

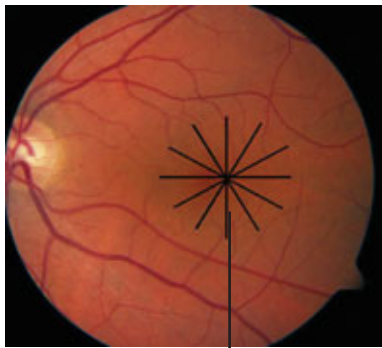
Stratus OCT™ Software Version 4.0

Real Answers in Real Time.

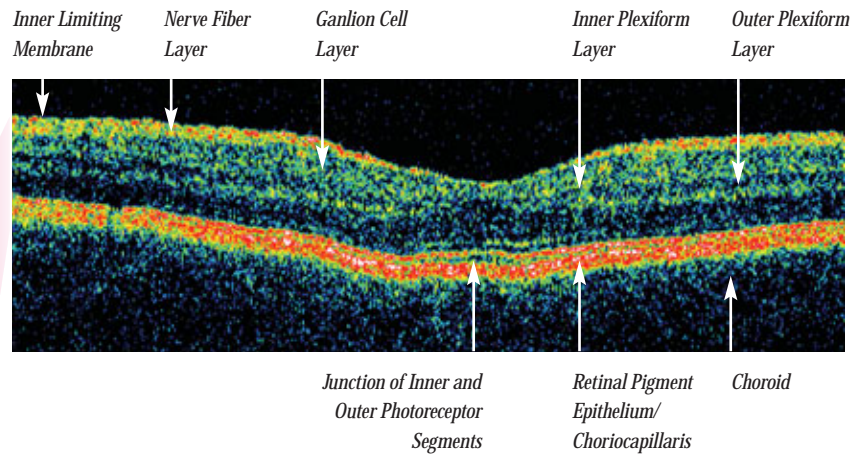
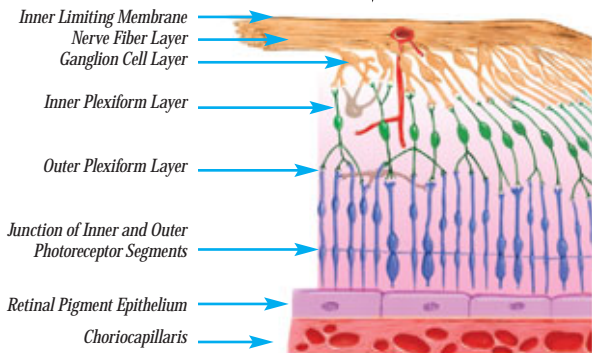


Stratus OCT™

Add depth to your diagnosis.



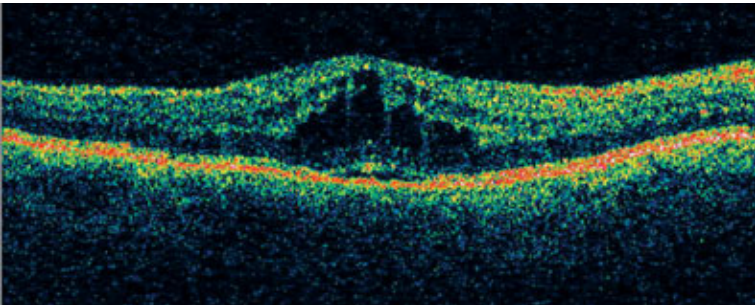
Stratus OCT provides a higher level of diagnostic insight - a significant contribution to therapeutic confidence across a broad spectrum of ophthalmic diseases. Using near-infrared frequency light, Stratus OCT reveals an in vivo cross-sectional view with an axial resolution of 10 μm , and quantitative analysis of the retinal layers.



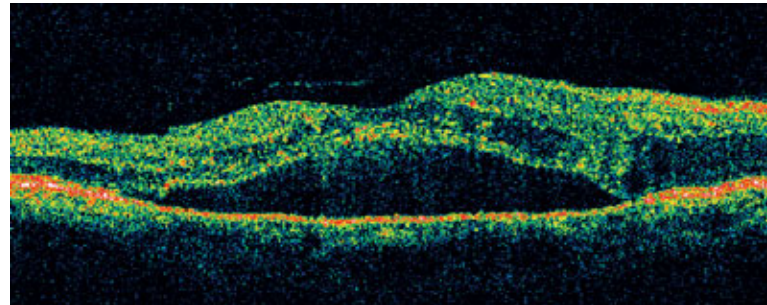
In the Stratus OCT image display, retinal layers with the highest reflectivity appear red. In a healthy retina, these include the nerve fiber layer, retinal pigment epithelium and choriocapillaris. The layers that exhibit minimal reflectivity appear blue or black, such as the photoreceptor layer, choroid, vitreous fluid or blood.

Obtain real-time non-invasive histology of live tissue.

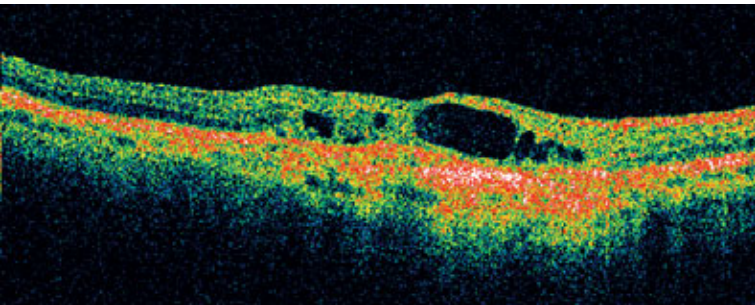
Stratus OCT reveals the retinal layers in high-resolution, cross-sectional views, offering insight for diagnosis, therapy and ongoing management of retinal disorders.



