Proven Clinical Performance
Numerous studies have validated the diagnostic accuracy and performance of the GDx technology for the clinical management of glaucoma.

The ideal glaucoma assessment tool for your practice

User Features	
General	Scanning Laser Polarimetry (SLP)
	Retinal Nerve Fiber Layer Analysis
	Integrated design
	Portable
	New Windows® XP, SP3
Acquisition	Non-mydriatic
	New Touch Screen operation
	New Point-and-click mouse drive operation
	New AutoFocus
	New Simple-touch Automatic Pupil Alignment
	New Live Fundus View
	New Iris Image Check
	New Low Vision Target
	New Triple Scan Mode
	Technician time for two eyes < 3 min
Software	**New** HIPAA-friendly software design
	New Automatic Image Alignment
	New DICOM Gateway *[Optional]*
	New Print Preview
Images	Fundus Image
	Nerve Fiber Layer Map
	Deviation Map
Analyses	RNFL Integrity analysis
	New RNFL Normative database - ECC
	RNFL Normative database - VCC
	New Guided Progression Analysis (GPA)
	New Nerve Fiber Indicator (NFI) - ECC
	Nerve Fiber Indicator (NFI) - VCC

Technical Specifications	
Illumination laser source	GaAIAs laser diode, 780 – 798 nm, 40 mW primary power
Laser classification	Class I laser system
Imaging area	40° x 20°
Scan speed	41 frames / sec
Ametropia correction	-13 to +8 diopters
Data acquisition time	<1 second
Fixation	Internal target
Display	Integrated color liquid crystal display
Electrical requirements	100 – 240 volts, 50/60 Hz Complies with US and Canadian medical electrical system safety requirements and 93/42/EEC Medical Device Directive.
Dimensions	63.5 L x 30.5 W x 40.6 H (cm)
Weight	50 lbs (31 kg)
Ambient temperature	50°F – 95°F (10°C – 35°C)
Ambient humidity	10% – 75%

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The only measure of RNFL Integrity™: GDxPRO™

ZEISS

Look beyond thickness.

Underlying structural organization

is the key to **RNFL Integrity**

The science underlying RNFL Integrity

Recent scientific studies suggest that RNFL micro-structures undergo changes in orientation and density before RNFL anatomical thickness changes become apparent[1,2].

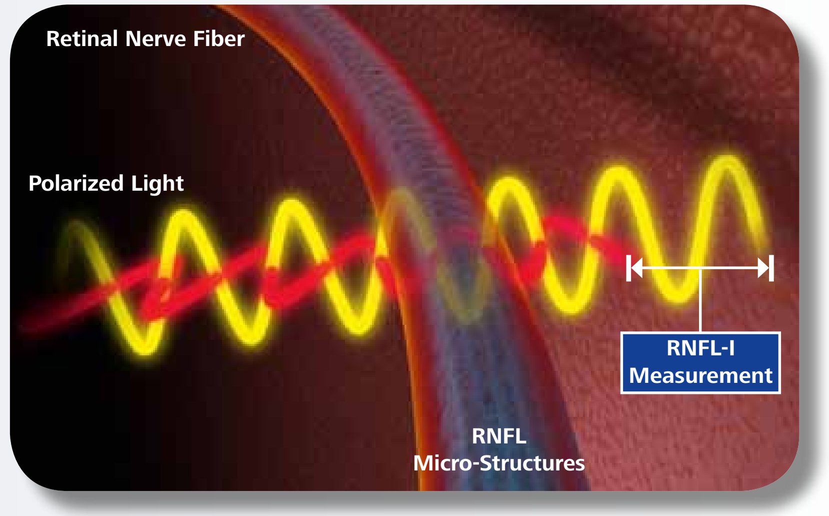
Scanning Laser Polarimetry (SLP) measures RNFL Integrity (RNFL-I™) – structural information that goes beyond thickness. GDx™, the world's only Scanning Laser Polarimeter, uniquely characterizes RNFL Integrity by directly measuring structural organization throughout the RNFL thickness[3,4,5,6].

Assess RNFL Health by measuring RNFL Integrity

RNFL Integrity is derived from both RNFL thickness and RNFL structural organization. As such, it is a discrete assessment of RNFL health that today only GDx Scanning Laser Polarimetry can quantify.

