CIRRUS HD-OCT
Model 6000

Instructions for Use

Patents

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

Table of Contents

1 Safety and Certifications

Before using the CIRRUS 6000, herein referred to as CIRRUS 6000, you must fully understand potential safety hazards. Read the following safety warnings and cautions in their entirety before using the instrument. Additional warnings and cautions are found throughout the instructions for use.

Under normal conditions, the risk/benefits profile of the CIRRUS 6000:

- Provides a high level of health and safety protection.
- Complies with MDD ER1.

1.1 Symbols and Labels

Warning

Caution

Note

Must follow Instructions for Use

Electronic Manuals

Stand-by

Fuse

Direct Current

Type B Applied Parts

SN Serial Number

REF Catalog Number/Part Number

MODEL Model Number

Manufacturer

EC REP Authorized European Community Representative

CE Conforms to applicable European Directive(s)

CE 0297 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.

LR 96697 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.

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

1.2 Definitions

Warnings and **Cautions** are defined as follows:

⚠ **WARNING!**	**Indicates hazards that, if not avoided, could cause the following:** **> Severe injury or even death** The warning message names the possible consequences. ▶ These are actions that can be taken to prevent the hazard.

⚠ **CAUTION!**	**Indicates hazards that, if not avoided, could result in the following:** **> Minor or moderate injury** **> Moderate damage to or impaired performance of equipment** The caution message names the possible consequences. ▶ These are actions that can be taken to prevent the hazard.

1.3 Safety

NOTE	**Report Serious Accidents** ▶ 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.

1.3.1 Product Safety

⚠ **WARNING!**	**Non-compliance with system requirements laid out in standard IEC 60601–1** could result in compromised patient safety. ▶ 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!**	**Device proximity to flammable gases or vapors** may cause ignition. ▶ Do NOT use in the presence of flammable anesthetics, or oxidizing gases such as nitrous oxide and pure oxygen.

⚠ WARNING!

Opening Instrument Covers

can lead to exposure to electrical and optical hazard.

- Do not open the instrument covers.
- Exceptions:
  - ⇨ You may remove the rear cover to access labels and connectors.
  - ⇨ You may remove the instrument's top cover to inspect or replace the fan filter.

⚠ WARNING!

Using the Device adjacent to, or stacked with, other equipment

could impact device operation.

- 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.

⚠ WARNING!

In case of an emergency

disconnect the appliance coupler.

- For the device, the most accessible power cord is the one that plugs into the bottom of the table.
- Do not position device so it is difficult to unplug power cord.

⚠ WARNING!

Use of the acquisition device, a printer, or the power table with an extension cord or a power strip (multiple portable socket outlet)

could cause electrical shock to the patient or operator.

- Do not use extension cords with the instrument.
- If you plug something other than an instrument into the Multiple Socket Outlet (MSO), the MSO may not have the designed level of safety.
- Do not use power strips with the instrument.
- Do not plug in any other equipment into the same wall outlet as the instrument.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

⚠ CAUTION!

Patients who hold on to the instrument before or during tests

risk having their fingers pinched and possibly injured.

- Make sure that the patient is not holding on to the instrument before or during tests.

⚠ CAUTION!

Using the instrument on an uneven or sloped surface or rolling the table in deep pile carpet or over objects on the floor such as power cords

could cause the table and/or instrument to tip, resulting in injury to operator or patient and damage to the instrument.

- ▶ Do not use the instrument on an uneven or sloped surface.
- ▶ Do not roll the table in deep pile carpet or over objects on the floor such as power cords.

⚠ CAUTION!

Using aerosols near or placing containers of liquid on or near the instrument

could damage the equipment. The instrument is not designed with any specific measures to protect against harmful ingress of water or other liquids (classified IPXO - ordinary equipment).

- ▶ Do not place containers of liquid, or use aerosols on or near the equipment.

⚠ CAUTION!

Using a non-approved or incorrectly connected device

could invalidate the system safety approval.

- ▶ Follow all indications in this user document to ensure that all connections are approved and correctly configured.

⚠ CAUTION!

Unauthorized modification or dismantling of the instrument or system components

could result in damage to the instrument or components or harm to the operator or other personnel.

- ▶ Only authorized ZEISS personnel are authorized to modify or dismantle the instrument or its components.

⚠ CAUTION!

Reconfiguring system components on the table, or adding non-system devices or components to the table, or replacing original system components with substitutes not approved by ZEISS

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.

- ▶ 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.

⚠ CAUTION!

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

- ▶ Purchasing from an unlicensed healthcare practitioner is against (United States) Federal law.
- ▶ Purchasing from an unlicensed healthcare could result in a non-standard, incorrectly installed, and faulty instrument that could risk result accuracy and patient or operator safety.

NOTE

The CIRRUS 6000 Power Table is safe to use within the patient environment when the instrument is powered through it, as instructed herein.

⚠ WARNING!

Installation or modification of devices and systems by persons not authorized by ZEISS

can lead to the injury of patients and operators, as well as to property damage. Installation and modification requires special knowledge and skills.

- ▶ Have the installation performed only by persons authorized by ZEISS.
- ▶ Do not modify or change the configuration of the instrument or the system after being installed by ZEISS trained personnel.

⚠ WARNING!

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment

could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation and potential safety hazards.

- ▶ Use only the accessories, transducers, and cables specified or provided by ZEISS.

1.3.2 Optical Safety

- ANSI Z80.36-2019.
- Classification: Group 1 Instrument – Per ANSI Z80.36. Group 1 instruments are ophthalmic instruments for which no potential light hazard exists.

⚠ WARNING!

Device produces visual stimuli, including flickering light and flashing patterns, between 5 and 65 Hz

may adversely affect certain patients, although this effect is yet unproven.

- ▶ Medical professionals need to determine whether this device should be used for patients who may be photosensitive, including those with epilepsy.

⚠ **WARNING!**

Patient injection with photo–dynamic therapy (PDT) treatment drugs, such as Visudyne®

could lead to unintended exposure and uncontrolled treatment of neovascular vessels.

- Do not scan patients who have been injected with photo–dynamic therapy (PDT) treatment drugs, such as Visudyne®, in the previous 48 hours.

⚠ **CAUTION!**

Applicable Phototoxicity Statements (Ophthalmoscope Guidance - (Direct and Indirect) - Guidance for Industry; July 1998; FDA CDRH):

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.
- **Note:**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.

1.3.3 Electrical Safety

Class I Equipment - Protection against electrical shock.

⚠ **WARNING!**

An ungrounded Device

could lead to electric shock.

- Do not remove or disable the ground pin.
- Only an authorized ZEISS service representative may service the instrument.
- Only an authorized ZEISS representative may install the instrument.

1.3.4 Printer and Peripherals Safety

⚠ **WARNING!**

Non-compliance with system requirements laid out in standard IEC 60601–1 for instruments externally connected to non-medical peripheral devices (i.e. printers, non-system storage devices, etc.)

compromises patient safety.

- ▶ If a non-medical peripheral device is located within 1.5 m from the patient, the usage of an isolation transformer is required.
- ▶ 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!**

Placing peripheral devices closer than 1.5 meters (4.9 feet) from the patient

could result in electrical shock to the patient and/or operator.

- ▶ Use a wireless configuration, if possible.
- ▶ Use an isolation transformer in the USB configuration.
- ▶ Ensure that patients cannot touch a peripheral device with any part of his or her body while being examined.
- ▶ Ensure the instrument operator does not attempt to touch the patient and a peripheral device at the same time.

⚠ **WARNING!**

Simultaneously touching a patient and a peripheral device

could compromise patient safety.

- ▶ The instrument operator must not touch the patient and a peripheral device simultaneously.

⚠ **CAUTION!**

Using peripheral devices not supplied or approved by Zeiss

could degrade the performance of the instrument and/or lead to corrupted diagnostic or therapeutic information and may cause safety hazards and void the instrument warranty.

- ▶ We strongly recommend you use peripheral devices supplied or approved by Zeiss, because they will have been tested to work safely with the instrument.
- ▶ Do not install any unapproved third party software on the instrument.

1.3.5 Networking Safety

⚠ CAUTION!

Internet connection of the Instrument

increases its vulnerability to serious security risks, including viruses and worms that could disable your system or adversely affect its performance and may void the instrument warranty.

- ▶ Only connect to the internet when it is absolutely necessary.
- ▶ Transfer data through internal networks.
- ▶ Ensure that all firewalls and internet security applications are up-to-date and running.

1.3.5.1 Unsupported Network Activities

NOTE

The user is responsible for system performance degradation or any other change or defect resulting from unsupported network activities.

ZEISS IS NOT RESPONSIBLE FOR SOFTWARE REPAIRS OR UPGRADES NECESSITATED BY THE ATTEMPTED PERFOR-MANCE OF THE FOLLOWING ACTIVITIES.

ZEISS does not support the following network activities, although they may be possible:

- Printing with a printer not approved by ZEISS for use with this instrument.

Refer to our website for the current list of approved hardware and software. If you want to use a third party device, seek technical support from the device manufacturer.

1.3.5.2 Networking Guidelines

CIRRUS 6000 provides IT–Network capabilities to allow data archiving and information sharing in the clinical environment and across medical facilities.

NOTE

Users are responsible for network setup and maintenance.

Users are responsible for installing and configuring all networking hardware and software.

ZEISS Technical Support is limited to testing instrument network connectivity.

- ▶ ZEISS Technical Support cannot troubleshoot or repair problems with network connectivity.
- ▶ Observe all guidelines in this document regarding instrument networking.

1.3.6 Record and Data Safety

1.3.6.1 Patient Record Deletion

⚠ CAUTION!

Deletion of a patient record

is permanent.

▶ Delete records with care!

⚠ CAUTION!

Merging incorrect patient records

can only be corrected using the **Move Scan** feature to separate the merged file.

▶ Be certain that you select the correct patient records to merge.

1.3.6.2 Prohibited Activities

⚠ CAUTION!

Attempting to carry out activities not specifically endorsed by ZEISS

may void your warranty and could result in damage to the instrument.

▶ Read the user documentation.

▶ Follow directions carefully.

▶ Do not make upgrades, or carry out repairs or modifications, without specific guidance and instruction from ZEISS or an authorized ZEISS represenative.

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

- 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.

1.4 Electromagnetic Compatibility (EMC)

⚠ WARNING!

Installing or putting the device into service without regard to EMC information provided

may void your ZEISS instrument warranty, result in damage to the instrument and/or compromise safety for patients and operators.

▶ This instrument has special EMC precaution requirements and needs to be installed and put into service according to the EMC information provided herein.

⚠ CAUTION!

This instrument is intended for use in a professional healthcare facility environment.

Using the instrument in any other environment may void the warranty and compromises the safety of the patient and/or operator.

NOTE

The emissions characteristics of this equipment

make it suitable for use in industrial areas and hospitals (CISPR 11 Class A).

- If it is used in a residential environment, this equipment might not offer adequate protection to radio-frequency communication services.
- The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

NOTE

Excessive electromagnetic events may temporary disable the instrument.

- If the instrument becomes disabled, reboot it.

Electromagnetic Emissions [▸ 20] and Electromagnetic Immunity [▸ 20] are required per IEC 60601-1-2:2014.

1.4.1 Electromagnetic Emissions

This instrument complies with the following emission requirements:

Phenomenon	Standard
Conducted and radiated RF emissions	Group 1 CISPR 11 Class A
Harmonic distortion	IEC 61000-3-2 Class A
Voltage fluctuations and flicker	IEC 61000-3-3: Complies

Table 1: Electromagnetic Emissions

1.4.2 Electromagnetic Immunity

This instrument complies with the following immunity requirements:

Phenomenon	Basic EMC standard or test method	Immunity test levels
Electrostatic Discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz

Phenomenon	Basic EMC standard or test method	Immunity test levels
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Wireless Communications [▸ 22]
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV
Surges line-to-ground	IEC 61000-4-5	± 0,5 kV,± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips, short interruptions, and voltage variations on power supply input lines	IEC 61000-4-11	0 % UT[1]; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT[1]; 1 cycle and 70 % UT[1]; 25/30 cycles Single phase: at 0°
Voltage Interruptions	IEC 61000-4-11	0 % UT[1]; 250/300 cycle

Table 2: Electomagnetic Immunity

[1]UT is the a.c. mains voltage prior to application of the test level.

1.5 Wireless Communications

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TERTRA 400	Pulse 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse 217 Hz	0.2	0.3	9

Table 3: Test specifications for enclosure port immunity to RF wireless communications equipment.

1.6 Operator Training and Equipment Maintenance

NOTE

Expected Service Life

The expected service life of CIRRUS 6000 is 7 years.

1.6.1 Operator Training

⚠ WARNING!

Incorrect use of equipment

could result in damage to patients or equipment.

✓ Only personnel who have undergone appropriate training and instruction may use this device.

- ▶ Operating personnel must be appropriately trained and instructed.
- ▶ Operating personnel must read and understand the User Manual.
- ▶ The User Manual must be made available to operating personnel at all times.
- ▶ To facilitate access for all operating personnel: Request additional copies of user documentation as required from ZEISS.
- ▶ Specify the competencies for handling the device and state who is authorized for what tasks.
- ▶ Determine the reporting obligations for instrument error and/or damage and make them known.
- ▶ Regularly review the applicable legal regulations regarding accident prevention, health and safety in the country of use.

1.6.2 Equipment Maintenance

⚠ CAUTION!

Lack of regular safety inspections

could result in a decrease in device safety, increase in the possibility of device damage, and/or inaccurate results.

✓ Regular technical safety inspections must be carried out as specified for this device by any and all applicable national regulations.

✓ Equipment inspections may only be performed by Zeiss or Zeiss-qualified personnel.

- ▶ Comply with the specified maintenance intervals.
- ▶ Carry out all inspections fully.
- ▶ Minimally, local system inspections must include the following:
  - ⇨ Availability of the Instructions for Use
  - ⇨ Visual inspection of system and accessories for damage and legibility of labels
  - ⇨ Current leakage test
  - ⇨ Test of protective ground conductor
  - ⇨ Function and wear test of brakes, if applicable

⇨ Function test of all switches, buttons, sockets and indicator lamps of the system

⚠ WARNING!

Making changes to equipment without first consulting your ZEISS Field Representative

could result in the equipment being Out of Compliance.

- ▶ Any additional equipment connected to medical electrical devices must demonstrably comply with the applicable IEC or ISO standards (e.g. IEC 60950 for data processing equipment).
- ▶ All configurations must meet the applicable requirements for medical systems, as specified in IEC 60601-1 standard.
- ▶ Anyone connecting additional equipment or modifying the configuration to a medical electrical device or system is a system configurer, and that individual is responsible for compliance of the complete system with the applicable standards such as IEC 60601-1 and other applicable collateral standards.
- ▶ Local legislation has priority over the above normative requirements.

1.6.3 Notification of Serious Incident

Any serious incident, affecting any person, that occurs in connection with the use of this medical device, must immediately be reported to the manufacturer or to the medical product distributor. In the European Union, the operator must report this serious incident to the responsible authorities in the applicable country.

1.7 RoHS Compliance

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

2 Introduction

2.1 Scope

2.1.1 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.

2.1.2 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.

The CIRRUS™ HD-OCT 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™ HD-OCT 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.

2.1.3 Essential Performance

The CIRRUS 6000 is a retinal imaging device intended to be used as a non-contact, diagnostic imaging instrument for in vivo viewing, axial cross-sectional imaging, and three-dimensional imaging of ocular structures. No cases have been identified in which the product's failure to perform its intended clinical functions would result in unacceptable risk.

The main clinical performance of this instrument is to capture, display and store images to aid in the diagnosis and monitoring of diseases and disorders. Since there are no surgical or treatment decisions made solely on data obtained by the instrument, it was determined that the instrument has no “essential performance” as defined in IEC 60601-1 standard.

2.1.4 Application

The CIRRUS™ HD-OCT 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 that has clean air free of soot, vapors from adhesives, grease, or volatile organic chemicals.

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 (see: Safety and Certifications [▸ 11]).

2.2 Subject/Patient Profile

NOTE

Patients must be able to sit upright and place their face in the chin and forehead rest of the instrument (with or without supplemental human or mechanical support).

The device may 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

The patient must be able to sit upright and place their face in the chin and forehead rest of the instrument (with or without supplemental human or mechanical support).

2.3 Operator Profile

2.3.1 Intended Demographic (Operators)

Operators are adults with professional training or experience in the use of ophthalmic imaging equipment. Specific assumptions regarding the qualifications of individuals operating the instrument are given below:

- Ophthalmologist or other Medical Doctor
- Optometrist or equivalent
- Nurse
- Certified Medical Technician

- Ophthalmic Photographer
- Non-certified Assistant

2.3.2 Required Occupational Skills (Operators)

Must possess all of the following skills:

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

2.3.3 Job Requirements (Operators)

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 reports using available reporting protocols
- Review reports for completeness
- Output reports
- Archive data
- Turn off the unit

2.4 Data Analyst Profile

⚠ CAUTION!

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

The data created using this device 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.

2.4.1 Intended Demographic (Analysts)

The **Data Analysts** are:

- Ophthalmologist or other Medical Doctor
- Optometrist or equivalent

2.4.2 Required Occupational Skills (Analysts)

Must possess all of the following skills:

- Computer literate
- Be professionally trained in the physiology of the eye and its variations
- Able to work with elderly patients and those with disabilities

2.4.3 Job Requirements (Analysts)

- Accurately identify ocular anomalies
- Have a history of correct diagnoses of eye disease or work solely within a research environment
- Be fully trained in the use of OCT equipment, and particularly, in the analyses that comprise the Review portion of the instrument software

2.5 User Documentation

2.5.1 Purpose

The user documentation that comes with your device is provided to ensure that all users operate and maintain it safely and successfully.

- Read all user documentation before starting and using the device
- Keep all user documentation where it is accessible at all times for all users
- Pass the user documentation on to the next owner of the device

2.5.2 Access

User documentation for your device is provided on the USB drive that came with the device as part of the Instrument Accessory Kit.

2.5.3 Organization

This User Manual has been written to provide a comprehensive overview of the Device and its software. It provides guidelines for successful:

- Clinical setup and workflow
- Data acquisition and acceptance
- Review and Interpretation of CIRRUS 6000 data

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

2.5.4 Conventions Used in This Document

Certain types of information are specially marked in this document for better recognition.

- This is a list.
  - This is a second level list.

This is a cross-reference: Questions and comments [▸ 29].

This is `software code` or `program text`.

The name of software windows are capitalized. For example: Patient Screen

Names of menus, and buttons or other selectable items, are shown in **Bold**.

- **View** menu.
- **File > Save as**
- **My documents > Documents**

2.5.5 Questions and Comments

If you have questions or comments about this user documentation or the device, contact your ZEISS representative.

2.6 CIRRUS HD-OCT Technology

The CIRRUS™ HD-OCT is a computerized instrument that acquires and analyzes cross-sectional and three-dimensional tomograms of the eye using spectral domain optical coherence tomography (SD-OCT).

In low-coherence interferometry, light is sent along two optical paths, one being the sample path (into the eye) and the other the reference path of the interferometer. The light source is an 840 nm superluminescent light emitting diode (SLD). Light returning from the sample and reference paths is combined and introduced to the detector, which is a spectrometer in SD-OCT. The spectrometer resolves the interference signals throughout the depth of each A-scan immediately by means of a Fourier transformation. This is possible because the spectrometer resolves the relative amplitudes and phases of the spectral components scattered back from all depths of each A-scan tissue sample, without varying the length of the reference path.

Different CIRRUS™ HD-OCT models use different technologies to create the image:

- All models include a CCD video camera to monitor the exterior eye and assist with scan alignment.
- **Model 5000** and **Model 6000** instruments include a Line Scanning Ophthalmoscope (LSO).
- **Model 500** instruments use the OCT beam to create the retinal image.

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3 System Overview

3.1 Hardware Overview

NOTE

CIRRUS™ HD-OCT includes user-replaceable alkaline batteries in the mouse and keyboard.

CIRRUS™ HD-OCT also includes a lithium battery. Only a certified ZEISS Technician can replace the lithium battery.

▶ Dispose of alkaline batteries in accordance with local laws (see: Disposal [▷ 449]).

CIRRUS™ HD-OCT instrument includes the following integrated components:

- scan acquisition optics
- interferometer
- spectrometer
- system computer

In addition, the following external components are provided:

- monitor
- keyboard
- mouse
- *(optional)* printer
- *(optional)* wheelchair-accessible motorized table (adjusts to each patient's height)

Figure 1: CIRRUS™ HD-OCT System Hardware

1	Monitor	2	Connectors (USB, network, etc.) and labels under rear cover

3	USB Ports (2)	4	Mouse
5	Keyboard	6	Table Height Control
7	Power Table (Optional)	8	Patient Handle
9	Power Switch	10	Motorized Patient Alignment Unit
11	Dual Chinrest with Automatic Right/Left Sensors	12	Imaging Aperture
13	Head Rest	14	Port for External Fixation Arm

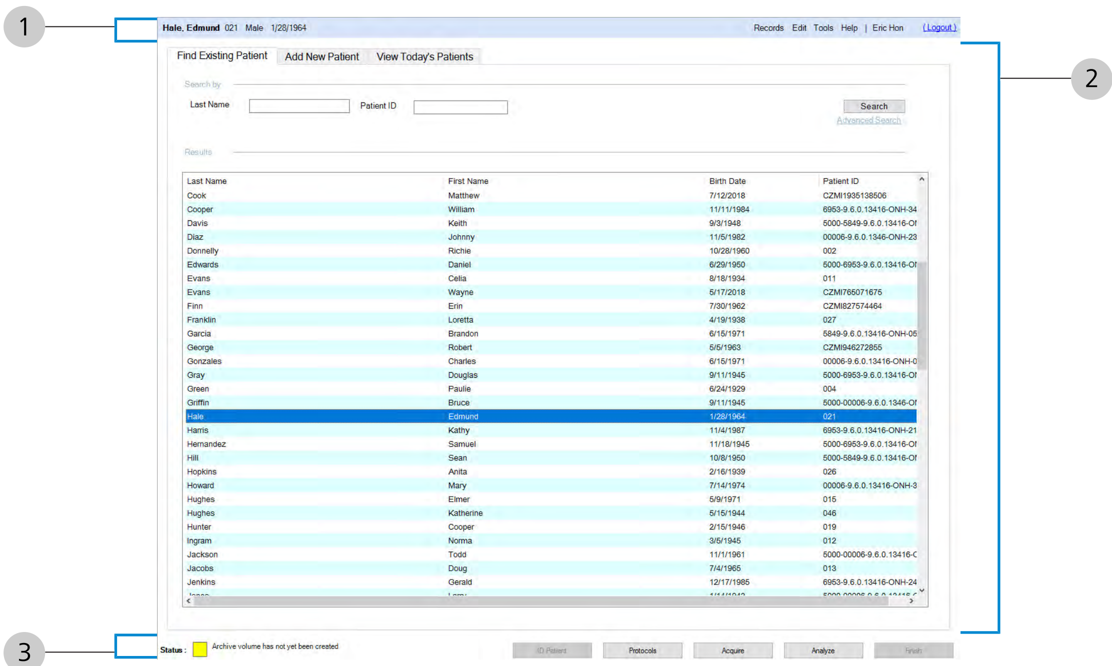
3.2 Software Overview

ZEISS pre-installs all software necessary to operate the CIRRUS 6000. Software updates with installation instructions may be provided on USB flash disk.

CIRRUS 6000 software has the following screen types:

- Patient Screen
- Protocol and History Screen
- Acquire Screen
- Check Scan Quality Screen
- Analysis and Report Screen

3.2.1 Screen Layout



Pos.	Name	Explanation
1	Toolbar	Menus common to all screens

Pos.	Name	Explanation
2	Work Area	Varies depending on mode and function
3	Navigation Bar	Status indicator and mode selection common to all screens

NOTE

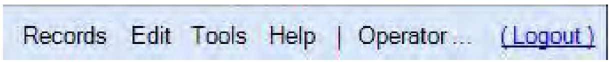
Viewing a Patient in the Work Area

When using the application, if you are viewing a patient in the Work Area, the following Current Patient field information appears on the left side of the Toolbar:

- ▶ Name
- ▶ Medical Record Number
- ▶ Sex
- ▶ Date of Birth (DOB)

3.2.2 Toolbar

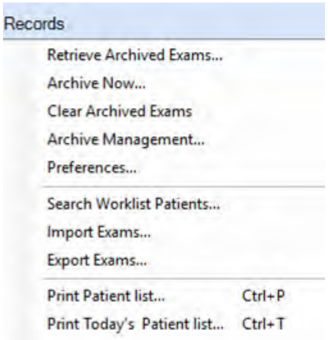
Each CIRRUS 6000 screen has context-specific menus and options.



3.2.2.1 Records Menu

The **Records** menu is different for instruments that use **Native Archive** and **DICOM Archive.**

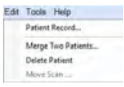
3.2.2.1.1 Records Menu (Native Archive)

Menu	Option	Description
	**Retrieve Archived Exams...**	Retrieve selected exams from the archive.
	Archive Now...	Archives all unarchived exams.
	Clear Archived Exams	Clear exams to free additional disc space.
	Archive Management:	Create archive locations and set default parameters.
	Preferences...	
	Archive/Synchronize	During instrument startup or shutdown, prompts you to archive exams and clear data.
	DICOM Archive	Disable **Auto-Query** or **Auto-Archive**.
	Display Options	Change display settings.
	IPv4 / IPv6	Select Internet Protocol.
	Search Worklist Patients ..	Opens the **Modality Worklist** to set parameters for patient search through DICOM Worklist server.
	Import Exams...	Opens **Import Options**.
	Export Exams..	Opens **Export Options**.
	Print Patient list..	Print the patient list currently displayed.
	Print Today's Patient list...	Prints the patient list in the Today's Patients.

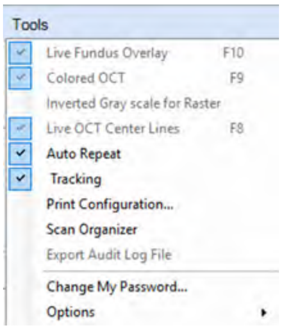
3.2.2.1.2 Records Menu (DICOM Archive)

Menu	Option	Purpose
	**Clear Archived Exams**	Clear exams to free additional disc space.
	Preferences...	
	Archive/Synchronize	During instrument startup or shutdown, prompts you to archive exams and clear data.
	Normative Database	Selects which normative database is 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.
	DICOM Archive	Allows patient record archive through the DICOM server.
	DICOM Retrieve	Allows patient records retrieval through the DICOM server.
	Search Worklist Patients...	Opens the **Modality Worklist** to set parameters for patient search through DICOM Worklist server.
	Import Exams...	Opens **Import Options**.
	Export Exams..	Opens **Export Options**.
	Print Patient list..	Print the patient list currently displayed.
	Print Today's Patient list...	Prints the patient list in the Today's Patients.

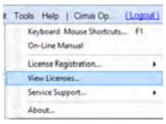
3.2.2.2 Edit Menu

Menu	Option	Description
	**Patient Record**	View or edit a patient's reccord.
	Merge Two Patients...	Combines duplicate patient records.
	Delete Patient	Delete selected patient record.
	Move Scan..	Move a scan from one patient record to another patient record.

3.2.2.3 Tools Menu

Menu	Option	Description
	**Live Fundus Overlay**	Enables overlay display. If disabled, the bounding box is visible, but not the vertical and horizontal slice locations.
	Colored OCT	Enables color OCT images display.
	Inverted Gray scale for Raster	Changes black pixels to white and white to black on gray scale raster scans.
	Live OCT Center Lines	Enables of a vertical center line display on OCT images.
	Auto Repeat	Automatically adjusts the ocular lens and chinrest to the previous settings for the same patient, eye, and acquisition function.
	Tracking	Enables FastTrac™ for all scans.
	Print Configuration...	Sets the printout options for Macular Thickness, ONH, and (HD 5 Line) Raster, and Macula multi-slice parameters.
	Scan Organizer	Sets show or hide available scans, or change scan order.
	Export Audit Log File...	Exports the log file.
	Change My Password...	Changes the current user's password.
	Options	
	Categories...	Creates, edits, or deletes categories for patient records and search.
	Institution Edit...	Adds your organization's name and logo to reports.
	Equipment Edit...	Creates a station name for the instrument, create DICOM AE Title, and view other equipment information.
	Users...	Creates, edits, or deletes staff / users.
	Select Database.. *(Review Station only)*	Switches to a different instrument database.

3.2.2.4 Help Menu

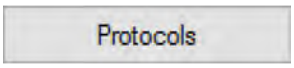
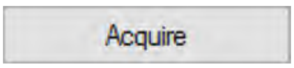
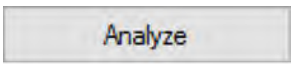
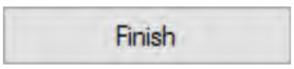
Menu	Option	Description
	**Keyboard Mouse Shortcuts**	Displays a categorized listing of keyboard shortcut keys and mouse functions.
	On-line Manual	Opens the CIRRUS 6000 User Manual PDF.
	License Registration	Register a license.
	View Licenses	Displays a list of CIRRUS™ HD-OCT licenses.
	Service Support	Enables you to select the TeleService web link for remote online servicing of the instrument, and save a Log file for troubleshooting.
	About	Displays the About dialog, which provides software version information.

3.2.3 Navigation

A navigation bar at the bottom that shows the current status of the instrument and buttons to change modes.

3.2.3.1 Navigation Buttons

Figure 2: Navigation Buttons

Button	Description
	Opens ID Patient mode.
	Opens Protocol page.
	Opens scan acquisition (when patient is selected).
	Opens image analysis (when patient is selected).
	Exits the current mode and opens the prior mode (from acquire or analyze mode).

3.2.3.2 Navigation Status

NOTE

Mouse over the status indicator and popup text will explain the current status.

Status (bottom left) displays a single green–yellow–red indicator along with a brief message about the instrument, hard drive, or NAS. For example:

■	**OK or normal:** The instrument is functioning normally.

	Warning: The instrument is operational but one or more problems exist.
	Critical: One or more serious problems exists that restricts use of the instrument.

For more information about status, refer to: Status Messages [▷ 425].

3.2.4 Basic Screens

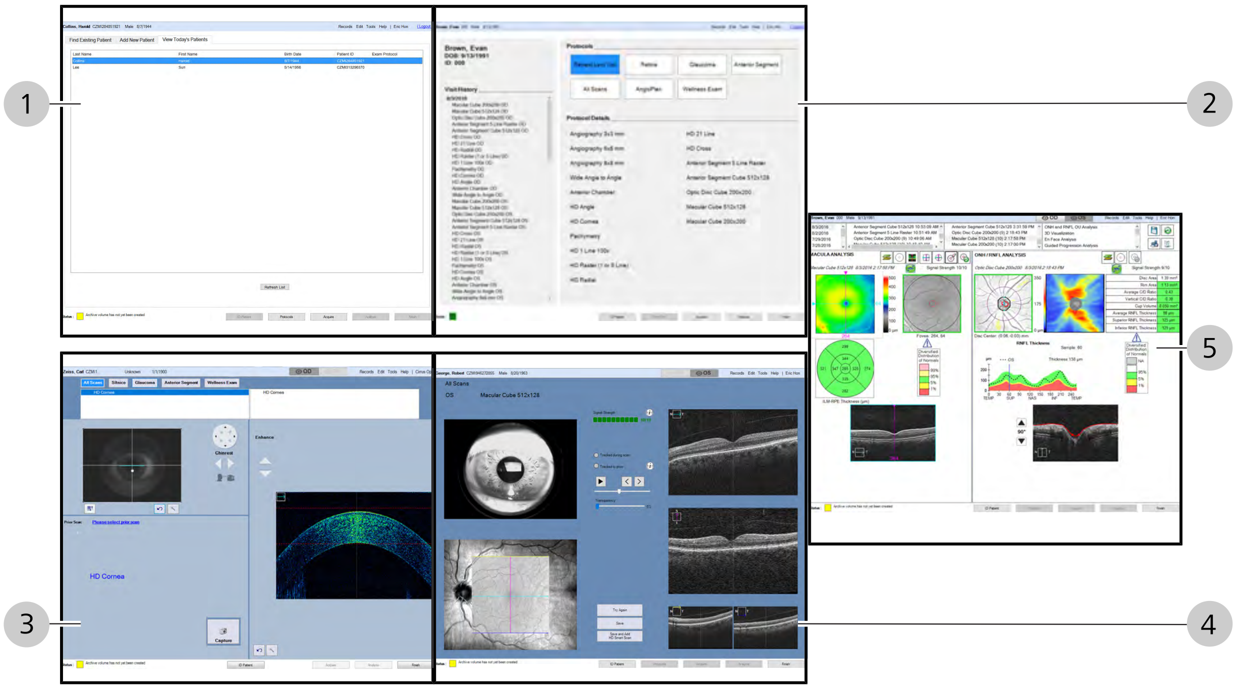


Figure 3: Basic Screen Examples

Pos.	Name	Explanation
1	Patient ID Screen	Select or add a patient.
2	Protocol Screen	Displays the most popular scans for the selected protocol.
3	Acquire Screen	*(Instrument Only)* Acquire scans for the selected patient.
4	Quality Check Screen	*(Instrument Only)* Assess the scan's quality and decide whether to save or retake the scan.
5	Analysis and Reports Screen	*(For saved scans)* Review, adjust, annotate, and assess scan results.

4 Installation

4.1 Safety During Installation

⚠ WARNING!

Unauthorized Installation

Unauthorized installation could lead to the injury of patients and operators, as well as to property damage.

- ▶ Only ZEISS authorized personnel may install Zeiss products.

⚠ WARNING!

Incorrectly configured or installed hardware

could damage the instrument or injure patients or operators.

- ▶ Allow only trained ZEISS Meditec personnel to install the instrument and its components.
- ▶ Do not attempt to unpack the instrument or its components.
- ▶ Do not attempt to install the instrument or its components.
- ▶ Do not attempt to connect the instrument or its components.
- ▶ Do not attempt to setup or start the device.

⚠ WARNING!

An ungrounded Device

could lead to electric shock.

- ▶ Do not remove or disable the ground pin.
- ▶ Only an authorized ZEISS service representative may service the instrument.
- ▶ Only an authorized ZEISS representative may install the instrument.

⚠ WARNING!

Opening instrument covers

could result in exposure to electrical and optical hazards.

- ▶ Do not open the instrument covers.
- ▶ Exception: You may remove the rear cover to access labels, change connectors, or clean fans.

4.2 About Changes to Hardware or Software

The CIRRUS™ HD-OCT is a medical device. The software and hardware were designed in accordance with U.S., European and other international medical device standards designed to protect clinicians, users and patients from potential harm caused by mechanical, diagnostic or therapeutic failures.

Read all safety information before installation and use. See: Safety and Certifications [▷ 11].

NOTE

Zeiss does not provide technical support for third party software.

For a list of approved Third Party Software and Hardware, refer to: www.zeiss.com/cirrus-specifications.

4.3 About Data Storage

⚠ CAUTION!

We strongly recommend that a knowledgeable IT professional assists with network configuration when installing review software.

NOTE

You can export data from the Native archive in DICOM format.

- ▶ You **do not** need an additional license to export data in DICOM format.
- ▶ You **do** need an additional license to connect to **FORUM**.

The CIRRUS™ HD-OCT instrument saves data locally; however we recommended that you archive your data to a network file server or a network attached storage device (external hard drive).

In addition to the **Native** archive, you can purchase a license for FORUM that connects directly to a DICOM network which allows you to:

- Save your data to a DICOM-compatible system automatically.
- Archive your data on a DICOM-compatible system automatically.
- Connect all ZEISS instruments to a DICOM-compatible network.

The following table explains the differences between using the **Native** or **DICOM** data archiving.

	Native Archiving	DICOM Archiving
Export DICOM EPDF Reports	YES	YES
Access *DICOM Modality Worklist* (MWL)	YES	YES
Connect multiple ZEISS instruments	NO	YES
Access CIRRUS™ HD-OCT review software.	YES Instrument Review Software	YES Local Database Review Software through FORUM DICOM Archive (with either FORUM-Floating licensing or Node-locked licensing)

Table 4: Comparing Native and DICOM Archiving

4.4 Installing the Instrument

NOTE

Use extreme care when handling and transporting the instrument shipping boxes.

The instrument contains fragile optics that require precise alignment.

You are not responsible for initially installing CIRRUS 6000 hardware or software.

The CIRRUS 6000 arrives with its table and associated components on a pallet in a number of separate shipping boxes. Do *not* allow institution personnel to unpack or open any of these containers.

On arrival, the ZEISS Field Representative will carefully unpack and assemble all system components at the location you have selected for its placement.

When the instrument installation is complete, configure the software (see Configuring Software [▸ 57]).

4.4.1 Embedded Windows License

The CIRRUS™ HD-OCT instrument is issued with an embedded Windows® license. The Windows license number is on a label under the rear cover.

4.4.2 Preparing to Install

Install the CIRRUS 6000 instrument in an environment that meets the following requirements:

- no direct sunlight
- properly grounded, dedicated 15 A power source that meets all local electrical codes
- not connected to a power strip
- the device's ventilation openings are not blocked
- the device is not exposed to water or other liquids

Do not modify the instrument or use cables not provided by ZEISS.

The CIRRUS 6000 instrument arrives on a pallet with three boxes that contain all parts and accessories needed to assemble the instrument and table.

4.5 Software and Document Media

CIRRUS 6000 comes with a USB case that contains two flash drives.

USB Label	Content
SW	Software to install on the CIRRUS 6000 instrument and review stations.
UD	User Documentation.

4.6 Installing Review Station Software

NOTE

These instructions are provided only for installing CIRRUS 6000 Review software on a separate PC or laptop. Installing Review software on a separate PC or laptop will give you access to the Analysis/Review portion of the full CIRRUS 6000 application.

A Review Station is a laptop or PC that analysts can use to access, edit, and create reports for scans.

4.6.1 Review Station Requirements

NOTE

These instructions are provided for Review Station software installation *only*.

If you plan to run CIRRUS 6000 software on a Review Station, the laptop or PC must fulfill the following minimum system requirements.

	Minimum	Recommended
Operating System	■ Windows Server 2008 R2 ■ Windows Server 2012 R2 ■ Windows 7 SP1, 64-bit ■ Windows 8.1, 64-bit ■ Windows 10	
CPU	Core i5 family	Core i7 family
RAM	16 GB	32 GB
HDD	500 GB	1 TB
Graphics Capability	1920 x 1080 (only)	

Table 5: System Requirements for stand-alone Review Stations

4.6.2 Review Station Performance

NOTE

All times are calculated based on an estimated network performance of 50% of theoretical.

▶ Actual performance for a typical clinical setting may differ and will depend on the actual network configuration.

Ethernet Rating	100 Base-T	1 GbE	10 GbE
Speed (MB/sec)	12	120	1200
Network Efficiency	0.5	0.5	0.5

Table 6: Review Station Performance

Scan Type	Approx. Scan Size (MB)	Time to Display (sec)
3x3 mm OCT Angiography	140	5
6x6/8x8/12x12 mm OCT Angiography	270	13

Table 7: Scan Display Performance

4.6.3 Install or Update Review Station Software

NOTE

If an error message appears

the software did not install successfully.

▶ Press the **Print Screen** button on your keyboard and save the error message to inform ZEISS Customer Support: 800–341–6968. Outside the U.S., contact your local Zeiss distributor.

NOTE

In the Remote Desktop Services environment, Review Software does not support the following functions:

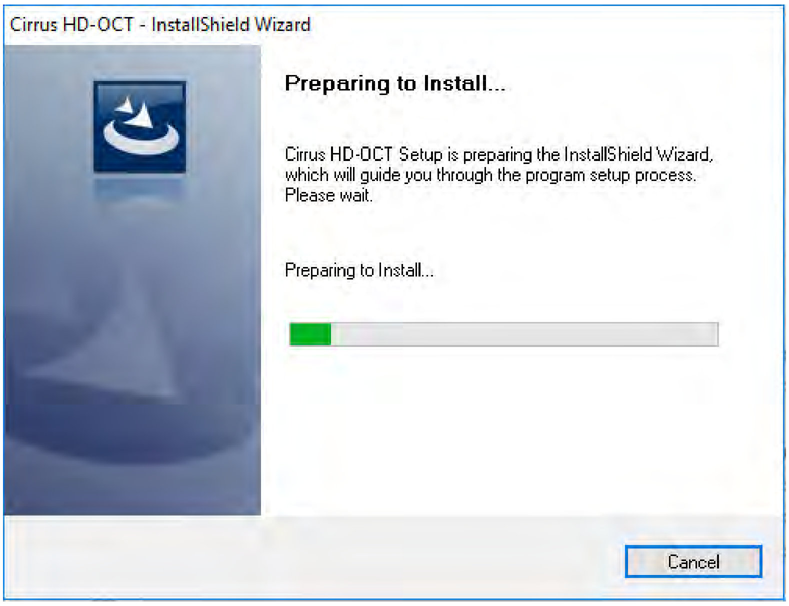
- ▶ Adding, Editing, and Deleting a patient record
- ▶ Deleting Scans
- ▶ Importing Scans
- ▶ Adding users or user accounts to the review software
- ▶ Adding, Editing, and Deleting the Equipment data
- ▶ Adding, Editing, and Deleting the Institution data
- ▶ 3D visualization analysis

☑ The Review Station fulfills the minimum system requirements for the Review Software (see: Review Station Requirements [▹ 42]).

☑ The installation media kit is available (see: Software and Document Media).

1. Insert the CIRRUS 6000 USB flash drive (SW) into the computer's USB port.
2. Navigate to the USB drive.
3. Double-click **Setup.exe**.

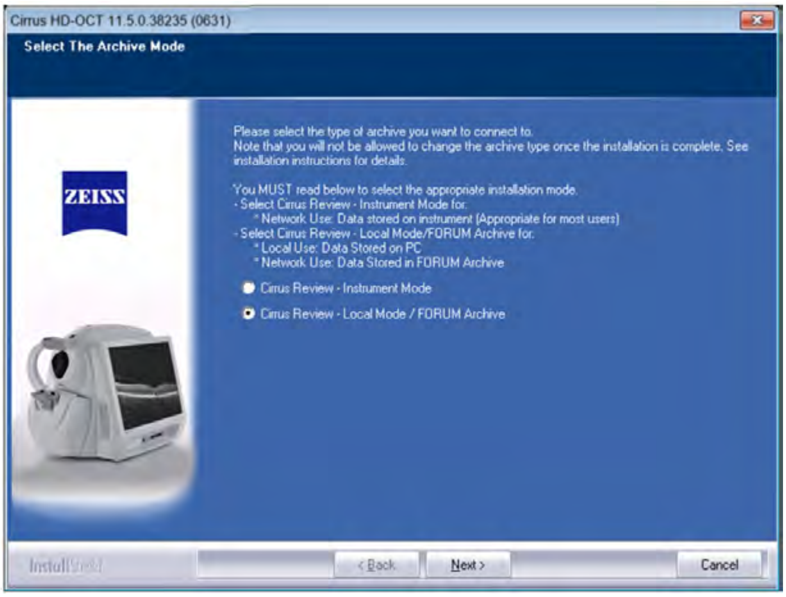
⇨ Installation takes a few moments to prepare before the installation wizard opens.



⇨ When preparation completes, the welcome page opens.

4. Click **Next**.
   ⇨ The license agreement page opens.

5. Read and accept the license agreement.
6. Click **Next**.
   ⇨ If you installing the review software for the first time, the mode selection window opens.



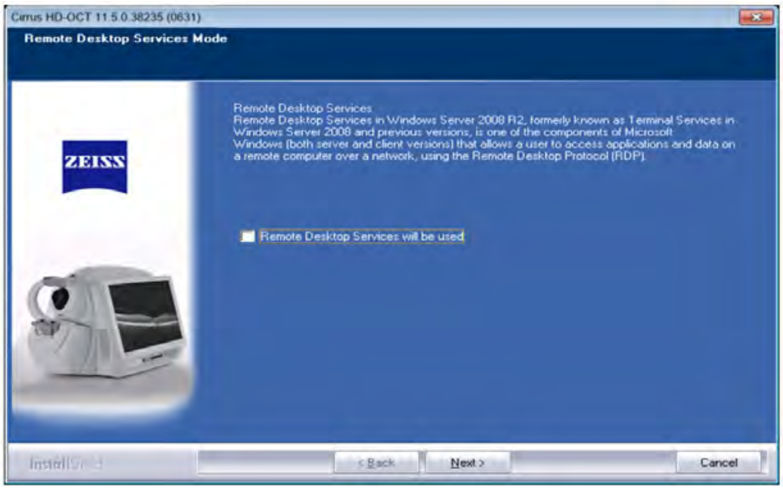
7. *(Initial installation only.)* If you archive exam data using the FORUM database environment, choose **Local Mode**.

   ⇨ For more information about FORUM, see: About Data Storage [▸ 40].

8. *(Initial installation only.)*If you do not, choose **Instrument Mode**.

9. Click **Next**.

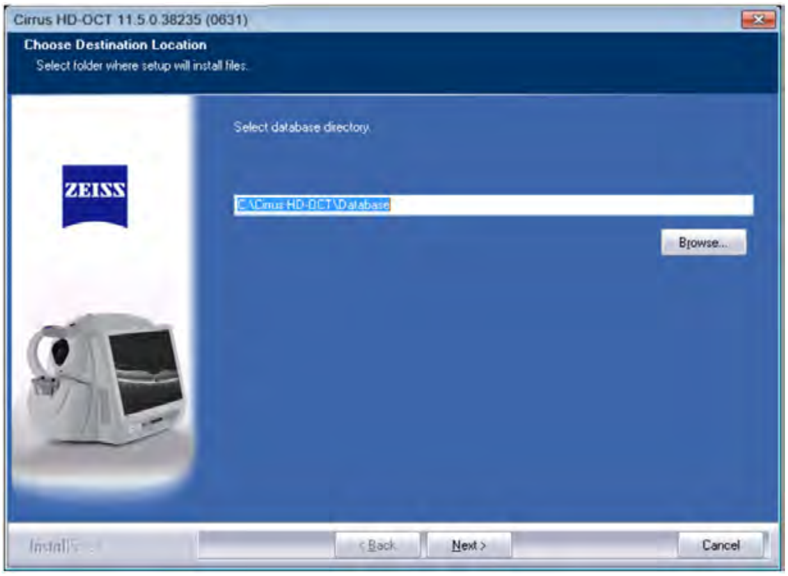
   ⇨ (Local Mode) The **Remote Desktop Services** selection window opens.



10. (Local Mode) If you use **Remote Desktop Services**, check **Remote Desktop Services will be used**.

11. Click **Next**.

   ⇨ (Local Mode) The installation location window opens.



12. (Local Mode) To select a different location for the application installation, click **Browse** and navigate to the location for installation.
13. Click **Next**.
    - ⇨ The review software installation takes a few minutes to complete. Progress bars indicate the progress as installation progresses.
    - ⇨ When installation completes, the finish prompt opens.

14. Click **Finish**.
    - ⇨ The CIRRUS 6000 shortcut appears on the computer's desktop.
15. To open the CIRRUS software, double-click on the icon.
16. Remove the USB flash drive from the USB port and return it to the media kit.
17. Configure the Review Station: Configuring an Additional Instrument or Review Station.

4.7 Update Instrument Software

NOTE

If an error message appears

the software did not install successfully.

- ▶ Press the **Print Screen** button on your keyboard and save the error message to inform ZEISS Customer Support: 800–341–6968. Outside the U.S., contact your local Zeiss distributor.

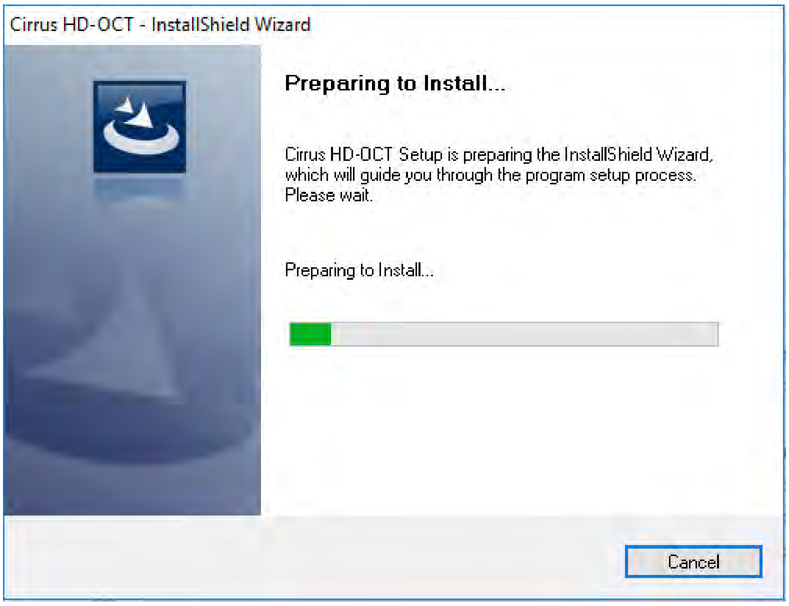
Prerequisite

☑ The installation media kit is available (see: Software and Document Media).

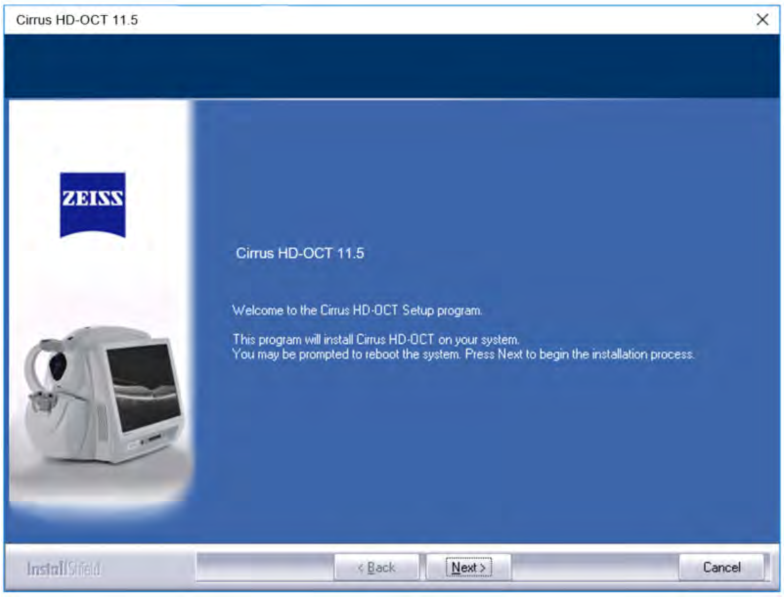
Action

1. Insert the CIRRUS 6000 USB flash drive (SW) into the computer's USB port.
2. Navigate to the USB drive.
3. Double-click **Setup.exe**.

   ⇨ Installation takes a few moments to prepare before the installation wizard opens.



   ⇨ When preparation completes, the welcome page opens.

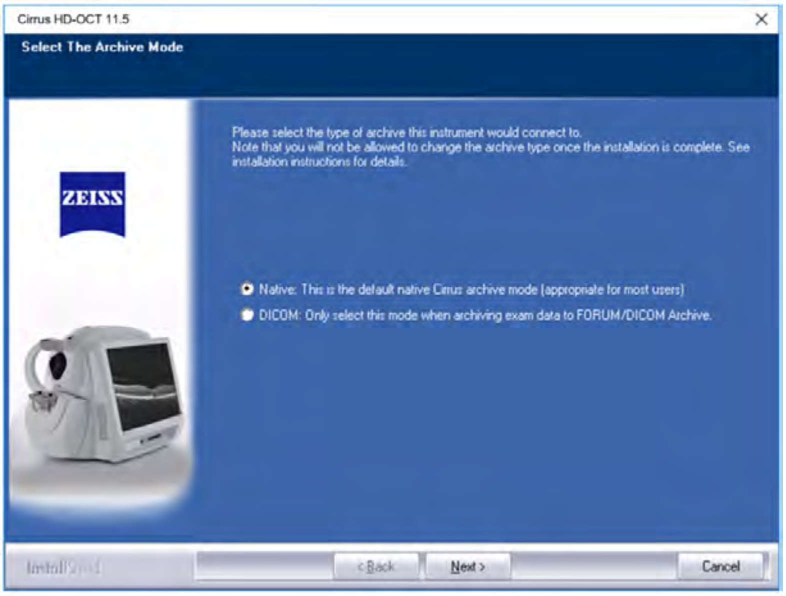


4. Click **Next**.

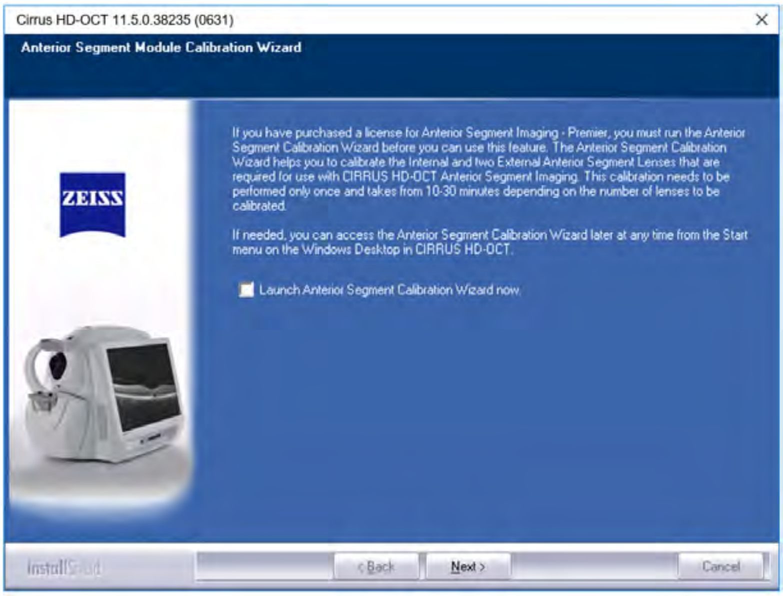
   ⇨ The license agreement page opens.

5. Read and accept the license agreement.
6. Click **Next**.

   ⇨ The mode selection window opens.



7. If you archive exam data using the FORUM database environment, choose **DICOM**.
   - ➩ For more information about FORUM, see: About Data Storage [▸ 40].
8. If you do not, choose **Native**.
9. Click **Next**.
   - ➩ Software installation takes a few minutes to complete. Progress bars indicate the progress as installation progresses.
   - ➩ When installation completes, the anterior segment calibration prompt opens.



10. To calibrate Anterior Segment, check **Launch Anterior Segment Calibration Wizard now** and refer to: Calibrate the Anterior Segment Lenses [▸ 418].

11. To skip Anterior Segment calibration, uncheck **Launch Anterior Segment Calibration Wizard now**.
12. Click **Next**.

13. Click **Finish**.
    ⇨ The CIRRUS 6000 shortcut appears on the computer's desktop.
14. Remove the USB flash drive from the USB port and return it to the media kit.

4.8 Installing User Documentation

The user document does not install automatically. You can install user documents from documentation flash drive so the online instructions open from the menu.

Documents are available in multiple languages.

To install the documentation:

Prerequisite

☑ The media kit is available (see: Software and Document Media).

Action

1. Insert the document USB flash drive (UD) into the instrument's USB port.
2. Open Windows Explorer and navigate to USB flash drive flash drive files.
3. Double-click **Setup.exe**.
   ⇨ The document installation wizard opens.
4. Follow the instructions in the installation wizard.
5. Remove the USB flash drive from the USB port and return it to the media kit.

Empty page, for your notes

5 Startup and Shutdown

5.1 Safety During Startup and Shutdown

⚠ **WARNING!**

In case of an emergency

disconnect the appliance coupler.

- For the device, the most accessible power cord is the one that plugs into the bottom of the table.
- Do not position device so it is difficult to unplug power cord.

⚠ **CAUTION!**

Protect Patient Health Information (PHI)

to maintain patient confidentiality.

- Health care providers are responsible for protection of patient health information (PHI), both hardcopy and electronic.
- Use encryption when you export electronic data.

⚠ **CAUTION!**

Do Not Transport the Instrument Outside the Office

to retain the instrument warranty.

- Contact a ZEISS service technician to transport the instrument.
- If you attempt to transport the instrument without consulting a ZEISS service technician, the instrument warranties are void.

⚠ **CAUTION!**

Unauthorized modification or dismantling of the instrument or system components

could result in damage to the instrument or components, or harm to the operator or other personnel.

- Only authorized ZEISS personnel may make modifications to, or dismantle, the instrument or its components.

⚠ **CAUTION!**

Using aerosols near or placing containers of liquid on or near the instrument

could damage the equipment. The instrument is not designed with any specific measures to protect against harmful ingress of water or other liquids (classified IPXO - ordinary equipment).

- Do not place containers of liquid, or use aerosols on or near the equipment.

NOTE

Health care providers are responsibility for protecting patient health information (PHI), both hardcopy and electronic.

- We recommend using encryption when you export data.

5.2 System Startup

Users are not authorized to dismantle or modify the CIRRUS™ HD-OCT hardware except to remove the rear cover.

- Keep the instrument and lenses clean. Refer to: Cleaning and Disinfection [▷ 407].
- Turn off when not in use for an extended period.
- The only user-replaceable part in the instrument is the top fan filter.

During system startup, CIRRUS™ HD-OCT checks the following:

- Database accessibility and integrity
- Instrument storage space
- Network storage space
- CIRRUS™ HD-OCT application installation
- Instrument connections

If any system checks fail or reports errors, refer to: System Startup Troubleshooting.

5.2.1 Turning on Power

NOTE

The first time you log in, change the password for the instrument.

There is a password that you can use for initial login.

▶ Change the password provided immediately after logging in for the first time.

To turn on the instrument:

Action

1. Turn the power switch (1) on.

2. Login to Windows. When logging in for the first time, use the following username and password and immediately change the password to a unique, secure password for your organization.
   - ⇨ **Initial Username:** `Zeiss`
   - ⇨ **Initial Password:** `November171846`
3.
   - ⇨ The system starts up and runs a series of checks, then the CIRRUS™ HD-OCT application opens automatically.

Result

✓ After a series of instrument checks, the CIRRUS software opens automatically.

5.2.2 Logging In

When system startup completes, the **User Login** dialog appears. The administrator can add and delete users and set passwords (see User Accounts).

For instructions on logging in as the administrator, see: Log in as Admin [▸ 58].

To log in:

Action

1. Select your **User Name**.
2. Type your password.
3. Click **OK**.

5.3 System Shutdown

The safest way to power down the system is:

1. Logout (ZEISS application)
2. Shut Down (Windows)

To shut down the system:

Action

1. Click **Logout**.
   - ⇨ If the system is set to archive data when you shut down the system, an archive dialog opens.

2. If the archive dialog opens, select the appropriate archive action.
3. Click **Yes**.
   - ⇨ A confirmation opens.
4. Click **Yes**.

⇨ The CIRRUS software application closes.

5. Select **Windows Start > Shut Down**.

   ⇨ A confirmation opens.

6. Click **OK**.

Result

✓ The instrument computer turns off.

6 Configuring Software

6.1 About User Roles

These are the general roles of users (as opposed to specific types of users) in CIRRUS 6000. For user types and permissions in the software, see User Types [▸ 70].

	Operator	Doctor	Adminis-trator
Settings and Maintenance			
Access ZEISS service link			X
Configure equipment and institution settings			X
Configure reports		X	X
Export log files		X	X
Manage licenses			X
View instruction manual	X	X	X
View licenses			X
View software version information	X	X	X
Patient Records			
Configure patient categories		X	X
Add or delete patients	X	X	
Edit patient records	X	X	
User Management			
Add or delete users			X
Acquire scans	X	X	
Review scans	X	X	
Select, edit and annotate scans	X	X	
Use review software installed on a separate computer	X	X	
Reset other user's passwords			X
Reset your own password	X	X	X
Delete a local patient record	X		
Save and print reports	X	X	
Import and export data	X	X	
Configure import and export settings			X

	Operator	Doctor	Adminis-trator
Configure network settings			X
Configure data backup	X	X	X
Restore data from a backup		X	X
Perform system maintenance			X

Table 8: User Roles

6.2 System Administration

Logging in as the System Administrator at the application level allows access to additional configuration, including:

- Managing User Accounts [▸ 70]
- Editing the Instrument Identifier [▸ 60]
- Editing Your Institution Information [▸ 59]

Refer to: User Names and Passwords [▸ 77] for Login information.

6.2.1 Log in as Admin

The **admin** is not listed as a username. You must type "admin" for username. The admin can add users and access advanced settings; cannot acquire or analyze scans (see About User Roles [▸ 57]).

To log in as the administrator:

Prerequisite

☑ Startup Sequence completed successfully (system login displayed).

Action

1. For **User Name**, type `admin`.
2. If this is the initial administrator login, type the password: `0000`. Immediately change this password.
3. Type the admin password.
4. Click **OK**.

6.2.2 Configuring the Instrument or Review Station

NOTE

Not available in DICOM Archive mode

This section describes how to configure settings on the CIRRUS 6000 instrument and review stations with your institution's information, users, and instrument identification.

6.2.2.1 About Assigning the Issuer of Patient ID

The **Issuer of Patient ID** field allows you to configure how your practice assigns patient IDs to new patients. Recommendations for configuring the Issuer of Patient ID:

- Set to the same **Issuer of Patient ID** value on every instrument in your practice.
- If you use an Electronic Medical Record (EMR) system, configure the **Issuer of Patient ID** to match the EMR system's patient ID value.

If you change the **Issuer of Patient ID**, the change will apply to future patient records; patient information already in the database does not change.

6.2.2.2 Editing Your Institution Information

NOTE

You must restart the software for the Institution Edit changes to appear in report headers.

We recommended that the administrator uniquely identify your institution, office clinic or hospital.

You can add your institution's logo. The institution name and logo appear on scan analysis reports.

To fit on the page, reports only print the first 24 characters of the institution name (including spaces).

To specify your institution name and add a logo:

Prerequisite

☑ On the CIRRUS™ HD-OCT instrument, Log in as Admin [▸ 58].

Action

1. Select **Tools > Options > Institution Edit**.
2. *(Required)* For **Name**, type the name of your institution (between 1 and 64 characters including spaces).
   ⇨ Reports only display the first 24 characters of the institution name.
3. *(Required)* For **Issuer of Patient ID**, type your institution's patient identification settings (see: About Assigning the Issuer of Patient ID [▸ 58]).
4. To add your institution's logo, click **Browse** and navigate to the logo image file (must be `BMP` format; for best results, use a square image).
   ⇨ Your logo appears in the preview box. If your image is not square, it will stretch to fit. The proportion shown in the preview box shows how your logo will appear in reports.
5. Click **Save**.
6. Click **Close**.
   ⇨ The new settings implement the next time you open the application.
7. To apply the new settings now, restart (close and reopen) the application.

6.2.2.3 Editing the Instrument Identifier

You must create a unique name for each CIRRUS 6000 instrument and review station.

Tip: Use station names meaningful to your organization (for example: "Imaging Room 215").

When configuring these settings, important instrument information displays, including:

- Model Number
- Sequence Number
- Serial Number
- Software Version
- ⊕DICOM AE Title (see: Connect to a DICOM Gateway [▸ 396]).

⊕ *Indicates optional features; license may be required.*

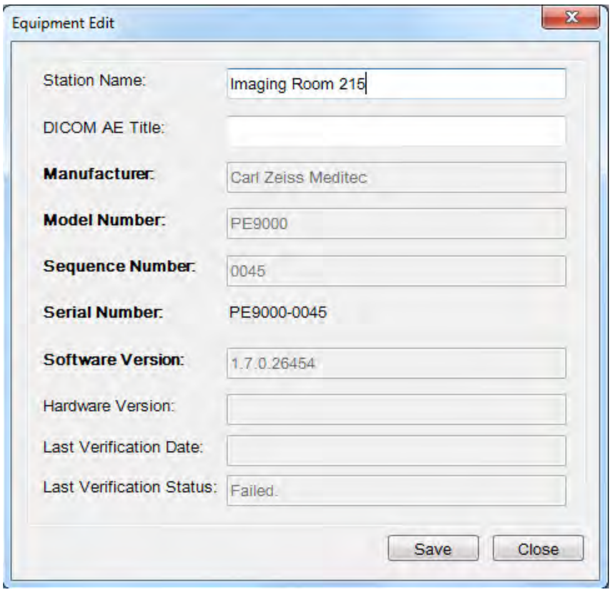
To edit instrument information:

Prerequisite

☑ On the CIRRUS™ HD-OCT instrument, Log in as Admin [▸ 58].

Action

1. Select **Tools > Options > Equipment Edit**.



2. For **Station Name**, type an instrument identifier that is meaningful to your institution.
3. If you have a license to connect to a DICOM Gateway, type the **DICOM AE Title** (see: Connect to a DICOM Gateway [▸ 396]).
4. Click **Save**.
5. Click **Close**.

6.2.3 Registering Licenses

NOTE

You will need your software Certificate Serial Number (shipped with your instrument) and optional feature licenses.

▶ If you cannot locate your software **Certificate Serial Number**, contact your ZEISS Representative to obtain this information.

NOTE

Register license(s) on instruments first, then on computers running review station software.

Some features of this instrument require licenses that you can purchase separately (see: About Licenses [▸ 61]).

All licenses you purchase with the instrument are already registered for you. If you purchase a license for optional features separately, you must register the license on each instrument and each computer running the review station software to enable the new features.

Before you register a license, ensure that you have the following information available:

- **Certificate Serial Number** (see the Software Product Certificate provided with your instrument)
- **Instrument Serial Number**

6.2.3.1 About Licenses

NOTE

Features described in this section are licensed separately and may not be available in all markets.

▶ For information about feature availability in your market and obtaining a license:

⇨ in the U.S.A, call 1-877-486-7473.

⇨ outside the U.S.A , contact your local ZEISS distributer.

Core License

The core license includes the features available without an additional license. When you view your installed licenses, both included and additionally purchased licenses are listed.

The core license includes software updates and features that were formerly licensed separately (now included).

<table>
<tr><th>License Name</th><th>Enables</th></tr>
<tr><td>4.0 Software Upgrade</td><td>Core Upgrades</td></tr>
<tr><td>6.0 Software Upgrade</td><td rowspan="6">Macular Cube 512 x 128
Macular Cube 200 x 200
Optic Disc Cube 200 x 200
1 or 5 Line
HD 1 Line 100x
HD 5 Line
HD Radial
HD 21 Line
HD Cross</td></tr>
<tr><td>6.0 Software Upgrade Plus Light</td></tr>
<tr><td>CIRRUS 11.1 Core License</td></tr>
<tr><td>CIRRUS 11.2 Core License</td></tr>
<tr><td>Software Upgrade Plus</td></tr>
<tr><td>Instrument Review Software</td><td>Install software for analysis on separate (Review Station) computers</td></tr>
<tr><td>Advanced RPE Analysis</td><td>Advanced RPE Analysis</td></tr>
<tr><td>Anterior Segment Imaging</td><td>Anterior Segment Cube
Anterior Segment 5 Line Raster
HD Angle</td></tr>
<tr><td>Epithelial Thickness Mapping</td><td>Epithelial thickness measurement calculations for Pachymetry</td></tr>
<tr><td>Ganglion Cell Analysis</td><td>Ganglion Cell OU</td></tr>
<tr><td>Ganglion Cell Guided Progression Analysis</td><td>Ganglion Cell Guided Progression</td></tr>
<tr><td>Guided Progression Analysis</td><td>Guided Progression Analysis</td></tr>
<tr><td>Macular Normative Data</td><td>Associates study data to compare macular thickness to normal reference range for a patients' age</td></tr>
<tr><td>Macular Change Analysis</td><td>Macular Change Analysis</td></tr>
<tr><td>Macular Reports</td><td>Reports for analyses</td></tr>
<tr><td>ONH Normative Data</td><td>Associates study data to compare optic disc and RNFL measurements to normal reference range for a patients' age.</td></tr>
<tr><td>ONH and RNFL Analysis</td><td>ONH/RNFL OU Analysis</td></tr>
<tr><td>RNFL Thickness Analysis and 3D Volume Rendering</td><td>3D Visualization Analysis</td></tr>
<tr><td>Segmentation Layer Editor</td><td>Macular cube segmentation editor for Macular Thickness Analysis, Macular Thickness OU Analysis, and Advanced RPE Analysis</td></tr>
<tr><td>Single Eye Summary Analysis</td><td>Single Eye Summary</td></tr>
<tr><td>Tracking</td><td>FastTrac feature</td></tr>
</table>

Table 9: Core Licenses

Some CIRRUS™ HD-OCT scans and analyses or features require separate licenses. Your instrument and review station list only the scans and analyses with an active license.

License Name	Enables
AngioPlex Metrix for 3x3 scan (Requires **AngioPlex OCT Angiography** license)	Enables analysis calculations (Metrix) 3x3mm scans for **Angiography Analysis** and **Angiography Change Analysis**.
AngioPlex Metrix for 6x6 scan (Requires **AngioPlex OCT Angiography** license)	Enables analysis calculations for 6x6mm scans for **Angiography Analysis** and **Angiography Change Analysis**.
AngioPlex Metrix for 3x3 and 6x6 *(Requires AngioPlex OCT Angiography license)*	Enables analysis calculations for 3x3mm and 6x6mm scans for **Angiography Analysis** and **Angiography Change Analysis**.
AngioPlex Metrix for 4.5x4.5 ONH Scan *(Requires AngioPlex OCT ONH Angiography license)*	Enables analysis calculations for ONH angiography scans for **ONH Angiography Analysis** and **ONH Angiography Change Analysis**.
AngioPlex OCT Angiography	■ **Angiography 3x3 mm** ■ **Angiography 6x6 mm** ■ **HD Angiography 6x6 mm** ■ **Angiography 8x8 mm** ■ **HD Angiography 8x8 mm** ■ **Angiography 12x12 mm** ■ **Montage Angiography 6x6 mm** ■ **Montage Angiography 8x8 mm**
AngioPlex OCT ONH Angiography	■ **ONH Angiography 4.5x4.5 mm**
Anterior Segment Imaging – Premier	■ **Anterior Chamber** ■ **Wide Angle to Angle** ■ **HD Cornea** ■ **Pachymetry**
Asian Normative Database	Associates study data to compare ganglion cell, optic disc, and RNFL measurements to normal reference range (Asian subjects only) for a patients' age.
Display Extrapolate Progression in GPA and GCP	Enables an algorithm that extends progression analyses to estimate future change for **Guided Progression** and **Ganglion Cell Guided Progression**

Table 10: Optional Instrument Licenses

Once you purchase and install a license, all related scans, analyses, and features activate for that instrument or review software.

To see what licenses are installed, see: Registering Licenses [▸ 61].

6.2.3.2 Register a License on an Instrument

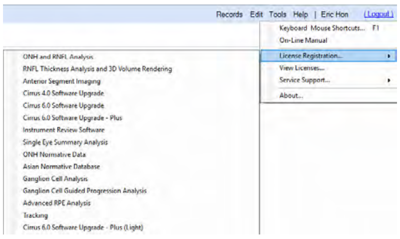
To register a license on the instrument:

Prerequisite

☑ Your instrument(s) are connected to the internet.

☑ On the CIRRUS™ HD-OCT instrument, Log in as Admin [▸ 58].

Action



1. Select **Help > License Registration**.
2. Select the name of the license you are installing.
   ⇨ The **CZM License Registration Utility** opens displaying the prefix for your Certificate Serial Number, Feature to be Registered, and Node ID for the license you selected.

3. Confirm that the prefix for your **Certificate Serial Number** matches and type the rest of the **Certificate Serial Number**.

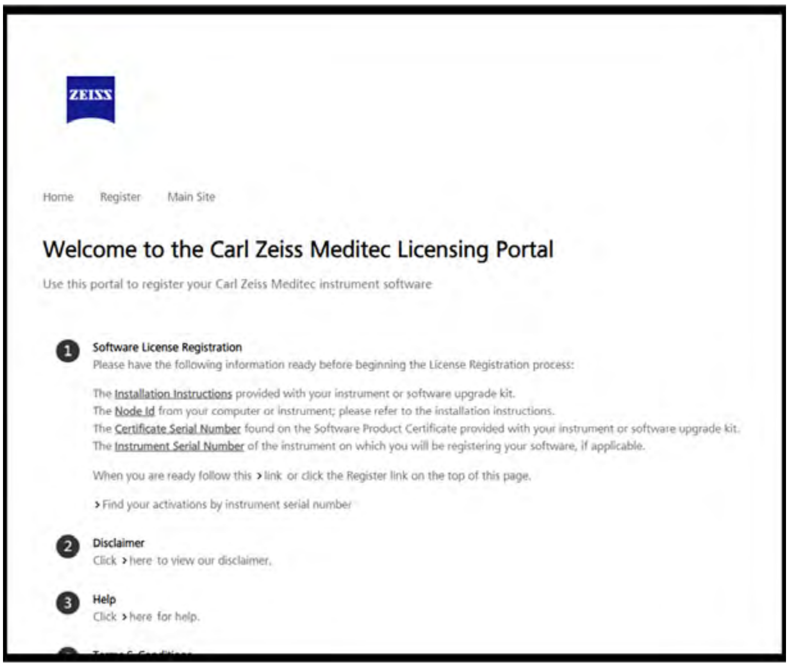
NOTE

Write down the Node ID.

You need the **Node ID** to obtain the **License Key** and **Security Code**.

4. Make a note of the **Node ID**.

   ⇨ You can leave the **CZM License Registration Utility** open. After you obtain the license key and security code from the ZEISS registration website, you need to return to the utility to complete registration.
5. Open a browser and go to the ZEISS registration website:http://www.zeiss.com/med/register.
   ⇨ The licensing portal opens.



6. Click **Register**.
   ⇨ The registration details page opens.
7. Type the **Certificate Serial Number** and click **Submit**.
   ⇨ The CZM registration site displays the **License Key** and **Security Code** for this license.
8. Make a note of the **License Key** and **Security Code**.
9. Close the web browser and return to (or re-open) the **CZM License Registration Utility**.

10. For **License Key**, type the number you noted from the CZM registration site.
11. For **Security Code**, type the number you noted from the CZM registration site.
12. Click **Save**.
13. Log Out [▸ 124].
14. Install the license on each instrument for which you purchased the optional features, then on computers running review station software (if required).
15. To check the status of your licenses, see: View Licenses [▸ 69].
16. To install a licenses on a computer running review station software, see: Register a License on a Review Station [▸ 66].

Result

✓ The new features are enabled on the instrument.

6.2.3.3 Register a License on a Review Station

NOTE

In instrument mode the review station inherits the licensed features of the instrument it accesses.

You do not need to register a licenses on computers running review station software.

- ▶ In an environment with multiple instruments, features available to the review station may differ when accessing different instruments (if optional features are licensed differently on instruments).

Some features of this instrument require licenses that you can purchase separately (see: About Licenses [▷ 61]).

In instrument mode, a review station accesses the database of scans stored on the instrument. The review station inherits the licenses of the instrument it accesses.

To register a license on the review station:

Prerequisite

☑ All instruments in the environment have already registered this license (Register a License on an Instrument [▷ 64]).

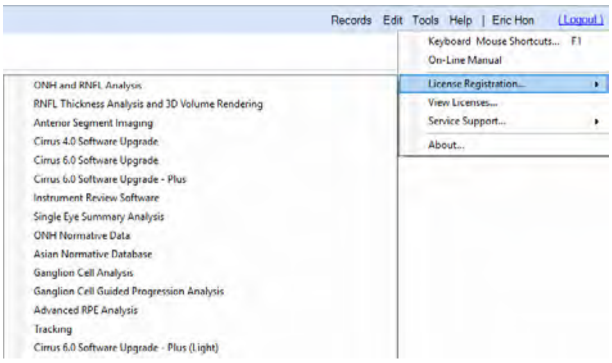
☑ The instrument licensing information is available.

☑ The Review Station environment is in Local or DICOM mode.

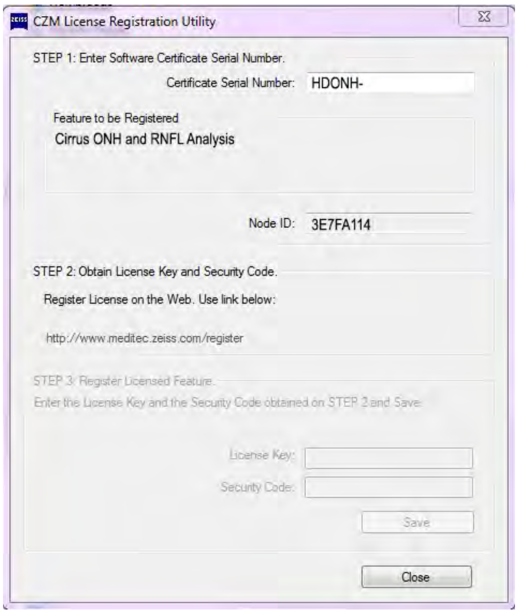
☑ Login to the CIRRUS software.

Action

1. Log in as Admin [▷ 58].
2. Select **Help > License Registration**.



3. Select the name of the license you are installing.
   ⇨ The **CZM License Registration Utility** opens displaying the prefix for your Certificate Serial Number, Feature to be Registered, and Node ID for the license you selected.



4. Confirm that the prefix for your **Certificate Serial Number** matches and type the rest of the **Certificate Serial Number**.

NOTE

Write down the Node ID.

You need the Node ID to obtain the **License Key** and **Security Code**.

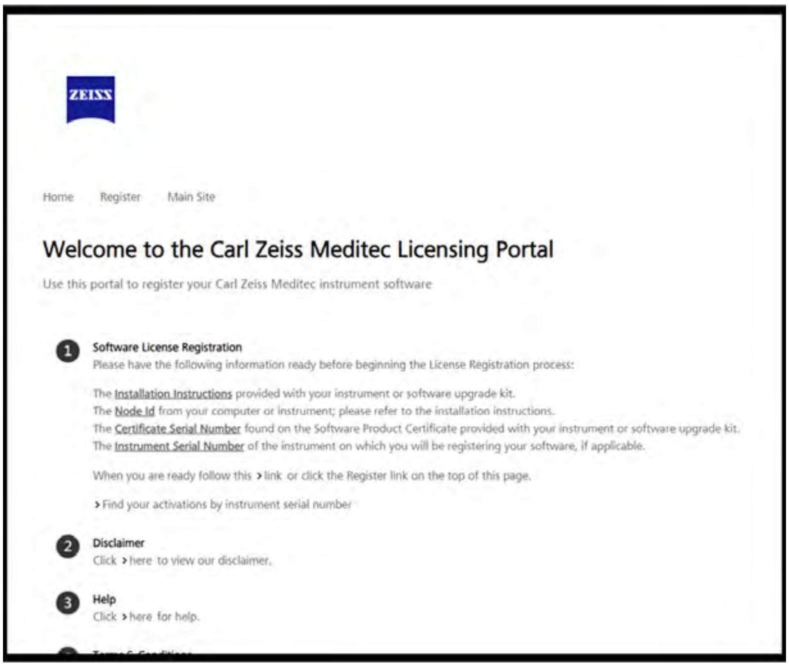
5. Make a note of the **Node ID**.

NOTE

You can leave the CZM License Registration Utility open.

After you obtain the license key and security code from the ZEISS registration website, you need to return to the utility to complete registration.

6. Open a browser and go to the ZEISS registration website:http://www.zeiss.com/med/register.
   ⇨ The licensing portal opens.



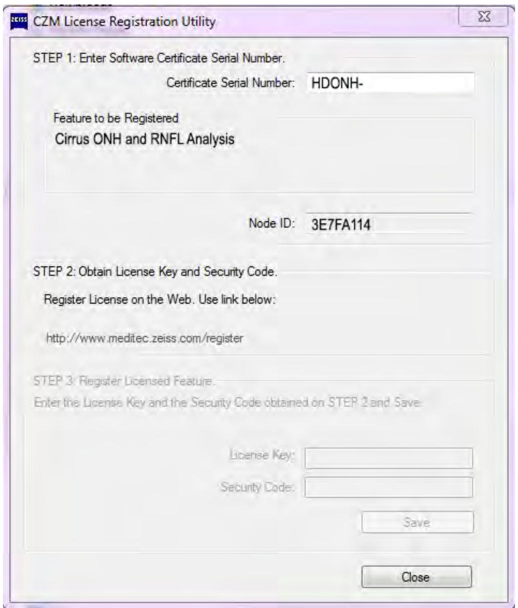
7. Click **Register**.
   ⇨ The registration details page opens.
8. Type the **Certificate Serial Number** and click **Submit**.
   ⇨ The CZM registration site displays the **License Key** and **Security Code** for this license.

NOTE

Write down the License Key and Security Code.

You need this information to complete the registration.

9. Make a note of the **License Key** and **Security Code**.
10. Close the web browser and return to (or re-open) the **CZM License Registration Utility**.



11. For **License Key**, type the number you noted from the CZM registration site.
12. For **Security Code**, type the number you noted from the CZM registration site.
13. Click **Save**.
14. To check the status of your licenses, see: View Licenses [▸ 69].

Result

✓ The new features are enabled.

6.2.3.4 View Licenses

NOTE

Features described in this section are licensed separately and may not be available in all markets.

▶ For information about feature availability in your market and obtaining a license:

⇨ in the U.S.A, call 1-877-486-7473.

⇨ outside the U.S.A , contact your local ZEISS distributer.

Many types of scans, analyses and features that originally required a separate license are now included as standard features. The licenses for these features still appear in the license view, even if they are now included with the instrument.

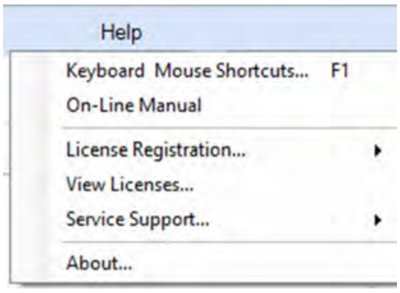
Some features require licenses that you can purchase separately (see: About Licenses [▸ 61]). You can check which optional features are enabled on your instrument.

To view licenses:

Prerequisite

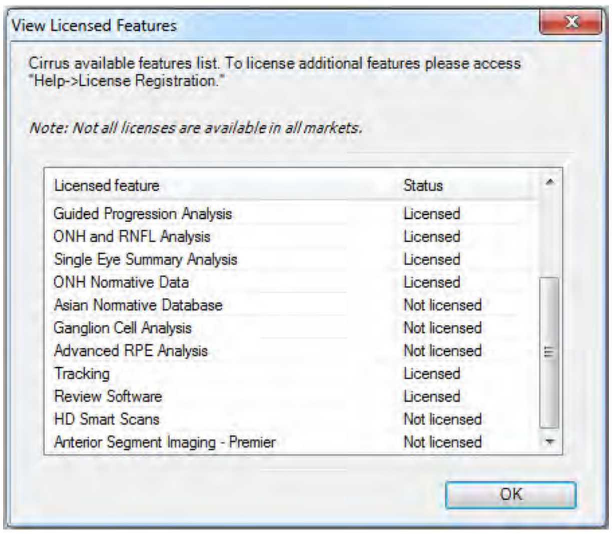
☑ On the CIRRUS™ HD-OCT instrument, login: Log In as Operator or Data Analyst [▸ 123] or Log in as Admin [▸ 58].

Action



1. Select **Help > View Licenses**.

⇨ A dialog opens displaying the status of all optional licenses for your instrument.



2. To register a licenses on an instrument, see: Register a License on an Instrument [▷ 64].
3. To register a licenses on a computer running review station software, see: Register a License on a Review Station [▷ 66]

6.2.4 Managing User Accounts

NOTE

Unsecured Logins

may result in unauthorized access or inaccurate record-keeping.

▶ Create individual user accounts for each staff member.

▶ Staff members should log out after every use.

CIRRUS 6000 saves the operator's user name for each scan acquired. The currently logged in user name displays in the top toolbar.

Analysis reports print the technician's name. To fit on the page, reports can only display the first 32 characters (including spaces)

6.2.4.1 User Types

	Operator	Referring Physician	Requesting Physician	Reading Physician
Ordering scans		✓	✓	
Reviewing scans				✓
Acquiring scans	✓			

Table 11: User Types and Permissions

6.2.4.2 Password Requirements

All passwords must follow these rules:

- Must be at least seven characters long.
- Must contain at least three of the following:
  - European language uppercase characters (A through Z, with diacritic marks, Greek, and Cyrillic characters).
  - European language lowercase characters (A through Z, with diacritic marks, Greek, and Cyrillic characters).
  - Numbers (0 through 9).
  - Non-alphabetic characters (for example: !, $, #, %)
- Any unicode character alphabetic character, including Asian language unicode characters.

6.2.4.3 Viewing User Accounts

NOTE

Only Administrators can complete this task.

Prerequisite

☑ On the CIRRUS™ HD-OCT instrument, Log in as Admin [▶ 58].

Action

1. Select **Tools >Options > Users**.

   ⇨ The **Staff Registration** dialog opens listing the users already added to the system. If no users exist, the list is empty.

6.2.4.4 Adding a New User

NOTE

Only Administrators can complete this task.

NOTE

First Name, Last Name and Password are case-sensitive.

Create a unique user account for each instrument operator who acquires scans and each clinician who analyzes scans.

When you add a new user, you must provide last name and first name. All other fields are optional.

To add a new user:

Prerequisite

☑ On the CIRRUS™ HD-OCT instrument, Log in as Admin [▶ 58].

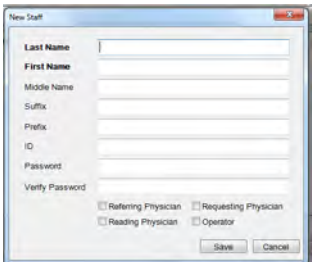
Action

1. Select **Tools >Options > Users**.

   ⇨ The **Staff Registration** dialog opens listing the users already added to the system. If no users exist, the list is empty.

2. Click **New**.

   ⇨ The **New Staff** dialog opens.



3. For **Last Name**, type the user's last name
4. For **First Name**, type the user's first name.
5. If available, complete **Middle Name**, **Suffix**, **Prefix**, and **ID**.
6. For **Password**, type a temporary password for the user.
7. For **Verify Password**, retype the temporary password.
8. Check the user type (see User Types [▶ 70]). Make sure to check **Operator** for anyone using the instrument or review software.
9. Click **Save**.
10. Provide the user with the password and ask them to log in and reset their password.

6.2.4.5 Editing User Information and Password

NOTE

Only Administrators can complete this task.

NOTE

First Name, Last Name and Password are case-sensitive.

When you edit user information, you must provide at least one name (last name or first name). All other fields are optional.

To edit a user:

Prerequisite

☑ On the CIRRUS™ HD-OCT instrument, Log in as Admin [▷ 58].

Action

1. Select **Tools >Options > Users**.
   ⇨ The **Staff Registration** dialog opens.
2. Select the user you want to edit.
3. Click **Edit**.
   ⇨ The **Edit Staff** dialog opens.
4. Update the user's **Last Name**, **First Name**, **Middle Name**, **Suffix**, **Prefix**, and **ID** user type as required.
5. To reset their password, for **Password**, type a temporary password for the user and for **Verify Password**, retype the temporary password.
6. Click **Save**.
7. If you changed the user's password, provide the user with the new password and ask them to log in and set a different password.

6.2.4.6 Deleting a User

NOTE

Only Administrators can complete this task.

NOTE

You cannot delete a user that any exam data references.

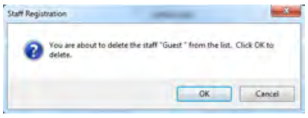
To delete a user:

Prerequisite

☑ On the CIRRUS™ HD-OCT instrument, Log in as Admin [▷ 58].

Action

1. Select **Tools >Options > Users**.
   ⇨ The **Staff Registration** dialog opens.
2. Select the user you want to delete.
3. Click **Delete**.
   ⇨ A confirmation opens.



4. Click **OK**.

6.2.5 Export Log Files

NOTE

Save (export) audit log files regularly

to ensure events are tracked in case you encounter a data error.

CIRRUS 6000 records the following events and identifies them by date, time, and User ID:

- Log on / log off
- Display analysis data
- Create, modify, or delete data
- Import/export data from removable media
- Receive and transmit 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 device overwrites the existing files.

The default folder for the audit log files is:
`C:\ProgramData\Carl Zeiss Meditec\...\Logs`.

6.2.5.1 Export a Log File

NOTE

Only Administrators can complete this task.

To export a log file:

Prerequisite

☑ On the CIRRUS™ HD-OCT instrument, Log in as Admin [▸ 58].

Action

1. Select **Tools > Export Audit Log File**.
   ⇨ A browse dialog opens.
2. Navigate to the folder you want to store the audit log file.
3. Click **Save**.

Result

✓ The log is exported as a .zip file with the format: AuditLog_dd_mm_yyyy_hh_mm.

6.2.6 Data Archiving and Retrieval

NOTE

We recommond you use a single archive location.

Archives are proprietary only readable from the device on which they were created.

You cannot port archives to other instruments or to review stations.

Archiving data stores a backup of CIRRUS 6000 data. Data is archived to the **Current** location. For more information about adding storage to the network for archiving, refer to: Adding a Network Storage Device

Archives are automatically named following the format: **[ID Unique to the Instrument]-A-[YEAR][MONTH][DAY][HOUR][MINUTE][SEC].** For example: `123456789-A-20190730154623`

6.2.6.1 Setting Up an Archive

NOTE

Although Administrators and Operators can set up an archive, we recommend Administrators oversee this process.

To maintain consistency in your environment, have the Administrator set up a new archive.

The label for the new archive location has two parts:

- Automatically generated name (model number, serial number and archive sequence number)
- (optional) Customizable suffix

To set up an archive:

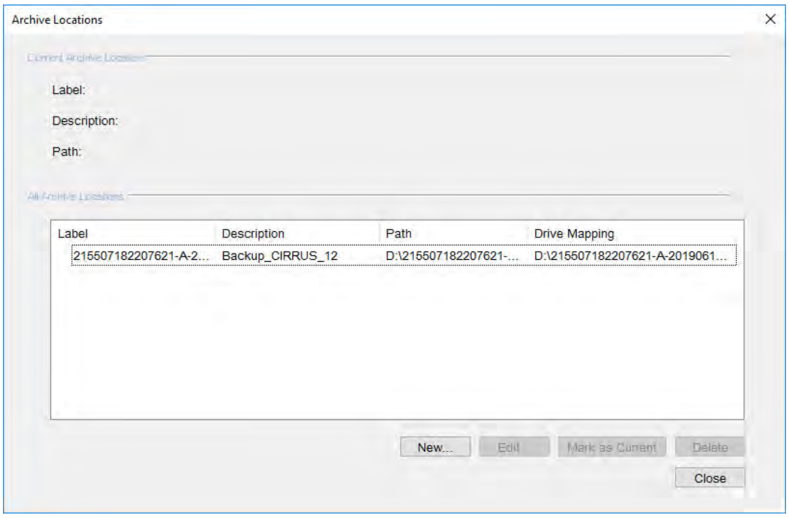
Prerequisite

☑ Log In as Operator or Data Analyst [▸ 123].

☑ You know the name and location of the new archive: Adding a Network Storage Device

Action

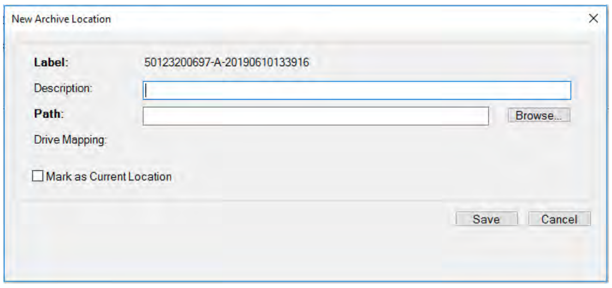
1. Select **Records > Archive Management**.



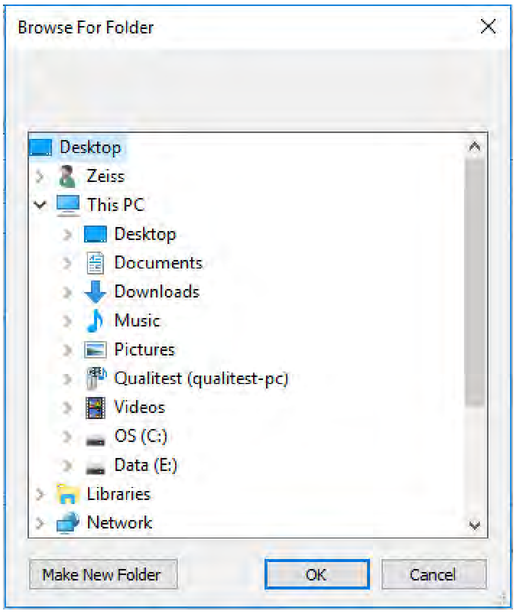
⇨ The **Archive Locations** dialog opens.

2. Click **New**.

   ⇨ The **New Archive Location** dialog opens.



3. To identify this archive location by description, for **Description**, type your description (up to 85 characters).
4. Click **Browse**.
5. Navigate to the shared archive folder on the network file server.



6. Click **OK**.
7. Click **Save**.
8. Click **Close**.

6.2.6.2 Changing the Archive

To change the archive location:

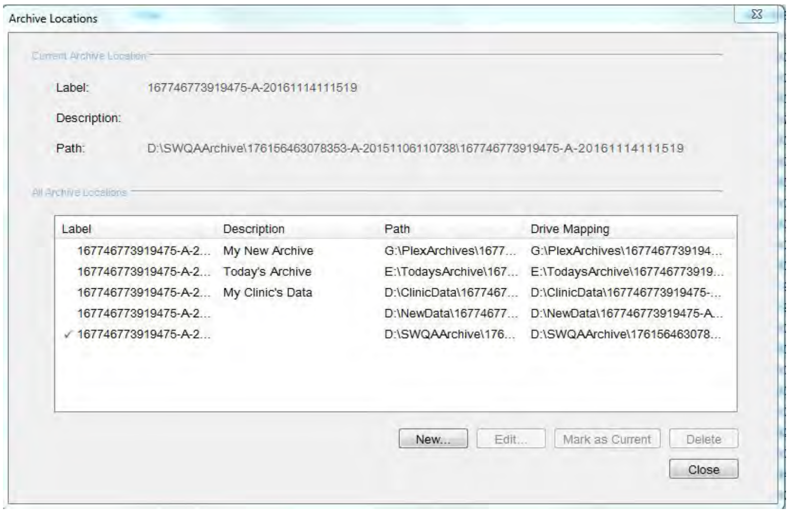
Prerequisite

☑ Log In as Operator or Data Analyst [▸ 123].

☑ You know the name of the new archive.

Action

1. Select **Records > Archive Management**.
   ⇨ The **Archive Locations** dialog opens listing all available archives.



2. Select name of the archive you want to use.
3. Click **Mark as Current**.
4. Click **Close**.

Result

✓ The archive location changed.

6.2.7 Windows 10 System Administration

NOTE

Only Administrators can complete this task.

This section contains detailed configuration information for system administrators. Only system administrators should make changes to these settings.

6.2.7.1 Windows Patches and Updates

Automatic Windows updates are disabled. Windows patches and updates are distributed with CIRRUS 6000 after they are tested and approved for use.

6.2.7.2 Data Safety

6.2.7.2.1 Auto-Lock

After 15 minutes of inactivity, the CIRRUS 6000 screen locks and the user must log in again.

6.2.7.2.2 Anti-Malware

When configuring anti-malware applications, ensure that updates and full system scans do not occur when data acquisition could be in progress. Windows Defender is configured and running on the CIRRUS 6000. Definition files will be automatically downloaded and installed if the system has Internet access.

Refer to the software release notes for a list of approved anti-malware software.

6.2.7.2.3 User Names and Passwords

NOTE

Passwords for Tech Support users are unique for each system.

Zeiss instruments initially have three user names and passwords. Initial passwords are shown in the table below. Change the ZeissAdmin passwords before using the instrument.

User Name	Type	Password	Purpose
`Zeiss`	Administrator	`November171846` **NOTE! Change this password after initial use.**	Instrument User
`ZeissAdmin`	Administrator	`November171846` **NOTE! Change this password after initial use.**	Instrument Adminis-tration
`Tech Support`	Administrator	*<unique>*	Zeiss Technical Support

Table 12: Initial User Names and Passwords

6.2.7.2.3.1 Password Requirements

All passwords must follow these rules:

- Must be at least seven characters long.
- Must contain at least three of the following:
  - European language uppercase characters (A through Z, with diacritic marks, Greek, and Cyrillic characters).
  - European language lowercase characters (A through Z, with diacritic marks, Greek, and Cyrillic characters).
  - Numbers (0 through 9).
  - Non-alphabetic characters (for example: !, $, #, %)

- Any unicode character alphabetic character, including Asian language unicode characters.

6.2.7.3 Networking

6.2.7.3.1 Network Controllers and IP Addressing

NOTE

This instrument is not compatible with networks using IPv4 addressing in the range of 192.168.52.0 to 192.168.52.254

This instrument contains two network controllers; Internal Network and External Network.

6.2.7.3.1.1 Internal Network

NOTE

Do not rename the Internal Network

Internal Network is for instrument use only with the following assignments:

- Static IPv4 address: `192.168.52.100`
- Subnet mask: `255.255.255.0`

6.2.7.3.1.2 External Network

The External Network is for instrument connectivity and automatically picks up an IP address. Do not change the name of the network controller.

6.2.7.3.2 Required Network Ports

The network ports listed in this section are required for proper instrument operation.

6.2.7.3.2.1 Required Internal Network Ports

Service	TCP	UDP
Internal Communication Port	80	

Table 13: Internal Network Ports (Required)

6.2.7.3.2.2 Required External Network Ports

Service	TCP	UDP
Database (for review software)	3051	

Table 14: External Network Ports (Required)

6.2.7.3.2.2.1 Required External Network Ports for EMR and FORUM

Service	TCP	UDP
DICOM outbound	11119	

Service	TCP	UDP
FORUM outbound	8080	
DICOM inbound	11112	
FORUM inbound The first available port in this range will be used.	8081 ~ 8101	
DNS (AutoConnect for instruments outbound)		5353

Table 15: External Network Ports (Required for EMR and FORUM)

6.2.7.3.3 Additional Network Ports

The following network ports are not required to operate the instrument. These ports facilitate instrument configuration and maintenance.

Service	TCP	UDP
Bonjour		1900, 5350, 5351, 5353
Remote service (outbound)	80	
DHCP		67 - 68
TCP/IP MS Networking	445	
NTP		123
NETBIOS Name Service (UDP open port visible externally)	137	137
NETBIOS Datagram Service	138	138
NETBIOS Session Service	139	139

Table 16: Additional Network Ports

6.2.7.4 Configuring Enhanced Security

Enhanced security settings are not required to operate the instrument properly. You can change these settings individually to match your network environment.

To remove Enhanced Security, log in as ZeissAdmin and run the “Remove Enhanced Security.CMD” script as an Administrator. The script is located on the desktop.

6.2.7.4.1 Disabling Enhanced Security Settings

When you received the CIRRUS 6000, enhanced security settings are turned on. These settings are not required for the instrument to operate properly.

You can change individual settings per your institution's requirements or you can disable these settings using the *Remove Enhanced Security* command on the desktop.

NOTE

Only Administrators can complete this task.

To disable enhanced security settings:

Action

1. Log in to the ZeissAdmin user account.
2. Locate and run the `Remove Enhanced Security.CMD` script as an Administrator by right-clicking on it and selecting **Run as Administrator**.
3. When the process completes, you are presented with a list of services and firewall rules that have been changed.
4. Reboot the device for the changed services and rules to take effect.

6.2.7.4.2 Enabling Enhanced Security Settings

When you received the CIRRUS 6000, enhanced security settings are turned on. These settings are not required for the instrument to operate properly.

If there were changes to individual settings or if all enhanced security settings were disabled, you can re-enable all of these settings using the *Install Enhanced Security* command on the desktop.

NOTE

Only Administrators can complete this task.

To enable enhanced security settings:

Action

1. Log in to the ZeissAdmin user account.
2. Locate and run the `Remove Enhanced Security.CMD` script as an Administrator by right-clicking on it and selecting **Run as Administrator**.
3. When the process completes, you are presented with a list of services and firewall rules that have been changed.
4. Reboot the device for the changed services and rules to take effect.

6.2.7.4.3 Enhanced Security Windows Firewall Rules

Enhanced security disables the following Windows firewall rules:

Disabled Firewall Rules
AllJoyn Router (TCP-In) AllJoyn Router (TCP-Out) AllJoyn Router (UDP-In) AllJoyn Router (UDP-Out) Cast to Device functionality (qWave-TCP-In) Cast to Device functionality (qWave-TCP-Out) Cast to Device functionality (qWave-UDP-In) Cast to Device functionality (qWave-UDP-Out) Cast to Device SSDP Discovery (UDP-In) Cast to Device streaming server (HTTP-Streaming-In) Cast to Device streaming server (RTCP-Streaming-In) Cast to Device streaming server (RTP-Streaming-Out) Cast to Device streaming server (RTSP-Streaming-In) Cast to Device UPnP Events (TCP-In) Cortana Delivery Optimization (TCP-In) Delivery Optimization (UDP-In) DIAL protocol server (HTTP-In) Microsoft.AccountsControl Microsoft.LockApp Microsoft.Windows.ContentDeliveryManager Microsoft.Windows.ParentalControls Microsoft.Windows.Apprep Network Discovery (WSD Events-In) Proximity sharing over TCP (TCP sharing-In) Proximity sharing over TCP (TCP sharing-Out) Remote Assistance (DCOM-In) Remote Assistance (PNRP-In) Remote Assistance (RA Server TCP-In) Remote Assistance (SSDP TCP-In) Remote Assistance (SSDP UDP-In) Remote Assistance (TCP-In) SmartScreen Windows.ShellExperience Windows Spotlight Wireless Display (TCP-In) Wireless Display (TCP-Out) Wireless Display (UDP-Out) Wireless Display Infrastructure Back Channel (TCP-In)

6.2.7.4.4 Enhanced Security Services

Enhanced security disables the following services:

Disabled Security Services
AllJoyn Router Service Application Layer Gateway Service Bluetooth Handsfree Service Bluetooth Support Service BranchCache Connected Devices Platform Service Connected User Experiences and Telenetry Downloaded Maps Manager Fax Function Discovery Resource Publication Geolocation Service HomeGroup Listener HomeGroup Provider Infrared Monitor Service Internet Connection Sharing (ICS) Microsoft iSCSI Initiator Service Microsoft Storage Spaces SMP Microsoft Windows SMS Router Service Network Connection Broker Phone Service Program Compatibility Assistant Service Quality Windows Audio Video Experience Retail Demo Service Shell Hardware Detection Telephony Touch Keyboard and Handwriting Panel Service Windows Camera Frame Server Windows Event Collector Windows Image Acquisition (WIA) Windows Insider Service Windows Media Player Network Sharing Service Windows Mobile Hotspot Service Work Folders Xbox Live Auth Manager Xbox Live Game Save Xbox Live Networking Service

6.3 Setting Preferences

6.3.1 Setting Archive/Synchronize Alerts

CIRRUS 6000 allows you to set an archive reminder for either system startup or system shutdown.

NOTE

If no archive preference is selected

The hard drive will become full. Indicators are:

Yellow - hard drive is nearly full.

Red - hard drive is full; you cannot scan patients or review data until the current data is archived.

▶ Select **Records > Archive Now** to immediately archive exams.

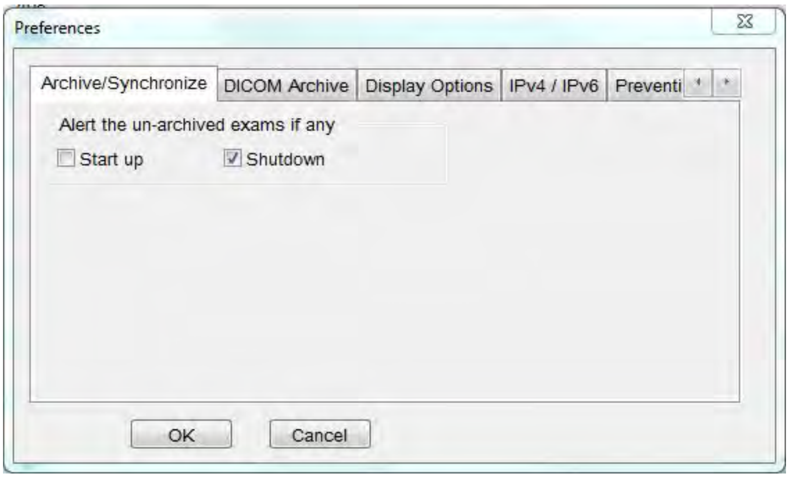
To set archive alerts:

Prerequisite

☑ Log In as Operator or Data Analyst [▸ 123].

Action

1. Select **Records > Preferences**.
2. Select the **Archive/Synchronize** tab.



3. To alert the operator of un-archived data each time the instrument starts up, check **Startup** .
4. To alert the operator of un-archived data each time the instrument shuts down, check **Shutdown**.
5. Select **Shutdown** to archive on shutdown.
6. Click **OK**.

6.3.2 Changing the Default for Normative Data

NOTE

Features described in this section are licensed separately and may not be available in all markets.

▶ For information about feature availability in your market and obtaining a license:

⇨ in the U.S.A, call 1-877-486-7473.

⇨ outside the U.S.A , contact your local ZEISS distributer.

If you have a license for the Asian normative database, an additional **Preferences** panel exists to allow you to change between **Diversified** and **Asian** normative data. For more information about the normative databases, refer to: Diverse Population Study [▷ 451].

You can set the default normative database. Changing the default normative database does not impact patient records for patients assigned to a specific normative database.

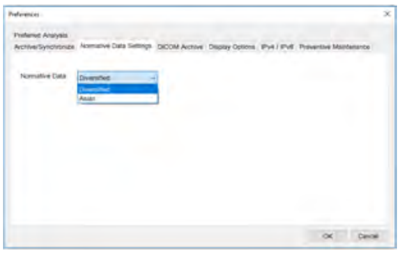
To change normative databases:

Prerequisite

☑ Log In as Operator or Data Analyst [▷ 123].

☑ Your instrument or review software has a license for Asian normative data: About Licenses [▷ 61]

Action



1. Select **Records > Preferences**.
2. Select the **Normative Data Settings** tab.
3. Choose the normative data to set.
4. Click **OK**.

Result

✓ The system is now set to use the normative data selected (for calculations).

6.3.3 Configure DICOM Archiving

If your system is not running DICOM Archive, only one option appears on the **DICOM Archive** tab (to enable it).

To set DICOM options:

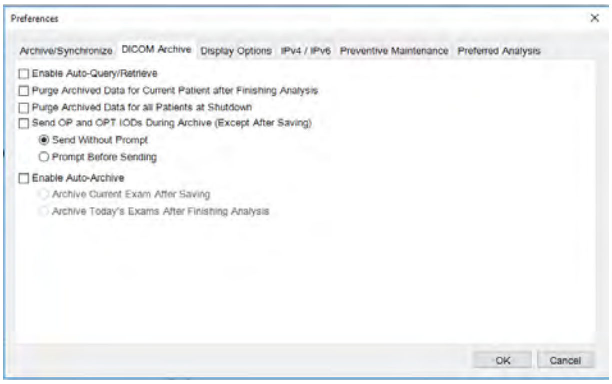
Prerequisite

☑ Log In as Operator or Data Analyst [▷ 123].

Action

1. Select **Records > Preferences**.
2. Select the **DICOM Archive** tab.
3. Check **Enable Auto-Query/Retrieve**.

⇨ Additional options display.



4. To automatically delete data stored locally when you exit **Analysis**, check **Purge Archived Data for Current Patient after Finishing Analysis**.
5. To delete data stored locally when you shut down the CIRRUS™ HD-OCT application, check **Purge Archived Data for all Patients at Shutdown**.
6. To enable exporting image files in a standard DICOM format, check **Send OP and OPT IODs During Archive (Except After Saving)** and select either:
   Send Without Prompt to disable prompt for export, or
   Prompt Before Sending to enable prompt for export.
7. To enable automatic archiving of newly acquired exams or a modified analysis, check **Enable Auto-Archive**.
8. Click **OK**.

6.3.4 Setting the Default Patient Screen

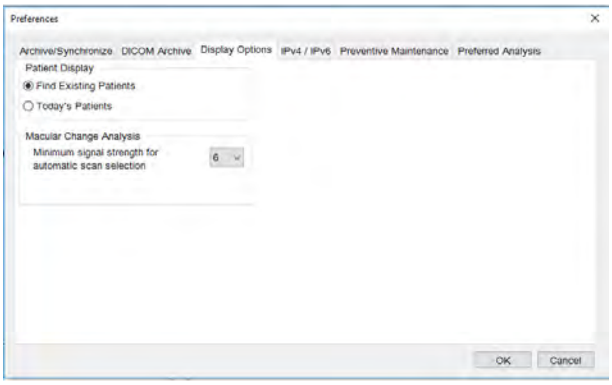
To set the default patient screen:

Prerequisite

☑ Log In as Operator or Data Analyst [▸ 123].

Action

1. Select **Records > Preferences**.
2. Select the **Display Options** tab.



3. To set the patient screen to start with Find Existing Patients, choose **Find Existing Patients**.
4. To set the patient screen to start with Today's Patients, choose **Today's Patients**.

5. Click **OK**.

6.3.5 Setting the Internet Protocol Version

CIRRUS 6000 instruments work on networks that support Internet Protocol version 6, as well as version 4. CIRRUS 6000 Review Software works *only* on version 4. The default setting is IPv4.

NOTE

Choosing the Incorrect Network Protocol

will result in no network connectivity.

▶ Consult your IT professional before selecting.

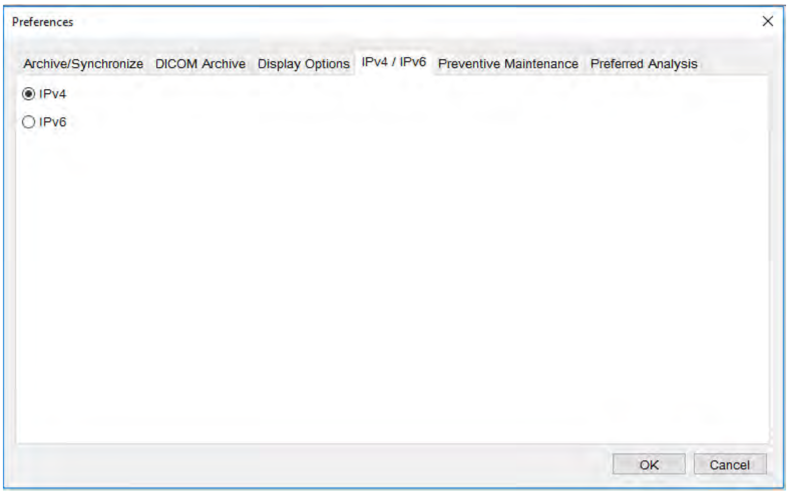
To set the internet protocol version you use:

Prerequisite

☑ Log In as Operator or Data Analyst [▷ 123].

Action

1. Select **Records > Preferences**.
2. Select the **IPv4 / IPv6** tab.



3. Select the internet protocol version your facility uses.
4. Click **OK**.

6.3.6 Setting the Preventive Maintenance Schedule

Two weeks prior to the scheduled date, the instrument begins to displays a reminder (at startup) that maintenance is due.

CIRRUS 6000 instruments require regular maintenance. The frequency of this maintenance depends on how much your institution uses the instrument.

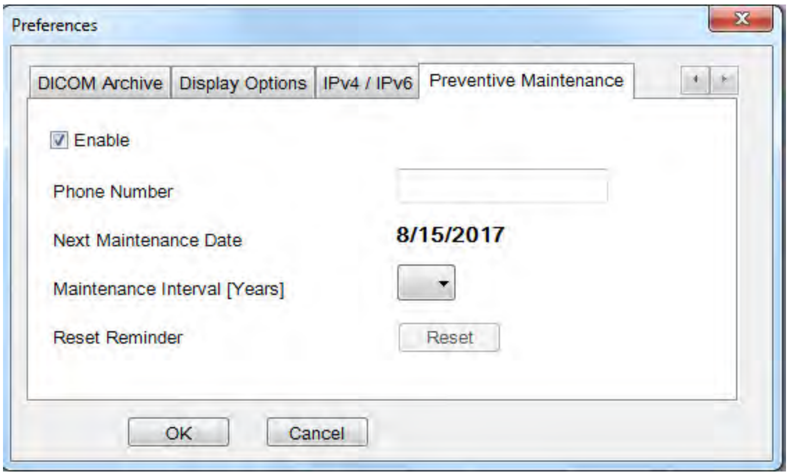
To set the maintenance schedule reminder:

Prerequisite

☑ Log In as Operator or Data Analyst [▷ 123].

Action

1. Select **Records > Preferences**.
2. Select the **Preventive Maintenance** tab.



3. Check **Enable**.
4. For **Phone Number**, type your local maintenance representative's phone number.
5. Click **OK**.

6.4 Manage Patient Data

6.4.1 Managing Patient Categories

NOTE

Not available in DICOM Archive mode

You can create custom categories for patient records. Then you can use categories to identify a group of patients that fit into your category (or combination of categories) using Advanced Search [▷ 132].

6.4.1.1 About Patient Categories

Some institutions create patient categories to apply to their patients. Your institution can create custom categories that are helpful to your clinicians. Your administrator can add new categories, edit them or delete them.

For example, an institution could create categories to distinguish the patient's age group like this:

- `Child (under 12)`
- `Teen (12-19)`
- `Adult 20-45`
- `Adult 45-60`
- `Adult 60-80`
- `Adult 80+`

Classification categories can help when a patient is diagnosed with a specific problem.

You can apply categories to a patient's record when you create it, then change or delete categories that no longer apply.

6.4.1.2 Adding a Category

To add a category:

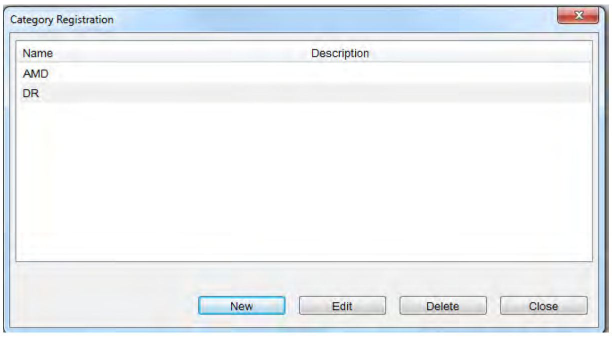
Prerequisite

☑ Log In as Operator or Data Analyst [▹ 123].

Action

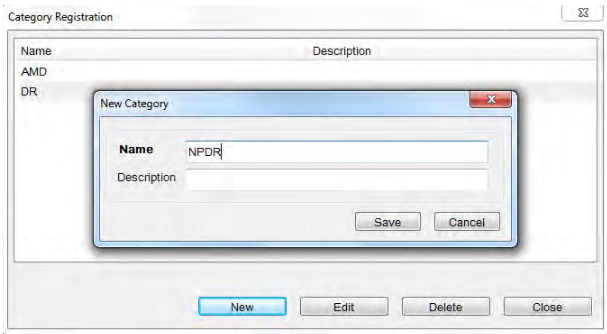
1. Select **Tools > Options > Categories**.

   ⇨ The Category Registration dialog opens listing existing categories in alphabetical order.



2. Click **New**.

   ⇨ The Category Edit dialog opens.



3. For **Name**, type a name for the category (up to 64-characters).
4. Click **Save**.
5. (Optional) For **Description**, type a description (up to 64-characters).

6.4.1.3 Editing a Category

NOTE

You cannot edit categories created by another institution.

To edit a category:

Prerequisite

☑ Log In as Operator or Data Analyst [▹ 123].

Action

1. Select **Tools > Options > Categories**.

   ⇨ The Category Registration dialog opens listing existing categories in alphabetical order.

2. Select a category.
3. Click **Edit**.
   ⇨ The **Category Edit** dialog opens.
4. Update the category information.
5. Click **Save**.

6.4.1.4 Deleting a Category

NOTE

You cannot edit categories created by another institution.

To delete a category:

Prerequisite
☑ Log In as Operator or Data Analyst [▹ 123]

Action
1. Select **Tools > Options > Categories**.
   ⇨ The Category Registration dialog opens listing existing categories in alphabetical order.
2. Select a category.
3. Click **Delete**.
   ⇨ A confirmation opens.
4. Click **OK**.

6.4.2 Patient Privacy

NOTE

Obscuring Patient Identities

leads to better security. The unique Patient ID is created when you export with this option, referred to as the **Obscured ID**.

▶ In order to search on a patient with an Obscured ID, enter the ID into the **Obscured ID** field of **Advanced Search** (see Advanced Search [▹ 132]).

⇨ Users who wish to obtain additional medical information about an anonymous patient must contact the originating clinic.

The device gives you the choice to export exam data (Export Data [▹ 93]) 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:

- the complete date of birth
- the month and year of birth
- the year of birth

6.4.3 Merge Patient Records

If a single patient is identified twice with two different ID numbers, you can merge the records.

To Merge Patient Records:

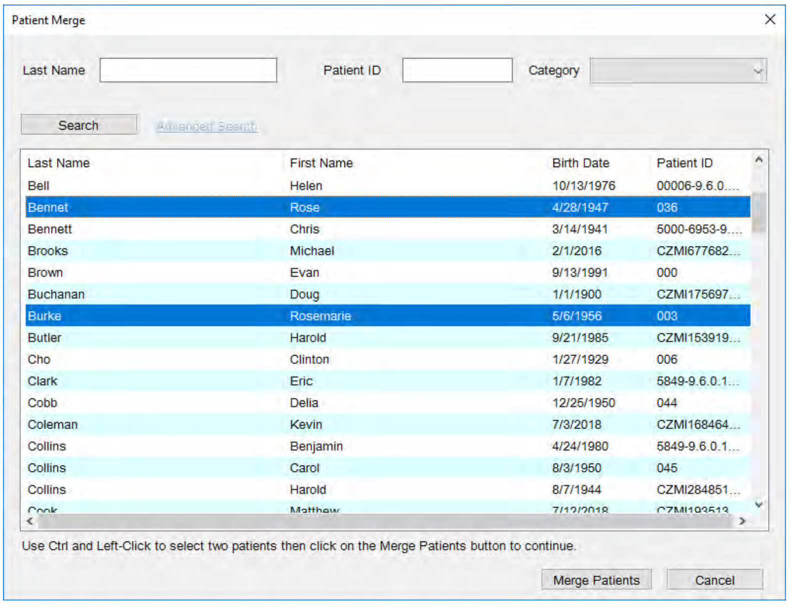
Prerequisite

☑ Log In as Operator or Data Analyst [▸ 123].

Action

1. Select **Edit > Merge Patients**.

   ⇨ The **Merge Patient** dialog opens.



2. Select the first record to merge.
3. Press **<Ctrl>** and select the second record to merge.
4. Click **Merge Patients**.

Result

✓ The patient records are now combined.

6.4.4 Move Scan

If a scan was acquired using an incorrect patient record, you can move the scan data to the correct patient using **Move Scan**.

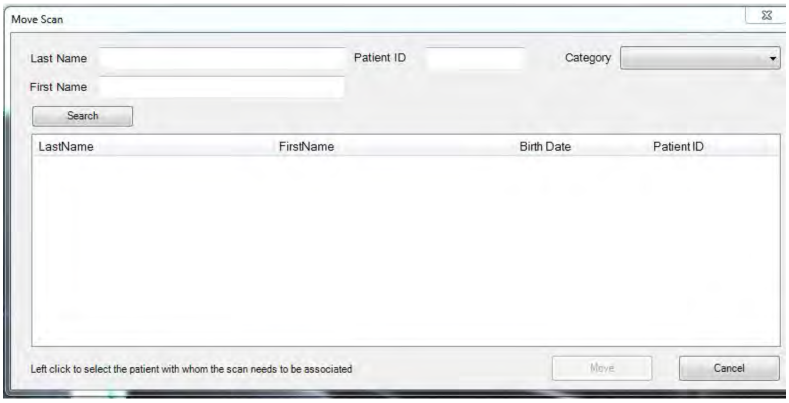
Prerequisite

☑ Log In as Operator or Data Analyst [▸ 123].

☑ A scan is selected in analyze mode.

Action

1. Select **Edit > Move Scan**.



⇨ The Move Scan window opens.