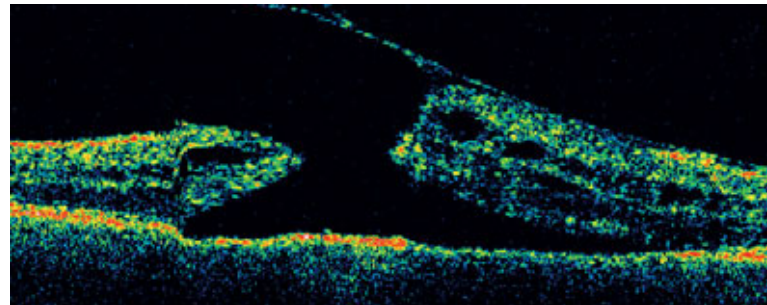
Cystoid Macular Edema



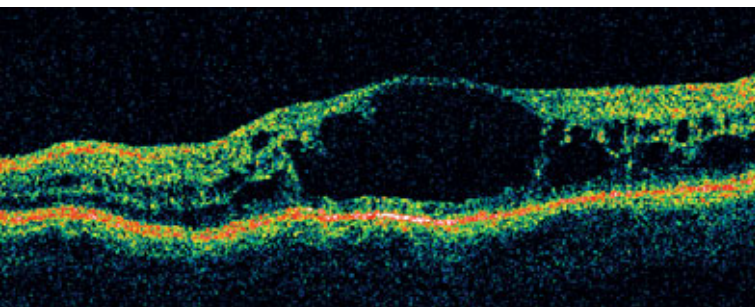
Central Serous Chorioretinopathy



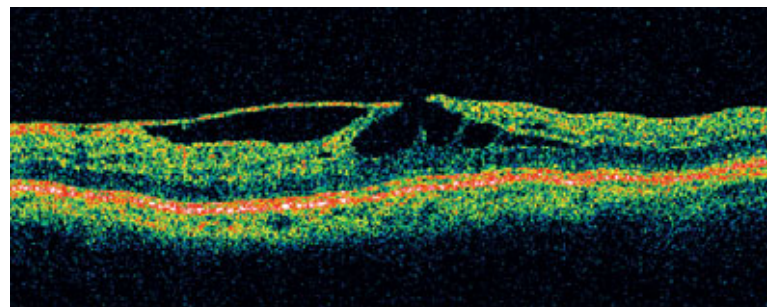
*Age-related Macular Degeneration
with Overlying Cystoid Macular Edema*



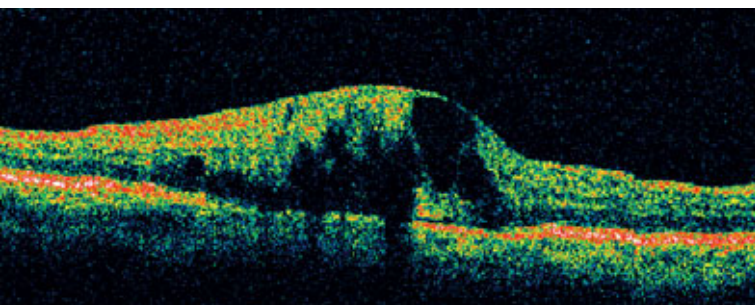
Macular Hole with Operculum



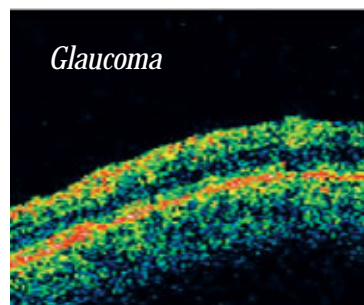
Diabetic Macular Edema



Epiretinal Membrane with Lamellar Hole and Cystoid Macular Edema

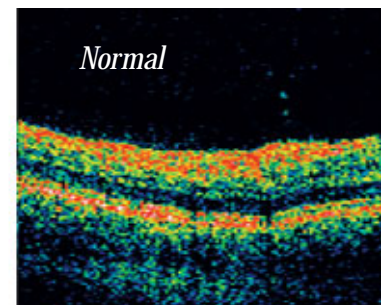


Branch Retinal Vein Occlusion



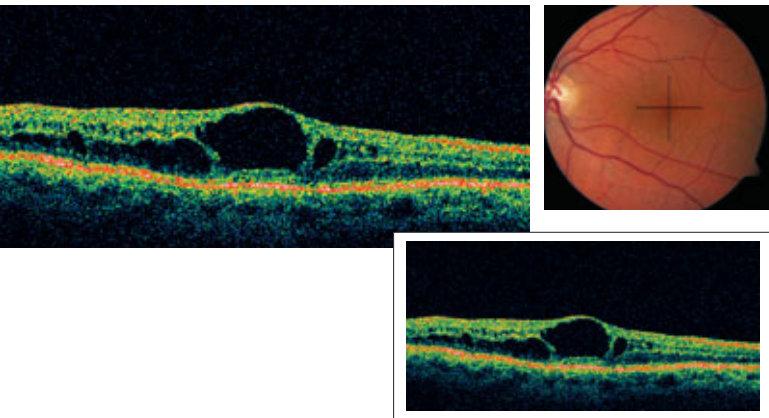
Glaucoma

RNFL Loss



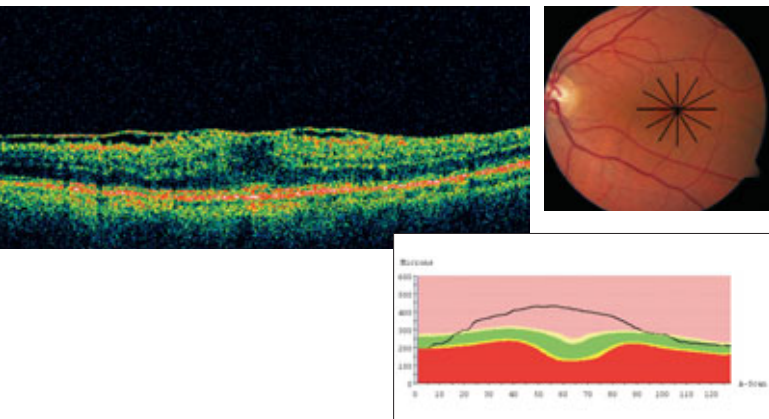
Normal

Visualize and analyze retinal disorders.



