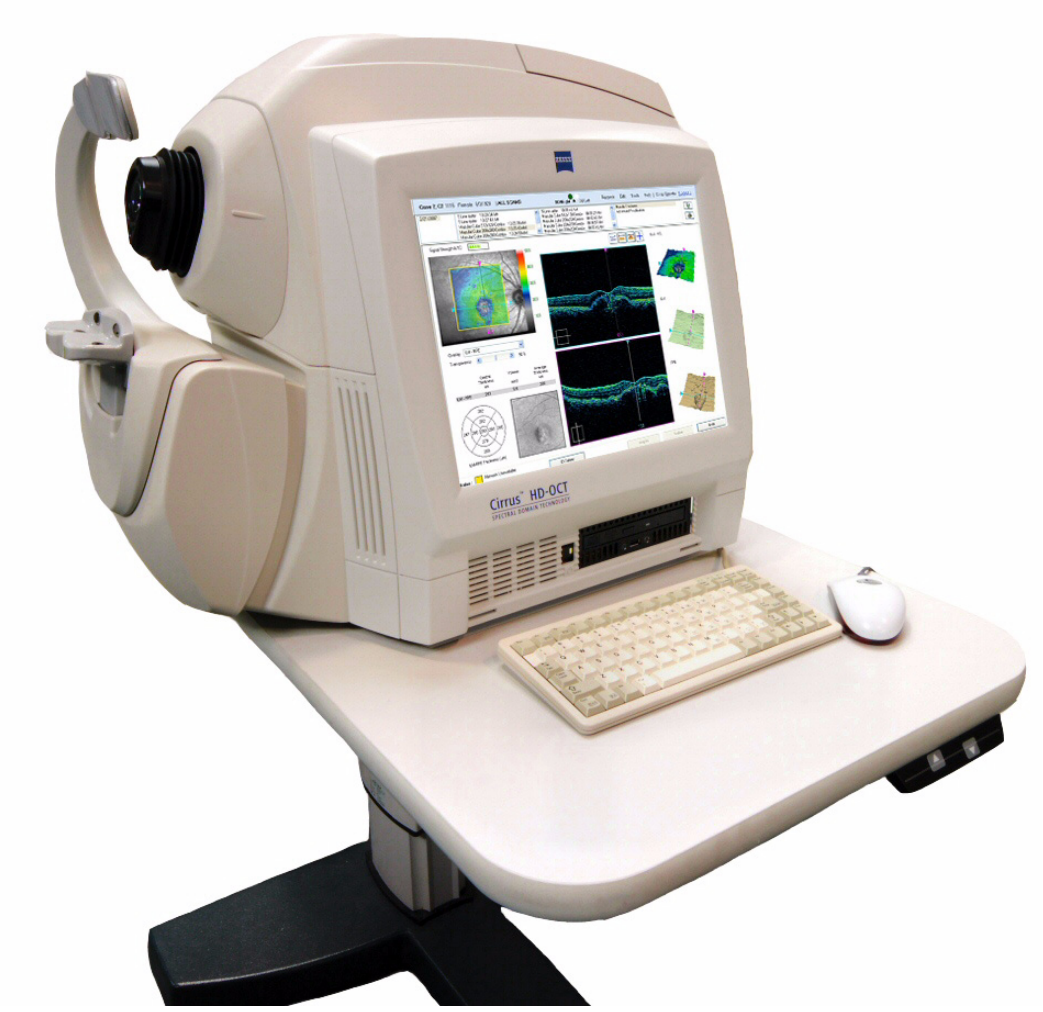
Cirrus HD-OCT

Models 400, 4000



User Manual

ZEISS

Copyright

Trademarks

Cirrus HD-OCT and Stratus OCT are either registered trademarks or trademarks of Carl Zeiss Meditec, Inc. in the United States and/or other countries.

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All other trademarks used in this document are the property of their respective owners.

Patents

Model 4000 — This product is protected by the following US Patents and their foreign equivalents: 6,758,564; 7,284,859; 7,301,644; 7,330,270; 7,365,856; 7,401,921; 7,433,046; 7,456,957; 7,505,142.

This product is also protected by German Patent DE 43 09 056.

Model 400 — This product is protected by the following US Patents and their foreign equivalents: 7,301,644; 7,330,270; 7,365,856; 7,401,921; 7,433,046; 7,456,957; 7,505,142.

This product is also protected by German Patent DE 43 09 056.

Contents

(1) Introduction

The ZEISS Cirrus™ HD-OCT Model 400 and Model 4000 (Cirrus HD-OCT or Cirrus) enable examination of the posterior and anterior of the eye at an extremely fine spatial scale, without surgical biopsy or even any contact with the eye. The Cirrus HD-OCT builds on and refines the retinal imaging technology first introduced with the ZEISS Stratus OCT™. HD-OCT stands for "high-definition optical coherence tomography."

Employing the advanced imaging technology of spectral domain optical coherence tomography, Cirrus HD-OCT acquires OCT data about 70 times faster (27,000 vs. 400 A-scans per second) and with better resolution (5 µm vs. ~10 µm axial resolution in tissue), compared to first-generation OCT technology. Cirrus acquires whole cubes of OCT image data, composed of hundreds of line scans, in about the same time as Stratus acquires a six-line scan. You can view these data cubes in three planes, or through three dimensions, giving you access to an extensive amount of retinal image data in one scan.

Intended Use

The Cirrus HD-OCT with Retinal Nerve Fiber Layer and Macular Normative Databases is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures.

Indications for Use

The Cirrus HD-OCT is a non-contact, high resolution tomographic and biomicroscopic imaging device. It is indicated for in-vivo viewing, axial cross-sectional, and three-dimensional imaging and measurement of anterior and posterior ocular structures, including cornea, retina, retinal nerve fiber layer, macula, and optic disc. The Cirrus HD-OCT with Retinal Nerve Fiber Layer (RNFL) and Macular Normative Databases is a quantitative tool for the comparison of retinal nerve fiber layer and the macula in the human retina to a database of known normal subjects. It is intended for use as a diagnostic device to aid in the detection and management of ocular diseases including, but not limited to, macular holes, cystoid macular edema, diabetic retinopathy, age-related macular degeneration, and glaucoma.

Note: The Cirrus HD-OCT is not intended to be used as the sole diagnostic for disease.

Purpose of This User Manual

Carl Zeiss Meditec designed this User Manual to serve as a training, usage and reference guide for proper scanning and operation. We assume that users are clinicians or technicians with professional training or experience in the use of ophthalmic imaging equipment, and in diagnostic interpretation of the images generated. While we offer training in the use of the Cirrus HD-OCT, we do not offer instruction in diagnostic interpretation of the images generated. This manual does not attempt to do so.

Organization of the Manual

This introductory chapter provides a system description, installation and safety information. Chapters (2) through (4) are organized according to the normal sequence of operation of the Cirrus HD-OCT, followed by data management and data transfer functions in Chapters (6) through (8), as follows:

- Operational Overview, explained in Chapter (2).
- Acquire Scans, explained in Chapter (3).
- Analyze Scans: Macula, explained in Chapter (4).
- Data Management, explained in Chapter (6).
- Archive and Retrieve, explained in Chapter (7).
- Export and Import, explained in Chapter (8).

Chapters (9), (10) and (11) cover Routine Maintenance, instrument Specifications and Legal Notices, respectively. Users who wish to use the Cirrus HD-OCT in a network environment should see Appendix (A) Networking Guidelines and Appendix (B) Using a Network Storage Device. Appendix (C) Printer Configuration provides instructions to use a printer in the USB or network configuration. Appendix (D) RNFL and Macula Normative Databases discusses the extensive collection of normative data. Appendix (E) Study: Retinal Segmentation Algorithms in Cirrus HD-OCT describes the algorithms that help to measure retinal thicknesses. The manual includes an Index.

Text Conventions

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

Access Menu Options

To access the options offered through each menu, click on the menu headings. Then click on an option to select it. Click outside all menu options to make the options disappear.

- Some menus are fields tagged with a down-arrow (drop-down lists). To access these menu options, click on the down-arrow.
- Grayed-out menu options or buttons are not available.

Electronic User Manual Access

The Cirrus HD-OCT User Manual is provided with the instrument electronically in three ways:

1. On-Line Manual: Select On-Line Manual from the Help (click Help > On-Line Manual) menu to access the user manual information through the Cirrus software.
2. On CD: Included in the instrument accessory kit. You can view the user manual PDF either using the Cirrus system computer, or any other computer.
3. On the computer desktop: To access the computer desktop without exiting the system software:
   A. Press Ctrl+Esc on the keyboard. Select My Computer.
   B. Open the pull down menu and scroll up to highlight Desktop.
   C. Double-click on the folder User Manuals.
   D. Double-click on the Cirrus HD-OCT User Manual.

☞ **Note: Once opened, you can switch between the user manual and the Cirrus application by pressing Alt+Tab.**

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). SD-OCT is a form of non-invasive, low-coherence interferometry that produces high-resolution tomograms without contacting the eye.

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 at 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. Eliminating the necessity of moving a mechanical reference arm makes it possible to acquire OCT image data about 70 times faster than conventional (time domain) OCT. The vast increase in scan speed makes it possible for Cirrus HD-OCT to acquire three-dimensional data sets, or entire cubes of data in about the same time (depending on the selected scan type) as conventional OCT. In spite of the increased speed of scanning, spectral detection of the interference signal provides superior resolution.

The two models of Cirrus HD-OCT employ different technologies to provide an image of the retinal area addressed by the scan. Model 4000 instruments include a line scanning ophthalmoscope (LSO). Model 400 instruments use the OCT beam to create the retinal image. Both models include a CCD video camera to monitor the exterior eye and assist with scan alignment.

Cirrus HD-OCT System Hardware

With the exception of the keyboard, mouse and printer, the Cirrus HD-OCT integrates all hardware components in a unit, which includes the scan acquisition optics, the interferometer and spectrometer, the system computer and video monitor. Carl Zeiss Meditec offers an optional wheelchair accessible motorized power table (shown below), which accommodates elevation adjustment to each patient's height. The illustration below labels hardware elements. System specifications are in Chapter (10).

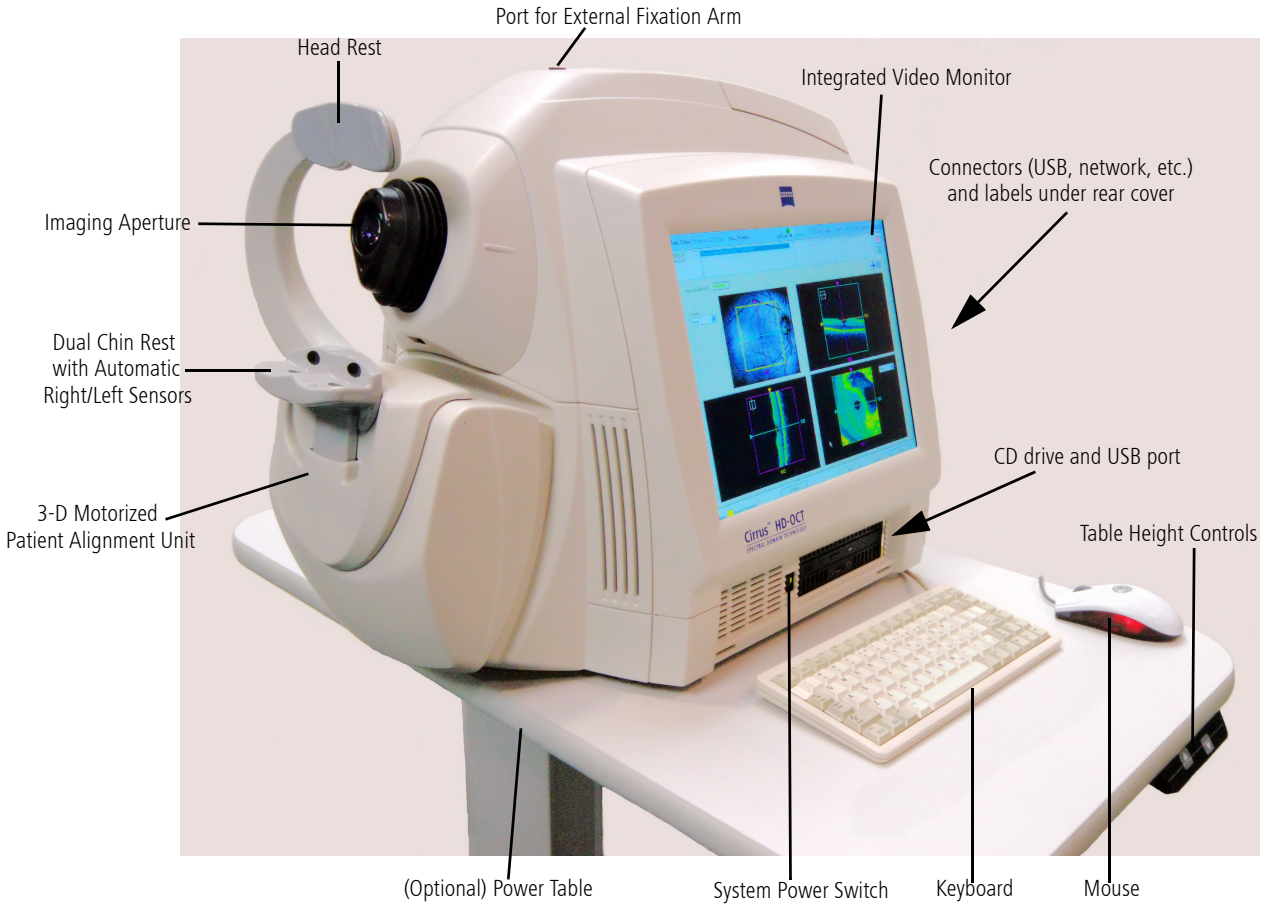


Figure 1-1 Cirrus HD-OCT system hardware

Software

Carl Zeiss Meditec pre-installs all software necessary to operate the Cirrus HD-OCT. Software updates with installation instructions may be provided on CD or on our website.

Data Storage

The system computer stores data locally. Archival storage of Cirrus HD-OCT exam data is designed to occur in a network environment. We recommend archiving data to a network file server or a network attached storage device (also known as a network hard drive), which operates just as a network file server. For more information, see Chapter (7) Archive and Retrieve, (A) Networking Guidelines, and (B) Using a Network Storage Device.

WARNING: User Changes to Software or Hardware

The Cirrus HD-OCT is a medical device. The software and hardware have been 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. Unauthorized modification of Cirrus HD-OCT software or hardware (including peripherals) can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data. Unauthorized modification also voids the instrument warranty.

Approved Software

Please refer to the Cirrus HD-OCT Technical Support section of our website (www.meditec.zeiss.com/cirrus) for the current list of approved software.

☞ Note: Carl Zeiss Meditec does not provide technical support for the use of third party software.

Instrument Installation

Only an authorized Carl Zeiss Meditec service representative should install the Cirrus HD-OCT. We do not provide assembly and installation instructions. In consultation with the buyer, Carl Zeiss Meditec schedules a free on-site installation appointment to coincide with delivery. System installation and initial calibration require approximately one business day.

☞ Note: Only trained CZM personnel may perform calibration. The Performance Verification Check (see page 2-15) is not calibration.

Care in Handling

Use extreme care when handling and transporting the Cirrus HD-OCT shipping boxes. The instrument contains fragile optics that require highly precise alignment.

Installation Requirements

- The instrument with the optional power table requires an area at least 6' x 8' (1.80 m by 2.4 m) for installation and patient comfort during use.
- You must install it in a ventilated room and must not block the ventilated instrument covers that allow heat to dissipate from the device. For more information on acceptable operating conditions, see Specifications on page 10-1.

WARNING: Failure to provide proper ventilation could potentially lead to heat buildup, which could cause component failure and/or fire.

- The Cirrus HD-OCT should operate on a dedicated power outlet. Based on your specification, we configure your Cirrus HD-OCT at the factory to use either 100/120V or 220/240V line voltage.

- When using the optional power table, the instrument must be powered through the table, as described in the Power Table User Instructions.

Tips to Avoid Damage

☞ **Note: Users are not authorized to dismantle (except to remove the rear cover) or modify the Cirrus HD-OCT hardware. To transport the instrument outside the office, you must consult with a Carl Zeiss Meditec service technician. Failure to do so voids all warranties offered with the Cirrus HD-OCT.**

- **Only Carl Zeiss Meditec authorized technicians should disassemble or service this instrument.** In the case of malfunction, error messages or operational problems, call Carl Zeiss Meditec customer service: In the U.S., call 800-341-6968. Outside the U.S., contact your local CZM distributor.
- This instrument has no special measures to protect against harmful ingress of water or other liquids (classified IPXO—ordinary equipment). Do not place containers of liquid on or near the instrument, and do not use aerosols on or near it.
    - The optional power table has an IP21 classification, which provides the specified degree of protection against harmful ingress of water. Still, do not place containers of liquid on or near the table where spillage onto the instrument or table could occur, resulting in a safety hazard and/or damage to the instrument or the table.
- In case of a non-medical emergency related to the instrument, unplug the power cord from the wall outlet and call for service immediately.
- To prevent heat buildup that could damage the instrument, you must install it in a ventilated room and must not block the ventilated instrument covers that allow heat to dissipate from the device. For more information on acceptable operating conditions, see Specifications on page 10-1.
- With the exception of the main power fuses, there are no user-replaceable parts in the instrument. For the replacement of any component, accessory, or peripheral, except fuses, call Carl Zeiss Meditec customer service: In the U.S., call 800-341-6968. Outside the U.S., contact your local CZM distributor.
- Although this instrument is designed for continuous operation, it should be turned off when not in use for an extended period.

Embedded Windows License

Each Cirrus HD-OCT instrument is issued with an embedded Windows license located under the rear cover.

Product Compliance

CE 0297 Complies with 93/42/EEC Medical Device Directive.

Complies with US and Canadian medical electrical system safety requirements.

Product Safety

- IEC 60601-1
- UL 60601-1
- CSA C22.2 No. 601.1-M90

This instrument is classified as follows:

- Class I Equipment – Protection against electrical shock.
- Type B – Degree of protection against electric shock of applied part (chin and forehead rests).
- Ordinary Equipment (IPX0)– Degree of protection against ingress of liquids (none).
- Continuous Operation – Mode of operation.

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

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

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

WARNING: To maintain patient safety, peripheral devices, such as printers, must be placed at least 1.5 meters (4.9 feet) away from the patient, such that the patient cannot touch a peripheral device with any part of his or her body while being examined. In addition, the instrument operator must not attempt to touch the patient and a peripheral device at the same time while examining the patient.

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

WARNING: 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 Carl Zeiss Meditec. Such actions could result in failure of the table height adjustment mechanism, instability of the table, tipping and damage to the instrument, and injury to operator and patient.

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

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

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

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

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

Caution: Federal law restricts this device to sale by or on the order of a Physician or Practitioner.

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

Applicable Phototoxicity Statements (FDA CDRH Ophthalmoscope Guidance #71): Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged. While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the exposure time for the patient's eye be limited to the minimum time that is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure with the same instrument or any other ophthalmic instrument using a visible light source during the previous 24 hours. This will apply particularly if the eye has been exposed to retinal photography. 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.

Electromagnetic Compatibility (EMC)

EN 60601-1-2:2001 compliant

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

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

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

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

Guidance and manufacturer's declaration - electromagnetic emissions		
The Cirrus HD-OCT is intended for use in the electromagnetic environment specified below. The customer or user of the Cirrus HD-OCT should assure that it is used in such an environment		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Cirrus HD-OCT uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Cirrus HD-OCT is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Cirrus HD-OCT is intended for use in the electromagnetic environment specified below. The customer or user of the Cirrus HD-OCT should assure that it is used in such an environment			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cirrus HD-OCT requires continued operation during power mains interruptions, it is recommended that the Cirrus HD-OCT be powered from an uninterruptible source.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

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

Recommended separation distance

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

$d = 2.33\sqrt{P}$ 800 MHz to 2,5 GHz

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

Recommended separation distances between portable and mobile RF communications equipment and the Cirrus HD-OCT

The Cirrus HD-OCT is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cirrus HD-OCT can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cirrus HD-OCT as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.17 \sqrt{P}$	$d = 1.17 \sqrt{P}$	$d = 2.33 \sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.370	0.370	0.737
1	1.170	1.170	2.330
10	3.700	3.700	7.368
100	11.700	11.700	23.300

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Accessory Equipment

WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g., IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

Symbols and Labels

Caution, consult accompanying documents. Note: There are important operating and maintenance instructions found in the manual.

Presence of electrical shock hazard. Note: Indicates risk of electrical shock due to the presence of uninsulated high voltage inside the instrument. Do not remove the instrument cover or parts.

Fuse

Type B applied parts

Manufacturer

Authorized European Community Representative

Serial number

Catalog number / part number

Model number

European Conformity

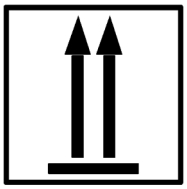
Protective Packing Symbols

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

Handling Requirements

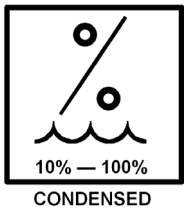
Fragile, Handle with Care

Keep Dry

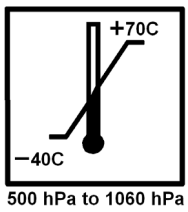


This end up

Transport and Storage Conditions



Relative Humidity (10% to 100%, including condensation)



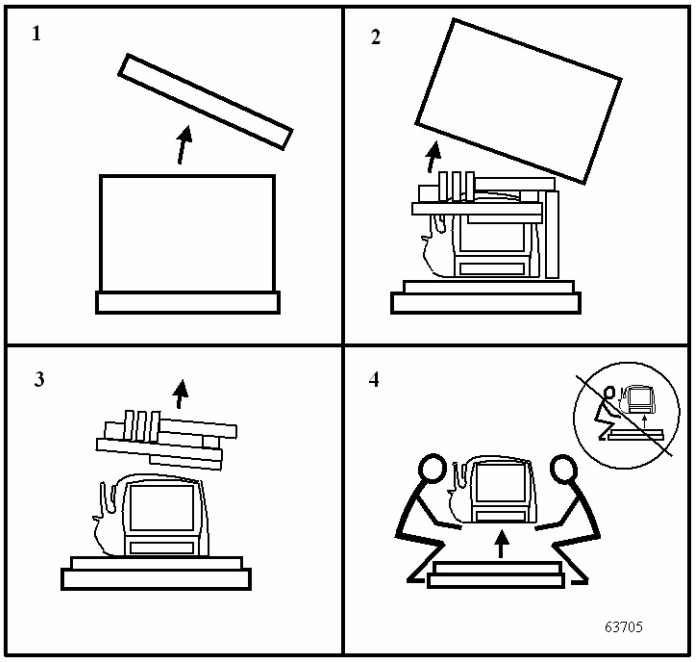
Temperature (-40 to +70 deg. C)

Atmospheric Pressure Limits (500 hPa to 1060 hPa)

☞ Note: The instrument is not intended to be transported outside its original package.

Unpacking Instructions Symbol Sheet

The following symbol sheet serves as instructions to safely unpack the instrument from its shipping box.



CAUTION: To prevent injury or damage to the instrument, observe especially instruction 4 at lower right, for two people—not one—to lift the instrument out of the box, bending the knees and keeping the back straight.

Note: When the Cirrus HD-OCT is being unpacked, save the original shipping materials for possible future use. To prevent damage, the instrument must be transported in its original shipping package.

Product Labels and Serial Number Location

Just above the rear cover is the product label:

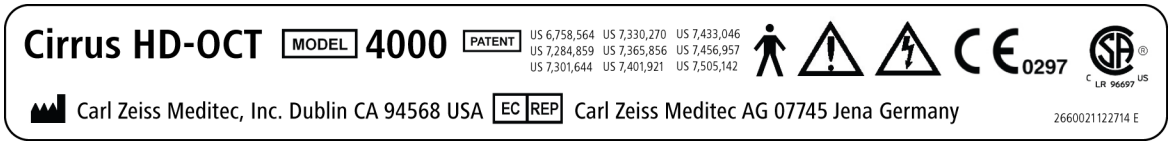


Figure 1-2 Product label, Model 4000

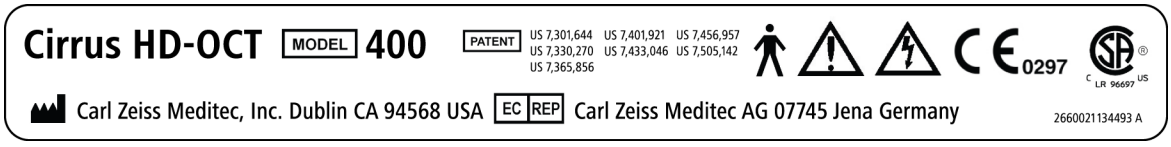


Figure 1-3 Product label, Model 400

Depress both snaps to remove rear cover.

Figure 1-4 Removing rear cover

To gain access to the label showing the serial number, you must remove the rear cover: To remove the rear cover, depress the two snaps at its top edge.

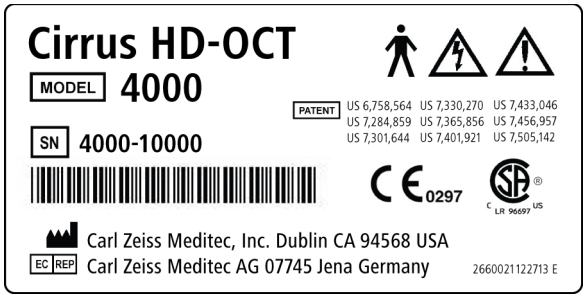


Figure 1-5 Product label with serial number, Model 4000

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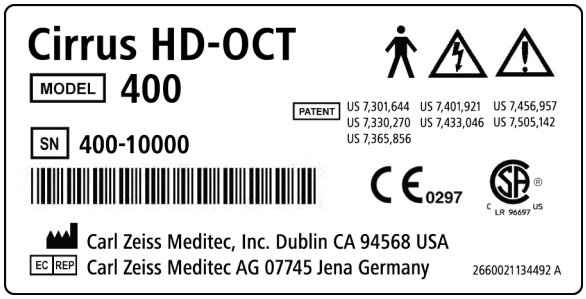
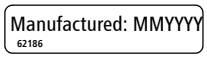
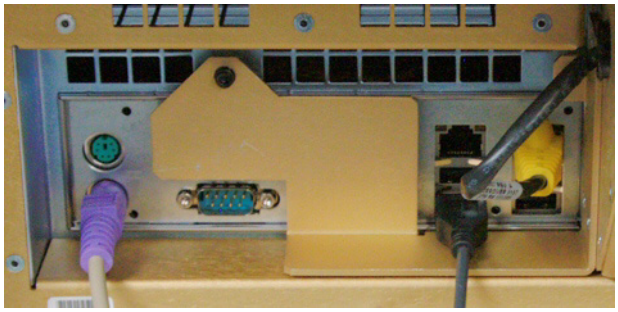


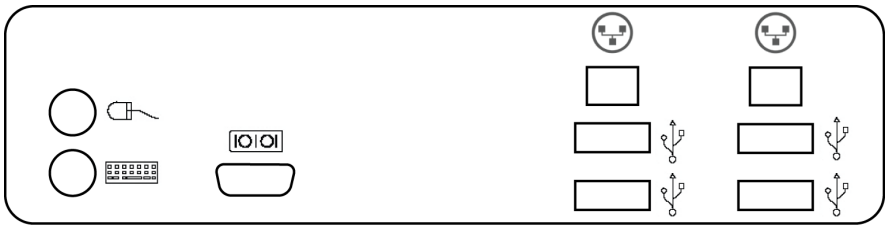
Figure 1-6 Product label with serial number, Model 400

A small label indicates the month and year of manufacture in MMYYYY format (for example, 042007): 

Rear Connectors Illustrated

Under the rear cover are connectors with inscriptions stamped in the nearby metal that illustrate the types of connectors found on the rear of the device, as shown below.





Mouse		USB (4)	
Keyboard		Ethernet (2)	
Serial Port		Note that the Ethernet port on the right is not available for customer use; it is a dedicated Cirrus connector port.	

Figure 1-7 Rear connectors and explanatory diagram

Instrument Disposition

When it comes time to upgrade the Cirrus HD-OCT, please contact Carl Zeiss Meditec to inquire about trade-in or upgrade values we may offer. Should you not wish to trade in the instrument, please dispose of it in accordance with local and national requirements.

(2) Operational Overview

Chapter Overview

This chapter provides an overview of how to operate the Cirrus HD-OCT. It explains basic operations like startup and shutdown, and initial system setup tasks. It introduces common features like the toolbar and menu system. It also provides an overview of the typical workflow and introduces the screens you will use in these contexts. Topics include:

System Start and Login

To activate power, press the system power switch, found below the monitor (see Cirrus HD-OCT System Hardware on page 1-4).

Log On to Windows

After the computer boots up you must login to the Windows operating system. The Log on to Windows dialog appears, showing the default user name **Zeiss**. Use the following password:

November171846

The password (representing the founding date of the Carl Zeiss company) is case-sensitive and has no spaces. After successful logon to Windows, the Cirrus HD-OCT software loads automatically and performs a system check before you can login to the application. It requires about 60 seconds for the startup process to complete.

☞ Note: The first time you login to Windows on a new Cirrus system, before you can use the Cirrus application, you must create an institution name and create at least one Cirrus user account. See Initial System Setup on page 2-4 for details.

☞ Note: To preserve system access and networking capabilities, do not change the default Windows user account and password.

☞ Note: Do not edit nor delete the **Tech Support** account, which is to be used only by Carl Zeiss Meditec technical support personnel. If you change or delete this account, CZM technical support may be unable to restore access to your system, in case you lose the password for the Administrator account. In this case, a service call would be required to replace the system hard drive.

System Check During Start

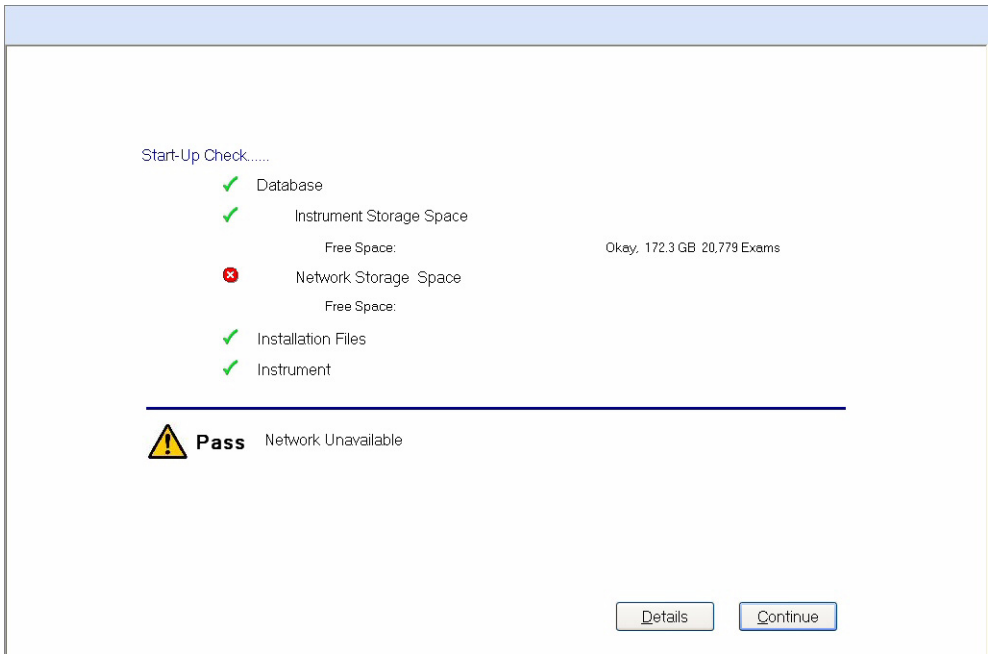


Figure 2-1 System check at startup

During system start, Cirrus HD-OCT checks the following items displayed on screen:

- Database: Checks accessibility and integrity of the database. If this check fails, you will not be able to login and use the instrument.
- Instrument Storage Space: Checks for adequate free space on the hard drive to acquire new scans. If free space is critically low, you may be required to clear archived exams before you acquire new scans.

- **Network Storage Space**: Checks accessibility of the network archive location and for adequate free space to archive new scans. You may continue without passing this check, but archiving may not be available. Under the default settings, you will be prompted upon shutdown to archive un-archived exams.
- **Installation Files:** Checks that critical system software files are present and have not been altered. If this check fails, you will not be able to login and use the instrument.
- **Instrument**: Checks the connectivity of the instrument hardware with the system computer. If this check fails, you will not be able to login and use the instrument.

Overall Pass or Fail: Below this list of items, the overall system check reports **Pass** or **Fail**.

- If the system passes all checks, it will automatically advance to user login.
- If it reports **Pass** but fails either storage space check, the system check will remain on screen and inform you of the results. You may click **Details** for more information. Click **Continue** to advance to login.
- If it reports **Fail**, the system check will remain on screen and the **Continue** button will not be available. If this occurs, call Carl Zeiss Meditec customer service: In the U.S., call 800-341-6968. Outside the U.S., contact your local CZM distributor. Be prepared to communicate the system check details, which are accessible by clicking the **Details** button.

User Login

You must log in to access the Cirrus HD-OCT functions. The User Login dialog appears when the instrument passes the system check upon startup, and each time a user logs out of the system software.

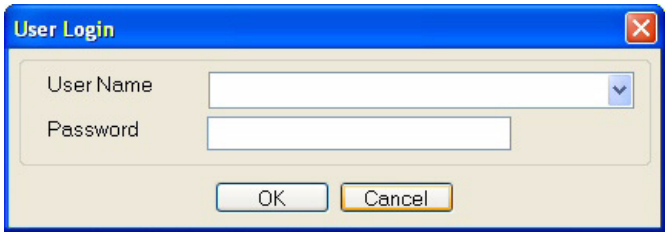


Figure 2-2 User Login dialog

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

- No user names appear in the drop-down list until user accounts are created (see Initial System Setup on page 2-4).

☞ **Note: We strongly recommend that you create individual user accounts for each staff member who acquires or analyzes scans, and that staff members routinely logout to secure the instrument. (To create user accounts, see Initial System Setup on page 2-4.)**

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

Figure 2-3 Invalid login—prompts you to try again

When you login successfully, the ID PATIENT SCREEN appears. See Identify a Patient on page 3-2 to use the ID PATIENT SCREEN.

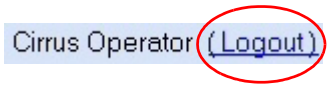


Figure 2-4 Logout link on toolbar

Logout Locks the System

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

Initial System Setup

Upon initial system start, before you can use the Cirrus application, you must create an institution name and create at least one Cirrus user account. Several other initial setup items are optional but also are worthy of consideration, and are explained in this section, which addresses the following topics:

This section explains how to perform both the required and optional initial setup tasks.

Create an Institution Name

Before you can use the Cirrus application, you must create an institution name for your system. The institution name is required as part of the information by which data is uniquely associated with the system where it is acquired. The Institution Edit dialog

appears automatically each time the Cirrus application starts until you save an institution name.

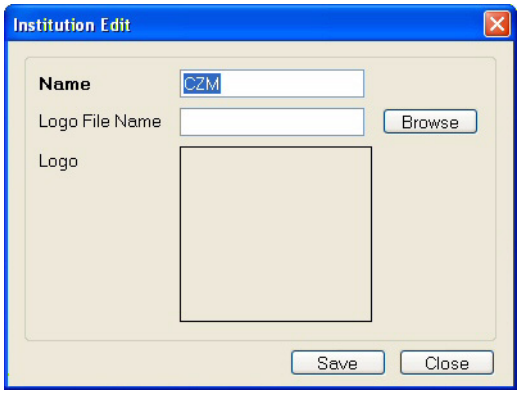


Figure 2-5 Institution Edit dialog

In the Name field, type the name of your institution. The field requires at least one character and accepts up to 64 characters, including spaces. The name field cannot be empty. The logo graphic is optional. If you are not going to use a logo graphic, click **Save** to save your changes and exit the dialog. To add a logo graphic now, see Add Institution Logo Graphic (Optional) on page 6-2. Once you have supplied the name and logo, they will appear on all analysis printouts.

The admin User Account

To manage administrative functions, Cirrus HD-OCT dedicates a special user account with the user name **admin**. Only the **admin** user can create and edit the institution name, user accounts and staff records. (See The admin User on page 6-1 for details.)

The admin account never appears in the drop-down list of user names on the login screen. You must type it in. The **admin** account accepts any password or none. The **admin** user cannot acquire or analyze scans.

Create User Accounts

No user names are available to log in with until user accounts are created. This section explains how to create user accounts.

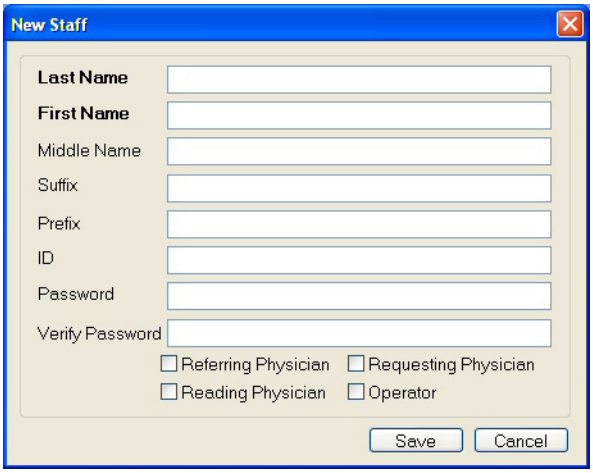
☞ **Note: We strongly recommend that you create individual user accounts for each staff member who acquires or analyzes scans, and that staff members routinely logout to secure the instrument. Following these procedures helps prevent unauthorized access to Cirrus HD-OCT data and functions, and enables accurate record-keeping. For record-keeping, Cirrus HD-OCT records the user name under which each scan is acquired; it displays the current user next to the Logout link at upper right.**

Register (Create) Staff Records

To access the Staff Registration dialog, you must be logged in as the **admin** user.

1. Click **Tools > Options > Users...**. The Staff Registration dialog appears.

2. In the Staff Registration dialog, click **New**. The New Staff dialog opens.



Required fields in bold

Figure 2-6 New Staff dialog

3. Edit the staff registration fields as desired. A staff record must have either a last name or first name or both; other fields are optional. To log in with this user name and acquire scans, the **Operator** checkbox must be selected. You may select more than one of the checkboxes to assign privileges. When finished with your changes, click **Save**.
    - To discard the changes before saving, click **Cancel**. A dialog prompts you to confirm your choice.

☞ Note: If the password field is left blank, that user must leave the password field blank to log in. User names are **not** case-sensitive, but passwords are.

☞ Note: Once logged in, any user can change his or her own password by selecting **Tools > Change My Password...** and completing the Password Change dialog. The admin user may take advantage of this feature by creating new user accounts with a temporary password, providing it to the user, and asking the user to change the password.

Preferences: Archive

Cirrus HD-OCT gives you a way to modify the default behavior for archive. Select **Records > Archive Options...** to access the Archive Preferences dialog,.

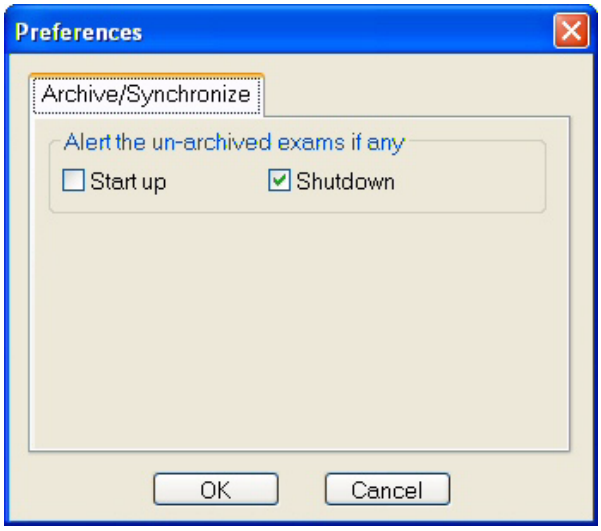


Figure 2-7 Archive Preferences dialog

Figure 2-7 displays the default settings. It is possible to select one, neither or both **Start up** and **Shutdown**. When finished selecting your preferences, click **OK** to save your changes and exit, or click **Cancel** to exit without saving. The options are described below.

☞ **Note: The Synchronize portion of this dialog refers to a feature planned for a future software release.**

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

Operational Modes and Screens

The Cirrus HD-OCT operates in four modes, three of which are associated with a primary screen:

Table 2-1 Operational Modes and Screens

Operational Mode	Primary Associated Screen
Data Management Mode	None
ID Patient Mode	ID Patient Screen
Acquire Mode	Acquire Screen
Analyze Mode	Analyze Screen

Sequence of Operation

The flow chart below illustrates the sequence of operation and the relationship of the operational modes.

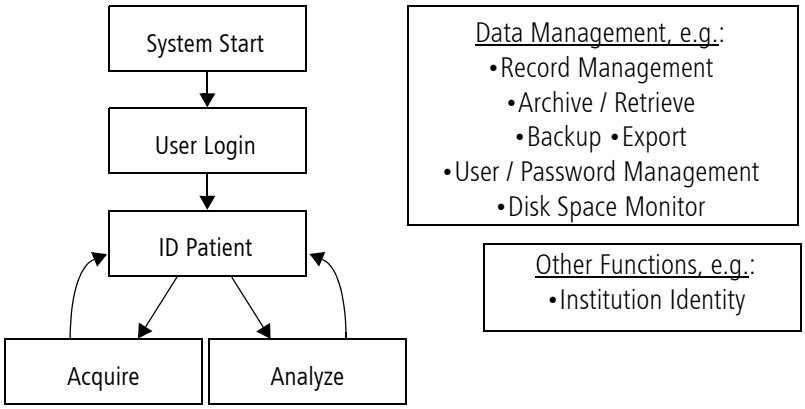


Figure 2-8 Sequence of operation

ID Patient mode is the default mode when you login to Cirrus HD-OCT. It is the launch point for the clinical functions of Cirrus HD-OCT: scan acquisition and analysis. You must identify a patient before you can either acquire or analyze exam data; and when you finish scan acquisition or analysis, you return to ID Patient mode. Other screens and dialogs are regularly used within each mode, as a subset of the primary function (e.g. scan review before save), or as an adjunct, like printing analysis output.

Data management mode operates independently and has no primary screen; it operates in various screens, which you access via menu options. Data management functions critical for data preservation, like backup, operate automatically.

Some functions do not fall strictly within any of the four modes, for example, customization of exam protocols. These functions you also access via menu options.

This manual will introduce each screen and dialog in relevant sections that explain its use.

Common Screen Elements

This section describes elements of the Cirrus screen that are always present, although their content and status varies depending on the current context. These common elements are:

- Patient Information Area, page 2-9
- Menu Bar and Menus, page 2-9
- Navigation Bar, page 2-13
- Status Area, page 2-14

These elements are illustrated in the sample screen below.

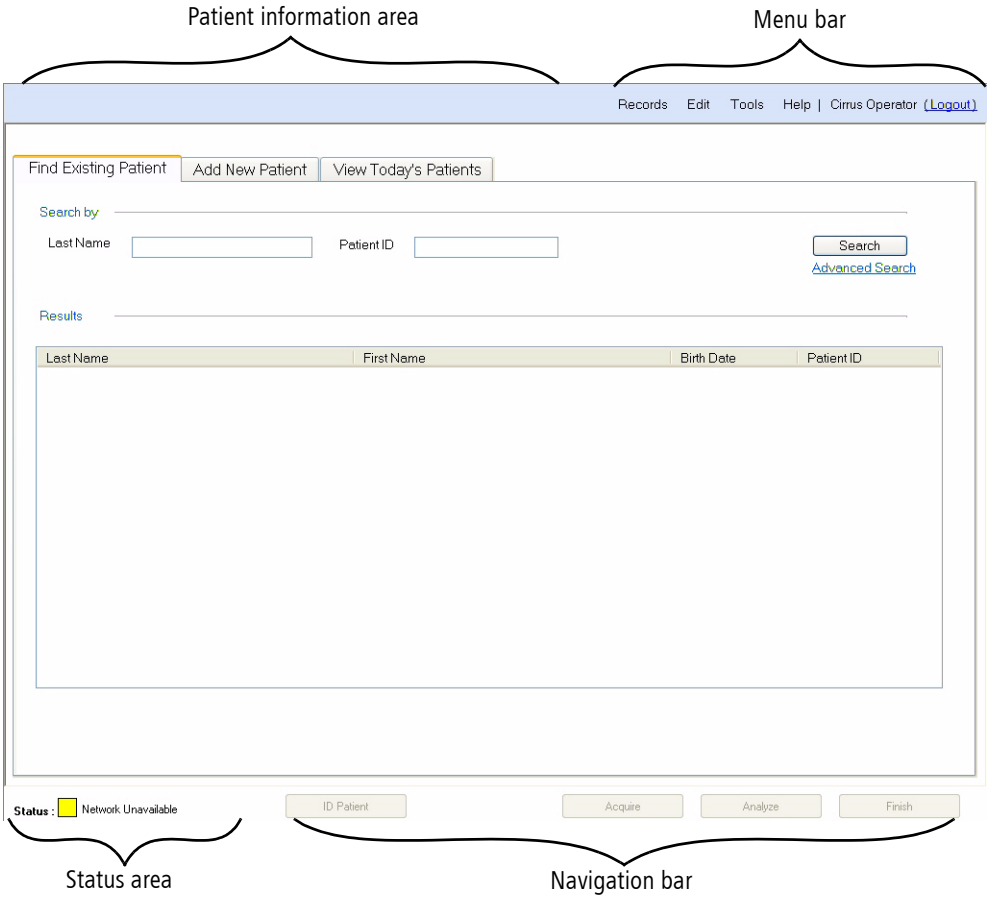


Figure 2-9 Sample screen showing common elements

Patient Information Area

This area from upper left to upper middle displays basic patient information (name, ID, gender, date of birth). Towards the middle it shows the current subject eye, when in Acquire or Analyze mode.

☞ **Note: This area remains blank until you select a patient.**

☞ **Note: The date of birth must be entered in the MM-DD-YYYY format, and always appears this way in the software and printouts.**

Menu Bar and Menus

The menu bar appears at upper right and contains the **Records, Edit, Tools** and **Help** menus. Click to select menus and menu items. Note the following general characteristics of the menus.

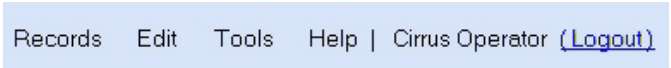
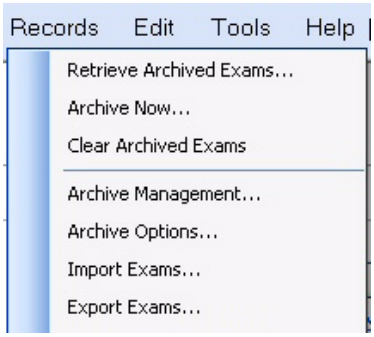


Figure 2-10 Menu bar (upper right)

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

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

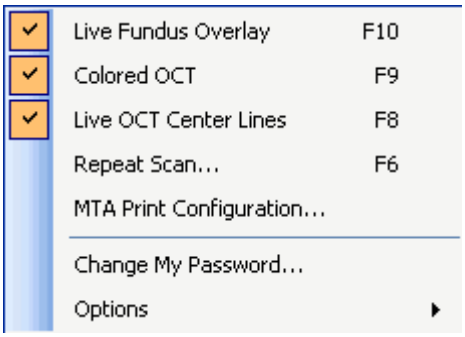
Records Menu



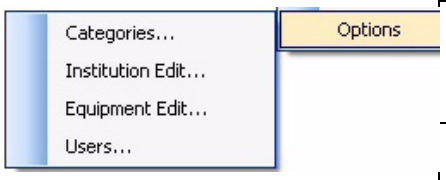
Edit Menu

Menu Items and Descriptions	Enabled in Mode
• **Retrieve Archived Exams...:** Enables you to retrieve data from an archive location.	ID Patient mode
• **Archive Now...:** Initiates archive of all un-archived exams.	ID Patient mode
• **Clear Archived Exams:** Clears (deletes) archived exams from the Cirrus HD-OCT hard drive.	ID Patient mode
• **Archive Management...:** Opens the Archive Locations dialog, where you can create and manage archives.	ID Patient mode
• **Archive Options...:** Opens the Preferences dialog, where you can select the archive preferences	ID Patient mode
• **Import Exams...:** Opens the Import Options dialog to import a Cirrus export database.	ID Patient mode
• **Export Exams...:** Opens the Export Options dialog, where you can select and export patient records.	ID Patient mode
• **Patient Record...:** Opens the Patient Edit dialog for the current patient, to view and/or edit the record.	ID Patient mode with a patient selected
• **Merge Two Patients...:** Opens the Patient Merge dialog, where you can select two patient records to merge.	ID Patient mode
• **Delete Patient:** Generates a confirmation prompt, asking user if they wish to delete the selected or opened patient record from the database.	ID Patient mode
• **Move Scan...**: Opens the Move Scan dialog, where you can select a patient file to move the selected scan into.	Analyze mode

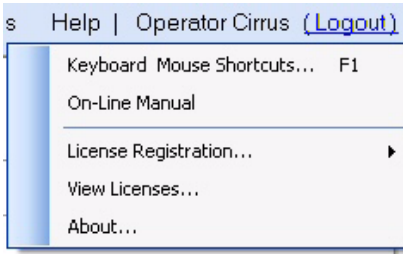
Tools Menu



Tools > Options



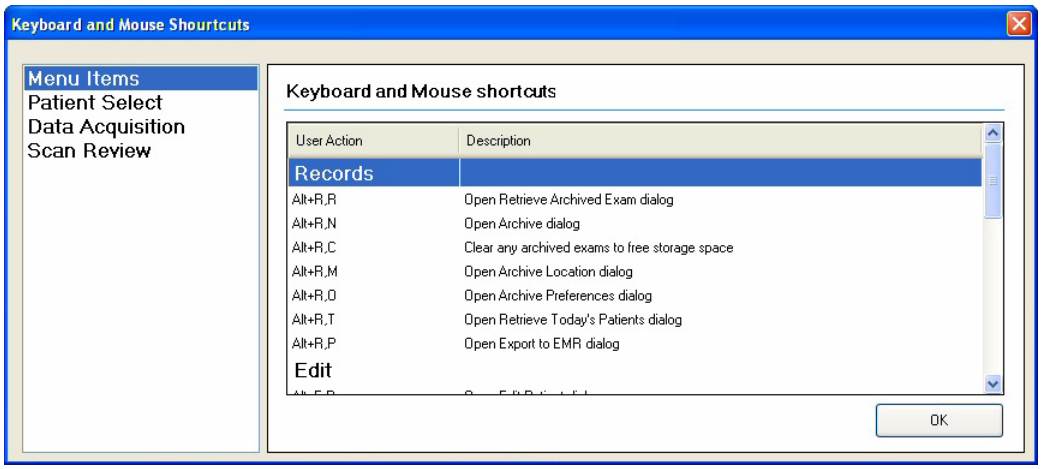
Help Menu

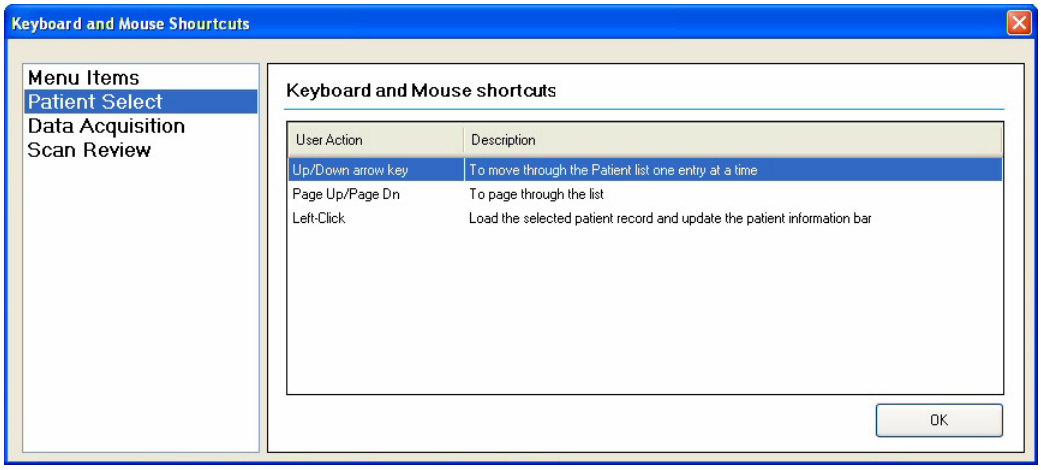


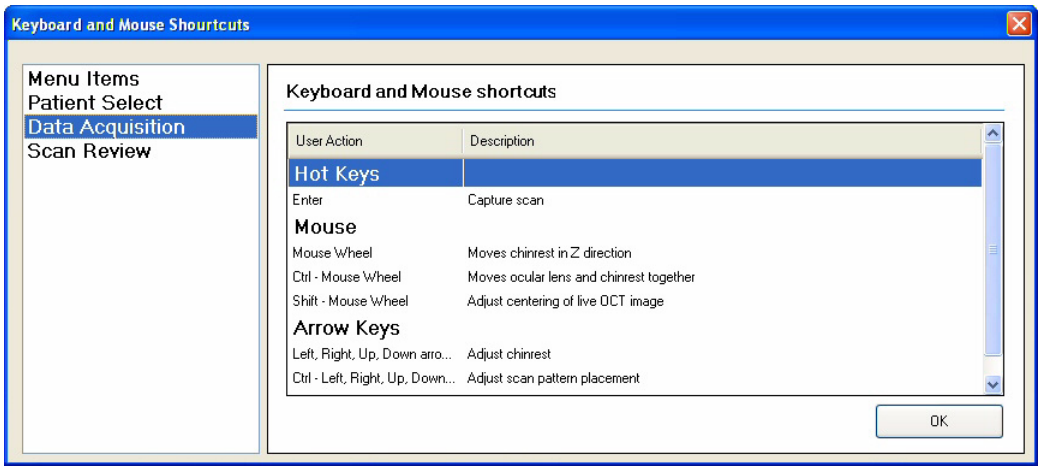
Menu Items and Descriptions	Enabled in Mode
• **Live Fundus Overlay:** Toggles the display of the overlay on or off. When off, only the outline of the scan region is visible (the bounding box) and not the vertical and horizontal slice locations. The default is checked (overlay visible).	Acquire mode
• **Colored OCT:** Toggles the display of OCT images from color to grayscale. The default is checked (colored OCT images).	Acquire and Analyze modes
• **Live OCT Center Lines:** Toggles the display of a vertical "centering" line on OCT images. The default is checked (center lines visible).	Acquire mode
• **Repeat Scan...:** Opens the Repeat Scan dialog, where you can select any previous scan of the current patient as a starting point for the parameters for the current scan.	Acquire mode
• **MTA Print Configuration...:** Opens the MTA Print Configuration dialog, where you can select the printout defaults for the Macular Thickness Analysis printout	Always
• **Change My Password...:** Enables you to change the password for the current user.	Always, except for **admin** user
• **Options...:** Enables access to the following options.	Always
• **Categories...:** Enables you to create, edit or delete categories, which you can apply to patient records and search with.	ID Patient mode
• **Institution Edit...:** Enables you to customize your Cirrus HD-OCT and reports generated from it by adding or editing the institution name and optional logo graphic.	When logged in as **admin** user
• **Equipment Edit...:** Open the Equipment Edit dialog, where you can create a station name for the instrument and view other equipment information.	When logged in as **admin** user
• **Users...:** Enables you to create, edit or delete staff as users and designate their user privileges.	When logged in as **admin** user
• **Keyboard Mouse Shortcuts...:** Displays a categorized listing of keyboard shortcut keys and mouse functions.	Always
• **On-Line Manual:** Opens the Cirrus User Manual.	Always
• **License Registration...:** Enables you to register a license through the License Registration Utility that appears when you select a license type.	Always
• **View Licenses:** Opens the View Licensed Features dialog, where you can view the licensing status of optional features.	Always
• **About...:** Displays the About dialog, which provides software version information.	Always

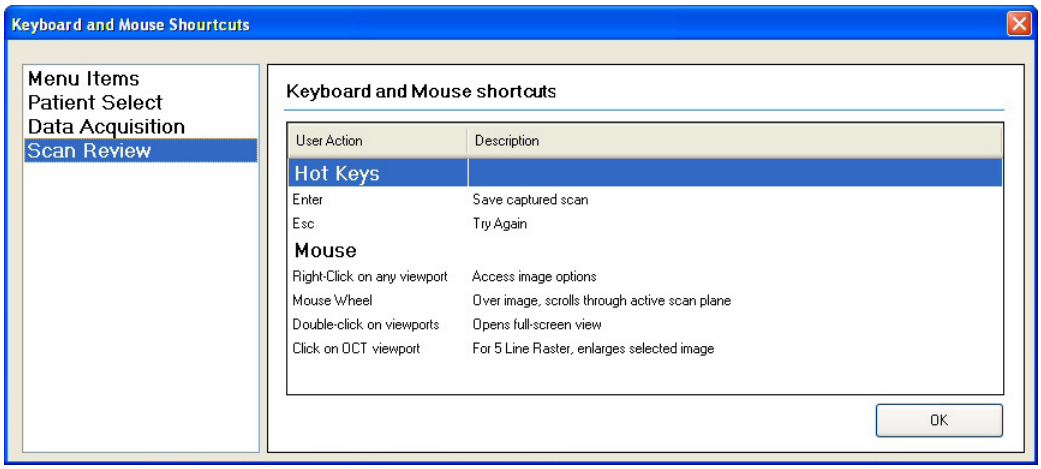
Keyboard and Mouse Shortcuts

Cirrus provides keyboard and mouse shortcuts in many contexts. Commonly used or recommended shortcuts are addressed in relevant sections of this manual. To access categorized list of all available shortcuts, click **Help > Keyboard Mouse Shortcuts...** or press the **F1** key. The following lists are available. When necessary, scroll down to view all the options.









Navigation Bar

The navigation bar, consisting of a series of buttons by which you access functions or other operational modes, appears at lower right and across most of the bottom of the screen.

Figure 2-11 Navigation bar (along bottom)

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

Status Area

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

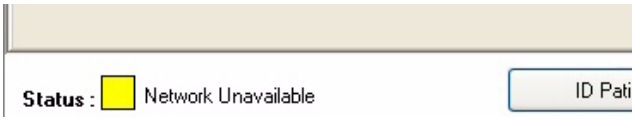


Figure 2-12 Status area showing yellow indicator (lower left)

Overall Status by Color

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

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

Components of Status

The following components contribute to the overall status.

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

Instrument Status

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

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

Hard Disk Status

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

- **Green**: Adequate free hard disk space.
- **Yellow**: Low hard disk space. When free hard disk space is low at startup, you must click **Continue** at system start before continuing to the login screen. Also, the system begins to automatically clear archived exam data.
- **Red**: Critically low hard disk space. When hard disk space is critically low, both scanning and analysis are disabled. You must clear a sufficient amount of hard disk space by clearing archived exams to continue. If there are insufficient archived exams to be cleared, you must first archive exams and then clear them. You cannot clear un-archived exams.

Network (Archive) Status

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

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

Performance Verification Check

With the Performance Verification Check, you can verify that the fundus image and the OCT scan image overlay are aligned within specifications as defined by the target inside the Verification Test Tool. Practically, this means the scan actually is placed where it appears to be placed, based on the fundus image. You can re-try the check if it does not pass initially. Upon failure of a performance verification check, data acquired since the last successful check may not be reliable.

☞ **Frequency: Weekly,** at the beginning of each week you will acquire new scans.

☞ **Time Required for Test:** Approximately 2 minutes.

☞ **Verification Test Tool Required:** We provide this tool with each instrument. It contains fragile parts that must be maintained in their original position for the test measurements to be accurate. **Handle it carefully to avoid dropping. Damage to the Verification Test Tool can affect test results.** If you drop it, we recommend that you do not use it for testing, and immediately contact Carl Zeiss Meditec customer service. In the U.S., call 800-341-6968. Outside the U.S., contact your local Carl Zeiss affiliate or distributor.

Install the Verification Test Tool

Install the Verification Test Tool in the correct orientation, with the part that says "Top" facing upward. The tool has short pegs at upper left and lower right, and thumbscrews at upper right and lower left. Each of these corresponds with a hole on the face of the ocular lens housing.

Using only your fingers, turn the screws (clockwise) on top and bottom to secure the tool in place. To avoid dropping the tool, make sure that both screws are tight before releasing the tool.

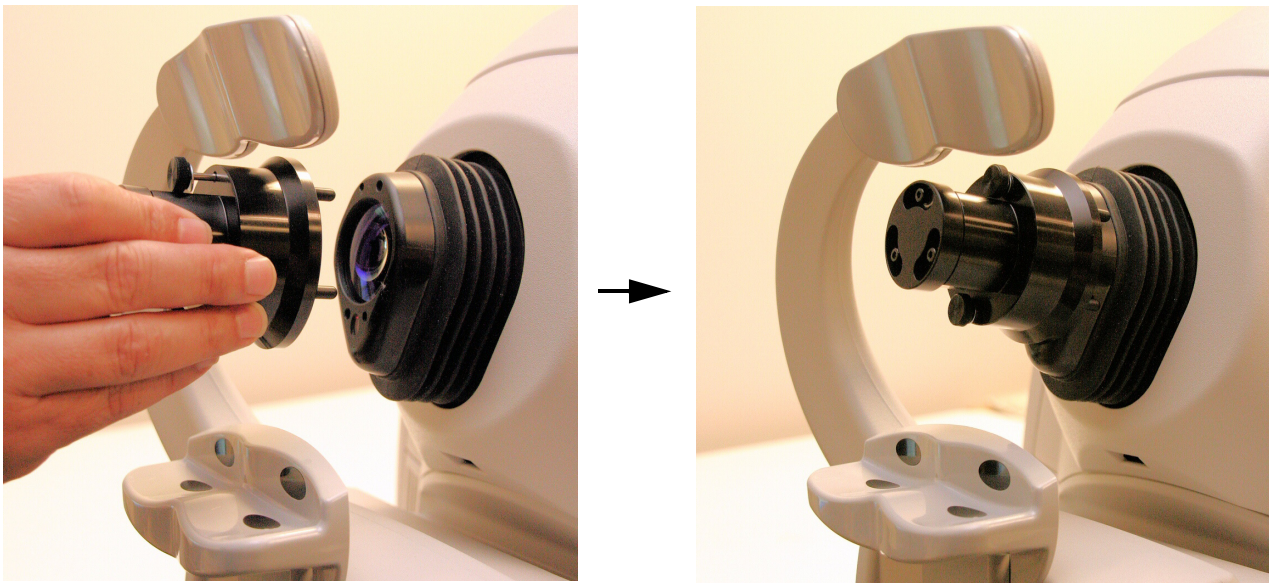


Figure 2-13 Proper Installation of Verification Test Tool

Run the Check

To run the check, follow these steps:

1. In the ID PATIENT SCREEN, select the patient named **Performance Verification** and then click **Acquire**.

☞ **Note: You cannot edit or delete the Performance Verification patient record.**

The ACQUIRE SCREEN appears, showing a default Macular Cube 512x128 scan.

