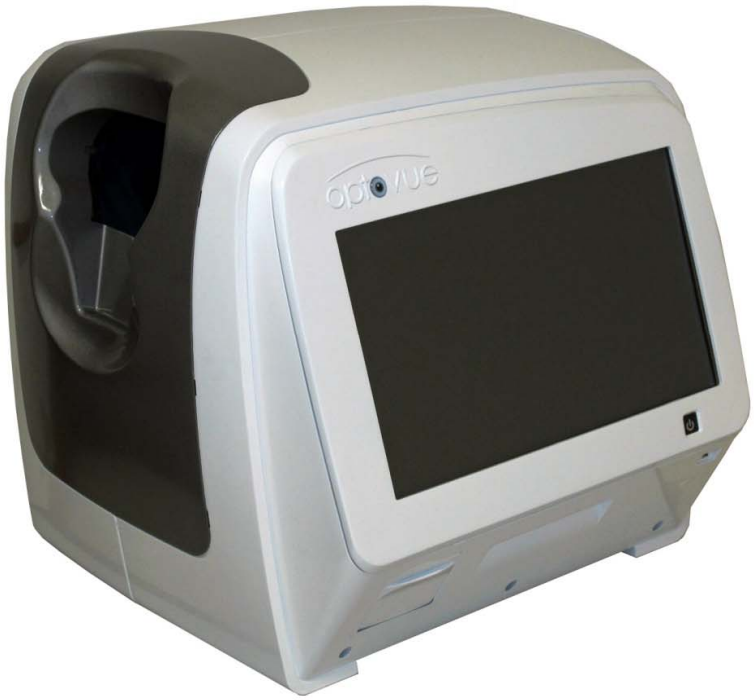
iScan™



User Manual, International
Software Version 2016.3

optovue

Optovue, Inc.
2800 Bayview Drive
Fremont, CA 94538, USA
Phone: (510) 623-8868
Fax: (510) 623-8668
www.optovue.com
E-mail: **info@optovue.com**
Telephone: (866) 344-8948

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

Revision Control

Part Number	Revision	Software Version	Description	Release Date
580-49328-004	A	2016.3	Reference ECR#01952	06/2016

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

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

Table of Contents

List of Figures and Tables

End of section

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. 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 the system facemask as necessary between patients.
- **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.

- 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.

- Adjust table and/or chair height properly to ensure patient comfort during the examination.
- Use the small facemask if appropriate for the patient or when performing anterior scans. The patient's forehead should make good contact with the forehead rest to enable the sensors.
- 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.

Note: For cornea scans, attach the CAM lens (cornea lens) before positioning the patient. See section 4.1.1.

1.1.2 Intended Use

The iScan system 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.

1.1.3 Indications for Use

The iScan system 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, and anterior chamber of the eye. The iScan system 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 iScan system with Normative Database is intended for use as a device to aid in the diagnosis, documentation, and management of ocular health and diseases in the adult population.

Contraindications

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

Note: The iScan system is not intended to be used as the sole diagnostic aid in disease identification, classification or management. The iScan system provides data to be used in conjunction with other information and is intended to assist an eye care clinician in determining a diagnosis. A patient diagnosis is the sole domain of a licensed eye care clinician.

1.1.4 Equipment Classification

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

1.1.5 Certification

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

1.2 System Overview

These are the primary components with which users interact regularly.

- **iScan unit:** The iScan unit consists of an integrated scanner, computer and monitor. It scans the patient eye, collects the OCT signal and displays the report. It includes fixation target lights to enable patients to fixate properly during the scan. The system uses a medical-grade power supply.
- **Mouse and keyboard** (additional monitor optional): The mouse and keyboard plug into the system and augment the touch-screen. As an option, you can connect an additional monitor.
- **Small facemask:** The small facemask fits in the forehead and chinrest. Use it when doing anterior segment (corneal) scans or when the patient has a smaller head, to achieve the correct head position.
- **Dust cover, lens cap:** Protect the system and lens when device not in use.
- **Verification tool:** The system must be checked after delivery with the verification tool prior to patient scanning. Upon delivery, the scan tab is disabled until the system passes the test. Repeat the test if you transport the system or if there is a concern that the system may have been damaged.

1.2.1 System Components

The following figures identify system components.

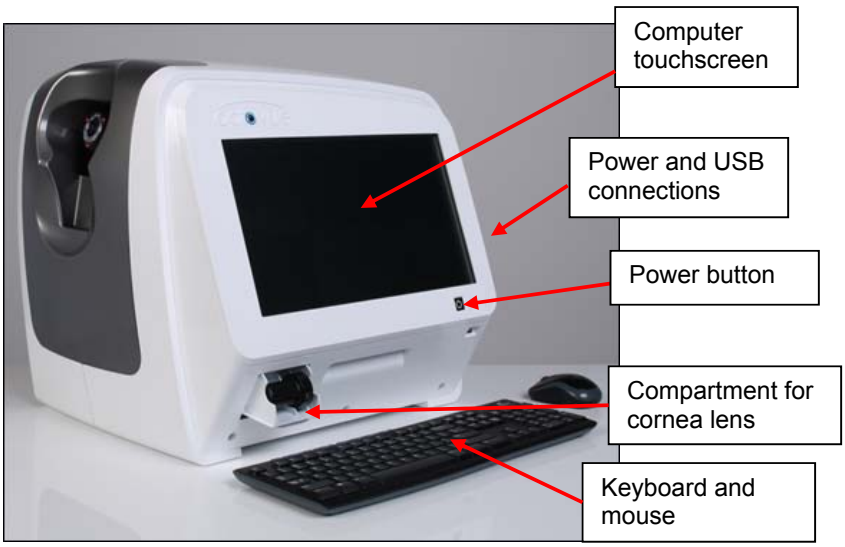


Figure 1 System Front View

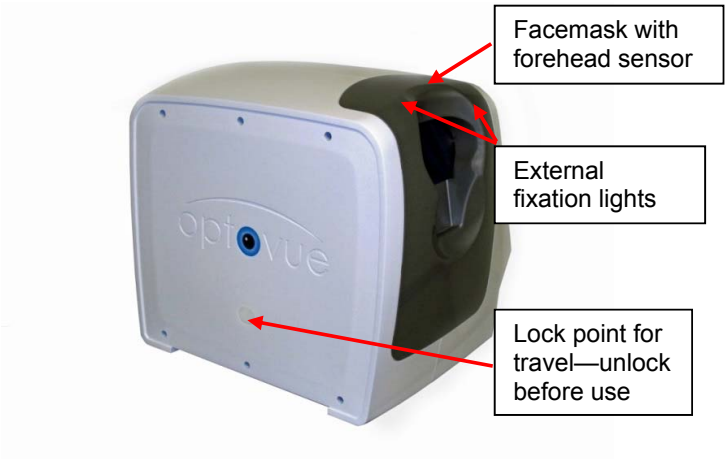


Figure 2 System Rear View

1.3 System Warnings

WARNING: During normal usage of iVue, 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, exit the application program 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: It is recommended that no accessories other than those specifically called out in this User's Guide may be connected to the system. Any customer accessory equipment connected to the interface ports must be certified according to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment) Also, all configurations shall comply with the system standard IEC 60601-1:2005. Any person who connects or installs accessories to the system has the responsibility to verify the compliance. If in doubt, consult an Optovue representative.

1.4 General Warnings

ESD WARNING: Before assembly, installation or interconnection of the iScan, it is recommended that all staff personnel (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 the 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 prior to making a connection. Finally, staff must be made aware that accessible pins of connectors identified with the ESD warning symbol should not be touched with the fingers or with a handheld tool unless proper precautionary procedures have been followed.

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

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

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

The iScan system is not intended to be used as the sole diagnostic aid in disease identification, classification or management. The iScan system provides data to be used in conjunction with other information, intended to assist an eye care clinician in determining a diagnosis. A patient diagnosis is the sole domain of a licensed eye care clinician.

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

WARNING: The iScan system has no special protection against harmful ingress of water or other liquids (classified IPX0). To avoid damage to the instrument and cause a safety hazard, the cleaning solutions, including water, should not be directly applied to the device. Using a dampened cloth (without dripping), is a good method to clean the exterior surface of the enclosure. The table can be cleaned in the same manner as the iScan instrument. Care should be taken to avoid excessive 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 iScan system. In addition, while examining the patient, the operator of the iScan system must not touch at the same time the patient and any electrical device that is not powered by the iScan system. Failure to observe these warnings could result in electrical shock to the patient and/or operator.

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

To remove power from the iScan system, you must disconnect the mains plug from the wall outlet. Do not position 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, 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 (outside 18 – 82 years of age), or outside the range of refractive error (worse 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. Misclassification risk can be reduced further by using multiple clinical tools for diagnosis.

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

1.4.1 WARNING: User Changes to Software or Hardware

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

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

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.

1.5 Standard Accessories

Description	Part No.	Quantity
User Manual	580-49328-004	1 pc.
Installation Manual	810-49813-002	1 pc.

1.5.1 Cabling

Cable Name	Type of Cable	Shielded or Unshielded	Max. Cable Length
Keyboard/Mouse, wireless	USB	Shielded	Std.
Power Cord	3-wire	Shielded	3.4 m

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, contact an Optovue representative or distributor. To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.

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

1.6 Transport Instructions

Directives de manipulation

☞ **Important:** Before moving the system, lock the base to prevent damage during transport. Remove the cover of the lock point on the back of the unit (from the operator's perspective) and use the slot screwdriver provided to turn the bar ¼ turn **counterclockwise**. (In this case, counterclockwise is to lock.

Clockwise is to **un**lock.) Replace the cover of the lock point. When the move is complete, unlock the base again before using the system.

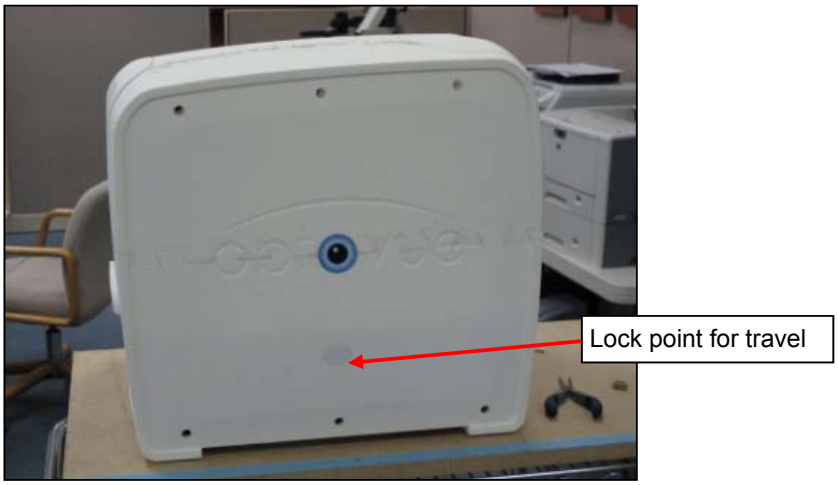


Figure 3 Lock Base Before Moving System

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.

Alternating Current

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.

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

The iScan system has been tested to comply with the emission and immunity requirements of IEC 60601-1-2 / BS EN 60601-1-2:2007. The iScan system 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 iScan system is intended for use in the electromagnetic environment specified below. The iScan system 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 iVue 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 iScan system is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following WARNING is heeded: **WARNING:** This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the iScan system, 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 iScan system is intended for use in the electromagnetic environment specified below. The customer or the user of the iScan 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.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
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	
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 iScan system requires continued operation during power mains interruptions, it is recommended that the iScan system be powered from an uninterruptible power supply or a battery.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY			
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 for the user.

European Conformity Mark for TUV Rheinland
European Notified Body:
TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nuremburg Germany

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

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

General mandatory action sign

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

Serial number

Catalog number / part number

Do not sit on

Do not stand on

Do not push

WARNING: Hand crush hazard

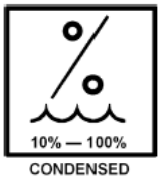
1.9.1 Protective Packing Symbols

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

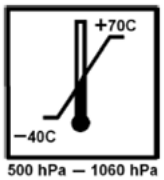
Fragile, handle with care

Keep dry

This side up



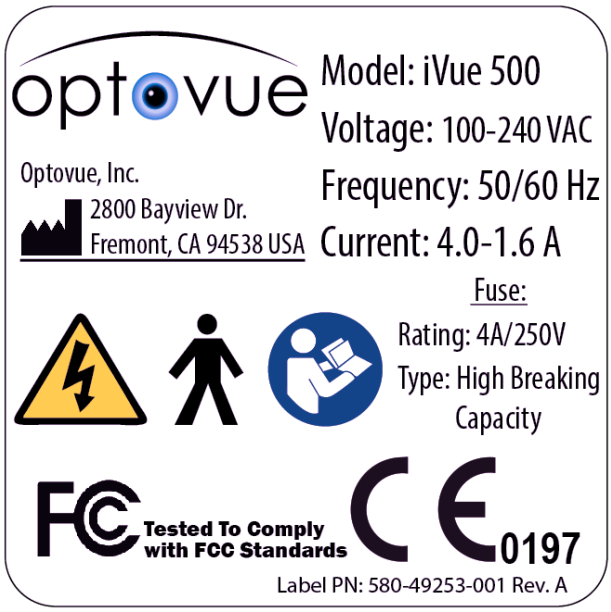
Environmental conditions during transport: Relative humidity (10% to 100%, including condensation)



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

1.10 System Label

A sample of the system label appears below:



1.11 Disposal

Dispose of the equipment per local regulations.

1.11.1 Waste Electrical and Electronic Equipment (WEEE) Recycling Instructions

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

Recycling Label

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

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. Instrument Description

_____End of section_____

2 Getting Started

2.1 Unpacking the System

The iScan shipment contains the following items on arrival:

1. iScan unit
2. Motorized table (optional)
3. Mouse and keyboard
4. Power cord
5. Installation manual P/N 810-49813-001 Dust cover
6. System verification tool
7. Small facemask
8. Dust cover
9. Lens cap
10. Slot screwdriver
11. CAM lens (optional, includes software)
12. User manual

Note: The iScan system does not include a printer.

Note: The system packaging is designed so that when the upper box is removed, component boxes can be lifted off the remaining platform.

WARNING: The iScan unit weighs approximately 43 pounds. To lift it out of its box, insert one hand in the front mask area and grasp the ledge above the USB connectors at the back with the other hand. Use the proper lifting technique: lift the scanner with your legs, not your back, and place it on the table top. If you doubt your ability to safely lift the scanner, have another person help you. Lifting improperly can result in injury. Dropping the system can damage sensitive equipment.

2.2 System Setup

2.2.1 Unlock System

1. On the back of the system from the operator's perspective is a warning label that prompts you to unlock the system base before using. Uncover the lock point and use the provided slot screwdriver to turn the bar ¼ turn **clockwise**. (In this case, clockwise is to **un**lock. Counterclockwise is to lock.)
2. Remove warning label and replace lock point cover.

2.2.2 System Connections

Figure 4 shows the connectors on the right side (from the operator's perspective).

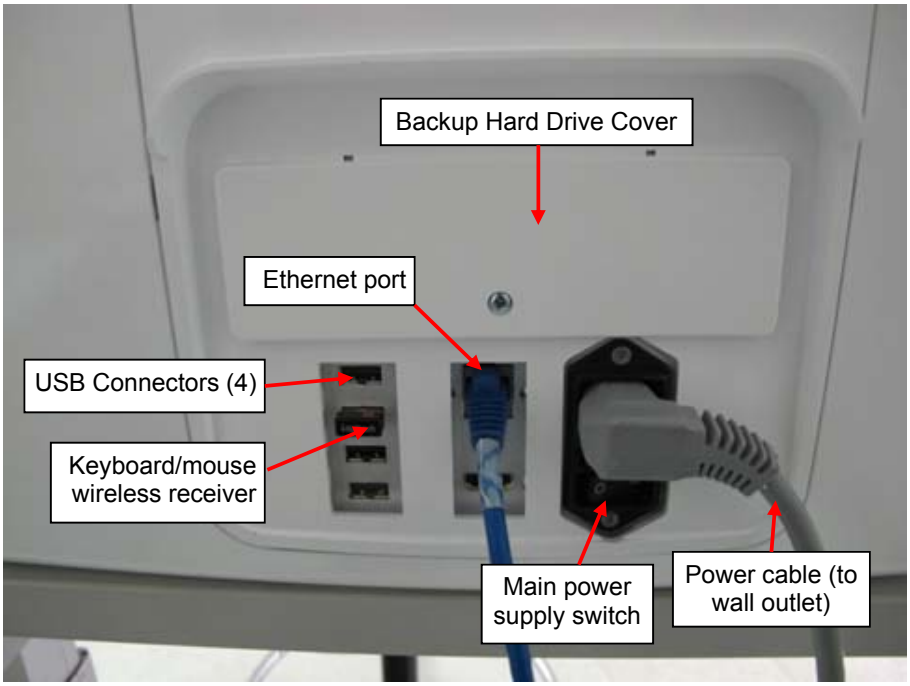


Figure 4 Connectors on Right Side

1. Plug the power cable into the back of the device and directly into a wall outlet. Do not use an extension cord or a power strip.
2. Plug the keyboard/mouse wireless USB receiver into a USB slot.
3. Turn on the main power supply switch.

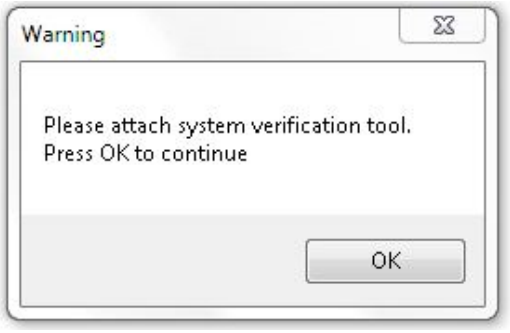
2.2.3 Start the System

1. Press the power switch below the touch screen.
2. Wait a minute while the Windows desktop opens, then double-click the **iVue** icon to launch the system software.

2.2.4 System Verification

Upon first use, scanning is disabled until you use the system verification tool to verify that the scanner is working properly within calibration limits. (This is because the equipment is sensitive to jarring movements that can occur during transport.) We recommend you repeat the verification test after you transport the system to another site, or if the system is dropped or jarred in a way that raises concern it might be damaged.

Until you complete verification one time, a warning dialog prompts you to attach the system verification tool when you start the system software.



- If you click OK before attaching the tool, a second dialog may appear, asking you to make sure the system verification tool is attached.

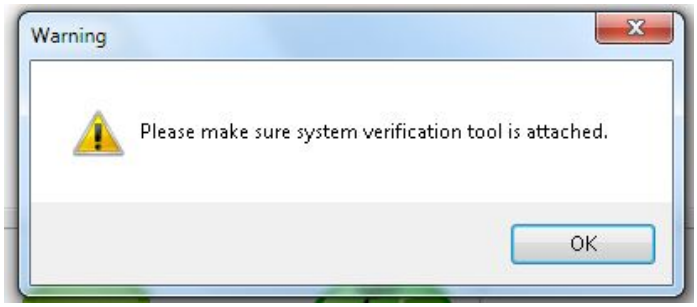


Figure 5 Make Sure Verification Tool is attached

1. The verification tool has three tabs that fit in matching slots on the system lens. Fit the tool tabs in the lens slots and, gently pressing in, turn the tool clockwise (to the right). It stops after a little less than a quarter turn. When the tool is attached, press **OK** to continue.

2. To start the verification test, go to the **Tools** menu and click **System Verification**. The verification test begins—the system performs a test scan on the artificial eye in the verification tool. After 10-20 seconds, the test completes and a dialog opens to tell you whether the system verification passed or failed.

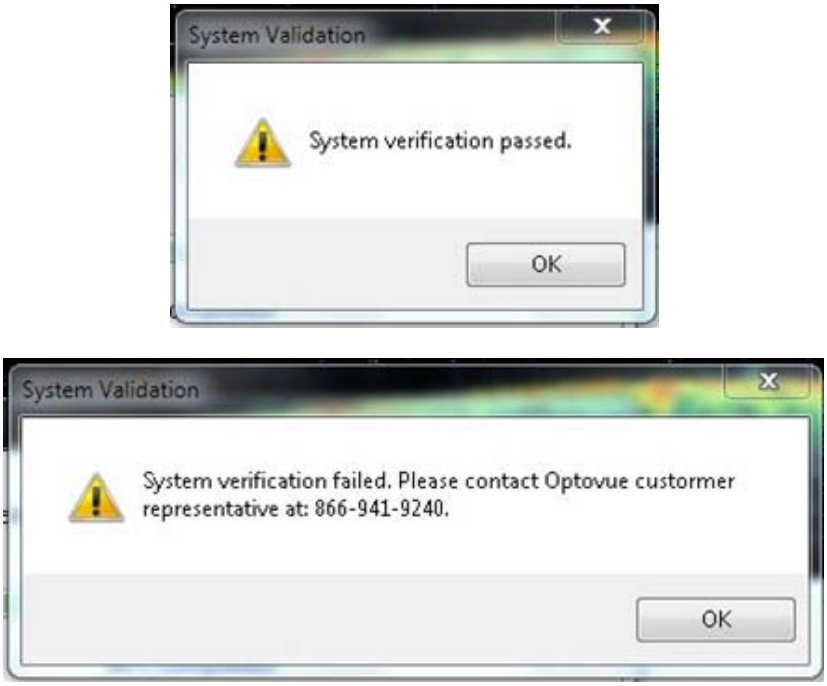


Figure 6 System Verification Passed or Failed Messages

If it passed, you can use the system normally, including scanning. If it failed, we recommend you make sure the verification tool is properly attached—remove and reattach it—and then repeat the test at least once again. If the verification fails twice or more, contact Optovue customer service for assistance.

2.2.5 Language Options

The iScan system software supports Chinese, Japanese, German, French, Polish, Spanish, Russian, Korean, Italian and Portuguese.

_____End of section_____

3 Manage Patient Information

The system application opens by default to the PATIENT window. The application also has a SCAN window (see chapter 4) and a REVIEW window (see chapter 5).

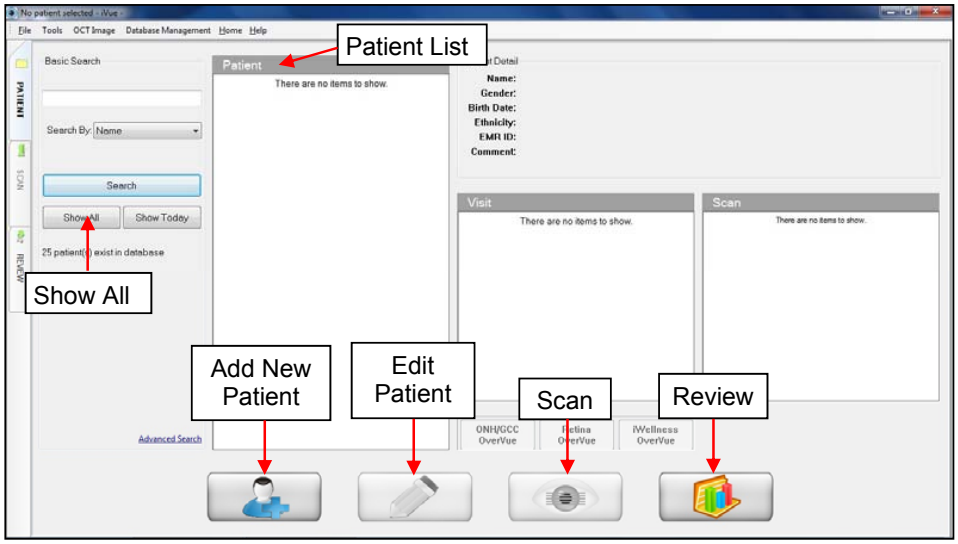


Figure 7 Patient Window

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.

3.1.1 Patient Search

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

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.

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.

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. 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.

3.1.2 Patient List

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

- The selected name is highlighted in the list and appears on the title bar.
- 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 3.5.)
- 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.

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.

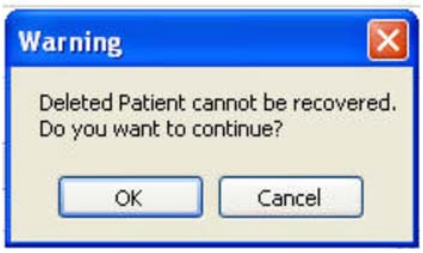


Figure 8 Patient Deletion Warning Message

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 opens.

Note: Select Patient language to change the language played by the iScan

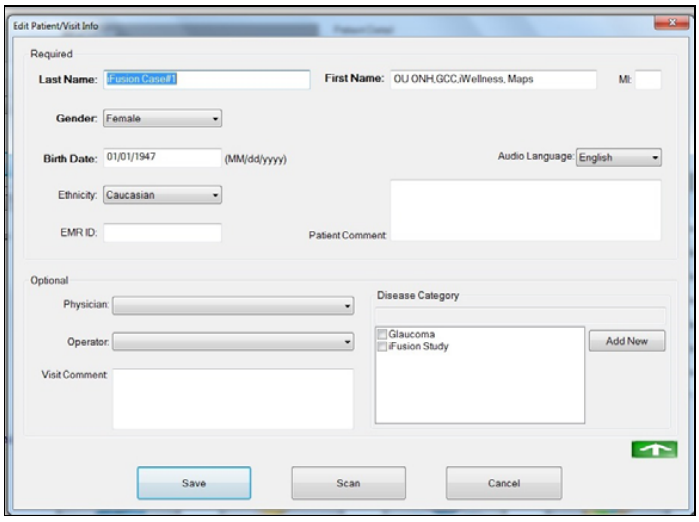


Figure 9 Add New Patient Screen Showing Optional Fields

1. You must fill out the fields marked in bold. Other fields are optional. You can also click the green arrow button at lower right to enter additional optional information.

2. When ready, click **Scan** to start scan capture; or click **Save** to save the new patient information and return to the **Patient** screen; or to cancel this operation, click **Cancel** to return to the **Patient** screen.

To add more information, click the green arrow. The **Optional** area of the **Add New Patient** dialog appears.

3.3 Create New Visit

To create a visit for a new patient or a new visit for an existing patient, select the desired patient in the **Patient** list and click the **Scan** button. The system creates a new visit with today's date and the SCAN window opens. Select the desired scan type to select the desired series of scans. To add more **Visit** information right click on the main patient screen visit window and select the **Add Visit** option.

3.4 Change Date of Birth Format

It is recommended that all patients be linked to a unique identifier, such as their date of birth. You can set the default format for date of birth in the **User Preference** dialog:

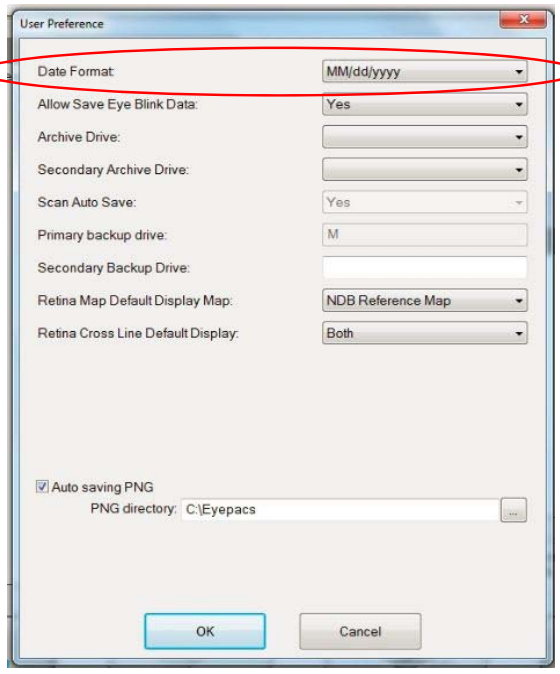


Figure 10 User Preference Dialog

Note: The iVue computer settings must match the date format specified above.

To change the computer date settings:

1. Go to **Regional and Language** Options in the control panel.
2. Click the **Customize** button under the **Regional Options** tab.
3. Select **Short Date Format** under the **Date** field. Click the **OK** button to finish.
4. Restart the iScan application after changing the date format.

3.5 Edit Patient or Visit Information

To edit a patient's information, select the patient name from the menu and click the **Edit** button.

3.6 Patient List Shortcuts

Click on the patient's name to view patient visits. Right click on the patient name or visit date to view options:

- **Add New Visit:** Create a new visit with the current date for the selected patient. This takes the system directly to the SCAN window (see chapter 4).
- **Delete Current Visit:** Deletes the selected visit.
- **Delete Current Patient**: Deletes the selected patient. A warning dialog notifies you that you cannot recover the deleted patient.

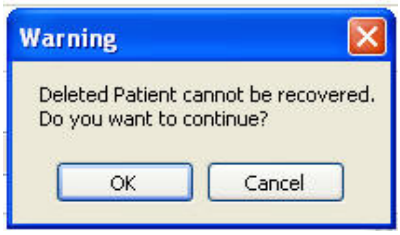


Figure 11 Delete Patient Warning Message

Click **OK** to confirm **Patient** deletion, or **Cancel** to cancel deletion.

3.6.1 Review Button and Scan Button

After selecting a patient, click the **Review** button to review that patient's scans (see chapter 5).

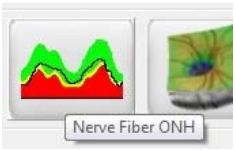
After selecting a scan in the PATIENT window, you can click the **Scan** button to switch to the SCAN window and repeat the selected scan.