2. Click **Search** to find and select the patient scan.
3. Select **Move** to move the scan into the correct patient record.

6.4.5 Editing Patient Categories

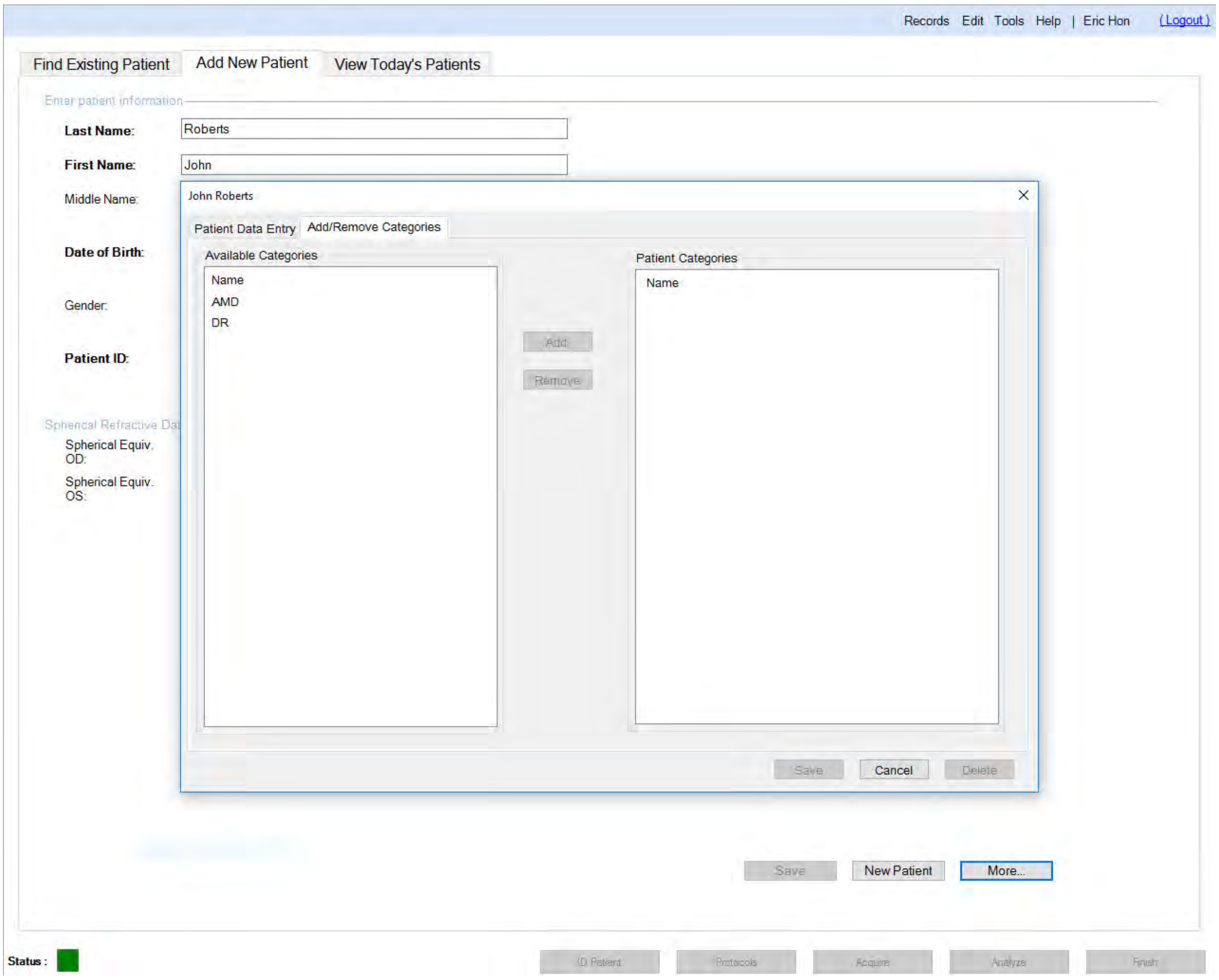
To edit a patient record:

Prerequisite

☑ Log In as Operator or Data Analyst [▸ 123].

Action

1. Select the Patient [▸ 124].
2. Select **Edit > Patient Record**.



3. Select the **Add/Remove Categories** tab.
4. To add a category, select the category from the left panel and click **Add** .
5. To remove a category, select the categories from the right panel and click **Remove**.
6. Click **Update**.
7. Click **Close**.

6.4.6 Edit Patient Records

The Edit Patient option is reached from **Edit > Patient Record.**

You must have selected a patient to edit for this option to be available. On selection, the **Patient Edit** screen appears. Follow the instructions in Adding a New Patient [▸ 126] to fill in or change the **Patient Edit** fields.

6.4.7 Print Patient Lists

Found in **Records > Print Patient Lists**, this option generates a report that includes all patients listed on the Patient screen in alphabetical order:

- Name
- Data of Birth
- Patient ID

The report can be viewed, saved or printed as described in Standard Print Options.

6.4.8 Export Data

You can export data several ways:

- Export in Native format
- Export in XML format
- Export in Native and XML format
- Export in IMG

You can export data to:

- A USB flash drive
- A folder on the instrument's hard drive
- Another CIRRUS™ HD-OCT instrument

6.4.8.1 About XML Data Export

XML Export you choose where to save the data and CIRRUS™ HD-OCT saves in a single XML file using patient and scan information to name the file as follows:

<Last Name>_<First Name>_<Middle Name>_<Patient ID>_<Date of Birth>_<Gender>_<Scan Type>_<Scan Date and Time>_<Eye>_<Export Date and Time>.xml

For example:

```
Wilson_Gordon_Matthew_46673598_1981-02-07_Pachymetry_2019-06-10093523_OU_2
0190712115204.xml
```

XML Export the following analysis types:

- Guided Progression Analysis
- Macular Change Analysis
- Anterior Chamber Analysis
- HD Angle Analysis
- Wide Angle to Angle Analysis
- Pachymetry Analysis
- HD Cornea Analysis

In addition to the analysis specific information, some XML data is the same for all types, including:

- Export Data
- Patient Data
- Visit Data
- General Scan Data

Field Name	Description
EXPORT_DATE_TIME	Date and time of export.
EXPORT_USER	User (account name) for the person who exported the file.
EXPORT_HOST	Host name of the system that created the export file.
EXPORT_INSTRUMENT_SERIAL_NUMBER	Serial number of the instrument.
EXPORT_VERSION	XML Export version and XML Schema.

Table 17: Export Data

Field Name	Description
FIRST_NAME	Patient name information.
LAST_NAME	
MIDDLE_NAMES	
NAME_PREFIX	
NAME_SUFFIX	
PATIENT_ID_ISSUER	Issuer of patient ID.
PATIENT_ID	Patient ID.
BIRTH_DATE	Patient’s Birth Date (yyyy-mm-dd or yyyy-mm).
GENDER	Patient’s Sex (Male, Female, Other, Unknown).
CATEGORY	Patient Category..
CATEGORY_NAME	The name of the category
OBSCURITY LEVEL	How much patient identification information is obscured (if applicable).
OBSCURITY ID	Obscured ID (if applicable).
ID SPHERICAL EQUIVALENT	Patient spherical equivalent.
NORMATIVE DATA	Patient Normative type (if applicable).
OTHER PATIENT IDS	Patient Other ID (if applicable).
ORIGINAL PATIENT ID	Patient ID (blank if obscured) .

Table 18: Patient Data

Field Name	Description
VISIT_DATE	Scan date (yyyy-mm-dd)

Field Name	Description
STUDY_ID	User or equipment-generated ID.
REFERRING PHYSICIAN	Patient’s primary referring physician.
REQUESTING PHYSICIAN	Physician who requested the scan (attending physician).
PROTOCOL	Scan protocol.
CREATION DATE	Study information (if applicable)
ACCESSION NUMBER	
STUDY INSTANCE UID	
UID SERIES Series level information.	

Table 19: Visit Data

Field Name	Description
SITE	Site name.
DATE TIME	The date and time of scan(yyyy-mm-ddThh:mm:ss).
PROTOCOL	Scan protocol.
SCAN LENGTH	Scan length (in mm).
SCAN DEPTH	Scan depth.
SCAN TYPE	Scan type.
Z MOTOR POSITION Z	Motor position information.
FIXATION POSITION X	Fixation target position information.
FIXATION POSITION Y	
SCAN SCALING FACTOR X	Zoom information.
SCAN SCALING FACTOR Y	
POLARIZATION SLIDER	Polarization Slider.
CHINREST LOCATION X	Chinrest adjustment information.
CHINREST LOCATION Y	
CHINREST LOCATION Z	
OCULAR LENS POSITION	Ocular lens position.
NOISE	Noise.
SATURATION	Saturation.
SIGNAL STRENGTH	Scan signal strength (0-10).
EYE TRACKING	Eye tracking.

Field Name	Description
FIXATION TARGET	Fixation target.
FIXATION BLINK RATE	Fixation blink rate.
SCAN PATTERN OFFSET X	Scan pattern adjustment information.
SCAN PATTERN OFFSET Y	
COMMENT	Scan comment.
OPERATORNAME	Username of the operator who acquired the scan.
SERIES INSTANCE UID	Series Instance unique id.

Table 20: General Scan Data

6.4.8.1.1 Macular Scans

6.4.8.1.1.1 Macular Thickness Analysis XML Export Values

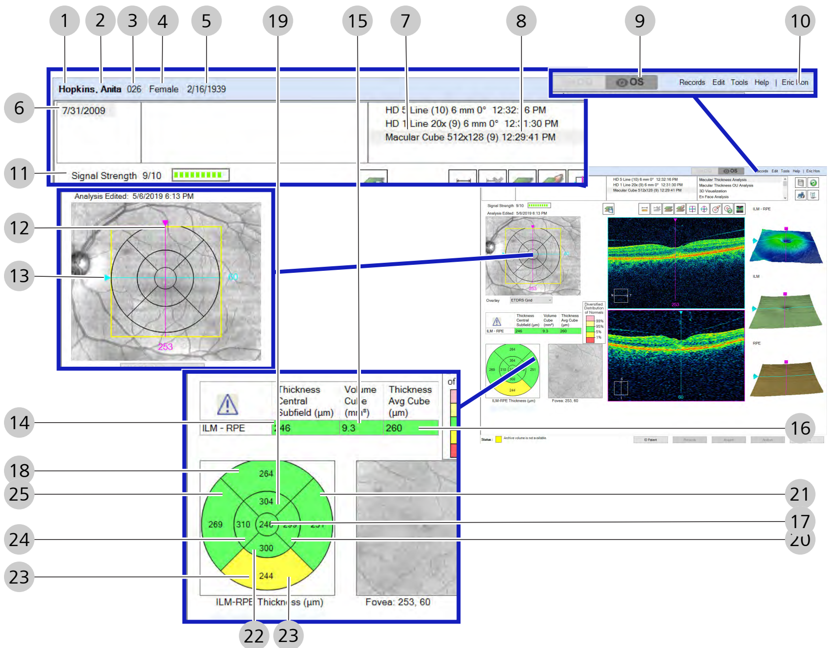


Figure 4: XML Export: Macular Thickness Analysis

1	LAST_NAME	2	FIRST_NAME
3	PATIENT_ID	4	GENDER
5	BIRTH_DATE	6	VISIT_DATE
7	PROTOCOL	8	DATE_TIME
9	SITE	10	OPERATORNAME
11	SIGNALSTRENGTH	12	FOVEA_Y
13	FOVEA_X	14	ILMRPECENTRAL

15	ILMRPEVOLUME	16	ILMRPEAVERAGE
17	Z_CENTER	18	Z_OUTERSUPERIOR
19	Z_INNERSUPERIOR	20	Z_INNERRIGHT
21	Z_OUTERRIGHT	22	Z_INNERINFERIOR
23	Z_OUTERINFERIOR	24	Z_INNERLEFT
25	Z_OUTERLEFT		

6.4.8.1.1.2 Macular Change Analysis XML Export Values

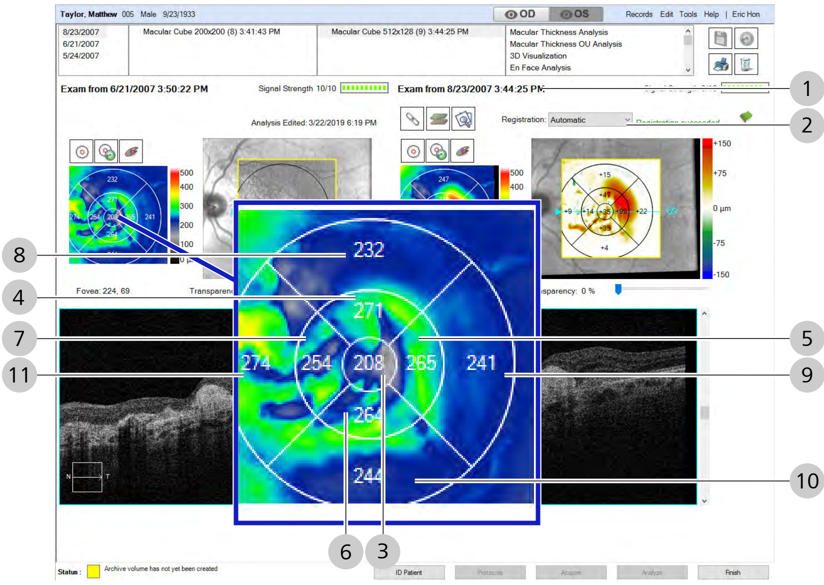


Figure 5: XML Export: Macular Change

1	DATE_TIME	2	REGISTRATION
3	Z_CENTER	4	Z_INNERSUPERIOR
5	Z_INNERRIGHT	6	Z_INNERINFERIOR
7	Z_INNERLEFT	8	Z_OUTERSUPERIOR
9	Z_OUTERRIGHT	10	Z_OUTERINFERIOR
11	Z_OUTERLEFT	12	FOVEA_X,Y

6.4.8.1.1.3 Advanced RPE Anaylsis XML Export Values

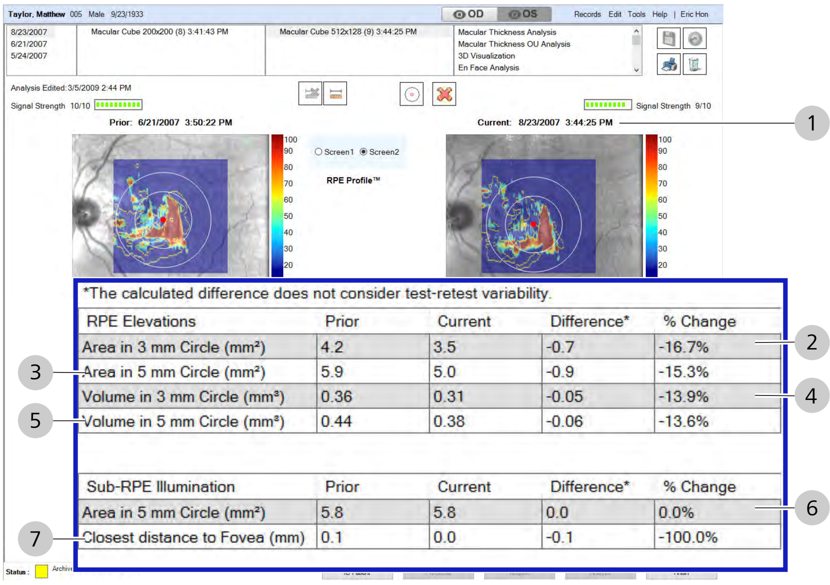


Figure 6: Advanced Export

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		

6.4.8.1.1.4 Ganglion Cell OU Analysis XML Export Values

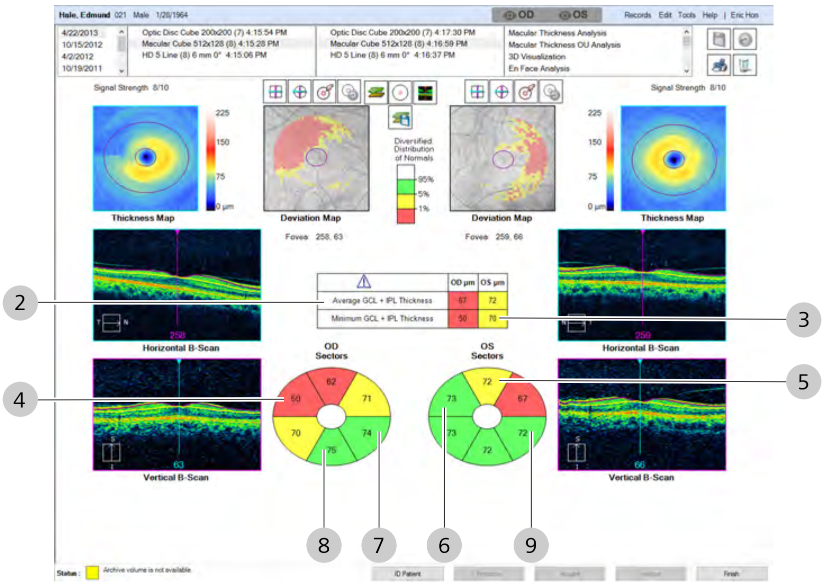


Figure 7: Ganglion Cell OU Advanced Export

1	SITE	2	GC_AVERAGE
3	GC_MINIMUM	4	GC_TEMPSUP

5	GC_SUP	6	GC_NASSUP
7	GC_NASINF	8	GC_INF
9	GC_TEMPINF		

6.4.8.1.1.5 Ganglion Cell Guided Progression XML Export Values

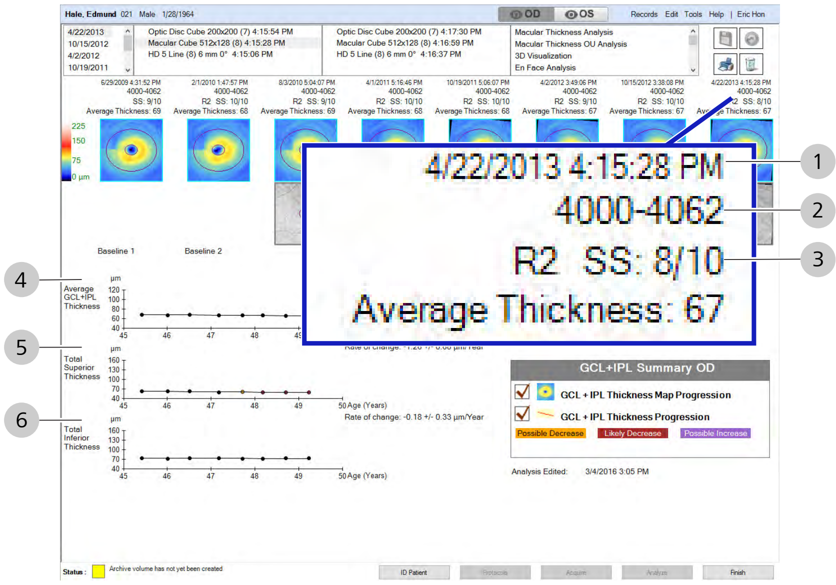


Figure 8: XML Export : Guided Progression Analysis

1	DATE_TIME	2	SERIAL_NUMBER
3	SIGNAL_STRENGTH	4	OVERALL_THICKNESS
5	SUPERIOR_THICKNESS	6	INFERIOR_THICKNESS

6.4.8.1.2 ONH and RNFL Scans

6.4.8.1.2.1 ONH and RNFL OU Analysis XML Export Values

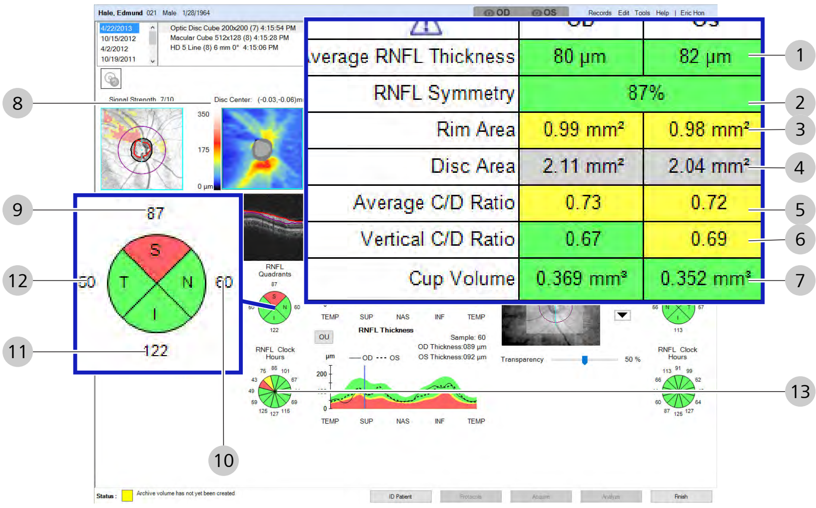


Figure 9: XML Export: ONH / RNFL OU

1	AVERAGETHICKNESS	2	SYMMETRY
3	RIMAREA	4	DISCAREA
5	AVERAGE_CD_RATIO	6	VERTICAL_CD_RATIO
7	CUPVOLUME	8	ONHCENTER_X,Y
9	QUADRANT_S	10	QUADRANT_N
11	QUADRANT_I	12	QUADRANT_T
13	CLOCKHOUR–1–12		

6.4.8.1.3 Angiography Scans

6.4.8.1.3.1 Angiography Analysis XML Export Values

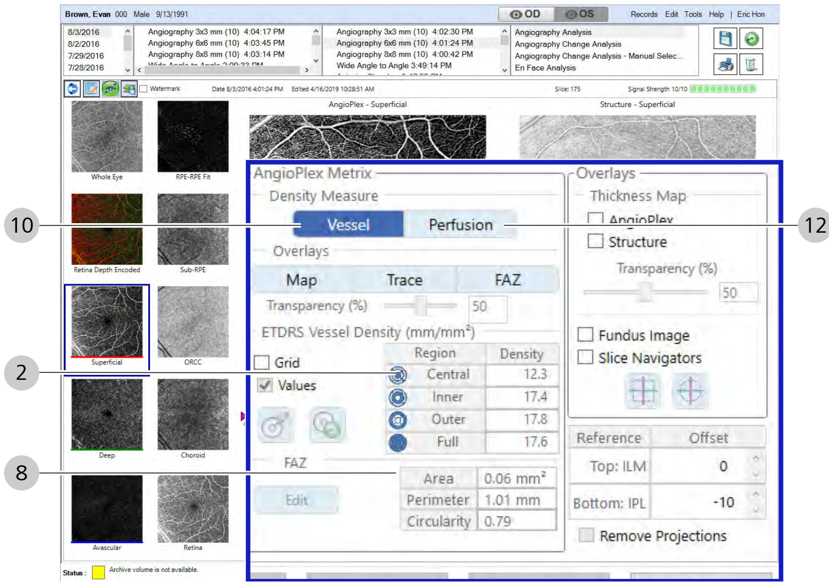


Figure 10: XML Export : Angiography Analysis

1	FOVEA_LOCATION {X,Y}	2	CENTRALSUBFIELDTHICKNESS ■ ILMRPE ■ ILMRPEFIT ■ RPERPEFIT
5	CUBEVOLUME ■ ILMRPE ■ ILMRPEFIT ■ RPERPEFIT	6	CUBEAVGTHICKNESS ■ ILMRPE ■ ILMRPEFIT ■ RPERPEFIT
7	FAZ_Center{X, Y}	8	FAZ_Area FAZ_Perimeter FAZ_CircularityIndex
9	FOVEA_LOCATION {X,Y}	10	VESSEL_ETDRS ■ Z_CENTER ■ Z_INNERRIGHT ■ Z_INNERSUPERIOR ■ Z_INNERLEFT ■ Z_INNERINFERIOR ■ Z_OUTERRIGHT ■ Z_OUTERSUPERIOR ■ Z_OUTERLEFT ■ Z_OUTERINFERIOR

11	VESSEL_CENTRAL_MEAN VESSEL_INNER_MEAN VESSEL_OUTER_MEAN VESSEL_FULL_MEAN	12	PERFUSION_ETDRS ■ Z_CENTER ■ Z_INNERRIGHT ■ Z_INNERSUPERIOR ■ Z_INNERLEFT ■ Z_INNERINFERIOR ■ Z_OUTERRIGHT ■ Z_OUTERSUPERIOR ■ Z_OUTERLEFT ■ Z_OUTERINFERIOR
13	PERFUSION_CENTRAL_MEAN PERFUSION_OUTER_MEAN PERFUSION_INNER_MEAN PERFUSION_FULL_MEAN		

6.4.8.1.3.2 ONH Angiography Analysis XML Export Values

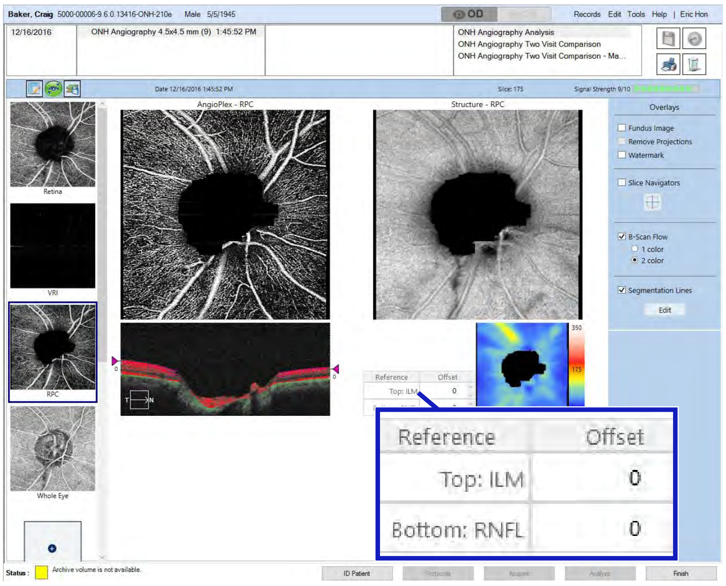


Figure 11: XML Export: ONH Angiography Analysis

1	ONH_CenterX ONH_CenterY	2	PERFUSION_ETDRS ■ Z_NASAL ■ Z_SUPERIOR ■ Z_TEMPORAL ■ Z_INFERIOR

3	FLUX_ETDRS ■ Z_NASAL ■ Z_SUPERIOR ■ Z_TEMPORAL ■ Z_INFERIOR	4	PERFUSION_OUTER_MEAN
5	FLUX_OUTER_MEAN		

6.4.8.1.4 Anterior Segment Scans

6.4.8.1.4.1 Anterior Chamber Analysis XML Export Values

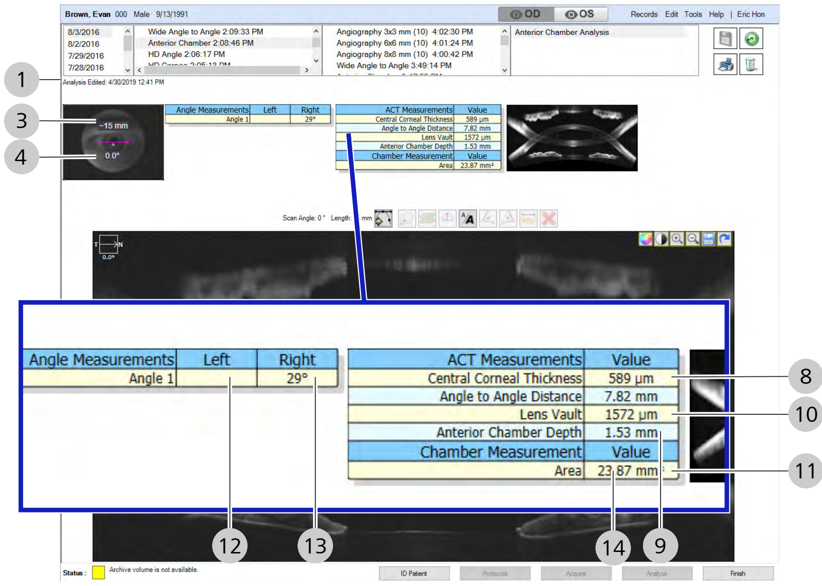


Figure 12: XML Export: Anterior Chamber Analysis

1	HD_LASTEDITED	2	SIGNAL_STRENGTH
3	SCAN_LENGTH	4	SCAN_ANGLE
5	SCAN_SPACING	6	CALIPER_MEASUREMENT
7	ANNOTATION_MEASUREMENT	8	CCT
9	ATA	10	CLR
11	ACD	12	LEFTANGLE
13	RIGHTANGLE	14	CHAMBER_AREA

6.4.8.1.4.2 HD Angle Analysis XML Export Values

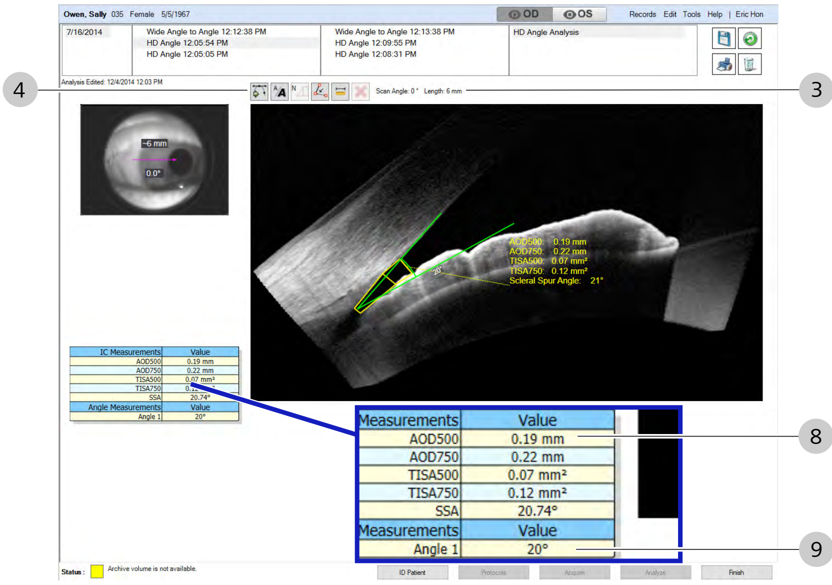


Figure 13: XML Export : HD Angle Analysis

1	HD_LASTEDITED	2	SIGNAL_STRENGTH
3	SCAN_LENGTH	4	SCAN_ANGLE
5	SCAN_SPACING	6	CALIPER_MEASUREMENT ■ DECIMAL_PLACES
7	ANNOTATION_MEASUREMENT ■ ANNOTATION_TEXT	8	IC_Angle ■ A0D500 ■ Distance ■ A0D750 ■ Distance ■ TISA500 ■ Space Area ■ TISA750 ■ Space Area ■ SSA ■ LOCATION – Nasal = Left eye, left angle or right eye, right angle – Temporal = Left eye, right angle or right eye, left angle
9	ANGLE		

6.4.8.1.4.3 HD Cornea Analysis XML Export Values

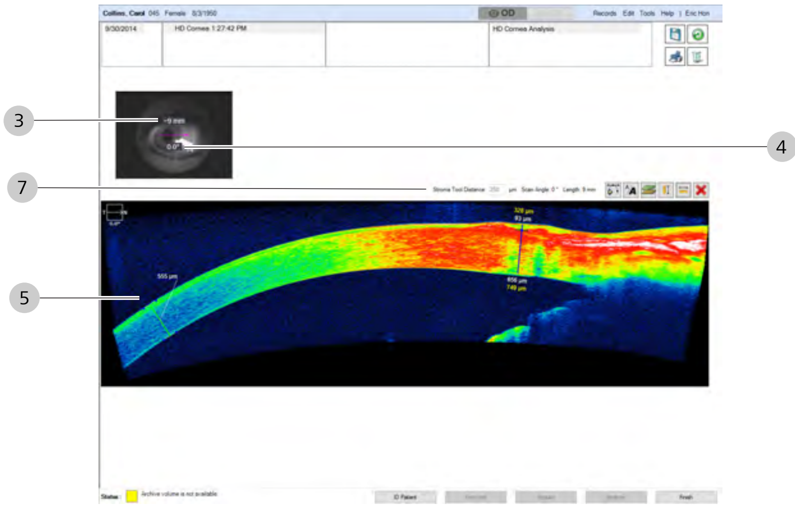


Figure 14: XML Export : HD Cornea Analysis

1	HD_LASTEDITED	2	SIGNAL_STRENGTH
3	SCAN_LENGTH	4	SCAN_ANGLE
5	CALIPER_MEASUREMENT	6	ANNOTATION_MEASUREMENT
7	STROMA_TOOL_DISTANCE		

6.4.8.1.4.4 Wide Angle to Angle Analysis XML Export Values

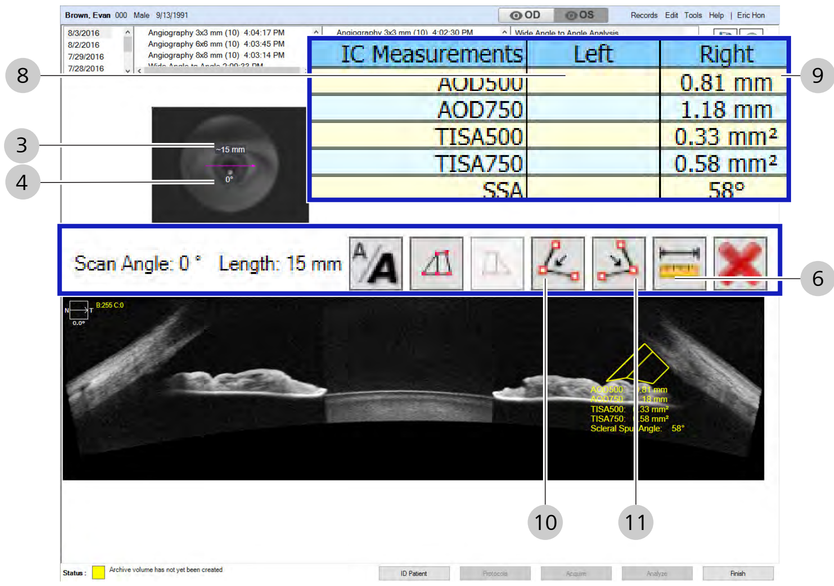


Figure 15: XML Export: Wide Angle to Angle Analysis

1	HD_LASTEDITED	2	SIGNAL_STRENGTH
3	SCAN_LENGTH	4	SCAN_ANGLE
5	SCAN_SPACING	6	CALIPER_MEASUREMENT ■ DECIMAL_PLACES

<table>
<tr><td>7</td><td>ANNOTATION_MEASUREMENT
ANNOTATION_TEXT</td><td>8</td><td>IC_LEFT
A0D500
Distance
A0D750
Distance
TISA500
Space Area
TISA750
Space Area
SSA
LOCATION
Nasal = Left eye, left angle or right eye, right angle
Temporal = Left eye, right angle or right eye, left angle</td></tr>
<tr><td>9</td><td>IC_RIGHT
A0D500
Distance
A0D750
Distance
TISA500
Space Area
TISA750
Space Area
SSA
LOCATION
Nasal = Left eye, left angle or right eye, right angle
Temporal = Left eye, right angle or right eye, left angle</td><td>10</td><td>LEFTANGLE</td></tr>
<tr><td>11</td><td>RIGHTANGLE</td><td></td><td></td></tr>
</table>

6.4.8.1.4.5 Pachymetry and Epithelial Thickness Analysis XML Export Values

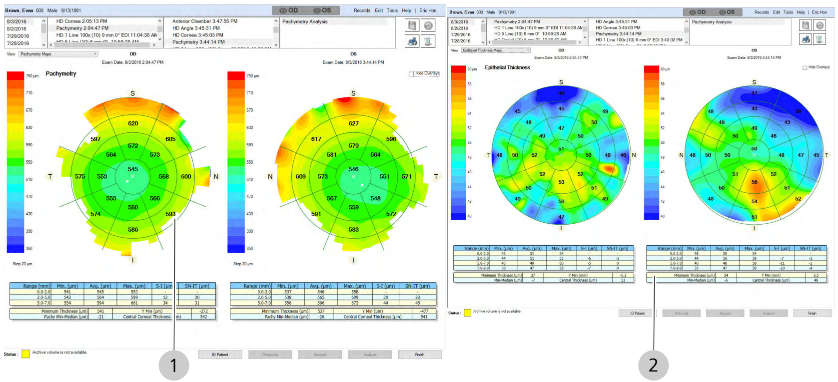


Figure 16: XML Export: Pachymetry Analysis

1	SUBFIELD_OD ■ SUBMAXDATA ■ SUBMEANDATA ■ SUBMINDATA ■ EPITHELIALSUBMAXDATA ■ EPITHELIALSUBMEANDATA	2	SUBFIELD_OS ■ SUBMAXDATA ■ SUBMEANDATA ■ SUBMINDATA ■ EPITHELIALSUBMAXDATA ■ EPITHELIALSUBMEANDATA

6.4.8.2 Data Export Options

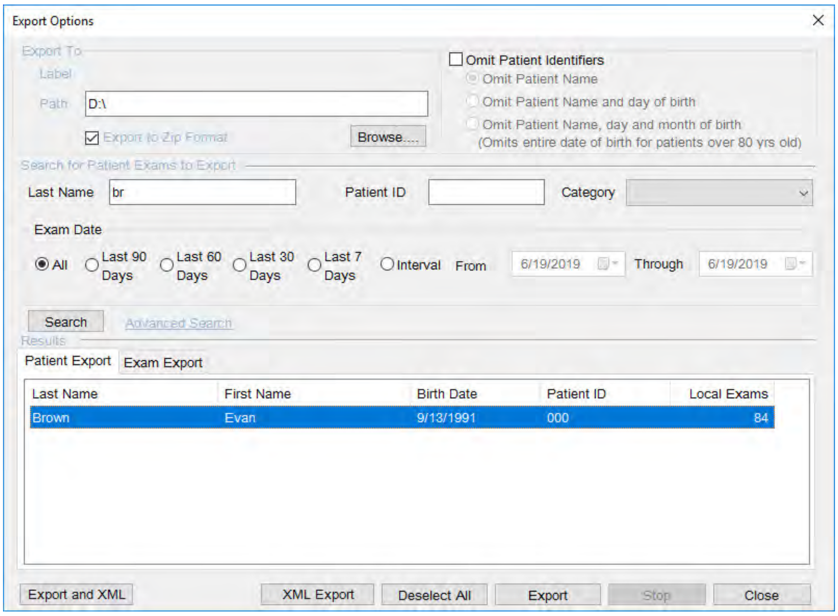


Figure 17: Data Export

Export Type	Description
Export and XML	Exports patient data in both its **Native** format and **XML** format simultaneously. ■ Maximum of 100 exams per export ■ **Export to Zip Format** not recommended

Export Type	Description
XML Export	Exports patient data formatted as an XML file with values of OCT Angiograpaphy and the Cube reports, including: ■ Patient Identifiers (or tokens if patient identification is omitted) ■ Study Identifiers ■ Scan Information including: – OD or OS – Scan Type, Scan identifiers, and instrument identifiers – Tracking details including fixation data over time (if available)
Export	Exports patient data in its existing format.

6.4.8.3 Exporting Data

NOTE

Creating a zip file takes extra time to compress.

Do not try to export a large numbers of patient exams into a single zip file.

NOTE

Always create a new folder when exporting zip files

If you export zip files to a folder that has existing files from previous exports, the new zip file will combine the newly exported records with the existing files (excluding existing zip files).

Tip: You can save time by using the same folder to export patient data.

If you export to the same folder as a prior export, you can choose to update the prior export or overwrite all data.

NOTE! If an export process is interrupted, you can restart the export. If you use the same folder, the export will continue.

Prerequisite

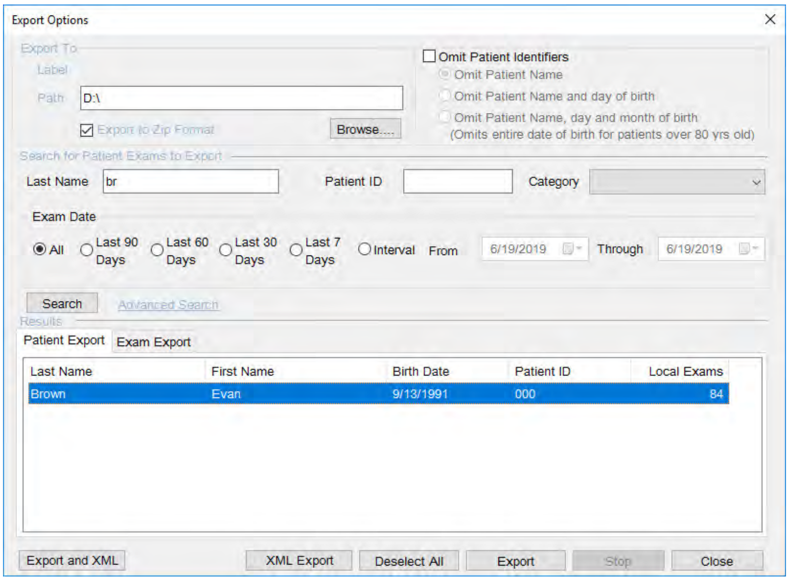
☑ Removable media is inserted (If saving to removable media such as a USB flash drive)

☑ Target system login is successful (If the target system requires a password for access).

☑ Log In as Operator or Data Analyst [▹ 123].

Action

1. Select **Records > Export Exams**.
   ⇨ The **Export Exams** dialog opens showing the last export path. (On first export, **Path** is empty.)



2. To change the export destination, click **Browse** and navigate to the desired location.
3. To create a new folder for the exported files, click **Make New Folder**.
4. Click **OK**.

   ⇨ **Path** displays the new path.
5. To export the data compressed into one zip file, check **Export to Zip**.
6. To hide patient identifying information (as for a clinical trials) check **Omit Patient Identifiers** and select an option. For more information, refer to: Patient Identifying Information Omission Options [▷ 110].
7. To find the exams for a patient, type the patient's last name, ID or select a category. You can also select a time interval to limit the search results.
8. Click **Search**.
9. Click **Search**.

   ⇨ For additional search options, refer to Advanced Search [▷ 132].
10. Under **Results**, click on the records to export.
    Click **Select All** in the Patient Export window to select all patients in the list.
    Press **Ctrl** while clicking on each record to select multiple records.
    In the Exam Export window, you may export individual scans for the patient you selected in the Patient Export window.
    Press **Ctrl** and click on each scan to select multiple scans.
11. Select an **Export Option** (see: Data Export Options [▷ 107]).
12. Click **Export**.

⇨ If you are exporting to a folder used in a prior export, a prompt opens.

13. If the prompt opens, select:
Increment to update the last export (retains existing exported data and add any new or changed data.)
Overwrite to replace all data.

Result

✓ A progress dialog opens to inform you as the export process progresses.

6.4.8.4 Patient Identifying Information Omission Options

NOTE

You cannot edit or merge patient information in data imported with identifying information omitted.

NOTE

System-generated patient identifiers do not change.

There was a change in the way patient identifiers are generated when you want to obscure the patient's *name*, *day*, and *month* of birth.

- ▶ If a patient's records were not yet exported, a unique identifier is assigned using the **New Method**.
- ▶ If a patient's records were already exported using the original ID generation process **Obsolete Method**, future exports will use the same identifier as before.

Option	Description
Omit: ■ Patient Name	■ Replaces patient's **Last Name** with the institution name. ■ Replaces patient's **First Name** and **Patient ID** with a unique 17-character number. **NOTE! The unique number is the date and time (to the thousandth of a second) that the patient record was originally created. Example: 20070609081320226.**
Omit: ■ Patient Name ■ *Day* of birthday	In addition: ■ Replaces the day of birth with **1**. For example, the birthday `10/22/1995` becomes `10/1/1995`. **NOTE! For patients over 80 years old, the year of birth changes to <current year> - 80.**

Option	Description
Omit: ■ Patient Name ■ *Day* of birthday ■ *Month* of birthday	**(New Method)** Generates a unique identifier for the patient (does not correlate to the patient name or birthday).
	(Obsolete Method) ■ Replaces patient's **Last Name** with the institution name. ■ Replaces patient's **First Name** and **Patient ID** with a unique 17-character number. ■ Replaces the day of birth and month of birth with **1**. For example, the birthday `10/22/1995` becomes `1/1/1995`. **NOTE! The unique number is the date and time (to the thousandth of a second) that the patient record was originally created. Example: 20070609081320226.** **NOTE! For patients over 80 years old, the year of birth changes to <current year> - 80.**

Table 21: Identifier Omission Options

6.4.9 Import Data

6.4.9.1 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 device encounters information associated with a patient that was already imported, the device 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 action prevents overwriting of newer patient data with older data.

6.4.9.2 Importing Data

NOTE

ZIP files containing a large number of patients a great deal of time to uncompress on import.

When importing data, you do not need to uncompress the `ZIP` file prior to importing it; all data will be imported.

To import data:

Prerequisite

☑ Removable media is inserted (If saving to removable media such as a USB flash drive)

☑ Target system login is successful (If the target system requires a password for access).

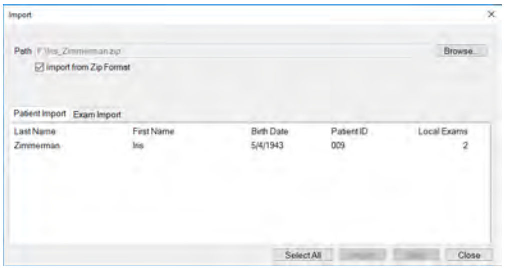
☑ Log In as Operator or Data Analyst [▷ 123].

Action

1. Select **Records > Import Exams**.

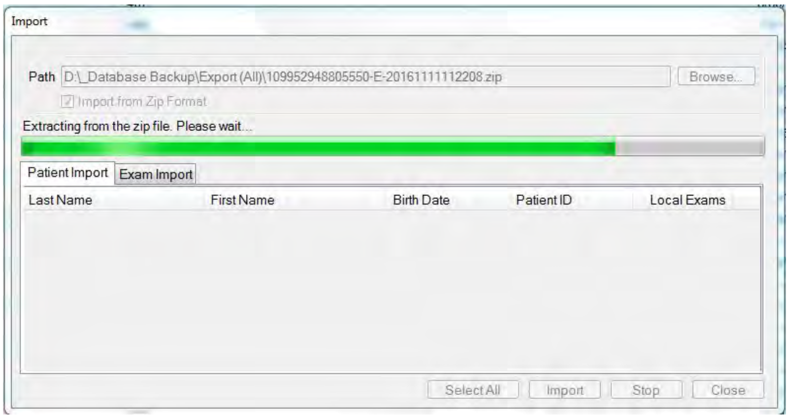
⇨ The **Import** dialog opens.

2. Navigate to the exams to import.
3. To import specific exams, select the **Exam Import** tab.



4. To import by patient identifiers, select the **Patient Import** tab.

5. Click on the patients to import.
   To select multiple patients, **Ctrl-click**.
   To select all patients in the list, click **Select All**.
6. Click **Import**.



Result

✓ The records are imported into your current database.

6.5 Configuring Reports

Some types of analysis offer custom options for the printed reports. The reports you can configure are:

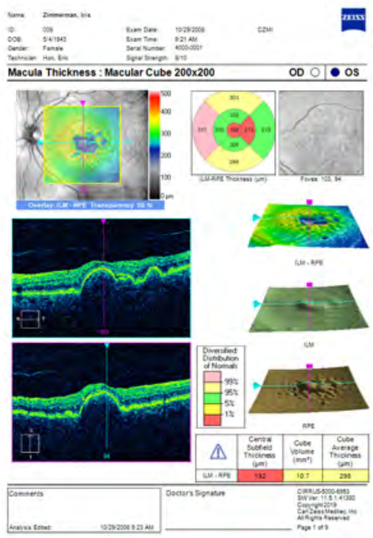
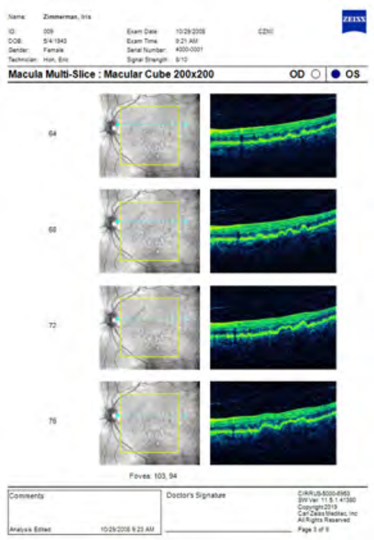
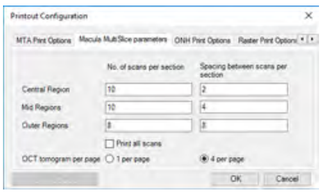
- Macular Thickness Report [▸ 113]
- ONH Report [▸ 115]
- HD Image Report [▸ 115]
- Guided Progression Reports [▸ 116]

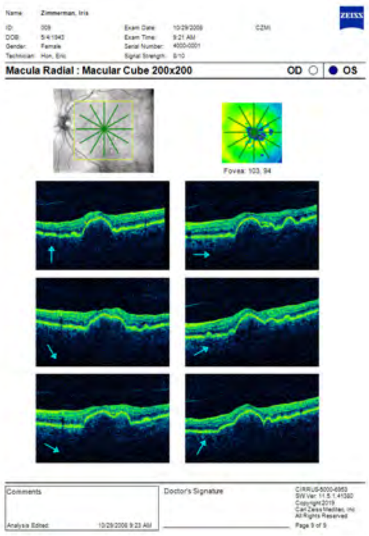
6.5.1 Configuring Macular Thickness Reports

There are three types of reports for the Macular Thickness analysis [▸ 238]:

- Macula Thickness Report
- Macula Multi-Slice Report
- Macula Radial Report

You can choose whether to include one, two or all three types of **Macula Thickness** reports.

Report	Settings
Macula Thickness Report 	None
Macula Multi-Slice Report 	Includes images of the central fast B-scan and adjacent B-scans on a series of pages, each showing a set of Macula slices. You can set which slices to print, the number of scans to print per region and the spacing between the scans (which determines the number of page the report produces).  For each region, set: ■ number of scans ■ spaces between scans **Central Region** the central 1 mm (1000 µm) of the cube (the equivalent of 500 µm above and 500 µm below the central B-scan) **Mid–Regions** the next 1.0 mm above and below the Central Region. **Outer Regions** the 1.5 mm of area above and below the Mid Regions. **Print all Scans** check or uncheck **OCT tomogram per page**1 or 4

Report	Settings
Macula Radial Report  	Produces a radial line report; six B-scans at meridians of: ■ 0 degrees ■ 30 ■ 60 ■ 90 ■ 120 ■ 150 (right eye) or 300 x 330 (left eye). If you select **Macula Multi-Slice**, complete additional settings for this report on the **Macula MultiSlice parameters** tab. **NOTE! If the radial pattern position causes a portion of a lines to extend outside the boundary, no OCT data appears.**

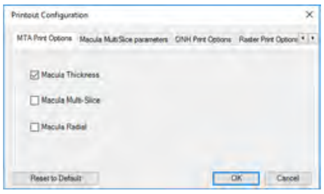
To configure macular thickness reports:

Prerequisite

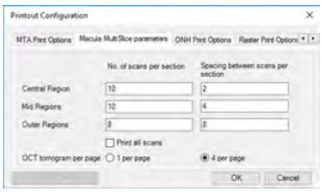
☑ Log In as Operator or Data Analyst [▸ 123].

Action

1. Select **Tools** > **Print Configuration**.
   ⇨ The **Printout Configuration** dialog opens.
2. Select the **MTA Print Options** tab.



3. To set report to the default, click **Reset to Default**.
4. To set report to Macular Multi Slice, check **Macula Multi Slice**, click **OK** and select the **Macula MultiSlice parameters** tab.



   ⇨ Type the number of scans for each section or to omit scans for the region, type 0.
   ⇨ Type the number of spaces between scans for each region.
   ⇨ To print all scans, check **Print all scans**.
   ⇨ Select whether to print 1 or 4 *OCT tomograms* per page.
5. To set report to Macular Radial, check **Macula Radial** .
6. Click **OK**.

Result

✓ Macular thickness analysis reports now include your new selection(s).

6.5.2 Configuring ONH Reports

You can customize the **ONH OU** report to include a second page for the patient.

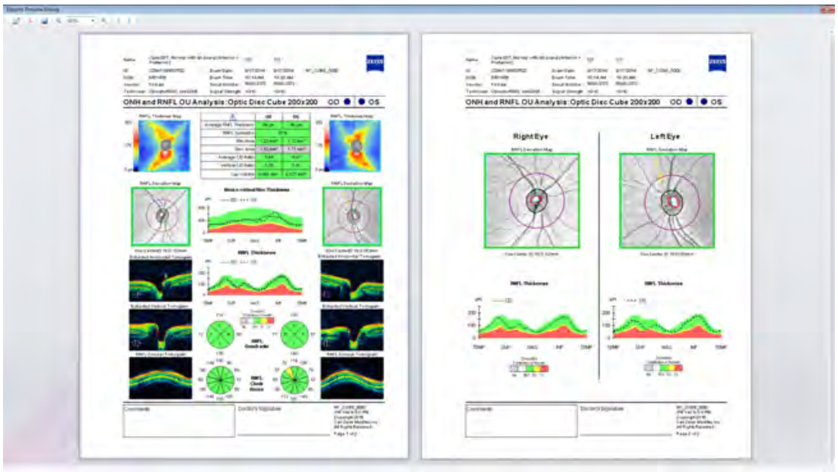


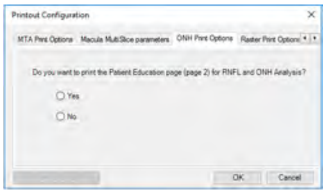
Figure 18: ONH OU Report with Patient Education Page

To configure ONH OU reports:

Prerequisite

☑ Log In as Operator or Data Analyst [▷ 123].

Action



1. Select **Tools** > **Print Configuration**.
   ⇨ The **Printout Configuration** dialog opens.
2. Select the **ONH Print Options** tab.
3. To include the patient education page, click **Yes**.
4. To omit the patient education page, click **No**.
5. Click **OK**.

6.5.3 Configuring HD Image Reports

The **HD Image** report includes:

- Fundus image showing the placement of the line scans
- thumbnails of the scan lines
- single larger image of the selected scan line (for HD Cross: middle vertical and horizontal images)

You can customize the **HD Image** report to print all lines (multiple pages) or only the selected line (single page).

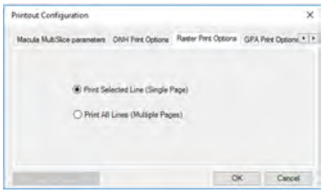
To configure HD Image reports:

Prerequisite

☑ Log In as Operator or Data Analyst [▷ 123].

Action

1. Select **Tools** > **Print Configuration**.
   ⇨ The **Printout Configuration** dialog opens.
2. Select the **Raster Print Options** tab.



3. To include only the line selected, choose **Print Selected Line**.
4. To include all lines, choose **Print All Lines**.
5. Click **OK**.

6.5.4 Configuring Guided Progression Reports

You can set the Guided Progression reports as 1-page or 2-page reports. If you set 1-page reports, you can set whether the page shows the summary or just the latest scan.

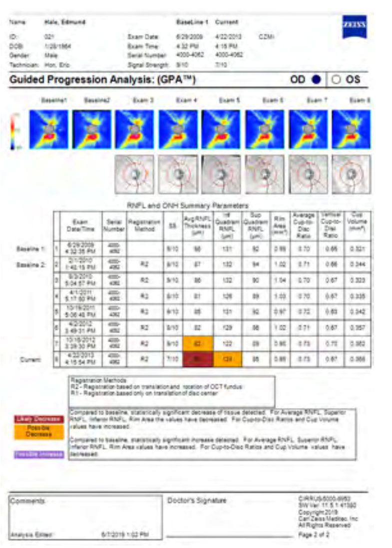
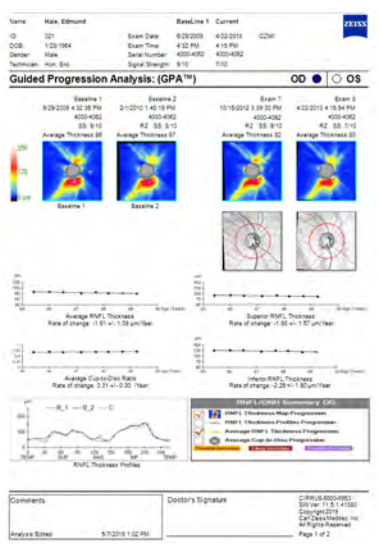
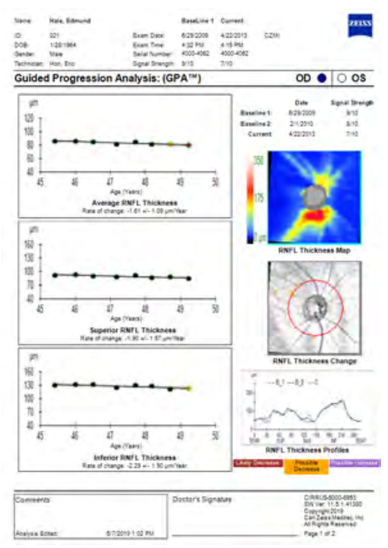
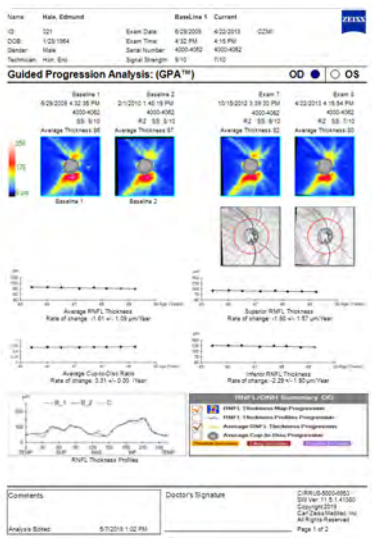
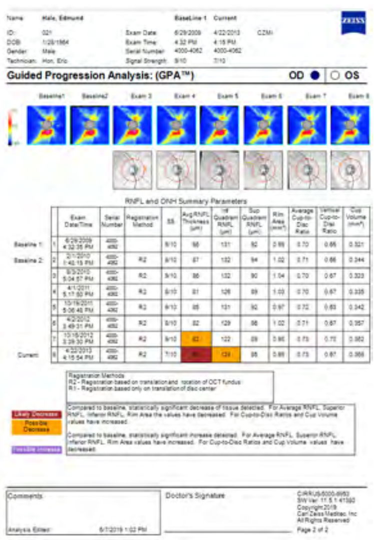
No Selection	Summary	Latest Scan
		

Table 22: Options for 1-Page Guided Progression Reports

Page 1	Page 2
Summary 	

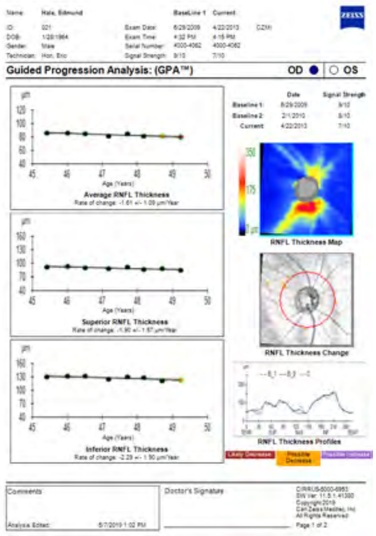
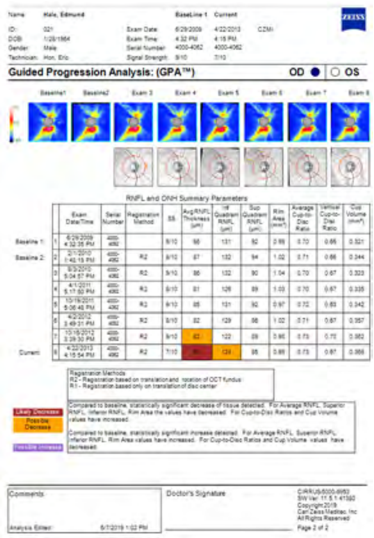
Page 1	Page 2
Latest Scan 	

Table 23: Options for Multi-Page Guided Progression Reports

To configure Guided Progression reports:

Prerequisite

☑ Log In as Operator or Data Analyst [▹ 123].

Action

1. Select **Tools** > **Print Configuration**.
   ⇨ The **Printout Configuration** dialog opens.
2. Select the **GPA Print Options** tab.
3. To generate guided progression as a one-page report, choose **Print Single Page** and select **Summary** or **Latest Scan Only**.
4. To generate guided progression as multi-page report , choose **Print All Pages** and select whether the first page includes **Summary** or **Latest Scan Only**.
5. Click **OK**.

6.6 Customizing Settings

6.6.1 Customizing the Available Scans List

NOTE

You must organize scans using the CIRRUS™ HD-OCT instrument.

Since review stations do not acquire scans, you cannot organize scan types from a review station.

NOTE

Your instrument might show a different list of scan types.

The types of scans that are available on the instrument depends on the licenses that you purchased for the instrument. Refer to: About Licenses [▹ 61].

You can change the list of scan types that appears at the top of the Acquire screen to make it easier for the instrument operator to find the type of scan(s) that your site uses most frequently. You can:

- Hide some types of scans from the list
- Re-organize the list

Prerequisite

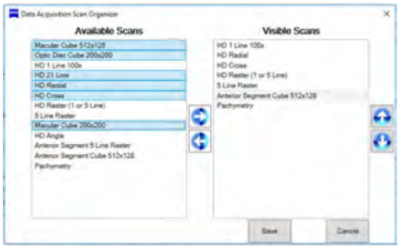
☑ Log In as Operator or Data Analyst [▸ 123]

☑ View Today's Patients Screen [▸ 134]

Action

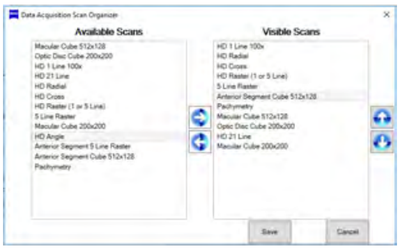
1. Select **Tools** > **Scan Organizer**.

   ⇨ The scan organizer opens showing the full list of scans types available for the instrument.



2. Under **Available Scans**, select the scan type(s) that you want the instrument to display and click .

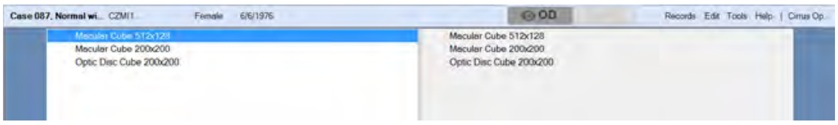
   ⇨ The scans appear under **Visible Scans**.



3. To hide a scan from the list select the scan type under **Visible Scans** and click .
4. To move a scan higher on the list, select the scan type under **Visible Scans** and click .
5. To move a scan lower on the list, select the scan type under **Visible Scans** and click .

Result

✓ The new list you created under **Visible Scans** now appears when an operator acquires scans.



6.6.2 Set Preferred Analyses

NOTE

Your instrument might show a different list of scans and analyses.

The types of scans and analyses available depends on the licenses installed the instrument or review station. See: About Licenses [▸ 61].

You can customize the preferred analyses to use for a particular type of scan.

For example, if you:

1. Set **Macular Change Analysis** as the preferred analysis for **Macular Cube 512 x 128** scan.
2. Select a patient with **Macular Cube 512 x 128** scans acquired during two different visits and click **Analyze**.

Macular Change Analysis opens automatically, showing the patient's macular cube images from both visits for change comparison.

You can set a preferred analyses for (up to) five types of scans.

CIRRUS 6000 uses the first applicable preferred analyses for the selected scan.

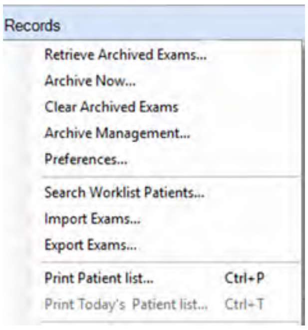
To set the preferred analysis for a type of scan:

Prerequisite

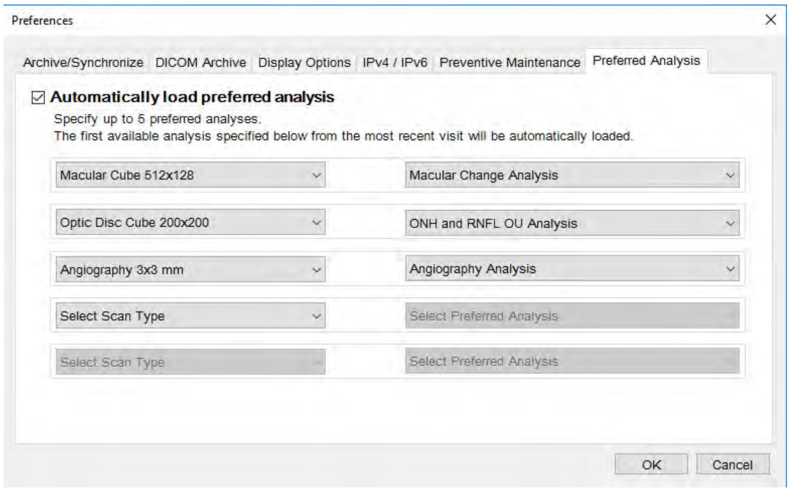
☑ Log In as Operator or Data Analyst [▹ 123]

☑ View Today's Patients Screen [▹ 134]

Action



1. Select **Records > Preferences.**
   ⇨ The **Preferences** dialog opens.



2. Select the **Preferred Analysis** tab.
3. For the first available **Select Scan Type**, choose the scan you want to associate with a preferred analysis.
   ⇨ The scan organizer shows the full list of scans types available for the instrument.
4. For **Select Preferred Analysis**, choose the analysis you want to associate to the scan.
5. To set additional preferred analyses, repeat the steps above. You can associate up to five scans with a preferred analysis.
6. Click **OK**.

Result

✓ When you analyze a scan, CIRRUS 6000 opens the first available scan specified in the preferred analysis list.

6.6.3 Turn FastTrac™ On or OFF

FastTrac™ performs two functions (see About FastTrac™ [▹ 217]):

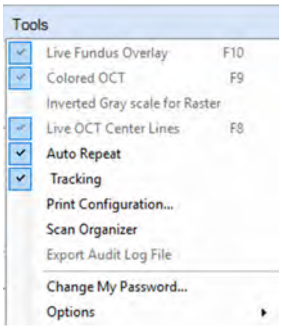
- When acquiring an OCT scan, **FastTrac™** tracks the position of the eye to minimize the effects of eye motion.
- **FastTrac™** also tracks an OCT scan to OCT scan acquired from a previous visit.

Before using the **FastTrac™** feature the first time, make sure you complete the Performance Verification Check.

Auto Repeat automatically reuses chinrest settings from an earlier scan for the same patient and same type of scan for the same eye (see About Auto Repeat [▸ 216]).

To enable FastTrac™:

Prerequisite



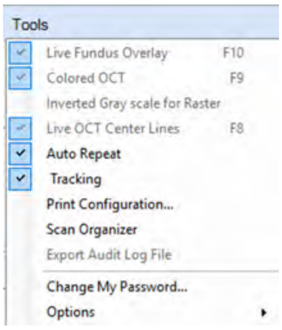
☑ Tracking is off (unchecked).

Action

1. Select **Tools** > **Auto Repeat**.
   ⇨ **Auto Repeat** is checked.
2. Select **Tools** > **Tracking**.
   ⇨ **Tracking** is checked.
   ⇨ The **Capture** button displays a green border for scans that can use **FastTrac™.**
3. If this is the first time **FastTrac™** is enabled on the instrument, complete the Performance Verification Check.

To disable FastTrac™:

Prerequisite



☑ Tracking is on (checked).

4. Select **Tools** > **Tracking**.
   ⇨ **Tracking** is unchecked.

7 Before Every Use

7.1 Safety During Preparation for Use

⚠ CAUTION!

Improper operator training

could lead to poor scan quality, damage to system components, or inadvertent patient safety compromise.

- Train all operators fully.
- Ensure all personnel are familiar with the information contained in the Safety and Certifications chapter.
- Ensure that routine maintenance has been properly carried out in conformance with the Maintenance Schedules described in the Maintenance chapter.

⚠ CAUTION!

Neglecting to prompt the patient to move their head away from the chinrest and sit back on completion of Patient ID or Scanning

could result in injury to the patient when the chinrest repositions itself.

- Before you click the **Finish** or **ID Patient** in the Acquire screen, always prompt the patient to sit back and move their head away from the chinrest.

⚠ CAUTION!

Patients who hold on to the instrument before or during tests

risk having their fingers pinched and possibly injured.

- Make sure that the patient is not holding on to the instrument before or during tests.

7.2 Prepare the Instrument for Use

⚠ CAUTION!

Neglecting to disinfect device could lead to cross infection between patients.

- Refer to Cleaning the Chin Cup and Forehead Rest [▸ 409] for more information.

NOTE

If a database, installation files, or instrument error occurs:

- Do not use the instrument.
- Contact your Zeiss representative.

NOTE

Make sure you archive scans frequently to ensure that there is enough storage space to acquire new scans.

Action

1. Wipe the chinrest and forehead rest with an alcohol pad and allow it to dry.
2. Turn on the instrument (see: System Startup).
3. Select the Patient [▸ 124].

7.3 Read and Understand Physician Instructions

For each patient scheduled for scans today:

Action

1. Carefully read all instructions from the officiating physician or researcher.
2. Ensure that you fully understand all instructions before starting the examination.

8 Operation

8.1 User Login/Logout

8.1.1 Log In as Operator or Data Analyst

NOTE

Passwords are case–sensitive.

You are prompted to log in:

- After system startup
- After application logout

For information about the features available for operators, data analysts and administrators, refer to: User Types [▸ 70].

To log in as operator or data analyst:

Prerequisite

☑ The instrument is on: System Startup [▸ 54].

☑ The administrator created your user account: Adding a New User [▸ 71].

Action

1. Open the CIRRUS 6000 application.

2. Select your user name from the list.
3. Type your password.
4. Click **OK**.
5. The ID Patient screen opens.

8.1.2 Review Station Login

NOTE

Passwords are case–sensitive.

You can use a *Review Station* to access, analyze, edit, save, and export scans and print reports.

To log in to a Review Station:

Prerequisite

☑ The administrator created your user account: Adding a New User [▸ 71].

☑ Review Station software is installed on the computer (Installing Review Station Software [▸ 42]).

Action

1. Open the CIRRUS 6000 application.

2. Select your user name from the list.
3. Type your password.
4. Click **OK**.
5. The ID Patient screen opens.

8.1.3 Log Out

NOTE

Inactivity causes the instrument to go into "sleep" mode.

You can set the time limit that triggers sleep mode and a password to wake the instrument.

You can also set hibernate or hybrid options.

▶ Refer to the Windows documentation for **Power Options**.

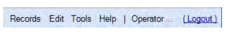
Logging out locks the CIRRUS 6000 and prevents unauthorized access.

To log out:

Prerequisite

☑ Patient ID screen is open.

Action



1. Select **Logout**.

Result

✓ The login screen opens.

8.2 Select the Patient

You must select the appropriate patient record before you scan or analyze images. You can add a new patient or select an existing patient.

If your institution connects to a DICOM system, you can also search a DICOM archive.

8.2.1 Add a New Patient

When you add a new patient, the patient automatically appears in the **View Today's Patients** list.

8.2.1.1 Add New Patient Screen

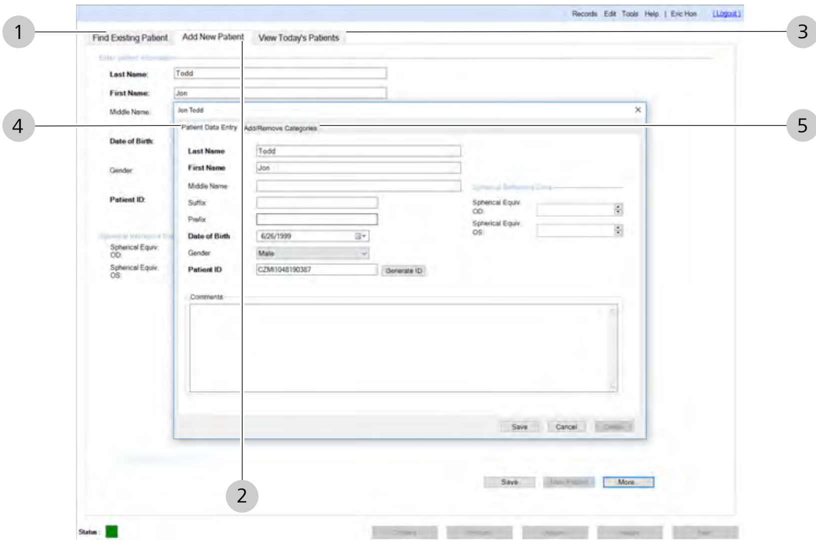


Figure 19: Add New Patient Screen

#	Symbol	Name	Explanation
1	Find Existing Patient	**Find Existing Patient** Tab	Finds an existing patient by last name, ID or advanced search criteria.
2	Add New Patient	**Add New Patient** Tab	Adds a new patient record.
3	View Today's Patients	**View Today's Patients** Tab	Lists patients scheduled for a scan today, patients added today, and patients who already had scans taken today.
4		**Last Name**	(Required) Type the patient's last name.
		First Name	(Required) Type the patient's first name.
		Middle Name **Suffix** **Prefix**	(Optional) Type additional patient information.
		Date of Birth	(Required) Type the patient's birthday.
		Gender	(Optional) Select the patient's gender.
		Patient ID	(Required) Type or generate a unique ID for the patient.
		Spherical Equiv. OD	(Optional) Type the patient's correction.
		Spherical Equiv. OS	
		Comments	Allows you to add comments to the patient record.
5		**Add/Remove Categories** Tab	Allows you to apply categories to the patient record (see: About Patient Categories [▸ 87]).

8.2.1.2 Adding a New Patient

NOTE

If you include refractive error information in the patient's record, it can save time when you acquire their scans.

When you add a new patient, you can enter their refractive error. The CIRRUS 6000 uses this information to determine the scan focus.

Each patient must have a unique patient ID for CIRRUS 6000 to save acquired images in their record. Your institution can use its own patient ID numbering system or have generate unique patient ID numbers.

Patient ID numbers that CIRRUS 6000 generates start with `CZMI`.

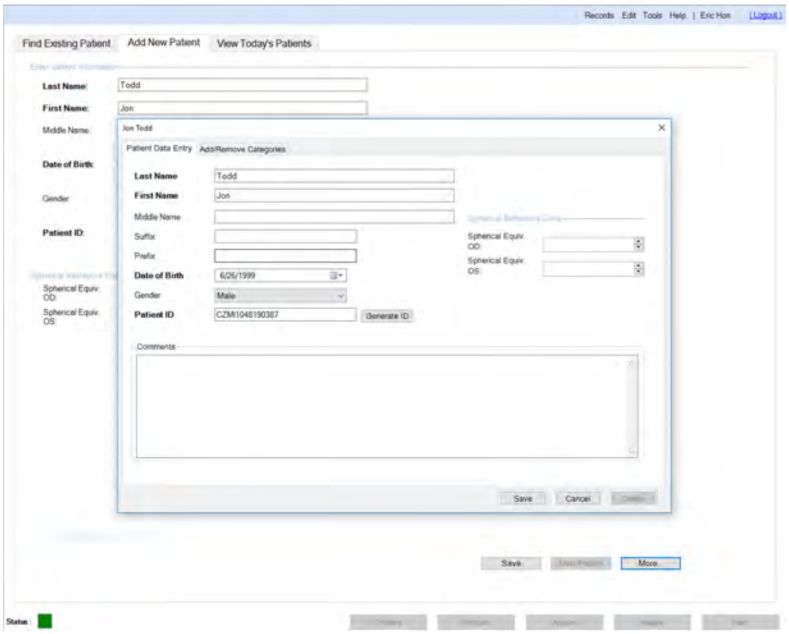
To add a new patient:

Prerequisite

☑ Log In as Operator or Data Analyst [▸ 123].

Action

1. Select the **Add New Patient** tab.
2. Type the patient's **Last Name** and **First Name**.
3. If applicable, type the patient's **Middle Name** and Suffix (Jr., Sr., etc.) or Prefix (Mr., Ms., Mrs., etc.).
4. Type the patient's **Date of Birth**.
5. Select the patient’s **Gender**.
6. To have CIRRUS 6000 create a **Patient ID**, click **Generate ID**.
7. To use your own numbering system, type a unique **Patient ID** number. **NOTE! To fit on the page, reports only show the first 23 characters of the patient ID (including spaces).**
8. To save the patient's refractive error, type the diopters for **Spherical Equiv. OD** and **Spherical Equiv. OS**.
9. To add comments to the patient's record, click **More**, type the comments, and click **Done**.



10. To apply categories to the new patient, select the **Add/ Remove Categories** tab and choose the applicable categories. For more information about categories, see: Managing Patient Categories [▷ 87].
11. Click **Save**.
12. To add another new patient, click **New Patient**.
13. Click **Close**.

8.2.2 Find an Existing Patient

8.2.2.1 Find Existing Patient Screen

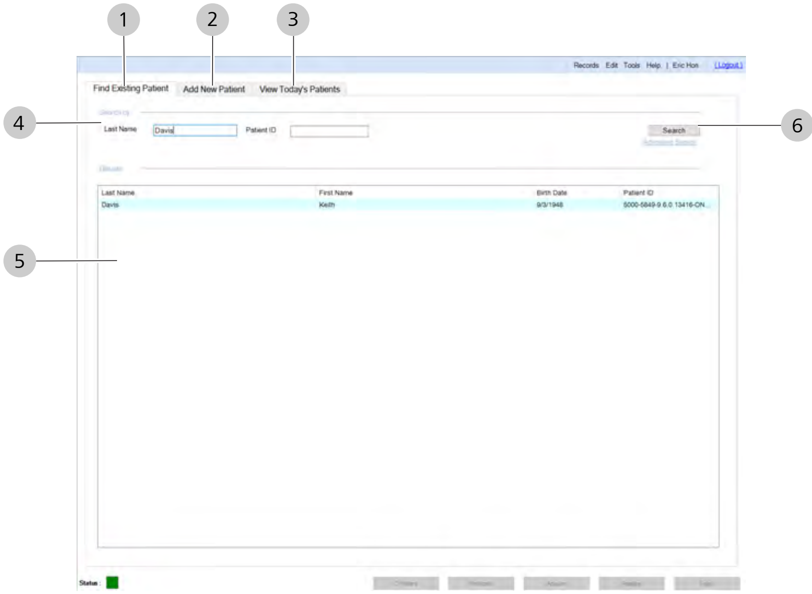


Figure 20: Find Existing Patient Tab

#	Symbol	Name	Explanation
1	Find Existing Patient	Find Existing Patient Tab	Finds an existing patient by last name, ID or advanced search criteria.
2	Add New Patient	Add New Patient Tab	Adds a new patient record.
3	View Today's Patients	View Today's Patients Tab	Lists the following: ▪ New patients (added today) using the CIRRUS 6000 instrument. ▪ Patients scheduled CIRRUS 6000 scans today.
4		Search By	Specifies all or part of a patient name or ID to include in results.
5	Results Last Name	Results	Lists the patients who fit the criteria (after you click **Search**).
6	Search Advanced Search	Search	Quick search to find a patient when all or part of their last name or ID is known.
		Advanced Search	Additional criteria to narrow the search results further or to search using different known criteria.

8.2.2.2 Finding an Existing Patient Record

Tip: If you leave the name and ID fields blank and click Search, the results lists all patients.

Simple search uses the patient's last name or ID to locate their record. If you want to search using other criteria or narrow the results further, see: Advanced Search [▷ 132].

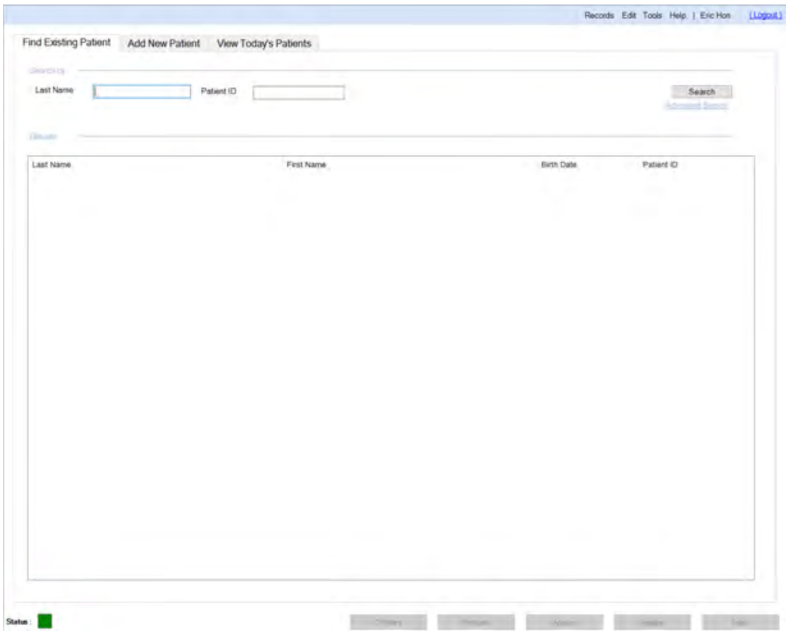
To find a patient record:

Prerequisite

☑ Log In as Operator or Data Analyst [▸ 123].

Action

1. Select the **Find Existing Patient** tab.



2. Type the patient’s **Last Name** or **Patient ID**.
3. Click **Search**.
   ⇨ The **Results** list displays the patient (or list of patients that have the same last name).
4. Select the patient's record.

8.2.2.3 Finding a Worklist Patient Record (DICOM)

NOTE

Edit patient records in your EMR system (if used).

Changes made directly on the instrument do not get synchronized into the EMR database.

▶ If you are connected to an EMR , always delete or edit patient records directly in the EMR system. If you can make changes directly on the instrument, the changes will only appear in the instrument's database and not the EMR database.

Modality Worklist allows you to search a DICOM EMR archive.

A **Broad Query** allows searches using the following parameters:

- **Date Range:** Search for patients scheduled for an exam within a selected range. To search for all dates, check **All Dates**.
- **AE Title:** Search for patients scheduled for a scan using a particular instrument's AE Title.
- **Modality:**
  - IOD
  - OP

- OPT
- OPT IOD
- OP IOD

A **Patient Based Query** allows searches using the following parameters:

- **First Name**
- **Last Name**
- **Patient ID**
- **Accession Number** (Determined from the Analysis screen when the mouse cursor is over an exam date in the upper left corner)
- **Requested Procedure ID**

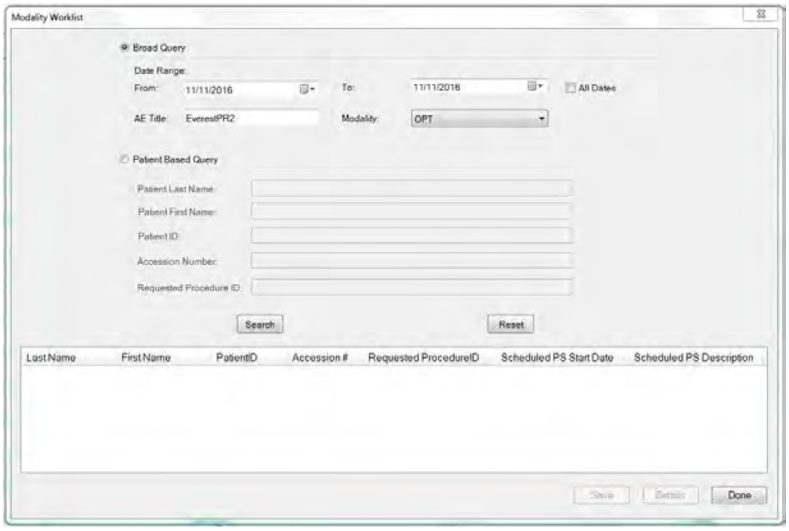
You can set a preference that automatically searches the DICOM archive for patients scheduled for a scan today (see Enabling Automatic Worklist Search (DICOM)).

Prerequisite

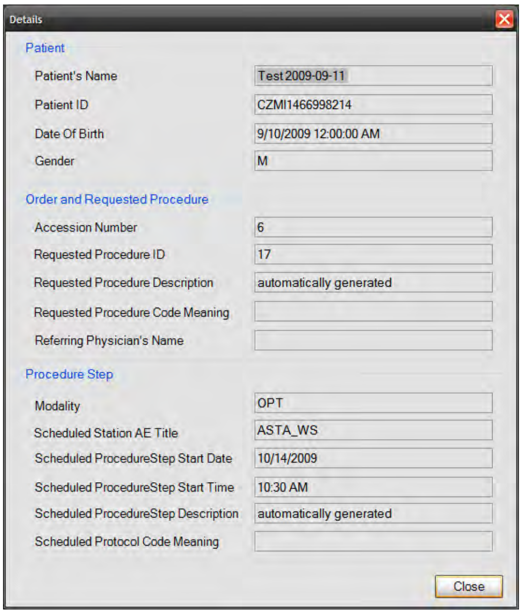
☑ Log In as Operator or Data Analyst [▷ 123].

Action

1. Select **Records > Search Worklist Patients**.



2. To use broad search parameters, select **Broad Query** and indicate what parameter(s) you want the search to include.
3. To use patient information parameters, select **Patient Based Query** and indicate what parameter(s) you want the search to include.
4. Click **Search**.
   ⇨ The list populates with all patient records that fit the parameters you indicated.
5. To view more information about a patient, select the patient and click **Details**.
   ⇨ A dialog opens showing more details of the patient's record.



6. To add patient records to your instrument database, select the patient(s), and click **Save**.
7. Click **Close**.

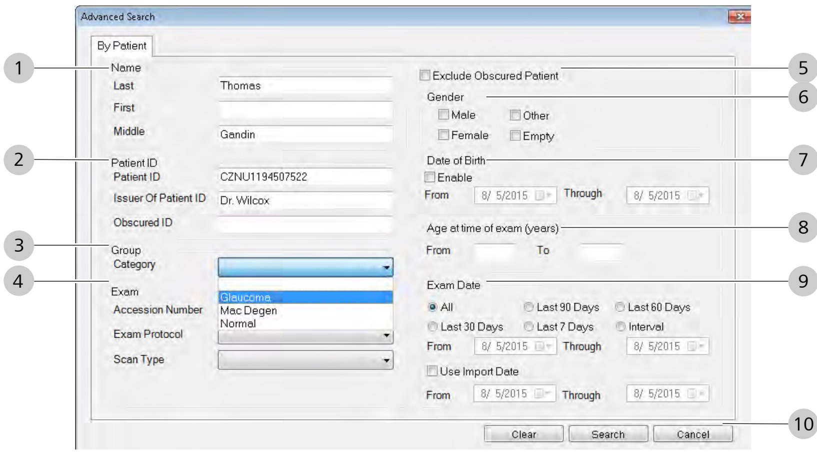
Result

✓ The patients you added are now listed in the **View Today's Patients** tab.

8.2.2.4 Advanced Search

Advanced Search allows you to use additional criteria to search for a patient. When you use **Advanced Search**, you can use as many or as few different search criteria that you want to use. Each criteria helps you narrow the results list.

8.2.2.4.1 Advanced Search Overview



#	Group	Name	Explanation
1	**Name**	**Last**	Type all or part of the patient's name.
		First	
		Middle	

#	Group	Name	Explanation
2	**Patient ID**	**Patient ID****	Type all or part of the patient's ID.
		Issuer of Patient ID**	Refer to: About Assigning the Issuer of Patient ID [▶ 58].
		Obscured ID*	If the patient identification information is obscured, you can type all or part of the **Obscured ID**. All other search criteria is ignored.
3	**Group**	**Category***	Select a category assigned to the patient (see: About Patient Categories [▶ 87]).
4	**Exam**	**Accession Number**	
		Exam Protocol*	
		Scan Type	Select a type of scan acquired for the patient.
5	**Exclude Obscured Patient***		
6	**Gender***		Check the patient's gender.
7	**Date of Birth**	**Enable**	Check to enable this search criteria.
			From: Select a start date for the search.
			Through: Select an end date for the search.
8	**Age***		**From**: Select a start date for the search.
			To: Select an end date for the search.
9	**Exam Date**	**All**	
		Interval	**From**: Select a start date for the search.
			Through: Select an end date for the search.
		Select	
		Use Import Date*	**From**: Select a start date for the search.
			Through: Select an end date for the search.
10	Buttons	**Clear**	Resets the search criteria.
		Search	Begins the search based on the criteria indicated.
		Cancel	Exits search.
** Not available for search in a DICOM archive.* *** Case-Sensitive.*			

Table 24: Advanced Search Criteria

8.2.2.4.2 Advanced Search

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

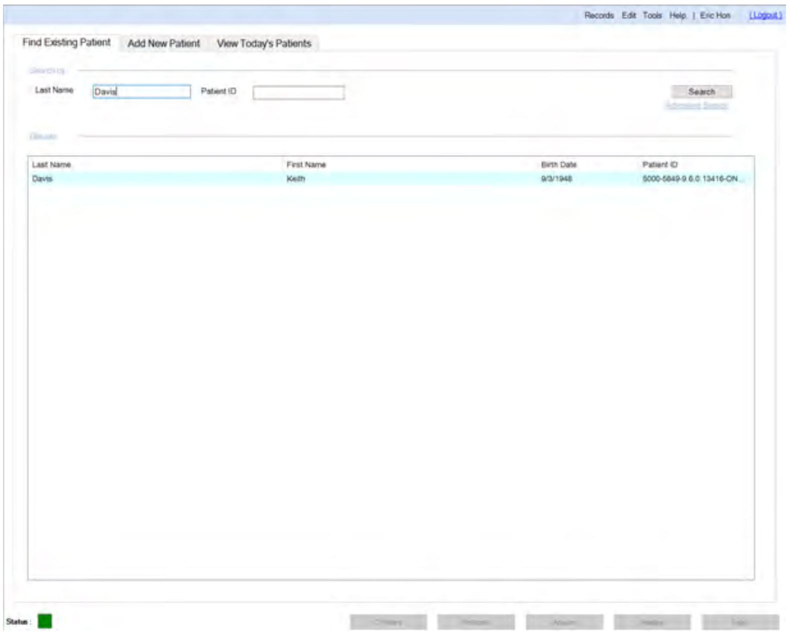
Prerequisite

☑ Log In as Operator or Data Analyst [▷ 123].

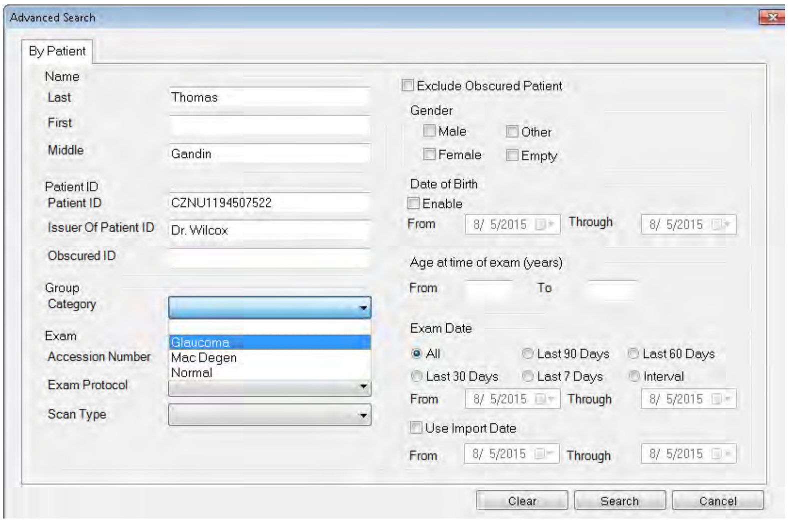
☑ Finding an Existing Patient Record [▷ 128]

Action

1. Select the **Find Existing Patient** tab (Find an Existing Patient [▷ 128]).



2. Click **Advanced Search**.



3. Fill in the known criteria for the patient you are searching for.
4. Click **Search**.

   ⇨ **Search Preview** opens.
5. To select a patient, click on the patient's name. Current patient information appears on the left side of the Toolbar.
6. To select the whole list of patients, check **Select All**.
7. Click **OK**.

8.2.3 Select from Today's Patients

8.2.3.1 View Today's Patients Screen

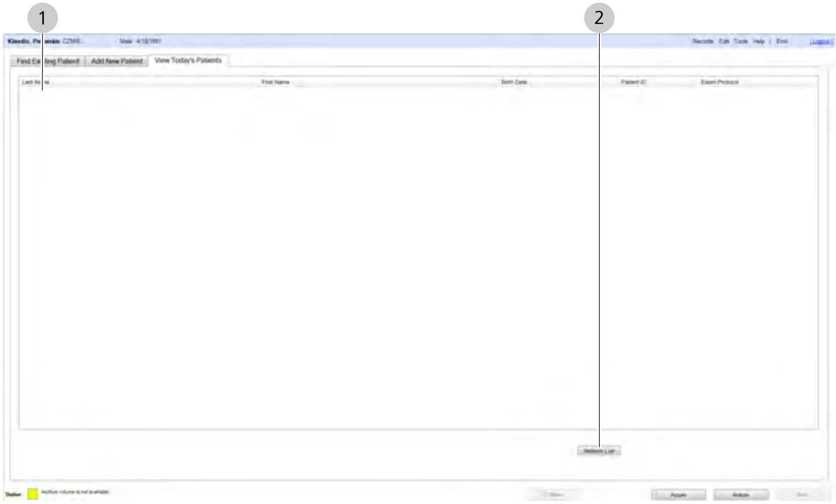


Figure 21: View Today's Patients Tab

#	Name	Explanation
1	Results	Lists patient information for patients scheduled for a CIRRUS 6000 exam today (from the electronic medical record system). **Results** also displays patient's records that were imported on the present day. These will not be on the list the following day.
2	Refresh List	Synchronizes with the electronic medical record system and updates the list. Pressing **Refresh List** will update the main patient list after the importing patient data from another CIRRUS 6000.

8.2.3.2 Viewing Today's Patients

The **View Today's Patients** tab lists:

- Patients added today (Adding a New Patient [▷ 126])
- Patients that were scanned earlier today
- DICOM patients scheduled for a scan today.

To view today's patients:

Prerequisite
☑ Log In as Operator or Data Analyst [▷ 123].

Action
1. Select the **View Today's Patients** tab.
2. To refresh this list, click **Refresh List**.
3. Select a patient's name.
   ⇨ **Current Patient** information appears on the left side of the Toolbar.
4. To acquire a scan for this patient, click **Acquire**.

8.3 Prepare the Patient

8.3.1 Dilate the Patient's Eyes (Optional)

NOTE

You do not need to dilate the patient's eye(s) for scans using this instrument.

Pupil size differences can cause variability in how the OCT beam enters the eye that can influence results for a series of repeated followup scans.

▶ If the patient's eye is dilated for their first scan, dilate the patient's eye for subsequent scans.

The minimum pupil size for the CIRRUS 6000 is 2 mm, which can usually be achieved without dilation. **For optimal repeatability, image the patient the same way at every visit.**

8.4 Scan Selector

The scan selector, shown in the figure below, is used to select the major options prior to capturing a scan.

The scan selector enables you to select the following buttons:

- **Laterality:** You can select either OD or OS, and the instrument adjusts the chinrest and alignment. If you change the Laterality button, it does not affect any of the other options in the scan selector.
- **Scan Speed:** Two speeds are available for scan speed, and they are 100 kHz and 200 kHz. Some scans, such as the Angio 3mm x 3 mm are Dual-Speed (DS) so either speed can be selected, but both buttons cannot be selected at the same time. Other scans, however, are only available as 100 kHz or 200 kHz. Any scan not available for a certain speed is greyed out and you cannot select it.
- **Scan Type:** Five types are available for scan type, and they are: Angio, Raster, Cube, ONH, and Montage. When you click on a scan type, the scan details displayed below it change for that type. The scan details appropriate for the scan types are listed in the table below:
  - **Angio**: 3 x 3 mm, 6 x 6 mm, 9 x 9 mm, 12 x 12 mm, 15 x 9 mm, HD 12 x 12 mm
  - **Raster:** 51 Line (6 x 6 mm), 51 Line (12 x 12 mm), HD Spotlight 1, UHD Spotlight 1
  - **Cube:** 512 x 512, 800 x 800, 1024 x 1024
  - **ONH:** 6 x 6 mm
  - **Montage:** 12 x 12 mm, 15 x 9 mm

- **Scan History Lists:** After capturing a scan, that scan and previous ones of that type from the current session appear in the Scan History list for the particular eye you scanned (OD/OS). The list provides information about the scan type, its speed, and how many scans were captured of that type. For example, if two Angio (3 x 3 mm) scans were taken at a speed of 200 kHz, the entry in the list would appear as follows: 2 Angio (3 x 3 mm)(200 kHz).

When you navigate to the Acquisition screen in CIRRUS 6000, the default settings for the scan selector display as follows:

Scan Default

- **Laterality:** OD
- **Scan Speed:** 200 kHz
- **Scan Type:** Angio
- **Scan Detail:** None

8.4.1 Selecting a Scan with the Scan Selector

Action

1. Select the **Laterality** button for the eye you want to scan.
2. Select the scan speed you want to use for the scan type. If the scan type is available for the speed, the buttons are available. Otherwise, the **Scan Type** buttons are greyed out.
3. Select the available **Scan Type** button and **Scan Details** button you want to use. If the scan details are available for the speed, the buttons are available. Otherwise, the **Scan Details** buttons are greyed out.

8.5 Scan Types

CIRRUS™ HD-OCT software provides a variety of scan types for in-depth analysis of ocular features and possible abnormalities. The three categories of scan types are:

- **Posterior Segment Scans**
- **OCT Angiography Scans**
- **Anterior Segment Scans**

Symbols for Scans and Analyses

The following lists include CIRRUS™ HD-OCT scans and analyses using the following symbols:

Indicates optional features; license may be required.

Requires (or best with) image of both eyes.

Requires (or best with) both **Macular Cube** and **Optic Disc Cube** images.

Macular

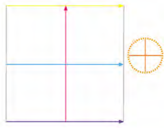
Scan Pattern	Scan	Analyses
	512 x 128 200 x 200	■ Macular Thickness ■ Macular Thickness OU ■ Macular Change ■ Advanced RPE ■ Wellness Exam ■ Panomap ■ Advanced Visualization ■ En Face ■ 3D Visualization ■ Ganglion Cell OU ■ Ganglion Cell Guided Progression (Extrapolate Progression) ■ Single Eye Summary

Table 25: Macular Cube Scans

Optic Disc

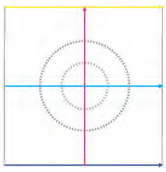
Scan Pattern	Scan	Analyses
	200 x 200	■ ONH/RNFL OU ■ Guided Progression (Extrapolate Progression) ■ Advanced Visualization ■ En Face ■ 3D Visualization ■ Wellness Exam ■ Panomap ■ Single Eye Summary

Table 26: Optic Disc Cube Scan

HD Raster (Including Smart Scans)

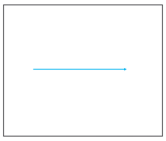
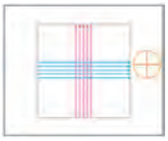
Scan Pattern	Scan	Analyses
	HD 1 Line 100X	High Definition Images
	HD 5 Line	
	HD Radial	
	HD 21 Line	
	HD Cross	

Table 27: HD Raster Scans (Includes Smart HD Scans)

AngioPlex

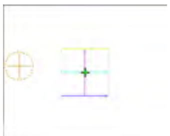
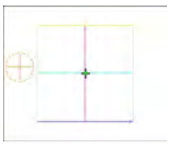
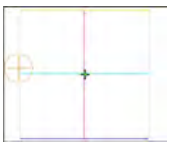
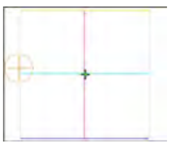
Scan Pattern	Scan	Analyses
	3mm x 3mm	■ Angiography ■ Angiography Change ■ En Face
	HD 6mm x 6mm 6mm x 6mm	
	HD 8mm x 8mm 8mm x 8mm	
	12mm x 12mm	

Table 28: Angiography Scans

AngioPlex ONH

Scan Pattern	Scan	Analyses
	4.5mm x 4.5mm	■ ONH Angiography ■ ONH Angiography Change ■ En Face

Table 29: AngioPlex ONH Scans

AngioPlex Montage

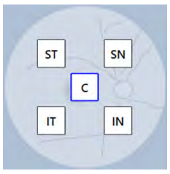
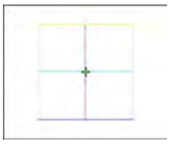
Scan Pattern	Scan	Analyses
	6mm x 6mm	Montage Angiography
	8mm x 8mm	

Table 30: AngioPlex Montage Scans

Many anterior segment scans are optional (see: About Licenses [▷ 61]).

Scan Pattern	External Lens	Scan	Analysis
Anterior Segment Scans			
	-	Anterior Segment Cube	■ Anterior Segment Analysis ■ 3D Visualization
	-	Anterior Segment 5 Line Raster	High Definition Images

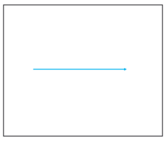
Scan Pattern	External Lens	Scan	Analysis
	-	HD Angle	HD Angle Analysis
		Anterior Chamber	Anterior Chamber Analysis
		Wide Angle-to-Angle	Wide Angle-to-Angle Analysis
		HD Cornea	HD Cornea Analysis
		Pachymetry	Pachymetry Analysis

Table 31: Anterior Segment Scans

8.6 Acquire Posterior Segment Overview

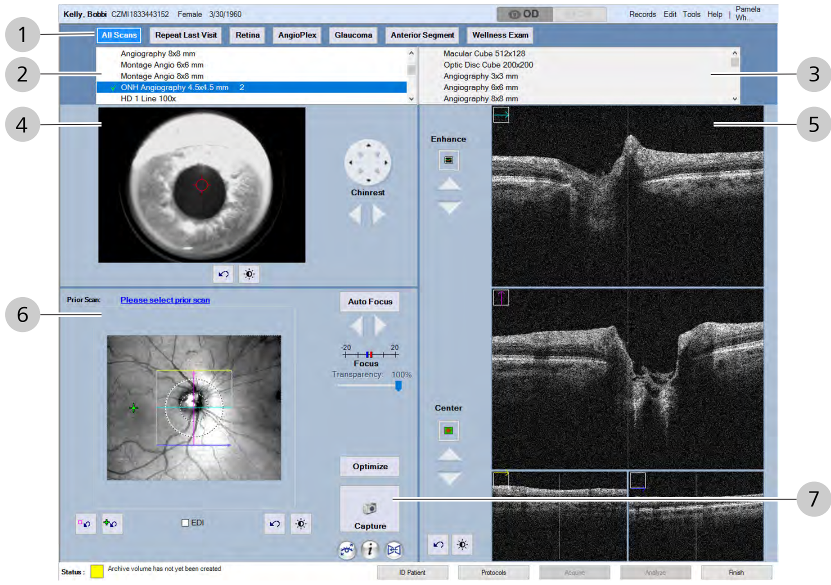
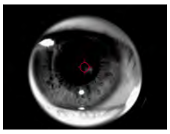
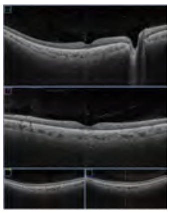
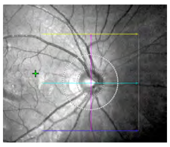
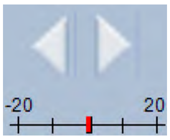
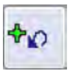
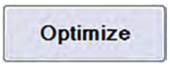
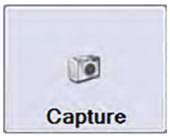
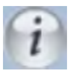


Figure 22: Acquire Screen

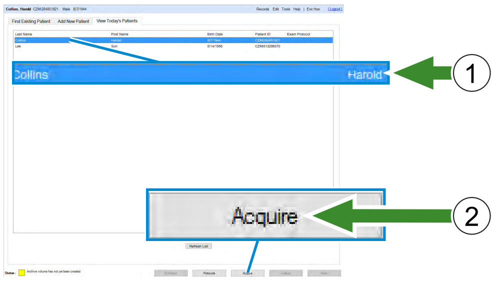
#	Symbol	Name	Explanation
1		Protocols	Selects a protocol (see: About Protocols [145]).
2		Scan Selector	Selects OD scan type.
3			Selects OS scan type.

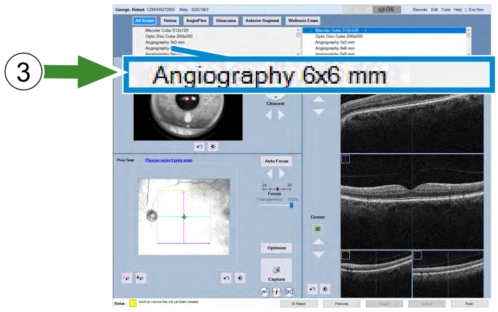
#	Symbol	Name	Explanation
4		Iris Viewport	Displays the live image of the iris.
		Pupil Target	Indicates the pupil center alignment.
		Brightness and Contrast	Opens brightness and contrast adjustment controls.
		Reset	Resets your adjustments of the iris image.
		Chinrest Controls	Circular controls adjust the patient chinrest up, down, right or left. Left arrow moves chinrest toward patient. Right arrow moves chinrest toward device.
5		B-scans	Displays the live B-scan images.
		Enhance	Button automatically adjusts polarization of the live B-scan images. Arrows adjust polarization manually.
		Center	Button automatically centers the live B-scan images. Arrows adjust centering manually.

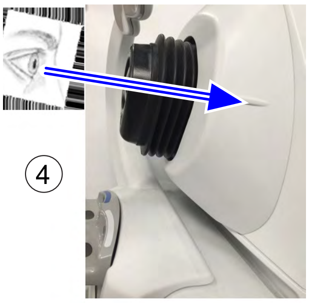
#	Symbol	Name	Explanation
6		*Identifies Selected Prior Scan*	Replicates the settings of a prior scan (to compare same scans of the same eye using the same settings).
		Fundus Viewport	Displays the live image and scan pattern.
		Fixation Target	Displays the location of the fixation target.
		**Auto Focus**	Automatically focuses the live scan.
		Manual focus	Focus slider or arrows adjust focus manually.
		**Transparency**	Controls the opacity of the overlay.
		Reset Scan Pattern	Returns the scan pattern to its default position.
		Reset Fixation Target	Returns the fixation target to the center.
		**EDI**	Inverts the OCT signal profile so the strong part of the signal is at the bottom of the B-scan.
7		**Optimize**	Automatically centers and enhances the B-scan.
		**Capture**	Captures the scan.
		FastTrac	Indicates whether FastTrac is on or off.
		Help	Displays tips for acquiring the best scan.
		Track to Prior	Sets tracking to align and track the scan at the same location on the retina as the selected prior scan. **NOTE! Tracking to prior automatically enables FastTrac.**

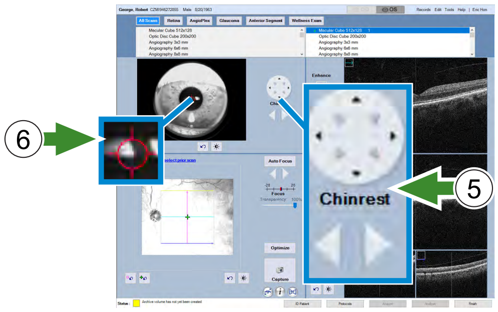
8.7 About Acquiring Scans

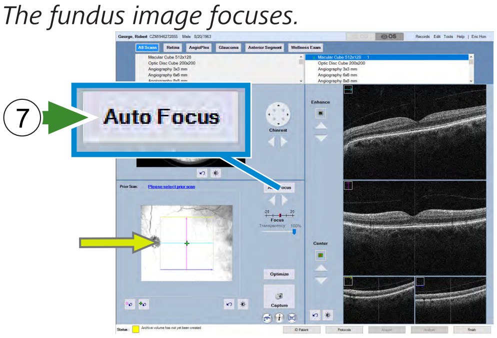
It typically takes several minutes per eye to acquire scans. In general, the steps to acquire a scan are:

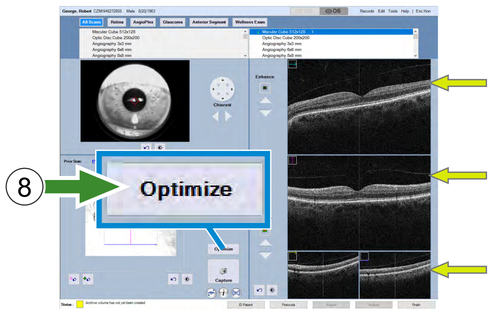
<table>
<tr>
<td>
1. Select the patient.
2. Click **Acquire**.


</td>
<td>
3. Select the scan.


</td>
</tr>
<tr>
<td>
4. Clean the chinrest and position the patient; raise or lower the table, if required.


</td>
<td>
5. Move the **Chinrest** controls until the iris is aligned and focused.
■ Move the chinrest closer or farther from the instrument as needed (right and left arrows).
■ Move the chinrest right, left, up, and down as needed (circle controls).
6. Click on the center of the pupil.
The red target is centered on the iris.


</td>
</tr>
<tr>
<td>
7. Click **Auto Focus**
The fundus image focuses.


</td>
<td>
8. Click **Optimize**.
The B-scans align and focus.


</td>
</tr>
</table>

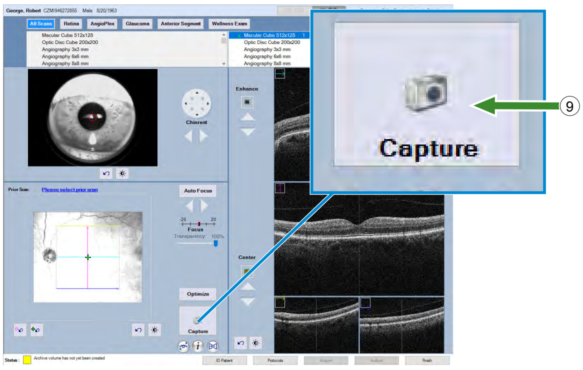
9. Click **Capture**. 	10.Check scan quality.

Table 32: Acquire Overview

Specific steps vary by the type of scan.

- Acquire Posterior Segment Scans [▶ 148]
  - Macular Cube Scans [▶ 150]
  - Optic Disc Cube Scans [▶ 153]
  - HD Raster Scans [▶ 159]
  - Angiography Cube Scans
  - HD Angiography Scans
  - ONH Angiography Scans
  - Montage AngioPlex Scans [▶ 171]
- Acquire Anterior Segment Scans [▶ 179]
  - Anterior Chamber Scans [▶ 184]
  - HD Angle Scans [▶ 194]
  - Wide Angle to Angle Scans [▶ 197]
  - Anterior Segment 5-Line Raster Scans [▶ 191]
  - HD Cornea Scans
  - Pachymetry Scans

8.7.1 About Protocols

A **Protocol** is a group of suggested scans for a particular purpose. You can access protocols at the top of any **Acquire** page.

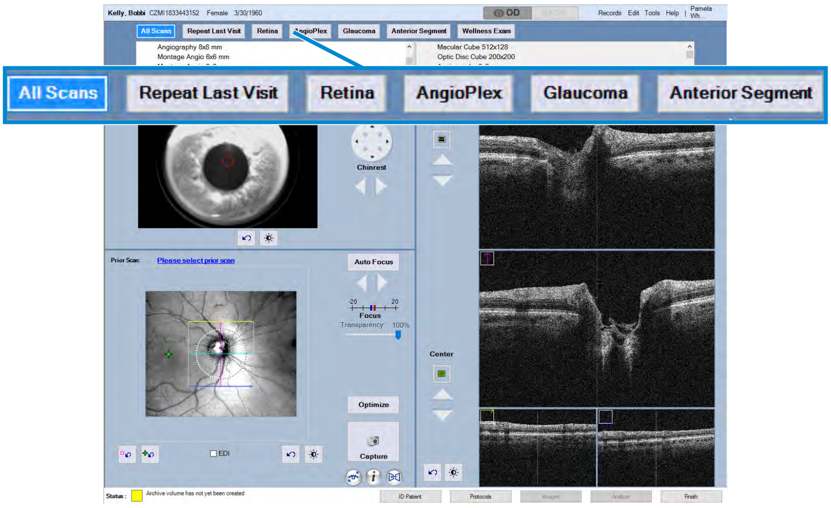


Figure 23: Protocol Overview

The protocol list only displays scans with an active license for the instrument (see: About Licenses [▸ 61]).

Protocol	OD / OS
All Scans	Shows all scans available on the instrument.
Repeat Last Visit	*(if this is a followup visit)* Selects the same set of images as the patient's last visit.
Retina	■ Macular Cube 512x128 ■ ⊕ AngioPlex 3x3 mm ■ ⊕ HD AngioPlex 6x6 mm ■ ⊕ HD AngioPlex 8x8 mm ■ ⊕ AngioPlex 12x12 mm ■ ⊕ Montage AngioPlex 6x6 mm ■ ⊕ Montage AngioPlex 8x8 mm ■ HD 1 Line 100x ■ HD 21 Line ■ HD Radial ■ HD Cross ■ 5 Line Raster ■ Macular Cube 200x200

Protocol	OD / OS
AngioPlex	■ AngioPlex 3x3 mm ■ HD AngioPlex 6x6 mm ■ HD AngioPlex 8x8 mm ■ AngioPlex 12x12 mm ■ Montage AngioPlex 6x6 mm ■ Montage AngioPlex 8x8 mm ■ ONH Angiography 4.5x4.5 mm
Glaucoma	■ Optic Disc Cube 200x200 ■ ONH Angiography 4.5x4.5 mm ■ Macular Cube 512x128 ■ Macular Cube 200x200
Anterior Segment	■ HD Angle ■ Anterior Segment 5 Line Raster ■ Anterior Segment Cube 512x128 ■ HD Cornea ■ Pachymetry ■ Anterior Chamber ■ Wide Angle to Angle
Wellness Exam	■ Macular Cube 512x128 ■ Optic Disc Cube 200x200

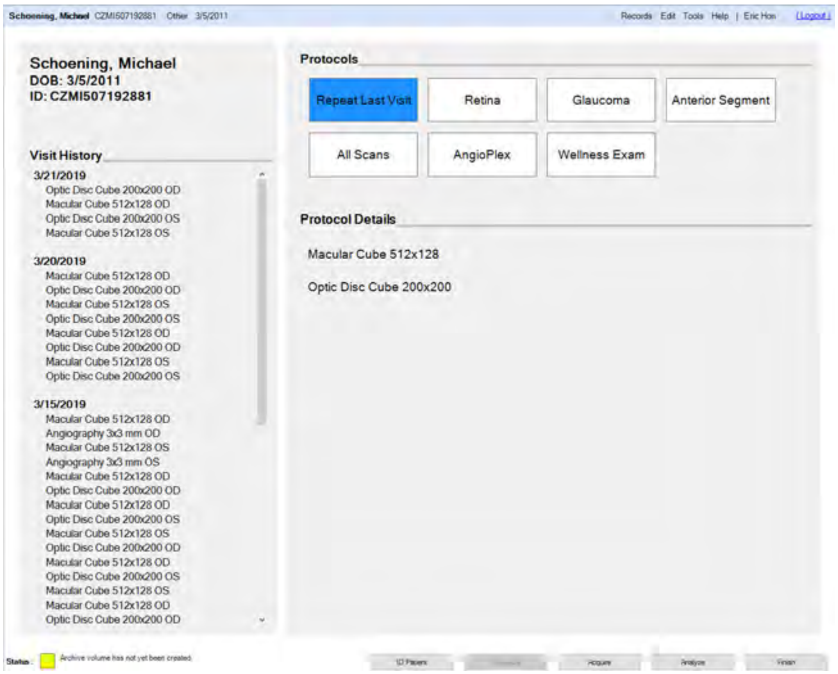
Table 33: Protocols

Indicates optional features; license may be required.

Tip: The protocol page is a quick way to view a patient's scan history; it lists each visit and all images acquired during each visit.

Protocol Page

The Protocol page lists a patient's scan history, shows what scans are available for each protocol, and allows you to select a protocol for acquisition.



8.8 View Protocols

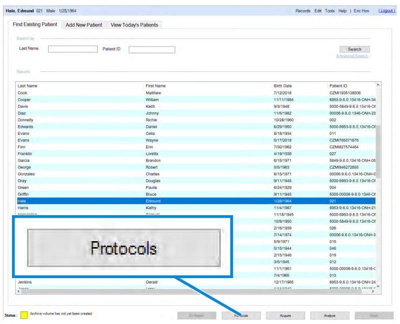
Access the **Protocols** page to see a list of the patient's prior scans, view which scans are available in each protocol, and select a protocol for acquisition.

To view protocols:

Prerequisite

☑ Log In as Operator or Data Analyst [▷ 123].

Action



1. Select the Patient [▷ 124].
2. Click **Protocols**.
3. Select a **Protocol** and click **Acquire**.

Result

✓ The **Acquire** screen opens with the protocol scans selected.

8.9 Acquire an Image Protocol

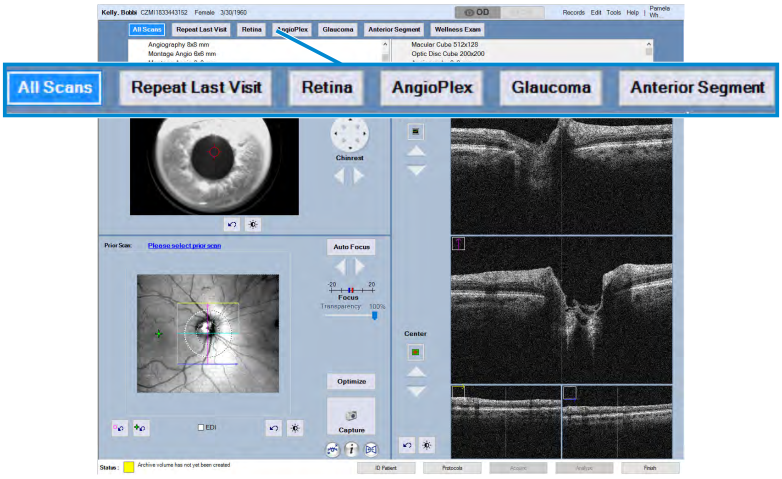
This procedure describes how to use the Protocol feature to filter the scan list for a particular purpose. For instructions on acquiring a scan, refer to acquisition instructions for the type of scan you are acquiring.

The **Protocol** list filters the scans for a particular purpose, but there might be more scans listed than you need to acquire.

To acquire an image protocol:

Action

1. Select the Patient [▷ 124].
2. Prepare the Patient [▷ 135]
3. Click **Acquire**.



4. Select a **Protocol**.

   ⇨ The scan lists filters the scans to show only scans for the selected protocol.

5. Acquire the scans you need for analysis (see acquisition instructions for each type of scan).

8.10 Acquire Posterior Segment Scans

Tip: To see details better in high-resolution images, switch to grayscale (see: View Color or Grayscale Image [▷ 375]).

Posterior segment scans provide detailed views of the patient's retinal micro-structure.

- Macular Cube Scans [▷ 149] provide a three-dimensional image of the macula.
- Optic Disc Scans [▷ 153] provide a three-dimensional image of the optic nerve head.
- HD raster scans [▷ 156] offer a variety of different patterns that provide two-dimensional details focused on specific areas or structures.
- Angiography [▷ 163] scans provide visualization and measurement of vascular structures of the retina and choroid.

8.10.1 Macular Cube Scans

Macular scans generate a cube of data through a 6 mm square grid with a central horizontal HD B-scan.

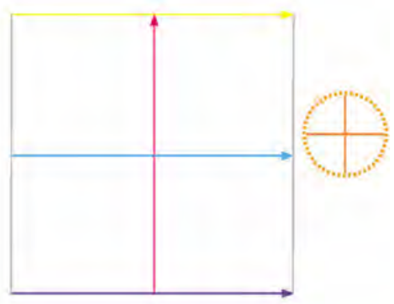


Figure 24: Macular Scan Pattern

Tip: If it is difficult to center or see the fovea (extreme edema, cataract, or floaters impede the view), center the circle on the optic disc instead.

The **Macular Cube** scan pattern has a square that indicates the scan area and the lines cross in the center where you align the fovea.

You can also place the yellow circle over the optic disc, and the fovea is centered within 1 mm for most patients.

