CIRRUS HD-OCT

User Manual – Models 500, 5000

Copyright

Trademarks

Patents

www.zeiss.com/meditec/en_us/imprint/patents

1 Safety and Certifications

2 Introduction

3 System Overview

6 Acquiring Scans

8 Analysis

11 Data Management

12 Routine Maintenance

B CIRRUS Algorithm Studies

C CIRRUS HD-OCT Repeatability and Reproducibility of Anterior Scan Measurements

1 Safety and Certifications

Before using the CIRRUS HD-OCT, you must fully understand potential safety hazards. Read the following safety warnings and cautions in their entirety before using the HD-OCT instrument. Additional warnings and cautions are found throughout the instructions for use.

Symbols and Labels


Warning


Caution


Note


Must Follow Instructions for Use


Stand–by


Fuse


Direct Current


Type B applied parts


Manufacturer

Authorized European Community Representative

Serial number

Catalog number / part number

Model number


Conforms to applicable European Directive(s)

CE Mark with identification number of DQS – accredited Notified Body for compliance assessment to the European Union directives, including Medical Device Directive 93/42/EEC.

Certification mark of CSA – Nationally recognized test laboratory for US and Canada

Disposal of the Product within the E.U. Do not dispose via domestic waste disposal system or communal waste disposal facility.

Caution: Federal law (or United States) restricts this device to sale by or on the order of a licensed healthcare practitioner

Warning and Caution Definitions

The terms WARNING and CAUTION and the symbol designating each are defined as follows.

WARNING: Indicates hazards that, if not avoided, may cause severe injury or death.

CAUTION: Indicates hazards that, if not avoided, may result in minor or moderate injury, or damage to or impaired performance of equipment.

Warnings

WARNING: To prevent electric shock, the instrument must be plugged into an earth grounded outlet. Do not remove or disable the ground pin. Only an authorized Zeiss service representative may install the instrument.

WARNING: Do not open the instrument covers. (Exception: You may remove the rear cover to access labels and connectors.) Opening the instrument covers could expose you to electrical and optical hazards.

WARNING: To maintain patient safety, if the instrument is externally connected to non–medical peripheral devices (i.e., printer, storage devices, etc.), the complete system must comply with the system requirements in standard IEC 60601–1. This standard requires the usage of an Isolation Transformer to power the non–medical peripheral device(s) if located within 1.5 m from the patient. If the peripheral device is located outside the patient environment (beyond 1.5 m) and is connected to the instrument, a separation device must be used or there shall be no electrical connection between the non–medical peripheral device and the instrument.

WARNING: The person or the responsible organization connecting additional devices or reconfiguring the system must evaluate the complete system to ensure compliance to the applicable IEC 60601–1 requirements.

WARNING: The instrument operator must not attempt to touch the patient and the peripheral device simultaneously.

WARNING: This instrument may cause ignition of flammable gases or vapors. Do NOT use in the presence of flammable anesthetics such as nitrous oxide, or in the presence of pure oxygen.

WARNING: The instrument itself is transportable and may be moved from one location to another. However, if the instrument is placed on a power table provided by CZMI, do not move the table to another location while the instrument and any other peripherals are placed on it. Doing so may cause the system components to tip over and cause harm to the patient, the operator, or others in the vicinity.

WARNING: Do not scan patients who have been injected with photo–dynamic therapy (PDT) treatment drugs, such as Visudyne®, in the previous 48 hours. Failure to observe this warning could result in unintended exposure and uncontrolled treatment of neovascular vessels.

WARNING: This device contains visual stimuli, including flickering light and flashing patterns, between 5 and 65 Hz. Medical professionals need to determine whether this device should be used for patients who may be photosensitive, including those with epilepsy.

Cautions

CAUTION: Failure to provide proper ventilation could potentially lead to heat build–up, which could cause component failure and/or fire.

CAUTION: Users are not authorized to dismantle (except to remove the rear cover) or modify the CIRRUS HD-OCT hardware. To transport the instrument outside the office, you must consult with a Zeiss service technician.

CAUTION: Avoid tipping. Do not use the instrument on an uneven or sloped surface. Also, do not roll the table in deep pile carpet or over objects on the floor such as power cords. Failure to observe these precautions could result in tipping of the instrument and/or table and resulting injury to operator or patient and damage to the instrument.

CAUTION: When you complete scan acquisition and before you click the *Finish* or *ID Patient* buttons in the *Acquire* screen, always prompt the patient to sit back and move the head away from the chinrest. Clicking either of these buttons in the *Acquire* screen causes the chinrest to reposition itself beyond the point where the patient's eye would contact the lens if the head remained in the chinrest. Failure to observe this warning could result in injury to the patient.

CAUTION: The operator should check that the patient is not holding on to the instrument before or during tests. Although movement of the motorized chinrest is slow, giving plenty of warning for patients to remove their fingers, there is potential for fingers to be squeezed and possibly injured.

CAUTION: Do not reconfigure system components on the table, nor add non–system devices or components to the table, nor replace original system components with substitutes not approved by Zeiss. Such actions could result in failure of the table height adjustment mechanism, instability of the table, tipping and damage to the instrument, and injury to operator and patient.

CAUTION: Do not use the printer, the instrument, or the optional power table with an extension cord or a power strip (multiple portable socket outlet).

CAUTION: Applicable Phototoxicity Statements (FDA CDRH Ophthalmologist Guidance #71): Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged. While no acute optical radiation hazards have been identified for direct or indirect ophthalmologist, it is recommended that the exposure time for the patient's eye be limited to the minimum time that is necessary for image acquisition. 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 with 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. This medical device has no user adjustable intensity settings for light incident on the retina, nor does it produce UV radiation or short–wavelength blue light.

CAUTION: The appliance coupler is the main disconnect device of the instrument. Position the instrument in such a way to have easy access to disconnect the appliance coupler in case of an emergency. For the CIRRUS HD-OCT, the most accessible power cord is the one that plugs into the bottom of the table.

CAUTION: In case of an emergency, disconnect the appliance coupler. For the CIRRUS HD-OCT, the most accessible power cord is the one that plugs into the bottom of the table.

Protection of Patient Health Information

NOTE: Health care providers have responsibility for the protection of patient health information (PHI), both hardcopy and electronic. To protect patient confidentiality of your exported electronic data, the use of encryption is recommended and is the responsibility of the user.

Safety

NOTE: If a serious incident has occurred in relation to this medical device, to the user, or to another person, then the user (or responsible person) must report the serious incident to the medical device manufacturer or the distributor. In the European Union, the user (or responsible person) must also report the serious incident to the Competent Authority in the state where the user is established.

Product Safety

WARNING: To prevent electric shock, the instrument must be plugged into an earth grounded outlet. Do not remove or disable the ground pin. Only an authorized Zeiss service representative may install the instrument.

WARNING: Do not open the instrument covers. Opening the instrument covers could expose you to electrical and optical hazards.

WARNING: To maintain patient safety, if the instrument is externally connected to non–medical peripheral devices (i.e., printer, storage devices, etc.), the complete system must comply with the system requirements in standard IEC 60601–1. This standard requires the usage of an Isolation Transformer to power the non–medical peripheral device(s) if located within 1.5 m from the patient. If the peripheral device is located outside the patient environment (beyond 1.5 m) and is connected to the instrument, a separation device must be used if there shall be electrical connection between the non–medical peripheral device and the instrument.

WARNING: The person or the responsible organization connecting additional devices or reconfiguring the system must evaluate the complete system to ensure compliance to the applicable IEC 60601–1 requirements.

CAUTION: The instrument operator must not attempt to touch the patient and the peripheral device simultaneously.

WARNING: This instrument may cause ignition of flammable gases or vapors. Do NOT use in the presence of flammable anesthetics such as nitrous oxide, or in the presence of pure oxygen.

WARNING: The instrument itself is transportable and may be moved from one location to another. However, if the instrument is placed on a power table provided by CZMI, do not move the table to another location while the instrument and any other peripherals are placed on it. Doing so may cause the system components to tip over and cause harm to the patient, the operator, or others in the vicinity.

WARNING: Do not scan patients who have been injected with photo–dynamic therapy (PDT) treatment drugs, such as Visudyne®, in the previous 48 hours. Failure to observe this warning could result in unintended exposure and uncontrolled treatment of neovascular vessels.

CAUTION: Avoid tipping. Do not use the instrument on an uneven or sloped surface. Also, do not roll the table in deep pile carpet or over objects on the floor such as power cords. Failure to observe these precautions could result in tipping of the instrument and/or table and resulting injury to operator or patient and damage to the instrument.

CAUTION: When you complete scan acquisition and before you click Finish or ID Patient in the Acquire Screen, always prompt the patient to sit back and move the head away from the chinrest. Clicking either of these buttons in the Acquire screen causes the chinrest to reposition itself beyond the point where the patient's eye would contact the lens if the head remained in the chinrest. Failure to observe this warning could result in injury to the patient.

CAUTION: The operator should check that the patient is not holding on to the instrument before or during tests. Although movement of the motorized chinrest is slow, giving plenty of warning for patients to remove their fingers, there is potential for fingers to be squeezed and possibly injured.

CAUTION: (United States) Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

CAUTION: Do not reconfigure system components on the table, nor add non–system devices or components to the table, nor replace original system components with substitutes not approved by Zeiss. Such actions could result in failure of the table height adjustment mechanism, instability of the table, tipping and damage to the instrument, and injury to operator and patient.

CAUTION: Do not use the printer, the instrument, or the optional power table with an extension cord or a power strip (multiple portable socket outlet).

NOTE: The optional CIRRUS HD-OCT Power Table is safe to use within the patient environment when the instrument is powered through it, as instructed herein.

Optical Safety

- IEC 60825–1
- EN ISO 15004–2
- Classification: Group 1 Instrument – Per EN ISO 15004–2. Group 1 instruments are ophthalmic instruments for which no potential light hazard exists.

WARNING: This device contains visual stimuli, including flickering light and flashing patterns, between 5 and 65 Hz. Medical professionals need to determine whether this device should be used for patients who may be photosensitive, including those with epilepsy.

CAUTION: Applicable Phototoxicity Statements (FDA CDRH Ophthalmoscope Guidance #71): Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged. While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the exposure time for the patient's eye be limited to the minimum time that 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 with 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. This medical device has no user adjustable intensity settings for light incident on the retina, nor does it produce UV radiation or short–wavelength blue light.

CAUTION: The appliance coupler is the main disconnect device of the instrument. Position the instrument in such a way to have easy access to disconnect the appliance coupler in case of an emergency.

CAUTION: In case of an emergency, disconnect the appliance coupler from the back of the instrument.

When the power cord is connected to the instrument, the green light on the power switch will start flashing. When the power switch is pressed, the light will change to solid green and the entire instrument will be powered.

Networking Safety

WARNING: When networking the CIRRUS HD-OCT, use only network cables with an unshielded RJ–45 connector. Use of a shielded network cable in the CIRRUS HD-OCT could result in electrical shock to the patient and/or examiner.

Network Attached Storage Device Safety

WARNING: To directly connect the NAS device to the CIRRUS HD-OCT, use a network patch cord only with an unshielded RJ–45 connector. Use of a shielded network patch cord will ground the NAS device through the CIRRUS HD-OCT, which could result in electrical shock to the patient and/or examiner.

CAUTION: We strongly recommend you use peripheral devices supplied or approved by Zeiss, when available, because they will have been tested to work with the instrument. If you do use a peripheral device that conforms with the requirements in this section but is not supplied by Zeiss, do not install any unapproved third party software on the instrument. Installation of any unapproved software, including drivers, could degrade the performance of the instrument and/or lead to corrupted diagnostic or therapeutic information and may void the instrument warranty.

CAUTION: Do not use the NAS device or the instrument with an extension cord or a power strip (multiple portable socket outlet). For additional safety, do not plug the NAS device and the instrument into the same wall outlet. Failure to observe this instruction could result in electrical shock to the patient and/or examiner.

Printer Safety

WARNING: Except when powering the printer through an isolation transformer in the USB configuration, peripheral devices such as printers must be placed at least 1.5 meters (4.9 feet) away from the patient, such that the patient cannot touch a peripheral device with any part of his or her body while being examined. In addition, the instrument operator must not attempt to touch the patient and a peripheral device at the same time while examining the patient. Failure to observe this warning could result in electrical shock to the patient and/or examiner. Use of a printer in a wireless configuration enables you to observe this warning more easily.

WARNING: When using the printer in the USB configuration, you must power the printer through an isolation transformer. Failure to observe this warning could result in electrical shock to the patient and/or examiner. To do so, you must use a special power cable. In North America, the required cable has an IEC–320–14 connector on one end and a NEMA S–15R connector on the other end. This cable is included in the accessory kit shipped with the instrument.

WARNING: To directly connect a printer to the CIRRUS HD-OCT using a network patch cord (UTP cable), only use an unshielded RJ–45 connector. Use of a shielded network patch cord will ground the printer through the CIRRUS HD-OCT, which could result in electrical shock to the patient and/or examiner. It could also invalidate the system safety approval. In this configuration, the printer must be placed at least 1.5 m away from the patient.

CAUTION: If you use a non–approved device or if you connect it incorrectly—for example, by plugging the printer into the wall while using a USB connection, or by using a shielded network (UTP) cable—you could invalidate the system safety approval.

CAUTION: We strongly recommend you use peripheral devices supplied or approved by Zeiss, when available, because they will have been tested to work with the instrument. If you do use a peripheral device that conforms with the requirements in this section but is not supplied by Zeiss, do not install any unapproved third party software on the instrument. Installation of any unapproved software, including drivers, could degrade the performance of the instrument and/or lead to corrupted diagnostic or therapeutic information and may void the instrument warranty.

CAUTION: Do not use the printer or the instrument with an extension cord or a power strip (multiple portable socket outlet). For additional safety, do not plug the printer and the instrument into the same wall outlet. Failure to observe this instruction could result in electrical shock to the patient and/or examiner.

Record and Data Safety

Patient Record Deletion

CAUTION: Deletion is permanent in Native Archive mode; you cannot recover a patient record nor retrieve its archived exams, because deleting a patient record includes deleting that patient's index data. The deleted index data includes where the archived exam data can be found.

Patient Records Merge

CAUTION: Be certain that you select the correct patient records to merge. Once you merge patient records, you must use the Move Scan feature to separate the merged file.

Data Archive and Retrieve

CAUTION: We strongly recommend that you archive daily to a network archive location (a network file server or network attached storage device). If you do not archive at all, paper records are the only way to retain patient information in case of system hard drive malfunction.

Risks of Internet Connectivity

CAUTION: When connected to the Internet, the CIRRUS HD-OCT may be vulnerable to serious security risks, including viruses and worms that could disable your system or adversely affect its performance. Internet connectivity enables third party software, software drivers and updates to be downloaded to your system, either automatically or intentionally. Installation of any unapproved software, including drivers, could degrade the performance of the instrument and/or lead to corrupted diagnostic or therapeutic information and may void the instrument warranty.

Windows Automatic Update

CAUTION: All non–high–priority updates (driver, hardware or optional updates, etc.) should not be installed.

Prohibited Activities

The following activities are prohibited using the CIRRUS HD-OCT instrument.

CAUTION: Attempting to perform these prohibited activities may void your CIRRUS HD-OCT warranty and may result in damage to your CIRRUS HD-OCT system. Zeiss is not responsible for software upgrades or repairs necessitated by the attempted performance of the following prohibited activities.

- Do not relocate the CIRRUS HD-OCT database to a network file server.
- Do not share CIRRUS HD-OCT folders with other computer systems via the network.
- Do not share the CIRRUS HD-OCT system printer on the network if the printer is connected to the USB port.

Networking Guidelines

CIRRUS HD-OCT provides IT–Network capabilities in order to allow for data archiving as well as information sharing within the clinical environment and across medical facilities.

NOTE: Users are responsible for network setup and maintenance, including installation and configuration of all necessary hardware and software. Zeiss Technical Support is limited to testing network connectivity of the CIRRUS HD-OCT. Technical Support cannot troubleshoot or repair problems with network connectivity. Please observe the following guidelines regarding networking of the CIRRUS HD-OCT instrument.

Refer to the *CIRRUS OCT Installation Guide* for all additional information on network connectivity.

Electromagnetic Compatibility (EMC)

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

WARNING: The CIRRUS HD-OCT should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

CAUTION: The CIRRUS HD-OCT has special EMC precaution requirements and needs to be installed and put into service according to the EMC information provided herein.

CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The CIRRUS HD-OCT is intended for use in the electromagnetic environment specified below. The customer or user of the CIRRUS HD-OCT should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The CIRRUS HD-OCT 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	Class A	The CIRRUS HD-OCT CIRRUS are suitable for use in all establishments other than domestic establishments and those connected to a low voltage power supply network which supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000–3–2	Class A	
Voltage fluctuations/flicker emissions IEC 61000–3–3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The CIRRUS HD-OCT is intended for use in the electromagnetic environment specified below. The customer or user of the CIRRUS HD-OCT 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 61000–4–2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	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 61000–4–4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000–4–5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 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 sec	<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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CIRRUS HD-OCT requires continued operation during power mains interruptions, it is recommended that the CIRRUS HD-OCT be powered from an uninterruptible source.
Power frequency (50/60 Hz) magnetic field IEC 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.
U_T is the a.c. mains voltage prior to application of the test level.			

<table>
<tr><td colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</td></tr>
<tr><td colspan="4">The CIRRUS HD-OCT is intended for use in the electromagnetic environment specified below. The customer or user of the CIRRUS HD-OCT should assure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF IEC 61000–4–6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 V</td><td rowspan="2">Portable and mobile RF communications equipment should be used no closer to any part of the CIRRUS HD-OCT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

Recommended separation distance

$d = 1.17\sqrt{P}$ 80 MHz to 800 MHz

$d = 2.33\sqrt{P}$ 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).
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000–4–3</td><td>3 V/m
80 MHz to 2,5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">Note 1: At 80 MHz and 800 MHz, the higher frequency applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
<tr><td colspan="4">a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CIRRUS HD-OCT is used exceeds the applicable RF compliance level above, the CIRRUS HD-OCT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CIRRUS HD-OCT.
b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

RoHS Compliance

The product is RoHS-compliant according to Directive 2011/65/EU.

2 Introduction

Intended Use

The CIRRUS™ HD-OCT with Retinal Nerve Fiber Layer (RNFL), Macular, Optic Nerve Head, Ganglion Cell and Asian Normative Databases is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures.

Indications for Use

The CIRRUS™ HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, ganglion cell plus inner plexiform layer, macula, and optic nerve head. In addition, the system physically interacts with the patient's forehead and chin.

The CIRRUS normative databases are quantitative tools for the comparison of retinal nerve fiber layer thickness, macular thickness, ganglion cell plus inner plexiform layer thickness, and optic nerve head measurements to a database of normal subjects. The CIRRUS Asian Normative Database is a quantitative tool for the comparison of these measurements to a database of normal subjects of Asian descent. The CIRRUS HD-OCT is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.

NOTE: The CIRRUS HD-OCT is not intended to be used as the sole diagnostic method for disease.

Usage

The CIRRUS instrument is designed for continuous use, although it is expected that most sites operate the instrument for 10 hours or less per day, indoors, within a medical office or hospital setting. This setting shall have clean air free of soot, vapors from adhesives, grease or volatile organic chemicals. Other Operating Environment specifications are given in Chapter 13 "Specifications". Application–related warnings are given in this chapter and elsewhere.

CIRRUS HD-OCT is not a portable device. It is intended for placement in one location. However, there is no permanently installed infrastructure associated with the instrument, and it can be moved between locations following the applicable guidelines and warnings in this chapter.

Intended Operator Profile

CIRRUS operators are clinicians or technicians with professional training or experience in the use of ophthalmic imaging equipment. Specific assumptions regarding the profiles of individuals performing instrument operation are given below.

Demographic

An adult with one of the following qualifications:

- Ophthalmologist or other Medical Doctor
- Optometrist or equivalent
- Nurse
- Certified Medical Technician
- Ophthalmic Photographer
- Non–certified Assistant

Occupational Skills

Must possess all of the following skills:

- Computer literate
- Basic knowledge of the eye
- Ability to work with elderly patients and those with disabilities

Job Requirements

Must be able to perform all of the following operations:

- Power on the unit and log on
- Enter, find and modify patient identifying data
- Clean surfaces that contact patient
- Position patient with the device, including moving the patient, the device, the table height and the patient's chair
- Select and acquire scan
- Review and save scan or try again
- Generate analysis report using available analysis protocols
- Review the analysis report for completeness
- Output analysis report
- Archive data
- Turn off the unit

Data Analyst Profile

CIRRUS data is to be interpreted by clinicians or technicians with professional training in diagnostic interpretation of the images generated. Specific assumptions regarding the profiles of individuals who carry out data interpretation are given below. This guide contains information that will aid in the proper interpretation of the resultant data.

Demographic

Must have one the following qualifications:

- Ophthalmologist or other Medical Doctor
- Optometrist or equivalent

Occupational Skills

Must possess all of the following skills:

- Computer literate
- Ability to work with elderly patients and those with disabilities

Job requirements

Must be able to perform the following requirements:

- Training and certification as required by governing bodies to interpret the analysis in the treatment of ophthalmic diseases or other eye-related medical issues.

Subject Profile

CIRRUS shall be used on all adults in need of diagnostic evaluation of the eye, including patients with the following disabilities or challenges:

- Wheelchair user
- Very low or not measurable visual acuity
- Fixation problems
- Postural problems
- Deafness
- Large body, but not those above 99th percentile based on anthropomorphic data

There is a general requirement that the patient be able to sit upright and be able to place their face in the chin and forehead rest of the instrument (with or without supplemental human or mechanical support).

Installation and Setup

If you have purchased a new CIRRUS HD-OCT instrument, it will arrive with licensed software fully installed. Your Zeiss Service Representative will arrive shortly thereafter, and

will work with your IT personnel to set up your network and archiving protocol based on the workflow of your institution.

If you are upgrading a CIRRUS HD-OCT instrument with new software, refer to the *CIRRUS HD-OCT Installation Guide* delivered with your CIRRUS kit, for instructions on software installation.

If you are installing version HD-OCT software on a separate PC or Laptop, in order to run stand alone **Review Software**, it is highly recommended that you only install the software with assistance of an IT professional. This will ensure that your computer is properly connected to reflect your clinical networking environment. This will increase security and reduce the chance of any loss of patient data.

Refer to the *CIRRUS HD-OCT Installation Guide* for all questions regarding:

- **Hardware Installation**
- **Software Installation**
- **Network Setup.**

User Documentation

CIRRUS HD-OCT user documentation includes the following:

- **Installation Guide**
- **User Manual (this manual)**
- **Release Notes**

User documentation has been written to train, use, and serve as a reference for proper installation, network access, operation, scanning and data analysis. The User Manual is delivered in PDF format, but you may request a hardcopy manual at any time.

Training is offered by Zeiss in the use of CIRRUS. Such training does *not* include training in diagnostic interpretation of the data and analyses.

Accessing PDF Versions

The PDF version of this User Guide is provided in two ways:

1. **Through the instrument:** Select **On–Line Manual** from the Help (click **Help > On-Line Manual**) menu to access the user guide information through the CIRRUS software.
2. **Via USB drive**. Included in the instrument accessory kit. You can view the user guide PDF either using the CIRRUS system computer, or any other computer.

Once opened, you can switch between the user guide and the CIRRUS application by pressing **Alt+Tab**, as shown on the right.

Organization

This User Manual has been written to provide a comprehensive overview of the CIRRUS HD-OCT system and its software. It provides guidelines for successful

- Clinical setup and workflow

- Data acquisition and acceptance
- Analysis and interpretation of CIRRUS data

A set of normative data studies is provided for comparison during patient assessment.

In addition, instructions and information are provided to ensure that data is safely managed and that the system is properly maintained.

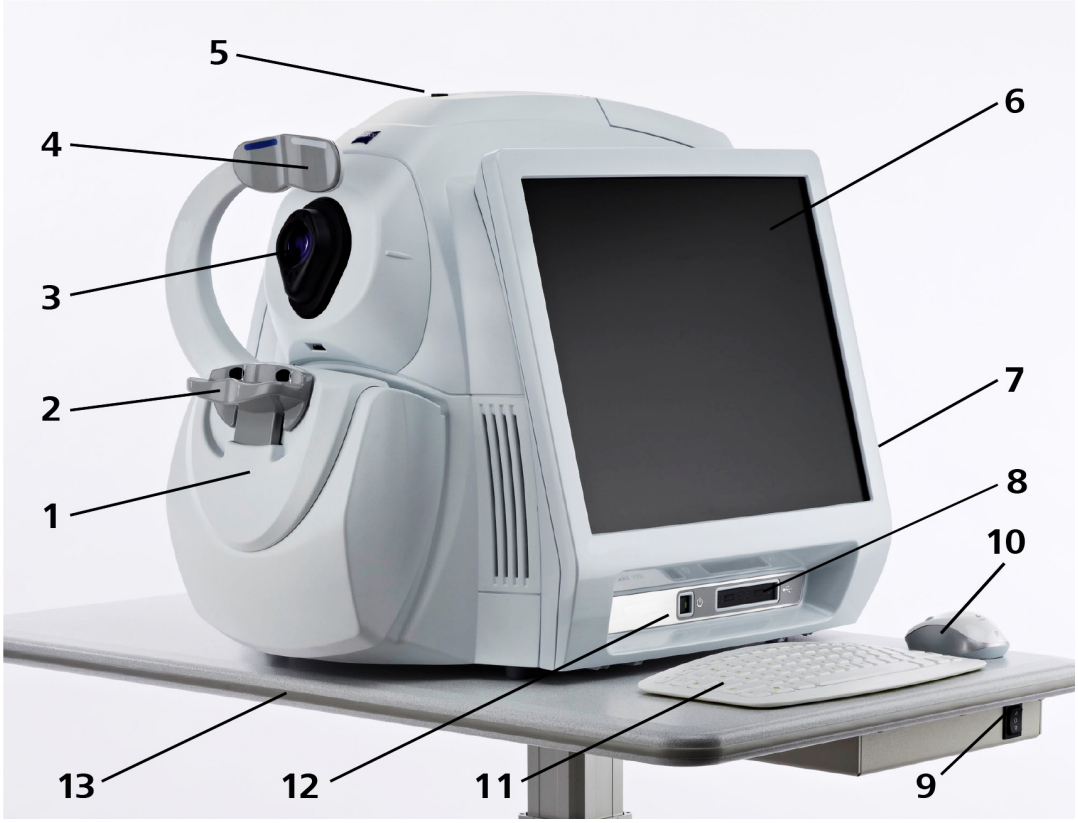
Instruction Conventions

- "Click" means "left–click" except where "right–click" is specified.
- Chains of menu items are indicated with the use of the "**>**" symbol between items. For example, "**File > Exit**" directs you to select **Exit** in the **File** menu.

3 System Overview

Hardware

As shown in Figure 3-1, the CIRRUS HD-OCT system is delivered as a single unit, except for keyboard, mouse, and an optional height–adjustable worktable.



1 Motorized Patient Alignment Unit
2 Dual Chinrest with Automatic Right/Left Sensors
3 Imaging Aperture
4 Head Rest
5 Port for External Fixation Arm
6 Integrated Video Monitor
7 Connectors (USB, network, etc.) and labels under rear cover
8 USB Ports (2)
9 Table Height Control
10 Mouse
11 Keyboard
12 System Power Switch
13 Power Table (Optional)

Figure 3-1 CIRRUS HD-OCT Hardware

Patients are instructed to sit at a 90 degree angle to the Integrated Video monitor, with chin on the Chinrest, head against the Head Rest, and selected eye looking into the Imaging Aperture. This procedure is discussed in detail in Chapter 5 "Clinical Workflow".

Power Up

The instrument is powered on just under the monitor (12).

The software will start automatically, and run a Data Validation Check which, once passed, will allow you to begin setting up your instrument, by pressing **Continue**.

Should the software fail for any reason, contact Zeiss Customer Service immediately.

Power Down

You can power down the system either through hardware or through software.

⚠ **CAUTION: We strongly recommend you power down through software to permit automatic archiving on shutdown and to avoid abrupt shutdowns that could result in loss of patient data.**

Power Down Through Software

1. Click **Logout** at the upper right on the **ID Patient** screen.
2. If archiving is set to occur upon shutdown, (see "Archive/Synchronize" on page 4-8), the system will prompt you to archive. This is true in both Native and DICOM Archive modes.

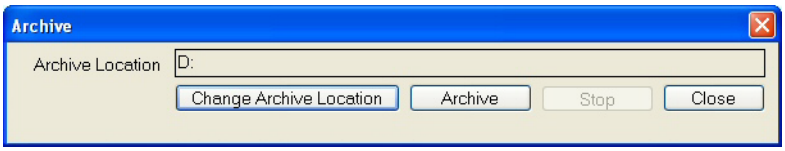


Figure 3-2 Archive Prompt Dialog – Native Archive Mode

   Execute the desired option to advance to the **Exit Dialog**.
3. When you archive or close the **Archive** dialog (see above), the **Exit Dialog** will ask if you are sure you want to exit.

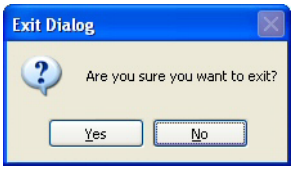


Figure 3-3 Exit Dialog

4. Click **Yes** to exit the CIRRUS software.
   - If you click **No**, the **Login** dialog will appear.

After you exit the system software through the soft shutdown sequence, Shutdown the CIRRUS HD-OCT instrument as you would any other PC.

Power Down Through Hardware

⚠ **CAUTION: We strongly recommend you power down through software to permit automatic archiving on shutdown and to avoid abrupt shutdowns that could result in loss of patient data.**

To power down through hardware, press the system power switch. The system will automatically close the operating system and power down the system. You will not have access to the computer operating system.

Software

Overview

The CIRRUS HD-OCT instrument is delivered with software installed. The set of licenses you purchased with the instrument will determine which scans are available (see Licensed Applications below). Your CIRRUS HD-OCT kit includes a USB flash drive with CIRRUS software. This can be installed on one or more separate workstations (PC's or laptops), to allow for review and analysis of data scanned on the CIRRUS HD-OCT instrument.

The *Installation Guide,* which can also be found on the USB flash drive that comes with your kit, provides instructions on how to install the software on separate (PC or Laptop) workstations (called Review Stations), or upgrade software on your CIRRUS HD-OCT instrument.

Licensed Applications

The CIRRUS HD-OCT instrument is delivered with the following basic licenses:

- All Posterior Segment Scans/Analyses *except* OCT Angiography
- Anterior segment 5 line raster
- Anterior Segment Cube 512x128

Access to the following options depends on the licenses purchased with the CIRRUS HD-OCT instrument:

- OCT Angiography
- HD Angle
- HD Cornea
- Pachymetry
- Wide Angle-to-Angle

To add a license to your CIRRUS HD-OCT instrument, contact your Zeiss Sales Representative for a license key. See the *CIRRUS HD-OCT Installation Guide* for information on how to unlock licenses.

Basic Screens

There are four root screens (shown in Figure 3-4) for the CIRRUS system, from which all other functionality derives:

- Patient Screen – The first screen seen on start up. You will always be using one of the three tabs on the Patient Screen to select or add a patient of interest before scanning or analysis can take place. The Patient Screen is fully described in Chapter 4 "System Administration" and Chapter 5 "Clinical Workflow".

- **Acquire Screen** – Described in connection with each of the scans available with your software license. See Chapter 6 "Acquiring Scans" for detailed descriptions.
- **Quality Check Screen** – After the completion of any scan, the Quality Check Screen will appear, allowing the clinician who made the scan, to review it for quality. If adequate, the scan will be completed; if not, the clinician will be returned to the previous Acquire Screen. See Chapter 7 "Scan Quality Check" for a full description of Quality Check Screens.
- **Analysis Screen** – Following scan acquisition and acceptance, data is reviewed on the Analysis Screen. The exact layout of the Screen is determined by the Analysis type selected. See Chapter 8 "Analysis" for a complete discussion of Analysis Screen.

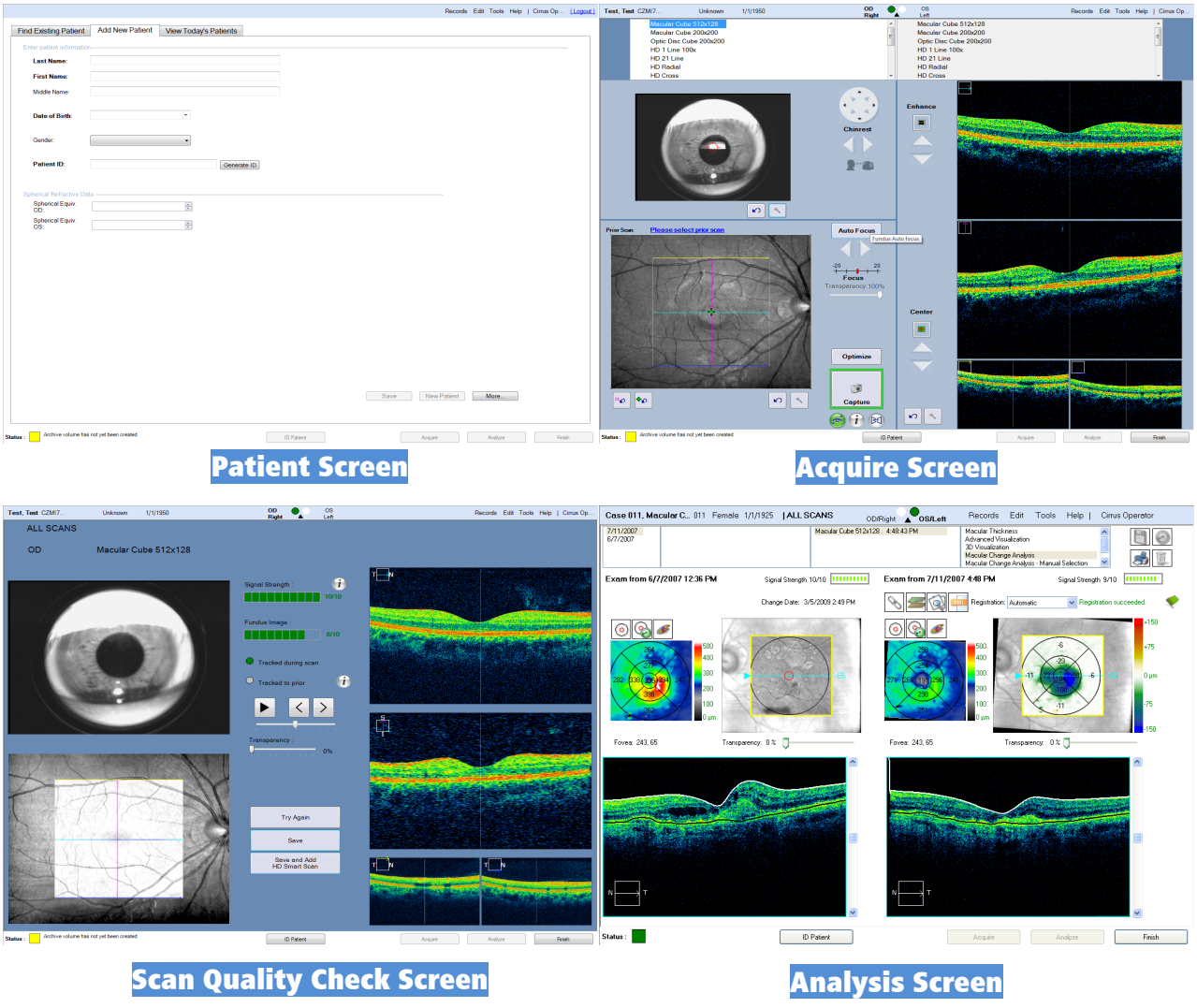


Figure 3-4 CIRRUS HD-OCT four root screens: Patient, Acquire, Quality Check, and Analysis

All CIRRUS software screens are comprised of three main parts as shown in Figure 3-5.

The **Toolbar** and **Navigation Bar** options are discussed below. The main **Working** portion of the screen will be described as they appear in the discussion of software functionality in the chapters which follow.

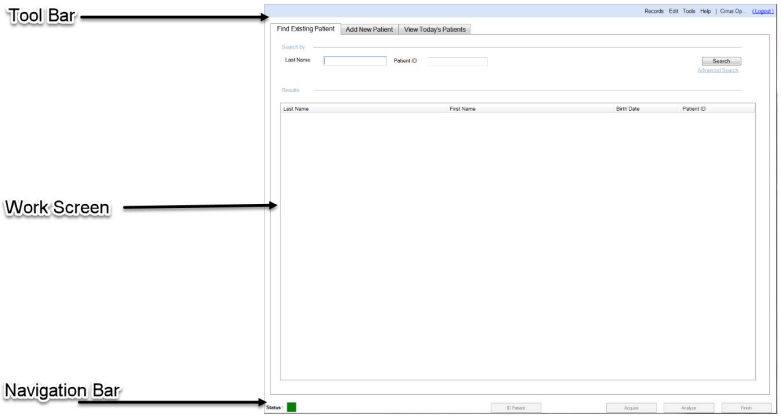


Figure 3-5 All CIRRUS software screens are comprised of the Toolbar at the top, the main Work portion of the screen in the center (which changes depending on the functionality of the screen), and the Navigation Bar along the bottom.

Toolbar Options

Each of the main CIRRUS screens has a series of associated menus and options that pertain to the way in which the screen is used. An overview of these items are shown here, however, additional options may become available during scan acquisition and analysis, and are described in the relevant chapters elsewhere.

The CIRRUS Toolbar appears above all of the 4 main CIRRUS screens shown in Figure 3-4. Access to information shown on the current screen, as well as a set of menus, **Records**, **Edit**, **Tools**, and **Help**, is always shown on the main CIRRUS Toolbar. Click to select menus and menu items. Note the following general characteristics of the menus.

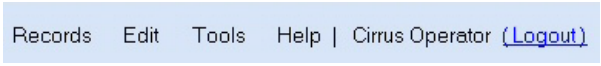
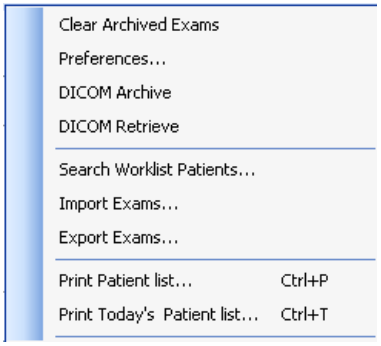


Figure 3-6 Menu Bar (upper right)

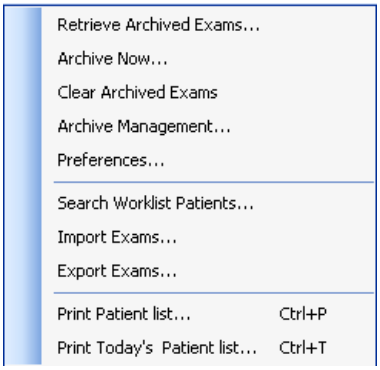
- **Disabled menu items** appear in gray. These items are not available in the current context.
- **Items with an ellipsis ["..."] following** indicate the menu item launches a dialog giving you further options before the command is executed.

The table below identifies and describes the items in each menu, and indicates when each item is enabled. Note the keyboard shortcuts to the right of applicable menu items.

Records Menu – DICOM Archive



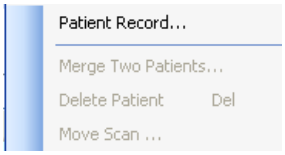
Records Menu – Native Archive



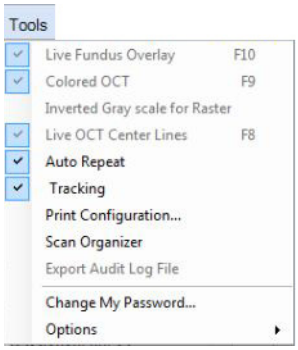
Menu Items and Descriptions	Enabled in Mode
• **Clear Archived Exams**: Prompts you to clear exams when disc space is low.	ID Patient mode
• **Preferences...**: **Archive/Synchronize:** During instrument startup or shutdown, alerts the user to archive exams and clear data after archiving. **Normative Database Settings** allows selection of the normative database to be used as the default. **Display Options** allows change to default setting. **DICOM Archive** allows you to disable Auto–Query and/or Auto–Archive. **IPv4 / IPv6** allows you to select Internet Protocol version.	ID Patient mode
• **DICOM Archive**: Allows archive of patient records through the DICOM server.	ID Patient mode
• **DICOM Retrieve:** Allows retrieval of patient records through the DICOM server.	ID Patient mode
• **Search Worklist Patients...**: Opens the **Modality Worklist** dialog, allowing you to set parameters for patient search through the DICOM server.	ID Patient mode
• **Import Exams...**: Opens the **Import Options** dialog to import a CIRRUS export database or to select specific patients to import.	ID Patient mode
• **Export Exams...:** Opens the **Export Options** dialog, where you can select and export patient records.	ID Patient mode
• **Print Patient list...**: Prints patient list that is displayed on the main screen.	ID Patient mode
• **Print Today's Patient list...**: Prints today's patient list that is displayed on the **View Today's Patients** tab.	ID Patient mode
• **Retrieve Archived Exams...**: Retrieves selected archived exams from the Native archive.	ID Patient mode
• **Archive Now...:** Archives all unarchived exams to the Native archive.	ID Patient mode
• **Clear Archived Exams**: Prompts you to clear exams when disc space is low.	ID Patient mode
• **Archive Management**: In Native Archive mode only, allows you to create archive locations and set default parameters.	ID Patient mode

Edit Menu – Native Archive

Edit Menu – DICOM Archive

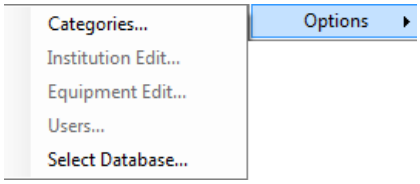


Tools Menu



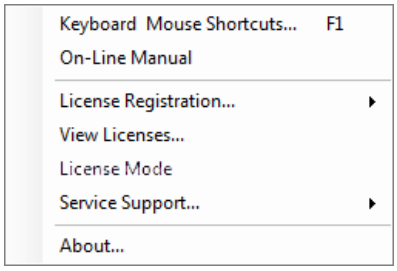
Menu Items and Descriptions	Enabled in Mode
• **Preferences...**: **Archive/Synchronize:** During instrument startup or shutdown, alerts the user to archive exams. Selecting **DICOM Archive**, user may disable Auto–Query of Modality Worklist. **Display Options** allows change to default setting. **IPv4 / IPv6** allows you to select Internet Protocol version 4 or 6.	ID Patient mode
• **Search Worklist Patients...**: Opens the **Modality Worklist** dialog, allowing you to set parameters for patient search through the DICOM Worklist server.	ID Patient mode
• **Import Exams...**: Opens the **Import Options** dialog to import a CIRRUS export database or to select specific patients to import.	ID Patient mode
• **Export Exams...**: Opens the **Export Options** dialog, where you can select and export patient records.	ID Patient mode
• **Print Patient list...**: Prints patient list that is displayed on the main screen.	ID Patient mode
• **Print Today's Patient list...**: Prints today's patient list that is displayed on the View Today's Patients tab.	ID Patient mode
• **Patient Record...**: Opens the **Patient Edit** dialog for the current patient, to view and/or edit the record.	ID Patient mode with a patient selected
• **Merge Two Patients...**: Opens the **Patient Merge** dialog, where you can select two patient records to merge.	ID Patient mode
• **Delete Patient**: Generates a confirmation prompt, asking user if they wish to delete the selected or opened patient record from the database.	ID Patient mode with a patient selected
• **Move Scan...**: Opens the **Move Scan** dialog, where you can select a patient file to move the selected scan into.	Analyze mode
• **Patient Record...**: Enabled in DICOM Archive Mode, if a record is selected, but only to use the Add/Remove Categories tab. If no record is selected, then all options are disabled.	
• **Live Fundus Overlay**: Toggles the display of the overlay on or off. When off, only the outline of the scan region is visible (the bounding box) and not the vertical and horizontal slice locations. The default is checked (overlay visible).	Acquire mode
• **Colored OCT**: Toggles the display of OCT images from color to grayscale.	Acquire and Analyze modes
• **Inverted Gray scale for Raster:** Changes black pixels to white and white to black on gray scale raster scans.	Acquire and Analyze modes

Tools > Options



Menu Items and Descriptions	Enabled in Mode
• **Live OCT Center Lines**: Toggles the display of a vertical "centering" line on OCT images. The default is checked (center lines visible).	Acquire mode
• **Auto Repeat**: Automatically adjusts the ocular lens and chinrest to the previous settings for the same patient, eye, and acquisition function.	Acquire mode
• **Tracking**: Toggles FastTrac™ on or off as a global choice for all scans.	Acquire mode
• **Print Configuration...**: Opens the **Printout Configuration** dialog, where you can select the report options for Macular Thickness, ONH, and (HD 5 Line) Raster, as well as set Macula Multi-slice parameters.	Always
• **Scan Organizer**...: Opens the **Scan Organizer** dialog from which you can choose to show or hide available scans, or change their order. See "Scan Organizer" on page 6-21.	ID Patient mode
• **Export Audit Log File**...: Records certain events and identifies them by date, time, and User ID. See "Log Files" on page 11-17.	**Admin** mode
• **Change My Password...**: Enables you to change the password for the current user.	Always, except for **admin** user
• **Options...**: Enables access to the following options.	Always
• **Categories...**: Enables you to create, edit, or delete categories, which you can apply to patient records and search with.	ID Patient mode
• **Institution Edit...**: Enables you to customize your CIRRUS HD-OCT and reports generated from it by adding or editing the institution name, ID Issuer, and optional logo graphic.	When logged in as **admin** user
• **Equipment Edit...**: Open the **Equipment Edit** dialog, where you can create a station name for the instrument, create DICOM AE Title, and view other equipment information.	When logged in as **admin** user
• **Users...**: Enables you to create, edit, or delete staff as users and designate their user privileges.	When logged in as **admin** user
• **Select Database...**: Enables you to switch between different instrument databases.	Review Software

Help



Menu Items and Descriptions	Enabled in Mode
• **Keyboard Mouse Shortcuts...**: Displays a categorized listing of keyboard shortcut keys and mouse functions.	Always
• **On–Line Manual**: Opens the CIRRUS User Manual PDF.	Always
• **License Registration...**: Enables you to register a license through the License Registration Utility that appears when you select a license type.	Always
• **View Licenses...**: Opens the **View Licensed Features** dialog, where you can view the licensing status of optional features.	Always
• **License Mode**: Enables you to configure the licensing option: **Use floating licenses from FORUM** or **Use Node–Lock Licensing**.	Review Software (DICOM Mode) Only
• **Service Support...**: Enables you to select the **TeleService** web link for remote online servicing of the instrument, and save a Log file for troubleshooting.	Always
• **About...**: Displays the **About** dialog, which provides software version information.	Always

Navigation Bar

The navigation bar resides at the bottom of all CIRRUS main screens and includes buttons by which from which you can direct CIRRUS operations.

Figure 3-7 Navigation Bar (along bottom)

- **ID Patient**: Returns you to the **ID Patient** screen.
- **Acquire**: Initiates scan acquisition. Only active when a patient is selected.
- **Analyze**: Initiates analysis. Only active when a patient with saved scans is selected.
- **Finish**: Exits the current activity (scan or analyze) and returns you to the appropriate screen. Only active when in Acquire or Analyze modes.

Status Area

The status area at bottom left presents current status information using a single green–yellow–red indicator.

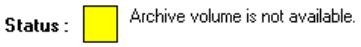


Figure 3-8 Status Area Showing Yellow Indicator (lower left)

Overall Status by Color

The overall instrument status is communicated by the color. The colors have the following meanings:

- **Green means OK or normal**: The instrument is functioning normally.

- Yellow means warning: The instrument is operational but a problem or set of problems exist.
- Red means critical: One or more serious problems exists that restricts use of the instrument.

Components of Status

The following components contribute to the overall status.

NOTE: Mouse over the status indicator and popup text will explain the current status in terms of the status components below.

Instrument Status

Indicates whether or not the instrument hardware is in communication with the system computer, and therefore capable of acquiring new scans. It can report status as either ready to acquire scans (green) or unable to acquire new scans (red).

- Red: If instrument status is red, we suggest you cycle power off and then power on the instrument). If the problem persists, contact CZMI customer service.

Hard Disk Status

Indicates available hard disk space status. It can report three statuses:

- Green: Adequate free hard disk space.
- Yellow: Low hard disk space. When free hard disk space is low at startup, you must click Continue at system start before continuing to the login screen. Also, the system prompts you to clear archived exam data.
- Red: Critically low hard disk space. When hard disk space is critically low, the Acquire button is disabled. You must clear a sufficient amount of hard disk space by clearing archived exams to continue. If there are insufficient archived exams to be cleared, you must first archive exams and then clear them. You cannot clear unarchived exams.
  Once you have created space on your hard drive, the indicator will change to green. However, the Acquire button remains disabled until you shut down, then restart the CIRRUS application.

Network (Archive) Status

Indicates available network (archive) storage space and availability status. It can report three statuses:

- Green: Network available with adequate network archive disk space.
- Yellow: Low network archive disk space or network unavailable. When archive disk space is low, you will be prompted to change the archive location, but you can continue using the same archive location for now. The message Archive volume is not available indicates that the current archive location is not accessible.
- Red: Critically low network archive disk space. When archive disk space is critically low, CIRRUS will stop archiving to this location. You must change to a new archive location to re–start archiving.

DICOM Connectivity Status

- **Green**: DICOM functions, if DICOM was selected during installation, are normal.

NOTE: On rare occasions, the DICOM features may not actually be available even though the Status Indicator is green, indicating that you are connected to DICOM. If this occurs, check the DICOM Gateway Configuration IP address (see the *CIRRUS HD-OCT Models 500, 5000 Installation Guide*) and ensure that the IP address is set to: **127.0.0.1.**

- **Red**: Networking and search errors are reported, along with recommendations for resolution.

4 System Administration

The person assigned as the Administrator for the CZMI network in your clinic will oversee the administrative functions of the software. These functions can be broken down into the following parts:

- Institution Setup
- Station Setup
- Staff Setup
- Category Registration
- Archive Setup

These topics are discussed in the sections which follow.

Adding patients and managing patient workflow is discussed in Chapter 5 "Clinical Workflow".

Institution Setup

It is not necessary, but highly recommended, that the person assigned as the CIRRUS Administrator set up information that uniquely identifies your institution, whether office, clinic, or hospital.

To Specify your Institution name and add a logo (if desired):

1. From the Toolbar, click **Tools > Options > Institution Edit** The dialog box opens as shown in Figure 4-1.

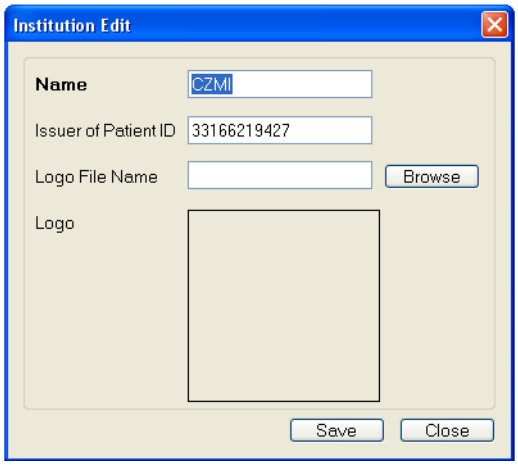


Figure 4-1 Institution Edit Dialog

2. In the **Name** field, type the name of your institution. The field requires at least one character and accepts up to 64 characters, including spaces. The name field cannot be empty.

3. Add the value of the Issuer of Patient ID in this field. The **Issuer of Patient ID** field denotes assigning authority of patient IDs entered at a particular site or practice. As a recommendation, it should be set to the same value on every instrument in the practice and to the same value as in the leading patient information system, if applicable. If the Issuer of Patient ID already exists—for example, the same one used in the previous software version—the value appears in the **Issuer of Patient ID** field, where it can be edited, if desired. Changes made to the identifier of the Issuer of Patient ID will be applied to patients going forward; the change will not appear on patient information already in the database.
4. Add Institution Logo Graphic (Optional). The graphic must be in bitmap format (**.bmp**). Use **Browse** to navigate to the graphic file of your choice. The selected file will appear in the Preview pane, which is 150 pixels square (1.9 cm or 0.75 inches square at 200 pixels/inch), and will be stretched or constrained to fit it. The graphic will then appear in these proportions on analysis reports, though in a smaller size.
5. Click **Save** to save your changes and exit the dialog, or click **Close** to exit the dialog without saving.

NOTE: You must restart the CIRRUS application to cause changes to the Institution Name to appear in the header of reports.

Station Setup

For every instrument or Review station, a unique station name and AE Title must be specified in order distinguish CIRRUS HD-OCT instruments, Review Stations, and any additional CZMI equipment your institution may use.

To access the **Equipment Edit** dialog, you must be logged in as the **Admin**. Follow these steps to create (or edit) the station name of the instrument:

1. From the Toolbar select **Tools > Options > Equipment Edit.** An example dialog box appears as shown in Figure 4-2.

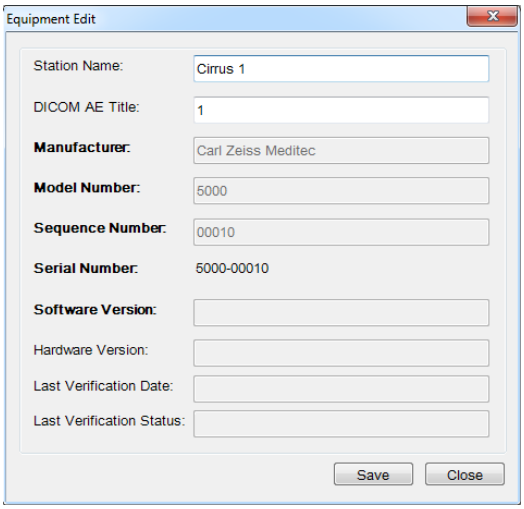


Figure 4-2 Equipment Edit Dialog

2. In the **Station Name and AE Title** fields, type in the desired information. The remainder of the information is already set.

NOTE: The AE Title is originally determined during setup of the DICOM Gateway which is discussed in Chapter 11 "Data Management". These names must match.

3. Click **Save** to save your changes and exit the dialog, or click **Close** to exit the dialog without saving.

Staff Accounts

It is strongly recommended that you create individual user accounts for each staff member who acquires or analyzes scans, and that staff members routinely log out to secure the instrument. Following these procedures helps prevent unauthorized access to CIRRUS HD-OCT data and functions, and enables accurate record–keeping.

For record–keeping, CIRRUS HD-OCT records the user name under which each scan is acquired; it displays the current user next to the **Logout** link at upper right.

Register New Staff

1. From the Toolbar ("Toolbar Options" on page 3-5) select **Tools >Options > Users**. The **Staff Registration** dialog box will appear as shown in Figure 4-3.
2. Click **New**. The **New Staff** dialog box appears.

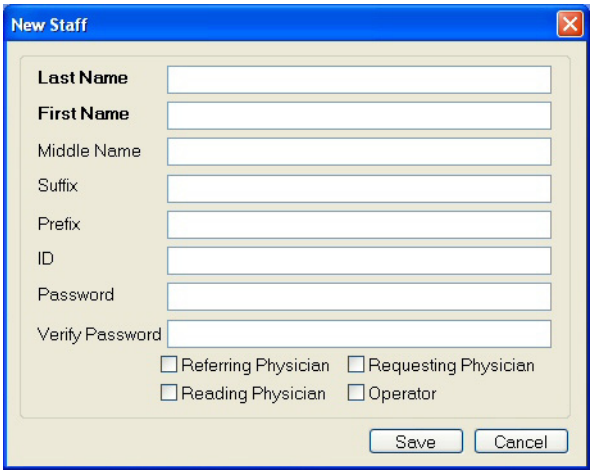


Figure 4-3 New Staff Dialog

3. Edit the staff registration fields as desired. A staff record must have either a last name or first name or both; other fields are optional. To log in with the specified user **ID** and acquire scans, the **Operator** checkbox must be selected. When finished with your changes, click **Save**. Both user names and passwords are case–sensitive. Once logged in, any user can change his or her own password by selecting **Options > Change My Password** see "Toolbar Options" on page 3-5. The **Admin** may take advantage of this feature by creating new user accounts with a temporary password, providing it to the user, and asking the user to change the password.

Edit Staff Records

To edit medical staff records, follow these steps:

1. In the **Staff Registration** dialog, select a staff record and click **Edit**. The **Staff Edit** dialog opens. It resembles Figure 4-3 above except that the name of the selected staff appears in the title bar.
2. Edit the staff registration fields as desired and then click **Save**. Only the bold **Last Name** and **First Name** fields are required; other fields are optional.
   - To discard the changes before saving, click **Cancel**. A dialog prompts you to confirm your choice.

Delete Staff Records

To delete medical staff records, follow these steps:

1. In the **Staff Registration** dialog, select a staff record and click **Delete**. A dialog will ask you to confirm your choice.

Figure 4-4 Confirm Staff Deletion Dialog

2. Click **OK** to confirm deletion, or click **Cancel** to cancel deletion.

You cannot delete a staff record if there are any references to it in exam data. If you try to delete it, a dialog appears and so informs you.

Category Registration and Maintenance

Category Registration

Patient Categories are created through the **Category Registration** dialog. Categories are essentially patient search criteria that allow CIRRUS HD-OCT users to search patient records by category. This function is not available in DICOM Archive mode.

To register a category:

1. Select **Tools > Options > Categories** The Category Registration dialog opens as shown in Figure 4-5.

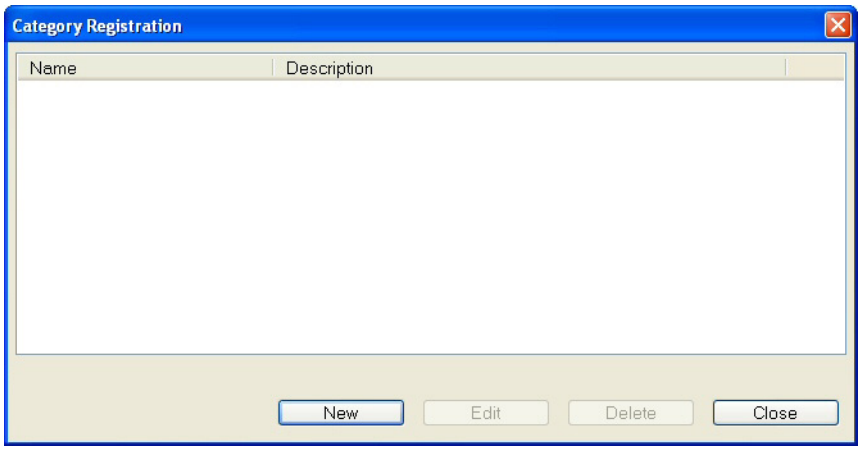


Figure 4-5 Category Registration Dialog

All categories already registered appear in the list, sorted alphabetically. None is selected by default.

2. Select **New.** The Category Edit dialog will appear as shown in Figure 4-6.

.

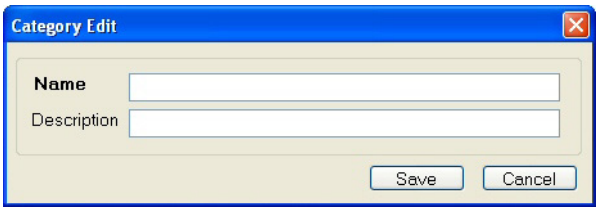


Figure 4-6 Category Edit Dialog

3. In the Name field, type in a name for the new category, up to 64 characters, including spaces. You may enter an optional description.
4. Click **Save**. The new category now will be available to place patients in it.

Edit Categories

NOTE: You cannot edit categories created at another institution.

1. In the **Category Registration** dialog (Figure 4-5), select a category and click **Edit**. The **Category Edit** dialog appears. (See Figure 4-6)
2. In the Name and Description fields, edit the category as desired.
3. Click **Save** to save your changes.

Delete Categories

1. In the **Category Registration** dialog, select a category and click **Delete**. A dialog will ask you to confirm your choice.
2. Click **OK** to confirm deletion, or click **Cancel** to cancel deletion.

Archive Setup and Selection

Operators as well as Admin's may set up and specify archives. However, it is recommended that the Admin oversee archive setup, in order to ensure that patient data is kept cohesive and transparent within the institutional environment.

NOTE: You cannot set up an archive from a Review Station in instrument mode.

Set up a CIRRUS HD-OCT Archive

1. From the CIRRUS HD-OCT instrument, obtain the **name** and **location** of the shared folder on the **Network File Server** that will be used to archive your data (see Chapter 4 of the *CIRRUS HD-OCT Installation Guide*).
2. Log in as a CIRRUS operator.
3. From the Toolbar, select **Records > Archive Management**. The **Archive Registration** dialog box appears (see Figure 4-7).

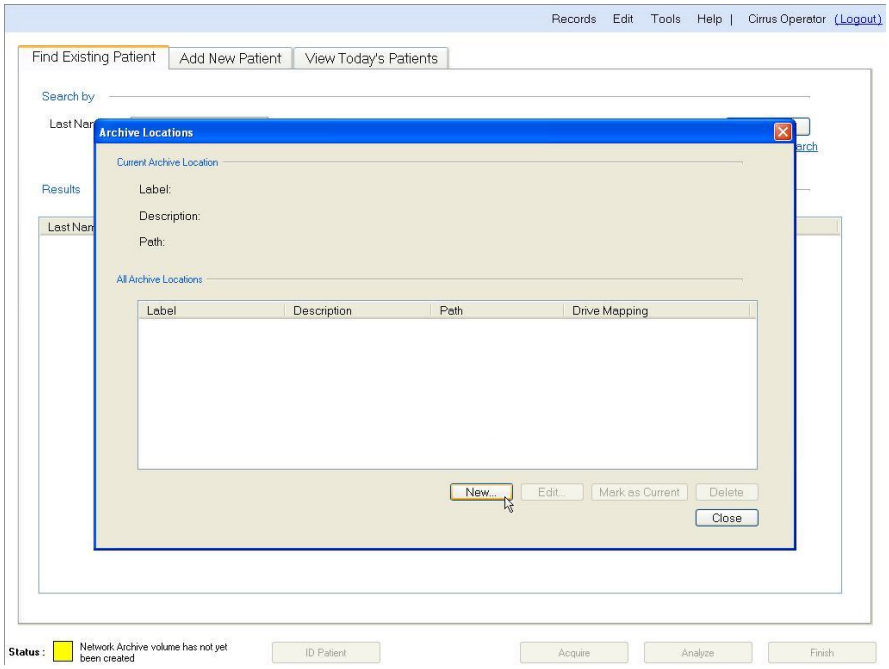


Figure 4-7 New Archive Registration Dialog

4. In the Archive Locations dialog, click **New**. The **New Archive Registration** dialog appears, as shown below (Figure 4-8).

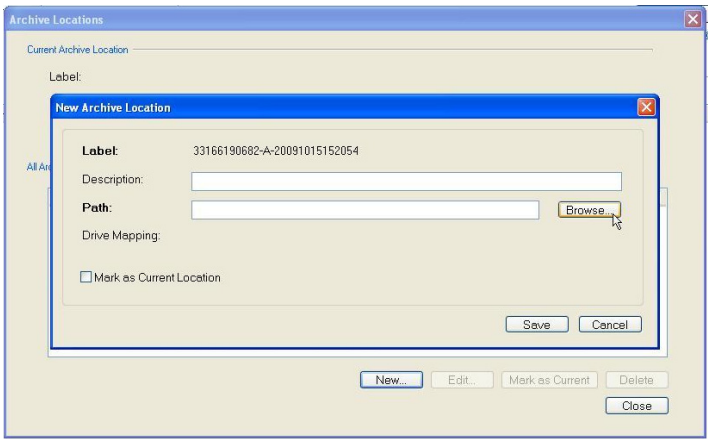


Figure 4-8 New Archive Location

In the New Archive Location, your label will be made up of made up of two parts. The first part, shown at the top of the dialog box, is generated automatically and cannot be changed. It is composed of the model number, serial number and archive sequence number. You can add a suffix to the name using the second part of the field.

5. If you want to be able to identify this archive location via a distinct descriptor, specify it in the **Descriptor** field (up to 85 characters).
6. Click **Browse** next to the **Path** field to find and select the shared archive folder on the network file server.
7. Select **Mark as Current,** if you want to begin using this archive location.
8. Click **Save** to register the new archive. The new archive will now appear in the list of **Archive Locations**. The check mark to the left of the archive name indicates that this is your current archive location (Figure 4-9).

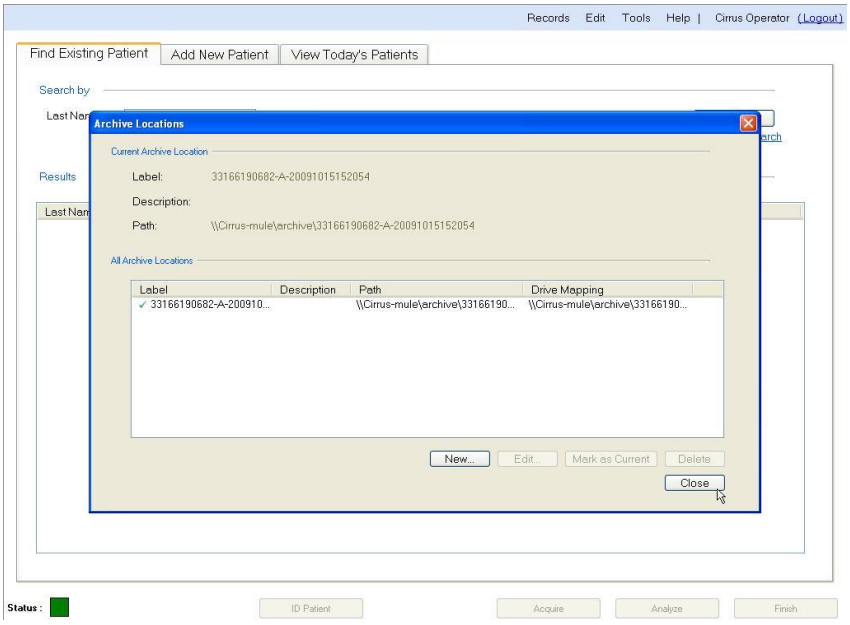


Figure 4-9 Current Archive

9. Click **Close** to close the dialog box.

Change The Current Archive

1. From the Toolbar, select **Records > Archive Management**. The **Archive Registration** dialog box appears (see Figure 4-7).
2. Select the archive of interest.
3. Check **Mark as Current**.
4. **Close**.

Set Preferences

Archive/Synchronize

CIRRUS HD-OCT gives you a way to modify the default archive behavior for both Native and DICOM Archive modes. Select **Records > Preferences** to access the **Preferences** dialog at the Archive/Synchronize tab.

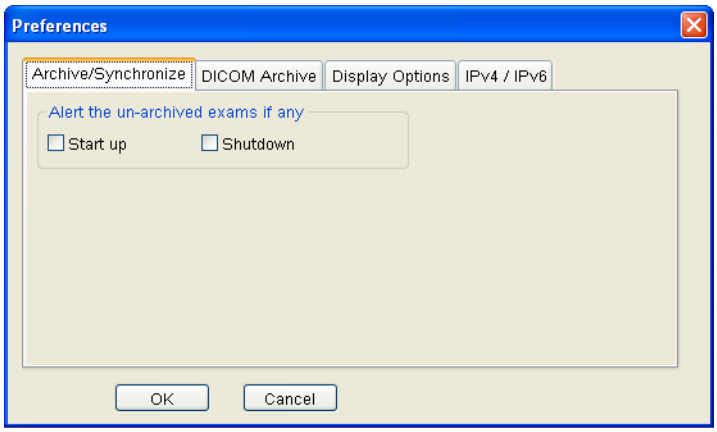


Figure 4-10 Preferences > Archive/Synchronize

Figure 4-10 displays the default settings for Archive/Synchronize. It is possible to select one, neither or both **Start up** and **Shutdown**. When finished selecting your preferences, click **OK** to save your changes and exit, or click **Cancel** to exit without saving. The options are described below.

Archive Alerts

By default, the system alerts you to the presence of unarchived exams upon shutdown and asks if you want to archive them. Should you choose neither archive checkbox, the system will not prompt you to archive at all. However, when the hard disk status turns yellow, you may have to archive exams in order to clear enough archived exams to return the status to green. At that time, archiving may take several hours. You must archive if the hard disk status turns red and you cannot clear enough space to enable scanning and analysis. You can archive manually at any time by selecting **Records > Archive Now**.

Normative Data Settings

If you have the Asian Normative Database License, the **Normative Data Settings** tab is displayed in the Preferences dialog.

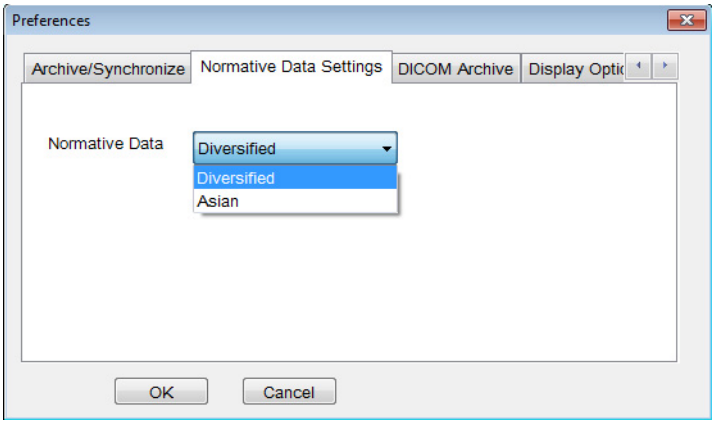


Figure 4-11 Preferences > Normative Data Settings

The normative database selected from the **Normative Data** menu becomes the default setting used for image normative data analysis for all patients on the system, unless a different normative database is specified in a patient's record (see "Add New Patients" on page 5-2). If you do not have an optional Asian Normative Database license, the Diversified normative database is used and the Normative Data Settings tab is not shown.

DICOM Archive

Select **Records > Preferences** to access the **Preferences** dialog, and then select the DICOM Archive tab.

In DICOM Archive Mode, the available options are shown in Figure 4-12. Checked options are the defaults—uncheck a checkbox to deselect an option. When finished, click **OK** to save those options or **Cancel** to leave this dialog.

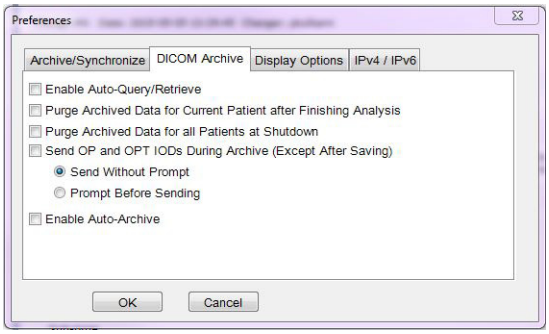


Figure 4-12 Preferences > DICOM Archive – DICOM Archive Mode

Enable Auto–Query/Retrieve: This option enables automatic query and retrieval from the FORUM® DICOM archive. Deselect this option when there is limited or no connectivity to the FORUM DICOM archive. On deselection, query and retrieval must be manually

performed using **Records > DICOM Retrieve**. This is the *only* option available under this tab for Native Mode. In Native Mode, this dialog appears as shown in Figure 4-13.

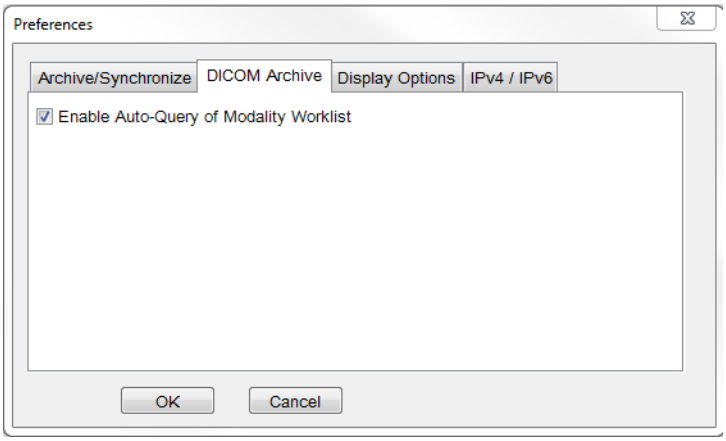


Figure 4-13 The DICOM Archive tab in Native Mode

Purge Archived Data for Current Patient after Finishing Analysis: With data already saved to the DICOM Archive, this option automatically deletes current patient data from the local database when you click **Finish** on the **Analysis** screen.

Purge Archived Data for all Patients at Shutdown: With data already saved to the DICOM Archive, this option deletes all patient data from the local database when you shut down the CIRRUS application.

Send OP and OPT IODs During Archive (Except After Saving): This functionality enables exporting image files from the instrument or CIRRUS Review Software in a standard DICOM format for viewing on a remote station. See "Transferring Images in OPT IOD and OP IOD Formats" on page 11-5 and "FORUM/DICOM or Native Environment" on page 11-1 for more information. With this option enabled, you may choose the desired prompt option:

- Send Without Prompt
- Prompt Before Sending

Enable Auto-Archive: This option enables automatic archiving of newly acquired exams or a modified analysis. Deselect this option when there is limited or no connectivity to the DICOM Archive. Exam data or modified analyses must be manually archived using **Records > DICOM Archive**, if Auto-Archive is disabled.

Display Options

A third option in the **Preferences** dialog, for both Native and DICOM Archive modes, is the **Display Options**, shown in Figure 4-14. This allows you to change the default setting, **Find Existing Patients**, to **Today's Patients**. Click the desired option, then click **OK**.

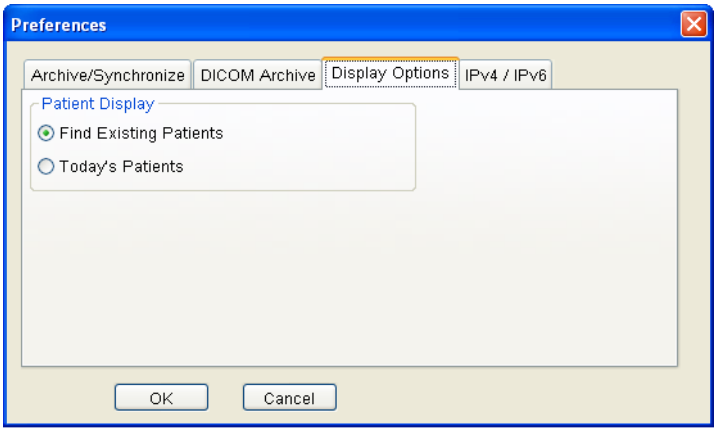


Figure 4-14 Preferences > Display Options

IPv4 / IPv6

CIRRUS instruments work on networks that support Internet Protocol version 6, as well as version 4. CIRRUS Review Software works only on IPv4. This option allows you to select the desired Internet Protocol version, as shown in Figure 4-15. The default is IPv4. Consult your IT professional *before* changing this.

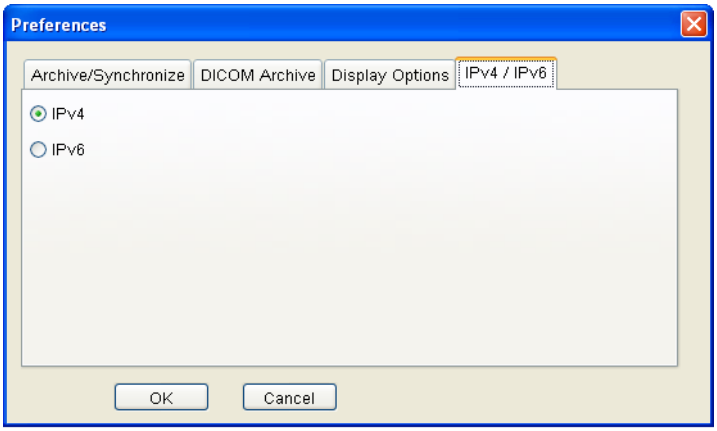


Figure 4-15 Preferences > IPv4 / IPv6

Preventive Maintenance Service Notifier

The service notifier displays the next Preventive Maintenance date during software startup from 14 days before service is due until Field Service completes the scheduled maintenance and resets the date for the next required service.

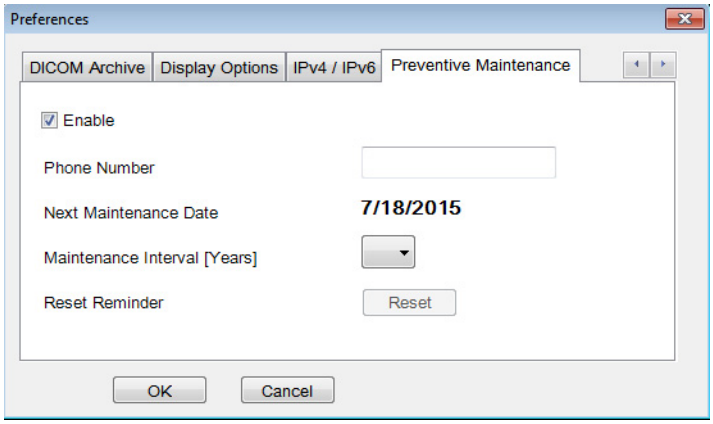


Figure 4-16 Preferences > Preventive Maintenance. Only the Zeiss Field Service Technician can set the maintenance date.

User Login/Logout

User Login

The **User Login** dialog appears when the instrument passes the system check upon startup, and each time a user logs out of the system software.

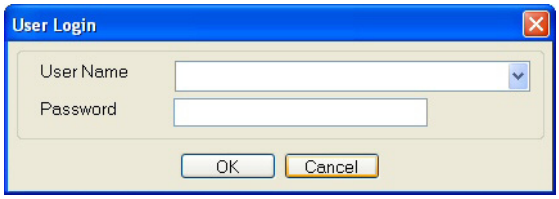


Figure 4-17 User Login Dialog

Select a user name from the drop–down list and enter the corresponding password to access the system software. Note that passwords are case–sensitive.

- No user names appear in the drop–down list until user accounts are created.

NOTE: It is strongly recommend that you create individual user accounts for each staff member who acquires or analyzes scans, and that staff members routinely logout to secure the instrument.

If you enter an invalid user name or password, a message will prompt you to try again.

When you log in successfully, the **ID Patient** screen ("Basic Screens" on page 3-3) appears.

User Logout

Logout Locks the System

To prevent unauthorized access, you can lock the CIRRUS HD-OCT software at any time by selecting **Logout** at upper right. When you lock the CIRRUS HD-OCT, it reverts to the **User Login** dialog, enabling login again. Upon successful login, the system always returns to the **ID Patient** screen.

NOTE: The **Logout** button is not available on the **Acquisition** or **Analysis** screens. To logout of the application from those screens, you must click **Finish** or **ID Patient** to return to the **ID Patient** screen.

Automatic Logout

You can configure Windows to go into sleep, hibernate, or hybrid mode after a specified time has elapsed without user input and can also require a password on wakeup. For instructions on configuring these options, see the Windows documentation at **Control Panel\All Control Panel Items\Power Options**.

5 Clinical Workflow

The Importance of Good Clinical Workflow

Patient Good Practices

A session for collecting images typically takes several minutes for each eye. Aligning the patient and optimizing the scan account for most of the session time. The patient may rest between scans as needed.

Specific to Iris Imaging

- Center the iris image within the pupil, unless a slight offset is required for retina tilt or to avoid opacity.
- Focus on the iris detail.

Specific to Fundus Imaging

- Ensure the focus is sharp and clear with good visibility of the branching blood vessels.
- Center the scan overlay on the fovea for macular scans and on the optic nerve head for optic disc scans.
- Ensure uniform illumination without dark corners.
- Eliminate or reduce artifacts that may cast shadows on the OCT scans.
- Attempt to move floaters away from the region of interest by asking the research subject to look up, down, and from side to side.
- Minimize corneal opacities by realigning the pupil.

Daily Tasks

Start of Day

Each day that the CIRRUS HD-OCT system is to be used the following steps must be followed:

1. Start the CIRRUS HD-OCT instrument
2. Wait for the system check to complete. If the system check passes with a non–critical error, such as inadequate hard drive or network archive space, click **Continue**, and then log on to the application. Scanning can proceed with inadequate local storage space, as long as the scans can be archived elsewhere when the system is shut down.

NOTE: Login to the software. You must be assigned an account by the System Administrator to use the software

NOTE: You may need to archive scans before acquiring new scans. If archive storage is inadequate, you can acquire new scans but will be prompted to archive all unarchived scans when shutting down the system. Or if a **Database**, **Installation Files**, or **Instrument** failure occurs, you will not be able to use the instrument. Contact your Zeiss representative.

End of Day

Archive Saved Exams

On the **ID Patient** screen, on the **Menu** bar, click **Records**, and then click **Archive Now** and

Shut Down the System

1. On the **ID Patient** screen, next to the **Menu** bar, click **Logout**.
2. If you are prompted to archive exams, in the **Archive** dialog box, click **Archive**, wait for the archive process to complete, and then click **OK** in the prompt asking if you want to exit.
3. Click the Microsoft Windows **Start** button, and then click **Shut Down**.
4. Wait until the computer and the monitor power off, and then turn off the CIRRUS instrument.

WARNING: Data loss and system corruption may occur if the system is turned off without first logging out of CIRRUS and shutting down Microsoft Windows.

Patient Records

Scanning and analysis are disabled until you identify a patient. The **ID Patient** screen will list any currently retrieved patients. This is the default screen that appears following system start and login. You can identify a patient using any of the three tabs provided, or you can query archived data to display a list of patients scheduled for exams (see Chapter 11 "Data Management").

The **ID Patient** screen has three tabs. These are discussed in the sections that follow.

Once you identify the patient, click **Acquire** to initiate a new exam for that patient. The **Acquire** screen appears. Specifying scan type and acquiring data for that scan is discussed in detail in Chapter 6 "Acquiring Scans".

Add New Patients

To add a new patient:

1. Select the **Add New Patient** tab from the ID Patient screen ("Basic Screens" on page 3-3). The **Patient Edit** dialog will appear as shown in Figure 5-1.
2. Enter the patient's first and last name in the fields provided as well as their date of birth.
3. Select the patient's gender from the drop-down list.

NOTE: The patient date of birth must be entered in the correct format that matches your Windows regional settings, and always appears this way in the software and printouts.

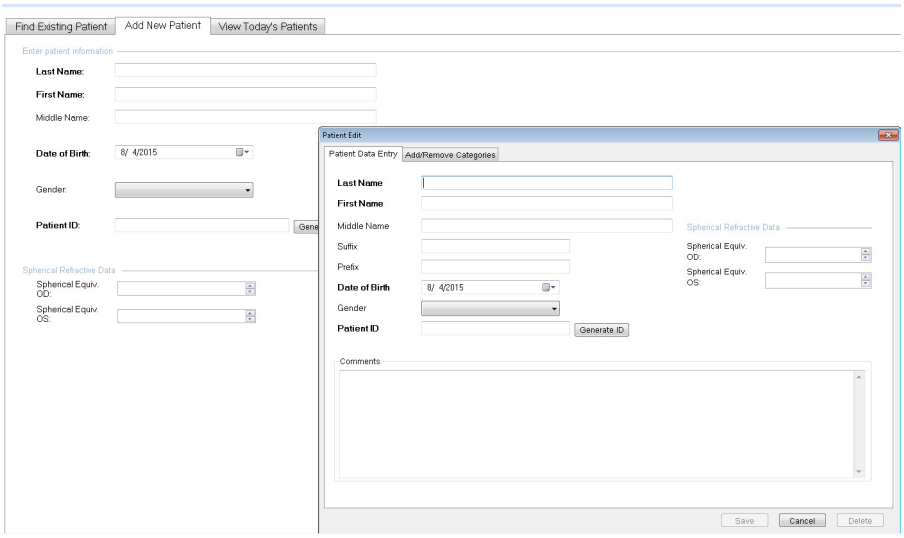
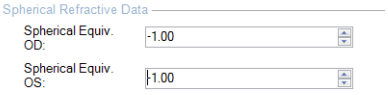


Figure 5-1 Select the "Add New Patient Tab" in the Patient screen. Select More to write comments. From this location you can also access the Add/Remove Categories dialog. This could be useful in situations in which a particular patient falls into a category not yet established.

4. Click **Generate ID** to have the system automatically create a unique ID for this patient. CIRRUS generated ID's all start with the prefix "CZMI". If your institution has its own Patient ID protocol, type that in here. A Patient ID is required for all patient files. No patient data can be saved without a patient ID.
5. Select Normative database of interest from the **Normative Data** drop-down list. For information on CIRRUS HD-OCT normative databases, see Appendix A "Normative Data Results".

Figure 5-2 Selecting the Normative Database



6. Enter the **Patient Refractive Error (optional)**. You may enter the refractive error in spherical equivalents (Diopters) for each eye on the patient demographic entry screen if desired. During scanning if you have entered a refractive error for a patient, the CIRRUS HD-OCT will automatically set the focus based on this information. While you may not need to use the Auto Focus feature if you entered a refractive error, you may need to use the focus arrows to manually adjust the focus for optimal clarity (see "Acquire Screen and Controls" on page 6-19.
7. Click **More** (optional), to enter a comment, or add Categories to a Patient Record. The dialog will appear.

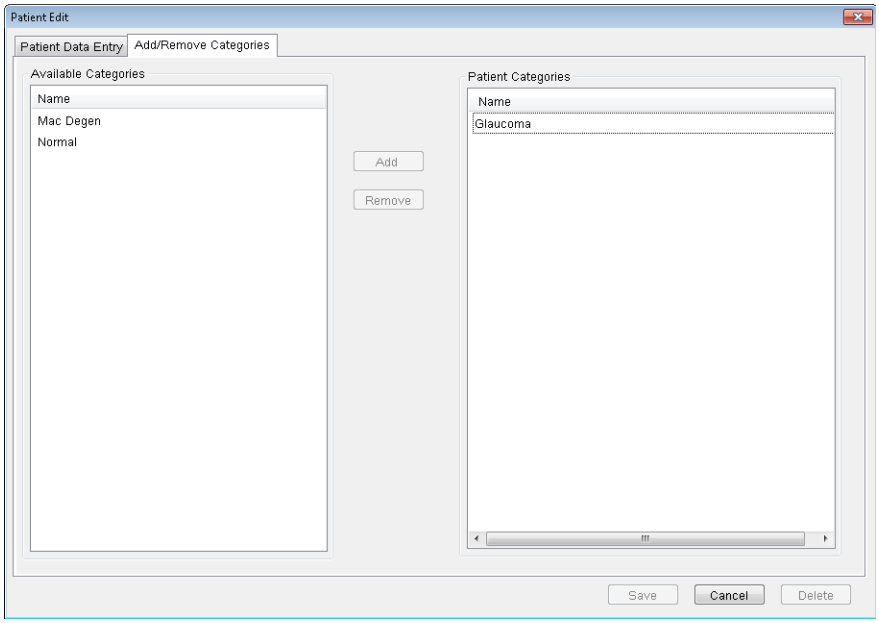


Figure 5-3 The Patient Edit dialog appears when you click More from the Add New Patient dialog

8. Click **Add** to add a category to the patient's record. **Remove** to remove it.
9. Click **Save**. The new patient information is saved to the database and to the list of today's patients. If data is missing from required fields, the **Save** button will not be enabled.

Find Existing Patients

To search a database (or DICOM archive) for a patient by name or ID:

1. Select the **Find Existing Patient** tab from the Patient screen ("Basic Screens" on page 3-3). The **ID Patient** screen will appear as shown in Figure 5-4.
2. Type in the patient's last name and/or Patient ID in the fields in the upper portion of the screen.
3. Click **Search**. The record will appear in the large patient list viewport. If you have only searched by last name, and you have more than one patient with that last name, the patient records will appear in alphabetical order.

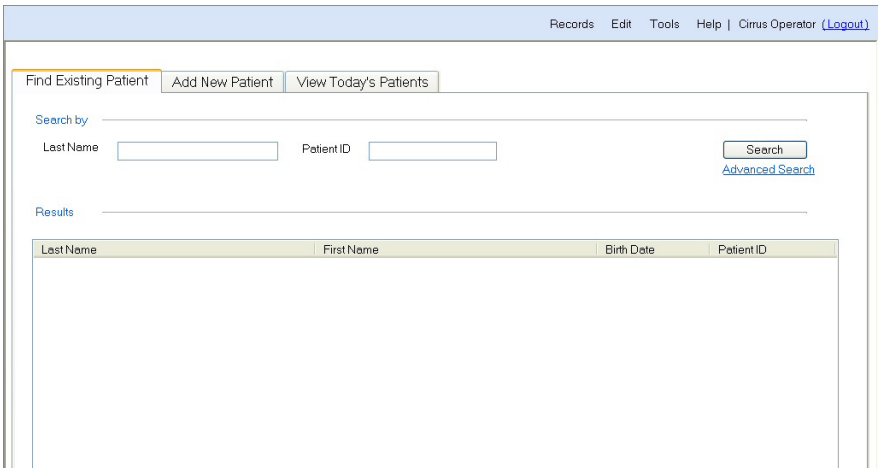


Figure 5-4 ID Patient screen—Default Tab: Find Existing Patient

To search a database (or DICOM archive) for a patient using additional criteria:

1. Select the **Find Existing Patient** tab from the Patient screen ("Basic Screens" on page 3-3). The **ID Patient screen** will appear as shown in Figure 5-4.
2. Select **Advanced Search**.
3. The **Advanced Search** screen appears as shown in Figure 5-5. You may now select a large number of additional search criteria, as discussed in full below.

Advanced Search

Click **Advanced Search** if you want to search for patients using additional parameters besides those provided in the basic search screen For example, you can search on **Scan Type** for a patient to bring up all the particular scan types associated with the patient using **Advanced Search**. (See "Find Existing Patients" on page 5-4). The **Advanced Search** dialog appears (Figure 5-5). If the **Use Import Date** checkbox is checked, you can also search for patients or exams imported on a specific date. Check the **Use Import Date** checkbox, then click the **From** and **Through** date drop–down menus below to select dates from a popup calendar.

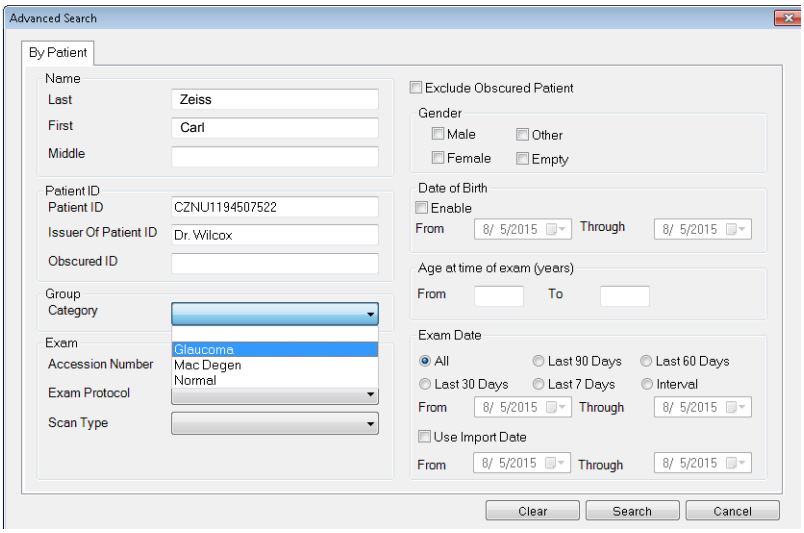


Figure 5-5 Advanced Search Dialog. If you have registered patient categories, the Category drop-down list will allow you to your user–specified criteria for the patient search.

1. Using the available fields, enter or select search parameters and then click **Search**.

   See "Data Management" on page 11-1 for information on the **Obscured ID** field.

NOTE: The following parameters are disabled in Advanced Search when in DICOM Archive mode:

- Obscured ID
- Category
- Exam Protocol
- Exclude Obscured Patient
- Gender
- Age at time of exam (years)
- Use Import Date

Search parameters you type in are not case–sensitive, except for Patient ID and Issuer of Patient ID. The Search Preview dialog (Figure 5-6) returns all matching patients, sorted alphabetically by last name.

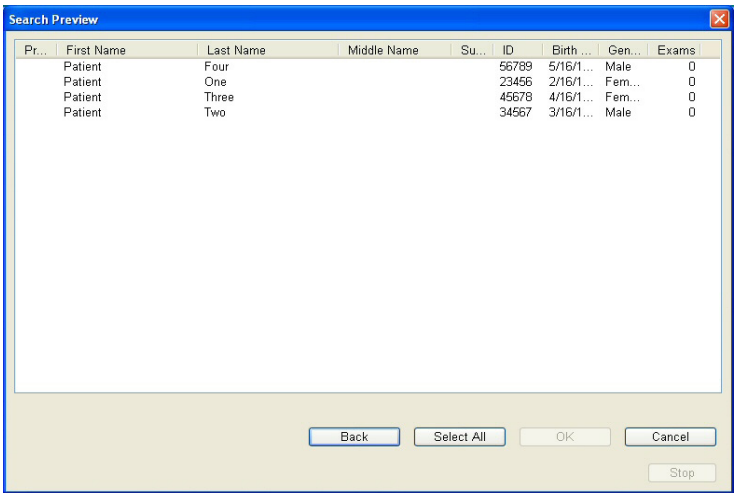


Figure 5-6 Search Preview Dialog

2. In the Search Preview dialog, select the patients of interest.
   - Click to select one patient; Ctrl–click to select multiple patients; Shift–click two patients to select all intervening patients; Ctrl–Shift–click to select all intervening patients plus those already selected.
   - Click **Select All** to select all patients in the **Search Preview** dialog; the button then toggles to **Deselect All**, in case you wish to start selecting again.
   - Click **Back** to return to the **Advanced Search** dialog.
   - Click **Cancel** to return to the **ID Patient** screen.
3. After you select patients, click **OK**. The selected patients will appear in the patient list where you started.
4. Select the patient of interest. The Acquire and Analyze buttons at the bottom of the screen will be activated.

Add or Remove Categories for Existing Patient Records

Categories are created by the System Administrator (see "System Administration" on page 4-1). Once patient categories are set up, they may be used in the clinical environment to assist in grouping patients and organizing records. Categories may be added by clinicians who have been properly trained.

To Add/Remove Categories for an Existing Patient Record:

1. Select a patient in the Patient List viewport of the Patient screen.
2. Select from the Toolbar, **Edit > Patient Record.** The **Patient Edit** dialog appears (see Figure 5-7). The name of the selected patient appears in the title bar of the dialog.
3. Select the **Add/Remove Categories** tab. Available categories are displayed on the left and applied categories on the right.

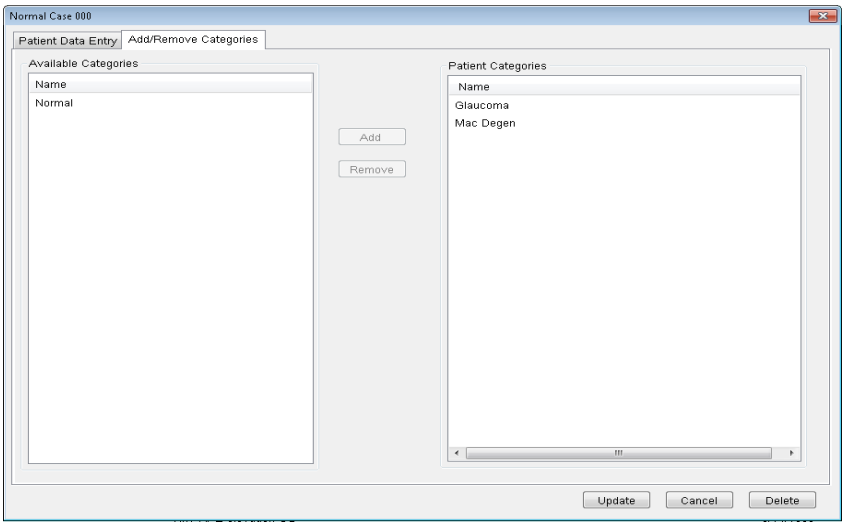


Figure 5-7 Add/Remove Categories Tab of the Patient Edit Dialog

4. **Add** the categories of interest to the patient record or **Remove** them.
5. Click **Save.**

View Today's Patients

To select patients who have either been scheduled to be scanned, or have been scanned today (DICOM mode only), select the **View Today's Patients** (Figure 5-8) tab.

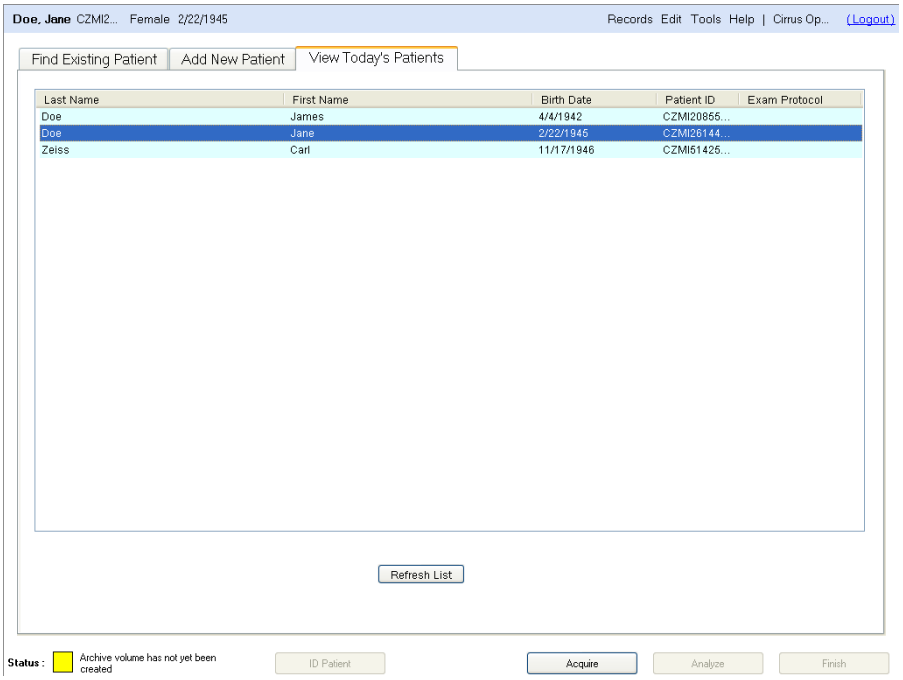


Figure 5-8 View Today's Patients tab of the ID Patient screen

How Today's Patients List Is Populated

Today's patients list is populated automatically with the following:

- New patients added today on local CIRRUS instrument.
- Patients with new exams completed today. If in DICOM Archive mode, and FORUM is being used as the DICOM Archive, this includes exams completed today from all CIRRUS instruments connected to your network.
- Patients scheduled for this CIRRUS instrument today.
- Imported exams (see Chapter 11 "Data Management").

