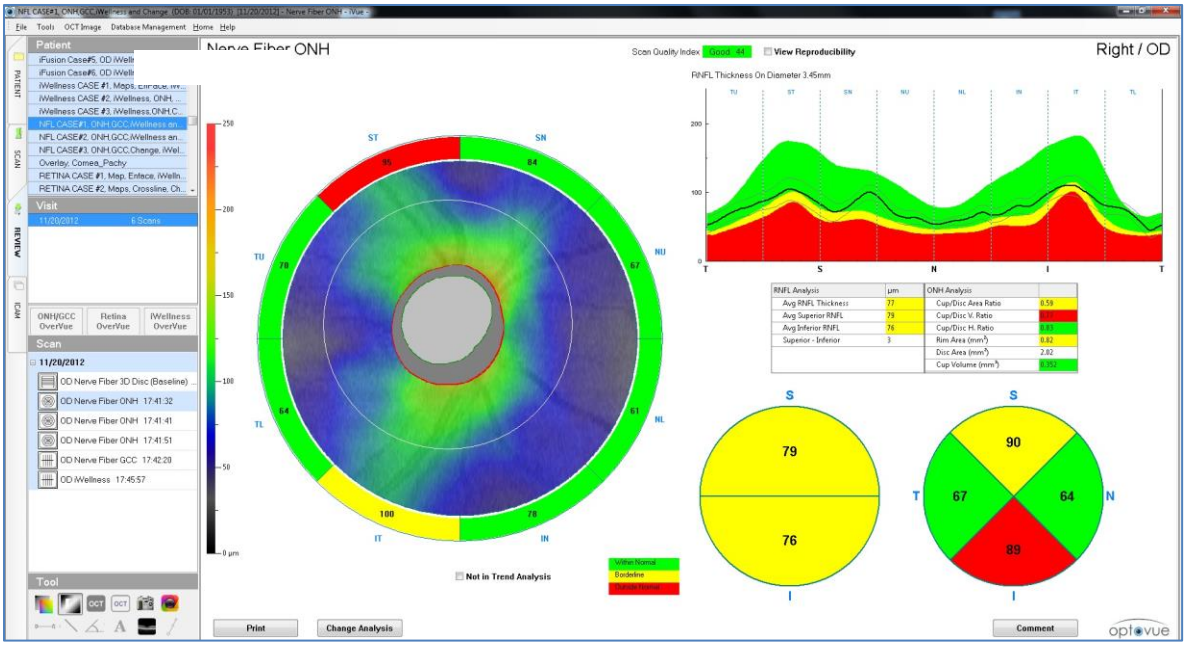


Figure 40 Nerve Fiber Scan Analysis Report Components

The ONH scan report conveys the device limits of ONH scan TSNIT plot reproducibility by displaying not only the measured TSNIT curve (that is, Result), but also the reproducibility range of the TSNIT curve calculated based on (Result ± 2 Reproducibility), where reproducibility is the standard deviation of reproducibility estimated from the iVue Reproducibility and Repeatability study.

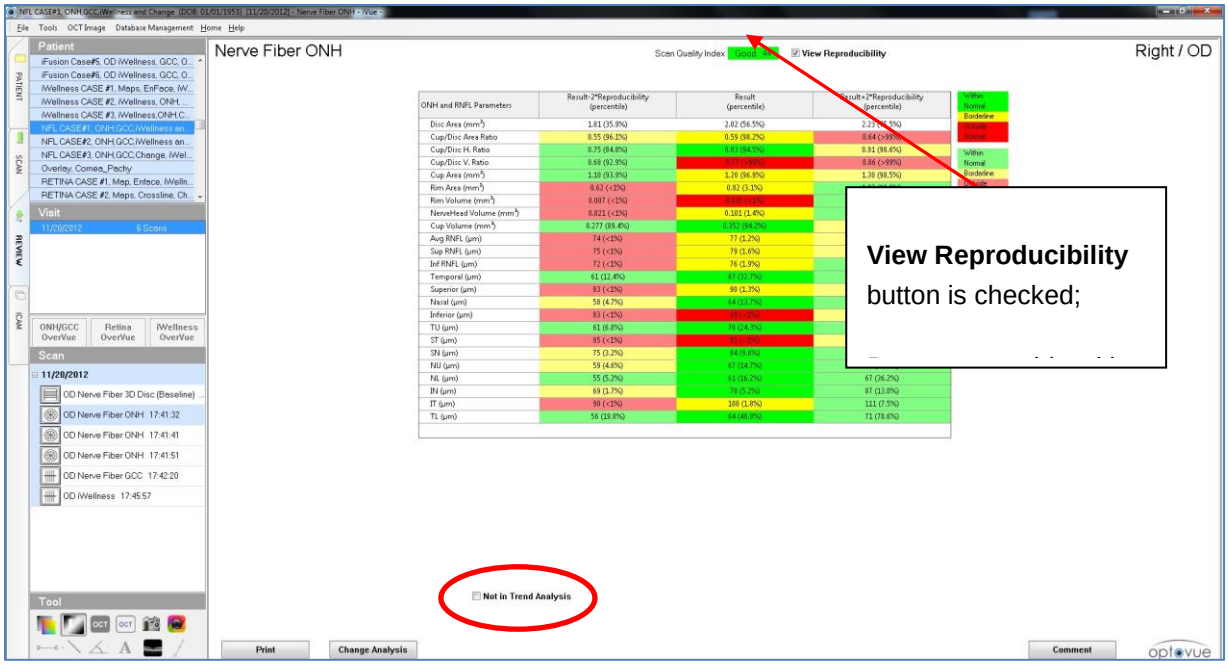


Figure 41 Nerve Fiber ONH With Reproducibility Parameters Values Table

ONH Scan Registration

The ONH scan utilizes a 3D scan pattern to produce an SLO type image for registration purposes. Providing vessel registration and optic disc centering for orientation and serial registration, these scans serve as the reference image that enables real change analysis for the ONH scan.

NOTE (Poor scans can be removed from analysis by checking" not in trend analysis", see red circle)

A new reference image may be desirable in the event of the vessel changing (orientation) or moving, due to disease progression or surgical intervention. ONH scans from that point would use the newer reference image.

ONH Manual Boundary Adjustment

This feature allows the operator to verify any automatic boundary detection performed by the software and allows for manual adjustment.

To manually adjust the RNFL layer boundary lines, click the **OCT Image** button on the top menu. The menu is displayed.

Select **Modify Boundary** from the menu. Select the designated boundary to be modified within the screen and make adjustments on those selected scans.

Click the **Save** button. Any manual boundary adjustments will recalculate measurements after the **Save** button is clicked.

To manually adjust the disc boundary line in the baseline image, click the **OCT Image** button on the top toolbar. The menu is displayed.

Select **Modify Disc Baseline** from the menu. Make the required adjustments in the screen. Click the **Save** button. Any manual boundary adjustments will result in measurement recalculations after the **Save** button is clicked.

☞ **Note:** The **Clean Diagnosis Data** function does not affect manually edited scans.

☞ Note: Disc boundary line modifications of the ONH will only apply to patients where no 3D is available; otherwise the disc boundary will be modified on the 3D scan.

Factors That Can Affect Scan Quality

ONH scan not centered on the optic disc: During the ONH scan acquisition, the operator should check to ensure the scan pattern is well centered on the optic disc. If it is not, the operator should move the scan pattern to be centered on the disc displayed onscreen in the en face window by clicking the disc center. If the operator does not center the scan pattern on the disc, the RNFL thickness measurements may be affected. The software will automatically position the RNFL TSNIT circle to be centered on the optic disc after the scan, however if the disc is too close to the edge of the scan pattern, some of the data may be missing if the measurement circle falls outside the scan pattern area. The scan should be retaken if this occurs.

For optimal centration, it is recommended that that the TSNIT be as centered with respect to the edge of the scan pattern, and for any offset the widest distance between the TSNIT line and the edge of scan pattern not exceed three times the minimum distance between the white TSNIT line and the scan pattern edge.

Check optic disc drawing and RPE tip placement: Ensure the optic disc drawing accurately marks the edge of the optic disc boundary. Also ensure the RPE tip placements are at the correct positions (end of RPE/choroid complex at the disc

margin). Redraw the optic disc margin drawing if required. Adjust the RPE/choroid tips placement if required. If the optic disc drawing or the RPE tip placement is not accurate, the measurements can be affected. See the **Verify RPE Tips** section as required. Scans should be retaken if the RNFL measurement circle falls outside the scan area after the disc drawing and RPE tip placement are in correct positions. This verification of RPE tips can be done at any time by right clicking on the NFL result map. NDB analysis is available for ONH when the baseline is derived from the clinician or by 3D optic disc scan.

Check the layer segmentation accuracy of the Nerve Fiber ONH scan: The segmented layers for ONH are ILM and NFL (Nerve Fiber Layer). If the segmentation lines are not accurate, the user should manually make the necessary corrections. If the segmentation is not accurate and the user does not make the correction, the results will be affected. If the user performs manual correction, the results will be valid and the scan can be used.

Nerve Fiber ONH Change Analysis

The Nerve Fiber ONH Change Analysis option allows the user to compare ONH scan results from the same patient for two different examination dates. The previous scan, or scan with the oldest date, will be displayed on the top portion. The recent scan will be displayed on the bottom portion.

In the center of the **Change Analysis** display screen will be the RNFL Plot which indicates the RNFL 3.45mm TSNIT plot thickness. The average RNFL thickness value for the former scan will be displayed. The change in average RNFL thickness and disc parameters between Previous and Recent Nerve Fiber ONH scans is displayed as **Change Analysis**. Pie charts represent the **TSNIT** chart for the two scans. The red text indicates the difference value between Previous and Recent Nerve Fiber scans. The S/I and quadrant maps are also shown for both visits with the recent visit maps also showing the difference in values. The Scan Quality Index is indicated for both scans.

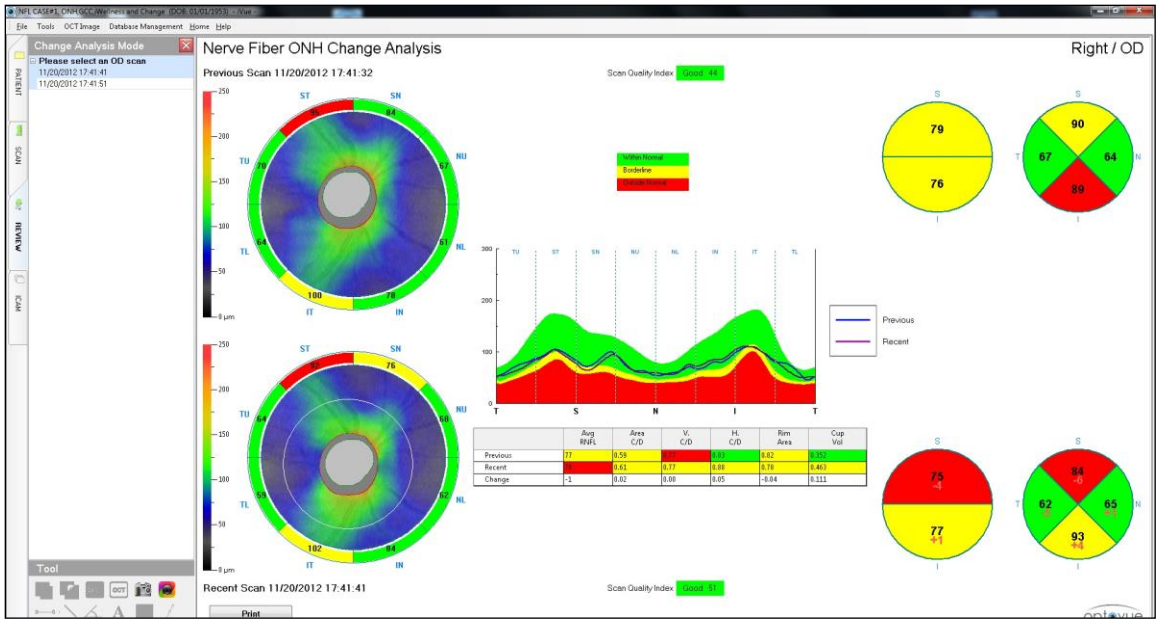


Figure 42 Nerve Fiber ONH Change Report

Note: Change analysis is a simple difference map without any statistical adjustments. The values are simple differences and may not be statistically or clinically significant. The comparison of all non-change measurements to NDB remains the same as the individual display pages.

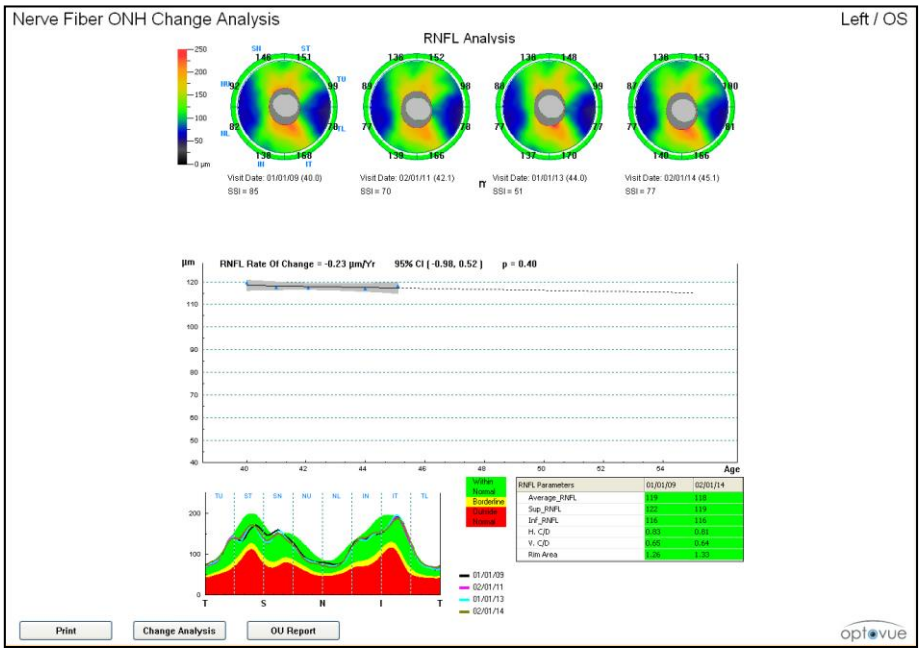


Figure 43 Nerve Fiber ONH Change Analysis

The report will show up to four Nerve Fiber ONH change analysis visits when there is no GCC data available. The RNFL thickness map, TSNIT, overlay, first and last visit RNFL average comparisons and disc values will be displayed. RNFL average values will be plotted over time to give the rate of change, in microns, as well as 95% CL and the P-value. (See section 6.4.3 for definitions and interpretation.)

The OU report for the ONH scan can also be generated and is shown below. Comparisons are calculated for inter- and intra-eye symmetry.

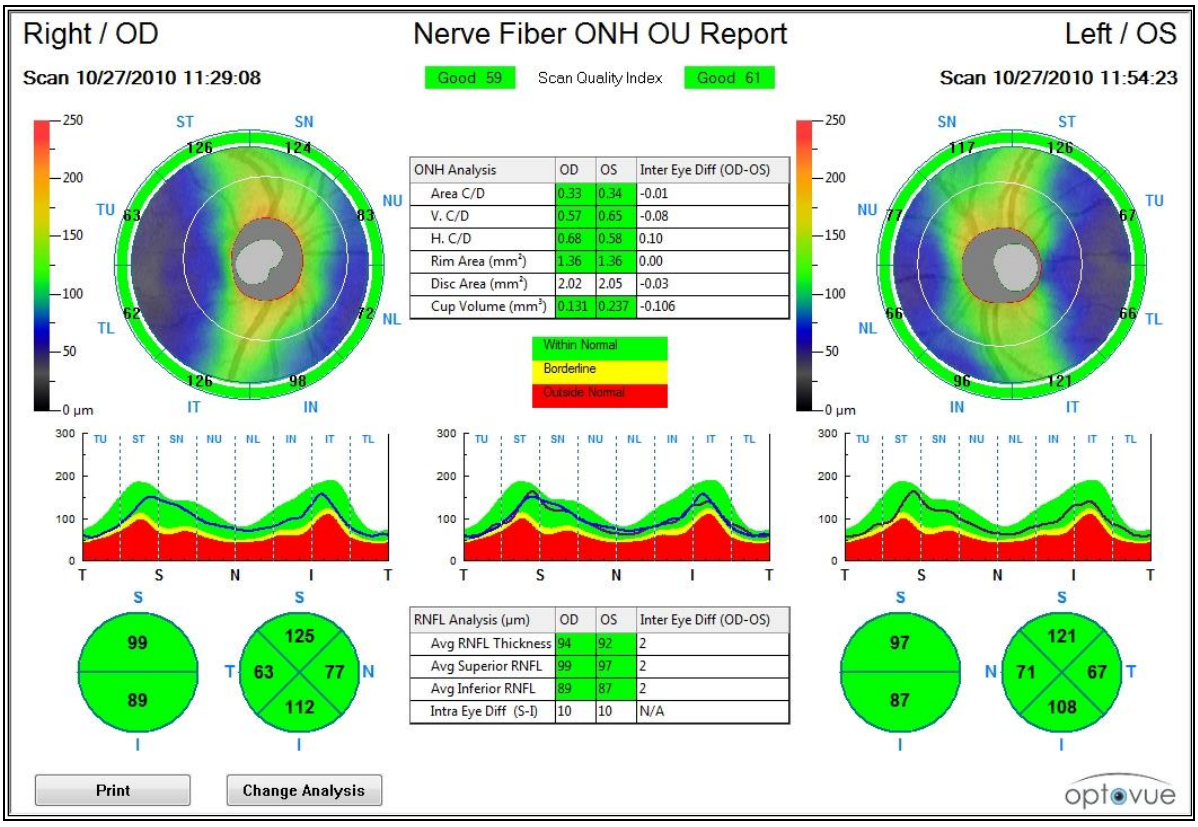


Figure 44 Nerve Fiber ONH OU Report

When OD/OS ONH scans and OD/OS GCC scans are all available the OU report displays all four scans. Different visits can be selected from the left column. Click the **OU Report** button to recalculate after selecting different scans, and only one of each scan can be checked.

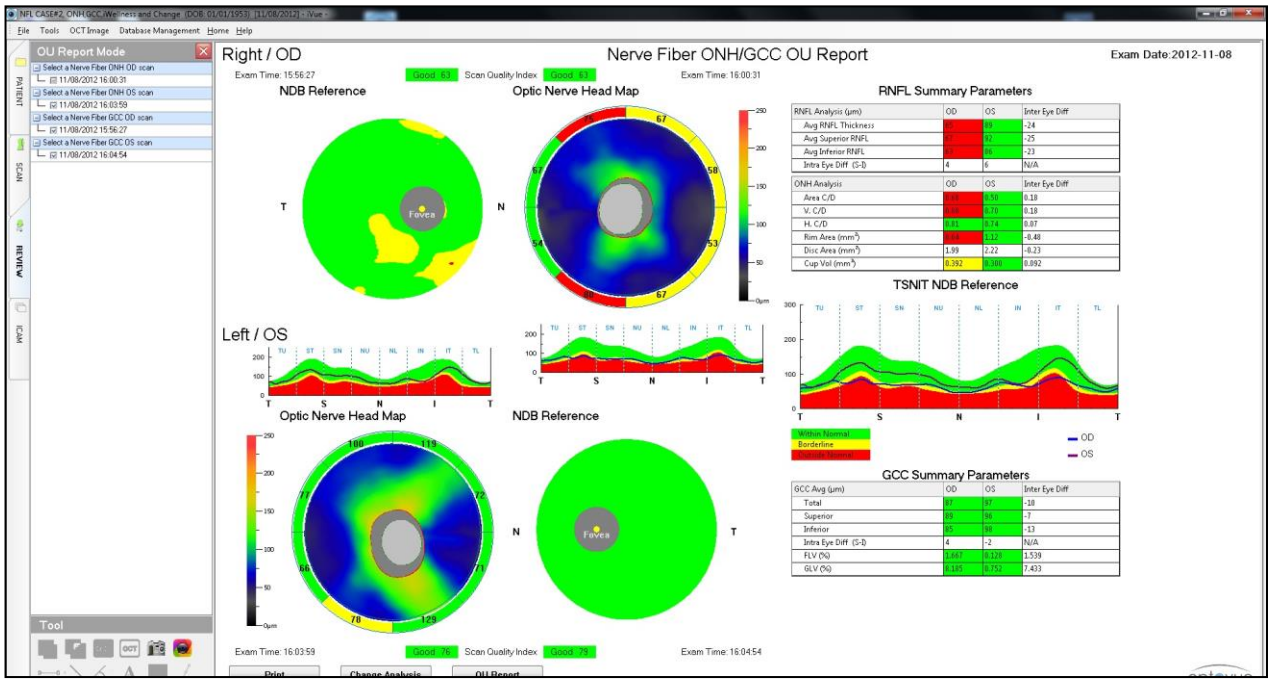


Figure 45 Nerve Fiber OU Report With Four Scans Displayed

TSNIT Histogram

RNFL thickness profile in the ONH Scan is the thickness of RNFL at a *calculated* **3.45mm diameter** around the *center* of the disc, ***not the center of the scan.***

The thickness measurement at 3.45mm is re-sampled relative to the disc center, not the scan beam center, so the de-centering of the disc relative to the scan beam will not affect the measurement.

Verify RPE Tips

The system algorithm automatically calculates and places the RPE end points (relevant to ONH scan only). However, should the operator wish to verify the placement of the end points, place the mouse cursor on the ONH report, right-click, and then select **Modify RPE Anchor Points**. The system will display the screen shown below and the operator may verify and/or adjust the tip selection (yellow points).

Only one screen presentation (one image pair out of the six possible pairs of radial scans) needs to be verified for tip placement. The selected pairing must be visible as the screen presentation when **OK** is selected to save the correct verification or adjustment.

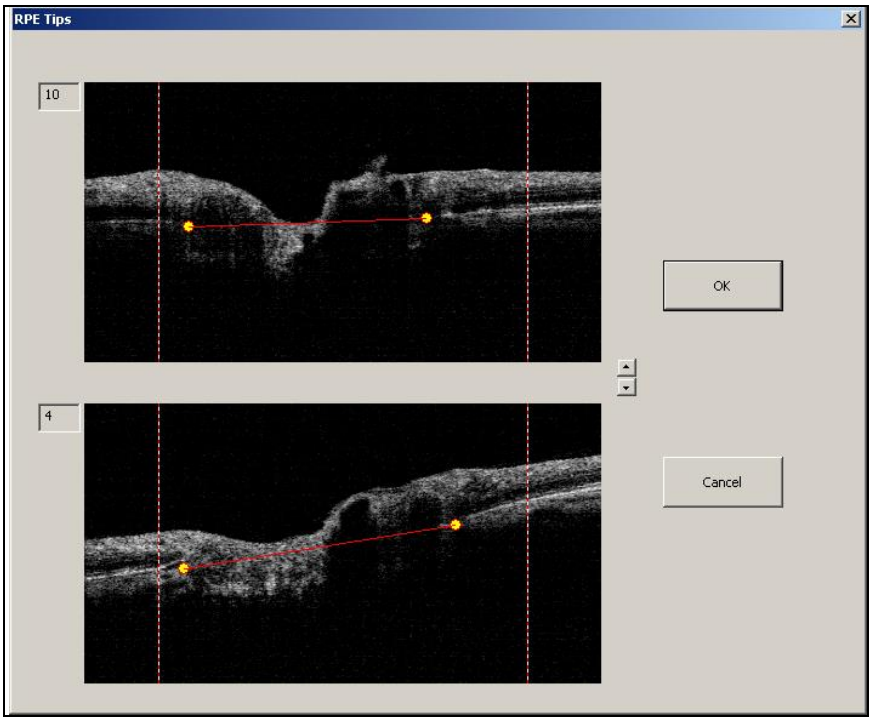


Figure 46 RFE Tip Verification

Verify/Modify Disc Baseline

The system algorithm automatically calculates and draws the disc baseline (relevant to 3D-Disc scan only). However, should the operator wish to verify the disc baseline, click the **Modify Disc Baseline** option in the **OCT Image** menu.

To modify the baseline, place the cursor on the disc and drag the anchor points to modify the disc. When this is completed, click **Save as Baseline** to save any baseline changes.

☞ **Note**: The baseline for the ONH disc should be captured through the Nerve Fiber 3D-Disc scan. If the ONH scan was captured previously without a 3D scan, the baseline will be based on the ONH scan until a Nerve Fiber 3D-Disc scan is captured and the data reprocessed.

NDB comparison is only available when disc margin is derived from a 3D-Disc scan.

3D-Disc reference may not be valid if motion artifacts are present in or near the disc. Motion artifact is recognizable, by disconnected/distorted blood vessel patterns or heavy black horizontal lines.

When viewing the editor, please make note whether the baseline is based on the ONH or 3D scan. For example, if the baseline is based on the 3D scan, the disc baseline may be displayed in the wrong location in the ONH disc baseline editor. In this case, the shape of the baseline will be correct but located off center from the disc. To properly edit the baseline view the original baseline scan and edit.

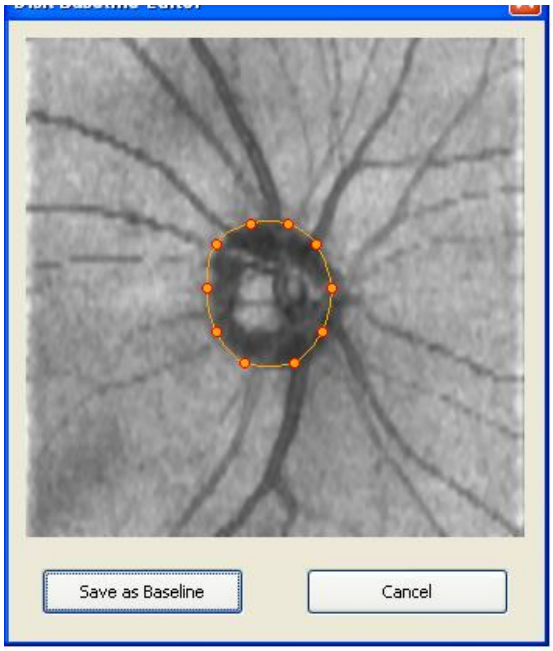


Figure 47 Modified Disc Baseline

Nerve Fiber 3D Disc Report

☞ Note: The Nerve Fiber 3D disc scan is an upgradable feature for client purchase.

The ONH 3D analysis scan is presented very similarly to the 3D Retina scan. The tab presentation window has three different views: **SLO,**
En Face, and **Thickness**. In the SLO view, users can view and modify the disc margin drawing for the 3D disc scan. The image below shows the different presentation controls.

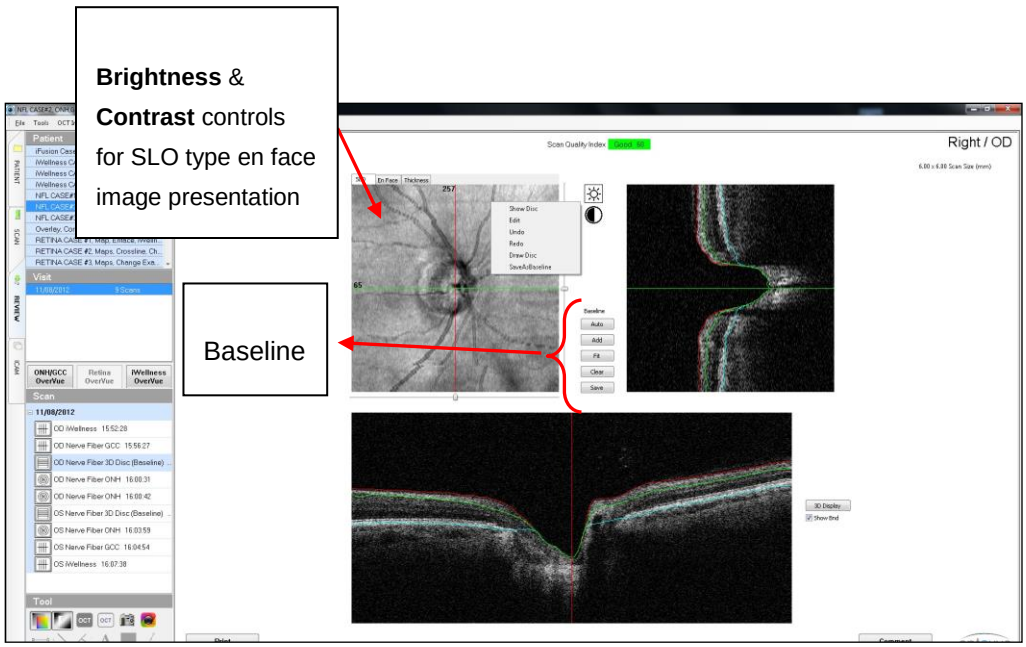


Figure 48 Nerve Fiber 3D Disc Report

Baseline Control Buttons:

- **Auto** – Draws the disc margin on the En face SLO image.
- **Add** – Adds an anchor point on the image for disc boundary. Click the SLO image to find the correct point (RPE tip) position, then click **Add**.
- **Fit** – Uses anchor points to draw the disc boundary to close contour.
- **Clear** – Clears any currently marked anchor points
- **Save** – Saves the resulting disc drawing as the baseline for the ONH scan

Note: As any position in the SLO image screen is selected the two perspective windows also change to reflect the location and cross section within the 3D presentation.

GCC Presentation

Note: The nerve fiber GCC scan is a payable upgradable feature.

The GCC presentation displays two thickness maps, GCC Thickness and Retinal NDB reference overlaid on retinal en face. The GCC, or inner retina, is considered to be comprised of the three retinal layers: the RNFL, the ganglion cell body layer, and the Inner Plexiform Layer (IPL).

Note: Clinicians refer to the three layers listed above collectively as the ganglion cell complex.

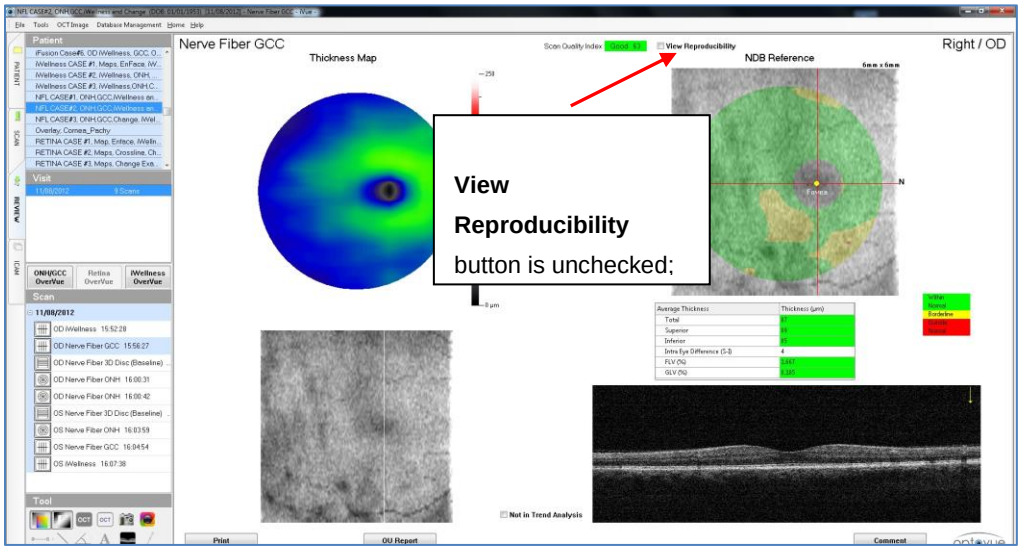


Figure 49 Nerve Fiber GCC Thickness Map

NDB Reference Map

A thickness map is provided on the top left portion of the report. This map can be changed to show three different thicknesses: **GCC, Full Retinal**, and **Outer Retinal**. The display for thicknesses may be changed based on user selection under the **Thickness** option located in the middle of the report. The top right portion of the report is the NDB Reference Map. The NDB Reference Map is color coded based on the normative database.