You can use macular scans to analyze:

- Macular layer thicknesses
- Macular change
- Ganglions cells / IPL
- RPE elevation details
- A 3-dimensional view of the macula

Scans	Horizontal Lines	A-Scans / Line	Description
200 x 200	200	200	Provides higher resolution vertically, but lower resolution along each horizontal line.
512 x 128	128	512	Provides higher resolution along each horizontal line, but lower resolution vertically.

Table 34: Macular Cube Scans

8.10.1.1 Acquire a Macular Cube Scan

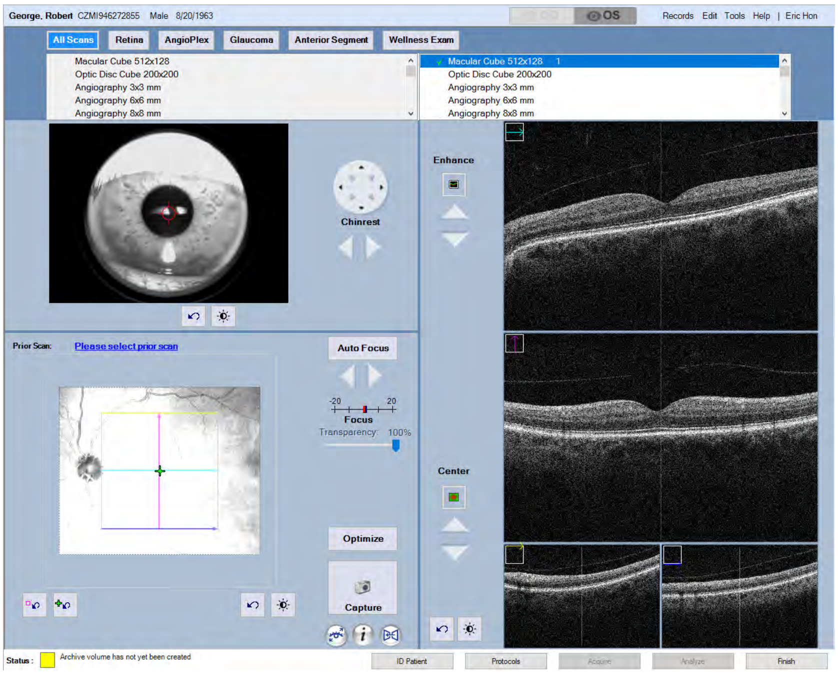
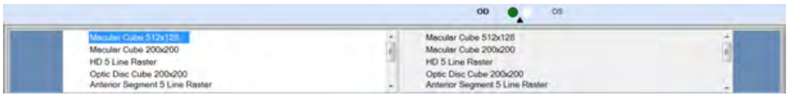


Figure 25: Macular Cube Scan

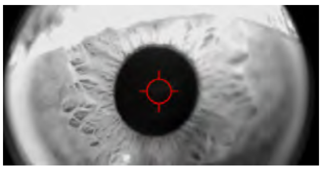
To acquire a macular cube scan:

Action

1. Select the Patient [▷ 124].
2. Prepare the Patient [▷ 135]

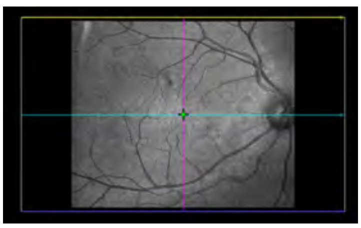


3. Under the appropriate eye (OD or OS), select **Macular Cube 512x128** or **Macular Cube 200x200**.



4. Align and Focus the Iris Image [▷ 214].

5. Ask the patient to hold their gaze steady and click **Auto Focus**.
   ⇨ The chinrest moves into place as the CIRRUS 6000 automatically corrects for the patient's refraction error and balances fundus brightness and contrast.



6. To change the position of the scan or fixation target, see: Select an Internal Fixation Target.
7. To manually focus the image, see: Focus the Fundus Image [▷ 209].

8. To manually adjust brightness or contrast, click brightness and contrast adjustment tool.
9. Click **Optimize**.

   ⇨ CIRRUS 6000 automatically centers and optimizes B-Scan settings. You can fine-tune these settings manually.
10. To fine-tune B-Scan image quality and centering, see: Manually Enhance B-Scans [▸ 211].
11. To use automatic eye tracking, Turn FastTrac™ On [▸ 219]. **NOTE! Once you turn FastTrac on, do not make further scan adjustments. If you need to make additional adjustments, turn off FastTrac, make adjustments, and turn FastTrac on again.**
12. Ask the patient to blink, then open their eyes wide.

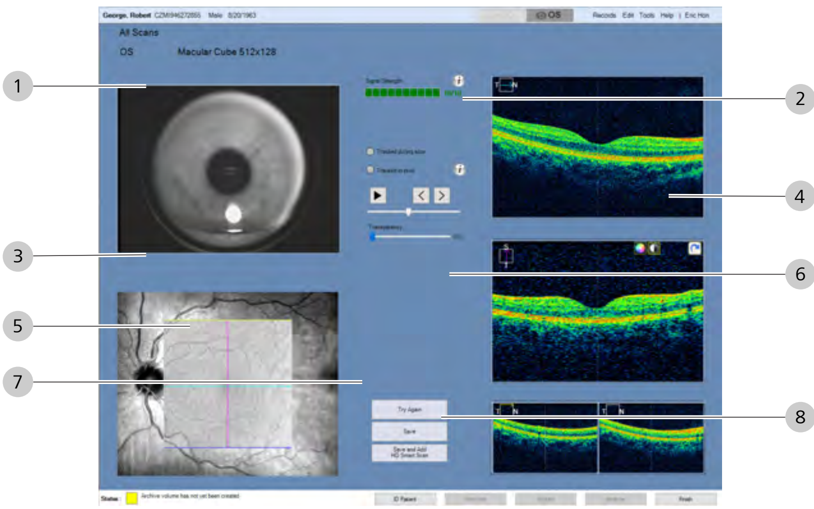
13. Click **Capture**.

    ⇨ The **Quality Check** screen opens.
14. Check Macular Cube Scan Quality [▸ 151].

8.10.1.2 Check Macular Cube Scan Quality

When you save a macular cube scan, you can add a **Smart HD Scan** for the image. The **Smart HD Scan** you save is the high-definition image that doctors can select when they analyze the scan.

For the **Smart HD Scan** , you can use the fovea location that CIRRUS™ HD-OCT detects automatically or you can select any other cube slice by navigating the cube data (see: Navigate Cube Layers Manually [▸ 226]).



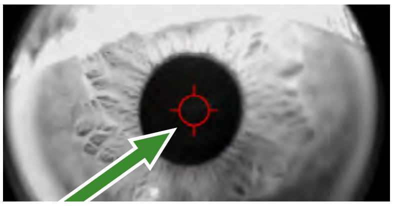
1	Iris Image	2	Signal Strength Fundus Image Rating Tracking Tracked to Prior
3	Fundus Image	4	B-Scan Images
5	Fundus Overlay	6	Fundus Overlay Trans-parency
7	Try Again	8	Save

To check Macular Cube scan quality:

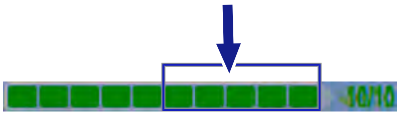
Prerequisite

☑ Acquire a Macular Cube Scan [▹ 150]

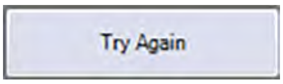
Action



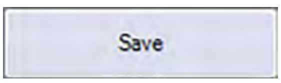
1. Ensure that the target is centered on the pupil.
2. Ensure that light intensity is uniform across the image.
3. To view a full-screen version of an image, double-click on the image.



4. If **FastTrac** is on, ensure that **Tracked during scan** is green (successful) and the **Fundus Image** rating is 6 or higher.
   ⇨ A rating of 6 or higher is needed to reuse the scan settings in the future (see: About Track to Prior [▹ 220]).
5. If this scan is tracked to a prior scan, ensure that it tracked scan successfully. (**Tracked to prior** is marked green.)
6. If the fundus scan has an overlay, adjust the transparency of the overlay.
7. Ensure that the fundus image is sharp and clear with good visibility of the branching blood vessels.
8. Ensure that the color density is the same across the image.
9. Ensure that there are few or no artifacts cast shadows on the OCT scan.
10. Ensure that the scan is complete in all windows (no missing data).



11. If the scan is not acceptable, click **Try Again** and retake the scan.
12. To select a slice for the **Smart HD** scan, navigate through the slices until you find the slice you want to use (see to: Navigate Cube Layers Manually [▹ 226]) and click **Save and Add Smart HD Scan**.



13. To save the scan without an HD image, click **Save**.

8.10.2 Optic Disc Scans

Optic Disc scans capture an image of the ONH. These scans generate a cube of data through a 6 mm square grid with a central horizontal HD B-scan.

The fixation target is offset to center the optic nerve in the scan. Concentric rings shown in the viewport help you align the optic disc.

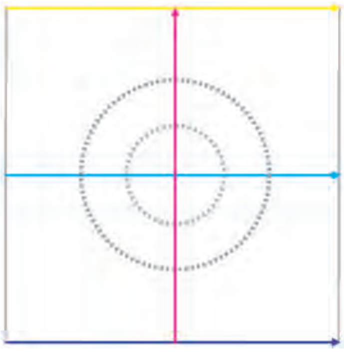


Figure 26: Optic Disc Scan Pattern

You can use ONH Cube Scans to:

- Measure RNFL thickness
- Observe RNFL progression
- Measure ONH parameters

Optic Disc Cube Scan	Horizontal Lines	A-Scans per Line
200 x 200	200	200

Table 35: ONH Cube Scan

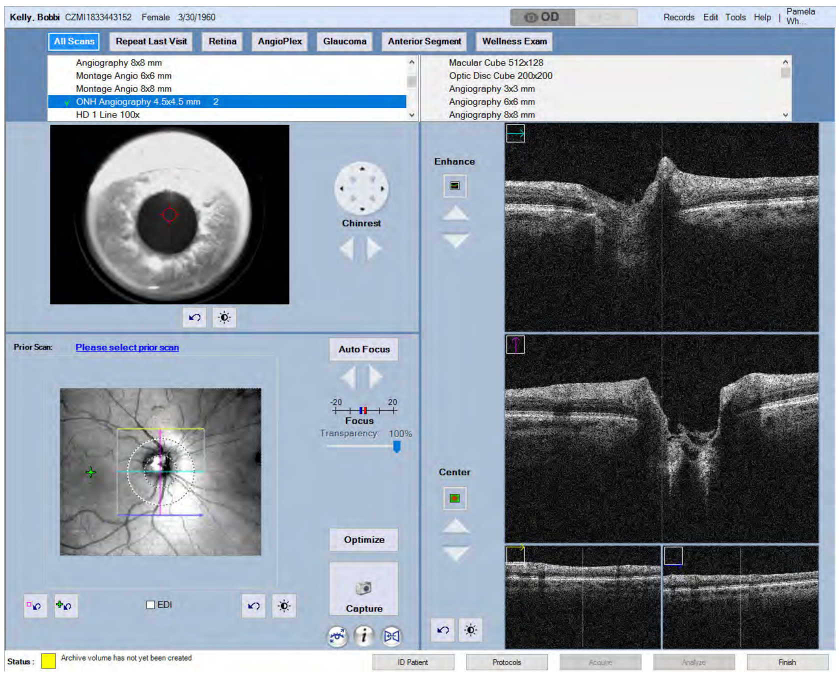
8.10.2.1 Acquire an Optic Disc Cube Scan

NOTE

You can select a different fixation target, but consider using a fixation target near the center.

Optic disc detection works best when the optic disc is close to the center of the image.

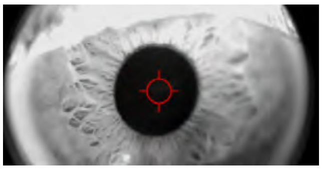
To acquire an optic disc cube scan:



Action

1. Select the Patient [▶ 124].

2. Prepare the Patient [▷ 135]
3. Under the appropriate eye (OD or OS), select **Optic Disc Cube 200x200** .



4. Align and Focus the Iris Image [▷ 214].

5. Ask the patient to hold their gaze steady and click **Auto Focus**.
   ⇨ The chinrest moves into place as the CIRRUS 6000 automatically corrects for the patient's refraction error and balances fundus brightness and contrast.
6. To manually focus the image, see: Focus the Fundus Image [▷ 209].

7. To change the position of the scan or fixation target, see: Select an Internal Fixation Target.

8. Click **Optimize**.
   ⇨ CIRRUS 6000 automatically centers and optimizes B-Scan settings. You can fine-tune these settings manually.
9. To fine-tune B-Scan image quality and centering, see: Manually Enhance B-Scans [▷ 211].
10. To adjust the brightness or contrast of a b-scan image, see: Edit Images (Hover Over) [▷ 370]
11. To use automatic eye tracking, Turn FastTrac™ On [▷ 219].
    NOTE! Once you turn FastTrac on, do not make further scan adjustments. If you need to make additional adjustments, turn off FastTrac, make adjustments, and turn FastTrac on again.
12. Ask the patient to blink, then open their eyes wide.

13. Click **Capture**.
    ⇨ The **Quality Check** screen opens.

8.10.2.2 Check Optic Disc Cube Scan Quality

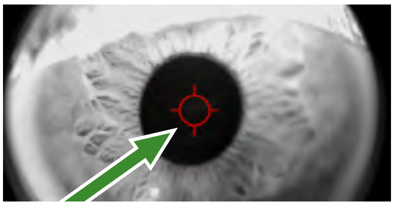
To check optic disc scan quality:

Prerequisite

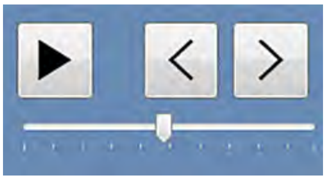
☑ Acquire Data (Scan).

Action

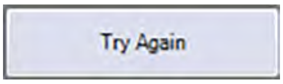
1. Ensure that the target is centered on the pupil.



2. To view a sequence of cube slices as a movie, use the movie controls.



3. Ensure that light intensity is uniform across the image.
4. To view a full-screen version of an image, double-click on the image.
5. Ensure that the fundus image focus is sharp and clear with good visibility of the branching blood vessels and that the lighting is uniform across the image.
6. Ensure that the scan overlaying the Fundus image is centered over the area to be analyzed.
7. Ensure that the scan is complete in all windows (no missing data).



8. If the scan is not acceptable, click **Try Again** and retake the scan.

9. Click **Save**.

8.10.3 HD Raster Scans

Different scan patterns help you spotlight an area of interest. You can reposition, stretch, and rotate patterns to capture the size and shape of the area you want to spotlight.

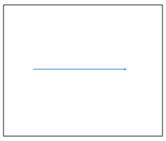
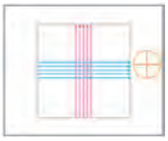
Pattern	B-Scans	Adjustments
	**HD 5-Line Raster Scan** **Averaging per line:** 5 **A-scans per B-scan:** 1024	■ **Length:** 3mm, 6mm or 9mm ■ **Placement:** Any fundus location ■ **Rotation:** -89° to 90° ■ **Spacing:** 0 to 0.4mm (in increments of 0.025 mm)
	**HD 1-Line Raster Scan** **Averaging per line:** 100 **A-scans:** 1024	■ **Length:** 3mm, 6mm, 9mm or 12mm ■ **Placement:** Any fundus location ■ **Rotation:** -89° to 90°
	**HD 21-Line Raster Scan** **Averaging per line:** 8 **A-scans:** 1024	■ **Length:** 3mm, 6mm or 9mm ■ **Placement:** Any fundus location ■ **Rotation:** -89° to 90° ■ **Spacing:** 0 to 0.4mm (in increments of 0.025 mm)
	**HD Cross** (5 horizontal & 5 vertical lines) **Averaging per line:** 8 **A-scans:** 1024	■ **Length:** 3mm or 6mm ■ **Placement:** Any fundus location ■ **Rotation:** -89° to 90° ■ **Spacing:** 0 to 1.5mm (in increments of 0.025 mm) between lines
	**HD Radial Scan** (12 radial lines) **Averaging per line:** 8 **A-scans:** 1024	■ **Length:** 3mm or 6mm ■ **Placement:** Any fundus location

Table 36: Posterior Segment HD Scan Types and Patterns

8.10.3.1 About Enhanced Depth Imaging

CIRRUS™ HD-OCT optimizes the signal in the top portion of the scan, which is the best option for most types of scans. However; for some types of **Raster Scans**, you might want to optimize a different area of the scan.

Enhanced Depth Imaging (EDI) improves image quality at the bottom of B-scans.

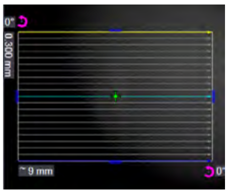
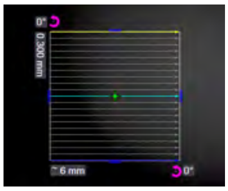
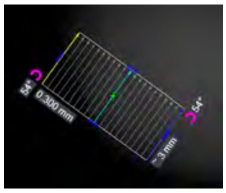
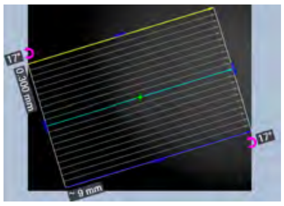
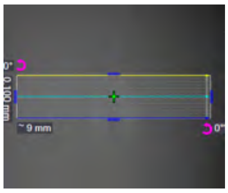
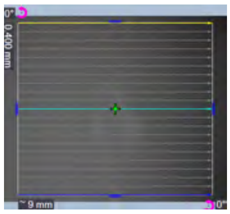
8.10.3.2 Adjusting HD Raster Scan Patterns

Scan patterns overlay the fundus image when you are preparing to acquire a scan. Most types of scans allow you to relocate the scan pattern within the live fundus preview.

Scan patterns help you center or place the scan in the location that obtains the best image of a particular area of interest for the patient's eye.

8.10.3.2.1 Customize Raster Scan Patterns (Drag)

You can rotate, stretch, or shrink scan patterns-- or create a custom scan pattern-- so you acquire the optimal area for each patient's eyes.

	Original	Adjustment Example 1	Adjustment Example 2
Adjust Line Length			
Rotate Scan Pattern			
Adjust Line Spacing			

You can customize scan patterns by dragging, pulling, or rotating the scan pattern that overlays the fundus image. The line length, spacing between lines, and rotation angle displays to show the measurements.

Figure 27: Adjust Scan Pattern Overlaying the Fundus Image

You can also click **Custom** to open the **Custom Scan Pattern** tool and change the measurements numerically.

Adjustments apply to all lines. For example, if you are acquiring a 5-Line raster scan and you rotate the scan pattern, all five lines rotate as a block. You cannot rotate each line independently.

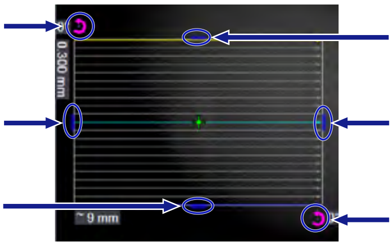
If you increase the distance between lines, the spacing between all lines increases. You cannot change the distance between particular lines of the scan pattern.

To adjust the scan pattern:

Prerequisite

☑ You are acquiring a scan and reached the step: *Customize a Raster Scan Pattern*.

Action



1. Mouse over the scan pattern that overlays the fundus image.
   ⇨ A set of blue adjustment bars and magenta rotation tools for the scan pattern open and the mouse pointer becomes a hand icon.
2. To lengthen the lines, drag a horizontal adjustment bar out.
3. To shorten the lines, drag a horizontal adjustment bar in.
4. To increase the spacing between lines, drag a vertical adjustment bar out.
5. To decrease the spacing between lines, drag a vertical adjustment bar in.
6. To rotate the scan pattern, drag a rotation tool to a different angle.

7. To reset the scan pattern to its original settings, click **Reset Scan Pattern**.
8. Complete the remaining steps of the acquire procedure.

8.10.3.2.2 Customize Raster Scan Patterns (Numeric)

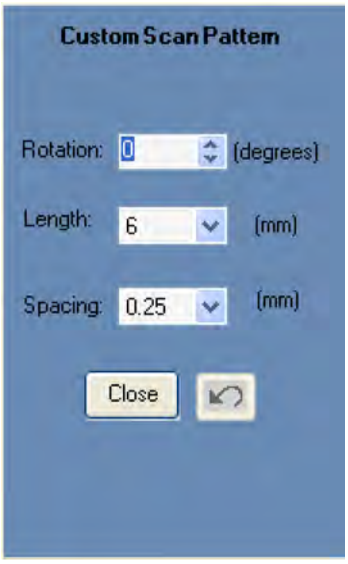
To adjust the scan pattern using the Custom tool:

Prerequisite

☑ You are acquiring a scan and reached the step: *Customize a Raster Scan Pattern*.

1. Click **Custom**.

Action



   ⇨ The **Custom Scan Pattern** tool opens.
2. To rotate the scan pattern: for **Rotation**, type a value between 0 (horizontal) and 360 that corresponds with the rotation angle you want to set.
   Values entered from 91 to 269 are automatically transposed 180 degrees to correspond with scan direction.
3. To change the line length: for **Length**, select the value you want to set.
   ⇨ Depending on the scan, you can select 3, 6, or 9 mm.
4. To change the spacing between lines: for **Spacing**, select an available value.
   ⇨ Depending on the scan, you can select a value between 0.00 and 1.25 mm in increments of 0.025 mm.

5. To reset the scan pattern to its original settings, click **Reset**.

6. Click **Close**.
7. Complete the remaining steps of the acquire procedure.

8.10.3.3 Acquire an HD Raster Scan

NOTE

Make sure that the B-scan images are not too high in the viewport.

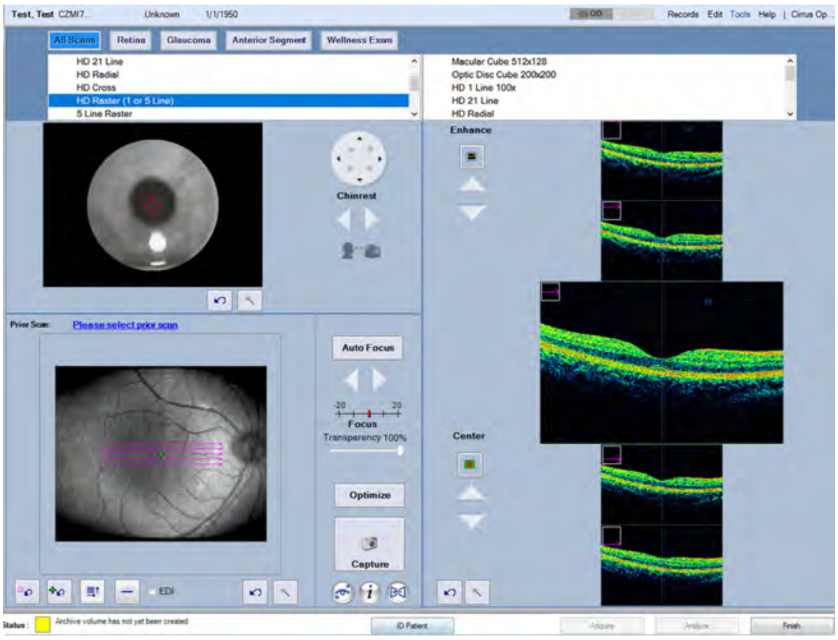
▶ If a B-scan image is too high, it can reflect a mirror image that makes the image appear inverted.

If this is a followup visit and you want to replicate the settings of an earlier scan, refer to: Repeating a Prior Scan (Track to Prior).

You can switch from a **5-Line HD Raster** scan to a **1-Line HD Raster** scan using the toggle button.

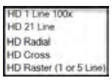
Tip: For HD 5-Line and HD 1-Line scans, position the scan pattern before you toggle between 1-Line and 5-Line.

To acquire an HD raster scan:

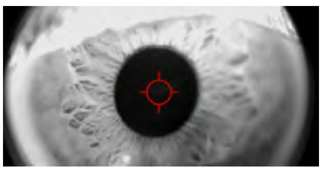


Action

1. Select the Patient [▷ 124].
2. Prepare the Patient [▷ 135]
3. Choose an **HD Raster** scan pattern (see: About HD Raster Scans).



4. Under the appropriate eye (OD or OS), select **HD 1 Line 100x**, **HD 21 Line**, **HD Radial**, **HD Cross**, or **HD Raster (1 or 5 Line)**.



5. Align and Focus the Iris Image [▷ 214].
6. To adjust the scan pattern, refer to: Adjusting HD Raster Scan Patterns [▷ 156]

7. If you selected **HD Raster (1 or 5 Line)**, click **Toggle** to switch between the 1-Line pattern and the 5-Line pattern.
   ⇨ If you adjust the 1-Line Raster scan pattern, the toggle button becomes disabled.

8. To enable EDI, check EDI.

   ⇨ EDI optimizes the signal in the lower portion of the scan.

9. Ask the patient to hold their gaze steady and click **Auto Focus**.

   ⇨ The chinrest moves into place as the CIRRUS 6000 automatically corrects for the patient's refraction error and balances fundus brightness and contrast.

10. To manually focus the image, see: Focus the Fundus Image [▸ 209].

11. Click **Optimize**.

    ⇨ CIRRUS 6000 automatically centers and optimizes B-Scan settings. You can fine-tune these settings manually.

12. To fine-tune B-Scan image quality and centering, see: Manually Enhance B-Scans [▸ 211].

13. Ensure that the live Iris, Fundus, and B-scan images are all properly focused and aligned.

14. Ask the patient to blink, then open their eyes wide.

15. Click **Capture**.

    ⇨ The **Quality Check** screen opens.

16. Check HD Raster Scan Quality [▸ 161]

8.10.3.4 Check HD Raster Scan Quality

Tip: To see more detail in high-resolution images, switch to black-and-white mode (hover over the image and click the color button:

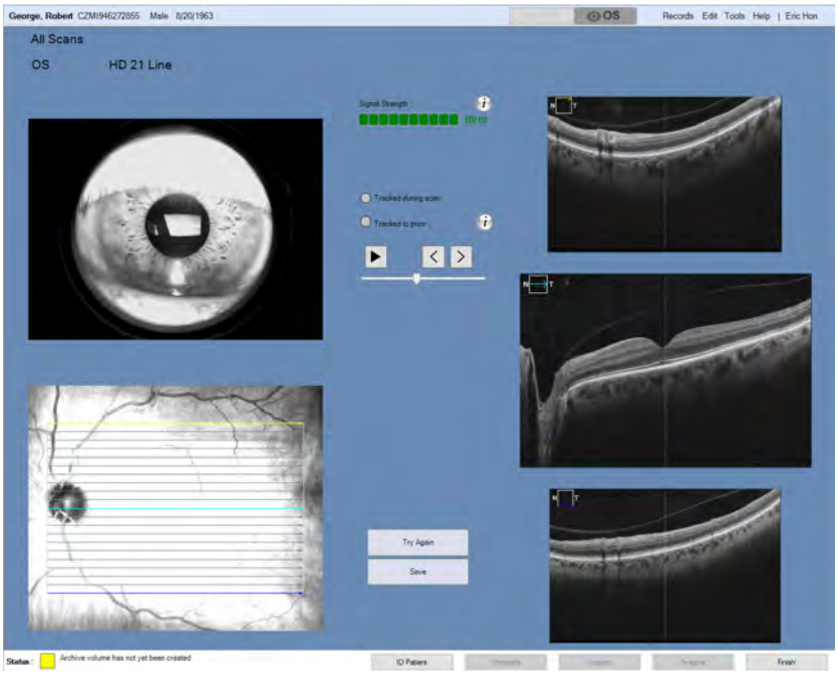


Figure 28: Quality Check for HD Raster 21-Line

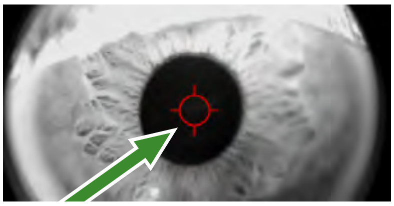
To check HD Raster scan quality:

Prerequisite

☑ Acquire an HD Raster Scan [▹ 159]

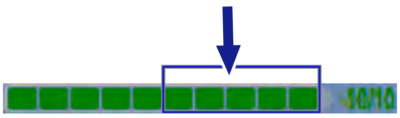
Action

1. Ensure that the target is centered on the pupil.

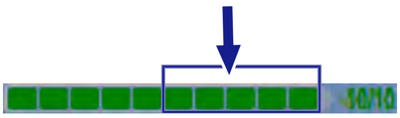


   ⇨ *The green arrow shows the iris target placed over the pupil.*

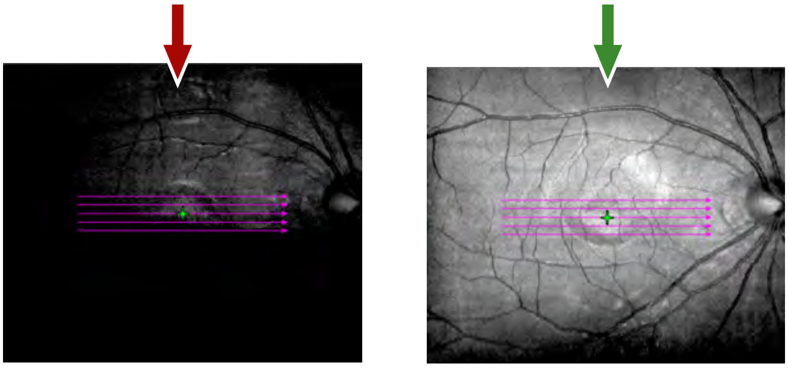
2. Ensure that the **Signal Strength** is 6 or higher.



3. If **FastTrac** is on, ensure that **Tracked during scan** is green (successful) and the **Fundus Image** rating is 6 or higher.



   ⇨ A rating of 6 or higher is needed to reuse the scan settings in the future (see: About Track to Prior [▹ 220]).

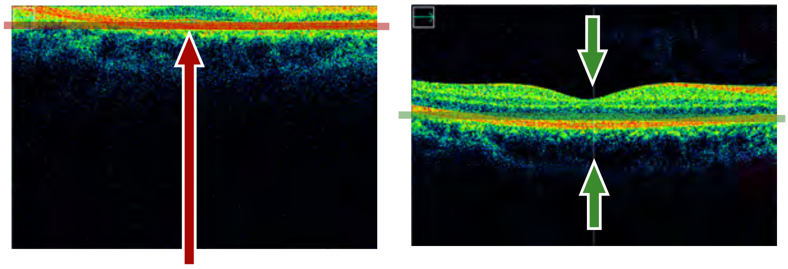


4. Ensure that the fundus image focus is sharp and clear with good visibility of the branching blood vessels and that the lighting is uniform across the image.

   ⇨ *The green arrow shows a good-quality fundus image.*

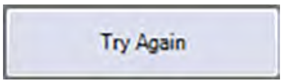
5. To view a full-screen version of an image, double-click on the image.

6. To adjust the brightness or contrast of the fundus image, hover over the fundus image and select the **Brightness** or **Contrast** tool (see:Edit Images (Hover Over) [▹ 370]).



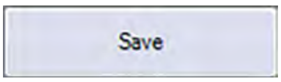
7. Ensure that the B-scan(s) are centered.

   ⇨ *The green arrows show a centered B-scan.*



8. If the scan is not acceptable, click **Try Again** and retake the scan.

   ⇨ See: Acquire an HD Raster Scan [▹ 159]



9. Click **Save**.

8.11 Acquire AngioPlex Scans

AngioPlex OCT Angiography scans capture high quality images of the retinal and choroidal vasculature.

High-definition (HD) 6x6 mm and 8x8 mm scans provide very high quality images, and the 12x12 mm scan offers the widest field of view in a single scan.

There are three types of **AngioPlex** scans:

- **AngioPlex Macular** scans acquire a cube of data centered on the fovea.
- **AngioPlex ONH** scans acquire a cube of data centered on the optic nerve head.
- **AngioPlex Montage** scans acquire multiple images from different areas and merge them into one larger, combined image.

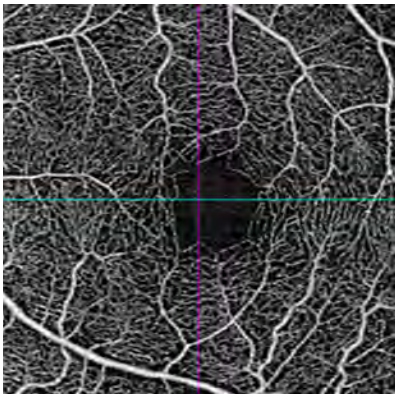
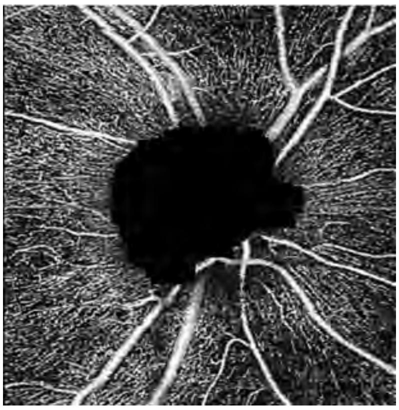
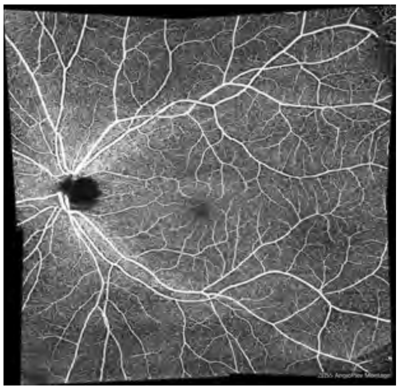
AngioPlex	AngioPlex ONH	AngioPlex Montage
		

Table 37: AngioPlex Scans

To image vascular flow, each AngioPlex scans acquire repeated, consecutive B-scans, then compares them. Erythrocyte motion shows areas of contrast changes over time in a particular location, which indicates the location of a vessel.

8.11.1 Acquire an OCT Angiography Scan

NOTE

AngioPlex OCT Angiography is not a substitute for fluorescein angiography.

- ▶ Vascular findings with fluorescein angiography may be absent or poorly defined with OCT angiography.
- ▶ OCT angiography does not feature leakage, staining, and pooling.

For the best results, acquire **OCT Angiography** scans with FastTrac turned **on** (see About FastTrac™ [▸ 217]).

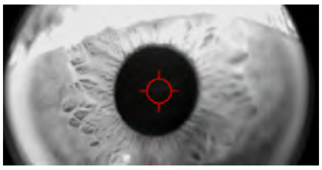
You can choose from the following **OCT Angiography** scan sizes:

- 3x3 mm
- 6x6 mm
- HD 6x6 mm
- 8x8 mm
- HD 8x8 mm
- 12x12 mm

To acquire an OCT angiography cube scan:

Action

1. Select the Patient [▸ 124].
2. Prepare the Patient [▸ 135]
3. Scan Types [▸ 136] (if needed).
4. Align and Focus the Iris Image [▸ 214].



5. Ask the patient to hold their gaze steady and click **Auto Focus**.
   ⇨ The chinrest moves into place as the CIRRUS 6000 automatically corrects for the patient's refraction error and balances fundus brightness and contrast.
6. To manually focus the image, see: Focus the Fundus Image [▸ 209].

7. To change the position of the scan or fixation target, see: Select an Internal Fixation Target.

8. Click **Optimize**.
   ⇨ CIRRUS 6000 automatically centers and optimizes B-Scan settings. You can fine-tune these settings manually.
   ⇨ **NOTE! Auto-centering moves the OCT B-scan higher in the imaging window to maximize signal strength.**
9. Confirm that the B-scan remains within the imaging window approximately 100 µm below the top of the scan.
   ⇨ If tracking is on, the B-scan might shift upwards.
10. If the B-scan shifts upwards, reposition the B-scan to approximately 100 µm below the top.
11. To fine-tune B-Scan image quality and centering, see: Manually Enhance B-Scans [▸ 211].

12. Turn FastTrac™ On [▸ 219]. **NOTE! Once you turn FastTrac on, you cannot make further scan adjustments. If you need to make additional adjustments, turn off FastTrac, make adjustments, and turn FastTrac on again.**
13. Ask the patient to blink, then open their eyes wide.

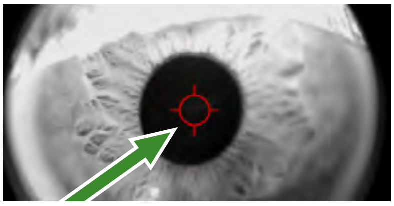
14. Click **Capture**.
    ⇨ The **Quality Check** screen opens.
15. Ask the patient to sit back.
16. Check AngioPlex Cube Scan Quality [▸ 165]

8.11.2 Check AngioPlex Cube Scan Quality

To check angiography cube scan quality:

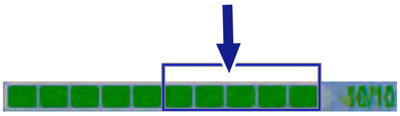
Prerequisite

☑ Acquire an OCT Angiography Scan [▸ 163]



1. Ensure that the target is centered on the pupil.

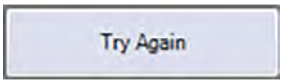
Action



2. Ensure that the **Signal Strength** is 6 or higher.
3. Ensure that light intensity is uniform across the image.
4. Ensure that the fundus image is sharp and clear with good visibility of the branching blood vessels.
5. If the fundus scan has an overlay, adjust the transparency of the overlay.

6. To adjust the brightness or contrast of the fundus image, hover over the fundus image and select the **Brightness** or **Contrast** tool (see:Edit Images (Hover Over) [▸ 370]).
7. Ensure that there are few or no artifacts cast shadows on the OCT scan.
8. Ensure that there are few or no saccades in the area to be analyzed.
   Saccades appear as discontinuities of the blood vessels (horizontal shifts of the vessel):
9. Ensure that the scan is complete in all windows (no missing data).
10. Scan passes: RPE Acceptance Criteria [▸ 228].
    Retina is not too low in the scan, which impacts sub-RPE slice detection.
11. Scan passes: Signal Quality Acceptance Criteria [▸ 228].
    Signal strength is 6 or higher; shadows and dark spots exhibit floaters or disease.
12. Scan passes: Decorrelation Tails Acceptance Criteria [▸ 229].
    Scan shows accurate motion, no decorrelation tails, no vasculature in the RPE layer, and superficial and deep retinal layers look appropriately different.

13. Scan passes: Segmentation Acceptance Criteria [▸ 230].
    Presence or absence of flow appears in layers as appropriate.



14. If the scan is not acceptable, click **Try Again** and retake the scan.

15. Click **Save**.

8.11.3 Acquire ONH AngioPlex Scans

8.11.3.1 Acquire ONH AngioPlex Overview

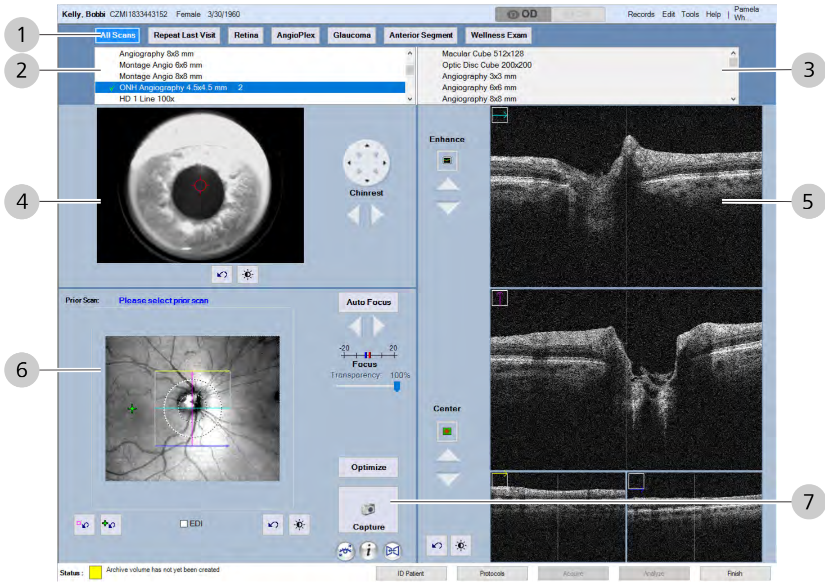
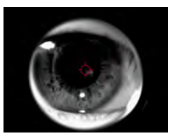
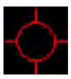
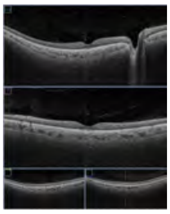
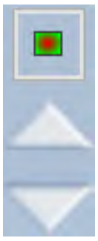
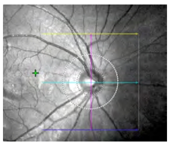
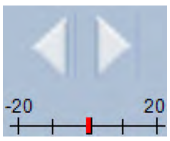
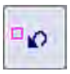
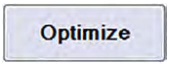
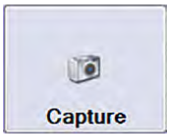


Figure 29: Acquire ONH AngioPlex Overview

#	Symbol	Name	Explanation
1		Protocols	Selects a protocol (see: About Protocols [▹ 145]).
2		Scan Selector	Selects OD scan type.
3			Selects OS scan type.
4		Iris Viewport	Displays the live image of the iris.
		Pupil Target	Indicates the pupil center alignment.
		Brightness and Contrast	Opens brightness and contrast adjustment controls.
		Reset	Resets your adjustments of the iris image.
		Chinrest Controls	Circular controls adjust the patient chinrest up, down, right or left. Left arrow moves chinrest toward patient. Right arrow moves chinrest toward device.

#	Symbol	Name	Explanation
5		B-scans	Displays the live B-scan images.
		Enhance	Button automatically adjusts polarization of the live B-scan images. Arrows adjust polarization manually.
		Center	Button automatically centers the live B-scan images. Arrows adjust centering manually.
6		*Identifies Selected Prior Scan*	Replicates the settings of a prior scan (to compare same scans of the same eye using the same settings).
		Fundus Viewport	Displays the live image and scan pattern.
		Fixation Target	Displays the location of the fixation target.
		**Auto Focus**	Automatically focuses the live scan.
		Manual focus	Focus slider or arrows adjust focus manually.
		**Transparency**	Controls the opacity of the overlay.
		Reset Scan Pattern	Returns the scan pattern to its default position.
		Reset Fixation Target	Returns the fixation target to the center.
		**EDI**	Inverts the OCT signal profile so the strong part of the signal is at the bottom of the B-scan.

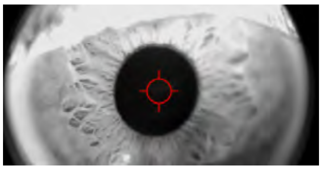
#	Symbol	Name	Explanation
7		**Optimize**	Automatically centers and enhances the B-scan.
		**Capture**	Captures the scan.
		FastTrac	Indicates whether FastTrac is on or off.
		Help	Displays tips for acquiring the best scan.
		Track to Prior	Sets tracking to align and track the scan at the same location on the retina as the selected prior scan. **NOTE! Tracking to prior automatically enables FastTrac.**

8.11.3.2 Acquire an AngioPlex ONH Scan

AngioPlex ONH scans helps you make vascular assessments of the optic nerve.

To acquire an AngioPlex ONH scan:

Action



1. Select the Patient [▹ 124].
2. Prepare the Patient [▹ 135]
3. Select the **ONH Angio** scan for the appropriate eye.
4. Align and Focus the Iris Image [▹ 214].

5. Ask the patient to hold their gaze steady and click **Auto Focus**.
   ⇨ The chinrest moves into place as the CIRRUS 6000 automatically corrects for the patient's refraction error and balances fundus brightness and contrast.
6. To manually focus the image, see: Focus the Fundus Image [▹ 209].
7. To change the position of the scan or fixation target, see: Select an Internal Fixation Target.

8. Click **Optimize**.
   ⇨ CIRRUS 6000 automatically centers and optimizes B-Scan settings. You can fine-tune these settings manually.
9. To fine-tune B-Scan image quality and centering, see: Manually Enhance B-Scans [▹ 211].

10. To use automatic eye tracking, Turn FastTrac™ On [▷ 219].
    NOTE! Once you turn FastTrac on, do not make further scan adjustments. If you need to make additional adjustments, turn off FastTrac, make adjustments, and turn FastTrac on again.
11. Ask the patient to blink, then open their eyes wide.

12. Click **Capture**.
    ⇨ The **Quality Check** screen opens.
13. Ask the patient to sit back.
14. Check ONH Angiography Scan Quality [▷ 170].

8.11.3.3 Check ONH Angiography Scan Quality

NOTE

Check scans quality carefully to ensure appropriate criteria for accurate disease diagnosis.

▶ If there are any questions regarding scan quality, rescan the image.

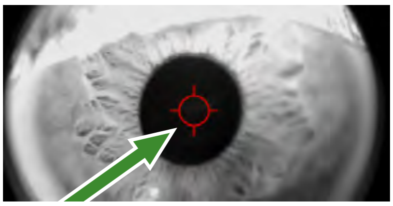
To check ONH Angiography scan quality:

Prerequisite

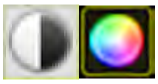
☑ Acquire an AngioPlex ONH Scan [▷ 169]

Action

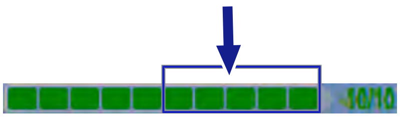
1. Ensure that the target is centered on the pupil.



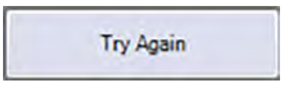
2. Ensure that light intensity is uniform across the image.
3. Ensure that the fundus image is sharp and clear with good visibility of the branching blood vessels.
4. If the fundus scan has an overlay, adjust the transparency of the overlay.



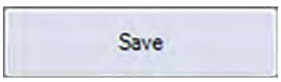
5. To adjust the brightness or contrast of the fundus image, hover over the fundus image and select the **Brightness** or **Contrast** tool (see:Edit Images (Hover Over) [▷ 370]).
6. Ensure that there are few or no artifacts cast shadows on the OCT scan.
7. Ensure that the scan is complete in all windows (no missing data).



8. Ensure that the **Signal Strength** is 6 or higher.



9. Ensure that the scan passes all acceptance criteria (refer to the *Instructions for Use*).
10. If the scan is not acceptable, click **Try Again** and retake the scan.



11. Click **Save**.

8.11.4 Acquire AngioPlex Montage Scans

AngioPlex Montage scans take a series of scans of an eye from different positions and fixation locations, then joins them together showing larger area of the retina.

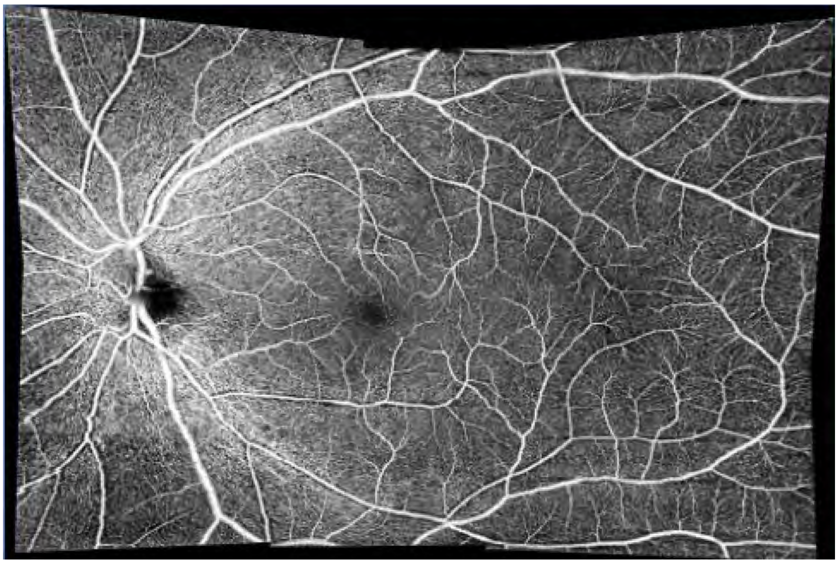


Figure 30: AngioPlex Montage

You can acquire all scans in the sequence or skip of the scans that you do not want to include in the montage.

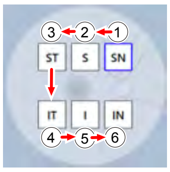
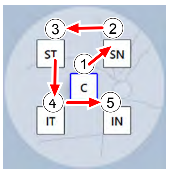
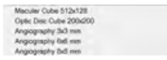
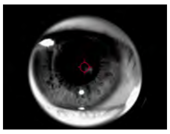
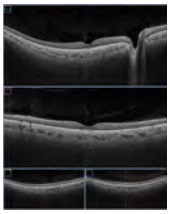
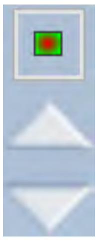
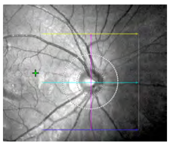
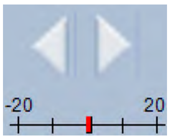
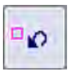
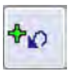
6 x 6 mm Montage		8 x 8 mm Montage	
	This scan acquires six images at different positions (four different fixation targets) in the following sequence: 1. Superior Nasal (SN) 2. Superior (S) 3. Superior Temporal (ST) 4. Inferior Temporal (IT) 5. Inferior (I) 6. Inferior Nasal (IN)		This scan acquires five images at different positions (five different fixation targets) in the following sequence: 1. Central (C) 2. Superior Nasal (SN) 3. Superior Temporal (ST) 4. Inferior Temporal (IT) 5. Inferior Nasal (IN)

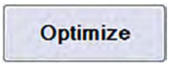
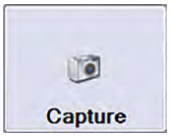
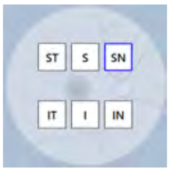
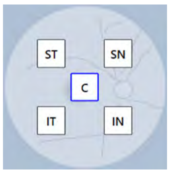
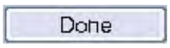
Table 38: **Montage AngioPlex** Scans

8.11.4.1 Acquire Montage Overview

Figure 31: Acquire AngioPlex Montage Overview

#	Symbol	Name	Explanation
1		Protocols	Selects a protocol (see: About Protocols [▸ 145]).
2		Scan Selector	Selects OD scan type.
3			Selects OS scan type.
4		Iris Viewport	Displays the live image of the iris.
		Pupil Target	Indicates the pupil center alignment.
		Brightness and Contrast	Opens brightness and contrast adjustment controls.
		Reset	Resets your adjustments of the iris image.
		Chinrest Controls	Circular controls adjust the patient chinrest up, down, right or left. Left arrow moves chinrest toward patient. Right arrow moves chinrest toward device.

#	Symbol	Name	Explanation
5		B-scans	Displays the live B-scan images.
		Enhance	Button automatically adjusts polarization of the live B-scan images. Arrows adjust polarization manually.
		Center	Button automatically centers the live B-scan images. Arrows adjust centering manually.
6		*Identifies Selected Prior Scan*	Replicates the settings of a prior scan (to compare same scans of the same eye using the same settings).
		Fundus Viewport	Displays the live image and scan pattern.
		Fixation Target	Displays the location of the fixation target.
		**Auto Focus**	Automatically focuses the live scan.
		Manual focus	Focus slider or arrows adjust focus manually.
		**Transparency**	Controls the opacity of the overlay.
		Reset Scan Pattern	Returns the scan pattern to its default position.
		Reset Fixation Target	Returns the fixation target to the center.
		**EDI**	Inverts the OCT signal profile so the strong part of the signal is at the bottom of the B-scan.

#	Symbol	Name	Explanation
7		**Optimize**	Automatically centers and enhances the B-scan.
		**Capture**	Captures the scan.
		FastTrac	Indicates whether FastTrac is on or off.
		Help	Displays tips for acquiring the best scan.
		Track to Prior	Sets tracking to align and track the scan at the same location on the retina as the selected prior scan. **NOTE! Tracking to prior automatically enables FastTrac.**
8		Scan Positions (6mm x 6mm)	Preset positions for each of the five component scans that are stitched together to create a 14 mm x 10 mm montage.
		Scan Positions (8mm x 8mm)	Preset positions for both component scans that are stitched together to create a 14 mm x 14 mm montage.
		Selected Scan Position	Indicates which scan will be acquired next (outlined in blue).
		Acquired Scan	Indicates which scans were already acquired.
		Scan Not Yet Acquired	Indicates scans they are not yet acquired.
		Retake Scan	Allows you to retake a component scan while acquiring the montage series.
		**Done**	Ends the montage series before all component scans are acquired.

8.11.4.2 Acquire a Montage AngioPlex Scan

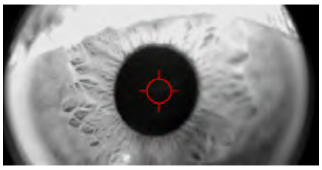
Montage AngioPlex scans increase the Field of View (FOV) by combining scans to form a montage image. Montage images provide high-resolution vascular imaging over a larger region of the retina.

When you acquire a **Montage AngioPlex** scan, you first acquire each component scan in the series, then check the quality of all component scans that make up the montage image at the same time.

To acquire a montage AngioPlex scan:

Action

1. Select the Patient [▸ 124].
2. Prepare the Patient [▸ 135]
3. Under the appropriate eye (OD or OS), select **Montage Angiography 8x8 mm** or **Montage Angiography 6x6 mm**.



4. Align and Focus the Iris Image [▸ 214].

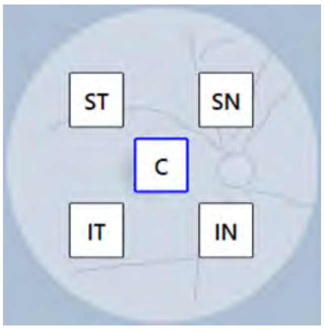
5. To change the position of the scan or fixation target, see: Select an Internal Fixation Target.
   ⇨ The fixation target might look blurry or out of fucus.

6. Ask the patient to hold their gaze steady and click **Auto Focus**.
   ⇨ The chinrest moves into place as the CIRRUS 6000 automatically corrects for the patient's refraction error and balances fundus brightness and contrast.
7. To manually focus the image, see: Focus the Fundus Image [▸ 209].

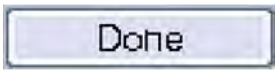
8. Click **Optimize**.
   ⇨ CIRRUS 6000 automatically centers and optimizes B-Scan settings. You can fine-tune these settings manually.
9. To fine-tune B-Scan image quality and centering, see: Manually Enhance B-Scans [▸ 211].

10. To use automatic eye tracking, Turn FastTrac™ On [▸ 219]. **NOTE! Once you turn FastTrac on, do not make further scan adjustments. If you need to make additional adjustments, turn off FastTrac, make adjustments, and turn FastTrac on again.**
11. Ask the patient to blink, then open their eyes wide.

12. Click **Capture**.
    ⇨ The instrument advances to the next image in the montage series (outlined in blue).



13. To acquire the next image in the series, repeat steps **5** - **13** above.
14. To select a different image in the series, click on the position of the image you want to capture, (the box becomes outlined in blue) and repeat steps **5** - **13** above.



15. To skip the remaining scans or finish the montage prior to acquiring all scans, click **Done**.
16. After the final scan of the series, ask the patient to sit back.
    ⇨ The **Quality Check** screen opens.
17. Check Montage AngioPlex Scan Quality [▸ 177].

8.11.4.3 Quality Check Screen (Montage)

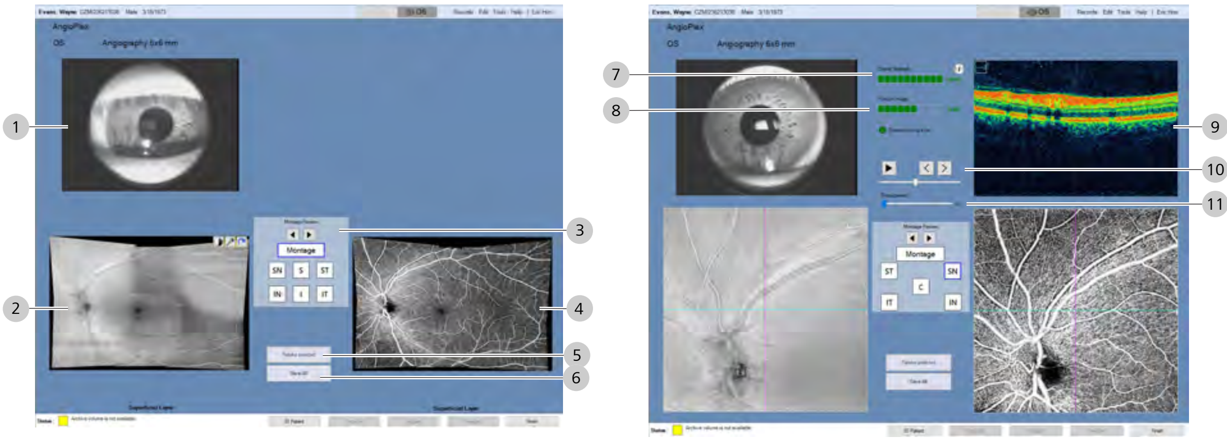
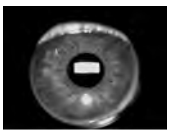
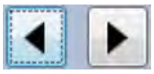
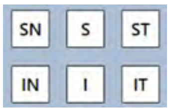
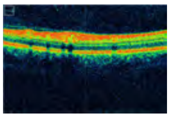
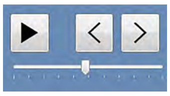


Figure 32: Angiography Montage Quality Check Overview

#	Symbol	Name	Explanation
1		Iris Image	Displays the iris image.
2		Fundus Image	Displays the fundus image (montage or individual image).

#	Symbol	Name	Explanation
3		Scroll Images	Navigates through the individual images that make up the montage.
		Individual Image Positions	Selects an individual image position: ■ **SN** - Superior Nasal ■ **S** - Superior (Center) ■ **ST** - Superior Temporal ■ **IN** - Inferior Nasal ■ **I** - Inferior (Center) ■ **IT** - Inferior Temporal
4		Angiography Image	Displays the angiography image (montage or individual image).
5		Selected for retake	Indicates which scan(s) will be retaken.
		**Retake selected**	Returns to the acquire screen to the re-scan the selected image position (without saving).
6		**Save All**	Saves the montage image and all individual images that make up the montage.
7		**Signal Strength**	Indicates the overall image signal strength.
8		**Fundus Image**	Indicates the overall fundus image signal strength.
9		B-Scan	Displays the B-scan of an individual image
10		Movie Controls	Scrolls through the cube as a movie.
		Movie Slider	Scrolls through the cube movie faster.
11		**Transparency**	Controls the opacity of the overlay.

8.11.4.4 Check Montage AngioPlex Scan Quality

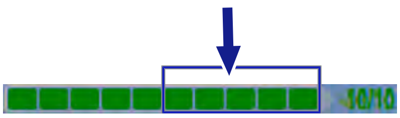
To check Montage AngioPlex scan quality:

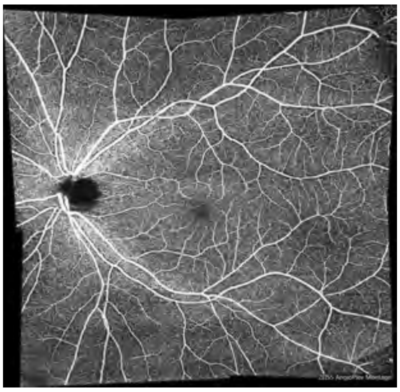
Prerequisite

☑ Acquire AngioPlex Montage Scans [▸ 171]

Action

1. Ensure that the target is centered on the pupil.
2. Ensure that the **Signal Strength** is 6 or higher.
3. Ensure that light intensity is uniform across the image.





4. Ensure that the fundus image is sharp and clear with good visibility of the branching blood vessels.
5. If the fundus scan has an overlay, adjust the transparency of the overlay.

6. To adjust the brightness or contrast of the fundus image, hover over the fundus image and select the **Brightness** or **Contrast** tool (see:Edit Images (Hover Over) [▸ 370]).

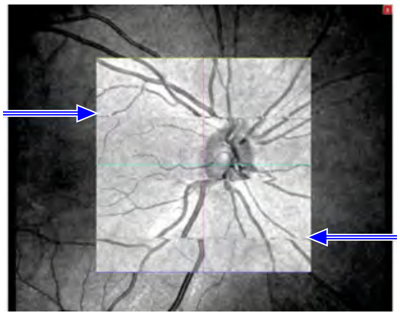
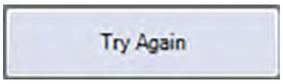


Figure 33: Saccades

7. Ensure that there are few or no saccades in the area to be analyzed.
   Saccades appear as discontinuities of the blood vessels (horizontal shifts of the vessel):
8. Ensure that the scan is complete in all windows (no missing data).
9. Ensure that the scan passes all acceptance criteria (refer to the *Instructions for Use*).



10. If the scan is not acceptable, click **Try Again** and retake the scan.

11. Click **Save**.

8.12 Acquire Anterior Segment Scans

NOTE

Features described in this section are licensed separately and may not be available in all markets.

▶ For information about feature availability in your market and obtaining a license:

⇨ in the U.S.A, call 1-877-486-7473.

⇨ outside the U.S.A , contact your local ZEISS distributer.

NOTE

Ensure that the patient is not wearing contact lenses for Anterior Segment scans.

Anterior segment measurements are not valid for patients wearing contact lenses.

NOTE

B-scan adjustment works differently for anterior segment scans.

Enhance and **Center** adjustment tools are not available.

▶ Adjust the chinrest to center images vertically.

▶ Shift + mouse scroll wheel does not bring the scan into the acquisition window.

CIRRUS™ HD-OCT images and measures structures in the anterior segment.

For some anterior segment scans, you must fist attach an external lens (see: Attach External Lens [▷ 181]). There are two different external lenses. Use the correct lens for the type of scan you are acquiring.

When you install an external lens or select an anterior segment scan:

- LSO illumination of the retina turns off
- Iris illumination dims (to avoid causing pupillary constriction)
- The internal lens clicks into position
- The internal fixation target centers
- The patient sees the green fixation target against a black background and with a (blurred) red flashing scan pattern.

CIRRUS™ HD-OCT software corrects the bean scanning geometry and refraction on the corneal surfaces for some anterior scan types. For these scans, you can view the raw image or corrected image during analysis. Corrected scans are:

- Anterior Chamber
- Wide Angle-to-Angle
- HD Cornea

- HD Angle
- Pachymetry

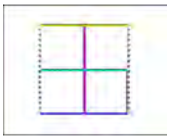
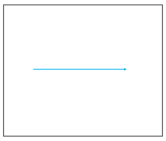
Scan Pattern	Scans	Details
	**Anterior Segment Cube** ■ Creates a 3D image ■ **B-Scans:** 128 ■ **A-Scans:** 512 ■ **HD B-Scans:** 2 ■ **A-Scans per HD B-Scan:** 1024	■ Creates a 3D image ■ **Scan Depth:** 2mm ■ **Scan Depth:** 2mm
	**Anterior Segment 5 Line Raster**	View images of the anterior chamber angle and cornea. ■ Five parallel horizontal lines 0.25mm apart (1mm width total). ■ **Length:** 3.0mm (fixed)
	⊕**Anterior Chamber** ■ **Averaging per line:** 20 ■ **A-Scans:** 1024	■ **Scan Depth:** 5.8mm ■ **Length:** 15.5mm (rotation may reduce to 14.0mm) ■ **Adjustments:** -89 to 90°
	⊕**HD Angle** ■ **Averaging per line:** 20 ■ **A-Scans:** 1024	Angle measurements for one iridocorneal angle ■ **Scan Depth:** 2.9mm ■ **Length:** 6.0mm ■ **Adjustments:** -89 to 90°
	⊕**Wide Angle-to-Angle** ■ **Averaging per line:** 20 ■ **A-Scans:** 1024	Angle measurements for a both iridocorneal angles (0° and 180°) ■ **Scan Depth:**2.9mm ■ **Length:** 15.5mm (rotation may reduce to 14.0mm) ■ **Adjustments:** -89 to 90°
	⊕HD Cornea ■ **Averaging per line:** 20 ■ **A-Scans:** 1024	Shows a wider field of view (than 5-Line). ■ **Scan Depth:** 2.0mm ■ **Length:** 9.0mm ■ **Adjustments:** -89 to 90°.
	⊕Pachymetry ■ **B-Scans:** 24 (radial) ■ **A-Scans:** 1024	Measure corneal thickness, epithelial thickness, and view a color-coded thickness map of the cornea. ■ **Scan Depth:**2.0mm ■ **Diameter** 9.0mm

Table 39: Anterior Chamber Lens

⊕ Indicates optional features (see: About Licenses [▹ 61]).

- Anterior Chamber Scans [▹ 184]
- HD Angle Scans [▹ 194]

- Wide Angle to Angle Scans [▷ 197]
- Anterior Segment 5-Line Raster Scans [▷ 191]
- Acquire HD Cornea Scans
- Acquire Pachymetry Scans

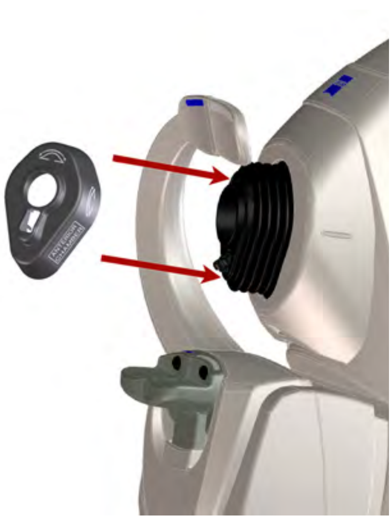
If this is a followup visit and you want to replicate the settings of an earlier scan, refer to: Repeating a Prior Scan (Track to Prior).

8.12.1 Attach External Lens

There are two external lenses. Use the appropriate lens for the type of scan.

Scans	Lens	Symbol	Label
■ Anterior Chamber ■ Wide Angle to Angle	 		ANTERIOR CHAMBER
■ HD Cornea ■ Pachymetry	 		CORNEA

Table 40: External Lens Identification



To attach an external lens:

1. Install the external lens onto the instrument lens mount.
   ⇨ The instrument detects the lens, adjusts lens position, and displays the scans appropriate for the lens.

Action

8.12.2 Acquire Anterior Segment Overview

For descriptions of the common acquire buttons and features, see: Acquire Posterior Segment Overview [▸ 140]

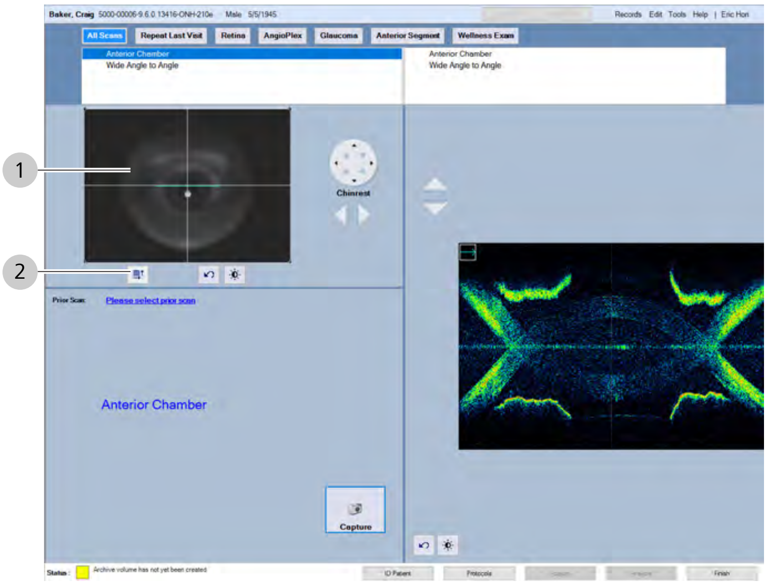
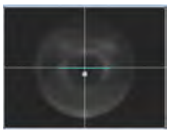
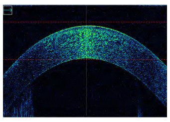
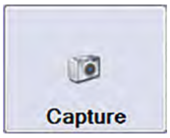


Figure 34: Acquire Anterior Chamber Scan Overview

#	Symbol	Name	Explanation
1		Protocols	Selects a protocol (see: About Protocols [▸ 145]).
2		Scan Selector	Selects OD scan type.
3			Selects OS scan type.

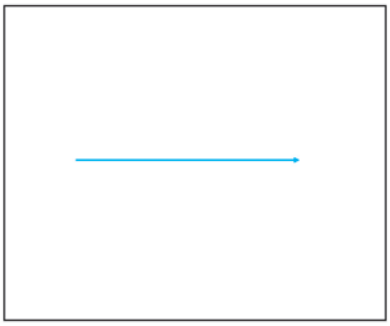
#	Symbol	Name	Explanation
4		Iris Viewport	Displays the live image of the iris.
		Brightness and Contrast	Opens brightness and contrast adjustment controls.
		Reset	Resets your adjustments of the iris image.
		Customize Scan Pattern	For scan patterns that adjust, set numeric values for line length, spaces between lines, etc..
		Chinrest Controls	Circular controls adjust the patient chinrest up, down, right or left. Left arrow moves chinrest toward patient. Right arrow moves chinrest toward device.

#	Symbol	Name	Explanation
5	**B-Scan**		
		**B-Scan**	Live display of alignment.
6	**Capture**		
		Identifies Selected Prior Scan	Replicates the settings of a prior scan (to compare same scans of the same eye using the same settings).
		**Capture**	Captures the scan.

8.12.3 Anterior Chamber Scans

The **Anterior Chamber** scan generates a wide field, speckle-reduced raster scan of the front of the eye that is higher contrast than the **Anterior Segment 5 Line Raster** scan. It produces 20 B-scans, each comprised of 1024 A-scans.

By allowing the source and mirror images to overlap, the CIRRUS™ HD-OCT shows a scan depth of 5.8mm. **NOTE! In the overlap region (indicated by blue overlay), there is less detail.**



The scan pattern is a single, horizontal line that you can rotate from -89° to 90°. You cannot lengthen or shorten the line or reposition it higher or lower.

You can enhance the image manually before you capture the scan.

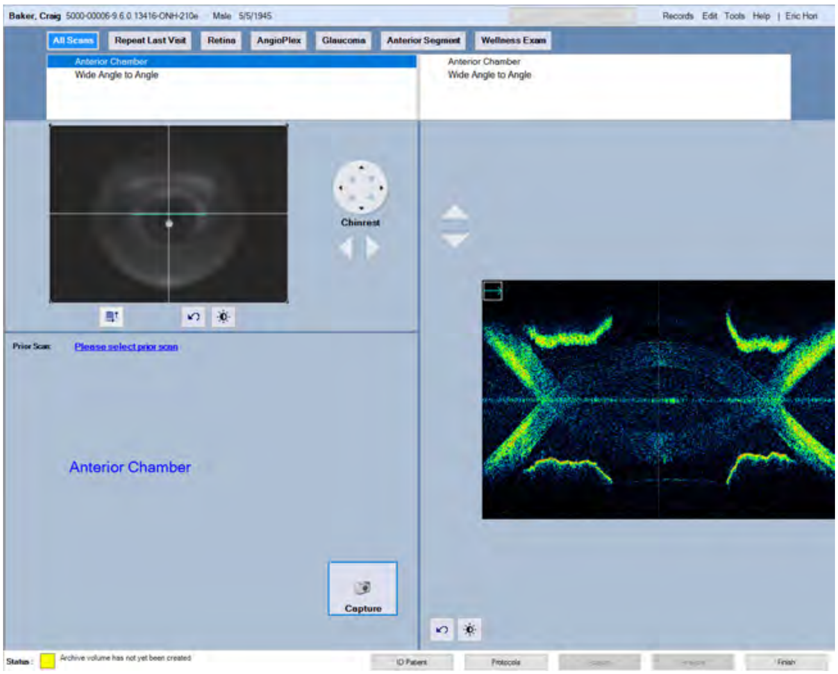


Figure 35: Acquire Anterior Chamber Scan

Analysis Considerations

For analysis, CIRRUS™ HD-OCT software adjusts the scan to account for beam scanning geometry and refraction on the corneal surfaces. For accurate results, center the scan 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.

Make sure you align the image for an **Anterior Chamber** scan correctly:

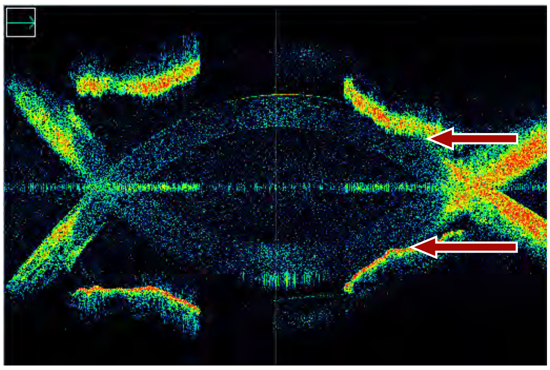
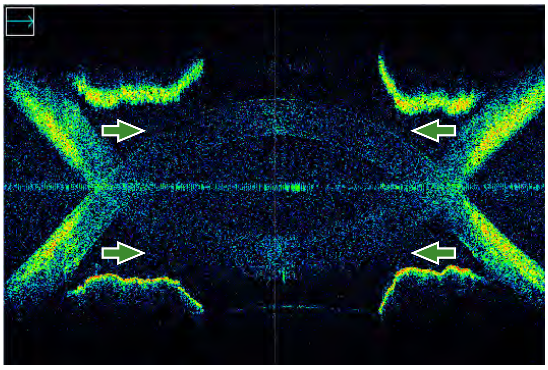
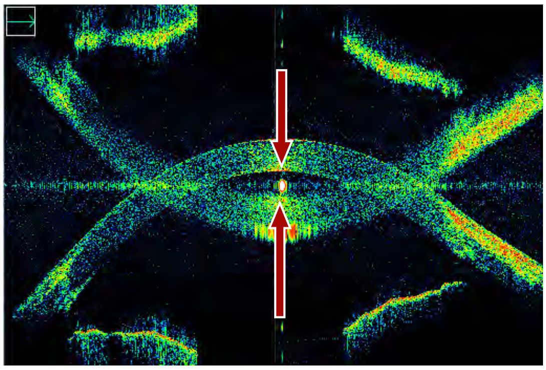
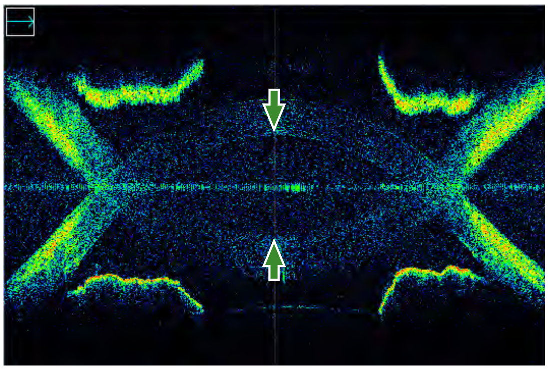
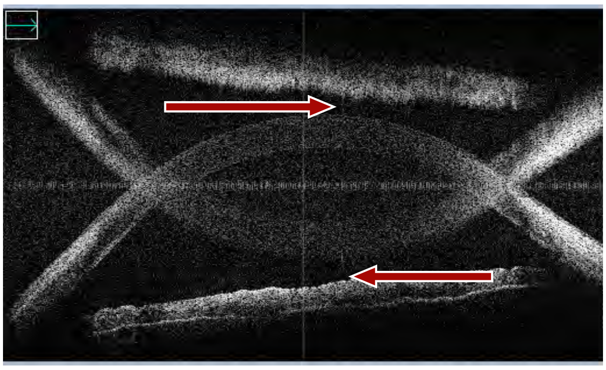
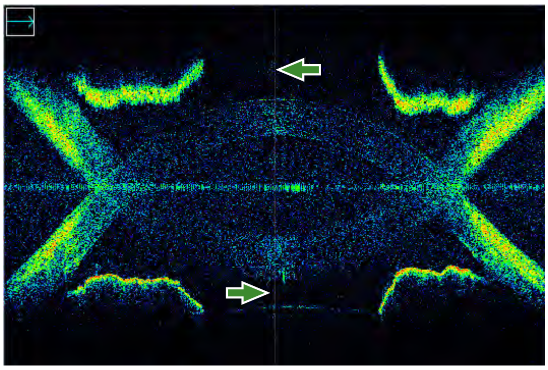
Incorrect Alignment	Correct Alignment
 Cornea and Iris are too close.	
 Cornea and Mirror Cornea are too close.	
 Image is not centered.	

Table 41: Aligning the Anterior Chamber Image

The analysis available for this scan is: Analyze Anterior Chamber Scans [342].

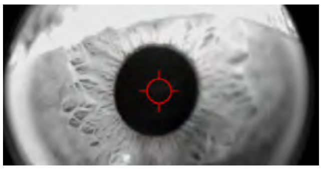
8.12.3.1 Acquire an Anterior Chamber Scan

To acquire an anterior chamber scan:

Action

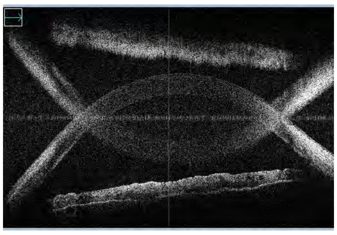
1. Select the Patient [124].
2. Prepare the Patient [135]

3. Attach the **Anterior Chamber** lens (Attach External Lens [▸ 181]).

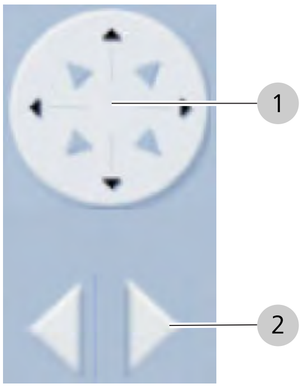


4. Align and Focus the Iris Image [▸ 214].
   ⇨ A strong vertical central reflection line on the B-scan indicates the scan is centered on the corneal vertex.

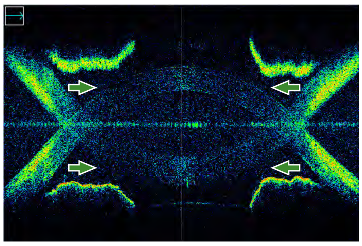
5. To change the position of the scan or fixation target, see: Select an Internal Fixation Target.
6. Instruct the patient to lean forward and fixate on the center of the fixation target.
   ⇨ The fixation target might look blurry or out of fucus.
7. To adjust the brightness or contrast of a b-scan image, see: Edit Images (Hover Over) [▸ 370]



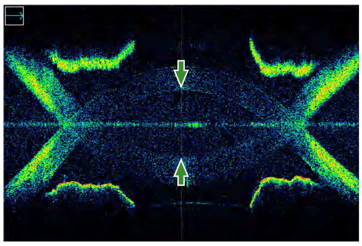
8. If the anterior chamber is tilted, instruct the patient to shift their gaze slightly (eft or right as needed) until the anterior chamber is horizontal.



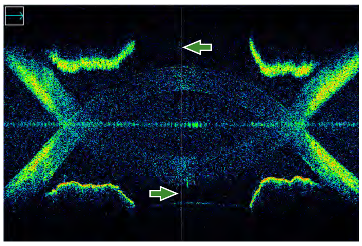
9. Use the chinrest controls to center and adjust the image:
   ⇨ Move the chinrest up or down as needed (1).
   ⇨ Move the chinrest right or left as needed (1).
   ⇨ Move the chinrest closer or further away as needed (2).



10. Adjust the image so that the cornea and iris are separated (cornea and iris are not too close or touching).



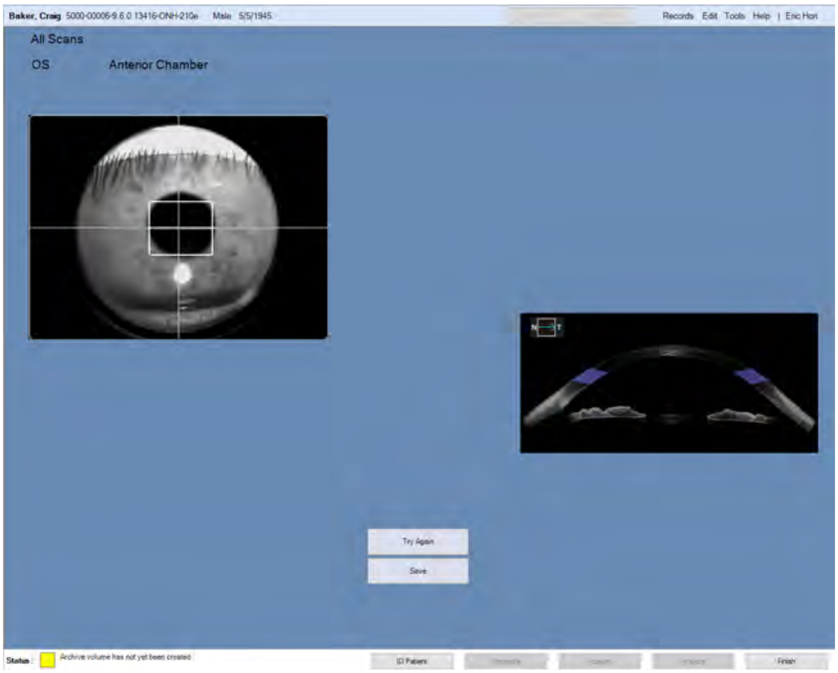
11. If the mirror image is turned on, align the image:
    ⇨ The cornea and mirror cornea image are separated properly (mirror image is not too close to the cornea).



12. Ask the patient to blink, then open their eyes wide.

13. Click **Capture**.
    ⇨ The **Quality Check** screen opens.
14. Ask the patient to sit back.
15. Check Anterior Segment Cube Scan Quality [▹ 190].

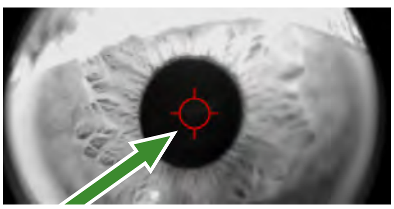
8.12.3.2 Check Anterior Chamber Scan Quality



To check anterior chamber cube scan quality:

Prerequisite

☑ Acquire an Anterior Chamber Scan [▹ 185].

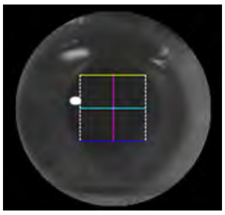


1. Ensure that the target is centered on the pupil.
   ⇨ *The green arrow shows the iris target placed over the pupil.*
2. To view a full-screen version of an image, double-click on the image.

Action

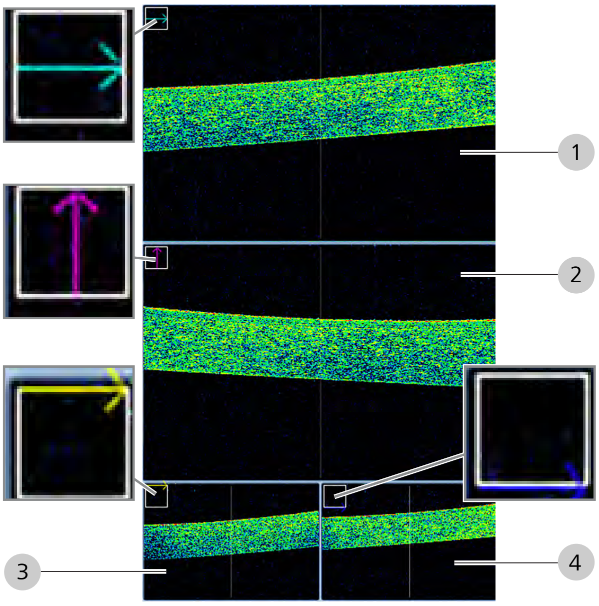
3. If the scan is not acceptable, click **Try Again** and retake the scan.
4. Click **Save**.

8.12.4 Anterior Segment Cube



The live iris image displays the position of the **Anterior Segment Cube 512x128** scan pattern.

When you acquire an anterior cube scan, the cornea appears flat in the display. The instrument focuses the OCT beam onto the anterior segment and scans in an arc to allow the curved cornea to better fit into the 2 mm scan depth. The cornea appears with the expected curvature during review and analysis.



The OCT B-scan images display:

- the horizontal scan lines of the selected cube slice (1).
- the vertical scan lines of the selected cube slice (2).
- the top horizontal cube slice (3) .
- the bottom horizontal cube slice (4) .

Aligning the Image

Make sure you align the image correctly:

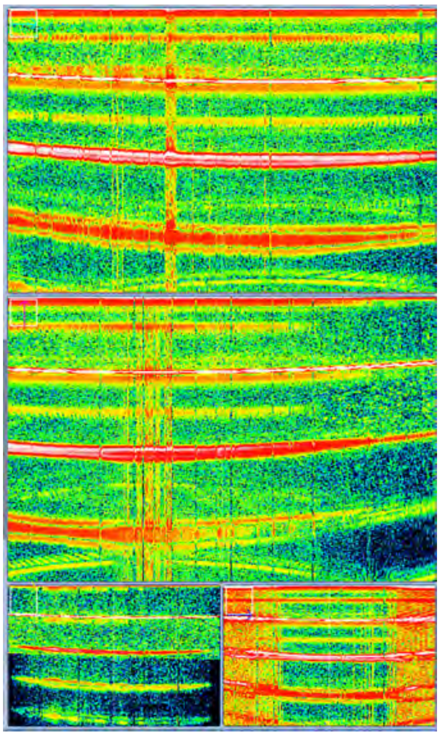
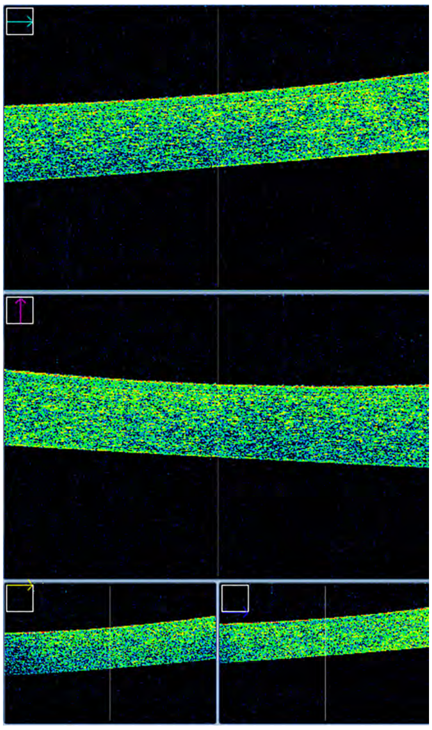
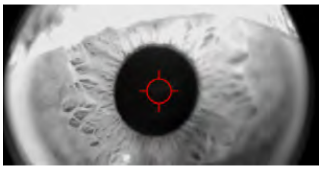
Incorrect Alignment	Correct Alignment
Corneal reflection causing bright artifact. 	Moved slightly away from center to avoid corneal reflection. 

Table 42: Aligning the Anterior Chamber Cube B-Scan

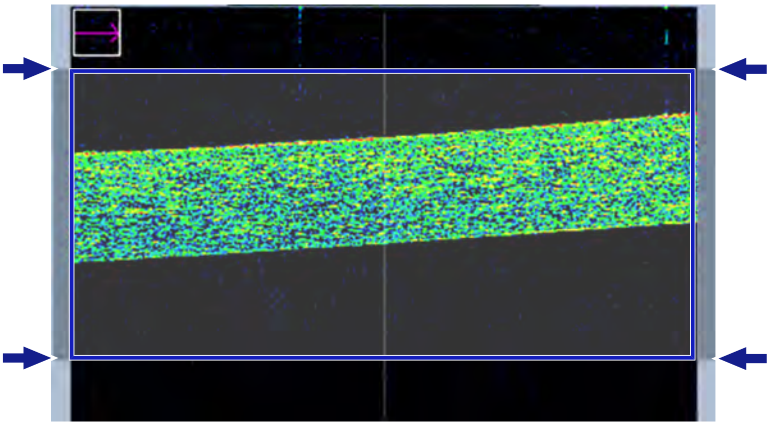
8.12.4.1 Acquire an Anterior Segment Cube Scan

Action

1. Select the Patient [▷ 124].
2. Prepare the Patient [▷ 135]
3. Select the **Anterior Segment Cube 512 x 128** scan for the appropriate eye.
   ⇨ The instrument moves into place.
4. Instruct the patient to lean forward and fixate on the center of the fixation target.



5. Align and Focus the Iris Image [▷ 214].



6. Use the chinrest controls to center and align the cornea. Make sure the cornea is between the gray bars outside the center B-scan.
7. Center the scan between the gray bars in the middle B-scan (slightly off center to avoid corneal reflection).
   ⇨ If the patient's cornea is completely centered, a strong reflection from the anterior cornea can produce unwanted bright artifacts.
   ⇨ A strong vertical central reflection line on the B-scan indicates the scan is centered properly on the corneal vertex.
8. If the corneal reflection causes a bright artifact, adjust the chinrest slightly to offset the image.
9. Ask the patient to blink, then open their eyes wide.

10. Click **Capture**.
    ⇨ The **Quality Check** screen opens.
11. Ask the patient to sit back.
12. Check Anterior Segment Cube Scan Quality [▸ 190].

8.12.4.2 Check Anterior Segment Cube Scan Quality

NOTE

Always check scan quality before saving a scan.

Good quality scans are essential for accurate disease diagnosis.

▶ If you are not sure of the image quality, retake the scan.

A cube pattern with slice navigators below the iris image allows you to sequence through cube slices.

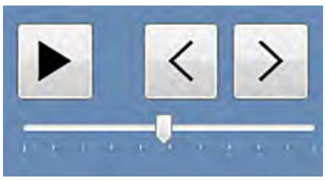
To check anterior chamber cube scan quality:

Prerequisite

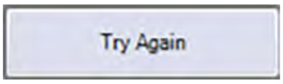
☑ Acquire an Anterior Chamber Scan [▸ 185]

Action

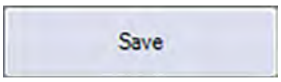
1. Ensure that the target is centered on the pupil.
2. To view a full-screen version of an image, double-click on the image.
3. To navigate through the cube data, move the cyan or magenta navigation lines (see: Navigate Cube Layers Manually [▸ 226]).



4. To view a sequence of cube slices as a movie, use the movie controls.



5. If the scan is not acceptable, click **Try Again** and retake the scan.



6. Click **Save**.

8.12.5 Anterior Segment 5-Line Raster Scans

The live iris image displays the position of the five-line scan pattern. You can move or rotate this pattern as needed. The B-scans correspond to the 5 scan lines.

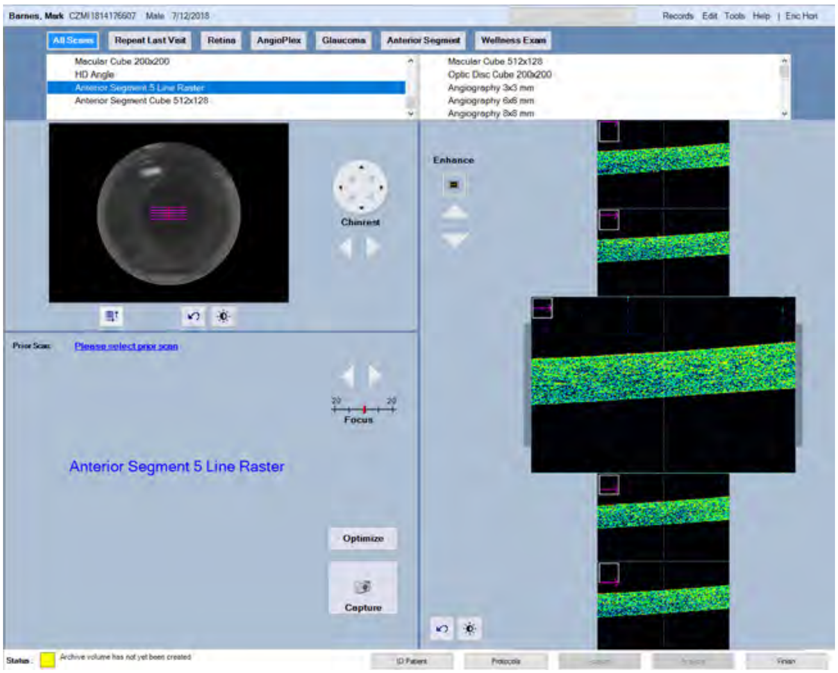


Figure 36: Acquire Anterior Segment 5 Line Raster Scan (Cornea)

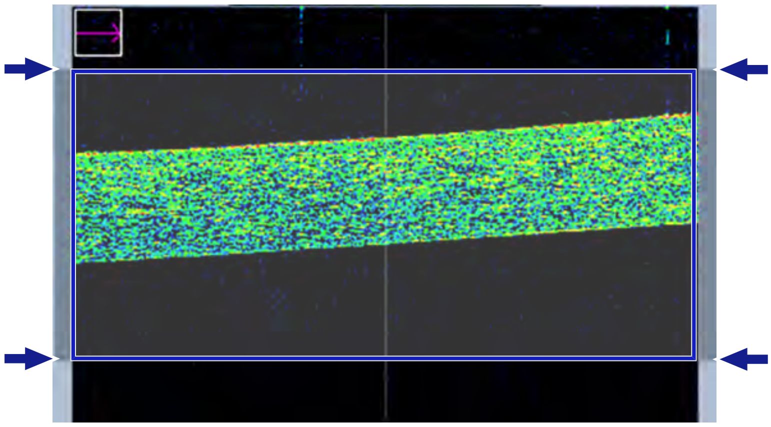
8.12.5.1 Acquire an Anterior Segment 5-Line Raster Scan

To acquire an anterior segment 5-line raster scan:

Action

1. Select the Patient [▷ 124].
2. Prepare the Patient [▷ 135]
3. Attach the **Anterior Chamber** lens (Attach External Lens [▷ 181]).
4. Select the **Anterior Segment 5-Line Raster** scan for the appropriate eye.
   ⇨ The instrument moves into place.

5. Align and Focus the Iris Image [▷ 214].

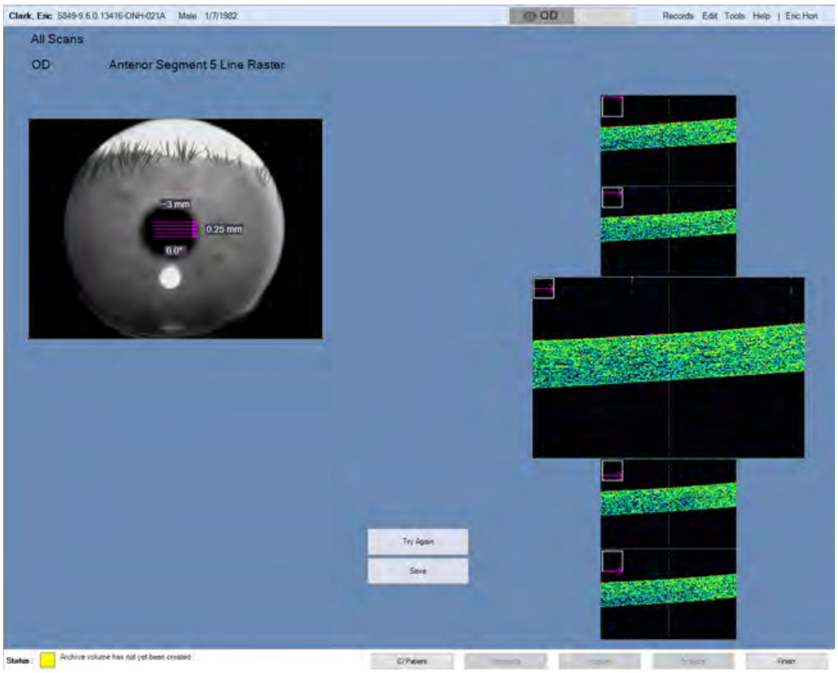


6. Use the chinrest controls to center and align the cornea. Make sure the cornea is between the gray bars outside the center B-scan.

7. To enhance image contrast and brightness, click **Adjust**.
8. Ask the patient to blink, then open their eyes wide.
9. Click **Capture**.
   ⇨ The **Quality Check** screen opens.
10. Ask the patient to sit back.
11. Check HD Angle Scan Quality [▸ 196].

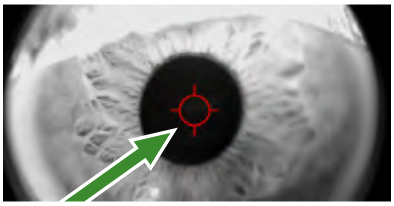
8.12.5.2 Check Anterior Segment 5-Line Raster Scan Quality

To check Anterior Segment 5-Line Raster scan quality:



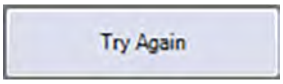
Prerequisite

☑ Acquire an Anterior Segment 5-Line Raster Scan [▸ 191].



Action

1. Ensure that the target is centered on the pupil.
2. To view a full-screen version of an image, double-click on the image.
3. To view a full-screen version of an image, double-click on the image.
4. Ensure that the cornea image is clear and you can see the layers of the cornea.
5. Ensure that light intensity is uniform across the image.
6. Ensure that the patient's eyelashes did not interfere with the image



7. If the scan is not acceptable, click **Try Again** and retake the scan.

8. Click **Save**.

8.12.6 HD Angle Scans

The **HD Angle** scan gives the highest resolution and greatest detail of one iridocorneal angle and provides the most accurate measurements.

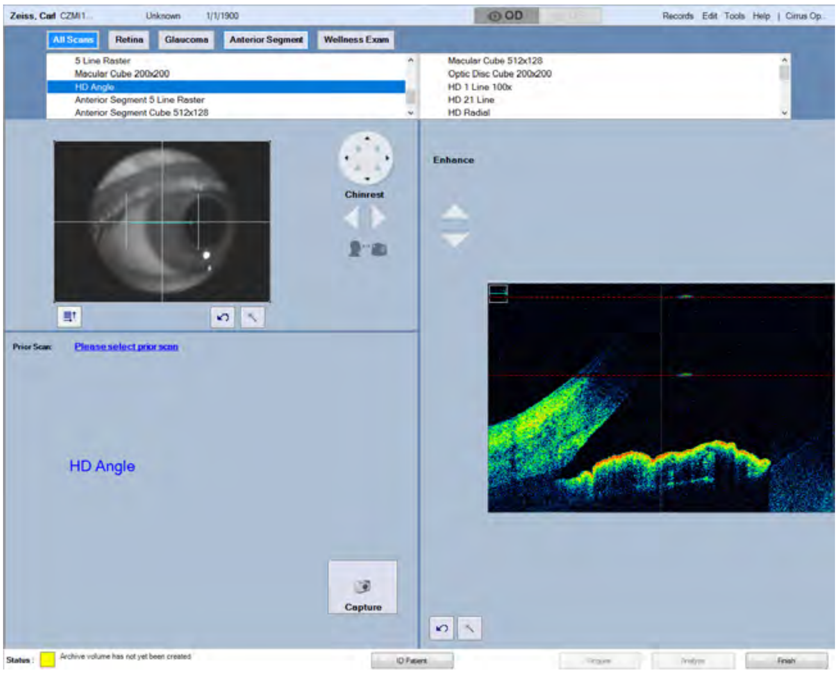


Figure 37: Acquire HD Angle Scan

- To view both angles and the iris shape in one image: Wide Angle to Angle Scans [▹ 197].
- To view five slices of the angle in one image: Anterior Segment 5-Line Raster Scans [▹ 191].

8.12.6.1 Acquire an HD Angle Scan

Tip: Scroll the mouse to center the B-scan.

Because there is no visible internal fixation target for the patient to view, the external fixation target can help the patient fixate.

To acquire an HD Angle scan:

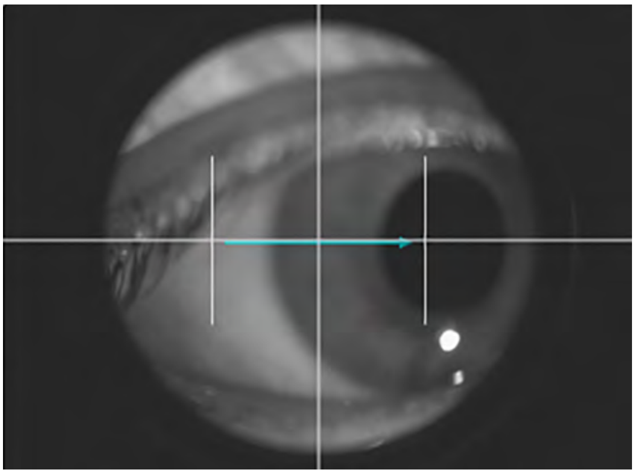
Prerequisite

☑ Install and position the external fixation target.

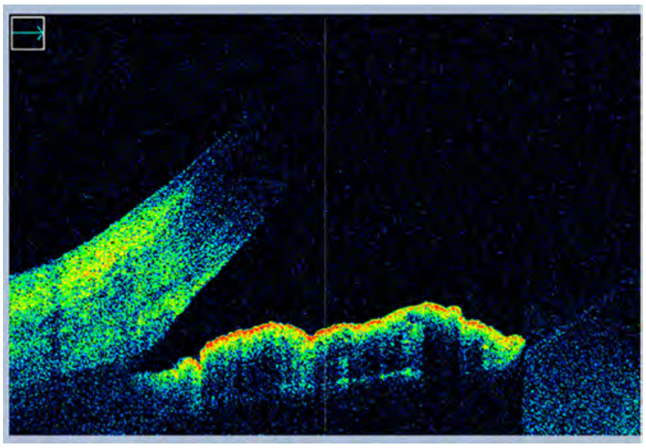
Action

1. Select the Patient [▹ 124].
2. Prepare the Patient [▹ 135]
3. Select the **HD Angle** scan for the appropriate eye.
   ⇨ The instrument moves into place.
4. Instruct the patient to lean forward and look straight ahead.

5. Align and Focus the Iris Image [▷ 214].



6. Click the edge of the iris where the angle you want to capture is located.



7. Adjust the chinrest controls until the angle (corneoscleral junction) is low in the B-scan viewport and the scan pattern is still in the middle of the iris (vertically).

   ⇨ Center the B-scan in the lower quadrant of the viewport to maximze the view of the cornea.

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

8. 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 look slightly to the left or right as needed.
9. Ask the patient to blink, then open their eyes wide.

10. Click **Capture**.

    ⇨ The **Quality Check** screen opens.

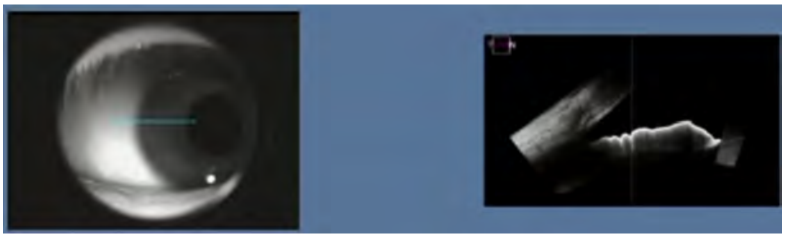
11. Ask the patient to sit back.
12. Check HD Angle Scan Quality [▷ 196].

8.12.6.2 Check HD Angle Scan Quality

To check HD angle scan quality:

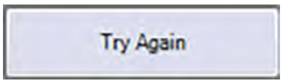
Prerequisite

☑ Acquire an HD Angle Scan [▸ 194].



Action

1. Ensure that the target is centered on the pupil.
2. To view a full-screen version of an image, double-click on the image.
3. Ensure that the angle, the iris and scleral spur are visible and clear.
4. Ensure that no shadows impede the angle view.



5. If the scan is not acceptable, click **Try Again** and retake the scan.

6. Click **Save**.

8.12.7 Wide Angle to Angle Scans

Wide Angle to Angle scans highlights both 0 and 180 degree iridocorneal angles.

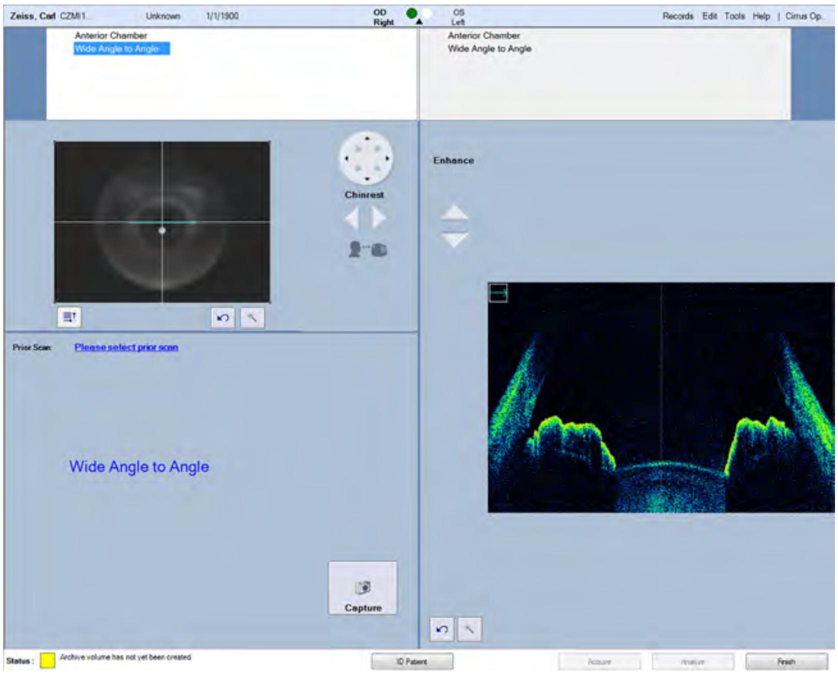


Figure 38: Acquire a Wide Angle to Angle Scan

8.12.7.1 Acquire a Wide Angle to Angle Scan

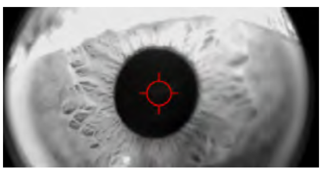
You can change the rotation of the **Wide Angle to Angle** scan, but you cannot resize or move the scan pattern to a different location on the iris.

To acquire a wide angle to angle scan:

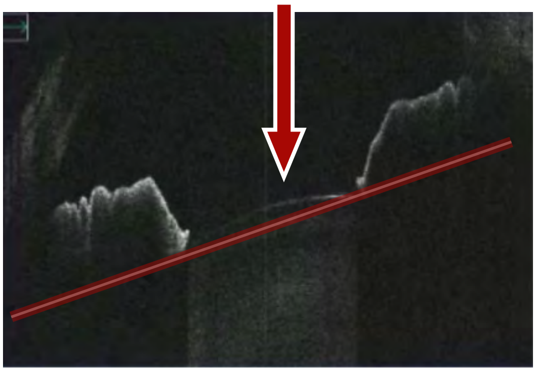
Action

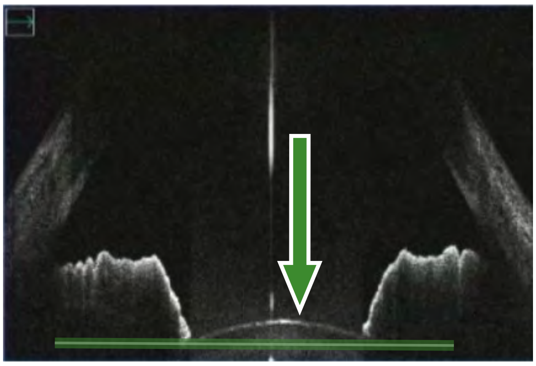
1. Select the Patient [▹ 124].
2. Prepare the Patient [▹ 135]
3. Attach the **Anterior Chamber** lens (Attach External Lens [▹ 181]).
4. Select the **Wide Angle to Angle** scan for the left or right eye.
   ⇨ The instrument moves into place.

5. Align and Focus the Iris Image [▹ 214].

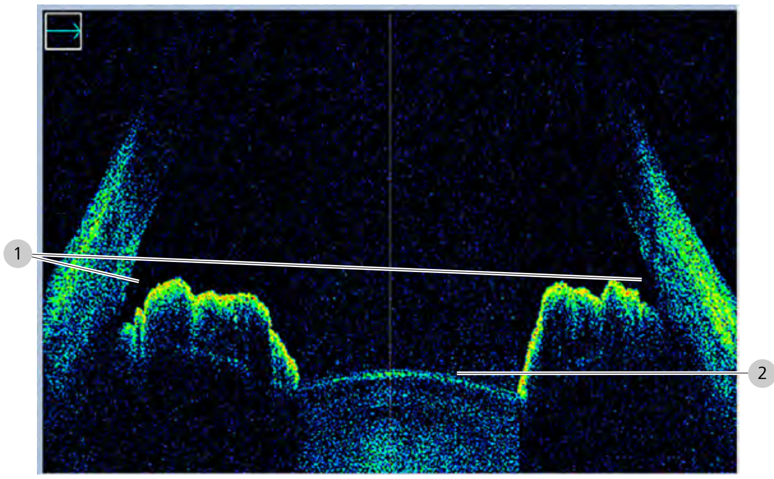


6. Instruct the patient to lean forward and fixate on the center of the fixation target.
   ⇨ The fixation target might look blurry or out of fucus.
7. Click the center of the pupil.
   ⇨ **NOTE! The iris appears slightly out of focus when correctly aligned.**





8. Adjust the chinrest until the anterior plane is straight and the iris is very low in the view.
   ⇨ The green arrow shows proper alignment.
9. If the anterior chamber appears tilted, instruct the patient to shift their gaze slight left or right (as needed) until the anterior chamber appears horizontal.



10. Adjust the chinrest until both iridocorneal angles (1) and iris (2) are visible.
   ⇨ The entire cornea does not appear in the image.
   ⇨ A strong vertical central reflection line on the B-scan indicates the scan is centered on the corneal vertex.

11. To rotate the scan pattern, click and drag the *rotation corner* of the cyan line to rotate that scan pattern into position.
   ⇨ You can adjust the scan pattern from –89 to 90 degrees.
   ⇨ **NOTE! Rotation can reduce the field to 14.0 mm vertically.**

12. Ask the patient to blink, then open their eyes wide.
13. Click **Capture**.
    ⇨ The **Quality Check** screen opens.
14. Ask the patient to sit back.
15. Check Wide Angle to Angle Scan Quality [▸ 199].

8.12.7.2 Check Wide Angle to Angle Scan Quality

NOTE

Always check scan quality before saving a scan.

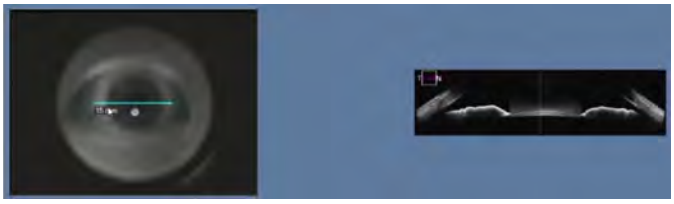
Good quality scans are essential for accurate disease diagnosis.

▶ If you are not sure of the image quality, retake the scan.

To check wide angle to angle scan quality:

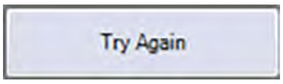
Prerequisite

☑ Acquire a Wide Angle to Angle Scan [▸ 197].



Action

1. Ensure that the target is centered on the pupil.
2. Ensure that both angles are in view.
3. To view a full-screen version of an image, double-click on the image.
4. Ensure that light intensity is uniform across the image.



5. If the scan is not acceptable, click **Try Again** and retake the scan.

6. If the scan is acceptable, click **Save**.

8.12.8 HD Cornea

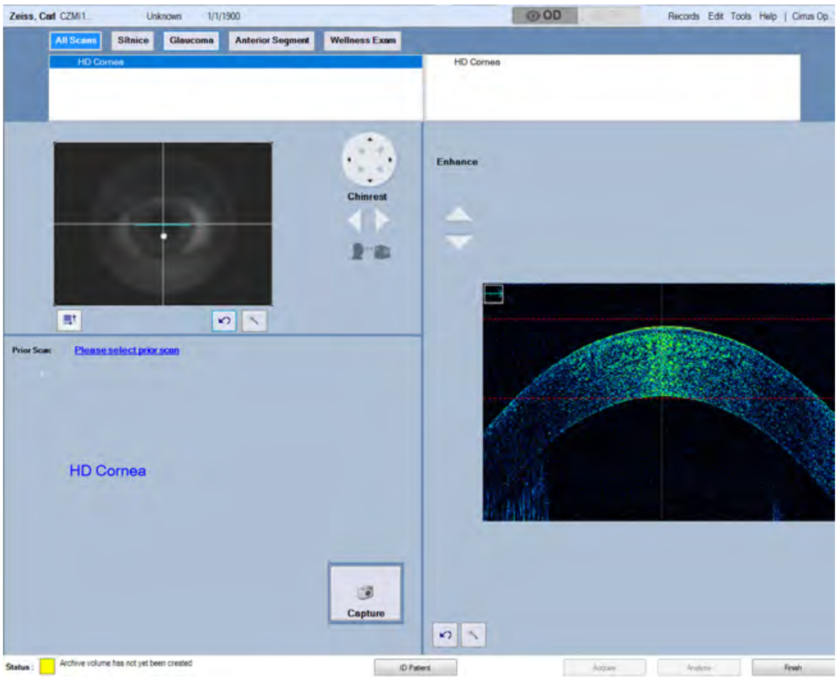


Figure 39: Acquire HD Cornea Scan

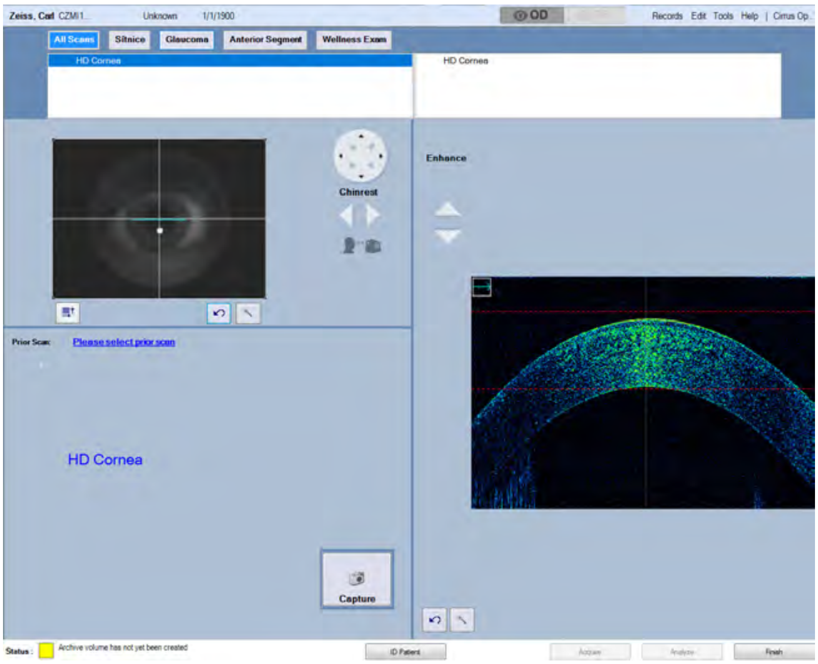
The HD Cornea scan is a straight line across the center of the eye. You can rotate the line to scan the cornea in a different direction.

8.12.8.1 Acquire an HD Cornea Scan

NOTE

This scan does not appear as a selection until you install the external lens.

When you acquire **HD Cornea** scans, center the live iris image and align the cornea between the guidelines in the B-scan image (see: About Image Position and Focus [▸ 213]).

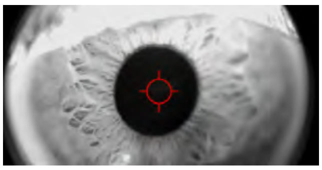


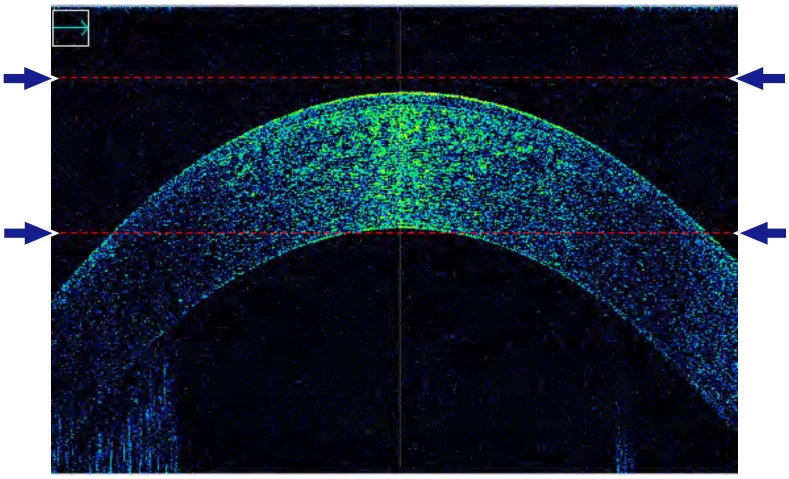
To acquire an HD cornea scan:

Action

1. Select the Patient [▸ 124].
2. Prepare the Patient [▸ 135]
3. Attach the **Cornea** lens (Attach External Lens [▸ 181]).
4. Select the **HD Cornea** scan for the appropriate eye.
   ⇨ The instrument moves into place.

5. Align and Focus the Iris Image [▸ 214].





6. Use the chinrest controls to center and align the cornea between the red guidelines in the B-scan viewport.
7. Ask the patient to blink, then open their eyes wide.
8. Click **Capture**.
   ⇨ The **Quality Check** screen opens.
9. Ask the patient to sit back.
10. Check HD Cornea Scan Quality [▸ 202].

8.12.8.2 Check HD Cornea Scan Quality

NOTE

Always check scan quality before saving a scan.

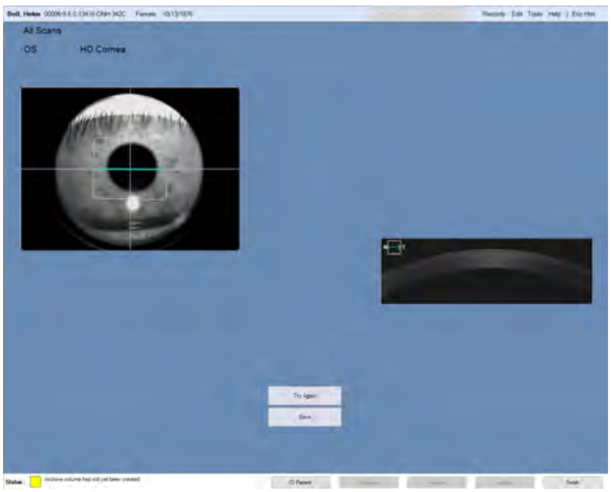
Good quality scans are essential for accurate disease diagnosis.

▶ If you are not sure of the image quality, retake the scan.

To check HD cornea scan quality:

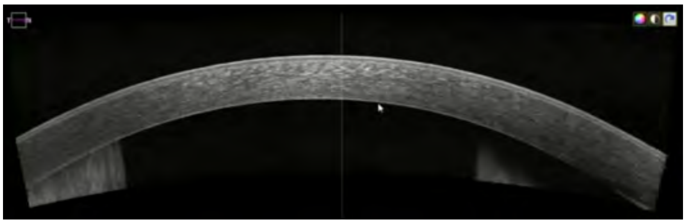
Prerequisite

☑ Acquire HD Cornea Scans.

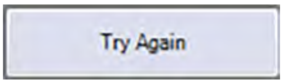


Action

1. Ensure that the target is centered on the pupil.



2. Ensure that the corneal image is clear and you can see its layers.
3. Ensure that the posterior and anterior surfaces are well-defined.
4. Ensure that there are no motion artifacts or corneal reflections on the central cornea (especially where measurements are needed).
5. Ensure that light intensity is uniform across the image.
6. Ensure that the patient's eyelashes did not interfere with the image.



7. If the scan is not acceptable, click **Try Again** and retake the scan.

8. Click **Save**.

8.12.9 Pachymetry

Pachymetry scans consist of 24 radial scan lines with a scan depth of 2.0 mm that generate a color-coded thickness map of the cornea. The scan uses 24 B-scans, each composed of 1024 A scans.

