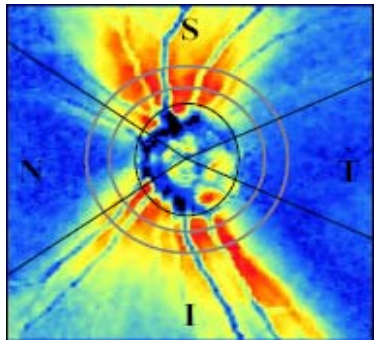
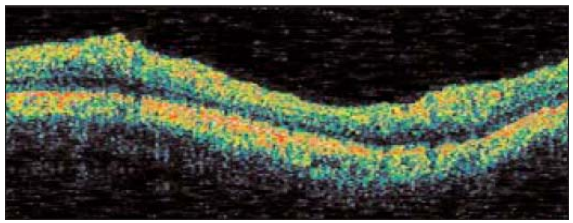
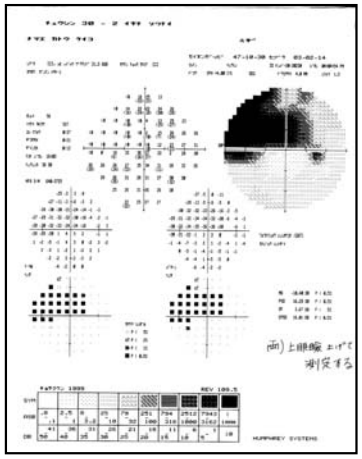
STRUCTURE & FUNCTION

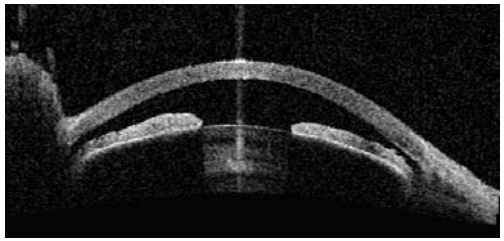
An Integrated Approach for the Detection and Follow-up of Glaucoma

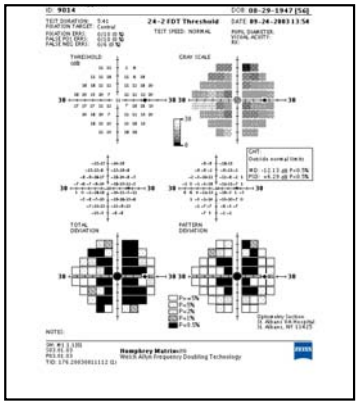
Module 3a – GDx











Educational Slide Deck
Carl Zeiss Meditec, Inc.
November 2005

Structure & Function Modules

- Module 1 - Glaucoma Background
- Module 2 - Structural Assessment
- **Module 3 - GDx**
  - **Module 3a – GDx Description**
  - **Module 3b – GDx Clinical Examples**
- Module 4 - Stratus OCT
- Module 5 - Perimetry

GDx Scanning Laser Polarimeter from Carl Zeiss Meditec

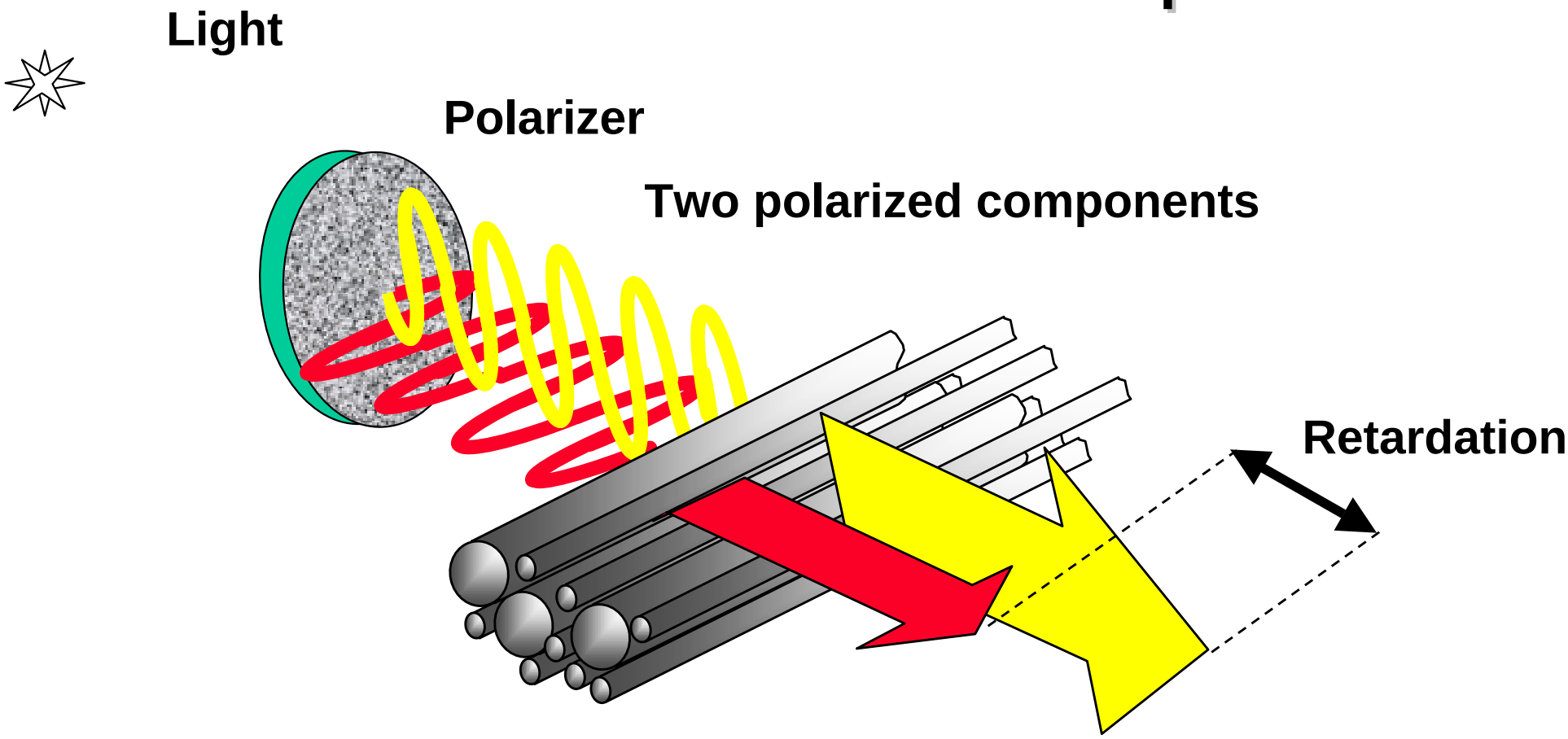
Precise RNFL analysis made simple, compact, and fast.

How Does the GDx Work?

- Polarized light is changed as it passes through the Retinal Nerve Fiber Layer
- The amount of change in polarized light is proportional to the Retinal Nerve Fiber Layer thickness[1]
- Variable Corneal Compensation eliminates the effect of Corneal Polarization

[1] Weinreb et al. *Arch Ophthalmology* 108: 557-560, 1990

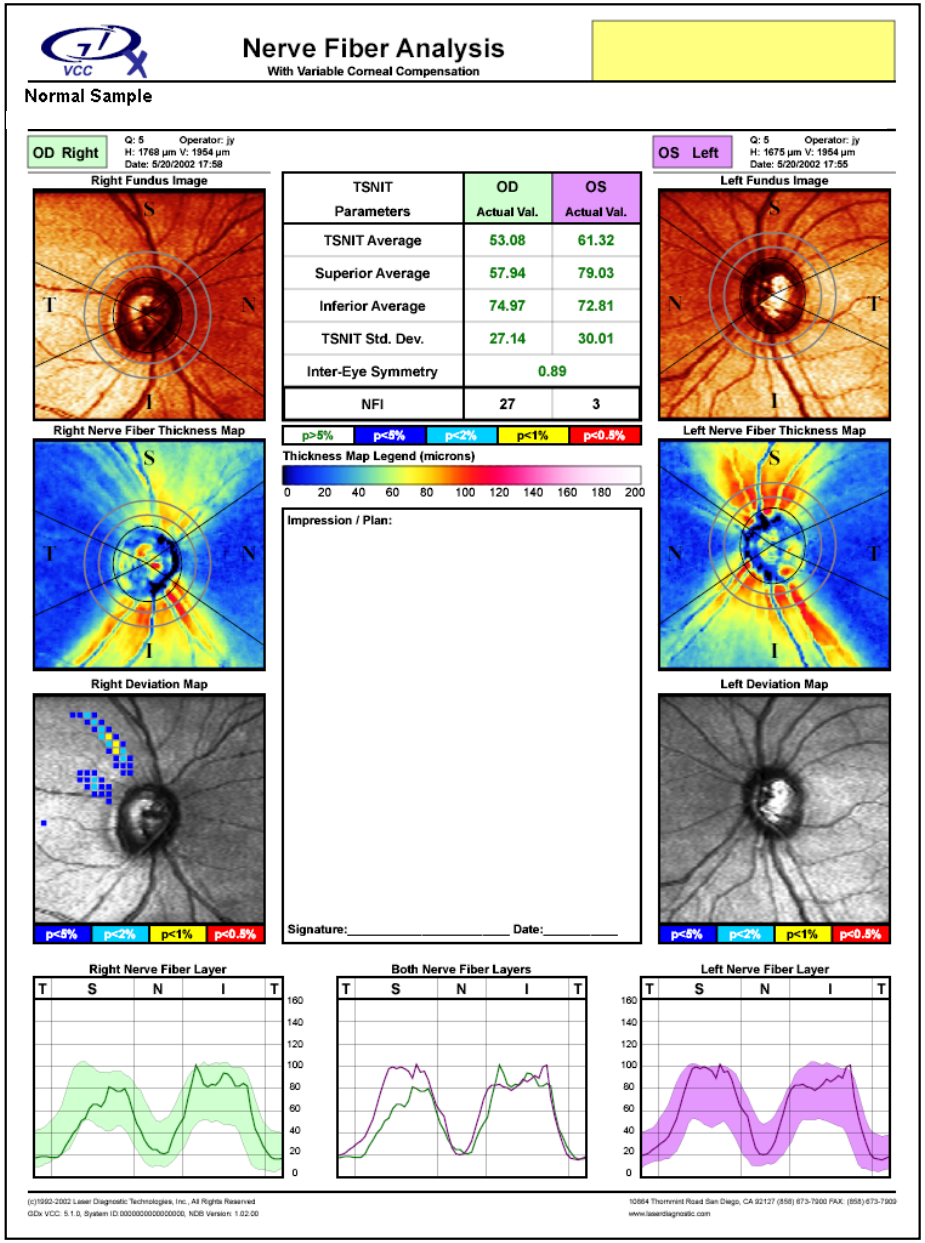
SLP Basic Principles



The amount of retardation from the RNFL is directly proportional to the RNFL thickness[1].

[1] Weinreb et al. *Arch Ophthalmology* 1990; 108: 557-560.

