



FORUM Glaucoma Workplace 2.0 from ZEISS

Clinical Interpretation Guide



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ZEISS FORUM Glaucoma Workplace 2.0

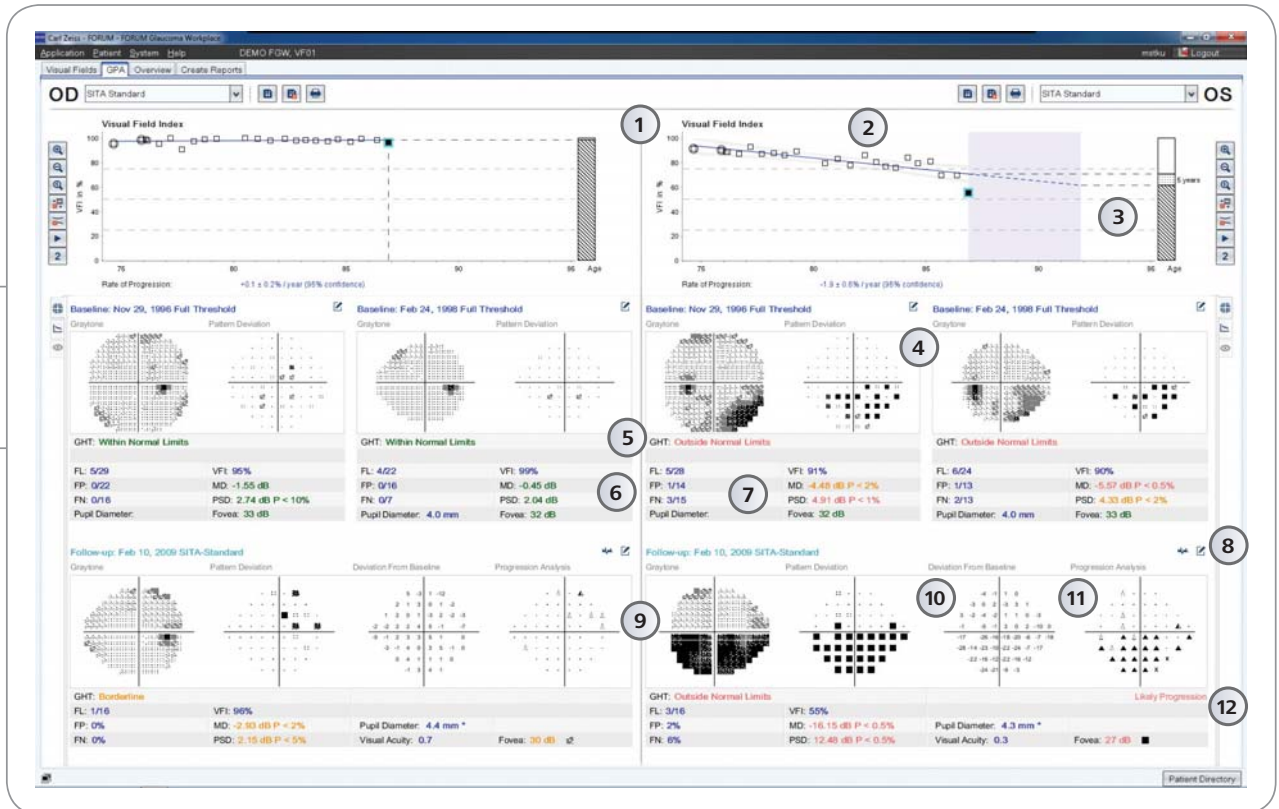
For years, doctors have asked for the operational capability to analyze data from their Humphrey® Field Analyzer (HFA™) using a Mac or PC. They have also requested greater integration of HFA and CIRRUS™ analysis data in a single report. Based on this feedback, ZEISS developed the FORUM® Glaucoma Workplace.

This new workplace application allows doctors to change baselines for Guided Progression Analysis™ (GPA™) and generate HFA reports using a Mac or PC. They can also combine structure and function test data into a single integrated report.

ZEISS FORUM Glaucoma Workplace analysis reports offer qualitative and quantitative information in an easy-to-read format. This interpretation guide explains various areas of each report and the valuable information they provide for a doctor's clinical assessment. The guide is intended to provide basic information only; it is not intended to replace the User Manual.

GPA Summary Report for HFA

The diagnosis and management of glaucoma relies on the assessment of visual field test status and progression. The GPA Summary Report can help estimate the current stage of visual loss and rate of progression, to support the assessment of a patient's risk of future vision loss.



1 VFI Rate of Progression Analysis

Trend analysis of the patient's overall visual field history.

2 VFI Plot

Regression analysis of VFI values and 2- to 5-year projection.

3 VFI Bar

A graphical estimate of the patient's remaining useful vision at the current VFI value along with a 2- to 5-year projection of the VFI regression line if the current trend continues.

4 Baseline Exams

Documents initial visual field status.

5 Glaucoma Hemifield Test (GHT)

Provides a plain language classification of 30-2 and 24-2 test results based upon patterns of loss commonly seen in glaucoma.

6 Reliability Indices

Presented to assist in the evaluation of test reliability – Fixation Loss (FL), False Positive (FP), and False Negative (FN).

7 Global Indices

Three summary indices of visual field status – Visual Field Index (VFI), Mean Deviation (MD), and Pattern Standard Deviation (PSD).

8 Gaze Tracking

To open the gaze tracking graph, click this symbol .

9 Selected Follow-up Visual Field Summary

Report of selected follow-up visual field including VFI, MD, PSD, the Progression Analysis Probability Plot and the GPA alert.

10 Deviation From Baseline Plot

Change in Pattern Deviation compared to baseline.

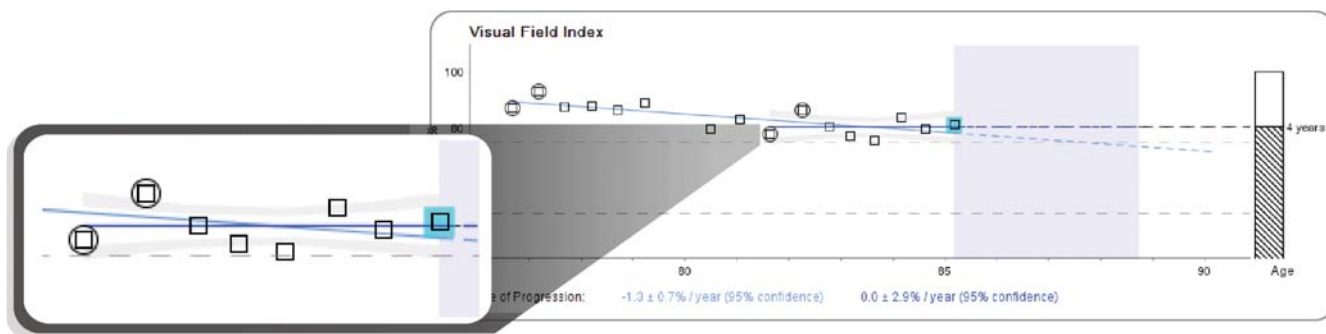
11 Progression Analysis Probability Plot

Shows test points that have changed by statistically significant amount.

12 GPA Alert

A message that indicates whether statistically significant deterioration was noted in consecutive tests.

Understanding the GPA Summary Electronic Report



Dual Baseline

Create a dual baseline showing a patient's original baseline and progression.

GPA uses the Visual Field Index™ (VFI™), a summary measurement of a patient's visual field status expressed as a percent of a normal age-adjusted visual field.

Pioneered by Boel Bengtsson, PhD¹ as a more intuitive assessment of visual function, VFI is designed to better reflect the vision associated quality of life. VFI is center-weighted to better correspond with the distribution pattern of ganglion cells across the retina. It is less affected by cataract and other media changes compared with earlier indices. VFI is used to quantify the rate of progression on the GPA summary screen, and provides an overview of the patient's available visual field history. The VFI is plotted relative to patient age to calculate the rate of functional change over time.