A difference table is provided to the right of the scan report. The **Total**, **Superior**, and **Inferior** thickness values are given in microns (µm). Values in the difference table are color coded for normative comparison. Focal Loss Volume (**FLV**) is a parameter that provides a quantitative measure for the amount of significant GCC variation from NDB. **FLV** is the total sum of significant GCC variation from NDB (in volume) divided by the map area. As such it provides a percent of significant tissue variation for volume.

Global Loss Volume (**GLV**) is the sum of the pixels where the Fractional Deviation map value is < 0, and then divided by the total area to give a percent loss of GCC thickness.

If the user changes the patient age, the GCC scan must be manually refreshed to reflect the correct FLV and GLV values. This can be done by either right clicking the scan and selecting reprocess data or by cleaning the diagnosis data through the menu. Refer to section 7.1.7 for more information on how to clean diagnosis data.

The GCC scan also registers the fovea. In processing, the pattern uses existing segmentation results to find the thinnest area in the map. Generally, this area coincides with fovea depression. Using this assumption, the software will compare two sets of GCC thicknesses (from different visits) based on alignment of the thinnest area. The fovea location should be checked on the GCC scan. It should be positioned 1mm off center, toward the nasal side (revealing more temporal retina) and aligned with the red cross lines. If the fovea is off center to a large degree, it should be excluded. The fovea location cannot be changed in the GCC scan. If the patient has any retina based pathology, the scan may not align correctly. During change analysis, patients with pre-existing retina pathology should be assessed subjectively by the clinician. The pooled reproducibility SD values are applied in the software to calculate the range of measurement reproducibility to accompany the measured result as illustrated in the example below when View Reproducibility is checked.

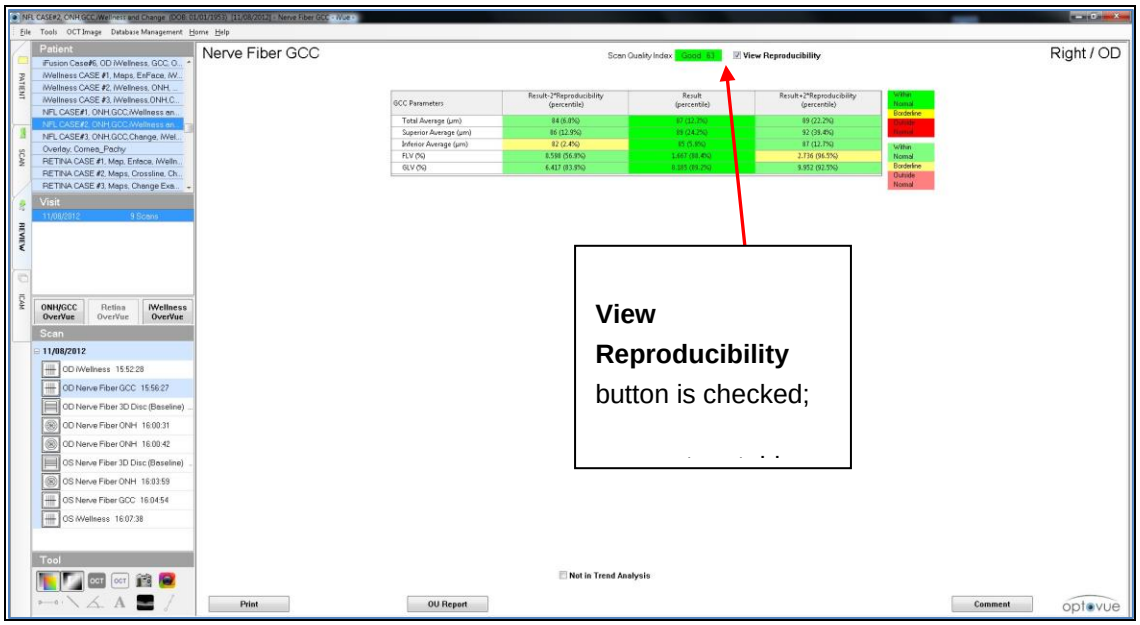


Figure 50 Nerve Fiber GCC Report With Parameters Table

GCC Change Analysis

The GCC Change report compares the two NDB Reference Maps from different visits overlaid on a retinal en face. Additionally, a thickness difference map is provided in the report middle. The difference chart comparing thickness values is located to the right. The B-scans on the right side of the report correspond to the red vertical line on the GCC thickness map. Use the mouse wheel to scroll through corresponding B-scans.

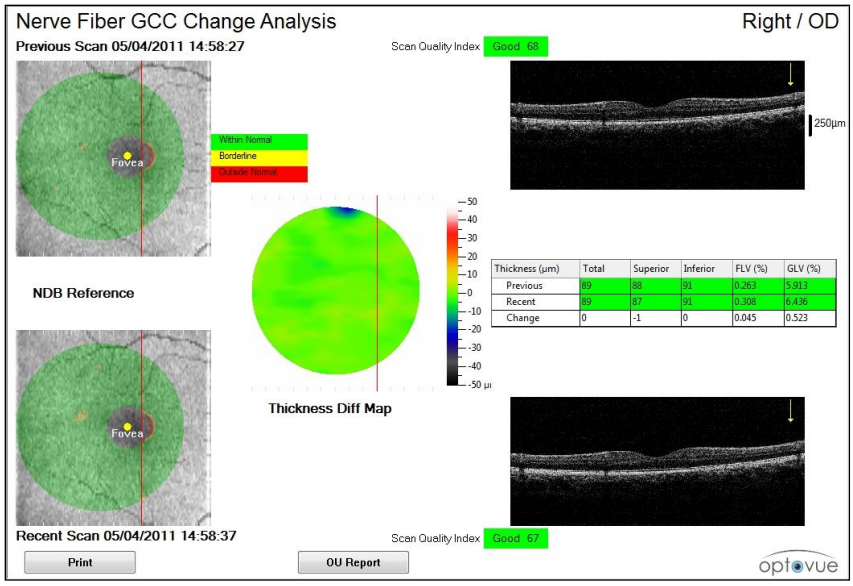


Figure 51 Nerve Fiber GCC Change Analysis Report

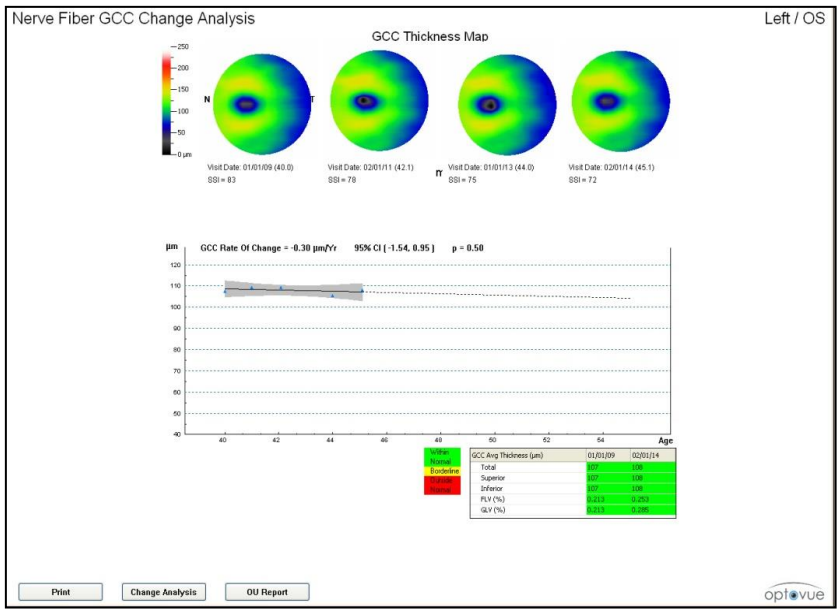
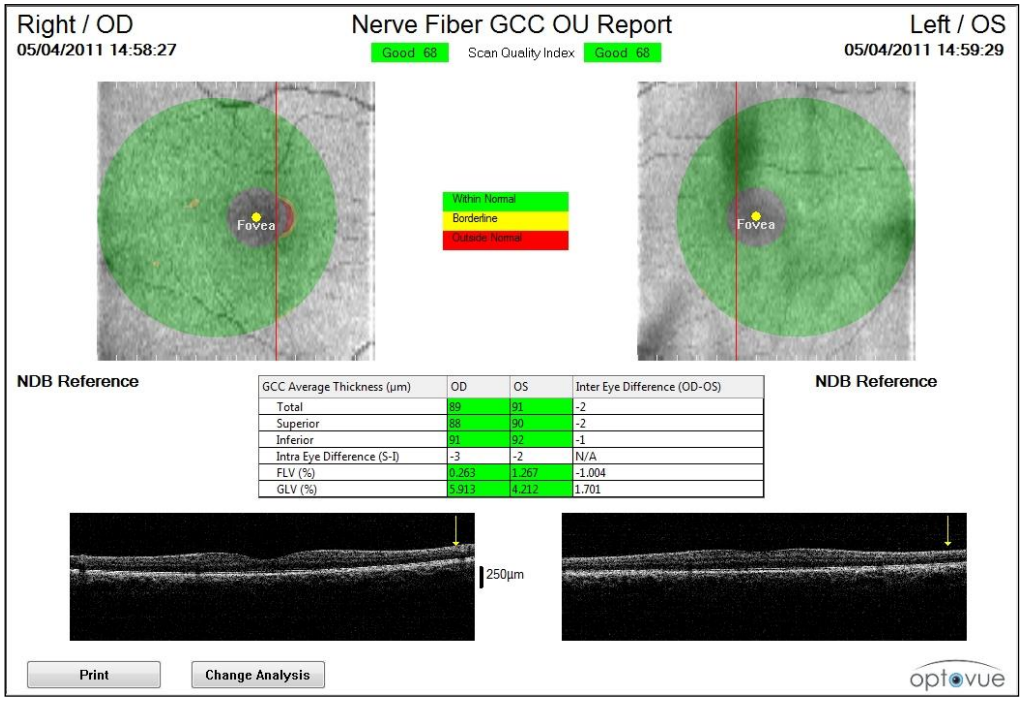


Figure 52 Multi-Visit Nerve Fiber GCC Change Analysis Report

In the case of multiple visits when no ONH data is available, a GCC Change Analysis report contains thickness maps, trend analysis, and the first and last visits compared to NDB comparisons. See section 6.4.3 for definitions and interpretation.

GCC OU Analysis

The GCC OU report compares the NDB Reference Maps from the right and left eyes. Underneath is a comparative difference chart giving **Inter-Eye Difference (OD-OS)** and intra**-eye** difference values.



GCC Average Thickness (µm)	OD	OS	Inter Eye Difference (OD-OS)
Total	89	91	-2
Superior	88	90	-2
Inferior	91	92	-1
Intra Eye Difference (S-I)	-3	-2	N/A
FLV (%)	0.263	1.267	-1.004
GLV (%)	5.913	4.212	1.701

Figure 53 Nerve Fiber GCC OU Report

6.3 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 thickness maps and data for up to four visits for the current patient eye.

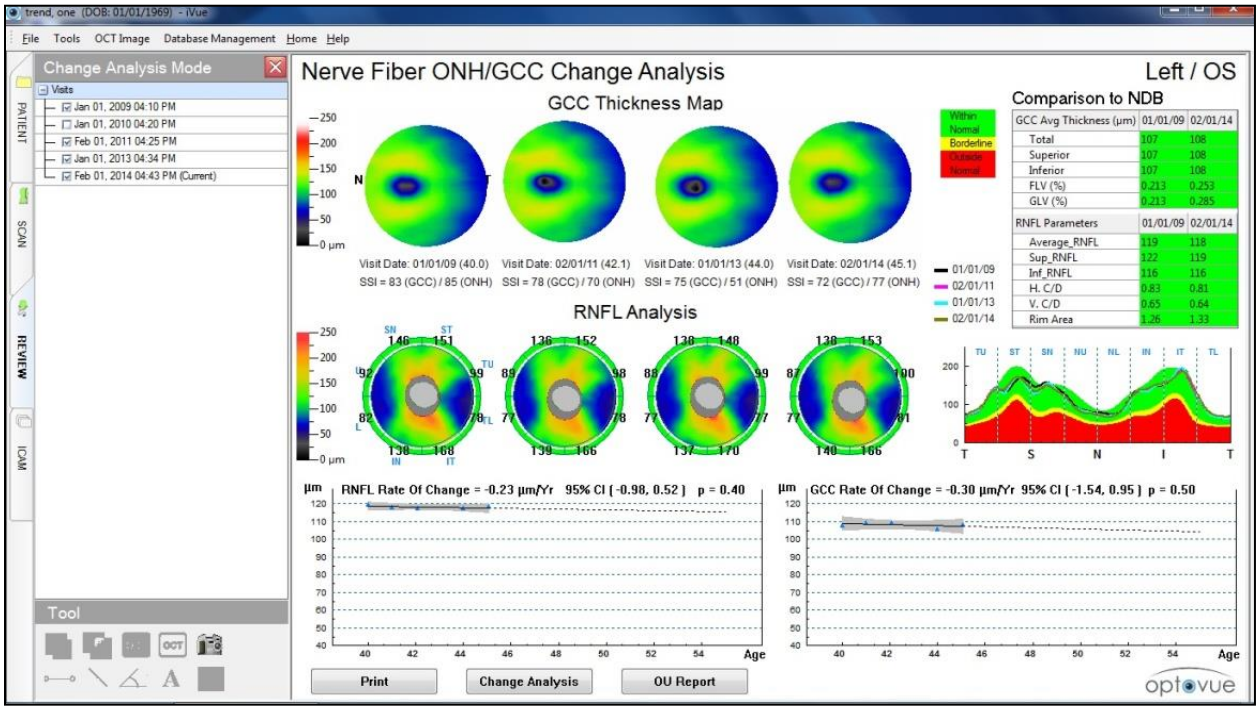


Figure 54 Nerve Fiber ONH/GCC Change Analysis Report

- **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.
    - 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.

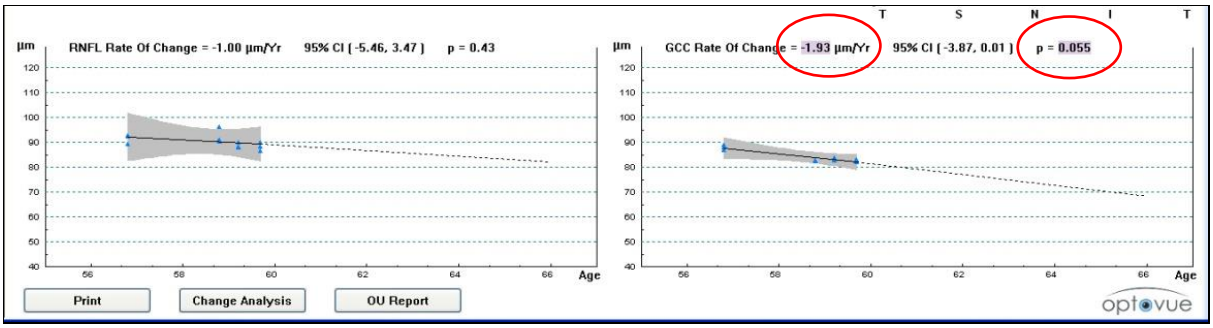


Figure 55 Marginally Significant Change

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.

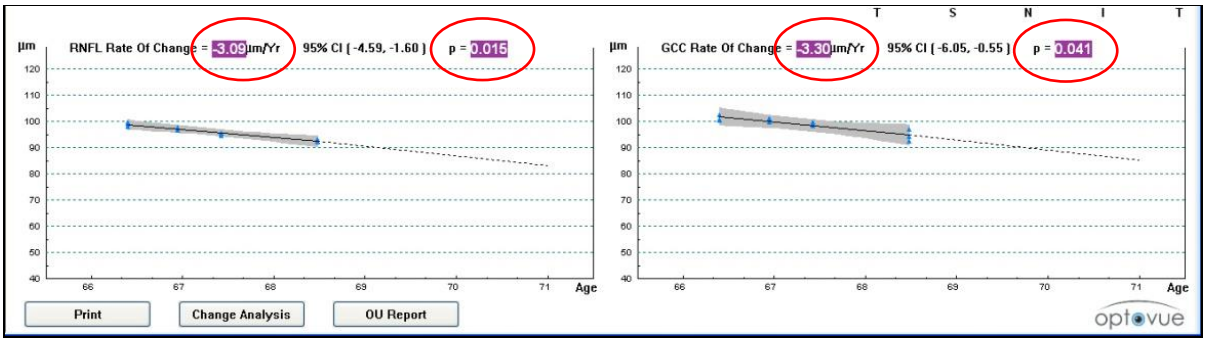


Figure 56 Statistically Significant Change

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.

6.4 Cornea Report

NOTE: A separate software license is required for the operational capability of corneal epithelial thickness measurement.

Cornea Pachymetry Report

The Cornea report includes the OCT image on top, a Pachymetry assessment table below to the left, and a pachymetry and Epithelial maps showing thickness at lower right. Alternately if the Stroma Map button is selected the thickness of the Stroma is shown.

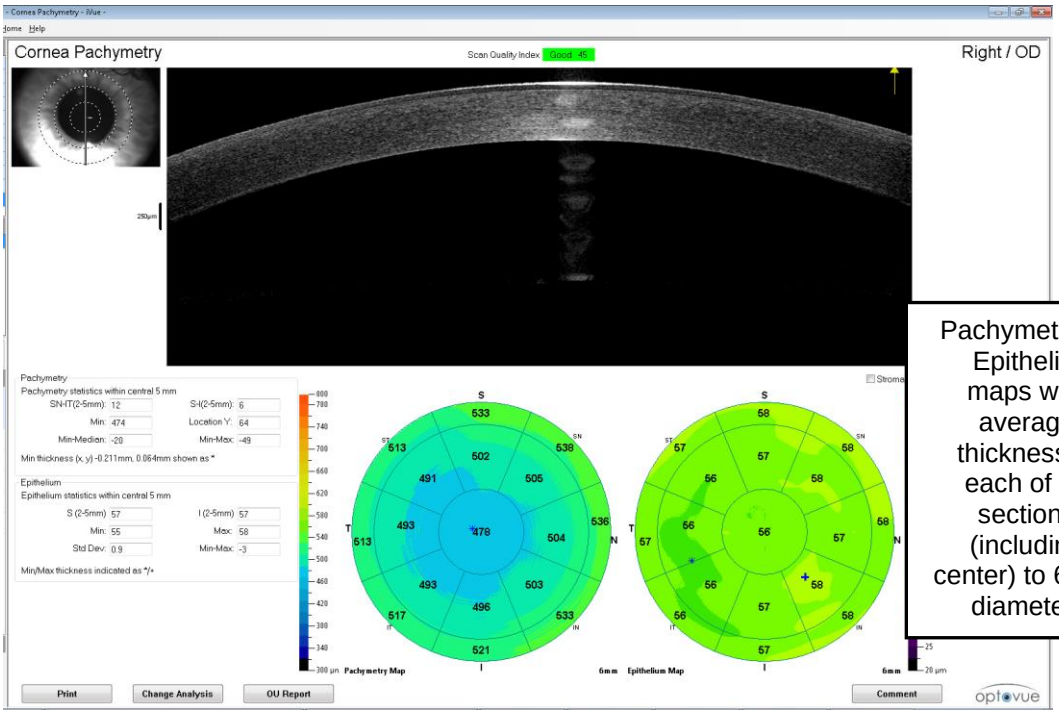


Figure 57 Cornea Pachymetry and Epithelial Report

Pachymetry Assessment Table

The Pachymetry Assessment table supports evaluation of symmetry by comparing thickness values for the opposite sectors SN-IT, and the opposite hemispheres S-I, within the 2 mm to 5 mm zone.

Manual Boundary Adjustment

Use this feature to manually adjust placement of the boundary lines the system automatically fit to the anterior and posterior cornea surfaces.

To manually adjust a boundary line, click the **B-Scan** button in the **Tool** menu and select a boundary line, or right-click on the OCT image and select **Modify Boundary**.

Adjust the boundary lines to fit each surface as necessary, then click **Save**, which triggers recalculation of measurements based on the new boundary lines.

Factors that Can Affect Accuracy of Thickness Measurements

- Cornea scan centering: Poorly centered scans can affect thickness accuracy. Make sure the pupil is centered on the alignment reticle within the scan window guidelines. If the pupil is not well centered, retake the scan.

- Accurate placement of cornea surface boundary lines: The software automatically detects the anterior and posterior surfaces of the cornea and fits lines to each surface. If the surface boundary lines are not accurate, you should manually correct their placement. Inaccurate boundary lines cause inaccurate thickness measurements. You should not use measurements if you do not correct the boundary lines, but if you correct them, you can use the resulting measurements. From the anterior surface the first Segmentation line corresponds to the air-to-corneal epithelium interface, the next Segmentation line corresponds to the corneal epithelium-to-Bowman's layer interface, and the third Segmentation line corresponds to the corneal endothelium-to-aqueous interface.

- As illustrated in the figure below, Segmentation line #1 corresponds to the air-to-corneal epithelium interface, Segmentation line #2 corresponds to the corneal epithelium-to-Bowman's layer interface, and Segmentation line #3 corresponds to the corneal endothelium-to-aqueous interface. The corneal epithelial thickness is measured from Segmentation line #1 to Segmentation line #2; Epithelial measurements with iVue software does not include Bowman's layer in the epithelial thickness. The anterior corneal epithelial boundary (Segmentation line #1) is identified by locating the bright reflectivity band at the air-to-cornea interface, and the posterior corneal epithelium boundary (Segmentation line #2) is identified by locating the bright reflectivity line anterior to the Bowman's layer which has lower reflectivity. The stromal thickness is measured with the iVue software from Segmentation line #2 to Segmentation line #3, which includes Bowman's layer, corneal stroma, Descemet's membrane, and the corneal endothelium. The posterior corneal boundary (Segmentation line #3) is identified by locating the bright reflectivity line at the corneal endothelium-to-aqueous interface.

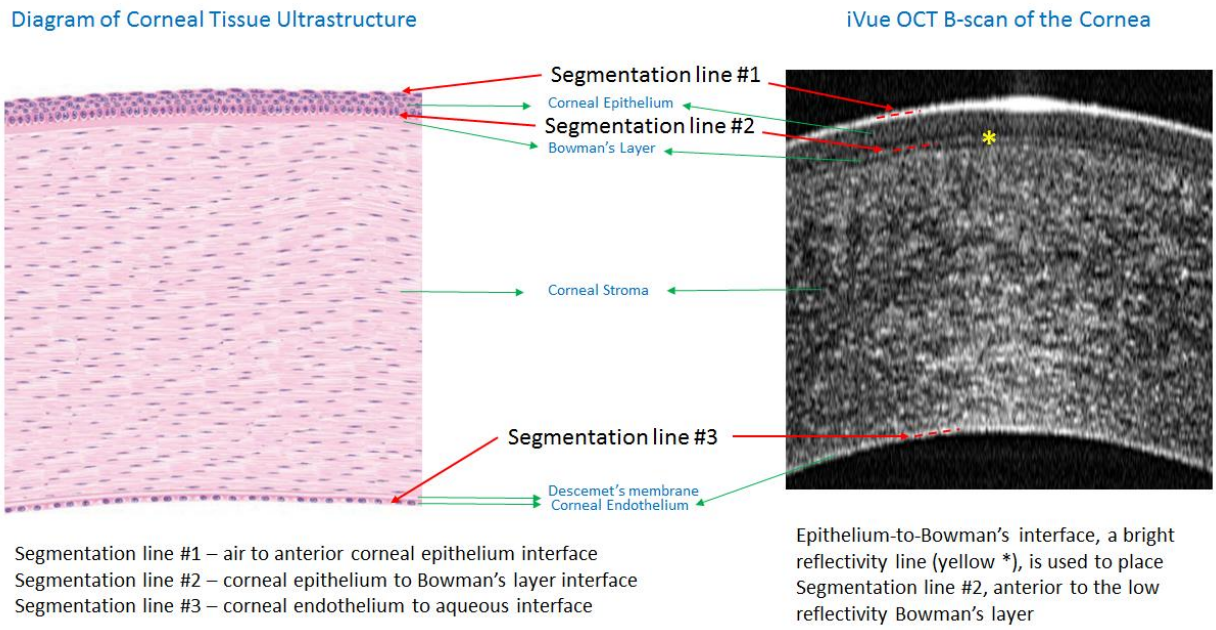
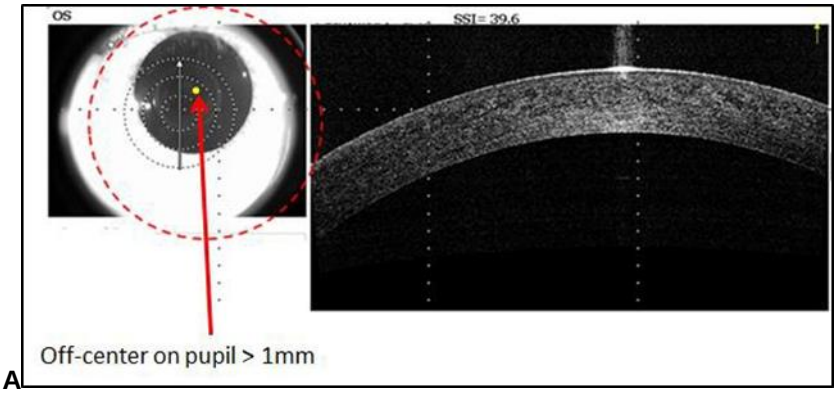


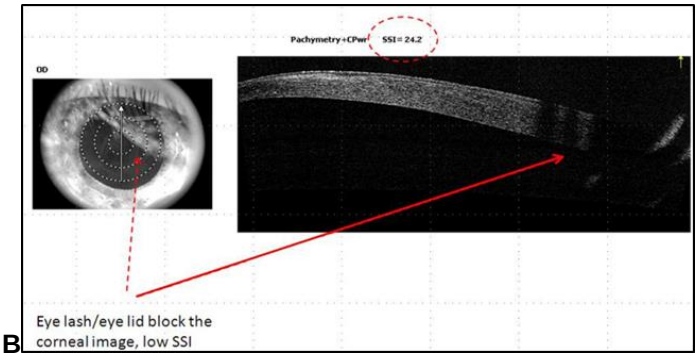
Figure 58 Corneal segmentation lines

See Appendix 14 for a description of the clinical precision study and the results.

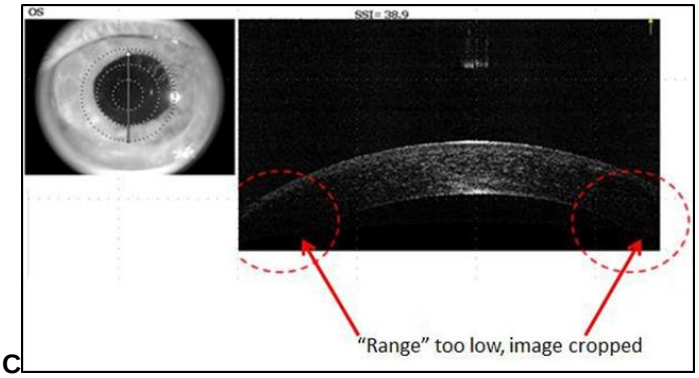
Examples of poor scans



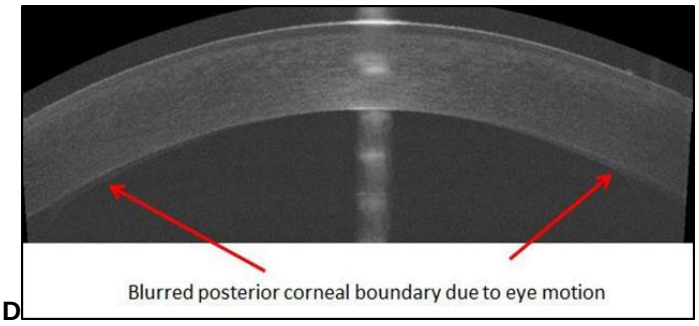
A



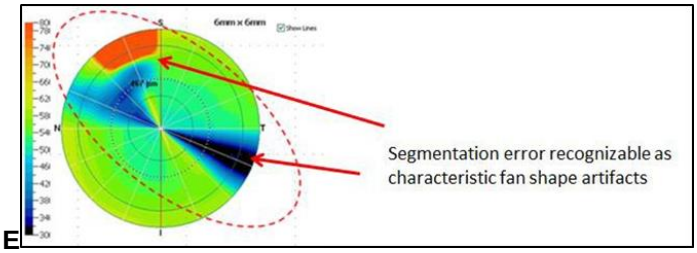
B



C



D



E

Examples of poor cornea scans

Examples of image quality issues. **A-** Pupil off-center exceeding 1mm (pupil center outside the smallest one of the 3 concentric rings.) **B-** A large section of the cornea image blocked by eyelid/lash and SSI below 27. **C-** Corneal image placed too low in the window, causing cropping of the corneal image at the corners. **D-** Blurred corneal image due to eye motion during scan acquisition. **E-** Segmentation error recognizable in the thickness map as characteristic fan shape artifacts

6.4.1 Cornea OU Report

Click the **OU Report** button to display the Cornea OU Report. (The **OU Report** button is available if you have acquired cornea scans for both eyes.)

