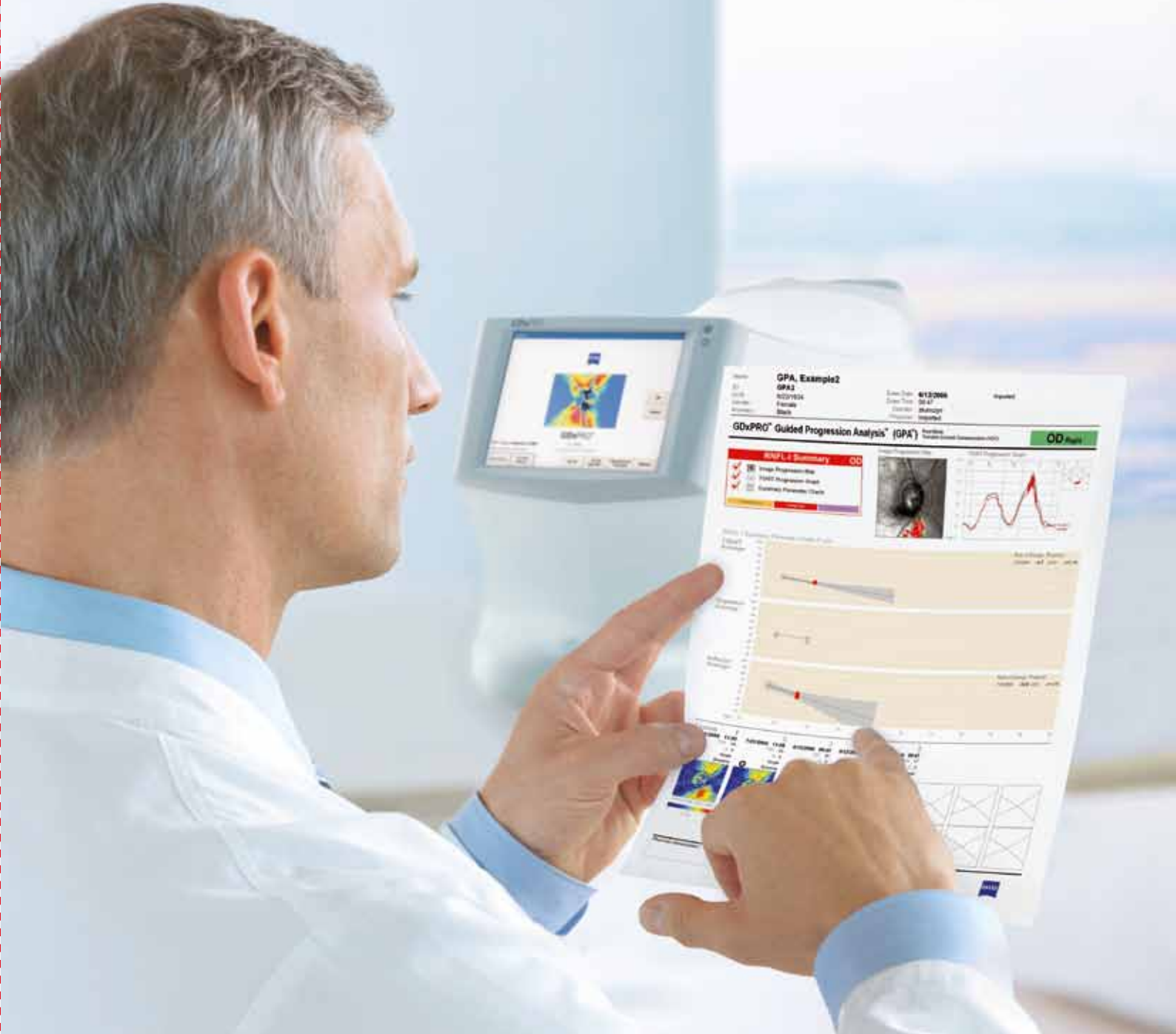