GPA Baseline Exams

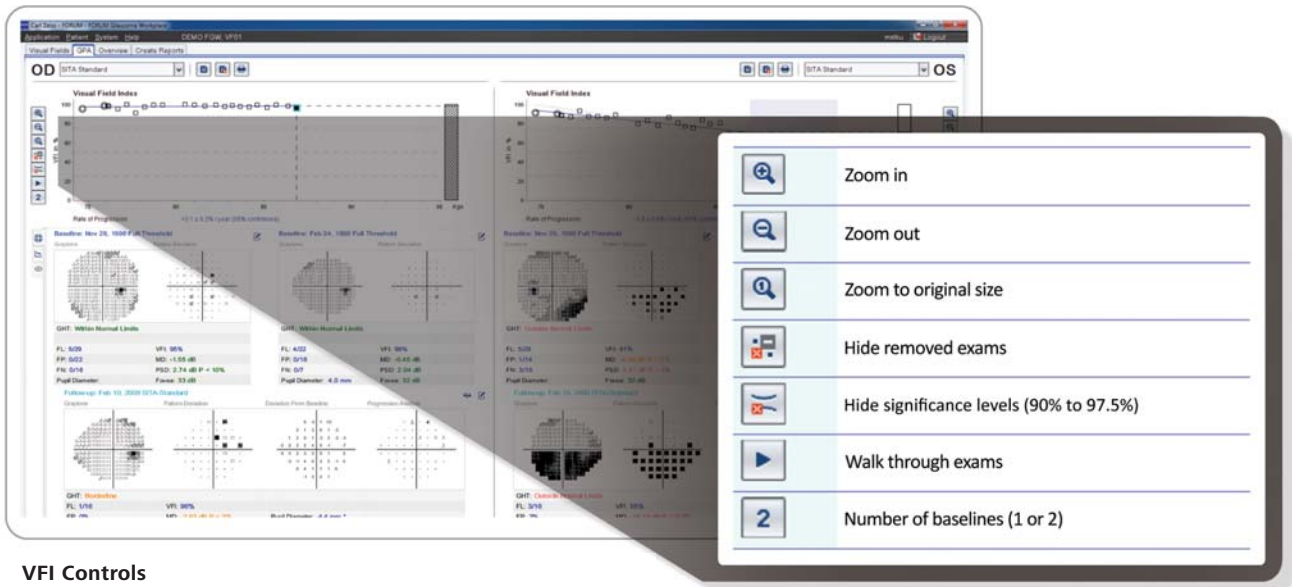
Two baseline exams appear at the top of the GPA summary tab. Graytone and Pattern Deviation Plots are shown for both GPA Baselines, as well as key indices such as VFI, MD and PSD. The software is programmed to automatically choose the oldest two matching exams as the Baseline. However, it is suggested that the user periodically review the computerized selections to verify that they reliably represent the patient's status.

Another feature, GPA with Dual Baselines, allows the user to compare rates of progression before and after a significant change in therapy, such as surgery. The initial selection of a SITA™ Standard or SITA Fast™ Exam determines the exams that will be included in follow-up evaluations. SITA Standard and SITA Fast Exams cannot be combined in the GPA analysis. If a series of Baseline and Follow-up examinations include both 24-2 and 30-2 tests, GPA will analyze all tests as if they are 24-2 tests. GPA is not designed to analyze 10-2 tests.

VFI Plot

In the center of the report, the VFI Plot graphs the VFI values of all exams included in the GPA analysis as a function of the patient's age. When appropriate, the VFI Plot also provides a linear regression analysis of the VFI over time. A minimum of five exams over at least two years must be included in GPA for the linear regression results to be presented.

Note: In glaucoma, the regression line slope may occasionally be positive due to statistical deviation or Learning Effect. In other cases, for instance, neuro-ophthalmic disease, the regression line slope may be positive due to resolution of the disease.



VFI Controls

ZEISS FORUM Glaucoma Workplace enables you to modify the VFI plot display according to your preferences.

VFI Bar

To the right of the VFI Plot is the VFI Bar. The VFI Bar indicates the patient's current VFI value. In addition, when the results of the regression analysis are displayed, the VFI Bar will also graphically indicate a two- to five-year projection of the linear regression line into the future, shown as a broken line. The length of projection is equal to the number of years of HFA data that is available, up to a maximum projection time of five years.

Deviation from Baseline Plot

The deviation from Baseline Plot compares the pattern deviation of the most recent Follow-up test to the average of the pattern deviation values of the two Baseline tests, and indicates changes at each tested point, in dB notation.

Progression Analysis

Probability Plot

The Progression Analysis Probability Plot gives the statistical significance of the dB changes shown in the deviation from Baseline Plot. It compares the changes between the Baseline and Follow-up exams to the inter-test variability typical of stable glaucoma patients² and then shows a plot of point locations, which have statistically significant change.

Points that have changed significantly more than the expected variability are identified with a simple and intuitive set of symbols:

- A **single, solid dot** indicates a point not changing by a statistically significant amount.
- △ A **small open triangle** identifies statistically significant change, i.e., a degree of deterioration expected less than 5% of the time at that location in stable glaucoma patients ($p < 5\%$).
- ▲ A **half-filled triangle** indicates statistically significant deterioration at that point in two consecutive tests.
- ▲ A **solid triangle** indicates significant deterioration at that point in three consecutive tests.
- ✕ An **X** signifies that the data at that point was out of range for analysis. For data that is out of range, GPA cannot determine whether or not the encountered deviation at that point is statistically significant. This occurs mainly with field defects that were already quite deep at Baseline.

GPA Alert

The GPA Alert is a plain language message that indicates whether the EMGT progression criteria were met. The EMGT progression criteria were developed for use in the Early Manifest Glaucoma Trial³. The GPA Alert assists you in recognizing deterioration in consecutive tests. In cases where each of three or more points shows deterioration in at least two consecutive tests, the progression analysis indicates "Possible Progression." In cases where each of three or more points shows deterioration in at least three consecutive tests, the progression analysis indicates "Likely Progression."

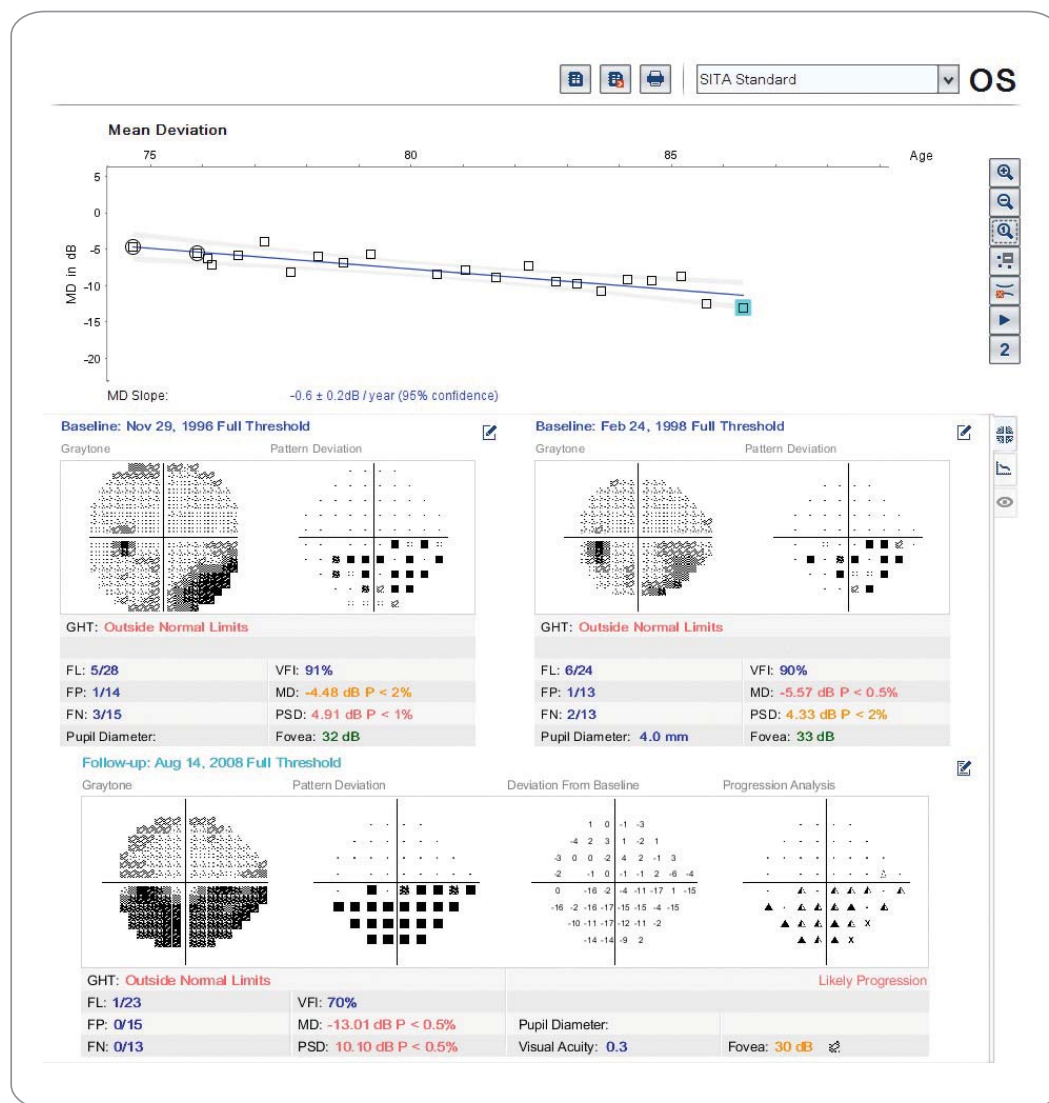
Two Possible GPA Alerts:

1. "Possible Progression"
2. "Likely Progression"

Progression Analysis using Mean Deviation

Working with Mean Deviation (MD) instead of the Visual Field Index (VFI) in the trend analysis

ZEISS FORUM Glaucoma Workplace gives the user the option of performing regression analyses using VFI, MD, or both.



Progression Analysis using Mean Deviation

If five or more fields are analyzed in a progression analysis, and all test results to be analyzed were run with the same strategy, ZEISS FORUM Glaucoma Workplace will automatically perform a linear regression analysis of MD, VFI, or both.

Baseline Exams

Document initial visual field status.