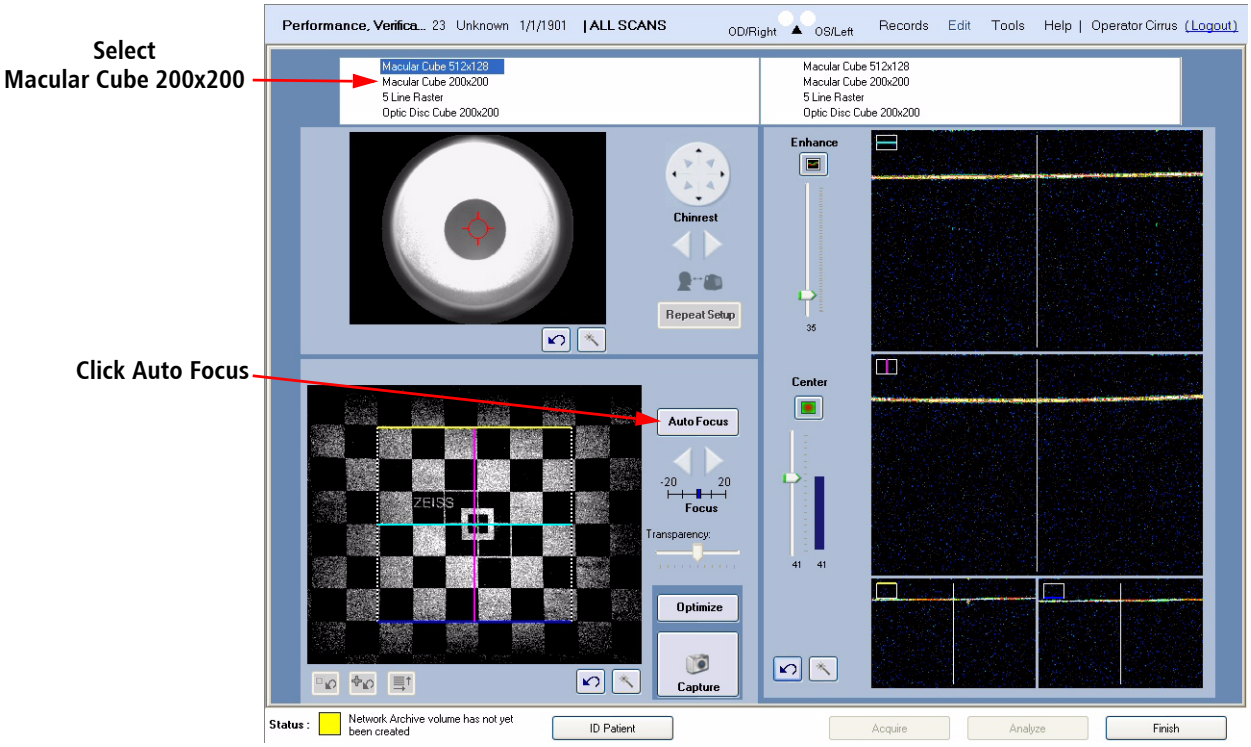


Figure 2-14 Performance Check Initial View

2. Select **Macular Cube 200x200** in the scan list.
3. Click **Auto Focus**[1] to get a clearer image of the checkered test pattern. (Use the focus arrows if your system does not have Auto Focus activated.) Besides focus, other adjustments usually are not necessary, although possible.
4. Click **Capture** and then select **OD** or **OS** in the Select Eye dialog that appears. The REVIEW SCREEN appears automatically.

Note: Pay no attention to the image appearance nor to the signal strength value in the Review Screen. They have no bearing on the co-alignment of the scan and fundus images, which is what this test evaluates. If necessary, you can adjust the brightness and contrast later in the Analyze Screen when evaluating the test.

5. Click **Save** and then either **Finish** or **ID Patient** to exit data acquisition. You will return to the ID PATIENT SCREEN.
6. Select the **Performance Verification** patient again and click **Analyze**.

1. Auto Focus is an optional feature that may not be activated on all instruments. If you do not have this feature and want to purchase it, contact Carl Zeiss Meditec. In the U.S.A., call 1-877-486-7473; outside the U.S.A., contact your local Carl Zeiss Meditec affiliate or distributor.

7. In the ANALYZE SCREEN, select the scan you just saved. Select Macular Thickness Analysis in the right-hand column.

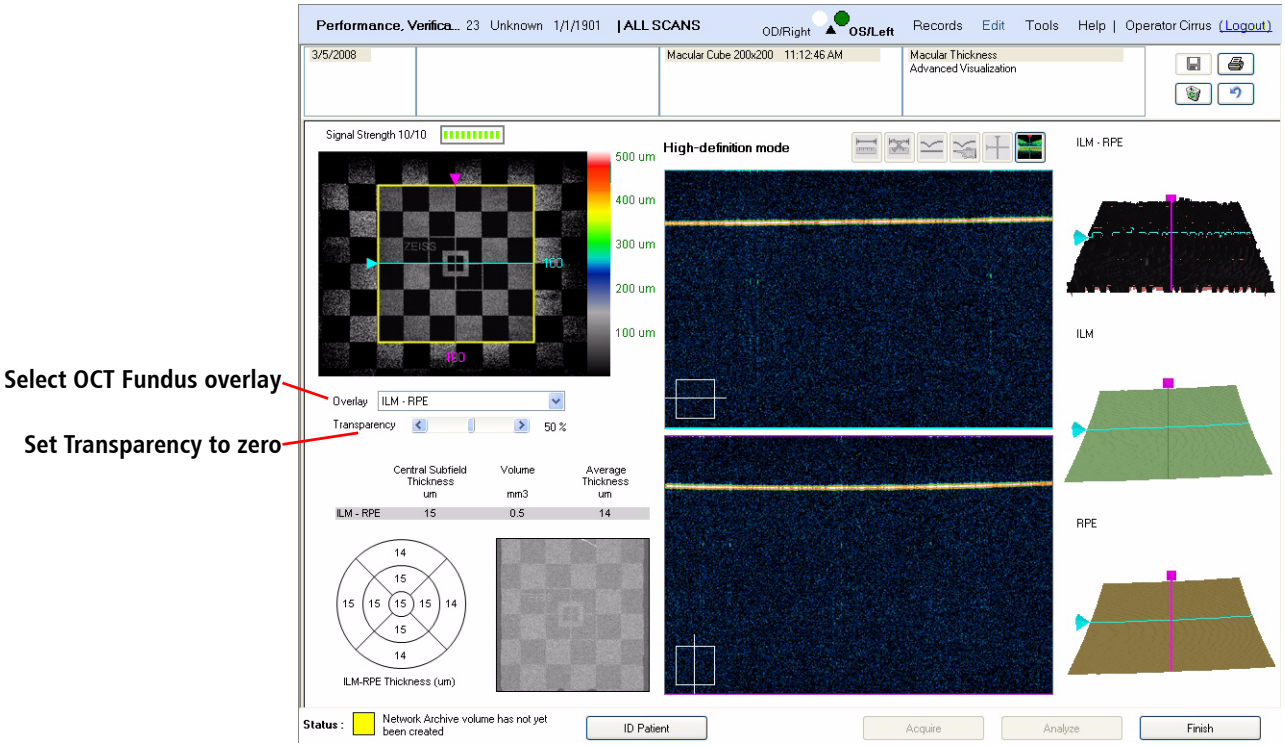


Figure 2-15 Performance Verification Analyze Screen Initially

8. When the scan loads, select **OCT Fundus** in the **Overlay** drop-down menu and set the **Transparency** slider to zero. Then double-click anywhere on the fundus image to make it appear full screen.

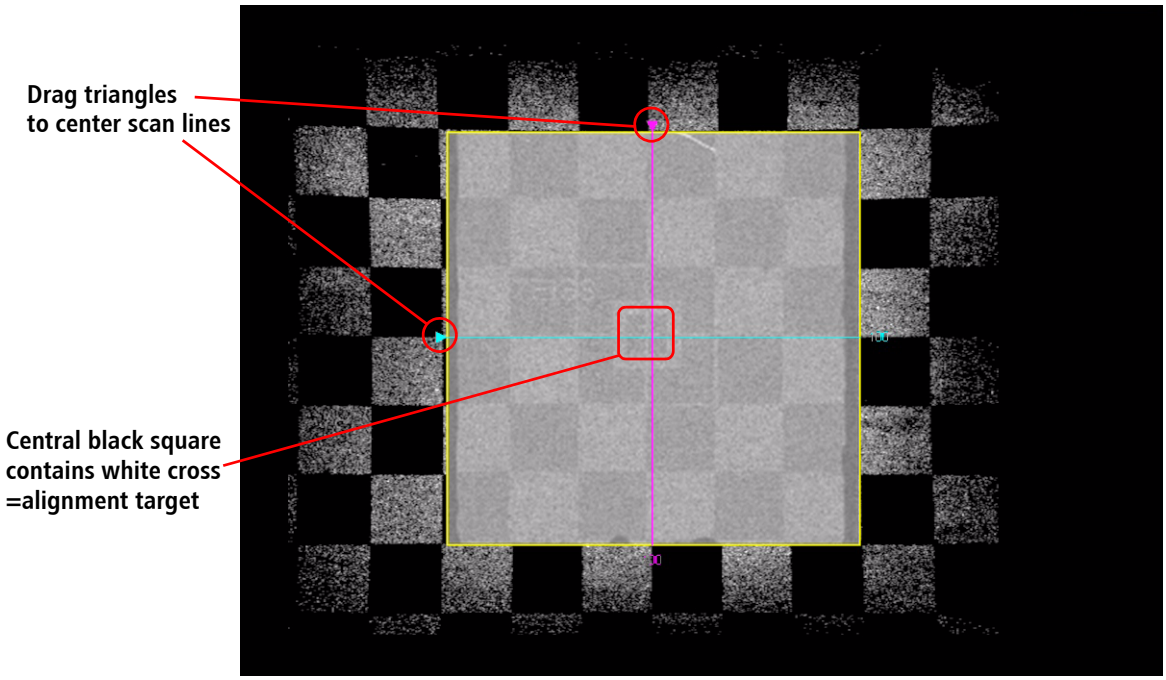


Figure 2-16 Fundus Viewport Full Screen With 0% Transparency (Opaque)

Note the checkerboard pattern and in particular the smallest black square in the center of the target. The alignment target is the central white cross within the center square. The white cross defines the acceptable range of alignment between the fundus image and the OCT scan image, as explained below.

☞ **Note: When the blue and magenta lines are correctly centered, you may find it difficult to see the central white cross in the center square, because the scan lines are nearly as thick as the white lines that comprise the central cross.**

9. With **Transparency** set at 0% (opaque), use the triangles to drag the horizontal and vertical scan line indicators until they intersect in the very center of the central small black square. Centered this way, they should mostly cover the central white cross, which is the alignment target

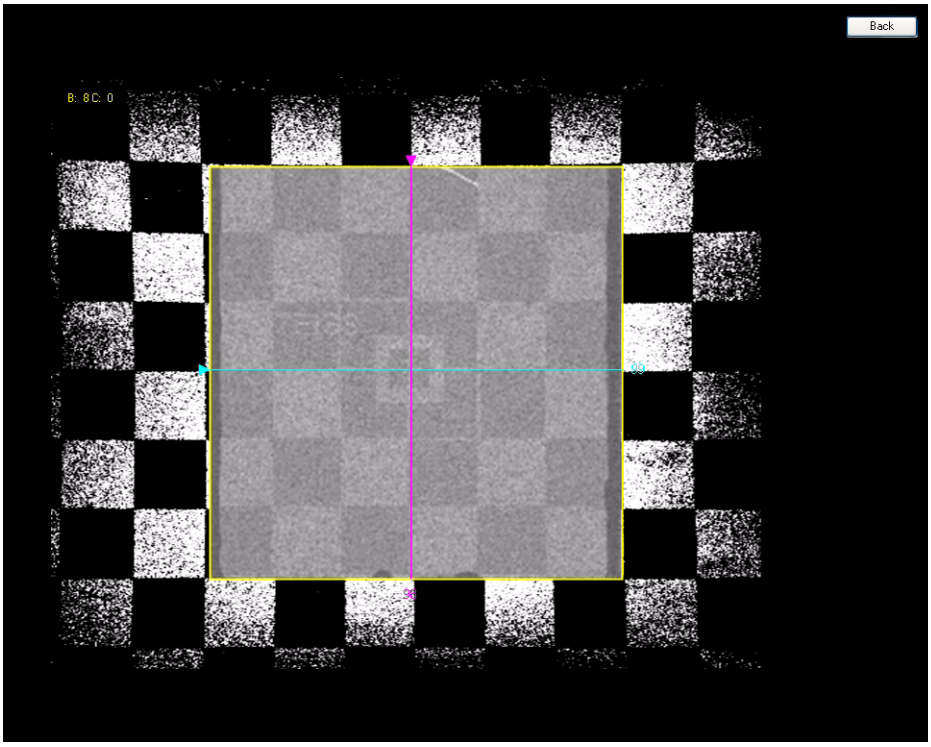
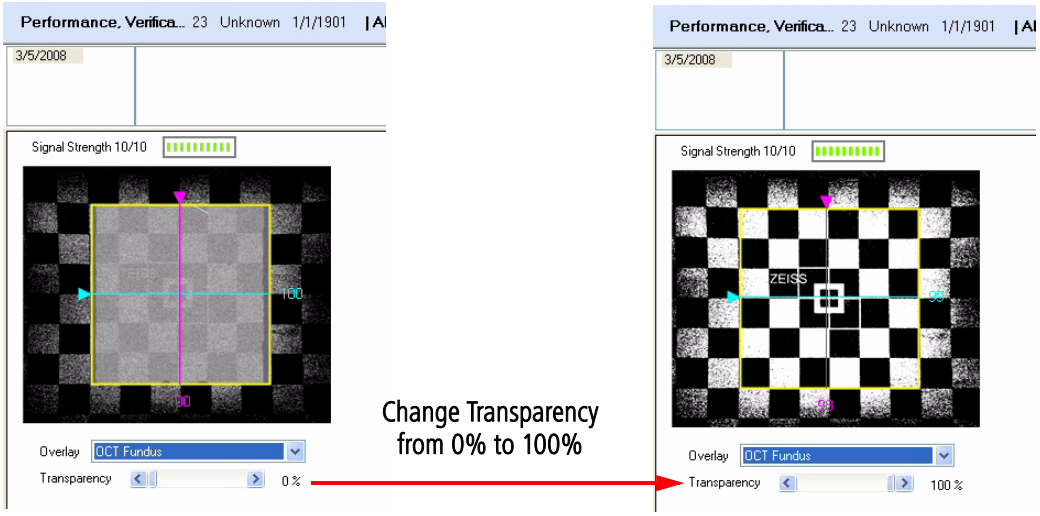


Figure 2-17 Blue and Magenta Lines Centered on Alignment Target

☞ Note for the Model 400 only:

The checkerboard pattern may be faint. Right-click on the checkerboard to access a list of image display options. Click the left mouse on **Brightness/Contrast**. To darken the image, move the curser horizontally to change the contrast and/or move it vertically to change the brightness.

10.Click **Back** at upper right (or double-click anywhere) to exit full screen mode.



11.Now move the **Transparency** slider to 100% (transparent) and double-click again to make the fundus image appear full screen. Now you are ready to evaluate the test.

Pass Condition

- **Pass:** After changing the **Transparency** to 100%, if both scan line indicators pass partially or wholly within the white cross portion of the center square, the system passes the check. This means the co-alignment of the fundus image and the OCT scan image is within the acceptable range. Some examples of pass conditions appear below.

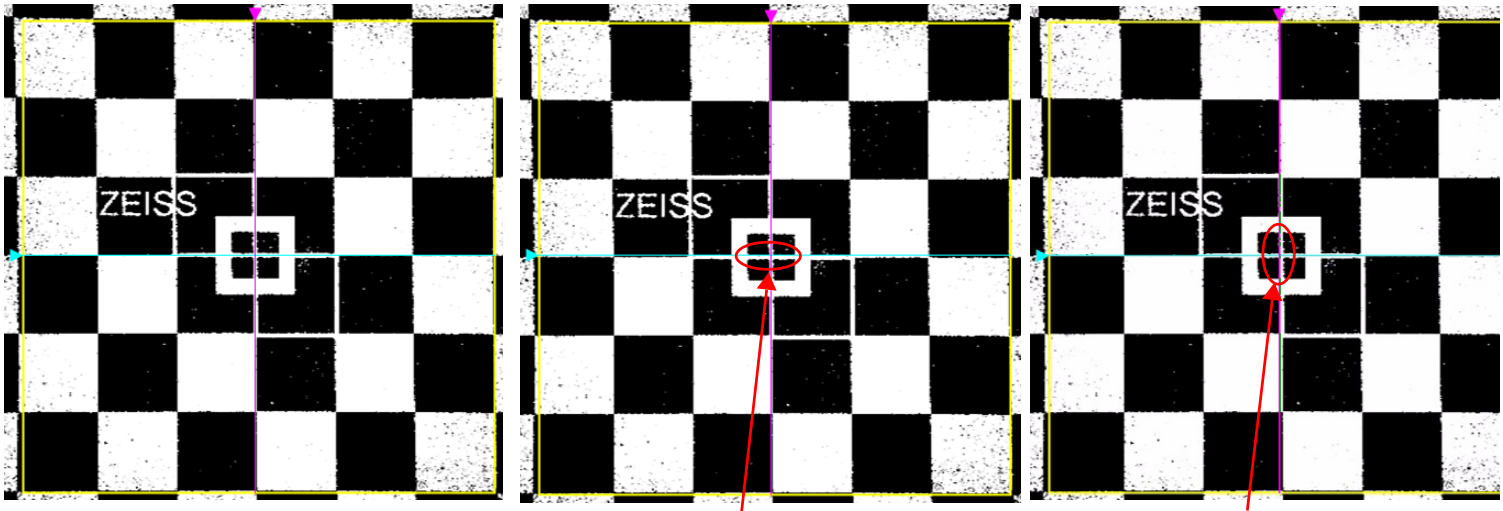


Figure 2-18 Examples of Pass Conditions

Failure Condition

- **Fail:** After changing the **Transparency** to 100%, if one or both scan line indicators pass clearly within the black portion of the center square, the system fails the check. Some examples of failure conditions appear below.

In effect, when there is a failure condition, you can clearly see that one or both of the scan line indicators fail to pass within, even marginally, the central white cross in the center square.

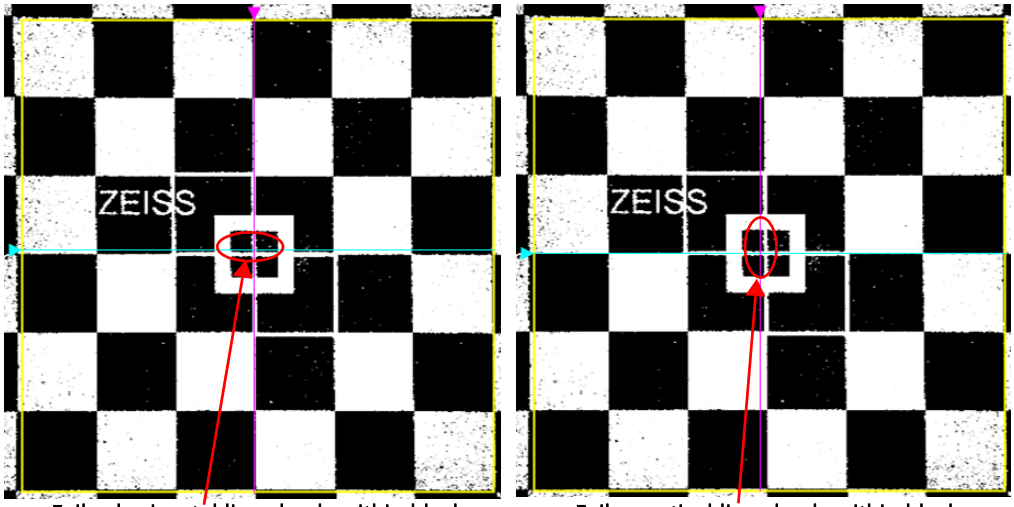


Figure 2-19 Examples of Failure Conditions

☞ Note: Evaluation is somewhat subjective. We offer the examples above as guidelines. If you drag the scan lines, you will observe that there is only a two or three pixel range of movement while still within the pass condition, and only a one pixel difference between a marginal pass and a failure. The central white cross defines a stringent range of tolerance. Therefore, you should confirm a failure only if the scan line indicators lie wholly within the black of the central square.

- To confirm your observation, you should switch back to 0% **Transparency**.
- If your observation is confirmed initially, you should remove and re-install the test tool to ensure it is seated properly and then run the check again.
- If the system still fails the test, contact Carl Zeiss Meditec customer service. In the U.S., call 800-341-6968. Outside the U.S., contact your local Carl Zeiss affiliate or distributor.

If you want to repeat the test, we recommend you first remove and re-install the test tool.

Power Down the System

You can power down the system either through hardware or through software. However, we strongly recommend you power down through software to permit automatic archiving on shutdown and to avoid abrupt shutdowns that could result in loss of patient data. When you power down through software, the system goes through a soft shutdown sequence.

Power Down Through Software

1. Click **Logout** at upper right.

If archive is set to occur upon shutdown (see Preferences: Archive on page 2-7), the system will prompt you to archive.

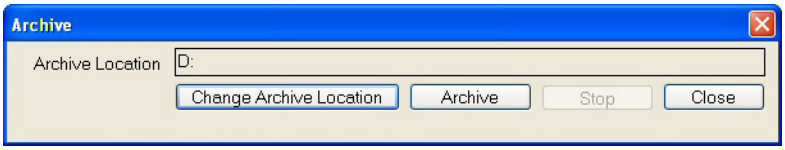


Figure 2-20 Archive prompt dialog

Execute the desired option to advance to the Exit Dialog.

2. When you archive or close the Archive dialog (see above), the Exit Dialog will ask if you are sure you want to exit.

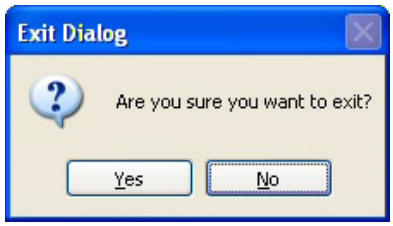


Figure 2-21 Exit Dialog

3. Click **Yes** to exit the Cirrus software.

- If you click **No**, the Login dialog will appear.

After you exit the system software through the soft shutdown sequence, you will have access to the computer operating system underlying the system software. To conclude system shutdown, you must click **Start > Shut Down...** and then select **Shut Down**, as with any PC.

WARNING: Do not modify or add to the software found on the Cirrus HD-OCT except as authorized by Carl Zeiss Meditec. Unauthorized modification or addition of software will void the instrument warranty and can potentially jeopardize the safety of users and patients, the performance of the instrument, and/or the integrity of patient data.

Power Down Through Hardware

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

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

(3) Acquire Scans

Chapter Overview

This chapter explains in detail how to acquire Cirrus HD-OCT scans. It covers the following steps:

Prepare the Patient

Patient preparation includes:

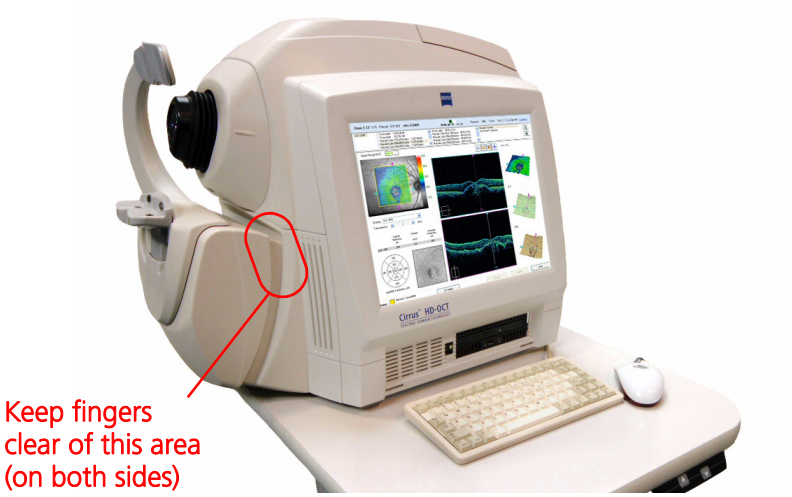
☞ Note: The forehead and chin rests should be cleaned between each examination with an alcohol prep swab.

Precautions

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

In Acquire Screen, have patient sit back before you click Finish or ID Patient.

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



Note: Screen images shown in this manual correspond to the Model 4000 instrument. There are no significant differences, however, in the appearance of the screen for the Model 400 instrument other than the resolution of the image in the fundus viewport and, depending on which setting is enabled, the refresh rate of the image in the fundus viewport. See Figure 3-9.

Identify a Patient

Scanning and analysis are disabled until you identify a patient. Use the ID PATIENT SCREEN to identify (select or add) a patient. After system start and login, the ID PATIENT SCREEN appears by default. (From other modes, click **ID Patient** to return to the ID PATIENT SCREEN.) You can identify a patient using any of the three tabs provided. For details on using these tabs to identify a patient, see the indicated sections.

- Find Existing Patient Tab, page 3-3
- Add New Patient Tab, page 3-4
- View Today's Patients Tab, page 3-5

On any of the three tabs, once you identify the patient, click **Acquire** to initiate a new exam for that patient. The ACQUIRE SCREEN appears. Proceed to Select Scan Type on page 3-5.

Find Existing Patient Tab

On the default, Find Existing Patient tab, you can select a patient from the patient list displayed.

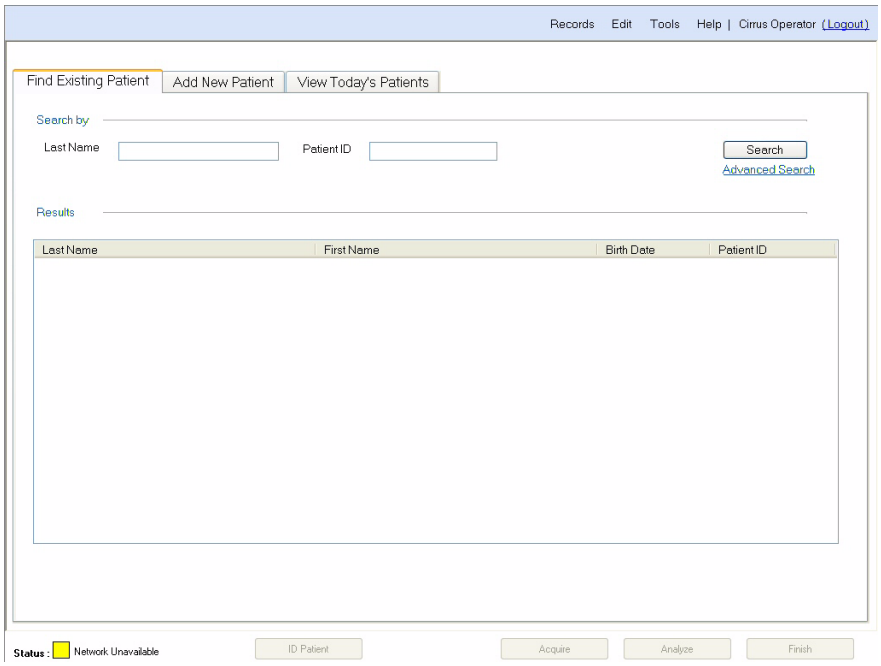


Figure 3-1 ID Patient Screen—default tab: Find Existing Patient

☞ **Note: The list is blank until you search.**

To populate the patient list:

1. Click **Search** to return all patients in the index database.
2. To search for patients by **Last Name** or **Patient ID**, type in the corresponding fields and click **Search.** You can search using partial information, and you can use one or both fields.

- Click **Advanced Search** if you want to search using additional parameters—see Advanced Search on page 6-8 for details.
- The search returns all patients that match all defined parameters, sorted alphabetically.
- When you search by **Last Name**, the search returns all patients that match from the beginning of the last name.
- In the **Results** list, you can select only one patient at a time. When you select a patient, the **Acquire** button becomes active. If the patient has saved exams, the **Analyze** button becomes active.

When you click **Acquire**, Cirrus HD-OCT initiates a new exam for the selected patient. The ACQUIRE SCREEN appears. Proceed to Select Scan Type on page 3-5.

Add New Patient Tab

To add a new patient, click the Add New Patient tab and fill in at least the required fields, which are indicated in bold type.

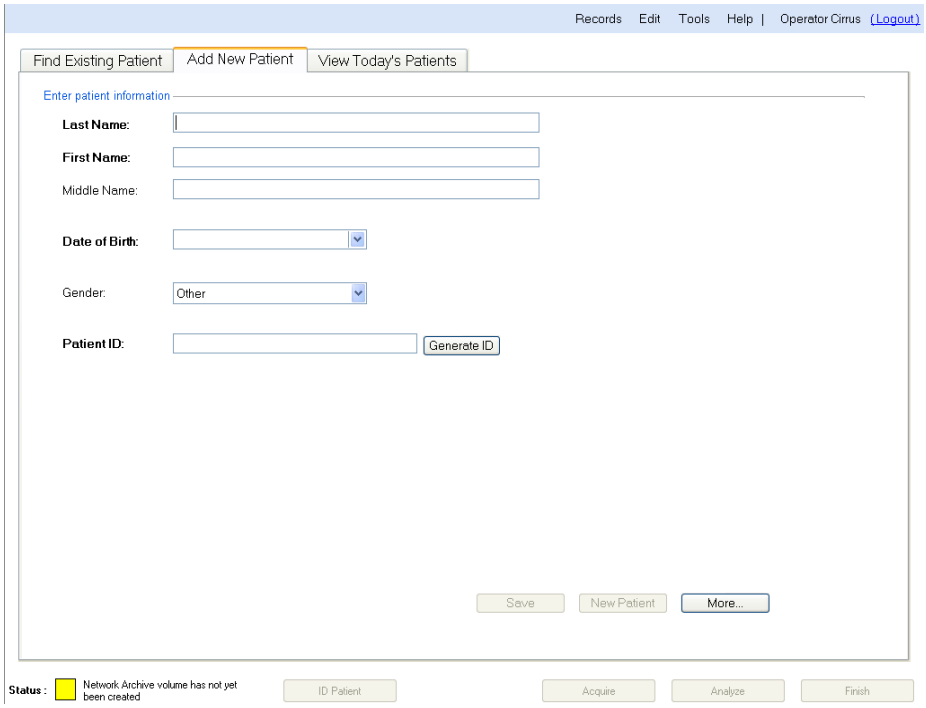


Figure 3-2 Add New Patient tab of the ID Patient Screen

WARNING: The date of birth must be entered in the MM-DD-YYYY format, and always appears this way in the software and printouts.

- If you want to enter additional information, click **More** and continue. The Patient Edit dialog will appear. For details, see Edit Patient Record on page 6-10.
- A Patient ID is required for all patient files. No patient data can be saved without a patient ID. If you choose not to assign an ID, you may click on Generate ID to have the system create a unique ID automatically for this patient. Unique passwords all start with the prefix "CZMI". Because a Patient ID is required for DICOM-compliant import and export of patient data, the system also creates a unique Patient ID when you export data for any patient that was created without a Patient ID (under previous software versions).
- When you click **Save**, the new patient information is saved to the database and to the list of today's patients. If data is missing from required fields, the **Save** button will not be enabled.

When you click **Acquire**, the Cirrus HD-OCT initiates a new exam for that patient. The ACQUIRE SCREEN appears. Proceed to Select Scan Type on page 3-5.

View Today's Patients Tab

To select a patient from the list of today's patients, select the View Today's Patients tab.

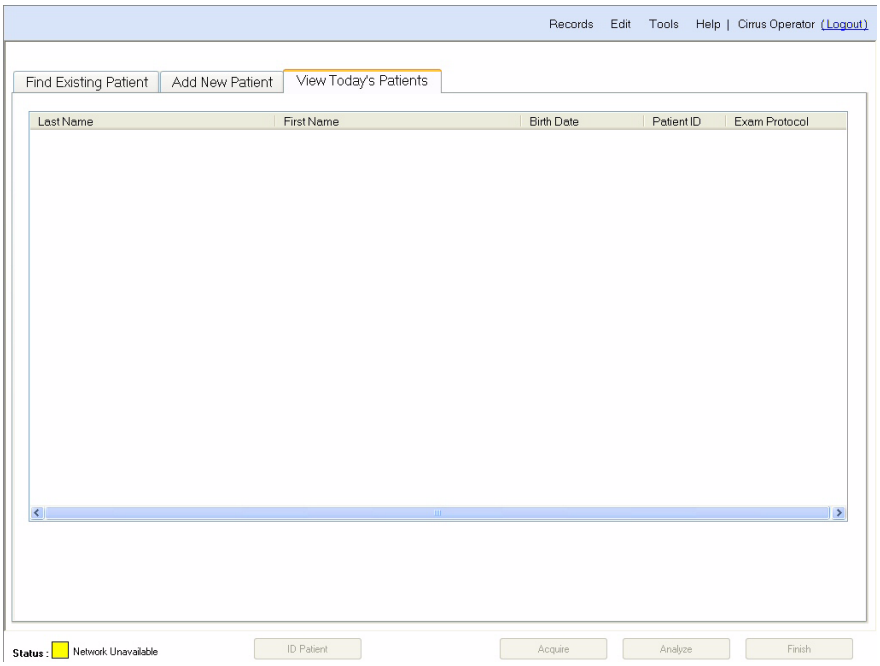


Figure 3-3 View Today's Patients tab of the ID Patient Screen

How Today's Patients List Is Populated

Today's patients list is populated automatically with new patients added today and patients with new exams completed today. The list is sorted alphabetically by last name.

- When you have completed exams for a patient, the Exam Protocol column indicates the exam protocol.

Click to select the desired patient and then click **Acquire**. The ACQUIRE SCREEN appears. Proceed to Select Scan Type next.

Select Scan Type

After you identify a patient and click **Acquire**, the ACQUIRE SCREEN appears, as in Figure 3-5 on page 3-9. **All Scans** is the default exam protocol, which contains all available scan types for each eye. Unless the patient's chin is in the chinrest for the left eye, the first scan type for the right eye is selected by default. You may select any scan type by clicking it. As you acquire and save scans, the scan list indicates scan acquisition with a green checkmark to the left and shows the number of saved scans of that type to the right.

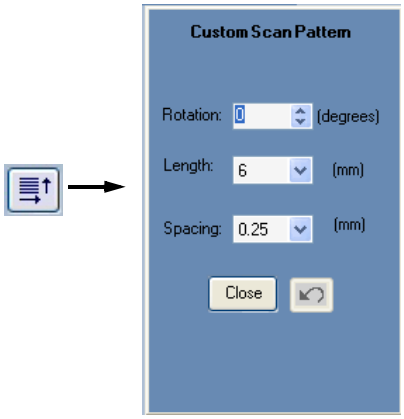
The same scan types for each eye are listed in the following order near the top of the screen. They are:

- **Macular Cube 512x128:** Generates a cube of data through a 6mm square grid by acquiring a series of 128 horizontal scan lines each composed of 512 A-scans. In

addition, a high-definition crosshair scan is acquired first. Each high-definition scan is composed of 1024 A-scans.

- **Macular Cube 200x200:** Generates a cube of data through a 6mm square grid by acquiring a series of 200 horizontal scan lines each composed of 200 A-scans. In addition, a high-definition crosshair scan is acquired first. Each high-definition scan is composed of 1000 A-scans.

☞ **Note: The Macular Cube 512x128 is the default scan. Compared to the 200x200, this scan has greater resolution in each line from left to right, but the lines are spaced further apart, giving less resolution from top to bottom.**



- **5 Line Raster:** Creates 5 parallel scans of equal length, and the line length, rotation and spacing are adjustable. Of all the Cirrus scan types, this scan gives the greatest resolution. While you can select line lengths of **3, 6** or **9** mm, each line is always composed of 4096 A-scans. (Thus, the highest resolution is 4096 A-scans over 3 mm length.) By default, the lines are horizontal and each line is 6 mm long and separated by 250 µm (0.25 mm) from the next, so that the 5 lines together cover 1 mm width. To make adjustments, click the **Adjust Rotation and Size** button, found at the bottom of the fundus viewport (see Figure 3-5). This button is active when you select **5 Line Raster** in the ACQUIRE SCREEN. The Custom Scan Pattern popup appears, as at left. All adjustments apply to all 5 lines uniformly.
  - For **Rotation** (default 0 degrees is horizontal), click the up arrow (for counterclockwise rotation) or down arrow (for clockwise rotation) or type in a value to adjust the angle in the ranges of 0 to 360 degrees. Values typed in from 91 to 269 are automatically changed to the corresponding value 180 degrees opposite.
  - For **Length**, you can select **3, 6** or **9** mm.
  - For line **Spacing**, you can select among the following options, in millimeters: **0** (five lines in same location), **0.01, 0.025, 0.05, 0.075, 0.125, 0.2, 0.25, 0.5, 1.25.**
- **Optic Disc Cube 200x200:** Generates a cube of data through a 6 mm square grid by acquiring a series of 200 horizontal scan lines each composed of 200 A-scans. The Optic Disc Cube 200x200 has the same scan dimensions as the Macular Cube 200x200, except there are no high-definition scans acquired with the cube data and the fixation target is offset to allow the center of the optic nerve to move to the center of the scan pattern. Also, the scan pattern overlay consists of concentric rings to assist in the alignment of the optic disc. See Figure 3-7.

Before the patient puts his or her head in the chinrest, click to select the desired scan type for either eye. The automated chinrest will go to the default position for the selected scan type and eye. Proceed to Acquire Scan below.

Preparing the Patient for the Exam Experience

The patient's exam experience with the Cirrus HD-OCT is normally brief and comfortable. An experienced operator can acquire several scans from each eye in the space of 5-7

minutes. An exam usually requires the patient to look inside the imaging aperture for 1-3 minutes at a time for each eye, depending on the number of scans desired. The instrument acquires most scans in about two seconds. The additional time is required to align the patient before scanning and to optimize scan quality. The patient need not remain in the head rest between scans since the operator can reposition the head rest as needed. Note that the Cirrus HD-OCT is never to contact the patient's eye.

☞ **Note: It is not necessary for the patient to put their head on the chinrest until after the desired scan type is selected. If you are using the Repeat Setup (see page 3-17) feature on a patient, the patient can wait until the Repeat Setup function has been selected and the chinrest motions are complete before placing their head in the chinrest. Reducing the amount of time the patient spends in the chinrest improves patient comfort.**

Optional dilation of patient's eye(s)

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

Select the Fixation Method

Cirrus HD-OCT provides for internal fixation as the default method. This method is preferred for its reproducibility and ease of use. However, if the patient's visual acuity in the subject eye precludes internal fixation, you have the option of attaching and using the external fixation device, which is a light-emitting diode on the end of an adjustable arm. Plug it into the port on the top of the instrument, and position the arm manually in the desired position.

What the Patient Sees

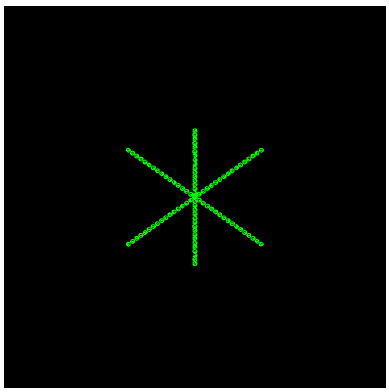


Figure 3-4 What the patient sees

Model 4000 Instrument

Before scan acquisition, the patient looks into the imaging aperture and sees a green star-shaped target against a black background. When scanning starts, the background changes to a bright, flickering red, and the patient may see thin bright lines of light, which is the scan beam moving across the field of view. Normally, the patient can look inside the imaging aperture for several minutes at a time without discomfort or tiredness.

☞ **Note: Instruct the patient to look at the center of the green target, and not at the moving lights (the scan beam).**

Model 400 Instrument

Before scan acquisition, the patient looks into the imaging aperture and sees a green star-shaped target against a black background. At the same time the patient will see thin bright lines of light scrolling from the top of the screen to the bottom, which is the scan beam moving across the field of view. Normally, the patient can look inside the imaging aperture for several minutes at a time without discomfort or tiredness. When scan acquisition starts, the patient may notice the thin, bright red lines of light scrolling more slowly and in some cases at a different angle.

☞ **Note: Instruct the patient to look at the center of the green target, and not at the moving lights (the scan beam).**

Acquire Scan

When you select **Acquire** in the previous screen, the ACQUIRE SCREEN appears. The example below shows a **Optic Disc Cube 200x200** scan.

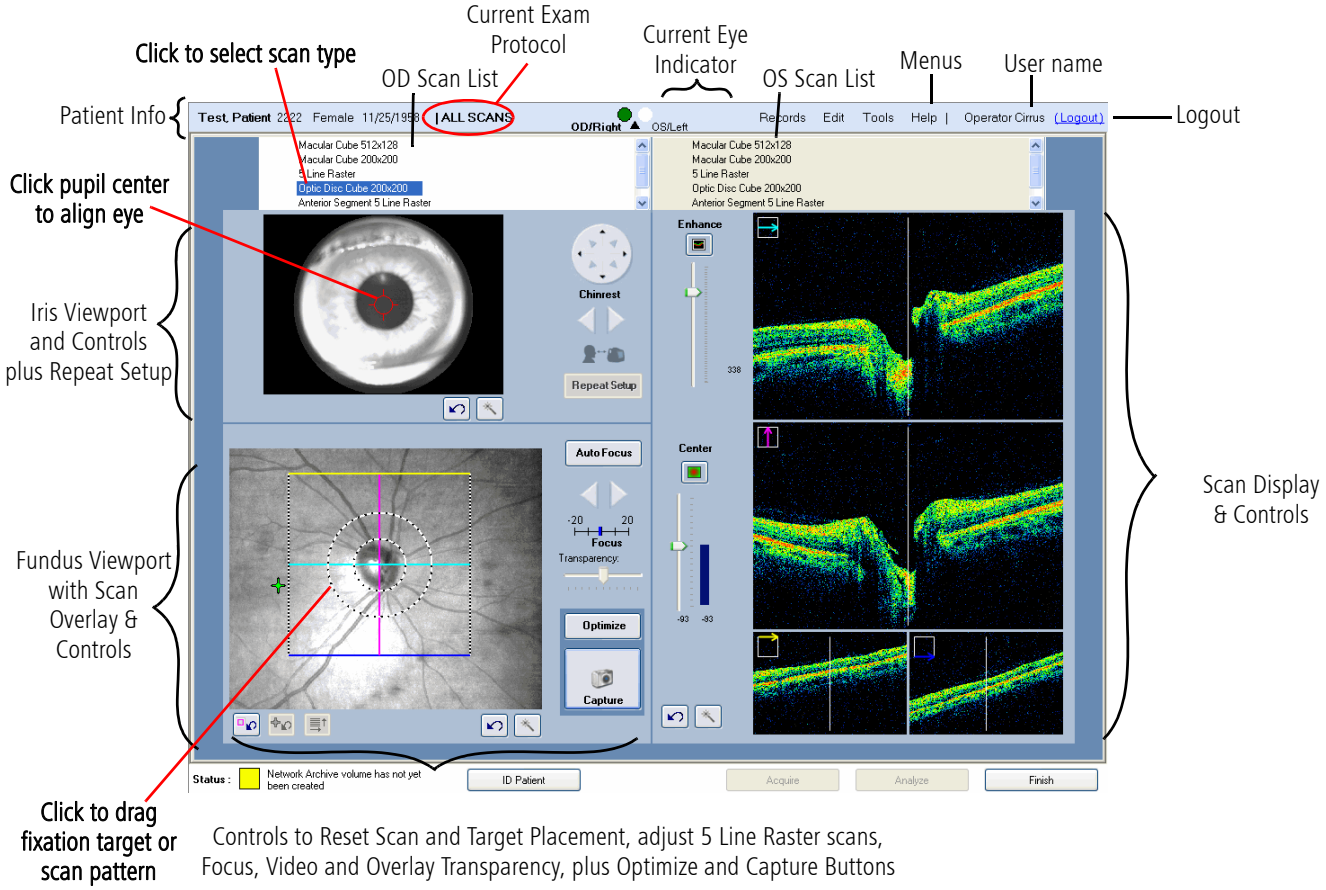


Figure 3-5 Sample Acquire Screen

All screen features are the same for all scan types, except that there will be five viewports in the scan display for the 5 Line Raster scan. Beneath the scan list, the screen is divided into three working areas:

- **The iris viewport** is at upper left, where you see a live video image of the iris and pupil. You use this to center the scan beam through the pupil by clicking on the pupil center and/or using the X-Y and Z controls to the right. (X means left and right; Y means up and down; Z means forward and back.) The circular X-Y control is for centering the pupil; it provides 8 directional options for moving the chinrest. The Z controls (left-right arrows or mouse scroll wheel) help you to reach the proper working distance by bringing the iris image into focus. The iris image must be in focus for the **Auto Focus** button in the fundus viewport to work properly.
- **The fundus viewport** is at the lower left, where you see a live fundus image from either the line scanning ophthalmoscope (LSO) on the Model 4000 or created using Live OCT Fundus Technology™ on the Model 400.
  The fundus view is overlaid with a box indicating the location of the scan pattern on

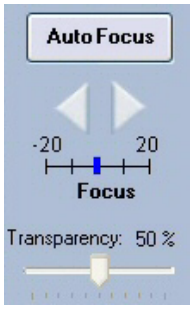
X, Y and Z Controls Explained

X, Y and Z refer to plane of motion.

X means left and right movement.

Y means up and down movement.

Z means forward and back movement.



the fundus and a small green cross indicating the location of the fixation target. (This green cross may be partially obscured by the scan overlay.) You can adjust the patient's fixation by moving the fixation target (for details, see step 2. under Place Scan Using Fundus Viewport on page 3-13). Click and drag the box to adjust scan placement. The **Auto Focus** button and Z controls (left-right **Focus** arrows) help you to focus the image. The **Transparency** slider is active when a saved scan image overlay is present, which occurs when you are using the Repeat Setup (see page 3-17) or the Repeat Scan Function (see page 3-18).

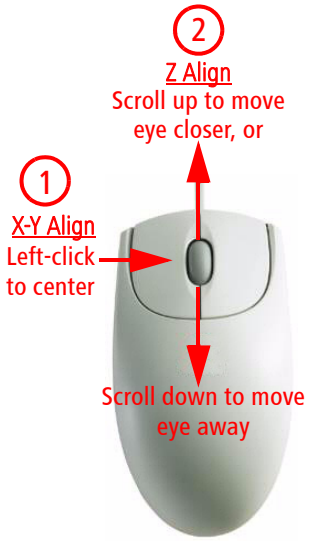
- **The scan display** is on the right. It has four viewports for the cube scan types, and five viewports for the 5 Line Raster. For cube scans, each viewport includes a color-coded scan marker at upper left, to identify each scan line. The color and orientation of each marker correspond to the color and orientation of the lines that make up the scan pattern overlay in the fundus viewport. The **Enhance** (polarization) and **Center** (Z-offset) buttons and sliders to the left help you improve the scan image quality and center it vertically.

Scan Display Left to Right Orientation

Left to Right Scan Display Summarized
For horizontal scans, left equals left and right equals right. For vertical scans, left to right equals bottom to top. For diagonal scans, left takes precedence over bottom.

Consistent with Stratus OCT™, Cirrus always displays left to right scan images as follows:

- For horizontal scans, left of scan equals left of scan display and right of scan equals right of scan display.
- For vertical scans, bottom of scan equals left of scan display and top of scan equals right of scan display.
- For diagonal scans in 5 Line Raster, left takes precedence over bottom, so that left of scan equals left of scan display and right of scan equals right of scan display.



Patient Setup

Ensure that the patient's chin and forehead rest comfortably in the chinrest and against the forehead fixture. Adjust table height (if available) for patient comfort.

Alignment Controls

Proper alignment of the scan beam to the pupil is required in three dimensions, X, Y (transverse) and Z (axial). Cirrus provides automated alignment controls by clicking on iris viewport, as well as manual controls both on-screen and via the keyboard (X-Y). We recommend you use the automatic controls primarily, applying them with the mouse, as illustrated. The manual controls are to be used secondarily, for fine-tuning the alignment when desired. The keyboard arrow controls correspond to the X-Y controls.

Tip: Clicking with the mouse scroll wheel acts like a left mouse click.

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

Align Eye Using Iris Viewport

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

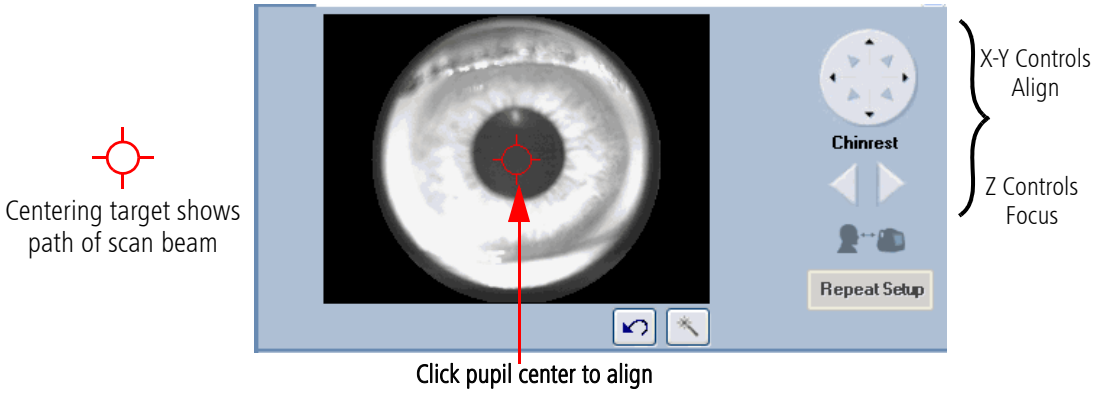


Figure 3-6 Iris viewport

3. Center the pupil in the iris viewport by clicking the center of the pupil. (Clicking anywhere in the iris viewport centers the field of view of the camera over the click point). The centering target overlays the video image. It remains in the center of the image and illustrates the path of the scan beam.

Note for the Model 4000 only: You may see a reflection of a rectangular band over the pupil, as seen in Figure 3-6 above. This artifact has no significance.

Repeat Setup Button: The **Repeat Setup** button is available if you have saved from a previous visit the same scan type for this patient and eye. Click **Repeat Setup** to repeat the chinrest alignment and other parameters used the last time you acquired this scan type on this patient and eye during a previous visit. This should get you close to the correct alignment for the current scan, although you still may have to make small adjustments. See Repeat Setup on page 3-17.

Options and Reset buttons

The iris viewport area has a pair of buttons. The **Options** button  opens to additional controls, which allow adjustment of the image settings for that viewport. These controls alter contrast (left vertical slider), brightness and illumination (right vertical slider). The area also has a **Reset** button  , which resets the chinrest position to default. The reset button within the options screen resets the contrast, brightness, and illumination.

Place Scan Using Fundus Viewport

1. **Focus fundus viewport:** The **Auto Focus** button will attempt to compensate for the patient's refractive error by automatically changing the focus adjustment. This may help clear up a dim fundus view and will also help clear up the fixation target for a patient whose refractive error is considerable. In addition to improving the overall focus, the Auto Focus feature will do an additional adjustment on the brightness and contrast of the fundus image.

   The focus arrows allow you to manually compensate for the patient's refractive error. Click the left arrow to add minus (-) power to compensate for myopic corrections; click the right arrow for adding plus (+) to compensate for hyperopic corrections. Asking the patient if the fixation target has cleared up after making a focus adjustment can help in some cases. When optimized, these focus settings will be retained and can be used in the future via the Repeat Setup button.

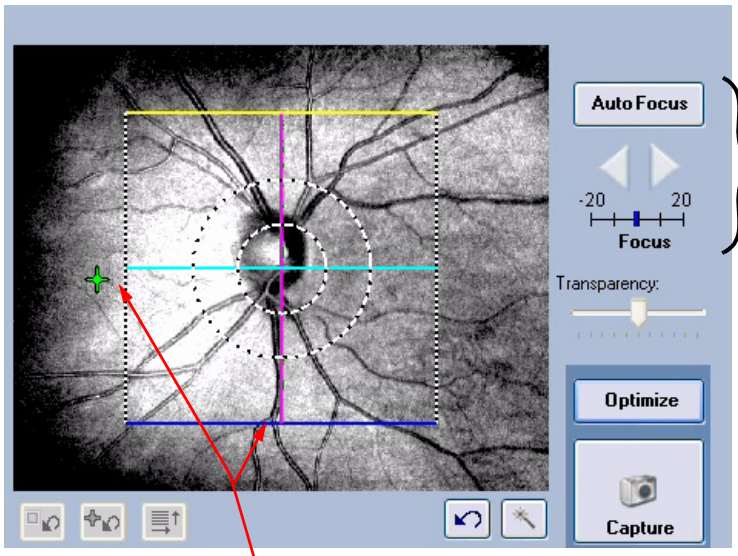


Figure 3-7 Fundus viewport

☞ Note: Ask the patient to hold their gaze and head steady during Auto Focus, as the chinrest assembly moves during this procedure. After Auto Focus, it may be necessary to check the Iris Viewport to ensure that the pupil is still centered. If the fundus viewport turns dark following Auto Focus, center the pupil, click  , then click the Auto B/C button. If additional brightness and contrast changes are necessary, use the appropriate slider controls (page 3-14).

When you mouse over the fixation target or the scan pattern, the cursor becomes a hand, indicating that you can click and drag to move it.

2. **(Optional)–Adjust scan pattern placement:** To do this, move the mouse so the cursor hovers over any lines of the scan pattern or the alignment target. The cursor will turn into a hand with a pointing finger. Hold the left mouse button down and drag the mouse to control the position of the scan pattern box. Release the mouse button to set the scan pattern in its new position. For the Model 400 instrument, when moving

the scan pattern box, the Live OCT Fundus Technology view also moves with the scan pattern box.

(Optional)–Adjust region of view: There are a number of ways to adjust the region of the fundus image visible within the fundus viewport. You can change the patient's fixation by either double-clicking anywhere on the fundus image to bring that point into the center of view, or click and drag the fixation target. In either case, instruct the patient to follow the fixation target, which has the effect of changing the region of view. It is desirable to center the area of interest in the field of view so that you always are scanning the deepest part of the bowl of the retina, which helps maintain the scan image in the vertical center of the display.

To reset either the scan pattern or the fixation target that had been moved from the default position, press the appropriate button below:

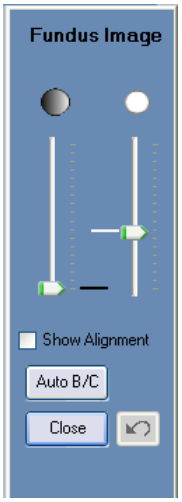
- Reset scan pattern
- Reset fixation target

☞ Note: If you adjust the scan pattern placement, check the OCT scan display at right to make sure that the retinal images are not too high in the viewport. When the edges of scan images are near the upper boundary, they tend to "fold over," reflecting a "mirror image" back into the viewport. If this occurs, or if the scan image is completely inverted, you must adjust the image using the **Optimize** button or **Center** controls. See Optimize the Scan Display on page 3-16.

☞ Note: For Optic Disc Cube 200x200 scans, it is not necessary to precisely center the optic disc in the scan image because the RNFL Analysis algorithm can correctly place the Calculation Circle around the optic disc even when it is not well centered. Though it is sufficient to keep the optic disc within the outer dashed circle, it is best to center the scan on the optic disc as well as possible.

Options and Reset buttons

The fundus viewport area has a pair of buttons. The **Options** button opens to additional controls, which allow adjustment of the image settings for that viewport. These controls alter contrast (left vertical slider) and brightness (right vertical slider). An example appears at the left for the fundus image. The area also has a **Reset** button, which resets the focus position to default. The reset button within the options screen resets the contrast and brightness.



In addition to the contrast and brightness controls, the fundus image options window also contains these features:

Select **Auto B/C** to have Cirrus automatically adjust the brightness and contrast levels of the fundus image.

An optional **Show Alignment** checkbox is available among the Fundus Image options. For either Macular Cube Scan, this checkbox toggles display of an alignment tool that is locked in position relative to the scan pattern; the alignment tool moves when you move the scan pattern and vice versa. This tool is designed to be placed over the optic

disc to assist in accurately repeating scan pattern placement for future scans of the same eye. For macular scans, placing the alignment tool over the optic disc results in the scan center being within 1 mm of the fovea for most patients. This tool is helpful when the fovea is difficult to find in extreme edema, cataract, or floater situations. For optic disc scans, the alignment tool is centered on the scan pattern and on by default.

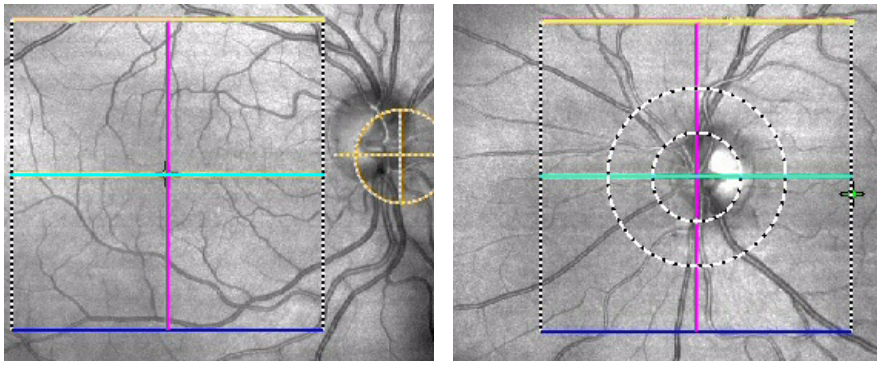
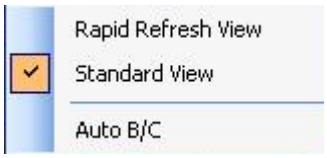


Figure 3-8 Fundus images showing alignment tools: Macula and Optic Disc

☞ Note for the Model 400 only:



The Live OCT Fundus Technology view can be seen in Figure 3-9. For patients with unsteady fixation, you may change the rate in which the screen refreshes by right-clicking on the image and highlighting the appropriate selection. When moving the scan pattern box, the Live OCT Fundus Technology view also moves with the scan pattern box. You may also select Auto B/C from the same right-mouse click menu as shown on the left.

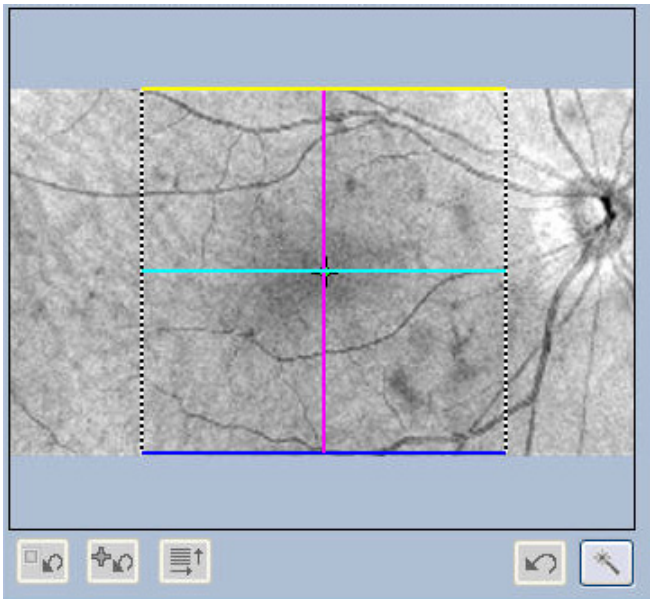
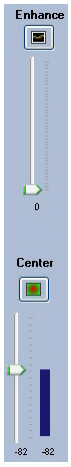


Figure 3-9 Standard viewport on the Model 400

Optimize the Scan Display

Click **Optimize**, just above the **Capture** button. This automatically optimizes first the scan image centering (Z-offset), and then optimizes the scan image quality (polarization). Instruct the patient not to blink during optimization.

If desired, you can use the **Center** and **Enhance** buttons to optimize each aspect independently. The associated sliders enable you to adjust each manually. Drag the sliders or click above or below them to move them in small increments.



Tip: The **Center** and **Enhance** buttons attempt to automatically find the optimal positions for Z-offset and polarization, respectively. Use **Center** first, since you must see the scan image before you can enhance it.

Options and Reset buttons

The scan display area has a pair of buttons. The **Options** button  opens to additional controls, which allow adjustment of the image settings for that viewport. These controls alter contrast (left vertical slider) and brightness (right vertical slider). The reset button within the options screen resets the contrast and brightness. The area also has a **Reset** button  , which resets the Center and Enhance settings to default.

Capture the Image

Briefly review the scan windows as described in Criteria for Obtaining Good Quality Cirrus HD-OCT Scans on page 3-24. Click **Capture**—or press **Enter** on the keyboard—to capture the images. The REVIEW SCREEN appears automatically to display the captured images.

Review Scan and Save or Try Again

Review the captured data to ensure it is of acceptable quality. See Review Screen on page 3-19 and Criteria for Reviewing Good Quality Cirrus HD-OCT Scans on page 3-25 for more information.

Note: Besides the observed image quality, an important element of acceptable quality is the Signal Strength indicator, which should be 6 or higher.

Note: Signal strength and image quality can be significantly reduced when the imaging aperture (the lens) is dirty or smudged. If you suspect this problem, follow the instructions to clean The Imaging Aperture (page 9-6).

If the captured scan is of good quality, click **Save** and continue. (You will return to the ACQUIRE SCREEN to acquire another scan, if desired.) If it is not, click **Try Again** to return to the ACQUIRE SCREEN.

When you are finished acquiring scans, click **Finish** in the ACQUIRE SCREEN. You will return to the ID PATIENT SCREEN.

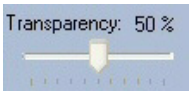
Repeat Setup

The **Repeat Setup** button is available if you have saved the same scan type for this patient and eye on a previous visit. Click **Repeat Setup** to repeat the parameters of the *last saved scan* of the currently selected type and eye *from a previous visit.* The Repeat Setup function enables you to repeat all the relevant parameters from the previously acquired scan for this patient. The repeated parameters include chinrest alignment, scan pattern and fixation target placement, Enhance (polarization) and Center (z-alignment) settings, focus, brightness, contrast and illumination settings.

You cannot use Repeat Setup to repeat a scan you have saved today, nor to repeat a scan type and eye other than those currently selected. The Repeat Scan Function on 3-18 offers these options, enabling you to select any previous scan of any type to repeat.

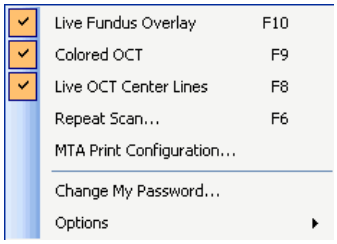
When you click **Repeat Setup**, it takes a few moments for the chinrest to move and all parameters to be applied. Repeat Setup should get you close to the correct alignment for the current scan, although you still may have to make small adjustments. To help you do so, the saved OCT fundus image from the scan you are repeating appears inside the scan pattern box.

Repeat Scan Alignment Using Saved Scan Overlay



When you are repeating a scan, the saved OCT fundus image of the scan you are repeating is overlaid in the scan pattern box on the live fundus image, to help you align the current scan with the one you are repeating. The **Transparency** slider activates when you are repeating a scan, so you can adjust the transparency of the overlay and view the correspondence of the underlying live fundus image with the saved overlay. You may need to increase the overlay transparency to see the fixation target location.

Repeat Scan Function



When you reach the ACQUIRE SCREEN for any patient with previous scans in the Cirrus database, the **Repeat Scan...** option becomes available in the **Tools** menu. Click **Tools > Repeat Scan...** or press **F6** on the keyboard to open the Repeat Scan dialog, where you can select a scan to repeat.