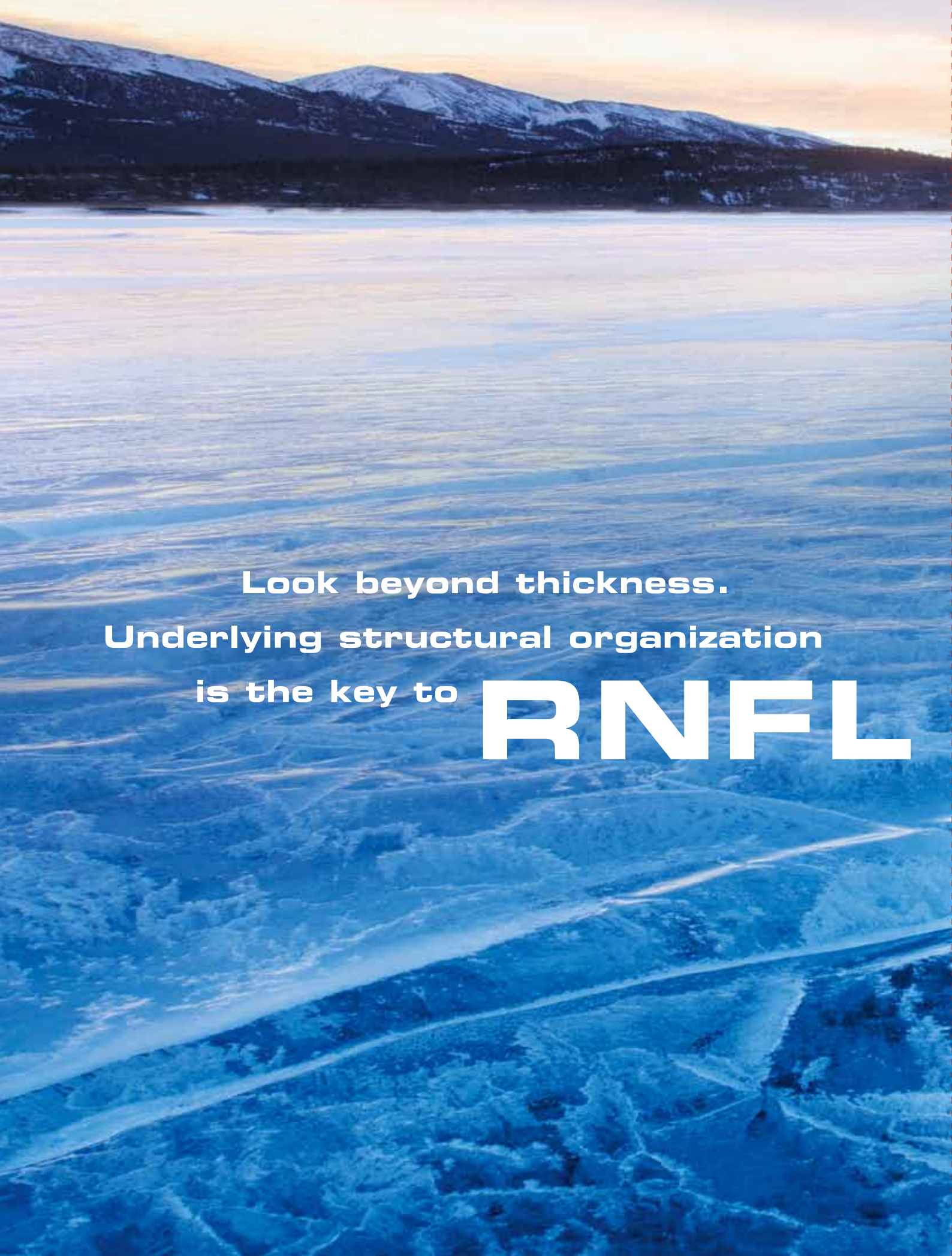