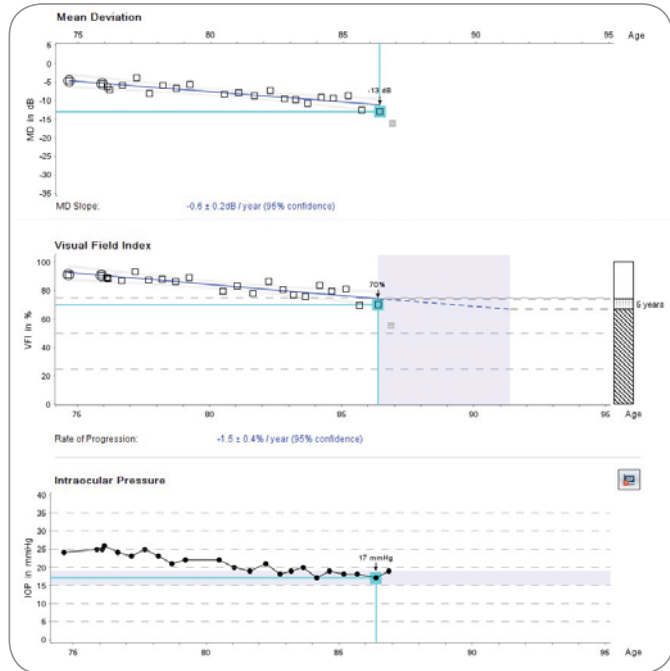
Selected Follow-up Visual Field

Report of selected follow-up visual field including VFI, MD, PSD, the Progression Analysis Probability Plot and the GPA alert.

Additional Features

Intraocular Pressure (IOP)

If IOP values are entered through the HFA or ZEISS FORUM Glaucoma Workplace, the IOP values are displayed in a graphical representation. ZEISS FORUM Glaucoma Workplace will allow the user to compare the graphics for MD, VFI and IOP all in a single report.



Complete Access to all standard HFA Analyses

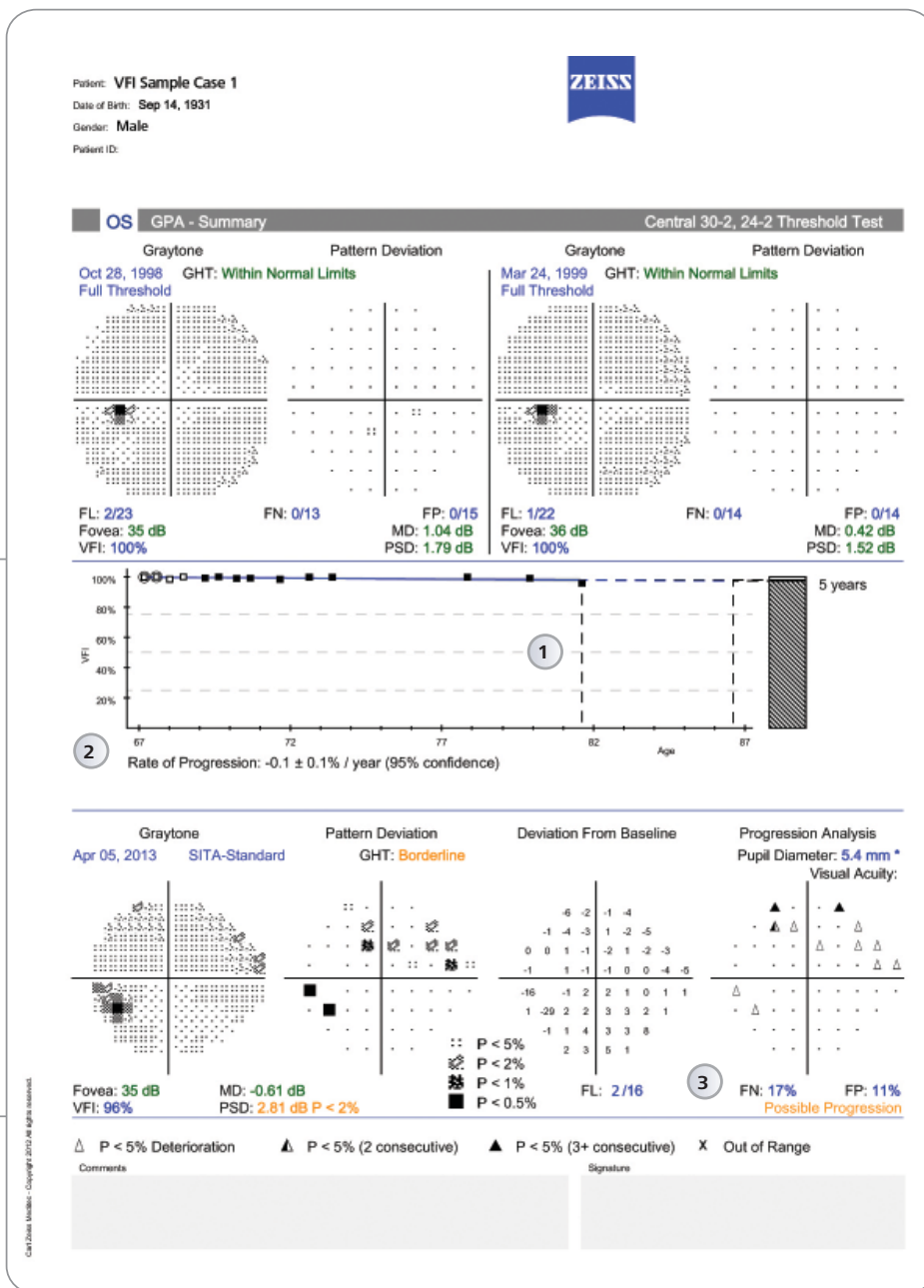
ZEISS FORUM Glaucoma Workplace supports all standard HFA Visual Field Analyses.



GPA Summary Report – Sample Case 1

Possible progression

This is an example of a patient with visual field progression that may be statistically significant but may not be clinically significant. While the event analysis, GPA Alert, indicates "Possible Progression" (3), the measured rate of progression in VFI is only 0.1% per year and the confidence interval on that rate estimate is narrow (2). If the present rate of progression continues, this patient would not seem to be presently at substantial risk of visual disability during his lifetime.

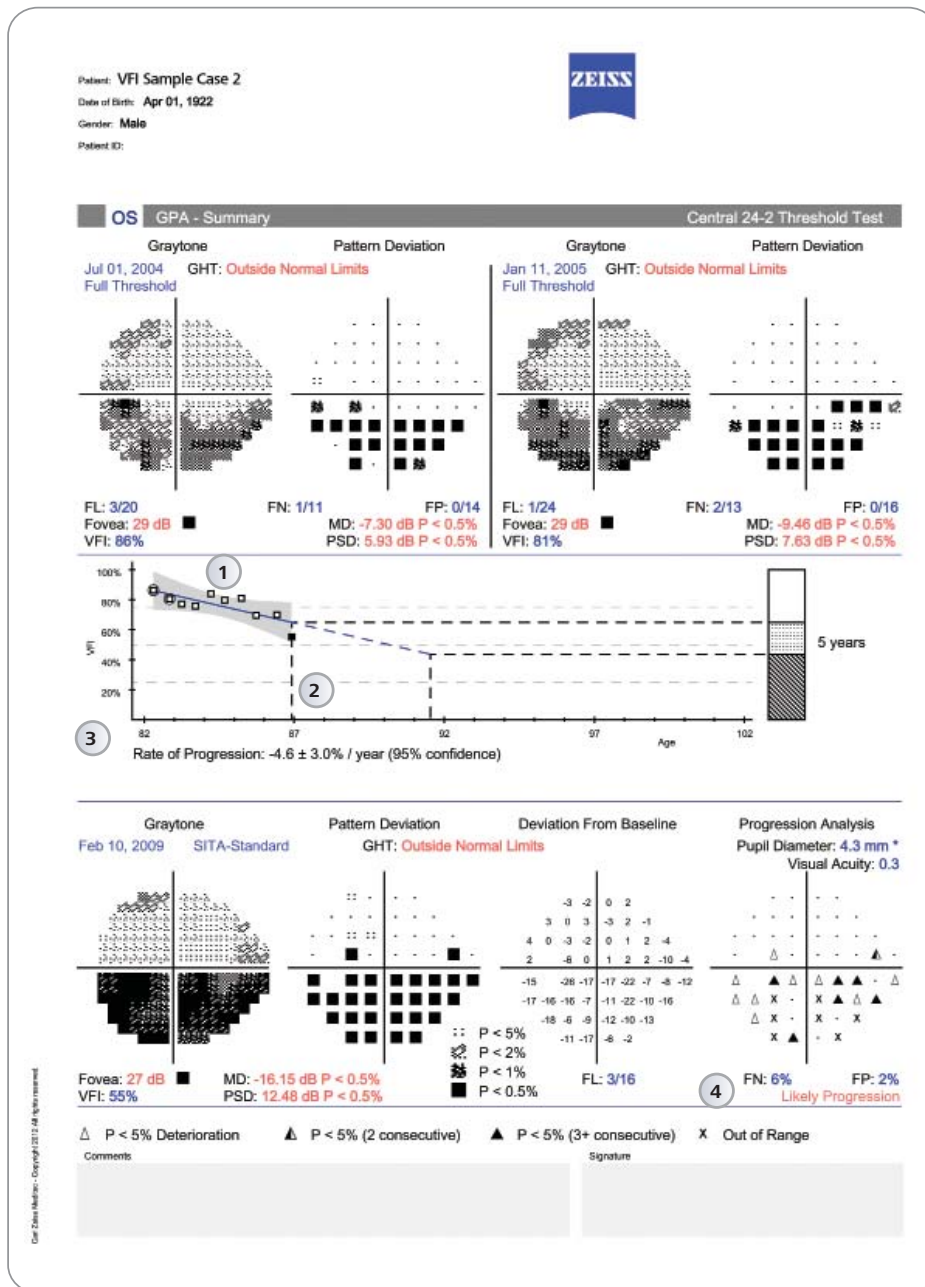


- 1 Patient was 81 years old at the time of the most recent test.
- 2 VFI slope is nearly flat and the confidence intervals are narrow.
- 3 Event analysis (GPA Alert) indicates "Possible Progression".

