GDxPRO

■ Scanning Laser Polarimeter

User Manual

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Trademarks

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Document Applicability

This document applies to GDxPRO System Software Version 1.0 or higher, unless superseded.

Contents

(1) Introduction

Chapter Overview

Topics covered in this chapter include:

Introduction to the GDxPRO

The GDxPRO™ employs patented GDx™ Scanning Laser Polarimetry (SLP) technology to provide quantitative information about the retinal nerve fiber layer (RNFL). This information can be used in two levels of analysis—Symmetry Analysis for comparing the right and left eye to each other and to normative data, and Guided Progression Analysis for comparing the eye to itself over time.

Intended Use

The GDx is a confocal polarimetric scanning laser ophthalmoscope that is intended for imaging and three-dimensional analysis of the fundus and retinal nerve fiber layer (RNFL) in vivo.

Indications for Use

The GDx is a confocal polarimetric scanning laser ophthalmoscope that is intended for imaging and three-dimensional analysis of the fundus and retinal nerve fiber layer (RNFL) in vivo. The GDx and its GDx Variable Corneal Compensation (VCC) and GDx Enhanced Corneal Compensation (ECC) RNFL Normative Databases aid in the diagnosis and monitoring of diseases and disorders of the eye that may cause changes in the polarimetric

retinal nerve fiber layer thickness. The GDx is to be used in patients who may have an optic neuropathy.

> ☞ Note: The full range of device settings and anatomical measurement functions of this device has not been validated and the clinical utility of these measurements has not been fully characterized. This device is not intended to be used as the sole basis for the diagnosis of disease, as the device has not been evaluated clinically for the diagnosis of specific ocular pathologies.

Note:

The GDxPRO may not produce reliable results for patients in the following categories:

- Patients with corneal phase shift greater than 140 nm. The system will provide an error message when such a phase shift measurement is detected.
- Patients with dense cataracts. Patients with cataracts may have a dark fundus image and low Image Quality Score. However, the effect of lenticular opacification (cataract) on image quality has not been established.
- Patients who are unable to fixate on a target with the subject eye. These typically are patients with loss of central vision.
- Patients with refractive errors outside the following ranges: +8 D to -13 D.
- Patients less than 18 years of age; such patients can be imaged, but they are not supported by the normative databases

Carl Zeiss Meditec does not offer advice in the diagnostic interpretation of GDxPRO scans. It is the clinician's responsibility to make diagnostic interpretations of GDxPRO scans.

GDxPRO Technology

The GDxPRO employs patented GDx Scanning Laser Polarimetry (SLP) technology to provide quantitative information about the retinal nerve fiber layer (RNFL). A measuring beam passes through the RNFL until it is reflected back by the fundus. As it goes through the retina and RNFL, the beam is split into two components with a relative phase shift proportional to the RNFL thickness and structural organization of the RNFL microstructures (illustrated in Figure 1-1).
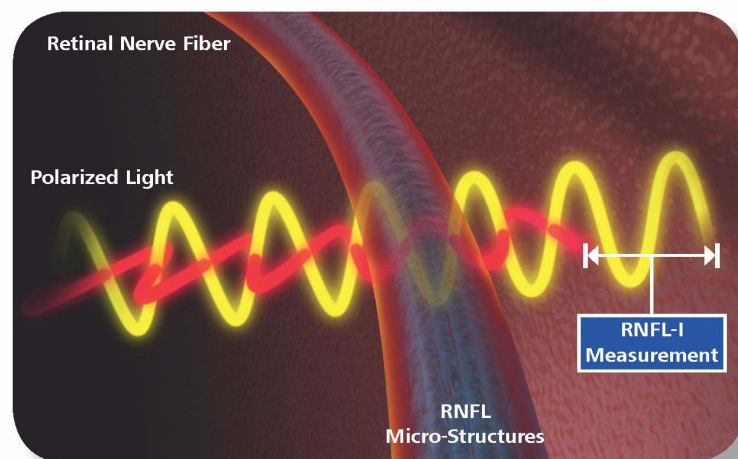
Figure 1-1 RNFL Assessment with SLP

To differentiate GDx RNFL Polarimetric Thickness™ measurements from RNFL thickness measurements from other devices, we introduce the term RNFL Integrity™ (RNFL-I™). As described in (G) Glossary the RNFL-I measurement is the phase shift that occurs when polarized light passes through the RNFL. A measurement capability unique to GDx, RNFL-I is derived from both RNFL thickness and RNFL structural organization.

This mechanism is distinctly different from other retinal imaging devices that quantify axonal loss by measuring RNFL thickness directly. Specifically, SLP captures birefringence, a tissue property that depends on the integrity of retinal ganglion cell axon microtubules and neurofilaments.[1–4]

SLP thus has the capacity not only to corroborate findings of RNFL thinning as determined by other methods, but may also provide insight into structural damage due to changes in density and orientation of the RNFL microstructures that may precede or occur in the absence of RNFL thinning.[5] A comparison of retinal imaging techniques can yield complementary information on RNFL abnormalities.[6]

☞ **Note: The output of previous generation GDx instruments was reported as "micrometers (µm)". This unit was renamed to polarimetric micrometers (P-µm) in the GDxPRO. "P-µm" reported in the GDxPRO is the same as "micrometers (µm)" reported in the GDxVCC.**

☞ **Note: RNFL-I, expressed as "P-µm", is distinct from thickness measured by other devices and expressed as "µm".**

Like the RNFL, the anterior segment (the cornea and lens) is also birefringent. However, the GDxPRO isolates anterior segment birefringence and compensates for it, so that only the RNFL is analyzed. There are two types of corneal compensation: Enhanced Corneal Compensation (ECC) and Variable Corneal Compensation (VCC). ECC is virtually always superior and is therefore the default; VCC is provided for continuity with historical scans

GDxPRO User Manual

Carl Zeiss Meditec designed this User Manual to serve as a detailed usage and reference guide for the GDxPRO instrument. The GDxPRO User Manual instructs you in the procedures for imaging the patient, creating and managing patient records, reviewing measurements, and creating reports. 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.

Organization of the Manual

This introductory chapter (1) provides a system description and safety information. Chapter (2) covers setup information and usage. Record management is discussed in chapter (3). Chapter (4) covers exam acquisition. Measurement management is discussed in chapter (5). Reports are covered in chapters (6) and (7). Other chapters cover System Functions, Data Transfer Using Optical Disks, Maintenance, Troubleshooting, Specifications and Legal Notices.

See (A) RNFL Normative Databases and NFI for ECC and VCC normative databases and NFI development, (B) Network Storage Device Configuration for NAS drive information, and (C) Printer Configuration for printer information. A Glossary and Index is included.

<u>Text Conventions</u>

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

<u>Selecting buttons</u>

Select buttons and text fields by using your fingers and touching the touch screen. You can also use your mouse over a button or text field and press (click) the left-mouse button. The **OK** button accepts the current screen and any data entered and moves to the next screen, if applicable. The **Cancel** button will cancel current activity on the current screen and return the display to the previous screen, if applicable.

Electronic User Manual Access

The GDxPRO User Manual in PDF format (version 8 or later) is provided electronically:

1. In the GDxPRO application, press the **F1** function key.
2. On the GDxPRO CD included in the instrument accessory kit. You can view the User Manual PDF using any computer.

☞ Note: Once the GDxPRO User Manual is opened, you can switch between the user manual and the GDxPRO application by pressing **Alt+Esc** or **Alt+Tab**.

System Hardware

With the exception of the keyboard, mouse, and printer, the GDxPRO System integrates all hardware components in a unit, which includes the image acquisition optics, the system computer and touch screen display. Carl Zeiss Meditec offers an optional motorized power table which accommodates elevation adjustment to each patient's height. The illustrations below label hardware elements. System specifications are in (H) Specifications.

Operator Console

Power button

Integrated Flat Panel
Touch Screen Display

Mouse

Keyboard
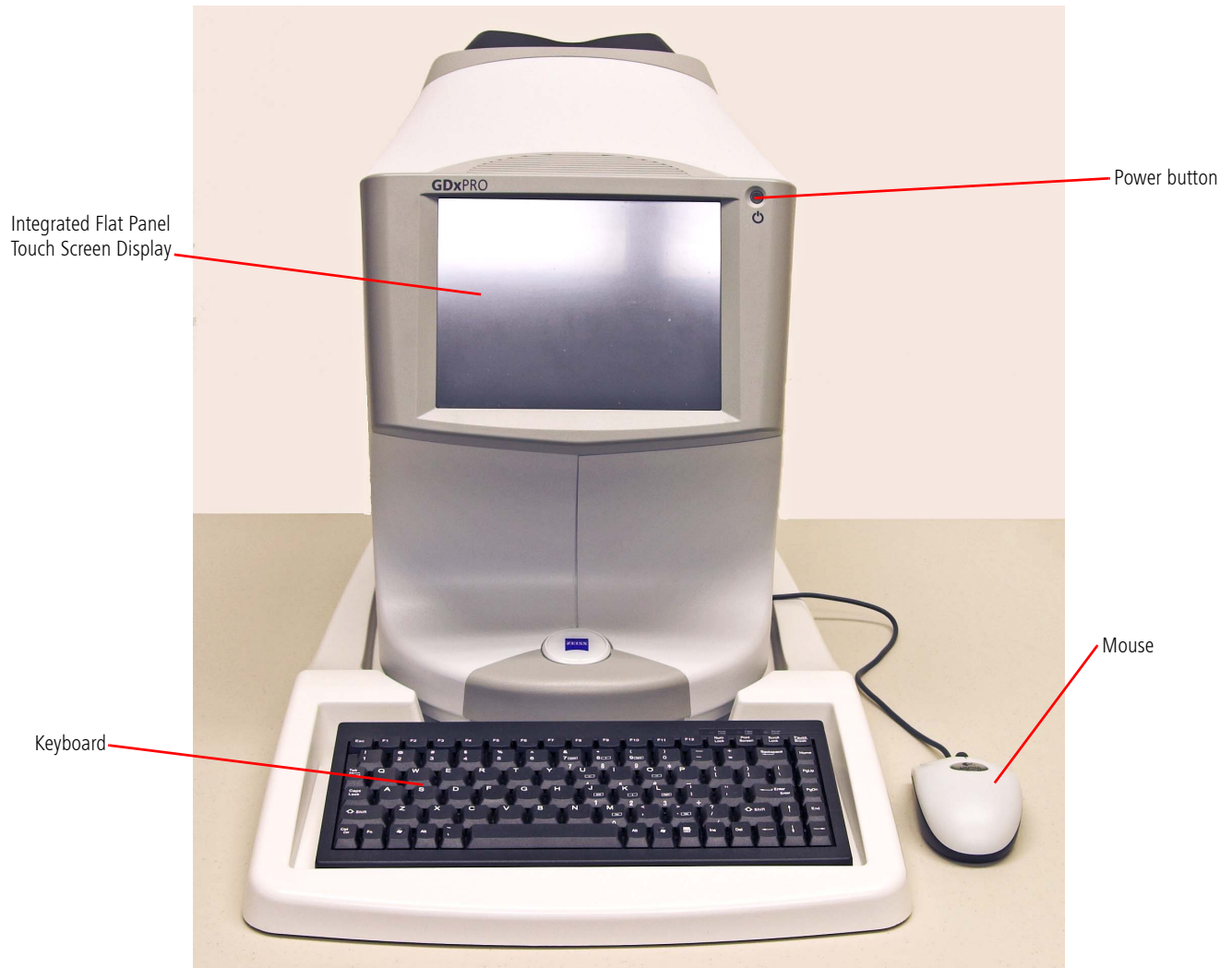
Figure 1-2 Operator Console

Touch Screen Operation

Operation of the GDxPRO literally is at your fingertips. You can perform all functions, whether entering data or selecting a test, simply by touching a button on the touch screen. An audible beep sounds whenever you touch the screen.

⚠ CAUTION: Do not use any sharp objects (ball point pens, etc.) to operate the touch screen. It can be easily scratched.

Patient Console

Patient face mask

Eye-level indicator
(canthus mark)

Patient lens
(Objective)

Figure 1-3 Patient Console Front

Patient
face mask

Optical and Hard Disk
drives access door

Optics Lockdown
screw hole

Figure 1-4 Right Side

Drive Access Door

The Drive Access door provides access to the optical and hard drives. See Removing Hard Disk Drives on page E-4 for information on accessing the drives.

Main Hard Disk Drive

Back-up Hard Disk Drive

Optical Drive

Figure 1-5 Drive Access Door Opened

Right Side Connectors

On the bottom right side of the GDxPRO are computer connectors as shown below.

Power Cord Connector   Power Switch   Fuse Holder   Ethernet Port   2 USB Ports
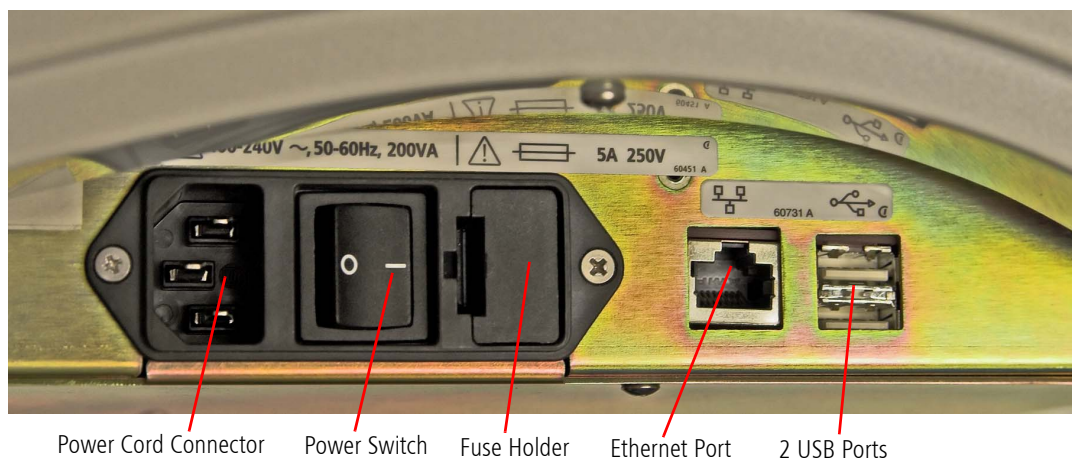
Figure 1-6 Bottom Right Side Connectors

Left Side Connectors

On the bottom left side of the GDxPRO are computer connectors as shown below.

Recessed USB Port   USB Port   DVI-I Port
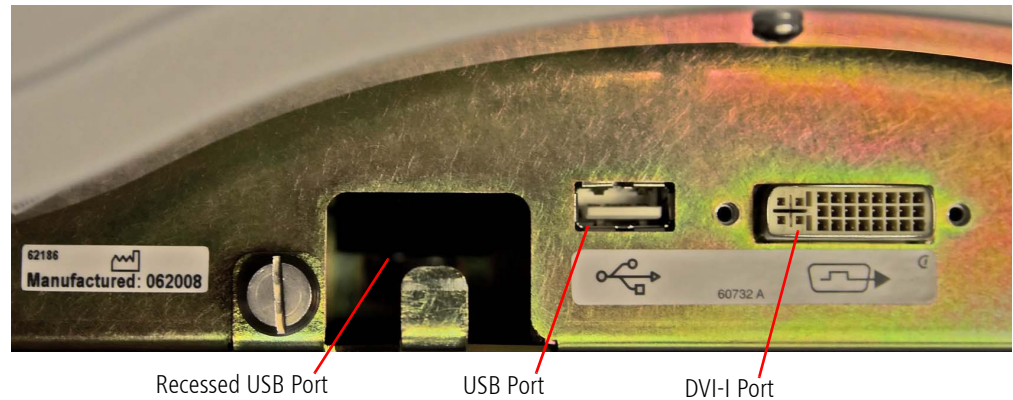
Figure 1-7 Bottom Left Side Connectors

Keyboard

The keyboard is used to type in patient information, such as names, birth dates, and examination remarks.

GDxPRO Instrument Software

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

Data Storage

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 (B) Network Storage Device Configuration. For non-networked environments, an external USB hard drive can be used.

External Device Equipment

WARNING: To maintain patient safety, an isolation transformer is required when connecting externally powered peripheral devices (i.e., printer, USB drive, etc.) within 1.5 meters (4.9 feet) from the patient. In addition, an isolation transformer is required for all externally powered peripheral devices outside this distance unless these devices are (1) connected to the GDxPRO using an Unshielded Twisted Pair (UTP) network cable (CZMI recommends using a least a CAT 5 UTP network cable), (2) plugged into a different power outlet than the GDxPRO, and (3) qualified by CZM for use with the GDx. Failure to observe this warning could result in electrical shock to the patient and/or examiner.

⚠ WARNING: To directly connect a printer to the GDxPRO only use a UTP network cable. Use of a shielded network cable will ground the printer through the GDxPRO, which could result in electrical shock to the patient and/or examiner. It could also invalidate the system safety approval.

⚠ 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.

External Monitor

You can connect an external monitor to the DVI-I Video port of the GDxPRO instrument (e.g., for presentations, larger monitor). The DVI-I video card supports analog and digital monitors with a resolution of 800 x 600 and 24-bit color (the GDxPRO touch screen is only 18-bit color). However, live eye video is unsupported for analog monitors.

USB Drives (Flash and Hard Drives)

Do not install any optional software.

NAS Drives

See (B) Network Storage Device Configuration for more information.

Printers

See (C) Printer Configuration for more information.

Isolation Transformer

Any isolation transformer used must be approved for medical use and must have a minimum rating that is sufficient for the device(s) being powered. CZM highly recommends contacting your CZM representative for an isolation transformer that has been formally qualified for the GDxPRO.

Note: Technical support is not provided for accessory devices that have not been qualified by CZM.

Instrument Installation

Only an authorized Carl Zeiss Meditec service representative should install the GDxPRO.

Care in Handling

Use extreme care when handling and transporting the GDxPRO shipping boxes.
The instrument contains fragile optics that have been precisely aligned at the factory.

Installation Requirements

- The GDxPRO should operate on a dedicated power outlet. Based on your specification, we configure your GDxPRO at the factory to use either 100V, 115V, or 230V line voltage.
- An isolation transformer is required when connecting peripheral devices (i.e., printer, USB drive, monitor, etc.) to the USB and DVI-I port that are plugged into electrical outlets.

Tips to Avoid Damage

Note: Users are not authorized to dismantle or modify the GDxPRO hardware.

- **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, nor use aerosols on or near it.
- In case of emergency related to the instrument, unplug the power cord from the wall outlet and call for service immediately.
- Do not attempt to open the protective housing of the GDxPRO for any reason. With the exception of the main power fuses and keyboard, there are no user-replaceable parts in the instrument. For the replacement of any component, accessory, or peripheral, except fuses or the keyboard, 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.
- This instrument operates according to specifications under standard indoor office (fluorescent) lighting conditions, without exposure to any direct sunlight.
- Use of controls, or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- Always clean the patient contact surfaces of the face mask with alcohol pads prior to each use.
- The GDxPRO weighs approximately 50 pounds (22.5 kg). To avoid injury, exercise proper lifting techniques when lifting or moving the GDxPRO.
- Allow the system to acclimate to room temperature before turning on the power.

- Be sure not to apply power to the GDxPRO until all connections are secure and the instructions specifically advise you to apply power. System lockup may occur and require a power down/power up sequence if all connections are not made as described in this manual.
- Remove the foam protector from in front of the objective lens and unlock the scan head before turning on the power (see Instrument Setup on page 2-1).
- Confirm that the objective lens is clean before imaging patients (see Routine Cleaning & Disinfecting on page E-12).
- Do not use any sharp objects (ball point pens, etc.) to operate the touch screen. It can be easily scratched.

WARNING: Do not insert a lens, mirror or other optically active device between the system and the patient (the patient may wear prescription contact lenses). Doing so may result in a higher than normal energy density in the eye that could injure the patient.

What to Do for the GDxPRO

Always handle the GDxPRO with care.

Always select a location for your GDxPRO that allows easy access for both patient and technician.

Always operate the GDxPRO from a power source as specified. This source should be a dedicated line. Use of a power source other than indicated on the unit will shorten the life of the unit and may cause damage in addition to improper operation.

Always operate the GDxPRO with the power cord inserted into a standard three-prong power outlet that is correctly grounded through normal wiring.

Always route electrical cables with safety as the first concern.

Always unplug the GDxPRO before moving the GDxPRO, opening the panels or inserting and replacing the removable hard drive.

Always let the GDxPRO reach room temperature before it is powered up. This is particularly important if the GDxPRO was exposed to temperature extremes.

Always operate the GDxPRO within the following working ranges of temperature and humidity:

- Ambient Temperature: 50º F – 95º F (10° C – 35° C)
- Ambient Humidity: 10% – 75%

Always unplug the GDxPRO before cleaning the plastic body panels or LCD screen. If the LCD or other body panels require more than a dusting, apply a mild household cleaner to a soft cloth to clean them.

Always clean the patient contact surfaces of the face mask with alcohol pads prior to each use.

Other Recommendations

- Use a UPS (Uninterrupted Power Supply) to protect data from power failures.
- Always place the lens cap over the patient lens when not in use.
- Use the CZM carrying case if transporting the GDxPRO (purchased separately).
- Wrap the GDxPRO in a plastic bag while the unit is in the carrying case to protect the optics from dust.

What Not to Do to the GDxPRO

Never lift the GDxPRO by the face mask.

Never transport the GDxPRO without locking down the optics head.

Never subject the GDxPRO to temperatures below 32° F (0° C) for more than 15 minutes. Prolonged exposure to freezing temperatures may require excessive time to warm up. System warm up will fail after 30 minutes.

Never position the GDxPRO in direct sunlight or near a direct source of heat.

Never position the GDxPRO in a dusty location.

Never install any software or utilities on this GDxPRO without prior approval from CZM. Any unauthorized modification to the system will void the warranty and any repair costs for damage to the GDxPRO may be billed to the customer.

Never remove any panels except the optical and hard disk drives access door from the GDxPRO.

Never clean with harsh chemicals or detergents.

Never use fluids or aerosol on or near the GDxPRO. These products can damage the GDxPRO surface and affect the delicate optics.

Never attempt to change any of the batteries in the system. Attempting to change a battery can cause damage and loss of data.

GDxPRO Embedded Windows License

Each GDxPRO instrument is issued with an embedded Windows® XP Pro operating system license located on the bottom of the instrument.

Product Compliance

Complies with 93/42/EEC Medical Device Directive.

Complies with US and Canadian medical electrical system safety requirements.

User Changes to Software or Hardware

The GDxPRO 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.

WARNING: Unauthorized modification of GDxPRO software or hardware (including peripherals) can jeopardize the safety of operators and patients, the performance of the instrument, and the integrity of patient data; it also voids the instrument warranty.

Approved Software (including Anti-Virus)

Please refer to the GDxPRO Home page (www.meditec.zeiss.com/GDxPRO) for a link to the current list of approved hardware and software.

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

WARNING: It is possible that GDxPRO functionality may be adversely affected by the presence, installation, or use of third party software on the same computer. The user, and not Carl Zeiss Meditec, assumes all risks associated with third party software.

Safety

Product Safety

This instrument complies with the following standards:

- 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 earthed ground 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. Opening the instrument covers could expose you to electrical and optical hazards.

WARNING: To maintain patient safety, an isolation transformer is required when connecting externally powered peripheral devices (i.e., printer, USB drive, etc.) within 1.5 meters (4.9 feet) from the patient. In addition, an isolation transformer is required for all externally powered peripheral devices outside this distance unless these devices are (1) connected to the GDxPRO using an Unshielded Twisted Pair (UTP) network cable (CZMI recommends using a least a CAT 5 UTP network cable), (2) plugged into a different power outlet than the GDxPRO, and (3) qualified by CZM for use with the GDx. Failure to observe this warning could result in electrical shock to the patient and/or examiner.

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.

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

Optical Safety

This instrument complies with the following standards and regulations:

- 21 CFR 1040.10
- 21 CFR 1040.11
- IEC 60825-1
- EN ISO 15004-2

This instrument is classified as follows:

- **Group 1 Instrument** – Per EN ISO 15004-2, Group 1 instruments are ophthalmic instruments for which no potential light hazard exists.
- **Class 1 Laser Product** – Complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to *Laser Notice No. 50*, dated June 24, 2007.

The GDxPRO is equipped with two different low-power laser devices:

- The **Imaging** laser – a laser diode, 785 nm wavelength, with 3 mW instantaneous power and < 1 mW average power at the cornea, that emits directionally variable radiation.
- The **Fixation** laser – a laser diode, 635 nm wavelength, with 0.5 mW instantaneous power and < 1 µW average power at the cornea.

The GDxPRO is equipped with electronic safety circuitry that constantly monitors the function of the scanning mirrors. In the case of a malfunction of any of the scanning mirrors, the laser beam is shut off automatically. The laser and its associated optics are enclosed in modules within the system's protective housing. There are no user-serviceable parts inside the protective housing. If the unit fails, contact CZM for instructions.

WARNING: Do not attempt to open the protective housing of the GDxPRO for any reason. Radiation inside the protective housing is hazardous (Class IIIb Laser) and could cause personal injury! No user maintenance is required, or allowed.

WARNING: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

WARNING: Do not use any additional mechanical or optical devices (lenses) in conjunction with use of the GDxPRO. Prescription contact lenses may be used.

Phototoxicity Statement

<u>FDA Opthalmoscope Guidance (Direct and Indirect) issued July 8, 1998</u>

Because prolonged intense light exposure can damage the retina, the use of the device for ocular examination should not be unnecessarily prolonged, and the brightness setting should not exceed what is needed to provide clear visualization of the target structures. This device should be used with filters that eliminate UV radiation (< 400 nm) and, whenever possible, filters that eliminate short-wavelength blue light (< 420 nm).

The retinal exposure dose for a photochemical hazard is a product of the radiance and the exposure time. If the value of radiance were reduced in half, twice the time would be needed to reach the maximum exposure limit.

While no acute optical radiation hazards have been identified for direct or indirect ophthalmoscopes, it is recommended that the intensity of light directed into the patient's eye be limited to the minimum level which is necessary for diagnosis. Infants, aphakes and persons with diseased eyes will be at greater risk. The risk may also be increased if the person being examined has had any exposure 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: The fundus illumination brightness of the GDxPRO is not adjustable. It is factory-set to a level that optimizes the exam efficacy and minimizes light exposure to the subject.

Note: The GDxPRO uses visible and infrared light to measure properties of the retinal nerve fiber layer and uses no ultraviolet light (< 400 nm). Ultraviolet protection by the use of filters or other optical apparatus is neither required or approved.

Electromagnetic Compatibility (EMC)

- EN 60601-1-2:2001

Note: The GDxPRO needs special precautions regarding EMC 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 GDxPRO should not be used adjacent to or stacked with other equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The GDxPRO is intended for use in the electromagnetic environment specified below. The customer or user of the GDxPRO should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The GDxPRO 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 B	The GDxPRO is suitable for use in all establishments, including 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	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity			
The GDxPRO is intended for use in the electromagnetic environment specified below. The customer or user of the GDxPRO 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 GDxPRO requires continued operation during power mains interruptions, it is recommended that the GDxPRO be powered from an uninterruptible source.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The GDxPRO is intended for use in the electromagnetic environment specified below. The customer or user of the GDxPRO should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the GDxPRO, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
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.			
[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 GDxPRO is used exceeds the applicable RF compliance level above, the GDxPRO should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the GDxPRO. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the GDxPRO			
The GDxPRO is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the GDxPRO can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the GDxPRO 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 $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 1.17 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.33 \sqrt{P}$
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.			

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

EC REP   Authorized European Community Representative

SN   Serial number

REF   Catalog number / part number

CE 0297   European Conformity

MODEL   Model

PATENT   Patent

Protective Packing Symbols

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

Handling Requirements
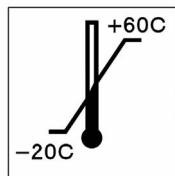
Fragile, Handle with Care

Keep Dry
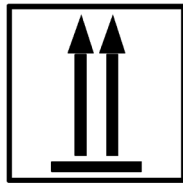
This end up

Transport and Storage Conditions
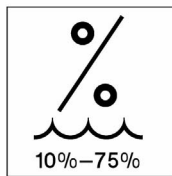
Relative Humidity (10% to 75%, non-condensing)

Temperature (-20 to +60 deg. C)

Atmospheric Pressure Limits (500 hPa to 1060 hPa)

Product Labels and Serial Number Location

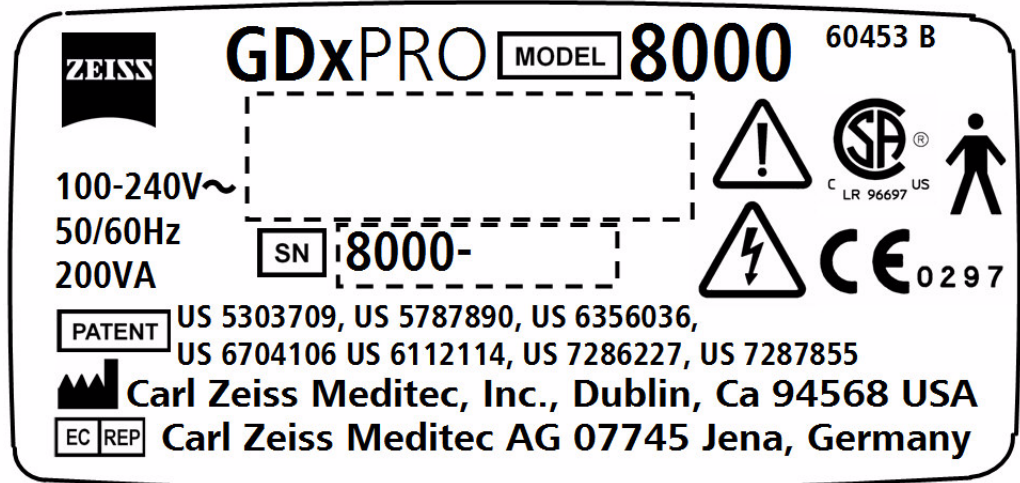On the lower left of the right side of the instrument is the product label and serial number:

Figure 1-8 Product Label on Exterior, Right Side

On the right side, a power and fuse label is above the power and fuse connectors:

Figure 1-9 Power and Fuse Label

A small Manufactured month and year label is on the bottom left side of the instrument:
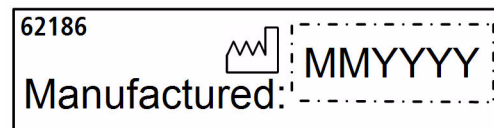

Figure 1-10 Manufactured Month and Year Label

A small laser classification label is on the bottom of the instrument.

Figure 1-11 Class 1 Laser Label

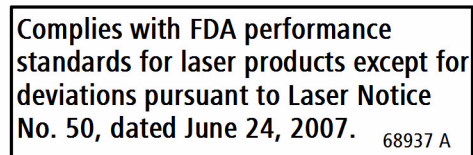A small FDA laser notice label is on the bottom of the instrument.

Complies with FDA performance standards for laser products except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007.   68937 A

Figure 1-12 Laser Notice No. 50 Label

Instrument Disposition

When it comes time to upgrade the GDxPRO, 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 electrical and electronic equipment recycling requirements.

References

1. Huang XR, Knighton RW. Microtubules contribute to the birefringence of the retinal nerve fiber layer. *Invest Ophthalmol Vis Sci*. 2005;46(12):4588-4593.
2. Fortune B, Wang L, Cull G, Cioffi GA. Intravitreal colchicine causes decreased RNFL birefringence without altering RNFL thickness. *Invest Ophthalmol Vis Sci*. 2008;49(1):255-261.
3. Dreher AW, Reiter K, and Weinreb RN. Spatially resolved birefringence of the retinal nerve-fiber layer assessed with a retinal laser ellipsometer. *Appl Opt*. 1992; 31: 3730-3735.
4. Huang X-R, Bagga H, Greenfield DS, and Knighton RW. Variation of peripapillary retinal nerve fiber layer birefringence in normal human subjects. *Invest Ophthalmol Vis Sci*. 2004; 45: 3073-3080.
5. Fortune B, Cull GA, and Burgoyne CF. Relative course of retinal nerve fiber layer (RNFL) birefringence, RNFL thickness and retinal function changes after optic nerve transaction. *Invest Ophthalmol Vis Sci*. 2008; 49: 4444-4452.
6. Zaveri MS, Conger A, Salter A, Frohman TC, et al. Retinal imaging by laser polarimetry and optical coherence tomography evidence of axonal degeneration in multiple sclerosis. *Arch Neurol*. 2008 Jul;65(7):924-8.

(2) Setup

Chapter Overview

This chapter explains how to set up and use the GDxPRO instrument.

Topics include:

Instrument Setup

The GDxPRO contains sensitive electronic, mechanical and optical components, as well as an internal computer. Handle it gently.

Note: The GDxPRO weighs approximately 50 pounds (22.5 kg). To avoid injury, exercise proper lifting techniques when lifting or moving the GDxPRO.

Note: Do not turn power on until all connections are made and all steps are completed.

1. Place the GDxPRO on a sturdy table, preferably one that is height adjustable.
2. Connect the keyboard and mouse to the USB ports on the bottom right side of the GDxPRO (Figure 1-6).
3. To export reports to a network server or PC, connect an Ethernet cable from the network server or PC to the network connector on the bottom right side of the GDxPRO (Figure 1-6).
4. (Optional) Connect an external color printer USB or Ethernet cable to the appropriate connector on the bottom left side of the GDxPRO (Figure 1-7). Plug the printer power cord into a power outlet. Be sure the ink cartridges and paper are installed per the manufacturer's directions. See (C) Printer Configuration.
5. Grasp the end of the plastic bag/foam objective lens shipping protector and pull it out and away from the face mask. Place the protector in a safe place for future transport. Remove the lens cap.
6. Unlock the GDxPRO optics box using the screwdriver and instructions provided in the accessory kit. See Unlocking the System on page 2-2.

Note: Be sure to remove the objective lens foam block protector and unlock the scan head optics before applying power to GDxPRO. System warm up and self tests will fail if the scan head optics are not unlocked with power applied.

7. Read and remove the Caution label from the LCD Display.

8. Connect the female end of the power cord into the power cord connector on the bottom right side of the GDxPRO (Figure 1-6). Plug the power cord male end into a power outlet.

Unlocking the System

If the **Shut Down For Transport** procedure (see Transporting on page E-9) was performed the last time the system was powered down, or if it is unknown, the procedure for unlocking the optics box should be performed as a precaution before powering up the system.

Insert the Phillips screwdriver, included in the GDxPRO accessory kit, into the optics lock down screw hole (the large hole) on the right side of the unit (Figure 2-1), engage the spring loaded screw and turn the screw counterclockwise to ensure that it is loosened and moves freely. This will ensure that the optics box is unlocked and it is safe to power up the system.

Figure 2-1 Unlocking the Optics Box

Powering Up the Instrument

Note: If the optics box is locked and the instrument is turned on, a message will be displayed to unlock it before you can power up.

Confirm that the system is unlocked (see Unlocking the System above). Make sure the power cord is plugged in. The power on/off switch is located on the underside of the unit by the power cord inlet. Power up the system by flipping the switch to the on position (**I = on, O = off**). If the power switch is already on, press the amber power button on the LCD to power up the instrument.

Note: It is recommended to leave the system running during daily use and to power down at the end of each day.

At power-up, GDxPRO will run a warm up test procedure. The test usually takes several minutes. If the unit is cold (e.g. if the unit was transported from another office), allow it to acclimate to normal room temperature before turning on the power. **It may take up to 30 minutes for GDxPRO to "warm-up" and pass the system test**. As the test is being performed, there will be a screen indicated that the test is in progress. If there are no errors, the system will start up normally. Once the GDxPRO MAIN screen is displayed, the system is ready for operation.

Powering Down the Instrument

Whenever the system will be left idle for more than 6-8 hours, it is recommended to turn off the power. To do so, first turn off the external printer, if connected, at the printer's power switch. You can safely power down the GDxPRO through hardware or software as described below.

CAUTION: You must power down the operating system safely. Not doing so may damage the hard drive causing it to boot into safe mode, display random errors, or cause the GDxPRO application to fail to launch. If the software or operating system is busy, you may have to wait for it to complete.

Hardware Power button on Operator Console

1. Press the green Power button on the Operator Console (Figure 1-2).
2. After the LCD turns off, the Power button changes color to amber.
3. Turn off the power by flipping the power switch on the bottom right of the instrument to the off position (**I = on, O = off**).

Software Log Off/Shutdown

1. To log off or shutdown through software select the **Log Off** button on the MAIN screen to close the application and log off the current user.
2. A dialog will be displayed to confirm your intention (Figure 2-2).
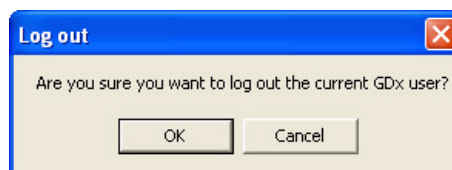

Figure 2-2 Log Out Dialog

3. Select **OK** to log out. A WINDOWS LOG IN screen will be displayed.

4. Select **Shut Down** and then **OK** to shut down Windows.

5. After the LCD turns off, the Power button on the Operator Console changes color to amber.

6. Turn off the power by flipping the power switch on the bottom right of the instrument to the off position (**I = on, O = off**).

<u>Shut Down for Transport</u>

The **Shut Down For Transport** button on the MAIN Screen moves the optics to the docked position. This enables the locking screw to be manually engaged and protects the optics from damage during transportation. See Transporting on page E-9 for more information.

Operating the Touch Screen

Operation of the GDxPRO literally is at your fingertips. You can perform all functions, whether entering data or selecting a test, simply by touching a button on the touch screen. An audible beep sounds whenever you touch the screen.

Note: While using the touch screen, the button is activated when your finger is removed from the button you select. Be careful not to pound or press too hard against the touch screen. A light touch works best.

CAUTION: Do not use any sharp objects (ball point pens, etc.) to operate the touch screen. It can be easily scratched.

Calibrating the Touch Screen

Note: Touch Screen calibration is the only calibration done by the user. All other GDxPRO calibration is done by Carl Zeiss Meditec.

To calibrate the Touch Screen, select **System > System Diagnostics > Calibrate Touch Screen** to display the first calibration screen (Figure 2-3).

Target

Touch the targets from a position of normal use.
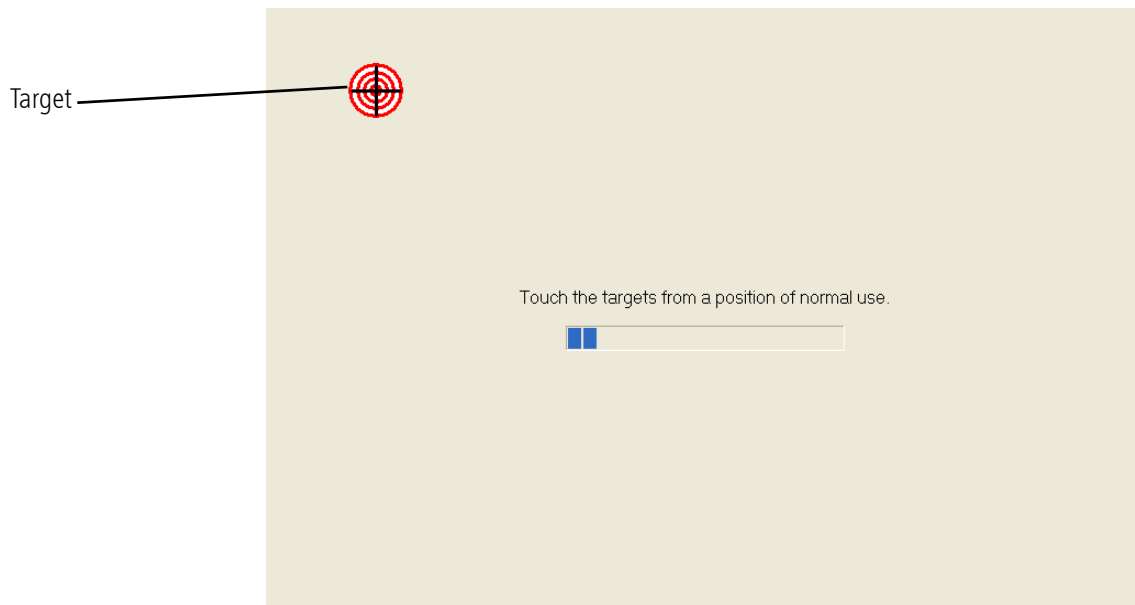
Figure 2-3 Calibrate Touch Screen 1

With your finger, touch the target in the upper left. Another target will be displayed on the lower right, and then the upper right for you to touch. After pressing these targets a screen will be displayed asking you to move your finger across the screen (Figure 2-4).
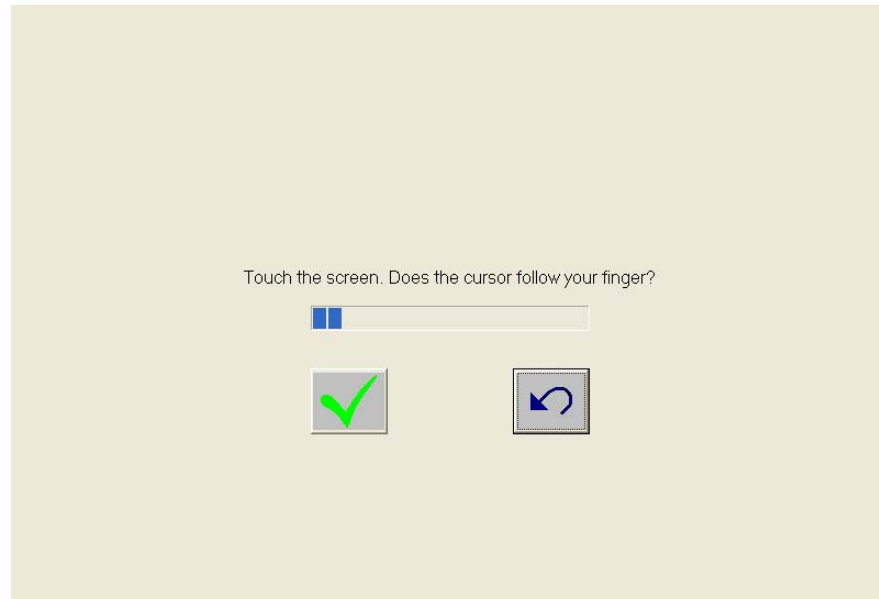

Figure 2-4 Calibrate Touch Screen 2

If the cursor follows your finger, press the green check button to complete the Touch Screen calibration.

Setting the Time and Date

At the MAIN screen, select **System** > **Set Time & Date** to display the Windows DATE AND TIME PROPERTIES screen. Update the fields as needed. When the correct time and date are displayed, press **OK** to close the screen.
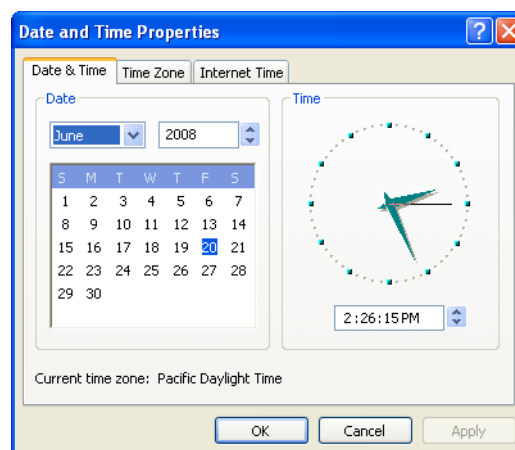
Figure 2-5 Windows Date and Time Properties Screen

Setting Up Operator/Doctor

To secure patient and exam data, only authorized operators which log into the GDxPRO system can access patient data. Users logged into the system not assigned to the GDxPRO as an operator will not have access to GDxPRO patient and exam data. An operator needs to be added for each Windows User Account that uses the GDxPRO.

Note: You must be logged into Windows with administrator privileges to create or modify an operator. If not logged in as an administrator, you will not see the **Set Up Operator** button on the Main screen. By default the GDxPRO will automatically be logged in as an administrator, with a User Name of **Zeiss** and password of **November171846**.

Note: If you have more than one Windows User Account, do not use "Fast User Switching" (an option of the Windows operating system) to switch between User Accounts while GDxPRO application is active.

When the GDxPRO is first started while logged in as an administrator, a default operator will automatically be created from your logged in administrator account.

The GDxPRO database contains operators, doctors, patients, and exams (measurements or images). Only an operator will be able to view exams and access patient records for those patients that are assigned to a doctor associated with the operator. Operators can be associated with one or more doctors.

Doctors associated with patients defined on the PATIENT INFORMATION screen are called *Primary or Referring Doctors* (see Patient Information Screen on page 3-8). Doctors associated with exams at exam acquisition time or mean creation are called *Exam or Attending Doctors* (see Figure 4-28) and are displayed on the MEASUREMENT LIST SCREEN (Figure 5-1).

To create an operator, select the **Set Up Operator** button on the MAIN screen. The SET UP OPERATOR screen (Figure 2-6) is displayed:
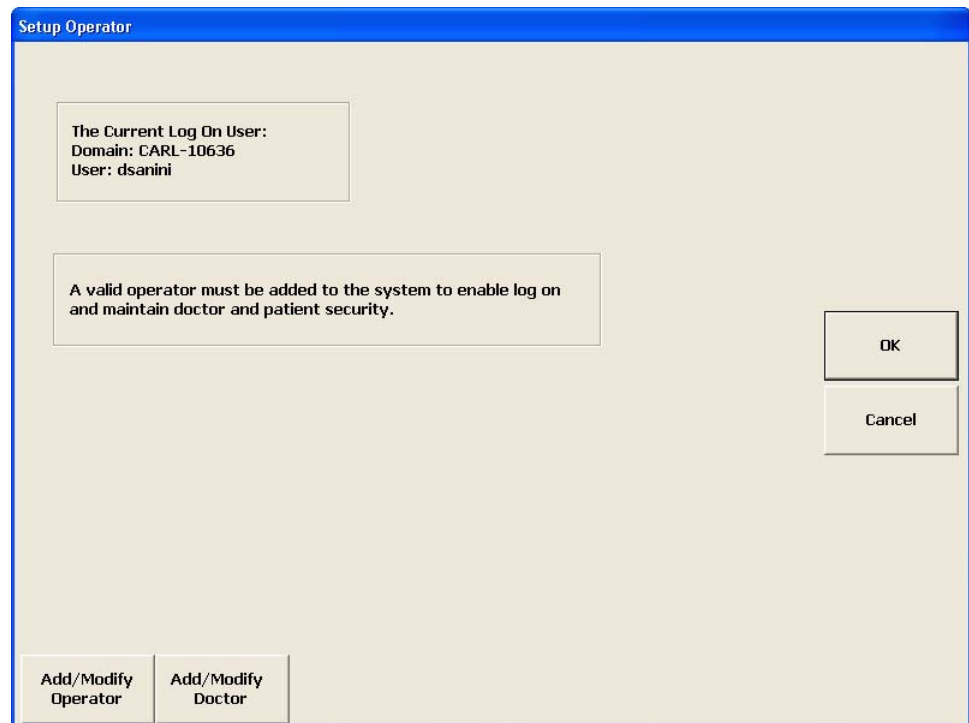
Figure 2-6 Set Up Operator Screen

Adding/Modifying Operator

To add or modify an operator, select the **Add/Modify Operator** button from the Set Up Operator screen (Figure 2-6) to display the Operator List screen (Figure 2-7).
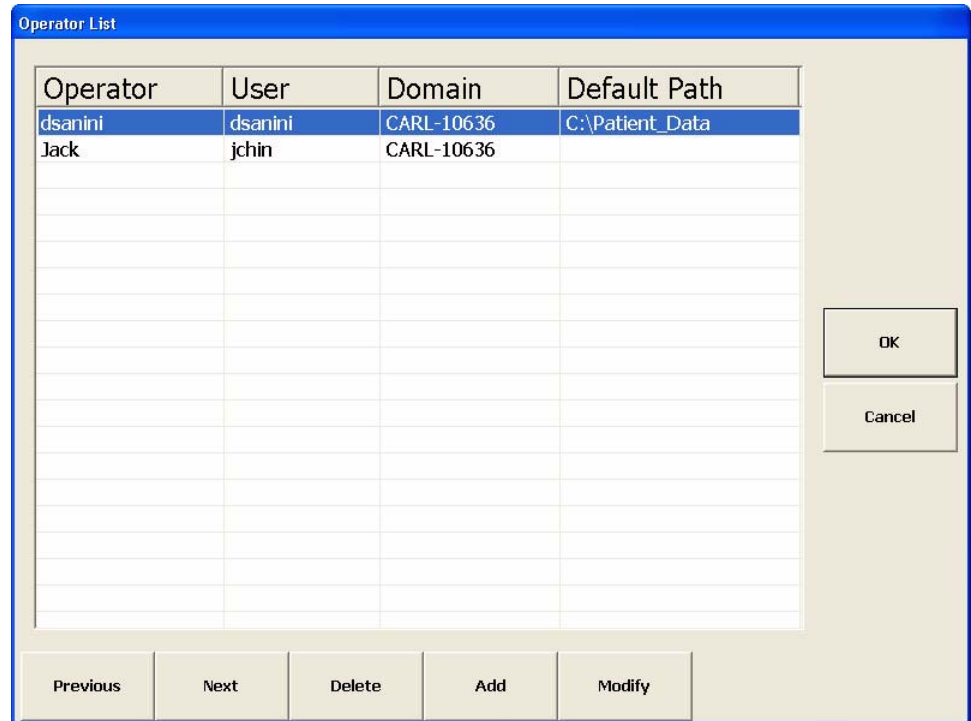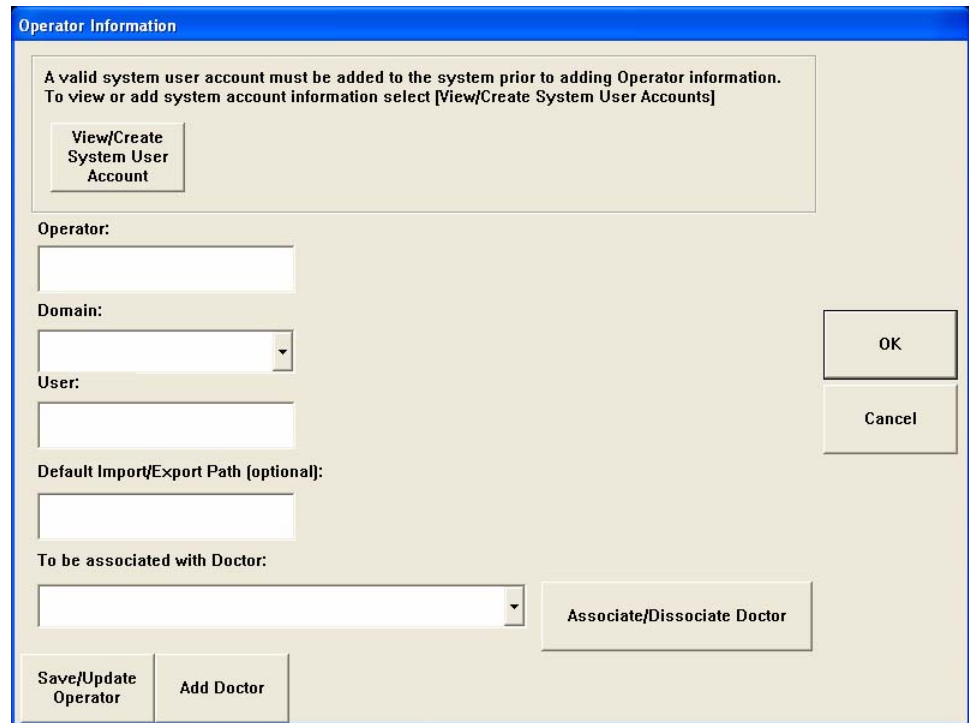

Figure 2-7 Operator List Screen

Use the mouse to select an operator (blue background), or select the **Previous** and **Next** buttons to move through the list until you select the operator of interest. You may also use the up and down arrow keys on the keyboard.

To modify an operator, select an operator and then select the **Modify** button. To delete an operator, select an operator and then select the **Delete** button.

To add a new operator, select the **Add** button to display the OPERATOR INFORMATION screen (Figure 2-8).

Figure 2-8 Operator Information Screen

A valid Windows User Account is needed to create an operator. Select **View/Create System User Account** to view or create a Windows user account. A Windows USER ACCOUNTS screen will be displayed (Figure 2-9).
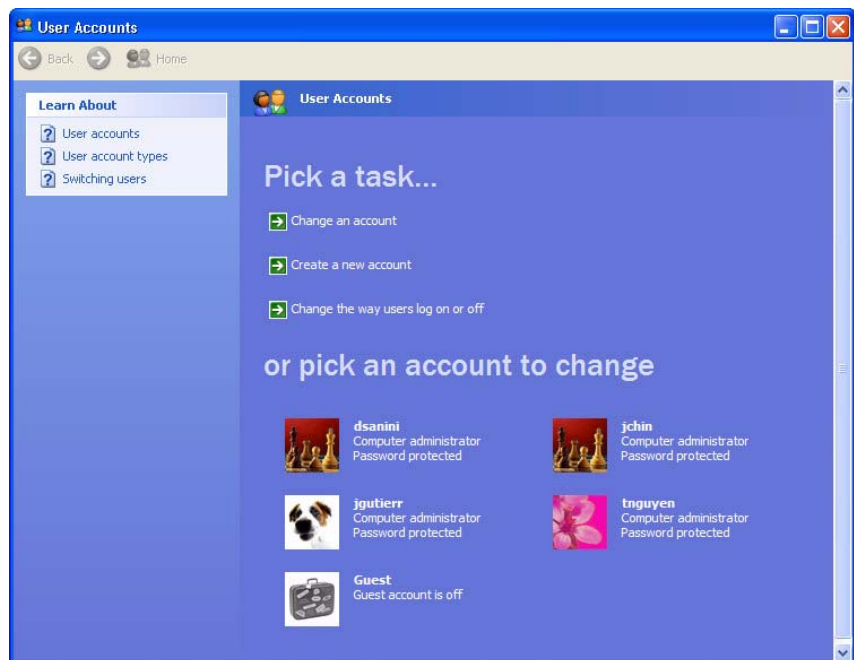
Figure 2-9 User Accounts Screen

Enter the following fields as described below:
- **Operator** – Enter a name for the operator (this can be any name).
- **Domain** – Enter the computer or domain name, or select a domain from the drop-down menu.
- **User** – Enter a valid Windows User Account name from this GDxPRO.
- **Default Import/Export Path (optional)** – Enter the default path to a folder you want to import from and/or export to for this GDxPRO. This folder is also used for the auto export functions at the end of exam acquisition (see Setting the Preview/Export Image Type on page 2-16).

☞ Note: Only one operator can have the same Domain and User name.

☞ Note: Each operator may have a different network default destination for exported/imported data. The currently selected operator determines the default network destination that will be used if you perform an import or export operation. See the Set Up Operator Screen on page 2-7 for the current operator.

☞ Note: We strongly recommend that operators routinely log out to secure the instrument and protect patient data privacy.

Associating/Dissociating Doctor

☞ Note: After importing data from a GDx instrument, all imported doctors will be automatically associated with the current operator.

In the **To be associated with Doctor** field, select a doctor (or **All Doctors** to assign all doctors from the GDxPRO database) from the drop-down menu, and then select the **Associate/Dissociate Doctor** button to display the **Create Association** dialog (Figure 2-10).
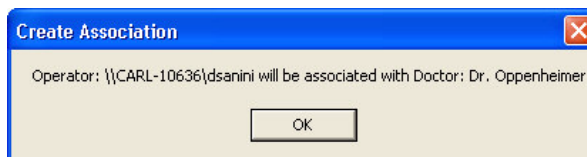

Figure 2-10 Create Association Screen

Select **OK** to associate the doctor(s) with the operator. The OPERATOR INFORMATION screen will be updated to reflect the association—the doctor(s) will be displayed in the

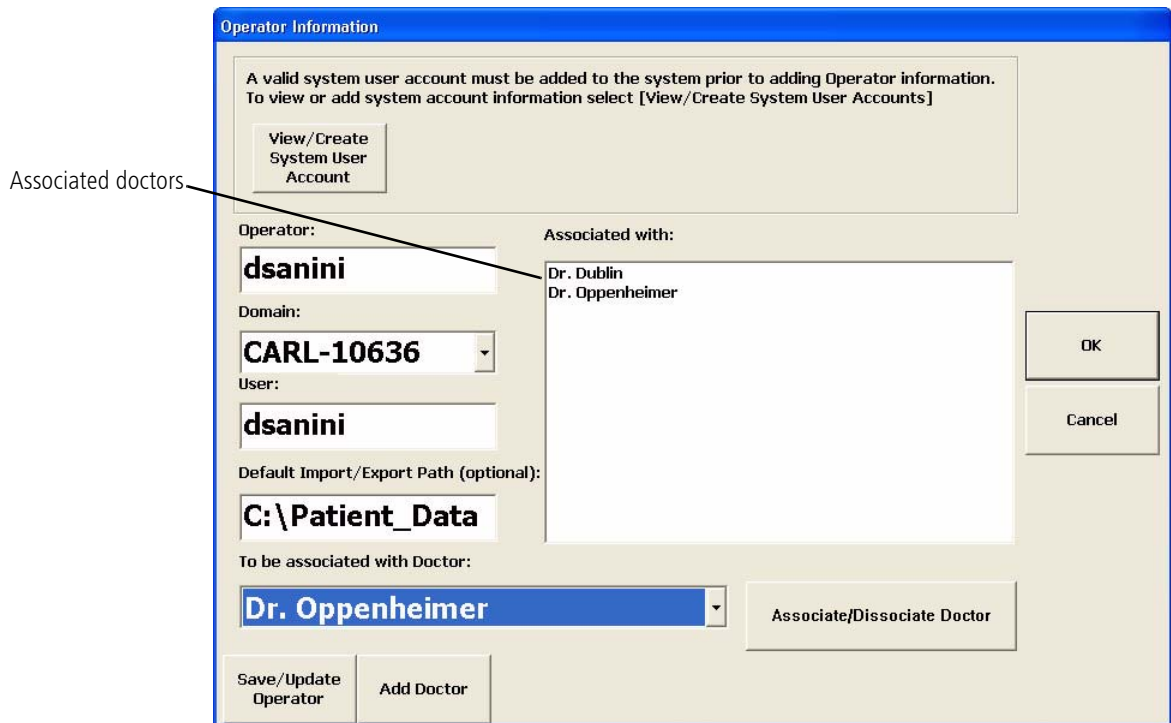Associated with field as shown in the following OPERATOR INFORMATION screen (Figure 2-11).

Associated doctors

Figure 2-11 Operator Information Screen with Associated Doctor

If you need to add a new doctor, select the **Add Doctor** button to display the DOCTOR INFORMATION screen (Figure 2-18).

To dissociate a doctor from an operator, select the doctor from the **To be associated with Doctor** drop-down menu, and then select the **Associate/Dissociate Doctor** button to display the DELETE ASSOCIATION screen (Figure 2-12).
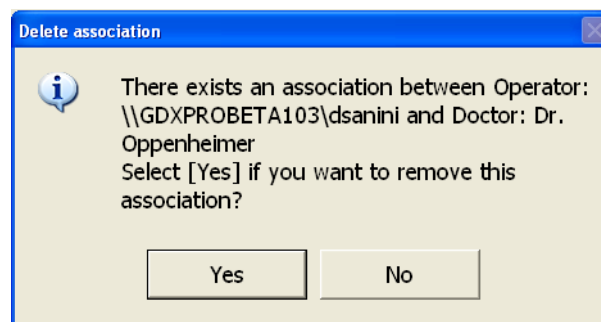
Figure 2-12 Delete Association Screen

Select **Yes** to delete the association between the operator and doctor. The OPERATOR INFORMATION screen will be updated to reflect the dissociation—the doctor will be removed from the **Associated with** field. Select **No** if you do not want to delete the association.

Select the **Save/Update Operator** or **OK** button to save the operator information you have entered.

Adding/Modifying Doctor

To add, modify, or delete a doctor select the **Add/Modify Doctor** button from the SET UP OPERATOR Screen (Figure 2-6) to display the DOCTOR LIST screen (Figure 2-13).
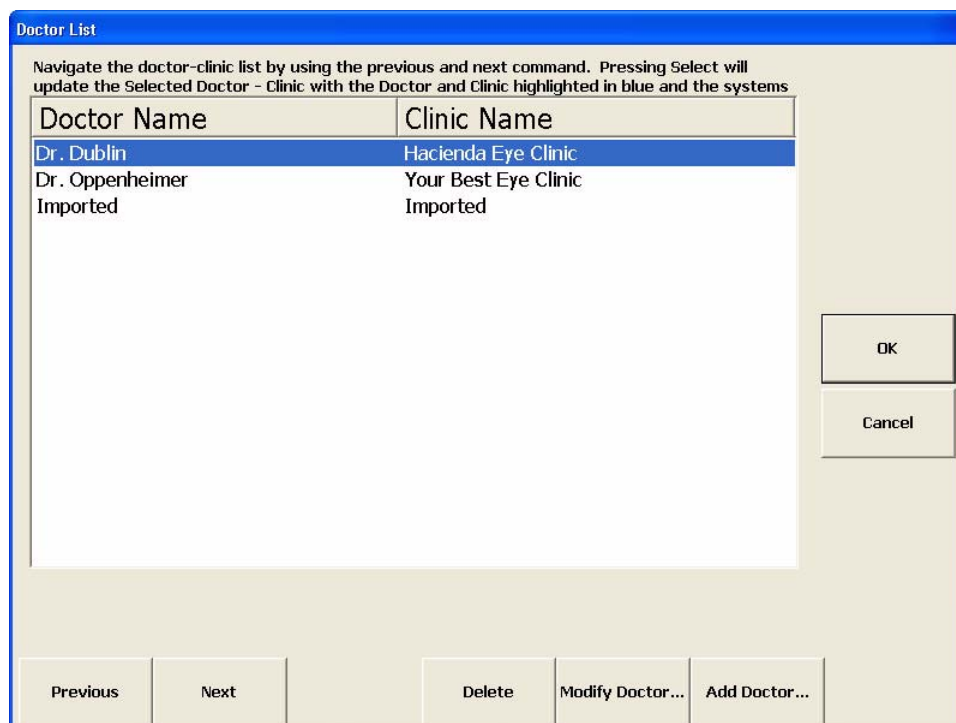

Figure 2-13 Doctor List Screen

Use the mouse to select a doctor (blue background), or select the **Previous** and **Next** buttons to move through the list until you select the doctor of interest. You may also use the up and down arrow keys on the keyboard.

To modify a doctor, select a doctor and then select the **Modify Doctor** button to display the DOCTOR INFORMATION screen (Figure 2-14).

Figure 2-14 Doctor Information Screen

To delete a doctor, from the DOCTOR LIST screen (Figure 2-13) select a doctor and then select the **Delete** button. If the doctor is not associated with any patients a CONFIRM DELETE dialog will be displayed (Figure 2-15).

Figure 2-15 Doctor Confirm Delete Screen

Select **OK** to delete the doctor. Select **Cancel** to cancel the deletion.

If a doctor is currently associated with at least one patient, you cannot delete the doctor if you do not assign the doctor's patients to another doctor. In this case, you will be given the option to assign the patient(s) to another doctor (Figure 2-16).

