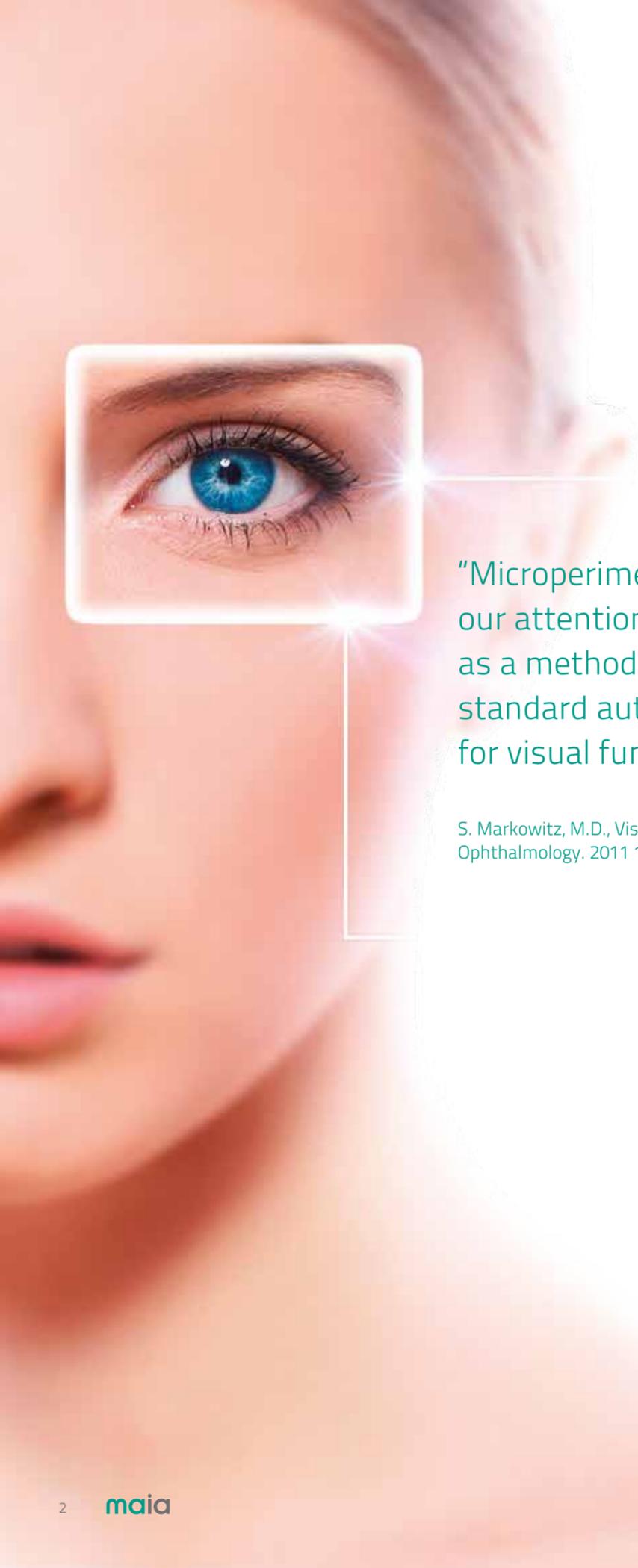


maia

Macular Integrity Assessment



The New Frontier of Microperimetry



“Microperimetry is attracting our attention more and more as a method that is superior to standard automated perimetry for visual function assessment.”

S. Markowitz, M.D., *Visual function and Glaucoma, Ophthalmology*. 2011 118:2528-9.

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centervue

Company Profile

CenterVue designs and manufactures highly automated medical devices for the diagnosis and management of ocular pathologies, including those that represent the leading causes of blindness.

Our goal is to design Smartly Simple devices and to provide high-value services that enable Eye Care Specialists, via early disease detection capabilities, to preserve patients vision and positively impact their quality of life.

CenterVue is headquartered in Padova, Italy, with the US branch in San Jose, California. CenterVue is present in over 70 countries with its distribution network.

“Visual acuity is unable to represent the functional impact of neovascular or atrophic AMD on daily-life activities. Limited information about retinal fixation, and presence and density of central scotoma in these patients is available. Conventional visual field examination is inadequate for the accurate functional evaluation when foveal function is compromised [...] Automatic microperimetry may overcome this limitation.”