_____End of section_____

4 Capture Scans

The SCAN window is where you capture scans.

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



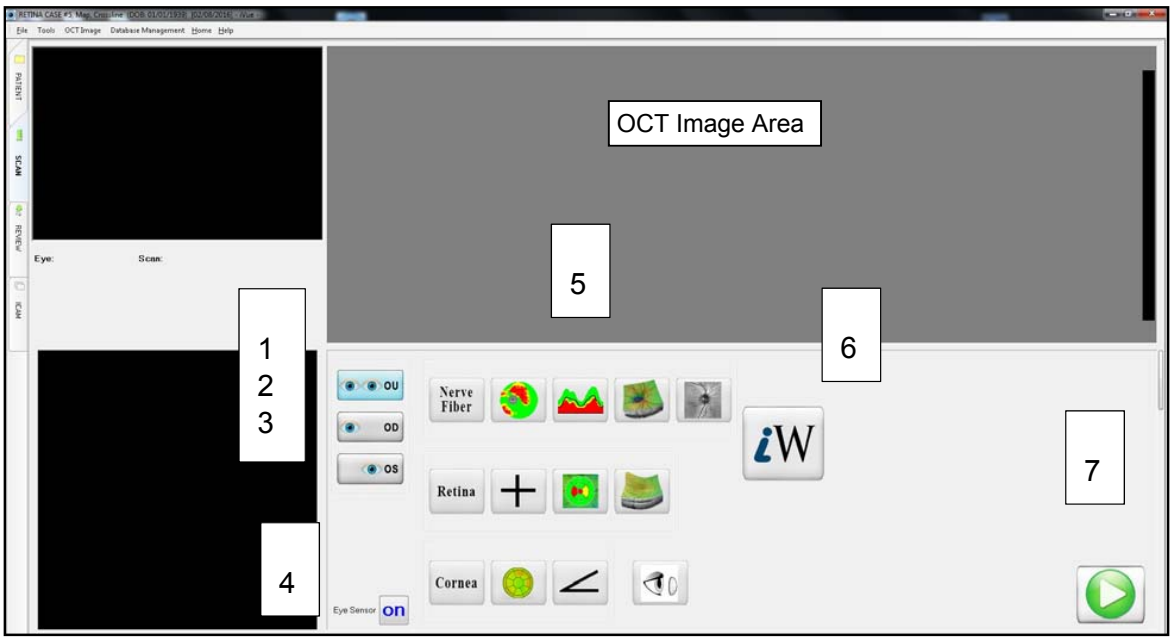


Figure 12 SCAN Window

Figure 12 Legend

1. **OU** (Both Eyes) Button
2. **OD** (Right Eye) Button
3. **OS** (Left Eye) Button
4. Eye Sensor on/off Toggle
5. Scan Protocol Buttons (3 Rows)
6. iWellness Button
7. Start Button

Nerve Fiber Protocol: GCC – ONH – 3D Disc,3D Fundus Enface	
Retina Protocol: Cross Line – Retina Map – 3D Retina	
Cornea Protocol: Pachymetry- Angle- Lens fitting	

4.1 Scan Capture Instructions

Follow these steps to capture scans.

1. In the PATIENT window, find and select the desired patient, or if the patient has not yet been added to the system, add the patient now. See chapter 3 for instructions.
2. Make sure to clean the face mask surfaces before asking the patient to place their face in the facemask. Use an isopropyl alcohol wipe or a germicide with a clean lint-free cloth. Section 8.2.1 has these cleaning instructions.

Note: You can also use a disposable biological barrier over the facemask. Paper barrier sheets designed for use with the iScan system are available from Optovue.

Note: Insert the small mask if the patient's head size is in the smallest one third of the normal population. You can also try the small mask if the system cannot find the correct working distance. Use the facemask for all cornea scans.

3. When you have selected the desired patient, click the **Scan** button to switch to the SCAN window.
4. In the SCAN window, the **OU** button is selected by default (see Figure 12 above. Select the corresponding button if you will scan only the right or left eye. The eye selected appears below the video image at upper left.
5. Select the desired scan protocol or scan from the three rows of icons.

Nerve Fiber Protocol: GCC – ONH – 3D Disc3D Fundus Enface,	
Retina Protocol: Cross Line – Retina Map – 3D Retina	
Cornea Protocol: Pachymetry- Angle-Lens Fitting	

Note: If you select a cornea scan, attach the CAM lens before scanning. See section 4.1.1 below.

6. Click the green **Start** button  . The scan process begins. In the default software-assisted mode, the system begins to give audio commands and proceeds through the scan process to scan capture. Attend to the process and assist as necessary. Proceed to section 4.2 to follow the automated process and understand what assistance may be required.

4.1.1 CAM Lens

The iScan cornea adaptor module, also known as the CAM lens or cornea lens, is required for corneal scans. It is not interchangeable with other iVue detachable lenses. It is unique to the iScan system and is distinguishable by six LEDs (that shine red when the lens is attached properly—see Figure 15).

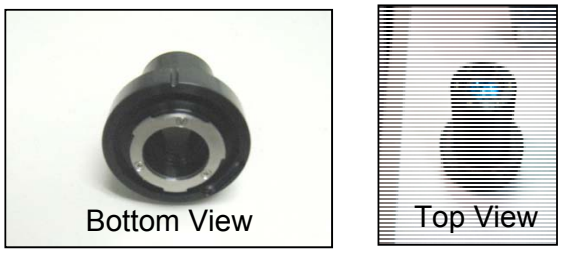


Figure 13 CAM Lens Unnattached

When you select a cornea scan, the system automatically advances the lens so you can attach the CAM lens. Figure 14 shows the system lens in the home position and advanced position.

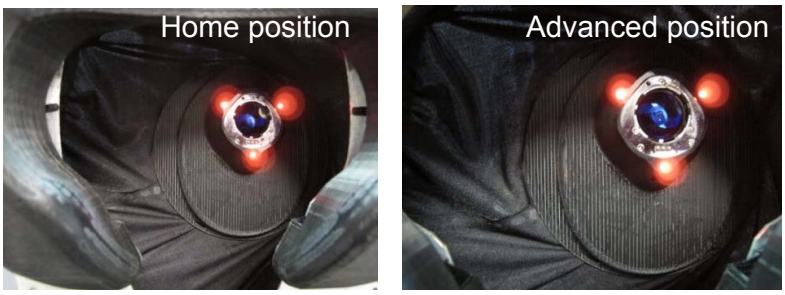


Figure 14 System Lens Advances to Attach CAM Lens

1. The CAM lens has tabs that fit in matching slots on the system lens. Fit the CAM lens tabs in the system lens slots and, gently pressing in, turn the tool clockwise (to the right). It stops after a little less than a quarter turn. The six LED lights illuminate when the lens is properly attached. Figure 15 shows the CAM lens attached.

Figure 15 CAM Lens Attached

4.1.2 Queuing Multiple Scans

Select the buttons of all the scans you wish to perform. The system performs individual scans by the eye and in the order you select them. The scan buttons are listed in the recommended order for each protocol (Nerve Fiber, Retina, Cornea rows).

4.1.3 Audio Commands

Before and during the scan, the system gives audio commands and shows on-screen messages to assist you and the patient as necessary. For example, if the patient's head is not properly seated in the mask, the message below appears. The patient's language can be selected when the patient information is entered or by using edit.

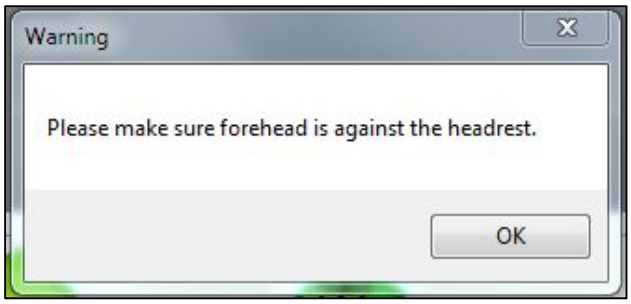


Figure 16 Make Sure Forehead Is Against Headrest Message

Most audio commands direct the patient in positioning their head or eye. The table below lists the audio commands the system uses.

Audio Commands	
Audio Command	**Notes**
Place your head into the middle of the mask. Your eyes should be level with the yellow lights.	Assist patient to put face in facemask. Enter patient information as necessary.
Please look at the center of the green fixation target.	Central fixation, used in all retinal scans
Please look at the green fixation target to the left of center.	For right eye disc scans (GCC, ONH, & 3D Disc).
Please look at the green fixation target to the right of center.	For left eye disc scans (GCC, ONH, & 3D Disc).
Operator: Please adjust patient's head.	When system cannot detect eye.
Aligning to your eye.	System aligns to the eye.
Adjusting to your eye.	System adjusts focus, polarization.
Auto mode has been paused.	Operator pauses scan.
Please blink. Then keep your eye open.	Restore tear film before capture.
Corneal Commands Only	
Please sit back while the cornea lens is attached	Before cornea scans.
Please look at the yellow light to your right	Position right eye for cornea scan.
Please sit back while the cornea lens moves to the other eye.	Rest between eyes.
Please look at the yellow light to your left.	Position left eye for cornea scan.
Please close your eyes.	Rest eyes after or between scans.
Scan is complete; please sit back.	Procedure done.
Operator Commands Only	
Please place your head against the mask.	System cannot detect forehead against facemask.
Operator: Please adjust patient's head.	System detects forehead, but cannot detect eye.

4.2 Auto Alignment

Follow these steps during auto alignment (in software-assisted mode) and assist as necessary.

1. The system finds the eye and advances. The camera shifts from far to near camera (see section 4.2.1). If the eye is not visible in the video image, the system cannot find the eye. Reposition the patient so the eye is visible with the pupil centered as shown below. The slider to the right of the plus and minus arrows indicates the camera position.

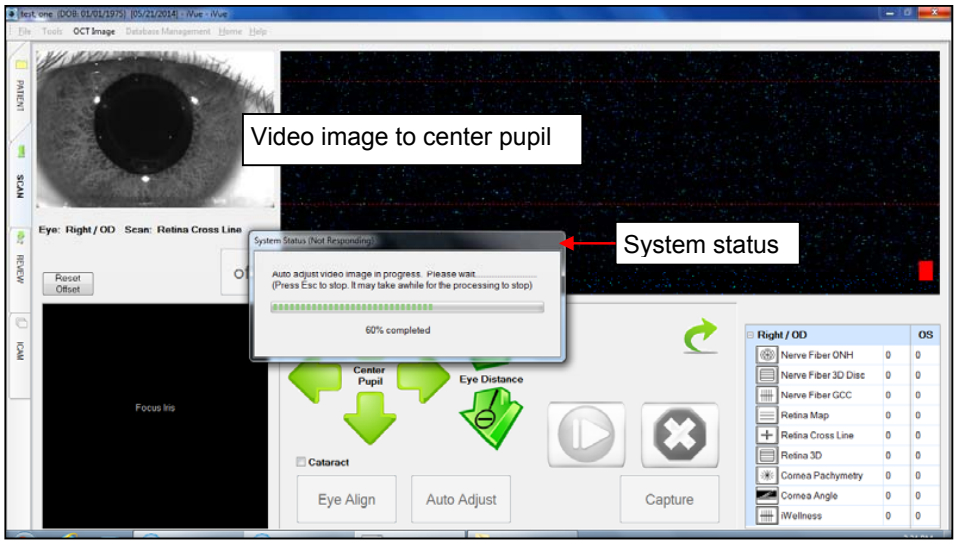


Figure 17 Scan Alignment in Progress

2. If the eye is visible in the video image but the system fails to acquire the image, click the center of the pupil or use the four green arrows to align the eye in the center as shown above.

Note: The camera has reached its limit if an arrow turns gray. In this case, reposition the patient as necessary.

3. When the auto eye sensor is on, the system identifies the eye based on the scanner position. If the patient's head is improperly positioned to acquire a scan, turn off the auto eye sensor.

To provide ease of use when performing a variety of scans on the same eye for a patient, the system remembers the last eye selection for a visit on that patient. At any point, if you leave the SCAN window (to review a captured scan, for example), you must select the eye again, since both **Right/OD** and **Left/OS** buttons will be deselected and disabled.

Note: There are a number of conditions which would render measurements unreliable, for example: the inability of subjects to maintain fixation; strong nystagmus; and dense media opacities. Myelinated nerve fibers could affect the RNFL thickness results adversely.

4.2.1 Software-Assisted Alignment, Far and Near Cameras

In software-assisted mode, during alignment, the system uses two cameras, far and near. It begins with the far camera (whole eye) as it moves forward to find the pupil and then the retina, aligning as it goes. At a certain distance from the eye, it switches to the near camera (iris and pupil). If the patient is out of range, the system asks that the patient be repositioned. Use the manual alignment controls to assist as necessary. See the tips in the following paragraphs. For details, see section 4.5.

Figure 18 Manual Alignment Controls

The IR real-time video in the top left-hand corner shows the system searching for the reflection of the projected dots when in far camera mode. As the system moves forward, the pupil should be centered and the iris in focus. (Note that the B-scan image at top center and live en face image at lower left may not be visible yet).

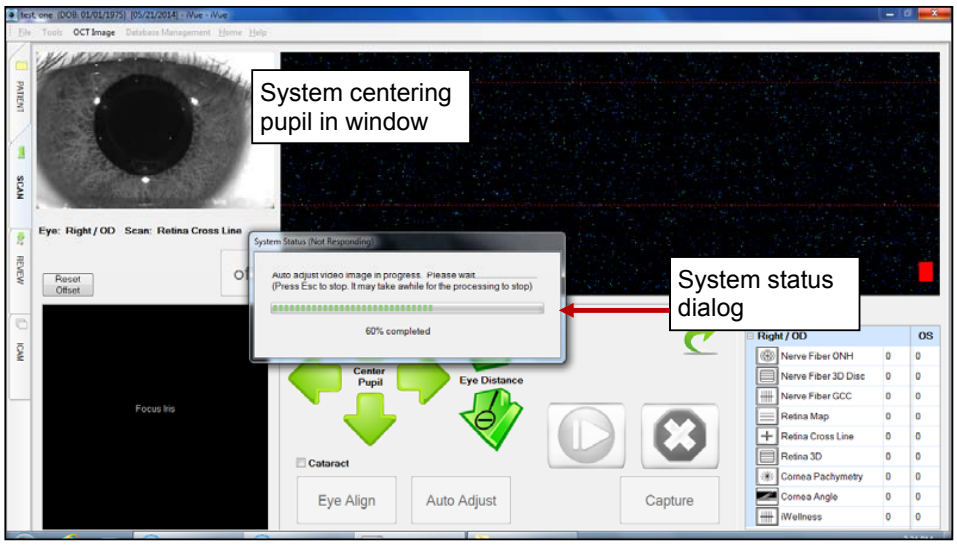


Figure 19 Scan Alignment and Adjustment in Progress

When the pupil is centered, guide the patient to open the eyes as wide as possible. You should see three dots of reflected light in the video image.

If the system seems unable to find the eye center, touch the pupil center in the live video image and the unit corrects for the appropriate distance. The system then advances to the correct working distance.

4.3 Auto Adjustment

Once auto alignment is complete, the system starts auto adjustment, in which the system automatically adjusts focus and polarization to optimize signal strength. A System Status dialog appears with the message **Auto Adjust in progress. Please wait ….** and includes a progress bar. The **Reset/Offset** button disappears and the **Reset** button is enabled.

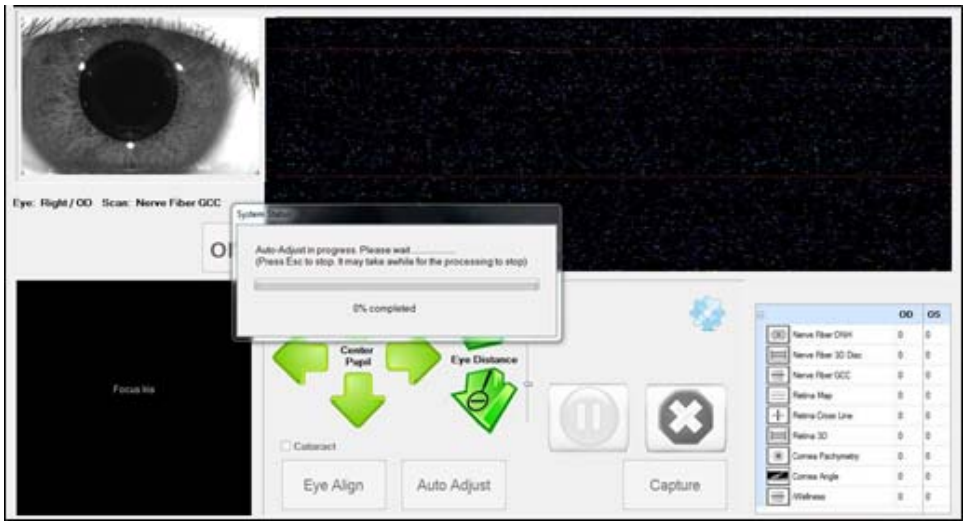


Figure 20 Auto-Adjustment In Progress

Note: If the system cannot achieve adequate signal strength after it attempts auto adjustment three times, it asks for manual assistance.

When auto adjustment is complete, the dialog disappears. If the scan is ready for capture, the en face image appears at lower left.

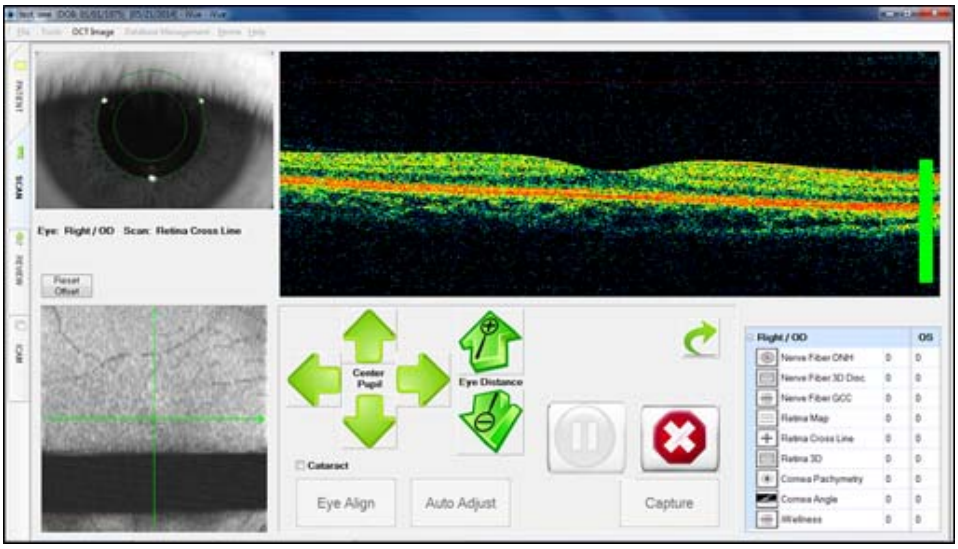


Figure 21 Auto-Adjustment Complete

4.4 Automatic Capture

When the camera is in position, the system audio asks the patient to blink and hold their eye open. Then the system automatically captures the scan and continues to the next scan. During scan capture, the B-scans appear at top center and a **System Status** dialog displays a progress bar.

Figure 22 Progress Bar

Once the scan is captured and saved, the system proceeds to the next scan in software-assisted mode, until all scans are completed.

4.5 Manual Scan Controls

The scan controls are present during the scanning process. Use them to make manual adjustments during software-assisted mode, or to capture scans in manual mode.

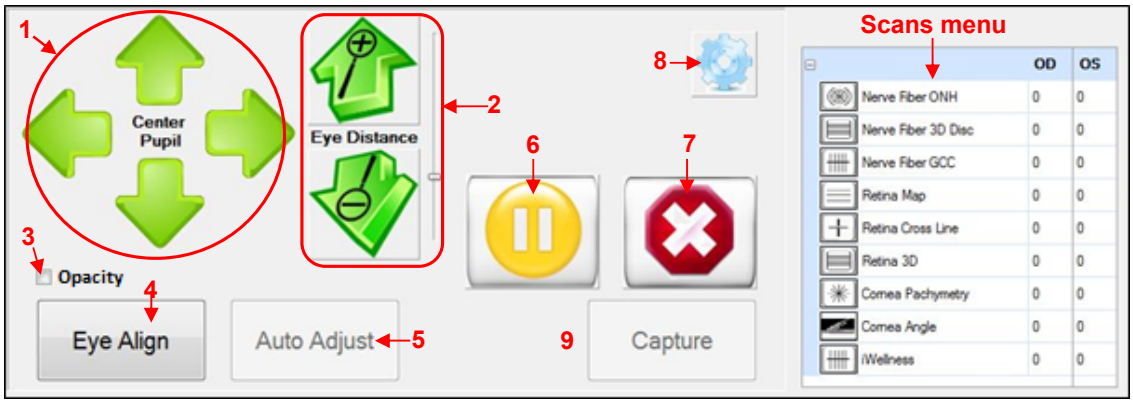


Figure 23 Scan Controls

Figure 23 Legend

1. **Center Pupil** Green Arrows: **Up, Down, Right, Left**
2. **Eye Distance**: Forward button (**+**), back button (**–**)
3. **Opacity** checkbox
4. **Eye Align** button
5. **Auto Adjust** button
6. **Resume/Pause** button (Pause shown)
7. Stop button
8. Manual scan adjustment (cog icon)
9. **Capture** button

4.5.1 Manual Mode On/Off

The **MANUAL on/off** button is below the video image. The button is **off** by default, so the system uses software-assisted mode by default. If the system cannot find the eye, click to toggle manual mode on, then use the green arrow buttons to align manually.

Figure 24 Manual on/off Button

Note: For all anterior (CAM) scans, you must use manual mode; software-assisted mode is not available.

Center Pupil Arrows

The four green **Center Pupil** arrows move the image up, down, left, and right.

Eye Distance Arrows and Slider

The two green **Eye Distance** 3D arrows move the scanner forward (+) and backward (-). The **Eye Distance** slider shows the scanner position relative to its range. You can drag the slider to move the scanner too. Use caution to avoid contacting the eye.

Pausing and Canceling

You can pause or cancel the scan process at any time. Click the yellow pause button to pause, and the button changes to a green start (resume). If a progress bar is active, use the ESC key on the keyboard to interrupt the system. The system pauses at the end of the task.

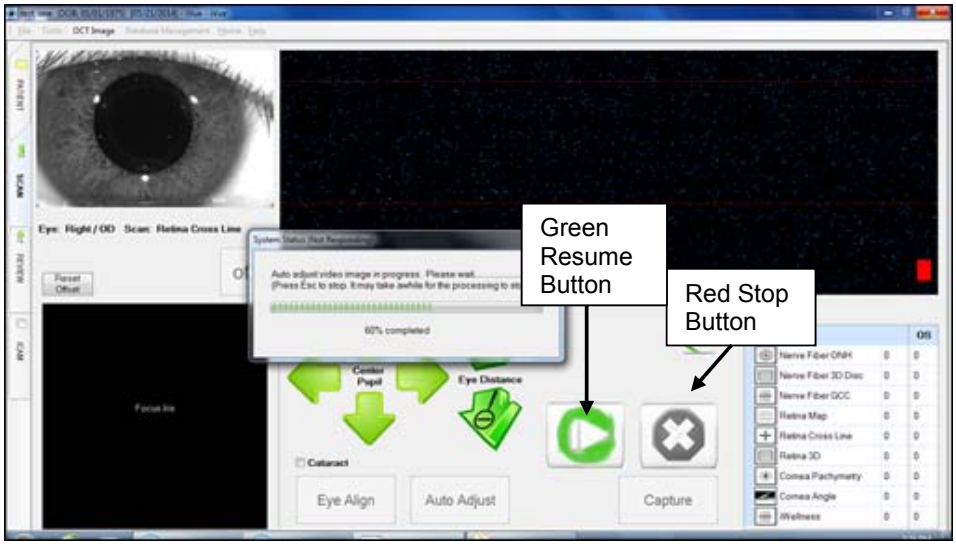


Figure 25 System Paused, Green Resume Button Visible

To cancel a scan, press the red **X** button. A **Cancel Options** dialog appears.

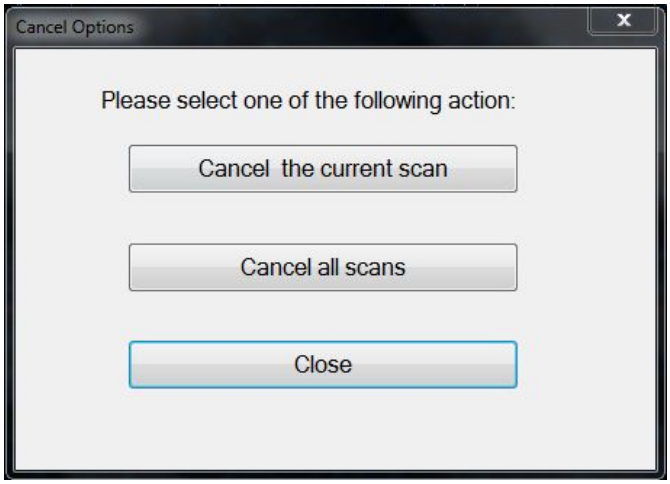


Figure 26 Cancel Options Dialog

The options are:

- **Cancel the current scan**: Cancels the current scan and proceeds to the next queued scan.
- **Cancel all scans**: Cancels all queued scans and returns to the SCAN window.
- **Close:** Closes the dialog and proceeds with the current scan.

4.5.2 Making Manual Adjustments

In manual mode, the **Center Pupil** and **Eye Distance** green arrows and slider are enabled.

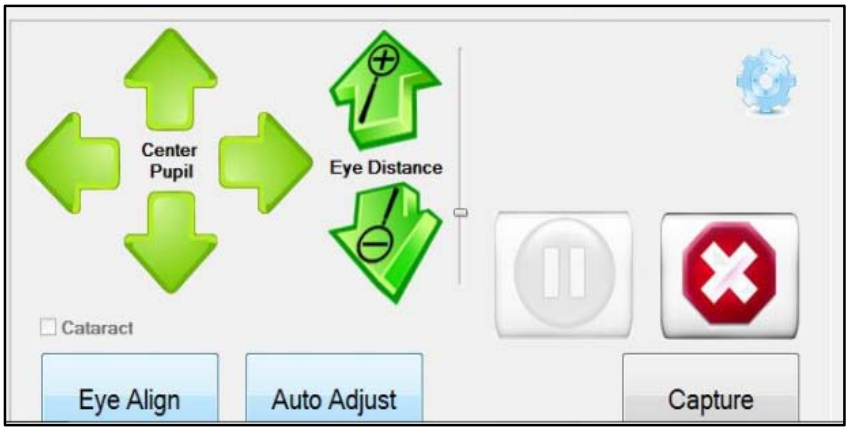


Figure 27 Center Pupil and Eye Distance Arrows

- To center the pupil in the video image at upper left, use the **Center Pupil** arrows or click the pupil center. You can also click the **Eye Align** button to have the scanner attempt to align automatically.
- After centering, use the green **Eye Distance** arrows to move the scanner forward (+) or backward (-) until the iris is in focus in the video image, for retinal scans. For corneal scans, move forward until the OCT image of the cornea is between the red lines.
- If an arrow is disabled (gray), it means that the scanner cannot go further in that direction and you should reposition the patient. After repositioning, check with the patient to confirm that the fixation target and scan pattern appear in the proper location. The fixation patterns for all scans are found in section 9.3.
- Once the pupil is centered and the iris is in focus, click the **Auto Adjust** button to find and enhance the OCT image. To manually adjust the OCT image, select **Manual Scan Adjustment**.
- When you see an OCT image of sufficient quality, click the **Capture** button. The system automatically saves the scan and the Completed Scans list updates.

After capture, you have four options:

- Click **Scan Again** to take another of the same scan type,
- Click **Stop** and select one of the cancel options,
- Click the **REVIEW** tab to analyze scans already captured, or
- Click the **PATIENT** tab to return to the PATIENT window.

4.6 Scan Capture Instructions for Certain Scan Types

The following instructions can help you capture good scans for these scan types.

4.6.1 Optic Nerve Head (ONH) Scans

For optic nerve head (ONH) scans, if the system is in manual mode, or if the software-assisted mode is having difficulty, click the center of the optic disc on the live en face image after auto-adjusting. The optic disc should then appear in the center of the circle on the en face image. If the system is in software-assisted mode, it continues; if in manual mode, then you can capture the scan. The system then asks to capture a 3D Disc scan as an ONH reference. Center the optic nerve for the 3D reference scan as before.

4.6.2 Cornea Angle Scans In Manual Mode

You can capture Cornea Angle scans only with manual alignment. Follow these steps:

1. Attach the CAM lens.
2. Use the external fixation lights at the sides of the facemask to guide the patient's fixation. Similar to the Retina Cross Line scan, you can rotate the Angle scan up to 90º, both clockwise and counterclockwise, in five degree intervals. To rotate the scan, move the mouse pointer to the video image and scroll the mouse wheel. The arrow on the video image shows the location and orientation of the scan. Touch the IR screen or use the four Center pupil arrows to position the scan line over the limbus of the eye with the arrow pointing to the center of the pupil.
3. Try to ensure the cornea scleral plane is as flat as possible, that is, perpendicular to the scan.
4. The fixation light turns on automatically for OD or OS.