Figure 2-16 Assign Patients to Another Doctor Screen

Select **Yes** to assign all the doctor's patients to another doctor and display the SELECT DOCTOR screen (Figure 2-17). If you select **No**, the doctor will not be deleted and you will return to the DOCTOR LIST screen.
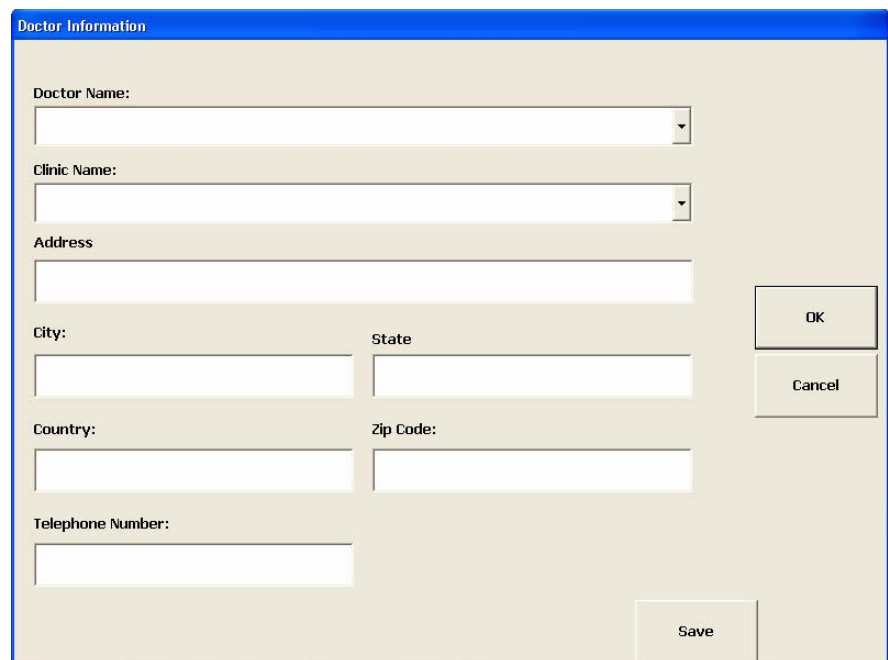

Figure 2-17 Select Doctor Screen

Select a doctor from the drop-down menu, then select **Select** or **OK** to assign the doctor.

To add a new doctor, select the **Add Doctor** button to display the DOCTOR INFORMATION screen (Figure 2-18). The Doctor Name and Clinic Name cannot be empty. The Doctor Name and Clinic Name combination must be unique.

Figure 2-18 Doctor Information Screen

Setting Up a Printer

The Printer Setup function (**System > Printer Setup**) will open your computer's PRINTERS AND FAXES window where you can see your printers, view and change printer settings, and set the default printer (Figure 2-19).
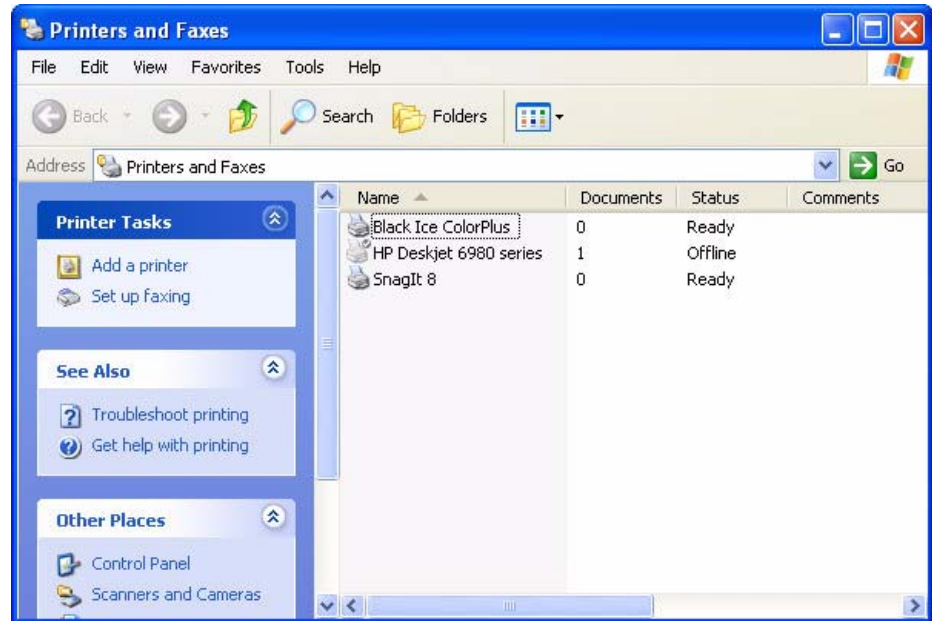

Figure 2-19 Printer Setup Screen

Setting the Preview/Export Image Type

From the Main Screen, select **System > Database...** to display the DATABASE OPTIONS screen (Figure 2-20).

Select the **Report Export Image Types** drop-down menu to select the Preview/Export image type.

Select these checkmarks to automatically export **Report** and/or **Raw Data** after exam acquisition to the default export path.
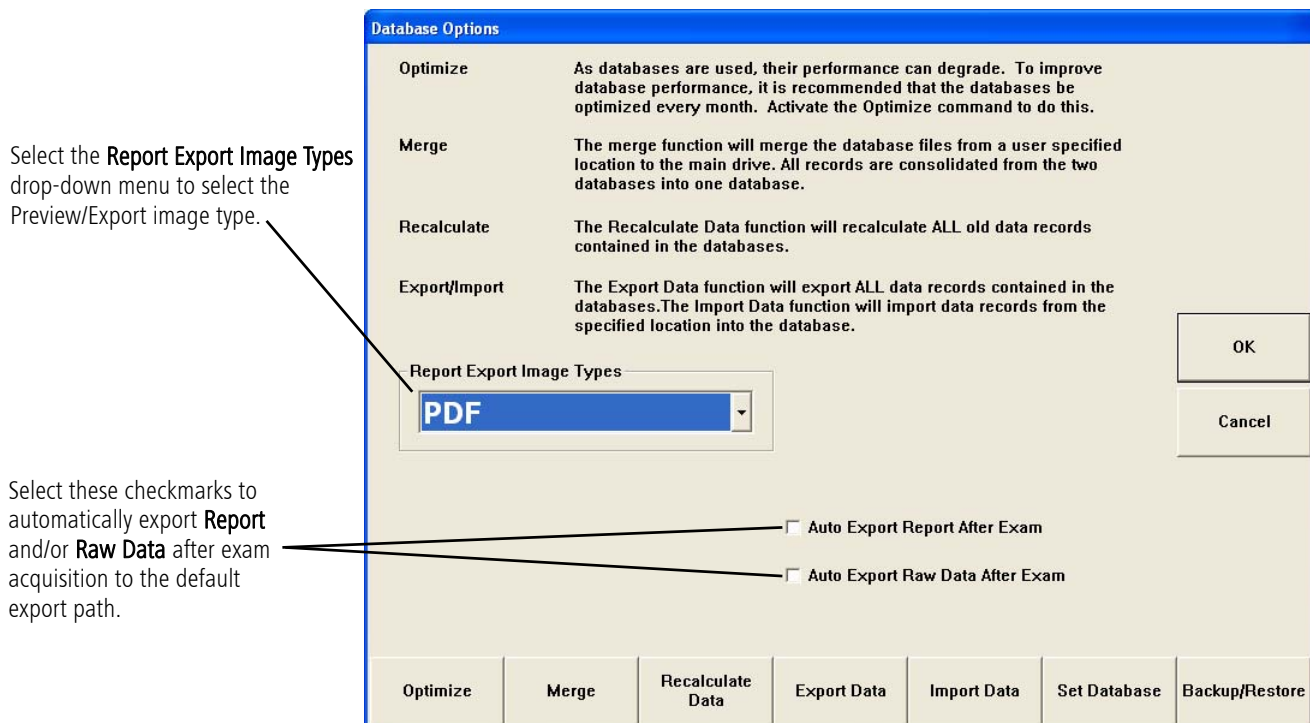

Figure 2-20 Database Options Screen

Select the **Report Export Image Types** drop-down menu to select the Preview/Export image type. The available image types are:

- PDF (recommended)
- TIFF
- JPEG

To close the preview report and return to the GDxPRO application, select the close box in the top right corner of the preview screen. Press **Alt-Esc** on the keyboard to toggle between the GDxPRO application and the preview screen.

Check the **Auto Export Report After Exam** checkbox to automatically export the exam's generated report to the default export path (see **Default Import/Export Path (optional) on** page 2-10).

Check the **Auto Export Raw Data After Exam** checkbox to automatically export the exam's measurement raw data to the default export path (see **Default Import/Export Path (optional) on** page 2-10).

Select **OK** to save your settings.

(3) Managing Patient Records

Chapter Overview

This chapter describes how to access and manage patient records on the GDxPRO. Topics covered in this chapter include:

Entering a New Patient

To scan a new patient with no previous exams stored in the database, you must first create a new patient record. At the MAIN screen (Figure 3-1), select **New Patient** to display the PATIENT IDENTIFICATION screen (Figure 3-2).
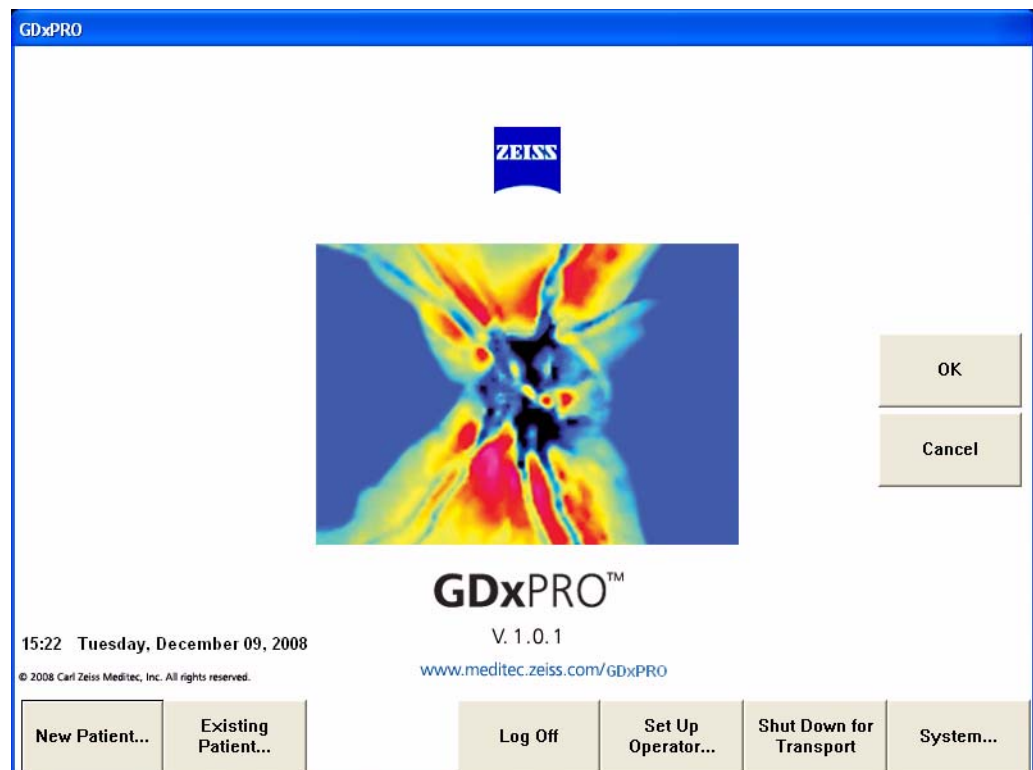

Figure 3-1 GDxPRO Main Screen

Figure 3-2 Patient Identification Screen

Enter a unique ID number (e.g., medical record number, EMR/PMS identification number) in the **Patient ID** field. The **Patient ID** field is not case sensitive.

☞　Note: If an EMR/PMS system will be used, either now or in the future, it is recommended to use a unique patient identifier generated from an EMR/PMS system for ease of integration.

Patient ID, Last Name, First Name, Date of Birth, and Doctor-Clinic fields are required data. If the desired doctor is not listed in the **Doctor - Clinic** field, you must exit the New Patient function and first associate the desired doctor with the current Operator, or add a new doctor (see Setting Up Operator/Doctor on page 2-6).

Select **OK** to continue to the ANCESTRY screen (Figure 3-3).

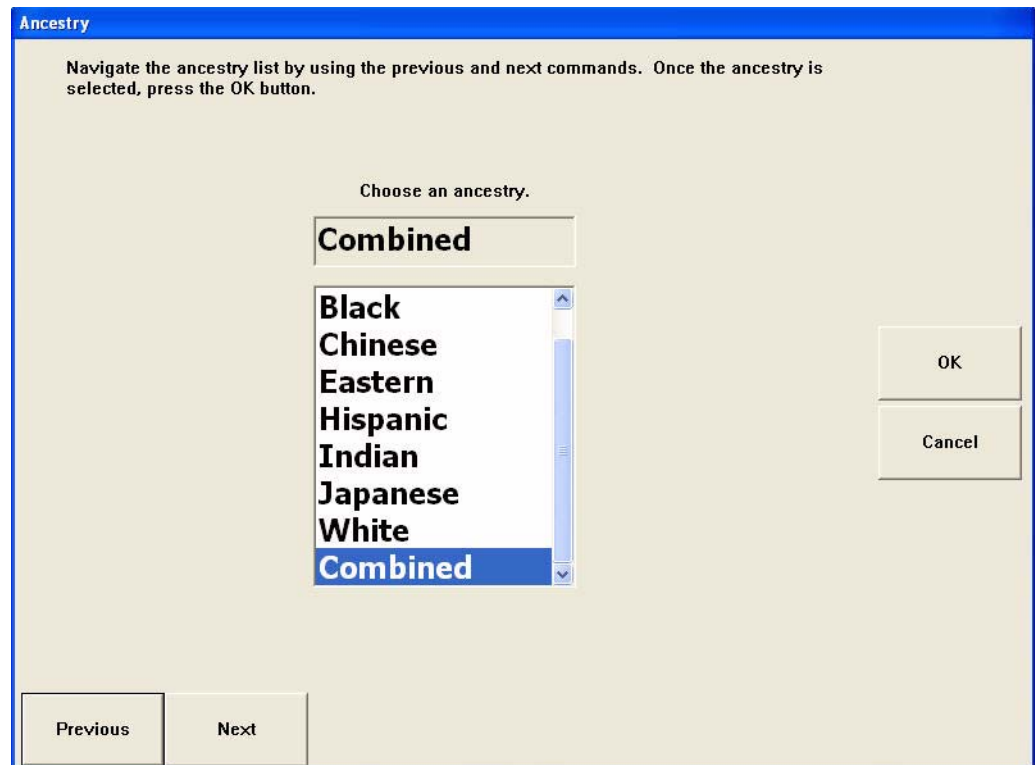*Figure 3-3 Ancestry Screen*

Select the appropriate ancestry from the drop-down list. The default is **Combined**—no specific ancestry is selected.

☞ Note: Neither ancestry nor gender selections have any bearing on calculations—the normative databases are a mixture of ancestry and stratified only by age. Ancestry selection is included in the event ethnic-specific normative databases are developed.

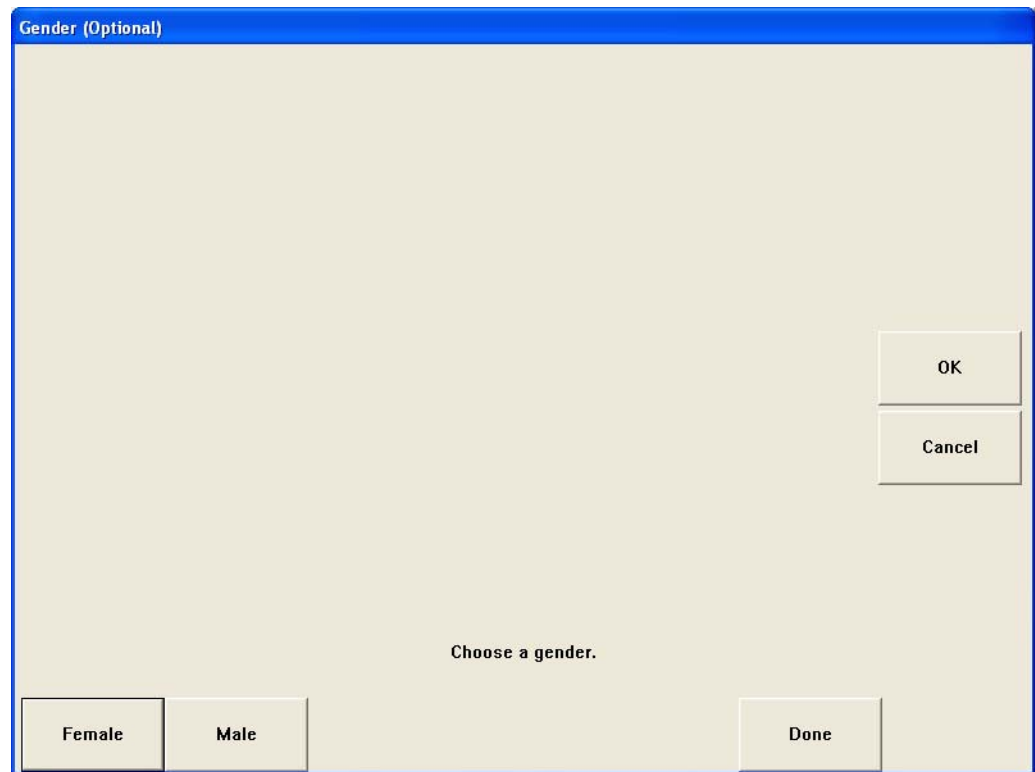Click **OK** to continue to the GENDER (OPTIONAL) screen (Figure 3-4).

Figure 3-4 Gender (Optional) Screen

At the GENDER (OPTIONAL) screen, select **Female** or **Male** to continue to the PATIENT INFORMATION screen (see Patient Information Screen on page 3-8).

Review the patient information. If the information is not accurate, select **Edit** on the PATIENT INFORMATION screen to change any or all of the information for this patient. If you select **Edit**, the PATIENT IDENTIFICATION, ANCESTRY, and GENDER screens will be displayed again for you to edit. You will be asked to confirm the patient update changes. Select **OK** to update the patient information.

Selecting an Existing Patient

This section describes how to select existing patient record(s) stored in the database. Once a patient is selected, the patient's information may be viewed and changed, and exams for that patient can be selected for reviewing, printing, exporting, and deleting, as described in (5) Managing Measurements.

At the MAIN screen, select **Existing Patient** to display the SEARCH FOR PATIENT screen (Figure 3-5).

Figure 3-5 Search for Patient Screen

You can search for patients in two ways:

- Do a direct patient search (see Direct Patient Search on page 3-6) by entering the Patient ID, Last Name, or First Name.
- Select the **View Full List** button (see Scrolling the Full List of Patients on page 3-6) to display all patients currently stored in the database.

Direct Patient Search

If you know the patient name or ID, the quickest way to select the patient is to enter this information into fields on the SEARCH FOR PATIENT screen. The currently selected field is shaded reddish-brown. As each character is entered, the database will sort to and display the first of all the patients that meet the criteria defined by the input so far. As each additional character is entered, the database will be sorted more specifically until sufficient characters have been entered to display the specific patient of choice. If the information on the SEARCH FOR PATIENT screen is not what is desired, select **Clear** to begin the selection process again.

While entering characters in any of the fields, the **View Full List** button may be selected at any time. The system will automatically display the PATIENTS LIST screen (Figure 3-6), starting with the first patient meeting the criteria of the characters entered up to that point.

Patients List Screen

The PATIENTS LIST screen (Figure 3-6) is displayed with the first patient selected by default. The selected patient is shown with a blue background.

Figure 3-6 Patients List Screen

Scrolling the Full List of Patients

If you wish to scroll through the entire list of patients stored in the GDxPRO database, select the **View Full List** button to display the PATIENTS LIST screen (Figure 3-6).

Selecting Patients

Use the mouse to select a patient, or select **Previous**, **Next**, **Page Up**, **Page Down** to move through the list until you select the patient of interest. You may also use the up and down arrow keys, and Page Up and Page Down keys on the keyboard.

You may change the field by which the list is ordered (*Patient Last Name, Patient First Name, Patient ID, Exam Date,* or *Doctor*) by clicking on the column header of the field. The PATIENTS LIST screen will remain in this sort order until a new sort is performed. The default full list is sorted by Patient ID.

The selected patient's date of birth, gender, ancestry, and middle name are shown at the bottom of the list. The total number of patients is also displayed.

Once the desired patient is selected, press **OK** (or **double-click** the selected patient) to display the PATIENT INFORMATION screen (see Patient Information Screen on page 3-8). Select **Cancel** if you want to return to the SEARCH FOR PATIENT screen.

Printing the Patients List

Select **Print Full Listing** to print the complete list of patients displayed on the PATIENTS LIST screen to the currently selected Windows default printer.

Patient Information Screen

The PATIENT INFORMATION screen (Figure 3-7) displays the patient information for the selected patient stored in the database.

Figure 3-7 Patient Information Screen

At the PATIENT INFORMATION screen, select **Review** to display the MEASUREMENT LIST screen and generate reports (see (5) Managing Measurements).

Select **Single Exam** or **OK** to take a Single Exam (see Scanning Procedure on page 4-3), or **Triple Scan** to take a Triple Scan (see Acquiring Triple Scans on page 4-27).

Selecting **Cancel** will return you to the opening MAIN screen.

Editing/Deleting Patient Records

At the PATIENT INFORMATION screen (Figure 3-7), select **Edit** to edit the patient information.

Select **Delete** to delete the patient and all measurements associated with the patient.

Selecting **Cancel** will return you to the opening MAIN screen.

Exporting and Importing Patient's Data

ON the PATIENTS LIST screen (Figure 3-6), select **Export** to export the selected patient's information and measurement data to an export folder. You will be asked if you want to use the currently defined default export folder for the current operator (see **Default Import/Export Path (optional) on** page 2-10). Select **Yes** to use the default export folder or select **No** to display a Browse for Folder dialog where you can select the export folder you want to use.

Merging Patients

If, by mistake, you have two patients that should really be the same patient, you can merge them into one patient. ON the PATIENTS LIST screen (Figure 3-6), select the two patients and then select **Merge** to merge the measurements of the two patients into one patient. A dialog is displayed to confirm the patient merge (Figure 3-8).
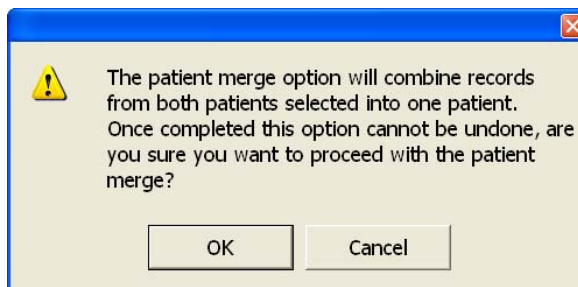
Figure 3-8 Confirm Patient Merge Dialog.

☞ Note: Once completed, merging cannot be undone.

Select **OK** to continue with the merge of two patients. Select **Cancel** to cancel the merge. A RESOLVE PATIENT ID CONFLICT dialog will be displayed (Figure 3-9).

Figure 3-9 Resolve Patient ID Conflict Dialog

Select **Use Main Record** to use the patient information (name, gender, etc.) from the Main Database shown above for the merged patient, and merge the patients. Select **Use Backup Record** to use the patient information from the Backup Database for the merged patient, and merge the patients. Select **Cancel** to cancel the merge.

(4) Scanning Procedures

Chapter Overview

This chapter describes the GDxPRO scanning procedure. Topics include:

Scanning Modes

The GDxPRO supports five types of scanning modes as described below:

AutoFocus Scan

An AutoFocus Scan is a scan performed at the patient's first visit and is used to determine the optimal focus position.

Corneal Scan

The Corneal Scan measures the anterior segment birefringence, using the unique properties of the macular region. The results in the macular region of this exam are analyzed to determine the optimum settings for the variable corneal compensator used to cancel out the effect of the birefringence of the cornea for subsequent VCC and ECC exams.

Single Exam (ECC or VCC)

A Single Exam performs one scan of one or both eyes.

ECC refers to Enhanced Corneal Compensation. ECC measures the retinal phase shift through a mathematical removal of the anterior segment contribution and significantly enhances the signal-to-noise ratio of RNFL measurements without hardware modification. ECC is the recommended and default imaging mode for new patients.

VCC refers to Variable Corneal Compensation. VCC measures the retinal phase shift with direct optical cancellation of the anterior segment birefringence.

Triple Scan (ECC or VCC)

Triple Scan acquisition allows you to perform from 3 to 5 consecutive ECC or VCC scans of one or both eyes. At the end of the Triple Scan acquisition, a mean image from the acquired images is created. Triple Scan acquisition facilitates the creation of means of three measurements used in Extended Mode GPA™ analysis.

Adding New Patient or Selecting Existing Patient

To scan a new patient with no previous exams stored in the database, you must first create a new patient record. At the MAIN screen, select **New Patient**. To perform an exam on a patient whose data is already stored in the system, you must locate and highlight the patient record in the database. At the MAIN screen, select **Existing Patient**. Please refer to (3) Managing Patient Records for instructions on adding a new patient or searching for an existing patient.

When the patient of interest is highlighted, either on the PATIENTS LIST screen or on the SEARCH FOR PATIENT screen, press **OK** and you will see the PATIENT INFORMATION screen (Figure 4-1). To begin the scan procedure, see Scanning Procedure on page 4-3.

Figure 4-1 Single Exam Button on Patient Information Screen

Scanning Procedure

☞ IMPORTANT: The GDxPRO quantitatively measures the RNFL by first measuring the value of corneal birefringence contribution for each eye imaged. The corneal contribution only needs to be measured once per eye and only on the first exam performed on each eye. The corneal compensation value for each eye is stored in a database and will then be used for all subsequent exams for that eye. However, you may choose to remeasure the corneal contribution to reestablish or update its value (for example, following patients with corneal procedures or pathology) prior to a new RNFL exam.

The scan procedure described in this section applies to the AutoFocus Scan, Corneal Scan, and the Single and Triple compensated RNFL scans (ECC or VCC). The procedure is the same for all scans.

The scan procedure is detailed in the following Step sections:

- Step 1: Positioning the Patient on page 4-5
- Step 2: Selecting Patient Fixation on page 4-6
- Step 3: Determining the Focus on page 4-7
- Step 4: Acquiring the Image on page 4-8

For image quality procedures see the following section:

- Checking Image Quality on page 4-13

At the end of exam acquisition see the following section:

- Final Step: Saving the Scans on page 4-25

Depending on the scanning mode, the subject, and operator, the typical exam time is between 2 and 5 minutes.

Single Exam

To perform a Single Exam select **Single Exam** or **OK** on the PATIENT INFORMATION screen (Figure 4-1). See Figure 4-2 for the Single Exam workflow for new and existing patients.

Triple Scan

To perform a Triple Scan select **Triple Scan** on the PATIENT INFORMATION screen (Figure 4-1). See Acquiring Triple Scans on page 4-27 for information on Triple Scan exams. See Figure 4-30 for the Triple Scan workflow for new and existing patients.
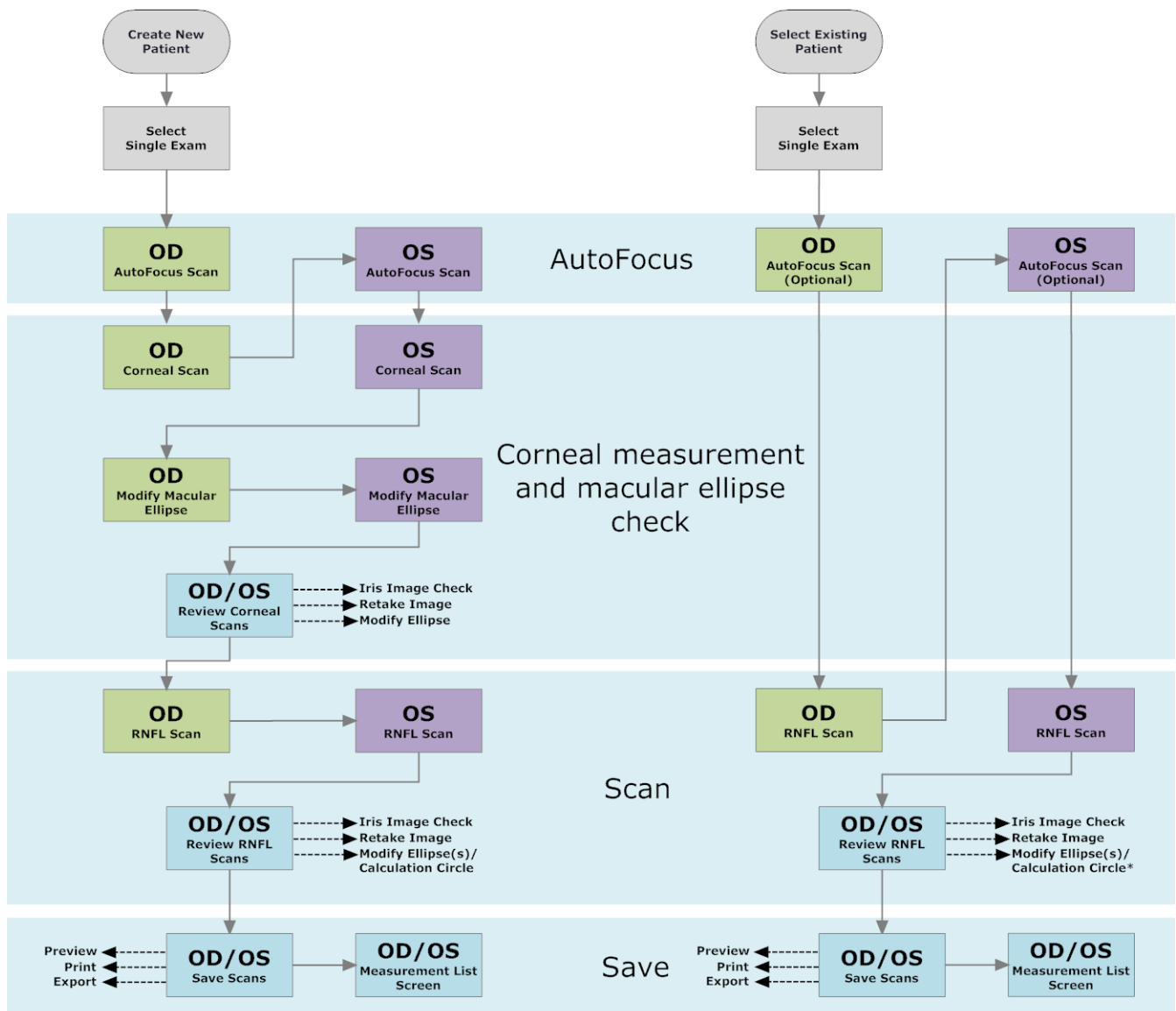
Single Exam Scan Workflow – New and Existing Patient

Figure 4-2 Single Exam Scan Workflow – New and Existing Patient

Step 1: Positioning the Patient

⚠️ IMPORTANT: The face mask should be cleaned with water and disinfected between each examination with an alcohol wipe (70% Isopropyl).

Clean all patient contact surfaces of the face mask with an alcohol pad before each patient. Allow the alcohol to evaporate before positioning the patient.

Seat the patient in front of the system as shown in Figure 4-3. Adjust the table or patient chair to allow the patient to lean forward and place his/her face comfortably into the face mask. *Make sure that the patient's forehead and cheeks are centered, gently and evenly touching the mask, and the patient is comfortable.* To help find proper eye positioning, align the eyes (the corner of the eye or the canthus) with the eye-level indicators on the face mask (see Figure 4-4).

The patient should be comfortably seated so that their head remains stationary; head movement interferes with the quality of the acquired image.
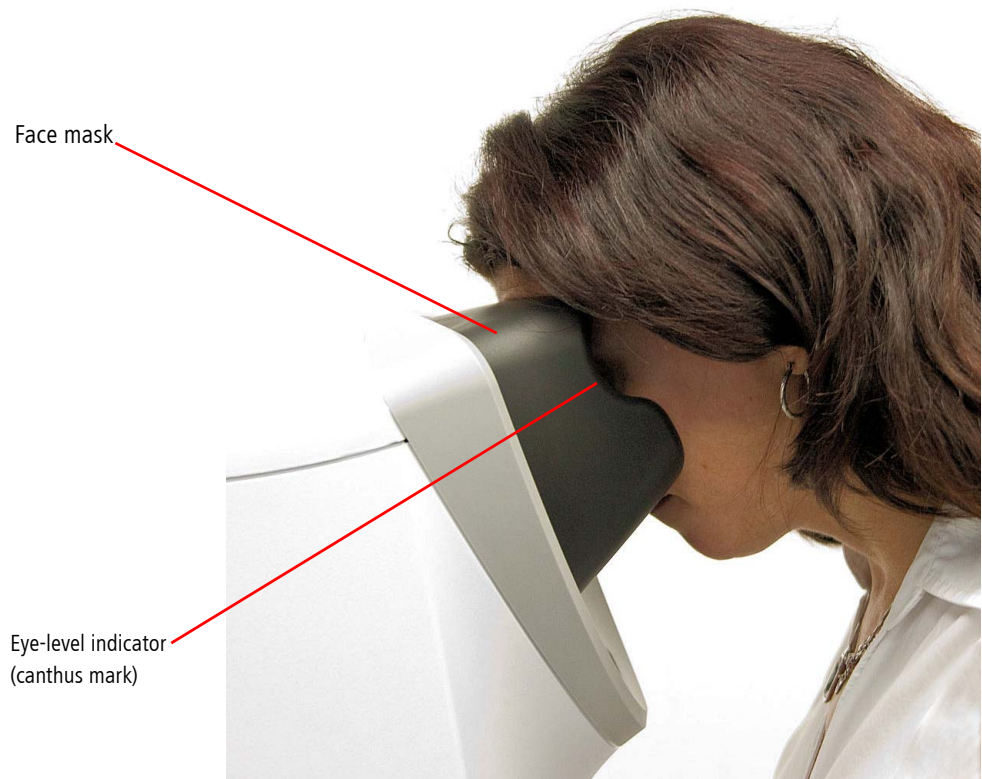

Face mask

Eye-level indicator
(canthus mark)

Figure 4-3 Positioning the Patient

Scanning Procedures

Eye-level indicator (canthus mark)

Eye-level indicator (canthus mark)

Figure 4-4 Eye-Level Indicators on Face Mask

Step 2: Selecting Patient Fixation

With the patient in position, instruct him/her that he/she will see a field of thin red horizontal lines. A fixation target is located on one side of the field. For the right eye, the target will be on the left side of the red field; for the left eye it will be on the right side. The GDxPRO features two different fixation targets, Standard and Low Vision, as described below.

Ask the patient to keep his/her gaze fixed at the fixation target. **Instruct the patient to hold as steady as possible, and to blink normally until told to not blink**.
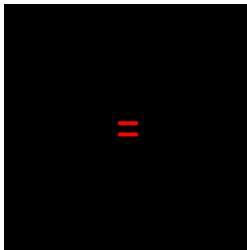
Standard Target (default for new patient)

When Standard Target fixation is enabled, the patient will see the fixation target as two small, bright, fast-blinking, red horizontal lights, similar to a small equal (=) sign. Click the image on the left to see a simulated Standard Target animation.
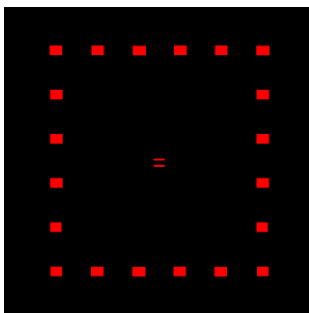
Low Vision Target

The Low Vision Target is an alternate option for patients that have difficulty seeing the Standard Target. When Low Vision Target fixation is enabled, the patient will see the fixation target as a bright red dashed rectangle zooming in continuously. The center of this rectangle is the fixation target—the same small red equal (=) sign of the Standard Target. Remind the patient to focus on the center of the box. Click the image on the left to see a simulated Low Vision Target animation.

Click images above to see animation.

Selecting the Fixation Target

On the ACQUISITION screen (Figure 4-6) select the **Low Vision Target** button to enable Low Vision fixation. Select the **Standard Target** button to enable Standard fixation. On subsequent exams, the fixation will default to the last selected target for a given patient.

Step 3: Determining the Focus

To correct for the patient's refraction error, two options are available: manually enter refraction or use the AutoFocus function. The GDxPRO uses the refraction information to set the best focus for scanning the eye. The refractive correction settings are stored in a database and are used for subsequent exams. The refractive range is -13 to +8 diopters.

For existing patients with previous exams, the SELECT REFRACTION screen (Figure 4-5) is displayed at the beginning of a new exam. Auto indicates the **AutoFocus** settings from the last AutoFocus scan will be used. For new patients, AutoFocus is enabled by default and the SELECT REFRACTION screen will be bypassed.

Refraction

To change patient refraction during image acquisition, select the **Refraction** button on an ACQUISITION screen (Figure 4-6) to display the SELECT REFRACTION screen (Figure 4-5).

Figure 4-5 Select Refraction Screen – AutoFocus Button

AutoFocus

Select **AutoFocus** to allow the system to determine the optimal focus position using the AutoFocus Scan, or enter patient refraction manually (Manual Refraction on page 4-8). Select **OK** to keep the current or new refraction settings and return to the ACQUISITION screen. Selecting **Cancel** will exit the SELECT REFRACTION screen and return to the MAIN screen for existing patient exams, or back to the ACQUISITION screen for new patients.

AutoFocus Scan

The GDxPRO performs the AutoFocus function as an additional scan performed before the corneal or RNFL scans (Figure 4-6).

☞ Note: You *should* repeat AutoFocus if patient refraction has changed from the last visit (e.g., due to a corneal procedure or pathology). Using AutoFocus each time has no adverse impact on GPA analysis. AutoFocus is recommended for every new exam.

<u>Manual Refraction</u>

Use the **Up Right (OD)**, **Down Right (OD)**, **Up Left (OS)**, **Down Left (OS)** buttons to select the correct spherical equivalent refraction for the appropriate eye. Alternatively, you may use the **Tab** key to highlight a refraction value box and then use the up and down arrow keys on the keyboard to select, or use the keyboard to enter the correct value. Select **OK** to save your settings.

The spherical equivalent (SE) is calculated by algebraically adding ½ the cylinder value to the sphere value from the spectacle refraction. Examples:

> If patient's spectacle refraction is +1.00 D sph -1.00 D cyl x 90°,
> SE = +1.00 D + ½ (-1.00 D) = +1.00 D − 0.50 D = +0.50 D.

> If patient's spectacle refraction is -1.00 D sph -1.00 D cyl x 120°,
> SE = -1.00 D + ½ (-1.00 D) = -1.00 D − 0.50 D = -1.50 D.

Step 4: Acquiring the Image

The ACQUISITION screen provides a live image of the patient's eye (Figure 4-6).

Current scan mode
(AutoFocus Scan)

Laser ON indicator

White ball

AutoFocus
measurement indicator

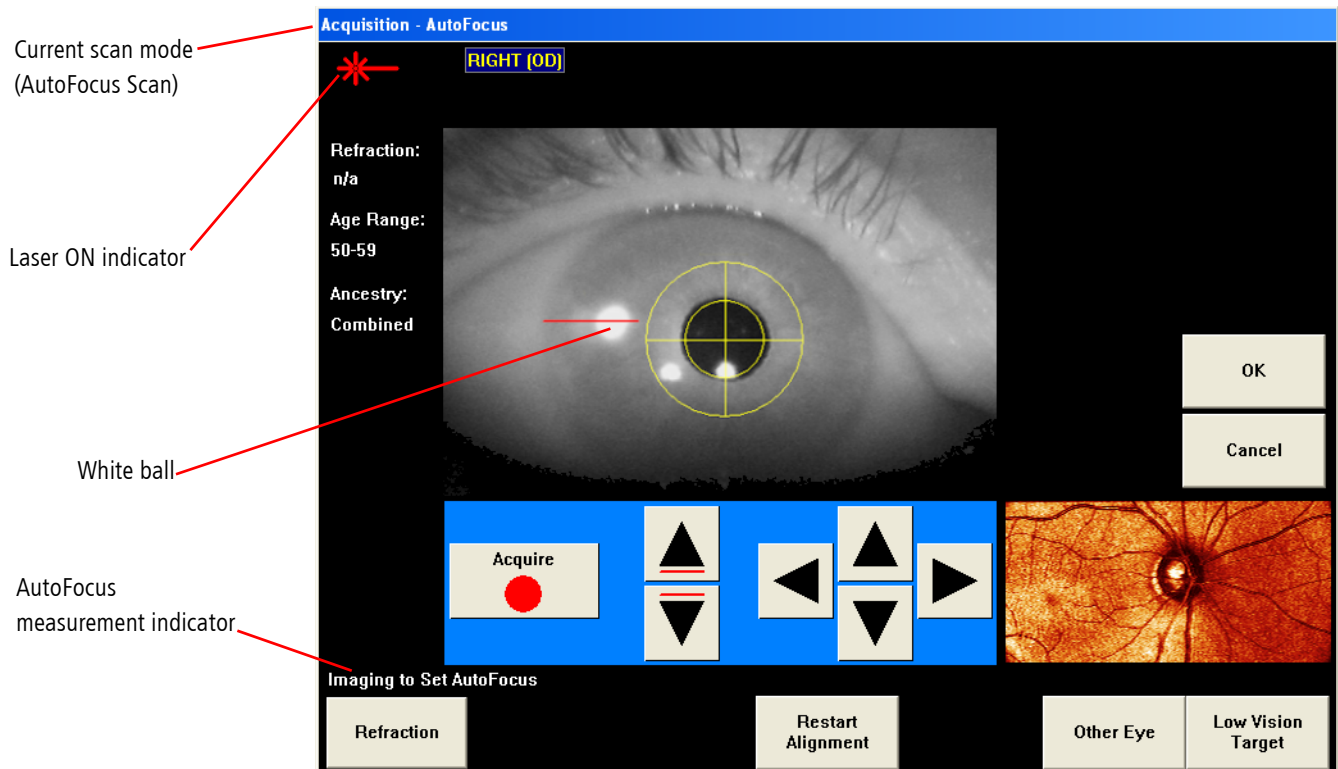*Figure 4-6 Acquisition - AutoFocus Screen*

The system will initially be in position to scan the right eye first. *Right (OD)* will be displayed on the top-left of the screen. If you want to skip to the other eye, wait for the *Please Wait* message to disappear and select **Other Eye**.

Ask the patient to remain still and focus on the fixation target (see Step 2: Selecting Patient Fixation on page 4-6).

Eye Alignment

Center white ball on the horizontal red line using the scroll wheel on the mouse, **Vertical Controls** (shown below), or keyboard **PgUp/PgDn** keys.
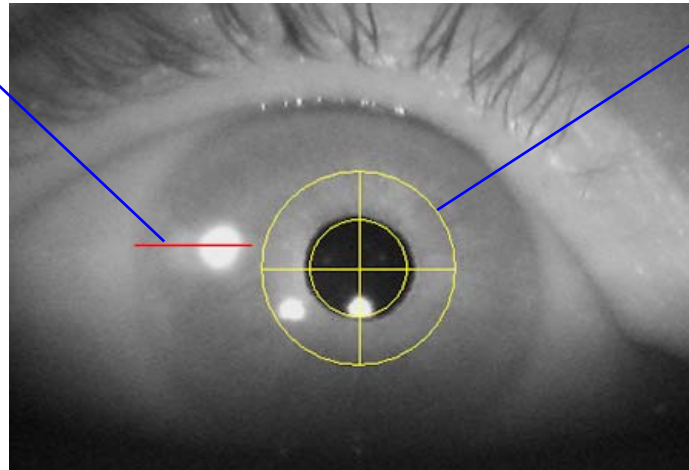
Center pupil in yellow crosshairs by touching (or left-clicking the mouse) on center of pupil and using **Pupil Alignment Controls** (shown below), or keyboard **arrow** keys.
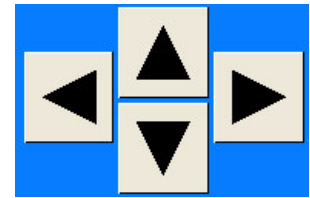
Figure 4-7 Correct Eye Alignment on Acquisition Screen, Live Image

Align pupil: Center the patient's pupil in the yellow crosshairs using the touch screen (touch center of pupil) and **Pupil Alignment Controls** (Figure 4-7). Note: You can also left-click the mouse on the center of pupil or use the keyboard arrow keys. See Figure 4-7 for an example of correct alignment.

Align white ball: Center the white ball on the horizontal red line using the scroll wheel on the mouse or the **Vertical Controls** (Figure 4-7) for optimal working distance. Note: You can also use the keyboard PgUp/PgDn keys. The white ball may not be visible or in focus until you scroll the mouse or use the Vertical Controls. See Figure 4-7 for an example of correct alignment.

☞ IMPORTANT: The mouse cursor must be in the live video image in order to use the scroll wheel for centering the white ball.

Refined adjustments of both the ball and pupil are often needed as the image approaches optimal alignment.

If needed, select **Restart Alignment** to bring the alignment back to the default setting.

☞ Note: You may notice two or three additional smaller white balls within the area of the patient's pupil. These are reflections from the eye that have no bearing on the image and working distance and should be disregarded.

☞ Note: Pupil dilation is not recommended and may make white ball alignment difficult, since the white ball is a reflection from the iris. For a *partially* dilated eye follow the steps below to catch the edge of the iris. Measurements on fully-dilated eyes are *not* recommended.

1. Align pupil slightly off the center of the yellow crosshairs until the white ball becomes visible.
2. Align the white ball until it is centered on the horizontal red line.
3. Center the partially-dilated pupil on the yellow crosshairs.

Right-Click

<u>Measurement Acquisition</u>

Instruct the patient to blink once. Promptly check the pupil and white ball alignment, make necessary fine adjustments, and then **Right-Click** the mouse (or select the **Acquire** button) to acquire the scan, making sure the *Please Wait* indicator is not displayed.

☞ **Note: The pupil must be centered on the yellow crosshairs and the red line must be centered on the white ball. Otherwise, the scan may not pass the image quality check and will need to be repeated.**

☞ **Note: Instruct the patient to blink just before selecting the Acquire button, then not to blink during acquisition (between the first and second beeps, less than 1 second).**

⚠ WARNING: If using the touch screen to select the Acquire button, touch gently so as to not make the instrument move. Using the mouse is recommended.

Note: While scan acquisition is in progress, a **Please Wait** indicator at the top-center of the display will turn red. Do not move or push any controls/buttons during the image acquisition period while the **Please Wait** indicator is red.

The system will beep once when the **Acquire** button is selected (or the mouse **right-clicked**) and again as soon as it has completed. *At the sound of the second beep, instruct the patient to remain in position and blink normally.*

☞ Note: The volume of the beep and the beep sound itself can be changed in the Windows XP Control Panel (**Start > Control Panel > Sounds and Audio Devices**). To change the beep sound, select the Sounds tab and then change the **Default Beep** to another sound.

During the AutoFocus scan the patient may notice the screen briefly going out of focus. After completion of an AutoFocus scan, the system will remain on the same eye so that the corneal or RNFL scans can be acquired next.

Corneal and RNFL scan acquisition takes less than one second. After completion of a corneal or RNFL scan acquisition of the right eye, the system will pause for a few seconds then move to position for the left eye scan. The *Please Wait* indicator will remain red from the time of selecting the **Acquire** button (or the mouse **right-clicked**) until the system is in position for the left eye scan.

If you do not want to scan the left eye, press **OK** to proceed. See Checking Image Quality on page 4-13.

<u>Acquire Corneal Measurement</u>

The ACQUISITION - MEASURING CORNEA screen is used to acquire the corneal measurement (Figure 4-8).

Current scan mode
(Corneal Scan)

Auto indicates refraction was
set to AutoFocus.

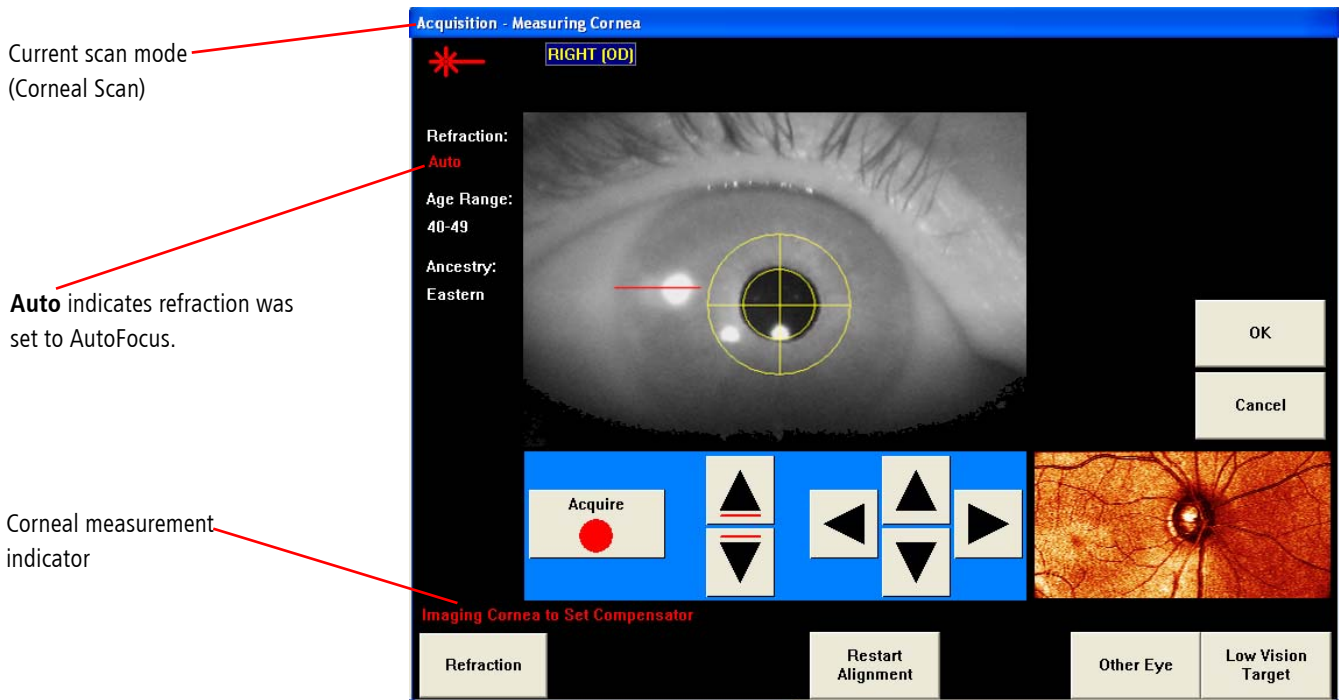Corneal measurement
indicator

Figure 4-8 Acquisition - Measuring Cornea Screen

<u>Acquire RNFL-I Measurements</u>

The GDxPRO supports the acquisition of ECC and VCC measurements (see Scanning Modes on page 4-1). ECC is the recommended and default scan mode for new patients. For existing patients, the GDxPRO will default to the patient's last scan mode. The scan mode can be changed (VCC to ECC, or ECC to VCC) on the RNFL-I ACQUISITION screen by selecting the **ECC** or **VCC** toggle button (Figure 4-10 and Figure 4-11). You cannot compare ECC measurements and VCC measurements, since they use different normative databases. If you select an **ECC** or **VCC** button, an acquisition message will be displayed (Figure 4-9). Select **OK** to change the scan mode.
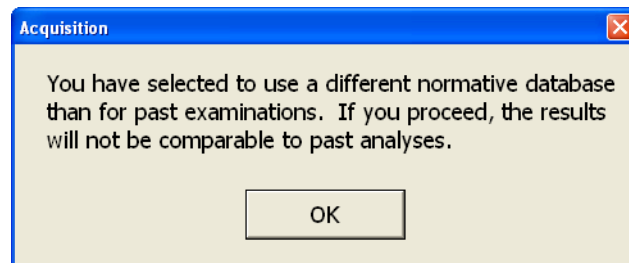
Figure 4-9 ECC/VCC Acquistion Image Mode Change Message

If a patient has a corneal pathology or procedure since their last exam, it is recommended to repeat the corneal measurement by selecting **Reset Compensation.**

The ACQUISITION- VCC screen is used to acquire the VCC RNFL-I measurement (Figure 4-10).
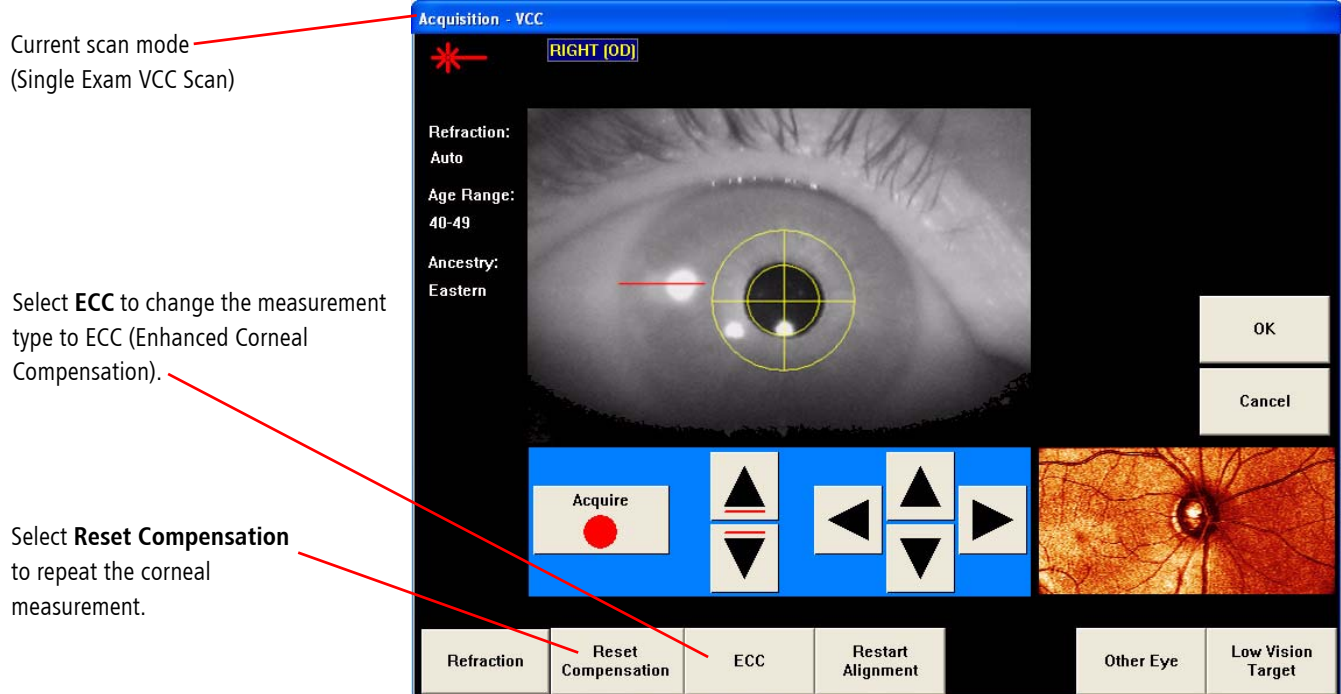
Current scan mode
(Single Exam VCC Scan)

Select **ECC** to change the measurement type to ECC (Enhanced Corneal Compensation).

Select **Reset Compensation** to repeat the corneal measurement.

Figure 4-10 Acquisition - VCC Screen

The ACQUISITION- ECC screen is used to acquire the ECC RNFL-I measurement (Figure 4-11).

Current scan mode
(Single Exam ECC Scan)

Select **VCC** to change the measurement type to VCC (Variable Corneal Compensation).

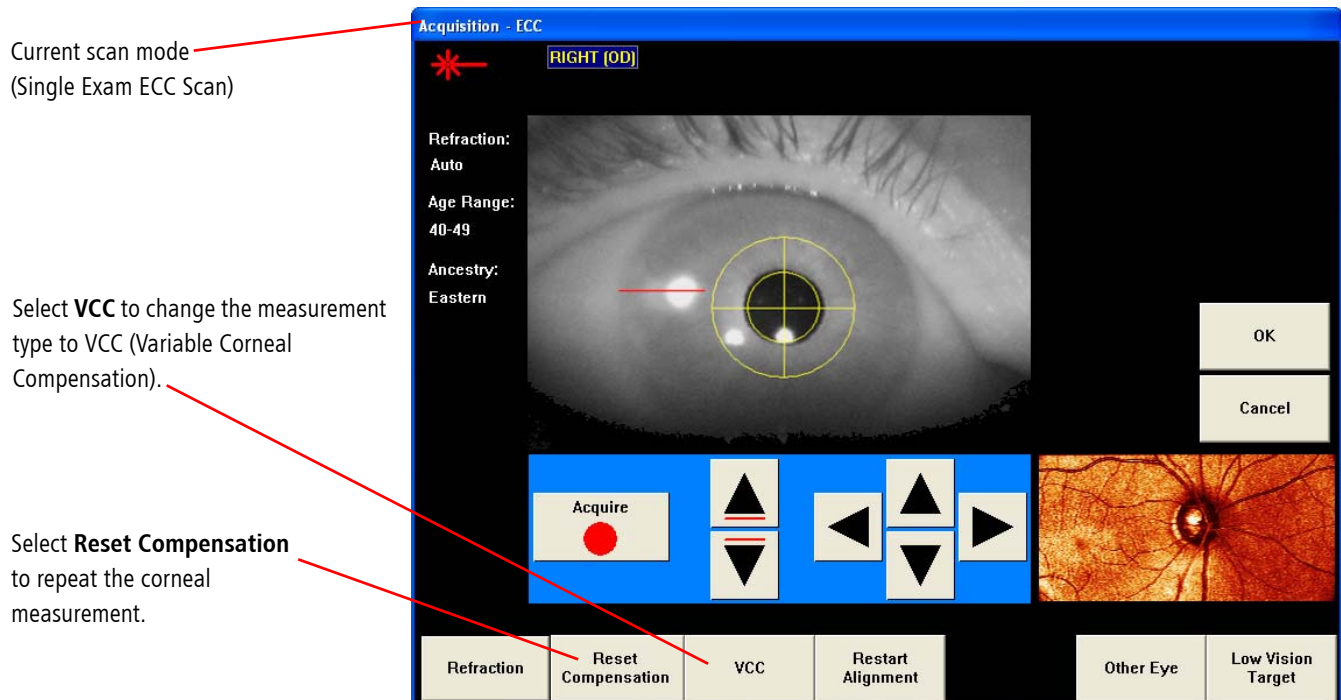Select **Reset Compensation** to repeat the corneal measurement.

Figure 4-11 Acquisition - ECC Screen

Checking Image Quality

When image acquisition (corneal or RNFL) is completed, the IMAGE CHECK screen (see Figure 4-15 for corneal and Figure 4-17 for RNFL) is displayed and should be reviewed before accepting the scan.

The IMAGE CHECK screen provides the following:

Quality Parameters

Quality parameters (listed in Table 4-1) for each image are displayed on the IMAGE CHECK screen. Review the scan Quality Scores and messages for both eyes.

A good quality image can be characterized as follows:

- a scan Quality Score of 7 or above
- OK's for *Alignment, Fixation, Refraction,* and *Other* parameters
- well focused
- well aligned
- even illumination
- minimal eye movement

Potential causes of image quality problems include:

- improper ellipse placement
- image out of focus indicating an incorrect refraction setting
- ONH ellipse not centered (too close to edge) indicating improper fixation
- uneven illumination indicating incorrect alignment
- an overexposed or black image indicating that the patient blinked during acquisition.
- black borders along one or more sides of the image indicating patient eye movement during acquisition.

If the images are not satisfactory, select **Retake Image** (see Retaking the Image on page 4-23). In some cases and for some eyes, it will not be possible to achieve the recommended score value and avoid all quality messages. See Table 4-1, "Image Quality Messages" on page 4-14 for more information on image quality messages. See Table F-1, "Image Troubleshooting Guide" on page F-3 for additional troubleshooting information. Accept the best scan that can be obtained.

☞ IMPORTANT: Proper ellipse placement influences image Quality Score and messages. Verify ellipse placement is correct before deciding to retake an image.

☞ Note: Canceling on the IMAGE CHECK screen will discard newly acquired images.

Table 4-1 Image Quality Messages

Parameter	Quality Message	Cause of Message	Recommended Action
Score	Overall score on a scale of 1 to 10, with 10 being "excellent."	Score will always be displayed after scan. A score of 7 or above is desired.	Retake image
Alignment	Focus dot not centered on red line or pupil not centered.	The red horizontal line may not evenly bisect the focus dot. The pupil may not be centered in the crosshairs.	See View Iris Image to confirm alignment; retake image
Fixation	Eye movement.	Patient may have lost fixation or moved. May also cause black border to appear in the image.	Retake image
	Poor fixation or ellipse movement.	Patient may not have fixated on the target.	Retake image, consider Low Vision Target
Refraction	Possible refraction setting error.	Refraction setting entered may not have been accurate.	Perform AutoFocus scan and retake image
Other	Analysis confidence low. Results could be unreliable.	Due to atypical corneal characteristics, RNFL-I measurements can be affected and the results may be incompatible with the normative database.	
	Image too dark or too light.	Factors could include: image out of focus, partial blinking, cataract, and small pupil (< 2 mm diameter).	For small pupil, slight dilation; retake image or retake AutoFocus scan
	Ellipse may be too big. Exam comparisons may be affected.	Ellipse may be set too large or too close to the edge of the image. If the ellipse is improperly placed, future comparisons may be affected.	Modify calculation circle
	Recommend resetting compensation.	Corneal compensation incomplete. May be due to poor alignment, poor circle placement on Cornea Scan, or change in cornea from refractive surgery or other causes.	Reset Corneal Scan

Checking the Corneal Measurement

After acquiring the Corneal Scan, two macular images, a fundus image and a thickness (polarization) image, appear at the top of the IMAGE CHECK - MEASURING CORNEA screen (Figure 4-15) for each eye scanned. The center two images are fundus images. The outer two images are the corresponding uncompensated thickness (phase shift) images that are used to determine the amount of corneal compensation required for each eye. The colors appearing on these images will vary greatly across the patient population.

The refractive correction settings and corneal measurements are saved and used for subsequent VCC/ECC RNFL examinations. The system will return to the ACQUISITION screen so you can proceed to obtain compensated RNFL images.

Modifying the Macula Ellipse after Corneal Measurement

Following a corneal measurement, the MODIFY ELLIPSE - MEASURING CORNEA screen appears (Figure 4-12), showing how the system automatically placed the corneal measurement ellipse for each imaged eye. A dotted square shows the optimal optic nerve head (ONH) centering, which allows you to verify correct patient fixation.

☞ Note: For accurate patient fixation, ensure that the ONH is within the dotted square.

To ensure accurate corneal measurement, the macular ellipse should be centered directly over the macula "bow tie" pattern. Use the **Left**, **Right**, **Up**, and **Down** positional buttons (one click moves one pixel, Shift-click moves 5 pixels) to adjust the macular ellipse position. A dot in the center of the ellipse makes it easier to center the ellipse (Figure 4-13). There is no need to change the size of the macular ellipse.