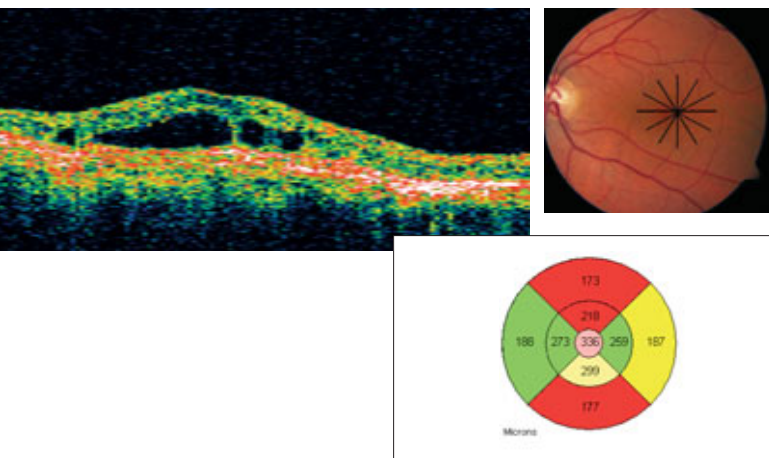
Diabetic Retinopathy

- Stratus OCT reveals and measures diffuse macular thickening and loss of foveal contour
- Intraretinal cysts and fluid accumulation are identifiable as areas of low reflectivity in the cross-sectional scan
- Post-treatment resolution of retinal thickening can be quantified and monitored



Epiretinal Membrane

- Stratus OCT scan shows the epiretinal membrane as a highly reflective band on the inner retinal surface
- Separation of the membrane from the retina is visible in areas
- Underlying retina is thickened, with loss of normal foveal contour

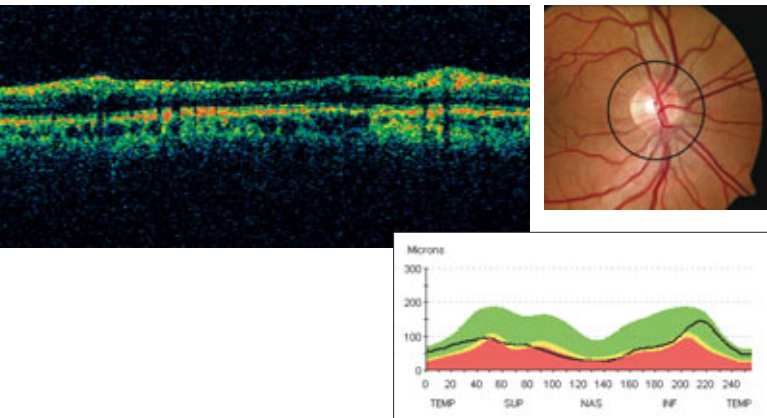


Age-related Macular Degeneration

- Disruption of RPE, caused by neovascularization and drusen, can be visualized
- Pockets of interretinal fluid are visible as areas of reduced reflectivity
- Structural changes resulting from therapy can be quantified and monitored

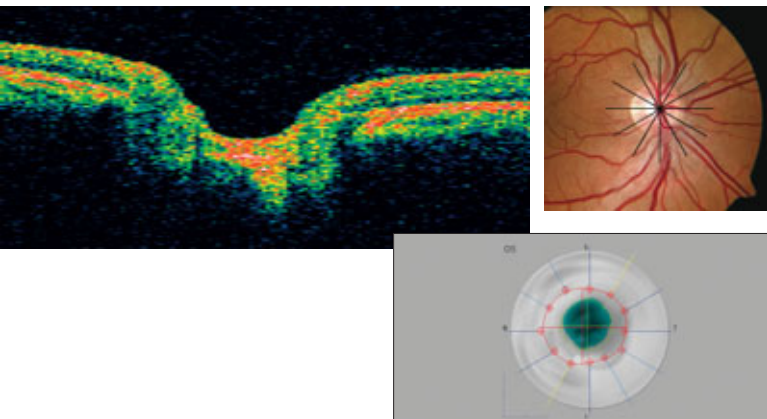


Detect glaucoma damage at an early stage.



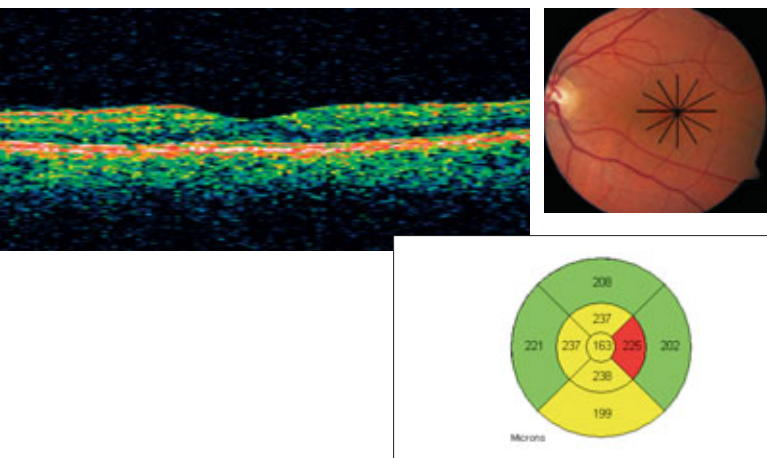
Retinal Nerve Fiber Layer Analysis

- Analysis of RNFL aids in identification of early glaucomatous loss
- Circular scans of 3.4 mm diameter around optic nerve head provide measurement of RNFL in the peripapillary region
- RNFL thickness measurement is graphed in a TSNIT orientation and compared to age-matched normative data