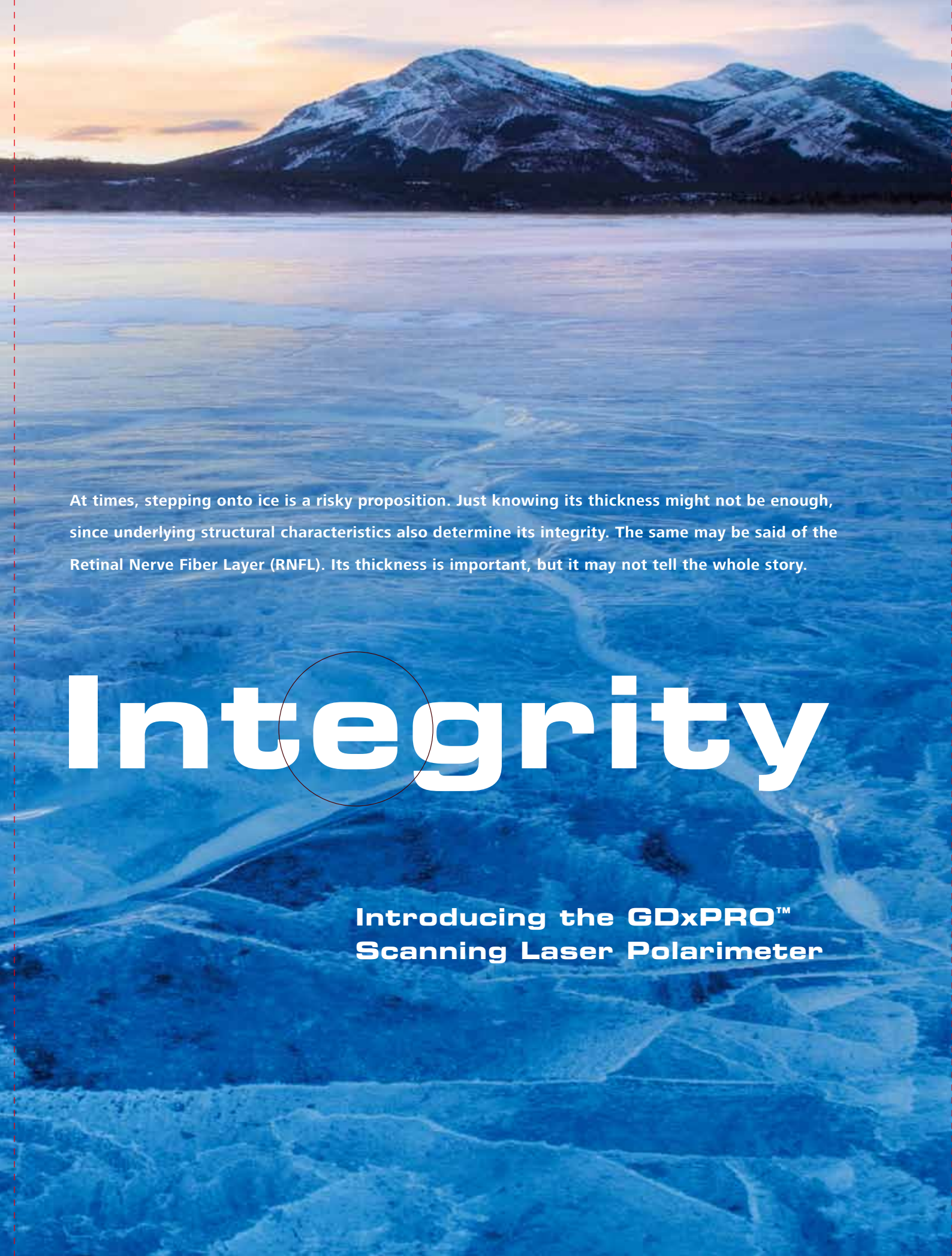