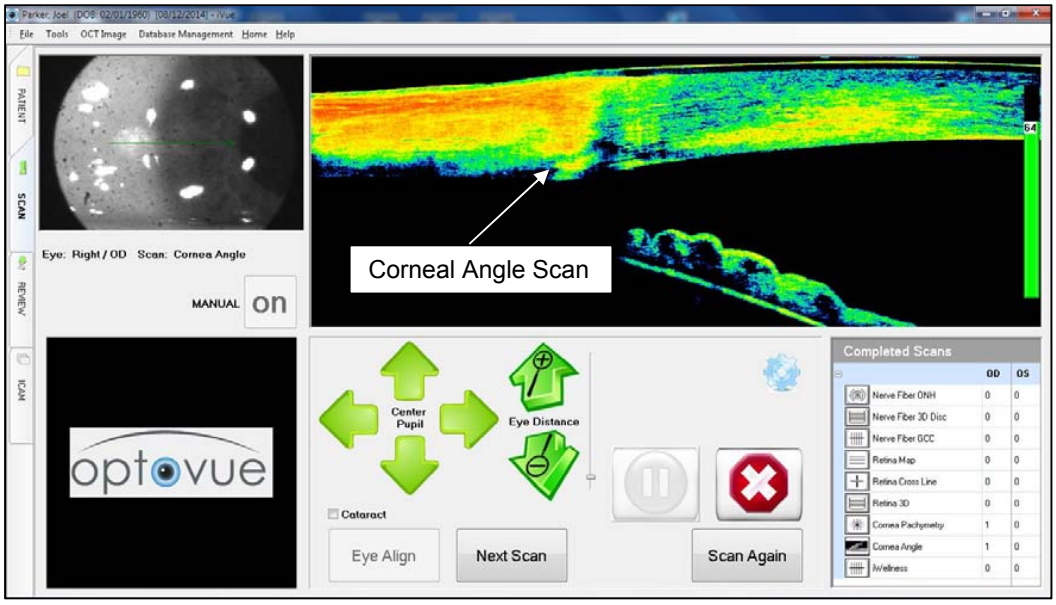


Figure 28 Corneal Angle Scan Sample

5. Advance using the plus arrow until the surface of the cornea/sclera touches the upper red line.

The Angle scan can also be used to visualize the landing zones of lenses, nasal, temporal, inferior and superior. The Angle scan line should be perpendicular to the plane where the lens contacts the sclera. Four images can be selected to display on a single page. . 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.

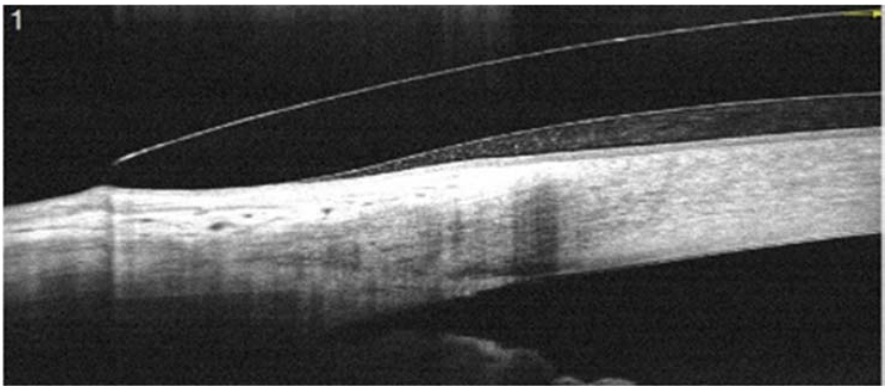


Figure 29 Landing Zones

4.6.3 Pachymetry Scans in Manual Mode

You can capture pachymetry scans only with manual alignment. When you initiate a pachymetry scan, a warning dialog prompts you **Please make sure the correct CAM lens is attached**.

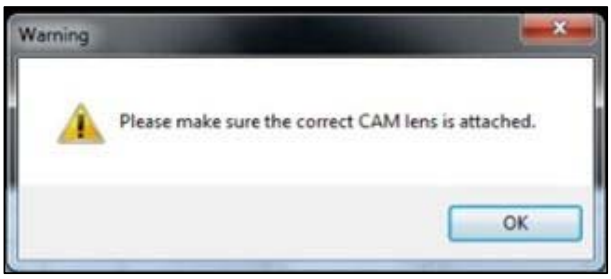


Figure 30 Make Sure CAM Lens Is Attached

1. Attach the CAM lens if not already attached. Click **OK** to proceed.
2. Use the four green directional arrows to center the pupil in the video image at upper left, using the two green concentric circles as a guide. Move the scan forward using the green 3D colored arrows until the OCT image of the cornea is between the red lines, as shown below.

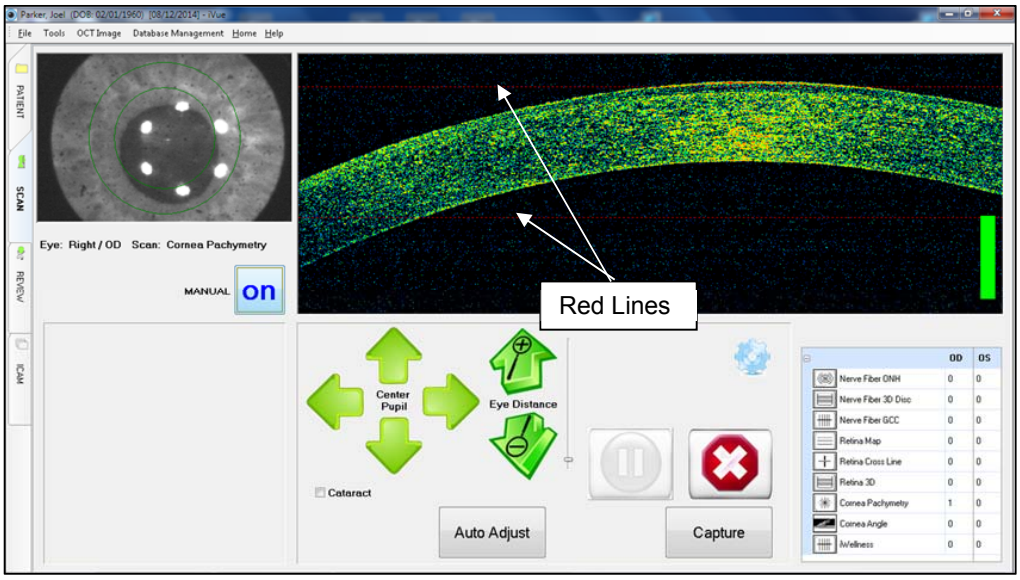


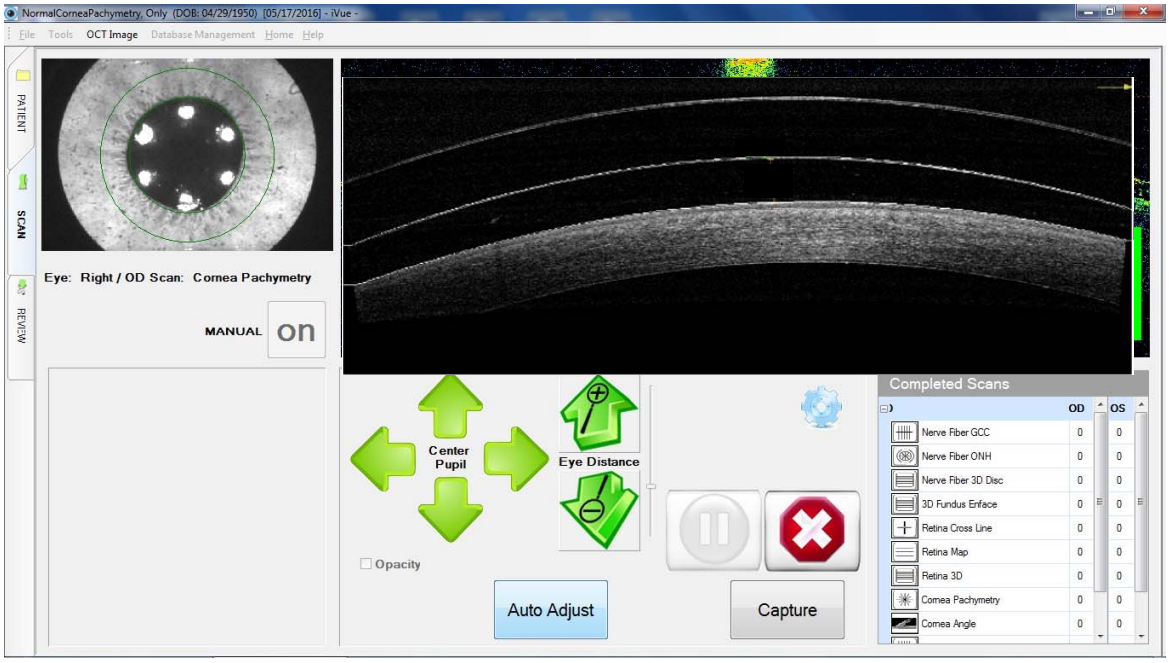
Figure 31 Use Distance Arrows to Place Cornea Image between Red Lines

3. Click **Capture** to capture the scan. When the scan completes, click **Scan Again** or **Next Scan** to capture another scan.

4.6.4 Lens Fitting Scan

The Lens Fitting scan is taken similar to the 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 scleral lens appears in the OCT image. Continue forward until the top and bottom surfaces of the scleral lens and the cornea are visible in the OCT image. Auto-adjust and capture.

Note: the top surface of the scleral lens must be visible in the OCT window for the algorithm to detect the vault/clearance. Also the index of refraction must be entered to complete analysis.



_____End of section_____

5 Review and Edit Scans

The REVIEW window is where you review scan reports. Each type of scan report has its own elements and layout in the REVIEW window. An example is shown below.

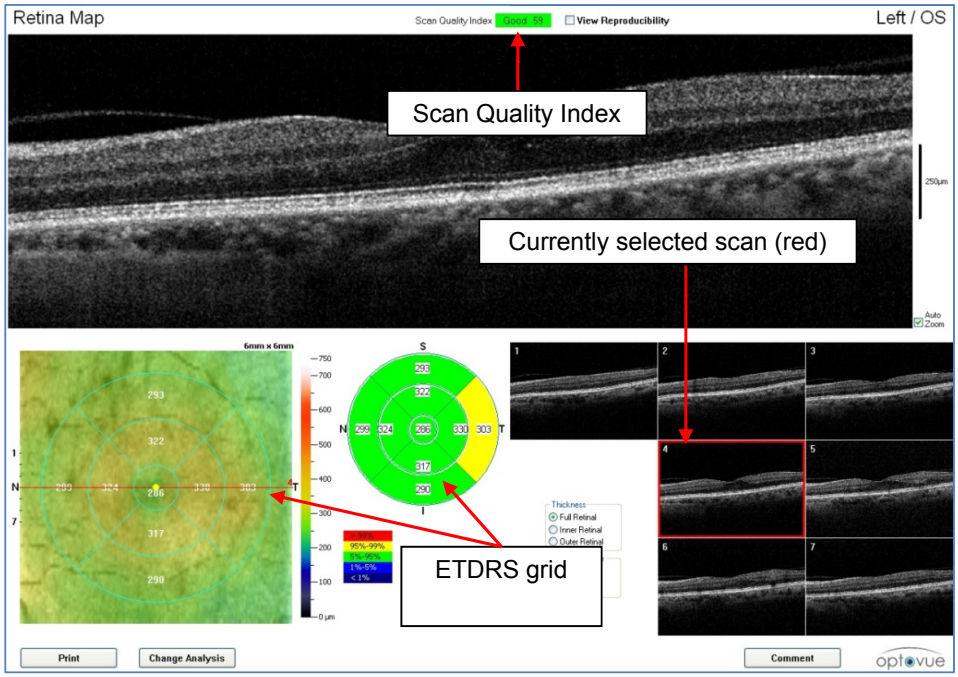


Figure 32 Example Review Window—Retina Map Scan

The REVIEW window opens when you double-click on any saved scan, or when you click the **REVIEW** tab. The left side of the REVIEW window includes **Patient**, **Visit** and **Scan** lists. At bottom left is a set of **Tools**.

5.1 Scan Registration for Comparison

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

5.1.1 3D 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.

5.2 Scan Quality Index

The Scan Quality Index (SQI) appears at the top of the screen for all scan types. The SQI can be either **Good** and highlighted green, or **Poor** and highlighted red. It includes a numeric value. 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 after retaking, the scan does not improve to **Good**, for example due to media opacity, we recommend caution in interpreting its results.

A **Good** SQI indicates that ocular structures and layers are generally visible and easily segmented. A **Poor** SQI indicates that ocular structures and layers may not be generally visible and easily segmented. The table below shows the SQI cutoff value for each type of scan.

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 range of patients including those without pathologies, contact Optovue Technical Support for assistance. For detailed information regarding the usability scans with a **Poor** SQI, see the relevant Appendix.

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.

1. **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.

2. **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.

3. **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.

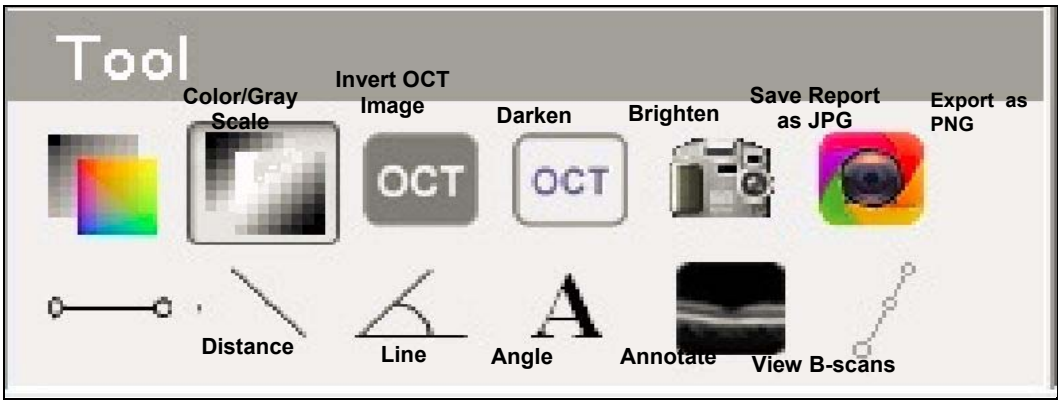


Figure 33 Review Screen Tools

- **View B-scans**: Opens the B-scan window. You must open the B-scan window to modify the segmentation boundary lines (see section 4.5.2 or to use the following four tools.
    - **Distance**: Select to measure the distance between two points you place on a B-scan.
    - **Line**: Select to draw a line on a B-scan.
    - **Angle**: Select to measures the angle you draw. 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.
    - **Annotate**: Select to annotate the B-scan.
- **Color/Gray Scale**: Toggles scan display between pseudo-color and gray scale.
- **Invert:** Inverts black and white in a grayscale image.
- **OCT noise**: Increase (white) and reduce (gray) OCT noise level.
- **Save Report as JPG**: Saves the report as an image in JPG format. The default filename created combines patient and scan information, but you can edit it. You can select the destination folder.
- 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

_____End of section_____

6 Scan Reports

6.1 Retina Map Report

The Retina Map report shows the 6 mm x 6 mm retina map with an ETDRS grid and its associated thickness values, along with an en face image from the scanning session. Seven scan images (each an average of five scans along that raster line) appear at lower right. The currently selected scan appears in the large image at the top. Click or scroll to select a different scan for larger display. The system applies the default **Auto Zoom** function to the large OCT image at the top. To see the large image without **Auto Zoom**, uncheck the **Auto Zoom** checkbox to the right of the image.

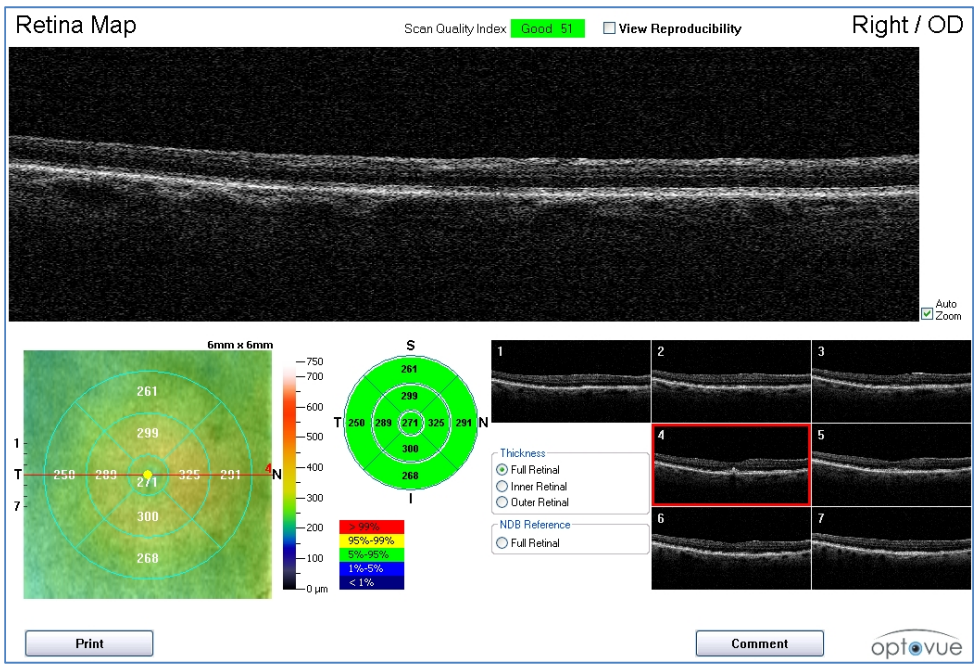


Figure 34 Retina Map Default View

At bottom left, the en face image is overlaid with a thickness map by default. In the Thickness box to the left of the scan images, you can select either **Full Retinal, Inner Retinal** or **Outer Retinal** thickness for display. When you select the **Full Retinal** radio button in the NDB Reference box, the overlay becomes an NDB (normative database) reference map. Note that the normative database applies only to full retinal thickness.

In the default **Retina Map** report, the **View Reproducibility** checkbox is not selected. Select the **View Reproducibility** checkbox to show the calculated range of reproducibility for each thickness parameter.

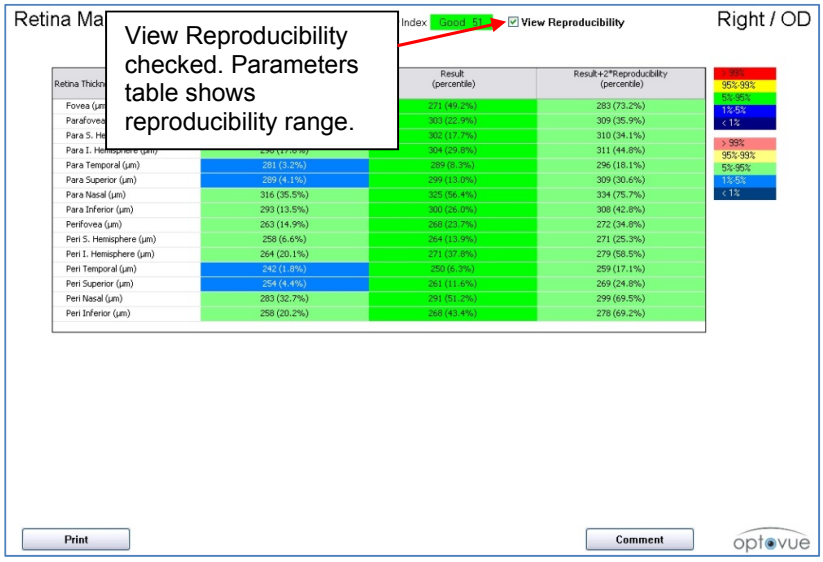


Figure 35 Retina Map, View Reproducibility Checked

6.1.1 NDB References

NDB references are available only for full retinal thickness.

NDB references can appear in the ETDRS Chart (center), the NDB Reference Map (lower left) and the retinal parameters table (when **View Reproducibility** is selected). The NDB color key explains that green is within normal thickness (p-value between 5% and 95%); yellow is borderline too thick (p-value between 95% and 99%); red is greater than normal thickness (p-value >99%); blue is borderline too thin (p-value between 5% and 1%); and dark blue is less than normal thickness (p-value <1%). See Appendix B for more detail on the Normative Database.

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

Note: The ETDRS chart in the center reflects 1, 3, and 5 mm diameter zones instead of the 1, 3, and 6 mm diameter zones in the traditional ETDRS chart.

Manual Boundary Adjustment: This feature enables you to review and manually adjust segmentation boundary lines applied by the software. To adjust boundary lines manually, click the **View B-scans** button on the **Tool** menu, or select **Modify Boundary** from the **OCT Image** menu. Adjust the segmentation boundaries and click **Save**. Manual boundary adjustments trigger recalculation of measurements when you click **Save**.

☞ **Note**: Any modification to the segmentation lines erases any prior annotations on the report. If you wish, restore 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 RPE elevation measurements for the full retina and other measurements are:

- **Full Retinal** – Segmentation from ILM to RPE
- **Inner Retinal** – Segmentation from ILM to outer limit of IPL.
- **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 (Inner Limiting Membrane), IPL (Inner Plexiform Layer), and RPE (Retinal Pigment Epithelium). 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. Inaccurate placement of the segmentation lines affects the resulting thickness measurements. If you perform any manual correction, the results will be valid and the scan can be used.

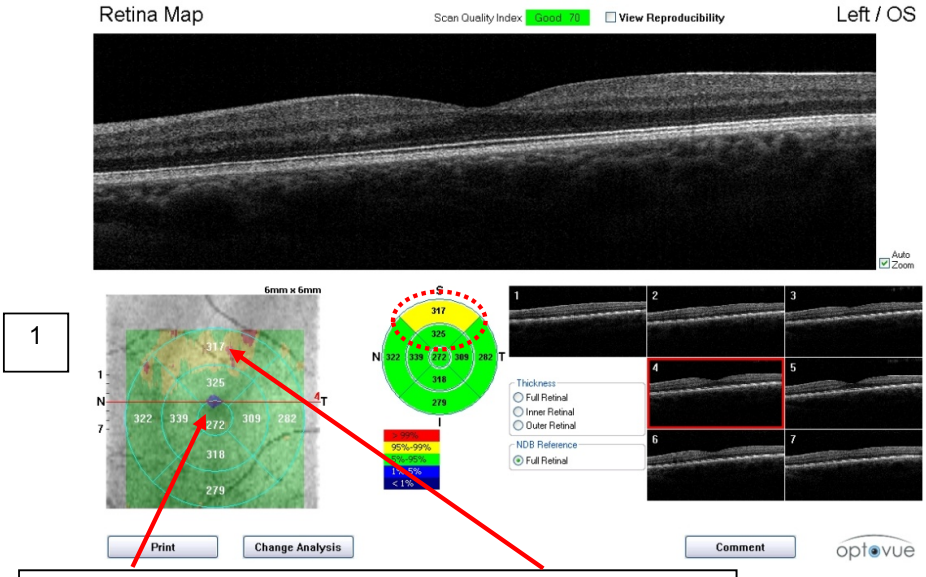
Fovea locator: Software automatically identifies fovea location for EMM5 scans, primarily based on detecting the thinnest location of the inner retinal thickness. To compare EMM5 scans from different visits, the software uses the fovea location as the basis for registration. The fovea location detection should be verified by user for individual EMM5 scans. The fovea location can be easily verified 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.

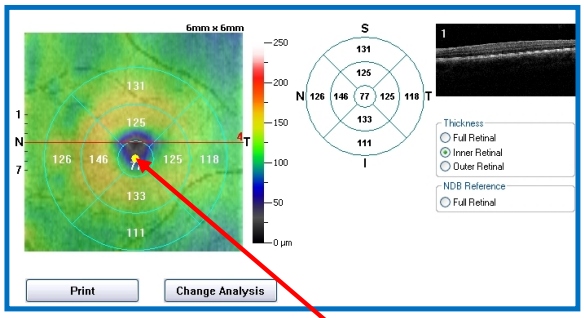
If the fovea is not in the center of the scan, you can move it manually. This ensures the measurements come from the expected locations. If the repositioned fovea causes some measurement areas to be outside the scan pattern, these measurements should not be used. Select either **Full Retina** or **Inner 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 changes to reflect the new values.

ETDRS Centering On Fovea



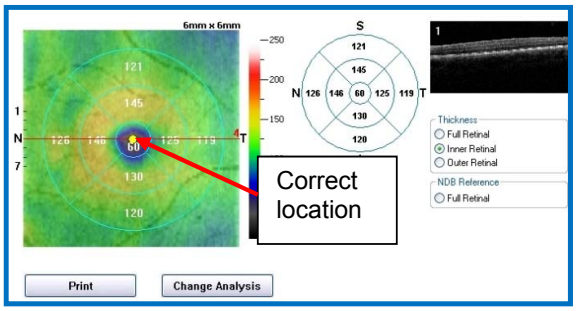
1

Blue area near fovea center & yellow/red area in superior zones possibly indicate that ETDRS is not aligned with fovea center.



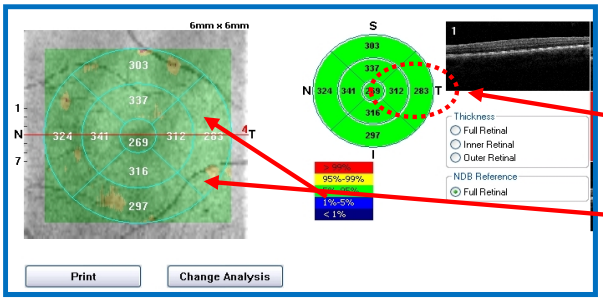
2

Drag yellow dot to foveal depression center. To reprocess data, click **Yes** In resulting message.



Correct location

3



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

4

6.1.2 Retina Map OU Report

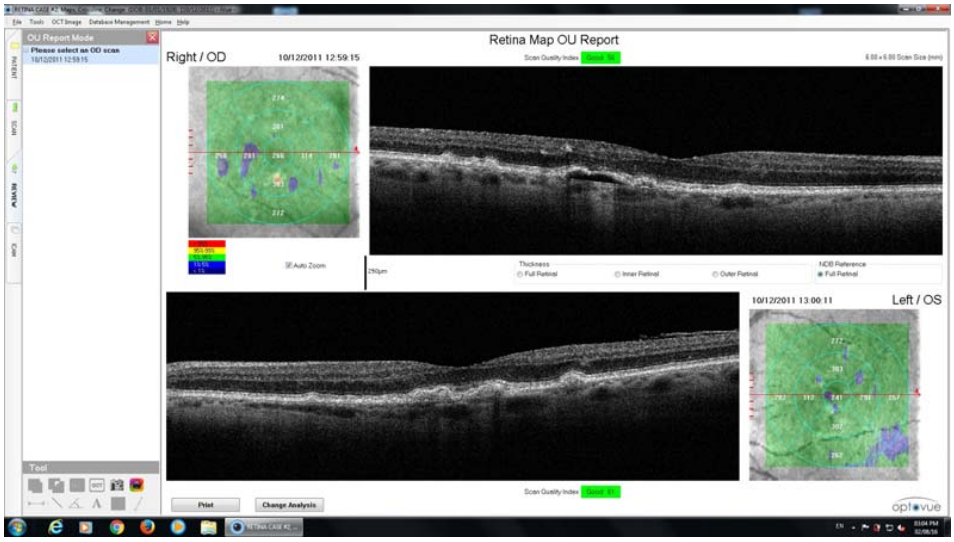


Figure 36 Retina OU Report

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

6.1.3 Retina Map Change Report

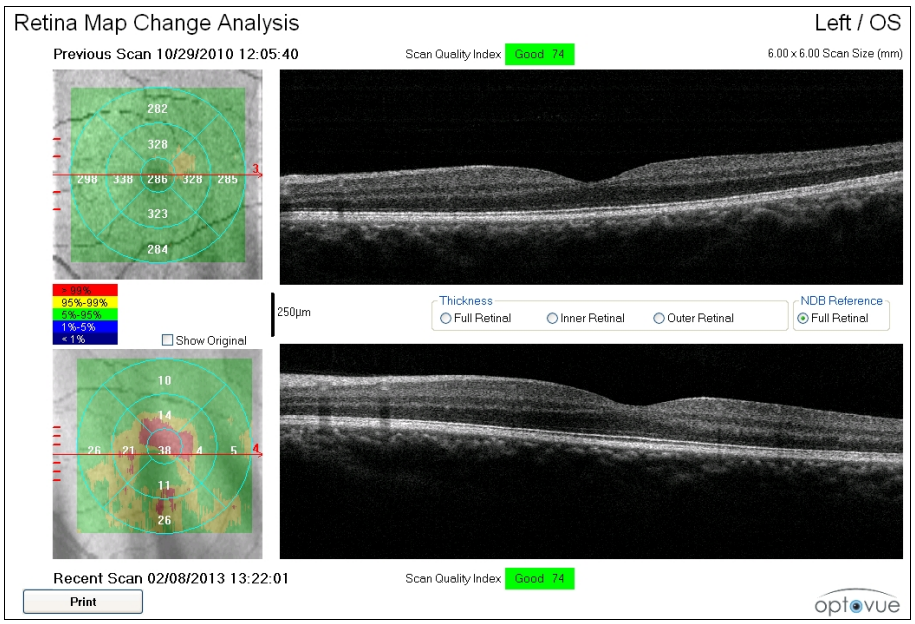


Figure 37 Retina Map Change Analysis Report

Retina Map Change reports display the previous scan at the top and the current scan at the bottom. The en face image 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 to 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.

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

☞ **Note:** Clicking the **OU Report** redisplays the original screen at any pointing the process.