Midena E. et al., Fixation pattern and macular sensitivity in eyes with subfoveal choroidal neovascularization secondary to age-related macular degeneration. A microperimetry study; Seminars in Ophthalmology 2004, Vol. 19, Nos. 1–2, pp. 55–61.

Microperimetry

Microperimetry is a technology that allows concurrent analysis of structural and functional aspects of the retina. It combines fundus imaging, retinal sensitivity mapping and fixation analysis in one exam and has been used for over a decade as a powerful tool to detect, describe and follow-up pathologies affecting the macular area.

Its great advantage is its ability to track patients' fixation activity while measuring visual field, hence eliminating errors caused by fixation losses.

Fixation assessment is unique to microperimetry and ensures correlation between microperimetric outcomes and subjective perception of visual quality.

Presenting Maia

MAIA represents the latest advance in confocal microperimetry. Retinal images are acquired by Scanner Laser Ophthalmoscopy (SLO). An eye tracker allows accurate, real-time compensation of eye movements. Luminance levels are compliant with existing standards (1000 asb.). MAIA is highly automated, very easy to use, non mydriatic and combines the best aspects of its predecessors.

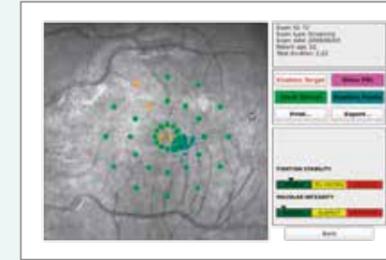
Similarly to Standard Automated Perimetry (SAP), MAIA measures light sensitivity of the retina by projecting Goldmann III stimuli over different retinal locations within the field of view. The main difference and great advantage over SAP is that retinal sensitivity is measured while simultaneously imaging the retina in real time. Retinal images, created by SLO technology, are processed by an eye tracker to calculate and compensate eye shifts (fixation losses) occurring during visual field measurement, in both physiological and pathological conditions. Fixation analysis is the second, fundamental outcome of Maia eye tracker.

MAIA performs different types of microperimetry tests with supra and full-threshold strategies, and follow-up tests to monitor functional progression. Each exam provides a measure of retinal sensitivity and fixation analysis (stability and position of the Preferred Retinal Locus). MAIA sensitivity scale is 0 to 36 dB.

Which diseases can be evaluated with MAIA

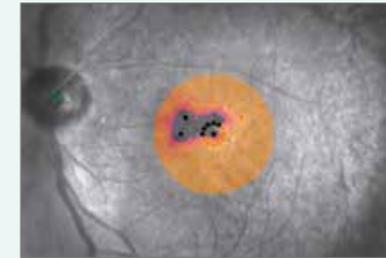
MAIA is used to functionally characterize and monitor a variety of macular pathologies, including for example:

- Age related macular degeneration
- Diabetic macular edema and retinopathy
- Macular puckers
- Macular holes
- Central serous retinopathy
- Stargardt's disease
- Choroideraemia
- Central retinal vein occlusion
- Macular telangiectasia
- Retinitis pigmentosa



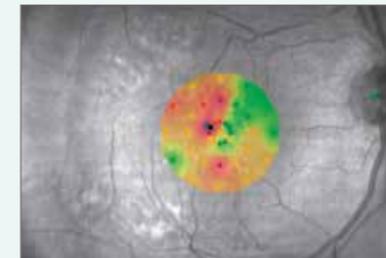
Fast

A supra-threshold test, used to screen patients with no known disease, measuring 2 levels of sensitivity (27 dB and 25 dB). Values are color coded in comparison with normative intervals. Typical duration (37 stimuli) is 2 min per eye.



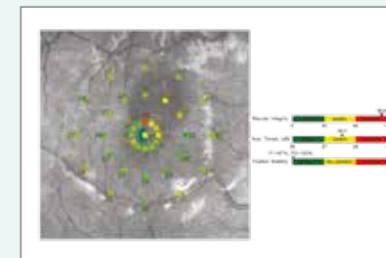
Scotoma finder

A supra-threshold test, used to examine highly pathologic patients, measuring one level of sensitivity (0 dB). Typical duration (37 stimuli) is about 2 min per eye.