Optic Nerve Head Analysis

- Radial line scans through optic disc provide cross-sectional information on cupping and neuroretinal rim area
- Disc margins are objectively identified using signal from end of RPE
- Key parameters include cup-to-disc ratio and horizontal integrated rim volume1



Macular Thickness Analysis

- Thinning of the macula may reflect glaucomatous loss
- Structural analysis of retinal sublayers reveals macular complications
- Cross-sectional view provides visualization and measurement of retinal layers

Stratus OCT Printout

Software Version 4.0

Retinal Thickness Report

Scan Protocol: Fast Macular Thickness, Macular Thickness, Line, Cross Hair

Used for: Assessment of overall macular region or specific areas of interest

STRATUS OCT
Retinal Thickness Report - 4.0.3 (0070)

DOB: 7/9/1924, ID: NA, Gender

Scan Type: Fast Macular Thickness Map OS
Scan Date: 3/31/2004
Scan Length: 6.0 mm

OCT Image

Fundus Image

Signal Strength (Max 10)	8
Retinal Thickness is	451 microns at A-scan 55
Caliper Length is	OFF

Thickness Chart

Signature: _____

Physician: _____

Normal Distribution Percentile

	100%
	99%
	95%
	5%
	1%
	0%

Patient Information

Scan Information

Scan Image

The image with the lowest signal strength or with a data message will be shown to facilitate operator review.

Fundus Image

Scan should be centered on fovea.

Signal Strength

Numbers range from 0 (weak) to 10 (strong). Analysis algorithm may fail on scans with low signal strength; therefore, images with a signal strength below 5 should not be used for analysis.

Legend

Arrow indicates direction and angle of individual scan displayed in scan image.

Data Message

"Scan Too High," "Scan Too Low" or "Missing Data" message will be shown, if applicable, regarding placement and completeness of scan.

Normative Data

Distribution is indicated by a stoplight color code, described in detail inside back cover.

Retinal Thickness

Displayed for A scan indicated. This corresponds to A scan (shown here) selected on thickness chart.

Thickness Chart

Graphic display of retinal thickness. Colored bands demonstrate range of normative data.

Caliper Length

Measurement indicates distance between calipers if they are placed on scan image during analysis.

Retinal Thickness Tabular Output

Scan Protocol: Radial Lines, Fast Macular Thickness, Macular Thickness

Used for: Imaging and measurement of macular pathology

Patient Information

Scan Image

The image with the lowest signal strength or with a data message will be shown to facilitate operator review.

Fundus Image

Scan should be centered on the fovea.

Signal Strength

Numbers range from 0 (weak) to 10 (strong). Analysis algorithm may fail for scans with low signal strength; therefore, images with a signal strength below 5 should not be used for analysis.

Data Message

“Scan Too High,” “Scan Too Low” or “Missing Data” message will be shown, if applicable, regarding placement and completeness of scan.

Map

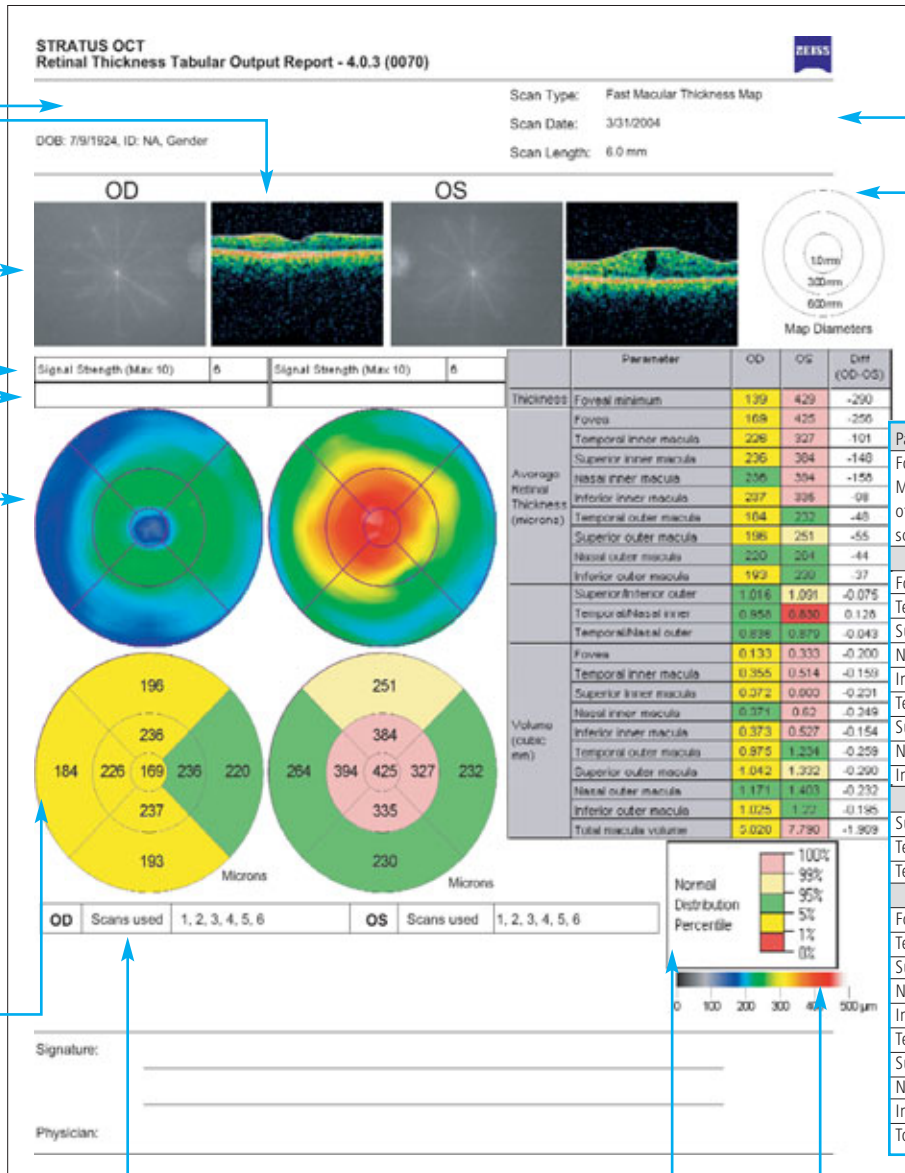
Thickness is displayed using a color scale. A normal eye will be displayed as blue centrally. Orange and red indicate greater thickness. Legend for color scale appears near bottom right of page.