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 scans in multiple visits were manually adjusted, make sure the foveal adjustments are consistent.

6.1.4 Retina Cross Line Report

The default screen of the Retina Cross Line report shows one or two OCT images (option **Both** selected as shown below), and the en face image. An arrow in the top right corner of each OCT image indicates the scan direction. Arrows on the en face image show the direction and location of the scan.

Note: You can choose the default display from **User Preference** (See section 7.2.1 for more information).

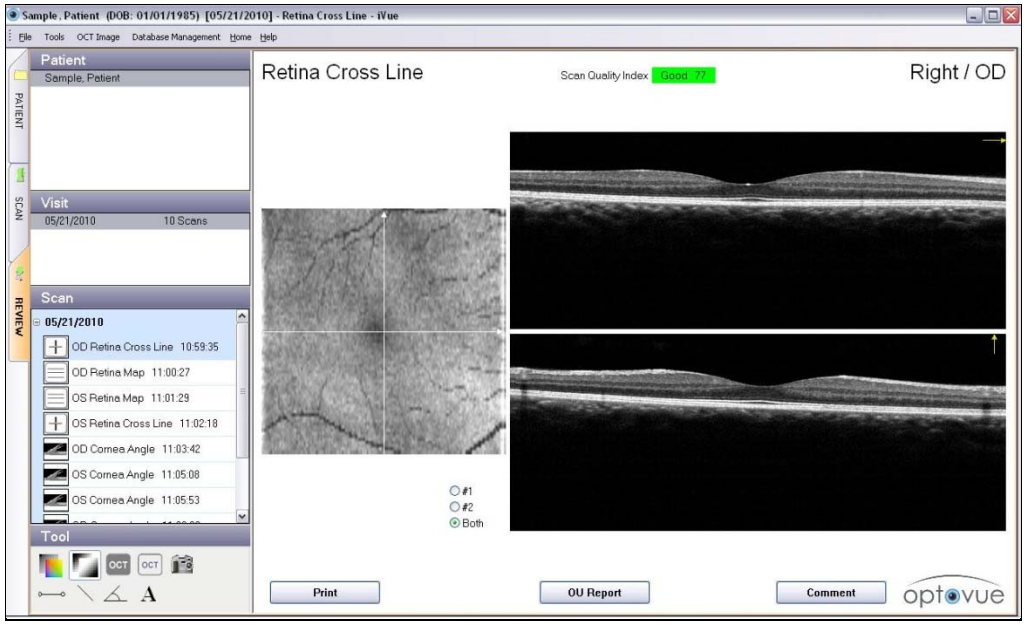


Figure 38 Retina Cross Line Report with Both Selected

The **Both** radio button (default) displays both scans, as shown above. Select the **#1** or **#2** radio button to see each single scan image in a larger display area, as shown in the image below. Again, the scan direction arrow in the top right corner illustrates the scan's correlation with the arrow on the en face image.

Figure 39 Retina Cross Line Report with #1 Selected

Retina Cross Line OU Report

When Retina Cross Line scans have been taken for both eyes, the **OU Report** button is available. Click it open the Retinal Cross Line OU Report, which shows both scan images by default (**Both** radio button selected).

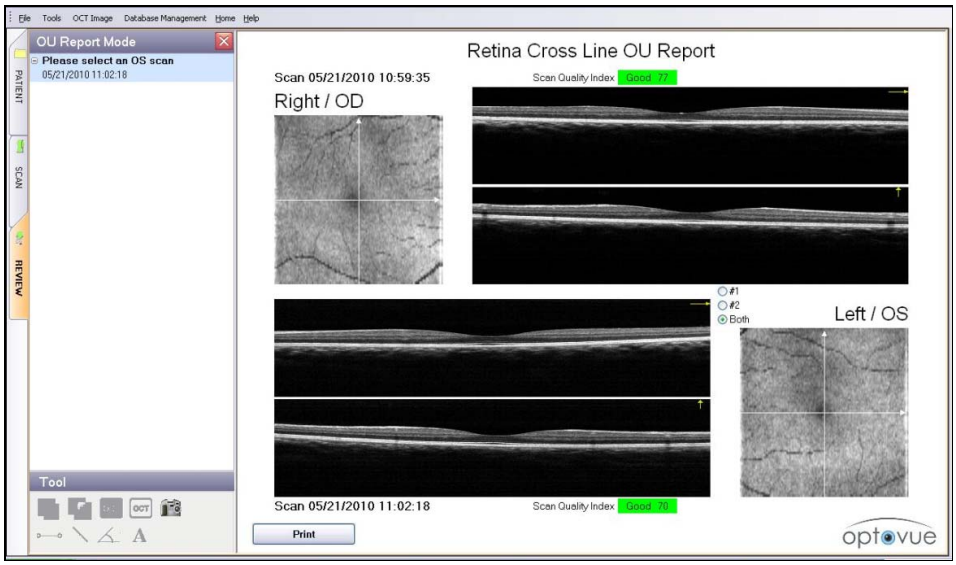


Figure 40 Retina Cross Line OU Report

Select **#1** or **#2** to show that scan in a larger display, as shown below.

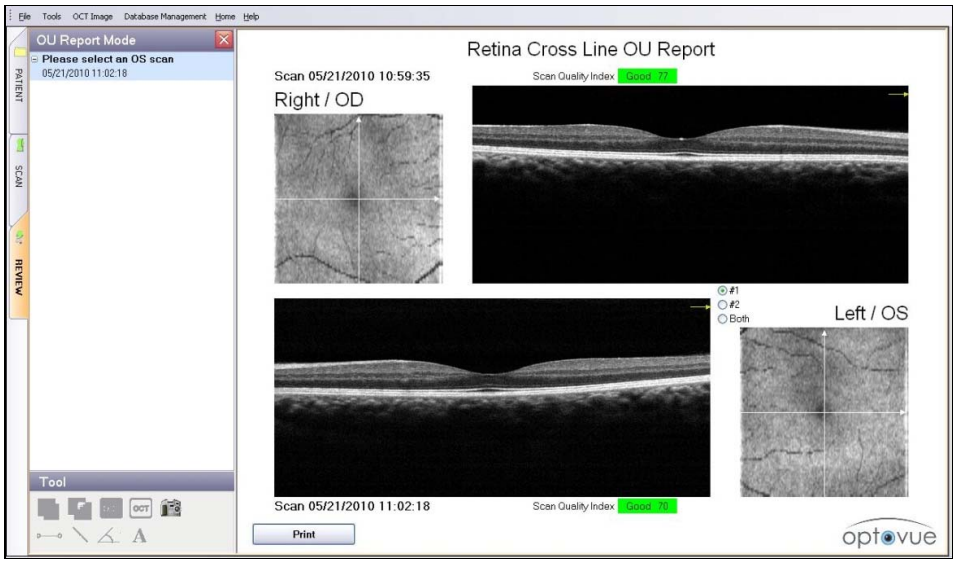


Figure 41 Retina Cross Line OU Report with Option #1 Selected

6.1.5 Retina 3D Report

A Retina 3D report appears below.

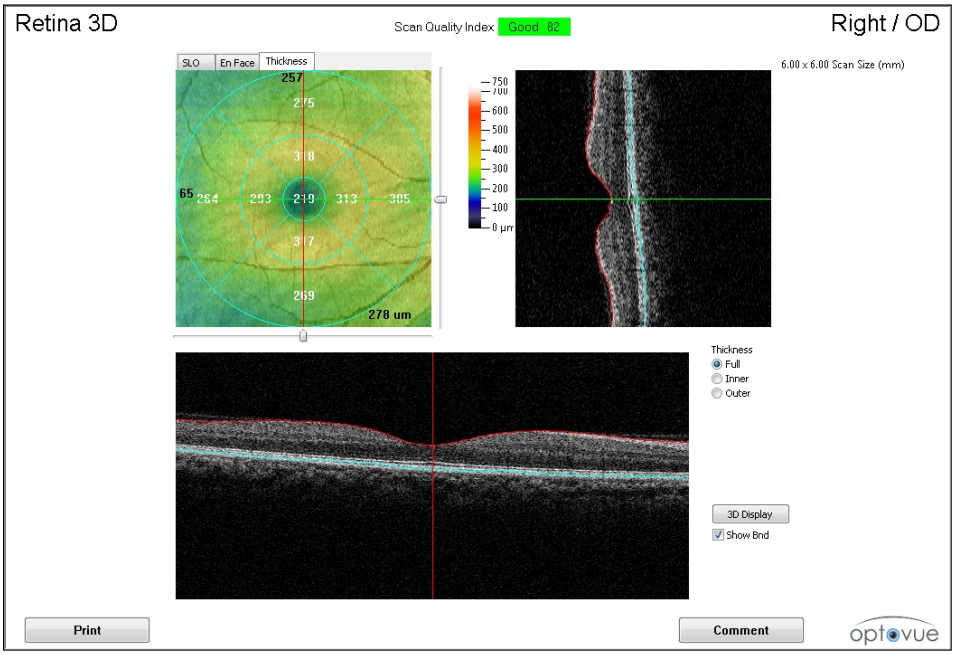


Figure 42 Retina 3D Report, Thickness Tab Selected

The image at upper left has three tabs which present different viewing options:

- **SLO**: Shows an SLO-like image created by the sum of all C-scans, producing a high contrast en face image.
- **En Face**: Shows the sum of C-scan planes indicated in the thickness value field. In this view, you can select from the **ILM, IPL,** and **RPE** radio buttons to view three different reference planes.
- **Thickness**: Shows retinal thickness using a color log scale. You can select from the **Full, Inner** and **Outer** radio buttons to view thickness in these retinal segment.

The lower panel and top right panel are the currently selected horizontal and vertical B-scans respectively, which correspond with the green (horizontal) and red (vertical) lines on the upper left image. Click anywhere (or use the sliders) on the upper left image to change the currently selected B-scans.

Click the **3D Display** button at lower right to open the 3D display.

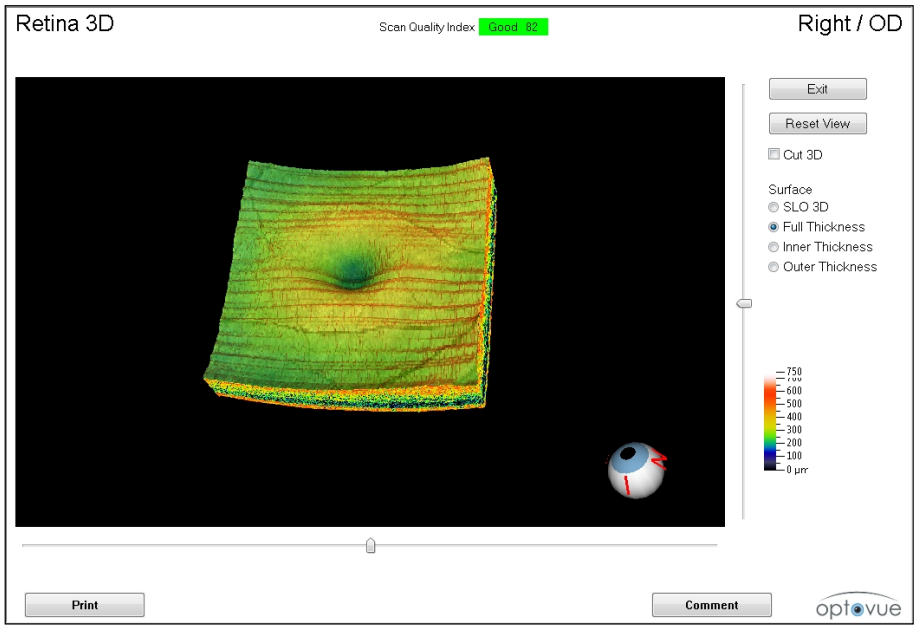


Figure 43 3D Retina Display

- Click a radio button at right to access the optional 3D views: **SLO 3D**, **Full Thickness**, **Inner Thickness** or **Outer Thickness**.
- Click and drag the 3D image to change its orientation. The eyeball at lower right moves in sync with the 3D image, and the red letters on the eyeball—**T** (temporal), **S** (superior), **N** (nasal) and **I** (inferior)—help you recognize the orientation.

- Click the 3D image and scroll with the mouse wheel to zoom the image in and out.
- Click **Reset View** to return to the default position.

6.2 Nerve Fiber ONH Report

The Nerve Fiber ONH report provides maps, a TSNIT chart and tables to enable qualitative and quantitative assessment of the retinal nerve fiber layer (RNFL) and the optic disc. All NDB software includes the basic 3D optic nerve scan for ONH scan registration. The full featured scan is available as an upgrade.

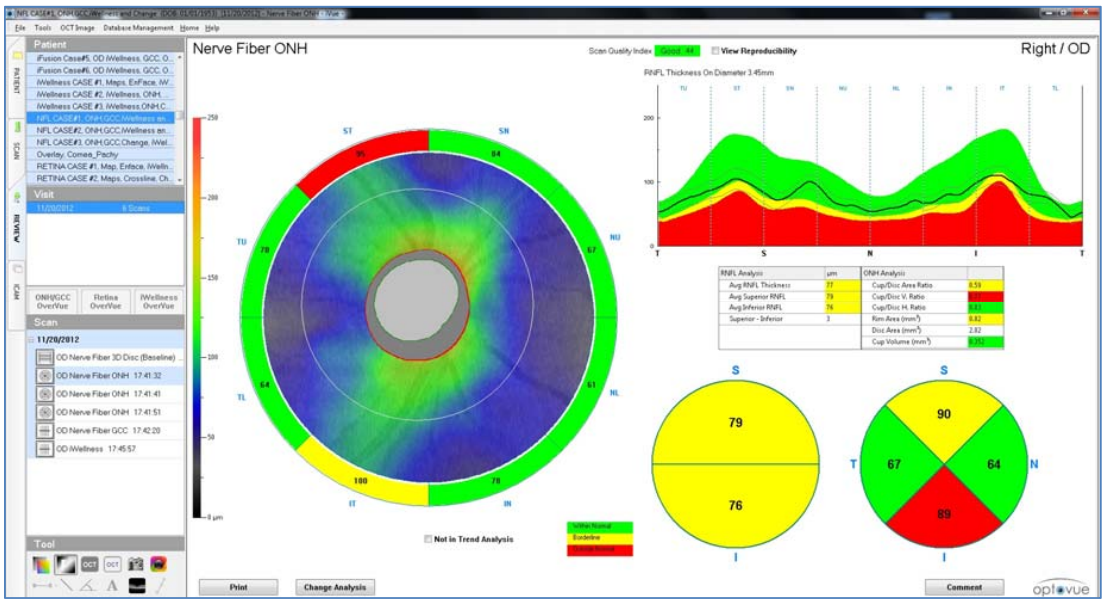


Figure 44 Nerve Fiber ONH Report

6.2.1 RNFL and ONH Analysis Table

At middle right is the RNFL and ONH Analysis table, which reports average RNFL thickness values on the left, and ONH analysis values on the right. Cell coloring reflects comparison of each value with the normative database. As the legend at bottom center shows, applicable measurement values are color-coded to show where measurements are within normal (green, p-value > 5%), borderline (yellow, p-value between 1% and 5%) or outside normal (red, p-value < 1%).

6.2.2 TSNIT RNFL Thickness Graph

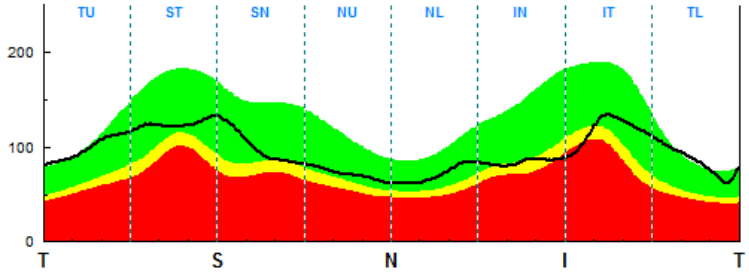


Figure 45 TSNIT RNFL Thickness Graph

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

☞ **Note:** RNFL thickness is calculated **at 3.45 mm diameter around the detected center of the disc, *not the center of the scan.*** If the disc was not centered relative to the scan beam it does not affect the measurement.

6.2.3 RNFL Thickness Map

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

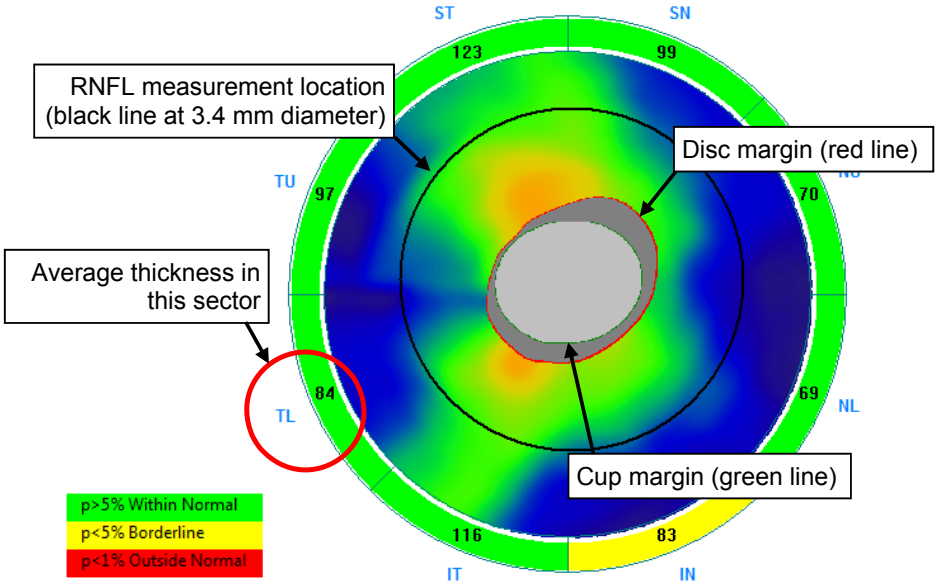


Figure 46 RNFL Thickness Map

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

6.2.4 Hemisphere and Quadrant Maps

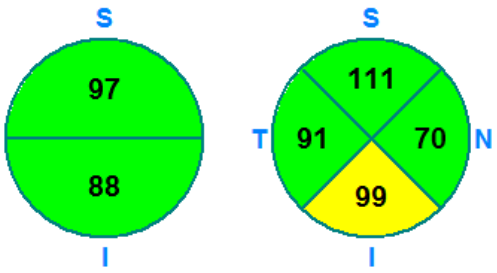


Figure 47 Hemisphere and Quadrant Maps

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

Select the **View Reproducibility** checkbox to show the calculated range of reproducibility for each thickness parameter. (The system calculates the reproducibility range of the TSNIT graph based on the measured thickness result ± 2 x [Reproducibility], where reproducibility is the standard deviation of reproducibility estimated from the iVue Reproducibility and Repeatability study—see section 11.2).

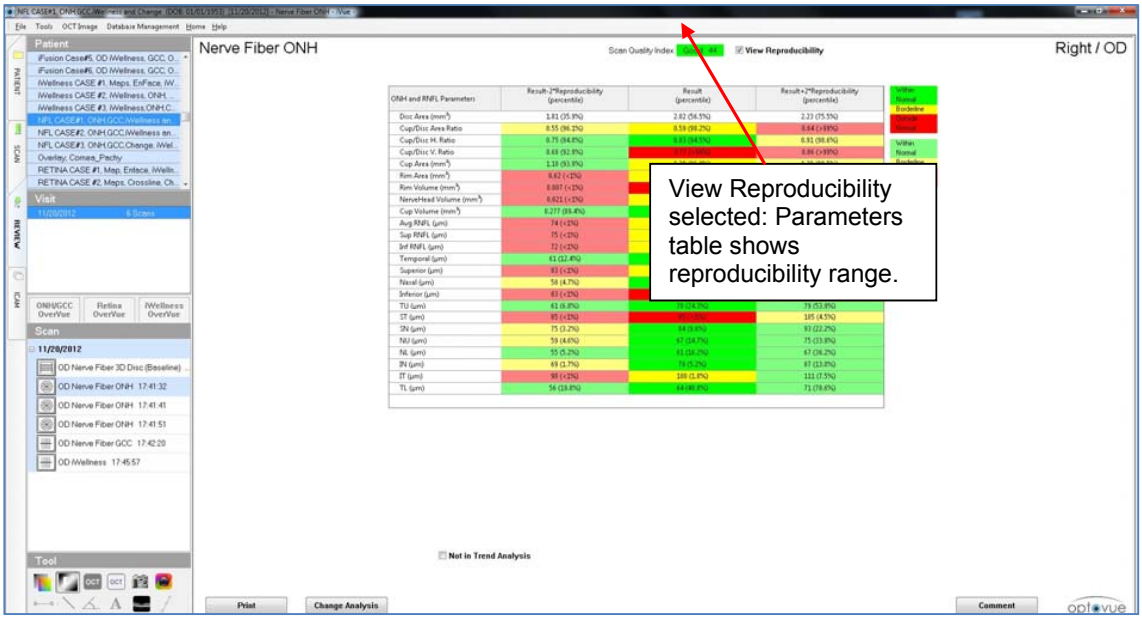


Figure 48 Nerve Fiber ONH Report Showing Reproducibility Parameter Values

6.2.5 ONH Manual Boundary Adjustment

This feature enables you to review and manually adjust the RNFL boundary lines applied by the software.

1. To manually adjust the RNFL layer boundary lines, select Modify Boundary from the **OCT Image** menu.
2. Select the desired boundary lines to modify and make adjustments on those selected scans.
3. Click **Save**, which triggers recalculation of measurements based on the new boundary lines.
4. To manually adjust the disc boundary line in the baseline image, select **Modify Disc Baseline** from the **OCT Image** menu. Make the required adjustments in the

screen. Click **Save,** which triggers recalculation of measurements based on the new boundary lines.

Note: Clean Diagnosis Data does not affect manually edited scans.

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

6.2.6 Factors that Can Affect ONH 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 automatically positions the RNFL TSNIT circle on the center of the optic disc after the scan. However, if the measurement circle falls outside the scan pattern area because the disc is too close to the edge of the scan pattern, some of the data may be missing. You should retake the scan if this occurs.

Ideally, the TSNIT circle should be centered with respect to the edge of the scan pattern. When offset from center, the widest distance between the TSNIT line and the edge of scan pattern should 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, you should manually make the necessary corrections. If the segmentation is

not accurate and you do not make the correction, the results will be affected. If you perform manual correction, the results will be valid and the scan can be used.

6.3 Nerve Fiber ONH Change Analysis

The **Change Analysis** button is available on the Nerve Fiber ONH report when ONH scans have been taken on three or more visits. Click this button and the system displays the Nerve Fiber ONH Change Analysis report; when the patient record includes both ONH and GCC scans, the system displays the Nerve Fiber ONH/GCC Change Analysis Report (see section 6.5.4). The **Nerve Fiber ONH Change Analysis** report appears as below when you have ONH scans from only two visits. It shows data from the previous scan on top and the recent scan on the bottom.

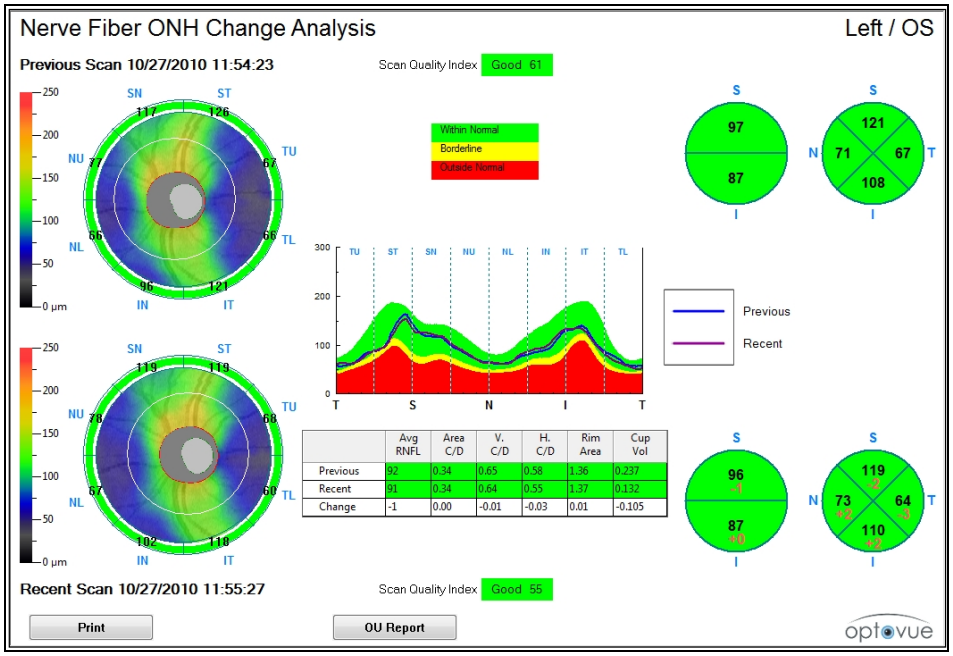


Figure 49 Nerve Fiber ONH Change Report, 2 Visits

The Nerve Fiber ONH Change Analysis report includes most elements of the Nerve Fiber ONH report side by side for each scan (see page 73).

Note: Change values in the bottom row of the table are simple differences that may not be statistically or clinically significant. The single-scan values are the same as in the Nerve Fiber ONH Analysis.

After three visits, the change analysis report changes, displaying up to four visits and an RNFL rate of change graph, as shown below.

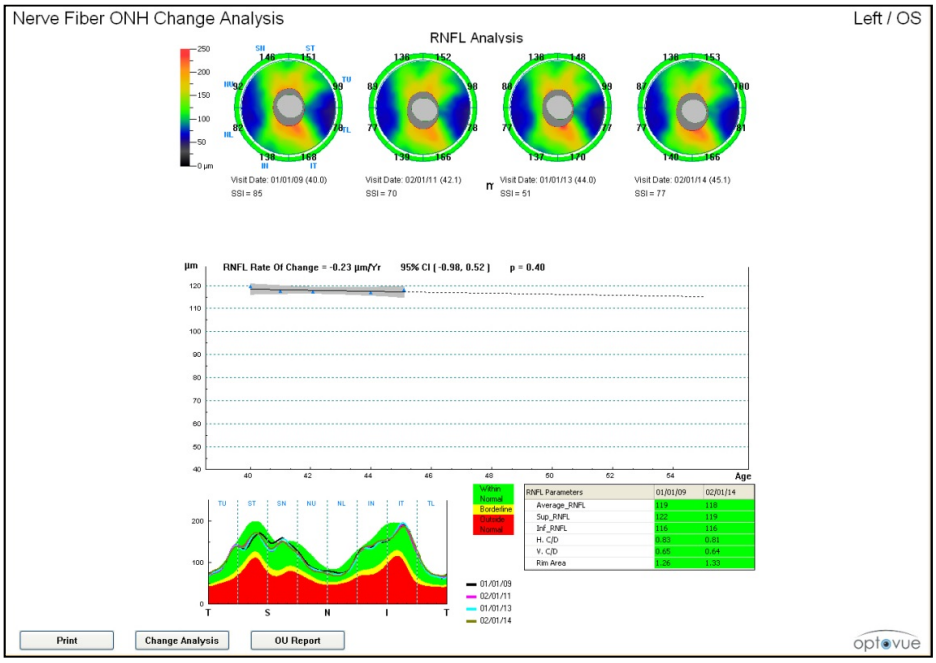


Figure 50 Nerve Fiber ONH Change Analysis, 4 Visits

The report shows up to four Nerve Fiber ONH change analysis visits when there is no GCC data available, as shown above. Recall that when the patient record includes both ONH and GCC scans, the system displays the Nerve Fiber ONH/GCC Change Analysis Report (see section 6.5.4). The report includes:

- The RNFL thickness map for each eye on top
- An RNFL Rate of Change graph in the middle plotting average RNL thickness over time. Above the graph appears the estimated rate of change (in µm) per year, the range of the 95% confidence interval in brackets, and its p-value. 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. 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.
- At lower left, the TSNIT RNFL thickness graph with different colored lines for each visit
- At lower right, an RNFL Parameters table that gives both RNFL thickness and disc-related values, with cells colored relative to the normative database.

6.3.1 Nerve Fiber ONH OU Report

The **OU Report** button is available when the patient record includes Nerve Fiber ONH scans for both eyes. Click the **OU Report** button to generate the Nerve Fiber ONH OU report. This report has all the same elements as the Nerve Fiber ONH Report and includes comparisons between the eyes.