If the macula "bow tie" is not well-defined, press the **Irregular Pattern** button. When **Irregular Pattern** is selected, the software uses an alternative corneal calculation based on the macula area within a dotted square which does not require macular ellipse placement, and the position buttons are not available (Figure 4-14).
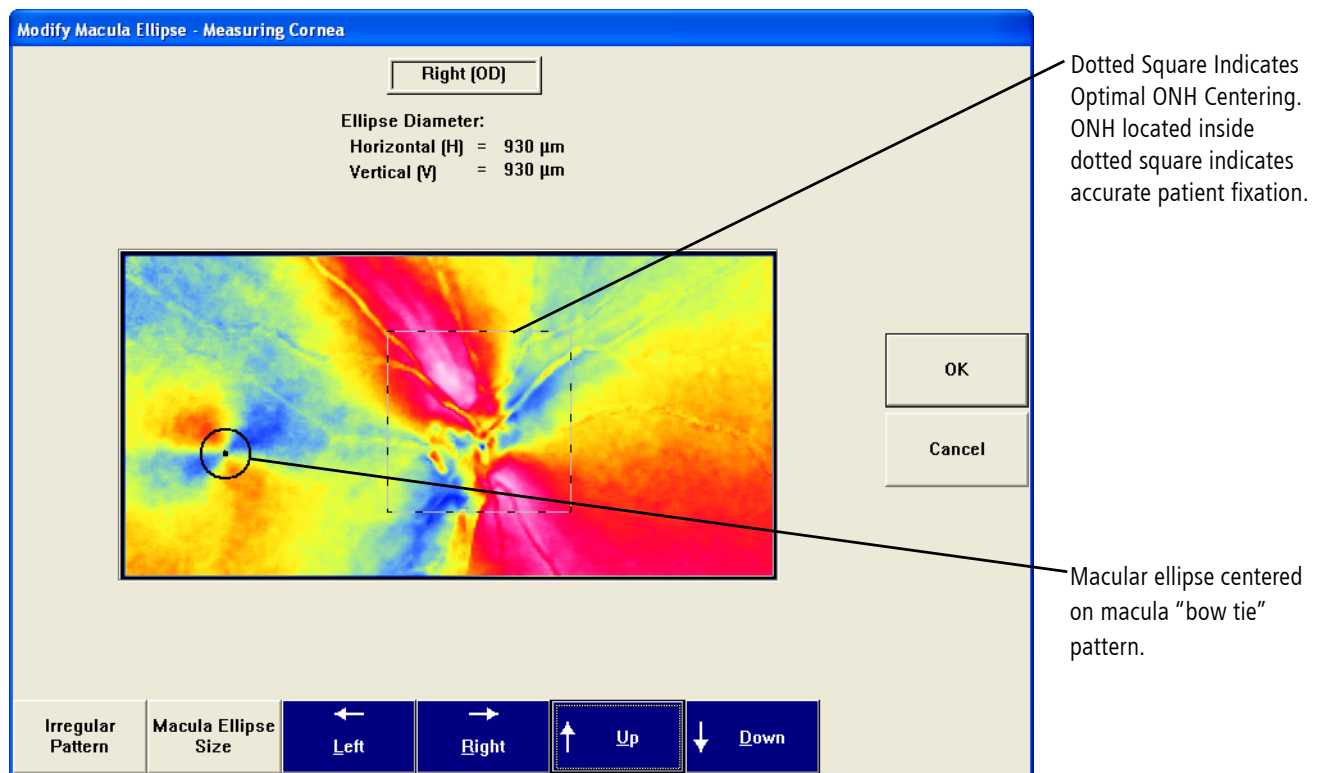

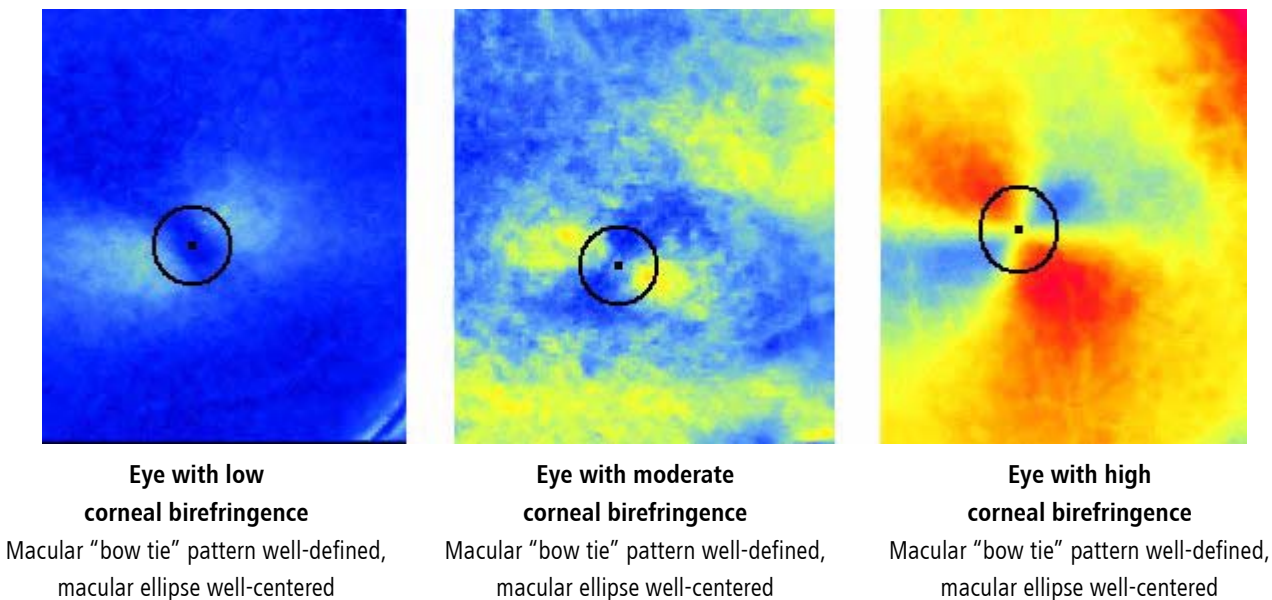*Figure 4-12 Modify Ellipse - Measuring Cornea Screen (after Corneal Scan)*

Eye with low
corneal birefringence
Macular "bow tie" pattern well-defined,
macular ellipse well-centered

Eye with moderate
corneal birefringence
Macular "bow tie" pattern well-defined,
macular ellipse well-centered

Eye with high
corneal birefringence
Macular "bow tie" pattern well-defined,
macular ellipse well-centered

Figure 4-13 Proper Positioning of Macula Ellipse

Dotted square indicates that Irregular Pattern is selected, the macula pattern is not well-defined.

Dotted Square Indicates Optimal ONH Centering.
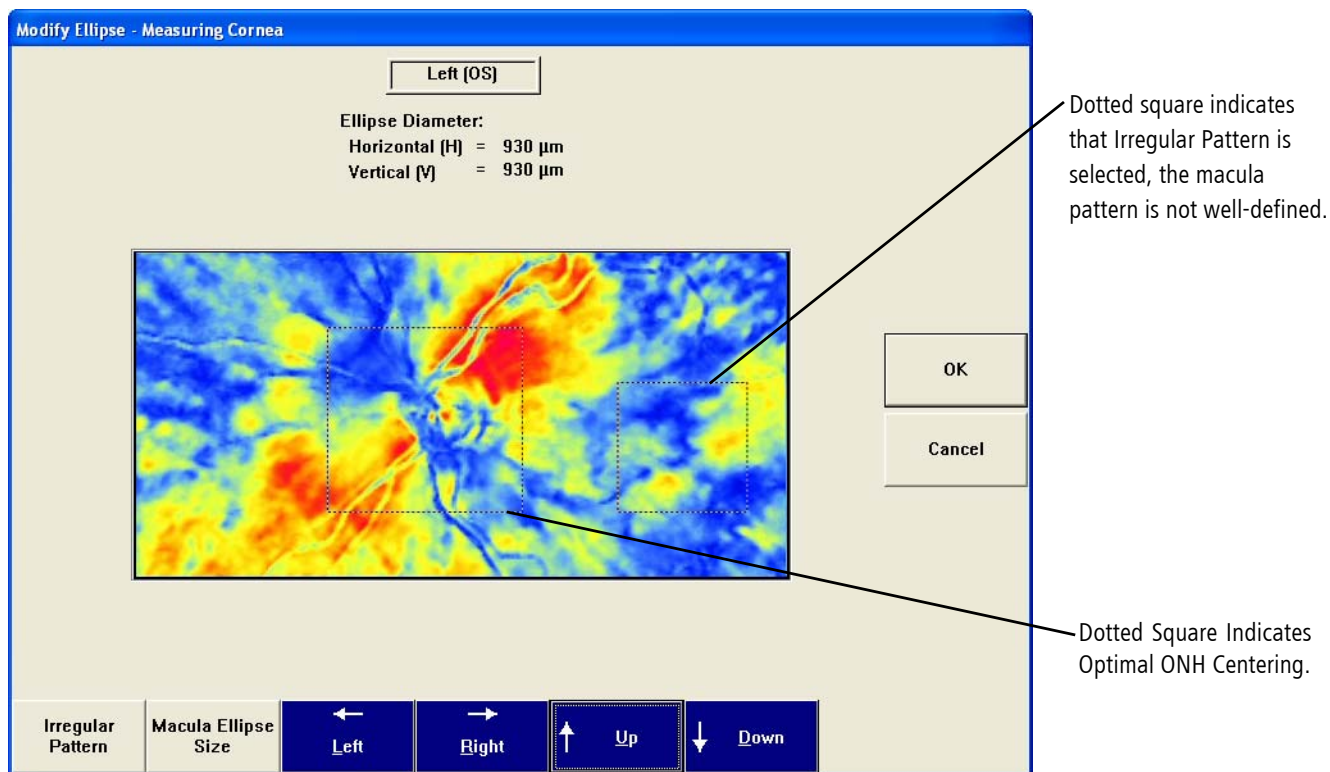
Figure 4-14 Modify Ellipse - Measuring Cornea Screen (Irregular Pattern)

When you have optimized the placement of the corneal measurement ellipse, press **OK** to go to the MODIFY ELLIPSE - MEASURING CORNEA screen for the next eye and optimize the placement of the corneal measurement ellipse in the same manner as for the first eye.

When finished, press **OK** and then **Accept** to go to the IMAGE CHECK - MEASURING CORNEA screen.
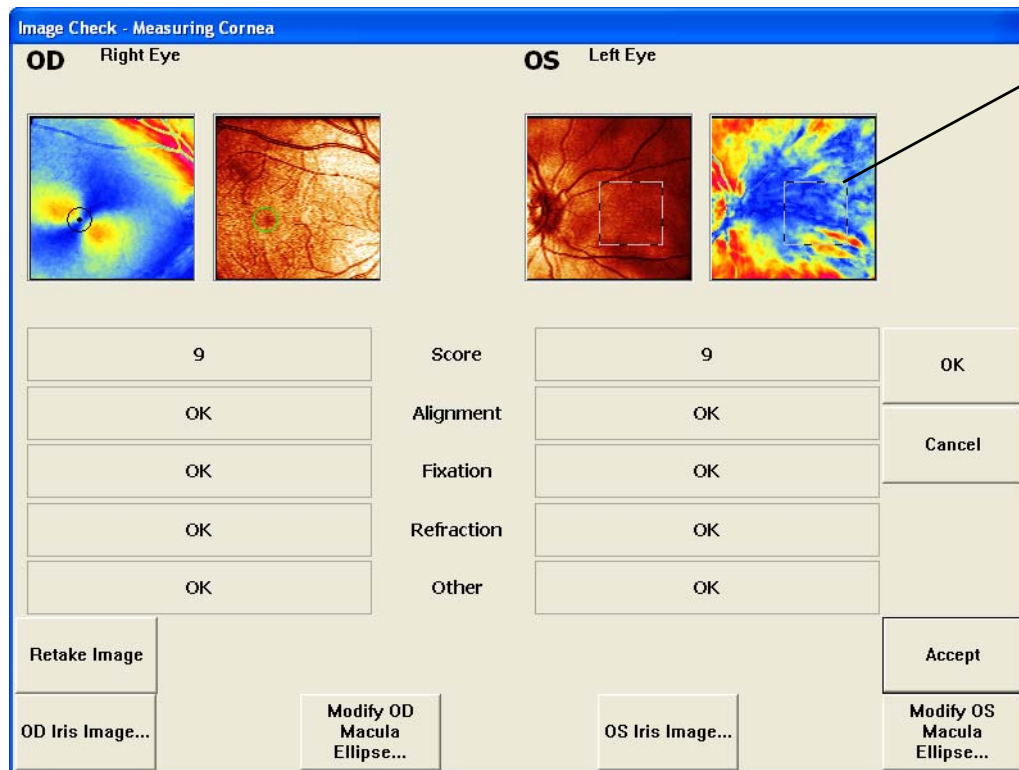

Dotted square indicates that Irregular Pattern is selected, the macula pattern is not well-defined.

Figure 4-15 Image Check - Measuring Cornea Screen

☞ Note: A normal macula is necessary for best results in assessment of the individual corneal compensation (ECC and VCC).

Checking the RNFL-I Measurement

Upon completion of the RNFL scans (as described in Scanning Procedure on page 4-3), review the scan Quality Scores and messages for both eyes on the IMAGE CHECK screen (Figure 4-17). If they are not satisfactory, select **Retake Image**. Press **OK** and the system will return to ACQUISITION to obtain new scans. To obtain a new scan of only the right eye, press **OK**. To obtain a new scan of only the left eye, select **Other Eye**. The system automatically replaces previous scan(s) with the new scan(s).

Modifying the Macular Ellipse after RNFL-I Measurement

After completion of the RNFL scans, or when reviewing measurements, on the IMAGE CHECK screen (Figure 4-17) select **Modify OD Macula Ellipse** or **Modify OS Macula Ellipse** to see the MODIFY MACULAR ELLIPSE screen (Figure 4-16). This screen is somewhat different than the MODIFY ELLIPSE - MEASURING CORNEA screen displayed right after taking the corneal measurement. The image displays only the macular ellipse region and there is no **Irregular Pattern** button.
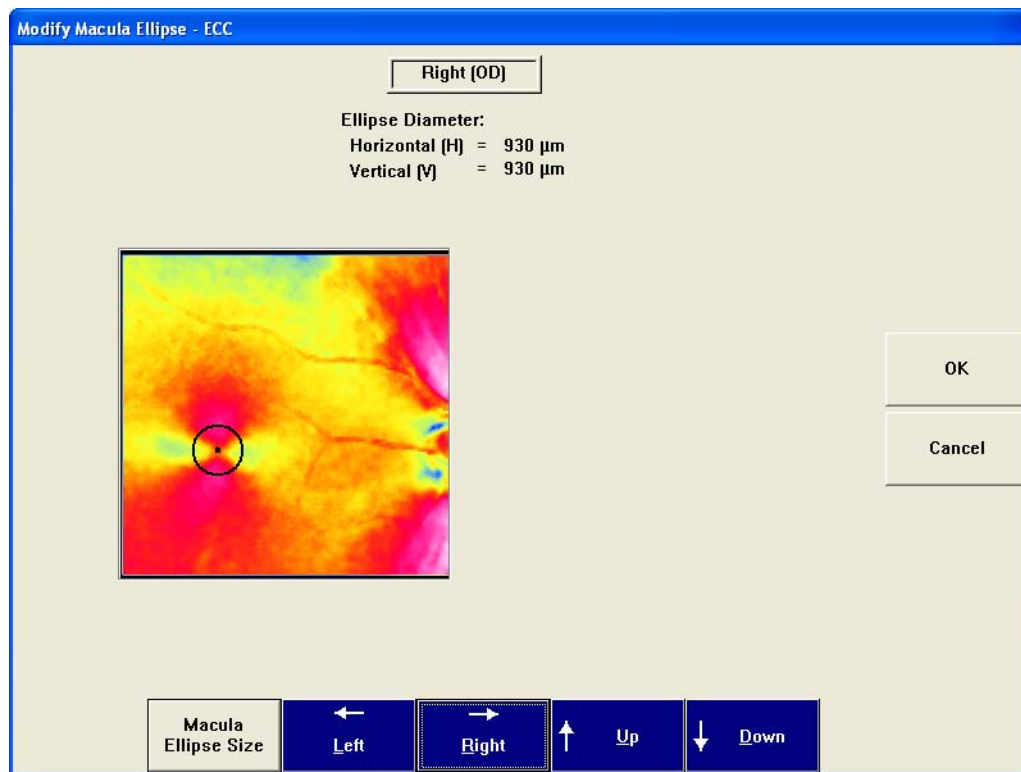
Figure 4-16 Modify Macular Ellipse Screen (ECC)

Modifying the ONH Ellipse

At the IMAGE CHECK screen (Figure 4-17), to change ellipse size or placement, select **Modify OD ONH Ellipse** or **Modify OS ONH Ellipse**. The MODIFY CALCULATION CIRCLE AND ONH ELLIPSE screen appears, as shown in Figure 4-18. The screen displays how the system automatically placed the ONH ellipse. It should be placed such that the ellipse is centered over the ONH.

☞ Note: If a reference image is already set for the patient, then the image is aligned to the reference image, and the ONH and macula ellipses are copied from the reference image. In this case, the **Modify ONH Ellipse** and **Modify Macula Ellipse** buttons on the IMAGE CHECK screen will not be shown for all images except the reference image (see Setting the Reference Image for Automatic Image Alignment on page 7-5).
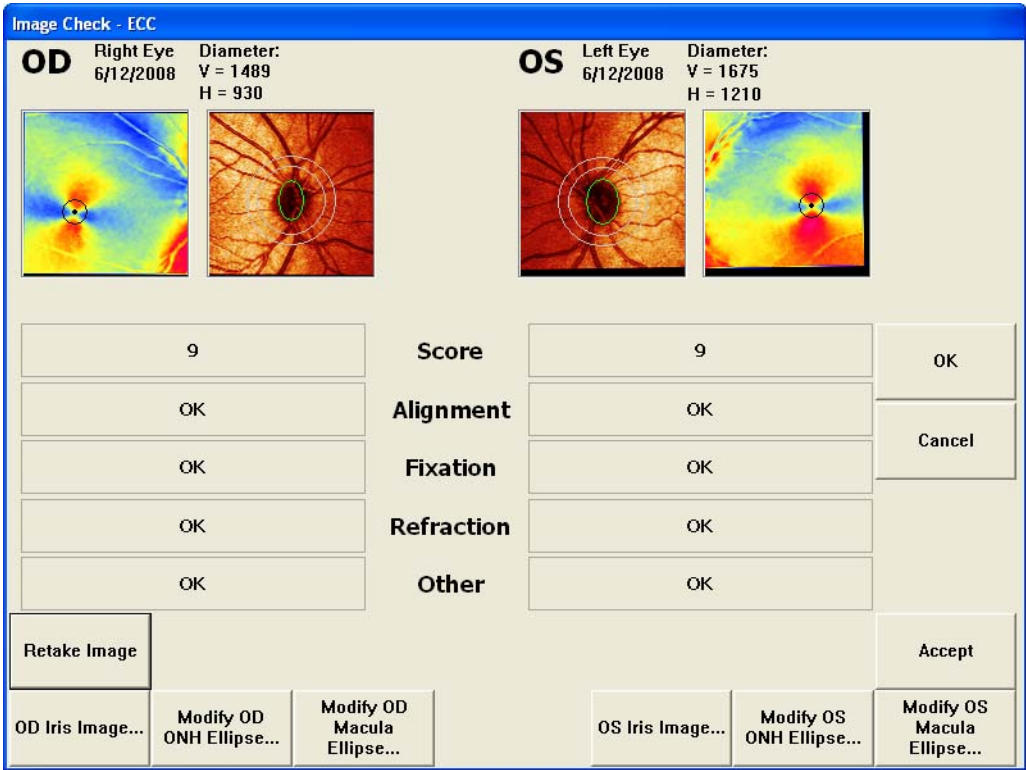
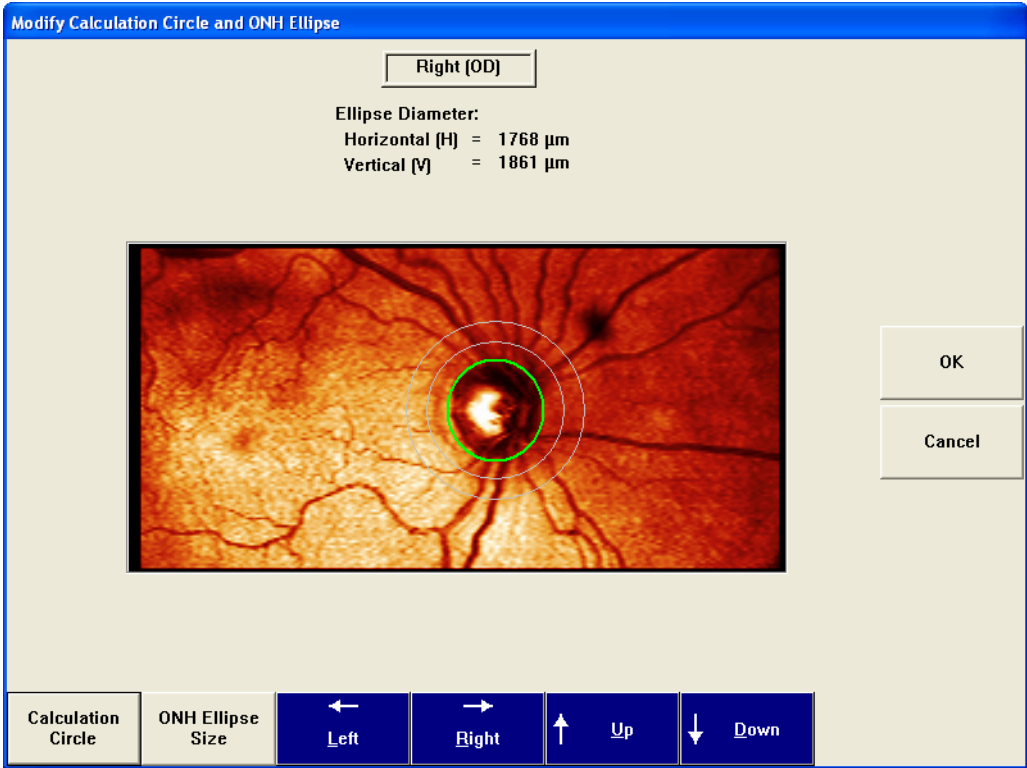*Figure 4-17 Image Check Screen (RNFL-I Measurement)*

Figure 4-18 Modify Calculation Circle and ONH Ellipse Screen (Position Buttons)

<u>Positioning the ONH Ellipse</u>

To modify the ONH ellipse position (ellipse shown in green), select the **ONH Ellipse Position** toggle button. The **ONH Ellipse Size** button is displayed along with the **Left**, **Right**, **Up**, and **Down** positional buttons as shown in Figure 4-18. Select the proper positioning buttons to center the ONH ellipse (one click moves one pixel, Shift-click moves 5 pixels). Proper placement of the ellipse over the ONH should appear as shown in Figure 4-19.

ONH ellipse well-centered   ONH ellipse not centered
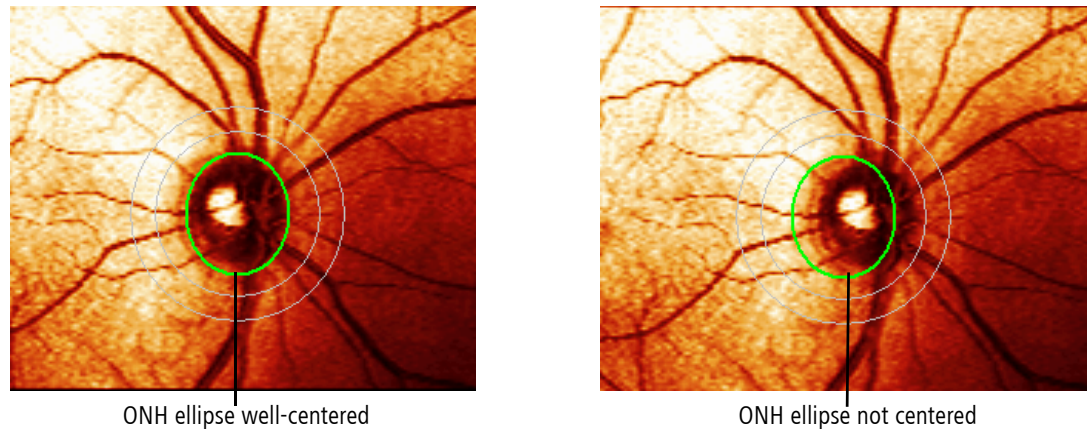
Figure 4-19 Proper Positioning of the ONH Ellipse

<u>Resizing the ONH Ellipse</u>

To modify the ONH ellipse size (ellipse shown in green), select the **OHN Ellipse Size** toggle button. The **ONH Ellipse Position** button is displayed along with the **Width +**, **Width -**, **Height +**, and **Height -** ellipse resize buttons, as shown in Figure 4-20. Select the proper resizing buttons to resize the ONH ellipse (one click moves one pixel, Shift-click moves 5 pixels). The ellipse position will remain unchanged.
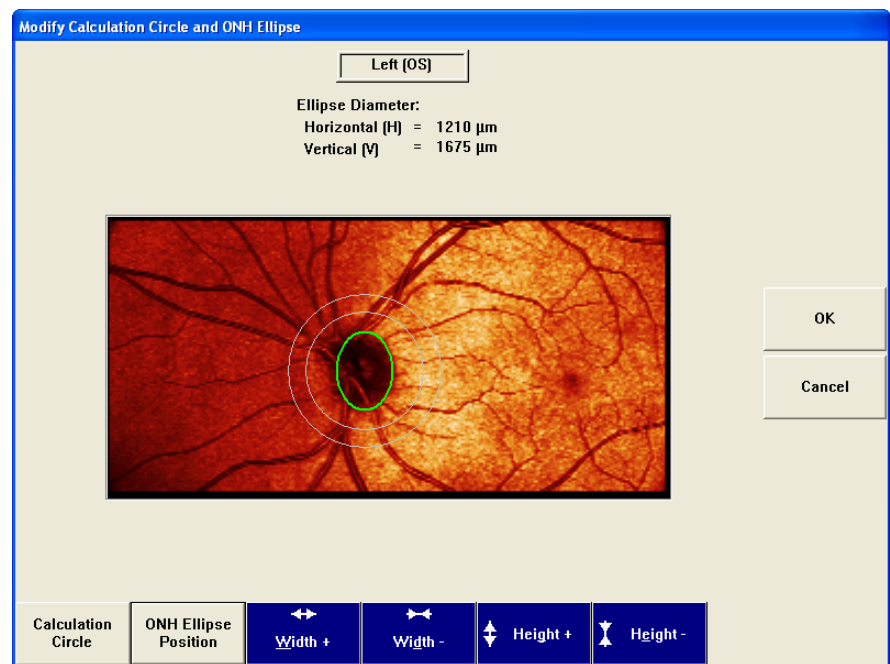

Figure 4-20 Modify Calculation Circle and ONH Ellipse Screen (Size Buttons)

Resizing the Calculation Circle

The Calculation Circle is the area between the two outer concentric circles on the IMAGE CHECK and other screens (Figure 4-21). This area is where measurement data is acquired for the TSNIT (Temporal-Superior-Nasal-Inferior-Temporal) and NFI parameters. By default, the Calculation Circle is set to the smallest size. It can be resized, if necessary, in order to obtain more meaningful results for patients with significant parapapillary atrophy (PPA) and scleral crescent (see Figure 4-24).

Calculation Circle
(area *between* these two circles)
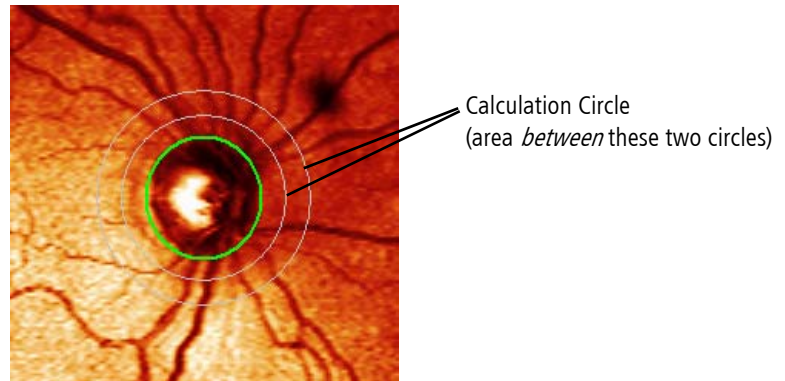
Figure 4-21 Calculation Circle

Use the following procedure to modify the size of the Calculation Circle in order to obtain higher quality measurement data for patients with PPA and scleral crescent (See Figure 4-24).
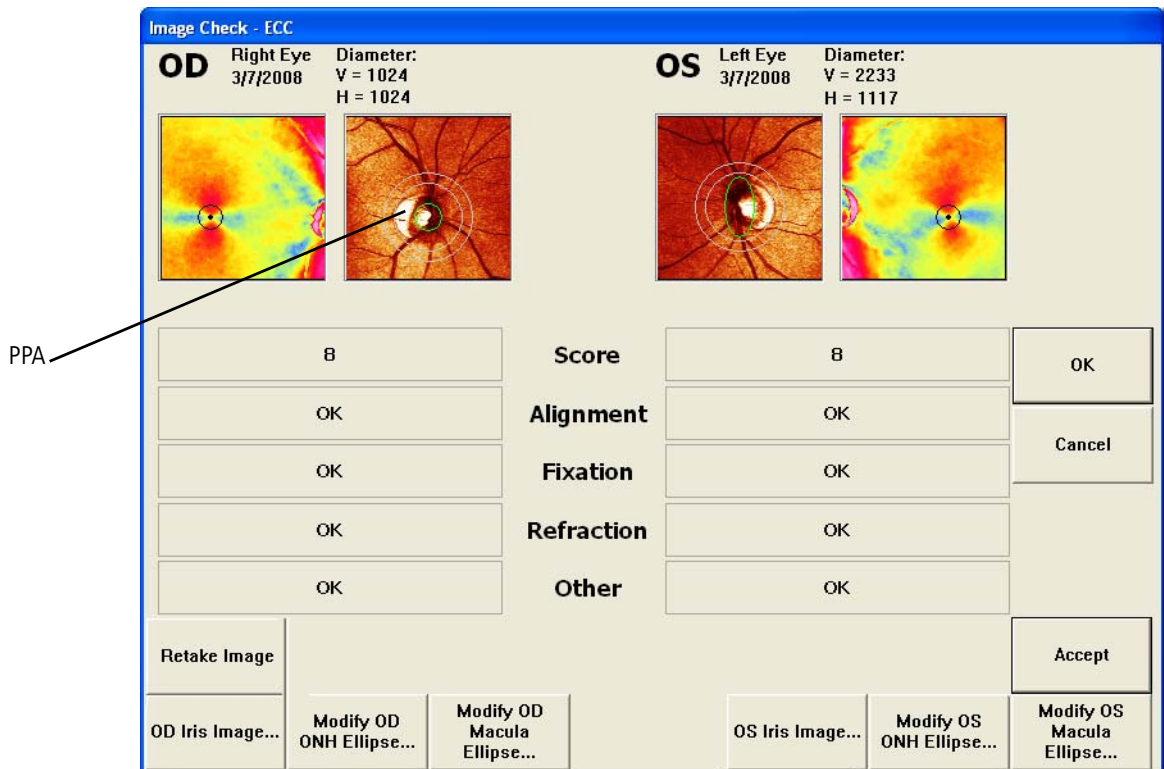

Figure 4-22 Calculation Circle with Parapapillary Atrophy (PPA)

1. From the IMAGE CHECK screen, select **Modify ONH Ellipse** for the desired eye. The MODIFY CALCULATION CIRCLE AND ONH ELLIPSE screen appears, as shown in Figure 4-18 Select **Calculation Circle**. The MODIFY CALCULATION CIRCLE AND ONH ELLIPSE screen appears, as shown in Figure 4-23.
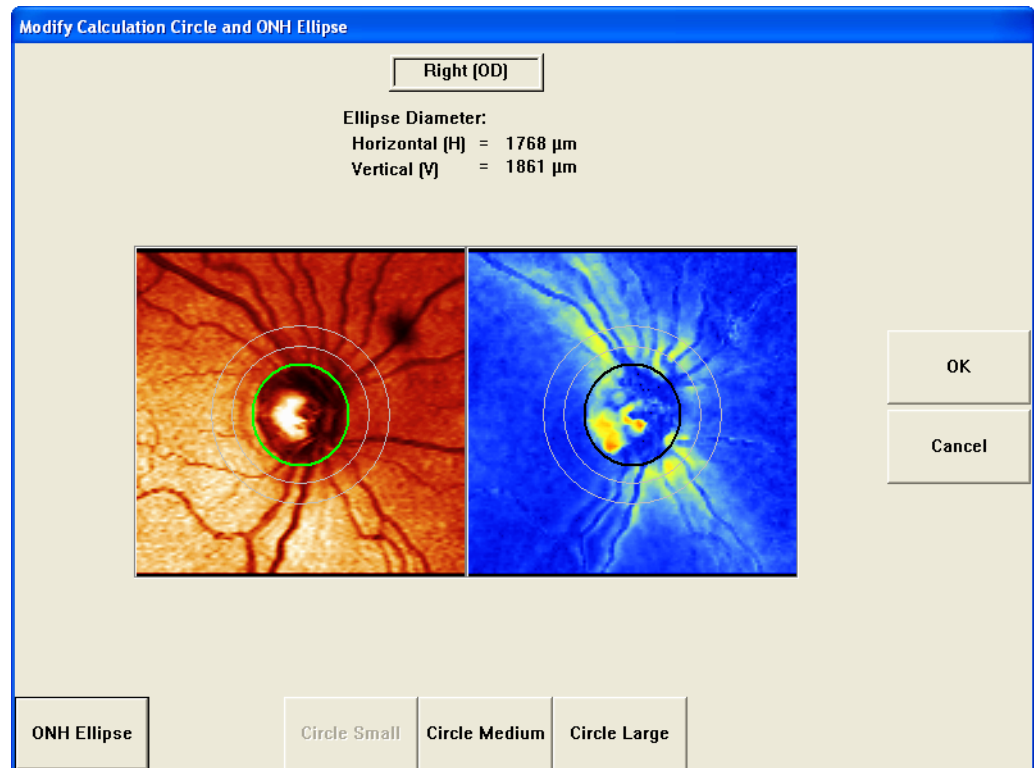

Figure 4-23 Fundus Image and Nerve Fiber Layer Map

2. **Circle Small** is the default setting. You can select **Circle Medium** or **Circle Large** to resize the Calculation Circle beyond the PPA or affected area in the image. The button for the currently selected circle size is deactivated. Figure 4-24 shows examples of small, medium, and large Calculation Circles.
3. You can see the results superimposed on the image, and visually determine whether or not the calculation circle is positioned optimally.
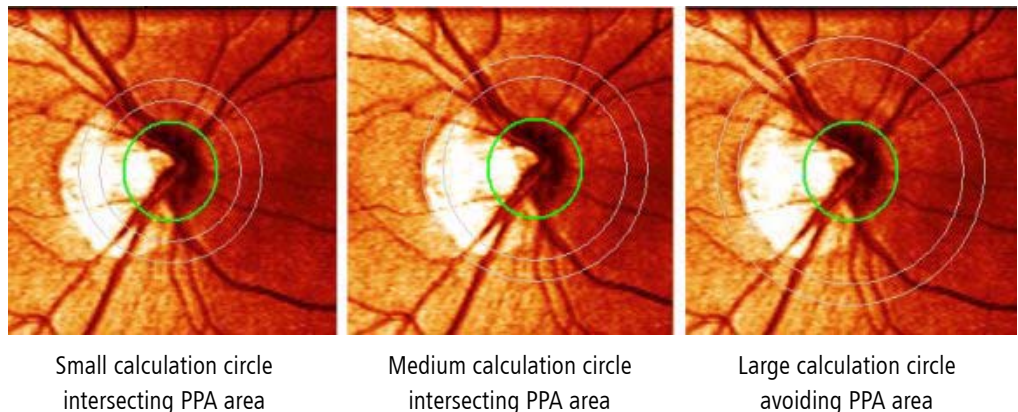

| Small calculation circle intersecting PPA area | Medium calculation circle intersecting PPA area | Large calculation circle avoiding PPA area |

Figure 4-24 Examples of Small, Medium, and Large Calculation Circles

☞ Note: When performing a GPA analysis, the software overlays the circle size from the reference image onto each subsequent image to calculate change. If it becomes necessary to resize the calculation circle for previously imaged patients, you must also resize the calculation circle on the reference scans prior to performing a GPA analysis.

Viewing the Iris Image

Select **(OD) Iris Image** or **(OS) Iris Image** to see the right and left iris image, respectively, with alignment overlays (Figure 4-25). The iris image allows you to see if the scan has been properly aligned. When the Q score is low, or when variation is high, you can use the Iris Image function to rule out alignment issues.
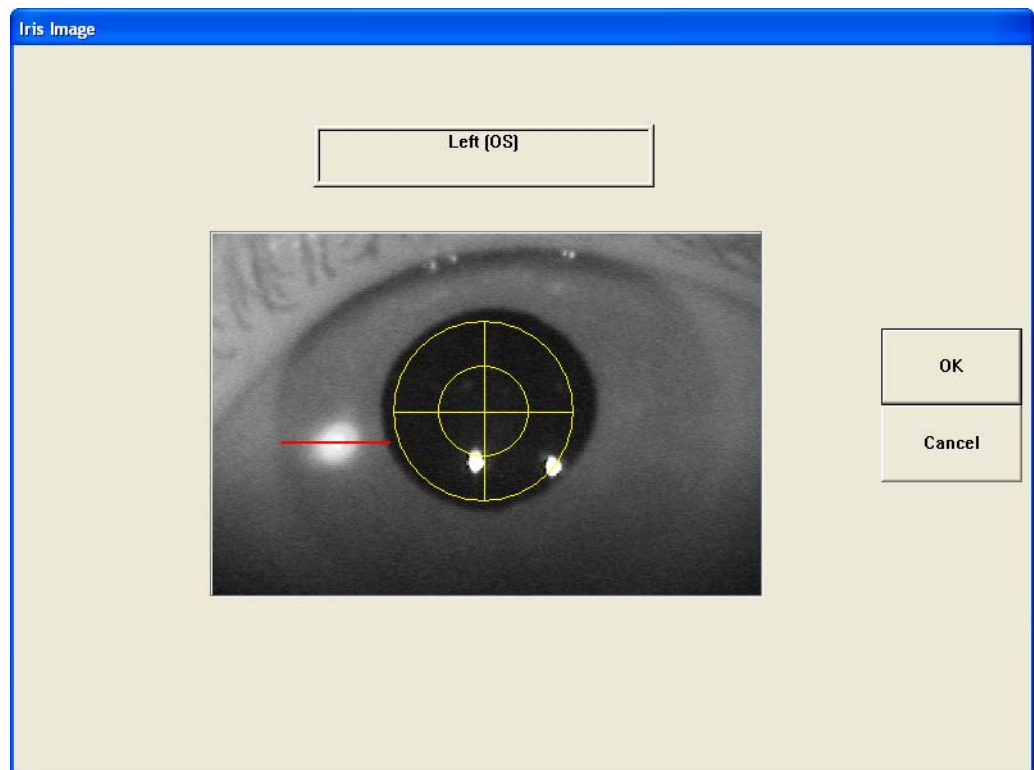

Figure 4-25 OS Iris Image Screen

Retaking the Image

☞ Note: Once image quality of an image has been accepted it cannot be retaken.

Upon completion of a scan you can choose to retake an image if the quality is not satisfactory.

At the IMAGE CHECK screen, select **Retake Image** to display the IMAGE RETAKE SELECTION screen (Figure 4-26). You can choose **Retake Both Eyes** (or **OK**), **Retake Right (OD) Eye**, or **Retake Left (OS) Eye**.
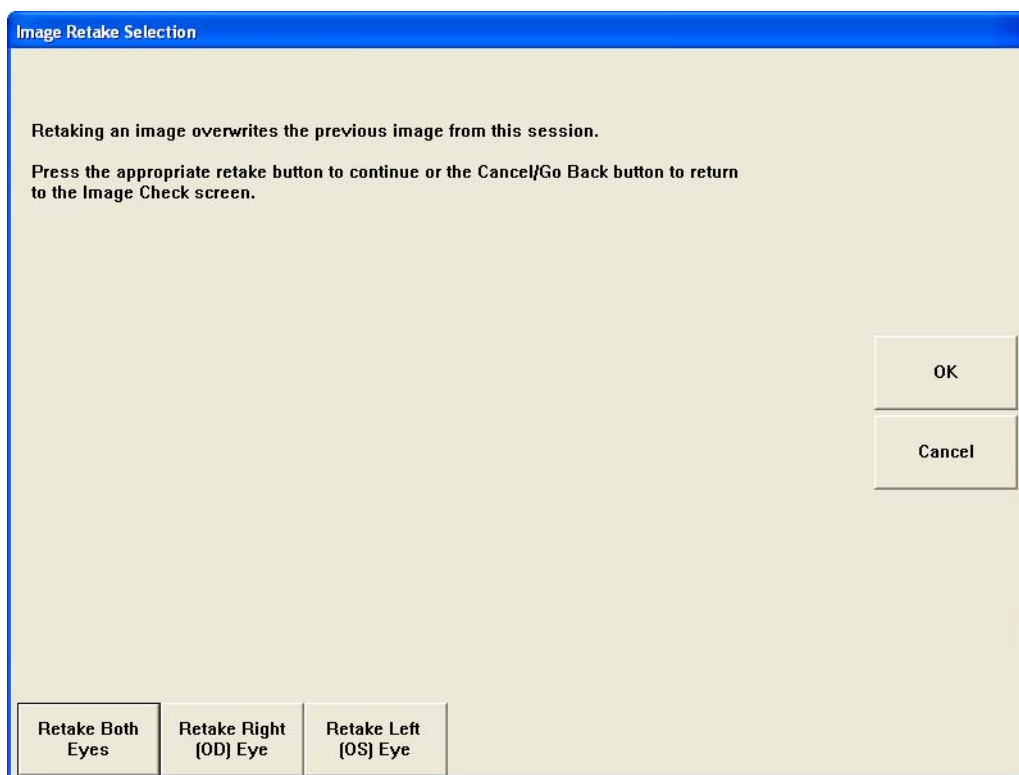

Figure 4-26 Image Retake Selection Screen

After you make your selection, the system returns to the previous ACQUISITION screen to obtain the selected new scan(s). The system will only overwrite the image or images that you retake. For example, if you only retake the image of the right eye, the previous image of the left eye is retained without being overwritten and the right image is replaced. When satisfied with the information on the IMAGE CHECK screen, select **Accept** or **OK** to go to the REVIEW CALCULATIONS screen (Figure 4-27).

Remeasuring the Corneal Compensation Image

During an exam, the system may alert you to reset compensation (obtain a new measurement for the corneal contribution), or you may choose to remeasure the corneal contribution to reestablish or update its value (for example, following cataract or refractive surgery) prior to a new RNFL exam.

Select **Reset Compensation** on an RNFL ACQUISITION screen (Figure 4-10 or Figure 4-11) and the ACQUISITION—MEASURING CORNEA screen appears. Refer to the Scanning Procedure section on page 4-3 to remeasure the cornea.

When satisfied with the image quality on the IMAGE CHECK screen, select **Accept** or **OK** to go to the REVIEW CALCULATIONS screen (Figure 4-27).

Final Step: Saving the Scans

At the end of exam acquisition, the Review Calculations screen (Figure 4-27) provides an abbreviated summary of the exam results including the TSNIT Graph, nerve fiber layer map, and parameter table. See (6) Symmetry Analysis for a discussion of the Review Calculations screen and the Symmetry Analysis report.
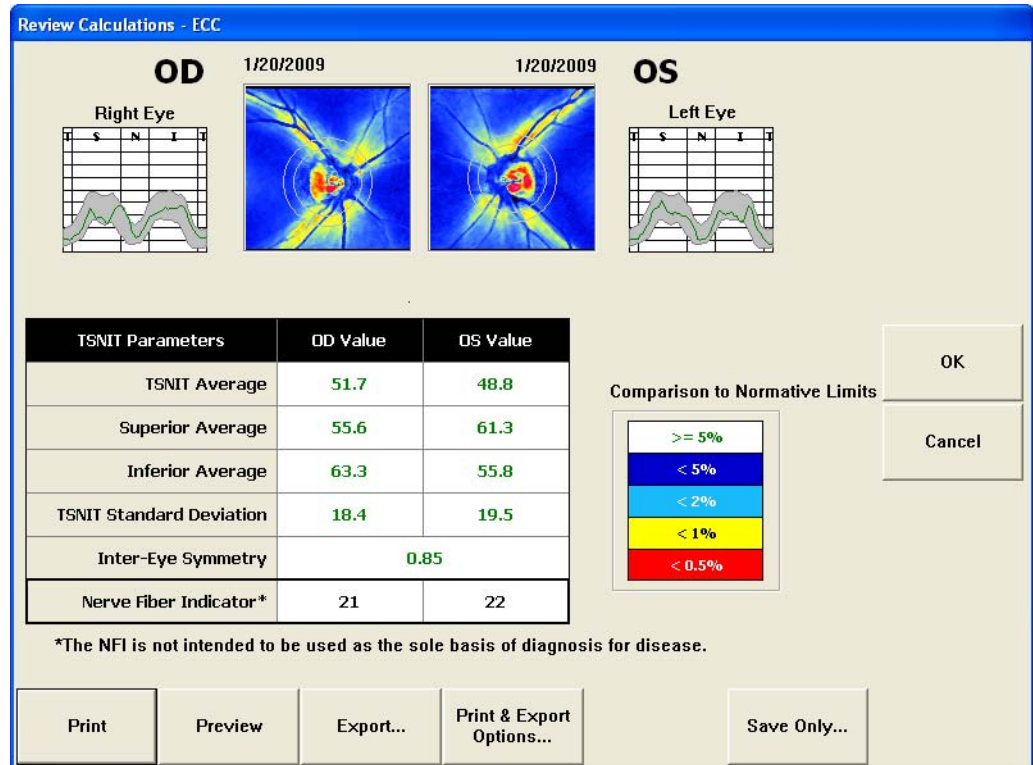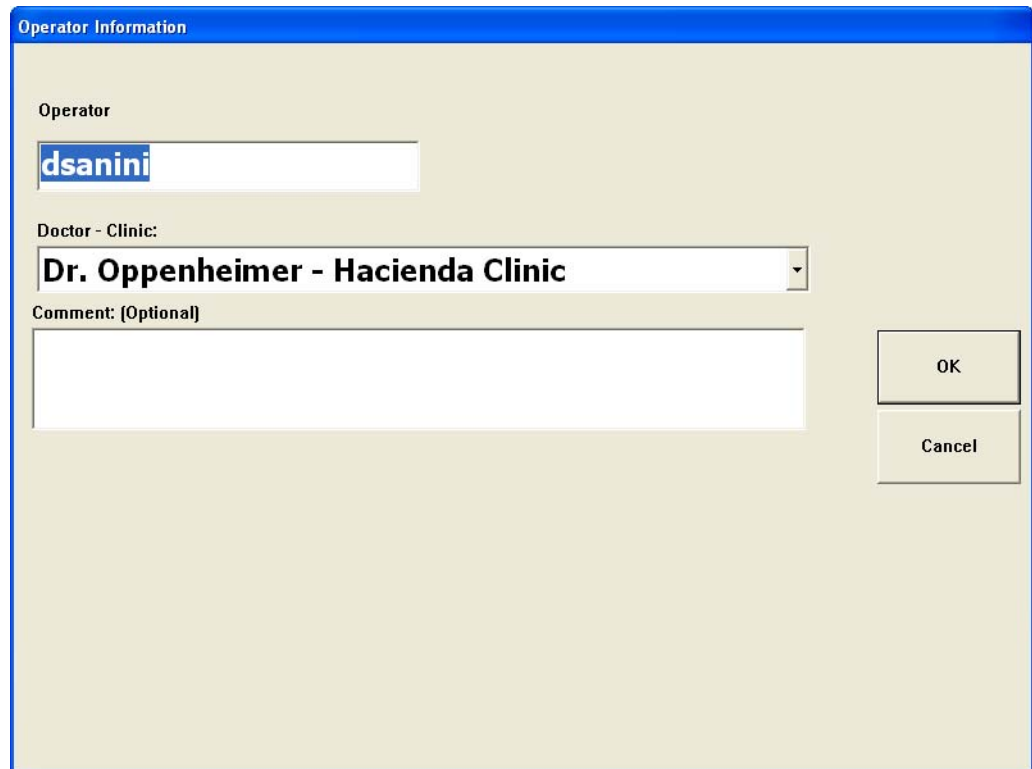

Figure 4-27 Review Calculations Screen – End of Exam Acquisition

The **Print**, **Export**, **Print & Export Options**, and **Save Only** (or **OK**) buttons will save the exams and display the Operator Information screen (Figure 4-28) where you can change the **Doctor - Clinic** field with any doctor that is associated with the current operator. This doctor is called the *Exam or Attending doctor* and is displayed on the Measurement List screen (Figure 5-1). The *Exam doctor* can be different from the *Primary doctor* associated with the patient and defined on the Patient Information screen (Figure 3-7).

You may also add any comments in reference to the exam in the **Comment** field. Text entered in the **Comment** field is displayed below the measurements list on the Measurement List screen when the measurement is selected, but is not displayed in any report.

The Operator will default to the currently logged in user. You can edit the **Operator** field if desired.
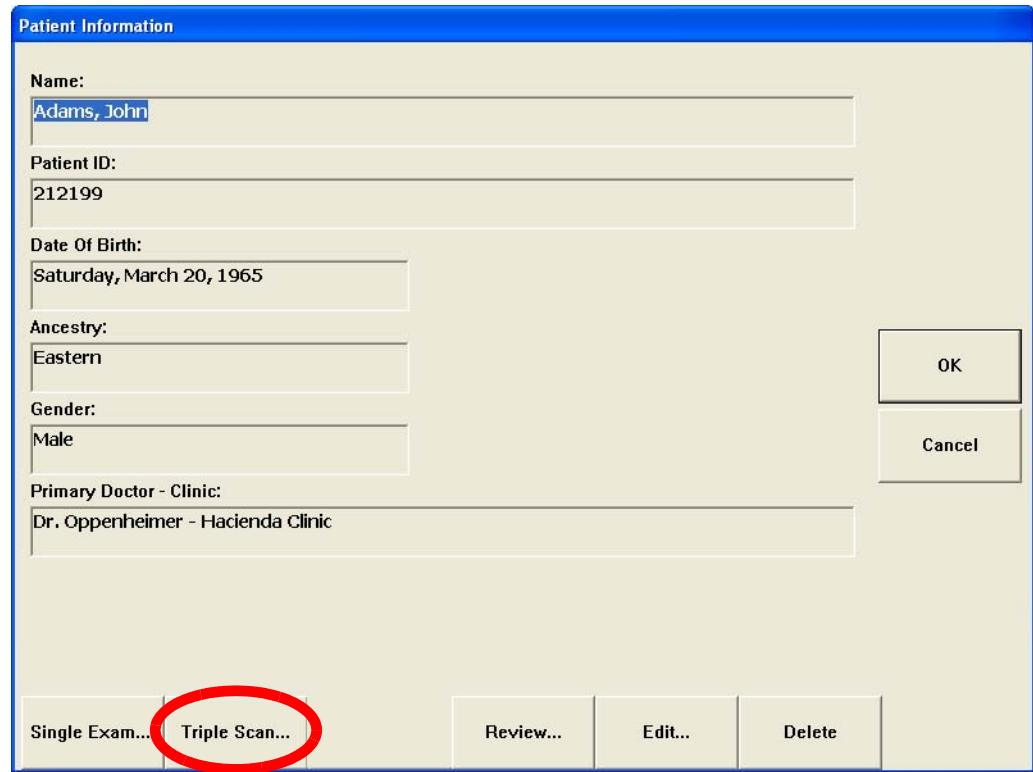

Figure 4-28 Operator Information Screen

Your exam is now complete. The system will automatically go to the MEASUREMENT LIST screen (see Figure 5-1 on page 5-2).

Acquiring Triple Scans

The Triple Scan option can be selected from the PATIENT INFORMATION screen (Figure 4-29).

Figure 4-29 Triple Scan Button on Patient Information Screen

Triple Scan acquisition allows you to acquire from 3 to 5 scans of one or both eyes. At the end of the Triple Scan acquisition, the REVIEW MEAN screen will be displayed to create a mean image from the acquired images. Triple Scan acquisition facilitates the creation of means of three measurements used in Extended Mode GPA analysis (see Fast and Extended GPA Modes on page 7-2).

See Figure 4-30 for the Triple Scan workflow for new and existing patients.
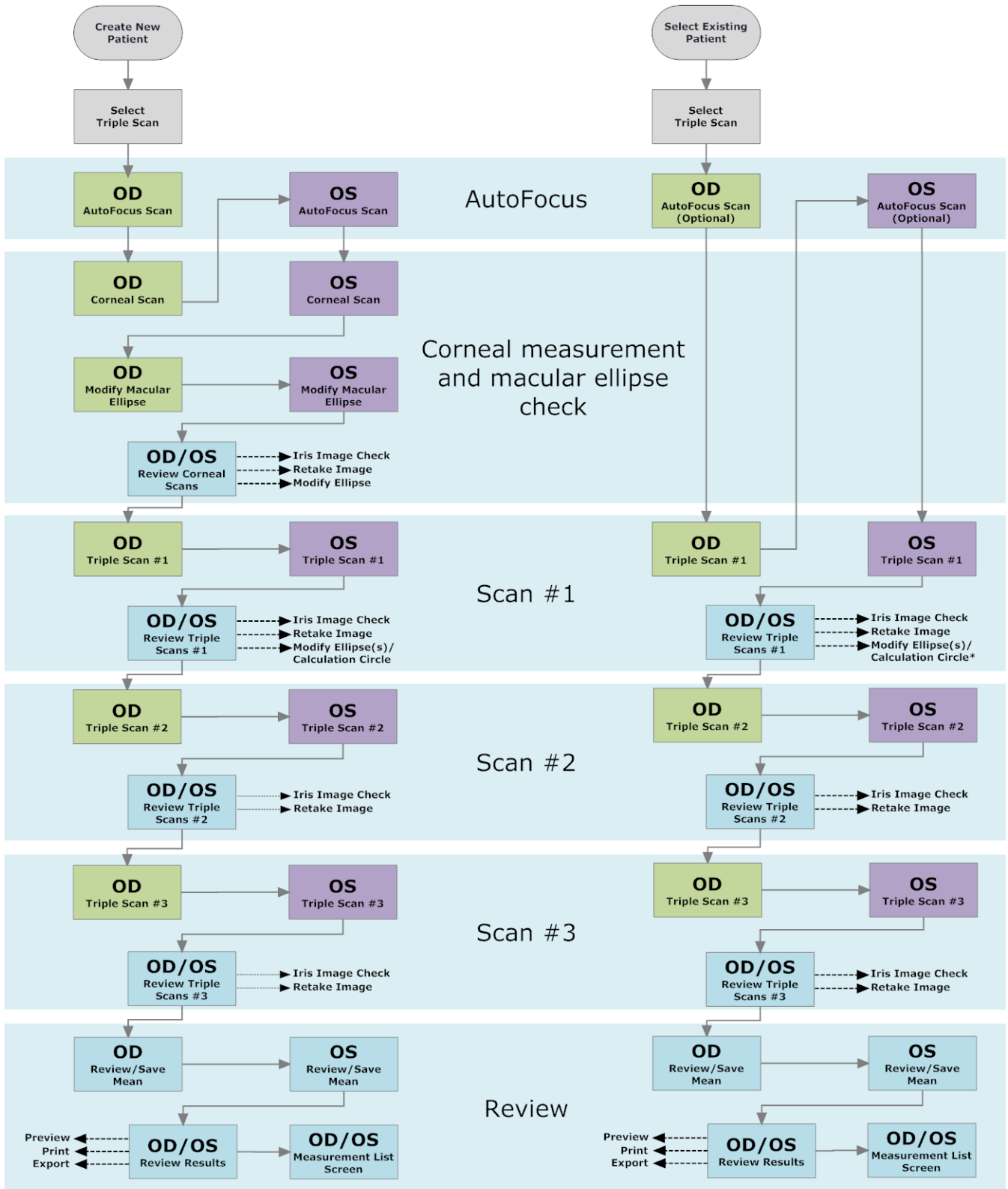
Triple Scan Workflow – New and Existing Patient

Figure 4-30 Triple Scan Workflow – New and Existing Patient

Follow these steps to acquire a Triple Scan:

1. On the PATIENT INFORMATION screen, select **Triple Scan** (Figure 4-29).

   If this is a new patient, you must first perform corneal compensation scan(s) as outlined in Scanning Procedure starting on page 4-3. When corneal compensation scan(s) are complete for a new patient or when refraction settings have been confirmed for an existing patient, the first Triple Scan ACQUISITION screen is displayed (Figure 4-31).
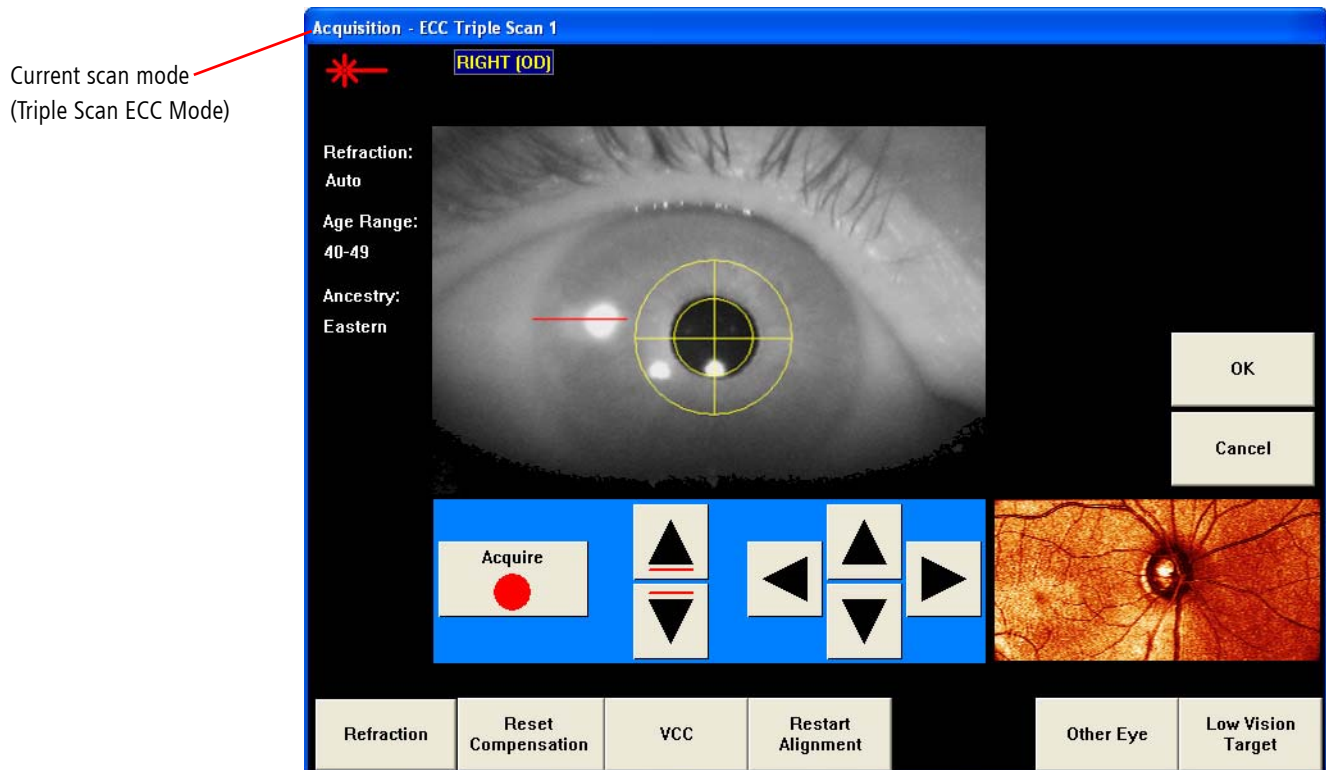
Current scan mode
(Triple Scan ECC Mode)

Figure 4-31 Acquisition Screen for Triple Scan 1

You can select **Refraction** to change the patient's refraction, **Reset Compensation** to reset corneal compensation and **Other Eye** to scan the other eye. **Refraction** and **Reset Compensation** are not available for subsequent scans in the Triple Scan process.

☞ Note: The imaging mode (ECC or VCC) cannot be switched once the first RNFL exam of the Triple Scan sequence is acquired.

☞ Note: Triple Scan acquisition may be cancelled during any part of the acquisition process. Images acquired are saved once the user accepts the image quality on the IMAGE CHECK screen during the Triple Scan sequence, even if the triple scanning is cancelled.

☞ Note: Patients whose last exam was acquired on a different instrument will be prompted to acquire one additional Triple Scan image.

2. Acquire the first RNFL scan as outlined in . The IMAGE CHECK screen is displayed, giving you the opportunity to modify the image, retake image(s) or accept the scan(s). When you select **Accept** or **OK**, the second Triple Scan ACQUISITION screen is displayed (Figure 4-32).
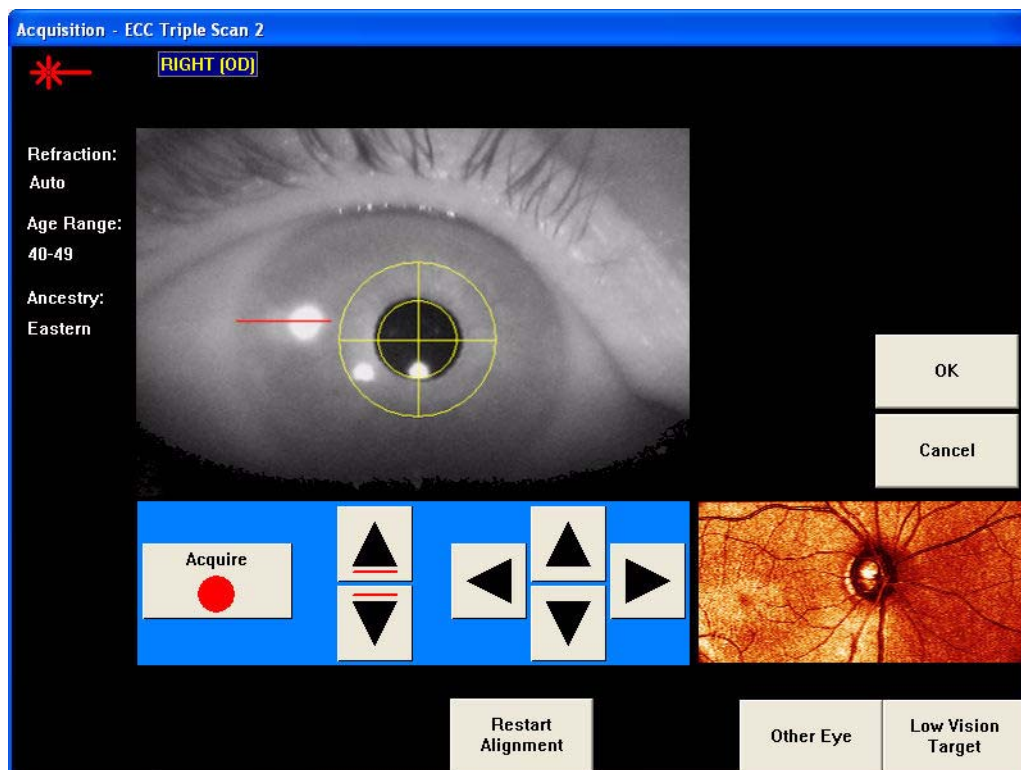

Figure 4-32 Acquisition Screen for Triple Scan 2

This same process is used to acquire subsequent scans. You can acquire up to five scans in one Triple Scan acquisition process. However, only the best three (based on lowest variability or STD) will be selected for the mean.