GDxPRO measures RNFL structural organization

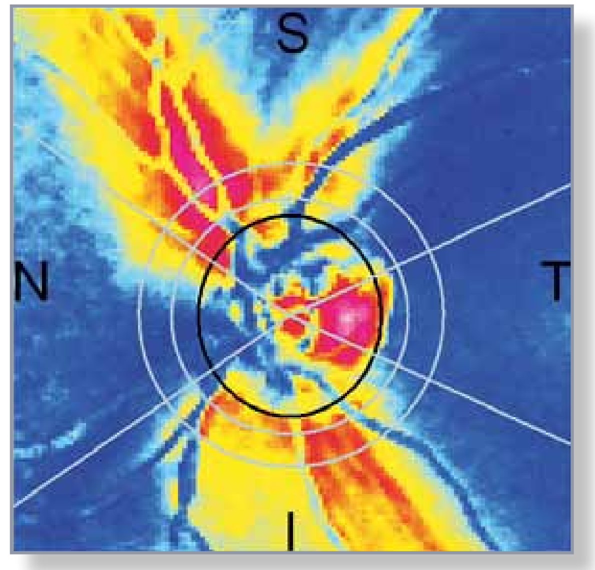
- SLP passes polarized light through the RNFL and creates a high resolution map from over 32,000 data points.
- A phase shift occurs because light polarized parallel to RNFL micro-structures travels more slowly than light polarized perpendicular to them.
- The size of this shift, termed RNFL Integrity, depends upon both the thickness of the RNFL and the cumulative level of organization of its micro-structures.



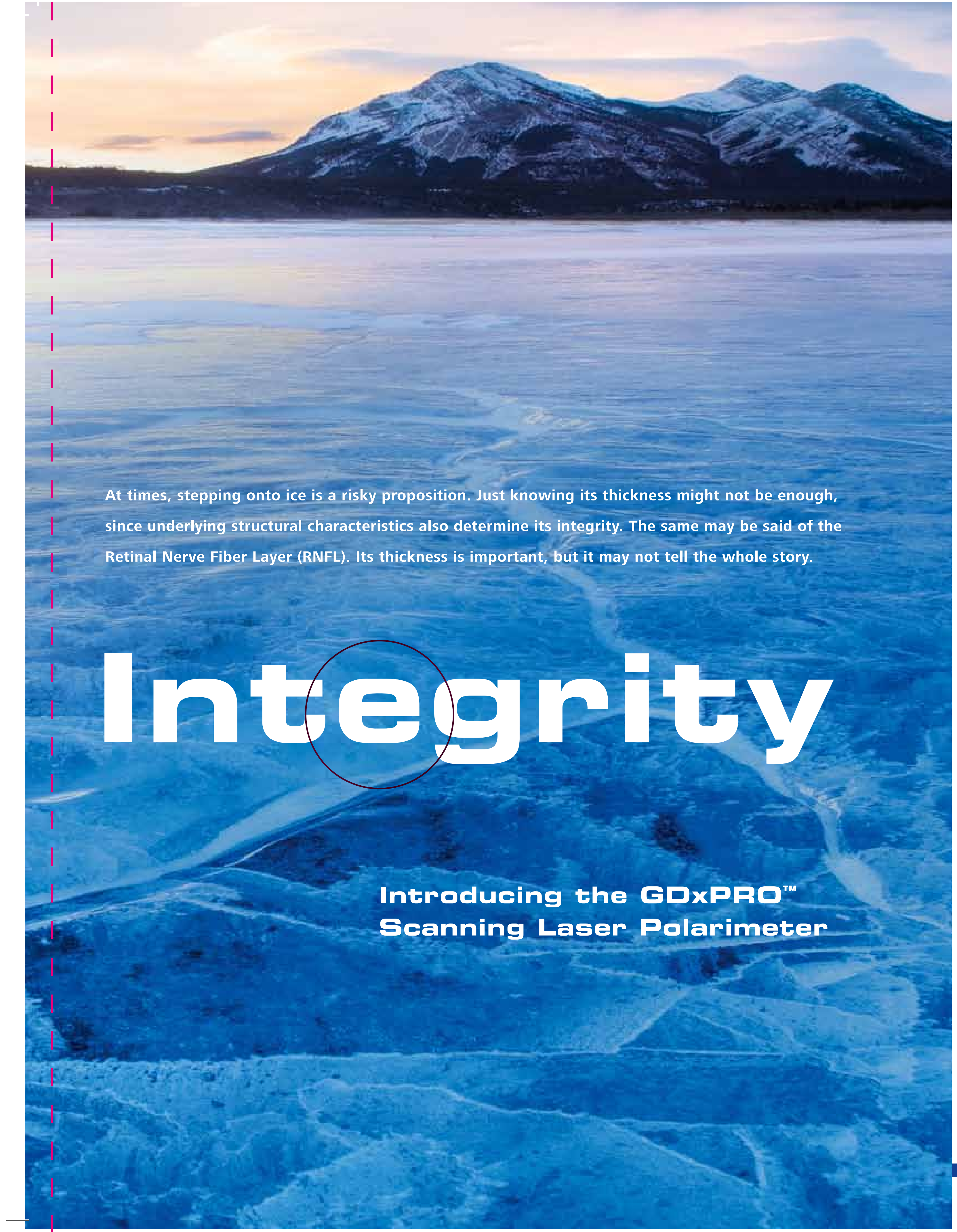
Polarized light passing through a single nerve fiber.