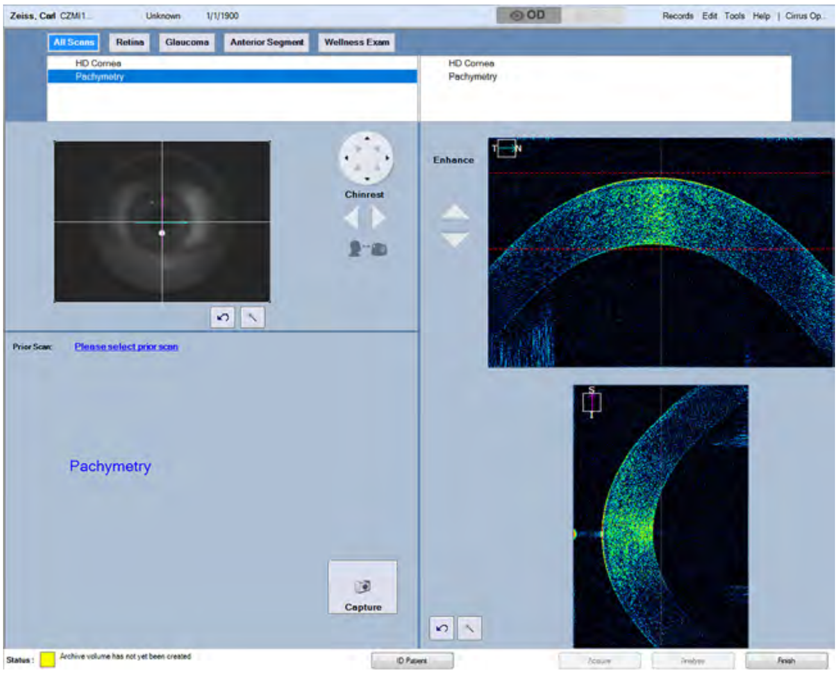


Figure 40: Acquire Pachymetry Scan

8.12.9.1 Acquire a Pachymetry Scan

NOTE	**This scan does not appear as a selection until you install the external lens.**

CIRRUS™ HD-OCT automatically corrects **Pachymetry** scans for beam scan geometry and refraction on the corneal surfaces. These corrections work best when the corneal vertex is properly centered between the two red guidelines in the **Temporal / Nasal** B-Scan.

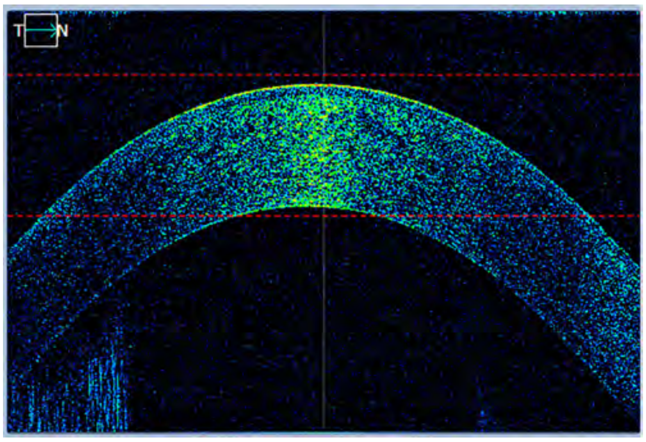


Figure 41: Temporal / Nasal B-scan

To acquire a pachymetry scan:

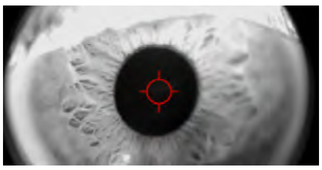
Prerequisite

☑ The patient is not wearing contact lenses.

☑ The patient's eyelashes are not impeding the images.

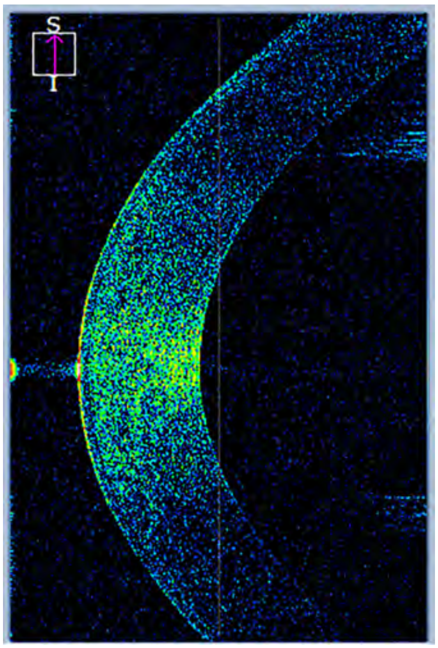
Action

1. Select the Patient [▸ 124].
2. Prepare the Patient [▸ 135]
3. Scan Types [▸ 136] (if needed).
4. Attach the **Cornea** lens (Attach External Lens [▸ 181]).
5. Select the **Pachymetry** scan for the appropriate eye.
   ⇨ The instrument moves into place.

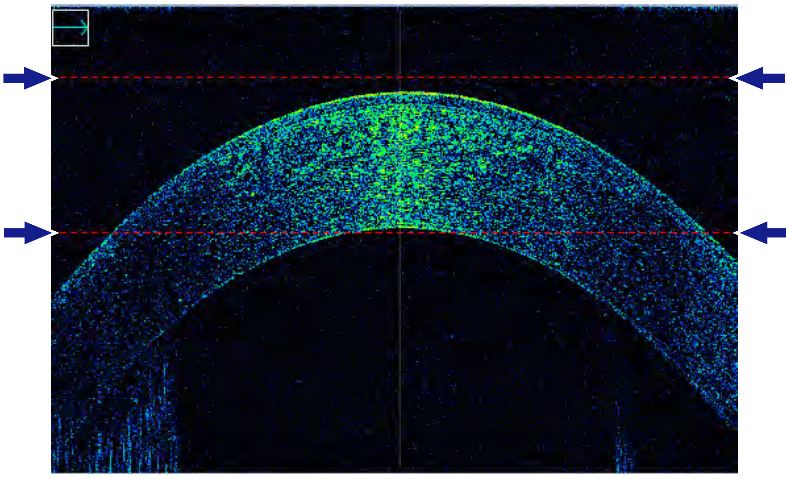


6. Align and Focus the Iris Image [▸ 214].

7. Instruct the patient to lean forward and fixate on the center of the fixation target.
   ⇨ The fixation target might look blurry or out of fucus.



8. Use the arrow keys to adjust the **Superior / Inferior** B-scan until you see the corneal reflex in the **Temporal- Nasal** B-scan.



9. To make fine adjustments, click **Ctrl** + arrow keys.
10. To adjust the brightness or contrast of a b-scan image, see: Edit Images (Hover Over) [▷ 370]

11. To enhance image contrast and brightness, click **Adjust**.
12. Ask the patient to blink, then open their eyes wide.

13. Click **Capture**.
    ⇨ The **Quality Check** screen opens.
14. Ask the patient to sit back.
15. Check Pachymetry Scan Quality [▷ 207].

8.12.9.2 Check Pachymetry Scan Quality

NOTE

Always check scan quality before saving a scan.

Good quality scans are essential for accurate disease diagnosis.

▶ If you are not sure of the image quality, retake the scan.

After you acquire a Pachymetry scan, the Quality Check screen opens automatically for you to ensure that the scan quality is acceptable.

Pachymetry scans do not show signal strength to indicate scan quality. Instead, an **Image Quality** indicator detects whether the scan quality is acceptable.

Acceptable Image	Low Quality Image Detected
Green 	**Yellow** 

Table 43: Pachymetry Image Quality Indicator

CIRRUS™ HD-OCT **Image Quality** indicator detects:

- Poor scan quality:
  - Patient blinked or partially blinked
  - Patient eyelid or eyelash interference
  - Scan contrast too low
- Scan not centered:
  - Scan misaligned
  - Scan not centered
- Excessive motion during scan

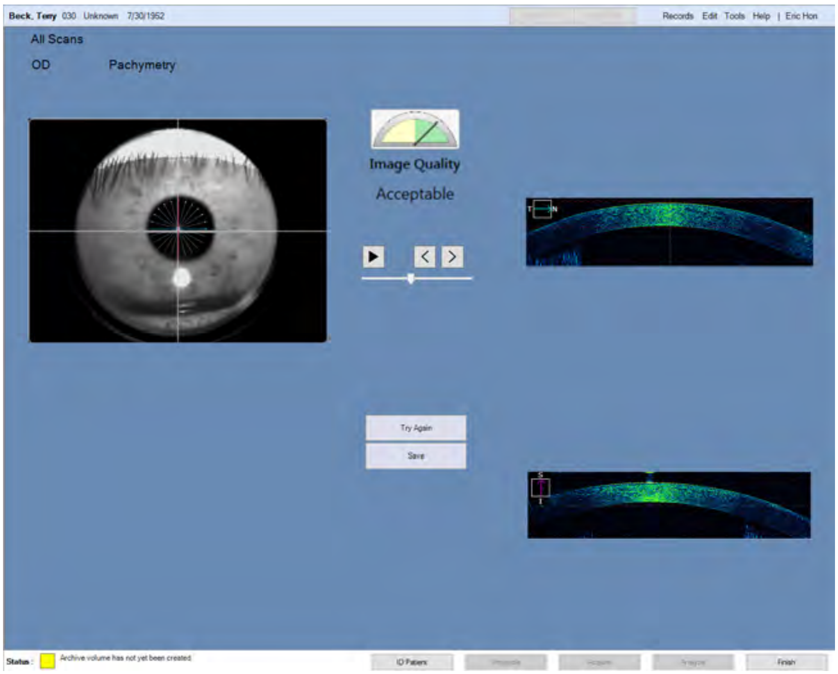
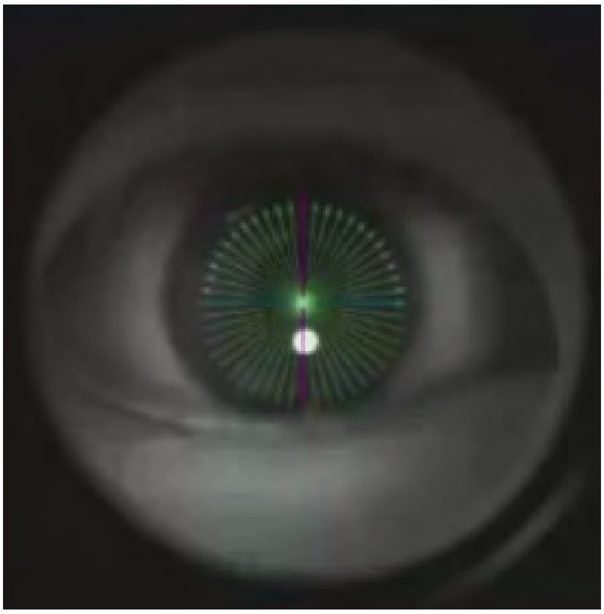


Figure 42: Check Quality: Pachymetry

To check Pachymetry scan quality:

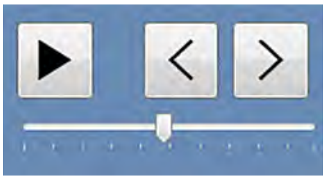
Prerequisite

☑ Acquire a Pachymetry Scan [▸ 204].



Action

1. Click on the iris image and use the mouse scroll wheel to select a radial scan line.
2. To view a full-screen version of an image, double-click on the image.
3. Check the image quality for each line.
4. To view the series of lines using the B-scans, click on the B-scan and use mouse scrolling to view the lines.



5. To view a sequence of the radial scan lines, use the movie controls.

6. If **Image Quality** is green, click **Save**.
7. If **Image Quality** is yellow, click **Try Again** and ensure that the lens is clean (see: Cleaning Optical Components [▸ 408]) , the scan is properly centered, and retake the scan: Acquire a Pachymetry Scan [▸ 204].

8.13 Acquisition Concepts, Tasks and Tools

8.13.1 Focus the Fundus Image

Tip: If a patient has floaters that obscure parts of the scan, ask the patient to shift their eyes several times prior to the scan to move floaters.

The fundus image is properly focused when the image is sharp and clear and the branching blood vessels are visible.

Macular cube scans have an alignment tool that you can place over the optic disc to help position followup scans more accurately--especially when a patient's fovea is difficult to locate.

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

Tip: If the patient's record includes their refractive error, Auto Focus adjusts accordingly-focusing the fixation target and optimizing fundus image brightness.

Auto Focus

Auto Focus automatically optimizes several settings:

- Adjusts focus to compensate for the patient’s refractive error
- Adjusts fundus image brightness and contrast

If the patient's refractive error is not saved in their record, you can help the patient see the fixation target more clearly by manually setting the correction.

Tip: If a patient has corneal opacities, realign the pupil to minimize effects.

For patients with unsteady fixation you can also set **Rapid Refresh View**.

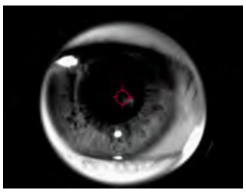
To focus the fundus image:

Prerequisite

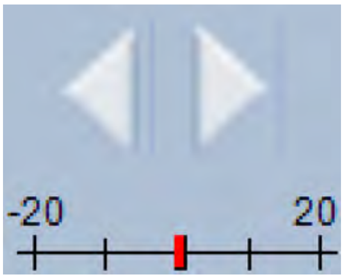
☑ You are acquiring a scan and reached the step: *Focus the Fundus Image*.

Action

1. Click **Auto Focus** and ask the patient to hold their gaze and head steady while the instrument moves into place.



2. Ensure that the iris target is still centered on the pupil.



3. If the patient cannot see the fixation target clearly, click the left arrow to compensate for myopic corrections or the right arrow to compensate for hyperopic corrections.
4. If the fundus image is not sharp and clear, manually adjust the focus.
5. Ensure the fundus is illuminated uniformly (no dark corners on the overlay).

6. If the fundus image is too dark, click **Fine Adjustment**.
   ⇨ The **Fundus Image** adjustment tool opens.

7. Click **Auto B/C**.
8. If needed, manually adjust image brightness and contrast sliders separately.
9. Click **Close**.

10. To discard your adjustments and return to the default settings, click **Reset**.
11. To increase the screen refresh rate, right-click on the image and select **Rapid Refresh View**.
12. Complete the remaining steps of the acquire procedure.

8.13.2 Adjusting B-Scan Images

For **Posterior Segment** scans and **Angiography** scans, an **Optimize** button automatically adjusts the B-scan(s) as follows:

1. Centers the image.
2. moves the B-scan higher to maximize signal strength. (Angiography Cube only)
3. Optimizes image quality (polarization).

8.13.2.1 Automatically Optimize B-Scans

NOTE

If tracking is turned on, the B-scan may shift upwards.

▶ If necessary, move the B-scan image down manually.

Tip: Press F9 to toggle between color and grayscale images.

For best results, position the B-scan approximately 100 µm below the top of the of the image area before capturing the image.

To adjust B-scans automatically:

Action

1. Instruct the patient to hold their gaze steady and do not blink.
2. Click **Optimize**.
   ⇨ The B-scan images are centered and polarization is optimized.
   ⇨

3. Confirm that the B-scan is:
   Visible in the imaging window
   Approximately 100 µm below the top of the scan.
4. To adjust image centering and polarization manually, refer to: Manually Enhance B-Scans [▸ 211].
5. Complete the remaining steps of the acquire procedure.

8.13.2.2 Manually Center B-Scans

Tip: Center the image first so you can see image enhancements better.

Optimize automatically centers the B-scan image, then optimizes image quality (polarization). You can also manually adjust B-scan centering and quality.

To manually center B-scans:

Prerequisite

☑ You are acquiring a scan and reached the step: *Manually Center or Enhance B-Scans*.

1. In the B-Scan panel, locate the control arrows that adjust **Centering**.

Action

2. To move the B-scan image up, click the **Up** arrow.
3. To move the B-scan image down, click the **Down** arrow.
4. Complete the remaining steps of the acquire procedure.

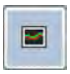
8.13.2.3 Manually Enhance B-Scans

Optimize automatically centers the B-scan image, then optimizes image quality (polarization). You can also manually adjust B-scan centering and quality.

To manually enhance B-scans:

Prerequisite

☑ You are acquiring a scan and reached the step: *Manually Center or Enhance B-Scans*.



1. In the B-Scan panel, locate the control arrows to adjust **Enhancement**.

Action

2. To increase polarization for the B-scan image, click the **Up** arrow.
3. To decrease polarization for the B-scan image, click the **Down** arrow.
4. Complete the remaining steps of the acquire procedure.

8.13.3 About Fixation Targets

CIRRUS 6000 has 21 fixation target locations. You can select a fixation target for the patient to fix their gaze during scan acquisition. Select a fixation target that makes it easiest to obtain a good-quality scan of the area of interest.

When you click on the fundus image, the nearest of the 21 fixation targets is selected.

Figure 43: Fixation Targets

8.13.3.1 Position the Fixation Target

NOTE

If the image is too close to the upper boundary, it could reflect a mirror image or appear inverted.

- ▶ Center or adjust the image until the mirror image is eliminated and image inversion is corrected.

Tip: Center the area of interest to scan the deepest part of the bowl of the retina and help keep the image centered vertically.

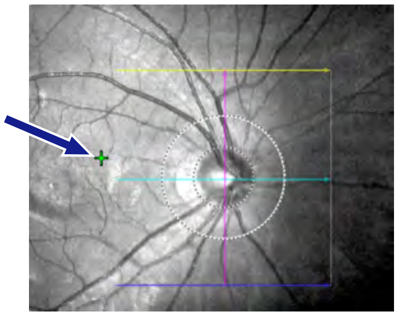
For the best results, center the area of interest in the live fundus view. You might need to:

- Select a different fixation target to redirect the patient's gaze.
- Move or rotate the scan pattern closer to the area of interest.

To select a different fixation target location:

Prerequisite

☑ You are acquiring a scan and reached the step: *Position the Fixation Target*.



1. Click on the fundus image where you want the fixation target to move (area of interest).
2. Instruct the patient to follow the fixation target and focus their gaze on the target in its new location.
   ⇨ A different area of the retina is centered in the fundus image.

Action

3. To reset the fixation target back to the center, click **Reset Fixation Target**.
4. To adjust the scan pattern to match the fixation target (area of interest), see: Customize Raster Scan Patterns (Drag) [▸ 157].
5. Complete the remaining steps of the acquire procedure.

8.13.4 About Scan Patterns

Scan patterns overlay the fundus image when you are preparing to acquire a scan. Most types of scans allow you to relocate the scan pattern within the live fundus preview.

Scan patterns help you center or place the scan in the location that obtains the best image of a particular area of interest for the patient's eye.

8.13.4.1 Position the Scan Pattern

If you want to capture a different area of the retina, you can move the scan pattern to acquire the optimal area for a patient's eye.

To move the scan pattern:

Prerequisite

☑ You are acquiring a scan and reached the step: *Reposition the Scan Pattern*.

Action

1. Mouse over the scan pattern that overlays the fundus image.
   ⇨ The mouse pointer becomes a finger pointing icon.
2. Click on the scan pattern and drag it to the location you want to capture.

3. To reset the scan pattern (and all other adjustments), click **Reset**.
4. Complete the remaining steps of the acquire procedure.

8.13.5 About Image Position and Focus

Once the patient's eye is aligned with the alignment mark on the instrument, use the chinrest controls to center and focus the iris image and B-scan images as needed. You might need to make a few adjustments before the image is both aligned and focused properly. The following table explains how the controls move the chinrest.

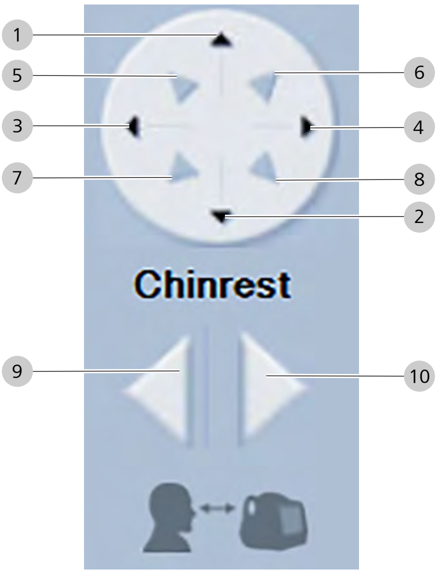
Buttons	Chinrest Movement	
	1	Moves chinrest up.
	2	Moves chinrest down.
	3	Moves chinrest left.
	4	Moves chinrest right.
	5	Moves chinrest up and to the left.
	6	Moves chinrest up and to the right.
	7	Moves chinrest down and to the left.
	8	Moves chinrest down and to the right.
	9	Moves chinrest away from the acqui-sition head.
	10	Moves chinrest toward the acquisition head.

Table 44: Chinrest Adjustments (Image Centering)

8.13.5.1 Align and Focus the Iris Image

Tip: For patients with opacities, try clicking slightly off-center of the pupil.

Proper alignment of the patient eye to the external marker is crucial to obtaining a good quality scan.

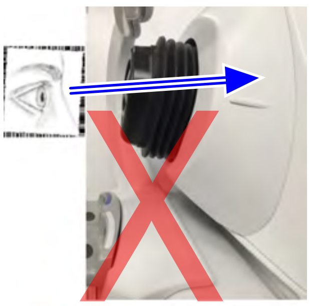
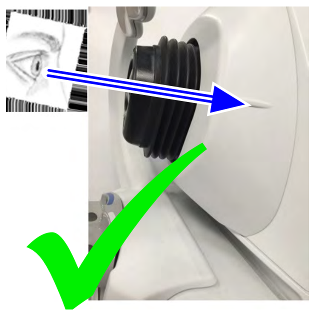
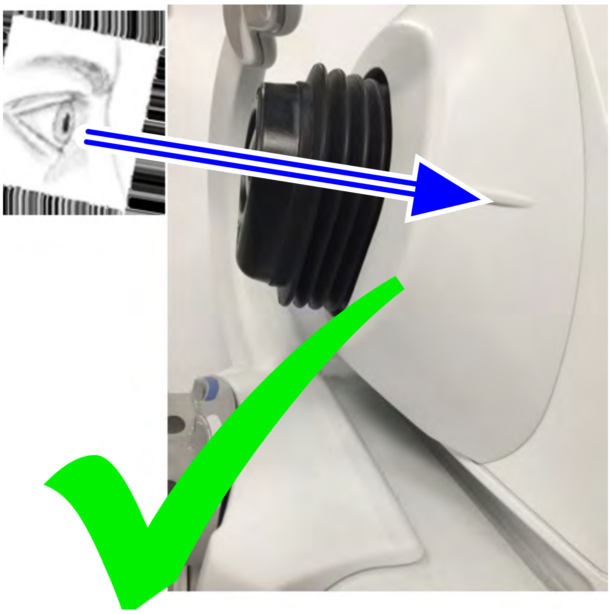
Improper Alignment	Proper Alignment
 Eye **is not** aligned with the instrument marker.	 Eye **is** aligned with the instrument marker.

Table 45: Alignment

To align the iris image:

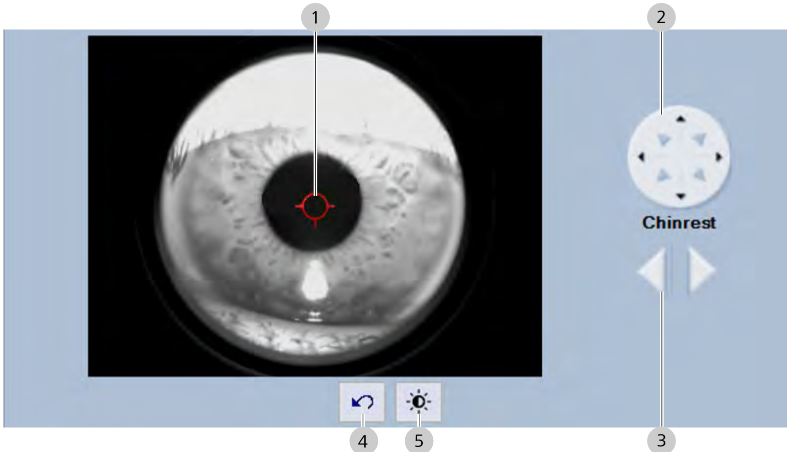
Prerequisite

☑ You are acquiring a scan and reached the step: *Align the Iris*.



Action

1. Ensure that the patient's eye aligns with the marker on the CIRRUS™ HD-OCT external surface.



2. Click on the center of the pupil (1).

   ⇨ The red target appears over the center of the pupil and chinrest automatically moves into position to center the iris in the viewport.

NOTE

If you reposition the iris manually, the chinrest moves as you make adjustments.

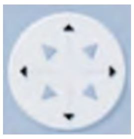
▶ Instruct the patient to:

⇨ Keep their chin down

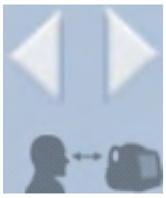
⇨ Keep their teeth together

⇨ Place their forehead against the forehead rest

⇨ Move along with the chinrest



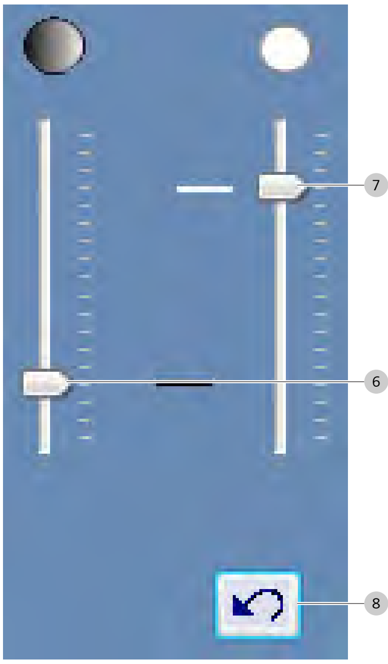
3. To adjust the image position manually, click on center of the pupil again (1) and move the chinrest controls (2) up, down, right, and left as needed to position the iris in the viewport.



4. Focus the iris image by moving the chinrest forward or back as needed (3).

5. To reset the chinrest position, click **Reset** (4).

6. Click **Brightness / Contrast** (5).
   ⇨ The adjustment panel opens.
7. To increase contrast, slide the contrast adjustment (6) up.
8. To decrease contrast, slide the contrast adjustment (6) down.
9. To brighten the image, slide the brightness adjustment (7) up.
10. To dim the image, slide the brightness adjustment (7) down.



11. To restore the default contrast and brightness, click **Reset** (8).
12. Complete the remaining steps of the acquire procedure.

8.13.6 About Auto Repeat

NOTE

Auto Repeat only works for scans acquired on a prior day.

When you enable **Auto Repeat**, CIRRUS™ HD-OCT automatically repeats the settings to match the patient's most recent scan.

Advantages of using **Auto Repeat** include:

- You can easily repeat the patient's earlier scans in a folow-up visit.
- The patient can remain in position between scans.

With **Auto Repeat** enabled:

1. Select the patient and the type of scan to acquire.
2. The instrument detects whether the patient already acquired that type of scan for the same eye in a past visit.
3. If the instrument finds one (or more), it selects the most recent scan and matches all of the settings used for that scan.

The instrument:

- Adjusts the ocular lens the same way
- Moves the chinrest into the same place
- Adjusts the scan pattern the same way (if applicable)
- Places the fixation target in the same place
- Adjusts to match all enhancements, positioning, focus, brightness, contrast and illumination settings
- Displays the scan pattern and the fundus image from the prior scan

The date and time of the most recent scan (with its settings reused for this scan) appears on the acquisition screen .

8.13.7 About FastTrac™

NOTE

FastTrac™ does not work properly for certain anatomical features.

If a patient exhibits features that impede FastTrac™, turn off FastTrac™ before capturing a scans. These features include:

- strongly tilted or curved retinas
- high myopia
- media opacities
- small pupils

NOTE

For optic disc scans, *Monitor Z Position* is off.

***Monitor Z Position* setting does not work properly for certain anatomical features:**

If a patient exhibits features that impede alignment of the B-scan, turn off *Monitor Z Position*. These features include:

- high myopia
- posterior staphylomas

CIRRUS™ HD-OCT FastTrac™ improves scans by:

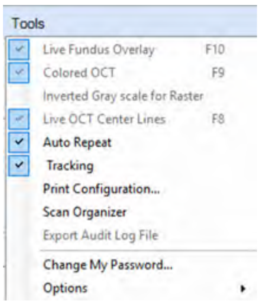
- **Minimizing effects of eye movements:** FastTrac™ automatically detects a patient's eye movement in real time, then minimizes its effect before you capture a scan.
- **Tracking only if tissue is vertically centered: FastTrac™** monitors whether B-scans are vertically centered and stops tracking if it detects that some or all of the tissue is outside the B-scan window.

The patient's first scans using **FastTrac™** takes a little longer to process, but subsequent scans are faster and more accurate (see Turn FastTrac™ On or OFF [▸ 119] and Turn FastTrac™ On [▸ 219]).

Advantages of using **FastTrac™** retinal tracking include:

- **Faster retakes:** because **FastTrac™** tracks eye motion, retaking a scan only re-captures the areas impacted by movement.
- **More accurate alignment:** by *registering* anatomical features of the eye, CIRRUS™ HD-OCT allows you to repeat a patient's scan precisely (see About Macular Scan Registration [▸ 247]).
- **Faster follow-up scans:** when a patient returns for follow-up visit, CIRRUS™ HD-OCT positions the instrument in the same location as the last scan.
- **Better change analysis:** accurate alignment for a series of scans over time facilitates better accuracy in assessing the progression of pathology.

Some patient anatomy or pathology can inhibit tracking. When tracking is on, you can turn it off for a particular scan (as needed). When acquiring a scan, click green tracking to button turn tracking off (the button becomes gray).

<table>
<tr><th>FastTrac™ Enabled</th><th>FastTrac™ Turned ON</th><th>FastTrac™ Turned OFF</th></tr>
<tr><td>

Auto Repeat and Tracking are checked.</td><td></td><td></td></tr>
</table>

Table 46: **FastTrac™** Settings

You can further simplify re-taking a series of scans for a patient when you use **FastTrac™** with **Track to Prior** to create a series of matched images over time (see About Track to Prior [▸ 220]).

8.13.7.1 Turn FastTrac™ On

FastTrac™ works best with when the fundus image is properly focused, illumination is uniform, and the blood vessels are sharp. While a tracked scan processes, the patient can remain focused on the fixation target and blink normally. Blinking increases tear film, which can improve signal quality.

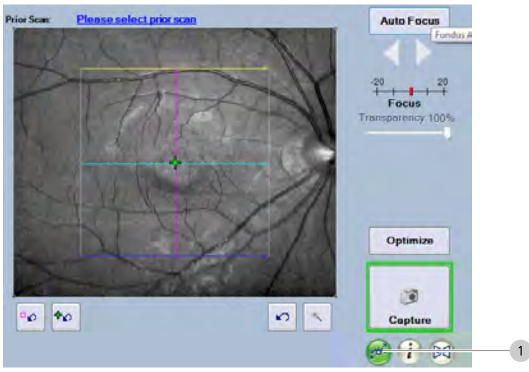
If **FastTrac™** is interrupted during processing, the progress bar turns red and stops.

To turn FastTrac™ on:

Prerequisite

☑ **FastTrac™** is enabled (Turn FastTrac™ On or OFF [▸ 119]).

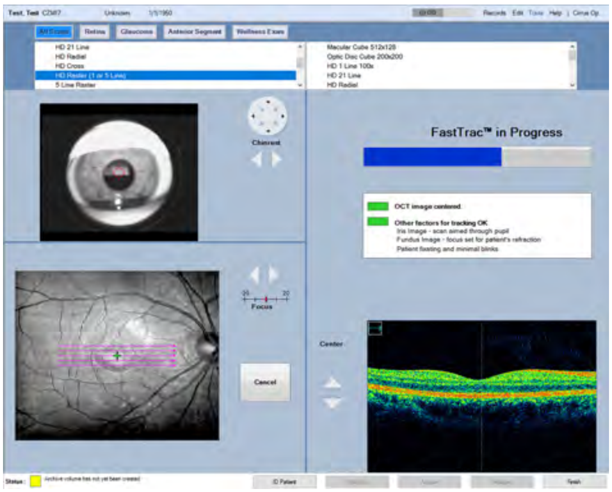
☑ You are acquiring a scan and reached the step: *turn on FastTrac™*.



Action

1. Click **FastTrac™** (1) .
2. If the **Capture** button has a red border, **FastTrac™** is not ready.
   Ensure the B-Scans are centered.
3. If illumination is not uniform across the fundus image, ensure that the pupil is centered and the iris and pupil are in focus.
4. If a **FastTrac™** scan does not process successfully, try turning off the **Monitor Z Position** setting.
5. To turn of the **Monitor Z Position** setting, click the **Fine Adjustment** icon (2) and uncheck **Monitor Z Position** .

   ⇨ **Fine Adjustment** opens the **OCT Tomogram** settings.



⇨ A **FastTrac™** progress indicator opens after capture. It can take a few moments to complete FastTrac processingl

6. If the **OCT image centered** indicator is red, recenter the image and try the scan again.
7. If the **Other factors for tracking OK** indicator is red, check that the iris and fundus image are adjusted properly and try the scan again.
8. To stop a scan during processing, click **Cancel**.
9. Complete the remaining steps of the acquire procedure.

To turn FastTrac™ off:

Prerequisite

☑ FastTrac™ is enabled (Turn FastTrac™ On or OFF [▸ 119]).

☑ You are acquiring a scan and reached the step: *turn off FastTrac™*.

10. Click FastTrac.

⇨ The icon turns gray.

11. Complete the remaining steps of the acquire procedure.

8.13.8 About Track to Prior

If you want to use tracking for a follow-up scan and the prior scan was acquired without FastTrac, you can track using**Track to Prior**.

Track to Prior allows you to select a patient's earlier scan and CIRRUS™ HD-OCT automatically adjusts to the same settings.

If the patient will likely return for the same followup series of scans, set up the initial scans using **Track to Prior**.

CIRRUS™ HD-OCT retains these settings so you can reuse them to capture followup scans more efficiently. You can use this feature for earlier scans that did not have **Track to Prior** turned on, but for optimal results, turn on the feature for the initial scans also.

With **Track to Prior** enabled:

1. Select the patient and the type of scan to acquire.

2. Turn on **Track to Prior**.

3. Select the **Prior Scan** linkand choose the scan to repeat.

The instrument automatically:

- Adjusts the ocular lens the same way
- Moves the chinrest into the same place
- Adjusts the scan pattern the same way (if applicable)
- Places the fixation target in the same place
- Adjusts to match all enhancements, positioning, focus, brightness, contrast and illumination settings
- Displays the scan pattern and the fundus image from the prior scan

Track to Prior ON	Track to Prior OFF
	

Table 47: **Track to Prior** Settings

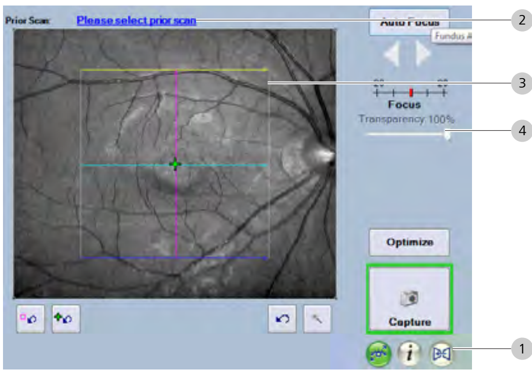
8.13.8.1 Track to a Prior Scan

Track to Prior allows you to reuse all the setting from an earlier scan for the same patient (see About Track to Prior [220]).

To track to a prior scan:

Prerequisite

☑ You are acquiring a scan and reached the step: *track to a prior scan*.



Action

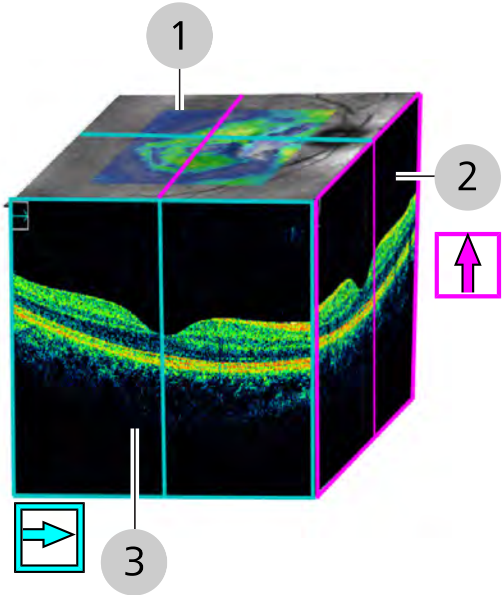
1. Click **Track to Prior** (1) .
   ⇨ The**Track to Prior** icon turns green.
2. To select a prior scan to reuse its settings, click **Please select prior scan** (2).
   ⇨ A scan selection dialog opens.
3. Choose the scan you want to repeat and click.

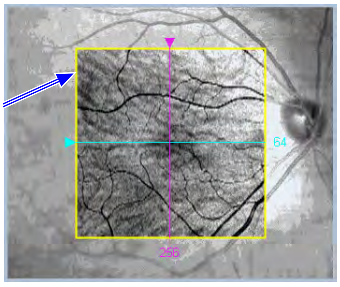
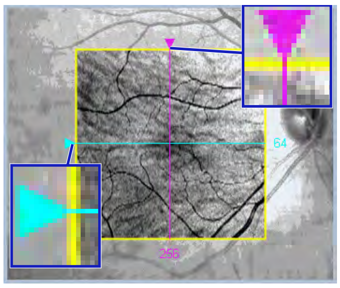
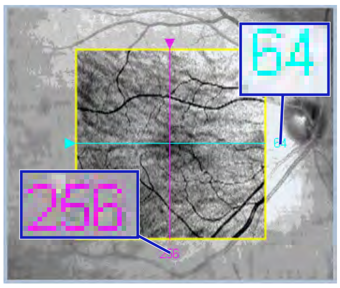
⇨ The instrument moves into place and sets the same adjustments as the prior scan. This process might take a few moments. The fundus image and scan pattern from the prior scan overlay the live fundus image.

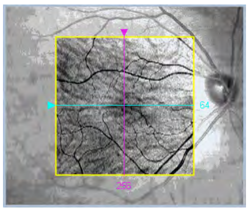
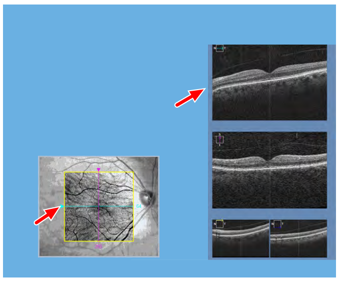
4. Align the live fundus view with the fundus overlay from the prior scan.
5. Click on the scan pattern (3) and drag it into position.
6. To view the live fundus image with the fixation target or overlays better, adjust the overlay **Transparency** (4).
7. Complete the remaining steps of the acquire procedure.

8.13.9 About Cube Scans

Cube scans stack and align consecutive axial-scans (A-scans) side by side to produce a two-dimensional B-scan. Consecutive B-scans align to produce a 3D cross-section of the retina.



1	En Face Scan Plane	**Yellow box** indicates the scan area.	
		Click and drag **cyan or magenta triangle** to move through the scan slices.	
		The number beside the line indicates which slice of the cube is in view.	

2	Slow B-Scan Plane	Reformatted, vertically parallel A-scans acquired in successive line scans. These slices are acquired more slowly; one per line of horizontal A-scans.	
3	Fast B-Scan Plane	Slices parallel to the front of the cube; each line of A-scans is acquired quickly .	

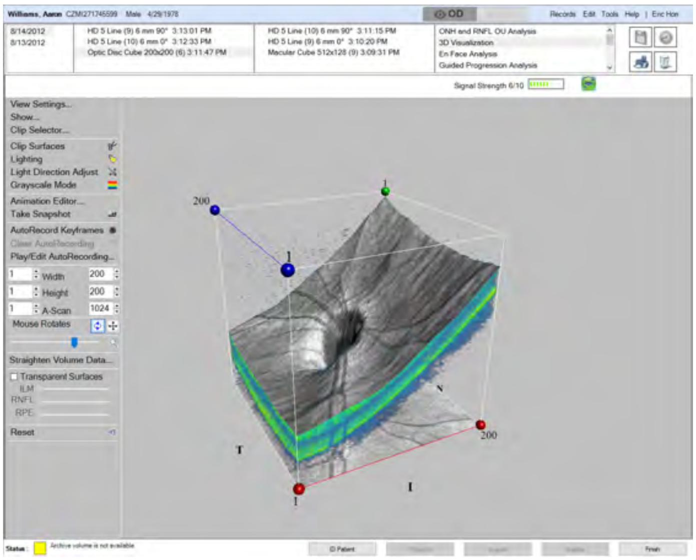
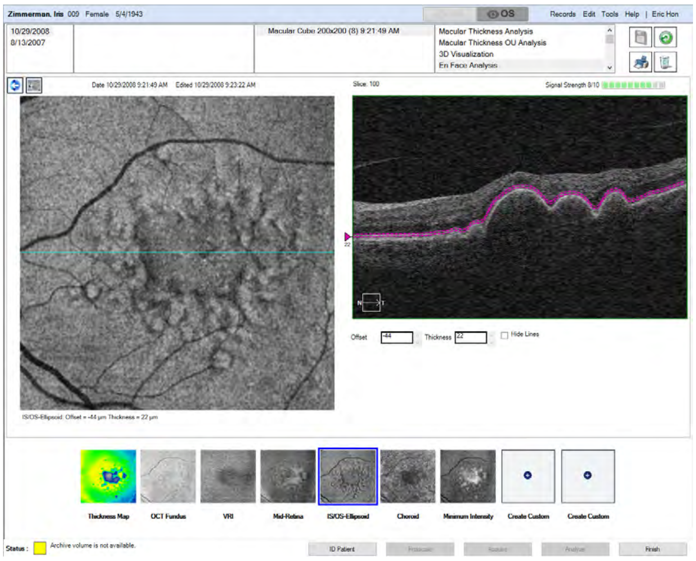
You can quickly navigate through the slices of either plane. Simply move the corresponding line displayed on the fundus image and the B-scan image moves accordingly. The slice number helps you know which area of the cube is selected.

CIRRUS™ HD-OCT displays scan images as follows:

- Horizontal scans:
  - left of scan equals the left of scan display
  - right of scan equals right of scan display
- Vertical scans
  - bottom of scan equals left of scan display
  - top of scan equals right of scan display
- Diagonal scans in 5 Line Raster
  - left takes precedence over bottom
  - left of scan equals left of scan display
  - right of scan equals right of scan display

Cube Analysis

Because cube scans contain this volume of information, there is are additional types of analyses available only for cube scans:

Analysis	Description
3D Visualization 	Shows a 3-dimensional image of the data. You can navigate through the 3D slices, adjust settings, and animate a series to save as a movie (see: 3D Visualization Analysis [▷ 289]).
En Face 	

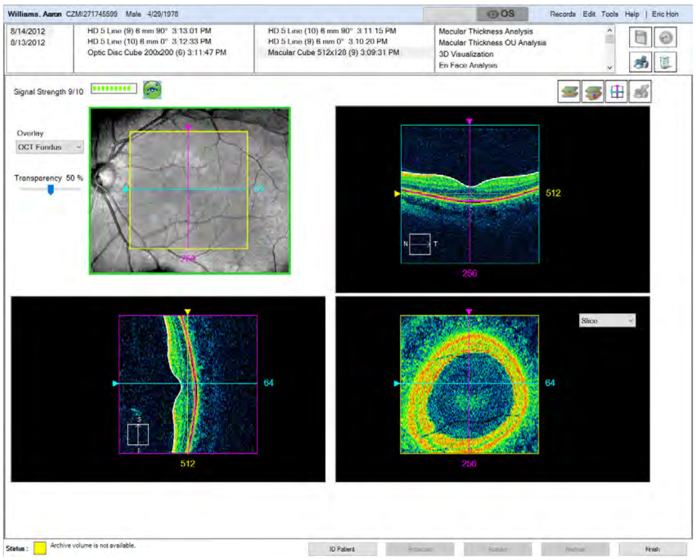
Analysis	Description
Advanced Visualization 	

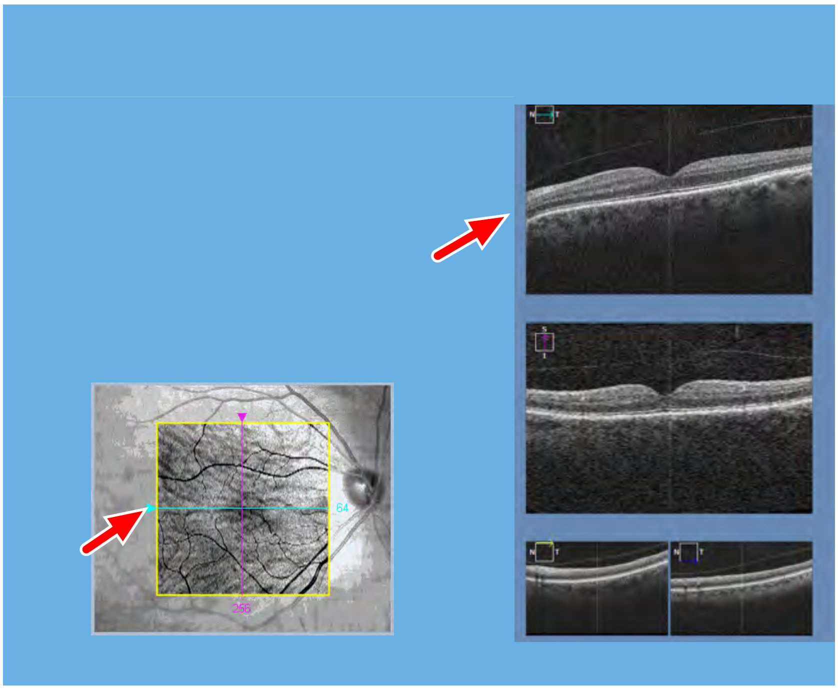
Table 48: Additional Visual Cube Scans

8.13.9.1 Navigate Cube Layers Manually

To ensure that the image shows the area of interest clearly for analysis, you can scroll through the B-scans to check individual layers to make sure the area is captured in the image.

By dragging the layer line to each area of interest, you can quickly scan the cube layers.

Tip: You can also navigate through layers by clicking the B-scan you want to navigate and scrolling the mouse.



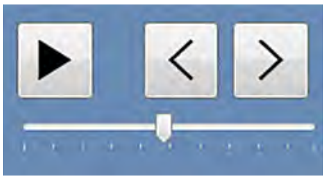
Prerequisite

☑ You are acquiring, checking quality or analyzing a scan and reach the step: *navigate cube data*.

Action

1. Click on the magenta triangle and move the line to the right or left to view different slices.
2. Click on the cyan triangle and move the line up or down to view different slices.
3. Complete the remaining steps of the acquire procedure.

8.13.9.2 Navigate Through Cube Slices as a Movie



Action

1. Use to view a movie of the fast B-scans or sequence through them one image at a time.

   ⇨

2. Complete the remaining steps of the acquire procedure.

   ⇨

You can view the scan as a movie that begins at the top of the B-Scan slice and moves down through the tissue in 51 µm increments. You can stop the movie, reverse or advance the movie frame by frame.

NOTE! The default frame rate for scan movies is 51 µm/sec.

To view the image as a movie:

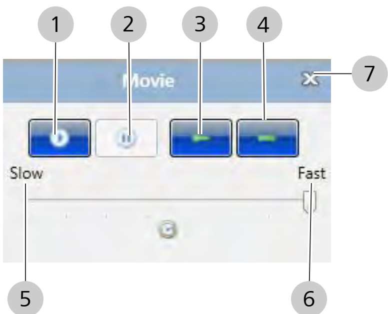
Prerequisite

☑ You reach the scan analysis step: *Edit an Image*.

☑ Editing tools are open: Open Image Editing Tools [372].

3. Click **Play Movie**.

   ⇨ The movie controls open.



4. To start the movie, click the **play button (1)**.
5. To stop the movie, click the **pause button (2)**.
6. To move backward one frame, click the **previous button (3)**.
7. To move forward one frame, click the **next button (4)**.
8. To decrease movie speed, move the slider toward **Slow (5)**.
9. To increase movie speed, move the slider toward **Fast (6)**.
10. To close the movie controls, click **Close (7)**.
11. Complete the remaining steps of the acquire procedure.

8.13.10 Acceptance Criteria

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 when assembling the data for analysis

. However, the OCT fundus image can have 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.

When reviewing CIRRUS 6000 Angiography Scans for acceptability, consider the following:

- RPE Acceptance Criteria [▸ 228]
- Signal Quality Acceptance Criteria [▸ 228]
- Decorrelation Tails Acceptance Criteria [▸ 229]
- Segmentation Acceptance Criteria [▸ 230]

Consider all these possibilities before accepting OCT Angiography scans for further analysis.

8.13.10.1 RPE Acceptance Criteria

Test	Pass	Fail	Explanation
Retina Position	Retina is in an appropriate position in the scan	Retina is too low in the scan Example of retina position too low: . 	If the retinal tissue is captured too low in the axial FOV of the scan, there will not be enough contrast to detect sub-RPE illumination.

Table 49: RPE Acceptance

8.13.10.2 Signal Quality Acceptance Criteria

CIRRUS 6000 OCT Angiography (AngioPLEX™) is more sensitive to signal quality than structural OCT imaging.

Test	Pass	Fail	Explanation
Signal Strength	6 or higher	Less than 5	Low signal strength causes poor scan quality and can affect interpretation of the images.
Shadows	Shadows exhibit floaters or disease ■ **Floater**: dark area appears in different locations in multiple scans (compare the flow en face and structural en face image). ■ **Possible disease**: Angiography image is dark, but the B-scan and the structural en face image are normal.	Dark spots, dark or blurry scans	OCT Angiography sensitivity sometimes show dark spots resulting from poor local signal, not capillary dropout. Poor signal quality appears throughout the image; the B-scan also looks dark or blurry.

Table 50: Signal Quality Acceptance

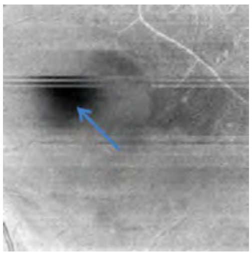
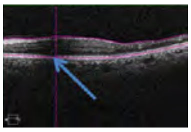
Enface Flow Image	Enface Structural Image	B-Scan	Explanation
			■ Blue arrow shows a floater ■ Red arrow shows possible impaired capillary flow: – Good signal in the structural en face and the B-scan – B-scan and en face images show a decreased signal in the same area

Table 51: Example: Signal Criteria Example: Angio 6mmx6mm

8.13.10.3 Decorrelation Tails Acceptance Criteria

Bright shadows of more superficial vessels that appear in posterior layers are decorrelation tails. Decorrelation tails result from light that passes through moving blood cells and returns to be detected.

Test	Pass	Fail	Explanation
Bright	No Decorrelation Tails; signal detected shows accurate motion. ■ **DRL** has a different characteristic appearance than the **SRL**. ■ RPE not showing vasculature	Decorrelation Tails Appear ■ **DRL** has the same characteristic appearance as the **SRL**. ■ Vessels appear exactly the same shape as a layer superior to it. ■ RPE shows vasculature (exactly the same shape as a superior layer)	Inaccurately detected motion causes a weaker signal to appear below the original signal. Because the effect is correlated with the brightness of the reflecting layer, decorrelation tails may seem to disappear within the outer nuclear layer, but appear strongly in the brightly-reflecting RPE.

Table 52: Decorrelation Tails Acceptance

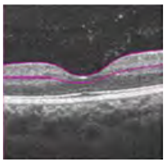
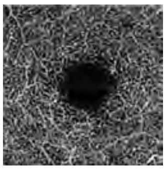
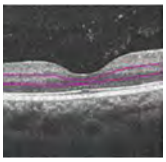
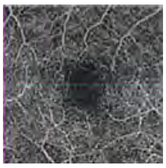
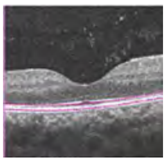
Layer	Enface	B-Scan	Explanation
SRL			The larger vessels that appear similar in SRL and DRL are decorrelation tails and not present in the DRL.
DRL	 *Decorrelation Tails*		DRL en face does not include the larger vessels; they appear due to the decorrelation tails.
Above RPE	 *Decorrelation Tails*		RPE enface does not normally have vessels; vasculature appears due to decorrelation tails.

Table 53: Decorrelation Tails Example: Normal Eye

8.13.10.4 Segmentation Acceptance Criteria

Test	Pass	Fail	Explanation
Flow Detection	Appropriate presence or absence of flow in the layers of interest.	Unexpected presence or absence of flow in the layers of interest.	Segmentation errors can result in incorrect visualization of flow. Boundary lines that determine a particular enface image appear as pink dotted lines overlying the B-scan.

Table 54: Segmentation Acceptance

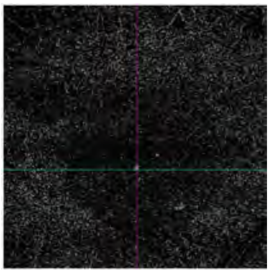
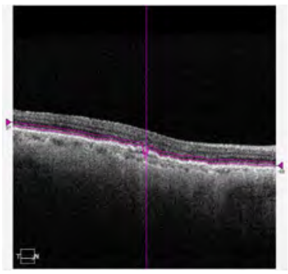
EnFace	B-Scan	Explanation
		■ Boundary lines that determine the enface image appear as pink dotted lines overlying the B-scan. ■ En face image shows a bright area not associated with pathological flow. ■ Bright area in the B-scan shows that segmentation pushed below the hyper-reflective retinal pigment epithelium. (Any signal detected here is likely due to decorrelation tails from the inner retinal vasculature). ■ B-scan shows that the segmentation is not correctly passing through the outer retinal layer expected to be free of signal (horizontal blue line location)

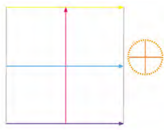
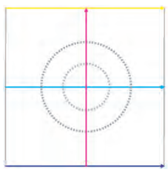
Table 55: Segmentation Criteria Example: Angio 6mmx6mm

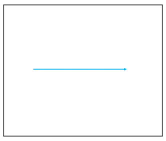
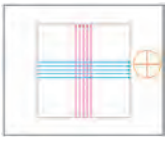
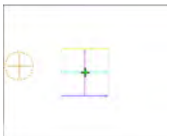
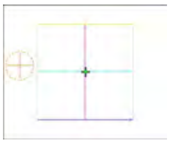
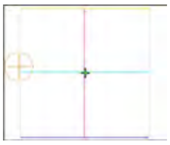
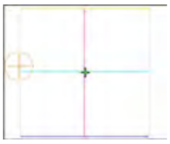
Empty page, for your notes

9 Analyzing Exam Data and Creating Reports

Using the Analysis and Report screens, you can view, group, characterize, measure, annotate, and adjust scanned data in multiple ways and save the adjusted scans and create reports.

9.1 About Analysis and Reports

Scan Pattern	Scan	Analyses
	512 x 128 200 x 200	■ Macular Thickness ■ Macular Thickness OU ■ Macular Change ■ Advanced RPE ■ Wellness Exam ■ Panomap ■ Advanced Visualization ■ En Face ■ 3D Visualization ■ Ganglion Cell OU ■ Ganglion Cell Guided Progression (Extrapolate Progression) ■ Single Eye Summary
	200 x 200	■ ONH/RNFL OU ■ Guided Progression (Extrapolate Progression) ■ Advanced Visualization ■ En Face ■ 3D Visualization ■ Wellness Exam ■ Panomap ■ Single Eye Summary

Scan Pattern	Scan	Analyses
	HD 1 Line 100X	High Definition Images
	HD 5 Line	
	HD Radial	
	HD 21 Line	
	HD Cross	
	3mm x 3mm	■ Angiography ■ Angiography Change ■ En Face
	HD 6mm x 6mm 6mm x 6mm	
	HD 8mm x 8mm 8mm x 8mm	
	12mm x 12mm	
	4.5mm x 4.5mm	■ ONH Angiography ■ ONH Angiography Change ■ En Face

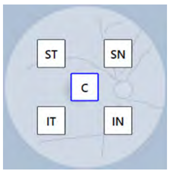
Scan Pattern	Scan	Analyses
	6mm x 6mm ⊕	Montage Angiography
	8mm x 8mm ⊕	

Table 56: Macular Cube Scans

Many anterior segment scans are optional (see: About Licenses [▹ 61]).

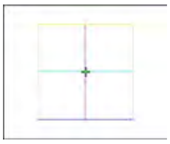
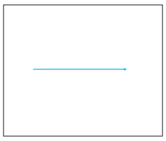
Scan Pattern	External Lens	Scan	Analysis
Anterior Segment Scans			
	-	Anterior Segment Cube	■ Anterior Segment Analysis ■ 3D Visualization
	-	Anterior Segment 5 Line Raster	High Definition Images
	-	HD Angle	HD Angle Analysis
		Anterior Chamber ⊕	Anterior Chamber Analysis
		Wide Angle-to-Angle ⊕	Wide Angle-to-Angle Analysis
		HD Cornea ⊕	HD Cornea Analysis
		Pachymetry ⊕	Pachymetry Analysis

Table 57: Anterior Segment Scans

Requires (or best with) image of both eyes.

Requires (or best with) both **Macular Cube** and **Optic Disc Cube** images.

⊕ *Indicates optional features; license may be required.*

You can set a preferred analysis for scans (see: Set Preferred Analyses [▸ 118]).

9.1.1 Analysis Overview

This section describes elements common to the analysis screens.

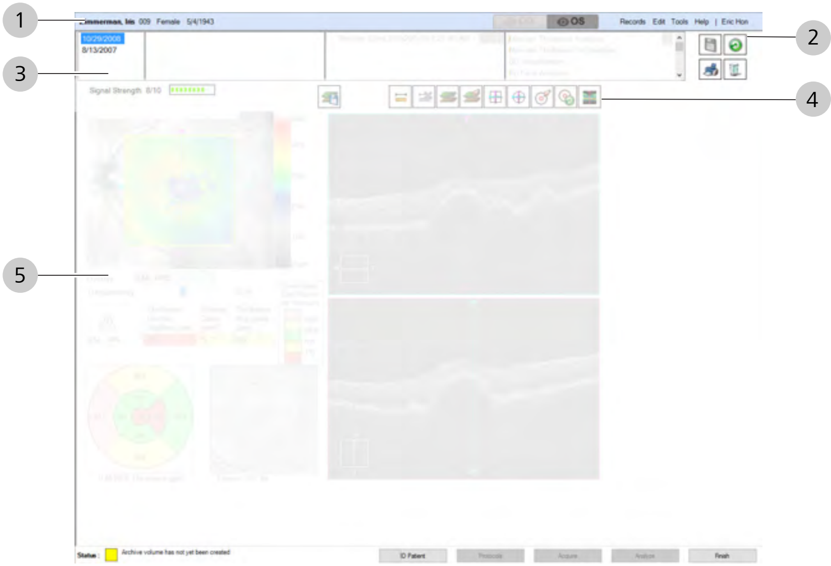


Figure 44: Analysis Screens

1	**Information Bar**		
	Hopkins, Anita 026 Female 2/16/1939	Patient Information	Displays the patient's name, gender, and date of birth.
	OD OS OD OS	OD / OS Indicator	Indicates which eye is selected. If the patient's other eye does not have a comparable scan to select, it's is grayed out.
2	**Print Tools** (See: Printing Reports)		
		Save	Saves the printed report with any changes you made.
		Export	Exports the analysis with any changes you made.
		Print	Prints the analysis with any changes you made.
		Delete	Deletes the report.

3	**Scan Selection**		
		Scan Date	Selects the date of the scan to analyze.
		OD Scans	Selects a scan of the patient's right eye.
		Analysis / Report Selection	Allows you to select the type of analysis you want to view. This list varies depending on the type of scan (see About Licenses [▸ 61].)
4	*Varies*	Scan Tools	Displays information about the scan and tools to make adjustments (varies depending on the type of scan and analysis).
5	*Varies*	Viewports	Displays in the viewport(s) vary depending on the type of scan and analysis.

Table 58: Posterior Segment Scans (Macula and Optic Nerve Head) Overview

9.1.2 About Reports

CIRRUS™ HD-OCT allows you to generate color reports that you can print or export. Some information on the reports is truncated to fit the page. For example, although a patient identification number can have as many as 32 characters, only the first 23 characters (including spaces) print on the report. Truncated fields are:

	Possible Characters	Characters on Reports
Patient ID	32	23
Technician Name	64	32
Institution Name	36	24

You can customize reports (refer to: Configuring Reports [▸ 112]).

Exporting Reports

You can export a report to DICOM (if configured) or export data into one of the following file formats:

- PDF
- BMP
- GIF
- JPEG
- PNG
- TIFF
- EMF
- WMF

For XML export details, see: About XML Data Export [▹ 93].

9.2 Posterior Segment Scan Analysis

9.2.1 Macular Analysis

9.2.1.1 Analyze Macular Thickness

NOTE

Good scan quality (strong signal strength) is essential for accurate comparisons to normative data.

▶ Scans with low signal strength may not compare to the normative data as accurately as higher quality scans.

Macular Thickness Analysis allows you to:

- View a retinal thickness map overlaying the fundus image and identify the fovea location.
- Edit and measure the layers and their boundaries.
- View high-resolution B-scans.
- Compare the patient's thickness and volume measurements to the normal reference range for their age.
- Scroll through automatically-detected IML - RPE three-dimensional thickness maps.
- Navigate color-coded thickness maps of the cube slices and identified layers.

Macular Thickness Analysis uses normative data to determine whether the patient's macular thickness is normal, above normal, or below normal. For more information about the normative data, refer to: Macular Thickness Parameters [▹ 456]

Macular Thickness Analysis is available for the following scans:

- Macular Cube 512x128
- Macular Cube 200x200

To study a series of scans and analyze macular thickness change over time, see: Analyze Macular Change [▹ 247].

For a more detailed examination of RPE elevation and sub-RPE illumination, see: Advanced RPE Analysis [▹ 257].

You can also view and navigate through the slices of any cube scan as a three-dimensional image (see: 3D Visualization Analysis [▹ 289]).

9.2.1.1.1 Interpreting Macular Thickness Parameters

NOTE

Normal reference ranges represent the general population.

However, when interpreting data, keep the following study limitations in mind (especially for 1% and 99%):

- Subjects:
  - ⇨ Ages 18-84
  - ⇨ Refractive errors –12.00 D to +8.00 D
- Age ranges with fewest subjects:
  - ⇨ 3 subjects over 80.
  - ⇨ 28 subjects aged (70-79).

NOTE

Normal reference range limits are adjust by age groups only (unless noted).

Other differences might occur for some measurements; however, the normal reference range does not adjust for these factors, such as:

- Image Signal Strength
- Ethnicity
- Axial Length
- Refraction
- Optic Disc Area

Macular Thickness Parameters [▸ 456] studies determine the normal reference range for the general population. The following table shows some examples of analyses for macular cube images that compare a patient's results to the normal reference range.

Color coding and measurements help you determine how a patient's macular thickness compares to the normal reference range for their age.

Color Code	Study Population Comparison
Above Normal	Thickest 1% *Higher than 99%.*
Suspected Above Normal	Thickest 5% *Higher than 95%.*
Normal	Middle 90%.
Below Normal	Thinnest 1% *Lower than 99%.*
Suspected Below Normal	Thinnest 5% *Lower than 95%*

Table 59: Color Key for Macular Thickness Comparison

The ETDRS grid shows the patients' average macular thickness measurement for each sector of the grid. For more information about the ETDRS grid, refer to: Macular Thickness Parameters [▷ 456].

The following examples comparing a patient's measurements to the general population subjects of the same age.

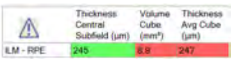
<table>
<tr><th>Analysis</th><th>Interpretation</th></tr>
<tr><td>
</td><td>ETDRS Grid
All sectors are green, which indicates that all measurements are Normal</td></tr>
<tr><td>
</td><td>ETDRS Grid
Five sectors are green, which indicates that their measurements are Normal (middle 90%).
Four sectors are red, which indicates that their average macular thickness measurements are Below Normal (lowest 1%).</td></tr>
<tr><td>
</td><td>ETDRS Grid
Seven sectors are green, which indicates that their measurements are Normal (middle 90%).
Two sectors are yellow, which indicates that their average macular thickness measurements are Possibly Below Normal (lowest 5%).</td></tr>
<tr><td>
<table><tr><th></th><th>Thickness Central Subfield (µm)</th><th>Volume Cube (mm³)</th><th>Thickness Avg Cube (µm)</th></tr><tr><td>ILM - RPE</td><td>245</td><td>8.8</td><td>247</td></tr></table></td><td>Macular Thickness Table
Combining the ETDRS Grid information with additional parameters in the table provides data you can use to inform your assessment.</td></tr>
</table>

Table 60: Macular Thickness Interpretation Examples

Studies that included a diverse population to determine the normal reference ranges for age. For more information about these studies, see: Macular Images [▷ 455].

Additional studies included only an Asian population to determine the normal reference ranges for age. For more information about these studies, see: Macular Images [▷ 469].

9.2.1.1.2 Macular Thickness Analysis

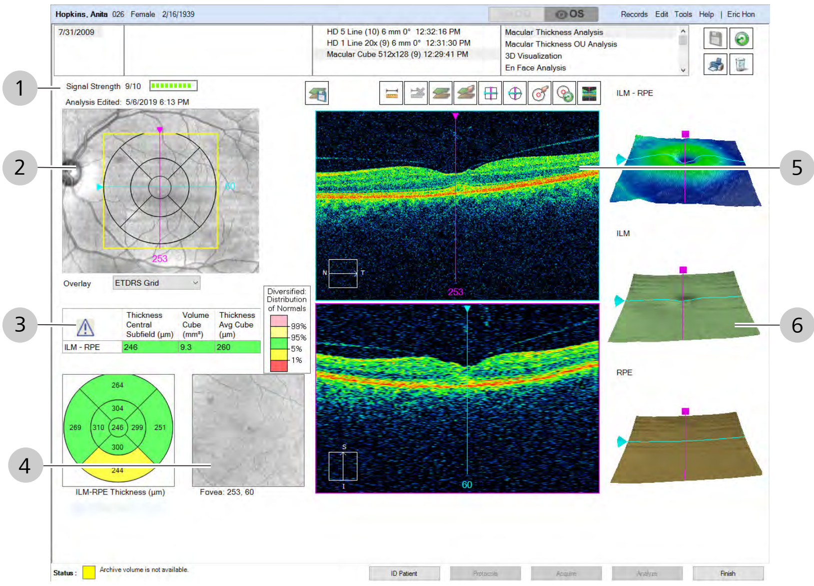
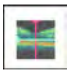
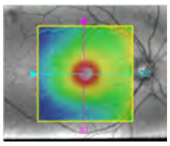
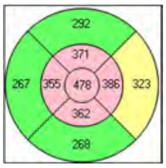
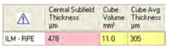
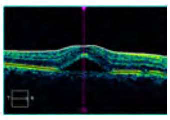
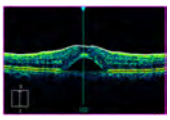
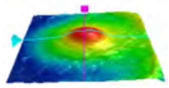
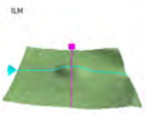
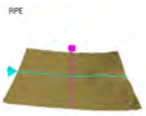


Figure 45: Macular Thickness Analysis Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Signal Strength	Indicates scan quality level; more green indicates a higher quality scan.
		Edit Layers	Opens the segment editing tools.
		Caliper	Adds a measurement line.
		Delete Measurement	Deletes a measurement line added with the caliper tool.
		Show / Hide Layers	Hides or shows the colored lines indicating the ILM and RPE layers.
		Edit Layers	Opens the segment editing tools.
		Snap to Center	Moves the slice navigators to the center of the 6x6 mm square.
		Snap to ETDRS Grid center	Moves the slice navigators to the ETDRS Grid center position.
		Center ETDRS Grid	Moves the ETDRS Grid to center on the slice navigator position.
		Reset ETDRS Grid	Moves the ETDRS Grid back to the CIRRUS-calculated fovea center location.

#	Symbol	Name	Explanation
		Show / Hide High-Resolution Images	Displays the high-resolution scans or standard-resolution scans. **NOTE! The ETDRS Grid does not change position when the High–Resolution image is displayed.**
2		Fundus Image	Fundus image showing scan area and cube navigation lines.
		Select Overlay	Selects which overlay to display over the fundus image.
3	**Thickness Measurements and Normative Data Comparisons**		
		ETDRS Grid	Shows overall average macular thickness in nine sectors. ■ central circle (radius = 500 micrometers; diameter =1 mm) ■ superior sectors ■ nasal sectors ■ temporal sectors ■ inferior sectors. Color coding shows how this patient's scan compares to the normal reference range for their age. See: Macular Thickness Parameters [▸ 456]).
		Thickness Measurement Table	Color coding shows how this patient's scan compares to the normal reference range for their age. Calculations shows the average thickness and volume measurements.
4		Fovea Finder	Automatically identifies the fovea and shows the surface of the area for the individual thickness measurements in the grid and table.
5	**B-Scans**		
		Horizontal B-Scan	Slice through cube front
		Vertical B-Scan	Slice through cube side

#	Symbol	Name	Explanation
6	**3D Surface Maps (interactive)**		
		ILM - RPE Map	Shows the thickness between the ILM and RPEas a color-coded three-dimensional surface.
		ILM Map	Shows the Anterior Layer (ILM) as a color-coded three-dimensional surface.
		RPE Map	Shows the Posterior Layer (RPE) as a color-coded three-dimensional surface.

9.2.1.1.3 Analyzing Macular Thickness and Macular Thickness OU

CIRRUS™ HD-OCT automatically traces retinal layers and calculates their thickness. You can adjust these layer boundaries, if needed. See (Editing Macular Thickness Layer Boundaries [▸ 245]).

If CIRRUS™ HD-OCT cannot detect the fovea, the measurement circles and calculations are based on the center of the 6 mm square.

High-Definition Images

You can view high–definition images and double-click for a full–screen view. High-definition image behavior is slightly different:

- You cannot navigate through the high-definition image using the slice navigators. If you move the slice navigators, the image changes back to the standard resolution.
- The **ETDRS Grid** does not change positions for the high-definition image.

Macular Thickness Analysis is available for the following scans:

- Macular Cube 512x128
- Macular Cube 200x200

To analyze macular thickness:

Prerequisite

☑ The patient has at least one macular cube scan: (Acquire a Macular Cube Scan [▸ 150]).

☑ You are logged in (review station or instrument): Login [▸ 123].

Action

1. Select the patient and click **Analyze**.
2. Select a **Macular Cube** scan and select **Macular Thickness Analysis**.

3. To show or hide the layer indicators, click **Show/Hide Layers**.

4. To edit the layer boundaries, refer to: Editing Layer Boundaries.

5. To change the overlay for the fundus image select a different overlay (or none).

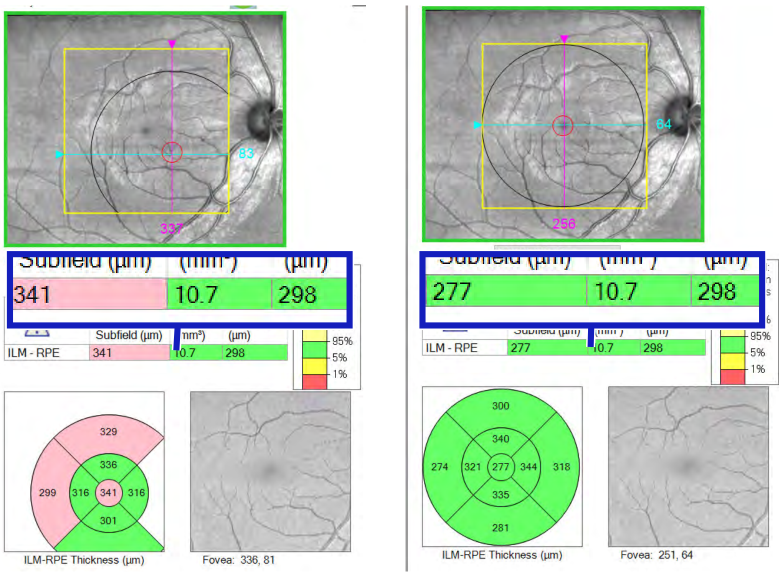
6. To export the all images, click **Export**.

7. To add a caliper, click **Caliper**.

   ➩ A caliper measurement appears over the image. You can move, stretch, and rotate calipers. You can add (up to) ten.

8. To delete a measurement or annotation, select it and click **Delete**.

9. To set the navigators to the center of the image, click **Center**.



10. To reposition the fovea, for **Overlay**, select **ETDRS position**. Select and drag the fovea overlay to the correct position.

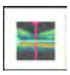
    ➩ The data recalculates according to the new fovea position.

11. To center the navigators on the middle of te ETDRS grid, click **Center**.

    ➩ The slice navigation lines move to the center of the grid.

12. To center the ETDRS grid onto the slice navigator position, click **Center Grid**.

13. To rest the ETDRS grid to its original position, click **Reset Grid**.



14. To show or hide the high-resolution image, click **HD**.

    ➩ The image toggles between the original resolution and high resolution versions.

15. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▸ 369]).
16. To view a full-screen image, double-click on the image.
17. To print, save, or export a report, see: Creating a Report [▸ 384].

9.2.1.1.4 Export Thickness Map Values

You can save the ILM-RPE thickness map data as comma–delimited values in a .csv file. The .csv file saves the fast B-scans as rows starting at the top and slow B-scans as columns starting at the far left.

You can open and view .csv files in Microsoft Excel Matlab, or other applications that accept the file .csv file type. Select this button to

To export thickness map values:

Prerequisite

☑ Logged in to review station (or instrument): Log In as Operator or Data Analyst [▹ 123]

☑ The scan report or analysis is open: Opening a Report or Analysis

Action

1. Click **Export Data**.
   ⇨ The navigation dialog opens.
2. Navigate to the folder where you want to save the file.
3. Click **OK**.

9.2.1.1.5 Editing Macular Thickness Layer Boundaries

NOTE

Top and bottom boundaries are the same color for each layer:

Blue line indicates the top layer.

Red line indicates the bottom layer.

CIRRUS™ HD-OCT automatically calculates **Macular Thickness** layer boundaries. Sometimes a patient's retinal structure has anomalies or pathology that causes algorithms to trace the boundaries inaccurately.

You can edit these boundaries per individual scan (as needed). You can drag any portion(s) of the boundary lines, but you cannot cross the top and bottom boundaries of a layer.

To edit layers:

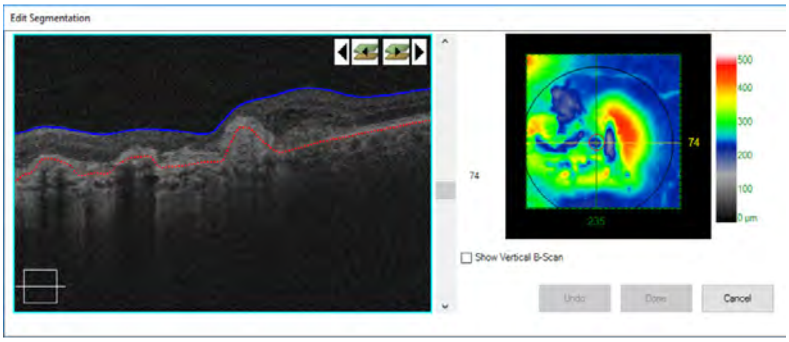
Prerequisite

☑ Logged in to review station (or instrument): Log In as Operator or Data Analyst [▹ 123].

☑ Analyze Macular Thickness [▹ 238]

Action

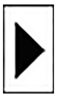
1. Select the layer or preset that you want to edit.
2. Click **Edit Layers**.
   ⇨ The layer boundary editor opens showing the top layer in blue and the bottom layer in red.



3. To adjust the top layer, drag the blue (upper) line into place.
4. To adjust the bottom layer, drag the red (lower) line into place.
   ⇨ The new segmentation location blends with the automatic segmentation and appears continuous.

5. To copy these changes to the next slice, click **Copy Next**.

6. To copy these changes to the previous slice, click **Copy Previous**.



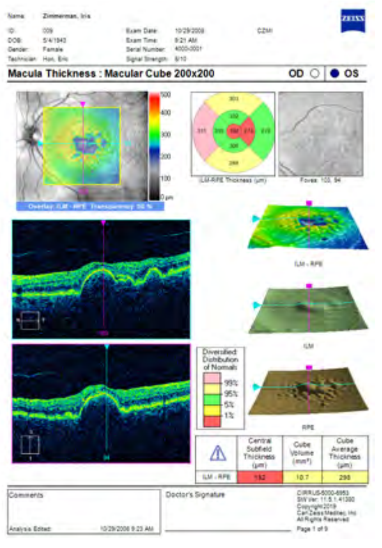
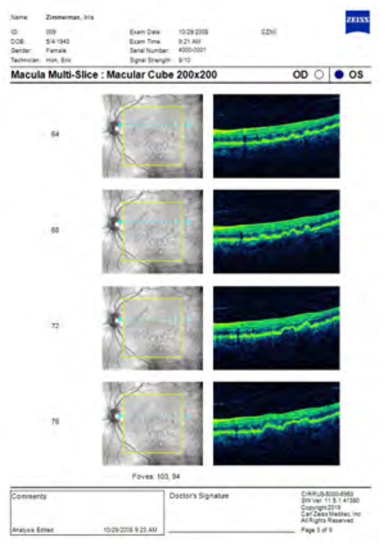
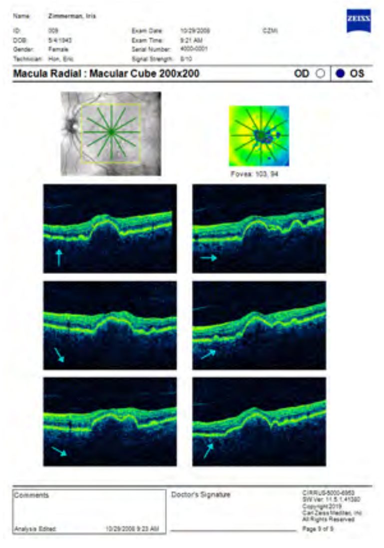
7. To view the next layer, click **Next**.

8. To view the previous layer, click **Previous**.
9. To show the vertical B-scan below the horizontal B-scan, check **Show Vertical B-Scan**.
10. Click **Done**.

9.2.1.1.6 Create a Macular Thickness Report

Macula Thickness Reports

There are three different types of reports for macular thickness analysis. To set which reports to include and customize their settings, see: Configuring Macular Thickness Reports [▸ 113].

Macula Thickness Report (One Eye, Both Eyes)	Macula Multi-Slice Report	Macula Radial Report
		

To create a macular thickness report, see: Creating a Report [▸ 384]

9.2.1.2 Analyze Macular Change

When you have two or more macular scans for the same patient taken at different times, you can compare scans together to analyze macular changes. The **Macular Change** analysis compares two of the patients macular cube scans taken at different times.

By comparing each of the patient's scans to the normal reference range and combining this information into one analysis, you can easily see how the patient's measurements have changed over time, which sectors changed, and how much change occurred between the images captured at the first visit and the followup visit.

Macular Change Analysis is available for the following scans:

- Macular Cube 512x128
- Macular Cube 200x200

An optional license provides progression analysis that compares a series of scans over time (see: About Licenses [▸ 61]).

9.2.1.2.1 About Macular Scan Registration

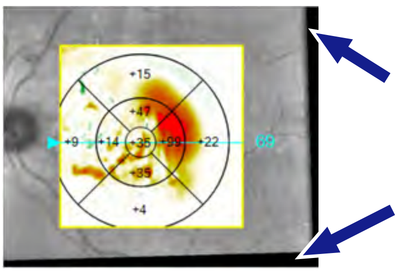


Figure 46: Unregistered Areas (Black Border)

When you compare a patient's scan to an earlier scan (of the same type), CIRRUS™ HD-OCT automatically aligns, or *registers*, the scans together. Registration synchronizes anatomical structures and corrects differences in rotation, which can occur if the patient is situated slightly differently for the two scans.

If areas in the current image do not overlap with the earlier image, those areas are not included in the registered pair; they appear as black borders along the edge of the fundus image and are not included in the b-scan image.

9.2.1.2.1.1 Automatic Scan Registration

There are two different methods for automatically registering scans, **R2** and **R1**.

CIRRUS™ HD-OCT's primary (preferred) registration method is **R2**.

However, if **R2** cannot adequately register the images, the instrument attempts **R1** registration.

Analyses and reports that use scan registration inform you of which method was applied.

Method	Order	Description
R2	Primary	■ Aligns scans using the blood vessels identified in the en face images of both scans. ■ For guided progression analyses, uses translation and rotation to align the follow-up scan(s) to the baseline scan
R1	Secondary	■ Aligns scans using the center of the optic disc of both scans. ■ R1 does not include rotation. ■ R1 might cause additional variability at the super-pixel level, which can affect change detection in a thickness map.

Table 61: Registration Types

If you want to override automatic registration, you can register scans manually or select a different set of scans to register together. (See: Manually Register Macular Images [▸ 253]).

9.2.1.2.1.2 No Registration

If automatic registration was not successful and no manual registration was applied yet, the scans will display **No Registration**. To register the scans, refer to: Manually Register Macular Images [▸ 253].

9.2.1.2.1.3 Manual Registration

When you manually register images, you set (up to five) corresponding points between two images. When you identify the same structure or feature in both images, click that structure in the first image, then the second image.

For example, use a blood vessel bifurcation or a bend in a blood vessel as a point to mark. A matching set of marks indicates corresponding features. Different colored marks indicate the next feature you mark in each image.

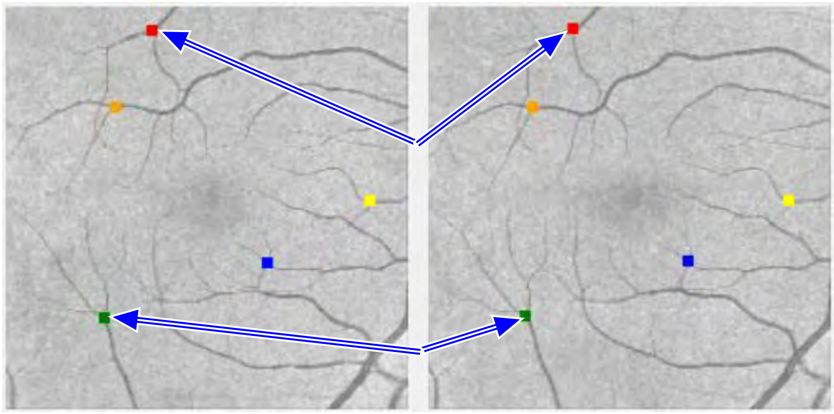


Figure 47: Registration Mark Pairing

After you register two images, the second image might display irregular black borders. These borders indicate areas that are not present in both images.

9.2.1.2.2 Macular Change Analysis

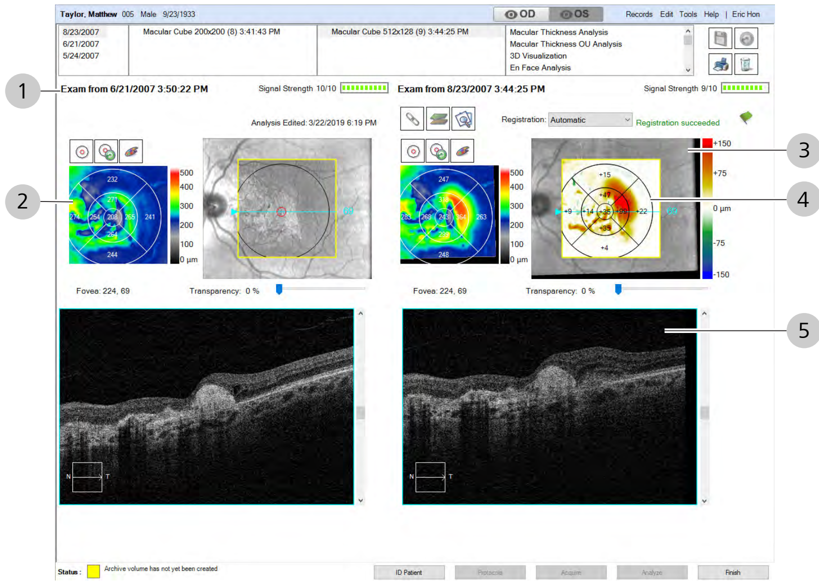
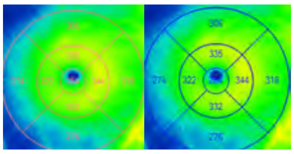
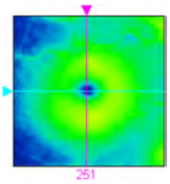
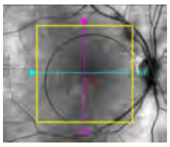
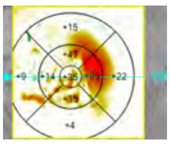
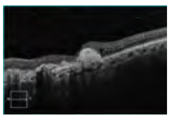


Figure 48: Macular Change Analysis Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Signal Strength	Indicates scan quality level; more green indicates a higher quality scan.
		Synchronize Images	Synchronizes images so they move together when you pan, zoom or navigate through the cube data.

#	Symbol	Name	Explanation
		Show / Hide Layers	Hides or shows the colored lines indicating the ILM and RPE layers.
		View Registration	Opens the registration viewer that shows each image. It also displays an overlay of both images with a transparency slider you can move right and left to compare image alignment.
		Reset ETDRS Grid	Moves the ETDRS Grid back to the CIRRUS-calculated fovea center location.
		Center ETDRS Grid	Moves the ETDRS Grid to center on the slice navigator position.
		ETDRS Grid Color Selector 	Changes the ETDRS Grid and displayed measurements color.
2		Macular Thickness Map	Shows ILM-RPE thickness maps.
3		Fundus image with ETDRS grid position displayed.	To reposition the ETDRS grid, select **Overlay > ETDRS position** and adjust the center or drag the lines.
	Transparency 50 %	Overlay Transparency	Sets the overlay transparency level.
4		ETDRS Differences	Shows the difference in measurements between the two images for each section of the ETDRS grid.
5		Macular Cube B-Scan	Slice through cube front.

9.2.1.2.3 Analyzing Macular Change

Macular Change Analysis is available for the following scans:

- Macular Cube 512x128 (2 or more)
- Macular Cube 200x200 (2 or more)

To analyze macular change:

Prerequisite

☑ The patient has at least one macular cube scan: (Acquire a Macular Cube Scan [▷ 150]).

☑ You are logged in (review station or instrument): Login [▸ 123].

Action

1. Select the patient and click **Analyze**.
2. Select a **Macular Cube** scan and select **Macular Change Analysis**

3. To synchronizes both comparison images so they move together when you pan, zoom or navigate through the cube data, **Lock** synchronization.

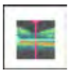
4. To show or hide the layer indicators, click **Show/Hide Layers**.

5. To see how the images are matched together for comparison, click **Review Registration** (see: Review Scan Registration [▸ 251]).

6. To center the ETDRS grid onto the slice navigator position, click **Center Grid**.

7. To rest the ETDRS grid to its original position, click **Reset Grid**.
8. To manually register the images, select **Manual** (see:Manually Register Macular Images [▸ 253]).

9. To change the color of the ETDRS grid and measurements, click Color and select a color (or create a custom color),



10. To show or hide the high-resolution image, click **HD**.
    ⇨ The image toggles between the original resolution and high resolution versions.
11. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▸ 369]).
12. To view a full-screen image, double-click on the image.
13. To print, save, or export a report, see: Creating a Report [▸ 384].

9.2.1.2.4 Changing Thickness Colors

If automatic registration was not successful and no manual registration was applied yet, the scans will display **No Registration**. To register the scans, refer to: Manually Register AngioPlex Images [▸ 317].

9.2.1.2.5 Review Scan Registration

With **Macular Change** analysis, you can review and fine-tune registration if automatic registration does not suit your needs. To register scans, see: Register Scans Manually.

9.2.1.2.5.1 Review Registration Overview

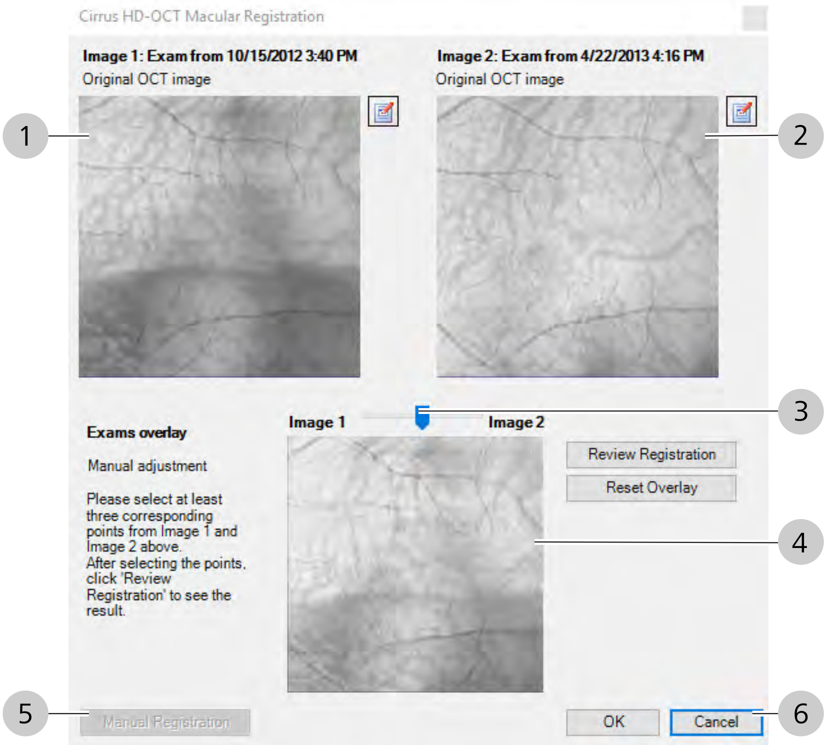
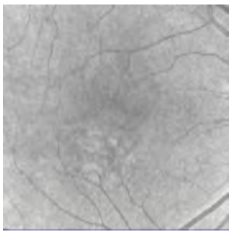
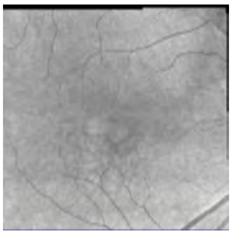
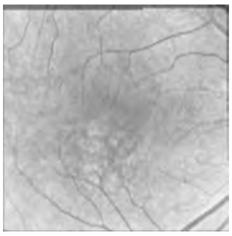
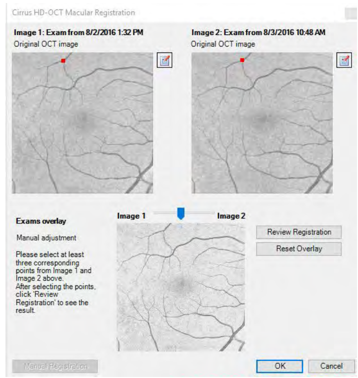
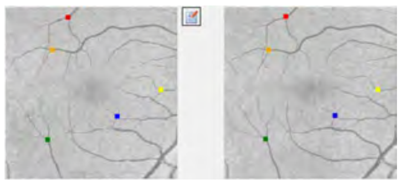


Figure 49: Review Registration Overview

Pos.	Symbol	Name	Explanation
1		Original (Baseline) Image	Fundus image of the earlier (baseline) exam(s).
2		Registered (Current) Image	En face image for the followup exam. Black borders incidate areas that do not correspond between the two images.
3		Overlay Adjustment	Image slider to adjust the registration overlay view: ■ slide left to view image 1, ■ slide right to view image 2.

Pos.	Symbol	Name	Explanation
4		Registration Overlay	Overlays both exam images.
5		Manual Registration	Opens Manual Registration.
6		Cancel	Exit registration review and return to analysis.

9.2.1.2.5.2 Manually Register Macular Images

	Macular Registration
Registration Tool	
Matched Marks	
Marked Example	

To adjust registration manually:

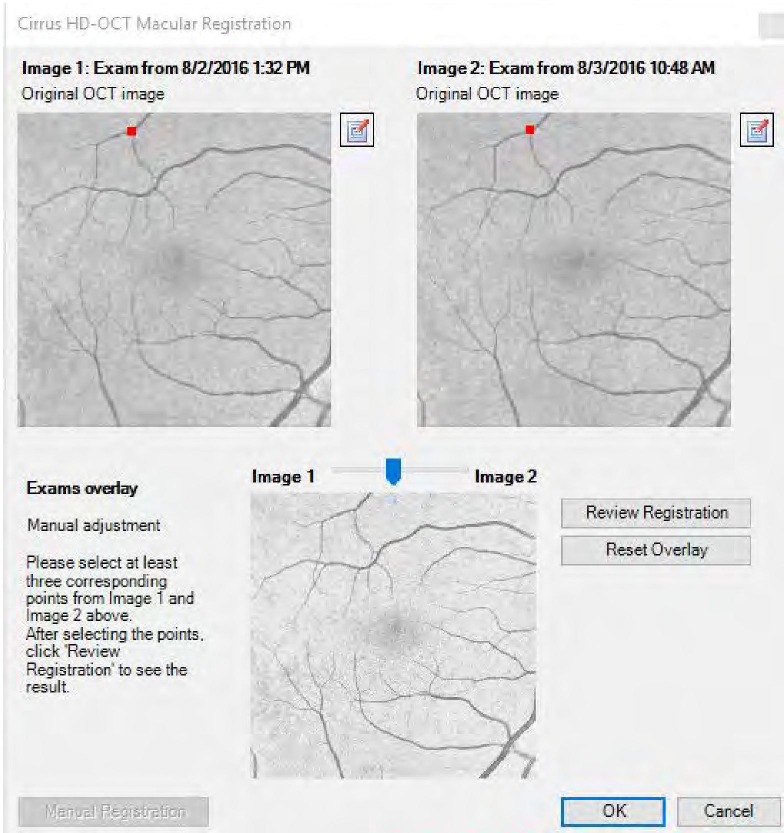
Prerequisite

☑ You are logged in (review station or instrument): Login [▸ 123].

☑ You have a comparison analysis open and you want to change the registration.

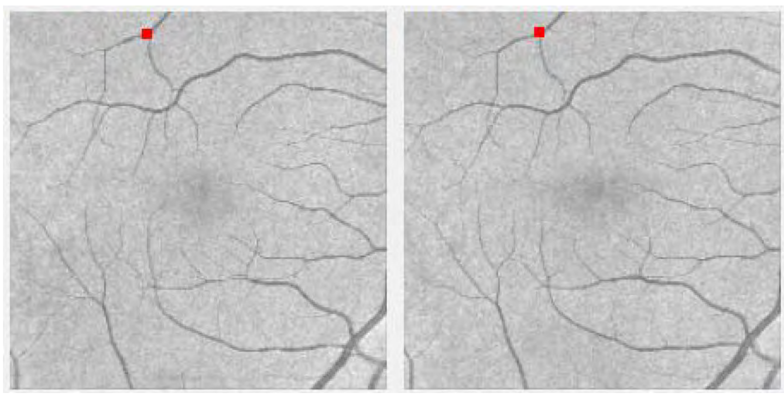
Action

1. For **Registration**, select **Manual**.

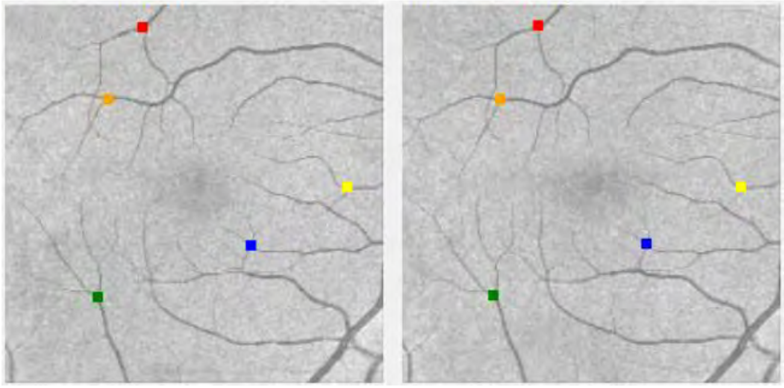


⇨ The registration review tool opens.

2. Identify a feature that appears in both images, like a blood vessel bifurcation or a bend in a blood vessel.



3. Mark the feature in each image.



4. Identify and mark additional identifiable features in other regions of the pair of images (between 3 and 5 marks in each image).
5. To change the transparency of Image 1 or Image 2, move the transparency slider right or left.
6. To view the manually-adjusted overlay, click **Review Registration**.
7. To return to the original registration, click **Reset**.
8. Click **OK**.

Result

✓ The **Registration succeeded** message and a green flag appear.

9.2.1.3 Analyze HD Images

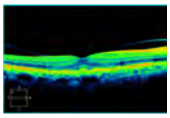
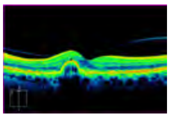
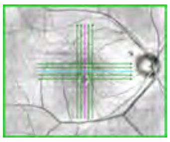
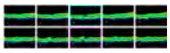
HD Images Analysis is available for the following scans:

- HD 1 Line 100X
- HD 5 Line
- HD Radial
- HD 21 Line
- HD Cross

9.2.1.3.1 HD Images Analysis

Figure 50: HD Images Analysis Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Signal Strength	Indicates scan quality level; more green indicates a higher quality scan.
		FastTrac	Indicates that the operator used FastTrac when acquiring the image.
		Tracked Image	Toggles: Show prior image used from tracking Retrun to current image (tracked)
		Toggle Color	Toggles among three options: Grayscale Reverse Grayscale Color
		Caliper	Adds a measurement line.
		Delete Measurement	Deletes a measurement line added with the caliper tool.

#	Symbol	Name	Explanation
2		Horizontal B-Scan	Enlarged imaged of a selected horizontal B-Scan
3		Vertical B-Scan	Enlarged imaged of a selected vertical B-Scan
4		Scan Pattern	Image area showing the scan pattern with customization adjustments (if applicable)
5		Thumbnails	Thumbnails of the B-scans; cyan and magenta outlined thumbnails are selected for enlarged view

9.2.1.3.2 Analyzing HD Images

To analyze HD images:

Prerequisite

☑ The patient has at least one macular cube scan: (Acquire a Macular Cube Scan [▸ 150]).

☑ You are logged in (review station or instrument): Login [▸ 123].

Action

1. Select the patient and click **Analyze**.
2. Select a **Macular Cube** scan and select **Macular Thickness Analysis**.

3. To toggle black-and-white, reverse black-and-white, and color images, click **Colors**.

   ⇨ A caliper measurement appears over the image. You can move, stretch, and rotate calipers. You can add (up to) ten.

4. To delete a caliper, click **Delete**.
5. To view a different part of the HD image, select a different thumbnail.
6. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▸ 369]).
7. To view a full-screen image, double-click on the image.
8. To print, save, or export a report, see: Creating a Report [▸ 384].

9.2.1.4 Advanced RPE Analysis

The **Advanced RPE Analysis** allows you to compare the current scan to a prior scan and automatically measure drusen and geographic atrophy. You can examine disturbances in the RPE to identify and measure RPE elevations and sub–RPE illumination.

By showing the RPE in greater detail, **Advanced RPE Analysis** can help in managing age–related macular degeneration-- even in advanced forms that exhibit RPE atrophy.

When you select a scan for **Advanced RPE Analysis**, CIRRUS™ HD-OCT automatically opens the latest prior scan for the same patient (same eye, same scan). If the patient has multiple scans taken over time, you can choose another scan for the comparison.

This analysis has two different screens:

- Screen 1: shows RPE elevation and the sub–RPE illumination results separately as en face images
- Screen 2: shows combined the RPE Elevation Map and the sub–RPE illumination segmentation images with calculated values.

Advanced RPE Analysis is available for the following scans:

- Macular Cube 200x200
- Macular Cube 512x128

9.2.1.4.1 Advanced RPE Analysis - Screen 1

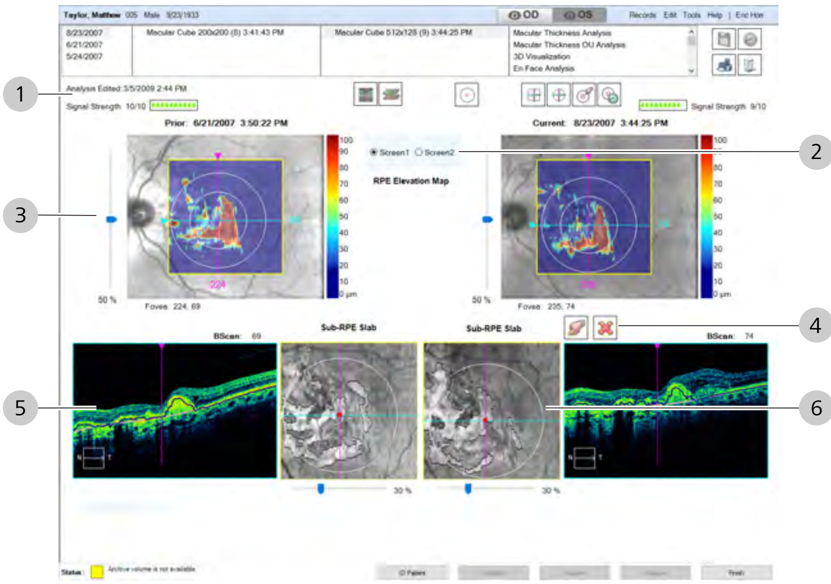
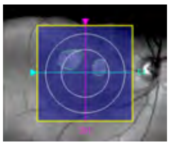
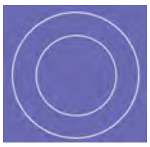
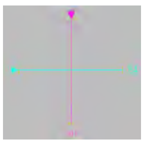
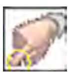
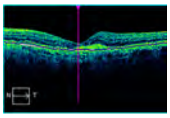
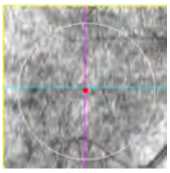


Figure 51: Advanced RPE Analysis - Screen 1 Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Signal Strength	Indicates scan quality level; more green indicates a higher quality scan.
		Show / Hide High-Resolution Images	Displays the high-resolution scans or standard-resolution scans. **NOTE! The ETDRS Grid does not change position when the High–Resolution image is displayed.**
		Show / Hide Layers	Hides or shows the colored lines indicating the ILM and RPE layers.

#	Symbol	Name	Explanation
		Show / Hide Circles	Toggles visibility of the **Fovea Fields**.
		Snap to Center	Moves the slice navigators to the center of the 6x6 mm square.
		Snap to ETDRS Grid center	Moves the slice navigators to the ETDRS Grid center position.
		Reset ETDRS Grid	Moves the ETDRS Grid back to the CIRRUS-calculated fovea center location.
		Center ETDRS Grid	Moves the ETDRS Grid to center on the slice navigator position.
2		Screen Selector	Toggles between the first and second screen of the analysis.
3		Fundus Image	Overlaid with the RPE Elevation Map for both scans.
		Scan Area	The yellow box indicates the area included in the scan.
		Fovea Fields	A pair of circles centered on the fovea (at 3mm and 5mm)
		Slice Navigators	Navigates cube slices horizontally (cyan line) and vertically (magenta line) and shows the slice number currently selected.
		Transparency Adjustment	Increases or decreases the transparency of the RPE elevation map overlay.
4	**Sub-RPE Slab Toolbar**	Screen Selector	Toggles between the first and second screen of the analysis.
		**Edit Segments**	Opens editor for Sub-RPE Illumination segments.
		**Show Hide Sub-RPE Illumination**	Toggles visibility of the illumination of the Sub-RPE segment.

#	Symbol	Name	Explanation
5		B-Scan	Displays the horizontal topogram showing RPE elevation segments.
6		**Sub-RPE Slab**	Displays the sub-RPE illumination layer.
		Fovea	Indicates the location of the fovea A red line connects the fovea to the closest Sub-RPE Illumination location- showing the distance (in mm).
		Transparency Slider	Increases or decreases the visibility of the sub-RPE illumination layer.

9.2.1.4.2 Advanced RPE Analysis - Screen 2

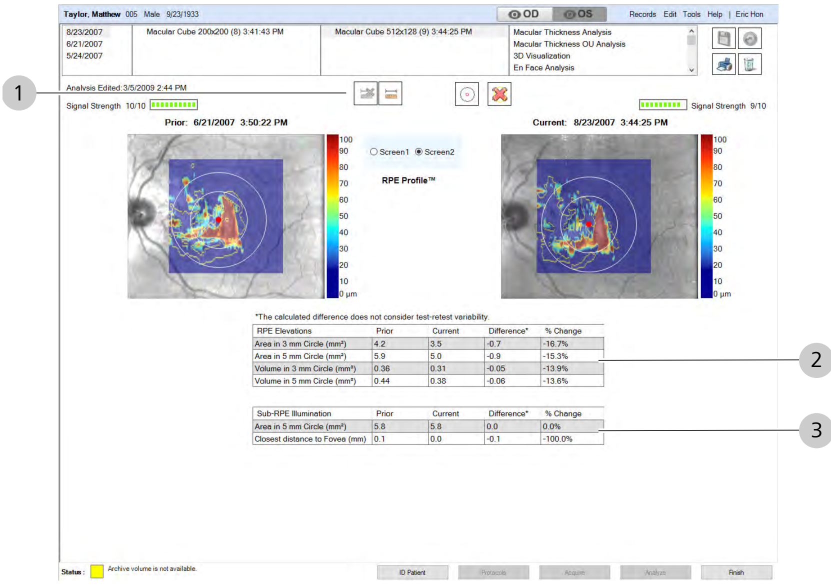


Figure 52: Advanced RPE Analysis - Screen 2 Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Caliper	Adds a measurement line.
		Delete Measurement	Deletes a measurement line added with the caliper tool.
		Show / Hide Circles	Toggles visibility of the **Fovea Fields**.
		Sub-RPE	Toggles visibility of the sub-RPE illumination boundaries.

#	Symbol	Name	Explanation
2		RPE Elevation Comparisons	Shows the data and differences in area and volume for the 3mm and 5mm circles.
3		Sub-RPE Illumination Comparisons	Shows the data and differences in area and the closest to the fovea.

9.2.1.4.3 Analyzing RPE (Advanced Analysis)

NOTE

Some characteristics can affect RPE elevation measurements, including presence, size, and extent of:

geographic atrophy

choroidal neovascularization

extensive epiretinal membrane

vitreomacular traction

NOTE

The minimum RPE elevation for calculations is 19.5 µm.

This analysis typically compares a patient's current scan to a prior scan from a series of scans taken over time. However, you can use some features of this analysis for a single patient scan.

Prerequisite

☑ You are logged in (review station or instrument): Login [▹ 123].

☑ The patient has at least one macular cube scan: (Acquire a Macular Cube Scan [▹ 150]).

Action

1. Select the patient and click **Analyze**.
2. Select a **Macular Cube** scan and select **Advanced RPE Analysis**.
   ⇨ If the patient had the same macular cube scan of the same eye taken during earlier visits, CIRRUS™ HD-OCT automatically loads the most recent prior scan for comparison.

3. To hide or show the circles around the fovea, click **Show / Hide Circles**.
4. If the patient exhibits characteristics that affect elevation, review the individual B-scans to determine where RPE elevation overlaps.
5. Check RPE elevation borders (black and purple lines) in the horizontal tomogram to ensure that retinal segments are accurate.
6. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▹ 369]).
7. To view a full-screen image, double-click on the image.
8. To print, save, or export a report, see: Creating a Report [▹ 384].

9.2.1.4.3.1 Editing Sub-RPE Illumination Segments

To edit the Sub RPE illumination boundaries:

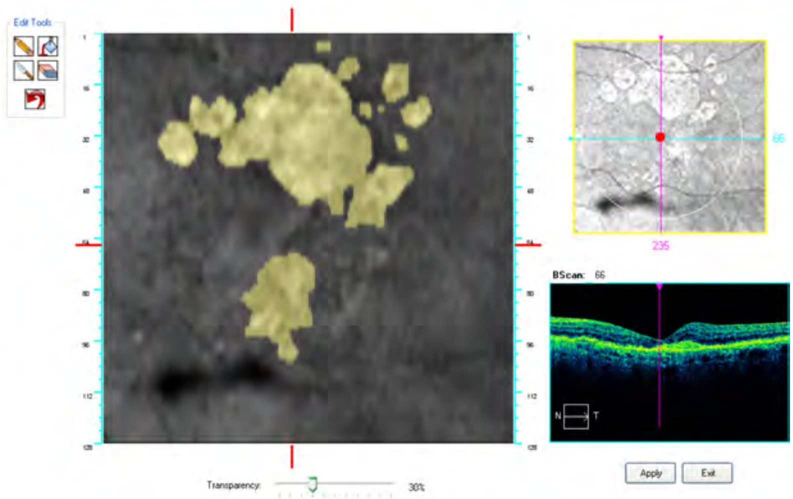
Prerequisite

☑ An **Advanced RPE** analysis is open.

Action

1. Click **Edit Illumination**.

   ⇨ The Sub-RPE Illumination boundary editor opens showing the sub–RPE illumination areas.



2. To draw fine details or outlines for **Floodfill**, select the **Pencil**, click in the image and draw a fine detail or the outline of a larger shape.

3. To fill the outline of a shape, select **Floodfill** and click inside the shape.

4. To delete fine details or draw outlines for the **Eraser**, select the **Knife**, click in the image and draw a fine detail or the outline of a larger shape.

5. To remove a large area, select the **Eraser** and click inside the shape drawn with the **Knife**.

6. To revert to the original (unedited) image, click **Reset**.
7. Click **Apply**.

9.2.2 Ganglion Cell Analysis

9.2.2.1 Analyze Ganglion Cell OU

Ganglion Cell OU Analysis measures the thicknesses for the sum of the ganglion cell layer and inner plexiform layer (GCL + IPL layers) using data from the Macular cube scan patterns. CIRRUS™ HD-OCT compares thickness information to the normative data gathered for their age (see Ganglion Cell Parameters [▸ 457]).

Ganglion Cell OU Analysis is available for the following scans:

- Macular Cube 512x128
- Macular Cube 200x200

9.2.2.1.1 Interpreting Ganglion Cell Results

NOTE

Normal reference ranges represent the general population.

However, when interpreting data, keep the following study limitations in mind (especially for 1% and 99%):

- Subjects:
  - Ages 18-84
  - Refractive errors –12.00 D to +8.00 D
- Age ranges with fewest subjects:
  - 3 subjects over 80.
  - 28 subjects aged (70-79).

NOTE

Normal reference range limits are adjust by age groups only (unless noted).

Other differences might occur for some measurements; however, the normal reference range does not adjust for these factors, such as:

- Image Signal Strength
- Ethnicity
- Axial Length
- Refraction
- Optic Disc Area

CIRRUS™ HD-OCT compares the patient's measurements to the normal reference range for their age. Different colors indicate the normal distribution percentiles. For more about normal reference range data, refer to: Ganglion Cell Parameters [457].

	Indication	Measurement Comparison	Interpretation
(white)	Above normal	Thickest 5%	Thicker than 95% of the database sample.
(green)	Normal	Middle 90%	Middle 90%.
(yellow)	Suspected below normal	Thinnest 5%	Thinner than 95% of the database sample.
(red)	Below normal limit	Thinnest 1%	Thinner than 99% of the database sample.

Table 62: Color Key for GCL + IPL Thickness Comparison to Normal Range

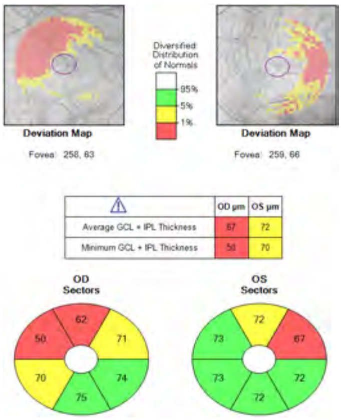
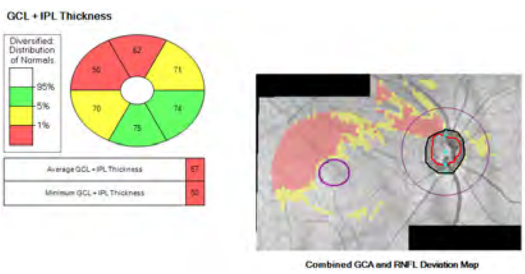
Analysis	Interpretation
Ganglion Cell OU  	**OD:** **Deviation map** - shows thin areas (yellow) and thinnest areas (red) **Table** - average = 67; minimum = 50. Both are *thinner than normal* **Grid** - 2 sectors are *normal* (green) 2 sectors are *suspected thinner than normal* (70 and 71) 2 sectors are *thinner than normal* (50 and 62)
	OS: **Deviation Map** - shows very little thin areas (yellow) **Table** - average = 72; minimum = 70. Both are *suspected thinner than normal* **Grid** - 4 sectors are *normal* (green) 1 sector is *suspected thinner than normal* (72) 1 sector is *thinner than normal* (67)
PanoMap  	**Grid** 2 sectors are *normal* (green) 2 sectors are *suspected thinner than normal* (70 and 71) 2 sectors are *thinner than normal* (50 and 62) **Table** - average = 67; minimum = 50. Both are *thinner than normal* **Deviation Map** - shows thin areas (yellow) and thinnest areas (red)

Table 63: Interpreting Normal Reference Range for Macular Thickness Results

9.2.2.1.2 Ganglion Cell OU Analysis

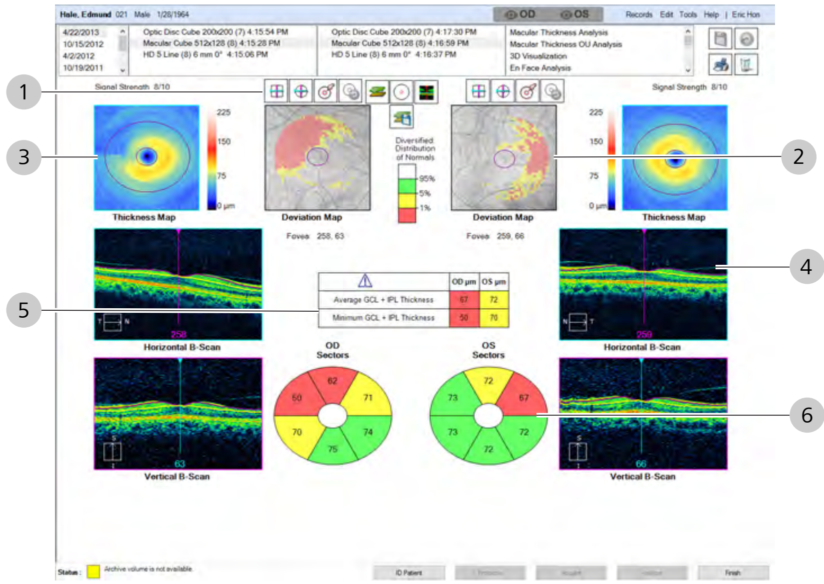
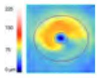
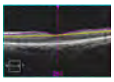
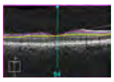
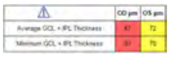


Figure 53: Ganglion Cell OU Analysis Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Snap to Center	Moves the slice navigators to the center of the 6x6 mm square.
		Snap to ETDRS Grid center	Moves the slice navigators to the ETDRS Grid center position.
		Center ETDRS Grid	Moves the ETDRS Grid to center on the slice navigator position.
		Reset ETDRS Grid	Moves the ETDRS Grid back to the CIRRUS-calculated fovea center location.
		Show / Hide Layers	Hides or shows the colored lines indicating the ILM and RPE layers.
		Show / Hide Circles	Toggles visibility of the **Fovea Fields**.
		Show / Hide High-Resolution Images	Displays the high-resolution scans or standard-resolution scans. **NOTE! The ETDRS Grid does not change position when the High–Resolution image is displayed.**
		Advanced Export	Exports maps of the ILM layer to RPE layer thickness values.
2		Deviation Map	Compares GCL + IPL thickness to normative data. ■ red indicates thinner than all but 1% of normals ■ yellow indicates thinner than all but 5% of normals

#	Symbol	Name	Explanation
3		Thickness Map	Shows thickness measurements of the GCL + IPL in the 6 mm x 6 mm cube with an elliptical annulus centered about the fovea. Signal strength indicates scan quality level.
4		Horizontal B-Scan	Slice through cube: ■ purple line indicates the inner boundary of the ganglion cell layer (outer boundary of the retinal nerve fiber layer) ■ yellow line indicates the outer boundary of the retinal nerve fiber layer
		Vertical B-Scan	
5		Normal Reference Range Comparison	Shows overall average and minimum GCL+IPL layer thickness with color-coded comparison to the normal reference range for the patient's age.
6		ETDRS Grid	Shows overall average macular thickness in nine sectors. ■ central circle (radius = 500 micrometers; diameter =1 mm) ■ superior sector ■ nasal sector ■ temporal sectors ■ inferior sectors. Color coding shows how this patient's scan compares to the normal reference range for their age. See: Macular Thickness Parameters [▷ 456]).

9.2.2.1.3 Analyzing Ganglion Cell OU

To analyze the ganglion cell layer for both eyes:

Prerequisite

☑ The patient has at least one macular cube scan: (Acquire a Macular Cube Scan [▷ 150]).

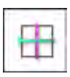
☑ You are logged in (review station or instrument): Login [▷ 123].

Action

1. Select the patient and click **Analyze**.
2. Select a **Macular Cube** scan and select **Ganglion Cell OU Analysis**.
3. To reposition the center of the thickness map on the fovea, click and drag the circles to a different location on the thickness map.

4. To export the all images, click **Export**.

5. To show or hide the layer indicators, click **Show/Hide Layers**.

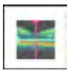


6. To set the navigators to the center of the image, click **Center**.

7. To center the navigators on the middle of te ETDRS grid, click **Center**.
   ⇨ The slice navigation lines move to the center of the grid.

8. To rest the ETDRS grid to its original position, click **Reset Grid**.

9. To center the ETDRS grid onto the slice navigator position, click **Center Grid**.



10. To show or hide the high-resolution image, click **HD**.
    ⇨ The image toggles between the original resolution and high resolution versions.
11. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▸ 369]).
12. To view a full-screen image, double-click on the image.
13. To print, save, or export a report, see: Creating a Report [▸ 384].
14. If you want to use a different scan, manually select it (Manually Select a Scan [▸ 367]).

9.2.2.2 Ganglion Cell Guided Progression

NOTE

Guided Progression is one component of a comprehensive clinical assessment of glaucoma progression.

▶ **Guided Progression** shows changes in GCL/IPL thickness, not the progression of glaucoma.

▶ Have a qualified professional evaluate all clinical factors for diagnosis.

This analysis helps you follow changes to the GCL/IPL thickness. An in-house study determined the normal reference ranges per age (see: Macular Algorithms [▸ 476]).

This analysis compares 3-8 exams for changes to thickness measurements over time and determines whether significant changes have occurred.

This analysis is available for the following scans:

- Macular Cube 512 x 128
- Macular Cube 200 x 200

9.2.2.2.1 Interpreting Ganglion Cell Guided Progression Results

NOTE

Normal reference ranges represent the general population.

However, when interpreting data, keep the following study limitations in mind (especially for 1% and 99%):

▶ Subjects:

   ⇨ Ages 18-84

⇨ Refractive errors −12.00 D to +8.00 D

- Age ranges with fewest subjects:

⇨ 3 subjects over 80.

⇨ 28 subjects aged (70-79).

NOTE

Normal reference range limits are adjust by age groups only (unless noted).

Other differences might occur for some measurements; however, the normal reference range does not adjust for these factors, such as:

- Image Signal Strength
- Ethnicity
- Axial Length
- Refraction
- Optic Disc Area

Tip: Choose a baseline pair of images from a period when treatment stabilized changes.

Guided Progression allows you to analyze information from 3 to 8 exams. **Guided Progression** 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.

Guided Progression analysis shows how a patient's measurements change over time by comparing images acquired in a series of visits and the normal reference range for their age. It works by establishing a *baseline* for the patient using images from two visits, then displays the difference between the baseline and each subsequent image. Guided progression is available for:

- Macular Cube 512 x 128
- Macular Cube 200 x 200

Ganglion Cell: shows how the ganglion cell layer thickness changed over time.

ONH and RNFL: shows how the RNFL thickness and other ONH parameters changed over time.