The list is sorted alphabetically by last name.

NOTE: If the selected patient is retrieved from the DICOM server and has more than one visit scheduled today, a study selection dialog (Figure 5-9) asks the user to select the desired visit from the list.

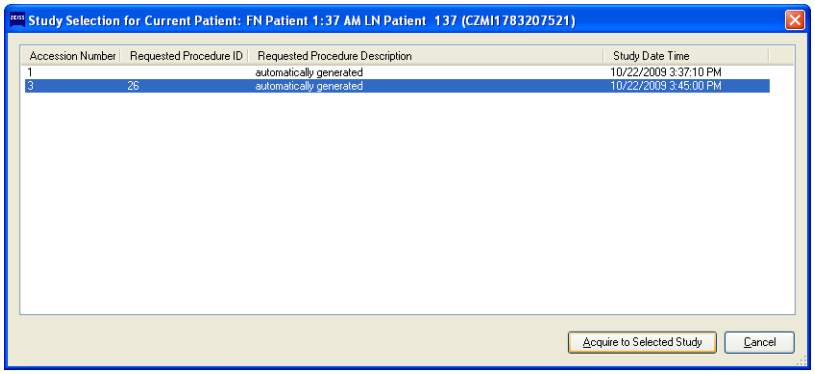


Figure 5-9 Patient Study Selection dialog

Patient ID Search Conflicts

When two patients—one saved in DICOM Archive and one saved in a local database — have the same Patient ID and Issuer of Patient ID, CIRRUS considers them to be the same patient, regardless of name, birth date or gender.

When a patient search is performed in DICOM Archive mode that results in a patient ID conflict, as show in Figure 5-10, you may:

- Click the **Update Local Data** button to save the patient information from the local database, over–riding the patient information in DICOM Archive; or,
- Click **Close** to exit the dialog. No data is saved.

If there are multiple conflicts in the patient list, you must confirm each patient individually.

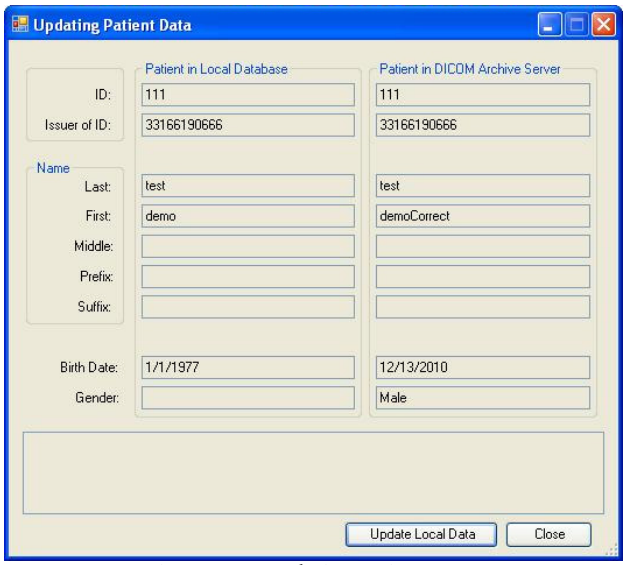


Figure 5-10 Updating Patient Data

Patient Preparation

In preparation for all patient visits, first clean Instrument Surfaces and adjust table height.

1. Wipe the chin rest and forehead rest with an alcohol pad, and allow the assembly to dry.
2. Adjust the table so the embossed line on the ocular cover is approximately at the same height as the patient's eye.

NOTE: The table adjustable height switch is mounted on the rear underside of the table, on the operator's right side.

3. After adjusting the table height, instruct the patient to sit back and relax.

Optional Dilation of Patient's Eye(s) (Posterior Segment)

The minimum pupil size for CIRRUS HD-OCT is 2 mm. This can usually be achieved without dilation. If dilation is performed on a subject for an exam, we recommend that dilation be used on subsequent visits if quantitative comparisons will be made. Dilation should not directly affect the quantitative measurements, but it may affect them indirectly by allowing more variability in how the OCT beam enters the eye. Although such an effect should be small, optimal repeatability will be achieved by imaging the patient in the same way at every visit.

Position the Patient on the Chinrest

NOTE: Before the patient puts his or her head in the chinrest, click to select the desired scan type for either eye as described in Chapter 6 "Acquiring Scans". Once the scan has been selected, the automated chinrest will go to the default position for the selected scan type and eye. By selecting an anterior segment scan, the CIRRUS HD-OCT will bring

the internal lens into position (you may hear a click while this occurs) and dim the illumination to avoid pupillary constriction by default.

The patient's exam experience with the CIRRUS HD-OCT is normally brief and comfortable. An experienced operator can acquire several scans from each eye in the space of 5–7 minutes. An exam usually requires the patient to look inside the imaging aperture for 1–3 minutes at a time for each eye, depending on the number of scans desired. The instrument acquires most scans in 1–5 seconds. The additional time is required to align the patient before scanning and to optimize scan quality. The patient may sit back between scans as needed. Note that the CIRRUS HD-OCT is never to contact the patient's eye.

Selecting a scan type moves the chinrest into the default or saved position for the scan. Wait until the chinrest automatic positioning is complete before instructing the research subject to place his or her chin on the chinrest.

If you are using a prior scan (see Patient Preparation on page 5-10) on a patient, the patient must wait until the prior scan has been selected and the chinrest motions are complete before placing their head in the chinrest. Reducing the amount of time the patient spends in the chinrest improves patient comfort.

Optional Eyelid Elevation

To get a scan unobstructed by the eyelids, especially for vertical scans, you may find it necessary to tape the eyelids of either eye or manually elevate the eyelid during scan acquisition in accordance with standard medical practice. For many patients, it is sufficient to ask them to open their eyes wide during scan acquisition. In certain cases however, it may be necessary to tape the patient's eyelids in order to get an unobstructed scan.

Precautions

CAUTION: When you complete scan acquisition and before you click the **Finish** or **ID Patient** button in the ACQUIRE screen, always prompt the patient to sit back and move the head away from the chinrest. Clicking either of these buttons in the ACQUIRE screen causes the chinrest to reposition itself beyond the point where the patient's face would contact the lens if the head remained in the chinrest. Failure to observe this warning could result in injury to the patient.

In the ACQUIRE screen, have patient sit back before you click **Finish** or **ID Patient**.

CAUTION: The operator should check that the patient is not holding on to the instrument before or during tests. Although movement of the motorized chinrest is slow, giving plenty of warning for patients to remove their fingers, there is potential for fingers to be squeezed and possibly injured if left in the area shown below.

Patient Instructions

1. Instruct the Patient to Focus on the Fixation Target.

Of Special Note for Anterior Scans

Ensure the corneal scans are centered on the corneal vertex

Instruct the patient to fixate on the center of the fixation target, even though it may not appear to be in focus.

- The internal fixation target is centered. For all anterior segment scans, the patient sees the green fixation target against a black background. The flashing red lines showing the scan pattern of the selected scan type are blurry.
- The iris illumination is dimmed by default to avoid causing pupillary constriction.
- The internal lens audibly clicks as it is brought into position.

The HD Angle is the preferred scan for imaging the anterior chamber angle. It gives the highest resolution and greatest detail of the iridocorneal angle. Wide Angle to Angle and Anterior Chamber scans may also be used for anterior chamber angle analysis.

2. Instruct the research subject to focus on the green star fixation target in the imaging aperture and blink naturally throughout the alignment process.
3. With the subject's eye aligned with the scan beam in three dimensions and image tools applied, instruct the research subject to blink and then open eyes wide during acquisition.

You will begin to see an image once the patient is positioned in the chinrest. The image may be poorly resolved until properly focused (see "Acquiring Scans" on page 6-1). Alignment progresses through a series of steps, although the order in which many of the steps are performed (and whether they are repeated) will vary depending on the cooperativeness of the patient (e.g., whether patients can fixate steadily at a requested location, opacity of their eye, etc.). In general, the sequence of user steps for non–repeat visits is as follows.

4. If necessary, remind the patient not to press against the head rest too firmly, so the forehead glides more easily across it during X-Y movements of the chinrest. The video image of the eye is clearest when the (Z alignment) is correct.
5. Instruct the Patient to relax after capture.
6. After the capture is complete, instruct the subject to relax but maintain chinrest position while the technician reviews the scan.
7. If necessary, repeat steps 4 through 6 above, until the technician is satisfied with the scan quality.
8. When the session is complete, instruct the subject to relax and move away from the chinrest.

NOTE: Clicking the **Finished** or **ID Patient** button moves the chinrest into the default or saved position. Instruct the research subject to move away from the chinrest before clicking the **Finished** or **ID Patient** button.

CIRRUS automatically names the file to include patient name, ID number, gender, type of scan, date of exam, eye examined, type of report, and date of report.

6 Acquiring Scans

Overview of Scan Types

CIRRUS HD-OCT software provides a large set of scan acquisition options that provide the basis for in depth analysis of ocular features and possible abnormalities. These are shown in Table 6-1 and discussed in the sections of this chapter which follow.

Anterior Segment	Scan Acquisition
	Anterior Chamber Scan
	Anterior Segment Cube Scan 512x128
	HD Angle Scan
	HD Cornea Scan
	Pachymetry Scan
	Wide Angle-to-Angle Scan
	Anterior Segment 5-Line Raster Scan
Posterior Segment	**Scan Acquisition**
CIRRUS OCT Angiography	Angiography Scan 3x3 / 6x6 / 8x8 Montage Angio Scan 6x6 / 8x8 ONH Angiography Scan 4.5x4.5
Macula	Macular Cube Scan 200x200 / 512x128
Macula and Optic Nerve (Integrated View)	Macular Cube Scan 200x200 / 512x128 *- and -* Optic Disc Cube Scan 200x200
Optic Nerve	Optic Disc Cube Scan 200x200
Visualization	Macular Cube Scan 200x200 / 512x128 *- or -* Optic Disc Cube Scan 200x200
	All Raster Scans

Table 6-1 Scan types available with the CIRRUS HD-OCT

Posterior Segment Scans

CIRRUS OCT Angiography

CIRRUS OCT Angiography is a method that uses differences between B-scans to generate contrast associated with motion, in particular the motion of blood through the vasculature.

CIRRUS OCT Angiography can be subject to several of the same artifacts seen in OCT structural imaging, and may also have some artifacts particular to this type of imaging. To minimize errors and artifacts, acquire Angiography Cube scans with FastTrac on.

The scans used for CIRRUS OCT Angiography are: Angiography scan, Montage Angio scan, and ONH Angiography scan.

NOTE: CIRRUS OCT Angiography is not intended as a substitute for fluorescein angiography.

NOTE: Vascular findings on fluorescein angiography may be absent, poorly defined, or variably defined on CIRRUS OCT Angiography. Additionally, leakage, staining, and pooling are not features of CIRRUS OCT Angiography.

Angiography Scan

Scanning results in either a 3x3 mm, 6x6 mm, or 8x8 mm square cube, and is similar to the Macular 512x128/200x200 cubes but uses an intensity-based frequency filtering technique to generate images with detailed vasculature. To image vascular flow, each B-scan in the scan pattern is repeated several times consecutively. Comparisons of contrast on consecutive B-scans in the same location reveal some areas with contrast change over time and some areas with constant contrast. Temporal contrast change in a specific location is thought to be due to erythrocyte motion and hence indicates a vessel location.

Montage Angio Scan

The 6 6x6 mm or 5 8x8 mm scans increase the Field of View (FOV) of Cirrus OCTA through the use of a montage to 10x14 mm and 14x14 mm respectively. The FOV, which is now fixed, is comparable to traditional imaging systems such as mydriatic and non-mydriatic fundus cameras. Wide-field montage images enable high-resolution vascular imaging over a larger region of the retina to further expand the applicability of OCT angiography.

The Montage Angio acquisition workflow is unique from the other Angiography scan acquisitions because you can acquire all the Angiography scans consecutively without going to the Quality Check screen each time. You review all of the scans at the end of the last scan you acquired. This ability shortens the time for both the patient and the operator.

ONH Angiography Scan

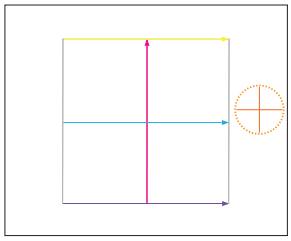
The 4.5x4.5 mm ONH Angiography scan expands the capability of CIRRUS, which enables the use of OCTA in the vascular assessment of the optic nerve.

Macula

The scans used for viewing the macula are: Macular Cube 200x200 and Macular Cube 512x128.

Macular Cube 200x200

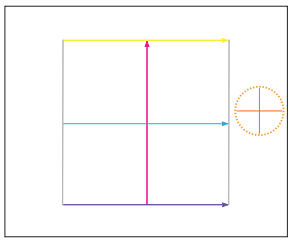
This scan generates a cube of data through a 6 mm square grid by acquiring a series of 200 horizontal scan lines each composed of 200 A-scans and a central horizontal HD B-scan.



Macular Cube 200x200

Macular Cube 512x128

This scan generates a cube of data through a 6 mm square grid by acquiring a series of 128 horizontal scan lines each composed of 512 A-scans and a central horizontal HD B-scan. The Macular Cube 512x128 is the default scan. Compared to the 200x200, this scan has greater resolution in each line from left to right, but the lines are spaced further apart, giving less resolution from top to bottom. This scan can be used to measure macular thickness (corneal thickness for anterior segment scans), and create a 3–D image of the data.



Macular Cube 512x128

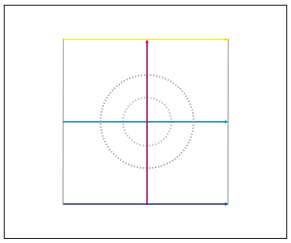
Optic Nerve

The scan used for viewing the optic nerve is the Optic Disc Cube 200x200 scan.

Optic Disc Cube 200x200

The Optic Disc Cube 200x200 generates a cube of data through a 6 mm square grid by acquiring a series of 200 horizontal scan lines each composed of 200 A-scans The fixation target is offset to one side to allow the center of the optic nerve to move to the center of

the scan pattern. In addition, the scan pattern overlay consists of concentric rings to assist in the alignment of the optic disc (see Figure 6-17).



Optic Disc Cube 200x200

Integration

For an integrated view, **both** the Macular Cube scan and Optic Disc Cube scan are used.

Macular and Optic Disc Cube Scans

For an integrated view, the Macular Cube (512x128 mm or 200x200 mm) and Optic Disc Cube (200x200 mm) scans are generated by combining a series of A-scans taken at varying depths. Macular and Optic Disc Cube scans provide information about disc and fovea parameters including (but not limited to):

- Size
- Cup, disc, rim area and volume
- Nerve fiber layer thickness
- Ganglion cell layer thickness (macular cube)

In turn, the post processing tools available for scan analysis Chapter 8 "Analysis" provide tools for RNFL and Ganglion cell layer estimation, which provide the earliest warnings of glaucoma and other, neuro-ophthalmic conditions.

Cube scans are the most common acquisition types, and are used as the basis for the largest number of CIRRUS HD-OCT analyses (see Table 8-1).

Depending on your requirements, you can specify cube scans based on several geometries:

Visualization

For a visualized view, either the Macular Cube scan **or** Optic Disc Cube scan is used.

Macular or Optic Disc Cube Scans

For an visualized view, either the Macular Cube (512x128 mm or 200x200 mm) or Optic Disc Cube (200x200 mm) scan is generated. See the previous sections for information about the two scans.

Raster Scans

- **HD 5 Line Raster and HD 1 Line 20x**: This is a single scan that generates 5 parallel B-scans composed of 1024 A-scans each, with an option to collapse the 5 lines into a

single high definition line. The scan can be positioned anywhere on the fundus image and has an adjustable line length of 3, 6, or 9 mm, an adjustable angle of –89 to 90 degree, and adjustable spacing from 0 to 1.25 mm in increments of 0.025 mm.

- **5 Line Raster**: This scan is the original version of the 5 line raster with less resolution than the HD 5 Line Raster. The scan can be positioned anywhere on the fundus image and has an adjustable line length of 3, 6, or 9 mm, an adjustable angle of –89 to 90 degree, and adjustable spacing from 0 to 1.25 mm in increments of 0.025 mm.
-

NOTE: HD 1 Line x100, HD 21 Line, HD Cross, and HD Radial scans are offered as an option that may not be available in all markets and,when available in a market, may not be on all instruments. If you do not have this feature and want to purchase it, contact Zeiss. In the U.S.A., call 1-877-486-7473; outside the U.S.A., contact your local Zeiss distributor.

Guidelines for Raster Scans

For HD 5 Line scans, to switch between the HD 1 20x single line and multi–line scanning, click the **Toggle Spacing** button located below the fundus image.

The toggle button remains available until the Single Line scan pattern is moved in the acquisition window. To move the scan pattern and keep the button active, switch to 5 Line mode before moving the scan pattern, and then switch back to Single Line mode. If you move the Single Line pattern and want to switch back to 5 Line mode, just collapse the scan.

NOTE: Sometimes switching from **Color OCT** to black and white ( ) will allow you to see more details in a high–resolution scan.

Scan Pattern Adjustments

Raster scans have adjustable scan patterns. You can use the image pattern controls on the live Fundus image (Fundus Viewport, Posterior Scans) to manually change line length, line spacing, or angle of rotation. You can also use the Custom Scan Pattern dialog box. Adjustments apply to all scan lines.

If you adjust the scan pattern position, check that the retinal OCT B-scan images are not too high in the viewport. When the edges of scan images are near the upper boundary, they tend to fold over, reflecting a mirror image back into the viewport. If this occurs, or if the scan image is completely inverted, adjust the image position using the **Center** controls.

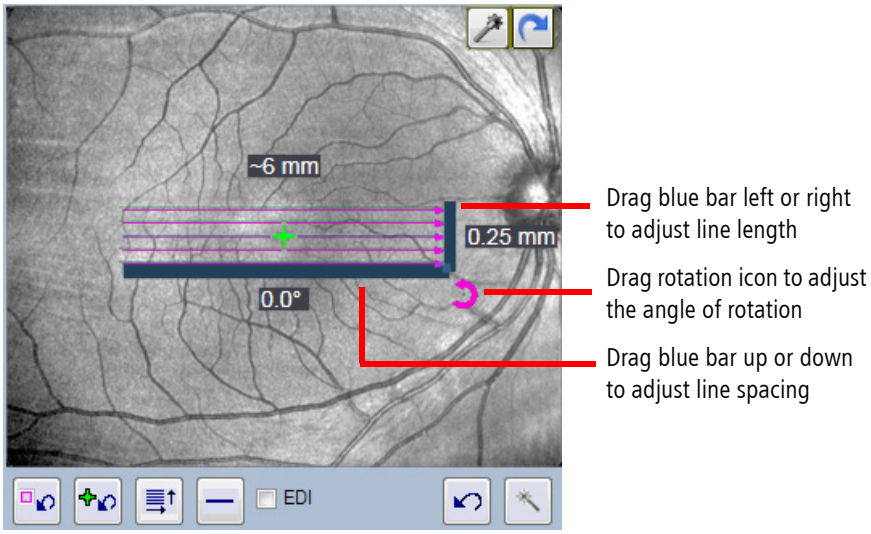


Figure 6-1 HD 5 Line Raster Scan Pattern On Acquire Fundus Image

Enhanced Depth Imaging (EDI)

Enhanced Depth Imaging (EDI) is an optional mode for single and multi–line raster scans that improves visibility of structures at the bottom of B-scans.

The signal to noise ratio in OCT scans varies across the axial range. The default CIRRUS setup is such that the best signal is obtained at the top portion of the scan. Enhanced Depth Imaging allows you to change the acquisition settings for the raster scans so that the best signal to noise ratio is obtained at the bottom of the B-scan. This allows you to obtain an HD image that is optimized in the region that is of interest for a particular scan.

To switch between EDI and standard scanning mode, select the EDI checkbox ☑ EDI below the fundus image.

Anterior Segment Scans

Scan Preparation

Instrument Imaging Process

When an anterior segment scan is selected or external lens mounted:

- The LSO illumination of the retina is turned off.
- The internal fixation target is centered. For all anterior segment scans, the patient sees the green fixation target against a black background. The flashing red lines showing the scan pattern of the selected scan type are blurry.
- The iris illumination is dimmed by default to avoid causing pupillary constriction.
- The internal lens audibly clicks as it is brought into position.

Scan Acquisition Controls

Not all posterior scan acquisition controls are available for anterior segment scans. For anterior segment scans:

- There is no fundus image, and therefore the **Auto Focus** button and Z controls (left–right **Focus** arrows) are not displayed. However, the **Focus** bar is still displayed, showing the last focus for the patient.
- FastTrac is not available for anterior segment scans, and therefore the three FastTrac buttons below the Capture button are not displayed.
- The **Optimize** button is available only for Anterior Segment Cube 512x128 and Anterior Segment 5 Line Raster scans.
- The **Auto–Enhance** button, the **Auto–Center** button, and manual–center controls are not available. The OCT display can be centered vertically in the live OCT window by using the chinrest control buttons or the mouse scroll wheel. However, the shift key + mouse scroll wheel does not bring the scan into the acquisition window for anterior scans as it does for posterior scans.

Scan Pattern Adjustments

The scan pattern for anterior scans is displayed on the iris image. The scan pattern cannot be moved, and scan length is not adjustable. Rotation and line spacing are adjustable for the Anterior Segment 5 Line Raster scan. Rotation is adjustable for the HD Angle, HD Cornea, Anterior Chamber, and Wide Angle-to-Angle scans. For more information on adjusting scan patterns, see "Scan Pattern Adjustments" on page 6-5.

Aligning Scans Corrected for Beam Scanning Geometry and Corneal Refraction

Anterior Chamber, Wide Angle-to-Angle, HD Cornea, HD Angle, and Pachymetry scans are corrected to account for beam scanning geometry and refraction on the corneal surfaces. These corrections are most accurate when acquired corneal scans are centered on the corneal vertex, which generates a strong central reflection line on the live OCT image. Typically the corneal vertex is just to the nasal side of the pupil center.

Center Corneal Scans on the Corneal Vertex

NOTE: HD Angle scans are *not* aligned to the corneal vertex.

1. Instruct the patient to fixate on the center of the fixation target, even though it may not appear to be in focus.

2. Follow the alignment guidelines for each scan to position the scan in the OCT viewport, making adjustments until there is a strong central reflection line indicating the scan is centered on the corneal vertex.

Anterior Chamber and Cornea External Lenses

Four anterior segment scans require an external lens:

Anterior Chamber External Lens:

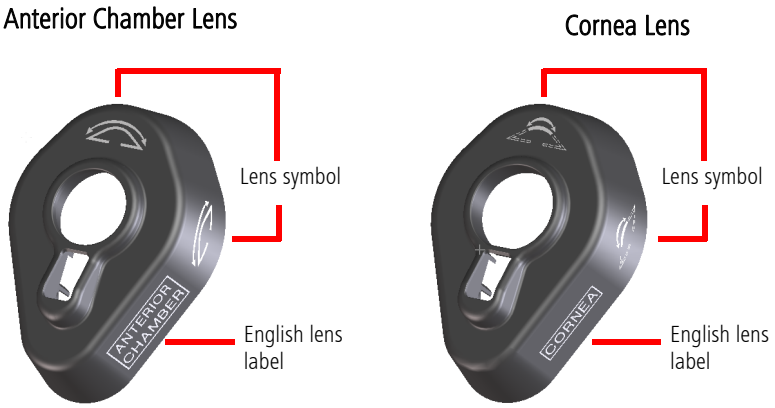
- Anterior Chamber Scan

- Wide Angle-to-Angle Scan

Cornea External Lens:

- HD Cornea Scan
- Pachymetry scan

Attaching an External Lens



To attach an external lens and select a scan

1. Attach the appropriate external lens to the instrument lens mount.

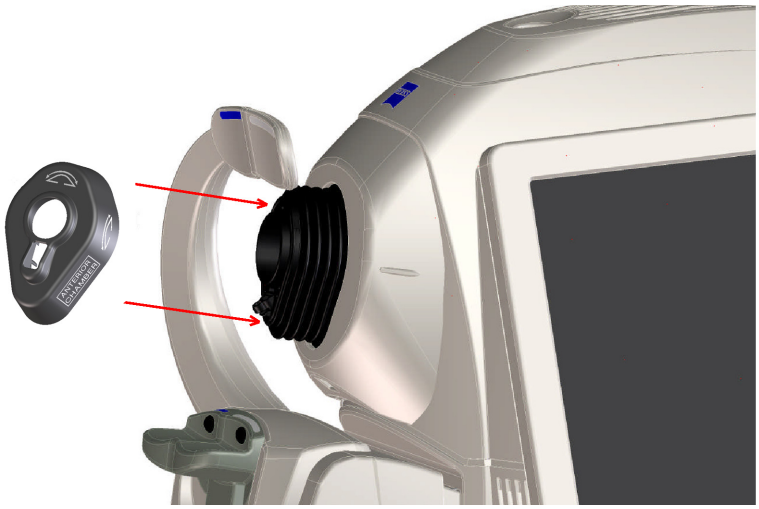


Figure 6-2 Attaching an Exterior Lens, Anterior Chamber Lens shown

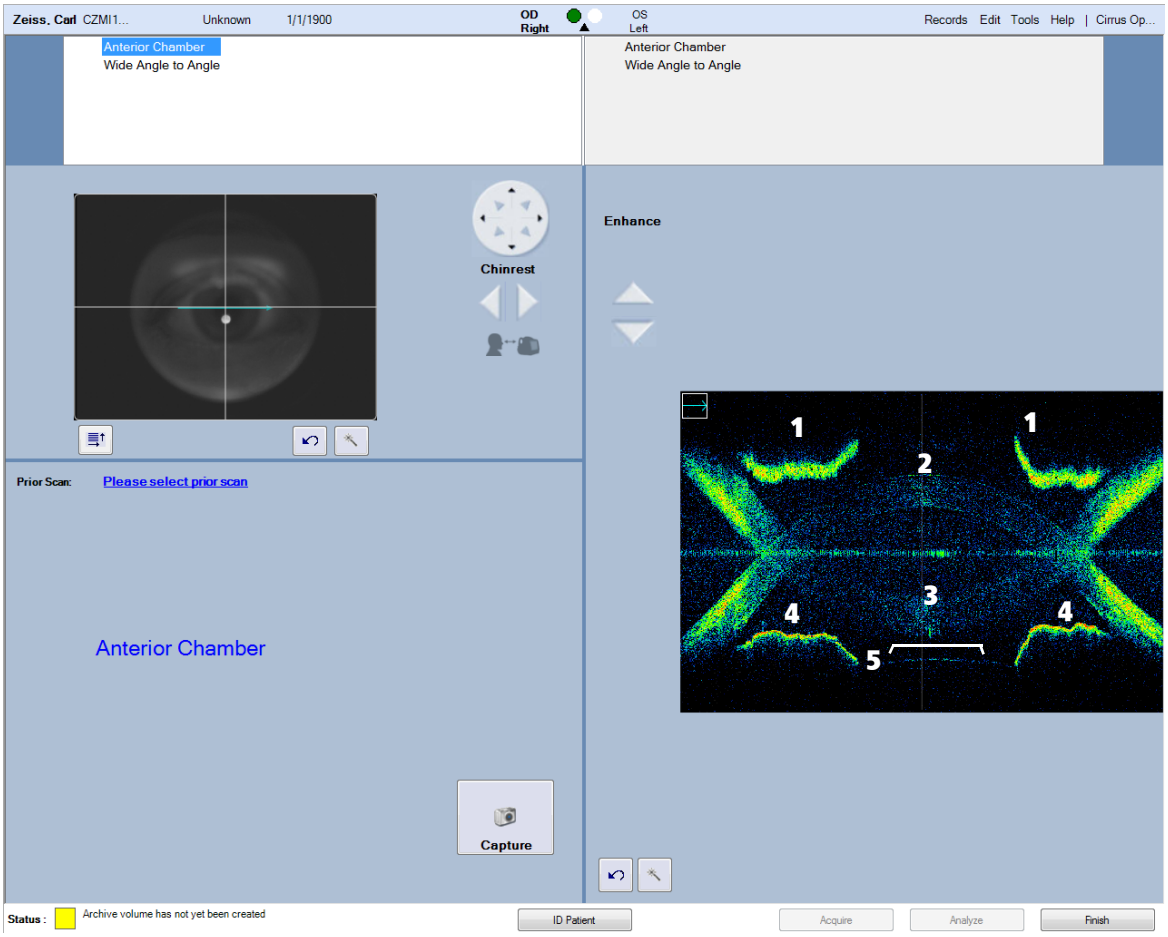
2. CIRRUS HD-OCT automatically detects the lens, adjusts lens positioning, and displays the scans that require the lens in the scan list.Select the scan from the scan list for the eye you want to scan.

Anterior Chamber Scan (Chamber View™)

This scan generates a wide field, speckle–reduced raster scan of the anterior chamber at a depth of 5.8 mm, with higher contrast than the Anterior Segment 5 Line Raster scan. It uses 20 B-scans, each composed of 1024 A scans, and is 15.5 mm in length when oriented

horizontally. The scan is adjustable from –89 to 90 degrees, though rotation may reduce the field The 5.8 mm scan depth is achieved by allowing the source and mirror images to overlap. Note that in the overlap region (indicated by blue overlay), source image detail may be compromised. This scan requires the Anterior Chamber external lens. The Anterior Chamber Scan provides the data used for Anterior Chamber measurements ("Anterior Segment Scans" on page 6-6).

The **Acquire** screen displays the position of the Anterior Chamber scan pattern on the live iris image. The OCT B-scan image on the right displays the cornea and mirror image of the scan. The Anterior Chamber scan requires the Anterior Chamber external lens.



1 Mirror iris image
2 Cornea image
3 Mirror cornea image
4 Iris image
5 Lens of the eye

Figure 6-3 Acquire screen, Anterior Chamber with Cornea and Mirror Images Correctly Aligned

Guidelines for Anterior Chamber Scan Acquisition

- Attach the external Anterior Chamber lens to the instrument lens mount, see "Attaching an External Lens" on page 6-8.
- Instruct the patient to fixate on the center of the fixation target even though it may not appear to be in focus.

- Click the center of the pupil and use the screen X-Y and Z controls or keyboard arrow keys and mouse scroll wheel to center the scan on the corneal vertex with the anterior chamber visible in the B-scan viewport.

  A strong vertical central reflection line on the B-scan indicates the scan is centered on the corneal vertex.

- Center the image to see the lens of the eye and the anterior chamber angles.
- If the anterior chamber seems tilted, instruct the patient to shift his/her gaze slightly to the left or right as needed to horizontally orient the anterior chamber.
- Separate the cornea image and mirror image as much as possible, without letting the cornea images touch the iris images.

The correct position of the scan is shown in Figure 6-3. Three incorrectly aligned images are shown in Figure 6-4: one with the iris touching the cornea, one with the cornea too close, and one with an off–center image that obscures the eye lens.

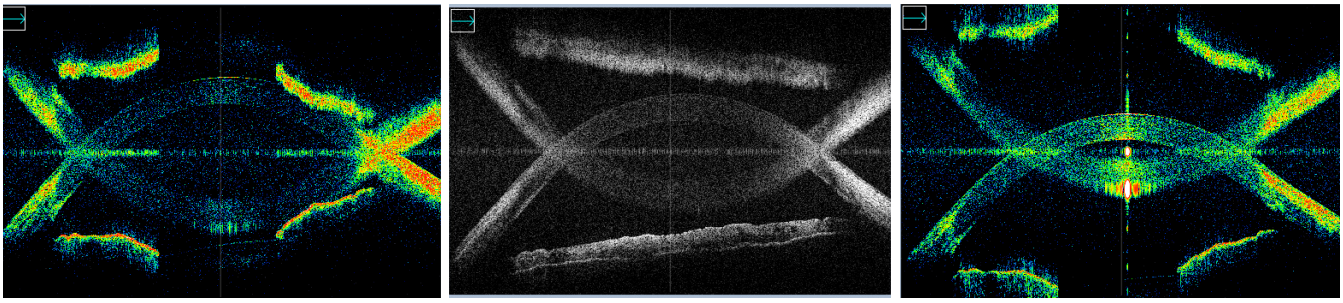
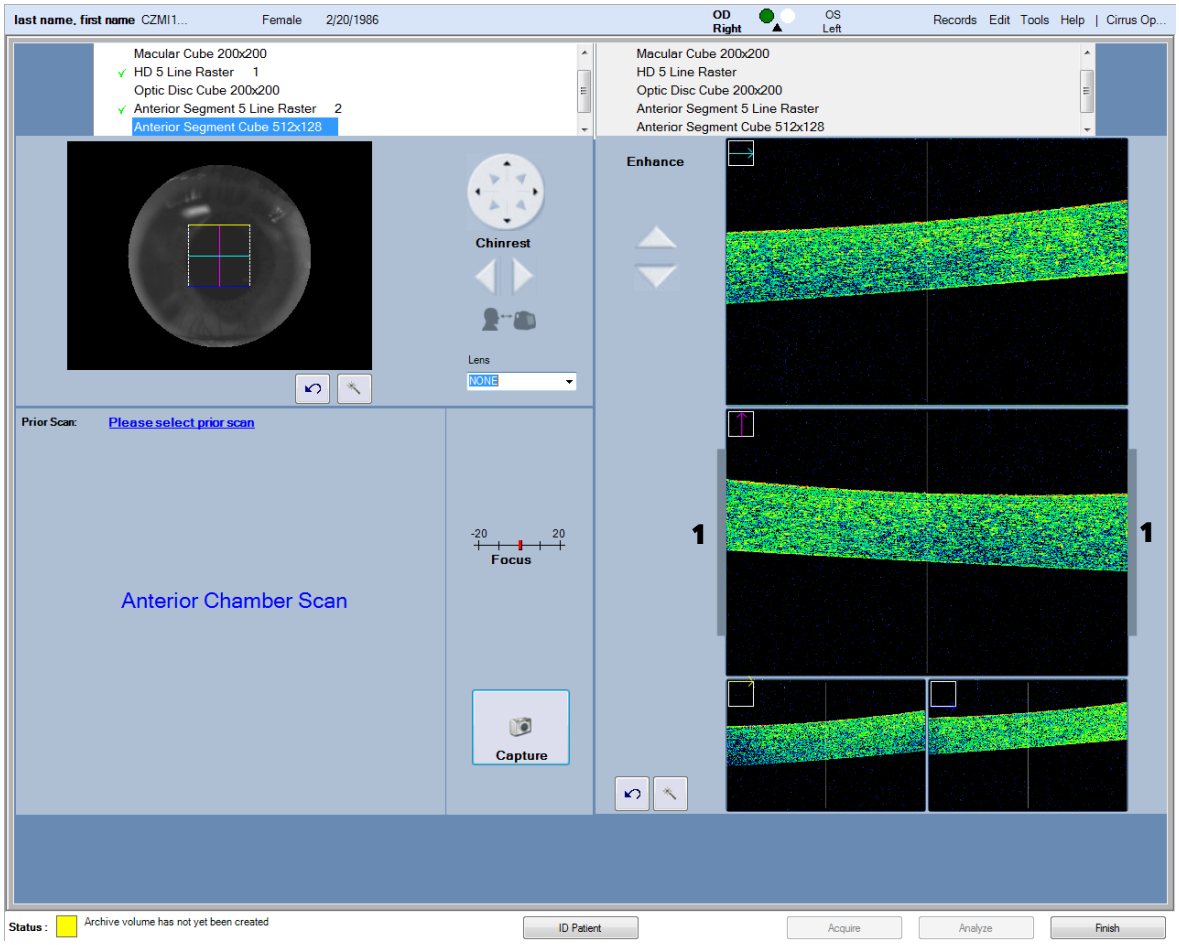


Figure 6-4 From left to right: iris touching cornea, not centered, cornea too close

Anterior Segment Cube Scan

The Anterior Segment Cube 512x128 Scan provides the data used for the Anterior Segment Analysis ("Anterior Segment Scans" on page 6-6)

The **Acquire** screen displays the position of the Anterior Segment Cube 512x128 scan pattern on the live iris image. The OCT B-scan images on the right correspond to the horizontal and vertical scan lines of the selected slice in the cube, with the smaller images corresponding to the top and bottom horizontal cube slices (see Figure 6-5).



1 Grey bar for aligning OCT scan

Figure 6-5 Acquire screen, Anterior Segment Cube 512x128

Guidelines for Anterior Segment Cube 512x128 Scan Acquisition

- Instruct the patient to fixate on the center of the fixation target.
- Use the screen X, Y and Z controls or keyboard arrow keys and mouse scroll wheel to center the scan on the corneal vertex with the anterior chamber visible in the B-scan viewport.to center the scan between the gray bars on either side of the B-scan display, as shown in Figure 6-5.
- If the patient's cornea is perfectly centered, a strong reflection from the anterior cornea can produce bright artifacts in the HD Cornea display (Figure 6-6). The scan alignment should be slightly offset from the center by adjusting the chinrest to avoid the corneal reflection.

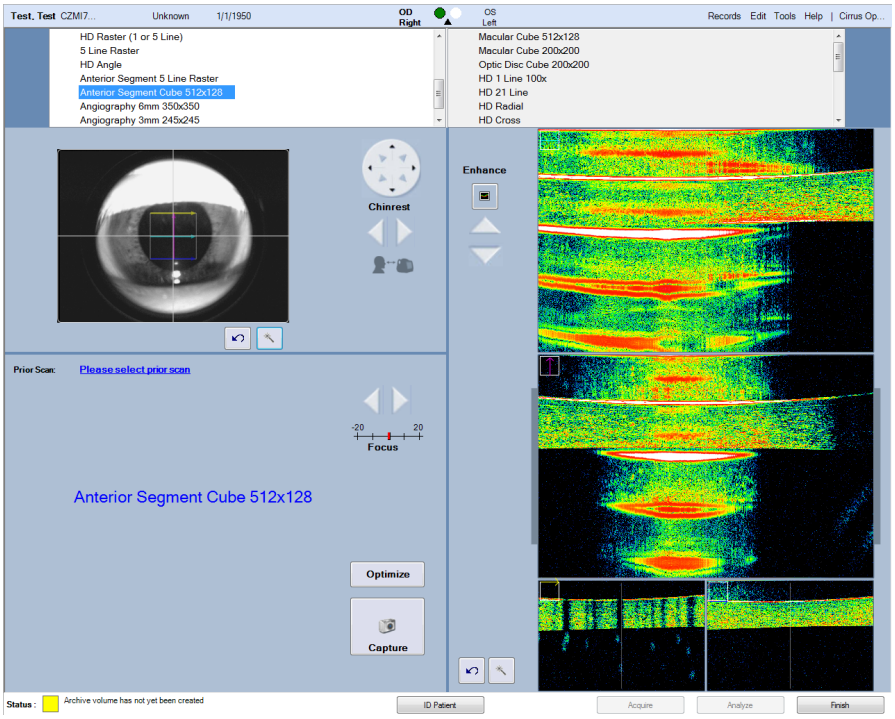


Figure 6-6 Strong reflection from the anterior cornea

NOTE: For the Anterior Segment Cube 512x128 and Anterior Segment 5 Line Raster scans, the instrument focuses the OCT beam onto the anterior segment. The OCT beam scans in an arc to allow the curved cornea to better fit into the 2mm scan depth. This will cause the cornea to appear flat in the display during alignment and acquisition. This effect is partially corrected for after acquisition, so the cornea will appear with the expected curvature during review and analysis.

HD Angle Scan

The HD Angle is the preferred scan for imaging the anterior chamber angle. It gives the highest resolution and greatest detail of the iridocorneal angle. Wide Angle-to-Angle and Anterior Chamber scans may also be used for anterior chamber angle analysis. All three scans have an angle measurement tool (see "In HD Angle Analysis" on page 8-53). The HD Angle and Wide Angle-to-Angle scans also have an iridocorneal (IC) angle tool to measure iridocorneal angle features (see "Angle Measurements" on page 8-53).

This scan, available for anterior segment scans only, generates a speckle–reduced raster scan at a depth of 2.9 mm using 20 B-scans, each composed of 1024 A scans. The scan is 6.0 mm in length, with an adjustable angle from –89 to 90 degrees. The scan highlights one iridocorneal angle, which can be measured via specialized angle calipers in the HD Angle Scan Analysis ("In HD Angle Analysis" on page 8-53).

The **Acquire** screen displays the position of the HD Angle scan pattern on the live iris image and displays the OCT B-scan image on the right.

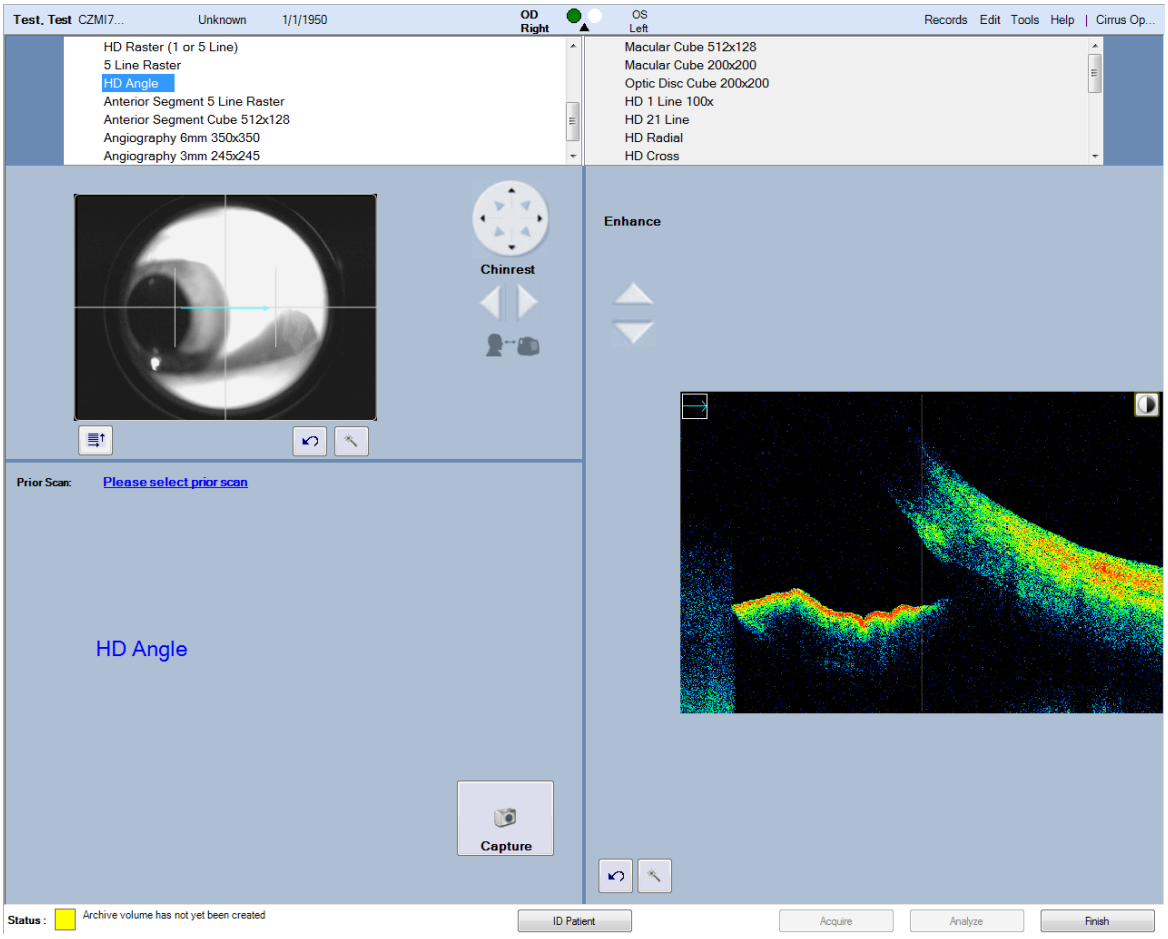


Figure 6-7 Acquire screen, HD Angle

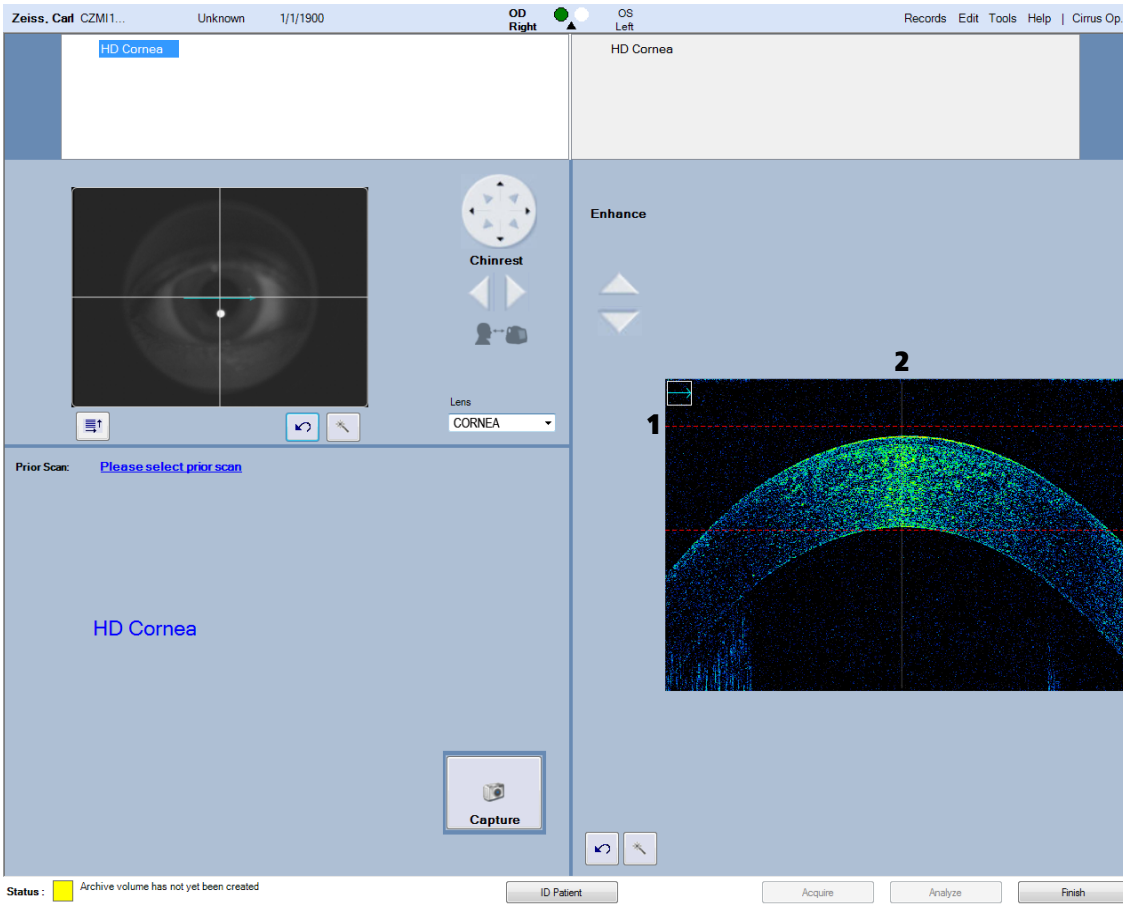
Guidelines for HD Angle Scan Acquisition

- For an HD Angle scan, you may need to use the external fixation device if the patient has difficulty fixating without the internal fixation target, which is not in view when the limbus of the scan eye is optimally exposed. The external fixation device may help the patient fixate with the eye that is not being scanned, for correct angle alignment.
- Adjust the area of the eye visible in the Iris viewport until the iris is in clear focus, and make coarse adjustments with the X-Y controls to move the chinrest until the corneoscleral junction is in view.
- Use the mouse scroll wheel to bring the angle into view on the B-scan, centering it in the lower quadrant of the B-scan viewport and maximizing exposure of the cornea.
- If the angle recess in the B-scan appears shadowed by the sclera, move the scan slightly along the limbus to minimize the effect, or ask the patient to adjust fixation further away from center.
- Align the scan at the desired location on the limbus, and then align the B-scan so that the anterior chamber angle falls in the lower left and lower right quadrant, respectively. Figure 6-7 shows a well–aligned scan and live OCT image of an HD Angle scan.

HD Cornea Scan

This (anterior segment) scan generates a single high–definition scan with a depth of 2.0 mm that has a wider field of view than the Anterior Segment 5 Line Raster. The scan uses 20 B-scans, each composed of 1024 A scans. The scan is 9.0 mm in length when oriented horizontally and has a depth of 2.0 mm. The scan is adjustable from –89 to 90 degrees. This scan requires the Cornea external lens. The HD Cornea Scan provides the data for the HD Cornea Analysis ("Corneal Thickness" on page 8-43).

The **Acquire** screen displays the position of the HD Cornea scan pattern on the live iris image and displays the OCT image of the scan on the right. The HD Cornea scan requires the Cornea external lens.



1 Upper red line 2 Corneal reflex line

Figure 6-8 Acquire screen, HD Cornea

Guidelines for HD Cornea Scan Acquisition

- Attach the external Cornea lens to the instrument lens mount, see "Attaching an External Lens" on page 6-8.
- Instruct the patient to fixate on the center of the fixation target even though it may not appear to be in focus

- Click the center of the pupil and use the X-Y and Z controls to center the scan on the corneal vertex, positioning the anterior corneal surface to the upper red line in the B-scan viewport as shown in Figure 6-8.

NOTE: A strong vertical central reflection line on the B-scan indicates the scan is centered on the corneal vertex.

Wide Angle-to-Angle Scan

This scan (for anterior segments only) generates a wide field, speckle–reduced raster scan with a depth of 2.9 mm. It uses 20 B-scans, each composed of 1024 A scans and is 15.5mm in length when oriented horizontally. The scan is adjustable from –89 to 90 degrees, though rotation may reduce the field The scan simultaneously highlights both 0 and 180 degree iridocorneal angles. This scan requires the Anterior Chamber external lens. The Wide Angle-to-Angle Scan is used as the basis for the Wide Angle-to-Angle Analysis ("Using Wide Angle-to-Angle Analysis" on page 8-43).

The Acquire screen displays the position of the Wide Angle-to-Angle scan pattern on the live iris image and the OCT image of the scan on the right.

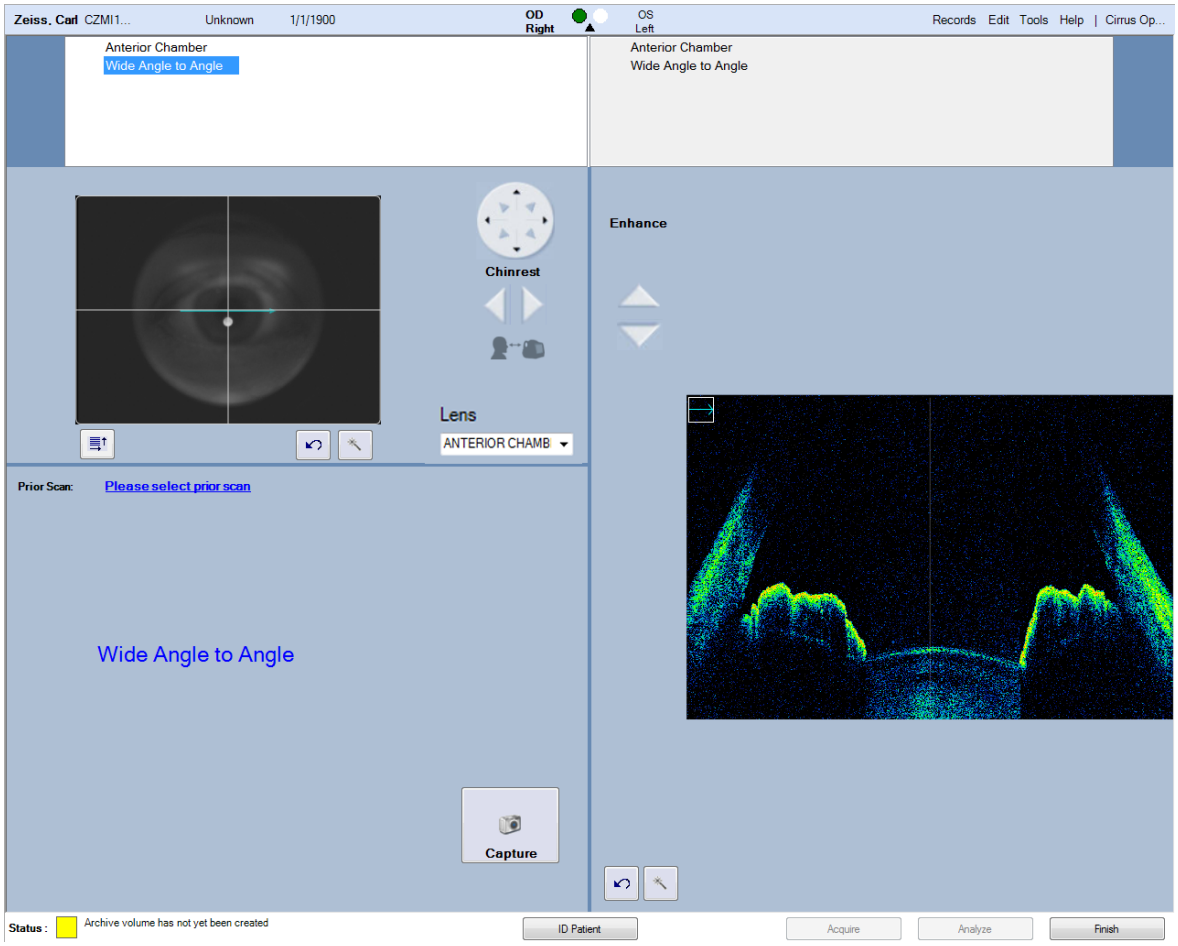


Figure 6-9 Acquire screen, Wide Angle-to-Angle

Guidelines for Wide Angle-to-Angle Acquisition

- Attach the external Anterior Chamber lens to the instrument lens mount, see "Anterior Chamber and Cornea External Lenses" on page 6-7.
- Instruct the patient to fixate on the center of the fixation target even though it may not appear to be in focus.
- If the anterior chamber seems tilted, instruct the patient to shift his/her gaze slightly to the left or right as needed to horizontally orient the anterior chamber.
- Click the center of the pupil and use the X, Y and Z controls or keyboard arrow keys and mouse scroll wheel to center the scan on the corneal vertex with both iridocorneal angles, iris, and pupil visible in the OCT scan display area and the anterior of the cornea extending slightly out of the field of view, as shown in Figure 6-9.

NOTE: A strong vertical central reflection line on the B-scan indicates the scan is centered on the corneal vertex.

NOTE: For the Wide Angle to Wide Angle scan, the iris will be slightly out of focus even when correctly aligned.

Pachymetry

This scan consists of 24 radial scan lines with a scan depth of 2.0 mm that are used to generate a color-coded thickness map of the cornea. The scan uses 24 B-scans, each composed of 1024 A scans. This scan requires the Cornea external lens. The Pachymetry scan is used as the basis for the Pachymetry Analysis. (See "In Pachymetry Analysis" on page 8-44 for more information.)

The Acquire screen displays the position of the Pachymetry scan pattern on the live iris image. The images on the right display the temporal/nasal and inferior/superior scans of the selected meridian. The Pachymetry scan requires the Cornea external lens.

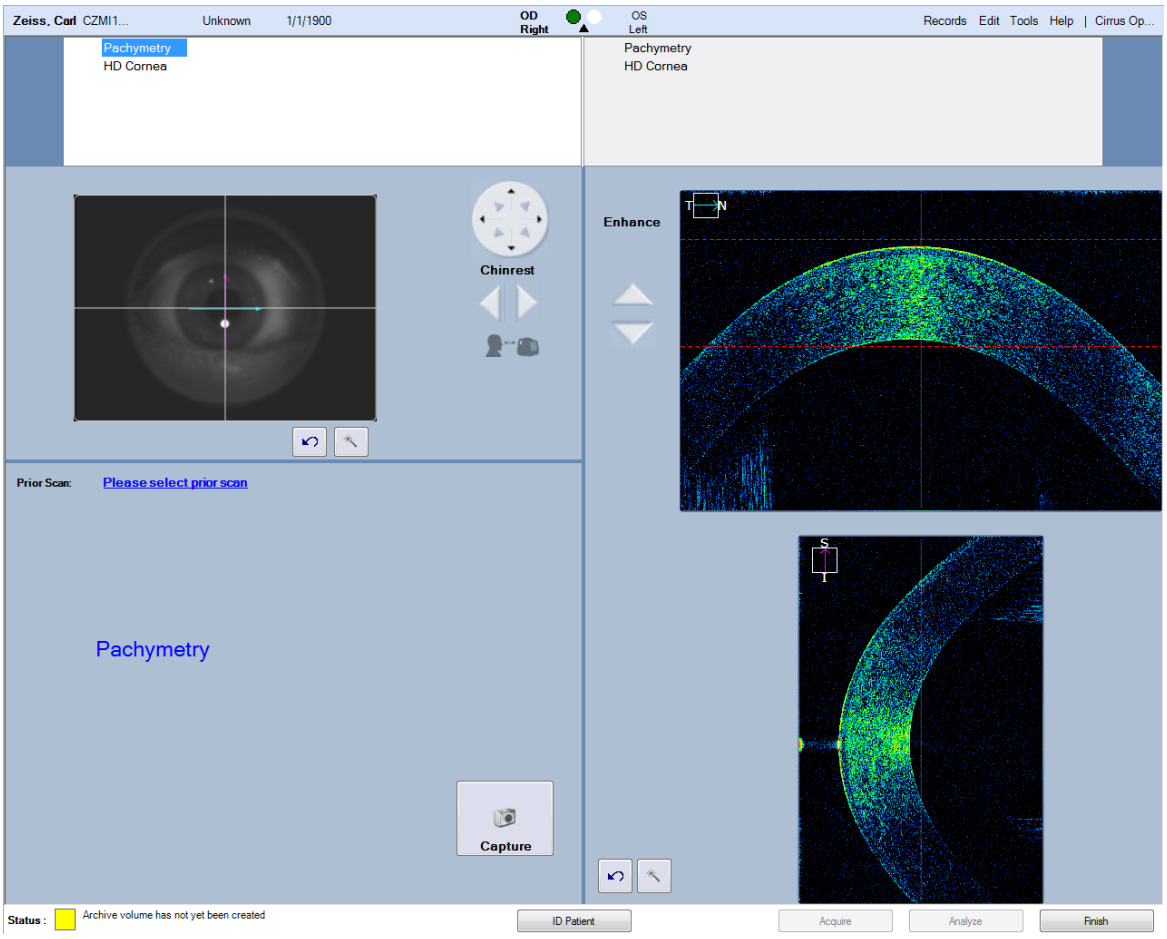


Figure 6-10 Acquire screen, Pachymetry

Guidelines for Pachymetry Scan Acquisition

The Pachymetry scan is similar to the HD Cornea scan, but you must align two scans rather than one.

- Attach the external Cornea lens to the instrument lens mount, see "Anterior Chamber and Cornea External Lenses" on page 6-7.
- Instruct the patient to fixate on the center of the fixation target even though it may not appear to be in focus.
- Click the center of the pupil and use the X-Y and Z controls to center the scan on the corneal vertex until the cornea is visible in the B-scan viewports.
- Align the images in the two B-scan viewports by fine adjustment of the X-Y controls using the keyboard arrow keys. To center both images, first center the bottom image with the keyboard arrow keys until you see the corneal reflex in the upper image. The up arrow brings the image down and to the right. The down arrow brings the image up and to the left. Press the Ctrl key with arrow keys for finer adjustments.

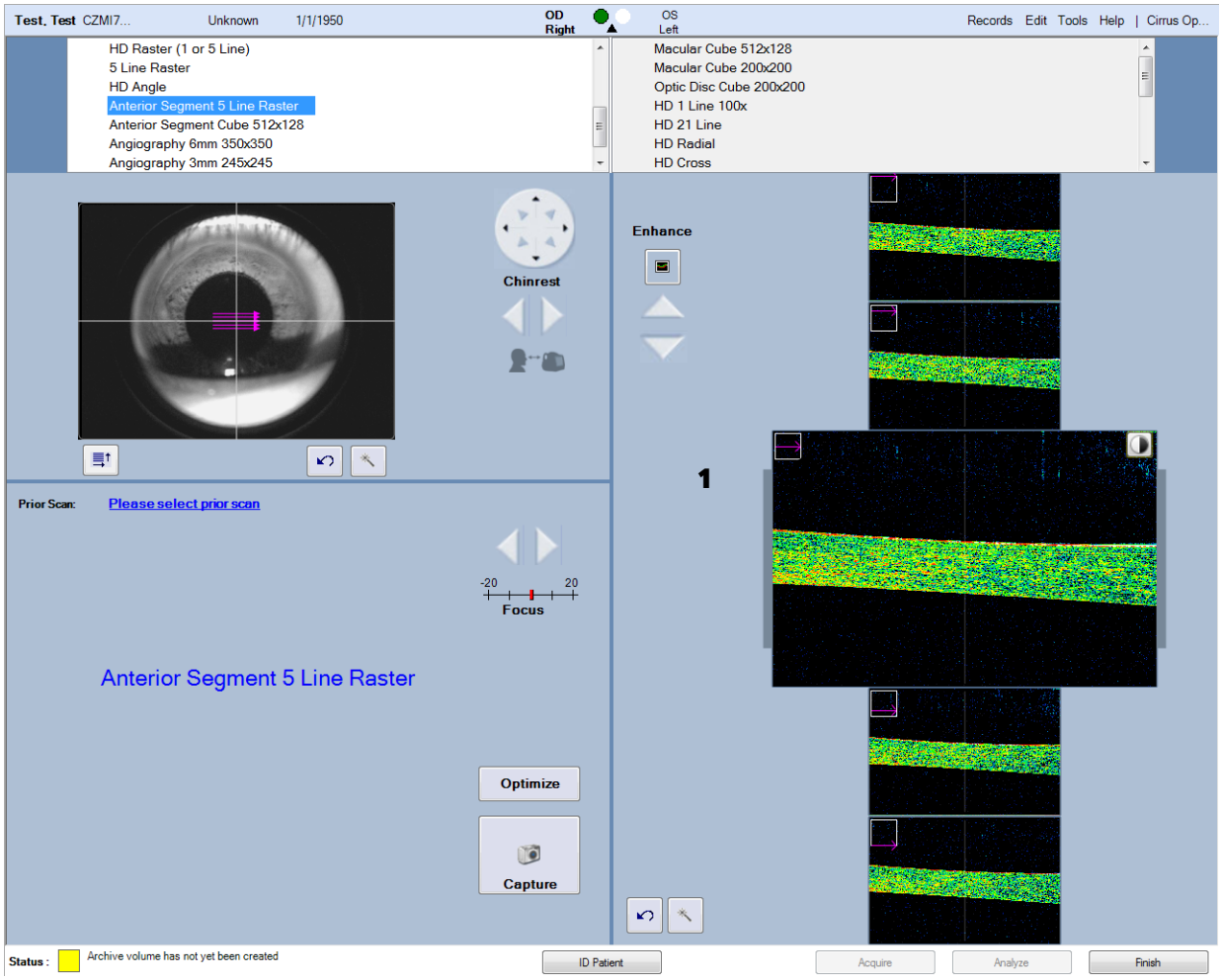
- The horizontal B-scan is correctly positioned when it fits between the two red lines on the viewport with the anterior corneal surface aligned with the upper red line, as shown in Figure 6-10.

NOTE: Minimize eyelash and eye interference as much as possible.

Anterior Segment 5–Line Raster Scan

This scan can be positioned anywhere on the Iris image and has an adjustable line length of 3, 6, or 9 mm, an adjustable angle of –89 to 90 degree, and adjustable spacing from 0 to 1.25 mm in increments of 0.025 mm. It is used as the basis for HD Images Analysis ("High Definition Images Analysis" on page 8-55).

The **Acquire** screen displays the position of the Anterior Segment 5 Line Raster scan pattern on the live iris image. The OCT B-scan images on the right correspond to the 5 scan lines, with the middle scan line corresponding to the larger middle OCT B-scan image.



1 Grey Bar for aligning B-scan

Figure 6-11 Acquire screen, Anterior Segment 5 Line Raster

Guidelines for Anterior Segment 5 Line Raster Scan Cornea Acquisition

- Instruct the patient to fixate on the center of the fixation target.
- Use the screen X-Y and Z controls or keyboard arrow keys and mouse scroll wheel to center the scan between the gray bars on either side of the B-scan display, as shown in Figure 6-11.

Acquire Screen and Controls

Once a patient is in your database (see "Patient Records" on page 5-2 for new and existing patient protocol) and the patient is selected, the **Scan** button at the bottom of the **Patient Screen** becomes active. Pressing **Scan** brings up the **Acquire Screen** (Figure 6-12) from which all operations for scanning from CIRRUS are conducted. The **Scan Screen** for all but the Montage Angio scan consists of the 5 main portions with associated menus and options to assist in targeting and optimizing scan acquisition.

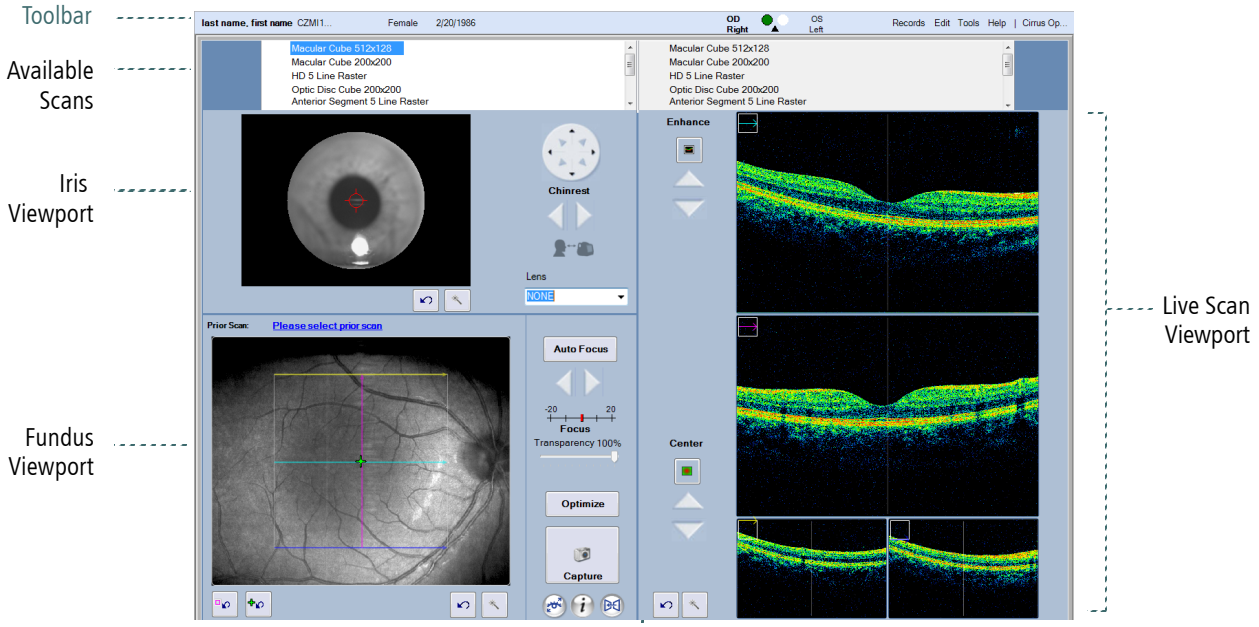


Figure 6-12 Sample Acquire screen for Posterior Scans (Macular Cube 512x128)

The **Scan Screen** for Montage Angio scans, as shown in the Figure 6-13, consists of 6 main portions and is discussed in the Montage Angio scan areas of this chapter.

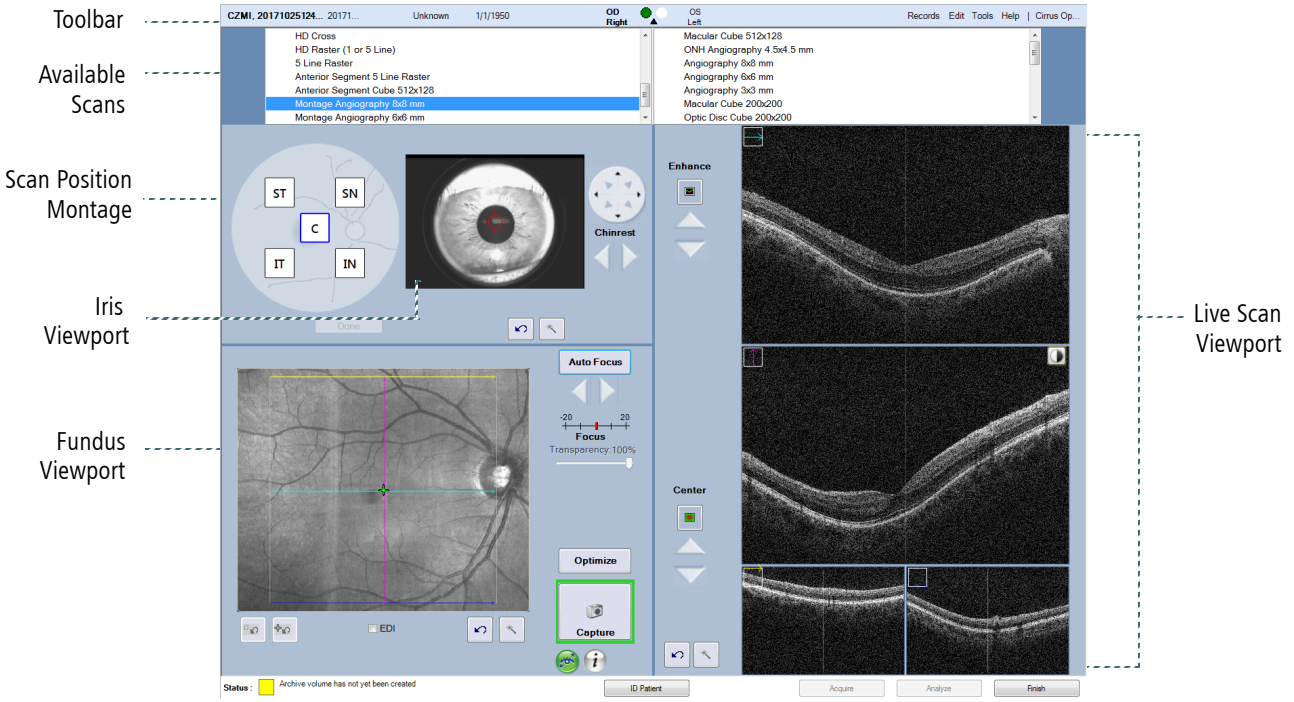


Figure 6-13 Sample Acquire screen for Posterior Scans (Montage Angio 6x6)

Acquire Screen Toolbar

As shown below, the **Acquire Screen** indicates the patient's name on the left, followed by gender and birthdate. Center right, a **green dot** indicates which eye is currently being scanned, and to the far right are a set of menus. Only **Tools** is of interest during acquisition. A discussion of the other items in the **Tool Bar** can be found in "Toolbar Options" on page 3-5.

Toolbar options specific to scan acquisition include:

- **Live Fundus Overlay**
- **Color OCT (F9)** allows you to switch between color and grayscale globally, for all viewports. Color OCT is the default.
- **Live OCT Center Line**
- **Auto Repeat**
- **Tracking**

Available Scans List

At the top of the **Acquire** Screen, two scan lists contain the list of scans—the left list is for the right eye, and the right list for the left eye.

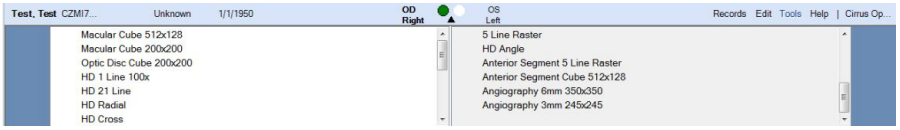


Figure 6-14 Available Scans. Note the location of the slider for each eye (OD and OS). Available scans may not appear at first (as shown on the left (OD) portion of the list). However, by moving the slider down (as shown on the right (OS) portion of the list), all scans can be found. This list can be simplified by using the Scan Organizer ("Scan Organizer" on page 6-21).

Selecting the scan type populates the Acquire screen with the correct image layout.

NOTE: Only the scans which your institution has licensed will be shown in the Available Scans list. You can check which scans have been licensed by going to **Help > View Licenses** in the Toolbar (see "Toolbar Options" on page 3-5).

Scan Organizer

The Scan Organizer is accessed from the Toolbar by selecting **Tools > Scan Organizer** in ID Patient mode.

NOTE: You cannot access the Scan Organizer from Review Software.

When **Scan Organizer** is selected, the dialog shown in Figure 6-15 below appears. All your licensed scans will appear in the left column. If your institution only uses certain scans, select the scans of interest. Select the right arrow, and the scans of interest will appear in the right side of the dialog. Subsequently, only those scan will appear at the top of Acquire screens as shown in Figure 6-16. You may change the set of scans that appear in Acquire screens at any time by using the left and right arrows to change selections.

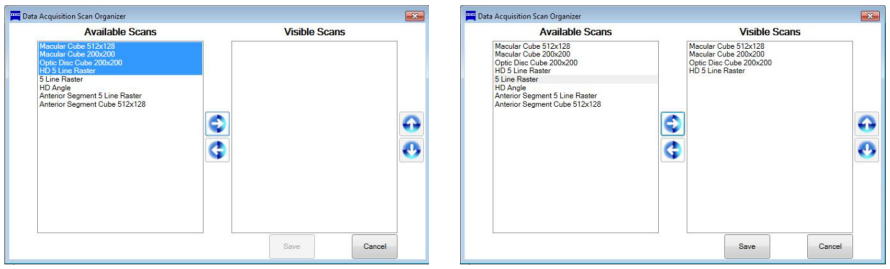


Figure 6-15 Scan Organizer Dialog, before (left) and after (right) scans have been selected for availability to use during Acquisition

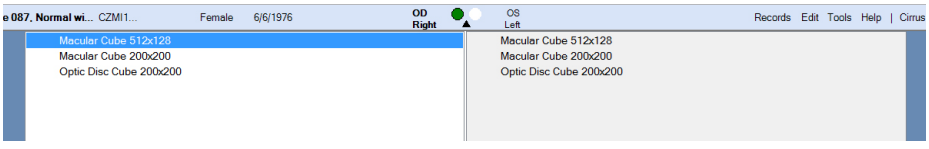


Figure 6-16 Available Scans after Using the Scan Organizer. In this example, all scans but Macular Cube and Optic Disc Cube Scans were removed from the list

Iris Viewport

The Iris Viewport lies in the upper left quadrant of the main Acquire screen Viewport (Figure 6-12). During scanning the iris and pupil of the current patient is shown in real time. Within this viewport you can:

- Select the appropriate lens type from the **Lens** drop-down menu, depending on the scan type you have selected.
- Adjust the chinrest either automatically or manually.
- Target the patient pupil using the left mouse button to move the fixation target to the center of the pupil image.
- Enhance ( ), adjust brightness and contrast ( ), or reset the pupil target .

Proper alignment of the scan beam to the pupil is required in three dimensions, X, Y (transverse), and Z (axial). CIRRUS provides automated alignment controls by clicking the Iris Viewport as well as manual controls both on–screen and via the keyboard (X-Y). These controls will adjust the chinrest and forehead rest so that the eye is properly aligned for the OCT scan. Start by using the mouse to change depth (mouse wheel), or move left to right. Once you've aligned the target as well as possible using the mouse controls, use the manual controls are to fine tune the alignment.

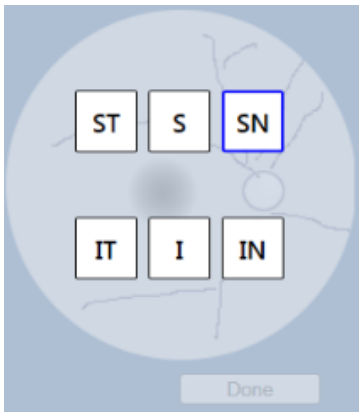
You may also use the keyboard to auto–adjust the alignment by using the keyboard arrow buttons that correspond to the X-Y controls. Press **Ctrl** with the keyboard arrow keys for finer adjustments. Adjustments occur in discrete steps when you click and release. When you click and hold the arrow, the adjustment motion becomes continuous until you release.

Scan Position Montage

The Scan Position Montage provides a visual representation of the retinal scan location.

6x6 mm Montage Angio Scan

The 6x6 mm Montage workflow includes 6 scans at different positions and the fixation moves 4 times.



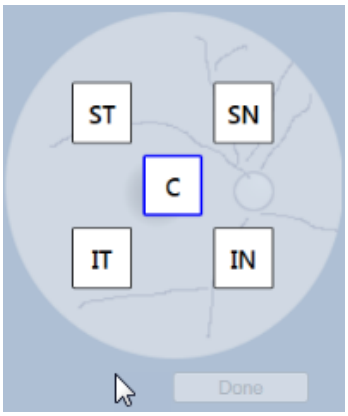
The initial scan location for this type of scan is Superior Nasal (SN), and the scan progression and fixation target automatically flows in the following sequence:

- Superior (S)
- Superior Temporal (ST)
- Inferior Temporal (IT)
- Inferior (I)
- Inferior Nasal (IN)

NOTE: You can skip scan locations or veer from the automatic sequence by clicking the mouse on location(s) you want to use. However, you can click **Done** after 1 scan is acquired.

8x8 mm Montage Angio Scan

The 8x8 mm Montage workflow includes 5 scans at different positions and the fixation moves 5 times.



The initial scan location for this type of scan is Central (C), and the scan progression and fixation target automatically flows in the following sequence:

- Superior Nasal (SN)
- Superior Temporal (ST)
- Inferior Temporal (IT)
- Inferior Nasal (IN)

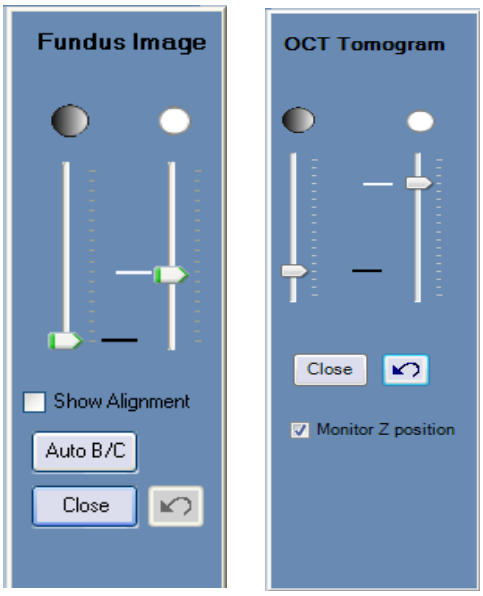
NOTE: You can skip scan locations or veer from the automatic sequence by clicking the mouse on location(s) you want to use. However, you can click **Done** after 1 scan is acquired.

Fundus Viewport

The Fundus Viewport lies in the lower left quadrant of the main Acquire screen Viewport as shown in Figure 6-12, and shows a live fundus image from the line scanning ophthalmoscope (LSO). The Fundus Viewport is not available for Anterior scans. As with the Iris Viewport, there are a number of options available for optimizing the patient scan:

- **Focus/Auto Focus** will attempt to compensate for the patient's refractive error by automatically changing the focus adjustment. This may help clear up a dim fundus view and will also help clear up the fixation target for a patient whose refractive error is considerable. In addition to improving the overall focus, the Auto Focus feature will do an additional adjustment on the brightness and contrast of the fundus image.
- The **Transparency** slider is active when a saved scan image overlay is present, which occurs when you are using a prior scan.
- Prior scan will appear as a selectable link, as shown in the margin. If your patient has been scanned previously, selecting this option will open up a small screen with a list of the patient's previous scans. Once you select a previous scan, the location of that scan will appear as a live link, and serve as a reference as you acquire the current scan. You can change the prior, reference scan, at any time. You can also initiate an exact replica of a prior scan using the Auto Repeat function (Figure 6-20).

- Optimize automatically optimizes first the scan image centering (Z-offset), and then optimizes the scan image quality (polarization). Instruct the patient not to blink during optimization.
- Enhance ( ), adjust brightness and contrast ( ), or reset the fixation target . When you select ( ), one of the following dialog boxes will appear.



- If you have the tracking selection enabled ("Toolbar Options" on page 3-5), tracking on the macula, FastTrac automatically monitors whether the OCT B-scans are

centered vertically–"Z" monitored–and stops the tracking progress when some or all of the tissue is outside the B-scan window. In some patients, it may be difficult to align the tissue within the B-scan entirely, such as those with high myopia or other kinds of atypical anatomies; for example, tilted retinas or posterior staphylomas. For these patients, the user may turn off Z monitoring, as shown in the OCT Tomogram figure on the previous page. To turn this option off, click the wand button next to the B-scan in the lower right of the **Acquire Scan** screen. If tracking is *not* enabled, the dialog box includes the Show Alignment checkbox. For any Macular Cube Scan, this checkbox toggles display of an alignment tool that is locked in position relative to the scan pattern; the alignment tool moves when you move the scan pattern and vice versa. This tool is designed to be placed over the optic disc to assist in accurately repeating scan pattern placement for future scans of the same eye. For macular scans, placing the alignment tool over the optic disc results in the scan center being within 1 mm of the fovea for most patients. This tool is helpful when the fovea is difficult to find in extreme edema, cataract, or floater situations.

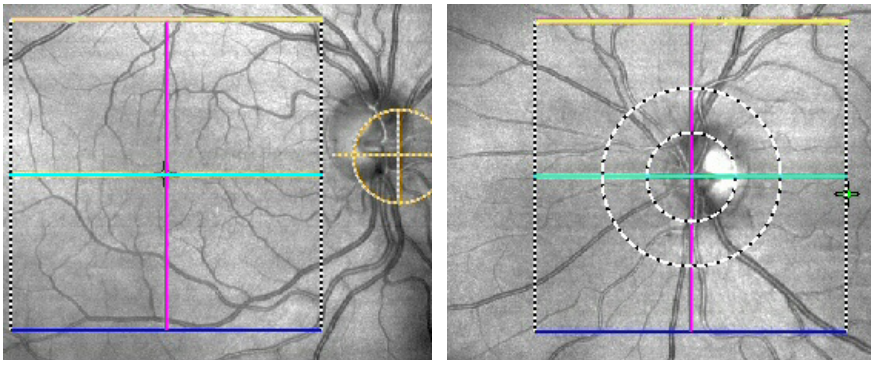


Figure 6-17 Fundus Images showing Alignment Tools: Macula and Optic Disc

For optic disc scans, the alignment tool is centered on the scan pattern and on by default.

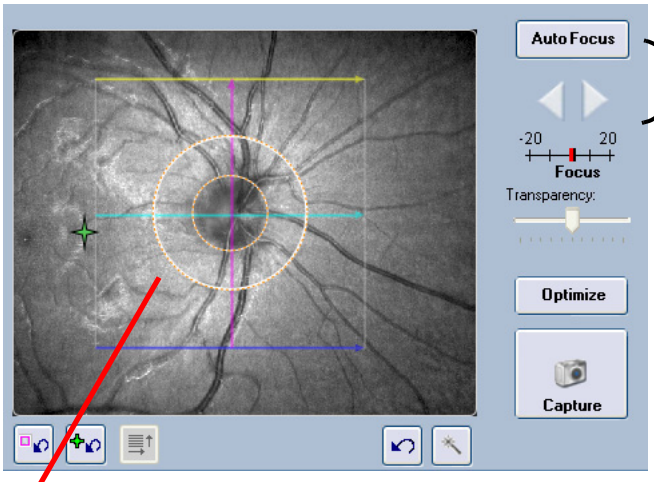
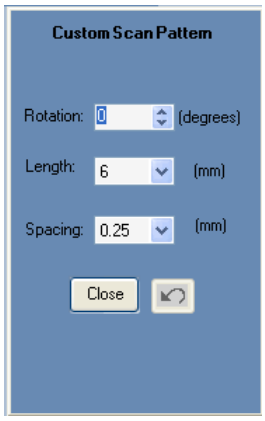


Figure 6-18 Fundus Viewport (Optic Disc Scan)

For Optic Disc Cube 200x200 scans, it is not necessary to precisely center the optic disc in the scan image because the analysis algorithm can correctly place the Calculation Circle around the optic disc even when it is not well centered. Though it is sufficient to keep the optic disc within the outer dashed circle, it is best to center the scan on the optic disc as well as possible. The *En Face* scan image overlay that shows the area scanned. This is the captured Live OCT fundus image

NOTE: For ONH Angiography scan, it is different than the Optic Disc Scan, in that for ONH angiography, you need to click and drag the scan pattern to be centered over the optic nerve.

Adjust Rotation and Size allows you to rotate the angle of the scan and its length. opens the **Custom Scan Pattern** dialog shown below, and allows you to specify a non–standard scan pattern.



- For **Rotation**, click the up arrow (for counterclockwise rotation) or down arrow (for clockwise rotation) or enter a value to adjust the angle in the ranges of 0 to 360 degrees. Values entered from 91 to 269 are automatically transposed 180 degrees to correspond with scan direction. **The** default 0 degree position is horizontal.
- For **Length**, depending on the scan, you can select **3, 6,** or **9** mm.
- For line **Spacing**, depending on the scan, you can select between 0.00 and 1.25 mm in increments of 0.025 mm.

Enhanced Depth Imaging (EDI) is an optional mode for single and multi–line raster scans that improves visibility of structures at the bottom of B-scans. The signal to noise ratio in OCT scans varies across the axial range. The default CIRRUS setup is such that the best signal is obtained at the top portion of the scan. Enhanced Depth Imaging allows you to change the acquisition settings for the raster scans so that the best signal to noise ratio is obtained at the bottom of the B-scan. This allows you to obtain an HD image that is optimized in the region that is of interest for a particular scan. To switch between EDI and standard scanning mode, select the EDI checkbox EDI below the fundus image.

- **Capture** starts the scan.
- **FastTrac Retinal Tracking**, is started and controlled by the 2 outer buttons ( ) and ( ) just under **Capture**. (Green icons are on and gray icons are off.) The FastTrac

retinal tracking system tracks eye movement and enables tracking of the current scan to the position of a prior scan. The FastTrac retinal tracking system on CIRRUS HD-OCT uses multiple channels of concurrent imaging to monitor the motion of the eye in real–time. During acquisition, motion is automatically detected and tracked to the eye. The motion of the retina is observed at a high rate to ensure higher efficiency in reducing the effects of motion. Most importantly, FastTrac ensures faster data acquisition by only re-scanning data affected by motion. FastTrac also allows precise scanning at follow-up visits to acquire data at the same region of the eye allowing for better progression analysis.

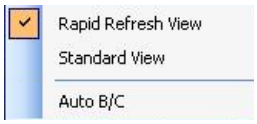
In addition to the selectable options that appear on the **Acquisition screen**, you can adjust certain system parameters using the left mouse button and scroll wheel, and open additional options by clicking the right mouse button. Mouse controls and options are discussed below.

Mouse Controls

Using your mouse provides a rapid way of accessing most of the controls that are available as buttons or in menus on the CIRRUS screens. During scan acquisition you can adjust scan pattern placement using your mouse for posterior scans by hovering over the fundus image (the mouse cursor will turn into a), and dragging the scan pattern box area to another position.

Hover the mouse over the fixation target icon (the mouse icon will turn into), and then click and drag the fixation target to change the center its location to one of 9 pre-set locations.

Right-clicking the mouse will bring up an option box that allows you to select to **Rapid Refresh View** (model 500 only)**.** This is a great tool for patients with unsteady fixation as it increases the rate at which the screen refreshes, reducing the affect of unsteady fixation.



Double-clicking anywhere on the fundus image will change the fixation location to bring that point (clicked) into the center of view.

Live Scan Viewports

The right half of the main Acquire Scan Viewport comprises the live data feed based on your current iris and fundus settings. The number of viewports may vary depending on the scan type selected. Each scan view includes a color–coded scan marker at upper left, to identify scan lines. The color and orientation of each marker correspond to the color and orientation of the lines that make up the scan pattern overlay derived from the Fundus Viewport (for posterior segment scans) or the Iris Viewport (for anterior segment scans). Live scans can be adjusted in real time using

- Center Live Scan allows you to adjust the zoom (Z-offset) of posterior segment live scans. Associated up and down arrow buttons enable you to adjust the value manually.

- Enhance Live Scan  allows you to adjust the polarization (X,Y–offsets) of posterior segment live scans. Associated up and down arrow buttons enable you to adjust each manually.

NOTE: HD Angle scans are not aligned to the corneal vertex.

NOTE: If a button or menu option does not appear on the **Acquisition screen** for your current scan selection then that function is not available for the current scan.

General Acquire Procedure

This section contains information about acquiring scans supported in CIRRUS HD-OCT.

NOTE: Review both the "Acquire Screen and Controls" on page 6-19 and "Set Up for Maximum Image Quality" on page 6-31 sections prior to acquiring scans.

Once you have selected the patient of interest, the **Acquire** button at the bottom of the Patient screen becomes selectable.

NOTE: The first scan selection and scan of the day will run slightly slower than all later scans.

NOTE: To minimize errors and artifacts, acquire OCTA Cube scans with FastTrac on.

- **HD Line 100x:** A single high definition OCT B-scan, using 1024 A-scans, with selectable B-scan averaging 100 frames with an adjustable length from 3 mm to 9 mm and an adjustable angle from 0 to 90 degrees.

To Begin Scan Acquisition:

1. Ensure that the Patient is fully prepared for the scan as described in "Patient Good Practices" on page 5-1.
2. Select **Acquire.** The screen will change to indicate the scan types available.
3. Select the scan type of interest
4. Ask the patient to hold their gaze and head steady (as the chinrest will be moving) and select **Auto Focus** in the Fundus Viewport.
5. Left–click the pupil center of the live image in the Iris Viewport to center the scan beam through the pupil.
6. After Auto Focus, check the Iris Viewport to ensure that the pupil is still centered. If the Fundus Viewport turns dark following Auto Focus, center the pupil, click  , then click the **Auto B/C** button. If additional brightness and contrast changes are necessary, use the appropriate slider controls.
7. Further adjust the chinrest manually, if necessary, by use the circular X-Y control (see "Iris Viewport (Posterior Segment Scan) and Anterior Segment Scan Patterns" on page 6-29). Use Z controls (left–right arrows or mouse scroll wheel) to reach the proper working distance by bringing the iris image into focus.
8. Use **Enhance** (polarization) and **Center** (Z-offset) (posterior segment scans only) buttons and sliders to the left help you improve the scan image quality and center it vertically.

9. Adjust the region of the iris visible in the Iris Viewport. Typically, make coarse adjustments using the X-Y controls (that move the chinrest) as needed until the pupil is visible.
10. Focus the iris image using the controls to the right of the viewport. For focusing, primarily use the Z controls. The mouse scroll wheel works well for fine adjustments. Try to get the iris as clear as possible before proceeding to the next step

.

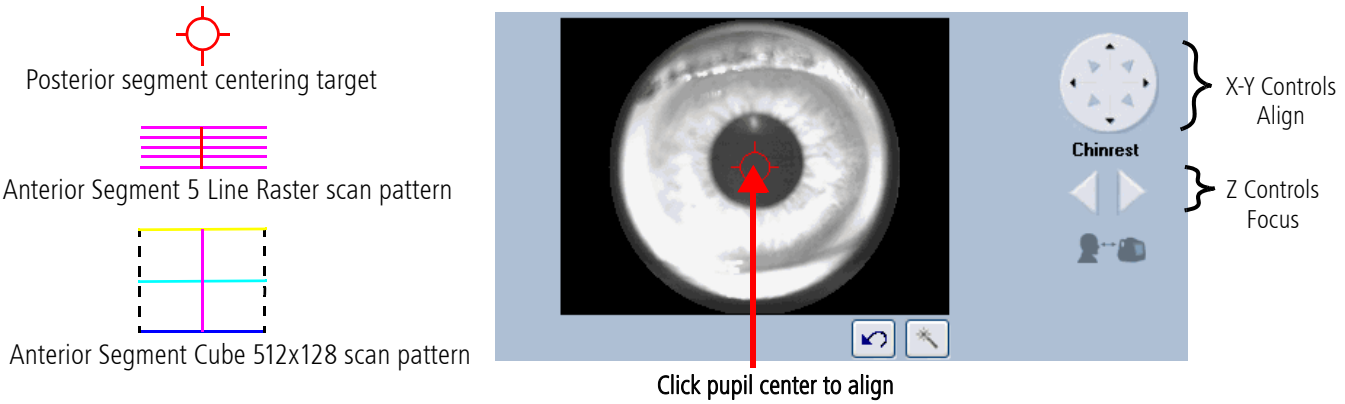


Figure 6-19 Iris Viewport (Posterior Segment Scan) and Anterior Segment Scan Patterns

11. Center the pupil in the Iris Viewport by clicking the center of the pupil. (Clicking anywhere in the Iris Viewport centers the field of view of the camera over the click point). A centering target overlays the video image for posterior segment scans. For anterior segment scans, a graphical scan pattern appears to show the alignment scan pattern position, size, shape, and orientation (see Figure 6-19 above). It remains in the center of the image and illustrates the path of the scan beam.
12. View the Fundus Viewport, just below the Iris Viewport (Figure 6-12 or Figure 6-13, depending on the scan type). The Fundus Viewport, is not available for Anterior Segment scans)
13. If you are not using prior scan data for comparison skip to Step 16. If you are using a Montage Angio scan, skip to Step 18.
14. If you want to compare the current scan to a previous scan of the same patient, select the **prior scan** option (just above the Fundus image) and the **Repeat Scan** dialog appears.

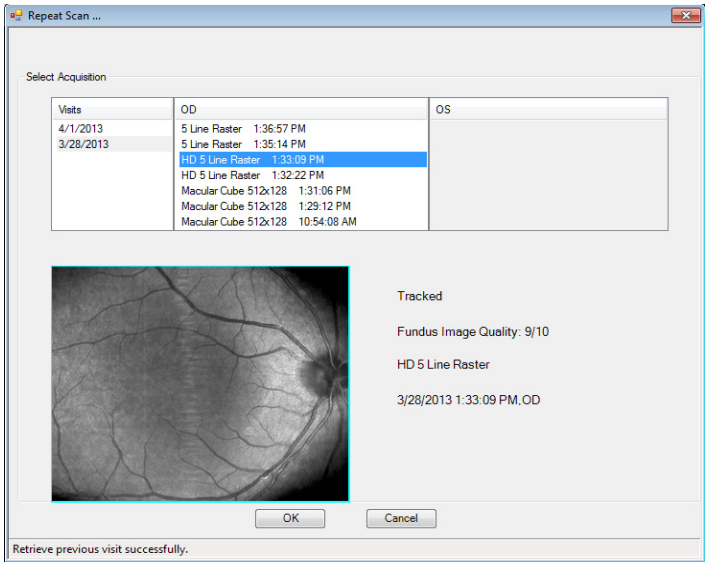


Figure 6-20 Repeat Scan Dialog

The **Repeat Scan** dialog lists all previous scans in the same scan type category for this patient by exam date and eye and shows the fundus image for the scan you select. This is especially useful when a scan had been captured away from the central fixation area or if a patient had been scanned previously with a Macular Cube 200x200 scan but now will be scanned using the Macular Cube 512x128 scan.

15. Select the scan of interest and press **OK**. This action will return you back to the **Acquire screen**. The system will apply all the parameters of the previous scan and displays the fundus image from that exam. The chinrest will move during this adjustment.

    The scan pattern for the selected scan type is overlaid on the fundus image and a small green cross indicating the location of the fixation target is displayed. (This green cross may be partially obscured by the scan overlay.)

16. ISelect **Capture**. An on–screen progress bar indicates how the data acquisition is progressing (see "Tracking and Repeat Scans" on page 6-32). Acquisition time depends on the fixation stability of the eye. If the instrument has difficulty tracking, the progress bar stalls and the user will have the option to either realign the eye or to turn tracking off (see Troubleshooting FastTrac on page 6-36).

17. Proceed to the **Review screen** (Chapter 7 "Scan Quality Check") where you will determine whether or not the scan is acceptable or if it should be repeated.

18. **For Montage Angio Scans Only:** You will see a different Scan Position Montage depending which Montage Angio Scan you select (for example, 6 scans possible for 6x6 mm and 5 scans possible for 8x8 Montage Angio Scan). The beginning position is outlined in blue, as shown in the Scan Position Montage.

    Select **Capture** for the first scan. An on–screen progress bar indicates how the data acquisition is progressing. Acquisition time depends on the fixation stability of the eye. When the first scan is complete, the "**SN**" box (for 6x6 mm) and the "**C**" box (for 8x8 mm) in the visual representation sequence will have a green checkmark through it

indicating completion, and the next position in the visual representation sequence is now selected. Repeat the **Capture** process again up to the maximum number of scans you want (6 scans possible for 6x6 mm and 5 scans possible for 8x8 mm).

You can skip scans by selecting clicking on an other retinal scan position. In addition, if you want to retake a scan that has already been acquired, you can hover over the existing scan and the gray redo arrow appears (there is no icon next to the retinal scan location). If you click on the icon, a popup appears and asks if you want to delete and acquire that scan. Once you click to rescan, the scan previously acquired will be deleted and it will be set up to retake the selected scan. See Figure 7-2 for more information.

When all the scans are complete, the screen automatically changes to the Montage Scan Quality Check screen. If fewer than 6 scans (6x6 mm) or 5 scans (8x8 mm), respectively, are acquired, click the **Done** button to advance to the Montage Scan Quality Check screen.

NOTE: If only 1 scan is performed, the application treats and saves the scan as a single Angiography scan.