The only measure of RNFL Integrity: GDxPRO





**Look beyond thickness.
Underlying structural organization
is the key to **RNFL****



At times, stepping onto ice is a risky proposition. Just knowing its thickness might not be enough, since underlying structural characteristics also determine its integrity. The same may be said of the Retinal Nerve Fiber Layer (RNFL). Its thickness is important, but it may not tell the whole story.

Integrity

**Introducing the GDxPRO™
Scanning Laser Polarimeter**



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}.

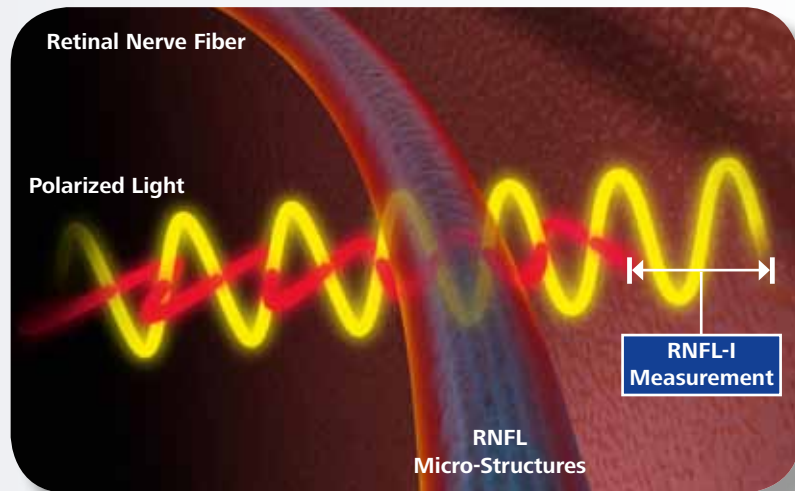
Scanning Laser Polarimetry (SLP) measures RNFL Integrity™ (RNFL-I) – structural information that goes beyond thickness. GDx™, the world's only Scanning Laser Polarimeter, uniquely characterizes RNFL Integrity by measuring structural organization throughout the RNFL thickness^{3,4,5,6}.

Assess RNFL Health by measuring RNFL Integrity

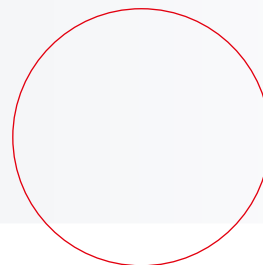
RNFL Integrity is derived from both RNFL thickness and RNFL structural organization. As such, it is a discrete assessment of RNFL health that today only GDx Scanning Laser Polarimetry can quantify.

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 the RNFL Integrity measurement, depends upon both the thickness of the RNFL and the cumulative level of organization of its micro-structures.

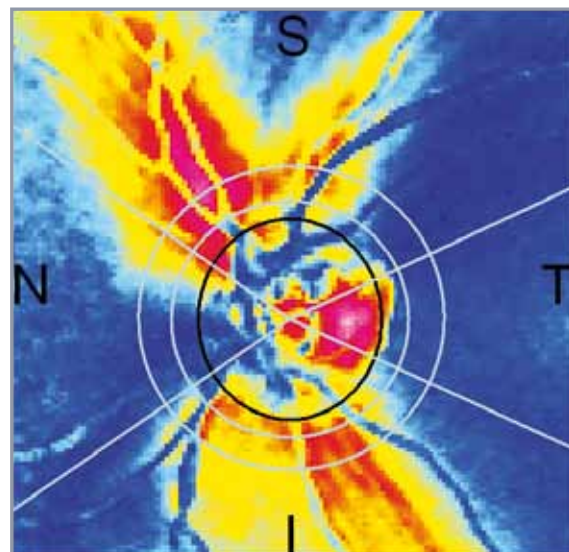


Polarized light passing through a single nerve fiber.



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 assessing early glaucoma

In a recent comparative study of patients 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

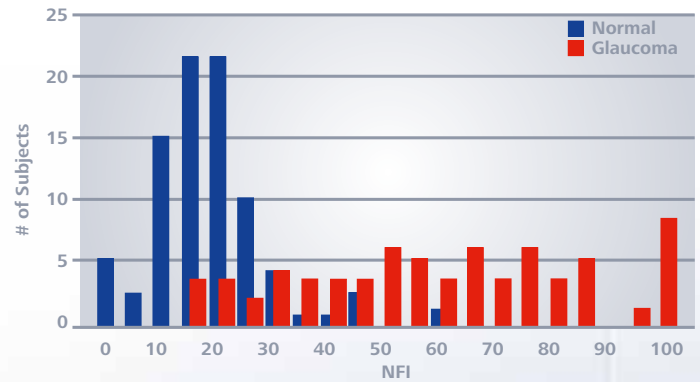
Imaging Technology	Best Parameter	ROC	Sensitivity	Specificity
GDxVCC	NFI	0.83	83%	70%
Other technology	Rim volume (mm ³)	0.70	63%	70%