Clinically proven performance

Understanding the nature of RNFL-I measurement provides insight into why the GDx technology is proven to be a superior glaucoma management tool. A number of clinical studies have verified the correlation between GDx measurements and glaucomatous damage[7,8,9,10]. Hundreds of published studies support the conclusion that GDx technology provides invaluable information for early disease detection and ongoing clinical management. The GDxPRO provides a unique and comprehensive view of RNFL health simply not available in other imaging technologies.



Nerve Fiber Layer Map (RNFL-I)



Superior diagnostic performance

Demonstrated superiority for classifying suspects

In a recent comparative study of glaucoma suspects with normal visual fields and suspicious optic disc appearance, GDxVCC™ RNFL parameters performed significantly better than an alternative method for confirming the diagnosis.

The best GDxVCC parameter, the Nerve Fiber Indicator (NFI), had a Receiver Operating Characteristic (ROC) curve area of 0.83 and sensitivity of 83% for specificity at 70%, whereas the best parameter for the other technology had an ROC of 0.70 with sensitivity of only 63% for similar specificity.

"Receiver operating characteristic curve areas above 0.80 are generally considered to be good for a diagnostic test, whereas areas ranging from 0.70 to 0.80 are only fair, and areas below 0.70 are generally considered poor."

Medeiros et al. Ophthalmology, 2008; 115(8)[11]

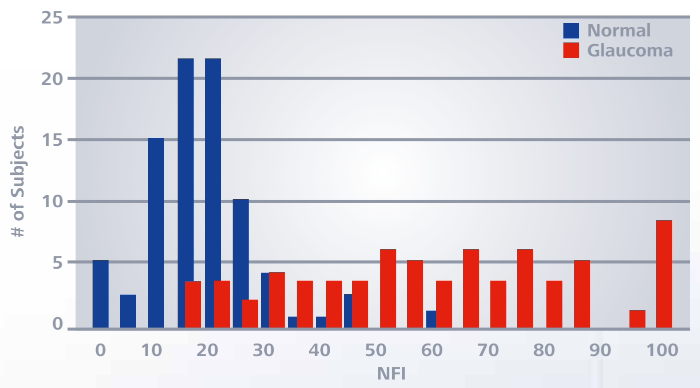
Imaging Technology	Best Parameter	ROC	Sensitivity	Specificity
GDxVCC	NFI	0.83	83%	70%
Other technology	Rim volume (mm³)	0.70	63%	70%

Comparative Study Results

NFI is a superior tool to assess glaucoma

The Nerve Fiber Indicator (NFI) is an artificial intelligence algorithm shown in numerous studies to be a superior discriminator between normal subjects and glaucomatous patients. The output is a single number between 1 and 100 representing the Integrity of the RNFL.

NFI distribution in normal and glaucoma subjects (N=152)



95% of the normal eyes had an NFI ≤ 35 for ECC. VCC NFI has similiar performance. (CZM study, data on file.)

Enhanced Corneal Compensation (ECC™) – building on excellent VCC performance

ECC raises SLP technology to a new level making it possible to acquire high quality scans on virtually every patient. ECC is a new enhanced imaging method which improves signal-to-noise ratio for GDxPRO measurements. The ECC normative database was collected from 10 international centers and included 251 normal subjects (of which 42% were Caucasian) and 215 glaucoma subjects (of which 47% were Caucasian)[13].