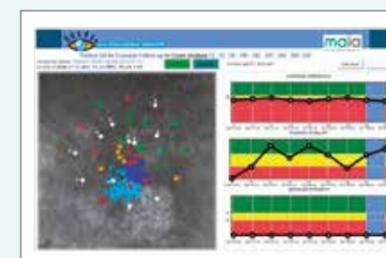
4 Levels fixed

A supra-threshold test, used to examine pathologic patients, measuring 4 levels of sensitivity (0 dB, 5 dB, 15 dB, 25 dB). Typical duration (37 stimuli) is about 3 min per eye.



Full threshold 4-2

Test used to examine retinal sensitivity in detail. The average threshold (dB) is color coded in comparison with normative intervals. Typical duration (37 stimuli) is less than 6 min per eye.



Follow-up

It measures exactly the same locations with the same projection strategy as in the baseline test, independently of fixation shifts.

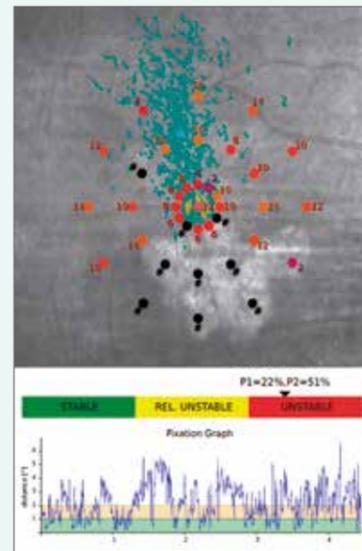
Fixation Test and Intended Use

Fixation analysis

Fixation is the process of attempting to “look at” a selected visual target and consists of optically aligning a functional area of the retina to that target. In normal subjects the retinal area predominantly used for fixation is the fovea, whereas when pathology affects the central retina, fixation degrades and patients may use extra-foveal regions. MAIA provides accurate and objective information regarding retinal location and stability of a patient’s fixation. Such parameters are assessed by tracking eye movements 25 times / sec and by plotting the resulting distribution over the SLO image.

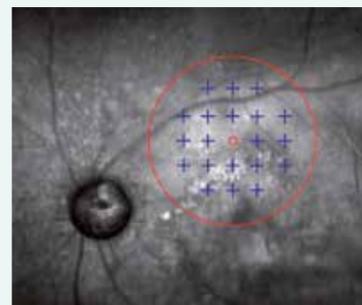
The region encompassed by these movements identifies the Preferred Retinal Locus (PRL) and describes the location of fixation, while their extension is an indication of fixation stability.

Fixation parameters are fundamental in describing retinal function and are as important prognostic factors as visual acuity and retinal sensitivity in patients with macular diseases.



Multi-fixation targets

MAIA is also able to project multiple fixation targets at selectable locations to help patients with central scotoma visualize the target during the sensitivity test. This new feature enhances the identification of the PRL and decreases the examination time in patients with highly unstable fixation.



Intended use

MAIA is used as a diagnostic device to aid in the detection and management of diseases affecting the macula, including, but not limited to, macular degenerations. Thanks to its combined structure-function analysis, microperimetry represents an essential tool for:

- Deriving the correct diagnostic decision in a variety of retinal diseases
- Monitoring the progression of retinal pathologies
- Planning retinal treatment
- Assessing macular function prior to cataract surgery
- Describing fixation characteristics prior to laser treatment
- Examining patients with unexplained vision loss
- Educating patients about their eccentric viewing
- Screening for macular pathologies
- Rehabilitation of low vision patients with eccentric vision



Great Ergonomic Advantages

Maia offers great ergonomic advantages in terms of easy interaction between the operator, the patient and the device.

Thanks to its Scanning Laser Ophthalmoscope (SLO) MAIA operates with a minimum pupil diameter of 2,5 mm, thus not requiring the use of dilating drops.



Ergonomic and motorized chin rest. Improved cleaning ability of the patient rest cushions thanks to the silicone material and detachable front rest.



The system is entirely operated via the integrated 10.4" touch-screen with 1024x768 resolution.



The patient push button is designed for improved ergonomics and can be attached to the system via a magnetic support.



The integrated PC offers dual USB and Ethernet interfaces.

PRL Training Module

PRL training testimonial

"...with determination and hard work my vision improved and I started to recognize faces; I could make out the eyes, ears and nose. Before that, I couldn't see anything, just darkness. My quality of life has got much better. Now I take the bus and the train."