3. Acquire the second and third RNFL scans. After you accept the images acquired from the third scan, the REVIEW MEAN screen is displayed (Figure 4-33).
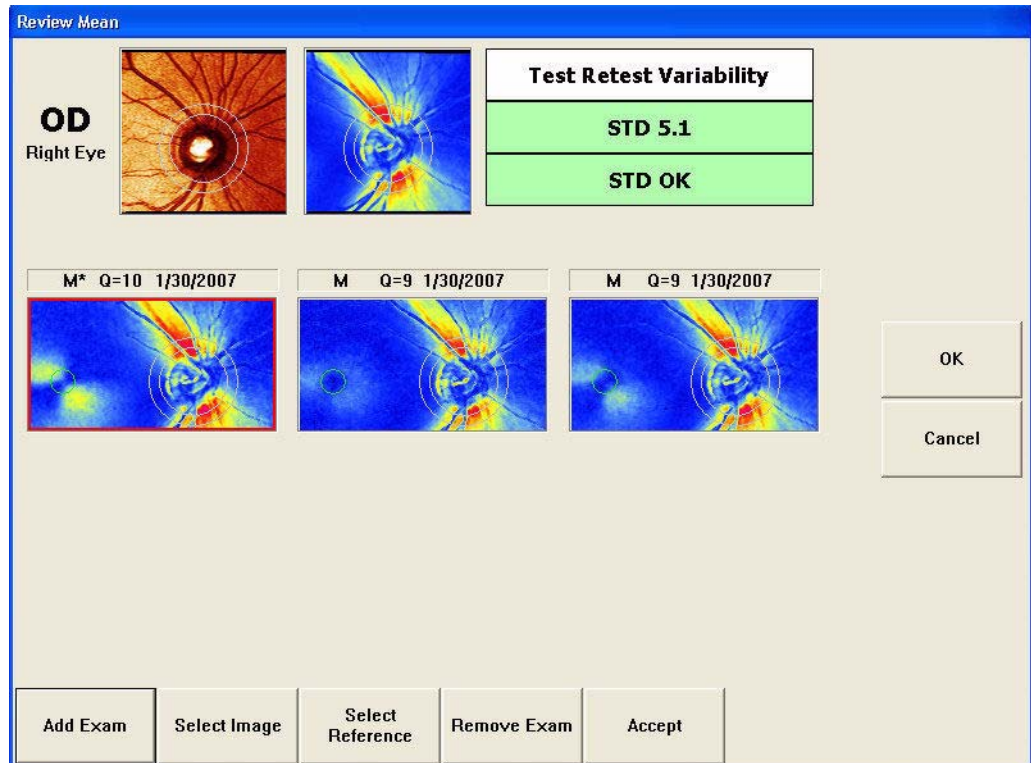

Figure 4-33 Review Mean Screen

The REVIEW MEAN screen enables you to evaluate the first three scans' quality, to accept the scans or to acquire one or two more scans, as needed. Select **Add Exam** to go to an ACQUISITION screen to acquire a fourth or fifth Triple Scan.

☞ Note: When creating a mean from the MEASUREMENTS LIST screen, the **Add Exam** button will display a list of previously acquired exams to select, rather than an ACQUISITION screen during a Triple Scan.

If there is no reference image for the eye when performing a Triple Scan, a reference image will be automatically created from the first acquired image. See Creating a Mean Measurement Manually on page 5-8 for more information on the REVIEW MEAN screen.

The Quality Score (Q) is given for each image, and can range from 1 to 10, with 10 indicating highest quality. If the Test Retest Variability is **Too High** or **Marginal** for an image, the software will prompt you for additional images until five scans have been accepted.

4. Select **Accept** or **OK** to create the mean and go to the REVIEW CALCULATIONS screen (see Final Step: Saving the Scans on page 4-25).

☞ Note: The Triple Scan images reside on the GDxPRO as single nerve fiber layer maps, sorted by exam time.

(5) Managing Measurements

Chapter Overview

This chapter describes how to select measurements and generate different types of reports. Topics covered in this chapter include:

- Automated Report Generation Summary, page 5-1
- Selecting Measurements, page 5-1
- On Screen Exam Review, page 5-5
- Printing/Exporting Exams, page 5-6
- Deleting Measurements, page 5-7
- Creating a Mean Measurement Manually, page 5-8

Automated Report Generation Summary

GDxPRO offers automated report selection for ease in generating reports. Follow these steps to generate a report:

1. Select the patient you want a report for (see Selecting an Existing Patient on page 3-5).
2. On the PATIENT INFORMATION screen, select **Review** to display the MEASUREMENT LIST screen.
3. On the MEASUREMENT LIST screen, the software automatically selects measurements for the report (see Auto Selection on page 5-4).
4. On the MEASUREMENT LIST screen, select **Review** or **OK** to display an on screen report. The report depends on the type and number of measurements selected (see On Screen Exam Review on page 5-5). To print the report without review, select the **Print & Export Options** button (see Printing/Exporting Exams on page 5-6).

Selecting Measurements

At the PATIENT INFORMATION screen (see Patient Information Screen on page 3-8) for a selected patient, select **Review** to display the MEASUREMENT LIST screen (Figure 5-1).

The MEASUREMENT LIST screen allows you to select one or more measurements (images or exams) for the selected patient. For a Symmetry Analysis report, select one right (OD) and one left eye (OS) of the same image type. For a Progression Analysis report (GPA), select three to eight measurements of the same eye and image type. You may select OD and OS measurements simultaneously. The software automatically selects measurements to generate a report based on the type and number of measurements in the MEASUREMENT LIST screen (see Auto Selection on page 5-4).

The list of measurements is sorted by **Exam Date** (acquisition time)—old to new. You can review these on screen, print reports, export, or delete.

GDx Device Identifier

Column width can be changed by dragging borders with mouse

Color-coded Eye Icons

Select **Mean Image List** to view only mean measurements

Select **Print & Export Options** to print or export   Select **Review** for on screen review

Figure 5-1 Measurements List - Full Screen

The **Mode** column identifies the image type, and whether the image is a baseline image (see Setting Baselines on page 7-6), reference image (see Setting the Reference Image for Automatic Image Alignment on page 7-5), or mean image (see Creating a Mean Measurement Manually on page 5-8).

The **Exam Doctor** column displays the *Exam doctor* for the measurement displayed, either selected during exam acquisition or mean generation. The *Exam doctor* can be different from the *Primary doctor* associated with the patient and defined on the PATIENT INFORMATION screen (Figure 3-7).

A GDx Device identifier is displayed below the operator name to identify the device on which the selected measurement was acquired.

Column width can be resized by dragging the borders between columns with your mouse. Your changes are saved with the software.

Image types are identified by a small icon at the left of the screen under the **Eye** column (see Figure 5-1). This eye icon is color-coded based on the image type and contains the text 'OD' or 'OS' for Right or Left eye, respectively.

Table 5-1 Image Types and Eye Icon Colors

| Image Type	Description	Eye Icon Color
Cornea	Cornea is a corneal measurement image performed at the patient's first visit.	Yellow
Single ECC/VCC	ECC refers to Enhanced Corneal Compensation. VCC refers to Variable Corneal Compensation.	Green
Single ECC/VCC used in mean	Single ECC/VCC used in mean creation.	Green
Mean of two measurements	A mean of two measurements created by averaging *two* single ECC/VCC measurements.	Dark Blue
Mean of three measurements	A mean of three measurements created by averaging *three* single ECC/VCC measurements.	Dark Blue
SCC	SCC refers to Software Corneal Compensation. SCC images were produced by earlier GDx systems and can be reviewed and printed, but not modified or acquired on the GDxPRO.	Green
FCC	FCC refers to Fixed Corneal Compensation. The FCC exam was produced by earlier GDx Access systems. FCC images can be reviewed and printed, but not modified or acquired on the GDxPRO.	Grey

You can view the entire list of measurements, or only a list of mean measurements by selecting the **Mean Image List** button. The screen title will change to MEASUREMENT LIST - MEAN when you select the **Mean Image List** button (Figure 5-2). Return to the full measurement list by selecting the now named **Full List** button (instead of **Mean Image List**).
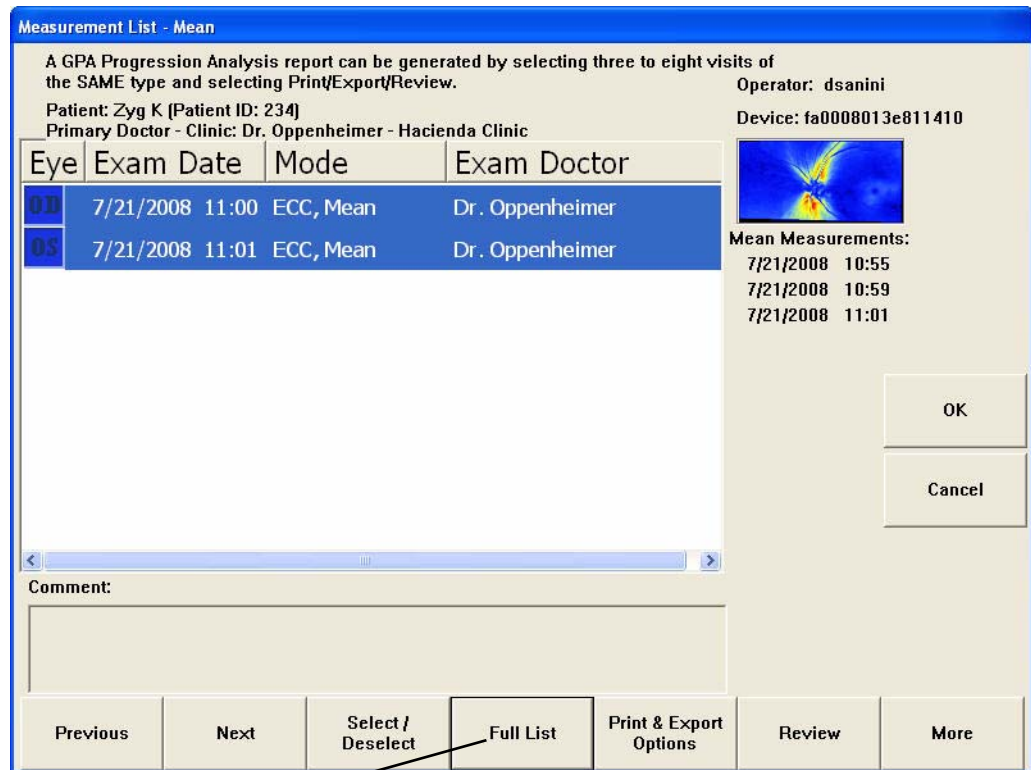
Select the **Full List** button to return to the full list of measurements.

Figure 5-2 Measurements List - Mean Screen

If you wish to review the exam(s) or preview the reports on screen before printing and/or exporting, select **Review**. If you wish to print and/or export exam(s) or reports without review, select **Print & Export Options** (see Printing/Exporting Exams on page 5-6).

Auto Selection

When you select **Review** on the PATIENT INFORMATION screen, GPA automatically selects the exams to be analyzed. Auto selection is based on the current measurement (last acquired) for both OD and OS and the baseline exams. The measurements automatically selected are of the same type as the current measurement.

If the current measurement is a mean created from *three* measurements, only previously acquired means of three measurements will be selected up to the first mean of three measurements baseline, or the oldest acquired image if a baseline mean of three measurements does not exist.

If the current measurement is a single or mean created from *two* measurements then all previous measurements will be selected up to the first single baseline, or the oldest acquired image if a baseline set does not exist.

If the current measurement is the only measurement of the same type from the same instrument, only the current measurement will be selected.

Baselines and reference images may also be automatically set.

Measurements may be marked for exclusion from automatic selection (See Excluding Measurements on page 7-7).

Manual Selection

To select measurements, first *highlight* one by using the **Previous** or **Next** buttons to scroll up and down the list. A highlighted measurement is indicated by a surrounding dotted box and a selected measurement has a blue background. Only one measurement is highlighted at a time. Use **Select/Deselect** to select or deselect the highlighted measurement. You can use the mouse by clicking to select one measurement, Ctrl-click to select multiple measurements, or Shift-click on two measurements to select all intervening measurements. You may also use the up and down arrow keys, and Page Up and Page Down keys on the keyboard to move through the list.

As a measurement is highlighted or selected, a thumbnail image of the measurement is displayed in the upper right of the display. Operator comments (entered at exam acquisition or mean generation) are displayed below the list for the currently highlighted measurement (see Figure 5-13).

On Screen Exam Review

The review screens displayed when you select the **Review** or **OK** button on the MEASUREMENT LIST screen depend on the type and number of measurements selected:

- The IMAGE CHECK–MEASURING CORNEA screen will be displayed for corneal measurements. See Checking the Corneal Measurement on page 4-14 for a discussion of the IMAGE CHECK–MEASURING CORNEA screen.
- The REVIEW CALCULATIONS screen will be displayed if there are only enough measurements for the Symmetry Analysis report. See (6) Symmetry Analysis for a discussion of the REVIEW CALCULATIONS screen and the Symmetry Analysis report. Examples of Symmetry Analysis reports are shown in Symmetry Analysis Examples beginning on page 6-12.
- The PROGRESSION ANALYSIS REPORT screen will be displayed if enough measurements were selected for GPA. See (7) Guided Progression Analysis (GPA) for a discussion of the Progression Analysis report. Examples of GPA reports are shown in GPA Examples beginning on page 7-16.

Printing/Exporting Exams

GDxPRO provides multiple report formats for printing and exporting. On the REVIEW CALCULATIONS screen (Figure 6-1), or with the desired measurements selected on the MEASUREMENT LIST SCREEN (see Selecting Measurements on page 5-1), you may print and/or export the measurements.

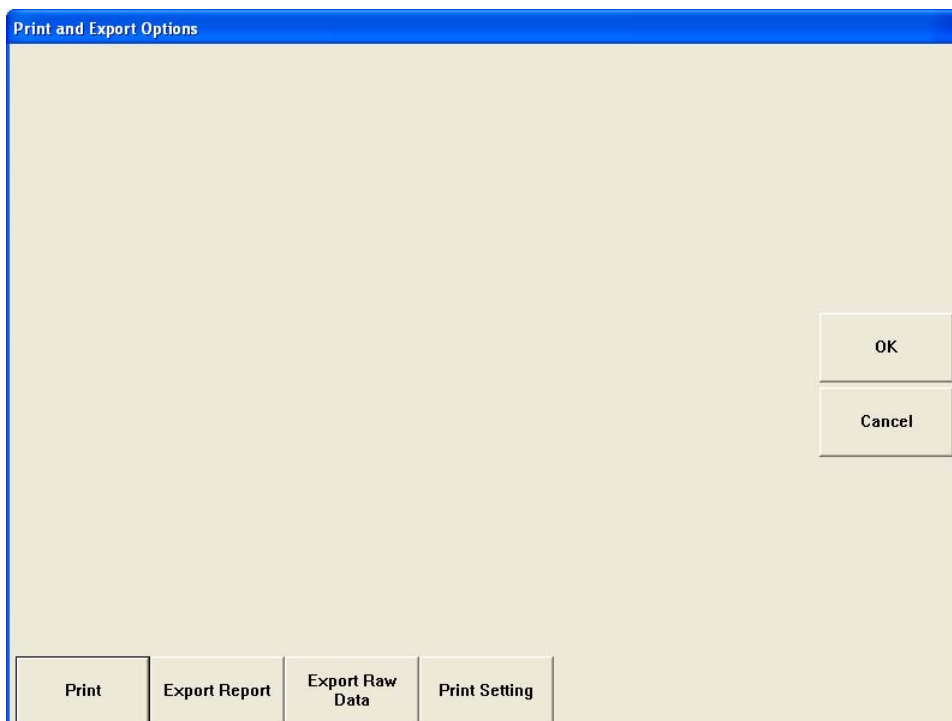Select **Print & Export Options** to display the PRINT AND EXPORT OPTIONS screen (Figure 5-3).

Figure 5-3 Print and Export Options Screen

Print will print one copy of the generated report(s) to the current default printer.

Export Report will export the generated report(s) to the default export path (see **Default Import/Export Path (optional) on** page 2-10). Select **Yes** to use the default export folder or select **No** to display a **Browse for Folder** dialog where you can select the export folder you want to use.

Export Raw Data will export the selected measurement(s) raw data to the default export path (see **Default Import/Export Path (optional) on** page 2-10). Select **Yes** to use the default export folder or select **No** to display a **Browse for Folder** dialog where you can select the export folder you want to use. The raw data includes the measurement data, calculations, patient data, and images (not formatted into reports). This allows you to analyze the data on another GDxPRO, store the data in an external drive, etc.

Print Setting will open the GDxPRO's PRINTERS AND FAXES window where you can see your printers, view and change printer settings, and set the default printer.

Deleting Measurements

To delete a measurement from the MEASUREMENTS LIST window, select the **More** button on the MEASUREMENT LIST screen to see the **Delete** button (Figure 5-4).
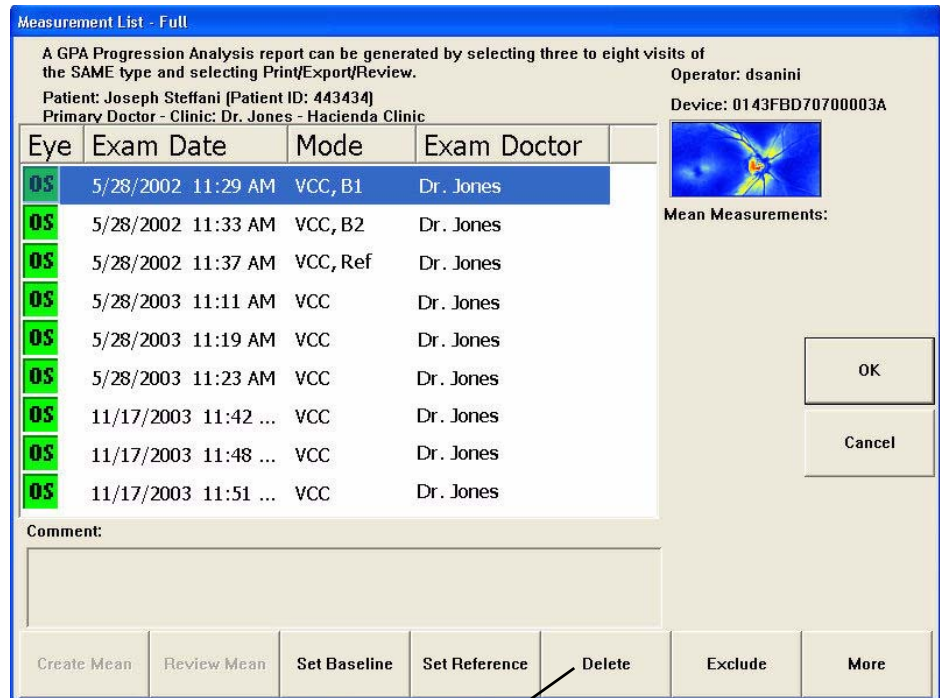
Select the **Delete** button to delete the selected measurement(s).

Figure 5-4 Measurement List Screen – Additional Buttons

Select the measurement(s) you want to delete, and then select the **Delete** button. A **Confirm Delete** dialog will be displayed (Figure 5-5).
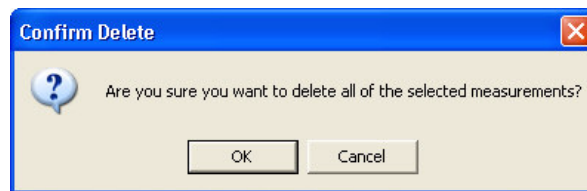

Figure 5-5 Confirm Delete Dialog

Select **OK** to delete the measurement(s) or **Cancel** to cancel the deletion.

- Multiple measurements selected for a given patient can be deleted at a time.
- Reference measurements cannot be deleted. You must first deselect a measurement as the reference image to delete it.
- Measurements that are used as part of a mean cannot be deleted. To delete measurements used in a mean, first remove the measurement from the mean and then delete it, or delete the mean.
- Deleting a mean will NOT delete images associated with that mean.
- Once deleted, the measurement information cannot be recovered.

Creating a Mean Measurement Manually

To create a mean image, select two to five measurements of the same type (ECC or VCC) and the same eye acquired on the same instrument within thirty days of each other, and then select the **Create Mean** button (Figure 5-6). Select the **More** button if you cannot see the **Create Mean** button. The **Create Mean** button is only active if you have two to five ECC or VCC measurements selected of the same eye.

☞ Note: Although GPA allows the creation of means from two scans, Extended Mode requires means of three.

Figure 5-6 Create Mean

If one of the selected measurements was acquired more than thirty days of another selected measurement, an error dialog (Figure 5-7) will be displayed and the mean image will not be created.
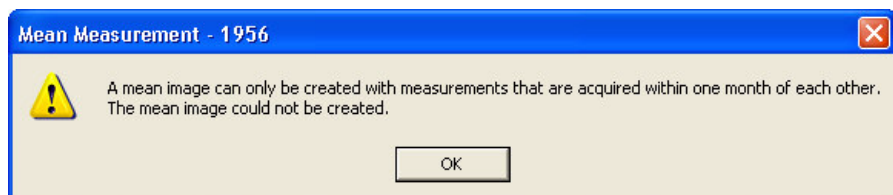

Figure 5-7 Create Mean Error dialog

Mean measurements cannot be used to create a mean, and a single measurement already used in a mean cannot be used to create another mean. As a general rule, a mean can only be created with measurements from the same GDxPRO instrument and/or calibration. The reference image and baseline images **can** be part of a mean.

After selecting the **Create Mean** button, the REVIEW MEAN screen is displayed (Figure 5-8).
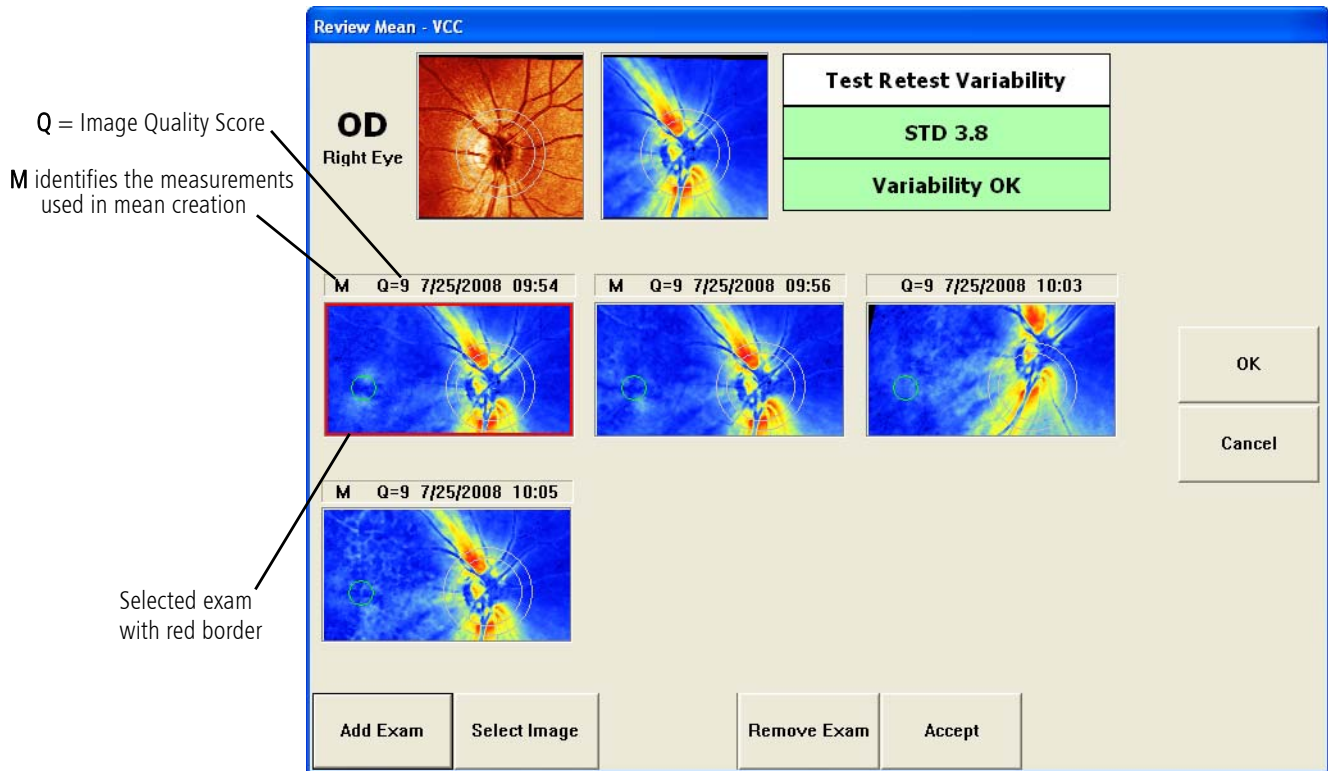
Figure 5-8 Review Mean Screen

If more than three measurements are present, the best three (based on lowest variability or STD) will be automatically selected for the mean.

Q represents the Image Quality Score. **M** identifies which three measurements are used to create the mean.

<u>Test Retest Variability STD</u>

At upper right, the screen reports the standard deviation (STD) of the scans using a plain language description, number, and background color as follows:

- **Variability OK:** STD $\leq$ 8.5, Green
- **Variability Marginal**: 8.5 < STD $\leq$ 11.5, Yellow
- **Variability Too High**: STD > 11.5, Red

Managing Measurements

If there is no reference image for the eye when creating a mean, a reference image will be automatically created from the selected images with the highest Quality Score. The REVIEW MEAN screen will display a **Select Reference** button and will have an asterisk* to the right of the **M** for the reference image (Figure 5-9). You can use the **Select Image** button to navigate to or select another image, and then use the **Select Reference** button to change the reference image to that image.

Selected
Reference Image
with asterisk*

Select Reference
button

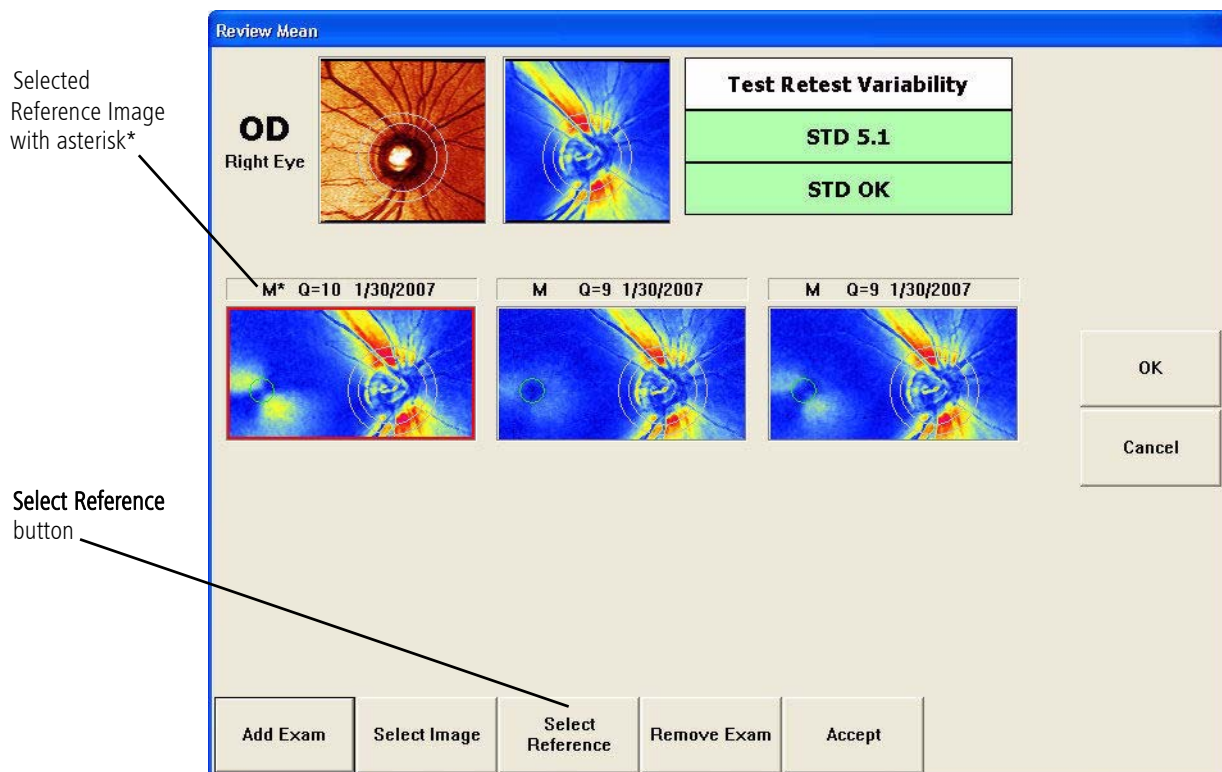*Figure 5-9 Review Mean Screen with Selected Reference Image*

To add an exam to your exam choices for creating the mean, select the **Add Exam** button to display a list of possible exams to add (Figure 5-10).

☞ Note: When creating a mean during a Triple Scan, the **Add Exam** button will display an ACQUISITION screen to take another exam, rather than a list of previously acquired exams to select.

Select an exam by using the mouse or the **Previous**, **Next** and **Select/Deselect** buttons. You may also use the up and down arrow keys on the keyboard.
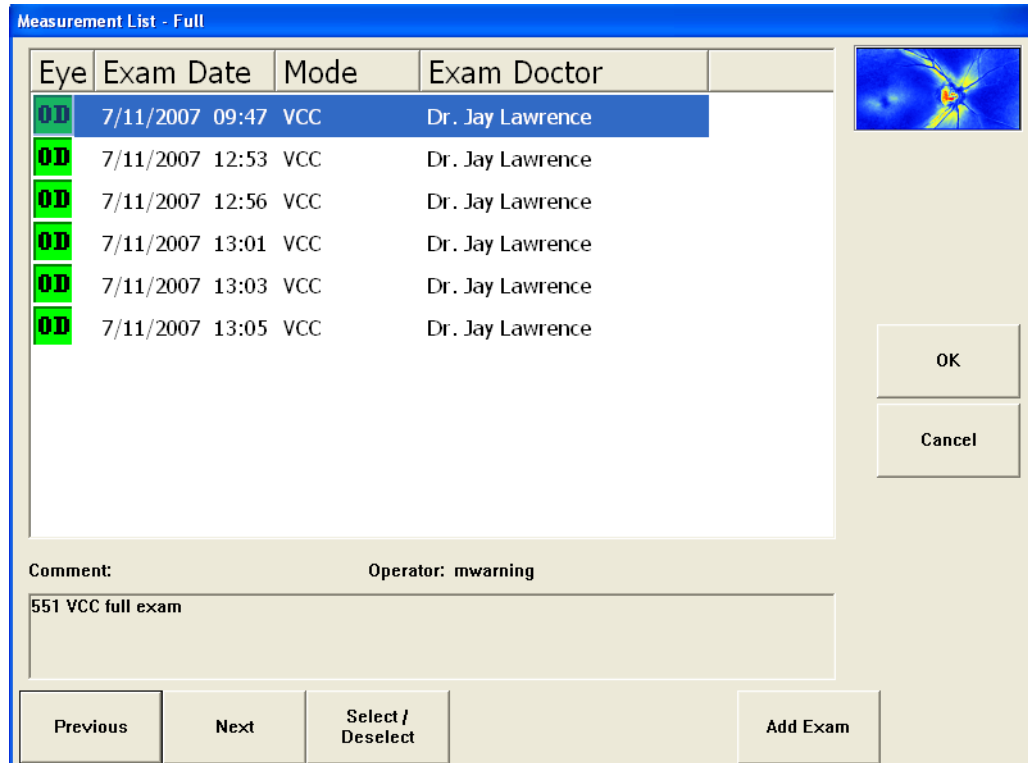
Figure 5-10 Add Exam to Mean (Manual Mean Creation)

Select the **Add Exam** button to add the selected exam to your list on the REVIEW MEAN screen.

To remove an exam from your exam choices, select an exam on the REVIEW MEAN screen by clicking on the **Select Image** button until the exam you want to remove is selected (with red border), and then select the **Remove Exam** button. A dialog (Figure 5-11) will be displayed confirming that you want to remove the exam. Select **OK** to remove the exam and regenerate the mean.

Figure 5-11 Remove Exam from Mean

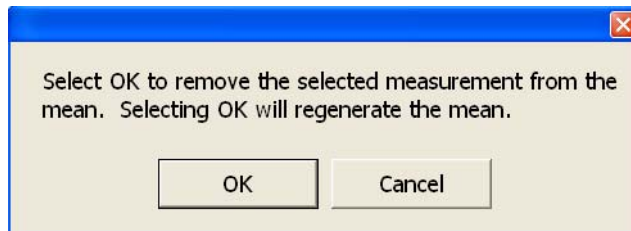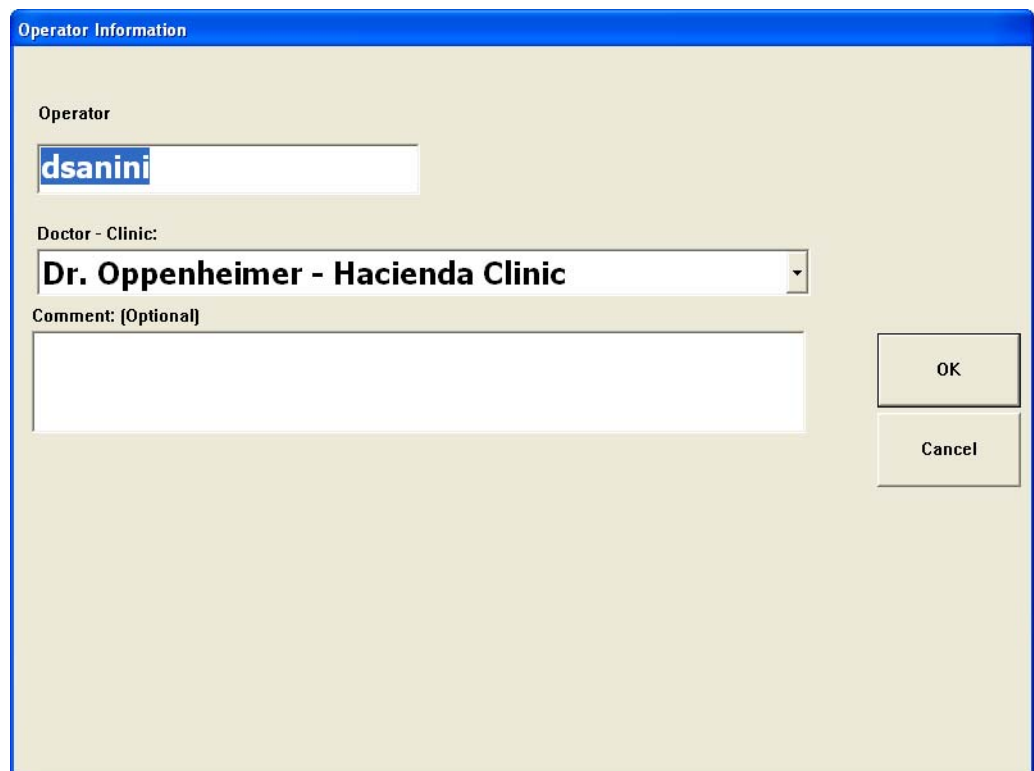Select **Accept** or **OK** to accept and save the mean created from the selected images. An OPERATOR INFORMATION screen (Figure 5-12) will be displayed allowing you to change the **Doctor - Clinic** field with any doctor that is associated with the current operator. This doctor is called the *Exam or Attending doctor* and is displayed on the MEASUREMENT LIST SCREEN. The Exam doctor (called the *Primary or Referring doctor*) can be different from the doctor associated with the patient and defined on the PATIENT INFORMATION screen (Figure 3-7).

You may also add any comments in reference to the mean in the **Comment** field. Text entered in the **Comment** field is displayed below the measurements list on the MEASUREMENT LIST SCREEN when the mean measurement is selected (see Figure 5-13), but is not displayed in any report.

The Operator will default to the currently logged in user. You can edit the **Operator** field if desired.

Figure 5-12 Operator Information Screen

Select **OK** to continue to save the mean measurement. The MEASUREMENT LIST screen will now display the mean measurement (Figure 5-13). The **Mode** field for the mean will indicate that the measurement is a mean. The Eye icon for a mean created from two or three measurements will be colored blue; however, means created from two measurements will have a small **2** subscript in the icon. The measurements used to create the mean will have a small **M** in the green Eye icon (see Table 5-1, "Image Types and Eye Icon Colors"). The **Exam Doctor** field will display the doctor selected on the OPERATOR INFORMATION screen.

Select the **Review Mean** button to edit/review the exams used to create the mean measurement. The REVIEW MEAN screen (Figure 5-8) will be displayed.

VCC measurements used in mean

Generated mean created with 3 measurements (Blue Color Icon)

Comments are displayed here

Review Mean button

List of exams used to generate mean listed by acquisition time

Figure 5-13 Generated Mean Measurement

(6) Symmetry Analysis

Chapter Overview

This chapter describes the Review Calculations screen and its corresponding report, the Symmetry Analysis report. Topics covered in this chapter include:

☞ Note: The GDxPRO and GDxVCC™ are clinically equivalent, and use the same normative databases. However, some variations may occur whenever the same eye is measured by two different instruments. There may also be variances if images are re-aligned to a reference image, which adjusts the Calculation Circle position.

Reviewing Measurements

The Review Calculations screen (Figure 6-1) is displayed:

- **At the end of exam acquisition** — when you select **Accept** on the Image Check screen.
- **On the Measurements List screen** — when selecting one or two RNFL-I measurements and selecting **OK** or **Review**.

The Review Calculations screen displays the measurement results where you can save, print, preview, export a Symmetry Analysis report (Figure 6-2), or review image quality.
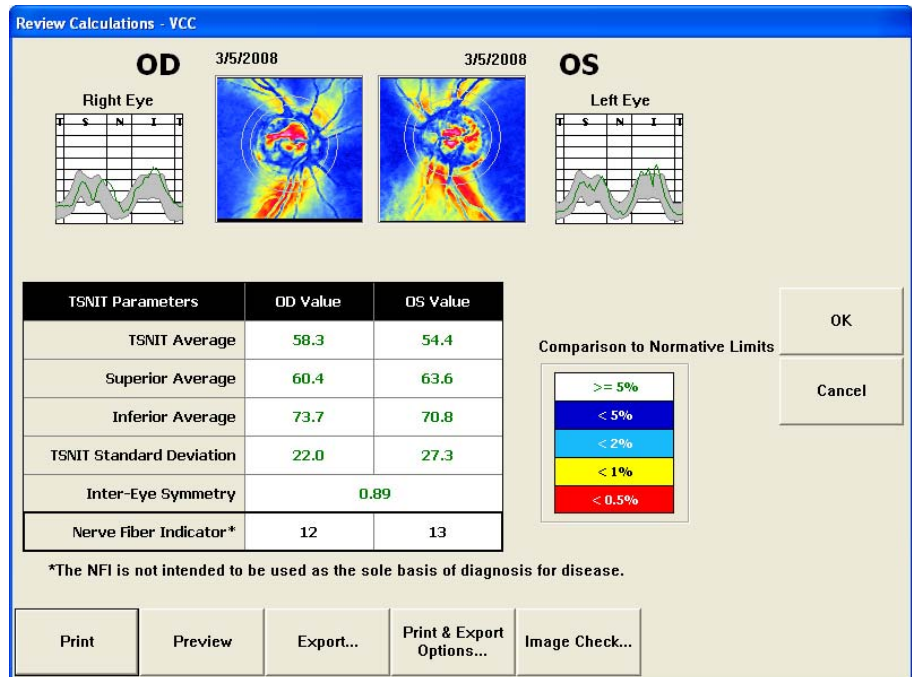

Figure 6-1 Review Calculations Screen – Reviewed Measurements

Select **Print** to print the Symmetry Analysis report to the current default printer. At the end of exam acquisition, selecting **Print** also saves the exams.

Select **Preview** to display the Symmetry Analysis report in PDF format, or a TIFF or JPEG image format. See Setting the Preview/Export Image Type on page 2-16 to set the image type. At the end of exam acquisition, selecting **Preview** does *not* save the exams.

Select **Export** to export the Symmetry Analysis report to the default export path (see **Default Import/Export Path (optional)** on page 2-10). See Setting the Preview/Export Image Type on page 2-16 to set the export image type. Select **Yes** to use the default export folder or select **No** to display a Browse for Folder dialog where you can select the export folder you want to use. At the end of exam acquisition, selecting **Export** also saves the exams.

Select **Print & Export Options** to display the PRINT AND EXPORT OPTIONS screen. See Printing/Exporting Exams on page 5-6 for information on this screen. At the end of exam acquisition, selecting **Print & Export Options** also saves the exams.

At the end of exam acquisition, select **Save Only** to save the exams.

During measurement review, select **Image Check** to display the IMAGE CHECK screen for the selected image(s). See Checking Image Quality on page 4-13 for information on this screen.

☞ **Note: Carl Zeiss Meditec does not offer advice in the diagnostic interpretation of GDxPRO scans. It is the clinician's responsibility to make diagnostic interpretations of GDxPRO scans.**

Overview of the Symmetry Analysis Report

Quality Indicators

Q ≥ 7, recommended
Residual (ECC) ≤ 4
Residual (VCC) < 12
TSS (ECC) > 40
TSS (VCC) > 60

Fundus Image

Reflectance image showing the optic nerve head (ONH).

RNFL-I Summary Parameters Table

Color-coded parameters indicating comparison to normative limits. All except the NFI are calculated only from the Calculation Circle.

Nerve Fiber Layer Map

An hourglass shape of yellow and red colors around the ONH is typical of normal eyes.

NFI

Nerve Fiber Indicator is related to the likelihood that the nerve fiber layer map is abnormal.

Deviation Map

Color-coded indicating comparison to normative limits.

TSNIT Graph

Displays normal range (shaded area) and patient's RNFL-I values along the Calculation Circle.
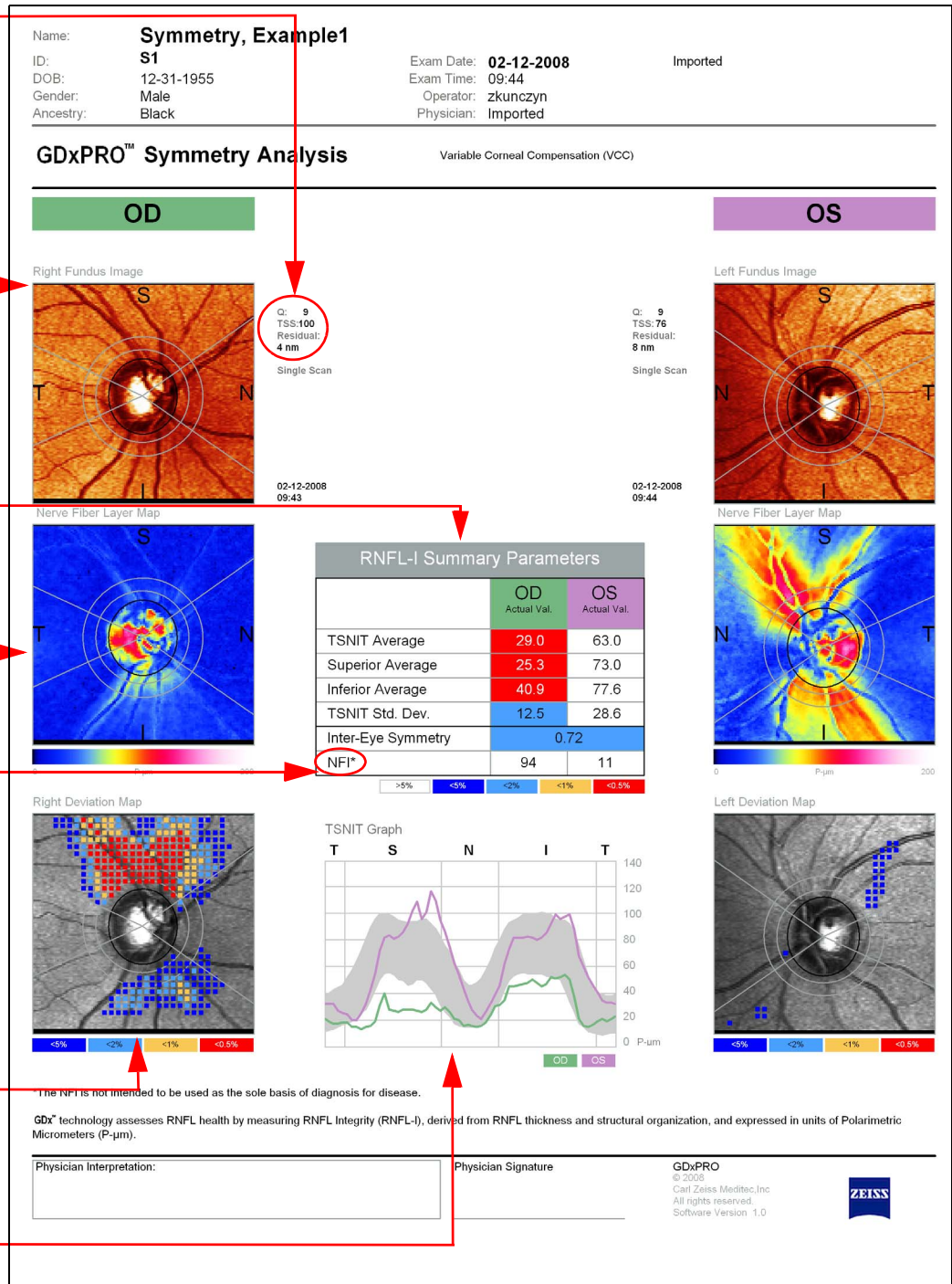
Sample courtesy of:
Joseph Sowka, OD, FAAO, Professor and Director of Glaucoma Services, Nova Southeastern University College of Optometry, Ft. Lauderdale.

Figure 6-2 Sample Symmetry Analysis Report – Abnormal OD and Normal OS

Symmetry Analysis

How to Read the Symmetry Analysis Report

1. Verify data quality

The Calculation Circles should be centered on the optic nerve. The image should be evenly illuminated and in focus.

Q (Quality Score)

Indication of image quality. Scores of 7 or higher are considered to be of good quality, while scores less than 7 should be interpreted with caution.

TSS (Typical Scan Score)

Measures the amount of artifact in the image. Using ECC, scores should be > 40, and using VCC, scores should be > 60.

Residual

Measures the error in corneal compensation. Scores should be ≤ 4 (ECC) and < 12 (VCC).

SD (Mean Images Only)

Standard deviation of the images in the mean image. Should be below 8.6.

2. Assess Nerve Fiber Layer Maps and Symmetry between Eyes

Use the graphic elements and the Inter-Eye Symmetry parameter to determine if the RNFL in one eye appears noticeably different than in the other.

3. Evaluate and Compare Deviation Maps

Look for groups of pixels in the inferior or superior RNFL adjacent to the optic nerve, especially yellow and red squares. Scattered pixels away from the ONH or located nasally or temporally often are not significant. Especially look for narrow wedge defects, since these may not be flagged by the summary parameters.

4. Look at the NFI and RNFL-I Summary Parameters

If any abnormality is observed in the images, check if these are confirmed by any flagged parameters. While 95% of the normal population shows ECC NFI ≤ 35 (or VCC NFI ≤ 30), the NFI is not always sensitive to narrow wedge defects.

☞ Note: The NFI is not intended to be used as the sole basis for the diagnosis of disease.

5. Apply Symmetry results in context of the patient

Correlate findings with those of other clinical tests or observations. If determined that glaucoma or a risk of glaucoma is present, follow patient with Guided Progression Analysis.

See Table F-1, "Image Troubleshooting Guide" on page F-3 for additional guidance.

Report Contents

The following sections describe components displayed in the Symmetry Analysis Report, as well as in the Progression Analysis Report, and on the REVIEW CALCULATIONS Screen. Results are based on data extracted from the area defined by the Calculation Circle.

Calculation Circle

The Calculation Circle defines the area where data is acquired for the TSNIT parameters. The data acquired in this area also affects the NFI calculation. The Calculation Circle appears on reports, and is described in .

Fundus Image

The Fundus Image () is a reflectance image depicting a 20° x 20° image of the posterior pole of the eye. The GDxPRO utilizes more than 16,000 data points from the scan area to produce and display the Fundus Image showing the optic nerve head. This image allows the initial quality evaluation of the scan to determine if it is adequate for further analysis and is used for centering the ONH ellipse.
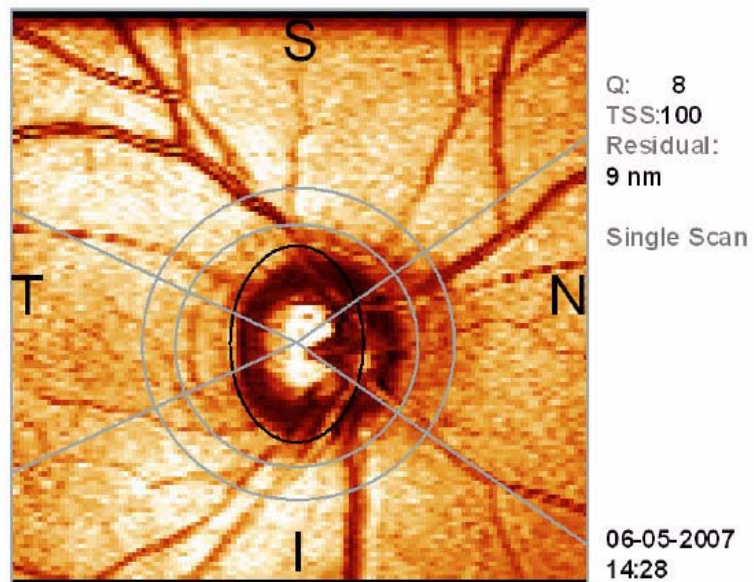

Figure 6-3 Fundus Image

To the right of the Fundus Image are image parameters described below.

Image Quality Score (Q)

Q is the Image Quality Score. For more information, refer to .

- If Q is below 7, an exclamation icon will be displayed next to the Q value:

- If the image has an alignment problem, an alignment icon will be displayed:

Typical Scan Score (TSS)

TSS is the Typical Scan Score. TSS provides a measure of the "typicality" of the RNFL image. In an atypical scan, the phase shift profile does not match the known anatomical RNFL distribution and can be characterized by a variable phase shift pattern. Atypical scans are more common in pale fundi, high myopes, and elderly eyes. TSS ranges from 0 (very atypical) to 100 (very typical). Exams with TSS (ECC) $\leq$ 40 or TSS (VCC) $\leq$ 60 should be interpreted with caution.

The following figure (Figure 6-4) show examples of an atypical and typical scan:
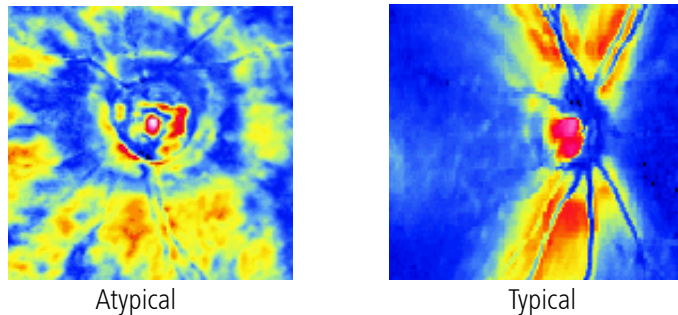

| Atypical | Typical |

Figure 6-4 Atypical and Typical Scan Examples

Residual (Single Images Only)

Residual represents the error of corneal compensation. Exams with a Residual Compensation value > 4 nm for ECC or $\geq$ 12 nm for VCC should be interpreted with caution. The normative database study protocols for both ECC and VCC stated that scans with residual compensation $\geq$ 12 would be excluded from the study. No scans with residual compensation > 4 were found during acquisition of the ECC normative database; therefore, such scans should be interpreted with caution in a clinical setting.

Single Scan (Single Images Only)

Identifies a scan as a Single Image as opposed to a Mean Image.

Mean Image (Mean Images Only)

Identifies a scan as a Mean Image as opposed to a Single Image.

SD (Standard Deviation) (Mean Images Only)

The standard deviation (SD) is displayed if the image is a mean of two or three measurements.

Exam Date and Time

The exam date and time are displayed.

Nerve Fiber Layer Map

The Nerve Fiber Layer Map (Figure 6-5) is a color map depicting the different RNFL-I levels in the 20° x 20° area surrounding the optic nerve head (ONH). This image presents the unique results provided by scanning laser polarimetry—measurements of the phase shift generated by RNFL thickness and structural organization. RNFL-I is represented using a color scale, with dark blue representing smaller RNFL-I values (smaller phase shift) and generally bright red representing larger RNFL-I values (greater phase shift).
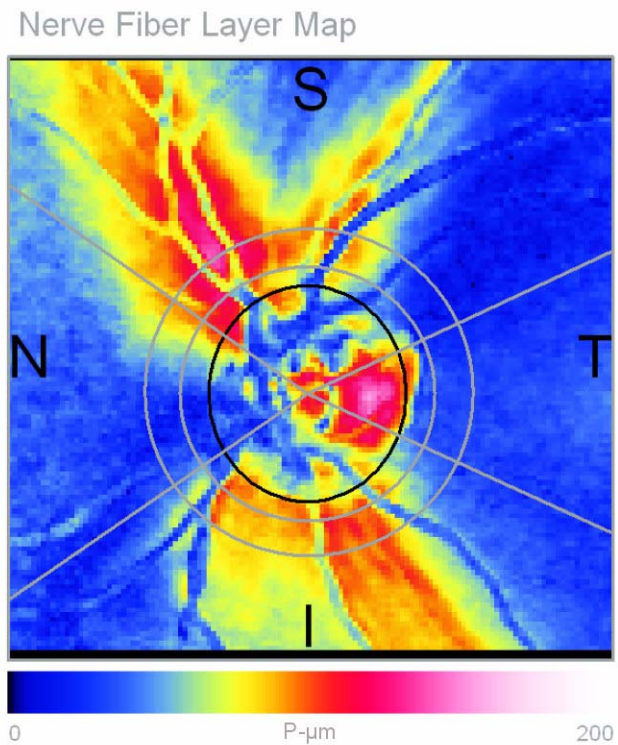

Figure 6-5 Nerve Fiber Layer Map

☞ **Note: GDx technology assesses RNFL health by measuring RNFL Integrity (RNFL-I), derived from RNFL thickness and structural organization, and expressed in units of Polarimetric Micrometers (P-μm). RNFL-I is distinct from thickness measured by other devices and expressed as micrometers (μm).**

A typical normal pattern is characterized by bright yellows and reds (thicker) in the superior and inferior sectors, and greens and blues (thinner) in the nasal and temporal sectors.

Deviations from normal may reflect:

- Lack of the typical RNFL-I distribution.
- Diffuse loss of RNFL resulting in blue areas where you would normally expect yellow or red.
- Focal defects, or areas of concentrated dark colors.
- Asymmetry between the superior and inferior quadrants.
- Asymmetry between right and left eye.

Symmetry Analysis

TSNIT Graph

On the Symmetry Analysis report, the TSNIT (Temporal-Superior-Nasal-Inferior-Temporal) nerve fiber layer graph (Figure 6-6) displays the normal range (shaded area) and patient's values of RNFL-I developed from the measurement data obtained along the Calculation Circle. The green plot displays the right eye (OD), and the purple plot displays the left eye (OS).
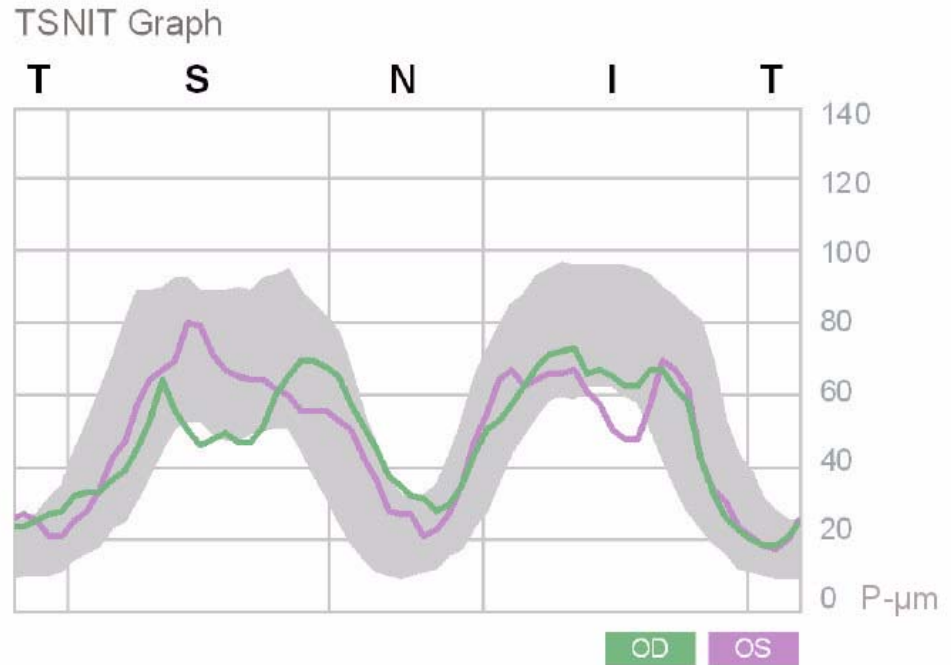

Figure 6-6 TSNIT Graph

The left side of the graph starts the plot from the Calculation Circle, beginning at the temporal side of the retina. As the map progresses to the right it plots the RNFL-I values obtained by tracing around the Calculation Circle, passing through the Temporal, Superior, Nasal, Inferior, and then back to the Temporal positions.

On the REVIEW CALCULATIONS screen, separate left and right eye TSNIT graphs are displayed.

☞ Note: The TSNIT Graph is based only on the data points within the Calculation Circle.

Deviation Map

The Deviation Map (Figure 6-7) shows how the patient's RNFL-I measurements compare with values derived from the normative database. Small color-coded squares indicate the amount of deviation from normal at each given location and are presented over a black-and-white fundus image to provide a visual frame of reference. A color legend displays the comparison to normative limits (see Table 6-1, "Color-Coding for Deviation Map" on page 6-9).
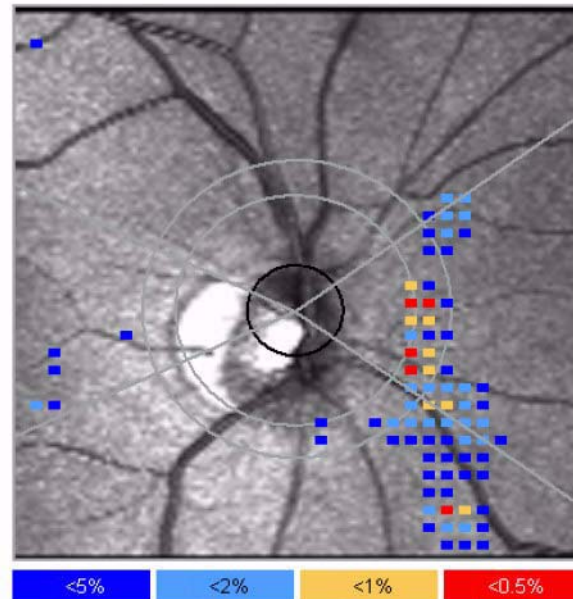

Figure 6-7 Deviation Map

Table 6-1 Color-Coding for Deviation Map

Color	Comparison to Normative Limits	Description
Red	< 0.5%	Indicates a value less than the lower 0.5% limit of the normal study population.
Yellow	< 1%	Indicates a value less than the lower 1% limit of the normal study population.
Light Blue	< 2%	Indicates a value less than the lower 2% limit of the normal study population.
Dark Blue	< 5%	Indicates a value less than the lower 5% limit of the normal study population.
No Square	≥ 5%	Indicates a value greater than or equal to the lower 5% limit of the normal study population.

Symmetry Analysis

RNFL-I Summary Parameters Table

The RNFL-I Summary Parameters table (Figure 6-8) presents parameters computed from the Calculation Circle (the NFI also includes data outside the Calculation Circle) and compared to similarly computed values from the normative database. Values are color-coded to indicate deviation from normal, as in the Deviation Map (Table 6-1, "Color-Coding for Deviation Map").

Figure 6-8 RNFL-I Summary Parameters Table

☞ Note: The RNFL-I Summary Parameters, especially NFI, were determined to be the most effective in helping doctors differentiate glaucoma patients from normal patients. These values should be evaluated together and in conjunction with all other clinical information for the patient.

The RNFL-I Summary Parameters table is populated by the following parameters:

TSNIT Average

This parameter evaluates the average RNFL-I (P-μm) in the Calculation Circle.

Superior Average

This is the average of all pixels (P-μm) in the superior 120 degrees of the Calculation Circle.

Inferior Average

This is the average of all pixels (P-μm) in the inferior 120 degrees of the Calculation Circle.

TSNIT Std. Dev. (Standard Deviation)

This number represents the standard deviation of the values contained in the Calculation Circle. The higher the number, the greater the modulation of the double-hump pattern.

Inter-Eye Symmetry

This is the correlation of corresponding points in the TSNIT data for right and left eyes. The closer the ratio is to 1.0, the more symmetric the nerve fiber layer. Because this is a right-left eye comparison, there is only one resulting value, rather than one for each eye as in the other parameters. If only one eye is evaluated, this value is not shown.

NFI (Nerve Fiber Indicator)

The Nerve Fiber Indicator (NFI) for GDx is an artificial intelligence algorithm that analyzes the entire RNFL profile. It is "trained" on known normal and glaucomatous eyes and essentially uses pattern recognition to discriminate between them. The NFI is an ordinal number that is related to the likelihood that the polarimetric retinal nerve fiber layer map is abnormal. A higher number is more likely to be related to abnormality, but is not definitive.

☞ **Note: The NFI cannot be used alone to classify patients into normal and glaucoma categories. This parameter cannot replace clinical judgement and is intended to be used in conjunction with the multiple clinical tools considered the standard of care for glaucoma diagnosis. This device is not intended to be used as the sole basis for diagnosis of eye disease.**

The NFI was developed and validated without using patients who were considered "glaucoma suspects," but only eyes with a clear-cut diagnosis of "normal" or "glaucoma." Thus, its utility in eyes diagnosed as "glaucoma suspects" remains to be established.

However, repeated studies have shown the NFI is the best single GDx parameter in differentiating between normal and glaucomatous eyes.[1–5]

Because ECC and VCC have separate normative databases, their NFIs were trained on different data sets. Data analysis of the normal subjects used in the ECC and VCC NFI training reveals the following:

- 95% of the normal population shows ECC NFI values ≤ 35, and VCC NFI values ≤ 30.
- 99% of the normal population shows ECC NFI values ≤ 55, and VCC NFI values ≤ 37.

Please see (A) RNFL Normative Databases and NFI for additional information on the NFI.

Symmetry Analysis Examples

Following the framework in How to Read the Symmetry Analysis Report on page 6-4, we can analyze the following Symmetry Analysis examples.

Example data is courtesy of Joseph Sowka, OD, FAAO, Professor and Director of Glaucoma Services, Nova Southeastern University College of Optometry, Ft. Lauderdale.

Example 1: Severe OD RNFL Loss

This report (Figure 6-9 on page 6-13) can be evaluated as follows:

<u>1. Verify data quality</u>

* Image quality is acceptable: Q, TSS, and Residual values are within the recommended limits for both images.
* The Calculation Circles are centered on the optic nerve.
* The fundus images are evenly illuminated and in focus.