Interpretation of Results



Nerve Fiber Analysis
With Variable Corneal Compensation

Normal Sample

OD Right — Q: 5 Operator: jy H: 1768 µm V: 1954 µm Date: 5/20/2002 17:58

OS Left — Q: 5 Operator: jy H: 1675 µm V: 1954 µm Date: 5/20/2002 17:55

Right Fundus Image

Left Fundus Image

TSNIT Parameters	OD Actual Val.	OS Actual Val.
TSNIT Average	53.08	61.32
Superior Average	57.94	79.03
Inferior Average	74.97	72.81
TSNIT Std. Dev.	27.14	30.01
Inter-Eye Symmetry	0.89	
NFI	27	3

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

Thickness Map Legend (microns)

0 20 40 60 80 100 120 140 160 180 200

Impression / Plan:

Signature:_____ Date:_____

Right Nerve Fiber Thickness Map

Left Nerve Fiber Thickness Map

Right Deviation Map

Left Deviation Map

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

Right Nerve Fiber Layer

Both Nerve Fiber Layers

Left Nerve Fiber Layer

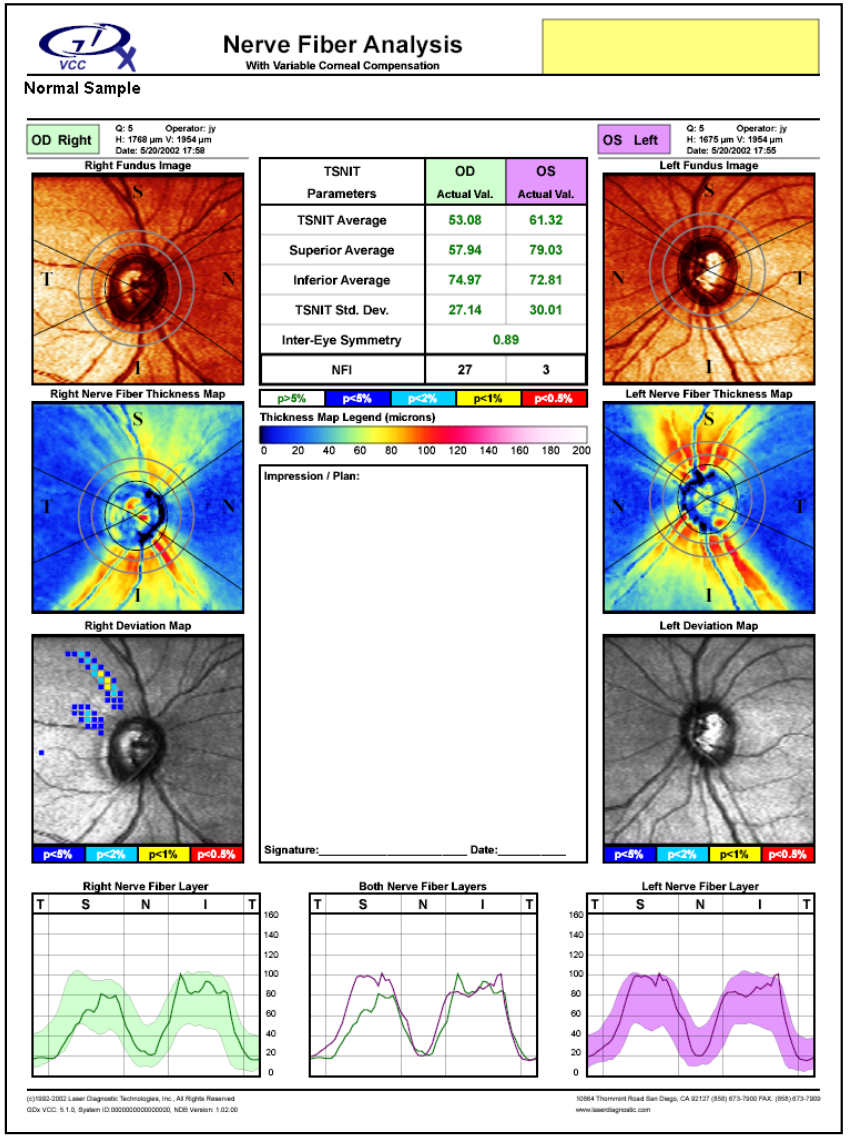
T S N I T

160 140 120 100 80 60 40 20 0

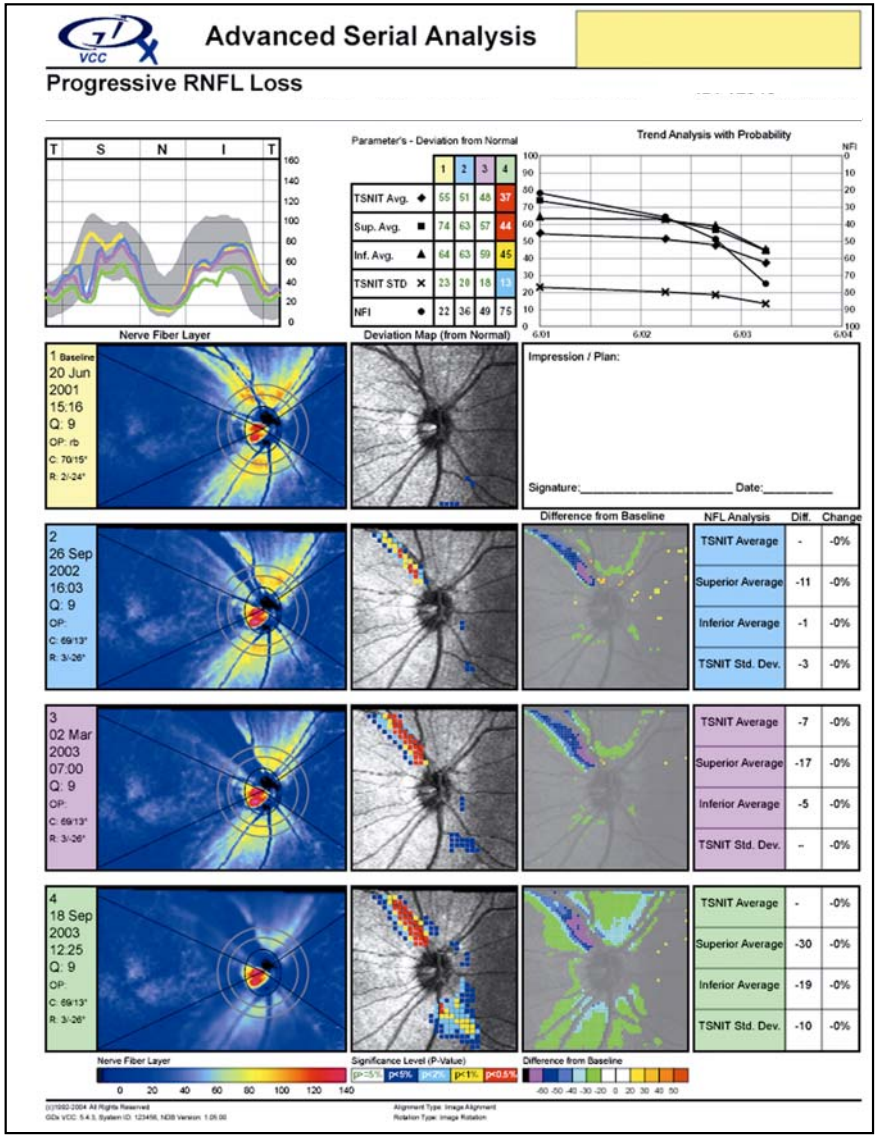
10664 Thornmint Road San Diego, CA 92127 (858) 673-7900 FAX: (858) 673-7909
www.laserdiagnostictc.com