Sector Averages

Numerical values indicate average thickness of each sector. Colors within each sector indicate comparison to normative data.

Scans Used

If any of the 6 radial line scans has been deselected, analysis might be incomplete.



Scan Information

Map Diameters

Diameters at which sector averages are calculated. Can be 1.0, 2.22 and 3.45 mm diameters or 1.0, 3.0 and 6.0 mm diameters as shown here.

Parameter	Normal Range
Fovea Minimum:	135 – 215 µm
Measurement at center of fovea where radial scan lines intersect	
	Average Thickness
Fovea	168 – 239 µm
Temporal Inner Macula	240 – 294 µm
Superior Inner Macula	243 – 296 µm
Nasal Inner Macula	240 – 297 µm
Inferior Inner Macula	246 – 297 µm
Temporal Outer Macula	199 – 276 µm
Superior Outer Macula	207 – 256 µm
Nasal Outer Macula	198 – 274 µm
Inferior Outer Macula	207 – 256 µm
	Ratios
Superior/Inferior Outer	0.832 – 1.222
Temporal/Nasal Inner	0.800 – 1.227
Temporal/Nasal Outer	0.557 – 1.845
	Volume
Fovea	0.13 – 0.19 cubic mm
Temporal Inner Macula	0.38 – 0.46 cubic mm
Superior Inner Macula	0.38 – 0.46 cubic mm
Nasal Inner Macula	0.38 – 0.47 cubic mm
Inferior Inner Macula	0.39 – 0.46 cubic mm
Temporal Outer Macula	1.06 – 1.46 cubic mm
Superior Outer Macula	1.10 – 1.36 cubic mm
Nasal Outer Macula	1.05 – 1.45 cubic mm
Inferior Outer Macula	1.10 – 1.35 cubic mm
Total Macula Volume	6.18 – 7.42 cubic mm

Normal distribution, macula thickness normative data, Carl Zeiss Meditec.

Legend

Normative data is displayed in stoplight color code, described in detail inside back page.

Color Scale

For thickness maps.

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Software Version 4.0

Optic Nerve Head Analysis Report

Scan Protocol: Optic Disc, Fast Optical Disc

Used for: Evaluation of the optic disc

Patient Information

Cup Markers

The edge of the cup is indicated with a green dot on the scan image and a green x on the composite diagram.

RPE Markers

The end of the RPE is indicated. Shown blue on the scan image, red on the composite diagram.

Signal Strength

Numbers range from 0 (weak) to 10 (strong). Analysis algorithm may fail on scans with low signal strength; therefore, images with a signal strength below 5 should not be used for analysis.

Optic Nerve Head Results

Data are derived from the 6 radial line scans.

Vertical Integrated Rim Area

Total volume of RNFL tissue in the rim is obtained by multiplying the average of the 6 individual rim areas by the circumference of the disc. Normal values are 0.36 ± 0.08 cubic mm.²

Horizontal Integrated Rim Width

Total rim area is obtained by multiplying the average of the 6 individual nerve widths by the circumference of the disc.

Disc Area

The area within the red outline on the composite diagram.

Cup Area

The area within the green outline on the composite diagram.

Rim Area

Disc area minus cup area.

Cup/Disc Area Ratio

Ratio of cup area to disc area.