<u>2. Assess Nerve Fiber Layer Maps and Symmetry between Eyes</u>

In this case, there is marked asymmetry between OD and OS. The Nerve Fiber Layer Map for the right eye (OD) is dark blue, indicating loss of the RNFL both superiorly and inferiorly. The map for the left eye (OS) reveals the hot colors of red and yellow, indicating a more robust and typical RNFL-I pattern. This asymmetry is also displayed in the Deviation Maps and the TSNIT curves. The Inter-Eye Symmetry parameter is flagged light blue, indicating less than 2% of normal patients have such asymmetry.

<u>3. Evaluate and Compare Deviation Maps</u>

The OD has a very large group of red squares adjacent to the ONH superiorly. There is also a large group of light and dark blue squares inferiorly. The OS has only small groups of dark blue squares, which are quite nasal and temporal and are not adjacent to the ONH, and therefore not likely to be clinically significant.

<u>4. Evaluate the NFI and other RNFL-I Summary Parameters</u>

All of the summary parameters confirm the asymmetry seen in the graphic elements.
In particular, the NFI for OD is 94 but only 10 for OS.

<u>5. Apply Symmetry results in context of the patient</u>

The results of this Symmetry Analysis suggest extensive RNFL damage in the OD. To confirm this damage is due to glaucoma, it should correlate with other data such as IOP measurements, visual fields, and a dilated examination of the optic nerve.

Name: **Symmetry, Example1**
ID: **S1**
DOB: 12-31-1955
Gender: Male
Ancestry: Black

Exam Date: **02-12-2008**   Imported
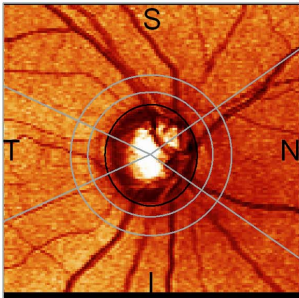Exam Time: 09:44
Operator: zkunczyn
Physician: Imported

GDxPRO™ Symmetry Analysis

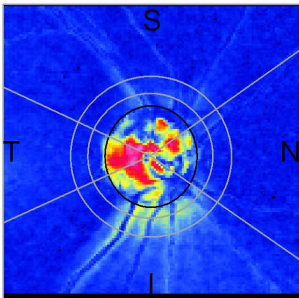Variable Corneal Compensation (VCC)

OD

OS

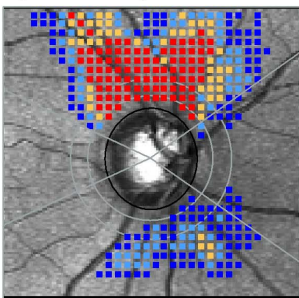Right Fundus Image

Q: 9
TSS: 100
Residual:
4 nm

Single Scan

02-12-2008
09:43

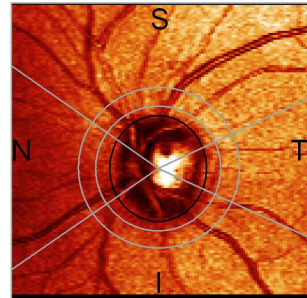Left Fundus Image

Q: 9
TSS: 76
Residual:
8 nm

Single Scan

02-12-2008
09:44

Sample courtesy of:
Joseph Sowka, OD, FAAO, Professor and Director of Glaucoma Services, Nova Southeastern University College of Optometry, Ft. Lauderdale.
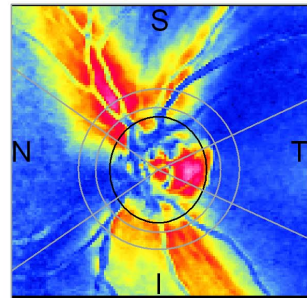
Nerve Fiber Layer Map

0   P-μm   200

Nerve Fiber Layer Map

0   P-μm   200

RNFL-I Summary Parameters

	OD Actual Val.	OS Actual Val.
TSNIT Average	29.0	63.0
Superior Average	25.3	73.0
Inferior Average	40.9	77.6
TSNIT Std. Dev.	12.5	28.6
Inter-Eye Symmetry	0.72	
NFI*	94	11

>5%	<5%	<2%	<1%	<0.5%
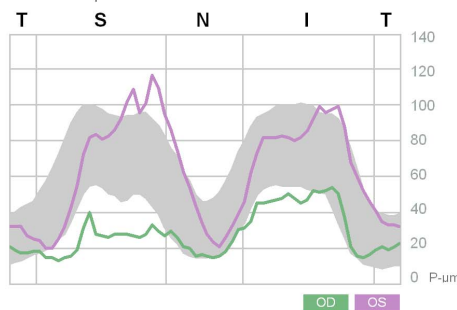
Right Deviation Map

<5%	<2%	<1%	<0.5%

TSNIT Graph

T   S   N   I   T

140
120
100
80
60
40
20
0 P-μm

OD   OS

Left Deviation Map

<5%	<2%	<1%	<0.5%

*The NFI is not intended to be used as the sole basis of diagnosis for disease.

GDx™ technology assesses RNFL health by measuring RNFL Integrity (RNFL-I), derived from RNFL thickness and structural organization, and expressed in units of Polarimetric Micrometers (P-μm).

Physician Interpretation:

Physician Signature

GDxPRO
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All rights reserved.
Software Version 1.0

ZEISS

Figure 6-9 Example 1 – Severe OD RNFL Loss

Example 2: Physiological Cupping

This report (Figure 6-10 on page 6-15) can be evaluated as follows:

1. Verify data quality

For OD, the TSS is lower than the recommended limit. Ideally, the scan would be repeated in an attempt to improve it, especially if the scan will be part of a baseline for GPA. However, the image may still cautiously be used because there is little visible artifact.

2. Assess Nerve Fiber Layer Maps and Symmetry between Eyes

Both Nerve Fiber Layer Maps display yellow and red patterns which are more pronounced inferiorly. This pattern is indicative of a normal RNFL. The Inter-Eye Symmetry parameter is within normal limits. The TSNIT Graph is also within normal limits, and highlights split bundles in both the superior and inferior areas, though these are more obvious superiorly.

3. Evaluate and Compare Deviation Maps

Neither Deviation Map has any colored squares, meaning all areas of both RNFLs are within normal limits.

4. Evaluate the NFI and other RNFL-I Summary Parameters

The NFI in each eye is 12, and no parameters are outside normal limits. This is consistent with what is displayed in the graphic elements.

5. Apply Symmetry results in context of the patient

Although this patient clearly has large optic nerves and large cups, based on the examination the RNFL appears to be healthy in both eyes. To confirm this is a case of physiological cupping, these findings should correlate with other data such as IOP measurements, visual fields, and a dilated examination of the optic nerve.

Name: **Symmetry, Example2**

ID: **S2**

DOB: 09-12-1973   Exam Date: **03-05-2008**   Imported

Gender: Female   Exam Time: 14:27

Ancestry: Black   Operator: zkunczyn

    Physician: Imported

GDxPRO™ Symmetry Analysis

Variable Corneal Compensation (VCC)
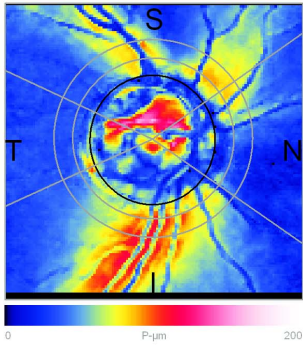
OD   **OS**

Right Fundus Image   Left Fundus Image
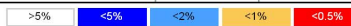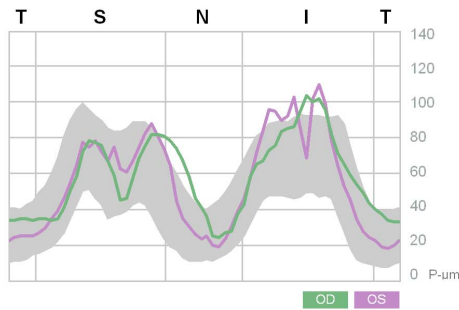
Sample courtesy of:
Joseph Sowka, OD, FAAO, Professor
and Director of Glaucoma Services,
Nova Southeastern University College
of Optometry, Ft. Lauderdale.

Q: 8   Q: 7
TSS: 40   TSS: 70
Residual: Residual:
11 nm   8 nm
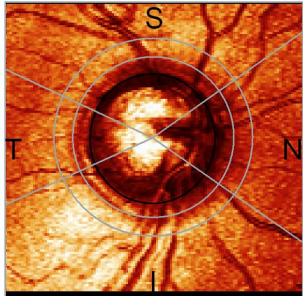
Single Scan   Single Scan

03-05-2008   03-05-2008
14:27   14:27

Nerve Fiber Layer Map   Nerve Fiber Layer Map
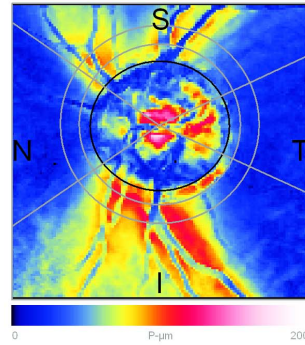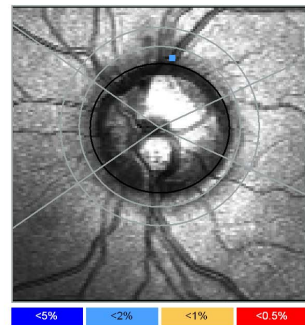
RNFL-I Summary Parameters		
	OD Actual Val.	OS Actual Val.
TSNIT Average	58.3	54.4
Superior Average	60.4	63.6
Inferior Average	73.7	70.8
TSNIT Std. Dev.	22.0	27.3
Inter-Eye Symmetry	0.89	
NFI*	12	13

>5%	<5%	<2%	<1%	<0.5%

0   P-μm   200

Right Deviation Map   Left Deviation Map

TSNIT Graph

T   S   N   I   T

140
120
100
80
60
40
20
0   P-um

OD   OS

<5%	<2%	<1%	<0.5%

*The NFI is not intended to be used as the sole basis of diagnosis for disease.

GDx™ technology assesses RNFL health by measuring RNFL Integrity (RNFL-I), derived from RNFL thickness and structural organization, and expressed in units of Polarimetric Micrometers (P-μm).

Physician Interpretation:

Physician Signature

GDxPRO
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Software Version 1.0

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Figure 6-10 Example 2 – Physiological Cupping

Example 3: Suspected Early RNFL Loss

This report (Figure 6-11 on page 6-17) can be evaluated as follows:

<u>1. Verify data quality</u>

- Image quality is acceptable: Q, TSS, and Residual values are within the recommended limits for both images.
- The Calculation Circles are centered on the optic nerve.
- The fundus images are evenly illuminated and in focus.

<u>2. Assess Nerve Fiber Layer Maps and Symmetry between Eyes</u>

Superiorly, the OD RNFL is noticeably different than the OS RNFL, as seen in the Nerve Fiber Layer Maps and the TSNIT Graph. Infero-temporally, the RNFL is noticeably depressed in the OS compared to the OD. Although the Inter-Eye Symmetry parameter is within normal limits, such local asymmetries are often indicative of early loss.

<u>3. Evaluate and Compare Deviation Maps</u>

The OS has red, yellow, and blue squares infero-temporally that suggest a wedge defect, especially since this pattern is not reflected in the OD.

<u>4. Evaluate the NFI and other RNFL-I Summary Parameters</u>

The NFI values are 32 and 34, which for VCC are outside the range of values found in 95% of the normal population, but inside the range of values found in 99% of the normal population. None of the global parameters are flagged. However, if there is wedge defect in the inferior OS, it may be too subtle to be flagged in the RNFL-I Summary Parameters Table.

<u>5. Apply Symmetry results in context of the patient</u>

The results are suspicious, especially because of the inferior asymmetry, and warrant a careful evaluation of other data.
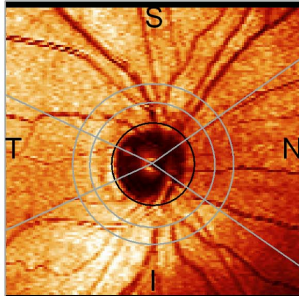
Name: **Symmetry, Example3**
ID: **S3**
DOB: 11-03-1959
Gender: Male
Ancestry: Black

Exam Date: **09-21-2004**   Imported
Exam Time: 11:36
Operator: zkunczyn
Physician: Imported

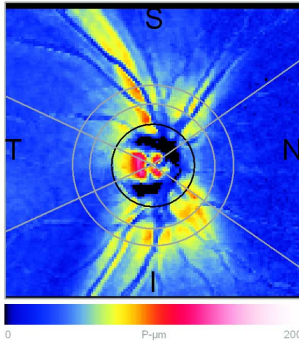## GDxPRO™ Symmetry Analysis

Variable Corneal Compensation (VCC)

OD

Right Fundus Image

Q: 9
TSS:100
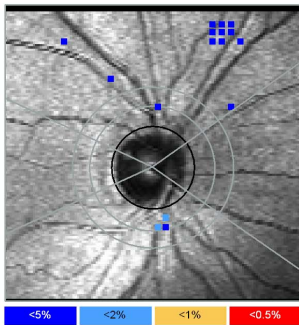Residual:
4 nm

Single Scan

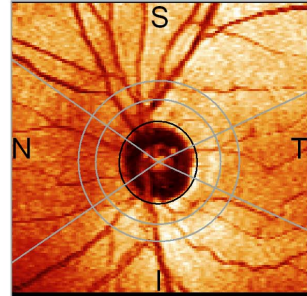09-21-2004
11:36

Nerve Fiber Layer Map

0   P-µm   200

Right Deviation Map

<5% <2% <1% <0.5%

Sample courtesy of:
Joseph Sowka, OD, FAAO, Professor and Director of Glaucoma Services, Nova Southeastern University College of Optometry, Ft. Lauderdale.
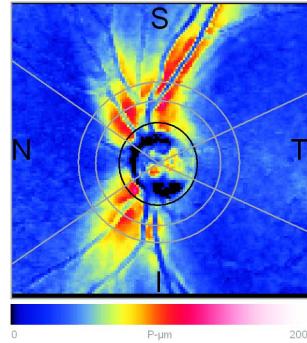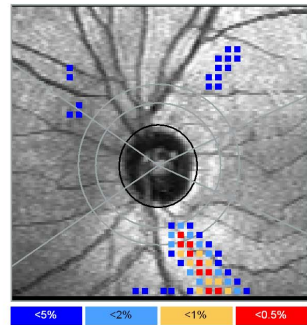
OS

Left Fundus Image

Q: 9
TSS: 85
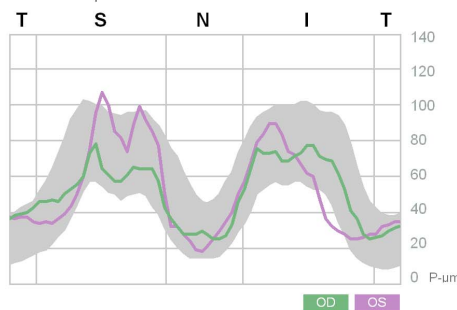Residual:
4 nm

Single Scan

09-21-2004
11:36

Nerve Fiber Layer Map

0   P-µm   200

Left Deviation Map

<5% <2% <1% <0.5%

RNFL-I Summary Parameters

	OD Actual Val.	OS Actual Val.
TSNIT Average	51.3	51.9
Superior Average	58.5	69.1
Inferior Average	62.2	54.4
TSNIT Std. Dev.	17.4	25.1
Inter-Eye Symmetry	0.77	
NFI*	32	34

>5%   <5%   <2%   <1%   <0.5%

TSNIT Graph

T   S   N   I   T

140
120
100
80
60
40
20
0 P-µm

OD   OS

*The NFI is not intended to be used as the sole basis of diagnosis for disease.

GDx™ technology assesses RNFL health by measuring RNFL Integrity (RNFL-I), derived from RNFL thickness and structural organization, and expressed in units of Polarimetric Micrometers (P-µm).

Physician Interpretation:

Physician Signature

GDxPRO
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Software Version 1.0

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Figure 6-11 Example 3 – Suspected Early RNFL Loss

References:

1. Reus, NJ, Lemij HG. Diagnostic Accuracy of the GDxVCC for Glaucoma. *Ophthalmology* 2004; 111:1860-1865.

2. Da Pozzo S, Iacono P., Marchesan R, Fantin A, Ravalico G. Scanning Laser Polarimetry with Variable Corneal Compensation and Detection of Glaucomatous Optic Neuropathy. *Grafes Arch Clin Exp Ophthalmology* 2005; 243:774-779.

3. Iester M, Perdicchi A, De Feo F, Fiesoletti E, Amodeo S, Sanna G, Leonardi A, Calabria G. Comparison between GDxVCC Parameter and Achromatic Perimetry in Glaucoma Patients. *J Glaucoma* 2006; 15:281-285.

4. Borque E, Ferreras A, Polo V, Larrosa JM, Pablo LE, Honrubia FM. Diagnostic Ability of GDxVCC for Glaucoma Diagnosis. *Arch Soc Esp Oftalmol* 2008; 83:357-364.

5. Medeiros FA, Vizzeri G, Zangwill LM, Alencar LM, Sample PA, Weinreb RN. Comparison of Retinal Nerve Fiber Layer and Optic Disc Imaging for Diagnosing Glaucoma in Patients Suspected of Having the Disease. *Ophthalmology* 2008; 115:1340-1346.

(7) Guided Progression Analysis (GPA)

Chapter Overview

This chapter discusses the Guided Progression Analysis (GPA) Report and related functions. Topics covered in this chapter include:

Introduction to GPA

Because glaucoma causes a slow loss of retinal nerve fiber layers, identifying this loss and its rate can help diagnose glaucoma early, assess which patients are at risk of reduced quality of life from glaucoma, and help measure treatment effectiveness. Guided Progression Analysis (GPA) compares measurements over time and determines if the differences are statistically significant. GDxPRO GPA reports "Possible progression" when a significant change is detected, and "Likely progression" when a significant change is confirmed. "Possible progression" requires a minimum of three visits, and "Likely progression" requires a minimum of four.

☞ Note: The GDxPRO GPA algorithms are designed to have 95% specificity for "Likely progression." Not all changes flagged by the software are true changes; there could be false positives.

GPA recognizes when data has been acquired on different instruments or if the instrument's calibration was changed during a repair. It can analyze data from two instruments, but it requires two measurements from each. GPA will automatically include inter-instrument variability in the total test-retest variability when analyzing data from multiple instruments. While specificity is not affected by the inter-instrument variability, the sensitivity of GPA may be lower due to increased total test-retest variability.

Fast and Extended GPA Modes

Progression Analysis has two modes as compared in Table 7-1, "Fast and Extended Modes," shown below.

Table 7-1 Fast and Extended Modes

Fast Mode	Extended Mode
Includes Single measurements.	Requires Means of three measurements (facilitated with Triple Scan).
Compares change to the pre-determined *average* measurement variability derived from a sample population.	Calculates the *individual* measurement variability of each eye for a selected patient.
Supports both ECC and VCC images	Supports both ECC and VCC images
Can be used for follow-ups of non-critical patients when there is no time to acquire Triple Scans.	Requires more time but is more sensitive. Highly recommended for critical patients.

☞ Note: For optimal performance, use of Extended Mode is encouraged.

☞ Note: We recommend acquiring baselines spaced 2 to 3 months apart for best results. Acquiring Triple Scan baselines provide the option of using Fast Mode or Extended Mode for follow-ups.

There could be patients for whom Fast Mode reports change, but Extended Mode does not. This may occur if a patient's individual measurement variability is higher than the test-retest variability that GPA assumes for the general population. However, in such a case there would be an increased chance that the Fast Mode result be a false positive.

Using Pre-existing Data

Until you have enough data to use Extended Mode, you can make mean images from Triple Scans and use them with your existing single scans in Fast Mode.

GDxPRO GPA Algorithms

GDxPRO GPA implements two different algorithmic approaches to determine significant change, based on GPA mode (Table 7-2). Both algorithms require a minimum of 3 visits.

* CFB (Change From Baseline): Based on changes from two baseline exams compared to measurement variability. CFB is most sensitive when there is little variability between the baselines. Mean readings are treated as single data points.
* SIM (Statistical Image Mapping): Based on trend analysis. All visits contribute to change detection, as opposed to CFB in which only the first two and last two visits are used to determine if change occurred (therefore, SIM is able to detect progression between the first two visits better than CFB).

Table 7-2 GPA Algorithms

GPA Indicator	Fast Mode	Extended Mode
Image Progression Map	CFB	CFB
TSNIT Progression Graph	CFB	SIM
RNFL-I Summary Parameter Charts	CFB	SIM

Statistical Significance

Progression Analysis compares an observed change with its expected test-retest variability, as illustrated in Figure 7-1.
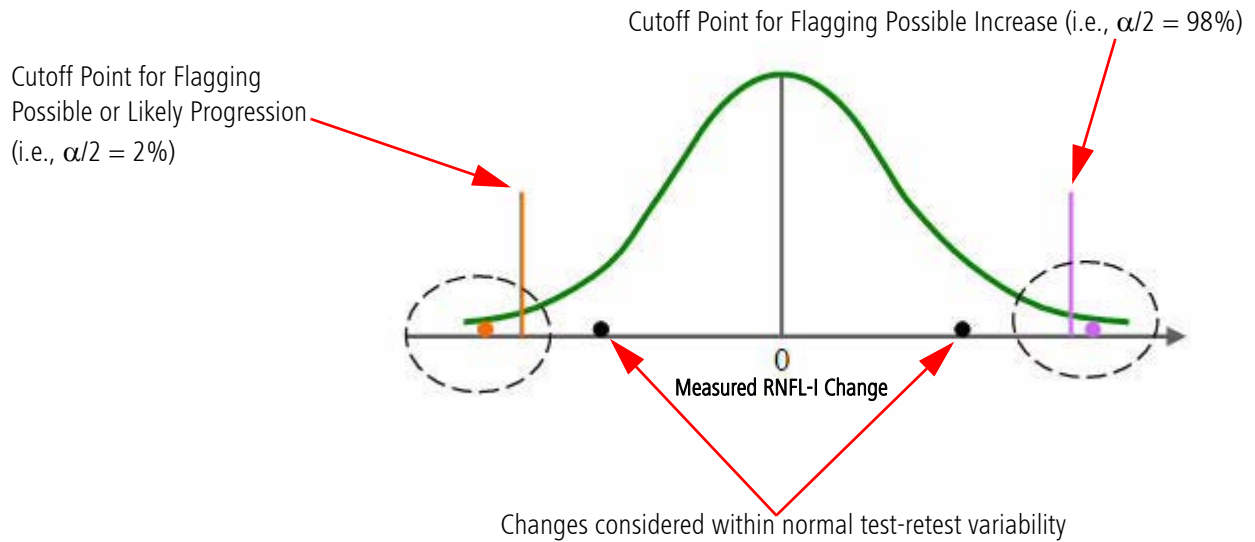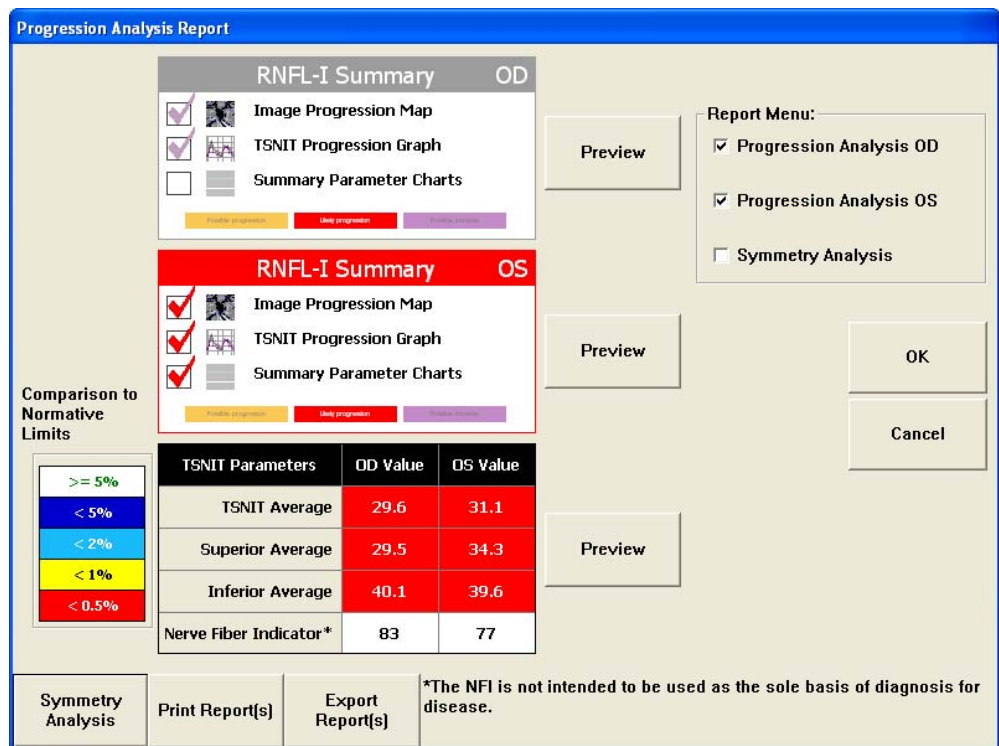

Cutoff Point for Flagging Possible Increase (i.e., $\alpha/2 = 98\%$)

Cutoff Point for Flagging Possible or Likely Progression (i.e., $\alpha/2 = 2\%$)

Measured RNFL-I Change

Changes considered within normal test-retest variability

Figure 7-1 Distribution of Test-Retest Variability

Generating a GPA Report

To generate a GPA Report, select three to eight ECC/VCC RNFL-I measurements per eye on the MEASUREMENT LIST screen (see Selecting Measurements on page 5-1). Fast and Extended Mode GPA reports are created the same way, except that Extended Mode reports only include means of three.

☞ Note: GPA can analyze data from two different instruments but there must be at least two visits from each. Factory calibration changes may be treated as a measurement change.

If you then select **Review,** the system will display a summary of the analyses on the PROGRESSION ANALYSIS REPORT screen (Figure 7-2).

Figure 7-2 Progression Analysis Report Screen

Select a **Preview** button to display the corresponding report in PDF format, or a TIFF or JPEG image format. See Setting the Preview/Export Image Type on page 2-16 to set the image type.

Use the **Report Menu** to select which reports to print, then select **Print Report(s)** to print them to the current default printer. You can also select **Export Report(s)** to export these selected report(s) to the default export path (see **Default Import/Export Path (optional)** on page 2-10). See Setting the Preview/Export Image Type on page 2-16 to set the export image type. Select **Yes** to use the default export folder or select **No** to display a **Browse for Folder** dialog where you can select the export folder you want to use.

Select **Symmetry Analysis** to display the REVIEW CALCULATIONS screen (see (6) Symmetry Analysis).

Reference Images, Baselines, and Excluded Measurements

To set baselines and reference images, and to exclude measurements, select the **More** button on the MEASUREMENT LIST screen. The MEASUREMENT LIST screen (Figure 7-3) with additional buttons is displayed.
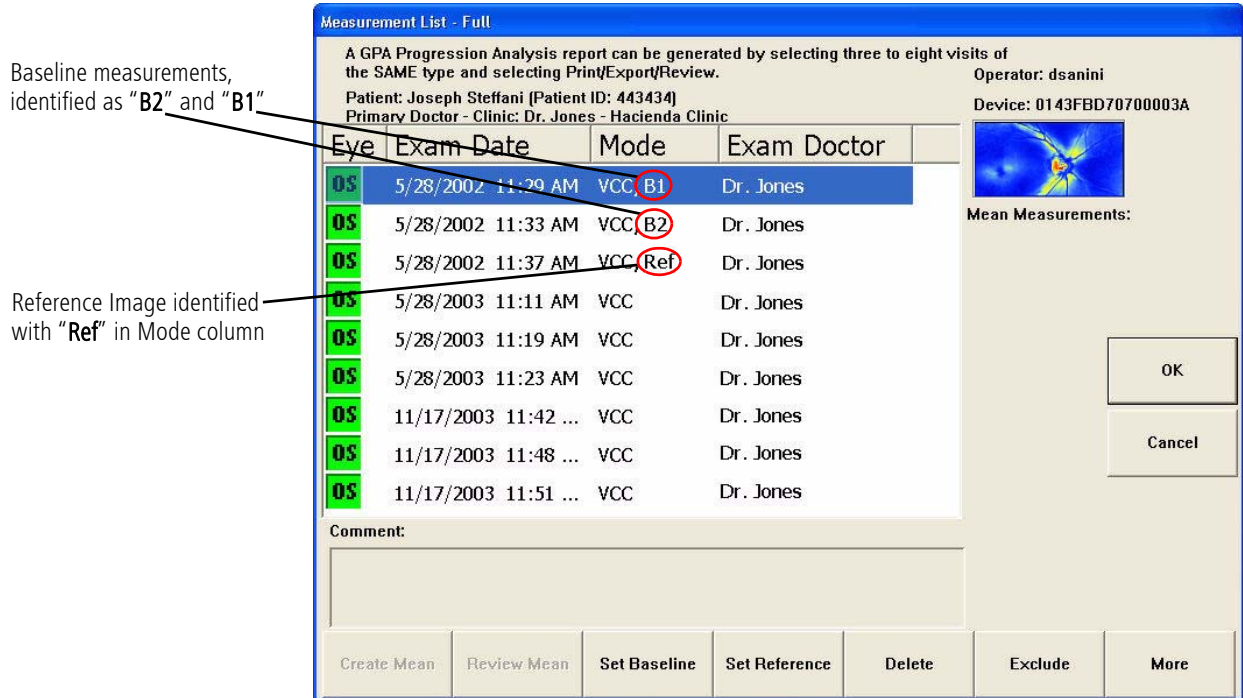
Baseline measurements, identified as "**B2**" and "**B1**"

Reference Image identified with "**Ref**" in Mode column

Figure 7-3 Measurement List Screen – Additional Buttons

Setting the Reference Image for Automatic Image Alignment

Retinal blood vessels are used as landmarks to align all images for a given eye to a single reference image. This step is required for mean image creation and progression analysis. Once the images are aligned, the ONH and macular ellipses from the reference image are copied to all other images.

If using Triple Scan mode, the first image is selected as the reference. For Single Exam mode, the image with the highest Quality Score (Q) out of the first three is automatically selected when first needed. The operator can override the automatic selection. The operator is asked to verify the ONH ellipse and the macular circle placement in the reference image.

Only one reference can be set per eye. It is identified by "**Ref**" in the **Mode** column of the MEASUREMENT LIST screen (Figure 7-3).

☞ Note: SCC, FCC, and excluded images cannot be automatically or manually selected as the reference image.

☞ Note: The size of the ONH ellipse is important for the reference image because it is used to mask the ONH area, which is not included in GPA. The ONH ellipse should be carefully placed to outline the optic disk margin.

To set a reference image, select the measurement you want as a reference image and then select the **Set Reference** button. A dialog will be displayed (Figure 7-4).
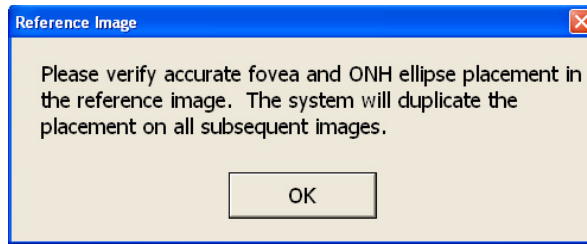

Figure 7-4 Reference Image – Setting

Select **OK** to display the IMAGE CHECK screen where you can verify/change the macular (fovea) and ONH ellipse placements, and the calculation circle. After verification/change, select the **OK** or **Accept** button to set the reference image. The selected measurement is set as the reference image, with "**Ref**" shown in its **Mode** column (see Figure 7-3).

Once a reference image is set, the reference image cannot be changed without first selecting another reference image. Select another measurement as a reference image and then select the **Set Reference** button. A dialog will be displayed (Figure 7-5).

Figure 7-5 Reference Image – Changing

Select **Yes** to deselect the old reference image and select the new reference image—"**Ref**" will be removed from the measurement's **Mode** column of the old reference image and **"Ref"** will be added to the measurement's **Mode** column for the newly selected reference.

☞ Note: If the reference image is changed, all images aligned to the reference will be realigned. Depending on the number of measurements, this may take some time.

Setting Baselines

The software automatically establishes the first two qualifying exams as the baselines, which are labeled B1 and B2. A second set of baselines can also be established to compare progression before and after an intervention (see Dual Baselines on page 7-14).

☞ Note: There is no limitation for the time difference between baselines, although a separation of two to three months is ideal.

To select different baselines, select the measurement you want as B1 and then select the **Set Baseline** button. The selected and next qualifying measurement will then be labeled "**B1**" and "**B2**" in the **Mode** column (Figure 7-3). To remove the baseline, select either measurement marked as B1 or B2, and then select the **Set Baseline** button. The "**B1**" and "**B2**" identifiers will be removed from the **Mode** column.

Excluding Measurements

Measurements that are of poor quality or outside of the time period being analyzed can be excluded from automatic selection. Excluded measurements are also excluded from mean, reference image, and baseline automatic selection. An excluded measurement cannot be included in a baseline set. A reference or baseline measurement cannot be excluded.

☞ Note: Excluded measurements can be manually selected to be reviewed in GPA/Symmetry Analysis reports.

To exclude a measurement, select it and then select the **Exclude** button (Figure 7-6). Select the **More** button if you cannot see the **Exclude** button. You will see a red **X** through the Eye icon. To unmark for exclusion, select the **Exclude** button again. The red **X** on the Eye icon will be removed.
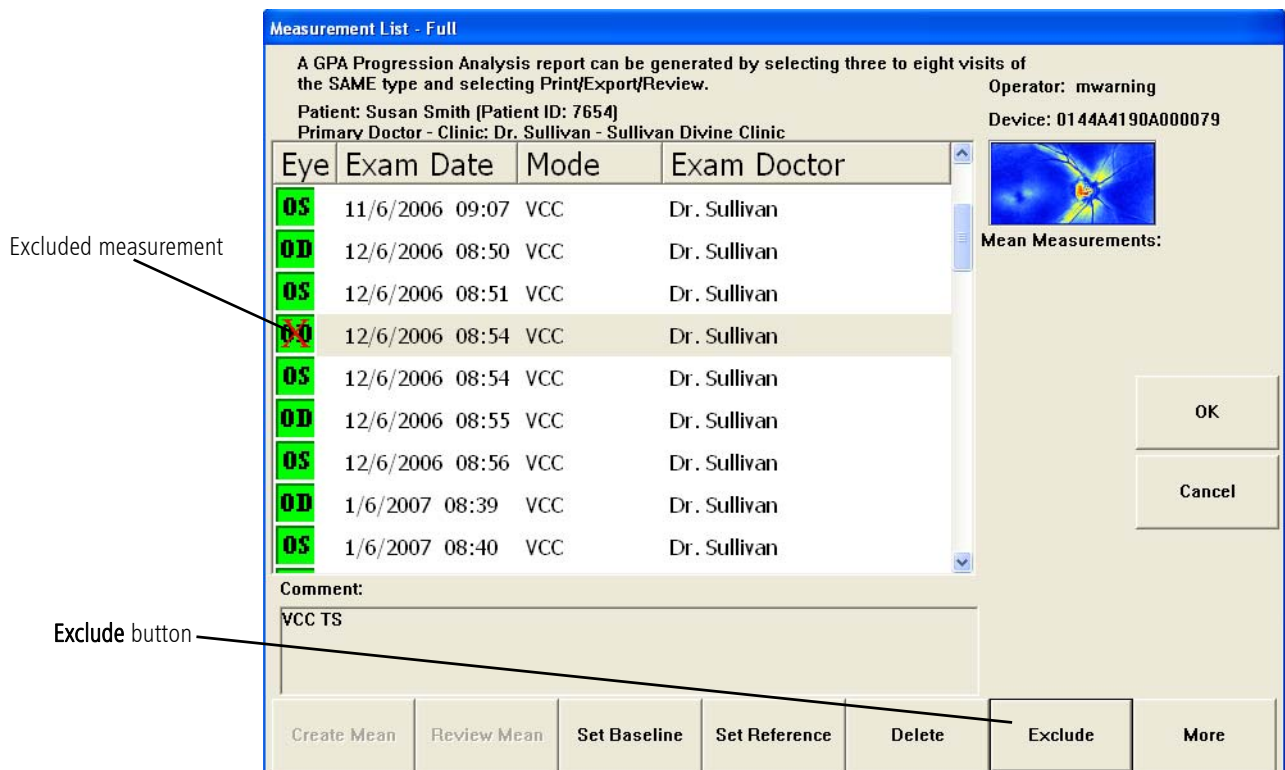

Figure 7-6 Excluded Measurement

Remeasuring Corneal Measurements

Over time, some patients require new corneal measurements in order to maintain image quality. This should be done whenever the need arises (see Remeasuring the Corneal Compensation Image on page 4-24).

Overview of the GPA Report

Color-Coded RNFL-I Summary Box

Indicates evidence of statistically significant change.

■ = No Progression

■ = Possible Progression

■ = Likely Progression

■ = Possible Increase*

Image Progression Map

Most sensitive to narrow focal change.

TSNIT Progression Graph
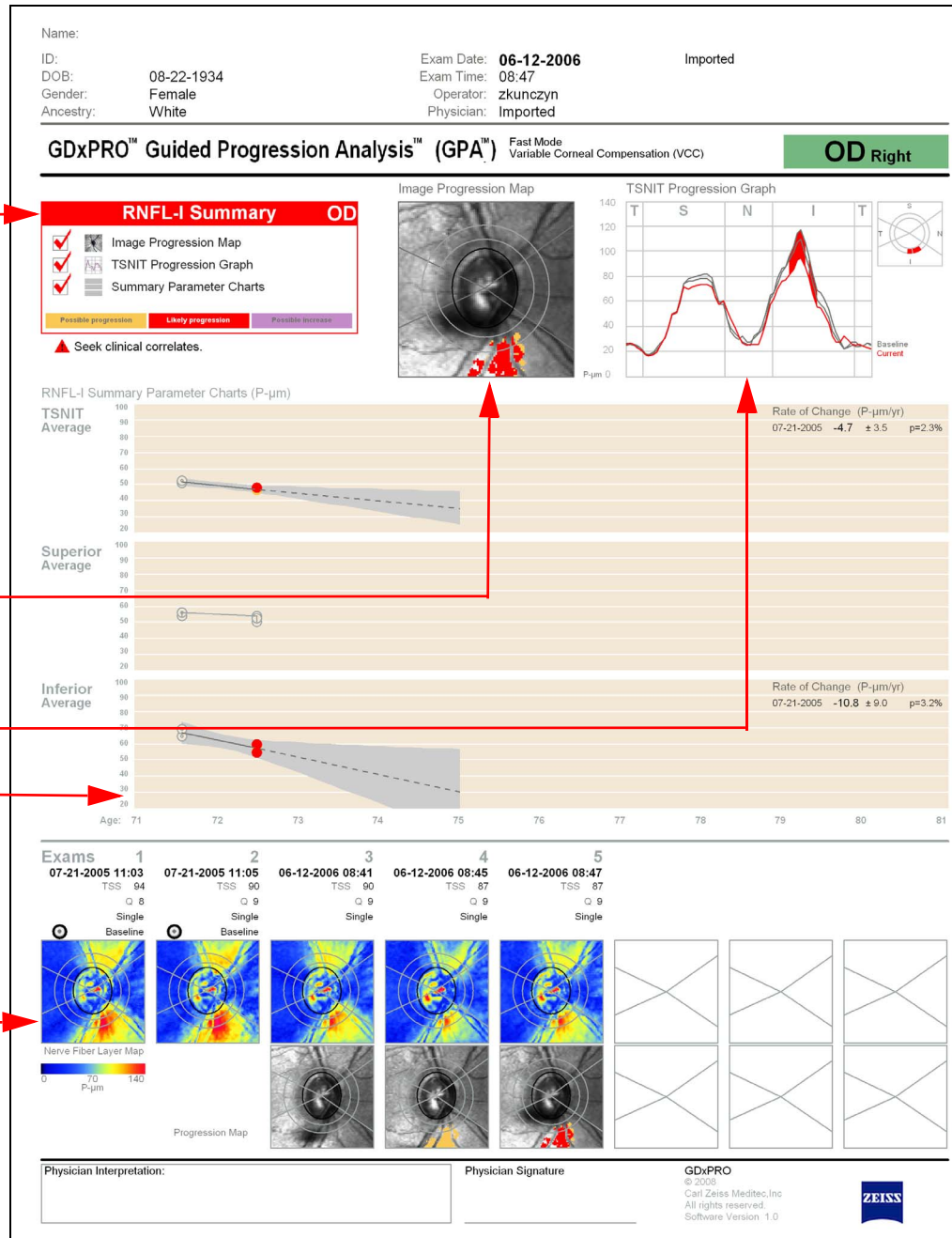
Most sensitive to broader focal change.

RNFL-I Summary Parameter Charts

Most sensitive to diffuse change. If a significant Rate of Change has been detected it is displayed.

Nerve Fiber Layer Maps

Sequence of up to 8 nerve fiber layer maps.

* Possible increase is often due to measurement variability, and is therefore displayed with a warning to check data quality.


Sample courtesy of:
Robert M. Weinreb, MD
Felipe A. Medeiros, MD, PhD
Hamilton Glaucoma Center
University of California, San Diego

Figure 7-7 Sample Guided Progression Analysis (GPA) Report – Right Eye (OD)

How to Read the GPA Report

1. Verify data quality

Verify image quality. If there were any quality issues, a flag (⚠ or ⚠) is displayed below the Image Progression Map. Discard or retake images with poor registration, Q < 7, or TSS (ECC) ≤ 40 or TSS (VCC) ≤ 60 whenever possible, or interpret with caution. For example, see the Nerve Fiber Layer Maps below:
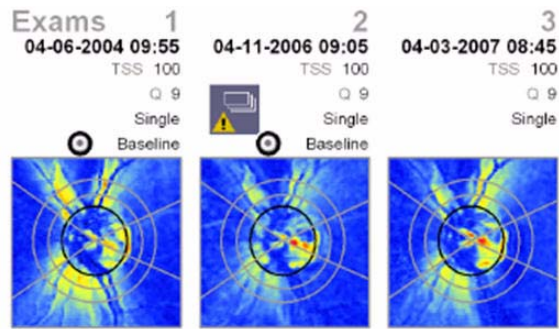
In the Nerve Fiber Layer Maps above, Visit 2 was taken with a dilated eye, which may have caused registration issues. You should delete it.

How similar are the baselines? Examine the TSNIT Graph, RNFL-I Summary Parameter Charts, and Nerve Fiber Layer Maps. If the baselines are not consistent, GPA will be less able to flag progression.

2. Examine GPA printout

Review the color-code RNFL-I summary box. A yellow "Possible progression" summary box indicates additional follow-up visits are recommended to confirm change. A red "Likely progression" summary box indicates statistically significant change is detected in measurements. A grey "Possible increase" summary box could indicate high measurement variability, especially when increase and progression are flagged simultaneously.

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. Correlate results with other clinical tests to detect glaucomatous progression. Rate of progression, locations of the detected progression, age of the patient, stage of the disease, and other clinical factors should be evaluated for clinical decision. Note: The NFI is not analyzed in GPA. It is a key component of the Symmetry Analysis report to help classify patients, but is not an optimal parameter to track change over time.

Report Contents

Summary Box

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

- Image Progression Map (best for focal change) (see page 7-11)
- TSNIT Progression Graph (best for broader focal change) (see page 7-12)
- RNFL-I Summary Parameter Charts (best for diffuse change) (see page 7-13)

The summary box reports progressive loss as either "Possible", shown in yellow, or "Likely", shown in red. "Possible" means progression has been detected once. "Likely" means it has been confirmed by consecutive follow-up examinations. Shown below are examples of summary box displays.
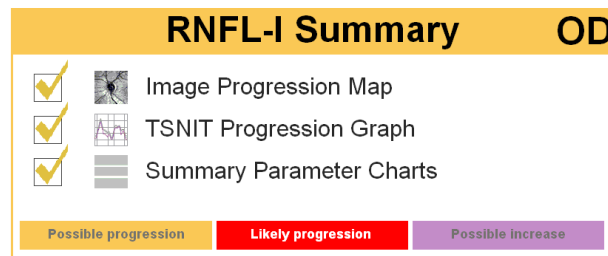
The yellow summary box above shows Possible progression detected by the Image Progression Map. Note the message to confirm with additional exams.
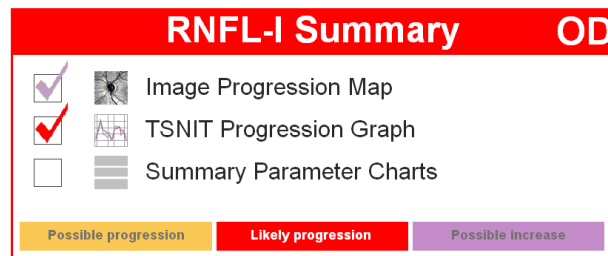
The red summary box above shows Likely progression detected by the TSNIT Progression Graph. Also, Possible increase was detected by the Image Progression Map. Possible increase is often due to measurement variability, and is therefore displayed with a warning to check data quality. The grey summary box below means that no progression has been detected.
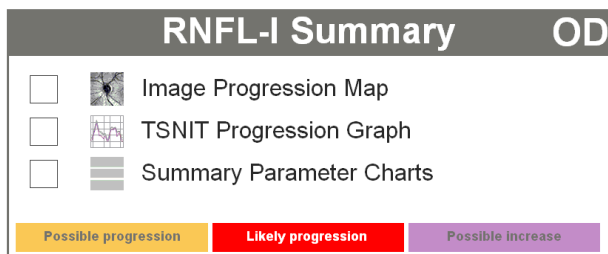
Image Progression Map (best for focal change)

The Image Progression Map (Figure 7-8) displays a fundus image with color-coded areas showing significant changes in RNFL-I measurements compared to the two individual baselines. "Possible progression" areas are shown in yellow, "Likely progression" areas in red, and "Possible increase" areas in purple.

In order to be reported on the summary box, an area of at least *150 adjacent pixels* must show significant change. GPA could theoretically report a change covering an area as small as 2% of the map area.
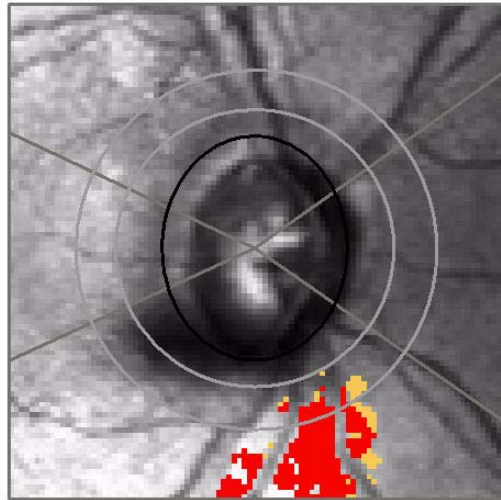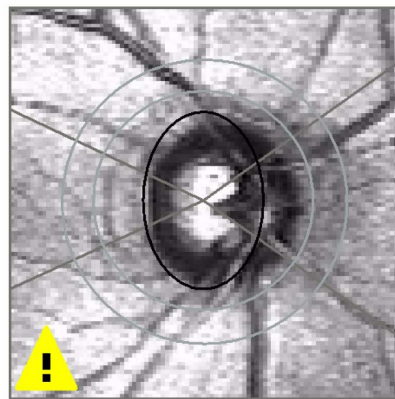

Figure 7-8 Image Progression Map

A warning (Figure 7-9) will be displayed if any image in the progression analysis has a Q < 7 or an alignment problem. The exam(s) causing this warning will display a warning icon in the Nerve Fiber Layer Maps (see Nerve Fiber Layer Maps and Progression Maps on page 7-14).

Figure 7-9 Image Progression Map – Check Data Quality Warning

TSNIT Progression Graph (best for broader focal change)

The TSNIT Progression Graph (Figure 7-10) plots RNFL-I values around the GDxPRO calculation circle, and shows three curves—two for the current baseline set shown in grey, and one for the most recent examination shown in red. TSNIT stands for the regions around the optic disc—Temporal, Superior, Nasal, Inferior, and Temporal. The GDxPRO calculation circle is divided into 64 segments. For "Likely progression" to be reported on the summary box, at least *four adjacent segments* must show significant change. Areas between the current baseline set and the current exam that report significant change are displayed with "Likely progression" shown in red, "Possible progression" shown in yellow, and "Possible increase" shown in purple.

Sample courtesy of:
Robert M. Weinreb, MD
Felipe A. Medeiros, MD, PhD
Hamilton Glaucoma Center
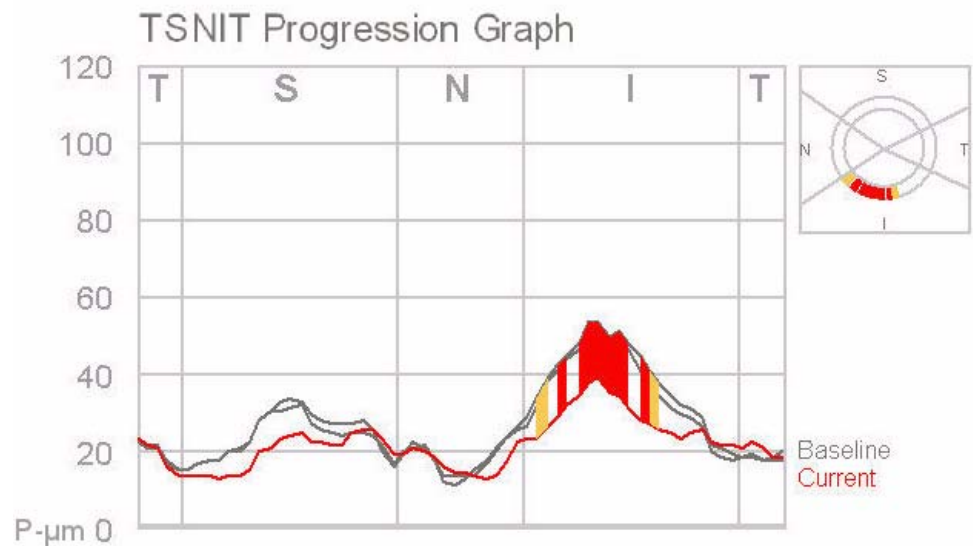University of California, San Diego

Figure 7-10 TSNIT Progression Graph

The TSNIT Progression Map to the upper right of the TSNIT Progression Graph is displayed to help the user orient the locations of change. In this example, it illustrates that change was found inferiorly.
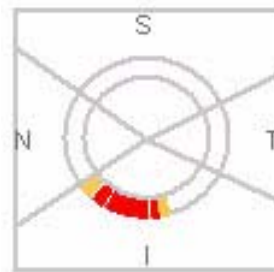

Figure 7-11 TSNIT Progression Map

RNFL-I Summary Parameter Charts (best for diffuse change)

RNFL-I Summary Parameter Charts (Figure 7-12) plot three parameter values—the TSNIT average, Superior Average, and Inferior Average. Each chart displays parameter data from 3 to 8 exams plotted in chronological order. The vertical axis represents parameter values ranging from 20–100 P-µm, and the horizontal axis represents patient age, spanning 10 years.

The charts use the same color code as the rest of the report. Possible Progression, Likely Progression, and Possible Increase are shown as yellow, red, and purple dots, respectively. Baseline images are shown as a circle with a black dot.

A regression line is only drawn if there is "Likely progression" *and* there is a significant linear trend (p < 5%).

RNFL-I Summary Parameter Charts (P-µm)

TSNIT Average

Rate of Change (P-µm/yr)
07-21-2005 -4.7 ± 3.5 p=2.3%

Superior Average

Sample courtesy of:
Robert M. Weinreb, MD
Felipe A. Medeiros, MD, PhD
Hamilton Glaucoma Center
University of California, San Diego

Inferior Average

Rate of Change (P-µm/yr)
07-21-2005 -10.8 ± 9.0 p=3.2%
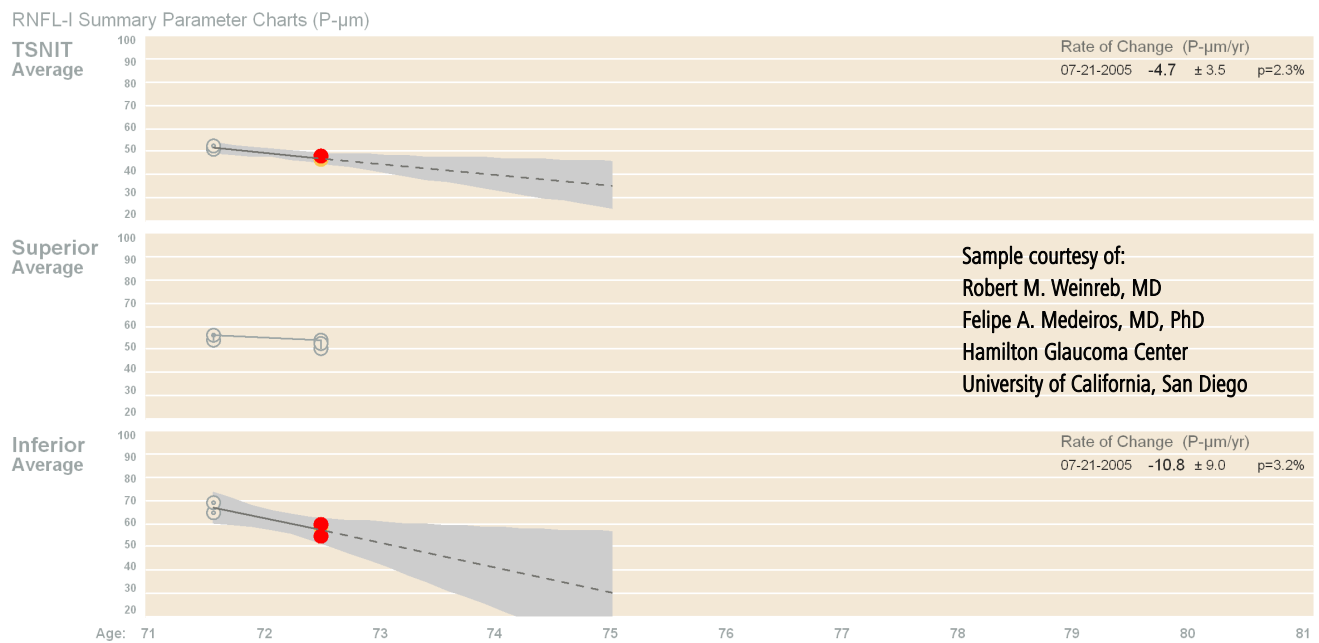
Age: 71 72 73 74 75 76 77 78 79 80 81

Figure 7-12 RNFL-I Summary Parameter Charts

The slope (rate of change) is displayed in (P-µm)/year with 95% *confidence interval* values. For example, with a slope of −3.9 ±1.1, we can be 95% confident that the slope is between −2.8 and −5.0 (P-µm)/year. This is shown graphically in the shaded gray area.

☞ Note: 20 P-µm is the lowest value on the charts because this is typically the lowest measurement.

☞ Note: GPA analysis does not perform any age-related corrections.

Dual Baselines

A useful feature of GPA is that the user can add a second pair of baselines. Two baseline sets can generate two regression lines and prediction intervals. The new prediction interval is shown on the chart with a darker grey color, its regression line is shown in red, and its rate of change is shown below the previous baseline's rate of change in a darker color.

In a simulated example (see Figure 7-17), the Inferior Average was progressing at 3.8 P-µm per year and then treated in 2003. The two data points closest to the time of treatment were selected as new baselines, and the "before" and "after" regression lines were compared.

Instrument or Calibration Change

Instrument or calibration change is indicated on the RNFL-I Summary Parameter Charts by a blue asterisk* at the top of the charts where a GDx instrument has changed. The software only supports data across two distinct instruments, each of which must have at least two visits (a mean is considered one visit). See Example 1: Focal Change with Data Acquired from Two Instruments on page 7-16 for an example of instrument change.

Nerve Fiber Layer Maps and Progression Maps

The bottom of the Progression Analysis report displays maps from 3 to 8 exams chronologically from left to right—the upper row displays Nerve Fiber Layer Maps and the lower row displays image progression maps (Figure 7-13).

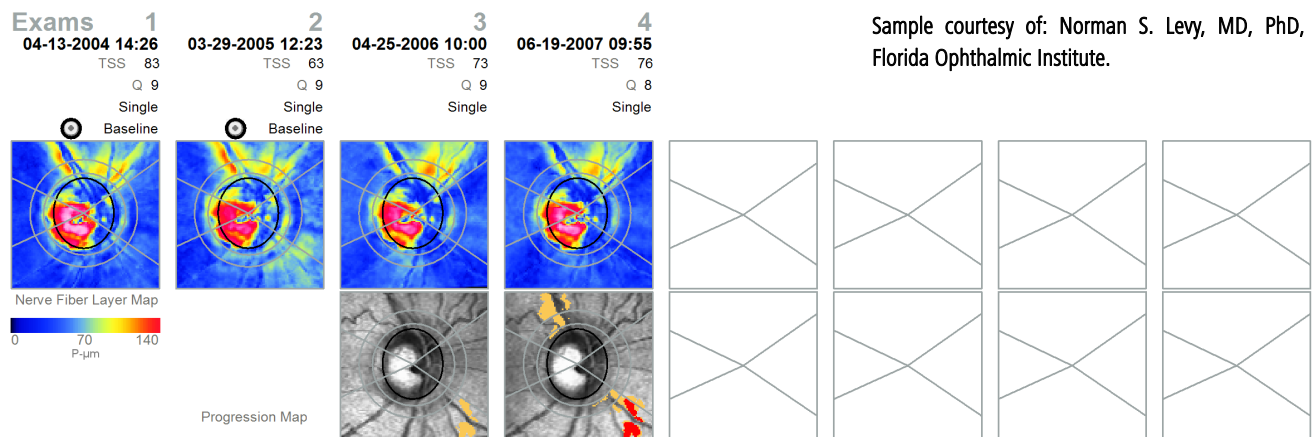*Figure 7-13 Nerve Fiber Layer Maps and Progression Maps*

In Figure 7-13, the first progression map, under Exam 3, is generated by comparing Exam 3 to the baseline images. The areas of significant change when first detected are displayed in yellow for "Possible progression." The next progression 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 progression." Notice that there are also some yellow areas in the last progression map showing changes not seen in the previous exam.

For each exam displayed on the top row, the following is displayed below the exam acquisition date:

- Typical Scan Score (TSS). TSS provides a measure of the "typicality" of the RNFL image. For more information see Typical Scan Score (TSS) on page 6-6.
- Image Quality Score (Q). For more information refer to Quality Parameters on page 4-13.
- If Q is below 7, an exclamation icon will be displayed next to the Q value:

- If the image has an alignment problem, an alignment icon will be displayed:

- "Single" is displayed for single measurements. The standard deviation (SD) is displayed if the image is a mean of two or three measurements.
- If the exam is part of a baseline set, it is indicated by displaying "Old Baseline" for the previous baseline, and "Baseline" with a icon for the current baseline.

GPA Examples

Following the framework in How to Read the GPA Report on page 7-9, we can analyze the following GPA Report examples.

Samples courtesy of Robert M. Weinreb, MD, and Felipe A. Medeiros, MD, PhD, Hamilton Glaucoma Center, University of California, San Diego.

Example 1: Focal Change with Data Acquired from Two Instruments

This report (Figure 7-15 on page 7-17) can be evaluated as follows:
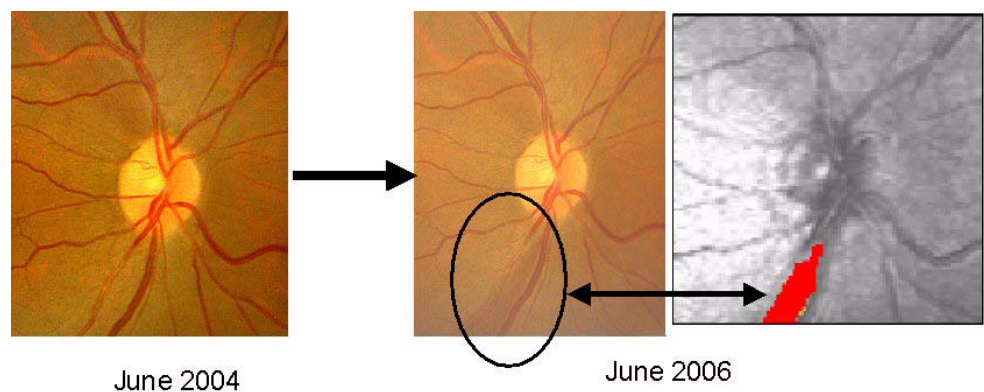
1. Verify data quality

- The Quality Scores of all images are within the recommended limits for both images. There are no alignment errors.
- The baselines were taken on the same day, and the RNFL-I Summary Parameter Charts, the TSNIT Progression Graph, and the Nerve Fiber Layer Maps all indicate the baselines are highly consistent.
- Visits 3 to 5 were taken with a different instrument than visits 1 to 2, as indicated by the blue asterisk* on the RNFL-I Summary Parameter Charts. When exams are taken by different instruments, or the same instrument with different calibrations, GPA requires at least two readings on each in order to account for inter-machine variability. This is why although the Nerve Fiber Layer Map for Visit 3 shows inferior loss, this loss is not flagged on the Progression Map until Visit 4.

2. Examine GPA printout

- Summary box: The Image Progression Map has a red check mark.
- The Image Progression Map shows focal inferior loss. The TSNIT Progression Graph does show a dip in the Inferior quadrant corresponding to this wedge, but it was not flagged because the change was too narrow to affect 4 adjacent segments.

3. Apply GPA results in context of patient

Determine if the changes indicated by GPA are clinically significant. The patient is over 70 and developed inferior loss over just two years, which is confirmed by the photos below (Figure 7-14). Here are the fundus images for this case:

Sample data courtesy of:
Robert M. Weinreb, MD
Felipe A. Medeiros, MD, PhD
Hamilton Glaucoma Center
University of California,
San Diego

Figure 7-14 Defect on Progression Image Map also Visible on Fundus Images

Figure 7-15 Example 1 – Focal Change with Data Acquired from Two Instruments

Example 2: Inferior Change, Identified by All Approaches

This report (Figure 7-16 on page 7-19) can be evaluated as follows:

<u>1. Verify data quality</u>

- The Quality Scores of all images are ≥ 7 and the TSS scores are > 40 for ECC or > 60 for VCC. There are no alignment errors.
- The baselines are consistent.

<u>2. Examine GPA printout</u>

- Summary box: All three analysis tools have red check marks, all corresponding to an inferior change.
- The Inferior Average RNFL-I Summary Parameter Chart reports the rate of change is -10.8 ±9 (P-µm)/year. The analysis was performed with only 1 year of data, and more follow-up over time is needed to narrow the confidence interval.

<u>3. Apply GPA results in context of patient</u>

Combine with other clinical observations to determine if the changes indicated by GPA are clinically significant. Note: The three images taken on 6-12-06 could be a baseline for future analyses in Extended Mode.

Figure 7-16 Example 2 – Inferior Change Identified by All Approaches

Example 3: Dual Baseline Analysis (Simulated Data)

This report (Figure 7-17 on page 7-21) can be evaluated as follows:

1. Verify data quality
- The Quality Scores of all images are 10 and the TSS scores are 100. There are no registration errors.
- The baselines look highly consistent. Visits 1 and 2 are the first set of baselines. Visits 3 and 4 are the second set of baselines.
- The analysis was done using Extended Mode for greater sensitivity. Standard Deviation (SD) values for the mean images are below 8.6.