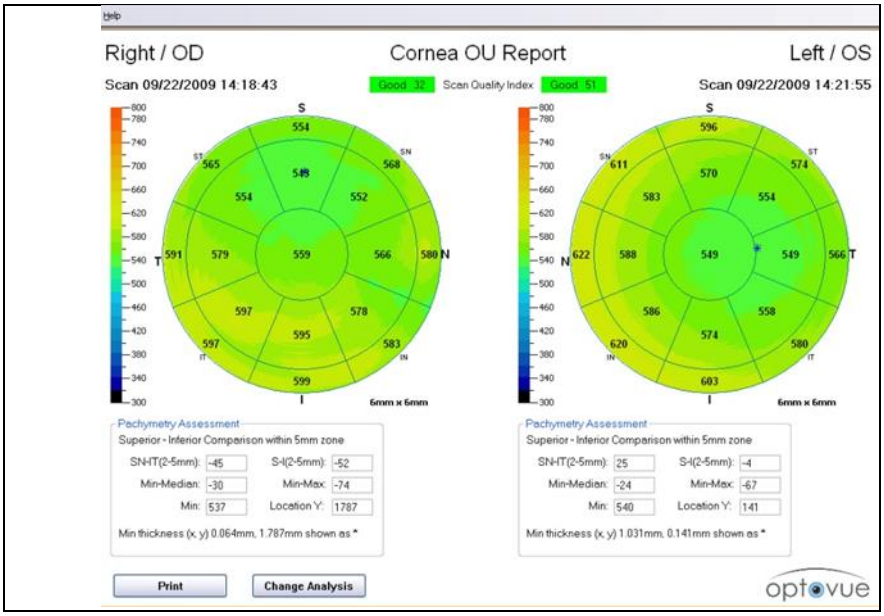


Figure 59 Cornea OU report

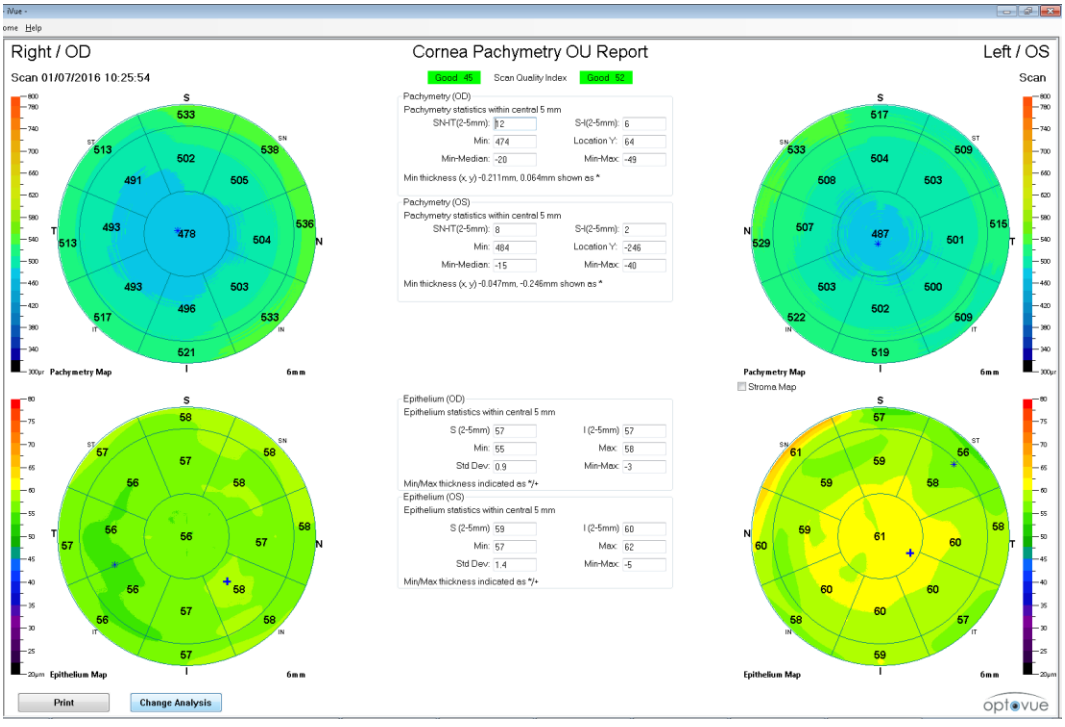


Figure 60 OU Report for Pachymetry & Epithelium

6.4.2 Cornea Change Analysis

Click the **Change Analysis** button to generate a Cornea Change Analysis. (The Change Analysis button is available when there are cornea scans from two or more visits for this patient.) This report compares Cornea scan results between two visits. For each visit, the report shows a corneal and epithelial thickness map, OCT image and pachymetry assessment values, from left to right, with the earlier visit to the right, and the more recent visit to the left. The system does not perform image registration for the Cornea scan.

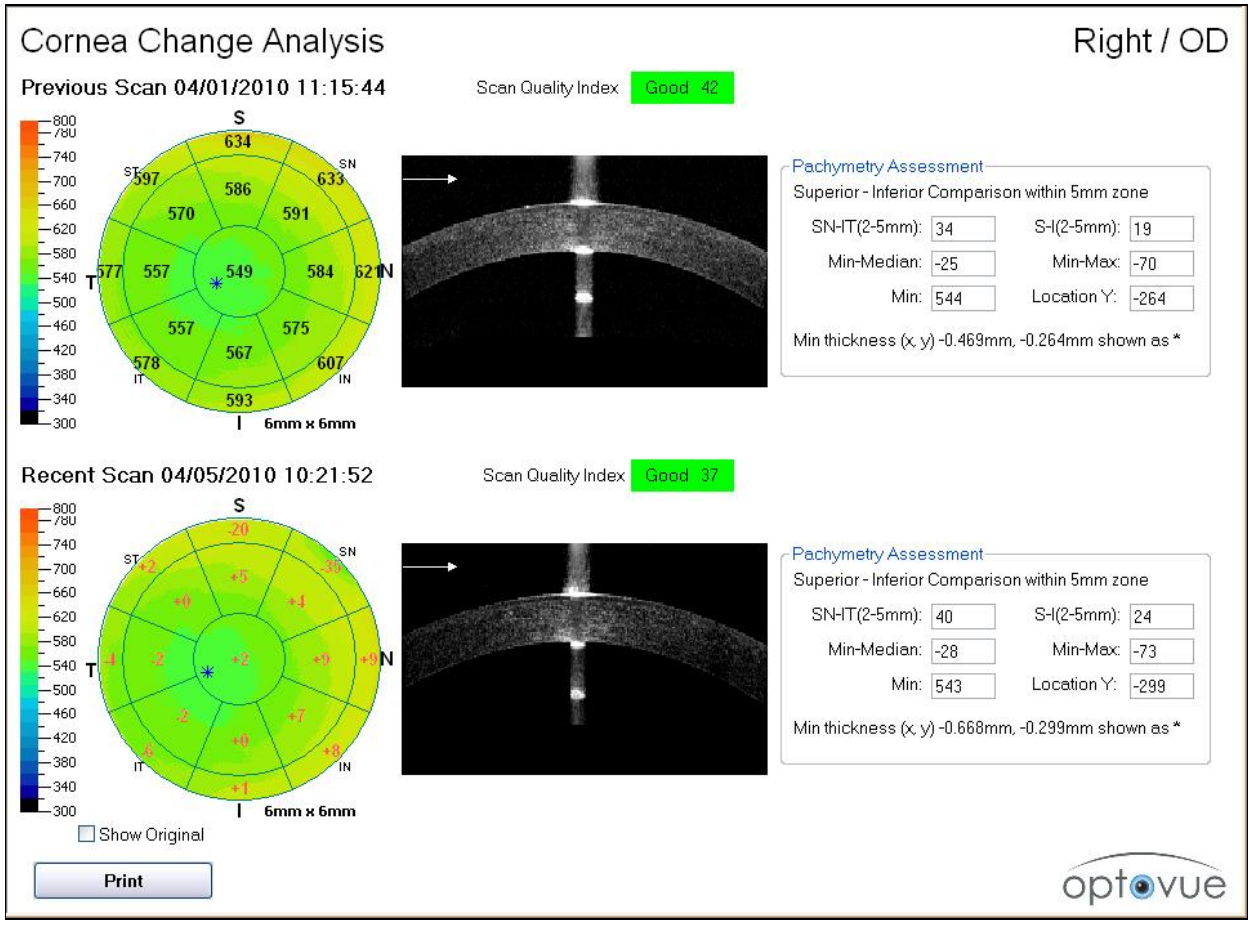


Figure 61 Cornea Change Analysis Report

Pachymetry scan alignment for change analysis is based on alignment to the pupil center at the time of capture.

Note: The maps in the Cornea Change Analysis show differences between visits without statistical analysis. Observed changes may not be statistically or clinically significant.

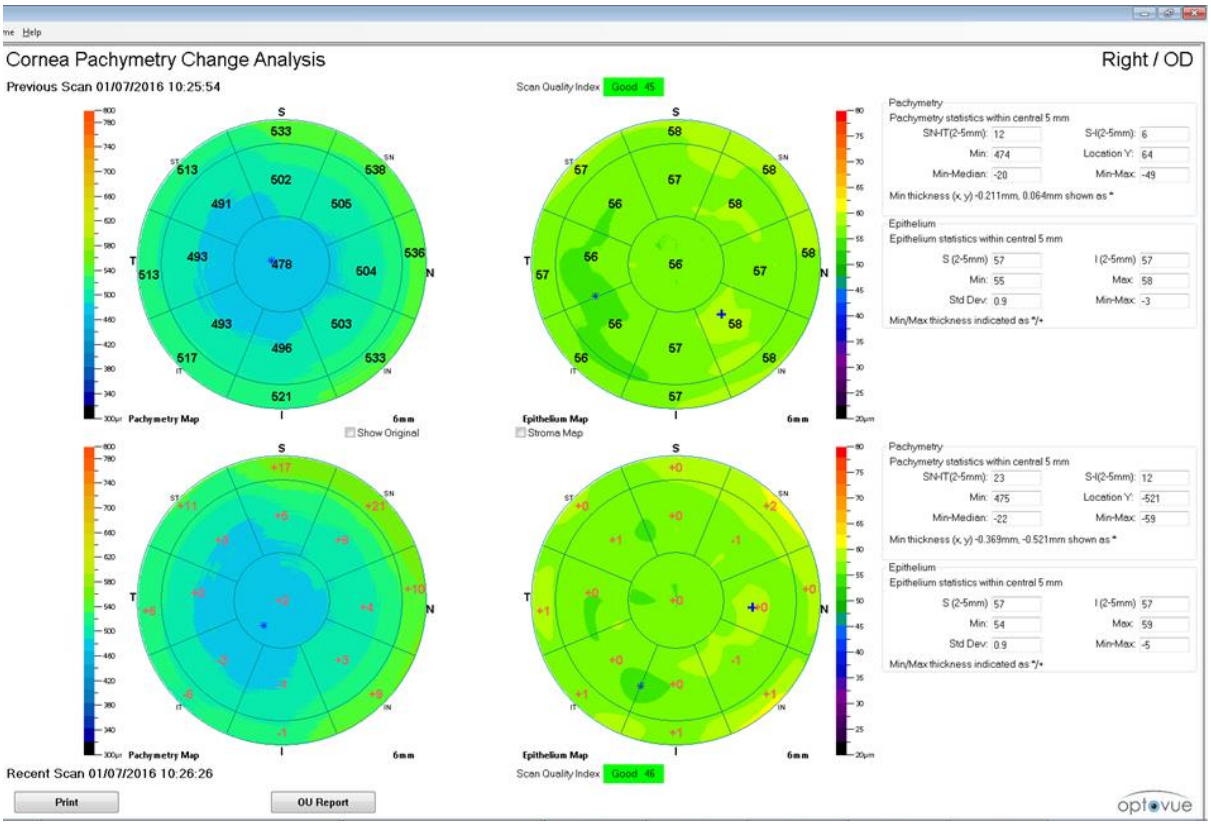


Figure 62 Change report for Pachymetry & Epithelial

6.4.3 Cornea Angle Report

A sample Cornea Angle report appears below. Use the angle tool from the **Tool** pane to measure the angle.

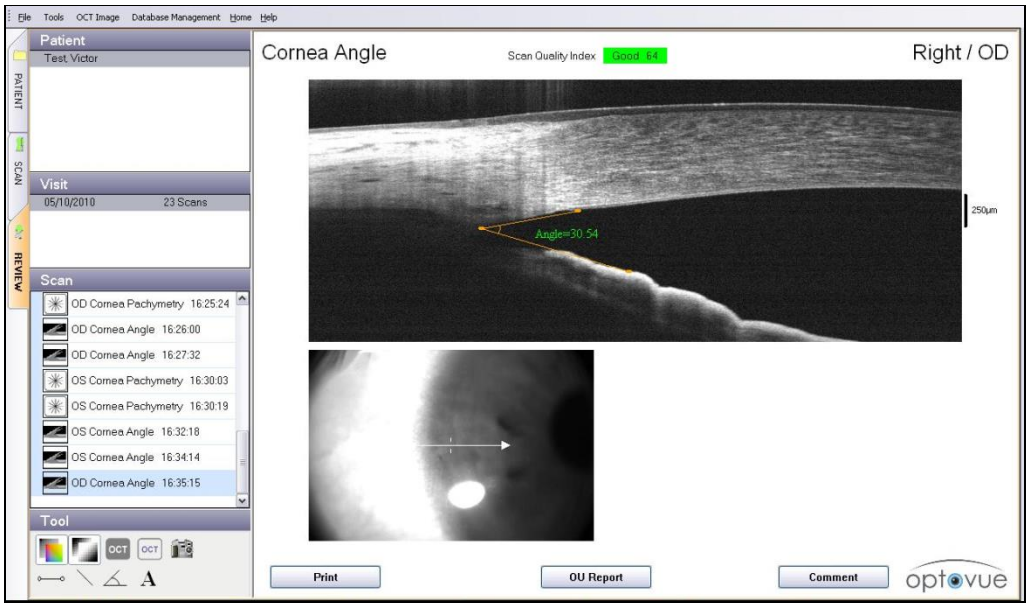


Figure 63 Cornea Angle Report

If you have acquired Cornea Angle scans for both eyes, click the **OU Report** button to generate a Cornea Angle OU Report. A sample report appears below.

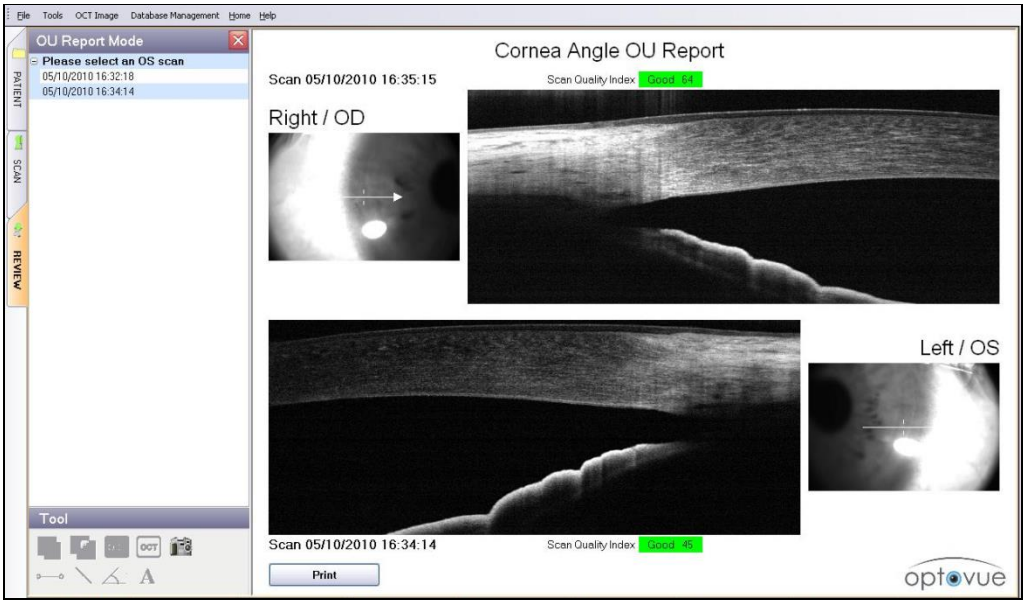


Figure 64 Cornea Angle OU Report

If you have acquired multiple Cornea Angle scans of the same eye, click the Change Analysis button to generate a 4 scan Cornea Angle Report. A sample report with 2 scans appears below.

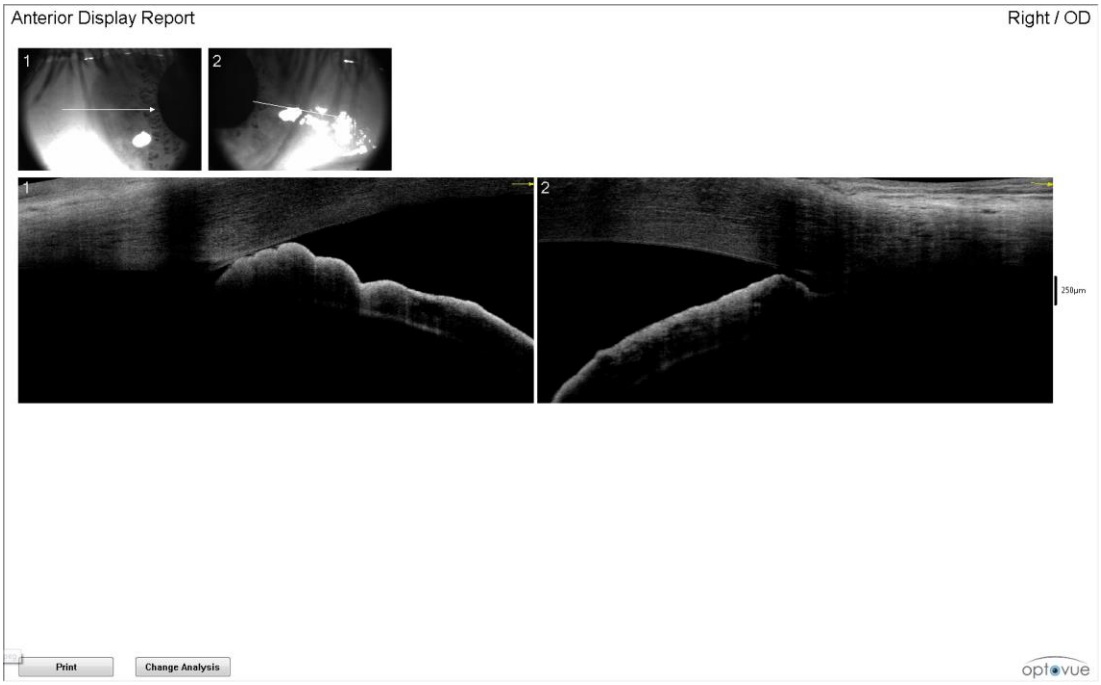


Figure 65 Multi Image report

6.5 iWellness Report

The iWellness report combines results from the Retina Map scan and the GCC scan.

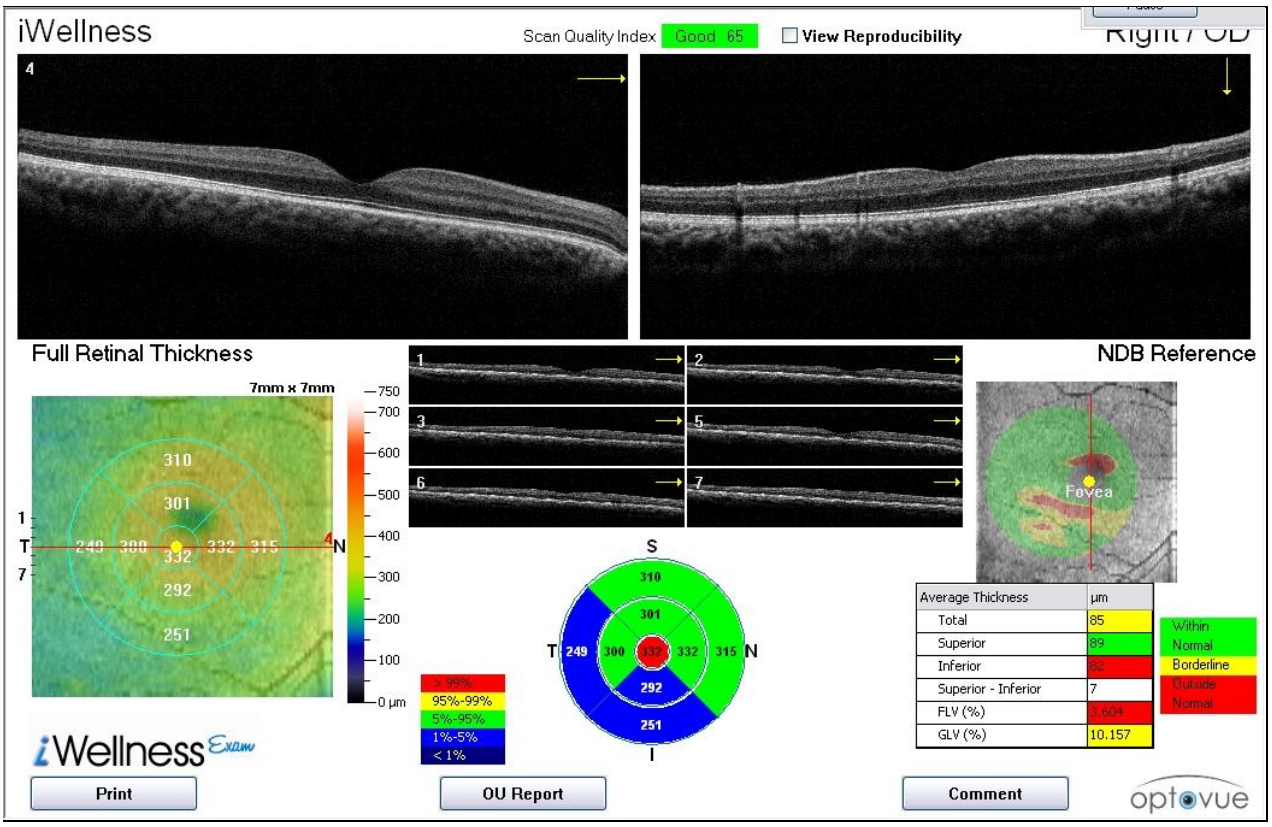


Figure 66 iWellness Report with Averaged Raster Scans

The top right OCT image is a vertical scan through the fovea; it does not change. The top left OCT image is the currently selected horizontal raster scan (one of seven) from the Retina Map scan; the six other raster scans appear in the middle of the report. Click one to display it at upper left. Each raster scan is an average of five scans. The report also includes:

- A **Full Retinal Thickness** map at lower left. The map colors report retinal thickness using a color code, the legend for which is just to the right. An overlaid map centered on the fovea defines nine ETDRS-like sectors, constructed with 1, 3, and 5 mm diameter circles divided into temporal, superior, nasal and inferior areas. The map reports average retinal thickness in each sector.
- Another ETDRS-like map at bottom center shows the same average thickness values in each sector and includes a color code with respect to the normative database, the legend for which is to the left of it.

- An **NDB Reference** map of GCC thickness at middle right, which reports GCC thickness in colors with respect to the normative database. The colored map overlays the en face scan image of the retina.

Note: GCC thickness has clinical significance in diagnosis of glaucoma. The reported parameters are **Total, Superior, Inferior, Superior – Inferior** (difference), **FLV%** and **GLV%**. The values are color-coded with respect to the normative database.

- An **Average Thickness** table at lower right. The reported parameters are **Total, Superior, Inferior, Superior – Inferior** (difference), **FLV%** and **GLV%**. The values are color-coded with respect to the normative database.

Select the **View Reproducibility** checkbox to show the calculated range of reproducibility for each thickness parameter.

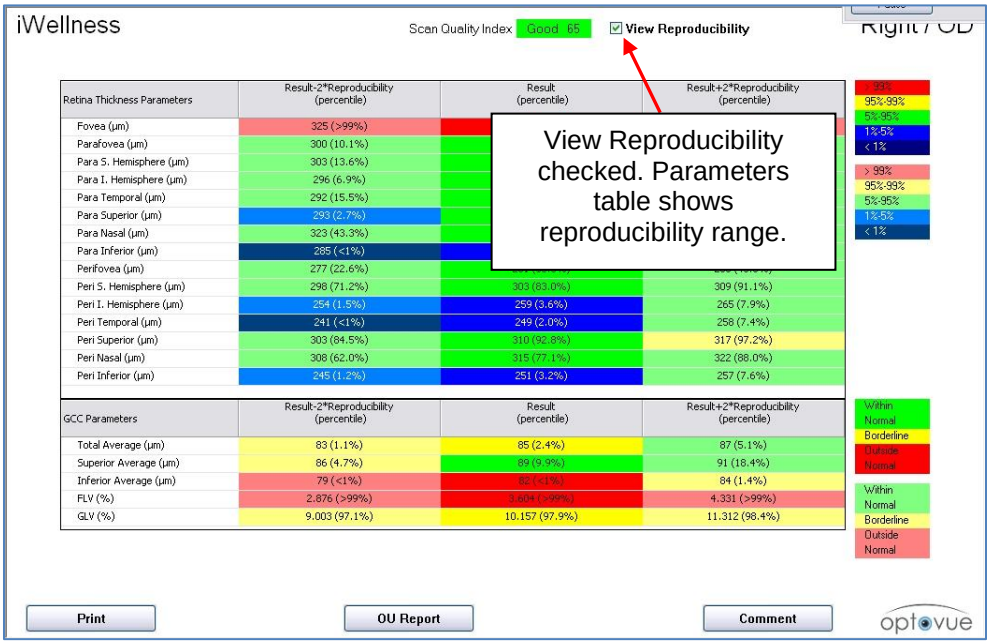


Figure 67 iWellness Report with Parameters Table

6.5.1 iWellness OU Report

Click the **OU Report** button when iWellness scans have been taken for both eyes. The iWellness OU Report includes the elements of the iWellness report for both eyes side by side. In the OU Report, the table reports differences in thickness parameters between eyes. A sample iWellness OU Report appears below.

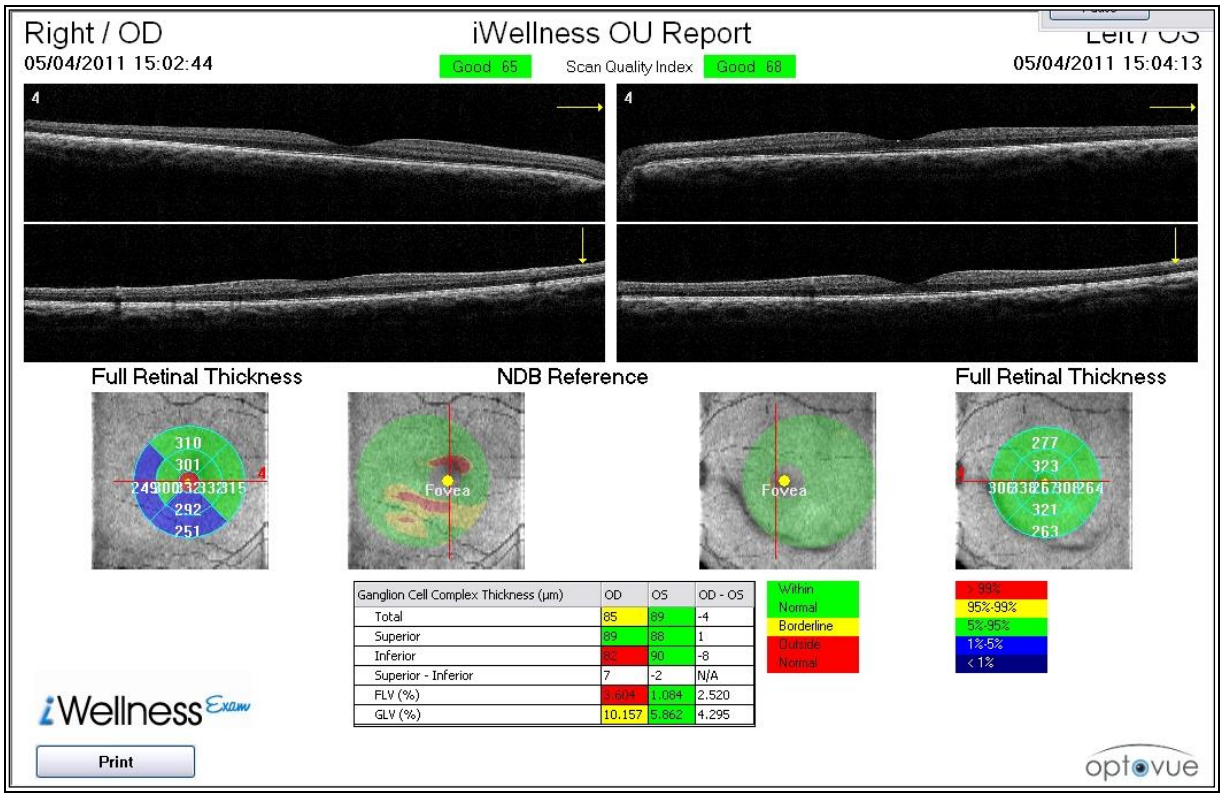


Figure 68 iWellness OU Report

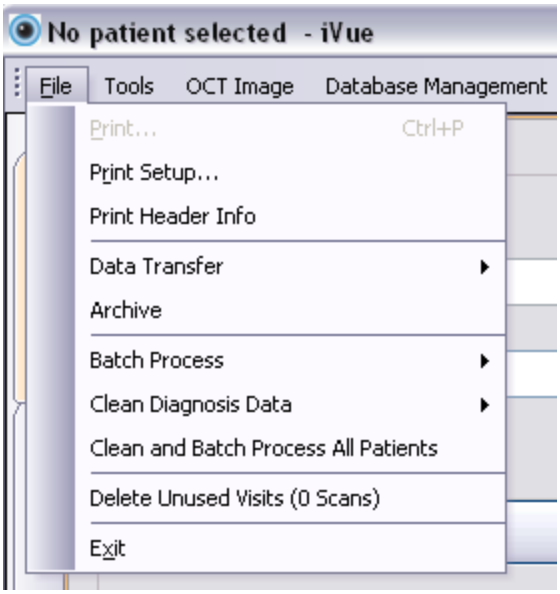
_____End of section_____

7 Main Menu

Figure 69 iVue Main Menu

7.1 File Menu

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



File Menu

7.1.1 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 Setup:** Opens the Print Setup dialog, where you can select the printer and adjust print preferences.

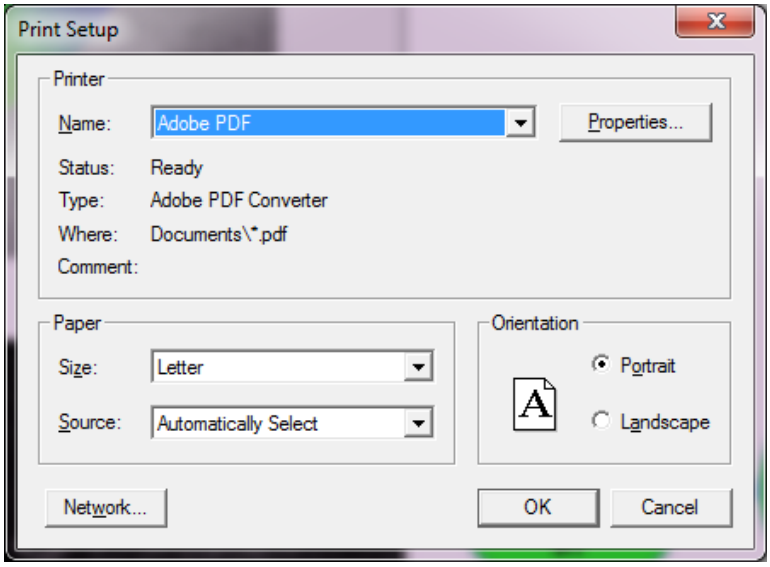


Figure 70 Print set up

Print Header: 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.