Two Printouts

Symmetry Analysis

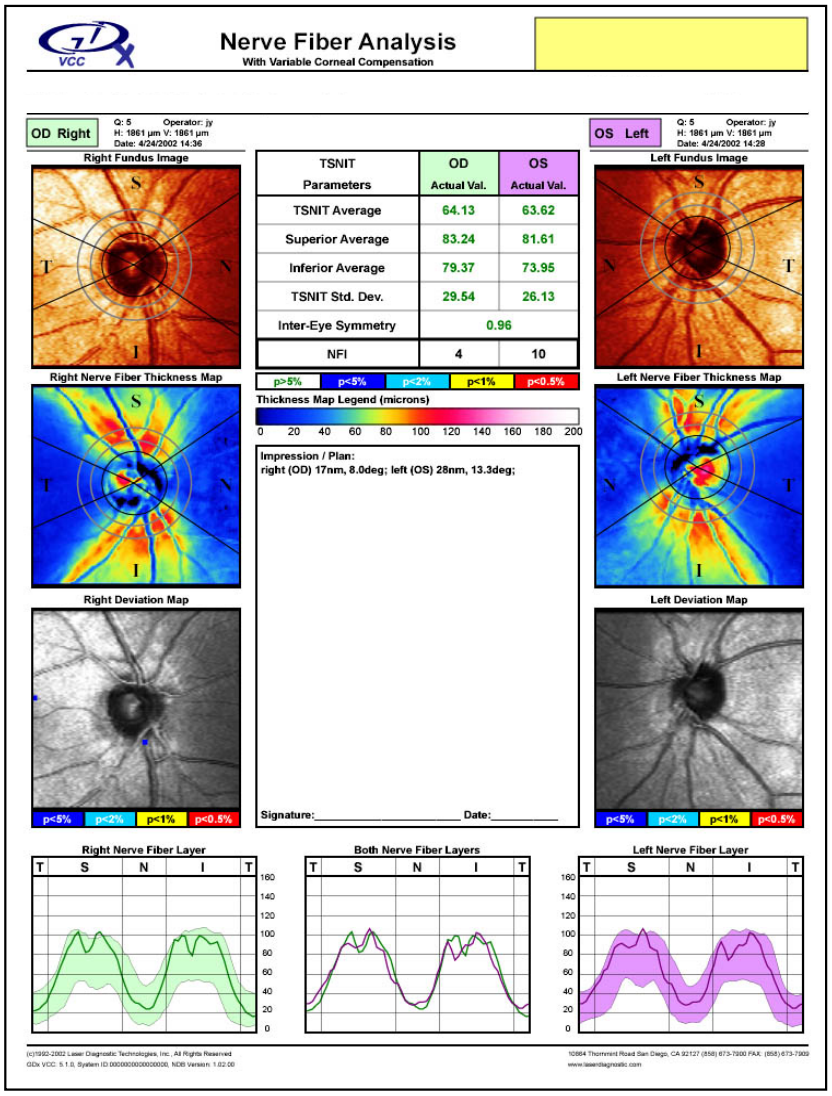


Advanced Serial Analysis

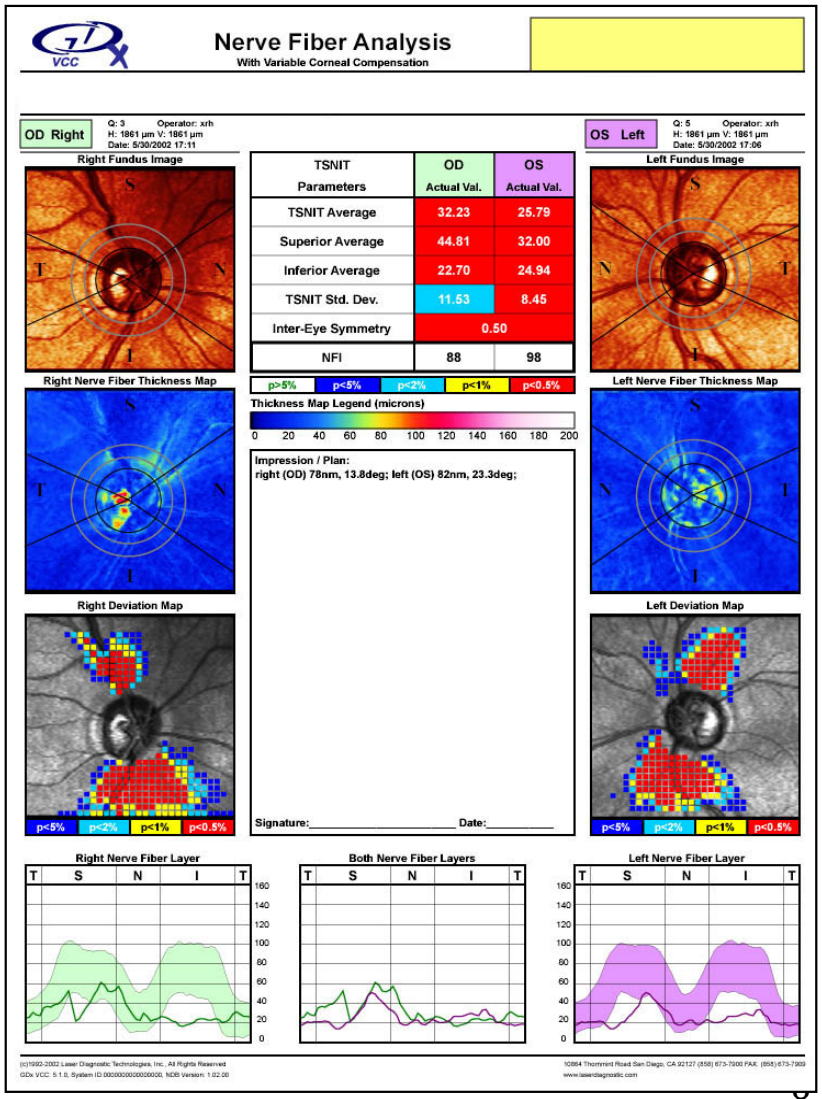


Symmetry Analysis Printouts

Normal

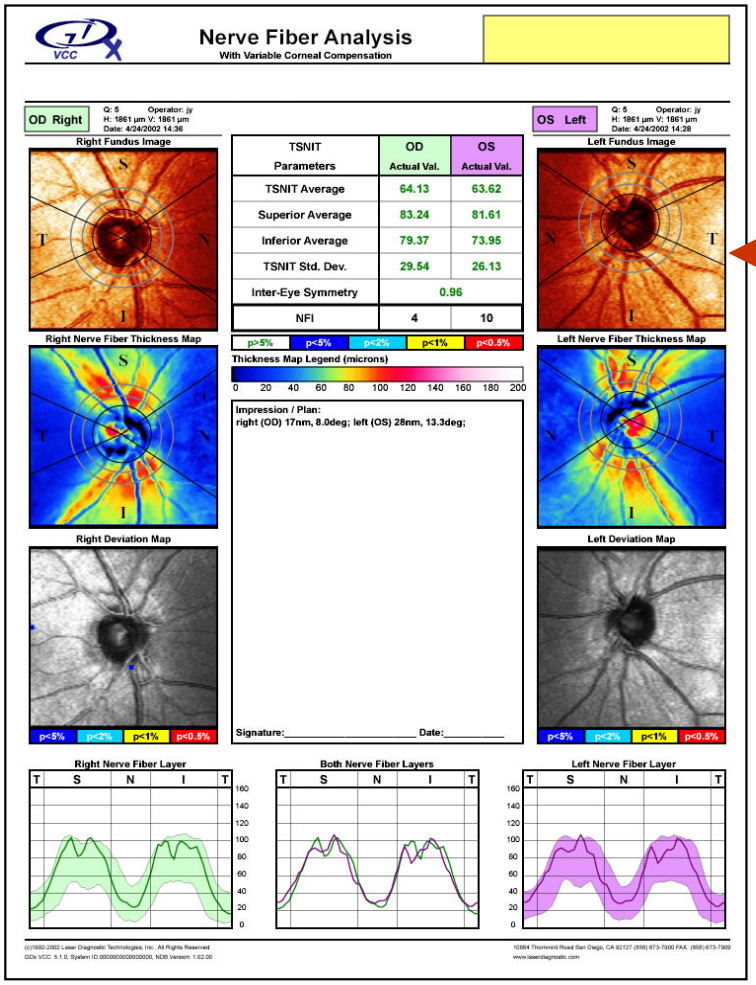


Glaucoma



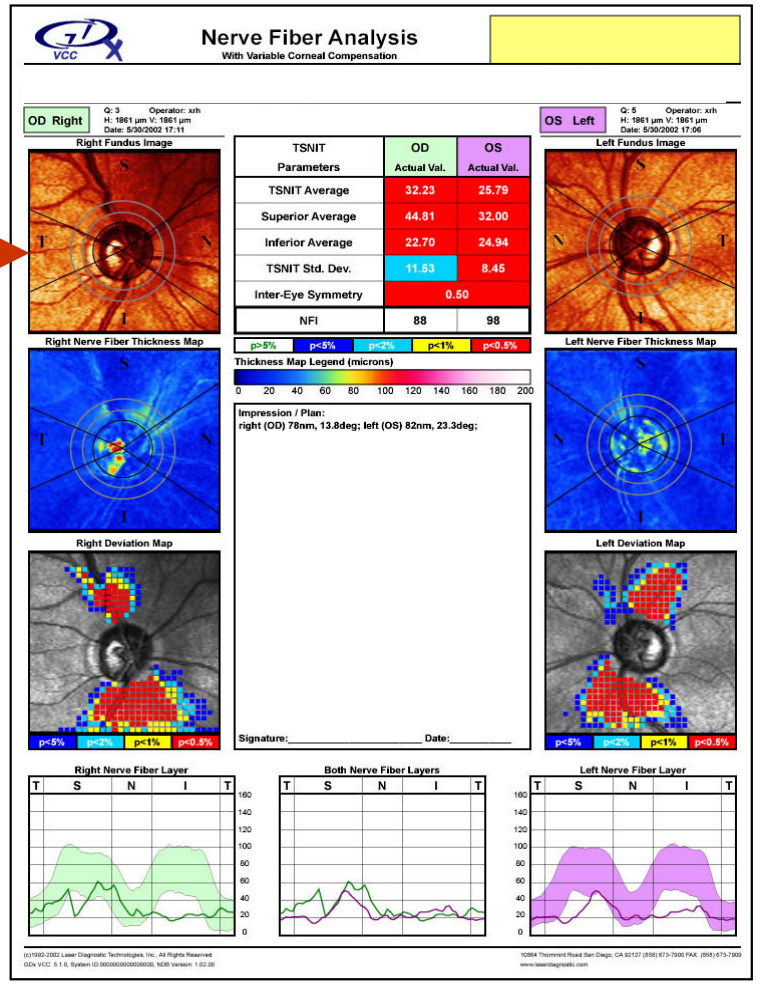
Key Feature: Fundus Image

Normal



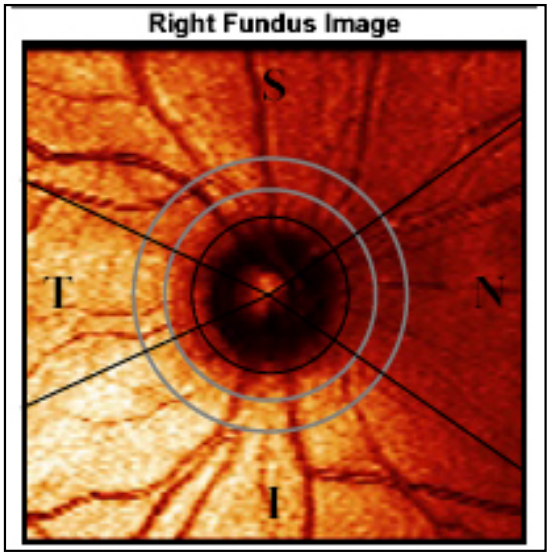
Fundus Image

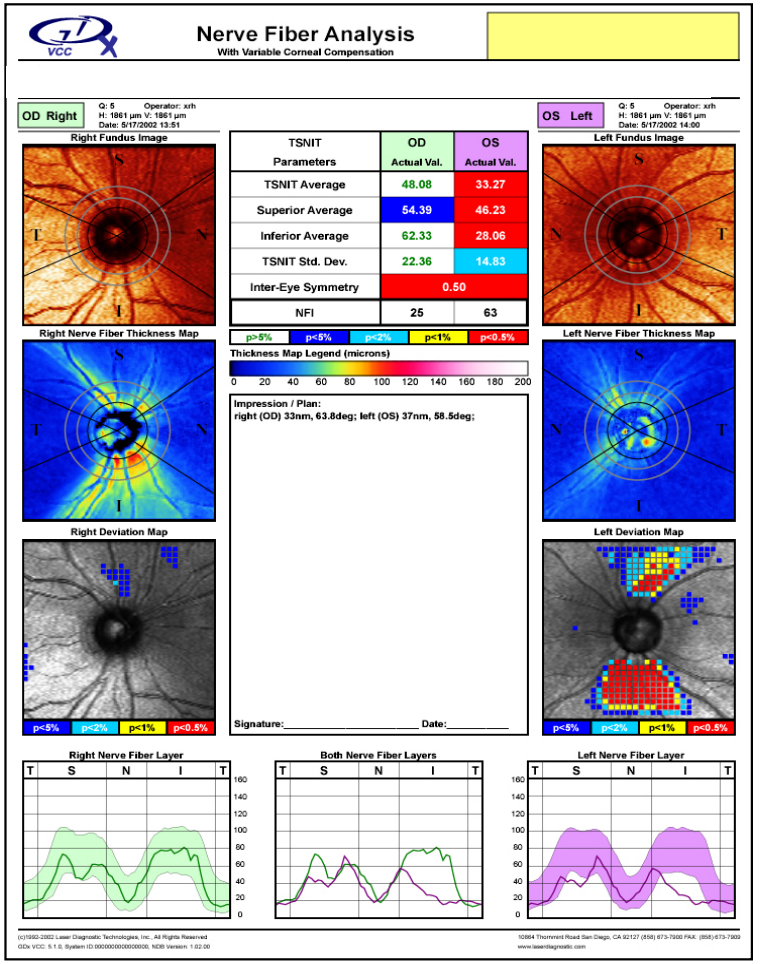
Glaucoma



Fundus Image: Documents image quality and centering around the optic nerve head.

Clinical Interpretation of Fundus Image



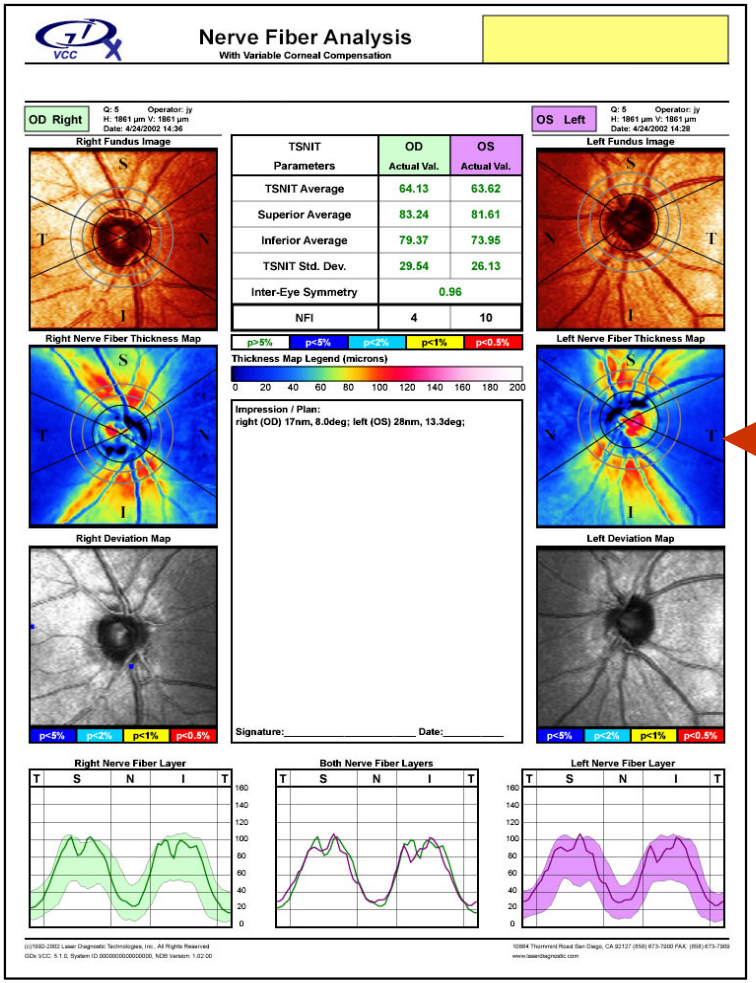


Fundus Image is useful for image quality

- Is the image focused?
- Is it adequately illuminated?
- Is the ellipse centered on the ONH?