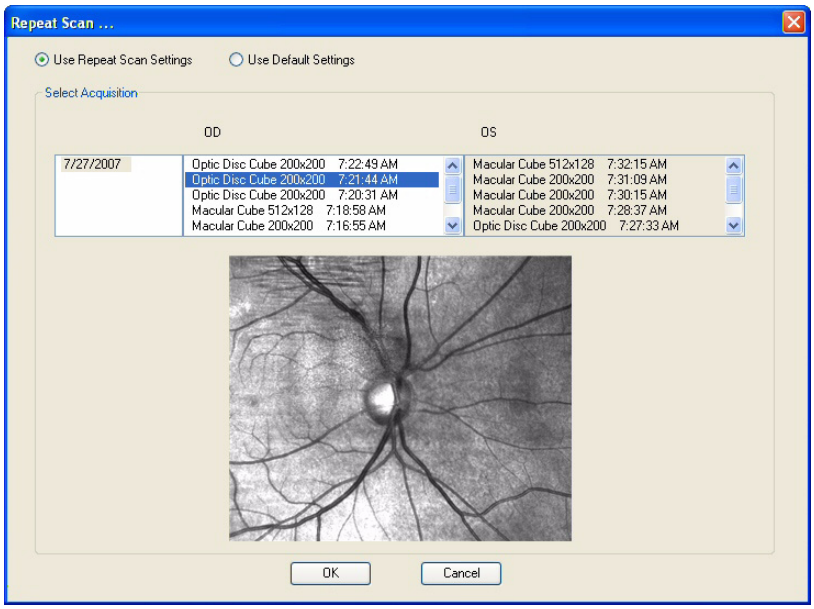


Figure 3-10 Repeat Scan dialog

The Repeat Scan dialog lists all previous scans for this patient by exam date and eye and shows the fundus image for the scan you select. This is especially useful when a scan had been taken away from the central fixation area or if a patient had been scanned previously with a Macular Cube 200x200 scan but now will be scanned using the Macular Cube 512x128 scan. The previous Macular Cube 200x200 scan can be used as reference in this manner whereas it could not be referenced via the Repeat Setup button.

Click **OK** to return to the ACQUIRE SCREEN and apply the parameters of the scan you selected to repeat. It takes a few moments for the chinrest to move and all parameters to be applied. You can use the repeated parameters as a starting point for further adjustments you may wish to make.

Review Screen

After you acquire a scan, the REVIEW SCREEN appears. The REVIEW SCREEN format depends on which scan type you have acquired.

Review Screen for Cube Scans

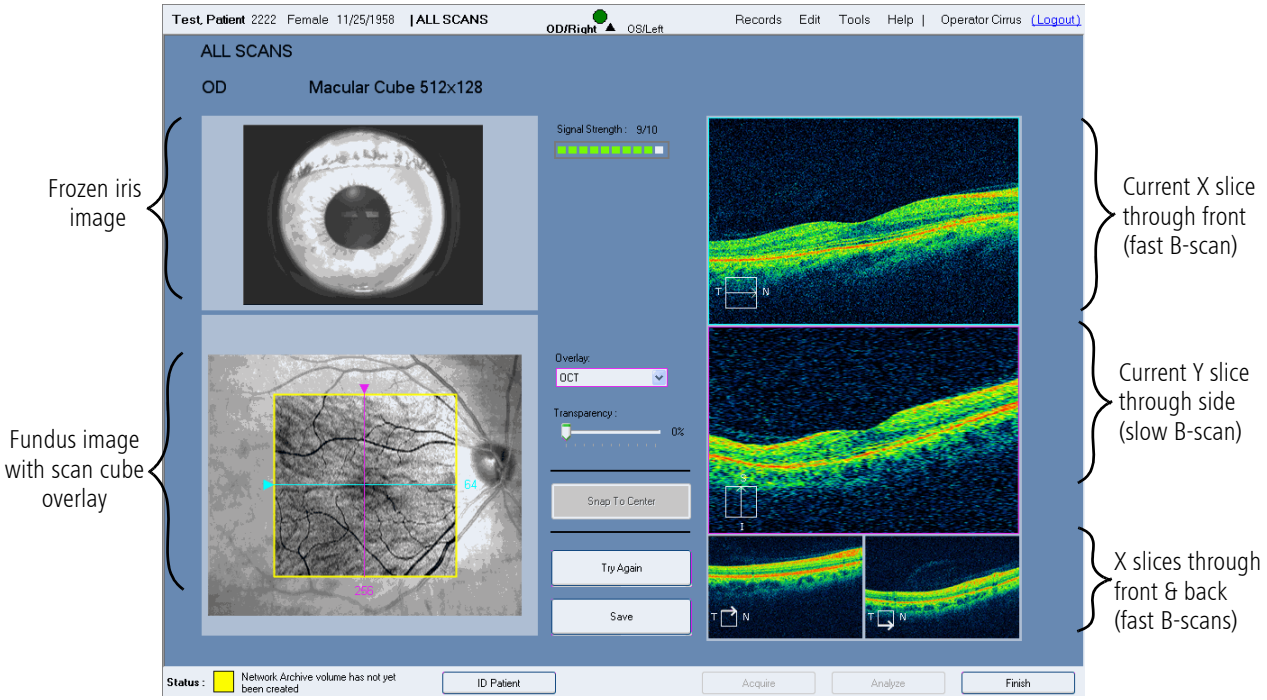
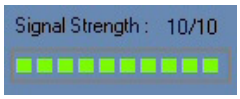
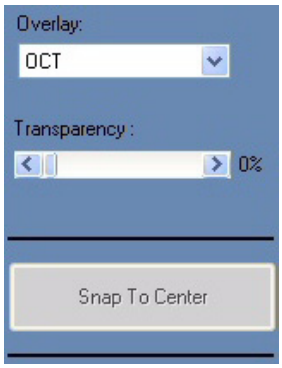


Figure 3-11 Review Screen for cube scans

For cube scans, the REVIEW SCREEN presents the captured iris and fundus images, along with an interactive multi-planar reformat (MPR), which enables you to view image cross-sections through two dimensions. The exam protocol (ALL SCANS) appears at top left, with the eye and name of the scan type below it. The example above is for a **Macular Cube 512x128**.



- **Signal Strength Indicator:** This appears in the center near the top. It ranges from 0-10, with 10 being maximum signal strength. When values are less than 6, the indicator color is red (below acceptable threshold); when 6 or higher, the color is green (acceptable).



Note: The Signal Strength indicator applies to the scan as a whole.

- **Overlay Options:** You can select **OCT** (default) or **None** in the **Overlay** drop-down menu. The OCT overlay is an *en face* OCT scan image of the scanned area. (*En face*, from the French, means literally, "on the face;" that is, looking directly into the eye, which is the same perspective as the fundus image.)
- **Transparency Slider:** The **Transparency** slider is present when the **OCT** overlay is selected. Use the **Transparency** slider to adjust the transparency of the overlay. Default is 0% transparency (opaque); 100% is fully transparent.

- **Snap To Center Button:** The **Snap to Center** button is present when the **OCT** overlay is selected. Click **Snap to Center** to return the slice navigators (see below) to their default central positions.

Reviewing Image Data using Multi-Planar Reformat (MPR)

- **The viewports are interactive:** Click and drag the triangles or click on a scan viewport and use the mouse scroll wheel to "move through" the active plane of the viewport; you will see the resulting cross-sections update simultaneously in the other viewports. This functionality enables you to quickly search through the data cube and stop when you see an area of interest.

  The upper left viewport shows the frozen iris image, while the lower left shows the fundus image with the high definition en face scan image overlay that shows the area scanned. Note that the Model 4000 instrument displays the LSO fundus image, while the Model 400 instrument displays the captured Live OCT Fundus Technology image.

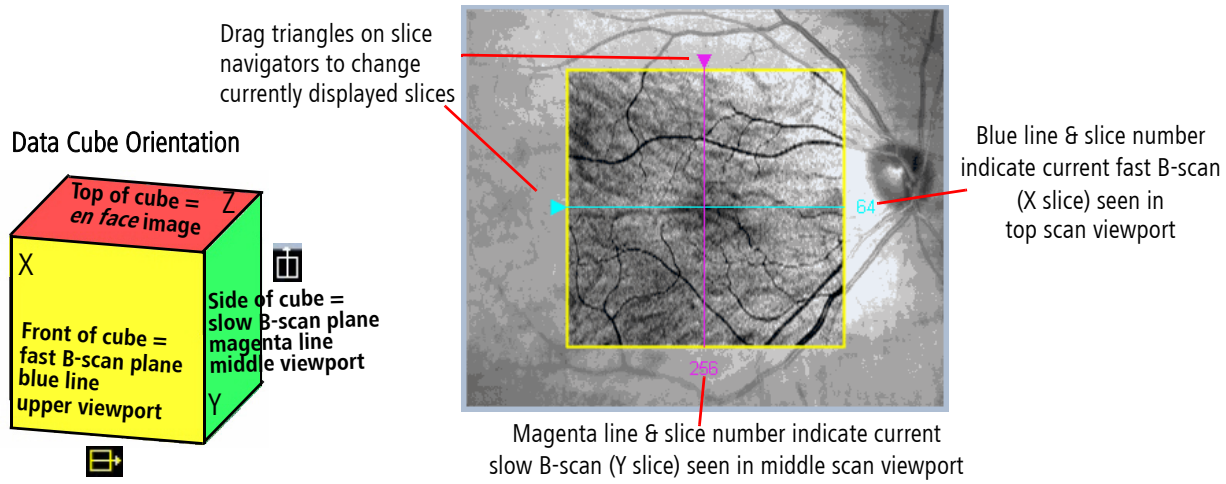


Figure 3-12 Fundus Image with Overlay in Review Screen

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

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

En Face Explained

En face, from the French, means literally, "on the face;" that is, looking directly into the eye, which is the same perspective as the fundus image.

slowly, one per line of horizontal A-scans, in comparison to the fast B-scans. The smaller, bottom two scan viewports are static and show the front and back X slices of the cube.

Scan Display Left to Right Orientation

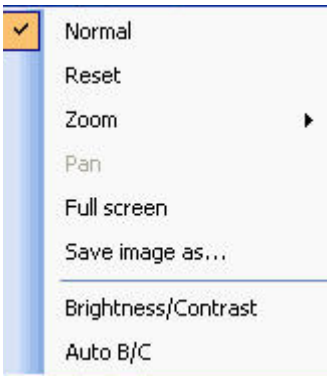
Left to Right Scan Display Summarized
For horizontal scans, left equals left and right equals right. For vertical scans, left to right equals bottom to top. For diagonal scans, left takes precedence over bottom.

Consistent with Stratus OCT™, Cirrus always displays left to right scan images as follows:

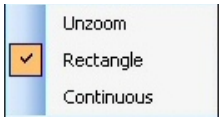
- For horizontal scans, left of scan equals left of scan display and right of scan equals right of scan display.
- For vertical scans, bottom of scan equals left of scan display and top of scan equals right of scan display.
- For diagonal scans in 5 Line Raster, left takes precedence over bottom, so that left of scan equals left of scan display and right of scan equals right of scan display.

Image Display Options During Review

Right-click on the fundus image, on its overlay, or on a scan image to access the image display options seen in the menu at left, or a subset of them. A checkmark indicates when an option is selected.



- **Normal:** Selected initially, clicking **Normal** exits other display-change modes, and thereby fixes or freezes the changes you have made to that point.
- **Reset:** Resets the current display to default settings.
- **Zoom:** Gives access to the following options:



  - **Zoom/Unzoom** (toggle)
  - **Rectangle:** When selected, click and drag to select a rectangular area to fill the screen.
  - **Continuous:** When selected, click and drag up to increase the zoom; click and drag down to decrease the zoom.
- **Pan:** This option is present only when the image is zoomed. When selected, click and drag the image to view other parts of it.
- **Full screen:** Select to view the image in full screen.

Tip: You can also double-click any image to open it in full screen. Double-click a full-screen image to return to normal view.

- **Save image as...:** Saves the current image on screen in the location you select.
- **Brightness/Contrast:** When selected, the brightness (B) and contrast (C) values appear numerically on the image; moving the cursor horizontally changes the contrast (noise) and vertically changes the brightness (OCT color range). They also work in combination when you move the mouse diagonally.
- **Auto/BC:** Optimizes brightness and contrast settings of the fundus view.

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

☞ Note: **Brightness/Contrast** and **Color** adjustments apply simultaneously to all scan viewports. Between the fundus image and its overlay, **Brightness/Contrast** and **Color** operate independently. Right-click on one or the other to apply such changes. Some options function as a distinct display mode and that viewport or overlay remains in that mode until you click **Reset, Normal** or select another mode.

- For example, if you select Brightness/Contrast for one viewport, the brightness and/or contrast changes every time you click and drag your mouse over that viewport, until you select Normal. Note that selecting Normal would not reset the viewport to its initial brightness and contrast settings. You must press Reset to return to the original Brightness and Contrast settings.
- Brightness/Contrast values adjusted in scan review for both fundus and OCT images are saved and later used when displaying those images during analysis. Note: Cirrus may override adjusted extreme values that could compromise image quality by saving default values.
- When you enter the acquisition screen, Brightness/Contrast for both fundus and OCT images are set to a default values. These values may be adjusted manually or by Auto Focus and Auto B/C (fundus viewport only), as desired, remaining in effect while viewing this particular patient. As soon as you select another patient, Brightness/Contrast reverts to default values.

☞ Note: Additional right-click menu options are available when viewing saved images in Analyze mode. See Image Display Options During AnalysisHigh Definition Image Analysis – 5 Line Raster on page 4-11 for details.

Fundus Image, Overlay and Scan Image Options

☞ Note: Not all display options apply to every kind of image, and in these cases they are not available. For example, **Movie** does not apply to the fundus image or its overlay, since these are single images. For more information on the Movie option, see Image Display Options During Analysis on page 4-11.

Review Screen for 5 Line Raster Scan

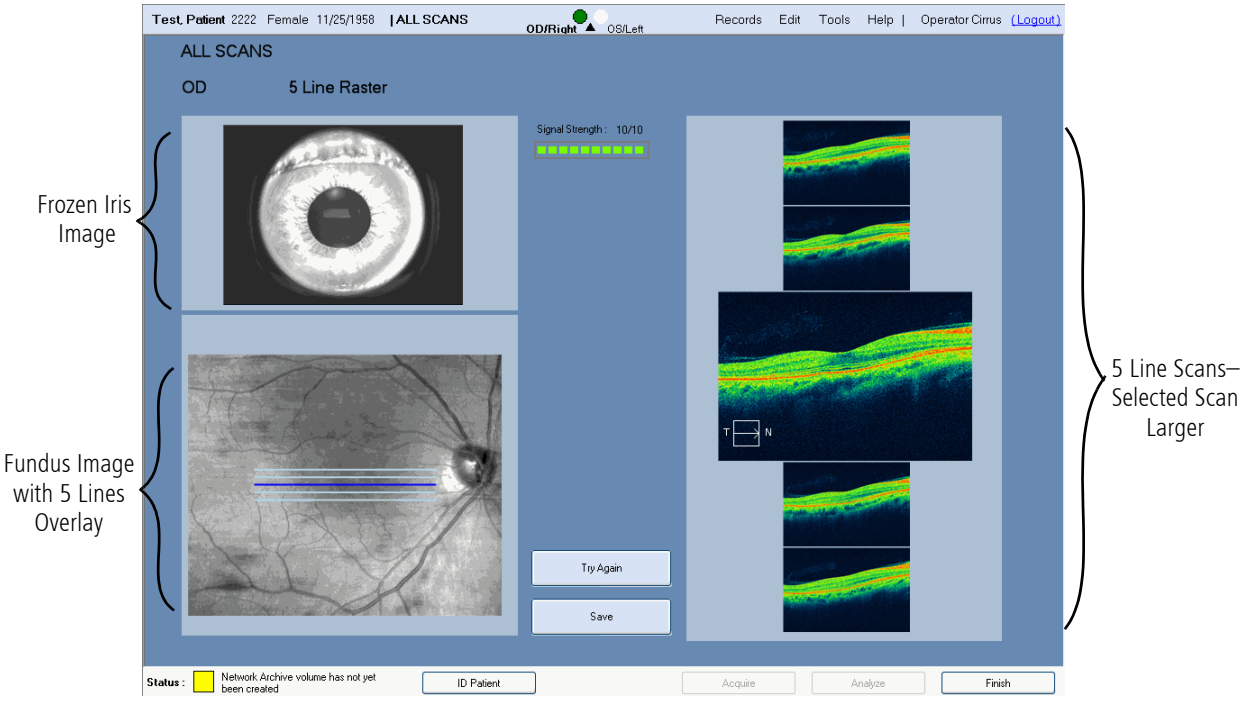
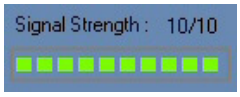


Figure 3-13 Review Screen for 5 Line Raster Scan

For the 5 Line Raster scan, the REVIEW SCREEN presents the frozen iris and fundus images, along with all five lines of the scan. The exam protocol (ALL SCANS) appears at top left, with the eye and name of the scan type below it. The upper left viewport shows the frozen iris image, while the lower left shows the fundus image with a scan image overlay that shows the placement of the 5 line scans with the currently selected line in blue. The five viewports on the right show each of the line scans from top to bottom. The center viewport (third line) is seen in larger view, by default. When you click any of the smaller scan images, it becomes the largest so you can view it in more detail.



- **Signal Strength Indicator:** This appears in the center near the top. It ranges from 0-10, with 10 being maximum signal strength. When values are less than 6, the indicator color is red (below acceptable threshold); when 6 or higher, the color is green (acceptable).

☞ **Note: The Signal Strength indicator applies to the scan as a whole.**

☞ **Note: Signal strength and image quality can be significantly reduced when the imaging aperture (the lens) is dirty or smudged. If you suspect this problem, follow the instructions to clean** The Imaging Aperture **(page** 9-6**).**

The applicable image display options are available—see Image Display Options During Review on page 3-21 for details.

Save Scan or Try Again

The purpose of the REVIEW SCREEN is for you to evaluate the scan image quality, whereupon you can either save the scan or delete it and try again:

- To save the scan, click **Save** (or press **Enter** on the keyboard). You will return to the ACQUIRE SCREEN, where Cirrus marks the scan as complete with a checkmark on the left, and puts a number on the right showing how many of that scan you have saved.

  Or

- Click **Try Again** (or press the **Esc** key on the keyboard) to delete the captured images and return to the ACQUIRE SCREEN to capture another scan using the same scan type.
- If you click **Finish** without saving first, a prompt will appear asking you if you want to save before returning to the ACQUIRE SCREEN.

Criteria for Obtaining Good Quality Cirrus HD-OCT Scans

Before capturing an image, follow these guidelines to optimize image quality.

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

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

3. The OCT scan:
   - Center the OCT scan in the mid to upper part of the scan acquisition screen.
   - The OCT B-scan should be complete in all windows without missing data.
     - A tilted retina may be corrected for by moving the pupil alignment off-center to allow for a more level OCT scan.
   - Adjust the enhancement setting to achieve the brightest and clearest scan.

Criteria for Reviewing Good Quality Cirrus HD-OCT Scans

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

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

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

(4) Analyze Scans: Macula

Chapter Overview

This chapter explains how to use the macula analysis portion of Cirrus HD-OCT software. Topics covered in this chapter include:

Access Analysis

To access analysis, click the **Analyze** button when it is active; it is active when a patient record with saved exams is selected or is open. Usually you will access it after selecting a patient from the ID PATIENT SCREEN. When you click the **Analyze** button, the ANALYZE SCREEN appears (see Figure 4-11 on page 4-20). Initially it shows four columns near the top, which list:

- the patient's exams by date (left column), with the most recent exam date selected by default;
- for the selected exam, the right eye OD scans (center left column) and left eye OS scans (center right column) by scan type;
- the column on the right where you can select among available analyses for the selected scan type, after you select a scan.

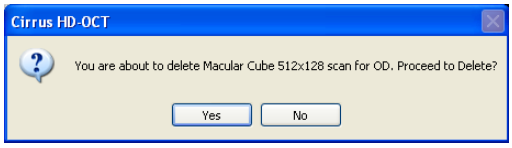
The image display portion of the screen is blank until you select a scan from the OD or OS column and then select the desired analysis. Click to select any scan from the OD or OS list, and click the corresponding analysis at the right. The images will appear in the image screen below, after a few seconds.

The ANALYZE SCREEN enables you to view and measure anatomical structures depicted in the scan images. Cirrus HD-OCT provides the following analyses for the macula:

- Macular Thickness Analysis for macular cube scans, page 4-3
- Macular Change Analysis for cube scans, page 4-14
- Advanced Visualization for cube scans, page 4-20
- High Definition Image Analysis – 5 Line Raster for optic disc cube scans, page 4-29

Analyze Screen Common Functionality

The following information applies to the ANALYZE SCREEN in general, independent of the type of scan you are viewing.



- **Delete Scan button:** Click the **Delete Scan** button to delete the currently selected scan. A dialog will prompt you to confirm your choice, as shown on the left.
- **Print button:** Click **Print** to initiate printing. You can print to paper, create a PDF, or export a number of image types, including PDF, TIFF, and JPEG to name a few. See Reports and Printing on page 4-30 for details.
- **Save Analysis button:** Click **Save Analysis** to save the current analysis with the changes currently applied. The next time you open this analysis on the same scan, the saved analysis will appear initially. You can discard saved changes at any time and return to the original analysis by using the **Discard Changes** button.
- **Discard Changes button:** Click **Discard Changes** to reload the original analysis, discarding all changes previously saved.

Left to Right Scan Display Summarized
For horizontal scans, left equals left and right equals right. For vertical scans, left to right equals bottom to top. For diagonal scans, left takes precedence over bottom.

Scan Display Left to Right Orientation

Consistent with Stratus OCT™, Cirrus always displays left to right scan images as follows:

- For horizontal scans, left of scan equals left of scan display and right of scan equals right of scan display.
- For vertical scans, bottom of scan equals left of scan display and top of scan equals right of scan display.
- For diagonal scans in 5 Line Raster, left takes precedence over bottom, so that left of scan equals left of scan display and right of scan equals right of scan display.

Retinal Layers Automatically Detected and Displayed

- Cube scan analyses incorporate an algorithm to automatically find and display the inner limiting membrane (**ILM**) and the retinal pigment epithelium (**RPE**).

  In the scan images, which are cross-sections (slices), the layers appear as colored lines that trace the anatomical feature on which they are based. The ILM is represented by a white line, the RPE by a black line. These lines are also known as segmentation lines. These layers serve as the basis for the macular thickness and volume measurements in the Macular Thickness Analysis (see page 4-3). In the Macular Thickness Analysis, the ILM and RPE layers are presented in their entirety as three-dimensional surface maps.

  Show/Hide Layers button: Click **Layers** to hide or show the colored lines indicating the ILM and RPE layers.

Macular Thickness Analysis

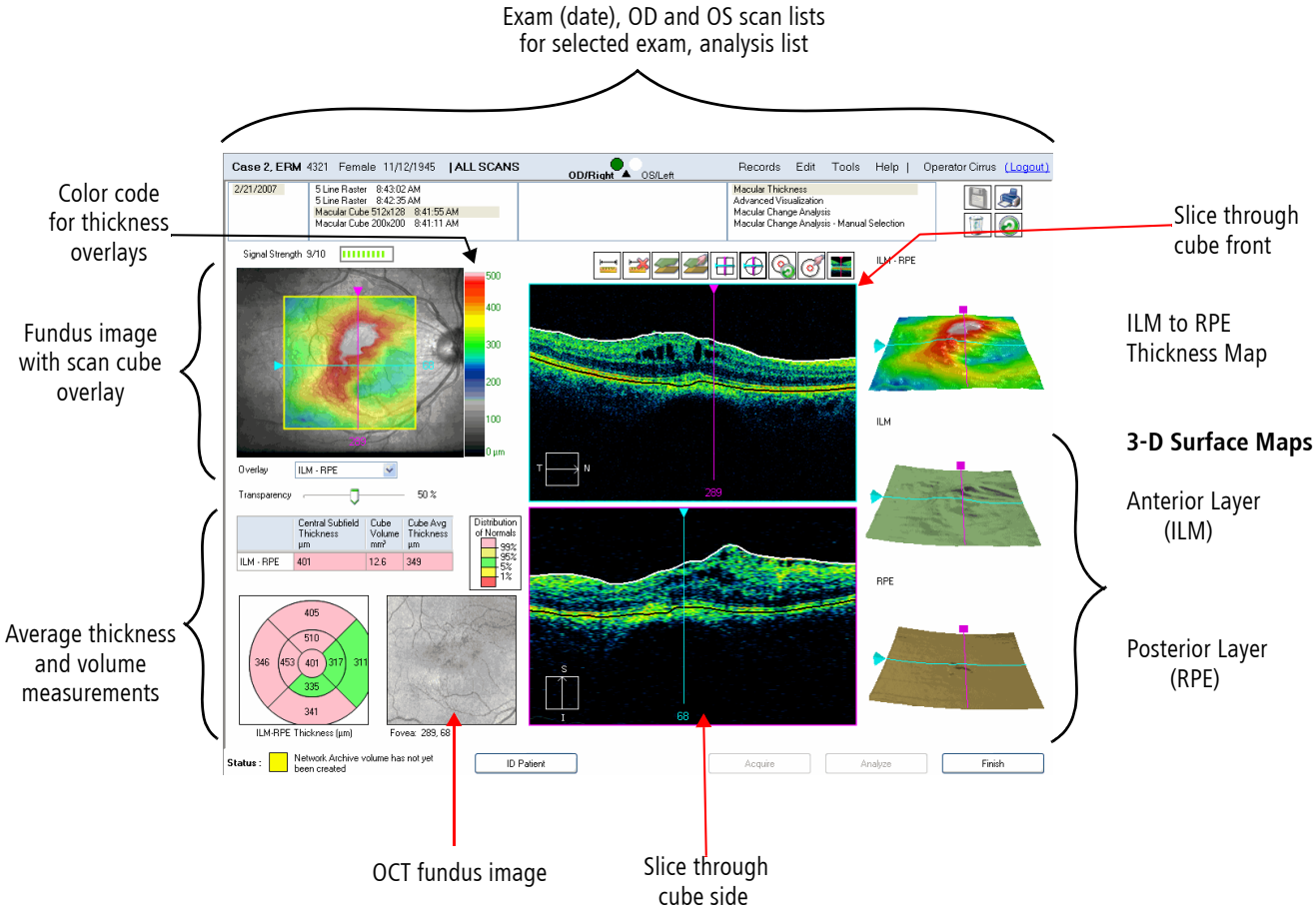


Figure 4-1 The Analyze Screen for Macular Thickness

The Macular Thickness Analysis (MTA) provides interactive scan images as well as the fundus image with scan cube overlay. To see this analysis after selecting a cube scan, select Macular Thickness from the list on the right. The default screen, shown in Figure 4-1 displays:

- the identified fovea location.
- the fundus image with scanned cube overlay or colored thickness map.
- the ETDRS grid map with normative data.
- a table containing average thickness and volume measurements.
- a colored 3-D thickness map.
- 3-D surface maps of the ILM and RPE.

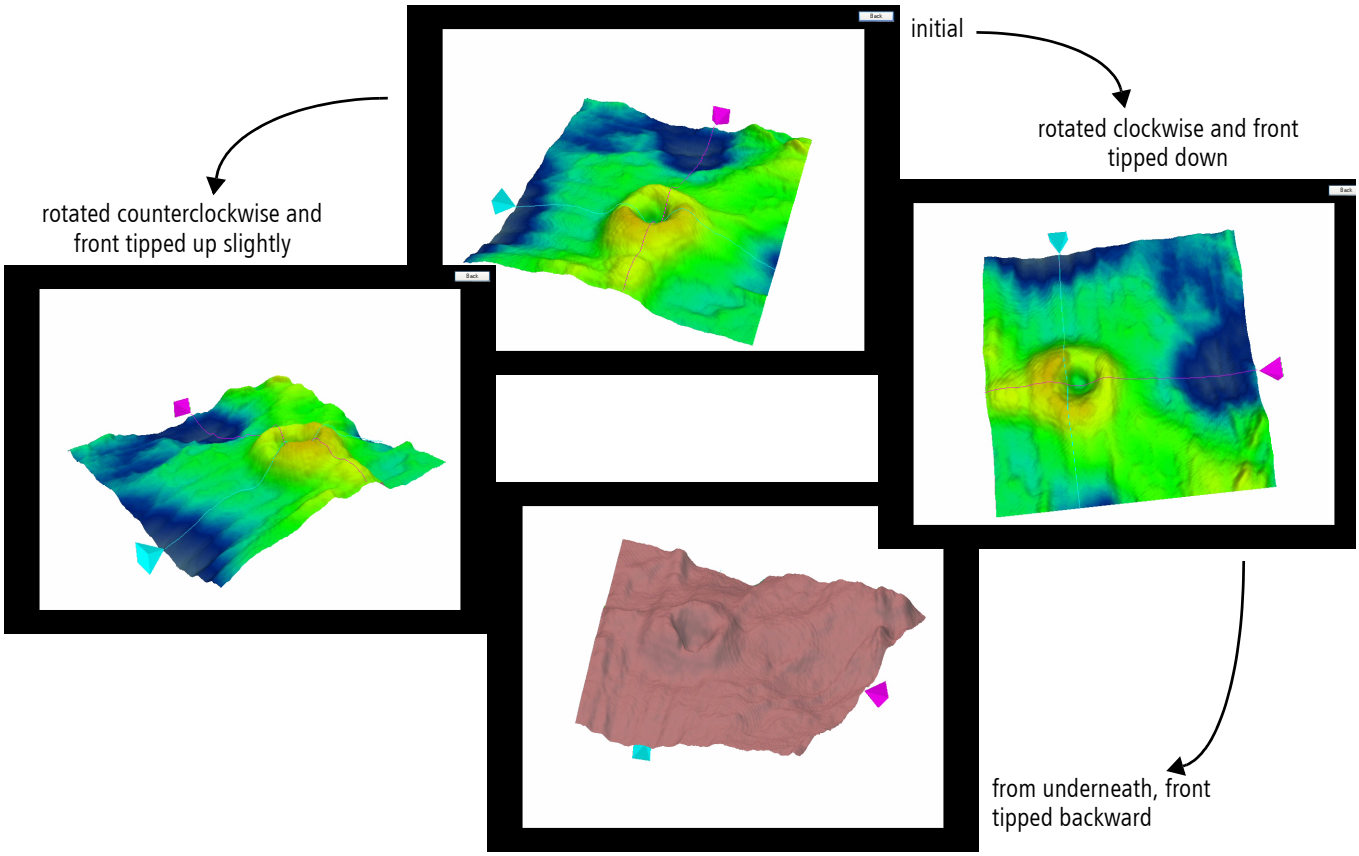
You may also manipulate the fovea location on this screen, which will update the data table and the ETDRS grid thickness measurements.

3-D Surface Maps

ILM = inner limiting membrane
RPE = retinal pigment epithelium

Interactive three-dimensional (3-D) surface maps appear down the right side. The top map displays the thickness between the ILM and RPE as a color coded three-dimensional surface. The middle map shows the upper (anterior) of the two layers, the ILM. The lower map shows the lower (posterior) of the two layers, the RPE.

- **The surface maps are fully interactive.** Click and drag to rotate a map in any direction and thereby view it from any perspective. The maps include the same slice navigators you are accustomed to seeing on the scan images and fundus overlay. As usual, you can click and drag each line to change the currently selected slices and the corresponding scan image updates immediately. You can double-click a map to view it in full screen (or right-click and select **Full screen)**. As in normal view, you can rotate full screen maps in three dimensions.



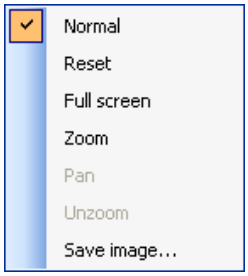
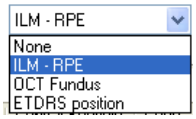


Figure 4-2 Same full screen 3-D surface map, showing rotated views

- **Right-click display options for 3-D surface maps.** Right-click on a 3-D surface map to access the display options at left, which function as in other contexts. See High Definition Image Analysis – 5 Line RasterImage Display Options During Analysis on page 4-11 for details.

Fundus Image Overlay Options



By default, the fundus image overlay displays **ILM - RPE,** where you view on the fundus image a corresponding (in terms of color) thickness representation from above (*en face*) as appears on the contoured thickness map to the right. The drop-down menu below the fundus image gives you the following options: **None, ILM - RPE, OCT Fundus,** and **ETDRS Position.** Use the **Transparency** slider below the drop-down menu to adjust the transparency of the overlay.

En Face Explained

En face, from the French, means literally, "on the face;" that is, looking directly into the eye, which is the same perspective as the fundus image.

Numerical Average Thickness and Volume Measurements

The area at lower left presents average thickness and volume numerically.

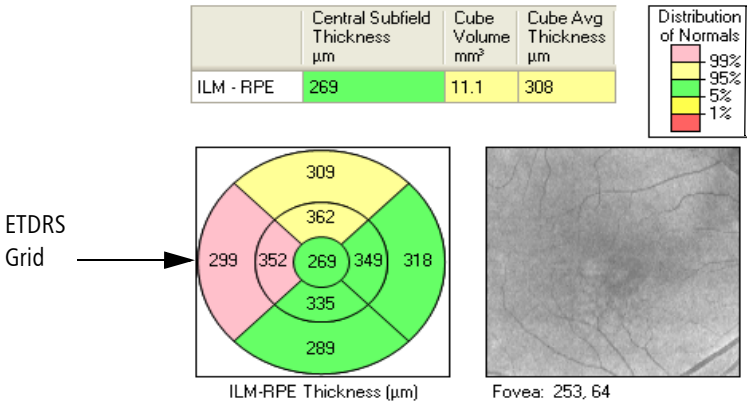


Figure 4-3 Numerical average thickness and volume information

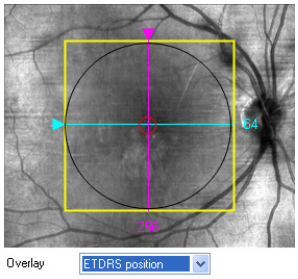
It includes a table with central subfield thickness for the central circle of the circular map known as the ETDRS Grid, and total volume and overall average thickness for the **ILM - RPE** tissue layer over the entire 6 x 6 mm square scanned area. The ETDRS Grid shows overall average thickness in nine sectors. This circular map is composed of three concentric circles with diameters of 1 mm, 3 mm and 6 mm, and except for the central circle, is divided into superior, nasal, inferior and temporal quadrants. The central circle has a radius of 500 micrometers (1 mm diameter). The OCT fundus image to the right shows the surface of the area over which the individual thickness measurements were made that contribute to the subfield averages.

Automatic Fovea Identification

This feature is active in the Macular Thickness Analysis and the Macular Change Analysis. Cirrus identifies the fovea location automatically by looking for the reduced reflectivity below the retina. When the analysis screen first comes up, the fovea location has been determined and is indicated by the overlay position, the position of the slice navigators in the cube, and on the 3-D surface maps. The ETDRS grid in Figure 4-3, shows the values, in micrometers (µm), of the ILM-RPE thickness, calculated as described above. You can change the position of the ETDRS grid. If you change it, the reported values also change. The position of the fovea and the center of the ETDRS grid is shown below the grid. In the example above, the fovea is located at the intersection of slice 253 and 64.

If Cirrus cannot identify a fovea in the scan, it reports: "Fovea not found." In this case, the center of the scan is used for the initial placement (position 256 and 64 for 512x128 scans and position 100 and 100 for 200x200 scans). It is also possible for the algorithm to find a depression in the reflectivity around the ILM that is not related to the fovea – in this case, the reported fovea will be wrong. In both of these cases, the user can set the fovea manually using the buttons described below. The most common pathologic conditions that cause failure of the fovea-finding algorithm are those that cause the greatest disturbance of the foveal architecture, such as AMD, other causes of macular edema, and proliferative diabetic retinopathy. Epiretinal membranes and other vitreoretinal interface disorders where the vitreoretinal interface becomes distorted can also cause the algorithm to fail.

If the fovea is very far from the center, the algorithm may fail to find it. In order to ensure that the fovea is within a reasonable distance of the center, it helps to use the alignment tool during acquisition (see Place Scan Using Fundus Viewport, on page 3-13 and Options and Reset buttons on page 3-14). It also helps for subsequent visits to use the Repeat Setup and Repeat Scan Alignment feature (see Repeat Setup on page 3-17 and Repeat Scan Alignment Using Saved Scan Overlay on page 3-17).



Working with Scan Cube Overlays

In the ILM-RPE overlay, the colors on the overlay correspond to the color-coded side bar scale on the right. The colors denote retinal thickness in micrometers (µm).

When ETDRS Position is selected from the overlay menu, a small red circle appears centered around the Cirrus-calculated fovea position. This calculated ETDRS Grid position can be repositioned by clicking and dragging the circle using the mouse.

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

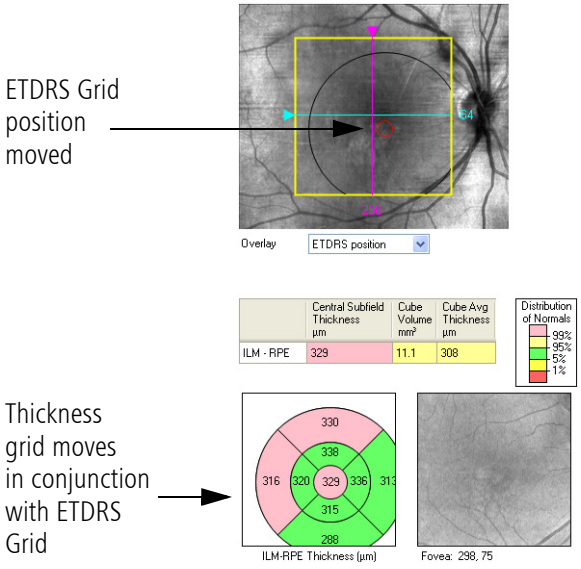


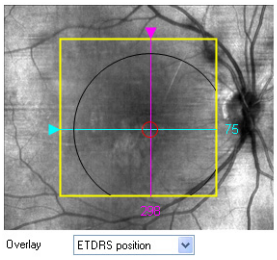
Figure 4-4 Thickness Grid Movement

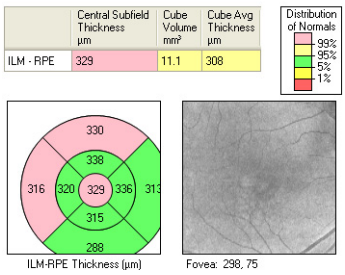
Interactive function buttons for ETDRS include:

- **Snap slice navigators to ETDRS Grid center position:** 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.
- **Set ETDRS Grid center to slice navigator position:** Moves the ETDRS Grid center to the center defined by the slice navigators position.
- **Snap to Center:** Moves slice navigators to the center of the 6x6 mm square.

These tools can be used to establish a new ETDRS Grid position after adjusting the position with the slice navigator in any of the various screen options. Also, as you adjust the ETDRS Grid position, the thickness grid also reflects the new values associated with the new setting. To save the new fovea position for future analysis, click on the **Save** button in the upper right-hand corner of the screen.

This interactive analysis screen gives you several options to view patient data. For example, when you move one of the slice navigator bars and then select , the thickness grid reflects that change as the grid moves and the values change. Select to move the ETDRS Grid back to its original location. Select to move the slice navigators to the ETDRS Grid center.





Use the button tools to line up the slice navigators with ETDRS Grid position and vice versa. For example, manually drag the ETDRS Grid to a new position on the overlay, then:

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

Now move the slice navigators to a new position, as shown in Figure 4-5. The ETDRS Grid position does not change, nor does the thickness grid position.

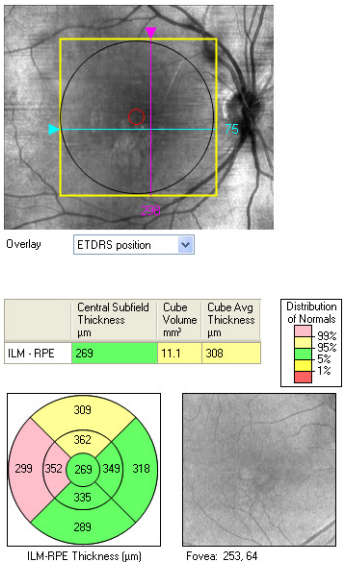
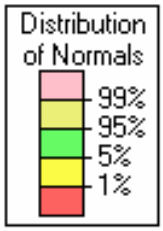


Figure 4-5 No Movement of Thickness Grid

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

Macula Normative Database



The Macular Thickness Analysis supports the clinician in identifying areas of the macula that may be of clinical concern by comparing the measured macular thickness to age-matched data in the Cirrus Macula Normative Database[1]. Normative data that is age-matched to the patient appears when you perform a Macular Thickness analysis on patients at least 18 years old. Data was not collected from subjects less than 18 years old.

The Normative Database uses a color code, as seen in the legend at left, to indicate the normal distribution percentiles. The color code applies to the ETDRS grid average thickness values and the data table (see Figure 4-10 above).

Among same-age individuals in the normal population, the percentiles apply to each particular retinal thickness measurement as follows:

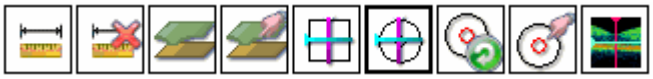
- The thickest 1% of measurements fall in the light red area. Measurements in light red are considered outside normal limits. (light red > 99%, above normal limits).
- The thickest 5% of measurements fall in the light yellow area or above (95% < light yellow ≤ 99%, suspect above normal)
- 90% of measurements fall in the green area (5% ≤ green ≤ 95%).

1. The Macula Normative Database is an optional feature that may not be activated on all instruments. If you do not have this feature and want to purchase it, contact Carl Zeiss Meditec. In the U.S.A., call 1-877-486-7473; outside the U.S.A., contact your local Carl Zeiss Meditec affiliate or distributor.

- The thinnest 5% of measurements fall in the yellow area or below (1% ≤ yellow < 5%, suspect below normal).
- The thinnest 1% of measurements fall in the red area. Measurements in red are considered below normal limits (red < 1%, below normal limits).

☞ **Note: Clinicians must exercise judgment in the interpretation of the macula normative data. For any particular measurement, note that 2 out of 20 normal eyes (10%) will fall either above or below green.**
Interpretation of the 1st Percentile: Values color-coded as "1st percentile" are lower than 99% of the database sample, but may not extrapolate well to the general population with less than 300 subjects in the reference database. Results falling in this region should be interpreted with caution.
Interpretation of the 5th Percentile: Values color-coded as "5th percentile" are lower than 95% of the database sample. The 95% Confidence Interval on the 5th Percentile extends from the 2.5th percentile to the 7.7th percentile of the normative database.

Additional Features in Macular Thickness Analysis



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

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

  The slice navigators will be set to slice 256 and 64 with the Macular Cube 512x128 or will be set to slice 100 and 100 with the Macular Cube 200x200 scan. To return to the standard resolution scans, re-select the **High-Res Images** button or move either the X or Y slice navigator to a different position.

 **Edit Layers**[1] button: Click Edit Layers to open the Edit Segmentation screen, as shown in Figure 4-6. Here you can edit the currently selected X and Y slice placement on the ILM and RPE layers; Cirrus calculates thickness between these layers.

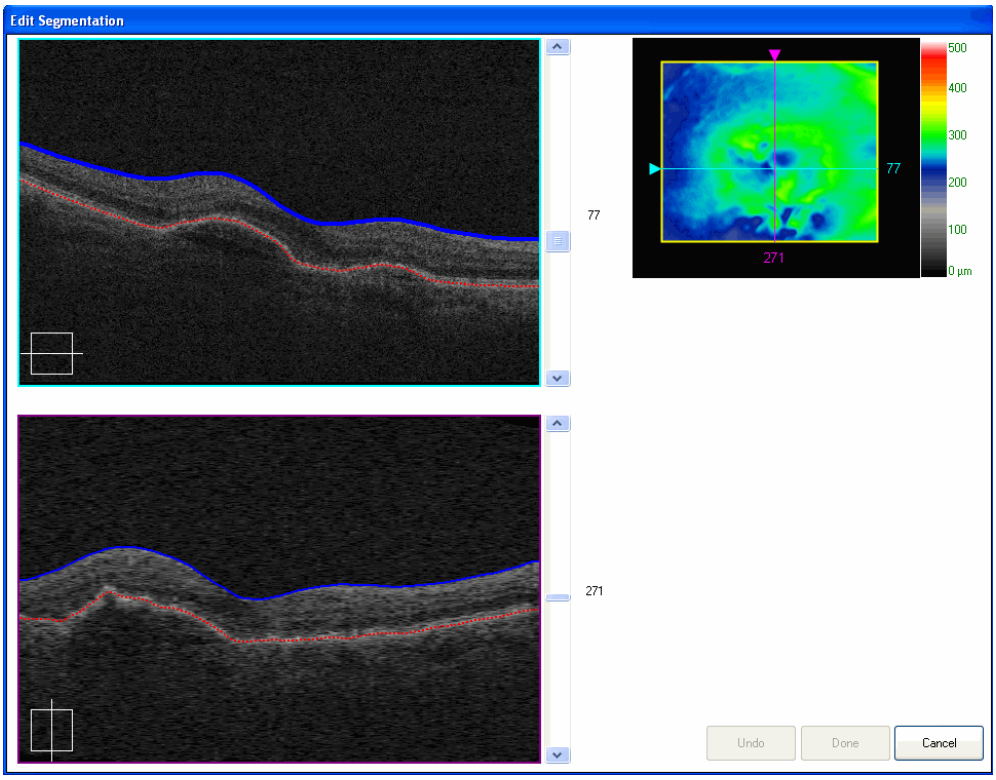


Figure 4-6 Edit Segmentation screen

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

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

Your changes are not saved as part of the Macular Thickness analysis until you click the **Save** button,  , on the ANALYZE SCREEN. Then they will persist with the analysis until you re-edit the same layers and click **Save** again, or click **Discard Changes,**  , when viewing the edited analysis. The segmentation changes affect only the specific X and Y slices you edit, but do take immediate effect in the 3D surface maps and all other ILM to RPE thickness measurements.

1. Edit Layers is an optional feature that may not be activated on all instruments. If you do not have this feature and want to purchase it, contact Carl Zeiss Meditec. In the U.S.A., call 1-877-486-7473; outside the U.S.A., contact your local Carl Zeiss Meditec affiliate or distributor.

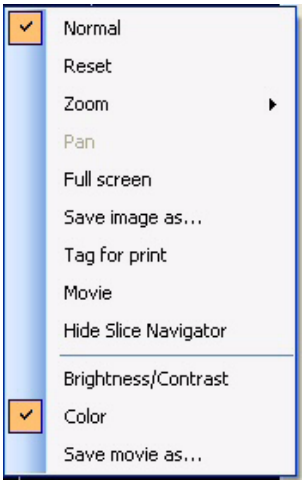
- **Ruler button:** Click **Ruler** and then click and drag in a scan image or the fundus image to draw a straight line that measures distance between the start and stop points. The resulting measurement appears next to the line in micrometers.
  - You can select and adjust the lines you draw: click and drag an endpoint to adjust its placement (and the line length), or click and drag the middle of the line to move it as a whole.
  - Click **Ruler** again to create additional measurement lines.
  - These measurements are saved after you close the analysis and will appear on reports (printouts) you make while they are present.

Note: You may use the ruler tools with the high definition images.

Delete Measurements button: Click **Delete** to delete the currently selected measurement lines. You can select lines in more than one image at a time. To deselect a line, click anywhere on the same image but off the line.

Image Display Options During Analysis

Right-click on the fundus image, on its overlay, or on a scan image to access the image display options seen in the menu at left, or a subset of them. A checkmark indicates when an option is selected. (Right-click menu options are not available for 3D volume renderings.)



- **Normal:** Selected initially, clicking **Normal** exits other display-change modes, and thereby fixes or freezes the changes you have made to that point.
- **Reset:** Resets the current display to default settings.
- **Zoom:** Gives access to the following options:

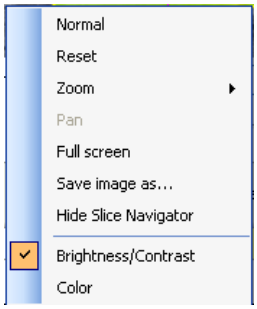
  - **Unzoom**: Unzooms the image.
  - **Rectangle:** When selected, click and drag to select a rectangular area to fill the screen.
  - **Continuous:** When selected, click and drag up to increase the zoom; click and drag down to decrease the zoom.
- **Pan:** This option is present only when the image is zoomed. When selected, click and drag the image to view other parts of it.
- **Full screen:** Select to view the image in full screen.

Tip: You can also double-click most images to open them in full screen. Double-click a full-screen image to return to normal view or click the Back button.

- **Save image as...:** Saves the current image on screen in the location you select. See the Warning Regarding Exporting/Saving to the Hard Drive below (page 4-13).

- **Tag for print:** Tags the current image for inclusion in a custom report printout. This option is available only for Advanced Visualization. See Custom Print on page 4-39 for details.
- **Movie:** Changes the display to movie mode—movie controls will appear—so you can view all slices in the current plane in succession as a movie. This option is available only for OCT viewports.

Figure 4-7 Movie Controls



- **Hide Slice Navigator:** Hides the slice navigator, including the colored outline around the image.
- **Brightness/Contrast:** When this feature is used, values B: 66 C: 21 appear on the image that reflect the numerical parameter values you select. Left-click the mouse and hold while moving the mouse up and down changes the brightness; moving the mouse left or right changes contrast. They also work in combination when you move the mouse diagonally. To retain the settings for this session, right-click the image to bring up the menu, then select **Normal**.
- **Color:** Selected by default; deselect to view in grayscale.

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

- **Save movie as...:** Opens the Save As dialog so you can save the movie of the current plane in video format. This option is available only for OCT viewports.

Warning Regarding Exporting/Saving to the Hard Drive

WARNING: Do not export or save data—including images and movies—to the C: drive of a Cirrus instrument, which includes the desktop. The Cirrus hard drive is partitioned into C: and either a D: or an E: drive, and the C: drive is reserved for operating system and Cirrus application files. The C: drive is relatively small and can be filled up quickly, which renders the system unusable. The D: (or E:) drive is reserved for data and therefore is relatively large. If you want to export or save data to the Cirrus hard drive, either locally or to a connected Cirrus system on the network, select (a location in) the D: (or E:) drive as the target.

Macular Change Analysis

Selecting the Macular Change Analysis (MCA) option allows you to compare two Macular Cube 512x128 scans or two Macular Cube 200x200 scans side by side, as shown in Figure 4-8. The default is to compare the two most recent scan dates. The Cirrus automatically registers the *en face* images from the two dates so that the images you see are synchronized to show the equivalent location of the retina in each image. In addition, the color-coded thickness maps for the two images, as well as the thickness difference map, are displayed.

When automatic registration occurs, the current image (which appears on the right-hand side) is aligned to the prior image (which appears on the left-hand side). Both the *en face* image and the fundus image are compensated for the differences in scan locations during acquisition. The registration process maps similar anatomical structures, such as blood vessels, to each other to obtain the proper registration. Rotation of an image due to the patient's eye being rotated from one session to another is also accounted for in the registration.

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

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

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

transparency slider beneath each overlay can be adjusted, as required, to enhance the image.

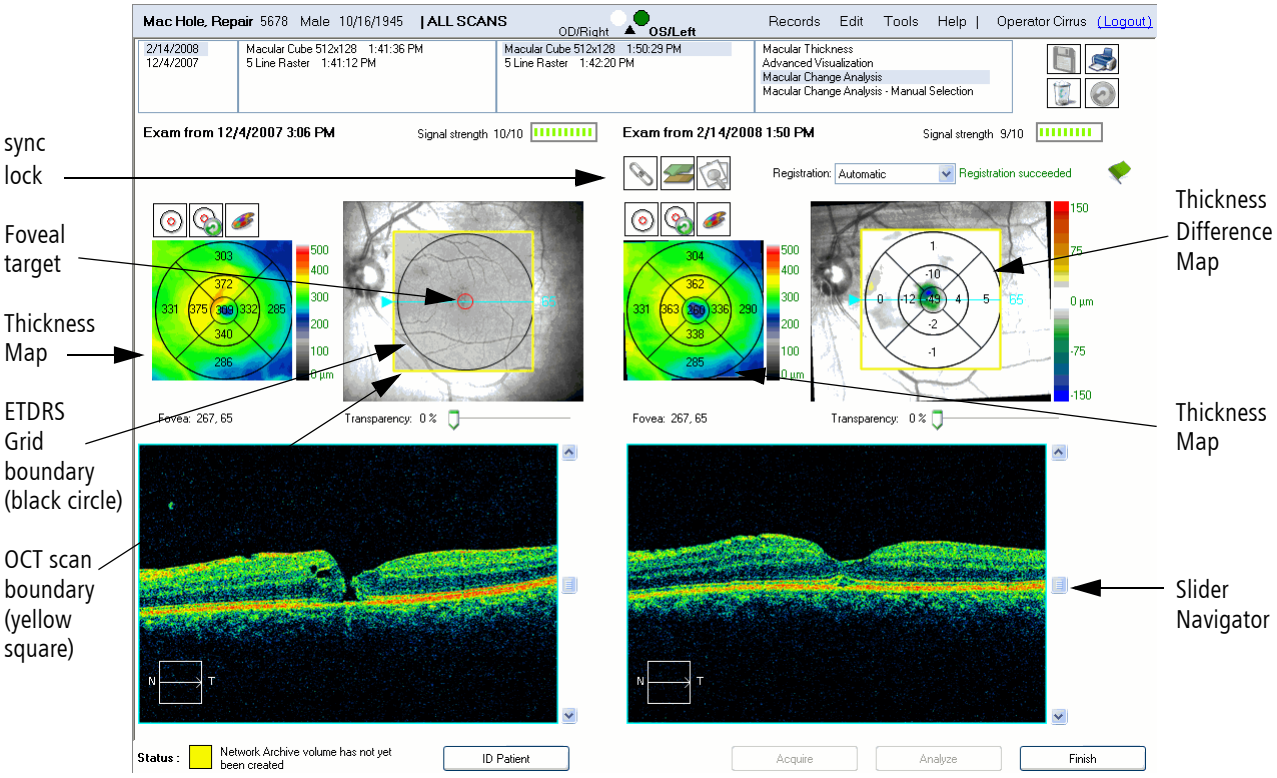


Figure 4-8 Macular Change Analysis screen

ETDRS Grid Location

Default ETDRS Grid center

When you enter Macula Change Analysis, Cirrus loads the saved fovea for each exam. This fovea location is determined by the last saved fovea location for that exam. Typically, this will be the fovea that Cirrus found automatically. However, if you or another user changes the fovea location for the exam in the Macula Thickness Analysis, and save the analysis result, then that is the fovea used in Macula Change Analysis.

1. When automatic registration is successful, or when manual registration is applied, the initial location of the ETDRS Grid center for both loaded scans is determined by the location of the fovea in the prior (left-hand) image. This is because successful registration implies that each pixel in the current image maps directly to the same pixel in the prior image. Thus, the foveas do not need to be independently identified.
2. When No Registration is applied, the initial location of the ETDRS grid center for both scans is taken from the saved value for that scan.

Synchronized Data Review

When the images are synchronized, the analysis allows the user to manipulate the data on one exam image, while the identical movements are tracked on the second exam for a side by side comparison.

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

Adjusting the ETDRS Grid centers

You can adjust the position of the ETDRS Grid center. If Sync lock is on, you can make the adjustment on either image, and it will be applied to the other image. If Sync lock is off, you must adjust each center individually.

Registration Successful

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

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

Registration Review

Registration between the two fundus images may be compared by selecting the Registration Review button: . The results are displayed on a pop-up screen, as shown in Figure 4-9.

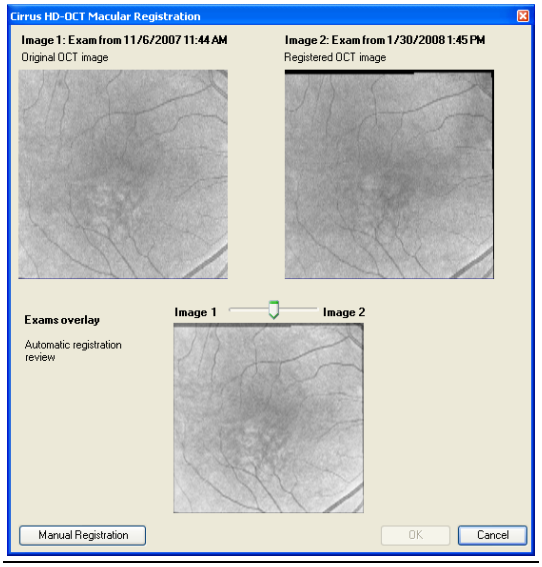


Figure 4-9 Registration between Fundus Images

In this screen, image 1 is the original image. Image 2 is the *en face* image from the most recent visit that has been registered to Image 1. The bottom image is an overlay of the two exams. The image slider allows you to adjust the view of the overlaid images: slide to the left to view image 1, to the right for image 2. Black borders might be seen in Image 2. This is the area of the second image that does not correspond to the first image when the two images were registered to each other.

To manually adjust the registration, select the **Manual Registration** button. Select three to five corresponding points on Image 1 and Image 2 by using the mouse click. See Figure 4-10. Place each point over an identifiable feature that appears in both scans that you

expect to be constant across scans. For example, a blood vessel bifurcation or a bend in a blood vessel can be used.

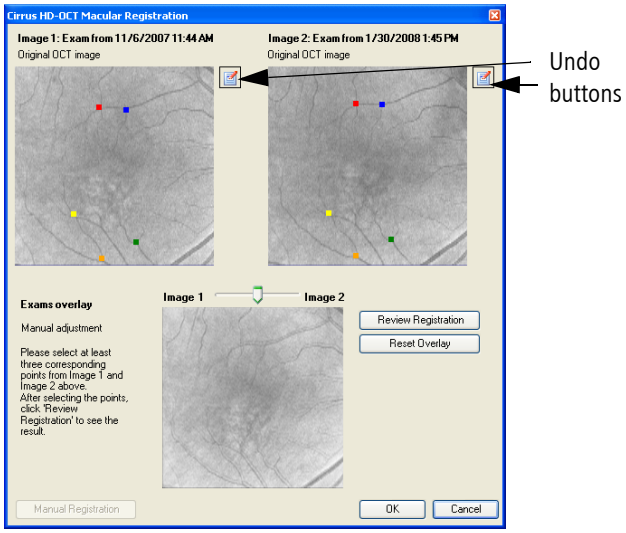


Figure 4-10 Manual Registration

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

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

Macular Change Analysis–Manual Selection

When there are two or more scans taken on the same day, the most recent scan (the one with the latest time stamp) is chosen as the default scan to be used in Macular Change Analysis. Sometimes, this scan is not the best to use for comparison. The scan may not have the best signal strength or the scan was taken in a position away from the center and, therefore, would not be a good match. You are able to manually choose a different scan from any earlier date using the manual selection process.

1. At the top of the Analysis screen, select the scan date and the scan you wish to use as the more current scan (the scan information that will appear on the right side of the screen).
2. Select Macular Change Analysis – Manual Selection from the far right column.
3. A list of eligible scans will appear in a dialog box (see Figure 4-11).
4. Click on the scan you wish to include in the MCA. A green check mark will appear next to the scan.
5. Click on Next to proceed. The window will collapse and the scan you chose will appear as the scan on the left-hand side of the MCA screen.

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

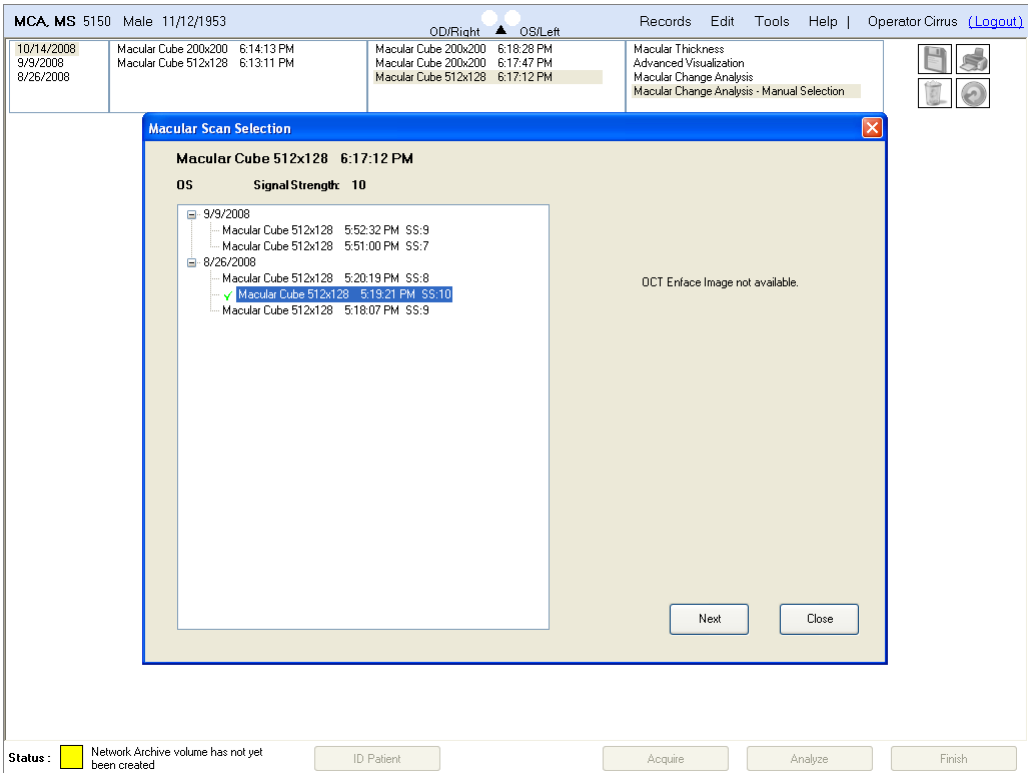


Figure 4-11 Macular Change Analysis–Manual Selection screen

Advanced Visualization

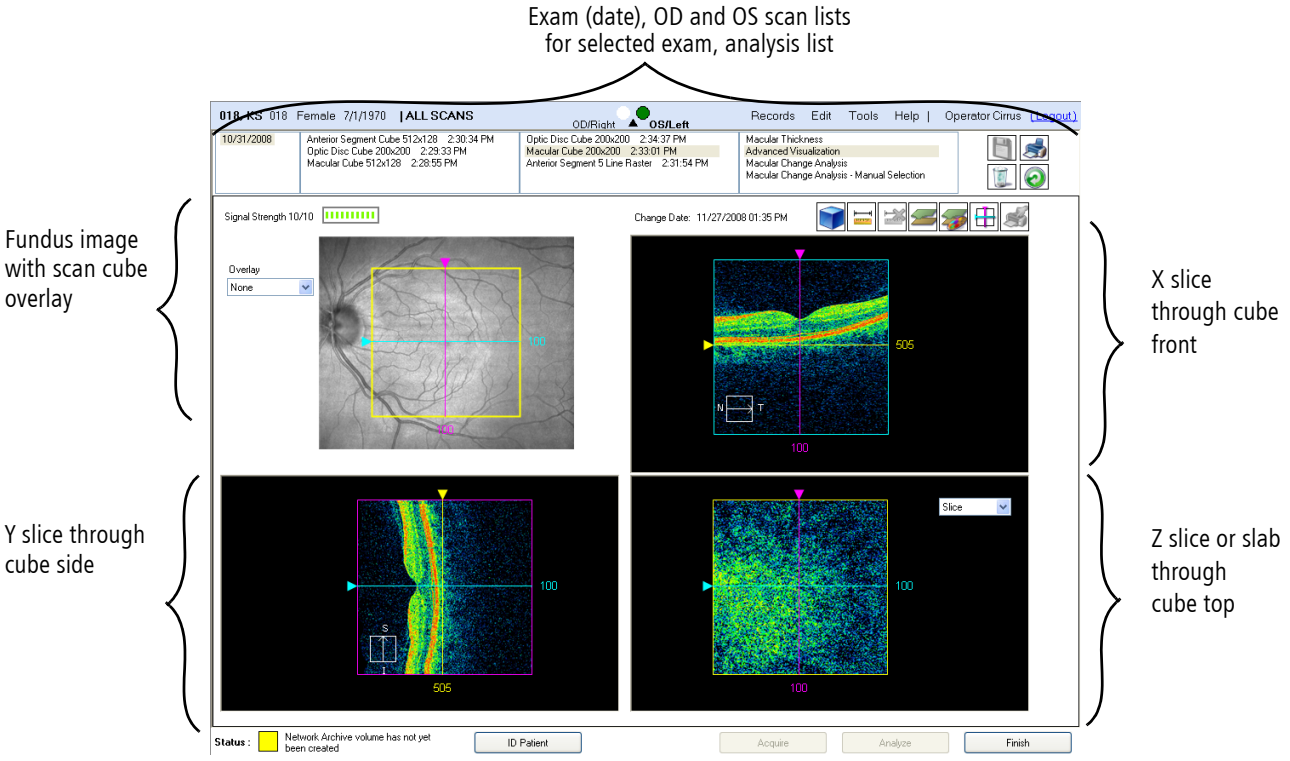
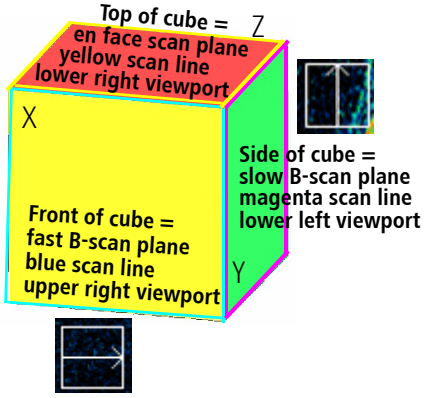


Figure 4-12 Advanced Visualization Analyze Screen

Data Cube Orientation



En Face Explained

En face, from the French, means literally, "on the face;" that is, looking directly into the eye, which is the same perspective as the fundus image.