Macular diseases affect people in different ways. In severe forms, when the foveal area is affected, central vision is lost, fixation capability is weakened and visual quality may be heavily reduced (low vision).

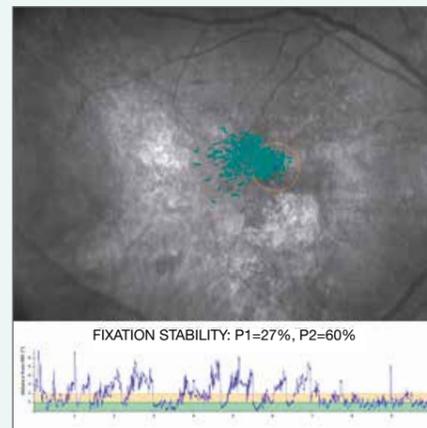
Patients with eccentric vision attempt to fixate objects with a retinal area defined as the Preferred Retinal Locus (PRL). During the progression of the pathology, the PRL may evolve towards a retinal area that lacks the optimal characteristics for eccentric viewing, resulting in unstable fixation. The PRL plays a crucial role in daily activities specially in patients with maculopathies affecting central vision.

MAIA PRL training can help eye care specialists to identify an optimal retinal area to train eccentric viewers in the use of a new PRL, improving fixation capabilities.

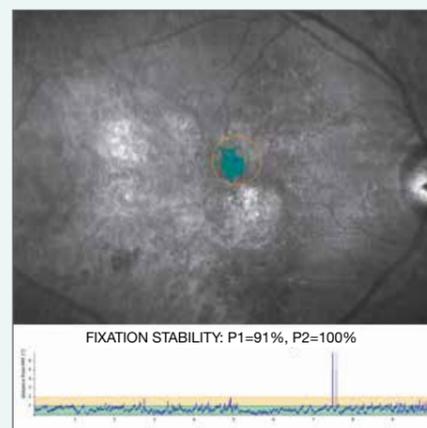
MAIA PRL training is a visual rehabilitation technique and uses audible and visible feedback signals to help patients develop a new retinal locus of fixation, which is functionally more suitable to fulfilling the fixation tasks. The Training involves multiple sessions.

Good use of peripheral vision can retain a good quality of life.