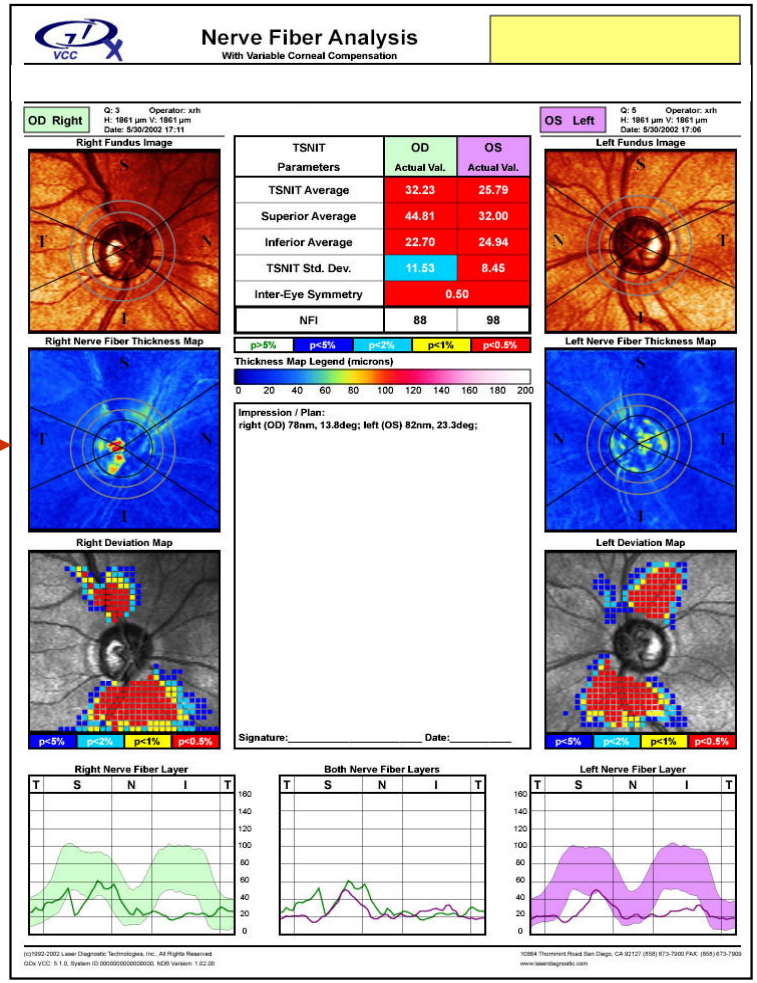
Key Feature: Thickness Map

Normal



Thickness Map

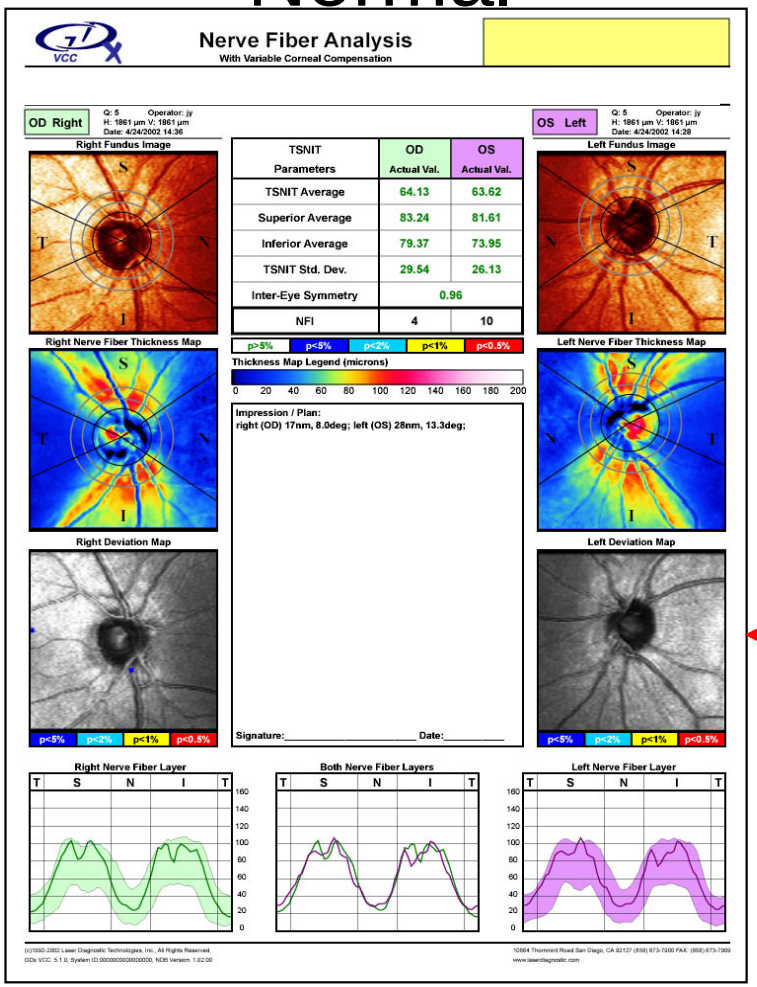
Glaucoma



Thickness Map: Presents RNFL thickness in color with thick regions in red and yellow and thin regions in blue and green

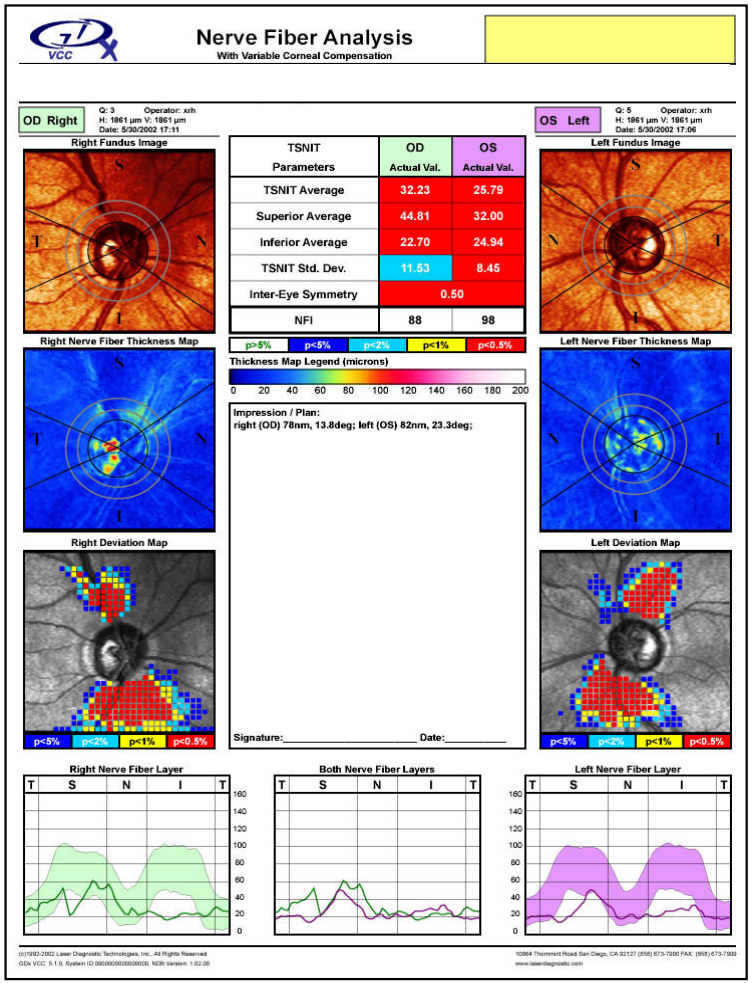
Key Feature: Deviation Map

Normal



Deviation Map

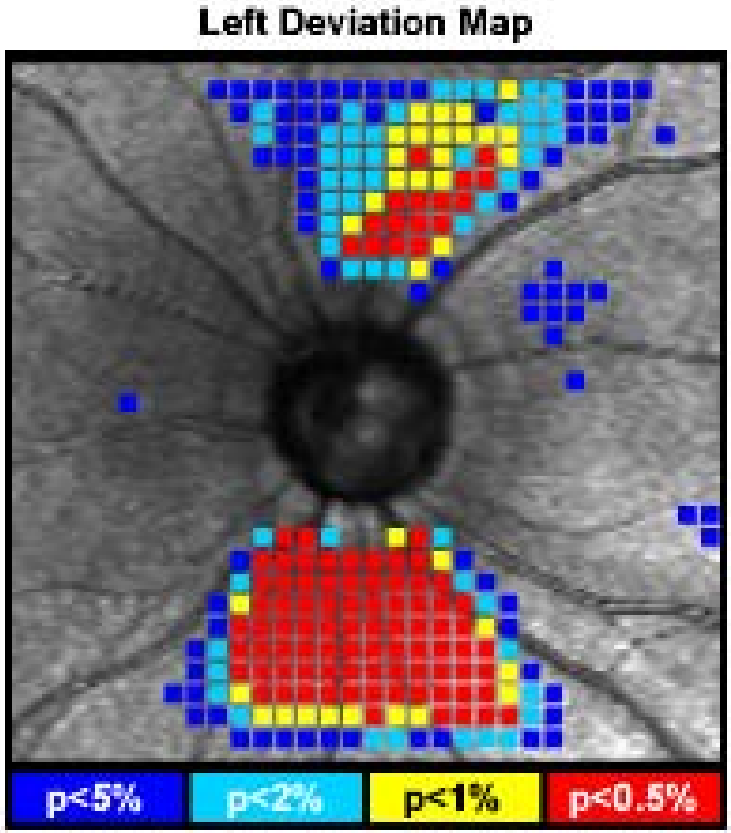
Glaucoma



Deviation Map: Compares RNFL measurements to a multiracial age-stratified normative database of 540 eyes.

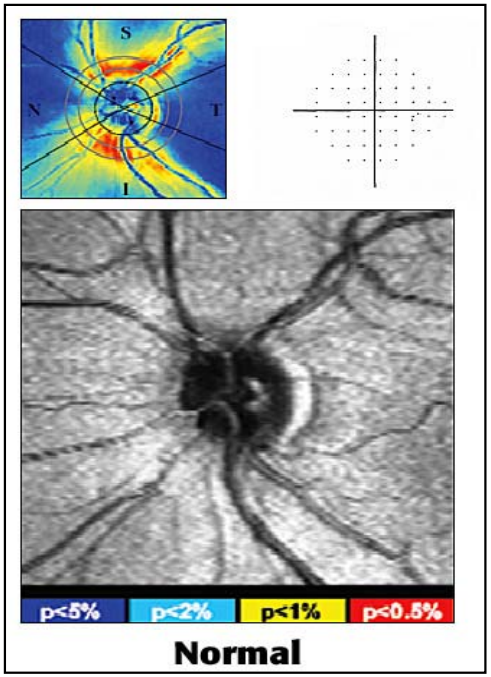
The Deviation Map

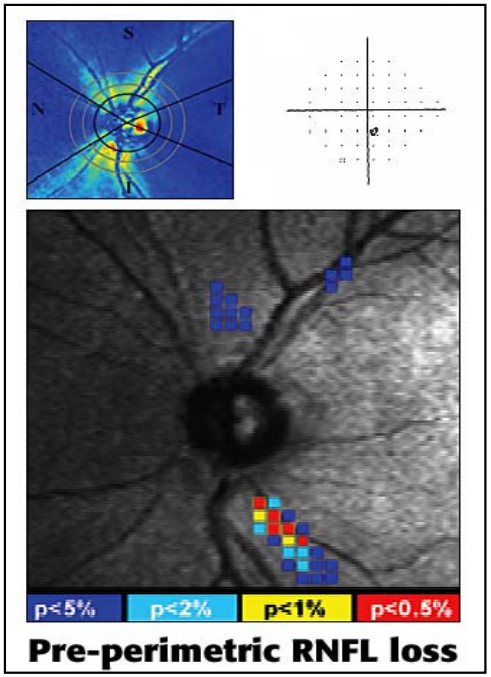
- Compares each individual's entire Retinal Nerve Fiber Layer scan to the normative database
- Reveals the location and magnitude of Retinal Nerve Fiber Layer thinning
- Defects are color-coded based on probability of normality
- Simplifies interpretation (similar to the visual field pattern deviation)

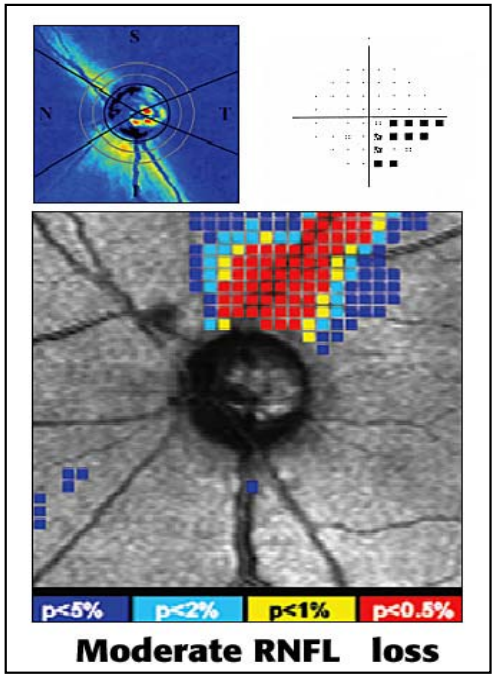


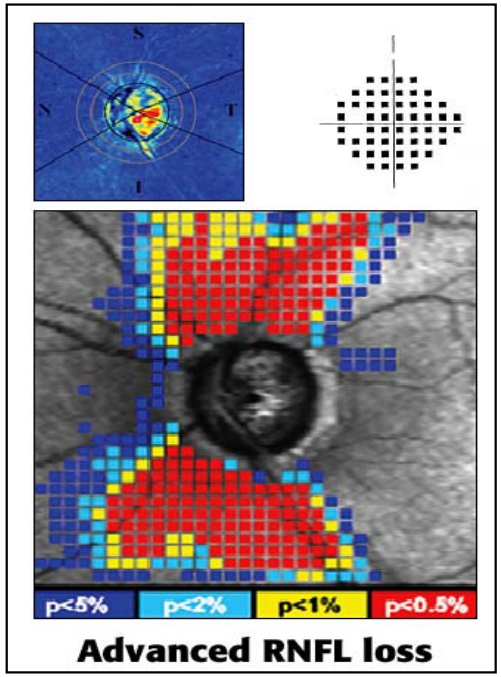
Deviation Map,Thickness Map and Visual Field Pattern Deviation Correlations