Comparative Study Results

NFI is a superior tool to assess diseased RNFL

The Nerve Fiber Indicator (NFI) is an artificial intelligence algorithm shown in numerous studies to be a superior discriminator between healthy and glaucomatous eyes. The output is a single number between 1 and 100 representing the likelihood that the polarimetric RNFL map is abnormal.*

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



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



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

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.

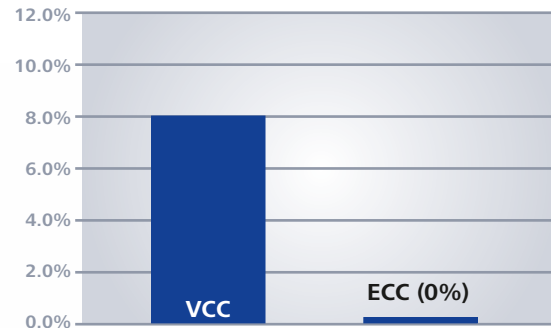
In this study ECC had a significantly lower atypical scan rate than VCC.

	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. 10¹²

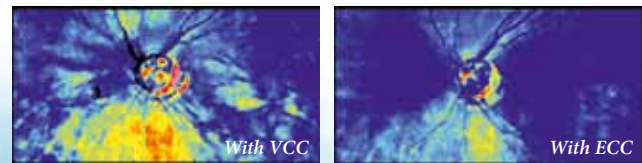
No atypical scans among 215 glaucoma subjects



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 196 eyes from *Medeiros et al. IOVS 2007*, the area under the empirical ECC ROC curve was 0.93 for the TSNIT average (vs. 0.751 for VCC). This performance could improve progression detection.



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

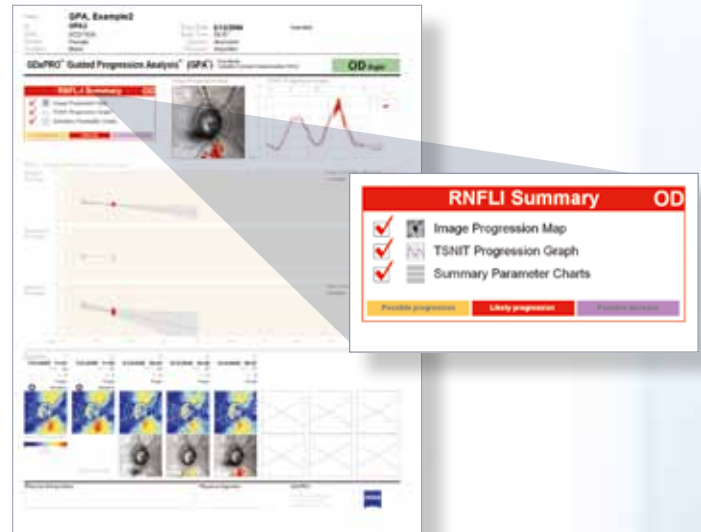


GPA: the new standard in progression analysis

Identify significant RNFL loss at a glance

Guided Progression Analysis™ (GPA™) helps to follow glaucoma patients and identify those who may need closer management.