GPA Summary Report – Sample Case 2

Likely progression

This is an example of a patient with statistically significant and possibly clinically significant progression. This patient's visual field loss is measurably progressing based upon the VFI slope and the GPA alert (3 and 4 below). The patient may be at significant risk of further visual loss in the future. These findings can be weighed in the context of patient life expectancy and also relative to the possible risks associated with any contemplated escalation in treatment.



- 1 Gray zone indicates the 95% confidence interval (the area between the 2.5 and 97.5 percentile).
- 2 Patient was 86 years old at the time of the most recent test.
- 3 VFI slope is pronounced, showing a decrease of almost 23% over the past 5 years.
- 4 Event analysis (GPA Alert) indicates "Likely Progression".



// INTEGRATION MADE BY ZEISS

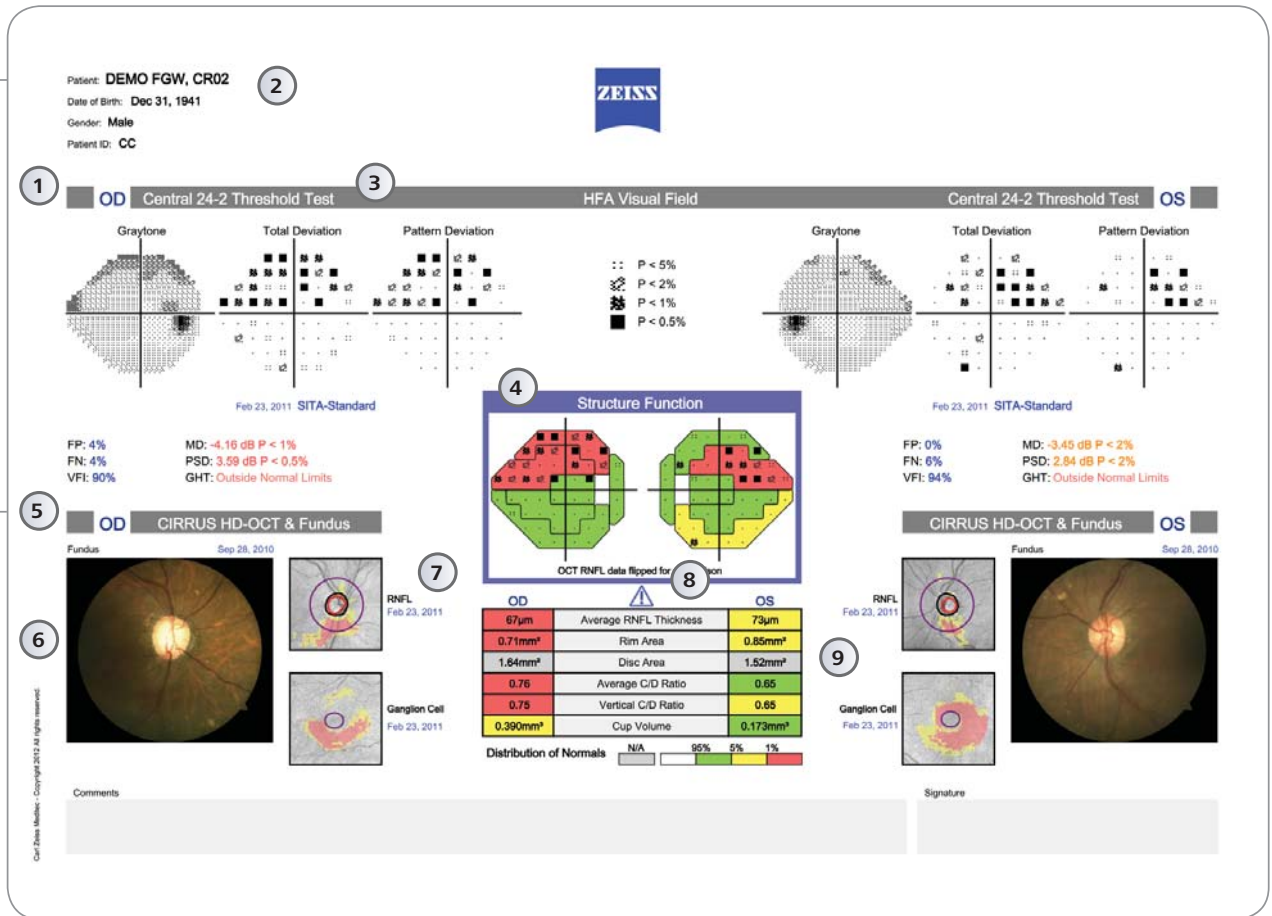
The Combined Report presents a clinical summary of patient status in a simple and easy-to-understand format.

The 24-2 / 30-2 and RNFL Combined Report presents a clinical summary of patient status, as derived from the HFA and the CIRRUS OCT analyses. The report is displayed in a simple, easy-to-understand format. It maps the anatomical relationship between visual field test points in the Humphrey 24-2 or 30-2 test pattern and regions of the Retinal Nerve Fiber Layer (RNFL). This mapping was developed based on the work of Dr. David F. Garway-Heath, et al. ⁴

In addition, optic nerve head parameters are compared to normative limits.

The Combined Report consists of two pages. The first page summarizes the combined, data from the HFA and CIRRUS, while the second page provides further detail. Depending on the type of test data available, different Combined Reports can be generated. These may include fundus photos and ganglion cell analyses.

24-2 / 30-2 and RNFL Combined Report



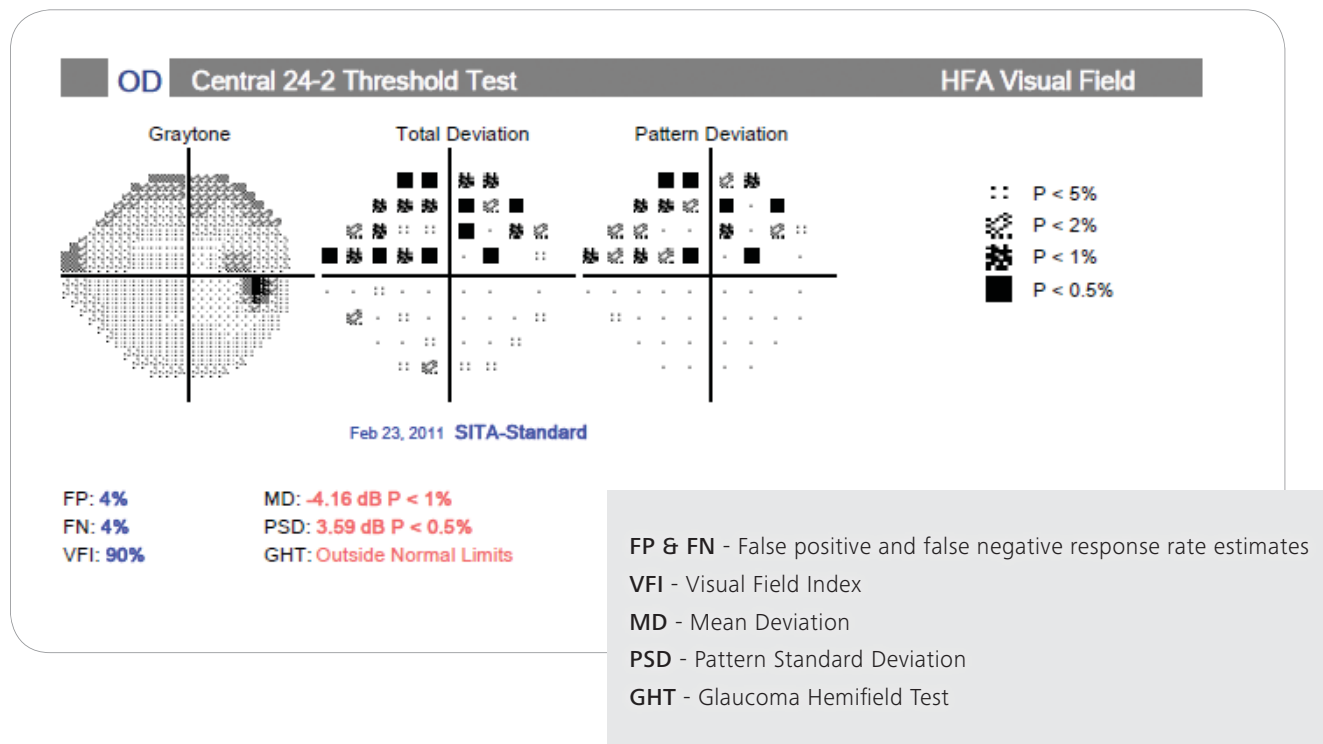
- ① HFA Test Data
- ② Patient Information
- ③ Visual Field Test Type
- ④ HFA and CIRRUS Combined Structure Function Section