The ANALYZE SCREEN for **Advanced Visualization**, Figure 4-12, presents an interactive multi-planar reformat (MPR), which enables you to view image cross-sections through three dimensions. The example above is for a **Macular Cube 200x200**. The upper left viewport shows the saved fundus image with an optional *en face* scan overlay. The other three viewports show cross-sectional scan images in three planes. Thinking of the data as a cube, the viewports show the data in planes parallel to the side of the cube (Y plane, lower left viewport), the front of the cube (X plane, upper right viewport) and the top of the cube (Z plane, lower right viewport), as shown in Figure 4-12 and to the left. Optionally, you can switch to a full-screen 3D Volume Rendering of the entire data cube when you click the **3D Volume Rendering**[1] button, if available. See 3D Volume Rendering on page 4-25 for details.

Multi-Planar Reformat (MPR)

- **The viewports are interactive:** Click and drag the triangles or click on a scan viewport and use the mouse scroll wheel to "move through" the active plane of the viewport;

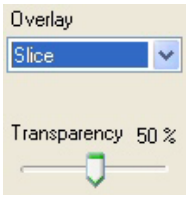
1. 3D Volume Rendering is an optional feature that may not be activated on all instruments. If you do not have this feature and want to purchase it, contact Carl Zeiss Meditec. In the U.S.A., call 1-877-486-7473; outside the U.S.A., contact your local Carl Zeiss Meditec affiliate or distributor.

you will see the resulting cross-sections update simultaneously in the other viewports. This functionality enables you to quickly search through the data cube and stop when you see an area of interest.

Retinal Layers Automatically Detected and Displayed

- Cube scan analyses incorporate an algorithm to automatically find and display the inner limiting membrane (**ILM**) and the retinal pigment epithelium (**RPE**). Cirrus also calculates and presents a layer called **RPEfit**, which is a representation of a normal parabolic RPE for this eye, based on the retina's overall curvature. You can use the RPEfit line to view variations from normal in the actual RPE contour.

  In the scan images, which are cross-sections (slices), the layers appear as colored lines that trace the anatomical feature on which they are based. The ILM is represented by a white line, the RPE by a black line, and the RPEFit line is magenta in color. These lines are also known as segmentation lines. You can customize the colors used to display each of these lines, as explained below. These layers serve as the basis for the macular thickness and volume measurements in the Macular Thickness Analysis (see page 4-3). In the Macular Thickness Analysis, the ILM and RPE layers are presented in their entirety as three-dimensional surface maps.



ILM = inner limiting membrane
RPE = retinal pigment epithelium

Fundus Image Overlay Options

- Use the **Overlay** drop-down menu to select which overlay to use on the fundus image: **None** (default), **Slice, OCT Fundus, Slab, ILM - RPE, ILM - RPEfit** or **RPE - RPEfit.** The slice and slab options correspond to the *en face* image in the lower right viewport. (The options **ILM, RPE** and **RPEfit** are variations of the slab. See Slice and Slab Options on page 4-22 page for a description.) You can adjust the associated **Transparency** slider from 0% (opaque) to 100% (fully transparent). The OCT Fundus option is the same overlay *(en face)* shown on the fundus image in the REVIEW SCREEN.

Slice and Slab Options

The lower right viewport, Figure 4-13, has a drop-down menu to select **Slice** (default), **Slab, ILM, RPE** or **RPEfit**.

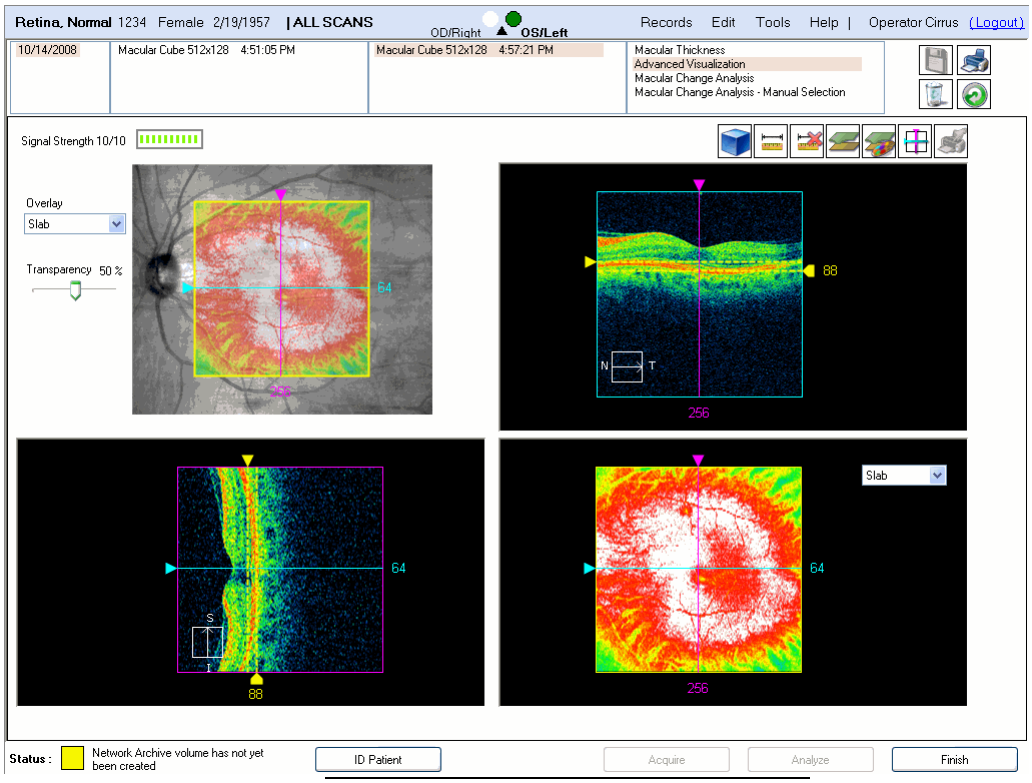


Figure 4-13 Analyze Screen showing a slab

When you select **Slab**, the other two scan viewports show two same-color dashed lines separated by a small distance. This separation is the slab thickness, which you can adjust in either of the other viewports by dragging the posterior line by its handle on the edge. Dragging the anterior line handle moves both lines of the slab together to reposition it in the scan image. The resulting slab image you see represents an average signal intensity value for each A-scan location through the selected depth of the slab.

- The drop-down options **ILM, RPE** and **RPEfit** are variations of the slab. When you select any of these, you view the slab (of selected thickness—you can adjust it as above) relative to the selected layer. For example, if you select **ILM**, a dashed line of the same color as the ILM appears posterior to it, and the resulting scan image appears in the lower right viewport (and in the scan cube overlay when **Slab** is selected there). You cannot raise the lower dashed line above the upper one, and the minimum separation is 2 micrometers.

ILM = inner limiting membrane
RPE = retinal pigment epithelium

Function Buttons in Advanced Visualization

The buttons shown on the left appear from left to right in the Advanced Visualization analysis, above the scan images at right. If you mouse over them, their function appears in the form of a tool tip.

-  **3D Volume Rendering button:** Click **3D Volume Rendering** to switch to a full-screen display of the entire data cube in three dimensions. The **Options** button  that appears above the image enables several additional viewing options. See 3D Volume Rendering on page 4-25 for details.
-  **Ruler button:** Click **Ruler** and then click and drag in a scan image or the fundus image to draw a straight line that measures distance between the start and stop points. The resulting measurement appears next to the line in micrometers.
  - You can select and adjust the lines you draw: click and drag an endpoint to adjust its placement (and the line length), or click and drag the middle of the line to move it as a whole.
  - Click **Ruler** again to create additional measurement lines.
  - These measurements are saved after you close the analysis and will appear on reports (printouts) you make while they are present.
  -  **Delete Measurements button:** Click **Delete** to delete the currently selected measurement lines. You can select lines in more than one image at a time. To deselect a line, click anywhere on the same image but off the line.
-  **Show/Hide Layers button:** Click **Layers** to hide or show the colored lines indicating the layers (ILM, RPE and RPEfit).
-  **Configure Layers button:** Click **Configure Layers** to open the Layer Configuration Dialog, Figure 4-14, where you can select the colors of the layers for ILM, RPE and RPEfit, and whether to display them or not.

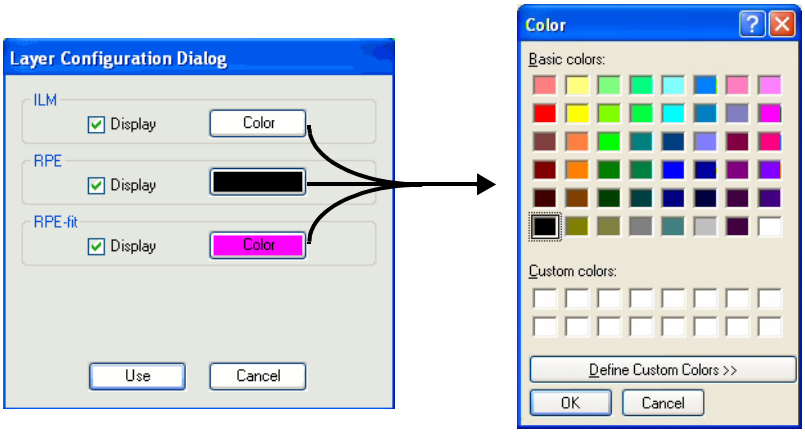


Figure 4-14 Layer Configuration Dialog and Color picker

- Click a **Color** button for ILM, RPE or RPE-fit to open a standard color picker, where you can select a new color for that layer, or even define a custom color.

- The layers with their **Display** checkbox selected appear in scan images for Advanced Visualization and Macular Thickness analyses for the scan you are viewing. Click to select or clear **Display** checkboxes as desired.

☞ Note: Switching to a different scan or leaving the Analysis screen causes the selected segmentation colors to default to the original colors.

-  **Center button:** Click **Center** to return the current slices to their default central positions.
-  **Tagged Images button:** Click the **Tagged Images** button to view and adjust which images are tagged for custom printing. This button is active when one or more images have been tagged for printing by selecting **Tag for print** from the right-click menu. (See Custom Print on page 4-39 for details.)

The Advanced Visualization screen also uses the image display options available by using the right mouse click. See Image Display Options During Analysis on page 4-11.

☞ Note: **Brightness/Contrast** and **Color** adjustments apply simultaneously to all X, Y and Z slices on screen (in OCT viewports or as the fundus overlay). If two Z slabs are on screen, one as the fundus overlay and one in the lower right viewport, **Brightness/Contrast** and **Color** adjustments made on either slab will apply to both. Between the fundus image and its overlay, **Brightness/Contrast** and **Color** operate independently. Right-click on one or the other to apply such changes. Some image display options function as a distinct display mode and that viewport or overlay remains in that mode until you click **Reset, Normal** or select another mode.

- For example, if you select **Brightness/Contrast** for one viewport, the brightness and/or contrast changes every time you click and drag your mouse over that viewport, until you select **Normal** or **Reset**. Note that selecting **Normal** would not reset the viewport to its initial brightness and contrast settings.

Fundus Image, Overlay and Scan Image Options

☞ Note: Not all display options apply to every kind of image, and in these cases they are not available. For example, **Movie** does not apply to the fundus image or its overlay, since these are single images. For the fundus overlay, the **Brightness/Contrast** and **Color** options are available only for **Slice** and **Slab**, not for **OCT Fundus** nor for the calculated thickness overlays (e.g., **ILM-RPE**). Another example is that **Tag for print** is available only in the Advanced Visualization analysis.

3D Volume Rendering

When you click the **3D Volume Rendering**[1] button, the entire data cube appears full screen, as shown in Figure 4-15.

Click and drag to rotate in any direction. Right-click on the cut plane and drag up or down to move the cut plane.

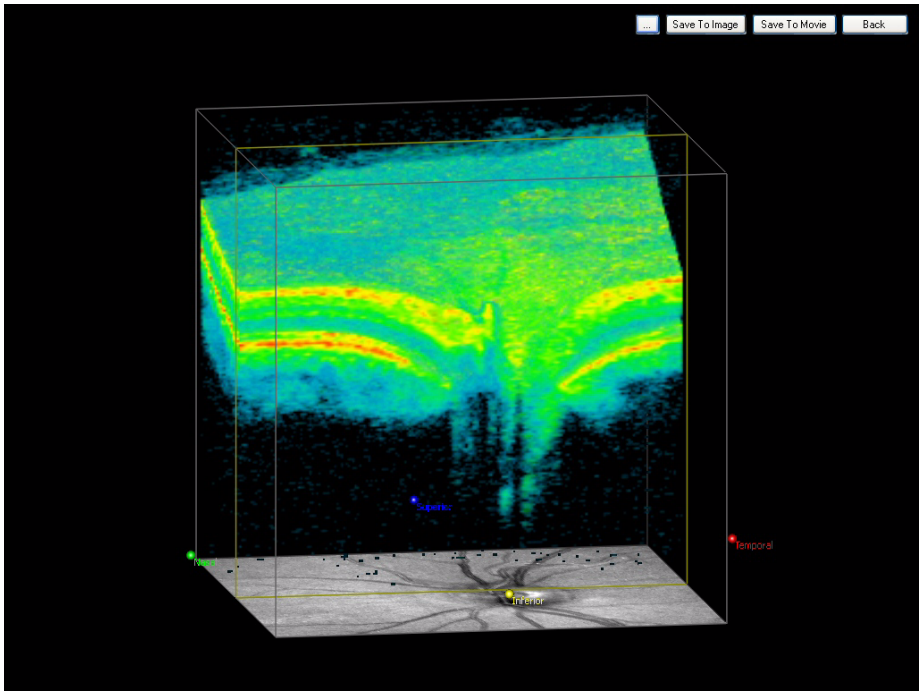
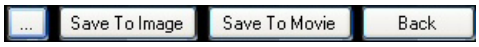


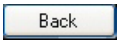
Figure 4-15 X plane cut midway in an optic disc cube

The 3D volume image above depicts the default view. In this case, it is an Optic Disc Cube 200x200 scan with half the retinal tissue image cut away in the X plane and the fundus image aligned underneath. Following this color pattern, an X plane cut is indicated by yellow lines, and when the Y plane is cut, the lines are purple. When a Z plane is cut, the lines are blue. The cube boundaries are shown with gray lines. Labels indicate the Nasal, Superior, Temporal and Inferior sides of the cube.

3D Volume Buttons

The buttons at upper right offer viewing and saving options.



- **Back** 

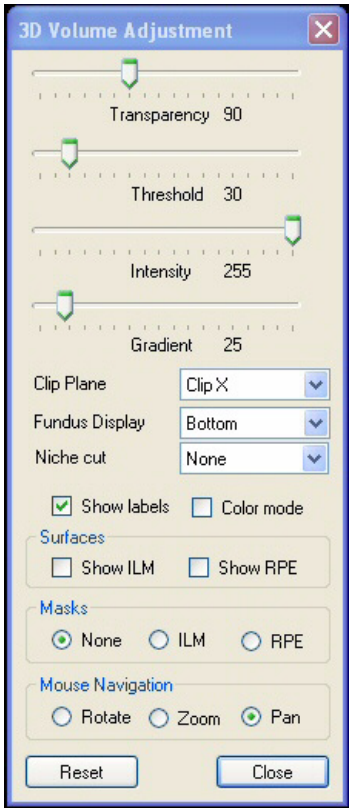
: Closes the 3D Volume Rendering and returns to the ANALYZE SCREEN for Advanced Visualization. You cannot double-click to close the 3D volume screen.
- **Save To Image** 

: Saves the current image as a BMP or JPG to the location you choose.
- **Save To Movie** 

: Saves a movie as the 3D volume automatically scrolls through the currently selected clip plane, either X, Y or Z.

1. 3D Volume Rendering is an optional feature that may not be activated on all instruments. If you do not have this feature and want to purchase it, contact Carl Zeiss Meditec. In the U.S.A., call 1-877-486-7473; outside the U.S.A., contact your local Carl Zeiss Meditec affiliate or distributor.

Note: Saved images and movies will not include the 3D Volume Adjustment dialog even if it is present when you click the Save button.



Viewing Options

Click the **Options** button [...] that appears above the image to access several viewing options. When you do, the 3D Volume Adjustment dialog appears, as at left. It offers the following options:

- Sliders for **Transparency, Threshold, Intensity** and **Gradient**, to adjust the tissue image appearance. All sliders range from 0 to 255. The settings you apply are a matter of preference, though the default settings may serve as a useful starting point for both color and black and white images. Click **Reset** to return all display parameters to default settings.

Tip: To move by single units on any slider, click (and release) the desired slider, then hold down the Ctrl key and press the left or right arrow key.

- **Show labels** and **Color mode** checkboxes: Select these checkboxes to display the orientation labels and the tissue images in color, respectively.
- **Clip Plane** drop-down menu: Lets you select which plane of tissue to clip or cut away. The options are **None, Clip X** (default), **Clip Y** or **Clip Z.** It is also possible to view the image with cuts through both the X and Y planes by selecting one of the quadrant cut options in the **Niche cut** drop-down menu--see Niche cut below.
- **Fundus Display** drop-down menu: Lets you select where to display the fundus image in relation to the 3D volume. The options are **None, Bottom** (default), **Top** or **Top & Bottom**.

When you use **Top** or **Top & Bottom** in combination with **Clip X** or **Clip Y**, the top fundus image cuts away in concert with the clip plane, as in the example shown in Figure 4-16.

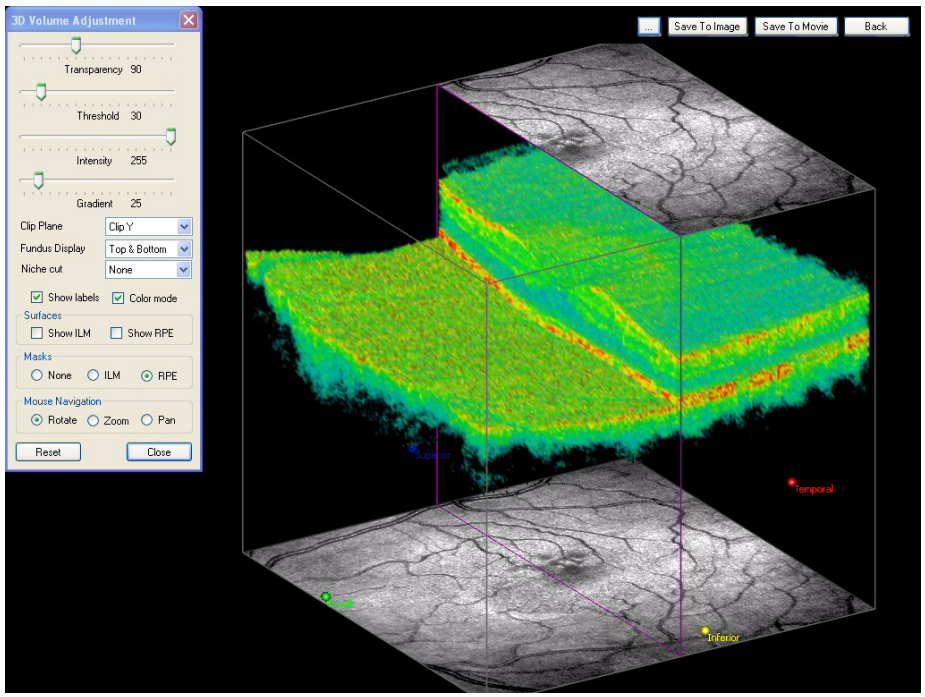


Figure 4-16 Y plane cut in a macular cube scan with RPE mask

Note the purple lines demarcating the Y plane cut, which is partially through the foveal depression.

ILM = inner limiting membrane
RPE = retinal pigment epithelium

- **Masks** radio buttons: The image above applies the additional option of the **RPE** mask, which masks from cutting the tissue below the RPE, and thereby enables you to use the clip plane to peel back the tissue above the RPE. Similarly, applying the **ILM** mask preserves the tissue below the ILM from being cut, so you can use the clip plane to peel back the ILM and above. **None** is the default.
- **Niche cut** drop-down menu: Lets you select simultaneous cuts in both the X and Y planes using the four quadrant options. **None** is the default. See examples in Figure 4-17.

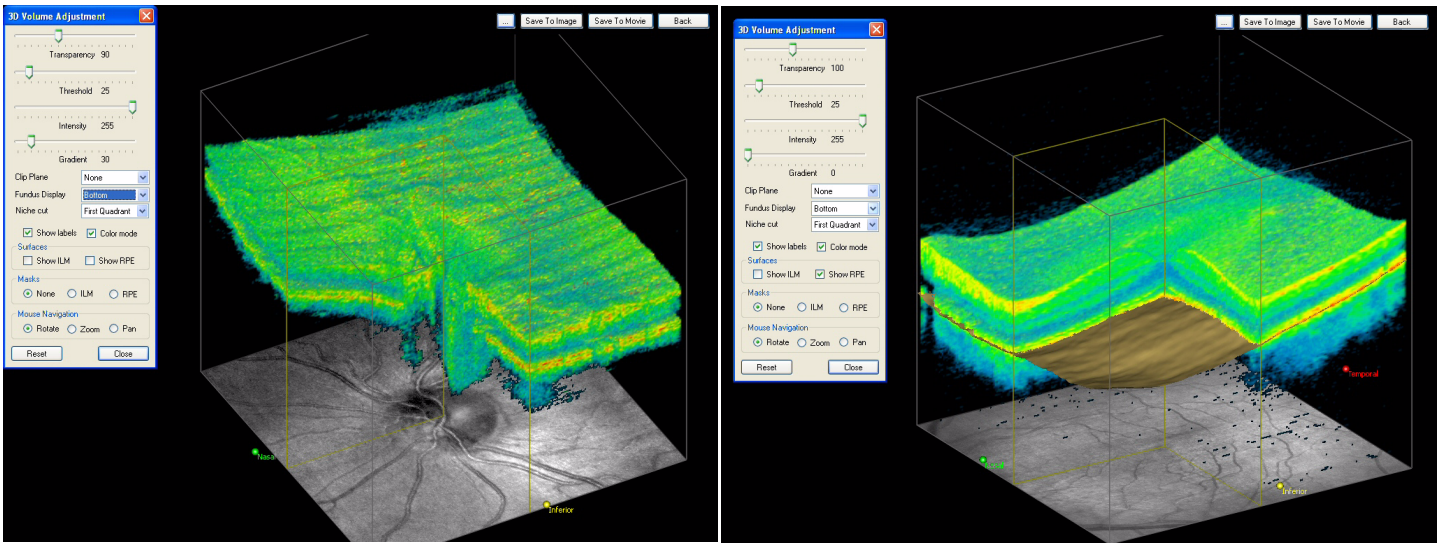


Figure 4-17 First Quadrant niche cut on an optic disc cube and a macular cube

When using a niche cut, you can move both cut planes independently by right-clicking on the desired plane and dragging up or down as usual. When necessary, rotate the cube to view the cut planes.

ILM = inner limiting membrane
RPE = retinal pigment epithelium

- **Surfaces** checkboxes: The image on the right in Figure 4-17 above has the **Show RPE** checkbox selected. By default, neither checkbox is selected. When you select **Show ILM** and/or **Show RPE**, the selected surfaces are shown as a single-color contour, using the same colors for ILM and RPE as in the Macular Thickness Analysis (see page 4-3).
- **Mouse Navigation** radio buttons: These options affect the left-click and drag behavior only. Right-click and drag up or down always moves the clip plane. The default is **Rotate**. When you select **Zoom**, click and drag down to increase zoom or up to decrease zoom. When you select **Pan**, click and drag the cube any direction to move the whole cube. Pan is particularly useful when the tissue image is zoomed.
- Click **Reset** to return the 3D cube to its default settings.
- Click **Close** to close the 3D Volume Adjustment dialog.

High Definition Image Analysis – 5 Line Raster

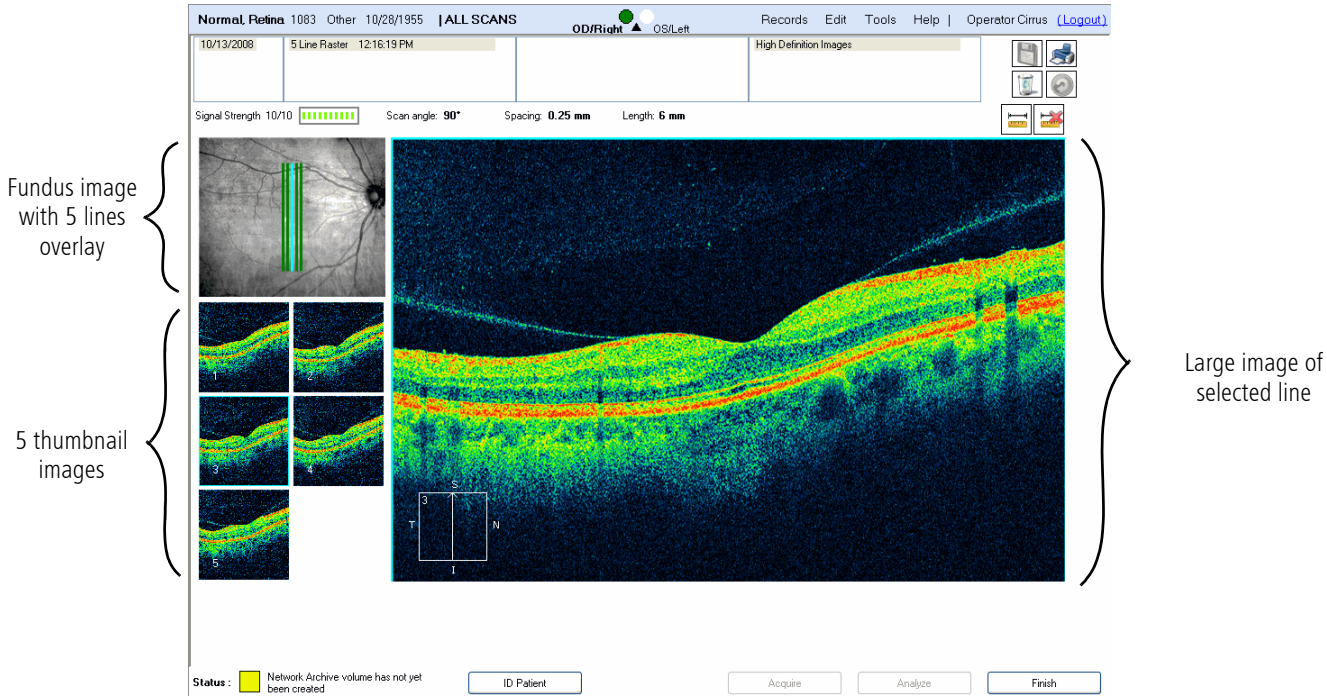


Figure 4-18 The Analyze Screen—High Definition Image Analysis

The ANALYZE SCREEN for **High Definition Image Analysis (HDIA)**, Figure 4-18,enables you to view the five line scans of the **5 Line Raster** scan. The scan angle, spacing and length are indicated above the images. The upper left viewport shows the saved fundus image with an overlay showing the location of each line scan. The currently selected line scan (middle line by default) is indicated in blue, the other lines in green. Below the fundus image are five thumbnail images of each line scan. You can click on a thumbnail to view that line scan in large size on the right.

The applicable image display options are available when you right-click on an image — see High Definition Image Analysis – 5 Line Raster Image Display Options During Analysis on page 4-11 for details.

Left to Right Scan Display Summarized
For horizontal scans, left equals left and right equals right. For all diagonal scans in 5 Line Raster, left takes precedence over bottom. For vertical scans, left to right equals bottom to top.

Scan Display Left to Right Orientation

Consistent with Stratus OCT™, Cirrus always displays left to right scan images as follows:

- For horizontal scans, left of scan equals left of scan display and right of scan equals right of scan display.
- For vertical scans, bottom of scan equals left of scan display and top of scan equals right of scan display.
- For diagonal scans in 5 Line Raster, left takes precedence over bottom, so that left of scan equals left of scan display and right of scan equals right of scan display.

Reports and Printing

Cirrus enables you to generate analysis reports in color, which you can then either print on paper or export in a number of electronic formats, such as PDF, TIFF or JPEG, to name a few. Cirrus provides two printing modes, stock or standard print mode and custom print mode. This section will describe each in turn.

☞ Note: All report pages have a header with fields for (patient) Name, ID, Technician and Institution (among other fields). (Institution name appears to the left of the ZEISS logo. See Create an Institution Name on page 2-4). The layout of these fields limits the number of characters that can be displayed on the report, even though you can enter additional characters on the instrument when creating the Name, ID, etc. Specifically, reports can display 23 characters for ID (you can enter up to 32); 24 for Institution name (you can enter up to 36); 32 characters for Technician (you can enter up to 64); and 64 characters for Name (you can enter up to 64). These character limits include spaces. **If you created patient names, IDs, etc., longer than can be displayed on the report, be aware that the information you see on screen may not be unique to that patient.**

☞ Note: If analysis is edited and not saved, printing a report automatically saves the edited analysis.

Stock Print

The stock print mode provides a standard print layout for each kind of analysis. To make a stock print, click the **Print** button at upper right to generate a report based on what is currently on screen. (The current cross-sections and/or surface maps will appear in the report.) The system presents a print preview, as shown in Figure 4-19, of the current analysis report.

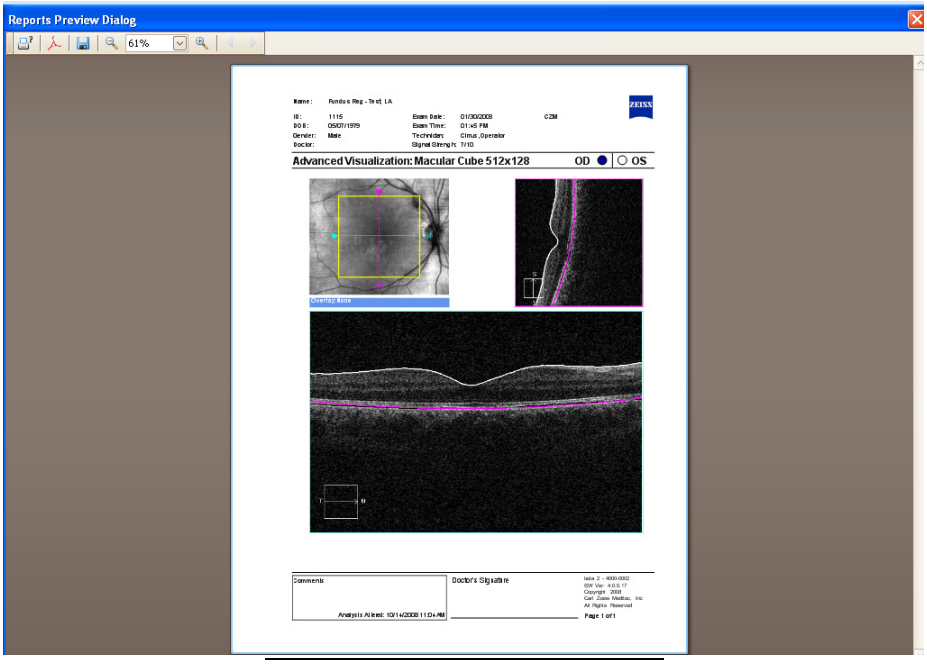


Figure 4-19 Report Preview Dialog

This screen also gives you the option to export in a number of electronic formats:

- PDF – Portable Document Format
- BMP – Bitmap
- GIF – Graphic Interchange Format
- JPEG – File Interchange Format
- PNG – Portable Network Graphics Format
- TIFF – Tag Image Format
- EMF – Enhanced Windows Metafile
- WMF – Windows Metafile

Click the appropriate button to generate a printout or to export the file to the format you choose. After completion of the printing or export, click the **X** in the upper right corner of the screen to close the Reports Preview screen and return to the Analysis screen.

Setting Print Configuration Defaults

There are three styles of printouts available for the Macular Cube scans: Macula Thickness, Macula Multi-Slice, and Macula Radial. You may choose one or more of these printouts for

each patient or set the defaults to print the same style(s) of printouts each time. To change the default setting (which is Macula Thickness), open the **Tools** pull-down from the upper menu bar and select **MTA Print Configuration**, Figure 4-20. Select the desired printouts by checking the appropriate boxe(s).

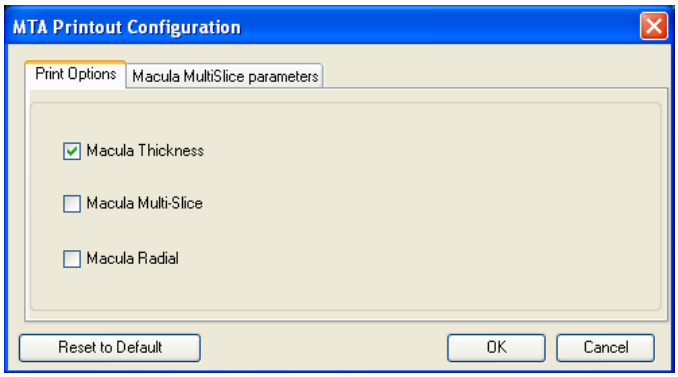


Figure 4-20 Print Options

To change the printout parameters of the Macula Multi-Slice printout, open the MTA Printout Configuration window and select the **Macula Multi-Slice parameters** tab, Figure 4-21. You can choose the number of scans per each section of the macula scan.

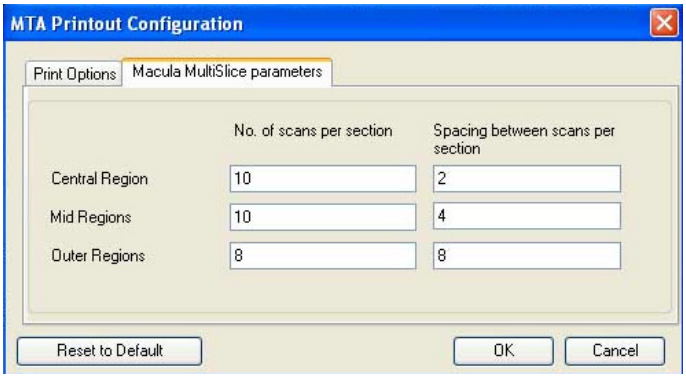


Figure 4-21 Macula MultiSlice Parameters Options

The Central Region is comprised of the central 1 mm (1000 micrometers) of the cube. This is the equivalent of 500 micrometers above and 500 micrometers below the central B-scan. The Mid-Regions are comprised of the next 1.0 mm above and below the Central Region. The Outer Regions are the final 1.5 mm of area above and below the Mid Regions. These three regions add up to the 6 mm height of the scan box and are equivalent to the EDTRS grid spacing in the vertical direction.

You may choose the number of scans to print per region or indicate the spacing between the scans. If you do not wish to print any scans for a particular region, enter "0" in the appropriate **Number of Scans per Section** field.

Macula Thickness Stock Printout

The stock printout for Macula Thickness (Figure 4-22) includes all the information on screen when you click **Print**.

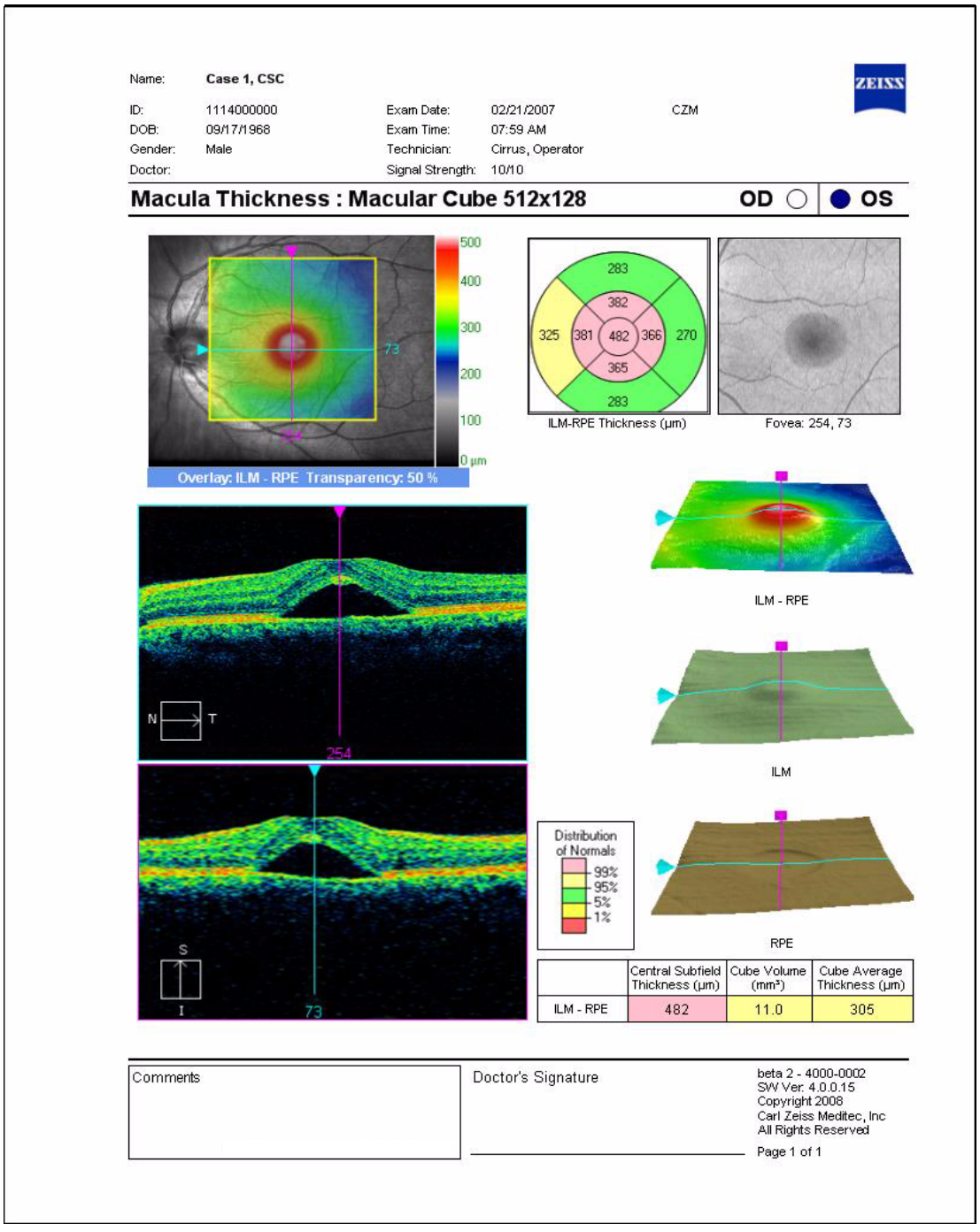


Figure 4-22 Macula Thickness Stock Printout

Macula Multi-slice Printout

An option to view the central fast B-scan and adjacent B-scans on a series of printouts is available when the Macula Multi-Slice printout is selected. This printout shows four fast B-scans per page, as shown in Figure 4-23, and you may select the number of B-scans to display in the multiple page printout. See Setting Print Configuration Defaults on page 4-31 for information on changing the scan spacing and the number of scans to be printed.

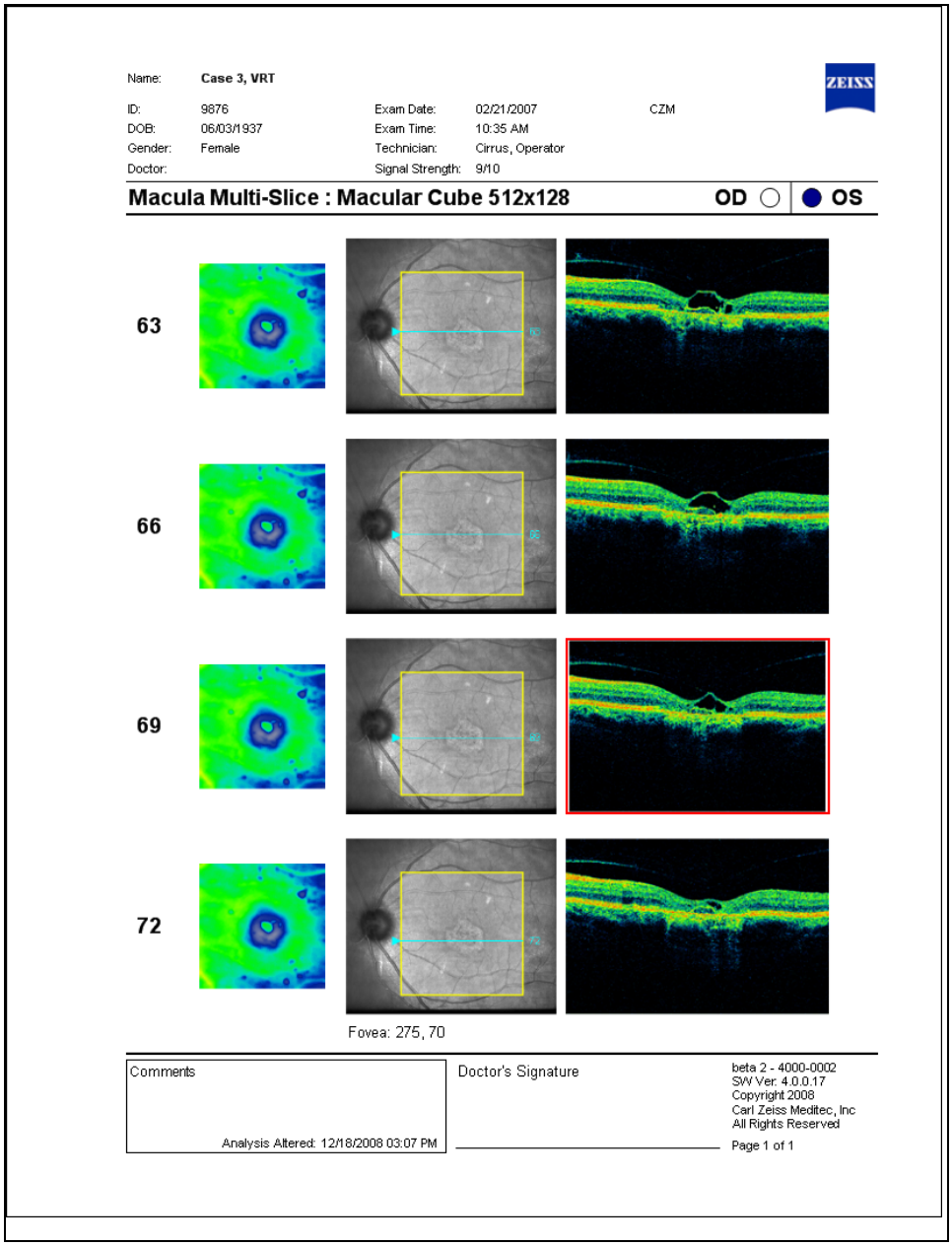


Figure 4-23 Macula Multi-slice Printout

Macula Radial Printout

The Cirrus HD-OCT provides a radial line printout option (Figure 4-24). Six B-scans are extracted at the meridians of 0 degrees, 30, 60, 90, 120, and 150 (300 x 330 in the left eye). This printout is available with either the Macular Cube 512x128 or the Macular Cube 200x200 scan.

As seen in the figure below, the direction of the arrow indicates the orientation of each image. These can be matched to the radial pattern overlay on the fundus image in the upper left portion of the printout. The retinal thickness map to the right shows these scans in relationship to the thickness map of the entire 512x128 Macular Cube.

The center of the radial pattern is dependent on the location of the center of the EDTRS Grid found on the Macular Thickness analysis screen. Moving the EDTRS Grid to a different position on the Macular Thickness analysis screen creates a different set of images on this printout. If the radial pattern is positioned such that a portion of the radial lines go outside the scan boundary, then no OCT data are displayed. For example, in the printout below, the top left-hand slice has a black edge on the left, where no data are displayed.

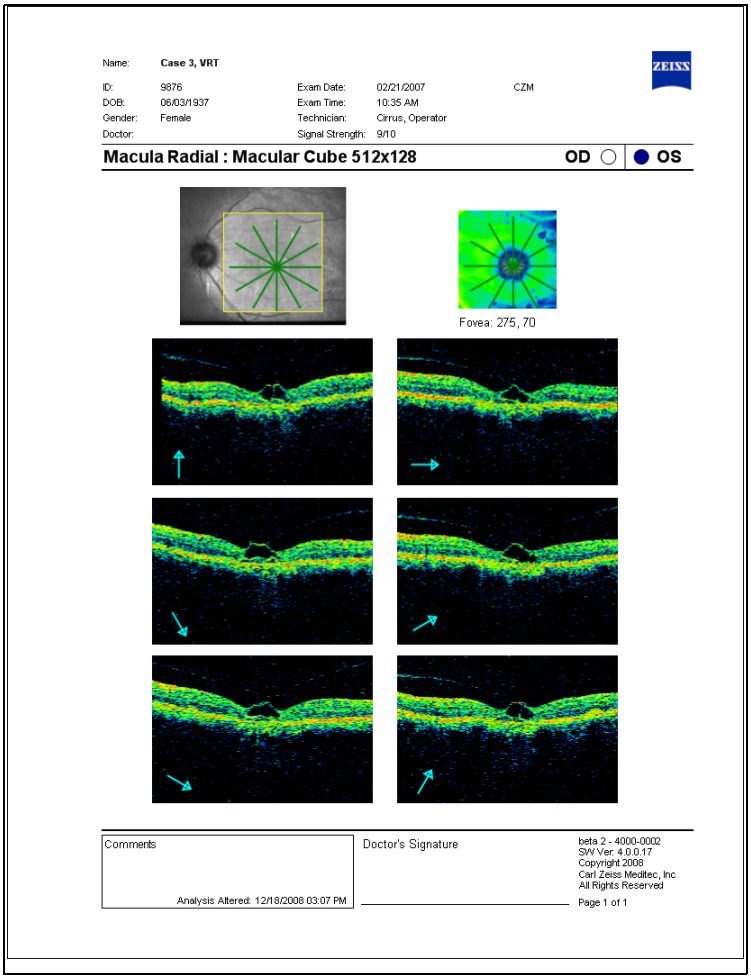


Figure 4-24 Macula Radial Printout

Macular Change Analysis Stock Printout

The stock printout for Macular Change Analysis includes all the information on screen in Figure 4-25 when you click **Print.**

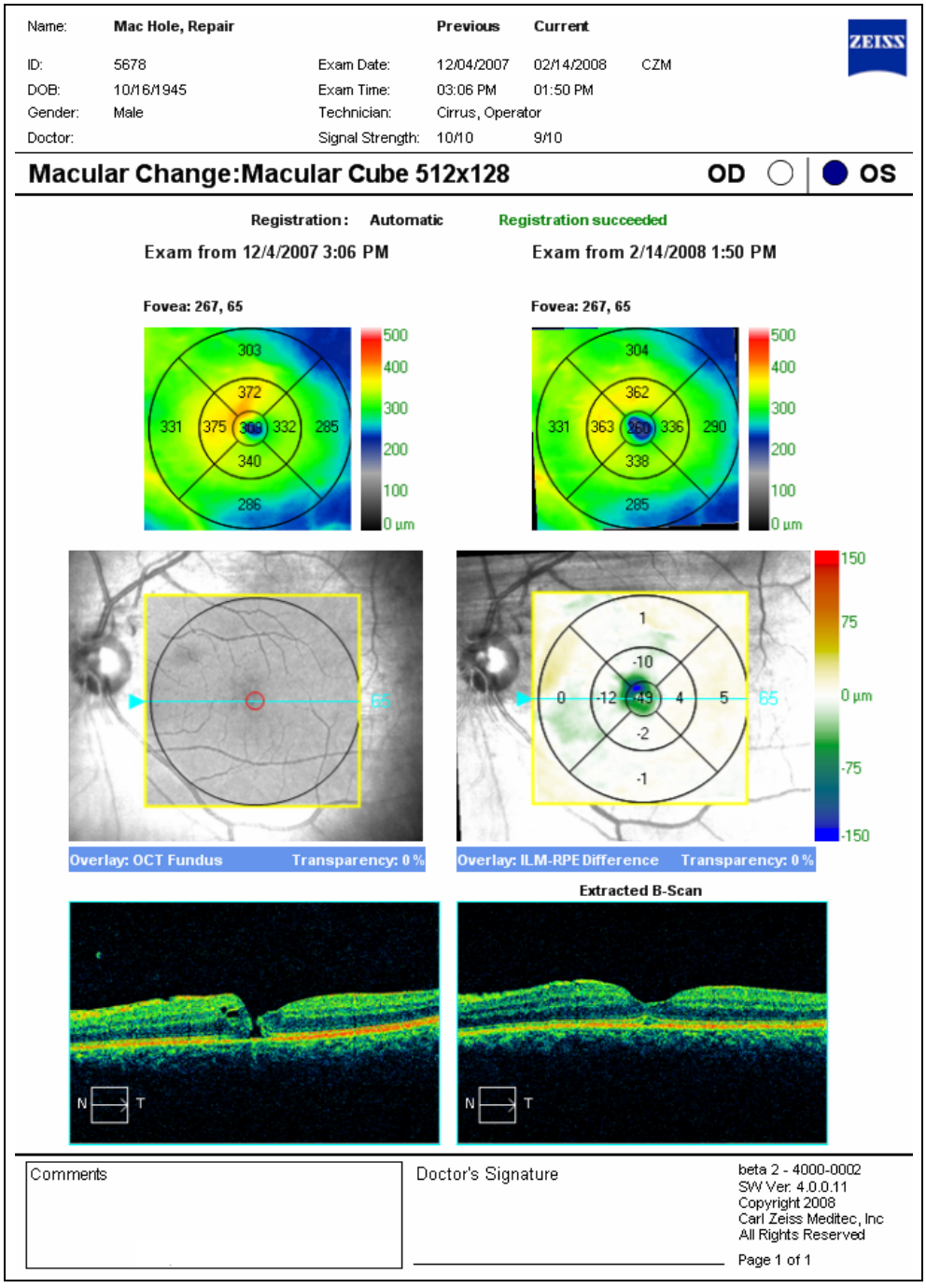


Figure 4-25 Macular Change Analysis Printout

Advanced Visualization Stock Printout

The stock printout for Advanced Visualization, Figure 4-26, includes three images, one fundus image and two B-scan images. The upper left fundus image has an overlay showing the area addressed by the cube scan and the two currently selected slices. The upper right scan image shows the currently selected slow B-scan, corresponding to the magenta (vertical) scan line in the fundus image overlay. The largest, bottom scan image shows the currently selected fast B-scan, corresponding to the blue (horizontal) scan line in the fundus image overlay.

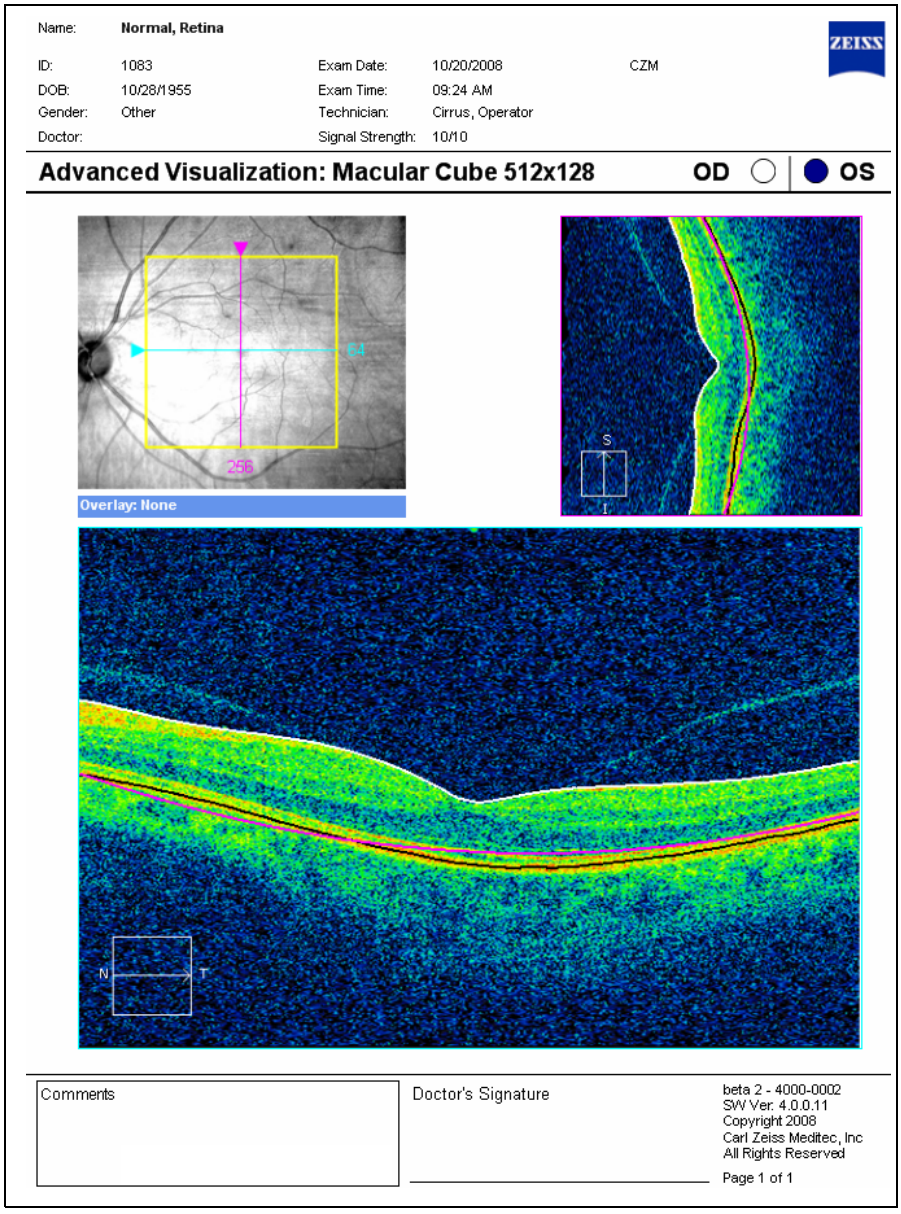


Figure 4-26 Advanced Visualization Stock Printout

High Definition Image Analysis (HDIA) Stock Printout

The stock printout for the High Definition Image Analysis (HDIA, for 5 Line Raster scans), Figure 4-27, includes a fundus image showing the placement of the line scans and all five scans, with the currently selected scan larger.

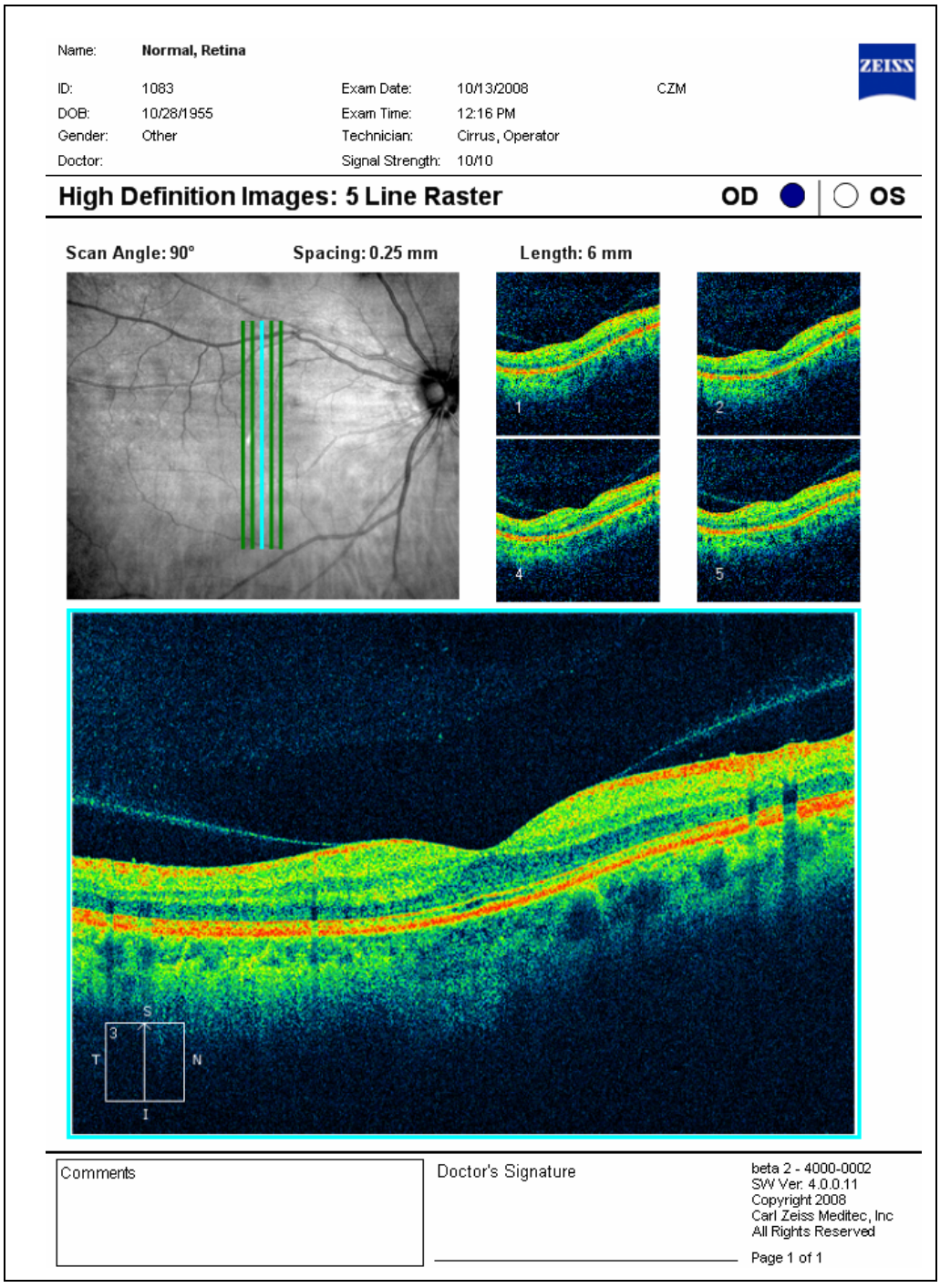


Figure 4-27 Stock Printout for 5 Line Raster

Custom Print

The custom print mode enables you to generate a multi-page report from an Advanced Visualization analysis showing as many scan images and fundus images with overlays (from the same scan) as you choose, as shown in Figure 4-28.

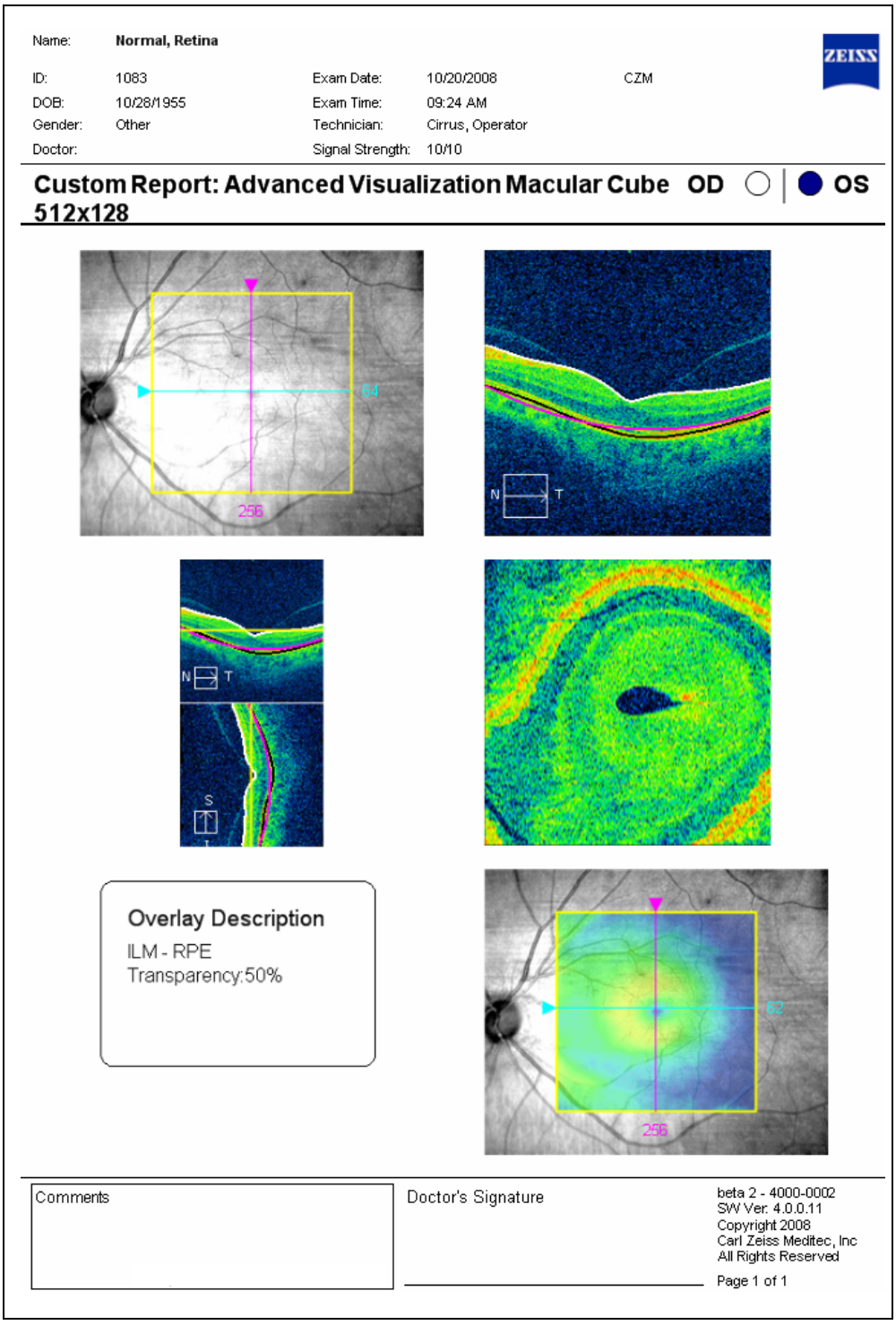


Figure 4-28 Example Custom Printout

To accomplish this, you must right-click and select **Tag for print** on each image you want to include in the report. When you are ready to generate the report, click the **Tagged Images** button above the upper right scan image on the ANALYSIS SCREEN for Advanced Visualization (see Figure 4-12 on page 4-20). This opens the Tagged Images dialog, Figure 4-29.