TIP: For curved retinas peripheral scans:

- **Turn off z monitoring.**
- **Do not change centering of b-scan during acquisition.**

If only 1 scan is performed, the application treats and

Set Up for Maximum Image Quality

Iris image

- Center the iris image within the pupil (may be offset slightly depending on tilt of retina or to avoid opacity).
- Focus on the iris detail.

Fundus image

- The focus should be sharp and clear, preferably with good visibility of the branching blood vessels. Use **Auto Focus** or adjust manually.
- Center the scan overlay on the fovea for macular scans and on the optic nerve head for optic disc scans.
- Ensure uniform illumination without dark corners.
- Eliminate or reduce artifacts that may cast shadows on the OCT scan (if possible).
- Floaters might be moved by asking subject to shift eyes around prior to image capture.
- Corneal opacities may be minimized by realignment of the pupil.

B-scans

To optimize signal strength for the best possible B-scan images, follow these guidelines:

- Center the B-scan in the mid to upper part of the scan acquisition screen.
  Click **Optimize** or **Center** to aid in placement.

- The OCT B-scan should be flattened to fit into all acquisition windows horizontally, avoiding top of the window.
- A tilted retina may be corrected for by moving the pupil alignment off–center to allow for a more level OCT scan.
- Media opacities may be minimized by searching different pupil positions for the brightest OCT image.

For All Scans

In all cases, adjust the enhancement settings to achieve the brightest and clearest scan.

NOTE: You may see a reflection of a rectangular band over the pupil, as seen in Figure 6-19. This artifact has no significance.

- Review the captured data to ensure it is of acceptable quality. Besides the observed image quality, an important element of acceptable quality is the Signal Strength indicator, which should be 6 or higher. Signal strength and image quality can be significantly reduced when the imaging aperture (the lens) is dirty or smudged. If you suspect this problem, follow the instructions to clean the "Imaging Aperture Lens and External Lenses" on page 12-3.
- If the captured scan is of good quality, click **Save** and continue. If it is not, click **Try Again to return to the Acquire** screen.
- When you are finished acquiring scans, click **Finish** in the **Acquire** screen. You will return to the **ID Patient s**creen.

Tracking and Repeat Scans

Repeat Scans

CIRRUS HD-OCT contains automatic and manual functions to repeat scan setup and alignment during follow–up patient visits. Repeat scans are separated into two types:

- **Auto Repeat,** available if you have saved the same scan type for a patient and eye on a previous visit. These scans are specifically geared toward previous patient visits, to reduce setup time and quickly compare macular changes that may have occurred in the interval between visits.
- Manual Selection is geared toward same–visit repeats, when it is desirable to change scan types, under the same conditions and settings as the previous scan.

Auto Repeat is accessed in the **Tools** menu of the **Acquire screen** Tool Bar "Toolbar Options" on page 3-5. When enabled, the instrument automatically adjusts the ocular lens and chinrest to the previous settings for the same patient, eye, and acquisition scan type. The repeated parameters include chinrest alignment, scan pattern and fixation target placement, Enhance (polarization) and Center (z–alignment) settings, focus, brightness, contrast, and illumination settings. These adjustments occur with the patients chin in or out of the chinrest. It takes a few moments for the chinrest to move and all parameters to be applied.

When the prior scan is found, its scan setup parameters are used, and a **Prior Scan** link is created (showing the eye, and exam date and time).

Auto Repeat can aid your workflow in the following situations:

- You perform only one type of scan per visit.
- You perform multiple scans and scan types but in different scan areas, for example Macula Cube 512x128 followed by Optic Disc Cube 200x200.
- The patient is able to maintain head position between scans.

Auto Repeat may not be desirable for use in the following situations:

- You perform multiple scans using different scan types in the same scan area per visit, for example: Macula Cube 512x128 followed by HD 5 Line Raster, or Macula Cube 512x128 followed by Macula Cube 200x200. In this instance, using settings from the current visit is more efficient.
- The patient has difficulty or is unpredictable in maintaining head position. In this instance, the repeat scan may be very different from the current position.

If you do not want the chinrest and ocular lens to move from the currently aligned position when switching to another scan type, you can select the **Prior Scan** link to use previous scan settings for any scan you wish to acquire.

Turn off **Auto Repeat** after the initial chinrest and focus adjustments are in place, or after acquiring the first scan, and prior to choosing the second scan. This will ensure that the settings used for the first scan will be maintained.

When you select a **Prior Scan**, the previously saved reference OCT fundus image is overlaid in the scan pattern box over the live fundus image.

FastTrac

Before using FastTrac, open the Tools menu and make sure both the **Auto Repeat** and **Tracking** features are checked.

FastTrac can be turned on and off as a global choice for all scans in the Tools menu.

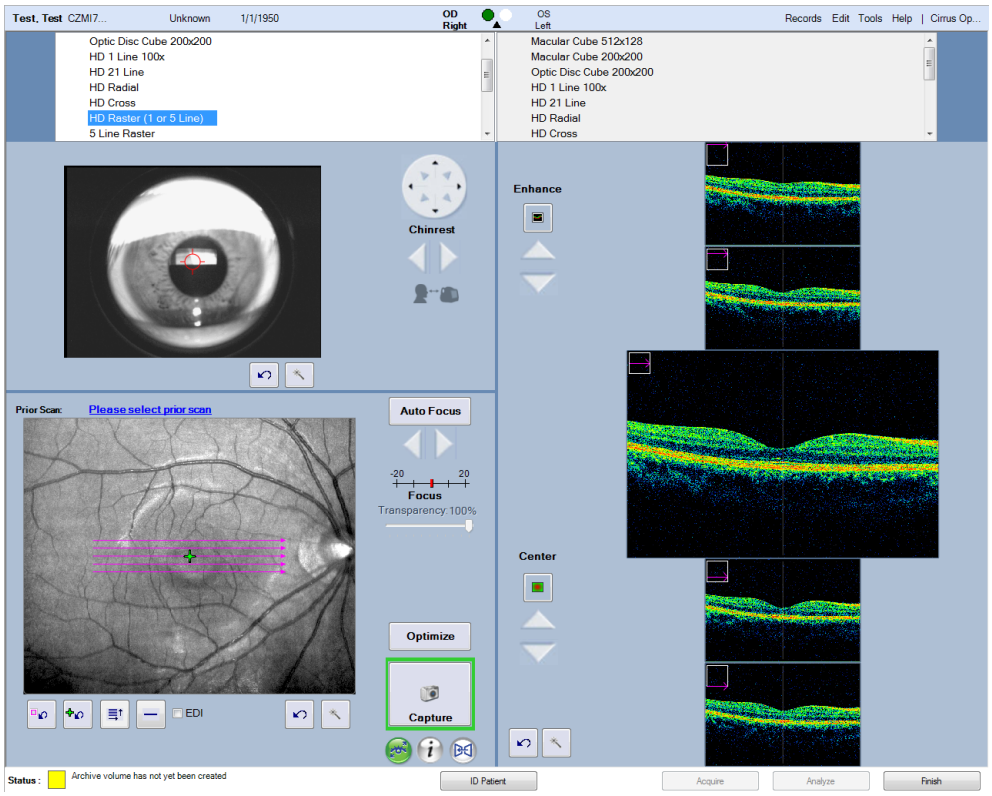


Figure 6-21 During FastTrac scanning, there is a border around the Capture button which turns from red to green when the scan can be performed with FastTrac.

Three buttons are located beneath the **Capture** button. When FastTrac is turned on, the button on the left is green . Clicking this button toggles FastTrac on and off for the current scan. The button turns gray when tracking is off.

Clicking the button in the middle provides information on how to ensure the scan can be performed with FastTrac.

The button on the right is the **Track to Prior** toggle button. When a previous scan is available, the button is green . If the user does not wish to track to a prior scan, this function can be turned off by clicking this button, which will turn from green to gray.

1. Follow the same alignment steps as for a non–tracked scan.
2. Ensure the B-scans are centered. Click the up and down arrows or use the mouse scroll wheel to make fine adjustments to center the scan. Clicking the **Optimize** or **Center** buttons automatically adjusts the vertical position of the B-scans.

NOTE: For optic disc scans, the **Capture** button may still be green if the scan is not completely centered.

3. Maximize fundus image quality. FastTrac is most robust and efficient when the fundus quality is high. Fundus quality is also important for ensuring accurate and successful tracking to the same location in subsequent scans. High quality fundus images are well focused with sharply delineated blood vessels and have uniform illumination without dark corners.

4. To achieve uniform illumination, ensure the scan beam is aimed through or near the center of the pupil and the iris and pupil are in focus. Corneal opacities may be minimized by realignment of the pupil. This can be assessed and adjusted in the iris camera viewport.
5. Proper focusing is essential for a good fundus image. This is accomplished by using Auto Focus or by manually adjusting focus. The user may also set the patient's spherical equivalent values when adding or editing the patient demographic information.
6. Select Track to Prior. If the border around the **Capture** button remains red, alignment may not be working. Change which prior scan to track to or disable **Track to Prior** for this scan. **Track to Prior** is possible for scans acquired before the tracking license was activated or for which tracking was not turned on. However, optimal results can be obtained by selecting a prior scan for which tracking had been on.

   When the **Track to Prior** feature is turned off and a **Prior Scan** is chosen, the CIRRUS operates as described in "Repeat Scans" on page 6-32
7. When the border around the **Capture** button is green, the scan can be performed with FastTrac. Click **Capture**.

During FastTrac acquisition, after clicking **Capture**, a screen appears that shows the scan in progress as shown in Figure 6-20, and provides controls to make adjustments to help complete the scan.

A tracked scan may take additional time as compared to a non–tracked scan. During this period, adjustments may be necessary to maintain the success of tracking and the quality of the acquired scan.

The information box below the progress bar has two indicators to clarify if the conditions for a successful FastTrac scan are being met. When FastTrac is interrupted, information box indicators and the progress bar turn red and the progress bar stops.

The user can stop the scan for any reason from this screen by clicking **Cancel** one time. The progress bar will complete but the scan will not be captured. The user is then returned to the **Acquire** screen to try again or finish.

NOTE: After five minutes on the **Scan in Progress** screen with no scan being acquired, the system will return to the **Acquire** screen.

NOTE: Unlike non–tracked scans, once scanning has started, you may advise the patient to blink normally, as needed, while maintaining focus on the fixation target. Additional tear film may improve the signal of the scan.

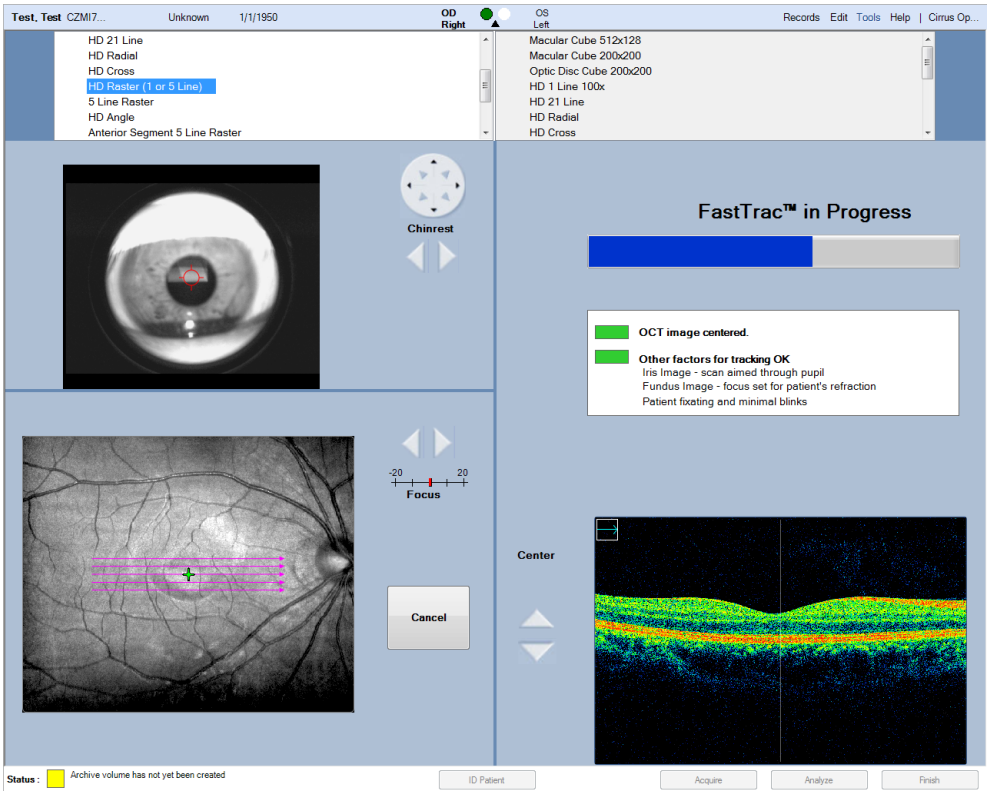


Figure 6-22 FastTrac Scan in Progress

Troubleshooting FastTrac

Indicator	Potential Problem	What you should do
OCT image centered	The OCT image is not centered properly and the scan is too high or too low in the window.	Use the up and down arrows (or mouse wheel) to center the scan.
	For patients with certain pathologies or anatomical features, it may be difficult to ensure centering across all B-scans in a cube.	Cancel the scan. On the **Acquire Scan** screen, turn off the monitoring of the Z position. Then, initiate a new scan with FastTrac.
Other factors for tracking	Iris image – scan may not be aimed through the pupil.	Adjust the scan position in the Iris Viewport.
	Fundus image – focus has drifted away from patient's refraction.	Manually adjust using the Focus controls.
	Patient fixation issues.	Communicate with the patient to ensure they are fixating in the same position as at the start of the scan.
	Excessive blinking or moving.	Communicate with the patient to reduce blinking and movement.

Figure 6-23 and Figure 6-24 illustrate cases where tracking is not progressing due to several of the reasons mentioned above.

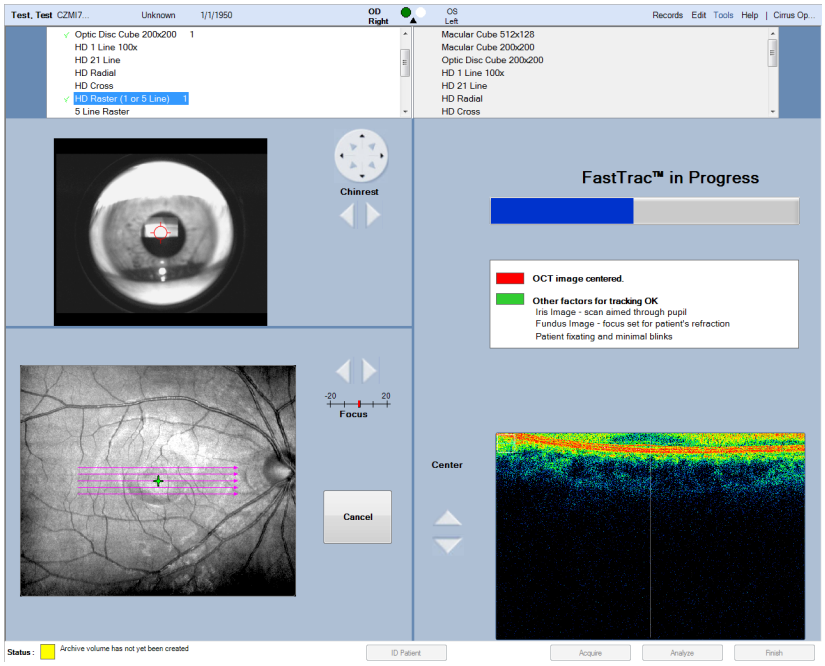


Figure 6-23 B-scan Too High on screen

In the example above, the B-scan is too high on the screen. If this occurs, use the up and down arrows next to the scan window or the mouse wheel to center the scan.

In this case (Figure 6-24), because light is not passing directly through the center of the pupil, the fundus image quality is reduced.

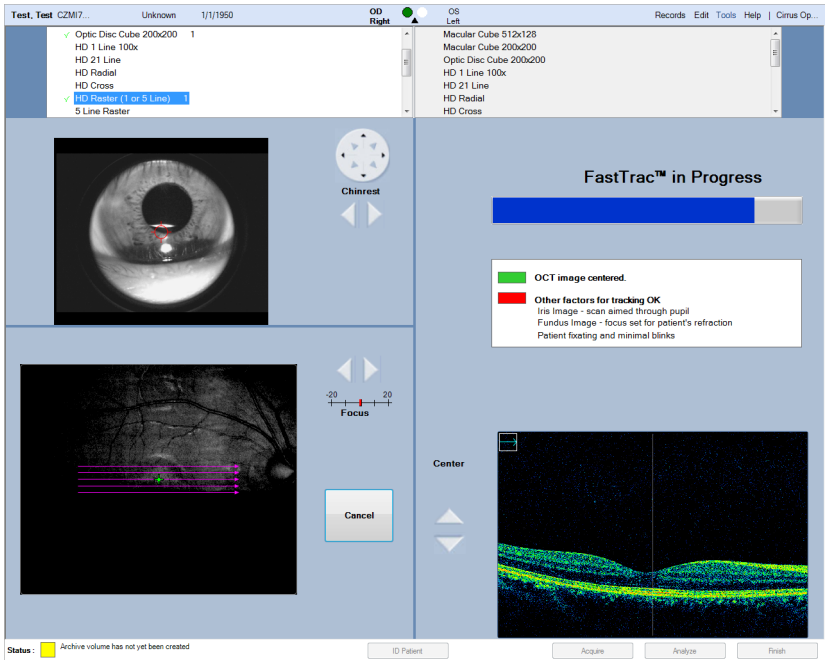


Figure 6-24 Poor Fundus Image Quality

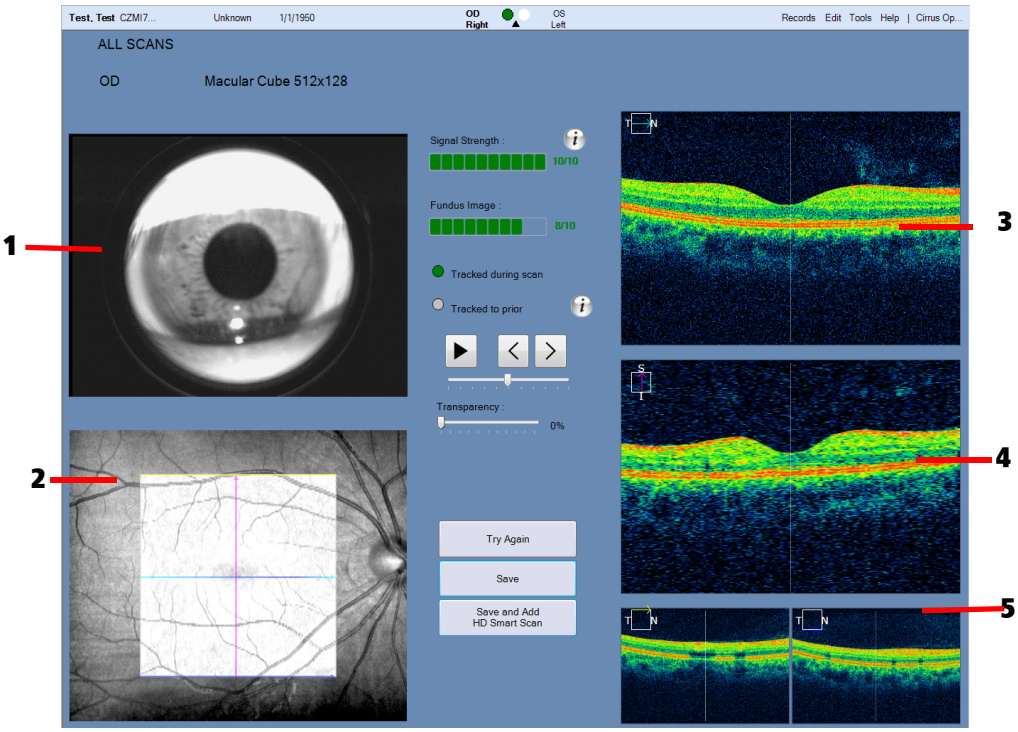
7 Scan Quality Check

Overview

Once data acquisition is complete, scans must be reviewed for acceptance and saved prior to being released for analysis. The **Scan Quality Check Screen** appears automatically, upon completion of data acquisition.

The screen is partitioned exactly like the scan acquisition screen for the selected scan type, with the exception that the data on the right is scanned data (as opposed to live data). In addition, the available controls pertain only to data review.

The **Scan Quality Check Screen** for all but the Montage Angio scans appears as shown in the Figure 7-1 example.

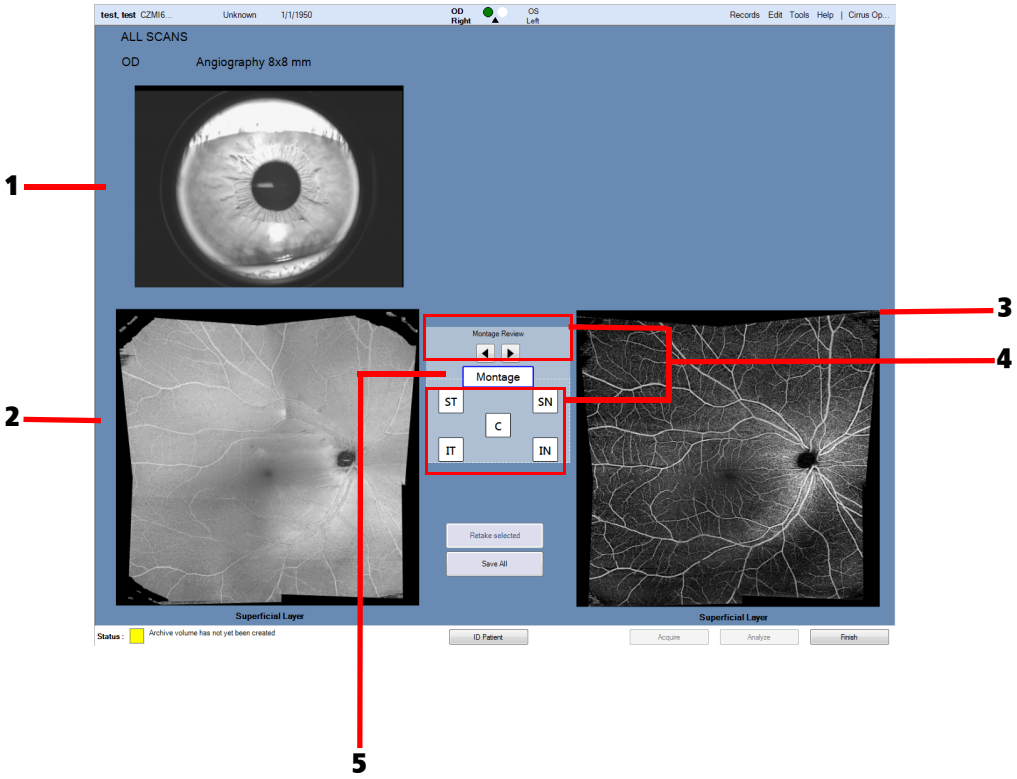


1 Iris image
2 Fundus image with scan overlay with blue and magenta slice navigators
3 Current X slice through front (fast B-scan)
4 Current Y slice through side (slow B-scan)
5 X slices through front and back (fast B-scans)

Figure 7-1 Quality Check Screen for Cube Scans (Macular Cube 512x128, FastTrac)

The **Scan Quality Check Screen** for the Montage Angio scans appears as shown in Figure 7-2. Scans that are not taken are automatically selected for a redo. Hover over an

acquired scan and you will see a gray circular redo arrow. Click again to select for a redo, and then the arrow will turn green.



7-2)

1 Iris image

2 Fundus image

3 Angiography en-face

4 Navigational aids for selecting and viewing the scans acquired as part of Montage Angio workflow.

Letters Indicating Scan Position (e.g., SN): Enables viewing the acquired Montage Angio scans.

Arrow Keys: Enables viewing the acquired Montage Angio scans.

Red X: Indicates that this acquired scan was unable to be montaged.

Gray Circular Arrow: IIf you hover over the thumbnail, after previously acquiring a scan, it will turn gray. This change indicates that it can be selected to be retaken. When you click on the thumbnail, the arrow will turn green indicating that the scan has been selected to be retaken.

Green Circular Arrow: Indicates that the green arrow indicates the scan is selected to be retaken.

5 **Montage Review** button (default view). Clicking the button displays the Superficial Structure in the lower-left viewport and the Superficial Angiography in the lower-right viewport.

Figure 7-2 Quality Check Screen for Montage Scans

All scans should be carefully reviewed and accepted only if the quality of the scans fulfills the requirements of the analyses for which the data was required. Tools are provided that allow you to enhance the images, where feasible. These tools and the criteria for acceptance are described in the following sections.

Quality Check Tools

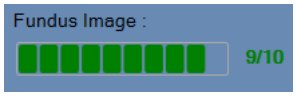
As in scan acquisition screens, you can adjust the brightness/contrast manually ( ) or automatically ( ) on the image in the Fundus Viewport for cube scans. Also for cube scans, you can use the Fovea Finder ( ) to automatically center on the image Fovea, and the transparency can be adjusted for scans based on prior images. Click to switch the image display between color and grayscale modes.

NOTE: You can switch between color and grayscale globally, for all viewports, by selecting or deselecting **Colored OCT** in the **Tools** menu (or by pressing **F9** on the keyboard). Colored OCT is the default.

As in all other data screens you can select to reset the image display to its default settings.

To assist in scan review, the scan signal strength of Posterior Segment scans is displayed on a scale of 0 to 10, with 10 being maximum. Signal strength values less than 6 are generally unacceptable. In these cases the indicator color will be red. For signal strengths of 6 or higher, the signal strength is acceptable, and the indicator color will be green. Click the Information button for additional suggestions on how to obtain better signal strength.

NOTE: The **Scan Quality Check Screen** for Anterior Segment scans does not show the Signal Strength indicator.



For FastTrac scans, in addition to **Signal Strength**, there is a quality rating for the acquired scan called the "Fundus Image Quality" score. A Fundus Image Quality score 6 or above confirms that the quality is satisfactory to be used for a future scan.

A green dot ( ) in **Tracked during scan** indicates tracking was successful during the scan, while a green dot ( ) in **Tracked to prior** indicates tracking to a prior scan was successful.

Select to obtain additional information on the prior scan.

Double-click any image on a **Scan Quality Screen** to open it in full screen mode. Double–click again to return to normal view.

During quality check, the cube scan slice locators used in scan acquisition become slice navigators which can be repositioned to allow you to move through scan slices. Either drag the blue or magenta triangle at the end of either cross-hair in the Fundus Viewport, or click a scan viewport and use the mouse scroll wheel to move through the active plane of the scan. The resulting cross–sections update simultaneously in the other viewports.

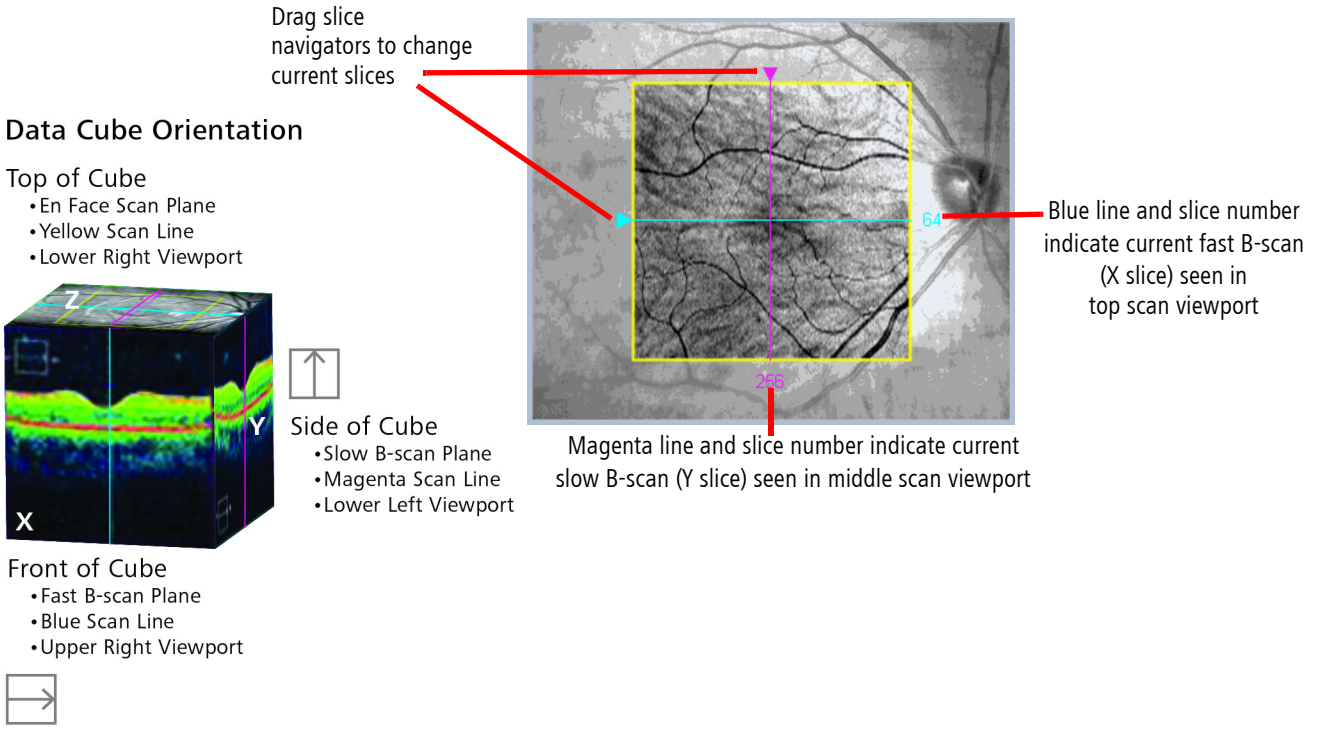


Figure 7-3 Fundus Image with Overlay in Review screen

The overlay on cube scans also has two lines that are centered by default, called slice navigators. These lines indicate the currently selected cross–sections (slices) seen in the upper two viewports on the right. The horizontal blue line in the overlay corresponds to the top scan viewport, which presents the fast B-scan. The vertical magenta line in the overlay corresponds to the middle scan viewport, which presents the slow B-scan. You can drag these slice navigators by the triangles on the edge to change the currently selected slices.

To better understand the perspectives, think of the data as a cube. The top and middle (larger) viewports show the data in planes parallel to the front of the cube and the side of the cube, respectively. The X slice parallel to the front of the cube (top viewport) is also known as the fast B-scan because this is the direction in which each line of A-scans is acquired extremely quickly (in milliseconds). (This is the direction of a horizontal line scan in first–generation OCT.) The Y slice parallel to the side of the cube (middle viewport) is also known as the slow B–scan because this scan comprises a reformatting of vertically parallel A-scans acquired in successive line scans. These re–combined lines are acquired relatively slowly, one per line of horizontal A-scans, in comparison to the fast B-scans. The smaller, bottom two scan viewports are static and show the front and back X slices of the cube.

Criteria for Image Acceptance

During scan review, use the following criteria to ensure that an image you have captured is acceptable.

Fundus

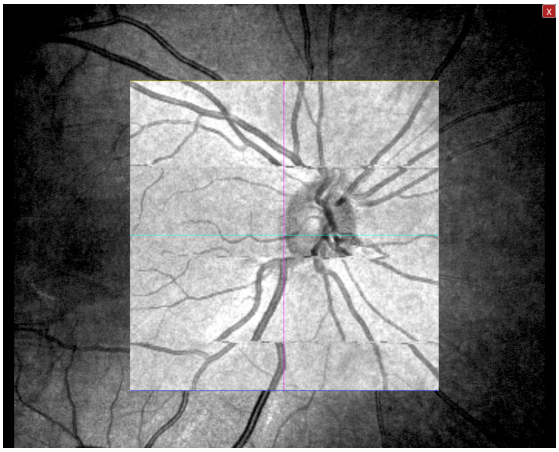
- The focus should be sharp and clear, preferably with good visibility of the branching blood vessels.
- The scan overlay should be centered on the fovea or optic nerve head.
- The Fundus image should have uniform illumination without dark corners.
- There should be few, if any, artifacts that may cast shadows on the OCT scan.
- The OCT *En Face* image should have minimal saccades and no saccades through the area of interest (macula, for example).

OCT

- OCT scan should be complete in all windows without missing data.
- Color density should be the same from end to end.
- Signal strength should be 6 or greater.

Check for Saccades and Banding

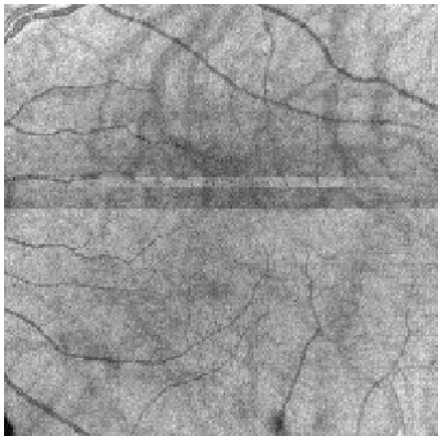
FastTrac minimizes, but does not completely eliminate, the possibility of saccades. For cube scans, the operator should review the OCT Fundus image to ensure there are minimal saccades and no saccades through the area of interest (macula, for example). A saccade can be detected by discontinuities in the appearance of the blood vessels (for example, a horizontal shift of the vessel at a specific location).



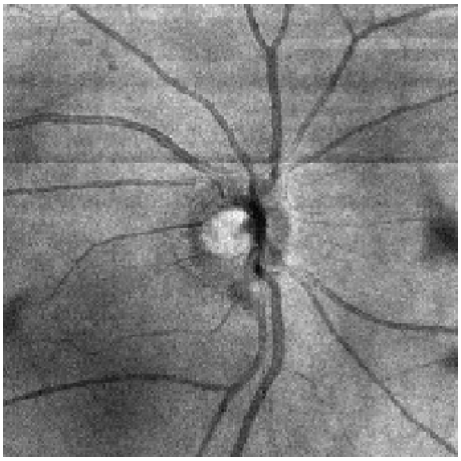
Example: Saccades

During the course of a scan with FastTrac, the individual B-scans in a cube may be acquired at different positions in the Z–direction (for example, tissue varies in vertical position in the B-scan window from B-scan to B-scan). CIRRUS corrects for this motion, however the OCT fundus image can contain artifacts from gradations in the intensity of each B-scan. These gradations appear as horizontal lines or bands in the OCT fundus image, as shown in the

OCT fundus image banding examples (A and B) below. As long as there are no saccades, scans with OCT fundus images like these should be acceptable for analysis and the operator is advised to save them.



Example A: OCT Fundus image banding



Example B: OCT Fundus image banding

Advanced RPE Analysis Acceptance Criteria

In order to detect sub–RPE illumination, CIRRUS looks for contrast in a slab created below the RPE. If the retinal tissue is captured too low in the axial field of view of the scan, then the algorithm will not produce a good result, because there will not be enough sub–RPE pixels to create good contrast. See Figure 7-4 below for an example of a scan with the retina too low for acceptable detection of sub–RPE illumination. If you obtain an image like this, it is advisable to retake the scan before running Advanced RPE Analysis (see "Advanced RPE Analysis" on page 8-17).

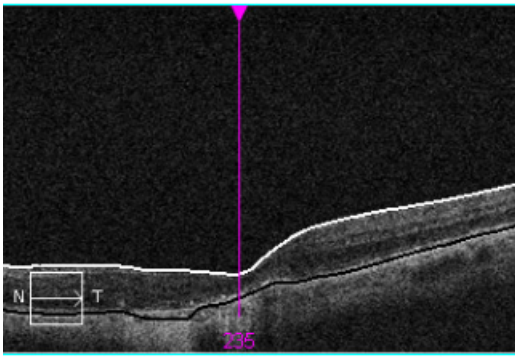


Figure 7-4 Example of Scan with Retina Too Low in Field

CIRRUS OCT Angiography Acceptance Criteria

When reviewing CIRRUS OCT Angiography Scans for acceptability, the following should be considered:

- Signal Quality
- Decorrelation Tails
- Segmentation Errors

Each of these is discussed in the sections which follow.

Signal Quality

CIRRUS OCT Angiography is more sensitive to signal quality than structural OCT imaging. The best CIRRUS OCT Angiography images are obtained when the signal strength is 8 or better. A low signal strength may lead to dark areas on the scan and poor quality scans, which can affect interpretation of the images. Figure 7-5 shows an example of an image with poor signal quality throughout the image. In these cases, the B-scan usually looks dark or blurry as well.

Because of this sensitivity, CIRRUS OCT Angiography can occasionally show dark spots that are not a result of capillary dropout but rather due to poor local signal as shown in Figure 7-5A. This can occur due to floaters or other media opacities. One way to confirm that an opacity is the source of the dark spot is to compare the angiography *en face* to the structural *en face* image Figure 7-5B. Another method is to examine the B-scanFigure 7-5C. In real disease, the CIRRUS OCT Angiography image will appear dark, but the B-scan and the structural *en face* image will not. Taking more than one scan may help in cases with floaters. If a dark area is in a different location between different scans, then it is a floater.

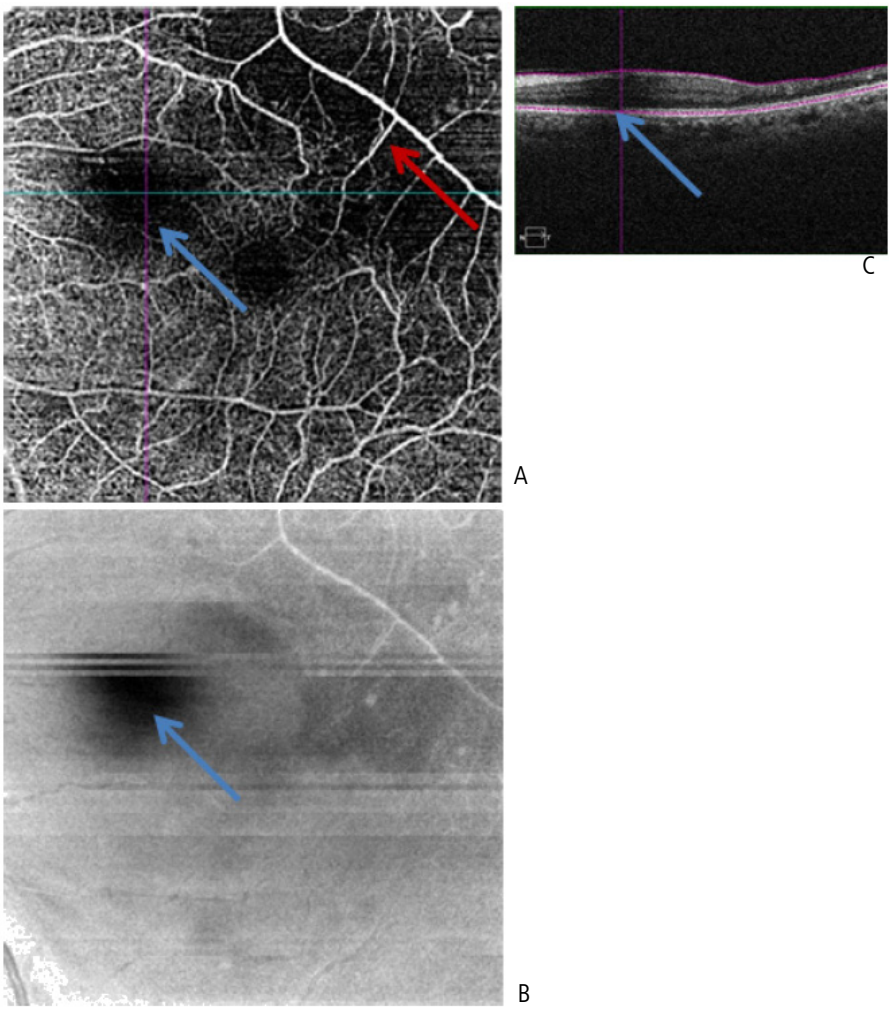


Figure 7-5 Retinal en face image (A) and en face structural image (B) and B-scan (C) from an Angiography 6x6 scan. In this example, the shadow (blue arrow) is caused by a floater. The B-scan and en face image both show a decreased signal in the same area. The red arrow shows good signal in the structural en face and the B-scan and may be associated with impaired capillary flow.

Decorrelation Tails

Decorrelation Tails: Frequently seen as bright shadows of more superficial vessels that appear in posterior layers, decorrelation tails result from light that passes through the moving blood cells and returns to be detected. This creates a signal that is below the original motion, but caused by the motion, and therefore is always found posterior to the original signal. Figure 7-6A and B are *en face* images showing the superficial and deeper retinal layers (SRL and DRL) for a normal subject. The larger vessels that appear similar in the two images are actually decorrelation tails in the DRL *en face* image. Figure 7-6E shows the OCT structural B-scan overlaid with the boundaries of the DRL. This demonstrates that the DRL *en face* summation clearly does not include the larger vessels. They appear anyway in Figure 7-6B due to the decorrelation tails. Figure 7-6C shows an *en face* image created just above the RPE. The limits of the *en face* summation are shown

overlaid on the B-scan in Figure 7-6F. There are no normal vessels at the level of the RPE, so the vasculature seen in the *en face* in Figure 7-6C is entirely due to decorrelation tails.

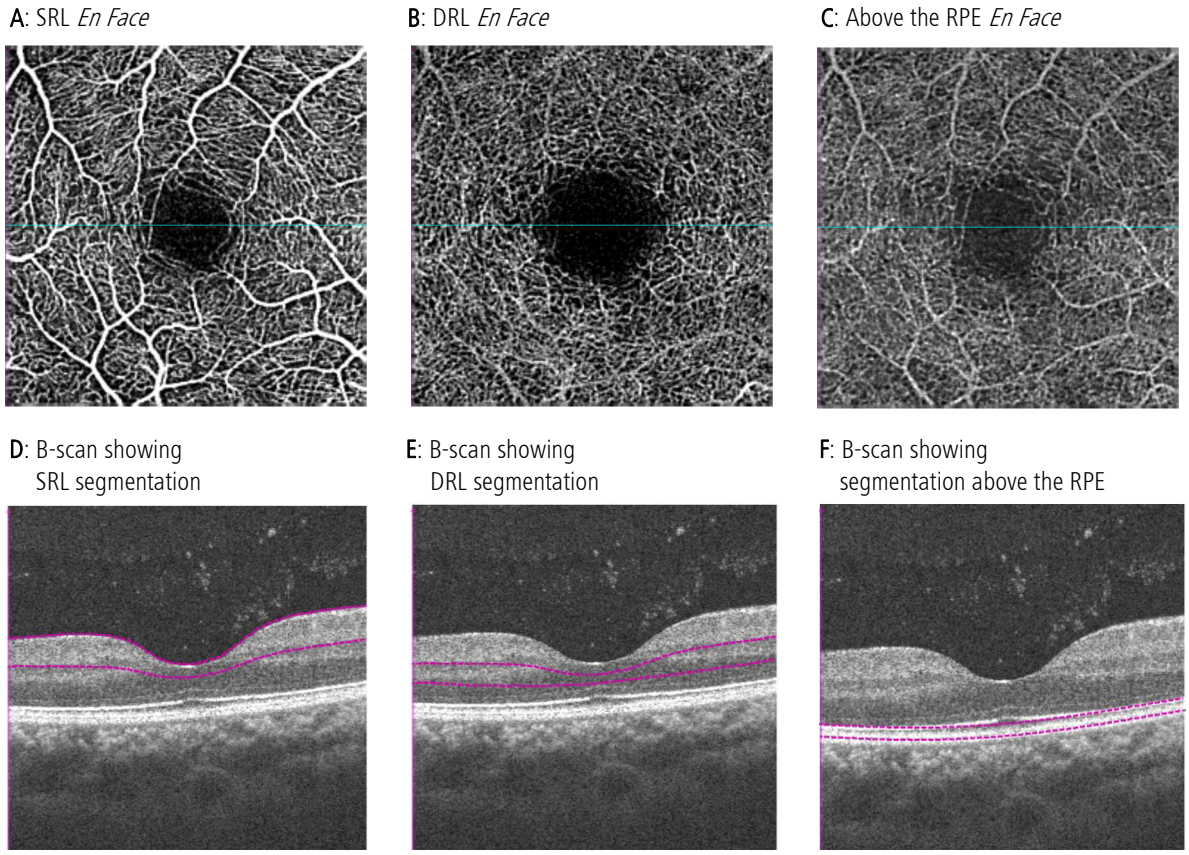


Figure 7-6 CIRRUS OCT Angiography en face images from a normal eye (top), and corresponding B-scans overlaid with segmentation lines (bottom). En face images in 3-6B and 3-6C show decorrelation tails.

This effect is always weaker than the original signal, and is also correlated with the brightness of the reflecting layer. Therefore, decorrelation tails may appear to have disappeared within the outer nuclear layer, but then appear strongly again in the brightly reflecting RPE. Figure 7-6C clearly shows that an *en face* image collected only around the RPE includes vasculature very similar to the overlying SRL. There are two potential ways to determine whether a signal is due to decorrelation tails or due to motion in the layer observed. One is the characteristic of the vasculature itself, even if it is disrupted. A typical normal eye demonstrates that the deeper retinal layer (Figure 7-6E) has a different characteristic appearance than the superficial retinal layer (Figure 7-6D). Another way is to note when the vessel of interest has exactly the same shape as a layer superior to it. The area around the RPE is not expected to have any vasculature, so the *en face* shown in Figure 7-6C is clearly due to decorrelation tails.

Segmentation Errors

Segmentation errors can result in incorrect visualization of flow. The boundary lines used to determine the particular *en face* image shown appear as magenta dotted lines overlying

the B-scan (see Figure 7-8, below). It is always important to examine the segmentation to confirm the presence or absence of flow is associated with the layers of interest. Figure 7-7 provides an example where the layer that should be avascular shows a bright area. Examination of the B-scan demonstrates that the drusen at this location has pushed the segmentation up into the hyper-reflective outer plexiform layer, and any bright signal detected at this location is likely due to ordinary inner retinal vasculature.

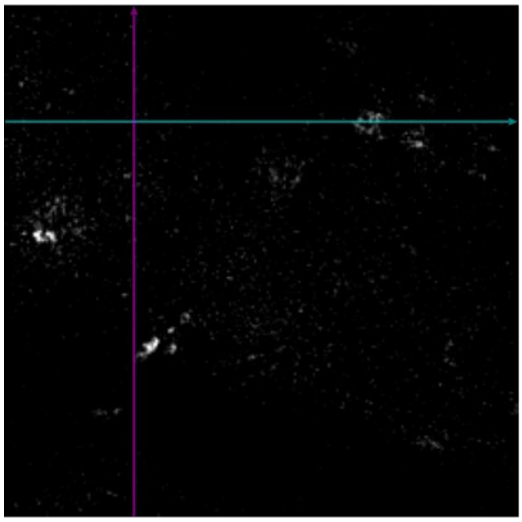


Figure 7-7 Avascular Retinal Layer from an Angiography 3x3 scan showing a bright area that is not associated with pathological flow. The B-scan below (through the location where the horizontal blue line appears) demonstrates that the segmentation is not correctly passing through the outer retinal layer that is expected to be free of signal.

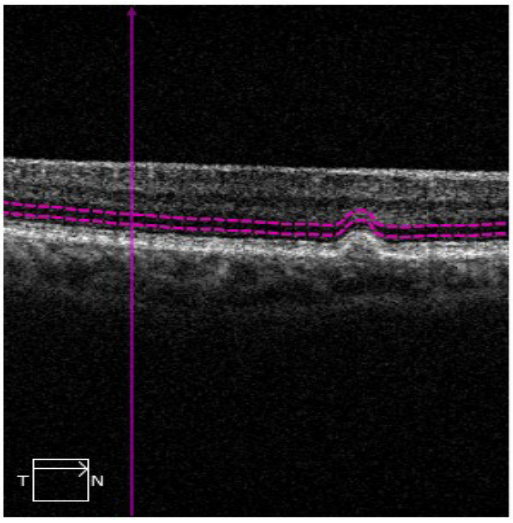


Figure 7-8 Boundary lines used to determine the particular en face image shown appear as pink dotted lines overlying the B-scan

All these possibilities should be taken into consideration before accepting OCT Angiography scans for further analysis.

Anterior Segment Acceptance Criteria

General

Anterior Chamber, Wide Angle-to-Angle, HD Cornea, HD Angle, and Pachymetry scans are corrected to account for beam scanning geometry and refraction on the corneal surfaces. These corrections are most accurate when acquired corneal scans are centered on the corneal vertex, which generates a strong central reflection line on the live OCT image. Typically the corneal vertex is just to the nasal side of the pupil center.

Anterior Segment Cube Scan

The operator is advised to evaluate the scanned image prior to making CCT measurements. The corneal image should have well–defined posterior and anterior surfaces, should not have excessive motion artifacts and corneal reflections on the central cornea, especially within the area where the measurement caliper is to be placed.

NOTE: CCT measurements may be easier to obtain on HD Cornea or Anterior Chamber scans.

The following conditions may affect the ability to obtain a good corneal image for CCT measurements:

1. Inability of the patient to maintain fixation, including patients with poor visual acuity.
2. Excessive corneal reflection resulting from certain intra-ocular lenses, corneal abrasions and corneal opacities.
3. Presence of contact lenses. The junction of some contact lenses and the corneal surface may not be easy to visualize. Patients should remove contact lenses prior to scanning for a CCT measurement.

Pachymetry Scan

Sequence through slices of the radial scan lines of a Pachymetry scan by clicking any one of the 24 radial scan lines displayed on the iris image.

Any one of the following methods may be used:

- Click an OCT B-scan image and use the mouse scroll wheel.
- In full screen mode, use the scroll bar at the right side of the image.
- Use the movie controls.

8 Analysis

Overview

CIRRUS HD-OCT includes a broad set of analytical tools with which to view, characterize, and measure scanned data. Analyses are generated depending on the type of acquired data, as shown in Table 8-1.

Anterior Segment	Scan Acquisition	Analysis
	Anterior Chamber Scan	Anterior Chamber
	Anterior Segment Cube Scan 512x128	Anterior Segment 3D Visualization
	HD Angle Scan	HD Angle
	HD Cornea Scan	HD Cornea
	Pachymetry Scan	Pachymetry (including Epithelial Thickness Maps)
	Wide Angle-to-Angle Scan	Wide Angle-to-Angle
	Anterior Segment 5-Line Raster Scan	HD Images
Posterior Segment	**Scan Acquisition**	**Analysis**
CIRRUS OCT Angiography	Angiography Scan 3x3 / 6x6 / 8x8 Montage Angio Scan 6x6 / 8x8 ONH Angiography Scan 4.5x4.5	See "CIRRUS OCT Angiography" on page 9-1."
Macula	Macular Cube Scan 200x200 / 512x128	Macular Thickness Macular Thickness OU Macular Change Ganglion Cell - OU - Guided Progression Advanced RPE
Macula and Optic Nerve (Integrated View)	Macular Cube Scan 200x200 / 512x128 *- and -* Optic Disc Cube Scan 200x200	PanoMap Single Eye Summary
Optic Nerve	Optic Disc Cube Scan 200x200	ONH/RNFL OU Guided Progression

Anterior Segment	Scan Acquisition	Analysis
Visualization	Macular Cube Scan 200x200 / 512x128 *- or -* Optic Disc Cube Scan 200x200	3D Visualization En Face Advanced Visualization
	All Raster Scans	HD Images

Table 8-1 Relationships between Scan Acquisition Type and CIRRUS HD-OCT Analysis Methods

Analysis of specific ocular features is often available via multiple CIRRUS analysis views, as described below.

Image Menu Options

For all CIRRUS HD-OCT Analyses, menu options can be shown by **right-clicking** on the scan image (see Figure 8-1).

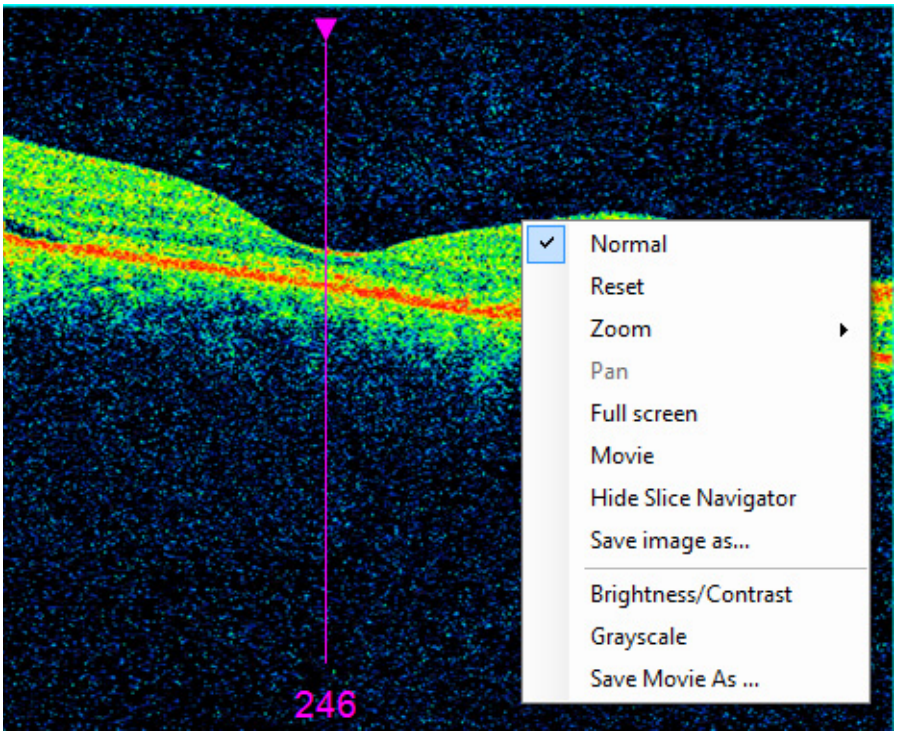


Figure 8-1Right-click on any scan image to bring up the allowable menu options for that analysis type.

NOTE: Not all of these options are available for every analysis. The menu options available are determined by the scan type. Options are described in detail where relevant, in the sections which follow.

Normative Database Comparisons

Appendix A "Normative Data Results" includes the results of Normative database studies for the following populations that have been used as the basis for deviation calculations in the CIRRUS HD-OCT software:

- RNFL and Macula Normative Database (Diversified)
- Optic Nerve Head Normative Database (Diversified)
- ONH and RNFL OU Normative Database
- Ganglion Cell Normative Database (Diversified)
- Asian Normative Database

Comparison with normative databases is selected in "Normative Data Settings" on page 4-9.

Adjusting Slab Locations

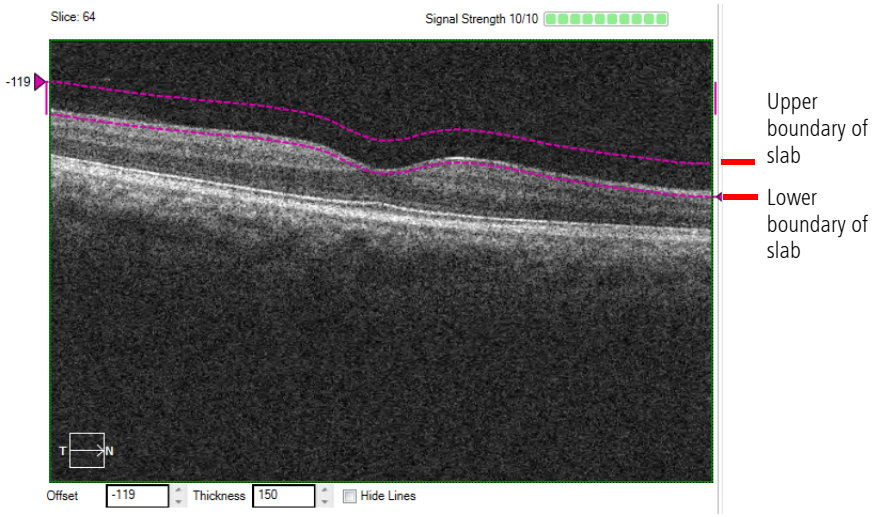
To adjust slab offset, do one of the following:

- Use the slice navigation arrows to drag the bottom boundary up or down.
- With the mouse pointer anywhere on the screen except on the B-scan, use the mouse scroll wheel.
- Enter a value in the Offset field below the image or click the up or down arrows.

To adjust slab thickness, do one of the following:

- Drag the top boundary up or down.
- Press SHIFT or CTRL and with the mouse pointer anywhere on the screen except on the B-scan, use the mouse scroll wheel.
- Enter a value in the Thickness field below the image, or click the up or down arrows.

As you move a slab boundary, the OCT en face image, offset, and thickness values are updated to reflect the slab adjustment.



Preset Slab Views

Standard Presets

Some Review options have sets of preset slab views that can be selected for a quick inspection of ocular features at various locations of significance in the retina. For example, the **En Face** analysis provides 6 preset options as described in "En Face Analysis Preset Slabs" on page 8-25, while the **OCT Angiography** analysis provides 8 preset options as described in "CIRRUS OCT Angiography Presets" on page 9-4.

These views may be modified as described in "Adjusting Slab Locations" on page 8-3, however once the analysis is closed, these adjustments will be lost. If you wish to keep a particular slab view that you have created, you can save these settings as a custom preset that is exclusive to a scan for a selected scan (**Custom (Scan)**), or as a custom preset available across all scans (**Custom**).

Create Global Custom

The **Create Global Custom** option allows you to create a slab that will, once saved, be available for all scans. This option is available in both the En Face analysis and the OCT Angiography analysis.

To Create a Global Custom Preset:

1. Following the steps for adjusting slab locations ("Adjusting Slab Locations" on page 8-3) determine the location of the new slab preset of interest.
2. Select one of the 2 **Custom** squares following the set of Preset Custom views. If you have not created a custom view previously, the square will be blank. If you have previously created a custom view, your previous view will contain the last custom view you create.
3. Select **Save** and your Custom slab view will become available in all scans.

NOTE: If you change values in any of the standard presets, these values will not change when you save the analysis. However, if you change values while a Custom view is selected and save the analysis, you will have saved new values for the Custom view - and thus your previous view in that Custom box will be lost!

You may specify up to 2 Custom views.

Create Scan Custom

The **Create Scan Custom** option allows you to create a slab that will, once saved, be available for that scan *only.* This option is only available in the OCT Angiography analysis.

To Create a Scan Custom Preset

1. Following the steps for adjusting slab locations ("Adjusting Slab Locations" on page 8-3) determine the location of the new slab preset of interest.
2. Select  (shown in Figure 9-1) to open the **Thumbnail Organizer Dialog** (Figure 8-2 below).

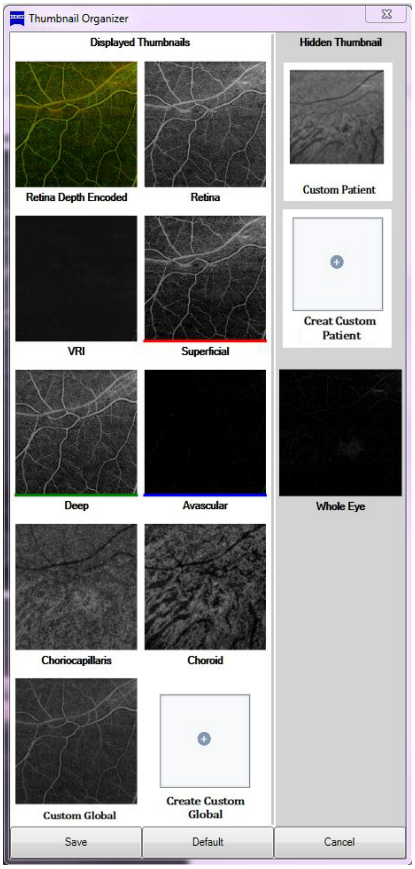


Figure 8-2 The Thumbnail Organizer Dialog

3. Select one of the 2 Scan **Custom** squares to the right of the Standard and Global Presets. If you have not created a custom view previously, the square will be blank. If you have previously created a custom view, your previous view will contain the last custom view you create.
4. Select **Save** and your Custom slab view will be saved for the current patient scan.

NOTE: If you change values in any of the standard presets, these values will not change when you save the analysis. However, if you change values while a Custom view is selected and save the analysis, you will have saved new values for the Custom view - and thus your previous view in that Custom box will be lost!

You may specify up to 2 Custom scan views.

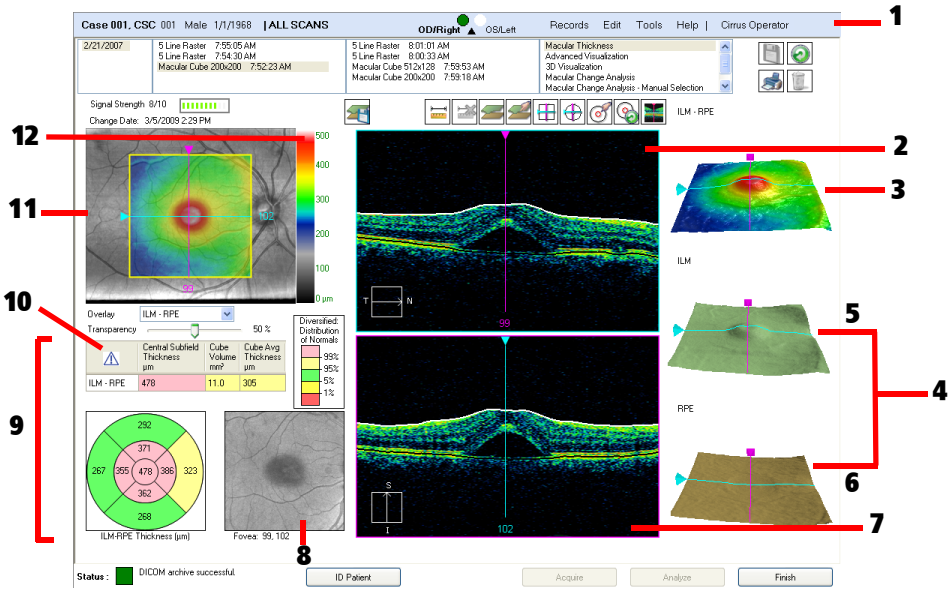
Specify a region of interest that, once created, is available for analysis for a specific patient.

Posterior Segment

Posterior Segment features are viewed and measured by accessing the following CIRRUS HD-OCT analyses. If you are unsure as to which scans need to be acquired in order to access the appropriate analysis

Macular Thickness Analysis

The CIRRUS **Macular Thickness Analysis (MTA)** provides interactive scan images as well as the Fundus image with a scan cube overlay as shown in Figure 8-3. The Fundus image with scanned cube is shown in the upper right quadrant, with an overlay whose colors correspond to the color–coded side bar scale on the right. The colors denote Macular thickness in micrometers (µm).



1 Exam (date), OD and OS scan lists for selected exam, analysis list
2 Slice through cube front
3 ILM to RPE Thickness Map
4 3–D Surface Maps
5 Anterior Layer (ILM)
6 Posterior Layer (RPE)
7 Slice through cube side
8 OCT Fundus image
9 Average thickness and volume measurements
10 Normative Data Details
11 Fundus image with scan cube overlay
12 Color code for thickness overlays

Figure 8-3 Macular Thickness Analysis

Fovea Location

This feature is active in:

- **Macular Thickness Analysis** (Figure 8-3)
- **Macular Change Analysis** (Figure 8-7)
- **Ganglion Cell Analysis** ("Ganglion Cell OU Analysis" on page 8-22)
- **Advanced RPE Analysis** ("Advanced RPE Analysis" on page 8-17)

CIRRUS software identifies the Fovea location automatically by looking for the reduced reflectivity below the retina. You can also change the Fovea location manually (see "ETDRS Position" on page 8-7), which will update the data table and the ETDRS grid thickness measurements.

Fovea Not Found

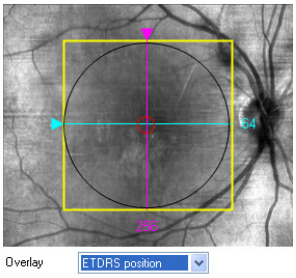
If the Fovea cannot be identified from the scan the message "Fovea not found" will appear on the screen. In this case, the center of the scan is used for the initial placement (position 256 and 64 for 512x128 scans and position 100 and 100 for 200x200 scans).

It is also possible for the algorithm to find a depression in the reflectivity around the ILM that is not related to the fovea. In such a case, the reported fovea will be wrong. In both of these cases, the user can set the fovea manually.

The most common pathologic conditions that can cause failure of the fovea–finding algorithm are those that cause the greatest disturbance of the foveal architecture, such as AMD, and macular edema, as well as epiretinal membranes and other vitreoretinal interface disorders where the vitreoretinal interface becomes distorted.

If the fovea is very far from the center, the algorithm may also fail to find it. In order to ensure that the fovea is within a reasonable distance of the center, it helps to use the alignment tool during acquisition (see Figure 6-17).

ETDRS Position



When **ETDRS position** is selected from the overlay menu, a small red circle appears centered around the CIRRUS–calculated fovea position, as shown on the left. This calculated ETDRS Grid position can be repositioned by clicking and dragging the circle using the mouse.

The thickness grid also moves in conjunction with the repositioning of the ETDRS Grid position on the overlay, as shown in Figure 8-4.

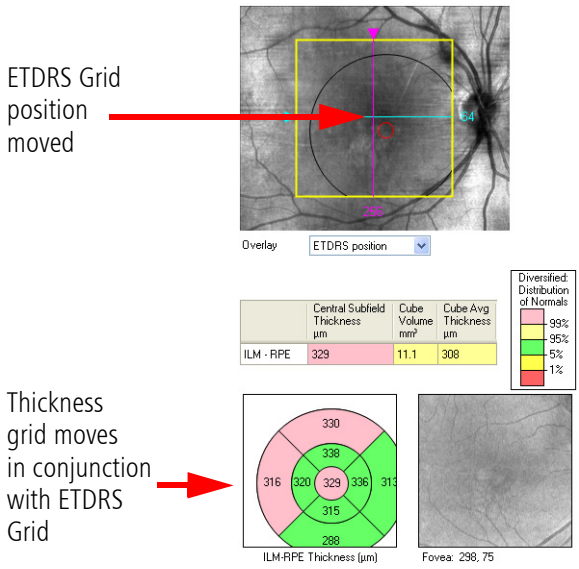


Figure 8-4 Thickness Grid Movement

This interactive analysis screen gives you several options to view patient data. Use the button tools to line up the slice navigators with ETDRS Grid position and vice versa. For example, manually drag the ETDRS Grid to a new position on the overlay, then:

- Select  to center the slice navigators over the new ETDRS Grid position, as shown on the left. Note that the thickness grid does not change location.
- Select  to reset the ETDRS Grid position to the original CIRRUS–calculated position. The slice navigators also move back to their original positions over the ETDRS Grid position.

Now move the slice navigators to a new position, as shown in Figure 8-4. The ETDRS Grid position does not change, nor does the thickness grid position.

- Select  to align the ETDRS Grid position with the slice navigators.
- Select  to move the ETDRS Grid and the slice navigators back to their original location.

To save the new fovea position for future analysis, click the **Save** button  in the upper right–hand corner of the screen.

ILM–RPE Layers

The Inner Limiting Membrane (ILM) and posterior portion of the Retinal Pigment Epithelium (RPE) may be viewed and measured quickly through the CIRRUS **Macular Thickness Analysis** (Figure 8-3).

Slab Overlay ILM–RPE Thickness Map

The ETDRS grid in Figure 8-5 shows the values, in micrometers, of the ILM–RPE thickness. You can change the position of the ETDRS grid. If you change it, the reported

values will also change. The position of the Fovea and the center of the ETDRS grid appear below the grid. In this figure, the Fovea is located at the intersection of slice 253 and 64.

The colors of the ILM–RPE color bar represent the depth in micrometers, ranging from 0 (blue) to 350 (white) in increments of 17.5 µm for each bar.

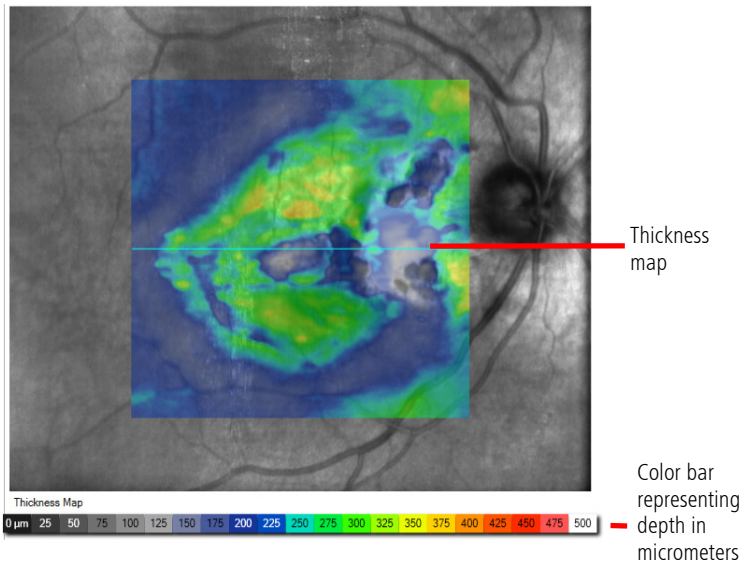


Figure 8-5 ILM–RPE Thickness Map

Additional Features

The buttons above appear from left to right in the Macular Thickness analysis. If you mouse over the buttons, their function appears in the form of a tooltip. The following paragraphs describe the additional features available on the **Macular Thickness Analysis** screen.

-  **High–Res Images** button: A pair of high–definition scans are taken at the beginning of each Macular Cube 512x128 and Macular Cube 200x200 scan. Select this button to display these central X and Y slices in high resolution. These two slices are composed of 1000 A-scans (for Macular Cube 200x200) or 1024 A-scans (for Macular Cube 512x128). The system provides this feature to enhance resolution in the central area of the scan, which corresponds to the center of the fixation target. The ETDRS Grid will not change position when the **High–Res Images** button is selected. These high–definition images may be enlarged to a full–screen view.

  The slice navigators will be set to slice 256 and 64 with the Macular Cube 512x128 or will be set to slice 100 and 100 with the Macular Cube 200x200 scan. To return to the standard resolution scans, re–select the **High–Res Images** button or move either the X or Y slice navigator to a different position.
-  **Edit Layers** button: Click **Edit Layers** to open the **Edit Segmentation** screen, as shown in Figure 8-6. Here you can edit the currently selected X and Y slice placement on the ILM and RPE layers—CIRRUS calculates thickness between these layers.

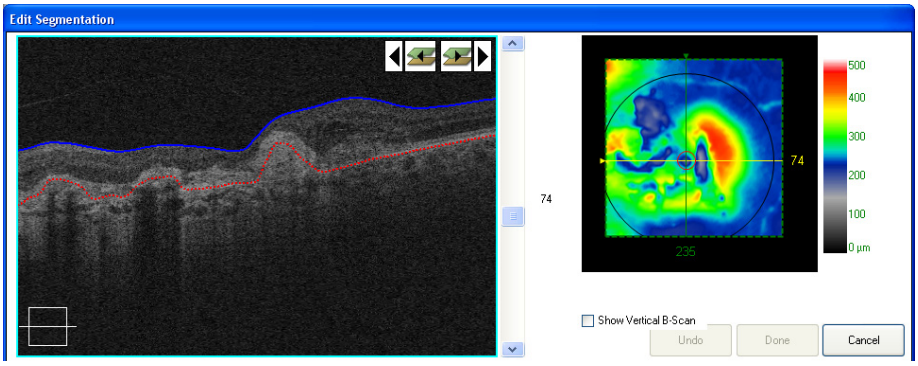
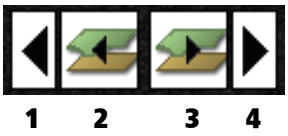


Figure 8-6 Edit Segmentation Dialog

This feature is especially useful in cases where the retina has structural anomalies or pathology that may cause the algorithms to incorrectly trace the actual boundaries. Click and drag the ILM line or the RPE line, shaping and placing it in the desired location by your mouse movement. You can draw and redraw the line or any portion of it repeatedly, selecting any point on a line to start each successive drawing action.

Hover over the Fundus image, on its overlay, or on a scan image to access the image display options.



Note that when you mouse over a line, it "pops," or becomes thicker. The boundary lines you trace will never break. However, they will not cross each other.

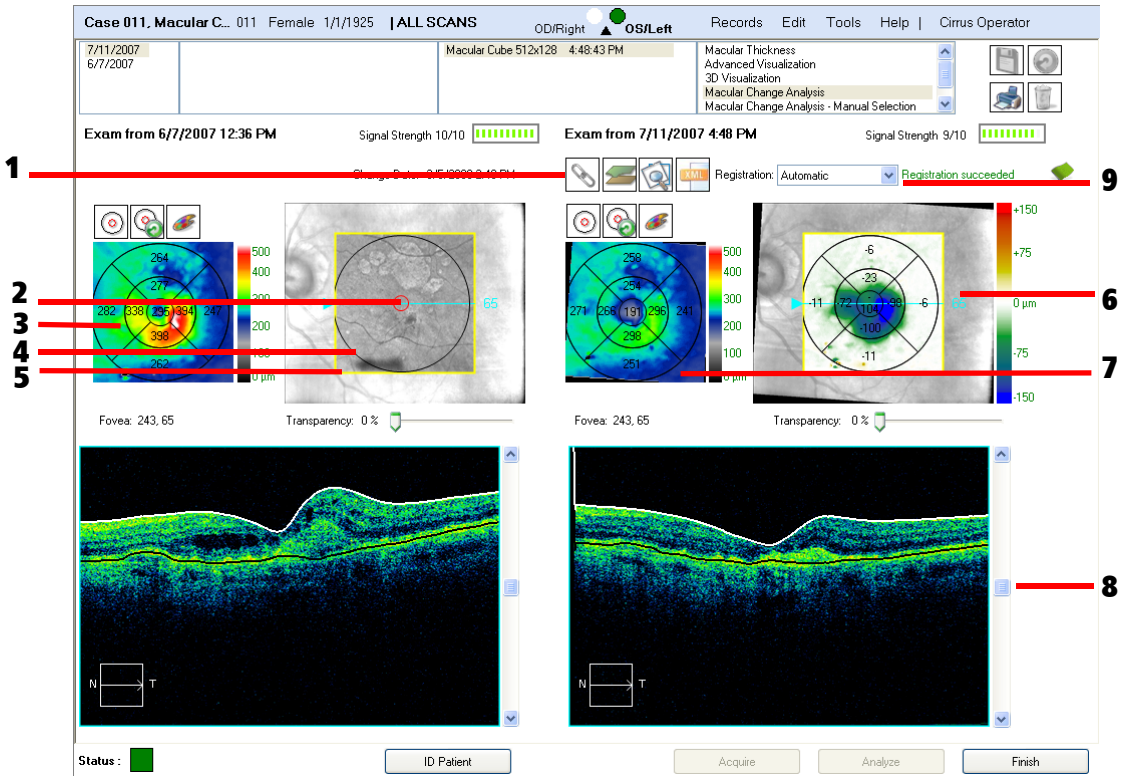
The buttons (shown at left) enable you to copy changes from one slice to the next slice or to the prior slice

Buttons 1 and 4 allow you to move through the layers. Button 2 copies your changes to the prior slice, and button 3 copies your changes to the next slice. These changes are saved when you close the analysis, and will appear on the Macular Thickness Analysis report.

Double-click most images to open them in full screen. Double-click a full screen image to return to normal view or click the **Back** button. When using the Zoom or Brightness/Contrast feature on the ONH and RNFL OU or RNFL Thickness analysis screens, do not click and drag the mouse inside the circle on the Fundus image. This will cause the circle to move to a different location on the image.

Macular Change Analysis

Selecting the Macular Change Analysis (MCA) option allows you to compare two Macular Cube 512x128 scans or two Macular Cube 200x200 scans side by side, as shown in Figure 8-7.



1 Sync Lock
2 Foveal Target
3 Thickness Map
4 ETDRS Grid boundary (black circle)
5 OCT scan boundary (yellow square)
6 Thickness Difference Map
7 Thickness Map
8 Slider Navigator
9 Fundus Registration

Figure 8-7 Macular Change Analysis

Manual Selection

Should you decide that the current scan does not have the best signal strength or that it was taken in a position away from the center and, therefore, would not be a good match you can manually choose a different scan using the manual selection process.

This option is also available in

- Advanced RPE Analysis
- Ganglion Cell Analysis
- ONH and RNFL Analysis
- Panomap
- Single Eye Summary
- OCT Angiography Change Analysis

How to select a scan manually:

1. At the top of the analysis screen, select the scan date and the scan you wish to use as the more current scan (the scan information that appears on the right side of the screen).
2. Select **Macular Change Analysis – Manual Selection** from the far right column.
3. A list of eligible scans will appear in a dialog box (see Figure 8-8).
4. Click the scan you wish to include in the analysis. A green checkmark will appear next to the selected scan.
5. Click **Next** to proceed. The window will collapse and the scan you chose will appear as the scan on the left–hand side of the screen.

NOTE: You may not choose two scans from different visits from the manual selection window. You may only select one scan in this way to use as the earlier of the two scans.

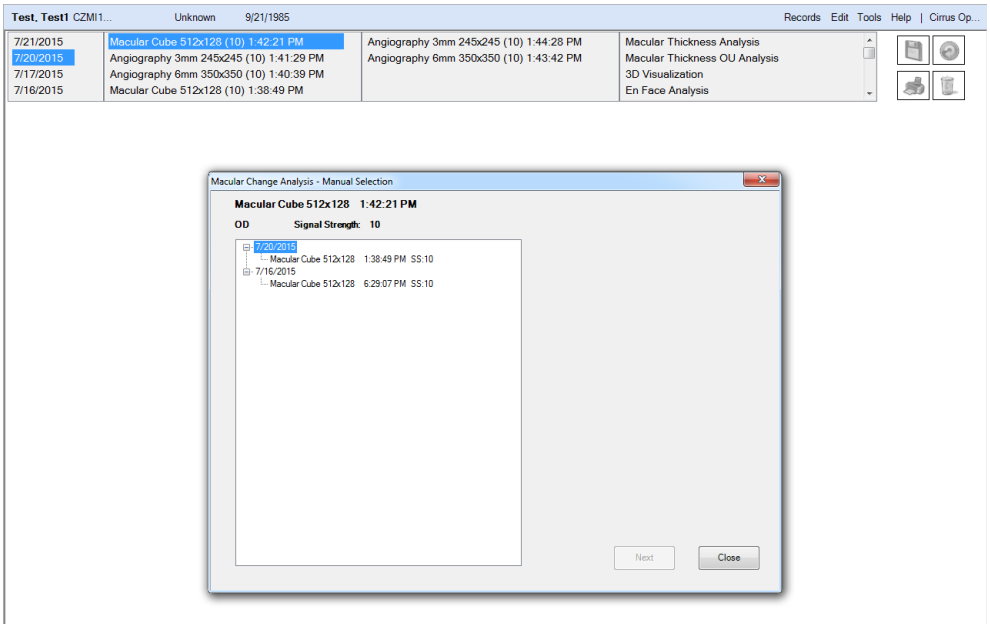


Figure 8-8 Macular Change Analysis – Manual Selection Dialog

Macular Registration

Automatic Registration

CIRRUS automatically *registers* the fundus images from the two dates so that the images you see are synchronized to show the equivalent location of the retina in each image. In addition, the color–coded thickness maps for the two images, as well as the thickness difference map, are displayed.

Automatic Registration (the default) "registers" the current image (which appears on the right side) to the prior image (which appears on the left side). Both the en face image and the Fundus image are aligned during registration. The registration process maps similar anatomical structures, such as blood vessels, to each other to obtain the proper registration. Rotation of an image due to the patient's eye being rotated from one session to another is also accounted for in the registration.

Areas of the current image that do not overlap with the prior image are not included in the final registered image. This causes the thickness map and the Fundus image on the right to display a black border around the outside edge(s) of each view. The size of the border depends on how much the current image was shifted to align with the prior image. In addition, the right B-scan will show an incomplete view in the areas where data was not acquired in both scans.

Manual Registration

To manually adjust the registration, select **Manual Registration**. Select points by clicking three to five corresponding points on Image 1 and Image 2. See Figure 8-9. Place each point over an identifiable feature that appears in both scans that you expect to be constant across scans. For example, a blood vessel bifurcation or a bend in a blood vessel can be used.

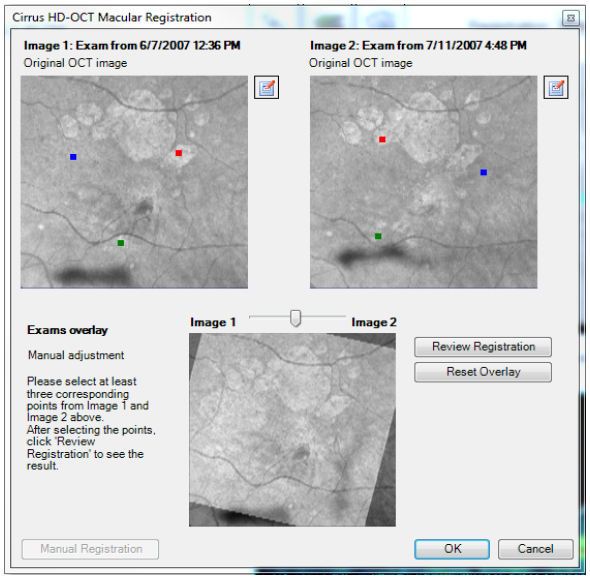


Figure 8-9 Manual Registration

Select **Review Registration** to view the manually adjusted overlay. Use the slider above the overlay, as needed, to change the transparency to see more of Image 1 or Image 2. By moving the slider back and forth, you can see if blood vessels or other features from one image align with the identical features in the other image. To return the registration to the original setting, click the **Reset Overlay** button. If you are not satisfied with the positioning of the points, click the **Undo** button  to delete all points and then make new point selections.

Darker areas on the lower registration screen occur where there is no data to compare. This will occur when the data points selected create an offset of the images. To see the final registered image, move the slider all the way to the right. This black border will also be seen on the thickness map and the thickness difference map on the MCA screen. When you are satisfied with the resulting overlay, select **OK.** To reset the values to the original registration, click **Cancel.**

NOTE: If you or another user have changed the fovea location for any exam while carrying out Macula Thickness Analysis and the result has been saved, then that will be the fovea location will be loaded.

No Registration

When **No Registration** is applied, the initial location of the ETDRS grid center for both scans is taken from the value for the previous scan.

The ETDRS Grid position circle is automatically positioned over the Fundus image of the older scan data. You can adjust this position by clicking anywhere within the OCT scan boundary, and dragging the ETDRS Grid to a new position. Thickness values are automatically recalculated corresponding to the new ETDRS Grid position.

The Thickness Difference Map is seen at the far right of the display. It displays the thickness differences between the two scan dates (current thickness minus prior thickness, in micrometers) at each pixel location. The difference map has a different color scale to represent the thickness change. This color map is indicated to the right. Warmer colors indicate an increase in the thickness; cooler colors indicate a decrease in thickness. The transparency slider beneath each overlay can be adjusted, as required, to enhance the image.

Registration Review

Registration between the two Fundus images may be compared by selecting the **Registration Review** button:  . The results appear on a popup screen, as shown in Figure 8-10.

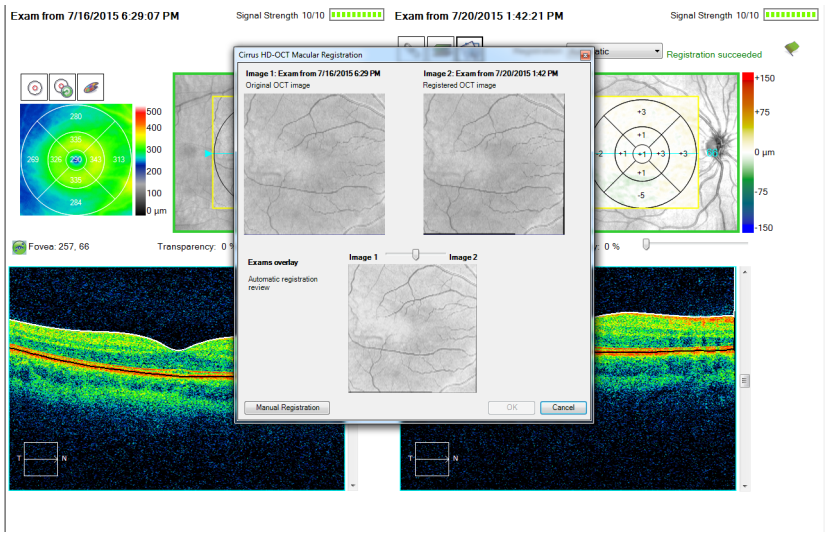


Figure 8-10 Registration Review of Fundus Images

In Figure 8-10, Image 1 is the an image taken from (an earlier) previous exam. Image 2 is the image from the most recent visit. The bottom image is an overlay of the two exams. The image slider allows you to adjust the view of the overlaid images: slide to the left to view Image 1, to the right for Image 2. Black borders might be seen in Image 2. This is the area of the second image that does not correspond to the first image when the two images were registered to each other.

Registration Successful

The "Registration Succeeded" message along with the green flag indicate that the two chosen images did register reliably. A red flag appears if the registration fails. This could be caused by weak signal strength, poor alignment, opacities, large differences in the scan areas, or larger differences in retinal anatomy. When that occurs, you may attempt to use **Manual** registration by selecting from the **Registration** dialog box or, if available, select another image for comparison. In the **Registration** dialog box, you may also choose **No Registration**.

NOTE: The indication for success or failure of the registration algorithm is based on a cross-correlation metric computed from the two images after registration. A threshold is used on this metric to make a binary decision of success or failure.

Synchronized Data Review

Once the images are synchronized, you can manipulate the data on one exam image, while the identical movements are tracked on the second exam for a side by side comparison.

When the sync lock is selected  you can adjust the slice navigator or image slider bar to simultaneously move through the images and view the data. If the sync is not locked  , adjustments to one overlay do not effect the other.

Adjusting the ETDRS Grid Centers

The ETDRS Grid position circle is automatically positioned over the Fundus image of the older scan data. You can adjust this position by clicking anywhere within the OCT scan boundary, and dragging the ETDRS Grid to a new position. Thickness values are automatically recalculated corresponding to the new ETDRS Grid position.

The **Thickness Difference Map** is seen at the far right of the display. It displays the thickness differences between the two scan dates (current thickness minus prior thickness, in micrometers) at each pixel location. The difference map has a different color scale to represent the thickness change. This color map is indicated to the right. Warmer colors indicate an increase in the thickness; cooler colors indicate a decrease in thickness. The transparency slider beneath each overlay can be adjusted, as required, to enhance the image.

XML Export

The XML export from the **Macular Change Analysis** screen is available by clicking the **XML Export** button (shown on the left). For further details on XML export, see "XML Export" on page 11-9.

Macular Thickness OU Analysis

Macular Thickness OU Analysis (Figure 8-11) provides interactive scan images, as well as the Fundus image with a scan cube overlay for both eyes together and includes:

- Colored thickness maps
- OCT Fundus image, including the identified fovea location with a red dot
- The ETDRS grid maps with normative data
- A table containing central subfield thickness, average thickness and volume measurements for the entire cube
- Horizontal and vertical B-scans

NOTE: Double-clicking the Thickness Map will show the image in full-screen mode, with the Thickness Map overlaid upon the Fundus Image.

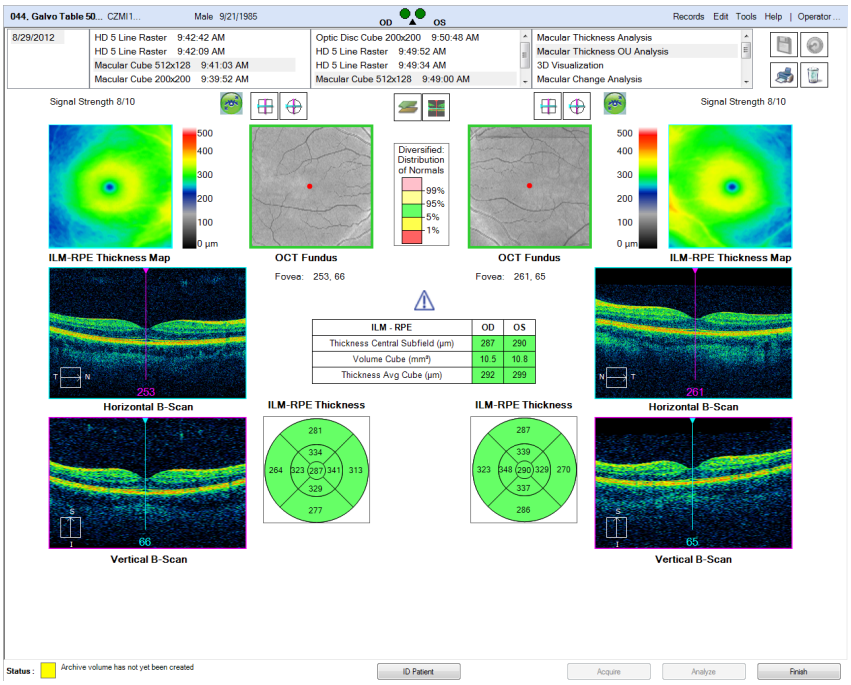


Figure 8-11 Macular Thickness OU Analysis

If the fovea is not found, the fovea location and measurement circles are centered in the 6 mm square and the calculations are made based on this position.

The background Fundus image is not on the main analysis screen. To see the Fundus image, double–click a thickness map or OCT Fundus image to see the full page view, which will have the Fundus image in the background.

Advanced RPE Analysis

Advanced RPE Analysis allows for examination of the status of the RPE in more detail than the Macular Thickness Analysis, allowing analysis of disturbances in the RPE.

Identification and measurement of elevations in the RPE and areas of sub–RPE illumination may be helpful in managing age–related macular degeneration, including advanced forms where atrophy of the RPE is present.

Two separate screens are available:

- **screen 1**: RPE elevation and the sub–RPE illumination results shown separately as *en face* images (Figure 8-12).
- **screen 2:** Images that combines the RPE Elevation Map and the sub–RPE illumination segmentation along with calculated values.

By default, the selected current scan is compared to the best scan of the same type from the patient's most recent prior visit. You can always change this scan using **Manual Selection** (see "Manual Selection" on page 8-12). If there is only data from one visit, the prior area will remain blank.

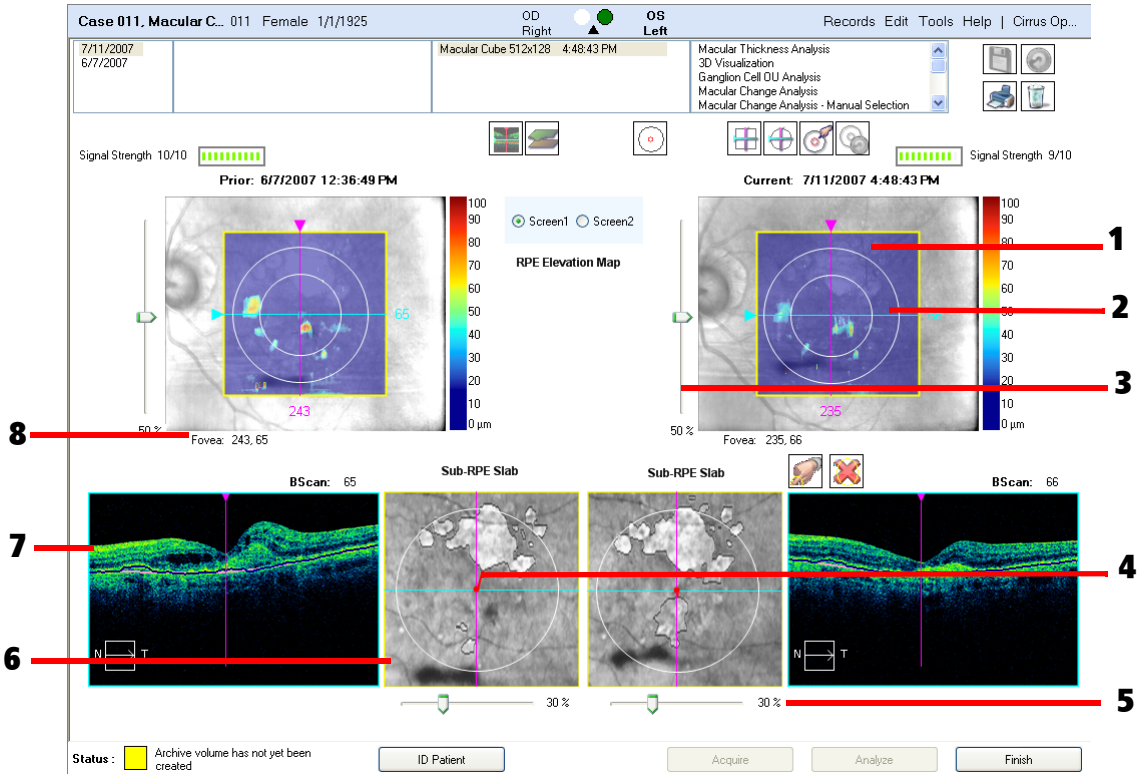
RPE Elevation Considerations

The RPE Analysis view displays an RPE Elevation Map as an overlay on the Fundus image. The transparency can be adjusted using the transparency slider.

The color coding aids in identifying bumps and discontinuities in the RPE. The map shows circles corresponding to 3 mm and 5 mm in diameter centered on the fovea. On the side of the map the legend shows how the colors correspond to the height of the elevations.

The RPE elevation measurements can be affected by the presence, size, or extent of

- geographic atrophy
- choroidal neovascularization
- extensive epiretinal membrane
- vitreomacular traction



1 RPE Elevation Map overlaid on Fundus image
2 Circles on the RPE Elevation Map centered on the fovea location
3 Transparency adjustment for RPE Elevation Map
4 Line from fovea connecting closest sub–RPE illumination area
5 Transparency control for Sub–RPE Slab overlaid on OCT Fundus image
6 Sub–RPE Slab with overlaid segmentation of Sub–RPE Illumination
7 Horizontal tomogram showing RPE Elevation segmentation line
8 Fovea location for exam shown above

Figure 8-12 Advanced RPE Analysis – Screen 1

The possible impact of such pathologies on the analysis can be taken into account by reviewing the individual B-scans and determining where areas of RPE elevation overlap with them.

As with all retinal pathology, check the retinal segmentation in questionable cases. View the horizontal tomogram and check the black and lavender lines indicating the borders of the RPE elevation measurement.

The RPE Elevation algorithm has not been tested on subjects who had geographic atrophy, choroidal neovascularization, or pigment epithelial detachments. The performance of the RPE Elevation algorithm on subjects with these conditions has not been determined. Since pigment epithelial detachments are elevations to the RPE, the Advanced RPE Analysis may be of clinical use. See Appendix Appendix B "CIRRUS Algorithm Studies" for the performance of Advanced RPE Analysis measurements.

Repeatability of measurements of RPE elevation are dependent on consistent and accurate identification of the fovea location. The system has an automatic fovea finder. Make sure the software was able to find the fovea location and evaluate if the location is correct (see "Fovea Location" on page 8-6). If the location is determined not to have been correct, the patient should be rescanned using a manual correction.

The minimum RPE elevation that the software will include in the quantitative result is 19.5 µm. Values below this threshold are not included in the area and volume calculations. In some cases, drusen may be observed in color Fundus photographs that are not seen in the Advanced RPE Analysis because either the drusen does not represent any elevation, or because the drusen is accompanied by an elevation that does not meet the minimum threshold for detection. Only small, shallow drusen are likely to be missed.

NOTE: RPE elevation measurements are not meant to replace other means of clinical evaluation such as color Fundus photographs for drusen documentation and measurement.

Sub–RPE Considerations

The Sub–RPE slab represents the summed reflectivity in the region below Bruch's membrane. This slab indicates the fovea location with a dot and a circle corresponding to 5 mm in diameter centered on the fovea. It also shows a red line from the fovea to the closest area with sub–RPE illumination (label 6 in Figure 8-12).

The automatic sub–RPE illumination segmentation is shown with an outline. The boundaries can be toggled on or off. If the sub–RPE illumination segmentation outlines are toggled on, these will become transparent to the same degree as the sub–RPE slab.

The Advanced RPE Analysis includes a horizontal tomogram. This tomogram shows the RPE elevation segmentation lines, but not the segmentation lines for the sub–RPE slab segmentation. The segmentation lines may be toggled on or off.

Increased sub–RPE illumination is not specific to geographic atrophy and can occur in any condition that causes RPE atrophy or thinning, absence or breaks, such as retinal dystrophies, scarring due to infections, and laser photocoagulation of the retina. In

addition, poor signal strength, pigmentation of the Fundus, and peripapilliary atrophy can occasionally cause misleading sub–RPE illumination findings.

To edit sub–RPE illumination:

1. Open an edit screen by clicking the **Segmentation Tool** (shown at left). The screen displays the sub–RPE illumination segmentation as a colored region on the sub–RPE slab. The current sub–RPE illumination segmentation becomes active for editing. The edit screen also includes the OCT *en face* image with slice navigators and the Horizontal B-scan tied to the navigator position.

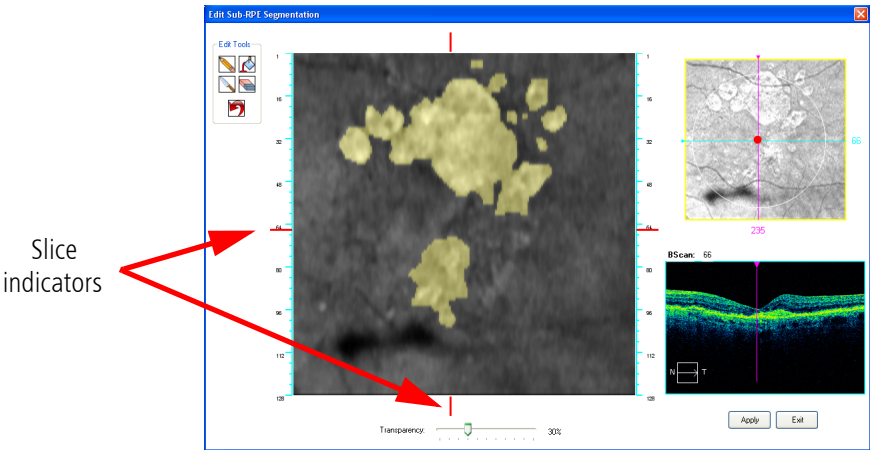


Figure 8-13 Edit Sub–RPE Segmentation Dialog

2. Use one of the available edit tools (shown clockwise at left) to modify the segmentation boundaries:

   - **Pencil**: Click and drag to draw with fine detail.
   - **Floodfill**: Adds gross detail. To fill in a full lesion, draw the boundary of the lesion with the pencil tool or the floodfill tool, click the floodfill icon, and then click the lesion to fill it in.
   - **Eraser**: Removes gross detail. To remove a large area, draw the boundary of the area with the knife or eraser, click the eraser icon, then click the area to erase.
   - **Knife**: Click and drag to delete with fine detail.