- Optic Disc Cube 200 x 200

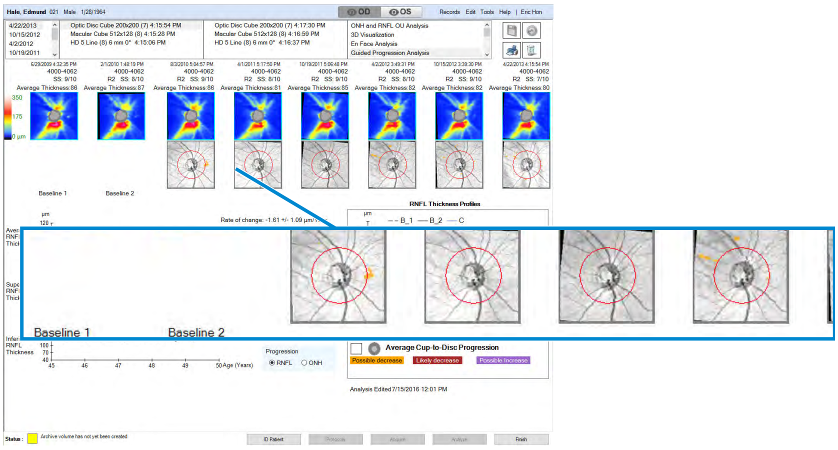
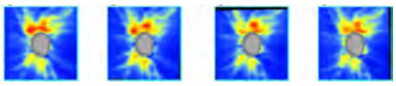
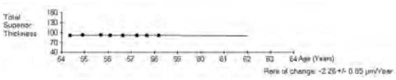
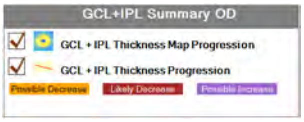
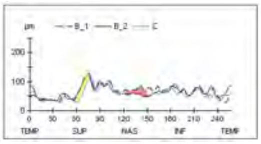


Figure 54: Guided Progression Example

Detecting Changes

CIRRUS™ HD-OCT detects changes from the patient's baseline to display progression. Using a good baseline pair established (with more similar images) is important for a more accurate depiction of progression.

Change Pesentation	Description		Interpretation
Thickness Maps 	Shows how each image compares to the normal reference range for the patient's age.	Red and Yellow	Thicker areas
		Blue and Green	Thinner areas
Deviation Maps 	Shows changes from their own baseline and areas that are . Shows how each image compares to the normal reference range for the patient's age.	Yellow	Thinner than 95% of people the same age.
		Red	Thinner than 99% of people the same age.
Graphs 	Charts measurements of overall change.		
Data Tables	Lists measurement summaries.		

Change Pesentation	Description		Interpretation
	Summary	✓	indicates progressive decrease detected and confirmed by consecutive follow-up exams.
		✓	indicates progressive decrease detected once.
		✓	indicates possible improvements.
	Graphs		

Checkmarks in the summary indicate significant changes. A number of measurements must show statistically-significant changes:

- **Baseline + one** progression image - at least two measurements
- **Baseline + two or more** progression images - at least three measurements

Ensuring Accurate Results

Guided progression analysis works best when:

- **Good registration**: images are registered properly (see: About Macular Scan Registration [247]).
- **Strong signal**: signal strength is 7 or higher for each image.
- **Good baseline**: baseline images with fewest detected changes

9.2.2.2.1.1 Interpreting Ganglion Cell Progression

NOTE

Features described in this section are licensed separately and may not be available in all markets.

▶ For information about feature availability in your market and obtaining a license:

⇨ in the U.S.A, call 1-877-486-7473.

⇨ outside the U.S.A , contact your local ZEISS distributer.

CIRRUS™ HD-OCT compares the patient's gathered for their age. Different colors indicate the normal distribution percentiles. For more about normative data was obtained, refer to: Ganglion Cell Parameters [457].

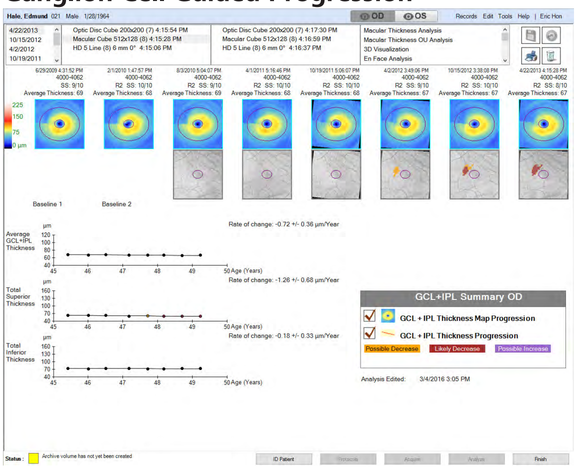
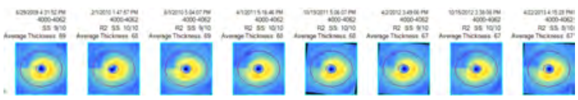
Color	Indication	Measurement Comparison	Interpretation
	Above normal	Thickest 5%	Thicker than 95% of the database sample.

Color	Indication	Measurement Comparison	Interpretation
	Normal	Middle 90%	Middle 90%.
	Suspected below normal	Thinnest 5%	Thinner than 95% of the database sample.
	Below normal limit	Thinnest 1%	Thinner than 99% of the database sample.

Table 64: Color Key for Thickness Maps

Color	Indication	Measurement Comparison	Interpretation
✓	Possible increase	Thickest 5%	Thicker than 95% of the database sample.
✓	Likely decrease	Thinnest 1%	Thinner than 99% of the database sample.
✓	Possible decrease	Thinnest 5%	Thinner than 95% of the database sample.

Table 65: Color Key for Graphs and Summary

Analysis	Interpretation
Ganglion Cell Guided Progression 	Analysis shows 8 images of the same patient, same eye taken over several years.
Thickness maps 	R2 registration was successful for all images. Signal strength is good for each image (6 or higher). Scans look similar.
Deviation Maps 	Deviation maps show progression over time starting with the 4th image. **Deviation maps -** (yellow) Areas began to thin with a patch thinner than 95%. (red) By the last image, a larger path is thinner than 99%.

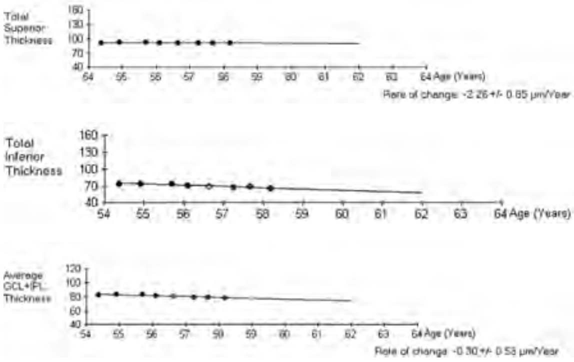
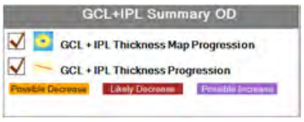
Analysis	Interpretation
Graph Series 	Also shows possible decrease starting with the 4th image progressing to likely decrease. ⊕ Extrapolate Progression: extends the progression line showing expected future progression. ● *possible decrease* ● *likely decrease*
Summary 	✓ Indicates *likely decrease* for both; detected statistically-significant change in measurements.

Table 66: Ganglion Cell Guided Progression Interpretation Examples

⊕ *Indicates optional features; license may be required.*

9.2.2.2.2 Ganglion Cell Guided Progression Analysis Overview

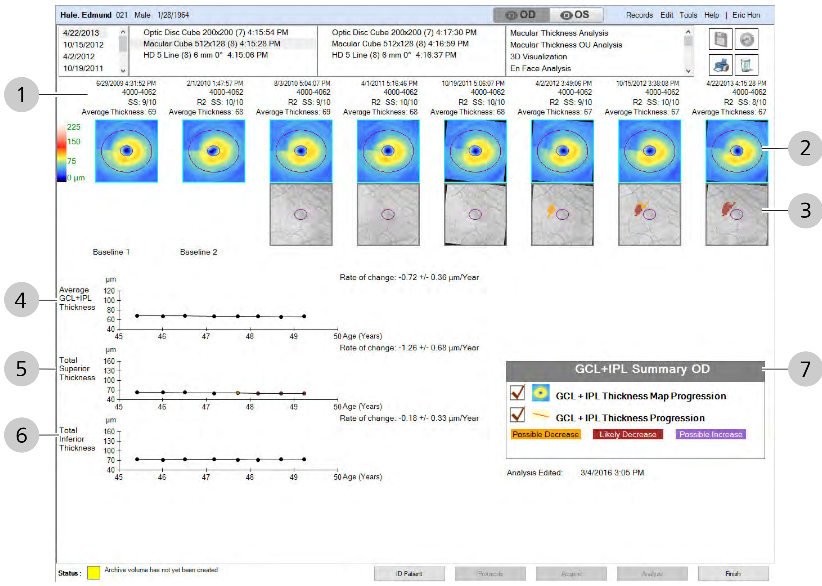
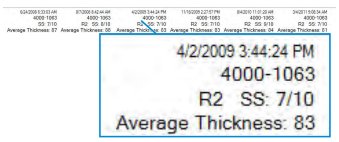
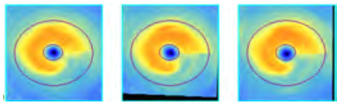
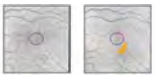
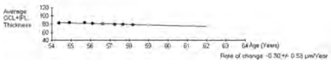
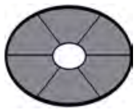
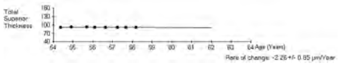
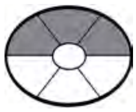
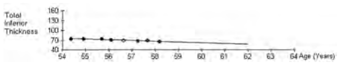
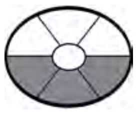
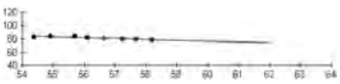
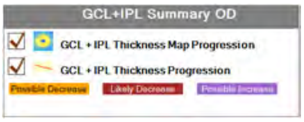


Figure 55: Ganglion Cell Guided Progression Analysis Overview

#	Symbol	Name	Explanation
1	**Scan Information** 	Top Row:	Date & Time of acquisition.
		Row 2:	Serial Number of the instrument that acquired the image.
		Row 3:	Registration type and signal strength.
		Bottom row:	Average thickness.

#	Symbol	Name	Explanation
2		Ganglion Cell Thickness Maps	Shows a series of thickness maps over time.
3	**Deviation Map** 	**Progression:** The first two scans (blank images) establish the baseline. Each subsequent scan shows deviation from the normal reference range (changes over time) as compared to normal patients of the same age.	
			red areas indicate thinner than 99%.
			yellow areas indicate thinner than 95%.
			purple areas indicate thicker than normal.
		Measurement Area	The red circle on the fundus image represents the measurement area for the charts and graphs.
4		Average Thickness Graph	Graphs the average of **all 6 sectors** of the annulus for each scan showing change over time. 
5		Superior Thickness Graph	Graphs the total of the **top 3 sectors** of the annulus for each scan showing change over time. 
6		Inferior Thickness Graph	Graphs the total of the **bottom 3 sectors** of the annulus for each scan showing change over time. 
		⊕ Extrapolate Progression	extends the progression line showing expected future progression.

#	Symbol	Name	Explanation
7		GCL +IPL Thickness Map Progression *(best for focal change)* GCL +IPL Thickness Progression *(best for diffuse change)*	
		Unchecked indicates no loss or increase detected.	
		✓	red indicates *Likely Decrease* (progressive loss detected once and confirmed by consecutive follow–up exams).
		✓	yellow indicates *Possible Decrease* (progressive loss detected once.)
		✓	purple indicates *Possible Increase*.

9.2.2.2.3 Analyzing Ganglion Cell Change Progression

You can customize **Guided Progression** reports. For customization information, see: Configuring Guided Progression Reports [▹ 116].

To analyze ganglion cell progression:

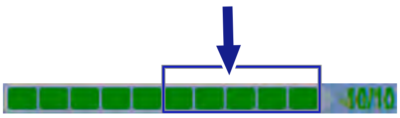
Prerequisite

☑ You are logged in (review station or instrument): Login [▹ 123].

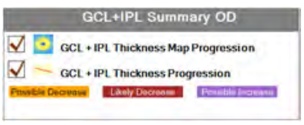
☑ The patient has at least one macular cube scan: (Acquire a Macular Cube Scan [▹ 150]).

Action

1. Select the patient and click **Analyze**.
2. Select a **Macular Cube** scan and select **Guided Progression.**
   ⇨ The analysis opens.



3. Ensure that the signal strength is 7 or higher for each image.
4. Ensure scans are registered properly; if needed, manually register the scans (see: Manually Register AngioPlex Images [▹ 317]).
5. To use a different scan, manually select it (Manually Select a Scan [▹ 367]).
6. Check the deviation progression series:
   ⇨ Evaluate the rate of decrease, locations of the detected decrease, age of the patient, stage of the disease, and other clinical factors to make clinical decisions.
   ⇨ Correlate these results with other clinical tests (perimetry, IOP) to confirm whether RNFL loss is clinically significant.
7. Check the **GCL+IPL Summary**.



8. If the **GCL+IPL Summary** indicates **Possible decrease**, consider recommending additional follow–up visits to confirm change.
9. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▹ 369]).
10. To view a full-screen image, double-click on the image.

11. To print, save, or export a report, see: Creating a Report [▷ 384].

9.2.3 ONH Analysis

9.2.3.1 Interpreting ONH Results

NOTE

Normal reference ranges represent the general population. However, when interpreting data, keep the following study limitations in mind (especially for 1% and 99%):

- Subjects:
  - ⇨ Ages 18-84
  - ⇨ Refractive errors −12.00 D to +8.00 D
- Age ranges with fewest subjects:
  - ⇨ 3 subjects over 80.
  - ⇨ 28 subjects aged (70-79).

NOTE

normal reference range limits are adjust by age groups only (unless noted).

Other differences might occur for some measurements; however, the normal reference range does not adjust for these factors, such as:

- Image Signal Strength
- Ethnicity
- Axial Length
- Refraction
- Optic Disc Area

9.2.3.1.1 Interpreting ONH Results

CIRRUS™ HD-OCT compares the patient's ONH parameters to the normative data gathered for their age. Different colors indicate the normal distribution percentiles. For more about normative data was obtained, refer to: ONH Parameters [▷ 462].

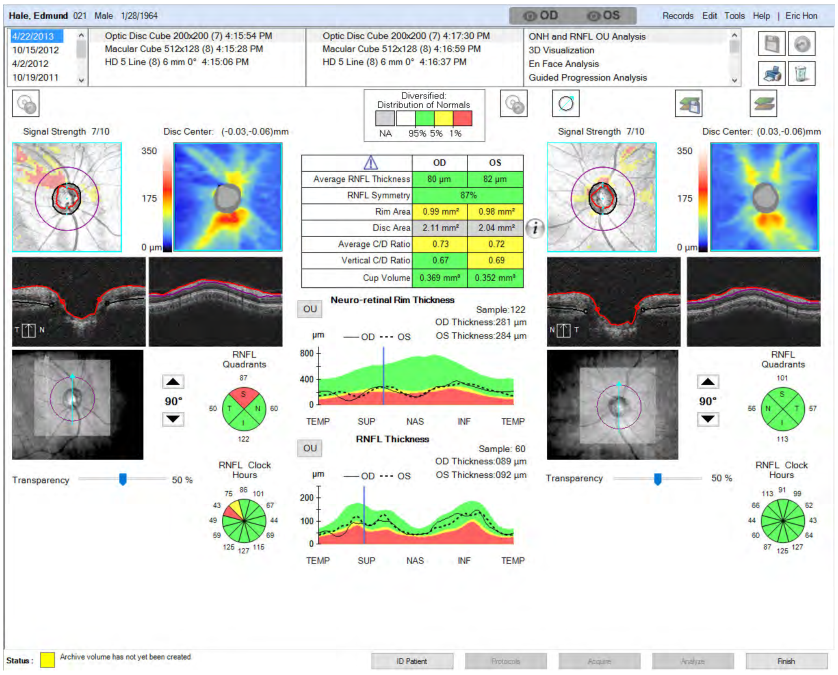
CIRRUS™ HD-OCT compares the patient's disc area and age to the general population "normal" reference range.

Rim Area and Neuroretinal Rim Thickness			
Color	**Indication**	**Measurement Comparison**	**Interpretation**
	No indicator	No comparison	Possible reasons include: ■ disc area is larger than 2.5 mm^2 ■ disc area is smaller than 1.33 mm^2 ■ average cup-to-disc ratio is below 0.25 ■ vertical cup-to-disc ratio is below 0.25 ■ not licensed for the ONH Normative Database (see: About Licenses [61]).
	Suspected thick	Largest 5%	Larger than 95% of the database sample.
	Normal	Middle 90%	Middle 90%.
	Suspected thin	Smallest 5%	Smaller than 95% of the database sample.
	Thin	Smallest 1%	Smaller than 99% of the database sample.

Table 67: Color Key for ONH Comparison (Rim Area and Neuroretinal Rim Thickess) to Normative Database

Average Cup-to-Disc Ratio and Vertical Cup-to-Disc Ratio			
Color	**Indication**	**Measurement Comparison**	**Interpretation**
	No indicator	No comparison	Possible reasons include: ■ disc area is larger than 2.5 mm^2 ■ disc area is smaller than 1.33 mm^2 ■ average cup-to-disc ratio is below 0.25 ■ vertical cup-to-disc ratio is below 0.25 ■ not licensed for the ONH Normative Database (see: About Licenses [61]).
	Suspected small	Smallest 5%	Smallest than 95% of the database sample.
	Normal	Middle 90%	Middle 90%.
	Suspected large	Largest 5%	Larger than 95% of the database sample.
	Large	Largest 1%	Largest than 99% of the database sample.

Table 68: Color Key for ONH Comparison (Average & Vertical Cup-to-Disc Ratio) to Normative Database



9.2.3.1.2 Interpreting RNFL Results

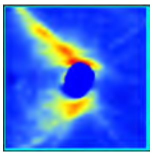
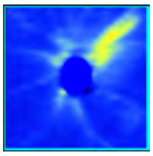
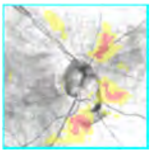
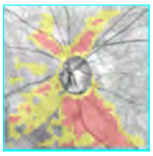
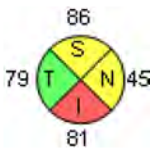
CIRRUS™ HD-OCT compares the patient's RNFL Thickness to the normative data gathered for their age. For more about normative data was obtained, refer to: ONH Parameters [462].

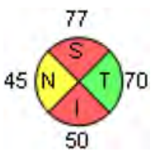
Color	Indication	Measurement Comparison	Interpretation
	Suspected thick	Thickest 5%	Thicker than 95% of the database sample.
	Normal	Middle 90%	Middle 90%.
	Suspected thin	Thinnest 5%	Thinner than 95% of the database sample.
	Thin	Thinnest 1%	Thinner than 99% of the database sample.

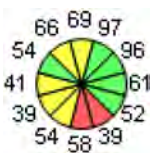
Table 69: Color Key for RNFL Normative Database

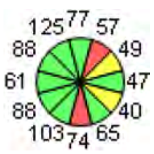
Shape	Indication
	Quadrants (Superior, Nasal, Temporal, Inferior)
	Clock Hours

Table 70: Shape Key for RNFL Normative Database

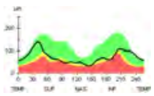
<table>
<tr><th>Name</th><th>Examples</th><th>Interpretation</th></tr>
<tr><td>Thickness Map</td><td>


</td><td>Two examples of thickness maps; interpreted as:
blue and green = thinner areas
yellow and red = thicker areas
solid blue = optic disc</td></tr>
<tr><td>Deviation from Normal Map</td><td>


</td><td>Two examples that show:
Red and yellow areas shows where this scan has areas that are thinner than normal. (Normal and thicker areas are omitted for image clarity.)
Thinner regions do not necessary indicate pathological loss of RNFL. Red and yellow areas can also appear for:
Strongly myopic or hyperopic eyes (which may have a different distribution of measured RNFL thickness values)
Split-bundle anatomy
A very tilted RNFL bundle</td></tr>
<tr><td rowspan="2">Quadrant Average (more detailed comparison)</td><td>


</td><td>Superior quadrant average is 86 µm and Suspected Thin
Nasal quadrant average is 45 µm and Suspected Thin
Inferior quadrant average is 81 µm and Thin
Temporal quadrant average is 79 µm and Normal</td></tr>
<tr><td>


</td><td>Superior quadrant average is 77 µm and Thin
Temporal quadrant average is 70 µm and Normal
Inferior quadrant average is 50 µm and Thin
Nasal quadrant average is 45 µm and Suspected Thin</td></tr>
<tr><td>Clock Hour Average (most detailed comparison)</td><td>




</td><td>Shows the measurement for each clock hour and indicates whether the measurement is Normal (green), Suspected Thin (yellow) or Thin (red).</td></tr>
</table>

Name	Examples	Interpretation
RNFL Table		Symmetry shows the correlation coefficient (converted to a percentage) that results from comparing the OD profile (256 points) with the OS profile (256 points). When the symmetry is close to 100%, the two eyes have similar profiles. Symmetry value decreases with the dissimilarity between the two eyes. **NOTE! Symmetry can (rarely) be less than zero if the two profiles are very different.**
TSNIT Thickness Chart		Displays thickness at each A-scan location along the selected circle (which is automatically calculated, but you can select a different position to calculate).

9.2.3.2 Analyze ONH/RNFL OU

ONH/RNFL OU Analysis is only available for **Optic Disc Cube** 200 x 200 scans.

You can also view and navigate through the slices of any cube scan as a three-dimensional image (see: 3D Visualization Analysis [▷ 289]).

9.2.3.2.1 About Advanced Export

Advanced Export produces two types of plain text files: DAT and TXT.

DAT Files

DAT files contain comma–delimited values that applications such as Excel or Matlab can read.

There is a DAT file for each A-scan thickness with rows (fast B-scans) and columns (slow B-scans). The first row is top fast B-scan; the first column is the left slow B-scan.

TXT Files

These files save patient information, exam information, and values (temporal to superior, superior to nasal, nasal to inferior, and inferior to temporal). Values are:

- Neuro–retinal rim thickness values at 180 points (2° each)
- RNFL thickness values at 256 points (1.41° each)

9.2.3.2.2 ONH/RNFL OU Analysis

You can customize the **ONH and RNFL Thickness** report. For customization information, see: Configuring ONH Reports [▸ 115].

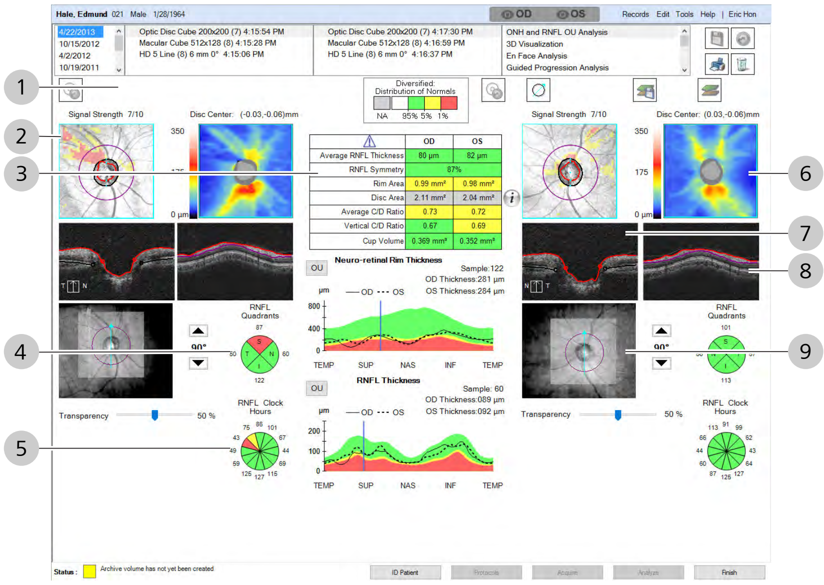
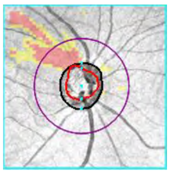
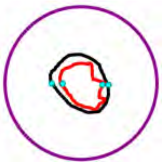
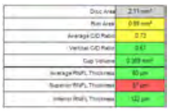
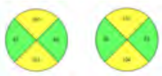
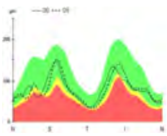
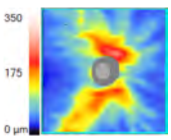
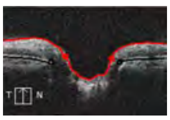
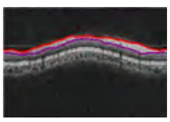


Figure 56: ONH and RNFL Thickness Analysis Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Center ETDRS Grid	Moves the ETDRS Grid to center on the slice navigator position.
		Show/Hide Radial Control	Hides or shows the radial indicator that shows the rotation angle selected.
		Advanced Export	Exports maps of the ILM layer to RPE layer thickness values.
		Show / Hide Layers	Hides or shows the red and black layer lines in the B-scan that correspond to the **Optic Disc** and **Optic Cup** outlines.
		Overlay Transparency	Sets the overlay transparency level.

#	Symbol	Name	Explanation
2		**Deviation Map**	
		Purple (outer) circle	RNFL calculation circle. **Interaction:** Move the RNFL calculation circle to recalculate: ■ **Deviation Map** ■ **Optic Disc** measurements
		Black (middle) Circle	Optic Disc Outline
		Red (inner) Circle	Optic Cup Outline
		Rotation Indicators	Cyan dots on the optic disc and optic dup outlines indicate the direction of rotation. When you change the angle of the ONH spoke, the circles move to correspond to the new angle selected.
3		Normal Reference Range Comparison	Displays measurements with color-coded comparison to the normal reference range for the patient's age.
4		Quadrant Averages	Shows overall average RNFL thickness for each eye in four quadrants (Superior, Nasal, Temporal, Inferior)
		RNFL Thickness Chart	Displays thickness profiles. Right-click toggles the display orientation: ■ TSNIT ■ NSTIN
5		RNFL Clock Hours	Shows the measurement for each clock hour and indicates whether the measurement is Normal (green), Suspected Thin (yellow) or Thin (red).
6		RNFL Thickness Map	RNFL thickness map.
7		ONH B-Scan	Slice through cube front
8		RNFL B-scan	Slice through cube front

#	Symbol	Name	Explanation
9		Angle Indicator	Shows the angle of the ONH spoke.
		Rotation Tool	Changes the angle of the ONH spoke.

9.2.3.2.3 Analyzing ONH and RNFL

The **ONH and RNFL OU Analysis** uses two kinds of thickness measurements:

- RNFL grid

  When you move the RNFL grid, the thickness maps, deviation maps, and ONH calculations update automatically.

- Super-pixels

  A total of 50 x 50 (2500) super-pixels are analyzed (optic disc excluded).

RNFL Thickness Maps report thickness by showing blue or green for thinner areas and yellow or red for thicker areas (the optic disc appears solid blue).

Deviation Maps compare the normal reference range for the patient's age and show yellow and red areas for that are thinner than 95% and 99% of the (age-adjusted) normal population, respectively.

Interpretation Considerations

For some patients, deviation maps can show decrease due to reasons other than pathology. such as:

- The patient has strongly myopic or hyperopic eyes
- The patient has split-bundle anatomy
- The patient has a tilted RNFL bundle pattern

If the patient's temporal RNFL that is very thin or absent, the maps might show thickened RNFL

- average thickness around the RNFL grid.
- a percentage of thickness symmetry between the eyes, which is the correlation coefficient (converted to a percentage) comparing the OD profile (256 points) with the OS profile (256 points).

CIRRUS™ HD-OCT compares the RNFL thickness and symmetry of the scan(s) with the normal reference range for the patient's age. For more information about how normal reference ranges were derived, refer to: Diverse Population Study [▸ 451].

To analyze ONH and RNFL OU:

Prerequisite

☑ You are logged in (review station or instrument): Login [▸ 123].

☑ The patient has at least one optic disc cube scan (Acquire an Optic Disc Cube Scan [▸ 153]).

Action

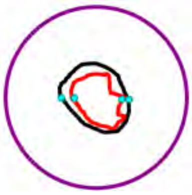
1. Select the patient and click **Analyze**.

2. Select an **Optic Disc Cube** scan and select **ONH and RNFL OU Analysis**.

3. To center the ETDRS grid onto the slice navigator position, click **Center Grid**.

4. To show or hide the radial control over the fundus image, click **Radial**.

5. To show or hide the layer indicators, click **Show/Hide Layers**.



6. To reposition the optic disc and cup over the fovea, click and drag the circles into place.

7. To rotate the angle of the ONH spoke, click **Up** or **Down**.

8. To export the all images, click **Export**.
9. To use a different scan, manually select it (Manually Select a Scan [▸ 367]).
10. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▸ 369]).
11. To view a full-screen image, double-click on the image.
12. To print, save, or export a report, see: Creating a Report [▸ 384].

9.2.3.3 ONH Guided Progression

This analysis helps you follow changes to the optic nerve head. In-house studies determined the normal reference ranges per age (see: ONH Algorithms [▸ 488]).

This analysis compares 3-8 exams for changes to thickness measurements over time and determines whether significant changes have occurred.

This analysis is available for the following scans:

- Optic Disc Cube 200 x 200

9.2.3.3.1 ONH Guided Progression Analysis Overview

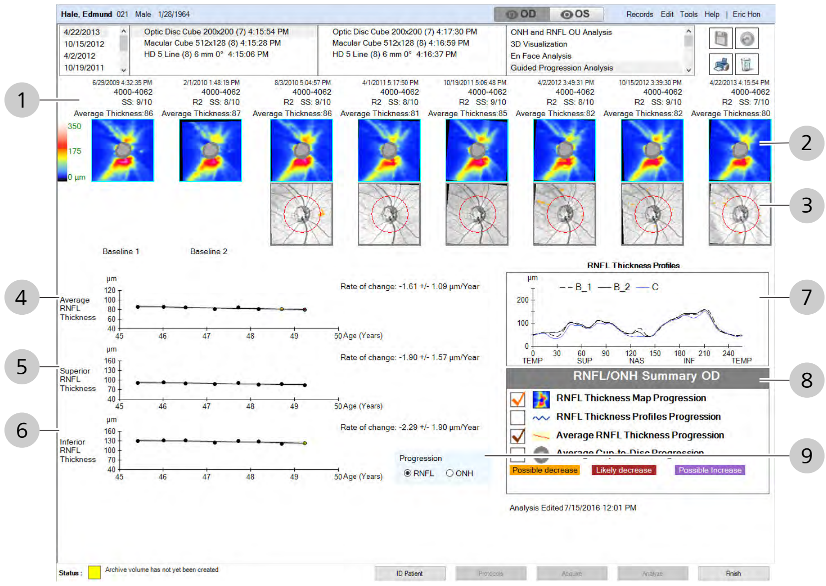
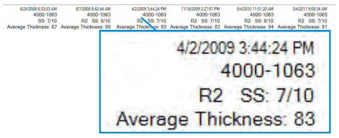
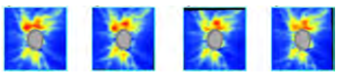
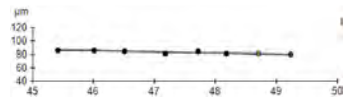
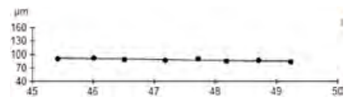
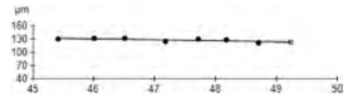
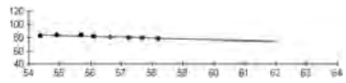
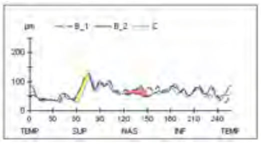
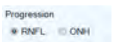


Figure 57: ONH Guided Progression Analysis Overview

#	Symbol	Name	Explanation
1	**Scan Information** 	Top Row:	Date & Time of acquisition.
		Row 2:	Serial Number of the instrument that acquired the image.
		Row 3:	Registration type and signal strength.
		Bottom row:	Average thickness.
2		RNFL Thickness Maps	Shows a series of RNFL thickness maps over time.
3	**Deviation Map** 	**Progression:** The first two scans (blank images) establish the baseline. Each subsequent scan shows deviation from the normal reference range (changes over time) as compared to normal patients of the same age.	
			red areas indicate thinner than 99%.
			yellow areas indicate thinner than 95%.
			purple areas indicate thicker than normal.
		Measurement Area	The red circle on the fundus image represents the measurement area for the charts and graphs.

#	Symbol	Name	Explanation
4		RNFL Average Thickness (Overall)	Graphs the superior quadrant average thickness trend for each exam.
5		RNFL Average Thickness (Superior)	Graphs the superior quadrant average thickness trend for each exam.
6		RNFL Average Thickness (Inferior)	Graphs the inferior quadrant average thickness trend for each exam.
		⊕ Extrapolate Progression	extends the progression line showing expected future progression.
7		RNFL Thickness Profile	Plots RNFL thickness values in the red measurement area centered on the optic disc. ■ **B1:** First baseline scan measurements. ■ **B2:** Second baseline scan measurements. ■ **C:** (Blue line) the most recent scan. The RNFL Thickness Profile identifies moderate focal thinning (at least 14 adjacent A-scans showing significant change) by comparing changes over multiple visits to test–retest variability.
			Shaded areas: red shading indicates likely decrease.
			yellow shading indicates possible decrease.
			purple shading indicates possible increase.
8		Summary	*Unchecked indicates no loss or increase detected.*
		✓	red indicates *Likely Decrease* (progressive decrease detected once and confirmed by consecutive follow–up exams).
		✓	yellow indicates *Possible Decrease* (progressive decrease detected once.)
		✓	purple indicates *Possible Increase* (improvement).
9		Progression Setting	Selects either: ■ ONH: graphs the Average Cup–to–Disc Ratio per patient's age ■ RNFL: graphs the RNFL thickness per patient's age

⊕ *Indicates optional features; license may be required.*

9.2.3.3.2 Analyzing RNFL Change Progression

You can customize **Guided Progression** reports. For customization information, see: Configuring Guided Progression Reports [▷ 116].

To analyze RNFL progression:

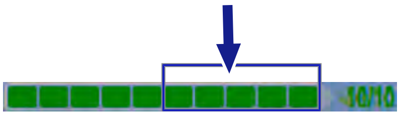
Prerequisite

☑ You are logged in (review station or instrument): Login [▷ 123].

☑ The patient has at least one optic disc cube scan (Acquire an Optic Disc Cube Scan [▷ 153]).

Action

1. Select the patient and click **Analyze**.
2. Select an **Optic Disc Cube** scan and select **Guided Progression Analysis**.



3. Ensure that the signal strength is 7 or higher for each image.
4. Ensure scans are registered properly; if needed, manually register the scans (see: Manually Register AngioPlex Images [▷ 317]).
5. To use a different scan, manually select it (Manually Select a Scan [▷ 367]).

6. To view optic nerve measurements, select **ONH**.
7. To view retinal nerve fiber layer measurements, select **RNFL**.
8. Check the baseline scans to ensure consistent results for:
   RNFL Thickness profiles
   Average RNFL Thickness graphs
   RNFL thickness maps
9. Check the deviation progression series:
   ⇨ Evaluate the rate of decrease, locations of the detected decrease, age of the patient, stage of the disease, and other clinical factors to make clinical decisions.
   ⇨ Correlate these results with other clinical tests (perimetry, IOP) to confirm that RNFL loss is clinically significant.
10. Check the **Summary**.

11. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▷ 369]).
12. To view a full-screen image, double-click on the image.
13. To print, save, or export a report, see: Creating a Report [▷ 384].

9.2.4 Advanced Visualization Analysis

Advanced Visualization Analysis is available for the following scans:

- Macular Cube 512x128
- Macular Cube 200x200
- Optic Disc Cube 200 x 200

9.2.4.1 Advanced Visualization Analysis

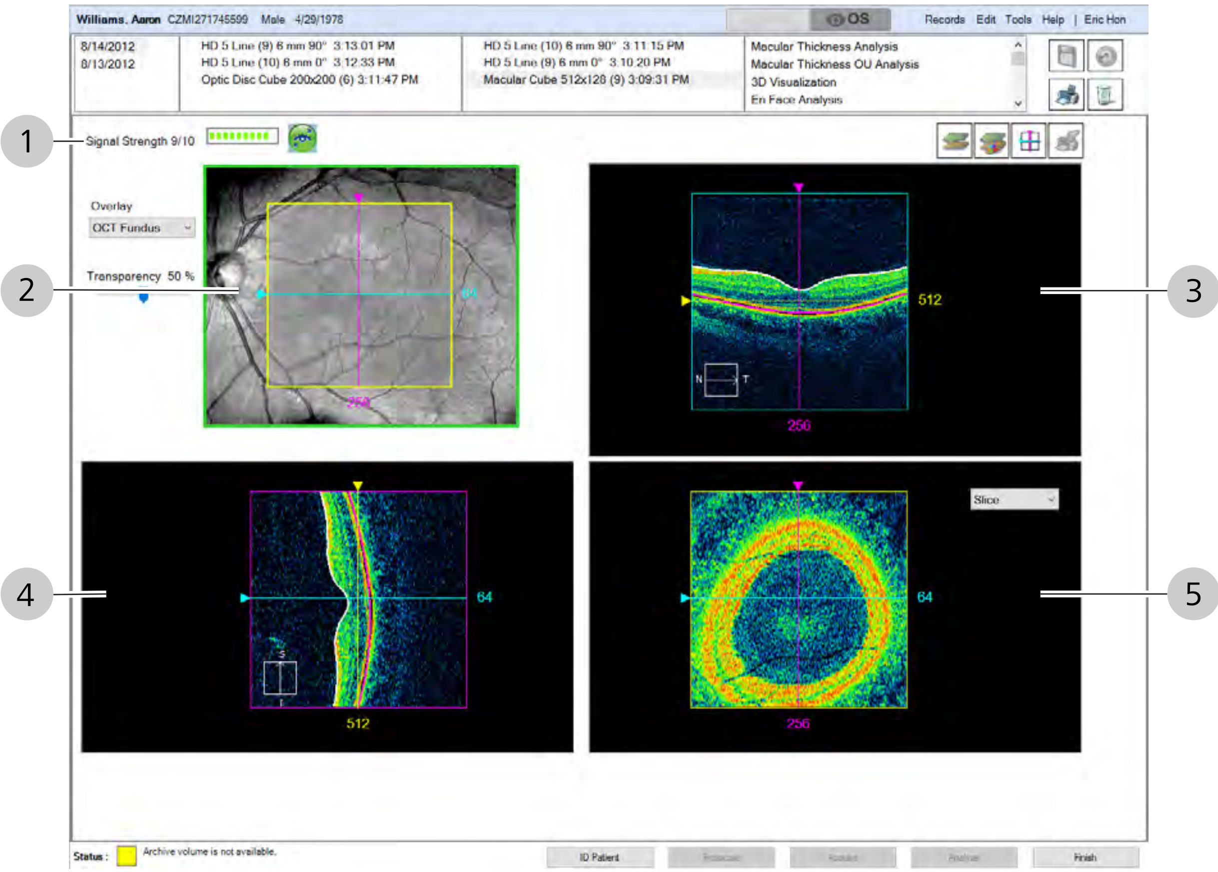
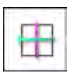
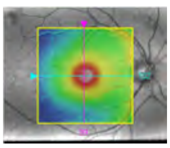
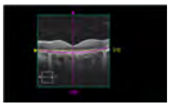
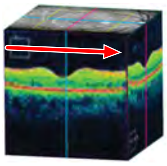
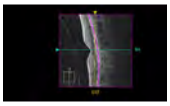
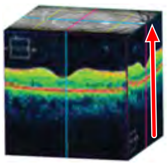
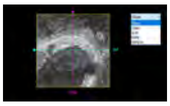
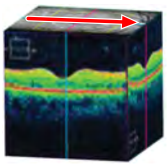


Figure 58: Advanced Visualization Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Signal Strength	Indicates scan quality level; more green indicates a higher quality scan.
		FastTrac	Indicates that the operator used FastTrac when acquiring the image.
		Show / Hide Layers	Hides or shows the colored lines indicating the ILM and RPE layers.
		Snap to Center	Moves the slice navigators to the center of the 6x6 mm square.
		Tag for Print	Tags particular image(s) for printing a report.
2		Fundus Image	Fundus image showing scan area and cube navigation lines.
		Select Overlay	Selects which overlay to display over the fundus image.

#	Symbol	Name	Explanation
		Overlay Transparency	Sets the overlay transparency level.
3	 	Front plane navigator	Shows cross–section of the cube front.
4	 	Side plane navigator	Shows cross–section of the cube side.
5	 	Top Plane Navigator	Shows cross–section of the cube top. ■ None (default) ■ Slice ■ OCT Fundus ■ Slab ■ ILM – RPE ■ ILM – RPEfit ■ RPE – RPEfit **Interaction:** When you select Slab, the dashed lines depict slab thickness in all three planes. ■ To adjust the slab, drag the posterior line of the front or side plane by its handle. ■ To reposition the slab, drag the anterior line handle and move both lines of the slab together.The image shows an average signal intensity value for each A-scan location through the depth of the slab. For ILM, RPE, and RPEfit (variations of the slab), you view the slab thickness relative to the layer.

9.2.4.2 Analyzing Advanced Visualization

Action

1. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▷ 369]).
2. To view a full-screen image, double-click on the image.
3. To print, save, or export a report, see: Creating a Report [▷ 384].

9.2.5 3D Visualization Analysis

3D Visualization Analysis is available for the following scans:

- Macular Cube 512x128
- Macular Cube 200x200
- Optic Disc Cube 200 x 200

9.2.5.1 3D Visualization Analysis

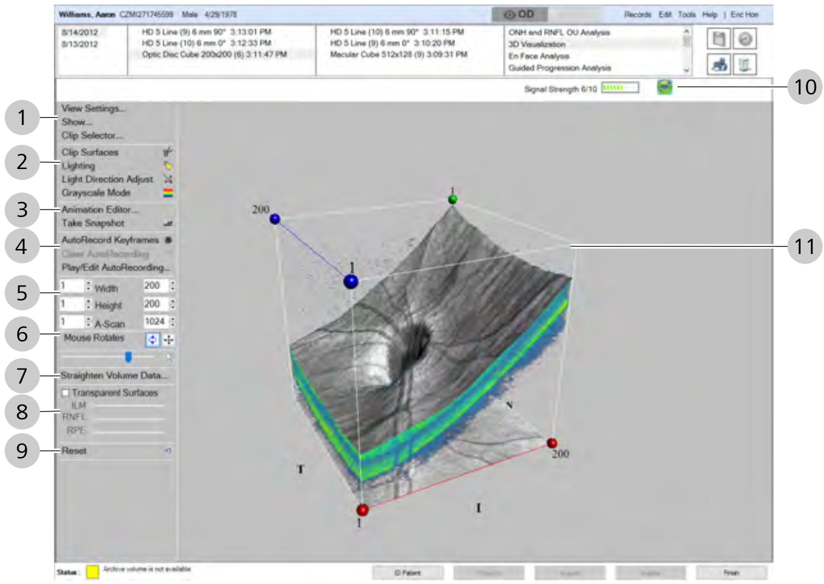
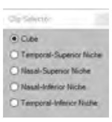
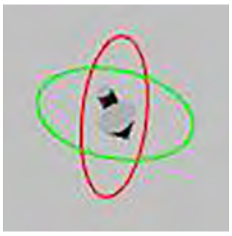


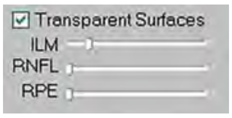
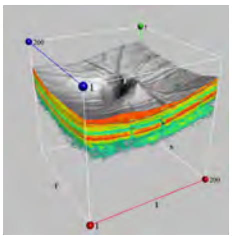
Figure 59: Optic Disc Cube 3D Visualization Overview

<table>
<tr><th>Pos.</th><th>Symbol</th><th>Name</th><th>Explanation</th></tr>
<tr><td rowspan="12">1</td><td rowspan="7">View Settings

</td><td>Brightness</td><td>increases or reduces image brightness.</td></tr>
<tr><td>Contrast</td><td>increases or reduces image contrast.</td></tr>
<tr><td>Threshold</td><td>Threshold removes darker tissue in the image.</td></tr>
<tr><td>Transparency</td><td>■ Use Same Transparency for all Pixels equalizes transparency allowing you to see through darker tissue better.
■ Transparency reduces or increases the transparency for all pixels by the same percentage</td></tr>
<tr><td>Intensity</td><td>■ Apply intensity filter adjusts intensity settings.
■ Intensity Value sets the grayscale intensity range.
■ Intensity Range limits the intensity range.</td></tr>
<tr><td>Lighting</td><td>■ Lighting changes the external light source (decreases the internal light of the cube).
■ Surface Light Weight changes the intensity of light on the surface of the image.
■ Gradient Step Size</td></tr>
<tr><td>Save / Apply</td><td>■ Save As Global saves your settings for all subsequent exams.
■ Apply Global restores previous global settings.
■ Apply Defaults restores the default settings.</td></tr>
<tr><td rowspan="5">Show Settings

</td><td>Fundus</td><td>check to include the top / bottom fundus images.</td></tr>
<tr><td>Resolution</td><td>shows images in normal or high resolution.</td></tr>
<tr><td>Surface</td><td>check to include surface(s)</td></tr>
<tr><td>Volume</td><td>check to include volume(s)</td></tr>
<tr><td>Box</td><td>check to show a box around the cube.</td></tr>
<tr><td></td><td>
</td><td>Clip Selector</td><td>selects the whole cube or a particular area of the cube to view</td></tr>
</table>

Pos.	Symbol	Name	Explanation
2		Clip Surfaces	selects which plane of tissue to clip or cut away.
		Lighting	enables exterior lighting.
		Light Direction Adjust	adjusts the light direction.
		Grayscale Mode	shows color or grayscale image.
3		Animation Editor	■ **Timeline** selects a particular point in the animation. ■ **Save snapshot** defines the length of animation. ■  plays or pauses playback. ■  stops playback. ■ **Save** saves the animation in CIRRUS™ HD-OCT-specific format. ■ **Load** plays a previously-saved animation. ■ **Save as Movie** saves an animation in a standard movie format. ■ **Close** exits the animation editor.
4		AutoRecord	■ **AutoRecord Keyframes** starts recording snapshots automatically at specific intervals ■ **Stop AutoRecord** finishes recording the animation ■ **Clear AutoRecording** starts a new animation. ■ **PlayEdit AutoRecording** play backs, allows you to edit, and saves the recording. ■ **Close** exits AutoRecord.

Pos.	Symbol	Name	Explanation
5		A-Scan Adjustments	■ **Width** manually adjusts the red sphere position. ■ **Height** manually adjusts the blue sphere position. ■ **A-Scan** manually adjusts the green sphere position.
6		Mouse Rotates	mouse movement rotates the image.
		Mouse Translates	mouse movement translates the image.
		Zoom	zooms in or out.
7		Straighten Volume Data	■ **Auto Straighten** automatically corrects the image tilt. ■ **Reset to Zero** resets corrections ■ **Units** sets **Degrees** or **Radians**. **Straighten X** straightens the image along the X axis. ■ **Straighten Y** straightens the image along the Y axis.
8		Transparent Surfaces	Check the view individual layers as transparent surfaces and adjusts transparency level. **NOTE! Transparent surfaces have lower resolution.**
9		Reset	**Reset** returns the image to its default settings.
10		Signal Strength	Indicates scan quality level; more green indicates a higher quality scan.
		Track	
11		3D Image	■ White lines show cube boundaries ■ Red, Green, and Blue lines show the slice planes. ■ Drag sphere along the line of the same color to change the slice.

9.2.5.2 Analyzing 3D Visualization

Action

1. Click **Analyze**.
2. Select a cube scan.
3. Select **3D Visualization**.

⇨ The 3D Visualization Analysis opens. The cube boundaries are shown with white lines. Labels indicate the Nasal (N), Superior (S), Temporal (T), and Inferior (I) sides of the cube.

4. To define the slice plane, drag the (red, green, or blue) sphere along the matching line.
5. To zoom in or out, scroll the mouse.
6. To adjust brightness, contrast, threshold and transparency, click **View Settings**.
7. To display settings, click **Show Settings > Show...**
8. To show or hide the cube boundary lines, and show or hide the view from the top or bottom of the box, click **Show Settings** and check the appropriate settings.
9. To select the whole cube or one of the four niches of the cube, select **Clip Selector** .
10. To adjust the light direction, move the red and green spheres left to right.
11. To toggle between color and grayscale, click **Grayscale Mode**.
12. To save a recorded animation, click **Save** or **Save as Movie.**
13. To close animation, click **Close**.
14. To record a movie in AVI format, click **Record**, make edits that you want to record, and click **Record** again.
15. To play back a movie, click **Play**, navigate to the folder with the movie file and click **Open**.
16. To start recording, click **AutoRecord Keyframes**.
17. To finish recording the animation, click **Stop AutoRecord**.
18. To play back, edit, and save, click **Play/Edit AutoRecording**.
19. To start a new animation, click **Clear AutoRecording** .
20. Click **Close**.
21. To capture an image of the screen, click **Take Snapshot**.
    ⇨ You can save the image as a BMP, JPG, or PNG file.
22. To automatically correct a tilted retina, click **Auto Straighten**.
23. To manually correct the retina angle, adjust the sliders, numbers, or arrows.
24. Check whether to view ILM, RNFL, or RPE as transparent surfaces.
    ⇨ Transparent surfaces cause the image to have lower resolution.
25. Use the sliders to adjust the transparency level.
26. To return to the original image settings, click **Reset**.

9.2.6 Combined (Macular and ONH) Analysis

9.2.6.1 Analyze Single Eye Summaries

When you select the **Single Eye Summary** analysis for any macular cube or optic disc scan, CIRRUS™ HD-OCT automatically selects the best companion scan to complete the analysis. For example, if you select a macular cube scan, the system selects the optic disc scan from the same day to include in the analysis.

If you want to select a different companion scan, select **Single Eye Summary - Manual Selection**.

Single Eye Summary Analysis is available for the following scans:

Either: ■ Macular Cube 512x128 ■ Macular Cube 200x200	+	Optic Disc Cube 200 x 200

9.2.6.1.1 Single Eye Summary Analysis

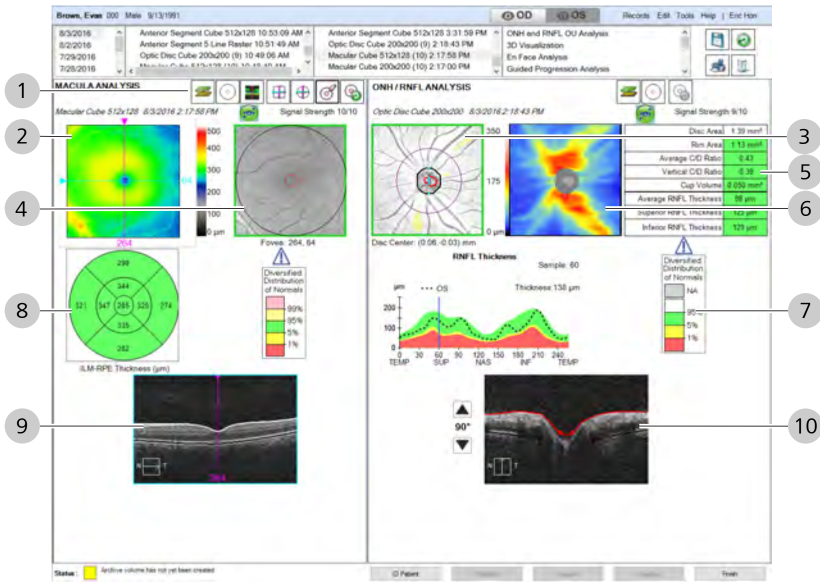
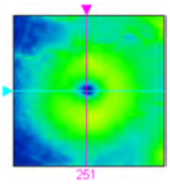
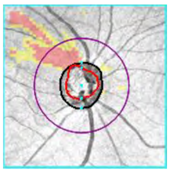
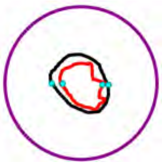
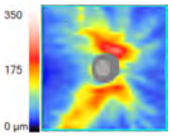
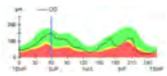
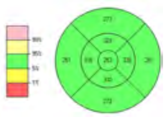
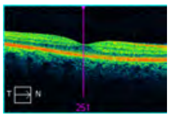
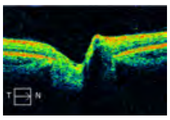


Figure 60: Single Eye Summary Analysis Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Show / Hide Circles	Toggles visibility of the **Fovea Fields**.
		Show / Hide High-Resolution Images	Displays the high-resolution scans or standard-resolution scans. **NOTE! The ETDRS Grid does not change position when the High–Resolution image is displayed.**
		Snap to Center	Moves the slice navigators to the center of the 6x6 mm square.

#	Symbol	Name	Explanation
		Snap to ETDRS Grid center	Moves the slice navigators to the ETDRS Grid center position.
		Reset ETDRS Grid	Moves the ETDRS Grid back to the CIRRUS-calculated fovea center location.
		Center ETDRS Grid	Moves the ETDRS Grid to center on the slice navigator position.
		Show / Hide Layers	Hides or shows the red and black layer lines in the B-scan that correspond to the **Optic Disc** and **Optic Cup** outlines.
		FastTrac	Indicates that the operator used FastTrac when acquiring the image.
2		Macular Thickness Map	Shows ILM-RPE thickness maps.
3		**Deviation Map**	
		Purple (outer) circle	RNFL calculation circle. **Interaction:** Move the RNFL calculation circle to recalculate: ■ **Deviation Map** ■ **Optic Disc** measurements
		Black (middle) Circle	Optic Disc Outline
		Red (inner) Circle	Optic Cup Outline
		Rotation Indicators	Cyan dots on the optic disc and optic dup outlines indicate the direction of rotation. When you change the angle of the ONH spoke, the circles move to correspond to the new angle selected.
4		Fovea Finder	Automatically identifies the fovea and shows the surface of the area for the individual thickness measurements in the grid and table.
5	Disc Area: 2.11 mm^2 Rim Area: 0.99 mm^2 Average C/D Ratio: 0.73 Vertical C/D Ratio: 0.67 Cup Volume: 0.369 mm^3 Average RNFL Thickness: 80 µm Superior RNFL Thickness: 87 µm Inferior RNFL Thickness: 122 µm	Measurements Table	Displays measurements with color-coded comparison to the normal reference range for the patient's age.

#	Symbol	Name	Explanation
6		RNFL Thickness Map	RNFL thickness map.
7		**Neuro-Retinal Rim Thickness** Graph **RNFL Thickness** Graph	Displays thickness at each A-scan location along the selected circle **Interaction:** Recalculate according to position if you: ■ Move the blue line right or left. ■ Toggle the lines to display OD, OS, or OU.
8		Macular Thickness Information	Shows overall average macular thickness in nine sectors. ■ central circle (radius = 500 micrometers; diameter =1 mm) ■ superior sectors ■ nasal sectors ■ temporal sectors ■ inferior sectors. Color coding shows how this patient's scan compares to the normal reference range for their age. See: Macular Thickness Parameters [▸ 456]).
9		Macular Cube B-Scan	Slice through cube front.
10		ONH B-Scan	Slice through cube front
		Rotation Angle	Allows you to change the angle of rotation for the optic nerve head spoke. **Interaction:** Changing rotation changes: ■ B-scan view ■ Cyan dots along the optic disc outline. ■ Cyan dots along the optic cup outline.

9.2.6.1.2 Analyzing a Single Eye Summary

Interactivity provided for this analysis includes:

- 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.

To analyze macular thickness and optic disc of the same eye:

Prerequisite

☑ The patient has at least one macular cube scan: (Acquire a Macular Cube Scan [▸ 150]).

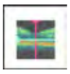
☑ You are logged in (review station or instrument): Login [▸ 123].

Action

1. Select the patient and click **Analyze**.
2. Select a **Macular Cube** or **Optic Disc** scan and select **Single Eye Summary**.

3. To export the all images, click **Export**.

4. To show or hide the circle guides overlaying the fundus image, click **Show/Hide Circles**.



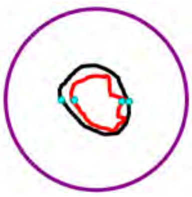
5. To show or hide the high-resolution image, click **HD**.
   ⇨ The image toggles between the original resolution and high resolution versions.

6. To set the navigators to the center of the image, click **Center**.

7. To center the navigators on the middle of te ETDRS grid, click **Center**.
   ⇨ The slice navigation lines move to the center of the grid.

8. To rest the ETDRS grid to its original position, click **Reset Grid**.

9. To center the ETDRS grid onto the slice navigator position, click **Center Grid**.



10. To reposition the optic disc and cup over the fovea, click and drag the circles into place.

11. To rotate the angle of the ONH spoke, click **Up** or **Down**.
12. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▸ 369]).
13. To view a full-screen image, double-click on the image.
14. To print, save, or export a report, see: Creating a Report [▸ 384].

9.2.6.2 Analyze PanoMap

The **PanoMap** analysis combines information from the Macular Thickness analysis, RNFL and ONH analysis, and Ganglion Cell OU analysis to provide an integrated, wide-field perspective for comprehensive analysis.

PanoMap Analysis is available for the following scans:

Either: ■ Macular Cube 512x128 ■ Macular Cube 200x200	+	Optic Disc Cube 200 x 200

For more information about interpreting data displayed in this analysis, refer to: Interpreting Normal Reference Range Comparison Data.

9.2.6.2.1 Panomap Analysis

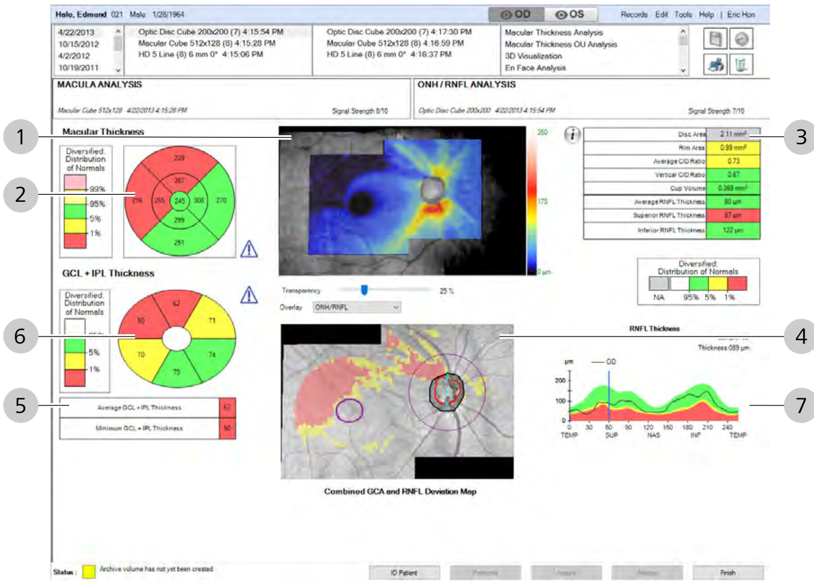
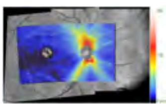
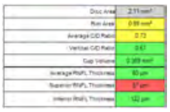
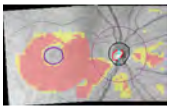
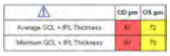
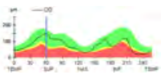
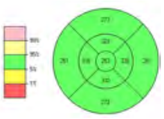


Figure 61: PanoMap Analysis Overview

#	Symbol	Name	Explanation
1		Macula and RNFL Thickness Map	Shows thickness maps.
		Overlay Transparency	Sets the overlay transparency level.
		Select Overlay	Selects which overlay to display over the fundus image. ■ ONH/RNFL thickness map for the optic disc cube and macular cube scans (default) ■ GC+IP layer thickness map for the macular cube scan ■ ILM-RPE layer thickness map for the macular cube scan

#	Symbol	Name	Explanation
3		Normal Reference Range Comparison	Displays measurements with color-coded comparison to the normal reference range for the patient's age.
4		Combined GCA and RNFL Deviation Map	Compares Ganglion Cell and RNFL thickness to the normal reference range for the patient's age. ■ **Red** indicates thinner than 99% of the (age-adjusted) normal reference population. ■ **Yellow** indicates thinner than 95% of the (age-adjusted) normal reference population.
5		Normal Reference Range Comparison	Shows overall average and minimum GCL+IPL layer thickness with color-coded comparison to the normal reference range for the patient's age.
6		ETDRS Grid	Shows overall average macular thickness in nine sectors. ■ central circle (radius = 500 micrometers; diameter =1 mm) ■ superior sector ■ nasal sector ■ temporal sectors ■ inferior sectors. Color coding shows how this patient's scan compares to the normal reference range for their age. See: Macular Thickness Parameters [▹ 456]).
7		**Neuro-Retinal Rim Thickness** Graph **RNFL Thickness** Graph	Displays thickness at each A-scan location along the selected circle **Interaction:** Recalculate according to position if you: ■ Move the blue line right or left. ■ Toggle the lines to display OD, OS, or OU.
8		Macular Thickness Information	Shows overall average macular thickness in nine sectors. ■ central circle (radius = 500 micrometers; diameter =1 mm) ■ superior sectors ■ nasal sectors ■ temporal sectors ■ inferior sectors. Color coding shows how this patient's scan compares to the normal reference range for their age. See: Macular Thickness Parameters [▹ 456]).

9.2.6.2.2 Analyzing a PanoMap

To analyze a panomap:

Prerequisite

- ☑ The patient has at least one macular cube scan: (Acquire a Macular Cube Scan [▷ 150]).
- ☑ The patient has at least one optic disc cube scan (Acquire an Optic Disc Cube Scan [▷ 153])
- ☑ You are logged in (review station or instrument): Login [▷ 123].

Action

1. Select the patient and click **Analyze**.
2. Under OD or OS, select a **Macular Cube** scan and select **PanoMap**.
   ⇨ The **PanoMap** analysis opens showing the selected macular cube scan and the most recent optic disc cube scan.

3. To change the overlay for the fundus image select a different overlay (or none).

4. To adjust the overly transparency, slide the adjustment tool to the right or left.
5. If you want to use a different scan, manually select it (Manually Select a Scan [▷ 367]).
6. Analyze the macular thickness and RNFL maps, charts and graphs. For more information, see: Interpreting Macular Thickness Parameters [▷ 239] and Interpreting RNFL Results.
7. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▷ 369]).
8. To view a full-screen image, double-click on the image.
9. To print, save, or export a report, see: Creating a Report [▷ 384].

9.2.6.3 Wellness Exam

NOTE

This report is intended to provide an eye health summary of both eyes for the patient.

▶ Acquire both macular and optic disc cube scans for each eye to provide a complete wellness report.

The **Wellness Exam** combines macular and optic disc image information to provide an integrated, easy-to-read, patient-focused report.

This analysis requires at least **one macular** and **one optic disc** image for the **same patient**, **same eye**, acquired the **same day**.

This analysis is available for the following scans:

Macular Cube Scan: 512x128* or 200x200 *512x128 is the default	+	Optic Disc Cube Scan: 200 x 200

You can select this analysis for any macular or optic disc cube scan. When you select a scan and the **Wellness Exam**, CIRRUS™ HD-OCT automatically finds the most recent companion scans needed for this report.

For example, if you select a patient's OD macular cube 200x200 image, CIRRUS™ HD-OCT finds the following companion images to use in the report:

- OD optic disc cube
- OS macular cube
- OS optic disc cube

9.2.6.3.1 Wellness Exam Overview

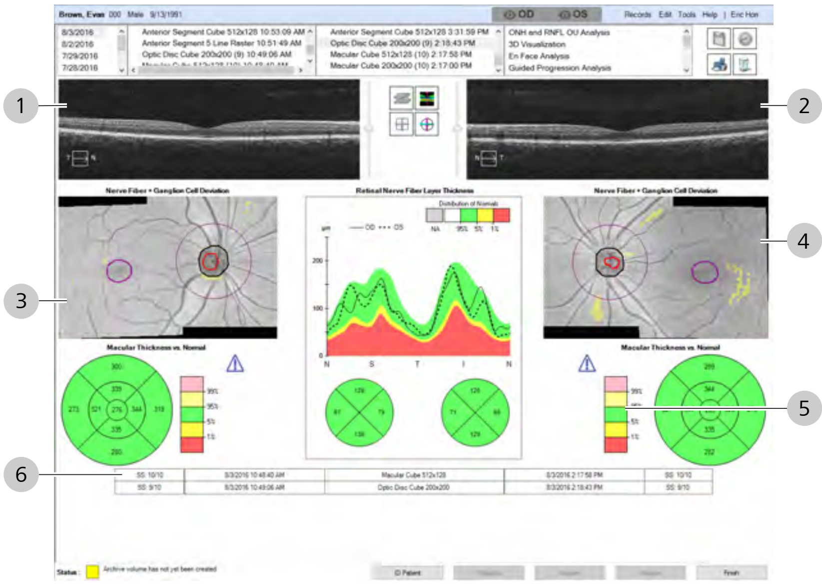
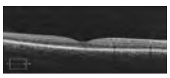
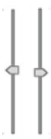
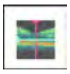
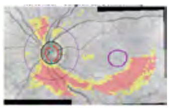
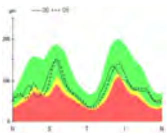
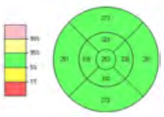


Figure 62: Wellness Exam Overview

#	Symbol	Name	Explanation
1		B-Scan Images	Shows OD and OS B-scans of the macula.
		Cube Navigation Sliders	Slides up and down to navigate through the slices.

#	Symbol	Name	Explanation
2	**B-Scan Image Tools**		
		Layers (Segmentation)	Hides or shows the lines that indicate segmentation boundaries.
		HR Images	Displays the high-resolution scans or standard-resolution scans.
		Snap to Center	Moves the slice navigators to the center of the image.
		Snap to ETDRS Grid Center	Moves the slice navigators to the ETDRS grid center position.
3		Ganglion Cell and RNFL Deviation Map	Compares Ganglion Cell and RNFL thickness to the normal reference range for the patient's age. ■ red indicates thinner than 99% of the (age-adjusted) normal population. ■ yellow indicates thinner than 95% of the (age-adjusted) normal population.
4		Quadrant Averages	Shows overall average RNFL thickness for each eye in four quadrants (Superior, Nasal, Temporal, Inferior)
		RNFL Thickness Chart	Displays thickness profiles. Right-click toggles the display orientation: ■ TSNIT ■ NSTIN
5		Macular Thickness Information	Shows overall average macular thickness in nine sectors. ■ central circle (radius = 500 micrometers; diameter =1 mm) ■ superior sectors ■ nasal sectors ■ temporal sectors ■ inferior sectors. Color coding shows how this patient's scan compares to the normal reference range for their age. See: Macular Thickness Parameters [▸ 456]).
6	**Scan Information**		
		OD Macula Scan	■ Signal strength (out of 10) ■ Date and time the scan was captured ■ Scan type and size.
		OS Macula Scan	
		OD Optic Disc Scan	
		OS Optic Disc Scan	

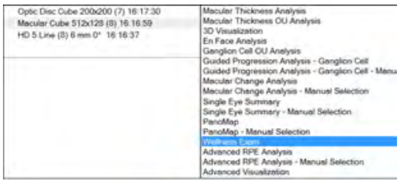
9.2.6.3.2 Creating a Wellness Exam Report

To create a Wellness Exam report:

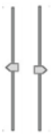
Prerequisite

- ☑ The patient has at least one macular cube scan: (Acquire a Macular Cube Scan [▹ 150]).
- ☑ (Optional) The patient has at least one optic disc cube scan (Acquire an Optic Disc Cube Scan [▹ 153]).
- ☑ You are logged in (review station or instrument): Login [▹ 123].

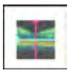
Action



1. Select the patient and click **Analyze**.
2. Under OD or OS, select a **Macular Cube** or **Optic Disc Cube** scan and select **Wellness Exam**.
   ⇨ The **Wellness Exam** opens showing the selected macular cube scan and the most recent optic disc cube scan (for both eyes, if available).
3. If you want to use a different scan, manually select it (Manually Select a Scan [▹ 367]).
4. To view a full-screen image, double-click on the image.



5. To navigate through slices, slide the slice navigator up, down, right and left as needed.
   ⇨ The slice number updates as you move the slider.



6. To show or hide the high-resolution image, click **HD**.
   ⇨ The image toggles between the original resolution and high resolution versions.

7. To set the navigators to the center of the image, click **Center**.

8. To center the navigators to the middle of the ONH, click **Center ONH**.
   ⇨ The slice navigation lines move to the center of the grid.
9. Analyze the ganglion cell and RNFL maps, charts and graphs. For more information, see: Interpreting Ganglion Cell Results [▹ 263] and Interpreting RNFL Results.
10. To print, save, or export a report, see: Creating a Report [▹ 384].

9.2.7 En Face Analysis

En-face Analysis (facing forward) is the same perspective as the fundus image-- looking directly into the eye.

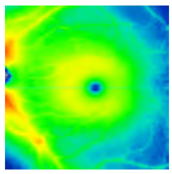
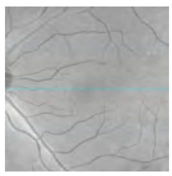
En Face Analysis is available for the following scans:

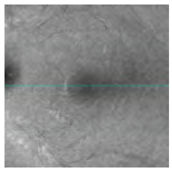
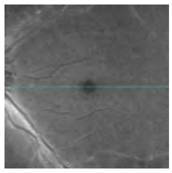
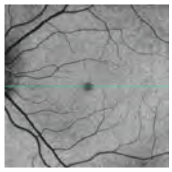
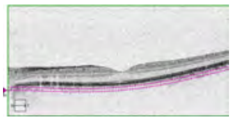
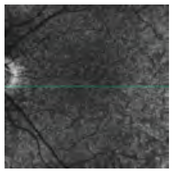
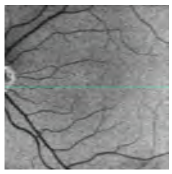
- Macular Cube 512x128
- Macular Cube 200x200
- Optic Disc Cube 200 x 200
- Angiography 3mm x 3mm
- Angiography 6mm x6mm
- Angiography 8mm x 8mm
- Angiography 12mm x 12mm
- HD Angiography 6mm x6mm
- HD Angiography 8mm x 8mm
- ONH Angiography 4.5mm x 4.5mm

9.2.7.1 En face Presets

You can click on the preset to overlay the en face image and adjust its transparency.

Figure 63: En Face Presets and Boundaries

#	Slab	Features		Example
		Boundary	Boundary	
1		**Thickness Map** Displays a color-coded slab of thicknesses ranging from 0 (black) to 500 (white). Each color bar is 25 micrometers (µm).		
2		**Fundus** Displays the structural view of the retina.		

<table>
<tr><th rowspan="2">#</th><th rowspan="2">Slab</th><th colspan="2">Features</th><th rowspan="2">Example</th></tr>
<tr><th>Boundary</th><th>Boundary</th></tr>
<tr><td rowspan="2">3</td><td rowspan="2"></td><td colspan="2">VRI
Highlights disorders of the VRI such as epiretinal membranes (ERM) and vitreomacular traction (VMT).
■ Bright areas may indicate vitreous attachments.
■ Variations in the background intensity may indicate macular pucker.</td><td rowspan="2"></td></tr>
<tr><td>ILM + 133 µm</td><td>ILM - 33 µm</td></tr>
<tr><td rowspan="2">4</td><td rowspan="2"></td><td colspan="2">Mid-Retina
Highlights fluid and exudates occurring from the Inner Nuclear Layer to the Outer Nuclear Layer.
Follows contours that are fractions of the distance between ILM and RPE.
Follows the RPE contour and is elevated slightly to put it at the level of the IS/OS – Ellipsoid Zone.</td><td rowspan="2"></td></tr>
<tr><td colspan="2">Central 1/3 of retinal thickness based on the ILM and RPE layers</td></tr>
<tr><td rowspan="2">5</td><td rowspan="2"></td><td colspan="2">IS/OS Ellipsoid
Highlights disruptions to the IS/OS – Ellipsoid Zone (shown as dark areas).
Follows the RPE contour and is elevated slightly to put it at the level of the IS/OS – Ellipsoid Zone.</td><td rowspan="2"></td></tr>
<tr><td>RPE + 39 µm</td><td>RPE + 9 µm</td></tr>
<tr><td rowspan="2">6</td><td rowspan="2"></td><td colspan="2">Choroid
Highlights choroidal vasculature - below the RPE-Fit, (approximately Haller's Layer), deep in the choroid.
■ Dark areas indicate vessels.
■ Bright areas may indicate RPE disturbance (such as GA).
Choroid thickness can vary; borders may need adjustment.</td><td rowspan="2"></td></tr>
<tr><td>RPE Fit - 72 µm</td><td>RPE-Fit - 128 µm</td></tr>
<tr><td rowspan="2">7</td><td rowspan="2"></td><td colspan="2">Minimum Intensity
Shows patterns of minimum scan intensity in the retina to help identify areas of fluid or other disruptions (see: About Minimum Intensity Projection (Min-IP)).
■ Dark areas may indicate fluid build-up.
■ Bright areas may indicate disruption of the retina.</td><td rowspan="2"></td></tr>
<tr><td>90% ILM + 10% RPE</td><td>RPE</td></tr>
</table>

#	Slab	Features		Example
		Boundary	Boundary	
■ ILM = *Inner Limiting Membrane* ■ IS/OS = *Inner Segment / Outer Segment*; `IS/OS = RPE Fit - 70 µm` ■ RPE = *Retinal Pigment Epithelium* ■ Min IP = *Minimum Intensity Projection*				

9.2.7.2 En Face Analysis

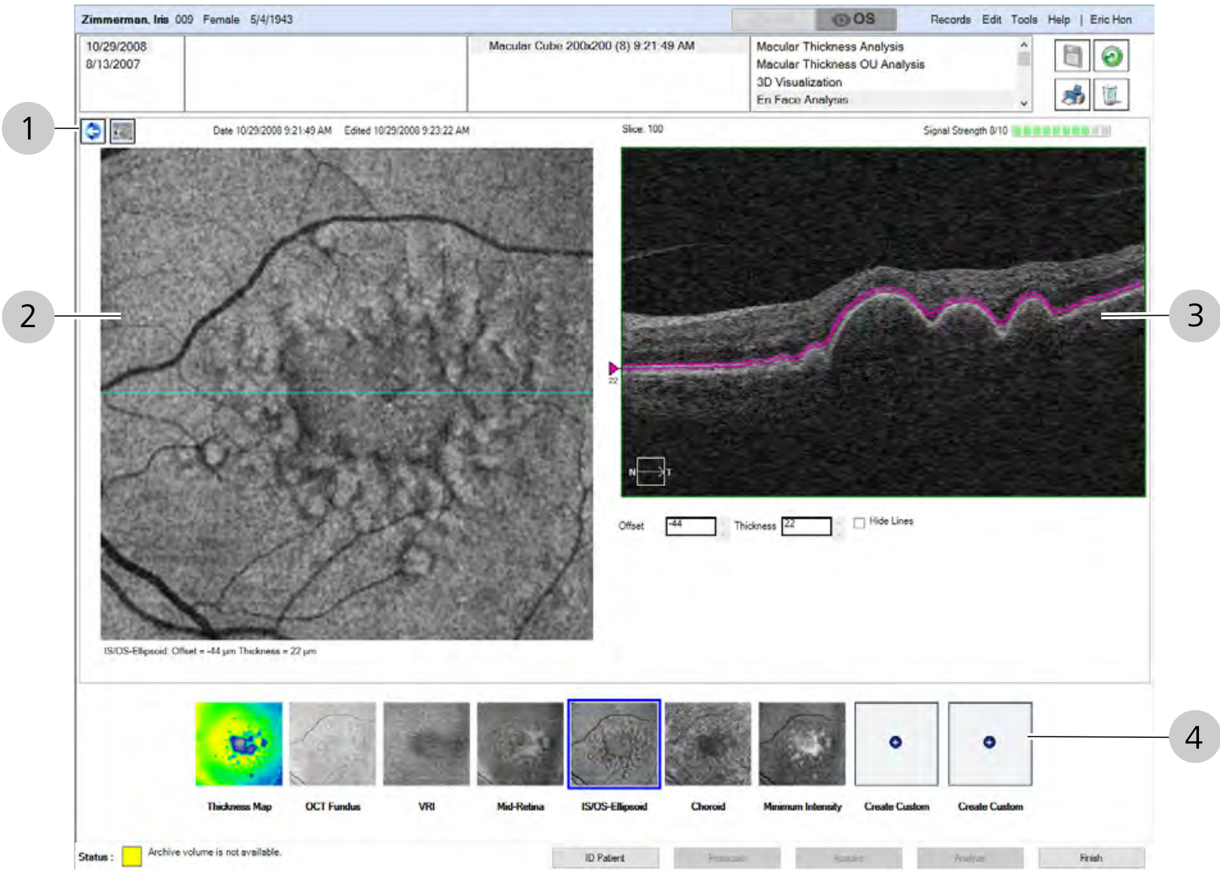


Figure 64: En Face Analysis Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Toggle Prior and Current Scan	Toggles:  Show prior image  Return to current image
		Hide/Show LSO	
		Signal Strength	Indicates scan quality level; more green indicates a higher quality scan.

#	Symbol	Name	Explanation
2	*varies*	Selected Preset	Displays the preset slab selected from the thumbnails.
3	*varies*	B-Scan	Displays the B-scan
		Adjustment Tools	**Offset**: Adjusts the boundary line up or down. **Thickness**: Adjust the space between the two boundary lines. **Hide Lines**: Hides or shows the boundary lines.
4	*varies*	Preset Selector	Selects the Preset.

9.2.7.3 Analyzing En Face Images

Prerequisite

☑ The patient has a scan that provides En Face Analysis.

☑ You are logged in (review station or instrument): Login [▷ 123].

Action

1. Select the patient and click **Analyze**.
2. Select a scan that provides En Face Analysis, ans select **En Face Analysis**.
   ⇨ The analysis opens.
3. Select a preset (see: En face Presets [▷ 305]).
4. To edit or adjust the image, hover over the image and select an adjustment tool (refer to: Edit Images (Hover Over) [▷ 370].
5. To view a full-screen image, double-click on the image.
6. To print, save, or export a report, see: Creating a Report [▷ 384].

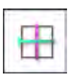
9.2.8 Position the Fovea

CIRRUS™ HD-OCT software identifies reduced reflectivity below the retina to detect the fovea automatically for the following analyses:

- Analyze Macular Thickness [▷ 238]
- Analyze Macular Change [▷ 247]
- Analyze Ganglion Cell OU [▷ 262]
- Advanced RPE Analysis [▷ 257]

If the algorithm could not detect the fovea location or if the fovea was detected inaccurately, you can manually reposition the fovea. When you manually reposition the fovea, the data tables and ETDRS thickness measurements update accordingly.

The set of tools that help you position the fovea include:

#	Symbol	Name	Explanation
		Snap to Center	Moves the slice navigators to the center of the 6x6 mm square.

#	Symbol	Name	Explanation
		Snap to ETDRS Grid center	Moves the slice navigators to the ETDRS Grid center position.
		Reset ETDRS Grid	Moves the ETDRS Grid back to the CIRRUS-calculated fovea center location.
		Center ETDRS Grid	Moves the ETDRS Grid to center on the slice navigator position.

9.3 Analyze Angiography Images

NOTE

12x12 cubes and 12 mm raster scan the resolution has changed compared to the case of the A-scan size of 2.0 mm.

Using the sum projection, weaker details of the images are enhanced. Specifically, by mathematical definition of the sum projection, with the sum projection the slower flow is enhanced and therefore smaller capillaries are more visible.

Before analyzing an Angiography image, re-assess scan quality, segmentation errors, and decorrelation tails.

Angiography Analysis is available for the following scans:

- Angiography 3mm x 3mm (AngioPlex Metrix)
- Angiography 6mm x 6mm (AngioPlex Metrix)
- Angiography 8mm x 8mm
- HD Angiography 6mm x 6mm
- HD Angiography 8mm x 8mm
- Angiography 12mm x 12mm

Indicates optional features; license may be required.

9.3.1 About Angiography Analysis

9.3.1.1 About AngioPlex® Metrix

When analyzing angiography scans, you can observe and measure vessel density and capillary perfusion using AngioPlex Metrix.

AngioPlex Metrix provides both visual results (map, trace, FAZ) with color overlays and measurement results.

AngioPlex Metrix measurements are available for the following images:

- Angiography cube (Superficial layer)
  - **3 mm x 3 mm**
  - **6 mm x 6 mm**
- ONH Angiography cube (RPC layer)

– **4.5 mm x 4.5 mm**

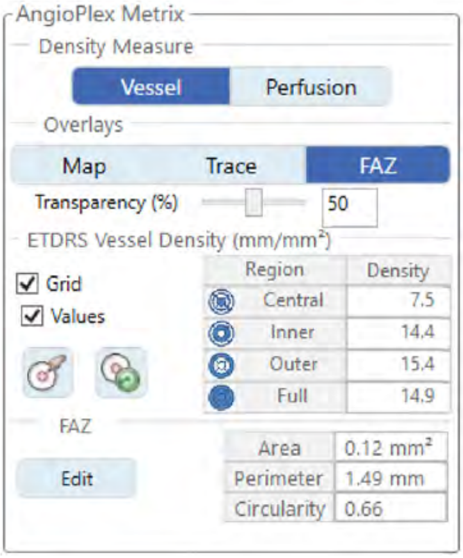
AngioPlex Cube	ONH AngioPlex Cube
	

Table 71: AngioPlex Metrix Examples

Map, **Trace**, and measurement information changes when you toggle between **Vessel** and **Perfusion**.

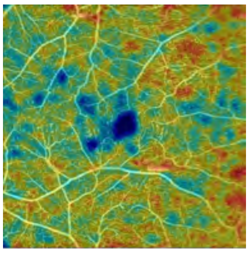
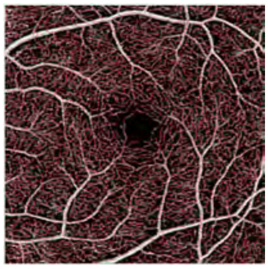
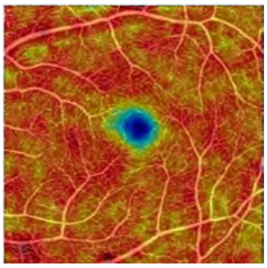
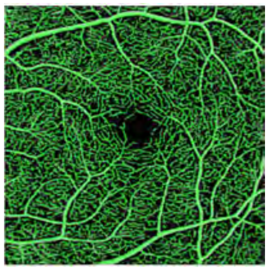
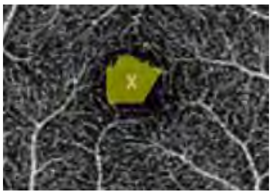
	Map	Trace
Vessel		
Perfusion		

Table 72: Overlays

9.3.1.1.1 About FAZ Measurements

CIRRUS™ HD-OCT automatically detects the **Foveal Avascular Zone** (FAZ) and outlines it.



If the application cannot detect the FAZ or if you want to change the outline, you can Edit the FAZ Outline [▹ 311].

AngioPlex Metrix calculates the values for Area, Perimeter, and Circularity of the FAZ.

FAZ Metrix	Units	Description
Area	mm^2	The area within the FAZ boundary.
Perimeter	mm	The length of the FAZ boundary.
Circularity	-	FAZ boundary similarity to a circle (range: 0-1). ■ **1** = FAZ forms a perfect circle ■ **0** = very different from a circle.

Table 73: FAZ Metrix

FAZ Circularity

Low circularity can result from loss in capillaries immediately surrounding the FAZ.

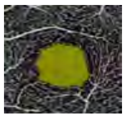
High Circularity	Low Circularity
Circularity = 0.75 	Circularity = 0.58 

Table 74: Circularity Examples

9.3.1.1.1.1 Edit the FAZ Outline

CIRRUS™ HD-OCT software automatically outlines the FAZ and calculates **AngioPlex Metrix** . You can manually edit the FAZ outline (must be a single closed shape).

When you draw a new outline for the FAZ, CIRRUS™ HD-OCT software automatically connects the end point and the beginning point where the line intersects, then recalculates the FAZ area, perimeter, and circularity using the new outline.

To Edit the FAZ:

Prerequisite

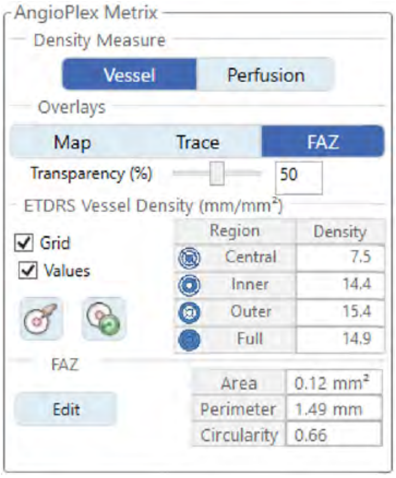
☑ You are logged in (review station or instrument): Login [▹ 123].

☑ The patient has at least one angiography scan: (Acquire an OCT Angiography Scan [▹ 163]).

Action

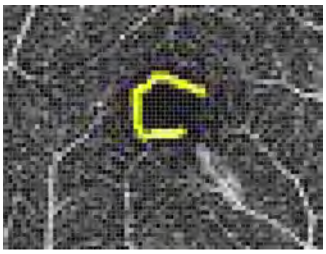
1. Select the Patient [▹ 124].
2. Under OD or OS, select a **Angiography** scan and select **Angiography Analysis**.

⇨ If licensed, AngioPlex Metrix appear.

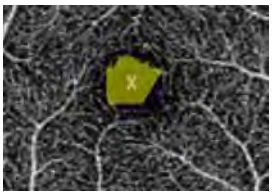


3. Select a **Density Measure** (**Vessel** or **Perfusion**).
4. Under **Overlays**, click **FAZ**.
   ⇨ ETDRS features are disabled (if selected).
5. Under **FAZ**, click **Edit**.
   ⇨ If the application detected and outlined the FAZ, an additional confirmations open.
6. If a confirmation opens, click **Delete**.

   ⇨ The cursor becomes a pencil.



7. Click on a point along the FAZ boundary and drag the pen around the outline until you reach the starting point.
   ⇨ The drawing tool automatically connects the end point to the beginning point when they intersect.



   ⇨ When you release the mouse, the FAZ area appears shaded yellow.
   ⇨ The CIRRUS™ HD-OCT application recalculates the **Area**, **Perimeter**, and **Circularity** of the new shape.

9.3.1.1.2 About Density Measurements

AngioPlex Metrix provide two different ways to measure vascular density:

- Vessel Density
- Perfusion Density

Vessel Density

Vessel Density is the total length of perfused vasculature per unit area in a region of measurement. Vessel Density is expressed as mm/mm² (total vessel length per unit area), similar to how road density is expressed (km of road per square kilometer of land, for example).

Vessel Density = `the total length of perfused vasculature per unit area in a region of measurement`

Vessel Density measurements helps to detect the loss of individual capillaries because vessel size does not influence the measurement. However, this measure is more sensitive to noise.

Perfusion Density

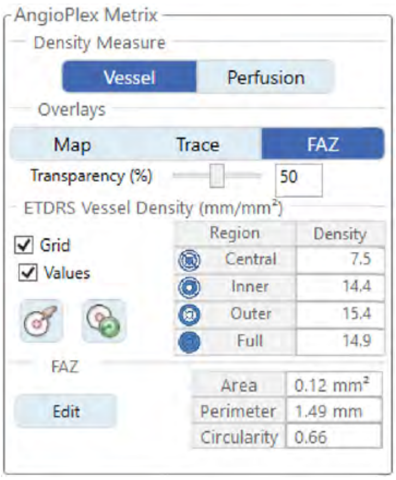
Perfusion Densitymeasures the percent total area of perfused vasculature in a given region of measurement. Perfusion Density accounts for the width (caliber) of the vessels in addition to the length. It provides the percent of the region that contains perfused vasculature, regardless of intensity of the OCTA signal.

Perfusion Density = `number of pixels with perfused vasculature` / `total number of pixels in the region`

The result is a percent ranging from 0 (no perfusion) to 100%.

In **Perfusion Density**, vessel size (caliber) **does** influence the measurement.

9.3.1.1.3 Viewing AngioPlex Metrix Measurements



AngioPlex Metrix measurements display as color maps and as numeric measurements of the ETDRS grid regions.

If you check **Grid** and **Values**, CIRRUS™ HD-OCT displays each section of the ETDRS grid and the **AngioPlex Metrix** values.

Measurements are dynamic; they change if you move the ETDRS grid to a different area of the image.

The options for centering options the ETDRS grid are:

Center on Slice Navigators: Centers the ETDRS grid on the current position of the slice navigators.

Center on the Fovea: Centers the ETDRS grid on the fovea.

9.3.1.2 About Analysis Presets

Tip: If CIRRUS™ HD-OCT does not detect segments successfully, you can use the layer segmentation editor to set layer boundaries (see: Edit Layer Boundaries).

Some analyses have preset slab views that highlight different features or locations. You can also create your own custom presets.

Presets provide a calculated slab location as a starting point. However, since exact layer location can vary by patient anatomy and pathology, you can drag these segmentation lines to adjust layers more precisely.

You can make additional image adjustments (such as brightness and contrast) and save the adjusted images.

Presets are available for the following analyses:

- Analyze Angiography Images [▸ 320]
- Compare Angiography Images [▸ 327]
- Analyze ONH Angiography Images [▸ 331]
- Compare ONH Angiography Images [▸ 333]
- Analyze En Face Images

9.3.1.2.1 Organize AngioPlex Presets

Not all AngioPlex presets appear in AngioPlex analysis. You can choose which presets to hide and which to display (including your own custom presets) by organizing the thumbnails.

To organize presets:

Prerequisite

☑ You are logged in (review station or instrument): Login [▸ 123].

☑ You are analyzing an AngioPlex image and you want to organize the presets.

Action

1. Open the **Thumbnail Organizer**.
   ⇨ Some thumbnails are displayed and others are hidden.
2. Move the presets you want to display under **Displayed Thumbnails**.
3. Move the presets you want to hide under **Hidden Thumbnails**.
4. To change to order of the presets, drag a displayed thumbnail to a new position.

Result

✓ The thumbnails you set for display appear for AngioPlex analysis in the same order.

9.3.1.2.2 Offset Preset Layer Boundaries

Tip: You can also left-click on the pink triangle and drag the layer boundary line into place.

Editing layers allows you to fine-tune layer boundaries. If a patient's retinal structure has anomalies or if the patient's retinal pathology causes CIRRUS™ HD-OCT algorithms to trace the boundaries inaccurately, you might need to adjust layer boundaries.

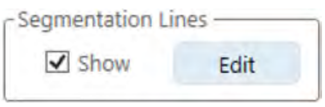
You can drag any portion(s) of the boundary lines, but you cannot cross the upper and lower boundaries.

To offset layer boundaries:

Prerequisite

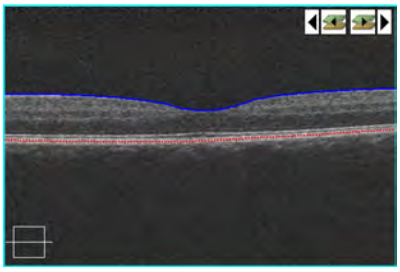
☑ You are logged in (review station or instrument): Login [▸ 123].

☑ An angiography cube scan is open: Analyze Angiography Images [▸ 309].

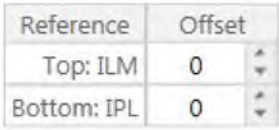


Action

1. Under **Segmentation Lines**, check **Show**.



⇨ Dashed lines indicating the top and bottom layers overlay the B-scan image.



2. To adjust the top layer, change the **Offset** number for **Top**.
3. To adjust the bottom layer, change the **Offset** number for **Bottom**.
4. Complete the analysis.

9.3.1.2.3 Custom Presets

There are two blank presets for you to create and reuse your own slab presets. There are two different types of custom presets:

Custom Scan Presets

You can create one or two custom presets to define your own boundaries and segmentation lines to use for the scan you are analyzing.

Custom Global Presets

You can also create one or two custom presets to define your own boundaries and segmentation lines to use for all **Angiography Analyses**. You can use custom presets to choose an inner boundary and an outer boundary, and then shift them to visualize the vasculature between existing presets.

You can step through the scan and drag segmentation lines to offset the outer and inner boundaries. However, you cannot use segmentation lines when images are overlaid with a thickness map.

9.3.1.3 About Angiography Registration

When you compare a patient's scan to an earlier scan (of the same type), CIRRUS™ HD-OCT automatically aligns, or *registers*, the scans together. Registration synchronizes anatomical structures and corrects differences in rotation, which can occur if the patient is situated slightly differently for the two scans.

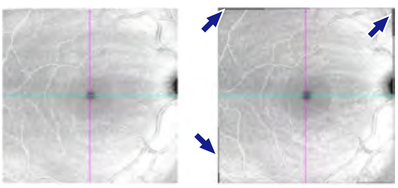


Figure 65: Unregistered Areas (Black Border)

Automatic Scan Registration

There are two different methods for automatically registering scans, **R2** and **R1**.

CIRRUS™ HD-OCT's primary (preferred) registration method is **R2**.

However, if **R2** cannot adequately register the images, the instrument attempts **R1** registration.

9.3.1.3.1

Analyses and reports that use scan registration inform you of which method was applied.

Method	Order	Description
R2	Primary	■ Aligns scans using the blood vessels identified in the en face images of both scans. ■ For guided progression analyses, uses translation and rotation to align the follow-up scan(s) to the baseline scan
R1	Secondary	■ Aligns scans using the center of the optic disc of both scans. ■ R1 does not include rotation. ■ R1 might cause additional variability at the super-pixel level, which can affect change detection in a thickness map.

Table 75: Registration Types

If you want to override automatic registration, you can register scans manually or select a different set of scans to register together. (See: Manually Register AngioPlex Images [▸ 317]).

9.3.1.3.2 No Registration

If automatic registration was not successful and no manual registration was applied yet, the scans will display **No Registration**. To register the scans, refer to: Manually Register AngioPlex Images [▸ 317].

9.3.1.3.3 Manual Registration

When you manually register images, you set (up to five) corresponding points between two images. When you identify the same structure or feature in both images, click that structure in the first image, then the second image.

For example, use a blood vessel bifurcation or a bend in a blood vessel as a point to mark. A matching set of marks indicates corresponding features. Different marks indicate the next features you mark (see: Manually Register AngioPlex Images [▸ 317]).

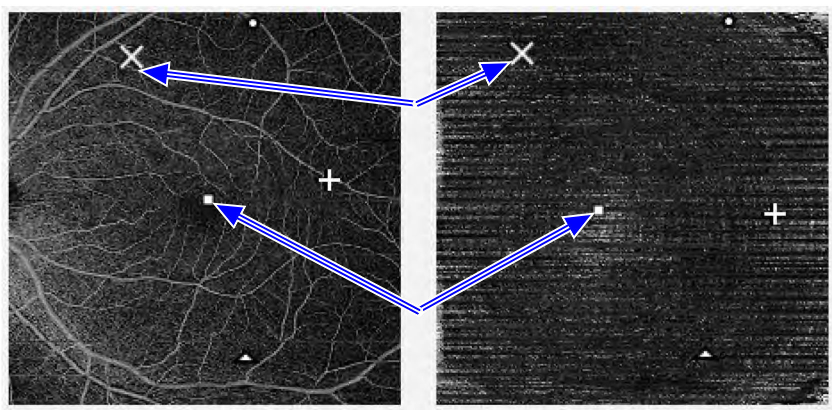
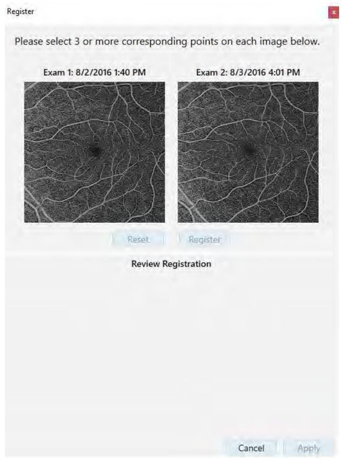
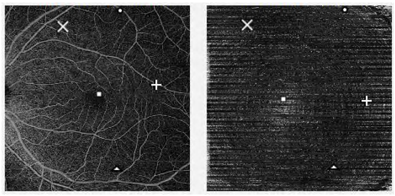


Figure 66: Registration Mark Pairing

After you register two images, the second image might display irregular black borders. These borders indicate areas that are not present in both images.

9.3.1.3.4 Manually Register AngioPlex Images

<table>
<tr><th></th><th>AngioPlex Registration</th></tr>
<tr><td>Registration Tool</td><td>
</td></tr>
<tr><td>Matched Marks</td><td></td></tr>
<tr><td>Marked Example</td><td></td></tr>
</table>

To adjust registration manually:

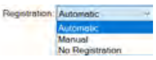
Prerequisite

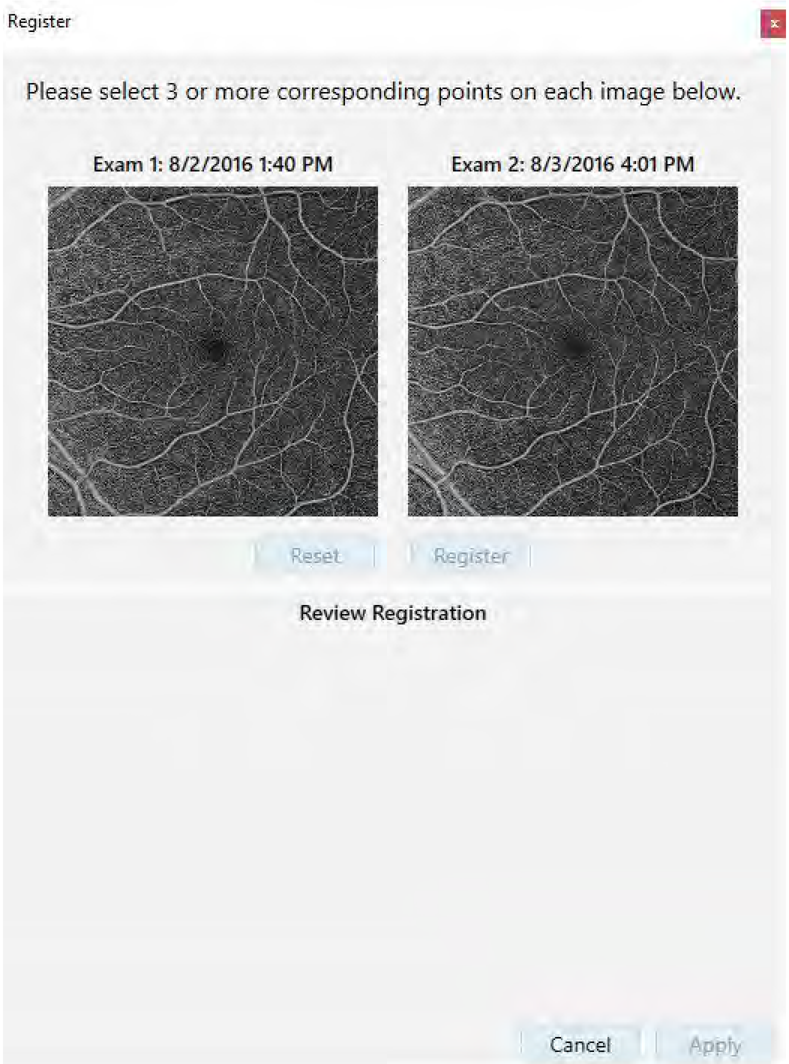
☑ You are logged in (review station or instrument): Login [▸ 123].

☑ You have a comparison analysis open and you want to change the registration.

Action

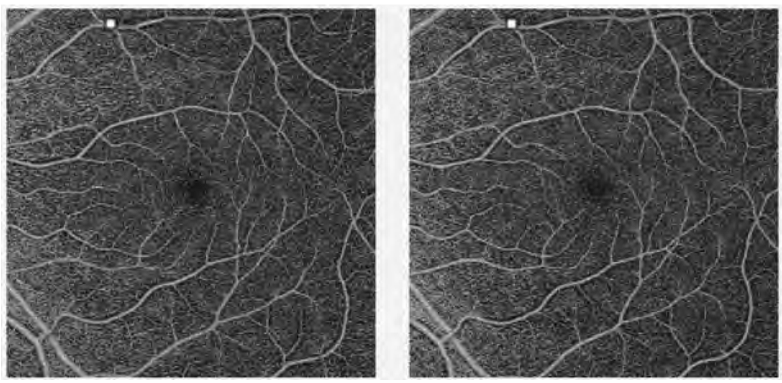
1. For **Registration**, select **Manual**.



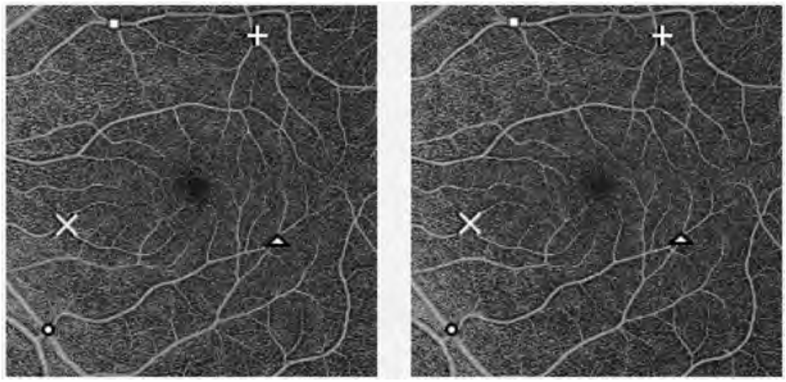


⇨ The registration review tool opens.

2. Identify a feature that appears in both images, like a blood vessel bifurcation or a bend in a blood vessel.



3. Mark the feature in each image.



4. Identify and mark additional identifiable features in other regions of the pair of images (between 3 and 5 marks in each image).
5. To change the transparency of Image 1 or Image 2, move the transparency slider right or left.
6. To view the manually-adjusted overlay, click **Review Registration**.
7. To return to the original registration, click **Reset**.
8. Click **OK**.

Result

✓ The **Registration succeeded** message and a green flag appear.

9.3.1.4 Verifying the Avascular Slab

Reviewing the Avascular Layer

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. These are listed below.

Examine the segmentation, flow, and intensity of B-scans carefully for abnormal-appearing vasculature in the Avascular slab.

- 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 should be uncommon in the outer retina, but it can occur.
- The segmentation, flow, and intensity of B-scans should be examined carefully if there is abnormal-appearing vasculature in the Avascular slab.

9.3.2 Analyze Angiography Images

9.3.2.1 Angiography Presets

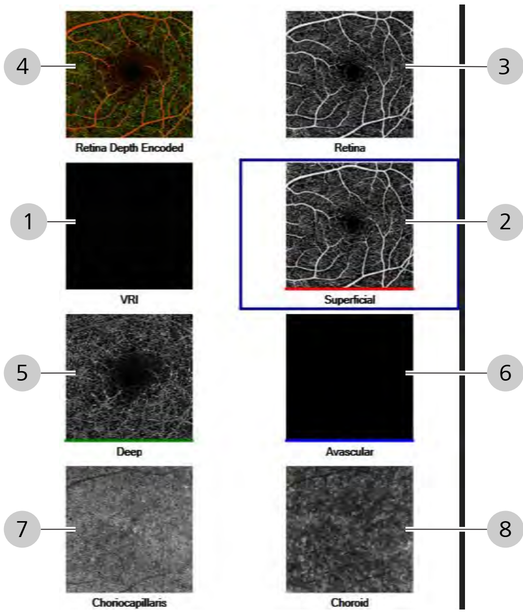
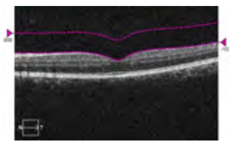
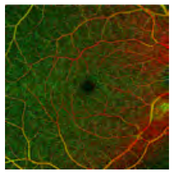
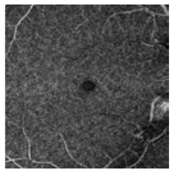
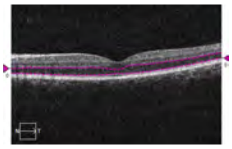
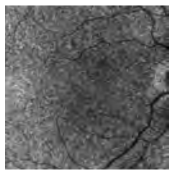
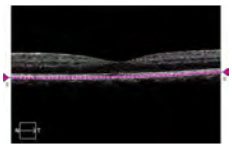
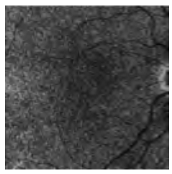


Figure 67: Angiography Analysis Presets and Boundaries

#	Slab	Features		Example
		Top Boundary	Bottom Boundary	
1		**VRI** Highlights disorders of the VRI such as epiretinal membranes (ERM) and vitreomacular traction (VMT). ■ Bright areas may indicate vitreous attachments. ■ Variations in the background intensity may indicate macular pucker.		
		ILM - 300 µm	ILM	

<table>
<tr><th rowspan="2">#</th><th rowspan="2">Slab</th><th colspan="2">Features</th><th rowspan="2">Example</th></tr>
<tr><th>Top Boundary</th><th>Bottom Boundary</th></tr>
<tr><td rowspan="2">2</td><td rowspan="2"></td><td colspan="2">Superficial
Displays the superficial retinal layer slab with the ILM layer segmented in the same manner as structural images. The IPL is approximate.</td><td rowspan="2"></td></tr>
<tr><td>ILM</td><td>IPL</td></tr>
<tr><td rowspan="2">3</td><td rowspan="2"></td><td colspan="2">Retina
Illustrates vasculature of the entire retina.
The lower boundary is offset by 70 µm to minimize the contribution of the hyper-reflective RPE.</td><td rowspan="2"></td></tr>
<tr><td>ILM</td><td>RPE fit – 70µm</td></tr>
<tr><td rowspan="2">4</td><td rowspan="2"></td><td colspan="2">Retina Depth Encoded
A color encoded slab with different colors representing different layers.
■ Red: Superficial
■ Green: Deep
■ Blue: Asascular</td><td rowspan="2"></td></tr>
<tr><td>ILM</td><td>RPE</td></tr>
<tr><td rowspan="2">5</td><td rowspan="2"></td><td colspan="2">Deep Retinal Layer (DRL)
Displays the deep retina layer slab.</td><td rowspan="2"></td></tr>
<tr><td>IPL*</td><td>OPL</td></tr>
<tr><td rowspan="2">6</td><td rowspan="2"></td><td colspan="2">Avascular
Displays parts of the retina that normally do not have vasculature. You can adjust brightness and contrast to help visualize potential abnormal vasculature, but these adjustments could also emphasize noise and weak decorrelation tail signals.</td><td rowspan="2"></td></tr>
<tr><td>OPL</td><td>IS/OS</td></tr>
<tr><td rowspan="2">7</td><td rowspan="2"></td><td colspan="2">Choriocapillaris
Choriocapillaris</td><td rowspan="2"></td></tr>
<tr><td>OPL</td><td>RPE fit + 38 µm</td></tr>
<tr><td rowspan="2">8</td><td rowspan="2"></td><td colspan="2">Choroid
Uses the summation of pixel values as the default.</td><td rowspan="2"></td></tr>
<tr><td>RPE</td><td>RPE Fit</td></tr>
</table>

#	Slab	Features		Example
		Top Boundary	Bottom Boundary	
*Estimated				

- ILM = *Inner Limiting Membrane*
- IPL = *Inner Plexiform Layer* `IPL = ILM + 70% * (Thickness of ILM - Thickness of OPL)`
- DRL = *Deep Retinal Layer*
- IS/OS = *Inner Segment / Outer Segment* `IS/OS = RPEfit - 70 µm`
- OPL = *Outer Plexiform Layer*
- RPE = *Retinal Pigment Epithelium*
- VRI = *VitreoRetinal Interface*

9.3.2.2 Angiography Analysis Overview

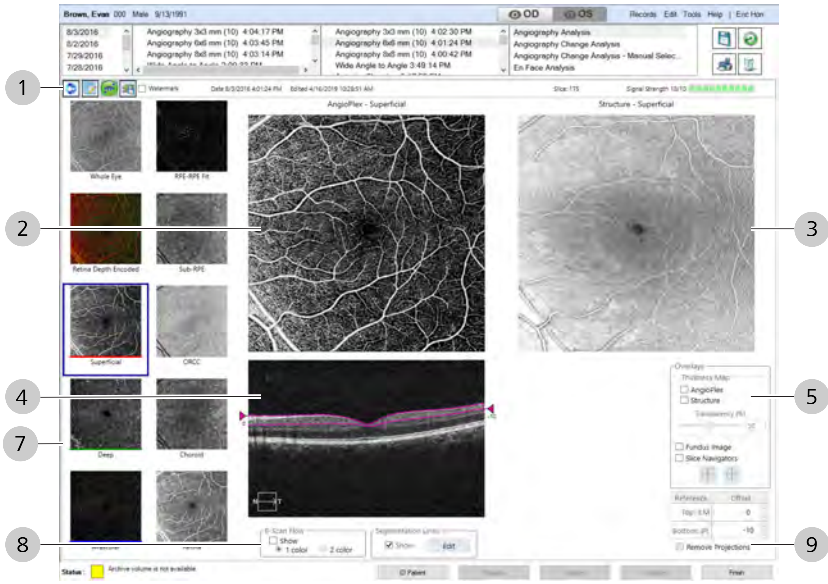
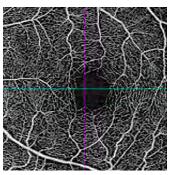
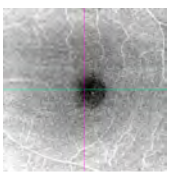
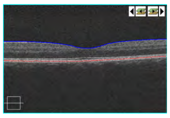
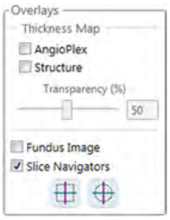
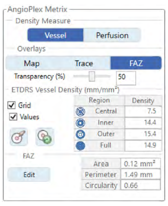
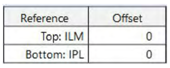


Figure 68: Angiography Analysis Overview

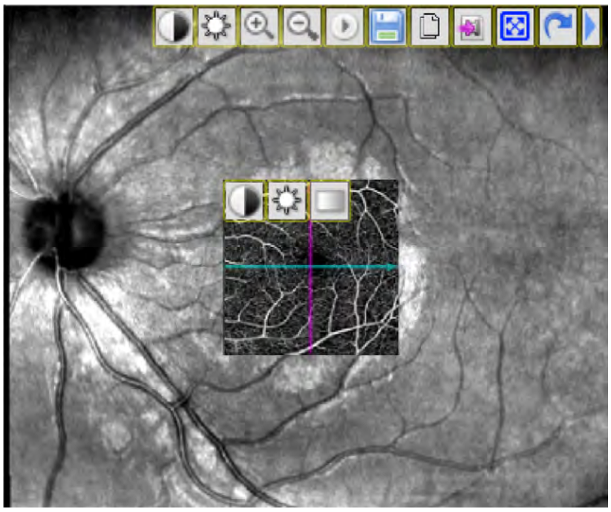
#	Symbol	Name	Explanation
1	**Tools and Indicators**		
		Back	Navigates to the prior preset
		Preset Organizer	Rearranges, hides, or shows presets.
		FastTrac Indicator	Green indicates the scan was acquired with FastTrac **on**.
		Advanced Export	Exports images and thickness values.
		Signal Strength	Indicates image quality level; more green indicates a higher quality image.
	Watermark	Watermark	Turns on or off the watermark.
2		AngioPlex Imagae	Displays the angiography image for the slab.
3		Structure Image	Displays the structure image for the slab.

#	Symbol	Name	Explanation
4		B-Scan	Slice through cube front
5		Overlay Tools (AngioPlex and Structure images)	**Thickness Map:** shows or hides the thickness map over AngioPlex® or Structure image (or both). **Transparency:** increases or deceases transparency of the thickness map overlaying the image. **Fundus Image:** shows or hides the fundus image over both AngioPlex® and Structure images. Slice Navigators: shows or hides the cyan (fast B-scans) and magenta (slow B-scans) over both AngioPlex® and Structure images.
6	**Superficial Preset only** 	AngioPlex Metrix	Tools to observe and measure vessel density, capillary perfusion and FAZ (see:About AngioPlex® Metrix [▷ 309])
7	Presets	Preset slabs (see:Angiography Presets [▷ 320]).	
8		B-Scan Settings	**B-Scan Flow** shows or hides an overlay depicting blood flow on the B-scan image: ■ **1 color**: shows all aspects of the flow in light red. ■ **2 color**: light red shows flow data above the RPE; green shows flow data below the RPE. **Segmentation Lines:** **Show:** shows or hides the dashed magenta layer lines of the selected slab over the B-scan image. **Edit:** opens segmentation editing.
9		Slab Boundaries	Shows the top and bottom boundaries for the selected slab preset.

9.3.2.3 Analyze an Angiography Image

Tip: You can use the toolbar arrows to navigate through the presets. The left arrow selects the prior preset. The right arrow selects the next preset.

You can edit the AngioPlex, Structure, and B-scan images individually. To access the editing tools, right click on the image you want to edit.



You can edit the images in the following ways:

- Adjust brightness and contrast
- Zoom in and zoom out
- Arrow
- Save your edits
- Copy the image
- Save as a movie
- View full screen
- Reset
- Add caliper measurements and text annotations
- Remove a caliper or annotation

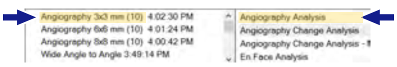
To analyze an angiography image:

Prerequisite

☑ You are logged in (review station or instrument): Login [▹ 123].

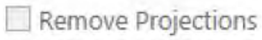
☑ The patient has at least one angiography scan: (Acquire an OCT Angiography Scan [▹ 163]).

Action

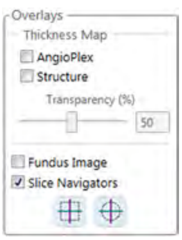


1. Select the patient and click **Analyze**.
2. Under OD or OS, select a **Angiography** scan and select **Angiography Analysis**.
   ⇨ The analysis opens.
3. Select a preset (About Analysis Presets [▹ 313]).
   ⇨ The selected slab opens in **Slab**, **Structure**, and **B-scan** views.
4. To view a full-screen image, double-click on the image.

5. To overlay the B-scan image with flow data, check **Show** under **B-Scan Flow** .
   ⇨ Select **1 color** to show all flow data in red or select **2 color** to show areas above the RPE in light red and below the RPE in green.
6. To show the layer segmentation lines over the B-scan image: under **Segmentation Lines** , check **Show**.
   ⇨ Dashed magenta lines show the layer boundaries over the B-scan.
7. To adjust a layer boundary, refer to: Offset Preset Layer Boundaries [▸ 314].
   ⇨ The **AngioPlex** and **Structure** images update to match the adjusted layer boundary.



8. To remove image artifacts such as decorrelation tails, check **Remove Projections**.
9. To adjust image brightness or contrast, right-click on the image and select **Brightness/Contrast**.
10. To show a color image, right-click on the image and select **Color**.
11. To hide the image, right-click on the image and select **Hide**.
12. To exit any editing mode and save the changes, right-click on the image and select **Normal**.



13. To show the thickness map over the angiography image, check **AngioPlex**.
14. To show the thickness map over the structure image, check **Structure**.
    ⇨ **NOTE! You cannot use segmentation lines on an image showing a thickness map.**
15. To adjust the transparency of the thickness map(s), increase or decrease **Transparency**.
16. To show the fundus image over the AngioPlex and Structure images, check **Fundus Image**.
17. To turn on slice navigators that allow you to navigate the cube layers, check **Slice Navigators**. See: Navigate Cube Layers Manually [▸ 226].
    ⇨ Cyan (fast B-scans) and magenta (slow B-scans) navigators show over both AngioPlex and Structure images.

18. To set the navigators to the center of the image, click **Center**.

19. To center the navigators to the middle of the ONH, click **Center ONH**.
    ⇨ The slice navigation lines move to the center of the grid.
20. To edit or adjust the image, hover over the image and select an adjustment tool (refer to: Edit Images (Hover Over) [▸ 370].

21. To view a full-screen image, double-click on the image.
22. To print, save, or export a report, see: Creating a Report [▸ 384].

9.3.3 Compare Angiography Images

9.3.3.1 Angiography Change Analysis

Angiography Change Analysis allows you to compare multiple scans to visualize changes in retinal vasculature over time.

This analysis is available for the following scans:

- Angiography 3mm x 3mm
- Angiography 6mm x6mm

9.3.3.1.1 Angiography Change Analysis Overview

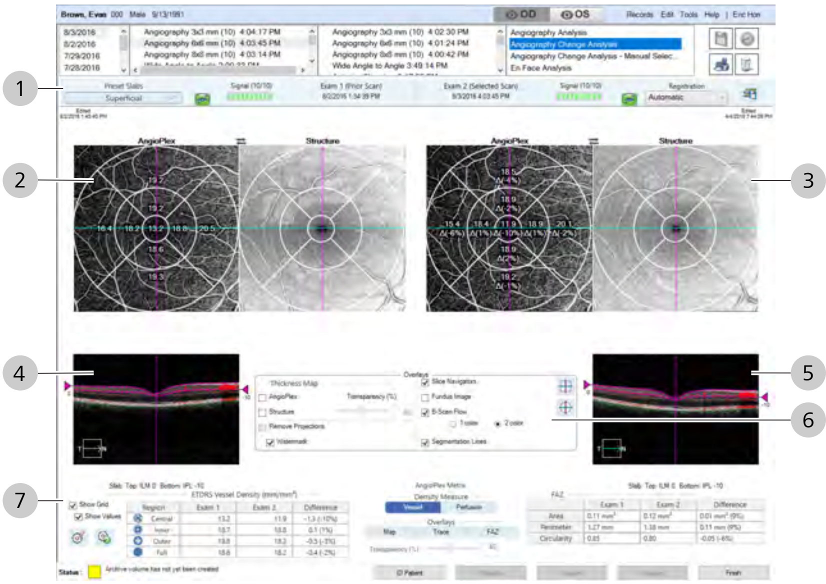
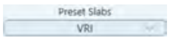
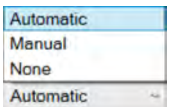
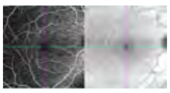
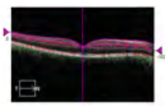


Figure 69: Angiography Change Analysis Overview

#	Symbol	Name	Explanation
1	**Tools and Indicators**		
		Preset Slabs	Selects the slab to view.
		FastTrac Indicator	Green indicates the scan was acquired with FastTrac **on**.
		Signal Strength	Indicates scan quality level; more green indicates a higher quality image.
	Prior Scan and Selected Scan	Exam 1 and Exam 2	Indicates the **Date** and **Time** each image was acquired.
		Registration	Indicates whether images are aligned to each other.
		Advanced Export	Exports images and thickness values.
2		Prior Images	Shows the slab and the structure for the earlier image.
3		Selected Images	Shows the slab and the structure for the selected image.
4		Prior Image B-Scan	Displays the B-scan image.
5		Selected Image B-Scan	

#	Symbol	Name	Explanation
6	**Overlays**		
		**AngioPlex**	Check to overlay thickness maps.
		Structure	Check to overlay thickness maps.
		Transparency	Adjusts overlay transparency.
		Remove Projections	Check to remove projections.
		Watermark	Check to add a watermark to images
		Slice Navigators	Shows or hides slice navigators on slab and structure images.
		Fundus Image	Check **Fundus** to overlay fundus image (instead of thickness maps).
		B-Scan Flow	Shows or hides an overlay depicting blood flow on the B-scan image: ■ **1 color**: shows all aspects of the flow in light red. ■ **2 color**: – light red shows flow data above the RPE. – green shows flow data below the RPE.
		Segmentation Lines	Shows or hides magenta lines that indicate top and bottom layers of slabs.

9.3.3.1.2 Analyze Angiography Change

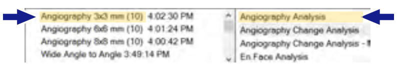
To analyze angiography change:

Prerequisite

☑ You are logged in (review station or instrument): Login [▹ 123].

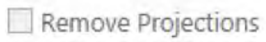
☑ The patient has at least one angiography scan: (Acquire an OCT Angiography Scan [▹ 163]).

Action

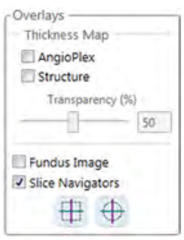


1. Select the patient and click **Analyze**.
2. Under OD or OS, select a **Angiography** scan and select **Angiography Analysis**.
   ⇨ The analysis opens.
3. Select a preset (About Analysis Presets [▹ 313]).
   ⇨ The selected slab opens in **Slab**, **Structure**, and **B-scan** views.
4. To view **AngioPlex Metrix**, select the **Superficial** slab.
5. To view **AngioPlex Metrix** for a different part of the image or a different cube slice, select the part image you want to measure.
   ⇨ **AngioPlex Metrix** recalculates measurements based on the new selection.
6. To view a full-screen image, double-click on the image.