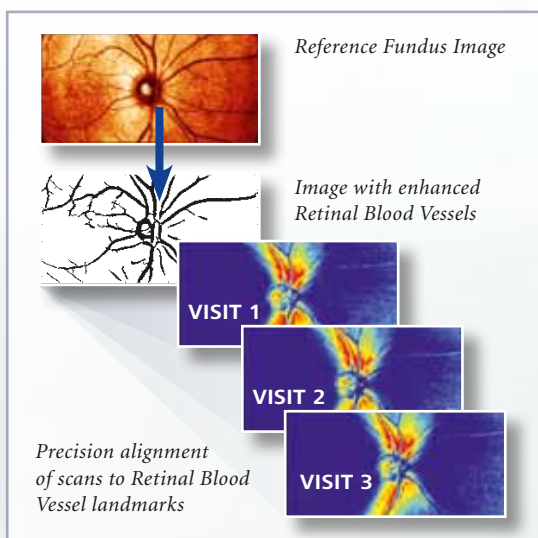
Building on the legacy of GPA for the Humphrey® Field Analyzer (HFA™), GPA in GDxPRO is a proprietary statistical tool with demonstrated high specificity of 95%¹⁷. It compares the RNFL-I variability of a study population with each patient's exam-to-exam variability. GPA identifies statistically significant, 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.



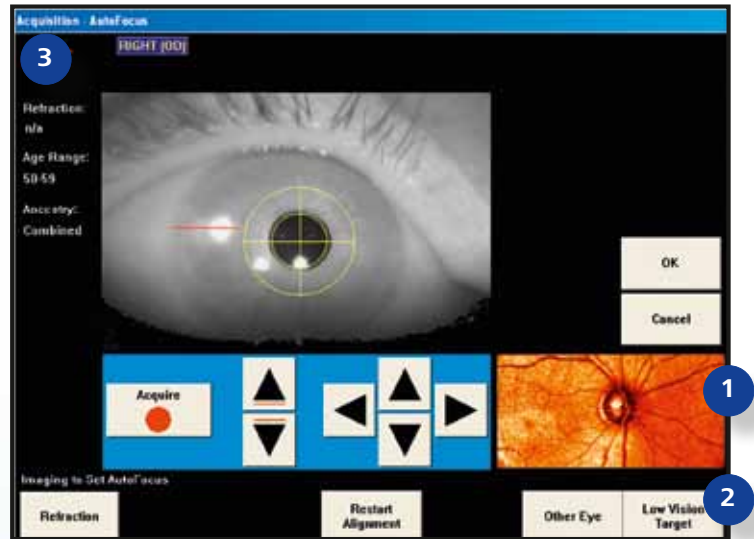
Automatic Image Alignment ensures exceptional registration.



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 ease¹⁸. 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

Designed with the clinician in mind

GDxPRO integrates clinical performance with workflow efficiencies.

- Interpret results at a glance with intuitive report designs.
- Print to qualified Windows® XP supported printers.
- Go paperless by automatically saving and exporting reports in standard file formats (PDF, TIFF, JPEG).
- Access Carl Zeiss DICOM networking solutions with optional FORUM® Eye Care Data Management.
- 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

Symmetry Analysis Report

1 Quality Indicators

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

2 Fundus Image

Reflectance image showing the optic nerve head (ONH).