3. Once you have completed editing, click **Apply** to complete the operation and return to the analysis screen with the updated segmentation. On the analysis screen, the segmentation is shown as an outline around the area that had been filled in on the edit screen.

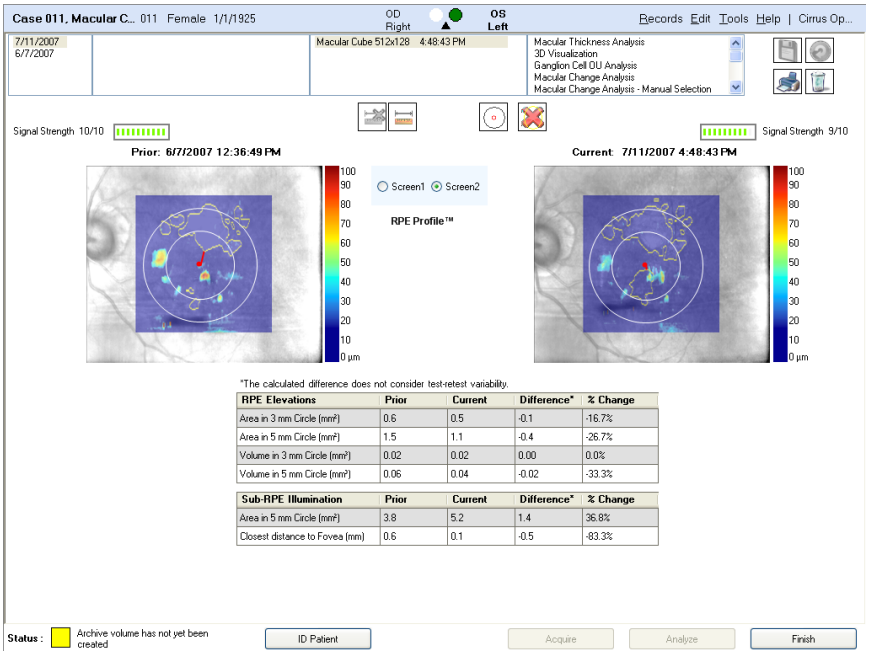


Figure 8-14 Advanced RPE Analysis – Screen 2

On Screen 2 (Figure 8-14), the sub-RPE illumination segmentation is overlaid on the RPE Elevation Map. The sub-RPE illumination segmentation is shown with an outline. This image shows the fovea location with a dot marking and a circle corresponding to 3 mm and 5 mm diameter circles centered on the fovea. This image is superimposed on top of the Fundus image.

Use the caliper to measure distances on the RPE Profile Map.

NOTE: Caliper measurements are not saved!

Calculated values are of the current scan minus the prior, as well as the percent change in elevations and illumination since the previous scan.

The volume of RPE elevations, as well as the area and distance of the sub-RPE illumination around and from the Fovea respectively, are shown. If no sub-RPE illumination is seen in the circle, the value shown is 0.0. A warning message will appear if the 5 mm circle extends outside of the scan window or if the scan is too low in the B-scan window.

Advanced RPE Analysis may occasionally identify RPE elevations or areas of sub-RPE illumination in normal subjects. In a post-hoc analysis of 115 subjects from the diversified normative database, the software identified RPE elevations in the 5 mm circle in 2.6% of the subjects, with a mean of 0.006 mm^2 for area and 0.0002 mm^3 for volume. In the same analysis, the software identified areas of sub-RPE illumination in 6.1% of the subjects, with a mean area of 0.08 mm^2.

NOTE: Calculated differences do not consider test-retest variability.

NOTE: Signal strength and image quality can be significantly reduced when the imaging aperture (the lens) is dirty or smudged. If you suspect this problem, follow the instructions to clean the "Imaging Aperture Lens and External Lenses" on page 12-3.

Ganglion Cell OU Analysis

Ganglion Cell OU Analysis[1] measures the thicknesses for the sum of the ganglion cell layer and inner plexiform layer (GCL + IPL layers) in both eyes. Comparisons can then be made with normative data (Appendix-A).

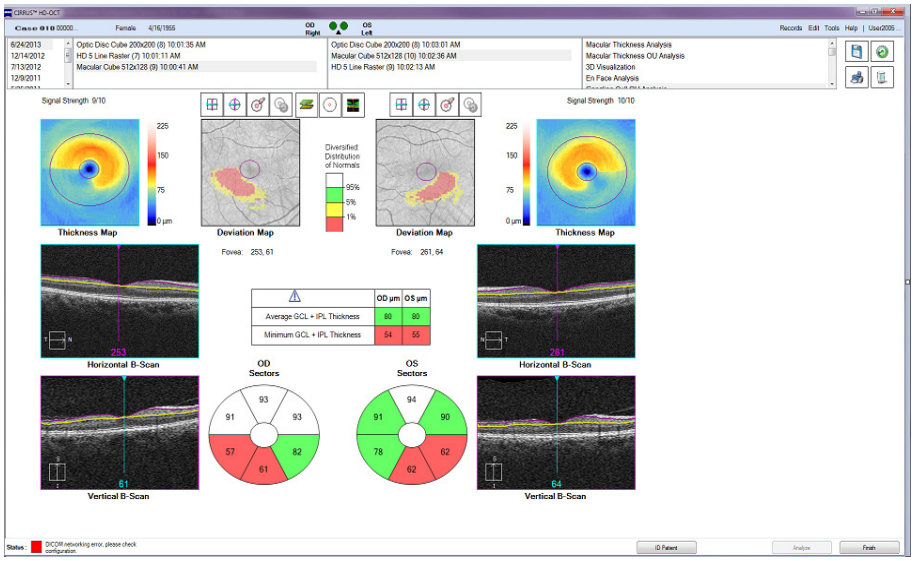


Figure 8-15 Ganglion Cell OU Analysis

The thickness maps (upper left and right of Figure 8-15) indicates thickness measurements of the GCL + IPL in the 6 mm by 6 mm cube and contains an elliptical annulus centered about the fovea.

A Deviation Map shows a comparison of GCL + IPL thickness to normative data (red to indicate thinner than all but 1% of normals, yellow to indicate thinner than all but 5% of normals) while a thickness table shows average and minimum thickness within the elliptical annulus.

Sectors in the lower portion of the screen divide the elliptical annulus of the Thickness Map into 6 regions: 3 equally sized sectors in the superior region and 3 equally sized sectors in the inferior region.

The slice navigator in the Vertical B-scan is used to adjust to a different Horizontal B-scan. The purple segmentation line represents the inner boundary of the ganglion cell layer, which is also the outer boundary of the retinal nerve fiber layer. The yellow line represents the outer boundary of the inner plexiform layer. The maps shown and quantitative values reported represent the combined thickness of the ganglion cell layer plus inner plexiform layers.

1 Ganglion Cell OU Analysis is an optional feature that may not be available in all markets, and when available in a market, may not be activated on all instruments. If you do not have this feature and want to purchase it, contact ZEISS. In the U.S.A., call 1-877-486-7473; outside the U.S.A., contact your local ZEISS distributor.

The screen allows editing the fovea location and navigating through the B-scans. Visually evaluate the image to determine if the segmentation lines are correctly finding the inner boundary of the Ganglion Cell layer and outer boundary of the Inner Plexiform Layer in such cases.

NOTE: The repeatability of GCA measurements is dependent upon consistent and accurate identification of the fovea location. The system has an automatic fovea finder. Operators should rigorously check that the software was able to find the fovea location and evaluate if the location is correct.

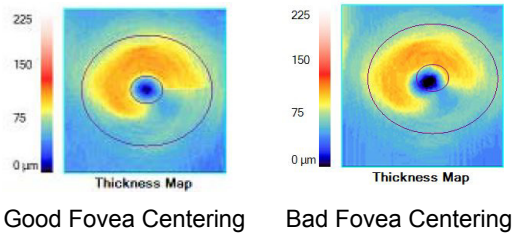


Figure 8-16 Compare a centered fovea (left) with an uncentered view (at right). The centered fovea shows a clear pinpoint at the center. As soon as the fovea is no longer centered, the center begins to expand and elongate.

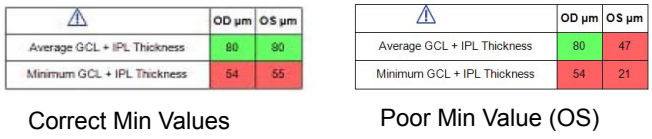
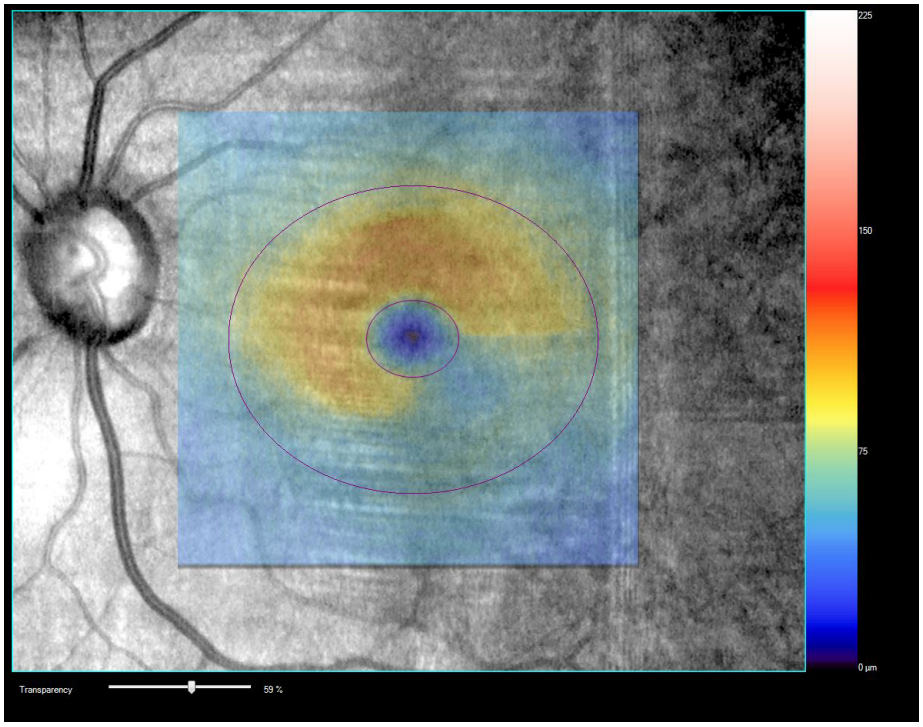


Figure 8-17 If the fovea is not centered, the values for the minimum thickness will begin to change. Observe in the figure above, that the minimum OS value has changed from the (correct) value of 55 to a value of 21 as the fovea is moved from the center of view.

If it is determined that the location was not correct, the location should be manually corrected. Manually move the annulus location and associated circle placements to the correct location.

Double-clicking on the image of choice will show the thickness map overlaid on the Fundus Image. This can be very useful in ensuring fovea is entirely centered.

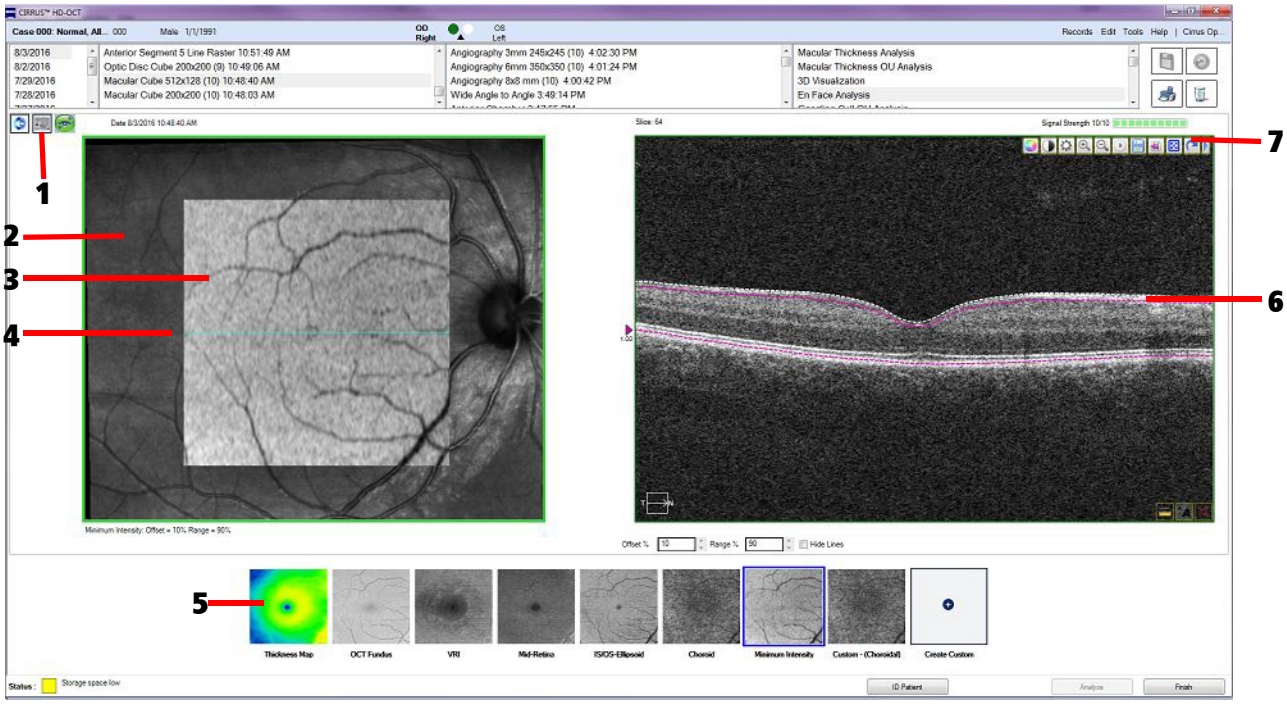


NOTE: Of particular importance for Ganglion Cell Guided Progression Analysis (see "Ganglion Cell Guided Progression Analysis" on page 8-38), do not use thickness maps or cubes with clear segmentation errors, or where the fovea is far from the center of the selected Cube scan.

NOTE: The GCA algorithm was tested on patients with glaucoma, but not other ocular conditions. The performance of this algorithm on patients with glaucoma and concomitant retinal disease, or retinal disease by itself involving the macula is not known, and disruption of the inner retinal layers in such conditions may lead to atypical measurements and deviation maps.

En Face Analysis

Information regarding VRI, Mid–Retina, IS/OS Ellipsoid, and Choroid layers is provided by the CIRRUS HD-OCT **En Face Analysis** (Figure 8-18).



1 Show/Hide Fundus Image
2 Fundus image
3 Selected preset
4 OCT slice navigator
5 Available Presets
6 OCT B-scan slice
7 Image Toolbar (shown for B-scan, but available by hovering the mouse over any image).

Figure 8-18 En Face Analysis, Macular Cube 512x128

En Face Analysis Preset Slabs

In addition to the Thickness Map overlay, En Face Analysis provides six preset slabs from which you can quickly select. The depths of each preset slab has been chosen to represent posterior layers of interest, as shown in Table 8-2.

Additionally, you may create your own custom preset by specifying a region of interest that, once created, is available for analysis across all patients. This option is described further in "Create Global Custom" on page 8-4.

En Face Preset	Description	Default Settings
VRI (Vitreoretinal Interface)	Designed to highlight disorders of the VRI, such as epiretinal membranes (ERM) and vitreomacular traction (VMT). Vitreous attachments show as bright areas, while macular pucker appears as variations in the background intensity.	Upper: 133 µm above the ILM layer Lower: 33 µm below the ILM layer
Mid–Retina	Highlights fluid and exudates occurring roughly in the general region from the Inner Nuclear Layer to the Outer Nuclear Layer. It follows contours that are fractions of the distance between ILM and RPE.	Central 1/3 of retinal thickness based on the ILM and RPE layers
IS/OS–Ellipsoid	Highlights disruptions to the IS/OS – Ellipsoid Zone. It follows the RPE contour and is elevated slightly to put it at the level of the IS/OS – Ellipsoid Zone. Disturbances to the IS/OS – Ellipsoid Zone show as dark areas.	Upper: 44 µm above the RPE layer Lower: 22 µm above the RPE layer
Choroid	Highlights Choroidal vasculature. It is placed below the RPE Fit, at the general level of Haller's Layer, deep in the choroid. Since choroid thickness can vary from patient to patient, this level may need to be adjusted. Vessels appear as dark areas, and areas of RPE disturbance such as GA may appear as bright areas.	Upper: 72 µm below the RPE Fit layer Lower: 128 µm below the RPE Fit layer
Minimum Intensity Projection (Min-IP)	Shows patterns of minimum scan intensity within the retina. Areas that appear dark may indicate fluid build-up, and areas that appear bright may indicate disruption of the retina. The Min-IP Preset allows the user to evaluate these areas in an en face view and to quickly identify B-scans that may show fluid or other disruptions.	Upper: 90% ILM + 10% RPE Layers Lower: RPE Layer

Table 8-2 Preset Slab Locations for the En Face Analysis

NOTE: The Mid-Retina B-Scan shown in the En Face Report indicates the ILM and RPE through the use of white dashed lines. For this preset, it is not possible to move the magenta segmentation lines above or below the bounding lines of the retina.

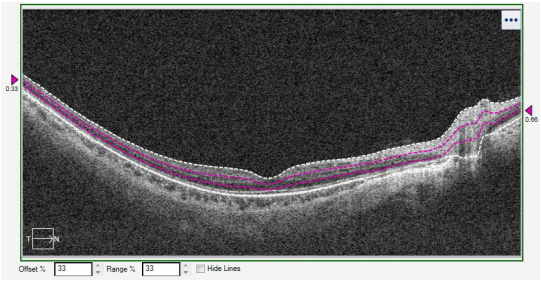
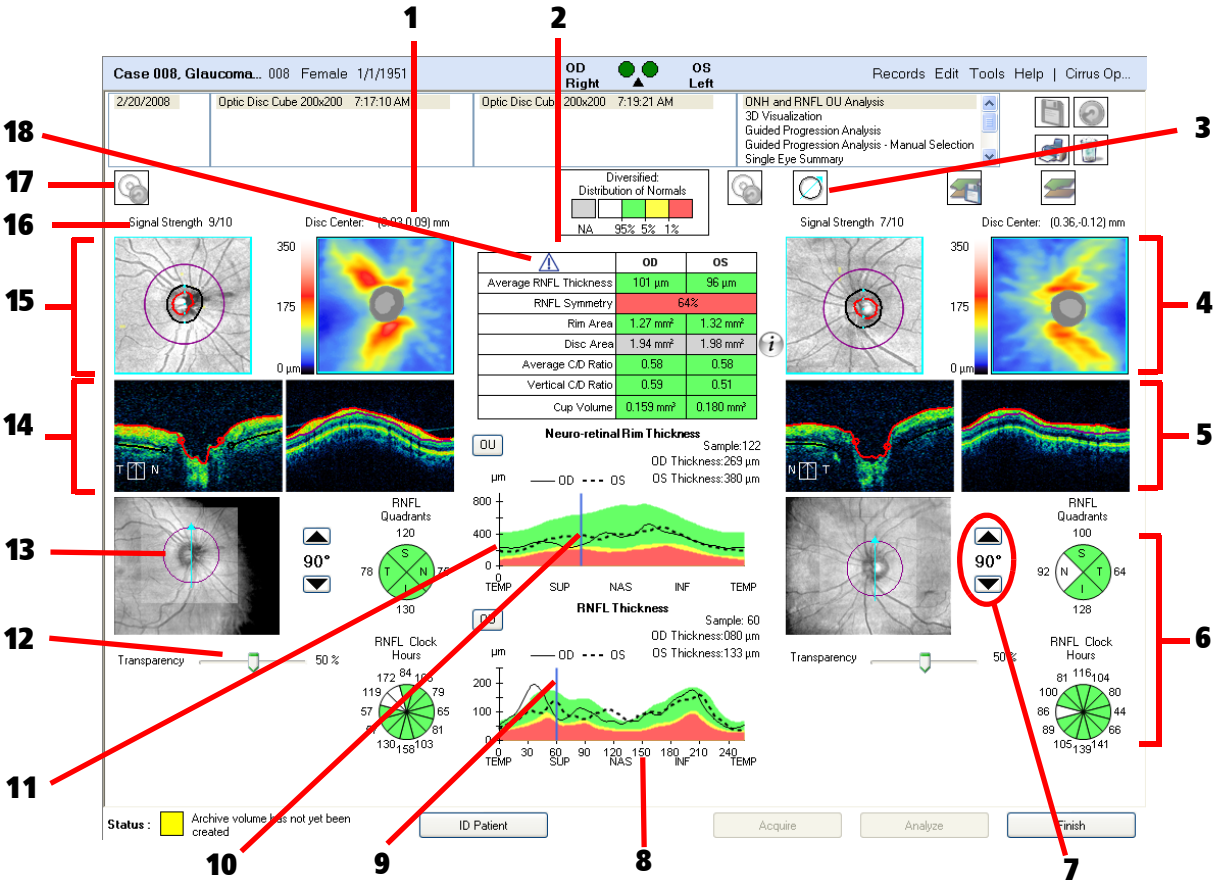


Figure 1. Mid-retina slab showing upper and lower bounds delineated by the white dashed lines.

ONH and RNFL OU Analysis

The ONH and RNFL OU Analysis is derived from Optic Disc Cube 200x200 scans. Along with the current scan image, a second scan image is shown of the opposite eye from the same visit (if available). You may also manually choose another scan using the **ONH and RNFL OU Analysis – Manual Selection** option (see "Manual Selection" on page 8-12).



1 Calculation Circle Offset (horizontal, vertical) in mm relative to the OCT center

2 Table includes Average RNFL Thickness, RNFL Symmetry, five optic disc parameters

3 Toggles ONH slice indicator

4 RNFL thickness map with optic disc and cup masks

5 B-scan extracted from RNFL Calculation Circle

6 Average RNFL thickness along Calculation Circle for quadrants and clock hours

7 Control to choose angle of ONH spoke extracted

8 Left and right eye RNFL thickness graph with normative data

9 Drag to select current A-scan sample

10 Drag to select an angular sample

11 Left and right eye neuro–retinal rim thickness

12 Transparency slider

13 Move purple circle to select a different center

14 4 mm B-scan extracted from ONH radial spoke

15 OCT Fundus with optic disc and cup outlines

16 Signal Strength

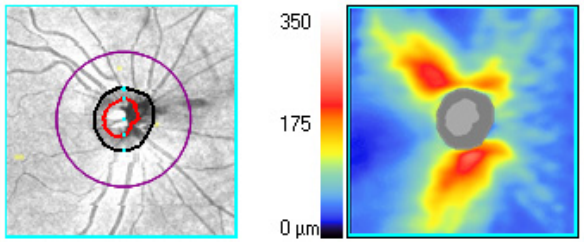
17 Auto center button

18 Normative Data Details Report button. (**NOTE:** A gray "N/A" for Disc Area indicates that is no normative data.)

Figure 8-19 ONH and RNFL OU Analysis

The ONH and RNFL OU Analysis derives the its elements from two kinds of thickness measurements: along the Calculation Circle and in super-pixels.

RNFL Thickness Maps and Deviation from Normal Maps



RNFL Thickness Maps and Deviation from Normal Maps are all based on calculated thickness data for the cube as follows:

- RNFL Thickness Maps derive from pixel average thickness measurements and report thickness using a color pattern, where cool colors (blues, greens) represent thinner areas and warm colors (yellows, reds) represent thicker areas. The maps exclude the optic disc, which appears solid blue. The color code expresses thickness ranging from zero (blue) to 350 µm (white).
- Deviation from Normal Maps derive from super-pixel average thickness measurements and report the results of a statistical comparison against the normal thickness range for each super-pixel, overlaid on the OCT fundus image. These maps apply the yellow and red colors (not the green) of the age-matched normative data to super-pixels whose average thickness falls in the yellow and red normal distribution percentiles. The green color of the normative data is not applied because most super-pixels would be green for normal patients, and the green color might obscure the anatomical detail in the underlying OCT fundus image. Any region that is not red or yellow falls within or above normal limits.

  A region that is yellow is thinner than all but 5% of normals. A region that is red is thinner than all but 1% of normals. The deviation map is created by binning individual pixels of thickness measurement into super-pixels consisting of 16 pixels (4 pixels or 120 um to a side of each super-pixel). There is a total of 50 by 50 (2500) super-pixels analyzed, although super-pixels at the edge or inside of the optic disc are not considered and not shaded.

There are several reasons why a particular region might differ from normal. The deviation map shows when a particular region of an eye is thinner than the same region in a population of normal subjects, but such deviation is not always due to pathological loss of RNFL, for any of the following reasons:

1. For each super-pixel, 5% of normals will in generally be highlighted yellow, and 1% of normals will in general be highlighted red. Since each map consists of 2500 super-pixels, 125 pixels on average might be expected to be highlighted on each normal.

2. The normative database consisted of a population with a limited range of spherical error (-12 D to +6 D) and axial length (22 to 28 mm). Subjects with strongly myopic or hyperopic eyes may have a different distribution of measured RNFL thickness values, and may tend to flag more often than subjects who fall within the range of the population used to create the normative database.

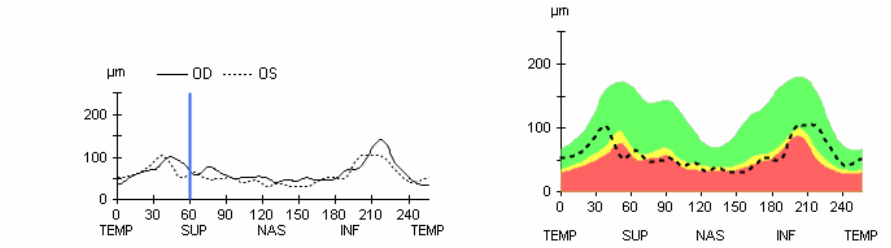
There is a wide variation in RNFL bundle anatomical distribution among the normal population. A person with split-bundle anatomy or a person with a very tilted RNFL bundle pattern may show a deviation from normal anatomy without indicating that this person has lost RNFL.

Changing RNFL Calculation Circle Placement

Changing the placement of the RNFL Calculation Circle changes the Deviation from Normal Map as well as the optic disc parameter calculations, since each super-pixel in the scanned area is defined relative to the center of the Calculation Circle. Super-pixel positions in the normative data are defined relative to a fixed center based on the age-matched normative samples. Therefore, when you change the position of the Calculation Circle, you change the specific super-pixel in the normative data against which each super-pixel in the exam data is compared.

NOTE: When the temporal RNFL is very thin or entirely absent, the RNFL algorithm may show an artificial thickening of the RNFL in this area. If the temporal RNFL appears thicker than normal, examine the algorithm lines as displayed on the extracted circular B-scan to determine if the algorithm has correctly identified the RNFL.

TSNIT Thickness Profiles



The TSNIT Thickness Profiles (TSNIT stands for Temporal, Superior, Nasal, Inferior, Temporal) display thickness at each A-scan location along the Calculation Circle and include as a backdrop the white-green-yellow-red color code based on the age-matched RNFL normative data. The profile shows left and right eye RNFL thickness together, to enable comparison of symmetry in specific regions. Drag the blue vertical line in the OU profile to select the current A-scan sample from among the 256 samples.

NOTE: You cannot select every specific A-scan sample by dragging the vertical blue line. To select an individual A-scan, click (and release) the vertical blue line, then hold down **Ctrl** and press the left or right arrow key.

RNFL Data Table

Thickness	OD	OS
Thickness at sample 60	69	62
Symmetry	79%	

RNFL Summary Data

The data table reports average thickness around the RNFL calculation circle. It also reports a percentage calculation of thickness **Symmetry** between the eyes. The color associated with each measurement derives from comparison to the age-matched RNFL normative data. The symmetry parameter is the correlation coefficient, converted to a percentage, that results from comparing the OD profile (256 points) with the OS profile (256 points). Normative data was collected for both eyes and the normal limits for this symmetry parameter were determined.

When the symmetry parameter is close to 100%, the two eyes have similar profiles. As one profile becomes different from the other, the reported symmetry value decreases. If there is no relationship between the two eyes, the symmetry approaches 0%. It is possible for the symmetry to report a value below zero if the two profiles are very different, but this is rare.

The data table also reports optic disc parameters as described previously.

RNFL and ONH Normative Databases

For completeness, please refer to "RNFL and ONH Normative Databases" on page A-15 for an explanation of the application of the RNFL Normative Database to these elements.

Advanced Export

Click on the **Advanced Export** button  on the ONH AND RNFL OU ANALYSIS screen, to export and store ILM-RNFL thickness maps as .DAT files and .txt files of Neuro-retinal Rim Thickness and RNFL Thickness profiles to a user-selectable directory. See "Advanced Export" on page 11-16 for a complete description of this function.

Guided Progression Analysis

Guided Progression Analysis (GPA™) is provided for two analyses:

- RNFL & ONH
- Ganglion Cell

GPA compares thickness measurements over time and determines if statistically significant change has occurred. GPA allows the user to analyze information from 3 to 8 exams.

GPA includes a chronological display of thickness maps and thickness change maps, average thickness graphs representing rate of change, and thickness profiles comparing the current exam to the baseline exams. Statistically significant changes are summarized with flags for possible or likely thickness loss (or possible thickness increase). The layout of these elements within the GPA window is shown in Figure 8-20 for RNFL & ONH GPA and Figure 8-23 for GC GPA.

The earliest two exams are treated as baseline exams (Baseline 1 and Baseline 2). The later or follow–up exams (3rd exam through last exam) are compared to the baselines to see if they have changed. All scans, including the Baseline 2, are registered to the first Baseline 1 in order to ensure accurate correspondence from the first scan to the last scan. The average RNFL thickness value is displayed for each exam above its corresponding thickness map.

There is an indication above each displayed exam to describe the registration performed. Prior to comparing scans, CIRRUS registers them to the first baseline scan using one of two methods. First, it attempts to use method R2, which is based on the blood vessels identified in the *en face* images of both scans. Method R2 uses translation and rotation to align the follow-up scan to the baseline scan.

If there is motion in either the baseline or the follow–up scans, the R2 method may not be possible because the blood vessels will not line up well enough. In this case, the center of the optic disc from the follow–up scan translated to the center of the optic disc of the first scan prior to making comparisons for the purposes of identifying change. This method is called R1. It does not include rotation.

If the R1 method is used, you may observe additional variability at the super-pixel level. This may affect detection of change in the Map.

NOTE: CIRRUS does not evaluate "progression of glaucoma", which can only be assessed through evaluating changes in several clinical factors, including optic nerve head appearance and visual fields. GPA only refers to change in the Nerve Fiber Layer or GCL+IPL thickness assessed by statistical analysis of certain CIRRUS parameters. Such changes in thickness may or may not be related to clinically relevant changes. GPA is not meant to diagnose. Diagnosis is the responsibility of the practitioner, who should base diagnosis on many parameters, including those not assessed by CIRRUS.

Parameter Summary Graphs

Parameter Summary graphs ("GCL+IPL Summary Graphs" on page 8-39 for Ganglion Cell, "RNFL & ONH Parameter Summary Graphs" on page 8-35 for RNFL) identify global thinning in the Retinal Nerve Fiber layer or the Ganglion Cell layer by calculating a trend over time. Statistically significant loss or improvement, based on comparisons to test-retest variability, is also reported by color-coding the markers for each visit. The Average Thickness Graphs are calculated by averaging large portions of the profile - this is why they detect only global loss. Each chart displays parameter data from 3 to 8 exams plotted in chronological order. The individual points are highlighted to indicate when the value plotted has changed from baseline by an amount more than the test–retest variability. Possible loss is indicated when the rate of loss is statistically significant for only a single visit and is indicated by a yellow symbol. Likely loss is indicated when the rate of loss is statistically significant for two visits in a row and is indicated by a red symbol. Possible increase is indicated when the rate of gain is statistically significant and is shown via a lavender symbol. Possible increase should only occur due to random fluctuations or due to problems with scan quality.

These plots are generated using linear regression in order to calculate the rate of loss. Confidence bands for the regression line are also shown. They are determined based on comparing the variability in the data to the rate of change. The slope (rate of change) is displayed in micrometers/year with 95% confidence interval values. For example, with a slope of −3.9 ±1.1, there is 95% confidence based on statistical analysis that the slope is between −2.8 and −5.0 µm/year. This is shown graphically in the shaded gray area.

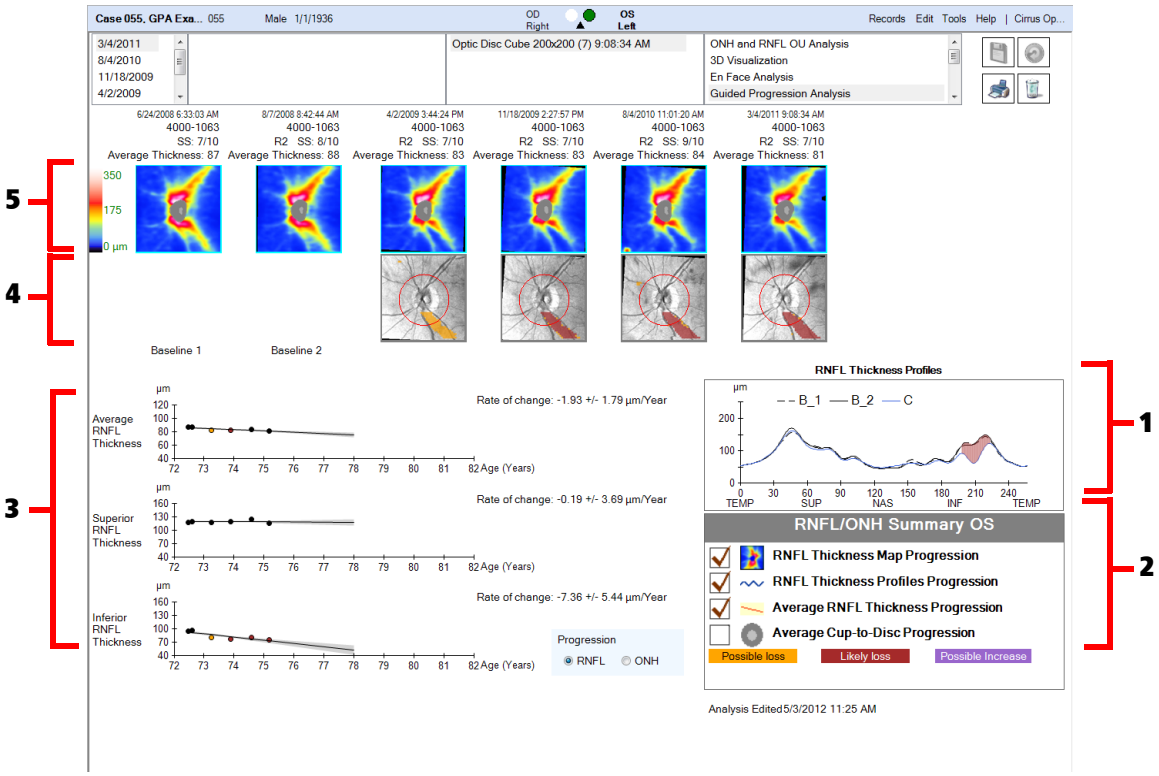
The graphical plots will show a rate of change and 95% confidence limits around that rate of change whenever at least 4 exams that span at least 2 years are loaded. If there are fewer than 4 scans loaded, or if there is less than two years between the first baseline and the current scan, no rate of change analysis will be provided.

NOTE: Linear regression fits the data to a linear model, assuming that the measurements are independent and normally distributed, and that variability does not depend on the size of the measurement. If the observed measurements do not change linearly, the rate of change may still provide information about how the patient has changed during the period of examination, but it should not be used to predict future change. Linear regression is a statistical analysis, and should not replace clinical evaluation of the patient's status and progress.

Summary Charts

Summary charts ("RNFL & ONH Summary Chart" on page 8-36 for RNFL, "GCL+IPL Summary Chart" on page 8-39 for Ganglion Cell) display color-coded summary boxes that provide alert if significant change has been detected.

RNFL & ONH Guided Progression Analysis



1 RNFL Thickness Profiles
2 RNFL Summary
3 Average RNFL Thickness Graphs
4 RNFL Thickness Change maps
5 RNFL Thickness maps

Figure 8-20 Guided Progression Analysis – RNFL screen

RNFL Thickness Profiles

The RNFL Thickness Profiles (Figure 8-21) plot RNFL thickness values around the CIRRUS RNFL Calculation Circle. All of the OCT Fundus images are overlaid with the red circle that shows where the thickness profile measurements are evaluated. The location of the red circle on the first baseline exam is determined by the automatic algorithm that finds the center of the optic disc. Because the remaining scans are registered to the first baseline scan, the same center and circle are used for all other scans.

There are three curves: two for the current baseline exams shown in gray (labeled B1 and B2), and one for the most recent examination shown in blue (labeled C for current). The profile analysis identifies moderate focal thinning in the RNFL thickness by comparing observed change in the RNFL Thickness Profiles to test–retest variability, and then looking for instances where the apparent change is confirmed over multiple visits.

For "Likely Loss", "Possible Loss", or "Possible Increase", to be reported, at least 14 adjacent A-scans must show significant change. This value was chosen to allow the TSNIT profile to be sensitive to defects of 20–degrees or more. Areas between the baseline pair

and the current exam that report significant change are displayed with "Possible Loss" shown in yellow, "Likely Loss" shown in red, and "Possible Increase" shown in lavender.

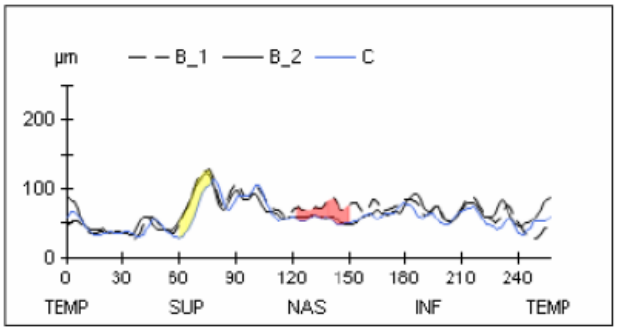


Figure 8-21 RNFL Thickness Profiles

RNFL & ONH Parameter Summary Graphs

As described in "Guided Progression Analysis" on page 8-31 RNFL Average Thickness Graphs identify global thinning in the retinal nerve fiber layer by calculating a trend over time.

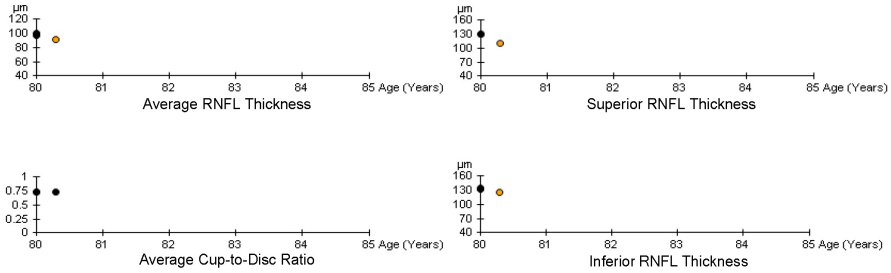


Figure 8-22 Average RNFL Thickness and ONH Cup–to–Disc Ratio Graphs

For RNFL GPA four graphs can be seen as shown in Figure 8-22:

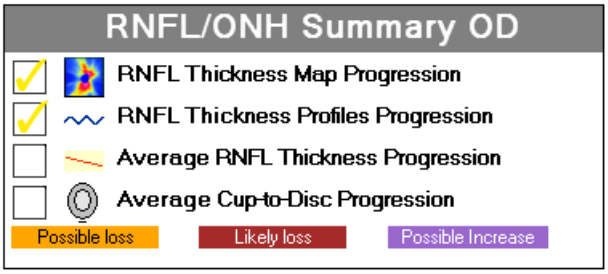
1. A graph of the overall average thickness trend from the CIRRUS RNFL Calculation Circle for each exam.
2. A graph of Average Cup–to–Disc Ratio. Note that "Possible Loss" (orange color coding) and "Likely Loss" (red color coding) are associated with a positive slope or increase in the measurement.
3. A graph of the average thickness trend for the superior quadrant of the RNFL Calculation Circle for each exam.
4. A graph of the average thickness trend for the inferior quadrant of the RNFL Calculation Circle for each exam.

RNFL & ONH Summary Chart

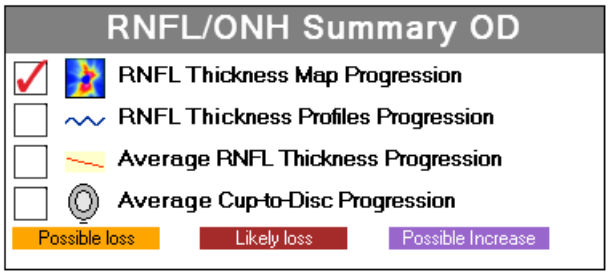
RNFL GPA has three different indicators for detecting RNFL change and one indicator for detecting ONH change, each with a checkbox in the summary:

- RNFL Thickness Map Progression (best for focal change)
- RNFL Thickness Profiles Progression (best for broader focal change)
- Average RNFL Thickness Progression (best for diffuse change)
- Average Cup–to–Disc Progression

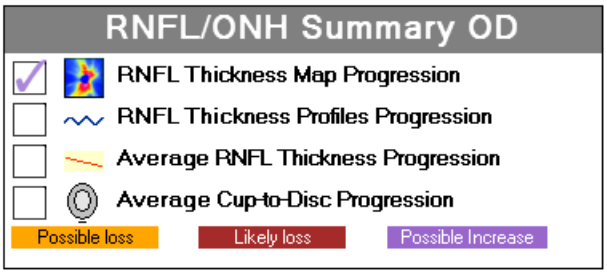
The summary box reports progressive change as one of "Possible Loss" (yellow), "Likely Loss" (red), or "Possible Increase" (lavender). "Possible Loss" means progressive loss has been detected once. "Likely Loss" means it has been confirmed by consecutive follow–up examinations. Shown below are examples of summary box displays.



The yellow checkmarks in the RNFL Thickness Map Progression and RNFL Thickness Profiles Progression summary boxes above show "Possible Loss".



The red checkmark in the RNFL Thickness Map Progression summary boxes above shows "Likely Loss".



The lavender checkmark in the RNFL Thickness Map Progression summary box above shows "Possible Increase".

Optic Nerve Head Changes

RNFL Guided Progression Analysis includes features to follow changes to the optic nerve head. This includes the following:

- A graphical plot of the Average Cup–to–Disc Ratio as a function of patient age using the same layout as the graphical plots of RNFL average thickness measurements versus patient age. This graphical plot is available on a second page of the analysis screen. You may access this page by selecting the ONH toggle button.
- The GPA summary box also includes a colored checkmark whenever "Possible Loss", "Likely Loss", or "Possible Increase" has been detected using the Average Cup-to-Disc Ratio. Note that ACDR increases as the thickness of RNFL decreases. Therefore, "Possible Loss" of RNFL is indicated by an increase in ACDR, and thus "Possible Loss" is checked when an there is an increase in ACDR observed (that exceeds the expected variability of ACDR).
- The RNFL thickness maps that are displayed as a function of time include a mask to indicate the location of the cup and disc boundaries. This display is similar to what is seen on the ONH & RNFL OU Analysis.

Ganglion Cell Guided Progression Analysis

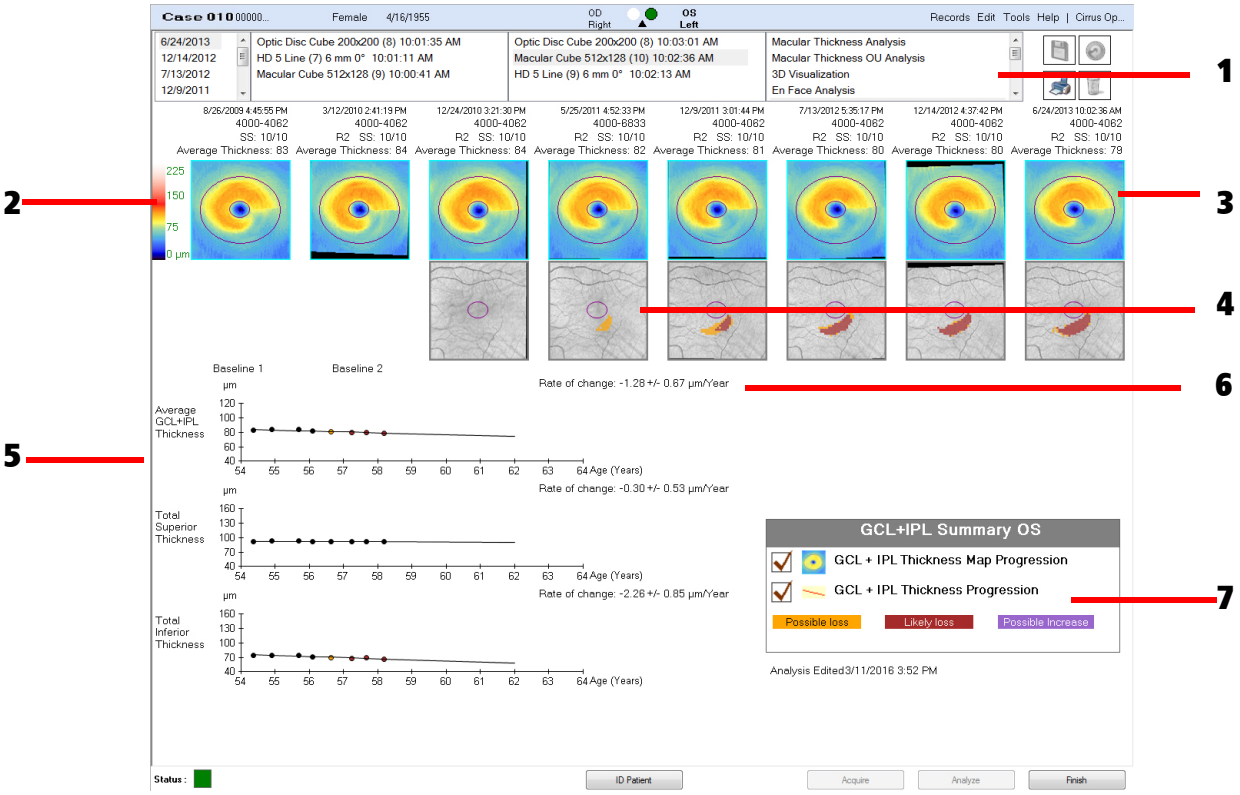


Figure 8-23 Ganglion Cell Guided Progression Analysis

1 Ganglion Cell Guided Progression Analysis is selectable for any Macular Cube scan

2 Thickness Map Color Legend

3 Progressive Ganglion Cell Change shown as Thickness Maps

4 Previous two "normal" GC thickness maps

5 Ganglion Cell thickness change shown quantitatively

6 Overall avg. Rate of Change of Ganglion Cell layer

7 GCL+IPL Summary

GCL+IPL Summary Graphs

As described in "Guided Progression Analysis" on page 8-31 GCL+IPL Average Thickness Graphs identify global thinning in the retinal nerve fiber layer by calculating a trend over time.

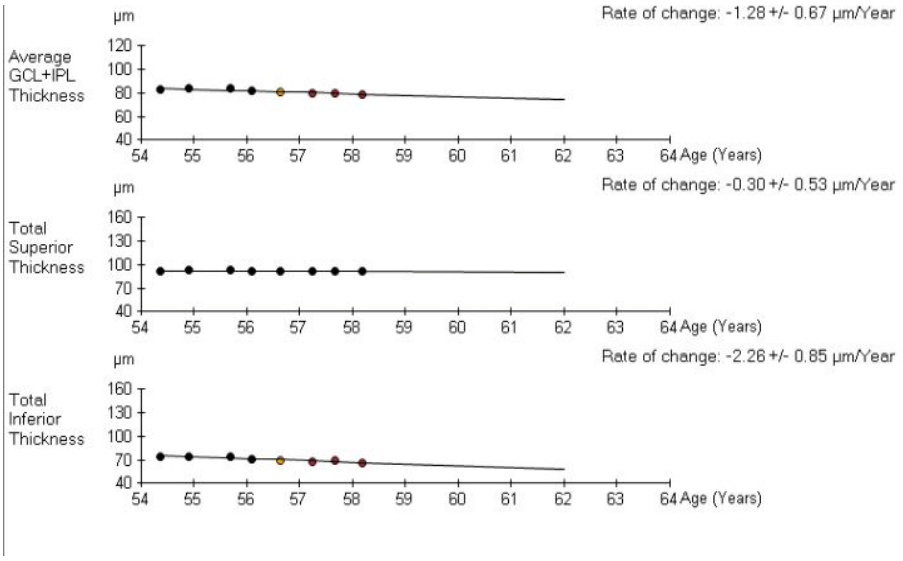


Figure 8-24 Average GCL+IPL Thickness and Total Superior/Inferior Thickness Graphs over time

For Ganglion Cell GPA three graphs can be seen as shown in Figure 8-24:

1. The graph of the overall average thickness of the GCL + IPL is calculated by dividing the selected GCA annulus into 6 sectors and taking the average. For example, in Figure 8-15, the average of all 6 OS sectors is 79.5.
2. The graph of the Total Superior Thickness is determined by averaging the top 3 sectors (in Figure 8-15, 91.6)
3. The graph of the Total Inferior Thickness is determined by averaging the bottom 3 sectors (in Figure 8-15, 67.3).

NOTE: Do not use GCL Guided Progression Analysis with thickness maps or cubes with clear segmentation errors, or where the fovea is far from the center of the scan. If the annulus is simply off-center, return to the Ganglion Cell OU Analysis ("Macular Thickness OU Analysis" on page 8-16) to make adjustments.

NOTE: The GCL Guided Progression Analysis automatically excludes data where the Scan Strength is less than 6. However, such data can be included by using the Manual Selection function.

GCL+IPL Summary Chart

Ganglion Cell GPA has two different indicators for detecting Ganglion Cell change, each with a checkbox in the summary:

- GCL +IPL Thickness Map Progression (best for focal change)
- GCL +IPL Thickness Progression (best for diffuse change)

The summary box reports progressive change as one of "Possible Loss" (yellow), "Likely Loss" (red), or "Possible Increase" (lavender). "Possible Loss" means progressive loss has been detected once. "Likely Loss" means it has been confirmed by consecutive follow–up examinations. Shown below is an example of a summary box display.

The yellow checkmark by GCL + IPL Thickness Map Progression indicates "Possible Loss," while the red checkmark by the GCL + IPL Thickness progression indicates "Likely Loss."

Were any improvement indicated, a lavender checkmark would appear beside one of the two progression options.

Ganglion Cell Guided Progression Analysis is also available in Manual Selection ("Manual Selection" on page 8-12).

Anterior Segment

Anterior Segment features are viewed and measured by accessing the following CIRRUS HD-OCT analyses. If you are unsure as to which scans need to be acquired in order to access the appropriate analysis, see Table 8-1.

Anterior Chamber Depth and Lens Vault

To measure Anterior Chamber depth and the Lens Vault, you must have scanned Anterior Chamber data (see "Anterior Segment Scans" on page 6-6).

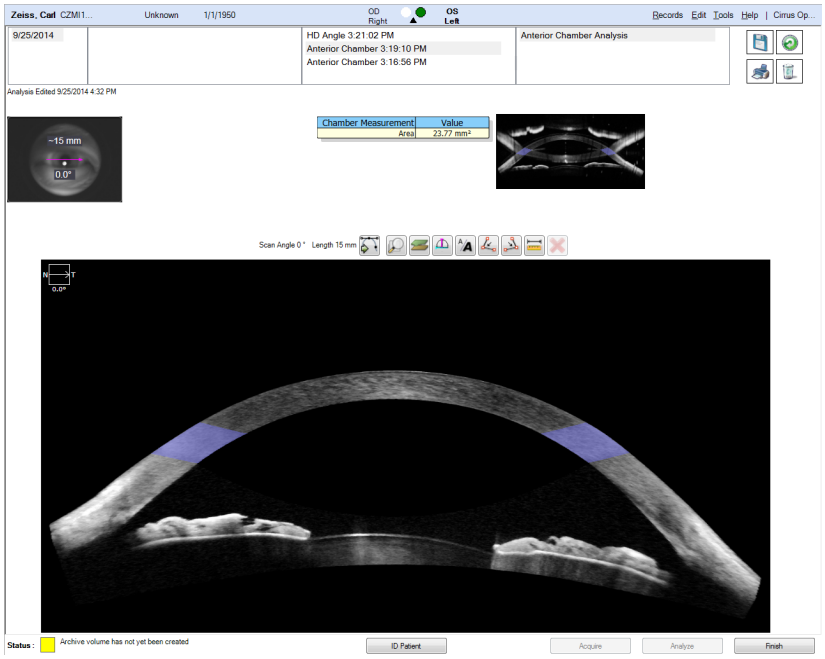


Figure 8-25 Analysis screen, Anterior Chamber

The iris image with the single line scan pattern in Figure 8-25 indicates the location used to generate the displayed Anterior Chamber scan. The length and angle of the scan is indicated both on the iris image and above the OCT B-scan. A chart indicating the Chamber Area Measurement and the Value (in mm^2) is displayed to the right of the iris image. A small image of the mirrored corneal image that is not processed is also displayed.

A mirror artifact indicating an area of data that is poorly resolved and inverted in the axial direction is often detectable. While it is possible to hide the mirror artifact in most parts of the image, it will invariably intersect the true data at two places in the cornea. These intersections appear as distinctive bars on the image. You can view image data in these 2 locations by selecting the HD Cornea scan ("Anterior Segment Scans" on page 6-6).To measure Anterior Chamber Depth:

1. Click the **Add ACD Tool button** (above the image of the anterior chamber) to access the tool. It will appear on the image of the Anterior Chamber such that the vertical arm is positioned at the anterior surface of the cornea, and another marker is positioned at the corneal vertex of the posterior surface, as shown below.

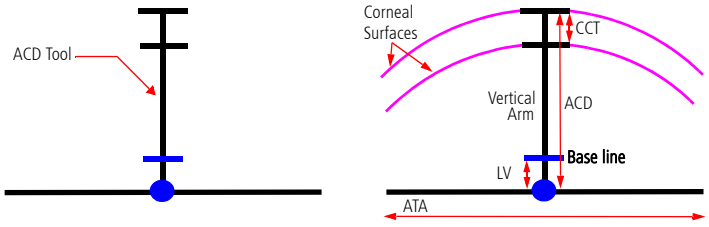


Figure 8-26 Working with the ACD tool to measure anterior chamber depth and lens vault

2. Click and drag the center of the base line of the ACD Tool (Figure 8-26), to the anterior surface of the crystalline lens to measure anterior chamber depth (ACD) and the lens vault (LV). To measure ACD in eyes with aphakia or pseudophakia, drag the base line to the pupillary plane.

   The measurements will appear on the OCT image and a summary of the measurements will appear in a table above the OCT image. Figure 8-27 below shows the ACD Tool placed correctly at the angles and the anterior surface of the lens.

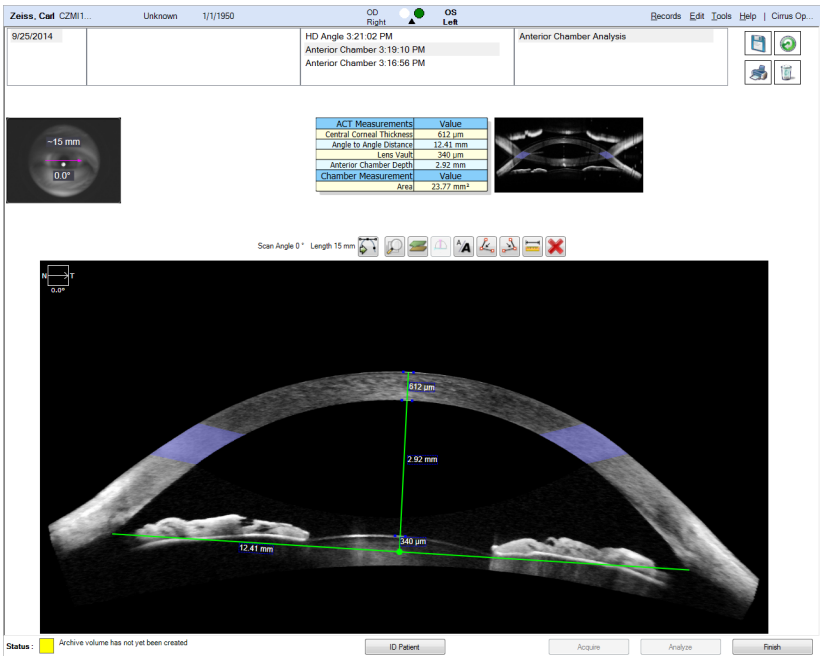


Figure 8-27 Anterior chamber analysis screen with the ACD tool correctly placed to measure lens vault and angle–to–angle distance.

NOTE: Measurements made with the Anterior Chamber scan should not be directly compared with Visante measurements.

Angle-to-Angle Distance

Using Anterior Chamber Analysis

Click and drag the ends of ACD tool baseline to place the right and left endpoints in each angle of the posterior portion of the Anterior Chamber, to measure the Angle-to-Angle distance (ATA) or the Corneal Diameter. (Figure 8-27)

Using Wide Angle-to-Angle Analysis

The CIRRUS HD-OCT **Wide Angle-to-Angle Analysis** displays the Iris Viewport image and one wide angle scan. The length, and angle of the scan are shown numerically in the Iris Viewport. You may also use the Add Angle Tool(s) (and) or Caliper to make manual measurements.

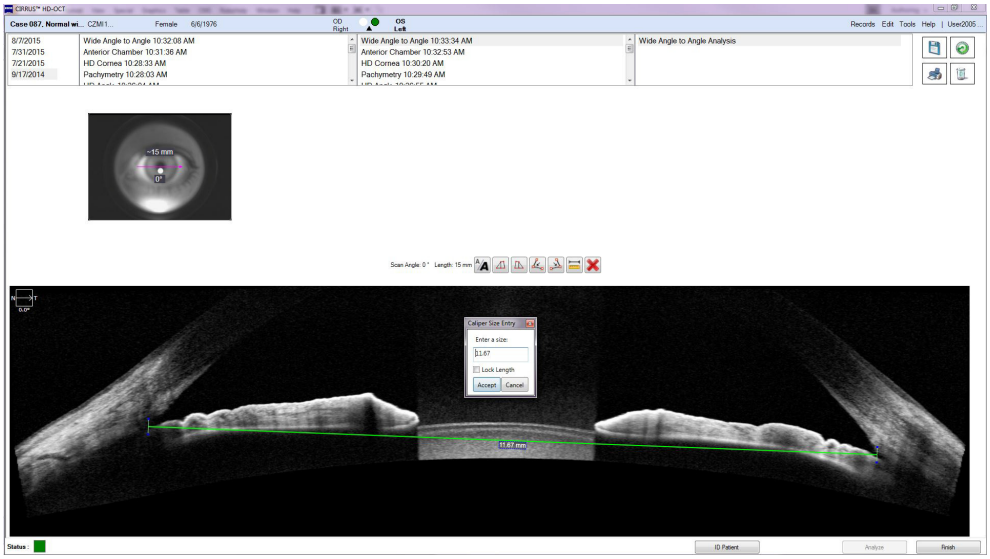


Figure 8-28 Wide Angle-to-Angle Analysis

NOTE: For Wide Angle-to-Angle, HD Angle, and Anterior Chamber Analyses, the Caliper Tool has additional functionality. **Right-click** the tool once it is placed on the image and the **Caliper Size Entry** popup will appear, as shown to the left, and in Figure 8-28. Using these added functions you can type in a specific length of interest, and/or lock the length of the caliper.

Corneal Thickness

Performance studies (see Tables 1, 2, 4 and 5 in Appendix C "CIRRUS HD-OCT Repeatability and Reproducibility of Anterior Scan Measurements", as well as Table G18 in Appendix B "Study 5: Anterior Segment Accuracy, Repeatability and Reproducibility"), show that the repeatability of the central thickness measurement from pachymetry is much better than the repeatability of the CCT as measured on the Anterior Chamber scan or Anterior Segment 512x128 scan. In addition, the central thickness measured in this manner has better agreement with Visante CCT. The improved performance is likely due to the fact that the pachymetry measurement averages over a 3mm central area, while the Anterior Chamber scan depends on subjective placement of

the scan directly over the central cornea for a single measurement. It is recommended that you use the pachymetry central thickness value.

In Pachymetry Analysis

Once a Pachymetry Scan is acquired (see "Pachymetry" on page 6-16) the CIRRUS HD-OCT Pachymetry Analysis will be selectable. You can measure corneal thickness variation via the Pachymetry map that comprises the Pachymetry Analysis screen (Figure 8-29).

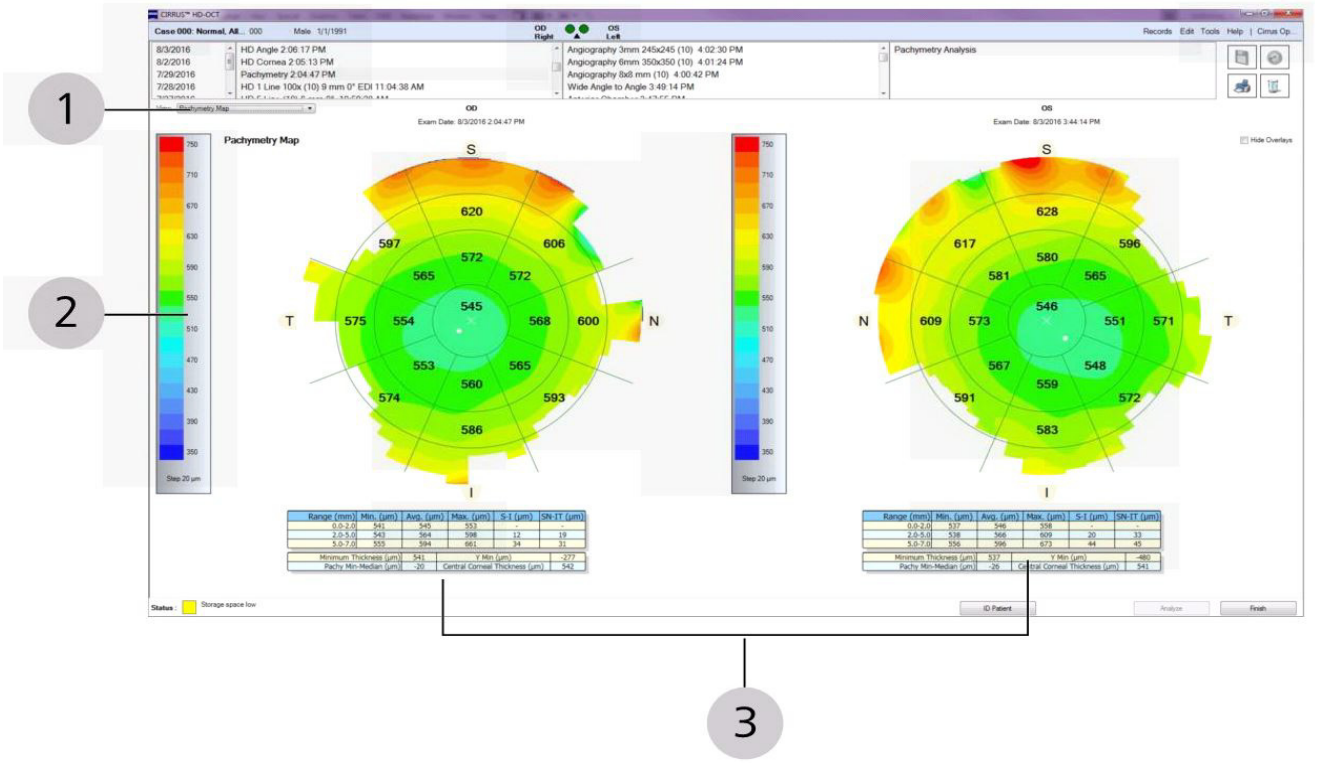


Figure 8-29 The CIRRUS HD-OCT Pachymetry Analysis screen

View Dropdown

Located in the upper left quadrant of the Pachymetry Analysis Screen is a dropdown menu labeled **View**. The view screen options shown to the left may be selected from the dropdown menu. Pachymetry Map is the default. The additional options are described below.

View and Mark Corneal Thickness Locations

2

Move the mouse over any point on the Pachymetry map to see the corneal thickness (in micrometers) calculated at that point and the location (relative to the center of the map) in radial (distance and angle) coordinates above the map (shown on the left). Click a point on a pachymetry map to mark a thickness value at that location—this value is printed on

reports. Right-click a map and check **Clear User Selection** to clear the thickness marker you have selected. Right-click at a location on a map to deselect **Show Mean Only** (the default setting), to show only all three values per sector: **Min, Max, Avg.** Right-click and select **Hide Data** to hide all data values on a map.

Cornea Thickness Data Tables

3

The data tables displayed below the pachymetry maps contain thickness measurements for the zones on the pachymetry maps. Minimum, average, and maximum thickness measurements in micrometers for the three radial zones appear. The zone range is defined in millimeters away from the center of the map. The central ring has a diameter corresponding to 2 mm, the second ring a diameter corresponding to 5 mm, and the outer ring corresponding to a diameter of 7 mm. The zone grid is centered on the corneal vertex. The "X" shows the location of the vertex. The white dot on each map in Figure 8-29 shows the location of minimum corneal thickness. This value is also reported in the data table.

The values S-I are calculated by subtracting the average value in the I sector at the specified distance from the center, from the average value in the S sector, at the corresponding distance.

Likewise, The values SN-SI are calculated by subtracting the average value in the SI sector at the specified distance from the center, from the average value in the SN sector, at the corresponding distance.

Epithelial Thickness Maps

Select the Epithelial Thickness Maps option from the **View** dropdown, to change the screen so that the two thickness maps reflect values for the Corneal Epithelium alone as shown in Figure 8-30. This option is discussed in detail in "In Pachymetry Analysis" on page 8-51.

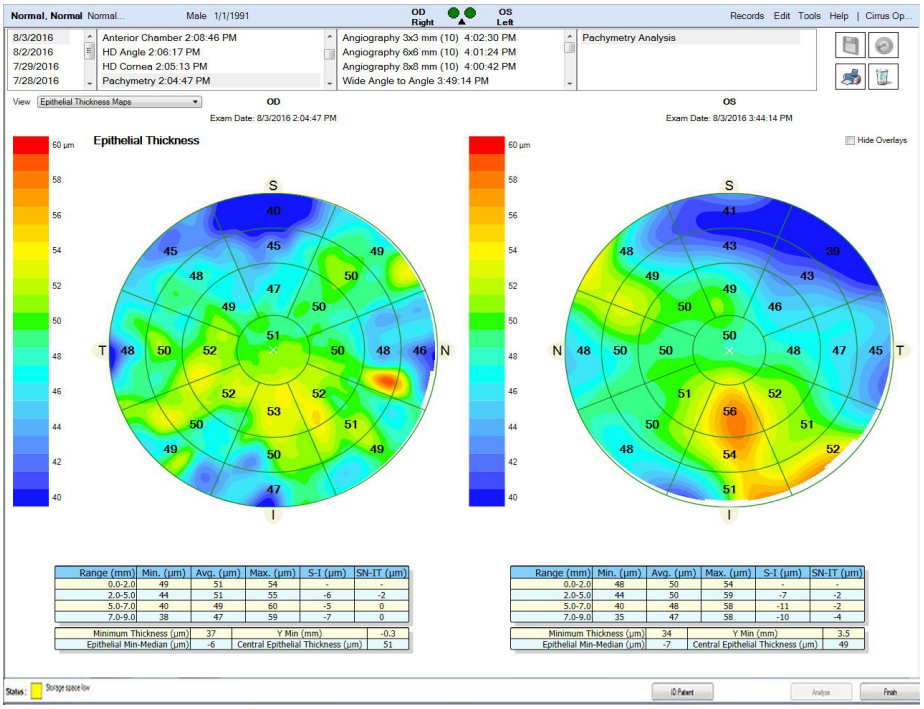


Figure 8-30 The Epithelial Thickness Maps are accessed from the Pachymetry Analysis screen by selecting it from the View dropdown list in the upper left quadrant of the screen (3) in Figure 8-29.

All Maps

Select this option from the **View** dropdown of the Pachymetry Analysis screen, to change the screen so that both the Pachymetry thickness maps and the Epithelial thickness maps are shown, as shown in Figure 8-31.

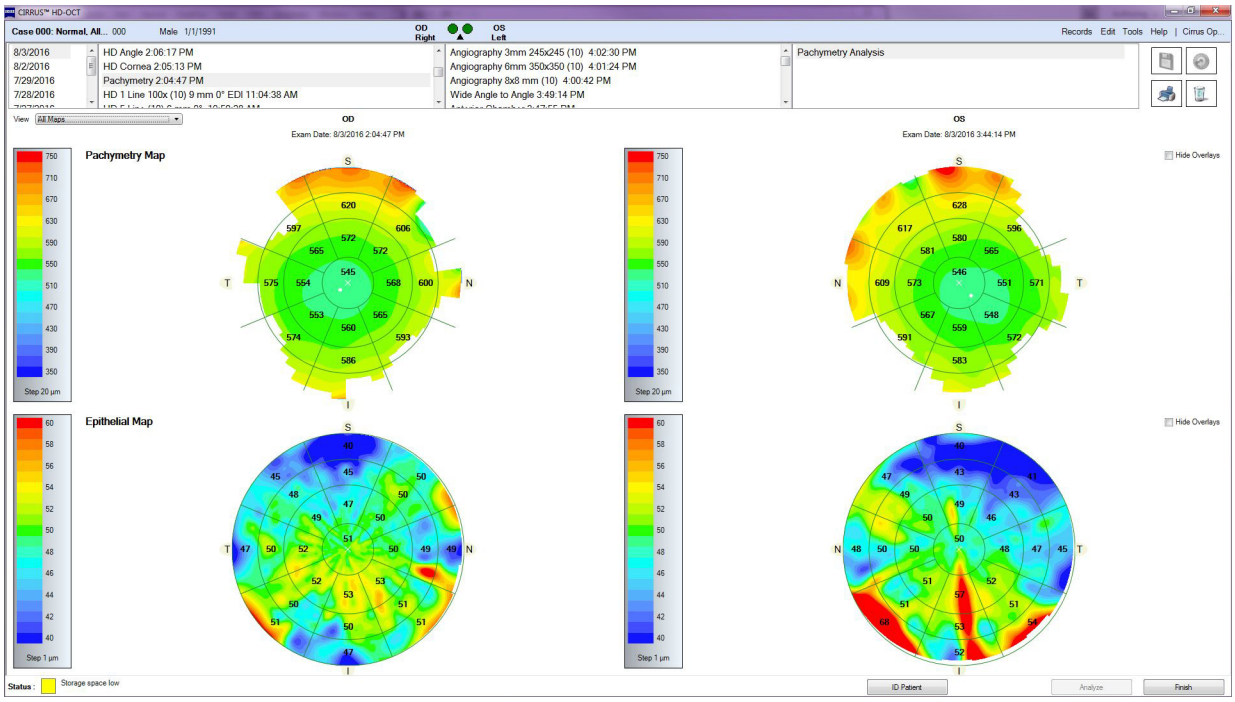


Figure 8-31 Selecting All Maps from the View dropdown list in the upper left quadrant of the screen will change the display to show both the Pachymetry Maps (Top) and the Epithelial Thickness Maps (Bottom).

Viewing Thumbnails of Cornea Scans

To view the 24 thumbnail scans used to generate the Pachymetry scan for a selected eye, select either **Images (OD)** or **Images (OS)** from the **View** dropdown list in the upper right quadrant of the Pachymetry Analysis screen ("1" in Figure 8-29).

The anterior surface of the cornea is highlighted with a green line and the posterior surface of the cornea is highlighted with a red line (Figure 8-32). Bowman's Layer is highlighted with a yellow line. To view a thumbnail in full screen, double-click on the thumbnail image. Double-click again to return to the thumbnail view.

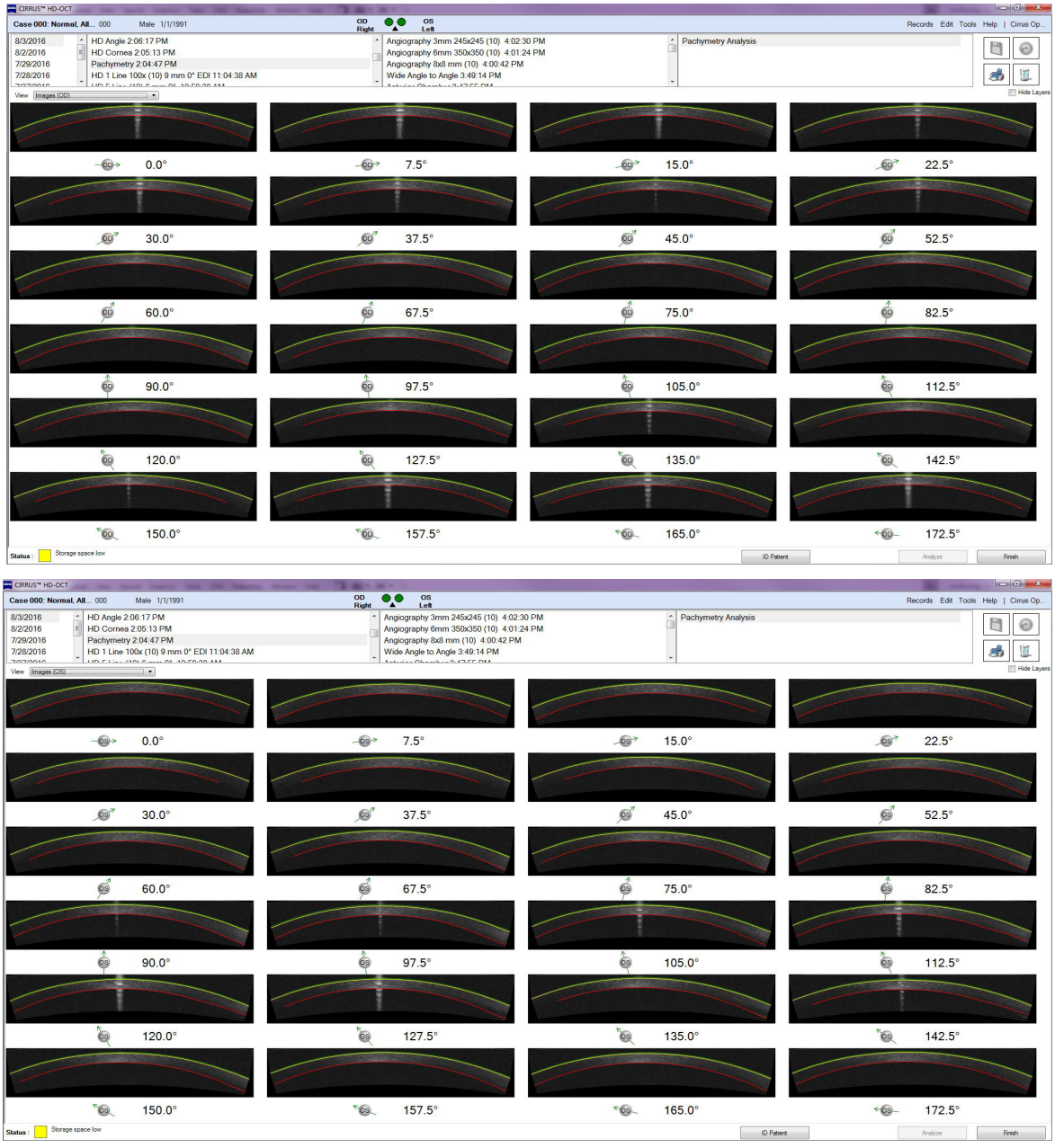


Figure 8-32 Pachymetry Thumbnails (OD on top, OS on bottom).

In HD Cornea Analysis

The HD Cornea Analysis screen shows the iris viewport with the scan line, the length of scan, and the scan angle displayed (Figure 8-33). The length of the scan and the scan angle are also displayed above the OCT image.

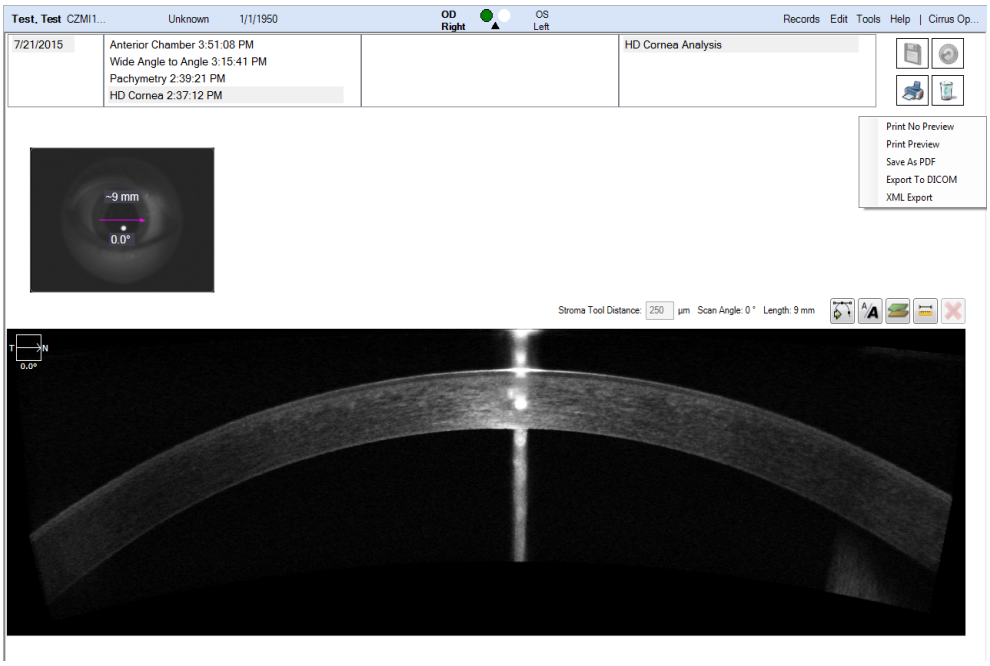


Figure 8-33 HD Cornea Analysis

In Anterior Chamber Analysis

To measure the Center Corneal Thickness (CCT) via the Anterior Chamber Analysis screen, adjust the position of the vertical arm of the ACD tool by clicking and dragging it horizontally. The measured value will appear in the Anterior Chamber Analysis Viewport (Figure 8-25).

The measurements will appear on the OCT image and a summary of the measurements will appear in a table above the OCT image. See "Using Anterior Chamber Analysis" on page 8-42 for a complete description of the use of the ACD and Add Angle tool.

In Anterior Segment Cube Analysis

The Anterior Segment Analysis screen (Figure 8-34) for the Anterior Segment Cube 512x128 scan displays the iris viewport with the scan area and scan navigators superimposed. The X slice (fast – B-scan) is shown in the upper OCT viewport and the Y slice (slow – B-scan) is shown below it. Click and drag the slice navigators in the iris viewport to move through the slices.

NOTE: The Caliper function for Anterior Segment Cube Analysis only works in the vertical direction.

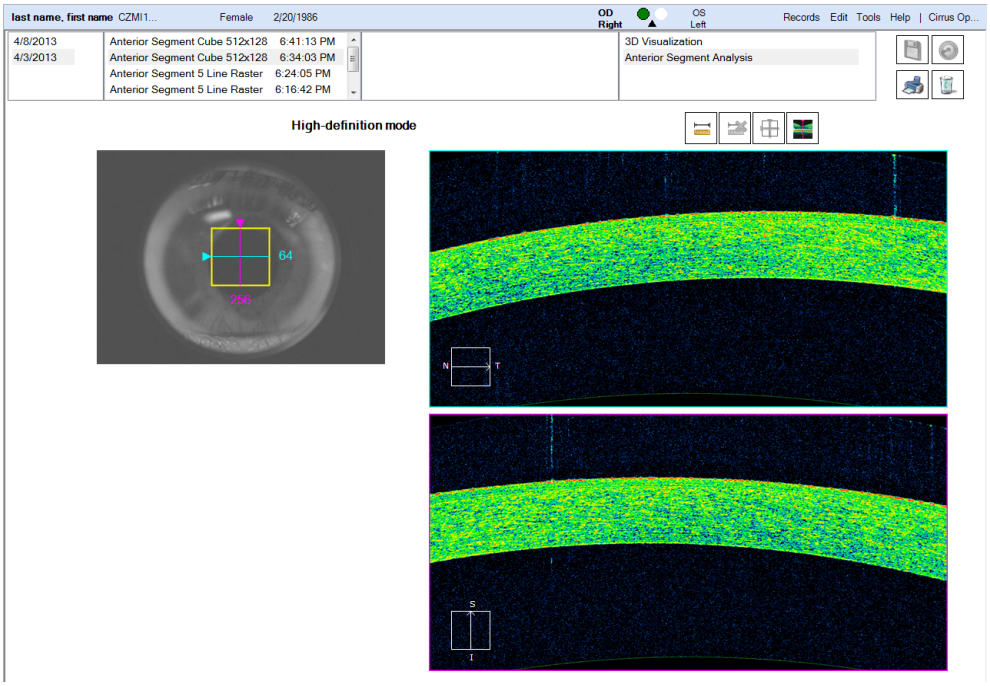


Figure 8-34 Anterior Segment Analysis – Cornea Thickness

In HD Images Analysis

When you select an Anterior Segment 5 Line Raster scan from the **Analysis screen** scan list, the High Definition Images analysis for that scan is automatically displayed.

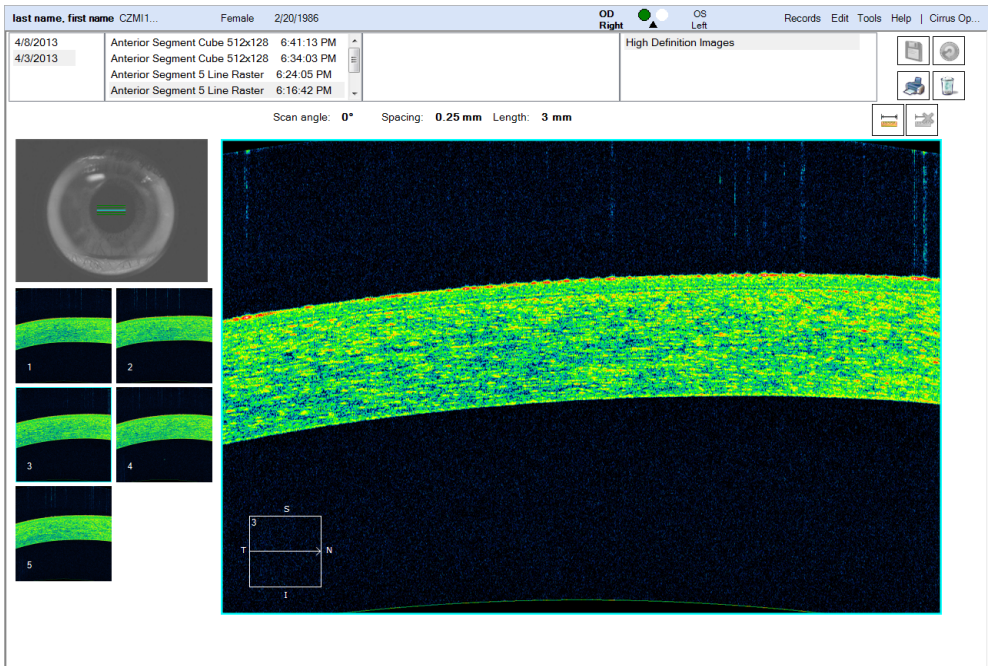


Figure 8-35 High Definition Images Analysis – Cornea Thickness

The High Definition Images analysis screen displays the iris viewport with the scan pattern superimposed. The length, line spacing, and angle of the scan are displayed above the large OCT scan. The thumbnails of the five lines are shown below the iris viewport. The large scan image on the right corresponds to the highlighted blue thumbnail and the highlighted blue scan line. Click another thumbnail image or a raster line in the iris viewport to display it as the large image.

Epithelial Thickness

In Pachymetry Analysis

To access the Epithelial Thickness Maps, open Pachymetry Analysis and go to the dropdown list [(1) in Figure 8-29], and select **Epithelial Thickness Maps**.

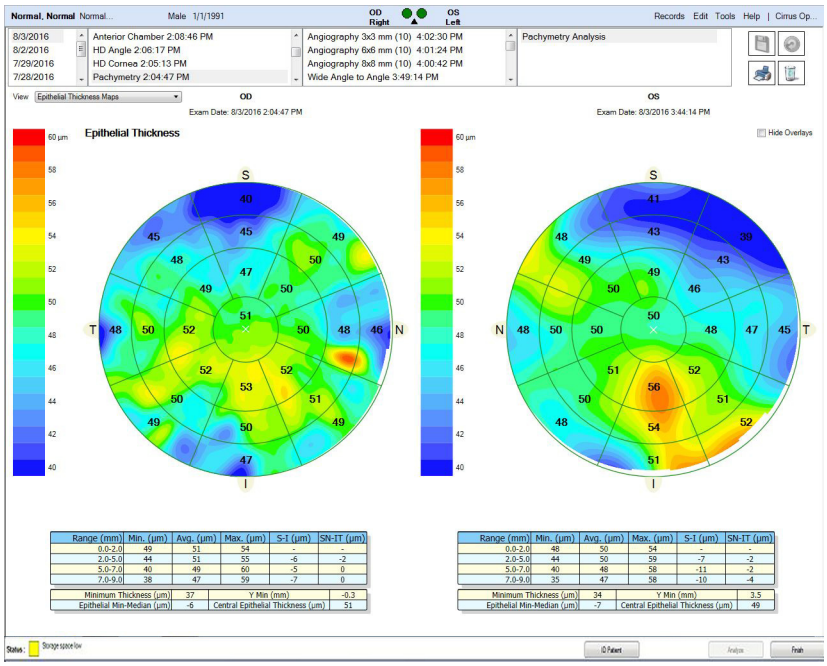


Figure 8-36 The Pachymetry Analysis screen shows the Epithelial Thickness Maps when that option is selected from the View dropdown list

Epithelial Thickness Data Tables

As with the Pachymetry maps, the data tables displayed below the Epithelial maps contain thickness measurements for the zones shown on the thickness maps. Minimum, average, and maximum thickness measurements in micrometers for the four radial zones appear. The zone range is defined in millimeters away from the center of the map. The central ring has a diameter corresponding to 2 mm, the second ring a diameter corresponding to 5 mm, the third ring corresponding to a diameter of 7 mm, and the fourth ring 9 mm. The zone grid is centered on the corneal vertex (the intersection of the visual axis with the corneal surface). The "X" shows the location of the vertex. This value is also reported in the data table.

The values S-I are calculated by subtracting the average value in the I sector at the specified distance from the center, from the average value in the S sector, at the corresponding distance.

Likewise, The values SN-SI are calculated by subtracting the average value in the SI sector at the specified distance from the center, from the average value in the SN sector, at the corresponding distance.

Central Corneal Thickness (CCT) Measurement

Central corneal measurements should be made at the apex of the cornea using the Anterior Segment Cube 512x128 Cube Analysis or the Anterior Segment 5 Line Raster. To determine the apical area:

1. Estimate where the center of the pupil is on the image and move the scan navigators so that they intersect at that point.
2. Click the Caliper button, and align the Caliper vertically against the magenta slice navigator on the horizontal scan.
3. The center of the cornea can be identified by moving the scan navigators throughout the entire scan volume and noting how the scans appear to move up and down within the box. The apical area, being closest to the instrument lens, will have the highest scans. By using the Caliper as a reference point while moving the slice navigators, find the highest horizontal and vertical scans.
4. The CCT measurement should be made at the intersection of the highest horizontal and vertical scans, using the Caliper on the horizontal scan. The intersection of the scans is identified by the position of the mauve slice navigator. Adjust the position of the Caliper and place the white horizontal lines of the Caliper ends on the anterior and posterior surfaces of the cornea. The measurement is in micrometers. See Figure 8-37 for the correct position of the Caliper and the proper placement of the calipers.

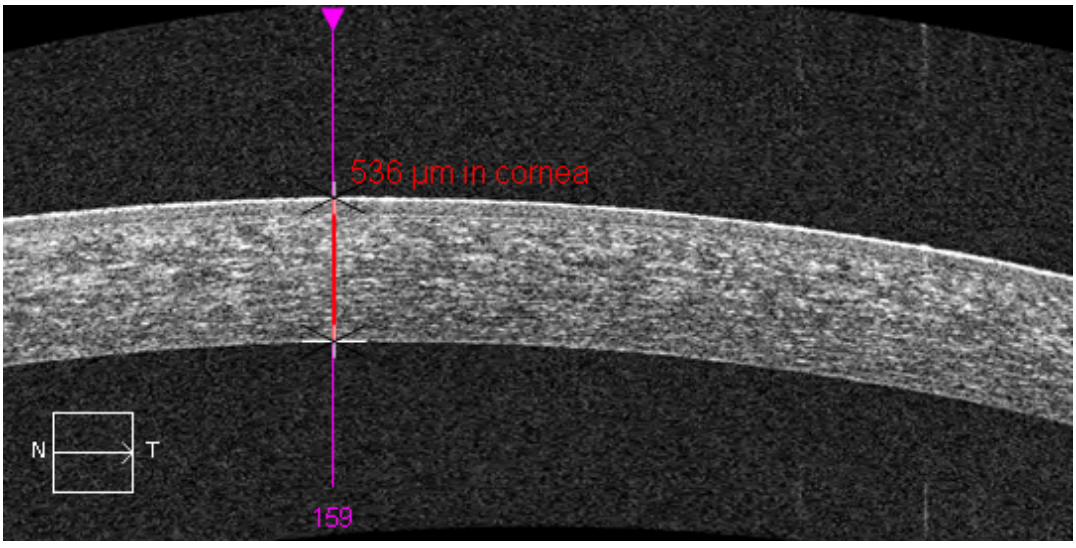


Figure 8-37 Positioning the Caliper

NOTE: Vertical distances on the tomogram reliably show tissue thickness and tissue refractive index. Horizontal distances cannot be measured quantitatively on these tomograms. When applied to Anterior Segment scans, the Ruler measures only vertical distances, with the scale factor set appropriately for measurements within the cornea.

NOTE: The Ruler is calibrated for measuring corneal tissue only, based on the refractive index of the cornea. It is not calibrated for other tissue types.

NOTE: The Anterior Scan Cube 512x128 is initially be displayed in the High–definition mode. Click the Show/hide high–resolution images button to allow scrolling through the cube images or move a slice navigator to a different slice.

NOTE: For the Anterior Segment 5 Line Raster scan, only the ruler and reverse grayscale buttons are available.

Angle Measurements

Three analysis types allow you to measure the angles of the Cornea.

In HD Angle Analysis

This is the recommended analysis type for anterior angle measurement.

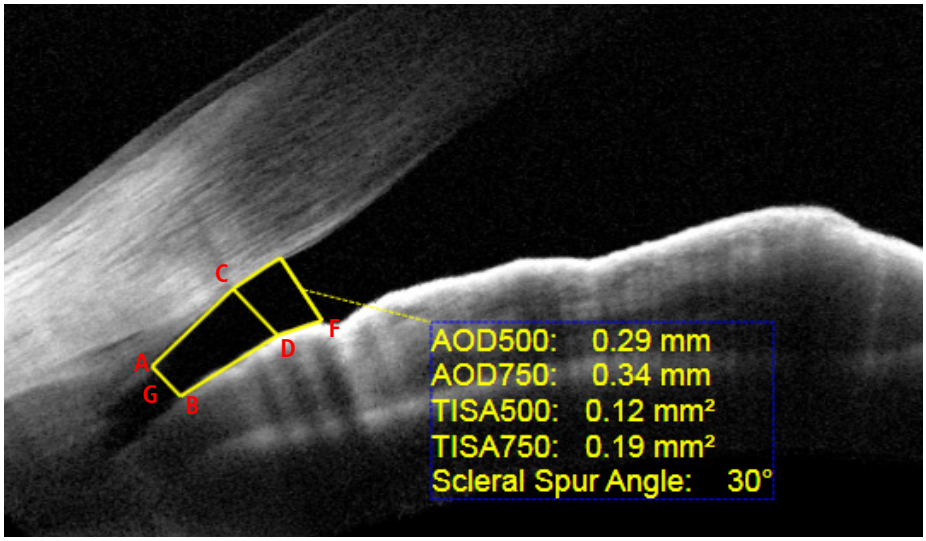


Figure 8-38 IC Angle Tool for HD Angle Scan

Abbreviation	Measurement
AOD500	Angle Opening Distance at 500 mm: Distance between C and D.
AOD750	Angle Opening Distance of 750mm: Distance between E and F.
TISA500	Trabecular Iris Space Area 500 (mm^2): The area of the polygon defined by the sides forming a circuit through points A,C,D, and B.
TISA750	Trabecular Iris Space Area 750 (mm^2): The sum of the areas of the two quadrangles defined by the sides A, C, D, B, and C, E, F, D.
SSA	Scleral Spur Angle: This is a measure of the angle formed by CAD, that is, the angle measured at the conjunction of lines CA and AD. Note that line AD, which is not shown in Figure 8-38, is the line connecting the Scleral Spur (point A) to the AOD 500 iris endpoint (point D).

Click the **Add Left IC Angle** button or **Right IC Angle** button to place the left or right iridocorneal angle tool on the image.

The iridocorneal angle tool is a trapezoid that can be moved and adjusted to graphically display angle opening distance (AOD) at 500mm and 750mm, trabecular iris space area at 500mm and 750mm, and sclera spur (SSA) angle. A table based on the dimensions of the trapezoid is displayed with values for the AOD 500 and 750, TISA 500 and 750, and SSA parameters.

Move the pointer to any line on the trapezoid, and then drag the tool to an area of interest. Move the pointer to the end of any line on the trapezoid until it changes to a yellow circle, and then drag the end.

Example:

1. Identify the scleral spur and place point A of the IC Angle Tool at the scleral spur.
2. Adjust point C (AOD 500 corneal endpoint) to touch the corneal endothelium.
3. Adjust point E (AOD 750 corneal endpoint) to touch the corneal endothelium.
4. Adjust point F (AOD 750 Iris Endpoint) to touch the iris.
5. Adjust point D (AOD 500 Iris Endpoint) to touch the iris.
6. Adjust point B (Scleral Spur Iris Endpoint) to touch the iris.

In Anterior Chamber Analysis

1. Select **Add Left Angle Tool** or **Add Right Angle Tool** above the main viewport of the Anterior Chamber Analysis screen.
2. Place point A of the Angle Tool at the scleral spur.
3. Adjust point B to touch the corneal endothelium.
4. Adjust point C to touch the iris. See Figure 8-39.

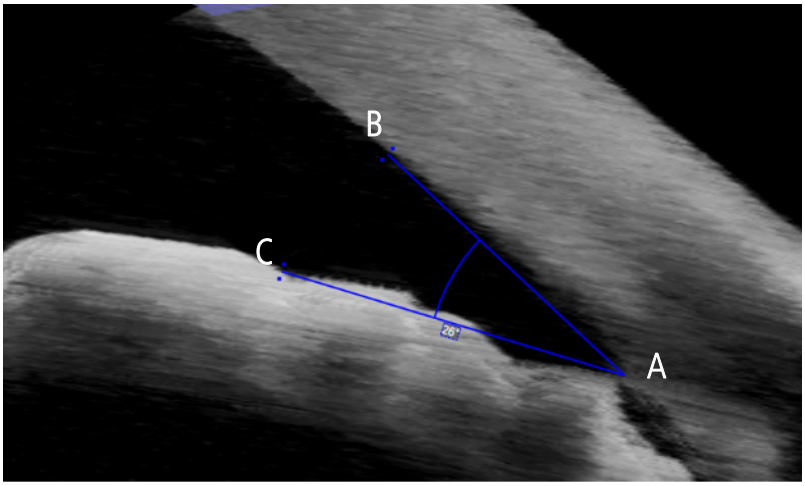


Figure 8-39 How to apply the Add Angle Tool

The Anterior Chamber Angle measurements provided by CIRRUS HD-OCT are not intended to be a substitute for gonioscopy, which is the current reference standard for evaluating the anterior chamber angle configuration. For example, during gonioscopy, end users can view the ACA through a mirror/prism under dynamic conditions, and can examine the angle over the full extent. CIRRUS HD-OCT provides an optical image of the angle as represented (and analyzed) by the software at a single location.

In Wide Angle-to-Angle Analysis

In addition to providing a wide view image of the anterior chamber, angle tools and calipers are provided with the **Wide Angle-to-Angle Analysis** to allow angle measurement as shown in Figure 8-28.