Examples from normal to advanced glaucoma



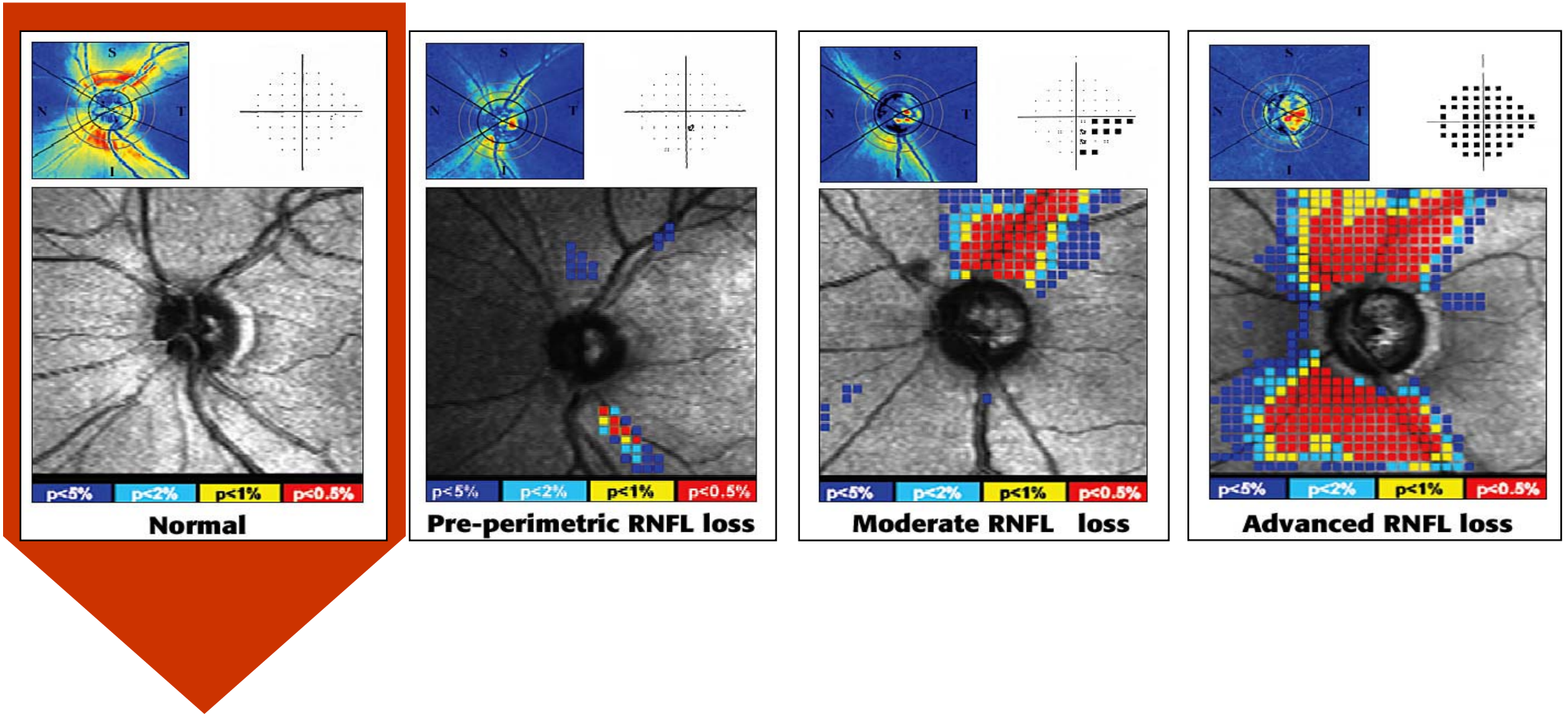






Deviation Map,Thickness Map and Visual Field Pattern Deviation Correlations

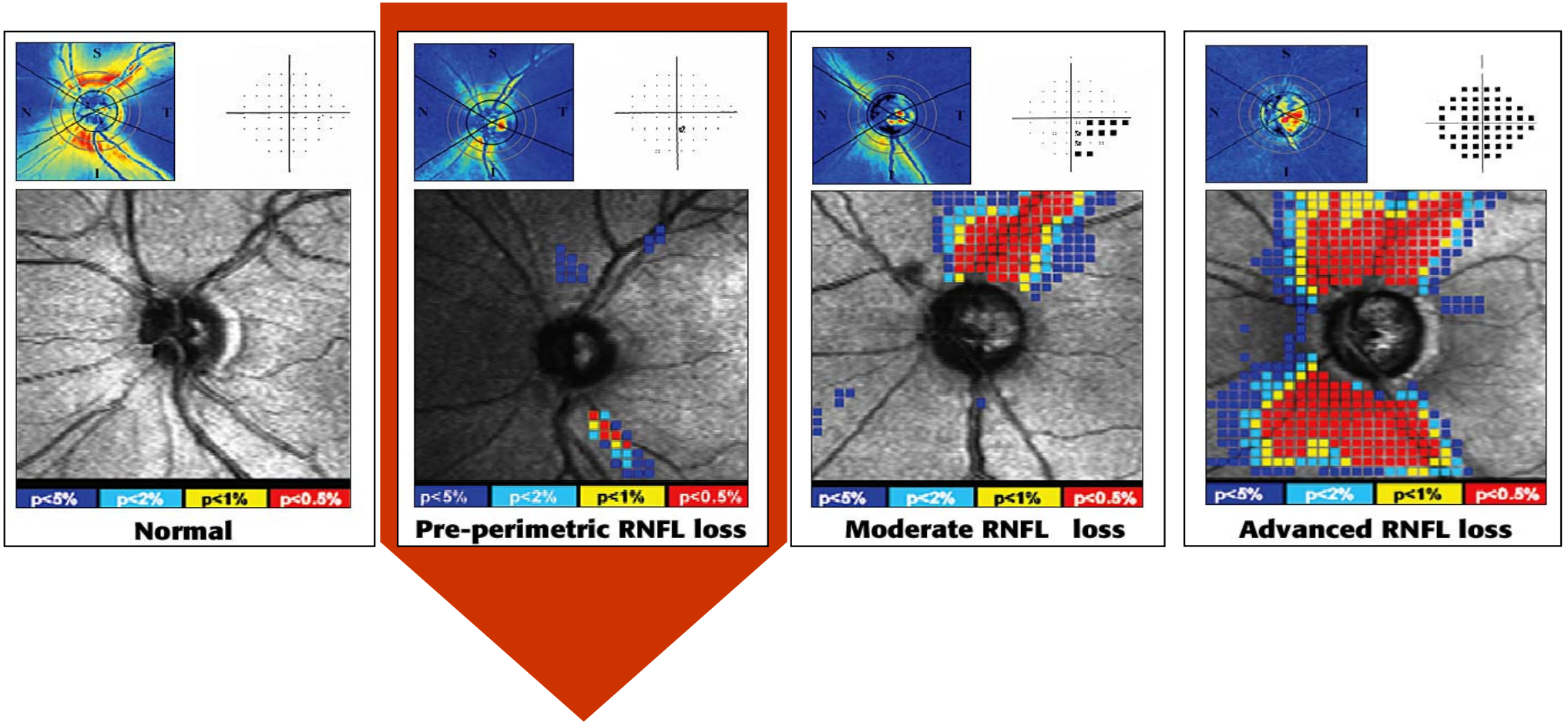
Examples from normal to advanced glaucoma



A normal eye with normal thickness and deviation maps and normal visual field

Deviation Map,Thickness Map and Visual Field Pattern Deviation Correlations

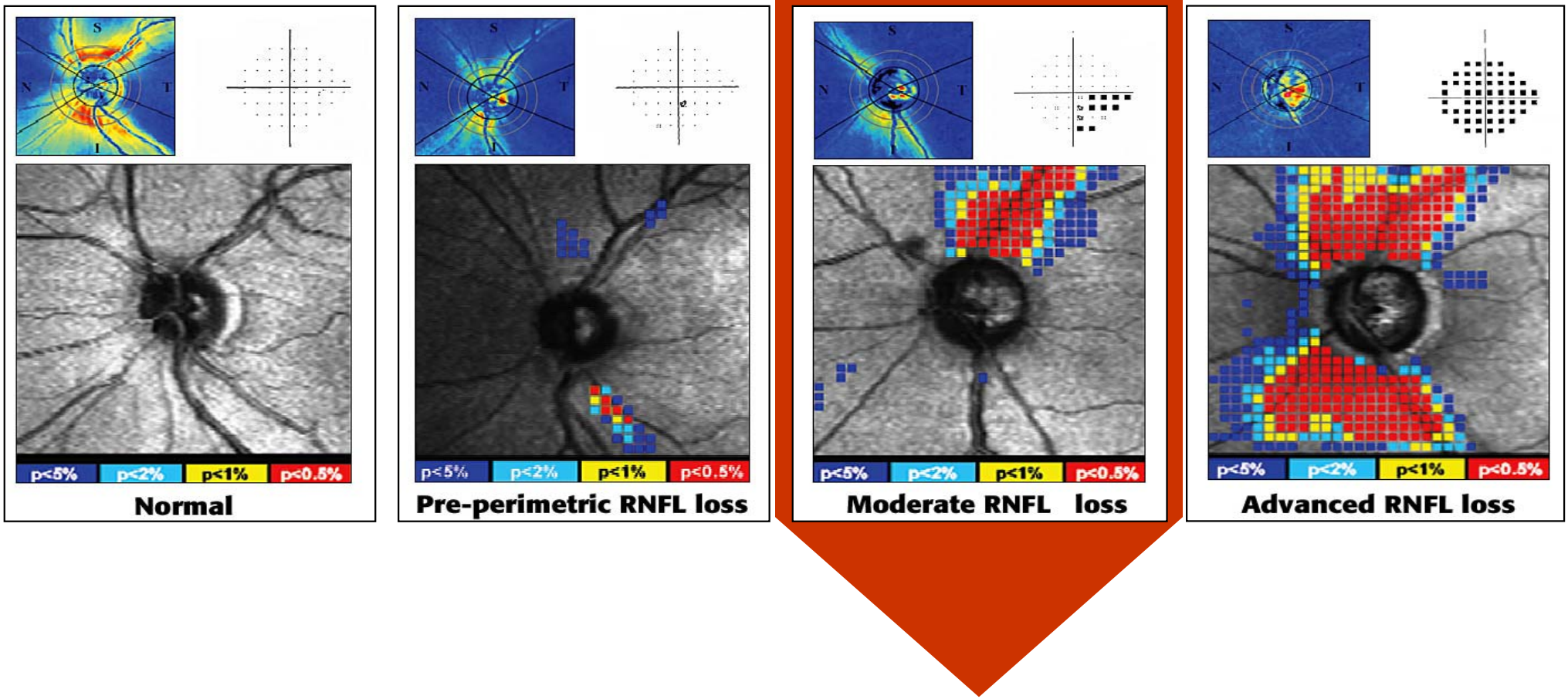
Examples from normal to advanced glaucoma