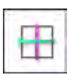
7. To overlay the B-scan image with flow data, check **Show** under **B-Scan Flow** .
   ⇨ Select **1 color** to show all flow data in red or select **2 color** to show areas above the RPE in light red and below the RPE in green.
8. To show the layer segmentation lines over the B-scan image: under **Segmentation Lines** , check **Show**.
   ⇨ Dashed magenta lines show the layer boundaries over the B-scan.
9. To adjust a layer boundary, refer to: Offset Preset Layer Boundaries [▸ 314].
   ⇨ The **AngioPlex** and **Structure** images update to match the adjusted layer boundary.



10. To remove image artifacts such as decorrelation tails, check **Remove Projections**.
11. To adjust image brightness or contrast, right-click on the image and select **Brightness/Contrast**.
12. To show a color image, right-click on the image and select **Color**.
13. To hide the image, right-click on the image and select **Hide**.
14. To exit any editing mode and save the changes, right-click on the image and select **Normal**.



15. To show the thickness map over the angiography image, check **AngioPlex**.
16. To show the thickness map over the structure image, check **Structure**.
    ⇨ **NOTE! You cannot use segmentation lines on an image showing a thickness map.**
17. To adjust the transparency of the thickness map(s), increase or decrease **Transparency**.
18. To show the fundus image over the AngioPlex and Structure images, check **Fundus Image**.
19. To turn on slice navigators that allow you to navigate the cube layers, check **Slice Navigators**. See: Navigate Cube Layers Manually [▸ 226].
    ⇨ Cyan (fast B-scans) and magenta (slow B-scans) navigators show over both AngioPlex and Structure images.



20. To set the navigators to the center of the image, click **Center**.

21. To center the navigators to the middle of the ONH, click **Center ONH**.
    ⇨ The slice navigation lines move to the center of the grid.
22. To print, save, or export a report, see: Creating a Report [▸ 384].

9.3.4 Analyze ONH Angiography Images

Before analyzing an ONH Angiography image, re-assess scan quality, segmentation errors, and decorrelation tails.

ONH Angiography Analysis is available for the following scans:

- ONH Angiography 4.5 x 4.5 mm

9.3.4.1 ONH Angiography Presets

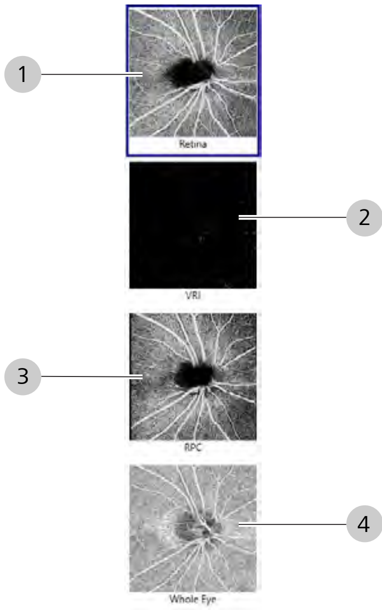
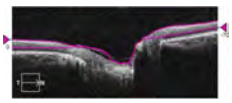
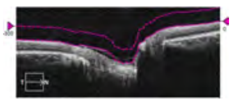
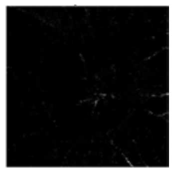


Figure 70: ONH Angiography Presets and Boundaries

#	Slab	Features		Example
		Top Boundary	Bottom Boundary	
1		**Retina** Illustrates vasculature of the entire retina. The lower boundary is offset by 70 µm to minimize the contribution of the hyper-reflective RPE.		
		ILM	RPE fit – 70µm	
2		**VRI** Highlights disorders of the VRI such as epiretinal membranes (ERM) and vitreomacular traction (VMT). ■ Bright areas may indicate vitreous attachments. ■ Variations in the background intensity may indicate macular pucker.		
		ILM - 300 µm	ILM	
3		**Retina Depth Encoded** Color encoded slab with different colors representing different layers (Red: Superficial; Green: Deep; Blue: Avasculature).		
		ILM	RNFL	

#	Slab	Features		Example
		Top Boundary	Bottom Boundary	
4		**Whole Eye** Illustrates the vasculature of entire posterior segment, including vitreous, retina and choroid.		

- ILM = *Inner Limiting Membrane*
- RNFL = *Retinal Nerve Fiber Layer*

9.3.4.2 Analyze ONH Angiography

To analyze ONH angiography images:

Prerequisite

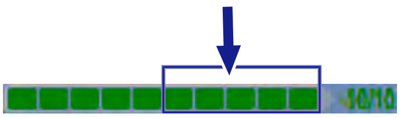
☑ You are logged in (review station or instrument): Login [▸ 123].

☑ The patient has at least one ONH Angiography scan (Acquire an AngioPlex ONH Scan [▸ 169]).

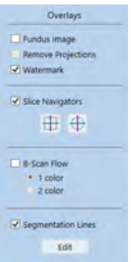
Action

1. Select the patient and click **Analyze**.
2. Under OD or OS, select an **ONH Angiography 4.5 x 4.5mm** scan and select **ONH Angiography Analysis**.
   ⇨ The analysis opens.

3. To create custom slab presets or rearrange, hide or show existing presets, click **Organize Presets** (see: Organize AngioPlex Presets [▸ 314]).



4. Select a preset (About Analysis Presets [▸ 313]).
   ⇨ The selected slab opens in **Slab**, **Structure**, and **B-scan** views.
5. Ensure that the **Signal Strength** is 6 or higher.
6. To view or edit a full-screen image, double-click on the image.



7. To show the fundus image over the AngioPlex and Structure images, check **Fundus Image**.
8. To remove image artifacts such as decorrelation tails, check **Remove Projections**.
9. To turn on slice navigators that allow you to navigate the cube layers, check **Slice Navigators**. See: Navigate Cube Layers Manually [▸ 226].
   ⇨ Cyan (fast B-scans) and magenta (slow B-scans) navigators show over both AngioPlex and Structure images.
   ⇨ The slice navigation lines move to the center of the grid.
10. To overlay the B-scan image with flow data, check **B-scan Flow** and select **1 color** or **2 color**.
    ⇨ Select **1 color** to show all flow data in red or select **2 color** to show areas above the RPE in light red and below the RPE in green.

11. To show layer segmentation lines over the B-scan image, check **Segmentation Lines**.
    - ⇨ Dashed magenta lines show the layer boundaries over the B-scan.

12. To set the navigators to the center of the image, click **Center**.
13. To adjust a layer boundary, refer to: Offset Preset Layer Boundaries [▸ 314].

14. To export the all images, click **Export**.
15. To edit or adjust the image, hover over the image and select an adjustment tool (refer to: Edit Images (Hover Over) [▸ 370].
16. To view a full-screen image, double-click on the image.
17. To print, save, or export a report, see: Creating a Report [▸ 384].

9.3.5 Compare ONH Angiography Images

9.3.5.1 ONH Angiography Change Analysis

ONH Angiography Change Comparison Analysis allows you to view any two ONH angiography scans from a patient’s history to visualize changes in vasculature.

This analysis is available for the following scans:

- ONH Angiography 4.5mm x 4.5 mm

9.3.5.1.1 ONH Angiography Change Analysis

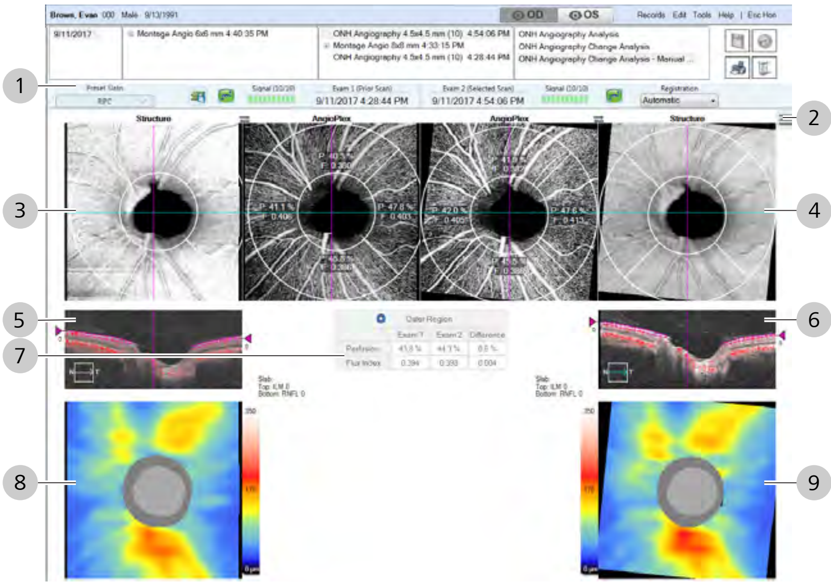
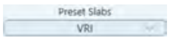
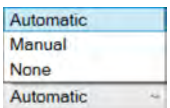
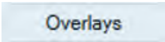
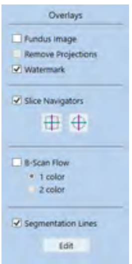
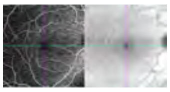
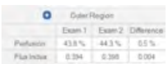
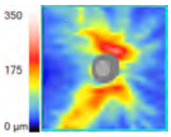


Figure 71: ONH Angiography Change Comparison Overview

#	Symbol	Name	Explanation
1	**Tools and Indicators**		
		Preset Slabs	Selects the slab to view.
		FastTrac Indicator	Green indicates the scan was acquired with FastTrac **on**.
		Signal Strength	Indicates scan quality level; more green indicates a higher quality image.
	Prior Scan and Selected Scan	Exam 1 and Exam 2	Indicates the **Date** and **Time** each image was acquired.
		Registration	Indicates whether images are aligned to each other.
		Advanced Export	Exports images and thickness values.

#	Symbol	Name	Explanation
2	**Overlays**		
		Overlay Slider	Opens the overlay panel.
		**Fundus Image**	Check **Fundus** to overlay fundus image (instead of thickness maps).
		Remove Projections	Check to remove projections.
		Slice Navigators	Shows or hides slice navigators on slab and structure images.
		B-Scan Flow	Shows or hides an overlay depicting blood flow on the B-scan image: ■ **1 color**: shows all aspects of the flow in light red. ■ **2 color**: – light red shows flow data above the RPE. – green shows flow data below the RPE.
		Segmentation Lines	Shows or hides magenta lines that show the upper and lower boundary in the B-scans.
2		Prior Images	Shows the slab and the structure for the earlier image.
3		Selected Images	Shows the slab and the structure for the selected image.
7		Comparison Table	Shows the measurement differences between the two visits.
8		Prior Image Heat Map	RNFL thickness map.
9		Current Image Heat Map	

9.3.6 Analyze Montage AngioPlex Images

Wide-field montage images increase the Field of View (FOV) to produce high-resolution vascular imaging over a larger region of the retina.

Montage Angiography Analysis is available for the following scans:

- Montage AngioPlex 6x6mm
- Montage AngioPlex 8x8mm

9.3.6.1 Montage AngioPlex Analysis

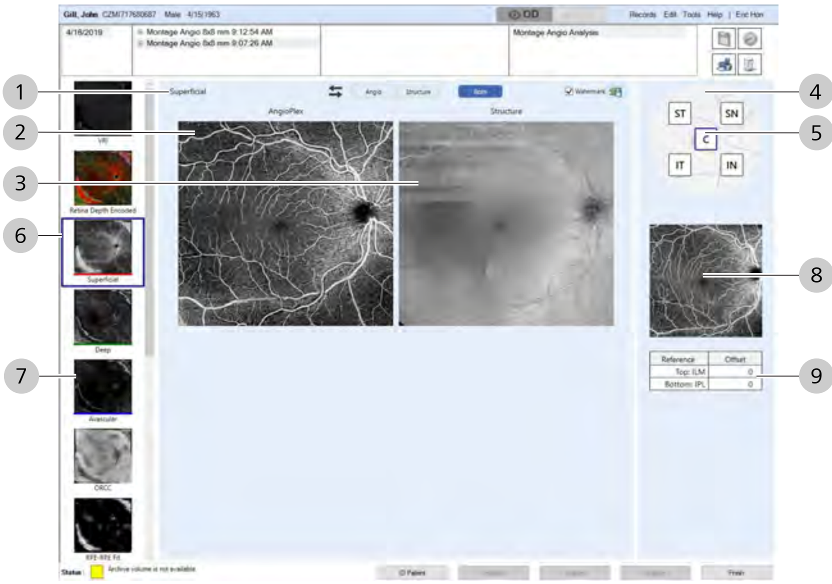
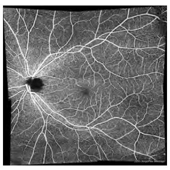
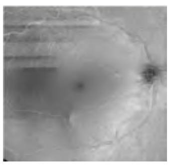
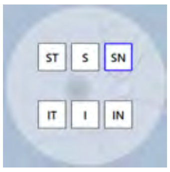
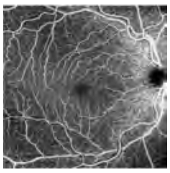
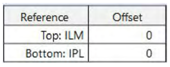


Figure 72: Montage Angiography Analysis Overview

#	Symbol	Name	Explanation
1	**Toolbar**		
		Toggle	Toggles between showing the **AngioPlex** and **Structure** image.
	Angio	**Angio**	Shows or hides the **AngioPlex** image.
	Structure	**Structure**	Shows or hides the **Structure** image.
	Both	**Both**	Shows both the**AngioPlex** and **Structure** images.
	☑ Watermark	Watermark	Turns on or off the watermark.
		Advanced Export	Exports maps of the ILM layer to RPE layer thickness values.
2		AngioPlex Image	Displays the **AngioPlex** image of the selected slab.
3		Structure Image	Displays the **Structure** image of the selected slab.

#	Symbol	Name	Explanation
4		Scan Positions	Shows the positions of the individual images that make up the montage. Select a position to view its thumbnail.
5	Selected Image	Blue outline indicates selected image.	
6	Selected Presets	Outlined in blue.	
7	Presets	Preset slabs (see:Angiography Presets [▷ 320]).	
8		Thumbnail	Thumbnail of the individual image.
9		Slab Boundaries	Shows the top and bottom boundaries for the selected slab preset.

9.3.6.2 Analyze an Angiography Montage Image

To analyze a montage image:

Prerequisite

☑ You are logged in (review station or instrument): Login [▷ 123].

☑ The patient has at least one montage angiography scan (Acquire AngioPlex Montage Scans [▷ 171]).

Action

1. Under OD or OS, select a **Montage** scan and select **Montage Angio Analysis**.

   ⇨ The **Montage Angio Analysis** opens.

2. Select a preset (About Analysis Presets [▷ 313]).

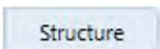
   ⇨ The selected slab opens in **AngioPlex** and**Structure** views.

Reference	Offset
Top: ILM	0
Bottom: IPL	0

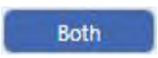
3. To view the boundaries of the selected slab, refer to the table.
4. To view a full-screen image, double-click on the image.

5. To switch the positions of the AngioPlex and Structure images, click the arrows toggle.

6. To view the AngioPlex image only, click **Angio**.

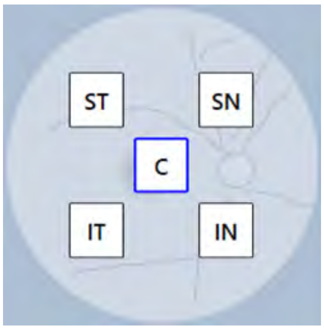


7. To view the Structure image only, click **Structure**.



8. To view both AngioPlex and Structure images, click **Both**.

9. To export all montage images, click **Export**.



10. To view a thumbnail of an individual image from the montage, click on the position of the image.
    ⇨ The thumbnail under the selector shows the image of the selected position.
11. To analyze an individual image that makes up the montage, expand the montage, select the image and analysis you want to use.
12. To edit or adjust the image, hover over the image and select an adjustment tool (refer to: Edit Images (Hover Over) [▸ 370].
13. To view a full-screen image, double-click on the image.
14. To print, save, or export a report, see: Creating a Report [▸ 384].

9.4 Analyze Anterior Segment Scans

Typical Applications	Anterior Chamber	Anterior Segment Cube	5-Line Raster	HD Angle	Wide Angle to Angle	HD Cornea	Pachymetry
Measure Iridocorneal Angles	X Most accurate angle measurement	-	X	X Highest resolution and greatest detail of individual angle	X Both angles in one image	-	-
Measure additional angles	X	-	-	-	-	-	-
Measure anterior chamber depth, angle-to-angle distance	X	-	-	-	-	-	-
Measure angle-to-angle distance	X				X		
Measure lens vault	X						
Measure corneal thickness	X	X	X			X	X
Measure central corneal thickness	X	X				X	X
Measure angle to angle distance	X				X		
Navigate through slices horizontally and vertically	-	X	-	-	-	-	-
Measure corneal tissue and anterior segment structures below the cornea (vertically)			X			X	

Typical Applications	Anterior Chamber	Anterior Segment Cube	5-Line Raster	HD Angle	Wide Angle to Angle	HD Cornea	Pachymetry
View a color-coded thickness map of the cornea *with detailed thickness measurement data*	-	-	-	-	-	-	X
View color-coded thickness map of the corneal epithelium *with detailed thickness measurement data*							X

9.4.1 About Analyzing Anterior Segment Scans

Anterior segment reports do not include customization or additional options.

Many anterior segment scans are optional (see: About Licenses [▹ 61]).

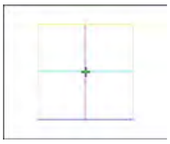
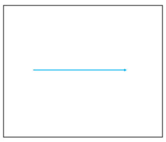
<table>
<tr><th>Scan Pattern</th><th>External Lens</th><th>Scan</th><th>Analysis</th></tr>
<tr><td colspan="4">Anterior Segment Scans</td></tr>
<tr><td></td><td>-</td><td>Anterior Segment Cube</td><td>■ Anterior Segment Analysis
■ 3D Visualization</td></tr>
<tr><td></td><td>-</td><td>Anterior Segment 5 Line Raster</td><td>High Definition Images</td></tr>
<tr><td rowspan="4"></td><td>-</td><td>HD Angle</td><td>HD Angle Analysis</td></tr>
<tr><td rowspan="2">
</td><td>Anterior Chamber</td><td>Anterior Chamber Analysis</td></tr>
<tr><td>Wide Angle-to-Angle</td><td>Wide Angle-to-Angle Analysis</td></tr>
<tr><td rowspan="2">
</td><td>HD Cornea</td><td>HD Cornea Analysis</td></tr>
<tr><td></td><td>Pachymetry</td><td>Pachymetry Analysis</td></tr>
</table>

Table 76: Anterior Segment Scans

9.4.2 About Central Corneal Thickness Measurement

Some conditions make it more difficult to obtain an image that measures Central Corneal Thickness (CCT) accurately, including:

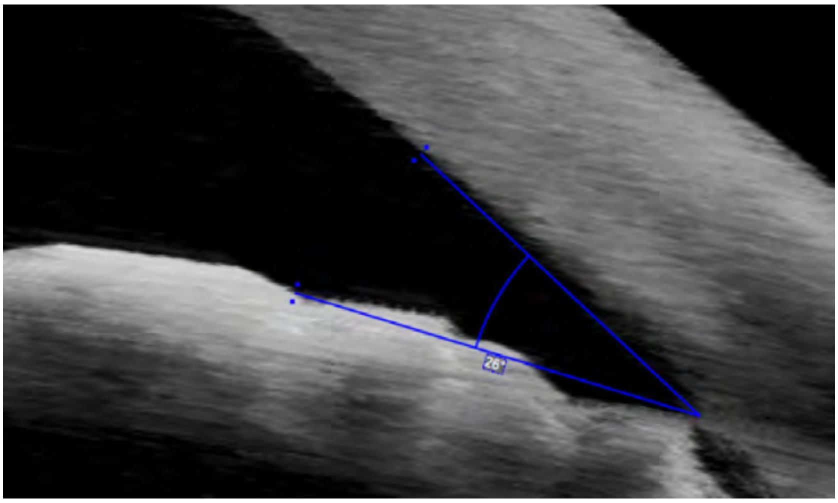
- Patient wearing contact lenses (obscuring the junction of contact lenses and the corneal surface).
- Patient with poor visual acuity (cannot maintain fixation).
- Patient with intraocular lenses, corneal abrasions or corneal opacities that cause excessive corneal reflection.
- Have the patient remove contact lenses.
- Use **HD Cornea** and **Anterior Chamber** scans to measure CCT more easily.

9.4.3 About Angle Measurement

There are two types of tools that measure angles: **Angle** tools and **IC Angle** tools.

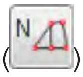
Angle Tools

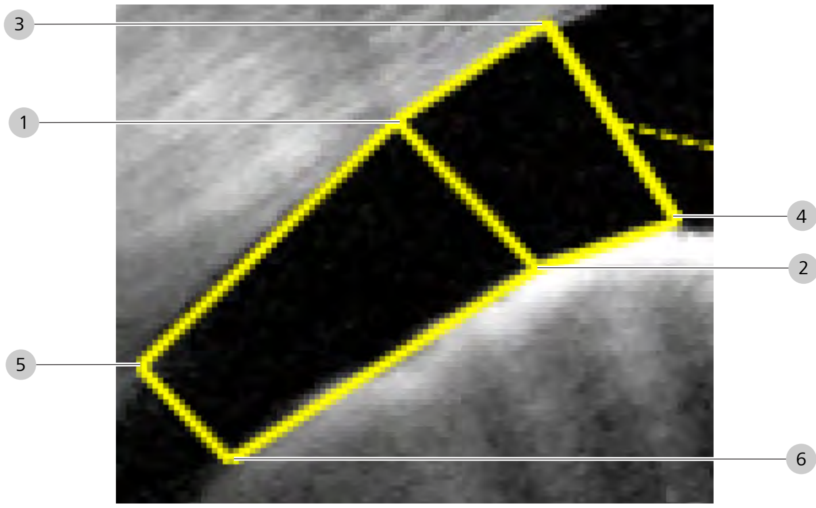
Left Angle tool () and **Right Angle** tool () allow you to place three points over an image and measure the angle.

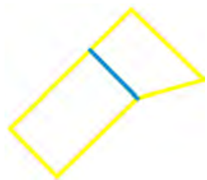
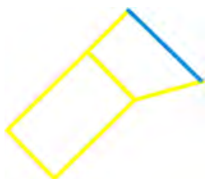


When you place an angle tool, place the intersection at the scleral spur and the other two points at the corneal endothelium and iris. CIRRUS™ HD-OCT calculates the angle.

IC Angle Tools

IC Left Angle tool () and **IC Right Angle** tool () allow you to place multiple points over an image to measure additional aspects of the angle.



	**AOD500**	Angle Opening Distance at 500 mm (Distance between 1 and 2)
	**AOD750**	Angle Opening Distance of 750mm (Distance between 3 and 4)
	**TISA500**	Trabecular Iris Space Area 500 (mm^2) (Area of the polygon that joins points 1, 2, 5, and 6)
	**TISA750**	Trabecular Iris Space Area 750 (mm^2) Area of the polygon that joins points 1, 2, 5, and 1, 3, 4, 2.
	SSA	Scleral Spur Angle: (Angle formed by 1, 5, and 2)

9.4.4 Analyze Anterior Chamber Scans

Anterior Chamber analysis is only available for Anterior Chamber Cube Scans [▷ 184], which produce a 512 x 128 image 20 B-scans comprised of 1024 A-scans across the center of the eye at the depth of 5.8 mm.

Using this analysis you can measure:

- anterior chamber depth
- central corneal thickness
- left or right angles
- corneal tissues
- anterior chamber structures

You can also view and navigate through the slices of any cube scan as a three-dimensional image (see: 3D Visualization Analysis [▷ 289]).

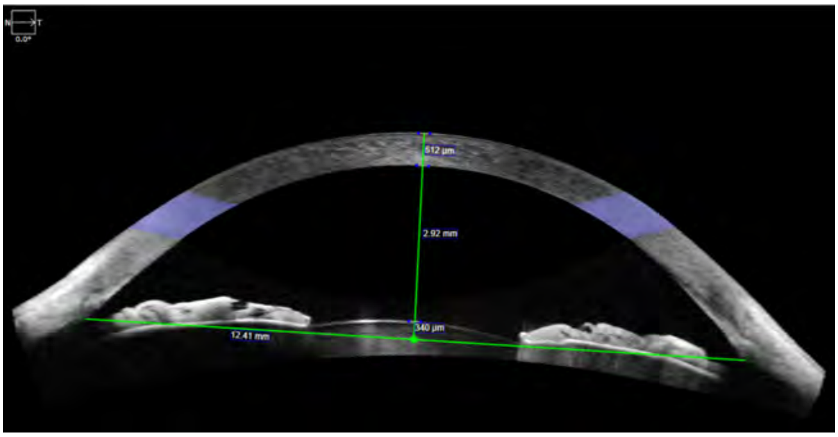
9.4.4.1 Anterior Chamber Depth Tool

NOTE

You can place the Anterior Chamber Depth Tool in any position on the image.

Although this tool is designed to facilitate routine measurements, you can place the endpoints in other locations to measure different structures.

When you place the **Anterior Chamber Depth Tool**, the cornea caliper automatically positions itself to the cornea aligned to the anterior and posterior (corneal vertex) surfaces.



You can drag the caliper along the cornea to adjust its position. Once you drag the endpoints into each angle and the base line to the anterior surface of the crystalline lens, CIRRUS™ HD-OCT automatically calculates and displays measurements for:

- corneal thickness
- angle-to-angle distance

- anterior chamber depth
- lens vault

NOTE! For eyes with aphakia or pseudophakia, drag the base line to the pupillary plane.

9.4.4.2 Anterior Chamber Analysis

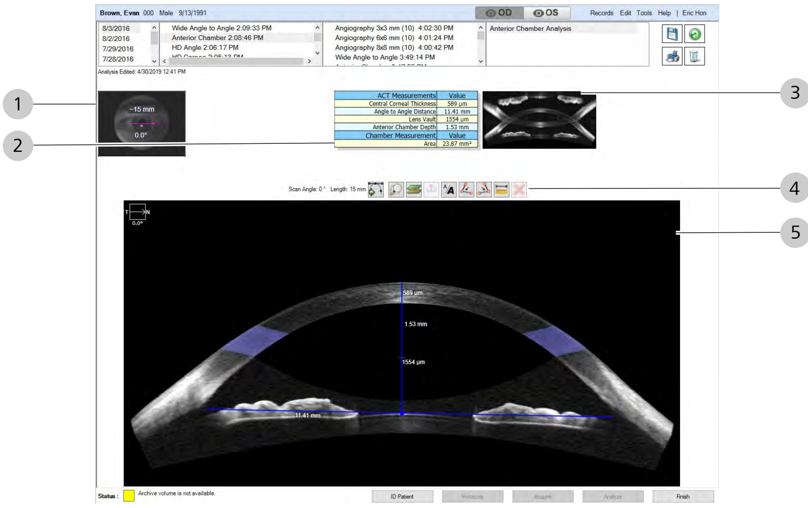
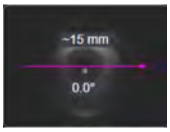
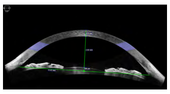


Figure 73: Anterior Chamber Analysis Overview

#	Symbol	Name	Explanation
1		Iris Image	Shows the scan pattern over the iris image and indicates the rotation direction set during acquisition.
2		Angle Measurements	(See: About Angle Measurement [▸ 340]).
3		Mirror Image Preview	Shows a thumbnail image with the corneal mirror image.
2	**Toolbar**		
		Raw / Processed Image	Toggles between the raw acquired image and the processed (corrected) image.
		Show / Hide Mirror Images	Shows or hides the corneal mirror image.
		Show / Hide Layers	Overlays lines to indicate: ■ **Green**: anterior cornea ■ **Red**: posterior cornea ■ **Magenta**: residual stromal line
		Anterior Depth Tool	(See: Anterior Chamber Depth Tool [▸ 342]).

#	Symbol	Name	Explanation
		Annotate Image	Adds your notes onto the image.
		Right Angle Measurement Tool	(See: About Angle Measurement [▸ 340]).
		Left Angle Measurement Tool	
		Caliper	Adds a measurement line.
		Delete	Deletes an angle or caliper measurement line.
5		B-Scan	(See: Anterior Chamber Depth Tool [▸ 342]).

9.4.4.3 Analyzing Anterior Chamber Scans

NOTE

The Anterior Chamber Angle measurements are not intended as a substitute for gonioscopy, which is the current reference standard for evaluating the anterior chamber angle configuration.

During gonioscopy the operator can dynamically view the mirror/prism to examine full extent of the angle.

The **Anterior Chamber Depth** analyzes a single location.

NOTE

The Anterior Chamber scan uses a full axial field of view to display both the true image data and an inverted mirror artifact.

Even if you hide the mirror image, distinct bars remain where the mirror intersect the image.

To see these parts of the cornea, use the HD Cornea scan.

When you place the **Anterior Chamber Depth**, CIRRUS™ HD-OCT displays the measurements over the image and in the summary table.

Prerequisite

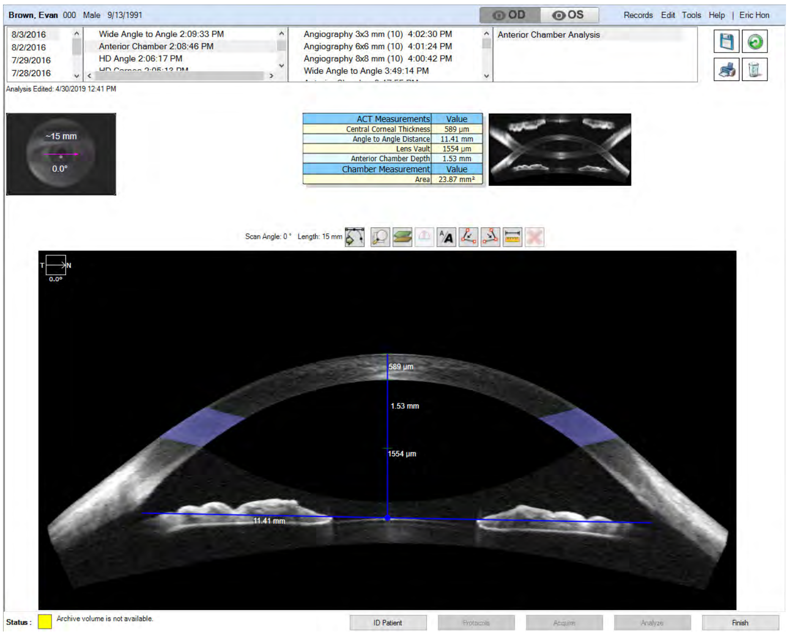
☑ The patient has at least one Anterior Chamber scan: (Anterior Chamber Scans [▸ 184])

☑ You are logged in (review station or instrument): Login [▸ 123].

Action

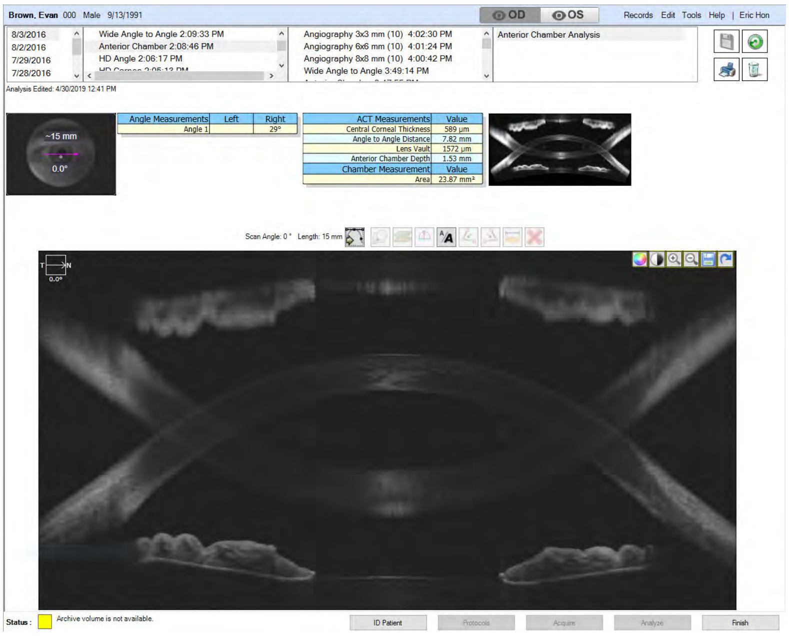
1. Select the patient and click **Analyze**.
2. Under OD or OS, select an **Anterior Chamber** scan and select **Anterior Chamber Analysis**.

   ⇨ The **Anterior Chamber** analysis opens.



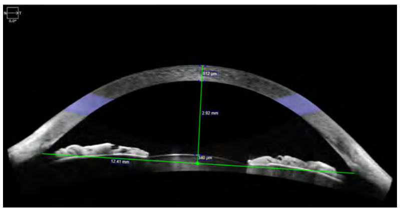
3. To view the raw (unprocessed) image, click **Raw / Processed Image**.

4. To view the mirror image, click **Show / Hide Mirror**.
   ⇨ The mirror image appears on the image.



5. To show the layer lines for cornea anterior and posterior surfaces and the residual stromal line, click **Hide / Show Layers**.
   ⇨ Layer lines indicate: **Green**: anterior cornea; **Red**: posterior cornea; **Magenta**: residual stromal line.

6. Click the **Anterior Chamber Depth** tool.



⇨ The tool opens with the corneal caliper aligned to the top and bottom surfaces of the cornea at the posterior vertex.

7. To adjust the corneal caliper, drag the caliper along the cornea.
8. Drag the base line to the anterior surface of the crystalline lens. **NOTE! For eyes with aphakia or pseudophakia, drag the base line to the pupillary plane.**

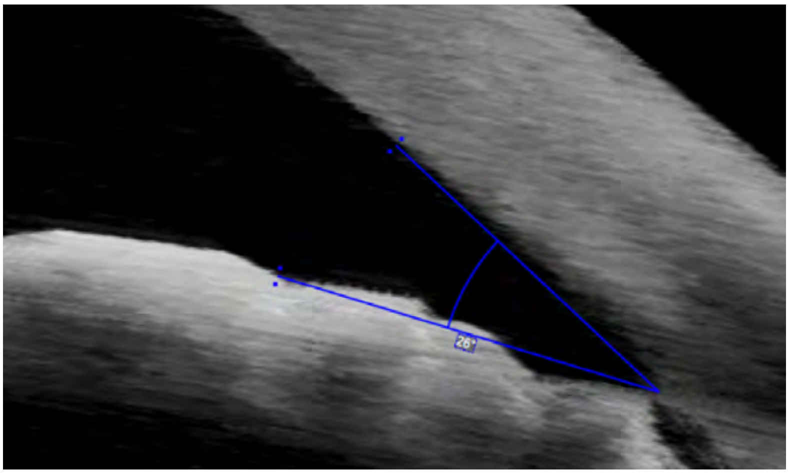
   ⇨ CIRRUS™ HD-OCT calculates and displays the anterior chamber depth and lens vault.

9. Drag the endpoints of the base line into each angle.

   ⇨ CIRRUS™ HD-OCT calculates and displays the angle-to-angle distance.

10. To add a text annotation to the image, click **Annotate** and type text.

    ⇨ You can change the color and size of the text or move it somewhere else in the image (see: Add Annotations to Images [▷ 377]).



11. To place an angle measurement, click (right or left) **Angle Tool** and place the intersection at the scleral spur and the other two points at the corneal endothelium and iris.

    ⇨ CIRRUS™ HD-OCT calculates the angle.

12. To add a caliper, click **Caliper**.

    ⇨ A caliper measurement appears over the image. You can move, stretch, and rotate calipers. You can add (up to) ten.

13. To delete a measurement or annotation, select it and click **Delete**.
14. To edit or adjust the image, hover over the image and select an adjustment tool (refer to: Edit Images (Hover Over) [▷ 370].
15. To view a full-screen image, double-click on the image.

16. To print, save, or export a report, see: Creating a Report [▷ 384].

9.4.5 Analyze Anterior Segment Cube Scans

The **Anterior Segment Analysis** is the only analysis available for the Anterior Segment Cube [▷ 188] scan.

The **Fast B-scan** displays above the **Slow B-scan**.

9.4.5.1 Anterior Segment Cube Analysis

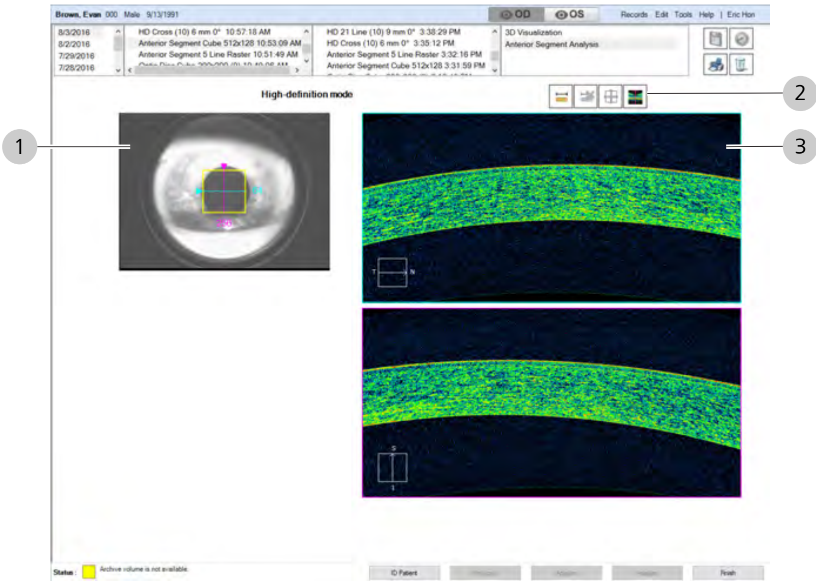
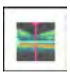
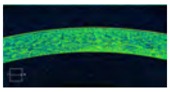
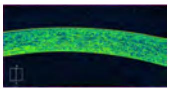


Figure 74: Anterior Segment Cube Overview

#	Symbol	Name	Explanation
1		Iris	Displays the iris, scan area (yellow square) and scan pattern placement.
2	**Toolbar**		
		Caliper	Adds a measurement line.
		Delete Measurement	Deletes a measurement line added with the caliper tool.
		Snap to Center	Moves the slice navigators to the center of the 6x6 mm square.
		Show / Hide High-Resolution Images	Displays the high-resolution scans or standard-resolution scans. **NOTE! The ETDRS Grid does not change position when the High–Resolution image is displayed.**

#	Symbol	Name	Explanation
3		Horizontal B-Scan	
		Vertical B-scan	

9.4.5.2 Analyzing Anterior Segment Cube Scans

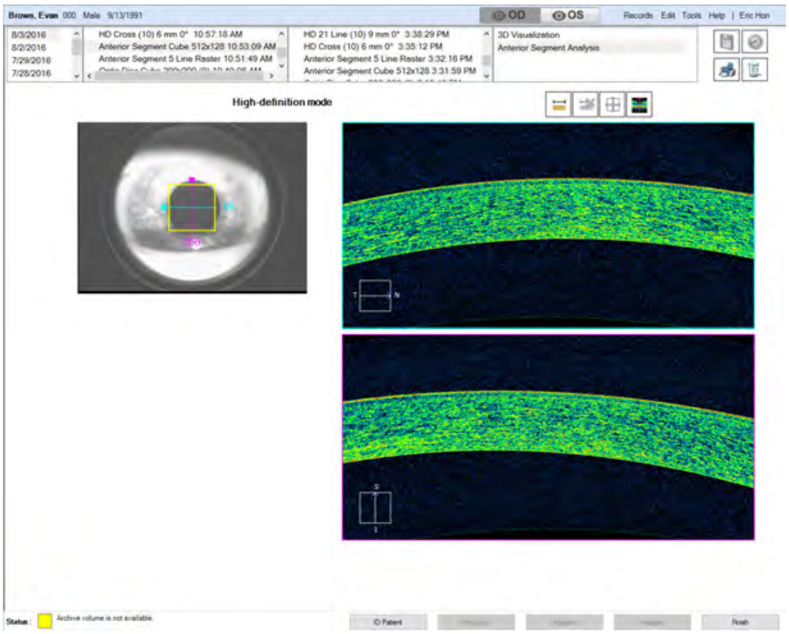
Prerequisite

☑ The patient has at least one Anterior Segment Cube scan: (Anterior Segment Cube [▷ 188]).

☑ You are logged in (review station or instrument): Login [▷ 123].

Action

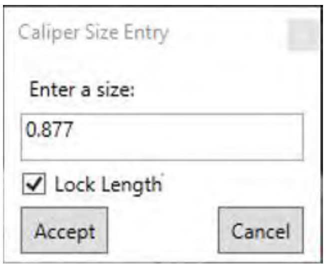
1. Select the patient and click **Analyze**.
2. Under OD or OS, select an **Anterior Segment Cube** scan and select **Anterior Segment Cube Analysis**



⇨ The **Anterior Segment Cube** analysis opens.

3. To add a caliper, click **Caliper**.

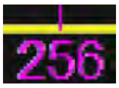
⇨ A caliper measurement appears over the image. You can move, stretch, and rotate calipers. You can add (up to) ten.



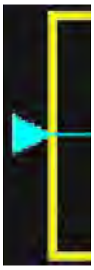
4. To lock the length of the caliper, right-click on the caliper to open its settings, check **Lock Length** and click **Accept**.

5. To delete a caliper, click **Delete**.

6. To navigate through the vertical slices of the cube, click on the magenta triangle and drag the line right or left.



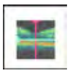
   ⇨ The current slice number changes dynamically as you navigate through slices.



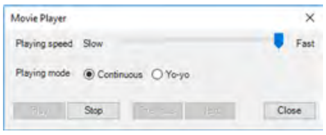
7. To navigate through the horizontal slices of the cube, click on the cyan triangle and drag the line up or down.

   ⇨ The current slice number changes dynamically as you navigate through slices.

8. To set the navigators to the center of the image, click **Center**.



9. To show or hide the high-resolution image, click **HD**.
   ⇨ The image toggles between the original resolution and high resolution versions.



10. To open movie tools, right-click on the image and select **Movie**.
    ⇨ The movie player opens and automatically scrolls through the slices. For more information about these controls, refer to: Navigate Through Cube Slices as a Movie [▹ 389].
11. To edit an image, right-click to access the edit menu (see: Editing Images Using the Menu [▹ 369]).
12. To view a full-screen image, double-click on the image.
13. To print, save, or export a report, see: Creating a Report [▹ 384].

9.4.6 Analyze HD Angle Scans

NOTE

Features described in this section are licensed separately and may not be available in all markets.

▶ For information about feature availability in your market and obtaining a license:

   ⇨ in the U.S.A, call 1-877-486-7473.

   ⇨ outside the U.S.A , contact your local ZEISS distributer.

9.4.6.1 HD Angle Analysis

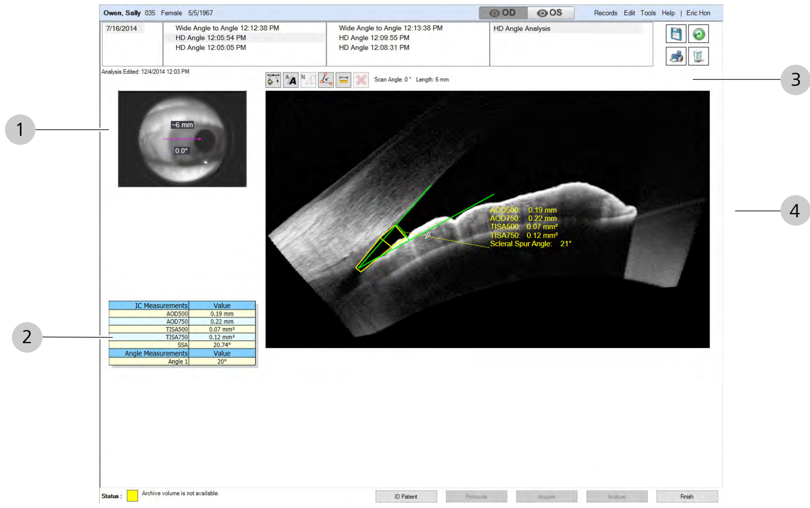
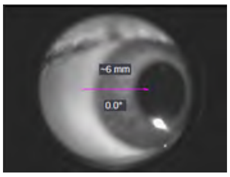
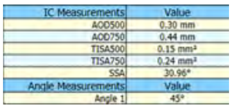
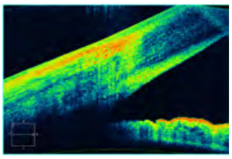


Figure 75: HD Angle Analysis Overview

Pos.	Symbol	Name	Explanation
1		Iris Image	Shows the scan pattern over the iris image and indicates the rotation direction set during acquisition.
2	 IC Measurements Value AOD500 0.30 mm AOD750 0.44 mm TISA500 0.15 mm² TISA750 0.24 mm² SSA 30.96° Angle Measurements Value Angle 1 45°	Angle Measurements	(See: About Angle Measurement [▸ 340]
3	**Toolbar**		
		Dewarp	Shows the curvature-adjusted image or the original (flat) image.
		Annotate Image	Adds your notes onto the image.
		IC Angle Measurement Tool	(See: About Angle Measurement [▸ 340]).
		Angle Measurement Tool	
		Caliper	Adds a measurement line.
		Delete	Deletes an angle or caliper measurement line.

Pos.	Symbol	Name	Explanation
4		Angle Image	Editing Options: ■ View Images in Full-Screen Mode [▸ 373] ■ Adjust Image Brightness [▸ 373] ■ Adjust Image Contrast [▸ 374] ■ Zoom In and Out [▸ 378] ■ Save Edited Images [▸ 381] ■ Reset Edited Images [▸ 379]

9.4.6.2 Analyze an HD Angle Scan

Editing available for the **HD Angle** images:

- View Color or Grayscale Image [▸ 375]
- Adjust Image Brightness [▸ 373]
- Adjust Image Contrast [▸ 374]

Prerequisite

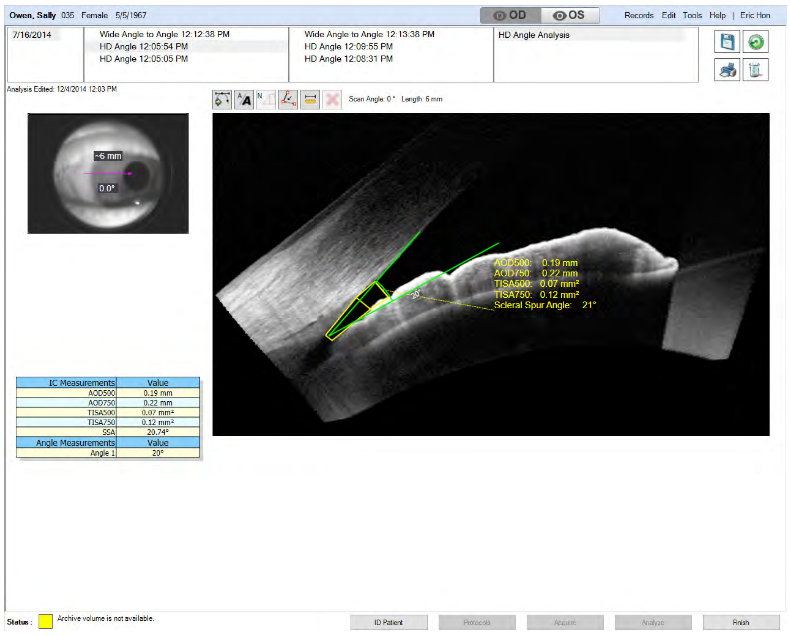
☑ The patient has at least one HD Angle scan: (HD Angle Scans [▸ 194])

☑ You are logged in (review station or instrument): Login [▸ 123].

Action

1. Select the patient and click **Analyze**.
2. Under OD or OS, select an **HD Angle** scan and select **HD Angle Analysis**.

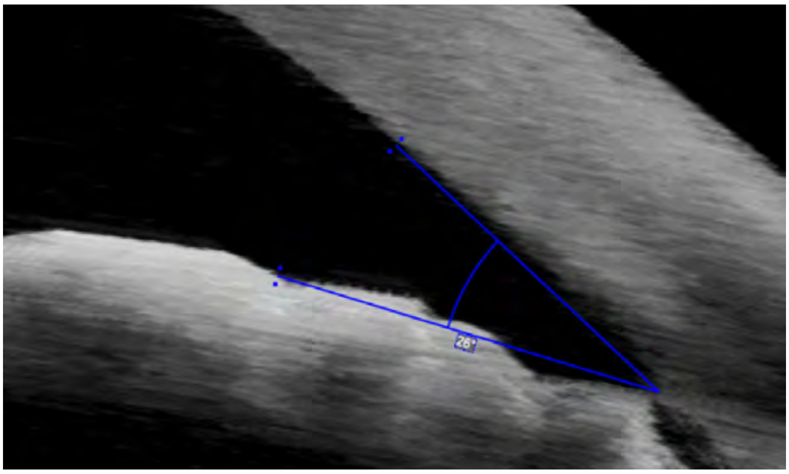
   ⇨ The **HD Angle** analysis opens.



3. To view the raw (unprocessed) image, click **Raw / Processed Image**.

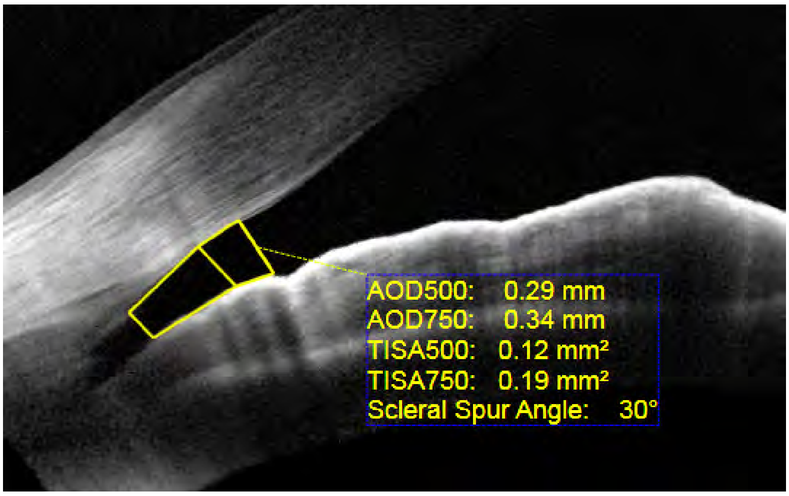
4. To add a text annotation to the image, click **Annotate** and type text.

⇨ You can change the color and size of the text or move it somewhere else in the image (see: Add Annotations to Images [▷ 377]).



5. To place an angle measurement, click (right or left) **Angle Tool** and place the intersection at the scleral spur and the other two points at the corneal endothelium and iris.

   ⇨ CIRRUS™ HD-OCT calculates the angle.



6. To place an iridocorneal angle measurement, click (right or left) **IC Angle Tool**, drag the trapezoid into position over the angle you want to measure and adjust the points to touch the corneal endothelium and iris.

   ⇨ CIRRUS™ HD-OCT calculates the measurements (see: About Angle Measurement [▷ 340]).

7. To add a caliper, click **Caliper**.

8. To delete a measurement or annotation, select it and click **Delete**.
9. To edit or adjust the image, hover over the image and select an adjustment tool (refer to: Edit Images (Hover Over) [▷ 370].
10. To view a full-screen image, double-click on the image.

11. To print, save, or export a report, see: Creating a Report [▷ 384].

Also see

🗎 HD Angle Scans [▷ 194]

9.4.7 Analyze HD Cornea Images

The **HD Cornea** scan helps you analyze the residual stromal bed on post-LASIK patients.

When acquiring the scan, the operator can rotate the scan pattern, but not change its length or central position.

9.4.7.1 HD Cornea Analysis Overview

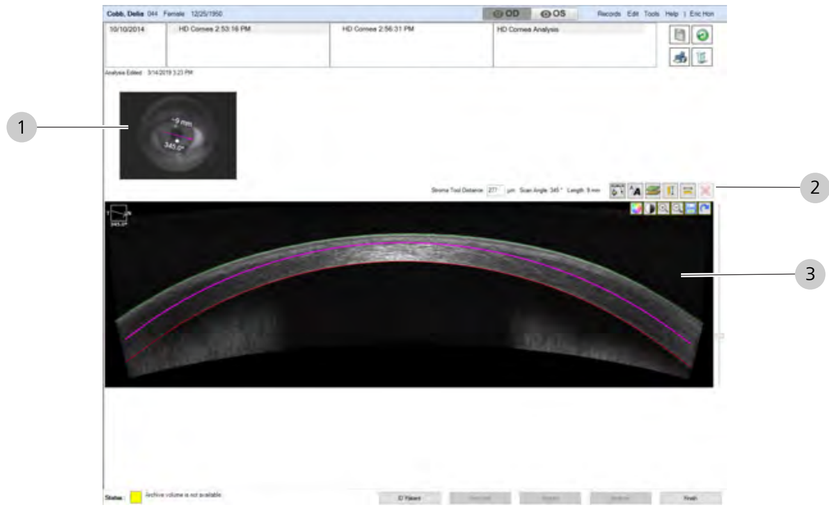
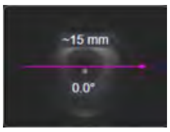
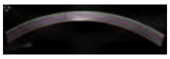


Figure 76: HD Cornea Analysis Overview

#	Symbol	Name	Explanation
1		Iris Image	Shows the scan pattern over the iris image and indicates the rotation direction set during acquisition.
2	**Toolbar**		
		Raw / Processed Image	Toggles between the raw acquired image and the processed (corrected) image.
		Annotate Image	Adds your notes onto the image.
		Show / Hide Layers	Overlays lines to indicate: ■ **Green**: anterior cornea ■ **Red**: posterior cornea ■ **Magenta**: residual stromal line

#	Symbol	Name	Explanation
		Cornea Caliper	Adds a measurement line across the cornea that snaps to the anterior and posterior corneal surfaces and slides along the corneal contour.
		Caliper	Adds a measurement line.
		Delete Measurement	Deletes a measurement line added with the caliper tool.
3		Cornea Image	Corneal layer lines show: ■ **Green**: anterior corneal surface ■ **Magenta**: adjustable residual stromal line (RSL) ■ **Red**: posterior corneal surface.

9.4.7.2 Analyze an HD Cornea Scan

HD Cornea Analysis is only available for HD Cornea Scans.

Tip: You can also move the pink line by typing a different value for "Stromal Tool Distance"

Editing available for the **HD Cornea** images:

- View Color or Grayscale Image [▸ 375]
- Adjust Image Brightness [▸ 373]
- Adjust Image Contrast [▸ 374]

To analyze an HD Cornea scan:

Prerequisite

☑ You are logged in (review station or instrument): Login [▸ 123].

☑ The patient has at least one HD Cornea scan: (Acquire HD Cornea Scans)

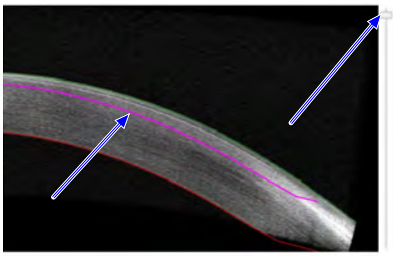
Action

1. Select the patient and click **Analyze**.
2. Under OD or OS, select an **HD Cornea** scan and select **HD Cornea Analysis**.
   ⇨ The **HD Cornea Analysis** opens.

3. To view the raw (unprocessed) image, click **Raw / Processed Image**.
   ⇨ You cannot add measurement calipers to the raw (unprocessed) image.

4. To add a text annotation to the image, click **Annotate** and type text.
   ⇨ You can change the color and size of the text or move it somewhere else in the image (see: Add Annotations to Images [▸ 377]).

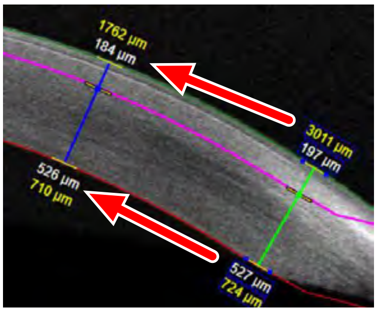
5. To show or hide the green, pink and red layer indicators, click **Show/Hide Layers**.



6. To adjust the residual stromal bed indicator (pink line) move the slider (right of the image) up or down.

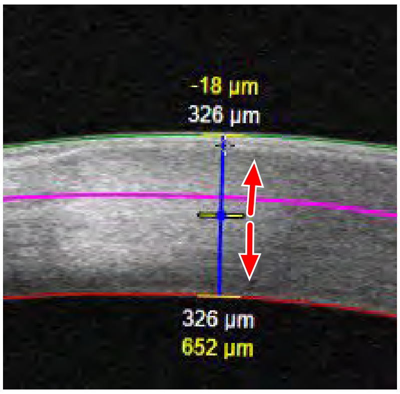
7. To add a corneal thickness measurement, click **Corneal Caliper**.

   ➩ A **Corneal Caliper** with an internal marker appears over the image. You can add (up to) ten.



8. To reposition the **Corneal Caliper**, select and drag it along the cornea.

   ➩ CIRRUS™ HD-OCT automatically detects the corneal surfaces and measures the thickness dynamically as you move the caliper along the cornea.



9. To move the internal measurement mark, click on it and drag it up or down.

   ➩ CIRRUS™ HD-OCT automatically measures (and displays) the following information:
   Horizontal distance from the center of the scan.

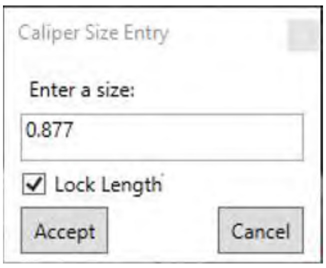
   Distance between the anterior corneal surface and the demarcation line.

   Distance between the demarcation line and the posterior corneal surface.

   Total corneal thickness.

10. To add a caliper, click **Caliper**.

   ➩ A caliper measurement appears over the image. You can move, stretch, and rotate calipers. You can add (up to) ten.



11. To lock the length of the caliper, right-click on the caliper to open its settings, check **Lock Length** and click **Accept**.

12. To delete a measurement or annotation, select it and click **Delete**.

13. To edit or adjust the image, hover over the image and select an adjustment tool (refer to: Edit Images (Hover Over) [▶ 370].
14. To view a full-screen image, double-click on the image.
15. To print, save, or export a report, see: Creating a Report [▶ 384].

9.4.8 Analyze Pachymetry Scans

Pachymetry Analysis uses the 24 radial scan lines of the Pachymetry scan to display a color-coded map of the cornea allowing you to measure corneal thickness variation.

9.4.8.1 Pachymetry Analysis

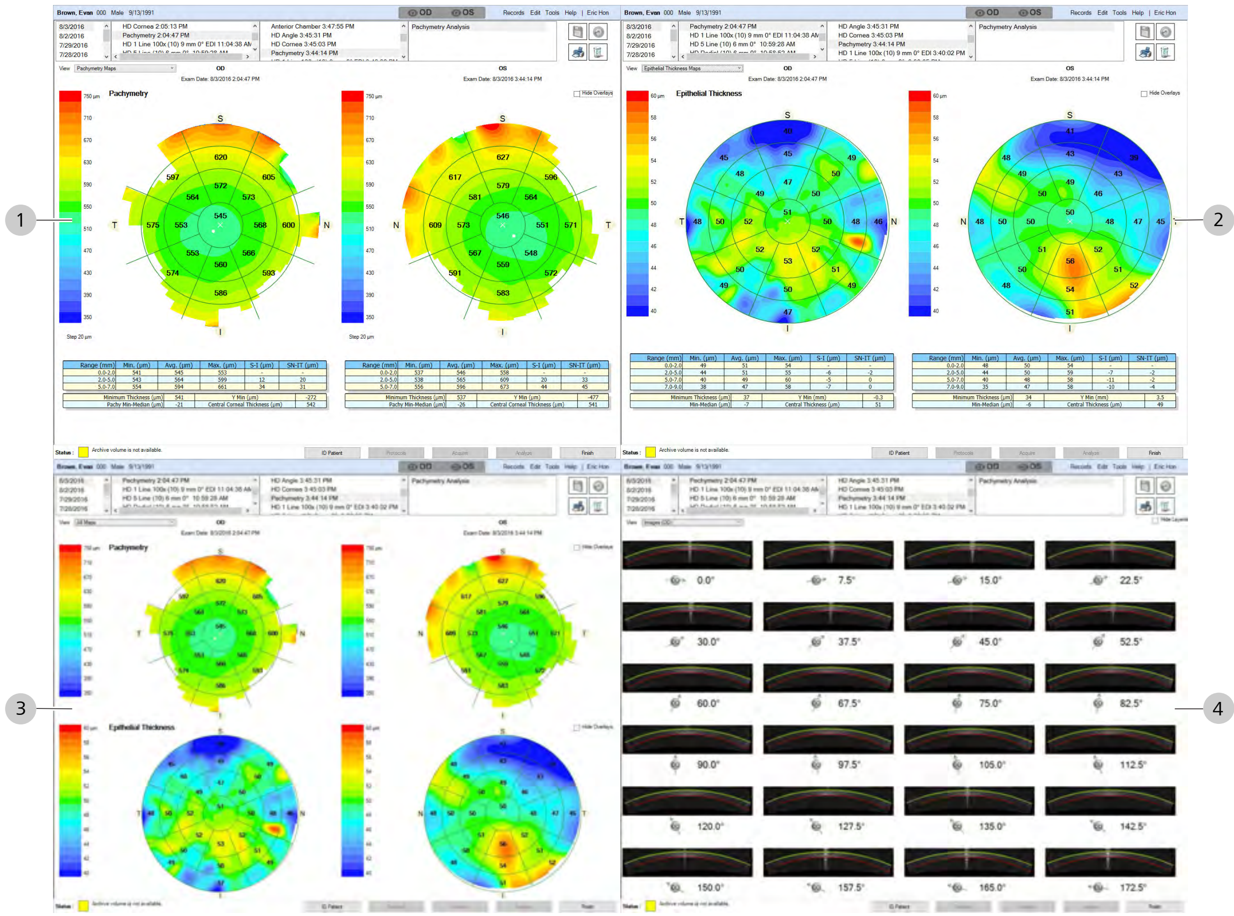


Figure 77: Pachymetry Analyses

1	Pachymetry Maps	2	Epithelial Thickness Maps
3	All Maps	4	OD or OS

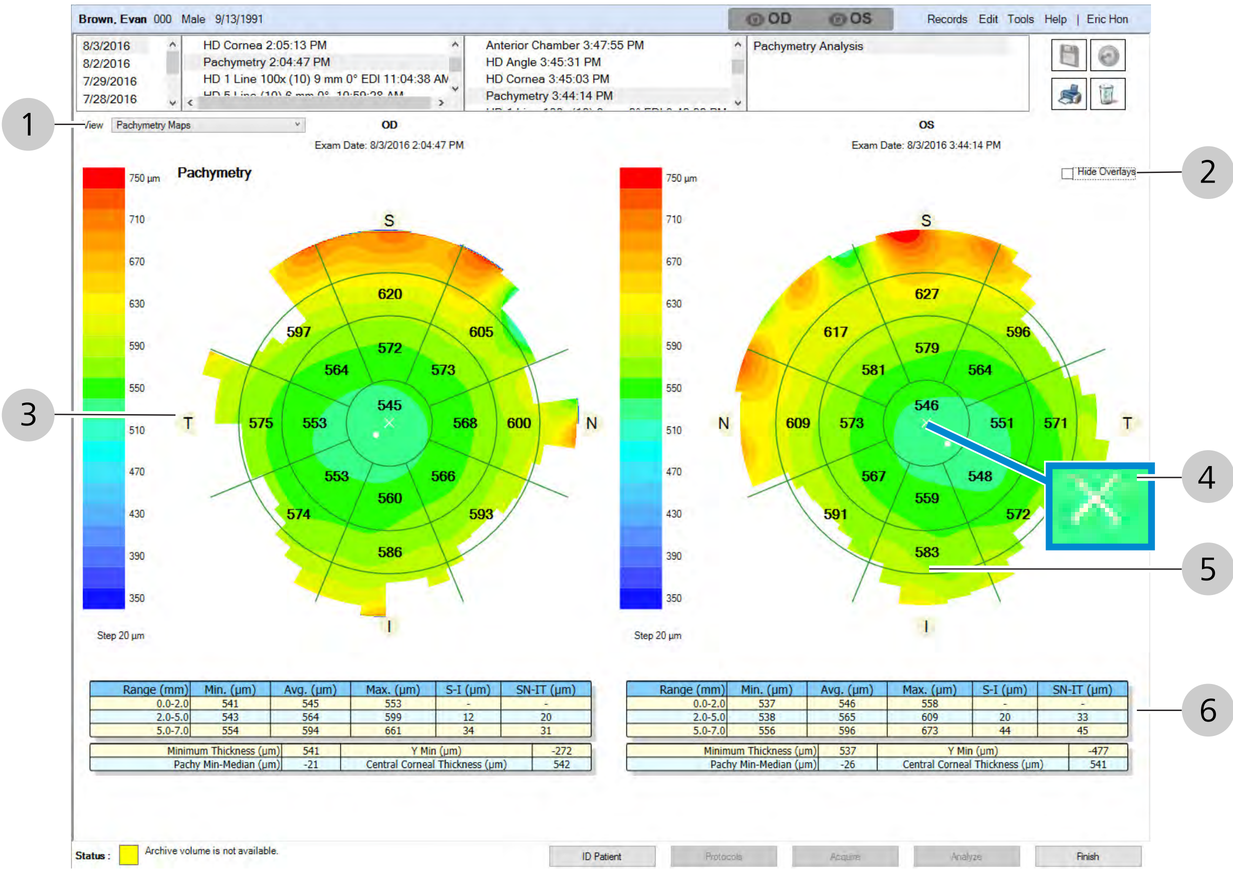
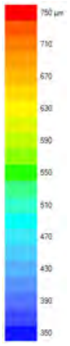
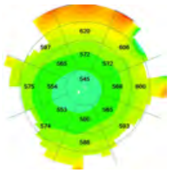
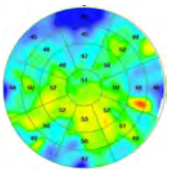


Figure 78: Pachymetry Analysis Overview

#	Symbol	Name	Explanation
1		View Selection	Changes the view of the scan: ■ **Pachymetry Map** ■ **Epithelial Thickness Map** ■ **All Maps** ■ **OD Images** ■ **OS Images**
2		Show / Hide Overlays	Shows or hides the grid and numbers.

#	Symbol	Name	Explanation
3		Color Scale	Sets the color coding options (right-click on the color scale): ■ **Standard** (default): Shows a constant thickness for red at 750 mm and blue at 350 mm. ■ **Auto:** Adjusts the maximum and minimum thickness values to the thickness variation for the selected scan. ■ **Custom**: Opens a custom color scale tool for you to set your own color coding. Your selection applies to both scans and is saved with the analysis.
		Pachymetry Map	Shows the corneal thickness of any area on the map and allows you to mark thickness points on the map (for reports). **NOTE! Note: Towards the periphery of the cornea, the data may have lower signal and the boundaries of the surfaces may be difficult to detect. If the algorithm has low confidence in a region, that region does not appear on the map.**
		Epithelial Thickness Map	Shows a map of the epithelial thickness with a grid centered on the corneal vertex *(the intersection of the visual axis with the corneal surface)*. **X** indicates the vertex. Grid ring diameters: ■ Central ring: 2 mm ■ Inner ring: 5 mm ■ Third ring: 7 mm ■ Outer ring: 9 mm Thickness measurements for each sector display inside the sector. **NOTE! Note: Towards the periphery of the cornea, the data may have lower signal and the boundaries of the surfaces may be difficult to detect. If the algorithm has low confidence in a region, that region does not appear on the map.**
		OD Images OS Images	Shows all 24 B-scan images for the **Pachymetry** scan.
4		Vertex	Shows the location of the corneal vertex.
5		Minimum Corneal Thickness	shows the location of minimum corneal thickness.

<table>
<tr><th>#</th><th>Symbol</th><th>Name</th><th>Explanation</th></tr>
<tr><td rowspan="2">6</td><td colspan="2">Cornea Thickness Table

<table>
<tr><th>Range (mm)</th><th>Min. (µm)</th><th>Avg. (µm)</th><th>Max. (µm)</th><th>S-I (µm)</th><th>SN-IT (µm)</th></tr>
<tr><td>0.0-2.0</td><td>541</td><td>545</td><td>553</td><td>-</td><td>-</td></tr>
<tr><td>2.0-5.0</td><td>543</td><td>564</td><td>598</td><td>12</td><td>19</td></tr>
<tr><td>5.0-7.0</td><td>555</td><td>594</td><td>661</td><td>34</td><td>31</td></tr>
</table>
<table>
<tr><td>Minimum Thickness (µm)</td><td>541</td><td>Y Min (µm)</td><td>-277</td></tr>
<tr><td>Pachy Min-Median (µm)</td><td>-20</td><td>Central Corneal Thickness (µm)</td><td>542</td></tr>
</table></td><td>Provides details of the corneal thickness within annular ranges. For each ring of the grid, the table displays:
Range = inner and outer diameters of the annular region.
Min = minimum thickness.
Avg = average thickness.
Max = maximum thickness.
S-I = average value in the Superior (S) sector - average value in the Inferior (I) sector
SN-IT = average value in the Superior Nasal (SN) sector - average value in the Inferior Temporal (IT) sector.</td></tr>
<tr><td colspan="2">Epithelial Thickness Table

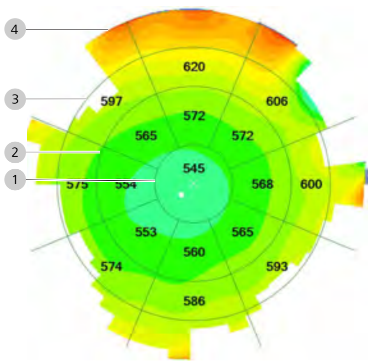
<table>
<tr><th>Range (mm)</th><th>Min. (µm)</th><th>Avg. (µm)</th><th>Max. (µm)</th><th>S-I (µm)</th><th>SN-IT (µm)</th></tr>
<tr><td>0.0-2.0</td><td>49</td><td>51</td><td>54</td><td>-</td><td>-</td></tr>
<tr><td>2.0-5.0</td><td>44</td><td>51</td><td>55</td><td>-6</td><td>-2</td></tr>
<tr><td>5.0-7.0</td><td>40</td><td>49</td><td>60</td><td>-5</td><td>0</td></tr>
<tr><td>7.0-9.0</td><td>38</td><td>47</td><td>59</td><td>-7</td><td>0</td></tr>
</table>
<table>
<tr><td>Minimum Thickness (µm)</td><td>37</td><td>Y Min (mm)</td><td>-0.3</td></tr>
<tr><td>Epithelial Min-Median (µm)</td><td>-6</td><td>Central Epithelial Thickness (µm)</td><td>51</td></tr>
</table></td><td>Provides details of the epithelial thickness within annular ranges.
Range =inner and outer diameters of the annular region.
Min = minimum thickness.
Avg = average thickness.
Max = maximum thickness.
S-I = average value in the Superior (S) sector - average value in the Inferior (I) sector
SN-IT = average value in the Superior Nasal (SN) sector - average value in the Inferior Temporal (IT) sector.</td></tr>
</table>

9.4.8.2 Analyzing Pachymetry

Pachymetry analysis displays a color-coded map showing corneal thickness variation.

Data tables below the Epithelial maps show minimum, average, and maximum thickness measurements (in micrometers) for the four radial zones.

Zone range is defined in millimeters away from the center of the map:



- **Central ring (1):** diameter corresponds to 2 mm
- **Second ring (2):** diameter corresponds to 5 mm
- **Third ring (3):** diameter corresponds to 7 mm
- **Fourth ring (4):** diameter corresponds to 9 mm

The grid centers on the corneal vertex (white "X") at the intersection of the visual axis with the corneal surface.

S-I values: `average value of Superior (S) - average value of Inferior (I) at the same distance`

SN-IT values: `average value of SN - average value of IT at the same distance`

To analyze pachymetry:

Prerequisite

☑ You are logged in (review station or instrument): Login [▸ 123].

☑ The patient has at least one pachymetry scan: (Acquire a Pachymetry Scan [▸ 204])

Action

1. Select the patient and click **Analyze**.
2. Under OD or OS, select a **Pachymetry** scan and select **Pachymetry Analysis**.
   ⇨ The analysis opens showing the corneal thickness map and details table. White areas indicate peripheral regions with low signal that were not quantified for the map.
3. To view the thickness (in micrometers) and location (relative to the center of the map) of any point on the map, hover over the point.
4. To mark a point on the map, click on the point.
   ⇨ The point's location, thickness and map coordinates are marked for reports.
5. To delete a marked location, right-click on the marked point and check **Clear User Selection**.
6. To show all three values of per sector, (Min, Max, Avg.), right-click a point on the map and uncheck **Show Mean Only**.
7. To hide all data values on a map, right-click a point on the map and check **Hide Data**.
8. To view epithelial thickness maps, select **View** > **Epithelial Thickness Map**.
9. To view both the pachymetry and epithelial thickness maps, select **View** > **All Maps**.
   ⇨ A **green** line indicates the anterior surface of the cornea. *(No line indicates that he algorithm has low confidence in the posterior surface of the cornea and did not calculate the value.)*
   ⇨ A **red** line indicates the posterior surface of the cornea.
   ⇨ A **yellow** line indicates the Bowman’s Layer.
10. To view all 24 thumbnail scans that make up a pachymetry map, select **View** > **OS** or **View** > **OD**.
11. To view a full-screen image, double-click on the image.
12. To print, save, or export a report, see: Creating a Report [▸ 384].

9.4.9 Analyze Wide Angle-to-Angle Scans

NOTE

Features described in this section are licensed separately and may not be available in all markets.

▶ For information about feature availability in your market and obtaining a license:

⇨ in the U.S.A, call 1-877-486-7473.

⇨ outside the U.S.A , contact your local ZEISS distributer.

9.4.9.1 Wide Angle-to-Angle Analysis

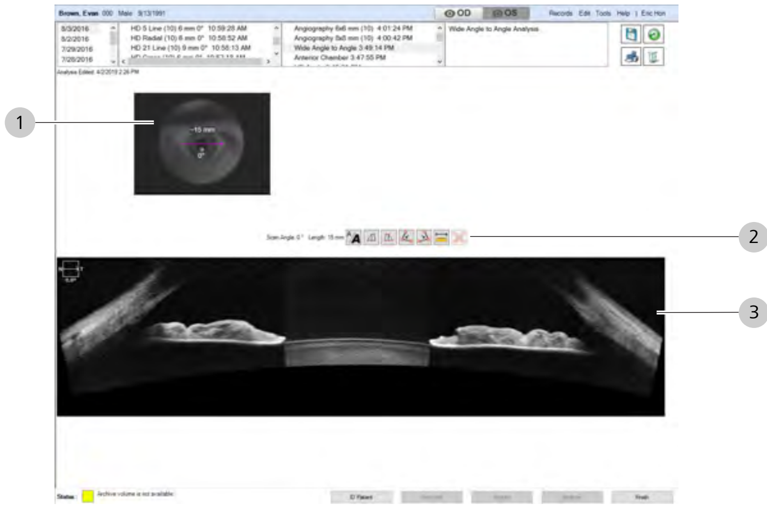
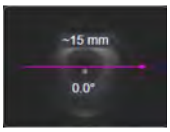
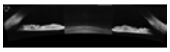


Figure 79: Wide Angle to Angle Analysis Overview

#	Symbol	Name	Explanation
1		Iris Image	Shows the scan pattern over the iris image and indicates the rotation direction set during acquisition.
2	**Toolbar**		
		Annotate Image	Adds your notes onto the image.
		Right Angle Measurement Tool	(See: About Angle Measurement [▸ 340]).
		Left Angle Measurement Tool	
		Caliper	Adds a measurement line.

#	Symbol	Name	Explanation
		Delete	Deletes an angle or caliper measurement line.
		Right IC Angle	Adds a (trapezoid-shaped) Iridocorneal angle tool onto the image to help determine angle measurements. Adjust the shape to fit the structures in the image: ■ angle opening distance ■ trabecular iris space area ■ sclera spur angle
		Left IC Angle	
3			

9.4.9.2 Analyzing Wide Angle-to-Angle Scans

To analyze Wide Angle to Angle scans:

Prerequisite

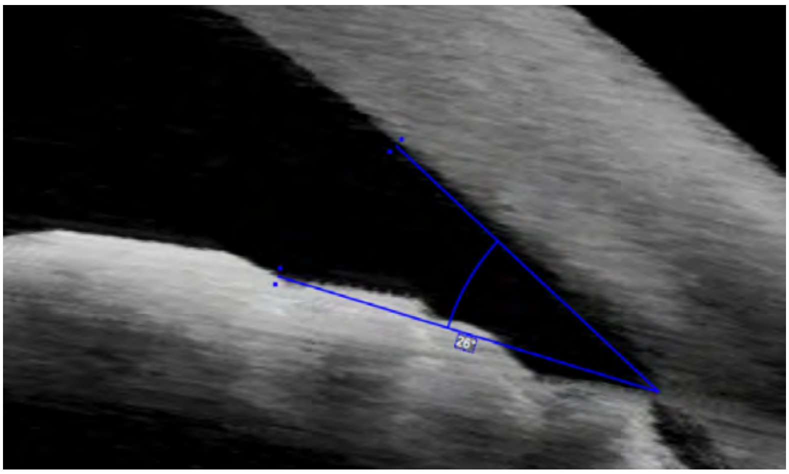
☑ The patient has at least one Wide Angle to Angle scan: (Wide Angle to Angle Scans [▸ 197])

☑ You are logged in (review station or instrument): Login [▸ 123].

Action

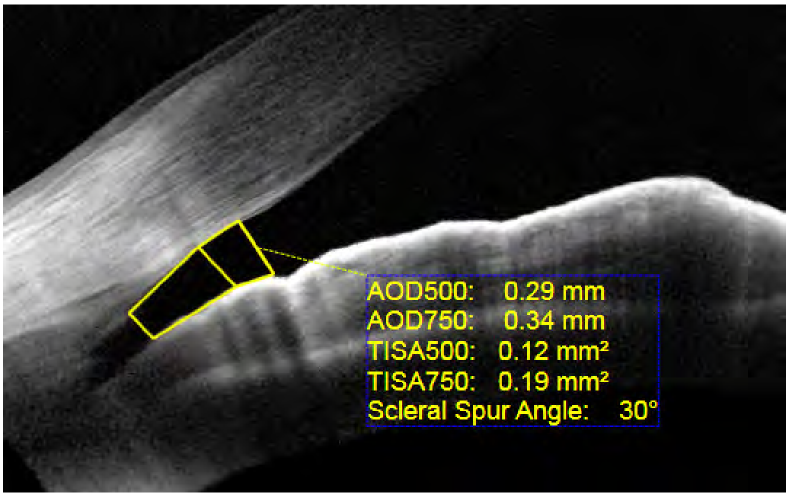
1. Select the patient and click **Analyze**.
2. Select an **Wide Angle to Angle** scan and select **Wide Angle to Angle Analysis**.
   ⇨ The **HD Angle** analysis opens.

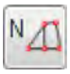
3. To add a text annotation to the image, click **Annotate** and type text.
   ⇨ You can change the color and size of the text or move it somewhere else in the image (see: Add Annotations to Images [▸ 377]).



4. To place an angle measurement, click (right or left) **Angle Tool** and place the intersection at the scleral spur and the other two points at the corneal endothelium and iris.

⇨ CIRRUS™ HD-OCT calculates the angle.





5. To place an iridocorneal angle measurement, click (right or left) **IC Angle Tool**, drag the trapezoid into position over the angle you want to measure and adjust the points to touch the corneal endothelium and iris.

   ⇨ CIRRUS™ HD-OCT calculates the measurements (see: About Angle Measurement [▸ 340]).

6. To delete a measurement or annotation, select it and click **Delete**.
7. To edit or adjust the image, hover over the image and select an adjustment tool (refer to: Edit Images (Hover Over) [▸ 370].
8. To view a full-screen image, double-click on the image.
9. To print, save, or export a report, see: Creating a Report [▸ 384].

9.4.10 Analyze Anterior Segment 5-Line Raster Scans

NOTE

Features described in this section are licensed separately and may not be available in all markets.

▶ For information about feature availability in your market and obtaining a license:

⇨ in the U.S.A, call 1-877-486-7473.

⇨ outside the U.S.A , contact your local ZEISS distributer.

You can use the **Anterior Segment 5 Line Raster** scan to create images of the cornea or the iridocorneal angle. Since this analysis is the same for all HD scans, there are no angle measurement tools available for this scan.

To measure angles, use one the following scans and their custom analysis tools:

- HD Angle [▹ 349] for the most accurate measurements of an angle
- Wide Angle to Angle [▹ 361] to view and measure both irido-corneal angles of an eye

To analyze a high-definition cornea cube scan that has 1024 A-scans and 20 B-scans, refer to:HD Cornea [▹ 353].

9.4.10.1 Anterior HD 5-Line Raster Analysis

You can use the **Anterior Segment 5 Line Raster** scan to create images of the cornea or the iridocorneal angle. Since this analysis is the same for all HD scans, there are no angle measurement tools available for this scan. To measure angles, use one the following scans and their custom analysis tools:

- HD Angle [▹ 349] for the most accurate measurements of an angle
- Wide Angle to Angle [▹ 361] to view and measure both irido-corneal angle angles

  of an eye

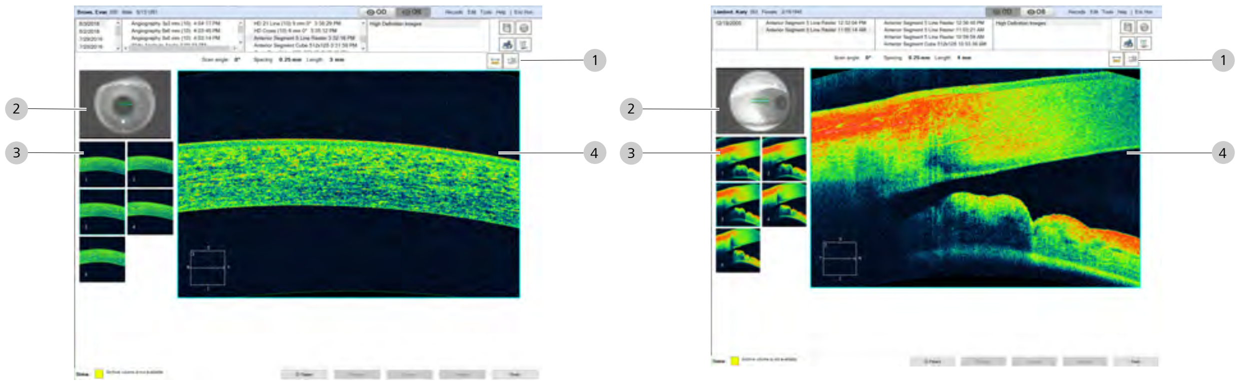
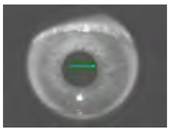
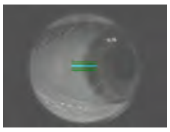
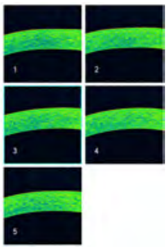
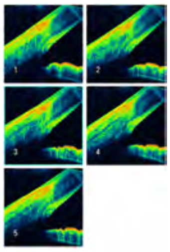
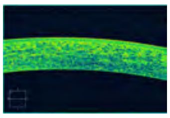
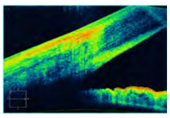


Figure 80: Anterior HD Image Analysis Overview (Cornea)

#	Symbol	Name	Explanation
1	**Toolbar**		
		Caliper	Adds a measurement line.
		Delete Measurement	Deletes a measurement line added with the caliper tool.

#	Symbol	Name	Explanation
2	**Cornea**  **Angle** 	Iris Image	Shows the scan pattern over the iris image and indicates the length, line spacing, and rotation direction set. For **Angle**, offset to capture the angle.
3	**Cornea**  **Angle** 	B-scan Selection Panel	Shows the B-scan slices and allows you to select a slice to display.
4	**Cornea**  **Angle** 	B-scan	Shows a larger view of the selected B-scan. The number inside the TSNIT square (lower left) corresponds to the B-scan slice number in the selection panel.

9.4.10.2 Analyzing Anterior Segment 5-Line Raster Images

You can use the **Anterior Segment 5 Line Raster** scan to create images of the cornea or the iridocorneal angle. Since this analysis is the same for all HD scans, there are no angle measurement tools available for this scan. To measure angles, use one the following scans and their custom analysis tools:

- HD Angle [▸ 349] for the most accurate measurements of an angle
- Wide Angle to Angle [▸ 361] to view and measure both irido-corneal angle angles

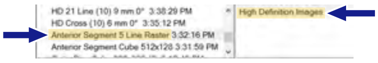
  of an eye

Prerequisite

☑ You are logged in (review station or instrument): Login [▸ 123].

☑ The patient has at least one **Anterior Segment 5-Line Raster** scan of the cornea or angle: (Acquire HD Cornea Scans)

Action



1. Under OD or OS, select an **Anterior Segment 5-Line Raster** scan.

   ⇨ The **HD Images** analysis opens.
2. To display a different B-scan, select a different image from the selection panel.

   ⇨ The B-scan you selected displays.
3. To exit any editing mode and save the changes, right-click on the image and select **Normal**.
4. To reset an image to default settings, **Normal**
5. To zoom in our out, right-click on the image and select **Zoom**.
   Unzoom returns the image to the original size.
   Rectangle selects a rectangular zoom area.
   Continuous allows you to zoom in or out (click and drag).
6. To pan a zoomed image, right-click on the image, select **Pan** , and drag to image to view a different part of the image.
7. To view a full-screen image, double-click on the image.
8. To save an image, right-click on the image, select **Save image as...**, select a file type, name, and path for the image.
9. To show or hide the navigator lines, right-click on the image and select **Hide Slice Navigator**.
10. To adjust image brightness or contrast, right-click on the image and select **Brightness/Contrast**.
11. To show a color image, right-click on the image and select **Color**.
12. To print, save, or export a report, see: Creating a Report [▸ 384].

9.5 Common Analysis Tasks and Tools

9.5.1 Manually Select a Scan

Some analyses automatically select a companion scan for the most comprehensive information. You can choose a different scan instead. For example, if CIRRUS™ HD-OCT selects a scan that does not have good signal strength or is not centered properly, you can select a different scan for the analysis.

This feature is available for the following analyses:

- Analyze Macular Change [▸ 247]
- Analyze Ganglion Cell OU [▸ 262]
- Advanced RPE Analysis [▸ 257]
- Analyze ONH/RNFL OU [▸ 279]
- Analyze Single Eye Summaries [▸ 295]
- Analyze PanoMap [▸ 299]
- Wellness Exam [▸ 301]
- Compare Angiography Images [▸ 327]

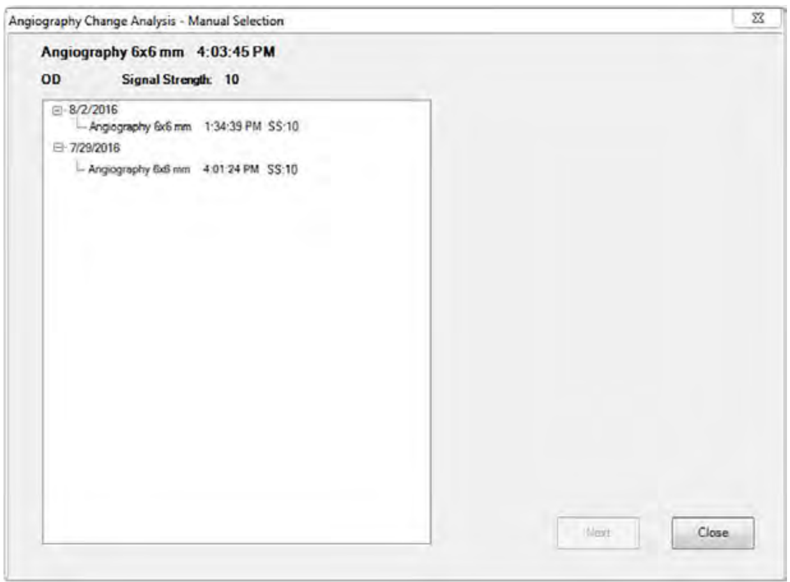
To manually select a different scan:

Prerequisite

☑ You are using an analysis listed above and you want to select a different scan.

Action

1. Under OD or OS, select a scan for an analysis in the list above.
2. Click the same analysis with an suffix: **– Manual Selection**.
   ⇨ A dialog opens listing scans you can use for comparison (two examples shown).



3. Click the scan you want to use.
4. Click **Close**.

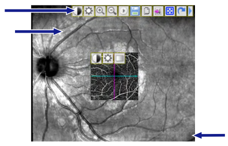
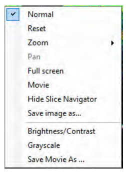
9.5.2 Edit Images

9.5.2.1 About Image Editing

During image analysis, you can view and edit images. There are two different ways to access editing tools:

- Right-click to select from a menu
- Hover over the image to open editing icons.

Editing tool access depends on the type of analysis you are using.

Access Type	Analyses
Hover 	■ Angiography ■ Compare Angiography ■ ONH Angiography ■ Compare ONH Angiography ■ Montage AngioPlex ■ En Face ■ Anterior Chamber ■ HD Angle ■ HD Cornea ■ Wide Angle to Angle
	■ Macular Thickness ■ Macular Change ■ Ganglion Cell OU ■ Guided Progression: Ganglion Cell ■ Advanced RPE Analysis ■ ONH Guided Progression ■ ONH/RNFL OU ■ HD Images ■ Same Eye Summary ■ Panomap ■ Wellness Exam ■ Advanced Visual Analysis ■ Anterior Segment ■ Pachymetry ■ Anterior Segment 5-Line Raster

The following image shows how the same editing functions access correlates.

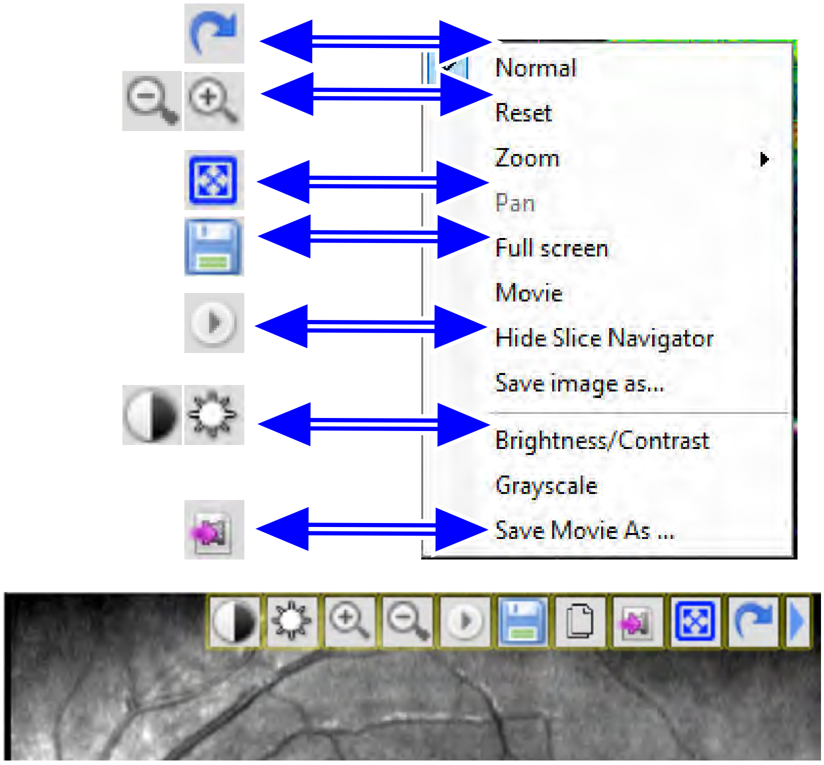


Figure 81: Menu and Toolbar Buttons

9.5.2.2 Editing Images Using the Menu

This method of accessing image editing tools applies to the following analyses:

- Macular Thickness
- Macular Change
- Ganglion Cell OU
- Guided Progression: Ganglion Cell
- Advanced RPE Analysis
- ONH Guided Progression
- ONH/RNFL OU
- HD Images
- Same Eye Summary
- Panomap
- Wellness Exam
- Advanced Visual Analysis
- Anterior Segment

- Pachymetry
- Anterior Segment 5-Line Raster

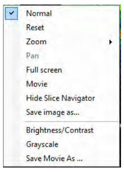
To edit images using the menu:

Prerequisite

☑ You are logged in (review station or instrument): Login [▸ 123].

☑ You reach the scan analysis step: *Edit an Image*.

Action



1. To view a full-screen image, double-click on the image.
2. To adjust image brightness or contrast, right-click on the image and select **Brightness/Contrast**.
3. To show a color image, right-click on the image and select **Color**.
4. To hide the image, right-click on the image and select **Hide**.
5. To exit any editing mode and save the changes, right-click on the image and select **Normal**.
6. To pan a zoomed image, right-click on the image, select **Pan** , and drag to image to view a different part of the image.
7. To reset an image to default settings, **Normal**
8. To zoom in our out, right-click on the image and select **Zoom**.
   Unzoom returns the image to the original size.
   Rectangle selects a rectangular zoom area.
   Continuous allows you to zoom in or out (click and drag).
9. To save an image, right-click on the image, select **Save image as...**, select a file type, name, and path for the image.

9.5.2.3 Edit Images (Hover Over)

NOTE

The image editing tools vary depending on the type of analysis.

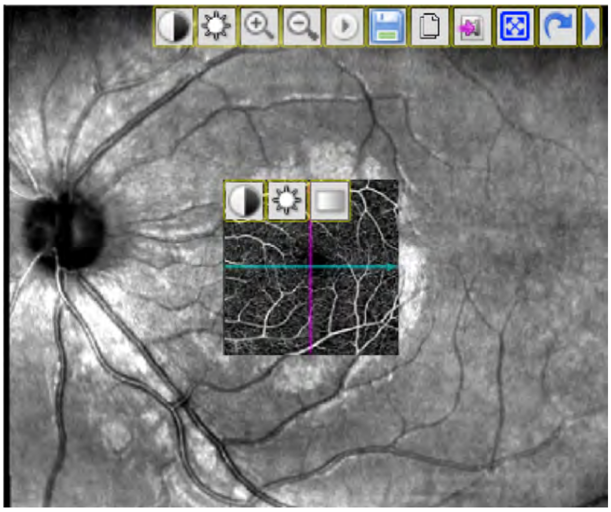
▶ Refer to a particular analysis to see which editing tools you can use for its images.

This method of accessing image editing tools applies to the following analyses:

- Angiography
- Compare Angiography
- ONH Angiograpju
- Compare ONH Angiograpju
- Montage AngioPlex
- En Face
- Anterior Chamber
- HD Angle

- HD Cornea
- Wide Angle to Angle

You can adjust and edit most images in an analysis viewport. Right-click on an image to open the editing toolbar.



Tool	Reference	Tool	Reference
	Adjust Image Contrast [▸ 374]		Export a Movie [▸ 380]
	Adjust Image Brightness [▸ 373]		View Images in Full-Screen Mode [▸ 373]
	Zoom In and Out [▸ 378]		Reset Edited Images [▸ 379]
	Adjust Image Transparency [▸ 375]		Hide / Show Toolbar [▸ 372]
	View the Images as a Movie [▸ 379]		Add Freeform Shapes to Images [▸ 376]
	View Color or Grayscale Image [▸ 375] (toggles):		Add Circles to Images [▸ 376]
	Copy Edited Images [▸ 380]		Add Calipers to Images [▸ 378]
	Save Edited Images [▸ 381]		Add Annotations to Images [▸ 377]
			Remove Shapes, Tools and Annotations [▸ 379]

Table 77: Image Editing Tools

9.5.2.3.1 Open Image Editing Tools

NOTE

Not all image tools are available for all images.

Image tools vary by type of image.

You can adjust, edit, annotate, export and save most images in the viewport. Each image has its own toolbar that opens when you right-click on the image.

To open the image editing tool:

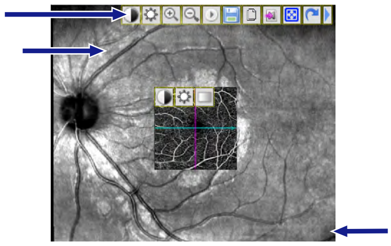
Prerequisite

☑ You are logged in (review station or instrument): Login [▷ 123].

☑ You reach the scan analysis step: *Edit an Image*.

Action

1. Click on the image that you want to edit.



⇨ Adjustments open at the top right side and annotations open at the bottom.

9.5.2.3.2 Hide / Show Toolbar

To hide or show the image editing toolbar:

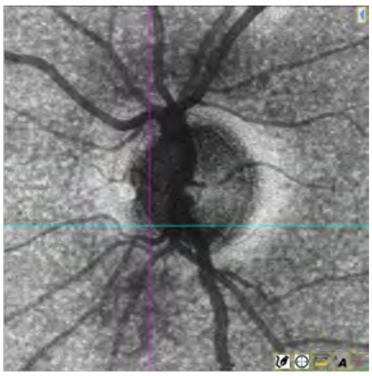
Prerequisite

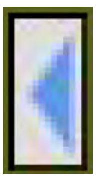
☑ Editing tools are open: Open Image Editing Tools [▷ 372].

Action

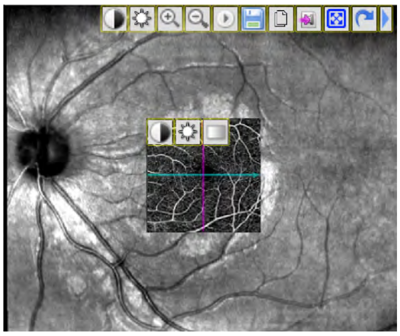
1. To hide the toolbar, click **Hide Toolbar**.

⇨ The toolbar collapses.





2. To show the toolbar, click **Show Toolbar**.



⇨ The toolbar expands.

3. Complete the analysis.

9.5.2.3.3 View Images in Full-Screen Mode

Tip: You can also click Esc to close full-screen mode.

To view an image in full-screen mode, you can either double-click on the image or click on the full-screen icon.

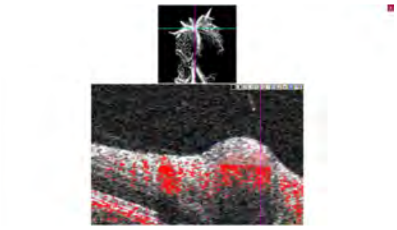
To view an image in full-screen mode:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▸ 372].

Action

1. Click **Full-Screen**.



⇨ The image opens in full-screen mode.

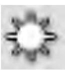
2. Click **Close**.
3. Complete the analysis.

9.5.2.3.4 Adjust Image Brightness

To adjust image brightness:

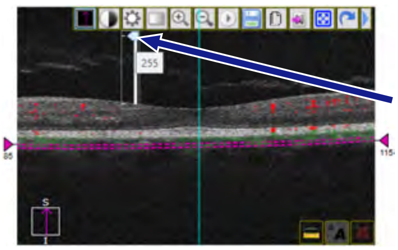
Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▸ 372].



Action

1. Click **Brightness**.

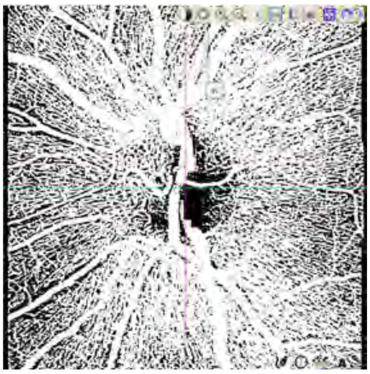


⇨ An adjustment slider opens below the **Brightness** icon.

2. To increase image brightness, slide the marker up.

⇨ The image lightens.

⇨ The brightness level also appears as a number from **0** (lowest brightness level) to **255** (highest brightness level).



3. To decrease image brightness, slide the marker down.
   ⇨ The image dims.
4. Save Edited Images [▸ 381].

9.5.2.3.5 Adjust Image Contrast

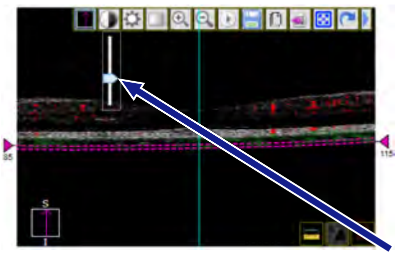
To adjust image contrast:

Prerequisite

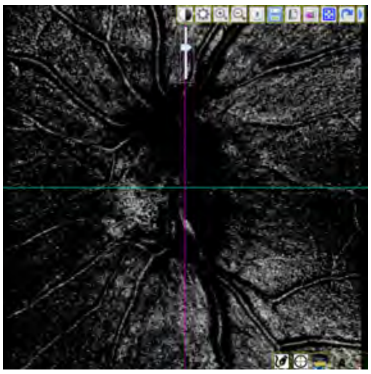
☑ Editing tools are open: Open Image Editing Tools [▸ 372].

1. Click **Contrast**.

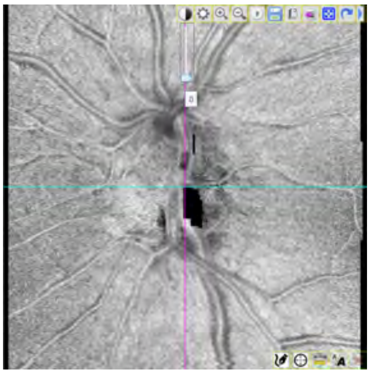
Action



⇨ An adjustment slider opens below the contrast icon.



2. To increase image contrast, slide the marker up.
   ⇨ Image contrast increases.



3. To decrease image contrast, slide the marker down.
   ➩ Image contrast decreases.
4. Save Edited Images [▸ 381].

9.5.2.3.6 Adjust Image Transparency

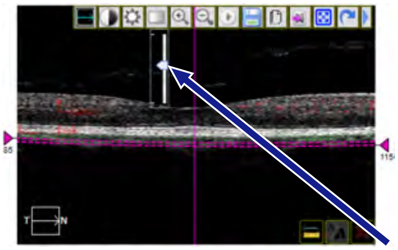
To adjust image transparency:

Prerequisite

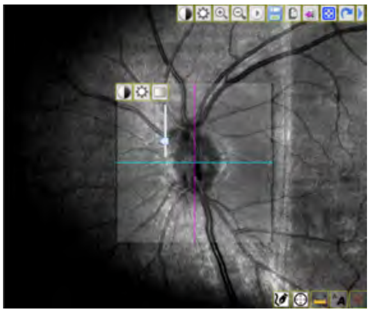
☑ Editing tools are open: Open Image Editing Tools [▸ 372].

Action

1. Click **Transparency** .



   ➩ An adjustment slider opens below the transparency icon.



2. To increase image transparency, slide the marker down.
   ➩ The image becomes more transparent.

3. To decrease image transparency, slide the marker up.
   ➩ The image becomes less transparent.
4. Save Edited Images [▸ 381].

9.5.2.3.7 View Color or Grayscale Image

The image toggles among three color options:

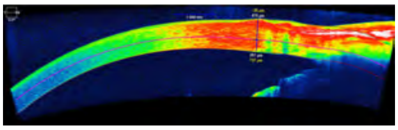
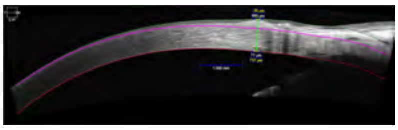
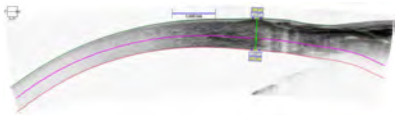
Option	Example
Color	
Grayscale	
Reverse Grayscale	

Table 78: View Color Options

To toggle color settings:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▸ 372].

Action

1. To toggle among a color, grayscale image, and reverse grayscale, click **Color**.
2. Click **Save** ( ).
3. Complete the analysis.

9.5.2.3.8 Add Circles to Images

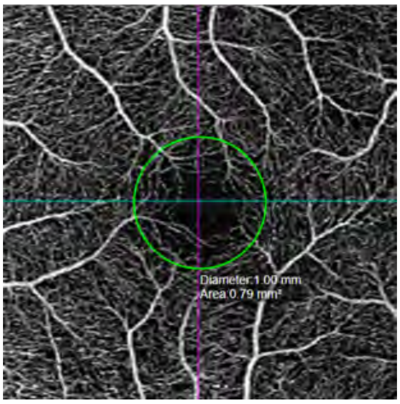
When you add a circle to an image, CIRRUS™ HD-OCT automatically calculates the perimeter and area of the circle.

To add a circle to an image:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▸ 372].

Action



1. Click **Add Circle**.
   ⇨ A circle annotation appears in the center of the image.
   ⇨ The area and diameter of the circle are displayed.
2. To make the circle larger or smaller, click on a corner and drag the corner in or out.
   ⇨ The area and diameter of the circle update.
3. To move a circle, click on the middle of the circle and drag it to a new location.
4. Save Edited Images [▸ 381].

9.5.2.3.9 Add Freeform Shapes to Images

When you create a free-form shape on an image, CIRRUS™ HD-OCT automatically calculates the perimeter and area of the shape.

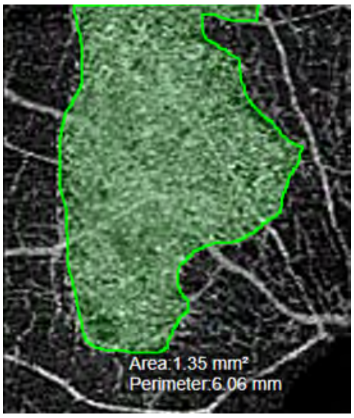
To draw a free-form shape on an image:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▸ 372].

Action

1. Click **Free-Form Shape**.



2. Click on the image where you want the shape to start and drag in any direction to draw a freeform shape.
3. Continue to draw the shape and complete the shape by returning to the starting point.
   NOTE! You do not end exactly at the starting point. The shape automatically closes.
   ⇨ The area and perimeter of the shape are displayed.
4. To move a freeform shape, click on the middle of the shape and drag it to a new location.

5. To delete a freeform shape, click on the shape to select it and click **Delete**.
6. Save Edited Images [▸ 381].

9.5.2.3.10 Add Annotations to Images

In each annotation, you can enter up to 32 characters, including spaces. You can change the size and color for each annotation individually. You can also add an arrow to any annotation.

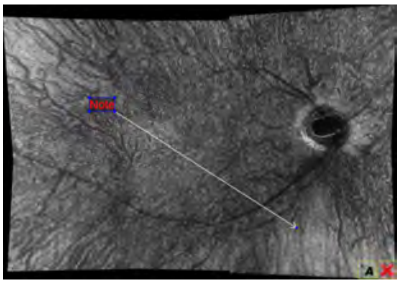
To add annotations to images:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▸ 372].

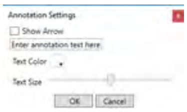
Action

1. Click **Annotations**.
   ⇨ The annotation tool appears in the image.



2. Type your annotation.
3. To move the text, click to select it and drag it to a new location on the image.
4. To edit the text, click to select the text and type .
5. To start a new line in an annotation, click **Enter**, then**OK**.

6. To customize the text, double-click an existing text annotation on the image.
   ⇨ **Annotations Settings** open.



7. To add an arrow, check **Show Arrow**.
8. To change the text color, click on the **Text Color** pallette and select a color.
9. To change the size of the text, slide **Text Size** to the right to enlarge or left to shrink the text.
   ⇨ The annotation displays the new size, color and arrow (if selected).
10. To resize an arrow, click on the arrow tip and drag it in to make the arrow smaller or out to make the arrow larger.
11. Save Edited Images [▸ 381].

9.5.2.3.11 Add Calipers to Images

NOTE

For some analyses, calipers detect and measure a particular structure.

For example, **HD Cornea Analysis** adds a caliper that detects and measures the cornea, so you can move it along the cornea, but not to other areas of the image.

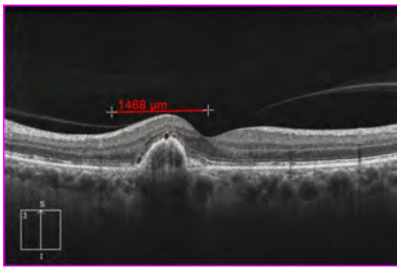
You can add up to ten calipers on an image or B-Scans. Calipers add a line that measures microns (µm).

To add calipers to images:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▸ 372].

Action



1. Click the **Caliper**.
   ⇨ A caliper tool appears in the image.
2. To move a caliper, click on the middle of the caliper and drag it to a new location.
3. To change the direction of the caliper, click on an end and drag to rotate it.
4. To shorten or lengthen a caliper, click on and end and drag it in or out.
5. To move the measure callout, click on the number and drag it to another location.
6. Save Edited Images [▸ 381].

9.5.2.3.12 Zoom In and Out

To zoom in:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▸ 372].

Action

1. Click **Zoom In**.
   ⇨ The image zooms in.
2. To zoom in again, click **Zoom In** again.
   ⇨ The image zooms in further.

To zoom out:

3. Click **Zoom Out**.
   ⇨ The image returns to its original dimensions.
4. Save Edited Images [▷ 381].
5. Complete the analysis.

9.5.2.3.13 Remove Shapes, Tools and Annotations

You can remove measurements, shapes, and annotations individually. To undo all editing and reset the image, see: Reset Edited Images [▷ 379]

To remove an item from an image:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▷ 372].

1. Select a shape or annotation added to the image.

Action

2. Click **Delete**.
   ⇨ The item is removed from the image.
3. Save Edited Images [▷ 381].

9.5.2.3.14 Reset Edited Images

When you reset an image, all editing and adjustments are removed from the image and the image returns to its last saved state.

To reset an image:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▷ 372].

Action

1. Click **Reset**.
2. Save Edited Images [▷ 381].

9.5.2.3.15 View the Images as a Movie

You can view the scan as a movie that begins at the top of the B-Scan slice and moves down through the tissue in 51 µm increments. You can stop the movie, reverse or advance the movie frame by frame.

NOTE! The default frame rate for scan movies is 51 µm/sec.

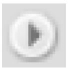
To view the image as a movie:

Prerequisite

☑ You reach the scan analysis step: *Edit an Image*.

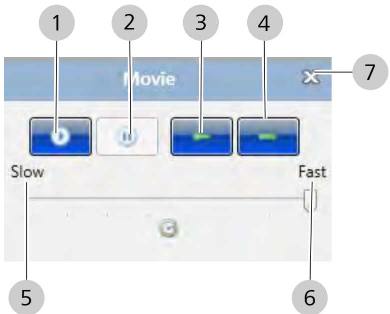
☑ Editing tools are open: Open Image Editing Tools [▷ 372].

Action



1. Click **Play Movie**.

   ⇨ The movie controls open.



2. To start the movie, click the **play button (1)**.
3. To stop the movie, click the **pause button (2)**.
4. To move backward one frame, click the **previous button (3)**.
5. To move forward one frame, click the **next button (4)**.
6. To decrease movie speed, move the slider toward **Slow (5)**.
7. To increase movie speed, move the slider toward **Fast (6)**.
8. To close the movie controls, click **Close (7)**.

9.5.2.3.16 Export a Movie

Movies are available for En Face, B-scan, and Angiography images. You can export a movie as an avi file type.

To export a movie:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▷ 372].

Action

1. Click **Export Movie**.
2. Navigate to the location you want to save the movie file.
3. Click **OK**.

   ⇨ A dialog with a progress bar opens.

4. Click **Save**.

Result

✓ The movie takes a few moments to save.

9.5.2.3.17 Copy Edited Images

You can copy an image or an edited image onto the clipboard, then paste it into a separate document or image file.

To add copy an image to the clipboard:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▷ 372].

Action

1. Click **Copy**.

   ⇨ The image or edited image is saved to the clipboard.

2. To paste the image into a document or image, open the file and select **Paste** or **CTRL+V**.

   ⇨ The image is pasted into the file.

3. Complete the analysis.

9.5.2.3.18 Save Edited Images

After you complete adjustments and edits, save the changes.

To save an edited image:

Prerequisite

☑ Editing tools are open: Open Image Editing Tools [▸ 372].

Action

1. Click **Save**.
2. Complete the analysis.

9.5.3 Reports Overview

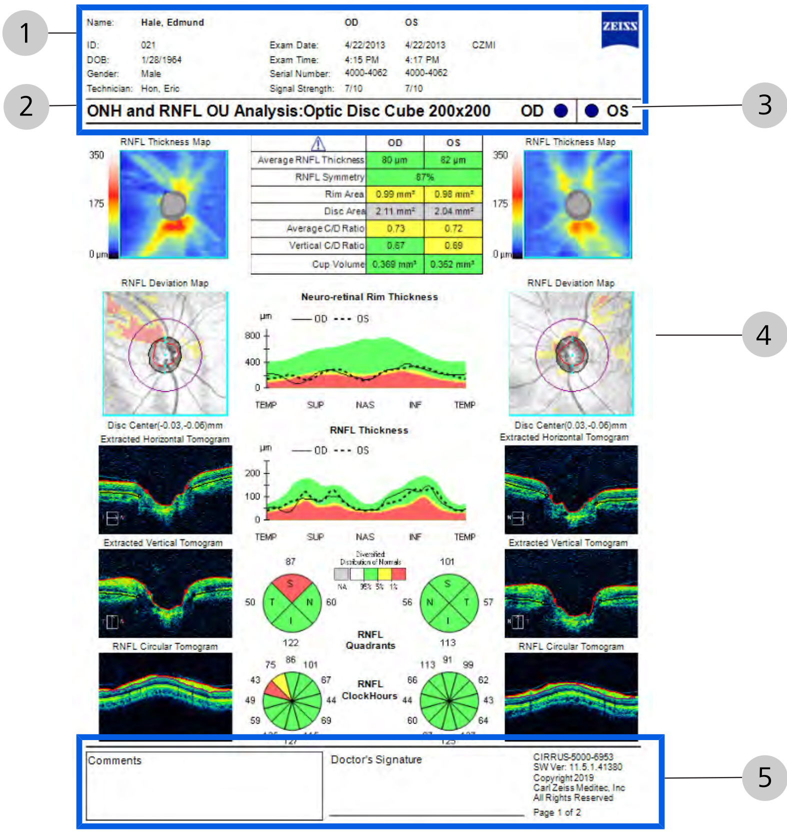
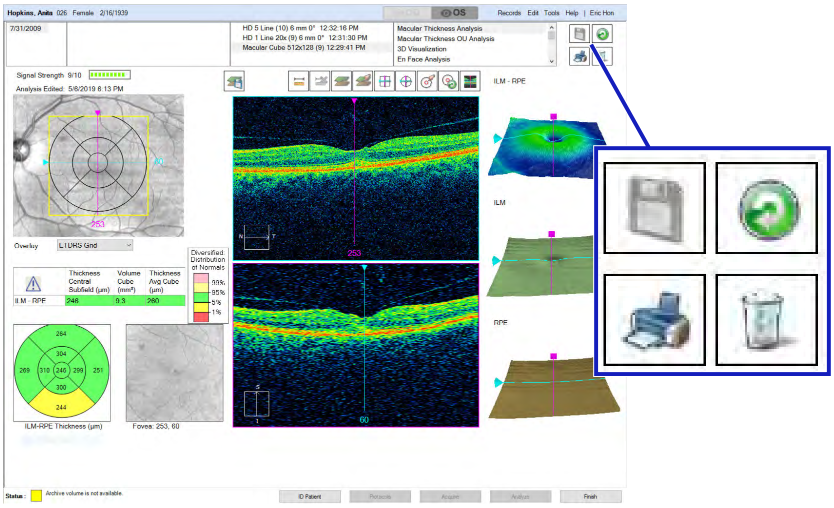


Figure 82: Reports Overview

Pos.	Name	Explanation
1	**Header**	
	Name:	Patient name
	ID:	Patient identification number
	DOB:	Patient date of birth
	Gender:	Patient gender
	Technician:	Instrument operator name
	OD / **OS**	Patient eye(s) included in the report
	Exam Date:	Date the scan was acquired.
	Exam Time:	Time the scan was acquired.
	Serial Number:	Serial number of the instrument that acquired the scan.
	Signal Strength:	The signal strength of the scan.
	Institution Name:	The name of your institution.
	ZEISS logo	
2	*Report Name*	The type of analysis used to create the report.
	Scan Type	The type of scan used for the analysis.
3	**OD** / **OS**	Indicates which eye(s) is included in the report.
4	*Report Content*	The content varies by scan and analysis type.
5	**Footer**	
	Comments:	Field to add written comments on the printed report.
	Analysis Edited:	The date and time the analysis was edited.
	Doctor's Signature	Field to sign the printed report.
	ZEISS Software and copyright information	
	Page *x* of *x*	Page number and total number of pages of the report.

9.5.4 Creating a Report

You can create a report to print, save or export. You can access report features from any analysis screen. The cross-sections and/or surface maps currently displayed in the analysis are included in the report.



To create a report:

Prerequisite

☑ You are logged in (review station or instrument): Login [▹ 123].

☑ Open and edit an analysis.

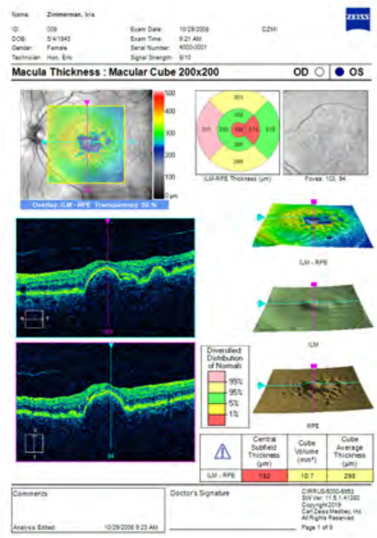
Action

1. Click **Print**.

   ⇨ The print menu expands.

2. To print a report without preview, select **Print**.

   ⇨ The report prints on the default printer.



3. To see a preview of the report (all pages), select **Print Preview...**.

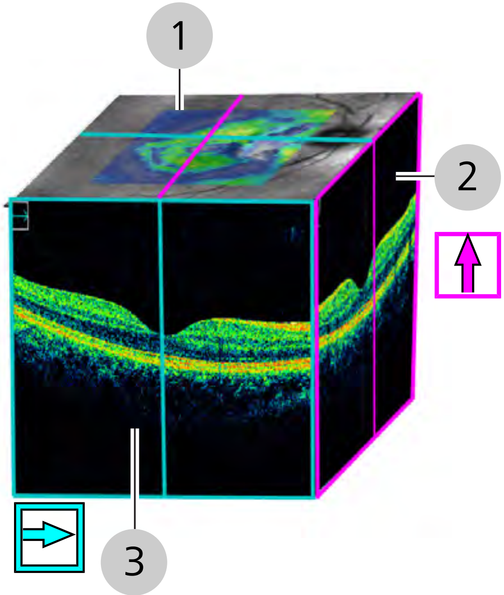
   ⇨ A preview opens showing all pages of the report. You can zoom, pan, print, or save the report from the preview toolbar.

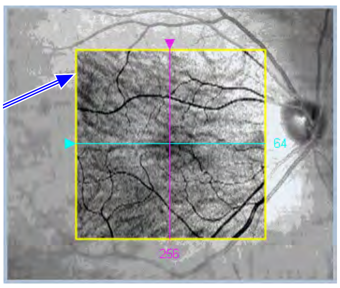
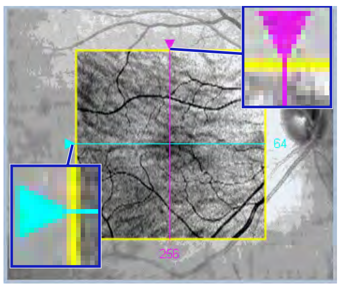
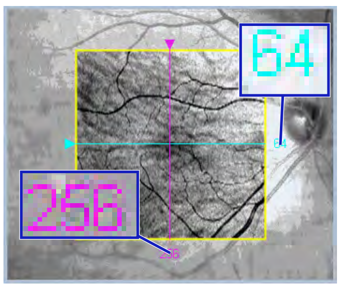
4. To save a PDF report, click select **Save as PDF...**.
5. To save a high-definition report, select **Save as HD PDF...**.