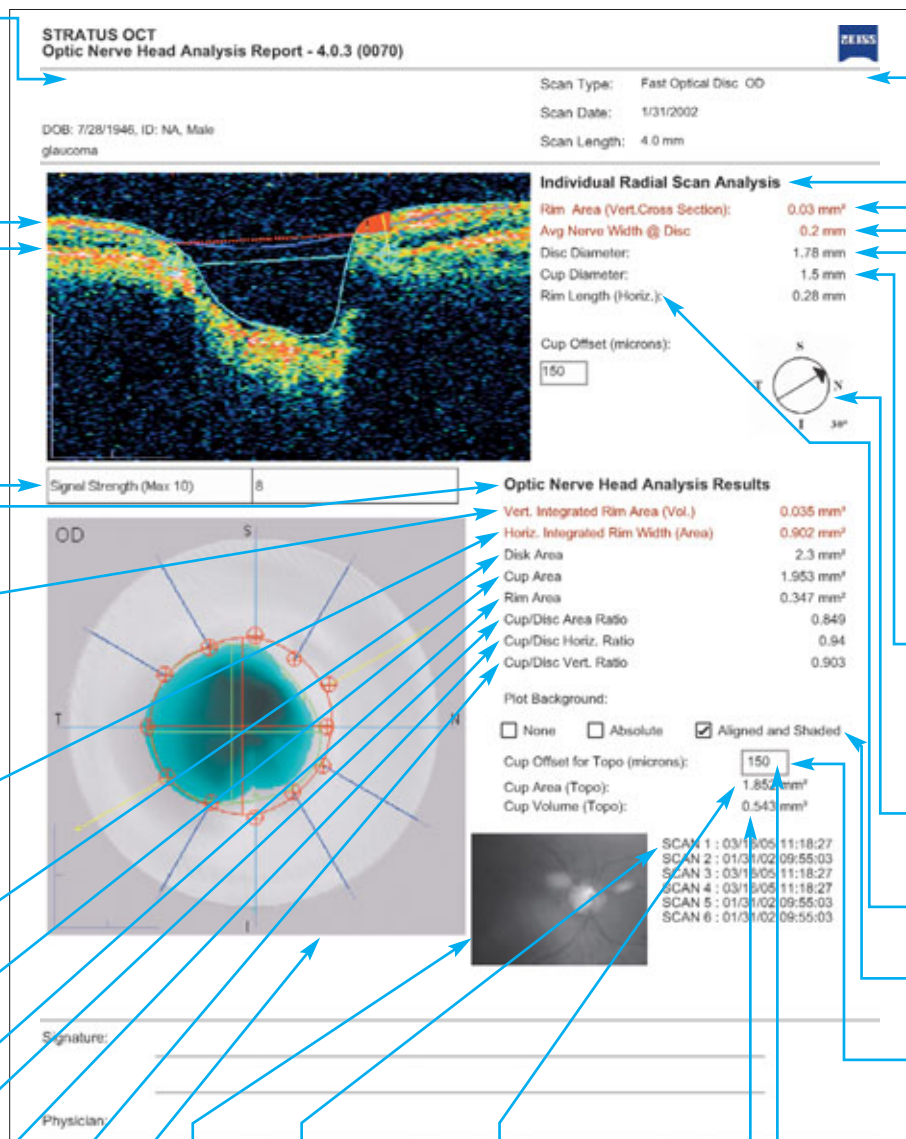
Cup/Disc

Horizontal Ratio

Ratio of the longest horizontal line across the cup to the longest horizontal line across the disc.

Cup/Disc Vertical Ratio

Ratio of the longest vertical line across the cup to the longest vertical line across the disc.



Scan Information

Individual Radial Scan Analysis

Data relates only to the individual scan image displayed.

Rim Area

Indicated with red shading on scan image, this area is bounded by the cup diameter line and a line from the RPE marker to the anterior surface of the disc, at a 90-degree angle to the cup diameter line.

Average Nerve Width@Disc

The average of the nerve bundle widths at the disc on each side. Nerve bundle width indicated by yellow line from RPE marker to anterior surface.

Disc Diameter

Illustrated and measured on a straight line between the 2 RPE markers. Blue line on scan image.

Cup Diameter

Illustrated and measured on a straight line parallel to, and 150 μm anterior to, the disc diameter line. Red on image, green on diagram, this line is adjustable.

Legend

Arrow indicates direction and angle of individual scan displayed in scan image.

Horizontal Rim Length

Disc diameter minus the cup diameter.

Plot Background

There are 3 optional backgrounds; two are similar to a topographic map. Aligned and Shaded (default) provides a shaded relief topographic map and corrects for patient motion. Absolute provides a non-shaded topographic map with no correction for movement. None shows a solid gray background with no appearance of depth.

Cup Offset

Point at which cup diameter is measured. Default placement is 150 μm anterior to the RPE markers; this point is adjustable.

Composite Diagram

Yellow line indicates individual scan selected and displayed above.

Fundus Image

Can be used to verify scan placement.

Scan List

For each of the 6 radial line scans, this indicates the date when the scan was last adjusted and saved.

Cup Area

The area within the green outline on the composite diagram.

Cup Volume

Volume of cup area on the topographic display.

Cup Offset for Topo

Default is 150 μm anterior to disc. Represents edge of blue shading on topographic display - the surface of the cup as if it were filled with water.

RNFL Thickness Average Analysis

Scan Protocol: RNFL 3.4 mm, Fast RNFL 3.4 mm

Used for: Retinal nerve fiber layer thickness assessment and comparison to normative database

Patient Information

RNFL Thickness Chart

Peripapillary RNFL thickness is displayed in TSNIT format. Colored bands demonstrate range of normative data.

Sector Averages

Comparison to normative data in each sector is indicated with stoplight color scheme. Values are displayed numerically.

Quadrant Averages

Comparison to normative data in each quadrant is indicated with stoplight color scheme. Values are displayed numerically.

OD/OS Graph

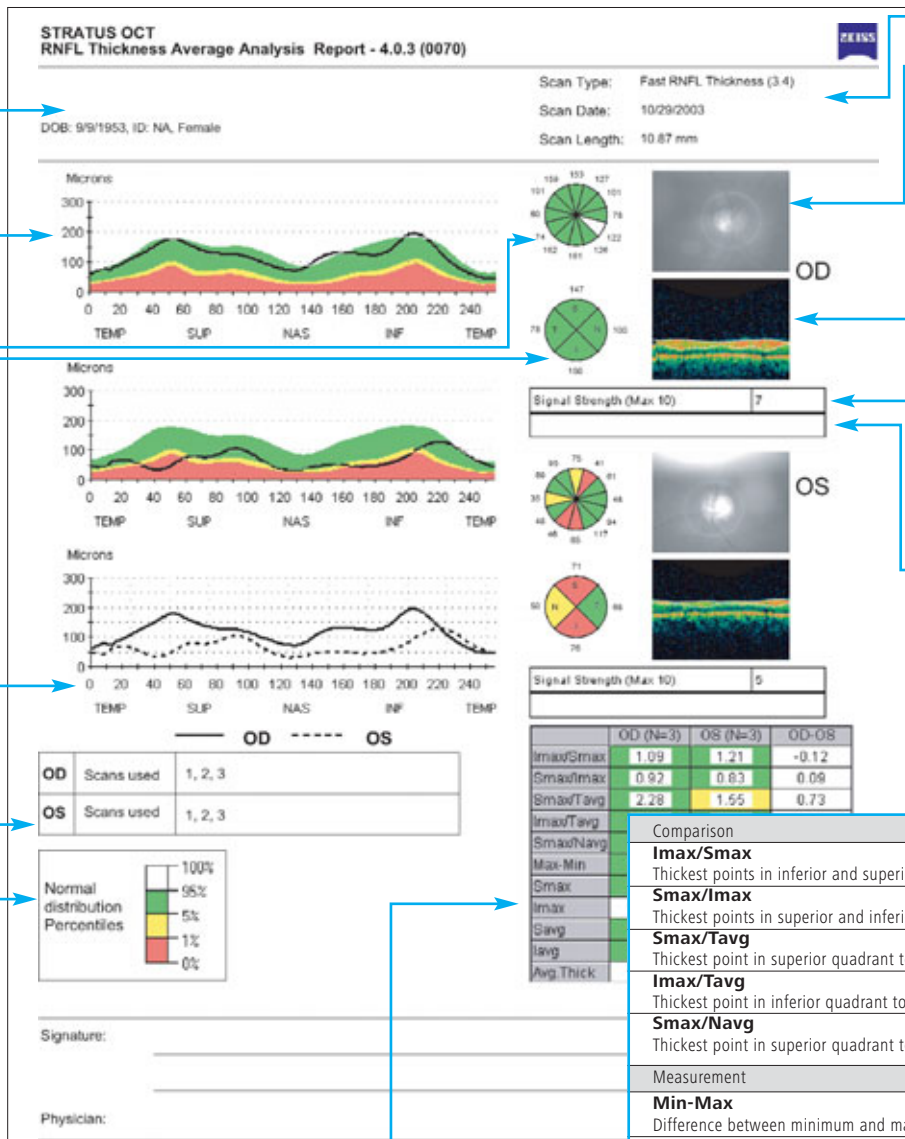
TSNIT line graph displays RNFL thickness in both eyes. Asymmetry may be indicative of glaucomatous loss.