- ⑤ CIRRUS OCT Exam and fundus photo section
- ⑥ Optional fundus photo.
- ⑦ RNFL and Ganglion Cell Thickness Deviation Maps (GCL + IPL)
- ⑧ Symbol appears ▲ if at least one parameter is near a normative limit.
- ⑨ CIRRUS Data Table with ONH Summary and RNFL Parameters

Elements of 24-2 / 30-2 and RNFL Combined Report

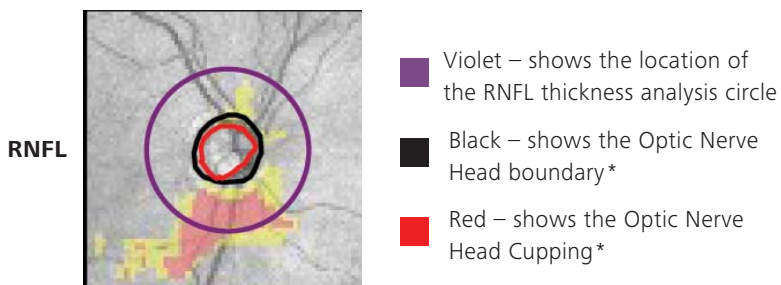
HFA Test Data

Results of the HFA test are shown in three formats: Graytone Plot, Total Deviation and Pattern Deviation Probability Maps.



Optic Nerve Head Analysis and RNFL Deviation Map

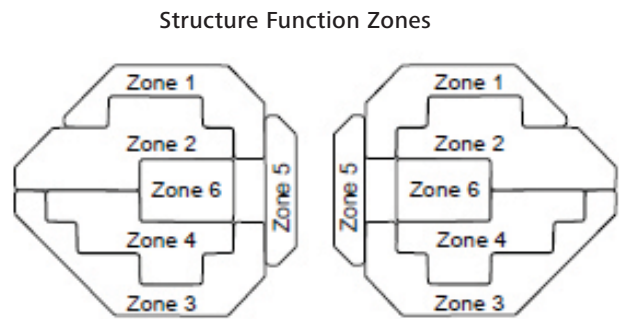
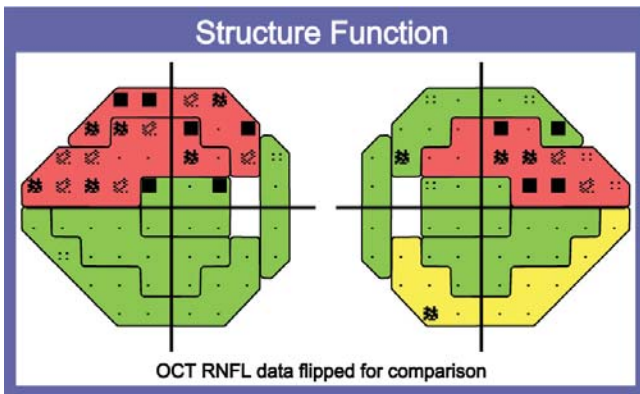
Comparison display of the Retinal Nerve Fiber Layer (RNFL) thickness with normative data. Areas of RNFL that are outside normal limits are shown in yellow (P < 5%) and red (P < 1%).



* Based on CIRRUS ONH Analysis

HFA and CIRRUS Combined Structure Function Section

The Structure Function Combined Display divides the visual field into six sectors based upon the typical patterns of retinal nerve fibers emanating from the optic nerve. This mapping was based on the publication of Dr. Garway-Heath, et al.⁴





The OCT display is flipped along the horizontal axis to correspond to the orientation of the Visual Field data.

The mean RNFL thickness in each of the six visual field sectors is compared to age-corrected normal values, with yellow indicating deviations from normal that are statistically significant at P < 5% and red indicating deviations significant at P < 1%. Green indicates areas where RNFL thickness is within normal limits.

ONH Summary & RNFL parameters

If normative data are applicable, the table cells (except for Disc Area) are color-coded according to the distribution of normal values, in the RNFL and ONH normative databases.

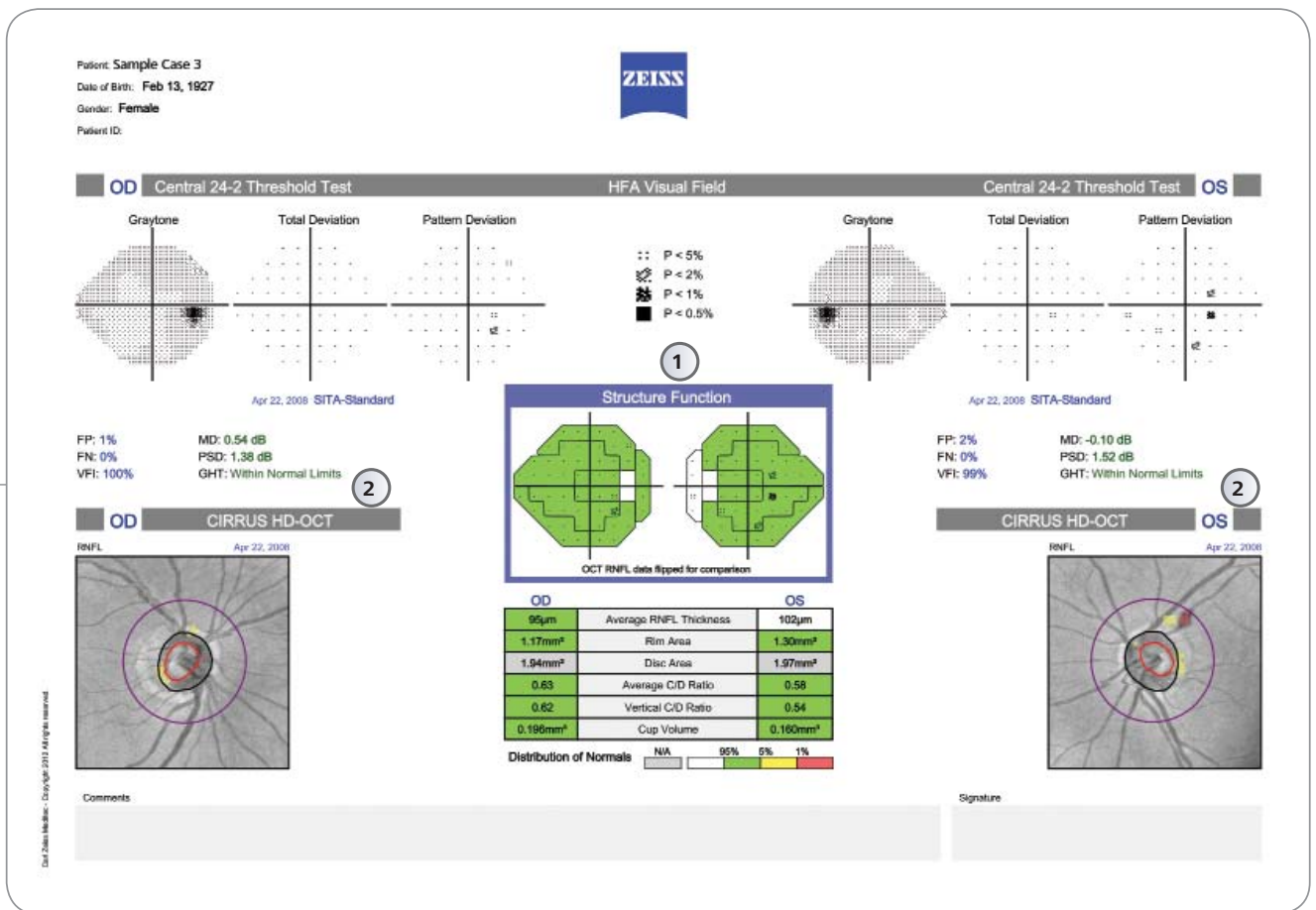
OD		OS
67µm	Average RNFL Thickness	73µm
0.71mm ²	Rim Area	0.85mm ²
1.64mm ²	Disc Area	1.52mm ²
0.76	Average C/D Ratio	0.65
0.75	Vertical C/D Ratio	0.65
0.390mm ³	Cup Volume	0.173mm ³

 The triangle with an exclamation mark is displayed if at least one parameter in the table is close to the classification boundary of the normative data. Details can be accessed on a separate page / screen.

24-2 and RNFL Combined Report – Sample Case 3

Within Normal Limits

This is an example of a patient whose visual field and OCT findings are Within Normal Limits. The Structure Function combined display indicates that measured RNFL thickness is within normal limits (green). The HFA Glaucoma Hemifield Test, MD, and PSD all are within normal limits for both eyes.