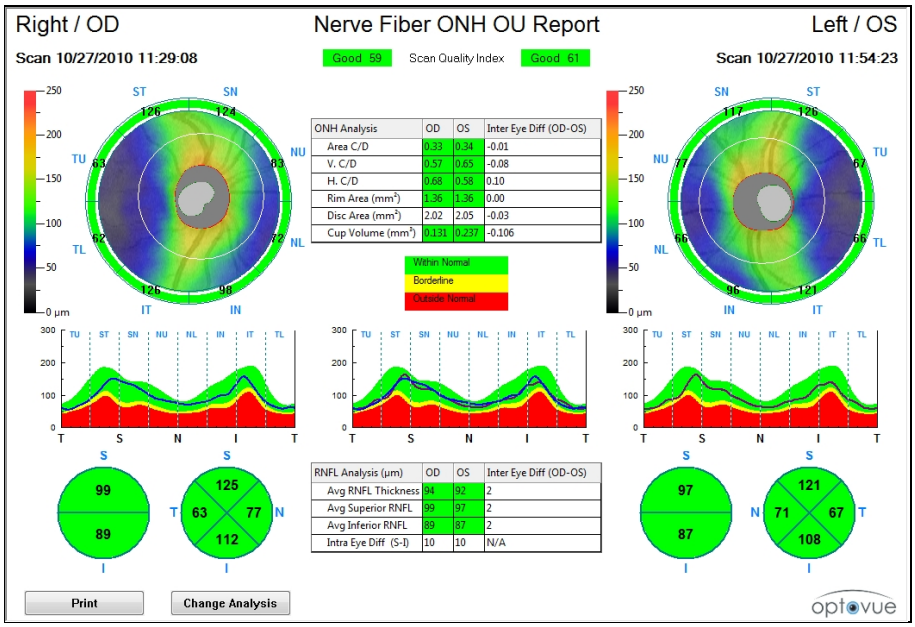


Figure 51 Nerve Fiber ONH OU Report

6.3.2 Nerve Fiber ONH/GCC OU Report

When the patient record includes both ONH and GCC scans for both patient eyes, clicking the **OU Report** on the Nerve Fiber ONH report and the Nerve Fiber GCC report both open the Nerve Fiber GCC OU Report. You can select from the Visits list on the left which ONH and GCC scans to include, and then click the **OU Report** button to show the report.

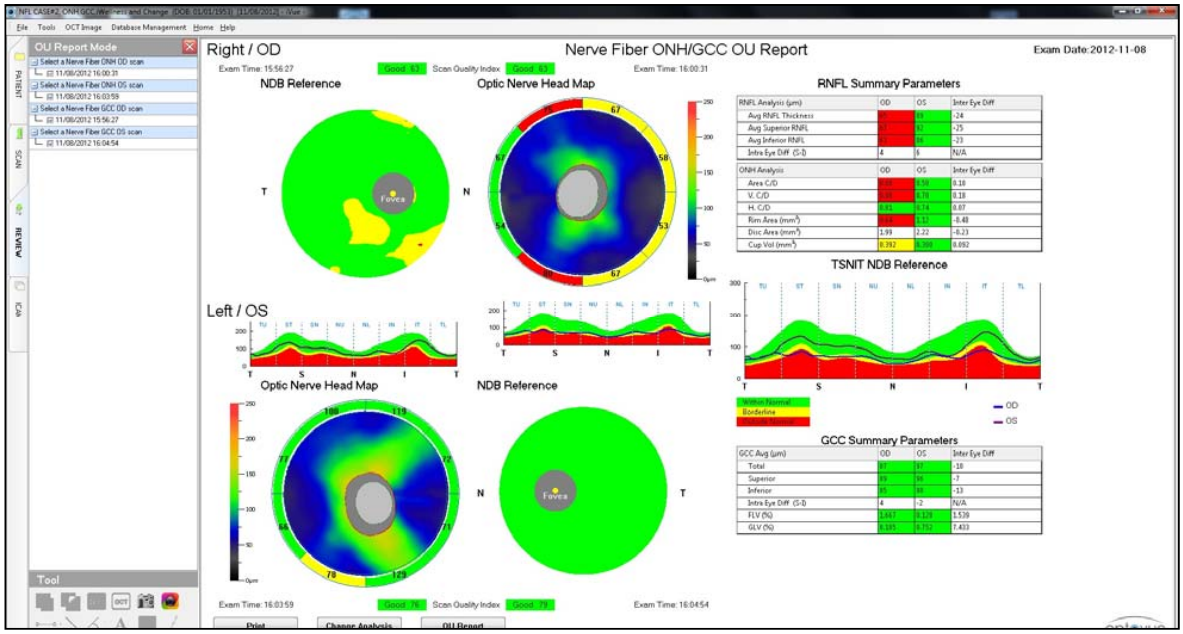


Figure 52 Nerve Fiber ONH/GCC OU Report

6.3.3 Verify or Adjust RPE Anchor Points

For the ONH scan only, the system automatically identifies the RPE anchor points (also called end points or RPE tips). However, you can review and verify or adjust placement of the anchor points. To do so, right-click on the ONH report and select **Modify RPE Anchor Points**. The system displays one pair of scan images with yellow RPE anchor points. It is sufficient to verify or adjust the anchor point placement on only one image pair (out of the six pairs of radial scans taken). Use the arrow buttons to the right of the images to select the desired pair. If you make adjustments, you must click **OK** while the adjusted pair is on screen for the adjustment to be saved. If you move to another pair and click **OK**, the adjustment will not be saved.

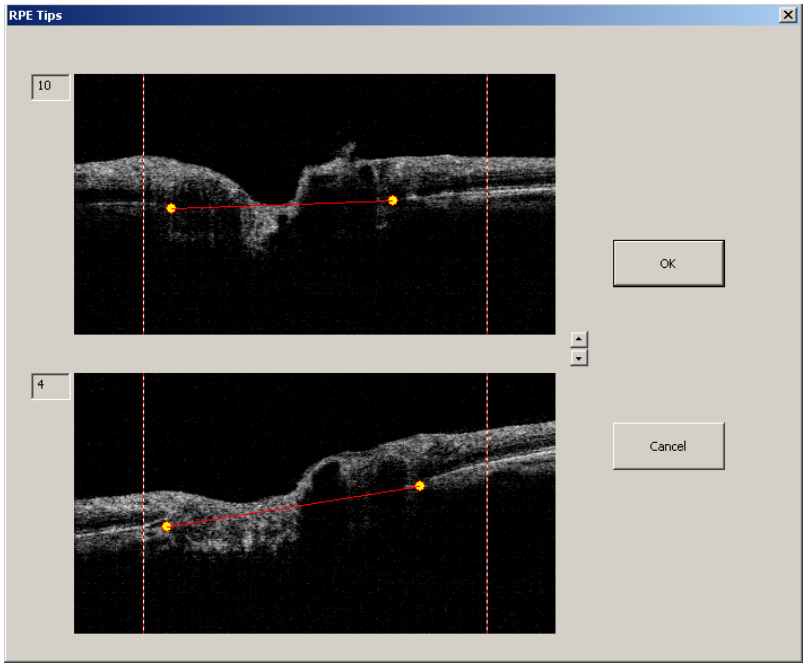


Figure 53 Verify or Adjust RPE Tips

6.4 Nerve Fiber 3D Disc Report

Note: On the iScan Neuro system, descriptions of the 3D Disc scan and report still are present because the system prompts you to take a 3D Disc scan for

use as the baseline for the ONH scan. The 3D Disc baseline scan is required for comparisons of the ONH scan to the normative database.

The ONH 3D Disc scan is presented very similarly to the 3D Retina scan. At upper left is the SLO image, where you can view and modify the disc margin drawing for the 3D Disc scan. The image below shows the different presentation controls.

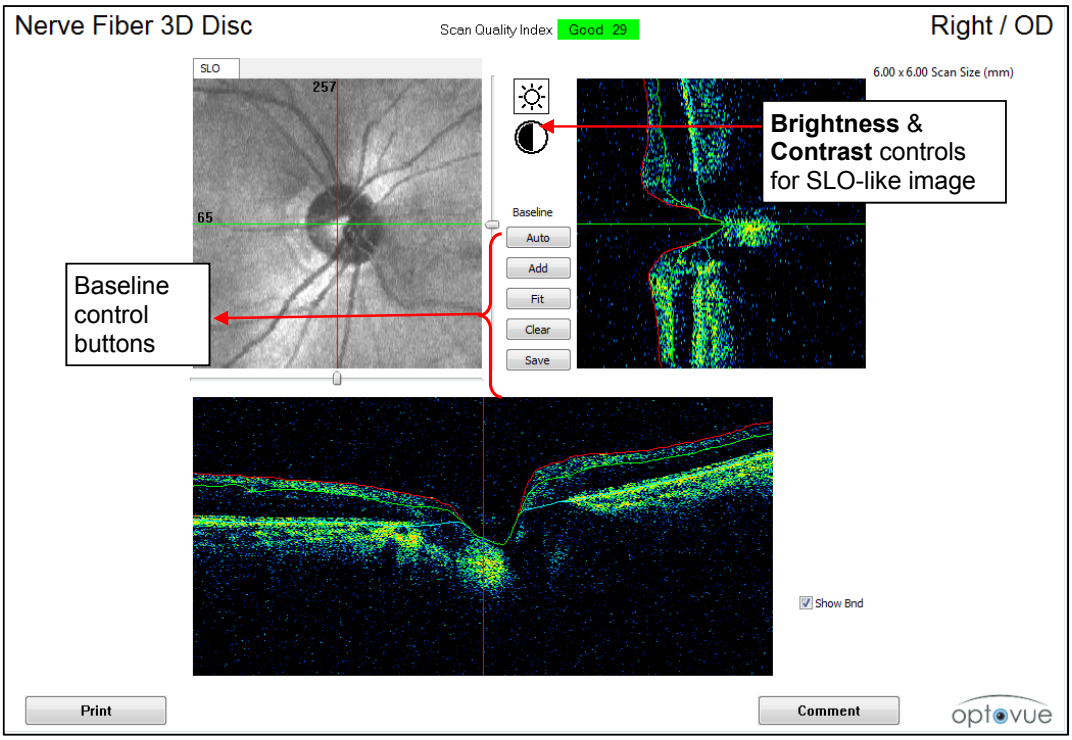


Figure 54 Nerve Fiber 3D Disc Report

6.4.1 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: Click anywhere on the SLO image to select the horizontal (green line) and vertical (red line) B-scans displayed at bottom and right, respectively.

3D Fundus En Face

(8x8 mm 3D Fundus Enface – 385 x141) One Enface window and One NFL thickness map window to visualize the nerve fiber over the superior and inferior arches

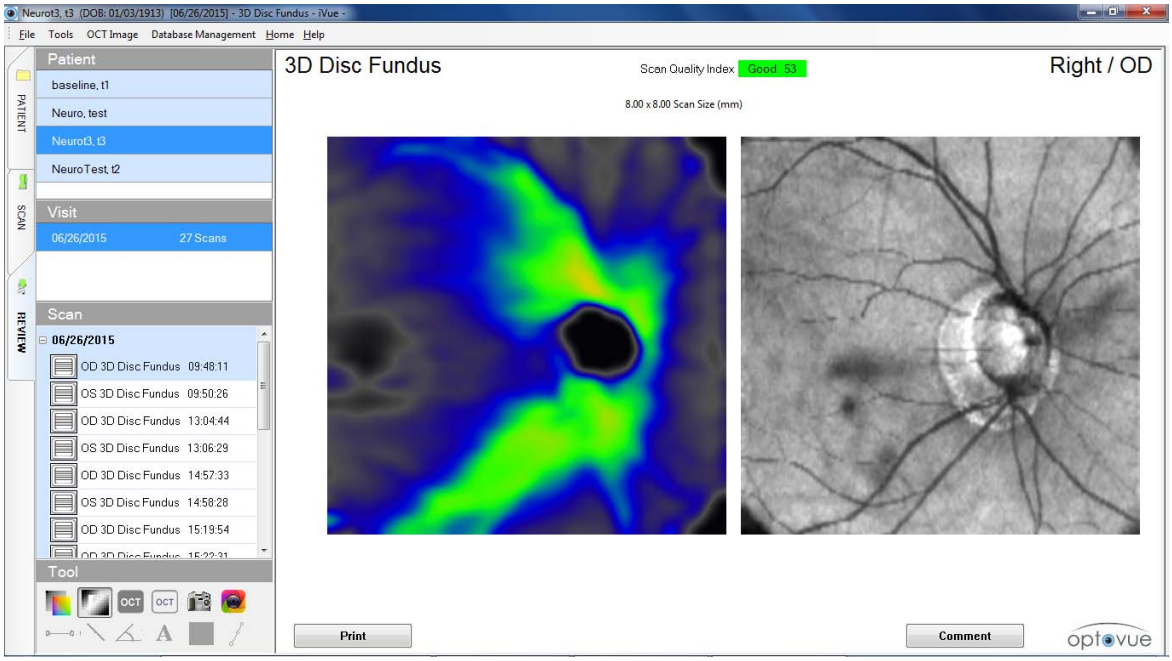


Figure 55 3D Fundus En Face

6.4.2 Verify or Modify Disc Baseline

For 3D Disc scans, the system automatically calculates and draws the outline of the optic disc to be used as the baseline. However, you can verify or modify the disc baseline. To do so, select the **Modify Disc Baseline** in the **OCT Image** menu. A disc image showing the automatically drawn baseline appears.

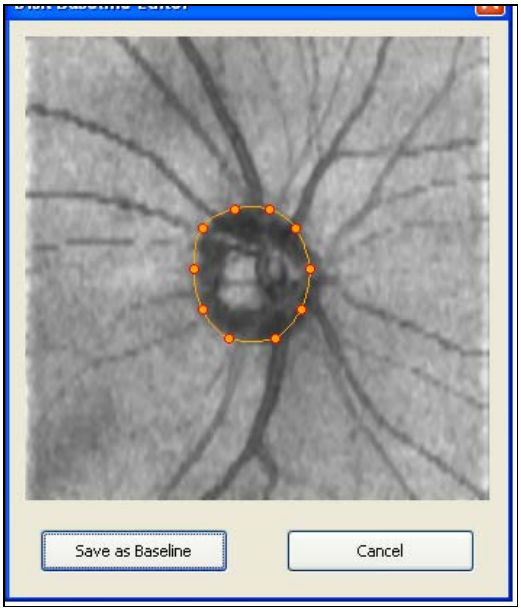


Figure 56 Modified Disc Baseline

Click and drag the anchor points to modify the disc outline used as baseline. When you are finished, click **Save as Baseline** to save the changes.

☞ **Note**: The Nerve Fiber 3D Disc scan is the preferred source of the disc baseline for the ONH scan. If an ONH scan was captured before a Nerve Fiber 3D Disc scan, the disc baseline is based on the ONH scan until a Nerve Fiber 3D Disc scan is captured. At that point, the data is reprocessed.

☞ **Note:** NDB comparison is only available when disc margin is derived from a 3D Disc scan.

Normative database references for the 3D Disc report may not be valid if motion artifacts are present in or near the disc. You can recognize motion artifacts by disconnected/distorted blood vessel patterns or heavy black horizontal lines.

When viewing the editor, note whether the baseline is based on an ONH or 3D scan. For example, if the baseline is based on a 3D scan, the disc baseline may be displayed in the wrong location in the ONH disc baseline editor. In this scenario, the shape of the baseline is correct but located off center relative to the disc. To properly edit the baseline, view and edit the original baseline scans.

6.5 Assessing the GCC

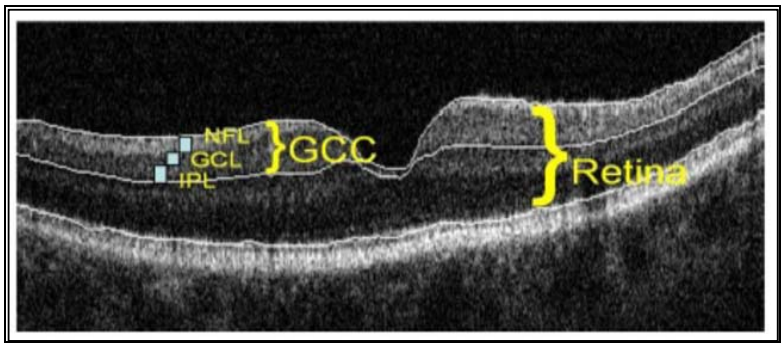


Figure 57 The GCC and Its Layers

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

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

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

6.5.1 Nerve Fiber GCC Report

The Nerve Fiber GCC report includes a GCC thickness map, and NDB reference map, an en face image, an OCT image and a thickness and volume parameters table to support qualitative and quantitative assessment of the GCC. The elements are described below.

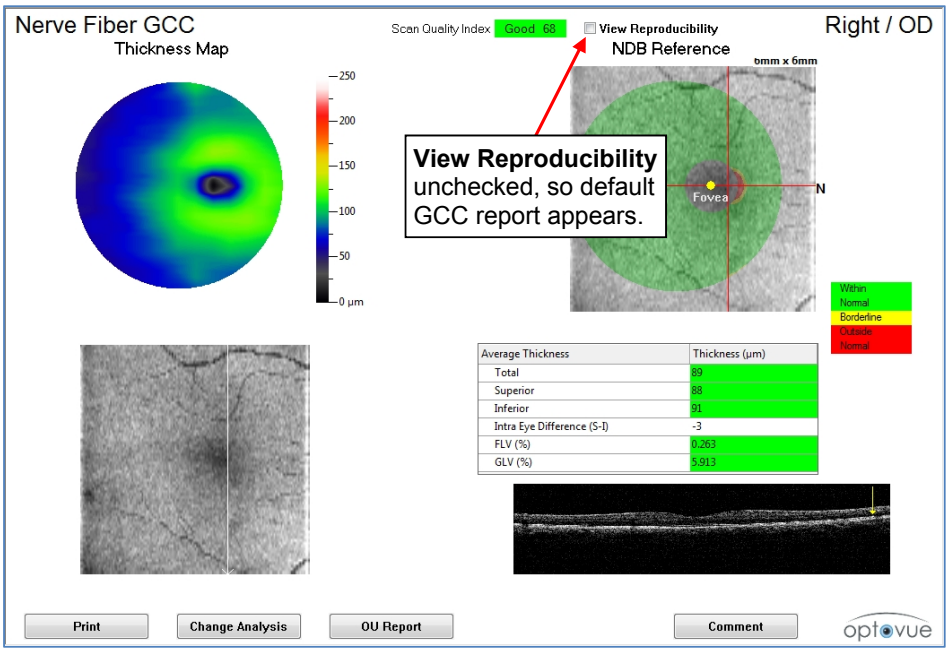


Figure 58 Nerve Fiber GCC Report

GCC Thickness Map

At upper left appears a GCC Thickness Map. This map is 6 mm diameter and uses a color scale to indicate thickness. The color key next to the maps explains the values (in µm) associated with the colors. Warmer colors from yellow, orange and red to white represent greater values. Cooler colors from green to blue to black represent lesser values.

The GCC map for a normal eye shows a broad sweep of bright color around the fovea, indicating a GCC with healthy ganglion cells (healthy eye at left in Figure 59). (The fovea has no ganglion cells and therefore shows darker color.) In glaucoma, the GCC thins as ganglion cells are lost; consequently, the extent of bright color around the fovea contracts (glaucoma eye at right in Figure 59).

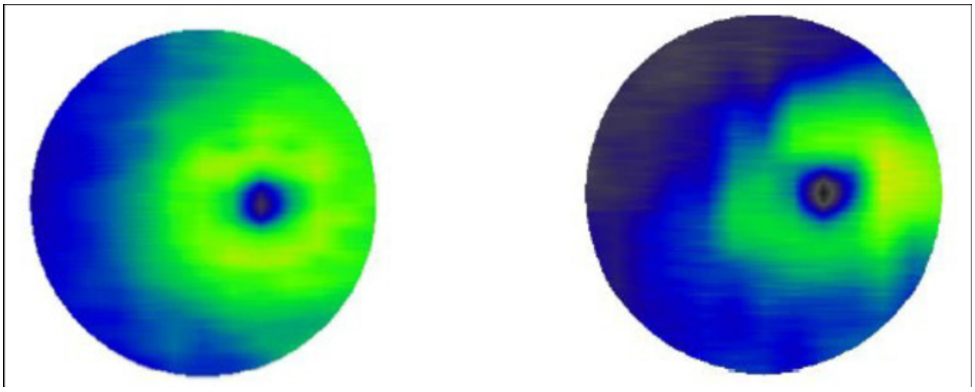


Figure 59 GCC Thickness Maps: Healthy Eye (Left), Glaucoma Eye (Right)

NDB Reference Map

At upper right, a color-coded NDB Reference Map (overlying the en face image) shows regions where thickness is normal (green), borderline (yellow) and outside normal (red). The grey circle around the fovea is to exclude reference to normative data colors because this region lacks ganglion cells.

Thickness and Volume Parameters Table

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

- **Average GCC thickness** (in µm) overall (Total), in the superior and inferior hemispheres, and the difference in average between the superior and inferior hemispheres. GCC thickness is measured from ILM to IPL. Each measurement appears against a green, yellow or red background, indicating whether the

measurement is within normal (green), borderline (yellow) or outside normal (red).

- **FLV (%) Focal Loss Volume** quantifies the amount of significant GCC loss. FLV is expressed as a percentage of the map area with significant ganglion cell loss (by volume). Early study results indicate that FLV may be the most accurate parameter to distinguish glaucoma eyes from normal eyes, better than overall average GCC thickness.
- **GLV (%) Global Loss Volume** quantifies the average amount of GCC loss over the entire GCC map. GLV is the sum of the pixels where the fractional deviation map value is < 0, divided by the total map area to give a percent loss of GCC thickness.

Note: If you change the age of the patient, you must manually refresh the GCC scan to reflect the correct FLV% and GLV% values. Do this by either right clicking the scan and selecting **Reprocess Data**, or selecting **Clean Diagnosis Data** from the **File** menu. Refer to section 7.1.7 for more information on how to clean diagnosis data.

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

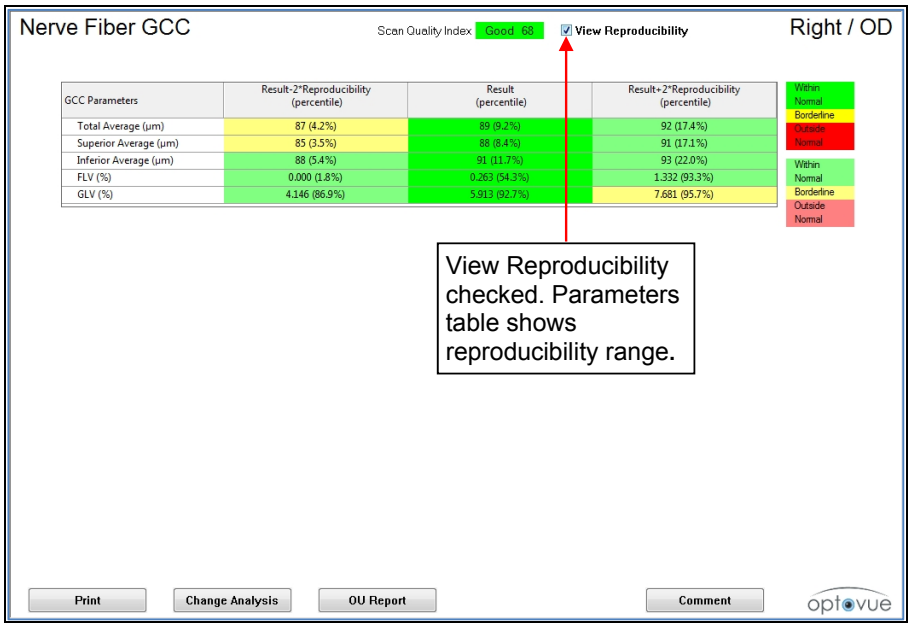


Figure 60 Nerve Fiber GCC Report with Parameters Table

B-Scan Display

The B-scan at lower right is the currently selected vertical B-scan. The red lines on the NDB Reference Map at upper right indicate the currently selected scan lines of the GCC scan pattern, which correspond to the B-scan shown at bottom right.

- When you click on the NDB Reference Map, the red lines change to blue and the vertical lines move to where you click. The vertical line then follows the pointer until you click again, and the lines turn back to red. While you move the vertical blue line, the B-scan also updates to show the B-scan at that location.

6.5.2 Nerve Fiber GCC Change Analysis

The GCC Change Analysis compares two visits only. The GCC scan registers the fovea to support accurate registration (alignment) of GCC scans during comparison. Check the fovea location on the NDB Reference map, shown as a yellow dot. It should be about 1 mm off center toward the nasal side, and aligned with the red lines. If the fovea is greatly off center, exclude it from change analysis. It is not possible to change the fovea location in the GCC scan. If the patient has retina-based pathology, the scans may not align correctly.

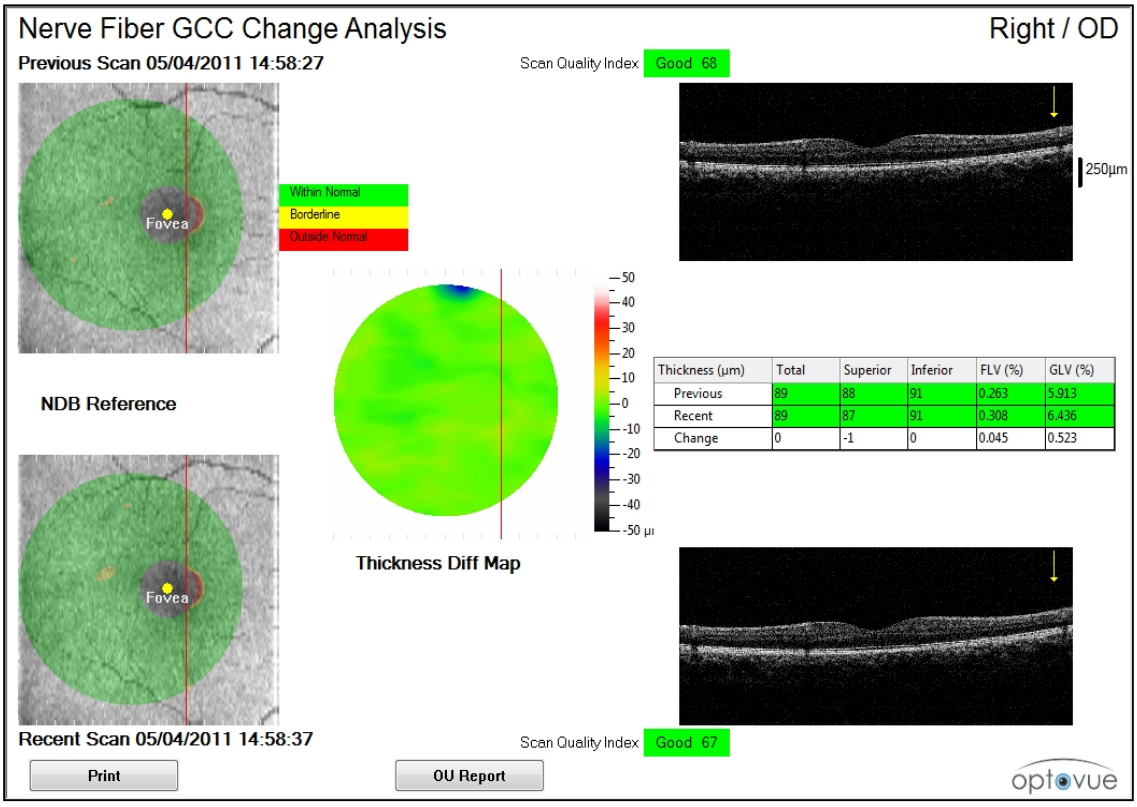


Figure 61 Nerve Fiber GCC Change Analysis

The report includes:

- On the left side, a color-coded **NDB Reference** map overlaid on the retinal en face image for each visit. As the legend to the right explains, green means within normal, yellow means borderline and red means outside normal with respect to the normative database for GCC thickness,
- In the middle of the report, a **Thickness Difference Map** shows thickness differences (in µm) between visits using a color scale, the legend for which is just to the right.
- On the right side for each visit is the B-scan corresponding to the red vertical line on the GCC thickness map. Use the mouse wheel to scroll through the B-scans.
- A table at right center shows GCC thickness values and change between visits.

In the case of multiple visits when no ONH data is available, a Nerve Fiber GCC Change Analysis shows a GCC thickness map for each visit at the top, a GCC Rate of Change analysis in the middle, and a table showing average GCC thickness for the first and last visits compared to the normative database.