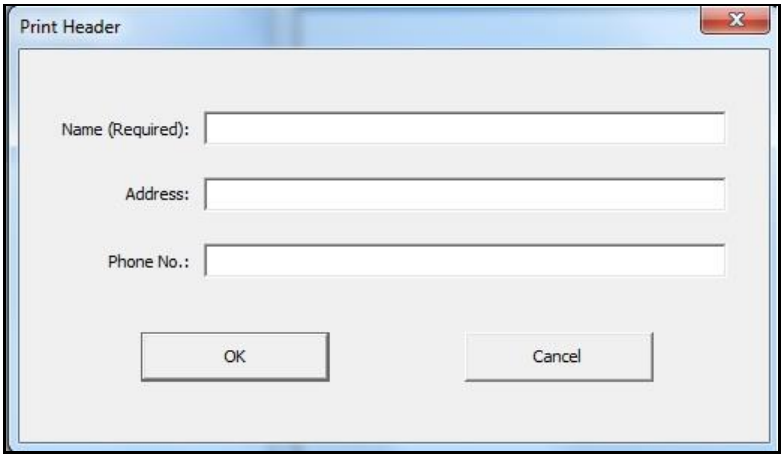


Figure 71 Print Header Dialog

7.1.2 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.

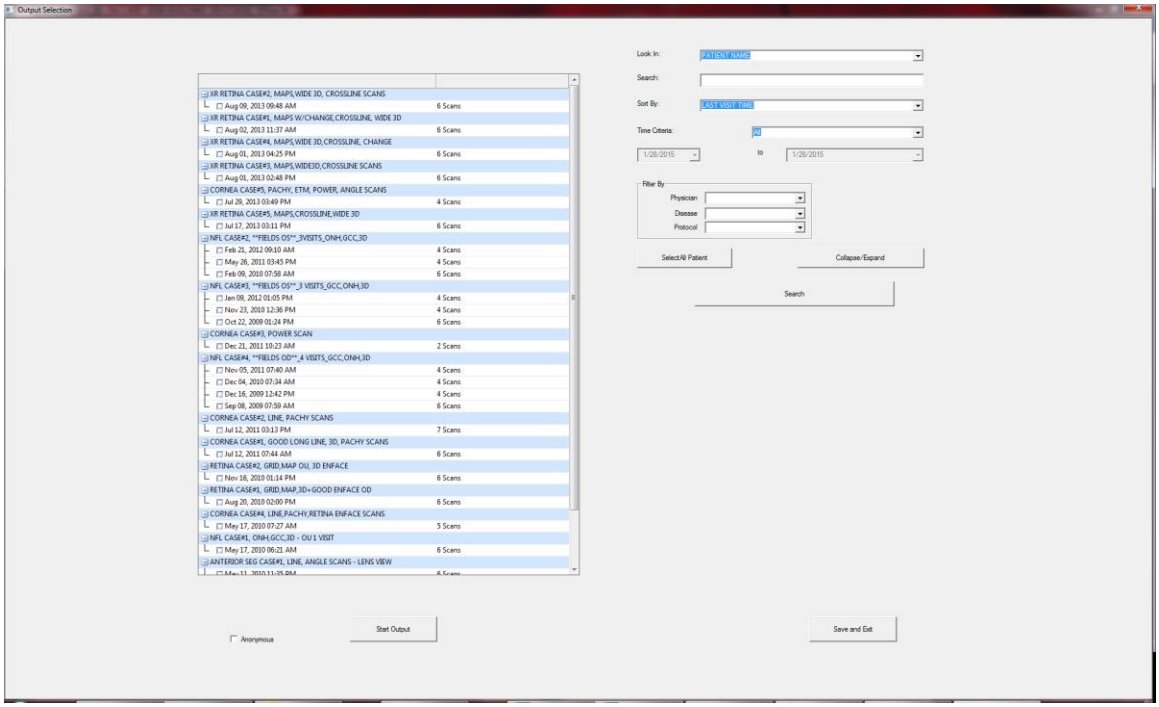
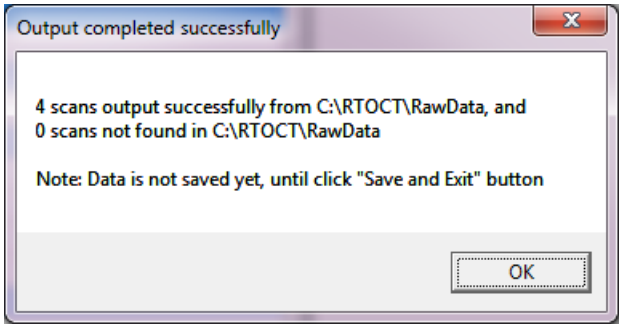


Figure 72 Output Selection Dialog

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.**



3. 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.

7.1.3 Archive

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

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

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

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

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

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

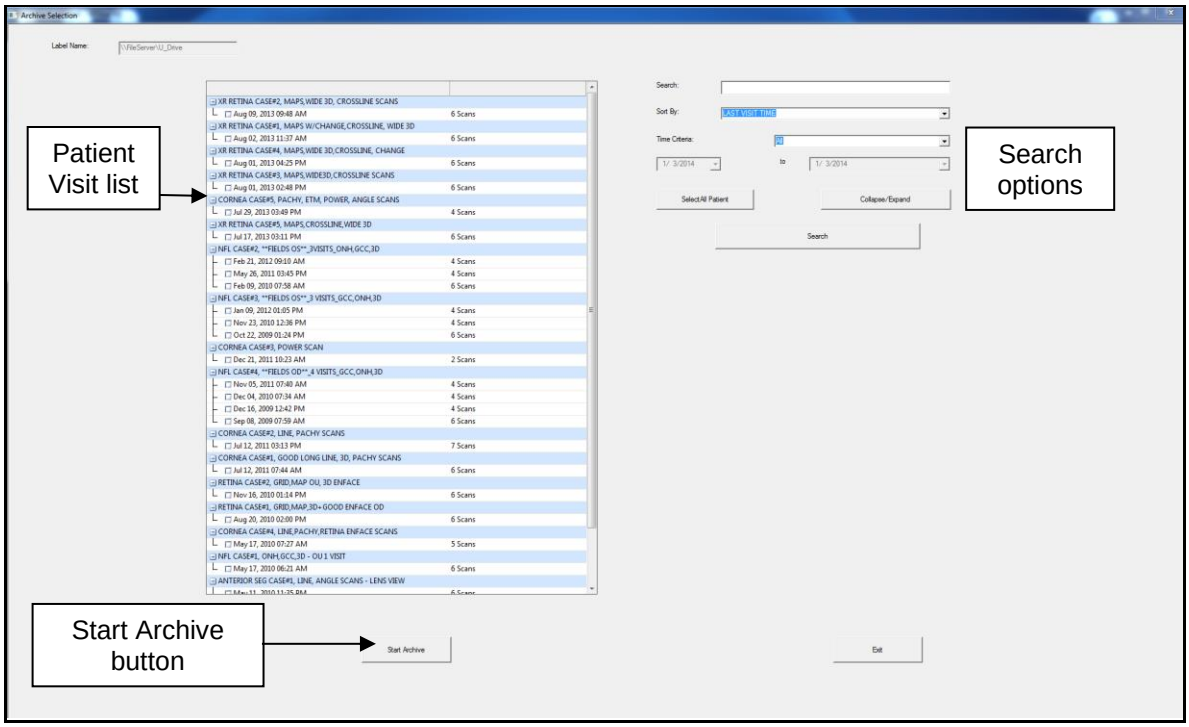


Figure 73 Archive Selection Dialog

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.

7.1.4 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.

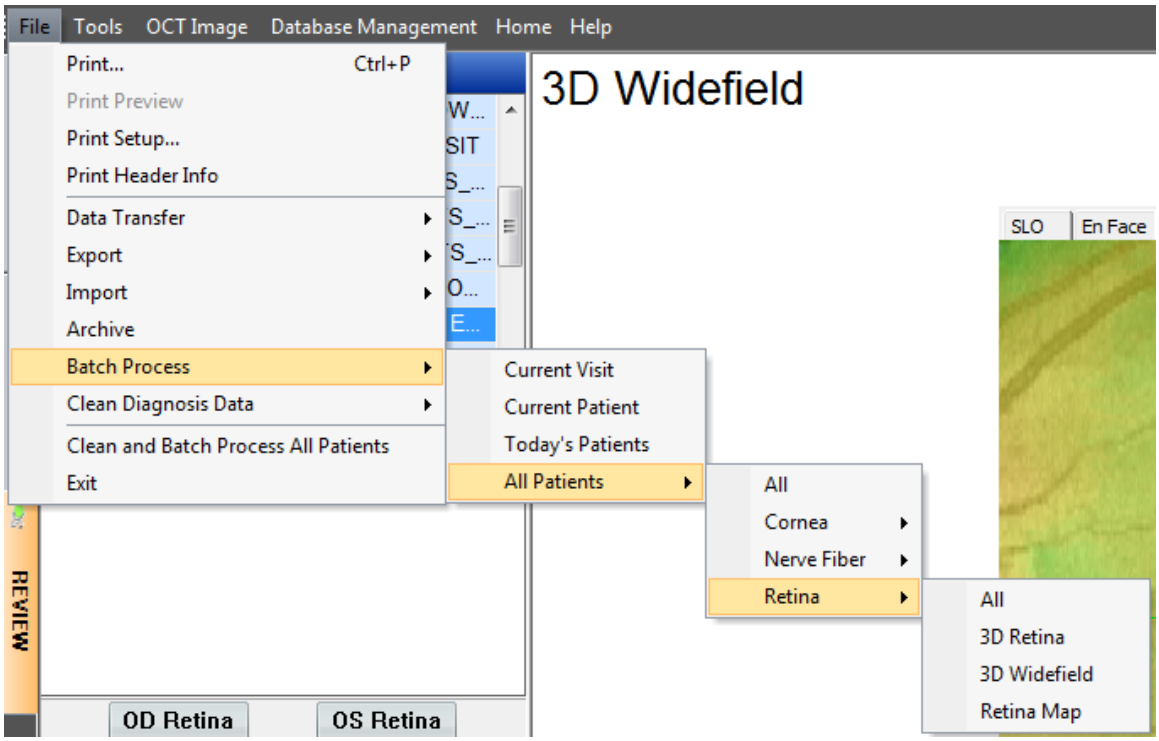


Figure 74 Batch Process Options

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

7.1.5 Clean Diagnosis Data

The **Clean Diagnosis Data** process undoes previous scan processing, leaving raw scan data. Scans are then processed as usual when opened in the REVIEW window, or when you run a batch process. 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.

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

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 7.1.4 above for details.

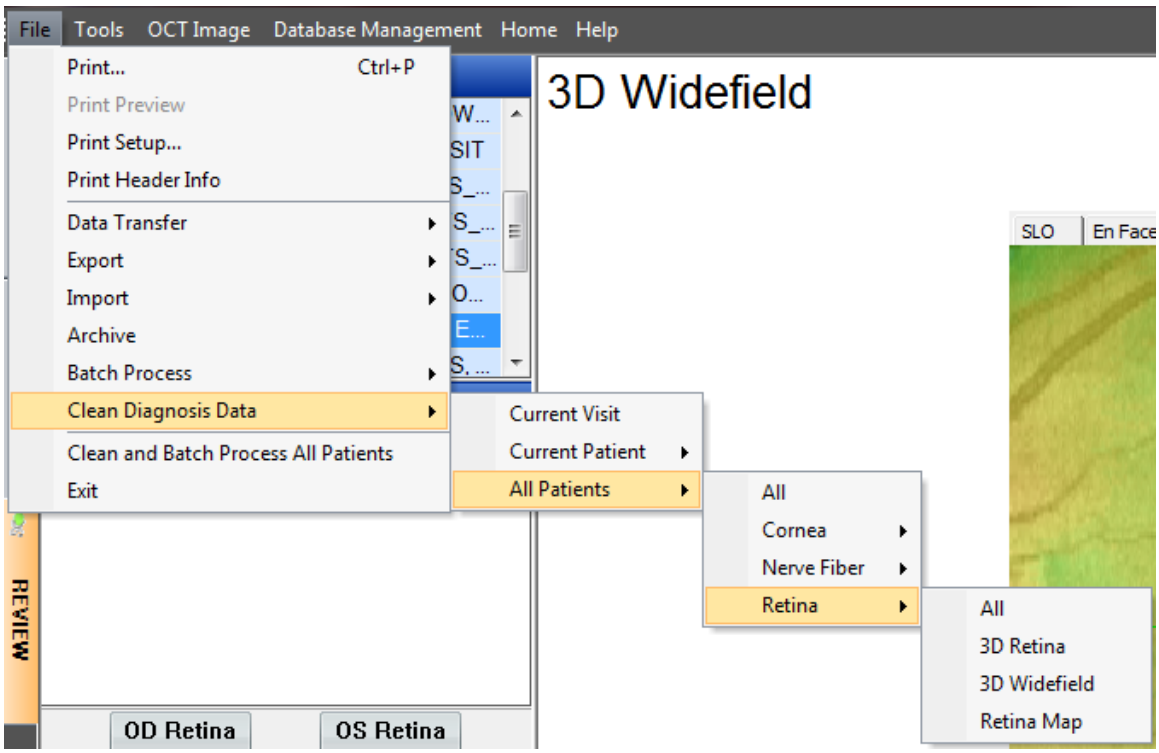


Figure 75 Clean Diagnosis Data Options

7.1.6 Clean and Batch Process All Patients

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

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.

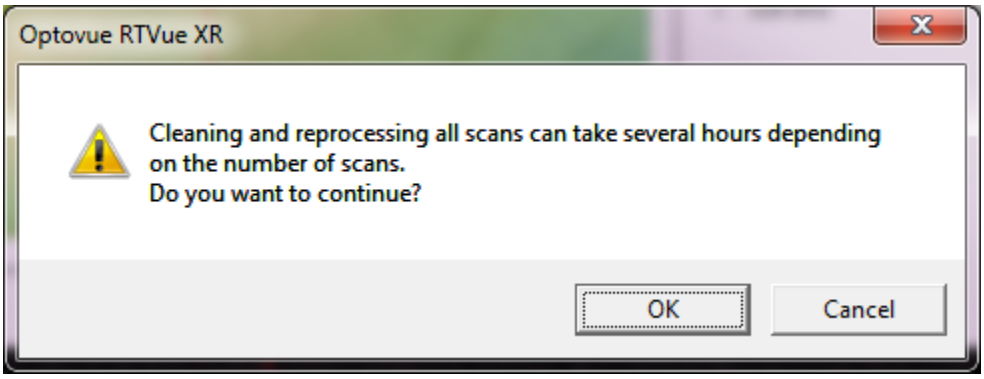
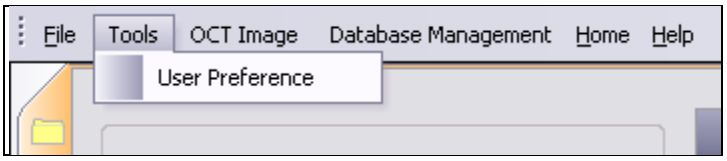


Figure 76 Confirm Cleaning and Reprocessing

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

7.2 Tools Menu

The **User Preference** option is the only one available from the **Tools** dropdown.



Tools Menu

7.2.1 User Preference

The **User Preference** dialog allows the user to modify various default settings for the system.

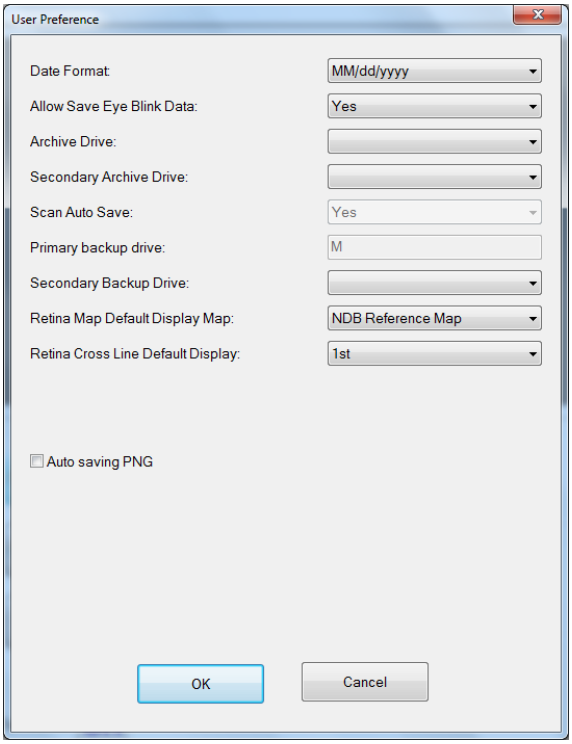


Figure 77 User Preference Dialog

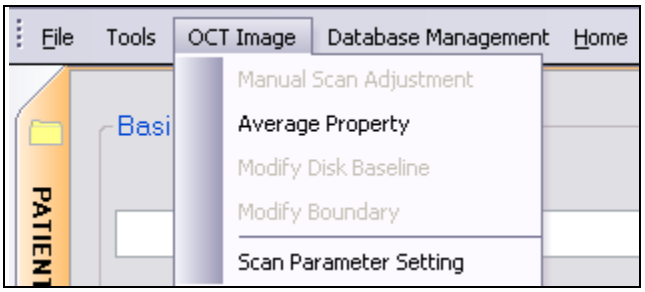
1. **Date Format:** Allows you to choose different date formats.
2. **Allow save eye blink data**: Select **YES** to save even if there are blinks, or **NO** to force a rescan when an eye blink is detected.
3. **Archive Drive**: Sets the default drive for archiving function. This may be set to another type of removable media or a mapped network drive.
4. **Secondary Archive Drive**: Sets the secondary archive drive location.
5. **Scan Auto Save:** Default is **YES** providing **Capture** + **Save** in one step and cannot be modified.
6. **Primary Backup Drive:** Default is located in the iVue control box.
7. **Secondary Backup Drive**: Sets the secondary backup drive location where the system sends a copy of the database, raw data and processed data (recovery drive).
8. **Retina Map Default Display Map:** Disabled in the sample shown.

- **Retina Cross Line Default Display:** Choose default scan display for both Retina Cross Line Display and Retina OU Cross Line Display. Options listed are: **1st, 2nd**, and **Both**.

9. **Display RNFL & GCC Thickness References**: Choose **Yes** or **No** for each option.

Click the **OK** button to save user preference changes. If the **Cancel** button is clicked, no changes will be saved.

7.3 OCT Image Menu



OCT Image Menu

7.3.1 Manual Scan Adjustment

Manual adjustment (override) for the auto-adjust function.

Manual Scan Adjustment Dialog

These are the manual scan adjustment buttons with their functions:

Auto Z: adjustment for the axial length

Auto F: adjustment for the refractive state

Auto P: adjustment for polarization

7.3.2 Average Property

The **Frame Average Property** is used to change the frame average value.

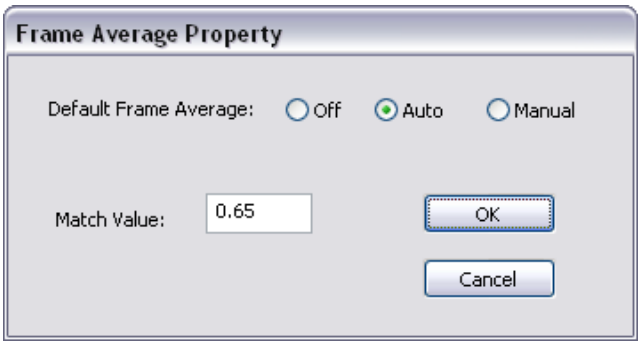


Figure 78 Frame Average Property Dialog

7.3.3 Modify Disc Baseline

This option displays the en face image of the optic disc. It allows the auto-drawn disc boundary verification and can adjust/modify/redraw the boundary for reprocessing.

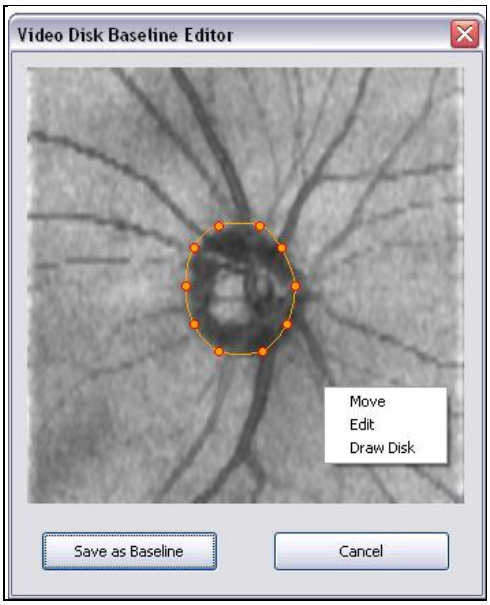


Figure 79 Video Disc Baseline Editor

7.3.4 Modify Boundary

This option displays all scans from selected pattern (Retina, Nerve Fiber, and Cornea) for review and allows the user to modify or correct the segmentation tracing (lines). Move cursor over line until a small **+** is displayed in place of the cursor arrow. Hold down the left mouse button and drag to the new location, and the segmentation line will follow the **+** icon. Select **Save**.

☞ **Note:** Segmentation lines corrected manually cannot be batch cleaned or undone, only redrawn manually.

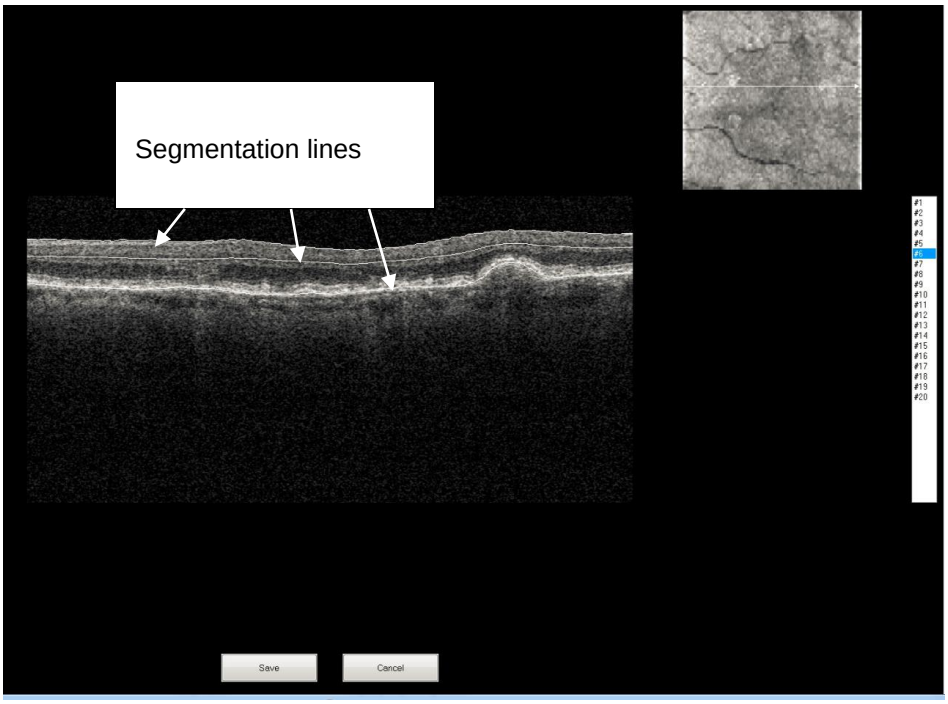


Figure 80 Segmentation Lines

7.3.5 Scan Parameter Setting

This option allows setting the live acquisition OCT scan presentation and the **Review** mode OCT scan presentation to color or gray scale at user's preference.

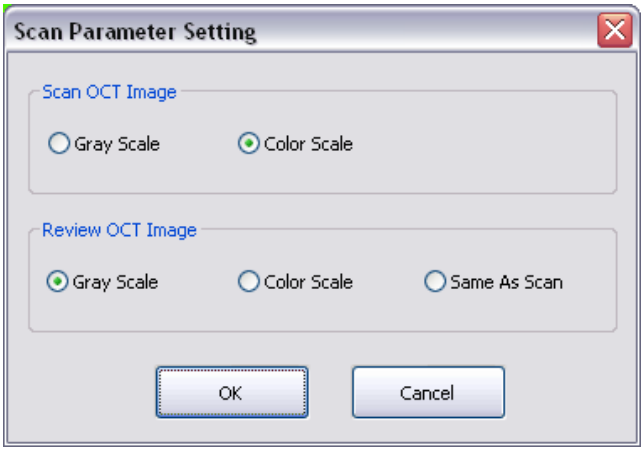


Figure 81 Scan Parameter Setting Dialog

7.4 Database Management Menu

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

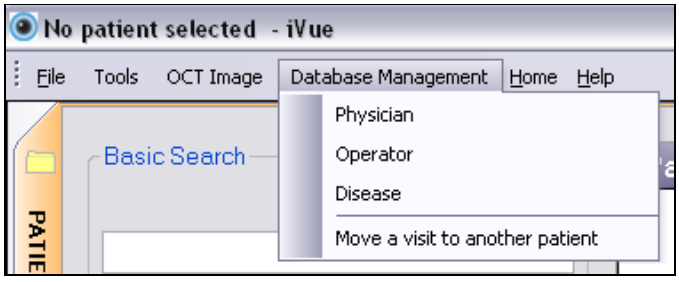


Figure 82 Database Management Menu

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

7.4.1 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.

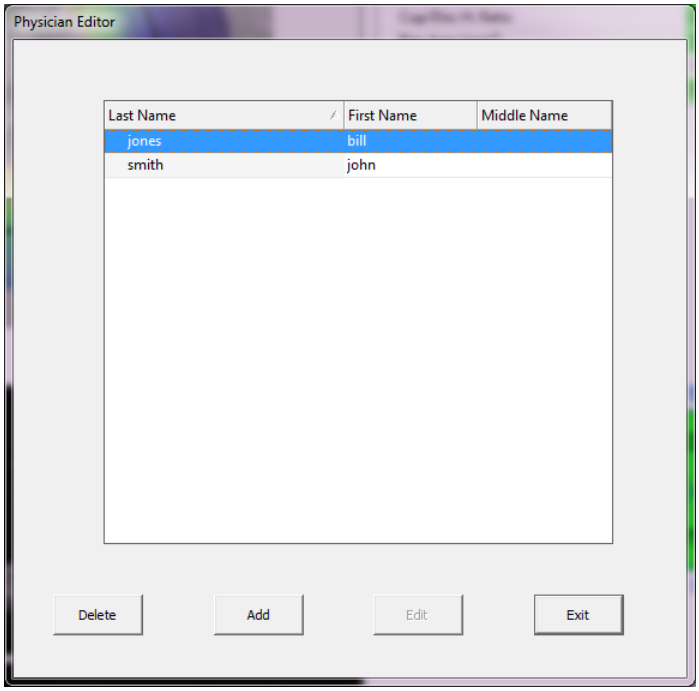


Figure 83 Physician Editor Dialog

Select a physician from the list and click Delete **to delete a physician.**

- Click **Add** to open a dialog where you can enter the name of a physician, then click **OK** to save.

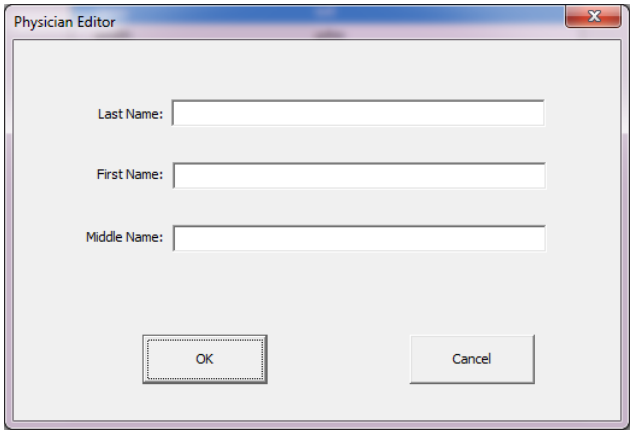


Figure 84 Dialog to Add or Edit Physician Name

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.**

7.4.2 Operator

Use the **Operator Editor** to add, edit or delete system operators.

7.4.3 Disease

Use the **Disease Editor** to add, edit or delete disease categories.

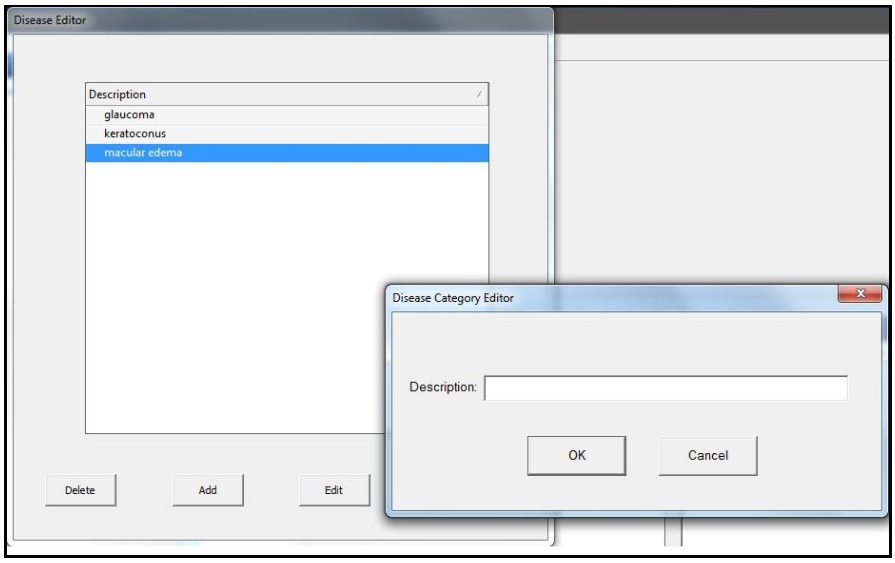


Figure 85 Disease Editor Dialog

Note: **You cannot delete a disease if any scan data is associated with that disease.**

7.4.4 Move a visit to another patient

Select **Move a visit to another patient** when exam data was incorrectly taken under the wrong patient.

11. Select the patient and visit to move.
12. Select the **Move a visit to another patient** option from the **Database Management** menu. A confirmation message appears.