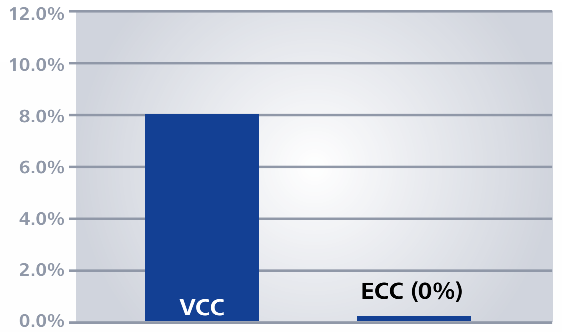
In this study ECC had a significantly lower atypical scan rate than VCC.

	ECC Versus VCC
Normal subjects	0% versus 2.8%
Glaucoma subjects	0% versus 8.0%

"The GDxVCC allows easy, rapid, and accurate discrimination between healthy and glaucomatous eyes (and) fulfills all nonfinancial criteria for a glaucoma screening device".

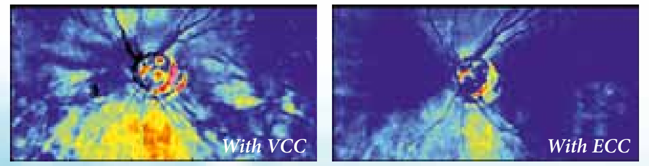
Reus et al. Ophthalmology, 2004, Vol. 111, No. 10[12]

No atypical scans among 215 glaucoma subjects



Carl Zeiss ECC normative data study

Furthermore, studies have shown that ECC performance has demonstrated outstanding measurement sensitivity, and specificity.[14,15,16] For example, in the study of 157 eyes from *Medeiros et al. IOVS 2007*, the area under the empirical ECC ROC curve was 0.93 for the TSNIT average. This performance could improve progression detection.

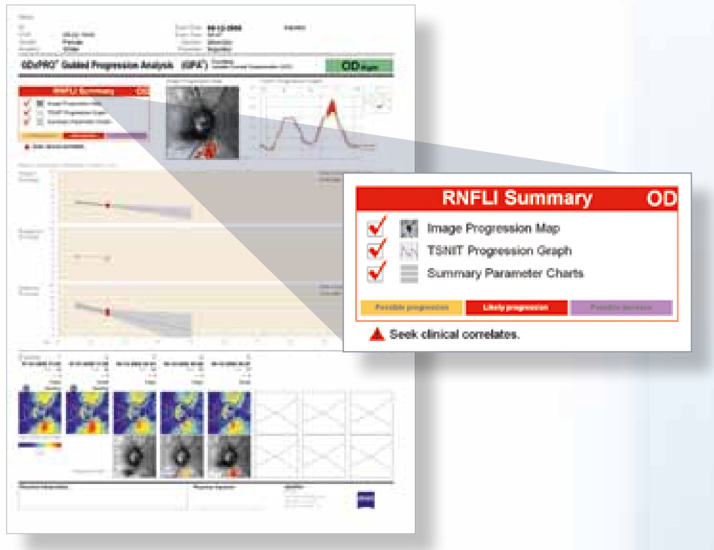


ECC dramatically improves the diagnostic value of scans from this technically difficult patient. (OS, Male, 65 years old)

GPA™: the new standard in progression analysis

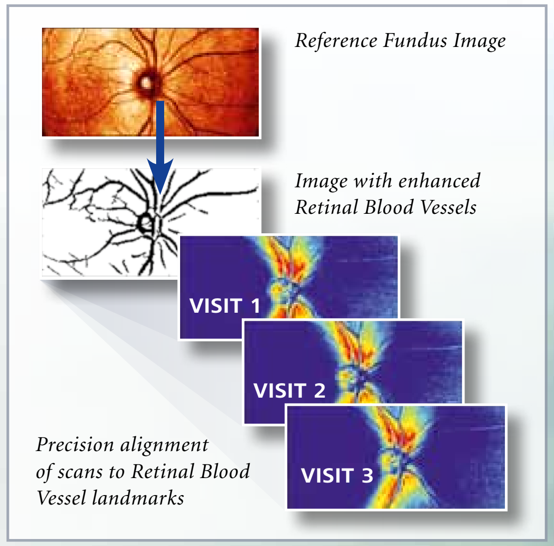
Identify fast progressors at a glance
Guided Progression Analysis (GPA) helps to follow glaucoma patients and identity fast progressors in need of more aggressive treatment.