Before PRL training



After PRL training

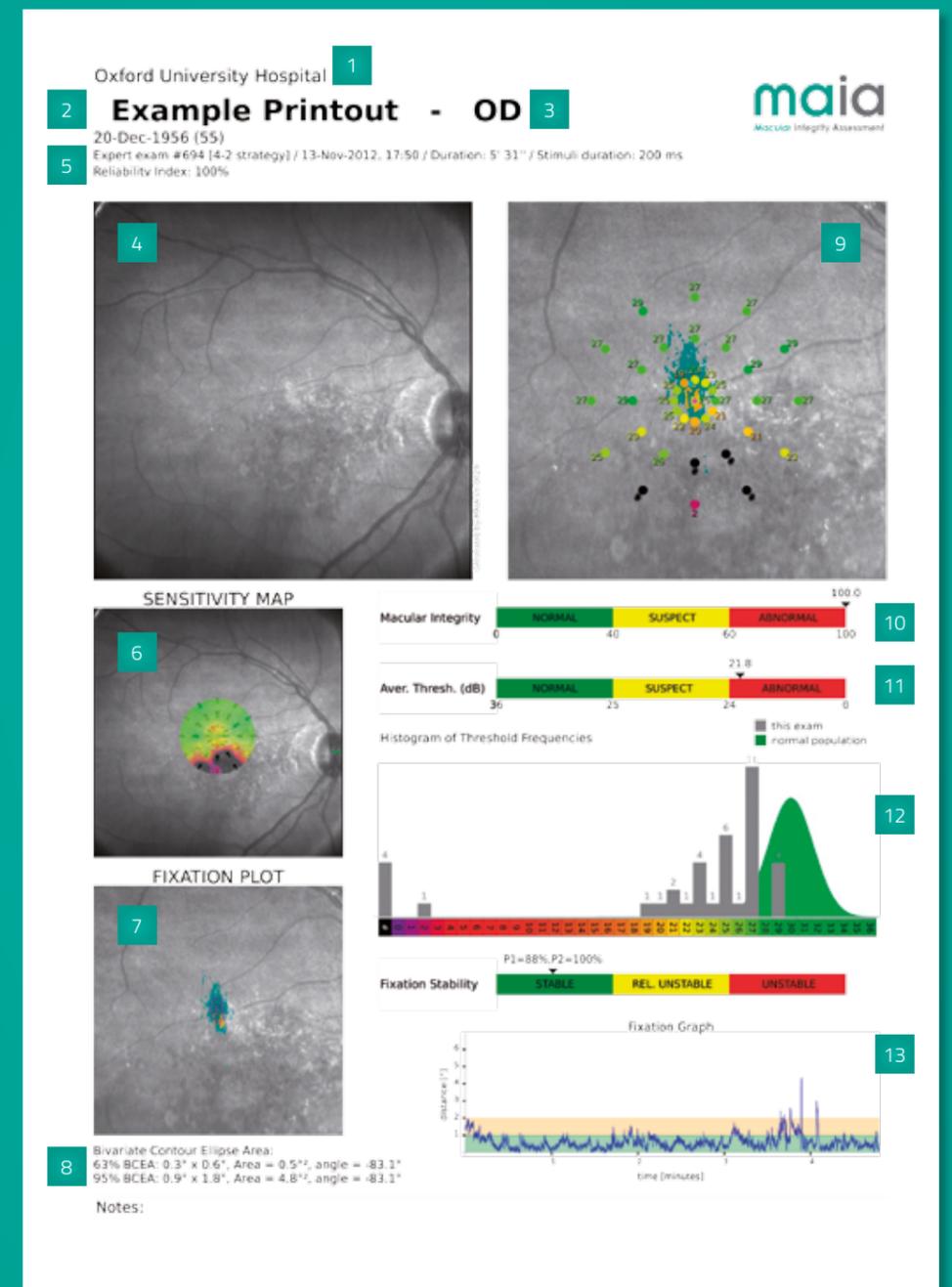


How to Read Printouts

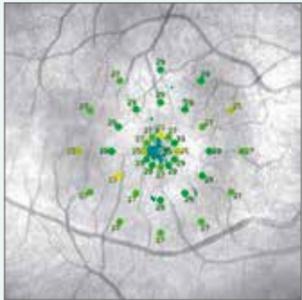
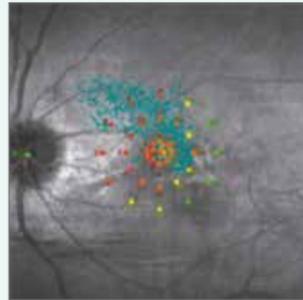
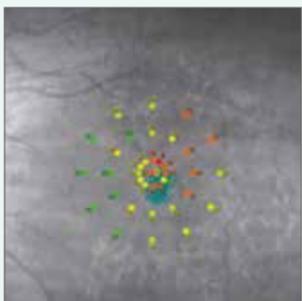
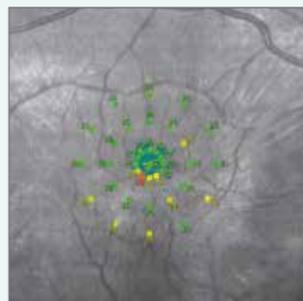
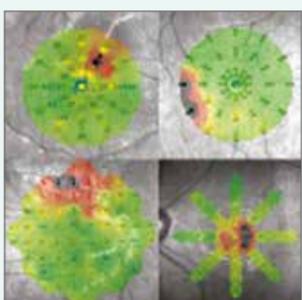
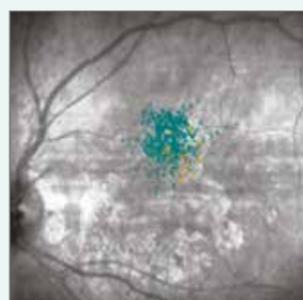
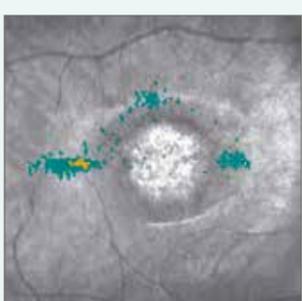
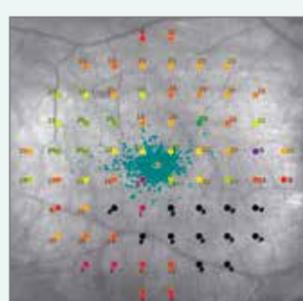
MAIA contains a reference database for the quantitative comparison of retinal sensitivity to the corresponding normal ranges. MAIA provides a very detailed printout that encompasses all collected information.