An eye with focal Retinal Nerve Fiber Layer loss prior to visual field loss

Deviation Map,Thickness Map and Visual Field Pattern Deviation Correlations

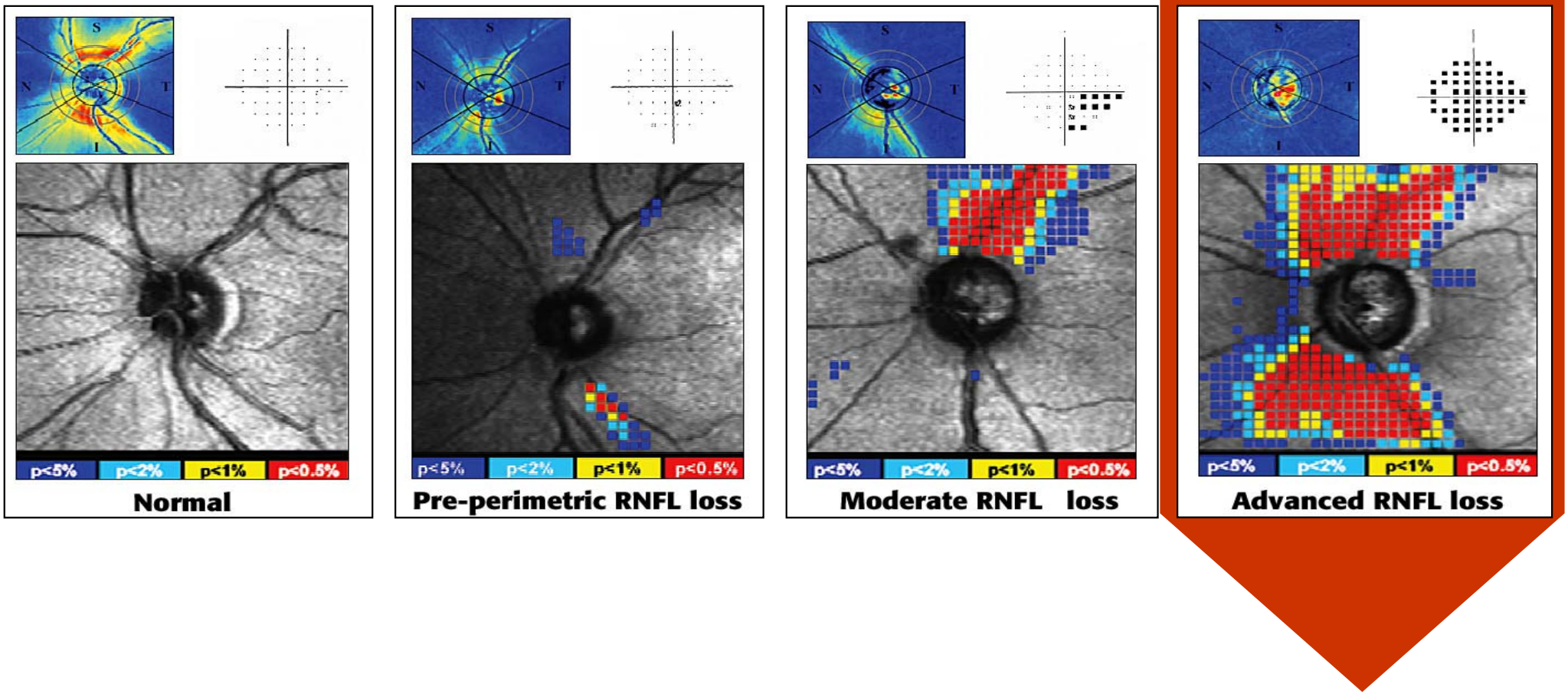
Examples from normal to advanced glaucoma



A moderate glaucoma eye with superior RNFL loss and inferior visual field loss

Deviation Map,Thickness Map and Visual Field Pattern Deviation Correlations

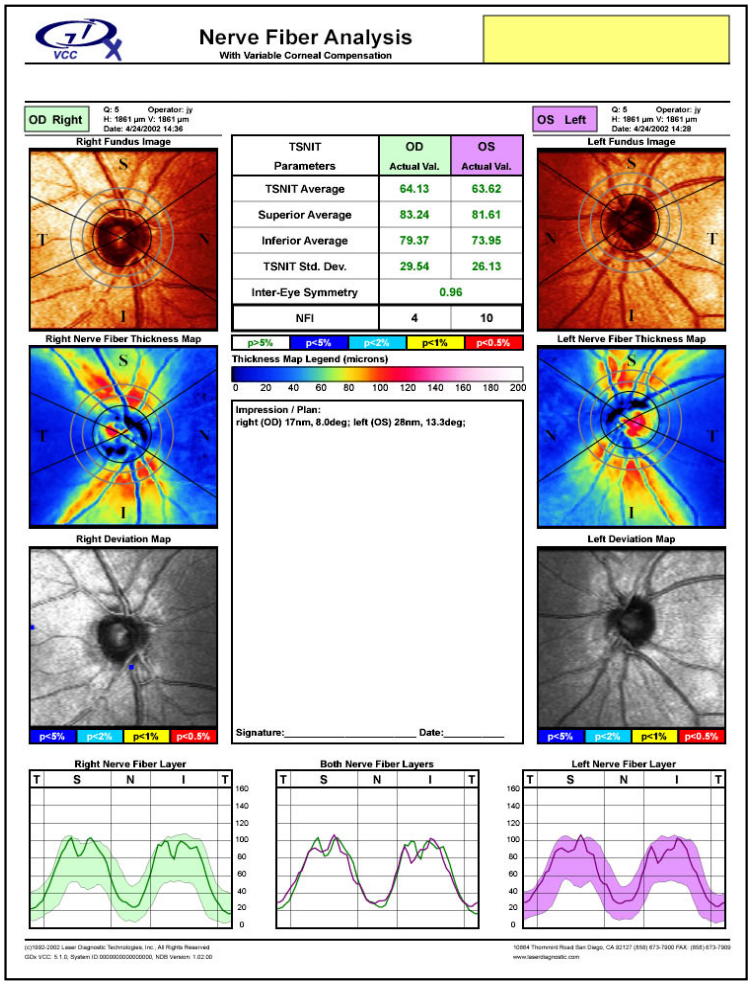
Examples from normal to advanced glaucoma



An advanced glaucoma eye with advanced RNFL and visual field loss

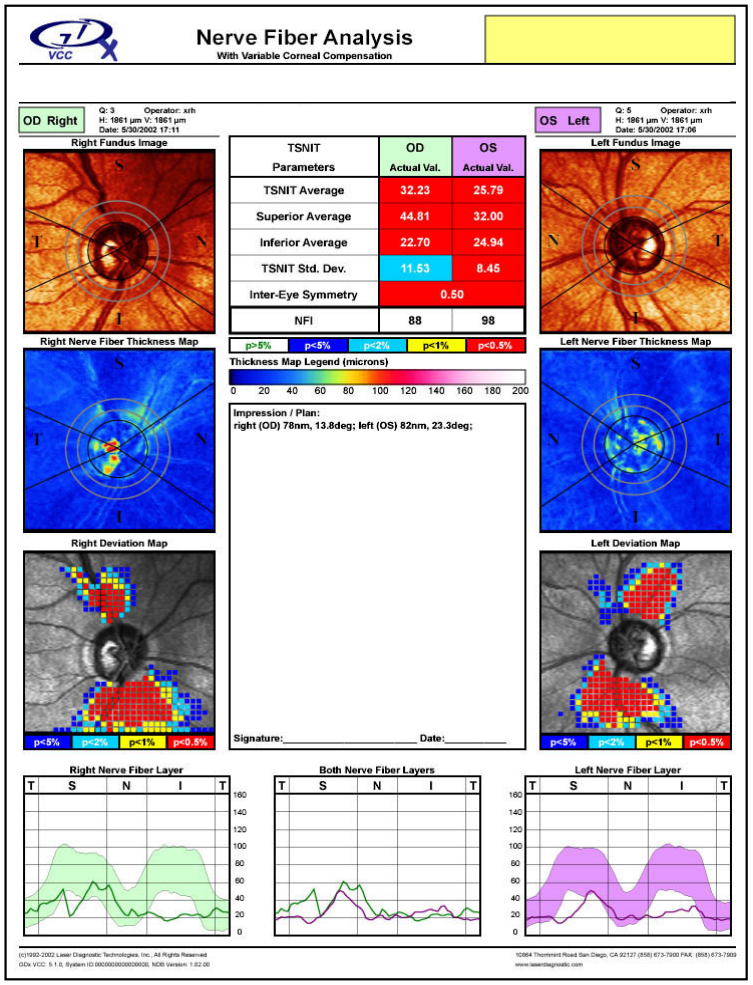
Key Feature: TSNIT Graph

Normal



TSNIT Graph

Glaucoma

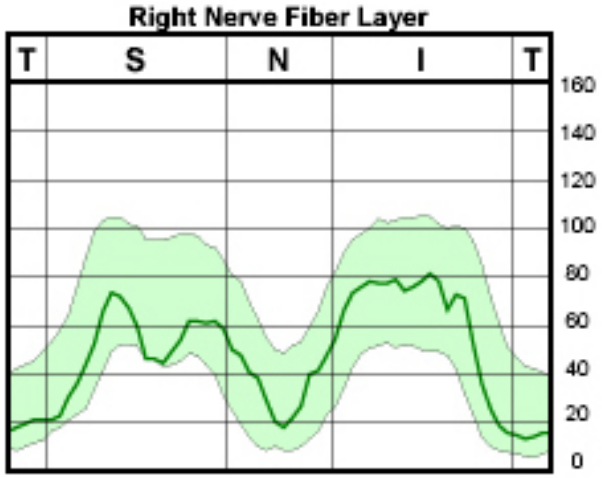


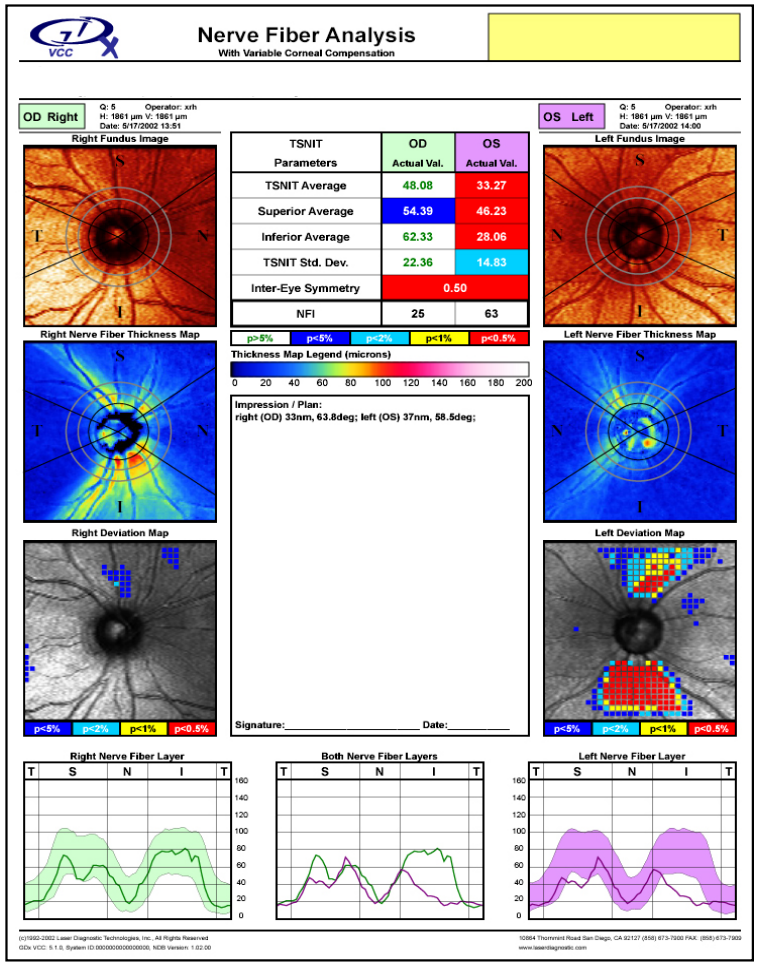
TSNIT Graph: Compares RNFL thickness around the optic disc to the normative database.

