objectiveFIELD® Requirements, Contraindications & Other Considerations

Introduction

Thank you for considering objectiveFIELD® (aka OFA®), the first and only *truly objective* perimeter FDA 510(k) cleared to assess visual field abnormalities. OFA directly and objectively measures visual function by measuring pupil reactivity to novel multifocal stimuli. As such, no cognitive/motor response is required.

The objective, bilateral exam is well tolerated by patients and exam times are predictable, with test-protocols as fast as 90 seconds, for both eyes. Normal blinking during the exam is well tolerated.

Both eyes are tested individually but concurrently (a dichoptic presentation).

- Objective: No button to push, no cognitive / motor response required
- Bilateral: Both eyes tested at the same time, no eye patch
- Novel stimuli: Less susceptible to refractive error, gaze error and lens brunescence from cataracts
- Easy to administer: Patient compliance is monitored by the operator in real-time

Fundamental Principals

The objectiveFIELD® Analyzer (OFA®) utilizes a novel method called multifocal pupillographic objective perimetry (mfPOP), which is analogous to multifocal VEP (mfVEP), but without electrodes. Cortically driven pupillary responses to multifocal stimuli are measured using video cameras under infrared light.

Sensitivity is calculated from the amplitude of *relative* pupil constriction transformed to a familiar decibel scale, while time-to-peak pupil constriction is measured in milliseconds, providing *delay data* previously unavailable in perimetry.

Available Test-Protocols

OFA includes test protocols for 30° & 24° (together), two other 30° variants, 15° and 10°. OFA reports are presented in a classic format for both sensitivity and delay, with familiar grey-scale and numeric maps, as well as a table of global VF indices including MD, PSD, SF, CPSD etc.

Exam Time

Two High-Resolution test-protocols (30° & 15°) take approximately 8-9 mins, each, for both eyes, concurrently. These tests are administered as 9 shorts steps (~40 seconds each / ~6:30 actual test time). The patient can take a short break between steps while the system checks the reliability of the data collected in each step. Cadence of the exam is controlled by the operator.

High-Efficiency test-protocols (30° & 10°) take only 90 seconds, also for both eyes, administered as one continuous 90 second step.

Requirements/Contraindications/Other Considerations

- Patients must not be dilated.
- Drugs that may affect pupil reactivity (a lot) are contraindicated.
- The system requires two eyes, two trackable pupils and one reactive pupil to obtain a visual field for *both eyes*.
- Monocular testing is not possible. Patients with a prosthetic eye cannot be tested.
- Patients with strabismus, nystagmus, very small and/or misshapen pupils *may* not be suitable.
- Excessive consecutive blinking, for example from dry eye (which is a problem for all perimeters) may cause pupil tracking to fail. One or more applications of artificial tears may help.
- Up to ~15% of the upper curvature of the pupil can be obscured by lids or lashes, so the system can account for some upper lid ptosis, however OFA cannot perform a ptosis visual field test.
- An Esterman visual field test or other widefield tests beyond 30° (x2) are not available.
- Operators must carefully observe the patient at all times during testing.

I understand and accept the capabilities and differences from SAP of the objectiveFIELD device outlined in this document.

Name (please print):_____

Signature:_____

Date:_____