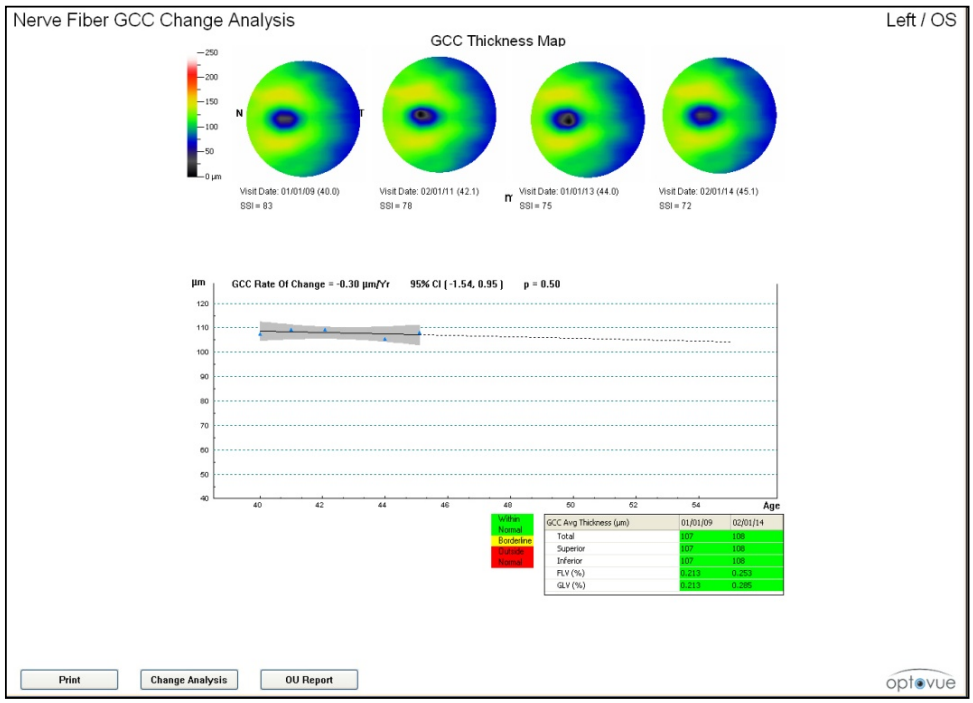


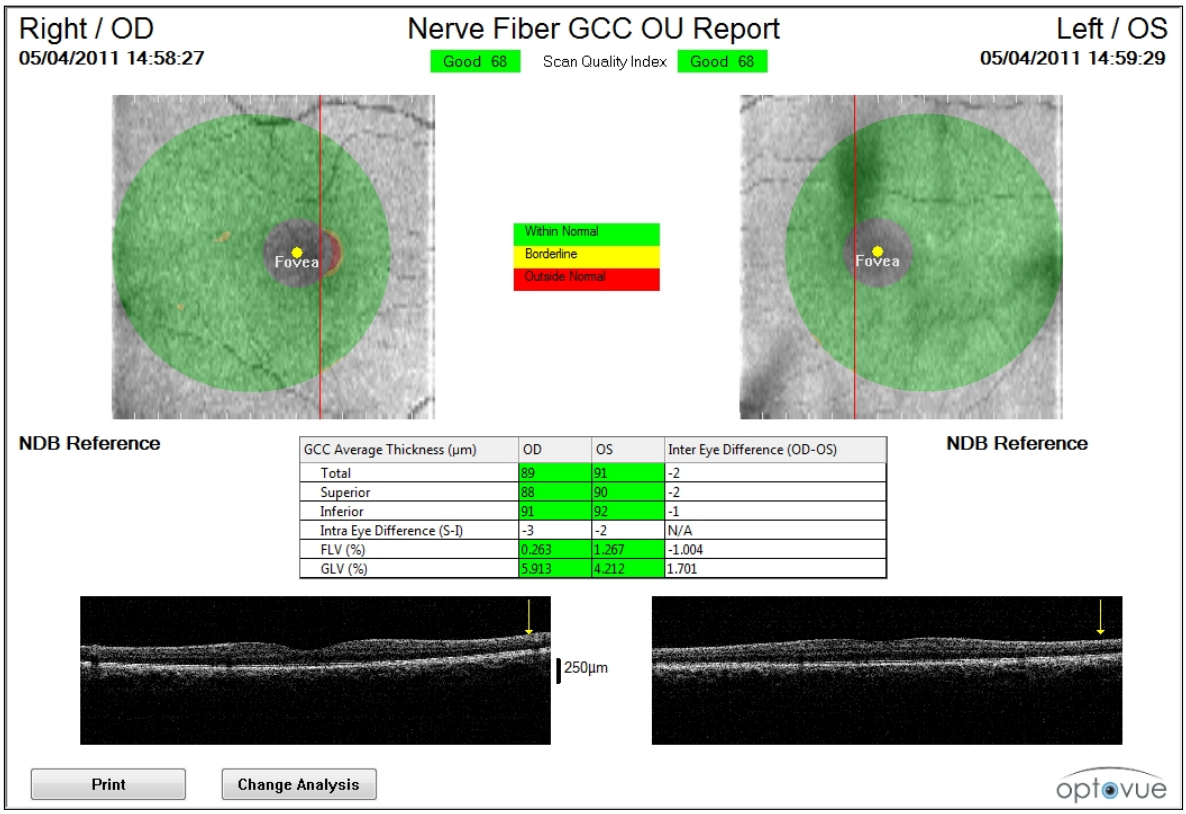
Figure 62 Multi-Visit Nerve Fiber GCC Change Analysis

Above the GCC Rate of Change graph appears the estimated rate of change (in µm) per year, the range of the 95% confidence interval in brackets, and its p-value. 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. 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.

6.5.3 Nerve Fiber GCC OU Report

When the patient record includes GCC scans for both eyes, clicking the **OU Report** button generates a Nerve Fiber GCC OU Report. This report supports assessment of symmetry between eyes. At the top are the NDB Reference Maps for each eye. In the middle, the same thickness and volume parameters table as described above (see page 88) and also includes inter-eye differences. At bottom are the vertical B-scans corresponding to the red line on the NDB reference map for each eye. Click and drag the red line or scroll on the map to change the current B-scan shown.



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 63 Nerve Fiber GCC OU Report

6.5.4 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 six visits for the current patient eye.

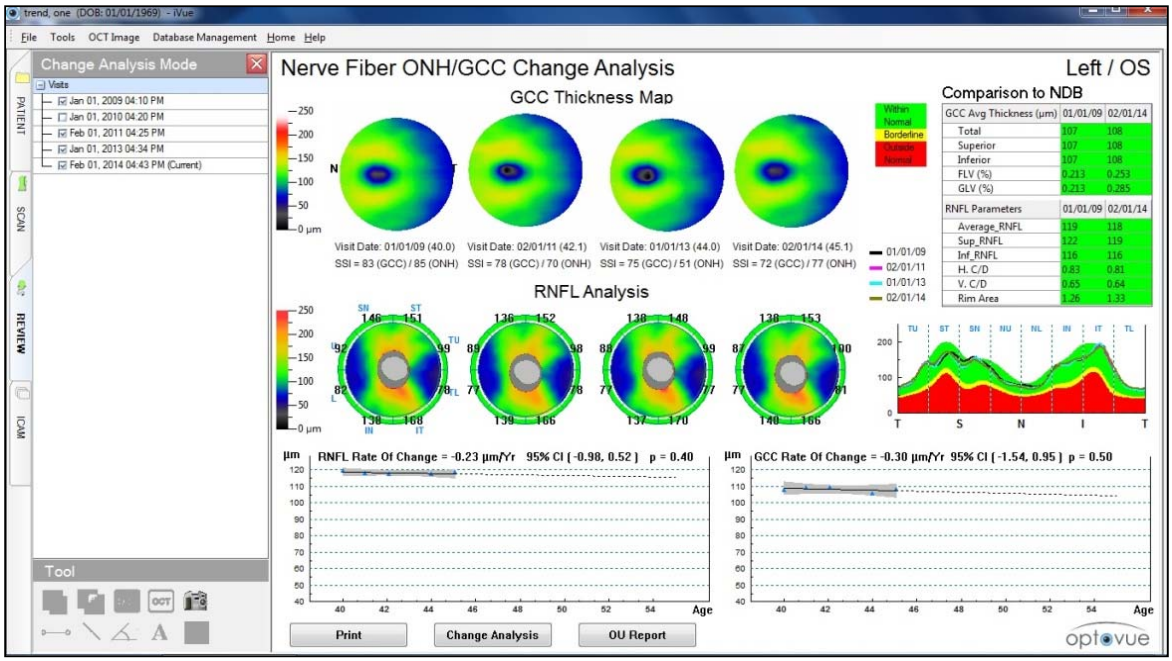


Figure 64 Nerve Fiber ONH/GCC Change Analysis Report

- **Thickness Maps:** At upper left and center, 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. This information helps you assess the status of the eye relative to normal eyes over the time span between the first and last visit.
- **TSNIT Graph:** At middle right is a TSNIT graph displaying RNFL thickness at each visit. The TSNIT graph helps you assess RNFL thickness around the eye relative to the normative database, as well as consistency and regions of change between visits.
- **Rate of Change Graphs:** At bottom are graphs that plot age versus RNFL thickness (left graph) and GCC thickness (right graph). 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 followup 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 followup, 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.

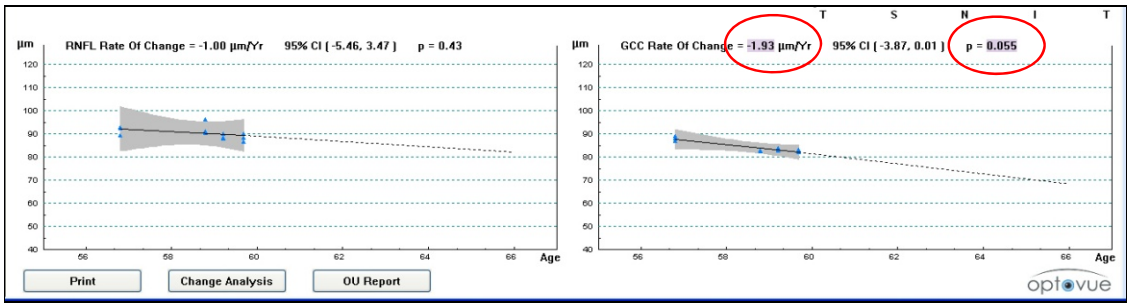


Figure 65 Marginally Significant Change

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.

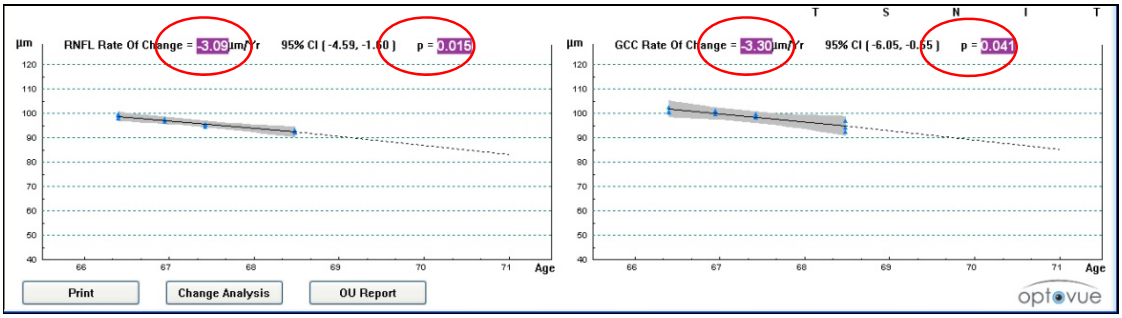


Figure 66 Statistically Significant Change

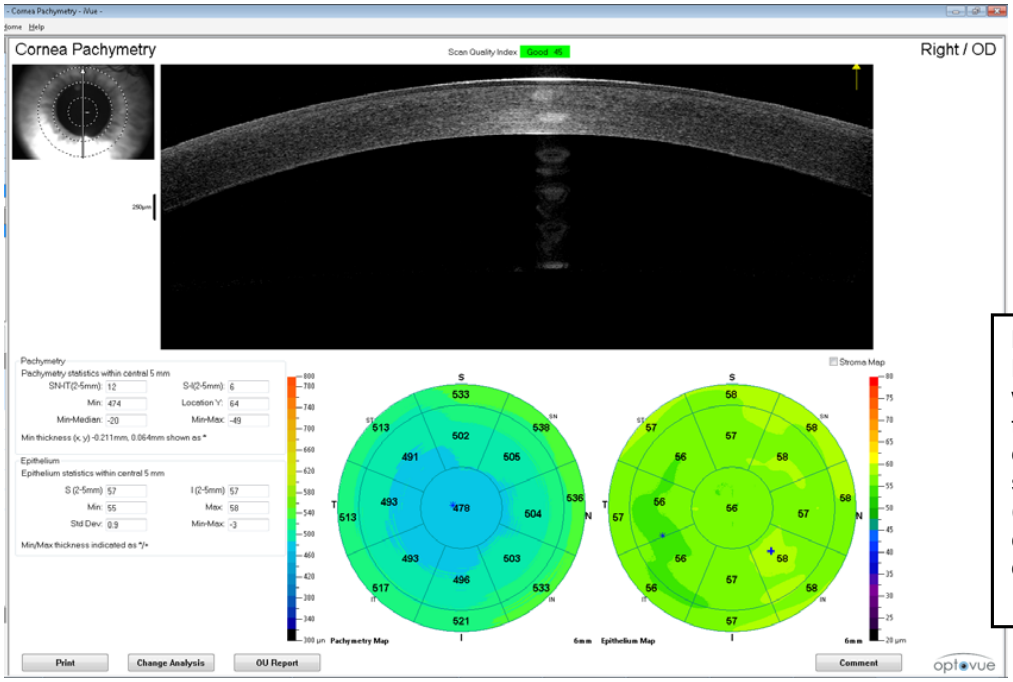
The rate of change, if estimated with high reliability, could be used to estimate RNFL and GCC thickness measurements in future years. For example, a rate of -3 µm/year could mean loss of 30 µm of thickness in 10 years if it continues at the same rate. For reference, based on the OCT normative database (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.

6.6 Cornea Report

Note: Epithelial mapping is not available for sale in the USA

6.6.1 Cornea Pachymetry Report

The Cornea report includes the OCT image on top, a Pachymetry and Epithelium Assessment table below to the left, and a pachymetry and Epithelium maps showing corneal thickness at lower right.



Pachymetry & Epithelial map with average thickness in each of 17 sections (including center) to 6 mm diameter.

Figure 67 Cornea Pachymetry Report Manual Boundary Adjustment

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.

1. 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**.

2. 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.
- Precision (repeatability and reproducibility of cornea thickness measurements in the central 0-2 mm for normal and cornea [pathology] patients): See the following table.

Table 1 Precision for Normal and Cornea Patient Scans

Central Cornea 0-2 mm	Normal Patients	Cornea Patients
Number of Scans	70	72
Overall Mean (Overall SD)	549.83 (20.85)	531.80 (48.20)
Repeatability SD* (Min, Max)	1.71 (1.71, 1.71)	3.58 (3.58, 3.58)
Reproducibility SD (Min, Max)**	1.71 (1.71, 1.71)	14.52 (14.52, 14.52)

* Standard deviation estimate among measurements taken on same subject using same operator and device in same testing session with repositioning.
** Standard deviation estimate among measurements taken on different subjects using different operators and devices, including repeatability; in some cases maximum reproducibility estimates were impacted by mean thickness difference between subjects in different sites.

6.6.2 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.)

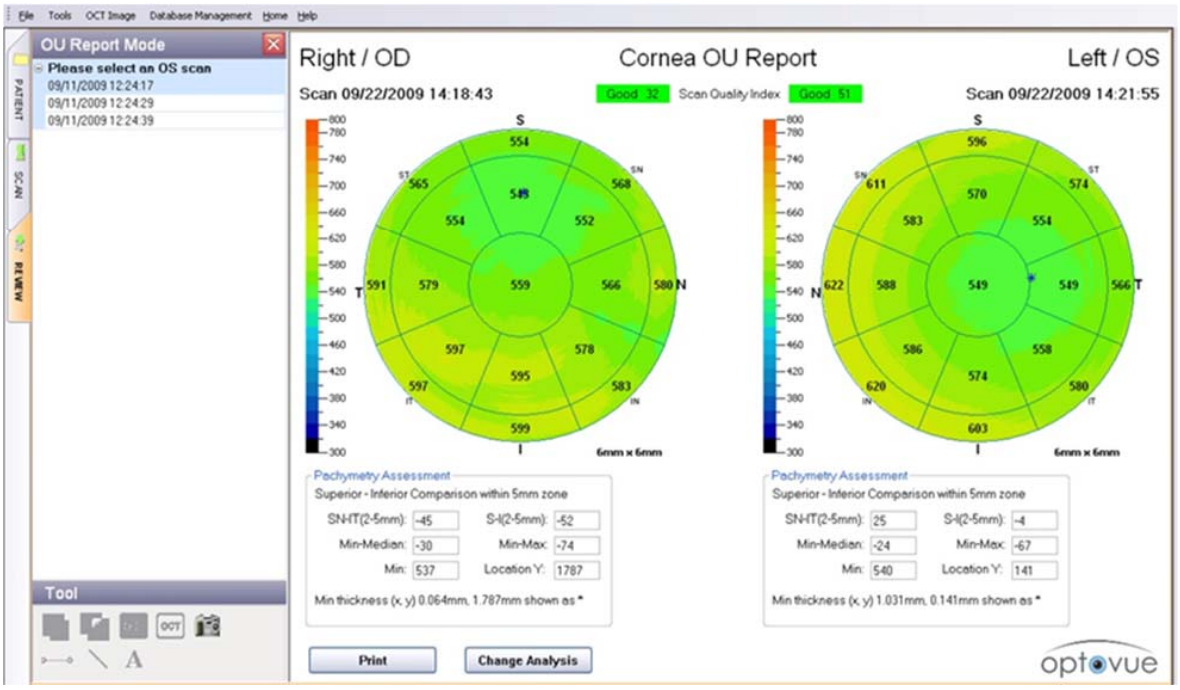


Figure 68 OU Report for Cornea Scan

6.6.3 Pachymetry & Epithelium 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.)

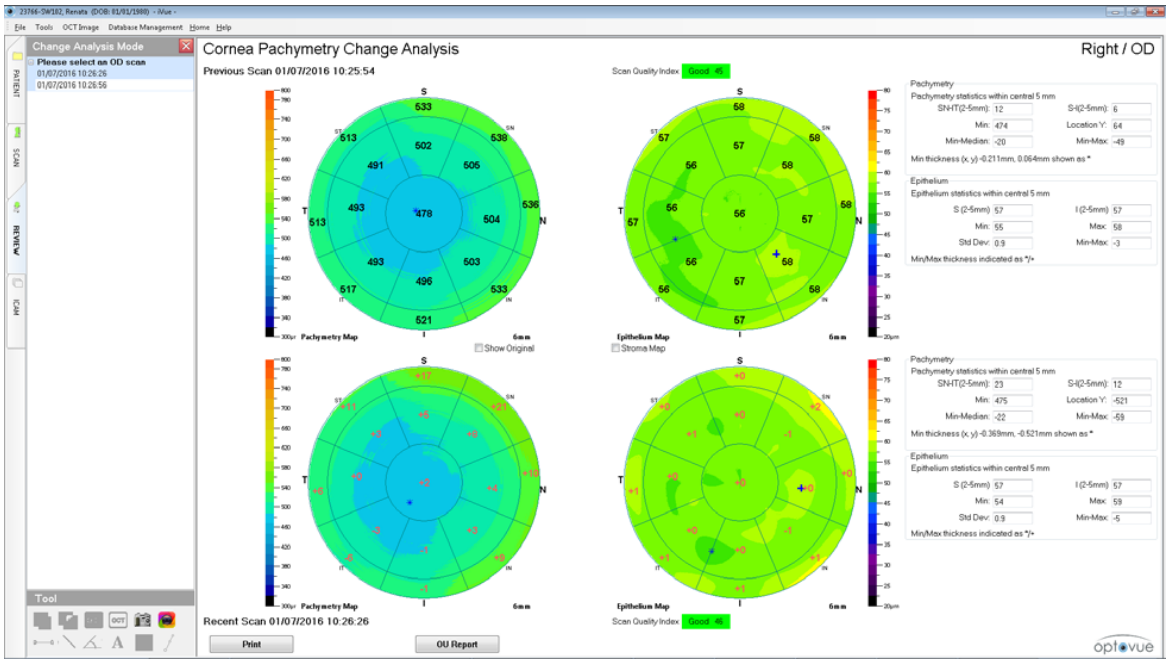


Figure 69 OU Report for Pachymetry & Epithelium

6.6.4 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 cornea 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.

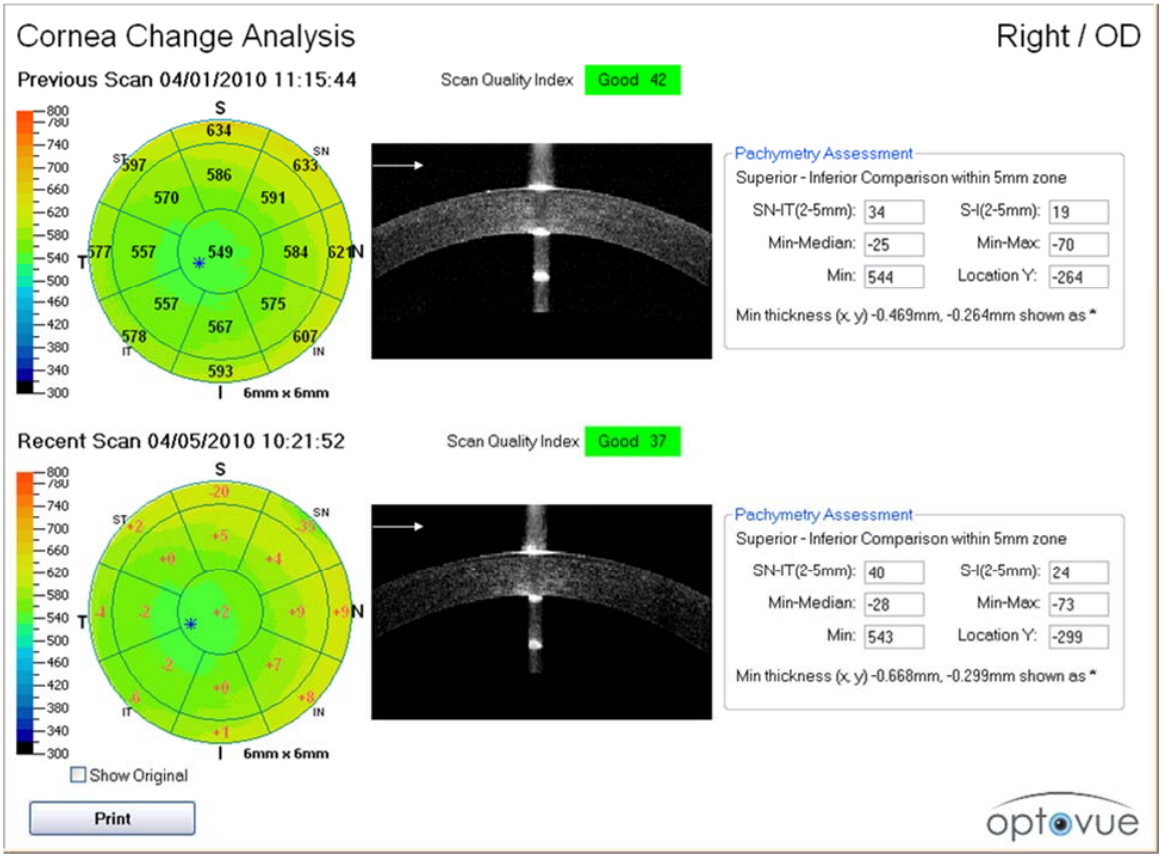


Figure 70 Cornea Change Analysis Report

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.

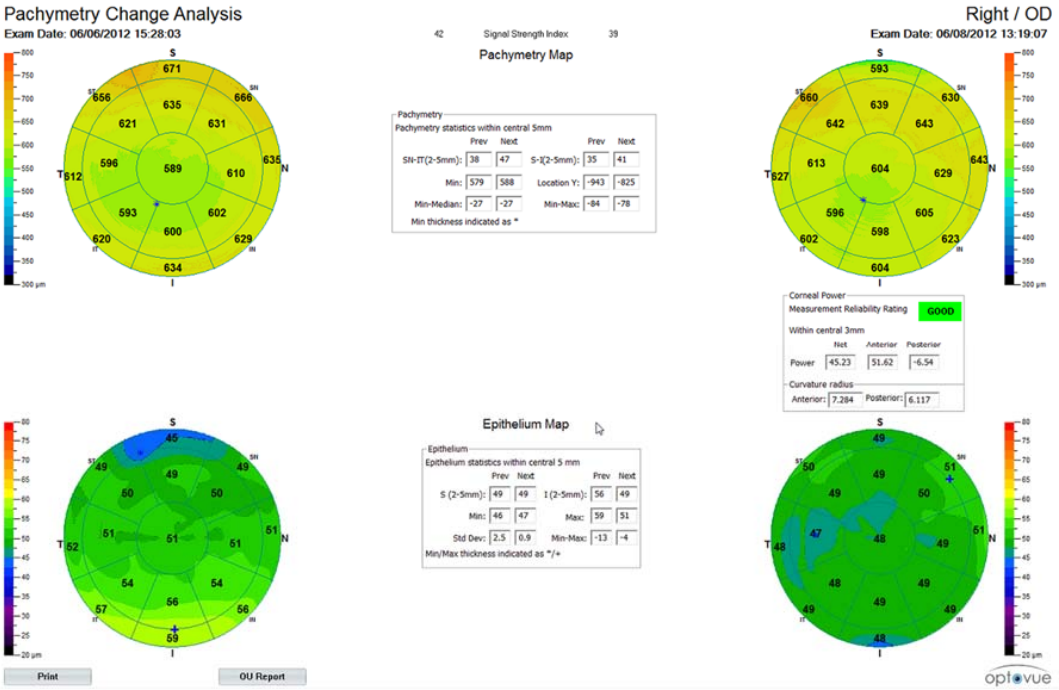


Figure 71 Change report for Pachymetry & Epithelial

6.6.5 Lens fitting Report

The Lens fitting Report maps the clearance (Vault) space between the posterior surface of the scleral lens and the anterior surface of the Cornea 6mm.

The index of refraction must be entered to see the results. The clearance assessment statistics 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.

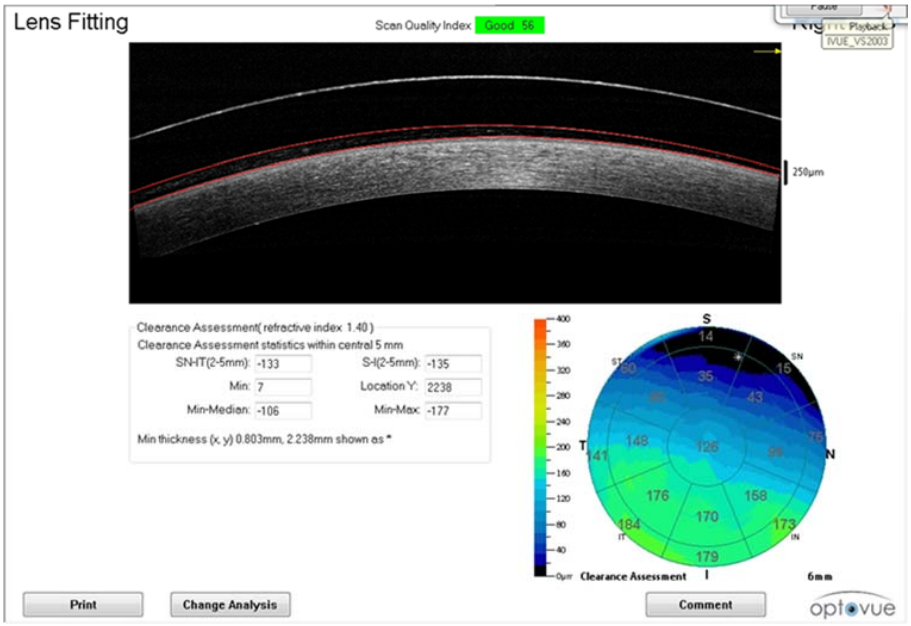


Figure 72 Lens Fitting Report

6.6.6 Lens Fitting-Clearance Assessment Change Analysis

Change between clearance maps of Lens fitting exams

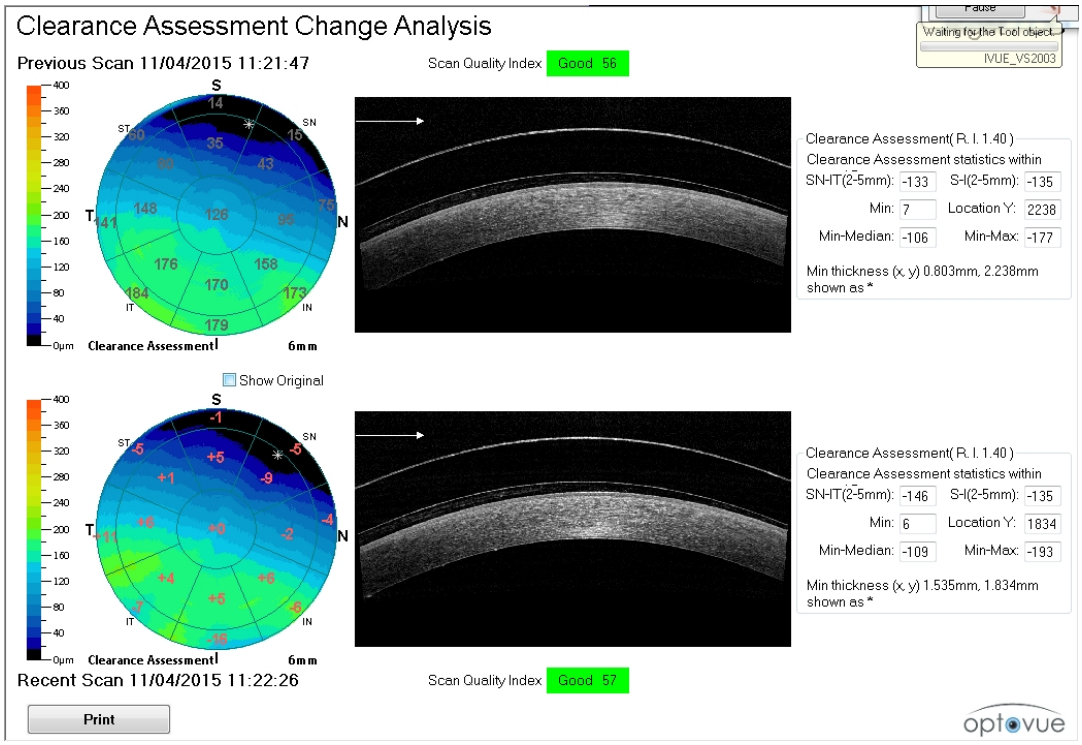


Figure 73 Change between clearance maps of Lens fitting exams

6.6.7 Cornea Angle Report

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

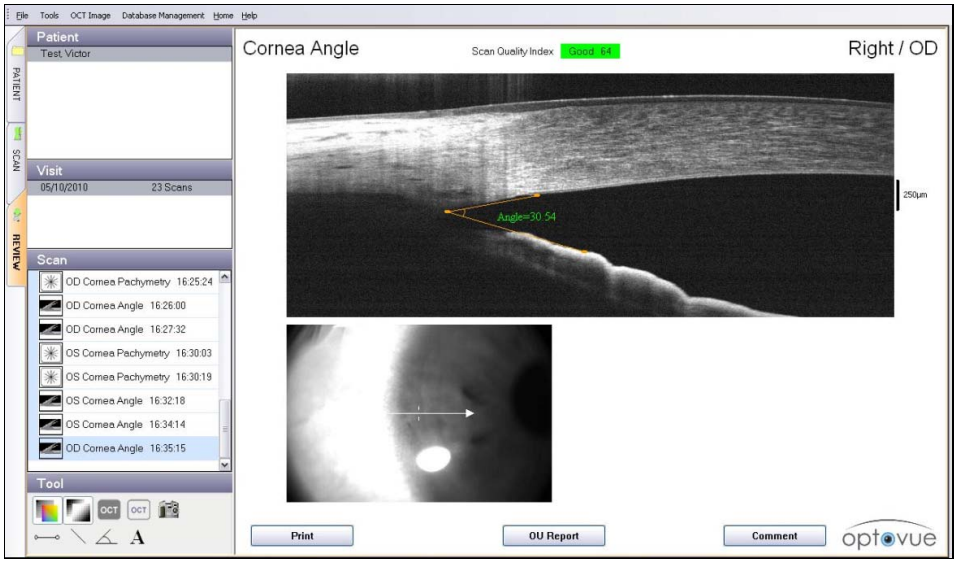


Figure 74 Cornea Angle Report

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.