Building on the legacy of GPA for the Humphrey® Field Analyzer (HFA), GPA in GDxPRO is a proprietary statistical tool with high design specificity of 95%. It compares the RNFL-I variability of a widespread population with each patient's exam-to-exam variability. GPA identifies statistically significant, reproducible change in focal, regional, and difficult to identify diffuse global defects. GPA results are presented in a single-page report that can be read intuitively at a glance or exported electronically.



Designed for exceptional precision
Automatic Image Alignment ensures exceptional registration between the reference image and subsequent measurements, even across multiple visits. To achieve this, retinal blood vessels are used as landmarks to align all images with one reference image. This precise alignment enables the high reproducibility and GPA performance of GDxPRO.

- **AutoFocus** ensures the scan is performed at the optimal imaging position.
- **Proven high repeatability,** independent of operator expertise.

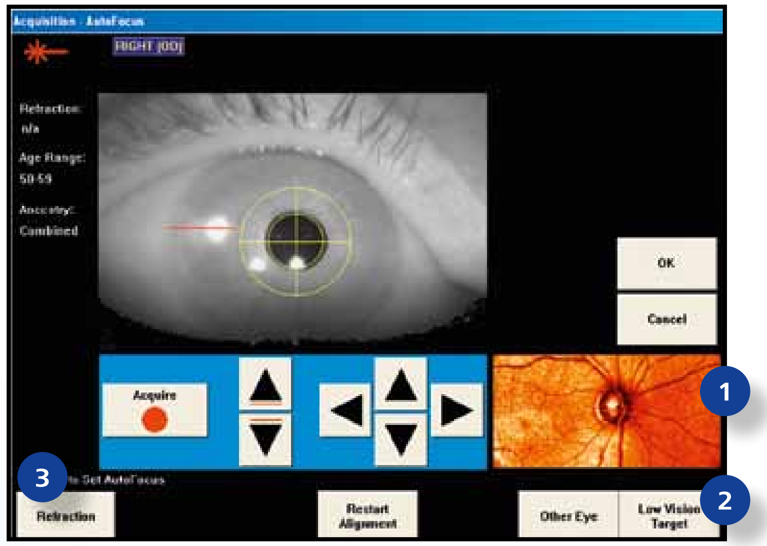


Automatic Image Alignment ensures exceptional registration.

Designed with the operator in mind

The GDxPRO is delightfully simple to operate.

- Scan without delay with non-mydriatic operation.
- Acquire high quality scans with ease[17]. Simple-touch Automatic Pupil Alignment requires virtually no operator experience.
- Ensure proper patient fixation with Live Fundus View.
- Scan more patients easily with Low Vision Target.



Scan Acquisition Screen

1 Live Fundus View

2 Low Vision Target

3 AutoFocus / Refraction

Designed with the clinician in mind

GDxPRO integrates clinical performance with workflow efficiencies.

- Interpret results at a glance with intuitive report designs.
- Print to virtually any Windows® XP supported printer.
- Go paperless by automatically saving and exporting reports in standard file formats (PDF, TIFF, JPEG).
- Access Carl Zeiss networking solutions with optional DICOM Gateway connectivity.
- Consolidate GDxVCC and GDxPRO patient data on the same GPA report.
- Enjoy portability convenience with GDxPRO's small, lightweight design with exclusive lockdown feature for optics protection.

Interpret results at a glance with intuitive report designs

1 **Quality Indicators**
Ideally, Q ≥ 7
Residual ≤ 4 (ECC)
Residual < 12 (VCC)
TSS > 40 (ECC)
TSS > 60 (VCC)

2 **Fundus Image**
Reflectance image showing the optic nerve head (ONH) and ellipse placement.

3 **RNFLI Summary Parameters Table**
Color-coded parameters indicating comparison to normative limits. All except the NFI are calculated directly from the Calculation Circle.