Specialized and Integrative Visualization Tools

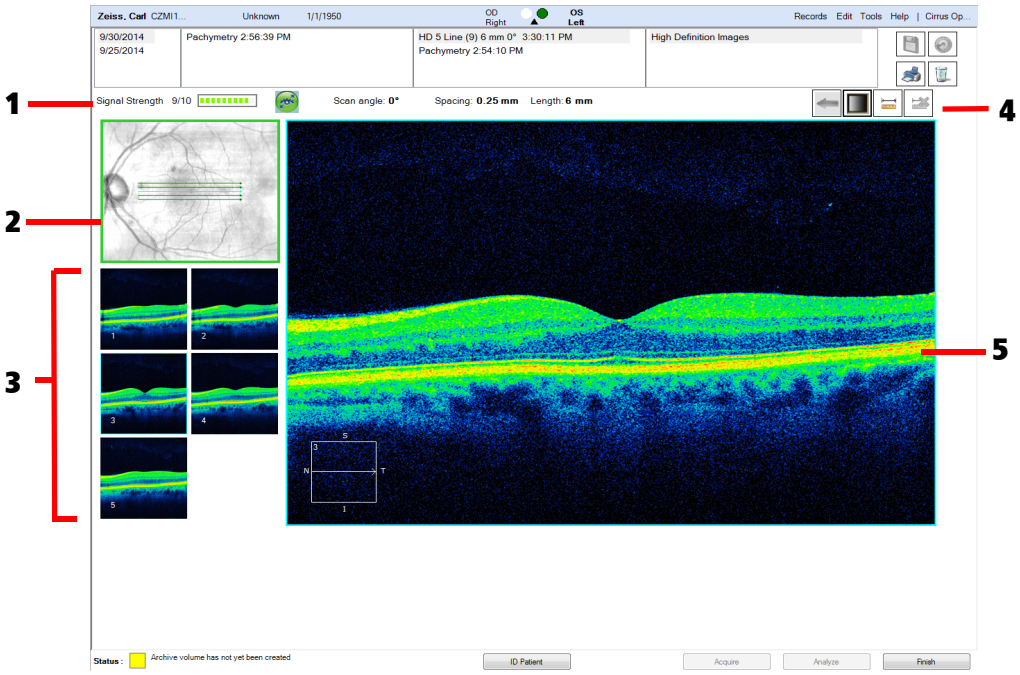
High Definition Images Analysis

For all raster scans, **High Definition Images** is the only available analysis.

When you select a high-definition raster scan from the **Analysis screen** scan list, the High Definition Images analysis for that scan is automatically displayed.

The High Definition Images analysis screen displays the following:

- Signal strength, scan length, scan angle, line spacing, and image tools
- A fundus image with an overlay showing the location of the scan lines
- For multi-line scans, thumbnails of the scan line images
- A single larger image of the selected scan line for HD 1 Line 20x scans



1 Scan information
2 Fundus image with scan lines overlay
3 Thumbnail images of scan lines
4 Image tools for displayed scan line
5 Display of selected scan line

Figure 8-40 High Definition Images Analysis for HD 5 Line Raster Scan

Tracking

If the scan used a previous scan for tracking, the green previous scan information icon is shown and the display previous scan button is available. Move the pointer to the previous scan information icon to display the previous scan information. Click the previous scan button to switch to the tracking scan, and click it again to switch back to the current scan.

EDI

If EDI was used to acquire the scan, the note "Acquired using enhanced depth mode" is displayed on the screen.

NOTE: The enhancement process combines data from multiple line scans. Registration of these line scans may result in reduced data at the edges of the images, which may show up as a thin, darker region with a sharp edge. This is a natural result of the enhancement process, but should only occur at the extreme edges of the image.

NOTE: By default, all raster line scans are displayed in grayscale. You can change the display to inverted grayscale or color using the change display mode button . You can also make adjustments to image brightness and contrast by using the Brightness/Contrast menu option available when you right click on the displayed larger scan image.

Change the Displayed Scan Line

When you select High Definition Images analysis for multi–line scans, the scan lines are displayed on the fundus image with the middle scan selected and displayed in the larger image window. The selected line on the fundus image, corresponding large displayed image, and thumbnail are all highlighted blue. For all multi–line scans, the scan lines on the fundus image are green.

To change the line displayed in the larger viewport, do either of the following

- Click the scan line thumbnail of interest.

  or
- Click the scan line of interest on the fundus image.

NOTE: For HD 5 Line scans, all thumbnails are visible on the screen.

Image Display Options Buttons

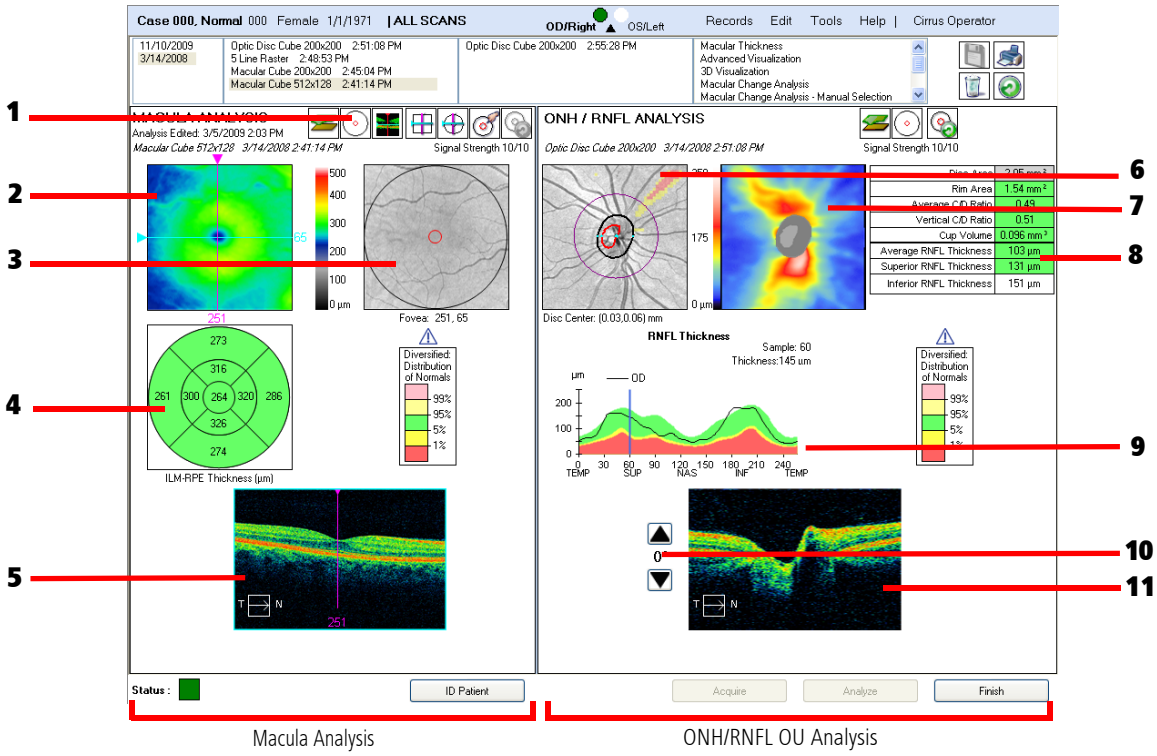
The following display options buttons can be found above scan image on The High Definition Analysis screen.

Image Tool	Use to	Do this
	Display either the previous image used to track the current image (left arrow) or the current image (right arrow)	Click the button to switch between the two options.
	Change the display mode of the scan line image: grayscale, inverse, color	Click the button to sequence through the three options.
	Measure distances between image features	• Click the button, and then click again to place the caliper. • Drag the cross-hair at either end of the caliper line to shorten, lengthen, or rotate it. • Drag the caliper line to move it.
	Delete selected caliper	Select a caliper and click the button.

Right-click the image to bring up additional menu options.

Single Eye Summary

The **Single Eye Summary** Analysis combines data from the Macula 512x128 or 200x200 Cube Scan and the Optic Disc 200x200. For inclusion, the data for both scans must have been taken that day. You can also manually select the second exam, which may be from the same or different date (see "Manual Selection" on page 8-12).



1 Show/hide fundus lines icon
2 Macular Thickness Map
3 OCT fundus image
4 ETDRS grid for macular thickness with normative data comparison
5 Slice through cube front
6 OCT fundus with optic disc and cup outlines and RNFL thickness deviation color coding
7 RNFL thickness map with optic disc and cup masks
8 Table includes RNFL and optic disc parameter with normative data comparison
9 RNFL thickness graph with normative data
10 Control to choose angle of spoke extracted
11 4 mm B-Scan extracted from radial spoke

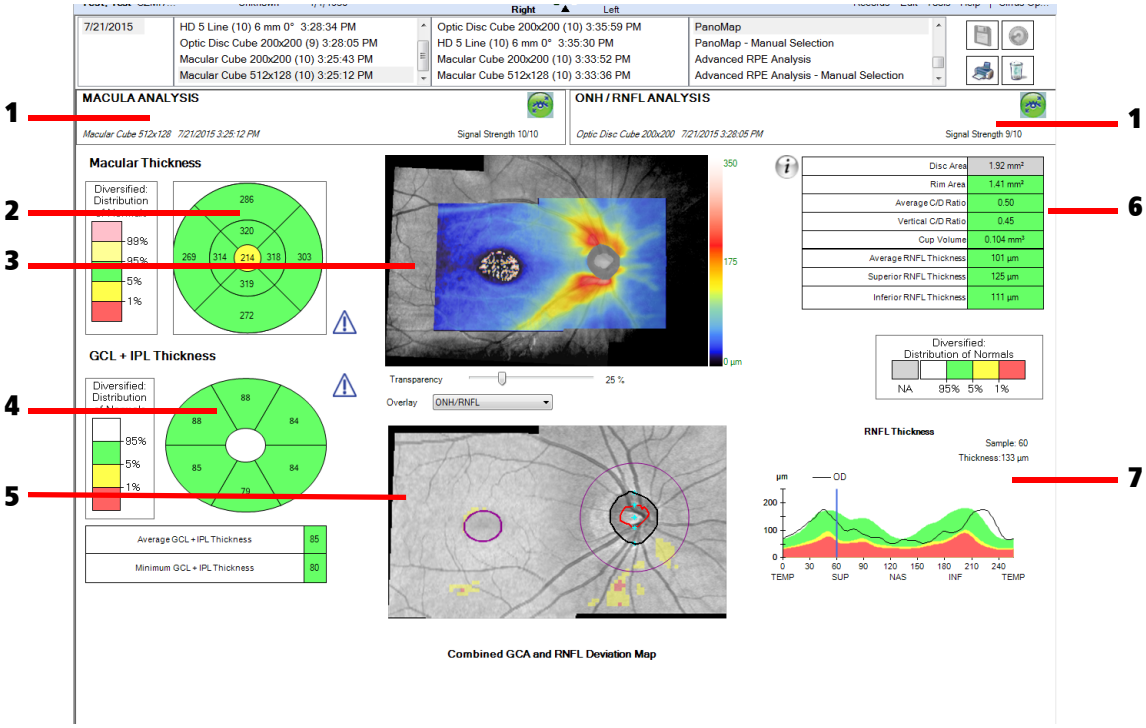
Figure 8-41 Single Eye Summary Analysis

The Single Eye Summary screen provides the following interactivity:

- Navigate through the OCT B-scans (macula and ONH).
- Toggle between Macula B-scans in the same window.
- Toggle between the Macula Cube B-scans and HD Cross Hair scans in the same window.
- Reset fovea location, which will update the data table and the ETDRS grid thickness measurements.
- Reset peripapillary RNFL circle location, which updates the RNFL and ONH analysis.
- Turn on and off the segmentation lines.
- Turn on and off the disc and cup boundaries and fovea indicator.

The Panomap

The Panomap Analysis integrates data from the Macular Thickness Analysis, RNFL and ONH Analysis and the Ganglion Cell OU Analysis to provide a wide–field perspective for comprehensive posterior segment analysis.



1 Information about the macular cube and optic disc cube used for the analysis
2 ETDRS macular thickness grid with normative data comparison
3 Registered macular and optic disc LSO Fundus images with overlay
4 GCL + IPL Thickness grid with normative data comparison
5 Combined GCA and RNFL deviation map
6 Table includes RNFL and optic disc parameters with normative data comparison
7 RNFL thickness graph with normative data comparison

Figure 8-42 PanoMap Analysis

For Posterior Segment analysis the LSO Fundus image is automatically registered from the selected scan type Macular Cube or Optic Disc and by default, overlays the composite image with an RNFL thickness map created with that data.

Three overlay options are available:

- ONH/RNFL thickness map (from either an optic disc cube or macular cube scan)
- GC+IP layer thickness map (from a selected macular cube scan)
- ILM–RPE layer thickness map (from a selected macular cube scan)

The default PanoMap view shows both an RNFL deviation map as well as a deviation map with GC+IP layer thickness.

The RNFL deviation map includes:

- the RNFL extraction circle

- outlines of the cup and disc
- Pixel shading of deviation from normal RNFL thickness

The GC+IP layer thickness deviation map includes

- the circle marking the fovea location
- pixel shading of the deviation from normal GC+IP thickness

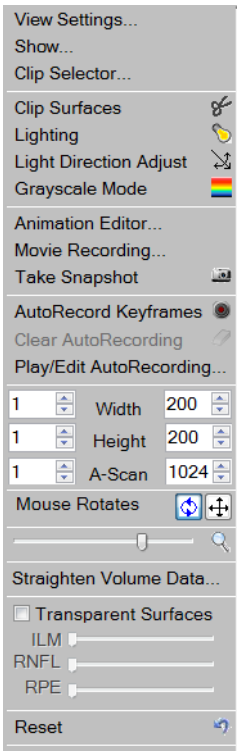
You can display or hide the disc and cup boundaries and fovea indicator.

You can also show the following grids, sector maps, and summaries:

- Macular Thickness ETDRS grid with sector average thickness, colored to correspond with normative data
- Sector map for GC+IP layer thicknesses, colored to correspond with normative data
- Table summary of parameters for Ganglion Cell + Inner Plexiform Layer average thickness and minimum thickness, colored to correspond with normative data
- Table summary of parameters for ONH and RNFL average thickness, Superior RNFL Thickness and Inferior RNFL Thickness values, colored to correspond with normative colors

3D Analysis

Select **3D Visualization** from the list of available analyses. The following **3D Visualization** screen appears.



3D Menu

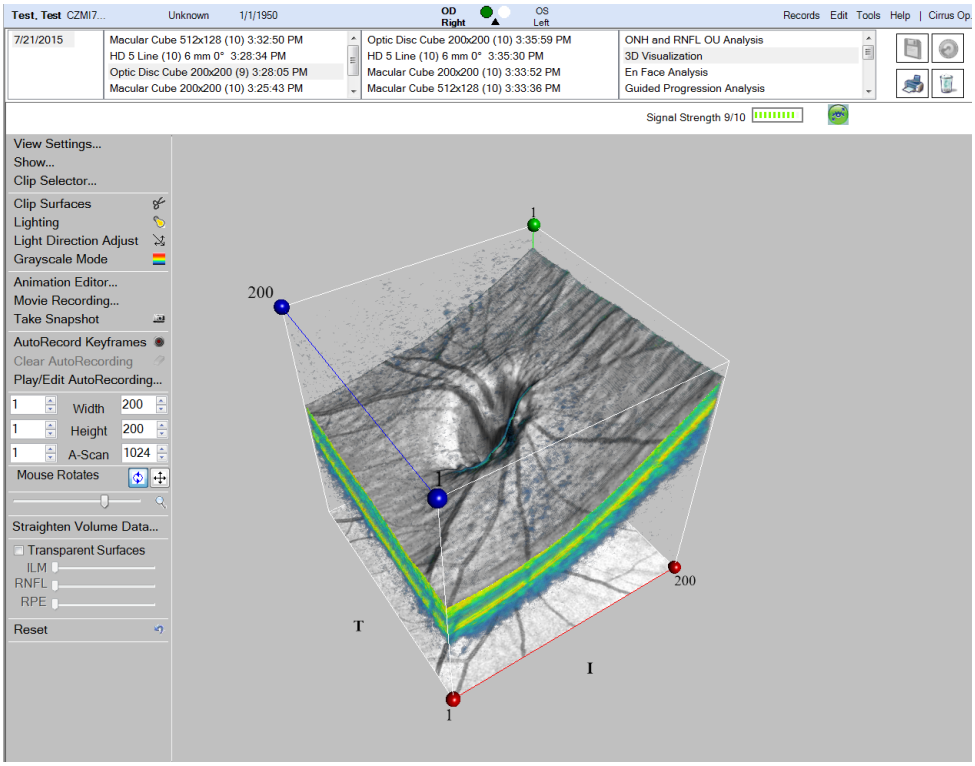


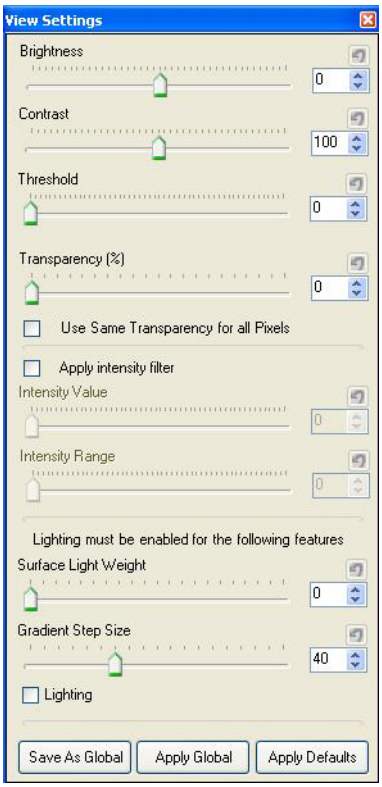
Figure 8-43 3D Visualization screen

The image above depicts the default view. The cube boundaries are shown with white lines. Labels indicate the Nasal (N), Superior (S), Temporal (T), and Inferior (I) sides of the

cube. The red, green, and blue spheres can be dragged along the matching colored lines to define slice planes.

The default setting for the mouse is to rotate the image. You can zoom in or out using the mouse scroll button.

The 3D Menu appears on the left side of the screen. An enlarged image of the menu is shown at left. The following functions are available in the menu.



View Settings

Clicking the **View Settings** button displays the dialog shown at left.

The **View Settings** dialog allows you to make the following adjustments and options:

- Sliders for **Brightness**, **Contrast**, **Threshold**, and **Transparency (%)** to adjust the tissue image appearance. The settings you apply are a matter of preference, though the default settings may serve as a useful starting point for both color and black and white images. Click **Apply Defaults** to return all display parameters to default settings.

  The **Threshold** slider allows the user to remove darker tissue in the image. For example, setting the threshold to 50 displays only the tissue that has an intensity value of more than 50. This enables the user to filter out parts of the image that are not of interest.
- **Use Same Transparency for all Pixels**: The default setting is unchecked. This setting uses high transparency for darker pixels and low transparency for brighter pixels. These settings enables the user to see through darker tissue. The slider reduces or increases the transparency for all pixels by the same percentage. For example: setting the slider at 50% sets all pixels to 50% of their original value.

  When **Use Same Transparency for all Pixels** is checked, all pixels will share the same transparency value regardless of grayscale value. At slider position 0%, all pixels are completely opaque. At slider position 100%, all pixels are completely transparent.
- **Apply Intensity Filter:** Check this checkbox to view a specific tissue intensity and range. When this checkbox is checked and **Greyscale Intensity Range** is set to 20, only tissues with intensity values from 80 to 120 are displayed.
- **Lighting**: Check this checkbox to change the lighting of the image. By default, the light source for the volume data is internal. Each pixel emits its own light like a light bulb. When the **Lighting** checkbox is checked, the external light source can be changed so each pixel emits less light and more light comes from an outside light source. This action yields a more solid appearance. The **External Light** slider increased the external light source and decreases the internal light of the volume.

At any time you can select one of the buttons at the bottom of the dialog:

- **Save As Global**: Saves your changes and remembers them for all subsequent exams. It does not save the exam, just the settings.
- **Recall Global**: Restores previously saved Global settings.
- **Apply Defaults**: Restores the Default settings.

NOTE: The Save As Global function in this dialog does not save the exam. You must use the Save Exam icon at the top of the screen to save the settings for the exam.

Show Settings

Click Show... in the Menu to display the Show Settings dialog below.

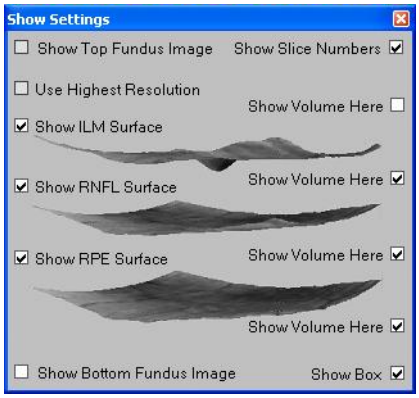
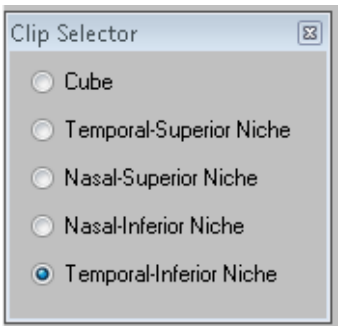


Figure 8-44 Show Settings Dialog

Use the checkboxes to show and hide surfaces and the volumes between or below surfaces. You can show or hide the cube boundary lines, and show or hide the view from the top or bottom of the box. The default settings are shown in the figure above.



Clip Selector

Clip Selector allows you to select the whole cube or one of the four niches of the cube. Once you select a niche, move the colored spheres to cut into the corner to the desired depth. Figure 8-45 is an example of a niche cut.

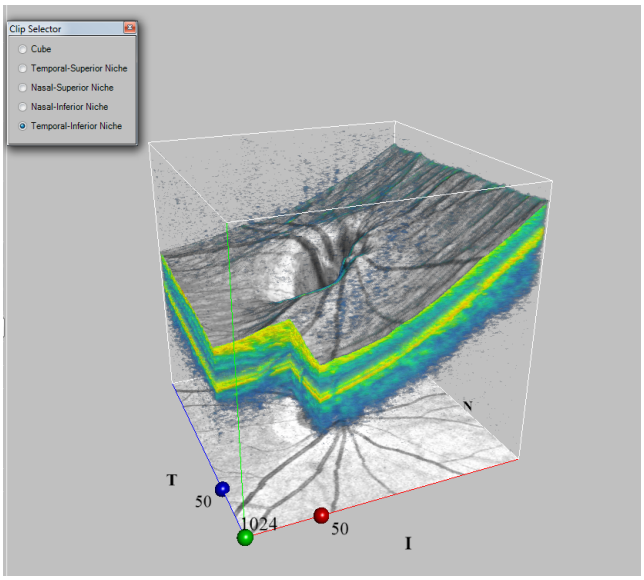


Figure 8-45 Niche Cut

Clip Surfaces

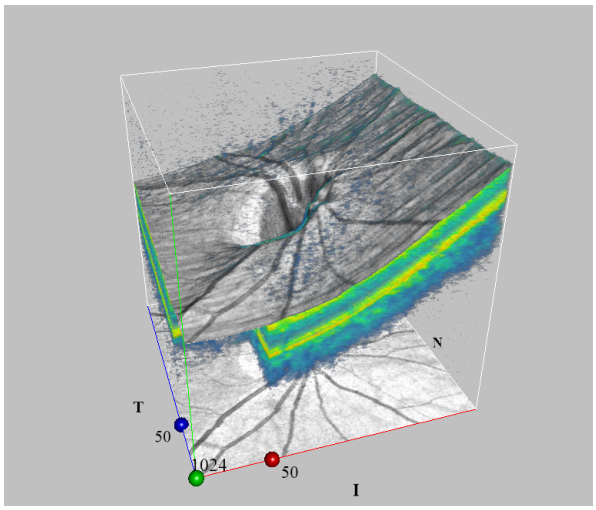
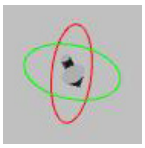


Figure 8-46 Clip Surfaces

Clip Surfaces, an on/off toggle button, lets you select which plane of tissue to clip or cut away. The blue, red, and green spheres can be dragged along the matching colored lines to define the clipping plane.

Lighting

The Lighting button is the same as the Enable Lighting function in the View Settings dialog.



Light Direction Adjust

To adjust the light direction, grab the red and green spheres with the mouse and move the mouse left to right. The arrow icon indicates the light source direction.

Greyscale Mode

Use this button to toggle between color and grayscale.

Animation

There are three options for creating animations: Animation Editor, Movie Recording, and AutoRecord Keyframes. These options are described below.

Animation Editor

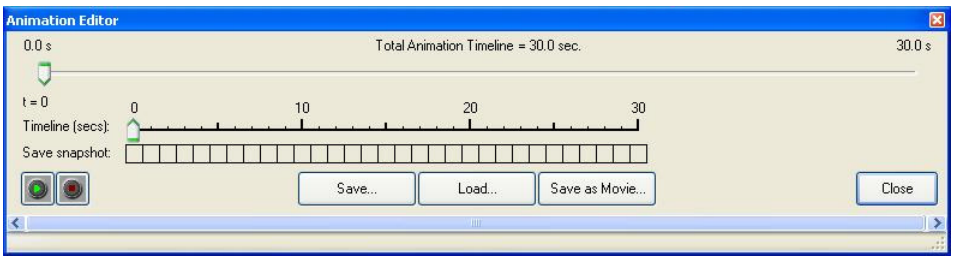
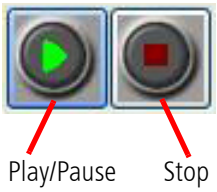


Figure 8-47 Animation Editor Dialog

The Animation Editor provides the smoothest motion of the 3 animation options. You can capture up to 30 seconds of animation in multiple segments.

To Record:

1. Click the first box in the **Save snapshot** timeline.
2. Perform your first activity. Examples of activities: moving, rotating, slicing.
3. Click one of the boxes in the **Save snapshot** timeline to define the length of time for the activity. The box becomes highlighted in green. You can deselect any box by clicking it again.
4. Perform your next activity.
5. Repeat Step 3 to define the length of time for the second activity.
6. Repeat Steps 4 and 5 until you have completed your activities.
7. When you have completed all activities, you can drag the timeline pointer to see snapshots at any point in the timeline.



To Play and Save:

1. Click the **Play/Pause** button to play back and review your animation.
2. To pause or resume play, click the **Play/Pause** button. Both the top animation and the timeline scroll bars move as the animation is played back.
3. To stop playback, click the **Stop** button.
4. If you want to make changes to the animation, start over from the first step.
5. To save your recorded animation, click **Save** or **Save as Movie**:

   Save: saves the animation in a CIRRUS–specific format, which can only be viewed using a CIRRUS HD-OCT Instrument or CIRRUS Review Software.

   Save as Movie: saves the animation in a format that can be viewed with standard movie players, such as Windows Media® Player or QuickTime® Player.

Play back any animations previously saved in CIRRUS format by clicking **Load**. You are prompted to select the animation. Double click to play the desired file.

Close the Animation Editor by clicking the **Close** button.

Movie Recording

Use the **AVI Recording** feature to record multiple activities (moving, rotating, slicing) automatically. Movies recorded with this feature are saved in a format than can be viewed with standard movie players such as Windows Media Player or QuickTime Player.

To record a movie:

1. Click the **Record** button to start recording.
2. Perform all desired activities: moving, rotating, slicing.
3. Click the **Record** button again to finish recording. You are prompted to save your file.
4. Browse to the folder where you want to save your file. Name your file and click **Save**.

To play back a movie:

1. Click the **Play** button.
2. Browse to the location of the movie you want to play, select it, and click **Open**. The movie will start to play in your default movie viewer (Windows Media Player or QuickTime Player).
3. Click **Close** to exit the **Movie Recorder** dialog.

AutoRecord Keyframes

The **AutoRecord Keyframes** is another method for creating animations and saving them in CIRRUS–specific format. The feature generates snapshots automatically at specific intervals, similar to how it is done manually with the **Animation Editor.**

To record:

1. To start recording, click **AutoRecord Keyframes**. The button automatically changes to show that recording is in progress.
2. Perform activities (rotating, moving, slicing). A message appears on the screen that shows the feature is auto-recording.
3. Click **Stop AutoRecord** to finish recording the animation. Two buttons become active: **Clear Auto Recording** and **PlayEdit AutoRecording**.

To play back, edit, and save:

1. Click **Play/Edit AutoRecording** to play back or edit what you recorded. The **Auto Generated Animation** dialog appears.

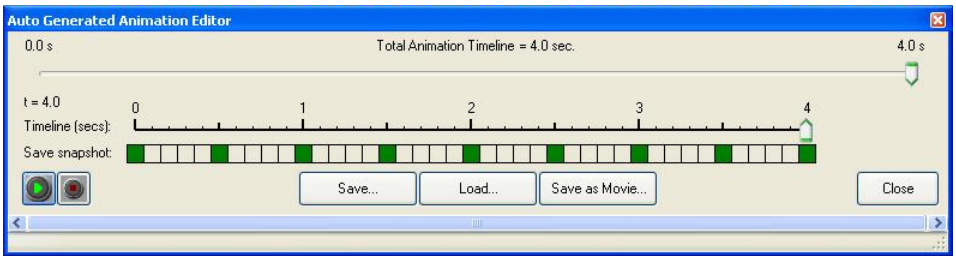


Figure 8-48 Auto Generated Animation Editor

2. See the Animation Editor section for details on how to play, pause, stop and save animation.
3. By default this feature adds a newly–recorded animation to the existing animation from the current session.
4. Click **Clear AutoRecording** to start a new animation.
5. Click **Close** to exit the **Auto Generated Animation** dialog.

Take Snapshot

Take Snapshot captures a screenshot of the image currently displayed. You are prompted to save the image to a file. You may save as bmp, jpg, or png.

Width, Height, and A–Scan Adjustments

You can manually adjust the red (Width), blue (Height), and green (A–Scan) sphere positions by clicking the up/down arrows, or by typing the desired position in the Width, Height, and A–Scan fields. These fields may provide finer control of the sphere positions.

Mouse Rotates/Mouse Translates

Two buttons allow the user to set the left mouse to either rotate or translate the image on the screen.

Zoom

Use the slider to zoom in or out on the image.

Straighten Volume Data

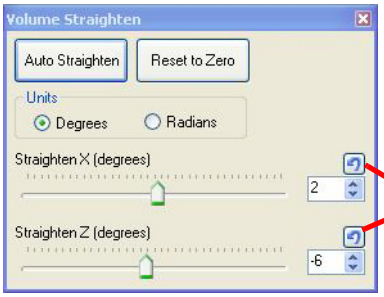


Figure 8-49 Volume Straighten Dialog

This function allows you to adjust the surface of the scan to be horizontal in those cases where the retina is highly tilted. Click **Auto Straighten** to automatically correct the image. The slider controls, number field, and up/down arrows are used to manually correct the image by adjusting the X and Z axes. Click **Reset to Zero** to undo your corrections. The reset buttons (see figure above) located above each field allow you to reset X and Z axes separately. Figure 8-50 illustrates before and after Auto Straighten has been applied. The left figure shows a tilted image, and the right figure shows the straightened image.

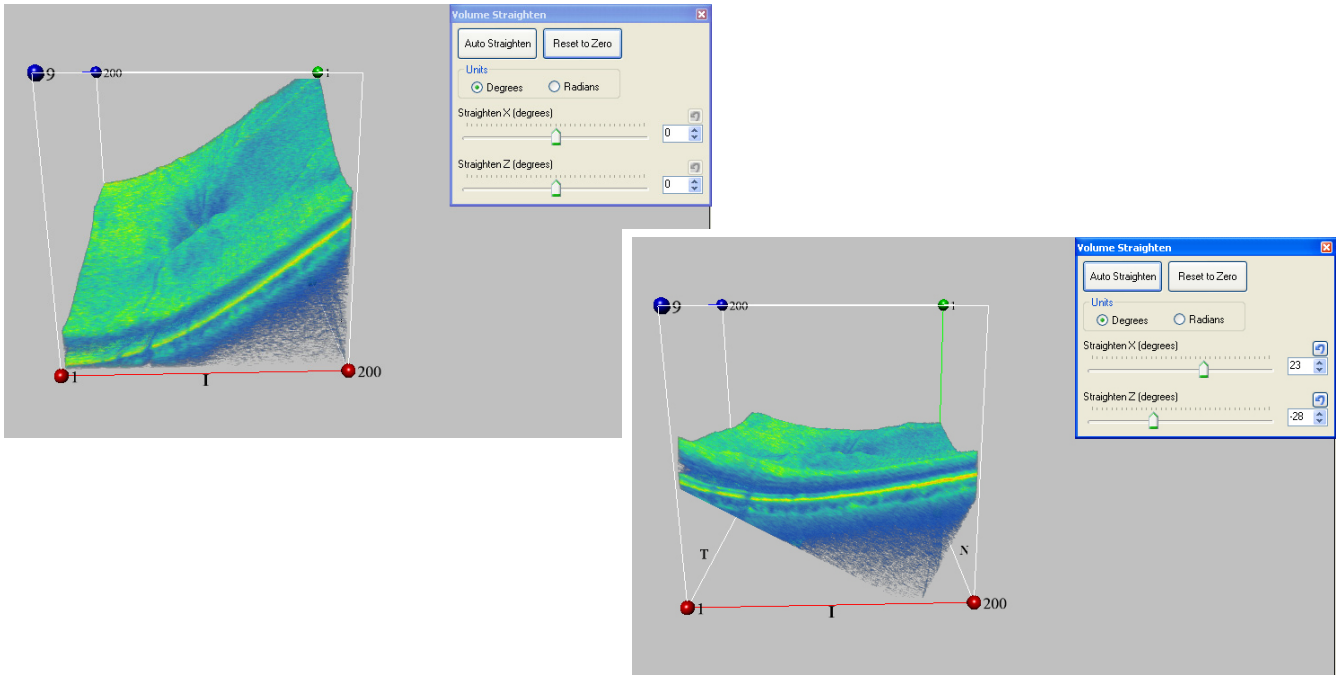
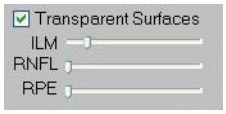


Figure 8-50 Volume Straighten, Before (left) and After (right)

Transparent Surfaces



Checking the **Transparent Surfaces** checkbox allows you to view ILM, RNFL, or RPE as transparent surfaces. Use the sliders to adjust the transparency level.

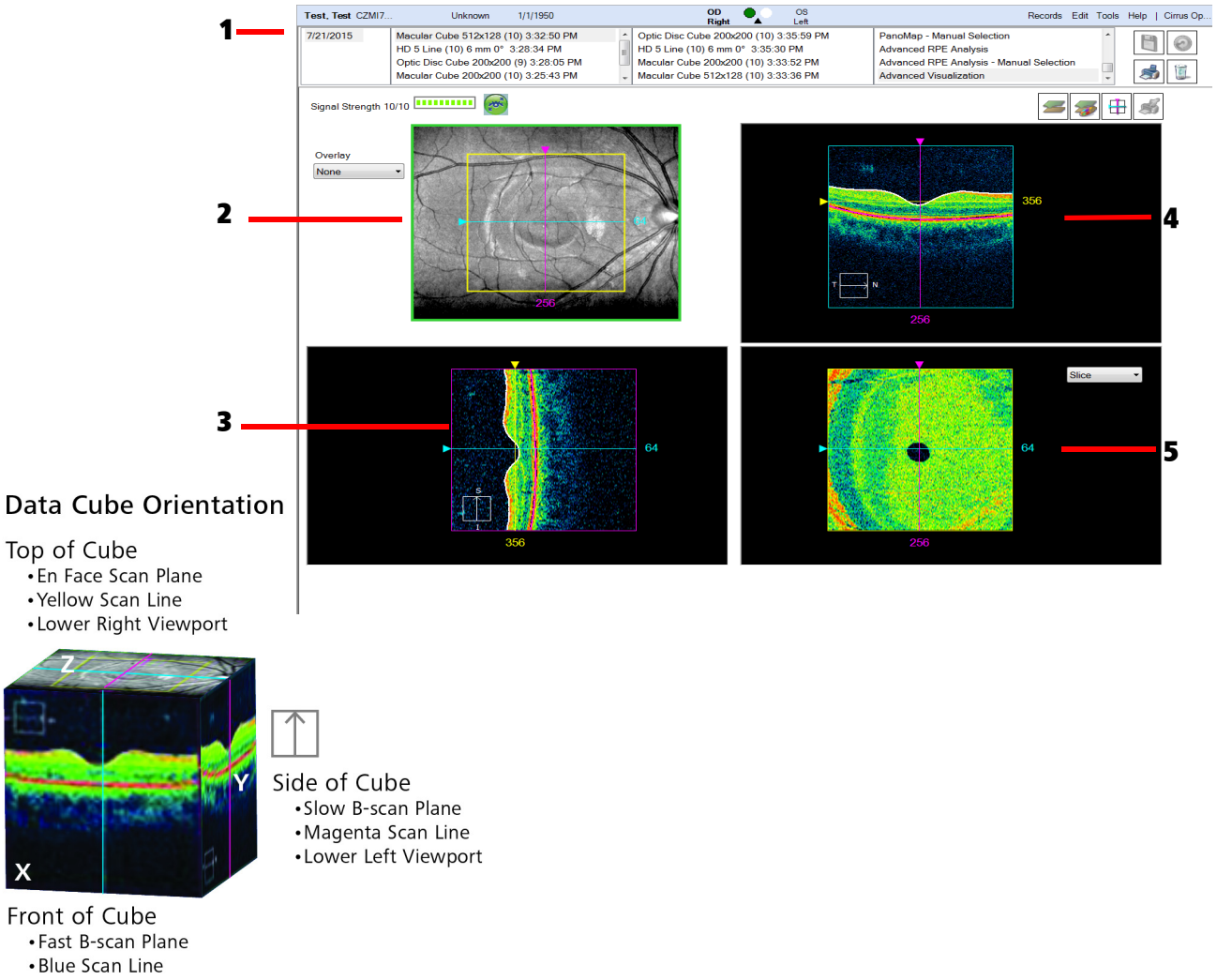
NOTE: When you use Transparent Surfaces, the image will have lower resolution.

Reset

Click **Reset** to return the image to its default settings.

Click **Save Exam** to save the 3D "View Settings" on page 8-61 for this exam.

Advanced Visualization Analysis



Data Cube Orientation

Top of Cube
- En Face Scan Plane
- Yellow Scan Line
- Lower Right Viewport

Front of Cube
- Fast B-scan Plane
- Blue Scan Line

Side of Cube
- Slow B-scan Plane
- Magenta Scan Line
- Lower Left Viewport

1 Exam (date), OD and OS scan lists for selected exam, analysis list
2 Fundus image with scan cube overlay
3 Y slice through cube side
4 Z slice or slab through cube top
5 X slice through cube front

Figure 8-51 Advanced Visualization Analysis

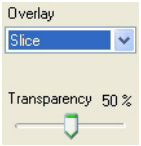
Available for Macular Cube 512x129, Macular Cube 200x200 scans, and Optic Disc Cube 200x200 scans, the **Analysis screen** for **Advanced Visualization**, Figure 8-51, presents an interactive multi–planar reformat (MPR), which enables you to view image cross–sections through three dimensions. The example above is for a **Macular Cube 512x128**. The upper left viewport shows the saved Fundus image with an optional *en face* scan overlay. The other three viewports show cross–sectional scan images in three planes. Thinking of the data as a cube, the viewports show the data in planes parallel to the side of the cube (Y plane, lower left viewport), the front of the cube (X plane, upper right viewport), and the top of the cube (Z plane, lower right viewport), as shown in Figure 8-51 and Figure .

The viewports are interactive: Click and drag the triangles or click a scan viewport and use the mouse scroll wheel to "move through" the active plane of the viewport; you will see the resulting cross–sections update simultaneously in the other viewports. This functionality enables you to quickly search through the data cube and stop when you see an area of interest.

Retinal Layers Automatically Detected and Displayed

Cube scan analyses incorporate an algorithm to automatically find and display the inner limiting membrane (**ILM**) and the retinal pigment epithelium (**RPE**). CIRRUS also calculates and presents a layer called **RPEfit**, which is a representation of a normal parabolic RPE for this eye, based on the retina's overall curvature. You can use the RPEfit line to view variations from normal in the actual RPE contour.

In the scan images, which are cross–sections (slices), the layers appear as colored lines that trace the anatomical feature on which they are based. The ILM is represented by a white line, the RPE by a black line, and the RPEfit line is magenta in color. These lines are also known as segmentation lines. You can customize the colors used to display each of these lines, as explained below. These layers serve as the basis for the macular thickness and volume measurements ("Macular Thickness Analysis" on page 8-6), the ILM and RPE layers are presented in their entirety as three–dimensional surface maps.



Fundus Image Overlay Options

Use the **Overlay** drop–down menu to select which overlay to use on the fundus image: **None** (default), **Slice**, **OCT Fundus**, **Slab**, **ILM – RPE**, **ILM – RPEfit**, or **RPE – RPEfit.** The slice and slab options correspond to the *en face* image in the lower right viewport. (The options **ILM**, **RPE**, and **RPEfit** are variations of the slab. See "Slice and Slab Options" on page 8-70). You can adjust the associated **Transparency** slider from 0% (opaque) to 100% (fully transparent). The OCT Fundus option is the same overlay (*en face*) shown on the fundus image in the **Review** screen.

Slice and Slab Options

The lower right viewport, Figure 8-52, has a drop–down menu to select **Slice** (default), **Slab**, **ILM**, **RPE**, or **RPEfit**.

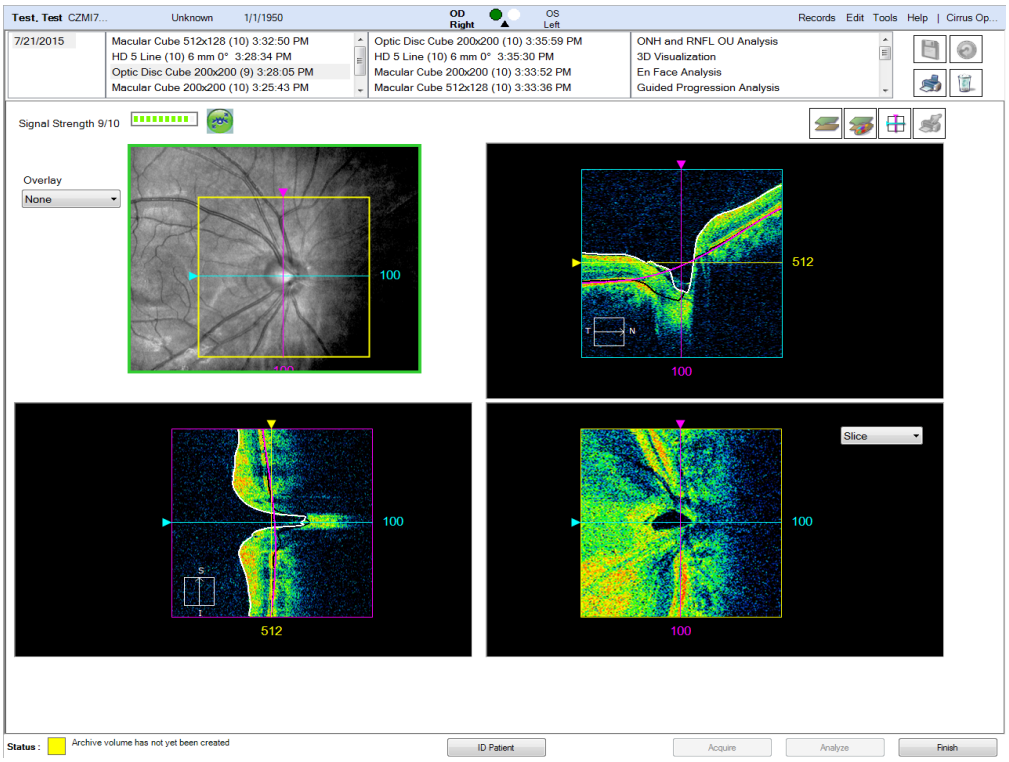
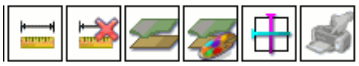


Figure 8-52 Analysis screen showing a Slab

When you select **Slab**, the other two scan viewports show two same–color dashed lines separated by a small distance. This separation is the slab thickness, which you can adjust in either of the other viewports by dragging the posterior line by its handle on the edge. Dragging the anterior line handle moves both lines of the slab together to reposition it in the scan image. The resulting slab image you see represents an average signal intensity value for each A-scan location through the selected depth of the slab.

The drop–down options **ILM**, **RPE**, and **RPEfit** are variations of the slab. When you select any of these, you view the slab (of selected thickness—you can adjust it as above) relative to the selected layer. For example, if you select **ILM** (Figure 8-52), a dashed line of the same color as the ILM appears posterior to it, and the resulting scan image appears in the lower right viewport (and in the scan cube overlay when **Slab** is selected there). You cannot raise the lower dashed line above the upper one, and the minimum separation is 2 µm.



Function Buttons in Advanced Visualization

The buttons shown on the left appear from left to right in the Advanced Visualization analysis, above the scan images at right. If you mouse over them, their function appears in the form of a tooltip.

- Caliper button: Click **Caliper** and then click and drag in a scan image or the fundus image to draw a straight line that measures distance between the start and stop points. The resulting measurement appears next to the line in micrometers.
  - You can select and adjust the lines you draw: click and drag an endpoint to adjust its placement (and the line length), or click and drag the middle of the line to move it as a whole.
  - Click **CaliperCaliper** again to create additional measurement lines.
  - These measurements are saved after you close the analysis and will appear on reports (printouts) you make while they are present.
  - **Delete Measurements** button: Click **Delete** to delete the currently selected measurement lines. You can select lines in more than one image at a time. To deselect a line, click anywhere on the same image but off the line.
- **Show/Hide Layers** button: Click **Layers** to hide or show the colored lines indicating the layers (ILM, RPE, and RPEfit).
- **Configure Layers** button: Click **Configure Layers** to open the **Layer Configuration Dialog**, Figure 8-53, where you can select the colors of the layers for ILM, RPE, and RPEfit, and whether to display them or not.

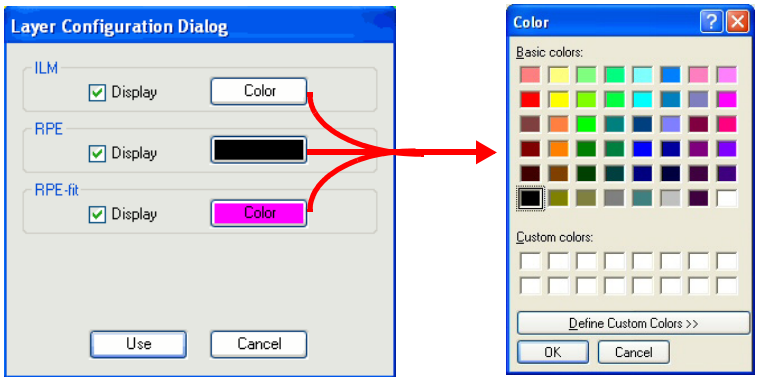


Figure 8-53 Layer Configuration Dialog and Color Picker

  - Click a **Color** button for ILM, RPE, or RPE–fit to open a standard color picker, where you can select a new color for that layer, or even define a custom color.
  - The layers with their **Display** checkbox selected appear in scan images for Advanced Visualization and Macular Thickness analyses for the scan you are viewing. Click to select or clear **Display** checkboxes as desired.

NOTE: Switching to a different scan or leaving the analysis screen causes the selected segmentation colors to default to the original colors.

-  **Center** button: Click **Center** to return the current slices to their default central positions.
-  **Tagged Images** button: Click the **Tagged Images** button to view and adjust which images are tagged for custom printing. This button is active when one or more images have been tagged for printing by selecting **Tag for print** from the right–click menu. (See "Advanced Visualization Report Options" on page 10-6.)

The **Advanced Visualization** screen also uses the image display options available by using the right mouse click. See "Advanced Export" on page 11-16.

Brightness/Contrast and **Color** adjustments apply simultaneously to all X, Y and Z slices on screen (in OCT viewports or as the fundus overlay). If two Z slabs are on screen, one as the fundus overlay and one in the lower right viewport, **Brightness/Contrast** and **Color** adjustments made on either slab will apply to both. Between the fundus image and its overlay, **Brightness/Contrast** and **Color** operate independently. Right–click one or the other to apply such changes. Some image display options function as a distinct display mode and that viewport or overlay remains in that mode until you click **Reset**, **Normal**, or select another mode.

For example, if you select **Brightness/Contrast** for one viewport, the brightness and/or contrast changes every time you click and drag your mouse over that viewport, until you select **Normal** or **Reset**. Note that selecting **Normal** would not reset the viewport to its initial brightness and contrast settings.

9 CIRRUS OCT Angiography

Overview

CIRRUS OCT Angiography (AngioPlex®) provides non-invasive, high quality images of the retinal and choroidal vasculature. Careful review of CIRRUS OCT Angiography scans should be carried out before accepting scanned images, as described in "CIRRUS OCT Angiography Acceptance Criteria" on page 7-7. Even after scan acceptance, it is recommended that, during CIRRUS OCT Angiography image analysis, you re-assess the possible impact of scan quality, segmentation errors, and decorrelation tails.

Angiography scan slabs can be acquired in 3x3, 6x6, and 8x8 mm, but only 3x3 mm and 6x6 mm scans include the additional metrics available. Montage Angio scan slabs can be acquired in 6x6 mm and 8x8 mm and analyzed in both. Additionally, ONH Angiography scan slabs can be acquired in 4.5x4.5 mm and analyzed. AngioPlex scans can be analyzed using the methods and metrics shown in Table 9-1. These methods are described in the sections which follow.

Scan Acquisition	Analysis	Additional Metrics Available
Angio Scan 3x3 / 6x6 / 8x8	OCT Angiography OCT Angiography Change OCT Angiography Change (*Manual*) En Face	Vessel / Perfusion Density Foveal Avascular Zone (FAZ) Applies to 3x3 mm and 6x6 mm scans only.
Montage Angio 6x6 / 8x8	Montage Angio Analysis	
ONH Angiography 4.5x4.5	OCT Angiography OCT Angiography Change OCT Angiography Change (*Manual*)	Perfusion Density / Flux Index

Table 9-1 CIRRUS OCT Angiography

CIRRUS OCT Angiography, Montage Angio, and ONH Angiography Analysis

The CIRRUS OCT Angiography Analysis screen (Figure 9-1), Montage Angio Analysis screen (Figure 9-2), and ONH Angiography Analysis screen (Figure 9-3) are used for the Angiography Analysis option in CIRRUS OCT.

For all CIRRUS OCT Angiography Analysis options (Angiography, Montage Angio, and ONH Angiography), the left side of the screen (1) displays pre-defined angiography slabs or "Presets" (and user-defineable or "custom" presets), which are arranged in 1 or 2 columns. The preset slabs for both Angiography, Montage Angio, and ONH Angiography are discussed in detail in "CIRRUS OCT Angiography Presets" on page 9-4.

For the CIRRUS OCT Angiography Analysis screen (Figure 9-1), the top-middle viewport shows the angiography OCT image while the top-right image shows the corresponding structure OCT enface image.

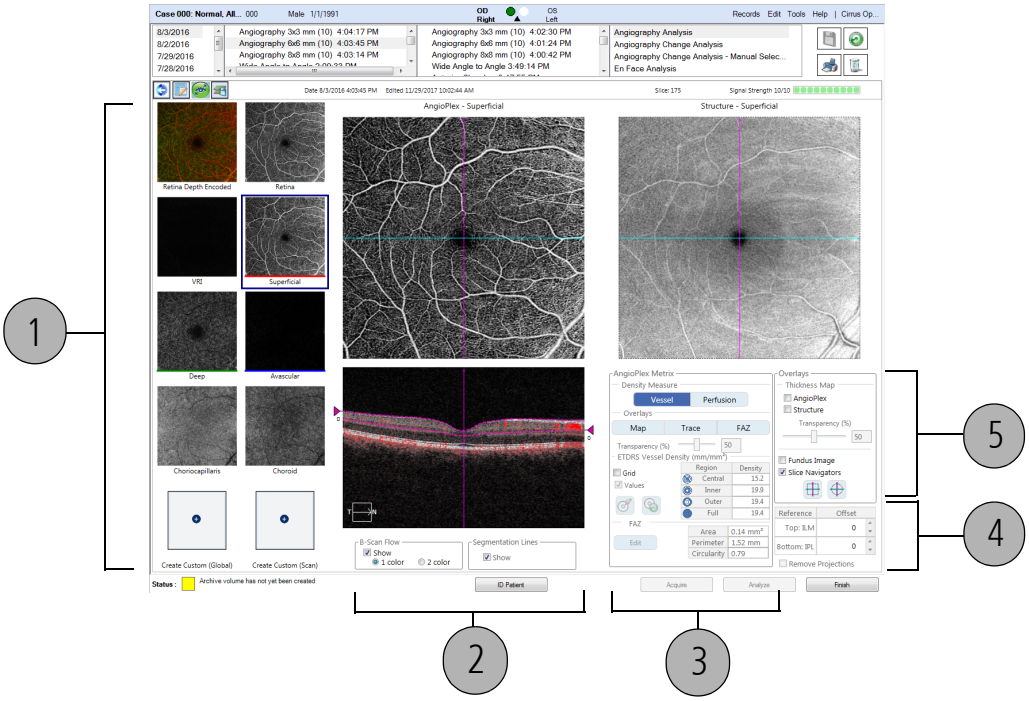


Figure 9-1 CIRRUS OCT Angiography 6x6 sample image with associated, selectable image views

For the Montage Angio Analysis screen (Figure 9-2), the middle viewport (2) shows the CIRRUS OCT Montage Angio image, while the middle-right viewport shows the individual panes of the Montage image and will change depending where you click the cursor in the middle viewport.

Finally, for the ONH Angiography Analysis screen (Figure 9-3), the top-middle viewport shows the ONH angiography image while the top-right image shows the structure image.

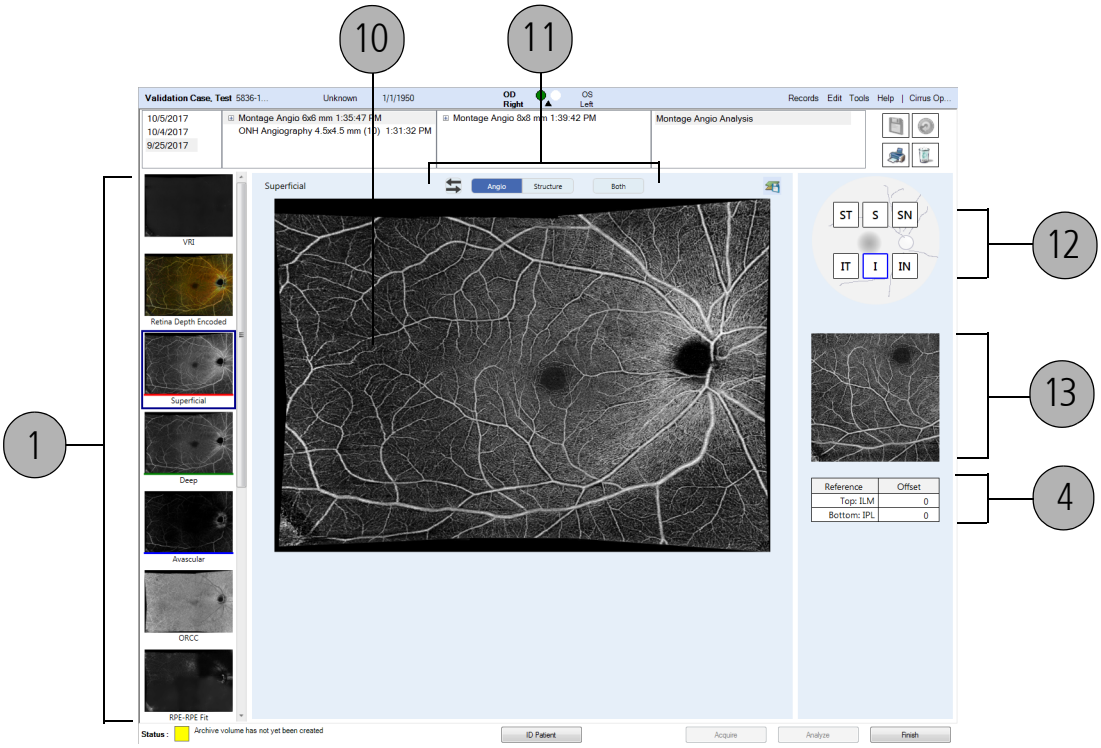


Figure 9-2 CIRRUS OCT Montage Angio sample image with associated, selectable image views

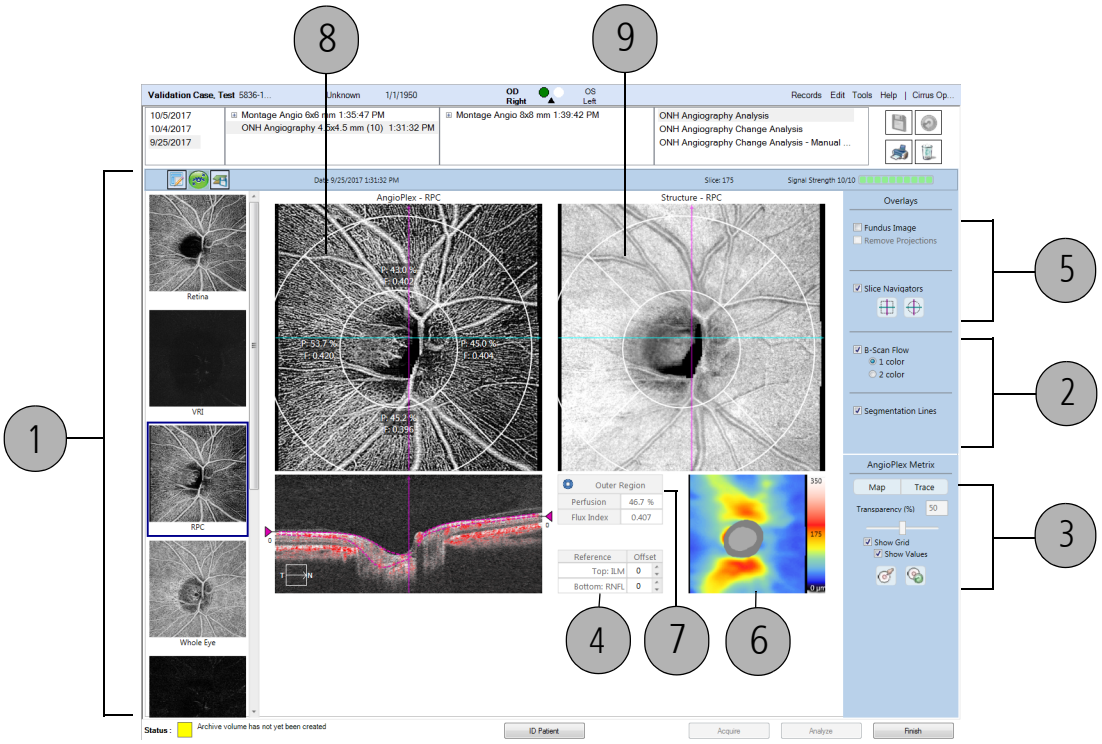


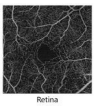
Figure 9-3 CIRRUS OCT ONH Angiography image with associated, selectable image views

1 CIRRUS OCT Angiography Presets

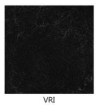
The CIRRUS HD-OCT Angiography and Montage Angio analysis screen includes 12 pre-defined angiography presets, which are the same. The CIRRUS HD-OCT ONH Angiography includes 4 predefined angiography presets. These slabs are discussed below. Larger images of each, and a further discussion of the algorithms used to define their boundaries, can be found in Table 9-4.


Retina Depth Encoded

- **Retina Depth Encoded**: This is a color encoded slab with different colors representing different layers (Red: Superficial; Green: Deep; Blue: Avasculature).
  NOTE: This preset is not available for ONH Angiography.


Retina

- **Retina:** This is intended to illustrate vasculature of the entire retina. The inner boundary is the ILM. The outer boundary is offset above the RPE by 70 µm to minimize the contribution of the hyper-reflective RPE.


VRI

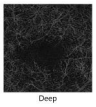
- **VRI:** This preset is designed to highlight neovascularization above the vitreoretinal interface (VRI), such as in proliferative diabetic retinopathy. The outer boundary is the ILM, and the inner boundary is offset above the ILM by 300 µm.


Superficial

- **Superficial**: Superficial retinal layer slab. The inner surface is the ILM layer segmented in the same manner as CIRRUS HD-OCT structural images, such as Macular Cube 512x128. The outer surface is an approximation of the inner plexiform layer (IPL), which is estimated by the following equation:

  $Z_{IPL}=Z_{ILM}+70\%*(T_{ILM-OPL})$

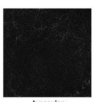
  Where Z_{IPL} is the boundary location of the estimated IPL, Z_{ILM} is the boundary location of the ILM, and $T_{ILM-OPL}$ is the thickness between ILM and the outer plexiform layer (OPL), which is estimated as discussed below.
  NOTE: This preset is not available for ONH Angiography.


Deep

- **Deep**: Deep retina layer slab. The inner surface is IPL as described above. The outer surface is OPL, which is approximated as:

  $Z_{OPL}=Z_{RPEfit}-110\ \mu m$

  Where Z_{OPL} is the boundary location of the estimated OPL, and Z_{RPEfit} is the boundary location of the RPE segmented in the same manner as CIRRUS HD-OCT structural images.
  NOTE: This preset is not available for ONH Angiography.


Avascular

- **Avascular**: The inner surface of the Avascular slab is the estimated OPL. The outer surface is the boundary between the inner and outer segment junctions (IS/OS), the position of which is estimated as:

  $Z_{IS/OS}= Z_{RPEfit}-70\ \mu m$

NOTE: The Avascular slab was constructed with the goal of bounding the parts of the retina that are expected to have no vasculature in normal anatomy. There are many situations for which there may appear to be bright patches or areas in this image that are not necessarily due to pathology, including:

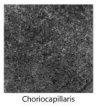
Errors in segmentation may cause there to be apparent vasculature. This is particularly common in the presence of geographic atrophy. Bright areas below the Bruch's Membrane are common in the presence of geographic atrophy due to the fact that the highly scattering RPE is missing. When this happens, the RPE segmentation can frequently fall into the choroidal areas and be irregular.

Because the boundaries of the inner layers of the retina are estimated rather than segmented, they may incorrectly include bright areas that could contain decorrelation tails or even actual vasculature.

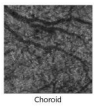
The brightness and contrast of the avascular layer is enhanced in order to assist in visualizing any potential abnormal vasculature, but this can also tend to emphasize both noise and weak decorrelation tail signals.

Exudates or migrated RPE may cause there to be artifacts in different layers. This issue should be uncommon in the outer retina, but it can occur.

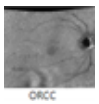
The segmentation and flow and intensity B-scans should be examined carefully if there is abnormal-appearing vasculature in the Avascular slab.
NOTE: This preset is not available for ONH Angiography.



- **Choriocapillaris**: The inner surface is 29 µm below the RPE-Fit and the outer surface is 49 µm below the RPE-Fit, therefore the slab has a uniform thickness of 20 µm.
  NOTE: This preset is not available for ONH Angiography.

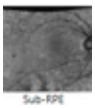


- **Choroid:** The inner surface is 64 µm below the RPE-Fit, which is segmented as described in "Advanced Visualization Analysis" on page 8-68. This is intended as an estimate of the Bruch's Membrane (BM). The outer surface is 115 µm below the RPE-Fit, therefore the slab has a uniform thickness of 51 µm.
  NOTE: This preset is not available for ONH Angiography.



- **ORCC:** The OCT Analysis uses a predefined Outer Retina to Choriocapillaris (ORCC) slab that covers the region between the outer retina and choriocapillaris layers. The ORCC slab uses a **Pixel** option that can calculate the pixel values or maximum pixel values. The ORCC preset is the default preset and is defined as follows:
  Top: OPL=RPE-Fit - 110 µm
  Bottom: RPE-Fit + 38 µm

  NOTE: This preset is not available for ONH Angiography.

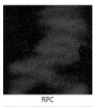


- **Sub-RPE**: The OCT Analysis uses a predefined Sub-RPE slab. The Sub-RPE slab uses a **Pixel** option that can calculate the pixel values or maximum pixel values. The Sub-RPE preset default Project type MAX project method is defined as follows:
  Top: RPE + 29 µm
  Bottom: RPE + 49 µm

  NOTE: This preset is not available for ONH Angiography.

- **RPE RPE-Fit**: The RPE to RPE-Fit preset uses the summation of pixel values as the default. The RPE RPE-Fit preset covers the region between the RPE to RPE-Fit layers.
  NOTE: This preset is not available for ONH Angiography.

- **Whole Eye**: This preset is intended to illustrate vasculature of the whole posterior segment that was scanned. There are no top or bottom reference layers.



- **RPC**: The Radial Peripapillary Capillary (RPC) preset performs a vessel perfusion measurement analysis for the RPC layer. The RPE preset is defined as follows:
  Top: ILM
  Bottom: RNFL

  NOTE: This preset is only available for ONH Angiography.

These slab / en face definitions should be considered reasonable starting points, especially for normal eyes, but the inner and outer boundaries can be offset by grabbing magenta lines and shifting them in the B-scans. Furthermore, the slabs will not appropriately illustrate the vasculature of interest if the segmentation has failed. In this case, a layer segmentation editor is available as a licensed feature for the user to edit the ILM and RPE boundaries.

As with the En Face analysis, you may create your own custom presets as follows:

- **Create Global Custom:** Specify a region of interest that, once created, is available for analysis for all scans.
- **Create Scan Custom**: Specify a region of interest that, once created, is available for analysis for a specific scan.

The custom slabs uses a **Pixel** option that can calculate the pixel values or maximum pixel values. These two custom options are described further in "Create Global Custom" on page 8-4 and "Create Scan Custom" on page 8-4 respectively.

You can use custom presets to choose an inner boundary and an outer boundary, and then shift them to visualize the vasculature between any of the defined layers.

2 B-Scan Settings

Based on the selected slab (Current View), allows you to step through the scan by dragging the segmentation lines, offsetting the outer and/or inner segmentation boundaries, in µm. Images generated using settings on this screen can be recorded using , which will allow you to save the image(s) in a number of selectable raster formats, in the location specified.

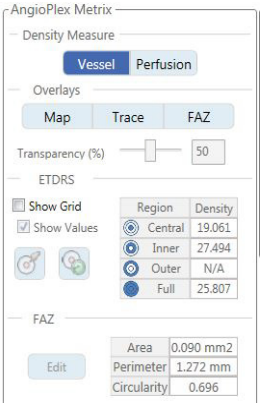
- **B-scan Flow (one color** or **two color):** Selecting this option adds one or two colors to the B-scan viewport. Selecting *One Color* will show all aspects of the flow in light red. Choosing *Two Color* will overlay the scan such that the light red will overlay the data lying above the RPE and green will overlay data lying below the RPE.
- **Segmentation Lines:** Selecting this option adds the dashed magenta lines to the segment viewport (lower left).

  1. Select **Edit**.
  2. Left-click the mouse at an end (where the triangle is) of one of the lines and hold down the mouse button to move it. This will change the offset and define a new slab.

  These changes will be reflected in the AngioPlex and Structure images above. You cannot use segmentation lines when the images are overlaid with a thickness map.

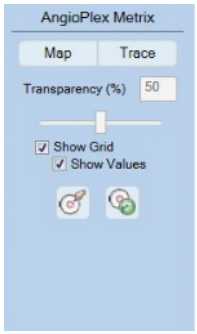
NOTE: This option is not available for Montage Angio.

3 AngioPlex Metrix



AngioPlex Metrix provides quantification for various OCTA parameters. The appearance of the AngioPlex Metrix for Angiography looks like the example margin graphic on the left. The appearance of the AngioPlex Metrix for ONH Angiography looks like the example margin graphic on the following page. The AngioPlex Metrix is available for the following scans:

- Angiography 6 mm x 6 mm
- Angiography 3 mm x 3 mm
- ONH Angiography 4.5 mm x 4.5 mm



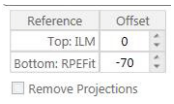
The AngioPlex Metrix fields appear *only* when the default Superficial (SRL) Preset or Radial Peripapillary Capillaries (RPC) for ONH Angiography Analysis is selected (see "CIRRUS OCT Angiography Presets" on page 9-4.

These AngioPlex Metrix fields provide information regarding vessel density and the Foveal Avascular Zone (FAZ) and are described fully in "Vessel Density and Capillary Perfusion" on page 9-11.

This option is not available for Montage Angio.

4 Current View References

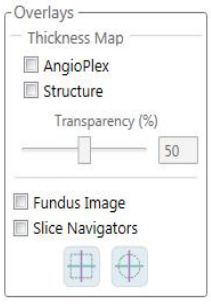
For the selected Preset (shown on the left), the location of upper and lower boundaries are indicated. The appearance of the Current View References for Angiography looks like the example margin graphic on the top left. The appearance of the Current View References for Montage Angio and ONH Angiography looks like the example margin graphic on the bottom left.



Reference	Offset
Top: ILM	0
Bottom: IPL	0

In addition, selecting the **Remove Projections** check box (Angiography only) will remove projection artifacts, such as decorrelation tails, from the images. Once the check box is selected, it remains so until unchecked. For more information, refer to "CIRRUS OCT Angiography Acceptance Criteria" on page 7-7.

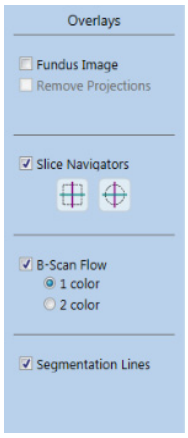
5 Overlays



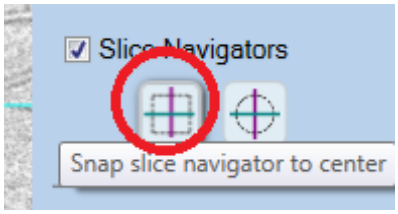
The appearance of the Overlay for Angiography looks like the example margin graphic on the left. The appearance of the Overlay for ONH Angiography looks like the example margin graphic on the next page.

- **Thickness Map:** Overlay an image with a thickness map. You can choose to add the thickness map to either the AngioPlex viewport (left), the Structure viewport (right), or both. The thickness map is a topographic representation of the total retinal thickness (ILM to RPE). The surfaces of the ILM and RPE layers are segmented in the same manner as CIRRUS HD-OCT structural images (for example the Macular cube 512x128).
- **Fundus Image**: Overlay both the AngioPlex image and the Structure image with the Fundus Image.

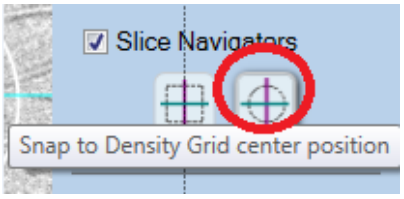
Slice Navigators: Overlays the blue (fast B-scans) and magenta (slow B-scans) on the images. Turn them off by deselecting the option. Hovering over the icons provides a brief description of what the icon does, as shown on the following page.



The left icon, will move the navigators to the center of the box, not taking into account the locations of the structures.



The right icon will move your navigators to the center of the ONH.

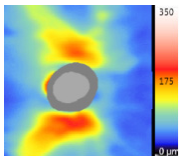


For more information about the Overlay features, see "ONH Overlay and Angio Metrix Bar" on page 9-22.

This option is not available for Montage Angio.

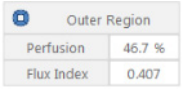
6 RNFL Thickness Map

ONH Angiography Analysis uses Item 6 (Figure 9-3) for the **RNFL Thickness** option.



7 ONH Outer Region

ONH Angiography Analysis uses Item 7 (Figure 9-3) for the **Outer Region** option. This option indicates the blood flow intensity and area of flow.



- **Perfusion:** The total area of perfused vasculature per unit area in a region of interest (ROI.)
- **Flux Index**: The total area of perfused vasculature per unit area in a region of interest (ROI), weighted by the brightness (intensity) of the flow signal.

See "Vessel Density and Capillary Perfusion" on page 9-11 for information about Perfusion

8 AngioPlex En Face

ONH Angiography Analysis displays the AngioPlex En Face in Item 8 (Figure 9-3).

9 Structure En Face

ONH Angiography Analysis displays the AngioPlex En Face in Item 9 (Figure 9-3).

10 Montage Angio Image

Item 10 in the Montage Angio represents the Montage Angio image of all scans taken.

11 Montage Angio Both Option

Item 11 in Figure 9-2 represents a toggle option to show the **Angio** or **Structure** option in which to view the Montage. In addition, you can choose the **Both** option that provides a view of both Angio and Structure, as shown in Figure 9-4.

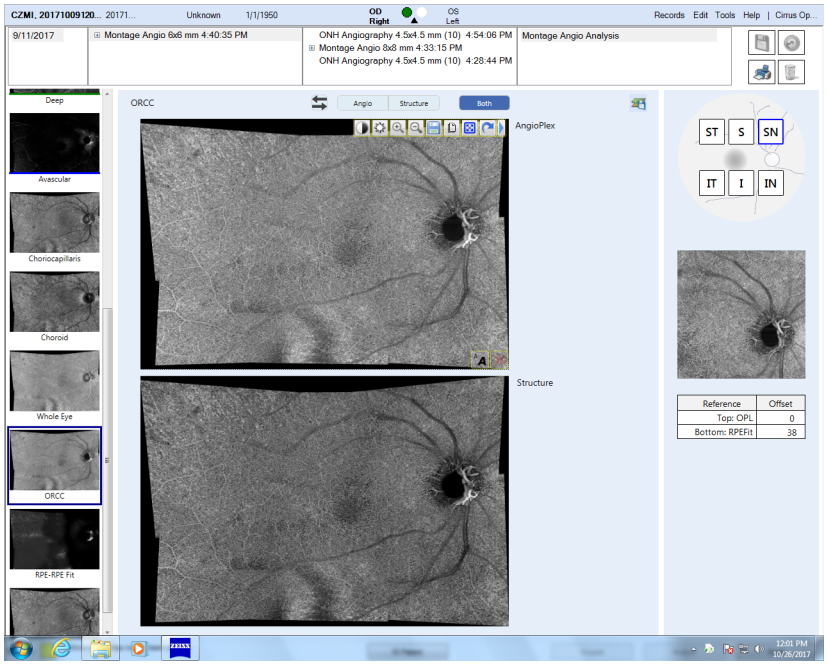


Figure 9-4 Montage Angio Both Option

12 Scan Position Montage

Item 12 in the Montage Angio provides a visual representation of the retinal scan location (Scan Position Montage).

13 Individual Scan Images of Montage Image

Item 13 shows the individual scan images of the Montage image (Figure 9-2) and will change depending where you click the cursor on the Montage image.

Vessel Density and Capillary Perfusion

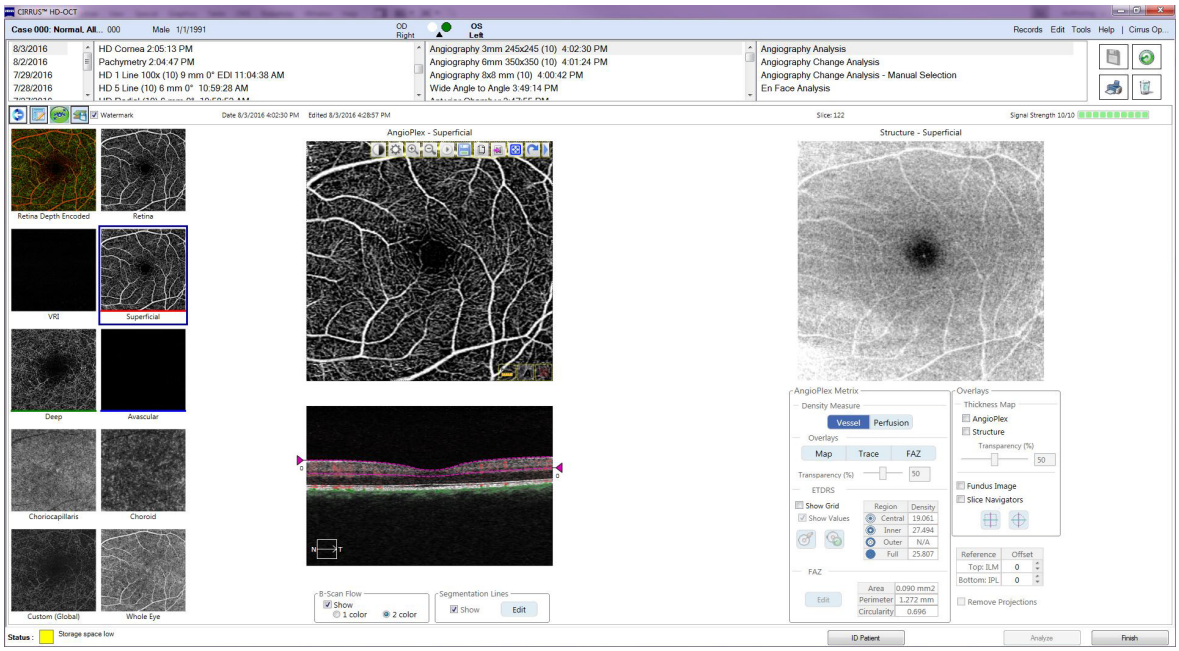


Figure 9-5 When the Superficial preset is selected from the Angiography Analysis screen, the AngioPlex Metrix will appear.

Select the Superficial preset (see Presets "CIRRUS OCT Angiography Presets" on page 9-4) from the OCT Angiography Analysis screen (for 3x3 and 6x6 scans only) to bring up tools for observing and measuring vessel density and/or capillary perfusion. (For ONH Angiography, see Figure 9-3.) Measuring capillary non-perfusion or impaired capillary perfusion can be useful in case of macular ischemia caused by vascular pathologies including but not limited to Diabetic Retinopathy.

Table 9-2 shows describes both Vessel Density and Perfusion Density and provides measurements for each.

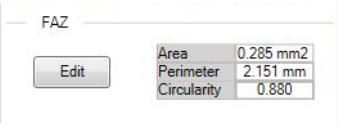
Name	Description	Units
Vessel Density	Vessel Density is defined as the total length of perfused vasculature per unit area in a region of measurement. It is measured in units of inverse millimeters. Vessel density can be thought of as untangling all the vasculature in a region of tissue, measuring its length with a ruler, then dividing it by the area it originally occupied. The result is a number with a minimum of 0 (no vessels) and an unbounded maximum.	mm^{-1} (mm/mm^2)
Capillary Perfusion Density	Capillary Perfusion Density is defined as the total area of perfused vasculature per unit area in a region of measurement. This metric is calculated by summing up the number of pixels which contain perfused vasculature, and dividing the sum by the total number of pixels in the considered region (typically a region in the ETDRS grid). The result is a unitless number ranging from 0 (no perfusion) to 1 (fully perfused).	Unitless (mm^2/mm^2)

Table 9-2 Vessel Density and Perfusion Density

Vessel Density vs. Capillary Perfusion

The main difference between Vessel Density and Capillary Perfusion is that in Vessel Density, all vessels are treated equally. In Capillary Perfusion Density, larger vessels influence the measurement more than smaller capillaries and therefore, can overshadow loss of individual capillaries. Vessel Density attempts to provide a higher sensitivity to loss of individual capillaries by providing the same weight to all vasculature. This attempt occurs by replacing each vessel in the image with a vessel with thickness of 1 pixel. The trade-off is a higher sensitivity to noise.

Foveal Avascular Zone (FAZ)



When FAZ overlay is selected, a yellow overlay is applied to the segmented FAZ area. Values for the total calculated Area, Perimeter, and Circularity of the FAZ are shown in the AngioPlex Metrix view and described in Table 9-3.

.

Metrice	Description	Units
FAZ Area	The area contained within the boundary of the FAZ.	mm^2
FAZ Perimeter	The length of the boundary of the FAZ.	mm
FAZ Circularity	How similar the boundary of the FAZ is to a circle. Values range from 0 to 1. A value of 1 means the FAZ forms a perfect circle while a value near zero means that the boundary of FAZ is very different from a circle. An FAZ can result in a low circularity for a number of reasons including, but not limited to, loss in capillaries immediately surrounding the FAZ.	Unitless

Table 9-3 FAZ Metrics

The two figures below display the both High FAZ Circularity and Low FAZ Circularity.

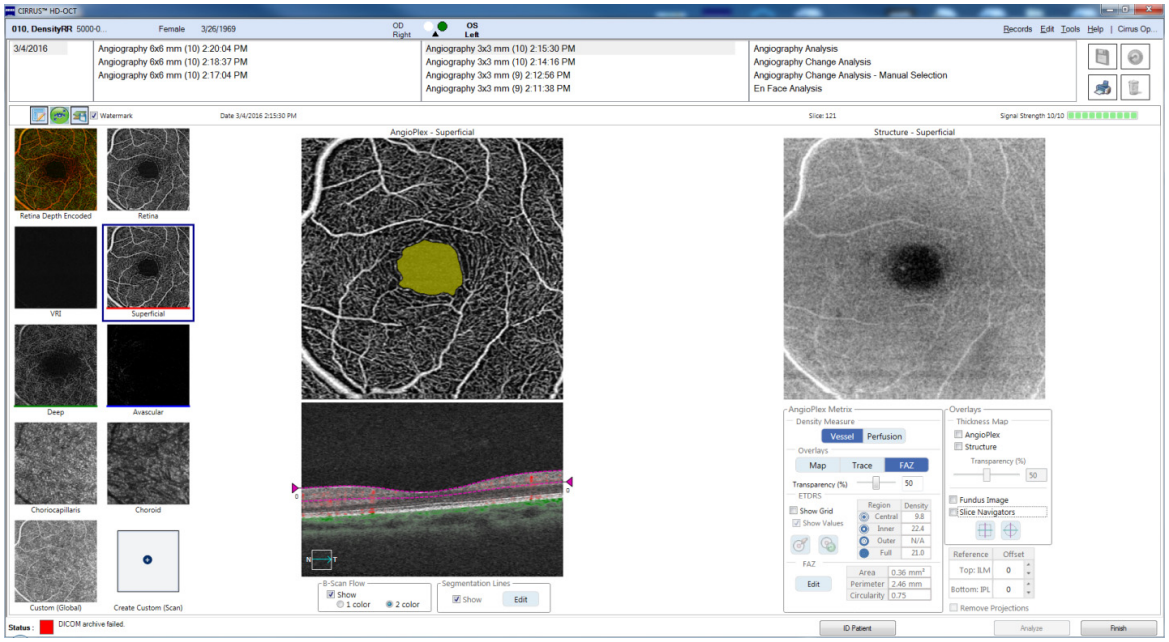


Figure 9-6High FAZ Circularity (0.75)

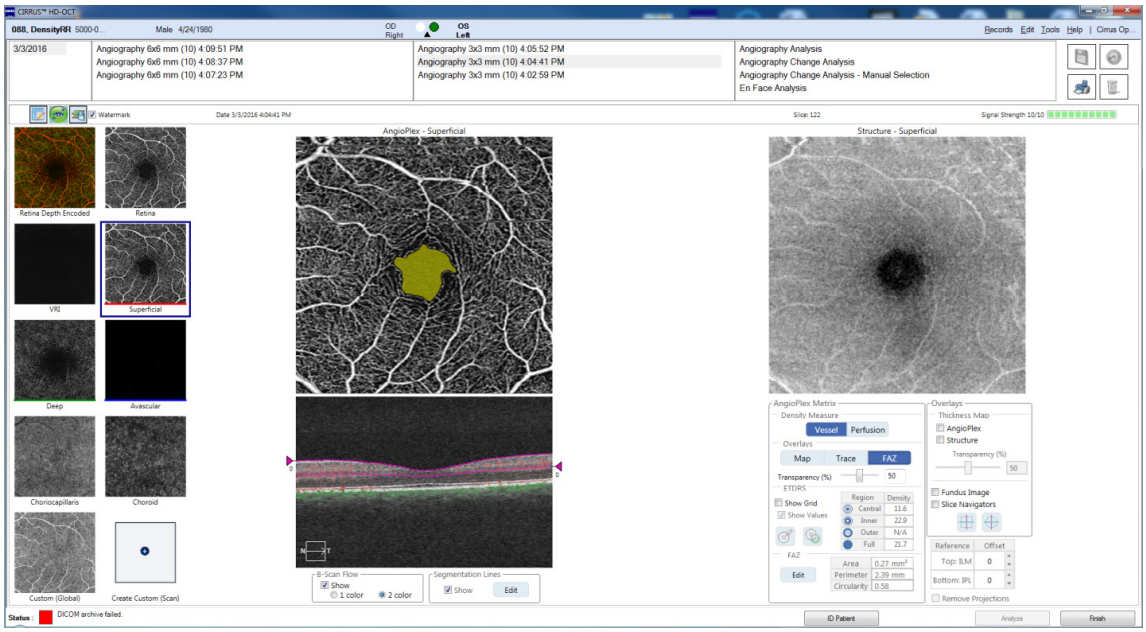


Figure 9-7Low FAZ Circularity (0.58)

Editing a FAZ

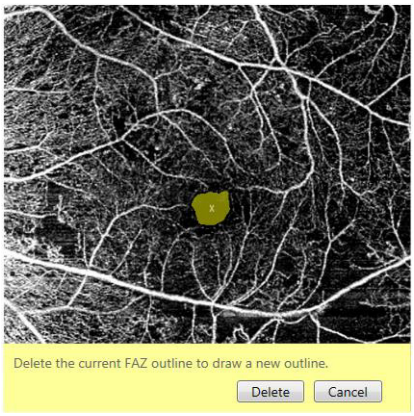
You can manually draw the outline of the FAZ if the one provided by the application is not acceptable.

The **Edit** function of the FAZ controls will cause a drawing tool to replace the standard mouse pointer and allow you to draw your own FAZ outline if desired. The drawn FAZ outline must be a single closed shape. The drawing tool has several features to aid in drawing a single closed shape, such as automatically connecting the end point to the beginning point, ending when two parts of the boundary intersect, and discarding "extra" closed shapes created by the auto-complete function.

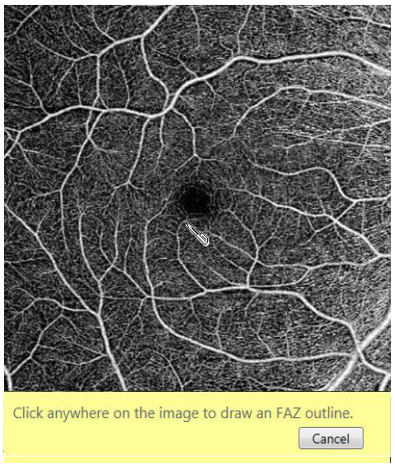
When the drawing is completed, the new FAZ area will be shaded yellow, and the values will be automatically recalculated in the FAZ table of the AngioPlex Metrix view.

To Edit the Foveal Avascular Zone:

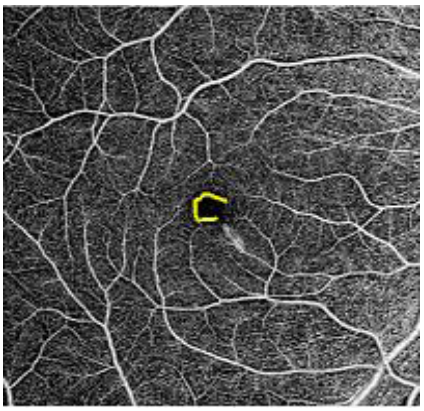
1. Select **FAZ** from the AngioPlex Metrix. If the automatic FAZ algorithm has identified a FAZ it will be outlined as shown below, on the left. If the automatic FAZ algorithm has not been able to identify the FAZ, the message shown below, on the right will appear.



2. If a FAZ has been found, and you wish to edit it, select **Edit** from the FAZ in the AngioPlex Metrix box. The message shown below will appear.



3. Holding the left mouse button down, draw a FAZ outline.



4. Release the mouse button to complete the area.

AngioPlex Metrix Measurements

Measurements are provided in both tabular form and as Vascular Density maps via the AngioPlex Metrix toolbox. Density values for selected regions are shown both in the AngioPlex Metrix table (see Item 3 above), and when selected in the ETDRS grid with values shown in the individual sectors

Table 9-4 and Table 9-5, on the following pages, illustrate each of the graphic options provided by the AngioPlex Metrix. In addition, the ETDRS grid, if enabled, can be moved and/or recentered based on the Slice Navigator position ( ) or the center of the Fovea ( ) calculated by CIRRUS Fovea Finder.

Overlay Options

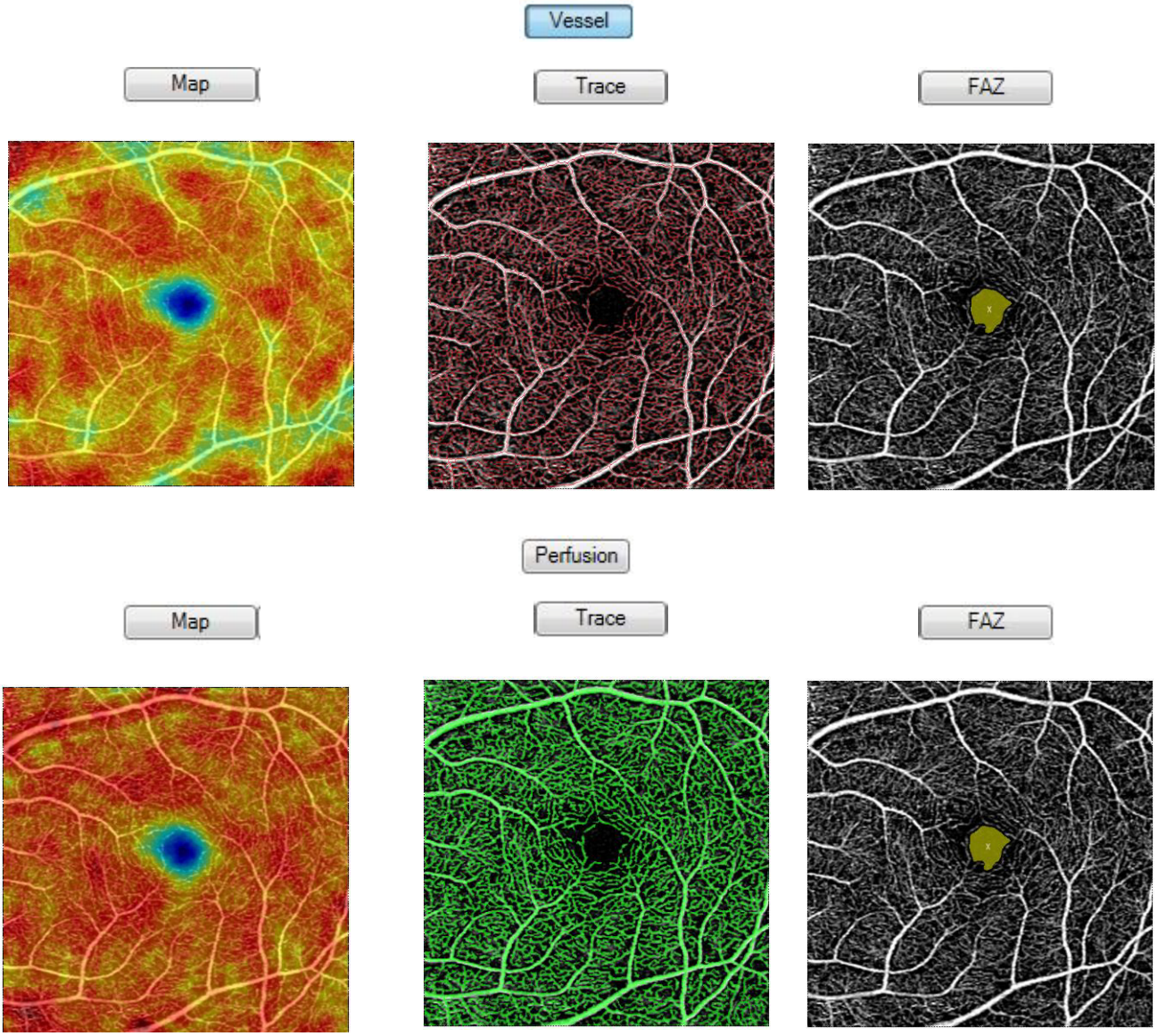
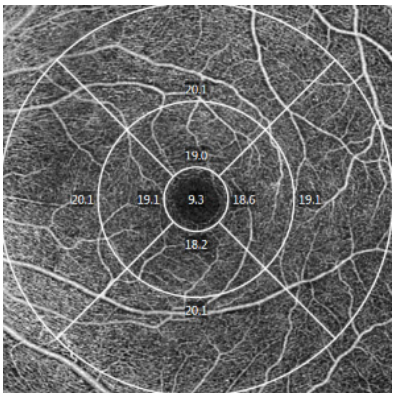


Table 9-4 Overlay options available for visualizing vessels and perfusion, as well as FAZ shape and size

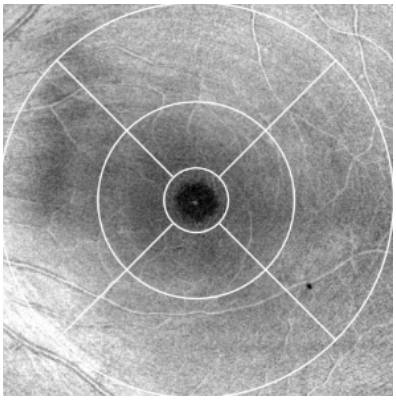
ETDRS Options

Vessel | Perfusion

ETDRS Grid with Vessel Density Values

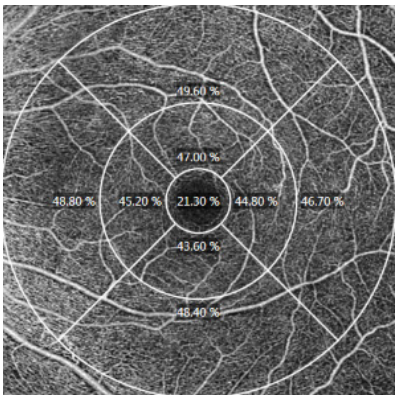


ETDRS Grid



Vessel | Perfusion

ETDRS Grid with Perfusion Density Values



ETDRS Grid

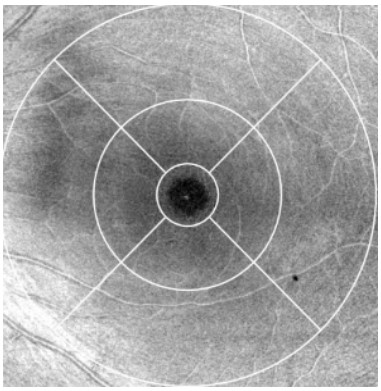


Table 9-5 ETDRS Overlays can show values for either vessel density or perfusion

Angiography and ONH Angiography Change Analysis

The Angiography Change Analysis screen (Figure 9-8) allows you to compare two Angiography scans from a patient's history to visualize changes in retinal vasculature, capillary density and perfusion, FAZ size, and geometry.

.

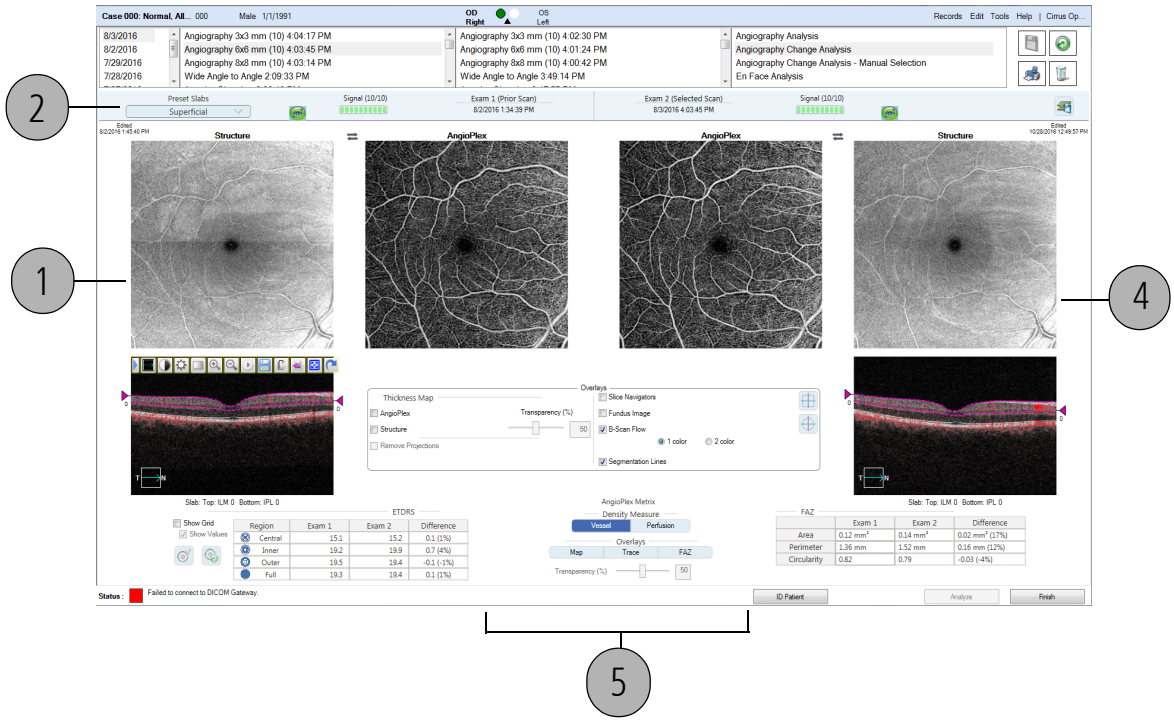


Figure 9-8 CIRRUS OCT Angiography Change Analysis screen

For a change analysis of Montage Angio individual scan images, use the CIRRUS OCT Angiography Change Analysis screen (Figure 9-8) as well.

The ONH Angiography Change Analysis screen (Figure 9-9) allows you to compare two scans from a patient's history to visualize any changes. To open the Overlay area (shown and described on page xxx), select the toggle icon (Item 3) in the upper-right hand area of the screen.