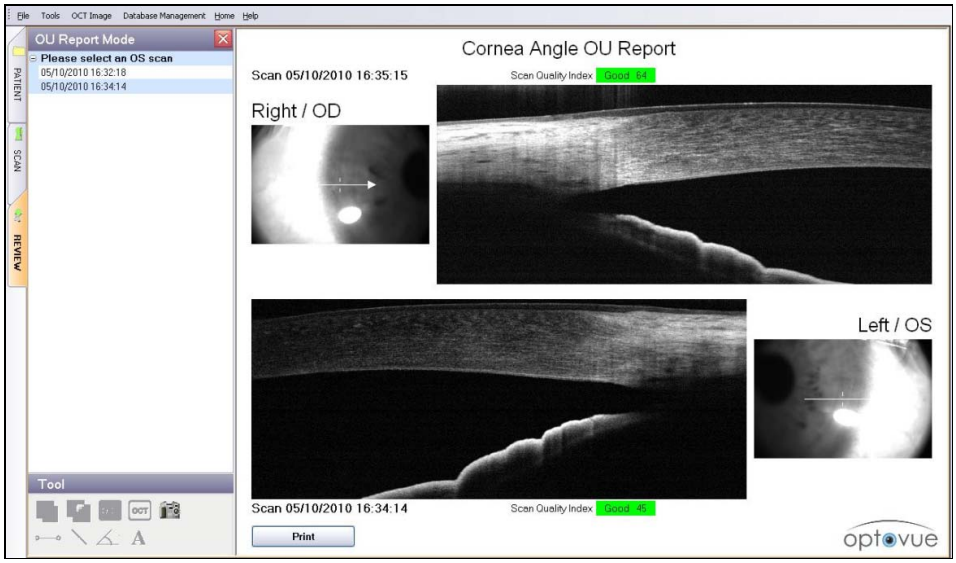


Figure 75 Cornea Angle OU Report

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.

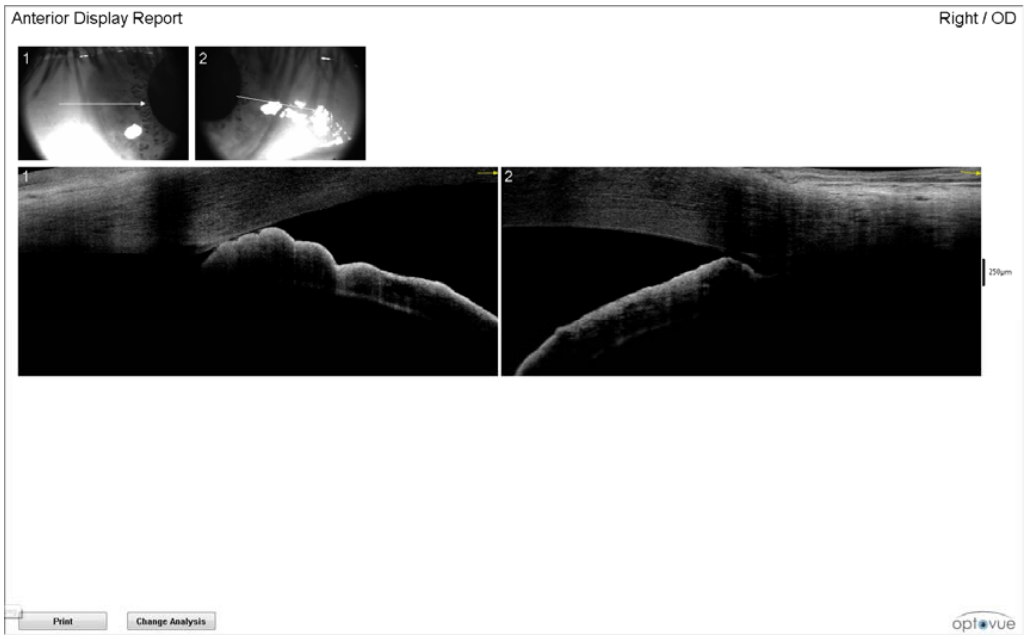


Figure 76 Multi Image report

6.7 iWellness Report

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

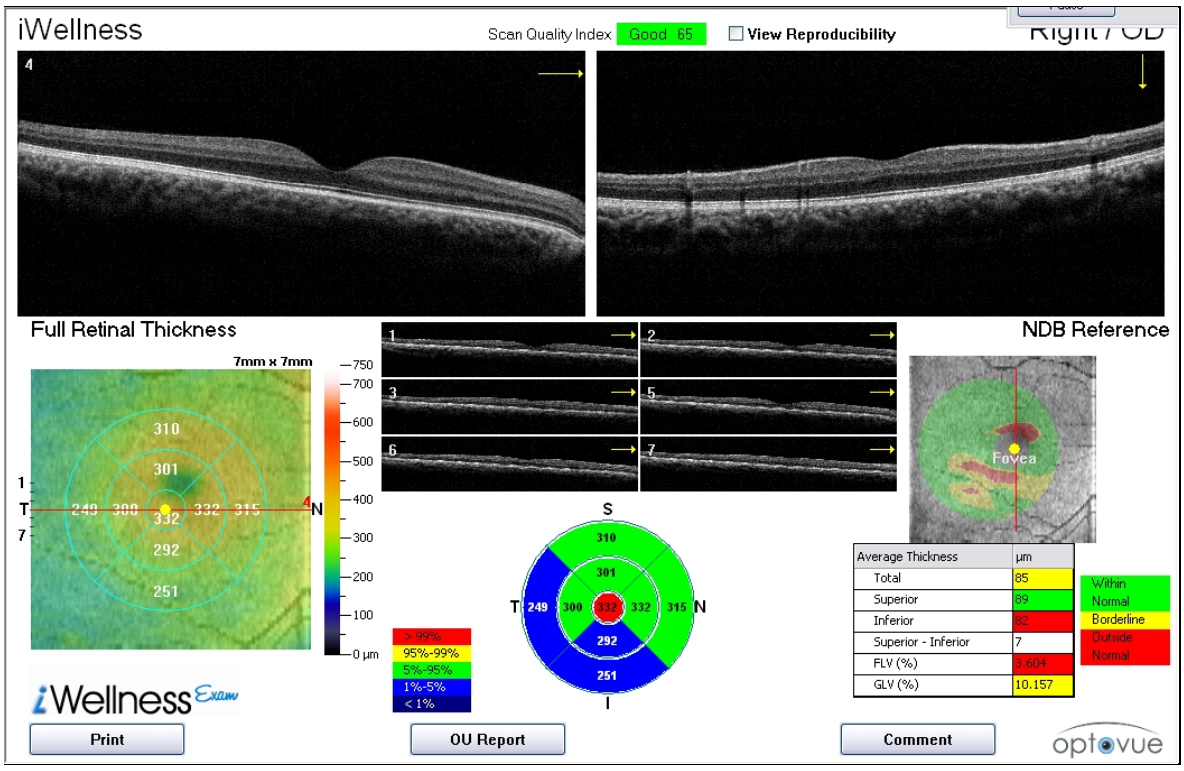


Figure 77 iWellness Report with Averaged Raster Scans

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.

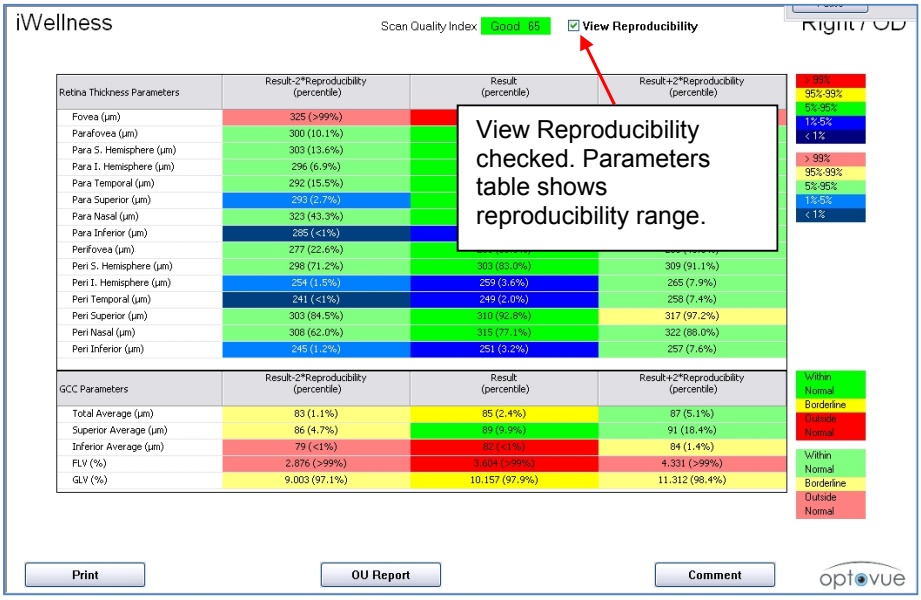


Figure 78 iWellness Report with Parameters Table

6.7.1 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.

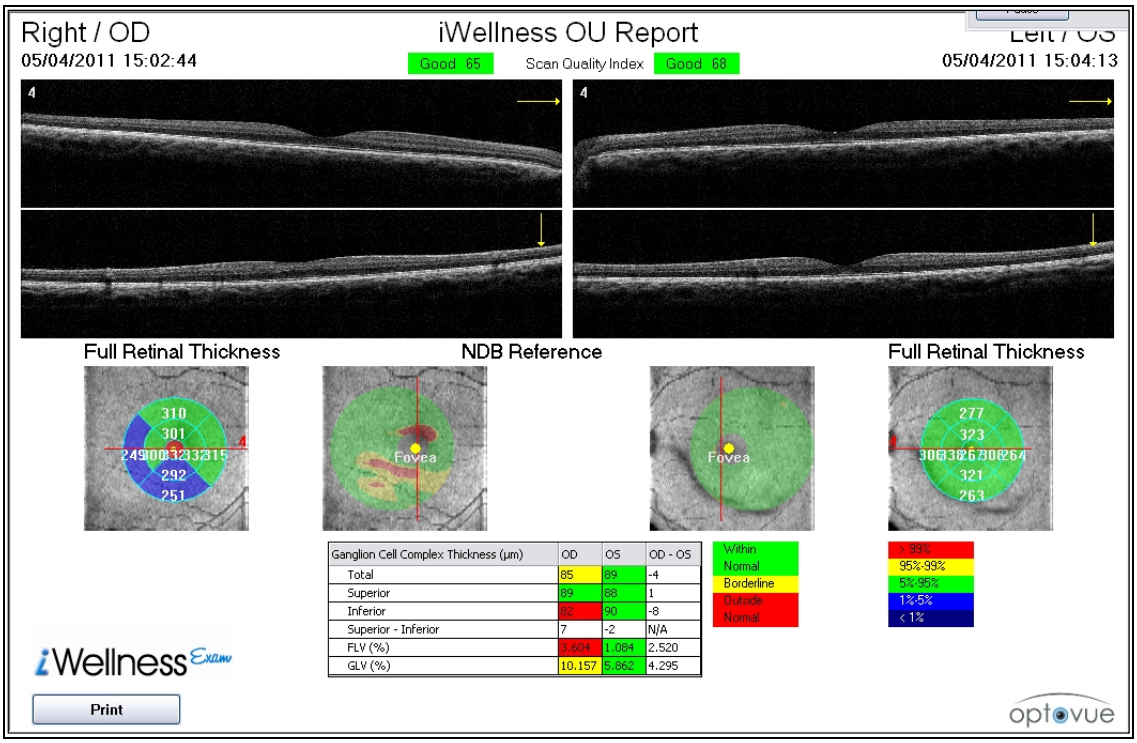


Figure 79 iWellness OU Report

_____End of section_____

7 Main Menu

This section provides an overview of the main menu. The figure below shows the six main menu items.

Figure 67. iVue Main Menu Toolbar

7.1 File Menu

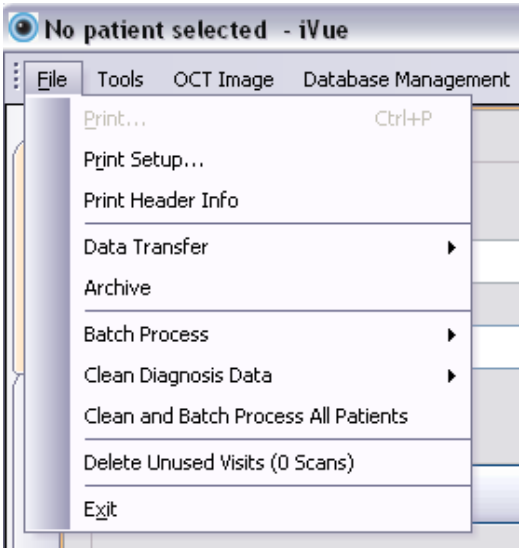


Figure 68. File Menu

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.

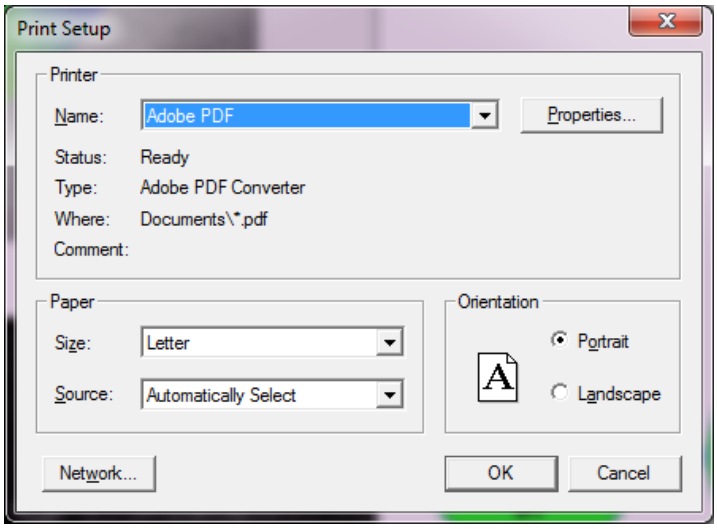


Figure 80 Print Setup Dialog

- **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**.

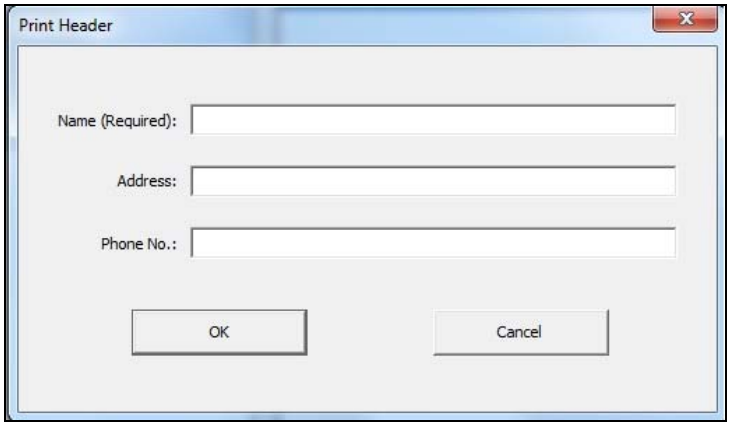


Figure 81 Print Header Dialog

7.1.2 Print Setup

Selecting **Print Setup** from the menu displays the standard Windows™ **Print Setup** window.

7.1.3 Print Header Information

This option displays the window to insert the practice or facility information that you wish to be printed at the top of every report when printed or saved as a digital file (.jpg and/or PDF).

7.1.4 Data Transfer

This option displays the **Output Data** function, enabling you to transfer part or all of the data required, for a variety of reasons, including clinical studies.

7.1.5 Archive Data

Patient data is automatically backed up onto a removable backup hard drive on the right side of the unit (from the operator's perspective), underneath a plastic cover (see Figure 4, page 31). When the system hard drive and backup drive are completely full, it is necessary to remove data from the system to make room for new scan data. You can archive to a network drive (if the iScan system is connected to your office network); or you can archive to an external USB hard drive (formatted in NTFS format). Archived data is retrieved automatically as long as the network drive or external USB drive is connected to the system. Before archiving, you must set the archive drive: **Select Tools > User Preference** and use the Archive Drive field in the User Preference dialog. See section 7.2.1 for details.

☞ **Important Note: Unlike automatic backup, archiving removes the raw patient data from both the primary and backup hard drives. We highly recommend that you back up the archive drive, so you maintain a backup copy of all patient data.** We also recommend that you continue archiving data to the same drive as long as possible to maintain all archived data together. To ensure the security of your patient data, call Optovue Technical Support for assistance before archiving patient data.

Hardware and Setup Requirements to Archive

The hardware requirements to archive are:

- **To archive to a USB external hard drive:** At least two same-size external hard drives, at least 1TB each in size, one to be the primary archive drive and the other to be the secondary archive drive. See setup instructions below.

☞ **Note**: The secondary drive is necessary to back up the primary drive, in case the primary drive becomes corrupted or inaccessible.

- **To archive to a network drive:** The system computer must be on the office network and have a drive letter mapped to the network archive drive, which resides on the office server computer. To map to the network drive, use Windows Explorer to open the **My Computer** (or just **Computer**) folder on the iScan system computer, then map a drive letter to the chosen archive folder on the network drive. For data security, the network drive should be backed up regularly, which usually happens as part of the regular backup of the server.

Set Up Primary and Secondary USB Drives

1. Connect the hard drives to the system computer one after the other so that the system can identify each drive uniquely. Write down the drive letters assigned to each hard drive by Windows. You will use them later to specify the primary and secondary archive drives in the User Preference dialog.
2. Format both external hard drives in NTFS format. Rename one **Primary Archive** and the other **Secondary Archive**. Then physically mark—write on--each external hard drive to distinguish the **Primary Archive** and the **Secondary Archive**.

Note: If you are using a network attached storage device (NAS drive) as the primary archive drive, use Windows Explorer to open the **My Computer** (or just **Computer**) folder on the system computer, then map a drive letter to a folder on the NAS drive. Make sure to back up the NAS drive periodically if you are not using a secondary archive drive.

3. Select **User Preference** from the **Tools** menu.

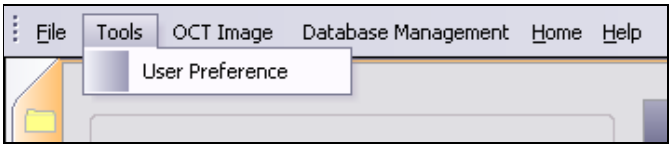


Figure 82 Tools Menu

The **User Preference** dialog opens.

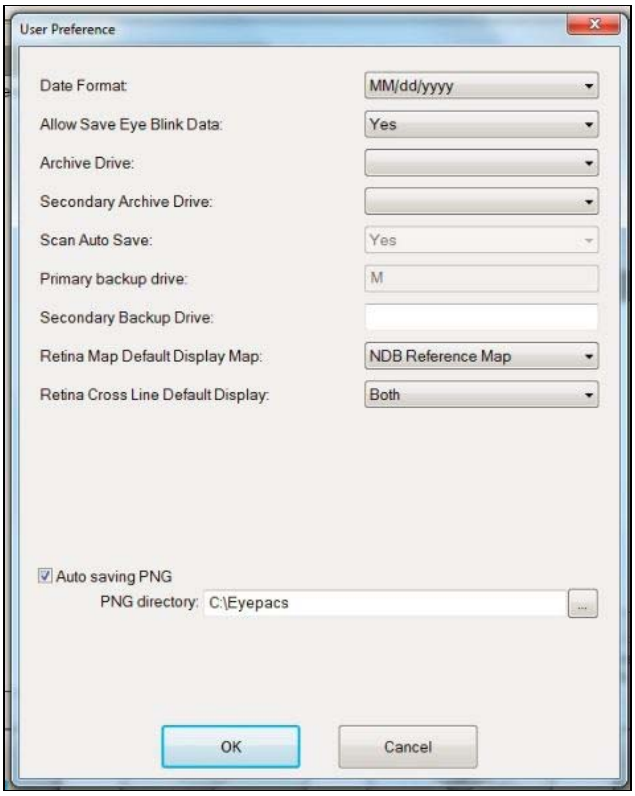


Figure 83 User Preference Dialog

4. Set the drive letter for the **Primary Archive Drive** and for the **Secondary Archive Drive**. Click **OK**.

You have to perform these initial steps only once. Once set up, follow the procedure below to perform scheduled archiving. Once you complete archiving, remove from the system and securely store the secondary archive.

Steps to Archive

Follow these steps to archive patient data.

1. Select **Archive** from the **File** menu.

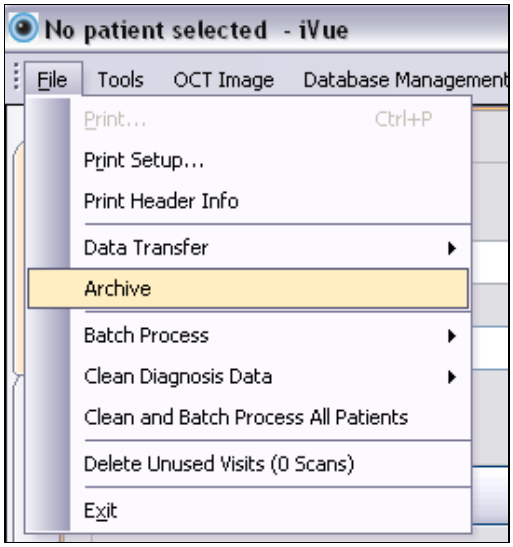


Figure 84 Archive Selection

2. The **Archive** dialog opens. You can use the **Search** field to search for specific patients, or leave it blank and use the **Sort By** field to search for all patients or for scans by visit date. Normally, users leave the **Search** field blank and proceed.

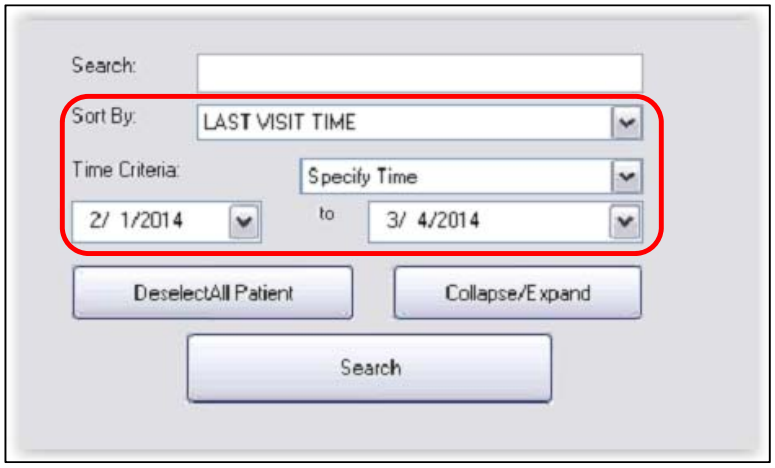


Figure 85 Specify Visit Dates to Archive

4. In the **Sort By** field, you can select:
    - **ALL** to archive all scans currently on the system hard drive.
    - **LAST VISIT TIME** to archive scans based on the visit date. In the **Time Criteria** field you can select:
        - **Specify Time** to archive scans from the range of visit dates you specify in the date fields below.
        - **This Week** to archive scans taken this week.
        - **Today** to archive scans taken today.
3. Click the **Search** button. A patient selection dialog opens.
4. Since you have searched for all patients or by date so far, the expected action at this point is to click the **Select All Patients** button, rather than select specific patients. Selected patients have a checkmark in their checkbox.
5. Click the **Start Archive** button. A **System Status** dialog opens and shows archiving progress and remains until archiving is complete.
6. Click the **Exit** button.

7.1.6 Batch Process

Use Batch Process to pre-process all scans that have not been processed yet by opening in the REVIEW window. This reduces the time required to open scans in the REVIEW window. Select **Batch Process** from the **File** menu, and then select from the four further options: **Current Visit, Current Patient, Today's Patients, All Patients**.

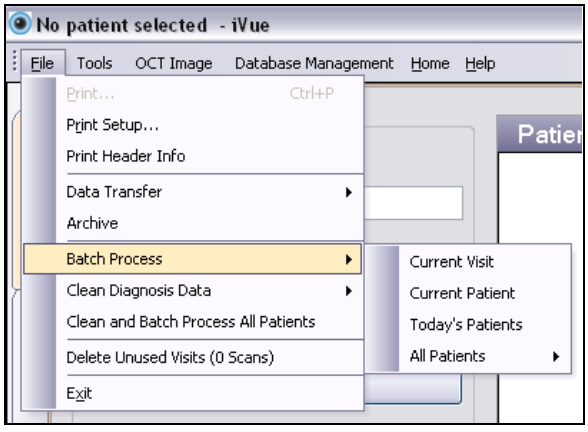


Figure 86 Select Batch Process

If you installed a system software upgrade from Optovue that includes new analysis algorithms, you should clean scans of previous processing before batch processing all patients. To do this, select **Clean Diagnosis Data** from the **File** menu (see next section below). When complete, select **File > Batch Process > All Patients**.

Batch Process works best when the system is not in use. Processing time depends upon the number of patients and scans in the database.

7.1.7 Clean Diagnosis Data

Clean Diagnosis Data removes any previous analysis processing, leaving only the raw (clean) scan data. This enables reprocessing the clean data with the current analysis algorithms, either by opening a scan in the REVIEW window, or by using Batch Processing (see previous section). Clean Diagnosis Data does not remove manual edits to scan data.

To clean diagnosis data, select **File > Clean Diagnosis Data**, and then select from the further options shown below.

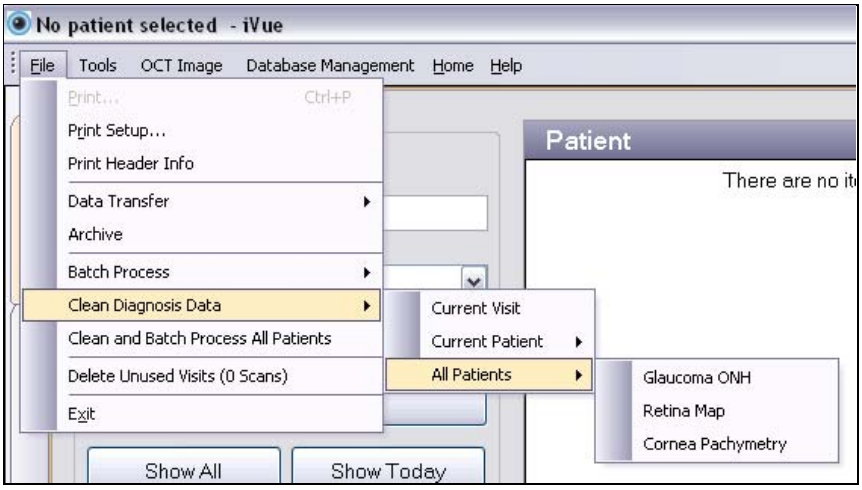


Figure 87 Clean Diagnosis Data Options

7.1.8 Clean and Batch Process All Patients

This process enables you to clean and batch process all patients (all scans on the system) with one click: Select File > Clean and Batch Process All Patients. This provides an easier way to remove previous processing (except manual scan edits) and process all scans again, which is especially useful after a system software upgrade that provides new analysis algorithms.

7.2 Tools Menu

User Preference is the only option in the **Tools** menu.

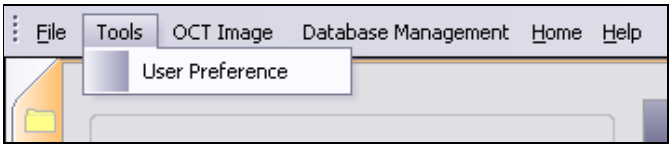


Figure 88 Tools Menu

7.2.1 User Preference Dialog

The **User Preference** dialog enables you to modify various system settings.