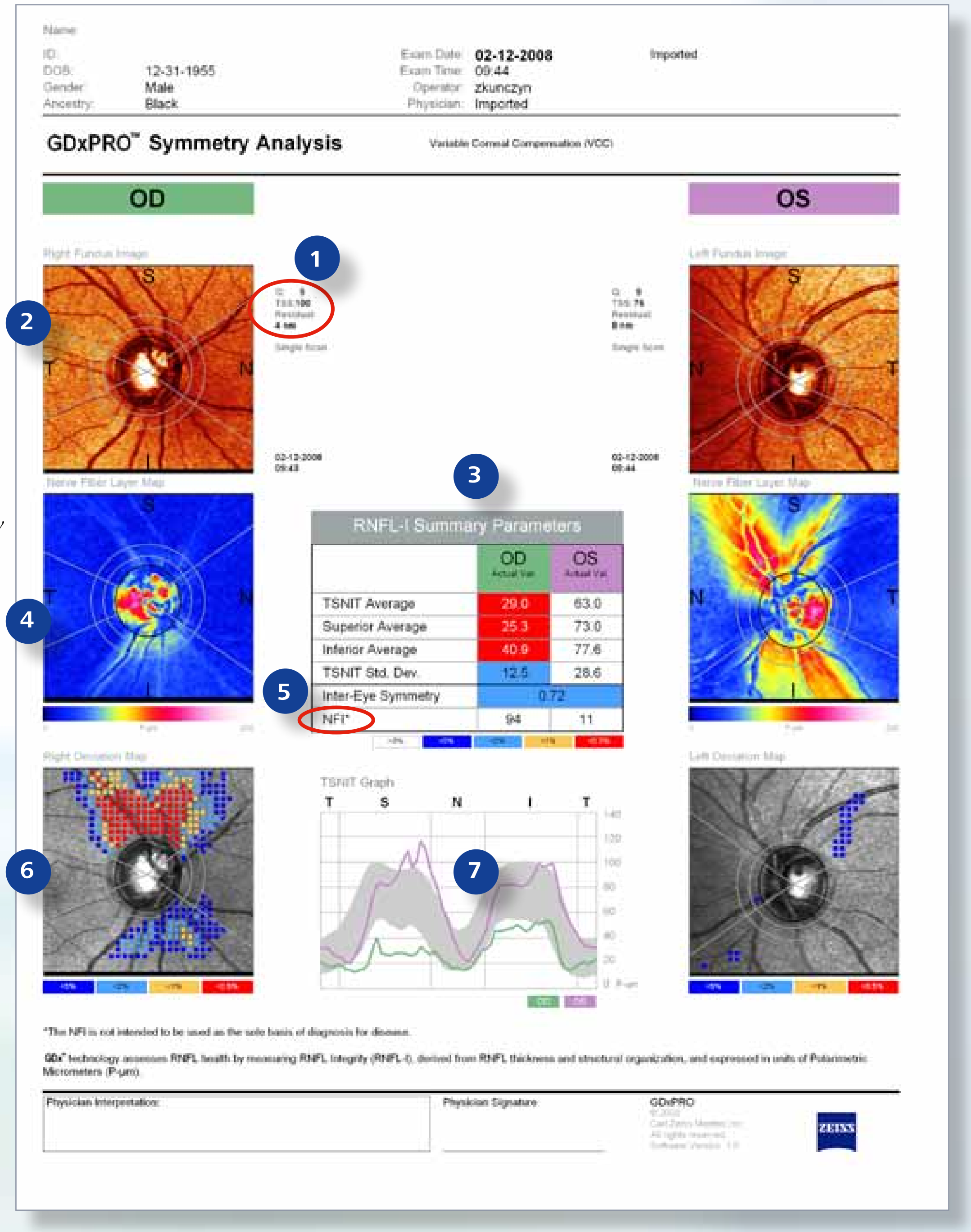
4 **Nerve Fiber Layer Map**
An hourglass shape of yellow and red colors around the ONH is typical of normal eyes.