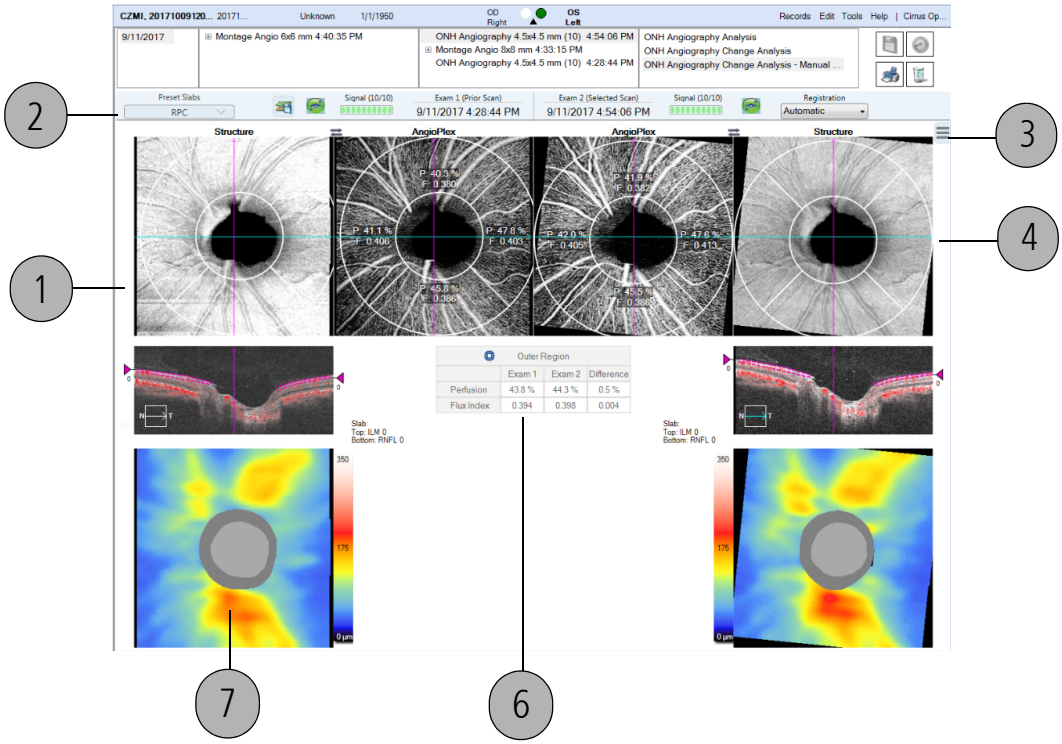


Figure 9-9 ONH Angiography Change Analysis

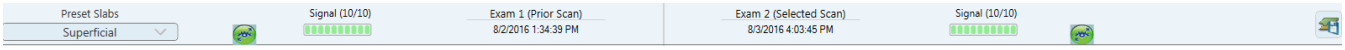
Previous Scan

1

Any AngioPlex scan acquired for the same patient and the same eye, during a visit prior to the currently selected scan may be used as the Previous Scan. The data from the selected scan will populate the scan images on the left side of the Change Analysis screen.

2 Options Bar

There are a number of options that can be specified for the various Angiography Change Analysis screens. These can be found on the **Options** bar (enlarged from Figure 9-8, and shown below), and are discussed in the paragraphs that follow.



Preset Selector

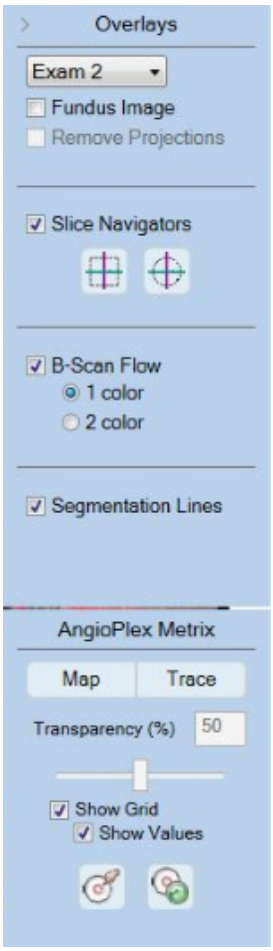
Use the Preset Selector drop-down list to select a preset of interest. Superficial is the default preset for a change analysis of CIRRUS OCT Angiography and for Montage individual scans, because it is the only slab preset from which AngioPlex Metrix (see "AngioPlex Metrix" on page 9-7) selections can be made. However, any preset can be chosen for visual inspection of possible changes in vasculature.

For ONH Angiography change analysis, RPC is the default preset for change analysis.

AngioPlex presets are discussed in detail in "CIRRUS OCT Angiography Presets" on page 9-4 and the algorithms used for their derivation are discussed in "AngioPlex Preset Algorithms" on page 9-24.

3 Toggle Icon

The triple bar or toggle icon in the upper-right area of the ONH Angiography Change Analysis screen in Figure 9-9 opens and closes the Overlay and AngioPlex Metrix bar. An open Overlay and Angio Metrix bar is shown on the following page.



ONH Overlay and Angio Metrix Bar

Fundus Image: Overlays both the AngioPlex image and the Structure image with the Fundus Image.

Remove Projections: Filters out any projections. Projection artifacts can potentially give false information about blood vessels.

Slice Navigators: Overlays the blue (fast B-scans) and magenta (slow B-scans) on the images. Turn them off by deselecting the option.

B-Scan Flow: Enables the use of either one or two colors in the B-Scan when viewing its flow. A single color shows all aspects of the flow in red. Two colors overlays the scan so the red will overlay the data lying above the RPE and green will overlay data lying below the RPE.

Segmentation Lines: Adds the dashed magenta lines to the segment viewport.

Map: Displays the density of perfusion.

Trace: Indicates where flow is detected.

Transparency: Active when you are using a prior scan. This option provides visual control of prior scans. Transparency is relative to the Map and Trace overlays.

Show Grid: Shows/hides the circle with the quadrants from the view. The values shown display the P and F numbers.

4

Selected Scan

The Selected Scan is the scan you had selected from the scan list, prior to selecting Angiography Change Analysis. The date of the exam is shown above the scan images.

5

AngioPlex Metrix in Change Analysis

The AngioPlex Metrix features described in "ONH Overlay and Angio Metrix Bar" on page 9-22 are available from the Angiography Change Analysis screen for OCT Angiography and for Montage individual scan images when the Superficial Preset is selected. You can not edit the FAZ outline in the Change Analysis.

In the Angiography Change Analysis, the ETDRS and FAZ tables are expanded to include the densities of the previous scan, the current scan, and the difference between the two.

This option is available for ONH Angiography, and provides the ability to quantify RNFL microvasculature around the ONH. However, you must select toggle icon in the upper-right area of the ONH Angiography Change Analysis screen to display it.

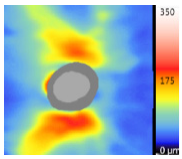
Outer Region

Item 6 in the ONH Angiography Change Analysis screen is used for **Outer Region** information.

Outer Region			
	Exam 1	Exam 2	Difference
Perfusion	43.8 %	44.3 %	0.5 %
Flux Index	0.394	0.398	0.004

ONH RNFL Thickness

Item 7 in the ONH Angiography Change Analysis screen is for the **RNFL Thickness.**



OCT Angiography Change - Manual Selection

Should you decide that the current scan does not show the best characteristics for a OCT Angiography comparison, you can manually choose a different scan using the manual selection process:

1. At the top of the analysis screen, select the scan date and the scan you wish to use as the more current scan (the scan information that appears on the right side of the screen).
2. Select **Angiography Change Analysis – Manual Selection** from the far right column.
3. A list of eligible scans will appear in a dialog box (see Figure 9-10).
4. Click the scan you wish to include in the analysis. A green checkmark will appear next to the selected scan.
5. Click **Next** to proceed. The window will collapse and the scan you chose will appear as the scan on the left–hand side of the screen.

NOTE: You may only select one scan in this way to use as the earlier of the two scans.

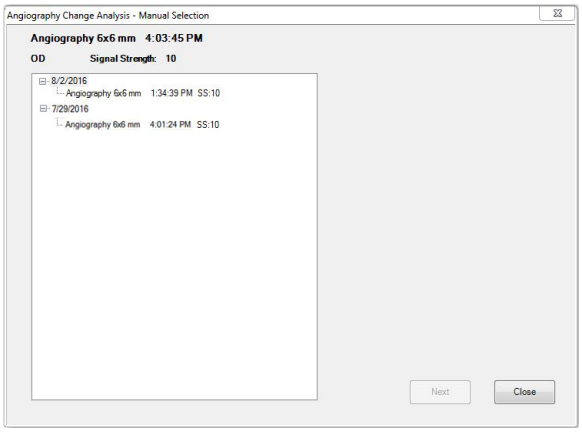


Figure 9-10 OCT Angiography Change Analysis - Manual Selection

AngioPlex Preset Algorithms

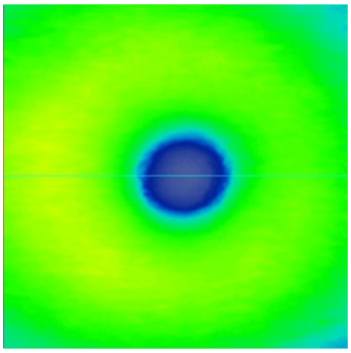
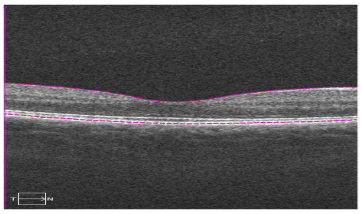
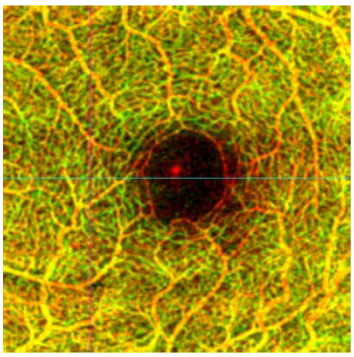
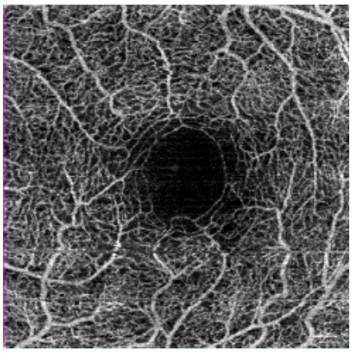
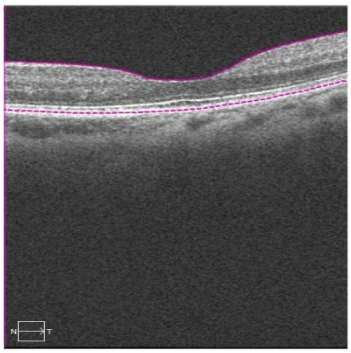
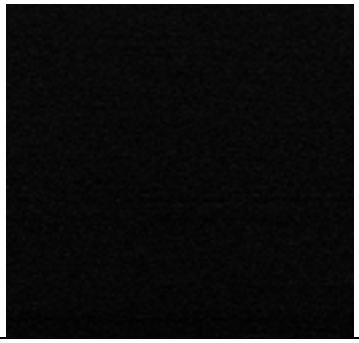
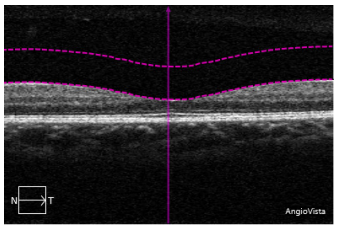
Slab Name	Layer Boundaries	Example En Face	B-scan with Layers
Thickness Map	Inner Boundary: ILM Outer Boundary: RPE		
Retina Depth Encoded	Combination of the above three layers, with the following coding: SRL = Red DRL = Green Avascular = Blue		Combination of the three above
Whole Retina Slab	Inner Boundary: Z_{ILM} Outer Boundary: $Z_{RPE} = Z_{RPEfit} - 70\ \mu m$		
VRI	Inner Boundary: $Z_{IVRI} = Z_{ILM} - 300\mu m$ Outer Boundary: Z_{ILM}		

Table 9-4 Layers in a typical normal eye demonstrates that the deeper retinal layer has a different characteristic appearance than the superficial retinal layer

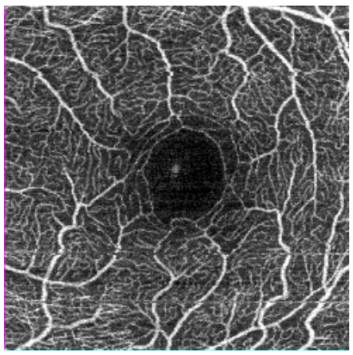
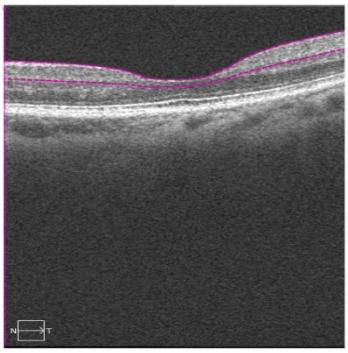
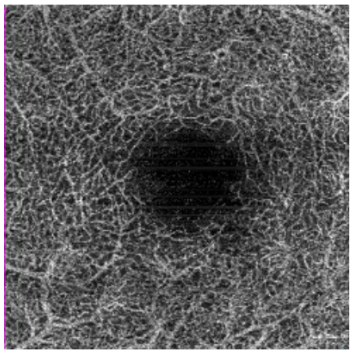
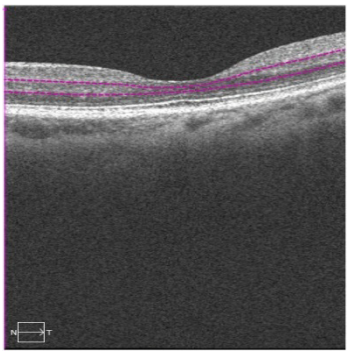
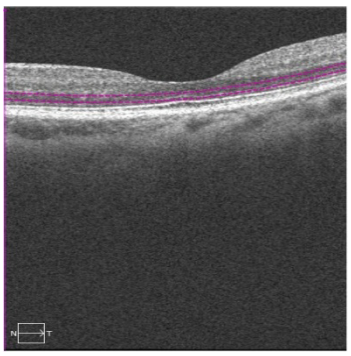
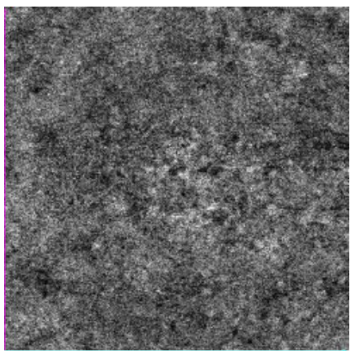
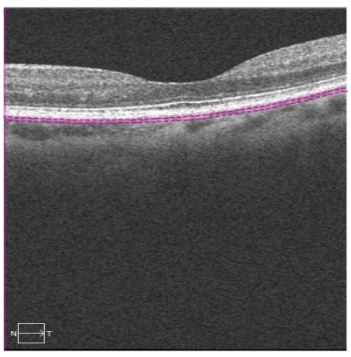
SRL: Superficial Retinal Layer	**Inner Boundary:** Z_{ILM} **Outer boundary:** $Z_{IPL}=Z_{ILM}+70\%(T_{OPL-ILM})$		
DRL Slab: Deeper Retinal Layer	**Inner boundary:** Z_{IPL} **Outer boundary:** $Z_{OPL}=Z_{RPEfit} - 110\mu m$		
Avascular Slab	**Inner Boundary:** Z_{OPL} **Outer Boundary:** $Z_{IS/OS}=Z_{RPEfit} - 70\mu m$		
Choriocapillaris Slab	**Inner Boundary:** $Z_{CCIB} = Z_{RPEfit} + 29\ \mu m$ **Outer Boundary:** $Z_{CCOB} = Z_{RPEfit} + 49\ \mu m$		

Table 9-4 Layers in a typical normal eye demonstrates that the deeper retinal layer has a different characteristic appearance than the superficial retinal layer

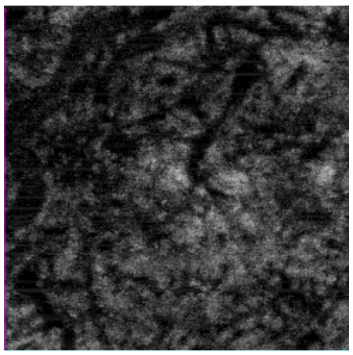
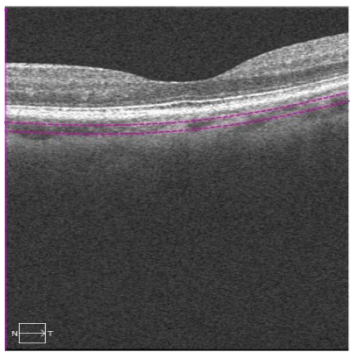
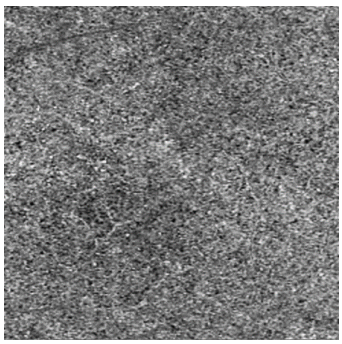
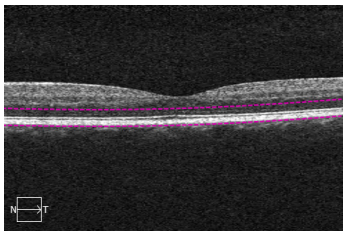
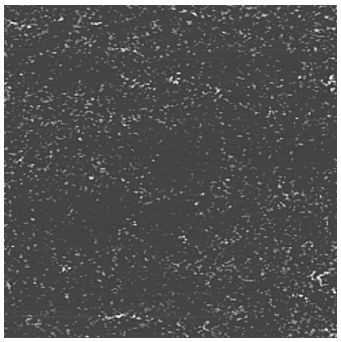
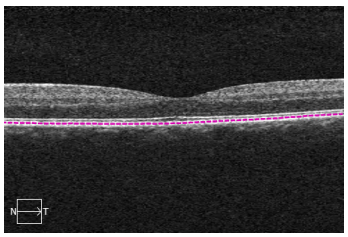
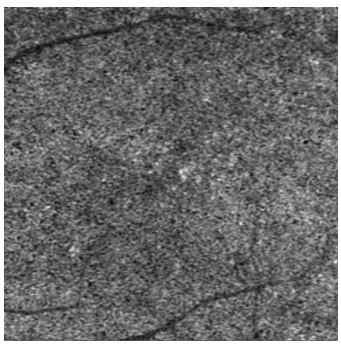
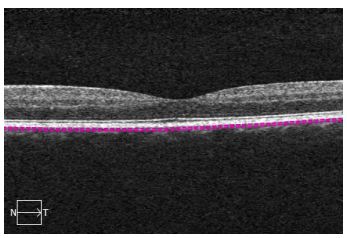
Choroid Slab	Inner Boundary: $Z_{ChIB} = Z_{RPEfit} + 64\ \mu m$ Outer Boundary: $Z_{ChOB} = Z_{RPEfit} + 115\ \mu m$		
ORCC	Inner Boundary: $Z_{OPL} = Z_{RPEfit} - 110\ \mu m$ Outer Boundary: $Z_{ChOB} = Z_{RPEfit} + 115\ \mu m$		
RPE-RPE Fit	Inner Boundary: Z_{RPE} Outer Boundary: Z_{RPEfit}		
Sub-RPE	Inner Boundary: Z_{RPE} Outer Boundary: $Z_{RPE} + 49\ \mu m$		

Table 9-4 Layers in a typical normal eye demonstrates that the deeper retinal layer has a different characteristic appearance than the superficial retinal layer

ONH Angiography Change Analysis Image Registration

Both Automatic Registration and Manual Registration are available for ONH Angiography in CIRRUS. The process parallels the registration process found in "Macular Registration" on page 8-13. Refer to the section for more details.

10 Reports and Printing

CIRRUS HD-OCT software provides tools for report generation, which can then be either printed or saved in number of file formats.

The allowable options for saving and/or printing reports always reflect the analysis from which the report has been generated. In addition, many reports have specific options that can be selected as described in the sections which follow.

Standard Print Options

NOTE: To print a report you must be in the Analysis screen of the analysis for which you want a report.

To Print a Report:

1. Hover the mouse point over the print icon in the upper right corner of the Analysis screen. The Standard Print Options Drop-down List will appear as shown in Figure 10-1.

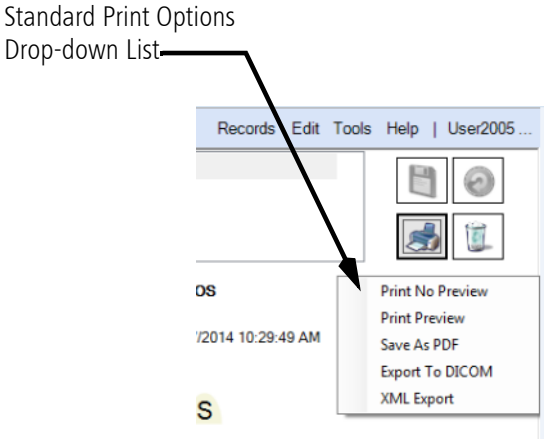


Figure 10-1 Hover over the Printer icon, to reveal the Standard Print Options Drop-down List.

Five options are available from any given analysis screen, as shown in Figure 10-1.

- **Print No Preview:** Opens a standard printer dialog box
- **Print Preview:** Opens the Report Preview screen (see "The Report Preview Screen" on page 10-2 for options available from this window).
- **Export as PDF:** Creates a PDF file of the Report, in the specified location.
- **Export to DICOM:** If you are using a DICOM archive, exports the report as an ePDF file to the location of your DICOM archive.
- **XML Export:** Creates an XML file of the report data for web viewing.

2. Select the option that reflects your work requirements.

The Report Preview Screen

Reports are accessed when you select the **Print Preview** option, described in the previous section. The analysis for which you had the screen open, will appear as shown in Figure 10-2 (although the images themselves will vary depending on the analysis type and data recorded).

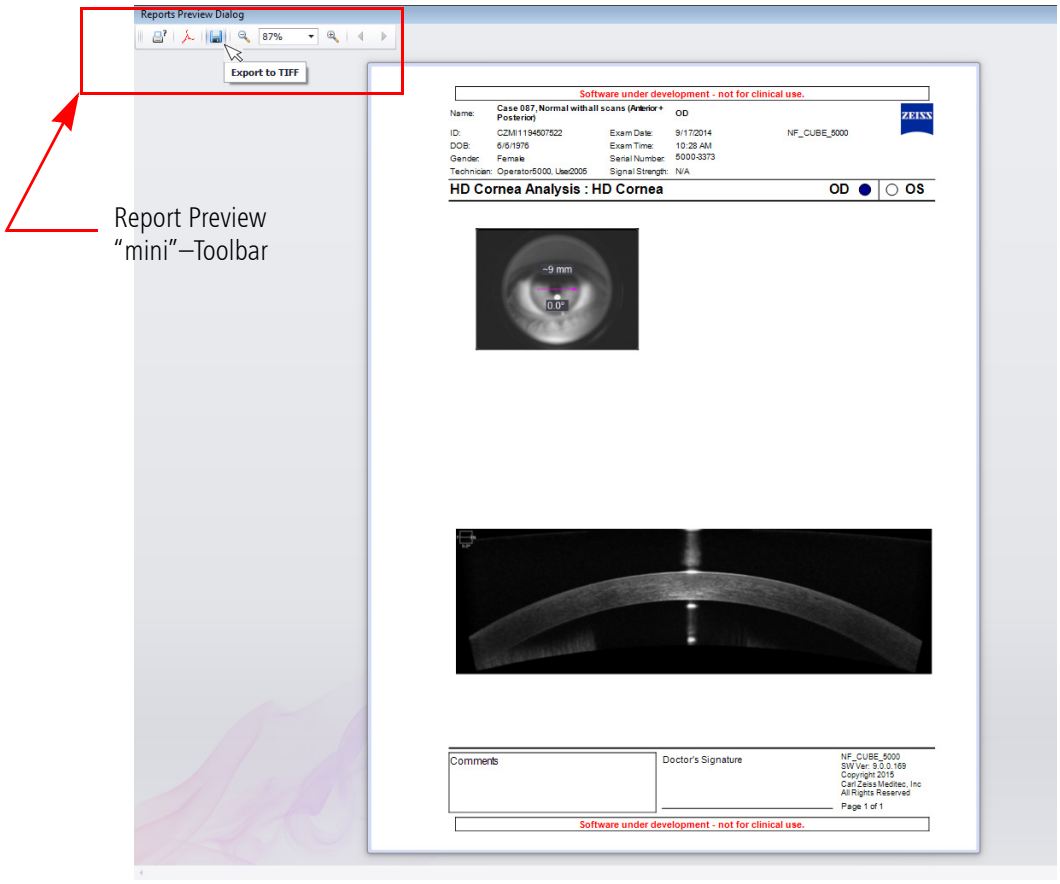


Figure 10-2 Example of a Report Preview screen. Report Preview screens are accessed from the Print Preview option of the drop-down list accessed from the Save icon, as discussed in "Standard Print Options" on page 10-1 above.

Reports are comprised of a header, the main window which contains analysis data, and a footer.

Report headers include the following information:

- Patient Name
- Patient ID
- Technician Name
- Institution

Patient names, IDs, etc., are extracted from information provided in the **New Patient** and **Edit Institution** screens, as described in "Add New Patients" on page 5-2 and "Institution Setup" on page 4-1 respectively.

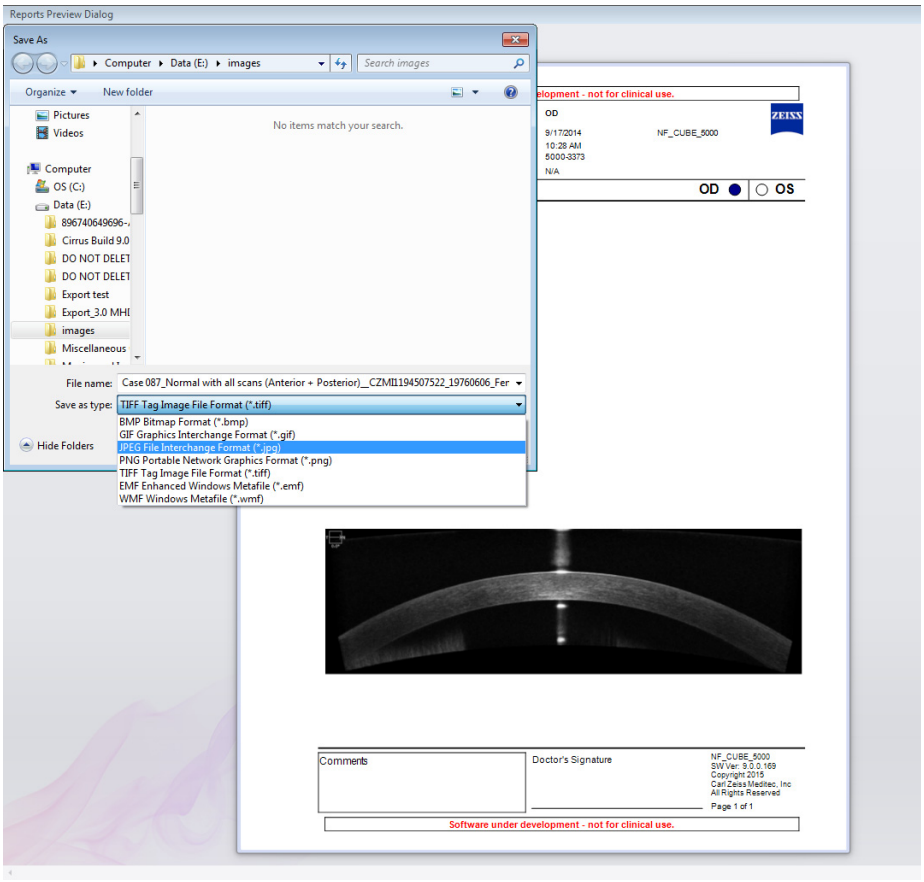


Figure 10-3 The drop-down list in the Save icon on the Report Review screen, provides multiple filetype options for saving.

The original analysis exam date and time always appears at the top of the report. When an analysis is altered and saved, the original analysis date/time still appears at the top of the page, while a new date/time for the alteration is printed in the Comments box at the bottom of the page. If alterations are eventually deleted, that date/time stamp in the Comments box is also deleted from the next report.

The mini–Toolbar at the top left of the Report Review screen, provides the same print options as described in the previous section. In addition, if you select the Save icon ( ), from this location, you may also select other file formats as follows:

- BMP – Bitmap
- GIF – Graphic Interchange Format
- JPEG – Joint Photographic Experts Group
- PNG – Portable Network Graphics Format
- TIFF – Tag Image Format
- EMF – Enhanced Windows Metafile
- WMF – Windows Metafile

NOTE: Do not be misled by the default message "Save to Tiff" which appears when you mouse over the Save button at this location. This is an artifact of the default selection, but in no way represents the only available file format. After you have clicked on the Save icon, click the lower bar (**Save as Types)** in the popup window that appears, and select the format of interest from the drop-down list (see Figure 10-3).

Close the Review screen by clicking the in the upper right corner of the screen to close the **Reports Preview** screen and return to the **Analysis** screen.

Analysis Related Report Options

Reports distill important information provided on the given analysis screen itself. The standard (default) options may not always provide all the information required. To accommodate this you can specify additional information in connection with certain analyses that will then appear on the selected Report as (an) additional(s) page(s). **These analysis–related special options for reports are specified as follows:**

1. From the Toolbar ("Toolbar Options" on page 3-5) select **Options > Print Configuration**. The window shown in Figure 10-4 will appear.

The **Printout Configuration** window has a total of 5 tabs:

- MTA (Macula Thickness Analysis) Options
- Macula Multi-slice Parameters
- ONH Print Options
- Raster Print Options
- GPA Print Options

Use the arrows at the top right of the window to move through the tabs.

Each of these options is described briefly below.

Macula Thickness Report Options

There are three report styles, selectable as check boxes, from the **MTA Options** tab of the Printout Configuration Window, that pertain to Macula Thickness Analysis:

- Macula Thickness
- Macula Multi Slice
- Macula Radial

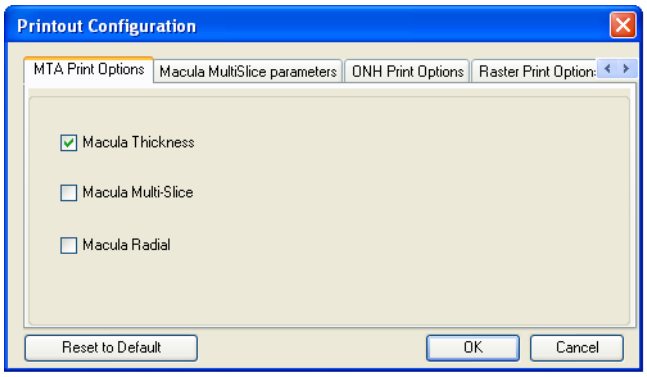


Figure 10-4 MTA Print Options

The Macula Thickness Option, is the default option. You can reset any tab by selecting **Reset to Default** in the lower right corner of the screen.

The Macula Multi–Slice Option

The Macula Multi–Slice Option, the second checkbox within the first tab of the **Printout Configuration** screen will set up a report that, when saved and/or printed, yields a series of pages, each of which show a set of selected Macula slices.

Which slices are shown, is determined by selecting the *second* tab of the **Printout Configuration** window, the **Macula Multi-slice Parameters** tab, Figure 10-5.

When the Macula Multi–Slice option is selected, reports generated from macula cube scans will include images of the central fast B-scan and adjacent B-scans. Such reports include four fast B-scans per page. Selecting the number of B-scans to display and the spacing between them, determines how many pages the report will be.

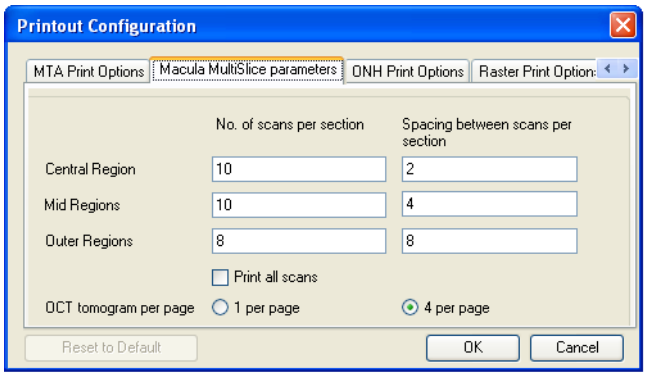


Figure 10-5 Macula Multi–Slice Parameters

The Central Region is comprised of the central 1 mm (1000 µm) of the cube. This is the equivalent of 500 µm above and 500 µm below the central B-scan. The Mid–Regions are comprised of the next 1.0 mm above and below the Central Region. The Outer Regions are the final 1.5 mm of area above and below the Mid Regions. These three regions add up to the 6 mm height of the scan box and are equivalent to the ETDRS grid spacing in the vertical direction.

You may choose the number of scans to print per region or indicate the spacing between the scans. If you do not wish to print any scans for a particular region, enter "0" in the appropriate Number of Scans per Section field.

Macula Radial Report Option

The Macula Radial Option, the third checkbox within the first tab of the Printout Configuration screen, will set up a report that, when saved and/or printed, provides a radial line report option. Six B-scans are extracted at the meridians of 0 degrees, 30, 60, 90, 120, and 150 (300 x 330 in the left eye). This report is available for either the Macular Cube 512x128 or the Macular Cube 200x200 scan.

The direction of the arrows shown in each slice indicates the orientation of each image. These can be matched to the radial pattern overlay on the Fundus image in the upper left portion of the report. The retinal thickness map to the right shows these scans in relationship to the thickness map of the entire 512x128 Macular Cube.

The center of the radial pattern is dependent on the location of the center of the ETDRS Grid found on the Macular Thickness Analysis screen. Moving the ETDRS Grid to a different position on the Macular Thickness Analysis screen creates a different set of images on this report. If the radial pattern is positioned such that a portion of the radial lines go outside the scan boundary, then no OCT data appears. For example, in the report below, the top left–hand slice has a black edge on the left, where no data appears.

Advanced Visualization Report Options

The stock report for Advanced Visualization includes three images, one Fundus image and two B-scan images. The upper left Fundus image has an overlay showing the area addressed by the cube scan and the two currently selected slices. The upper right scan image shows the currently selected slow B-scan, corresponding to the magenta (vertical) scan line in the Fundus image overlay. The largest, bottom scan image shows the currently selected fast B-scan, corresponding to the blue (horizontal) scan line in the Fundus image overlay.

From the Advanced Visualization Analysis Screen, right–click any image you want included in the report and select Tag for print. When you are ready to generate the report, click the Tagged for Print button (shown on the left) just above the upper right scan image on the Analysis screen for Advanced Visualization. This opens the Tagged Images dialog, Figure 10-6.

NOTE: Tagged for Print is not the same button as Print (described in "Standard Print Options" on page 10-1).

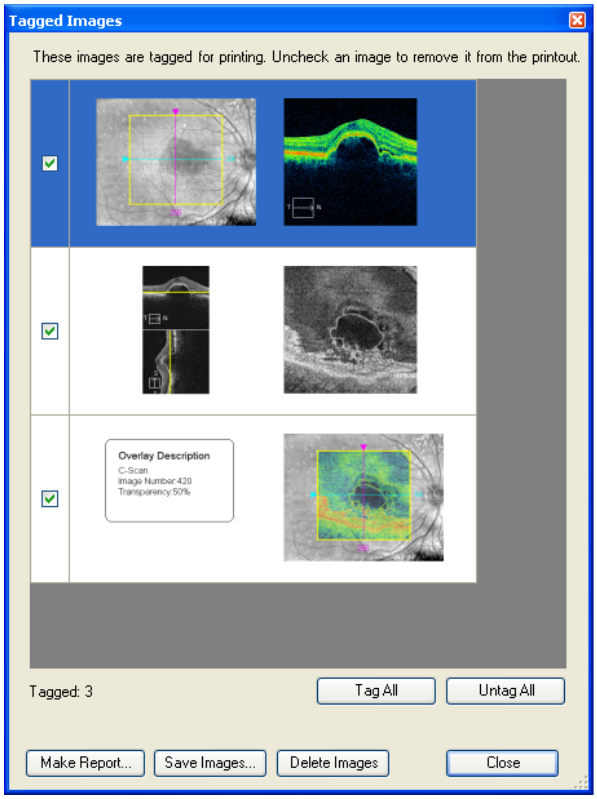


Figure 10-6 The Tagged Images dialog

The maximum number of images that may be tagged for print is 18 (or 6 pages).

When you tag an OCT image or a Fundus image that includes an overlay, CIRRUS automatically presents the image you select plus a companion Fundus image for orientation or a text description of the overlay, respectively. Thus, for each image you tag, two images appear per row of the **Tagged Images** dialog, except for a Fundus image that does not include an overlay.

For OCT images, the companion Fundus image has an overlay that highlights the position of the slice or slab. For Fundus images with an overlay, the companion text box describes the overlay characteristics.

In the **Tagged Images** dialog, you have the following options:

- **Deselect images**: All checkboxes are selected by default. Uncheck a checkbox to deselect its image and exclude it from the report.
- **Tag All**: Click to select all images.
- **Untag All**: Click to deselect all images.
- **Make Report**: Click **Make Report** to generate the report using the currently selected images. The **Print Preview** screen opens (see Figure 10-2). You will then have the further options to print it out or save it as a PDF or TIFF or any of the other electronic formats listed.

- **Save Images**: Saves the currently selected images in BMP or JPG format in the location you select in the **Save As** dialog that appears. Each image in the pair is saved individually; thus, two images are saved for each selected row. The system automatically appends an image number to the end of the name you enter.
- **Delete Images**: Deletes the currently selected images from the **Tagged Images** dialog. (This does not delete any of the data from the scan itself.)
- **Close**: Exits the **Tagged Images** dialog.

ONH and RNFL Thickness Report Options

The report for ONH and RNFL Thickness Analysis includes all the information shown on the Analysis Screen plus a second page, the **Patient Education Page**. You can turn this option on and off by going into **Tools > Print Configuration > ONH Print Options** (see Figure 10-7).

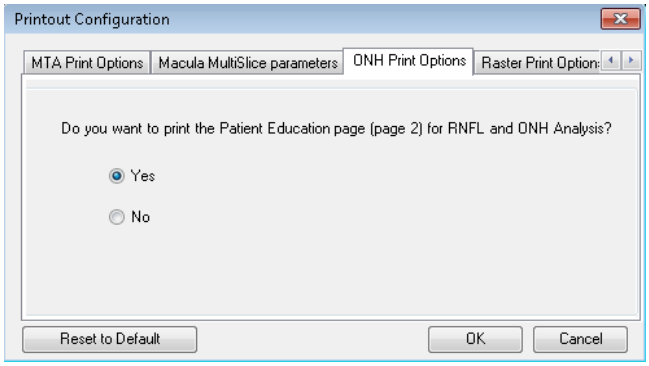


Figure 10-7 The ONH Print Options tab in Printout Configuration

The first page of the ONH and RNFL Thickness Report includes the analysis parameters discussed in "ONH and RNFL OU Analysis" on page 8-28. If you select the **Yes** option on the dialog box, you will also be able to print out a second report page called the "Patient Education Page." As shown in Figure 10-8, this page contains a version of the ONH and RNFL Thickness Report, that illustrate thicknesses as graphs for ease of explanation and interpretation (Figure 10-8).

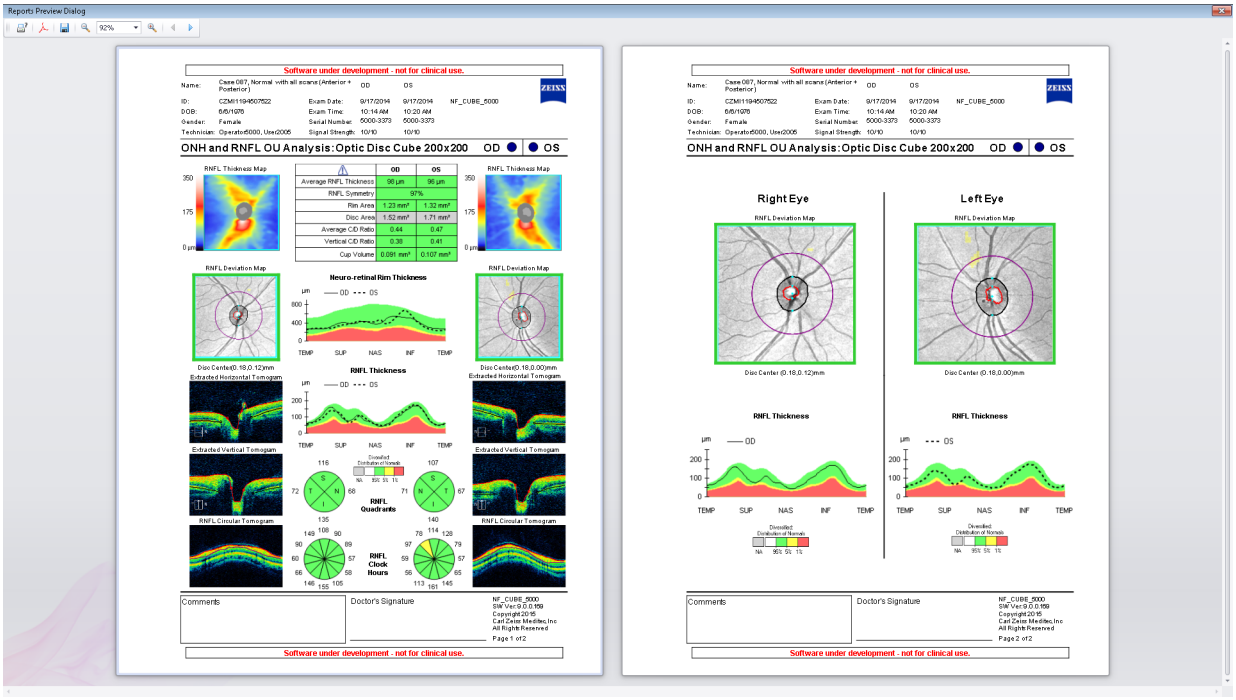
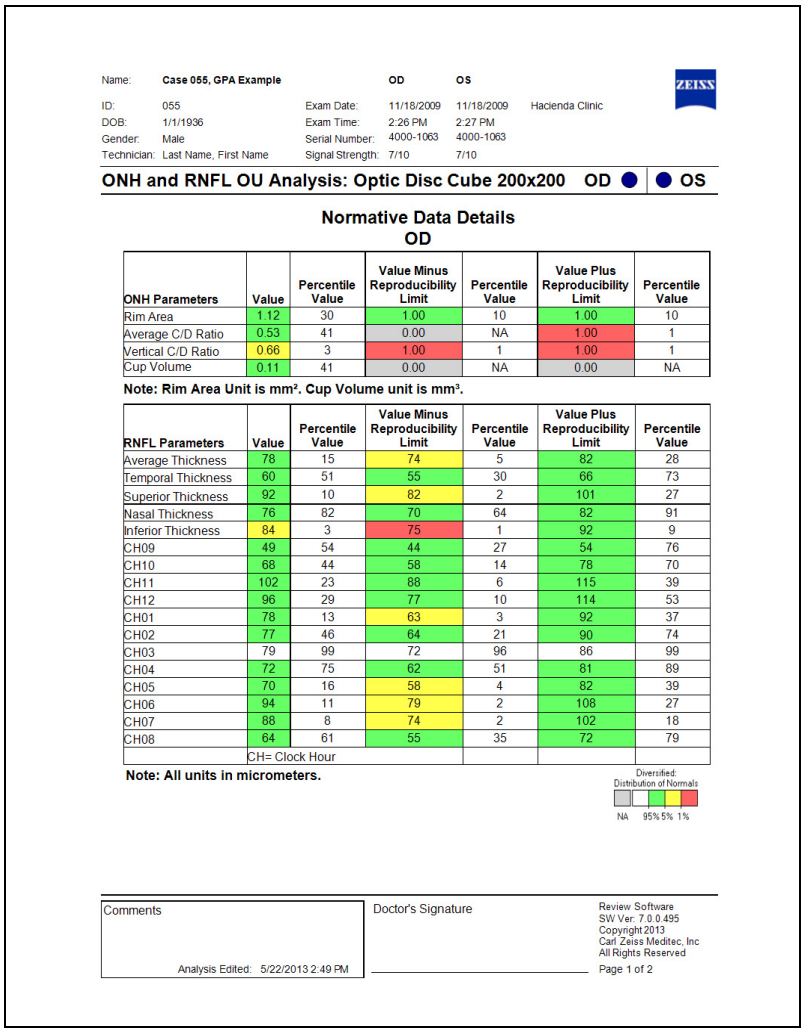


Figure 10-8 The ONH and RNFL Thickness

Normative Data Details Report

If you click the blue icon button you can select **Print Preview** or **Export to DICOM**. A PRINT PREVIEW screen displays the Normative Data Details Report, as shown in Figure 10-9. The report can be printed from the PRINT PREVIEW screen. Each eye will print on a separate page for an OU Printout.



Name:	Case 055, GPA Example		OD	OS	
ID:	055	Exam Date:	11/18/2009	11/18/2009	Hacienda Clinic
DOB:	1/1/1936	Exam Time:	2:26 PM	2:27 PM	
Gender:	Male	Serial Number:	4000-1063	4000-1063	
Technician:	Last Name, First Name	Signal Strength:	7/10	7/10	

ONH and RNFL OU Analysis: Optic Disc Cube 200x200 OD ● ● OS

Normative Data Details
OD

ONH Parameters	Value	Percentile Value	Value Minus Reproducibility Limit	Percentile Value	Value Plus Reproducibility Limit	Percentile Value
Rim Area	1.12	30	1.00	10	1.00	10
Average C/D Ratio	0.53	41	0.00	NA	1.00	1
Vertical C/D Ratio	0.66	3	1.00	1	1.00	1
Cup Volume	0.11	41	0.00	NA	0.00	NA

Note: Rim Area Unit is mm². Cup Volume unit is mm³.

RNFL Parameters	Value	Percentile Value	Value Minus Reproducibility Limit	Percentile Value	Value Plus Reproducibility Limit	Percentile Value
Average Thickness	78	15	74	5	82	28
Temporal Thickness	60	51	55	30	66	73
Superior Thickness	92	10	82	2	101	27
Nasal Thickness	76	82	70	64	82	91
Inferior Thickness	84	3	75	1	92	9
CH09	49	54	44	27	54	76
CH10	68	44	58	14	78	70
CH11	102	23	88	6	115	39
CH12	96	29	77	10	114	53
CH01	78	13	63	3	92	37
CH02	77	46	64	21	90	74
CH03	79	99	72	96	86	99
CH04	72	75	62	51	81	89
CH05	70	16	58	4	82	39
CH06	94	11	79	2	108	27
CH07	88	8	74	2	102	18
CH08	64	61	55	35	72	79
CH= Clock Hour						

Note: All units in micrometers.

Diversified Distribution of Normals
NA 95% 5% 1%

Comments
Analysis Edited: 5/22/2013 2:49 PM

Doctor's Signature

Review Software
SW Ver: 7.0.0.495
Copyright 2013
Carl Zeiss Meditec, Inc
All Rights Reserved

Page 1 of 2

Figure 10-9 Normative Data Details Report

High Definition Images Report (Raster Scan Options)

The stock report for High Definition Images analysis for raster scans includes a Fundus image showing the placement of the line scans, thumbnails of the scan lines and a single larger image of the selected scan line for HD 1 Line 20x, HD 5 Line, and 5 Line Raster, scans. If EDI was used to acquire the scan, the note "Acquired using enhanced depth mode" is displayed in the "Comments" field of the report.

For analysis, you can print the selected line (single page) or print all lines (multiple pages). When **Print All Lines (Multiple Lines)** is selected, each page displays a different scan line in the larger format window. To change the current configuration:

1. Select **Tools > Print Configuration > Raster Print Options** as shown in Figure 10-10.

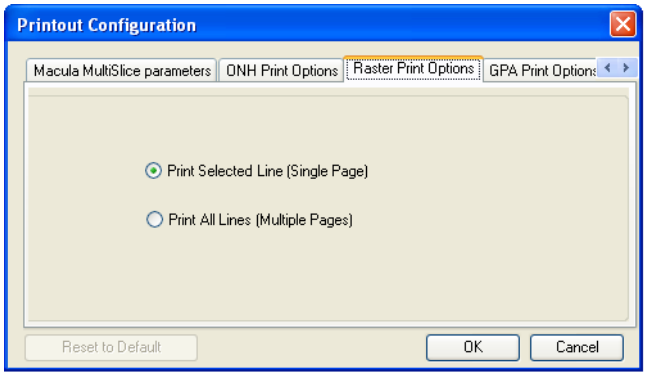


Figure 10-10 Raster Print Options

2. Click **Print Selected Line (Single Page)** to print just the selected line, or **Print All Lines (Multiple Pages)** to print all lines. This configuration will persist each time the report is generated.

When **Print All Pages** is selected in the **Print Configuration** dialog box, each page displays a different scan line in the larger format window.

Guided Progression Report Options

The Guided Progression Analysis (GPA) report has three report options:

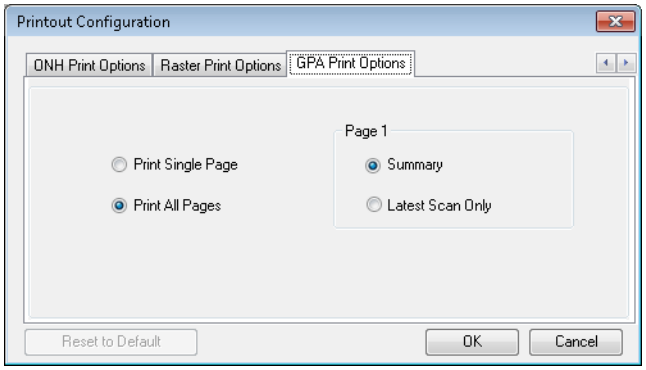
- Summary report
- Latest Scan report
- Parameters Summary Table report.

The GPA report is configurable to print a single page or two pages with either the Summary or Latest Scan Only report as the default single page or first page of a two–page report. The Parameters Summary Table report is the second page.

To change GPA report settings

1. On the **Tools** menu, click **Print Configuration**, and then click the **GPA Print Options** tab.
2. Select either **Summary** or **Latest Scan Only** as the default single page or first page of a two page report.
3. Select **Print Single Page** to print only the selected Page 1 option.

4. Select **Print All Pages** to print the selected Page 1 option and the Parameters Summary Table report.



Summary

The Summary report is the default single page or first page of a two–page GPA report. It displays all the information shown on the Guided Progression Analysis screen.

Latest Scan

The Latest Scan report is configurable as the default single page or first page of a two page GPA report. It displays only the latest exam RNFL thickness map and corresponding *en face* OCT Fundus image, but has the same GPA RNFL Thickness profiles and graphs as the summary report.

Parameters Summary Table Report

The Parameters Summary Table report is the second page of a two–page GPA report. It displays the baseline exam maps, latest exam map, past exam maps, corresponding OCT Fundus images indicating the location of the cup and disc boundaries, and a table that summarizes RNFL and ONH parameter data for Baseline 1, Baseline 2, and Current exams.

How to Read the GPA Report

Verify Data Quality

Verify the images. Discard or retake images with poor registration and/or poor signal strength (SS < 6) whenever possible, or interpret with caution. On the Report, SS = Signal Strength.

Verify image registration

Examine the RNFL Thickness profiles, Average RNFL Thickness graphs, and RNFL thickness maps. If the Baselines are not consistent, GPA will be less able to flag RNFL loss.

Examine GPA Report

Review the color–code RNFL/ONH Summary box. A yellow "Possible Loss" summary box indicates additional follow–up visits are recommended to confirm change. A red "Likely Loss" summary box indicates statistically significant change is detected in the

measurements. A lavender "Possible Increase" summary box could indicate high measurement variability.

Apply GPA Results in Context of the Patient

GPA reports statistically significant change for one eye, which may or may not be clinically significant. Rate of loss, locations of the detected loss, age of the patient, stage of the disease, and other clinical factors should be evaluated for clinical decisions. To confirm that RNFL loss is clinically significant, correlate your results with other clinical tests such as perimetry and IOP.

Consider Resetting the Baseline Scans

It is prudent to occasionally review the current Baseline scans and consider changing to a more recent Baseline pair if there has been a significant change in the course of the patient's care. A stable period of RNFL thickness may follow a period of RNFL thinning due to a change in therapy. This leveling off would be a good time to update the Baseline images. This will allow GPA to flag change from this new point in time instead of having the summary flags continuously checked off due to thinning that occurred at an earlier, less stable time.

Statistical Significance

Guided Progression Analysis compares an observed change with its expected test–retest variability, as illustrated in Figure 10-11.

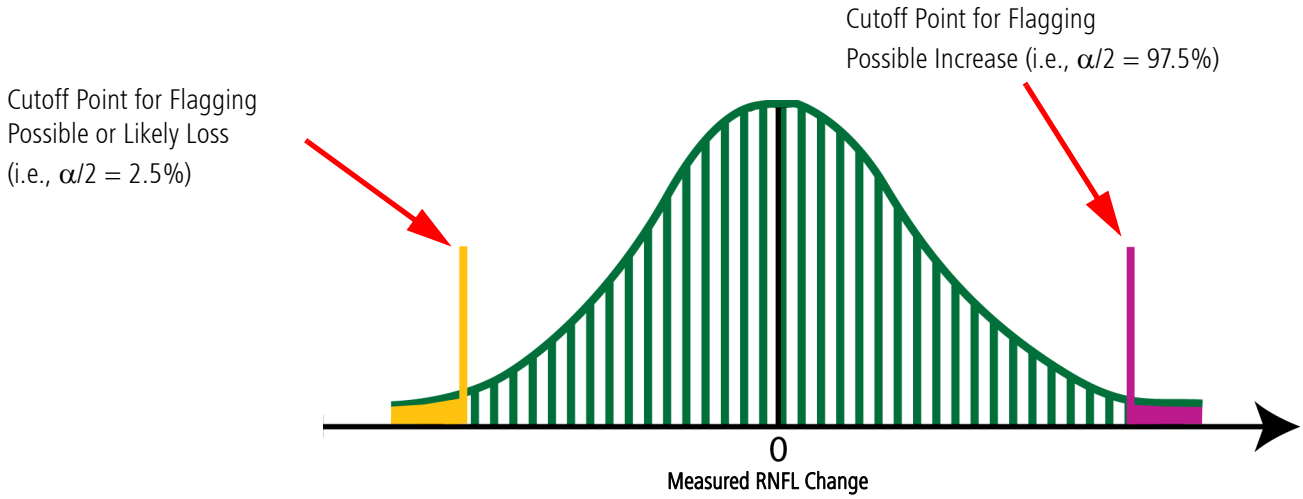


Figure 10-11 Distribution of Test–Retest Variability

Statistically Significant Change from Baseline

Guided Progression Analysis compares an observed change with its population test–retest variability. The test–retest variability was determined by performing an in–house repeatability and reproducibility study (results reported at ARVO 2008 in a poster, "*Inter–Visit and Inter–Instrument Variability for CIRRUS HD-OCT Peripapillary Retinal Nerve Fiber*

Layer Thickness Measurements" – M.R. Horne, T. Callan, M. Durbin, T. Abunto; Poster 4624, ARVO 2008).

The difference between a current exam and the Baseline is assumed to have a normal distribution with a standard deviation determined from clinical measurements on subjects over a short period of time. Only 5% of paired measurements are expected to have an absolute difference more than 1.96 times the standard deviation of differences observed in an in–house reproducibility study of normals, which is the test–retest variability. This is also equal to 2.77 times the reproducibility standard deviation observed. Figure 10-11 illustrates a normal distribution of differences, centered at a mean difference of zero. The yellow line shows the cutoff for declaring "Possible Loss" or "Likely Loss" and the lavender line shows the cutoff for declaring "Possible Increase." For any individual comparison of a measurement to Baseline, only 2.5% of measurements are expected to show change to the left of the yellow line when real loss has not occurred, and only 2.5% of measurements are expected to show change to the right of the lavender line.

Because thickness maps and profiles have multiple points available for testing, the observed rate of false positives would be higher than 5% if the cutoff is set based on the 95% confidence limit depicted in Figure 10-11. To achieve a reasonable false positive rate of no more than 5% for any given visit, the limits are set at 99% for the TSNIT profile and 99.5% for the change map.

Using Confirmation to Improve Specificity

In order to increase the specificity of the measurement over multiple visits, CIRRUS also requires that statistically significant change from Baseline be observed for at least two pairs of measurements when only three measurements are available, and for at least three pairs of measurements when four or more measurements are available. In this case, CIRRUS will report "Possible Loss" for a parameter. For example, a super-pixel on the change map will be colored yellow, or the RNFL Profile will show a yellow region between the Baseline and current scans, or the Average Thickness plot will show a yellow symbol for that visit. If, on the following visit, these same conditions are met for the same parameter, CIRRUS will report "Likely Loss", because now the change has been flagged for more than one visit. These confirmation strategies help improve the specificity, and reduce the effects of individual outlier measurements.

NOTE: RNFL thickness is expected to decrease slowly as a function of normal aging. The RNFL data collected for the normative database ("RNFL and ONH Normative Databases" on page A-15) showed a rate of loss for overall thickness of –0.2 µm per year, with a 95% confidence interval of –0.25 to 0.13 µm per year. For superior thickness, the rate was –0.25 µm per year (–0.35, –0.15), and for inferior thickness, it was –0.3 µm per year (–0.42, –0.21). This slow rate of change is consistent with observations of RNFL thickness loss measured on Stratus OCT. All of these results are based on cross–sectional data, and an individual patient's normal aging rate may vary. Because the exact rate of change for any individual is unknown, CIRRUS reports the 95% confidence limits on the slope. In the usual statistical understanding, a rate of change would be considered

statistically significant if the range of rates covered by the 95% confidence limits exclude zero.

It may be more useful to note that if the 95% confidence bands include a rate consistent with normal aging, the observed change may be due to normal aging process rather than glaucomatous loss.

Normative Data Details Reports

There is measurement variability for the macula parameters which may impact the normative database color coding. If the true value is near the limit of what the software uses to determine the normative database color code, then it is possible that the color code could vary from exam to exam. When at least one parameter is close to a normative limit, a blue icon button ⚠ displays. When your cursor hovers over this icon button, the tooltip appears as shown below.

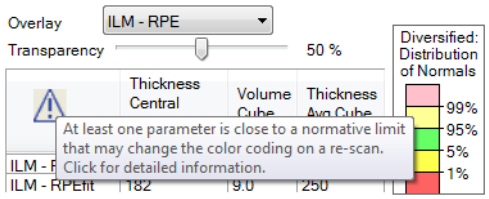


Figure 10-12 Measurement Variability Tooltip

If you click the blue icon button, you can select **Print Preview** or **Export to DICOM**. A **Print Preview** screen displays the Normative Data Details Report as shown below. The report can be printed from the **Print Preview** screen.

Macula Thickness Normative Data Details Report

The Normative Data Details Report displays the parameters of the analysis in the units measured and as a percentile from the normative database. In addition, the report displays the result minus the reproducibility limit, as well as the result plus the reproducibility limit, and their corresponding percentiles. Each of these measurements are presented with the appropriate normative database color code.

This report provides the ability to see how close a particular measurement comes to a normative limit cutoff by checking the actual percentile. In addition, the plus measurement variability and the minus measurement variability values are also color–coded so the user can determine if the original normative database designation would cross over to a different color level when considering the measurement variability. Due to measurement variability, it is possible that the normative data color coding may change on subsequent visits without representing a change in the condition of the patient. For more information on measurement variability, please see Appendix B.

You may generate a Normative Data Details Report from the following analyses:

- Macula Thickness Analysis
- Ganglion Cell Analysis
- Single Eye Summary
- ONH and RNFL OU Analysis
- RNFL Thickness Analysis

NOTE: ONH and RNFL OU Analysis and RNFL Thickness Analysis reports will print two pages of the Normative Data Details Report as these reports are OU reports (two eyes).

NOTE: The Normative Data Details Report is only available for the Diversified Database. The Normative Data Details Report is not available for a patient for whom the Asian Normative Database has been applied.

11 Data Management

FORUM/DICOM or Native Environment

When your CIRRUS HD-OCT instrument is installed, your CZMI Representative will visit your site, and ensure that your software has been installed correctly and in accordance with your network and archiving requirements.

Most often, unless you are part of a large organization and have many Zeiss instruments, your instrument (and hence, your Review Stations – PC's or Laptops running only licensed Review Software) will be configured in "Native mode." That is, your patient data will reside on your CIRRUS HD-OCT instrument database only. In this case, the amount of data stored locally is limited by the size of the CIRRUS hard-drive. When your hard-drive is full, the oldest data will be cleared (if archived) to make room for new data. You will be informed if this is necessary.

If, however, you have purchased the FORUM/DICOM option, your patient data will reside on a separate (even remote) FORUM archive storage device. When data is saved, it will always be sent as DICOM Archive storage location, while the data on your CIRRUS instrument will be cleared. This means that you will never run out of storage on your instrument.

FORUM is useful because it runs "on top" of the DICOM protocol, and specifically designed for the exchange of data modalities within configurations of Zeiss instruments. This simplifies the review of patient data when such data has been compiled as a result of multiple screenings of various types on more than one instrument.

Whether or not you have a FORUM enabled DICOM system or you are running in Native mode, you must still specify certain system parameters in a way that is DICOM compatible. This is because Zeiss equipment conforms to the DICOM standard for medical equipment. See http://dicom.nema.org/ for additional information on the DICOM standard.

Importing and Exporting Data

Patient Privacy

The CIRRUS HD-OCT gives you the choice to export exam data without information that could identify the patient. Upon import, anonymous or "obscured" patient records appear in the patient list with the originating institution name in the last name field and a unique Patient ID generated during export. You have the further option to export a complete date of birth, only the month and year of birth, or only the year of birth (see Table 11-1).

NOTE: The unique Patient ID created when you export with this option is referred to as the Obscuration ID. The originating clinic can perform an advanced search with the Obscuration ID by entering it into the Obscured ID field of the advanced search function. This will find the original exported patient. See "Advanced Search" on page 5-5 for

more information. Users who wish to obtain additional medical information about an anonymous patient must contact the originating clinic.

Data Integrity of Imported Records

For all imported patient records, it is possible to import new scan data and update patient data, including obscured patient records. If during import the CIRRUS HD-OCT encounters information associated with a patient that was already imported, the CIRRUS HD-OCT does the following:

- imports all scan data (exams) not previously imported, but never deletes nor overwrites any scan data already imported;
- updates patient data only if it was created on a later date than the data already imported. This prevents overwriting of newer patient data with older.

Import/Export Native Mode

To export data:

1. If you are exporting to removable media, insert the media into its drive. If not, skip to the next step.
2. From the Toolbar ("Toolbar Options" on page 3-5) (with the Patient Screen ("Basic Screens" on page 3-3) open), select **Records > Export Exams.** The **Export Options** dialog will appear.

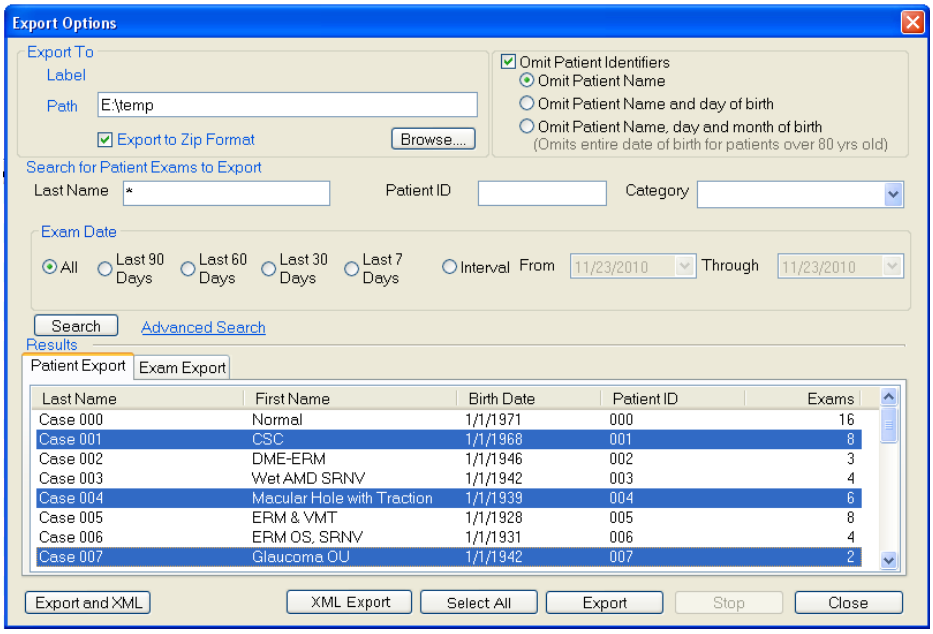


Figure 11-1 Export Options Dialog

The first time anyone exports using this system, the export **Path** field will be empty. After the first time, the last export path used will appear initially.

3. To change the export destination, in the **Export To** area, click **Browse** and select the desired folder in the desired location, or click the **Make New Folder** button to make and name a new folder for this export in the currently selected location.

NOTE: If the target system on the network requires a password for access, you must have already logged in to the target system via Windows before attempting to export there.

4. Click **OK** to save and close the dialog. The destination you selected will appear in the **Path** field back in the **Export Options** dialog.

Export to Zip Format is checked by default. The export volume will be compressed into one zip file inside the export folder. The name of the zip file will be the Label of the export volume. You do not need to uncompress the zip file before importing—just select the zip file for import and all data will be imported. Export to Zip Format takes extra time to compress and then uncompress the files when imported. For export of a large number of patients/exams, the extra time can be significant and is not recommended. It is recommended to always create a new folder when exporting zip files. If you select **Export to Zip Format** and the export folder already contains patients exported to the same folder without using the zip format, a zip file will be created that contains the currently selected patients *and p*reviously exported patients. Any existing zip files in the folder will not be included.

5. Search for patients whose exams you wish to export in the middle area of the **Export Options** dialog (Figure 11-1, page 11-2) labeled **Search for Patient Exams to Export**. You can search for patients by **Last Name, Patient ID, Category** or **Exam Date** range. Select the desired options and click **Search**. The **Results** lists shows the patients matching all search criteria used. You may also search and export a single exam.

   - For more search options, click **Advanced Search**—see "Advanced Search" on page 5-5 for details.

6. In the **Results** list, click to select one patient whose exams you wish to export. Ctrl–click to select multiple patients, or click **Select All** to select all patients in the list.
7. Patient information can be hidden (as for a clinical trial). Check the **Omit Patient Identifiers** checkbox if you want to omit any patient identifiers in the resulting exported exams. Select the radio button to one of three possible identifier omit options as described in Table 11-1 below.

Option	Description
Omit Patient Name	This option inserts the Institution name in the patient's **Last Name** field and a 17 character Unique Patient ID number in the **First Name** and **Patient ID** fields (e.g., 20070609081320226, the date and time of patient creation to a thousandth of a second).
Omit Patient Name and day of birth	In addition to above, 1 will be used for day of birth.
Omit Patient Name, day and month of birth	In addition to above, 1 will be used for the birth month. For patients over 80 years old, the birth year will be 80 years in the past from the current year.

Table 11-1 Patient Identifier Omit Options

NOTE: You cannot edit or merge patient information for patients imported with omitted patient identifiers.

8. When you have made your selections, click **Export**. Export progress is shown in an expanded area at the bottom of the **Export Options** dialog.

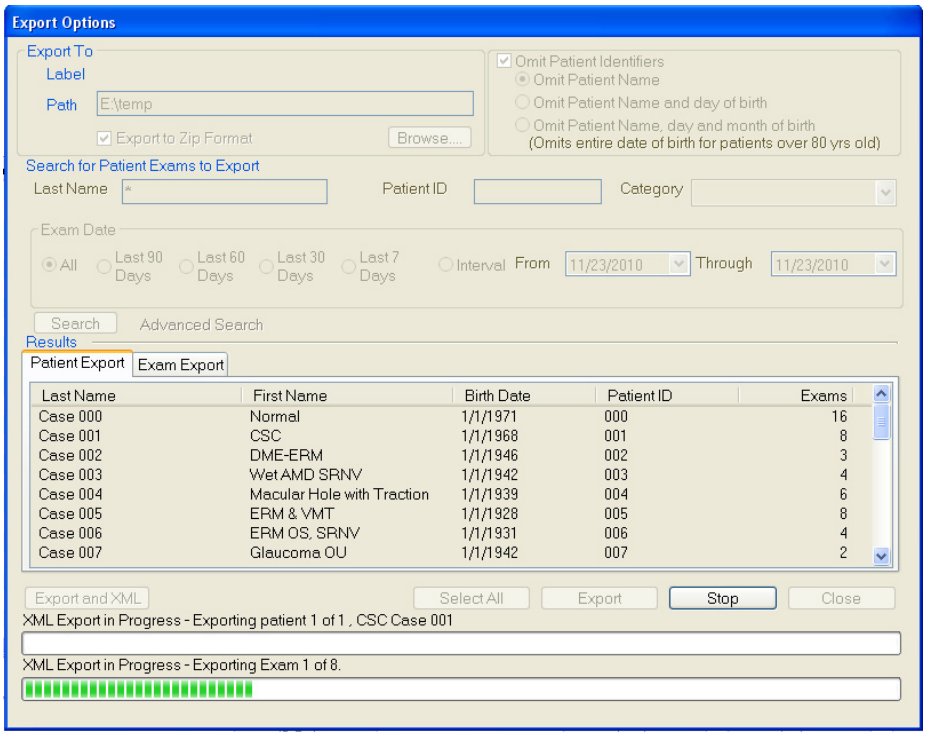


Figure 11-2 Export Progress

A unique name for each export database is generated automatically and appears in the **Label** field at upper left.

NOTE: If a previous export volume exists on the selected destination path, a user message appears to confirm the following selected options for the exam export. See Figure 11-3.

Figure 11-3 Export Volume Alert Screen

- **Increment**: This option adds the exported exams to the existing exported volume on the same destination path.
- **Overwrite**: This deletes the existing exported volume at the same destination path location and a new export volume is created.
- **Cancel**: Cancels the export operation.

NOTE: CIRRUS HD-OCT enables you to export cleared archive data. If the cleared data is on a network archive, the data will be exported from the archive automatically. If the file server is not connected, you will be prompted to connect with it.

You may export repeatedly to the same export folder (on a network drive or the same removable media), in which case CIRRUS adds only those exams that were not already exported and does not overwrite any data previously exported. You may interrupt an export operation and then start it again later, and only the exams not already present in the export database are exported.

It is possible to export data:

- **To a hard-drive on the CIRRUS instrument itself**. Do not use the C: drive however. Specify a location for data export that is not the same location where the local database is stored.
- **Directly to another CIRRUS HD-OCT instrument** (see "FORUM/DICOM Mode" on page 11-5).

FORUM/DICOM Mode

Transferring Images in OPT IOD and OP IOD Formats

This function allows the export of image files from the instrument or CIRRUS Review Software, in a standard DICOM format for viewing on a remote station.

NOTE: This option is not available for the Optic Disc Cube scan and both Anterior Segment scans.

Terms

- IOD – Information Object Definition
- OP – Ophthalmic Photography
- OPT – Ophthalmic Tomography
- OPT IOD – DICOM standard format for archiving and transferring OCT images as black and white images
- OP IOD – DICOM standard 8–bit Image format for archiving and transferring the fundus images as black and white images

Enabling this Operation and Setting Transfer Times

To start using this functionality:

1. Go to **Records > Preferences > DICOM Archive** and select **Send OP and OPT IODs During Archive (Except After Saving)** (see Figure 11-4 below).

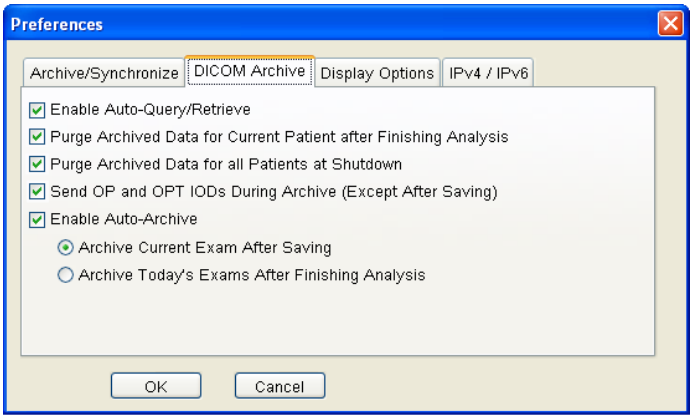


Figure 11-4 DICOM Preferences Options

2. Configure archiving preferences by selecting **Enable Auto–Archive** and selecting either **Archive Current Exam After Saving** or **Archive Today's Exams After Finishing Analysis**.

When you select **Finish** at the end of an analysis, there is the choice to **Archive Now** or to wait until later. The duration of the image transfer can vary depending on the system, the network connection and other factors.

NOTE: If you are adding the FORUM Data Management system to your practice and plan to migrate existing data to the FORUM Archive, consult with Zeiss regarding options for creating and migrating files in OP/OPT format. Creating these files from prior data can significantly extend the time for data migration.

Data Queries and Search Options

DICOM Workflow for Modality Worklist allows queries of archived patients.

To display a list of archived patients scheduled for exams:

1. Select **Records > Search Worklist Patients**. The Modality Worklist dialog appears (Figure 11-5).

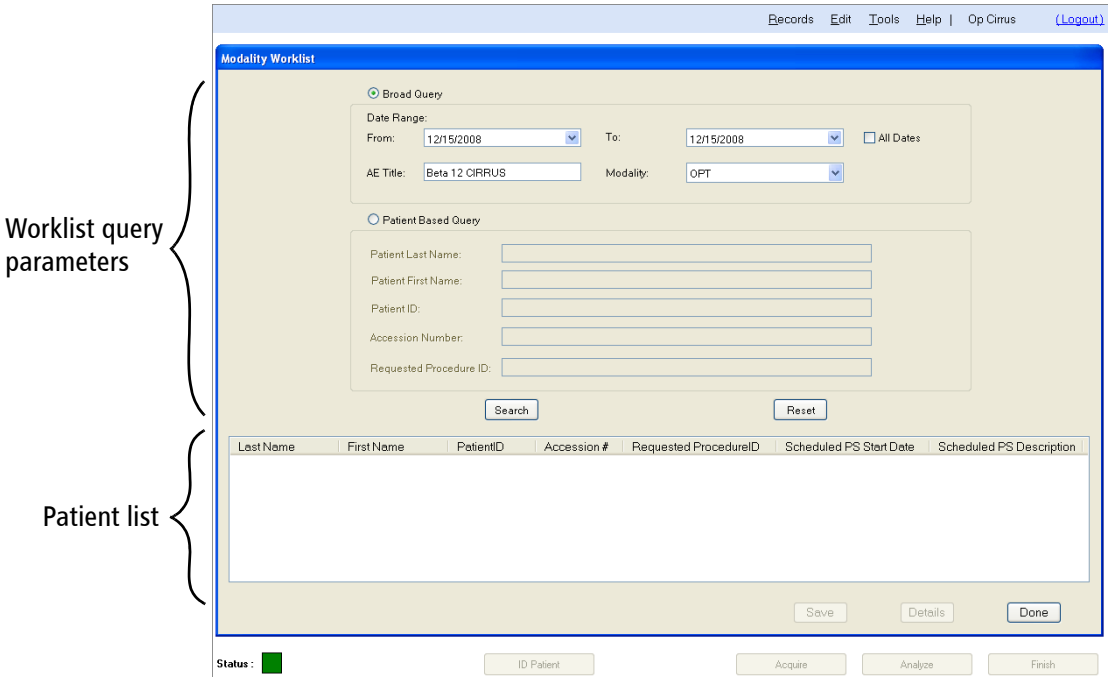
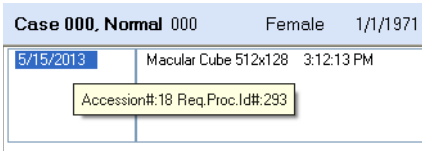


Figure 11-5 Modality Worklist

Patients can be searched based on the following parameters:

- **Broad Query** – Access by **Date Range**, **AE Title**, or **Modality**.
- **Date Range** – Search for Patients scheduled for an exam within the range selected. The default date range is for the current date. To enable searching for all dates, check the **All Dates** checkbox.
- **AE Title** – Read from the **Equipment Edit** dialog (Figure 4-2). Any changes to AE Title do not affect the **AE Title** of this instrument. It is only for use in searching for patients.
- **Modality** – For the CIRRUS instrument is OPT. Other options are provided for searching purposes only.
- **Patient Based Query** – You can also search for a study by clicking **Patient Based Query** and filling in one or more of the parameters listed, then clicking **Search**.
- **Accession Number** – Determined from the **Analysis** screen when the mouse cursor is over an exam date in the upper left corner, as shown on



the left. The Requisition Procedure ID number also appears here.

2. Click **Search** to see the list of patients within the search parameters. Patients retrieved are loaded into the **Patient List** in the **Modality Worklist** window.
3. To view the details of any retrieved patient, select the patient and click **Details**. The **Details** dialog appears, as shown below (Figure 11-6).

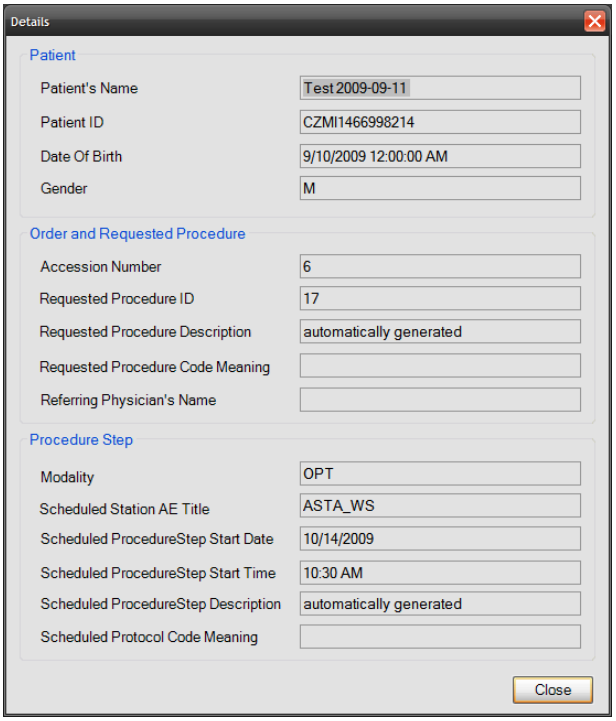


Figure 11-6 Selected Patient Details

4. To add a patient to your instrument database, select the desired patient(s), then click **Save**. Repeat this step until all desired patients are added to the local database.
5. Click **Done** to close the **Modality Worklist** window. The application returns to the same tab that was previously selected on the main window before worklist search.

Once the operation is complete, click the **View Today's Patients** tab on the **ID Patient** screen to see the patients imported from the DICOM server.

NOTE: Avoid changing any patient information for the worklist patients retrieved from the DICOM server. Conflicting patient information will elicit a message from the DICOM server regarding disposition of patient. You will be asked to choose which patient you want to retrieve on subsequent retrieval queries.

XML Export

The XML option allows the numerical export of values that appear on certain analysis screens.

Batch XML Export

The numeric values of **Macular Thickness Analysis** and **ONH and RNFL OU Analysis** are exported in batch. To initiate the batch XML export, in ID patient mode, select **Records > Export Exams...** to open the **Export Options** dialog, Figure 11-7.

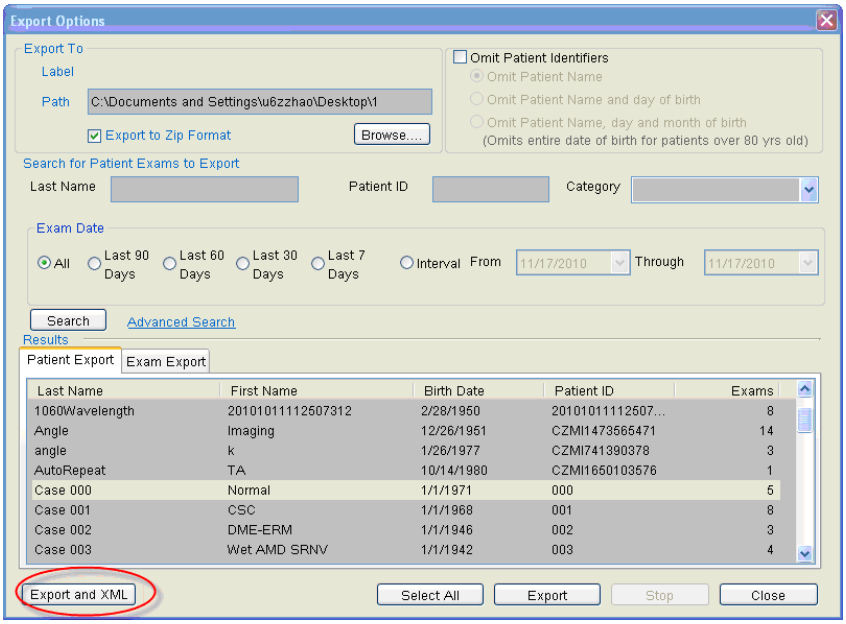


Figure 11-7 XML Export

XML Export from Analysis Screens

The following CIRRUS HD-OCT analyses allow XML export of specific values as described in the sections which follow:

- Macular Thickness Analysis
- ONH and RNFL OU Analysis
- Macular Change Analysis
- Guided Progression Analysis
- Ganglion Cell OU
- Advanced RPE

Values Exported: Macular Thickness Analysis

The values labeled on the **Macular Thickness Analysis** screen, Figure 11-8, are exported to a XML file. The labels of these values in the XML file are listed in the table below.

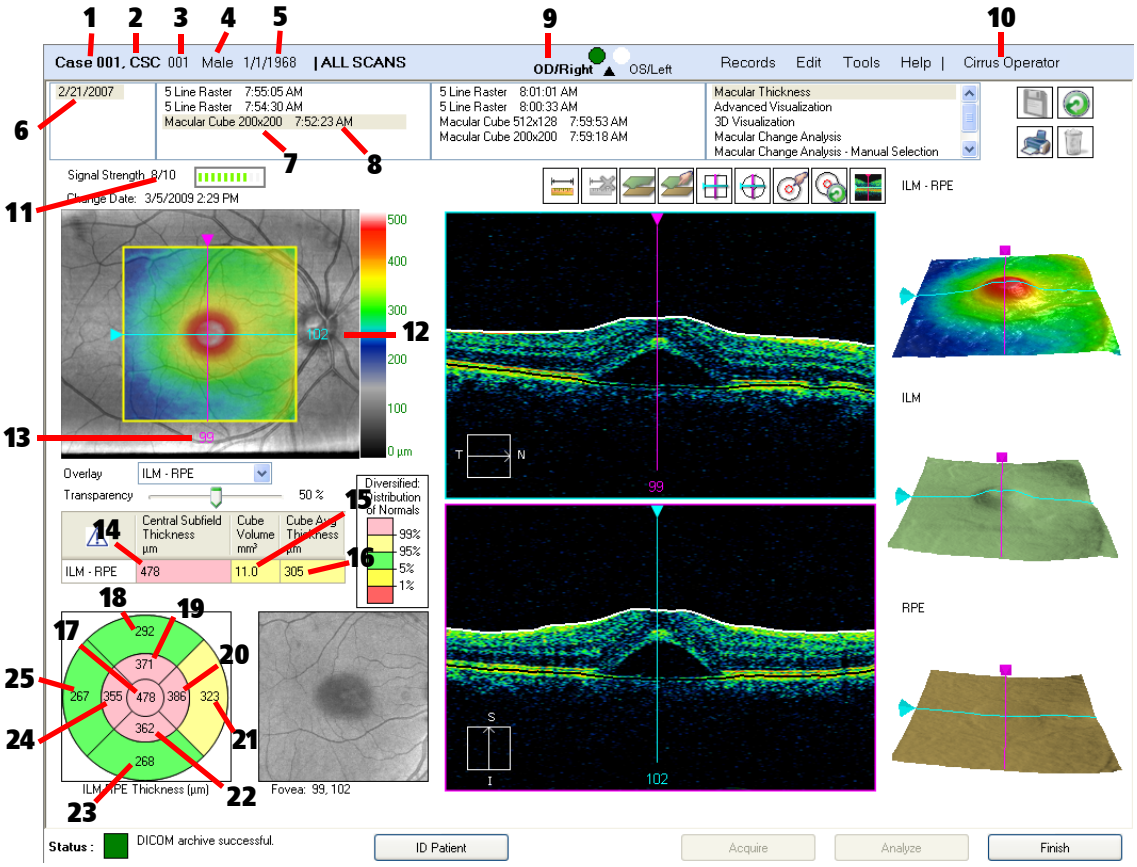


Figure 11-8 Values Exported from Macular Thickness Analysis

Index	XML File Label	Index	XML File Label	Index	XML File Label
1	LAST_NAME	9	SITE	17	Z_CENTER
2	FIRST_NAME	10	OPERATORNAME	18	Z_OUTERSUPERIOR
3	PATIENT_ID	11	SIGNALSTRENGTH	19	Z_INNERSUPERIOR
4	GENDER	12	FOVEA_Y	20	Z_INNERRIGHT
5	BIRTH_DATE	13	FOVEA_X	21	Z_OUTERRIGHT
6	VISIT_DATE	14	ILMRPECENTRAL	22	Z_INNERINFERIOR
7	PROTOCOL	15	ILMRPEVOLUME	23	Z_OUTERINFERIOR
8	DATE_TIME	16	ILMRPEAVERAGE	24	Z_INNERLEFT
				25	Z_OUTERLEFT

NOTE: Fields 20, 21, 24, and 25 are exported exactly as they are shown on the screen. As an example, field 20, Z_INNERRIGHT, refers to the inner right hand sector as seen on the screen. Thus for the right eye (OD), it is the Inner Nasal sector. For the left eye (OS), it is the Inner Temporal Sector.

Values Exported: ONH and RNFL OU Analysis

The values, labeled on the **ONH and RNFL OU Analysis** screen, Figure 11-9, are exported to a XML file. The labels of these values in the XML file are listed in the table below the figure.

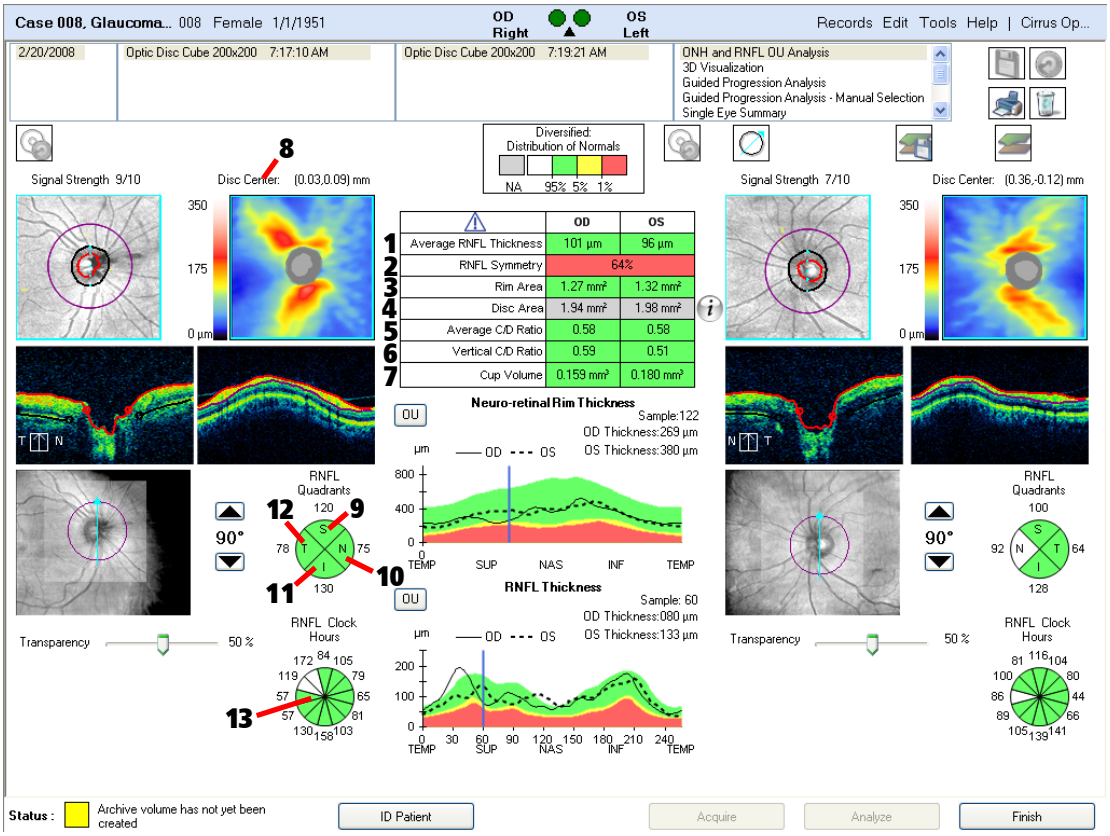


Figure 11-9 Values Exported from ONH and RNFL OU Analysis

Index	XML File Label	Index	XML File Label	Index	XML File Label
1	AVERAGETHICKNESS	6	VERTICAL_CD_RATIO	11	QUADRANT_I
2	SYMMETRY	7	CUPVOLUME	12	QUADRANT_T
3	RIMAREA	8	ONHCENTER_X,Y	13	CLOCKHOUR–1–12
4	DISCAREA	9	QUADRANT_S		
5	AVERAGE_CD_RATIO	10	QUADRANT_N		

Where Field 10 is the nasal quadrant, which will appear on the right in the report for the right eye (OD) and on the left for the left eye (OS). Field 12 is the temporal quadrant, which

will appear on the left in the report for the right eye (OD) and on the right for the left eye (OS).

Export Values: Macular Change Analysis

The XML export from the **Macular Change Analysis** screen is performed by clicking the **XML Export** button (shown on the left). The values, labeled in the **Macular Change Analysis** screen, Figure 11-10, are exported to a XML file. The labels of these values in the XML file are listed in the table below.

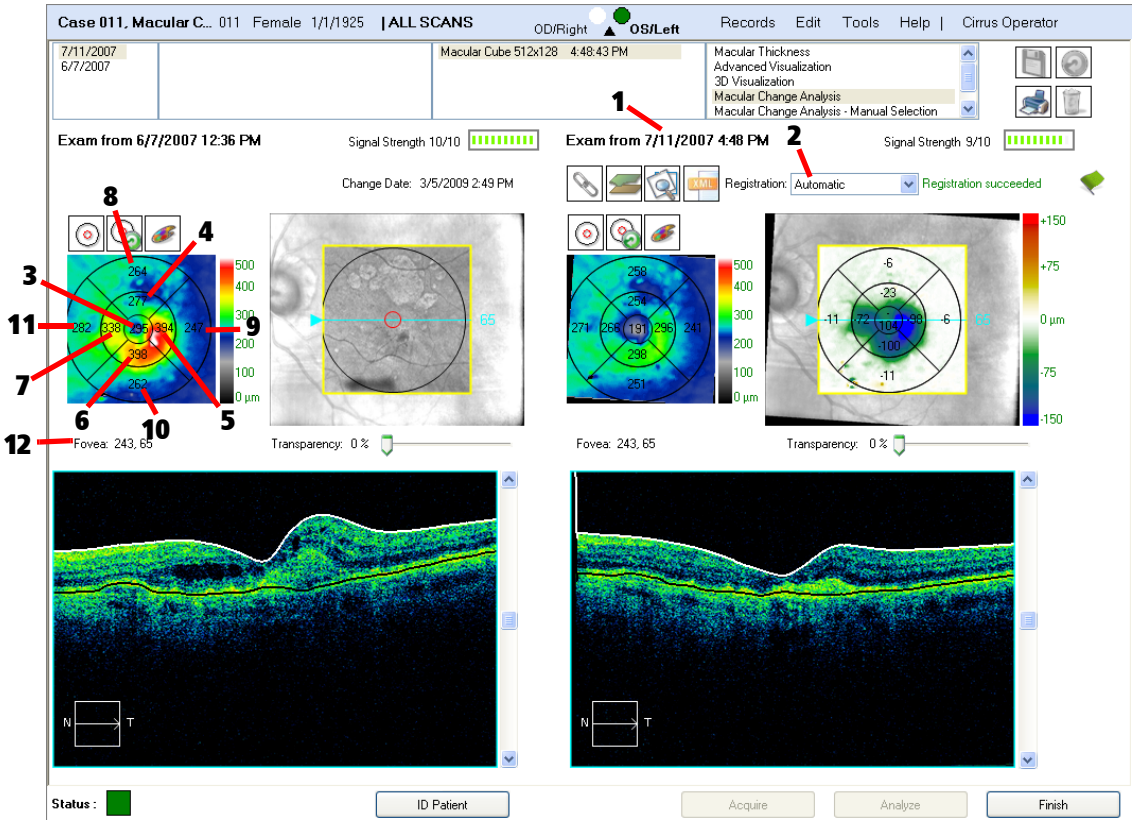


Figure 11-10 Values Exported from Macular Change Analysis

Index	XML File Label	Index	XML File Label	Index	XML File Label
1	DATE_TIME	5	Z_INNERRIGHT	9	Z_OUTERRIGHT
2	REGISTRATION	6	Z_INNERINFERIOR	10	Z_OUTERINFERIOR
3	Z_CENTER	7	Z_INNERLEFT	11	Z_OUTERLEFT
4	Z_INNERSUPERIOR	8	Z_OUTERSUPERIOR	12	FOVEA_X,Y

NOTE: Fields 5, 9, 7, and 11 are exported exactly as they are shown on the screen. As an example, field 5, **Z_INNERRIGHT**, refers to the inner right hand sector as seen on the screen. Thus for the right eye (OD), it is the Inner Nasal sector. For the left eye (OS), it is the Inner Temporal Sector.

Values Exported: Guided Progression Analysis

The XML export from Guided Progression Analysis is performed from analysis screen by clicking the **XML Export** button. The values, labeled in the **Guided Progression Analysis** screen, Figure 11-11, are exported to a XML file. The labels of these values in the XML file are listed in the table below.

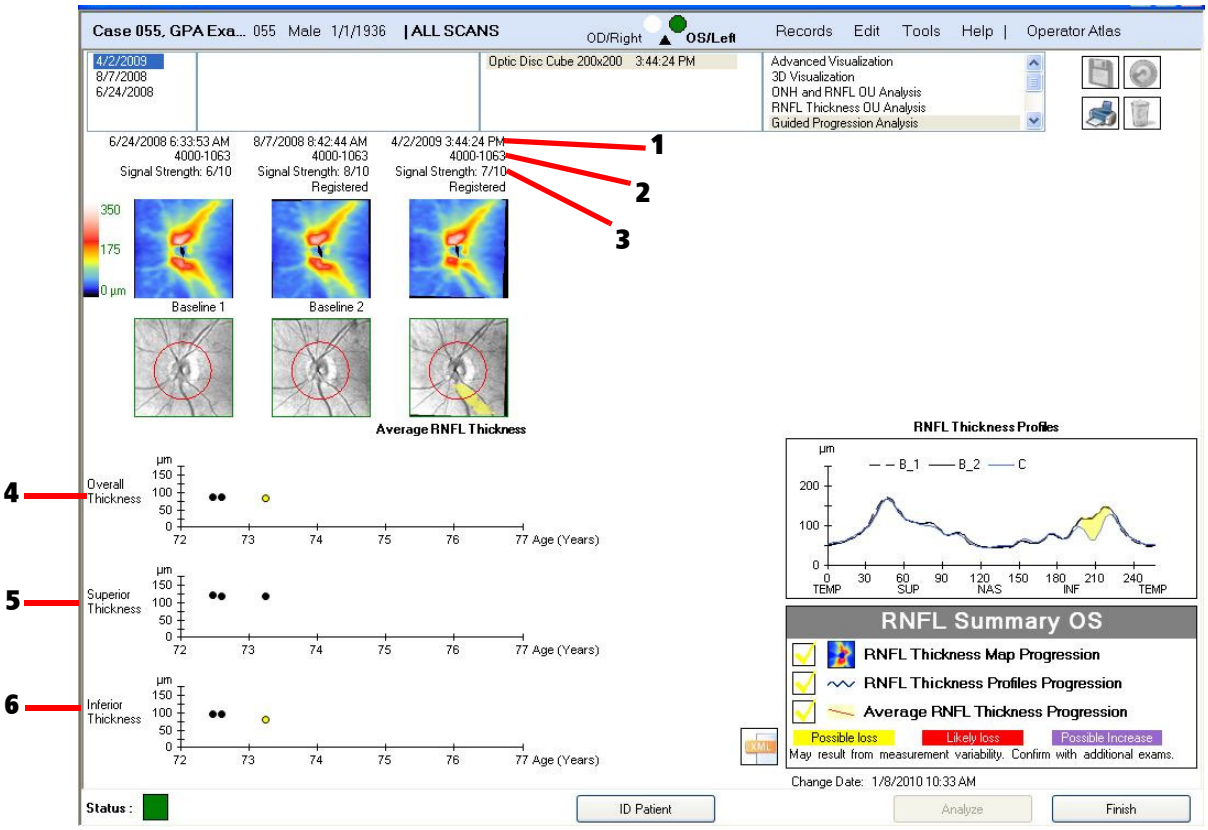


Figure 11-11 Values Exported from Guided Progression Analysis

Index	XML File Label	Index	XML File Label	Index	XML File Label
1	DATE_TIME	3	SIGNAL_STRENGTH	5	SUPERIOR_THICKNESS
2	SERIAL_NUMBER	4	OVERALL_THICKNESS	6	INFERIOR_THICKNESS

Values Exported: Ganglion Cell OU Analysis

The values, labeled in the **Ganglion Cell OU Analysis** screen, Figure 11-12, are exported to a XML file. The labels of these values in the XML file are listed in the table below.