3 RNFL-I Summary Parameters Table

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

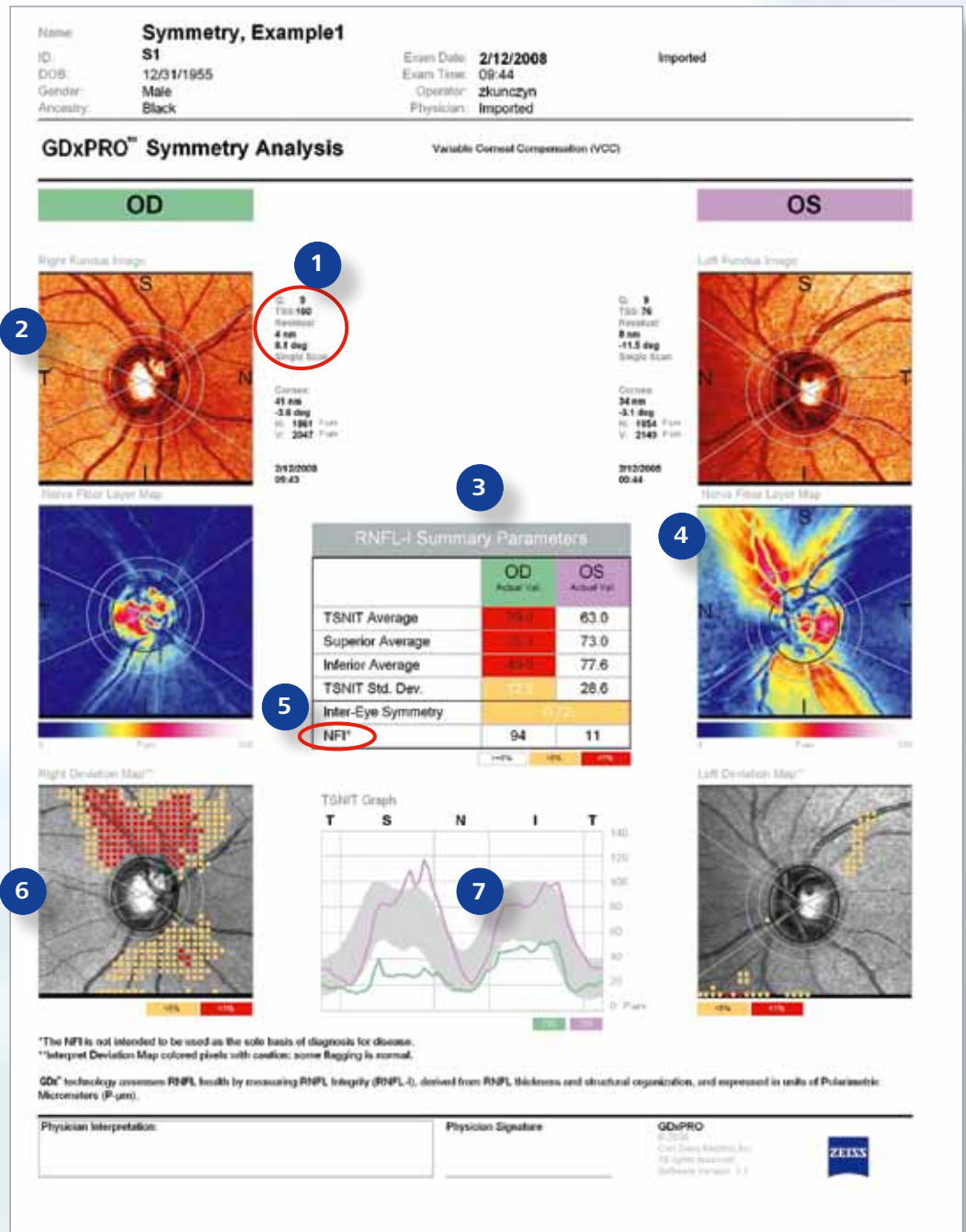
Nerve Fiber Indicator is related to the likelihood that the nerve fiber layer is abnormal.