5 **NFI**
95% of normal population study showed:
NFI ≤ 35 (ECC)
NFI ≤ 30 (VCC)

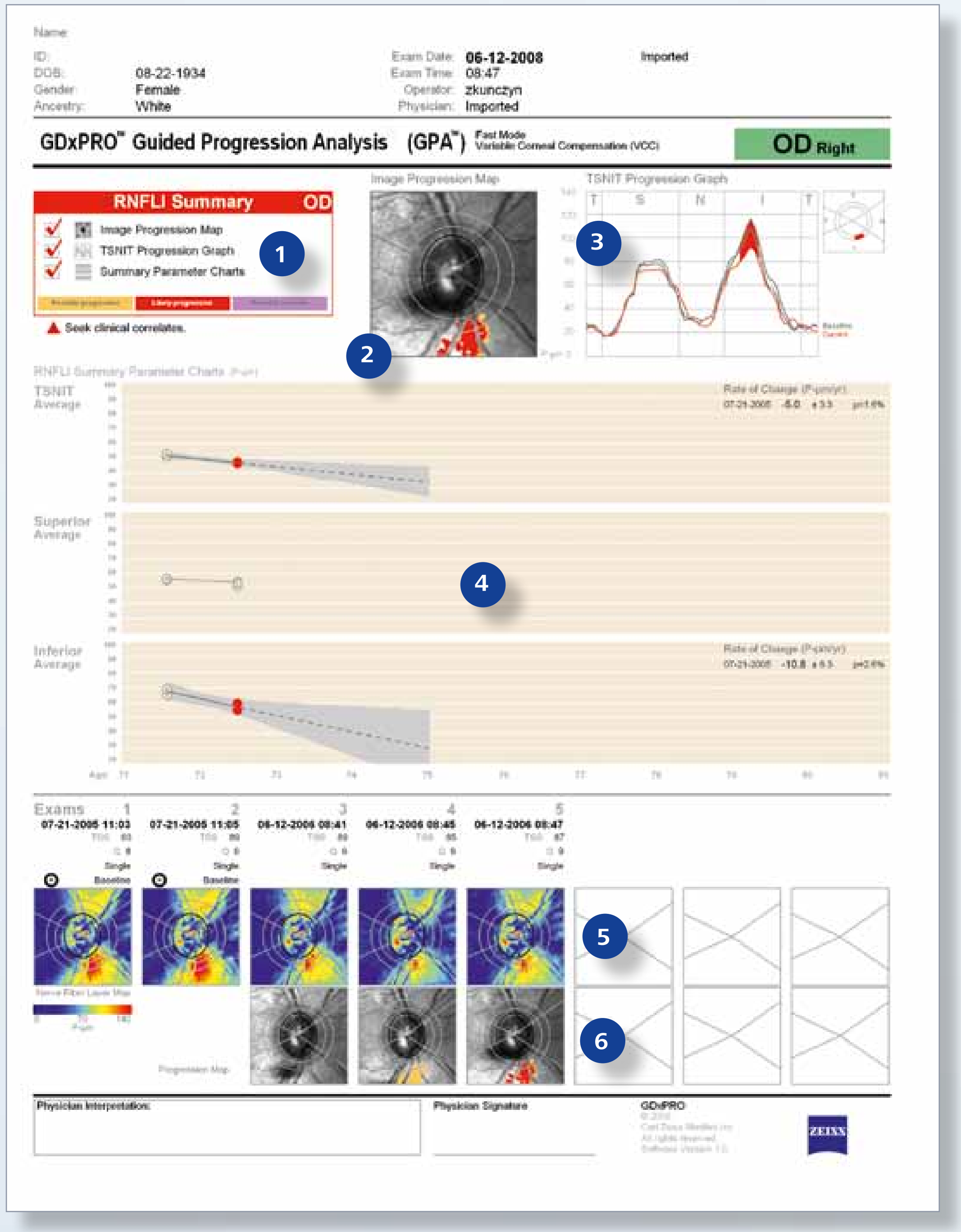
6 **Deviation Map**
Color-coded comparison to normative limits.

7 **TSNIT Graph**
Displays normal range (shaded area) and RNFL-I measurements along the Calculation Circle.

Symmetry Analysis Report



GPA Report



1 **Color-Coded RNFLI Summary Box**
Indicates evidence of statistically significant change.

= *No Progression*
= *Possible Progression*
= *Likely Progression*
= *Possible Increase**

2 **Image Progression Map**
Most sensitive to focal change.

3 **TSNIT Progression Graph**
Most sensitive to regional change.

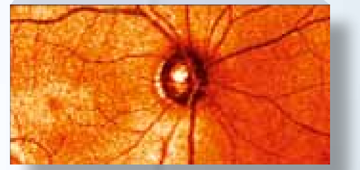
4 **RNFLI Summary Parameter Charts**
Most sensitive to diffuse change. Rate of change is displayed only if statistically significant.