Scans Used

If any of the 3 circular scans has been deselected, analysis might be incomplete and for the fast RNFL scan, normative data will not be displayed.

Legend

Normative data is displayed in stoplight color code, described in detail on inside back cover.



Scan Information

Fundus Image
To verify scan placement.

Scan Image
The image with the lowest signal strength or with a data message will be shown to facilitate operator review.

Signal Strength
Numbers range from 0 (weak) to 10 (strong). Analysis algorithm may fail on scans with low signal strength; therefore, images with a signal strength below 5 should not be used for analysis.

Data Message
"Scan Too High," "Scan Too Low" or "Missing Data" message will be shown, if applicable, regarding placement and completeness of scan.

Tabular Data

For each eye, values are compared to normative data and displayed in stoplight color code, described in detail on inside back cover.

	OD (N=3)	OS (N=3)	OD-OS
I _{max} /S _{max}	1.09	1.21	-0.12
S _{max} /I _{max}	0.92	0.83	0.09
S _{max} /T _{avg}	2.28	1.55	0.73
I _{max} /T _{avg}			
S _{max} /N _{avg}			
Max-Min			
S _{max}			
I _{max}			
S _{avg}			
I _{avg}			
Avg.Thick			

Comparison	Average Ratios
I_{max}/S_{max} Thickest points in inferior and superior quadrants	0.80 – 1.25
S_{max}/I_{max} Thickest points in superior and inferior quadrants	0.77 – 1.25
S_{max}/T_{avg} Thickest point in superior quadrant to average in temporal	1.70 – 3.06
I_{max}/T_{avg} Thickest point in inferior quadrant to average in temporal	1.69 – 3.12
S_{max}/N_{avg} Thickest point in superior quadrant to average in nasal	1.37 – 2.93
Measurement	Average Values
Min-Max Difference between minimum and maximum measurements	96 – 154 μm
S_{max} Thickest measurement in superior quadrant	124 – 189 μm
I_{max} Thickest measurement in inferior quadrant	125 – 194 μm
S_{avg} Average measurement in superior quadrant	97 – 152 μm
I_{avg} Average thickness in inferior quadrant	98 – 156 μm
Average Thickness	82 – 118 μm

Normal distribution, RNFL normative data, Carl Zeiss Meditec.

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Software Version 4.0

RNFL Thickness Serial Analysis

Scan Protocol: Fast RNFL Thickness (3.4), RNFL Thickness (2.27 x disc)

Used for: Comparative analysis of RNFL thickness over time. Can be applied to up to 4 OD and/or 4 OS scan groups

Patient Information

DOB: 7/12/1968, ID: NA, Male

Scan Type: Fast RNFL Thickness (3.4)

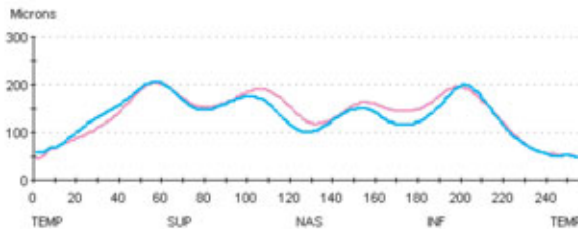
Scan Date: Multiple, See Table

Scan Length: 10.87 mm

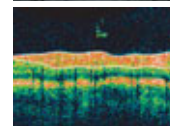
Scan Information

TSNIT Graph

Peripapillary RNFL thickness is displayed in TSNIT format. Colors distinguish lines by scan date.



OD



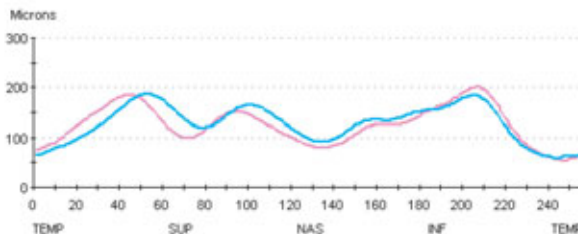
Signal Strength (Max 10) 9

Fundus Image

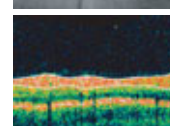
Shows most recent scan. Can be used to verify scan placement.

Scan Image

For most recent scan data, the image with the lowest signal strength or with a data message will be shown to facilitate operator review.



OS



Signal Strength (Max 10) 9

Signal Strength

Numbers range from 0 (weak) to 10 (strong). Analysis algorithm may fail on scans with low signal strength; therefore, images with a signal strength below 5 should not be used for analysis.