2. Examine GPA printout
- Summary box: Likely Progression was found on both the TSNIT Progression Graph and the RNFL-I Summary Parameter Charts (applies to Visits 3–6).
- All detected RNFL loss was in the inferior bundle. The trend for the Inferior Average seen for Visits 1–4 was -3.9 ±1.1 (P-µm)/year. The trend for the Inferior Average seen between Visits 3–6 was -1.8 ±1.1 (P-µm)/year

3. Apply GPA results in context of patient

The dual baseline analysis implies the rate of RNFL loss decreased since Visit 3, presumably as the effect of intervention. Combine this information with other clinical observations to determine if further changes should be made in the patient's treatment plan.

Name:

ID:
DOB: 06-02-1974
Gender: Male
Ancestry: Asian

Exam Date: **02-17-2006**   Imported
Exam Time: 10:50
Operator: mpintsberg
Physician: Imported

GDxPRO™ Guided Progression Analysis™ (GPA™) Extended Mode
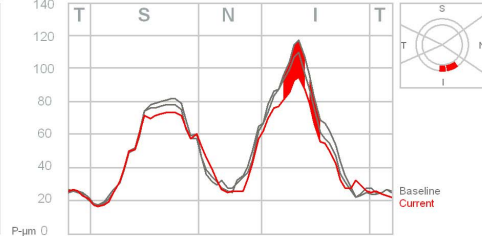Variable Corneal Compensation (VCC)

OD Right

RNFL-I Summary **OD**
- ☐ Image Progression Map
- ☑ TSNIT Progression Graph
- ☑ Summary Parameter Charts

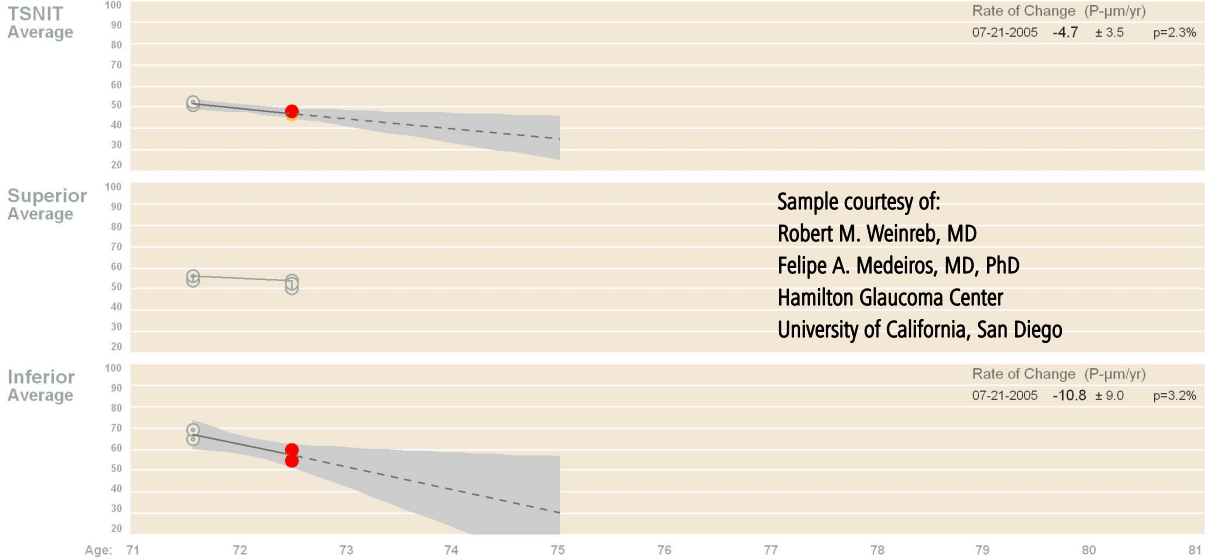Possible progression | Likely progression | Possible increase
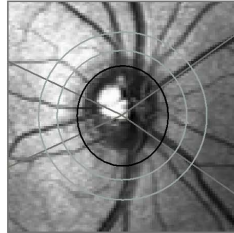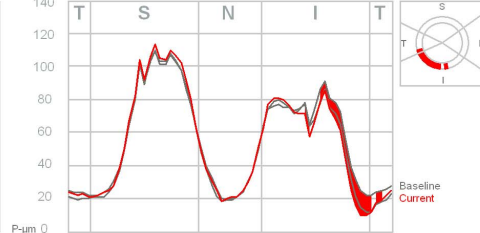
⚠ Seek clinical correlates.

Image Progression Map

TSNIT Progression Graph

Baseline
Current

RNFL-I Summary Parameter Charts (P-µm)

TSNIT Average

Rate of Change (P-µm/yr)
01-20-2001   -2.0   ± 0.6   p<0.1%

Superior Average

Inferior Average

Rate of Change (P-µm/yr)
01-20-2001   -3.9   ± 1.1   p<0.1%
04-15-2003   **-1.8**   ± 1.1   p=0.4%

Baseline Reset

Age: 27   28   29   30   31   32   33   34   35   36   37
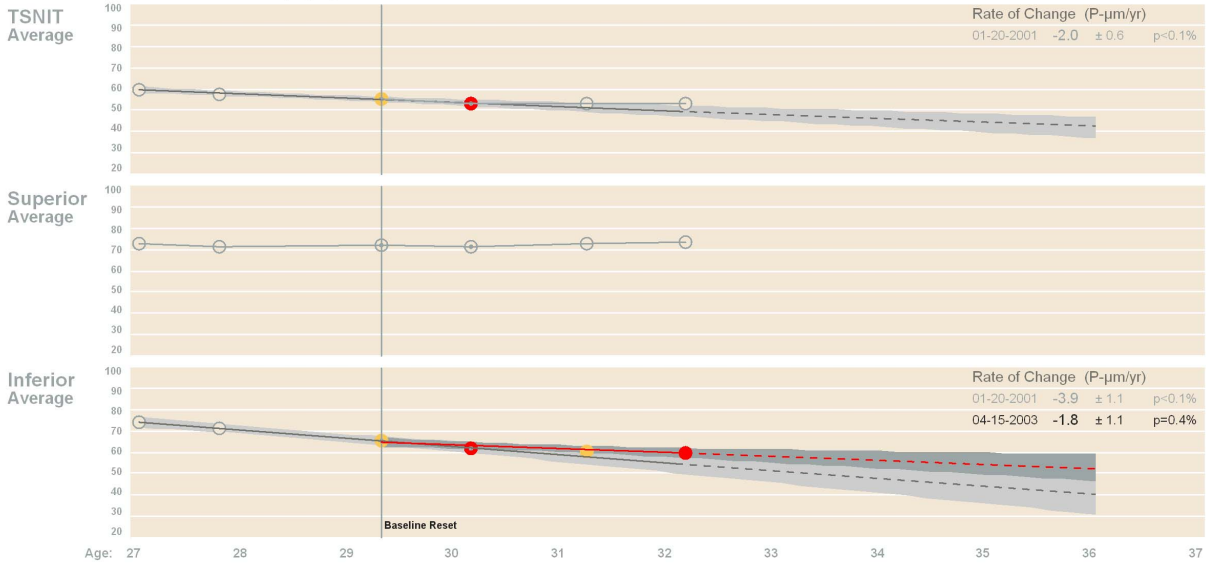
Exams

1	2	3	4	5	6
01-20-2001 11:29	10-02-2001 13:00	04-15-2003 08:42	02-14-2004 14:31	03-22-2005 08:20	02-17-2006 10:50
TSS 100	TSS 100	TSS 100	TSS 100	TSS 100	TSS 100
Q10	Q10	Q10	Q10	Q 9	Q10
SD 4.30	SD 4.31	SD 3.56	SD 4.29	SD 3.52	SD 4.34
Old Baseline	Old Baseline	Baseline	Baseline		

Nerve Fiber Layer Map

0   70   140
P-µm

Progression Map

Physician Interpretation:

Physician Signature

ZEISS

*Figure 7-17 Example 3 – Baseline Reset Displays Decreased Range of Progression
Beginning with Visit 3 (Simulated Data)*

(8) System Functions

Chapter Overview

Topics covered in this chapter include:

System Options

The SYSTEM OPTIONS screen (from the MAIN screen, select the **System** button) displays software and system information and contains system related functions.
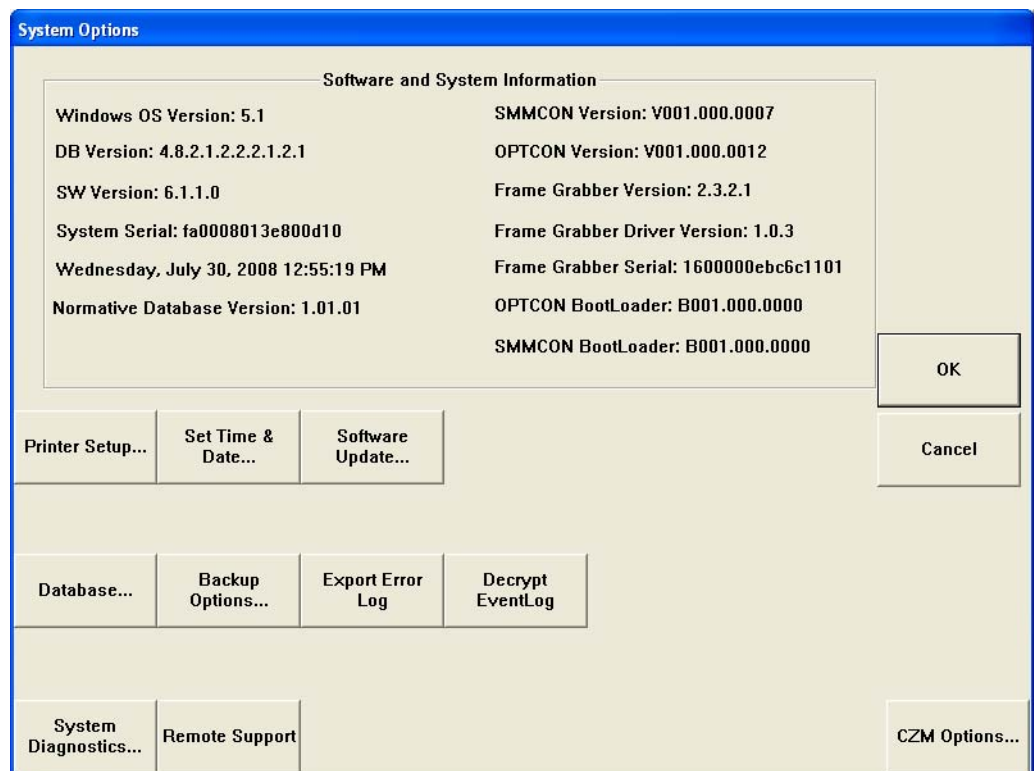
Figure 8-1 System Options Screen

Printer Setup

The Printer Setup function (**System > Printer Setup**) is described in the Setup chapter. See Setting Up a Printer on page 2-15.

Set Time & Date

The Set Time & Date function (**System > Set Time & Date**) is described in the Setup chapter. See Setting the Time and Date on page 2-5.

Software Update

You may receive optical disks from CZM that update the System software for the GDxPRO. To update the System software, select **System > Software Update** to display the SOFTWARE UPDATE screen.
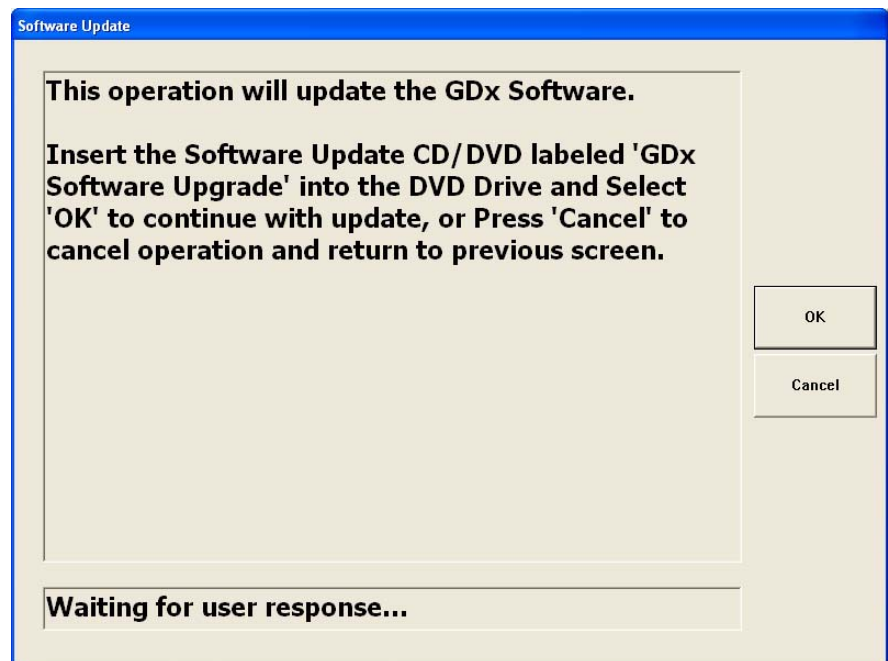
Figure 8-2 Software Update Screen

Insert the optical disk labeled "GDxPRO Software Upgrade" into the optical drive and select **OK** to continue with the update. Follow the on-screen prompts. Select **Cancel** to cancel the update and return to the MAIN screen.

Database Options

The DATABASE OPTIONS screen (**System > Database**, Figure 8-3) allows the user to optimize database performance and merge exam files from another GDx. A Full Backup and Restore database function is also available.

Figure 8-3 Database Options Screen

Optimize

As with any computer-based system, the more reading and writing to and from a database, the more the data becomes fragmented on the hard disk. Therefore, the performance of these operations will slow over time. The Optimize function packs and re-indexes the database for efficiency. The system is routinely optimized during the system warm up. Only run the Optimize function at the recommendation of the CZM Service department.

At the MAIN screen select **System** > **Database** > **Optimize** (Figure 8-4). GDxPRO will optimize the database and return to the MAIN screen automatically.
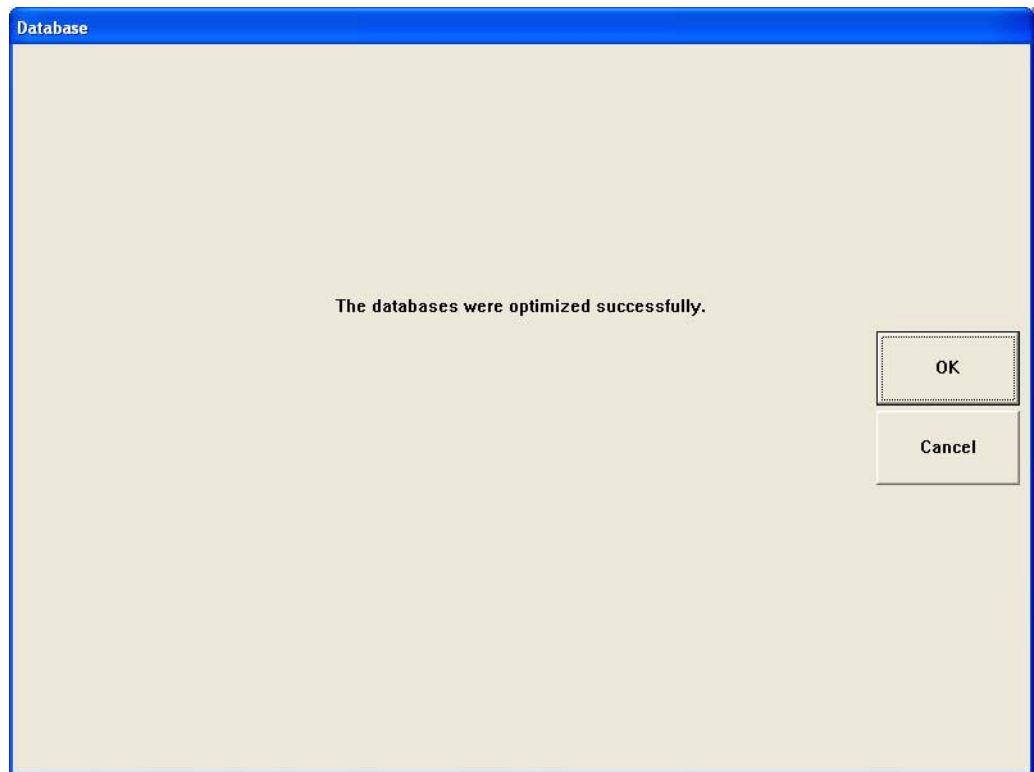
Figure 8-4 Database Optimize Screen

Merge

The Merge function is used to transfer data from a GDxVCC or GDxPRO to another system. Merge will merge the database files from a user specified location (source) to the main drive (destination). All records are consolidated from the two databases into one database. This operation is available to any user with administrative privileges. The merge can support any database version as long as the data on the master drive is newer or the same version than the database being merged to.

To perform the Merge operation, at the MAIN screen, select **System** > **Database** > **Merge**. Browse to the location where the database to be merged is located and then select the **OK** button.
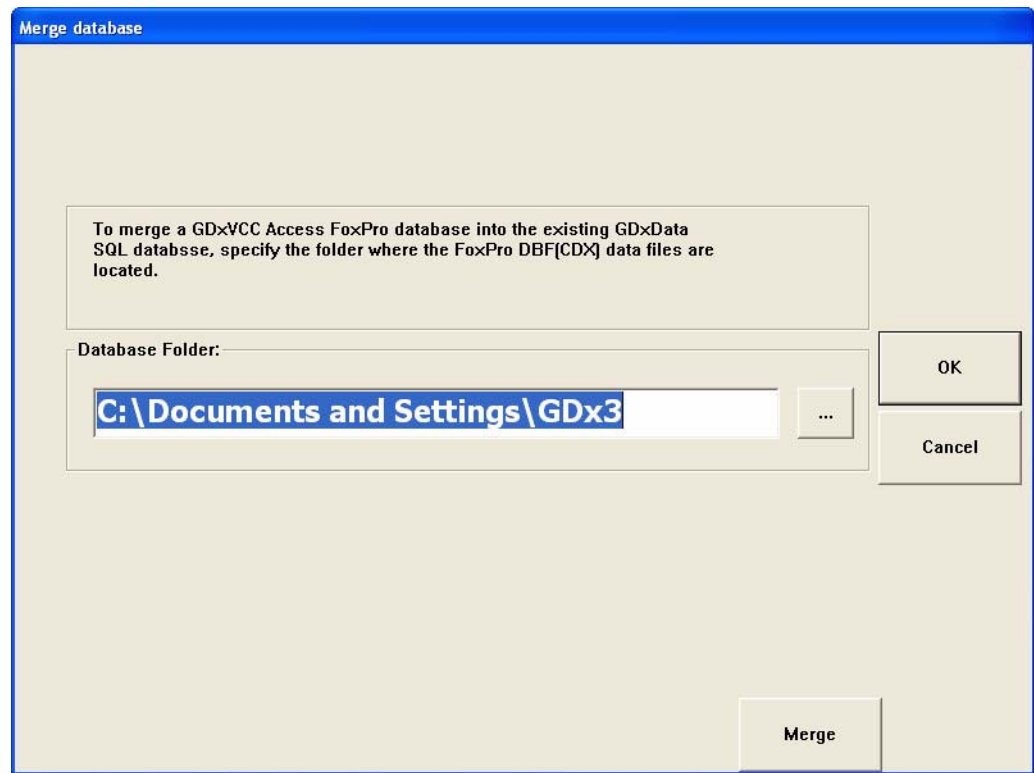
Figure 8-5 Database Merge Screen

Recalculate Data

Performing the Recalculate Data function will update all records in the database with the most current version of calculations. This function may be performed after a software update and may take a while depending on the number of records in the database. This process can be cancelled at anytime.

To perform the Recalculate Data operation, at the MAIN screen, select **System** > **Database** > **Recalculate Data.** Select **OK** on the Recalculate Data dialog (Figure 8-6).
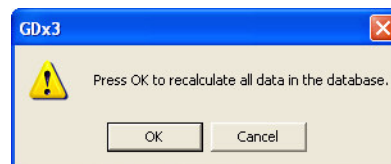
Figure 8-6 Recalculate Data Dialog

A PROGRESS STATUS screen will be displayed (Figure 8-7).
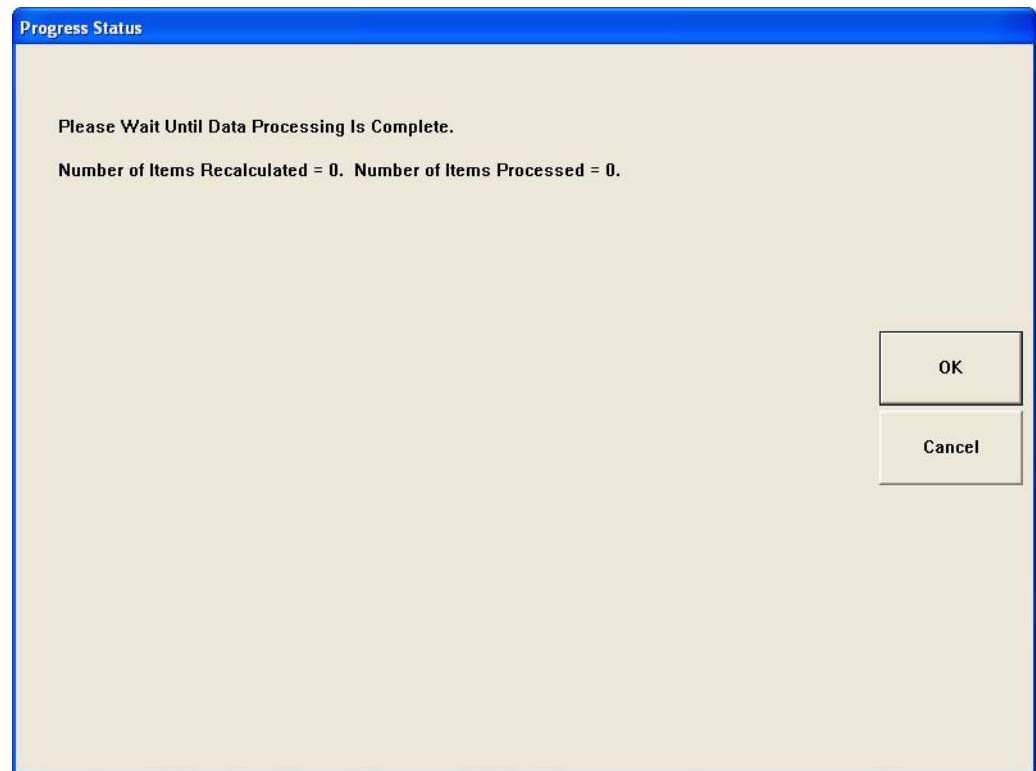
Figure 8-7 Recalculate Data Progress Status Screen

When the Recalculate Data function is complete a dialog will be displayed (Figure 8-8).
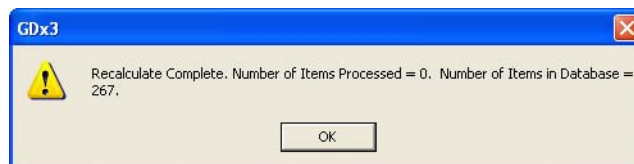
Figure 8-8 Recalculate Data Complete Dialog

Importing and Exporting Data

You can connect a GDxPRO directly to a Windows PC or network server via the Ethernet network card in your PC. Alternatively, if you have a local area network (LAN) in your office, you can attach a GDxPRO to the LAN, allowing it to communicate with any of the networked Windows PCs or printers within your clinic. Using either of these methods, you can import and export raw measurement data (without formatting).

There are several reasons that you might want to perform data imports and exports. For example, you can export measurement data to a PC in order to back up the data. Later the data can be imported again, possibly to a different GDxPRO instrument. This might be useful in a practice where doctors perform exams on multiple instruments, since this allows patient data to be easily transferred from one GDxPRO to another as needed. You can even place the exported data on removable media such as USB flash disk or optical disk (see (D) Data Transfer Using Optical Disks), and transport it to another clinic where it can be imported from a networked PC to any GDxPRO instrument at that clinic. In this way, doctors who see the same patients at different clinics can easily transfer data from clinic to clinic.

☞ Note: For GPA analysis, it is not recommended to perform scans for the same patient on different instruments.

For exporting and individual patient information see Printing/Exporting Exams on page 5-6.

To use the database importing and exporting features, see Export Data and Import Data below.

Export Data

The **Export Data** function exports all information required to regenerate the database. To perform the Export Data operation, at the MAIN screen, select **System** > **Database** > **Export Data.** A Browse for Folder dialog will open where you can select the folder for the data export. Selecting the optical disk drive will initialize burning of a CD/DVD.

Import Data

Selecting **Import Data** imports data into the current systems database. Importing only imports updated or new database records. All calculation records are recalculated prior to saving into the database. To perform the Import Data operation, at the MAIN screen, select **System** > **Database** > **Import Data.** A Browse for Folder dialog will open where you can select the data import folder.

Set Database

The Set Database function allows the GDxPRO database to be located on a remote network computer rather than on the instrument.

To set the remote database on the GDxPRO, follow these steps:

1. Select **System > Database > Set Database** to display the DATABASE CONNECTION SETTINGS screen (Figure 8-9).

Figure 8-9 Database Connection Settings Screen

2. Enter the **Server/Computer Name** for the network location.
3. Enter the **SQLServerInstance** name **SQLServer password**.
4. Enter the location of the Primary Data Folder which resides on the database server in the Primary Data Folder edit box.
5. Enter the location of the Secondary Data Folders which resides on the database server in the Secondary Data Folder edit box.
6. Select **Test Connection** to ensure a successful connection to the central database.
7. If needed, select **Reset Settings** to reset the settings to those automatically entered at installation.
8. Select **OK** to test and save the configuration.

☞ Important: The GDxPRO Server computer should never be turned off while transferring data. In addition, hibernation mode and turning off hard drives should be disabled.

Full Backup/Restore

The GDxPRO database can be stored in a backup location in addition to the default location by using the Full Backup function. For backing up data, the user should use this function. Just copying the directory will not back up the files in a format the database can recover. To perform a full database backup or restore select the **System** button from the MAIN screen, select the **Database** button from the SYSTEMS OPTIONS screen, and then the **Backup/Restore** button to display the DATABASE FULL BACKUP AND RESTORE screen (Figure 8-10).
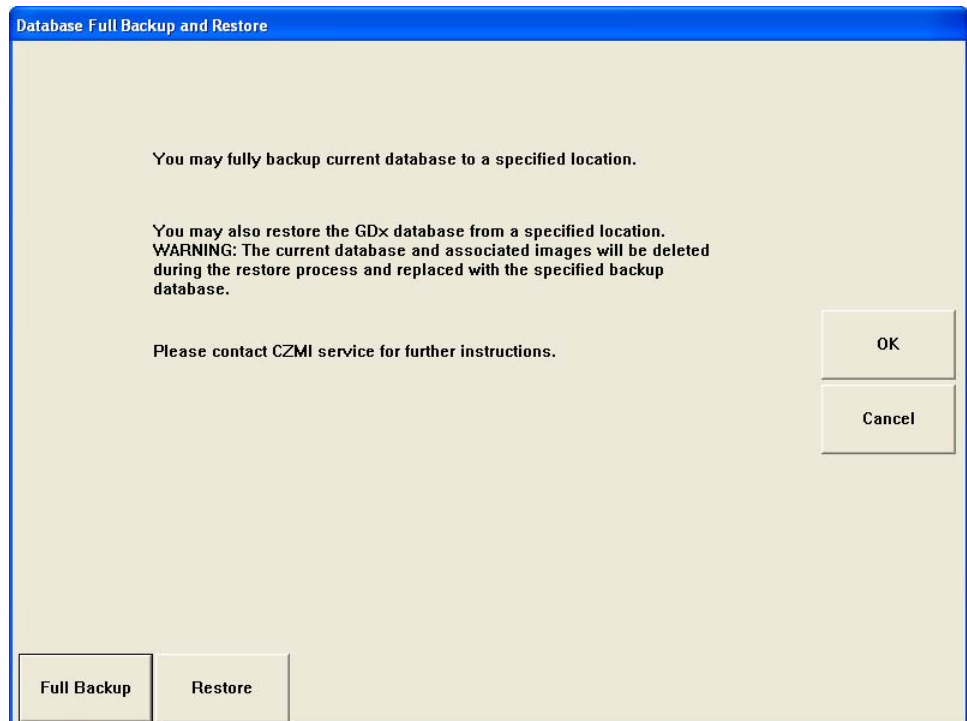

Figure 8-10 Database Full Backup and Restore Screen

Full Backup

To perform a full database backup, select the **Full Backup** button to display a **Browse for Folder** dialog (Figure 8-11) where you can select the folder for the backup.
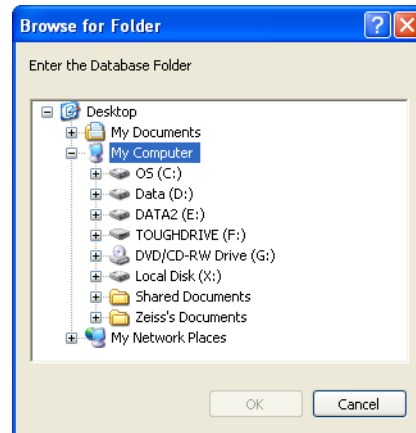
Figure 8-11 Full Backup Browse for Folder Dialog

After you select the folder, select **OK** to perform the full database backup. Select **Cancel** to cancel the backup.

<u>Restore</u>

The database can be restored from the full backup replacing the existing system database.

⚠ **WARNING: The restore operation will replace all data on the master drive. Once started, there is no way to recover the data to the previous state.**

Select the **Restore** button to restore a database that you have backed up with the Full Backup function. A Browse for Folder dialog (Figure 8-12) will be displayed where you can select the folder where the database has been backed up.
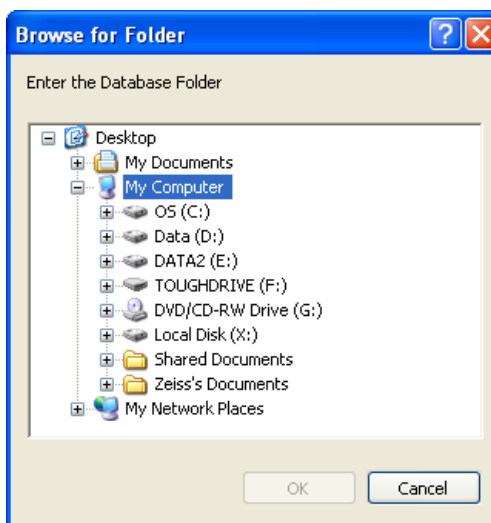
Figure 8-12 Restore Browse for Folder Dialog

After you select the folder, select **OK** to perform the database restore. Select **Cancel** to cancel the restore. If you select **OK**, a warning message will be displayed (Figure 8-13).
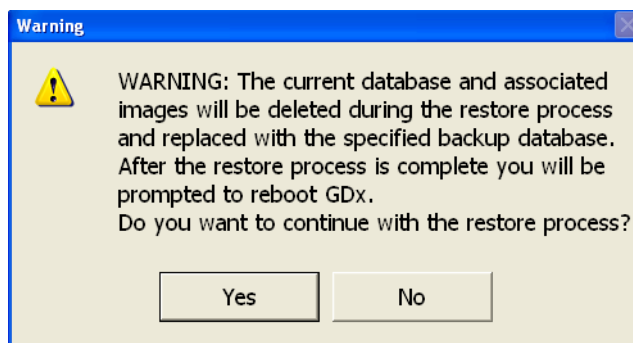
Figure 8-13 Restore Database Warning

Select **Yes** to begin the database restore, or **No** to cancel. If you select **Yes**, the GDxPRO application will close. Restart the GDxPRO application or reboot the GDxPRO instrument to use the restored database.

Disk Backup Options

The system saves data to both a primary and a backup hard disk drive for data safety. If one of the hard drives fails, it will need to be replaced.

⚠️ WARNING: Only disable disk backups when instructed by CZMI. This option may cause adverse side effects.

To turn the Backup Options off, at the MAIN screen select **System** > **Backup Options** > **Turn Backups Off** to display the BACKUP OPTIONS screen (Figure 8-14).
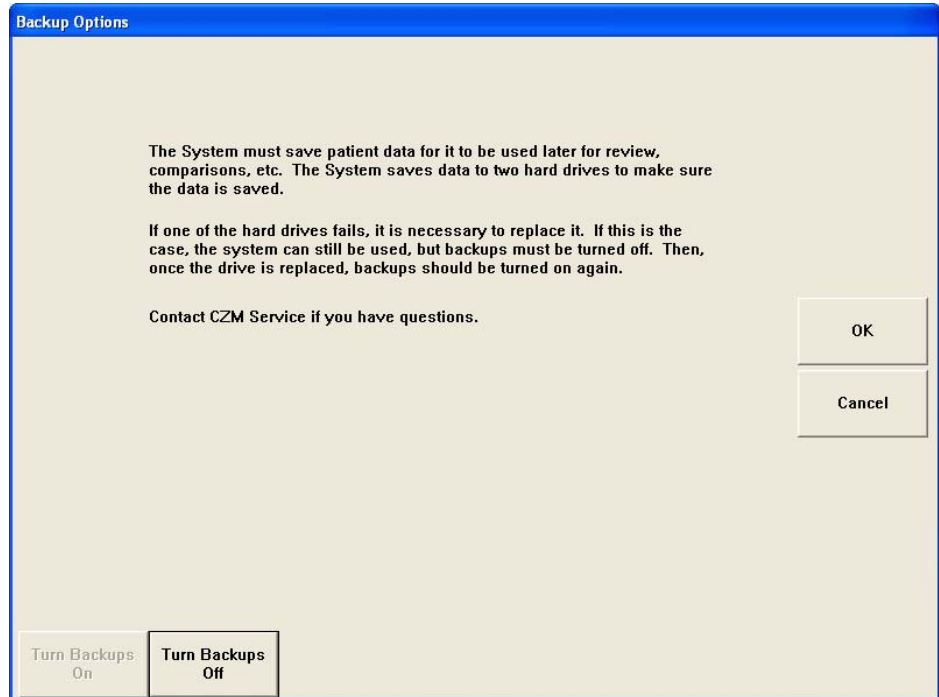
Figure 8-14 Backup Options Screen

The system will display a warning dialog asking if you are sure you want to turn backups off (Figure 8-15).
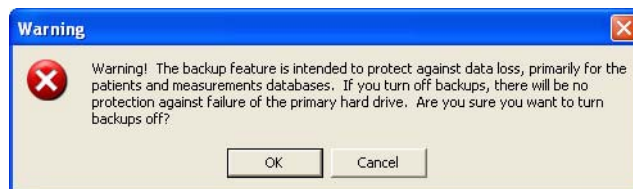
Figure 8-15 Backup Options Warning Dialog

Press **OK** to turn backups off and return to the MAIN screen. Press **Cancel** to keep backups turned on and return to the BACKUP OPTIONS screen.

If data was saved when the system contained only one functioning hard drive, the system will update the replaced hard drive with the data acquired while it was absent. When the system is powered up after replacing the hard drive, the system will automatically copy the Master (top) drive contents to the Backup (bottom) drive.

Export Error Log

The Export Error Log function exports all the system's error log files to a user specified folder (e.g., removable media). Error log files include the following:

- Application (user displayed errors; e.g., duplicate Patient ID)
- Hardware (hardware specific failures; e.g., laser safety)
- Database (database errors; e.g., creation, merge)
- Focus Stage (exercise focus stage – step count)
- Compensators (exercise compensator – step count)
- XYZ Table (exercise XYZ table axis – step count)
- Modulator (exercise modulator – calibration values)

Select **System > Export Error Log** to display a **Browse for Folder** dialog (Figure 8-16).
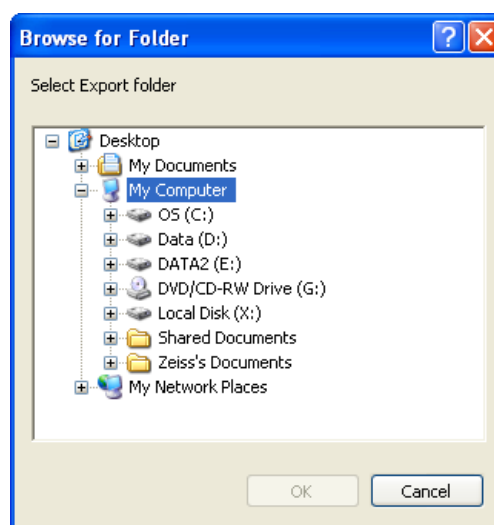
Figure 8-16 Export Error Log Dialog

Select the export folder you want and then select **OK**. The error log files will be saved to this folder.

Event Log File

A log records user events for GDxPRO (for all operators) such as deleting, adding, merging, or modifying patient data, and the operator performing the event. The Event Log File can be used for security, troubleshooting, or as an audit trail. The following events are logged.

- Log in/Log out
- New/Update/Delete Patient
- New/Update/Delete Measurement
- Export/Import Data
- Optimize Database
- Merge from MSDE (GDxPRO)/Fox Pro (GDxVCC)
- Backup Database
- Merge Single Patients

An encrypted Event Log File is created each month. To make the file readable, you need to decrypt it into a readable text file. Only a user logged in as an administrator can decrypt the Event Log. Also, to decrypt, the selected Event Log must have been created on the current instrument or computer. To select an Event Log File, select the **System** button from the MAIN screen, and then select the **Decrypt EventLog** button to display the DECRYPT EVENT LOG screen (Figure 8-17).
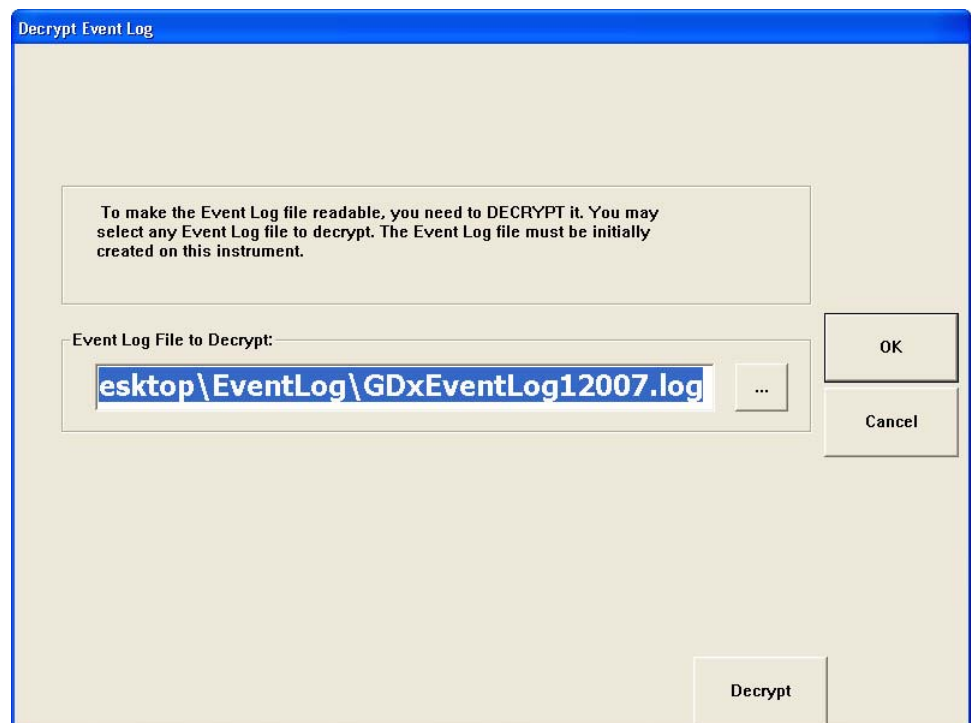
Figure 8-17 Decrypt Event Log Screen

Select the **Browse (...)** button in the EVENT LOG FILE TO DECRYPT field to display an OPEN dialog (Figure 8-18) where you can select the Event Log File for the month you want. For example, the Event Log for January, 2007 will be named GDxEventLog12007, and the file

for December, 2006 will be named GDxEventLog122006. The current month Event Log File is selected as default.
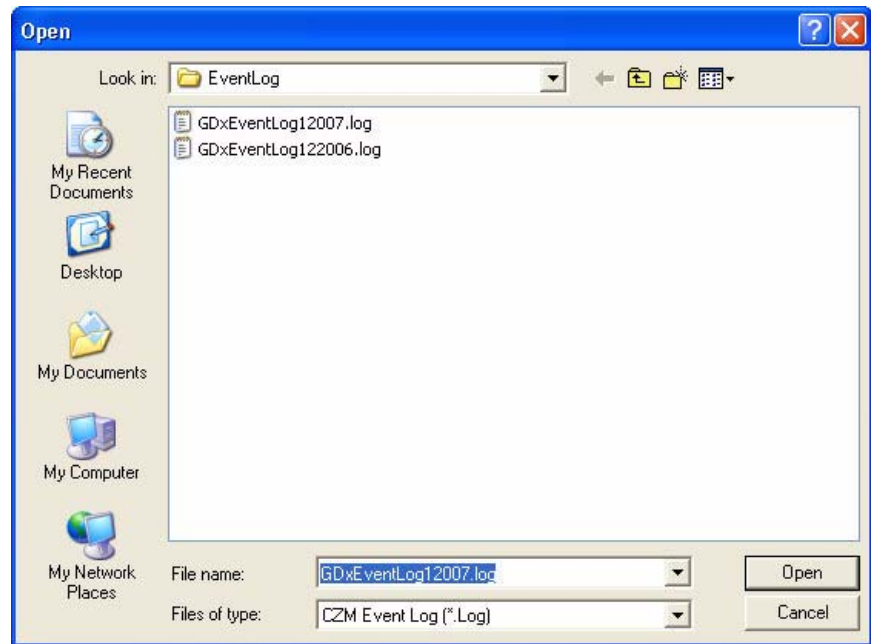
Figure 8-18 Open Decrypt Event Log Dialog

Select the **Decrypt** button to decrypt the file. A dialog (Figure 8-19) will be displayed showing the path where the decrypted text file will be located.
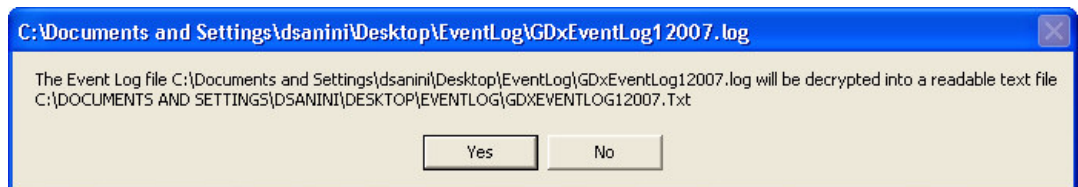
Figure 8-19 Decrypt Event Log Path Dialog

Select **Yes** to proceed. The Event Log text file will be opened in Windows Notepad (see Figure 8-20 for an example). The date and time for each event is recorded. The operator

is recorded at the end of each event. You can save the Event Log File to any location on your computer, network, or removable drive.

Figure 8-20 Example Event Log File in Notepad

System Diagnostics

System diagnostic tests verify that your system is operating correctly. As a part of the tests, the software will verify that the calibration is consistent over time. Some system test measurements are classified as "critical." Failure of these critical tests will cause image acquisition to be disabled (Figure 8-21).
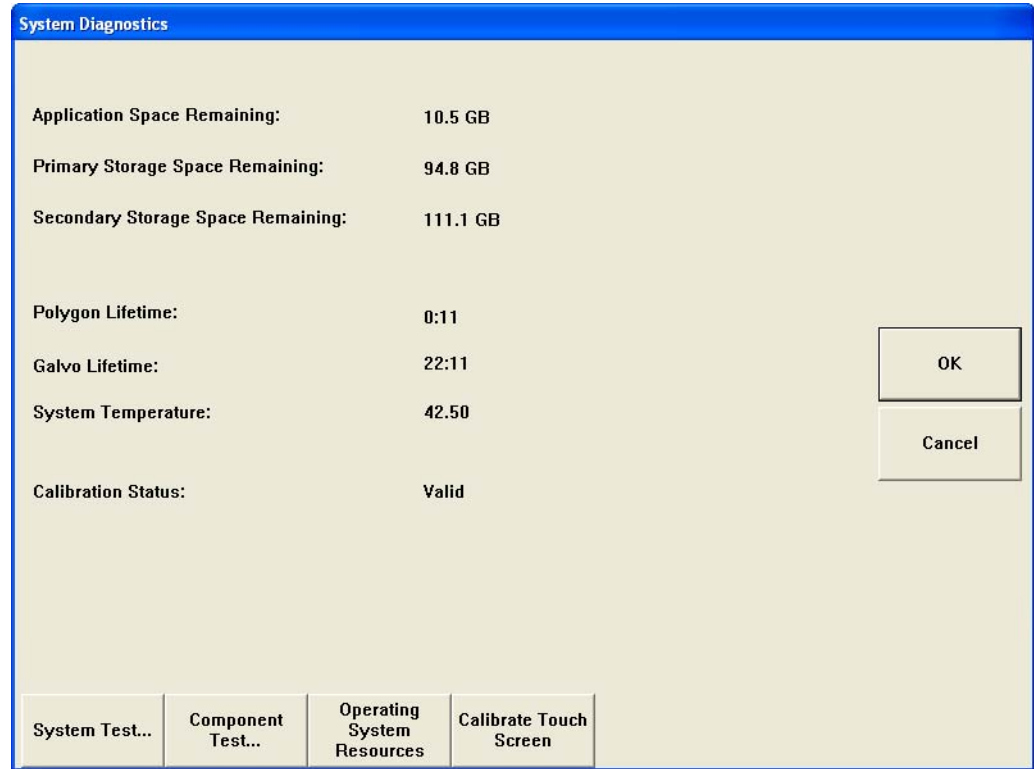
Figure 8-21 System Diagnostics Screen

Automatic System Test

The automatic system warm up is set to run each day when the unit is first turned on. If your system is left on overnight (not recommended), it will run at 2:00 am each day. The test usually takes several minutes. If the unit is cold (i.e. if the unit was transported from another office) it may take up to 30 minutes for the system to "warm-up" and pass the system test. During the test, the clock in the upper left of the WARM UP screen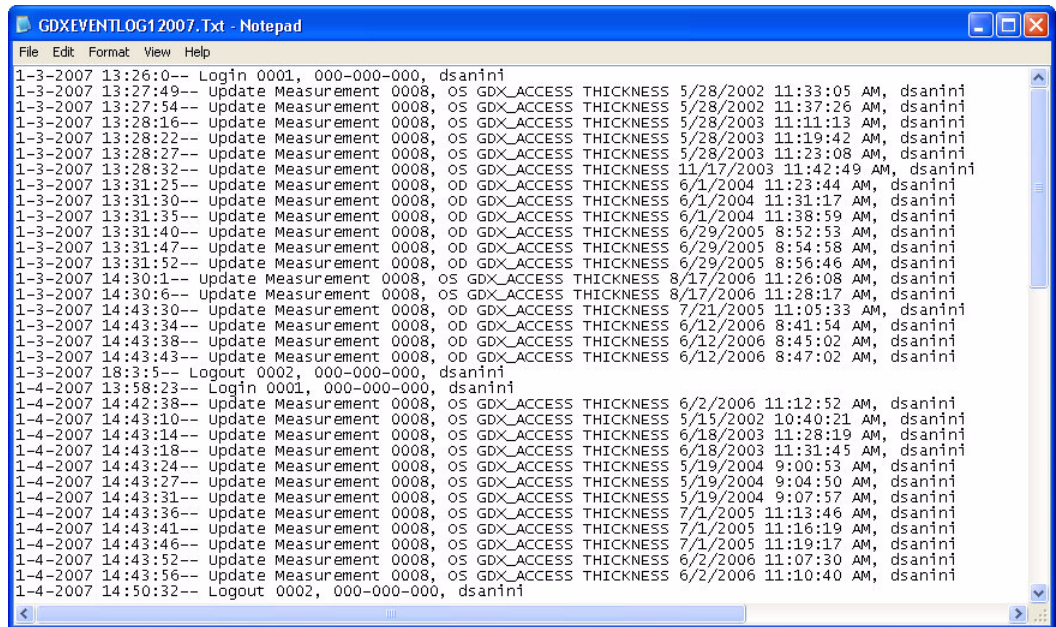 counts up the time from the start of the test, and the light blue dot continuously repeats moving across the screen, left to right, indicating the test is in progress. If there are no errors, the GDxPRO will start up normally. If there are any errors the startup procedure will stop and a screen will be displayed with a list of the errors. If any of the errors are critical and affect scan acquisition, acquisition mode will be disabled. If this happens you will be directed to the next step through the SYSTEM ERROR LIST screen (Figure 8-24).

User Initiated Tests

User Initiated Tests can be run by selecting **System** > **System Diagnostics > System Test** (Figure 8-21).

Figure 8-22 System Test Screen

Single System Test

If you feel your system is not operating properly, it is recommended that you run the System Test **prior** to calling CZM customer service: in the U.S., call 800-341-6968; outside the U.S., contact your local CZM distributor. Information on whether or not the system passed the System Test will be helpful to your CZM service representative.

To run the System Test, at the MAIN screen select **System** > **System Diagnostics >
System Test > Single System Test** (Figure 8-21).
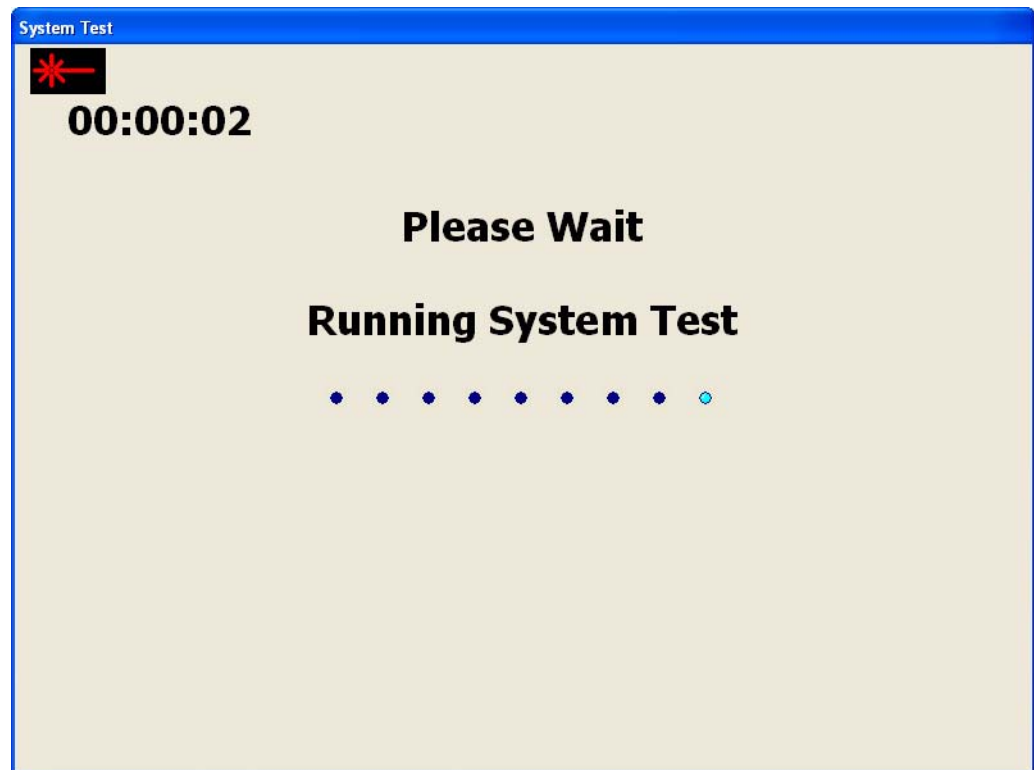
Figure 8-23 Single System Test Screen

The System Test will run one time and progress during the test is displayed on the LCD
display. The System Test may be stopped at any time by pressing **Esc**. If the test is cancelled
before the end of the test, the system may take up to a minute before testing actually
stops.

☞   Note: Never power down the instrument during a System Test.

On completion, if there were no errors a dialog will display that the test is complete, press
OK to close the dialog. If there were errors or if the test was terminated before completion,

errors will be displayed on the SYSTEM ERROR LIST screen (Figure 8-24). Additional information to display is indicated by the scroll bar below the list of errors.
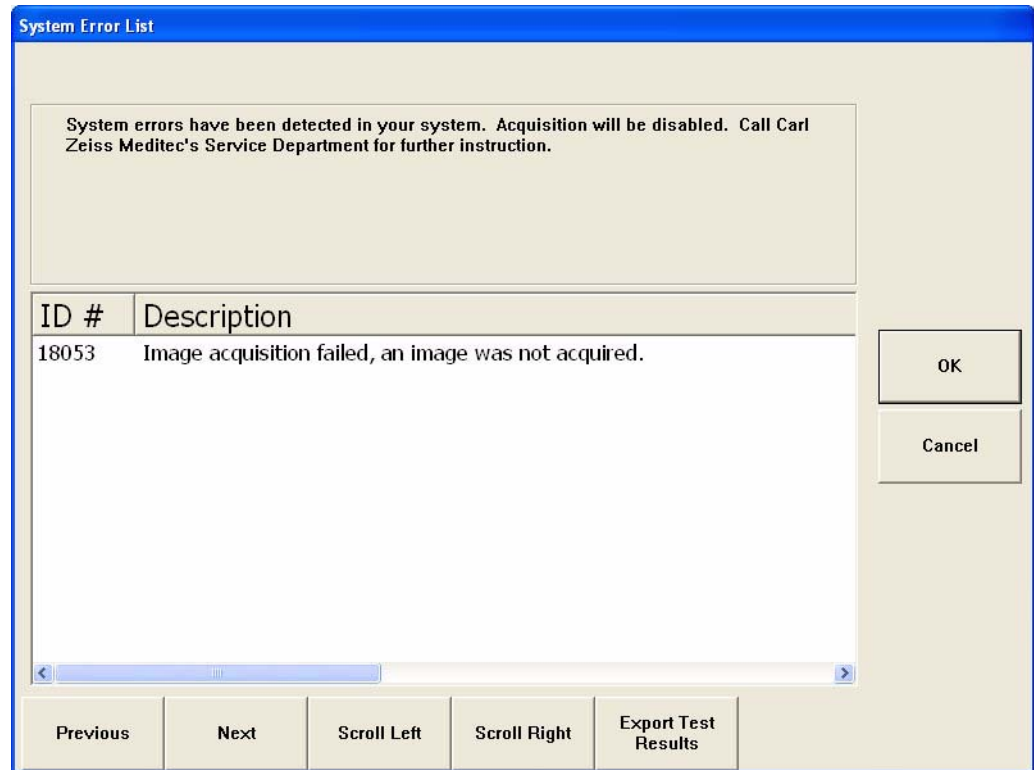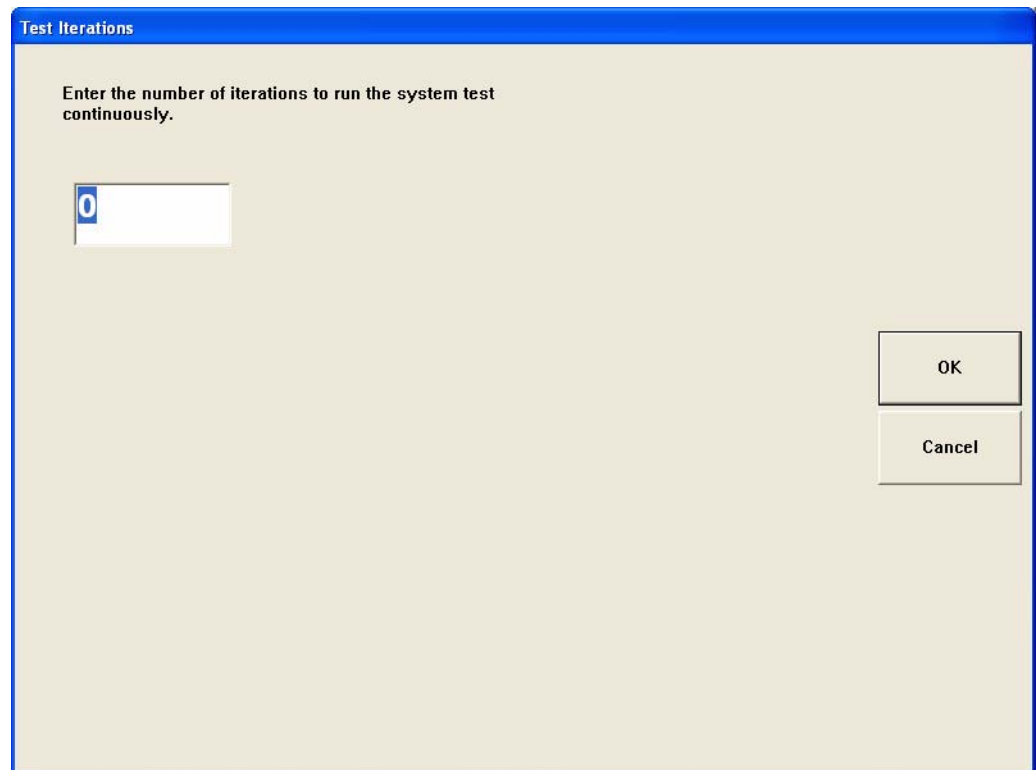
Figure 8-24 System Error List screen

Continuous Test

If you suspect that your system is intermittently demonstrating a problem, it is recommended to run the Continuous System Test for a period commensurate with the period between suspected problem occurrences. Continuously passing the system test over that suspect period indicates that the system operation is stable.

To run the System Test continuously, at the SYSTEM TEST screen select **Continuous** (Figure 8-25).

Figure 8-25 Continuous Test Screen

Enter the number of iterations you want to run the system test. Entering "0" will run the system test continuously until the user cancels the test. Select **OK** to begin the test. A test progress screen will be displayed (Figure 8-26).
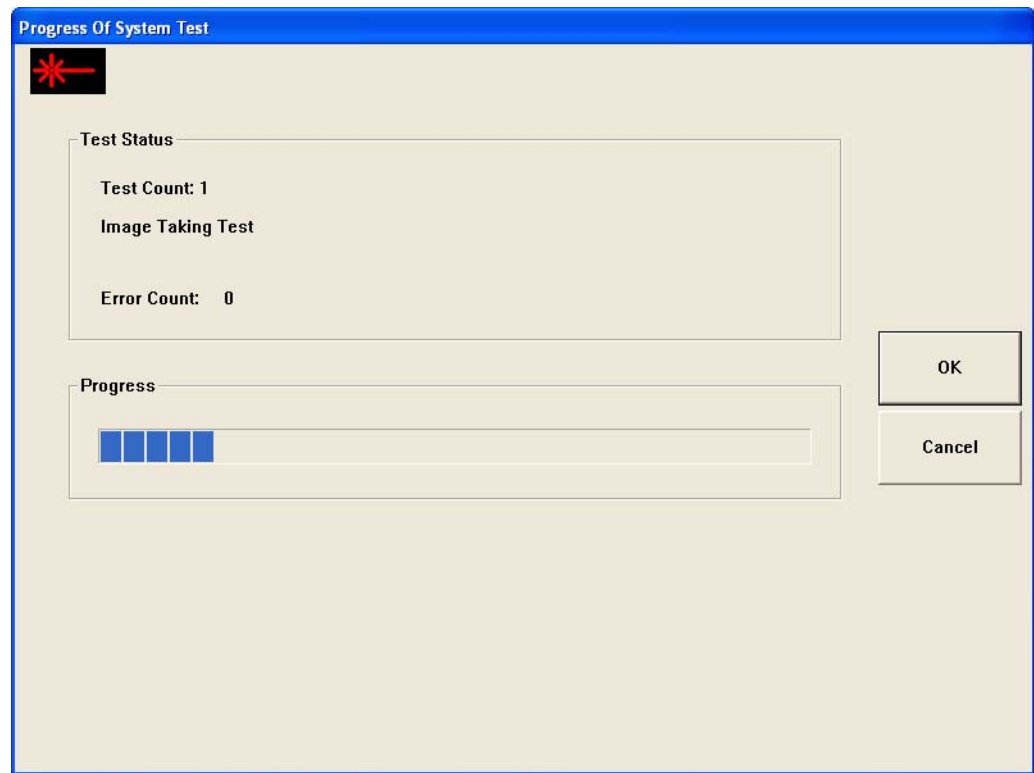
Figure 8-26 Continuous Test Progress Screen

Once the test ends, errors will be displayed on the SYSTEM ERROR LIST screen (Figure 8-24). Additional information is indicated by the lightly shaded portion(s) of the horizontal scroll bar below the list of errors.

You can cancel the test by pressing the **Esc** or **Cancel** button. If the test is cancelled before the end of a full test sequence, the system may take up to a minute before testing actually stops.

☞ Note: Never power down the instrument during a System Test.

Component Test

Selecting the **System > System Diagnostics > Component Test** button will display the EXERCISE HARDWARE screen (Figure 8-27) which contains instrument hardware component tests.