5 **RNFL Maps**
Sequence of up to 8 Nerve Fiber Layer Maps.

6 **Progression Maps**
A series of up to 6 Progression Maps comparing each exam with the baseline images. Areas of statistically significant change are color coded yellow when first noted and then red when the change is sustained over consecutive visits.

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

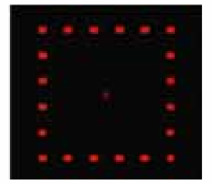
Designed with the patient in mind



Live Fundus View

The GDxPRO is designed for optimum patient comfort.

- Minimize patient fatigue with quick scan times.
- Improve patient comfort with non-mydriatic operation and ergonomic design.
- Reduce patient exam time with Live Fundus View.
- Accommodate patients with compromised central vision using Low Vision Target.



Low Vision Target

[1] *Huang XR, and Knighton RW. Microtubules contribute to the birefringence of the retinal nerve fiber layer. Invest Ophthalmol Vis Sci. 2005; 46: 4588-4593.*

[2] *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.*

[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] *Huang X-R and Knighton RW. Linear birefringence of the retinal nerve fiber layer measured in vitro with a multispectral imaging micropolarimeter. J Biomed Opt. 2002; 7: 199 –204.*

[6] *Cense B, Chen TC, Hyle Park B, Pierce MC, and de Boer JF. In vivo birefringence and thickness measurements of the human retinal nerve fiber layer using polarization-sensitive optical coherence tomography. J Biomed Opt. 2004; 9: 121–125.*

[7] *Weinreb RN, Bowd C and Zangwill LM. Glaucoma detection using scanning laser polarimetry with variable corneal polarization compensation. Arch Ophthalmol. 2003; 121: 218–224.*

[8] *Bagga H, Greenfield DS, Feuer W, and Knighton RW. Scanning laser polarimetry with variable corneal compensation and optical coherence tomography in normal and glaucomatous eyes. Am J Ophthalmol. 2003; 135: 521–529.*

[9] *Mohammadi K, Bowd C, Weinreb RN, Medeiros FA, Sample PA, and Zangwill LM. Retinal nerve fiber layer thickness measurements with scanning laser polarimetry predict glaucomatous visual field loss. Am J Ophthalmol. 2004; 138: 592–601.*

[10] *Cense B, Chen TC, Park BH, Pierce MC, and de Boer JF. Thickness and birefringence of healthy retinal nerve fiber layer tissue measured with polarization sensitive optical coherence tomography. Invest Ophthalmol Vis Sci. 2004; 45: 2606–2612.*

[11] *Medeiros FA, Vizzeri G, Zangwill LM, Alencar LM, Sample PA, and 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: 1340-6.*

[12] *Reus NJ and Lemij HG. Diagnostic accuracy of the GDx VCC for glaucoma. Ophthalmology, 2004; 111: 1860-5.*

[13] *Gurses-Ozden R. CZMI Internal Clinical Report: Collection of Normative and Glaucoma Data Using GDxVCC™ Scanning Laser Polarimetry.*

[14] *Medeiros FA, Bowd C, Zangwill LM, Patel C, and Weinreb RN. Detection of Glaucoma Using Scanning Laser Polarimetry with Enhanced Corneal Compensation. Invest Ophthalmol Vis Sci. 2007; 48: 3146-3153.*

[15] *Mai ThF, Reus NJ, and Lemij HG. Structure-Function Relationship Is Stronger with Enhanced Corneal Compensation than with Variable Corneal Compensation in Scanning Laser Polarimetry. Invest Ophthalmol Vis Sci. 2007; 48: 1651-1658.*

[16] *Reus NJ, Zhou Q, and Lemij HG. Enhanced Imaging Algorithm for Scanning Laser Polarimetry with Variable Corneal Compensation. Invest Ophthalmol Vis Sci. 2006; 47: 3870 -3877.*

[17] *Frenkel S, Slonim E, Horani A, Molcho M, Barzel I, and Blumenthal EZ. Operator learning effect and interoperator reproducibility of the scanning laser polarimeter with variable corneal compensation. Ophthalmology, 2005; 112: 257-61.*

- *Example Symmetry Analysis Report was provided courtesy of Joseph Sowka, OD, FAAO.*
- *Example Guided Progression Analysis (GPA™) Report was provided courtesy of Robert N. Weinreb, MD.*