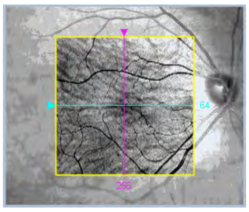
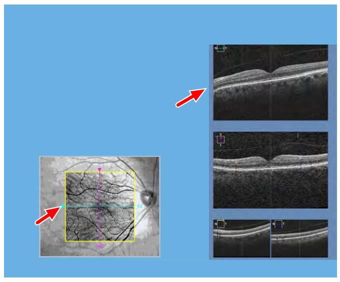
6. To save the report in another format, select **Print Preview...**, click **Save**, and select a file format.
7. To export the report to DICOM, select **Export to DICOM**.
8. To export as XML, select **XML Export**.

9.5.5 Navigating Cube Scans

Cube scans stack and align consecutive axial-scans (A-scans) side by side to produce a two-dimensional B-scan. Consecutive B-scans align to produce a 3D cross-section of the retina.



1	En Face Scan Plane	**Yellow box** indicates the scan area.	
		Click and drag **cyan or magenta triangle** to move through the scan slices.	
		The number beside the line indicates which slice of the cube is in view.	

2	Slow B-Scan Plane	Reformatted, vertically parallel A-scans acquired in successive line scans. These slices are acquired more slowly; one per line of horizontal A-scans.	
3	Fast B-Scan Plane	Slices parallel to the front of the cube; each line of A-scans is acquired quickly .	

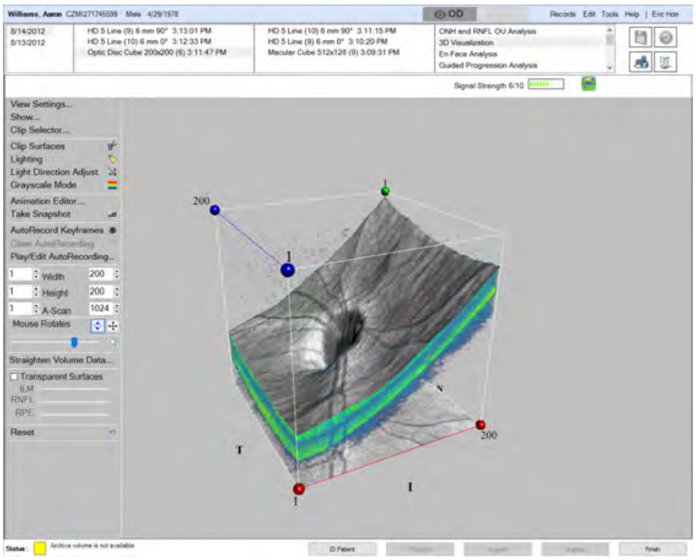
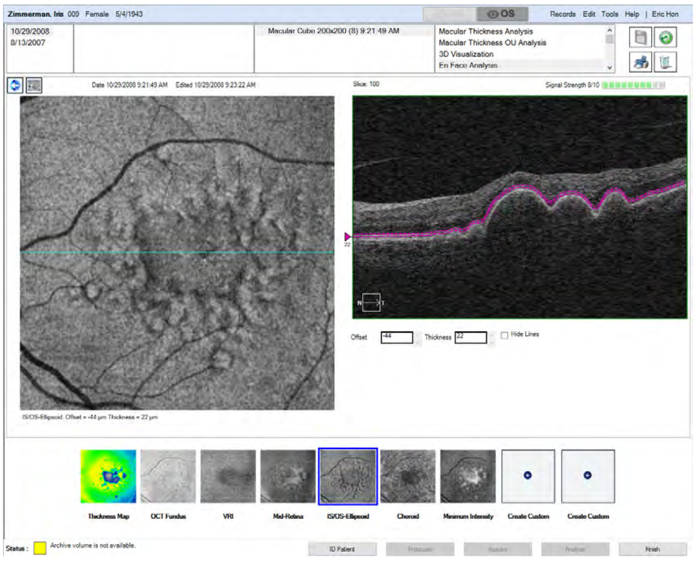
You can quickly navigate through the slices of either plane. Simply move the corresponding line displayed on the fundus image and the B-scan image moves accordingly. The slice number helps you know which area of the cube is selected.

CIRRUS™ HD-OCT displays scan images as follows:

- Horizontal scans:
  - left of scan equals the left of scan display
  - right of scan equals right of scan display
- Vertical scans
  - bottom of scan equals left of scan display
  - top of scan equals right of scan display
- Diagonal scans in 5 Line Raster
  - left takes precedence over bottom
  - left of scan equals left of scan display
  - right of scan equals right of scan display

Cube Analysis

Because cube scans contain this volume of information, there is are additional types of analyses available only for cube scans:

Analysis	Description
3D Visualization 	Shows a 3-dimensional image of the data. You can navigate through the 3D slices, adjust settings, and animate a series to save as a movie (see: 3D Visualization Analysis [▹ 289]).
En Face 	

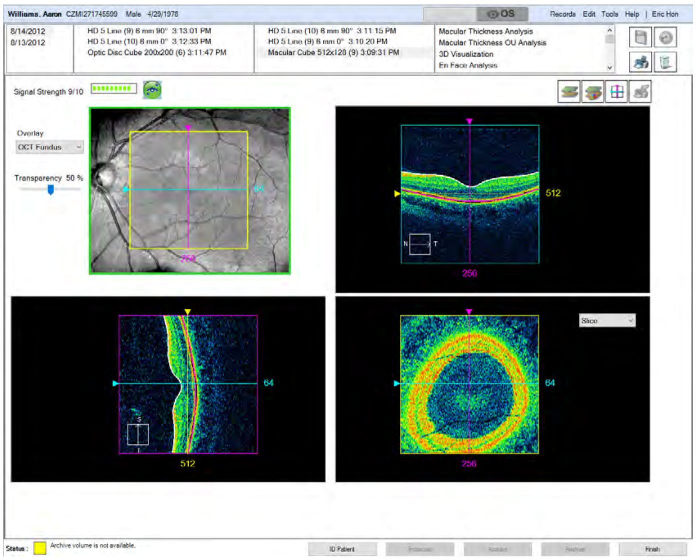
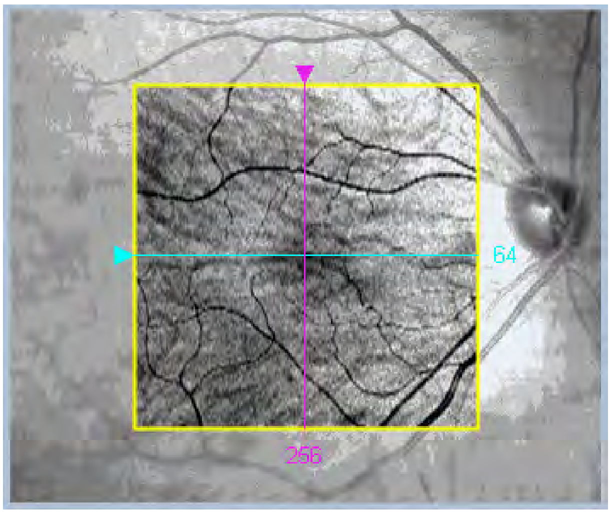
Analysis	Description
Advanced Visualization 	

Table 79: Additional Visual Cube Scans

9.5.5.1 Navigate Cube Layers Manually

Tip: You can also navigate through layers by clicking the B-scan you want to navigate and scrolling the mouse.



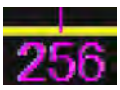
You can drag the vertical and horizontal slice lines to scroll through the image cube. The current slice number displays on the opposite side of the arrow you use to select and drag the line.

Prerequisite

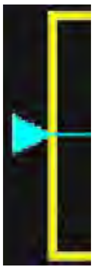
☑ You are acquiring, checking quality or analyzing a scan and reach the step: *navigate cube data*.

Action

1. To navigate through the vertical slices of the cube, click on the magenta triangle and drag the line right or left.



⇨ The current slice number changes dynamically as you navigate through slices.

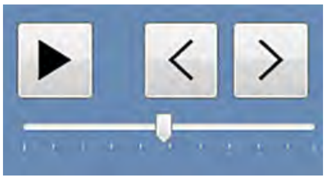


2. To navigate through the horizontal slices of the cube, click on the cyan triangle and drag the line up or down.

⇨ The current slice number changes dynamically as you navigate through slices.

3. Complete the remaining steps of the acquire procedure.

9.5.5.2 Navigate Through Cube Slices as a Movie



Action

1. Use to view a movie of the fast B-scans or sequence through them one image at a time.

   ⇨

2. Complete the remaining steps of the acquire procedure.

   ⇨

You can view the scan as a movie that begins at the top of the B-Scan slice and moves down through the tissue in 51 µm increments. You can stop the movie, reverse or advance the movie frame by frame.

NOTE! The default frame rate for scan movies is 51 µm/sec.

To view the image as a movie:

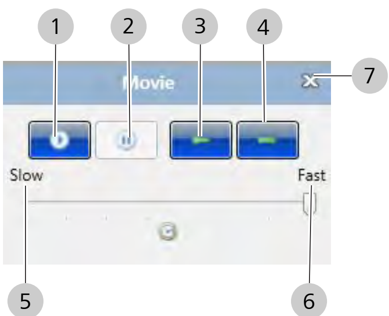
Prerequisite

☑ You reach the scan analysis step: *Edit an Image*.

☑ Editing tools are open: Open Image Editing Tools [▸ 372].

3. Click **Play Movie**.

   ⇨ The movie controls open.



4. To start the movie, click the **play button (1)**.
5. To stop the movie, click the **pause button (2)**.
6. To move backward one frame, click the **previous button (3)**.
7. To move forward one frame, click the **next button (4)**.
8. To decrease movie speed, move the slider toward **Slow (5)**.
9. To increase movie speed, move the slider toward **Fast (6)**.
10. To close the movie controls, click **Close (7)**.
11. Complete the remaining steps of the acquire procedure.

Empty page, for your notes

10 Networking

10.1 Safety During Network Configuration

⚠ WARNING!

Use of a power strip

may cause an electric shock.

- ▶ To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

⚠ WARNING!

Connecting the NAS device Directly to the instrument using a shielded network patch cable

could cause electrical shock to the patient and/or operator.

- ▶ Use a network patch cable with an unshielded RJ–45 connector to connect the NAS device directly to the instrument.

⚠ CAUTION!

Not archiving data daily

increases the risk of data loss.

- ▶ 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.

⚠ CAUTION!

Connecting the instrument to the Internet

increases its vulnerability to serious security risks, including viruses and worms that could disable your system or adversely affect its performance and may void the instrument warranty.

- ▶ Transfer data through internal networks.
- ▶ Ensure that all firewalls and internet security applications are up-to-date and running.
- ▶ Connecting the device to the internet or transferring data via USB devices may result in compromised patient privacy and expose the network to malware.

⚠ CAUTION!

It is strongly recommended that you allow a knowledgeable IT professional to assist you with network configuration and software installation.

⚠ CAUTION!

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.

When connected to the Internet, the instrument 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.

▶ Do not download or install any unapproved software or drivers.

NOTE

ZEISS does not provide technical support for the use of third party hardware or software.

NOTE

Users are responsible for network setup and maintenance.

Users are responsible for installing and configuring all networking hardware and software.

ZEISS Technical Support is limited to testing instrument network connectivity.

▶ ZEISS Technical Support cannot troubleshoot or repair problems with network connectivity.

▶ Observe all guidelines in this document regarding instrument networking.

NOTE

ZEISS does not provide technical support for the use of third party hardware or software.

NOTE

Do not perform a virus scan while acquiring exam data.

NOTE

These instructions assume that a TCP/IP network is already installed in your institution. If you are unsure of your network status or if you want to set up a network, consult a networking professional.

10.2 Network Capabilities

The CIRRUS 6000 is designed for network data transfer. Software supports the following networks and network activities:

- Windows and Novell ® networks
- Creating user accounts
- Networking via a local area network or intranet

- Archiving to and retrieving from a network file server
- DICOM gateway connection

Indicates optional features; license may be required.

10.2.1 About Local Connections (Remote Desktop)

NOTE

Only Administrators can complete this task.

To connect locally, use Remote Desktop. If you need help using Remote Desktop, ask your institution's local IT personnel or consult the documentation for Remote Desktop.

10.2.2 Select the Installation Mode

Your CZMI Representative installs your CIRRUS 6000

- Software is installed correctly.
- Software is configured properly for your network.
- Archiving is configured.
- Software connects to your archive.

10.2.2.1 Installation Modes

<table>
<tr><th></th><th>Stand-alone</th><th>Native</th><th>DICOM/FORUM</th></tr>
<tr><td>Typical Use</td><td>Very small office (not recommended).</td><td>Most practices.</td><td>Office or practice that shares data between two or more instruments or uses FORUM Retina or Glaucoma Workplaces.</td></tr>
<tr><td>ZEISS Instrument Connections</td><td>None</td><td>Connects instruments to review stations.</td><td>Connects instruments to review stations, additional CIRRUS 6000 instruments, and other types of ZEISS instruments.</td></tr>
<tr><td>Data Storage</td><td colspan="2">CIRRUS 6000 internal storage.</td><td>Separate, sometimes remote FORUM archive storage device.
(CIRRUS 6000 internal storage cleared when data is archived to FORUM storage.</td></tr>
<tr><td>Storage Limit</td><td colspan="2">CIRRUS 6000 internal drive limit.
When the instrument's internal drive is full, the oldest data is archived and cleared to make room for new data.</td><td>External storage device (any size; expandible).
When the instrument's internal drive does not become full.</td></tr>
</table>

	Stand-alone	Native	DICOM/FORUM
Data exchange	DICOM MWL and EPDF compatible.		DICOM MWL, EPDF, and Raw data compatible using FORUM, integrates with other DICOM-compatible systems.
Additional Storage Requirements	None (provided the CIRRUS 6000).		■ DICOM/FORUM License. ■ DICOM-compatible storage or EMR system.

Table 80: Mode Comparison

10.3 Network File Server Minimum Requirements

Using a Network File Server is recommended in offices that have a local area network and want to archive data to a network storage location.

The network file server must meet the following minimum requirements:

- 256 MB RAM
- Windows, Unix or Linux server operating system. (You can use SAMBA with Unix and Linux file servers).
- NTFS drive partition(s) for CIRRUS 6000 data.
- 250 GB available disk space for data storage
- Tape backup unit
- BaseT network connection

10.3.1 Additional Recommendations

In addition to the minimum requirements listed above, we recommend the following for the network file server:

- A mirrored RAID array for data storage—strongly recommended.
- An uninterruptible power supply (UPS)—strongly recommended.
- 1000 BaseT network connection.
- Removable backup drive with capacity of at least 250 GB.

10.4 Connect to a Networked Storage Device

You can archive your data using **Network Attached Storage** (NAS).

You can use one, multiple or mirrored NAS devices to back up your data.

When you use two or more NAS devices concurrently, you must also use a switch or router that is connected to the network or directly to the instrument.

10.4.1 NAS Requirements

To use a NAS device for archiving your data, the NAS device must meet the following minimum requirements:

- **1000Base Ethernet capable**: For safety reasons, do not connect the NAS directly to the instrument.
- **Network patch cord:** for direct connection to the instrument, UTP CAT5e cord with an unshielded RJ-45 connector.
- **Compliance:** The NAS device you select must comply with local requirements.
  - In Europe, CE approval is required
  - In North America, UL, CSA, or equivalent and FCC approval is required.

10.4.2 Configure Networked Storage Device Connections

Most NAS devices have a default name on the network. We recommend that you retain the default name for the NAS device. Workgroup Name Must Match the CIRRUS HD-OCT Workgroup Name:

Some NAS devices automatically map the NAS device to a drive letter on the instrument.

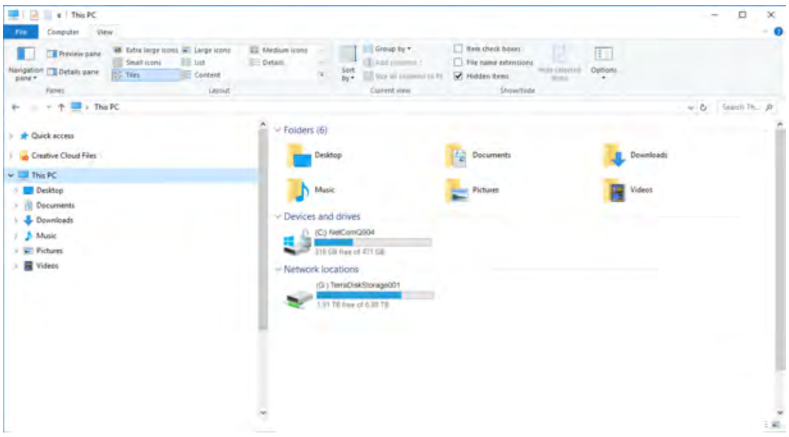
To configure NAS connections:

Prerequisite

☑ The NAS device is on and initialization is complete (see manufacturer's instructions)

Action

1. Start up the CIRRUS 6000 (see: System Startup [▸ 54]).
2. Note the name of the NAS.
3. Open **Windows Explorer** and navigate to **This PC**.



4. Ensure the NAS device appears in your network.

5. If necessary, map a drive for the NAS device. Refer to the Windows documentation or online help for instructions on mapping a public drive.

10.5 Connect to a DICOM Gateway

NOTE

This section is intended for an IT or DICOM network administrator.

For assistance:

- In the U.S., call Zeiss at 800-341-6968.
- Outside the U.S., contact your local CZM distributor

DICOM Gateway allows you to connect CIRRUS 6000 instruments to other patient scheduling, record management, and storage applications such as:

- DICOM-compatible EMR or patient management system
- DICOM archive, such as a PACS server

10.5.1 Review Station Requirements

Review stations must meet the minimum requirements listed in this section for DICOM Gateway connections.

10.5.1.1 Operating System Requirements

To use the DICOM Gateway, your review station must run one of the following operating systems:

- Windows 7 SP1, 64-bit
- Windows 8.1, 64-bit
- Windows 10, 64-bit
- Windows Server 2008 R2
- Windows Server 2012 R2
- Windows Server 2008 / 2012 RDS support

10.5.1.2 Computer Requirements

To use the DICOM Gateway, your review station must meet the following minimum system requirements:

Requirement	Minimum and Recommendations
CPU	2.0 GHz **Recommend:** Intel Quad Core
Available Disk Space	20 GB
Memory (RAM)	4 GB **Recommend:**8 GB

Requirement	Minimum and Recommendations
USB Port	1 (required for installation)
Network Card (TCP/IP Protocol)	100 MB
Screen Resolution	1024 x 768 pixels

Table 81: Review Station Requirements for DICOM Connection

10.5.2 Configure DICOM Connections

NOTE

ZEISS FORUM application enables you to use AutoConnect.

Each instrument and review station connected to the DICOM network must have a unique Application Entity (AE) title registered with your DICOM system.

To configure DICOM connections:

Prerequisite

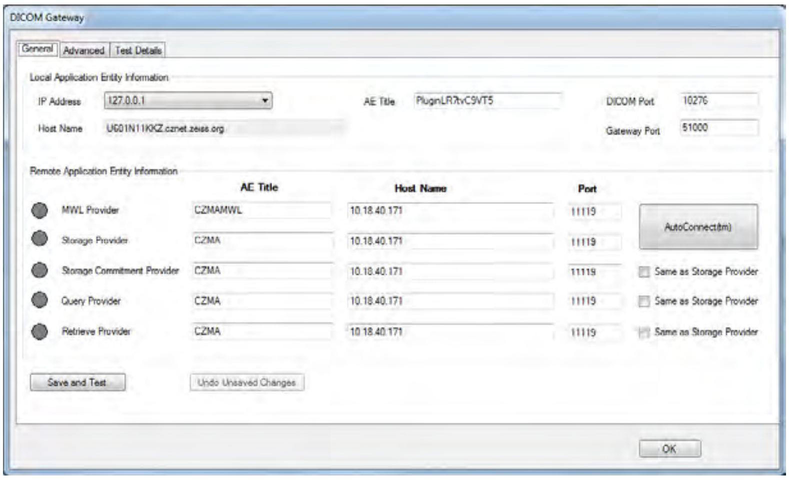
☑ On the CIRRUS™ HD-OCT instrument, Log in as Admin [58].

☑ **AE Titles** are registered in the DICOM system

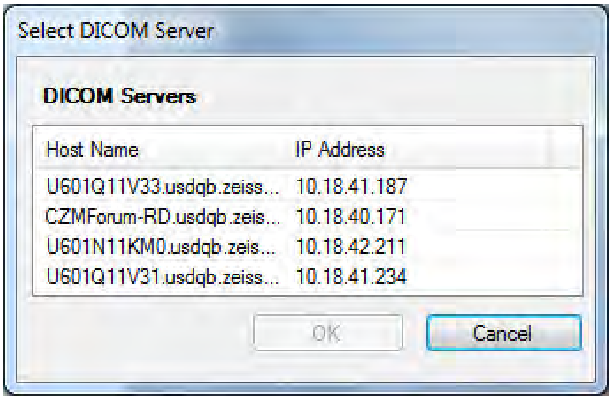
Action

1. From the Windows desktop, navigate to **C: \ Program Files \ Carl Zeiss Meditec \ DICOM Gateway**.
2. Double-click **Configuration Tool.**

   ⇨ The **DICOM Gateway** tool opens.



3. Select the **General** tab.
4. For **IP Address** , set to: `127.0.0.1` *(instruments and Review Stations)*.
5. For **AE Title**, type the **DICOM Gateway** title registered in the DICOM system.
6. For **DICOM Port**, type the local port number for DICOM Gateway (e.g., FORUM).
7. For **Host Name**, type the server address.
8. Click **AutoConnect**.



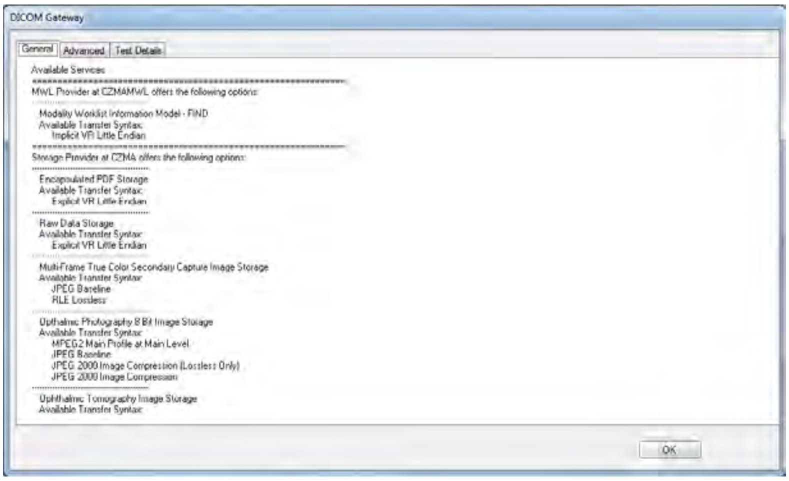
⇨ If multiple FORUM servers are discovered, a selection dialog opens.

⇨ If only one FORUM server is discovered, the DICOM-registered **AE Title**,**Host Name**, and **Port** for the **MWL Provider**and **Storage Provider** populate automatically.

9. If the **Storage Provider**, **Storage Commitment Provider**, and **Retrieve Provider** are the same, check **Same as Storage Provider**.
10. If the **Storage Provider**, **Storage Commitment Provider**, and **Retrieve Provider** are the different, type the DICOM-registered **AE Title**,**Host Name**, and **Port** for the providers.
11. Click **Save and Test**.

⇨ When the network testing is complete, a green indicator confirms success.

12. For advanced configuration options, refer to: DICOM Advanced Configuration [▹ 399].
13. To view a detailed list of the connection testing, select the **Test Details** tab.



⇨ A detailed list of connection testing opens.

14. If indicators are not red, confirm the connection data and click **Save and Test**

15. If the connections are not working properly, refer to: Troubleshooting Connections [▷ 427].
16. Click **OK**.

10.5.3 DICOM Advanced Configuration

NOTE

Not all systems use Extended Negotiation.

Make sure you use the correct settings for your system. Setting **Enable DICOM Extended Negotiation**:

- **Uncheck** for United States Veterans Administration's VistA™
- **Check** for FORUM

The recommended default values for the **Advanced** tab are listed in the table below.

Setting	Value
Maximum Query Responses	100
Timeouts	
Maximum Association Idle Time	30
DIMSE RSP Timeout	20
Network Timeout	20
Enable DICOM Extended Negotiation	Checked
Allow Local AETitle Edit (if Review Stations are included in the network)	Checked

Table 82: Recommend Values for Advanced Configuration for Connections

You can adjust these values as needed to optimize performance or allow for slower network connections.

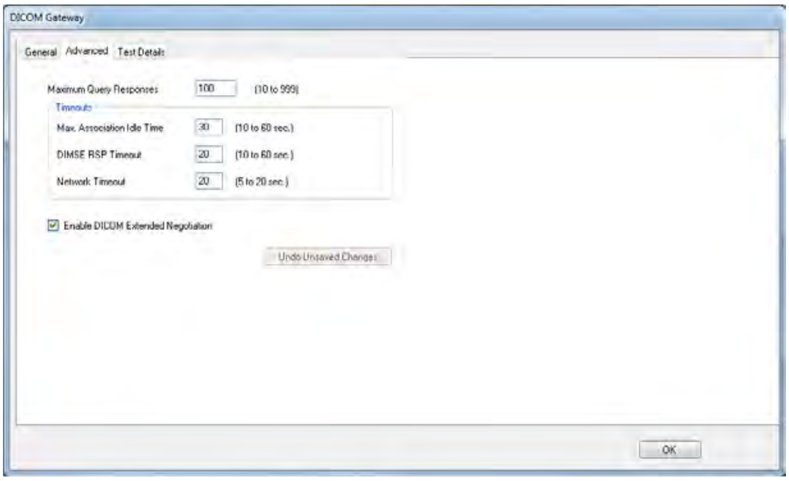
To configure DICOM advanced configuration settings:

Prerequisite

☑ Log in to the computer.

Action

1. From the Windows desktop, navigate to **C:\ Program Files > Carl Zeiss Meditec > DICOM Gateway**.
2. Double-click **Configuration Tool.**
   ⇨ The **DICOM Gateway** tool opens.



3. Make adjustments as needed to accommodate your network's response time.
4. Click **OK**.

Also see

🗎 Log In as Operator or Data Analyst [▹ 123]

10.6 Connecting Review Stations to Instrument Data Archives

NOTE

Some IT departments only allow computer administrators to map network drives.

If your computer does not allow you to map network drives, contact your institution's IT representative to request that a computer administrator map this drive for you.

When a review station connects to one or more CIRRUS 6000 instruments, a reviewer can access patient scans. After an operator saves a patient's scans, a doctor can view, compare, annotate, edit them from their review station computer on the same networks.

This procedure describes how map a network drive using the Windows control panel. When you map a network drive from the review station to the instrument, the review station retains this connection for future access.

Prerequisite

- ☑ The instrument 's data folder is shared: (Setting Up a Network File Server (external NAS)).
- ☑ Review software is installed on the review station: (Installing Review Station Software [▹ 42]).
- ☑ The review station is on the same network as the instrument: (Networking [▹ 391]).
- ☑ You have administrator rights to the review station.

Action

▶ Map a network drive to the instrument's shared folder on the network. Refer to the Windows documentation or online help for instructions on mapping a drive.

10.7 Connecting to Printers

⚠ **WARNING!**

Adding peripheral equipment

may result in noncompliance with the safety requirements of IEC 60601-1.

▶ You are responsible for ensuring that the system meets the safety requirements of IEC60601-1.

▶ Place any AC-powered, non-medical device peripherals at least 1.5 m away from the device and connect them to a separation device, or else use an isolation transformer.

⚠ **WARNING!**

Placing peripheral devices closer than 1.5 meters (4.9 feet) from the patient

could result in electrical shock to the patient and/or operator.

▶ Use a wireless configuration, if possible.

▶ Use an isolation transformer in the USB configuration.

▶ Ensure that patients cannot touch a peripheral device with any part of his or her body while being examined.

▶ Ensure the instrument operator does not attempt to touch the patient and a peripheral device at the same time.

⚠ **WARNING!**

Powering peripherals directly through a wall socket

could result in electrical shock to the patient and/or examiner.

▶ When using a printer in the USB configuration, always power the printer through an isolation transformer. Some ZEISS equipment comes with an isolation transformer that may be used by plugging into a special power strip provided with the equipment. Talk to your ZEISS Service Representative to determine if this is true for your equipment.

▶ If you are not sure, plug all peripherals (such as a printer), into an isolation transformer. This requires 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!

Use of the acquisition device, a printer, or the power table with an extension cord or a power strip (multiple portable socket outlet)

could cause electrical shock to the patient or operator.

- ▶ Do not use extension cords with the instrument.
- ▶ If you plug something other than an instrument into the Multiple Socket Outlet (MSO), the MSO may not have the designed level of safety.
- ▶ Do not use power strips with the instrument.
- ▶ Do not plug in any other equipment into the same wall outlet as the instrument.
- ▶ To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

This section provides generic requirements and recommendations for printers. Specific configuration instructions vary by printer. Refer to the printer manufacturer's instructions. If you use a third-party device, seek technical support from the device manufacturer. Repairs necessitated by the attempt to use a non-approved device are not covered under warranty.

Direct Connection (USB) 	General steps for USB connection: 1. Install the ZEISS approved printer drivers on the instrument (if needed). 2. Connect the printer power cord plug **to an isolation transformer**. 3. Connect the printer to the instrument using a USB cable. 4. Power on the printer.
Local Area Network Connection 	Use any of the following connection methods: ■ Connect both the instrument and the printer to the local area network ■ Connect instrument and printer with the network (Ethernet) cable ■ Connect the printer to a network switch/router/hub connected to the instrument **NOTE! Use the same kind of network cable. Do not use an RJ-45 crossover cable to connect the printer to the instrument.**

WiFi Network Connection 	General steps for Wi-Fi connection: 1. Connect the wireless access point to the network. 2. Install the ZEISS-approved wireless access point drivers on the instrument (if needed). 3. Turn on the printer. 4. Install the ZEISS approved printer drivers on the on the instrument (if needed). 5. Connect the printer follow the manufacturer’s instructions for wireless operation. 6. Configure the printer to use WPA2 encryption. 7. Configure the wireless access point as necessary to communicate with the printer.

Table 83: General Steps to Connect a Printer

10.8 Database Selection

Like CIRRUS 6000 instruments, Review Stations typically have a designated primary database. When data is imported, it is placed into this database. The option **Database Selection** is available on Review Stations for this purpose. For more information about connecting review stations with instruments, see Networking [391].

Operators and Administrators can select the working database. However, it is recommended that the Administrators oversee databases to ensure that patient data is kept cohesive and transparent within the institutional environment.

10.8.1 Select a Database

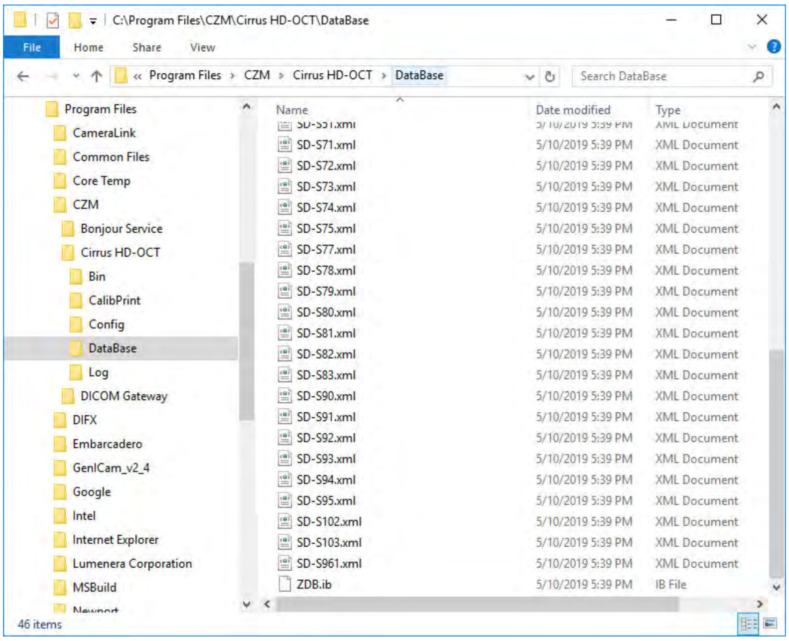
Action

1. From the Toolbar, select **Tools > Options > Select Database**, and an Explorer window appears.
2. Navigate to the location of the database of interest. Database files have an "**.ib**" extension. For example: **C:\SSOCT\Database\ZDB.ib** is a valid CIRRUS 6000 database.
3. Click **Open**.
4. Restart the software.

10.8.2 Copy a Database

Action

1. From the review station desktop, click the Windows Explorer icon from the Desktop.
2. Navigate to `C:\Program Files\CZM\CIRRUS HD-OCT\Database`.



3. Select **ZDB.ib**. This file is the software database. **Do not modify this database.** It is empty and intended to be copied as a database template for the database you will use to store patient data.
4. Right-click and select **Copy**.
5. Navigate to the location where you want your database to reside, preferable in an empty folder. Note where on the system you are storing the database, because you will periodically need it.
6. Right-click and select **Paste**.
7. Right-click the copied database and select **Properties**.
8. In the **General** tab, uncheck the **Read-only** attribute and then select **Apply > OK**.
9. Launch the CIRRUS 6000 application software.
10. During startup, the Equipment Edit dialog box will appear.
    - ⇨ Enter information in the **Station Name** field (if needed).
    - ⇨ Enter information in the **DICOM AE Title** field (if needed). This information should match the AE Title assigned in the DICOM Gateway.
    - ⇨ Enter the model number in the **Model Number** field. The model number is the first set of numbers *before* the dash and after the **SN** box on the **Instrument Serial Number** label.
    - ⇨ Enter the sequence number in the **Sequence Number** field. The sequence number is the second set of numbers *after* the dash and after the **SN** box on the **Instrument Serial Number** label.
    - ⇨ Select **Save**.

11. Log in using the **Admin** user and then create the CIRRUS 6000 **Operator** user. Refer to the CIRRUS™ HD-OCT Instructions for Use for Managing User Accounts [▸ 70].
12. Log out of the CIRRUS™ HD-OCT application software.

Empty page, for your notes

11 Cleaning and Disinfection

11.1 Safety During Cleaning and Disinfection

⚠ CAUTION!

Improper care and cleaning of optical components

could lead to coating failure.

Contaminants on the optical surfaces increase scatter off the surface and absorb light energy.

- Do not use alcohol prep wipes to clean lenses or optical surfaces.
- Wipe gently and carefully to avoid scratching the instrument and auxiliary lenses.

⚠ CAUTION!

Cleaning lenses too frequently

can damage optic surfaces.

- Clean optics only when necessary.
- Keep the protective cover on your device when not in use.

⚠ CAUTION!

Using aerosols near or placing containers of liquid on or near the instrument

could damage the equipment. The instrument is not designed with any specific measures to protect against harmful ingress of water or other liquids (classified IPXO - ordinary equipment).

- Do not place containers of liquid, or use aerosols on or near the equipment.

11.2 Cleaning Agents

Item	Explanation
Latex Finger Cots and Gloves	Solvents are harsh to the skin; wear protection.
Optics Cleaning Tissue	Soft, absorbent, lint-free lens tissue is best.
Swabs	Cotton swabs with wooden handles or polyester swabs with polypropylene handles are best.
Blower	Filtered dry nitrogen blown through an antistatic nozzle is best. Canned dusters also work. Bulb-type blowers and brushes must be kept clean to prevent recontamination.
Mild Soap	Neutral soap, 1% in water. Avoid perfumed, alkali, or colored soaps. Several drops of green soap (available at a pharmacy) per 100 cc of distilled water is acceptable.
Isopropyl Alcohol	Spectroscopic grade; evaporates more slowly than acetone.
Acetone	Spectroscopic grade.

Item	Explanation
Hemostats	For holding lens tissue.
Bright Light	For inspection.

11.3 Cleaning Optical Components

11.3.1 Brush Cleaning Method

NOTE

Edges on mounted optics

are often hard to reach.

- Wrap a lens tissue around a swab.
- Soak the covered swab in acetone.
- Brush around the edge of the lens and then across the middle using a continuous figure-eight stroke.
- Repeat if necessary.

Use this technique to clean small lenses. Hold a folded lens tissue with a hemostat to brush the surface clean.

Action

1. Fold a lens tissue about as wide as the lens. Do not touch the area of the tissue that will contact the lens.
2. Using hemostats, hold the tissue near the fold.
3. While holding the optic, using tweezers if necessary, blow off any dust.
4. Soak the tissue with acetone.
5. Brush the fold in the tissue across the surface of the optic using light pressure.
6. Repeat as necessary until the optic is clean, using a new lens tissue with each wipe.

11.3.2 Wipe Cleaning Method

Use this technique to clean very dirty lenses and mirrors.

Action

1. Blow off dust.
2. Fold a lens tissue as with the brush method.
3. Apply acetone to the tissue.
4. Holding the lens tissue in your hand with the fold near the tip of your fingers, apply uniform pressure while gently wiping across the surface of the optic.
5. Repeat as necessary until the optic is clean, using a new lens tissue with each wipe.

11.3.3 Dust Cleaning

Static electricity can bind dust tightly onto optics. Blowing removes some dirt; use a wet alcohol swab to remove the remainder. Acetone dries the optic quicky, which helps eliminate streaks.

Action

1. Blow off dust.
2. If any dust remains, twist lens tissue around a swab, soak in alcohol, and wipe the optic in one direction with a gentle figure-eight motion.
3. Repeat as necessary.
4. Repeat the steps above, using acetone.

11.3.4 Cleaning Heavy Contamination

NOTE

Always clean fingerprints, oil, and water spots from lens and optics immediately.

Skin acids can permanently damage optical coatings. Solvents can redistribute dirt and oil.

- ▶ Use soap or other wetting agent to clean the optical surfaces.
- ▶ Use water to remove the soap.
- ▶ Use alcohol to remove the water.
- ▶ Use acetone to speed drying and eliminate streaks.

Use this technique to clean fingerprints, oil, or water spots.

Action

1. Blow off dust.
2. Using a soap-saturated lens tissue placed around a swab, wipe the optic gently in a figure-eight motion.
3. Repeat as necessary.
4. Repeat this procedure with distilled water.
5. Repeat again with alcohol.
6. Repeat once more with acetone.

11.4 Cleaning the Chin Cup and Forehead Rest

⚠ WARNING!

Strong solvents such as Acetone or Methyl Alcohol

will damage the chin cup and forehead rest.

- ▶ Use a gentler disinfectant such as isopropyl alcohol.

Action

1. Clean the chin cup and forehead rest with a disinfectant such as isopropyl alcohol.
2. If disinfectant contacts the ocular lens during cleaning, gently wipe the lens (see: Wipe Cleaning Method [▸ 408]).

11.5 Cleaning Peripherals and Table

⚠ CAUTION!

Do not use any cleaning agent on the screen.

Action

1. Wipe the monitor with a soft, non-linting cloth.
2. Regularly dust or wipe down the table.

12 Maintenance and Repair

NOTE

Expected Service Life

The expected service life of CIRRUS 6000 is 7 years.

12.1 Safety During Maintenance

⚠ WARNING!

Opening instrument covers

could result in exposure to electrical and optical hazards.

- ▶ Do not open the instrument covers.
- ▶ Exception: You may remove the rear cover to access labels, change connectors, or clean fans.

⚠ CAUTION!

Unauthorized modification or dismantling of the instrument or system components

could result in damage to the instrument or components, or harm to the operator or other personnel.

- ▶ Only authorized ZEISS personnel may make modifications to, or dismantle, the instrument or its components.

Before performing cleaning or maintenance, refer to: Safety [▷ 12].

12.2 Maintenance Schedule

Periodically inspect the CIRRUS 6000 system to ensure that:

- The system is well maintained and free of dust
- Wiring is intact and connected.
- Optics are clean (see: Cleaning and Disinfection [▷ 407]).

The frequency of these inspections depends on the frequency of use and the environmental conditions where the system resides.

12.2.1 Every Week (Before Use)

Component	Activity	Time required
Scan Alignment	Performance Verification Check	2 minutes

12.2.2 Every Month

Component	Activity	Time required
Instrument Computer	Defragment the Disk Drives [▷ 417]	(Varies)

12.2.3 Every 6 Months

Component	Activity	Time required
Fan Filter	Inspect, Clean or Replace the Fan Filter [▹ 416]	2 minutes

12.3 Run the Verification Test

12.3.1 Verification Test Tool Overview

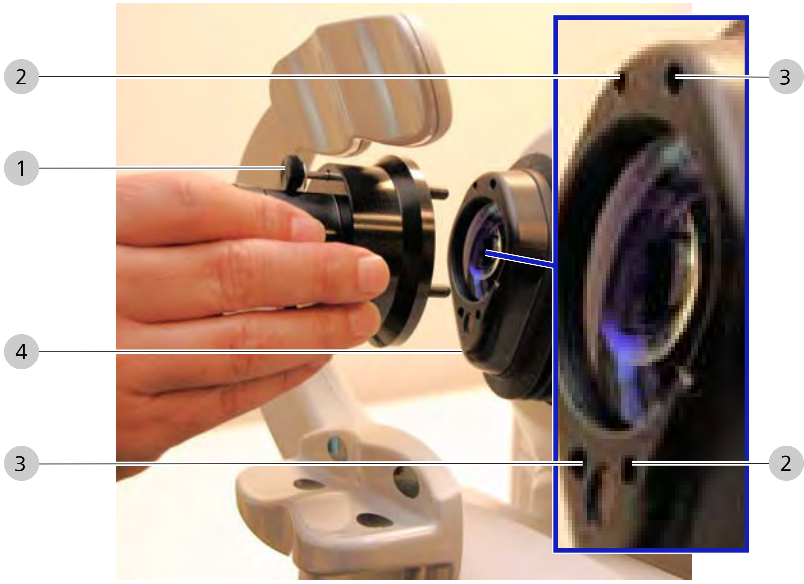


Figure 83: Verification Test Tool

1	Thumbscrews	2	Peg mounts
3	Thumbscrew mounts	4	Ocular lens housing

12.3.2 Install the Verification Test Tool

Install the **Verification Test Tool** before you Run the Verification Test [▹ 413].

Do not drop the **Verification Test Tool**; hold the test tool in place until you tighten the thumbscrews.

To install the Verification Test Tool:

Action

1. Install the **Verification Test Tool** on the face of the ocular lens housing.

2. Align the short pegs with holes on upper left and lower right.
3. Align the thumbscrews with holes on the upper right and lower left.
4. Tighten the thumbscrews with your fingers.

12.3.3 Run the Verification Test

NOTE	**You do not need to make adjustments for image appearance or signal strength.** You can adjust brightness and contrast in the **Analyze** step.

NOTE	**You cannot edit or delete the Performance Verification patient record.**

NOTE

If a performance verification check fails, the data acquired since the last successful check may not be reliable.

Evaluating this test is somewhat subjective. The examples provided are guidelines. Note that:

- The alignment target defines a stringent range of tolerance.
- There is only a two or three-pixel difference between **PASS** and **FAIL**.

Before confirming that a test **FAILED**:

- Switch between 0% and 100% transparency multiple times to confirm navigation line alignment (see steps below).
- Remove and reinstall the **Verification Test Tool** to make sure it is seated properly and rerun the test.

To verify performance:

Prerequisite

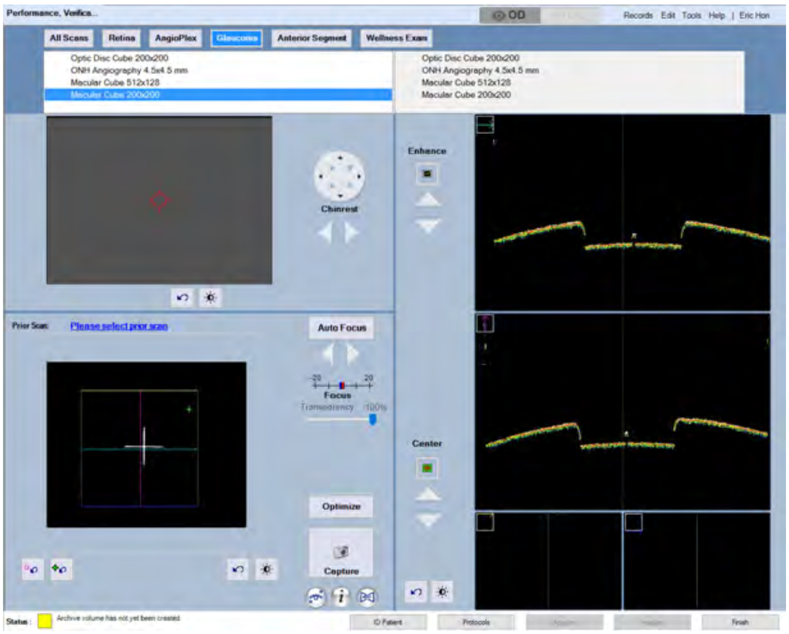
☑ The **Verification Test Tool** is installed (Install the Verification Test Tool [▹ 412]).

☑ The **Patient** window is open (Select the Patient [▹ 124]).

Action

1. Select the patient: **Performance Verification** and click **Acquire**.

   ⇨ The **Acquire** screen opens.

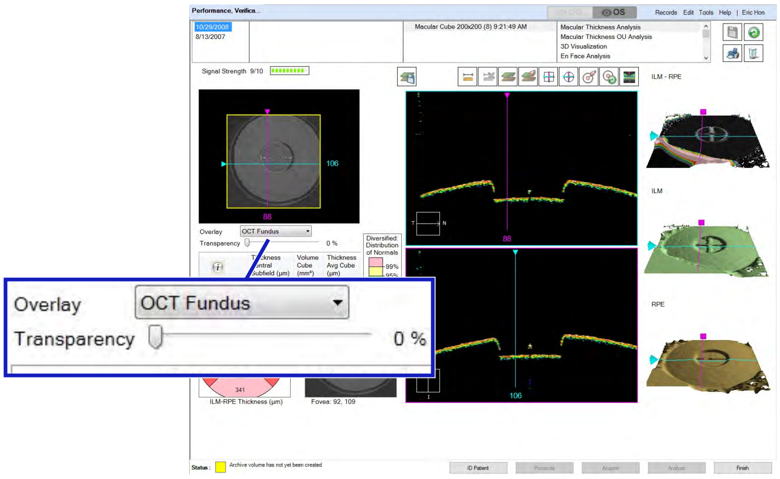


2. Select **Macular Cube 200x200** and click **Auto Focus**.

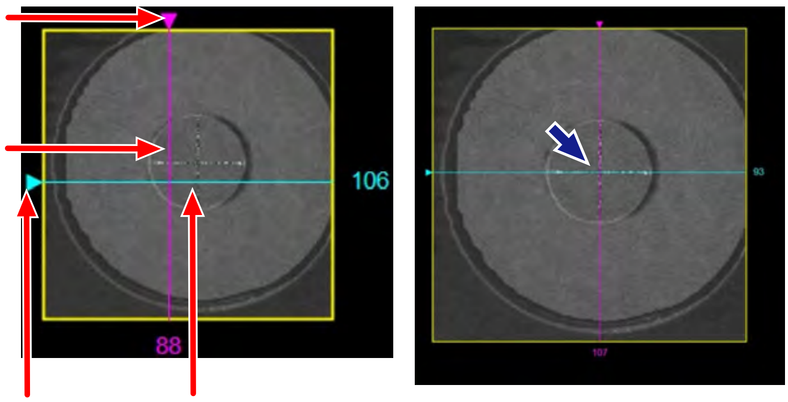
3. Click **Capture**.

   ⇨ The **Select Eye** dialog opens.
4. Select either **OD** or **OS**.
5. Click **Save**.

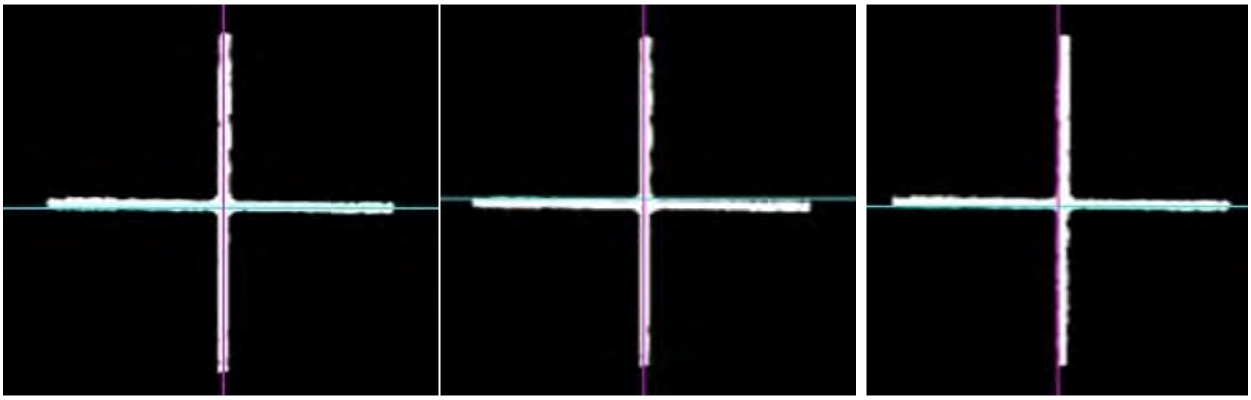
6. Click **Finish**.
   ⇨ The **Patient** page opens.
7. Select the patient: **Performance Verification** and click **Analyze**.
   ⇨ The **Analysis** screen opens.



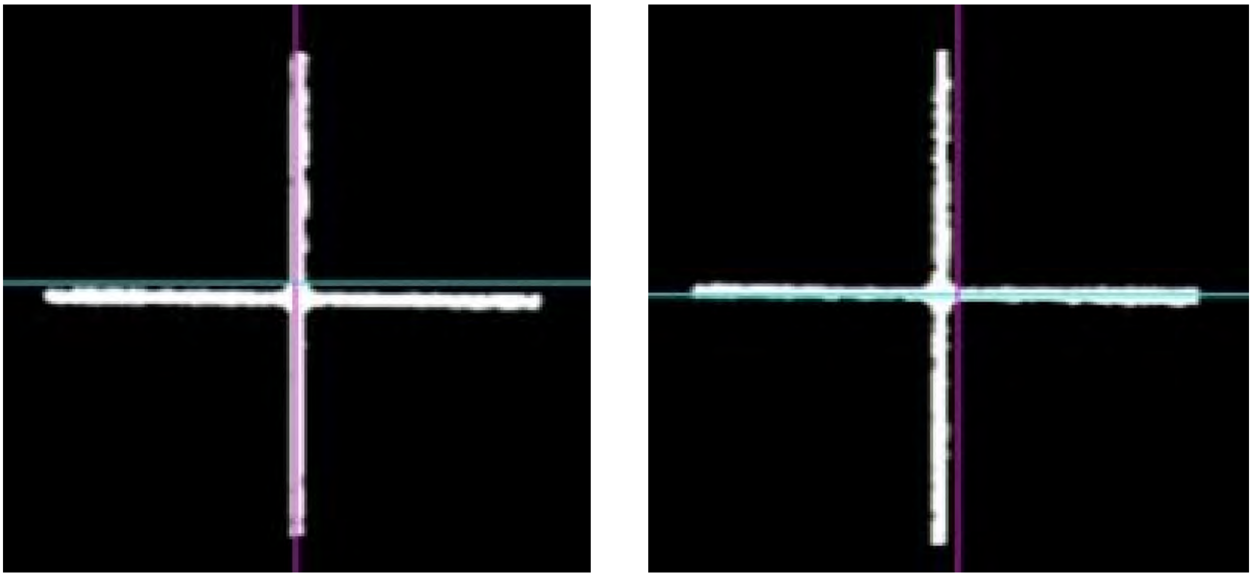
8. Select the scan saved in the steps above.
9. For **Overlay**, choose **OCT Fundus**.
10. Set **Transparency** to **0%**.
11. Double-click on the fundus image.
    ⇨ The fundus image opens in full-screen mode.



12. Drag the horizontal and vertical navigation lines to center them directly over the alignment target (white crossed lines) in the center of the circle.
13. Exit full-screen mode.
14. Set **Transparency** to **100%**.
    ⇨ The circles fade and the fundus image panel is black showing only the alignment target and navigation lines.
15. Double-click on the fundus image.
    ⇨ The fundus image opens in full-screen mode.



16. If both the horizontal and vertical navigation lines are centered on the alignment target or are touching the alignment target, the verification test **PASSES**.



17. If either the horizontal and vertical navigation lines are in the black (above, below, to the right or left of the alignment target), the verification test **FAILS**.
18. If the test **FAILS**, contact Zeiss customer service.
    - ⇨ In the U.S., call 800–341–6968.
    - ⇨ Outside the U.S., contact your local Zeiss distributor.
19. If you are not sure of the results, remove the verification test tool and repeat the test.
20.
21. Click **Finish**.

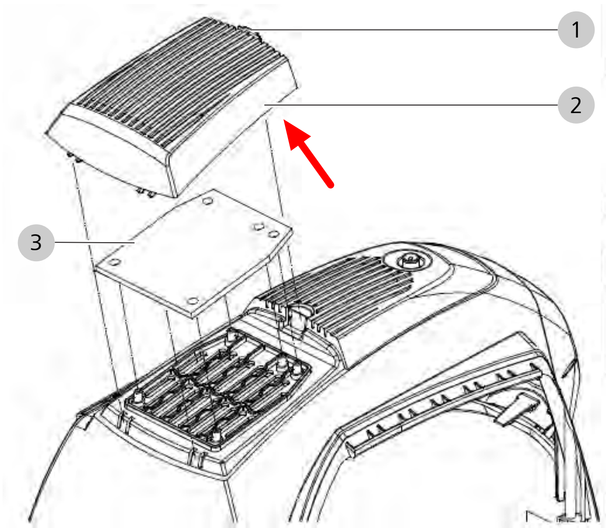
12.4 Inspect, Clean or Replace the Fan Filter

Inspect the fan filter at least twice a year to determine if it needs cleaning or replacement.

To check or replace the fan filter:

Action

▶ Press the snap connector (1) and gently pull the cover back (2).



▶ If the filter (3) does not need replacement, gently clean the filter with water or alcohol and wipe dry with a clean, soft cloth.

▶ If the filter (3) needs replacement, remove and discard the old fan filter.

▶ Install the new fan filter (3) in the fan cover (2).

▶ Carefully install the fan cover (2) and snap the connector (1) into place.

12.5 Defragment the Disk Drives

NOTE

Hard disk defragmentation usually requires several hours to complete

▶ We recommend that you start defragmentation at the end of the day and let the process run overnight.

This procedure explains how to determine whether a drive needs defragmentation and now to defragment it.

If defragmentation does not complete by the time you need to use the instrument, stop defragmentation and start again when the instrument will not be in use for several hours.

When you clear archived exams regularly, the database and system performance degrade over time. Defragment the drives to maintain peak performance.

The CIRRUS™ HD-OCT might be segmented into several drives. For example, an instrument could have the disk drives:

- **D:**
- **E:**

Check each drive and defragment all drives that require it.

To defragment the computer:

Prerequisite

☑ The instrument is not needed for several hours (overnight recommended).

Action

- Exit the CIRRUS™ HD-OCT software (Log Out [▸ 124]).
- From Windows, select **Search** and type `Defrag`.
- Open the app **Defragment and Optimize Drives**.
  - ⇨ The Windows **Optimize Drives** tool opens.
- Select the first disk drive.
- Click **Analyze**.
  - ⇨ The app analyzes the disk to determine whether it requires optimization.
- If the analysis recommends optimization, click **Optimize**.
  - ⇨ This process takes several hours. Do not use the system during the optimization process.
- Repeat these steps for each remaining disk drive and optimize as needed.

12.6 Calibrate the Anterior Segment Lenses

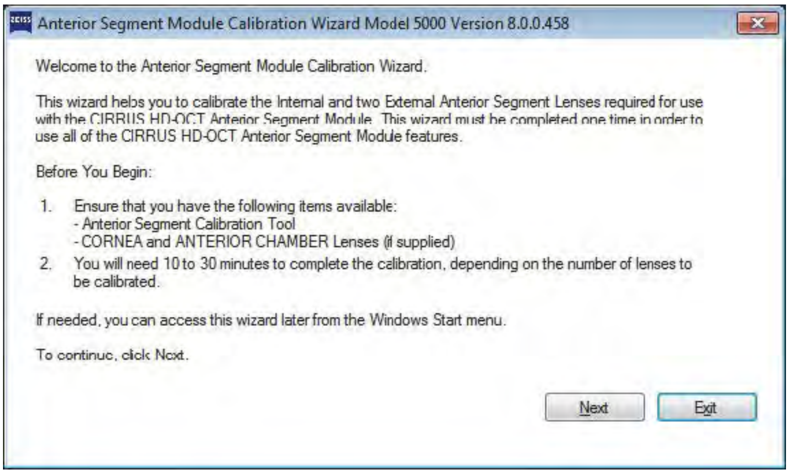
NOTE

Do not touch the Calibration Tool, External Lens, or instrument while the calibration is in progress.

To calibrate the anterior segment lenses:

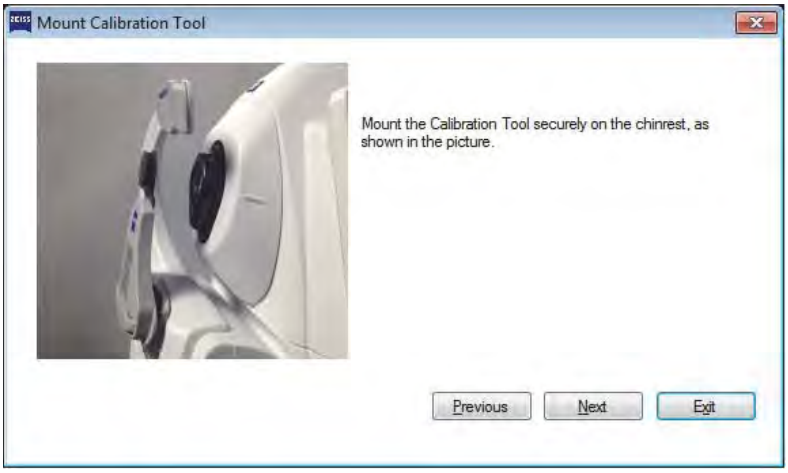
Action

1. In Windows, navigate to the **Carl Zeiss Meditec** folder.
2. Double-click the **Anterior Segment Module Calibration Wizard** file.
   - ⇨ The calibration wizard opens.



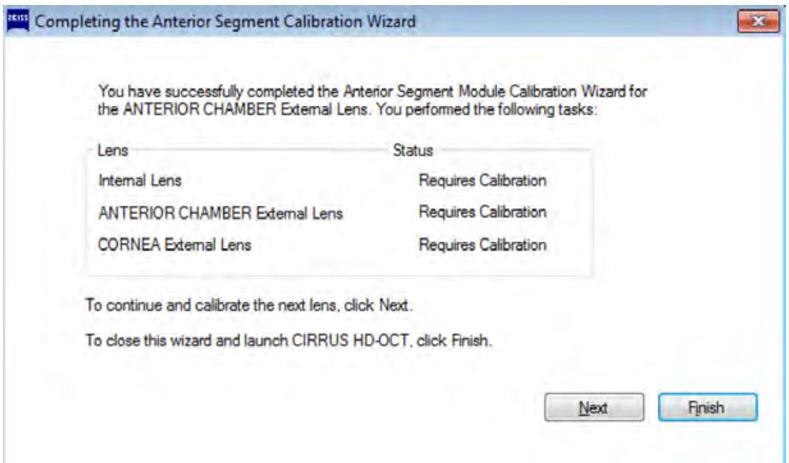
3. Click **Next**.

⇨ Hardware initializes and the calibration tool installation dialog opens.



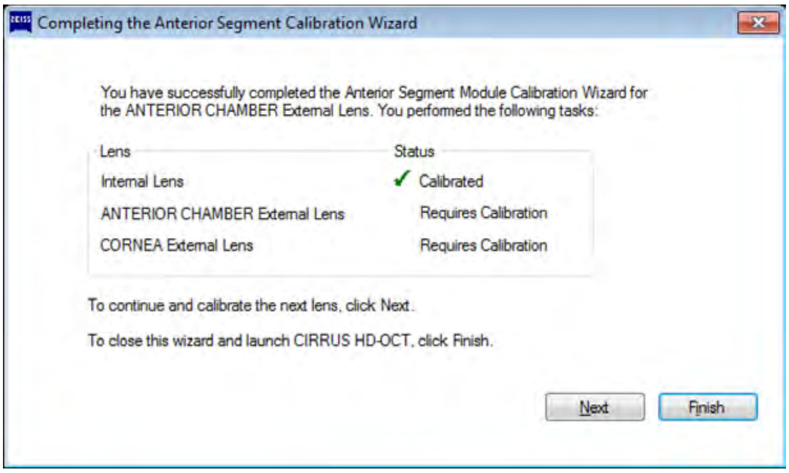
4. Click **Next**.

⇨ The lens selection dialog opens.



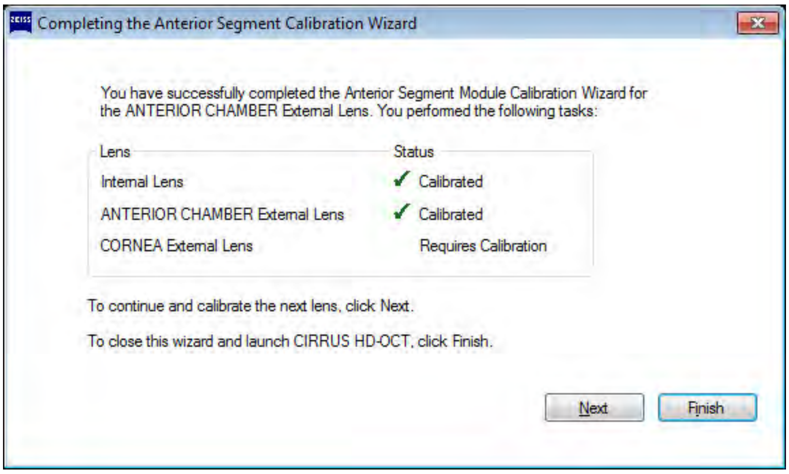
5. Select **Internal Lens.**
6. Click **Next**.

⇨ Lens calibration starts. When calibration is complete, a confirmation opens.



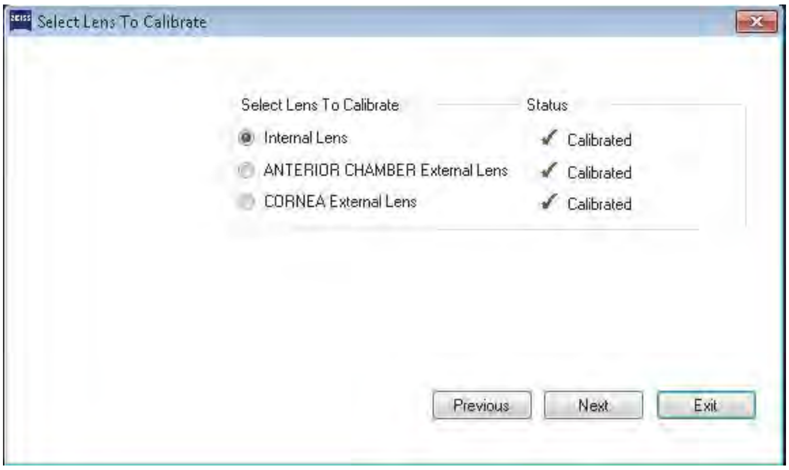
7. If your instrument does not have an **Anterior Segment** license, click **Finish** and exit calibration.
8. If your instrument has an **Anterior Segment** license, install the **Anterior Chamber** lens (see: Attach External Lens [▸ 181]).
9. Click **Next**.

   ⇨ Lens calibration starts. When calibration is complete, a confirmation opens.



10. Install the **Cornea** lens (see: Attach External Lens [▸ 181]).
11. Click **Next**.

    ⇨ Lens calibration starts. When calibration is complete, a confirmation opens.



12. Click **Exit**.

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13 Troubleshooting

13.1 Safety During Troubleshooting

⚠ WARNING!

Opening Instrument Covers

can lead to exposure to electrical and optical hazard.

- Do not open the instrument covers.
- Exceptions:
  - ⇨ You may remove the rear cover to access labels and connectors.
  - ⇨ You may remove the instrument's top cover to inspect or replace the fan filter.

⚠ CAUTION!

Reconfiguring system components on the table, or adding non-system devices or components to the table, or replacing original system components with substitutes not approved by ZEISS

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.

- 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.

⚠ CAUTION!

Improper care and cleaning of optical components

could lead to coating failure.

Contaminants on the optical surfaces increase scatter off the surface and absorb light energy.

- Do not use alcohol prep wipes to clean lenses or optical surfaces.
- Wipe gently and carefully to avoid scratching the instrument and auxiliary lenses.

⚠ CAUTION!

Attempting to carry out activities not specifically endorsed by ZEISS

may void your warranty and could result in damage to the instrument.

- ▶ Read the user documentation.
- ▶ Follow directions carefully.
- ▶ Do not make upgrades, or carry out repairs or modifications, without specific guidance and instruction from ZEISS or an authorized ZEISS represenative.

⚠ CAUTION!

Using a non-approved or incorrectly connected device

could invalidate the system safety approval.

- ▶ Follow all indications in this user document to ensure that all connections are approved and correctly configured.

NOTE

Report Serious Accidents

- ▶ 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.

13.2 Status Messages

NOTE

Qualification recommendation for these solutions: Local IT.

Instrument Status

Message / Fault	Cause	Solution
■	The instrument is ready for use.	N/A
■ Critical Storage	Not enough storage space for patient data.	▶ Archive patient data or add an external storage device. ▶ Turn instrument power off and then on. ▶ If the problem persists, contact ZEISS customer service.

Hard Drive Status

Message / Fault	Cause	Solution
■	Adequate free data storage space	N/A
□ Low disk space	Hard drive space is low at startup.	▶ You can continue to use the instrument software. ▶ Free some space on the hard drive soon.
■ Critically low hard drive space.	Not enough hard drive space to acquire or analyze patient data. You cannot **Acquire** or **Analyze** data.	▶ Create additional hard disk space by deleting unused, saved exams. ▶ Save the exams to an external storage unit or an additional NAS. ▶ Shut down and restart the software to enable the **Acquire** button. ▶ If using a Review Station and you only plan to review one or two scans, you can temporarily change the storage requirements. *Result* ✓ When you have adequate space on the hard drive, status changes to green.

Network Archive Status

Message / Fault	Cause	Solution
■	Network available with adequate storage for data.	N/A
□ Low network disk space	Low network disk space for data storage, or network unavailable.	▶ Verify the network connection. ▶ When connected, change the database location. *(You can use the database temporarily.)*
■ Critically low archive storage space.	Not enough free space on the archive to save additional patient data.	▶ Save the exams locally and consider attaching to an additional archive storage space.

13.3 System Startup Troubleshooting

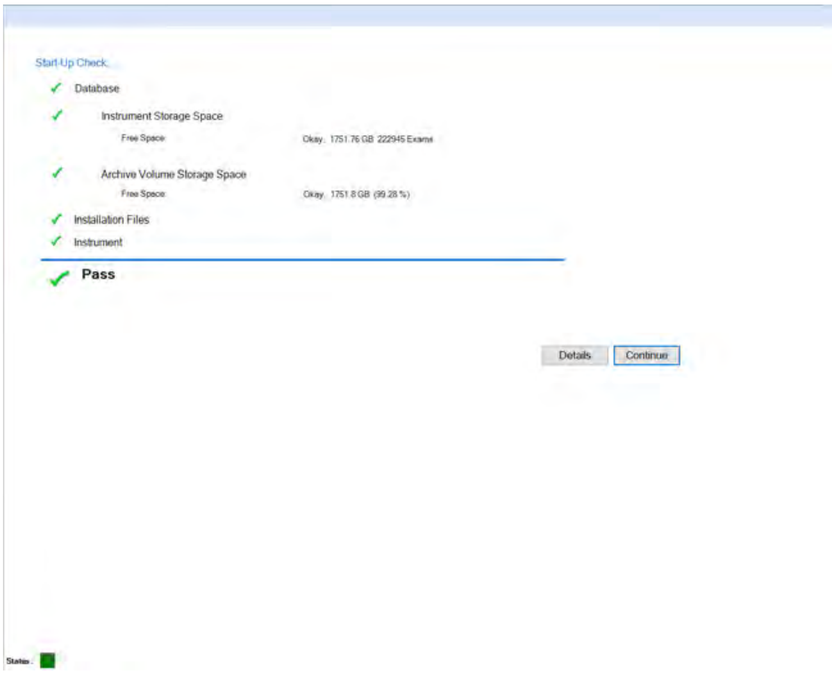


Figure 84: System Startup Results Example

Fault	Cause	Solution
Database	The system cannot access patient records successfully.	You cannot log in or use the instrument. *Action* ▶ Call ZEISS customer service: In the U.S., call 800-341-6968. Outside the U.S., contact your local CZM distributor.
Instrument Storage Space	The CIRRUS™ HD-OCT instrument storage is low or full.	▶ Clear archived exams. ▶ To bypass the error and login, click **Continue**. ⇨ You might not be able to archive additional data
Network Storage Space	Network archive storage space is low or full.	▶ Click **Details** for more information. Correct the failure reported in details. If free space is critically low, you may need to clear archived exams or add storage before you acquire new scans. ▶ If prompted, shutdown to archive exams data. ▶ To bypass the error and login, click **Continue**.

Fault	Cause	Solution
Installation Files	Critical system software files are not available or were altered.	▶ Click **Details** and note system check details. ▶ Call ZEISS customer service: In the U.S., call 800-341-6968. Outside the U.S., contact your local CZM distributor.
Instrument	Checks the connectivity of the instrument hardware with the system computer.	
Fail	Instrument startup failure.	

Table 84: Startup Check Failure (Operator)

13.4 Troubleshooting Instrument Power

Fault / Indicator	Cause	Solution
The instrument will not turn on.	General power outage.	▶ Ensure that there is not a localized power outage in your office or a general power outage in your neighborhood.
	Power cord is not attached to the instrument.	▶ Ensure that the power cord is properly plugged into the instrument.
	The table's power cord is not plugged into the wall outlet.	▶ Ensure that the power cord is properly plugged into the wall outlet.

Table 85: Troubleshooting Instrument Power

13.5 Troubleshooting Connections

Fault / Indicator	Cause	Solution
Review station cannot connect to an instrument.		
Review station does not connect to the network.	The internet protocol version is set incorrectly.	▶ Set the internet protocol version correctly (see: Setting the Internet Protocol Version [▸ 86]).

Fault / Indicator	Cause	Solution
Connection to the current database failed. Do you want to specify another database?	The database service is not turned on.	▶ Open Windows **Task Manager**. ▶ Select **Services**. ▶ Start the sevice: `Interbase XE3 Guardian CZM_DB`.
	Firewall rules are configured incorrectly.	Ensure that the following **Windows Firewall** rules are enabled for **Public**, **Private** and **Domain** network profiles: ■ `Interbase Server` ■ `File and Printer Sharing (SMB-In)` ■ `File and Printer Sharing (Edho Request-ICMPv4-In)` ■ `File and Printer Sharing (Edho Request-ICMPv6 -In)`
	Server Port 3051 needed for instrument and review station communi-cation is not available, blocked or already in use.	▶ Contact an IT professional to assist you to make port 3051 available (both the review station and instrument). ▶ Assign a different port for communication on both review station and instrument. To change the port, use a text edit (like Notepad) to open the file: `C:\WINDOWS\system32\drivers\etc\services` (no file extension) and find the line that starts: `czm_db`.
	TCP/IP filtering is blocking the port.	▶ Turn off TCP/IP filtering: From the Windows desktop, open **Control Panel > Network Connections**, right-click **Local Area Connection** and select **Properties**. ▶ Select the **General** tab, select **Internet Protocol (TCP/IP)**, click **Properties**, and click **Advanced**. ▶ Select the **Options** tab, select **TCP/IP filtering** and click **Properties**.
		▶ Add **port 3051** to the list of permitted ports.
Failure to load scanned data. Unable to open DICOM File for Retrieval.	Network drive not mapped properly or inadequate permissions for the network drive.	▶ On the review station, map a drive to the archive and set shared permissions.

Fault / Indicator	Cause	Solution
Frequent connection timeouts.	The network drive map uses the name of the storage computer.	▶ Remap the drive using the IP address instead of the computer name.
	Slow or weak network connection.	▶ Increase timeout values (see: DICOM Advanced Configuration [▸ 399]).
	LAN adapter setting is disabled.	▶ From the Windows desktop, open **Control Panel > Network and Internet >Network and Sharing Center**. ▶ Click **Change adapter settings.** ▶ Right-click **Local Area Connection** and select **Properties**.
DICOM connection status indicator is red	Connection information is set incorrectly.	▶ Set the internet protocol version correctly (see: Setting the Internet Protocol Version [▸ 86]).
	Connect test failed.	
United States Veterans Admin-istration’s VistA™ is not connecting properly.	**DICOM Extended Negotiation** is enabled.	▶ Uncheck **DICOM Extended Negotiation** (see: DICOM Advanced Configuration [▸ 399]).
FORUM is not connecting properly.	**DICOM Extended Negotiation** is disabled.	▶ Check **DICOM Extended Negotiation** (see: DICOM Advanced Configuration [▸ 399]).
During DICOM configuration, **AE Title** and **DICOM Port** fields are not editable.	**Allow Local AETitle Edit** is disabled.	▶ Check **Allow Local AETitle Edit** (see: DICOM Advanced Configuration [▸ 399]).
Worklist records searches timeout or message: " exceeds the configured maximum"	The **Maximum Query Response** is too low for the network.	▶ Use additional search criteria to return faster, narrower search results.
		▶ Increase **Maximum Query Response** value (see: DICOM Advanced Configuration [▸ 399]).
FORUM/DICOM is not automatically connecting.	Auto-query is disabled.	▶ Enable auto-query (see: Configure DICOM Archiving [▸ 84]).

13.6 Troubleshooting Archive Management

Fault / Indicator	Cause	Solution
Cannot set an archive location.	You are using a review station in **Instrument** mode.	▶ Use a CIRRUS™ HD-OCT instrument or review station set to DICOM mode to set up an archive.

13.7 Troubleshooting User Management

Fault / Indicator	Cause	Solution
Cannot add a user.	You are logged in as an operator or analyst.	▶ Log in as Admin [▹ 58].
Cannot delete a user.	The user is assigned to one or more existing patient scans.	▶ Retain the inactive user to keep their association to existing scans.

13.8 Troubleshooting Patient Management

Fault / Indicator	Cause	Solution
Cannot open the scan organizer.	You are using a review station.	▶ Use a CIRRUS™ HD-OCT instrument to organize scans.

13.9 Troubleshooting Scan Acquisition

Fault / Indicator	Cause	Solution
Cannot obtain a complete image.	The patient's eyelid is obstructing the image.	▶ Elevate the patient's eyelid during scan acquisition (see:).
Image has breaks or saccades.	The patient is moving their eyes during the scan or blinking excessively.	▶ Turn FastTrac™ On [▹ 219].
Poor image quality and blurry B-scan.	Weak signal strength.	▶ Re-take the scan.
FastTrac stalls or does not complete.	The image is too high or too low.	▶ Center the B-scan image (see: Adjusting B-Scan Images [▹ 210]).
	The iris target is not centered on the pupil.	▶ Align and Focus the Iris Image [▹ 214].
	The fundus image is not focused.	▶ Focus the Fundus Image [▹ 209].
	The patient's pathology or anatomical features make it difficult to center all B-scans.	▶ Turn off **Z position monitoring** (see:).
	The patient is not fixating properly during the scan.	▶ Ask the patient to try to move and blink less frequently during the scan.
	The patient is blinking or moving too much during the scan.	
Cannot center all of the B-scans at the same time.	The patient's pathology or anatomical features make it difficult to center all B-scans.	▶ Turn off **Z position monitoring** (see:).
Cannot turn on FastTrac.	FastTrac is disabled.	▶ Enable FastTrac (see: Turn FastTrac™ On or OFF [▹ 119]).

Fault / Indicator	Cause	Solution
HD image appears inverted.	The B-scan image is too high in the viewport (creating a reflection).	▶ Center the B-scan image (see: Adjusting B-Scan Images [▷ 210]).
Fundus image is partially or completely obscured.	The B-scan is too low in the viewport; light is not passing directly through the center of the pupil.	

13.9.1 Troubleshooting FastTrac

Fault / Indicator	Cause	Solution
The image is not centered properly (too high or too low).	For patients with certain pathologies or anatomical features, it may be difficult to ensure centering across all B-scans in a cube.	▶ Use the up and down arrows to center the image.
		▶ Cancel the scan. ▶ Turn off the monitoring of the Z position. ▶ Re-scan with FastTrac.
FastTrac stalls or cannot successfully track using FastTrac.	The iris image is not aligned properly	▶ Adjust the position in the Iris viewport.
	The fundus image is not focused properly.	▶ Manually adjust the focus.
	Fixating problems.	▶ Ensure that the patient is fixating in the same position throughout scan acquisition.
	Excessive blinking or moving.	▶ Ensure that the patient remains still and blinks less frequently throughout scan acquisition.

13.10 Troubleshooting Image Analysis

Fault / Indicator	Cause	Solution
Fovea Not Found	The system's automatic fovea location algorithm could not detect the Fovea.	▶ Manually position the Fovea.
The Fovea location was not detected properly.	The systems' automatic fovea location algorithm detected a depression in the reflectivity around the ILM that is not related to the fovea.	
	The patient's fovea is very far from the center.	

Table 86: Troubleshooting Posterior Segment Image Analysis

13.11 Troubleshooting Image Registration

Success or failure of registration is based on a cross-correlation metric computed from the two images after registration. A threshold for this metric concludes whether registration failed or succeeded.

Fault / Indicator	Cause	Solution
Red Flag Registration Failed Message	Weak signal strength Poor alignment Opacities Differences between the scan areas Differences in retinal anatomy between the images.	▶ If another image is available, select another image for comparison. ▶ To register the images, see: Manually Register AngioPlex Images [▶ 317]. ▶ To proceed without registering the images, select **No Registration**.

14 Specifications

14.1 Imaging Specifications

	CIRRUS 6000
Methodology	Spectral domain OCT
Optical source	Superluminescent diode (SLD), 840 nm
Optical power	Nominal 1200 +/– 300 µW at cornea
Maximum Scan speed	100k A-scans/sec

14.1.1 Posterior Segment Imaging Specifications

	CIRRUS 6000
A-scan depth	2.9 mm for 12 mm 1 line 100x Raster, Angio HD 8x8, Angio 8x8 and 12x12 2.0 mm for all other scans
Axial resolution	5 µm
Transverse resolution	12 µm

14.1.2 Anterior Segment Imaging Specifications

<table>
<tr><th>Scan</th><th>A-Scan Depth</th><th>Axial resolution</th><th>Transverse resolution</th></tr>
<tr><td>Anterior Segment Cube 512x128</td><td rowspan="4">2.0 mm, 1024 points</td><td rowspan="7">5 µm</td><td rowspan="2"><20 µm</td></tr>
<tr><td>Anterior Segment 5 Line Raster</td></tr>
<tr><td>HD Cornea</td><td rowspan="2"><25 µm</td></tr>
<tr><td>Pachymetry</td></tr>
<tr><td>HD Angle</td><td rowspan="2">2.9 mm, 1024 points</td><td><20 µm</td></tr>
<tr><td>Wide Angle-to-Angle</td><td rowspan="2"><45 µm</td></tr>
<tr><td>Anterior Chamber</td><td>5.8 mm, 2048 points</td></tr>
</table>

14.1.3 Fundus Imaging Specifications

	CIRRUS 6000
Methodology	Line scanning ophthalmoscope

	CIRRUS 6000
Live fundus image	During alignment and during OCT scan
Optical source	Superluminescent diode (SLD), 750 nm
Optical power	< 1.5 mW at the cornea
Field of view	36 degrees W x 30 degrees H
Frame rate	> 20 Hz
Transverse resolution	25 µm (in tissue)

14.1.4 Iris Imaging Specifications

	CIRRUS 6000
Methodology	CCD camera
Resolution	1280 x 1024
Live iris image	During alignment

14.1.5 Imaging Properties

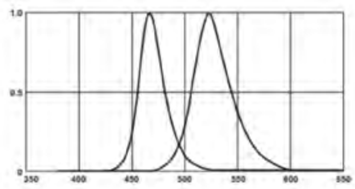
The following tables lists the optical properties of the four light sources incorporated into the CIRRUS 6000 instrument:

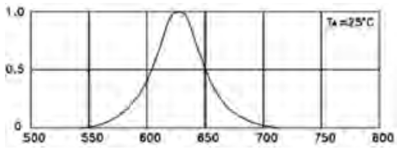
OCT	
Source	Super-luminescent diode (SLD)
Wavelength	840 nm Wavelength range: 795 nm – 885 nm (10 dB width, approximate Gaussian intensity distribution)
Scan Angle	10° minimum, 42° maximum
Maximum Beam Power	2.2 mW at cornea
Operating Beam Power	0.9 to 1.5 mW at cornea

LSO	
Source	SLD, lensed to illuminate a line subtending 30°
Center Wavelength	750 nm Wavelength range: 740 nm – 760 nm (3 dB width, approximate Gaussian intensity distribution)
Scan Angle	36° horizontal scan of the 30° vertical line
Operating Beam Power	1.0 mW at cornea

Iris View	
Source	Infrared LED

Iris View	
Wavelength	700 nm Wavelength range: 678 nm – 722 nm (45 nm 3 dB width, approximate Gaussian intensity distribution)
Radiance	260 mW/cm^2/sr

Internal Fixation		
Source	Green LED	
Wavelength	523 nm Wavelength range: (Approximate Gaussian intensity distribution) 	x-Axis = wavelength λ (nm) y-Axis = Relative intensity % 1=Blue 2=Green
Luminance	0.31 lumens/cm^2/sr	

External Fixation		
Source	Red LED	
Wavelength	627 nm Wavelength range: 604 nm – 650 nm (45 nm 3dB width, approximate Gaussian intensity distribution) 	x-Axis = wavelength λ (nm) y-Axis = Relative radiant intensity
Radiance	0.64 mW/cm^2/sr	

Based on an analysis of relevant laser and ophthalmic standards, all CIRRUS™ HD-OCT light sources together comprise a safe instrument, for which the standards prescribe no warnings or limitations on viewing the light sources beyond the label “Class 1 laser product.” The analysis includes consideration of the spatial distribution of intensities of the light sources on the cornea and retina during scanning to determine the hazard classification of the product.

14.2 Mechanical Specifications

14.2.1 Physical Specifications

	CIRRUS 6000
Weight	35 kg (77 lbs) *(without monitor)*
Dimensions	62.2L x 42.5W x 29.2H (cm) *(without monitor)*
Input devices	keyboard mouse
Fixation	Internal, external
Internal Fixation (focus adjustment)	-20D to +20D (diopters)

14.2.2 Computer Specifications

	CIRRUS 6000
Processor	i7 Intel® processor (7th gen)
Internal storage	> 80,000 scans
USB ports	6
Monitor	22” Widescreen HD
Operating system (Instrument)	Windows 10
Operating system (Review Station)	Windows 10 Windows 8.1 Windows 7 (64 Bit)

Table 87: Computer Specifications

14.3 Electrical Specifications

Rating	CIRRUS 6000
Electrical (115V)	100-120 V~ 50-60 Hz 6.3A 220-240 V~ 50-60 Hz 3.15A
Fuse	T 6.3A L 250V
Electrical (230V)	220-240 V~ 50-60 Hz 3.15A

Table 88: CIRRUS 6000 Electrical Specifications

14.4 Conditions for Use

	CIRRUS 6000
Temperature	+10° C to +35° C

	CIRRUS 6000
Relative humidity	30% to 75% *(excluding condensation)*
Atmospheric pressure	700 hPa to 1060 hPa
Altitude (above sea level)	Up to 3000m
Room Lighting	Standard indoor office fluorescent lamp environment; not to be used in direct sunlight or near a window.

14.5 Conditions for Transport and Storage

	CIRRUS 6000
Temperature	–40 to +70° C
Relative humidity	10% to 100% *(including condensation)*
Atmospheric pressure	500 hPa to 1060 hPa

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15 Legal Notices

Software Copyright

End User Software License Agreement

Upon initial configuration of your CIRRUS 6000, you will be presented with an End User Software License Agreement (the ”EULA”), which you must accept in order to use the Software. The EULA is a legal contract between You and Carl Zeiss Meditec, Inc., which governs Your use of the Software. If you do not agree with the terms and conditions of the EULA and do not agree to be bound by the EULA, do not use the Software. If You have any questions concerning the EULA, contact Carl Zeiss Meditec, Inc., Attention: Customer Service, 5160 Hacienda Drive, Dublin, CA 94568. Telephone 800–341–6968.

Acknowledgment

You acknowledge that you have read all the provisions in this Chapter, including End User Software License Agreement, understand them, and agree to be bound by their terms and conditions.

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16 Accessories and User Replaceable Spare Parts

This section contains parts lists and associated information for the device. It also contains instructions for ordering parts and returning defective parts.

NOTE

The procedure for returning defective parts from International operations differs somewhat from that for U.S. domestic operations

These differences are noted in the instructions.

▶ Please follow the instructions carefully.

16.1 Accessories and User Replaceable Parts

⚠ WARNING!

Using parts that are not authorized by ZEISS

may compromise device safety during operation.

▶ Use only accessories authorized by ZEISS.

▶ In the U.S., call 800–341–6968. Outside the U.S., contact your local Zeiss distributor. You can find the ZEISS contact partner for your country on our website: www.zeiss.com.

16.2 Parts Orders

16.2.1 U.S. Domestic Parts Ordering

Spare parts may be ordered as needed following established parts ordering procedures. Parts needed overnight may be ordered by phone from the Parts Department. The cost of shipping parts for next day delivery is very high and should be used only in emergencies. The Parts Department phone number is:

- 1-800-341-6968 (domestic toll-free)
- 1-925-557-4843 (domestic)
- 1-925-557-4652 (domestic fax)

16.2.2 International Service Operations

Customers are billed for shipping charges, including any customs fees required.

For International Service Operations, please use the ordering procedures that have been established for your area of operations, and which meet the requirements of the Carl Zeiss Meditec International Parts Department.

16.3 Returning Defective Parts

The return of defective parts is a very important part of ZEISS' responsibility to its customers and helps us to:

Action

- Evaluate returned parts to assist in root cause analysis.
- Rebuild and return them to service stock, so they are available in the future as needed.

16.4 Equipment Return Authorization

Authorization must be obtained from Carl Zeiss Meditec before equipment is returned for repair. A Return Material Authorization (RMA) number is required on each return shipment to Carl Zeiss Meditec. The procedure for obtaining an RMA number varies, depending on your area of operation. Use the procedure that has been established by Carl Zeiss Meditec for your area of operations.

16.5 International Service Operations

Customers are billed for shipping charges, including any customs fees required.

For International Service Operations, please use the ordering procedures that have been established for your area of operations, and which meet the requirements of the Carl Zeiss Meditec International Parts Department.

16.6 Part Numbers

NOTE

Part numbers are subject to change

- When ordering, confirm all part numbers with your ZEISS Representative.

16.6.1 Power Cords

Designation	Specification	Part Number
Power Cord IEC 320	1 m/39 Inch	0000001217033
Power Cord IEC 320 to NEMA	.3 m/12 In	2660021115973

16.6.2 Cables

Designation	Length	Part Number
Ethernet CAT5E Shielded	14 ft.	2660021121819
Cable, USB MA-MB	6 ft.	2660021116418

16.6.3 Cleaner

Designation	Specification	Part Number
Alcohol Wipes	-	2660100006566
Camera Lens Cleaner	-	2660100007672
Camera Lens Wipes	-	2660100007673

16.6.4 Kit, Test Eye

Designation	Specification	Part Number
The Kit includes: ■ Verification Test Tool ■ Fixation Device ■ Occluding Sleeve for Fixation Device ■ Red Fixation Lamp	-	2660021161047

16.6.5 Miscellaneous Spare Parts

Description	Specification	Part Number
Anterior Chamber Lens	-	2660021158406
Anterior Segment Calibration Tool	-	2660021150088
Instrument Dust Cover	-	2660021174524
Cornea Lens	-	2660021158407
Fan Filter	-	2660021161991
Fixation Device	(External)	2660021149361
Fixation Lamp	Red	3013509052000
Occluding Sleeve for Fixation Device	-	3197519005000
Ocular Lens Cover	-	2660021124008
Verification Test Tool	-	2660021160365

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17 Decommissioning

17.1 Safety During Decommissioning

⚠ **CAUTION!**

Attempting to decommission your system

may result in damaged equipment and danger to personnel.

- Never attempt to decommission a ZEISS system or device. Only ZEISS approved field service representatives are qualified to safely decommission your system.
- Contact your ZEISS Representative to set up an appointment for system/device decommissioning.

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18 Packaging and Transport

18.1 Safety During Packaging and Transport

⚠ **CAUTION!**

Packaging and transport by non-ZEISS personnel

could result in damage, loss, or non-compliance within the country of transit.

- Allow only change to Zeiss approved representative to prepare the instrument and associated components for transport.
- Allow only ZEISS-approved personnel to transport the instrument and associated components.

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19 Disposal

19.1 Packaging Disposal

- Keep instrument packing material in the event of a relocation or repair.
- If you want to dispose of the packing material: Dispose of packing material by sending it for recycling through an acknowledged collection system.

19.2 Device Disposal

The device contains electronic components with integrated batteries.

- Dispose of the device and integrated batteries correctly, in accordance with national legislation.

The device specified on the delivery note must not be disposed of via household waste or communal disposal companies according to the applicable EU guidelines valid at the time the device was placed on the market.

For more information about the disposal of the device, please contact the ZEISS contact partner in your country.

If you want to sell the device or its components: Inform the purchaser that they must dispose of the device according to the regulations valid at that time.

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A Diverse Population Study

NOTE

Normal reference ranges represent the general population.

However, when interpreting data, keep the following study limitations in mind (especially for 1% and 99%):

- Subjects:
  - ⇨ Ages 18-84
  - ⇨ Refractive errors –12.00 D to +8.00 D
- Age ranges with fewest subjects:
  - ⇨ 3 subjects over 80.
  - ⇨ 28 subjects aged (70-79).

NOTE

Normal reference range limits are adjusted only by age (unless noted).

Other differences might occur for some measurements; however, the normal reference range does not adjust for these factors, such as:

- Image Signal Strength
- Ethnicity
- Axial Length
- Refraction
- Optic Disc Area

This appendix explains how normal reference ranges were determined for the general population.

A.1 Purpose

Initial Study

The purpose of the original normative study was to establish normal reference ranges for:

- **Macular Thickness** (macular images)
- **RNFL Thickness** (ONH images)

Follow-up Study

A later study analyzed the same data (collected in the original study) to establish normal reference ranges for:

- **Ganglion Cell Thickness** (macular images)
- **ONH Features** (ONH images)

A.2 Results in Image Analysis

CIRRUS™ HD-OCT analyses compare a patient's results to the normal reference range and depict the results visually in different ways.

The following table shows examples of different visual results.

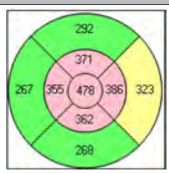
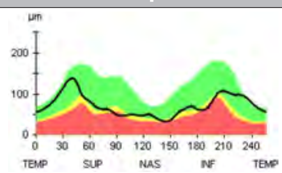
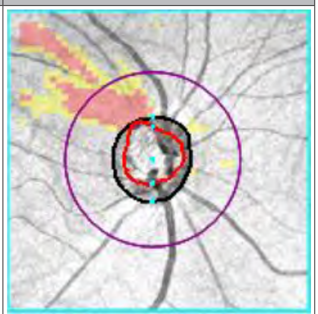
<table>
<tr><th>Table</th><th>Chart</th><th>Graph</th><th>Maps</th></tr>
<tr>
<td>
<table>
<tr><th>⚠</th><th>Central Subfield Thickness µm</th><th>Cube Volume mm³</th><th>Cube Avg Thickness µm</th></tr>
<tr><td>ILM - RPE</td><td>478</td><td>11.0</td><td>305</td></tr>
</table>
</td>
<td>
</td>
<td>
</td>
<td></td>
</tr>
<tr><td colspan="4">Key:
■ Within normal reference range.
■ Near upper/lower limit of stand range.
■ Above/below normal reference range.</td></tr>
</table>

Table 89: Examples of Visual Results

A.3 Study Subjects

The following table describes the selection criteria for subjects of this study.

Inclusion Criteria	Exclusion Criteria
■ 18 years or older. ■ Willing to make the required study visits. ■ Willing to give consent and follow study instructions. ■ Normal and valid Humphrey 24-2 SITA. ■ Standard visual field in both eyes.	**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. ■ RNFL defect in either eye. ■ Amblyopia in either eye. ■ Previous laser or incisional surgery. ■ Active infection in 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. ■ Life-threatening or debilitating disease. ■ Current or recent use of an agent with photosensitizing properties *(Visudyne®, ciprofloxacin, Bactrim®, doxycycline, etc.)*.

Table 90: Subject Selection Criteria

Subject Medical History

Investigators took medical and ophthalmic histories and conducted an ophthalmic examination on each subject prior to enrollment, which included:

- Distance visual acuity.
- Humphrey 24-2 SITA perimetry (standard threshold 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.

A.4 Age Groups

NOTE

For the study, subjects were categorized into age groups.

Image analyses compare a patient's measurements to subjects of the same age (not age group).

For the study, subjects were divided into age groups as follows:

<table>
<tr><th>Group</th><th>Age Range</th><th colspan="2">Gender Diversity</th><th>Ethnic Diversity</th></tr>
<tr><td>1</td><td>18-29</td><td rowspan="6">Macula & Ganglion Cell Study
■ 133 Male
■ 149 Female
■ Median age: 46.6</td><td rowspan="6">RNFL & ONH Study
■ 134 Male
■ 150 Female
■ Median age: 46.5</td><td rowspan="6">■ 43% Caucasian
■ 24% Asian
■ 18% African American
■ 12% Hispanic
■ 1% Indian
■ 2% mixed ethnicity</td></tr>
<tr><td>2</td><td>30-39</td></tr>
<tr><td>3</td><td>40-49</td></tr>
<tr><td>4</td><td>50-59</td></tr>
<tr><td>5</td><td>60-69</td></tr>
<tr><td>6</td><td>70-84</td></tr>
<tr><td colspan="5">Observations:
■ 0 subjects under 19 years old.
■ 28 subjects between 70 and 79 years old.
■ 3 subjects 80 and older.</td></tr>
</table>

Table 91: Age Groups

A.5 Data Collection

CIRRUS™ HD-OCT operators obtained the following images from each subject:

<table>
<tr><th>Subjects</th><th>Scan Type</th><th># of Scans</th><th>Eyes</th></tr>
<tr><td rowspan="3">284</td><td>Optic Disc Cube 200x200</td><td>3</td><td rowspan="3">OD & OS</td></tr>
<tr><td>Macular Cube 200x200</td><td>3</td></tr>
<tr><td>Macular Cube 512x128</td><td>1</td></tr>
</table>

Table 92: CIRRUS™ HD-OCTStudy Images

All 284 subjects qualified for the **RNFL** study.

282 subject eyes qualified for the **Macula**, **Ganglion Cell**, and **ONH** study.

A.6 Image Selection

Investigator reviewed each image to determine:

- Poor quality images to exclude, such as images with:
  - Signal strength of 5 or lower.
  - Saccade(s) within the central 80% of the image (due to excessive eye motion during image acquisition).
  - Data loss greater than 10% at the edge of the scan area.
  - Floaters obscuring the macular area (macular images).
  - Floaters obscuring the measurements of ONH image.
- The best quality image for each eye.

A.7 Data Analysis

By defining a set a normal reference ranges, CIRRUS™ HD-OCT image analysis can compare a patient's measurements to determine whether a patient's measurements are within the normal reference range for their age.

The subject's **age** is a clinically important factor for determining normal reference ranges.

Regression model analyses estimated the limits of thickness parameters adjusted by age.

A.7.1 Deriving Percentiles and Limits

The following table provides the formulas that derived the normal reference range limits:

Purpose	Formula
Derive residuals for fitted regression model (each eye).	`Residual = Obs(age0) - ET(age0)`
Established estimated 1%, 5%, 95% and 99% limits for a normal subject with an age of age0. *Empirical distribution of the residual estimated the percentiles.*	`ET(age0) + NL(100xα %) < Obs(age0)`
■ `ET(age0)` = *the estimated expected mean reading* ■ `Obs(age0)` = *the measured or observed reading* ■ `NL(100xα %)` = *the normative limit of the residuals*	

A.8 Macular Images

Measurement	Parameters	Analyses
Macular Thickness	■ Macular thickness ■ Average macular thickness ■ Average volume (ILM-RPE)	■ Macular Thickness [▸ 238] ■ Macular Change [▸ 247] ■ *Panomap [▸ 299] ■ *Single Eye Summary [▸ 295] ■ Wellness Report [▸ 301]
Ganglion Cell Thickness	■ Ganglion cell thickness	■ Ganglion Cell OU [▸ 262] ■ Ganglion Cell Guided Progression [▸ 267] ■ *Panomap [▸ 299]

Table 93: Normal Reference Ranges for Macular Images

A.8.1 Macular Thickness Parameters

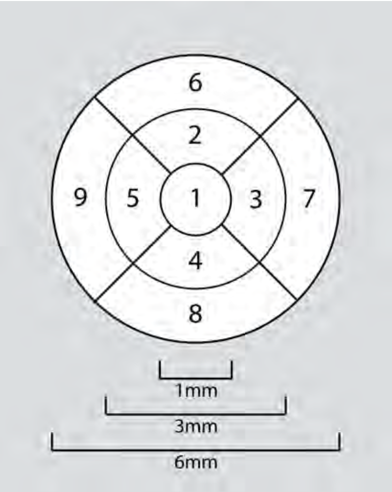


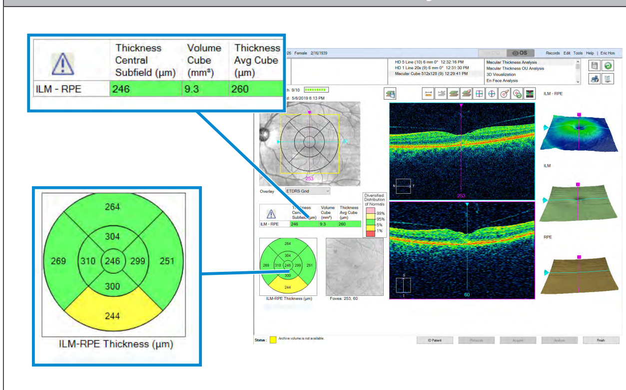
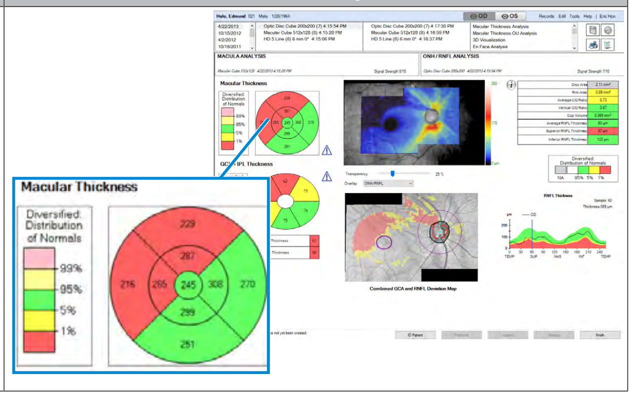
Figure 85: Early Treatment Diabetic Retinopathy Study (ETDRS) Grid

Normal reference ranges for macular thickness provides the basis to compares a patient's macular thickness to the normal reference range for their age.

Normal reference ranges apply to the following measurements:

- **Macular Thickness:** Average thickness for the ILM - RPE tissue layer for each sector of the ETDRS grid.
- **Average Thickness:** Overall average thickness for the ILM - RPE tissue layer over the entire scanned area.
- **Volume:** Overall average volume for the ILM - RPE tissue layer over the entire scanned area.

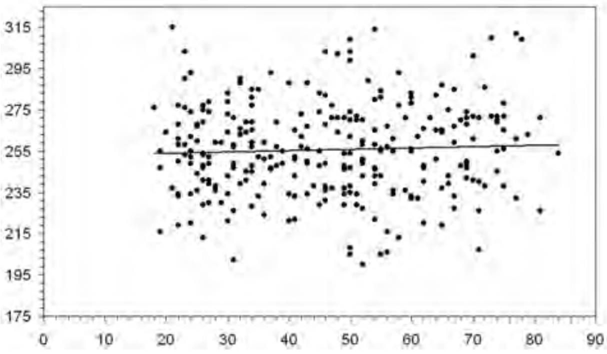
A.8.1.1 Examples

Macular Thickness Analysis	PanoMap
	

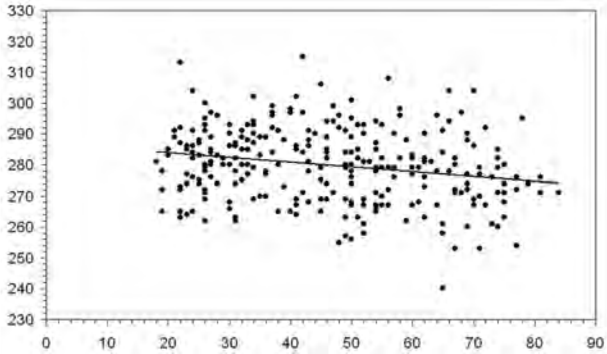
A.8.1.2 Factors That Affect Normal Reference Ranges

A.8.1.2.1 Affect of Age

Central Subfield



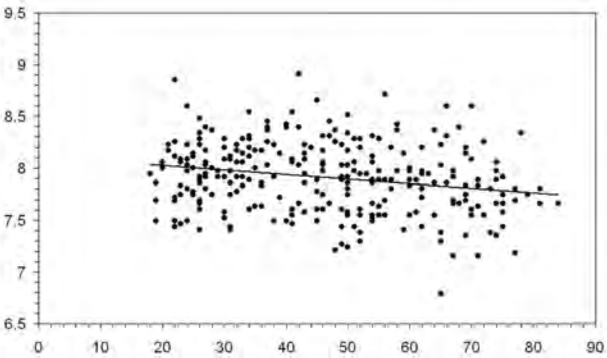
Average Thickness (all ETDRS subfields)



Key:

- *X-axis (horizontal) = Age in years*
- *Y-axis (vertical) = Average Retinal Thickness (μm)*
- *Line = Fitted regression line*

Average Volume (all ETDRS subfields)



Key:

- *X-axis (horizontal) = Age in years*
- *Y-axis (vertical) = Average Retinal Volume (mm^3)*
- *Line = Fitted regression line*

A.8.2 Ganglion Cell Parameters

The **Ganglion Cell** normal reference ranges provide normative data for the thickness of the ganglion cell and the inner plexiform layer in healthy subjects ages 19 to 84.

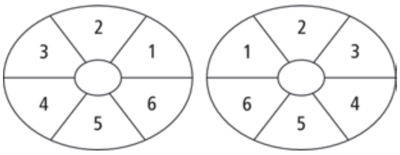


Figure 86: GCL + IPL Thickness Grid

To establish reference values, the images from the original study were analyzed using a (proprietary) segmentation algorithm that identifies the thickness of the combined ganglion cell and inner plexiform layers.

Average GCL + IPL thickness sectors:

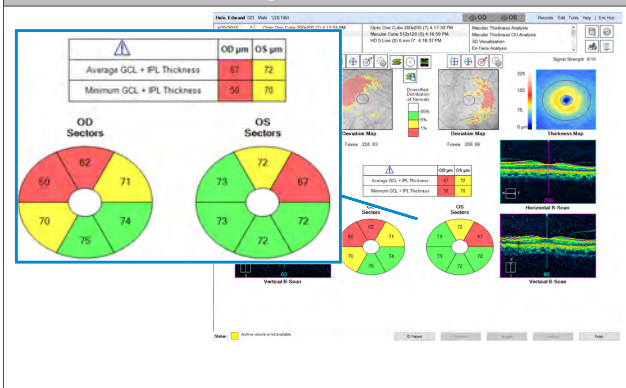
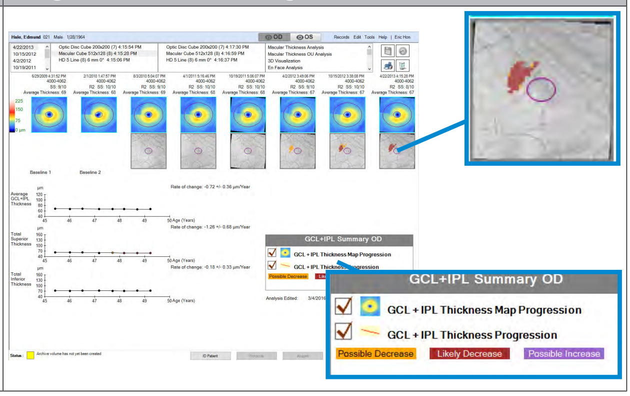
- 60° segments of an elliptical annulus
- inner minor axis radius of 0.5 mm
- outer minor axis radius of 2.0 mm
- stretched by 20% in the horizontal direction

Minimum average value:

A set of 360 spokes, (average of the pixels along each spoke).

NOTE! The thinnest portion of the ganglion cell plus inner plexiform layers in the perifoveal region likely shows if there is ganglion cell damage.

A.8.2.1 Examples

Ganglion Cell OU	Ganglion Cell Guided Progression
	

A.8.2.2 Ganglion Cell Data

Parameter	Mean	Std	Min	Max
Average GCL + IPL Thickness	84.7	7.1	67.7	104.2
Sector 1	82.9	6.3	68.0	102.0
Sector 2	86.4	7.9	67.0	113.0
Sector 3	86.8	8.3	65.0	112.0
Sector 4	85.3	9.0	62.0	111.0
Sector 5	83.2	7.8	62.0	109.0
Sector 6	83.8	6.5	68.0	106.0
Minimum Average Axial Thickness	82.1	6.9	53.2	101.8

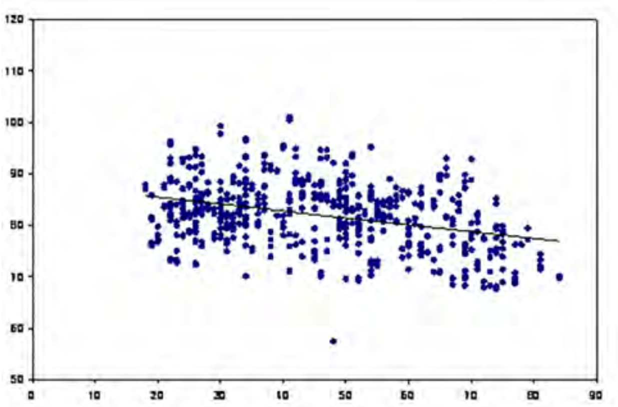
Table 94: Ganglion Cell Data

A.8.2.3 Factors That Effect Normal Reference Ranges

Normal reference ranges are adjusted by age. Factors that influenced ganglion cell normal reference range limits for some parameters included:

- Age (12% variability)
- Image Signal Strength (4% variability).
- Refractive error and axial length (< 2% variability)

A.8.2.3.1 Effect of Age



Key:

- *X-axis (horizontal) = Age in years*
- *Y-axis (vertical) = Ganglion Cell Average Thickness (µm)*
- *Line = Fitted regression line*

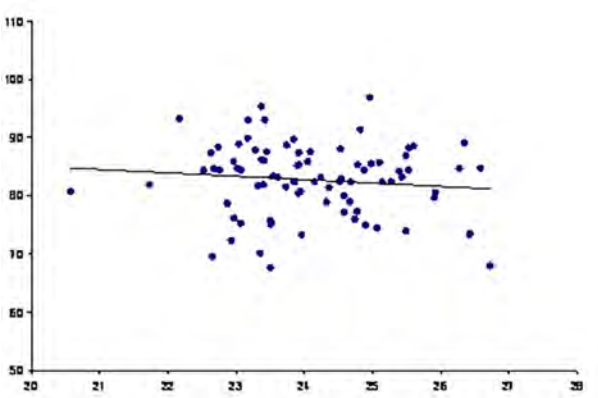
A.8.2.3.2 Effect of Ethnicity

Descent	Mean	Std
European	84.1	7.8
Hispanic	88.8	6.4
African	86.3	7.8
Asian	89.4	7.2

Observations:

- *There are statistically significant differences among different ethnic groups in GCL + IPL thickness.*
  The mean difference in the average thickness between any two race groups is within 4.3 mm.
- *Subjects of European Descent have* **thinner** *GCL + IPL thickness (on average).*
- *Subjects of Hispanic and Chinese descent have* **thicker** *GCL + IPL thickness (p < 0.001).*

A.8.2.3.3 Effect of Axial Length and Refractive Error



Key

- *X-axis (horizontal) = Age in years*
- *Y-axis (vertical) = Average Ganglion Cell Thickness (microns)*
- *Line = Fitted regression line*

Observations:
GCL + IPL thickness decreases slightly with axial length (less than 2% of the total variability of the ganglion cell parameters).

A.9 ONH Images

Measurement	Parameters	Analyses
RNFL [▸ 456] Thickness	■ Average RNFL Thickness ■ Superior RNFL Thickness ■ Inferior RNFL Thickness ■ RNFL Quadrants (TSNIT) ■ RNFL Clock Hours ■ RNFL Symmetry	■ ONH/RNFL OU [▸ 279] ■ Guided Progression Analysis [▸ 283] ■ *Panomap [▸ 299] ■ *Single Eye Summary [▸ 295] ■ Wellness Report [▸ 301]
ONH Features [▸ 462]	■ Rim Area (mm^2) ■ Disc Area (mm^2) ■ Average Cup-to-Disc Ratio ■ Vertical Cup-to-Disc Ratio ■ Cup Volume (mm^2)	■ ONH/RNFL OU [▸ 279] ■ Guided Progression Analysis [▸ 283] ■ *Panomap [▸ 299] ■ *Single Eye Summary [▸ 295]

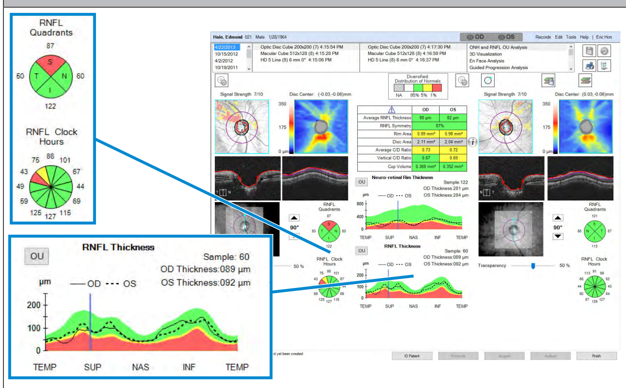
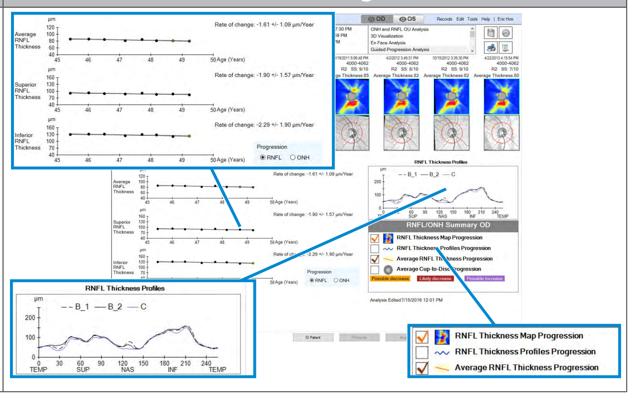
Table 95: Estimated Normal Reference Ranges for ONH Images

A.9.1 RNFL Parameters

This study determined the normal reference ranges for the following the retinal nerve fiber layer (RNFL) parameters in healthy subjects ages 19 to 84:

- Average RNFL Thickness
- Superior RNFL Thickness
- Inferior RNFL Thickness
- RNFL Thickness for Quadrants (TSNIT)
- RNFL Thickness for Clock Hours

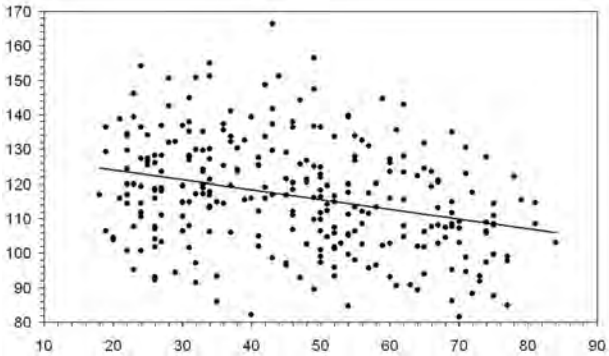
A.9.1.1 Examples

ONH and RNFL OU	ONH Guided Progression
	

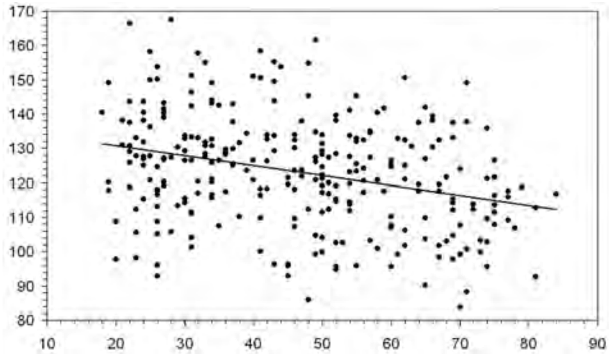
A.9.1.2 Factors That Effect Normal Reference Ranges

A.9.1.2.1 Effect of Age

Superior Quadrant Average



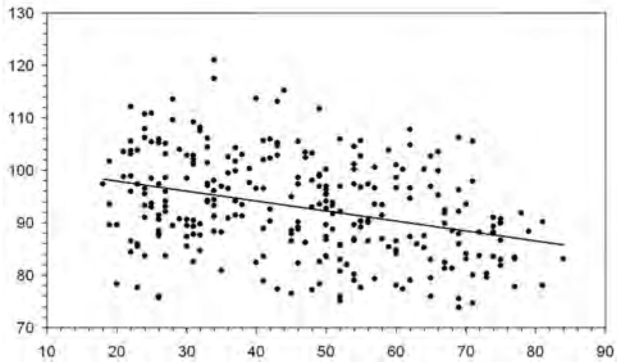
Inferior Quadrant



Key:

- *X-axis (horizontal) = Age in years*
- *Y-axis (vertical) = RNFL Thickness (µm)*
- *Line = Fitted regression line*

Average



Key:

- *X-axis (horizontal) = Age in years*
- *Y-axis (vertical) = Average RNFL Thickness (µm)*
- *Line = Fitted regression line*

A.9.1.2.2 Effect of Ethnicity

Ethnicity [1][2][3]	RNFL Thickness
Caucasian	Thinner mean average thickness, superior quadrant average, and inferior quadrant average.
Asian	Thinner mean nasal quadrant average and thicker temporal quadrant average.

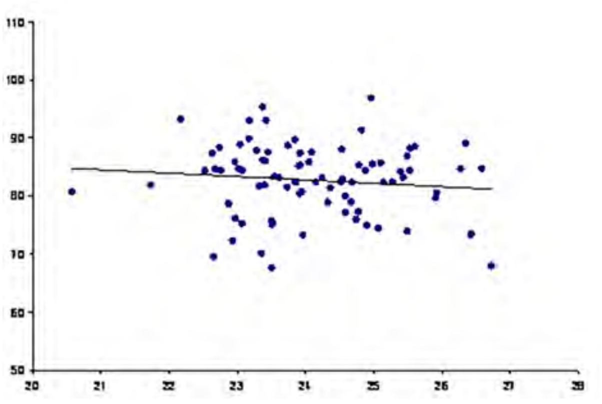
[1] Artes, Crabb: *Estimating normative limits of Heidelberg Retina Tomograph optic disc rim area with quantile regression,* Invest Ophthalmol Vis Sci. 2010 Jan;51(1):335-61

[2] Knight, Oakley, Durbin, Callan, Budenz: *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.

[3] Spaeth, Henderer, Steinmann: *The disc damage likelihood scale: its use in the diagnosis and management of glaucoma*, Highlights Ophthalmol 31: 4-16, 2003.

Ethnicity [1][2][3]	RNFL Thickness
Observations: ■ *The mean difference in the average thickness between any two race groups is within 6 µm.* ■ *People of Asian descent 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.*	

A.9.1.2.3 Effect of Axial Length and Refractive Error



Key

- *X-axis (horizontal) = Age in years*
- *Y-axis (vertical) = Average GCA (microns)*
- *Line = Fitted regression line*

Observations:
decreases slightly with axial length (less than 2% of the total variability of the Ganglion Cell parameters)

A.9.2 ONH Parameters

NOTE

These ONH parameters are adjusted for age and optic disc area.

▶ Refer to: Factors That Effect Normal Reference Ranges [▸ 464].

The data originally collected for the database was analyzed again to create the normal reference ranges for the following ONH parameters:

- Rim Area (mm^2)
- Disc Area (mm^2)
- Average Cup-to-Disc Ratio
- Vertical Cup-to-Disc Ratio
- Cup Volume (mm^3)

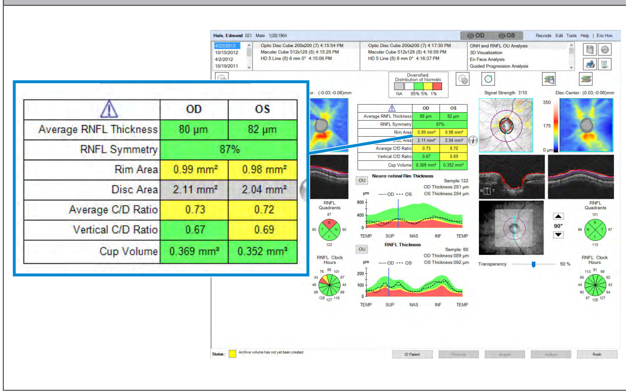
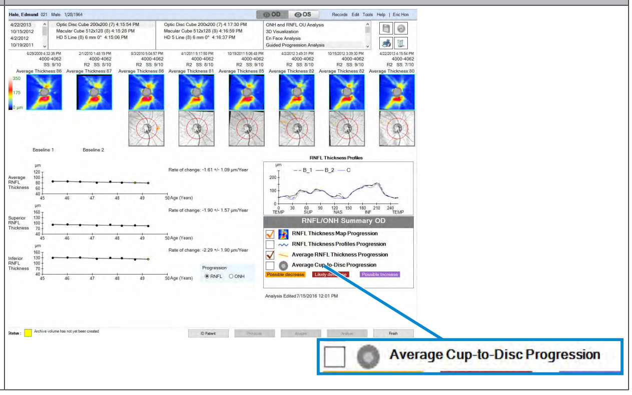
Additional Image Analysis Criteria

All three scans for each subject were reviewed again after processing with the optic nerve head analysis algorithm to ensure that:

- no floaters impacted the optic nerve head region
- optic nerve head data was within the axial field-of-view

In three instances, it was necessary to select a different scan for one eye to obtain acceptable results for both ONH and RNFL.

A.9.2.1 Examples

ONH and RNFL OU	ONH Guided Progression
	

A.9.2.1.1 Analysis Application and Limitations

If there was not enough data for an adequate representative for a particular normal reference range, the results have gray shading. Results in this category include:

- Disc Area < 1.3 mm^2
- Disc Area > 2.5 mm^2
- Average Cup-to-Disc Ratio ≤ 0.25
- Vertical Cup-to-Disc Ratio ≤ 0.25

OU Analysis

A patient can have different disc areas for each eye, which applies a different normal reference range to each. OU analysis uses the normal reference range for the average disc area.

A.9.2.2 Quantile Regression Data Analysis

Because the subject's **age** and **disc size** are both a clinically important factors for determining normal reference ranges, we used quantile regression to determine limits for Disc Area.