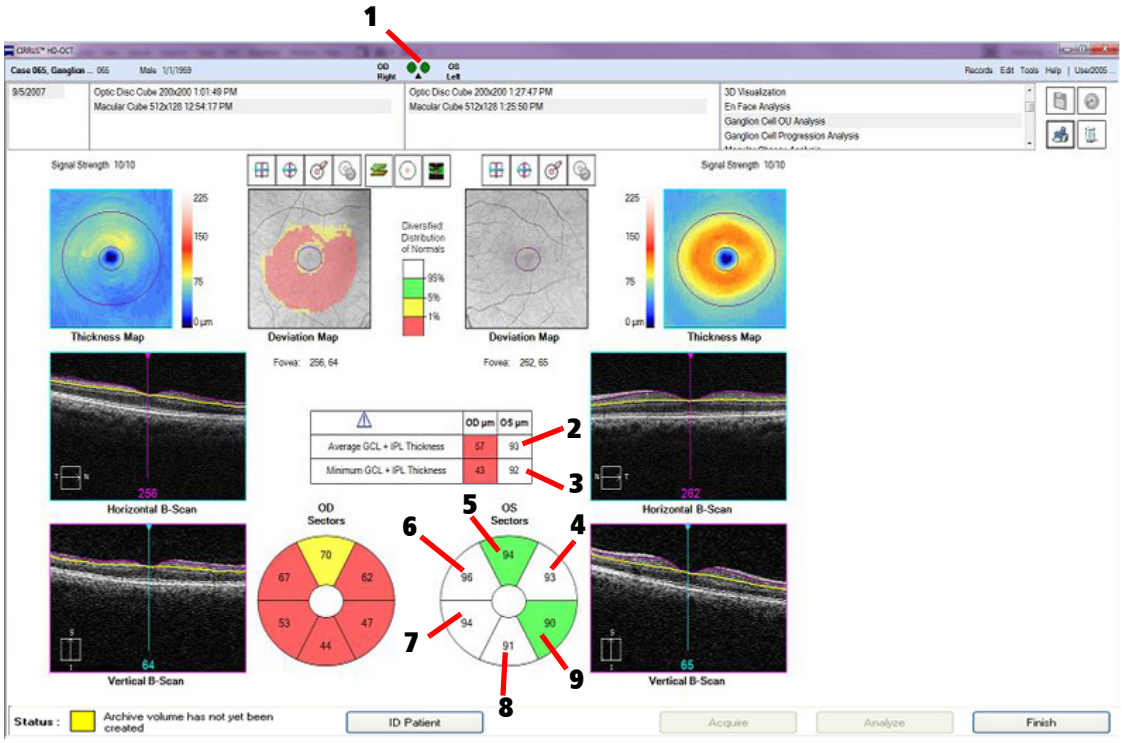


Figure 11-12 Values Exported from Ganglion Cell OU Analysis

Index	XML File Label	Index	XML File Label	Index	XML File Label
1	SITE	4	GC_TEMPSUP	7	GC_NASINF
2	GC_AVERAGE	5	GC_SUP	8	GC_INF
3	GC_MINIMUM	6	GC_NASSUP	9	GC_TEMPINF

NOTE: Fields 4 through 9 are exported as they are labeled. Field 4 is the temporal superior sector, which appears to the upper left of the annulus for the right eye (OD) and to the upper right of the annulus for the left eye (OS). Field 6 is the nasal superior sector, which appears to the upper right of the annulus for the right eye (OD) and to the upper left of the annulus for the left eye (OS). Field 7 is the temporal inferior sector, which appears to the lower left of the annulus for the right eye (OD) and to the lower right of the annulus for the left eye (OS). Field 9 is the nasal inferior sector, which appears to the lower right of the annulus for the right eye (OD) and to the lower left of the annulus for the left eye (OS).

Values Exported: Advanced RPE Analysis

The values, labeled in the **Advanced RPE Analysis** screen, Figure 11-13, are exported to a XML file. The labels of these values in the XML file are listed in the table below.

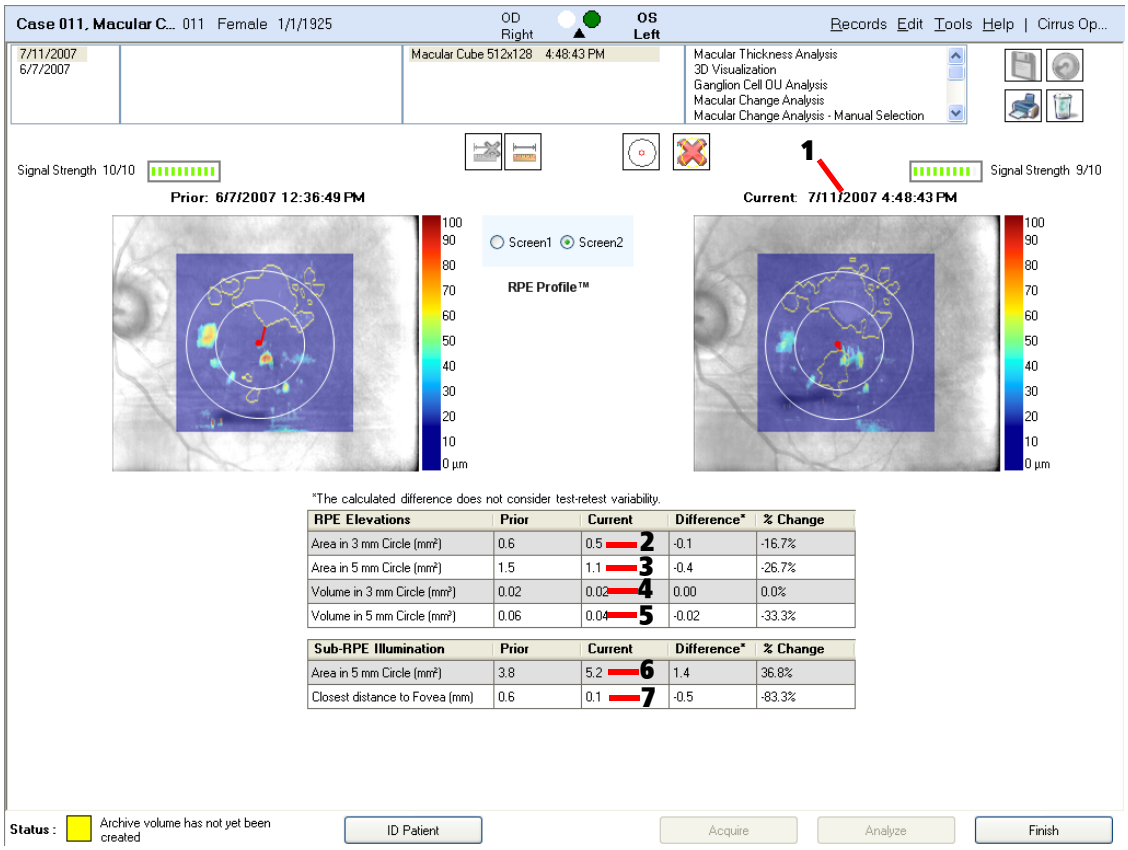


Figure 11-13 Values Exported from Advanced RPE Analysis

Index	XML File Label	Index	XML File Label
1	DATE_TIME	5	VOLUME_OF_RPEELEVATIONSFIVEMMCIRCLE
2	AREA_OF_RPEELEVATIONSTHREEMMCIRCLE	6	AREA_OF_SUBRPE_ILLUMINATION
3	AREA_OF_RPEELEVATIONSFIVEMMCIRCLE	7	CLOSEST_DISTANCE_TO_FOVEA
4	VOLUME_OF_RPEELEVATIONSTHREEMMCIRCLE		

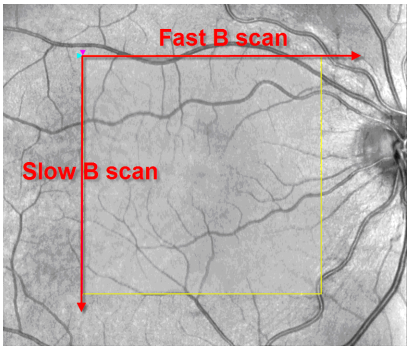
Advanced Export

Click on the **Advanced Export** button on the **ONH and RNFL OU Analysis** screen, to export and store ILM-RNFL thickness maps as .DAT files and .txt files of Neuro-retinal Rim Thickness and RNFL Thickness profiles to a user-selectable directory

Dat Files of ILM–RNFL Thickness Maps

NOTE: DAT files are plain text files that can be read from an Excel or Matlab application.

Each comma–delimited value is the thickness of an A-scan. Each row represents a fast B-scan. Each column represents a slow B-scan, as shown in the figure below. The first row represents the topmost fast B-scan and the first column represents the leftmost slow B-scan.



Txt Profiles of Neuro–retinal Rim Thickness and RNFL Thickness

The profiles of Neuro–retinal Rim Thickness and RNFL Thickness are saved to **.txt** files by clicking on the **Advanced Export** button on the **ONH and RNFL OU Analysis** screen. The files are plain text files.

The neuro–retinal rim thickness values at 180 points, each point representing 2 degrees, are saved. Furthermore, the RNFL thickness values at 256 points, each point representing 1.41 degrees, are saved in the files.

For both profiles, the thickness data points start from temporal, to superior, nasal, inferior and finally back to temporal — the same direction as on the screen. Patient and exam information is also saved in these files.

Move Scan Data (Native Mode Only)

Occasionally, in Native Mode, a scan is acquired and saved in the wrong person's file. Scans that are incorrectly stored can be moved to a different file by using the **Move Scan** feature. To access the **Move Scan** dialog:

1. Open the file with the incorrect or misplaced scan and choose an analysis to display the data. For example, for a Macula Cube scan, choose Macular Thickness analysis.

2. Select **Edit > Move Scan....** The **Move Scan** dialog opens. To populate the patient list, either click **Search** to return all patients, or specify search parameters in the fields provided. You can also click **Advanced Search** to search with more parameters.

Select the patient whose file you wish to move the scan data into by left–clicking that patient name. Click **Move** to start the move process (you will need to confirm) or click **Cancel** or to close the dialog without moving the scan.

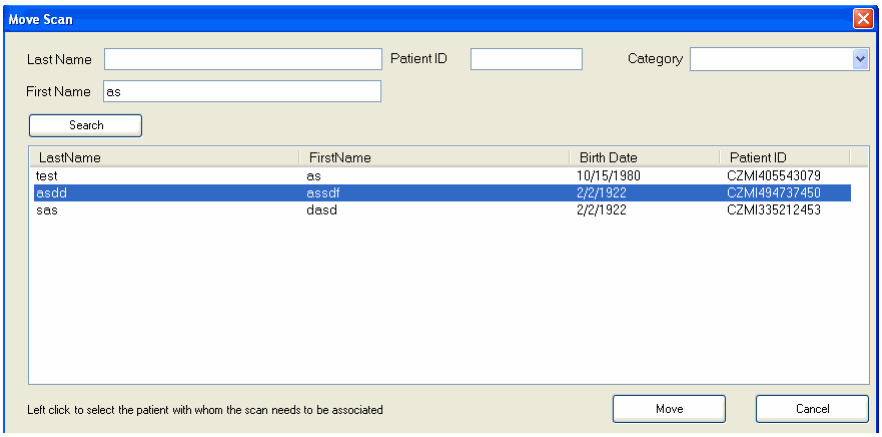


Figure 11-14 Move Scan Dialog

Log Files

The CIRRUS HD-OCT records the following events and identifies them by date, time, and User ID:

- Log on/log off
- Display of analysis data
- Creation, modification, deletion of data
- Import/export of data from removable media
- Receipt/transmission of data from/to an external connection (network, for example)
- Remote service activity

The events are automatically recorded in up to 5 audit files of 5 Mb each. When the maximum limit for files and file size is reached, the CIRRUS overwrites the existing files.

The default folder for the audit log files is
C:\ProgramData\Carl Zeiss Meditec\CIRRUS HD-OCT\Logs.

NOTE: It is highly recommended that you archive audit log files are regularly.

To export audit log files:

1. Log on as administrator.
2. Click **Tools > Export Audit Log File**.

In the **Browse For Folder**, browse to the folder you want to export to, and then click **Save**. The log is exported as a .zip file with the name: AuditLog_*dd_mm_yyyy_hh_mm*.

12 Routine Maintenance

NOTE: Except for the top fan filter, the CIRRUS HD-OCT has no user–replaceable parts. The user must not attempt hardware repairs without consulting Zeiss service personnel. To do so voids the instrument warranty. However, we may provide software updates that users can install.

Troubleshooting Power Problems

This section assumes that the instrument will not power on. Troubleshooting your power problem depends on whether or not you power the instrument through the optional power table.

If Not Using the Optional Power Table

If you power the instrument directly from a wall outlet (not through the optional power table), check the following to determine the source of the power problem:

1. Is there power available everywhere in your office?
   - If not, there may be a localized power outage in your office or a general power outage in your neighborhood.
   - If so, proceed to Step 2.
2. Is the instrument power cord plugged in at both ends?
   - If not, plug in the cord and try to power up the instrument.

If Using the Optional Power Table

If you are using the optional power table, the instrument is powered through it. Check the following to determine the source of the power problem, in order:

1. Is there power available everywhere in your office?
   - If not, there may be a localized power outage in your office or a general power outage in your neighborhood.
   - If so, proceed to Step 2.
2. Does the table have power (while the instrument does not)? You can test the table by trying the lift.
   - If the table has power, the power problem is within the instrument. First, check that the instrument power cord is plugged in at the power table and at the instrument. If the table does not have power, check that the table is plugged in at both the wall outlet and at the table.

Handling Error Messages

In normal instrument start–up, the User Login dialog appears. If the system fails the system check, or if some other error prevents the system's normal function, document the circumstances and any associated error messages, and report it to Zeiss customer service. In the U.S., call 800–341–6968. Outside the U.S., contact your local Zeiss distributor. Often error messages can be resolved with solutions provided over the telephone.

Please be prepared to provide CZMI the serial number of your instrument. It is located on the label affixed to the back of the instrument, under the rear cover.

Product Labels and Serial Number Location

The product label is located just above the rear cover of the instrument.

To gain access to the label showing the serial number, remove the rear cover. To remove the rear cover, depress the two snaps at its top edge.

Figure 12-1: Removing Rear Cover

A small label indicates the month and year of manufacture in MMYYYY format (for example, 042013).

Routine Cleaning

The forehead and chinrests, and to a lesser extent the imaging aperture and LCD screen, are the only parts that require routine cleaning. Instructions are included below for occasional cleaning of the instrument covers and optional power table.

CAUTION: The instrument has no special measures to protect against harmful ingress of water or other liquids (classified IPX0—ordinary equipment). To avoid damage to the instrument and a safety hazard, cleaning solutions, including water, must be applied sparingly, with a non–linting cloth that is dampened only—not dripping wet! You must not use aerosols on or near the instrument.

Forehead and Chinrests

The instrument parts that routinely contact the patient—the forehead and chinrests—should be cleaned between each examination with an alcohol prep wipe. These parts are not removable.

External Surfaces of the Instrument

To remove dust and oily smudges from the external surfaces of the instrument, periodically clean plastic covers and housings with an alcohol prep wipe, and dry with a soft, non–linting cloth.

CAUTION: Alcohol prep wipes may damage glass lens components of the imaging aperture and external lenses. Do not use alcohol prep wipes to clean glass lenses.

Imaging Aperture Lens and External Lenses

To clean the glass lens components of the imaging aperture and external lenses, use the dry camera lens wipes (2660100007673) and camera lens cleaner (2660100007672) listed in "User Replacement Accessories" on page 12-5. Apply a small amount of the camera lens cleaner to the dry lens wipe and gently clean the lens.

If a patient's eye inadvertently contacts any part of the imaging aperture or an external lens, clean the imaging aperture or the external lens before proceeding with the examination.

CAUTION: Wipe gently and carefully to avoid scratching the instrument and auxiliary lenses.

LCD (Monitor) Screen

Clean the LCD screen when necessary to remove dust and oily smudges that impair viewing. Turn off the monitor first. We recommend that you use a soft cotton cloth; if a dry cloth does not completely clean the screen, you can dampen the cloth with water only and wipe the screen with the damp cloth.

Top Fan Filter

Periodically, inspect the top fan filter located under the removable cover on top of the instrument (Figure 12-1). The filter should be checked, at least, twice a year; in dusty environments, more frequently. Push on the snap connector and pull the cover back and up. It will swing open and can then be easily removed.

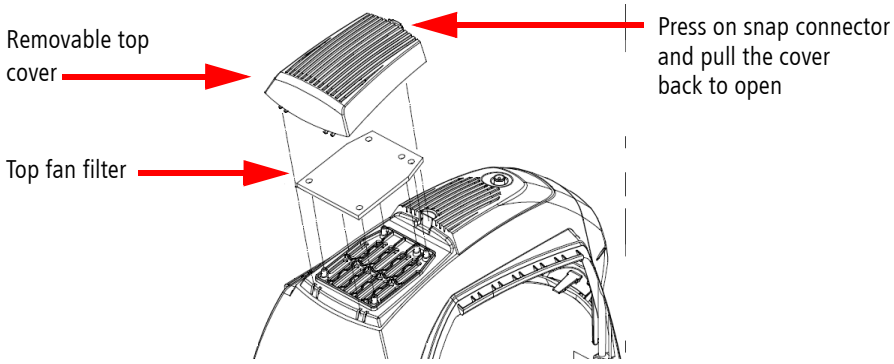


Figure 12-1 Top Fan Filter Illustration

Clean and/or replace, as necessary. Brush off excess dust and dirt. Clean with a mild liquid soap and water. Allow to thoroughly dry before placing it back in the instrument. Replace cover after replacing the filter.

CAUTION: When dusting of the instrument or table is necessary, use a dry non–linting soft cloth. Do not use aerosols, as these can penetrate the instrument covers and damage the instrument.

CAUTION: When the instrument covers or table require cleaning or disinfecting, wipe with a non–linting cloth or wipe, dampened only—not dripping wet!—with water or alcohol. Wipe dry with a clean and soft non–linting cloth.

User Replacement Accessories

Part Number	Description
0000001217033	Power Cord, IEC 320, 39 Inch
2660021115973	Power Cord, IEC 320 to NEMA, 12 Inch
2660021123062	Dust Cover, Instrument
2660021149361	Fixation Device (External)
3197519005000	Occluding Sleeve for Fixation Device
3013509052000	Red Fixation Lamp
2660021124008	Ocular Lens Cover
2660021158407	Cornea Lens (Models 500/5000)
2660021158406	Anterior Chamber Lens (Models 500/5000)
2660021150088	Anterior Segment Calibration Tool
2660100061991	Top Fan Filter
2660100006566	Alcohol Wipes
2660100007672	Camera Lens Cleaner
2660100007673	Camera Lens Wipes
2660021160365	Verification Test Tool
2660021121819	Cable, Network, CAT5e, 14FT
2660021116418	Cable, USB MA–MB, 6FT
2660021161047	Kit, Test Eye, includes: • Verification Test Tool • Fixation Device • Occluding Sleeve for Fixation Device • Red Fixation Lamp

NOTE: Item part numbers and descriptions are subject to change.

To order: In the U.S., call 800–341–6968. Outside the U.S., contact your local Zeiss distributor.

Performance Verification Check

With the Performance Verification Check, you can verify that the fundus image of the CIRRUS HD-OCT instrument and the OCT scan image overlay are aligned within specifications as defined by the target inside the Verification Test Tool. Practically, this means the scan actually is placed where it appears to be placed, based on the fundus image. You can re–try the check if it does not pass initially.

NOTE: If a performance verification check fails, the data acquired since the last successful check may not be reliable.

- **Frequency**: Weekly, or at the beginning of each week you will acquire new scans.
- **Time Required for Test**: Approximately 2 minutes.
- **Verification Test Tool Required**: Zeiss provides this tool with each instrument. It contains fragile parts that must be maintained in their original position for the test measurements to be accurate.

CAUTION: Handle the Verification Test Tool carefully to avoid dropping. Damage to the Verification Test Tool can affect test results. If you drop the tool, it is recommended that you do not use it for testing. Immediately contact Zeiss customer service. In the U.S., call 800–341–6968. Outside the U.S., contact your local Zeiss distributor.

Install the Verification Test Tool

Install the Verification Test Tool in the correct orientation. The tool has short pegs at upper left and lower right, and thumbscrews at upper right and lower left. Each of these corresponds to a hole on the face of the ocular lens housing.

Using only your fingers, turn the screws (clockwise) on top and bottom to secure the tool in place. To avoid dropping the tool, make sure that both screws are tight before releasing the tool.

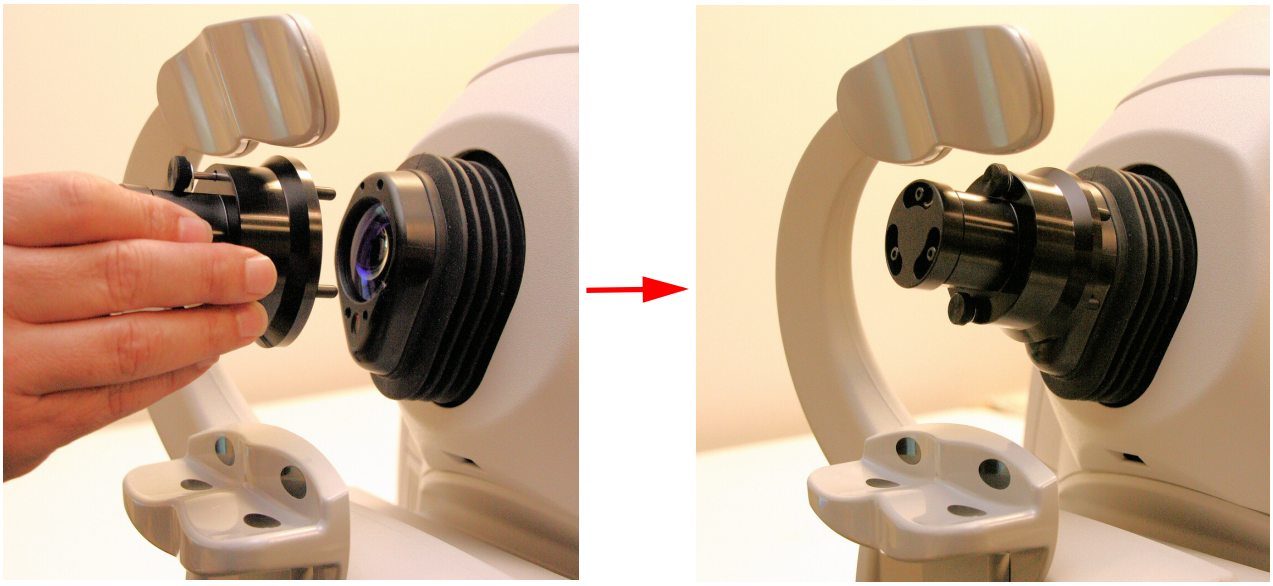


Figure 12-2 Proper Installation of Verification Test Tool

Run the Check

To run the check, follow these steps:

1. In the ID Patient Screen, select the patient named **Performance Verification** and then click **Acquire**.

NOTE: You cannot edit or delete the Performance Verification patient record.

The **Acquire** screen appears, showing a default Macular Cube 512x128 scan.

2. Select **Macular Cube 200x200** in the scan list.

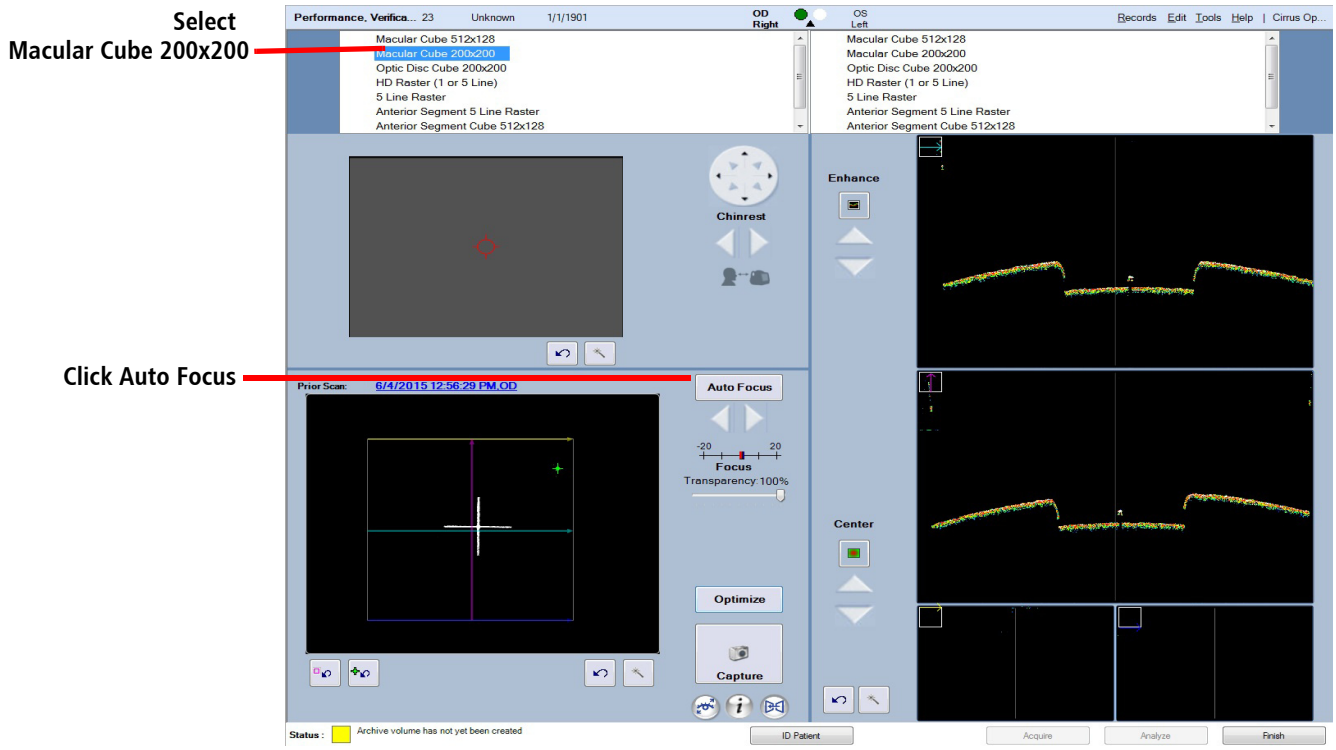


Figure 12-3 Performance Check – Macular Cube 200x200 Selected

3. Click **Auto Focus** to get a clearer image of the cross–hair test pattern. (Use the focus arrows if your system does not have Auto Focus activated.) Besides focus, other adjustments usually are not necessary, although possible.
4. Click **Capture** and then select **OD** or **OS** in the **Select Eye** dialog that appears. The **Review** screen appears automatically.

NOTE: Pay no attention to the image appearance nor to the signal strength value in the **Review** screen. They have no bearing on the co–alignment of the scan and fundus images, which is what this test evaluates. If necessary, you can adjust the brightness and contrast later in the **Analysis screen** when evaluating the test.

5. Click **Save** and then either **Finish** or **ID Patient** to exit data acquisition. You will return to the **ID Patient** screen.
6. Select the **Performance Verification** patient again and click **Analyze**.
7. In the **Analysis screen**, select the scan you just saved.
8. Select **Macular Thickness Analysis** in the right–hand column.

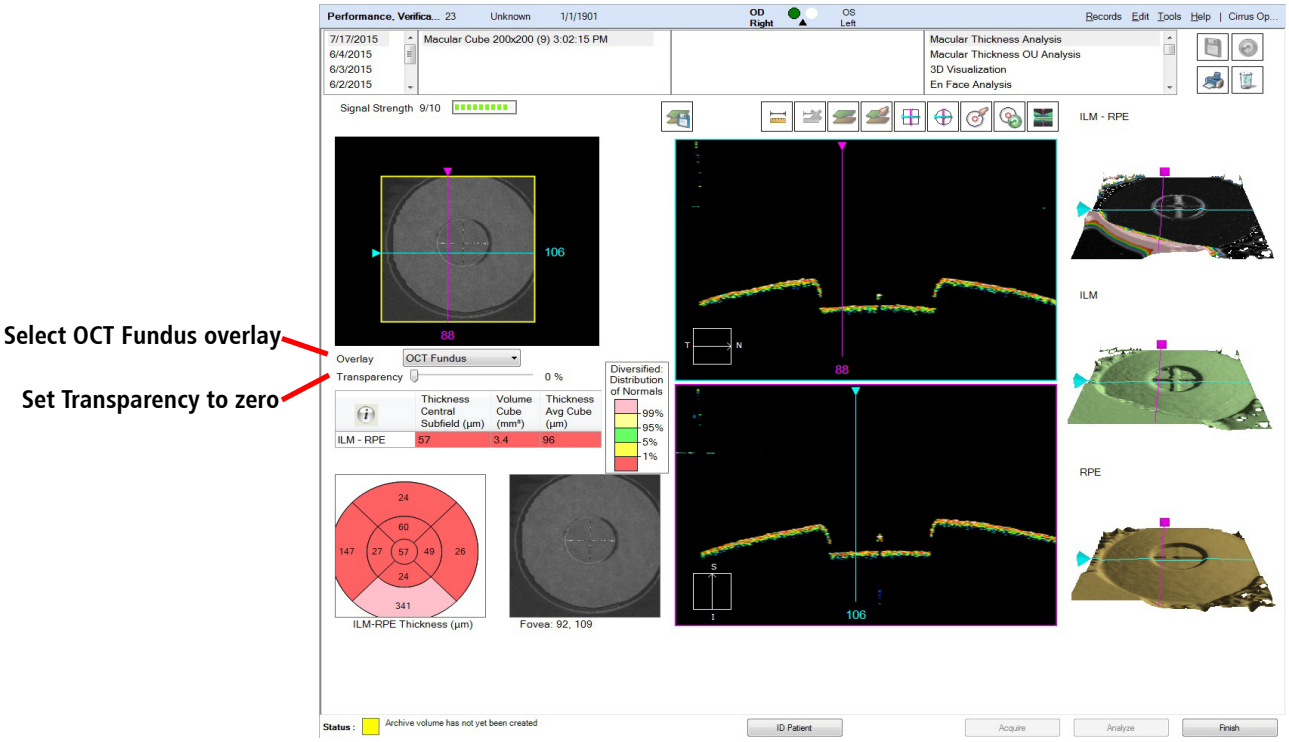


Figure 12-4 Performance Verification Analysis Screen Initially

9. When the scan loads, select **OCT Fundus** in the **Overlay** drop–down menu.
10. Set the **Transparency** slider to zero.

11.Double–click anywhere on the fundus image to make it appear full screen.

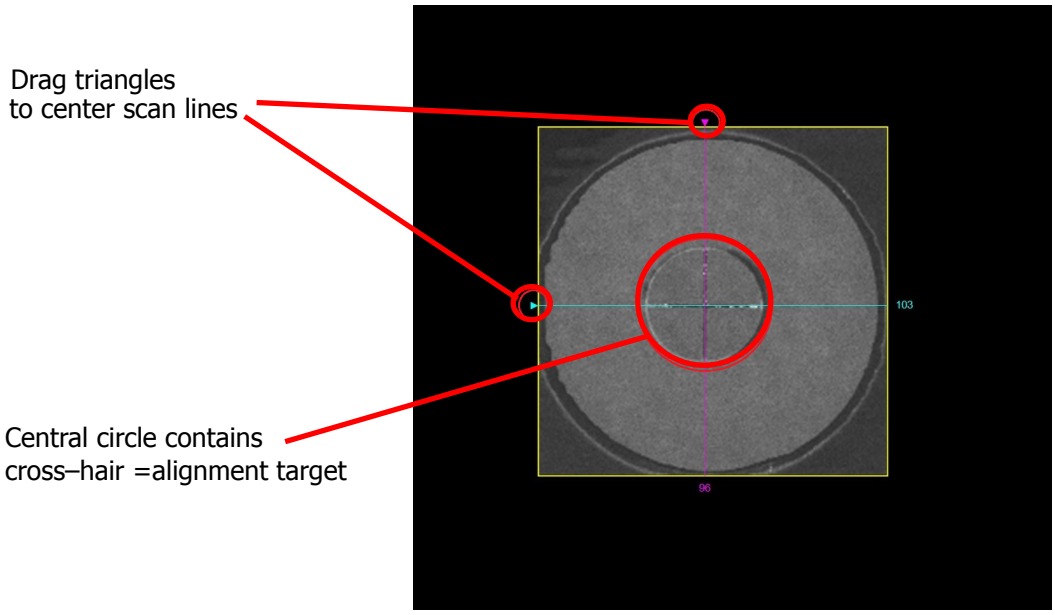


Figure 12-5 Fundus Viewport Full Screen With 0% Transparency (Opaque)

Note the cross–hair pattern in the center of the target. The alignment target is in the center of the cross–hair. The white cross defines the acceptable range of alignment between the fundus image and the OCT scan image, as explained below.

NOTE: When the blue and magenta lines are correctly centered, you may find it difficult to see where they cross, because the scan lines are nearly as thick as the lines that comprise the central cross.

12.With **Transparency** set at 0% (opaque), use the triangles to drag the horizontal and vertical scan line indicators until they intersect in the very center. This way, they should cross in the center of the circle, which is the alignment target.

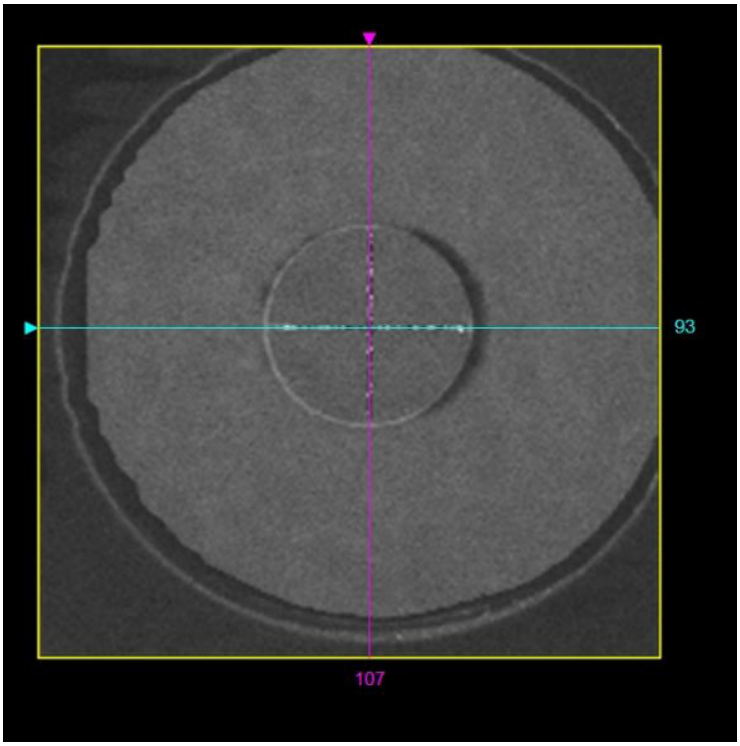
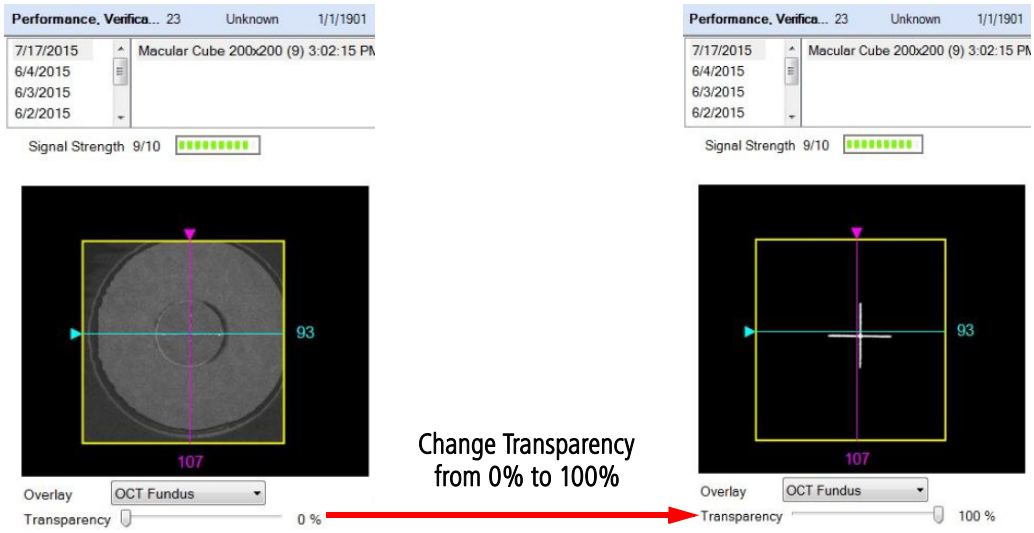


Figure 12-6 Blue and Magenta Lines Centered on Alignment Target

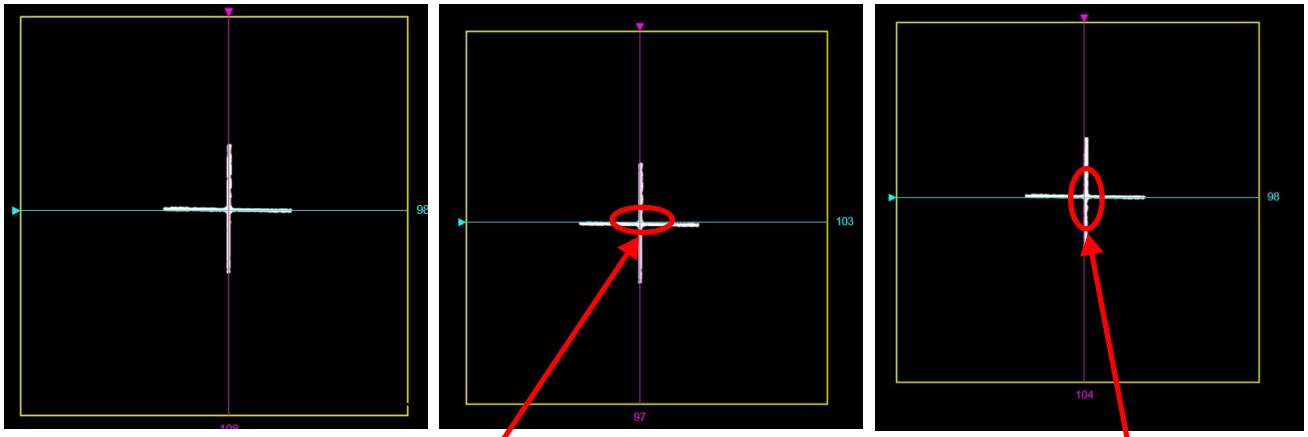
13. Click **Back** at upper right (or double–click anywhere) to exit full screen mode.



14.Move the **Transparency** slider to 100% (transparent) and double–click again to make the fundus image appear full screen. Now you are ready to evaluate the test.

Pass Condition

- **Pass**: After changing the **Transparency** to 100%, if both scan line indicators pass partially or wholly through the center, the system passes the check. This means the co–alignment of the fundus image and the OCT scan image is within the acceptable range. Some examples of pass conditions appear below.



Pass—both lines centered | Pass—horizontal line marginal, but OK | Pass—vertical line marginal, but OK

Figure 12-7 Examples of Pass Conditions

Failure Condition

- **Fail**: After changing the **Transparency** to 100%, if one or both scan line indicators pass clearly within the black portion of the center, the system fails the check. Some examples of failure conditions appear below.

In effect, when there is a failure condition, you can clearly see that one or both of the scan line indicators fail to pass within, even marginally, the white cross–hair in the center.

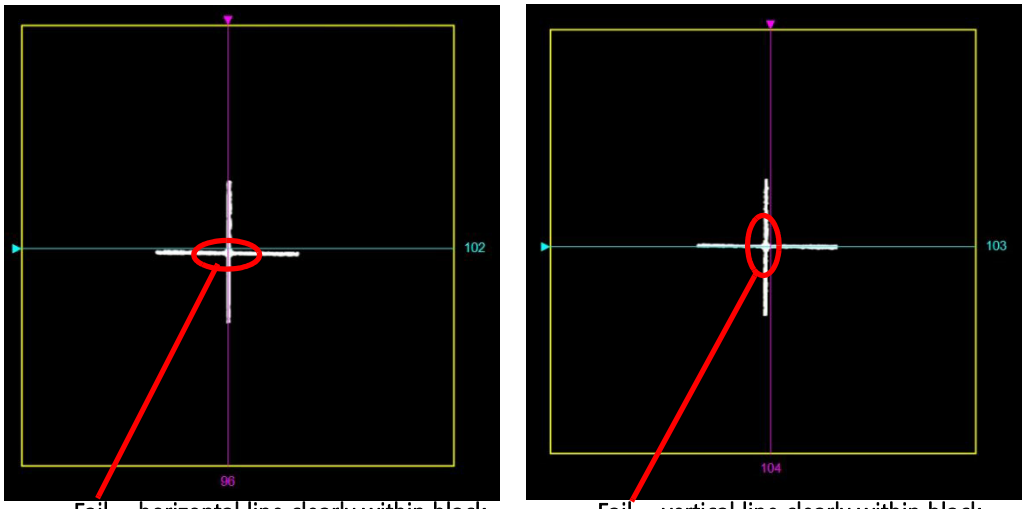


Figure 12-8 Examples of Failure Conditions

NOTE: Evaluation is somewhat subjective. We offer the examples above as guidelines. If you drag the scan lines, you will observe that there is only a two or three pixel range of movement while still within the pass condition, and only a one pixel difference between a marginal pass and a failure. The center cross–hair defines a stringent range of tolerance. Therefore, you should confirm a failure only if the scan line indicators lie wholly within the center of the cross–hair pattern.

- To confirm your observation, you should switch back to 0% **Transparency**.
- If your observation is confirmed initially, you should remove and re–install the test tool to ensure it is seated properly and then run the check again.
- If the system still fails the test, contact Zeiss customer service. In the U.S., call 800–341–6968. Outside the U.S., contact your local Zeiss distributor.

If you want to repeat the test, we recommend you first remove and re–install the test tool.

13 Specifications

HD-OCT Imaging

	Model 500	Model 5000
Methodology	Spectral domain OCT	
Optical source	Superluminescent diode (SLD), 840 nm	
Optical power	Nominal 600+/–60 µW at cornea Safety shutoff: maximum 825 µW at cornea	
Maximum Scan speed	68k A-scans/sec	

HD-OCT Imaging for Posterior Segment Scans

	Model 500	Model 5000
A-scan depth	2.0 mm (in tissue), 1024 points	
Axial resolution	5 µm (in tissue)	
Transverse resolution	15 µm (in tissue)	

HD-OCT Imaging for Anterior Segment Scans

Model 500 and Model 5000						
	Anterior Segment Cube 512x128	Anterior Segment 5 Line Raster	Anterior Chamber	HD Angle Scan	HD Cornea/ Pachymetry Scan	Wide Angle-to-Angle
A-scan depth	2.0 mm (in tissue) 1024 points	2.0 mm (in tissue) 1024 points	5.8 mm (in tissue), 2048 points	2.9 mm (in tissue), 1024 points	2.0 mm (in tissue), 1024 points	2.9 mm (in tissue), 1024 points
Axial resolution	5 µm (in tissue)					
Transverse resolution	<20 µm	<20 µm	<45 µm	<20 µm	<25 µm	<45 µm

Fundus Imaging

	Model 500	Model 5000
Methodology	Live OCT Fundus technology	Line scanning ophthalmoscope
Live fundus image	During alignment	During alignment and during OCT scan
Optical source	Superluminescent diode (SLD), 840 nm	Superluminescent diode (SLD), 750 nm
Optical power	Nominal: 600+/–60 µW at the cornea. Safety shutoff power: maximum 825µW at cornea	< 1.5 mW at the cornea
Field of view	36 degrees W x 22 degrees H	36 degrees W x 30 degrees H
Frame rate	> 1.7 Hz	> 20 Hz
Transverse resolution	45 µm (in tissue)	25 µm (in tissue)

Iris Imaging

	Model 500 and Model 5000
Methodology	CCD camera
Resolution	1280 x 1024
Live iris image	During alignment

Electrical, Physical and Environmental

	Model 500	Model 5000
Weight	34 kg (76 lbs)	36 kg (80 lbs)
Dimensions	65L x 46W x 53H (cm)	
Fixation	Internal, external	
Internal fixation focus adjustment	–20D to +20D (diopters)	
Input devices	Keyboard, mouse	
Electrical rating (115V)	Single Phase, 100/120V~ systems:50–60Hz, 5A Line and Neutral are fused.	
Fuse rating	N/A	
Electrical rating (230V)	Single Phase, 220/240V~ systems:50–60 Hz, 2.5A Line and Neutral are fused.	
Convenience Receptacle output ratings	N/A	
Temperature (transport and storage)	–40° to +70° C	
Relative humidity (transport and storage)	10% to 100%, including condensation	
Atmospheric pressure (transport and storage)	500 hPa to 1060 hPa	
Temperature (operation)	+10° to +35° C	
Relative humidity (operation)	30% to 75%, excluding condensation	
Altitude (operation)	Up to 3000 m above sea level.	
Atmospheric Pressure (operation)	700 hPa to 1060 hPa	
Computer	• i7 Intel® processor • Internal storage: > 80,000 scans • USB ports, 6 • Integrated 19" color flat panel display • Windows 7 Ultimate, 64 bit	
Room Lighting	Standard indoor office fluorescent lamp environment. Not to be used in direct sunlight (e.g., near a window).	

Maintenance

Zeiss recommends regular preventative maintenance.

NOTE: Only trained CZMI personnel may perform calibration.

Measurement Units

All units on the CIRRUS HD-OCT are measured in the SI format. Unless otherwise noted, measurements are made in micrometers (µm).

14 Legal Notices

Software Copyright

The software program ("Software") included with your CIRRUS HD-OCT is a proprietary product of Zeiss and in certain instances contains material proprietary to Microsoft Corporation. These proprietary products are protected by copyright laws and international treaty. You must treat the software like any other copyrighted material.

Software License Agreement

This Software license agreement ("License") is a legal contract between the Purchaser ("You", "Your" "Licensee") and Zeiss governing Your use of the Software. Opening the sealed package indicates Your acceptance of the terms and conditions of this License. If You have any questions concerning this License, contact Carl Zeiss Meditec, Attention Customer Service, 5160 Hacienda Drive, Dublin, CA 94568. Telephone 800–341–6968.

License Terms and Conditions

1. In consideration of payment of the License fee which is part of the price You paid for Your CIRRUS HD-OCT, and Your agreement to abide by the terms and conditions of this License and the Limited Warranty, Zeiss grants to You a non–exclusive, non–transferable and non–assignable license to use and display this Software on a single CIRRUS HD-OCT, under the terms of this License. If the CIRRUS HD-OCT on which You use the Software is a multi–user system, this License covers all users on that single system.
2. The license is granted solely for the use of Your own internal computing requirements and does not grant You any right, title or ownership in the licensed software or its documentation. You own the physical media, CIRRUS HD-OCT, on which the Software is originally or subsequently recorded or fixed, but You understand and agree that Zeiss retains title and ownership to the Software recorded on the original disk copies and all subsequent copies of the Software.
3. This Software is copyrighted. Unauthorized copying of the Software, including Software that has been modified, merged or included with other software, is expressly forbidden. You may not, nor may You permit others to (a) disassemble, decompile or otherwise derive source code from the Software (b) reverse engineer the Software, (c) modify or prepare derivative works of the Software, (d) provide on–line or similar uses to third parties, or (e) use the Software in any manner that infringes the intellectual property or other rights of another party. You may be held legally responsible for any copyright infringement that is caused or encouraged by Your failure to abide by the terms of the License.

4. Zeiss may create updated versions of the Software, which You may purchase separately.
5. This license does not include the right to make copies of software, nor to transfer the software or copies from the Product(s) to third parties, nor to extract, modify or incorporate any part of the software or source code, without prior written consent from Zeiss and payment of licensing fees. Further, sales of CIRRUS HD-OCT instruments may not include any software or software licensee transfers. You may not sublicense, rent or lease the Software.
6. Zeiss warrants the operation of the Software only with the operating system for which it was designed. Use of the Software with an operating system other than that for which it was designed will not be supported by Zeiss. Zeiss does not claim that the software provided is free from defects and shall have no obligation to supply software upgrades (i.e., new versions, or new, or in–line releases).

Acknowledgment

You acknowledge that you have read all the provisions in this Chapter, including this License and Limited Warranty, understand them, and agree to be bound by their terms and conditions.

Appendix A: Normative Data Results

Overview

This chapter may be used in conjunction with the referenced analyses to provide normative references for OCT results.

RNFL and Macula Normative Databases: Diversified

The CIRRUS HD-OCT RNFL and Macula Normative database contains normative data for retinal nerve fiber layer (RNFL) and macular thickness from healthy subjects ages 19 to 84. Seven centers participated in the prospective, non–randomized, multi–center study. Enrolled subjects were representative of healthy individuals with no history of eye disease and were carefully screened and evaluated for eligibility. After undergoing a general ophthalmic examination, qualifying and consented subjects underwent retinal scanning with the CIRRUS HD-OCT instrument.

Medical and ophthalmic histories were taken prior to enrolling the subjects in the study. Subjects were given a complete ophthalmic examination that included the following tests:

- Distance visual acuity.
- Perimetry using the Humphrey 24–2 SITA Standard threshold test, bilaterally. Any defects found were verified with a second test.
- Goldmann applanation tonometry.
- Keratometry
- Axial length measurement using an IOLMaster.
- Slit lamp examination of the anterior segment of both eyes.
- Gonioscopy
- Dilated ophthalmoscopic examination, bilaterally.
- Fundus and stereodisc photography of the maculas and the optic nerves of both eyes.
- Corneal thickness measurement using ultrasound pachymetry.

Subjects were grouped into six categories, by subject age: 18–29, 30–39, 40–49, 50–59, 60–69, and 70 and older. Results in patients 70 years of age or older should be interpreted with caution since only three subjects were included in the normative database who were 80 years of age or older, and only 28 subjects were included who were between 70 and 79 years of age. It should also be noted that this normative database does not have any subject younger than 19 years old.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria for enrollment in the study were as follows:

Inclusion Criteria

- Males or females 18 years of age or older.
- Able and willing to make the required study visits.
- Able and willing to give consent and follow study instructions.
- Must have a normal and valid Humphrey 24–2 SITA Standard visual field in both eyes.

Exclusion Criteria

Ophthalmic

- Best corrected visual acuity in either eye worse than 20/40.
- Refractive error (spherical equivalent) outside –12.00 D to +8.00 D range.
- Glaucoma or glaucoma suspect diagnosis in either eye.
- Presence or history of ocular hypertension (IOP $\geq$ 22 mm Hg) in either eye.
- Occludable angle or history of angle closure in either eye.
- Presence or history of disc hemorrhage in either eye.
- Presence of RNFL defect in either eye.
- Presence of amblyopia in either eye.
- Previous laser or incisional surgery.
- Any active infection of anterior or posterior segments.
- Evidence of diabetic retinopathy, diabetic macular edema, or other vitreo–retinal disease.

Systemic

- History of diabetes, leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis.
- A life threatening or debilitating disease.
- Current or recent (within the past 14 days) use of an agent with photosensitizing properties by any route (e.g., Visudyne®, ciprofloxacin, Bactrim®, doxycycline, etc.).

Normal subjects were defined by Principal Investigators at each site after review of clinical and visual field data, and considering inclusion and exclusion criteria. The CIRRUS instrument was not used in determining the normalcy of the subjects.

The subjects were defined as normal if they met the following criteria:

- Best corrected visual acuity of 20/40 or better in both eyes.
- IOP less than or equal to 21 mm Hg.
- No history of ocular, neurological, or systemic diseases that might affect the visual system.

- Normal visual field, indicated by a Glaucoma Hemifield Test within normal limits, and MD and PSD > 5% probability level.

Data Collection

284 subjects were qualified as normal subjects and enrolled in this study. 284 subjects were qualified for the RNFL database while 282 subjects were qualified for the Macula normative database (poor scan quality disqualified the macula scans from two subjects). For the RNFL normative database, each eye was scanned three times with the Optic Disc Cube 200x200 scan. For the macula normative database, each eye was scanned three times with the Macular Cube 200x200 scan. The Macular Cube 512x128 was scanned once per each eye.

The CIRRUS RNFL and Macula databases do not have subjects with refractive errors outside the −12.00 D to +8.00 D range. Therefore, the normative limits for subjects with refractive errors outside the −12.00 D to +8.00 D range should be used with caution.

Scan Selection Criteria

The scans were reviewed for image quality. One best quality scan for each scan type was chosen for each subject per eye. Scans having the following characteristics were excluded from the normative database:

- Signal Strength of 5 or lower.
- Large eye motion during image acquisition, resulting in a saccade that was within the central 80% of the scan area.
- Area of data loss greater than 10% at the edge of the scan area.
- Presence of floater(s) obscuring macular area on Macular Cube scans or measurement circle on Optic Disc Cube scans.

In practice, clinicians and operators should quantitatively and qualitatively review scans before comparing them to the CIRRUS RNFL or Macula normative databases. The normative limits for scans that have poor scan quality should be used with caution.

Database Population

The CIRRUS RNFL and Macula normative databases were developed utilizing 284 subjects (aged 19–84) and 282 subjects (aged 19–84); respectively. These normative databases have a similar gender distribution (134 males, 150 females and 133 males, 149 females; respectively). Ethnicity breakdown of the CIRRUS RNFL and Macula normative databases is as follows: 43% Caucasians, 24% Asians, 18% African American, 12% Hispanic, 1% Indian, and 2% mixed ethnicity.

Results revealed that the mean difference in the average thickness between any two race groups is within 6 µm. Caucasians have thinner mean average thickness, superior quadrant average, and inferior quadrant average. Asians seem to have thinner mean nasal quadrant average and thicker temporal quadrant average. The largest difference in the RNFL thickness between two race groups is for the temporal quadrant average between Asian and African American, with a difference of 16 µm.

Note that CIRRUS RNFL and Macula normative databases are adjusted only by age, not by ethnicity or any other parameter. The normative limits provided for comparisons of individual data to the normative database do not take into account differences that may be present due to ethnicity, axial length, refraction, optic disc area, or signal strength.

Data Analysis

From these scans the normative databases for the Macular Cube 512x128, the Macular Cube 200x200 and the Optic Disc Cube 200x200 scans were created. The age range for all databases was from 18 to 84 years. Mean age of the subjects was 46.5 years for the RNFL normative database and 46.6 years for the macula normative database.

The regression model analyses were used to estimate the normative limit of each of the CIRRUS HD-OCT RNFL and macular thickness parameters adjusted by age. Subject's age is considered as a clinically important factor for the RNFL and macular thickness measurements.

For each fitted regression model, the residuals were derived for each eye by subtracting estimated expected mean reading, ET(age0), from the measured or observed reading, Obs(age0). In other words, residual = Obs(age0) − ET(age0). The goal was to predict the $100x\alpha^{th}$ percentiles (NL, normative limit) of the residuals, so that the $100x\alpha$ % limit of the CIRRUS HD-OCT parameter readings could be estimated as follows:

$ET(age0) + NL(100x\alpha\ \%) < Obs(age0)$ (A)

The 1st, 5th, 95th, and 99th percentiles of the residuals were estimated by the empirical distribution of residual. Then the estimated 1%, 5%, 95% and 99% normal limits of CIRRUS HD-OCT parameters for a normal subject with an age of age0 were established by Equation (A). It should be noted that the study site effect was not considered in the normative limits calculation since the objective was to establish the normative limits for the general population.

Age Coefficient – RNFL Thickness

Analysis of subject demographics determined that expected thickness was dependent upon age. Thus age correction is incorporated into the calculated results. Subject ethnicity was self–reported by the subjects in the population comprising the normative database but was not used as a variable in constructing the RNFL and macula normative databases.

Figure A-1, Figure A-2, and Figure A-3 display scatter plots for RNFL Summary Parameters versus age along with the fitted regression lines. These demonstrate that the RNFL summary parameters decrease gradually as the age increases.

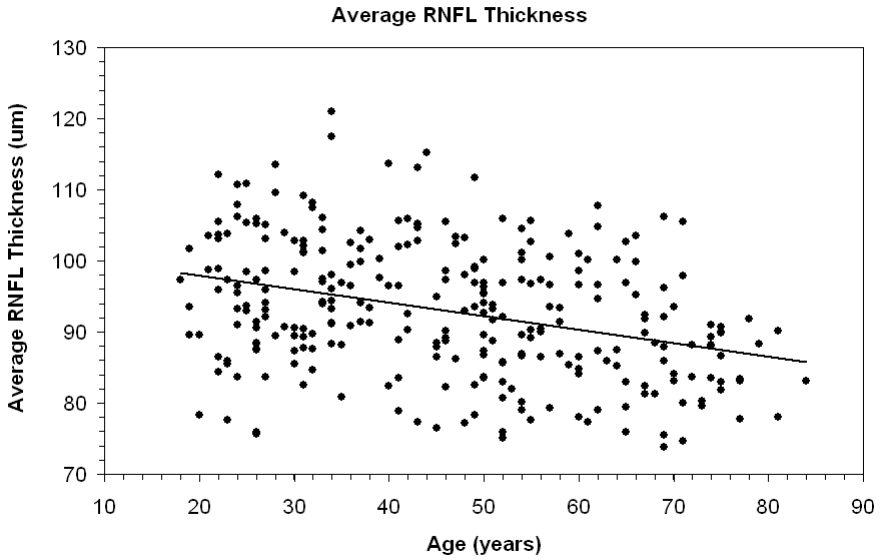


Figure A-1 Average RNFL Thickness Versus Age

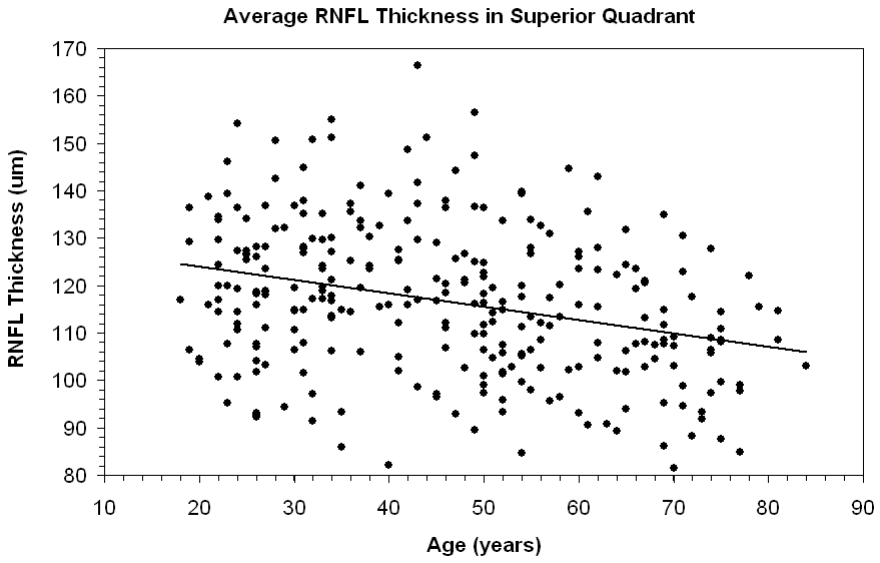


Figure A-2 Superior Quadrant Average RNFL Thickness Versus Age

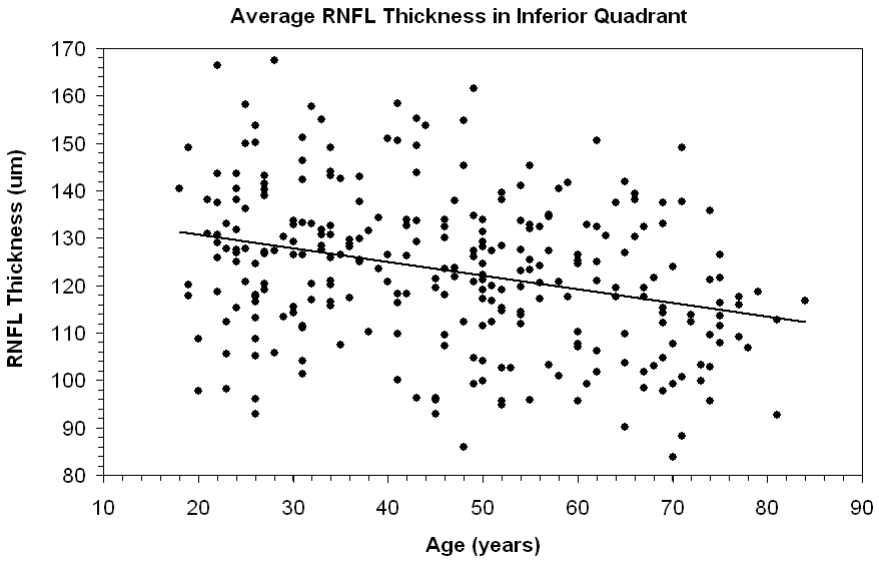
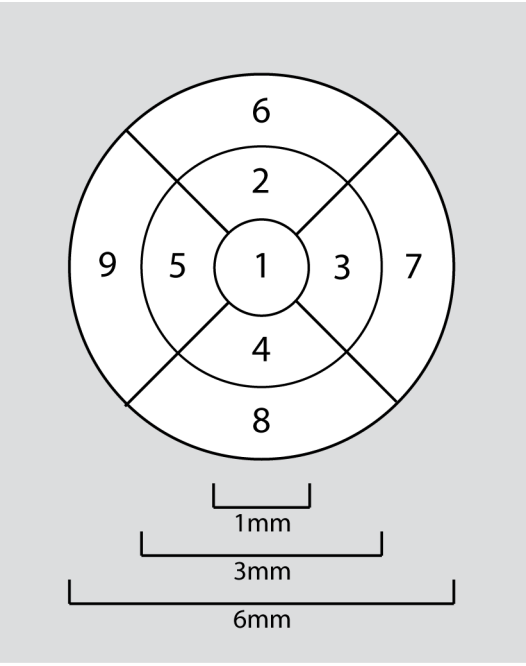


Figure A-3 Inferior Quadrant Average RNFL Thickness Versus Age

Description of Macular Scan Parameters Used in CIRRUS HD-OCT

CIRRUS Macular Scan parameters were derived from the Early Treatment Diabetic Retinopathy Study (ETDRS) Grid below:



Central Subfield Retinal Thickness: Average thickness of the retina in a disk–shaped region of 1 mm diameter centered on fovea (Region 1).

Inner Subfield Retinal Thickness: Average thickness of the retina in each inner quadrant of an annulus centered on the fovea with inner 1 mm diameter and outer 3 mm diameter.

- Inner Superior Subfield – Region 2
- Inner Inferior Subfield – Region 4
- Inner Temporal Subfield – Region 5 in OD, Region 3 in OS
- Inner Nasal Subfield – Region 3 in OD, Region 5 in OS

Outer Subfield Retinal Thickness: Average thickness of the retina in each outer quadrant of an annulus centered on the fovea with inner 3 mm diameter and outer 6 mm diameter (Regions 6, 7, 8 and 9).

- Outer Superior Subfield – Region 6
- Outer Inferior Subfield – Region 8
- Outer Temporal Subfield – Region 9 in OD, Region 7 in OS
- Outer Nasal Subfield – Region 7 in OD, Region 9 in OS

In addition, these normative values were also established for the 6 mm x 6 mm square area scanned.

- Average Retinal Thickness ILM to RPE (Macular Cube Average Thickness): Overall average thickness for the ILM – RPE tissue layer over the entire 6 x 6 mm square scanned area.
- Retinal Volume ILM to RPE (renamed as Macular Cube Volume): Overall average volume for the ILM – RPE tissue layer over the entire 6 x 6 mm square scanned area.

Age Coefficient – Macula Thickness

Figure A-4 displays a scatter plot for the Central Subfield retinal thickness average versus age along with the fitted regression line. Figure A-5 displays a scatter plot for the average macular thickness for all subfields along with the fitted regression line. Figure A-6 displays a scatter plot for the average macular volume for all subfields along with the fitted regression line. These demonstrate that the central subfield has almost no dependence on age, but the remaining subfields decrease very gradually when the age increases.

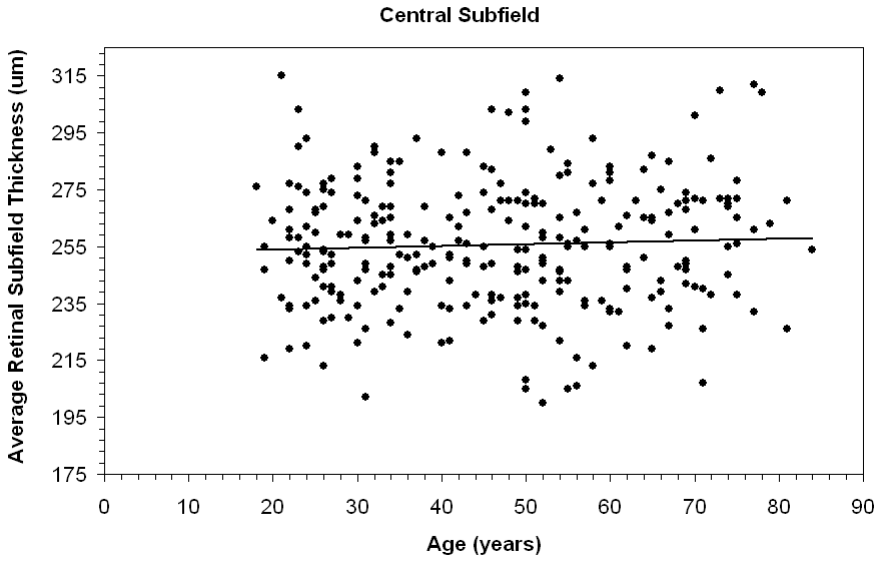


Figure A-4 Average Macula Thickness Versus Age – Central Region 1

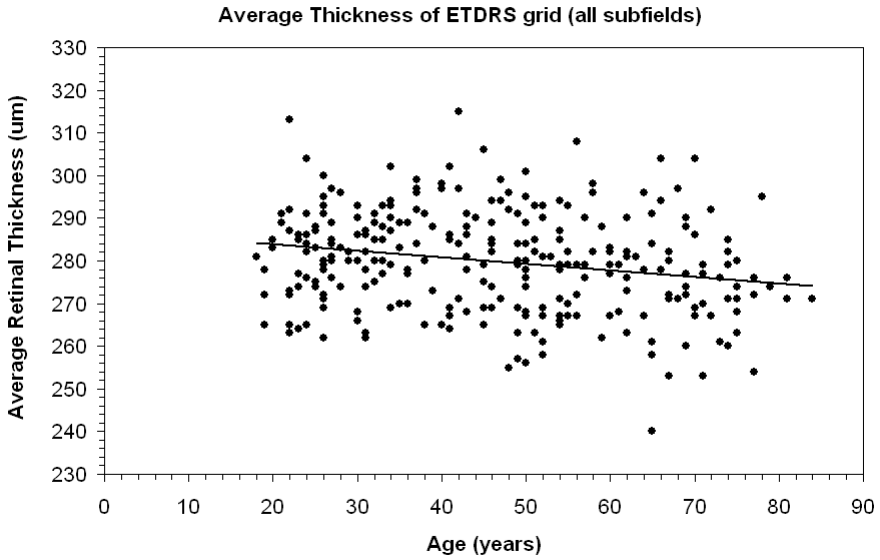


Figure A-5 Average Macula Thickness Versus Age – All Regions

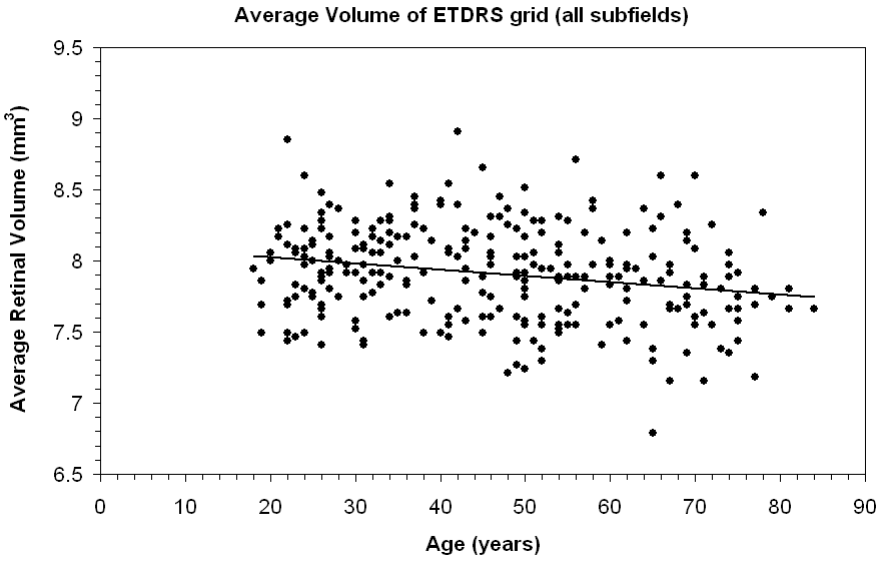


Figure A-6 Average Macula Volume Versus Age – All Regions

Conclusion

The CIRRUS HD-OCT RNFL and macular thickness normative databases were created using data from subjects that were deemed representative of a normal population. The CIRRUS HD-OCT normative database for RNFL thickness established reference values for the Optic Disc Cube 200x200 scan. The Macula normative database established reference values for the Macular Cube 512x128 and Macular Cube 200x200 scans. The doctor can use these normative databases to compare individual patient measurements to those acquired in a normal population.

Optic Nerve Head Normative Database: Diversified

The CIRRUS HD-OCT Optic Nerve Head Normative Database was collected to provide normative data for use with Optic Nerve Head (ONH) and RNFL OU Analysis module.

Post–hoc analysis was performed on the Optic Disc 200x200 cube scan, originally acquired for RNFL normative data, to determine the typical distribution for Optic Nerve Head parameters and the Neuroretinal Rim Profile. An example of the ONH parameters is shown in Figure A-7. This addendum summarizes the data collection methodology and further describes the analysis and characteristics of the normative limits for Optic Nerve Head parameters.

Methods

Data Collection

In summary, 282 subjects were qualified as normal subjects, enrolled in the NDB study, and included for the RNFL database. Data from the same scans was analyzed and evaluated to determine the normal range of ONH parameters. The normative database does not have subjects with refractive errors outside the −12.00 D to +8.00 D range. Therefore, the analysis below should be applied with caution to subjects with refractive errors outside the −12.00 D to +8.00 D range.

Scan Selection Criteria

The scans were reviewed for image quality as part of the original study. One best quality scan for each scan type was chosen for each subject per eye. Scans having the following characteristics were excluded from the normative database:

- Signal Strength of 5 or lower.
- Large eye motion during image acquisition, resulting in a saccade that was within the central 80% of the scan area.
- Area of data loss greater than 10% at the edge of the scan area.
- Presence of floater(s) obscuring macular area on Macular cube scans or measurement circle on Optic Disc cube scans.

Scans were reviewed again after processing with the optic nerve head analysis algorithm, to ensure that no floaters impacted the optic nerve head region, and to ensure that the optic nerve head data was within the axial field of view of the scan. For three eyes a new scan was selected to ensure acceptable ONH as well as RNFL results.

In practice, clinicians and operators should quantitatively and qualitatively review scans before comparing them to normal ranges.

Data Analysis

Data was analyzed using the proprietary optic nerve head analysis algorithm to obtain five main summary parameters: Disc Area (mm^2), Average Cup to Disc Ratio (CDR), Vertical Cup to Disc Ratio, Rim Area (mm^2), and Cup Volume (mm^3).

Results

The descriptive statistics for each optic nerve head parameter are reported in Table A-1 below.[1]

Table A-1 Normal Values for CIRRUS ONH measurements in the Sample Population

	Rim Area mm^2	Disc Area mm^2	Average CDR	Vertical CDR	Cup Volume mm^3
Minimum	0.720	1.003	0.071	0.058	0.000
Maximum	2.272	2.925	0.812	0.762	0.796
Average	1.311	1.769	0.458	0.435	0.137
Standard Deviation	0.218	0.340	0.173	0.166	0.134

The disc area is of particular interest. Only eleven subjects (less than 5%) had discs larger than 2.5 mm^2 in the study eye. Eleven subjects (less than 5%) had discs smaller than 1.3 mm^2. Disc area showed no dependence on subject age. Classifying disc size as small, medium or large has been previously done (see example, Spaet[2], but typically the sizing was based on a vertical diameter measured from the slit–lamp. By measuring the disc area we consider all meridians. Table A-2 serves as a very general size classification guide based on dividing the normative data into thirds. One third of the database had discs of 1.58 mm^2 or smaller, one third had discs between 1.58 and 1.88 mm^2, and the remainder had discs larger than 1.88 mm^2.

Table A-2 Disc Size Classification from the Sample Population

Disc Size Classification	Smallest 1/3 of Discs	Medium 1/3 of Discs	Largest 1/3 of Discs
Disc Area	< 1.58 mm^2	1.58 mm^2 to 1.88 mm^2	> 1.88 mm^2

Factors that Affect CIRRUS ONH Normative Ranges

The normal ranges described above do not take into account differences that may be present due to age, ethnicity, axial length, refraction, optic disc area, or signal strength. In multiple regression analysis, we found that optic disc area and age were the two parameters with the greatest effect on the remaining ONH parameters. Based on R^2 values, disc area explains as much as 40% of the variability in some parameters, while age explains no more than 5%. All other continuous parameters, such as refractive error and axial length, explain less than 7% of variability. For these reasons, only age and optic disc area were used when applying normative limits to ONH parameters.

1 Knight, OJ, Oakley, JD, Durbin, MK, Callan, TM, Budenz, DL "Cirrus Normative Database Study Group: Effect of Ethnicity, Age, and Axial Length on Optic Nerve Head Parameters Measured by Cirrus™ HD-OCT," ARVO abstract 2010.

2 Spaeth, GL, Henderer, J, Steinmann, W "The disc damage likelihood scale: its use in the diagnosis and management of glaucoma," Highlights Ophthalmol 31: 4-16, 2003.

2Age

The CIRRUS RNFL normative database was developed utilizing 282 subjects aged 19 to 84. Disc Area and Cup Volume showed no effect of Age. The Rim Area decreases slowly with age (slope = –0.002 mm^2 / year, $R^2 = 0.033$, $p = 0.002$), while CDR (average and vertical) increased slowly with age (slope = +0.002 per year, $R^2 = 0.032$, $p = 0.002$ for average CDR, slope = +0.002 per year, $R^2 = 0.041$, $p = 0.001$ for vertical CDR). As expected, disc area does not change with age ($p > 0.05$).

Optic Disc Area

The distribution of disc area for the normative database eyes is discussed in the paragraph above. Note that the majority of disc areas were between 1.3 mm^2 and 2.5 mm^2. Therefore, normal limits will not be well defined for this population outside of those disc sizes, and are not applied in CIRRUS. All optic nerve head parameters increase with disc size, including Rim Area (slope = +0.24 mm^2 of rim per mm^2 of disc, $R^2 = 0.13$, $p = 0.042$), Cup Volume (slope = +0.25 mm^3 of cup per mm^2 of disc, $R^2 = 0.39$, $p = 0.011$), and Cup to Disc Ratios (slope = +0.35 per mm^2 of disc, $R^2 = 0.35$, $p = 0.001$ for average CDR, slope = +0.29 per mm^2 of disc, $R^2 = 0.34$, $p = 0.001$ for vertical CDR).

Ethnicity

The ethnicity breakdown of the CIRRUS RNFL normative database is as follows: 43% Caucasians, 24% Asians, 18% African American, 12% Hispanic, 1% Indian, and 2% mixed ethnicity. As expected, subjects of African descent had the largest discs on average (1.93 ± 0.33 mm^2), while those of European descent had the smallest (1.68 ± 0.30 mm^2, $p << 0.001$). There was no statistically significant difference among different ethnicities with respect to the Rim Area ($p = 0.16$). The Cup to Disc Ratio (Average and Vertical) as well as the Cup Volume, showed differences among ethnicity groups (mean difference in ACDR is 0.10, $p = 0.008$, mean difference in VCDR is 0.09, $p = 0.027$, mean difference in Cup Volume is 0.09 mm^3, $p = 0.003$).

Calculation of Normal Limits

Analysis of the ONH parameters found that these parameters depend on both optic disc area of the subject eye and subject age. A linear fit is used to model the age effects. The variability of parameters such as Rim Area and Cup to Disc Ratio on Disc Area was found to depend on the size of the disc. For this reason, quantile regression was used rather than linear regression to set the limits on the ONH parameters with respect to Disc Area. This is a method whereby the slope and offset are independently fit for each limit. See Artes et al[3] for a description of quantile regression. For the Average and Vertical Cup–to–Disc Ratios, data with a Cup–to–Disc ratio less than or equal to 0.25 were excluded prior to performing the quantile regression.

3 Artes, PH and Crabb, DP. "Estimating normative limits of Heidelberg Retina Tomograph optic disc rim area with quantile regression," Invest Ophthalmol Vis Sci. 2010 Jan;51(1):335-61

Presentation of Normative Limits

Figure A-7 shows the ONH and RNFL OU Analysis with normative limits applied to the ONH parameters of Rim Area, Cup to Disc Ratio, Vertical Cup to Disc Ratio, and Cup Volume, as well as to the neuroretinal rim (NR) profile.

Because each eye may have a different disc area, the normal limits shown behind the NR profile depend on which eye is selected for comparison. If OU is selected, normal limits appropriate to the average disc area are shown.

If the disc area is larger than 2.5 mm^2 or smaller than 1.3 mm^2, then normative limits are not applied because not enough data is available in the database to determine the limits. In this case the area behind the number or the NR plot is shown as gray. In addition, Average and Vertical C/D Ratios less than or equal to 0.25 will be shown as gray.

Conclusion

The CIRRUS HD-OCT optic nerve head normative database was created using data from subjects that were deemed representative of a normal population. To establish reference values, the scans acquired as part of the CIRRUS HD-OCT RNFL normative databases were analyzed using a optic nerve head segmentation algorithm. The doctor can use the normative database to compare individual patient measurements to those acquired in a normal population.

Report

The elements shown in the analysis screen in Figure A-7 are presented in a report as well, as shown below.

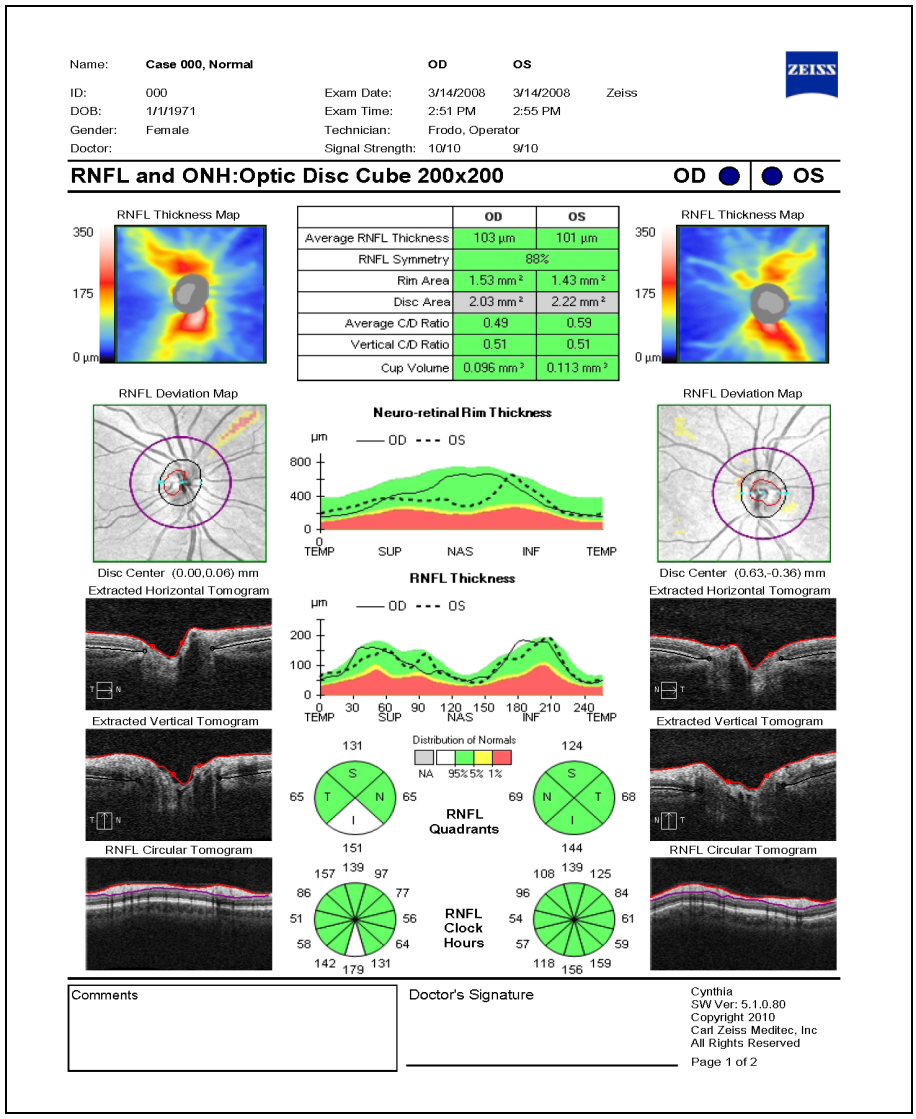
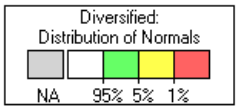


Figure A-7 ONH and RNFL OU Analysis Report

RNFL and ONH Normative Databases

The ONH and RNFL OU Analysis supports the clinician in identifying areas of the RNFL that may be of clinical concern by comparing the measured RNFL thickness to age–matched data in the CIRRUS RNFL Normative Databases. Normative data that is age–matched to the patient appears when you perform the "ONH and RNFL OU Analysis" on page 8-28 on patients at least 18 years old. Data was not collected from subjects less than 18 years old.

The same data used to develop the RNFL Database was re–processed to develop normal limits for optic nerve head parameters. As described further in "Optic Nerve Head Normative Database: Diversified" on page A-9, the ONH normative data is matched to the disc area of the eye as well as the age of the patient.



The RNFL Normative Database uses a white–green–yellow–red color code, as seen in the legend at left, to indicate the normal distribution percentiles. The color code applies to each particular A-scan location in the TSNIT thickness graphs, to the quadrant, clock hour and whole–circle averages, and to the OD and OS columns of the data table. Among same–age individuals in the normal population, the percentiles apply to each particular RNFL thickness measurement along the Calculation Circle as follows:

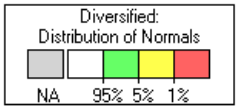
- The thinnest 1% of measurements fall in the red area. Measurements in red are considered outside normal limits (red ≤ 1%, outside normal limits).
- The thinnest 5% of measurements fall in the yellow area or below (1% < yellow ≤ 5%, suspect).
- 90% of measurements fall in the green area (5% < green ≤ 95%).
- The thickest 5% of measurements fall in the white area (white > 95%).

NOTE: Clinicians must exercise judgment in the interpretation of the normative data. For any particular measurement, note that 1 out of 20 normal eyes (5%) will fall below green. Interpretation of the 1st Percentile: Values color–coded as "1st percentile" are lower than 99% of the database sample, but may not extrapolate well to the general population with less than 300 subjects in the reference database. Results falling in this region should be interpreted with caution.Interpretation of the 5th Percentile: Values color–coded as "5th percentile" are lower than 95% of the database sample. The 95% Confidence Interval on the 5th Percentile extends from the 2.5th percentile to the 7.7th percentile of the normative database.

Information icons on the **Analysis** screen offer additional information about the normative database limits. Hovering over the icon will display a tooltip, and clicking the icon allows you to create a report of the additional information presented by selecting **Print Preview** or **Export to DICOM**. See "Normative Data Details Reports" on page 10-15 for more information.

NOTE: Normative data colors will not appear if the patient is less than 18 years old.

Distribution of Normals



The gray color, shown in the legend to the left, represents "Not applicable". Values will be shown in gray when normative data is not applicable because the database has insufficient data to match with the disc area.

The Distribution of Normals color scheme is used for both the RNFL and the Optic Nerve Head analysis parameters. The table below clarifies how the color scheme is used for each of the parameters.

Measurement	Matched to Normal Based On	Grey	White	Green	Yellow	Red
RNFL						
Average RNFL Thickness, RNFL Symmetry, RNFL Clock Hours, RNFL Quadrants, RNFL Thickness (graph)	Age	Grey shading does not apply to RNFL measurements	The thickest 5% of measurements fall in the white area (white > 95%).	90% of measurements fall in the green area (5% < green ≤ 95%).	The thinnest 5% of measurements fall in the yellow area or below (1% < yellow ≤ 5%, suspect).	The thinnest 1% of measurements. Measurements in red are considered outside normal limits (red ≤ 1%, outside normal limits).
Optic Nerve Head						
Rim Area and Neuroretinal Rim Thickness (graph)	Disc Area and Age	ONH Normative Database is not applicable if: 1) The disc area is larger than 2.5 mm^2 or smaller than 1.33 mm^2, or 2) The Average or Vertical C/D Ratio is below 0.25, or 3) The ONH Normative Database license has not been activated.	The largest 5% of measurements fall in the white area (white > 95%).	90% of measurements fall in the green area (5% < green ≤ 95%).	The smallest 5% of measurements fall in the yellow area or below (1% < yellow ≤ 5%, suspect).	The smallest 1% of measurements. Measurements in red are considered outside normal limits (red ≤ 1%, outside normal limits).
Average C/D Ratio, Vertical C/D Ratio, Cup Volume			The smallest 5% of measurements fall in the white area (white > 95%).	90% of measurements fall in the green area (5% < green ≤ 95%).	The largest 5% of measurements fall in the yellow area or below (1% < yellow ≤ 5%, suspect).	The largest 1% of measurements. Measurements in red are considered outside normal limits (red ≤ 1%, outside normal limits).

NOTE: For patients under 18 years old, the legend and color coding is not displayed. Data was not collected from patients under 18 years old.

There is measurement variability for the retinal nerve fiber layer and optic nerve head parameters which may impact the normative database color coding. If the true value is near the limit of what the software uses to determine the normative database color code, then it is possible that the color code could vary from exam to exam. When at least one parameter is close to a normative limit, a blue icon button ⚠ displays. When your cursor hovers over this icon button, the tooltip appears as shown below.

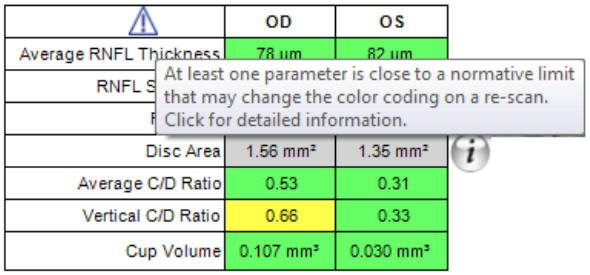


Figure A-8 Measurement Variability Tooltip

For more information on measurement variability, please see Appendix "CIRRUS HD-OCT Repeatability in Measuring Central Corneal Thickness" on page B-19.

If you click the blue icon button you can select **Print Preview** or **Export to DICOM**. A **Print Preview** screen displays the Normative Data Details Report, as shown in Figure A-9 below. The report can be printed from the **Print Preview** screen. Each eye will print on a separate page for an OU Printout. See "Normative Data Details Reports" on page 10-15 for more information.

Name:	Case 055, GPA Example		OD	OS	
ID:	055	Exam Date:	11/18/2009	11/18/2009	Hacienda Clinic
DOB:	1/1/1936	Exam Time:	2:26 PM	2:27 PM	
Gender:	Male	Serial Number:	4000-1063	4000-1063	
Technician:	Last Name, First Name	Signal Strength:	7/10	7/10	

ONH and RNFL OU Analysis: Optic Disc Cube 200x200 OD ● ● OS

Normative Data Details
OD

ONH Parameters	Value	Percentile Value	Value Minus Reproducibility Limit	Percentile Value	Value Plus Reproducibility Limit	Percentile Value
Rim Area	1.12	30	1.00	10	1.00	10
Average C/D Ratio	0.53	41	0.00	NA	1.00	1
Vertical C/D Ratio	0.66	3	1.00	1	1.00	1
Cup Volume	0.11	41	0.00	NA	0.00	NA

Note: Rim Area Unit is mm². Cup Volume unit is mm³.

RNFL Parameters	Value	Percentile Value	Value Minus Reproducibility Limit	Percentile Value	Value Plus Reproducibility Limit	Percentile Value
Average Thickness	78	15	74	5	82	28
Temporal Thickness	60	51	55	30	66	73
Superior Thickness	92	10	82	2	101	27
Nasal Thickness	76	82	70	64	82	91
Inferior Thickness	84	3	75	1	92	9
CH09	49	54	44	27	54	76
CH10	68	44	58	14	78	70
CH11	102	23	88	6	115	39
CH12	96	29	77	10	114	53
CH01	78	13	63	3	92	37
CH02	77	46	64	21	90	74
CH03	79	99	72	96	86	99
CH04	72	75	62	51	81	89
CH05	70	16	58	4	82	39
CH06	94	11	79	2	108	27
CH07	88	8	74	2	102	18
CH08	64	61	55	35	72	79
CH= Clock Hour						

Note: All units in micrometers.

Diversified Distribution of Normals
NA 95% 5% 1%

Comments
Analysis Edited: 5/22/2013 2:49 PM

Doctor's Signature

Review Software
SW Ver: 7.0.0.495

Page 1 of 2

Figure A-9 Normative Data Details Report

Interactivity

For both the RNFL Thickness and Neuro–retinal Rim Thickness TSNIT graphs, as shown in Figure A-10, the user can toggle between data for both eyes together, or separately for right eye or left eye. This is done by clicking the gray button in the upper left corner of the Neuro–retinal Rim Thickness graph and RNFL Thickness graph, which will be labeled "OU", "OD", or "OS" depending on what the user has chosen.

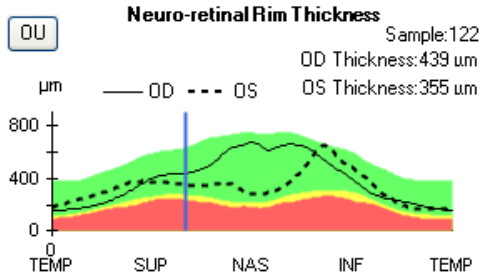


Figure A-10 Neuro–retinal Rim Thickness Graph

Ganglion Cell Normative Database: Diversified

The CIRRUS HD-OCT Ganglion Cell Normative Database was collected to provide normative data for use with The **Ganglion Cell Analysis** module, and presents information on the thickness of the ganglion cell plus inner plexiform layer.

Post–hoc analysis was performed on the Macular Cube 200x200 and Macular Cube 512x128 cube scans, originally acquired for Macular retinal thickness normative data, to determine the typical distribution for Ganglion Cell Analysis parameters and the GCL + IPL thickness map. This analysis compares the GCL + IPL thickness results to normal limits derived from post–hoc analysis of scans used for the Macular normative database. An example of the Ganglion Cell Analysis page with normal limits applied for the Ganglion Cell Analysis parameters is shown below in Figure A-11.

This section summarizes the data collection methodology (also described in the previous section) and further describes the analysis and characteristics of the normative limits for Ganglion Cell Analysis parameters.

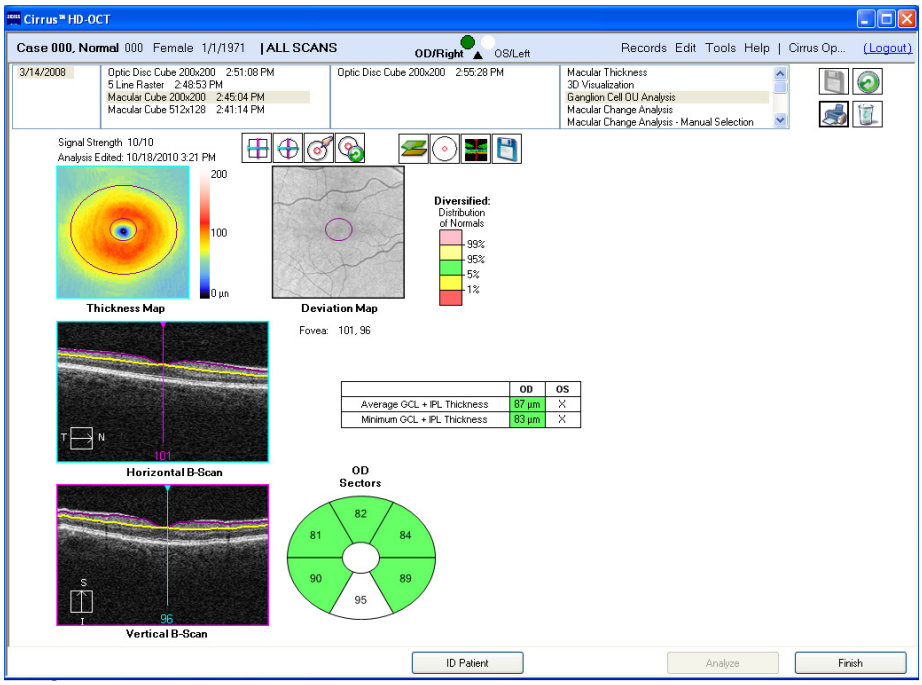


Figure A-11 Typical Ganglion Cell Analysis showing Comparison to Normal Limits

Methods

Data Collection

Data collection details are described in "RNFL and Macula Normative Databases: Diversified" on page A-1. In summary, 282 subjects were qualified as normal subjects, enrolled in the NDB study, and included for the Macular normative database. Data from the same scans was analyzed and evaluated to determine the normal range of Ganglion Cell Analysis parameters. The normative database does not have subjects with refractive errors outside the –12.00 D to +8.00 D range. Therefore, the analysis below should be applied with caution to subjects with refractive errors outside the –12.00 D to +8.00 D range.

Scan Selection Criteria

The scans were reviewed for image quality as part of the original study. One best quality scan for each scan type was chosen for each subject per eye. Scans having the following characteristics were excluded from the normative database:

- Signal Strength of 5 or lower.
- Large eye motion during image acquisition, resulting in a saccade that was within the central 80% of the scan area.
- Area of data loss greater than 10% at the edge of the scan area.
- Presence of floater(s) obscuring macular area on Macular cube scans or measurement circle on Optic Disc cube scans.

In practice, clinicians and operators should quantitatively and qualitatively review scans before comparing them to normal ranges.

Data Analysis

Data was analyzed using the proprietary ganglion cell analysis segmentation algorithm to obtain seven main summary parameters, all expressed in micrometers: Average GCL + IPL thickness, six sectoral thickness values, where the sectors are derived from 60° segments of an elliptical annulus with inner minor axis radius of 0.5 mm and outer minor axis radius of 2.0 mm, stretched by 20% in the horizontal direction to get the major axes. The sectors are shown below:

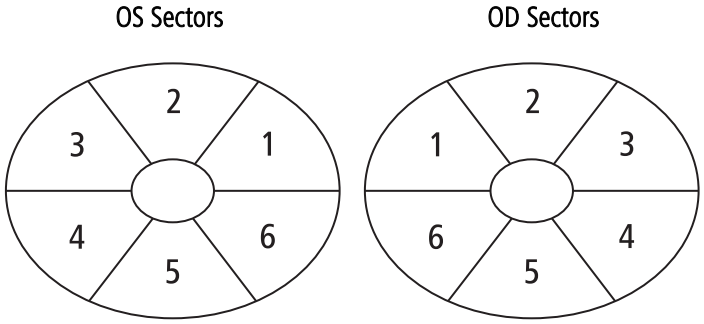


Figure A-12 Sector Schematic used for Ganglion Cell Analysis

The seventh parameter is the minimum average value of a set of 360 spokes, where each average represents the average of the pixels along that spoke that lie within the measurement annulus. The minimum is selected because the thinnest portion of the ganglion cell plus inner plexiform layers in the perifoveal region is considered likely to indicate damage to the ganglion cells.

Results

The descriptive statistics for Ganglion Cell Analysis parameters based on 282 normal eyes are reported in Table A-3 below.

Table A-3 Normal Values for CIRRUS Ganglion Cell Analysis Measurements in the Sample Population (µm)

	Average GCL + IPL Thickness	Sector 1	Sector 2	Sector 3	Sector 4	Sector 5	Sector 6	Minimum Average Axial Thickness
Mean	84.7	82.9	86.4	86.8	85.3	83.2	83.8	82.1
Std	7.1	6.3	7.9	8.3	9.0	7.8	6.5	6.9
Min	67.7	68.0	67.0	65.0	62.0	62.0	68.0	53.2
Max	104.2	102.0	113.0	112.0	111.0	109.0	106.0	101.8

Factors that Affect CIRRUS Ganglion Cell Analysis Normative Ranges

The normal ranges described above do not take into account differences that may be present due to age, ethnicity, axial length, refraction, optic disc area, or signal strength. In regression analysis, we found that signal strength and age were the two continuous parameters with the greatest effect on the Ganglion Cell Analysis parameters. All effects

were small. Based on R^2 values, age explains only 12% of the variability in some parameters, while signal strength explains no more than 4%. Refractive error and axial length explain less than 2% of variability. For these reasons, only age was used when applying normative limits to Ganglion Cell Analysis parameters.

Age

The Ganglion Cell Analysis was developed utilizing 282 subjects aged 19 to 84. All parameters decrease slowly with age. Figure A-13 shows the average Ganglion Cell Analysis within the measurement annulus as a function of age.

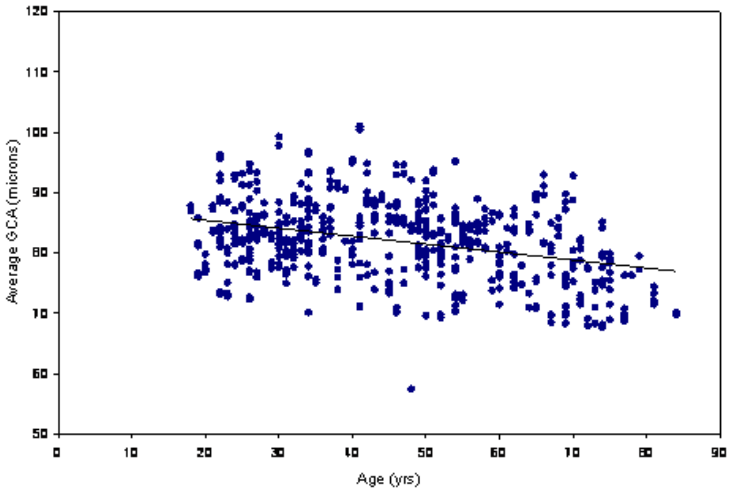


Figure A-13 Average Ganglion Cell Analysis Average Thickness as a Function of Age.

Ethnicity

The ethnicity breakdown of the Ganglion Cell Analysis is as follows:

43% Caucasians, 24% Asians, 18% African American, 12% Hispanic, 1% Indian, and 2% mixed ethnicity. There are statistically significant differences among them in GCL + IPL thickness as shown in the table below for Average GCL + IPL Thickness.