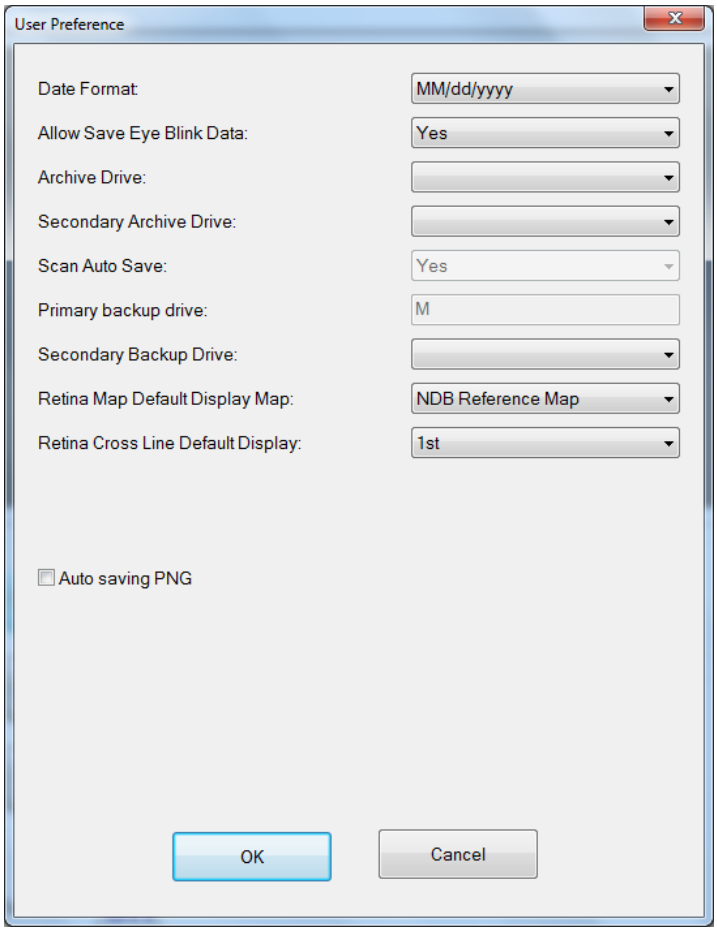


Figure 89 User Preference Dialog

- **Date Format:** Set the date format.
- **Allow Save Eye Blink Data:** Select **Yes** to save even if the system detects blinks, or **No** to force a rescan when the system detects blinks.

- **Archive Drive:** Set the primary archive drive (see section 7.1.5).
- **Secondary Archive Drive:** Set the secondary archive drive (see section 7.1.5).
- **Scan Auto Save:** The unchangeable **Yes** setting causes **Capture** and **Save** to occur automatically in succession.
- **Primary Backup Drive:** You cannot change this. The primary backup drive is the one under the cover on the right side of the system (from the operator's perspective).
- **Secondary Backup Drive**: Select the mapped drive letter for an optional secondary backup drive you have set up. A secondary backup drive would be used for recovery in case of corruption of the primary backup drive.
- **Retina Map Default Display Map**: You cannot change this feature.
- **Retina Cross Line Default Display:** Set which scan line(s) to display by default, **1st**, **2nd**, or **Both** This applies to Retina Cross Line and Retina OU Cross Line reports.

Click **OK** to save your changes, or click **Cancel** to discard them.

7.3 OCT Image Menu

The options available in the **OCT Image** menu vary based on whether you are in **PATIENT, SCAN**, or **REVIEW** mode.

In **PATIENT** mode, the menu provides three options:

- Modify Baseline
- Modify Boundary
- Reload Baseline

In **SCAN** mode, only **Scan Parameter Setting** is available.

In **REVIEW** mode, only **Modify Boundary** and **Scan Parameter Setting** are available.

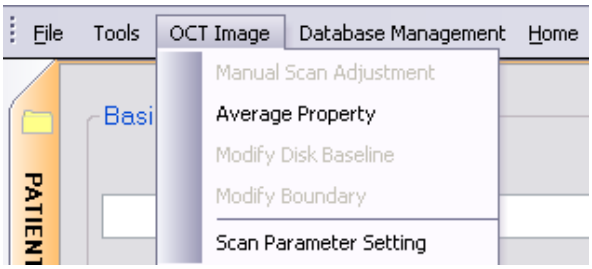


Figure 90 OCT Image Menu

7.3.1 Manual Scan Adjustment for Scan Capture

Select **Scan Parameter Setting** to adjust the settings for axial length, refractive state and polarization. The manual settings you choose override the system's automatic settings.

Figure 91 Manual Scan Adjustment Dialog

These are the manual scan adjustment buttons with their functions. The numerical values for **Z Motor, Focus**, and **P Motor** change as you move the sliders.

- **Auto Z**: adjusts for the axial length
- **Auto F**: adjusts for refractive state

- **Auto P**: adjusts for polarization

7.3.2 Average Property

Click **Average Property** to adjust the frame average value.

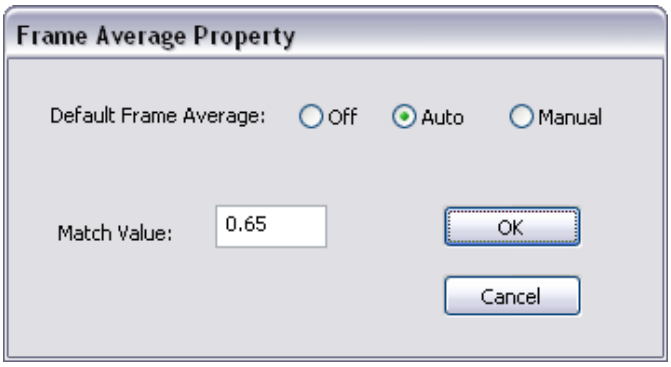


Figure 92 Frame Average Property Dialog

7.3.3 Modify Disc Baseline

Click **Modify Disc Baseline** to display the en face image of the optic disc. You can then review and adjust the disc boundary determined by the software. Changes you make trigger recalculation of measurements based on the new disc boundary.

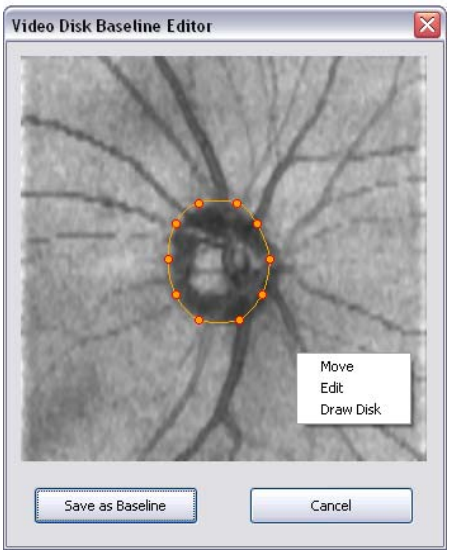


Figure 93 Video Disc Baseline Editor

7.3.4 Modify Boundary

Click **Modify Boundary** to display all scans from the selected pattern (**Retina, Nerve Fiber,** and **Cornea**). You can then review and adjust the segmentation boundary lines identified by the software. Move the cursor over a line until the cursor changes to a small plus **(+)** sign, then click and drag the line to the desired location. Click **Save**.

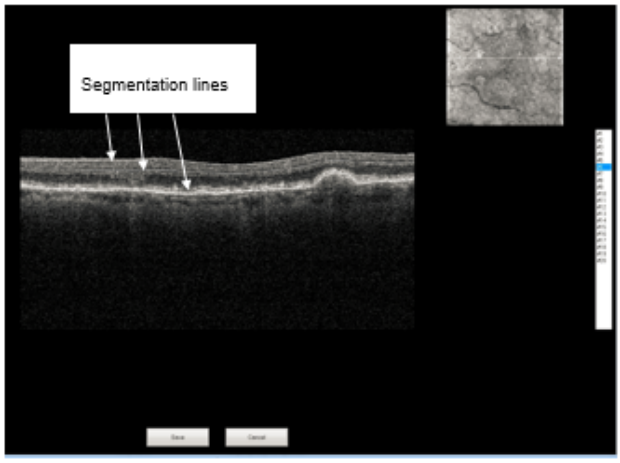


Figure 94 Segmentation Lines

☞ **Note:** You cannot undo or batch-clean adjustments you make to segmentation lines. You can only further readjust them manually.

7.3.5 Scan Parameter Setting

Use the **Scan Parameter Setting** dialog to select whether OCT scans appear in grayscale or color during scan acquisition and review. Note that the **Scan Parameter Settings** should be established in **User Preference.**

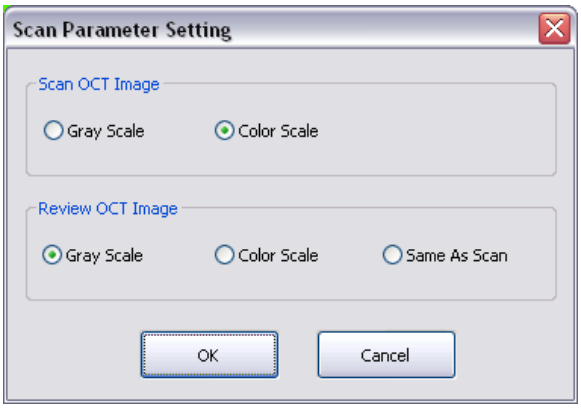


Figure 95 Scan Parameter Setting Dialog

7.4 Database Management Menu

In the **Database Management** menu, you can create, edit and delete physicians, operators and diseases, which you can then associate with exam data. You can also move visits to another patient, and recover scans. Note that all menu options are available.

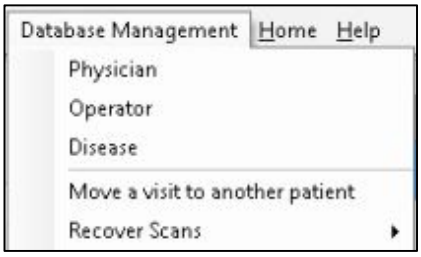


Figure 96 Database Management Menu

7.4.1 Physician

Use the **Physician Editor** to add, edit or delete physicians.

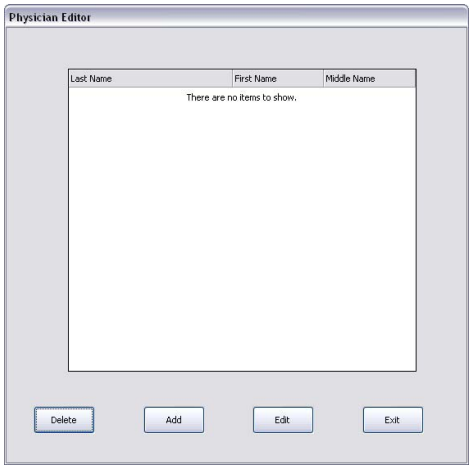


Figure 97 Physician Editor Dialog

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

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.

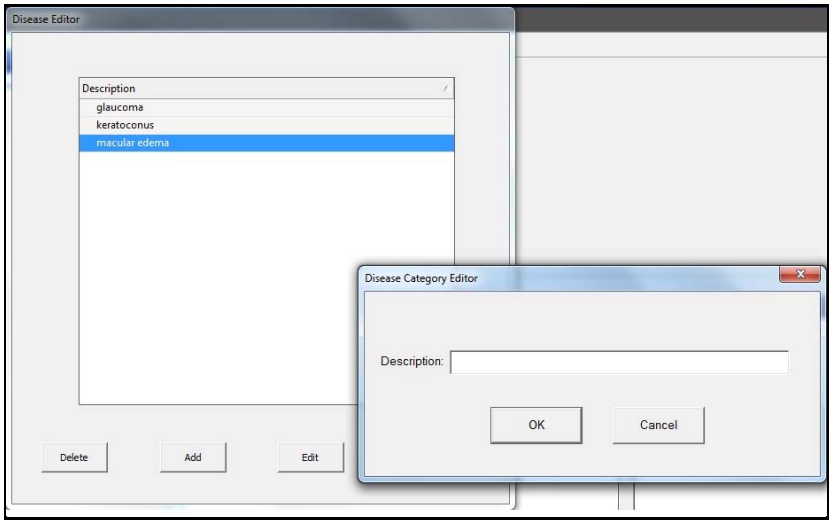


Figure 98 Disease Editor Dialog

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.

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

Figure 99 Move Selected Visit Confirmation Message

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

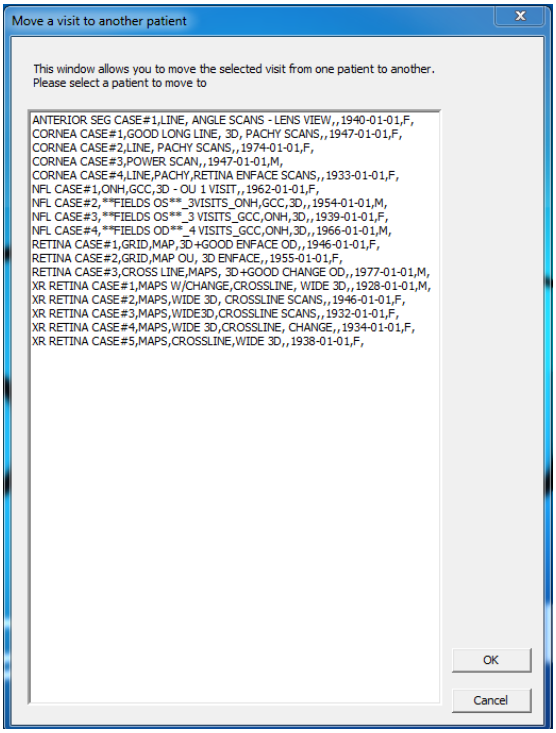


Figure 100 Select patient to move exam data to

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

Figure 101 Move Visit Confirmation

7.5 Help Menu

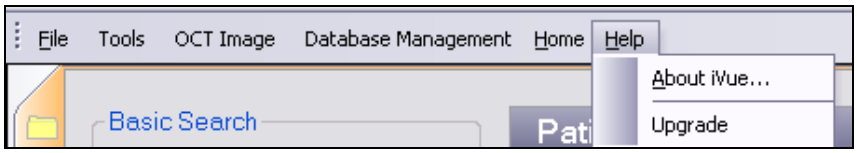


Figure 102 Help Menu

7.5.1 About iVue

Select **About iVue** from the **Help** menu to display the About iVue dialog, which provides general information about the system, including software version number, license key and activated version.

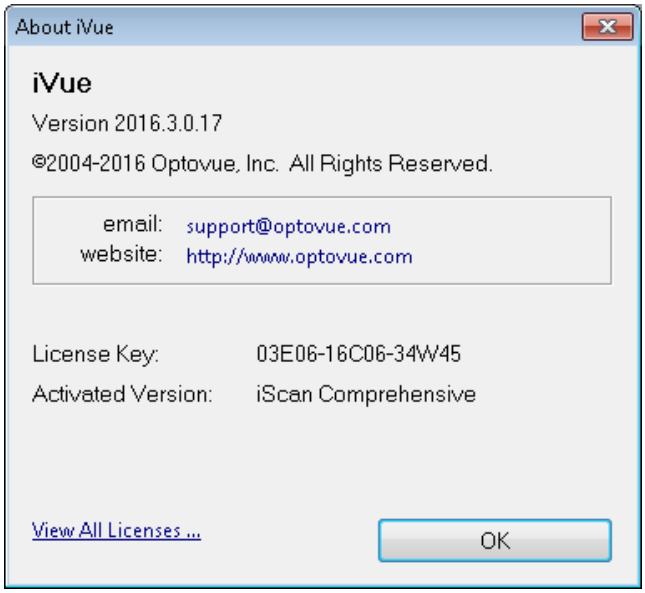


Figure 103 About iVue Dialog

iScan Versions

There are two versions of iScan: iScan Essential and iScan Comprehensive. These versions are distinguished by the scans available in each, as shown below.

Scans	iScan Comprehensive	iScan Essential
iWellness	**X**	**X**
Cross Line	**X**	
Retina Map	**X**	**X**
3D Retina	**X**	
GCC	**X**	
ONH	**X**	**X**
3D Disc	**X**	**X (taken once, as a reference, no review)**
Pachymetry	**X**	
Angle	**X**	

7.5.2 Upgrade

Select **Upgrade** from the **Help** menu to display the feature upgrade dialog. Use this dialog to select an available license to upgrade features or to upgrade to the latest software version.

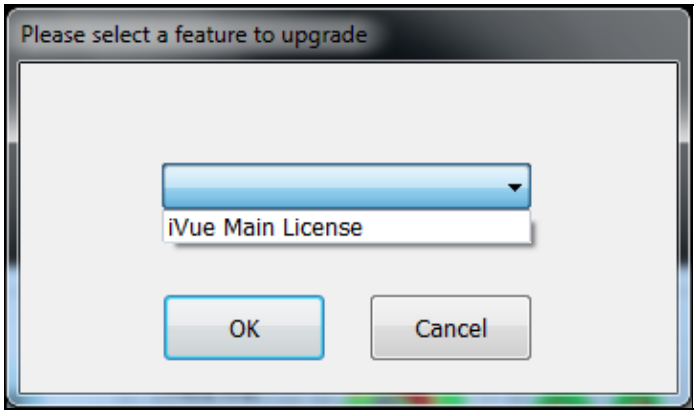


Figure 104 Feature Upgrade Dialog

_____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 Facemask

Optovue recommends cleaning the facemask between patients using either:

- An isopropyl alcohol wipe

OR

- A disinfecting agent, such as an anti-germicide or isopropyl alcohol, on a clean, lint-free cloth

Note: You can use a biological barrier for the face mask area. Use the disposable biological paper barrier available from Optovue.

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 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).

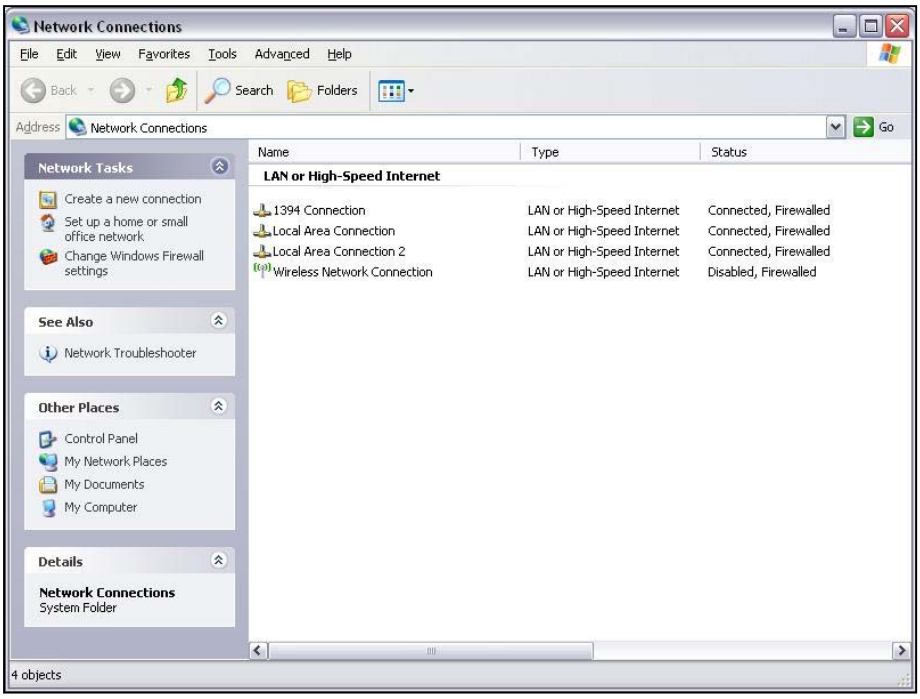


Figure 105 Windows™ Network Connections Screen

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

_____End of section_____

9 Scan Pattern Specifications

9.1 Scan Patterns Table

The table below describes all iVue scan patterns.

Table 2 iVue Scan Patterns

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 scan	8 radial line scans at 6 mm length. Horizontal line scanned eight times for averaging	7 lines: 1024 A-scans/line 1 line: 1024 A-scans/line x 8	Fixed	6 mm diameter
Lens Fitting	8 radial line scans at 6 mm length. Horizontal line scanned eight times for averaging	7 lines: 1024 A-scans/line 1 line: 1024 A-scans/line x 8	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°
Retina 3D	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
3D Fundus En Face	141 frames equally spaced B-scans to cover a square volume center fixation	385x141	Fixed	8mm x 8mm

9.2 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.

9.2.1 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 centered on optic disc.

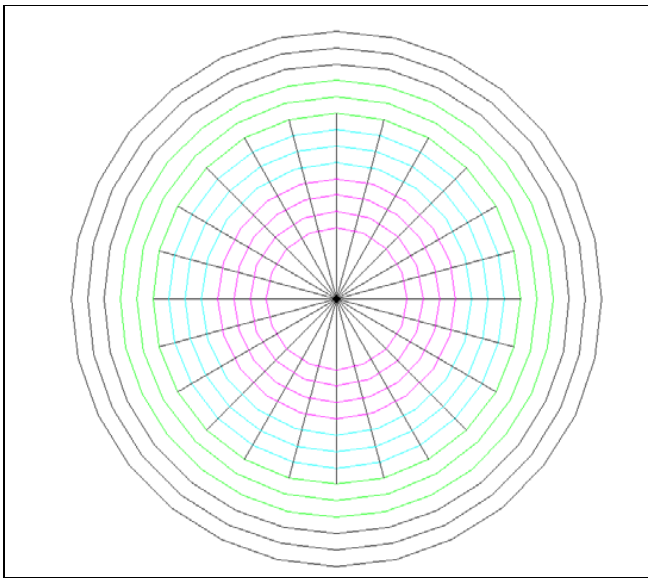


Figure 106 Nerve Fiber ONH Scan Pattern

9.2.2 Retina Map Scan

Objective: Measure the macular retinal thickness map.

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

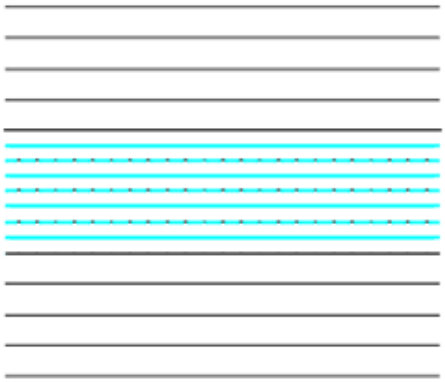


Figure 107 Macular Raster 6x6 (Retina) Scan Pattern

9.2.3 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.

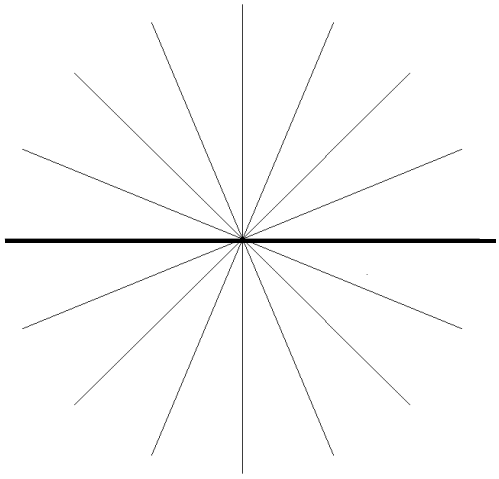


Figure 108 Pachymetry 6 mm Diameter (Cornea) Scan Pattern

9.2.4 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.

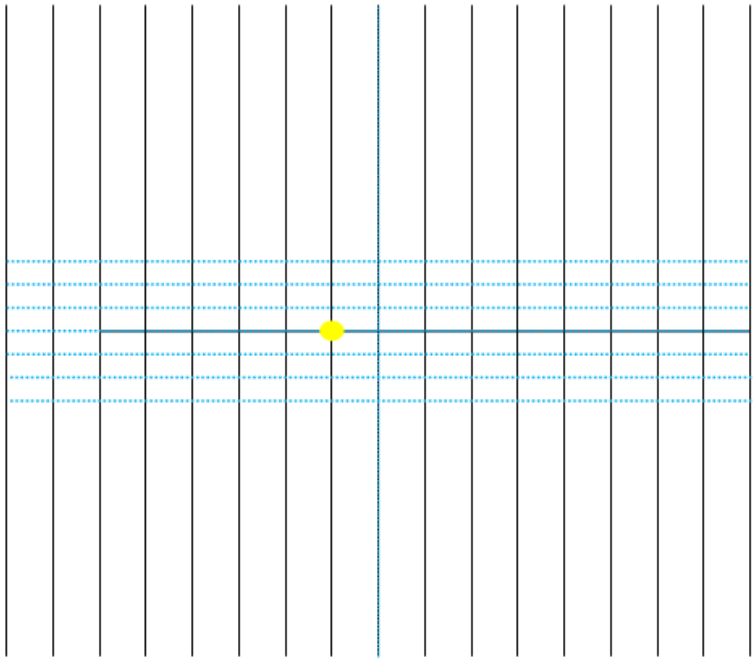


Figure 109 iWellness Scan Pattern

9.3 Fixation Patterns

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

9.3.1 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.

9.3.2 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.

9.3.3 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.

9.3.4 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
- 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
- I/O ports: at least three USB 2.0 ports; one 1394 port
- Networking: Intel Gigabit Ethernet chipset
- Operating system: 32 or 64 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

_____End of section_____

11 Appendices

11.1 Appendix A: Normative Database

Using the iVue 100 system on a study population deemed representative of the normal population, Optovue established a normative database (NDB) for measurements of retinal thickness, GCC thickness, RNFL thickness, and optic nerve parameters. The normative database comprises 458 qualified normal subjects out of an initial enrollment of 521 subjects. The final normative database includes at least 442 normal subjects with one or more qualified scans per subject for the four scan types: nerve fiber ONH scan (449 normal subjects), GCC map scan (451 normal subjects), and Retina Map scan (452 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, and
- 1.4% Other.

The iVue 100 NDB covers the age range of 18 to 82 years, refractive error (spherical equivalent) range of -8.63D to +6.00D, IOP range of 8.0 to 21.0 mmHg, and CCT range of 350 µm to ~ 666 µm. The gender ratio of the database is 39.5% male to 60.5% 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 261.4 µm ±19.3 µm, for the average RNFL thickness was 99.1 µm ± 9.5 µm, and for the average GCC thickness was 93.9 µm ± 6.8 µm.

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 Ganglion Cell Complex).*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 normative database coloring indicates where the patient's measurements fall within the range of the "normal" population range for their age group. The color coding for the normative display uses green (within normal range), yellow (borderline normal range) and red (outside normal range).

☞ **Note**: The ETDRS thickness and NDB results are affected by the positioning of the foveal indicator (yellow dot on Retina Map thickness display). If the fovea is not in the center of the scan, you can move it manually by simply dragging and dropping the yellow dot, and selecting **Yes** at the prompt to reprocess.

11.1.1 Color Legend for NDB References

For GCC, ONH Analysis, TSNIT, and RNFL Thickness, the Percentile Color Legend represents: > 5% for Within Normal (green), < 5% and > 1% for Borderline (yellow) and < 1% for Outside Normal (red). For GLV, FLV, Optic disc C/D and Cup, the Percentile Color Legend represents: < 95% is Within Normal (green), > 95% and < 99% for Borderline (yellow), and > 99% for Outside Normal (red).

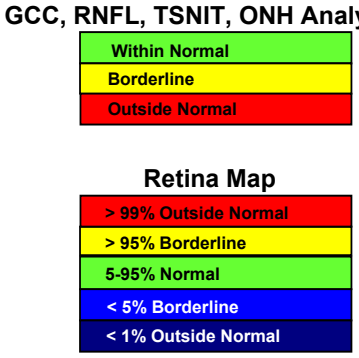


Figure 110 Posterior Thickness Percentile Color Legend

End of section

11.2 Appendix B: 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 scan patterns (ONH, Retina, GCC, iWellness) per iVue 100 instrument and imaged across three instrument/operator pairs. The three iVue 100 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).

11.2.1 Retina Scan

Table 1. 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 2. 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 3. 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.

11.2.2 GCC Scan

Table 4. 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 5. 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 6. 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.

11.2.3 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 7. 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 8. 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 9. 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.

11.2.4 ONH Scan

Table 10. 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 (mm²)	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
V_C_D_ratio	0.470	0.035	0.036	7.62%	0.099

ONH Scan	Normal Eyes (14 subjects, 123 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
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
SN (µm)	104.7	4.2	4.2	4.03%	11.7

ONH Scan	Normal Eyes (14 subjects, 123 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
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 11. 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 (mm²)	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 (mm²)	0.814	0.052	0.055	6.69%	0.151
Rim Area (mm²)	1.603	0.111	0.115	7.37%	0.318

ONH Scan	Retinal Disease Eyes (13 subjects, 101 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
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
NL (µm)	75.2	3.7	3.7	5.01%	10.4

ONH Scan	Retinal Disease Eyes (13 subjects, 101 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
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 12. 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
Nervehead_Volume (mm^3)	0.152	0.030	0.030	19.66%	0.084

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

ONH Scan	Glaucoma Eyes (13 subjects, 112 scans)				
	Mean	Repeatability (SD)	Reproducibility (SD)	Reproducibility (COV)	Reproducibility (Limit*)
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_____

11.3 Appendix C: 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 3 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 14. 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 15. 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 16. 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
	ST	7.44	17.78

Cornea		Good	Poor
	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 17. 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 18. 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_____

11.4 Appendix D: 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 19. 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

Table 20. 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 21. 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 22. 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 23. 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 24. 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

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	21	302.44	306.66	-4.22	7.97	(-7.850, -0.593)	-20.64	12.20
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

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 Superior	16	288.93	283.61	5.31	12.99	(-1.607, 12.231)	-20.95	31.57
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

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