For assistance, call Carl Zeiss Meditec customer service: In the U.S., call 800-341-6968. Outside the U.S., contact your local CZM distributor.
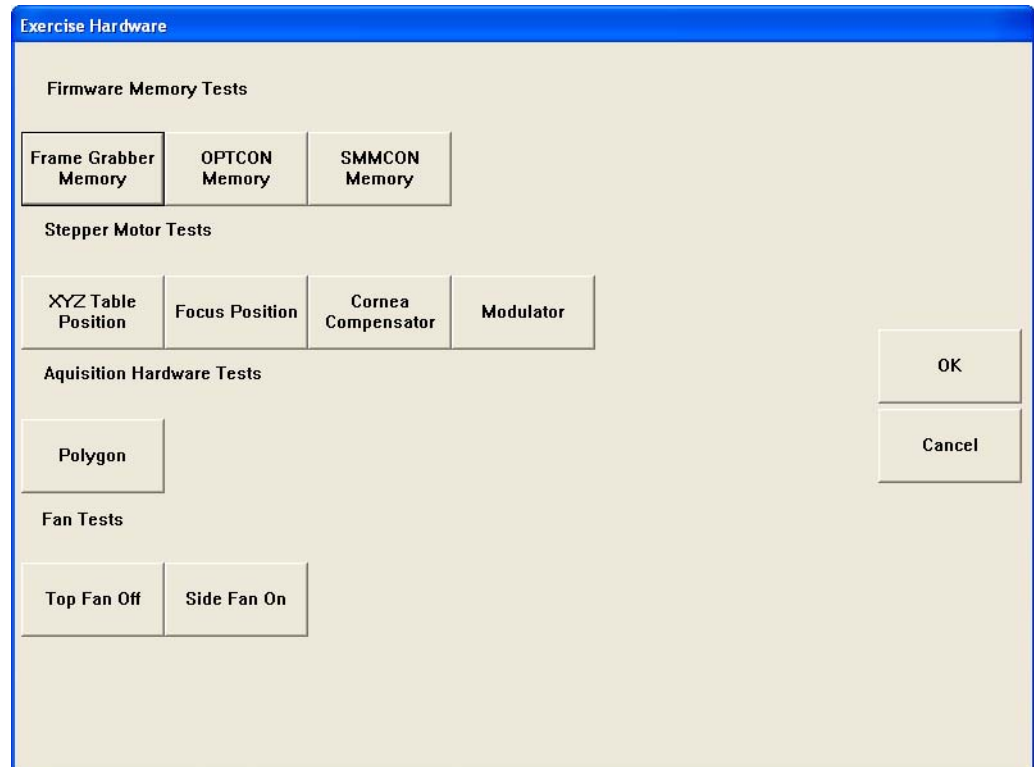
Figure 8-27 Exercise Hardware Screen

Operating System Resources

Selecting the **System > System Diagnostics > Operating System Resources** button will open the Windows Control Panel folder (Figure 8-28).
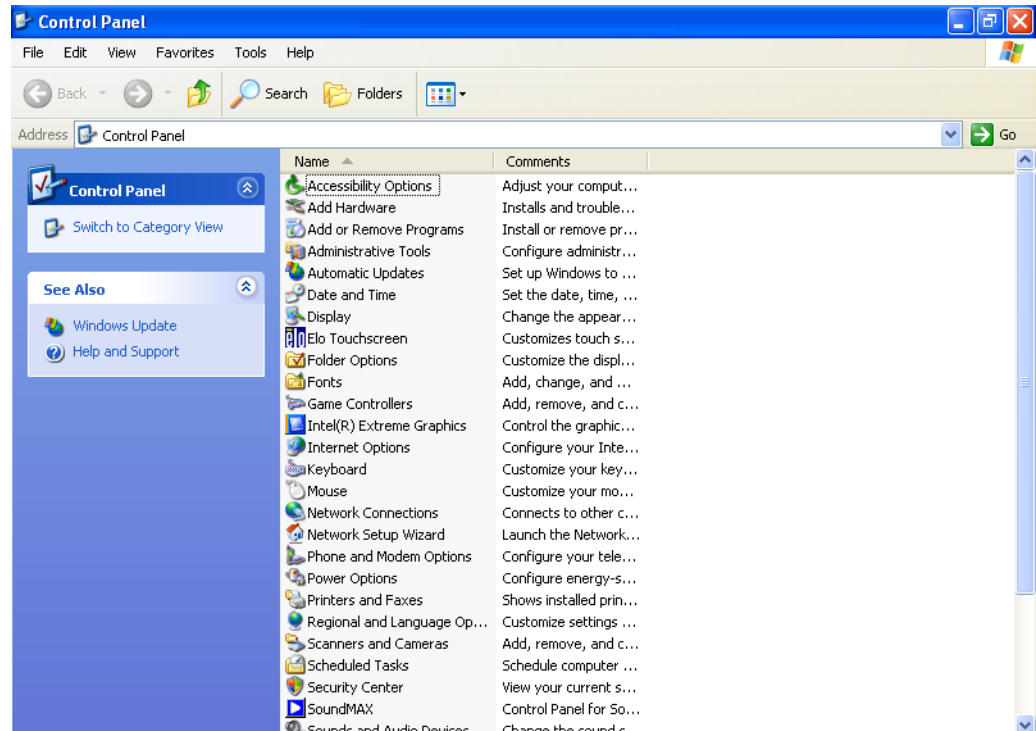
Figure 8-28 Windows Control Panel Folder

Calibrate Touch Screen

The Calibrate Touch Screen function (**System > System Diagnostics > Calibrate Touch Screen**) is described in the Setup chapter. See Calibrating the Touch Screen on page 2-4.

Remote Support

Selecting the **System > Remote Support** button will open the Carl Zeiss Meditec Live Remote Assistance web page (Figure 8-29) if your GDxPRO is connected to the internet through a network connection. With Live Remote Assistance, a Carl Zeiss Meditec Technical Support technician can view your GDxPRO Windows desktop and share control of your mouse and keyboard to help solve a technical problem.

For assistance, call Carl Zeiss Meditec customer service: In the U.S., call 800-341-6968. Outside the U.S., contact your local CZM distributor.

Figure 8-29 Remote Support Web Page

CZM Options

The CZM Options function (**System > CZM Options**) is used by Carl Zeiss Meditec to set up the GDxPRO system. This function is password protected so that only qualified Carl Zeiss Meditec personnel can access it (Figure 8-30).
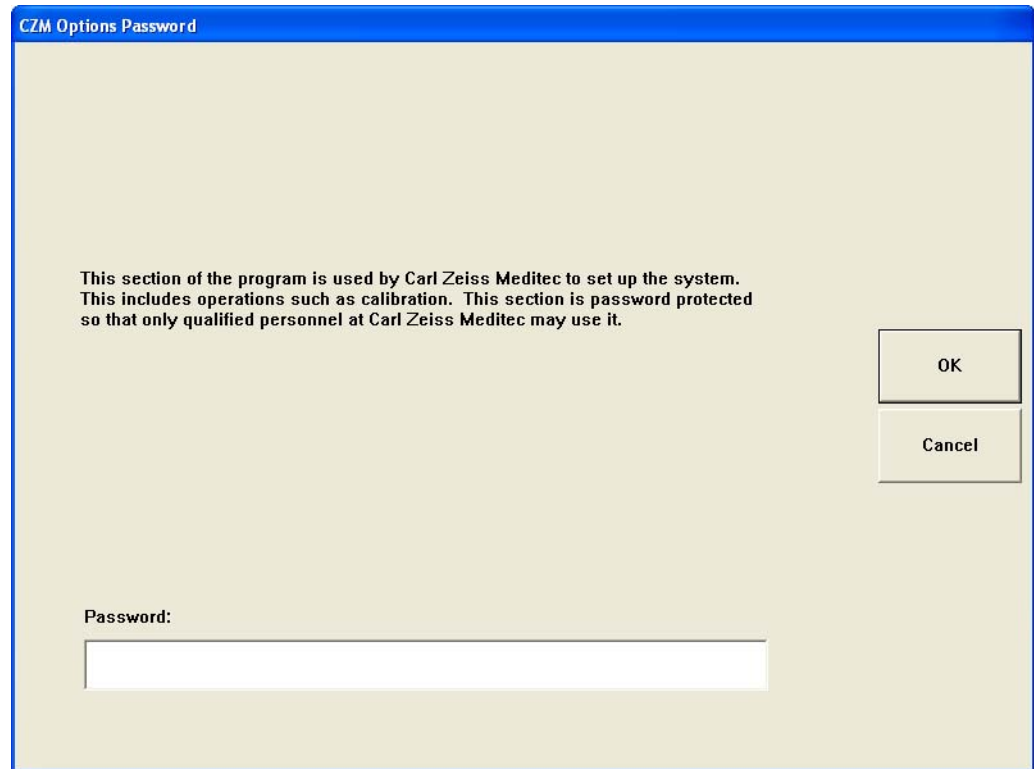
Figure 8-30 CZM Options Password Screen

(A) RNFL Normative Databases and NFI

Introduction

This appendix discusses development of the RNFL Normative Databases and NFIs for ECC and VCC:

ECC is virtually always superior and is therefore the default; VCC is provided for continuity with historical scans. While many of the steps in development are similar for ECC and VCC, there are some noteworthy differences. And recall that ECC and VCC measurements cannot be compared, as they use different normative databases.

ECC Normative Database and NFI

The *Collection of Normative and Glaucoma Data Using GDx VCC™ Scanning Laser Polarimetry* study was performed to collect data for the development of the ECC RNFL Normative Database and the ECC NFI. This study was carried out at ten sites under an Institutional Review Board and Ethics Committee approved protocol.

Both normal and glaucoma subject data was collected in this study. Normal data was grouped into seven categories, by subject age: 18–29, 30–39, 40–49, 50–59, 60–69, 70–79, and 80 and older. Overall, the age distribution in normal subjects was fairly even among all age groups, except the 80 years or older group. The normative limits for subjects 80 years or older should be used with caution, as there are only two subjects in this group. It should also be noted that this normative database does not have any subjects younger than 18 years old.

Glaucoma subjects were categorized into the following three visual field defect groups:

- Early visual field defect: The mean deviation (MD) index is less than -6 dB
- Moderate visual field defect: MD is equal to or greater than -6, and less than -12 dB
- Advanced (severe) visual field defect: MD is equal to or greater than -12 dB

Selection and Testing of Subjects

All subjects had complete ophthalmic exams of both eyes. These exams included:

- Refraction and visual acuity
- Perimetry using the Humphrey 24-2 SITA Standard threshold test. Any defects found were verified with a second test.
- Goldmann applanation tonometry
- Keratometry
- Central corneal thickness measurement by ultrasound pachymetry
- Axial length measurement using an IOL Master
- Slit lamp examination
- Gonioscopy

- Dilated opthalmoscopic examination
- Fundus photography and optic disc stereophotography

Inclusion and Exclusion Criteria

Inclusion Criteria for Normal Subjects

- Males or females 18 years of age or older
- Normal Visual Field in both eyes

Exclusion Criteria for Normal Subjects

- Best corrected visual acuity less than 20/40
- Refractive error outside -10.00D to +5.00D range
- Presence of glaucoma or ocular hypertension
- History of angle closure glaucoma or occludable angles
- Presence of disc hemorrhage
- Previous laser and incisional surgery[1]
- Evidence of diabetic retinopathy, macular degeneration or other vitreo-retinal disease
- History of diabetes, leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis
- Life threatening or debilitating disease

Inclusion Criteria for Glaucoma Subjects

- Males or females 18 years of age or older
- Glaucomatous Visual Field abnormality in either eye
- Diagnosis of glaucoma

Exclusion Criteria for Glaucoma Subjects

- Best corrected visual acuity less than 20/40
- Refractive error outside -10.00D to +5.00D range
- Previous laser and incisional surgery
- Evidence of a visual field abnormality consistent with disease other than glaucoma
- Evidence of diabetic retinopathy, macular degeneration or other vitreo-retinal disease
- History of diabetes, leukemia, AIDS, uncontrolled systemic hypertension, dementia or multiple sclerosis
- Life threatening or debilitating disease

Normal and glaucoma subjects were defined by Principal Investigators at each site by reviewing clinical and visual field data, considering inclusion and exclusion criteria. The GDx instrument was not used in the diagnosis of subjects. Furthermore, GDx data was not used to include or exclude any subjects from either normal or glaucoma groups.

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1. Previous uncomplicated cataract surgery in the study eye more than one year prior to enrollment is acceptable.

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 or equal 21 mm Hg
- No history of ocular, neurological, or systemic diseases that might affect the visual field system
- Normal visual field, indicated by a Glaucoma Hemifield Test within normal limits, and MD and PSD > 5% probability level

Subjects were defined as Glaucoma Patients if they met the following criteria:

- Except for glaucoma, no history of ocular, neurological, or systemic diseases that might affect the visual field system
- Glaucomatous visual field defined as any two of the following:
  - PSD significant at p < 5% level
  - Abnormal Glaucoma Hemifield test result
  - A cluster of 3 or more non-edge points in a location typical for glaucoma depressed at p < 5% level, and one of the points depressed at p < 1% level

Data Collection

After undergoing a thorough ophthalmic examination, 251 normal and 215 glaucoma subjects had scans of their retinas taken with the GDxVCC device using ECC and VCC scan protocols. Both protocols were repeated three times to acquire the RNFL-I measurements. These three GDx ECC scans were averaged and that average was used in the development of the ECC normative database and the ECC NFI. Therefore, to be consistent with the development criteria, it is recommended that three scans be obtained and averaged for valid utilization of the ECC normative database and the ECC NFI.

GDx Scan Selection Criteria

The scans were reviewed for image quality, and the scans having the following characteristics were excluded from the normative database and NFI development:

- Image quality score of six or lower
- Fundus images that were blurred, too dark, or saturated
- Optic nerve head position that was too low or too high, resulting in the edge of the image extending beyond the largest measurement circle.
- Large eye motion during image acquisition, resulting in measurement area loss of greater than six percent.
- Presence of floaters in all measurement circles
- Presence of peripapillary atrophy in all measurement circles
- Compensation residual $\geq$ 12. Note, however, than no ECC scans showed a compensation residual > 4.
- Typical Scan Score (TSS) $\leq$ 40 (ECC)

In practice, clinicians and operators should quantitatively and qualitatively review scans for quality. Quantitatively, a scan with a image quality score < 7, a TSS $\leq$ 40, or a compensation residual > 4 should be cautiously evaluated.

ECC RNFL Normative Database Development

The ECC RNFL normative database was developed utilizing the 251 normal subjects (aged 18–82) from the study, *Collection of Normative and Glaucoma Data Using GDx VCC™ Scanning Laser Polarimetry.* This normative database has an even gender distribution (128 females vs. 123 males). Ethnicity breakdown of the ECC normative database is as follows: 42% Caucasians, 36% Asians, 14% Hispanics, 6% African Americans, 2% Indians. Note that ECC normative data is not stratified by race: the percentile values provided for comparisons of individual data to the normative database do not take into account differences that may be present due to race/ethnicity. This data is provided for your information only.

Data Analysis

For each calculation circle, the ECC readings of the same parameter from different images of an eye were averaged and the average readings were treated as the measurement of the parameter at that region of the eye.

The regression model analyses were used to estimate the normative limit of the GDx parameters adjusted by age. Since the gender differences were not statistically significant, the gender was not included in the regression model. The site effect was not considered in the normative limits calculation since the objective was to establish the normative limits for the general population.

For each fitted regression model, the residuals were derived for each eye by subtracting the estimated mean GDx reading, ET(*age*), from the measured or observed reading, rt(*age*). In other words, residual = rt(*age*) - ET(*age*). The goal was to estimate the $100x\alpha^{th}$ percentiles (NL, normative limit) of the residuals, so that $100x\alpha\%$ of normal subjects would have a value of the GDx parameter less than the following limit:

$$ET(age) + NL(100x\alpha\%) \qquad (A)$$

For each GDx parameter, the percentiles $NL(100x\alpha\%)$ of its regression residuals were estimated by the empirical distribution of the residuals. Hence, the age specific normative limit of each GDx parameter was estimated by limit (A) above. The levels (α) of the normative limits were presented as 0.5%, 1%, 2%, 5%. The normative limits were estimated for the Nerve Fiber Layer Map based on the same regression analysis approach.

The following is an example taken from actual database values:

> For the TSNIT Average at age 50,
>   5% Normal Limit = 45.2
>   2% Normal limit = 43.1

Thus 5% of healthy individuals have TSNIT Average measurements below 45.2, and 2% of healthy individuals have TSNIT Average measurements below 43.1 Therefore, a person with a TSNIT average of 45 would be flagged at the 5% level. The widths of confidence interval for the residual percentiles of ECC TSNIT Average, Superior Average, Inferior Average, TSNIT Standard Deviation, and Inter-Eye Symmetry are presented in Table A-1.

Parameter	Percentile	Width
TSNIT Average	0.5th	4.0
	1st	4.1
	2nd	5.5
	5th	3.1
Superior Average	0.5th	1.0
	1st	2.6
	2nd	6.8
	5th	5.4
Inferior Average	0.5th	3.6
	1st	5.6
	2nd	9.8
	5th	3.8
TSNIT Standard Deviation	0.5th	0.5
	1st	1.4
	2nd	2.0
	5th	2.0
Inter-Eye Symmetry	0.5th	0.2
	1st	0.2
	2nd	0.2
	5th	0.1

Table A-1 Width of Confidence Intervals of Percentiles

For reference, the repeatability and reproducibility of the GDx ECC measurements are presented in Table A-2 and Table A-3 below.

Parameter	Repeatability SD	Reproducibility SD	Repeatability Limit	Reproducibility Limit
NFI	2.5	3.9	7.1	10.9
TSNIT Average	1.2	1.8	3.3	5.1
Superior Average	1.8	2.7	5.1	7.4
Inferior Average	2.1	3.3	5.8	9.1
TSNIT Standard Deviation	1.3	1.6	3.5	4.4
TSNIT Plot Position #14	3.7	4.2	10.4	11.7
Inter-Eye Symmetry	0.03	0.04	0.09	0.1

Table A-2 ECC Repeatability and Reproducibility Normal Study Eyes

Parameter	Repeatability SD	Reproducibility SD	Repeatability Limit	Reproducibility Limit
NFI	5.6	6.6	15.8	18.6
TSNIT Average	1.6	2.5	4.6	6.9
Superior Average	2.3	3.9	6.4	10.9
Inferior Average	2.3	2.7	6.3	7.5
TSNIT Standard Deviation	1.1	1.5	3.1	4.2
TSNIT Plot Position #14	3.8	5.1	10.5	14.1

Table A-3 ECC Repeatability and Reproducibility Glaucoma Study Eyes

Age Coefficient

Analysis of subject demographics determined that expected RNFL-I was dependent upon age. Thus age correction is incorporated into the calculated results. Subject ethnicity/race was self-reported by the subjects in the population comprising the normative database but was not used as a variable in constructing the RNFL normative database.

As shown in Figure A-1, Figure A-2, Figure A-3, the data for TSNIT Average, Superior Average, and Inferior Average comprises multiple data points. Linear regression analysis was used to determine the age coefficient. The three figures present RNFL-I measurements versus age, and suggest that RNFL-I decreases with increasing age.
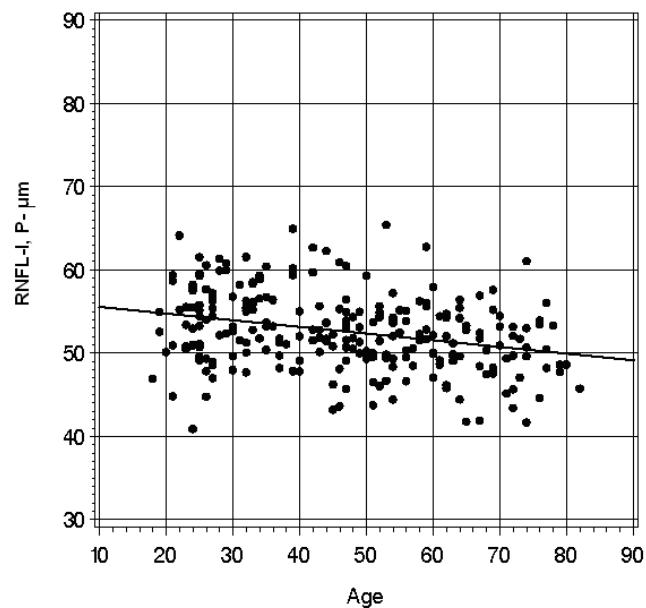
Figure A-1 TSNIT Average RNFL-I for Small Calculation Circle Versus Age
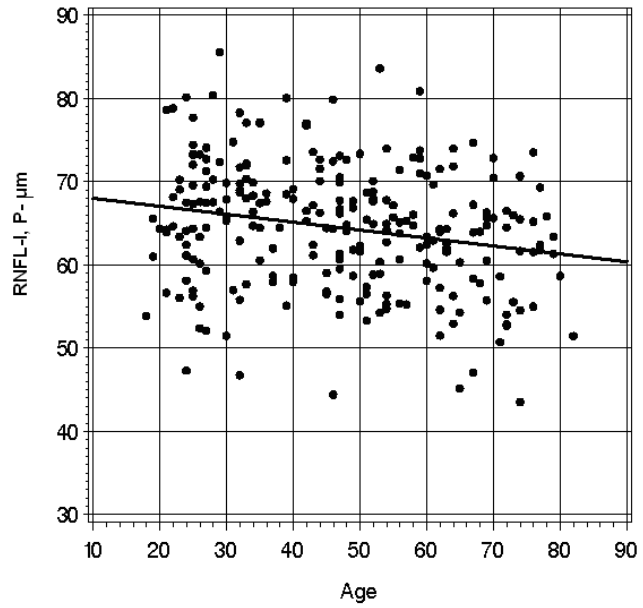
Figure A-2 Superior Average RNFL-I for Small Calculation Circle Versus Age
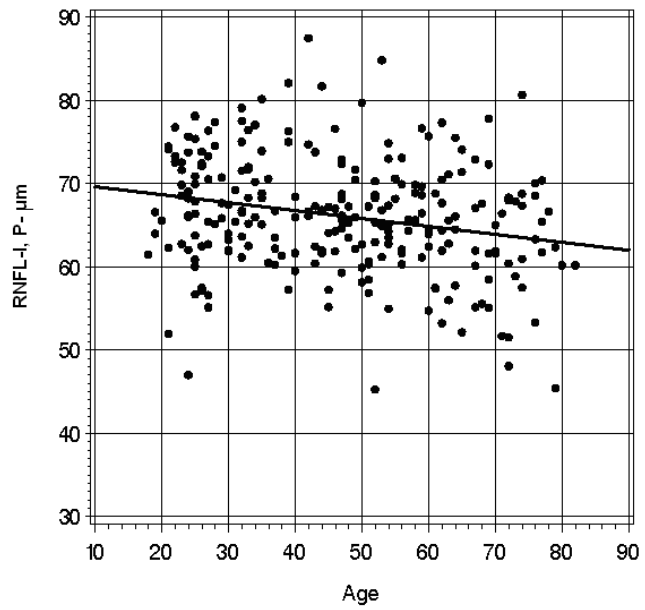
Figure A-3 Inferior Average RNFL-I for Small Calculation Circle Versus Age

ECC NFI Development

The NFI is a global parameter that uses a machine learning classifier to analyze the entire RNFL profile. It is expressed as an ordinal number, from 1 to 100, related to the likelihood that the polarimetric retinal nerve fiber layer map is abnormal. A higher number is more likely to be related to abnormality, but is not definitive. It is calculated using an advanced form of neural network, called Support Vector Machine (SVM).

The NFI is trained on known normal and glaucomatous eyes and essentially uses pattern recognition to establish an outcome. Specifically, the ECC NFI was developed utilizing 251 normal subjects (aged 18-82) and 215 glaucoma subjects (aged 28-89) from the clinical study, *Collection of Normative and Glaucoma Data Using GDx VCCTM Scanning Laser Polarimetry.*

Of the 466 subjects in the study, 314 were in the model building dataset on which the NFI was trained. The remaining 152 subjects were in the validation dataset. Data analysis from this validation dataset is presented below.

Figure A-4 shows the ECC NFI distribution of normals and glaucoma subjects in the validation data set (N = 152).

ECC NFI (N = 152)
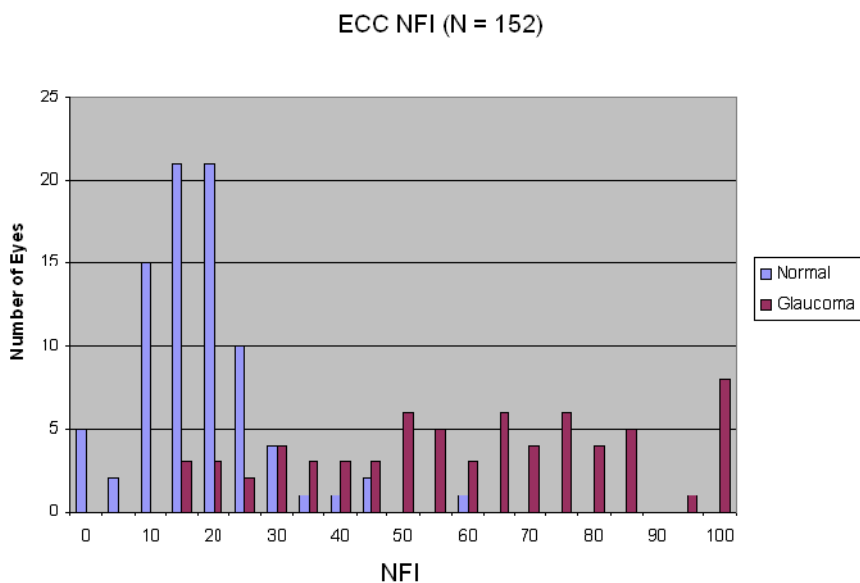
Figure A-4 ECC NFI Distribution – Validation Dataset

Data analysis of the normal subjects used in ECC NFI validation reveals the following (Table A-4):
- 95% of the normal population shows ECC NFI values under 35
- 99% of the normal population shows ECC NFI values under 55

	ECC NFI	**95% Confidence Interval**
95%	35	[27.9, 60.2]
99%	55	[42.9, 60.2]

Table A-4 NFI Guidelines for Likelihood for Normal

The characteristics of the normal subjects were explained in the ECC RNFL Normative Database Section. Characteristics of the glaucoma subjects are presented in Table A-5.

Gender	Male	114 (53%)
	Female	101 (47%)
Race	Caucasian	101 (47%)
	Asian	71 (33%)
	Hispanic	12 (6%)
	African American	27 (13%)
	Indian	1 (0.5%)
Severity of Visual Field (VF) defect	Early VF defects	76 (35%)
	Moderate VF defects	72 (34%)
	Severe VF defects	67 (31%)

Table A-5 Make-Up of Glaucoma Subjects

Histograms further detailing the NFI values by visual field loss are presented in Figure A-5 through Figure A-7. This information is provided for your information only; no statistical analysis has been conducted to determine if a relationship exists between NFI and varying degrees of visual field defect attributable to glaucoma.
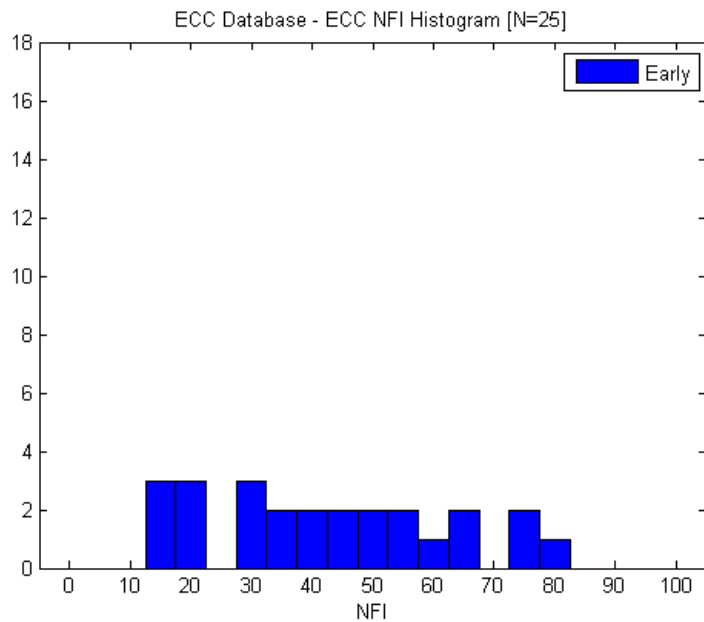
Figure A-5 ECC NFI Distribution for Glaucoma Subjects with Early Visual Field Defects (Validation Dataset)
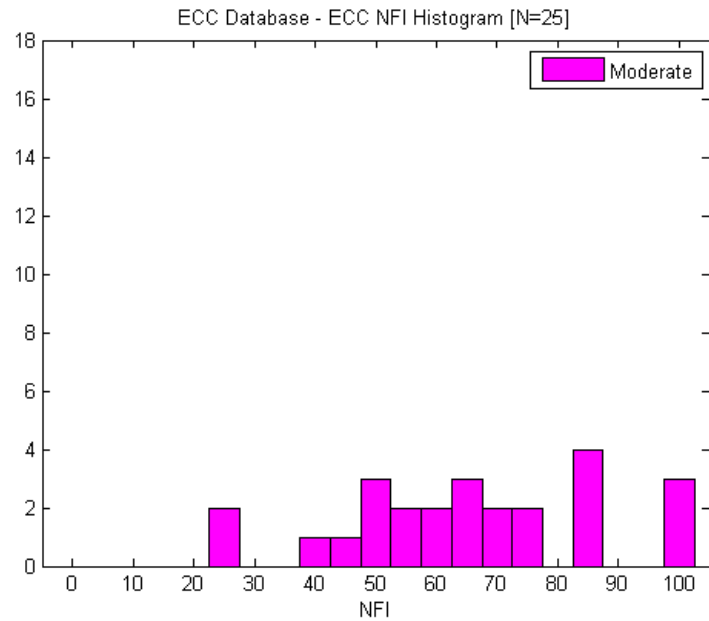
Figure A-6 ECC NFI Distribution for Glaucoma Subjects with Moderate Visual Field Defects (Validation Dataset)
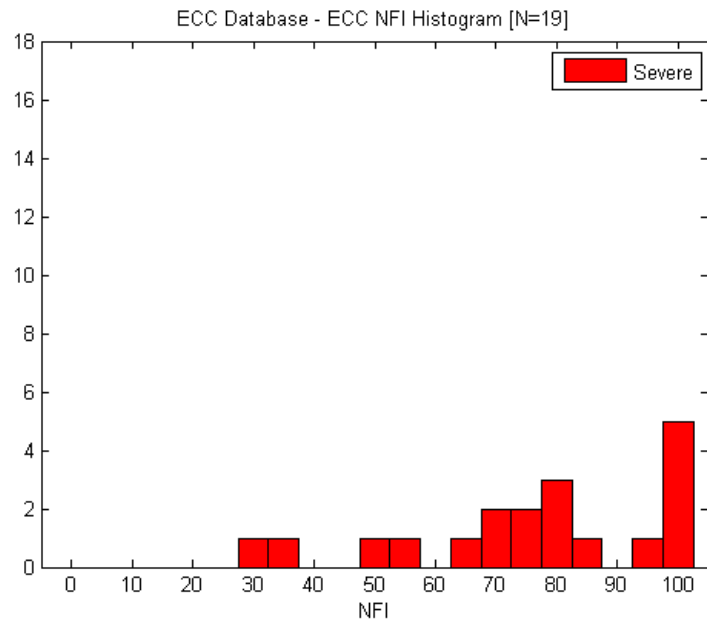
Figure A-7 ECC NFI Distribution for Glaucoma Subjects with Severe Visual Field Defects (Validation Dataset)

Note that ECC NFI values were created for all three calculation circles. The small calculation circle is presented as the "default" in the current GDx unit.

Conclusion

The GDx ECC RNFL Normative Database was based upon GDx ECC scans collected from subjects whom, per protocol, were deemed representative of a normal population. The GDx ECC RNFL Normative Database establishes reference values for GDx ECC scans which the physician can use to compare individual patient measurements to those acquired in a normal population. The ECC NFI is a global parameter that uses a machine learning classifier to analyze the entire RNFL profile. It was trained using ECC images obtained from normal and glaucoma subjects.

VCC Normative Database and NFI

The GDx VCC database was collected based on a study which contained 300 normal subjects and 120 glaucoma subjects. The objective of the study was to establish normative limits for GDx VCC RNFL-I measurements and to train the Nerve Fiber Indicator (NFI). Seven centers in the United States participated in the prospective, non-comparative study, using the commercially available GDxVCC device under external Institutional Review Board (IRB) approval.

Seven age groupings were categorized for normal and glaucoma subjects: 18–29, 30–39, 40–49, 50–59, 60–69, 70–79, and 80 and older. Overall, the age distribution in normal subjects was fairly even among all age groups, except the 80 years or older group. The normative limits for subjects 80 years or older should be used with caution due to small sample size. It should also be noted that this normative database does not have any subjects younger than 18 years old.

Selection and Testing of Subjects

All individuals in the database (normal and glaucoma patients) had complete ophthalmic exams. Specifically, data was captured from:

- Medical history reviews
- Refraction and Visual Acuity exams
- Biomicroscopy exams
- IOP exams
- Standard Automated Perimetry exams (Humphrey 24-2 SITA standard program)
- Ophthalmoscopy exams
- GDx VCC exams

Inclusion and Exclusion Criteria

Inclusion Criteria for Normal Subjects:

- Males or females 18 years of age or older
- Best corrected visual acuity of 20/40 or better in each eye

Exclusion Criteria for Normal Subjects:

- Presence of glaucoma or history of ocular hypertension in either eye
- Intraocular pressure of 22 mm Hg or greater in either eye
- A visual field test showing one or more of the following:
  - An unreliable visual field test result ($>$ 25% false positive or false negative responses or
    $>$ 15% fixation losses)
  - Mean Deviation (MD) or Pattern Standard Deviation (PSD) of p $<$ 5% or worse
  - Glaucoma Hemifield Test (GHT) result of "Borderline" or "Outside Normal Limits"
- Optic discs that demonstrate hemorrhage, notching, peripapillary atrophy extending into the area of analysis, rim thinning, exudation, local RNFL injury, and/or asymmetry between the eyes of more than 0.2 C/D ratio
- Concomitant active ocular disease

- Congenital ocular abnormalities
- Previous intraocular surgery (other than cataract)
- Previous retinal surgery
- History of glaucoma among first-degree relatives
- History of diabetes, leukemia, AIDS, uncontrolled systemic hypertension, dementia, or multiple sclerosis

Inclusion Criteria for Glaucoma Subjects:

- Males or females 18 years of age or older
- Glaucoma as evidenced by optic discs that demonstrate hemorrhage, notching, rim thinning, exudation, local RNFL injury, observed change in C/D from prior examination, and/or asymmetry between the eyes of more than 0.2 C/D ratio (assuming no difference in disc size)
- Best corrected visual acuity of 20/40 or better in each eye

Exclusion Criteria for Glaucoma Subjects:

- Active ocular disease, except glaucoma
- Previous intraocular surgery (except cataract)
- History of diabetes, leukemia, AIDS, uncontrolled systemic hypertension, arteriosclerosis, dementia, or multiple sclerosis

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 or equal 21 mm Hg
- No history of ocular, neurological, or systemic diseases that might affect the visual field system
- Normal visual field indicated by a Glaucoma Hemifield Test within normal limits, and MD and PSD > 5% probability level
- Normal optic disc indicated by the following: no evidence of hemorrhage, notching, rim thinning, exudation, local RNFL injury, and/or asymmetry between the eyes of more than 0.2 C/D ratio indicative of glaucoma or other ocular abnormalities

Subjects were defined as Glaucoma Patients if they met the following criteria:

- Glaucomatous optic neuropathy as evidenced by optic discs that demonstrate hemorrhage, notching, rim thinning, exudation, local RNFL injury, observed change in C/D from prior examination, and/or asymmetry between the eyes of more than 0.2 C/D ratio (assuming no difference in disc size)
- Except for glaucoma, no history of ocular, neurological, or systemic diseases that might affect the visual field

Data Collection and Review

GDx Scan Selection Criteria

The following scan review criteria applies to both normal and glaucoma subjects. Three VCC scans were obtained per study eye. The scans were then reviewed for image quality, and scans having the following characteristics were excluded:

- Fundus images that were blurred, too dark, or saturated
- Optic nerve head position that was too low or too high, resulting in the edge of the image extending beyond the largest measurement circle (radius of 59 pixels)
- Large eye motion during image acquisition, resulting in measurement area loss of greater than 6%
- Presence of floaters in the measurement area
- Peripapillary atrophy in the measurement area

Of the scans passing the image quality review, only one image per study eye was flagged for inclusion in the calculation data set as meeting the image quality review criteria. From this flagged set, scans with the following characteristics were excluded:

- Compensation residual $\geq$ 12 nm or
- Typical Scan Score $\leq$ 60

Scans remaining after this exclusion process were included in the normative database and the database for NFI training. Note that the image quality score was not used as a criterion for exclusion of scans. While the GDxVCC does provide the Image Quality Score to assist users in flagging potentially problematic scans, this image quality score cannot replace the training, experience, and judgement of a clinician or operator in deciding whether to discard or accept a particular scan. Additional information on the Image Quality Score can be found in Q (Quality Score) on page 6-4.

In practice, clinicians and operators should quantitatively and qualitatively review scans for quality. Quantitatively, a scan with a TSS $\leq$ 60, or a compensation residual $\geq$ 12, should be cautiously evaluated.

VCC RNFL Normative Database

The following sections describe the makeup of the VCC Normative Database. For your information, Table A-6 provides data on the overall number of normal study eyes, and Table A-7 provides data on the gender, race, and age of the normal subjects whose scans were included in the normative database.

OS	OD	Total
243	237	480

Table A-6 VCC Normative Database (Normal Eyes)

		Normal
Gender	Male, n (%)	99 (39.4%)
	Female, n (%)	151 (60.2%)
	N/A, n (%)	1 (0.4%)
Race	Combined N	251
	Asian, n (%)	43 (17.1%)
	Black, n (%)	28 (11.2%)
	Eastern, n (%)	8 (3.2%)
	Hispanic, n (%)	15 (6.0%)
	White, n (%)	157 (62.5%)
Age	N	251
	Mean (SD)	42.5 (16.29)
	Median	41
	Minimum, Maximum	18, 81

Table A-7 GDx VCC Database, Gender, Ethnicity, and Age Groupings (Normal Subjects)

While gender and racial make-up of the database is provided above, please note that the VCC normative data is not stratified by either gender or race: the percentile values provided for comparisons of individual data to the normative database do not take into account differences that may be present due to gender or race/ ethnicity. The table above simply provides this data for your information.

The GDx VCC normative limits are age-corrected. The normal RNFL loss with age is small, but significant, making age-matched comparisons an important aspect of the analysis. It is estimated that a healthy eye loses roughly 5,000 ganglion cells per year as part of the normal aging process. Several studies have used scanning laser polarimetry to document RNFL thinning with age. In order to accurately differentiate RNFL changes due to the aging process from loss due to disease, the relationship of the RNFL profile with age in the normative database was evaluated.

NFI Development

The NFI is a global parameter that uses a machine learning classifier to analyze the entire RNFL profile. It is expressed as an ordinal number, from 1 to 100, related to the likelihood that the polarimetric retinal nerve fiber layer map is abnormal. A higher number is more likely to be related to abnormality, but is not definitive. The VCC NFI was trained with the entire GDx VCC database of 480 known normal eyes (both eyes of normal subjects included) and 215 known glaucoma eyes. Gender, race and age make-ups of the normal subjects and glaucoma subjects in the NFI training dataset are provided in Table A-7 (normal subjects) and Table A-8 (glaucoma subjects) respectively.

		Glaucoma
Gender	Male, n (%)	54 (45.4%)
	Female, n (%)	65 (54.6%)
	N/A, n (%)	
Race	Combined N	119
	Asian, n (%)	6 (5.0%)
	Black, n (%)	43 (46.1%)
	Eastern, n (%)	
	Hispanic, n (%)	8 (6.7%)
	White, n (%)	62 (52.1%)
Age	N	119
	Mean (SD)	64.14 (12.93)
	Median	67
	Minimum, Maximum	24, 88

Table A-8 GDx VCC Database, Gender, Ethnicity, and Age Groupings
(Glaucoma Subjects)

A histogram of the NFI values from the training dataset (480 normal eyes and 215 glaucoma eyes) is shown in Figure A-8.
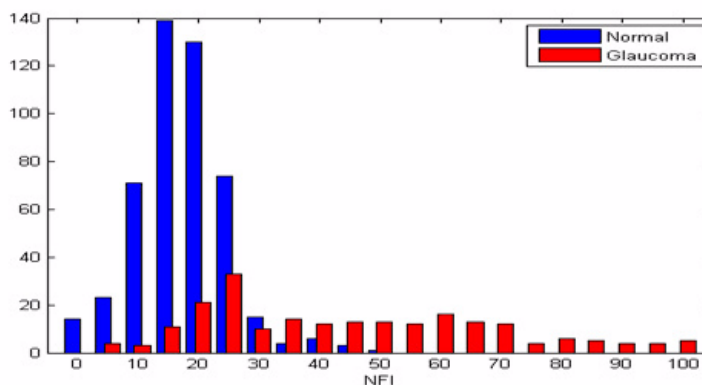
Figure A-8 VCC NFI Histogram (Small Calculation Circle) – Training Dataset

While glaucoma patients were not stratified for disease severity, for informational purposes only, NFI distributions were generated during data analysis, in which the glaucoma

subjects were separated into two categories: pre-perimetric (no glaucomatous visual field damage), and glaucoma patients with visual field loss (Figure A-9 and Figure A-10).
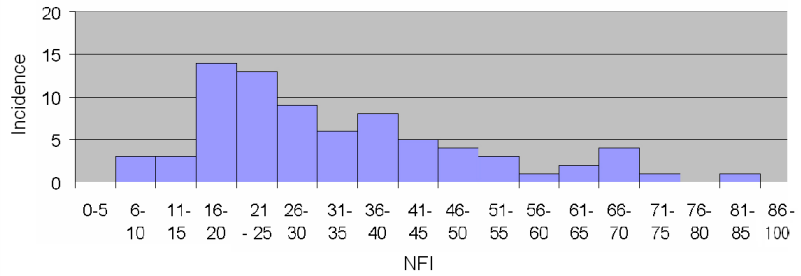
Figure A-9 NFI Distribution for Pre-Perimetric Patients
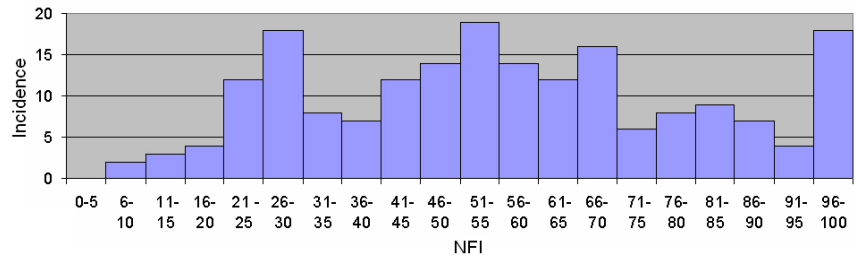
Figure A-10 NFI Distribution for Glaucoma Patients with Visual Field Loss

Validation of VCC NFI was performed using independent study data collected subsequently for the GDxVCC instrument, titled *Collection of Normative and Glaucoma Data Using GDxVCC™ Scanning Laser Polarimetry*. 432 subjects (243 normals, 189 glaucoma patients) were used to validate the NFI. A histogram of NFI values from this validation dataset is presented in Figure A-11.
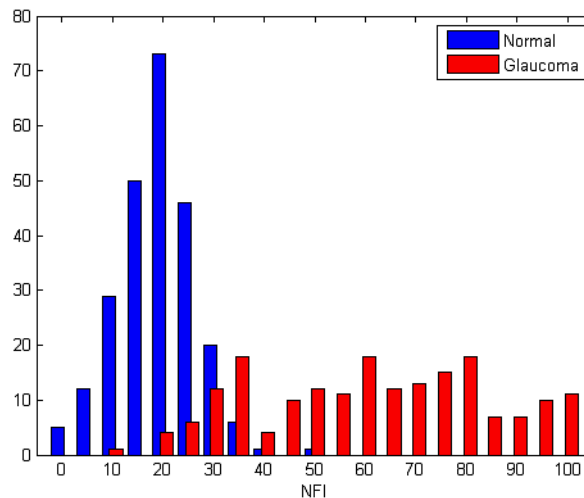
Figure A-11 VCC NFI Distribution – Validation Dataset

Note that the distribution of normals from the validation dataset is similar to the training dataset. However, the distribution of glaucoma subjects varies between the two because the training dataset includes both pre-perimetric patients and patients with visual field loss, while the validation dataset only includes patients with visual field loss.

Data analysis of the normal subjects used in VCC NFI validation reveals the following:

- 95% of the normal population shows VCC NFI values under 30
- 99% of the normal population shows VCC NFI values under 37

Please see Table A-9 below for confidence intervals for these values.

|	NFI	95% Confidence Interval
95th percentile	30	[29.0, 33.5]
99th percentile	37	[33.5, 50.1]

Table A-9 Confidence Intervals

Note that the NFI was developed and validated without using patients who were considered "glaucoma suspects," but only eyes with a clear-cut diagnosis of "normal" or "glaucoma." Thus, its utility in eyes diagnosed as "glaucoma suspects" remains to be established.

☞ **Note: The NFI cannot be used alone to classify patients into normal and glaucoma categories. This parameter cannot replace clinical judgement and is intended to be used in conjunction with the multiple clinical tools considered the standard of care for glaucoma diagnosis. This device is not intended to be used as the sole basis for diagnosis of eye disease.**

In summary, a high NFI value usually indicates increased likelihood that the polarimetric retinal nerve fiber layer is abnormal, but is not definitive. It should not be used in isolation to diagnose glaucoma.

(B) Network Storage Device Configuration

Introduction

This appendix instructs you how to configure a network attached storage device (NAS device), also known as a network drive, for use with the GDxPRO. 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 GDxPRO 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 GDxPRO, the NAS device serves the same functions as a network server, and the instructions for using a network server apply to the 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.

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: To directly connect the NAS device to the GDxPRO, use an Unshielded Twisted Pair (UTP) network cable (CZMI recommends using a least a CAT 5 UTP network cable). Use of a shielded network cable will ground the NAS device through the GDxPRO, 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 GDxPRO, the user must select a NAS device with the following characteristics:

- **Ethernet cable for direct connection to GDxPRO:** Unshielded Twisted Pair (UTP) network cable (CZMI recommends using a least a CAT 5 UTP network cable).
- **Drive media formatted using NTFS:** GDxPRO 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 GDxPRO hard drive, currently 80 GB.
- **Backup solution:** To maintain redundancy of data backup, we strongly recommend you use the backup solution of your choice for the NAS device.
  - You can use multiple NAS devices as a backup solution, but when you use two or more NAS devices concurrently, you must use a switch. The switch may be directly connected to the instrument or elsewhere on the local area network. Configuration in this scenario is the user's responsibility.

Installing and Configuring the NAS Device

You can attach the NAS device directly to the GDxPRO 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 GDxPRO and the NAS device turned off, use a network patch cord to connect the NAS device either directly to the GDxPRO, or to the office network (local area network or LAN) on which the GDxPRO 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-2 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 GDxPRO. 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 GDxPRO. After you complete the startup process, select the Windows key

   [icon]   on the keyboard to see the Windows Task Bar.

   • 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 GDxPRO optical 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 GDxPRO. You can use the space below:

NAS Device Name (also known as Network ID): _____

   C. Workgroup Name Must Match GDxPRO 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 GDxPRO, which is "WORKGROUP" by default—this name is not case-sensitive on GDxPRO. If the GDxPRO 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 GDxPRO optical drive.

On the GDxPRO, 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 GDxPRO. 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 GDxPRO to the proper folder of the NAS device using Windows Explorer:

1. Select the Windows key [⊞] on the keyboard to see the Windows **Start** menu. 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**.

☞ 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 Windows XP example below.
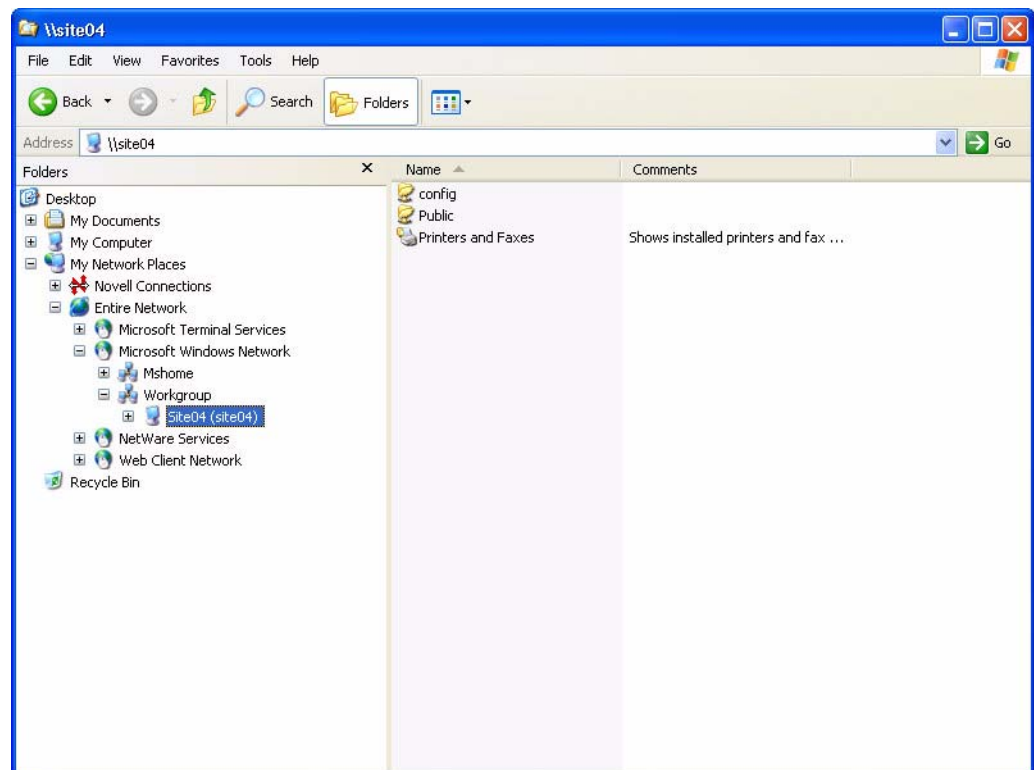

Figure B-1 Explorer Finds NAS Device and Displays Its Contents

3. Now you must map a drive on the GDxPRO 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. Click **Tools > Map Network Drive**. The Map Network Drive dialog appears.
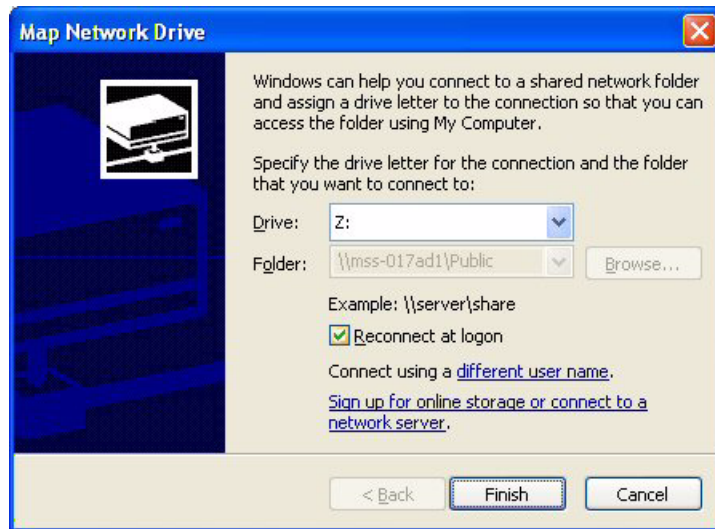

Figure B-2 Map Network Drive Dialog

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.

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 the GDxPRO. 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. 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-4), via direct USB connection between instrument and printer.

Approved Printers

CZM recommends using a printer that has been specifically qualified for the GDxPRO, because untested drivers could interfere with instrument operation. Please contact your CZM representative for qualified printers in your geography.

Many printers are available that are compatible with Microsoft Windows XP. Please note if you use an unqualified printer with the GDxPRO, CZM cannot guarantee technical support. Repairs necessitated by the attempt to use a non-qualified device are not covered under warranty. Any printer considered must meet the following criteria:

• Windows XP compatible
• Network port or USB port (the network port must be 100, 10/100, or 10/100/1000 Base T. If a USB port is used, an isolation transformer is required).
• Color printing
• Ability to print on 8.5 x 11 paper in the US or appropriate paper size outside the US.

WARNINGS: We strongly recommend you use printers supplied or approved by Carl Zeiss Meditec, when available, because they will have been tested to work with 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.

Prior to installing any printer other than one qualified by CZM, please perform an external data backup. Many printers come with optional software. Install the required drivers only. Do not install any optional software.

Printer Safety Warnings

WARNING: To maintain patient safety, an isolation transformer is required when connecting externally powered peripheral devices (i.e., printer, USB drive, etc.) within 1.5 meters (4.9 feet) from the patient. In addition, an isolation transformer is required for all externally powered peripheral devices outside this distance unless these devices are (1) connected to the GDxPRO using an Unshielded Twisted Pair (UTP) network cable (CZMI recommends using a least a CAT 5 UTP network cable), (2) plugged into a different power outlet than the GDxPRO, and (3) qualified by CZM for use with the GDx. Failure to observe this warning could result in electrical shock to the patient and/or examiner.

WARNING: To directly connect a printer to the GDxPRO only use a UTP network cable. Use of a shielded network cable will ground the printer through the GDxPRO, 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 typically not required.
2. **Connect hardware to enable communication between instrument and printer.** The hardware used depends on the type of configuration you select: either a network cable or a USB cable.
3. **Configure the instrument software to communicate with the printer**, including installation of printer drivers, if required. If there are no driver installation instructions provided with the printer, then driver installation is not required.

Network Configuration

A network connection can be established either (1) directly between the GDxPRO and the printer, or (2) by connecting both the GDxPRO and the printer to the local area network or to a network switch or hub connected to the GDxPRO. Follow the general instructions below.

1. Connect the Hardware

For the direct connection between GDxPRO and printer, use one UTP network cable to connect the network ports on both devices.

For the connection to a local area network, use two shielded or unshielded network cables. Connect the network ports on each device to the corresponding ports on the local area network.

Connect the power supply output to the printer.

Connect a UTP network cable to the printer and to the network port on the bottom right side of the GDxPRO (Figure C-1). (Use one cable to connect the printer and computer directly, or two network cables to connect printer and computer separately to a network, switch or hub.)

Network Port
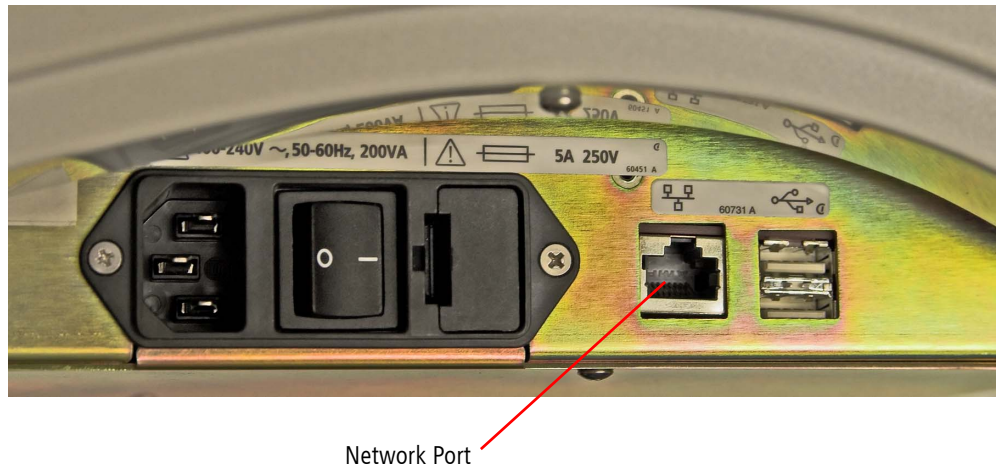
Figure C-1 GDxPRO Network Connector on Side of Instrument

☞ Note: Use the same kind of UTP network cable in all cases. (If you connect instrument and printer to the network rather than to each other, you will need two UTP network cables.) Do not use an RJ-45 crossover cable for direct connection between instrument and printer.

Printer Configuration

2. Configure the Printer for Network Use

Power on the printer and then start the GDxPRO. Select the Windows key ⊞ on the keyboard to see the Windows **Start** menu and Task Bar.

See the instructions that came with your printer to configure it for network use. If available, use a Network Wizard program for the printer configuration. Install the required drivers only. Do not install any optional software.

Please refer to the GDxPRO Home page (www.meditec.zeiss.com/GDxPRO) for a link to the current list of qualified printers and downloads of printer drivers, or call Carl Zeiss Meditec customer service: In the U.S., call 800-341-6968. Outside the U.S., contact your local CZM distributor.

☞ Note: Consult your network administrator or information technology (IT) professional to make sure you install and configure the print driver correctly. Specific characteristics of individual network configurations can vary greatly.

USB Configuration

No printer configuration is required for the USB configuration. Three general steps are required for configuration: install printer drivers on the GDxPRO if required, connect the printer to the GDxPRO via USB, and power on the printer.

(D) Data Transfer Using Optical Disks

Overview

You can transfer data between GDxPRO instruments with an optical drive and Roxio$^{®}$ Drag-to-Disc™ software installed. This appendix explains the features and limitations of GDx data transfer using optical disks, and provides instructions for data transfer.

⚠️ **Important Note:** The Roxio Drag-to-Disc software is pre-installed on the GDxPRO instrument and specially configured for use with it. Do not re-install Roxio Drag-to-Disc on the instrument. The Roxio Easy Media Creator CD included with your instrument is provided to satisfy licensing requirements only.

Compatible Media Formats

The GDxPRO instrument can use the following types of disks to transfer data:

- CD-R – writable CD
- CD-RW – rewriteable CD
- DVD±R – writable DVD
- DVD±RW – rewriteable DVD

☞ Note: The optical disks you use must first be formatted, as explained in the section Disk Formatting on page D-3.

Compatible Data Transfer Functions

Optical disks can be used for all export and import functions.

Export and Import

You can burn an GDxPRO export database to an optical disk for transfer to another GDxPRO instrument.

☞ Note: On a PC, it may be possible to view and analyze GDx data using third party software. Beyond the instructions here, Carl Zeiss Meditec does not support the import of GDx data to a PC; neither do we specify third party software you can use on a PC to view and analyze GDx data, nor support its use.

Data Transfer Instructions

The actual data transfer functions—export and import—are done using the GDxPRO software in the usual way, except that you select the optical drive as the target or source drive for data transfer, and you insert a compatible formatted disk in the optical drive.

The **Export Data** function exports all information required to regenerate the database. To perform the Export Data operation, at the MAIN screen, select **System** > **Database** > **Export Data.** A **Browse for Folder** dialog will open where you can select the folder for the data export. Selecting the optical disk drive will initialize burning of a CD/DVD.

Upon completion of the data transfer, press the CD\DVD eject button. A **Drag-to-Disc Eject Options** dialog box is displayed (Figure D-1). Select **Eject** to eject the disk.

Figure D-1 Drag-to-Disc Eject Options Dialog Box

☞ Note: You must first format the disk, as described in Disk Formatting on page D-3.

See Importing and Exporting Data on page 8-7 for more information.

Rename Disc

After export is complete, to rename the disc follow these steps:

1. Select the Windows key 🪟 on the keyboard. This will cause the Windows 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.)

2. Right-click the Roxio Drag-to-Disc icon 🔲 and select **Rename Disc** from the pop-up menu, as shown on the left, or press **Alt+R** from the keyboard. The **Drag-to-Disc Rename Disc** dialog is displayed (Figure D-2).

Figure D-2 Rename Disc

3. Enter a new name and select **OK** to save the name.

Proper Disk Care

We do not recommend that you use optical disks 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. Optical disks are very susceptible to scratches that could render them unreadable.

Disk Formatting

This section explains how to format optical disks using Roxio Drag-to-Disc as it is installed on the GDxPRO instrument. To backup or export requires an optical disk formatted in the Universal Disk Format (UDF1.5).

Warning: Formatting permanently erases any data currently on the disk!

General Steps

1. Install the optical disk into the GDxPRO 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 Drag-to-Disc software, you do not have to close the GDxPRO software. Select the Windows key [   ] on the keyboard. This will cause the Windows 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** from the pop-up menu, as shown on the left. The **Drag-to-Disc Format Options** dialog appears. See Disk Format Options below.

Disk Format Options

CD-R and DVD±R disks

No format options are available for CD–R or DVD±R disks (Figure D-3).
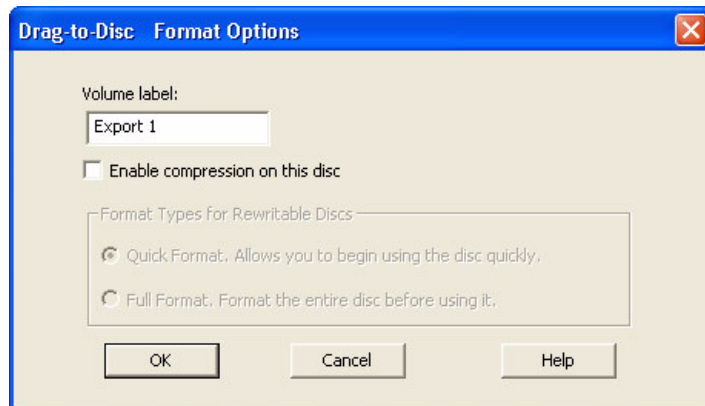
Figure D-3 CD-R Format Options

If desired, type a name in the **Volume Label** field. Click **OK** to begin formatting. A **Drag-to-Disc Preparation** dialog appears during formatting. Formatting is brief. The dialog disappears when it is complete. Once formatted, you cannot format CD–R or DVD±R disks again, nor can you erase them.

CD–RW and DVD±RW Format Options

For a new, blank CD–RW or DVD±RW, you have only the option to perform a full format (Figure D-4).
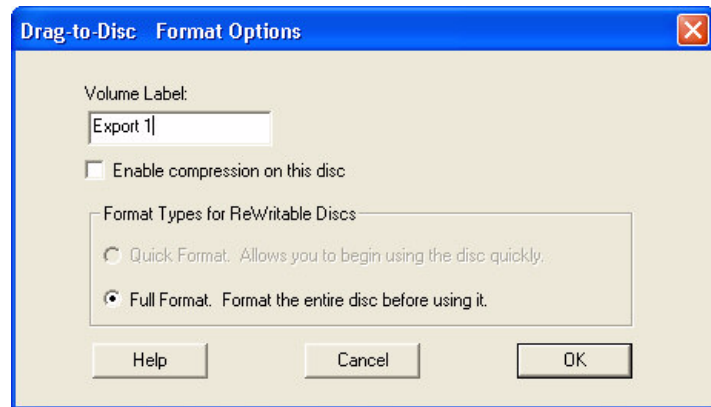

Figure D-4 Disk Full Format Option
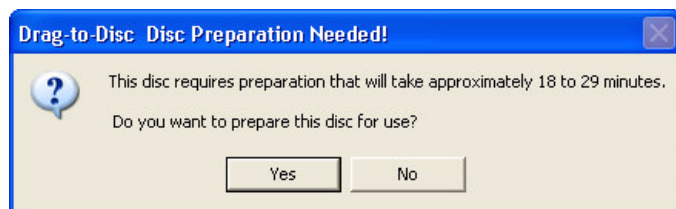
A full format requires 18-29 minutes (Figure D-5).

Figure D-5 Full Format Disc Preparation

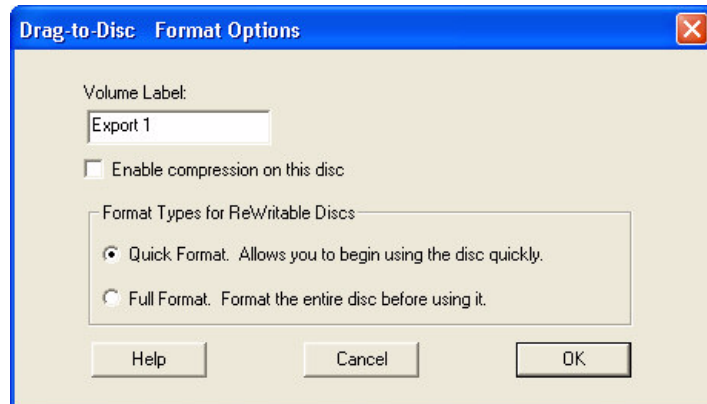If the CD–RW or DVD±RW was previously formatted, you can perform a quick (Figure D-6) or full format.

Figure D-6 Disk Quick Format Option

☞ 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 after writing when you eject it. If the disk is quick formatted, it requires 15 seconds to 4 minutes for the disk to eject after writing to it, depending on the amount of data written.

Rewriteable Disk Use Restrictions

GDxPRO will not write export data to a CD-RW or DVD±RW disk that already contains export data. Only one export database can be present on a CD-RW or DVD±RW at a time. If you attempt to export to a rewriteable disk that already has an export database, you will overwrite the previous database.

⚠ Note and Warning: It is possible to reuse a CD-RW or DVD±RW disk for export, but you must overwrite—and in the process delete—the current export database. You can also re-purpose any dedicated CD-RW or DVD±RW disk, but only if you first delete all files on the disk or reformat the disk—and thereby permanently erase all data on the disk.