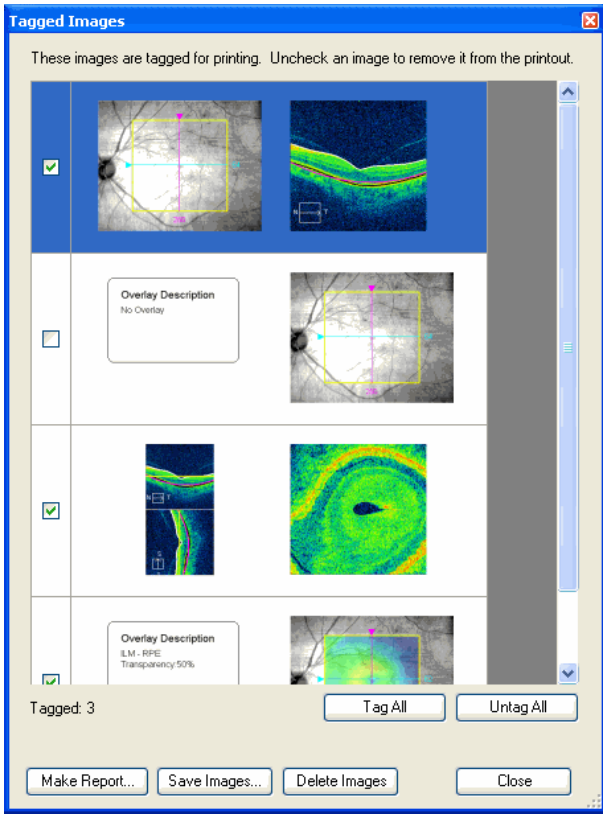


Figure 4-29 Tagged Images Dialog

Tagged Images Dialog

The Tagged Images dialog enables you to change your image selection, create and view a report, save the report as a PDF, print it out, or save the selected images in multiple electronic formats (see list on page 4-31). The layout and number of pages of the custom report depends on the number of images and the order you selected them for inclusion.

Note: The Tagged Images dialog is cumulative by scan while the current Advanced Visualization analysis is open. That is, the images you tag remain tagged and available in the Tagged Images dialog until you delete them or exit the analysis. The maximum number of images that may be tagged for print is 18 (or 6 pages).

When you tag an OCT image or a fundus image that includes an overlay, Cirrus automatically presents the image you select plus a companion fundus image for orientation or a text description of the overlay, respectively. Thus, for each image you tag, two images appear per row of the Tagged Images dialog, except for a fundus image that does not include an overlay.

- For OCT images, the companion fundus image has an overlay that highlights the position of the slice or slab.
- For fundus images with an overlay, the companion text box describes the overlay characteristics.

Tagged Images Dialog Functionality

In the Tagged Images dialog, you have the following options:

- **Deselect images:** All checkboxes are selected by default. Click a checkbox to deselect its image and exclude it from the printout.
- **Tag All:** Click to select all images.
- **Untag All:** Click to deselect all images.
- **Make Report:** Click **Make Report** to generate the report using the currently selected images. The Report Preview Dialog opens (see Figure 4-19 on page 4-31). You will then have the further options to print it out or save it as a PDF or TIFF or any of the other electronic formats listed.
- **Save Images:** Saves the currently selected images in BMP or JPG format in the location you select in the Save As dialog that appears. Each image in the pair is saved individually; thus, two images are saved for each selected row. The system automatically appends an image number to the end of the name you enter.
- **Delete Images:** Deletes the currently selected images from the Tagged Images dialog. (This does not delete any of the data from the scan itself.)
- **Close:** Exits the Tagged Images dialog.

(5) Analyze Scans: RNFL and Optic Nerve

Chapter Overview

This chapter explains how to use the RNFL and optic nerve analysis portion of Cirrus HD-OCT software. Topics covered in this chapter include:

Access Analysis

To access analysis, click the **Analyze** button when it is active; it is active when a patient record with saved exams is selected or is open. Usually you will access it after selecting a patient from the ID PATIENT SCREEN. Initially, the analysis screen shows four columns near the top, which list:

- the patient's exams by date (left column), with the most recent exam date selected by default;
- for the selected exam, the right eye OD scans (center left column) and left eye OS scans (center right column) by scan type;
- in the column on the right with which you can select among available analyses for the selected scan type, after you select a scan.

The image display portion of the screen is blank until you select a scan from the OD or OS column and then the desired analysis. Click to select any scan from the OD or OS list, then click on the analysis on the right. The corresponding analysis screen will appear in the image screen below, after a few seconds.

The ANALYZE SCREEN enables you to view and measure anatomical structures depicted in the scan images. In this chapter, these analyses are discussed:

RNFL Thickness Analysis

The RNFL Thickness Analysis[1] appears when you choose one **Optic Disc Cube 200x200** scan and then select RNFL Thickness Analysis in the right-hand column. The most recent **Optic Disc Cube 200x200** for the other eye for the same visit (if available) is presented along with the scan you first chose, unless you manually select a different scan for the other eye before clicking on RNFL Thickness Analysis. Once the RNFL Thickness Analysis is presented, you may choose any other **Optic Disc Cube 200x200** scan from the same day if you wish to change scans.

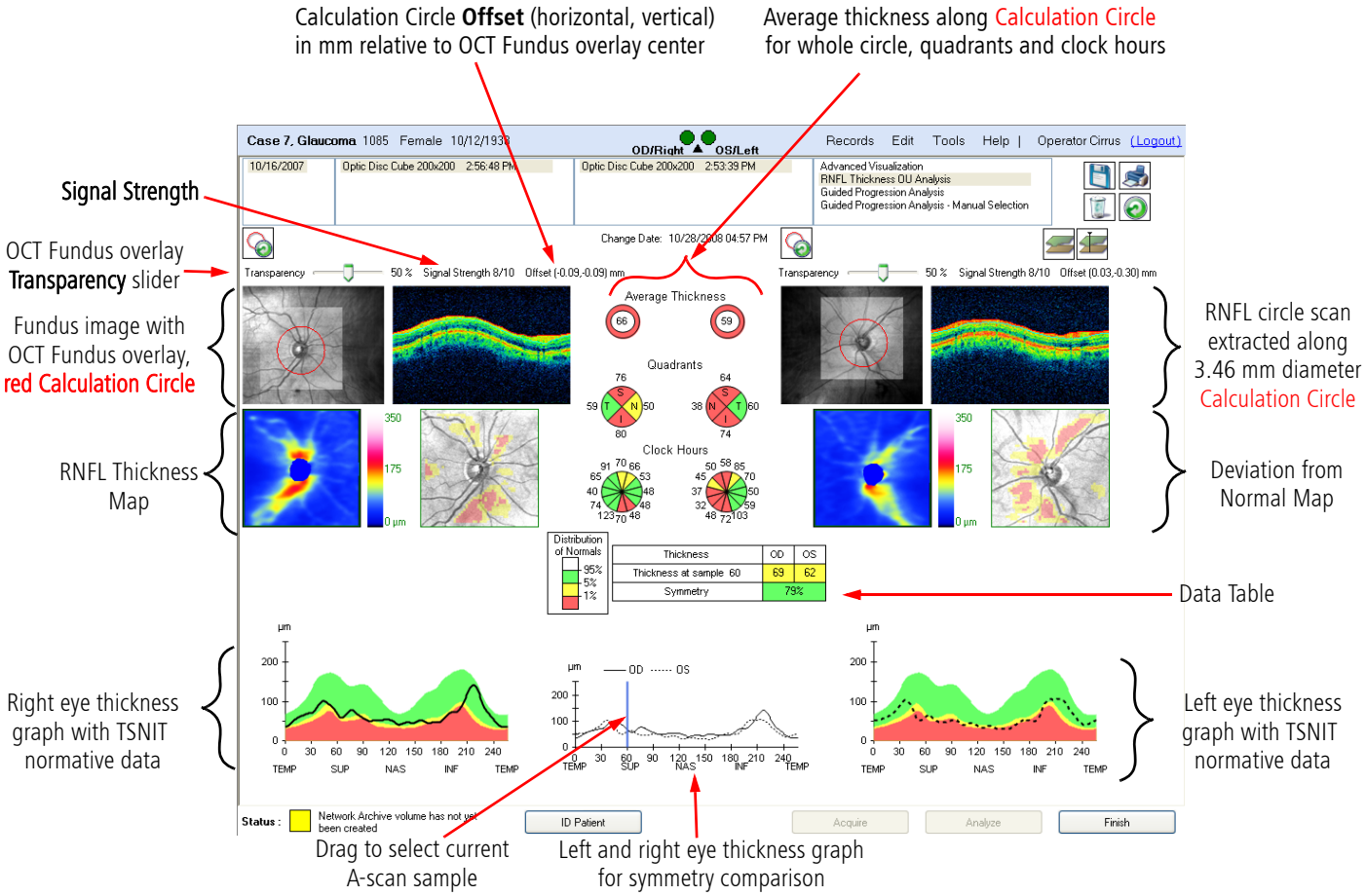


Figure 5-1 RNFL Thickness Analysis

Calculation Circle and Peripapillary RNFL Thickness

In the RNFL Thickness Analysis, Cirrus HD-OCT algorithms find the center of the optic disc, even if it is not well-centered in the scan image, and automatically place a red Calculation Circle of 3.46 mm diameter evenly around it. Cirrus identifies the center of the optic disc by finding a dark spot near the center of the scan that has a shape and size consistent with a

1. RNFL Thickness Analysis is an optional feature that may not be activated on all instruments. If you do not have this feature and want to purchase it, contact Carl Zeiss Meditec. In the U.S.A., call 1-877-486-7473; outside the U.S.A., contact your local Carl Zeiss Meditec affiliate or distributor.

range of optic discs. Using this as a starting point, the algorithm finds the outline of the optic disc using a graph-based method. The outline is used only to mask the regions of the optic disc where the segmentation is not expected to be well-defined (the blue optic disc area seen in the thickness map).

You can click and drag the Calculation Circle to adjust its placement, if you feel it is not optimally placed. A pink circle will remain in the original location as a reference point (as seen in the example below). You can click the **Reset Calculation Circle** button (for either eye) to return it to its automatically defined position.

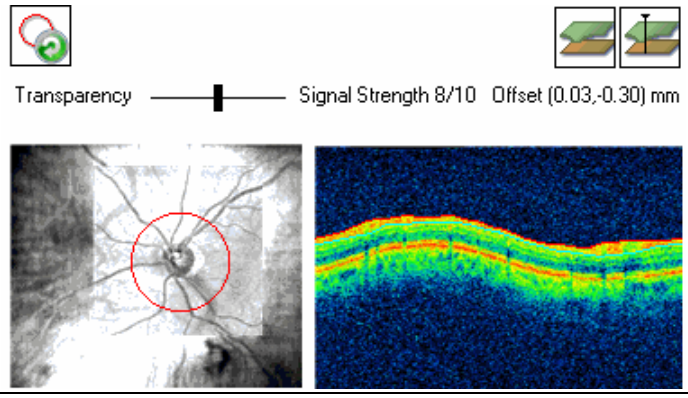


Figure 5-2 Calculation Circle and extracted RNFL circle scan image

Note: For circular scans (as extracted in the RNFL Thickness Analysis), left of scan starts at the most temporal point of the 3.46mm circle, and travels around the circle starting in the superior direction, then nasal, then inferior, then back to temporal (TSNIT). This is clockwise for the right eye and counterclockwise for the left eye.

Image Quality Information

- **Signal Strength Value:** This appears above the RNFL circle scan image. It ranges from 0-10, with 10 being maximum signal strength. When values are less than 6, the value is below the acceptable threshold; when 6 or higher, the value is acceptable.

Note: The Signal Strength value applies to the entire cube scan.

- The **Offset** values indicate the location of the Calculation Circle in mm relative to the center of the scanned area (horizontal offset and vertical offset). If you move the Calculation Circle, the offset values will update.

Thickness Calculations

Layer-seeking algorithms find the RNFL inner (anterior) boundary and RNFL outer (posterior) boundary for the entire cube, excepting the optic disc. The system extracts from the data cube 256 A-scan samples along the path of the Calculation Circle that together comprise the RNFL scan image displayed (seen in Figure 5-2). Based on the RNFL layer boundaries in the extracted circle scan image, the system calculates the RNFL thickness at each point along the Calculation Circle. The thickness data is plotted in the right and left eye thickness graphs and the symmetry comparison graph.

Click **Show/Hide Layers** to toggle display of the RNFL inner and outer boundary layers and the RPE layer in the extracted RNFL circle scan image.

The system also calculates, throughout the data cube (except the optic disc), the average RNFL thickness for each A-scan in pixels 30 micrometers square. For comparison to normative data, Cirrus combines 16 such A-scan pixels into superpixels composed of 16 A-scans, 4 by 4 square. Since each A-scan covers a 30 micrometer square, Cirrus measures thickness over superpixel squares 120 micrometers on a side.

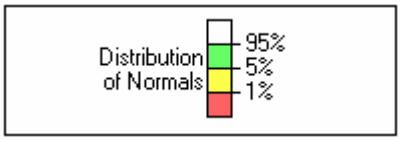
The RNFL Thickness Analysis derives the rest of its elements from these two kinds of thickness measurements: along the Calculation Circle and in superpixels. The rest of the elements are:

- RNFL Thickness Maps and Deviation from Normal Maps, page 5-5
- Average Thickness Values, page 5-6
- TSNIT Thickness Profiles, page 5-6
- Data Table, page 5-6

For completeness, it is necessary to introduce and explain the application of the RNFL Normative Database in these elements.

RNFL Normative Database

The RNFL Thickness Analysis supports the clinician in identifying areas of the RNFL that may be of clinical concern by comparing the measured RNFL thickness to age-matched data in the Cirrus RNFL Normative Database[1]. Normative data that is age-matched to the patient appears when you perform the RNFL Thickness Analysis on patients at least 19 years old. Data was not collected from subjects less than 19 years old.



The RNFL Normative Database uses a white-green-yellow-red color code, as seen in the legend at left, to indicate the normal distribution percentiles. The color code applies to each particular A-scan location in the TSNIT thickness graphs, to the quadrant, clock hour and whole-circle averages, and to the OD and OS columns of the data table. Among same-age individuals in the normal population, the percentiles apply to each particular RNFL thickness measurement along the Calculation Circle as follows:

- The thinnest 1% of measurements fall in the red area. Measurements in red are considered outside normal limits (red < 1%, outside normal limits).
- The thinnest 5% of measurements fall in the yellow area or below (1% ≤ yellow < 5%, suspect).
- 90% of measurements fall in the green area (5% ≤ green ≤ 95%).
- The thickest 5% of measurements fall in the white area (white > 95%).

☞ **Note: Clinicians must exercise judgment in the interpretation of the normative data. For any particular measurement, note that 1 out of 20 normal eyes (5%) will fall below green.**

1. The RNFL Normative Database is an optional feature that may not be activated on all instruments. If you do not have this feature and want to purchase it, contact Carl Zeiss Meditec. In the U.S.A., call 1-877-486-7473; outside the U.S.A., contact your local Carl Zeiss Meditec affiliate or distributor.

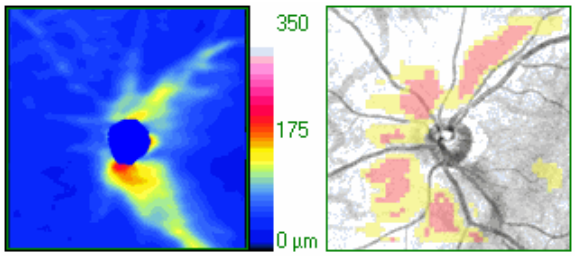
Interpretation of the 1st Percentile: Values color-coded as "1st percentile" are lower than 99% of the database sample, but may not extrapolate well to the general population with less than 300 subjects in the reference database. Results falling in this region should be interpreted with caution.
Interpretation of the 5th Percentile: Values color-coded as "5th percentile" are lower than 95% of the database sample. The 95% Confidence Interval on the 5th Percentile extends from the 2.5th percentile to the 7.7th percentile of the normative database.

☞ Note: Normative data colors will not appear if the patient is less than 18 years old.

Thickness-Derived Analysis Elements

Cirrus uses the thickness measurements to construct and display the following elements of the RNFL Thickness Analysis.

RNFL Thickness Maps and Deviation from Normal Maps



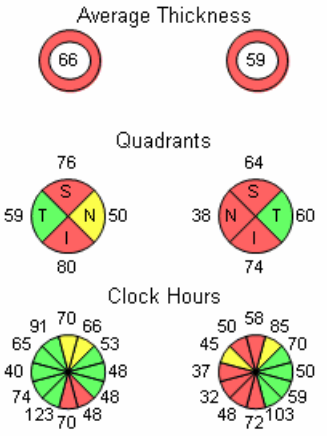
These maps are based on all calculated thickness data for the cube. Each is further described below.

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

☞ Note: Changing the placement of the Calculation Circle changes the Deviation from Normal Map, since each superpixel in the scanned area is defined relative to the center of the Calculation Circle. Meanwhile, the superpixel positions in the normative data are defined relative to a fixed center based on the age-matched

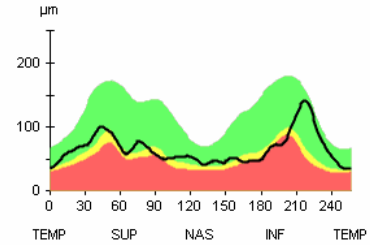
normative samples. Therefore, when you change the position of the Calculation Circle, you change the specific superpixel in the normative data against which each superpixel in the exam data is compared.

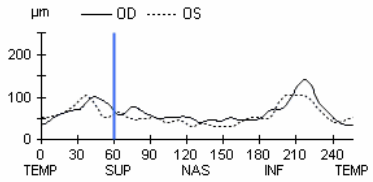
Average Thickness Values

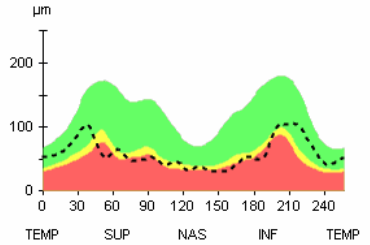


These values report average thickness along the whole Calculation Circle and by quadrants and clock hours. The color associated with each measurement derives from comparison to the age-matched RNFL normative data.

TSNIT Thickness Profiles







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

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

Data Table

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

The data table reports **Thickness at sample X**, where **X** is the current A-scan sample location (ranging from 0 to 256), as selected using the vertical blue line in the OU

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

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

Advanced Visualization Analysis

The Advanced Visualization Analysis is available to view any Optic Disc Cube 200x200 scan. This analysis screen functions the same as described in Advanced Visualization on page 4-20. A similar printout is available for this analysis. For horizontal scans, left of scan equals left of scan display and right of scan equals right of scan display. For vertical scans, bottom of scan equals left of scan display and top of scan equals right of scan display.

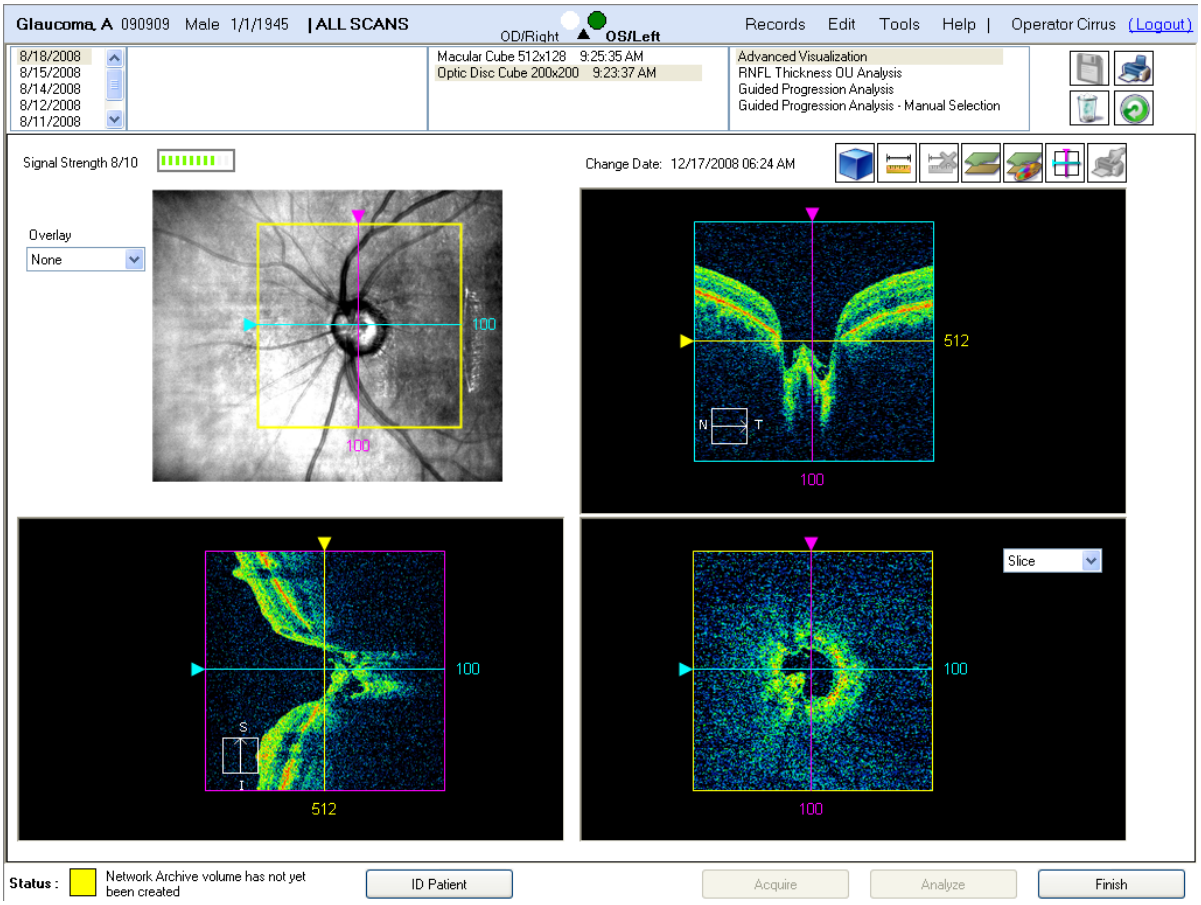


Figure 5-3 Advanced Visualization Analysis Screen

Guided Progression Analysis

Guided Progression Analysis™ (GPA) compares RNFL thickness measurements from the Optic Disc Cube 200x200 scan over time and determines if statistically significant change has occurred. GPA allows the user to analyze information from 3 to 8 exams.

The analysis includes a chronological display of RNFL thickness maps and RNFL thickness change maps, average RNFL thickness graphs representing rate of change, and RNFL thickness profiles comparing the current exam to the Baseline exams. Statistically significant changes are summarized with flags for possible or likely RNFL thickness loss (or possible RNFL thickness increase). The layout of these elements within the GPA window is shown in Figure 5-4.

Guided Progression Analysis Screen (GPA)

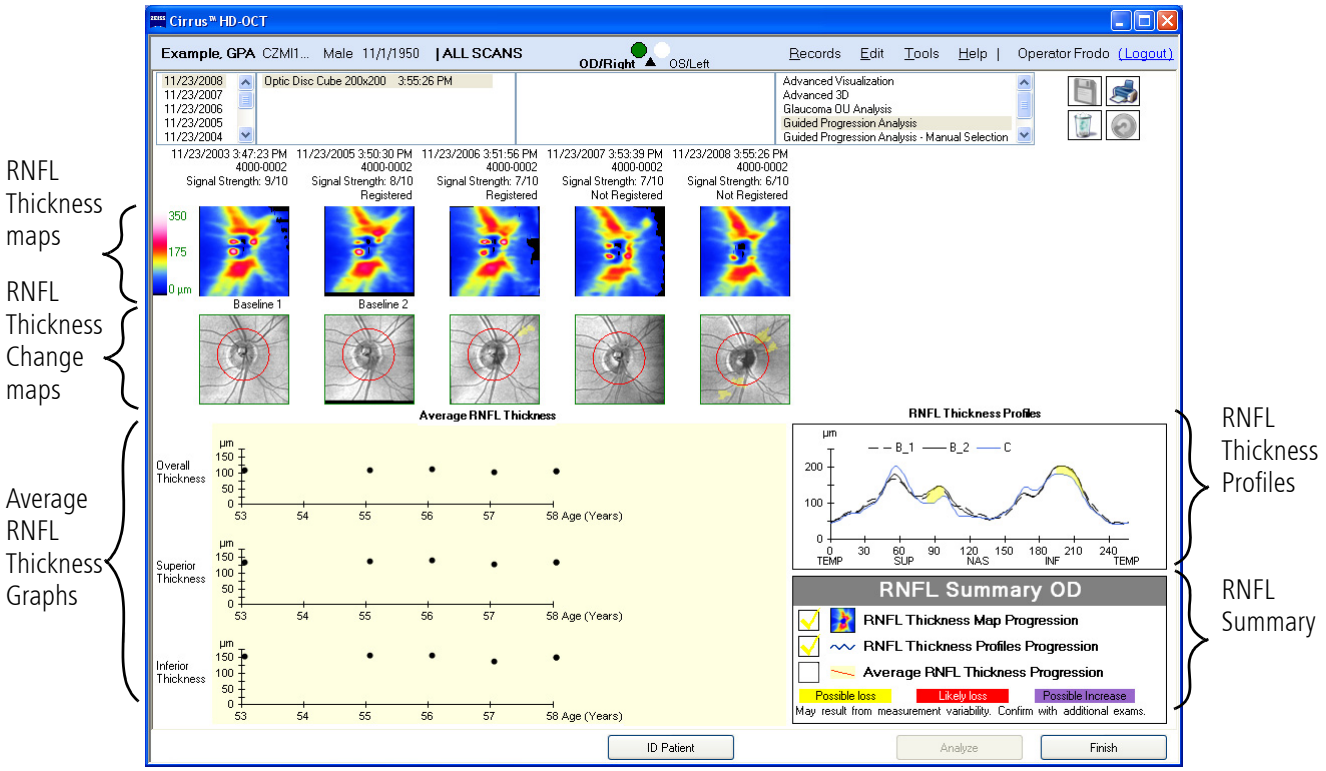


Figure 5-4 Guided Progression Analysis Screen

The earliest two exams are treated as Baseline exams. The later or Follow-up exams (3rd exam through last exam) are compared to the Baselines to see if they have changed. All scans, including the 2nd Baseline, are registered to the first Baseline in order to ensure accurate correspondence from the first scan to the last scan.

☞ **Note: Cirrus does not evaluate "progression of glaucoma," which can only be assessed through evaluating changes in several clinical factors, including optic nerve head appearance and visual fields. GPA only refers to change in the nerve fiber layer thickness assessed by statistical analysis of certain Cirrus parameters.**

Such change of RNFL thickness may or may not be related to clinically relevant changes. GPA is not meant to diagnose. Diagnosis is the responsibility of the practitioner, who should base diagnosis on many parameters, including those not assessed by Cirrus.

GPA Scan Selection

GPA automatically selects the appropriate scans from the most recent 8 visits. The automatic selection algorithm looks for scans with the highest signal strength from each previous visit. Scans with signal strength of 5 or lower will not be loaded automatically, although you may load them using the manual tool if necessary. The software automatically establishes the first two qualifying exams as the Baselines. You may override the GPA selections by choosing Guided Progression Analysis–Manual Selection. A list of eligible scans will be displayed so that you may choose alternative scans, as shown in Figure 5-5.

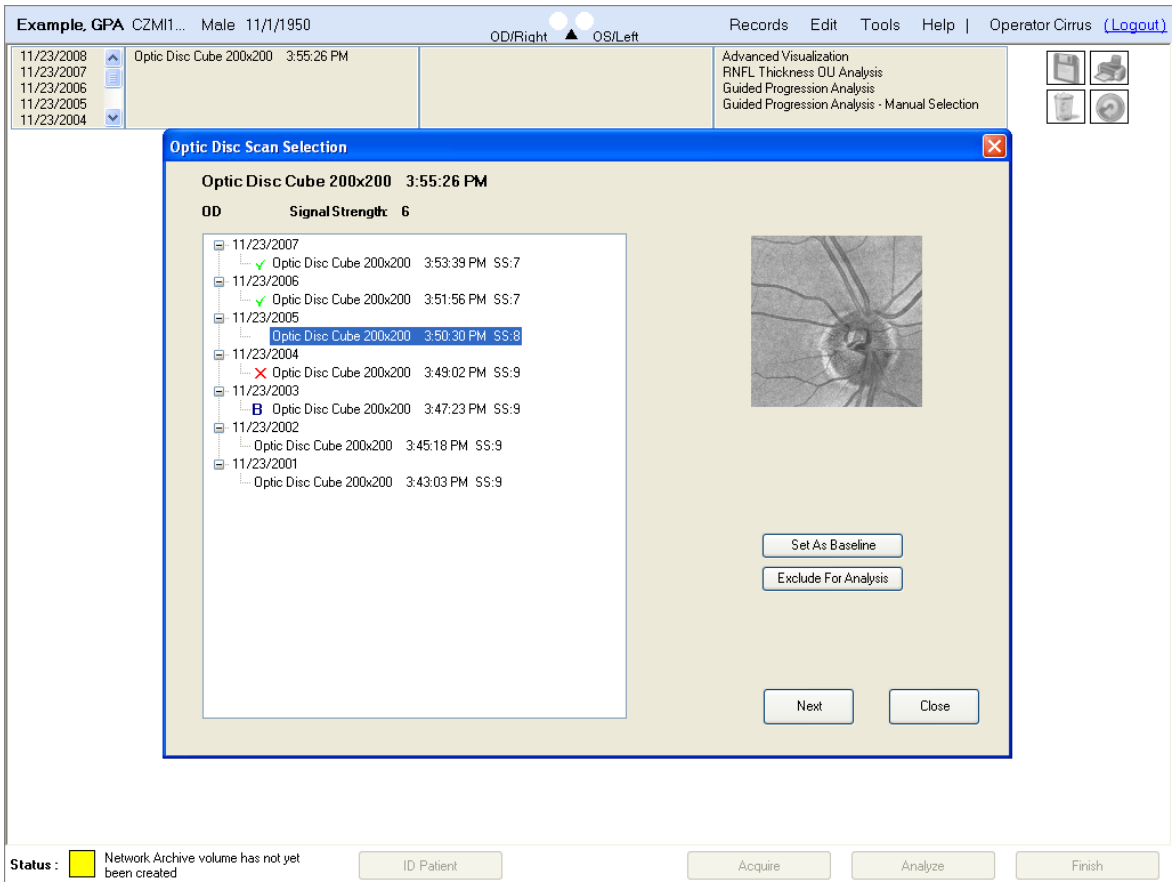


Figure 5-5 GPA Manual Selection of Scans

The first Baseline scan is indicated by the letter B. All the rest of the scans to be included in the analysis are indicated by green check marks (✓). Scans that have been excluded from all GPA's are marked with a red X. Scans that are not selected for the current analysis do not have any mark next to the scan. You may change an unchecked scan to be included by

clicking on the scan. The green check mark toggles with each click. To permanently exclude a scan from any GPA, you must designate with the red X.

Changing the Baseline Image

The Baseline image will always be the oldest image in the GPA sequence. Any images older than the Baseline image will not be included in the GPA.

1. Select Guided Progression Analysis–Manual Selection.
2. Select the desired scan for the Baseline.
3. Click on **Set as Baseline.** The letter **B** will indicate the Baseline exam.

The exam you selected will be the first Baseline and the next qualified exam will be the second Baseline. The second Baseline exam is not indicated by a letter B. It will only be indicated by a green check mark. GPA will recalculate all follow up exam comparisons based on the new Baseline.

☞ **Note: Baselines should be separated by at least a day. However, if the Baselines are separated by too great of a time period, change may have occurred between Baselines, which would make it more difficult to detect loss.**

Excluding Scans

You may wish to exclude a scan from ever being included in the GPA. This may be due to a poor quality scan, a desire to have a different time interval between scans, or other reasons. You may designate scans to not be included in the GPA with the following method. This does not delete the scan, it only excludes it from the GPA.

1. Select Guided Progression Analysis–Manual Selection.
2. Click on the scan to exclude.
3. Click on **Exclude from Baseline**. A red X will appear next to the scan.
4. Repeat for any additional scans to be excluded.

Including Scans

1. Select Guided Progression Analysis–Manual Selection.
2. Click on the scan to include. A green check mark will appear next to the scan.
3. Repeat for any additional scans to be included.

☞ **Note: A scan that is excluded is excluded not from only the current analysis, but from any future analysis using GPA. You must choose the scan and select Include for Analysis again if you wish to use the scan in a future GPA.**

When exam selection is complete, click on **Next** to exit the selection screen and continue to the GPA analysis. The GPA exam selections made during this process are set as the new default exams for the patient. Subsequent use of GPA using the automatic exam selection option will use these exams and will automatically select any new exams completed after the last manually selected exam. Should you have more than 8 eligible exam dates, the first Follow-up (exam 3) will be removed from the list and replaced with the most recent exam.

The two Baselines are used in GPA in two ways:

1. The two baseline exams are included in the linear regression that determines the rate of change, confidence limits on that rate, and statistical significance of the trend for the summary parameters (Average RNFL Thickness Graphs, page 5-13). For this part of the analysis, no distinction is made between the two baseline points and later points.
2. The two baseline exams are used to determine if Possible or Likely change has occurred. Two baselines are required to allow confirmation of change over multiple visits (Using Confirmation to Improve Specificity, page 5-18).

RNFL Thickness and Change Maps

The top of the GPA screen (Figure 5-6) displays from 3 to 8 RNFL Thickness maps chronologically from left to right. These allow you to visualize the change in RNFL thickness over time. The maps are labeled with the date and time of acquisition, serial number of the instrument on which the data was acquired, the signal strength of the scan, and information on whether the registration of that scan to Baseline succeeded.

The system automatically registers the enface OCT fundus images from the selected exams to the first Baseline exam. You can see a good example of registration in Figure 5-6. The images of the second Baseline scan and the two Follow up visits have been rotated to align with the first Baseline scan. This gives precise registration of the red Calculation Circle.

Below each thickness map is the OCT fundus image from that exam. For the Follow-up scans (3rd through last), regions where RNFL thickness has exceeded the test-retest variability are highlighted. These maps are referred to as the RNFL Thickness Change Maps, and the highlighted areas are areas of statistically significant change. RNFL Thickness Change Maps help you:

1. look for local thinning of the RNFL by comparing observed change to the test-retest variability, and
2. confirm the instances of apparent change by tracking the changes over multiple visits.

When no regions are flagged, no change has exceeded the test-retest variability. When a region is flagged yellow, it has changed relative to the two Baselines, but an additional scan is required to confirm that the change is likely. This is called "Possible Loss." When a region is flagged red, then it has changed relative to the two Baselines, and furthermore, the same region on the previous exam had also changed by more than the expected test-retest variability. This is called "Likely Loss." A region that is flagged lavender indicates an increase in thickness relative to the two Baselines. This may occur due to statistical fluctuations or poor data quality. For "Likely Loss," "Possible Loss," or "Possible Increase," to be reported, at least 20 adjacent superpixels must show significant change.

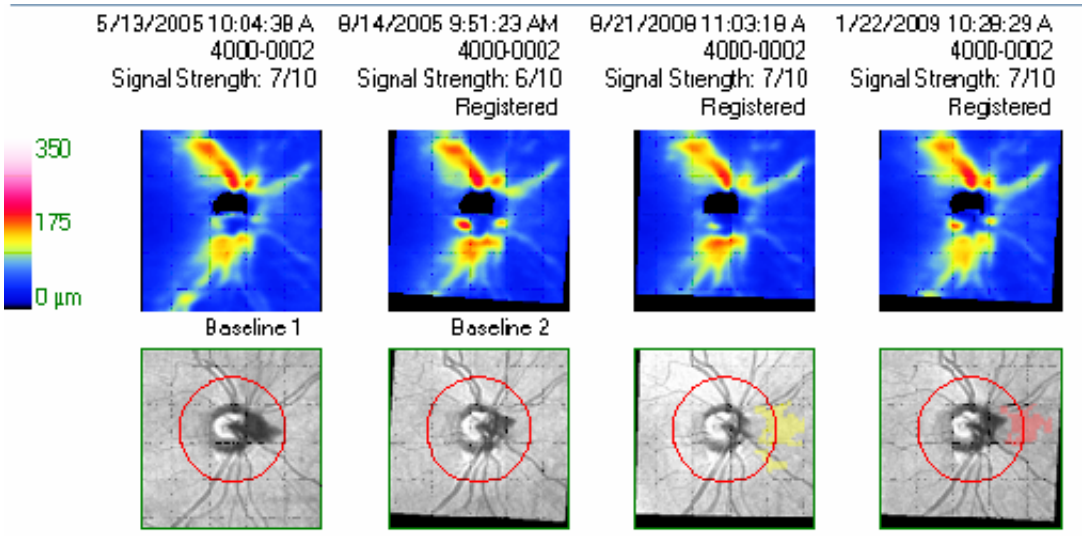


Figure 5-6 Simulated Comparison of RNFL Loss Over Time

In Figure 5-6, the first change map under Exam 3, which is the first Follow-up exam, is generated by comparing Exam 3 to the Baseline images. The areas of significant change when first detected are displayed in yellow for "Possible Loss." The next change map is generated by comparing Exam 4 (the current exam) to the Baseline images, and significant change is found in some of the same areas as the previous exam. Since this significant change has been seen two consecutive times, the areas of change are displayed in red for "Likely Loss." Notice that there are also some yellow areas in the last change map showing changes not seen in the previous exam.

RNFL Thickness Profiles

The RNFL Thickness Profiles (Figure 5-7) plots RNFL thickness values around the Cirrus RNFL Calculation Circle. All of the OCT fundus images are overlaid with the red circle that shows where the thickness profile measurements are evaluated. The location of the red circle on the first Baseline exam is determined by the automatic algorithm that finds the center of the optic disc. Because the remaining scans are registered to the first Baseline scan, the same center and circle are used for all other scans.

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

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

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

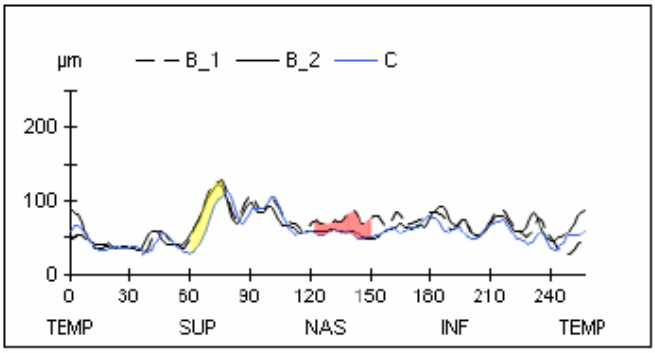


Figure 5-7 RNFL Thickness Profiles

Average RNFL Thickness Graphs

The Average RNFL Thickness Graphs (Figure 5-8) identify global thinning in the retinal nerve fiber layer by calculating a trend over time. The trend must be confirmed over multiple visits. Statistically significant loss, based on comparisons to test-retest variability, is also required. The Average RNFL Thickness Graphs are calculated by averaging large portions of the profile — this is why they detect only global loss. Each chart displays parameter data from 3 to 8 exams plotted in chronological order. The vertical axis represents RNFL thickness values ranging from 0–175 micrometers, and the horizontal axis represents patient age, spanning five years.

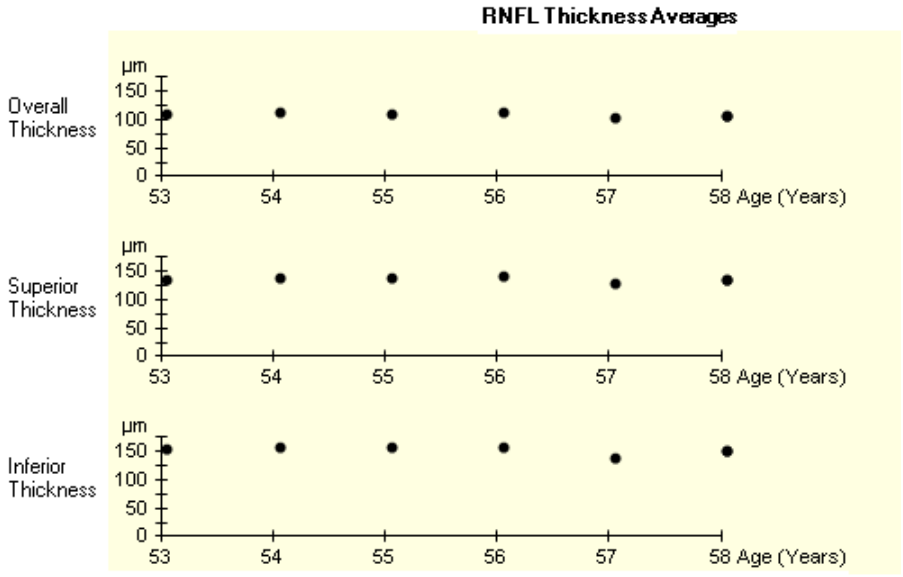


Figure 5-8 Average RNFL Thickness Graphs

Three RNFL Thickness graphs are presented (Figure 5-8):

1. A graph of the overall average thickness trend that shows the overall average thickness from the Cirrus RNFL Calculation Circle for each exam.
2. A graph of the average thickness trend for the superior quadrant of the RNFL Calculation Circle for each exam.
3. A graph of the average thickness trend for the inferior quadrant of the RNFL Calculation Circle for each exam.

The individual points are highlighted to indicate when the value plotted has changed from Baseline by an amount more than the test-retest variability. Possible loss occurs when the rate of loss is statistically significant for only a single visit and is indicated by a yellow symbol. Likely loss occurs when the rate of loss is statistically significant for two visits in a row and is indicated by a red symbol. Possible increase occurs when the rate of gain is statistically significant and is indicated by a lavender symbol. Possible increase should only occur due to random fluctuations or due to problems with scan quality.

These plots are fit using linear regression in order to calculate the rate of loss. The linear regression line is plotted on each graph whenever there is both "Likely Loss" *and* a significant linear trend ($p < 5\%$). Confidence bands for the regression line are also shown. They are determined based on comparing the variability in the data to the rate of change. The slope (rate of change) is displayed in micrometers/year with 95% confidence interval values. For example, with a slope of -3.9 ± 1.1, there is 95% confidence based on statistical analysis that the slope is between -2.8 and -5.0 µm/year. This is shown graphically in the shaded gray area.

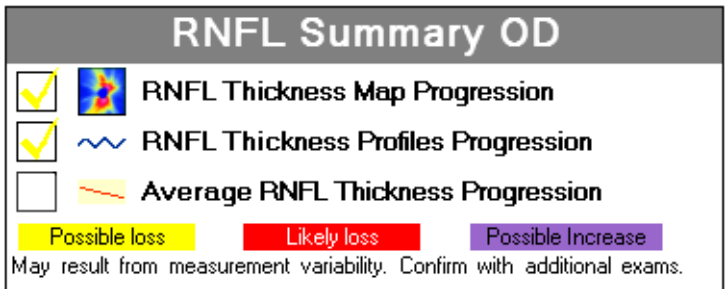
☞ **Note: Linear regression fits the data to a linear model, assuming that the measurements are independent, normally distributed, and that variability does not depend on the size of the measurement. If the observed measurements do not change linearly, the rate of change may still provide information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

RNFL Summary

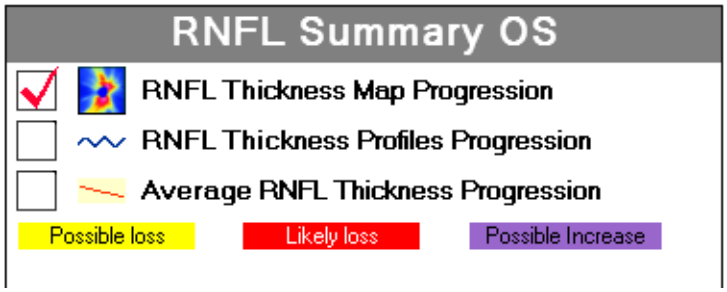
The RNFL Summary displays a color-coded summary box that alerts you if significant change has been detected. GPA has three different indicators for detecting RNFL change, each with a check box in the summary:

- RNFL Thickness Map Progression (best for focal change)
- RNFL Thickness Profiles Progression (best for broader focal change)
- Average RNFL Thickness Progression (best for diffuse change)

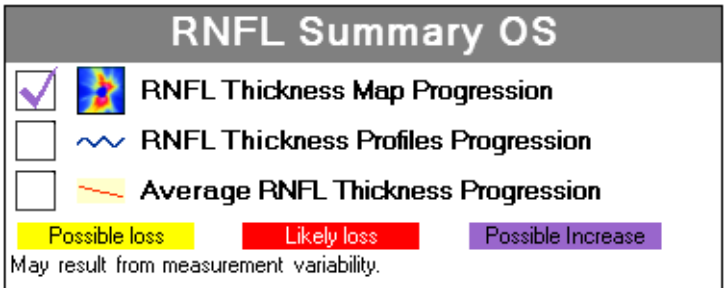
The summary box reports progressive change as one of "Possible Loss" (yellow), "Likely Loss" (red), or "Possible Increase" (lavender). "Possible Loss" means progressive loss has been detected once. "Likely Loss" means it has been confirmed by consecutive follow-up examinations. Shown below are examples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



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



The red check mark in the RNFL Thickness Map Progression summary boxes above shows Likely Loss.



The lavender check mark in the RNFL Thickness Map Progression summary box above shows Possible Increase.

How to Read the GPA Report

1. Verify data quality

Verify the images. Discard or retake images with poor registration and/or poor signal strength (SS < 6) whenever possible, or interpret with caution.

Verify image registration. Discard or retake any images that fail to register to Baseline.

How similar are the Baselines? Examine the RNFL Thickness profiles, Average RNFL Thickness graphs, and RNFL thickness maps. If the Baselines are not consistent, GPA will be less able to flag RNFL loss.

2. Examine GPA printout

Review the color-code RNFL Summary box. A yellow "Possible Loss" summary box indicates additional follow-up visits are recommended to confirm change. A red "Likely Loss" summary box indicates statistically significant change is detected in the measurements. A lavender "Possible Increase" summary box could indicate high measurement variability.

3. Apply GPA results in context of the patient

GPA reports statistically significant change for one eye, which may or may not be clinically significant. Rate of loss, locations of the detected loss, age of the patient, stage of the disease, and other clinical factors should be evaluated for clinical decisions. To confirm that RNFL loss is clinically significant, correlate your results with other clinical tests such as perimetry and IOP.

4. Consider Resetting the Baseline Scans

It is prudent to occasionally review the current Baseline scans and consider changing to a more recent Baseline pair if there has been a significant change in the course of the patient's care. A stable period of RNFL thickness may follow a period of RNFL thinning due to a change in therapy. This leveling off would be a good time to update the Baseline images. This will allow GPA to flag change from this new point in time instead of having the summary flags continuously checked off due to thinning that occurred at an earlier, less stable time.

Statistical Significance

Guided Progression Analysis compares an observed change with its expected test-retest variability, as illustrated in Figure 5-9.

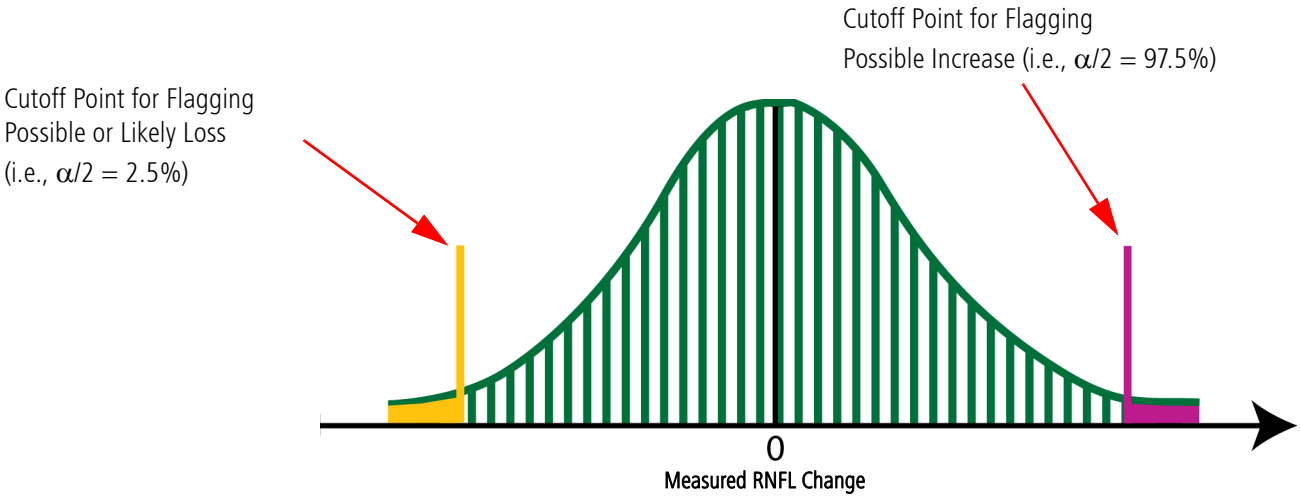


Figure 5-9 Distribution of Test-Retest Variability

Statistically Significant Change from Baseline

Guided Progression Analysis compares an observed change with its population test-retest variability. The test-retest variability was determined by performing an in-house repeatability and reproducibility study (results reported at ARVO 2008 in a poster, "Inter-Visit and Inter-Instrument Variability for Cirrus HD-OCT Peripapillary Retinal Nerve Fiber Layer Thickness Measurements" – M.R. Horne, T. Callan, M. Durbin, T. Abunto; Poster 4624, ARVO 2008).

The difference between a current exam and the Baseline is assumed to have a normal distribution with a standard deviation determined from clinical measurements on subjects over a short period of time. Only 5% of paired measurements are expected to have an absolute difference more than 1.96 times the standard deviation of differences observed in an in-house reproducibility study of normals, which is the test-retest variability. This is also equal to 2.77 times the reproducibility standard deviation observed. Figure 5-9 illustrates a normal distribution of differences, centered at a mean difference of zero. The yellow line shows the cutoff for declaring 'Possible Loss' or 'Likely Loss' and the lavender line shows the cutoff for declaring 'Possible Increase'. For any individual comparison of a measurement to Baseline, only 2.5% of measurements are expected to show change to the left of the yellow line when real loss has not occurred, and only 2.5% of measurements are expected to show change to the right of the lavender line.

Because thickness maps and profiles have multiple points available for testing, the observed rate of false positives would be higher than 5% if the cutoff is set based on the 95% confidence limit depicted in Figure 5-9. To achieve a reasonable false positive rate of

no more than 5% for any given visit, the limits are set at 99% for the TSNIT profile and 99.5% for the change map.

Using Confirmation to Improve Specificity

In order to increase the specificity of the measurement over multiple visits, Cirrus also requires that statistically significant change from Baseline be observed for at least two pairs of measurements when only three measurements are available, and for at least three pairs of measurements when four or more measurements are available. In this case, Cirrus will report 'Possible Loss' for a parameter. For example, a superpixel on the change map will be colored yellow, or the RNFL Profile will show a yellow region between the Baseline and current scans, or the Average Thickness plot will show a yellow symbol for that visit. If, on the following visit, these same conditions are met for the same parameter, Cirrus will report 'Likely Loss', because now the change has been flagged for more than one visit. These confirmation strategies help improve the specificity, and reduce the effects of individual outlier measurements.

☞ Note: RNFL thickness is expected to decrease slowly as a function of normal aging. The RNFL data collected for the normative database (RNFL Normative Database on page 5-4) showed a rate of loss for overall thickness of -0.2 micrometers per year, with a 95% confidence interval of -0.25 to 0.13 micrometers per year. For superior thickness, the rate was -0.25 micrometers per year (-0.35, -0.15), and for inferior thickness, it was -0.3 micrometers per year (-0.42, -0.21).

This slow rate of change is consistent with observations of RNFL thickness loss measured on Stratus OCT. All of these results are based on cross-sectional data, and an individual patient's normal aging rate may vary. Because the exact rate of change for any individual is unknown, Cirrus reports statistical significance if the 95% confidence limits on the slope exclude zero, rather than determining if they exclude normal age-related loss.

If Cirrus reports that a rate of change is statistically significant, but the 95% confidence bands include a rate consistent with normal aging, the observed change may be due to normal aging process rather than glaucomatous loss.

(1) R. Gurses-Ozden, M. Durbin, T. Callan, M. Horne, K. Soules, Cirrus Normative Database Study Group, "Distribution of Retinal Nerve Fiber Layer Thickness Using Cirrus™ HD-OCT Spectral Domain Technology" Poster 4632, ARVO 2008

(2) Ramakrishnan R, Mittal S, Sonal A, et al. Retinal nerve fibre layer thickness measurements in normal Indian population by optical coherence tomography. Indian J Ophthalmol. 2006;54:11-15.

(3) Sony P, Sihota R, Tewari Hem K, et al. Quantification of the retinal nerve fibre layer thickness in normal Indian Eyes with optical coherence tomography. Indian J Ophthalmol. 2004;52:303-309.

(4) Hougaard JL, Ostenfeld C, Heijl A, et al. Modeling the normal retinal nerve fiber layer thickness as measured by Stratus optical coherence tomography. Graefes Arch Clin Exp Ophthalmol. 2006.

(5) Budenz DL, Anderson DR, Varma R, et al. Determinants of normal retinal nerve fiber layer thickness by Stratus OCT. Ophthalmology. 2007;114:1046-1052.

(6) Parikh RS, Parikh SR, Sekhar GC, et al. Normal age-related decay of retinal nerve fiber layer thickness. Ophthalmology. 2007;114:921-926.

(7) Ronald S. Harwerth "Age-Related Losses of Retinal Ganglion Cells and Axons," Investigative Ophthalmology & Visual Science, October 2008, Vol. 49, No. 10

RNFL Thickness Analysis Stock Printout

The stock printout for RNFL Thickness Analysis includes all the information on screen when you click **Print**.

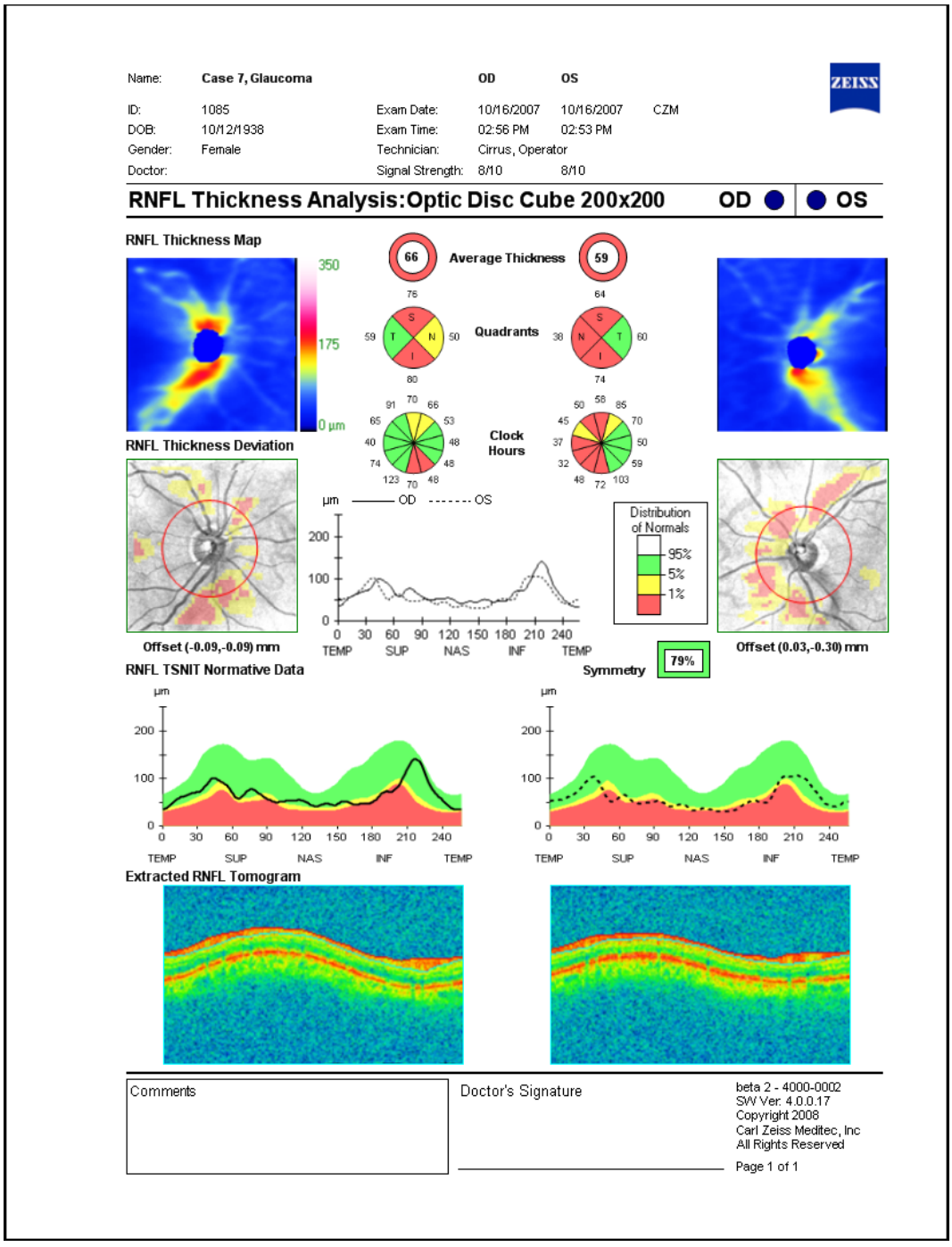


Figure 5-10 RNFL Thickness Analysis Printout

Guided Progression Analysis (GPA) Printout

The stock printout for Guided Progression Analysis includes all the information on screen when you click **Print**.

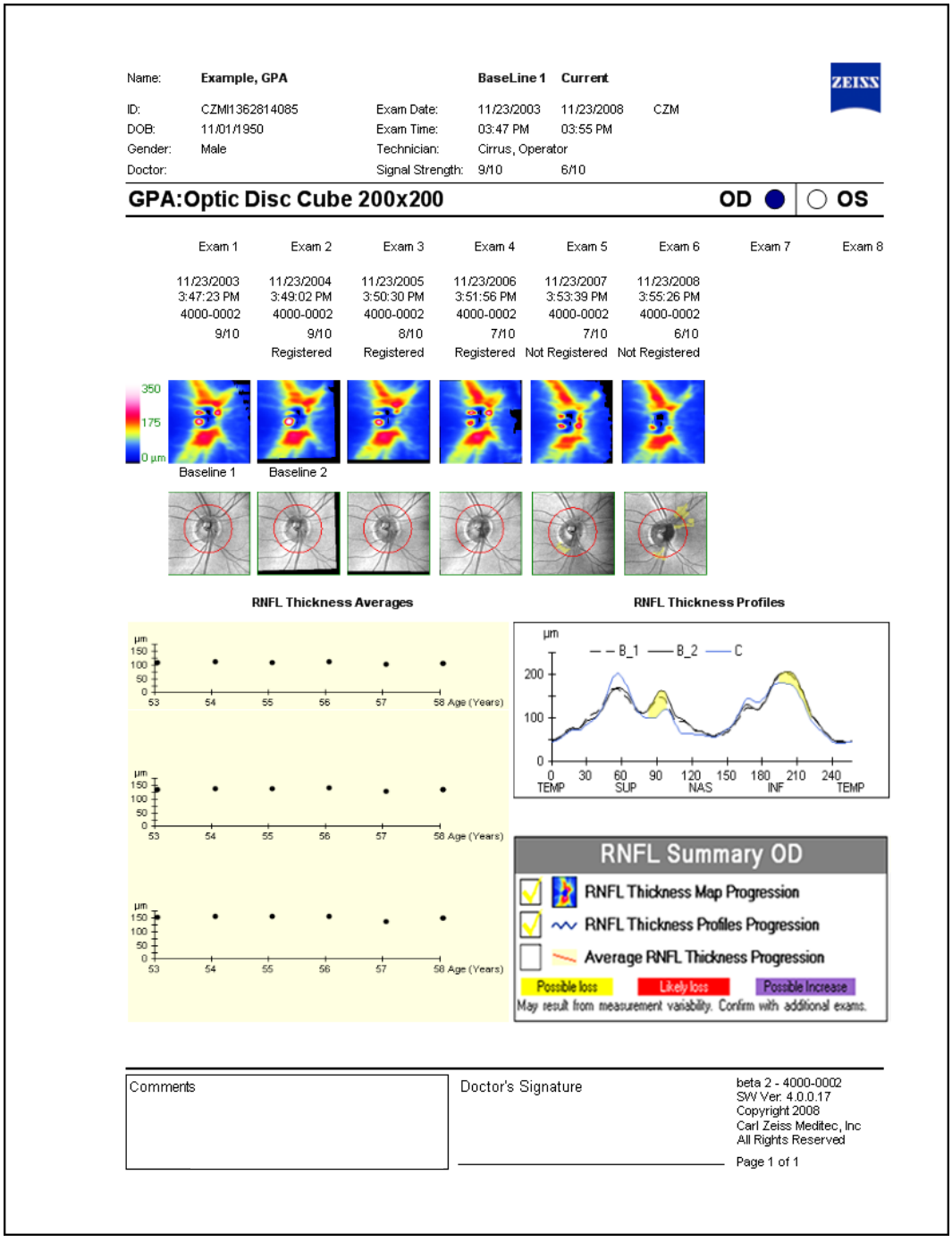


Figure 5-11 Guided Progression Analysis printout

Performance of Cirrus HD-OCT RNFL Analysis

Repeatability and Reproducibility

CZM performed an in-house study on normal subjects to determine the inter-visit and inter-instrument repeatability of Cirrus RNFL thickness measurements. The repeatability and reproducibility (including effects of multiple visits and multiple instruments), along with the coefficient of variability, are shown in Table 5-1 on page 5-22. Similar results were also found in an independent study, which reported a coefficient of variability of 1.5% in normal subjects and 1.6% in patient eyes[1].

Comparison to Stratus OCT

A recent study[2] of normal subjects and patients (N = 130) found that although there were differences between Stratus and Cirrus, the Pearson correlation coefficient for the average RNFL thickness was 0.953, indicating good correlation. However, they also found a systematic difference between Cirrus and Stratus RNFL measurements. Cirrus measures thicker than Stratus at thinner RNFL values and measures thinner at thicker (more normal) RNFL values. Measurements from the two systems should not be used interchangeably.