Legend

- 1 Clinic name
- 2 Patient info
- 3 Examined eye
- 4 SLO image of fundus
- 5 Exam Info
- 6 Interpolated sensitivity map over full SLO image
- 7 Fixation Plot over zoomed SLO image and PRL identification
- 8 Bivariate Contour Ellipse Area indices
- 9 Sensitivity values (dB) and PRL over zoomed SLO image
- 10 Color coded Macular Integrity index
- 11 Color coded Average Threshold
- 12 Histogram of Threshold values (grey) compared with normal distribution (green)
- 13 Fixation graph describing amplitude of eye movements vs. time



Clinical Examples

 <p>Early AMD Reduced retinal sensitivity in localized macular areas can be correlated with the appearance of early stage AMD.</p>	 <p>Severe AMD The PRL has shifted over a low sensitivity area causing unstable fixation and visual discomfort.</p>
 <p>Macular Edema Peri-foveal PRL and partially preserved macular sensitivity may indicate positive prognosis following treatment.</p>	 <p>Macular Pucker Traction lines, clearly visible on the SLO image and localized functional losses explain reported visual discomfort.</p>
 <p>Interpolated color map Interpolated sensitivity maps showing localized functional defects. Scotoma is represented in black.</p>	 <p>Central Geographic Atrophy The PRL has shifted in the superior hemi-field, with unstable fixation. This information is critical for eccentric viewing rehabilitation.</p>
 <p>Stargardt's disease Multiple PRLs may be relocated into a single region using Maia PRL Training.</p>	 <p>Glaucoma Advanced stages of glaucoma may threaten central fixation. Maia can be used to assess the rate of disease progression.</p>

Benefits, Features and Specifications

BENEFITS	FEATURES
Sensitive to functional changes due to macular pathologies even in the early stages	➔ 36 dB measurement range, 25 Hz eye tracker, 4 asb background, normative intervals
Easy interpretation	➔ Comparison with normative intervals and Normal – Suspect – Abnormal indicators
Patient comfort	➔ Test can be paused and automatically restarted at any time
Facilitates correct diagnostic decision	➔ Overlay of structural and functional information
Highly repeatable	➔ 25 Hz eye tracking+ high resolution confocal imaging
High quality imaging	➔ Confocal SLO imaging (25 microns optical resolution)

Technical specifications*

<p>Fundus imaging:</p> <ul style="list-style-type: none"> Line scanning laser ophthalmoscope Field of view: 36° x 36° Digital camera resolution: 1024 x 1024 pixel Optical resolution on the retina: 25 microns Optical source: infrared super luminescent diode (850 nm) Imaging speed: 25 fps Working distance: 33 mm 	<ul style="list-style-type: none"> Auto-focus (-15D to +10D) Automatic OD/OS recognition <p>Dimensions:</p> <ul style="list-style-type: none"> Unit size: W 348 x H 580 x D 600 mm (13.7 x 22.8 x 23.6 in) Unit weight: 23 kg (50.7 lbs) <p>Power requirement:</p> <ul style="list-style-type: none"> Voltage: 100-240 VAC, 50-60 Hz, fuse 3.15 A (T type) Power consumption: 300 VA
<p>Fundus Perimetry:</p> <ul style="list-style-type: none"> Projection field: 30° x 30° Tracking speed: 25 Hz Stimuli size: Goldmann III (26 arcmin) Background luminance: 4 asb Maximum luminance: 1000 asb Stimuli dynamic range: 36 dB 	<p>Laser classification:</p> <ul style="list-style-type: none"> Class I laser product conforming with 60825-1 IEC:2007 <p>Accessories:</p> <ul style="list-style-type: none"> power cord, push-button, spare fuses, operating manual, dust cover, front lens cap, silicon head-rest, eye occluder
<p>Other features:</p> <ul style="list-style-type: none"> Non mydriatic operation (minimum pupil diameter: 2.5 mm) 	<p>* Specifications are subject to change without notice for improvement.</p>



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Macular Integrity Assessment

The best tool for detecting and monitoring retinal functional changes

Microperimetry provides important contributions to Eye Care Specialists for a precise understanding of the anatomy, physiology and functionality of the macula. This turns into enhanced prevention, more accurate diagnosis and better treatment.



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