Figure 86 Move Selected Visit Confirmation Message

13. Select the patient to whom the visit is to be moved.

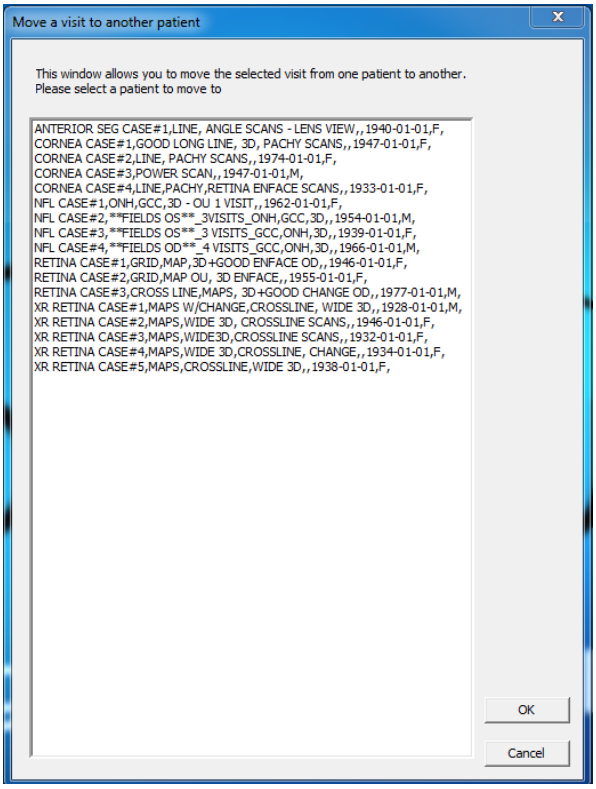


Figure 87 Select patient to move exam data to

14. Click **Yes** to confirm the move or **No** to cancel it.

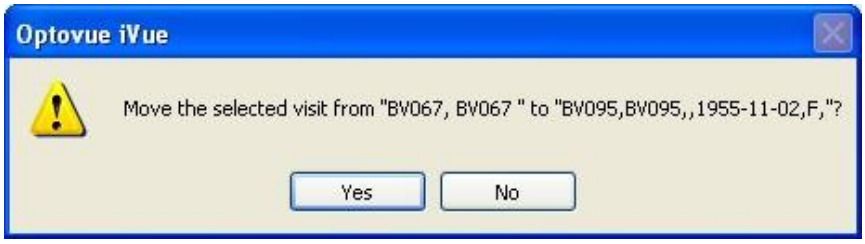


Figure 88 Move Visit Confirmation

7.4.5 Activating iWellness Unlimited Scan

The information below only pertains to customers who have purchased the iWellness Unlimited scan. Follow the activation instructions provided with the license key, which are in the document titled **iWellness Unlimited Feature License Key – Activation Instructions.**

7.5 Help Menu

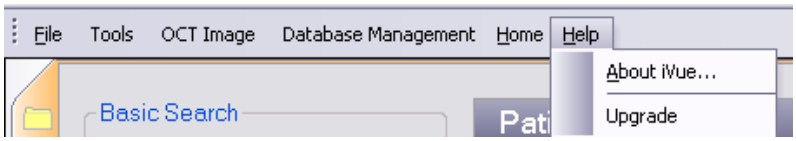


Figure 89 Help Menu

7.5.1 About iVue

Selecting **About iVue** from the **Help** menu displays a new window containing general information about iVue 100 including version number, license, and features upgraded.

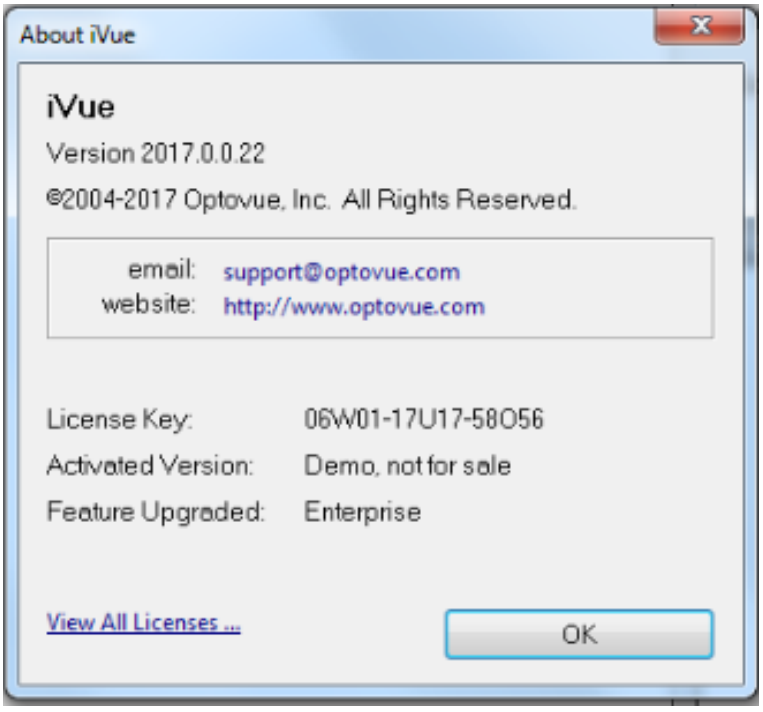


Figure 90 About iVue Dialog

7.5.2 Upgrade

Select **Upgrade** from the **Help** menu to display the feature upgrade dialog. Additional features available include NetVue Enterprise networking product, 3D, GCC, iWellness (iWellness scan in pay-per-use model), and iWellness Unlimited (unlimited number of iWellness scans for a onetime charge).

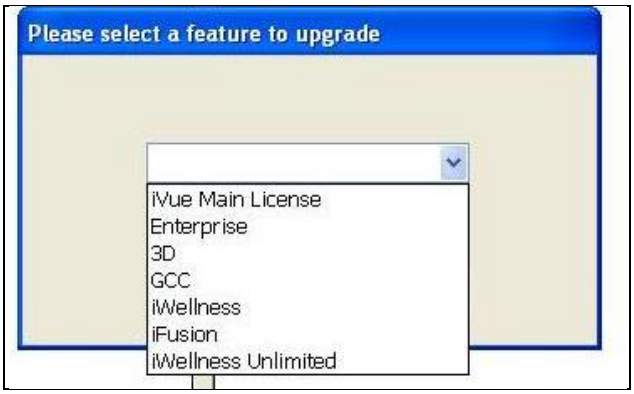


Figure 91 Feature Upgrade Dialog

_____End of section_____

8 System Maintenance

8.1 Error Codes

If the system displays an error code; follow any directions displayed, if no directions are associated with the error code, record the number, close the program and restart the software. If the error fails to clear, close the software and turn off the system then reboot the entire system. If the problem persists call Optovue Technical Support.

8.2 Routine Cleaning

8.2.1 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
- 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.

8.2.2 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

8.3 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.

8.4 Network Connections

The system laptop connects to the network with an Ethernet cable. You must not change settings for the Local Area Connection; if they are changed, the system will no longer be able to connect. The IP address for the Local Area Connection is static in order to connect. All necessary changes to network settings are to be made in the Local Area Connection 2 port. (You see only Local Area Connection 2 when you connect the USB to Ethernet Adapter shipped with the system).

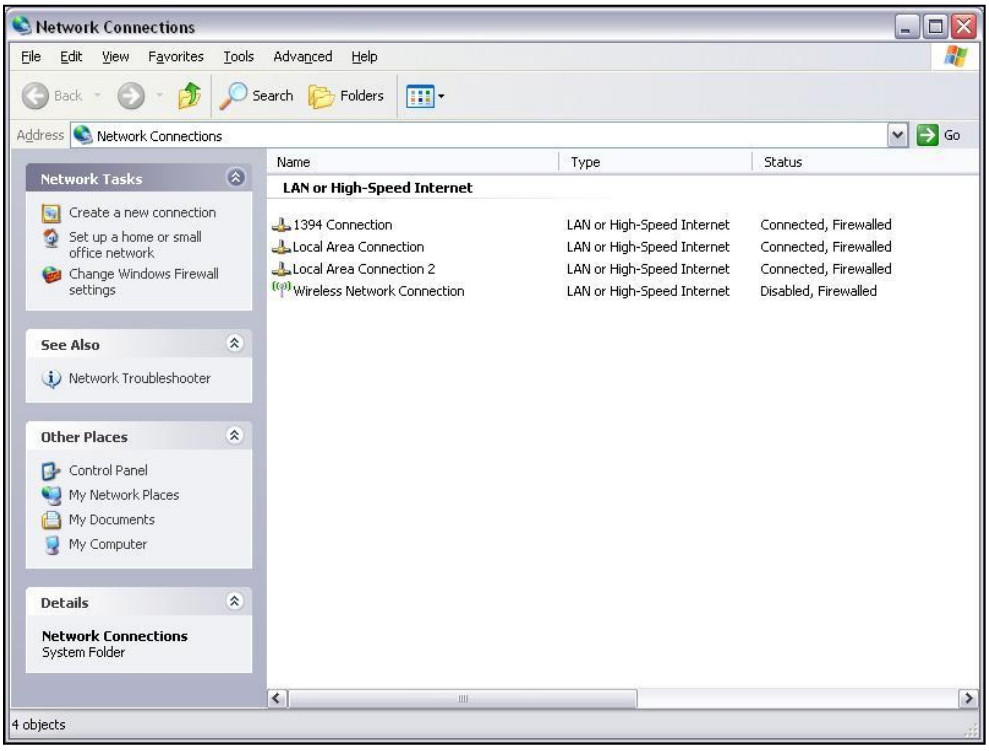


Figure 92 Windows™ Network Connections Screen

☞ **Note**: D**o not change the computer name** when configuring the system computer.

_____End of section_____

9 Scan Pattern Specifications

Table 1 iVue Scan Pattern Specifications

Scan Name	Description	# A-Scan	Adjustability	Default
Nerve Fiber ONH scan	13 concentric rings at the following diameters: 4.9 mm, 4.6 mm, 4.3 mm → 4.0 mm, 3.7 mm, 3.4 mm → 3.1 mm, 2.8 mm, 2.5 mm → 2.2 mm, 1.9 mm, 1.6 mm, 1.3 mm → 12 radial line scans at 3.4 mm length.	Concentric lines: 969 A-scans 779 A-scans 591 A-scans 429 A-scans Radial lines: 459 A-scans per line	Fixed	4.9 mm
Retina Map scan	Raster pattern of 13 horizontal line scans (6 mm long & 512 A-scans each). An additional 7 horizontal line scans (1024 A-scans) within central 1.5 mm vertical zone. Each horizontal line scan sampled 5 or more times & averaged.	13 lines: 512 A-scans 7 lines: 1024 A-scans	Fixed	6 mm x 6 mm
Retina Cross Line	Cross line scan with speckle elimination process	2 x 1024 (24 scans in each direction are then averaged)	Angle: 0 to 180°, (5° increment)	6 mm at 0° and 90°
Cornea Pachymetry and Epithelium Thickness	8 radial line scans at 6 mm length.	Each radial scan is repeated 4 times for averaging 8 lines: 1024 A-scans per line (averaged 4 times)	Fixed	6 mm diameter
Cornea Angle	Single line scan with speckle elimination process	1 x 1024 (16 scans averaged to a single line scan)	Angle: 0 to 180°, (5° increment)	5 mm at 90°
3D Retina	128 frames equally spaced B-scans to cover a square volume center fixation	128x512 (65,536 data points)	Fixed	6 mm x 6 mm
Nerve Fiber 3D Disc	128 frames equally spaced B-scans to cover a square volume fixation at 20° nasal	128x512 (65,536 data points)	Fixed	6 mm x 6 mm

Scan Name	Description	# A-Scan	Adjustability	Default
Nerve Fiber GCC Map	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	1x934 (horizontal) 15x934 (vertical)	Fixed	7 mm x 7 mm
iWellness	1 horizontal line with 7 mm scan length, followed by 17 vertical lines with 7 mm scan length & 0.5 mm interval, centered 1 mm temporal to fovea. 8 HD scans - 7 horizontal scans with 0.25 mm interval covering central 1.5 mm, 1 vertical scan. Each HD scan averaged 5 times	1 x 937 17 x 937 7 x (1024+32) (5 scans averaged) 1 x (1024+32) (5 scans averaged)	Fixed	7 mm x 8 mm

9.1 Scan Orientation Convention

- **Nerve Fiber ONH scan**: First line from the 6:00 position to 12:00 then rotate the lines clockwise.
- **Retina Map scan**: 13 (6 mm long) horizontal lines plus 7 (6 mm long) horizontal lines within central 1.5 mm vertical zone
- **Cross Line scan:** 1 horizontal line plus 1 vertical line. Each line has 12 scans averaged.
- **Pachymetry (Cornea) scan:** 8 radial lines scans, 1024 A-scans each.
- **Angle (Cornea) scan:** 1 horizontal line scan averaged 16 times.

9.1.1 Nerve Fiber ONH scan

Objective: Measure the RNFL thickness and optic disc.

Description: 12 radial lines with 3.4 mm scan length, followed by 13 concentric rings, all center at optic disc.

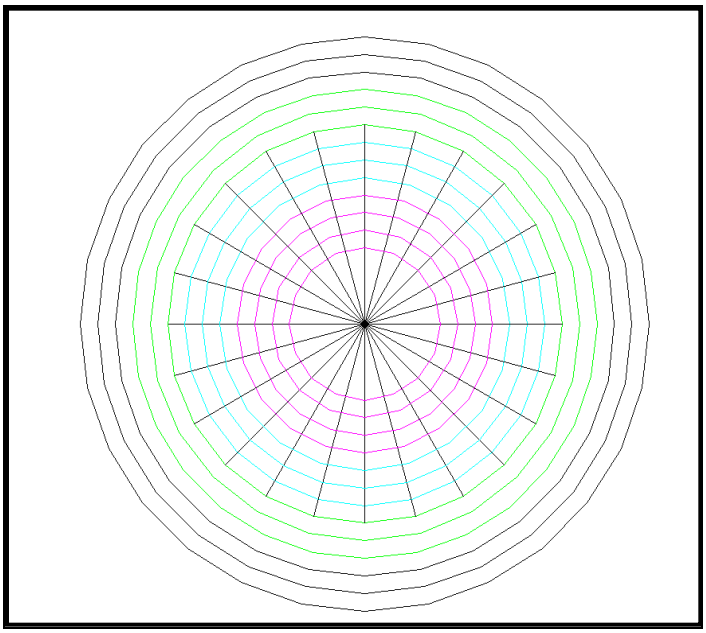


Figure 93 Nerve Fiber ONH Scan Pattern

9.1.2 Retina Map Scan

Objective: Measure the macular retinal thickness map.

Description: 6x6 mm raster centered on fixation. The raster spacing is 0.25 mm in the inner 1.5x6 mm area and 0.5 mm in the outer area.

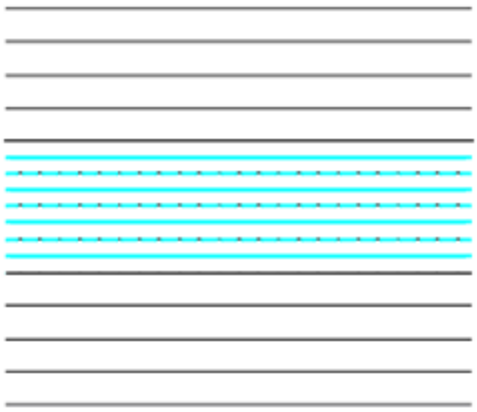


Figure 94 Macular Raster 6x6 (Retina) Scan Pattern

9.1.3 Cornea Pachymetry Scan

Objective: Measure the corneal thickness and map it.

Description: Pachymetry Map: 8 radial line scans with 1024 A-scans each. Horizontal line scan is captured 8 times and then averaged.

Horizontal scan presentation is the averaged result only.

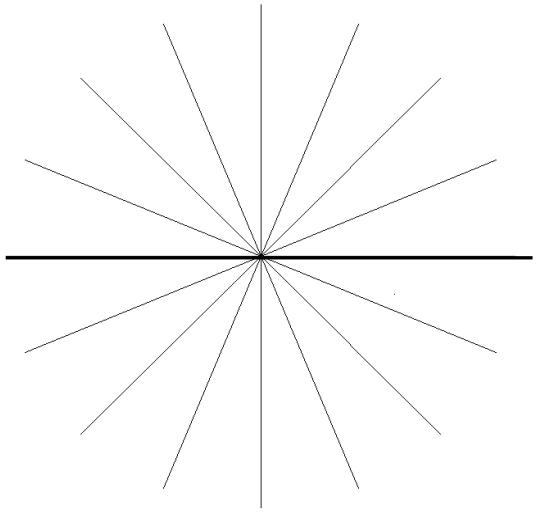


Figure 95 Pachymetry 6 mm Diameter (Cornea) Scan Pattern

9.1.4 iWellness Scan

Objective: Measure the inner retinal thickness map and total retinal thickness map for retina.

Description: 1 horizontal line with 7mm scan length, followed by 17 vertical lines with 7mm scan length and 0.5mm interval, centered 1mm temporal to fovea. 8 HD scans - 7 horizontal scans with 0.25mm interval covering central 1.5mm, 1 vertical scan. Each HD scan is averaged 5 times.

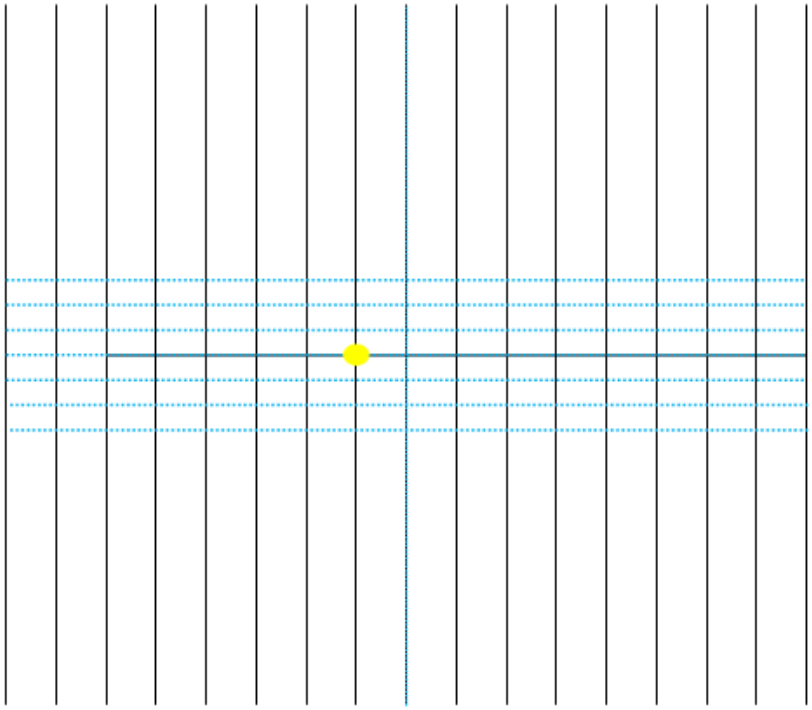


Figure 96 iWellness Scan Pattern

9.2 Fixation Patterns

☞ **Note**: The fixation patterns shown below replace the LED patterns in previous models.

9.2.1 Retina Scan Fixation Pattern

All retinal scans(Retina Map, Cross Line, and 3D) use the same fixation. The patient should fixate on the **X** in the center of the pattern. If the patient cannot see the center **X** due to pathology, they should look to the edges of the pattern and follow the lines inward and fixate where they cross centrally.

9.2.2 Nerve Fiber ONH and 3D Optic Nerve Scan Fixation Pattern

The Nerve Fiber ONH and 3D Disc fixation pattern is a green cross, located nasally.

9.2.3 GCC Map Scan and iWellness Fixation Pattern

The fixation pattern for GCC Map and iWellness scans is a green cross, located temporally 1 mm from the center.

9.2.4 Cornea Scan Fixation Pattern

The cornea fixation pattern is a large green **X** located directly in the center.

_____End of section_____

10 Technical Specifications

10.1 System Specifications

10.1.1 Scanner

- OCT Image Acquisition Rate: 25,000 A-scan/second
- Frame Rate: 256 to 1024 A-scan/frame
- Optical Resolution: (in tissue)
    - Depth: 5 µm
    - Transverse resolution 15 µm (retina)
- Image Sampling Rate:
    - Transverse: 8 µm nominal (4 µm to 40 µm)
- Scan Range:
    - Depth: 2 or 2.3 mm
    - Transverse: 2 mm to 12 mm
- Scan Beam Wavelength: 830 nm to 850 nm
- Exposure Power at pupil: 700 µW to 750 µW

10.1.2 Iris Imager

- FOV: Approximately 13 mm (H) x 8 mm (V)
- Image sensor: 752 x 480 pixels, 1/3 in. monochrome CMOS sensor
- NIR Illumination: 735 nm LED

10.1.3 Cornea Imager

- Cornea FOV: 10 ±1 mm x 8 ±1 mm
- Image sensor 1/3” wide VGA
- NIR Illumination: 735 nm LED

10.1.4 Patient Interface

- Working Distance: 21.2 mm for retina, 16.6 mm for cornea
- Motorized Focus Range: -15 D to +10 D
- Chin-Rest adjustable range: 40 mm

- Joystick controlled X-Y-Z adjustment: X-90 m, Y-80 mm, Z-30 mm

10.1.5 Computer Unit

- Screen Size and Resolution: 14.1 in. or 15.4 in., 1280 × 800
- CPU: Intel Core2 Duo
- Memory: ≥ 2 GB
- Hard disk: ≥ 300 GB
- Optical disk: DVD±R/±RW with CD-R/RW capability
- Footswitch: 2-button switch (optional)
- Graphics: dedicated graphic controller and memory
- I/O ports: at least three USB 2.0 ports; one 1394 port
- Networking: Intel Gigabit Ethernet chipset
- Operating system: 32 or 64 bit Windows XP Pro. Ed./Win 7

10.1.6 Power

- Power Input: AC100-240V, 50/60 Hz
- Current: 1.6 AMPS
- Power Rating: 75W

10.1.7 Compliance

- General Medical IEC/ BS EN 60601-1
- Medical System IEC/ EN 60601-1-1
- EMC of Medical System IEC/ EN 60601-1-2

General requirements for basic safety and essential performance. IEC/ BS EN 62366-1.

10.1.8 Fuse (Base Unit)

- Rating: 3.15A/250VAC
- Package: 5 mm x20 mm
- Type: Slow blow

10.1.9 Environmental Specifications

Operating Conditions:

- Temperature: 10 – 35°C
- Relative Humidity: 30 – 90%
- Atmospheric pressure: 800 – 1060 hPa

Storage Conditions:

- Temperature: -10 – 55°C
- Relative Humidity: 10 – 95%
- Atmospheric pressure: 700 – 1060 hPa

Transport Conditions

- Temperature: -40 – 70°C
- Relative Humidity: 10 – 95%
- Atmospheric pressure: 500 -1060 hPa
- Vibration, Sinusoidal: 10 – 500Hz, 0.5g
- Shock: 30g, duration 6ms
- Bump: 10g, duration 6ms

10.1.10 Additional Technical Specifications

- Electrical supply: Class 1
- Installation category: II
- Pollution degree: 2

10.2 Cybersecurity Information

10.2.1 Objective

The purpose of this section is to summarize the cybersecurity controls for the iVue system with embedded Windows 7 operating system.

10.2.2 System Overview

The iVue 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

10.2.3 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.

10.2.4 Cybersecurity Functions

10.2.4.1 Limit Access to Trusted Users Only

Authentication of Users

- iVue device uses Microsoft Windows 7 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.

10.2.4.2 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.

10.2.4.3 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 iVue 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 iVue 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 iVue 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.

10.2.4.4 Other implemented mechanisms

Institutional IT Infrastructure

- The iVue device uses the Windows 7 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 iVue device will support these site-specific IT systems and this is verified during the installation process by Optovue personnel.

Stand Alone Mode

- The iVue 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 iVue 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

11 APPENDIX - Precision Data for iVue 100 with NDB

A new repeatability and reproducibility study was conducted with IRB approval to assess iVue precision. Fourteen (14) normal subjects, thirteen (13) patients with glaucoma, and thirteen (13) patients with retina disease were included in the study to evaluate the repeatability and reproducibility of iVue 100 measurements.

Only one eye per subject was included in the study. Each study eye was imaged 3 times with each of the four scan patterns (ONH, Retina, GCC, iWellness) per iVue 100 instrument and imaged across three instrument/operator pairs. The three iVue100 instruments were operated by different operators, therefore, the combined effect of machine and operator was estimated for measurement reproducibility.

Subject enrollment criteria were as follows:

Normal Subjects

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

Exclusion Criteria

- History of ocular diseases
- History of ocular surgery except laser refractive surgery
- Pathological findings in fundus based on ophthalmoscopic examination

Glaucoma and Retinal Subjects

Inclusion Criteria

- At least 18 years of age
- Able and willing to provide consent
- Able and willing to complete the required examinations and visits
- Refractive error within +/- 8 diopters sphere and within +/- 2.5 diopters cylinder in study eye
- Best corrected visual acuity equal or better than 20/100
- Glaucoma subjects have clinical exam results consistent with glaucoma, either with glaucomatous visual field defect (e.g. PSD < 5%, and/or a GHT *Outside Normal Limits*) or structural damage consistent with glaucoma (e.g. neuroretinal rim thinning, notching, and RNFL defect)

- Retina subjects have clinical exam results consistent with retinal pathologies such as drusen, Geographic Atrophy (GA), wet AMD, diabetic retinopathy (DR), diabetic macular edema (DME), epiretinal membranes (ERM), and macular hole, etc.

Exclusion Criteria

- Other ocular pathologies except glaucoma and/or retinal pathologies.

The precision of iVue 100 measurements was estimated for all parameters measured and discussed in Section 4.7 (15 retinal parameters from the Retina scan, 5 GCC parameters from the GCC scan, 15 Retinal Nerve Fiber Layer (RNFL) parameters from ONH scan, 9 optic disc parameters from ONH scan, 11 retinal parameters from the iWellness scan, and 5 GCC parameters from the iWellness scan).

The precision for each iVue 100 parameter is provided for the normal eyes, the retinal disease eyes, and the glaucoma eyes respectively as follow: 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).

11.1 Retina Scan

Table 2 Repeatability and Reproducibility of Retina Thickness (Normal Eyes)

Retina Scan	Normal Eyes (14 subjects, 125 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
Fovea (µm)	255.9	2.27	2.35	0.92%	6.5
ParaFovea (µm)	313.2	3.16	3.29	1.05%	9.1
Para S Hemisphere (µm)	314.5	3.95	4.11	1.31%	11.4
Para I Hemisphere (µm)	311.9	3.12	3.21	1.03%	8.9
Para Tempo (µm)	307.5	3.22	3.35	1.09%	9.3
Para Superior (µm)	315.1	4.54	4.75	1.51%	13.2

Retina Scan	Normal Eyes (14 subjects, 125 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
Para Nasal (µm)	320.5	4.35	4.36	1.36%	12.1
Para Inferior (µm)	309.9	3.33	3.43	1.11%	9.5
Perifovea (µm)	284.2	2.47	2.64	0.93%	7.3
Peri S Hemisphere (µm)	288.0	3.31	3.40	1.18%	9.4
Peri I Hemisphere (µm)	280.4	2.90	3.07	1.09%	8.5
Peri Tempo (µm)	275.2	2.73	3.03	1.10%	8.4
Peri Superior (µm)	287.0	4.20	4.28	1.49%	11.9
Peri Nasal (µm)	301.0	3.82	3.82	1.27%	10.6
Peri Inferior (µm)	273.7	3.39	3.55	1.30%	9.9

* 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 3 Repeatability and Reproducibility of Retina Thickness (Retina Disease Eyes)

Retina Scan	Retinal Disease Eyes (13 subjects, 109 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
Fovea (µm)	284.4	3.41	3.49	1.24%	9.7
ParaFovea (µm)	312.0	2.60	2.83	0.91%	7.8
Para S Hemisphere (µm)	312.8	4.01	4.28	1.37%	11.9
Para I Hemisphere (µm)	311.3	2.80	2.94	0.95%	8.2
Para Tempo (µm)	302.9	6.78	6.83	2.26%	18.9
Para Superior (µm)	312.7	5.49	5.75	1.84%	15.9
Para Nasal (µm)	321.1	6.56	6.56	2.05%	18.2
Para Inferior (µm)	311.4	3.54	3.68	1.19%	10.2
Perifovea (µm)	279.4	2.03	2.04	0.73%	5.7
Peri S Hemisphere (µm)	282.5	3.09	3.09	1.10%	8.6
Peri I Hemisphere (µm)	276.2	4.15	4.17	1.51%	11.6
Peri Tempo (µm)	267.3	3.76	3.80	1.42%	10.5
Peri Superior (µm)	282.7	4.14	4.14	1.47%	11.5
Peri Nasal (µm)	295.1	3.57	3.57	1.21%	9.9
Peri Inferior (µm)	272.4	5.94	5.94	2.19%	16.5

* 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 4 Repeatability and Reproducibility of Retina Thickness (Glaucoma Eyes)

Retina Scan	Glaucoma Eyes (13 subjects, 101 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
Fovea (µm)	251.7	2.74	2.97	1.17%	8.2
ParaFovea (µm)	293.4	2.14	2.33	0.79%	6.4
Para S Hemisphere (µm)	294.1	2.55	2.74	0.93%	7.6
Para I Hemisphere (µm)	292.8	2.58	2.68	0.91%	7.4
Para Tempo (µm)	288.6	2.51	2.79	0.96%	7.7
Para Superior (µm)	294.0	2.99	3.20	1.08%	8.9
Para Nasal (µm)	299.6	2.78	2.80	0.93%	7.8
Para Inferior (µm)	291.5	2.95	3.03	1.03%	8.4
Perifovea (µm)	266.1	1.71	2.03	0.76%	5.6
Peri S Hemisphere (µm)	270.4	2.93	3.29	1.21%	9.1
Peri I Hemisphere (µm)	261.8	3.42	3.53	1.34%	9.8
Peri Tempo (µm)	260.6	2.62	2.87	1.09%	7.9
Peri Superior (µm)	269.4	3.77	4.17	1.55%	11.6
Peri Nasal (µm)	278.7	2.84	2.90	1.04%	8.0
Peri Inferior (µm)	255.6	4.43	4.56	1.78%	12.6

* 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.

11.2 GCC Scan

Table 5 Repeatability and Reproducibility of GCC (Normal Eyes))

GCC Scan	Normal Eyes (14 subjects, 124 scans)				
	Mean	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility (COV)**	**Reproducibility (Limit*)**
GCC_Average (µm)	97.5	1.3	1.3	1.32%	3.6
GCC_Superior_Avg (µm)	97.0	1.4	1.4	1.40%	3.8
GCC_Inferior_Avg (µm)	98.1	1.3	1.3	1.37%	3.7
GCC_FLV (%)	0.742	0.197	0.197	26.67%	0.546
GCC_GLV (%)	3.220	0.730	0.730	22.80%	2.022

* 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. Interpret the data with this information in mind.

Table 6 Repeatability and Reproducibility of GCC (Retina Disease Eyes)

GCC Scan	**Retinal Disease Eyes (13 subjects, 98 scans)**				
	Mean	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility (COV)**	**Reproducibility (Limit*)**
GCC_Average (µm)	98.6	1.4	1.4	1.39%	3.8
GCC_Superior_Avg (µm)	99.0	1.6	1.6	1.59%	4.4
GCC_Inferior_Avg (µm)	98.1	1.5	1.5	1.56%	4.2
GCC_FLV (%)	1.790	0.746	0.746	41.79%	2.067
GCC_GLV (%)	3.072	0.940	0.940	29.01%	2.606

* 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. Interpret the data with this information in mind.

Table 7 Repeatability and Reproducibility of GCC (Glaucoma Eyes)

GCC Scan	Glaucoma Eyes (13 subjects, 109 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
GCC_Average (µm)	85.7	1.1	1.2	1.39%	3.3
GCC_Superior_Avg (µm)	86.2	1.4	1.5	1.80%	4.3
GCC_Inferior_Avg (µm)	85.2	1.2	1.3	1.53%	3.6
GCC_FLV (%)	3.604	0.539	0.579	16.58%	1.605
GCC_GLV (%)	11.673	0.936	0.999	8.65%	2.770

* 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. Interpret the data with this information in mind.