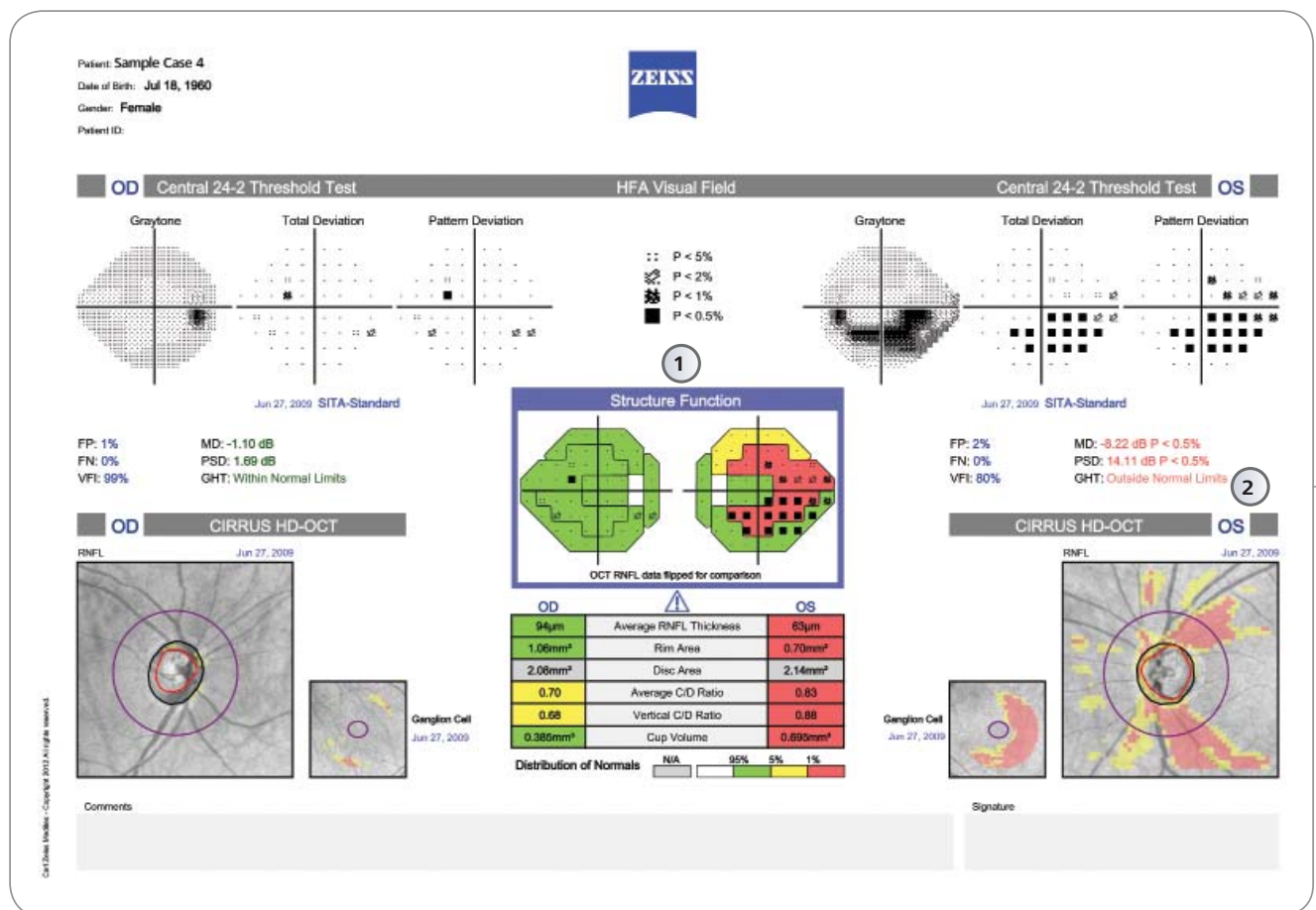


- ① HFA and CIRRUS Combined Structure Function Section
- ② Within Normal Limits

24-2 and RNFL Combined Report – Sample Case 4

Outside Normal Limits

In this example, the patient's left eye findings appear to be Outside Normal Limits. There appears to be significant overlap between RNFL and HFA findings.

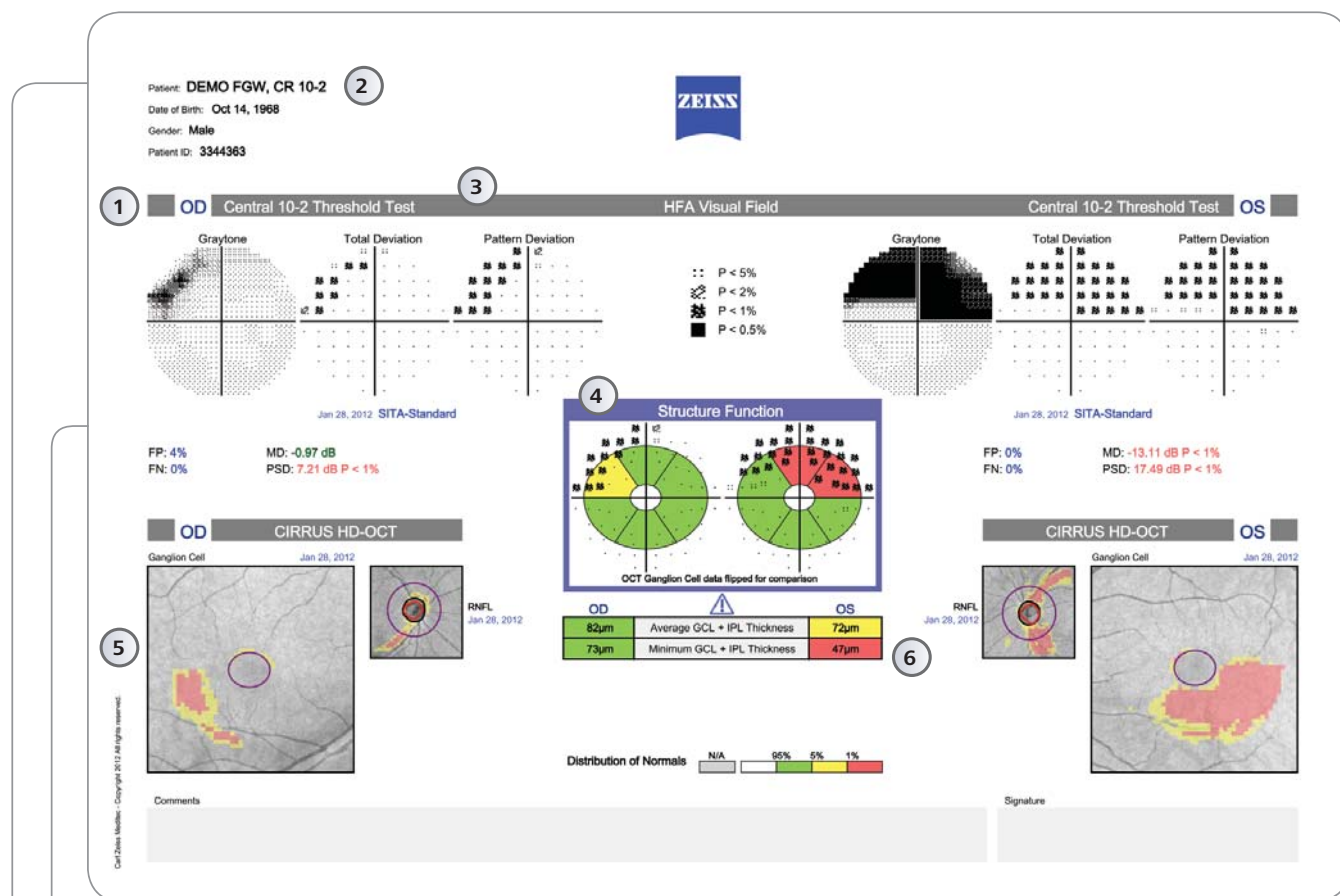


- ① HFA and CIRRUS Combined Structure Function Section
- ② Outside Normal Limits

10-2 and GCA Combined Report

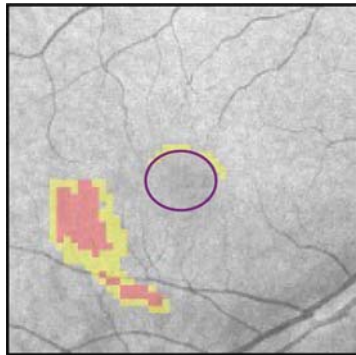
The 10-2 and GCA Combined Report presents a clinical evaluation of test results derived from both the HFA and the Macular Ganglion Cell Analysis of the CIRRUS OCT. The report presents structural and functional measures of glaucomatous damage, in order to facilitate comparison of visual field findings to observed retinal ganglion cells losses. This combination of visual field and OCT probability information was suggested by Hood & Raza (2011).⁵ For accurate registration, the visual field points must be positioned to take into consideration the displacement of ganglion cells near the fovea. The displacement in this presentation corresponds to that in Hood DC, Raza AS, Method for comparing visual field defects to local RNFL and RGC damage seen on frequency domain OCT in patients with glaucoma. *Biomed Opt Express*. 2011 Apr 5;2(5):1097–1105 and is based upon a study by Drasdo, Millican, Katholi, and Curcio (2007).⁶

The 10-2 and GCA Combined Report consists of two pages, the first page includes the combined, overlaid data from the HFA and CIRRUS, while the second page provides further details.