Color Legend and Exam Dates

Shows dates of selected scans and corresponding line colors.

Color Legend and Exam Dates		
	OD	OS
First Exam	5/28/2003 (N=3)	5/28/2003 (N=3)
Second Exam	7/16/2005 (N=3)	7/16/2005 (N=3)
Third Exam	NA	NA
Fourth Exam	NA	NA

Data Message

"Scan Too High," "Scan Too Low" or "Missing Data" message will be shown, if applicable, regarding placement and completeness of scan.

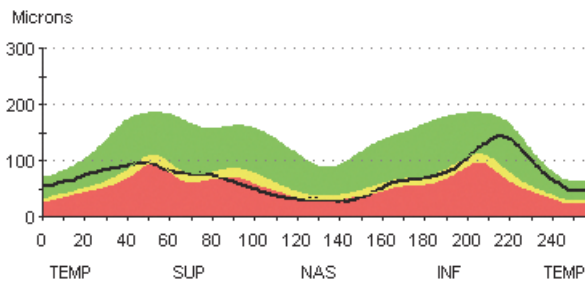
Signature: _____

Physician: _____

Stratus OCT Normative Data.

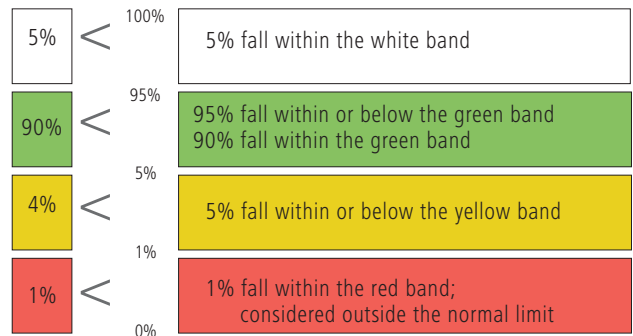
Stoplight Color Scheme

RNFL Normative Data Display

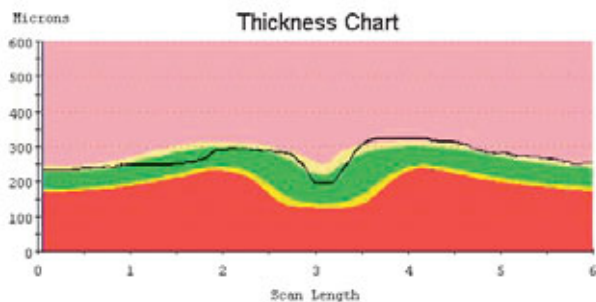


RNFL Normative Distribution

Of the normal population:

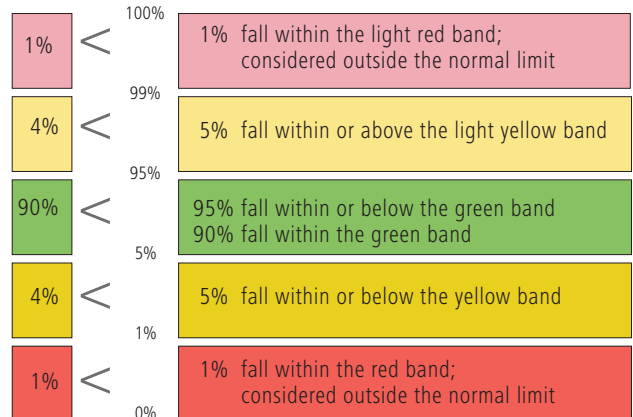


Macula Normative Display



Macula Normative Distribution

Of the normal population:





When your patients entrust you with their eyesight, their vision and your expertise converge. For the world's most advanced surgical and diagnostic solutions in ophthalmology, you can turn to Carl Zeiss Meditec. We're committed to earning your trust anew, every day.

Technical Specifications

Tomographic Imaging

Purpose	Cross-sectional imaging of retina
Signal type	Optical scattering from tissue
Signal source	Superluminescent diode, 820 nm
Optical power	≤750 microwatts at cornea
Longitudinal/Axial resolution	≤10 µm in tissue
Transverse sample size	20 µm in tissue
Scanners	Galvanometric mirror
Scan patterns	Line, circle, concentric rings, radial lines
Scan pixels	Adjustable from (1024 axial x 128 transverse) to (1024 axial x 768 transverse)
Longitudinal (depth) range	2 mm in tissue
Scan rate	400 A scan/sec

Fundus Imaging

Purpose	Fundus alignment, documentation
Signal type	CCD image
Field of view	26° x 20.5°
Viewing method	Flat panel display
Illumination	Near IR/red-free
Internal fixation	32 x 16 LED dot matrix
External fixation	Slit lamp type adjustable blinking LED
Minimum pupil diameter	3.2 mm

Electrical

Power consumption	100 V approx. (±10%), 50/60 Hz, 6.0 A 115 V approx. (±10%), 60 Hz, 6.0 A 230 V approx. (±10%), 50/60 Hz, 3.0 A 700 VA
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Footprint

Patient module	48 inches x 34 inches
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User Features

Processor	2.4 GHz Pentium® IV
Operating system	Windows® 2000
Memory	512 MB

Standards and Approvals

UL 2601-1	
CSA 22.2 No. 601.1	
MDD	

1. Wollstein G, Ishikawa H, Wang J, Beaton SA, Schuman JS. Comparison of three optical coherence tomography scanning areas for detection of glaucomatous damage. *Am J Ophthalmol.* 2005;139(1):39-43.
2. Schuman JS, Wollstein G, Farra T, et al. Comparison of optic nerve head measurements obtained by optical coherence tomography and confocal scanning laser ophthalmoscopy. *Am J Ophthalmol.* 2003;135(4):504-512.

Pentium is a registered trademark of Intel Corp.
Windows is a registered trademark of Microsoft Corp.

Note: All technical specifications are subject to change without notice.

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