11.3 iWellness

Note that 11 retina thickness parameters are provided for iWellness scan retinal measurements; the four hemisphere parameters (Para S Hemisphere, Para I Hemisphere, Peri S Hemisphere, and Peri I Hemisphere) are not included in the iWellness scan report.

Table 8 Repeatability and Reproducibility of GCC and Retina Thickness (Normal Eyes)

iWellness Scan	Normal Eyes (14 subjects, 125 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
GCC Parameters					

iWellness Scan	Normal Eyes (14 subjects, 125 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
GCC_Average (µm)	97.2	0.9	0.9	0.97%	2.6
GCC_Superior_Avg (µm)	96.6	1.1	1.1	1.12%	3.0
GCC_Inferior_Avg (µm)	97.8	0.9	0.9	0.97%	2.6
GCC_FLV (%)	0.737	0.149	0.151	20.36%	0.417
GCC_GLV (%)	3.095	0.428	0.428	13.79%	1.187
Retina Parameters					
Fovea (µm)	257.4	2.6	3.1	1.22%	8.7
ParaFovea (µm)	315.1	3.6	3.7	1.17%	10.3
Para S Hemisphere (µm)	316.1	4.2	4.2	1.33%	11.7
Para I Hemisphere (µm)	314.1	3.7	3.8	1.21%	10.5
Para Tempo (µm)	304.8	3.8	4.0	1.30%	11.0
Para Superior (µm)	319.8	4.6	4.6	1.45%	12.8
Para Nasal (µm)	320.2	5.1	5.1	1.59%	14.1
Para Inferior (µm)	315.6	3.9	4.1	1.30%	11.4
Perifovea (µm)	285.9	2.7	2.8	0.97%	7.7
Peri S Hemisphere (µm)	289.6	3.7	3.7	1.27%	10.2

iWellness Scan	Normal Eyes (14 subjects, 125 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
Peri I Hemisphere (µm)	282.2	2.9	2.9	1.03%	8.1
Peri Tempo (µm)	279.8	4.5	4.6	1.66%	12.9
Peri Superior (µm)	289.2	4.3	4.4	1.51%	12.1
Peri Nasal (µm)	299.3	4.4	4.4	1.48%	12.3
Peri Inferior (µm)	275.3	3.3	3.4	1.22%	9.3

* 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. Interpret the data with this information in mind.

Table 9 Repeatability and Reproducibility of GCC and Retina Thickness (Retina Disease Eyes)

iWellness Scan	Retinal Disease Eyes (13 subjects, 108 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
GCC Parameters					
GCC_Average (µm)	98.7	1.3	1.4	1.38%	3.8
GCC_Superior_Avg (µm)	98.7	1.6	1.7	1.71%	4.7
GCC_Inferior_Avg (µm)	98.6	1.5	1.5	1.50%	4.1
GCC_FLV (%)	1.851	0.504	0.508	28.64%	1.408
GCC_GLV (%)	3.111	0.671	0.690	22.59%	1.912

iWellness Scan	Retinal Disease Eyes (13 subjects, 108 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
Retina Parameters					
Fovea (µm)	281.7	3.1	3.6	1.29%	10.1
ParaFovea (µm)	313.2	2.6	2.6	0.84%	7.3
Para S Hemisphere (µm)	314.1	3.2	3.2	1.02%	8.9
Para I Hemisphere (µm)	312.3	2.6	2.6	0.83%	7.2
Para Tempo (µm)	303.9	3.9	4.2	1.38%	11.6
Para Superior (µm)	316.1	3.7	3.8	1.20%	10.5
Para Nasal (µm)	319.1	4.7	4.8	1.51%	13.3
Para Inferior (µm)	313.7	3.2	3.2	1.01%	8.8
Perifovea (µm)	280.3	1.7	1.9	0.67%	5.2
Peri S Hemisphere (µm)	283.7	2.0	2.0	0.72%	5.7
Peri I Hemisphere (µm)	276.8	2.2	2.6	0.94%	7.2
Peri Tempo (µm)	272.0	3.9	4.2	1.54%	11.6
Peri Superior (µm)	284.0	2.4	2.4	0.85%	6.7
Peri Nasal (µm)	292.7	2.6	2.6	0.89%	7.2
Peri Inferior (µm)	272.3	2.6	3.1	1.14%	8.6

* 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. Interpret the data with this information in mind.

Table 10 Repeatability and Reproducibility of GCC and Retina Thickness (Glaucoma Eyes)

iWellness Scan	Glaucoma Eyes (13 subjects, 106 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
GCC Parameters					
GCC_Average (µm)	85.3	0.8	0.8	0.91%	2.2
GCC_Superior_Avg (µm)	85.6	1.0	1.0	1.11%	2.7
GCC_Inferior_Avg (µm)	85.0	1.1	1.1	1.28%	3.0
GCC_FLV (%)	3.521	0.354	0.375	10.68%	1.040
GCC_GLV (%)	11.644	0.606	0.606	5.32%	1.680
Retina Parameters					
Fovea (µm)	253.4	2.7	3.0	1.18%	8.3
ParaFovea (µm)	295.1	2.4	2.5	0.83%	6.8
Para S Hemisphere (µm)	295.6	2.9	2.9	0.98%	8.1
Para I Hemisphere (µm)	294.7	2.7	2.7	0.93%	7.6
Para Tempo (µm)	288.4	2.7	2.8	0.97%	7.8
Para Superior (µm)	297.7	3.0	3.1	1.02%	8.5
Para Nasal (µm)	298.3	3.6	3.6	1.20%	10.0

Para Inferior (µm)	296.2	2.9	2.9	0.98%	8.1
Perifovea (µm)	266.4	1.6	1.7	0.65%	4.8
Peri S Hemisphere (µm)	270.7	2.1	2.1	0.78%	5.9
Peri I Hemisphere (µm)	262.1	2.4	2.6	1.00%	7.3
Peri Tempo (µm)	263.2	4.0	4.1	1.55%	11.3
Peri Superior (µm)	269.5	2.4	2.4	0.90%	6.7
Peri Nasal (µm)	276.9	3.0	3.0	1.07%	8.2
Peri Inferior (µm)	256.0	2.3	2.7	1.04%	7.4

* 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. Interpret the data with this information in mind.

11.4 ONH Scan

Table 11 Repeatability and Reproducibility of Disc and RNFL Thickness (Normal Eyes)

ONH Scan	**Normal Eyes (14 subjects, 123 scans)**				
	Mean	**Repeatability (SD)**	**Reproducibility (SD)**	**Reproducibility (COV)**	**Reproducibility (Limit*)**
Disc Parameters					
disc Area (mm^2)	2.141	0.084	0.093	4.33%	0.258
Area_C_D_ratio	0.286	0.020	0.021	7.25%	0.057
H_C_D_ratio	0.576	0.041	0.041	7.22%	0.115

ONH Scan	Normal Eyes (14 subjects, 123 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
V_C_D_ratio	0.470	0.035	0.036	7.62%	0.099
Cup Area (mm^2)	0.625	0.042	0.043	6.94%	0.120
Rim Area (mm^2)	1.516	0.079	0.087	5.72%	0.242
Rim Volume (mm^3)	0.176	0.014	0.015	8.34%	0.041
Nervehead_Volume (mm^3)	0.352	0.047	0.049	13.89%	0.137
Cup Volume (mm^3)	0.136	0.024	0.025	18.81%	0.070
RNFL Parameters					
Avg_RNFL (µm)	97.9	1.4	1.5	1.56%	4.2
Sup_RNFL (µm)	100.6	1.7	1.7	1.67%	4.7
Inf_RNFL (µm)	95.3	1.9	2.2	2.35%	6.2
Tempo (µm)	70.9	2.3	2.3	3.27%	6.4
Superior (µm)	120.7	2.8	2.8	2.34%	7.8
Nasal (µm)	77.1	2.7	2.7	3.46%	7.4
Inferior (µm)	123.2	3.6	3.9	3.15%	10.7
TU (µm)	77.2	3.2	3.2	4.17%	8.9
ST (µm)	136.7	3.9	3.9	2.85%	10.8

ONH Scan	Normal Eyes (14 subjects, 123 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
SN (µm)	104.7	4.2	4.2	4.03%	11.7
NU (µm)	83.7	3.5	3.5	4.14%	9.6
NL (µm)	70.4	2.9	3.0	4.22%	8.3
IN (µm)	109.0	4.4	4.6	4.20%	12.7
IT (µm)	137.3	5.3	5.5	4.03%	15.3
TL (µm)	64.6	2.5	2.6	3.99%	7.1

* 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 12 Repeatability and Reproducibility of Disc and RNFL Thickness (Retinal Disease Eyes)

ONH Scan	Retinal Disease Eyes (13 subjects, 101 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
Disc Parameters					
disc Area (mm^2)	2.417	0.118	0.118	4.99%	0.328
Area_C_D_ratio	0.322	0.023	0.026	7.90%	0.073
H_C_D_ratio	0.592	0.051	0.051	8.41%	0.141
V_C_D_ratio	0.512	0.057	0.062	11.85%	0.172
Cup Area (mm^2)	0.814	0.052	0.055	6.69%	0.151

ONH Scan	Retinal Disease Eyes (13 subjects, 101 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
Rim Area (mm^2)	1.603	0.111	0.115	7.37%	0.318
Rim Volume (mm^3)	0.155	0.015	0.015	10.01%	0.041
Nervehead_Volume (mm^3)	0.339	0.036	0.036	11.20%	0.101
Cup Volume (mm^3)	0.147	0.022	0.023	15.49%	0.063
RNFL Parameters					
Avg_RNFL (µm)	99.5	1.5	1.9	1.94%	5.3
Sup_RNFL (µm)	101.2	2.0	2.5	2.49%	6.8
Inf_RNFL (µm)	97.8	2.0	2.2	2.24%	6.0
Tempo (µm)	73.1	3.5	3.7	5.17%	10.4
Superior (µm)	119.2	3.6	4.0	3.43%	11.1
Nasal (µm)	80.1	3.7	3.7	4.74%	10.3
Inferior (µm)	125.5	3.1	3.3	2.64%	9.0
TU (µm)	81.2	4.8	5.6	6.93%	15.4
ST (µm)	129.4	5.5	6.0	4.73%	16.6
SN (µm)	109.1	4.9	4.9	4.58%	13.7
NU (µm)	84.9	4.6	4.6	5.56%	12.7

ONH Scan	Retinal Disease Eyes (13 subjects, 101 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
NL (µm)	75.2	3.7	3.7	5.01%	10.4
IN (µm)	122.7	4.7	4.8	4.05%	13.3
IT (µm)	128.3	4.5	4.6	3.60%	12.8
TL (µm)	65.1	3.7	3.7	5.80%	10.4

* 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 13 Repeatability and Reproducibility of Disc and RNFL Thickness (Glaucoma Eyes)

ONH Scan	Glaucoma Eyes (13 subjects, 112 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
Disc Parameters					
disc Area (mm^2)	2.513	0.072	0.105	4.15%	0.291
Area_C_D_ratio	0.564	0.022	0.023	4.07%	0.064
H_C_D_ratio	0.794	0.021	0.021	2.66%	0.058
V_C_D_ratio	0.736	0.035	0.036	4.88%	0.099
Cup Area (mm^2)	1.473	0.051	0.055	3.72%	0.152
Rim Area (mm^2)	1.040	0.082	0.098	9.29%	0.271
Rim Volume (mm^3)	0.062	0.012	0.012	18.75%	0.032

ONH Scan	Glaucoma Eyes (13 subjects, 112 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
Nervehead_Volume (mm^3)	0.152	0.030	0.030	19.66%	0.084
Cup Volume (mm^3)	0.465	0.047	0.057	12.29%	0.159
RNFL Parameters					
Avg_RNFL (µm)	84.6	1.3	1.4	1.70%	4.0
Sup_RNFL (µm)	90.2	1.9	1.9	2.11%	5.3
Inf_RNFL (µm)	79.0	1.9	2.0	2.51%	5.5
Tempo (µm)	65.2	3.3	3.4	5.28%	9.5
Superior (µm)	108.5	3.0	3.0	2.81%	8.4
Nasal (µm)	66.6	2.5	2.6	3.93%	7.2
Inferior (µm)	98.3	2.7	2.8	2.88%	7.9
TU (µm)	69.8	4.3	4.6	6.68%	12.9
ST (µm)	121.1	4.7	4.9	4.01%	13.5
SN (µm)	95.9	4.1	4.1	4.24%	11.3
NU (µm)	74.2	3.9	4.1	5.56%	11.4
NL (µm)	58.9	2.6	2.6	4.49%	7.3
IN (µm)	88.9	3.7	3.7	4.17%	10.4

ONH Scan	Glaucoma Eyes (13 subjects, 112 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
IT (µm)	107.8	4.9	4.9	4.59%	13.7
TL (µm)	60.6	4.6	4.6	7.67%	12.8

* 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.

_____End of section_____

12 APPENDIX – Scan Quality Index

For the iVue, a Scan Quality Index classification is provided for each scan type, resulting in a “Good” or “Poor” classification. If the iVue 100 scan classification is “Poor,” it is deemed unacceptable and unusable. These scans should not be used for clinical decisions.

The iVue 100 Scan Quality Index (SQI) is **Good** or **Poor** based on the cutoff values for each scan type in the table below. The SQI value is displayed to the user and is the same as the Signal Strength Index (SSI) number in RTVue. Optovue made the nomenclature change from SSI to SQI to better reflect clinical usage of the value. When the SQI falls below the cutoff value for the respective scan type, it is labeled “Poor” and should not be used clinically.

Table 14 Image Quality Classification Based On SQI Cutoffs

SQI	“Poor”
Retina	SQI < 40
Glaucoma	SQI < 27
Cornea	SQI < 27
GCC	SQI < 32
iWellness	SQI < 40

These SQI cutoff values used for iVue 100 were determined based on an in-house review of a large data set from the iVue, made up of approximately 100 scans with a wide range of SQI values and including all scan types (retina, glaucoma, cornea, GCC, iWellness). To establish this cutoff, approximately 100 B scans were reviewed for all 5 scan types on the iVue 100 (cornea, retina, glaucoma, GCC, iWellness). The basic criteria for review was whether visualization of the critical retinal layers was possible or not, including the ILM (for all scan types), the RNFL (for glaucoma scans), the IPL (for retina. GCC, iWellness scans), and the RPE (for retina, iWellness scans). For cornea scans, the B scans were reviewed to determine if the anterior and posterior cornea surface could be adequately visualized in order to ascertain accurate segmentation. It was determined, for each scan pattern, the SQI value where the various retinal or cornea layers could no longer be visualized in the B scans. These scans cannot be segmented accurately if there is no ocular structure that can be visualized. Scans with SQI values below this point would be classified as “Poor.” Once the SQI was strong enough to reliably provide visualization of the ocular layers, then the scan was determined to be of “Good” quality.

In order to validate the cutoff between acceptable and not acceptable scans, the repeatability of scans considered unusable (“Poor”), and scans considered usable (“Good”), was evaluated by the above classification. For this evaluation, repeat scans

were performed on six normal subjects with clear ocular media to establish a baseline precision level. All five scan patterns on the iVue 100 were evaluated and scans in the same label (“Poor” or “Good”) were used to calculate repeatability defined as the standard deviation of the thickness values for each measurement. The image quality was manipulated by defocusing the OCT image during scan acquisition. The defocusing and resulting lowered image quality emulates the clinical situation which would occur with media opacity and small pupils. A live feedback bar on image quality was used to guide the operator to take the images. All measurements were analyzed and the results are provided in the following tables (numbers are the average standard deviation of the same label scans averaged across all six subjects). The standard deviation represents the amount of measurement variability present under different image quality classifications; the higher the standard deviation, the greater the measurement variability.

Table 15 Retina Scan Results (Standard Deviation)

Retina			
Good			Poor
Inner Retina	Fovea	2.52	9.11
	Tempo	3.04	12.48
	Superior	4.45	8.52
	Nasal	6.02	12.26
	Inferior	7.44	14.72
	Tempo1	3.49	8.27
	Superior1	3.09	4.72
	Nasal1	5.75	9.02
	Inferior1	3.36	11.33
Full Retina	Fovea	5.67	23.96
	Tempo2	3.53	30.31
	Superior2	3.26	5.15
	Nasal2	4.14	24.08
	Inferior2	2.59	48.84
	Tempo3	5.21	36.71
	Superior3	2.37	10.27
	Nasal3	2.37	21.06
	Inferior3	5.97	33.83
	Average	4.13	18.04

The table above shows the standard deviation values of the scans with the same image quality label averaged over all subjects for each retina thickness parameter. The first column of data shows the results when the image qualities are listed as “Good” and the scans are deemed acceptable and usable. The second column of data shows the results when the image qualities are listed as “Poor” and the scans are deemed unacceptable and not usable. It can be seen that the standard deviations are small when the image qualities are “Good” and therefore the scans are usable, and the standard deviations increase when the image qualities are “Poor” and therefore the scans are unusable.

From the high variability in the unusable scans, it is recommended that “Poor” scans are not to be used for clinical decision making due to their poor image quality.

Table 16 Glaucoma Scan Results (Standard Deviation)

Glaucoma	Good	Poor
Avg RNFL	5.16	16.89
Sup RNFL	4.63	17.58
Inf RNFL	8.67	21.70
Tempo	6.56	12.25
Superior	8.25	17.75
Nasal	12.15	37.08
Inferior	9.80	25.80
TU1	6.98	10.45
TU2	7.62	6.86
ST2	8.52	12.35
ST1	11.48	17.14
SN1	10.77	23.79
SN2	8.37	36.23
NU2	13.17	40.92
NU1	11.46	34.83
NL1	16.29	31.85
NL2	19.32	44.26
IN2	8.57	34.15
IN1	14.40	30.62
IT1	11.63	28.55
IT2	12.19	26.48
TL2	13.71	23.86
TL1	7.50	12.21
Average	10.31	24.51

The table above shows the standard deviation values of the scans with the same image quality label averaged over all subjects for each glaucoma thickness parameter. The first column of data show the results when the image qualities are listed as “Good” and the scans are deemed acceptable and usable. The second column of data shows the results when the image qualities are listed as “Poor” and the scans are deemed unacceptable and not usable. It can be seen that the standard deviations are small when the image qualities are “Good” and therefore the scans are usable, and the standard deviations increase when the image qualities are “Poor” and therefore the scans are unusable.

From the high variability in the unusable scans, it is recommended that “Poor” scans are not to be used for clinical decision making due to their poor image quality.

Table 17 Cornea Scan Results (Standard Deviation)

Cornea		Good	Poor
0-2 mm	V2 mm	1.42	36.23
2-5 mm	V5 mm T	2.98	66.08

Cornea		Good	Poor
	ST	7.44	17.78
	S	11.18	21.57
	SN	6.71	20.12
	N	3.98	55.84
	IN	3.30	22.83
	I	3.58	20.87
	IT	2.52	28.59
5-6 mm	V6 mm T	5.42	57.62
	ST2	15.12	20.84
	S2	17.47	17.90
	SN2	9.41	25.58
	N2	5.80	11.45
	IN2	6.34	24.98
	I2	5.67	20.44
	IT2	7.25	49.67
	Average	6.80	30.49

The table above shows the standard deviation values of the scans with the same image quality label averaged over all subjects for each Cornea thickness parameter. The first column of data shows the results when the image qualities are listed as “Good” and the scans are deemed acceptable and usable. The second column of data shows the results when the image qualities are listed as “Poor” and the scans are deemed unacceptable and not usable. It can be seen that the standard deviations are small when the image quality are “Good” and therefore the scans are usable, and the standard deviations increase when the image qualities are “Poor” and therefore the scans are unusable.

From the high variability in the unusable scans, it is recommended that “Poor” scans are not be used for clinical decision making due to their poor quality.

Table 18 GCC Scan Results (Standard Deviation)

Good		Poor
Average	1.819841	4.790386
Superior Avg	2.392628	6.685251
Inferior Avg	1.909602	4.30937
GCC-FLV	0.562347	0.926966
GCC-GLV	0.814944	0.804625

The table above shows the standard deviation values of the scans with the same image quality label averaged over all subjects for each GCC parameter. The first column of data shows the results when the image qualities are listed as “Good” and the scans are deemed acceptable and usable. The second column of data shows the results when the image qualities are listed as “Poor” and the scans are deemed unacceptable and not usable. It can be seen that the standard deviations are small when the image qualities are “Good” and therefore the scans are usable, and the standard deviations increase when the image qualities are “Poor” and therefore the scans are unusable.

From the high variability in the unusable scans, it is recommended that “Poor” scans are not to be used for clinical decision making due to their poor quality.

Table 19 iWellness Scan Results (Standard Deviation)

		Good	Poor
GCC	Average	1.613258	4.669008
	Superior Avg	1.720426	4.55784
	Inferior Avg	1.937574	5.421068
	FLV	0.351951	0.654639
	GLV	0.833165	1.179751
Full Retina	Fovea	9.845381	39.86225
	Tempo	4.399735	25.84062
	Superior	5.204816	21.2472
	Nasal	4.70569	18.99658
	Inferior	5.067598	10.11727
	Tempo2	5.246559	19.06622
	Superior2	4.379145	5.422231
	Nasal2	3.603066	5.056085
	Inferior2	4.952697	7.333335
	Average	3.847219	12.10172

The table above shows the standard deviation values of the scans with the same image quality label averaged over all subjects for each iWellness parameter. The first column of data shows the results when the image qualities are listed as “Good” and the scans are deemed acceptable and usable. The second column of data shows the results when the image qualities are listed as “Poor” and the scans are deemed unacceptable and not usable. It can be seen that the standard deviations are small when the image qualities are “Good” and therefore the scans are usable, and the standard deviations increases when the image qualities are “Poor” and therefore the scans are unusable.

From the high variability in the unusable scans, it is recommended that ‘Poor’ scans are not to be used for clinical decision making due to their poor quality.

_____End of section_____

13 APPENDIX iVue 100 NDB vs. RTVue NDB Substantial Equivalence

The results in following tables support substantial equivalence between the iVue 100 with NDB (K121739) and the predicate RTVue with NDB (K101505) for GCC parameters, RNFL thickness parameters, Optic disc parameters, and Retina thickness parameters. Mean differences were small and the ranges of differences are reasonably tight for all thickness parameters associated with GCC scan, ONH scan, Retina map scan, and iWellness scan. While the two devices may not be interchangeable due to the small differences, considering each device is equipped with its own normative database collected specifically for itself, it is reasonable to conclude that the two devices are substantially equivalent.

Table 20 iVue 100 GCC Vs. RTVue GCC In Normal And Glaucoma Groups

iVue GCC vs. RTVue GCC	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Normal Group								
GCC_Average	21	95.65	96.90	-1.25	2.92	(-2.577, 0.077)	-7.77	5.27
GCC_Superior_Avg	21	95.89	97.25	-1.37	2.89	(-2.681, -0.049)	-8.14	5.41
GCC_Inferior_Avg	21	95.41	96.55	-1.13	3.21	(-2.595, 0.325)	-8.10	5.83
GCC_FLV	21	1.083	0.813	0.270	0.757	(-0.074, 0.614)	-1.519	2.059
GCC_GLV	21	3.964	4.146	-0.182	1.857	(-1.027, 0.662)	-4.266	3.901
Glaucoma Group								
GCC_Average	24	79.10	80.44	-1.34	1.50	(-1.974, -0.709)	-5.31	2.62
GCC_Superior_Avg	24	79.75	80.76	-1.01	2.66	(-2.133, 0.114)	-7.35	5.34

iVue GCC vs. RTVue GCC	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
GCC_Inferior_Avg	24	78.45	80.13	-1.67	2.17	(-2.591, -0.758)	-6.99	3.64
GCC_FLV	24	4.641	4.854	-0.213	1.328	(-0.773, 0.347)	-3.445	3.019
GCC_GLV	24	14.648	16.813	-2.165	1.095	(-2.626, -1.702)	-5.280	0.951

21Table 22 Normal And Glaucoma Groups iVue 100 ONH Vs. RTVue ONH (Disc Parameters)

iVue ONH vs. RTVue ONH (Disc Parameters)	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Normal Group								
Disc Area	21	1.916	2.090	-0.174	0.180	(-0.256 , -0.092)	-0.528	0.179
Area C D ratio	21	0.300	0.261	0.038	0.044	(0.018 , 0.0580)	-0.057	0.134
H C D ratio	21	0.566	0.595	-0.029	0.087	(-0.068 , 0.010)	-0.221	0.163
V C D ratio	21	0.462	0.479	-0.017	0.057	(-0.042, 0.009)	-0.142	0.108
Cup Area	21	0.584	0.549	0.035	0.076	(0.000, 0.069)	-0.136	0.205
Rim Area	21	1.332	1.541	-0.209	0.187	(-0.294, -0.124)	-0.586	0.167

iVue ONH vs. RTVue ONH (Disc Parameters)	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Rim Volume	21	0.159	0.236	-0.077	0.097	(-0.121, -0.032)	-0.320	0.166
Nervehead Volume	21	0.334	0.409	-0.075	0.094	(-0.118, -0.032)	-0.320	0.169
Cup Volume	21	0.112	0.116	-0.004	0.028	(-0.016, 0.009)	-0.067	0.060
Glaucoma Group								
Disc Area	23	2.035	1.952	0.083	0.246	(-0.023, 0.189)	-0.399	0.566
Area C D ratio	23	0.599	0.586	0.013	0.089	(-0.025, 0.052)	-0.202	0.228
H C D ratio	23	0.800	0.854	-0.054	0.075	(-0.086, -0.021)	-0.220	0.113
V C D ratio	23	0.708	0.789	-0.081	0.093	(-0.120, -0.040)	-0.283	0.122
Cup Area	23	1.243	1.149	0.095	0.211	(0.003, 0.186)	-0.375	0.565
Rim Area	23	0.792	0.802	-0.011	0.222	(-0.106, 0.085)	-0.503	0.482
Rim Volume	23	0.068	0.067	0.001	0.019	(-0.006, 0.009)	-0.040	0.042
Nervehead Volume	23	0.151	0.128	0.023	0.038	(0.006, 0.039)	-0.061	0.107
Cup Volume	23	0.341	0.328	0.013	0.095	(-0.028, 0.054)	-0.212	0.237

Table 23 Normal and Glaucoma Groups iVue100 ONH Vs. RTVue ONH (RNFL Parameters)

iVue ONH vs. RTVue ONH (RNFL Parameters)	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Normal Group								
Avg RNFL	21	100.42	104.85	-4.43	3.15	(-5.862, -2.991)	-11.56	2.70
Sup RNFL	21	101.53	103.75	-2.23	5.28	(-4.630, 0.179)	-13.53	9.08
Inf RNFL	21	99.31	105.94	-6.63	4.54	(-8.697, -4.562)	-16.73	3.47
Tempo	21	78.43	84.33	-5.91	6.20	(-8.728, -3.085)	-21.60	9.79
Superior	21	118.17	121.79	-3.62	7.61	(-7.083, -0.154)	-19.38	12.14
Nasal	21	74.99	78.76	-3.77	6.60	(-6.776, -0.765)	-20.26	12.71
Inferior	21	130.09	134.50	-4.41	6.50	(-7.369, -1.451)	-18.30	9.48
TU	21	87.96	86.81	1.15	9.26	(-3.067, 5.362)	-20.61	22.90
ST	21	135.64	134.82	0.82	6.96	(-2.352, 3.988)	-14.57	16.20
SN	21	100.70	108.76	-8.05	10.89	(-13.008, -3.096)	-30.71	14.60
NU	21	81.80	84.62	-2.82	8.28	(-6.583, 0.951)	-21.32	15.69

iVue ONH vs. RTVue ONH (RNFL Parameters)	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
NL	21	68.18	72.97	-4.80	6.11	(-7.576, -2.016)	-22.89	13.30
IN	21	111.51	119.78	-8.27	7.89	(-11.864, -4.679)	-30.04	13.50
IT	21	148.68	149.21	-0.54	8.71	(-4.502, 3.430)	-21.51	20.44
TL	21	68.89	81.82	-12.93	6.39	(-15.837, -10.022)	-29.47	3.61
Glaucoma Group								
Avg RNFL	23	78.17	81.54	-3.37	3.19	(-4.750, -1.989)	-10.26	3.52
Sup RNFL	23	79.49	81.45	-1.96	3.89	(-3.644, -0.283)	-10.63	6.71
Inf RNFL	23	76.86	81.64	-4.78	4.79	(-6.847, -2.708)	-14.89	5.33
Tempo	23	59.48	63.83	-4.36	4.82	(-6.442, -2.275)	-16.20	7.48
Superior	23	93.17	96.03	-2.86	6.37	(-5.614, -0.105)	-16.47	10.75
Nasal	23	63.19	66.37	-3.18	5.06	(-5.369, -0.990)	-15.56	9.20
Inferior	23	96.87	99.96	-3.08	7.63	(-6.382, 0.214)	-18.88	12.71
TU	23	64.95	64.15	0.80	6.00	(-1.796, 3.391)	-13.91	15.51
ST	23	102.82	99.61	3.21	7.73	(-0.134, 6.547)	-13.74	20.16

iVue ONH vs. RTVue ONH (RNFL Parameters)	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
SN	23	83.52	92.41	-8.90	8.42	(-12.534, -5.255)	-26.56	8.77
NU	23	66.67	69.61	-2.94	5.05	(-5.127, -0.757)	-15.74	9.86
NL	23	59.70	63.16	-3.46	6.82	(-6.409, -0.514)	-19.45	12.52
IN	23	88.54	96.69	-8.14	9.29	(-12.160, -4.128)	-27.44	11.15
IT	23	105.20	103.24	1.96	9.23	(-2.035, 5.948)	-17.36	21.27
TL	23	54.00	63.49	-9.49	6.48	(-12.293, -6.689)	-24.65	5.67