Elements of the 10-2 and GCA Combined Report

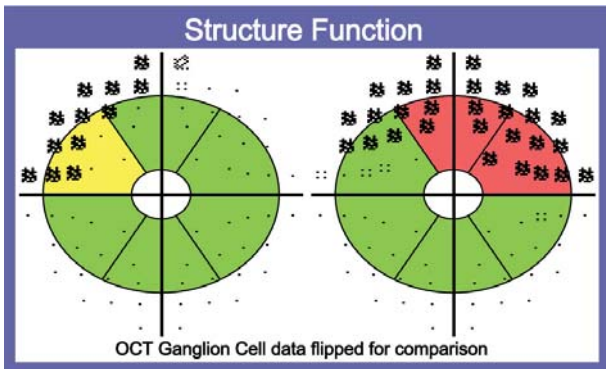
**Ganglion Cell
Cell**



GCA Report Deviation Map

The Ganglion Cell Thickness Deviation Map shows a comparison of the Ganglion Cell Layer and Inner Plexiform Layer (GCL + IPL) thickness to the normative data.

- **Violet** – shows the fovea
- **Red** – below the first percentile of the normative data
- **Yellow** – below the 5th percentile of the normative data



Three sectors are located in the upper region and three are located in the lower region. The fovea is indicated at the center.

HFA and CIRRUS OCT Combined

Structure Function Section

Comparison of structure and function in the macular area requires displacement of the visual field test locations to match the respective locations on the Ganglion Cell Analysis and is based on the publication of Hood DC, Raza AS.⁵

The GCA sectors are color-coded according to the normative database. The Pattern Deviation map from the HFA exam is overlaid on the GCA sector display. As in the 24-2/30-2 RNFL Combined Report, the OCT display is flipped along the horizontal axis to correspond to the orientation of the visual field data.

OD		OS
82µm	Average GCL + IPL Thickness	72µm
73µm	Minimum GCL + IPL Thickness	47µm

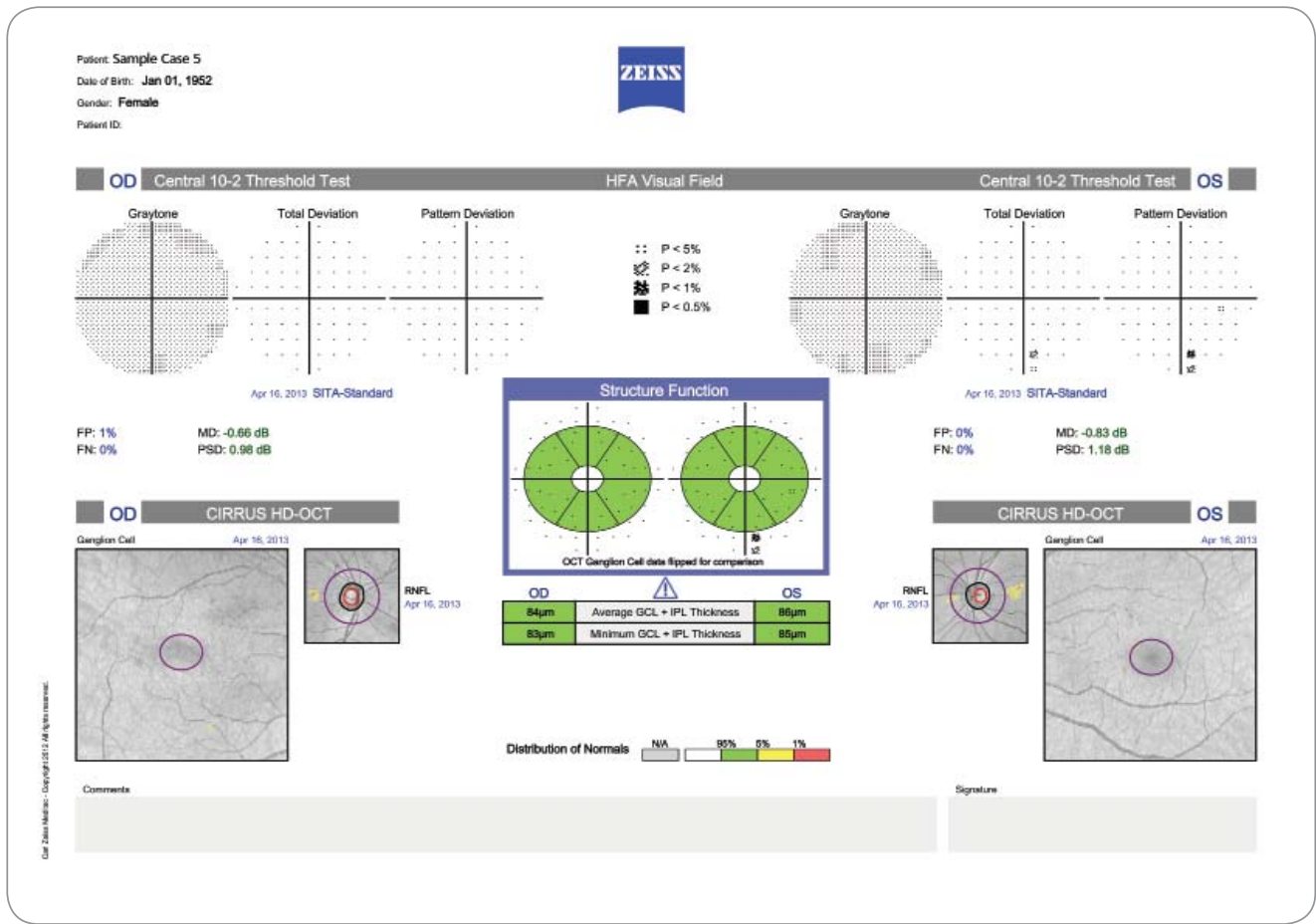
GCL plus IPL Thickness Parameters

A triangle with an exclamation mark is displayed on the table if at least one parameter is close to a significance limit of the normative data. This indicates that the color could change if the test is repeated simply because of typical measurement variability.

10-2 and GCA Combined Report – Sample Case 5

Within Normal Limits

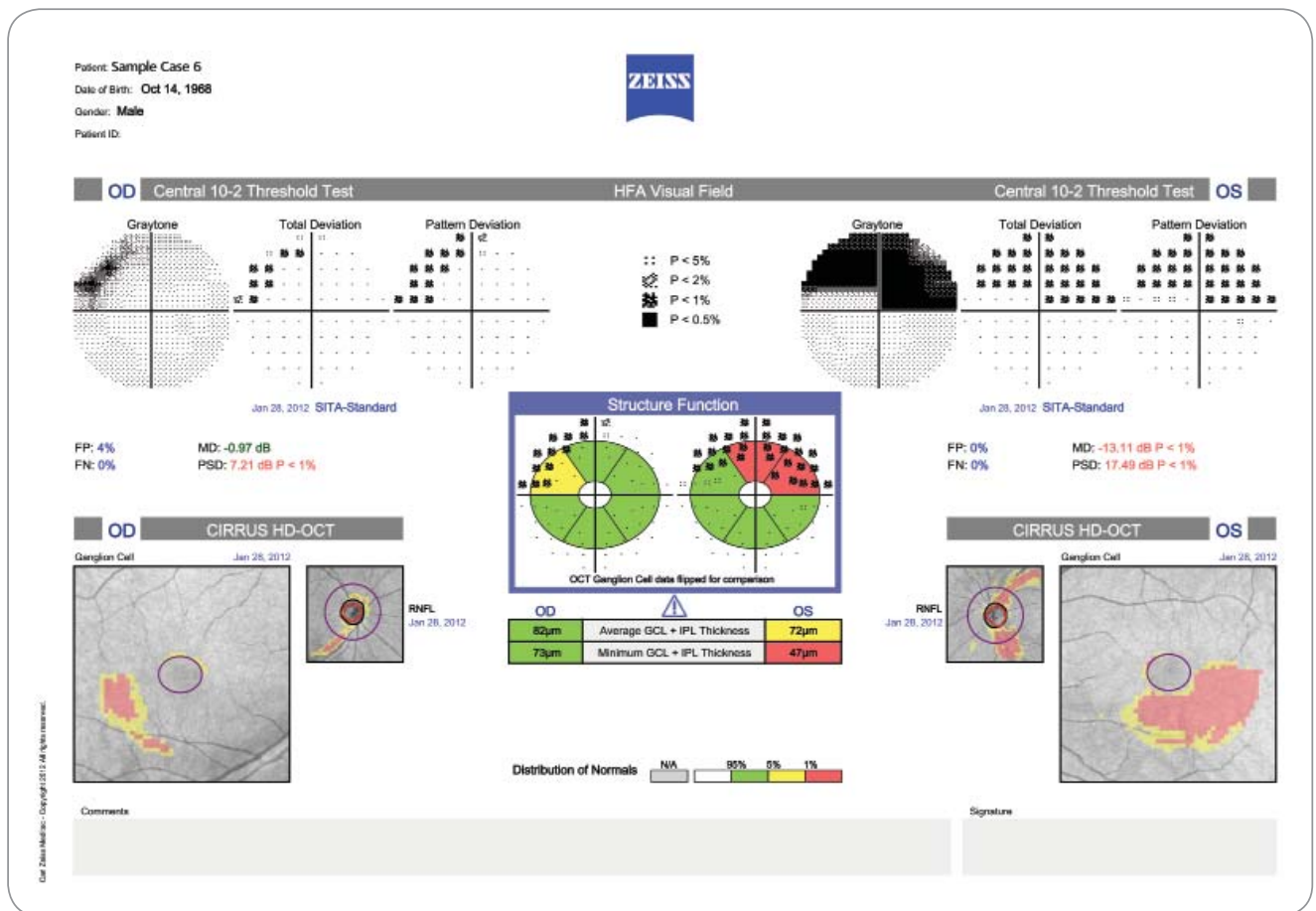
In this example, the patient's eye findings appear to be Within Normal Limits. The ganglion cell and RNFL deviation maps show no significant areas outside normal limits. The Structure Function combination display and the average and minimum GCL findings show no areas of concern. The only finding not perfectly within normal limits is a small area in the left eye's lower 10-2 visual field, where two test point locations have been found to be outside normal limits. In the absence of confirmatory findings or risk factors in the present examination, this area of the visual field might best be noted and considered in subsequent follow-up examinations.