Clinical Interpretation of TSNIT Graph

Temporal – Superior – Nasal – Inferior - Temporal

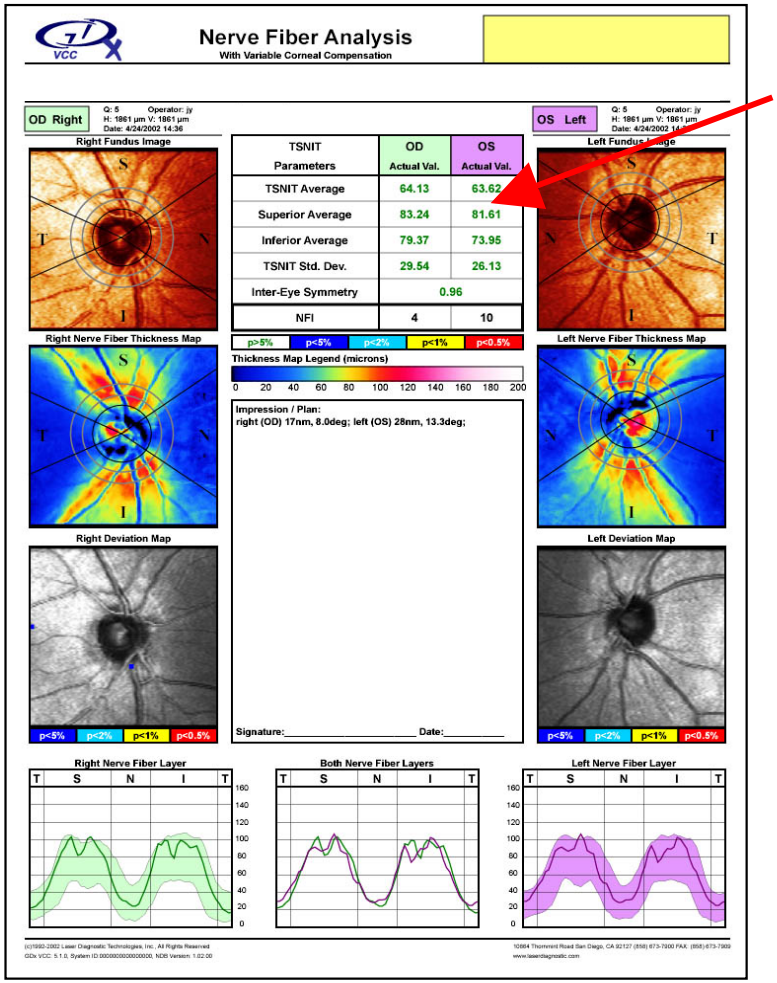
- Displays the thickness values along the Calculation Circle
  - Normal values are within the shaded area
  - Abnormal values fall below shaded area





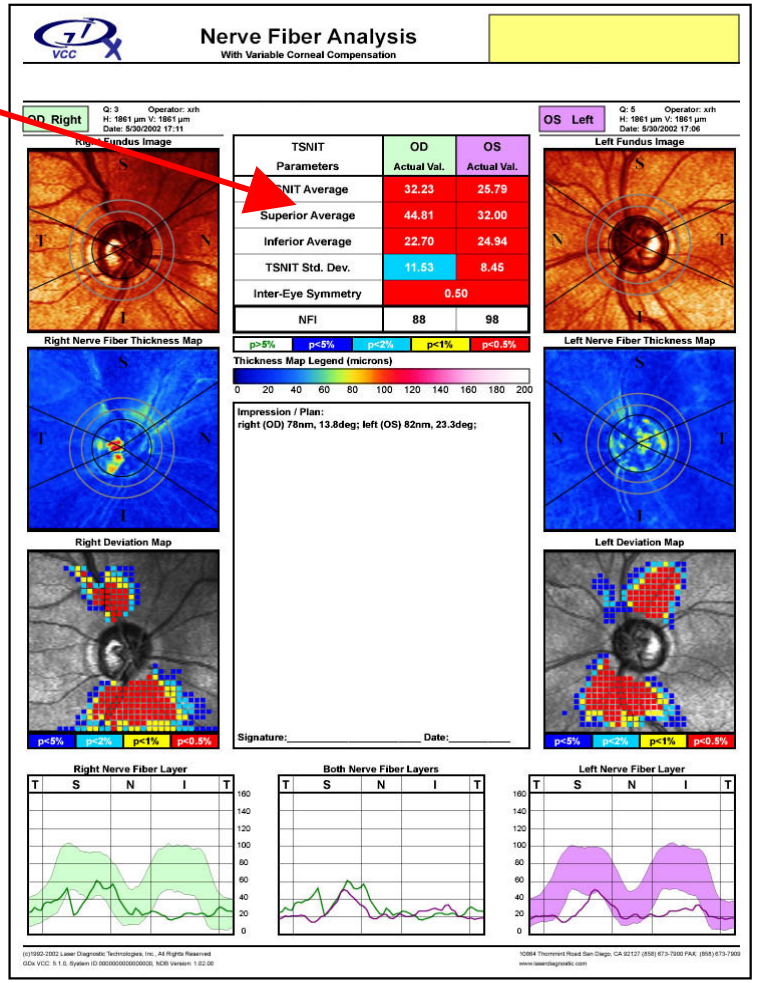
Key Feature: Parameters

Normal



Parameters

Glaucoma

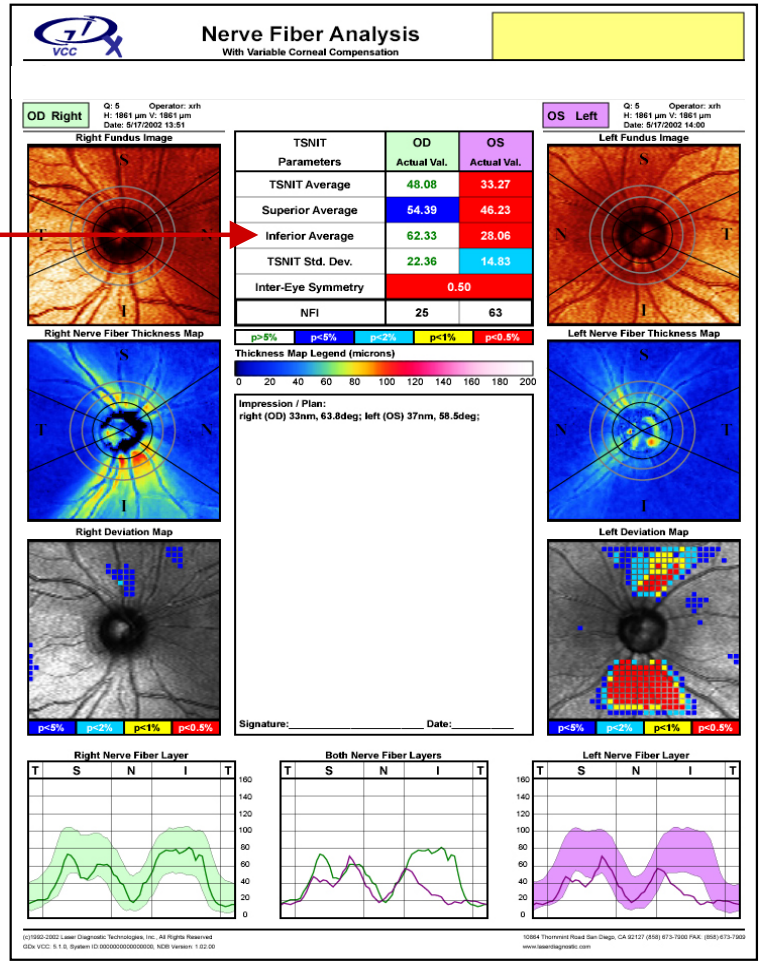


Parameters are color-coded if they fall outside the normal limits.

Clinical Interpretation of TSNIT Parameters

TSNIT Parameters	OD Actual Val.	OS Actual Val.
TSNIT Average	48.08	33.27
Superior Average	54.39	46.23
Inferior Average	62.33	28.06
TSNIT Std. Dev.	22.36	14.83
Inter-Eye Symmetry	0.50	
NFI	25	63

p>5% | p<5% | p<2% | p<1% | p<0.5%

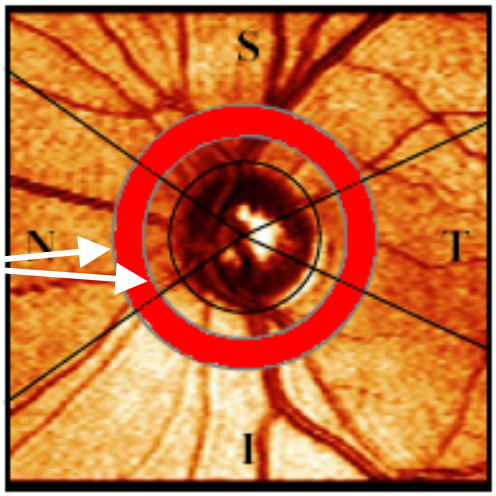


Parameters:

- Summary measures based on the calculation circle.
- Values outside normal are color-coded based on probability of normality.

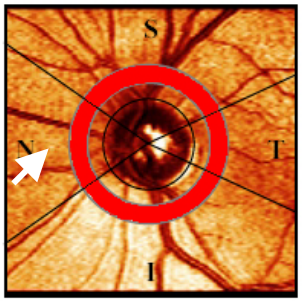
TSNIT Parameters

TSNIT Parameters are calculated from within the calculation circle (red band within gray circles)



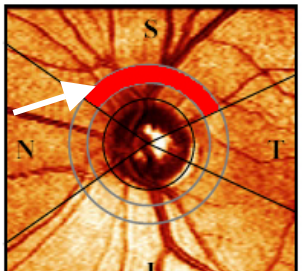
TSNIT Average

- average RNFL thickness from the entire Calculation Circle (area shown in red)



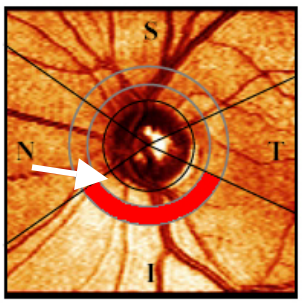
Superior Average

- average RNFL thickness in the superior 120°of the Calculation Circle (area in red)



Inferior Average

- average RNFL thickness in the inferior 120°of the Calculation Circle (area in red)

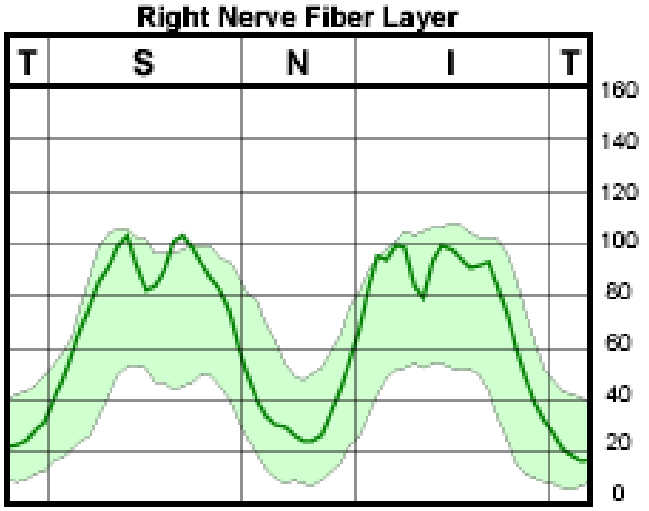


TSNIT Parameters

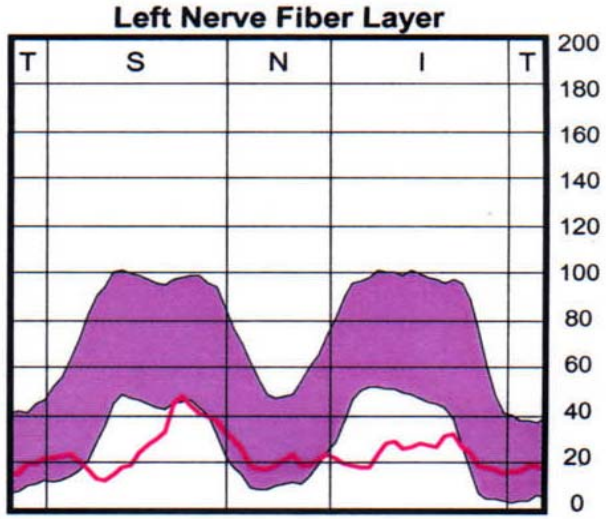
TSNIT Standard Deviation

- the standard deviation of the thickness values contained within the Calculation Circle
- captures the modulation (peak to trough difference) of the “double-hump” pattern