1. Vizzeri, G, Weinreb, RN, Gonzalez-Garcia, AO, Bowd, C, Medeiros, F, Sample, PA, Zangwill, LM: Agreement between spectral-domain and time-domain OCT for measuring RNFL thickness, Br J Ophthalmol, March 2009.

2. O.J. Knight, R.T. Chang, W.J. Feuer, D.L. Budenz, "Comparison of Retinal Nerve Fiber Layer Measurements Using Stratus OCT and Cirrus Spectral Domain OCT," Poster 4628, ARVO 2008

Table 5-1: Repeatability and Reproducibility of Cirrus RNFL measurements for seventeen sectors, including the overall average thickness, four quadrants (temporal, superior, nasal, and inferior), and twelve sectors, labeled by clock hour, with the 9 o'clock hour most temporal, measured on 32 normal subjects.

	Mean Thickness (µm)	Repeatability SD (µm)	Reproducibility SD (µm)	Repeatability Limit[a] (µm)	Reproducibility Limit[b] (µm)
Average	93.1	1.33	1.35	3.72	3.78
Temporal	64.6	2.03	2.05	5.68	5.74
Superior	118.8	3.42	3.45	9.58	9.66
Nasal	68.6	2.19	2.24	6.13	6.27
Inferior	123.6	3.01	3.14	8.43	8.79
Clock hour 1	113.6	4.84	5.05	13.55	14.14
Clock hour 2	84.3	4.7	4.74	13.16	13.27
Clock hour 3	56.4	2.43	2.56	6.80	7.17
Clock hour 4	63.0	3.25	3.37	9.10	9.44
Clock hour 5	102.5	4.35	4.37	12.18	12.24
Clock hour 6	133.5	4.93	5.21	13.80	14.59
Clock hour 7	134.7	5	5.01	14.00	14.03
Clock hour 8	66.1	3	3	8.40	8.40
Clock hour 9	53.0	1.71	1.78	4.79	4.98
Clock hour 10	76.3	3.53	3.53	9.88	9.88
Clock hour 11	125.2	4.75	4.77	13.30	13.36
Clock hour 12	121.6	6.43	6.51	18.00	18.23

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. Per ISO 5725-1 and ISO 5725-6, Repeatability Limit = 2.8 x Repeatability SD.

b. Reproducibility Limit is the upper 95% limit calculated for the difference between results repeated with different operators on different instruments. Each subject was imaged three times each during three visits on a single instrument (Phase 1) or twice during a single visit on five instruments (Phase 2). Per the ISO quoted in the main text, Reproducibility limit = 2.8 x Reproducibility SD.

(6) Data Management

Chapter Overview

This chapter explains how to manage data with the Cirrus HD-OCT. The topics covered in this chapter include:

This manual treats data transfer functions in a separate chapter:

The admin User

To manage administrative functions, Cirrus HD-OCT dedicates a special user account with the user name **admin**. Only the **admin** user can create and edit the institution name, user accounts and staff records.

The admin account never appears in the drop-down list of user names on the login screen. You must type it in. The **admin** account accepts any password or none. The **admin** user cannot acquire or analyze scans. When the admin user is logged in, the only available menu functions are:

- Logout
- Tools > MTA Print Configuration
- Tools > Options > Categories (edit categories)
- Tools > Options > Institution Edit (edit institution information)
- Tools > Options > Equipment Edit (edit equipment information)
- Tools > Options > Users (register or edit staff, assign privileges)
- Help > On-Line Manual (open this user manual)
- Help > License Registration... (register licenses)
- Help > View Licenses (view license status)
- Help > About... (view software version information)

Only the **admin** user can access the Institution Edit dialog, Equipment Edit dialog and Staff Registration dialog. These special administrative functions are explained next.

Create Institution Name and Logo

Use the Institution Edit dialog to customize your system. Besides the institution name, it also gives you the option of adding a logo graphic in bitmap (.bmp) format. Once you have supplied the name and logo, they will appear on all analysis printouts.

☞ **Note: You must restart the Cirrus application to cause changes to the Institution Name to appear in the header of reports.**

To access the Institution Edit dialog, you must be logged in as the **admin** user.

Follow the steps below to customize your system:

1. Click Options > Institution Edit.... The Institution Edit dialog opens.

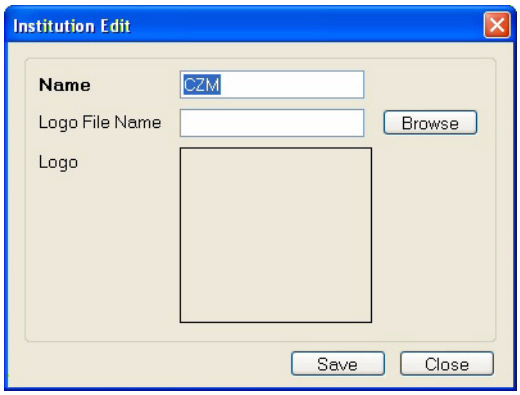


Figure 6-1 Institution Edit dialog

2. In the Name field, type the name of your institution. The field requires at least one character and accepts up to 64 characters, including spaces. The name field cannot be empty.
    - If you are not going to use a logo graphic, click Save to save your changes and exit the dialog.

Add Institution Logo Graphic (Optional)

Recall that the graphic must be in bitmap format (and have a .bmp file extension after its name).

1. To add a logo graphic, do one of the following to enable access to the graphic file:
    - Copy the logo graphic file from the source system to removable media and insert the media into its drive on the Cirrus HD-OCT.
    - Import the logo graphic file directly from a network location.
2. Click Browse. A standard directory browser will appear. The Files of type field will be limited to bitmap, so you can view and select only files with the .bmp extension.

3. Locate and select the logo graphic file, either on the applicable drive for removable media, the system hard drive (D: or E:), or from a network location. Click **OK** to save your selection and return to the Institution Edit dialog.
    - The selected logo graphic will appear in the **Preview** pane.

☞ **Note: The Preview pane is 150 pixels square (1.9 cm or 0.75 inches square at 200 pixels/inch). The selected graphic will be stretched or constrained to fit it, and the graphic will appear in these proportions on analysis printouts, though in a smaller size. To avoid distortion of the logo graphic, we suggest you select one (or edit one to be) approximately the same size as the Preview pane.**

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

Equipment Edit: Create a Station Name

Only the **admin** user can access the Equipment Edit dialog. This dialog presents information about the system's identity, including the model, serial number and software version. This system information is fixed; the user cannot change it. The Equipment Edit dialog has the singular purpose of creating a station name for the device to distinguish Cirrus HD-OCT instruments, in an institution where more than one Cirrus HD-OCT is in use.

☞ **Note: The station name, in addition to the institution name, is used to identify the instrument on which exam data originated; it will appear on Cirrus printouts.**

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

1. Select **Options > Equipment...**. The Equipment Edit dialog opens.

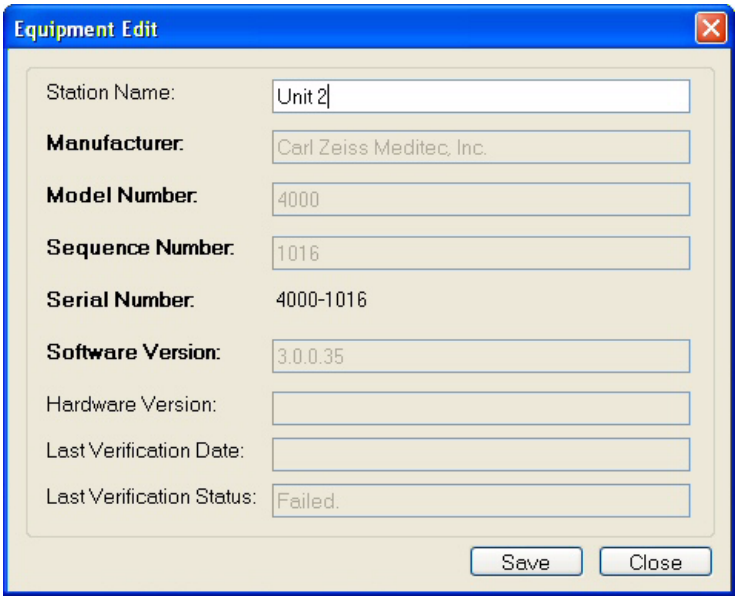


Figure 6-2 Equipment Edit dialog

2. In the Station Name field, type in the desired name. Click **Save** to save your changes and exit the dialog, or click **Close** to exit the dialog without saving.

Staff Registration

Using the Staff Registration dialog, the **admin** user can create (register) medical staff records and assign a user name, password and privileges to users. Users can then search for patient records by association with registered staff. Cirrus automatically and permanently associates saved scans with the current user when saving.

Operator Privileges

The **Operator** privilege provides access to the system software and all functions. Only staff registered as Operator can access the system software because only the user names of Operators are available in the drop-down list on the login dialog. (Reading Physician, Requesting Physician and Referring Physician have no practical effect in the current software version.)

Register (Create), Edit and Delete Staff

To register, edit or delete staff records, use the Staff Registration dialog. To access this dialog, you must be logged in as the **admin** user, and the **admin** user must have created an institution name previously. (See Create Institution Name and Logo on page 6-2.)

Select **Options > Users...**. The Staff Registration dialog opens.

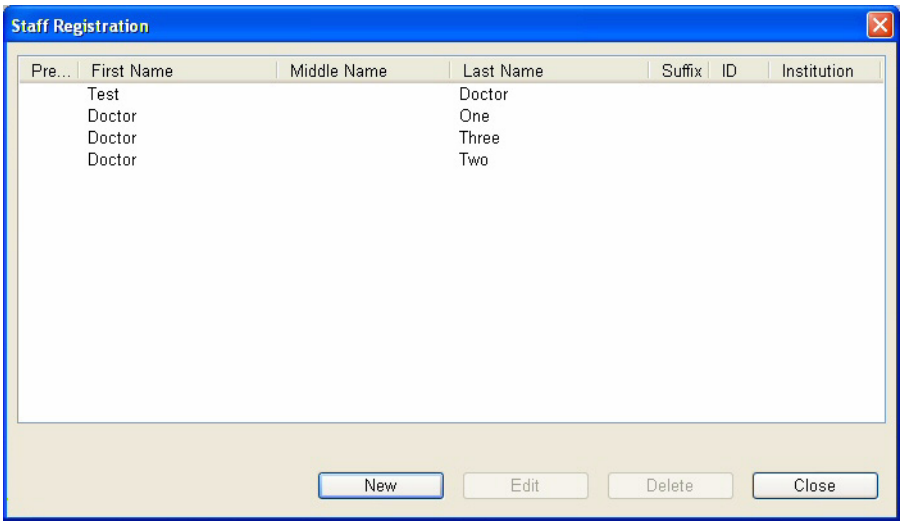


Figure 6-3 Staff Registration dialog

All registered staff appear in the list, sorted alphabetically by last name. None is selected by default.

Register (Create) Staff

1. In the Staff Registration dialog, click **New**. The New Staff dialog opens.

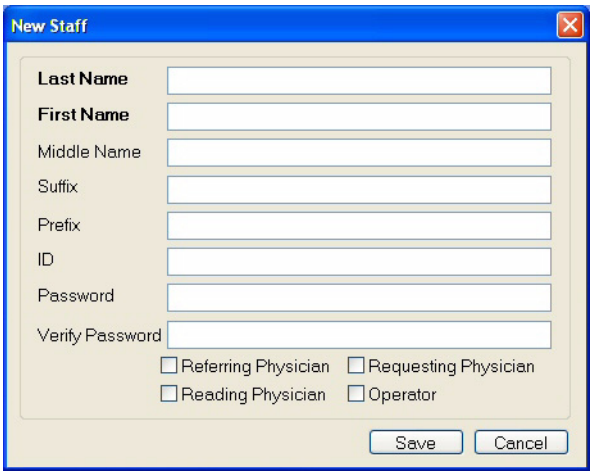


Figure 6-4 New Staff dialog

2. Edit the staff registration fields as desired. A staff record must have either a last name or first name or both; other fields are optional. To log in with this user name and acquire scans, the **Operator** checkbox must be selected. When finished with your changes, click **Save**.
   - To discard the changes before saving, click **Cancel**. A dialog prompts you to confirm your choice.

☞ Note: If the password field is left blank, that user must leave the password field blank to log in. User names are **not** case-sensitive, but passwords are.

☞ Note: Once logged in, any user can change his or her own password by selecting **Options > Change My Password...** and completing the Password Change dialog. The **admin** user may take advantage of this feature by creating new user accounts with a temporary password, providing it to the user, and asking the user to change the password.

Edit Staff Records

To edit medical staff records, follow these steps:

1. In the Staff Registration dialog, select a staff record and click **Edit**. The Staff Edit dialog opens It resembles Figure 6-4 above except that the name of the selected staff appears in the title bar.
2. Edit the staff registration fields as desired and then click **Save**. Only the bold **Last Name** and **First Name** fields are required; other fields are optional.
   - To discard the changes before saving, click **Cancel**. A dialog prompts you to confirm your choice.

Delete Staff Records

To delete medical staff records, follow these steps:

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

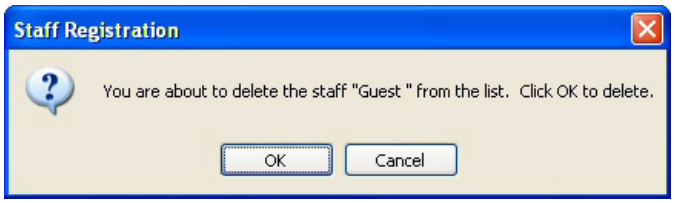


Figure 6-5 Confirm staff deletion dialog

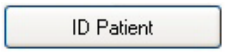
2. Click **OK** to confirm deletion, or click **Cancel** to cancel deletion.

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

Record Search

Search functionality is incorporated into several dialogs within the Cirrus system software. In each instance, the software provides basic search functionality on the dialog itself and an **Advanced Search** link. With advanced search, you can search using all possible parameters. The advanced search, no matter where initiated, always uses a common dialog (see Advanced Search on page 6-8). Dialogs that include basic search sometimes provide different sets of search parameters. This section presents basic search using the most common example: the ID PATIENT SCREEN.

Basic Search



1. To search for patient records, use the **Find Existing Patient** tab of the ID PATIENT SCREEN, which appears automatically after login. From other modes, click the **ID Patient** button to return to the ID PATIENT SCREEN.

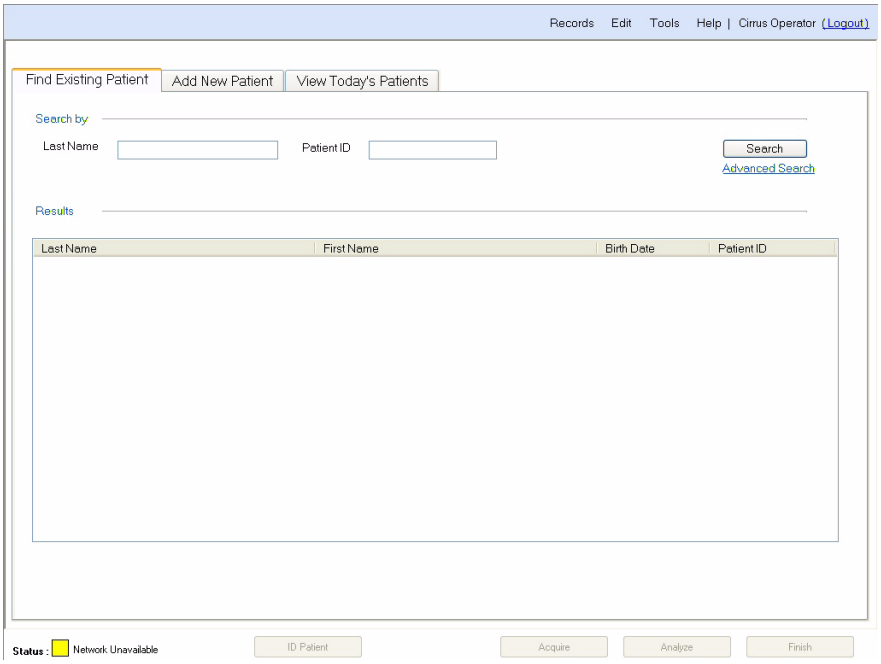
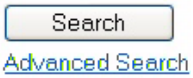


Figure 6-6 ID Patient Screen—default tab: Find Existing Patient



2. Click **Search** to return all patients in the index database. To search for patients **Last Name** or **Patient ID**, type in the corresponding fields and click **Search.**

- You can search using partial information, and you can use one or both fields.
- Click **Advanced Search** if you want to search using additional parameters—see Advanced Search on page 6-8 for details.
- The search returns all patients that match all defined parameters, sorted alphabetically.
- When you search by **Last Name**, the search returns all patients that match from the beginning of the last name.
- In this list, you can select only one patient at a time. When you select a patient, the **Acquire** button becomes active. If the patient has saved exams, the **Analyze** button becomes active.

Advanced Search

1. Click **Advanced Search** if you want to search using additional parameters. The Advanced Search dialog appears.

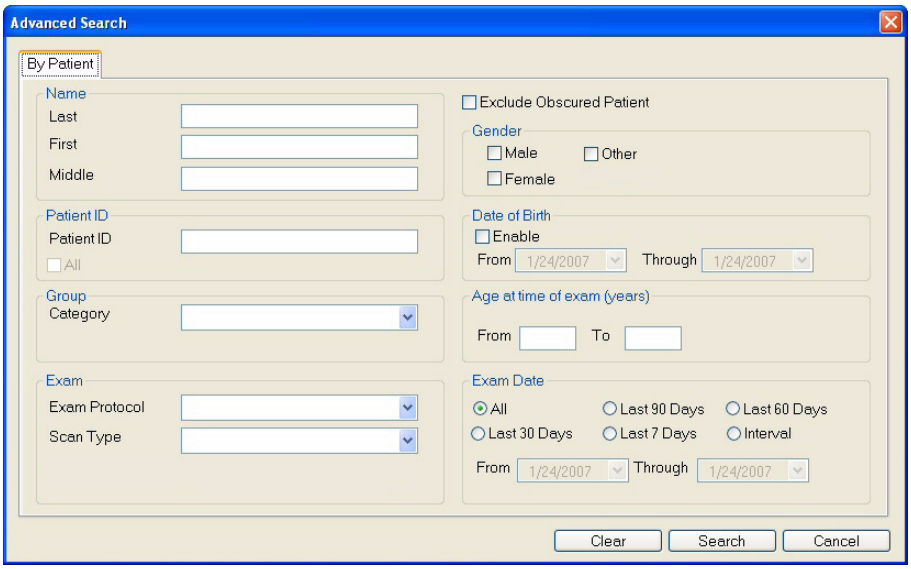


Figure 6-7 Advanced Search dialog

2. Using the available fields, enter or select search parameters and click **Search**. Search parameters you type in are not case-sensitive. The Search Preview dialog returns all matching patients, sorted alphabetically by last name.

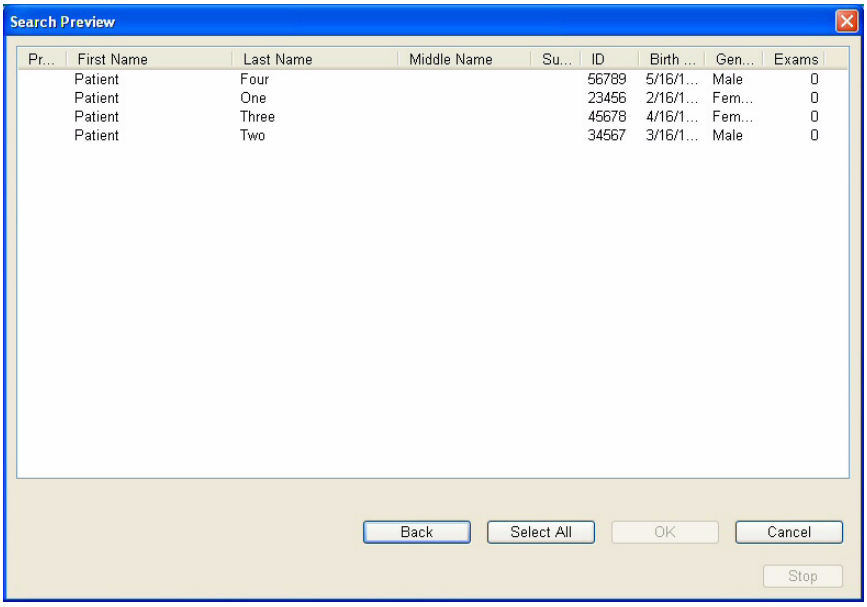


Figure 6-8 Search Preview dialog

☞ Note: The search returns only the patients that match all search parameters used. If your search does not return all patients desired, you may want to broaden your search by using fewer parameters or partial information. Clicking **Search** without using any parameters returns all patients in the Cirrus index database.

3. In the Search Preview dialog, select the patients you wish to populate the patient list where your search originated.
   - Click to select one patient; Ctrl-click to select multiple patients; Shift-click on two patients to select all intervening patients; Ctrl-Shift-click to select all intervening patients plus those already selected.
   - Click **Select All** to select all patients in the Search Preview list; the button then toggles to **Deselect All**, in case you wish to start selecting again.
   - Click **Back** to return to the Advanced Search dialog.
   - Click **Cancel** to return to the ID PATIENT SCREEN.
4. After you select patients, click **OK**. The selected patients will appear in the patient list where you started.

Create, Edit and Delete Patient Records

To manage patient records, start in the ID PATIENT SCREEN, which appears automatically after login. From other modes, click the **ID Patient** button to return to the ID PATIENT SCREEN.

Add a New Patient

To add a new patient, click the **Add New Patient** tab and fill in at least the required fields, which are indicated in bold type.

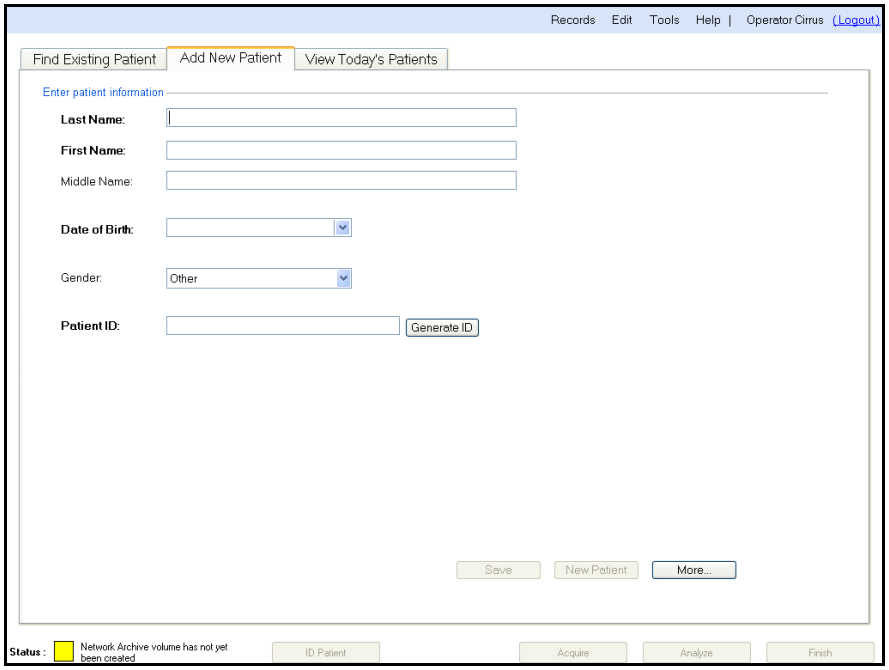


Figure 6-9 Add New Patient tab of the ID Patient Screen

WARNING: The date of birth must be entered in the MM-DD-YYYY format, and always appears this way in the software and printouts.

- When you click **Save**, the new patient information is saved to the database and to the list of today's patients. If data is missing from required fields, the **Save** button will not be enabled.
- Click **New Patient** to clear the fields and start over, before or after saving. This is useful to add multiple new patients in succession, because when you click **Save**, the patient is saved but the **Add New Patient** tab remains open.
- When you click **Acquire,** the Cirrus HD-OCT initiates a new exam for that patient. The ACQUIRE SCREEN appears. For instructions, see Select Scan Type on page 3-5.
- To enter additional information, such as categories or comments, click **More**. The Patient Data Entry tab of the Patient Edit dialog appears.

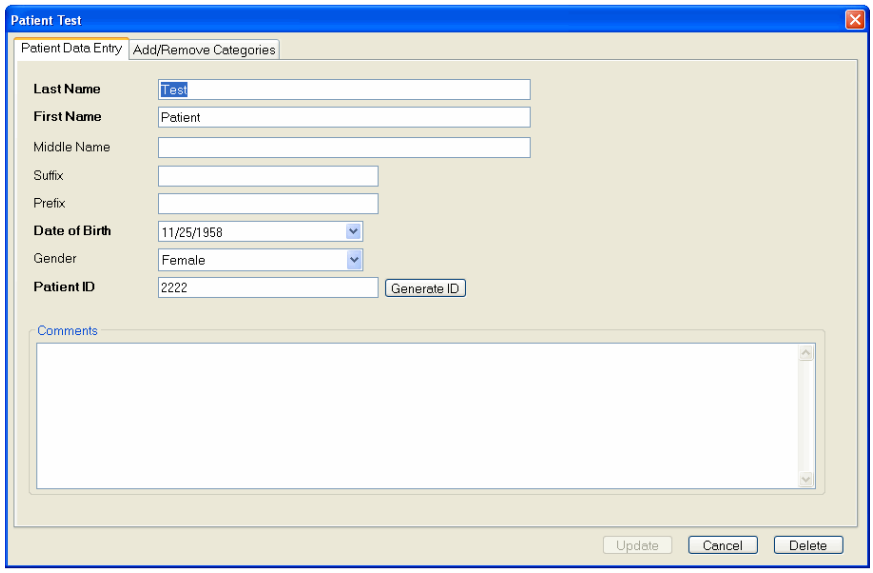


Figure 6-10 Patient Data Entry tab (default) of the Patient Edit dialog

Enter information on this and the other available tabs as desired. See Edit Patient Record below for details.

Edit Patient Record

1. Select a patient from the **Find Existing Patients tab** or from the **View Today's Patients tab** of the ID PATIENT SCREEN. (To populate the patient list, see Record Search on page 6-6.)

2. Click **Edit > Patient Record...**. (This menu option is available only if you are in ID Patient mode and one patient is selected.) The Patient Edit dialog appears.

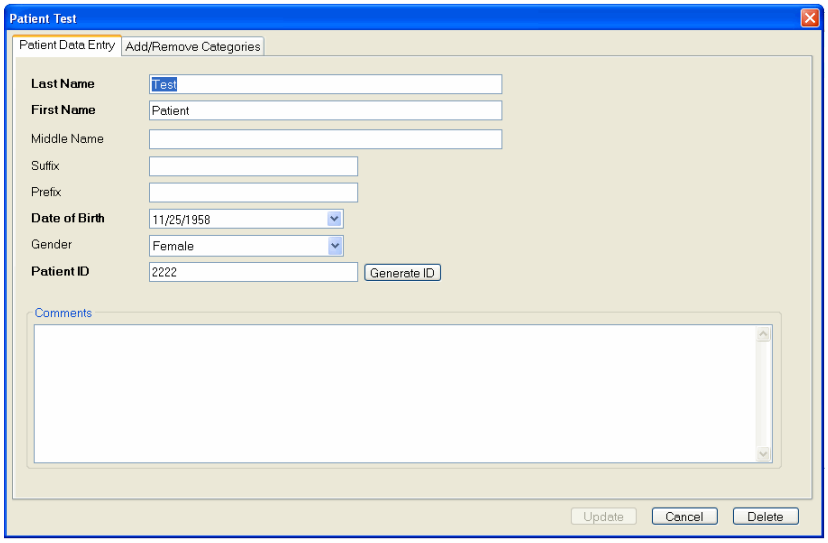


Figure 6-11 Patient Edit dialog

The name of the selected patient appears in the title bar.

3. Edit the desired fields and click **Save** to save the changes. Click **Cancel** to cancel the changes and return to ID Patient mode.

Obscured Patients

- If the patient identifying data is obscured (as for a clinical trial), you will not be able to edit the patient name, date of birth or patient ID. For obscured patients less than 80 years of age, the **Last Name** field will have the originating institution name and the **Patient ID** fields will have a unique Patient ID generated during export. The **Date of Birth** field will display the month and year of birth or just the year of birth, depending on the assigned level of obscurity. For patients over 80 years of age, the year only will appear, and it will be 80 years prior to the current year, no matter the actual year of birth.

Add/Remove Categories Tab

Use this tab to assign categories to and remove them from the patient record. For details, see Add Categories to Patient Record on page 6-17.

Delete Patient Record

WARNING: When you try to delete a patient record, you will receive the following warning.

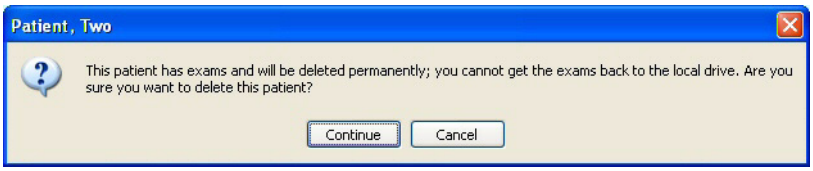


Figure 6-12 Warning: Patient deletion is permanent

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

To delete a patient record:

1. Select a patient from the Find Existing Patient Tab (see page 3-3) or from the View Today's Patients Tab (see page 3-5) of the ID PATIENT SCREEN. If necessary, perform a Record Search (see page 6-6) to access the desired patient record.
2. Click **Edit > Delete Patient**. This option is available only if you are in ID Patient mode and have selected one patient.
   - You can also click the **Delete** button from any tab of the Patient Edit dialog (see Figure 6-11 on page 6-11).
   - The following notice will appear if you try to delete a patient for which all exam data has not been archived.

Figure 6-13 Not all exam data archived

   When you try to delete a patient record that has saved exams, a dialog prompts you to confirm your choice, as in Figure 6-12 above.
3. Click **Continue** to delete the patient record, or click **Cancel** to cancel deletion.

Merge Patient Records

In Cirrus HD-OCT, every patient record has a unique identifier that consists of the **Name (First, Middle, Last), Date of Birth and Patient ID in combination**. It is possible that two or more patient records may exist for the same patient because this information was entered differently on separate occasions. To correct such errors, it is possible to merge two patient records.

To merge two patient records, follow these steps:

1. Select **Edit > Merge Two Patients...**. The Patient Merge dialog opens.

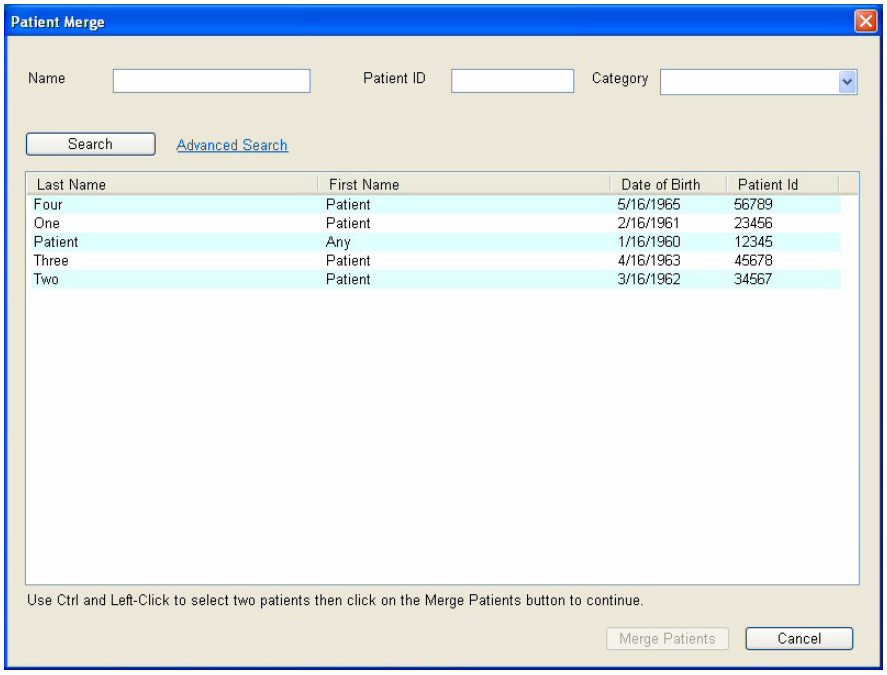


Figure 6-14 Patient Merge dialog

   To populate the patient list with the records you wish to merge, either click **Search** to return all patients, or specify search parameters in the fields provided.

2. Select the two patients whose records you wish to merge. You must hold down the **Ctrl** key while clicking (Ctrl-click) the second patient. The Merge Patients button will not be active unless exactly two patients are selected.

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

3. Click **Merge Patients**. A dialog prompts you to select the correct patient record, that is, the patient record whose information you wish to retain for the newly merged record.

Figure 6-15 Patient Merge: Select correct patient

4. Select the desired patient record and click **Merge**. A dialog prompts you to confirm the merge.

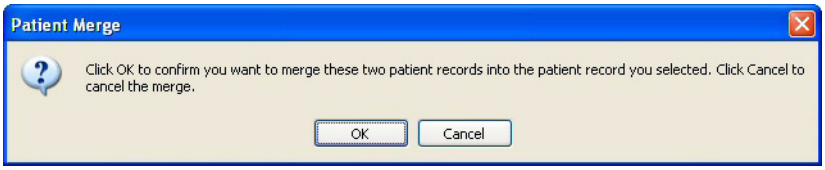


Figure 6-16 Confirm patient merge

Note that merging is not reversible. Click **OK** to proceed with merging.

When complete, you will return to the Patient Merge dialog, where you will observe just one record for the patient in the patient list. If you wish to merge additional records, repeat the steps above. When finished merging, click **Cancel** or to close the dialog.

Move Scan Data

Occasionally, a scan is acquired and saved in the wrong person's file. Scans that are incorrectly stored can be moved to a different file by using the **Move Scan** feature. To access the **Move Scan...** dialog:

1. Open the file with the incorrect or misplaced scan and choose an analysis to display the data. For example, for a Macula Cube scan, choose Macular Thickness analysis.
2. Select **Edit > Move Scan...** The Move Scan... dialog opens. To populate the patient list, either click **Search** to return all patients, or specify search parameters in the fields provided. You can also click **Advanced Search** to search with more parameters.
3. Select the patient whose file you wish to move the scan data into by left-clicking on that patient name. Click on **Move** to start the move process (you will need to confirm) or click **Cancel** or the red X to close the dialog without moving the scan.

.

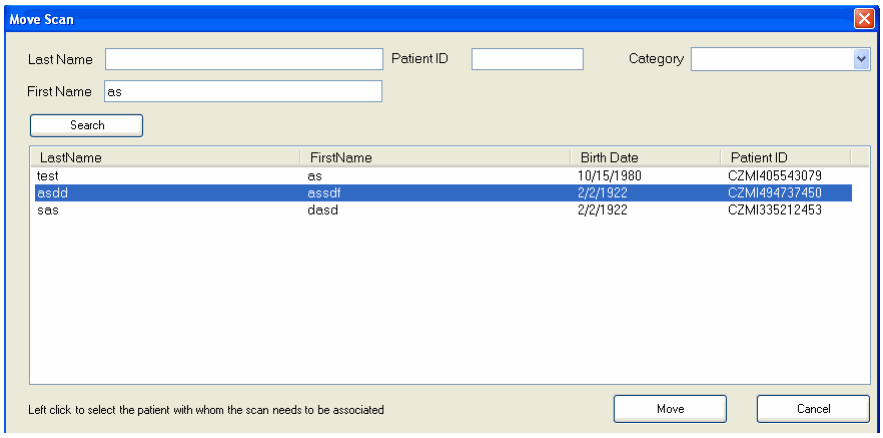


Figure 6-17 Move Scan dialog

Categorize Patient Records

You can create your own categories and place patient records in them. This enables you to search for groups of patient records by category. In general, the advantage of the categories function is that it provides you the ability to create groups of your own design for any reason, and to directly control their membership. All other search criteria arise from objective data.

Create, Edit and Delete Categories

To create, edit and delete categories, use the Category Registration dialog.

☞ **Note: To access this dialog, the admin user must have created an institution name, because categories must be associated with an institution. (See Create Institution Name and Logo on page 6-2.)**

To access the Category Registration dialog:

1. While in ID Patient mode, select **Tools > Options > Categories...**. The Category Registration dialog opens.

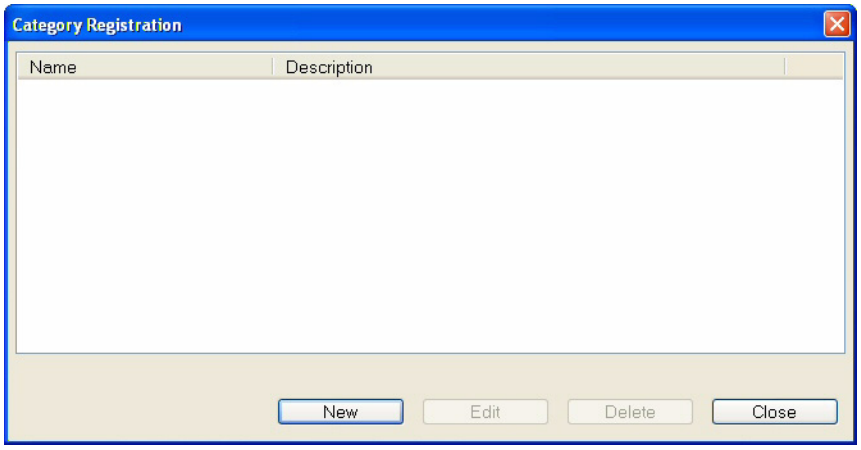


Figure 6-18 Category Registration dialog

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

Create (Register) Categories

1. In the Category Registration dialog, click **New**. The Category Edit dialog appears.

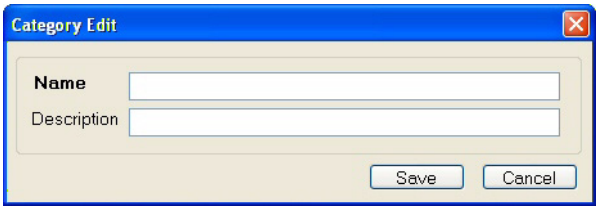


Figure 6-19 Category Edit dialog

2. In the Name field, type in a name for the new category, up to 64 characters, including spaces. You may enter an optional description.
3. Click **Save**. The new category now will be available to place patients in it.
    - Click **Cancel** at any time to cancel changes and exit the dialog.

Edit Categories

Note: You cannot edit categories created at another institution.

1. In the Category Registration dialog, select a category and click **Edit**. The Category Edit dialog appears. (See Figure 6-19 above.)
2. In the Name and Description fields, edit the category as desired.
3. Click **Save** to save your changes.
    - Click **Cancel** at any time to cancel changes and exit the dialog.

Delete Categories

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

Apply Categories to Patients: Add or Remove

To apply categories, follow these steps:

1. Select a patient and click **Edit > Patient Record...**. The Patient Edit dialog appears (see Figure 6-11 on page 6-11). The name of the selected patient appears in the title bar of the dialog.
2. Select the **Add/Remove Categories** tab. It displays available categories on the left and applied categories on the right.

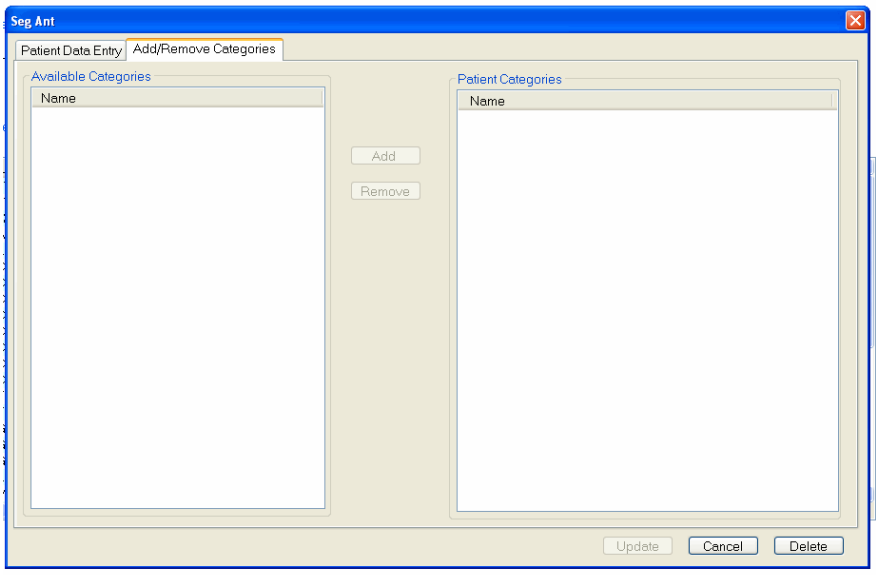


Figure 6-20 Add/Remove Categories tab of the Patient Edit dialog

☞ Note: The **Delete** button applies to the patient record itself, not to categories. Click the **Delete** button only if you want to delete the patient record. For details, see Delete Patient Record on page 6-12.

Add Categories to Patient Record

1. In the Categories tab, select the desired categories to apply to this patient from the list at left. Ctrl-click to select multiple categories.
2. Click Add to associate the selected categories with the patient. Applied categories will now appear in the list at right.
3. Click Save to save your changes and close the Patient Edit dialog, or click Cancel to exit the dialog without saving.

Remove Categories from Patient Record

1. From the applied categories list at right, select the desired categories to remove from this patient record. Ctrl-click to select multiple categories.
2. Click Remove to remove the selected categories from the list of applied categories at right. The newly removed categories will now appear in the list of available categories at left.
3. Click Save to save your changes and close the Patient Edit dialog, or click Cancel to exit the dialog without saving.

(7) Archive and Retrieve

Chapter Overview

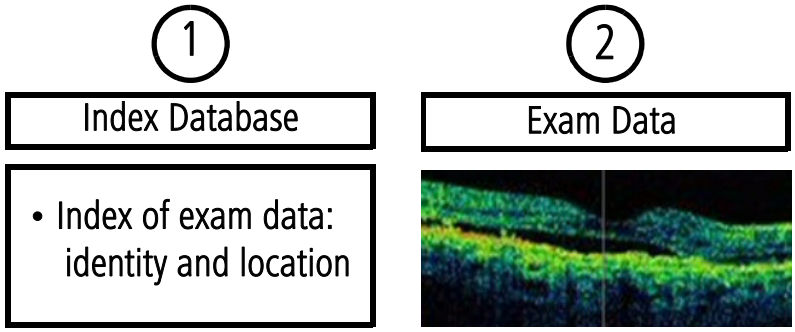
Cirrus HD-OCT provides the archive function to preserve your exam data, and the retrieve function to access archived exam data, or restore it in case of computer malfunction. This chapter explains how to perform these functions.

Advisory: 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.

Topics covered include:

The Patient Database

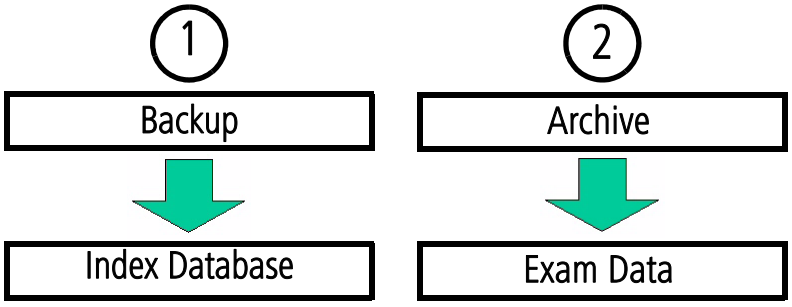
To enable excellent database performance along with long-term data protection, the patient database separates data-intensive exam data from the index database. Thus, the Cirrus HD-OCT patient database contains two kinds of stored data:



1. The index database identifies each saved exam and analysis by patient, date and type of scan or analysis, and records where its associated bulk exam data can be found—on the local hard drive or which archive location.
2. Exam data or bulk data includes the OCT images generated during an examination, along with the associated patient, exam, scan and analysis data.

Data Maintenance Requirements

The complete index database always remains on the Cirrus HD-OCT computer hard drive (unless you delete individual patient data). Exam data, because it includes large OCT image files, eventually must be cleared from the system hard drive to make space to save new scans. Two actions must occur to protect your data against loss in case of computer malfunction:



1. Backup: Occurs Automatically

Upon startup, the system automatically backs up (copies) the index database to the current archive location to protect it from a system malfunction that would otherwise render it inaccessible. Backup is an important data protection function, but since it is automatic, you need not be concerned with it unless the current archive location is inaccessible. In that case, a dialog will notify you, and the recommended course is to restore access to the current archive location or to change the current archive location. See Archive Management on page 7-6 for details.

2. Archive: User Must Initiate

Preservation of exam data, on the other hand, requires user intervention. Exam data remains on the instrument hard drive until the hard disk reaches capacity, or until you choose to remove it. The system software prompts you to archive un-archived exams, either at startup or shutdown, but the user must initiate the archive option when offered, or initiate archive manually (select **Records > Archive Now...**).

By copying exam data to another location, archiving protects data from loss due to system malfunction. But archiving has the secondary purpose of enabling you to clear archived exams and thereby maintain adequate hard disk space to save more scans. Because exam data has unique and persistent identifiers that link it to the index database, it can be safely removed from the system hard drive. You can readily access or retrieve archived exam data when the Cirrus HD-OCT has access to the correct archive location.

Clear Exam Data

Data maintenance eventually requires the clearance (deletion) of archived exam data.

☞ **Note: Cirrus HD-OCT never clears un-archived exam data.**

Only when the hard drive gets too full must you clear enough hard disk space to allow you to save more scans. With a new instrument, it takes many months up to a few years, depending on its usage rate, before the Cirrus HD-OCT prompts you to clear archived exams.

Automatic Clearance

When the hard disk status becomes yellow, the system automatically initiates clearance of archived exams upon startup. However, if the amount of archived exams available for clearance is insufficient to return the status to green, you will be notified as in Figure 7-2 below. In this case, you must archive exams and then clear again.

☞ **Note: If you do not clear archived exams when prompted, eventually the hard disk status will reach red, whereupon scanning and analysis are disabled. At that point, you must archive and clear exam data to restore use of these primary functions.**

Manual Clearance

1. While in ID Patient mode, select **Records > Clear Archived Exams...** to initiate clearance.

Clearance Behavior

☞ **Note: The clearance function, whether automatic or manual, has the same characteristics.**

The system searches for archived exams to clear. If it finds any, it begins to clear archived data immediately. The Clear Progress dialog reports progress.

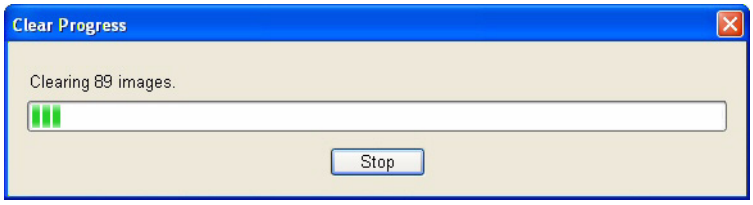


Figure 7-1 Clear Progress dialog

- If there is no data to clear, a dialog reports it, as at left.
- When clearing completes successfully, a dialog reports it.
- If clearing completes but insufficient space has been cleared on the hard drive to return the hard drive status to green, the following message appears:

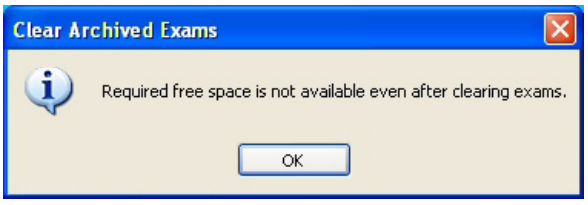


Figure 7-2 Insufficient data cleared

If this occurs, you must archive exams to make additional exam data available for clearance from the hard drive, and then clear again.

Which Exams Are Cleared

- The Cirrus HD-OCT clears only enough exams to forestall the reappearance of the yellow or red indicator for several weeks or months, depending on the acquisition rate of new exams.
- It does not clear exams that have not been archived.
- It does not clear an archived exam if its archive location is disabled.
- Among those allowed to be cleared, archived exams are cleared oldest first, based on the last viewed date. Data viewed in the last month is not cleared even if archived.

Archive Recommendations

WARNING: It is the user's responsibility to protect exam data from loss. Un-archived data is at risk of permanent loss in case of computer malfunction. We recommend that you archive daily, as described in this section.

The Cirrus HD-OCT makes it possible to archive to a network location, which includes to a network attached storage device (NAS device, also known as a network hard drive). Once installed, a network attached storage device operates just as a network archive location and offers the same advantages. Instructions regarding NAS devices are found in Appendix (B) Using a Network Storage Device.

Note: For archive to a network file server, configuring the server and the instrument should be attempted only by a network administrator or system administrator. Instructions for network administrators to set up network archive are found in Appendix (A) Networking Guidelines. Users are responsible for network setup and maintenance. Carl Zeiss Meditec Technical Support is limited to testing network connectivity of the Cirrus HD-OCT. Technical Support cannot troubleshoot or repair problems with network connectivity.

Note: Cirrus HD-OCT does not support archiving to removable media.

Advantages of Network Archiving

Archiving to a network location offers the following advantages:

- Protects your high value exam data: Server hardware and software are engineered for better long-term data security and preservation.
- Ease of use: Plug the Cirrus HD-OCT into your existing office network—or plug a network attached storage device into the instrument—create an archive location, and you are ready to archive with little or no ongoing intervention.

Preferences: Archive

Cirrus HD-OCT gives you a way to control the automated behavior for archive alerts. Select **Records > Archive Options...** to access the Archive Preferences dialog.

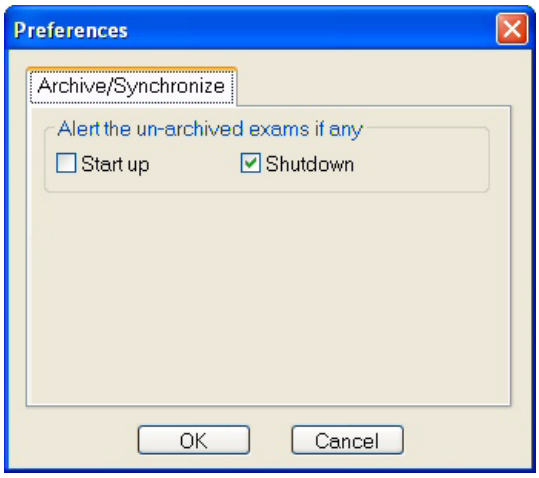


Figure 7-3 Archive Preferences dialog

Figure 7-3 displays the default settings. It is possible to select one, neither or both **Start up** and **Shutdown**.

When finished selecting your preferences, click **OK** to save your changes and exit, or click **Cancel** to exit without saving. The options and our recommendations are described below.

Archive Alert: Shutdown Recommended

By default, the system alerts you to the presence of un-archived exams upon shutdown and asks if you want to archive them. Click **OK** to proceed with archiving, or **Cancel** to not archive.

To help you follow our recommendation to archive daily, we recommend you do not change the default setting. If you select neither option, it is possible for un-archived exams to accumulate without your knowledge because the system will not prompt you to archive. However, when the hard disk status turns yellow, you may have to archive exams in order to then clear enough archived exams to return the status to green. At that time, archiving may take several hours. You must archive if the hard disk status turns red and you cannot clear enough space to enable scanning and analysis. You can archive manually at any time by selecting **Records > Archive Now**.

☞ **Note: The Cirrus HD-OCT will archive exams only to the current archive location. (For details, see Set Current Archive on page 7-9.) If no current archive is selected, the system will not archive. If an error occurs that prevents a successful archive, the Cirrus HD-OCT will notify you.**

Archive Management

Archive locations are directories on a network file server or network storage drive. When you create a new archive or add a pre-existing archive, it is registered on your Cirrus HD-OCT, which then can access the archive location.

☞ **Note: "Register" is a useful term that means to add an archive to your system's list of available archives.**

Archive management, and this section, includes the following functions:

- Create a New Archive Location, page 7-6
- Edit an Archive Location, page 7-8
- Disable an Archive Location, page 7-8
- Set Current Archive, page 7-9
- Delete Archive Locations, page 7-9

☞ **Note: You cannot write to an archive created on another Cirrus system.**

To access archive management:

1. While in ID Patient mode, click **Records > Archive Management...**. The Archive Locations dialog appears.

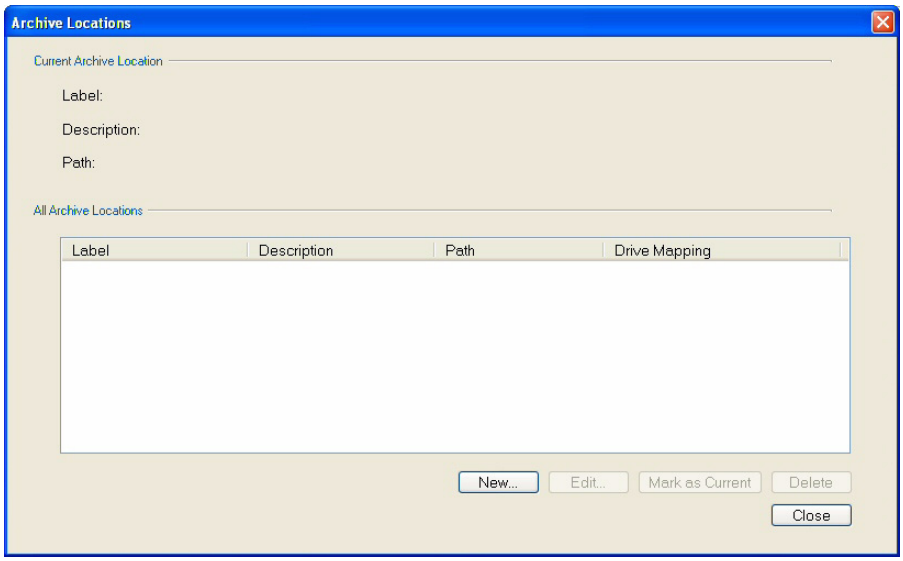


Figure 7-4 Archive Locations dialog

It shows all registered archives, sorted alphabetically by label. The current archive is indicated on the left with a green checkmark. Any disabled archives will have a gray background.

Create a New Archive Location

☞ **Note: To create a network archive location, an information technology specialist must first configure the network file server and the Cirrus HD-OCT to communicate.**

See the instructions to Set Up Network Archiving in (A) Networking Guidelines. If you are using a network hard drive, see the instructions in (B) Using a Network Storage Device.

☞ **Note: Cirrus does not support archiving to drives with FAT or FAT32 file systems. Only NTFS files system is supported.**

To create a new archive location:

1. In the Archive Locations dialog, click **New**. The New Archive Location dialog appears.

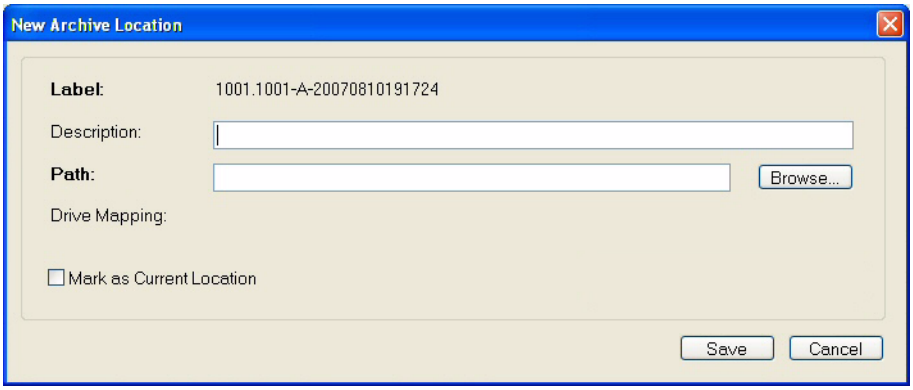


Figure 7-5 New Archive Location dialog

   The label is generated automatically and will be unique. You cannot edit it. Optionally, you may type in a description.

2. In the **Path** field, you can type in the exact path to the new archive folder, if you know it, but usually users will click **Browse** to find and select (or make) the new archive folder. A Browse for Folder dialog appears, enabling you to browse anywhere in a local or network path that is accessible.

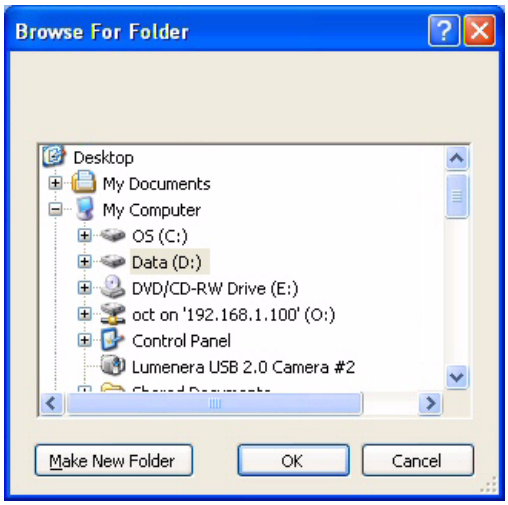


Figure 7-6 Browse for Folder dialog

3. When you have found the path where the new archive will reside, select the desired archive folder, or click **Make New Folder** to create a new archive folder.

☞ **Note: The system prevents you creating an archive on the instrument hard drive.**

4. When you have selected or created the new archive folder, click **OK** to save your selection and return to the New Archive Location dialog. The new archive path will appear in the **Path** field, and the **Drive Mapping** field will also be completed automatically.
5. If you wish to archive to this new archive location, select the **Mark as Current Location** checkbox. You can also select the current archive in the Archive Locations dialog.
6. Click **Save** to save your changes, or **Cancel** to cancel changes without saving. When you click **Save**, the new archive will appear in the list of Archive Locations.

Edit an Archive Location

Among the things you can do while editing an archive location are:

- remove or select the current archive designation
- disable the archive—see the effects of this below
- change the description of an archive

To edit an archive location:

1. In the Archive Locations dialog, select the desired archive and click **Edit**. The Edit Archive Location dialog appears.

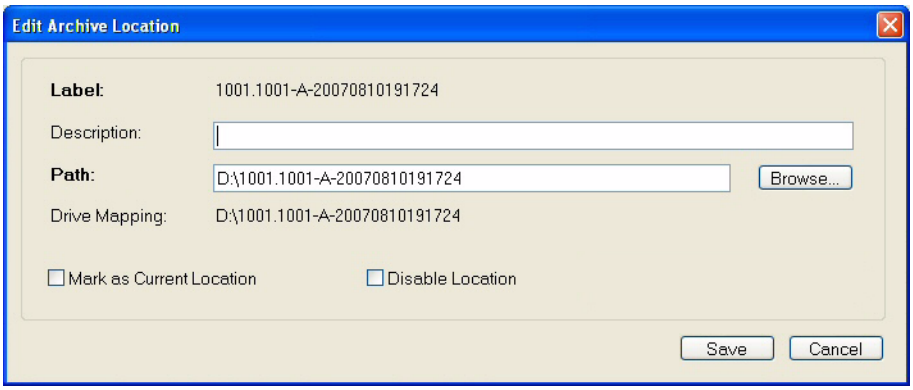


Figure 7-7 Edit Archive Location dialog

2. Edit the fields as desired. You can select and deselect the checkboxes for **Mark as Current Location** and for **Disable Location**, the functions of which are described below.
3. When you are finished editing, click **Save** to save your changes, or click **Cancel** to cancel changes without saving.

Disable an Archive Location

The purpose of disabling an archive location is so that exam data archived to this location will not be cleared from the Cirrus HD-OCT hard drive.

To disable an archive:

1. In the Archive Locations dialog, select the desired archive and click **Edit**. The Edit Archive Location dialog appears, as in Figure 7-7 above.
2. Select the **Disable Location** checkbox.

3. Click **Save** to save your changes, or click **Cancel** to cancel changes without saving.

Back in the Archive Locations dialog, the disabled archive will now have a gray background.

☞ **Note: The Disable Location checkbox is not available if you are editing the current archive location. It does not appear when you are creating a new archive.**

Set Current Archive

The current archive is the one to which new scans will be archived (assuming the archive location is accessible), and is marked with a green checkmark to the left of the label.

☞ **Note: If no current archive is selected, the system will not archive. If an error occurs when you attempt to archive, the system will notify you.**

If you wish to change the network archive location to which new scans will be archived, follow these instructions:

1. In the Archive Locations dialog, click on the archive you want to make current and then click **Mark as Current**. The archive you selected will be marked as the current archive.
   - You can also select the Mark as Current Location checkbox in the Edit Archive Location dialog.
2. Click **Close** or the  at upper right to exit the Archive Locations dialog.

Delete Archive Locations

☞ **Note: Cirrus HD-OCT permits deletion of an archive location only if the archive location contains no patient data. Also, you cannot delete the current archive location.**

To delete an archive location:

1. In the Archive Locations dialog, click on the archive you want and then click **Delete**. A dialog prompts you to confirm your choice.

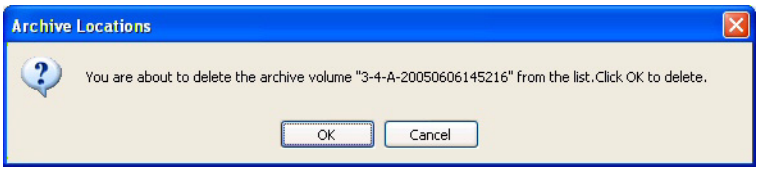


Figure 7-8 Confirm archive deletion

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

Manual Archive

You can archive exam data manually at any time.

☞ **Note: It does not affect the instrument or its performance to leave it running overnight while archiving.**

1. Select **Records > Archive Now...**. A dialog reports the number of un-archived patients and asks if you want to archive them now.
2. Click **OK** to proceed with archiving, or **Cancel** to not archive. When you click **OK**, archiving begins immediately. An Archive Progress dialog appears.

Figure 7-9 Archive Progress dialog

Archive Behavior

- All un-archived exams will be archived, unless you click **Stop**. If you click **Stop**, archiving stops immediately after the system completes archiving the current exam for the current patient when you clicked **Stop**. Data already archived will not be erased from the archive location.
- It can take several seconds to several minutes for the Cirrus HD-OCT to finish writing to the archive location, depending on the number of un-archived exams. When complete, a message reports a successful archive, or if some exams were not archived successfully, a summary dialog reports information about exams not archived successfully.
- The system does not overwrite previously archived data.

Access archived exams

You can view and analyze any archived scan as usual if the system is connected to the necessary archive location. If not, a dialog will inform you that the archive is not accessible, identifying which archive is needed. Establish a connection with the necessary archive to continue.

☞ **Note: The system automatically retrieves archived data, if necessary to access the data, for example, when analyzing cleared archive data. After retrieval, the data will be available for clearance again, according to the usual parameters for clearing.** **(See Which Exams Are Cleared on page 7-4 for details.)**

Retrieve Exam Data

To retrieve exam data is to copy it from an archive location to the Cirrus HD-OCT hard drive, thereby making it available for viewing and analysis without further connection to the archive location.

To retrieve exam data, follow these steps.

1. Make sure that the archive location is accessible. Network archives must be registered on the list of archives, and your system must be connected to the network archive location.