Table 24 Normal And Retina Groups iVue 100 Retina Map Vs. RTVue EMM5

iVue Retina Map vs. RTVue EMM5	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Normal Group								
Fovea	21	260.21	258.65	1.56	4.29	(-0.395, 3.510)	-9.07	12.18
Para Fovea	21	314.79	319.40	-4.61	6.87	(-7.736, -1.485)	-18.68	9.45
Para S. Hemisphere	21	316.34	322.04	-5.70	7.97	(-9.325, -2.071)	-22.09	10.69
Para I. Hemisphere	21	313.25	316.82	-3.57	6.38	(-6.475, -0.667)	-16.87	9.73
Para Tempo	21	307.67	310.90	-3.23	7.47	(-6.625, 0.173)	-18.75	12.30

iVue Retina Map vs. RTVue EMM5	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Para Superior	21	317.09	323.86	-6.76	8.66	(-10.704, -2.821)	-24.63	11.10
Para Nasal	21	322.71	325.90	-3.18	8.01	(-6.828, 0.463)	-20.19	13.82
Para Inferior	21	311.70	316.89	-5.19	6.56	(-8.177, -2.208)	-18.90	8.51
Peri Fovea	21	286.43	290.16	-3.73	5.95	(-6.441, -1.026)	-15.93	8.46
Peri S. Hemisphere	21	289.58	291.01	-1.43	6.26	(-4.281, 1.419)	-14.45	11.58
Peri I. Hemisphere	21	283.27	289.27	-6.00	6.85	(-9.115, -2.876)	-20.72	8.72
Peri Tempo	21	278.59	282.36	-3.77	9.33	(-8.012, 0.478)	-24.20	16.67
Peri Superior	21	288.50	287.40	1.11	6.14	(-1.687, 3.903)	-12.38	14.59
Peri Nasal	21	301.59	308.02	-6.43	6.15	(-9.229, -3.629)	-19.75	6.89
Peri Inferior	21	277.02	282.75	-5.73	7.98	(-9.359, -2.094)	-22.92	11.46
Retina Group								
Fovea	19	297.60	293.11	4.50	1.85	(3.605, 5.386)	-4.94	13.93
Para Fovea	19	327.57	325.25	2.31	5.37	(-0.276, 4.902)	-9.23	13.85
Para S. Hemisphere	19	330.69	327.29	3.40	9.61	(-1.233, 8.026)	-16.89	23.69
Para I. Hemisphere	19	324.45	323.31	1.14	3.67	(-0.628, 2.911)	-7.77	10.06

iVue Retina Map vs. RTVue EMM5	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Para Tempo	19	328.04	324.88	3.16	7.11	(-0.266, 6.588)	-12.07	18.39
Para Superior	19	330.69	327.51	3.18	13.22	(-3.189, 9.551)	-24.66	31.02
Para Nasal	19	331.07	327.80	3.27	7.18	(-0.195, 6.729)	-13.08	19.62
Para Inferior	19	320.48	320.95	-0.47	4.62	(-2.699, 1.755)	-11.96	11.02
Peri Fovea	19	291.19	288.67	2.52	5.05	(0.089, 4.954)	-7.76	12.81
Peri S. Hemisphere	19	294.75	290.30	4.45	10.48	(-0.595, 9.504)	-16.69	25.60
Peri I. Hemisphere	19	287.62	287.08	0.55	5.49	(-2.101, 3.192)	-11.16	12.25
Peri Tempo	19	288.82	285.95	2.87	6.29	(-0.161, 5.902)	-11.91	17.65
Peri Superior	19	292.12	286.32	5.80	14.20	(-1.046, 12.638)	-22.99	34.58
Peri Nasal	19	303.39	301.97	1.42	8.79	(-2.816, 5.653)	-17.15	19.99
Peri Inferior	19	280.42	280.37	0.06	7.52	(-3.568, 3.678)	-15.59	15.70

Table 25 Normal And Glaucoma Groups iVue 100 iWellness vs. RTVue GCC (GCC Parameters)

iVue iWellness vs. RTVue GCC (GCC Parameters)	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Normal Group								
GCC Average	21	95.01	96.86	-1.86	2.65	(-3.062, -0.650)	-7.73	4.02
GCC Superior Avg	21	95.30	97.14	-1.85	2.72	(-3.085, -0.608)	-8.15	4.46
GCC Inferior Avg	21	94.73	96.59	-1.86	2.83	(-3.150, -0.573)	-8.01	4.29
GCC FLV	21	0.976	0.784	0.193	0.652	(-0.104, 0.489)	-1.351	1.736
GCC GLV	21	3.871	4.259	-0.389	1.802	(-1.208, 0.431)	-4.118	3.340
Glaucoma Group								
GCC Average	23	79.13	81.11	-1.98	1.78	(-2.752, -1.208)	-6.21	2.25
GCC Superior Avg	23	79.14	81.42	-2.27	2.47	(-3.340, -1.206)	-8.05	3.51
GCC Inferior Avg	23	79.10	80.79	-1.69	1.72	(-2.429, -0.944)	-6.11	2.73
GCC FLV	23	5.056	4.504	0.552	1.085	(0.082, 1.020)	-2.249	3.352
GCC GLV	23	12.672	16.125	-3.453	1.645	(-4.164, -2.741)	-7.353	0.447

Table 26 Normal And Retina Groups iVue 100 iWellness Vs. RTVue EMM5 (Retina Parameters)

iVue iWellness vs. RTVue EMM5 (Retina Parameters)	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Normal Group								
Fovea	21	258.40	258.61	-0.20	5.55	(-2.730, 2.323)	-12.05	11.64
ParaFovea	21	317.10	317.75	-0.65	7.15	(-3.902, 2.611)	-15.20	13.91
Para S. Hemisphere	21	318.63	319.73	-1.10	8.64	(-5.032, 2.837)	-18.60	16.41
Para I. Hemisphere	21	315.57	315.64	-0.08	6.40	(-2.988, 2.838)	-13.30	13.15
Para Tempo	21	307.71	310.16	-2.45	8.43	(-6.290, 1.387)	-19.70	14.79
Para Superior	21	322.94	321.44	1.50	8.64	(-2.433, 5.432)	-16.16	19.16
Para Nasal	21	320.39	323.54	-3.15	8.15	(-6.857, 0.563)	-20.23	13.94
Para Inferior	21	317.36	315.58	1.78	7.16	(-1.482, 5.039)	-12.95	16.50
PeriFovea	21	287.25	288.26	-1.02	6.08	(-3.783, 1.749)	-13.32	11.28
Peri S. Hemisphere	21	290.94	289.63	1.31	7.14	(-1.941, 4.555)	-13.26	15.87
Peri I. Hemisphere	21	283.55	286.92	-3.37	6.53	(-6.342, -0.401)	-17.02	10.27
Peri Tempo	21	278.40	279.97	-1.57	8.95	(-5.646, 2.506)	-20.47	17.33
Peri Superior	21	290.76	286.32	4.44	7.79	(0.896, 7.989)	-11.65	20.53
Peri Nasal	21	302.44	306.66	-4.22	7.97	(-7.850, -0.593)	-20.64	12.20

iVue iWellness vs. RTVue EMM5 (Retina Parameters)	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Peri Inferior	21	277.38	280.06	-2.68	7.61	(-6.144, 0.787)	-18.80	13.45
Retina Group								
Fovea	16	278.96	276.71	2.24	3.71	(0.269, 4.218)	-6.09	10.57
ParaFovea	16	318.55	315.23	3.32	4.94	(0.684, 5.953)	-6.77	13.41
Para S. Hemisphere	16	320.32	317.10	3.22	6.65	(-0.325, 6.757)	-10.42	16.85
Para I. Hemisphere	16	316.78	313.46	3.32	5.40	(0.442, 6.193)	-7.83	14.47
Para Tempo	16	311.60	308.58	3.02	7.33	(-0.885, 6.922)	-12.85	18.88
Para Superior	16	323.57	319.10	4.47	8.32	(0.037, 8.901)	-12.51	21.45
Para Nasal	16	322.46	321.10	1.36	5.41	(-1.523, 4.242)	-10.37	13.08
Para Inferior	16	316.55	312.29	4.26	6.37	(0.869, 7.655)	-9.11	17.64
PeriFovea	16	285.46	283.14	2.33	5.60	(-0.658, 5.313)	-8.99	13.65
Peri S. Hemisphere	16	289.42	285.44	3.99	10.05	(-1.367, 9.338)	-16.35	24.32
Peri I. Hemisphere	16	281.50	280.84	0.66	3.97	(-1.458, 2.775)	-7.95	9.27
Peri Tempo	16	275.39	271.74	3.65	4.65	(1.171, 6.128)	-8.39	15.69
Peri Superior	16	288.93	283.61	5.31	12.99	(-1.607, 12.231)	-20.95	31.57

iVue iWellness vs. RTVue EMM5 (Retina Parameters)	Subjects (n)	Mean of iVue	Mean of RTVue	mean of Differences	STDEV of Differences	95%CI of mean of Differences	LOA lower bound	LOA upper bound
Peri Nasal	16	301.53	301.41	0.12	7.71	(-3.990, 4.228)	-16.20	16.44
Peri Inferior	16	276.01	275.66	0.35	5.87	(-2.776, 3.484)	-12.11	12.82

_____End of section_____

14 Appendix: Clinical Study Report for Evaluation of the Repeatability and Reproducibility of Corneal Epithelial Thickness Mapping with iVue SD-OCT

14.1 Introduction

The study was performed to evaluate repeatability and reproducibility (R&R) of ETM 6 mm scan, for which 3 iVue devices were used. Same scanning protocol with device-specific designated operator was implemented to scan each qualified subject on 3 different devices, with 3 repeated ETM 6 mm scans per device.

A heterogeneous population of qualified study subjects was evaluated and included Normal subjects group (12 subjects) and Corneal Patients group (47 subjects), further stratified into 4 subgroups - Contact Lens (12 subjects), Dry Eye (11 subjects), Post-LRS (12 subjects), KCN (12 subjects).

14.2 Enrollment Criteria

14.2.1 Normal Group

Inclusion Criteria:

1. 18 years of age or older
2. Able and willing to provide consent
3. Able and willing to complete the required examinations

Exclusion Criteria:

1. History of laser refractive surgery or cataract surgery
2. Worn or wearing soft or hard contact lens in the past 3 months
3. Blepharitis/meibomitis
4. History of dry eye or current diagnosis of dry eye
5. History or current diagnosis of corneal pathologies, including keratoconus and corneal scar etc.
6. Inability to complete the required SD-OCT scans (e.g., unable to fixate due to poor vision)

14.2.2 Patient Group

Inclusion Criteria:

1. 18 years of age or older

2. Able and willing to provide consent
3. Able and willing to complete the required examinations
4. History or clinical diagnosis of one or more of the following conditions
    a. Dry eye patients: clinical diagnosis of dry eye and no history of refractive surgery
    b. Contact lens patients: wear soft or hard contact lens regularly for refractive error correction for at least 3 months immediately prior to the study visit without complications, and no history of refractive surgery or dry eye
    c. Post-laser refractive surgery patients: At least one month post laser refractive surgery without complications
    d. Keratoconus patients: clinical diagnosis of keratoconus in the study eye

Exclusion Criteria:

1. Inability to complete the required SD-OCT scans (e.g., unable to fixate due to poor vision)

14.3 Regional Thickness Parameters

As shown in Fig. 6A, the region definition for zonal thickness parameters is identical for all 3 thickness maps. The naming convention of the zonal thickness parameters is illustrated in Fig. 6A. Each map is divided first into 3 concentric rings (2mm, 2-5mm, and 5-6mm in diameters) and then further divided into 8 sectors (T, ST, S, SN, N, IN, and I) with the exception of the inner most 2mm region (labeled as C). For each region, the average thickness of all points within the region of a thickness map is calculated and displayed on the map as zonal thickness value. The zonal thickness parameter is named first by sectors, followed by diameters of the ring, and then by the thickness map type (“Pachy” for Pachymetry Map, “Epi” for Epithelial Map, and “Stroma” for Stroma Map).

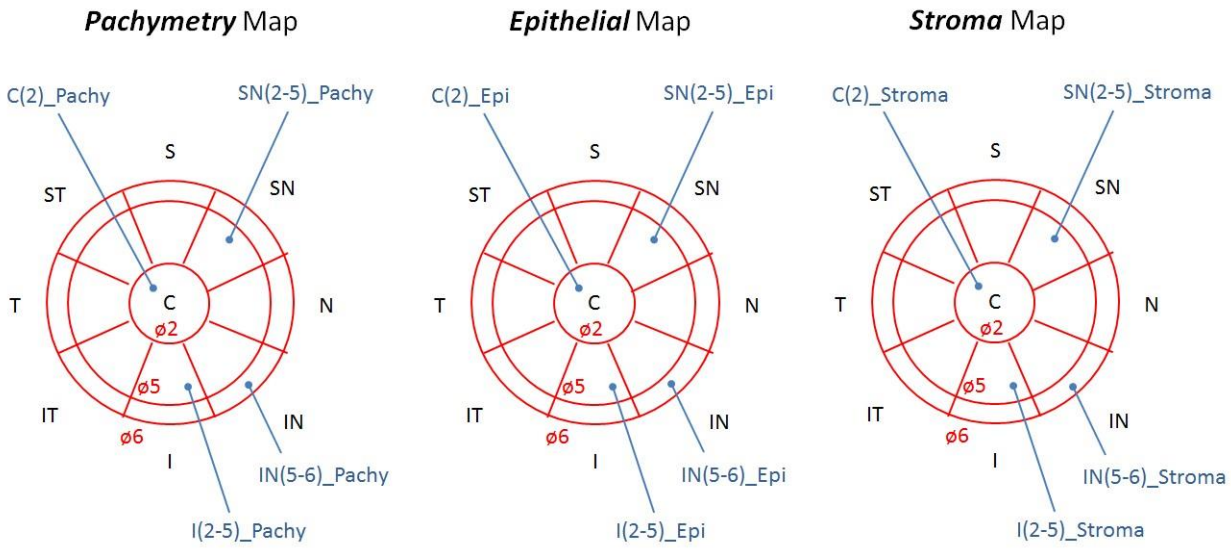
There are 17 zonal parameters for each of the 3 thickness maps. Therefore, a total 51 zonal parameters are included in the R&R evaluation.

The 17 zones are labelled as follows:

C(2),

T(2-5), ST(2-5), S(2-5), SN(2-5), N(2-5), IN(2-5), I(2-5), IT(2-5),

T(5-6), ST(5-6), S(5-6), SN(5-6), N(5-6), IN(5-6), I(5-6), IT(5-6),



Diagrams showing the zonal thickness parameters for each of the 3 maps generated from the iVue ETM scan (i.e., modified Pachymetry scan) and the zonal parameters naming convention in this study.

The repeatability and reproducibility are provided for all 51 zonal thickness parameters (17 parameters per map type).

14.4 Summary Statistical Parameters

In addition to the zonal thickness parameters displayed on the thickness maps, there are summary statistics parameters derived from the thickness maps. The parameter names below (in bold font) describe the statistical calculations from pre-defined map regions:

- **Min** represents the minimum thickness value within the 5mm diameter of a map area
- **Max** represents the maximum thickness value within 5mm diameter of a map area
- **Median** represents the median thickness value within 5mm diameter of a map area
- **Std Dev** represents the standard deviation of thickness values within 5mm diameter of a map area
- **Min–Max** is the difference between the two parameters Min and Max
- **Min-Median** is the difference between the two parameters Min and Median
- **S-I(2-5mm)** and **SN-IT(2-5mm)** are the differences between the average thickness values between the corresponding zones
- **S(2-5)** and **I(2-5)** are the average thickness of the superior and inferior hemi circular regions between the diameters of 2 and 5 mm.

For pachymetry map, as illustrated in Fig. 6 (Pachymetry Map), the 5 summary statistics parameters are calculated based on points in the central 5mm diameter of the pachymetry map

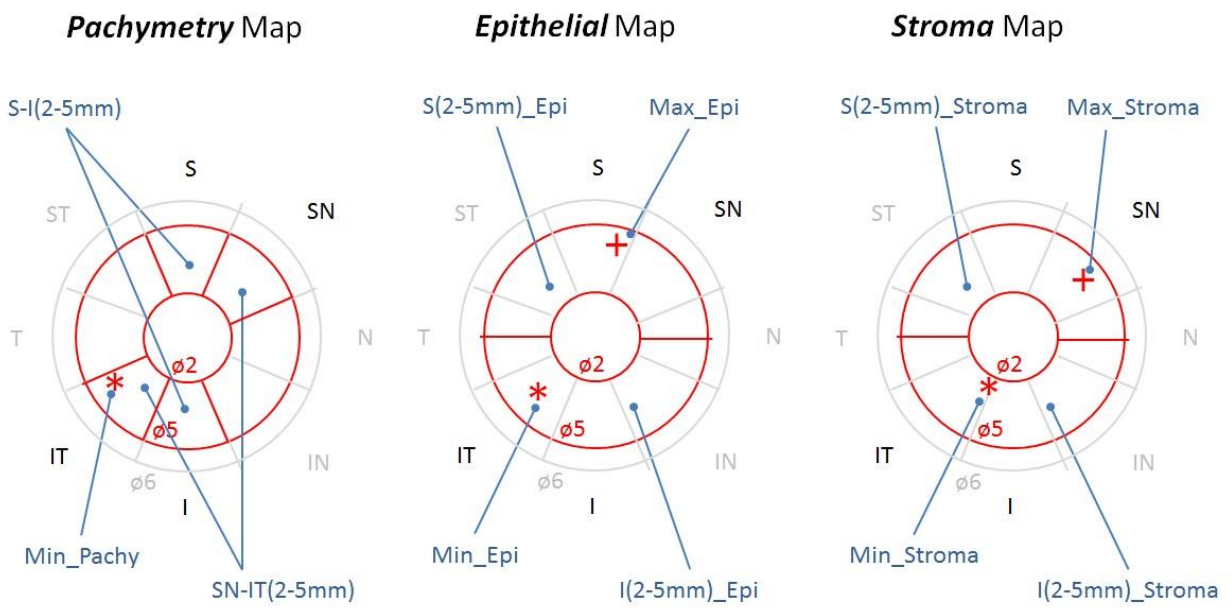
S-I (2-5mm), SN-IT(2-5mm), Min, Min-Median, and Min-Max.

For epithelial measurements, as illustrated in Fig. 6 (Epithelial Map), the 6 summary statistics parameters are calculated based points in the central 5mm diameter of the epithelial map:

S (2-5), I(2-5), Min, Max, Min-Max, and Std Dev.

For stromal measurements, as illustrated below (Stromal Map), the 6 summary statistics parameters are calculated based on points in the central 5mm diameter of the stromal map:

S (2-5), I(2-5), Min, Max, Min-Max, and Std Dev.



Diagrams showing the regions (outlined in red) for summary statistics calculations for the iVue ETM scan (i.e., modified Pachymetry scan) and parameters naming convention in this study. Pachymetry parameters, epithelial parameters, and stroma parameters are all calculated from the central 5 mm diameter of the corresponding maps.

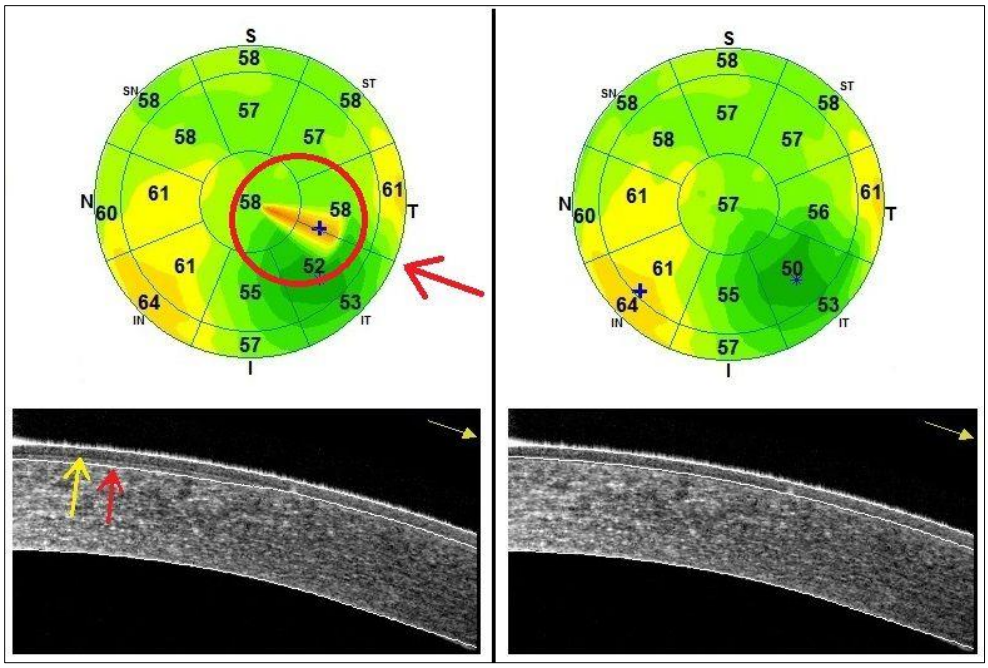
Total 17 summary statistics parameters will be included in the R&R study.

14.5 Manual Correction

For qualified scans, the operators reviewed the thickness maps for obvious segmentation error and reviewed the individual corneal meridian (B-scan) images to verify segmentation for erroneous maps. While B-scan is the most reliable way to identify segmentation error, segmentation errors may also be recognized as abrupt change in the thickness map. B-scans were reviewed with and without segmentation

lines using a toggle feature to confirm the segmentation error. Segmentation edit tools were used to perform manual correction and then the epithelial map was reprocessed .

Noticeable segmentation errors were manually corrected by the operator and marked for “Manual Correction” in the case report form. Scans with manual correction qualified for R&R data analysis.



Epithelial map (upper panels) before edit (left panel) and after edit (right panel). Left panel: Note the artifact in the epithelial map (red circle) which appears as a hot orange spot that is not uniform with surrounding area. The corresponding meridian B-scan (lower left) shows segmentation error: the segmentation line (red arrow) is not aligned to the epithelial posterior boundary (yellow arrow). The edit feature is used to align segmentation line to correct boundary (lower right) and reprocess the map (upper right).

Conversely, some segmentation errors are not significant enough to edit or not correctable (due to image quality issue) and the operators determined whether a scan was edited or excluded.

The rate of scans requiring manual correction among the qualified scans is reported herein.

After the completion of the scan quality review and manual correction (as needed), the study data set was exported and submitted to Optovue for analysis.

14.6 Demographic Description

Demographic descriptive data described herein is based on qualified subjects who completed at least one OCT scan on more than one device so there are 59 subjects included in the data analysis. The ethnic distribution was majority Caucasian, followed by Asian, Hispanic, African American and Other/Combined as shown in the table below.

ETHNICITY	Total	% Total (n=59)
Caucasian	24	40.7%
Asian	15	25.4%
Hispanic	12	20.3%
African American	5	8.5%
Other/Combined	3	5.1%

Ethnic distribution for all subjects. .

There is fair distribution of gender with 25 male and 34 female subjects enrolled.

GENDER	Total	% Total (n=59)
Female	34	58%
Male	25	42%

Gender distribution for all subjects.

The study evaluated 29 right eyes and 30 left eyes across all study subjects.

Age distribution of Normal and Patient groups and subgroups is listed in table below. Out of 12 subjects in the Normal group, 3 were older than 55 years of age, and 3 were below 30 years of age. Age distribution was similar in Normal vs Patients group (total)

Age by Category	Min	Median	Mean	Max	SD
Normal	**18**	**43**	**42**	**63**	**15.7**
Corneal Patients (total)	**18**	**40**	**45**	**79**	**16.9**
Contact Lens Group	20	36	38	58	10.8
Dry Eye Group	30	62	57	79	18.8
Post Laser Refractive Surgery Group	30	47	50	78	18.7
Keratoconus Group	19	36	39	63	14.7

Age distribution for all subjects by enrollment Category.

14.7 Study Group Characterization

14.7.1 Contact Lens Group

All subjects in the Contact Lens group wore soft contact lens regularly for 8 or more hours per day and for at least 3 months at the time of enrollment. The duration and the daily wear of contact lens are summarized below.

Contact Lens Wear	Min	Median	Mean	Max	SD
Duration (years)	2	11	11	20	6.3
Hours/Day	8	11	12	18	3.6

Contact lens wear data for the Contact Lens study group.

14.7.2 Dry Eye Group

For 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). The distribution of the OSDI score and TBUT for this group are summarized below.

Dry Eye	Min	Median	Mean	Max	SD
ODSI Score	14.6	54.5	48.8	83.3	21.5
TBUT (seconds)	1	7	7	10	3

OSDI Score and Tear Break Up Time (TBUT) distribution of the Dry Eye study group.

14.7.3 Post – LRS Group

For the Post LRS group, the majority (75%) had LASIK procedure versus the PRK procedure (25%), mainly for myopic vision correction (83.3%) and most had the procedure done at least 1 year or more prior to testing (91.7SD of 3.9108 scans%). The summary details are shown in Table below

Procedure	**Total**	**% Total**
LASIK	9	75
PRK	3	25
Correction	**Total**	**% Total**
Myopic	10	83.3%
Hyperopic	1	8.3%
Astigmatism	1	8.3%
Duration since procedure		
> 1yr	11	91.7%
> 3mo	1	8.3%

Clinical data for Post LRS study group

14.7.4 KCN Group

The subjects in the KCN group all had clinical diagnosis of keratoconus. The clinical signs and severity of keratoconus for the study group are summarized in Table 7.5.4a and further details on corneal curvature are summarized in Table 7.5.4b. In addition to one subject had INTACS implant, we identified another subject in the KCN sub-group had PK (penetrating keratoplasty) five years prior to the study visit in the study eye. There were no other surgical treatments in the study eyes. (ie Cross linking)

Clinical Signs	**Total**	**% Total**
Slit lamp exam	7	58.3%
Topographic patterns	11	91.7%
Slit lamp exam & Topographic patterns	6	50%
Retinoscope reflex	2	16.7%
Severity	**Total**	**% Total**
Mild	2	16.7%
Moderate	8	66.7%
Severe*	2	16.7%

KCN group distribution by clinical signs and severity

Corneal Curvature	**Min**	**Median**	**Mean**	**Max**	**SD**
Steep K	42.1	49	48.1	54	3.9
Delta K	0.6	2.3	2.4	4.3	1.1

Distribution of Steep K and Delta K (difference between Steep K and Flat K) in KCN group.

NOTE – Study Data available on request

14.8 SUMMARY

The study was performed to evaluate repeatability and reproducibility (R&R) of the iVue with corneal ETM 6 mm scan, for which 3 iVue devices were used. Same scanning protocol with device-specific designated operator was implemented to scan each qualified subject on 3 different devices, with 3 repeated ETM 6 mm scans per device.

Heterogeneous population of qualified study subjects was evaluated and included Normal subjects group (12 subjects) and corneal Patients group (47 subjects), further stratified into 4 subgroups: Contact Lens (12 subjects), Dry Eye (11 subjects), Post-LRS (12 subjects), and KCN (12 subjects).

The evaluated ETM 6 mm scan showed good performance across all study groups in terms of ease of acquisition (no subjects excluded due to inability to perform the scan) and scan quality.

Seventy-one out of 598 total acquired scans (11.9%) were excluded from R&R analysis due to the following scan quality issues: decentration of the scan, eyelid artifacts, cropped OCT image, low SSI and motion artifacts. The percentage of disqualified scans was similar across Normal eyes (10.7%) and Corneal Patients eyes. For details refer to Section 7.1. The distribution of non-qualifying scans across three different device/operator pairs was also similar: 20/194 (10.3%), 23/199 (11.6%) and 28/205 (13.6%) accordingly for iVue 24220, iVue 20847 and iVue 20779

Out of 527 scans qualified for final analysis, 40 (7.6%) required manual edits of the segmentation lines. Manual edits were not required in Normal eyes scans, and ranged from 2.8% in Contact Lens sub-group to 17.9% in KCN sub-group, with similar distribution between the 3 iVue devices.

Overall, the study showed good repeatability and reproducibility for all study groups, for all map zones, and for all 3 thickness parameters evaluated – pachymetry (total thickness), epithelial thickness and stromal thickness.

The mean and range of the reproducibility for pachymetry, epithelial thickness and stromal thickness for Normal and Corneal Patients study groups is summarized below per each one of the following map zones: 2 central mm, 2-5 mm ring, 5-6 mm ring.

Repeatability SD was quite similar to the Reproducibility SD for all study parameters and therefore are not detailed separately in the summary tables below.

14.8.1 Pachymetry

Table 1a Pachymetry measurements - Normal group.

Normal Group (N scans=108)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Pachy	538.1	19.4	506.8	588.4	1.7	2.2	0.4%	6.0
T_2_5__Pachy	546.3	22.5	503.2	604.4	2.8	2.9	0.5%	8.0
ST_2_5__Pachy	564.0	23.2	528.4	628.5	3.7	3.9	0.7%	10.9
S_2_5__Pachy	577.3	22.4	542.1	642.6	4.4	4.7	0.8%	12.9
SN_2_5__Pachy	576.0	21.3	543.4	644.1	5.1	5.1	0.9%	14.2
N_2_5__Pachy	563.0	21.4	532.5	630.3	3.8	3.8	0.7%	10.6
IN_2_5__Pachy	551.6	20.2	520.0	607.0	2.3	2.7	0.5%	7.4
I_2_5__Pachy	544.1	19.7	506.4	592.5	2.1	2.7	0.5%	7.5
IT_2_5__Pachy	540.3	21.1	499.7	590.4	2.1	2.3	0.4%	6.4
T_5_6__Pachy	565.1	25.0	512.9	631.2	3.8	3.9	0.7%	10.7
ST_5_6__Pachy	593.4	24.8	553.7	667.6	5.6	5.8	1.0%	16.0
S_5_6__Pachy	613.9	23.8	573.7	685.3	6.3	6.8	1.1%	18.7
SN_5_6__Pachy	609.1	23.6	570.6	685.9	7.6	7.7	1.3%	21.3
N_5_6__Pachy	589.4	24.3	550.3	666.2	5.2	5.2	0.9%	14.5
IN_5_6__Pachy	573.4	22.9	538.4	635.3	3.7	3.7	0.7%	10.4
I_5_6__Pachy	564.7	22.1	523.2	621.0	3.3	3.5	0.6%	9.8
IT_5_6__Pachy	557.1	24.0	508.5	616.4	3.8	3.8	0.7%	10.6

* 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 1b Pachymetry measurement – Corneal Patients pooled group

Corneal Patients Group (Pooled) (N scans=419)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Pachy	507.5	49.2	389.4	678.7	3.3	3.6	0.7%	10.0
T_2_5__Pachy	521.3	46.4	415.6	694.7	3.8	3.8	0.7%	10.6
ST_2_5__Pachy	541.2	46.6	439.5	717.9	4.7	4.8	0.9%	13.2
S_2_5__Pachy	554.3	47.2	445.1	726.2	5.3	5.4	1.0%	15.0
SN_2_5__Pachy	551.3	46.1	445.1	723.0	5.7	5.8	1.0%	16.0
N_2_5__Pachy	538.0	44.9	439.1	704.9	5.0	5.2	1.0%	14.4
IN_2_5__Pachy	524.7	46.3	430.3	687.3	4.2	4.5	0.9%	12.6
I_2_5__Pachy	513.3	50.7	404.7	679.6	3.3	3.7	0.7%	10.3
IT_2_5__Pachy	510.3	49.9	386.3	676.8	3.5	3.7	0.7%	10.2
T_5_6__Pachy	545.2	44.3	443.6	719.9	5.0	5.0	0.9%	14.0
ST_5_6__Pachy	575.1	46.8	461.1	747.7	6.7	6.8	1.2%	18.8
S_5_6__Pachy	595.6	48.7	478.4	757.8	8.6	8.8	1.5%	24.4
SN_5_6__Pachy	587.6	46.7	482.7	759.0	8.6	8.8	1.5%	24.4
N_5_6__Pachy	568.2	43.3	473.0	733.0	6.5	6.6	1.2%	18.2
IN_5_6__Pachy	553.3	42.9	460.6	711.2	5.2	5.5	1.0%	15.1
I_5_6__Pachy	540.4	47.7	444.2	707.9	5.6	5.8	1.1%	15.9
IT_5_6__Pachy	533.2	47.0	414.2	700.2	5.8	5.9	1.1%	16.3

* 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 1c. Pachymetry measurements – Contact Lens group.