10-2 and GCA Combined Report – Sample Case 6

Outside Normal Limits

In this example, the patient's left eye findings appear to be Outside Normal Limits. The Structure Function box indicates that two GCA sectors for the left eye are flagged at the 1% significance limit (red). The Pattern Deviation Probability Plot from the HFA shows much of the superior visual field flagged at the $P < 1\%$ significance level. The right eye shows one sector of ganglion cell thinning that is significant at the $P < 5\%$ level. This yellow area corresponds to a number of pattern deviation points flagged at the $P < 1\%$ level in the visual field.






// TRUST
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Normative Data Details*

Expected OCT measurement variability may impact normative database color-coding. If the true value is near a normative significance limit, then it is possible that the color code could vary from exam to exam simply due to typical measurement variability, without representing an actual change in the condition of the patient.⁷ When at least one parameter is close enough to a normative limit that the color

coding might change due to expected measurement variability, then this sign  is displayed.

The normative data detail report displays the parameters of the analysis in the units measured and as a percentile relative to the normative database. In addition, the report displays each result *minus* the expected variability and also the same result *plus*

the expected variability, together with the corresponding percentiles. Each of these measurements is presented with the appropriate normative database color code.

**Normative Data Details are only available for the Diversified Normative Database. It is currently not available for the Asian Normative Database.*

Normative Data Details

1 Patient: DEMO FGW, CR02
 Date of Birth: Dec 31, 1941
 Gender: Male
 Patient ID: CC



OD Normative Data Details OS

2

ONH Parameters	Value	Percentile Value	Value minus Reproducibility Limit	Percentile Value	Value plus Reproducibility Limit	Percentile Value
Rim Area	0.71mm ²	<1%	0.53mm ²	<1%	0.88mm ²	2%
Average C/D Ratio	0.76	<1%	0.69	3%	0.83	<1%
Vertical C/D Ratio	0.75	<1%	0.67	3%	0.83	<1%
Cup Volume	0.39mm ³	2%	0.36mm ³	2%	0.42mm ³	<1%

ONH Parameters	Value	Percentile Value	Value minus Reproducibility Limit	Percentile Value	Value plus Reproducibility Limit	Percentile Value
Rim Area	0.85mm ²	2%	0.68mm ²	<1%	1.03mm ²	14%
Average C/D Ratio	0.65	6%	0.59	15%	0.72	<1%
Vertical C/D Ratio	0.65	2%	0.57	13%	0.74	<1%
Cup Volume	0.17mm ³	11%	0.14mm ³	18%	0.20mm ³	9%

3

RNFL Parameters	Value	Percentile Value	Value minus Reproducibility Limit	Percentile Value	Value plus Reproducibility Limit	Percentile Value
Average RNFL Thickness	86.53µm	<1%	62.73µm	<1%	70.33µm	2%
Zone 1	57.66	<1%	45.57	<1%	69.75	6%
Zone 2	57.87	<1%	45.47	<1%	70.27	<1%
Zone 3	77.34	13%	65.93	4%	88.75	28%
Zone 4	103.42	19%	92.51	7%	114.33	37%
Zone 5	68.96	39%	62.14	19%	75.79	59%
Zone 6	50.34	15%	46.40	9%	54.28	29%

RNFL Parameters	Value	Percentile Value	Value minus Reproducibility Limit	Percentile Value	Value plus Reproducibility Limit	Percentile Value
Average RNFL Thickness	73.31µm	4%	69.51µm	2%	77.11µm	9%
Zone 1	72.06	8%	59.97	2%	84.15	21%
Zone 2	73.19	<1%	60.79	<1%	85.58	2%
Zone 3	68.49	5%	57.08	<1%	79.90	16%
Zone 4	109.73	28%	98.82	14%	120.65	50%
Zone 5	70.94	44%	64.12	23%	77.76	66%
Zone 6	63.05	63%	59.11	46%	66.99	75%



⚠ At least one parameter is close to a normative limit that may change the color coding on a re-scan.




- 1 Patient Information
- 2 Exam Details
- 3 Normative Data tables
- 4 Identification of OCT Zones according to the Garway-Heath publication
- 5 Color code of the measurement values within the distribution of the normal values



Normative Databases

CIRRUS HD-OCT RNFL and ONH Normative Databases

The normative databases use a color code to show distribution in percentiles. This allows the user to evaluate the measurement results in comparison to normal limits. The ONH and RNFL OU Analysis helps identify structural characteristics that may be of clinical concern. It compares the measured RNFL thickness and optic nerve head findings to age-matched data in the CIRRUS Normative Databases (ND)⁷.

Measurement	Matched to Normal Based On:	Gray	White	Green	Yellow	Red
RNFL						
Average RNFL Thickness, RNFL Summertry, RNFL-Clock Hours, RNFL Quadrants, RNFL Thickness (graph)	Age	Gray shading does not apply to RNFL measurements.	The thickest 5% of measurements fall in the white area (white > 95%).	90% of measurements fall in the green area (5% < green < 95%).	The thinnest 5% of measurements fall in the yellow area or below (1% < yellow < 5%).	The thinnest 1% of measurements. Measurements in red are considered outside normal limits (red < 1%).
Optic Nerve Head						
Rim Area and Neuroretinal Rim Thickness (graph)	Disc Area and Age	ONH Normative Database is not applicable if: 1) The disc area is larger than 2.5 mm ² or smaller than 1.33 mm ² or 2) the Average or Vertical C/D Ratio is below 0.25, or 3) the ONH Normative Database license has not been activated.	The largest 5% of measurements fall in the white area (white > 95%).	90% of measurements fall in the green area (5% < green < 95%).	The smallest 5% of measurements fall in the yellow area or below (1% < yellow < 5%).	The smallest 1% of measurements. Measurements in red are considered outside normal limits (red < 1%).
Average C/D Ratio, Vertical C/D Ratio, Cup Volume			The smallest 5% of measurements fall in the white area (white > 95%).	90% of measurements fall in the green area (5% < green < 95%).	The largest 5% of measurements fall in the yellow area or below (1% < yellow < 5%).	The largest 1% of measurements. Measurements in red are considered outside normal limits (red < 1%).

 Note: For patients under 18 years old, the legend and color coding is not displayed. Data was not collected from patients under 18 years old.

 There is measurement variability for the retinal nerve fiber layer and optic nerve head parameters which may impact the normative database color coding. If the true value is near the limit of what the software uses to determine the normative database color code, then it is possible that the color code could vary from exam to exam. If at least one parameter is near a normative limit, the following symbol appears: . More details on measurement variability can be found under "Appendix M: CIRRUS: Repeatability and Reproducibility of GCA and ONH Parameters".

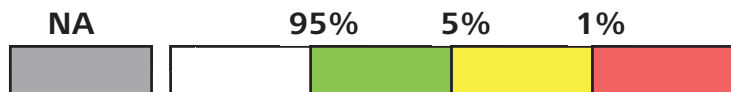
GCA Normative Database

The CIRRUS HD-OCT GCA normative database was created using data from subjects deemed representative of a normal population. To establish reference values, scans acquired as part of the CIRRUS HD-OCT Macular Thickness database were analyzed using a segmentation algorithm that identifies the thickness of the combined ganglion cell, and inner plexiform layers.

The CIRRUS HD-OCT Normative Databases use the following color code::

- Red: < 1%
- Yellow: 1% < yellow < 5%
- Green: 5% < green < 95%
- White: > 95%

Distribution of Normals



¹ Bengtsson B, Heijl A. A visual field index for calculation of glaucoma rate of progression. *Am J Ophthalmol*, Feb 2008; 145(2):343-53.

² Arnalich-Montiel F, Casas-Llera P, Muñoz-Negrete FJ, Rebolleda G. Performance of glaucoma progression analysis software in a glaucoma population. *Graefes Arch Clin Exp Ophthalmol*, Mar 2009;247(3):391-7. Epub 2008 Nov 4.

³ Leske MC, Heijl A, Hyman L, Bengtsson B. Early Manifest Glaucoma Trial: design and baseline data. *Ophthalmology*, Nov 1999;106(11):2144-53.

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⁷ Normative Databases are optional features of CIRRUS HD-OCT that may not be available in all countries. If the feature is available in your country and it is not activated, please contact your local representative of Carl Zeiss Meditec for assistance.



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