2. While in ID Patient mode, click **Records > Retrieve Archived Exams...**. The Retrieve dialog appears

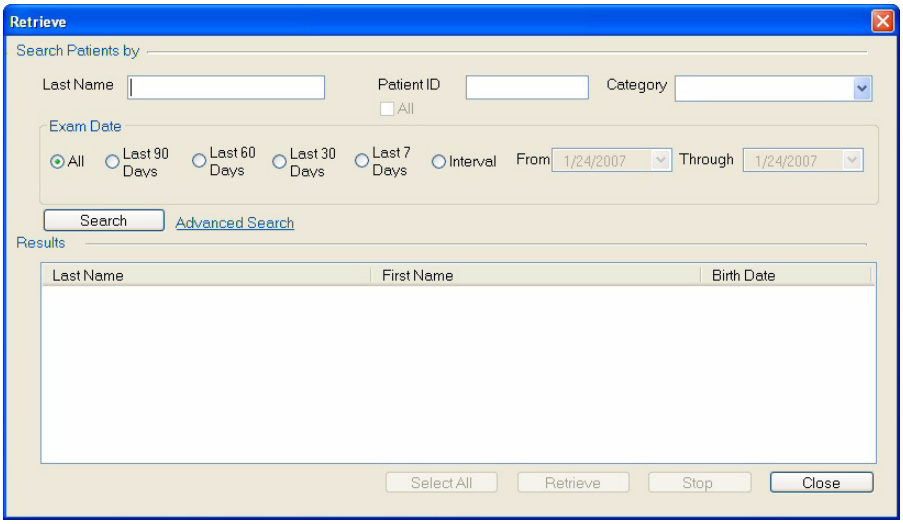


Figure 7-10 Retrieve dialog

3. Use this dialog to search for and then retrieve the exams you want. Enter search parameters in the fields provided and click **Search**, or click **Advanced Search** to use additional search parameters. (See Advanced Search on page 6-8 for details.) The search returns all matching patients, sorted alphabetically by last name.
   - Select the desired patients in the **Results** list: Click to select one patient; Ctrl-click to select multiple patients; Shift-click on two patients to select all intervening patients.
4. When you have made your selections, click **Retrieve**. The software checks in which archive location(s) the matching exam records are stored.
5. Click **Continue** to proceed with retrieval, or **Cancel** to cancel retrieval.
   - If the hard drive is too full to retrieve all selected records, the system will initiate clearance of archived exams automatically, making space available before retrieval continues.
6. When you click **OK**, retrieval begins and a Progress dialog appears.
   - When retrieval is complete, the system notifies you.
   - If any exam data is not retrieved, a summary report appears. It reports information about all exams that were not retrieved.

(8) Export and Import

Chapter Overview

The Cirrus HD-OCT offers the capability of exporting data for viewing and analysis on another Cirrus HD-OCT instrument. This chapter explains how to export and import Cirrus HD-OCT data, but first it details the technical measures employed to ensure patient privacy and data integrity. These are the topics covered:

Privacy and Data Integrity Features

It is the user's responsibility to observe applicable privacy restrictions and to maintain data integrity. The Cirrus HD-OCT incorporates options in its data transfer functions that enable the user to do this.

Patient Privacy

The Cirrus HD-OCT gives you the choice to export exam data without information that could identify the patient. Upon import, anonymous or "obscured" patient records appear in the patient list with the originating institution name in the last name field and a unique Patient ID generated during export. You have the further option to export a complete date of birth, only the month and year of birth, or only the year of birth.

☞ **Note: Users who wish to obtain additional medical information about an anonymous patient must contact the originating clinic.**

Data Integrity

Cannot Edit Identifying Information

The Cirrus HD-OCT applies a permanent electronic tag to patient records that are imported without patient identifying information and treats them as a protected category of data. For these records, you cannot edit the following fields: Last Name, First Name, Middle Names, Date of Birth, and Patient ID. You can edit other fields of the anonymous patient record, as well as analyze, archive and re-export the data. Data that is imported with identifying patient information can be edited without restriction.

Updating Imported Records

For all imported patient records, it is possible to import new scan data and update patient data, including obscured patient records. If during import the Cirrus HD-OCT encounters information associated with a patient that was already imported, the Cirrus HD-OCT does the following:

- imports all scan data (exams) not previously imported, but never deletes nor overwrites any scan data already imported;
- updates patient data only if it was created on a later date than the data already imported. This prevents overwriting of newer patient data with older.

Export Data

The Cirrus HD-OCT offers the ability to export data to another Cirrus HD-OCT instrument. This method exports all exams for the patients you select. (You cannot select specific exams for export.) You have the option to obscure patient data.

Export Media & Methods

It is possible to export data:

1. To removable media. Compatible removable media can include optical media (CDs and DVDs) as well as USB devices.

☞ **Note: See Export to Optical Media on page 8-8 for special instructions to successfully export to optical media, that is, to CDs and DVDs.**

2. To a network destination. The Export Options dialog enables you to select a network destination. Users are responsible for setting up and maintaining their own networks, and for selecting the desired network destination when exporting.
3. Directly to a Cirrus HD-OCT instrument. However, see the Warning Regarding Exporting/Saving to the Hard Drive below (page 8-3). To do this, the sending and receiving platforms must be connected by an RJ-45 crossover cable between their respective ethernet ports. It is the user's responsibility to acquire and install the necessary crossover cable, to configure both instruments to communicate (see Appendix (A) Networking Guidelines) and to select the correct export path when exporting.

☞ **Note: Cirrus supports incremental export to the same export location. That is, you can export repeatedly to the same export folder (on a network drive or the same removable media) and Cirrus adds only those exams that were not already exported and does not overwrite any data previously exported. Also, you can interrupt an export operation and then start it again later, and Cirrus exports only the exams not already present in the export database.**

Warning Regarding Exporting/Saving to the Hard Drive

WARNING: Do not export or save data—including images and movies—to the C: drive of a Cirrus instrument, which includes the desktop. The Cirrus hard drive is partitioned into C: and D: (or E:) drives, and the C: drive is reserved for operating system and Cirrus application files. The C: drive is relatively small and can be filled up quickly, which renders the system unusable. The D: (or E:) drive is reserved for data and therefore is relatively large. If you want to export or save data to the Cirrus hard drive, either locally or to a connected Cirrus system on the network, select (a location in) the D: (or E:) drive as the target.

Recommended Export/Save Locations

We recommend that you export and save data—including images and movies—either to removable media or to a network destination, rather than to the Cirrus hard drive. Usually, one exports data with the intention of moving it to another system, and therefore uses an external target for export (removable media or a network location). However, if you do export or save data to a Cirrus hard drive, locally or over a network, select the D: (or E:) drive as the target, not the C: drive, which includes the desktop—see the Warning Regarding Exporting/Saving to the Hard Drive above (page 8-3). Additionally, if you export or save to the D: (or E:) drive, we recommend that you delete the exported or saved files once they have served their purpose. This preserves space for acquiring additional data. Finally, if you export or save files to the local desktop or anywhere else on the C: drive, you are at risk of filling up the C: drive and rendering the system unusable if you do not delete the exported or saved files.

Export Steps

To export a Cirrus database to another Cirrus HD-OCT instrument, follow these steps:

1. If you are exporting to removable media, insert the media into its drive. If not, skip to the next step.

2. In ID Patient mode, select **Export Exams...** from the **Records** menu (click **Records > Export Exams...**) to open the Export Options dialog.

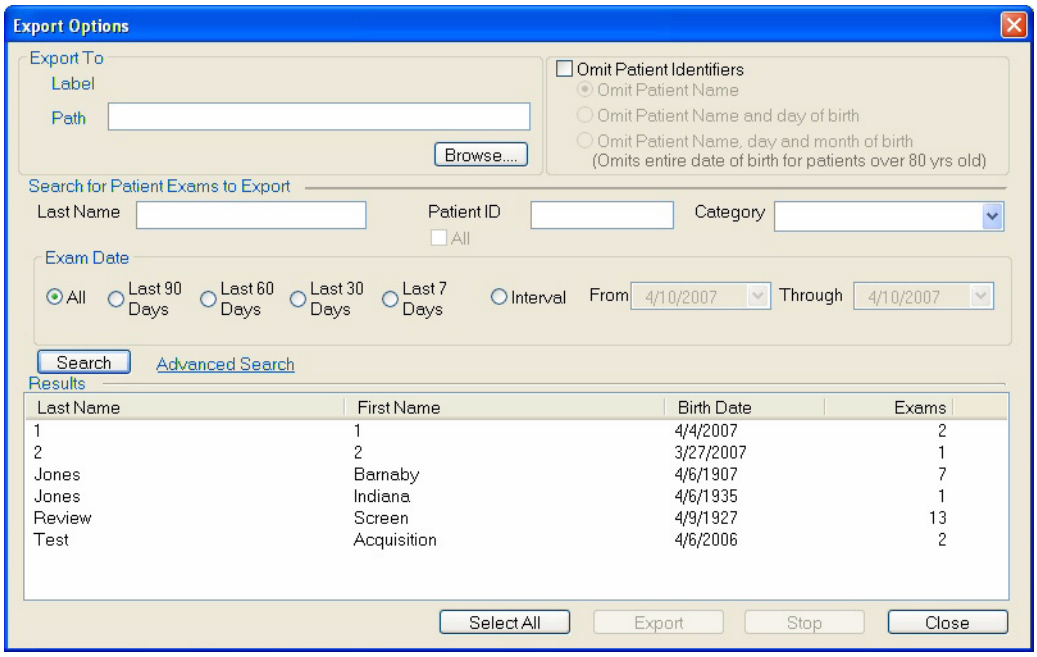
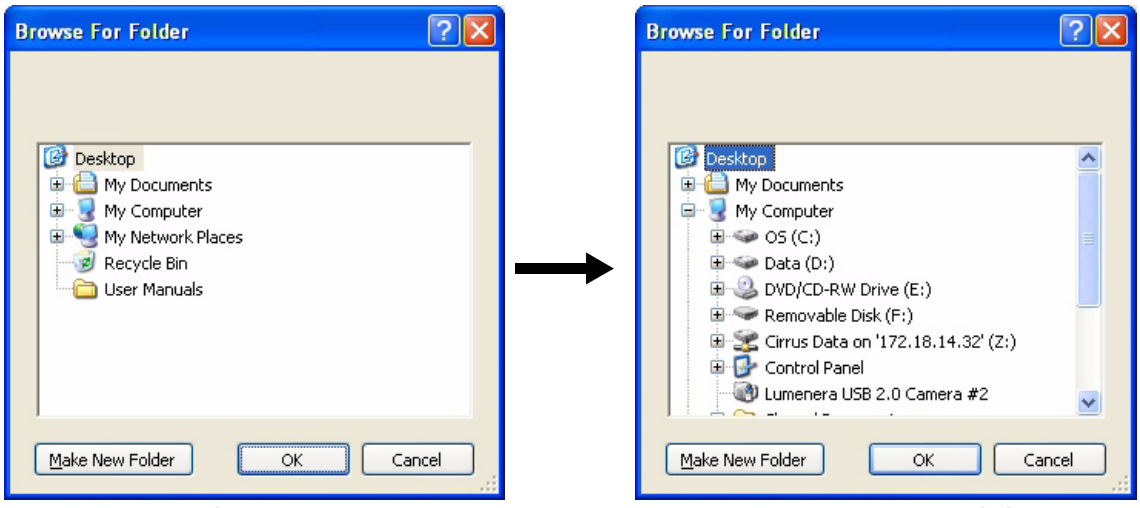


Figure 8-1 The Export Options dialog

The first time anyone exports using this system, the export **Path** field will be empty. After the first time, the last export path used will appear initially.

3. To change the export destination, in the **Export To** area, click **Browse** to find and select the desired export path. A standard Browse for Folder dialog appears.



Initial appearance **My Computer expanded**

Figure 8-2 Browse for Folder dialog, initially and My Computer expanded

A. To export to removable media or to a mapped network drive, click the plus sign ⊞ next to **My Computer** to view the available drive locations.

- If you are exporting to removable media like a USB device, select the drive corresponding to the installed media.

- If you are exporting to a network destination to which you have already mapped a drive on your Cirrus, select the mapped drive. For instructions to map a network drive, see Map a Network Drive to the Shared Folder on page A-8.

☞ **Note: If the target system on the network requires a password for access, you must have already logged in to the target system via Windows before attempting to export there.**

☞ **Note: Observe the Warning Regarding Exporting/Saving to the Hard Drive on page 8-3.**

B. Click to select the desired folder in the desired location, or click the **Make New Folder** button to make and name a new folder for this export in the currently selected location.

C. When finished selecting or making the folder, click **OK** to save and close the dialog. The destination you selected will appear in the **Path** field back in the Export Options dialog.

4. Search for patients whose exams you wish to export in the middle area of the Export Options dialog (Figure 8-1, page 8-4) labeled **Search for Patient Exams to Export**. You can search for patients by **Last Name, Patient ID, Category** or **Exam Date** range. Select the desired options and click **Search**. The **Results** lists shows the patients matching all search criteria used.

- For more search options, click **Advanced Search**—see Advanced Search on page 6-8 for details.

5. In the **Results** list, click to select one patient whose exams you wish to export. Ctrl-click to select multiple patients, or click **Select All** to select all patients in the list.

☞ **Note: For the patients you select, Cirrus exports all exams. You cannot select specific exams for export.**

6. To obscure the identifying data for all patients you are about to export, select the **Omit Patient Identifiers** checkbox at upper right. You will then have the further option to omit the day of birth or the day and month of birth. For patients over 80 years of age, the year only will appear, and it will be 80 years prior to the current year, no matter the actual year of birth. Obscured patient records are exported with the originating institution name in place of the last name and a unique **Patient ID**.

7. When you have made your selections, click **Export**. Export progress is shown in an expanded area at the bottom of the Export Options dialog.

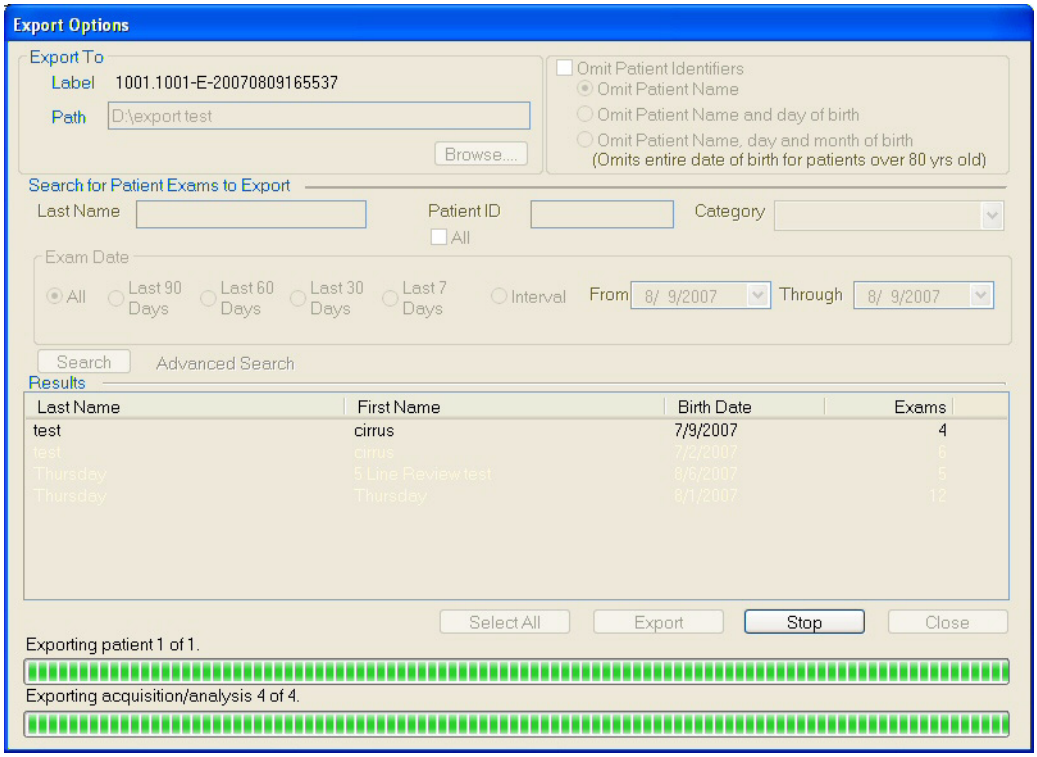


Figure 8-3 Export progress

A unique name for each export database is generated automatically and appears in the **Label** field at upper left.

☞ **Note: Cirrus HD-OCT enables you to export cleared archive data. If the cleared data is on a network archive, the data will be exported from the archive automatically. If the file server is not connected, you will be prompted to connect with it.**

- At any time, you can click **Stop** to stop export. If you do, the system completes exporting all data from the exam being exported when you clicked **Stop**. No data already exported is removed from the export database.

When the export process is complete, an Export dialog notifies you of successful export to the chosen destination.

Figure 8-4 Export success message

When you click OK, if any problems occurred, a Summary Log appears and informs you.

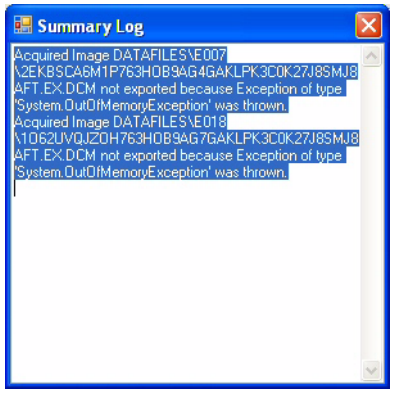


Figure 8-5 Export Summary Log reports export problems

- The first time you eject an optical disk after exporting, you will be prompted to choose among the Roxio Eject Options—see page 8-11 for details.

Export Behavior

Cirrus HD-OCT export behavior is as follows:

- Before exporting, the system checks the export destination for sufficient available space and returns an error message if insufficient space is available.
  - If exporting to removable media, you must re-select patient records for export, choosing patients whose total amount of data does not exceed the capacity of the media.
  - If exporting to a network path with insufficient space, you must select another network path.
- The system attempts to export cleared archive data. If the cleared data is on an available network archive, the data will be exported automatically. If the file server is not connected, you will be prompted to connect with it. If you cannot connect, you can skip it and continue exporting.
- You can export imported patient data. If an imported patient was obscured, it will be re-exported as is, that is, it will retain its original Patient ID and institution name.
- If the export options are the same, you can export to the same network export database created by this Cirrus system. The system will not overwrite previously exported data. It will supplement previously exported patient records with new exam data. It associates exam data based on patient identification.
- You cannot export to a network export database created by another Cirrus system.
- You cannot export to a network path that contains an archive database.
- The system does not allow concurrent export to the same network path. If another application is currently exporting to the selected path, a dialog will inform you.

Export to Optical Media

Cirrus HD-OCT instruments are equipped with a drive capable of writing to optical media and Roxio™ Drag-to-Disc software (part of Roxio Easy CD and DVD Creator), which together enable you to transfer data.

Important Note: The Roxio software is pre-installed on the Cirrus HD-OCT instrument and specially configured for use with it. Do not re-install Roxio software. The Roxio CD included with your instrument is provided to satisfy licensing requirements only.

Compatible Optical Media Formats

You can use the following types of optical media to transfer data:

- CD–R
- CD–RW
- DVD-R
- DVD-RW

Note: UDF formatting is required for compatibility with Cirrus HD-OCT. Blank CD-R disks used for export are automatically formatted in the Roxio Drag-to-Disc format, which is a UDF format. Optical media with an incompatible format can be reformatted using the preinstalled Roxio software, as explained in the section Formatting for Drag-to-Disc on page 8-8.

Note: Except for CD-R disks, which can only be quick formatted, you can save 1-4 minutes when ejecting optical media after export by performing a full format of the disk before export. To do so, use the Roxio Drag-to-Disc software, as explained in the section Formatting for Drag-to-Disc on page 8-8.

Use and Care of Optical Media

We do not recommend that you use optical media for long-term data storage. Use should be limited to data transfer between systems. Take care to protect these media from damage. We recommend you use hard plastic cases when transporting and shipping these media. DVDs in particular are very susceptible to scratches that could render them unreadable.

Formatting for Drag-to-Disc

This section explains how to format each of the compatible optical media types using Roxio Drag-to-Disc as it is installed on the Cirrus HD-OCT.

General Steps

Specific format options for each media type are explained after these general steps, which are common to all media types.

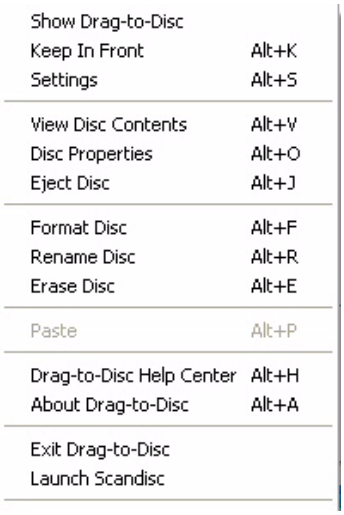


Figure 8-6 Drag-to-Disc Right-Click Menu

1. Install the disk into the optical drive. Wait approximately 30 seconds for the drive to recognize the media type. If you attempt the next step before the drive is ready, you will get an error message, "There is no disk."
2. To access the Roxio Drag-to-Disc software, you do not have to close the Cirrus HD-OCT software. Hold down the **Ctrl** key and press **Esc** (press **Ctrl+Esc**).

   This will cause the Windows **Start** menu and Task Bar to appear along the bottom. Notice the icons in the System Tray at bottom right. (When you mouse-over an icon, its name appears.)

3. Right-click the Roxio Drag-to-Disc icon and select **Format Disc**. The Drag-to-Disc Format Options dialog appears.
   - You can also access Roxio Drag-to-Disc through the Windows Start menu: **Start > Programs > Roxio > Drag-to-Disc.**

   The available format options depend on the installed media type, as explained next.

CD–R and CD-RW Format Options

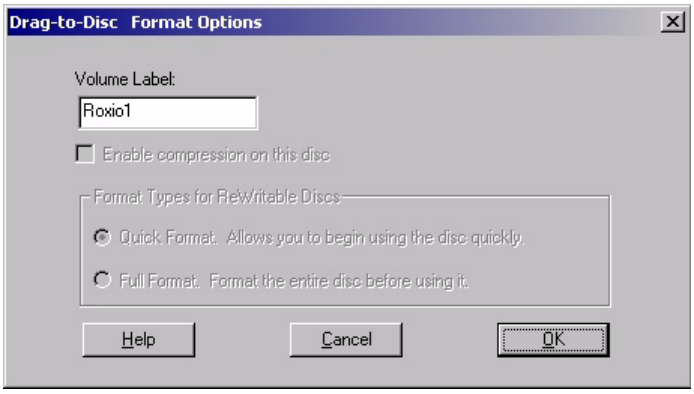


Figure 8-7 CD-R Format Options

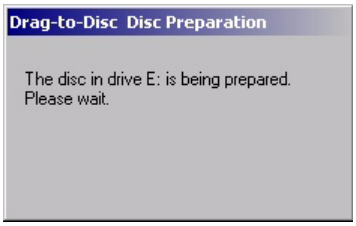


Figure 8-8 Read-only Media

No format options are available for CD–R disks. If desired, type a name in the **Volume Label** field. Click **OK** to begin formatting. A Drag-to-Disc Preparation dialog appears during formatting (as at left). Formatting is brief. The dialog disappears when it is complete. Once formatted, you cannot format CD–R disks again, nor can you erase them.

You can write repeatedly to the disk, but each write operation uses disk space. Less disk space will be available for each successive write operation.

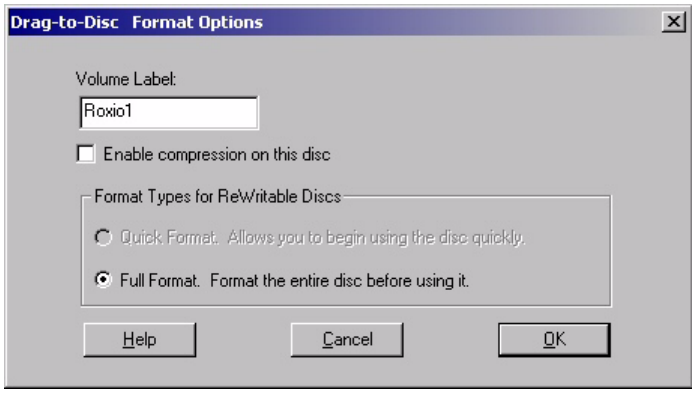


Figure 8-9 CD-RW Format Options

For a new, blank CD–RW, you have only the option to perform a full format. If the CD–RW was previously formatted, you can perform a quick or full format. A full format requires 25-45 minutes.

☞ **Note: Both quick and full formatting effectively erase any data currently on the disk. Use these options with care to prevent loss of patient data.**

The Advantage of Full Format

Full format has this advantage: the disk ejects immediately when you eject it. If the disk is quick formatted, it requires 1 to 4 minutes for the disk to eject, as illustrated below.

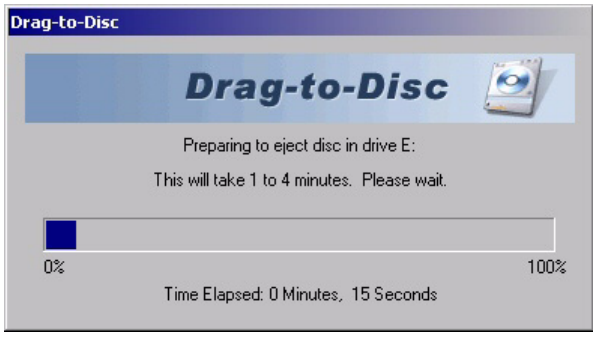


Figure 8-10 Waiting to Eject a Quick Formatted Read/Write Disk

Erasing Read/Write Disks

You can erase or re-format rewritable (RW) disks. Use these options carefully: **Once you erase or re-format, you will no longer have access to the data that was present.** If you erase rewritable disks, you must re-format them to use them again.

Roxio Eject Options

When you eject a disk, Roxio Drag-to-Disc will prompt you as below regarding planned usage of the disk.

Figure 8-11 Roxio Drag-to-Disc Eject Options

We recommend that you do not change the default options, but simply click **Eject** to eject the disk.

Warning: Unauthorized modification of Cirrus HD-OCT software or hardware (including peripherals) can jeopardize the safety of users and patients, the performance of the instrument, and the integrity of patient data; it also voids the instrument warranty.

Import Data

On Cirrus HD-OCT, you can import data only from a Cirrus export database (on removable media or in a network location) to the local Cirrus database. You cannot select an alternate import destination. Imported records are added to the local database.

Import Sources

It is possible to import data from three sources, which correspond to the Export Media & Methods above (page 8-2).

1. **From removable media**. Compatible removable media can include optical media (CDs an DVDs) as well as USB devices.
2. **From a network location**. The Import Options dialog enables you to select a network directory as a source. Users are responsible for setting up and maintaining their own networks, and for selecting the desired network source when importing.
3. **Directly from a Cirrus HD-OCT instrument.** To do this, the sending and receiving platforms must be connected by an RJ-45 crossover cable between their respective ethernet ports. It is the user's responsibility to acquire and install the necessary crossover cable, to configure both instruments to communicate (see Appendix (A) Networking Guidelines) and to select the correct import path when importing.

Import Instructions

To import data, follow these steps:

1. If you are importing data from removable media, insert the media containing export data created with Cirrus HD-OCT into its drive. If you are importing from any other path on the network or hard drive, skip to step 2.
2. In ID Patient mode, select **Import Exams...** from the **Records** menu (click **Records > Import Exams...**). The Import Options dialog opens.

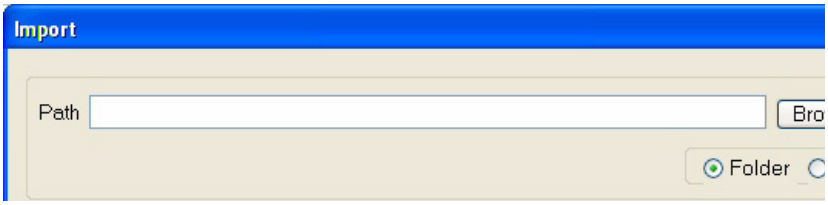


Figure 8-12 The Import Options Dialog

The first time anyone imports using this system, the import **Path** field will be empty. After the first time, the last import path used will appear initially.

3. You can import Cirrus data from any accessible location where a Cirrus export database has been created. This includes removable media, any location in a network path through a mapped drive, and the local hard drive (if an export database has been copied there, which is not recommended). Click **Browse** to find and select the desired import path. A Browse for Folder dialog appears.

A. To import from removable media or from a mapped network drive, click the plus sign ⊞ next to **My Computer** to view the available drive locations.

- If you are importing from removable media like a USB key, select the drive corresponding to the installed media.
- If you are importing from a network destination to which you have already mapped a drive on your Cirrus, select the mapped drive. For instructions to map a network drive, see Map a Network Drive to the Shared Folder on page A-8.

☞ Note: If the target system on the network requires a password for access, you must have already logged in to the target system via Windows before attempting to import from there.

B. Click to select the desired source folder in the desired location, then click **OK** to save and close the dialog. The source path you selected will appear in the **Path** field back in the Import Options dialog.

4. Back in the Import Options dialog, click **Import**. If you selected a folder that does not contain a Cirrus export database, a message will notify you.

Figure 8-13 Path selected does not contain export data

In this case, you must select another folder where an export database is present.

☞ Note: The import path must terminate in a folder (or drive) that contains a file named **Export.xml**, which is the name of all Cirrus export files.

If an export database is present, a dialog prompts you to confirm that you wish to import from this export database.

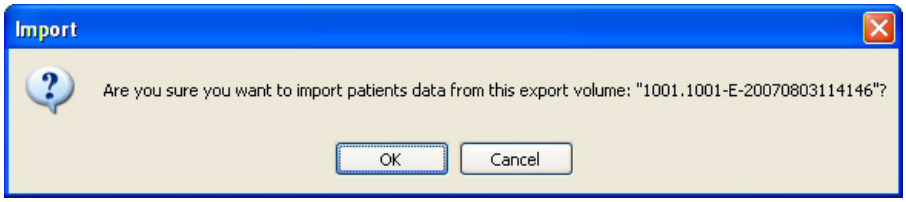
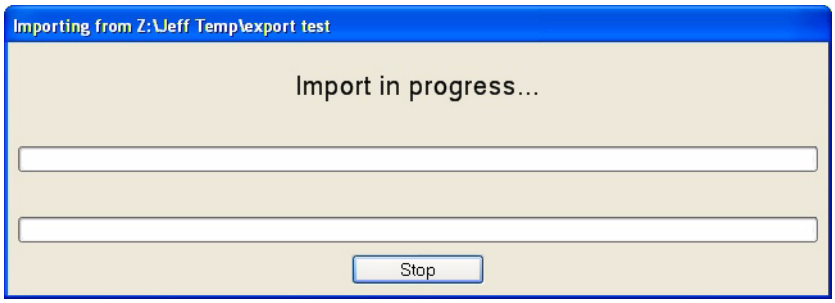


Figure 8-14 Confirm import from this export volume

☞ Note: You must import all the exams in the export database; you cannot import exams selectively.

5. Click **OK** to confirm and import begins. A dialog reports import progress.



- It can take several seconds to several minutes for the Cirrus HD-OCT to finish importing to the hard drive, depending on the number of exams in the export database, and whether you are importing over the network, which can be slower.

- At any time, you can click the **Stop** button to stop import. The import process will stop after the next whole record has been imported. Already imported patient records will not be removed.

A message on the same dialog tells you when the operation is complete.

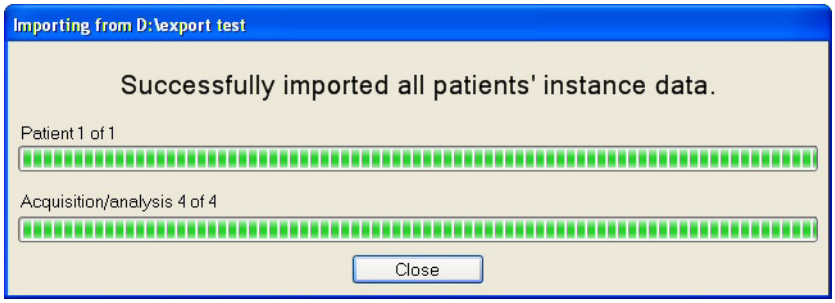
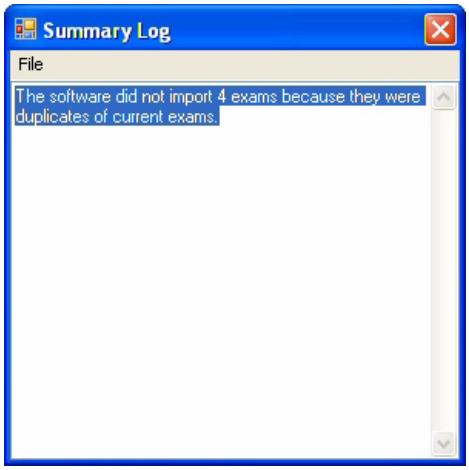


Figure 8-15 Same dialog reports when complete

- When you click **Close**, if a record is not transferred due to error or another reason, a Summary Log appears and reports it.



- Imported records will appear in the patient list when you search as usual.

Import Behavior

- Before importing, the system checks for sufficient available space on the system hard drive and if insufficient space is available, initiates clearance of archived exams automatically, making space available before import continues.
- Cirrus displays obscured imported patients in the patient list with the originating institution name as the last name and a unique **Patient ID** generated during export.
- When exam data is imported, its last modified date and time are changed to the current system date and time. This makes it unavailable for clearance until sufficient time passes.
- Imported data does not overwrite already existing records in the database. It associates new exam data based on patient identification.

(9) Routine Maintenance

Chapter Overview

Carl Zeiss Meditec designed the Cirrus HD-OCT (and the optional power table) to require very little user maintenance. Most maintenance activities covered here are required only occasionally, except for routine cleaning between patients. This chapter covers the following topics:

Note Regarding Warranty

☞ **Note: Except for the main power fuses, the Cirrus HD-OCT has no user-replaceable parts. The user must not attempt hardware repairs, except fuse replacement, without consulting Carl Zeiss Meditec service personnel. To do so voids the instrument warranty. However, we may provide software updates that users can install.**

Fuse Replacement

The instrument has two fuses. Instructions to check and replace the fuses are included below. First we offer help in determining the source of power problems.

☞ **Note: Except for fuse replacement, only authorized Carl Zeiss Meditec service engineers may disassemble the instrument and replace parts.** If fuse replacement does not repair the problem, or if another sort of problem prevents normal operation, contact Carl Zeiss Meditec customer service. In the U.S., call 800-341-6968. Outside the U.S., contact your local Carl Zeiss affiliate or distributor.

Determine the Source of the Power Problem

This section assumes that the instrument will not power on. Troubleshooting your power problem depends on whether or not you power the instrument through the optional power table.

If Not Using the Optional Power Table

If you power the instrument directly from a wall outlet (not through the optional power table), check the following to determine the source of the power problem, in order:

1. Is there power available everywhere in your office?
    - If not, there may be a localized power outage in your office or a general power outage in your neighborhood.

- If so, proceed to step 2.

2. Is the instrument power cord plugged in at both ends?
   - If not, plug in the cord and try to power up the instrument.
   - If so, check the instrument fuses and replace them if necessary. See Check and Replace Instrument Fuses on page 9-2 for instructions.

If Using the Optional Power Table

If you are using the optional power table, the instrument is powered through it. Check the following to determine the source of the power problem, in order:

1. Is there power available everywhere in your office?
   - If not, there may be a localized power outage in your office or a general power outage in your neighborhood.
   - If so, proceed to step 2.
2. Does the table have power (while the instrument does not)? You can test the table by trying the lift.
   - If the table has power, the power problem is within the instrument. First, check that the instrument power cord is plugged in at the power table and at the instrument. Next, check the instrument fuses and replace them, if necessary. See Check and Replace Instrument Fuses for instructions.
   - If the table does not have power, the power problem is likely within the table. First, check that the table is plugged in at both the wall outlet and at the table. Check and replace fuses as directed in the applicable Power Table User Instructions.

Check and Replace Instrument Fuses

Two fuses are located in the rear of the unit just above the instrument power cord inlet.

Carefully follow these instructions to safely check and replace fuses. Always power down the instrument and unplug the power cord before proceeding. At all times, use the minimum force necessary to accomplish each step so as to prevent damage or injury.

1. Power down the instrument. Unplug the power cord.
2. To remove the rear cover, depress the two snaps at its top edge. Unplug the power cord from the rear of the unit.
   - The fuse assembly can be found under the rear cover at upper right, just above the power cord inlet. It is very difficult to open until you perform the next step.

Depress both snaps to remove rear cover.

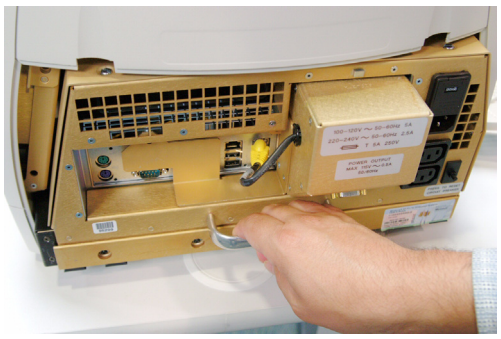
Figure 9-1 Removing rear cover

3. For better access, the bottom portion of the instrument pulls out like a large tray. To pull it out:
   A. Note the large silver handle. When unlatched, you can use this handle to pull out the tray.
   B. Below the silver handle, apparently resting on the bottom cover, two flat, dark metal brackets splay out toward you like an inverted V. These can be compressed easily together to unlatch the tray.

Compress splayed metal brackets → Grab handle and pull out tray

Figure 9-2 Unlatching and pulling out computer tray

   C. With one hand compressing the brackets together, use the other hand to pull the silver handle and slide out the entire tray until it is clears the outer edge of the instrument, as shown below.



Pull tray out until clear of outer edge.

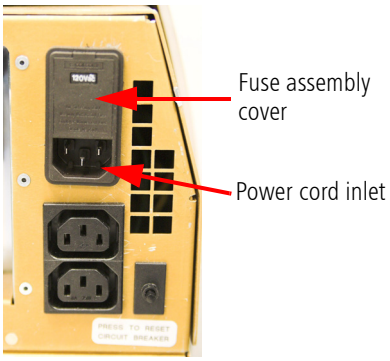
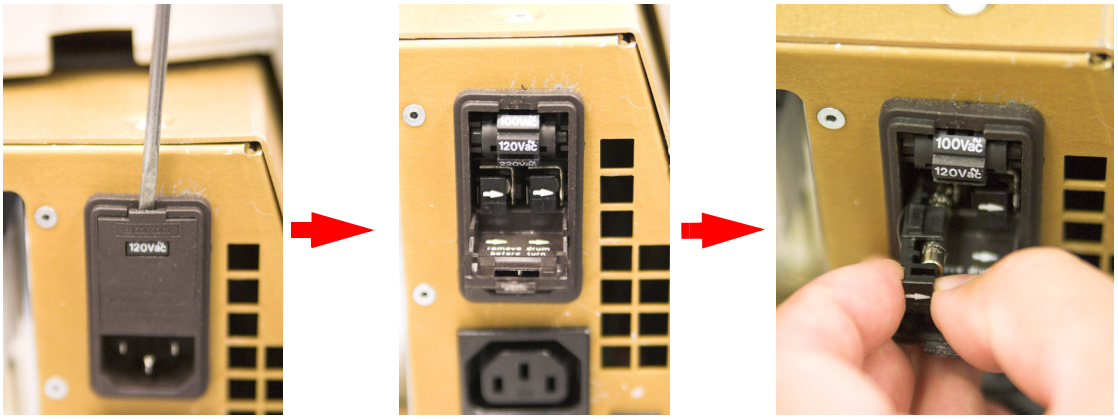


Figure 9-3 Computer tray fully out, giving access to fuse assembly

You will now have easy access to the fuse assembly.

☞ **Note: Do not pull out the tray more than a few inches beyond this point. If you do, it may disengage the rails, making it more difficult to reinstall.**

4. Using a narrow-bladed screwdriver, gently pry open the cover of the fuse assembly, from the top, to expose the fuse holders.



With screwdriver, pry open cover from top. Cover open; fuse holders exposed. Remove fuse holders with fingers.

Figure 9-4 Opening instrument fuse assembly and removing fuse holders

Information about the proper replacement fuses is found adjacent to the fuse holder.

☞ Fuse type and rating for both instrument fuses: T 5A 250V.

WARNING: Always replace fuses with the same type and rating. Failure to do so may create a risk of fire.

WARNING: Do not rotate the drum immediately above the fuses, since this changes the instrument power voltage setting. Powering the instrument with the incorrect setting could result in electrical shock to users and patients and severe damage to the instrument.

5. Slide out each fuse holder (marked with a white arrow pointing to the right) and check the filament for breakage. Dispose of any defective fuses.
6. Insert the new fuse in the holder. Slide the holder back into the housing with white arrows pointing to the right. Push the cover up and in until it snaps closed.
7. Push the tray fully back into the unit. Plug in the power cord at both ends.
8. Replace the rear cover: position bottom first, then tilt up and push in top until both snaps engage. Your instrument is now ready to be powered on.

Handling Error Messages

In normal instrument start-up, the User Login dialog appears. If the system fails the system check, or if some other error prevents the system's normal function, document the circumstances and any associated error messages, and report it to Carl Zeiss Meditec customer service. In the U.S., call 800-341-6968. Outside the U.S., contact your local Carl Zeiss affiliate or distributor. Often error messages can be resolved with solutions provided over the telephone.

Please be prepared to provide CZM the serial number of your instrument. It is located on the label affixed to the back of the instrument, under the rear cover.

Hard Disk Defragmentation

Defragmentation of the Cirrus HD-OCT computer hard disk becomes necessary when you begin to clear archived exams regularly. The process of deleting data and then writing again to the hard disk fragments the hard drive, which degrades database and system performance over time. To maintain peak performance, we recommend that you check if the hard disk requires defragmentation after each five times archived exams are cleared. Recall that the system can initiate clearance of archived exams automatically when necessary.

☞ **Note: Since 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. If defragmentation is not complete in the morning, it does no harm to stop defragmentation and continue using the instrument.**

To defragment the hard drive, follow these steps:

1. Exit the Cirrus system software (click **Logout** and select **Yes** in the Exit Dialog) to enter the Windows environment.
2. Click **Start > All Programs > Accessories > System Tools > Disk Defragmenter.** The Disk Defragmenter appears.

☞ **Note: The Cirrus HD-OCT hard disk is partitioned into C: and D: or E: drives, C: for the operating system and D: or E: for the database. It is necessary to analyze and defragment each partition in succession.**

3. Select the **C:, D: or E:** drive and click **Analyze** to determine whether the drive requires defragmentation. When analysis completes, a dialog will appear to inform you whether or not the drive requires defragmentation. If it does, click **Defragment**. If it does not, click **Close**.

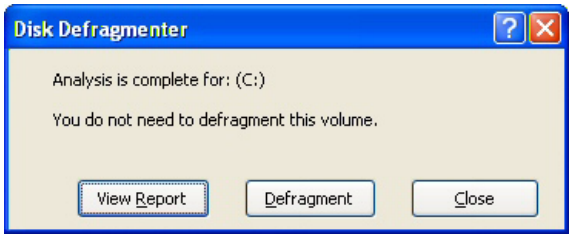


Figure 9-5 Sample defragmenter analysis outcome

4. Perform step 3 again for the other partition (**C:, D: or E:**).

Routine Cleaning

The forehead and chin rests, and to a lesser extent the imaging aperture and LCD screen, are the only parts that require routine cleaning. Instructions are included below for occasional cleaning of the instrument covers and optional power table.

WARNING: The instrument has no special measures to protect against harmful ingress of water or other liquids (classified IPX0—ordinary equipment). To avoid damage to the instrument and a safety hazard, cleaning solutions, including water, must be applied sparingly, with a non-linting cloth that is dampened only—not dripping wet! You must not use aerosols on or near the instrument.

Forehead and Chin Rests

The instrument parts that routinely contact the patient—the forehead and chin rests—should be cleaned between each examination with an alcohol prep swab. These parts are not removable.

The Imaging Aperture

The imaging aperture should not contact the patient's eye. You may clean it as necessary to remove dust and oily smudges, ensuring true images. You may use an alcohol prep swab. Wipe dry with a soft, non-linting cloth. If the lens inadvertently contacts the patient's eye, clean it before proceeding with the examination.

☞ Note: Wipe gently and carefully to avoid scratching the lens.

The LCD (Monitor) Screen

Clean the LCD screen when necessary to remove dust and oily smudges that impair viewing. Turn off the monitor first. We recommend that you use a soft cotton cloth; if a dry cloth does not completely clean the screen, you can dampen the cloth with water only and wipe the screen with the damp cloth.

Occasional Cleaning of Instrument Covers and Optional Power Table

☞ Note: When dusting of the instrument or table is necessary, use a dry non-linting soft cloth. Do not use aerosols, as these can penetrate the instrument covers and damage the instrument.

☞ Note: When the instrument covers or table require cleaning or disinfecting, wipe with a non-linting cloth or swab, **dampened only—not dripping wet!—**with water or alcohol. Wipe dry with a clean and soft non-linting cloth.

List of User Replacement Accessories

Part Number	Description
0000001217033	Power Cord, IEC 320, 39 Inch
2660221115973	Power Cord, IEC 320 to NEMA, 12 Inch
0000001217026	Keyboard, Mini
2660021123062	Dust Cover, Instrument
Z00000014577330	Fixation Device (External)
Z3197519005	Occluding Sleeve for Fixation Device
Z3013509052	Red Fixation Lamp
2660100006566	Alcohol Wipes
2660100007672	Camera Lens Cleaner
2660100007673	Camera Lens Wipes
0000001345415	Mouse
2660100060344	Verification Test Tool
2660100022513	Fuse 5A 250V (For 100-120V and 220-240V Systems)
2660021121819	Cable, Network, CAT5e
2660021116418	Cable, USB
2660021123341	Kit, Test Eye, includes: • Verification Test Tool • Fixation Device • Occluding Sleeve for Fixation Device • Red Fixation Lamp

To order: In the U.S., call 800-341-6968. Outside the U.S., contact your local Carl Zeiss affiliate or distributor.

(10) Specifications

HD-OCT Imaging

	Model 400	Model 4000
Methodology	Spectral domain OCT	Spectral domain OCT
Optical source	superluminescent diode (SLD), 840 nm	superluminescent diode (SLD), 840 nm
Optical power	< 725 µW at the cornea	< 725 µW at the cornea
Scan speed	27,000 A-scans per second	27,000 A-scans per second
A-scan depth	2.0 mm (in tissue), 1024 points	2.0 mm (in tissue), 1024 points
Axial resolution	5 µm (in tissue)	5 µm (in tissue)
Transverse resolution	15 µm (in tissue)	15 µm (in tissue)

Fundus Imaging

	Model 400	Model 4000
Methodology	Live OCT Fundus Technology™	Line scanning ophthalmoscope
Live fundus image	During alignment	During alignment and during OCT scan
Optical source	Superluminescent diode (SLD), 840 nm	Superluminescent diode (SLD), 750 nm
Optical power	< 725 µW at the cornea	< 1.5 mW at the cornea
Field of view	36 degrees W x 22 degrees H	36 degrees W x 30 degrees H
Frame rate	>0.7 Hz	>20 Hz
Transverse resolution	45 µm (in tissue)	25 µm (in tissue)

Iris Imaging

	Model 400	Model 4000
Methodology	CCD camera	CCD camera
Resolution	1280 x 1024	1280 x 1024
Live iris image	During alignment	During alignment

Electrical, Physical and Environmental

	Model 400	Model 4000
Weight	36 kg (79 lbs)	38 kg (83 lbs)
Dimensions	65L x 44W x 53H (cm)	65L x 44W x 53H (cm)
Fixation	Internal, external	Internal, external
Internal fixation focus adjustment	-20D to +20D (diopters)	-20D to +20D (diopters)
Input devices	Keyboard, mouse	Keyboard, mouse
Electrical rating (115V)	Single Phase, 100-120V~ systems:50/60Hz, 5A	Single Phase, 100-120V~ systems:50/60Hz, 5A
Fuse rating (115V)	T 5A 250V	T 5A 250V
Electrical rating (230V)	Single Phase, 220-240V~ systems:50/60 Hz, 2.5A	Single Phase, 220-240V~ systems:50/60 Hz, 2.5A
Fuse rating (230V)	Fuse rating: T 5A 250V	Fuse rating: T 5A 250V
Temperature (transport and storage)	–40º to +70º C	–40º to +70º C
Relative humidity (transport and storage)	10% to 100%, including condensation	10% to 100%, including condensation
Atmospheric pressure (transport and storage)	500 hPa to 1060 hPa	500 hPa to 1060 hPa
Temperature (operation)	+10º to +35º C	+10º to +35º C
Relative humidity (operation)	30% to 75%, excluding condensation	30% to 75%, excluding condensation
Atmospheric Pressure (operation)	700 hPa to 1060 hPa	700 hPa to 1060 hPa
Computer	• High performance multi-core processor • Internal storage: > 80,000 scans • CD-RW, DVD-ROM drive • Integrated 15” color flat panel display	

WARNING: Always replace fuses with the same type and rating. Failure to do so may create a risk of fire.

Maintenance

Carl Zeiss Meditec recommends regular preventative maintenance.

Note: Only trained CZM personnel may perform calibration.

Measurement Units

All units on the Cirrus HD-OCT are measured in the SI format. Unless otherwise noted, measurements are made in micrometers.

(11) Legal Notices

Limited Warranty

This Warranty gives you specific legal rights, and you may have other rights, which vary from state to state. For one year from the date of delivery (the "Warranty Period") to the original purchaser ("You," "Your," "Purchaser"), Carl Zeiss Meditec, Inc. ("ZEISS," "Seller," "We," "Our," "Us") warrants its Cirrus HD-OCT Model 4000 and Model 400, excluding components and software as stated below (the "Cirrus HD-OCT") to be free from defects in material or workmanship. In the event of failure, Seller's obligation is limited to repairing or replacing on an exchange basis the parts that have been promptly reported as defective by Purchaser during the Warranty Period and are confirmed as defective by Seller upon inspection. This Warranty covers all parts, labor, travel and expenses for the Warranty Period, except as otherwise stated herein. This Warranty only applies to the original Purchaser and shall not, in any way, be transferable or assignable.

The procedure for warranty claims shall be as follows: when You believe the Cirrus HD-OCT is defective, promptly report the defect to ZEISS. Whenever possible, We will provide "in the customer's office" service to repair Your Cirrus HD-OCT. However, at Our discretion, repairs may be made in Our repair department. In this case, We will pay all shipping costs unless Your Cirrus HD-OCT is found upon inspection not to be eligible for repair under this Warranty, in which case You will be responsible for one-half the shipping costs. If Your Cirrus HD-OCT is ineligible for repair under Warranty, We will notify You, and any repairs You authorize will be performed at Our normal rates. All replaced parts will become the property of ZEISS.

This Warranty specifically covers the Cirrus HD-OCT, including the instrument table. This Warranty does NOT cover: consumable items such as operating supplies, paper or storage media, or the servicing of any external printer. Those items will be covered by their manufacturer's warranty and arrangement for service must be made through that manufacturer. This Warranty will NOT apply if repair or parts replacement is required because of accident, neglect, misuse, acts of God, transportation or causes other than ordinary use, or supplies or accessories that do not meet the proper operating specifications of ZEISS. This Warranty does NOT apply to any articles that have been repaired or altered except by ZEISS.

All data stored on the hard disk, magneto-optical and/or floppy discs are the Purchaser's records, and it is Your responsibility to preserve the integrity of these files. ZEISS is not responsible for the loss of patient files stored on the hard disk, floppy discs, backup magneto-optical discs or backup floppy discs.

You bear the entire risk as to the quality and performance of the software. ZEISS does not warrant that the software will meet Your requirements, that the operation of the software will be uninterrupted or error-free, or that all software errors will be corrected. You assume the responsibility for the installation, use and results obtained from the Cirrus HD-OCT and programs.

The Warranty does NOT extend to any removable media that has been damaged as a result of accident, misuse, abuse, or as a result of service, or modification by anyone other than ZEISS. Should such software prove defective following its purchase, You (and not ZEISS) assume the entire cost of all necessary service, repair, or correction. ZEISS has no liability or responsibility to any person or entity with respect to any claim, loss, liability, or damage caused or alleged to be caused directly or indirectly by any software supplied with the Cirrus HD-OCT or by ZEISS.

Every reasonable effort has been made to ensure that the product manuals and promotional materials accurately describe the Cirrus HD-OCT specifications and capabilities at the time of publication. However, because of on-going improvements and product updates, We cannot guarantee the accuracy of printed materials after the date of publication, and disclaim liability for changes, errors or omissions. All instrument specifications are subject to change without notice.

Limitation Of Liability

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Service Contract

In the U.S.A., a Warranty Extension Agreement (Service Contract) is available after the one-year, new Cirrus HD-OCT warranty expires. For information, call the Customer Service Department at 800-341-6968.

Software Copyright

The software program ("Software") included with your Cirrus HD-OCT is a proprietary product of ZEISS and in certain instances contains material proprietary to Microsoft Corporation. These proprietary products are protected by copyright laws and international treaty. You must treat the software like any other copyrighted material.

Software License Agreement

This Software license agreement ("License") is a legal contract between the Purchaser ("You", "Your" "Licensee") and ZEISS governing Your use of the Software. Opening the sealed package indicates Your acceptance of the terms and conditions of this License. If You have any questions concerning this License, contact Carl Zeiss Meditec, Attention Customer Service, 5160 Hacienda Drive, Dublin, CA 94568. Telephone 800-341-6968.

License Terms and Conditions

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from ZEISS and payment of licensing fees. Further, sales of Cirrus HD-OCT instruments may not include any software or software licensee transfers. You may not sublicense, rent or lease the Software.

6. ZEISS warrants the operation of the Software only with the operating system for which it was designed. Use of the Software with an operating system other than that for which it was designed will not be supported by ZEISS. ZEISS does not claim that the software provided is free from defects and shall have no obligation to supply software upgrades (i.e., new versions, or new, or in-line releases).

Acknowledgment

You acknowledge that you have read all the provisions in this Chapter, including this License and Limited Warranty, understand them, and agree to be bound by their terms and conditions.

(A) Networking Guidelines

Notice

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

Network Capabilities

The Cirrus HD-OCT is designed for network data transfer. Software supports the following.

- Windows and Novell networks.
- Creation of user accounts
- Networking via a local area network or intranet.
- Users can archive to and retrieve from a network file server.

WARNING: Risks of Internet Connectivity

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

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

Security Recommendations

If the system is connected to the Internet, we recommend you use the Windows auto-update feature to install all operating system patches and fixes. We also recommend routinely scanning for viruses.

Anti-Virus Software

Please refer to the Cirrus HD-OCT Technical Support section of our website (www.meditec.zeiss.com/cirrus) for the current list of approved hardware and software.

☞ Note: Do not perform virus scanning while acquiring exam data.

Approved Third Party Hardware and Software

☞ Note: Carl Zeiss Meditec does not provide technical support for the use of third party hardware or software.

Please refer to the Cirrus HD-OCT Technical Support section of our website (www.meditec.zeiss.com/cirrus) for the current list of approved hardware and software.

Windows Automatic Update

The default (shipped) and recommended Windows Automatic Update setting and update steps are described below. Note: If you have installed Windows XP SP3 (Service Pack 3), the system will prompt you to turn on/off automatic updates upon reboot. Select **Yes** and then follow the configuration steps below to configure Windows Automatic Update to the recommended setting.

1. Select **Start > Settings (Classic Start Menu only) > Control Panel > Automatic Updates** to display the AUTOMATIC UPDATES window.
2. Select **Notify me but don't automatically download or install them** as shown in Figure A-1 below.

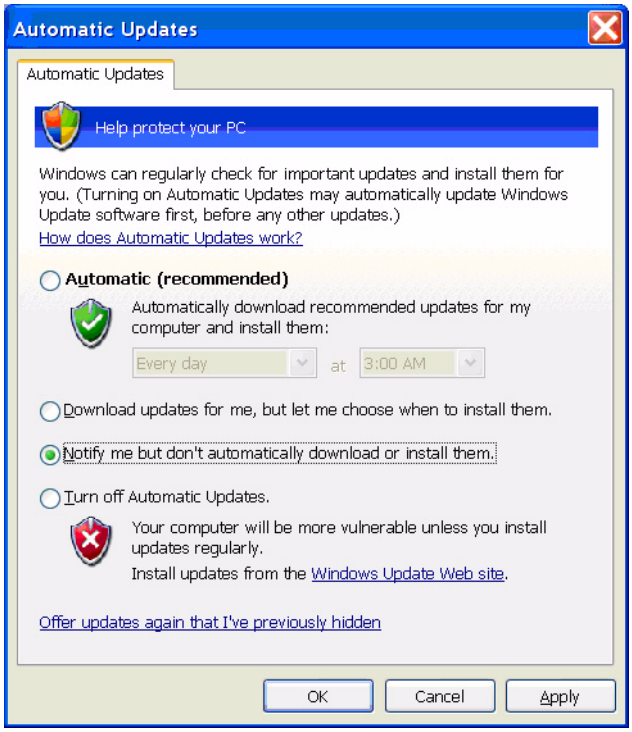
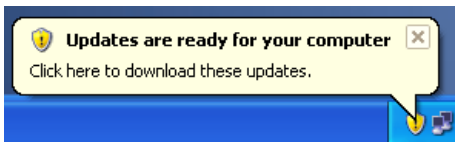


Figure A-1 Automatic Updates Window (Recommended Setting)

3. Select **OK** to save your setting and close the window.

4. When new updates become available, click on the text prompt shown below



or later on the yellow shield icon ( ) in the Windows Taskbar to choose the updates to download.

5. Review the updates shown in the AUTOMATIC UPDATES window and unselect any driver or hardware update. See Figure A-2 below where a hardware driver update has been unselected.

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

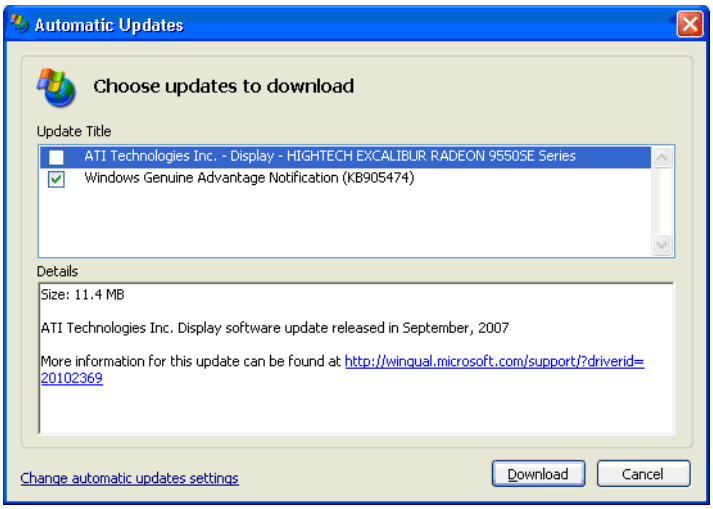


Figure A-2 Automatic Updates Window (Choose updates to download)

6. Select **Download** to begin downloading the selected updates.
7. If you unselect an update, a HIDE UPDATES window will be displayed. Click to display a green checkmark next to **Don't notify me about these updates again** as shown in Figure A-3 below and then select **OK**.

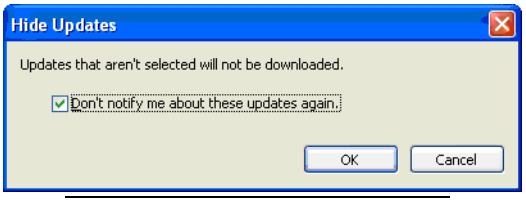
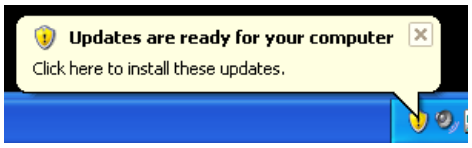


Figure A-3 Hide Updates Window

8. When the downloads are complete for the selected updates, click on the text prompt shown below



or later on the yellow shield icon ( ) in the Windows Taskbar to install the updates.

9. An AUTOMATIC UPDATES window will be displayed prompting for an installation method as shown in Figure A-4 below.

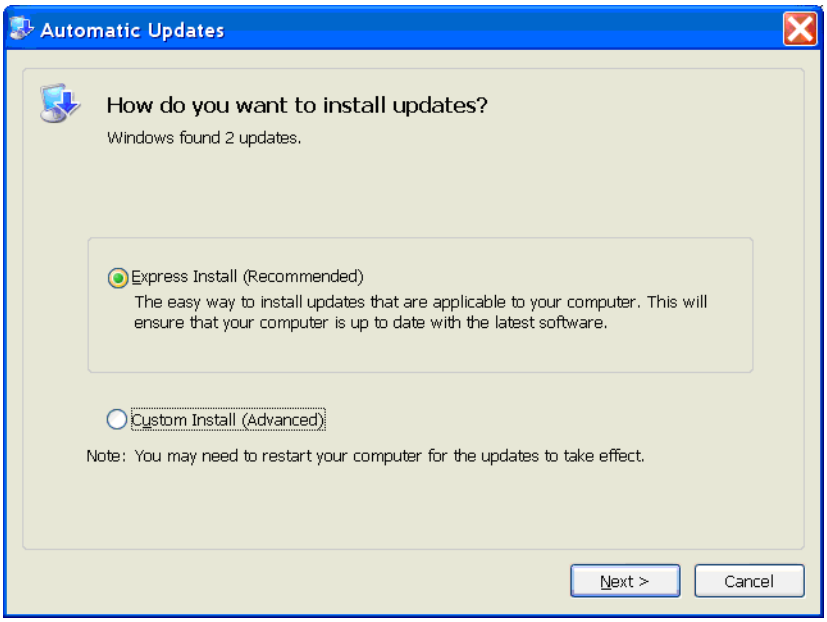


Figure A-4 Automatic Updates Window (How do you want to install updates?)

10. Select **Express Install** and then **Next** to install all of the downloaded updates.
11. Depending on the update, you may need to restart Cirrus HD-OCT after installation is complete.

Prohibited Activities

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

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

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

Network Activities Not Supported

Carl Zeiss Meditec does not support the following network activities, although they may be possible.

☞ Note: The user bears responsibility for any system performance degradation or any other change or defect resulting from the attempt to perform the following activities. **CARL ZEISS MEDITEC IS NOT RESPONSIBLE FOR SOFTWARE REPAIRS OR UPGRADES NECESSITATED BY THE ATTEMPTED PERFORMANCE OF THE FOLLOWING ACTIVITIES.**

- Printing with a printer not approved for use with the Cirrus HD-OCT by Carl Zeiss Meditec.

Please refer to the Cirrus HD-OCT section of our website (www.meditec.zeiss.com/cirrus) for the current list of approved hardware and software. If you wish to use a third party device, seek technical support from the device manufacturer.

Network File Server Minimum Requirements

The network file server must meet the following minimum requirements:

- Server class 800 MHz processor with 128 KB cache
- 256 MB RAM
- Windows, Unix or Linux server operating system
- NTFS drive partition(s) for Cirrus HD-OCT data. Cirrus HD-OCT is compatible only with NTFS on network drives.

☞ Note: You can use SAMBA with Unix and Linux file servers.

- 250 GB available disk space for data storage
- Tape backup unit
- 100 BaseT network connection

Network File Server 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
    - It is the user's responsibility to protect their exam data from loss by frequent backup of the network server. Backup media should be of archival quality, and the media should be stored in a secure, remote location.

WARNING: Failure to backup the network file server may result in the loss of medical exam data.

- The file server must be started prior to networked Cirrus HD-OCT instruments and shut down after Cirrus HD-OCT instruments.
- Strongly recommended that the file server not be used for interactive programs, such as web browsing or word processing.