High Modulation



Normal



Glaucoma

Low Modulation

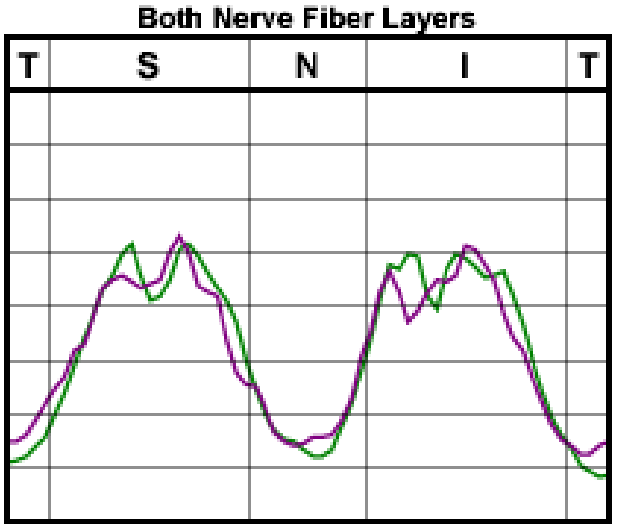
High modulation = high value

Low modulation = low value

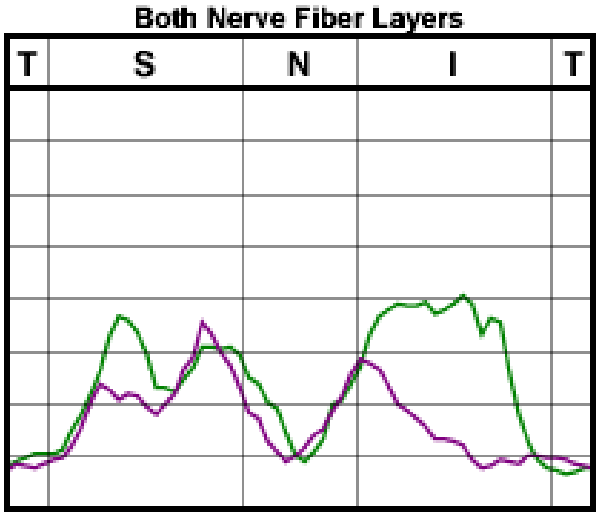
TSNIT Parameters

Inter-Eye Symmetry

- Values near 1 represent good symmetry
- Values near 0 represent poor symmetry



Normal
Good Symmetry



Glaucoma
Poor Symmetry

Nerve Fiber Indicator (NFI)

- Based on both focal and diffuse Retinal Nerve Fiber Layer loss
- Utilizes a neural network, trained to discriminate normal from glaucoma
- Is the most sensitive parameter for discriminating normal from glaucoma[1]
- Classification

Normal		Borderline		Abnormal	
1	30	31	50	51	100

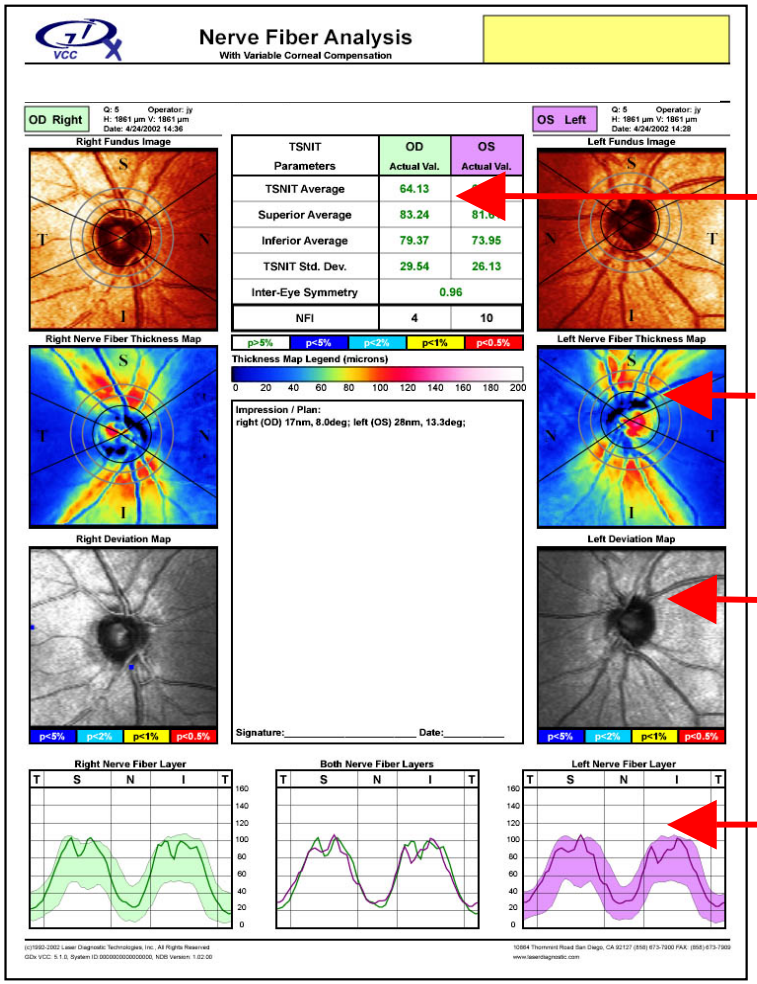
TSNIT Parameters	OD Actual Val.	OS Actual Val.
TSNIT Average	48.08	33.27
Superior Average	54.39	46.23
Inferior Average	62.33	28.06
TSNIT Std. Dev.	22.36	14.83
Inter-Eye Symmetry	0.50	
NFI	25	63

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

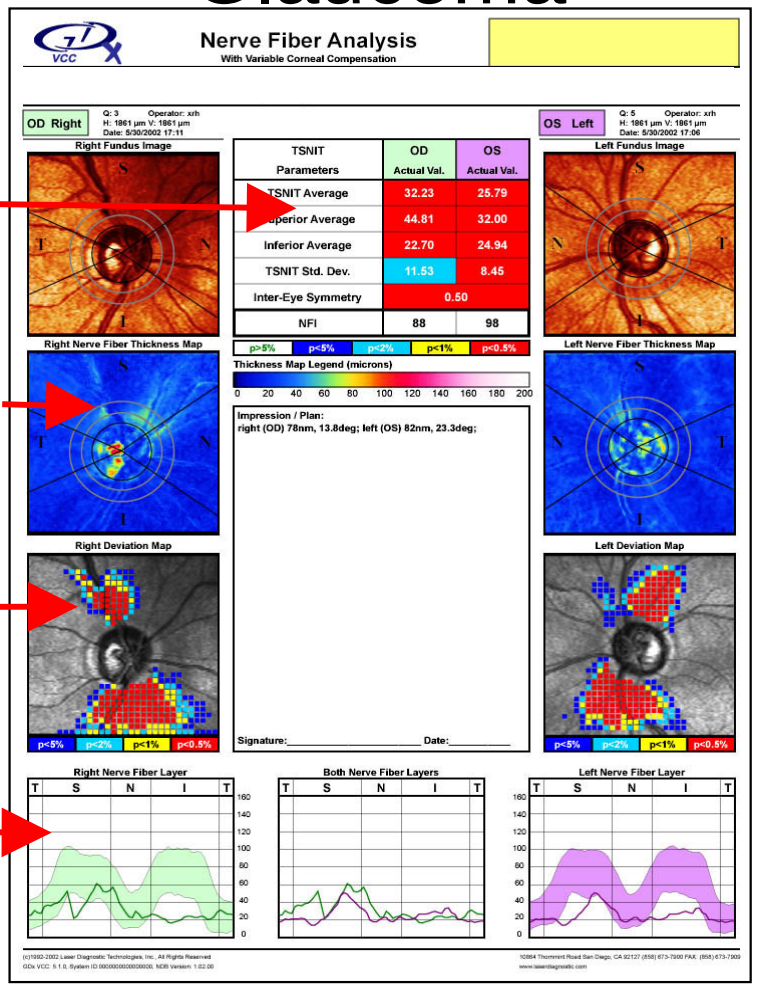
[1] Medeiros, Zangwill, Bowd, Mohammadi and Weinreb, *ISIE* May 2-3, 2003

GDx Printout

Normal



Glaucoma



Parameters

Thickness Map

Deviation Map

TSNIT Graph

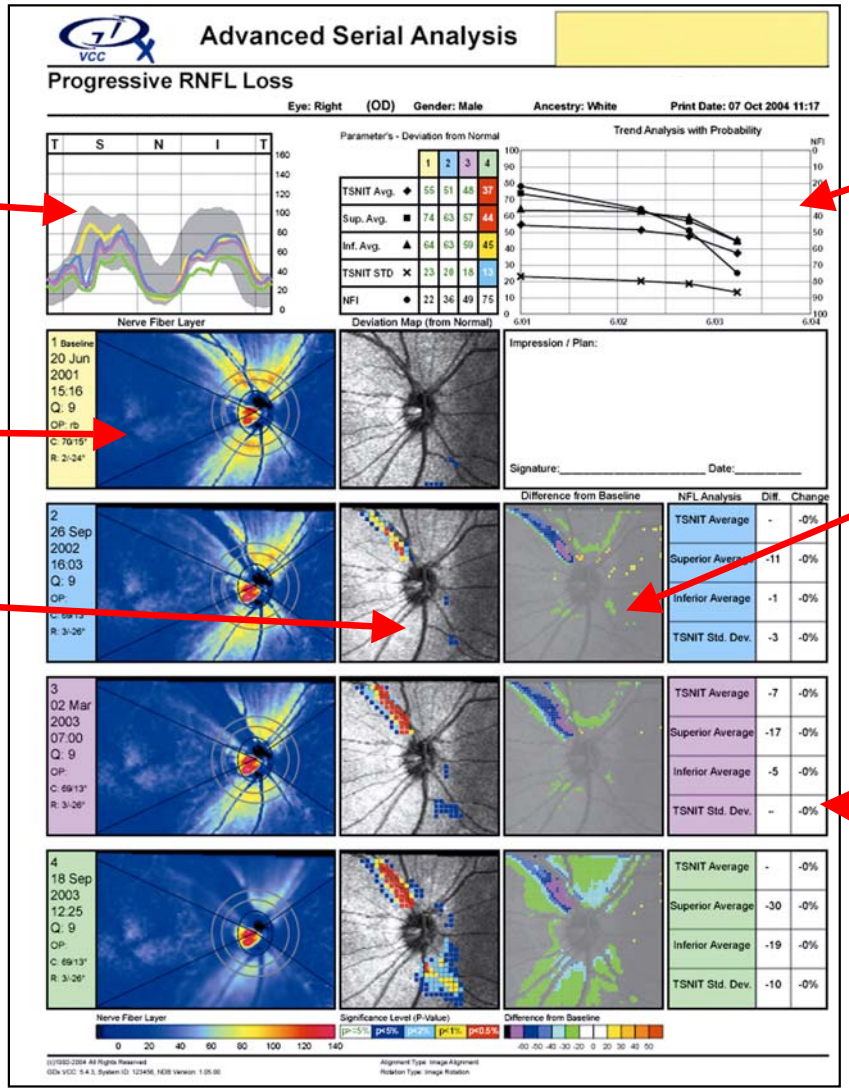
Comparisons of each scan to the Normative Database allows accurate and rapid interpretation in one exam.

Advanced Serial Analysis Printout

TSNIT Comparison

Thickness Maps

Deviation Maps



Trend Analysis

Deviation from Baseline

TSNIT Parameters

Advanced Serial Analysis provides easy-to-interpret identification of changes from baseline.

GDx Comparative Database

- A comprehensive database is essential for accurate glaucoma detection.
  - 540 normal eyes[1]
  - Ages range from 18-82
  - Multi-ethnic
- The database also contains 262 glaucomatous eyes used by the NFI to discriminate between normal and glaucoma.

[1] Sinai, MJ and Zhou, Q. *Invest Ophthalmol Vis Sci, Suppl.* 44:3402, 2003

GDx for POAG Screening

- “Screening is a part of the comprehensive adult eye evaluation, and it constitutes the single most effective method to identify individuals with glaucoma.”
- “Screening is more efficient and cost-effective when targeted at populations that are at particularly high risk for glaucoma, such as African Americans, those with a family history of glaucoma, and the elderly.”

GDx Screening Mode

- Designed to be part of a comprehensive examination:
  - for patients with risk factors
  - to help determine which patients may need a full glaucoma workup.
- Single scan
- 60 seconds