Table A-4 Ethnicity Breakdown of the Ganglion Cell Analysis

	European Descent	Hispanic Descent	African Descent	Asian Descent
Average GCL + IPL Thickness (µm)	84.1 (7.8)	88.8 (6.4)	86.3 (7.8)	89.4 (7.2)

Results revealed that the mean difference in the average thickness between any two race groups is within 4.3 mm. Subjects of European Descent have thinner ganglion cell plus inner plexiform layer thickness on average, while subjects of Hispanic and Chinese descent have thicker ganglion cell plus inner plexiform layer thickness ($p < 0.001$).

Axial Length and Refractive Error

Figure A-14 below shows a plot of Ganglion Cell Analysis Average Thickness versus axial length of the study eye. It can be seen that GCL + IPL thickness decreases slightly as a function of axial length. This contributes less than 2% of the total variability of the Ganglion Cell Analysis parameters.

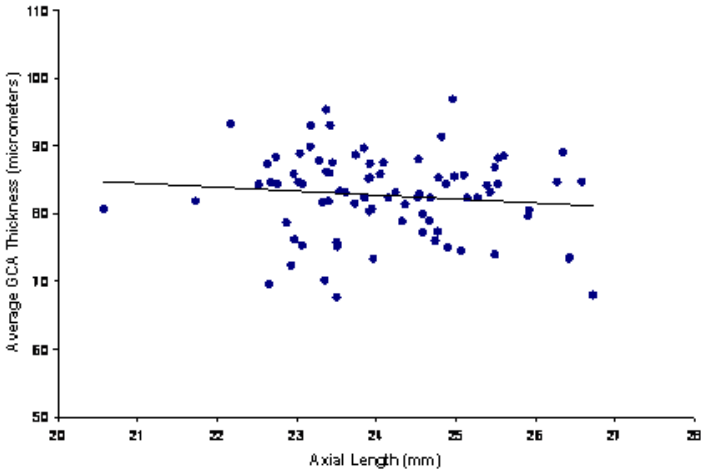


Figure A-14 Axial Length and Refractive Error

Data Analysis

The same analysis model was used as was used for the Macular Thickness normative data analysis, see "RNFL and Macula Normative Databases: Diversified" on page A-1.

A regression model analysis was used to estimate the normative limit of each of the Ganglion Cell Analysis parameters adjusted by age. The subject's age is considered as a clinically important factor for the ganglion cell plus inner plexiform layer thickness measurements.

For each fitted regression model, the residuals were derived for each eye by subtracting the estimated expected mean reading, ET(age0), from the measured or observed reading, Obs(age0). In other words, residual = Obs(age0) − ET(age0). The goal was to predict the $100x\alpha^{th}$ percentiles (NL, normative limit) of the residuals, so that the $100x\alpha$ % limit of the CIRRUS HD-OCT parameter readings could be estimated as follows:

ET(age0) + NL($100x\alpha$ %) < Obs(age0) (A)

The 1st, 5th, 95th, and 99th percentiles of the residuals were estimated by the empirical distribution of residual. Then the estimated 1%, 5%, 95% and 99% normal limits of CIRRUS HD-OCT parameters for a normal subject with an age of age0 were established by Equation (A). It should be noted that the study site effect was not considered in the normative limits calculation since the objective was to establish the normative limits for the general population.

Conclusion

The CIRRUS HD-OCT Ganglion Cell Analysis normative database was created using data from subjects that were deemed representative of a normal population. To establish reference values, the scans acquired as part of the CIRRUS HD-OCT Macular Thickness normative databases were analyzed using a segmentation algorithm that identifies the thickness of the combined ganglion cell plus inner plexiform layers. The doctor can use the Ganglion Cell Analysis normative database to compare individual patient measurements of Ganglion Cell Analysis parameters to those acquired in a normal population.

Asian Normative Database[4]

Overview

The Asian Normative Database is a licensed feature. It enables you to choose whether to apply the Asian or Diversified Normative Database to each patient, as part of the patient record.

When you license the Asian Normative Database, you are prompted to select a default database that will be applied to patients. After selecting the default, all new and existing patients will be assumed to be the default unless you manually select another database for that specific patient.

For details on how to select or change the normative database, see the "Add New Patients" on page 5-2.

Introduction

The Asian Normative Database was developed using sites located in Japan, China, and India. The Asian normative data was collected and analyzed in a manner identical to the collection of the diversified data. Details are described in this section.

The Asian Normative Database was intended to collect normative data for retinal nerve fiber layer (RNFL) and macular thickness from healthy subjects ages 19 to 79. Post–hoc analysis was performed to create normative limits for Optic Nerve Head (ONH) analysis and Ganglion Cell Analysis as well.

Five new centers participated in the prospective, non–randomized, multi–center study. Data from a site in Hong Kong which was included in the Diversified Normative Database was also included in the Asian Normative Database.

4The Asian Normative Database is an optional feature that may not be available in all markets, and when available in a market, may not be activated on all instruments. If you do not have this feature and want to purchase it, contact Carl Zeiss Meditec. In the U.S.A., call 1–877–486–7473; outside the U.S.A., contact your local Zeiss distributor.

Enrolled subjects were representative of healthy individuals with no history of eye disease and were carefully screened and evaluated for eligibility. After undergoing a general ophthalmic examination, qualifying and consented subjects underwent retinal scanning with the CIRRUS HD-OCT instrument. Medical and ophthalmic histories were taken prior to enrolling the subjects in the study. Subjects were given a complete ophthalmic examination that included the following tests:

- Distance visual acuity.
- Perimetry using the Humphrey 24–2 SITA Standard threshold test, bilaterally. Any defects found were verified with a second test.
- Goldmann application tonometry.
- Keratometry.
- Axial length measurement using an IOLMaster.
- Slit lamp examination of the anterior segment of both eyes.
- Gonioscopy.
- Dilated ophthalmoscopic examination, bilaterally.
- Fundus and stereodisc photography of the maculas and the optic nerves of both eyes.
- Corneal thickness measurement using ultrasound pachymetry.

Subjects were grouped into six categories, by subject age: 18–29, 30–39, 40–49, 50–59, 60–69, and 70–80. It should be noted that this normative database does not have any subject younger than 19 years old or older than 79 years old.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria for enrollment in the study were as follows:

Inclusion Criteria

- Males or females 18 years of age or older.
- Able and willing to make the required study visits.
- Able and willing to give consent and follow study instructions.
- Must have a normal and valid Humphrey 24–2 SITA Standard visual field in both eyes.

Exclusion Criteria

Ophthalmic:

- Best corrected visual acuity in either eye worse than 20/40.
- Refractive error (spherical equivalent) outside –12.00 D to +8.00 D range.
- Glaucoma or glaucoma suspect diagnosis in either eye.
- Presence or history of ocular hypertension (IOP ≥22 mm Hg) in either eye.
- Occludable angle or history of angle closure in either eye.
- Presence or history of disc hemorrhage in either eye.
- Presence of RNFL defect in either eye.
- Presence of amblyopia in either eye.
- Previous laser or incisional surgery.
- Any active infection of anterior or posterior segments.

- Evidence of diabetic retinopathy, diabetic macular edema, or other vitreo–retinal disease.

Systemic:

- History of diabetes, leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis.
- A life threatening or debilitating disease.
- Current or recent (within the past 14 days) use of an agent with photosensitizing properties by any route (e.g., Visudyne®, ciprofloxacin, Bactrim®, doxycycline, etc.).

Normal subjects were defined by Principal Investigators at each site after review of clinical and visual field data, and considering inclusion and exclusion criteria. The CIRRUS instrument was not used in determining the normalcy of the subjects.

The subjects were defined as normal if they met the following criteria:

- Best corrected visual acuity of 20/40 or better in both eyes.
- IOP less than or equal to 21 mm Hg.
- No history of ocular, neurological, or systemic diseases that might affect the visual system.
- Normal visual field, indicated by a Glaucoma Hemifield Test within normal limits, and MD and PSD > 5% probability level.

Data Collection

315 subjects were qualified as normal subjects and enrolled in this study for the RNFL Database and for the Macula Normative Database.

For the RNFL Normative Database, each eye was scanned three times with the Optic Disc Cube 200x200 scan. For the macula normative database, each eye was scanned three times with the Macular Cube 200x200 scan and three times with the Macular Cube 512x128 scan.

The CIRRUS RNFL and Macula databases do not have subjects with refractive errors outside the –12.00 D to +8.00 D range. Therefore, the normative limits for subjects with refractive errors outside the –12.00 D to +8.00 D range should be used with caution.

Scan Selection Criteria

The scans were reviewed for image quality. One best quality scan for each scan type was chosen for each subject per eye. Scans having the following characteristics were excluded from the normative database:

- Signal Strength of 5 or lower.
- Large eye motion during image acquisition, resulting in a saccade that was within the central 80% of the scan area.
- Area of data loss greater than 10% at the edge of the scan area.
- Presence of floater(s) obscuring macular area on Macular Cube scans or measurement circle on Optic Disc Cube scans.

In practice, clinicians and operators should quantitatively and qualitatively review scans before comparing them to the CIRRUS RNFL or Macula Normative Databases. The normative limits for scans that have poor scan quality should be used with caution.

The Asian Dataset

The CIRRUS Asian RNFL and Macula Normative Databases were developed utilizing 315 subjects (aged 19–79). These normative databases have a similar gender distribution (159 males, 156 females). Ethnicity breakdown of the CIRRUS Asian RNFL and Asian Macula Normative Databases is as follows: 44% Japanese, 44% Chinese, and 12% Indian. Ganglion Cell Analysis normative data was developed using post–hoc analysis utilizing the same analysis design described here. ONH normative data was developed using post–hoc analysis with a different design, described in a later section.

Results revealed that the mean difference in the average RNFL thickness between any two race groups is within 5 µm. Chinese have thicker mean average thickness, superior quadrant average, and inferior quadrant average while Indians have the thickest measurements for these parameters. The largest difference in the RNFL thickness between two race groups is for the temporal quadrant average between Chinese and Indians, with a difference of 15 µm.

Note that CIRRUS Asian RNFL, Asian Macula, and Asian Ganglion Cell Analysis Normative Databases are adjusted only by age, not by ethnicity or any other parameter. The normative limits provided for comparisons of individual data to the normative database do not take into account differences that may be present due to ethnicity, axial length, refraction, optic disc area, or signal strength.

Normative Database Analyses

From these scans the normative databases for RNFL, Macular Thickness and GCL + IPL Thickness were created. The age range for all databases was from 19 to 79 years. Mean age of the subjects was 47 years.

Regression model analyses were used to estimate the normative limit of each of the CIRRUS HD-OCT RNFL, macular thickness, and ganglion cell analysis parameters adjusted by age. For each fitted regression model, the residuals were derived for each eye by subtracting estimated expected mean reading, ET(age0), from the measured or observed reading, Obs(age0). In other words, residual = Obs(age0) − ET(age0). The goal was to predict the $100x\alpha^{th}$ percentiles (NL, normative limit) of the residuals, so that the 100 x 1% limit of the CIRRUS HD-OCT parameter readings could be estimated as follows:

ET (age 0) + NL(100 x 1%) < Obs (age0) (Equation A)

The 1st, 5th, 95th, and 99th percentiles of the residuals were estimated by the empirical distribution of residual. Then the estimated 1%, 5%, 95% and 99% normal limits of CIRRUS HD-OCT parameters for a normal subject with an age of age0 were established by Equation (A). It should be noted that the study site effect was not considered in the normative limits calculation since the objective was to establish the normative limits for the general population.

Description of RNFL Parameters

The RNFL Parameters that are compared to normal limits include:

- Average RNFL Thickness around a measurement circle with 3.46 mm diameter.
- Average RNFL Thickness in 4 quadrants distributed evenly around the measurement circle (Superior, Temporal, Inferior, and Nasal).
- Average RNFL Thickness in 12 clock–hours (30° segments of the measurement circle).
- Thickness in a TSNIT profile around the measurement circle (255 points distributed evenly around the measurement circle, starting at the temporal most point and traveling superior – nasal – inferior and back to temporal, or TSNIT).
- RNFL Symmetry: correlation coefficient between left eye TSNIT profile and right eye TSNIT profile.

Age Coefficient – RNFL Thickness

Analysis of subject demographics determined that expected thickness was dependent upon age, although the effect was small, and sometimes positive (slightly increasing thickness with age). Thus age correction is incorporated into the calculated results. Subject ethnicity was self–reported by the subjects in the population comprising the normative database but was not used as a variable in constructing the RNFL and macula normative databases.

Figure A-15 below displays a scatter plot for average RNFL thickness versus age along with the fitted regression line.

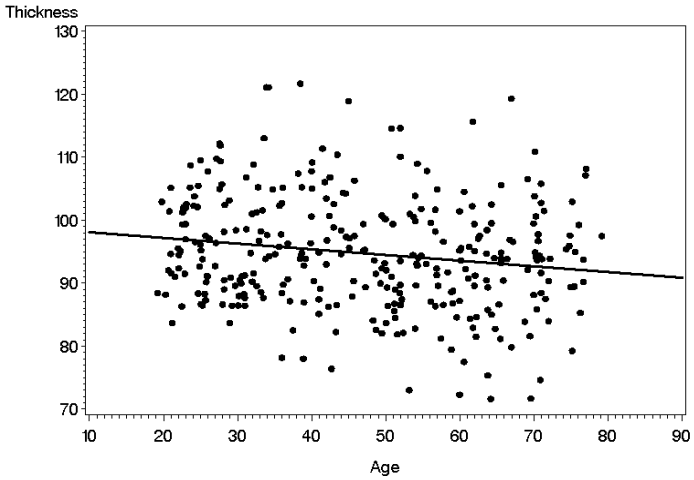


Figure A-15 Average RNFL Thickness (µm) Versus Age

Age Coefficient – Macula Thickness

The same macular parameters were calculated for the Asian Normative Database as were calculated for the Diversified Normative Database. The full description of the macular scan parameters can be found in "RNFL and Macula Normative Databases: Diversified" on page A-1.

Figure A-16 displays a scatter plot for the Central Subfield retinal thickness average versus age along with the fitted regression line. Figure A-17 displays a scatter plot for the average macular thickness for all subfields along with the fitted regression line. These demonstrate that the central subfield has almost no dependence on age, but the remaining subfields decrease very gradually when the age increases.

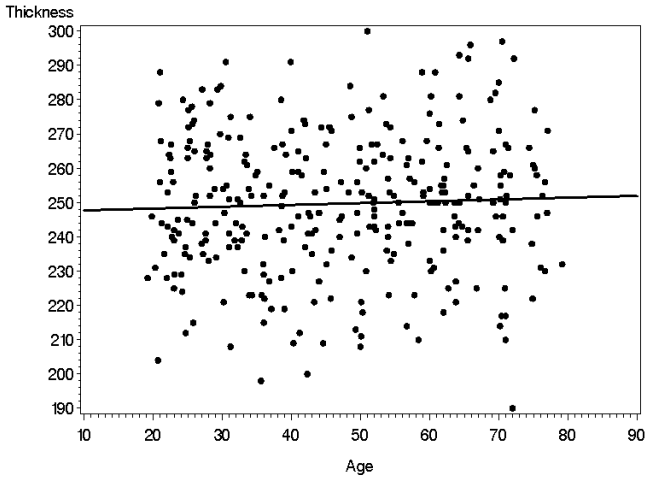


Figure A-16 Asian Macular Central Subfield Thickness (µm) Versus Age

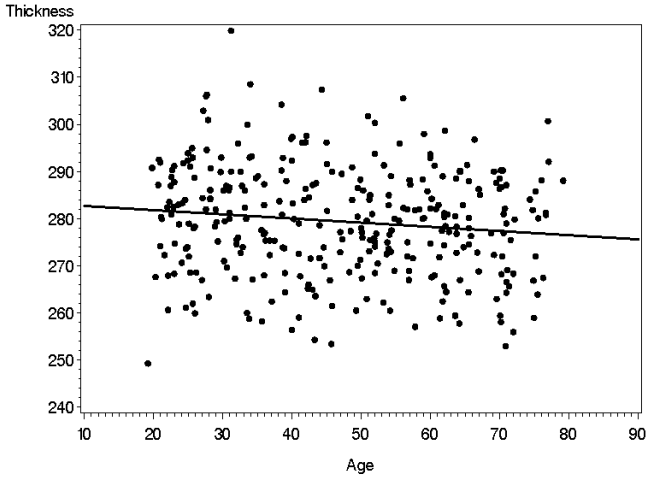


Figure A-17 Average Asian Macular Thickness (µm) Versus Age

Normal Values for Ganglion Cell Analyses

Post–hoc analysis was performed on the Macular Cube 200x200 and Macular Cube 512x128 cube scans, originally acquired for macular retinal thickness normative data, to determine the typical distribution for Ganglion Cell Analysis parameters and the GCL + IPL thickness map. This analysis compares the GCL + IPL thickness results to normal limits derived from post–hoc analysis of scans used for the Asian macular normative database.

Data were analyzed using the CIRRUS 6.0 proprietary ganglion cell analysis segmentation algorithm to obtain seven main summary parameters. The seven summary parameters were Average GCL + IPL thickness and six sectoral thickness values of an elliptical annulus centered on the macula. The schematic of the annulus can be seen in Figure A-12.

All Ganglion Cell Analysis parameters decrease slowly with age. Figure A-18 below shows the average GCL + IPL thickness within the measurement annulus as a function of age.

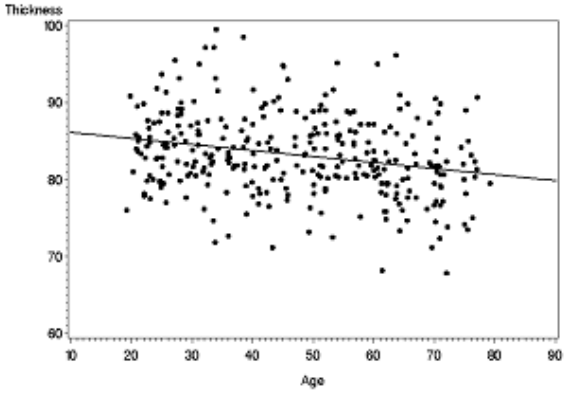


Figure A-18 Average GCL + IPL Thickness (µm) Versus Age

It should be noted that, although the age effect was statistically significant, the R^2 (coefficient of determination) of the simple regression model was small for each parameter. This finding indicates that, although age affects GCL + IPL thickness significantly, it can only explain a small percentage of the variation of the Ganglion Cell Analysis parameters.

The summary parameters for Asian study eyes displayed in Table A-5 show that the GCL + IPL thicknesses, which are measured in an annulus around the fovea, have a homogeneous distribution. The mean thicknesses of the six zones in the annulus ranged from 80.7 to 85.8 µm. This finding is consistent with the expectation that in a healthy eye, the retinal nerve fibers are uniformly distributed in a radial pattern around the fovea.

Table A-5 CIRRUS Ganglion Cell Analysis Summary Parameters for Normal Asian Study Eyes (µm)

Parameters	Mean	SD	Minimum	Maximum
Average Thickness	83.2	5.3	67.8	99.5
Minimum Thickness	80.9	5.4	63.8	95.2
Temporal–Superior Thickness	82.2	5.6	65.0	99.0
Superior Thickness	84.6	5.9	62.0	102.0
Nasal–Superior Thickness	85.8	5.9	70.0	103.0
Nasal–Inferior Thickness	83.0	5.9	66.0	105.0
Inferior Thickness	80.7	6.0	65.0	98.0
Temporal–Inferior Thickness	82.8	5.5	70.0	102.0

Normal Values for Asian ONH Measurements

CIRRUS ONH parameters are described in "Optic Nerve Head Normative Database: Diversified" on page A-9. They include:

- Rim Area (in units of mm^2)
- Average cup to disc ratio (ratio of cup area to disc area)
- Vertical cup to disc ratio (ratio of cup height to disc height at the cup center)
- Cup Volume (in units of mm^3)

Note that disc area is calculated and presented, but not compared to normal limits.

In addition, the plot of neuroretinal rim (NR) thickness around the disc is compared to normative limits.

The descriptive statistics for each optic nerve head parameter are reported in Table A-6, below.

Table A-6 CIRRUS ONH Summary Parameters for Normal Asian Study Eyes

	Rim Area (mm^2)	Disc Area (mm^2)	Average CD Ratio	Vertical CD Ratio	Cup Volume (mm^3)
Minimum	0.75	1.15	0.06	0.05	0.00
Maximum	2.27	3.14	0.78	0.77	0.73
Average	1.29	1.87	0.51	0.48	0.16
Standard Deviation	0.21	0.36	0.15	0.15	0.14

The disc area is of particular interest. Only thirteen subjects (less than 5%) had discs larger than 2.5 mm^2 in the study eye. Ten subjects (less than 5%) had discs smaller than 1.3 mm^2. Disc area showed no dependence on subject age. Classifying disc size as small, medium or large has been previously done (see example, Spaeth), but typically the sizing was based on a vertical diameter measured from the slit–lamp. By measuring the disc area we consider all meridians. Table A-7 serves as a very general size classification guide based on dividing the normative data into thirds. One third of the database had discs of 1.7 mm^2 or smaller, one third had discs between 1.7 and 2.0 mm^2, and the remainder had discs larger than 2.0 mm^2.

Table A-7 Disc Size Classification from the Sample Population

Disc Size Classification	Smallest 1/3 of Discs	Medium 1/3 of Discs	Largest 1/3 of Discs
Disc Area	< 1.7 mm^2	1.7 mm^2 to 2.0 mm^2	> 2.0 mm^2

Factors that Affect ONH Normative Ranges

The normal ranges described above do not take into account differences that may be present due to age, ethnicity, axial length, refraction, optic disc area, or signal strength. In regression analysis, we found that optic disc area and age were the two parameters with the greatest effect on the remaining ONH parameters. Based on R^2 values, disc area explains as much as 40% of the variability in some parameters, while age explains no more than 5%. All other continuous parameters, such as refractive error and axial length, explain less than 7% of variability. Only age and optic disc area were used when applying normative limits to ONH parameters.

Age

The CIRRUS Asian RNFL Normative Database was developed utilizing 315 subjects aged 19 to 79. Disc Area and Cup Volume showed no effect of Age. CD Ratio (average and vertical) increased slowly with age (slope = +0.002 per year, R^2= 0.0133, p = 0.0409 for average CD Ratio, slope = +0.0011 per year, R^2= 0.011, p = 0.03 for vertical CD Ratio).

Optic Disc Area

The distribution of disc area for the normative database eyes is discussed in the paragraph above. Note that 90% of disc areas were between 1.3 mm^2 and 2.5 mm^2. Therefore, normal limits will not be well defined for this population outside of those disc sizes, and are not applied (gray is shown for not applicable instead of the usual color coding). All optic nerve head parameters increase with disc size, including Rim Area (slope = +0.24 mm^2 of rim per mm^2 of disc, R^2 = 0.13, p = 0.042), Cup Volume (slope = +0.25 mm^3 of cup per mm^2 of disc, R^2 = 0.39, p = 0.011), and Cup to Disc Ratios (slope = +0.35 per mm^2 of disc, R^2 = 0.35, p < 0.001 for average CDR, slope = +0.29 per mm^2 of disc, R^2 = 0.34, p < 0.001 for vertical CDR).

Ethnicity

The ethnicity breakdown of the CIRRUS RNFL Normative Database is as follows: 44% Chinese, 44% Japanese and 12% Indians. Only thirteen subjects (less than 5%) had discs larger than 2.5 mm^2 in the study eye. Ten subjects (less than 5%) had discs smaller than 1.3 mm^2. There was no statistically significant difference among different ethnicities with respect to the Rim Area (p = 0.16) or the Disc Area (p = 0.38).

The Cup to Disc Ratio (Average and Vertical) as well as the Cup Volume, showed differences among ethnicity groups (mean difference for both ACDR and VCDR was 0.06, $p = 0.012$, mean difference in Cup Volume was 0.04 mm^3, $p = 0.03$).

Results revealed that the mean difference in the average GCL + IPL thickness between any two race groups is within 2.5 mm. Indians have thinner GCL + IPL thickness on average, while Chinese have thicker ($p = 0.02$).

Calculation of Normal Limits

As with the post–hoc analysis of the original normative databases, analysis of the ONH parameters for the Asian normative data found that these parameters depend on both optic disc area of the subject eye and subject age. A linear fit is used to model the age effects. The variability of parameters such as Rim Area and Cup to Disc Ratio on Disc Area was found to depend on the size of the disc. For this reason, quantile regression was used rather than linear regression to set the limits on the ONH parameters with respect to Disc Area. This is a method whereby the slope and offset are independently fit for each limit. See *Artes and Crabb*[3] for a description of quantile regression.

Conclusion

The CIRRUS HD-OCT Asian RNFL, macular thickness, ONH, and Ganglion Cell Analysis Normative Databases were created using data from subjects that were deemed representative of a normal population. The CIRRUS HD-OCT Asian Normative Database for RNFL thickness established reference values for the Optic Disc Cube 200x200 scan. The Macula Asian Normative Database established reference values for the Macular Cube 512x128 and Macular Cube 200x200 scans. Post–hoc analysis was used to develop reference values for Ganglion Cell Analysis and ONH as well. The doctor can use these normative databases to compare individual patient measurements to those acquired in a normal population.

Appendix B: CIRRUS Algorithm Studies

Study 1: Retinal Segmentation and Analysis

Introduction

Zeiss partnered with respected members of the academic and clinical community to study the accuracy and precision of the CIRRUS retinal segmentation algorithm, and to evaluate the agreement between CIRRUS HD-OCT and Stratus OCT, which is the standard of care for diagnosing and managing retinal diseases. The Retinal Segmentation Study Group consisted of faculty, fellows, and physicians at:

- Medical University of Vienna (MUV)
- Bascom Palmer Eye Institute (BPEI) – University of Miami Miller School of Medicine
- Wilmer Eye Institute (WEI) – Johns Hopkins University School of Medicine
- Northern California Retina–Vitreous Associates (NCRVA)

Preliminary results have been reported at conferences (see References on page B-8), and are summarized in this report. Final results are being submitted for publication.

Purpose

The primary purpose of the "Spectral Domain OCT (SD–OCT) Evaluation Study of Retinal Segmentation and Analysis" was to: 1) evaluate the accuracy and precision of the CIRRUS HD-OCT retinal thickness segmentation algorithms, and 2) to evaluate the agreement between the resulting measurements and similar measurements made on Stratus OCT. A secondary objective of the study was to evaluate the effectiveness of data registration on repeatability.

Methods

Data Collection

This was a prospective, non–randomized, multi–center study. Subjects 18 years of age or older, who were willing and able to give consent, and follow study instructions were recruited from the clinics of four study sites (WEI, BPEI, MUV, NCRVA) from March 2007 to October 2007, following an informed consent process including signing of a written consent form approved by the respective clinic's Institutional Review Board.

Both eyes of the subjects where scanned, with one eye being chosen as the study eye based on eligibility guidelines. When both eyes were eligible, the Principal Investigator arbitrarily assigned one eye as the study eye. Subjects were classified into six groups based on the primary diagnosis causing the most pathologic abnormalities in the study eye as follows:

Group 1 – Age–related macular degeneration (AMD),

Group 2 – Diabetic retinopathy (DR),

Group 3 – Vitreoretinal interface abnormalities (including macular holes),

Group 4 – Other retinal pathology,

Group 5 – Macular edema for which treatment was planned,

Group 6 – No retinal pathology.

Any subjects with a primary diagnosis that placed them within Groups 1 through 4, for whom treatment of macular edema was scheduled, were categorized into Group 5.

Two (2) 200x200 scans and two (2) 512x128 scans of the study and fellow eyes were acquired using the CIRRUS HD-OCT instrument during a single visit. Retinal thickness in every subfield (based on the ETDRS 6 mm grid centered on the fovea; see "ETDRS Position" on page 8-7) was calculated using CIRRUS 3.0 software for each of the scans. The scans were reviewed to identify scans with poor image quality due to poor signal strength, poor scan placement within the axial field of view of the instrument resulting in missing data, and shifts in location between scans prior to analyzing the repeatability or reproducibility data. Scans with more than 10% missing data or data missing from the center, very large shifts (greater than 3 mm), and very poor image quality were excluded from the analysis as these factors would preclude accurate assessments of repeatability between scans.

Each subject also underwent a Stratus Fast Macula scan of the study eye.

Data Analysis

Accuracy was assessed by having 14 trained clinicians perform hand segmentations of selected B-scans from a single scan of each type from each subject. Layers segmented by CIRRUS HD-OCT were compared to the hand–segmentations.

Agreement of the CIRRUS HD-OCT analysis with Stratus OCT was assessed by comparing the average retinal thickness in nine retinal subfields.

Repeatability of the average measurements for each of the nine subfields was assessed using analysis of variance. Repeatability was assessed with and without the use of an algorithm that registers a repeated scan to a prior scan, and with and without aligning the subfields to the subject's fovea for each scan. Both of these capabilities were introduced with the CIRRUS Version 4.0 software.

Results and Discussion

Accuracy

The CIRRUS HD-OCT internal limiting membrane (ILM) and retinal pigment epithelium (RPE) segmentations were scored as accurate if software–segmentations and hand–segmentations agreed, for 100% of A-scans that were evaluated, where agreement was defined as being within 16 µm for the central 1 mm of the scan and within 32 µm elsewhere in the scan. The accuracy of segmentations was found to depend on layer (RPE or ILM) and disease category, and is summarized below in Table B-1 and Table B-2.

Table B-1: Accuracy of Segmentations for RPE layer by Pathology Category

Category	200x200		512x218	
	n/N (%)	95% CI	n/N (%)	95% CI
AMD	60/70 (85.7%)	(77.5%, 91.3%)	62/72 (86.1%)	(78.1%, 98.5%)
Diabetic Retinopathy	40/42 (95.2%)	(86.6%, 98.4%)	41/42 (97.6%)	(90.0%, 99.5%)
VRI Disorder	27/28 (96.4%)	(85.5%, 99.2%)	25/28 (89.3%)	(76.0%, 95.5%)
Other Retinal Disease	44/51 (86.3%)	(76.5%, 92.4%)	46/52 (88.5%)	(79.2%, 93.9%)
Macular Edema	27/28 (96.4%)	(85.5%, 99.2%)	27/29 (93.1%)	(82.2%, 97.7%)
No Retinal Disease	37/37 (100.0%)	(93.2%, 100%)	40/40 (100.0%)	(93.7%, 100%)

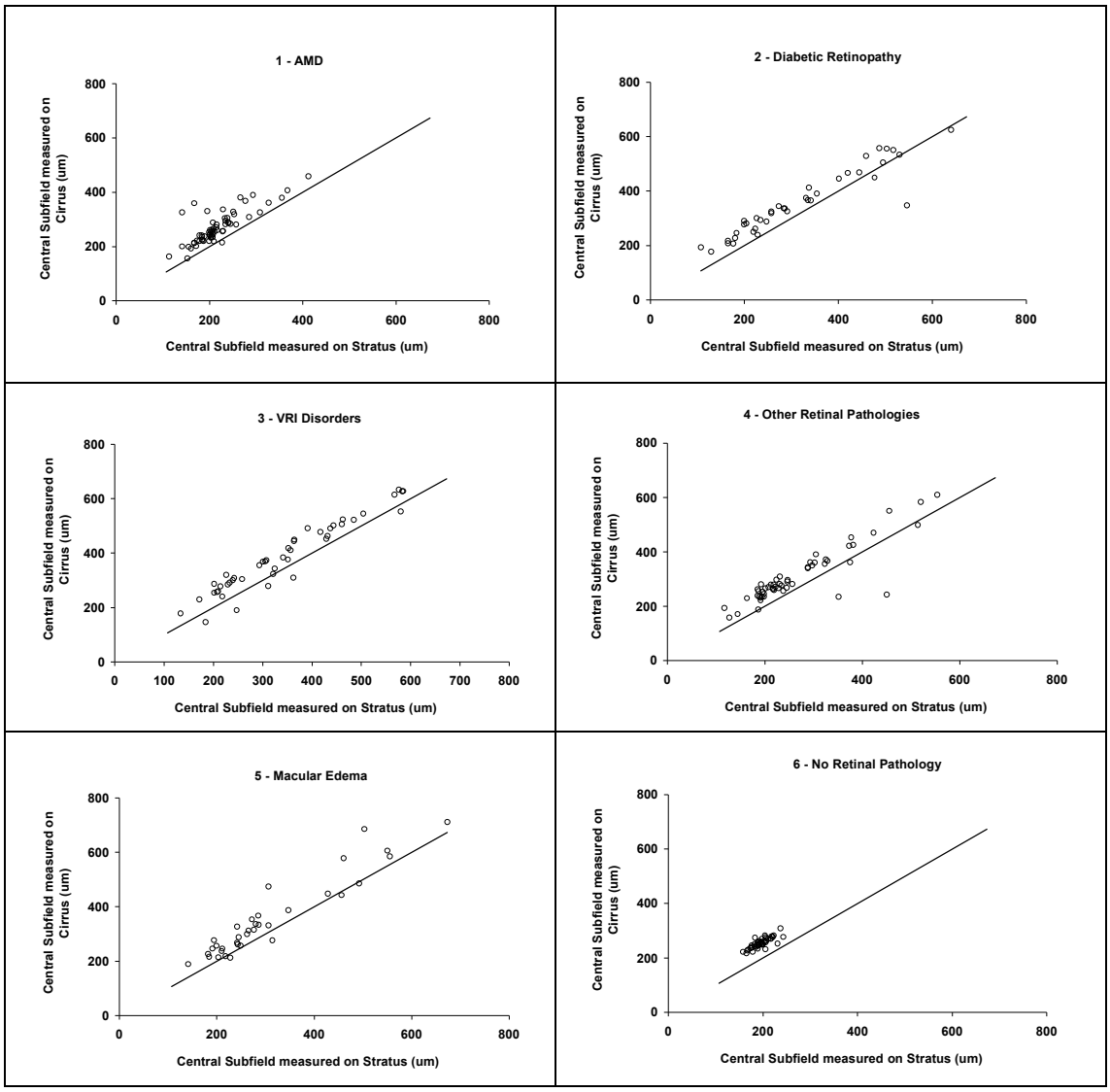
Table B-2: Accuracy of Segmentations for ILM layer by Pathology Category

Category	200x200		512x218	
	n/N (%)	95% CI	n/N (%)	95% CI
AMD	68/70 (97.1%)	(91.7%, 99.1%)	73/74 (98.6%)	(94.2%, 99.7%)
Diabetic Retinopathy	40/42 (95.2%)	(86.6%, 98.4%)	40/42 (95.2%)	(86.6%, 98.4%)
VRI Disorder	26/28 (92.9%)	(80.6%, 97.6%)	26/27 (96.3%)	(85.0%, 99.2%)
Other Retinal Disease	50/51 (98.0%)	(91.7%, 99.6%)	51/52 (98.1%)	(91.8%, 99.6%)
Macular Edema	28/28 (100.0%)	(91.2%, 100%)	28/29 (96.6%)	(85.9%, 99.2%)
No Retinal Disease	37/37 (100.0%)	(93.2%, 100%)	40/40 (100.0%)	(93.7%, 100%)

Agreement with Stratus OCT

Both CIRRUS HD-OCT and Stratus OCT provide estimates of the retinal thickness, and there is good correlation between them, as can be seen in Table B-3.

Table B-3: Comparison of CIRRUS HD-OCT Central Subfield Mean Thickness to Stratus OCT for the Six Categories



By design, the segmentation algorithms in CIRRUS HD-OCT search for different boundaries than those in Stratus OCT. Specifically, Stratus OCT locates the top of the bright reflective layer that is now known to represent the junction between inner and outer segments of the photo receptors as the lower boundary of the retina for its thickness calculations; whereas CIRRUS locates the brightest layer in the RPE / outer segment complex, which is thought to correspond to the RPE. Figure B-1 shows an example of the layers identified for a normal eye by Stratus OCT, while Figure B-2 shows the same eye scanned and segmented on CIRRUS HD-OCT. Although the retinal tissue has the same vertical extent (thickness) in both

images, the identification of layers is different, so the CIRRUS HD-OCT is expected to provide a thicker measurement than the Stratus OCT.

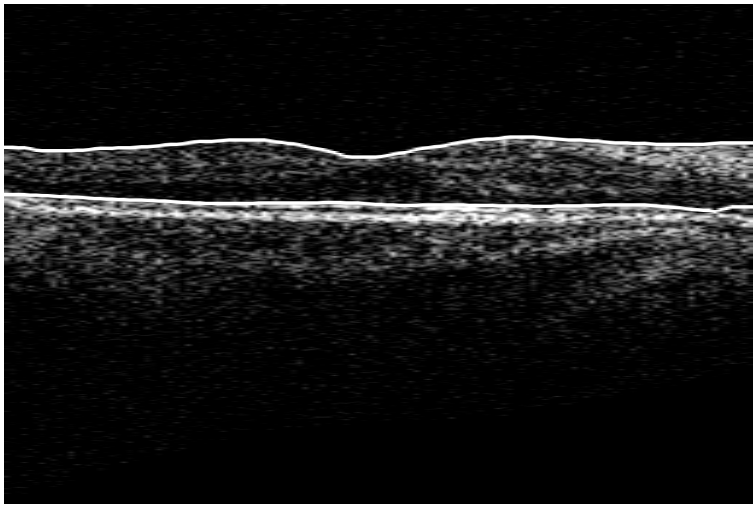


Figure B-1 Stratus OCT B-scan showing locations of RPE and ILM layers

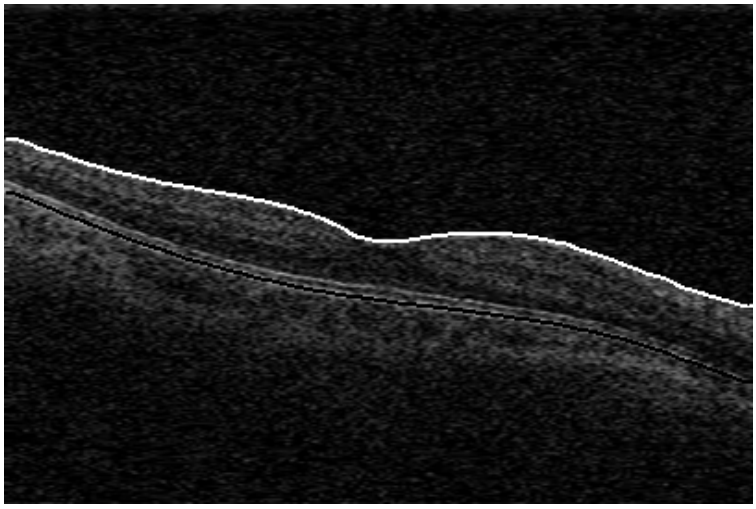


Figure B-2 CIRRUS HD-OCT B-scan showing locations of RPE and ILM layers

Because of this difference in segmentation strategy, there is a mean difference in the retinal thickness found by each instrument. Furthermore, because the integrity of the layers sought varies with pathology, the mean difference between instruments varies with pathology, as can be seen in Table B-4. Even after the mean difference has been accounted for, there is a residual difference that can be seen in the standard deviation of the difference reported in the last column of Table B-4. Because of the residual difference, it is better to compare scans between Stratus OCT and CIRRUS HD-OCT qualitatively, looking for changes in retinal morphology, rather than making decisions based on quantitative evaluation.

Table B-4: Difference between CIRRUS HD-OCT and Stratus OCT for the Central Subfield Mean Thickness for each of the Six Categories.

	Mean (SD) Difference CIRRUS – Stratus (µm)			
	N	CIRRUS	Stratus	Difference
1 – AMD	63	271.3 (60.6)	217.7 (54.2)	53.6 (35.0)
2 – DR	39	356.6 (118.7)	316.6 (135.8)	40.0 (47.1)
3 – VRI	45	386.3 (128.0)	342.5 (125.0)	43.8 (35.9)
4 – Other	53	310.6 (99.5)	268.9 (101.6)	41.7 (47.1)
5 – ME	35	351.1 (140.3)	305.7 (127.9)	45.5 (45.3)
6 – Normal	48	256.1 (18.6)	196.7 (18.6)	59.4 (11.7)

Repeatability

The repeatability of CIRRUS HD-OCT retinal thickness measurements varies with pathology.

Table B-5 shows the repeatability standard deviation for each disease category for the central subfield average thickness. This is the expected standard deviation between two scans acquired and analyzed using CIRRUS 3.0.

Repeatability can be improved by ensuring that two scans are registered to each other, as when the Macular Change Analysis is used. Repeatability can also be improved using the Macular Thickness Analysis in CIRRUS 4.0 when the fovea is correctly identified and used as the reference point for subfield average thickness calculations. These repeatability improvements are shown in Table B-6. It is important to note that the algorithm to find the fovea may fail in certain disease cases, as is shown in Table B-7. The user should always review the location of the fovea, and adjust it as necessary (see "Fovea Location" on page 8-6 for instructions on how to do this).

Repeatability when registration and fovea placement are performed is better than 9 µm for all pathologies, which implies a coefficient of variability (repeatability standard deviation divided by mean thickness) of 3.3% or better. Coefficient of variability is better than 1% for normals.

Table B-5: Repeatability Standard Deviation in micrometers for Central Subfield Measurements using CIRRUS 3.0 for the 200x200 Scan and for the 512x128 Scan.

	CSMT Repeatability Standard Deviation[a] (µm)			
	N	200x200	N	512x128
AMD	77	17.5	66	11.6
DR	51	16.8	50	13.7
VRI	44	14.4	44	8.4
Other	62	10.1	61	9.5
ME	41	13.5	39	27.2
No disease	44	4.8	47	3.6

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. For this study, two scans were acquired per subject during a single visit on a single system by a single operator at one of four sites. ISO 5725–1 and ISO 5725–6, Repeatability limit = 2.8 – Repeatability SD.

Table B-6: Repeatability Standard Deviation[a] in micrometers for Central Subfield Measurements on the 200x200 scan using CIRRUS 3.0 Macular Thickness Analysis (MTA), CIRRUS 4.0 MTA with the ability to adjust the Fovea Position, and CIRRUS 4.0 Macular Change Analysis, which uses Registration and Fovea Placement.

	N	Mean ±SD CSMT (µm) for CIRRUS 4.0 MTA	CSMT Repeatability Standard Deviation (µm)		
			CIRRUS 3.0 MTA	CIRRUS 4.0 MTA with fovea placement	CIRRUS 4.0 MCA with registration and fovea placement
AMD	77	255 ±65	17.5	6.3	8.7
DR	51	335 ±109	16.8	9.8	8.1
VRI	44	360 ±128	14.4	5.4	4.3
Other	62	303 ±114	10.1	7.5	4.5
ME	41	339 ±141	13.5	7.9	7.0
No disease	44	256 ±21	4.8	2.2	2.5

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. For this study, two scans were acquired per subject during a single visit on a single system by a single operator at one of four sites. ISO 5725–1 and ISO 5725–6, Repeatability limit = 2.8 – Repeatability SD.

Table B-7: Rate of failure of the Fovea Finding Algorithm by Disease Category

	N	Percent of scans with fovea failures	
		Fovea not found	Fovea not correct
AMD	77	11%	6%
DR	51	19%	10%
VRI	44	24%	5%
Other	62	10%	6%
ME	41	18%	6%
No disease	44	0%	0%

Conclusion

CIRRUS HD-OCT retinal thickness measurements are accurate and repeatable. Better than 85% of all scans are correctly segmented, even in the presence of pathology. Features introduced with CIRRUS 4.0 software improve repeatability standard deviation to 2.5 µm in normals and to better than 9 µm for subjects with a variety of pathologies.

References

1. M. Weisbrod, P. Stetson, M. Wieland, N. Bressler, U. Schmidt–Erfurth, R. Knighton. G. Gregori, "Comparison of Hand–Drawn ILM and RPE Segmentation to the Retinal Segmentation Algorithm of the CIRRUS HD-OCT," ARVO 2008, poster 4240.
2. M. Chang, M. Durbin, M. Weiland, U. Schmidt–Erfurth, G. Gregori, N. Bressler, "Repeatability of retinal thickness measurements using CIRRUS HD-OCT Spectral Domain Technology," ARVO 2008, poster 4253.
3. W. Geitzenauer, C. Kiss, M. Durbin, T. Abunto, M. Wieland, N. Bressler, G. Gregori, U. Schmidt–Erfurth, "Comparing Retinal Thickness Measurements From CIRRUS Spectral–Domain and Stratus Time–Domain OCT," ARVO 2008, poster 930.

Study 2: Repeatability and Reproducibility of Illumination Area Measurements Under the Retinal Pigment Epithelium

The objective of this study was to determine the repeatability and reproducibility of the CIRRUS HD-OCT measurement of illumination areas under the retinal pigment epithelium (RPE). For Phase 1, the inter–device analysis, 49 eyes of 37 subjects were qualified for inclusion. A single operator performed all scans during Phase 1 of the protocol. For Phase 2, the inter–operator phase, 53 eyes of 39 subjects were qualified for inclusion into the analysis of scans from a single CIRRUS HD-OCT taken by three operators. Subjects in each phase of the study underwent the following series of CIRRUS HD-OCT scans:

Phase 1: Inter–Device Variability

- Three acceptable Macular Cube 200x200 scans on one eye from three CIRRUS HD-OCT instruments for a total of 9 scans
- Three acceptable Macular Cube 512x128 scans on the fellow eye from three CIRRUS HD-OCT instruments for a total of 9 scans

Phase 2: Inter–Operator Variability

- Three acceptable Macular Cube 200x200 scans on one eye from one CIRRUS HD-OCT instrument by three operators for a total of 9 scans
- Three acceptable Macular Cube 512x128 scans on the fellow eye from the same CIRRUS HD-OCT instrument by three operators for a total of 9 scans

The repeatability standard deviation (SD) is the square root of the random variance component. The reproducibility SD is the square root of the sum of all contributions to variance except subject variance. The repeatability limit is 2.8x repeatability SD. The reproducibility limit is 2.8x the reproducibility SD. The larger random error variation from the two study phases was selected as the random error variation for the corresponding endpoint (and scan type) and was used to calculate the repeatability. The reproducibility includes variation due to random error, operator, device, interaction between subject and device, and interaction between subject and operator.

Table B-8 shows the repeatability and the reproducibility SD and limits of the sub–RPE illumination area measurements and the closest distance to the fovea determined by the automated algorithm for both 200x200 and 512x128 scans. For the area measurements, the repeatability limit of the 200x200 vs. the 512x128 scans were very similar (2.4885 and 2.4313 mm^2 respectively). The reproducibility limit of the 200x200 scan was smaller compared to that of the 512x128 scans (2.6460 and 2.8889 mm^2 respectively). The repeatability and reproducibility limits will affect the ability to determine when measurements have changed due to a change in pathology as opposed to random variability.

The coefficient of variation (CV) is defined as the ratio of the standard deviation to the mean. The coefficient of variation is useful because the standard deviation of data must always be understood in the context of the mean of the data. For the 200x200 scans, the CV for the sub–RPE illumination was 12.5%. For the 512x128 scans, the CV was 15.8%.

Table B-8: Repeatability and Reproducibility of Area of Sub–RPE Illumination Automated Algorithm

Scan	Repeatability		Reproducibility		
	Repeatability SD (mm^2)	Repeatability Limit[a] (mm^2)	Reproducibility SD (mm^2)	Reproducibility Limit[b] (mm^2)	CV[c] %
200x200 Scan	0.8887	2.4885	0.9450	2.6460	12.5%
512x128 Scan	0.8683	2.4313	1.0317	2.8889	15.8%

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD
b. Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725–1 and ISO 5725–6, Reproducibility Limit = 2.8 x Reproducibility SD.
c. CV = Coefficient of variation = SD ÷ Mean.

Manual editing of the 200x200 scans by trained clinical personnel was carried out in cases where the algorithm did not find the outline of the lesion accurately. Each scan was evaluated, and the determination of whether it needed manual editing or not was made by the designated clinical personnel. Table B-9 illustrates that for the manual area measurements, the repeatability limit of the 200x200 scans was considerably lower than the automated measurements (0.6365 and 2.4885 mm^2 respectively). For the manually edited scans, the area of sub–RPE illumination had a coefficient of variation of 4.3% which was much lower compared to that of the automated algorithm.

Table B-9: Repeatability and Reproducibility of Area of Sub–RPE Illumination Manually Edited

Scan	Repeatability		Reproducibility		
	Repeatability SD (mm^2)	Repeatability Limit[a] (mm^2)	Reproducibility SD (mm^2)	Reproducibility Limit[b] (mm^2)	CV[c] %
200x200 Scan	0.2273	0.6365	0.3823	1.0705	4.3%

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD
b. Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725–1 and ISO 5725–6, Reproducibility Limit = 2.8 x Reproducibility SD.
c. CV = Coefficient of variation = SD ÷ Mean.

For the closest distance to the fovea measurements using the automated algorithm, the repeatability limit of the 200x200 scan was more repeatable compared to the 512x128 scan (0.2070 and 0.3492 mm respectively). Likewise, the reproducibility limit of the 200x200 scan was smaller compared to that of the 512x128 scans (0.2133 and 0.3520 mm respectively) as shown in Table B-10.

Table B-10: Repeatability and Reproducibility of the Closest Distance to Fovea Automated Algorithm

Scan	Repeatability		Reproducibility	
	Repeatability SD (mm)	Repeatability Limit[a] (mm)	Reproducibility SD (mm)	Reproducibility Limit[b] (mm)
200x200 Scan	0.0739	0.2070	0.0762	0.2133
512x128 Scan	0.1247	0.3492	0.1257	0.3520

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD.
b. Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725–1 and ISO 5725–6, Reproducibility Limit = 2.8 x Reproducibility SD.

Prior to the manual editing of the algorithm, each scan was checked to ensure that they were centered correctly on the fovea using the tools in Macular Thickness Analysis. Table B-11 shows the repeatability and reproducibility of the closest distance to the fovea after manual editing of the 200x200 scans. Note that there was a significant improvement in the repeatability and reproducibility values for these measurements.

Table B-11: Repeatability and Reproducibility of the Closest Distance to Fovea Manually Edited

Scan	Repeatability		Reproducibility	
	Repeatability SD (mm)	Repeatability Limit[a] (mm)	Reproducibility SD (mm)	Reproducibility Limit[b] (mm)
200x200 Scan	0.0354	0.0990	0.0439	0.1229

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD.
b. Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725–1 and ISO 5725–6, Reproducibility Limit = 2.8 x Reproducibility SD.

Study 3: Repeatability and Reproducibility of Macular Retinal Pigment Epithelium Elevation Measurements

The objective of this study was to determine the repeatability and reproducibility of the CIRRUS HD-OCT measurements of macular retinal pigment epithelium (RPE) elevation. A total of 50 eyes of 44 subjects were qualified for inclusion into the data analysis. There were 26 qualified eyes for Phase 1 and 24 qualified eyes for Phase 2. Subjects in each phase of the study underwent a series of CIRRUS HD-OCT scans:

Phase 1: Inter–Device Variability

Subjects assigned to Phase 1 of the study underwent the following series of CIRRUS HD-OCT scans using the three CIRRUS units. A single operator, Operator A, performed all scans during Phase 1 of the protocol. The following study measures were acquired:

- Three acceptable Macular Cube 200x200 scans on one eye from three CIRRUS HD-OCT instruments for a total of 9 scans
- Three acceptable Macular Cube 512x128 scans on the fellow eye from three CIRRUS HD-OCT instruments for a total of 9 scans

Phase 2: Inter–Operator Variability

Subjects assigned to Phase 2 of the study underwent the following series of CIRRUS HD-OCT scans using only CIRRUS Unit 1. Three operators acquired the scans on each subject. the following study measures were acquired:

- Three acceptable Macular Cube 200x200 scans on one eye from one CIRRUS HD-OCT instrument by three operators for a total of 9 scans
- Three acceptable Macular Cube 512x128 scans on the fellow eye from the same CIRRUS HD-OCT instrument by three operators for a total of 9 scans

The repeatability and reproducibility SD and limits of the area of RPE elevations are seen in Table B-12 below. The repeatability limit of area measurements within the 3 mm circle was higher than that of the 5 mm circle in the 200x200 scans (0.3626 and 0.2834 mm^2 respectively). The reverse was true for the 512x128 scan (0.2343 and 0.4304 mm^2 respectively). The reproducibility limit of area measurements within the 3 mm circle was almost the same as that of the 5 mm circle in the 200x200 scans (0.4389 and 0.4073mm^2 respectively). For the 512x128 scan, the reproducibility limits for the 5 mm circle was double that of the 3 mm circle (0.5422 vs. 0.2794 mm^2). The repeatability and reproducibility limits will affect the ability to determine when measurements have changed due to a change in pathology as opposed to random variability.

Table B-12: Repeatability and Reproducibility of Area of RPE Elevations

	Repeatability		Reproducibility		
	Repeatability SD (mm^2)	Repeatability Limit[a] (mm^2)	Reproducibility SD (mm^2)	Reproducibility Limit[b] (mm^2)	CV[c] %
200x200 Scan					
3mm Circle	0.1295	0.3626	0.1568	0.4389	10.1%
5mm Circle	0.1012	0.2834	0.1455	0.4073	4.9%
512x128 Scan					
3mm Circle	0.0837	0.2343	0.0998	0.2794	7.5%
5mm Circle	0.1537	0.4304	0.1936	0.5422	9.6%

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD.
b. Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725–1 and ISO 5725–6, Reproducibility Limit = 2.8 x Reproducibility SD.
c. CV = Coefficient of variation = SD ÷ Mean.

The repeatability and reproducibility SD and limits of the volume of RPE elevations are seen in Table B-13 below. The repeatability limit of volume measurements within the 3 mm circle was higher than that of the 5 mm circle in the 200x200 scans (0.0327 and 0.0275 mm^3 respectively). For the 512x128 scan, the opposite was true, although the difference was smaller (0.0206 and 0.0245 mm^3 respectively). The reproducibility limit of volume measurements within the 3 mm circle was higher than that of the 5 mm circle in the 200x200 scans (0.0341 and 0.0298 mm^3 respectively). For the 512x128 scan, the reproducibility limits for the 5 mm circle was higher than that of the 3 mm circle (0.0288 vs. 0.0235 mm^3). The repeatability and reproducibility limits will affect the ability to determine when measurements have changed due to a change in pathology as opposed to random variability.

Table B-13: Repeatability and Reproducibility of Volume of RPE Elevations

	Repeatability		Reproducibility		
	Repeatability SD (mm^3)	Repeatability Limit[a] (mm^3)	Reproducibility SD (mm^3)	Reproducibility Limit[b] (mm^3)	CV[c] %
200x200 Scan					
3mm Circle	0.0117	0.0327	0.0122	0.0341	15.2%
5mm Circle	0.0098	0.0275	0.0106	0.0298	8.3%
512x128 Scan					
3mm Circle	0.0074	0.0206	0.0084	0.0235	12.0%
5mm Circle	0.0088	0.0245	0.0103	0.0288	11.4%

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD.
b. Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725–1 and ISO 5725–6, Reproducibility Limit = 2.8 x Reproducibility SD.
c. CV = Coefficient of variation = SD ÷ Mean.

For the area of RPE elevations, the coefficient of variation (CV) was lowest for the measurements in the 5 mm circle of the 200x200 scan (4.9%) and highest for the measurements in the 3 mm circle of the 200x200 scan (10.1%).

For the volume of RPE elevations, the CV was lowest for the measurements in the 5 mm circle of the 200x200 scan (8.3%) and highest for the measurements in the 3 mm circle of the 200x200 scan type (15.2%).

Study 4: Repeatability and Reproducibility of GCA and ONH Parameters

A study was conducted to determine the repeatability and reproducibility of the Ganglion Cell Analysis (GCA) and Optic Nerve Head (ONH) parameters. Sixty–three (63) subjects were enrolled in this study that was performed in two phases. Phase 1 was inter–operator testing, where four operators (A, B, C, and D) acquired measurements on one CIRRUS HD-OCT unit (C1). The order of the operators used for scanning each subject was determined using a randomization table. For each subject, a series of twelve (12) RNFL/ONH scans were taken for one eye and twelve (12) macular thickness scans were taken for the fellow eye for a total of 24 scans. Each of the four operators acquired 3 scans per eye on one CIRRUS 4000 unit. Phase 2 was inter–device testing where four CIRRUS HD-OCT units (C1, C2, C3, C4) were operated by a single operator (A). The order of devices used for each subject was randomized.

Table B-14 presents the repeatability and reproducibility standard deviation (SD) and limits for the CIRRUS HD-OCT. Among the GCA parameters, the minimum thickness had the largest repeatability limit and reproducibility limit (8.0165 µm and 8.1018 µm respectively) and the average thickness had the smallest repeatability limit and reproducibility limit (1.6348 µm and 2.0942 µm respectively). The repeatability of the minimum thickness measurement was notably lower than the rest of the parameters; this is expected as the minimum thickness is a more variable measurement from subject to subject, depending upon disease severity.

Among the ONH parameters, the disc area measurement had the largest repeatability limit (0.1506 mm^2) and the smallest repeatability limit was the cup volume measurement (0.0181 mm^3). The largest reproducibility limit was for the disc area (0.0942 mm^2) and the smallest reproducibility limit was for the cup volume measurement (0.0102 mm^3). The reproducibility limits will affect the ability to determine when measurements have change due to a change in pathology as opposed to random variability.

The optic nerve head algorithm may show increased variability in certain anatomical variants. For tilted discs and discs with large clusters of blood vessels, shadowing of the underlying RPE and Bruch's membrane may render the disc edge difficult to identify. Variability may also be increased due to ambiguity in cup marker placement for small, crowded discs with shallow cups, and discs with large clusters of blood vessels. Cups with excavation or embryonic tissue remnants may have variable cup volume measurements.

The coefficient of variation (CV) was also determined for the CIRRUS HD-OCT GCA and ONH parameters. Among the GCA parameters, the minimum thickness had the largest CV of 2.5% and the average thickness had the smallest CV of 0.7%. Among the ONH parameters, the cup volume measurement had the largest CV of 7.8% and the smallest CV was the rim area of 4.7%.

Table B-14: CIRRUS Repeatability and Reproducibility of GCA and ONH Parameters – Normal Subjects

	Repeatability		Reproducibility		
	Repeatability SD	Repeatability Limit[a]	Reproducibility SD	Reproducibility Limit[b]	CV[c] %
GCA Parameters (µm)					
Average GCL + IPL Thickness	0.5839	1.6348	0.7479	2.0942	0.7%
Minimum GCL + IPL Thickness	2.8630	8.0165	2.8935	8.1018	2.5%
Temporal–Superior GCL + IPL Thickness	0.8394	2.3502	0.9496	2.6590	1.0%
Superior GCL + IPL Thickness	0.9115	2.5522	1.0723	3.0024	1.1%
Nasal–Superior GCL + IPL Thickness	0.9198	2.5753	1.0412	2.9154	1.0%
Nasal–Inferior GCL + IPL Thickness	1.6735	4.6857	1.7330	4.8525	1.5%
Inferior GCL + IPL Thickness	0.9962	2.7894	1.1907	3.3339	1.2%
Temporal–Inferior GCL + IPL Thickness	0.8196	2.2948	0.9177	2.5696	1.0%
ONH Parameters					
Average Cup–to–Disc Ratio	0.0136	0.0380	0.0242	0.0679	5.4%
Vertical Cup–to–Disc Ratio	0.0243	0.0681	0.0302	0.0846	7.1%
Disc Area (mm^2)	0.0538	0.1506	0.0942	0.2637	5.4%
Rim Area (mm^2)	0.0420	0.1177	0.0619	0.1733	4.7%
Cup Volume (mm^3)	0.0065	0.0181	0.0102	0.0287	7.8%

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD.
b. Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Per ISO 5725–1 and ISO 5725–6, Reproducibility Limit = 2.8 x Reproducibility SD.
c. CV = Coefficient of variation = SD ÷ Mean.

A clinical study was conducted with 55 glaucomatous subjects to determine the intra–visit and inter–visit repeatability of CIRRUS HD-OCT optic nerve head parameters. The study was performed in two phases. Phase 1 of the study was designed to determine intra–visit variability, wherein each subject was imaged three times during a single visit on one CIRRUS HD-OCT by one operator. Phase 2 was designed to determine inter–visit variability, wherein each subject was imaged on four subsequent visits by one operator.

The study subjects ranged in age from 46 to 87 years; the mean was 70.7 ± 11.1 years. The glaucomatous subjects were comprised of 26 mild, 11 moderate, and 18 severe cases. The repeatability and visit–to–visit variability SD and limits for the ONH parameters are shown in Table B-15.

Table B-15: Repeatability and Visit–to–Visit Variability of ONH Parameters – Glaucomatous Subjects

	Repeatability SD	Repeatability Limit[a]	Visit–to–Visit Variability SD	Visit–to–Visit Variability Limit[b]	CV% [c]
Disc Area	0.084 mm^2	0.233 mm^2	0.084 mm^2	0.233 mm^2	4.4%
Rim Area	0.045 mm^2	0.125 mm^2	0.045 mm^2	0.125 mm^2	6.6%
Average Cup–to–Disc Ratio	0.009	0.025	0.009	0.025	1.2%
Vertical Cup–to–Disc Ratio	0.014	0.039	0.015	0.042	1.9%
Cup Volume	0.032 mm^3	0.089 mm^3	0.063 mm^3	0.175 mm^3	11.7%

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD.
b. Visit–to–Visit Variability Limit is the upper 95% limit calculated for the difference between individual measurements. Per ISO 5725–1 and ISO 5725–6, Visit–to–Visit Variability Limit = 2.8 x Visit–to–Visit Variability SD.
c. Coefficient of Variability is CV = SD divided by the mean.
Note: Operator and device variability were not considered for this study.

A total of 119 subjects with glaucoma were enrolled in a clinical study conducted at four sites. Ninety–four subjects with two qualified scans each were included in the analysis, of which 45 were categorized as mild glaucoma, 20 as moderate glaucoma and 19 as severe glaucoma. The mean age of the included subjects was 66.9 years, with a range from 43 to 89 years. The repeatability SD and limits for the GCA parameters are shown in Table B-16.

1. Derived from Mwanza, JC, Chang, RP, Budenz, DL, Durbin, MK, Gendy, MG, Ski, W, Feauer, WJ. Reproducibility of Peripapillary Retinal Nerve Fiber Layer Thickness and Optic Nerve Head Parameters Measured with Cirrus HD-OCT in Glaucomatous Eyes. IOVS 2010; 51:5724-5730.

Table B-16: Repeatability of GCA Parameters Measured – Glaucomatous Subjects

GCA Parameters (µm)	Repeatability		
	Repeatability SD	Repeatability Limit[a]	CV[b] %
Overall			
Average GCL + IPL Thickness	0.6274	1.7567	1.0%
Minimum GCL + IPL Thickness	1.5246	4.2689	2.6%
Temporal–Superior GCL + IPL Thickness	1.2204	3.4171	1.8%
Superior GCL + IPL Thickness	1.2653	3.5429	1.8%
Nasal–Superior GCL + IPL Thickness	0.8219	2.3013	1.2%
Nasal–Inferior GCL + IPL Thickness	1.1204	3.1371	1.7%
Inferior GCL + IPL Thickness	1.0569	2.9593	1.7%
Temporal–Inferior GCL + IPL Thickness	1.2160	3.4049	2.0%
Mild Glaucoma			
Average GCL + IPL Thickness	0.5099	1.4277	0.7%
Minimum GCL + IPL Thickness	0.9000	2.5200	1.4%
Temporal–Superior GCL + IPL Thickness	0.8062	2.2574	1.2%
Superior GCL + IPL Thickness	1.0198	2.8555	1.4%
Nasal–Superior GCL + IPL Thickness	0.8367	2.3426	1.1%
Nasal–Inferior GCL + IPL Thickness	1.1489	3.2170	1.6%
Inferior GCL + IPL Thickness	1.0677	2.9896	1.6%
Temporal–Inferior GCL + IPL Thickness	1.0488	2.9367	1.6%
Moderate Glaucoma			
Average GCL + IPL Thickness	0.7661	2.1352	1.2%
Minimum GCL + IPL Thickness	1.1132	3.1169	2.1%
Temporal–Superior GCL + IPL Thickness	1.3433	3.7611	2.1%
Superior GCL + IPL Thickness	1.8238	5.1065	2.9%
Nasal–Superior GCL + IPL Thickness	0.8209	2.2986	1.2%
Nasal–Inferior GCL + IPL Thickness	0.8341	2.3354	1.4%
Inferior GCL + IPL Thickness	1.1325	3.1711	2.0%
Temporal–Inferior GCL + IPL Thickness	0.8723	2.4424	1.5%
Severe Glaucoma			
Average GCL + IPL Thickness	0.7071	1.9799	1.2%
Minimum GCL + IPL Thickness	2.6682	7.4708	5.3%
Temporal–Superior GCL + IPL Thickness	1.7728	4.9639	2.9%
Superior GCL + IPL Thickness	1.0235	2.8659	1.6%
Nasal–Superior GCL + IPL Thickness	0.7868	2.2030	1.2%
Nasal–Inferior GCL + IPL Thickness	1.3093	3.6661	2.1%
Inferior GCL + IPL Thickness	0.9386	2.6281	1.6%
Temporal–Inferior GCL + IPL Thickness	1.7795	4.9826	3.3%

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD.
b. CV = Coefficient of variation = SD ÷ Mean.

Study 5: Anterior Segment Accuracy, Repeatability and Reproducibility

Benchtop Scanning Accuracy, Repeatability and Reproducibility

Accuracy, repeatability, and reproducibility of scanning in the CIRRUS HD-OCT have been measured in benchtop studies. Table B-17 below summarizes the results for axial dimensions in the basic image geometry.

Accuracy is reported as a 95% confidence interval for the absolute difference between a measured and actual distance. Repeatability and reproducibility are given both as standard deviation (SD) estimates and as estimates for the 95% upper limit of the difference between two measurements. The Repeatability Limit = 2.8 X Repeatability SD. The Reproducibility Limit = 2.8 X Reproducibility SD.

Table B-17: Repeatability and Reproducibility of Axial Distance in Tissue

Measurement	Accuracy (µm)	Repeatability SD (µm)	Repeatability Limit[a] (µm)	Reproducibility SD (µm)	Reproducibility Limit[b] (µm)	Average Measurement (µm)
Axial Distance in Tissue	6.2	2.6	7.1	2.7	7.6	1165.6

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD.

b. Reproducibility Limit is the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. Each test object was imaged three times by two operators on each of five instruments. Per ISO 5725–1 and ISO 5725–6, Reproducibility Limit = 2.8 x Reproducibility SD.

CIRRUS HD-OCT Repeatability in Measuring Central Corneal Thickness

A study was conducted to determine repeatability and reproducibility of the CIRRUS HD-OCT instrument measurements of Central Corneal Thickness (CCT). Phase I of the study enrolled 28 subjects and was designed to determine inter–device variability, wherein each subject was imaged 3 times during a single visit on each of three CIRRUS OCT instruments by one operator. Phase II enrolled 22 subjects and was designed to determine inter–operator variability, wherein each subject was imaged three times during a single visit by each of three operators. Phases I and II enrolled different subjects.

The CIRRUS HD-OCT repeatability and reproducibility are shown in Table B-18. Mean thickness of each phase and overall (Phase I and II combined) are also shown. Since the random error variability from Phase II of the study was larger than that from Phase I, the variance components from Phase II were used to estimate the random measurement variability and the repeatability standard deviation.

Table B-18: Repeatability and Reproducibility of Central Corneal Thickness

CIRRUS HD-OCT Repeatability		CIRRUS HD-OCT Reproducibility		Mean Thickness (µm)		
Repeatability SD (µm)	Repeatability Limits[a] (µm)	Reproducibility SD (µm)	Reproducibility Limits[b] (µm)	Phase I	Phase II	Overall
4.08	11.42	4.23	11.84	544.25	532.25	538.25

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725–1 and ISO 5725–6, Repeatability Limit = 2.8 x Repeatability SD

b. Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated using different operators. Each subject was imaged three times during a single visit by each of three operators. Per ISO 5725–1 and ISO 5725–6, Reproducibility Limit = 2.8 x Reproducibility SD.

Comparison of CIRRUS HD-OCT and Ultrasound Pachymetry in Central Corneal Thickness Measurements

Table B-19 shows the mean difference in central corneal thickness measurements between CIRRUS HD-OCT and ultrasound pachymetry. The negative difference means that the CIRRUS CCT measurement is thinner than the ultrasound CCT measurement. This data was taken from a total of 50 eyes enrolled in one site measured by a single operator for each device.

Table B-19: Difference in Central Corneal Thickness measurement Between CIRRUS HD-OCT and Ultrasound Pachymetry

			95% CI of the Difference	
	Mean Difference	SD	Lower	Upper
CIRRUS CCT– Ultrasound pachymetry CCT (µm)	–9.06	5.63	–10.66	–7.46

OCT devices in general measure thinner than ultrasound pachymetry. The Visante User Manual reports an average measurement difference of 15.1 µm. In the literature, reported differences between OCT and ultrasound pachymetry range from 11.64 to 49.4 µm (see References below).

Performance of CIRRUS HD-OCT RNFL Analysis

Repeatability and Reproducibility

CZMI performed an in–house study on normal subjects to determine the inter–visit and inter–instrument repeatability of CIRRUS RNFL thickness measurements. The repeatability and reproducibility (including effects of multiple visits and multiple instruments), along with the coefficient of variability, are shown in Table B-20 on page B-21. Similar results were also found in an independent study, which reported a coefficient of variability of 1.5% in normal subjects and 1.6% in patient eyes[2].

2. Vizzeri, G, Weinreb, RN, Gonzalez-Garcia, AO, Bowd, C, Medeiros, F, Sample, PA, Zangwill, LM: Agreement between spectral-domain and time-domain OCT for measuring RNFL thickness, Br J Ophthalmol, March 2009.

Comparison to Stratus OCT[3]

A study of normal subjects and subjects with glaucoma (N = 130) found that although there were differences between Stratus and CIRRUS, the Pearson correlation coefficient for the average RNFL thickness was 0.953, indicating good correlation. However, they also found a systematic difference between CIRRUS and Stratus RNFL measurements. CIRRUS measures thicker than Stratus at thinner RNFL values and measures thinner at thicker (more normal) RNFL values. Measurements from the two systems should not be used interchangeably.

Table B-20 Repeatability and Reproducibility of CIRRUS RNFL measurements for seventeen sectors, including the overall average thickness, four quadrants (temporal, superior, nasal, and inferior), and twelve sectors, labeled by clock hour, with the 9 o'clock hour most temporal, measured on 32 normal subjects.

	Mean Thickness (µm)	Repeatability SD (µm)	Reproducibility SD (µm)	Repeatability Limit[a] (µm)	Reproducibility Limit[b] (µm)
Average	93.1	1.33	1.35	3.72	3.78
Temporal	64.6	2.03	2.05	5.68	5.74
Superior	118.8	3.42	3.45	9.58	9.66
Nasal	68.6	2.19	2.24	6.13	6.27
Inferior	123.6	3.01	3.14	8.43	8.79
Clock hour 1	113.6	4.84	5.05	13.55	14.14
Clock hour 2	84.3	4.7	4.74	13.16	13.27
Clock hour 3	56.4	2.43	2.56	6.80	7.17
Clock hour 4	63.0	3.25	3.37	9.10	9.44
Clock hour 5	102.5	4.35	4.37	12.18	12.24
Clock hour 6	133.5	4.93	5.21	13.80	14.59
Clock hour 7	134.7	5	5.01	14.00	14.03
Clock hour 8	66.1	3	3	8.40	8.40
Clock hour 9	53.0	1.71	1.78	4.79	4.98
Clock hour 10	76.3	3.53	3.53	9.88	9.88
Clock hour 11	125.2	4.75	4.77	13.30	13.36
Clock hour 12	121.6	6.43	6.51	18.00	18.23

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.

b. Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated with different operators on different instruments. Each subject was imaged three times each during three visits on a single instrument (Phase 1) or twice during a single visit on five instruments (Phase 2). Per the ISO quoted in the main text, Reproducibility limit = 2.8 x Reproducibility.

3. Knight OJ, Chang RT, Feuer WJ, Budenz DL. "Comparison of retinal nerve fiber layer measurements using time domain and spectral domain optical coherent tomography." Ophthalmology. 2009 Jul;116(7):1271-7.

Study 6: CIRRUS OCT Angiography

A series of case studies comparing CIRRUS OCT angiography cube scans of 3x3 mm and 6x6 mm with fluorescein angiography images was completed. The findings demonstrate that the OCT Angiography in combination with OCT intensity-based information (B-scans and en face images) can give non-invasive 3-dimensional information regarding retinal microvasculature in a variety of retinal diseases.

NOTE: CIRRUS OCT Angiography is not intended as a substitute for fluorescein angiography.

NOTE: Vascular findings on fluorescein angiography may be absent, poorly defined, or variably defined on CIRRUS OCT Angiography. Additionally, leakage, staining, and pooling are not features of CIRRUS OCT Angiography.

References

1. Sallet G. Comparison of optical and ultrasound central corneal pachymetry. Bull Soc Belge Ophthalmol 2001; 281:35–38.
2. Ho T, Cheng A, Rao S, Lau S, Leung C, Lam D. Central Corneal thickness measurements using Orbscan II, Visante, ultrasound, and Pentacam pachymetry after laser in situ keratomileusis for myopia. J Cataract Refract Surg 2007;33:1177–1182.
3. Zhao PS, Wong TY, Wong WL, Saw SM, Aung T. Comparison of central corneal thickness measurements by visante anterior segment optical coherence tomography with ultrasound pachymetry. Am J Ophthalmol 2007 Jun;143(6):1047–9.
4. Bechmann M, Thiel MJ, Roesen B et al. Central corneal thickness determined with optical coherence tomography in various types of glaucoma. Br.J. Ophthalmol 2000;84:1233–1237.
5. Bechmann M, Thiel MJ, Neubauer AS et al. Central corneal thickness measurement with a retinal optical coherence tomography device versus standard ultrasonic pachymetry. Cornea 2001;20:50–54.
6. Kim HY, Budenz DL, Lee PS, Feuer WJ, Barton K.Comparison of central corneal thickness using anterior segment optical coherence tomography vs. ultrasound pachymetry. Am J Ophthalmol. 2008; 145(2):228–232.
7. Li E, Mohamed S, Leung C, Rao S, Cheng A, Cheung C, Lam D. Agreement among 3 methods to Measure corneal thickness: Ultrasound pachymetry, Orbscan II, and Visante Anterior Segment Optical Coherence Tomography. Ophthalmol 2007; 114 (10) 1842 – 1847.

Appendix C: CIRRUS HD-OCT Repeatability and Reproducibility of Anterior Scan Measurements

Study 1: Performance of Pachymetry and Anterior Chamber scan measurements in normal corneas and in subjects with corneal pathology, and performance of Pachymetry in post-LASIK subjects, including repeatability, reproducibility, and comparison to Visante

Purpose

A non-significant risk clinical study was conducted to determine the repeatability and reproducibility of the CIRRUS HD-OCT in measuring Central Corneal Thickness (CCT), Angle to Angle Distance (ATA), Anterior Chamber Depth (ACD), and Pachymetry. In addition, the comparability of these anterior segment measurements to corresponding measurements from the Visante OCT was also evaluated.

Data Collection

The study enrolled subjects from three population groups. Group 1 consisted of 48 subjects with normal cornea. Group 2 included 40 subjects, who had previously undergone LASIK. Group 3 was made up of 49 subjects with corneal pathology. The subjects ranged in age from 25 to 69 years.

CIRRUS HD-OCT Anterior Chamber scans to measure CCT, ATA, ACD, and Pachymetry scans were taken in the Normal Cornea and Corneal Pathology groups. For the Post-LASIK group, only the Pachymetry scans, yielding nine measurement zones, were taken.

Visante OCT Anterior Segment Single scans were taken in the Normal Cornea and Corneal Pathology groups. Pachymetry scans were taken on each subject in each group. Enhanced High Resolution Cornea scans were taken only on subjects in the Post-LASIK group.

Inclusion Criteria

The study inclusion criteria required adult males or females who were able and willing to make the required study visits, give consent and follow study instructions. In addition, inclusion criteria specific to the particular group were as follows:

Normal Cornea Group

Subjects with normal corneas.

Corneal Pathology group

Subjects who had received a pathological diagnosis in the anterior segment that involved or affected the cornea. Such diagnoses could have included but was not limited to: keratoconus, pellucid marginal degeneration, corneal scarring, corneal degeneration, corneal dystrophy and corneal changes secondary to disease or surgery.

Post-LASIK group

Subjects who had undergone uncomplicated LASIK surgery for either myopia or hyperopia within 2 - 24 weeks prior to participating in the study.

Exclusion Criteria

The study exclusion criteria included subjects with a history of leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis. The Normal Cornea and Post-LASIK groups also excluded subjects with blindness, low vision and/or severely diseased eyes, whereas the Corneal Pathology group also excluded subjects with blindness or low vision rendering the subject unable to fixate to keep gaze still enough to acquire images. The following exclusion criteria were applicable to their respective group:

Normal Cornea Group

- Subjects who had undergone prior surgery or a procedure involving or affecting the cornea in the study eye.
- Presence of corneal pathology, either inflammatory or non-inflammatory, in the study eye.

Corneal Pathology Group

- Subjects with normal corneas in the study eye.
- Subjects who had undergone LASIK in the study eye.
- Blindness or low vision rendering the subject unable to fixate to keep gaze still enough to acquire images.

Post-LASIK Group

- Subjects who had undergone prior refractive and corneal surgery, except LASIK, in the study eye.
- Subjects who had LASIK less than 2 weeks or more than 24 weeks prior to the day of data collection.
- Presence of corneal pathology, either inflammatory or non-inflammatory, in the study eye.
- History of complicated LASIK surgery necessitating re-treatment and enhancements.

Data Analysis

The data was acquired and analyzed by a single operator on the Visante OCT and by three operators on three CIRRUS HD-OCT 4000 and three CIRRUS HD-OCT 5000 devices. Measurements were compared between CIRRUS HD-OCT 4000 and Visante OCT as well as between CIRRUS 5000 and Visante OCT. The first qualified Visante OCT scan was used for comparison with the first qualified CIRRUS 4000 and CIRRUS 5000 scan from any of the three devices.

The results of the repeatability and reproducibility analyses for the CIRRUS HD-OCT Model 5000 from all three groups are provided in Tables 1 (Normal Cornea), 2 (Corneal Pathology), and 3 (Post-LASIK).

Tables 4 and 5 show the mean difference in CCT, ATA, ACD and Pachymetry measurements between the CIRRUS HD-OCT Model 5000 and Visante OCT for the Normal Cornea and Corneal Pathology groups.

Table 6 shows the Pachymetry measurements of the Post-LASIK group, comparing the results from the CIRRUS HD-OCT Model 5000 and Visante OCT.

Table C-1: Repeatability and Reproducibility of CIRRUS HD-OCT 5000 Normal Cornea Group

Scan Type		Repeatability			Reproducibility		
Parameter	Mean	SD	Limit	CV%	SD	Limit	CV%
Anterior Chamber							
CCT	549.5	9.749	27.297	1.774	11.897	33.311	2.165
Angle to Angle	12.030	0.171	0.479	1.423	0.300	0.840	2.494
ACD	2.858	0.034	0.096	1.199	0.046	0.128	1.601
Pachymetry							
Center	528.3	1.197	3.350	0.226	1.628	4.557	0.308
Inner Nasal	552.8	2.674	7.486	0.484	3.218	9.011	0.582
Inner Superior	557.9	3.399	9.518	0.609	4.261	11.930	0.764
Inner Inferior	541.9	2.714	7.598	0.501	3.306	9.257	0.610
Inner Temporal	532.5	1.870	5.237	0.351	2.085	5.837	0.392
Outer Nasal	588.9	4.061	11.370	0.690	4.739	13.268	0.805
Outer Superior	599.7	4.786	13.402	0.798	6.897	19.312	1.150
Outer Inferior	572.4	3.511	9.830	0.613	5.326	14.912	0.930
Outer Temporal	554.8	3.170	8.875	0.571	3.430	9.603	0.618

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.

Mean = Intercept of the ANOVA model

Repeatability SD = Square root of the residual variance.

Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance.

Repeatability limit = 2.8 x Repeatability SD.

Reproducibility limit = 2.8 x Reproducibility SD.

Repeatability CV% = (Repeatability SD)/Intercept x 100%.

Reproducibility CV% = (Reproducibility SD)/Intercept x 100%.

Table C-2: Repeatability and Reproducibility of CIRRUS HD-OCT 5000 Corneal Pathology Group

Scan Type		Repeatability			Reproducibility		
Parameter	Mean	SD	Limit	CV%	SD	Limit	CV%
Wide Angle to Angle							
CCT	532.1	12.061	33.772	2.267	18.951	53.061	3.561
Angle to Angle	12.363	0.175	0.491	1.418	0.247	0.693	2.002
ACD	3.060	0.040	0.113	1.321	0.061	0.171	1.991
Pachymetry							
Center	521.0	2.739	7.670	0.526	2.788	7.807	0.535
Inner Nasal	553.4	3.928	11.000	0.710	4.394	12.303	0.794
Inner Superior	558.3	4.346	12.169	0.779	4.884	13.677	0.875
Inner Inferior	534.0	3.115	8.723	0.583	4.325	12.109	0.810
Inner Temporal	527.9	2.867	8.027	0.543	3.837	10.742	0.727
Outer Nasal	594.3	4.496	12.589	0.756	5.298	14.835	0.891
Outer Superior	606.5	5.534	15.495	0.912	6.185	17.319	1.020
Outer Inferior	572.5	4.233	11.851	0.739	8.945	25.046	1.563
Outer Temporal	556.2	3.821	10.699	0.687	4.792	13.418	0.862

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.

Mean = Intercept of the ANOVA model

Repeatability SD = Square root of the residual variance.

Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance.

Repeatability limit = 2.8 x Repeatability SD.

Reproducibility limit = 2.8 x Reproducibility SD.

Repeatability CV% = (Repeatability SD)/Intercept x 100%.

Reproducibility CV% = (Reproducibility SD)/Intercept x 100%.

Table C-3: Repeatability and Reproducibility of CIRRUS HD-OCT 5000 Post-LASIK Group

Scan Type		Repeatability			Reproducibility		
Parameter	Mean	SD	Limit	CV%	SD	Limit	CV%
Pachymetry							
Center	465.1	1.784	4.994	0.383	2.068	5.791	0.445
Inner Nasal	514.8	6.912	19.355	1.343	6.912	19.355	1.343
Inner Superior	508.8	4.785	13.398	0.940	5.749	16.098	1.130
Inner Inferior	500.8	4.557	12.759	0.910	5.919	16.572	1.182
Inner Temporal	481.8	4.657	13.040	0.967	4.657	13.040	0.967
Outer Nasal	583.7	9.104	25.492	1.560	9.197	25.752	1.576
Outer Superior	580.2	6.972	19.522	1.202	8.915	24.963	1.537
Outer Inferior	560.4	5.560	15.568	0.992	9.557	26.760	1.705
Outer Temporal	530.0	7.294	20.424	1.376	7.382	20.670	1.393

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.

Mean = Intercept of the ANOVA model

Repeatability SD = Square root of the residual variance.

Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance.

Repeatability limit = 2.8 x Repeatability SD.

Reproducibility limit = 2.8 x Reproducibility SD.

Repeatability CV% = (Repeatability SD)/Intercept x 100%.

Reproducibility CV% = (Reproducibility SD)/Intercept x 100%.

Table C-4: Mean Difference between CIRRUS HD-OCT 5000 and Visante OCT for the Normal Cornea Group

Scan Type		CIRRUS	Visante	Difference	95% CI		95% LOA
Parameter	N	Mean (SD)	Mean (SD)	Mean (SD)	Mean Difference	p-value	Mean Difference
Anterior Chamber							
CCT	46	551.5 (33.9)	537.8 (33.8)	13.7 (16.7)	8.7, 18.6	<.001	-19.8, 47.1
Angle to Angle	46	12.004 (0.538)	11.638 (0.480)	0.365 (0.371)	0.255, 0.476	<.001	-0.376, 1.107
ACD	46	2.860 (0.448)	2.948 (0.459)	-0.088 (0.064)	-0.107, -0.069	<.001	-0.215, 0.039
Pachymetry							
Center	45	528.3 (32.7)	527.3 (32.3)	1.0 (4.9)	-0.4, 2.5	0.168	-8.8, 10.8
Inner Nasal	45	552.7 (33.2)	554.0 (33.6)	-1.3 (9.1)	-4.0, 1.4	0.347	-19.5, 16.9
Inner Superior	45	558.7 (36.4)	558.0 (35.4)	0.7 (11.6)	-2.8, 4.2	0.692	-22.5, 23.9
Inner Inferior	45	541.9 (32.6)	542.8 (34.9)	-0.9 (6.8)	-2.9, 1.1	0.372	-14.5, 12.6
Inner Temporal	45	533.0 (32.9)	537.9 (32.4)	-4.9 (6.9)	-6.9, -2.8	<.001	-18.7, 8.9
Outer Nasal	45	589.2 (33.8)	598.2 (36.3)	-9.1 (13.8)	-13.2, -4.9	<.001	-36.6, 18.5
Outer Superior	44	601.7 (39.4)	606.3 (41.3)	-4.6 (22.7)	-11.5, 2.3	0.183	-50.1, 40.8
Outer Inferior	45	574.2 (33.1)	583.7 (38.7)	-9.6 (12.5)	-13.3, -5.8	<.001	-34.6, 15.5
Outer Temporal	45	555.8 (33.5)	571.3 (33.7)	-15.5 (11.3)	-18.9, -12.1	<.001	-38.1, 7.2

N is the number of eyes with measurements.
Difference = CIRRUS - Visante.
ACD of Visante was adjusted by CCT (i.e. ACD = original ACD - CCT/1000).
95% confidence interval (CI) for mean difference is based on t-distribution.
p-value is based on paired t-test.
95% Limits of Agreement (LOA) = mean difference ± 2 x difference SD.

Table C-5: Mean Difference between CIRRUS HD-OCT 5000 and Visante OCT for the Corneal Pathology Group

Scan Type		CIRRUS	Visante	Difference	95% CI		95% LOA
Parameter	N	Mean (SD)	Mean (SD)	Mean (SD)	Mean Difference	p-value	Mean Difference
Anterior Chamber							
CCT	36	538.2 (53.4)	511.4 (55.0)	26.8 (26.9)	17.7, 35.9	<.001	-27.0, 80.7
Angle to Angle	36	12.293 (0.473)	11.939 (0.467)	0.353 (0.382)	0.224, 0.482	<.001	-0.411, 1.117
ACD	33	3.049 (0.306)	3.144 (0.320)	-0.095 (0.089)	-0.126, -0.063	<.001	-0.272, 0.083
Pachymetry							
Center	30	521.0 (66.4)	520.8 (65.7)	0.2 (8.1)	-2.9, 3.2	0.911	-16.1, 16.4
Inner Nasal	30	553.2 (58.7)	557.2 (59.0)	-4.0 (10.1)	-7.8, -0.2	0.038	-24.1, 16.1
Inner Superior	30	559.4 (67.2)	563.2 (71.0)	-3.9 (14.9)	-9.4, 1.7	0.165	-33.6, 25.9
Inner Inferior	30	534.6 (62.7)	536.3 (58.9)	-1.8 (13.5)	-6.8, 3.3	0.479	-28.7, 25.2
Inner Temporal	30	528.9 (63.7)	535.1 (64.8)	-6.2 (8.6)	-9.4, -3.0	<.001	-23.4, 11.0
Outer Nasal	29	593.9 (59.6)	607.7 (63.6)	-13.8 (14.1)	-19.1, -8.4	<.001	-42.0, 14.4
Outer Superior	29	607.1 (85.1)	618.8 (85.5)	-11.7 (13.9)	-17.0, -6.4	<.001	-39.5, 16.1
Outer Inferior	29	574.3 (67.5)	583.6 (64.2)	-9.3 (23.1)	-18.0, -0.5	0.039	-55.4, 36.9
Outer Temporal	29	557.6 (59.2)	573.2 (66.9)	-15.6 (14.0)	-20.9, -10.2	<.001	-43.6, 12.5

N is the number of eyes with measurements.
Difference = CIRRUS - Visante.
ACD of Visante was adjusted by CCT (i.e. ACD = original ACD - CCT/1000).
95% confidence interval (CI) for mean difference is based on t-distribution.
p-value is based on paired t-test.
95% Limits of Agreement (LOA) = mean difference ± 2 x difference SD.

Table C-6: Mean Difference between CIRRUS HD-OCT 5000 and Visante OCT for the Post-LASIK Group

Scan Type		CIRRUS	Visante	Difference	95% CI		95% LOA
Parameter	N	Mean (SD)	Mean (SD)	Mean (SD)	Mean Difference	p-value	Mean Difference
Pachymetry							
Center	40	465.6 (44.3)	463.7 (44.8)	1.8 (6.1)	-0.1, 3.8	0.064	-10.3, 13.9
Inner Nasal	40	515.8 (39.8)	515.8 (38.9)	0.0 (14.7)	-4.7, 4.7	1.000	-29.4, 29.4
Inner Superior	40	509.5 (39.6)	515.6 (39.4)	-6.2 (13.6)	-10.5, -1.8	0.007	-33.4, 21.1
Inner Inferior	40	500.6 (39.1)	499.2 (39.2)	1.4 (10.8)	-2.1, 4.9	0.418	-20.2, 23.0
Inner Temporal	40	481.7 (39.0)	490.7 (38.5)	-9.0 (9.5)	-12.0, -6.0	<.001	-28.0, 10.0
Outer Nasal	40	584.8 (35.3)	591.9 (36.1)	-7.2 (19.3)	-13.3, -1.0	0.024	-45.7, 31.4
Outer Superior	40	580.7 (35.3)	595.9 (35.6)	-15.3 (18.5)	-21.2, -9.4	<.001	-52.2, 21.6
Outer Inferior	40	562.5 (35.1)	569.1 (37.2)	-6.6 (17.9)	-12.3, -0.9	0.025	-42.5, 29.3
Outer Temporal	40	529.8 (33.6)	552.0 (34.9)	-22.3 (16.4)	-27.5, -17.0	<.001	-55.0, 10.5

N is the number of eyes with measurements.
Difference = CIRRUS - Visante.
ACD of Visante was adjusted by CCT (i.e. ACD = original ACD - CCT/1000).
95% confidence interval (CI) for mean difference is based on t-distribution.
p-value is based on paired t-test.
95% Limits of Agreement (LOA) = mean difference ± 2 x difference SD.

These tables show that the central cornea as measured using the pachymetry scan has much better repeatability and agreement with Visante OCT than the central corneal thickness as measured with the Anterior Chamber scan. The improved performance is likely due to the fact that the pachymetry measurement averages over a 3mm central area, while the Anterior Chamber scan depends on subjective placement of the scan directly over the central cornea for a single measurement. For this reason, we recommend using the pachymetry scan to get the best possible estimate of central corneal thickness.

NOTE: Measurements made with the CIRRUS HD-OCT Anterior Segment scans should not be directly compared with Visante OCT measurements.

Study 2: Repeatability and reproducibility of Wide Angle to Angle and HD Angle scan measurements in subjects with glaucoma, including repeatability, reproducibility, and comparison to Visante

Purpose

A non-significant risk clinical study was conducted to determine the repeatability and reproducibility of the CIRRUS HD-OCT instrument's measurements of Anterior Chamber Angle (ACA), Trabecular Iris Space Area (TISA), Angle Opening Distance (AOD) and Scleral Spur Angle (SSA). Another objective of the study was to evaluate the comparability of CIRRUS HD-OCT to Visante OCT.

Data Collection

Subjects were examined three CIRRUS HD-OCT Model 5000 (CIRRUS 5000) instruments by three operators; each operator was assigned to a specific CIRRUS 5000 device. For each subject, study eye 1 was scanned with three Nasal and three Temporal HD Angle scans on three CIRRUS 5000 devices. Study eye 2 from each subject was scanned with three Wide Angle to Angle scans on three CIRRUS 5000 devices. The Visante OCT Model 1000 was used by one operator only. The measurements taken on the CIRRUS were compared separately with the corresponding measurements taken on the Visante OCT.

The study enrolled 27 subjects ranging in age from 43 to 77 years; the mean was 62 years. The study population consisted of glaucoma suspects and those with established glaucoma. The severity of the disease ranged from mild to severe. All enrolled subjects had a variety of angle configurations ranging from Grade II to Grade IV as assessed with gonioscopy by the Shaffer[1] method of angle grading.

Inclusion Criteria

The study inclusion criteria required adult males or females who had been diagnosed with glaucoma of any severity and type or were glaucoma suspects and who were able and willing to make the required study visits, give consent and follow study instructions.

Exclusion Criteria

The study exclusion criteria included any condition that rendered the subject unable to fixate well enough to acquire the images and that the subject's study eye did not have any active infection of the anterior segment.

Data Analysis

All images were reviewed by the operators that acquired them. Study measurements were generated by manual placement of software tools (Angle tool; TISA tool) for both CIRRUS and Visante OCT devices.

---

1. Shaffer RN. Primary glaucomas. Gonioscopy, ophthalmoscopy,and perimetry. Trans Am. Acad Ophthalmol Otolaryngol. 1960;64:112-127.

The data was taken on a total of 26 eyes for the Wide Angle to Angle scan and 27 eyes for the HD Angle scan measured by three operators on three CIRRUS 5000 devices and by a single operator on the Visante OCT. The first qualified CIRRUS scan from any of the three CIRRUS 5000 devices was used for comparison with the first qualified Visante scan.

Table 7 shows the results of the repeatability and reproducibility analyses for CIRRUS CIRRUS 5000. Table 8 shows the mean difference between CIRRUS 5000 and Visante OCT. Negative differences mean that the measurement on CIRRUS is smaller than the Visante OCT.

Table C-7: Repeatability and Reproducibility of CIRRUS HD-OCT 5000

Scan Type		Repeatability			Reproducibility		
Parameter	Mean	SD	Limit	CV%	SD	Limit	CV%
Wide Angle to Angle							
TISA 500 Nasal	0.151	0.025	0.071	16.801	0.030	0.083	19.614
TISA 750 Nasal	0.263	0.028	0.080	10.827	0.037	0.103	14.053
AOD 500 Nasal	0.439	0.075	0.209	17.012	0.081	0.226	18.365
AOD 750 Nasal	0.570	0.055	0.153	9.598	0.084	0.236	14.783
SSA Nasal	37.696	3.774	10.569	10.013	4.552	12.746	12.076
AC Angle Nasal	36.165	3.427	9.595	9.475	4.861	13.612	13.442
TISA 500 Temporal	0.150	0.027	0.076	18.169	0.032	0.090	21.368
TISA 750 Temporal	0.275	0.041	0.115	14.946	0.045	0.126	16.353
AOD 500 Temporal	0.445	0.080	0.223	17.893	0.090	0.252	20.243
AOD 750 Temporal	0.586	0.076	0.213	12.972	0.085	0.237	14.434
SSA Temporal	37.846	4.442	12.438	11.737	5.024	14.068	13.276
AC Angle Temporal	35.951	3.725	10.430	10.361	5.184	14.514	14.418
HD Angle							
TISA 500 Nasal	0.158	0.017	0.048	10.764	0.022	0.061	13.786
TISA 750 Nasal	0.281	0.023	0.065	8.305	0.034	0.095	12.085
AOD 500 Nasal	0.461	0.053	0.148	11.496	0.066	0.185	14.332
AOD 750 Nasal	0.621	0.054	0.151	8.699	0.075	0.211	12.162
SSA Nasal	39.186	2.772	7.762	7.074	3.638	10.188	9.285
AC Angle Nasal	38.282	2.517	7.048	6.575	3.433	9.612	8.968
TISA 500 Temporal	0.161	0.020	0.057	12.685	0.026	0.072	16.033
TISA 750 Temporal	0.270	0.028	0.078	10.319	0.032	0.090	11.950
AOD 500 Temporal	0.475	0.064	0.179	13.415	0.075	0.209	15.699
AOD 750 Temporal	0.576	0.062	0.173	10.750	0.072	0.202	12.534
SSA Temporal	38.440	3.478	9.738	9.048	4.197	11.751	10.918
AC Angle Temporal	37.209	2.868	8.031	7.708	3.630	10.164	9.756

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.
Mean = Intercept of the ANOVA model
Repeatability Limit = 2.8 x Repeatability SD
Repeatability CV% = (Repeatability SD)/Intercept x 100%
Reproducibility SD = Square root of the sum of the operator/device variance, the interaction variance and the residual variance
Reproducibility Limit = 2.8 x Reproducibility SD
Reproducibility CV% = (Reproducibility SD)/Intercept x 100%

Table C-8: Mean Difference between CIRRUS HD-OCT 5000 and Visante OCT

Scan Type		CIRRUS	Visante	Difference	95% CI		95% LOA
Parameter	N	Mean (SD)	Mean (SD)	Mean (SD)	Mean Difference	p-value	Mean Difference
Wide Angle to Angle							
Nasal	26	36.054 (18.137)	38.831 (18.272)	-2.777 (5.665)	-5.065, -0.488	0.019	-14.107, 8.554
Temporal	26	35.255 (18.767)	38.573 (18.385)	-3.318 (6.493)	-5.940, -0.695	0.015	-16.304, 9.669
HD Angle							
Nasal	27	37.677 (17.408)	39.974 (19.074)	-2.297 (8.411)	-5.625, 1.030	0.168	-19.119, 14.525
Temporal	27	37.141 (19.649)	36.767 (18.295)	0.374 (5.934)	-1.974, 2.722	0.746	-11.495, 12.243

N is the number of eyes with measurements.
Difference = CIRRUS - Visante.
95% confidence interval (CI) for mean difference is based on t-distribution.
p-value is based on paired t-test.
95% Limits of Agreement (LOA) = mean difference ± 2 x difference SD.

Index

Q

R

S

T

U

V

W

X

Y

Z

Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
Dublin, CA 94568
USA
Toll Free: 1–800–341–6968
Phone: 1–925–557–4100
Fax: 1–925–557–4101
info@zeiss.com/med
www.zeiss.com/med

EC REP **Carl Zeiss Meditec AG**
Goeschwitzer Strasse 51–52
07745 Jena
Germany
Phone: +49 36 41 22 03 33
Fax: +49 36 41 22 01 12
info@zeiss.com/med
www.zeiss.com/med

CE 0297

26600211 69012 Rev. A 2017-12

CIRRUS HD-OCT Models 500, 5000

User Manual