Quantile regression fits slope and offset independently for each limit[4].

Regression model analyses estimated the limits of thickness parameters adjusted by age. Cup-to-Disc Ratios ≤ 0.25 were excluded prior to quantile regression.

A.9.2.3 ONH Parameter Data

Parameter	Average	Standard Deviation	Minimum	Maximum
Rim Area (mm^2)	1.311	0.218	0.720	2.272
Disc Area (mm^2)	1.769	0.340	1.003	2.925
Average Cup-to-Disc Ratio	0.458	0.173	0.071	0.812

[4] Artes, Crabb: *Estimating normative limits of Heidelberg Retina Tomograph optic disc rim area with quantile regression,* Invest Ophthalmol Vis Sci. 2010 Jan;51(1):335-61

Parameter	Average	Standard Deviation	Minimum	Maximum
Vertical Cup-to-Disc Ratio	0.435	0.166	0.058	0.762
Cup Volume (mm^3)	0.137	0.134	0.000	0.796
Observations: ■ *11 subjects (less than 5%) had discs larger than 2.5 mm^2.* ■ *11 subjects (less than 5%) had discs smaller than 1.3 mm^2.* ■ *Disc area did not depend on age.*				

Table 96: ONH Parameter Data[5]

In earlier studies, researchers measured the disc's vertical diameter with a slit-lamp and classified the discs as small, medium, and large[6].

In this study we measured disc area, which considers all meridians. The classifications for disc area are:

- **Smallest ⅓:** < 1.58 mm^2
- **Medium ⅓:** 1.58 mm^2 to 1.88 mm^2
- **Largest ⅓:** > 1.88 mm^2

A.9.2.4 Factors That Effect Normal Reference Ranges

This study found that optic disc area and age had the greatest effect on the ONH parameters.

- **Disc Area:** as much as 40% of variability for some parameters
- **Age:** no more than 5% of variability for ONH parameters
- **All Other Factors:** (refractive error, axial length, etc.) no more than 7% of variability for ONH parameters

A.9.2.4.1 Effect of Age

Measurement	Slope	R^2	p
Rim Area	-0.002 mm^2 / year	0.033	0.002
Average Cup-to-Disc Ratio	+0.002 / year	0.032	0.002
Vertical Cup-to-Disc Ratio	+0.002 / year	0.041	0.001
Observations : ■ *Average and Vertical Cup-to-Disc Ratios slowly increase with age.* ■ *Rim Area slowly decreases with age.* ■ *Disc area does not change with page (p>0.05).*			

A.9.2.4.2 Effect of Ethnicity

Measurement	Slope	R^2	p
Rim Area	-0.002 mm^2 / year	0.033	0.002
Average Cup-to-Disc Ratio	+0.002 per year	0.032	0.002
Vertical Cup-to-Disc Ratio	+0.002 per year	0.041	0.001

[5] Knight, Oakley, Durbin, Callan, Budenz: *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.
[6] Spaeth, Henderer, Steinmann: *The disc damage likelihood scale: its use in the diagnosis and management of glaucoma*, Highlights Ophthalmol 31: 4-16, 2003.

Measurement	Slope	R^2	p
Observations : ■ *Subjects of African descent had the largest discs on average* (1.93 ± 0.33 mm^2). ■ *Subjects of European descent had the smallest discs on average* (1.68 ± 0.30 mm^2). ■ *Rim Area show no significant difference among different ethnic groups.*			

Measurement	Mean Difference	p
Average Cup-to-Disc Ratio	0.10	0.008
Vertical Cup-to-Disc Ratio	0.09	0.027
Cup Volume	0.09 mm^3	0.003

A.9.2.4.3 Effect of Optic Disc Area

Measurement	Slope (of rim / mm^2 of disc)	R^2	p
Rim Area	+0.24 mm^2	0.13	0.002
Average Cup-to-Disc Ratio	+0.35 mm^2	0.35	0.042
Vertical Cup-to-Disc Ratio	+0.29 mm^2	0.34	0.001
Cup Volume	+0.25 mm^2	0.39	0.011
Observation: ■ *Most disc areas are between 1.3 mm^2 and 2.5 mm^2.* ■ *All parameters increase with disc size.*			

A.10 Conclusions

Doctors can use these normal reference ranges to compare a patient's measurements to the general population.

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B Asian Population Study

NOTE

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⇨ outside the U.S.A , contact your local ZEISS distributer.

NOTE

Normal reference ranges represent the general population.

However, when interpreting data, keep the following study limitations in mind (especially for 1% and 99%):

▶ Subjects:

⇨ Ages 18-84

⇨ Refractive errors –12.00 D to +8.00 D

▶ Age ranges with fewest subjects:

⇨ 0 subjects over 79.

⇨ 0 subjects under 19.

The normal reference range limits for the Diverse Population Study [▸ 451] do not adjust for ethnic differences.

An additional study established normal reference range limits for the same parameters adjusted for Asian populations. This appendix explains how normal reference ranges were determined for Asian populations.

Five new centers participated in the study; these results combined with data from Hong Kong (part of the diverse population study) to establish normal reference range limits for Asian populations.

When you license the Asian Normative Database, you can select whether to apply the **Asian Normative Database** or **Diversified Normative Database** as the default database for new patients.

Although the system automatically assigns the default database to each new patient, you can override the default and select the other database for individual patients. For more information, refer to:

- About Licenses [▸ 61]
- Changing the Default for Normative Data [▸ 84]
- Database Selection [▸ 403]

B.1 Purpose

This study establishes normal reference ranges for the following parameters for Asian populations:

Macular Images

- Macular Thickness
- Ganglion Cell Thickness

Optic Nerve Head Images

- RNFL Thickness
- ONH Features

B.2 Study Subjects

This study included 315 subjects.

This study used the same inclusion and exclusion criteria as the **Diverse Population Study** (see: Study Subjects [▸ 453]).

B.3 Age Groups

Subjects were divided into age groups as follows:

<table>
<tr><th>Group</th><th>Age Range</th><th>Gender</th><th>Ethnicity</th></tr>
<tr><td>1</td><td>18-29</td><td rowspan="6">■ 159 male
■ 156 female
■ Median age: 47</td><td rowspan="6">■ 44% Japanese
■ 44% Chinese
■ 12% Indian</td></tr>
<tr><td>2</td><td>30-39</td></tr>
<tr><td>3</td><td>40-49</td></tr>
<tr><td>4</td><td>50-59</td></tr>
<tr><td>5</td><td>60-69</td></tr>
<tr><td>6</td><td>70-80</td></tr>
<tr><td colspan="4">Observations:
■ 0 subjects under 19 years old.
■ 0 subjects over 79 years old.</td></tr>
</table>

Table 97: Asian Normative Database Subjects

B.4 Data Collection

This study used the same data collection, image selection and analysis techniques as the diverse population study. Refer to:

- Data Collection [▸ 454]
- Image Selection [▸ 454]
- Data Analysis [▸ 455]

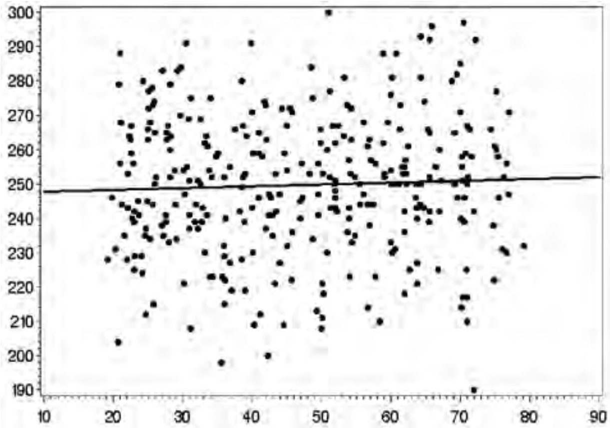
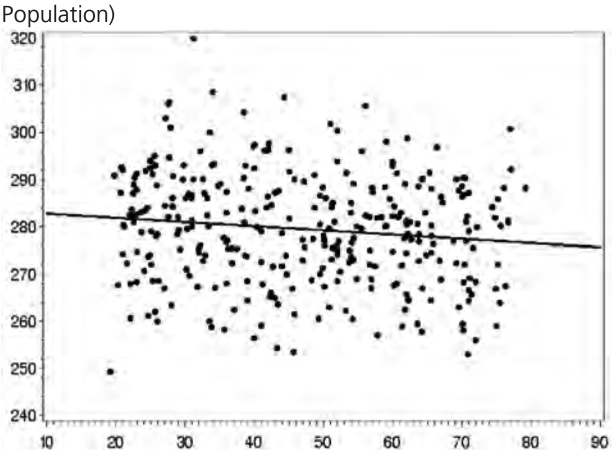
B.5 Macular Images

B.5.1 Macular Thickness Parameters

This study establishes the same macular thickness parameters as the diverse population study (see: Macular Thickness Parameters [▸ 456]).

B.5.1.1 Factors That Effect Normal Reference Ranges

B.5.1.1.1 Effect of Age

<table>
<tr><td>Central Subfield (Asian Population)

</td><td>Key:
X-axis (horizontal) = Age in years
Y-axis (vertical) = Macular Thickness (µm)
Line = Fitted regression line</td></tr>
<tr><td>Average Thickness (all ETDRS subfields) (Asian Population)

</td><td>Key:
X-axis (horizontal) = Age in years
Y-axis (vertical) = Average Macular Thickness (µm)
Line = Fitted regression line</td></tr>
<tr><td colspan="2">Observations:
Central subfield thickness has almost no dependence on age.
All other subfields decrease very gradually when the age increases.</td></tr>
</table>

B.5.2 Ganglion Cell Parameters (Asian)

This study establishes the same ganglion cell thickness parameters as the diverse population study (see: Ganglion Cell Parameters [▸ 457]).

B.5.2.1 Ganglion Cell Data

Parameters	Mean	Standard Deviation	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
Observations: ■ *All ganglion cell parameters decrease slowly with age.* ■ *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 98: Ganglion Cell Data

B.6 ONH Images

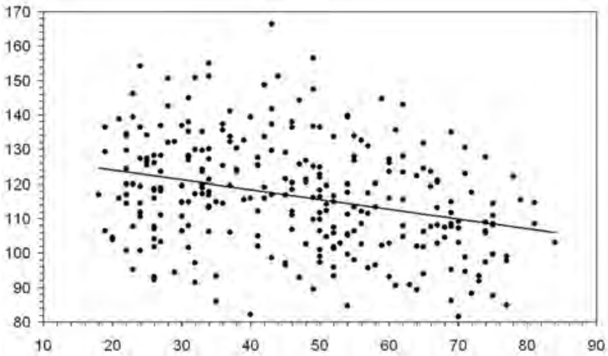
B.6.1 RNFL Parameters

This study establishes the same macular thickness parameters as the diverse population study (see: RNFL Parameters [▸ 460]).

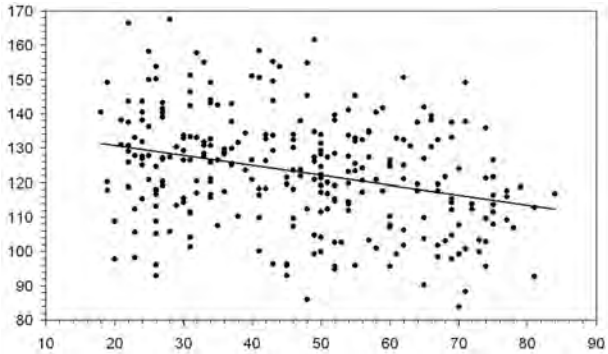
B.6.1.1 Factors That Effect Normal Reference Ranges

B.6.1.1.1 Effect of Age

Superior Quadrant



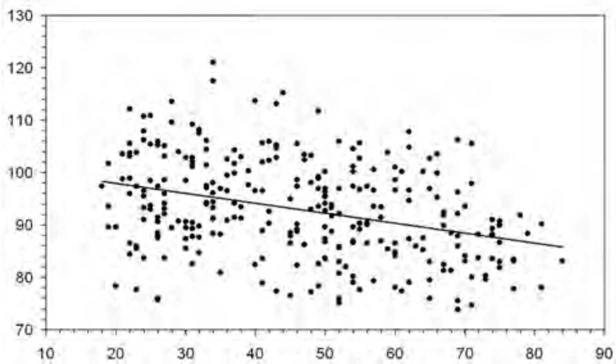
Inferior Quadrant



Key:

- *X-axis (horizontal) = Age in years*
- *Y-axis (vertical) = Average RNFL Thickness (µm)*
- *Line = Fitted regression line*

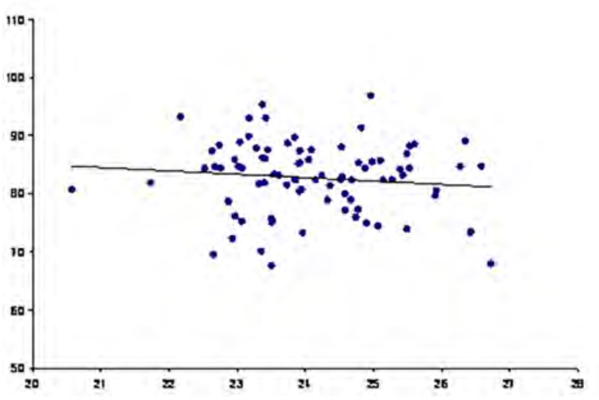
Overall



Key:

- *X-axis (horizontal) = Age in years*
- *Y-axis (vertical) = Average RNFL Thickness (µm)*
- *Line = Fitted regression line*

B.6.1.1.2 Efffect of Axial Length and Refractive Error



Key

- *X-axis (horizontal) = Age in years*
- *Y-axis (vertical) = Average GCA (microns)*
- *Line = Fitted regression line*

Observations:
RNFL Thickness decreases slightly with axial length (less than 2% of the total variability of the Ganglion Cell parameters).

B.6.2 ONH Parameters

This study establishes the same ONH parameters as the diverse population study (see: ONH Parameters [▸ 462]).

B.6.2.1 ONH Parameter Data

There are a few differences for ONH parameter data for Asian populations, including:

- An additional parameter: Neuroretinal Rim (NR) thickness plot around the disc.
- Disc area is calculated and presented, but not compared to normal limits.

Parameter	Minimum	Maximum	Average	Standard Deviation
Average Cup–to–Disc Ratio	0.06	0.78	0.51	0.15
Vertical Cup–to–Disc Ratio	0.05	0.77	0.48	0.15
Disc Area (mm^2)	1.15	3.14	1.87	0.36
Rim Area (mm^2)	0.75	2.27	1.29	0.21
Cup Volume (mm^3)	0.00	0.73	0.16	0.14

Observations

- *90% of the subjects' disc areas were between 1.3 mm ^{2} and 2.5 mm ^{2}.*
- *Disc area showed no dependence on subject age.*
- *13 subjects (less than 5%) had discs larger than 2.5 mm ^{2} in the study eye.*
- *10 subjects (less than 5%) had discs smaller than 1.3 mm ^{2}:*
  - *1/3 of the subjects had discs 1.7 mm ^{2} or smaller*
  - *1/3 of the subjects had discs between 1.7 and 2.0 mm ^{2}.*
  - *1/3 of the subjects had discs larger than 2.0 mm ^{2}.*

Table 99: ONH Parameters for Asian Populations

B.6.2.2 Factors That Effect Normal Reference Ranges

This study found that optic disc area and age had the greatest effect on the ONH parameters.

- **Disc Area:** as much as 40% of variability for some parameters
- **Age:** no more than 5% of variability for ONH parameters
- **All Other Factors:** (refractive error, axial length, etc.) no more than 7% of variability for ONH parameters

B.6.2.2.1 Effect of Age

Measurement	Slope	R^2	p
Rim Area	-0.002 mm^2 / year	0.033	0.002
Average Cup-to-Disc Ratio	+0.002 per year	0.032	0.002
Vertical Cup-to-Disc Ratio	+0.002 per year	0.041	0.001
Observations : ▪ *Average and Vertical Cup-to-Disc Ratios slowly increase with age.* ▪ *Rim Area slowly decreases with age.*			

B.6.2.2.2 Effect of Optic Disc Area

Parameter	Slope	R^2	P
Cup Volume	+0.25 mm^3 of cup per mm^2 of disc	0.39	0.011
Rim Area	+0.24 mm^2 of rim per mm^2 of disc	0.13	0.042
Cup-to-Disc Ratio (Average)	+0.35 per mm^2 of disc	0.35	0.001
Cup-to-Disc Ratio (Vertical)	+0.29 per mm^2	0.34	0.001
Observation: ▪ *All parameters increase with disc size.*			

B.7 Conclusions

The following observations were made:

- The mean difference in the average RNFL thickness between any two race groups is within 5 µm.
- Chinese subjects have thicker mean average thickness, superior quadrant average, and inferior quadrant average.
- Indian subjects have the thickest mean average thickness, superior quadrant average, and inferior quadrant average.
- The largest difference in the RNFL thickness between two race groups is for the temporal quadrant average between Chinese and Indian subjects (difference of 15 µm).

The doctor can use these normative databases to compare individual patient measurements to those acquired in a normal population.

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C Algorithm Performance Studies

Algorithm Studies evaluated the performance of the CIRRUS™ HD-OCT software algorithms by repeating scans of the same subjects or comparing the scans with similar scans using a different OCT instrument. This appendix describes the studies, study results, and conclusions.

C.1 Posterior Segment Algorithms

CIRRUS™ HD-OCT posterior segment algorithm results appear in the scan analyses shown below.

Algorithm Studied	Parameters	Applicable Analyses
Retinal Segmentation Performance [▸ 476]	Segmentation performance for RPE layer and ILM layer by pathology: ■ AMD ■ Diabetic Retinopathy ■ VRI Disorder ■ Other Retinal Disease ■ Macular Edema ■ No Retinal Disease	■ Analyze Macular Thickness [▸ 238] ■ Analyze Macular Change [▸ 247] ■ Analyze Ganglion Cell OU [▸ 262] ■ Ganglion Cell Guided Progression [▸ 267] ■ Advanced RPE Analysis [▸ 257] ■ Advanced Visualization Analysis [▸ 286] ■ Analyze PanoMap [▸ 299] ■ Wellness Exam [▸ 301] ■ Analyze Single Eye Summaries [▸ 295]
Ganglion Cell Measurement Performance [▸ 485]	GCL + IPL thickness performance in glaucoma subjects grouped by: mild, moderate, and severe glaucoma measurements-- ■ Average ■ Minimum ■ Temporal-Superior ■ Superior ■ Nasal-Superior ■ Nasal-Inferior ■ Inferior ■ Temporal-Inferior	■ Analyze Ganglion Cell OU [▸ 262] ■ Ganglion Cell Guided Progression [▸ 267] ■ Analyze PanoMap [▸ 299] ■ Wellness Exam [▸ 301]
RPE Illumination Performance [▸ 481]	Comparing automated algorithm to expert manual editing for both sizes of macular scans.	Advanced RPE Analysis [▸ 257]
RPE Elevation Performance [▸ 483]	Performance of RPE elevation algorithm (area and volume) for both sizes of macular scans.	

Algorithm Studied	Parameters	Applicable Analyses
Optic Nerve Head Measurement Performance [▸ 488]	Optic nerve measurement performance in glaucoma subjects grouped by: mild, moderate, and severe glaucoma -and- Optic nerve measurement performance for same visit scans and follow-up visits in glaucoma subjects grouped by: mild, moderate, and severe glaucoma for parameters: ■ Average cup-to-disc ratio ■ Vertical cup-to-disc ratio ■ Disc Area ■ Rim Area ■ Cup Volume	■ ONH Guided Progression [▸ 283] ■ Analyze PanoMap [▸ 299] ■ Wellness Exam [▸ 301] ■ Analyze Single Eye Summaries [▸ 295] ■ Analyze ONH/RNFL OU [▸ 279]

Table 100: Posterior Algorithms

C.1.1 Terms and Acronyms

Term	Explanation
CV	*Coefficient of variation = SD ÷ Mean.*
N	Reproducibility DSS divided by the mean
Repeatability Limit	the upper 95% limit for the difference between repeated results. *Repeatability limit = 2.8 x Repeatability SD* (ISO 5725-1 and 5725-6) .
Repeatability SD	the square root of the random variance component.
Reproducibility Limit **Visit-to-Visit Variability Limit**	the upper 95% limit calculated for the difference between individual measurements using different operators and instruments. *Reproducibility Limit = 2.8 x Reproducibility SD* (ISO 5725-1 and 5725-6).
Reproducibility SD	the square root of the sum of all contributions to variance except subject variance.
SD	Standard Deviation

Table 101: Posterior Segment Algorithm Study Terms

C.1.2 Macular Algorithms

C.1.2.1 Retinal Thickness Measurement Performance

ZEISS partnered with the academic and clinical community to study the performance and precision of the CIRRUS™ HD-OCT retinal segmentation algorithm in a prospective, non-randomized, multi-center study. The 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)

Reports of these results presented at conferences and submitted for publication. [7][8][9]

Purpose

The primary objectives of the study were:

- evaluate the performance of CIRRUS™ HD-OCT retinal thickness segmentation algorithms.
- compare CIRRUS™ HD-OCT measurements to Stratus OCT measurements.

A secondary objective of the study was to evaluate data registration effectiveness.

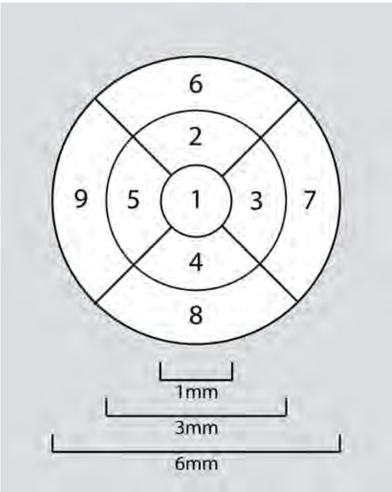


Figure 87: ETDRS Grid

For the CIRRUS™ HD-OCT scans, investigators reviewed scan image quality and selected the best scan for each eye. CIRRUS 6000 software calculates retinal thickness for every sector of the ETDRS 6 mm grid centered on the fovea.

Fourteen trained investigators assessed performance using the following procedure:

1. Manually segmented B-scans from one scan per subject.
2. Compared manually-segmented B-scans with automatically-segmented B-scan.
3. Compared average retinal thickness measurements in all sectors to Stratus OCT measurements and analyzed the variance.
4. Assessed performance of the average measurement for each sector.
5. Assessed automatic and manual registration performance.
6. Assessed automatic and manual fovea alignment for all sectors.

Investigators determined that segmentation was accurate when CIRRUS™ HD-OCT ILM and RPE automatic segmentation agreed with manual segmentation in 100% of A-scans evaluated.

Agreement definition:

- Within 16 µm for the central sector.
- Within 32 µm for all remaining sectors.

Because the segmentation strategy is different, there is a mean difference in the retinal thickness found by each instrument. The mean difference between instruments varies with pathology because the integrity of the layers detected varies with pathology.

[7] Weisbrod, Stetson, Wieland, Bressler, Schmidt–Erfurth, Knighton, Gregori:*Comparison of Hand–Drawn ILM and RPE Segmentation to the Retinal Segmentation Algorithm of the CIRRUS HD-OCT*, ARVO 2008, poster 4240.
[8] Chang, Durbin, Weiland, Schmidt–Erfurth, Gregori, Bressler: *Repeatability of retinal thickness measurements using CIRRUS HD-OCT Spectral Domain Technology*, ARVO 2008, poster 4253.
[9] Geitzenauer, Kiss, Durbin, Abunto, Wieland, Bressler, Gregori, Schmidt–Erfurth: *Comparing Retinal Thickness Measurements From CIRRUS Spectral–Domain and Stratus Time–Domain OCT*, ARVO 2008, poster 930.

After accounting for the mean difference, there is a residual difference in the standard deviation. 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), not *quantitatively*.

C.1.2.1.1 Subjects

Demographics	Inclusion Criteria	Exclusion Criteria
■ Number of Subjects: 137 ■ Age Range: 25-69	■ 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. Subjects were classified into six groups based on the primary diagnosis causing the most pathologic abnormalities in the study eye as follows:	History of leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis. If both eyes were eligible, the principal investigator arbitrarily assigned the study eye.

Table 102: Subject Demographics

Pathology	Description
AMD	Age-related macular degeneration
DR	Diabetic retinopathy
VRI	Vitreoretinal interface abnormalities (including macular holes)
Other	Other retinal pathology
ME	Macular edema for which treatment was planned
Normal	No retinal pathology

Table 103: Subject Pathology Groups

C.1.2.1.2 Method: Instrument Variability

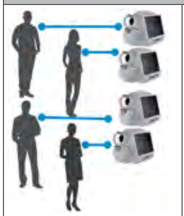
CIRRUS™ HD-OCT 5000		Scans	Study Eye	Fellow Eye
	Before analyzing the data, investigators **excluded** poor quality scans.	Macular Cube 200x200	1	1
		Macular Cube 512x128	1	1

Table 104: Instrument Variability Study

C.1.2.1.3 Method: Instrument Comparison

Stratus		Scans	Study Eye	Fellow Eye
	Before analyzing the data, investigators **excluded** poor quality scans.	Fast Macula Scan	1	1

Table 105: Instrument Comparison Study

Poor quality scans include:

- Poor signal strength.
- Poor scan placement in the axial field of view (causing missing data or shifts in location between scans).
- Data missing from the center.
- Data loss greater than 10% of the scan area.
- Large shifts (greater than 3mm).
- Poor image quality.

C.1.2.1.4 RPE and ILM Boundary Performance Results

Pathology	200 x 200 Scans		512 x 218 Scans	
	n/N (%)	95% CI	n/N (%)	95% CI
RPE Layer Segmentation Performance				
AMD	60/70 (85.7%)	(77.5%, 91.3%)	62/72 (86.1%)	(78.1%, 98.5%)
DR	40/42 (95.2%)	(86.6%, 98.4%)	41/42 (97.6%)	(90.0%, 99.5%)
VRI	27/28 (96.4%)	(85.5%, 99.2%)	25/28 (89.3%)	(76.0%, 95.5%)
Other	44/51 (86.3%)	(76.5%, 92.4%)	46/52 (88.5%)	(79.2%, 93.9%)
ME	27/28 (96.4%)	(85.5%, 99.2%)	27/29 (93.1%)	(82.2%, 97.7%)
Normal	37/37 (100.0%)	(93.2%, 100%)	40/40 (100.0%)	(93.7%, 100%)
ILM Layer Segmentation Performance				
AMD	68/70 (97.1%)	(91.7%, 99.1%)	73/74 (98.6%)	(94.2%, 99.7%)
DR	40/42 (95.2%)	(86.6%, 98.4%)	40/42 (95.2%)	(86.6%, 98.4%)
VRI	26/28 (92.9%)	(80.6%, 97.6%)	26/27 (96.3%)	(85.0%, 99.2%)
Other	50/51 (98.0%)	(91.7%, 99.6%)	51/52 (98.1%)	(91.8%, 99.6%)
ME	28/28 (100.0%)	(91.2%, 100%)	28/29 (96.6%)	(85.9%, 99.2%)
Normal	37/37 (100.0%)	(93.2%, 100%)	40/40 (100.0%)	(93.7%, 100%)
Observations: *Segmentation performance varied between layers (RPE, ILM) and among different disease categories.* *More than 85% of scans are correctly segmented.*				

Table 106: Segmentation Performance By Pathology

C.1.2.1.5 Repeatability Standard Deviation by Pathology

Pathology	Central Sector Macular Thickness Repeatability SD (µm)			
	N	200 x 200	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
Normal	44	4.8	47	3.6

Table 107: Repeatability Standard Deviation by Pathology

Repeatability Standard Deviation - Adjusted

These results show the repeatability standard deviation for central sector measurements of the 200 x 200 scan using:

- v 3.0 Macular Thickness Analysis
- v 4.0 Macular Thickness Analysis with adjustable fovea position

- v 4.0 Macular Change Analysis using registration and adjustable fovea position

Pathology	N	Mean ±SD CSMT (µm)	CSMT Repeatability SD (µm)		
		CIRRUS 4.0	CIRRUS 3.0	CIRRUS 4.0 Fovea	CIRRUS 4.0 Fovea / Registration
		Macular Thickness Analysis			Macular Change Analysis
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
Normal	44	256 ±21	4.8	2.2	2.5
Observations: *Repeatability improves with the (correctly-identified) fovea as the reference point for sector average thickness calculations.* *Repeatability improves when scans are registered to each other.* *Features introduced with CIRRUS 4.0 software improve repeatability standard deviation.* *Registration and fovea placement improved repeatability.*					

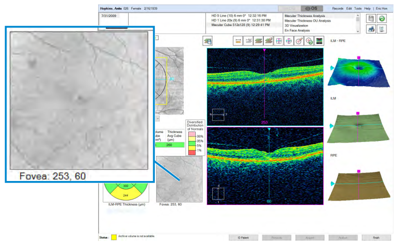
Table 108: 200 x 200 Scan Standard Deviation - Adjusted

C.1.2.1.6 Instrument Comparison Results

Pathology	Mean Difference (SD) OCT (µm)			
	N	CIRRUS™ HD-OCT	Stratus OCT	Difference
AMD	63	271.3 (60.6)	217.7 (54.2)	53.6 (35.0)
DR	39	356.6 (118.7)	316.6 (135.8)	40.0 (47.1)
VRI	45	386.3 (128.0)	342.5 (125.0)	43.8 (35.9)
Other	53	310.6 (99.5)	268.9 (101.6)	41.7 (47.1)
ME	35	351.1 (140.3)	305.7 (127.9)	45.5 (45.3)
Normal	48	256.1 (18.6)	196.7 (18.6)	59.4 (11.7)
Observations: *There is good correlation between the two instruments.*				

Table 109: Difference between CIRRUS™ HD-OCT and Stratus OCT

C.1.2.1.7 Fovea Finder Accuracy Results



CIRRUS™ HD-OCT automatically detects the fovea. This study also examined the rate of failure of the algorithm that detects the fovea location.

Pathology	N	Scans with fovea failures	
		Not found	Incorrect
AMD	77	11%	6%
DR	51	19%	10%
VRI	44	24%	5%
Other	62	10%	6%
ME	41	18%	6%
Normal	44	0%	0%
Observations: *Pathology can influence the algorithm's ability to locate the fovea.*			

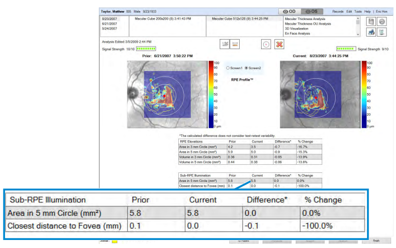
Table 110: Rate of failure of the Fovea Finding Algorithm by Pathology

C.1.2.1.8 Conclusion

CIRRUS™ HD-OCT retinal thickness measurements are accurate and repeatable.

C.1.2.2 Sub-RPE Illumination Performance

This study determined the repeatability and reproducibility of the CIRRUS™ HD-OCT measurement of illumination areas under the retinal pigment epithelium (RPE).



The study (Instrument Variation or Operator Variation) with the larger random error variation 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.

The repeatability and reproducibility limits affect the ability to determine when measurements change due to pathology or random variability.

Trained investigators evaluated each scan to determine if the algorithm accurately:

- identified the outline of the lesion automatically.

  If not, the investigator manually edited the scan to outline the lesion accurately.
- centered the fovea automatically.

  If not, the investigator manually edited the scan to center the fovea accurately.

C.1.2.2.1 Method: Instrument Variability

CIRRUS™ HD-OCT 5000		Scans	Instrument		
			1	2	3
	■ Number of Subjects: 37 ■ Eyes: 49 A single operator acquired scans using three different CIRRUS™ HD-OCT instruments.	Macular Cube 200x200	3	3	3
		Macular Cube 512x128	3	3	3

C.1.2.2.2 Method: Operator Variability

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	■ Number of Subjects: 39 ■ Eyes: 53 Three operator acquired scans using the same CIRRUS™ HD-OCT instrument.	Macular Cube 200x200	3	3	3
		Macular Cube 512x128	3	3	3

C.1.2.2.3 Measurement Performance Results

Sub-RPE Illumination	Macular Cube Scan	Repeatability (mm^2)		Reproducibility (mm^2)		CV%
		SD	Limit	SD	Limit	
Automated Algorithm	200 x 200	0.8887	2.4885	0.9450	2.6460	12.5%
	512 x 128	0.8683	2.4313	1.0317	2.8889	15.8%
Manually Edited	200 x 200	0.2273	0.6365	0.3823	1.0705	4.3%
Observations: *Repeatability for both sized scans is similar.* *Reproducibility for 200 x 200 scans is lower.* *Repeatability and Coefficient of Variation for manually-edited scans is much lower.*						

Table 111: Repeatability and Reproducibility of Sub-RPE Illumination Algorithm

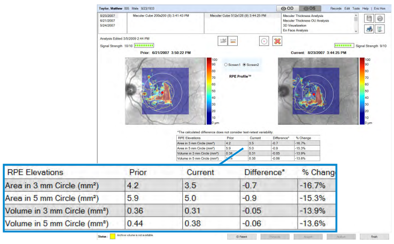
Closest Distance to Fovea	Macular Cube Scan	Repeatability (mm)		Reproducibility (mm)	
		SD	Limit	SD	Limit
Automated Algorithm	200 x 200	0.0739	0.2070	0.0762	0.2133
	512 x 128	0.1247	0.3492	0.1257	0.3520
Manually Edited	200 x 200	0.0354	0.0990	0.0439	0.1229

Closest Distance to Fovea	Macular Cube Scan	Repeatability (mm)		Reproducibility (mm)	
		SD	Limit	SD	Limit
Observations: *Repeatability and Reproducibility for 200 x 200 scans is lower.* *Coefficient of Variation for manually-edited scans is much lower.*					

Table 112: Repeatability and Reproducibility of the Closest Distance to the Fovea Algorithm

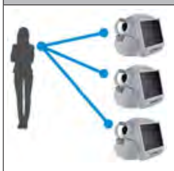
C.1.2.3 RPE Elevation Performance

This study evaluated the performance of macular retinal pigment epithelium (RPE) elevation area and volume measurements.



Method: Instrument Variability

C.1.2.3.1

CIRRUS™ HD-OCT 5000		Scans	Instrument		
			1	2	3
	■ Eyes: 26 A single operator acquired scans using three different CIRRUS™ HD-OCT instruments.	Macular Cube 200x200	3	3	3
		Macular Cube 512x128	3	3	3

C.1.2.3.2 Method: Operator Variability

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	■ Eyes: 24 Three operator acquired scans using the same CIRRUS™ HD-OCT instrument.	Macular Cube 200x200	3	3	3
		Macular Cube 512x128	3	3	3

C.1.2.3.3 Measurement Performance Results

Macular Cube Scan		Repeatability (mm^2)		Reproducibility (mm^2)		CV%
		SD	Limit	SD	Limit	
200 x 200	3mm Circle	0.1295	0.3626	0.1568	0.4389	10.1%
	5mm Circle	0.1012	0.2834	0.1455	0.4073	4.9%
512 x 128	3mm Circle	0.0837	0.2343	0.0998	0.2794	7.5%
	5mm Circle	0.1537	0.4304	0.1936	0.5422	9.6%

Macular Cube Scan		Repeatability (mm^2)		Reproducibility (mm^2)		CV%
		SD	Limit	SD	Limit	
Observations: *Repeatability for 200 x 200 scans, 3 mm circle is higher.* *Repeatability for 512 x 128 scans, 5 mm circle is higher.* *Reproducibility for 200 x 200 scans, 3 mm circle and 5 mm circle is about the same.* *Reproducibility for 512 x 128 scans, 5 mm circle is much higher (double).* *Coefficient of Variation for 200 x 200 scans, 3 mm circle is the highest.* *Coefficient of Variation for 200 x 200 scans, 5 mm circle is the lowest.* *Repeatability for 200 x 200, manually-edited scans is much lower.* *Coefficient of Variation for 200 x 200, manually-edited scans is much lower*.						

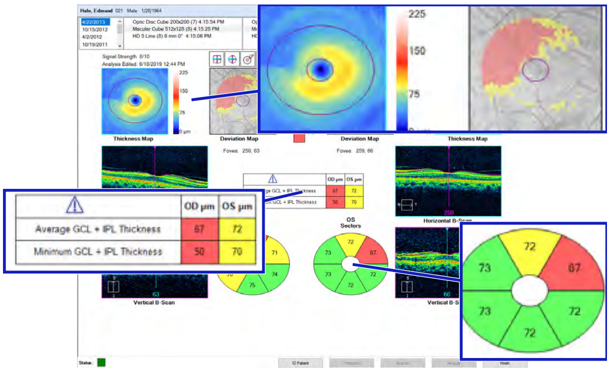
Table 113: Repeatability and Reproducibility of Area of RPE Elevations

Macular Cube Scan		Repeatability (mm^3)		Reproducibility (mm^3)		CV%
		SD	Limit	SD	Limit	
200 x 200	3mm Circle	0.0117	0.0327	0.0122	0.0341	15.2%
	5mm Circle	0.0098	0.0275	0.0106	0.0298	8.3%
512 x 128	3mm Circle	0.0074	0.0206	0.0084	0.0235	12.0%
	5mm Circle	0.0088	0.0245	0.0103	0.0288	11.4%
Observations: *Coefficient of Variation for 200 x 200 scans, 3 mm circle is highest.* *Coefficient of Variation for 200 x 200 scans, 5 mm circle is lowest.*						

Table 114: Repeatability and Reproducibility of Volume of RPE Elevations

The repeatability and reproducibility limits affect the ability to determine when measurements have changed due to a change in pathology as opposed to random variability.

C.1.2.4 Ganglion Cell Measurement Performance



This study determined ganglion cell and IPL thickness measurement performance.

C.1.2.4.1 Normal Eyes

C.1.2.4.1.1 Subjects

Demographics	Inclusion Criteria	Exclusion Criteria
▪ Number of Subjects: 63	▪ Normal eyes. ▪ 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.	History of leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis. Subjects in groups 1 through 4 who were scheduled for treatment of macular edema were moved into group 5. If both eyes were eligible, the principal investigator arbitrarily assigned the study eye.

C.1.2.4.1.2 Method: Instrument Variability

CIRRUS™ HD-OCT		Scans	Instrument			
			1	2	3	4
	Operator used four different instruments; same eye.	Macular Cube Scan	3	3	3	3

Table 115: Ganglion Cell Measurement Instrument Variability

C.1.2.4.1.3 Method: Operator Variability

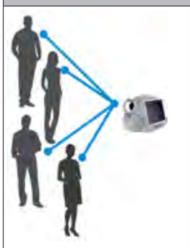
CIRRUS™ HD-OCT		Scans	Operator			
			A	B	C	D
	Each operator used the same instrument; same eye.	Macular Cube Scan	3	3	3	3

Table 116: Ganglion Cell Measurement Operator Variability

C.1.2.4.1.4 GCL Thickness Performance Results

GCL + IPL Thickness	Repeatability (µm)		Reproducibility (µm)		CV%
	SD	Limit	SD	Limit	
Average	0.5839	1.6348	0.7479	2.0942	0.7%
Minimum	2.8630	8.0165	2.8935	8.1018	2.5%
Temporal–Superior	0.8394	2.3502	0.9496	2.6590	1.0%
Superior	0.9115	2.5522	1.0723	3.0024	1.1%
Nasal–Superior	0.9198	2.5753	1.0412	2.9154	1.0%
Nasal–Inferior	1.6735	4.6857	1.7330	4.8525	1.5%
Inferior	0.9962	2.7894	1.1907	3.3339	1.2%
Temporal–Inferior	0.8196	2.2948	0.9177	2.5696	1.0%
Observations: *Repeatability, Reproducibility, and Coefficient of Variation for minimum thickness is highest.* *Repeatability, Reproducibility and Coefficient of Variation for average thickness is lowest.*					

Table 117: Ganglion Cell Algorithm Performance

C.1.2.4.2 Glaucoma

C.1.2.4.2.1 Subjects

Demographics	Inclusion Criteria	Exclusion Criteria
▪ Number of Subjects: 94 ▪ Age Range: 43-89 ▪ Mean Age: 66.9	▪ Normal eyes. ▪ 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.	History of leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis.
Mild (45)	Mild Glaucoma	
Moderate (20)	Moderate Glaucoma	
Severe (19)	Severe Glaucoma	

C.1.2.4.2.2 Method: Instrument / Operator Variability

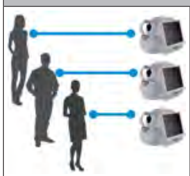
CIRRUS™ HD-OCT 4000		Scans	Operator		
			A	B	C
	Each operator used a different instrument; same eye.	Macular Cube 200x200	3	3	3
		Macular Cube 512x128	3	3	3

Table 118: Operator Variability of Ganglion Cell Measurements

C.1.2.4.2.3 Method: Instrument / Operator Variability (5000)

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	Each operator used a different instrument; same eye.	Macular Cube 200x200	3	3	3
		Macular Cube 512x128	3	3	3

Table 119: Operator and Instrument Variability of Ganglion Cell Measurements

C.1.2.4.2.4 Method: Instrument Comparison

Visante Compare		Scans	Operator
	■ One operator used one Visante OCT instrument. ■ The first qualified Visante OCT image was compared to the first qualified CIRRUS 6000 image.	HD Angle (Nasal)	3
		HD Angle (Temporal)	3

Table 120: Instrument Comparison of Ganglion Cell Measurements

C.1.2.4.2.5 Measurement Performance Results

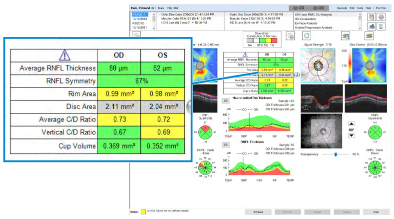
	Mild			Moderate			Severe		
GCL + IPL Thickness	SD	Limit	CV%	SD	Limit	CV%	SD	Limit	CV%
Average	0.5099	1.4277	0.7%	0.7661	2.1352	1.2%	0.7071	1.9799	1.2%
Minimum	0.9000	2.5200	1.4%	1.1132	3.1169	2.1%	2.6682	7.4708	5.3%
Temporal–Superior	0.8062	2.2574	1.2%	1.3433	3.7611	2.1%	1.7728	4.9639	2.9%
Superior	1.0198	2.8555	1.4%	1.8238	5.1065	2.9%	1.0235	2.8659	1.6%
Nasal–Superior	0.8367	2.3426	1.1%	0.8209	2.2986	1.2%	0.7868	2.2030	1.2%
Nasal–Inferior	1.1489	3.2170	1.6%	0.8341	2.3354	1.4%	1.3093	3.6661	2.1%
Inferior	1.0677	2.9896	1.6%	1.1325	3.1711	2.0%	0.9386	2.6281	1.6%
Temporal–Inferior	1.0488	2.9367	1.6%	0.8723	2.4424	1.5%	1.7795	4.9826	3.3%

Table 121: Ganglion Cell Algorithm Performance: Glaucoma

GCL + IPL Thickness	SD	Limit	CV%
Average	0.6274	1.7567	1.0%
Minimum	1.5246	4.2689	2.6%
Temporal–Superior	1.2204	3.4171	1.8%
Superior	1.2653	3.5429	1.8%
Nasal–Superior	0.8219	2.3013	1.2%
Nasal–Inferior	1.1204	3.1371	1.7%
Inferior	1.0569	2.9593	1.7%
Temporal–Inferior	1.2160	3.4049	2.0%

Table 122: Overall Ganglion Cell Algorithm Performance: Glaucoma

C.1.3 ONH Algorithms



ONH Measurement Performance

This study determined the repeatability and reproducibility of Optic Nerve Head (ONH) parameters.[10]

C.1.3.1

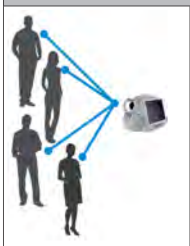
C.1.3.2 ONH and RNFL Normal Eye Measurement Performance

This study determined the repeatability and reproducibility of Optic Nerve Head (ONH) parameters.

C.1.3.2.1 Method: Instrument Variability

CIRRUS™ HD-OCT 5000		Scans	Instrument			
			1	2	3	4
	■ Subjects: 63 A single operator acquired scans using four different CIRRUS™ HD-OCT instruments.	ONH Cube	3	3	3	3

C.1.3.2.2 Method: Operator Variability

CIRRUS™ HD-OCT 5000		Scans	Operator			
			A	B	C	D
	■ Subjects: 63 Three operators acquired scans using the same CIRRUS™ HD-OCT instrument.	ONH Cube	3	3	3	3

C.1.3.2.3 Measurement Performance Results

	Repeatability		Reproducibility		CV %
	SD	Limit	SD	Limit	
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%

Table 123: Repeatability and Reproducibility of Optic Nerve Head Algorithms (Normal Subjects)

[10] Mwanza, Chang, Budenz, Durbin, Gendy, Ski, Feauer: *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 (derived from).

C.1.3.3 Glaucoma Measurement Performance

	Repeatability		Reproducibility		CV%
	SD	Limit	SD	Limit	
Normal Subjects					
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%
Glaucoma Subjects					
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%

Table 124: Repeatability and Reproducibility of Optic Nerve Head Algorithms

	Repeatability		Visit-to-Visit		CV %
	SD	Limit	SD	Limit	
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%
Disc Area (mm^2)	0.084	0.233	0.084	0.233	4.4%
Rim Area (mm^2)	0.045	0.125	0.045	0.125	6.6%
Cup Volume (mm^3)	0.032	0.089	0.063	0.175	11.7%
Observations: *Repeatability and Reproducibility for disc area measurement is highest and cup volume measurement is lowest.* *Coefficient of Variation for cup volume measurement is highest and rim area is lowest.*					

Table 125: Repeatability and Reproducibility of Optic Nerve Head Algorithms (Glaucoma Subjects)

General observations:

- The optic nerve head algorithm might 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.

  Ambiguity in cup marker placement may increase variability for:
  - small, crowded discs with shallow cups
  - discs with large clusters of blood vessels
- Cups with excavation or embryonic tissue remnants may have variable cup volume measurements.

C.1.3.3.1 Subjects: Glaucoma Same Visit

This study included four sites.

Subject Demographics	Subject Pathology
▪ Subjects: 94	▪ Mild Glaucoma: 45 subjects
▪ Age range: 43 to 89	▪ Moderate Glaucoma: 20 subjects
▪ Mean age: 66.9	▪ Severe Glaucoma: 19 subjects

Table 126: Glaucoma Same Visit Study Subjects

C.1.3.3.2 Method: Operator Variability

CIRRUS™ HD-OCT 5000		Scans	Operator			
			A	B	C	D
	■ Subjects: 63 Three operators acquired scans using the same CIRRUS™ HD-OCT instrument.	ONH Cube	3	3	3	3

C.1.3.3.3 Subjects: Glaucoma Follow-Up Visit

Demographics	Inclusion Criteria	Exclusion Criteria
■ Number of Subjects: 84 ■ Age Range: 43-89 ■ Mean age: 66.9	■ 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. ■ Glaucoma diagnosis.	
Mild (45)	Mild Glaucoma	Normal Eyes
Moderate (20)	Moderate Glaucoma	
Severe (19)	Severe Glaucoma	

C.1.3.3.4 Method: Follow-up Visit

Glaucoma: Follow-up Visit Variation

A clinical study was conducted to determine the intra–visit and inter–visit repeatability of CIRRUS™ HD-OCT optic nerve head parameters. [10]

Subject Demographics	Subject Pathology
■ Subjects: 55 ■ Age range: 46 to 87 ■ Mean age: 70.7 ± 11.1	■ Mild Glaucoma: 26 subjects ■ Moderate Glaucoma: 11 subjects ■ Severe Glaucoma: 18 subjects

Table 127: Glaucoma Follow-up Visit Study Subjects

CIRRUS™ HD-OCT 5000		Visits	Scans	Instrument 1
	At each visit, one operator acquired scans using the same CIRRUS™ HD-OCT instrument.	Visit 1	ONH Cube	3
		Visit 2		3
		Visit 3		3
		Visit 4		3

C.1.3.3.5 Measurement Performance Results

	Repeatability		Visit-to-Visit		CV %
	SD	Limit	SD	Limit	
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%
Disc Area (mm^2)	0.084	0.233	0.084	0.233	4.4%
Rim Area (mm^2)	0.045	0.125	0.045	0.125	6.6%
Cup Volume (mm^3)	0.032	0.089	0.063	0.175	11.7%

	Repeatability		Visit-to-Visit		CV %
	SD	Limit	SD	Limit	
Observations: *Repeatability and Reproducibility for disc area measurement is highest and cup volume measurement is lowest.* *Coefficient of Variation for cup volume measurement is highest and rim area is lowest.*					

Table 128: Repeatability and Reproducibility of Optic Nerve Head Algorithms (Glaucoma Subjects)

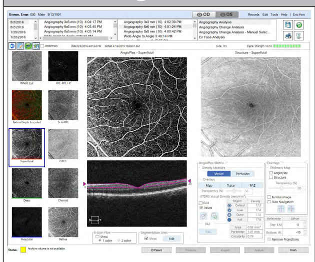
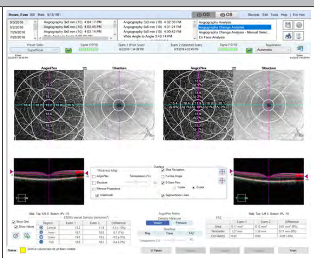
C.1.3.4 General Observations

- The optic nerve head algorithm might 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.

  Ambiguity in cup marker placement may increase variability for:
  - small, crowded discs with shallow cups
  - discs with large clusters of blood vessels
- Cups with excavation or embryonic tissue remnants may have variable cup volume measurements.

C.2 AngioPlex Metrix Algorithms

CIRRUS™ HD-OCT**AngioPlex Metrix** algorithm results appear in the scan analyses shown below.

Macular AngioPlex Metrix		ONH AngioPlex Metrix	
			

Algorithm Studied	Parameters	Applicable Analyses
Vessel Density Performance [494] Vessel Profusion Performance [496]	**Vessel Density** and **Vessel Perfusion** performance comparing ground truth images and vasculature phantom images that simulate: ■ Vessel distribution ■ Vessel sizes ■ Vessel widths ■ Background speckle ■ Vessel dropouts	■ Analyze Angiography Images [320] ■ Angiography Change Analysis [327]
Vessel Density Performance [498] Wellness Exam [301]		■ Analyze ONH Angiography Images [331] ■ ONH Angiography Change Analysis [333]

Table 129: AngioPlex Metrix Algorithms

C.2.1 Terms and Acronyms

Term	Explanation
Phantom Image	*Coefficient of variation = SD ÷ Mean.*

Term	Explanation
Ground Truth	Number of subjects

Table 130: Posterior Segment Algorithm Study Terms

C.2.2 AngioPlex Metrix Macular Algorithms

An analysis of the accuracy of Cirrus AngioPlex density metrics was done using digital phantoms. This analysis found that the metrics are most valuable when viewed or analyzed as relative values, rather than as being representations of the absolute density of vasculature. The study found some differences between ground truth and the Cirrus measurement due to the 15-20 microns beam width associated with OCT imaging.

Because the Perfusion Density attempts to account for vessel width, while Vessel Density reduces all Vessels to a single pixel wide, the Perfusion Density is more affected than the Vessel Density by the fact that the beam width is larger than the smallest capillary widths. Some of the inaccuracies observed were also due to the density of A-scans, which is lower for the 6x6mm scan than for the 3x3mm scan. Overall, the 6x6 scans were less accurate than the 3x3 scans, and the Perfusion Density was less accurate than the Vessel Density. In spite of the lack of agreement, the analysis showed a good correlation between the underlying ground truth and the reported measurement that supports the utility of these types of measurements in evaluating microvascular density. In particular, as the ground truth density decreases, the reported Vessel Density and Perfusion Density both also decrease, for both the 3x3 and the 6x6 scans.

The results in the study showed that the ability to monitor change over time is best with Vessel Density in the 3x3 scans.

Because of its axial resolution, OCTA enables visualization of fine retinal vasculature that is difficult to achieve with conventional dye-based angiography. This gives rise to the opportunity to quantitatively analyze vasculature data obtained on OCTA. Zeiss has developed algorithms to measure vascular density by examining en face slabs generated from the superficial retinal layer of the 3-dimensional OCTA data.

This report evaluates the accuracy of Cirrus AngioPlex density measurement algorithms in determining the density of microvasculature in the eye as compared to a ground truth determined by newly developed digital phantoms. These digital phantoms are images designed to have characteristics such as noise and speckle similar to Cirrus and vascular features that resemble those in the human eye.

Cirrus offers two measures of vascular density in the superficial retinal layer (SRL). These are referred to as Vessel Density and Perfusion Density. Both metrics attempt to quantify blood vessels per unit area in a region of measurement.

Perfusion Density is the total area of perfused vasculature per unit area in a region of measurement. It is a ratio and has no units.

Vessel Density is the total length of perfused vasculature per unit area in a region of measurement and has units of mm/mm2.

To calculate the perfusion density and the vessel density, a thresholding algorithm is applied to the SRL en face images to create a binary slab that assigns to each pixel a 1 (perfused) or 0 (background). From this slab, a skeletonized slab is created, representing vessels with a trace of 1 pixel in width. If there is flow, white pixels will be present. We define the Perfusion Density as the total area of perfused vasculature per unit area in a region of measurement, calculated by taking the mean of the binary slab within a desired region of interest. We define the Vessel Density as the total length of perfused vasculature per unit area in a region of measurement.

We calculate the Vessel Density by taking the mean of the skeletonized slab within a desired region of interest and scaling the result by the distance between pixels (in this case, 512 pixels per 3 mm). The mean of the skeletonized slab is only a first-order estimate of the length of perfused vasculature. A more accurate calculation would require considering the relationship between neighboring pixels with a value of 1 in the skeletonized slab. Cirrus AngioPlex OCT Angiography scans have been demonstrated to correspond to the clinical status of eyes with diabetic retinopathy both qualitatively and quantitatively]. In particular, reference 1 demonstrates that both Vessel Density and Perfusion Density show good diagnostic efficacy when evaluated in a population of normal eyes and eyes with early diabetic retinopathy (with an area under the receiver operating characteristic curve of 0.893 for Vessel Density and of 0.794 for Perfusion Density).

The density metrics have also been shown to be repeatable and reproducible in normal eyes and eyes with a wide range of severity of diabetic retinopathy and retinal vein occlusions. Ideally, we would like to understand the accuracy of Cirrus density measurements compared to a gold standard, but because OCT Angiography shows the retinal microvasculature over the macular region in more detail than has previously been possible in vivo, no validated gold standard exists. For this reason, we developed a set of digital phantoms to mimic the vasculature in the eye as well as the image capture process, which can serve as a gold standard for comparison.

The goal of this report is to determine how accurate the metrics are. Since no gold standard exists, we constructed a set of digital phantoms consisting of features similar to those typically seen in Cirrus AngioPlex images of the superficial retinal layer, and compared the quantitative outputs to the known values defined in the artificially created images.

C.2.2.1 Vessel Density Performance

This study determined the repeatability and reproducibility of the CIRRUS™ HD-OCT

C.2.2.1.1 Method: Image Comparison

CIRRUS™ HD-OCT 5000		Scans	Instrument		
			1	2	3
	■ Number of Subjects: 37 ■ Eyes: 49 A single operator acquired scans using three different CIRRUS™ HD-OCT instruments.	Macular Cube 200x200	3	3	3
		Macular Cube 512x128	3	3	3

C.2.2.1.2 Method: Image Comparison Over Time

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	■ Number of Subjects: 39 ■ Eyes: 53 Three operator acquired scans using the same CIRRUS™ HD-OCT instrument.	Macular Cube 200x200	3	3	3
		Macular Cube 512x128	3	3	3

C.2.2.1.3 Comparison Results

Observations (3x3 scans):

- The overall mean difference: -1.5 mm/mm^2 ; measurements range: 12.5 to 27.5 mm/mm^2.
- The offset is worse for eyes with higher density (more for normal eyes).
- The errors in accuracy are consistent with the fact that OCT Angiography is imaging with limited resolution that is not perfectly matched to the size of the features we are attempting to image. That is, capillaries are expected to be as small as 5 um, and the beam width of Cirrus is approximately 15 um, while the pixel spacing for the 3x3 scan is 12 um. It makes sense to expect some inaccuracy in measurement for images of the most densely packed and smallest vessels. There is nonetheless a strong relationship between the Vessel Density as measured in ground truth images and as measured in simulated Cirrus images. As an individual eye experiences capillary loss, it is reasonable, based on these results, to expect that the loss will be reflected as a reduction in the Vessel Density measurements. See Figure 6 for an example of this using one specific case.

Factor	Higher Impact for:	Mean Difference
Morphology	Morphological factor applied to the smallest vessels	30-micron vessels: -2.17 (SD 0.87)
Vessel Density	Densely-packed vessels with fewest dropouts	6-micron vessels: -3.8 12-micron vessels: 1.6

Table 131: Factors that Impact the Mean Difference

Factor	Low Impact for	Mean Difference
Morphology	Morphological factor applied to larger vessels	36-micron vessels: -0.81 (SD 0.54)
Vessel Density	Vessels with more spacing and more dropouts	6-micron vessels: -1.2 12-micron vessels: -0.2
Noise level	did not impact the mean offset.	
Hand-drawn large and medium vessel phantom		Measurements

Table 132: Factors that Do Not Impact the Mean Difference

For vessels with more spacing and more dropouts, the error could reduce to as little as -1.2 for 6 micron thick microvessels and -0.2 for 12 micron thick microvessels. The size of the morphological factor applied to the larger vessels has a very small effect on the magnitude of error. Noise level did not affect the mean offset. Choice of hand-drawn large and medium vessel phantom did not affect the mean offset. The errors in accuracy are consistent with the fact that OCT Angiography is imaging with limited resolution that is not perfectly matched to the size of the features we are attempting to image. That is, capillaries are expected to be as small as 5 um, and the beam width of Cirrus is approximately 15 um, while the pixel spacing for the 3x3 scan is 12 um. It makes sense to expect some inaccuracy in measurement for images of the most densely packed and smallest vessels. There is nonetheless a strong relationship between the Vessel Density as measured in ground truth images and as measured in simulated Cirrus images. As an individual eye experiences capillary loss, it is reasonable, based on these results, to expect that the loss will be reflected as a reduction in the Vessel Density measurements. See Figure 6 for an example of this using one specific case

, the error could reduce to as little as -1.2 for 6 micron thick microvessels and -0.2 for 12 micron thick microvessels. The size of the morphological factor applied to the larger vessels has a very small effect on the magnitude of error.

Key for graphs shown in the following table:

- x axis = ground truth
- y axis= CIRRUS™ HD-OCT imaging and algorithm

	Linear Regression (mm/mm^2)				Bland-Altman Analysis (mm/mm^2)			
	y	r^2	SSE	n	RPC	CV	SD	p
3x3 Vessel Density	0.86x+1.42	0.97	1700	3240	1.9 (8.1%)	5.1%	1.96	-1.5

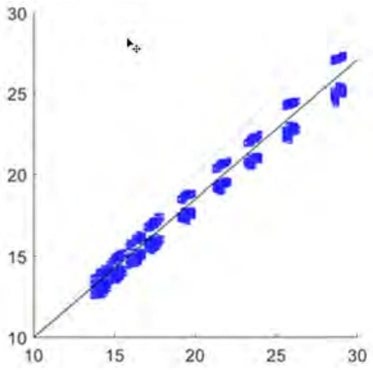
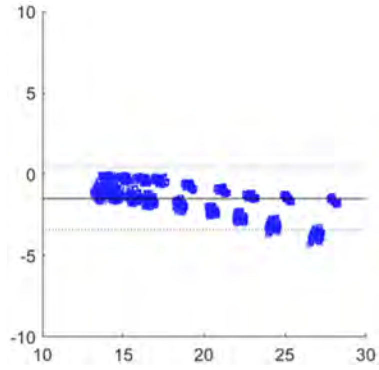
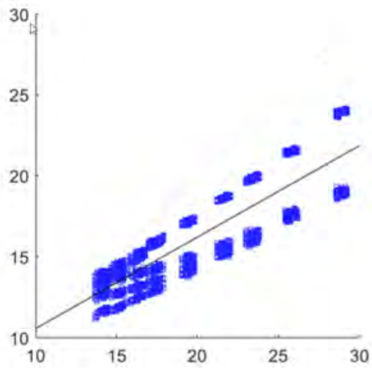
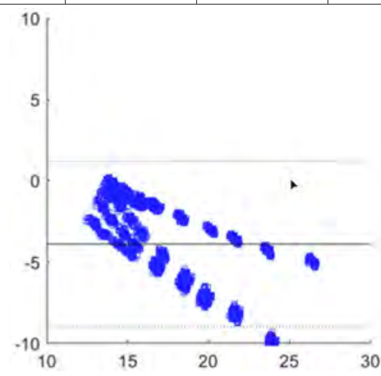
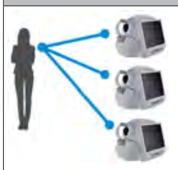
	Linear Regression (mm/mm²)				Bland-Altman Analysis (mm/mm²)			
	y	r^2	SSE	n	RPC	CV	SD	p
								
6x6 Vessel Density	0.57x+4.92	0.74	8000	3240	5.1 (23%)	14%	1.96	-3.9
								
Observations (6x6 scans):								

Table 133: Comparisons of CIRRUS™ HD-OCT Vessel Density algorithm to digital ground truth for angiography scans.

C.2.2.2 Vessel Profusion Performance

This study evaluated the performance of

C.2.2.2.1 Method: Instrument Variability

CIRRUS™ HD-OCT 5000		Scans	Instrument		
			1	2	3
	■ Eyes: 26 A single operator acquired scans using three different CIRRUS™ HD-OCT instruments.	Macular Cube 200x200	3	3	3
		Macular Cube 512x128	3	3	3

C.2.2.2.2 Method: Operator Variability

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	■ Eyes: 24 Three operator acquired scans using the same CIRRUS™ HD-OCT instrument.	Macular Cube 200x200	3	3	3
		Macular Cube 512x128	3	3	3

C.2.2.2.3 Measurement Performance Results

Macular Cube Scan		Repeatability (mm^2)		Reproducibility (mm^2)		CV%
		SD	Limit	SD	Limit	
200 x 200	3mm Circle	0.1295	0.3626	0.1568	0.4389	10.1%
	5mm Circle	0.1012	0.2834	0.1455	0.4073	4.9%
512 x 128	3mm Circle	0.0837	0.2343	0.0998	0.2794	7.5%
	5mm Circle	0.1537	0.4304	0.1936	0.5422	9.6%
Observations: *Repeatability for 200 x 200 scans, 3 mm circle is higher.* *Repeatability for 512 x 128 scans, 5 mm circle is higher.* *Reproducibility for 200 x 200 scans, 3 mm circle and 5 mm circle is about the same.* *Reproducibility for 512 x 128 scans, 5 mm circle is much higher (double).* *Coefficient of Variation for 200 x 200 scans, 3 mm circle is the highest.* *Coefficient of Variation for 200 x 200 scans, 5 mm circle is the lowest.* *Repeatability for 200 x 200, manually-edited scans is much lower.* *Coefficient of Variation for 200 x 200, manually-edited scans is much lower.*						

Table 134: Repeatability and Reproducibility of Area of RPE Elevations

Macular Cube Scan		Repeatability (mm^3)		Reproducibility (mm^3)		CV%
		SD	Limit	SD	Limit	
200 x 200	3mm Circle	0.0117	0.0327	0.0122	0.0341	15.2%
	5mm Circle	0.0098	0.0275	0.0106	0.0298	8.3%
512 x 128	3mm Circle	0.0074	0.0206	0.0084	0.0235	12.0%
	5mm Circle	0.0088	0.0245	0.0103	0.0288	11.4%
Observations: *Coefficient of Variation for 200 x 200 scans, 3 mm circle is highest.* *Coefficient of Variation for 200 x 200 scans, 5 mm circle is lowest.*						

Table 135: Repeatability and Reproducibility of Volume of RPE Elevations

The repeatability and reproducibility limits affect the ability to determine when measurements have changed due to a change in pathology as opposed to random variability.

C.2.3 AngioPlex Metrix ONH Algorithms

An analysis of the accuracy of Cirrus AngioPlex density metrics was done using digital phantoms. This analysis found that the metrics are most valuable when viewed or analyzed as relative values, rather than as being representations of the absolute density of vasculature. The study found some differences between ground truth and the Cirrus measurement due to the 15-20 microns beam width associated with OCT imaging. The analysis showed a good correlation between the underlying ground truth and the reported measurement that supports the utility of these types of measurements in evaluating microvascular density.

C.2.3.1 ONH Measurement Performance

This study determined the repeatability and reproducibility of Optic Nerve Head (ONH) parameters.[11]

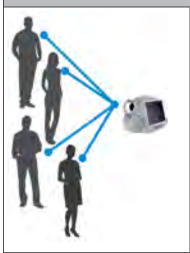
C.2.3.2 Vessel Density Performance

This study determined the repeatability and reproducibility of Optic Nerve Head (ONH) parameters.

C.2.3.2.1 Method: Instrument Variability

CIRRUS™ HD-OCT 5000		Scans	Instrument			
			1	2	3	4
	■ Subjects: 63 A single operator acquired scans using four different CIRRUS™ HD-OCT instruments.	ONH Cube	3	3	3	3

C.2.3.2.2 Method: Operator Variability

CIRRUS™ HD-OCT 5000		Scans	Operator			
			A	B	C	D
	■ Subjects: 63 Three operators acquired scans using the same CIRRUS™ HD-OCT instrument.	ONH Cube	3	3	3	3

C.2.3.2.3 Measurement Performance Results

	Repeatability		Reproducibility		CV %
	SD	Limit	SD	Limit	
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%

[11] Mwanza, Chang, Budenz, Durbin, Gendy, Ski, Feauer: *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 (derived from).

	Repeatability		Reproducibility		CV %
	SD	Limit	SD	Limit	
Cup Volume (mm^3)	0.0065	0.0181	0.0102	0.0287	7.8%

Table 136: Repeatability and Reproducibility of Optic Nerve Head Algorithms (Normal Subjects)

C.2.3.3 Vessel Profusion Performance

	Repeatability		Reproducibility		CV%
	SD	Limit	SD	Limit	
Normal Subjects					
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%
Glaucoma Subjects					
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%

Table 137: Repeatability and Reproducibility of Optic Nerve Head Algorithms

	Repeatability		Visit-to-Visit		CV %
	SD	Limit	SD	Limit	
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%
Disc Area (mm^2)	0.084	0.233	0.084	0.233	4.4%
Rim Area (mm^2)	0.045	0.125	0.045	0.125	6.6%
Cup Volume (mm^3)	0.032	0.089	0.063	0.175	11.7%
Observations: *Repeatability and Reproducibility for disc area measurement is highest and cup volume measurement is lowest.* *Coefficient of Variation for cup volume measurement is highest and rim area is lowest.*					

Table 138: Repeatability and Reproducibility of Optic Nerve Head Algorithms (Glaucoma Subjects)

General observations:

- The optic nerve head algorithm might 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.

  Ambiguity in cup marker placement may increase variability for:
  - small, crowded discs with shallow cups
  - discs with large clusters of blood vessels
- Cups with excavation or embryonic tissue remnants may have variable cup volume measurements.

C.2.3.3.1 Subjects: Glaucoma Same Visit

This study included four sites.

Subject Demographics	Subject Pathology
■ Subjects: 94 ■ Age range: 43 to 89 ■ Mean age: 66.9	■ Mild Glaucoma: 45 subjects ■ Moderate Glaucoma: 20 subjects ■ Severe Glaucoma: 19 subjects

Table 139: Glaucoma Same Visit Study Subjects

C.2.3.3.2 Method: Operator Variability

CIRRUS™ HD-OCT 5000		Scans	Operator			
			A	B	C	D
	■ Subjects: 63 Three operators acquired scans using the same CIRRUS™ HD-OCT instrument.	ONH Cube	3	3	3	3

C.2.3.3.3 Subjects: Glaucoma Follow-Up Visit

Demographics	Inclusion Criteria	Exclusion Criteria
■ Number of Subjects: 84 ■ Age Range: 43-89 ■ Mean age: 66.9	■ 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. ■ Glaucoma diagnosis.	
Mild (45)	Mild Glaucoma	Normal Eyes
Moderate (20)	Moderate Glaucoma	
Severe (19)	Severe Glaucoma	

C.2.3.3.4 Method: Follow-up Visit

Glaucoma: Follow-up Visit Variation

A clinical study was conducted to determine the intra–visit and inter–visit repeatability of CIRRUS™ HD-OCT optic nerve head parameters. [11]

Subject Demographics	Subject Pathology
■ Subjects: 55 ■ Age range: 46 to 87 ■ Mean age: 70.7 ± 11.1	■ Mild Glaucoma: 26 subjects ■ Moderate Glaucoma: 11 subjects ■ Severe Glaucoma: 18 subjects

Table 140: Glaucoma Follow-up Visit Study Subjects

CIRRUS™ HD-OCT 5000		Visits	Scans	Instrument 1
	At each visit, one operator acquired scans using the same CIRRUS™ HD-OCT instrument.	Visit 1	ONH Cube	3
		Visit 2		3
		Visit 3		3
		Visit 4		3

C.2.3.3.5 Measurement Performance Results

	Repeatability		Visit-to-Visit		CV %
	SD	Limit	SD	Limit	
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%
Disc Area (mm^2)	0.084	0.233	0.084	0.233	4.4%
Rim Area (mm^2)	0.045	0.125	0.045	0.125	6.6%
Cup Volume (mm^3)	0.032	0.089	0.063	0.175	11.7%
Observations: *Repeatability and Reproducibility for disc area measurement is highest and cup volume measurement is lowest.* *Coefficient of Variation for cup volume measurement is highest and rim area is lowest.*					

Table 141: Repeatability and Reproducibility of Optic Nerve Head Algorithms (Glaucoma Subjects)

C.2.3.4 General Observations

- The optic nerve head algorithm might 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.

  Ambiguity in cup marker placement may increase variability for:
  - small, crowded discs with shallow cups
  - discs with large clusters of blood vessels
- Cups with excavation or embryonic tissue remnants may have variable cup volume measurements.

C.3 Anterior Segment Algorithms

CIRRUS™ HD-OCTanterior segment algorithm results appear in the scan analyses shown below.

Measurement	Parameters	Analyses
Anterior Chamber [▹ 184]	Measurement performance of operator variability and instrument variability for normal eyes, corneal pathology: ■ Central Corneal Thickness ■ Angle to Angle Distance ■ Anterior Chamber Depth	Anterior Chamber Analysis [▹ 342]
HD Angle Scans [▹ 194]	Measurement performance of angles (nasal and temporal): ■ Angle Opening Distance (AOD) 500 and 750 ■ Trabecular Iris Space Area (TISA) 500 and 750 ■ Scleral Spur Angle (SSA) ■ Anterior Chamber Angle (ACA)	HD Angle [▹ 349]
Wide Angle to Angle Scans [▹ 197]		Wide Angle-to-Angle [▹ 361]

Measurement	Parameters	Analyses
Pachymetry [▹ 204]	Measurement performance of pachymetry algorithms for normal corneas, corneal pathology, and post-LASIK: ▪ Center ▪ Inner Nasal ▪ Inner Superior ▪ Inner Inferior ▪ Inner Temporal ▪ Outer Nasal ▪ Outer Superior ▪ Outer Inferior ▪ Outer Temporal ▪ Epithelial Thickness Measurement (ETM)	Pachymetry [▹ 356]

Table 142: Anterior Segment Algorithm Parameters

C.3.1 Terms and Acronyms

The following definitions apply to all results tables in this appendix.

All statistics are estimated from two-way random-effect ANOVA model with random effects operator/device, eye and interaction between operator/device and eye.

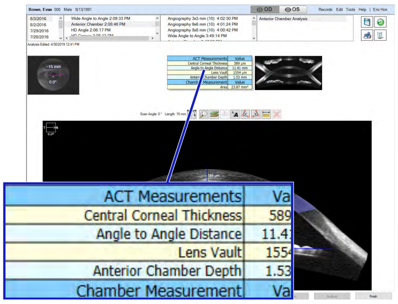
Term	Explanation
CV	Coefficient of variation = SD ÷ Mean.
Mean	Intercept of the ANOVA model
Repeatability CV%	(Repeatability SD)/Intercept x 100%.
Repeatability Limit	2.8 x Repeatability SD (per ISO 5725-1 and ISO 5725-6).
Repeatability SD	Square root of the residual variance.
Reproducibility CV%	(Reproducibility 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 (per ISO 5725-1 and ISO 5725-6).
SD	Standard Deviation

Table 143: Measurement Performance Results Tables

Term	Explanation
95% CI	*Confidence Interval* for mean difference is based on t-distribution.
95% LOA	*Limit of Agreement*
ACD of Visante	adjusted by CCT (i.e. ACD = original ACD - CCT/1000).
Difference	CIRRUS - Visante.
LOA	*Limit of Agreement* calculated as: `mean +/- 1.96 * SD` where “mean” is the mean of the differences between Algorithm and Manual results and SD is the standard deviation.
p-value	based on paired t-test.

Table 144: Comparison Results Tables

C.3.2 Anterior Chamber Measurements



A non-significant risk clinical study was conducted to:

- Determine the repeatability and reproducibility of the CIRRUS™ HD-OCT in measuring:
  - Central Corneal Thickness
  - Angle to Angle Distance
  - Anterior Chamber Depth
- Compare the corresponding measurements of CIRRUS™ HD-OCT and Visante OCT.

Operator Variability Study

	Mean	Repeatability			Reproducibility		
		SD	Limit	CV%	SD	Limit	CV%
Group 1: Normal Cornea							
CCT	549.5	9.749	27.297	1.774	11.897	33.311	2.165
Angle to Angle	12.030	0.171	0.479	1.4231	0.300	0.840	2.494
ACD	2.858	0.034	0.096	1.199	0.046	0.128	1.60
Group 2: Cornea Pathology (keratoconus)							
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

Table 145: Repeatability and Reproducibility of CIRRUS™ HD-OCT Anterior Chamber Measurements

Instrument Variability Study

	N	CIRRUS	Visante	Difference	95% CI	p-value	95% LOA
		Mean SD					
Group 1: Normal Cornea							
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 `
Group 2: Cornea Pathology (keratoconus)							
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

Table 146: Mean Difference Between CIRRUS™ HD-OCT and Visante OCT

C.3.2.1 Subjects

Demographics	Inclusion Criteria	Exclusion Criteria
■ Number of Subjects: 137 ■ Age Range: 25-69		■ Blindness, low vision or severely diseased eyes, ■ Prior surgery or a procedure involving or affecting the cornea in the study eye. ■ Corneal pathology, either inflammatory or non-inflammatory, in the study eye.
Group 1: Normal (46)	Normal Corneas	
Group 2: Corneal Pathology (36)	Diagnosed with keratoconus	■ Normal corneas in the study eye. ■ Prior LASIK surgery in the study eye.

C.3.2.2 Method

CIRRUS™ HD-OCT 4000		Scans	Operator		
			A	B	C
	Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3
		HD Angle (Temporal)	3	3	3

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3
		HD Angle (Temporal)	3	3	3

Visante Compare		Scans	Operator
	■ One operator used one Visante OCT instrument. ■ The first qualified Visante OCT image was compared to the first qualified CIRRUS 6000 image.	HD Angle (Nasal)	3
		HD Angle (Temporal)	3

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	This study included 28 subjects. A single operator acquired three scans using three different CIRRUS™ HD-OCT instruments (9 scans total). Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3

Operator Variability

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	This study included 22 subjects. Three different operators performed three scans of each subject with three different CIRRUS™ HD-OCT instruments (9 scans total). Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3

C.3.2.3 Measurement Performance Results

	Mean	Repeatability			Reproducibility		
		SD	Limit	CV%	SD	Limit	CV%
Nasal							
TISA 500	0.151	0.025	0.071	16.801	0.030	0.083	19.614
TISA 750	0.263	0.028	0.080	10.827	0.037	0.103	14.053
AOD 500	0.439	0.075	0.209	17.012	0.081	0.226	18.365
AOD 750	0.570	0.055	0.153	9.598	0.084	0.236	14.783
SSA	37.696	3.774	10.569	10.013	4.552	12.746	12.076
AC Angle	36.165	3.427	9.595	9.475	4.861	13.612	13.442
Temporal							
TISA 500	0.150	0.027	0.076	18.169	0.032	0.090	21.368
TISA 750	0.275	0.041	0.115	14.946	0.045	0.126	16.353
AOD 500	0.445	0.080	0.223	17.893	0.090	0.252	20.243
AOD 750	0.586	0.076	0.213	12.972	0.085	0.237	14.434
SSA	37.846	4.442	12.438	11.737	5.024	14.068	13.276
AC Angle	35.951	3.725	10.430	10.361	5.184	14.514	14.418

Table 147: Repeatability and Reproducibility of CIRRUS™ HD-OCT Wide Angle to Angle Measurements (Glaucoma)

C.3.2.4 Comparison Results

CIRRUS		Visante		Difference		95 % CI		p value	95% LOA	
Mean	SD	Mean	SD	Mean	SD	Mean	SD		Mean	SD
Nasal										
36.054	18.137	38.831	18.272	-2.777	5.665	-5.065	-0.488	0.019	-14.107	8.554
Temporal										
35.255	18.767	38.573	18.385	-3.318	6.493	-5.940	-0.695	0.015	-16.304	9.669

Table 148: Mean Wide Angle to Angle Difference Between CIRRUS™ HD-OCT and Visante OCT

C.3.3 Anterior Chamber Measurements: Glaucoma

C.3.3.1 Measurement Performance

C.3.3.1.1 Subjects

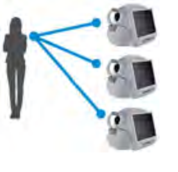
Demographics	Inclusion Criteria	Exclusion Criteria
■ Number of Subjects: 137 ■ Age Range: 25-69		History of leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis.
Group 1: Normal Cornea	Normal Corneas	■ Blindness, low vision or severely diseased eyes, ■ Prior surgery or a procedure involving or affecting the cornea in the study eye. ■ Corneal pathology, either inflammatory or non-inflammatory, in the study eye.
Group 2: Corneal Pathology	Anterior segment pathology diagnosis, including: ■ keratoconus ■ pellucid marginal degeneration ■ corneal scarring ■ corneal degeneration ■ corneal dystrophy ■ corneal changes secondary to disease or surgery	■ Could not fixate long enough to acquire images. ■ Normal corneas in the study eye. ■ Prior LASIK surgery in the study eye.

C.3.3.1.2 Method

CIRRUS™ HD-OCT 4000		Scans	Operator		
			A	B	C
	Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3
		HD Angle (Temporal)	3	3	3

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3
		HD Angle (Temporal)	3	3	3

Visante Compare		Scans	Operator
	■ One operator used one Visante OCT instrument. ■ The first qualified Visante OCT image was compared to the first qualified CIRRUS 6000 image.	HD Angle (Nasal)	3
		HD Angle (Temporal)	3

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	This study included 28 subjects. A single operator acquired three scans using three different CIRRUS™ HD-OCT instruments (9 scans total). Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3

Operator Variability

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	This study included 22 subjects. Three different operators performed three scans of each subject with three different CIRRUS™ HD-OCT instruments (9 scans total). Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3

C.3.3.1.3 Measurement Accuracy Results

Repeatability		Reproducibility		Operator Variability	Instrument Variability	Overall
SD (µm)	Limits (µm)	SD (µm)	Limits (µm)			
4.08	11.42	4.23	11.84	544.25	532.25	538.25
Random error variability for Operator Variability was larger than Instrument Variability, so Operator Variability variance components were used to estimate the random measurement variability and the repeatability standard deviation.						

Table 149: Repeatability and Reproducibility of the CIRRUS™ HD-OCT Central Corneal Thickness Algorithm

C.3.3.2 Comparison

C.3.3.2.1 Subjects

Demographics	Inclusion Criteria	Exclusion Criteria
▪ Number of Subjects: 27 ▪ Age Range: 43-77 ▪ Mean Age: 62	▪ Diagnosed with glaucoma. – Severity mild to severe. – Within the angle configuration range Grade II to Grade IV[12] ▪ Able to make study visits. ▪ Provided consent. ▪ Followed study instructions.	▪ Could not fixate long enough to acquire images. ▪ Active infection of the anterior segment of the eye.

[12] Shaffer: *Primary glaucomas. Gonioscopy, ophthalmoscopy and perimetry.* Trans Am Acad Ophthalmol Otolaryngol. 1960 Mar-Apr;64:112-27.

C.3.3.2.2 Method

CIRRUS™ HD-OCT 4000		Scans	Operator		
			A	B	C
	Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3
		HD Angle (Temporal)	3	3	3

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3
		HD Angle (Temporal)	3	3	3

Visante Compare		Scans	Operator
	■ One operator used one Visante OCT instrument. ■ The first qualified Visante OCT image was compared to the first qualified CIRRUS 6000 image.	HD Angle (Nasal)	3
		HD Angle (Temporal)	3

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	This study included 28 subjects. A single operator acquired three scans using three different CIRRUS™ HD-OCT instruments (9 scans total). Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3

Operator Variability

CIRRUS™ HD-OCT 5000		Scans	Operator		
			A	B	C
	This study included 22 subjects. Three different operators performed three scans of each subject with three different CIRRUS™ HD-OCT instruments (9 scans total). Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3

C.3.3.2.3 Central Corneal Thickness Measurement Accuracy (Comparison)

This study determined the difference in Central Corneal Thickness (CCT) measurements between the of the CIRRUS™ HD-OCT and Ultrasound Pachymetry.

This study included 50 subjects.

A single operator acquired scans using CIRRUS™ HD-OCT and an Ultrasound Pachymetry instrument.

	Mean Difference	SD (µm)	95% CI of the Difference	
			Lower	Upper
CIRRUS™ HD-OCT	-9.06	5.63	-10.66	-7.46

Table 150: Mean Central Corneal Thickness Difference Between CIRRUS™ HD-OCT

The negative difference means that the CIRRUS CCT measurement is thinner than the ultrasound CCT measurement. OCT instruments generally measure pachymetry thinner than ultrasound pachymetry.

The Visante User Manual reports an average measurement difference of 15.1 micrometers. Literature reports differences between OCT and ultrasound pachymetry range from 11.64 to 49.4 micrometers. [13][14][15]

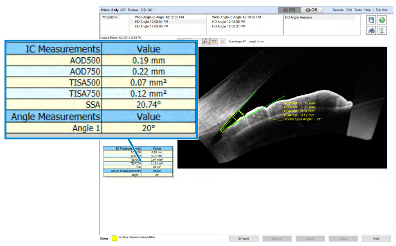
C.3.3.2.4 Axial Dimension Accuracy

Benchtop studies determine the repeatability and reproducibility performance of CIRRUS™ HD-OCT scans.

Measurement	Performance (µm)	Repeatability		Reproducibility		Average (µm)
		SD (µm)	Limit (µm)	SD (µm)	Limit (µm)	
Axial Distance	6.2	2.6	7.1	2.7	7.6	1165.6

Table 151: Performance of Axial Dimensions in Basic Image Geometry

C.3.4 HD Angle Measurements



A non-significant risk clinical study was conducted to:

- Determine the repeatability and reproducibility of the CIRRUS™ HD-OCT in measuring:
  - Angle Opening Distance (AOD)
  - Trabecular Iris Space Area (TISA)
  - Scleral Spur Angle (SSA)
  - Anterior Chamber Angle (ACA)
- Compare the corresponding measurements of CIRRUS™ HD-OCT .

[13] Weisbrod, Stetson, Wieland, Bressler, Schmidt–Erfurth, Knighton, Gregori:*Comparison of Hand–Drawn ILM and RPE Segmentation to the Retinal Segmentation Algorithm of the CIRRUS HD-OCT*, ARVO 2008, poster 4240.
[14] Chang, Durbin, Weiland, Schmidt–Erfurth, Gregori, Bressler: *Repeatability of retinal thickness measurements using CIRRUS HD-OCT Spectral Domain Technology*, ARVO 2008, poster 4253.
[15] Geitzenauer, Kiss, Durbin, Abunto, Wieland, Bressler, Gregori, Schmidt–Erfurth: *Comparing Retinal Thickness Measurements From CIRRUS Spectral–Domain and Stratus Time–Domain OCT*, ARVO 2008, poster 930.
[16] Shaffer: *Primary glaucomas. Gonioscopy, ophthalmoscopy and perimetry.* Trans Am Acad Ophthalmol Otolaryngol. 1960 Mar-Apr;64:112-27.

C.3.4.1 Subjects

Demographics	Inclusion Criteria	Exclusion Criteria
■ Number of Subjects: 27 ■ Age Range: 43-77 ■ Mean Age: 62	■ Diagnosed with glaucoma. – Severity mild to severe. – Within the angle configuration range Grade II to Grade IV[16] ■ Able to make study visits. ■ Provided consent. ■ Followed study instructions.	■ Could not fixate long enough to acquire images. ■ Active infection of the anterior segment of the eye.

C.3.4.2 Method

CIRRUS™ HD-OCT		Scans	Operator		
			A	B	C
	Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	HD Angle (Nasal)	3	3	3
		HD Angle (Temporal)	3	3	3

Visante Compare		Scans	Operator
	■ One operator used one Visante OCT instrument. ■ The first qualified Visante OCT image was compared to the first qualified CIRRUS 6000 image.	HD Angle (Nasal)	3
		HD Angle (Temporal)	3

C.3.4.3 Measurement Performance Results

Parameter	Mean	Repeatability			Reproducibility		
		SD	Limit	CV%	SD	Limit	CV%
Nasal							
TISA 500	0.158	0.017	0.048	10.764	0.022	0.061	13.786
TISA 750	0.281	0.023	0.065	8.305	0.034	0.095	12.085
AOD 500	0.461	0.053	0.148	11.496	0.066	0.185	14.332
AOD 750	0.621	0.054	0.151	8.699	0.075	0.211	12.162
SSA	39.186	2.772	7.762	7.074	3.638	10.188	9.285
AC Angle	38.282	2.517	7.048	6.575	3.433	9.612	8.968
Temporal							
TISA 500	0.161	0.020	0.057	12.685	0.026	0.072	16.033
TISA 750	0.270	0.028	0.078	10.319	0.032	0.090	11.950
AOD 500	0.475	0.064	0.179	13.415	0.075	0.209	15.699
AOD 750	0.576	0.062	0.173	10.750	0.072	0.202	12.534
SSA	38.440	3.478	9.738	9.048	4.197	11.751	10.918
AC Angle	37.209	2.868	8.031	7.708	3.630	10.164	9.756

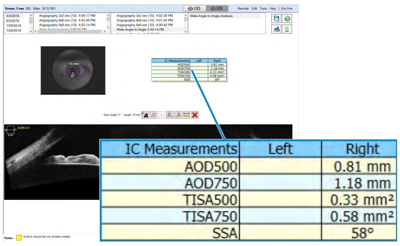
Table 152: Repeatability and Reproducibility of CIRRUS™ HD-OCT HD Angle Measurements

C.3.4.4 Comparison Results

CIRRUS		Visante		Difference		95 % CI		p value	95% LOA	
Mean	SD	Mean	SD	Mean	SD	Mean	SD		Mean	SD
Nasal										
37.677	17.408	39.974	19.074	-2.297	8.411	-5.625	1.030	0.168	-19.119	14.525
Temporal										
37.141	19.649	36.767	18.295	0.374	5.934	-1.974	2.722	0.746	-11.495	12.243

Table 153: Mean HD Angle Difference Between CIRRUS™ HD-OCT and Visante OCT

C.3.5 Wide Angle-to-Angle Measurements



A non-significant risk clinical study was conducted to:

- Determine the repeatability and reproducibility of the CIRRUS™ HD-OCT in measuring:
  - Anterior Chamber Angle (ACA)
  - Trabecular Iris Space Area (TISA)
  - Angle Opening Distance (AOD)
  - Scleral Spur Angle (SSA)
- Compare the corresponding measurements of CIRRUS™ HD-OCT and Visante OCT.

C.3.5.1 Subjects

Demographics	Inclusion Criteria	Exclusion Criteria
■ Number of Subjects: 26 ■ Age Range: 43-77 ■ Mean Age: 62	■ Diagnosed with glaucoma. – Severity mild to severe. – Within the angle configuration range Grade II to Grade IV[17] ■ Able to make study visits. ■ Provided consent. ■ Followed study instructions.	■ Could not fixate long enough to acquire images. ■ Active infection of the anterior segment of the eye.

C.3.5.2 Method

CIRRUS™ HD-OCT		Scans	Operator		
			A	B	C
	Each operator used a different instrument; same eye. Operators acquired and measured structures using angle tools.	Wide Angle to Angle	3	3	3
		Wide Angle to Angle	3	3	3

[17] Shaffer: *Primary glaucomas. Gonioscopy, ophthalmoscopy and perimetry.* Trans Am Acad Ophthalmol Otolaryngol. 1960 Mar-Apr;64:112-27.

Visante Compare		Scans	Operator
	■ One operator used one Visante OCT instrument. ■ The first qualified Visante OCT image was compared to the first qualified CIRRUS 6000 image.	Wide Angle to Angle Wide Angle to Angle	3 3

C.3.5.3 Measurement Performance Results

	Mean	Repeatability			Reproducibility		
		SD	Limit	CV%	SD	Limit	CV%
Nasal							
TISA 500	0.151	0.025	0.071	16.801	0.030	0.083	19.614
TISA 750	0.263	0.028	0.080	10.827	0.037	0.103	14.053
AOD 500	0.439	0.075	0.209	17.012	0.081	0.226	18.365
AOD 750	0.570	0.055	0.153	9.598	0.084	0.236	14.783
SSA	37.696	3.774	10.569	10.013	4.552	12.746	12.076
AC Angle	36.165	3.427	9.595	9.475	4.861	13.612	13.442
Temporal							
TISA 500	0.150	0.027	0.076	18.169	0.032	0.090	21.368
TISA 750	0.275	0.041	0.115	14.946	0.045	0.126	16.353
AOD 500	0.445	0.080	0.223	17.893	0.090	0.252	20.243
AOD 750	0.586	0.076	0.213	12.972	0.085	0.237	14.434
SSA	37.846	4.442	12.438	11.737	5.024	14.068	13.276
AC Angle	35.951	3.725	10.430	10.361	5.184	14.514	14.418

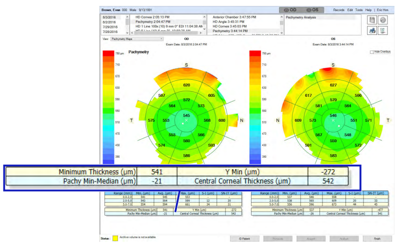
Table 154: Repeatability and Reproducibility of CIRRUS™ HD-OCT Wide Angle to Angle Measurements (Glaucoma)

C.3.5.4 Comparison Results

CIRRUS		Visante		Difference		95 % CI		p value	95% LOA	
Mean	SD	Mean	SD	Mean	SD	Mean	SD		Mean	SD
Nasal										
36.054	18.137	38.831	18.272	-2.777	5.665	-5.065	-0.488	0.019	-14.107	8.554
Temporal										
35.255	18.767	38.573	18.385	-3.318	6.493	-5.940	-0.695	0.015	-16.304	9.669

Table 155: Mean Wide Angle to Angle Difference Between CIRRUS™ HD-OCT and Visante OCT

C.3.6 Pachymetry Algorithm Accuracy



A non-significant risk clinical study was conducted to:

- Determine the repeatability and reproducibility of the CIRRUS™ HD-OCT in measuring:
- Compare the corresponding measurements of CIRRUS™ HD-OCT and Visante OCT.

Data Collection and Analysis

The data were acquired and analyzed by:

- 1 operator and 1 Visante OCT
- 3 operators and 3 CIRRUS 6000
- 3 operators and 3 CIRRUS 6000

The first qualified Visante OCT scan was used for comparison with the first qualified CIRRUS 6000 and CIRRUS 6000 scan from any of the three devices.

The operators who acquired the images also reviewed them. For the study measurement, operators used software tools (Angle tool; TISA tool) to identify structure measurements.

Instrument	Group	Pachymetry	Enhanced High Resolution Cornea
CIRRUS™ HD-OCT	Normal Corneas	✓	-
	Cornea Pathology	✓	-
	Post-LASIK	✓	-
Visante OCT	Normal Corneas	✓	-
	Cornea Pathology	✓	-
	Post-LASIK	✓	✓

Table 156: Pachymetry and Anterior Chamber Data Collected

C.3.6.1 Pachymetry Measurement Performance

	Mean	Repeatability			Reproducibility		
		SD	Limit	CV%	SD	Limit	CV%
Group 1: Normal Corneal							
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
Group 2: Corneal Pathology							
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
Group 3: Post-LASIK							
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

	Mean	Repeatability			Reproducibility		
		SD	Limit	CV%	SD	Limit	CV%
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

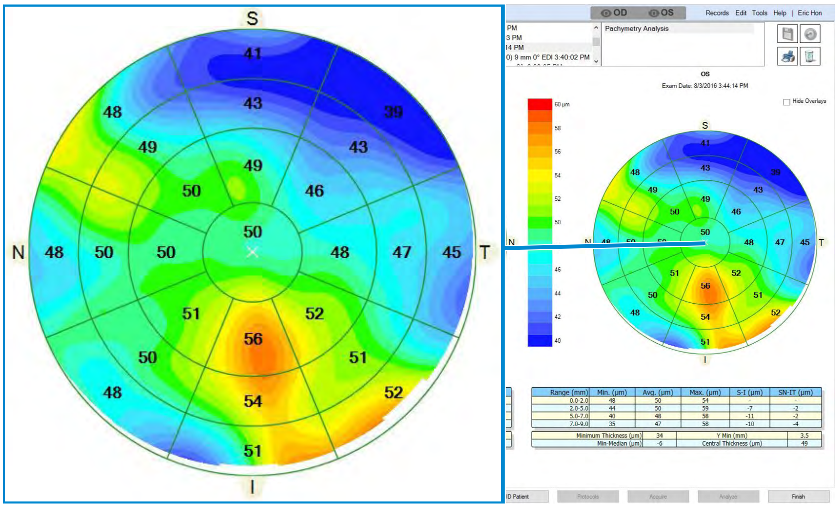
Table 157: Repeatability and Reproducibility of CIRRUS™ HD-OCT Pachymetry Measurements

C.3.6.1.1 Subjects

#	Ages	Inclusion Criteria	Exclusion Criteria
Normal Cornea 48	25-69	■ 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. ■ No history of: – leukemia – AIDS – uncontrolled systemic hypertension – dementia – multiple sclerosis	■ Subject unable to fixate well enough to acquire the images. ■ Active infection of the anterior segment. ■ Blindness, low vision or severely diseased eyes, ■ Prior surgery or a procedure involving or affecting the cornea in the study eye. ■ Corneal pathology, either inflammatory or non-inflammatory, in the study eye.
Corneal Pathology 49		Anterior segment pathology diagnosis, including: ■ keratoconus ■ pellucid marginal degeneration ■ corneal scarring ■ corneal degeneration ■ corneal dystrophy ■ corneal changes secondary to disease or surgery	■ Could not fixate long enough to acquire images. ■ Normal corneas in the study eye. ■ Prior LASIK surgery in the study eye.

Table 158: Pachymetry Algorithm Study Subjects

C.3.6.2 ETM Measurement Performance



A non-significant risk clinical study was conducted:

- To determine the repeatability and reproducibility of the CIRRUS™ HD-OCT in measuring epithelial thickness.
- Comparing calculated measurements to manual measurements.

This analysis used a subset of data collected in the Anterior Chamber Measurements [▷ 503]

C.3.6.2.1 Subjects

#	Ages	Inclusing Criteria	Exclusion Criteria
Normal Cornea 48	25-69	■ 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. ■ No history of: – leukemia – AIDS – uncontrolled systemic hyper-tension – dementia – multiple sclerosis	■ Subject unable to fixate well enough to acquire the images. ■ Active infection of the anterior segment. ■ Blindness, low vision or severely diseased eyes, ■ Prior surgery or a procedure involving or affecting the cornea in the study eye. ■ Corneal pathology, either inflam-matory or non-inflammatory, in the study eye.
Corneal Pathology 49		Anterior segment pathology diagnosis, including: ■ keratoconus ■ pellucid marginal degeneration ■ corneal scarring ■ corneal degeneration ■ corneal dystrophy ■ corneal changes secondary to disease or surgery	■ Could not fixate long enough to acquire images. ■ Normal corneas in the study eye. ■ Prior LASIK surgery in the study eye.

Table 159: Pachymetry Algorithm Study Subjects

C.3.6.2.2 Results (Group 1)

Sector	101	102	103	104	105	106	107	108	109	110	111
1	15	15	15	15	15	15	15	15	15	15	15
2	15	15	15	15	15	15	15	15	15	15	15
3	15	15	15	15	15	15	15	15	15	15	15
4	15	15	15	15	15	15	15	15	15	15	15
5	15	15	15	15	15	15	15	15	15	15	15
6	15	15	15	15	15	15	15	15	15	15	15
7	15	15	15	15	15	15	15	15	15	15	15
8	15	15	15	15	15	15	15	15	15	15	15
9	15	15	15	15	15	15	15	15	15	15	15
10	15	15	15	15	15	15	15	12	15	15	15
11	15	15	15	15	15	15	15	12	12	10	15
12	15	15	15	15	15	15	15	14	15	15	10
13	15	15	15	15	15	15	15	15	15	15	15
14	15	15	15	15	15	15	15	15	15	15	15
15	15	15	15	15	15	15	15	15	15	15	15
16	15	15	15	15	15	15	15	15	15	15	15
17	15	15	15	15	15	15	15	15	15	15	15
18	15	10	15	15	15	15	15	0	10	12	15
19	5	5	10	1	15	15	15	1	10	0	12

Sector	101	102	103	104	105	106	107	108	109	110	111
20	5	5	10	8	12	15	15	0	12	2	12
21	5	5	10	12	15	15	15	10	15	11	12
22	15	6	15	10	15	15	15	2	12	15	15
23	15	10	15	15	15	15	15	10	12	15	15
24	10	10	10	2	15	15	15	5	12	10	5
25	10	10	15	7	15	15	15	4	15	15	15

Table 160: ETM Measurements for Group 1

C.3.6.2.3 Results (Group 2)

Sector	201	202	203	204	206	207	208	209	210	211	212	213
1	15	15	15	15	15	15	15	15	15	15	15	15
2	15	15	15	15	15	15	15	15	15	15	15	15
3	15	15	15	15	15	15	15	15	15	15	15	15
4	15	15	15	15	15	15	15	15	15	15	15	15
5	15	15	15	15	15	15	15	15	15	15	15	15
6	15	15	15	15	15	15	15	15	15	15	15	15
7	15	15	15	15	15	15	15	15	15	15	15	15
8	15	15	15	15	15	15	15	15	15	15	15	15
9	15	15	15	15	15	15	15	15	15	15	15	15
10	15	15	15	8	15	15	15	15	15	15	15	15
11	15	6	15	5	15	15	15	15	15	11	15	15
12	10	10	10	7	15	15	15	15	15	15	15	15
13	6	15	15	13	10	15	15	15	15	13	15	15
14	15	13	15	15	15	15	15	15	15	15	15	15
15	15	15	15	15	15	15	15	15	15	15	15	15
16	15	15	15	15	15	15	15	15	15	15	15	15
17	15	15	15	15	15	15	15	15	15	15	15	15
18	7	10	10	7	10	7	15	15	15	15	15	15
19	10	0	5	5	10	10	5	10	10	8	13	15
20	3	3	2	5	5	11	12	5	3	10	10	15
21	4	4	10	6	5	12	9	5	15	5	10	15
22	15	10	13	11	10	15	15	5	15	1	15	15
23	10	15	15	15	10	15	15	4	15	15	15	15
24	12	0	15	14	15	15	15	8	15	4	15	15
25	14	4	15	13	15	15	15	10	15	9	15	15

Table 161: ETM Measurements for Group 2

C.3.6.2.4 Comparison Results: Deming Regression Analysis (Group 1)

Sector	Intercept (SE) µm	Int [95% CI] µm	Slope (SE)	Slope [95% CI]
1	4.69 (4.25)	[-3.65, 13.02]	0.88 (0.08)	[0.71, 1.04]
2	-9.71 (3.47)	[-16.52, -2.90]	1.16 (0.07)	[1.02, 1.29]
3	-3.13 (2.95)	[-8.91, 2.65]	1.02 (0.06)	[0.91, 1.13]
4	-11.09 (4.48)	[-19.87, -2.31]	1.18 (0.09)	[1.01, 1.35]
5	-5.11 (3.33)	[-11.64, 1.42]	1.05 (0.06)	[0.93, 1.18]
6	2.65 (3.00)	[-3.23, 8.54]	0.90 (0.06)	[0.79, 1.02]
7	0.18 (3.23)	[-6.15, 6.51]	0.96 (0.06)	[0.84, 1.09]
8	3.79 (3.35)	[-2.78, 10.35]	0.89 (0.07)	[0.76, 1.02]
9	-1.51 (3.04)	[-7.47, 4.45]	0.98 (0.06)	[0.87, 1.10]
10	1.34 (3.77)	[-6.06, 8.73]	0.92 (0.08)	[0.77, 1.08]
11	-27.06 (5.06)	[-36.98, -17.13}	1.47 (0.10)	[1.27, 1.66]
12	-12.70 (4.37)	[-21.26, -4.14]	1.19 (0.08)	[1.03, 1.36]
13	-11.56 (4.80)	[-20.96, -2.15]	1.17 (0.09)	[0.99, 1.36]
14	-6.34 (3.56)	[-13.31, 0.64]	1.08 (0.07)	[0.94, 1.22]
15	3.42 (3.57)	[-3.57, 10.41]	0.87 (0.07)	[0.73, 1.02]
16	-3.43 (2.88)	[-9.08, 2.22]	1.02 (0.06)	[0.91, 1.14]
17	-2.52 (3.10)	[-8.60, 3.55]	1.00 (0.06)	[0.88, 1.12]
18	-12.47 (3.22)	[-18.79, -6.15]	1.22 (0.07)	[1.09, 1.35]
19	3.18 (4.83)	[-6.30, 12.65]	0.90 (0.10)	[0.71, 1.09]
20	-5.80 (4.60)	[-14.82, 3.22]	1.07 (0.09)	[0.89, 1.25]
21	-10.72 (7.16)	[-24.75, 3.31]	1.17 (0.14)	[0.88, 1.45]
22	-1.92 (2.59)	[-6.99, 3.15]	1.00 (0.05)	[0.90, 1.10]
23	-6.47 (3.10)	[-12.55, -0.39]	1.07 (0.07)	[0.95, 1.20]
24	-5.77 (2.51)	[-10.70, -0.85]	1.06 (0.06)	[0.95, 1.17]
25	-4.91 (3.25)	[-11.27, 1.45]	1.07 (0.07)	[0.94, 1.20]
All	-5.92 (0.61)	[-7.11, -4.73]	1.07 (0.01)	[1.05, 1.10]

Table 162: Deming Regression Analysis Stratified by Sector (Group 1)

C.3.6.2.5 Comparison Results: Deming Regression Analysis (Group 2)

Sector	Intercept (SE) µm	Int [95% CI] µm	Slope (SE)	Slope [95% CI]
1	-2.46 (1.98)	[-6.35, 1.43]	1.03 (0.04)	[0.95, 1.10]
2	1.09 (1.16)	[-1.18, 3.35]	0.94 (0.02)	[0.90, 0.99]
3	-2.87 (1.45)	[-5.70, -0.03]	1.01 (0.03)	[0.95, 1.06]
4	-1.52 (1.28)	[-4.02, 0.99]	0.99 (0.02)	[0.94, 1.04]
5	-2.91 (1.21)	[-5.28, -0.55]	1.01 (0.02)	[0.97, 1.06]
6	-2.26 (1.71)	[-5.61, 1.10]	1.00 (0.03)	[0.94, 1.07]
7	-0.27 (1.03)	[-2.30, 1.76]	0.96 (0.02)	[0.92, 1.00]
8	-16.11 (3.49)	[-22.95, -9.26]	1.30 (0.07)	[1.16, 1.43]
9	-7.65 (2.67)	[-12.89, -2.41]	1.12 (0.05)	[1.02, 1.23]
10	-6.39 (1.53)	[-9.38, -3.40]	1.07 (0.03)	[1.01, 1.13]
11	-4.73 (1.60)	[-7.86, -1.60]	1.05 (0.03)	[0.98, 1.11]
12	-1.75 (2.00)	[-5.68, 2.18]	0.98 (0.04)	[0.90, 1.06]
13	1.11 (1.12)	[-1.08, 3.31]	0.93 (0.02)	[0.88, 0.97]
14	-8.46 (1.92)	[-12.21, -4.70]	1.11 (0.04)	[1.04, 1.18]
15	-0.60 (1.10)	[-2.75, 1.55]	0.96 (0.02)	[0.92, 1.00]
16	-9.25 (2.99)	[-15.10, -3.39]	1.14 (0.06)	[1.02, 1.26]
17	-8.33 (2.67)	[-13.57, -3.09]	1.12 (0.05)	[1.02, 1.22]
18	4.44 (1.43)	[1.65, 7.24]	0.86 (0.03)	[0.81, 0.92]
19	-2.91 (3.80)	[-10.37, 4.54]	1.02 (0.08)	[0.87, 1.17]
20	-1.25 (3.07)	[-7.27, 4.77]	0.98 (0.06)	[0.86, 1.11]
21	-1.05 (2.20	[-5.37, 3.26]	1.00 (0.05)	[0.91, 1.09]
22	-2.11 (2.38)	[-6.76, 2.55]	1.00 (0.05)	[0.90, 1.09]
23	3.59 (1.32)	[1.00, 6.18]	0.87 (0.03)	[0.81, 0.93]
24	-0.27 (1.86)	[-3.91, 3.37]	0.96 (0.04)	[0.88, 1.04]
25	1.91 (1.65)	[-1.32, 5.14]	0.92 (0.03)	[0.85, 0.99]
All	-2.54 (0.36)	[-3.25, -1.83]	1.01 (0.01)	[0.99, 1.02]

Table 163: Deming Regression Analysis Stratified by Sector (Group 2)

C.3.6.2.6 Comparison Results: Deming Regression Analysis (Combined)

Group	Intercept (SE) µm	Int [95% CI] µm	Slope (SE)	Slope [95% CI]
Normal	-5.92 (0.61)	[-7.11, -4.73]	1.07 (0.01)	[1.05, 1.10]
Pathology	-2.54 (0.36)	[-3.25, -1.83]	1.01 (0.01)	[0.99, 1.02]
All	-3.25 (0.30)	[-3.83, -2.66]	1.02 (0.01)	[1.01, 1.03]

Table 164: Deming Regression Analysis Stratified Combined (Group 1 & Group 2)

C.3.6.2.7 Comparison Results: Bland Altman (Group 1)

Sector	Mean Difference		Difference		LOA (Lower)				LOA (Upper)			
	Mean	SD	Min	Max	Estimate SE		95% CI		Estimate SE		95% CI	
1	-1.59	1.77	-7.4,	2.8 -	-5.05	0.24,	-5.5,	-4.6	1.88	0.24,	1.4,	2.3
2	-1.83	1.62	-5.9	2.2	-5.00	0.22	-5.4	-4.6	1.33	0.22	0.9	1.8
3	-1.94	1.71	-6.5	1.9	-5.29	0.23	-5.7	-4.8	1.41	0.23	1.0	1.9
4	-1.70	1.94	-7.3	2.3	-5.50	0.26	-6.0	-5.0	2.09	0.26	1.6	2.6
5	-2.49	1.79	-7.1	1.4	-6.00	0.24	-6.5	-5.5	1.03	0.24	0.6	1.5
6	-2.45	1.81	-7.7	2.0	-6.00	0.24	-6.5	-5.5	1.11	0.24	0.6	1.6
7	-1.64	1.75	-6.3	3.1	-5.07	0.23	-5.5	-4.6	1.79	0.23	1.3	2.3
8	-1.80	1.81	-6.3	1.8	-5.34	0.24	-5.8	-4.9	1.75	0.24	1.3	2.2
9	-2.29	1.80	-7.8	1.8	-5.81	0.24	-6.3	-5.3	1.23	0.24	0.8	1.7
10	-2.38	2.28	-9.8	2.7	-6.86	0.31	-7.5	-6.3	2.09	0.31	1.5	2.7
11	-3.10	2.80	-15.7	3.8	-8.58	0.39	-9.3	-7.8	2.38	0.39	1.6	3.1
12	-2.73	2.59	-10.1	4.0	-7.80	0.35	-8.5	-7.1	2.34	0.35	1.7	3.0
13	-2.70	2.53	-12.3	4.2	-7.66	0.34	-8.3	-7.0	2.25	0.34	1.6	2.9
14	-2.52	2.54	-7.9	3.0	-7.50	0.34	-8.2	-6.8	2.46	0.34	1.8	3.1
15	-2.70	2.33	-8.8	2.6	-7.26	0.31	-7.9	-6.6	1.86	0.31	1.2	2.5
16	-2.26	1.92	-8.3	1.4	-6.02	0.26	-6.5	-5.5	1.50	0.26	1.0	2.0
17	-2.53	2.34	-9.4	5.8	-7.12	0.31	-7.7	-6.5	2.06	0.31	1.4	2.7
18	-2.10	2.29	-8.3	4.6	-6.58	0.33	-7.2	-5.9	2.39	0.33	1.7	3.1
19	-1.87	2.01	-6.1	3.5	-5.82	0.37	-6.5	-5.1	2.08	0.37	1.3	2.8
20	-2.31	2.59	-9.0	4.0	-7.38	0.45	-8.3	-6.5	2.77	0.45	1.9	3.7
21	-2.55	2.84	-13.6	5.9	-8.12	0.44	-9.0	-7.3	3.02	0.44	2.2	3.9
22	-1.91	2.28	-8.2	3.8	-6.38	0.34	-7.0	-5.7	2.56	0.34	1.9	3.2
23	-2.93	2.22	-10.0	3.9	-7.27	0.31	-7.9	-6.7	1.41	0.31	0.8	2.0
24	-3.04	2.20	-9.3	2.7	-7.34	0.34	-8.0	-6.7	1.26	0.34	0.6	1.9
25	-1.67	2.36	-7.6	4.5	-6.30	0.35	-7.0	-5.6	2.96	0.35	2.3	3.6
All	-2.28	2.21	-15.7	5.9	-6.62	0.06	-6.7	-6.5	2.06	0.06	1.9	2.2

Table 165: Bland Altman Limits of Agreement by Sector (Group 1)

C.3.6.2.8 Comparison Results: Bland Altman (Group 2)

Sector	Mean Difference		Difference		LOA (Lower)				LOA (Upper)			
	Mean	SD	Min	Max	Estimate	SE	95% CI		Estimate	SE	95% CI	
1	-1.17	2.98	-7.8	14.7	-7.00	0.38	-7.8	-6.3	4.67	0.38	3.9	5.4
2	-1.86	2.15	-6.9	11.6	-6.08	0.27	-6.6	-5.5	2.36	0.27	1.8	2.9
3	-2.48	2.23	-8.1	5.2	-6.84	0.28	-7.4	-6.3	1.89	0.28	1.3	2.4
4	-1.93	1.96	-8.2	2.0	-5.77	0.25	-6.3	-5.3	1.90	0.25	1.4	2.4
5	-2.24	1.83	-7.5	2.9	-5.83	0.23	-6.3	-5.4	1.34	0.23	0.9	1.8
6	-2.04	2.21	-7.1	6.4	-6.37	0.28	-6.9	-5.8	2.30	0.28	1.7	2.9
7	-2.46	1.78	-6.9	2.5	-5.94	0.23	-6.4	-5.5	1.03	0.23	0.6	1.5
8	-1.22	3.55	-6.4	17.1	-8.19	0.45	-9.1	-7.3	5.75	0.45	4.9	6.6
9	-1.50	3.40	-6.9	14.7	0.43	-9.0	-7.3	5.16	0.43	4.3	-8.16	6.0
10	-2.94	2.36	-9.4	3.6	-7.58	0.31	-8.2	-7.0	1.69	0.31	1.1	2.3
11	-2.42	2.38	-9.1	6.7	-7.08	0.32	-7.7	-6.4	2.24	0.32	1.6	2.9
12	-2.72	2.61	-9.2	8.2	-7.84	0.36	-8.6	-7.1	2.40	0.36	1.7	3.1
13	-2.65	2.01	-7.8	1.8	-6.59	0.27	-7.1	-6.1	1.30	0.27	0.8	1.8
14	-2.92	2.68	-11.1	7.2	-8.17	0.34	-8.8	-7.5	2.34	0.34	1.7	3.0
15	-2.50	2.20	-8.7	3.3	-6.81	0.28	-7.4	-6.3	1.81	0.28	1.3	2.4
16	-2.65	3.76	-8.9	14.0	-10.02	0.48	-11.0	-9.1	4.72	0.48	3.8	5.7
17	-2.35	3.59	-15.5	14.7	-9.39	0.46	-10.3	-8.5	4.69	0.46	3.8	5.6
18	-2.09	2.72	-16.7	4.1	-7.42	0.40	-8.2	-6.6	3.24	0.40	2.4	4.0
19	-2.00	3.86	-18.0	5.7	-9.56	0.66	-10.9	-8.3	5.56	0.66	4.3	6.9
20	-2.01	3.45	-15.5	7.0	-8.77	0.65	-10.1	-7.5	4.74	0.65	3.5	6.0
21	-1.10	2.74	-7.0	5.5	-6.47	0.47	-7.4	-5.5	4.27	0.47	3.3	5.2
22	-2.26	3.68	-14.1	8.3	-9.48	0.53	-10.5	-8.4	4.96	0.53	3.9	6.0
23	-2.19	2.35	-7.4	4.2	-6.80	0.32	-7.4	-6.2	2.41	0.32	1.8	3.0
24	-2.24	2.38	-8.3	8.4	-6.91	0.34	-7.6	-6.2	2.44	0.34	1.8	3.1
25	-1.74	2.61	-9.6	4.3	-6.87	0.36	-7.6	-6.2	3.38	0.36	2.7	4.1
All	-2.17	2.77	-18.0	17.1	-7.60	0.07	-7.7	-7.4	3.26	0.07	3.1	3.4

Table 166: Bland Altman Limits of Agreement by Sector (Group 2)

C.3.6.2.9 Comparison Results: Bland Altman (Combined)

Sector	Mean Difference		Difference		LOA (Lower)				LOA (Upper)			
	Mean	SD	Min	Max	Estimate	SE	95% CI		Estimate	SE	95% CI	
All	-2.22	2.52	-18.0	17.1	-7.15	0.05	-7.2	-7.1	2.71	0.05	2.6	2.8

Table 167: Bland Altman Limits of Agreement by Sector (Groups 1 and 2)

Glossary

AngioPlex Metrix

tools in angiography analysis "Superficial" preset that allow you to observe and measure vessel density and capillary perfusion.

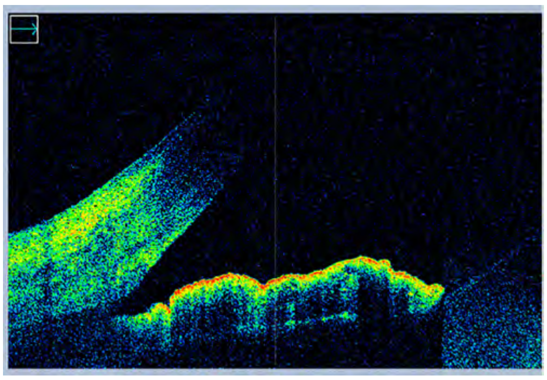
anterior segment

the front third of the eye that includes the structures in front of the vitreous humour: the cornea, iris, ciliary body, and lens.

Certificate Serial Number

a unique SERIAL NUMBER used in the license registration process. CZM includes a Software Product Certificate with software that requires license registration.

corneoscleral junction



the margin of the cornea overlapped by the sclera

CSMT

Central Subfield Measurement Thickness

CV

Coefficient of variation = SD ÷ Mean

DICOM

Digital Imaging and Communications in Medicine. A standard for data management, including a file format specification and a network communication protocol.

EDI

Enhanced Depth Imaging

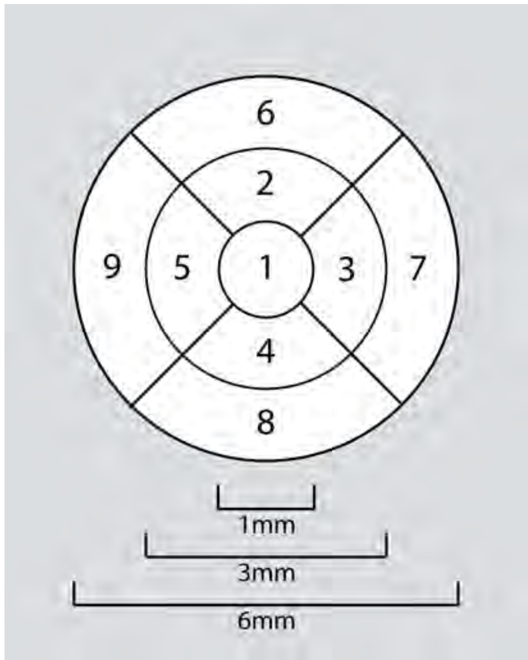
EMR

Any electronic medical records system, including FORUM, whether DICOM-compatible or not

ERM

Epiretinal membrane - a fibrocellular tissue found on the inner surface of the retina.

ETDRS grid

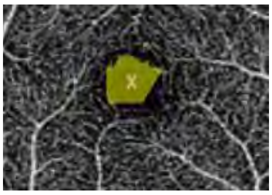


macular grid used to measure area and proximity of macular edema to the macular center (fovea) and aids in evaluating the changes in vision in patients with diabetic retinopathy.

FastTrac

FastTrac monitors retina movement and automatically compensates for detected motion

FAZ



Foveal Avascular Zone - a region within the fovea devoid of retinal vessels. The FAZ center is considered the macula center and the fixation point.

FORUM

A software product for managing, archiving, and viewing patient data, images, and reports from computerized diagnostic instruments or documentation systems.

ILM

The internal limiting membrane forms the innermost boundary of the retina between the retina and the vitreous body, formed by astrocytes and the end feet of Müller cells.

IOD

Information Object Definitions

IOP

Intraocular Pressure

IPL

Inner Plexiform Layer: an area of the retina that is made up of a dense reticulum of fibrils formed by interlaced dendrites of retinal ganglion cells and cells of the inner nuclear layer.

iridocorneal angle

the acute angle between the iris and the cornea at the periphery of the anterior chamber of the eye.

keratoconus

a progressive eye disease in which the normally round cornea thins and begins to bulge into a cone-like shape. This cone shape deflects light as it enters the eye on its way to the light-sensitive retina, causing distorted vision.

NAS

Network Attached Storage: a device for allowing multiple users remote access to large amounts of data.

Node ID

an internal alphanumeric identifier unique to each CZM instrument computer.

OP

Ophthalmic Photography

OPT

Ophthalmic Tomography

OPT IOD

DICOM standard format for archiving and transferring OCT images as black and white images

Optic Nerve Head (ONH)

The circular area in the back of the inside of the eye where the optic nerve connects to the retina.

Retinal Nerve Fiber Layer

RNFL

Review Station

A separate networked computer, laptop or PC (often in the doctor's office) with ZEISS instrument software installed to access patient data and images from the instrument for analysis.

RPC

The radial peripapillary capillaries of the retina are the most superficial of the capillary layers. They are limited to the area around the optic disc in the nerve fiber layer, especially along the upper and lower temporal vessels.

RPE

Retinal Pigment Epithelium: the pigmented cell layer just outside the neurosensory retina that nourishes retinal visual cells, and is firmly attached to the underlying choroid and overlying retinal visual cells.

scleral spurs

a protrusion of the sclera into the anterior chamber; the origin of the longitudinal fibres of the ciliary muscle attached anteriorly to the trabecular meshwork.

SD

Standard deviation

SD-OCT

Special Domain Optical Coherence Tomography: a form of non-invasive, low-coherence interferometry that produces high-resolution tomograms without contacting the eye

VMT

Vitreomacular traction - a disorder of the vitreo-retinal interface.

VRI

Vitreo Retinal Interface - a complex composite structure connecting the vitreous cortex and the inner retina.

XML

eXtensible Markup Language is a self-descriptive markup language designed to store and transport data

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