6 Deviation Map

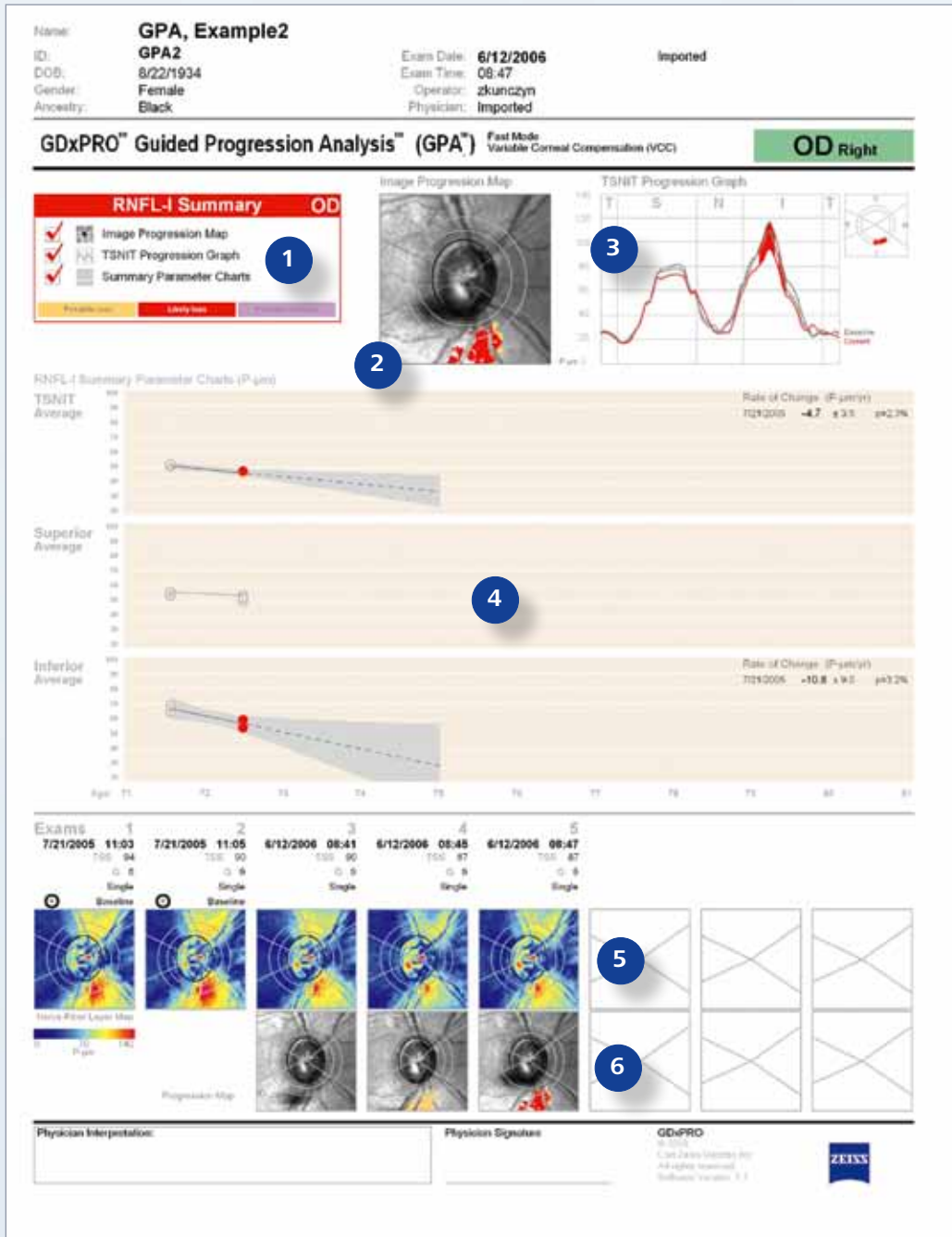
Color-coded indicating comparison to normative limits.

7 TSNIT Graph

Displays normal range (shaded area) and patient's RNFL-I values along the Calculation Circle.



GPA Report



1 Color-Coded RNFL-I Summary Box
Indicates evidence of statistically significant change.

- = No Loss
- = Possible Loss
- = Likely Loss
- = Possible Increase*

2 Image Progression Map
Most sensitive to narrow focal change.

3 TSNIT Progression Graph
Most sensitive to broader focal change.

4 RNFL-I Summary Parameter Charts
Most sensitive to diffuse change. If a significant rate of change has been detected it is displayed.

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



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.



Live Fundus View



Low Vision Target







◀ **Proven Clinical Performance**

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

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 Alencar LM, Zangwill LM, Weinreb RN, Bowd C, Vizzeri G, Sample PA, Susanna R Jr, Medeiros FA. Agreement for detecting glaucoma progression with the GDx guided progression analysis, automated perimetry, and optic disc photography. *Ophthalmology.* 2010 Mar;117(3):462-70. Epub 2009 Dec 24.

¹⁸ 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 Felipe A. Medeiros, MD, PhD and Robert N. Weinreb, MD.

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-mydratic
	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 with auto-generated mean
	Technician time for two eyes < 3 min
Software	New Patient privacy-friendly software design
	New Automatic Image Alignment
	New DICOM Gateway <i>[Optional]</i>
	New Connectivity to FORUM Eye Care Data Management <i>[Optional]</i>
	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	GaAlAs 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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