Roxio Drag-to-Disc Software Configuration

CD-R or DVD±R Optical Disks

To successfully import GDx data from a CD-R or DVD±R optical disk to the GDxPRO, the Roxio Drag-to-Disc Eject Options must be configured to finalize the disk upon ejection (enable the disk to be read on any computer), as shown in Figure D-7. Do not change the

configuration of the Roxio Drag-to-Disc software, particularly the eject settings. The correct eject settings are seen in Figure D-7 below.
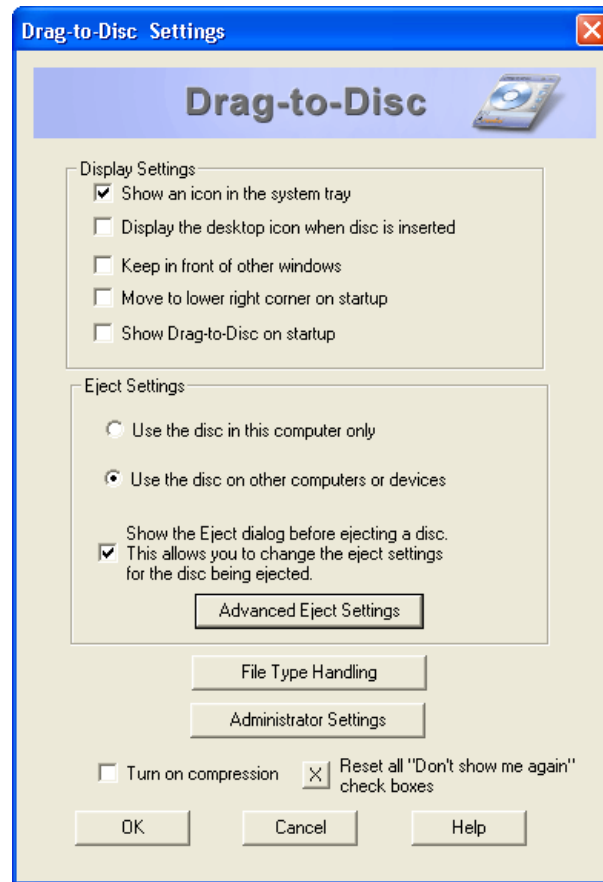

Figure D-7 CD-R and DVD±R Drag-to-Disc Eject Options

(E) Maintenance

Chapter Overview

Carl Zeiss Meditec designed the GDxPRO 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 GDxPRO 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.

Replacing Fuses

Both the instrument and the optional power table have two fuses. Instructions to check and replace the fuses in both the instrument and table 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 Meditec 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 E-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 on page E-2 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. Next, check the table fuses and replace them if necessary. See Replacing Fuses on page E-1 for instructions.
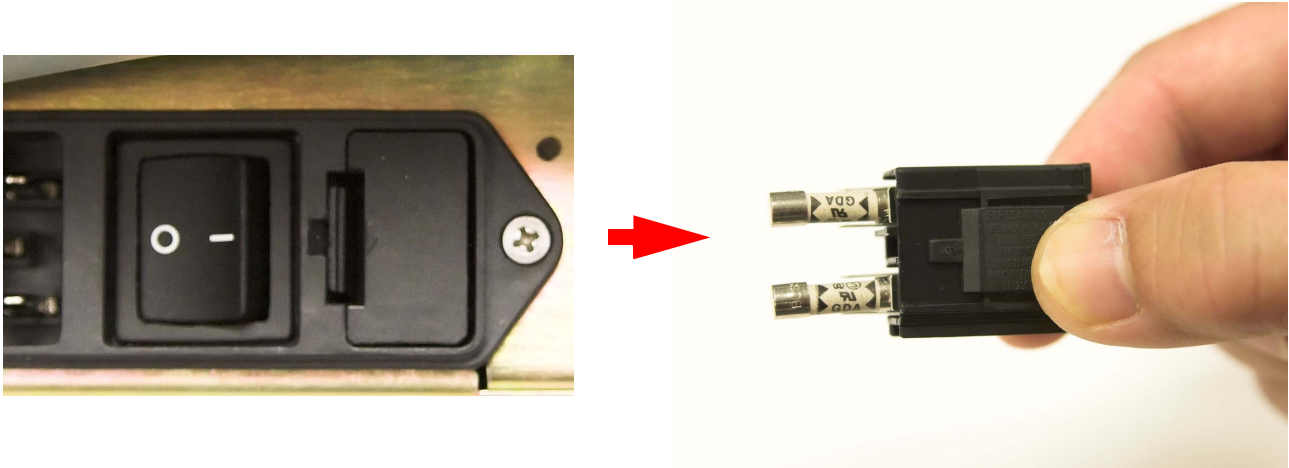
Check and Replace Instrument Fuses

Two fuses are located on the bottom right side of the instrument just to the left of the power cord inlet.

⚠ CAUTION: 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. Before replacing the main fuse be sure that GDxPRO is powered down (see Powering Down the Instrument on page 2-3), and that the power cord is disconnected from the unit. Gently place the GDxPRO on its left side.

2. Using a narrow-bladed screwdriver, gently pry open the fuse holder, from the side, to expose and remove the fuse holder.

With screwdriver, pry open fuse holder from the side.

Remove fuse holder with fingers.

Figure E-1 Opening instrument fuse assembly and removing fuse holder

Information about the proper replacement fuses is found adjacent to the fuse holder.

☞ **Fuse type and rating for both fuses: Fuse Metric 5A/250 V Slow Blow IEC 127.**

⚠ WARNING: Always replace fuses with the same type and rating. Failure to do so may create a risk of fire.

3. Slide out the fuse holder and check the filament for breakage. Dispose of any defective fuses.
4. Insert the new fuse in the holder. Slide the holder back into the housing until it snaps closed.
5. Gently return the GDxPRO to its upright, operating position.
6. Plug in the power cord at both ends.
7. Your instrument is now ready to be powered on.

Removing Hard Disk Drives

The two hard disk drives in GDxPRO should not be removed without contacting your CZM service representative.

☞   Note: Improper removal of one or both Hard Disk Drives may result in loss of valuable data. Do not attempt to remove the Hard Disk Drives in GDxPRO without specific instructions from CZM customer service: in the U.S., call 800-341-6968; outside the U.S., contact your local CZM distributor.

☞   Note: The Hard Disk Drives have a warning label (Figure E-2) to guard against removal without first removing the GDxPRO from any power source.
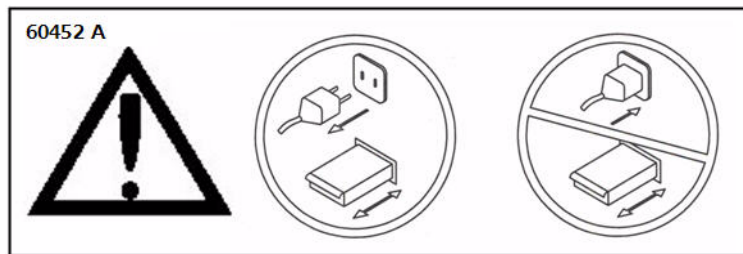
Figure E-2 Hard Disk Drive Warning Label

Hard Drive Replacement Procedure

The following procedure describes how to remove and replace the hard drives on the GDxPRO instrument. Make sure the system is powered down and the power cord is unplugged.

1. If the system is running, save all necessary data.
2. Verify that you are on the MAIN screen, and then push the power button on the Operator Console.

Power button
on Operator Console
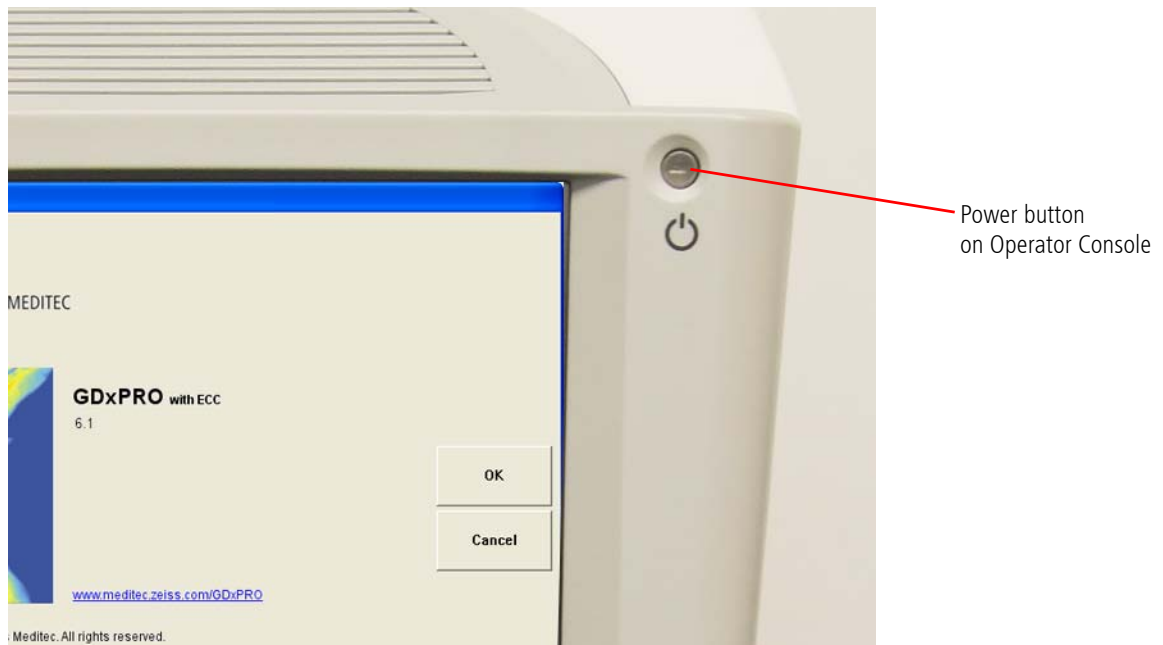
3. After the LCD turns off and the Power button changes color to amber, turn off the power switch on the bottom right of the instrument and unplug the power cord next to it.

Power Cord

Power Switch
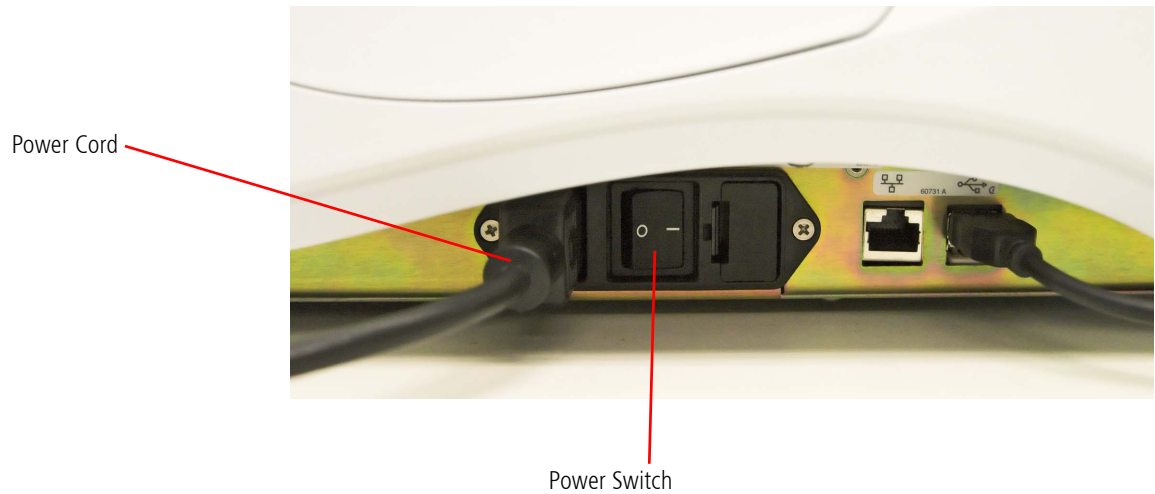
4. Turn the drive door locking screw about ¾ of a turn counter-clockwise using a flat bladed screw driver to open the drive access door.
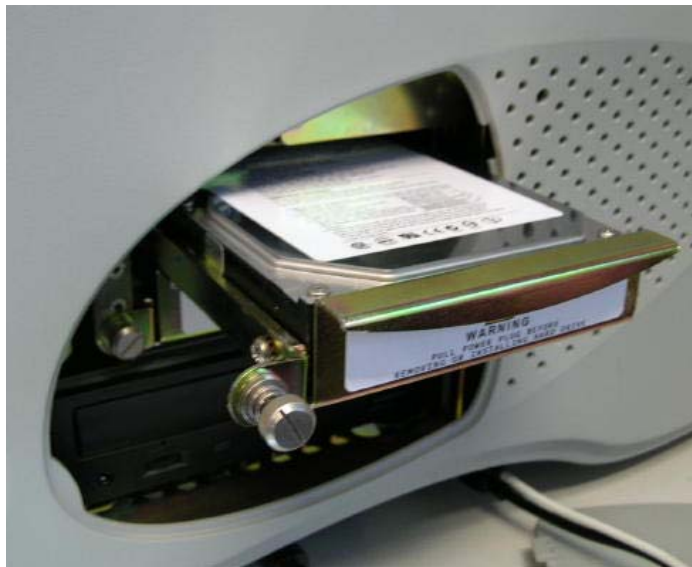
Drive Access Door
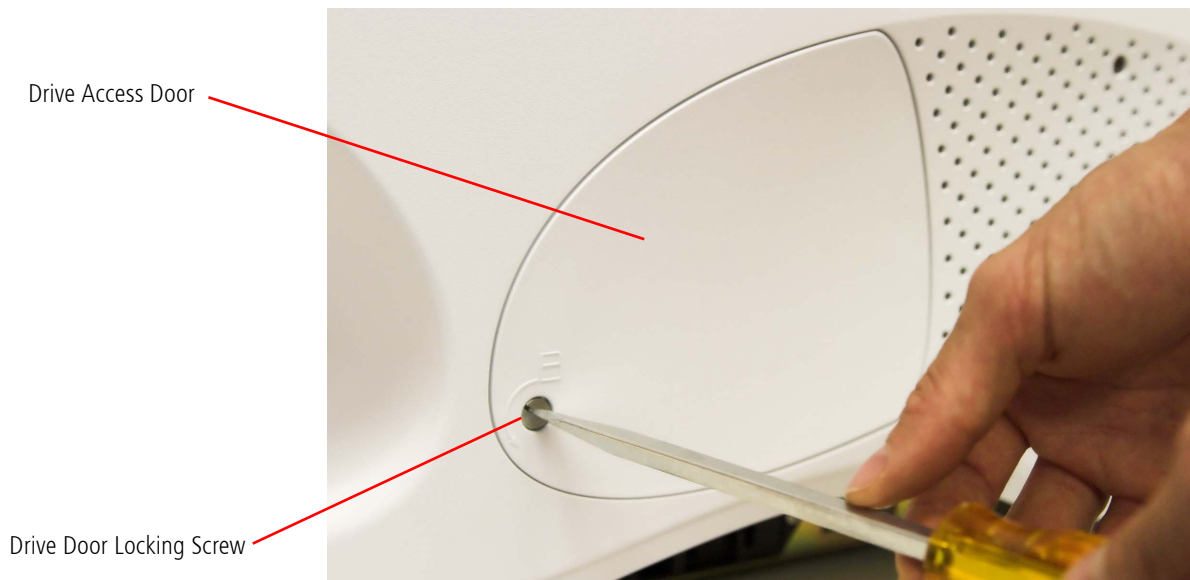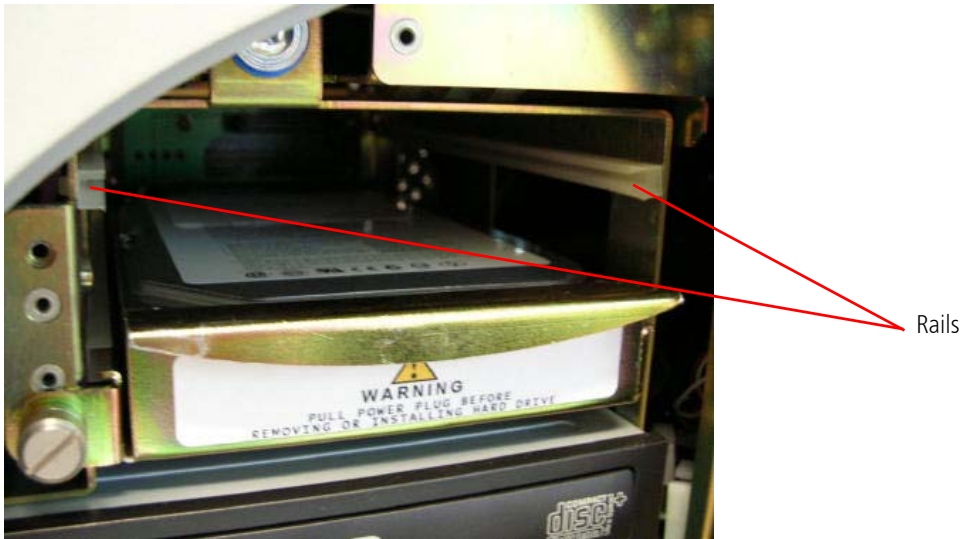
Drive Door Locking Screw

5. Turn the hard drive drawer locking screw several turns counter-clockwise using a flat bladed screw driver. The screw is captive and will stay with the hard drive drawer when fully loosened.


Hard Drive drawer Locking screws

Master Hard Drive

Back-up Hard Drive
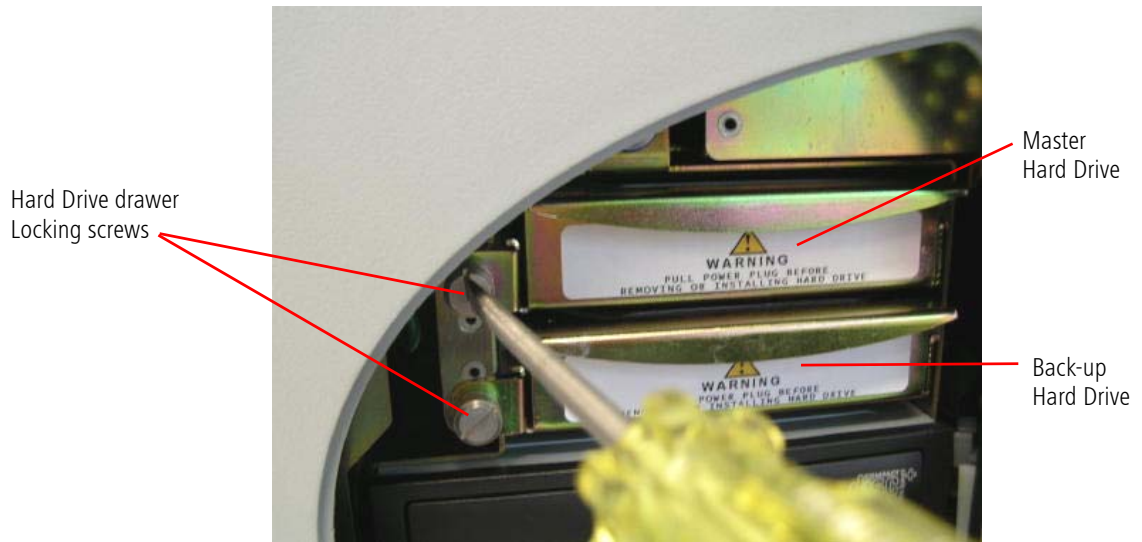
6. The hard drive drawer can now be pulled out straight.


Hard Drive drawer

7. When inserting the hard drive drawer, make sure to guide the hard drive drawer into the rails on each side.

Rails

8. Push the hard drive drawer all the way in. Push past the initial resistance until you can feel the connector in the back of the hard drive drawer engage.
9. The front screw tab should be flush with the mount and the locking screw can now be tightened clockwise till snug with a flat blade screw driver.

Flush with mount

Maintenance
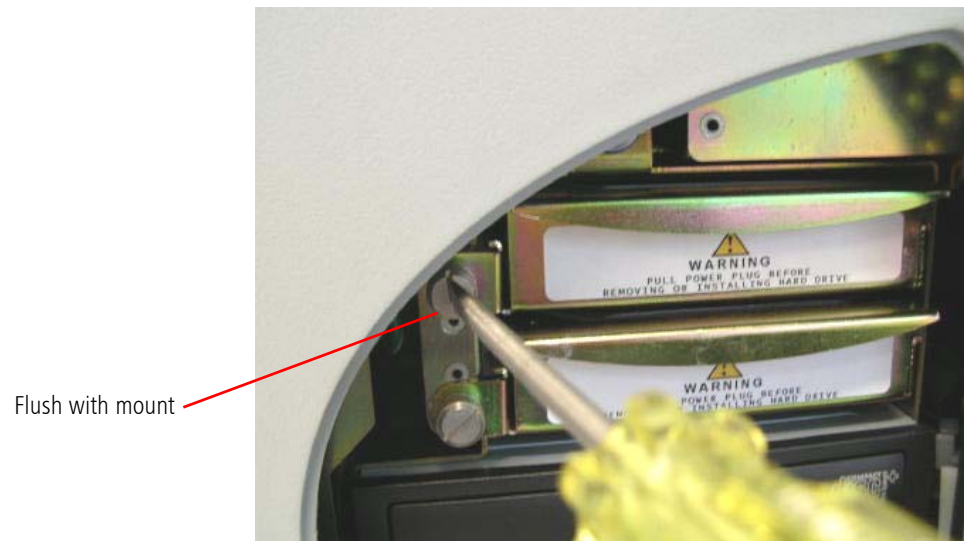
10. Re-install the drive access door at an angle by inserting the alignment tabs to the right of the drive door into the slots in the housing.

Alignment Tabs
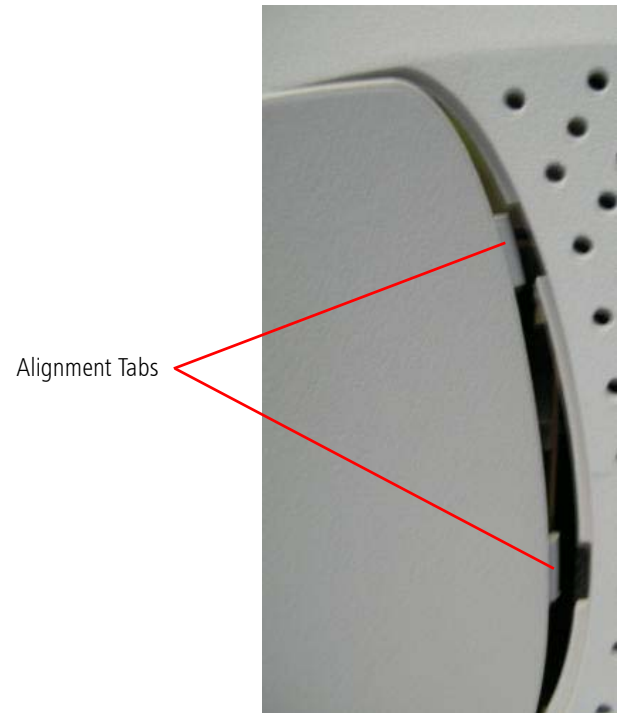
11. Once the drive door is completely installed, turn the drive access door locking screw about ¾ of a turn clockwise using a flat bladed screw driver to lock the drive door.
12. The power cord can now be re-inserted and the power switch next to it can be turned back on.

Transporting

☞ Note: The optics of the GDxPRO may be damaged if the system is jarred during transportation, either in office or out of office moves. If there is any chance of the GDxPRO being bumped or jarred, perform the *Shut Down for Transport* procedure. It is mandatory for out of office transportation.

This *Shut Down For Transport* procedure moves the optics to the docked position. This enables the locking screw to be engaged and protects the optics from damage during transportation.

At the MAIN screen, select **Shut Down for Transport**. The GDxPRO will display a message asking you to confirm that you wish to shut the system down (Figure E-3).
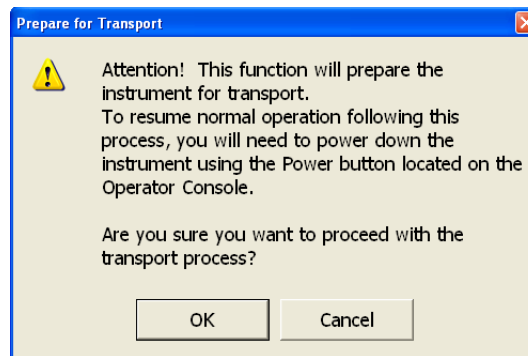

Figure E-3 Shut Down for Transport Dialog

Press **Cancel** if you do not want to shut the system down. Press **OK** if you do want to shut down the system. If you select **OK**, the GDxPRO internal optics will start moving towards its home position and the PREPARE FOR TRANSPORT screen will be displayed (Figure E-4).
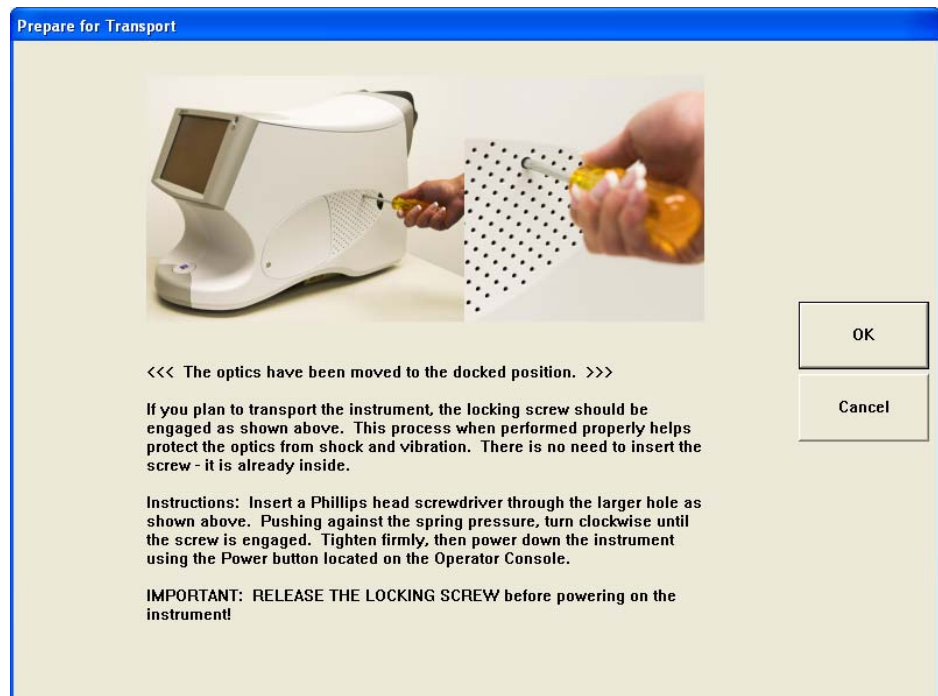

Figure E-4 Shut Down for Transport Screen

The PREPARE FOR TRANSPORT screen provides pictures and instructions for inserting the Phillips screwdriver, provided with the GDxPRO accessory kit, into the optics lock down screw hole (larger of the air vent holes) on the right side of the system (when facing the LCD Display). You are instructed to insert the screwdriver head through the hole, engage the spring-loaded screw, and tighten the screw firmly with a clockwise rotation of the screwdriver. Then press the green Power button on the Operator Console (Figure 1-2). After the LCD turns off, the Power button changes color to amber. Turn off the power by flipping the power switch on the bottom right of the instrument to the off position (I = on, O = off).

After transporting the GDxPRO and placing it in a secure position, release the locking screw by placing the Phillips screwdriver in the optics lock down screw hole on the right side of the system, engaging the spring loaded screw, and turning the screw counterclockwise until it is loose and turns freely (see Unlocking the System on page 2-2). Then perform the power up procedure (see Powering Up the Instrument on page 2-2).

☞ Note: Carl Zeiss Meditec offers an optional transport case for your convenience to safely transport your GDxPRO. We recommend that you use it whenever the need arises to transport the GDxPRO from one location to another. Contact CZM sales department to order a transport case: in the U.S., call 877-486-7473; outside the U.S., contact your local CZM distributor.

Handling Error Messages

If the system fails to start, 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 Meditec 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 on the lower left of the right side of the instrument (see Product Labels and Serial Number Location on page 1-22).

Hard Disk Defragmentation

Defragmentation of the GDxPRO computer hard disk may become necessary after some time. 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.

☞ **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. Select the Windows key [icon] on the keyboard to see the Windows **Start** menu.
 - Click **Start > All Programs > Accessories > System Tools > Disk Defragmenter.** The Disk Defragmenter appears.
2. Select the **C:** 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**.
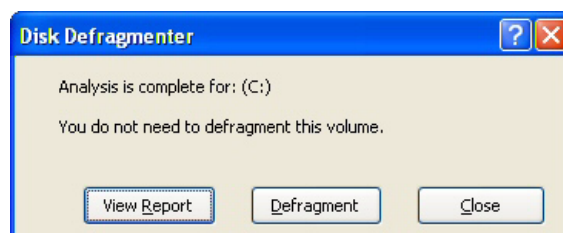

Figure E-5 Sample Disk Defragmenter Analysis Outcome

Routine Cleaning & Disinfecting

The face mask, and to a lesser extent the imaging aperture lens and LCD screen, are the only parts that require routine cleaning and disinfecting. Instructions are included below for occasional cleaning and disinfecting 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.

Face Mask

⚠ IMPORTANT: The instrument parts that routinely contact the patient—the face mask—should be cleaned with water, and disinfected between each examination with an alcohol wipe (70% Isopropyl).

The Imaging Aperture Lens

The imaging aperture should not contact the patient's eye. Still, you should clean it occasionally or as necessary to remove dust and oily smudges, ensuring true images. You can use an alcohol prep swab or cotton swab dipped in isopropyl alcohol to disinfect (you may use the Volk Precision Optical Lens Cleaner). Wipe dry with a soft, non-linting cloth or tissue. 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. Rub gently in a circular motion to remove dirt or foreign matter. Do not use harsh materials or chemicals. Keep the lens covered with the dust cap when the GDxPRO is not in use.

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.

Instrument Covers and 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, wipe with a non-linting cloth or swab (**dampened only, not dripping wet**) with water. Disinfect with an alcohol wipe (70% Isopropyl). Wipe dry with a clean and soft non-linting cloth.
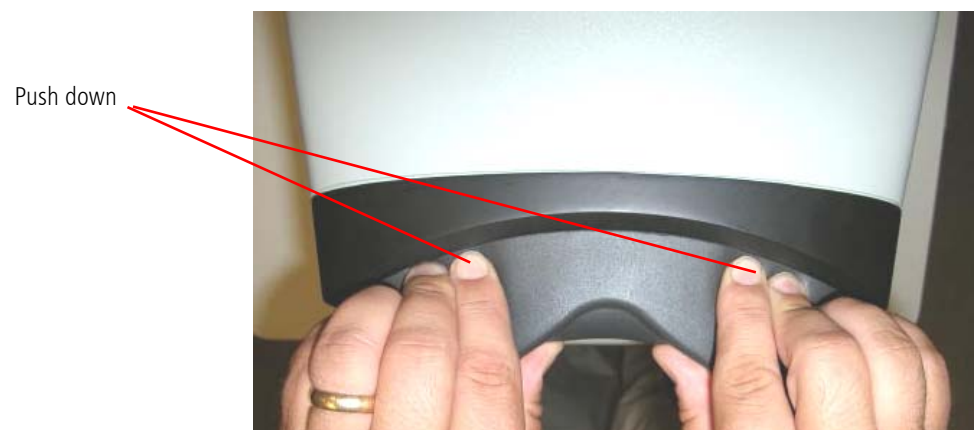
Replacing the Face Mask

Follow the instructions below to remove and install the face mask.

Removing the Face Mask

The face mask is captured in the patient bezel with two bottom hooks and two top snap features.

Indented areas

Face mask
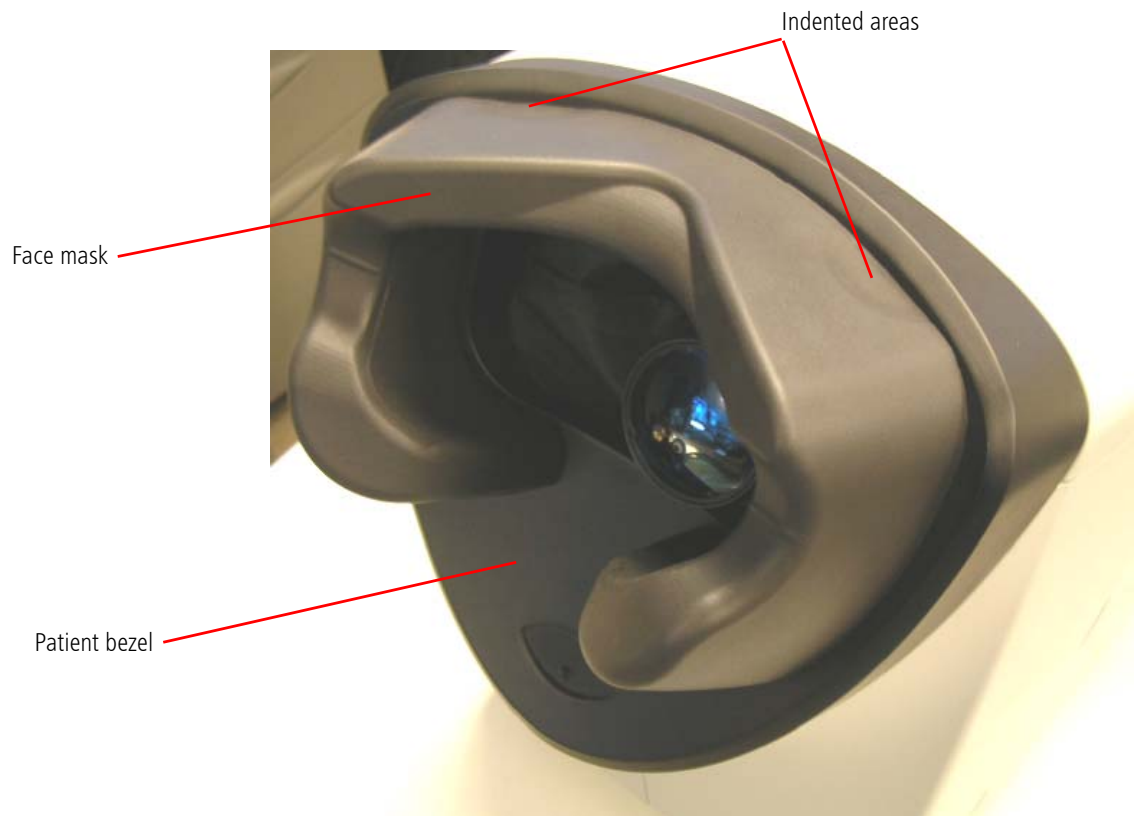
Patient bezel

1. To remove the face mask from the patient bezel, grab the top portion of the face mask with both hands as shown below and push with both index fingers down at the indented areas.

Push down

2. While pushing down, grab the face mask and pull the top portion towards you as shown below.

Pull out

Installing the Face Mask

1. To install the face mask, hold the face mask at an angle and push the two bottom hooks into the bottom openings of the patient bezel as shown below.

2. Keep the two bottom hooks engaged in the patient bezel while pushing the top of the face mask towards the bezel.

3. Guide the top two snap hooks of the face mask into the two openings of the patient bezel keeping the bottom hooks still engaged.

4. Firmly push the top portion of the face mask into the patient bezel to engage the snap hooks.

5. Lightly pull out on the top of the face mask to confirm engagement. Confirm that the face mask is flush against the patient bezel on both sides, indicating correct face mask installation.

List of User Replacement Accessories

Part Number	Description
2660100022511	Power Cord, 120 V
2660100022581	Power Cord, 220 V
2660021121801	Power Cord, China
2660021121716	USB Keyboard, Mini (Black)
2660021121631	Keyboard Tray
2660021128483	User Manual
2660021128777	GDxPRO Primer Book (subject to availability)
2660021128776	GDxPRO Report Analysis Quick Reference Guide
2660021128775	GDxPRO Scanning Quick Reference Guide
2660021114161	Objective Lens Cap
2660021128536	Screwdriver for unlocking the optics box (Phillips #2)
Variable	(Optional) USB/Network Printer
Variable	(Optional) Instrument Power Table
2660021128531	Dust Cover, Instrument
2660021102326	Antiseptic Wipes (Box of 200)
0000001345415	USB Mouse (Optical)
2660100022513	Fuse Metric 5A/250 V SB IEC 127 (For 100-120 V and 220-240 V Systems)
2660021121819	Cable, Ethernet, CAT5e (14')
2660021116418	Cable, USB MA-MB (6')
2660100057507	Roxio Software on Disk
2660021121363	Face Mask
2660021128537	User Documentation CD

To order: In the U.S., call 800-341-6968. Outside the U.S., contact your local Carl Zeiss Meditec distributor.

(F) Troubleshooting

If you are unable to resolve a problem with your GDxPRO please contact CZM customer service. In the U.S., call 800-341-6968; outside the U.S., contact your local CZM distributor.

GDxPRO Will Not Start Up

- Make sure the GDxPRO power cord is properly connected to the power outlet.
- Check for a broken power fuse.
- Check if a USB flash drive is inserted in a USB port. The GDxPRO may not boot if a USB flash drive is inserted in a USB port.

GDxPRO Locks Up

- Write down any error message received, including all numbers and codes.
- Write down the steps that were taken to produce the problem.
- Power down and then power up the GDxPRO (see Powering Down the Instrument on page 2-3, and Powering Up the Instrument on page 2-2).

Keyboard or Mouse Does Not Work

- Make sure the keyboard/mouse is properly connected.
- Disconnect and reconnect the keyboard/mouse while system is powered up.
- Cycle power.

External Color Printer Does Not Work

- Make sure the printer is properly connected, getting power, and is turned on.
- Cycle power.
- Check owner's manual for printer.
- Make sure that the printer settings are correct. See the printer manual for information.
- Perform a test print.

What to do when an Error Message is displayed

- Write down the error message received including all numbers and codes.
- Write down the steps that were taken to produce the error message.
- Follow any instructions given in the dialogue box.

Acquisition Mode is Suspended

- If the GDxPRO is idle for an extended period of time while in any acquisition mode (approximately 16 minutes), the ACQUISITION SUSPENDED SCREEN (Figure F-1) will be

displayed. Return to where your system was prior to the suspension of acquisition by selecting **OK**. Select **Cancel** to cancel the acquisition and return to the MAIN screen.
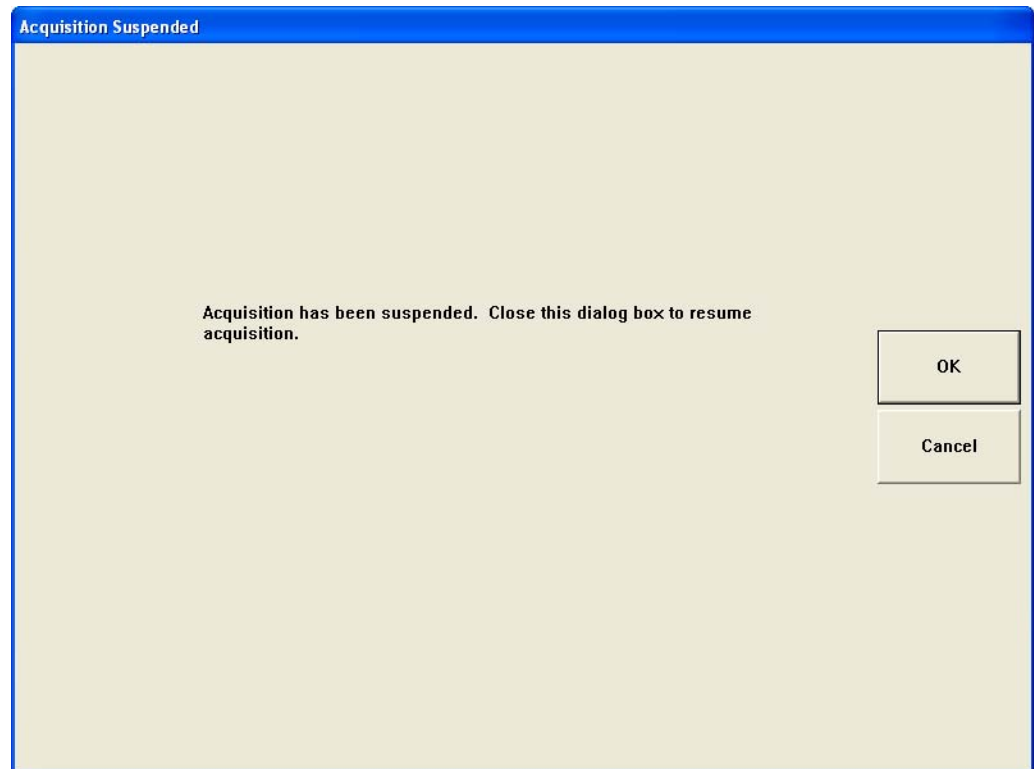

Figure F-1 Acquisition Suspended Screen

<u>"I want to make sure my GDxPRO data is backed up. Where is it located on the GDxPRO?"</u>

- For backing up data, the user should use the Full Backup function (**System > Database > Full Backup/Restore > Full Backup**). Copying the directory will not back up the files in a format the database can recover. The default data directory on the server is in *C:\Program Files\Carl Zeiss Meditec\GDxPRO\Databases\Main.*

<u>"I am unable to launch the GDxPRO application."</u>

- Ensure you are an Administrator or Power User in the Windows User Accounts (**Start > Settings** (Classic Start menu only) **> Control Panel > User Accounts)**.

Table F-1 Image Troubleshooting Guide

Issue/Message	Potential Cause(s)	Recommended Action(s)
Q < 7	• Unclear media, patient blink during scan, dry eyes, improper alignment on the eye. • Errors in corneal compensation. • In some patients, Q is low because anatomical variation makes the ONH position too low or high in the scan field.	• Repeat RNFL scan. Make sure patient blinks before scan, or use artificial tears. • Repeat RNFL scan if it has suspected flaws.Otherwise, repeat both the corneal and RNFL scans. • The image may be used if the calculation circle is entirely contained within the image.
"Image too dark or too light."	• Unclear media. • Patient blinked/improper alignment. • Improper focus. • Small pupil (< 2 mm diameter). • Retinal curvature or tilted disk.	• Check for cataract. • Repeat scan with more careful alignment on the eye. • Perform AutoFocus scan and retake image. • Mild dilation. • No action required.
"Focus dot not centered on red line or pupil not centered."	• Possible misalignment on the eye during image acquisition.	• See View Iris Image to check alignment; retake image if needed.
"Poor fixation or ellipse placement."	• Possible incorrect fixation or ONH ellipse placement. In some patients, could also be due to anatomical variation which makes the ONH position too low or high in the scan field.	• If patient cannot fixate properly, use Low Vision Target. • If a reference image has been selected, preview the printout to check for alignment flag. If there is a flag, retake RNFL scan or change reference image. If due to anatomical variation no action is required. • If no reference image selected, adjust ellipse placements as necessary.
"Possible refraction setting error."	• Possible improper focus.	• Perform AutoFocus scan and retake image.
"Analysis confidence low. Results could be unreliable."	• Excessive atypical scan artifact. • Error in corneal compensation.	• Switch to ECC if applicable or interpret results with caution. • Repeat RNFL scan. If necessary, repeat both the corneal and RNFL scans.
"Ellipse may be too big. Exam comparisons may be affected."	• Refers to Calculation Circle, which may be too close to the edge of the image.	• Reduce Calculation Circle size if applicable or interpret results with caution.
"Recommend resetting compensation."	• Errors in corneal compensation.	• Repeat RNFL scan if it has suspected flaws. Otherwise, repeat both the corneal and RNFL scans.
STD (SD) > 8.5	• Significant variability between images composing the mean image.	• Obtain additional images to generate a new mean.
Alignment Warning Icon (Symmetry Analysis report)	• Image not well aligned to reference, inconsistent patient fixation, or excessive eye motion.	• Retake RNFL scan or change reference image.
TSS ≤ 40 (ECC), TSS ≤ 60 (VCC)	• Image contains significant artifact.	• If using VCC, switch to ECC. • Interpret with caution.
Residual > 4 in ECC, or ≥ 12 in VCC (Symmetry Analysis report)	• Significant error in corneal compensation.	• Repeat RNFL scan if it has suspected flaws. Otherwise, repeat both the corneal and RNFL scans. • Consider switching from VCC to ECC or vice-versa.

Table F-1 Image Troubleshooting Guide

Issue/Message	Potential Cause(s)	Recommended Action(s)
Dark band(s) on edge(s) of scan.	• Eye movement during scan acquisition.	• Image may be used if no interference with Calculation Circle.
Blood vessels appear blurred.	• Eye movement during scan acquisition.	• Repeat the RNFL scan.

(G) Glossary

Anterior Segment

Front third of the eyeball, from the surface of the cornea to the start of the vitreous humor. As used in this document, this is used to refer to those anatomical features that are optically transmissive, including the cornea and the lens. The birefringence of these structures is dominated by the birefringence of the cornea.

Archive

1) The process of moving exam images to another computer, or 2) the physical media or volume on the computer used to store the images. Used for freeing hard drive space and backing up.

Automatic Image Alignment

Retinal blood vessels are used as landmarks to align all images for a given eye to a single reference image. This step is required for mean image creation and progression analysis. Once the images are aligned, the ONH and macular ellipses from the reference image are copied to all other images.

Baseline exams

The first two exams in a progression analysis. A baseline set is two measurements of the same eye used for GPA. Two baselines sets for a given eye refer to 4 individual measurements. Two baseline sets are referred to as previous and current baseline exam sets.

Birefringence

A property of optical materials in which the effective index of refraction encountered by an incident light beam varies depending upon polarization of the incident light. "Uniaxial" birefringent materials have two indices of refraction. The material has a "fast" axis associated with the smaller index, and a perpendicular "slow" axis for the larger index. An incident beam with a polarization direction parallel to the "slow" axis encounters the larger index of refraction, and thus travels at a slower speed.

Many optical structures in the eye exhibit birefringence, including the cornea, the lens, and the RNFL.

Button

An object displayed on the computer screen that can be selected with the mouse and activated by clicking.

Computer

GDxPRO instrument component that contains the central processing unit, random-access memory, and disk drive.

Cornea

Cornea refers to an image acquired without corneal compensation. Analysis of the macular region of this image allows the corneal polarization (magnitude and axis) to be measured. Cornea is a corneal measurement exam performed at the patient's first visit. The results in the macular region of this exam are analyzed to determine the optimum settings for the variable corneal compensator used to cancel out the effect of the birefringence of the cornea for subsequent ECC and VCC exams.

Corneal compensation

A method to compensate for corneal anterior segment birefringence of an eye. Necessary to isolate RNFL birefringence and determine accurate RNFL-I measurements.

CPU

Central Processing Unit. Also called "processor", a component of computer hardware where software instructions are processed and executed. The CPU performs most of the calculations which enable a computer to function, sometimes referred to as the "brain" of the computer.

CZM

Carl Zeiss Meditec.

Database

A complete record of all patient and exam information in the instrument. On the GDxPRO instrument, the database is stored on the instrument's hard disks. In Review Software, the database is stored on the Server computer.

DVI

Digital Visual Interface. DVI is a video interface standard designed to maximize the visual quality of digital display devices such as flat panel LCD computer displays and digital projectors. DVI-I stands for "DVI-Integrated" and supports both digital and analog transfers, so it works with both digital and traditional monitors. DVI-D stands for "DVI-Digital" and supports digital transfers only.

ECC

Enhanced Corneal Compensation. The use of a variable retarder and software compensation to cancel a particular patient's corneal birefringence. In this mode, a special corneal measurement exam is performed at the patient's first visit similar to the one in VCC. The results in the macular region of this exam are analyzed to determine the optimal bias birefringence that is superimposed onto the RNFL birefringence. This total birefringence form the bias and corneal birefringence which is then removed mathematically by the software to yield the RNFL-I measurement. ECC images can be acquired and reviewed on the GDxPRO.

EMR

Electronic Medical Records. See PMS.

Ethernet

Ethernet is a family of standard computer networking technologies for local area networks (LANs). Allows you to network your GDxPRO instrument with different computers, printers or office management systems to share information and exams.

Export

Process of copying exams from the GDxPRO instrument's hard drive.

Extended Mode

Progression Analysis mode using *individual* measurement variability. This mode requires means of three measurements.

Fast Mode

Progression Analysis mode which compares change to the pre-determined *average* measurement variability derived from a sample population.

FCC

Fixed Corneal Compensation. The FCC exam was produced by earlier GDx Access systems, which had compensators that were not adjustable. The same compensation is used for all patients. FCC images can be reviewed and printed but not modified on the GDxPRO.

Field

A portion of a screen display that contains information such as a patient's name or date of examination.

Fixation Target

A point of light that the patient fixates on (looks at) during the laser scanning process. The GDxPRO provides an internal fixation target (Standard and Low Vision) that is visible while the patient is in the scanning position.

Flash Drive

A flash drive (also known as a thumb drive, jump drive, pen drive, or keychain drive) is a small, portable storage device which, unlike a hard drive or optical drive, has no moving parts. Most connect to a computer via a built-in USB port. Storage capacity ranges from as small as 16MB to as much as 64GB and more. A flash drive can be used in place of a floppy disk, Zip drive disk, or an optical disk. When the user plugs the drive into the USB port, the computer's operating system recognizes the device as a removable drive and assigns it a drive letter. Unlike most removable drives, a flash drive does not require rebooting after it's attached, and does not require batteries or an external power supply.

Follow-up exam

An exam taken after the baseline exams in a progression analysis.

Fovea

A central pit in the macula that provides the sharpest vision.

Frame

A two-dimensional set of data points representing the amount of laser light reflected back from the retina for each point in a given set of scan lines. The returning light is split into orthogonally polarized beams, and each is directed to a light detector. For each detector, 32 frames are acquired in a scan, each with different modulator position and thus different incident-light polarization angles.

Fundus

The posterior interior surface of the eyeball. This portion of the retina is visible through the pupil. A fundus image is an intensity image generated from the first 8 of the 32 scans acquired during an exam. The fundus image excludes all results of birefringence.

GDx

Glaucoma Diagnostics.

GB

Gigabyte. A unit of computer storage meaning either exactly 1 billion bytes or approximately 1.07 billion bytes. 1,000 megabytes (MB) is equal to 1 gigabyte.

GDx Access

A legacy instrument that preceded the current CZMI GDxVCC and GDxPRO instrument. The GDx Access provided fixed rather than variable corneal compensation. The GDx Access performed scans consisting of 16 frames rather than the 32 frames acquired for each ECC or VCC scan on latter instruments.

GDxVCC

Second generation CZMI Glaucoma Diagnostics instrument with Variable Corneal Compensator.

Glaucoma

A group of diseases that result in damage to the optic nerve and retinal nerve fiber layer.

GPA

Guided Progression Analysis. The tracking of statistical significant change over time in parameters associated with glaucoma.

Import

Process of copying exams from another location (i.e., Network drive) to the hard drive; typically used to transfer exams between GDx instruments.

Infrared

Infrared (IR) radiation is electromagnetic radiation of a wavelength longer than that of visible light, but shorter than that of microwaves. The name means "below red" (from the Latin infra, "below"), red being the color of visible light with the longest wavelength. Infrared radiation has wavelengths between about 750 nm and 1 mm, spanning five orders of magnitude.

JPEG

A commonly used method of compression for photographic images. The compression method is usually lossy compression, meaning that some visual quality is lost in the process and cannot be restored. Image files that employ JPEG compression are commonly called "JPEG files" and the most common filename extensions are .jpg and .jpeg. The name JPEG stands for Joint Photographic Experts Group, the name of the committee that created the standard.

LAN

A local area network (LAN) is a computer network covering a small geographic area, like a home, office, or group of buildings.

LCD

Liquid Crystal Display. An LCD is a thin, flat display device made up of any number of color or monochrome pixels arrayed in front of a light source or reflector.

Likely progression

RNFL-I decrease that has been confirmed by a consecutive follow-up examination.

Macula

A small (approximately 3°) area of the retina that provides a patient's central vision. This area surrounds and includes the fovea.

MB

Megabyte. A unit of computer storage equal to either 1,000,000 bytes or 1,048,576 bytes, depending on context. 1,000 kilobytes is equal to 1 megabyte.

Mean

A mean is an image created by averaging two to three ECC or VCC measurements of the same eye acquired on the same instrument within thirty days of each other.

Measurement

The set of results obtained as a result of performing a scan of a patient's eye. There is one eye per measurement. The set includes the Nerve Fiber Layer Map, the fundus image and ellipse position, and the diagnostic parameters derived from the Nerve Fiber Layer Map.

Micrometer

A micrometer (symbol μm) is a unit of length in the metric system, equal to one millionth of a meter (i.e., 10^{-6} m, or one thousandth of a millimeter).

Nanometer

A nanometer (symbol nm) is a unit of length in the metric system, equal to one billionth of a meter (i.e., 10^{-9} m, or one thousandth of a micrometer).

Nerve Fiber Layer Map

An image presenting color-coded RNFL-I measurements, generated from the 32 scans acquired during an exam.

NFI

The Nerve Fiber Indicator (NFI) for GDx is an artificial intelligence algorithm that analyzes the entire RNFL profile. It is "trained" on known normal and glaucomatous eyes and essentially uses pattern recognition to discriminate between these. The NFI is an ordinal number that is related to likelihood that the polarimetric retinal nerve fiber layer map is abnormal. A high number is more likely to be related to abnormality, but is not definitive. The NFI is not intended to be used as the sole basis of diagnosis for disease.

Normative Database

A database of SLP imaging results collected under controlled conditions from normal patients of varying age and ancestry. The database is structured to allow a patient's results to be compared with normal patients of similar age and ancestry.

Optic Nerve Head (ONH)

An area of the retina where the optic nerve attaches to the fundus, and connects to the retinal nerve fiber layer (RNFL). This is roughly oval in shape. Blood vessels also enter the eye through the ONH (also known as the Optic Disc).

PC

Personal Computer. A PC may be a home computer, or may be found in an office, often connected to a local area network. The distinguishing characteristics are that the computer is primarily used, interactively, by one person at a time. A PC is the physical part of a computer, including the digital circuitry, as distinguished from the computer software that executes within the hardware. For the purposes of this manual, a PC only runs a Microsoft Windows operating system.

PDF

Portable Document Format from Adobe®. PDF is fixed-layout document format used for representing documents in a manner independent of the application software, hardware, and operating system. Each PDF file can encapsulate a complete description of the document that includes the text, fonts, images, and vector graphics that compose the document.

Phase Shift

The magnitude of the delay between two orthogonal components of polarized light.

PMS

Patient Management System. PMS is a category of software that deals with the day-to-day operations of a medical practice. Such software frequently allows users to capture patient demographics, schedule appointments, maintain lists of insurance payers, perform billing tasks, and generate reports. PMS is often connected to electronic medical records (EMR) systems. While some information in a PMS and an EMR overlaps—for example, patient and provider data—in general the EMR system is used for the assisting the practice with clinical matters, while PMS is used for administrative and financial matters.

Polarimetric Thickness

Unique to GDx technology, Polarimetric Thickness, also expressed as RNFL-I, is the RNFL measurement of both RNFL thickness and structural organization obtained from a GDx. Units are measured in "P-μm".

Possible increase

RNFL-I increase that has been detected once. Possible Increase is often due to measurement variability.

Possible progression

RNFL-I decrease that has been detected once.

P-value

A probability value widely used to indicate where a particular value lies in a normal distribution. It is expressed as a percent.

Quality Score

Image Quality Score (Q) is measure of image quality ranging from 1 (low) to 10 (high).
A good image has a score of 7 or higher.

RAM

Random Access Memory. Fast-access memory that is cleared when the computer is powered-down.

Reference image

A single measurement used as the reference to which all other measurements of the same eye are aligned. Required for mean creation and progression analysis.

Refraction setting

The "refraction" setting entered for each eye is actually the spherical equivalent of the patient's residual refractive error. "Residual" means that if the patient is wearing contacts, the correction provided by the contact lens should not be included in the entered refraction. Further, if the prescription is for bifocals, the far correction should be used.

Retina

The part of the eye that converts optical images into nerve pulses that are sent to the brain. Composed of a thin layer of tissue that lines the interior surface of the rear two-thirds of the eyeball. Contains the rods and cones, and the interconnecting nerve fibers.

RNFL-I

The measurement of the phase shift that occurs when polarized light passes through the RNFL. Light polarized parallel to RNFL micro-structures travels more slowly than light polarized perpendicular to them. The size of this shift depends upon both the RNFL thickness and the cumulative level of organization of its microstructures. The greater the phase shift, the higher the RNFL-I measurement.

Scan

The process of acquiring a measurement. During a scan, a projected laser dot is scanned across the retina, and the reflected light is collected. This is performed 32 times with different polarization settings, and a frame of data is collected each time.

Scanning Laser Polarimeter

Scanning laser polarimetry (SLP), a technology for glaucoma diagnosis, uses imaging polarimetry to detect the birefringence of the retinal nerve fiber layer. All GDx instruments use Scanning laser polarimetry technology.

SCC

Software Corneal Compensation. SCC is determined by analyzing the fixed-compensation Nerve Fiber Layer Map in the macular region, which is then applied to the same image to generate a compensated result. SCC images can be reviewed and printed but not modified on the GDxPRO.

Selection List

A list of choices, such as patient names or exams, that appear on the screen; choices can be made by positioning the arrow over a selection and clicking the mouse button.

SLP

Scanning Laser Polarimeter / Polarimetry. See Scanning Laser Polarimeter.

Statistically Significant Change

Change that exceeds the expected measurement variability.

STD (or SD)

Standard Deviation. The standard deviation of a multiset of values is a measure of the spread of its values. It is defined as the square root of the variance. Variance is the average of the squared differences between data points and the mean. Variance is tabulated in units squared. Standard deviation, being the square root of that quantity, therefore measures the spread of data about the mean, measured in the same units as the data. Stated more formally, the standard deviation is the root mean square (RMS) deviation of values from their arithmetic mean.

TFT

Thin Film Transistor. TFT is a special kind of field effect transistor whose primary application is in liquid crystal displays (LCDs). Transistors are embedded within the panel itself, reducing crosstalk between pixels and improving image stability.

TIFF

Tagged Image File Format, an image file format for storing images. Unlike standard JPEG, TIFF files using lossless compression (or no compression at all) can be edited and resaved without suffering a compression loss or image quality degradation. Storing a sequence of images in a single TIFF file is also possible.

Triple Scan

An option on the Patient Information Screen which allows you to acquire three images of the same eye or both eyes at one time. This facilitates mean creation for Extended Mode.

TSNIT

The regions around the optic disc—Temporal-Superior-Nasal-Inferior-Temporal.

TSS

Typical Scan Score (TSS) is a measure of the "typicality" of the RNFL image. TSS ranges from 0 (very atypical) to 100 (very typical). Exams with TSS (ECC) $\leq$ 40 or TSS (VCC) $\leq$ 60 should be interpreted with caution; the particular scan may not be reliable.

Glossary

USB

Universal Serial Bus. USB is serial bus standard to interface devices. USB was designed to allow peripherals to be connected using a single standardized interface socket and to improve plug-and-play capabilities by allowing devices to be connected and disconnected without rebooting the computer (hot swapping). USB is intended to help retire all legacy varieties of serial and parallel ports. USB can connect computer peripherals such as mouse devices, keyboards, digital cameras, printers, personal media players, and flash drives.

VCC

Variable Corneal Compensation. A VCC exam uses the results of the Corneal Scan to set the variable compensator and cancel the effect of the birefringence of the cornea. VCC images can be acquired and reviewed on the GDxPRO.

(H) Specifications

Illumination Laser Source

- GaAlAs laser diode, 785 nm nominal value (776 nm − 800 nm actual), 3 mW instantaneous power and < 1 mW average power at the cornea

Fixation Laser Source

- Laser diode 635 nm ± 15 nm, 0.5 mW instantaneous power and
  < 1 µW average power at the cornea

Laser Classification

- Class 1 Laser product

Maximum Instantaneous Power at Cornea

- 3.0 mW

Measurement Area

- 40° ± 1.2° (Horizontal) x 20° ± 0.6° (Vertical)

Digital Resolution

- 256 x 128 pixels x 8 bit

Video Camera (CMOS)

- Video FOV (Field of View): ≥ 13.3 mm horizontally; ≥ 10 mm vertically
- Depth of Focus: ≥ 4 mm
- Camera pixel resolution: 320 x 240 pixels
- Video image pixel resolution: 640 x 480 pixels (NTSC)
- Video frame rate: 30 frames/sec
- Camera: 0.5 Lux sensitivity
- Video image resolution: ≥ 3 lp/mm

Ametropia Correction

- -10 to +5 diopters (original VCC Systems), -13 to +8 diopters (for GDxPRO Systems)

Data Acquisition Time

- < 1 second

Measurement Repeatability and Reproducibility

Table H-1 RNFL-I Measurements

	Repeatability (standard deviation, P-µm)	Reproducibility (standard deviation, P-µm)
TSNIT Average	1.5	2.5
Superior Average	2	3.5
Inferior Average	2.5	4

AutoFocus Reproducibility:

- $\leq$ 0.25 D (standard deviation)

Measurement Accuracy

Retardation measurement:

- $\pm$ 5 nm (measuring uniform linear retarder with retardance in the range of 20 nm to 120 nm)

Measurement Reliability

Image Quality Score (Q):

- Image Quality Score summarizes the overall quality of a SLP measurement. Q ranges from 1 (poor) to 10 (excellent). A scan with Q < 7 should be interpreted with caution.

Typical Scan Score (TSS)

- Typical Scan Score provides an assessment of noise in the RNFL phase shift measurement. TSS ranges from 0 (poor signal/noise) to 100 (very good signal/noise). A scan with TSS (ECC) $\leq$ 40 or TSS (VCC) $\leq$ 60 should be interpreted with caution.

Corneal compensation:

- VCC Method: Scans with compensation residual magnitude $\geq$ 12 nm were not included in the normative database. A VCC scan with a residual $\geq$ 12 nm should be interpreted with caution.
- ECC Method: Corneal compensation residual magnitude usually does not exceed 4 nm. A scan with a residual > 4 nm should be interpreted with caution.

RNFL Analysis Tools

- Age-adjusted normals with diverse ancestry
- Machine learning classifier (known as the NFI) for SLP RNFL measurement
- GPA

Computer

- Windows XP Professional Operating System, Service Pack 3
- Pentium IV or equivalent ($\geq$ 2.2 Ghz)
- RAM: $\geq$ 512 MB
- Two hard disk drives to support data redundancy: $\geq$ 80 GB each
- Internal exam storage: Up to 35,000 exams
- Writable Optical Drive
- 1 Ethernet ports, 4 USB 2.0 ports
- Integrated 8.4" TFT-LCD color flat panel touch screen display, 18-bit color, 800 x 600 resolution, brightness $\geq$ 220 nits
- DVI-I Video port: Supports 24-bit color at 800 x 600 resolution
- Printer support: Standard printers and wireless printers via USB and/or Ethernet port

Physical

- Dimensions (instrument only): 63.5 L x 30.5 W x 40.6 H (cm)
- Dimensions (in crate): 77 L x 55 W x 80 H (cm)
- Weight (instrument only): 22.5 kg (50 lbs.)
- Weight (in crate): 31 kg (69 lbs.)

Electrical Requirements

Electrical Rating

- 100-240 V, 50-60 Hz

Power Rating

- 200 VA

Fuse Rating

- T 5A 250 V

WARNING: Always replace fuses with the same type and rating. Failure to do so may create a risk of fire.

Environmental Conditions

Transport and Storage

Temperature: −20 to +60 deg. C
Relative Humidity: 10% to 75%, non-condensing
Atmospheric Pressure: 50 to 106 kPa

Operation

Temperature: 50° F − 95° F (10° C − 35° C)
Humidity: 10% − 75%
Atmospheric Pressure: 70 to 106 kPa

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GDxPRO User Manual
System Software Version 1.0
Specifications subject to change

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