Using the Network File Server

Using a network file server is recommended in offices that have a local area network, especially if you have multiple Cirrus HD-OCT instruments. Once you have set up the instrument(s) on the network, you can use the network file server for routine archiving.

Set Up Network Archiving

Note: Configuring the server and the instrument for archiving to a network file server should be attempted only by a network administrator or system administrator, and the following instructions are intended only for personnel with such expertise. Users are responsible for network setup and maintenance. Carl Zeiss Meditec Technical Support is limited to testing network connectivity of the Cirrus HD-OCT. Technical Support cannot troubleshoot or repair problems with network connectivity.

Create and Share a Folder on the Network Drive

1. On the network file server, create a folder named "Cirrus HD-OCT Archive" or the like. Make this a shared folder.

2. To ensure access to the shared folder on the network file server:
   A. On the Cirrus HD-OCT, create a new administrator account for use as the default account. Follow these instructions:
      i. Exit the Cirrus system software. From the Windows desktop, select **Start > Control Panel**.
      ii. In the Control Panel, select **User Accounts**.
      iii. In the User Accounts dialog, select **Create a new account.**
      iv. Type a name for the new account in the screen that appears. Note that this name must match the name for the Cirrus account that you will create on the server. Click **Next**.
      v. Select **Computer administrator** for the account type and then click **Create Account**.
      vi. Back in the User Accounts dialog, double-click the new account you just created and then click **Create a password**. This account must have a password, and this password must be the same for the Cirrus account that you will create on the server.
      vii. To make this the default account when you start the instrument, select **Start > Programs > Accessories > System Tools > Configure Logon**.
      viii. In the User Accounts dialog that appears, first select the name of the new user account you just created. Then clear the checkbox that says, **Users must enter a user name and password to use this computer.** This will enable you to bypass the user account selection and/or login dialog when you start the instrument, and makes the new user account the default account.

WARNING: Once you have created an additional user account as instructed here, to switch between user accounts you must log off and then log on again. Do not use the Start > Switch User function to switch between user accounts; if you do, the Cirrus HD-OCT application will not be accessible. To restore access, you must log off users until only one user is logged on to the operating system (Windows XP).

   B. On the server, create a new account with the same user name and password as on the Cirrus HD-OCT.

Map a Network Drive to the Shared Folder

3. On the Cirrus HD-OCT, map a network drive to the shared folder you have created on the server.
   A. Open Windows Explorer®: Right-click the Windows **Start** button and select **Explore**.
   B. In Windows Explorer, select **Map Network Drive** from the **Tools** menu (click **Tools > Map Network Drive**). The Map Network Drive dialog appears.
   C. Select a drive letter.
   D. Click **Browse** to find and select the shared folder you created on the network file server. You will have to first find the file server name (machine name), and then the folder. (Do not clear the **Reconnect at logon** checkbox, which is selected by default.)
   E. When you have selected the correct folder and returned to the Map Network Drive dialog, click **Finish**. You have now mapped a network drive to the shared folder.

Register the New Archive on the Network Drive

4. On the Cirrus HD-OCT instrument, you must register the new archive on the network file server to make it current.
   A. From the Cirrus HD-OCT ID PATIENT SCREEN, select **Register Archive** from the **Options** menu (click **Options > Register Archive**). The Archive Registration dialog appears.
   B. In the Archive Registration dialog, click **New**. The New Archive Registration dialog appears.
   C. In the New Archive Registration dialog, the **Archive Name** field is made up of two parts. The first part is generated automatically and cannot be changed; it is composed of the model number, serial number and archive sequence number. You can add a suffix to the name using the second part of the field, if you wish.
      - The **Mark as current** checkbox is selected by default. Do not change this selection if you wish to use the archive you are about to register as the current archive.
      - The **Disabled** checkbox is not selected by default. Select the **Disabled** checkbox if you do not wish to archive to this archive location.
   D. Click the **Browse** button next to the **Local Path** field to find and select the local drive letter you have mapped to the shared archive folder on the network file server. When you select the local drive letter, the **Network Path** field is completed automatically.
   E. If you wish, you can enter up to about 85 characters in the **Description** field to describe the archive you have registered.
   F. When finished, click **Save** to register the new archive. It will now be the current archive to which exam data is copied when you save scans.

Data Transfer Over the Network

Once you have configured the instrument and the server for archiving, you can perform all data transfer functions as explained in the respective sections of this manual. See Chapter (7), Archive and Retrieve for instructions to archive and retrieve Cirrus HD-OCT data.

☞ **Note: If you attempt a data transfer function when the network is down or the server is down, the function will fail and the instrument will notify you that a connection could not be established.**

Configuration for Direct Export to a Personal Computer

It is possible to export data from a Cirrus HD-OCT to a personal computer (PC) via either a local area network or a direct cable connection. To accomplish this, it is necessary to configure both the Cirrus HD-OCT and the PC. To view and analyze data on the PC, you can use compatible third-party software.

Terminology

The "source system" is the Cirrus HD-OCT system, from which you will export; the "target system" is the remote computer to which you will export data.

☞ **Note: The choice and use of third party software on the target system for viewing and analysis is at the user's discretion. Carl Zeiss Meditec does not specify compatible third party software, nor support its use.**

☞ **Note: Carl Zeiss Meditec does not provide technical support for direct export to a personal computer. The following configuration requirements pertain to the example of direct export from the Cirrus HD-OCT to a PC running Windows 2000 or XP. We intend these requirements for information technology (IT) specialists, who will understand how to implement them. The user bears responsibility for any source or target system performance degradation or any other change or defect resulting from the attempt to perform these tasks.**

☞ **Note: The requirements below are for a target system running Windows 2000 or XP. If your intended target system is running another operating system, it may be possible to configure it to import from the Cirrus HD-OCT, but the configuration requirements may be different and are not explained here.**

Configuration requirements

1. If transferring data via a network, connect both the source and target systems to the network using a standard cable. If transferring via direct connection between source and target, connect the two using a crossover cable. The Cirrus HD-OCT system has a network connector (ethernet port) on the rear of the unit.
2. The source and target systems must have computer names, and these must be different. If necessary, create a computer name of your choice for one or both computers.

3. Both source and target systems must share the same set of networking protocols, as follows. (The Cirrus HD-OCT is shipped with the following protocols properly configured.)
    - Client for Microsoft Networks
    - File and Printer Sharing for Microsoft Networks
    - Internet Protocol (TCP/IP)
4. On the target system, create a shared folder that will receive the imported data and enable access to the target system from the source system.
5. On the source system, map a network drive to the shared folder you created on the target system in step 4. If the target system is password protected, you must access it with a user account having computer administrator privileges in Windows XP.
6. The Cirrus HD-OCT is configured by default to use DHCP. If the source system is connected to a network that uses static IP addressing, the following TCP/IP parameters must be configured: IP address, Subnet, and Default gateway.

(B) Using a Network Storage Device

Introduction

This appendix provides safety information, requirements, recommendations and configuration instructions for using a network attached storage device (NAS device), also known as a network drive, with Cirrus HD-OCT. These instructions provide requirements and recommendations for the NAS device, but are generic with respect to brand, the choice of which is at the discretion of the user. You can attach the NAS device directly to the Cirrus HD-OCT Ethernet port, or you can connect it via your office network (local area network or LAN). These instructions cover both scenarios.

Once installed and correctly configured for use with the Cirrus HD-OCT, the NAS device serves the same functions as a network server (primarily archiving), and the instructions in the Cirrus HD-OCT User Manual for using a network server apply to use of the NAS device.

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

Please refer to the Cirrus HD-OCT section of our website (www.meditec.zeiss.com/cirrus) for the current list of approved hardware and software. If you wish to use a third party peripheral device, seek technical support from the device manufacturer. Repairs necessitated by the attempt to use a non-approved peripheral device are not covered under warranty.

NAS Device Safety Warnings

WARNING: Place the NAS device outside the patient environment. Peripheral devices such as a NAS device must be placed at least 1.5 meters (4.9 feet) away from the patient, such that the patient cannot touch a peripheral device with any part of his or her body while being examined. In addition, the instrument operator must not attempt to touch the patient and a peripheral device at the same time while examining the patient. Failure to observe this warning could result in electrical shock to the patient and/or examiner.

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

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

NAS Device Requirements

For safety and minimally acceptable performance when used with Cirrus HD-OCT, the user must select a NAS device with the following characteristics:

- 100BaseT or 1000BaseT Ethernet capable. For safety reasons, USB connection is not permitted with Cirrus HD-OCT.
- Network patch cord for direct connection to Cirrus HD-OCT: UTP CAT5e cord with an unshielded RJ-45 connector, at least 10 feet (3.05 meters) long to enable you to place the NAS device outside the patient environment. See related safety warnings above. Note that many network drives you purchase may contain patch cords that are shielded or of insufficient length to use with Cirrus HD-OCT. In such cases, you must purchase this cord separately.
- Drive media formatted using NTFS: Cirrus HD-OCT data is compatible only with NTFS.
- Approvals: The NAS device you select must conform with local agency requirements. In Europe, CE approval is required. In North America, UL, CSA or equivalent approval is required; and FCC approval is required.

NAS Device Recommendations

- Recommended storage capacity: At least as large as the Cirrus HD-OCT hard drive.
- Backup solution: To maintain redundancy of data backup, we strongly recommend you use the backup solution of your choice for the NAS device, especially when you have used the Cirrus HD-OCT long enough for it to begin deleting archived exams automatically. Depending on the usage rate, it takes many months up to a few years before Cirrus HD-OCT begins to clear archived exams automatically.
    - You can use multiple or mirrored NAS devices as a backup solution, but when you use two or more NAS devices concurrently, you must use a switch or router. The switch/router may be directly connected to the instrument or elsewhere on the local area network. Configuration in this scenario is the user's responsibility.

Install and Configure the NAS Device

You can attach the NAS device directly to the Cirrus HD-OCT Ethernet port, or you can connect it via your office network (local area network or LAN). These instructions apply to both scenarios.

1. With the Cirrus HD-OCT and the NAS device turned off, use a network patch cord to connect the NAS device either directly to the Cirrus HD-OCT, or to the office network (local area network or LAN) on which the Cirrus HD-OCT resides. Refer to the manufacturer's instructions for details regarding installation of the NAS device.

☞ **Note: For safety, observe the warnings and requirements on page B-1 that relate to the type and length of cord.**

2. Turn on the NAS device and wait for initialization to complete before you turn on the Cirrus HD-OCT. Often a color change in a light on the front of the NAS device indicates initialization is complete, but see the manufacturer's instructions for details on initialization.
3. Turn on the Cirrus HD-OCT. After you complete the startup process, exit the Cirrus software, going to the Windows® desktop.
    - In the system tray at lower right, you may observe a Local Area Connection notice resulting from attachment of the NAS device. Ignore the message at this point.
4. In the Cirrus HD-OCT CD drive, install the CD that accompanies the NAS device, which will install and run the NAS device configuration program. Follow the on-screen instructions, using the default settings. While running the NAS device configuration, observe the following recommendations:

    A. Installation Type: If you are presented with an option to choose a type of installation, for example a choice between "typical," "minimal" and/or "custom" installation, we recommend you choose "typical" or "minimal." Do not perform a "custom" installation unless you have reason to do so and the knowledge and experience required, which would be equivalent to that of a network or system administrator.

    B. Record Storage Drive Name: If you are presented with the option to change the name of the NAS device, you can either use the default name or change it at your discretion, but in either case, you must write it down, because you may need it to complete configuration on the Cirrus HD-OCT. You can use the space below:

NAS Device Name (also known as Network ID):_____

    C. Workgroup Name Must Match Cirrus HD-OCT Workgroup Name: If you are presented with the option to change the workgroup name of the NAS device, you must make it match the workgroup name of the Cirrus HD-OCT, which is "CZM" by default—this name is not case-sensitive on Cirrus HD-OCT. If the Cirrus HD-OCT is connected to an office network as part of a different workgroup name, then you must use that workgroup name.
5. When you complete NAS device configuration, exit the configuration program and remove the CD from the Cirrus HD-OCT CD drive.

On Cirrus HD-OCT, Map a Network Drive to the NAS Device

In some cases, the configuration software of the NAS device automatically maps the correct folder of the NAS device to a drive letter on the Cirrus HD-OCT. When this is the

case, configuration is complete and the NAS device is ready to use. In other cases, you must map a drive on the Cirrus HD-OCT to the proper folder of the NAS device using Windows Explorer, as instructed below:

1. Back on the Windows desktop, open Windows Explorer: right-click on **Start** and select **Explore**.
2. In the Explorer Address field, type two backlashes and then the NAS device name you recorded in step 4.B. above, and press **Enter**. See the example below.

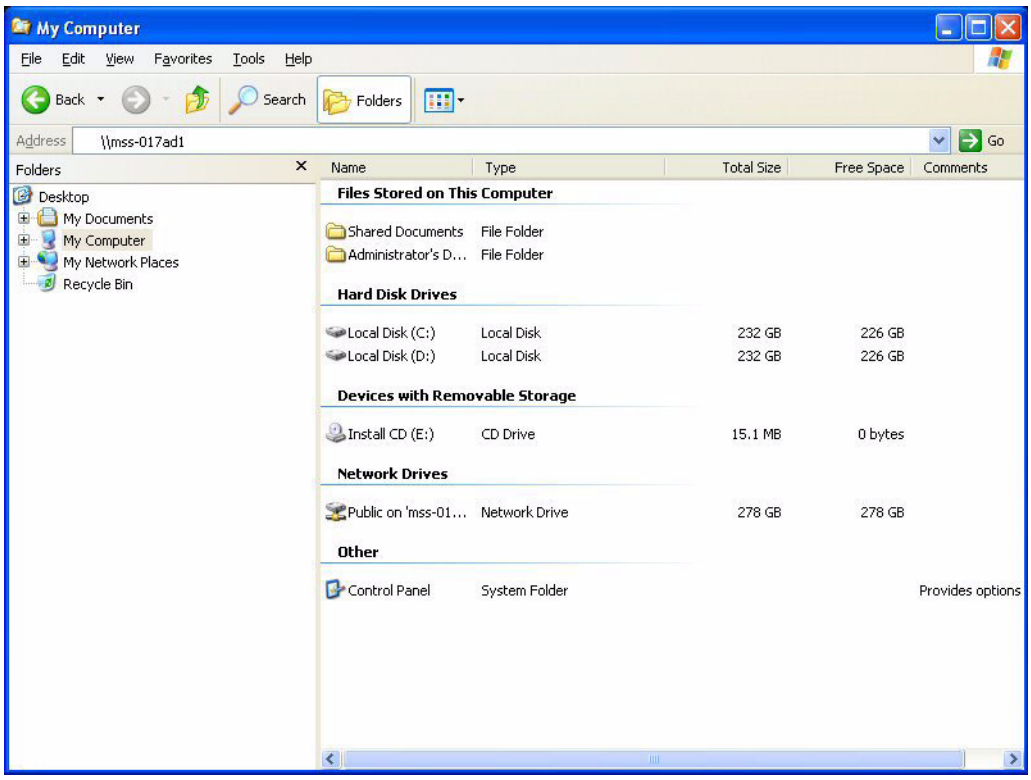


Figure B-1 Entering Device Name in Windows Explorer Address Field

☞ Note: If you failed to record it properly, note that you can often find the NAS device name on a label on the back of the NAS device. The device name, for this purpose, may be presented as the **Network ID**. Enter the entire network ID/device name after the two backslashes, with no spaces.

If you have typed the device name correctly, and the NAS device is correctly configured and turned on, when you press **Enter**, Explorer should find the NAS device on the left and display its contents on the right, as in the example below.

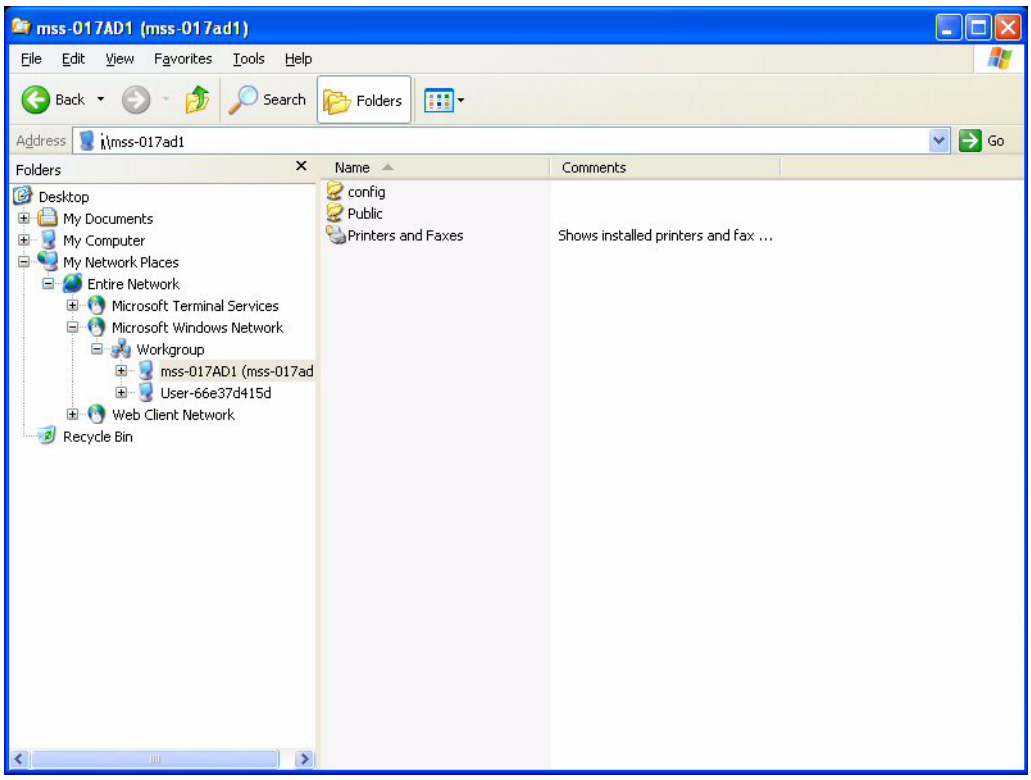


Figure B-2 Explorer Finds NAS Device and Displays Its Contents

3. Now you must map a drive on the Cirrus HD-OCT to the NAS device folder that is accessible to all users for storage. In the example above, the folder named **Public** is the correct folder. The folder name for your NAS device may be similarly indicative that it is intended for use as the storage folder. Consult the manufacturer's instructions to determine which folder is intended for this purpose.

4. Click to select the correct storage folder. Then click **Tools > Map Network Drive**. The Map Network Drive dialog appears.

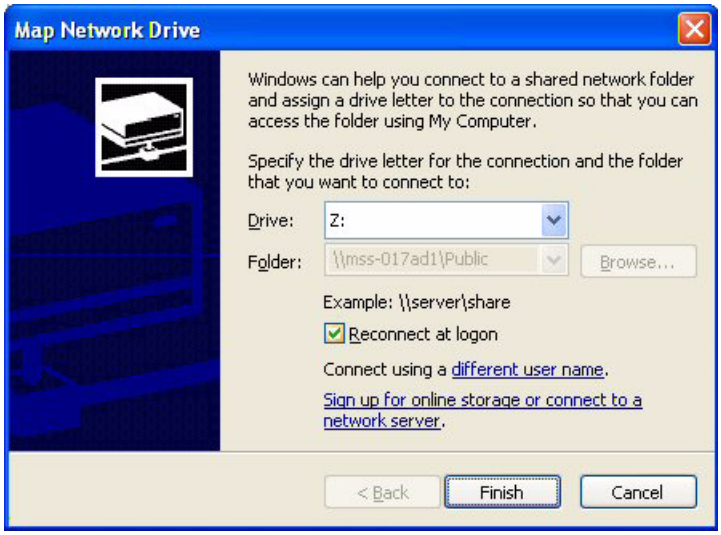


Figure B-3 Map Network Drive Dialog

5. In the **Drive** field, select any available network drive letter, using the down-arrow on the right. You may, for example, choose N: for network storage device.
   - In the **Folder** field, note that the folder name is already selected and unavailable to be changed.
   - Do not clear the **Reconnect at logon** check box.
6. Click **Finish**. You have now completed configuration. To archive to the NAS device, register the drive letter assigned to the NAS device as an archive volume. See Archive Management on page 7-6 for details.

Cleaning the NAS Device

Regular periodic cleaning of the NAS device is not required. However, if the device becomes dusty, you may clean it using a soft bristle brush such as a keyboard brush. Do not use liquid cleaners unless specifically directed by the manufacturer, since they may drip into the device and cause it to malfunction.

(C) Printer Configuration

Introduction

This appendix instructs you how to configure a printer for use with Cirrus™ HD-OCT. These instructions provide requirements and recommendations for the printer, but are generic with respect to brand, although one may be supplied with the instrument. Specific configuration instructions vary by printer, and users are advised to closely follow the instructions supplied by the printer manufacturer. These instructions cover two configurations for communication between instrument and printer:

1. Network Configuration (page C-3), either via direct connection between instrument and printer, or via connection of instrument and printer to a local area network
2. USB Configuration (page C-3), via direct USB connection between instrument and printer

Approved Printers

Please refer to the Cirrus HD-OCT section of our website (www.meditec.zeiss.com/cirrus) for the current list of approved hardware and software. If you wish to 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.

WARNING: If you use a non-approved device or if you connect it incorrectly—for example, by plugging the printer into the wall while using a USB connection, or by using a shielded network (UTP) cable—you could invalidate the system safety approval. See the general warning regarding accessory equipment on page **1-13**, and the warnings regarding USB and network connections on page **C-2** above.

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

Printer Safety Warnings

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

Use of the printer in the wireless configuration enables you to observe this precaution more easily.

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

WARNING: To directly connect a printer to the Cirrus HD-OCT using a network patch cord (UTP cable), only use an unshielded RJ-45 connector. Use of a shielded network patch cord will ground the printer through the Cirrus HD-OCT, which could result in electrical shock to the patient and/or examiner. It could also invalidate the system safety approval.

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

Installation Overview

The following three general steps are common to all configurations. These steps are explained further in the specific sections.

1. Printer hardware setup and configuration: Refer to the instructions provided with the printer to unpack and set up the printer hardware. Printer configuration is required only when you choose the wireless configuration; with a network or USB connection, printer configuration is automatic.
2. Connect hardware to enable communication between instrument and printer. The hardware used depends on the type of configuration you select: either a wireless networking adapter, a network cable or a USB cable.
3. Configure the instrument software to communicate with the printer, including installation of necessary printer drivers.

Network Configuration

Typically, no printer configuration is required for the network configuration. Three general steps are required for configuration:

1. Connect the printer to the Cirrus HD-OCT via network cabling
2. Power on the printer
3. Install printer drivers on the Cirrus HD-OCT.

This is the usual sequence of steps, but follow the printer manufacturer's instructions for details.

Using Network Cable(s) to Connect Cirrus HD-OCT and Printer

To establish network communication between the Cirrus HD-OCT and the printer, you can directly connect instrument and printer with the network (ethernet) cable, or connect both instrument and printer to the local area network or to a network switch/router/hub connected to the Cirrus HD-OCT.

☞ **Note: Use the same kind of network cable in all cases. (If you connect instrument and printer to the network rather than to each other, you will need two network cables.) Do not use an RJ-45 crossover cable for direct connection between instrument and printer.**

USB Configuration

No printer configuration is required for the USB configuration. Three general steps are required for configuration: install printer drivers on the Cirrus HD-OCT; connect the printer to the Cirrus HD-OCT via USB; and power on the printer. However, the sequence of steps may vary. **Follow the printer manufacturer's instructions to observe the correct sequence of steps.**

☞ **Note: To maintain patient safety, in the USB configuration, you must power the printer through the Cirrus HD-OCT isolation transformer. To do so, you must use a special power cable. In North America, the required cable has an IEC-320-14 connector on one end and a NEMA S-15R connector on the other end.** This cable is included in the accessory kit shipped with the instrument.

(D) RNFL and Macula Normative Databases

Introduction

The Cirrus HD-OCT normative database contains normative data for retinal nerve fiber layer (RNFL) and macular thickness from healthy subjects ages 19 to 84. Seven centers participated in the prospective, non-randomized, multi-center study. Enrolled subjects were representative of healthy individuals with no history of eye disease and were carefully screened and evaluated for eligibility. After undergoing a general ophthalmic examination, qualifying and consented subjects underwent retinal scanning with the Cirrus HD-OCT instrument.

Medical and ophthalmic histories were taken prior to enrolling the subjects in the study. Subjects were given a complete ophthalmic examination that included the following tests:

- Distance visual acuity.
- Perimetry using the Humphrey 24-2 SITA Standard threshold test, bilaterally. Any defects found were verified with a second test.
- Goldmann application tonometry.
- Keratometry
- Axial length measurement using an IOLMaster.
- Slit lamp examination of the anterior segment of both eyes.
- Gonioscopy
- Dilated ophthalmoscopic examination, bilaterally.
- Fundus and stereodisc photography of the maculas and the optic nerves of both eyes.
- Corneal thickness measurement using ultrasound pachymetry.

Subjects were grouped into six categories, by subject age: 18-29, 30-39, 40-49, 50-59, 60-69, and 70 and older. Results in patients 70 years of age or older should be interpreted with caution since only three subjects were included in the normative database who were 80 years of age or older, and only 28 subjects were included who were between 70 and 79 years of age. It should also be noted that this normative database does not have any subject younger than 19 years old.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria for enrollment in the study were as follows:

Inclusion Criteria

- Males or females 18 years of age or older.
- Able and willing to make the required study visits.
- Able and willing to give consent and follow study instructions.

- Must have a normal and valid Humphrey 24-2 SITA Standard visual field in both eyes.

Exclusion Criteria

Ophthalmic:

- Best corrected visual acuity in either eye worse than 20/40.
- Refractive error (spherical equivalent) outside -12.00D to +8.00D range.
- Glaucoma or glaucoma suspect diagnosis in either eye.
- Presence or history of ocular hypertension (IOP ≥22 mm Hg) in either eye.
- Occludable angle or history of angle closure in either eye.
- Presence or history of disc hemorrhage in either eye.
- Presence of RNFL defect in either eye.
- Presence of amblyopia in either eye.
- Previous laser or incisional surgery.
- Any active infection of anterior or posterior segments.
- Evidence of diabetic retinopathy, diabetic macular edema, or other vitreo-retinal disease.

Systemic:

- History of diabetes, leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis.
- A life threatening or debilitating disease.
- Current or recent (within the past 14 days) use of an agent with photosensitizing properties by any route (e.g., Visudyne®, ciprofloxacin, Bactrim®, doxycycline, etc.).

Normal subjects were defined by Principal Investigators at each site after review of clinical and visual field data, and considering inclusion and exclusion criteria. The Cirrus instrument was not used in determining the normalcy of the subjects.

The subjects were defined as normal if they met the following criteria:

- Best corrected visual acuity of 20/40 or better in both eyes.
- IOP less than or equal to 21 mm Hg.
- No history of ocular, neurological, or systemic diseases that might affect the visual system.
- Normal visual field, indicated by a Glaucoma Hemifield Test within normal limits, and MD and PSD > 5% probability level.

Data Collection

284 subjects were qualified as normal subjects and enrolled in this study. 284 subjects were qualified for the RNFL database while 282 subjects were qualified for the Macula normative database (poor scan quality disqualified the macula scans from two subjects).

For the RNFL normative database, each eye was scanned three times with the Optic Disc Cube 200x200 scan. For the macula normative database, each eye was scanned three times with the Macular Cube 200x200 scan. The Macular Cube 512x128 was scanned once per each eye.

The Cirrus RNFL and Macula databases do not have subjects with refractive errors outside the −12.00D to +8.00D range. Therefore, the normative limits for subjects with refractive errors outside the −12.00D to +8.00D range should be used with caution.

Scan Selection Criteria

The scans were reviewed for image quality. One best quality scan for each scan type was chosen for each subject per eye. Scans having the following characteristics were excluded from the normative database:

- Signal Strength of 5 or lower.
- Large eye motion during image acquisition, resulting in a saccade that was within the central 80% of the scan area.
- Area of data loss greater than 10% at the edge of the scan area.
- Presence of floater(s) obscuring macular area on Macular Cube scans or measurement circle on Optic Disc Cube scans.

In practice, clinicians and operators should quantitatively and qualitatively review scans before comparing them to the Cirrus RNFL or Macula normative databases. The normative limits for scans that have poor scan quality should be used with caution.

Cirrus RNFL and Macula Normative Database Development

The Cirrus RNFL and Macula normative databases were developed utilizing 284 subjects (aged 19-84) and 282 subjects (aged 19-84); respectively. These normative databases have a similar gender distribution (134 males, 150 females and 133 males, 149 females; respectively). Ethnicity breakdown of the Cirrus RNFL and Macula normative databases is as follows: 43% Caucasians, 24% Asians, 18% African American, 12% Hispanic, 1% Indian, and 6% mixed ethnicity.

Results revealed that the mean difference in the average thickness between any two race groups is within 6 µm. Caucasians have thinner mean average thickness, superior quadrant average, and inferior quadrant average. Asians seem to have thinner mean nasal quadrant average and thicker temporal quadrant average. The largest difference in the RNFL thickness between two race groups is for the temporal quadrant average between Asian and African American, with a difference of 16 µm.

Note that Cirrus RNFL and Macula normative databases are adjusted only by age, not by ethnicity or any other parameter. The normative limits provided for comparisons of individual data to the normative database do not take into account differences that may be present due to ethnicity, axial length, refraction, optic disc area, or signal strength.

Data Analysis

From these scans the normative databases for the Macular Cube 512x128, the Macular Cube 200x200 and the Optic Disc Cube 200x200 scans were created. The age range for all databases was from 18 to 84 years. Mean age of the subjects was 46.5 years for the RNFL normative database and 46.6 years for the macula normative database.

The regression model analyses were used to estimate the normative limit of each of the Cirrus HD-OCT RNFL and macular thickness parameters adjusted by age. Subject's age is considered as a clinically important factor for the RNFL and macular thickness measurements.

For each fitted regression model, the residuals were derived for each eye by subtracting estimated expected mean reading, ET(age_0), from the measured or observed reading, Obs(age_0). In other words, residual = Obs(age_0) - ET(age_0). The goal was to predict the $100x\alpha^{th}$ percentiles (NL, normative limit) of the residuals, so that the $100x\alpha$ % limit of the Cirrus HD-OCT parameter readings could be estimated as follows:

ET (age_0) + NL($100x\alpha$ %) < Obs (age_0) (A)

The 1st, 5th, 95th, and 99th percentiles of the residuals were estimated by the empirical distribution of residual. Then the estimated 1%, 5%, 95% and 99% normal limits of Cirrus HD-OCT parameters for a normal subject with an age of age_0 were established by Equation (A). It should be noted that the study site effect was not considered in the normative limits calculation since the objective was to establish the normative limits for the general population.

Age Coefficient – RNFL Thickness

Analysis of subject demographics determined that expected thickness was dependent upon age. Thus age correction is incorporated into the calculated results. Subject ethnicity was self-reported by the subjects in the population comprising the normative database but was not used as a variable in constructing the RNFL and macula normative databases.

Figures D-1, D-2 and D-3 display scatter plots for RNFL Summary Parameters versus age along with the fitted regression lines. These demonstrate that the RNFL summary parameters decrease gradually as the age increases.

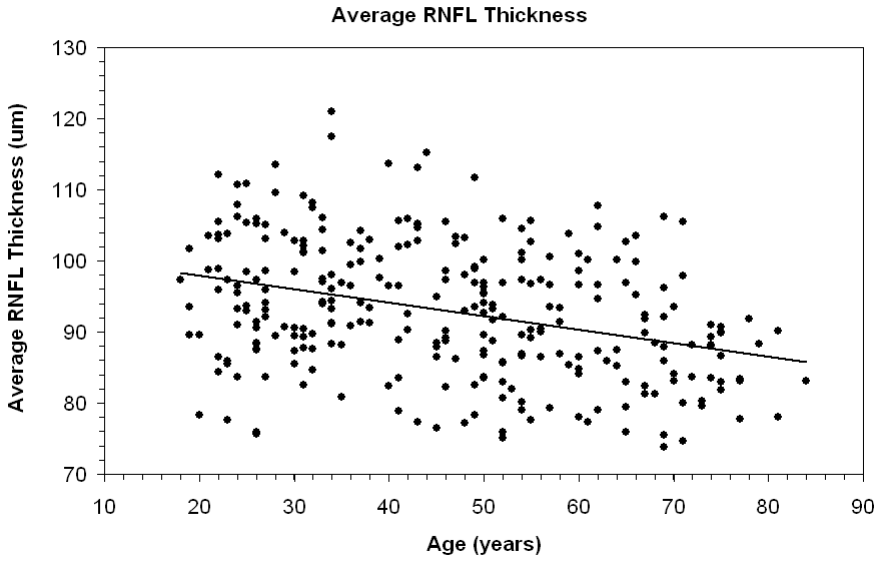


Figure D-1 Average RNFL Thickness Versus Age

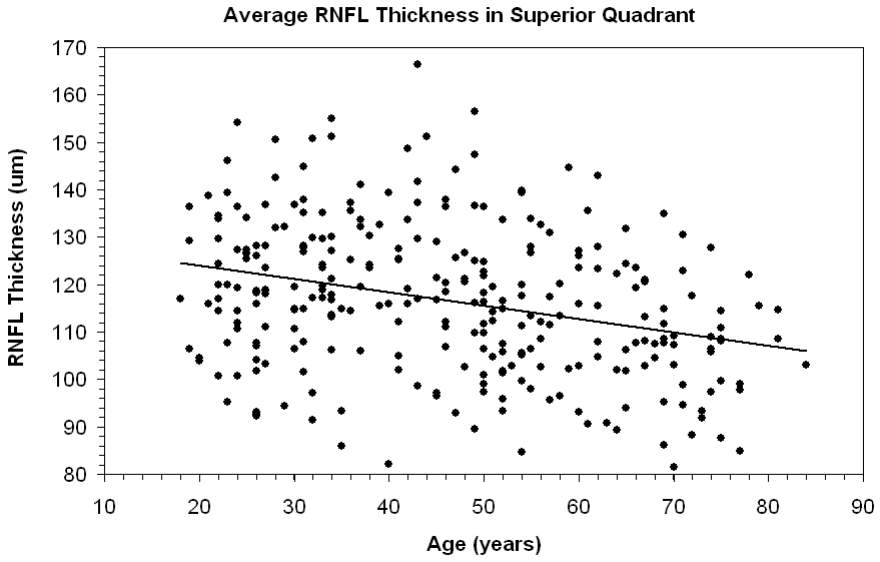


Figure D-2 Superior Quadrant Average RNFL Thickness Versus Age

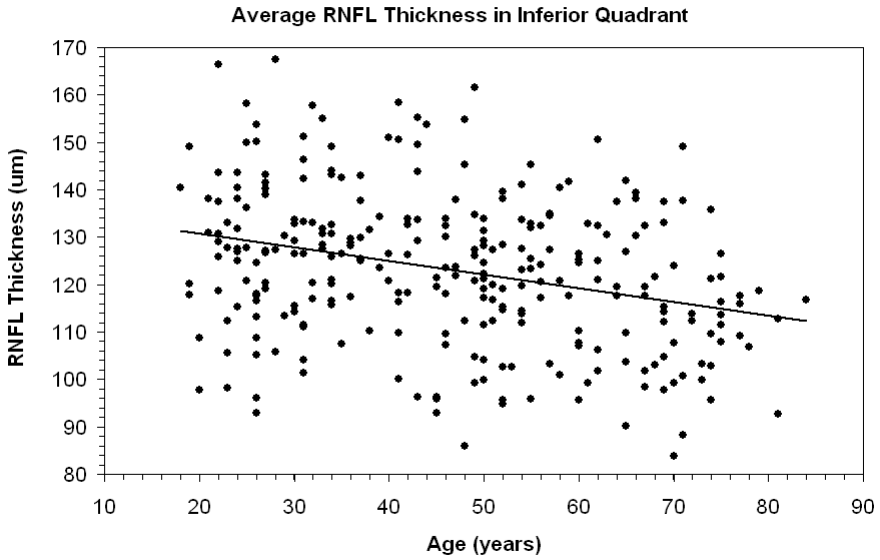
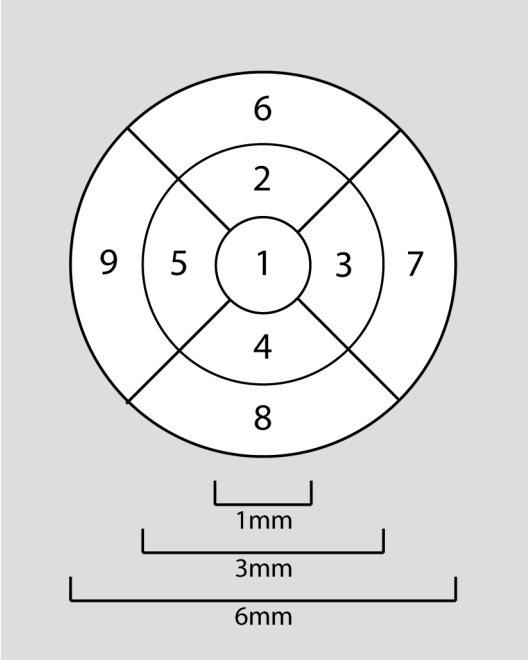


Figure D-3 Inferior Quadrant Average RNFL Thickness Versus Age

Description of Macular Scan Parameters Used in Cirrus HD-OCT

Cirrus Macular Scan parameters were derived from the Early Treatment Diabetic Retinopathy Study (ETDRS) Grid below:



Central Subfield Retinal Thickness: Average thickness of the retina in a disk-shaped region of 1 mm diameter centered on fovea (Region 1).

Inner Subfield Retinal Thickness: Average thickness of the retina in each inner quadrant of an annulus centered on the fovea with inner 1 mm diameter and outer 3 mm diameter.

- Inner Superior Subfield – Region 2
- Inner Inferior Subfield – Region 4
- Inner Temporal Subfield – Region 5 in OD, Region 3 in OS
- Inner Nasal Subfield – Region 3 in OD, Region 5 in OS

Outer Subfield Retinal Thickness: Average thickness of the retina in each outer quadrant of an annulus centered on the fovea with inner 3 mm diameter and outer 6 mm diameter (Regions 6, 7, 8 and 9).

- Outer Superior Subfield – Region 6
- Outer Inferior Subfield – Region 8
- Outer Temporal Subfield – Region 9 in OD, Region 7 in OS
- Outer Nasal Subfield – Region 7 in OD, Region 9 in OS

In addition, these normative values were also established for the 6 mm x 6 mm square area scanned.

Average Retinal Thickness ILM to RPE (Macular Cube Average Thickness): Overall average thickness for the ILM - RPE tissue layer over the entire 6 x 6 mm square scanned area.

Retinal Volume ILM to RPE (renamed as Macular Cube Volume): Overall average volume for the ILM - RPE tissue layer over the entire 6 x 6 mm square scanned area.

Age Coefficient – Macula Thickness

Figure D-4 displays a scatter plot for the Central Subfield retinal thickness average versus age along with the fitted regression line. Figure D-5 displays a scatter plot for the average macular thickness for all subfields along with the fitted regression line. Figure D-6 displays a scatter plot for the average macular volume for all subfields along with the fitted regression line. These demonstrate that the central subfield has almost no dependence on age, but the remaining subfields decrease very gradually when the age increases.

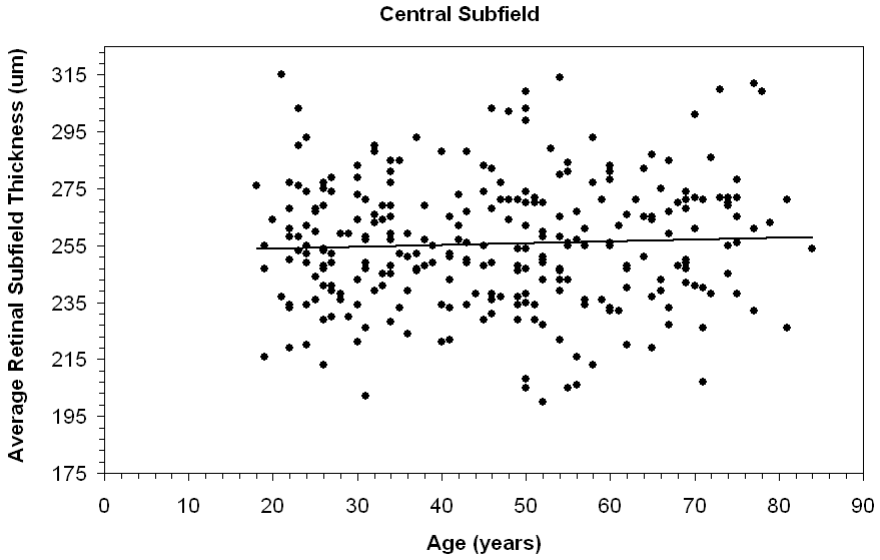


Figure D-4 Average Macula Thickness Versus Age - Central Region 1

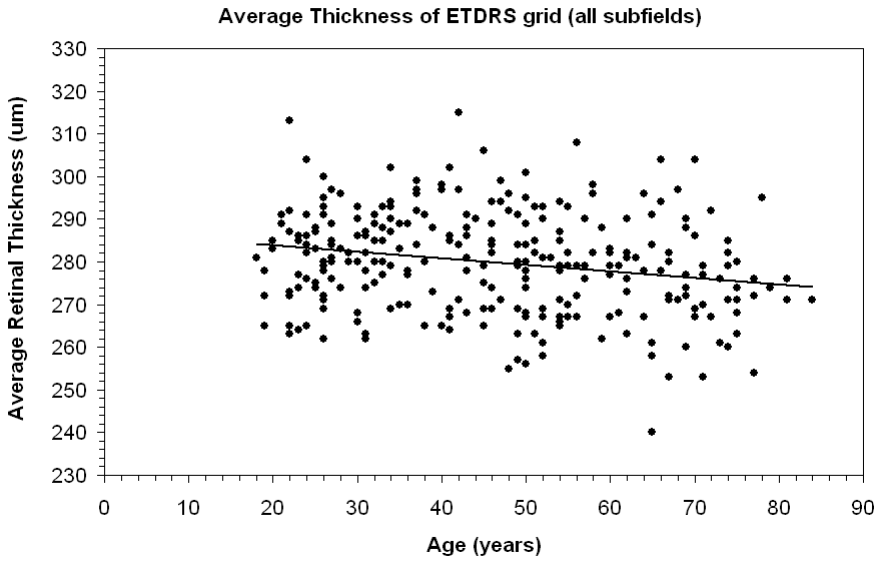


Figure D-5 Average Macula Thickness Versus Age - All Regions

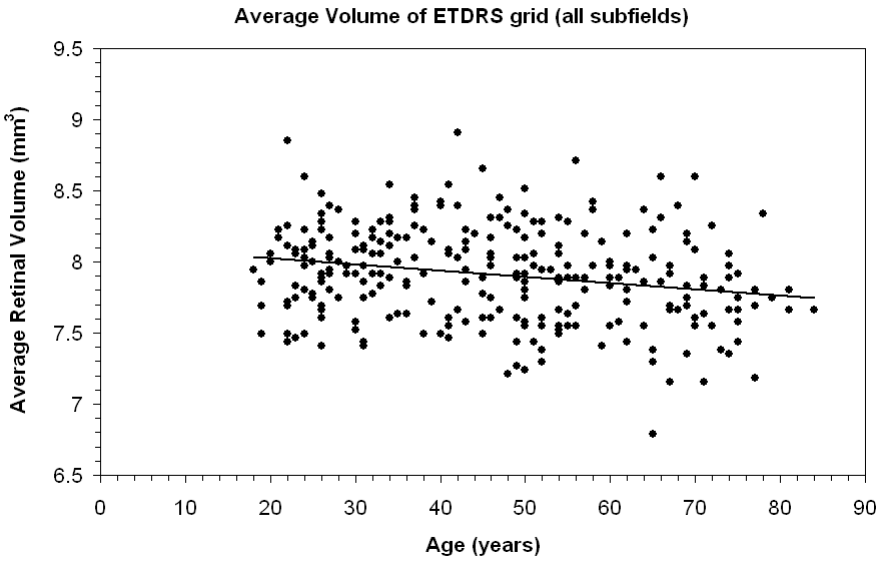


Figure D-6 Average Macula Volume Versus Age - All Regions

Conclusion

The Cirrus HD-OCT RNFL and macular thickness normative databases were created using data from subjects that were deemed representative of a normal population. The Cirrus HD-OCT normative database for RNFL thickness established reference values for the Optic Disc Cube 200x200 scan. The Macula normative database established reference values for the Macular Cube 512x128 and Macular Cube 200x200 scans. The doctor can use these normative databases to compare individual patient measurements to those acquired in a normal population.

(E) Study: Retinal Segmentation Algorithms in Cirrus HD-OCT

Introduction

Carl Zeiss Meditec partnered with respected members of the academic and clinical community to study the accuracy and precision of the Cirrus retinal segmentation algorithm, and to evaluate the agreement between Cirrus HD-OCT and Stratus OCT, which is the standard of care for diagnosing and managing retinal diseases. The Retinal Segmentation Study Group consisted of faculty, fellows, and physicians at:

- Medical University of Vienna (MUV)
- Bascom Palmer Eye Institute (BPEI), University of Miami Miller School of Medicine
- Wilmer Eye Institute (WEI) - Johns Hopkins University School of Medicine
- Northern California Retina-Vitreous Associates (NCRVA)

Preliminary results have been reported at conferences (see references 1-3), and are summarized in this report. Final results are being submitted for publication.

Purpose

The primary purpose of the "Spectral Domain OCT (SD-OCT) Evaluation Study of Retinal Segmentation and Analysis" was to 1) evaluate the accuracy and precision of the Cirrus HD-OCT retinal thickness segmentation algorithms, and 2) to evaluate the agreement between the resulting measurements and similar measurements made on Stratus OCT. A secondary objective of the study was to evaluate the effectiveness of data registration on repeatability.

Methods

Data Collection

This was a prospective, non-randomized, multicenter study. Subjects 18 years of age or older, who were willing and able to give consent, and follow study instructions were recruited from the clinics of four study sites (WEI, BPEI, MUV, NCRVA) from March 2007 to October 2007, following an informed consent process including signing of a written consent form approved by the respective clinic's Institutional Review Board.

Both eyes of the subjects where scanned, with one eye being chosen as the study eye based on eligibility guidelines. When both eyes were eligible, the Principal Investigator arbitrarily assigned one eye as the study eye. Subjects were classified into six groups based on the primary diagnosis causing the most pathologic abnormalities in the study eye as follows:

Group 1 - age-related macular degeneration (AMD),

Group 2 - diabetic retinopathy (DR),

Group 3 - vitreoretinal interface abnormalities (including macular holes),

Group 4 - other retinal pathology,

Group 5 - macular edema for which treatment was planned,

Group 6 - no retinal pathology.

Any subjects with a primary diagnosis that placed them within Groups 1 through 4, for whom treatment of macular edema was scheduled, were categorized into Group 5.

Two (2) 200 x 200 scans and two (2) 512 x 128 scans of the study and fellow eyes were acquired using the Cirrus HD-OCT instrument during a single visit. Retinal thickness in every subfield (based on the ETDRS 6 mm grid centered on the fovea; see Chapter 4 of the User Manual) was calculated using Cirrus 3.0 software for each of the scans. The scans were reviewed to identify scans with poor image quality due to poor signal strength, poor scan placement within the axial field of view of the instrument resulting in missing data, and shifts in location between scans prior to analyzing the repeatability or reproducibility data. Scans with more than 10% missing data or data missing from the center, very large shifts (greater than 3 mm), and very poor image quality were excluded from the analysis as these factors would preclude accurate assessments of repeatability between scans.

Each subject also underwent a Stratus Fast Macula scan of the study eye.

Data Analysis

Accuracy was assessed by having 14 trained clinicians perform hand segmentations of selected B-scans from a single scan of each type from each subject. Layers segmented by Cirrus HD-OCT were compared to the hand-segmentations.

Agreement of the Cirrus HD-OCT analysis with Stratus OCT was assessed by comparing the average retinal thickness in nine retinal subfields.

Repeatability of the average measurements for each of the nine subfields was assessed using analysis of variance. Repeatability was assessed with and without the use of an algorithm that registers a repeated scan to a prior scan, and with and without aligning the subfields to the subject's fovea for each scan. Both of these capabilities were introduced with the version 4.0 software.

Results and Discussion

Accuracy

The Cirrus HD-OCT internal limiting membrane (ILM) and retinal pigment epithelium (RPE) segmentations were scored as accurate if software-segmentations and hand-segmentations agreed, for 100% of A-scans that were evaluated, where agreement was defined as being within 16 µm for the central 1 mm of the scan and within 32 µm elsewhere in the scan. The accuracy of segmentations was found to depend on layer (RPE or ILM) and disease category, and is summarized below in Tables 1 and 2.

Table 1: Accuracy of segmentations for RPE layer by pathology category

Category	200x200		512x218	
	n/N (%)	95% CI	n/N (%)	95% CI
AMD	60/70 (85.7%)	(77.5%, 91.3%)	62/72 (86.1%)	(78.1%, 98.5%)
Diabetic Retinopathy	40/42 (95.2%)	(86.6%, 98.4%)	41/42 (97.6%)	(90.0%, 99.5%)
VRI Disorder	27/28 (96.4%)	(85.5%, 99.2%)	25/28 (89.3%)	(76.0%, 95.5%)
Other Retinal Disease	44/51 (86.3%)	(76.5%, 92.4%)	46/52 (88.5%)	(79.2%, 93.9%)
Macular Edema	27/28 (96.4%)	(85.5%, 99.2%)	27/29 (93.1%)	(82.2%, 97.7%)
No Retinal Disease	37/37 (100.0%)	(93.2%, 100%)	40/40 (100.0%)	(93.7%, 100%)

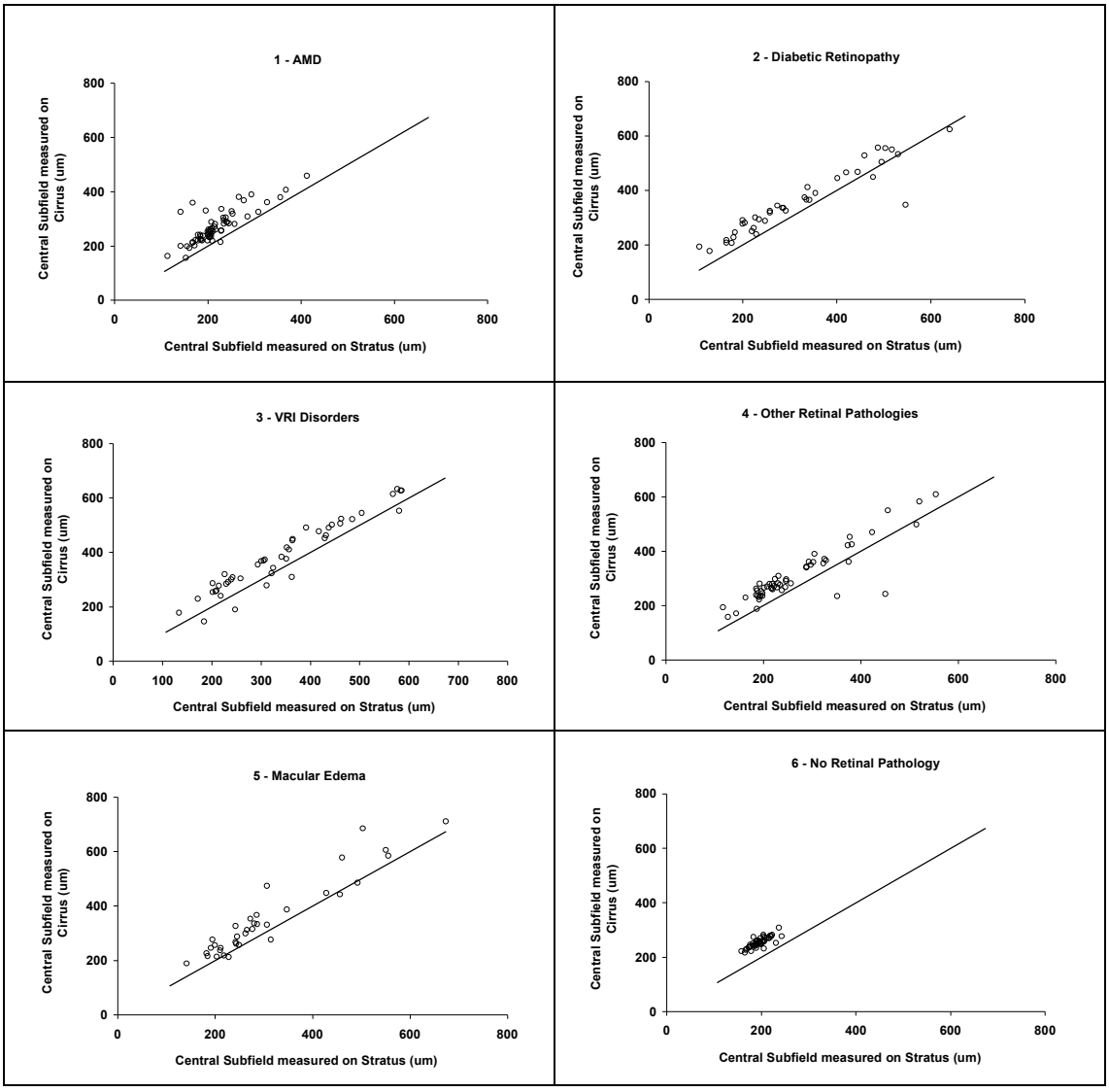
Table 2: Accuracy of segmentations for ILM layer by pathology category

Category	200x200		512x218	
	n/N (%)	95% CI	n/N (%)	95% CI
AMD	68/70 (97.1%)	(91.7%, 99.1%)	73/74 (98.6%)	(94.2%, 99.7%)
Diabetic Retinopathy	40/42 (95.2%)	(86.6%, 98.4%)	40/42 (95.2%)	(86.6%, 98.4%)
VRI Disorder	26/28 (92.9%)	(80.6%, 97.6%)	26/27 (96.3%)	(85.0%, 99.2%)
Other Retinal Disease	50/51 (98.0%)	(91.7%, 99.6%)	51/52 (98.1%)	(91.8%, 99.6%)
Macular Edema	28/28 (100.0%)	(91.2%, 100%)	28/29 (96.6%)	(85.9%, 99.2%)
No Retinal Disease	37/37 (100.0%)	(93.2%, 100%)	40/40 (100.0%)	(93.7%, 100%)

Agreement with Stratus OCT

Both Cirrus HD-OCT and Stratus OCT provide estimates of the retinal thickness, and there is good correlation between them, as can be seen in Table 3.

Table 3: Comparison of Cirrus HD-OCT Central Subfield Mean Thickness to Stratus OCT for the six categories.



By design, the segmentation algorithms in Cirrus HD-OCT search for different boundaries than those in Stratus OCT. Specifically, Stratus OCT locates the top of the bright reflective layer that is now known to represent the junction between inner and outer segments of the photoreceptors as the lower boundary of the retina for its thickness calculations; whereas Cirrus locates the brightest layer in the RPE / outer segment complex, which is thought to correspond to the RPE. Figure E-1 shows an example of the layers identified for a normal eye by Stratus OCT, while Figure E-2 shows the same eye scanned and segmented on Cirrus HD-OCT. Although the retinal tissue has the same vertical extent (thickness) in both

images, the identification of layers is different, so the Cirrus HD-OCT is expected to provide a thicker measurement than the Stratus OCT.

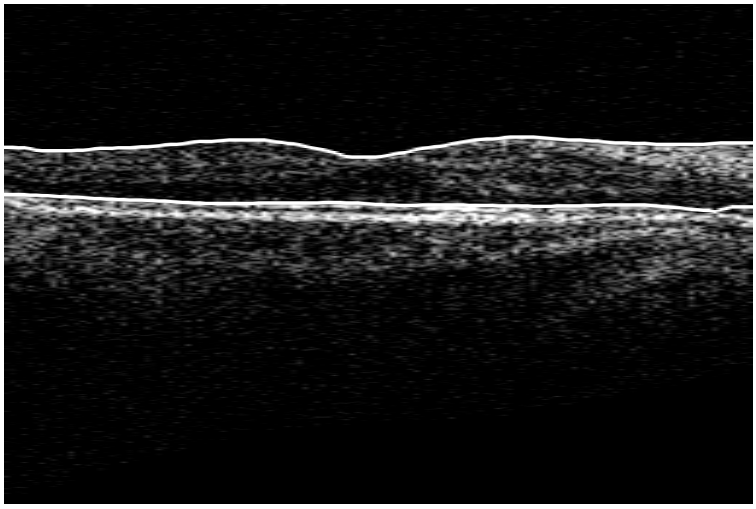


Figure E-1 Stratus OCT B-scan showing locations of RPE and ILM layers

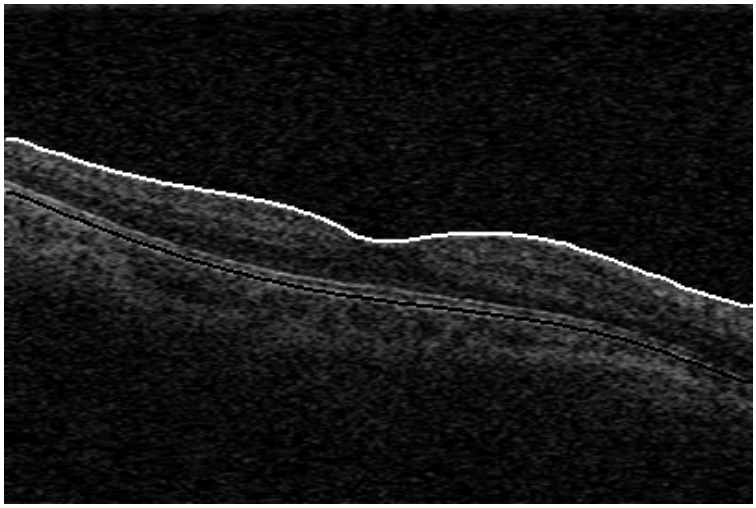


Figure E-2 Cirrus HD-OCT B-scan showing locations of RPE and ILM layers

Because of this difference in segmentation strategy, there is a mean difference in the retinal thickness found by each instrument. Furthermore, because the integrity of the layers sought varies with pathology, the mean difference between instruments varies with pathology, as can be seen in Table 4. Even after the mean difference has been accounted for, there is a residual difference that can be seen in the standard deviation of the difference reported in the last column of Table 4. Because of the residual difference, it is better to compare scans between Stratus OCT and Cirrus HD-OCT qualitatively, looking for changes in retinal morphology, rather than making decisions based on quantitative evaluation.

Table 4: Difference between Cirrus HD-OCT and Stratus OCT for the Central Subfield Mean Thickness for each of the six categories.

	Mean (SD) Difference Cirrus – Stratus (μm)			
	N	Cirrus	Stratus	Difference
1 - AMD	63	271.3 (60.6)	217.7 (54.2)	53.6 (35.0)
2 - DR	39	356.6 (118.7)	316.6 (135.8)	40.0 (47.1)
3 - VRI	45	386.3 (128.0)	342.5 (125.0)	43.8 (35.9)
4 - Other	53	310.6 (99.5)	268.9 (101.6)	41.7 (47.1)
5 - ME	35	351.1 (140.3)	305.7 (127.9)	45.5 (45.3)
6 - Normal	48	256.1 (18.6)	196.7 (18.6)	59.4 (11.7)

Repeatability

The repeatability of Cirrus HD-OCT retinal thickness measurements varies with pathology.

Table 5 shows the repeatability standard deviation for each disease category for the central subfield average thickness. This is the expected standard deviation between two scans acquired and analyzed using Cirrus 3.0.

Repeatability can be improved by ensuring that two scans are registered to each other, as when the Macular Change Analysis is used. Repeatability can also be improved using the Macular Thickness Analysis in Cirrus 4.0 when the fovea is correctly identified and used as the reference point for subfield average thickness calculations. These repeatability improvements are shown in Table 6. It is important to note that the algorithm to find the fovea may fail in certain disease cases, as is shown in Table 7. The user should always review the location of the fovea, and adjust it as necessary (see Chapter 4 of the User Manual for instructions on how to do this).

Repeatability when registration and fovea placement are performed is better than 9 μm for all pathologies, which implies a coefficient of variability (repeatability standard deviation divided by mean thickness) of 3.3% or better. Coefficient of variability is better than 1% for normals.

Table 5: Repeatability Standard Deviation[a] in micrometers for central subfield measurements using Cirrus 3.0 for the 200x200 scan and for the 512x128 scan

	CSMT Repeatability Standard Deviation (μm)			
	N	200x200	N	512x128
AMD	77	17.5	66	11.6
DR	51	16.8	50	13.7
VRI	44	14.4	44	8.4
Other	62	10.1	61	9.5
ME	41	13.5	39	27.2
No disease	44	4.8	47	3.6

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. For this study, two scans were acquired per subject during a single visit on a single system by a single operator at one of four sites. ISO 5725-1 and ISO 5725-6, Repeatability limit = 2.8 · Repeatability SD.

Table 6: Repeatability Standard Deviation[a] in micrometers for central subfield measurements on the 200x200 scan using Cirrus 3.0 Macular Thickness Analysis (MTA), Cirrus 4.0 MTA with the ability to adjust the fovea position, and Cirrus 4.0 Macular Change Analysis, which uses registration and fovea placement.

	N	Mean ±SD CSMT (µm) for Cirrus 4.0 MTA	CSMT Repeatability Standard Deviation (µm)		
			Cirrus 3.0 MTA	Cirrus 4.0 MTA with fovea placement	Cirrus 4.0 MCA with registration and fovea placement
AMD	77	255 ±65	17.5	6.3	8.7
DR	51	335 ±109	16.8	9.8	8.1
VRI	44	360 ±128	14.4	5.4	4.3
Other	62	303 ±114	10.1	7.5	4.5
ME	41	339 ±141	13.5	7.9	7.0
No disease	44	256 ±21	4.8	2.2	2.5

a. Repeatability Limit is the upper 95% limit for the difference between repeated results. For this study, two scans were acquired per subject during a single visit on a single system by a single operator at one of four sites. ISO 5725-1 and ISO 5725-6, Repeatability limit = 2.8 · Repeatability SD.

Table 7: Rate of failure of the fovea finding algorithm by disease category

	N	Percent of scans with fovea failures	
		Fovea not found	Fovea not correct
AMD	77	11%	6%
DR	51	19%	10%
VRI	44	24%	5%
Other	62	10%	6%
ME	41	18%	6%
No disease	44	0%	0%

Conclusion

Cirrus HD-OCT retinal thickness measurements are accurate and repeatable. Better than 85% of all scans are correctly segmented, even in the presence of pathology. Features introduced with Cirrus 4.0 software improve repeatability standard deviation to 2.5 µm in normals and to better than 9 µm for subjects with a variety of pathologies.

References

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(2) M. Chang, M. Durbin, M. Weiland, U. Schmidt-Erfurth, G. Gregori, N. Bressler, "Repeatability of retinal thickness measurements using Cirrus HD-OCT Spectral Domain Technology," ARVO 2008, poster 4253

(3) W. Geitzenauer, C. Kiss, M. Durbin, T. Abunto, M. Wieland, N. Bressler, G. Gregori, U. Schmidt-Erfurth, "Comparing Retinal Thickness Measurements From Cirrus Spectral-Domain and Stratus Time-Domain OCT," ARVO 2008, poster 930

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PN 2660021135611 A
Cirrus HD-OCT 4.0 User Manual