Contact Lens Group (N scans=108)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Pachy	513.4	40.0	425.5	589.0	1.6	2.1	0.4%	5.9
T_2_5__Pachy	522.7	40.5	432.1	597.9	2.5	2.8	0.5%	7.6
ST_2_5__Pachy	540.1	42.5	444.5	630.9	3.9	3.9	0.7%	10.7
S_2_5__Pachy	553.6	43.5	456.2	651.0	4.7	4.7	0.9%	13.1
SN_2_5__Pachy	551.4	42.1	455.4	641.8	4.7	4.7	0.8%	12.9
N_2_5__Pachy	538.3	40.3	449.3	620.2	3.7	3.7	0.7%	10.2
IN_2_5__Pachy	527.3	39.0	444.9	596.3	2.4	2.7	0.5%	7.6
I_2_5__Pachy	520.1	39.3	436.5	588.6	1.9	2.9	0.6%	7.9
IT_2_5__Pachy	516.8	39.5	430.4	586.0	1.9	2.7	0.5%	7.6
T_5_6__Pachy	541.4	41.7	443.6	618.7	3.7	3.7	0.7%	10.2
ST_5_6__Pachy	569.4	45.7	461.1	667.1	5.4	5.4	0.9%	14.9
S_5_6__Pachy	591.7	47.9	481.7	700.7	7.3	7.4	1.2%	20.4
SN_5_6__Pachy	585.9	44.7	483.5	688.2	7.6	7.8	1.3%	21.7
N_5_6__Pachy	565.3	41.3	473.6	652.9	5.1	5.1	0.9%	14.2
IN_5_6__Pachy	550.2	38.9	467.8	620.3	3.5	3.7	0.7%	10.2
I_5_6__Pachy	541.8	39.9	454.5	614.6	3.4	4.0	0.7%	11.0
IT_5_6__Pachy	534.1	40.5	442.4	610.3	3.5	4.1	0.8%	11.3

* 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 1d. Pachymetry measurements – Dry Eye group.

Dry Eye Group (N scans=98)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Pachy	531.7	40.6	445.6	606.0	3.4	3.8	0.7%	10.5
T_2_5__Pachy	540.3	36.0	469.7	600.9	3.4	3.5	0.6%	9.6
ST_2_5__Pachy	558.3	38.7	485.4	640.9	5.2	5.2	0.9%	14.5
S_2_5__Pachy	573.3	40.2	502.9	673.7	6.8	7.0	1.2%	19.3
SN_2_5__Pachy	570.3	38.0	501.5	669.3	7.4	7.7	1.3%	21.3
N_2_5__Pachy	558.0	35.6	491.8	644.8	5.8	6.3	1.1%	17.4
IN_2_5__Pachy	548.9	34.2	485.9	613.0	4.1	4.8	0.9%	13.3
I_2_5__Pachy	538.0	41.4	436.0	590.4	3.7	4.0	0.7%	11.2
IT_2_5__Pachy	531.8	44.1	418.3	588.6	3.7	3.7	0.7%	10.3
T_5_6__Pachy	557.1	36.0	483.4	615.2	4.4	4.5	0.8%	12.4
ST_5_6__Pachy	588.9	38.8	518.4	681.9	8.8	8.8	1.5%	24.4
S_5_6__Pachy	616.6	42.0	550.0	736.3	13.1	13.4	2.2%	37.1
SN_5_6__Pachy	607.0	37.6	547.3	725.0	11.6	12.1	2.0%	33.4
N_5_6__Pachy	586.7	32.4	531.6	680.0	8.1	8.4	1.4%	23.3
IN_5_6__Pachy	575.0	29.9	522.1	634.0	5.1	5.5	1.0%	15.3
I_5_6__Pachy	559.7	42.4	453.6	615.1	5.1	5.2	0.9%	14.5
IT_5_6__Pachy	546.4	48.4	414.2	605.3	5.4	5.4	1.0%	14.9

* 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 1e. Pachymetry measurements – Post-LRS group.

Post Laser Refractive Surgery Group (N scans=107)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Pachy	504.6	64.5	411.8	678.7	1.5	1.9	0.4%	5.2
T_2_5__Pachy	521.3	60.9	435.5	694.7	3.2	3.4	0.6%	9.3
ST_2_5__Pachy	538.6	63.4	439.5	717.9	4.2	4.2	0.8%	11.7
S_2_5__Pachy	552.0	63.2	445.1	726.2	4.5	4.5	0.8%	12.5
SN_2_5__Pachy	548.0	63.1	445.1	723.0	4.9	4.9	0.9%	13.7
N_2_5__Pachy	534.9	61.6	439.1	704.9	4.3	4.4	0.8%	12.3
IN_2_5__Pachy	527.0	59.9	432.0	687.3	3.4	3.9	0.7%	10.8
I_2_5__Pachy	522.0	58.2	433.8	679.6	3.0	3.5	0.7%	9.7
IT_2_5__Pachy	516.8	57.8	433.7	676.8	2.9	3.2	0.6%	8.8
T_5_6__Pachy	548.5	58.9	464.0	719.9	4.9	5.2	0.9%	14.3
ST_5_6__Pachy	577.0	60.7	472.5	747.7	5.7	5.9	1.0%	16.2
S_5_6__Pachy	599.0	57.7	484.3	757.8	6.3	6.4	1.1%	17.7
SN_5_6__Pachy	590.8	58.7	486.1	759.0	7.3	7.3	1.2%	20.3
N_5_6__Pachy	569.1	58.1	473.0	733.0	6.4	6.4	1.1%	17.7
IN_5_6__Pachy	558.4	56.2	460.6	711.2	5.6	5.8	1.0%	16.2
I_5_6__Pachy	553.2	54.3	465.6	707.9	4.6	4.9	0.9%	13.7
IT_5_6__Pachy	543.0	54.1	463.1	700.2	4.7	5.0	0.9%	13.7

* 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 1f Pachymetry measurements - KCN group.

Keratoconus Group (N scans=106)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Pachy	482.1	32.5	389.4	522.2	5.4	5.5	1.1%	15.1
T_2_5__Pachy	502.1	35.4	415.6	544.6	5.3	5.3	1.1%	14.6
ST_2_5__Pachy	529.1	30.6	450.5	567.3	5.5	5.6	1.1%	15.5
S_2_5__Pachy	539.9	29.3	463.3	576.5	4.9	5.0	0.9%	14.0
SN_2_5__Pachy	536.8	27.3	463.6	570.0	5.3	5.5	1.0%	15.2
N_2_5__Pachy	522.3	27.3	453.1	563.5	6.0	6.1	1.2%	16.9
IN_2_5__Pachy	497.2	31.1	430.3	548.0	5.9	6.1	1.2%	16.9
I_2_5__Pachy	474.7	38.1	404.7	533.3	4.2	4.4	0.9%	12.2
IT_2_5__Pachy	477.2	38.9	386.3	532.5	4.8	4.8	1.0%	13.3
T_5_6__Pachy	534.6	32.8	461.1	574.7	6.3	6.5	1.2%	17.9
ST_5_6__Pachy	566.3	34.6	478.6	608.7	6.4	6.7	1.2%	18.6
S_5_6__Pachy	576.6	36.2	478.4	623.3	6.6	6.6	1.2%	18.4
SN_5_6__Pachy	568.4	33.8	482.7	616.7	7.3	7.6	1.3%	21.0
N_5_6__Pachy	553.3	28.4	480.2	588.6	6.0	6.1	1.1%	17.0
IN_5_6__Pachy	531.2	28.1	472.5	579.0	6.3	6.5	1.2%	17.9
I_5_6__Pachy	508.2	34.9	444.2	558.9	8.1	8.1	1.6%	22.4
IT_5_6__Pachy	510.3	34.6	431.5	568.4	8.3	8.3	1.6%	23.1

* 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.

14.8.2 Epithelial Thickness

Table 2a. Epithelial thickness measurements - Normal group.

Normal Group (N scans=108)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Epi	52.9	3.4	47.5	61.2	0.9	0.9	1.8%	2.6
T_2_5__Epi	52.2	3.3	45.9	61.2	1.2	1.2	2.3%	3.4
ST_2_5__Epi	51.7	2.8	47.1	59.8	1.3	1.3	2.5%	3.5
S_2_5__Epi	52.0	2.8	47.3	59.9	1.2	1.2	2.4%	3.4
SN_2_5__Epi	52.9	3.1	47.6	61.5	1.2	1.2	2.2%	3.3
N_2_5__Epi	53.4	3.0	47.3	60.7	1.1	1.1	2.0%	3.0
IN_2_5__Epi	53.7	3.6	47.8	61.2	0.9	0.9	1.6%	2.4
I_2_5__Epi	54.0	3.9	47.7	65.3	1.0	1.0	1.8%	2.8
IT_2_5__Epi	53.2	3.9	46.4	63.4	1.1	1.1	2.1%	3.1
T_5_6__Epi	52.2	3.2	45.2	59.8	1.3	1.3	2.5%	3.6
ST_5_6__Epi	50.8	2.6	44.8	60.1	1.4	1.5	2.9%	4.0
S_5_6__Epi	50.9	3.0	43.7	60.7	1.3	1.4	2.7%	3.8
SN_5_6__Epi	53.0	3.4	46.9	62.9	1.2	1.2	2.3%	3.4
N_5_6__Epi	53.6	2.8	48.1	60.8	1.1	1.1	2.0%	3.0
IN_5_6__Epi	53.8	3.3	48.1	59.8	1.0	1.0	1.8%	2.7
I_5_6__Epi	54.1	3.8	47.9	66.0	1.3	1.3	2.3%	3.5
IT_5_6__Epi	53.4	3.6	46.7	62.4	1.3	1.3	2.4%	3.6

* 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 2b. Epithelial thickness measurements – Corneal Patients pooled group.

Corneal Patients Group (Pooled) (N scans=419)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Epi	51.3	4.6	38.2	64.1	1.2	1.2	2.4%	3.4
T_2_5__Epi	51.3	4.7	39.7	65.2	1.4	1.4	2.7%	3.9
ST_2_5__Epi	51.7	4.4	40.6	63.1	1.3	1.4	2.7%	3.8
S_2_5__Epi	51.8	4.6	39.1	63.7	1.4	1.4	2.7%	3.8
SN_2_5__Epi	52.5	4.5	41.8	63.5	1.5	1.5	2.8%	4.1
N_2_5__Epi	53.1	4.2	43.1	69.1	1.4	1.4	2.6%	3.9
IN_2_5__Epi	52.9	4.1	41.8	65.6	1.4	1.4	2.6%	3.8
I_2_5__Epi	52.2	4.9	38.0	64.9	1.4	1.4	2.7%	3.9
IT_2_5__Epi	51.4	5.4	37.2	65.8	1.4	1.4	2.7%	3.9
T_5_6__Epi	51.7	4.5	40.6	65.2	1.6	1.7	3.2%	4.6
ST_5_6__Epi	51.5	4.7	37.9	64.5	1.7	1.7	3.4%	4.8
S_5_6__Epi	51.1	4.8	36.5	65.1	1.7	1.7	3.4%	4.8
SN_5_6__Epi	52.3	4.6	41.1	66.1	1.6	1.7	3.2%	4.6
N_5_6__Epi	53.4	4.6	39.2	72.8	1.6	1.7	3.1%	4.7
IN_5_6__Epi	53.7	4.3	41.5	65.9	1.5	1.6	2.9%	4.3
I_5_6__Epi	53.0	4.4	39.1	66.7	1.9	1.9	3.6%	5.3
IT_5_6__Epi	52.4	4.7	40.9	72.5	1.9	1.9	3.6%	5.3

* 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 2c. Epithelial thickness measurements – Contact Lens group.

Contact Lens Group (N scans=108)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Epi	51.0	3.6	43.2	57.8	0.8	0.9	1.8%	2.6
T_2_5__Epi	50.6	3.4	42.3	56.9	0.9	1.1	2.1%	3.0
ST_2_5__Epi	50.9	3.4	43.7	57.2	1.0	1.1	2.2%	3.0
S_2_5__Epi	51.4	3.4	45.3	57.1	1.1	1.1	2.2%	3.2
SN_2_5__Epi	52.0	3.2	46.1	57.9	1.1	1.2	2.3%	3.2
N_2_5__Epi	51.9	2.9	45.6	57.6	0.9	1.0	2.0%	2.9
IN_2_5__Epi	52.0	2.9	45.4	57.0	0.8	0.8	1.6%	2.3
I_2_5__Epi	52.1	3.2	45.2	58.4	0.8	0.9	1.7%	2.5
IT_2_5__Epi	51.0	3.2	43.8	57.3	0.8	0.9	1.8%	2.6
T_5_6__Epi	50.8	2.9	43.3	55.4	1.1	1.3	2.6%	3.7
ST_5_6__Epi	51.0	3.3	44.5	57.8	1.6	1.7	3.3%	4.7
S_5_6__Epi	51.2	3.4	44.5	57.4	1.6	1.7	3.3%	4.6
SN_5_6__Epi	52.5	3.4	46.0	59.3	1.3	1.4	2.7%	3.9
N_5_6__Epi	52.5	3.2	46.8	60.3	1.1	1.3	2.4%	3.5
IN_5_6__Epi	52.7	3.1	47.2	60.4	0.9	1.0	1.9%	2.7
I_5_6__Epi	52.7	3.3	46.8	58.9	1.0	1.1	2.1%	3.0
IT_5_6__Epi	51.6	3.2	44.4	57.7	0.9	1.1	2.0%	2.9

* 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 2d. Epithelial thickness measurements – Dry Eye group.

Dry Eye Group (N scans=98)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Epi	51.7	3.4	43.6	60.0	1.6	1.6	3.2%	4.6
T_2_5__Epi	50.5	3.3	42.7	58.6	1.9	1.9	3.9%	5.4
ST_2_5__Epi	49.9	4.3	40.6	59.8	1.8	1.8	3.6%	5.0
S_2_5__Epi	50.0	5.5	39.1	63.7	2.0	2.0	4.1%	5.7
SN_2_5__Epi	51.1	5.2	41.8	63.5	2.4	2.4	4.7%	6.7
N_2_5__Epi	52.1	4.7	43.7	69.1	2.1	2.2	4.3%	6.1
IN_2_5__Epi	52.6	4.6	41.8	65.6	2.2	2.2	4.2%	6.1
I_2_5__Epi	52.7	4.4	40.9	64.9	2.4	2.4	4.5%	6.5
IT_2_5__Epi	52.1	4.0	42.2	65.3	2.2	2.2	4.1%	6.0
T_5_6__Epi	50.2	4.2	42.9	64.6	2.0	2.1	4.1%	5.8
ST_5_6__Epi	49.1	5.2	37.9	60.1	1.9	2.0	4.1%	5.5
S_5_6__Epi	49.3	6.9	36.5	65.1	2.0	2.1	4.2%	5.8
SN_5_6__Epi	50.9	6.3	41.1	66.1	2.4	2.4	4.7%	6.6
N_5_6__Epi	52.8	6.4	43.7	72.8	2.5	2.5	4.8%	7.0
IN_5_6__Epi	52.5	5.0	41.5	65.7	2.5	2.5	4.7%	6.8
I_5_6__Epi	52.4	5.1	39.1	66.7	2.9	2.9	5.5%	8.0
IT_5_6__Epi	52.4	5.4	41.7	72.5	2.6	2.6	4.9%	7.2

* 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 2e. Epithelial thickness measurements – Post-LRS group.

Post Laser Refractive Surgery Group (N scans=107)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Epi	54.0	4.6	42.8	64.1	0.6	0.7	1.2%	1.9
T_2_5__Epi	54.1	4.7	43.6	65.2	1.0	1.1	2.0%	3.0
ST_2_5__Epi	53.2	4.4	45.2	63.1	0.9	1.0	1.8%	2.7
S_2_5__Epi	52.9	4.5	44.1	62.2	0.8	0.8	1.5%	2.2
SN_2_5__Epi	53.4	4.1	45.6	61.4	0.7	0.7	1.4%	2.1
N_2_5__Epi	54.4	3.8	47.0	62.2	0.7	0.8	1.5%	2.3
IN_2_5__Epi	55.2	3.7	48.1	62.8	0.8	0.8	1.5%	2.4
I_2_5__Epi	56.1	3.7	47.3	63.3	0.8	0.9	1.5%	2.4
IT_2_5__Epi	55.5	4.8	44.5	65.8	0.9	1.0	1.7%	2.7
T_5_6__Epi	52.4	4.2	41.4	62.1	1.4	1.5	3.0%	4.3
ST_5_6__Epi	51.4	3.6	42.4	59.2	1.4	1.6	3.1%	4.3
S_5_6__Epi	51.5	3.7	42.7	58.0	1.1	1.2	2.3%	3.3
SN_5_6__Epi	53.0	3.8	43.5	58.3	1.0	1.1	2.0%	3.0
N_5_6__Epi	54.0	3.2	46.1	59.9	1.1	1.1	2.1%	3.1
IN_5_6__Epi	54.7	3.8	46.6	62.4	1.1	1.2	2.2%	3.3
I_5_6__Epi	54.9	3.9	45.2	63.2	1.4	1.6	2.9%	4.4
IT_5_6__Epi	54.6	4.2	40.9	65.5	1.4	1.6	2.9%	4.4

* 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 2f. Epithelial thickness measurements – KCN group.

Keratoconus Group (N scans=106)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Epi	48.6	4.8	38.2	58.4	1.4	1.5	3.0%	4.1
T_2_5__Epi	49.8	5.6	39.7	61.1	1.3	1.4	2.7%	3.8
ST_2_5__Epi	52.6	4.4	44.3	61.7	1.5	1.5	2.9%	4.3
S_2_5__Epi	52.7	4.5	45.1	61.8	1.3	1.3	2.4%	3.6
SN_2_5__Epi	53.3	5.0	44.2	62.2	1.2	1.2	2.3%	3.5
N_2_5__Epi	53.9	4.9	43.1	61.7	1.2	1.3	2.3%	3.5
IN_2_5__Epi	51.8	4.2	43.9	63.2	1.3	1.3	2.5%	3.6
I_2_5__Epi	48.1	4.6	38.0	55.8	1.1	1.2	2.4%	3.2
IT_2_5__Epi	47.0	5.5	37.2	58.4	1.2	1.3	2.7%	3.5
T_5_6__Epi	53.4	5.7	40.6	65.2	1.7	1.7	3.2%	4.7
ST_5_6__Epi	54.3	4.9	43.7	64.5	1.6	1.7	3.1%	4.7
S_5_6__Epi	52.1	4.4	42.1	60.8	1.8	1.9	3.6%	5.2
SN_5_6__Epi	52.7	4.5	41.2	63.8	1.5	1.6	3.1%	4.5
N_5_6__Epi	54.4	4.7	39.2	62.7	1.4	1.6	3.0%	4.4
IN_5_6__Epi	54.7	4.7	46.2	65.9	1.1	1.2	2.2%	3.4
I_5_6__Epi	51.8	4.6	42.5	61.2	1.7	1.7	3.2%	4.6
IT_5_6__Epi	51.1	5.1	42.7	62.4	2.1	2.1	4.1%	5.8

* 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.

14.8.3 Stromal Thickness

Table 3a. Stromal thickness measurements - Normal group.

Normal Group (N scans=108)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Stroma	485.2	20.0	449.8	539.5	1.6	2.0	0.4%	5.4
T_2_5__Stroma	494.1	23.1	450.8	555.7	2.4	2.6	0.5%	7.1
ST_2_5__Stroma	512.4	23.6	475.9	579.1	3.4	3.7	0.7%	10.3
S_2_5__Stroma	525.3	22.9	490.9	594.1	4.2	4.6	0.9%	12.7
SN_2_5__Stroma	523.2	21.9	491.2	593.8	4.9	4.9	0.9%	13.7
N_2_5__Stroma	509.6	21.8	476.7	578.9	3.6	3.6	0.7%	10.0
IN_2_5__Stroma	497.9	20.5	463.8	556.7	2.1	2.5	0.5%	7.0
I_2_5__Stroma	490.1	20.1	450.4	542.5	1.9	2.5	0.5%	6.9
IT_2_5__Stroma	487.2	21.7	444.3	540.9	1.9	2.1	0.4%	5.8
T_5_6__Stroma	512.9	25.4	461.2	581.9	3.6	3.7	0.7%	10.2
ST_5_6__Stroma	542.6	25.0	503.9	618.6	5.4	5.7	1.0%	15.7
S_5_6__Stroma	563.0	24.1	524.2	634.2	6.2	6.7	1.2%	18.5
SN_5_6__Stroma	556.0	24.2	519.8	634.5	7.6	7.6	1.4%	21.1
N_5_6__Stroma	535.7	24.5	498.2	614.0	5.1	5.1	0.9%	14.1
IN_5_6__Stroma	519.6	23.0	482.6	583.7	3.4	3.5	0.7%	9.7
I_5_6__Stroma	510.5	22.4	468.4	570.4	3.2	3.3	0.7%	9.3
IT_5_6__Stroma	503.7	24.3	451.0	567.0	3.6	3.6	0.7%	10.1

* 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 3b. Stromal thickness measurements – Corneal Patients pooled group.

Corneal Patients Group (Pooled) (N scans=419)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Stroma	456.2	49.7	351.2	630.5	2.8	3.1	0.7%	8.5
T_2_5__Stroma	470.0	46.8	375.9	646.2	3.5	3.6	0.8%	9.9
ST_2_5__Stroma	489.5	48.2	387.3	671.9	4.7	4.8	1.0%	13.3
S_2_5__Stroma	502.5	49.2	392.3	682.1	5.3	5.4	1.1%	14.9
SN_2_5__Stroma	498.8	48.0	391.2	677.4	5.6	5.6	1.1%	15.6
N_2_5__Stroma	484.9	46.7	383.3	656.9	4.7	4.8	1.0%	13.4
IN_2_5__Stroma	471.8	47.3	372.6	637.9	3.8	4.1	0.9%	11.3
I_2_5__Stroma	461.0	50.2	361.5	628.1	3.0	3.3	0.7%	9.1
IT_2_5__Stroma	458.9	49.5	349.1	627.4	3.2	3.3	0.7%	9.1
T_5_6__Stroma	493.4	45.2	389.7	672.0	4.8	5.0	1.0%	13.9
ST_5_6__Stroma	523.6	48.5	407.4	703.4	6.8	7.0	1.3%	19.3
S_5_6__Stroma	544.5	50.9	425.5	715.1	8.8	9.0	1.7%	25.0
SN_5_6__Stroma	535.3	48.4	425.4	714.4	8.6	8.9	1.7%	24.6
N_5_6__Stroma	514.8	45.0	415.0	686.6	6.4	6.4	1.2%	17.8
IN_5_6__Stroma	499.6	44.5	400.3	662.5	5.2	5.3	1.1%	14.8
I_5_6__Stroma	487.5	47.9	397.3	653.5	5.4	5.5	1.1%	15.3
IT_5_6__Stroma	480.8	47.5	355.8	649.5	5.2	5.3	1.1%	14.7

* 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 3c. Stromal thickness measurements – Contact Lens group.

Contact Lens Group (N scans=108)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Stroma	462.5	38.8	373.9	532.5	1.4	1.8	0.4%	4.9
T_2_5__Stroma	472.1	39.6	378.6	542.3	2.2	2.4	0.5%	6.6
ST_2_5__Stroma	489.2	41.8	391.1	573.8	3.5	3.6	0.7%	9.9
S_2_5__Stroma	502.1	43.3	400.6	594.0	4.4	4.4	0.9%	12.3
SN_2_5__Stroma	499.5	42.2	399.9	586.7	4.3	4.4	0.9%	12.2
N_2_5__Stroma	486.4	40.2	394.2	565.8	3.5	3.5	0.7%	9.7
IN_2_5__Stroma	475.3	38.6	389.9	541.1	2.3	2.6	0.5%	7.1
I_2_5__Stroma	468.0	38.4	382.4	531.7	1.9	2.6	0.6%	7.3
IT_2_5__Stroma	465.8	38.5	376.6	530.5	1.8	2.5	0.5%	7.0
T_5_6__Stroma	490.6	41.3	389.7	563.9	3.3	3.4	0.7%	9.3
ST_5_6__Stroma	518.4	45.2	407.4	610.2	5.3	5.3	1.0%	14.8
S_5_6__Stroma	540.6	47.7	427.3	645.4	7.1	7.4	1.4%	20.5
SN_5_6__Stroma	533.4	45.3	425.4	633.3	7.4	7.9	1.5%	21.8
N_5_6__Stroma	512.8	41.9	415.0	598.5	4.8	5.1	1.0%	14.1
IN_5_6__Stroma	497.5	39.3	409.1	565.4	3.5	3.6	0.7%	10.0
I_5_6__Stroma	489.1	39.9	397.5	558.7	3.4	3.8	0.8%	10.6
IT_5_6__Stroma	482.5	40.2	385.9	555.4	3.3	3.8	0.8%	10.4

* 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 3d. Stromal thickness measurements – Dry Eye group.

Dry Eye Group (N scans=98)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Stroma	480.0	42.2	390.9	560.3	3.0	3.4	0.7%	9.5
T_2_5__Stroma	489.8	37.9	414.6	555.2	3.2	3.2	0.7%	9.0
ST_2_5__Stroma	508.4	41.4	430.4	600.3	5.2	5.2	1.0%	14.4
S_2_5__Stroma	523.3	43.5	448.1	633.4	6.8	6.9	1.3%	19.0
SN_2_5__Stroma	519.2	40.9	449.0	627.5	7.2	7.4	1.4%	20.4
N_2_5__Stroma	506.0	38.5	433.2	597.7	5.4	5.8	1.1%	16.1
IN_2_5__Stroma	496.4	37.0	425.1	565.9	3.5	4.3	0.9%	11.8
I_2_5__Stroma	485.4	43.8	378.5	543.4	3.0	3.3	0.7%	9.1
IT_2_5__Stroma	479.7	46.7	358.3	540.0	3.1	3.1	0.7%	8.7
T_5_6__Stroma	506.9	38.7	426.7	569.0	4.2	4.2	0.8%	11.7
ST_5_6__Stroma	539.8	42.2	460.8	641.6	8.6	8.6	1.6%	23.8
S_5_6__Stroma	567.3	46.5	496.5	697.5	13.4	13.7	2.4%	38.0
SN_5_6__Stroma	556.1	41.1	493.4	683.9	11.5	11.9	2.1%	33.0
N_5_6__Stroma	533.9	35.5	470.6	632.4	7.6	7.8	1.5%	21.5
IN_5_6__Stroma	522.5	32.7	470.2	586.0	4.9	5.2	1.0%	14.5
I_5_6__Stroma	507.3	45.1	398.2	569.7	5.0	5.1	1.0%	14.0
IT_5_6__Stroma	494.0	52.3	355.8	557.8	5.1	5.1	1.0%	14.1

* 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 3e. Stromal thickness measurements – Post-LRS group.

Post Laser Refractive Surgery Group (N scans=107)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Stroma	450.6	66.9	355.5	630.5	1.5	1.8	0.4%	5.0
T_2_5__Stroma	467.2	63.0	380.3	646.2	3.5	3.7	0.8%	10.4
ST_2_5__Stroma	485.4	65.5	387.3	671.9	4.1	4.2	0.9%	11.7
S_2_5__Stroma	499.1	65.5	392.3	682.1	4.9	4.9	1.0%	13.6
SN_2_5__Stroma	494.6	65.1	391.2	677.4	5.0	5.0	1.0%	13.9
N_2_5__Stroma	480.5	63.4	383.3	656.9	3.9	4.0	0.8%	11.2
IN_2_5__Stroma	471.8	61.9	372.6	637.9	3.3	3.7	0.8%	10.2
I_2_5__Stroma	465.9	60.1	372.4	628.1	2.9	3.3	0.7%	9.3
IT_2_5__Stroma	461.3	60.1	373.6	627.4	3.0	3.2	0.7%	8.8
T_5_6__Stroma	496.1	59.4	415.2	672.0	5.5	5.9	1.2%	16.4
ST_5_6__Stroma	525.6	62.1	422.0	703.4	6.4	6.6	1.3%	18.4
S_5_6__Stroma	547.5	60.1	428.1	715.1	6.6	6.7	1.2%	18.5
SN_5_6__Stroma	537.7	60.2	431.3	714.4	7.5	7.5	1.4%	20.7
N_5_6__Stroma	515.1	59.4	418.1	686.6	6.8	6.8	1.3%	18.9
IN_5_6__Stroma	503.7	58.2	400.3	662.5	6.0	6.2	1.2%	17.2
I_5_6__Stroma	498.4	55.1	402.8	653.5	5.0	5.4	1.1%	14.9
IT_5_6__Stroma	488.4	55.2	404.7	649.5	4.8	5.1	1.0%	14.2

* 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 3e. Stromal thickness measurements – KCN group.

Keratoconus Group (N scans=106)								
	Mean	SD	Min	Max	Repeatability	Reproducibility		
					SD	SD	COV	Limit*
Zonal Parameters								
C_2__Stroma	433.5	31.6	351.2	471.9	4.4	4.4	1.0%	12.3
T_2_5__Stroma	452.4	33.4	375.9	486.6	4.5	4.6	1.0%	12.7
ST_2_5__Stroma	476.5	32.2	398.4	520.0	5.6	5.7	1.2%	15.8
S_2_5__Stroma	487.2	31.7	406.8	530.1	5.0	5.1	1.1%	14.2
SN_2_5__Stroma	483.5	29.9	404.3	521.7	5.3	5.4	1.1%	15.1
N_2_5__Stroma	468.4	29.8	395.4	513.0	5.4	5.5	1.2%	15.4
IN_2_5__Stroma	445.4	31.1	378.9	498.5	5.2	5.4	1.2%	15.0
I_2_5__Stroma	426.6	35.6	361.5	479.8	3.7	3.8	0.9%	10.6
IT_2_5__Stroma	430.2	35.7	349.1	477.4	4.1	4.1	1.0%	11.5
T_5_6__Stroma	481.2	33.1	406.4	521.2	5.8	6.0	1.2%	16.6
ST_5_6__Stroma	512.0	36.4	423.1	563.9	6.7	7.1	1.4%	19.8
S_5_6__Stroma	524.5	37.8	425.5	576.4	6.7	6.9	1.3%	19.0
SN_5_6__Stroma	515.7	34.5	426.8	565.0	7.3	7.8	1.5%	21.7
N_5_6__Stroma	498.9	30.7	421.8	533.4	5.7	5.9	1.2%	16.5
IN_5_6__Stroma	476.5	28.9	411.9	523.7	5.8	5.9	1.2%	16.5
I_5_6__Stroma	456.4	33.1	397.3	503.5	7.3	7.3	1.6%	20.1
IT_5_6__Stroma	459.2	32.4	386.4	511.7	6.9	6.9	1.5%	19.1

* 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.

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