The Next Generation ... icVEP

Touch Screen User Interface
intuitive, efficient

Practice Personalized Test Reports
print or PDF, the simplest way to get published

All-in-One Design
easy on the eyes, an inter-office dream!

Linearized OLED Stimulus Display
got luminance artifact?

Integrated Double Shielded 2 - Channel Amplifier
record bilateral ERG in one go!

Fourier Transform Analytics
which is better, 1 data point or 1,000s?

Auditory Cues
run start, run end, test end

KonanCare Remote Support
touch one button, we are there with you virtually, STAT

Pediatric Attention Animations
fun, friendly, important

Integrated Luminance Calibration
fully or semi automated

Visual Acuity
ETDRS and pediatric optotypes

Very Short Interval Testing
only about 2 to 10 seconds / run (oh so simplifies patient compliance)

Test Strategy Library
wide variety to explore conditions: icVEP, VEP, ERG

Patented icVEP™ Strategies
plus ISCEV standard tests

Gaze Tracking
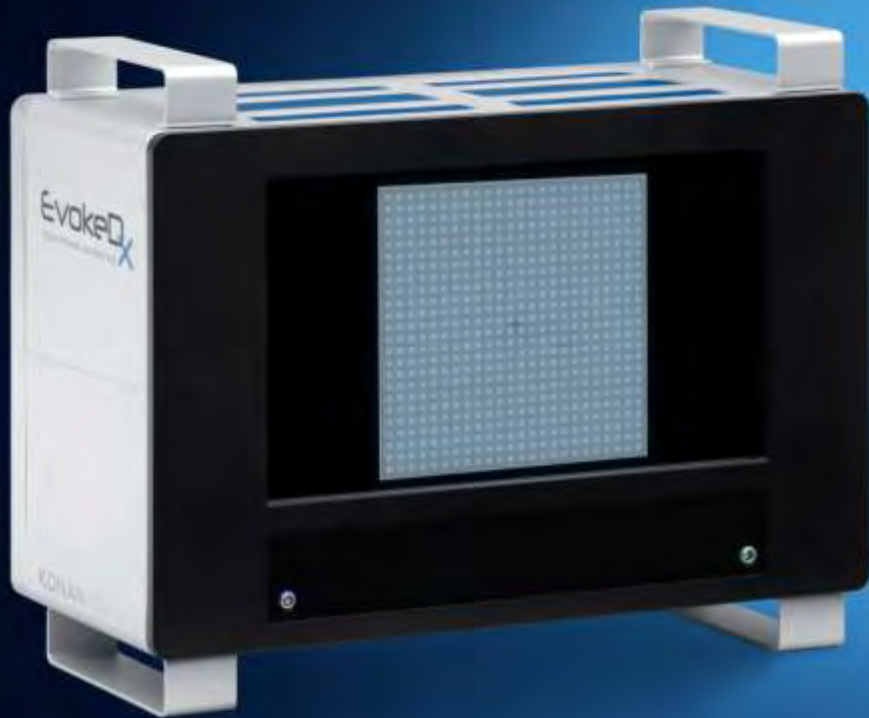attention monitoring + test distance aid

3 to 5 Lead Electrode Plug
use low cost, industry-standard snap-on EEG disposables

Where Did All the Wires, Bits, Parts, and Pieces Go?
(quiet, we are hiding in here)

EvokeDx
VISUAL PATHWAY DIAGNOSTICS

KONAN MEDICAL™

The Form Factor

Fourier Transform Anayltics

This is the secret sauce.

Powerful analytics simplify the physician's assessment of the amplitude-based raw data by using Fourier analysis techniques to transform the entire visual evoked response in the frequency domain.

Rather than trying to make a clinical determination solely on the latency of the N75 or P100, significant additional information is available from the thousands of data points hidden in the frequency domain. Additionally, this method benefits understanding by providing visibility into or removal of specific frequency components that may obscure the studied response.

T² CIRC
Advanced, multivariate analytics distill the complex VEP waveform into easy to interpret results.

F STAT
Provides clear statistical assessment to determine if two or more response functions (e.g., OD vs. OS) differ significantly.

M S C
Magnitude-squared coherence yields a normalized measure of signal power in the response. Statistical criteria are used with MSC to determine if each frequency response and distinct frequency mechanism in the evoked potential is significant.

Signficant Response

In this example, as the luminance modulation depth increases per step, a clear response curve is seen exiting the noise after the second step (DOM=2%). The SNR echoes these responses. The Fstat shows that there is an overall response that is significant
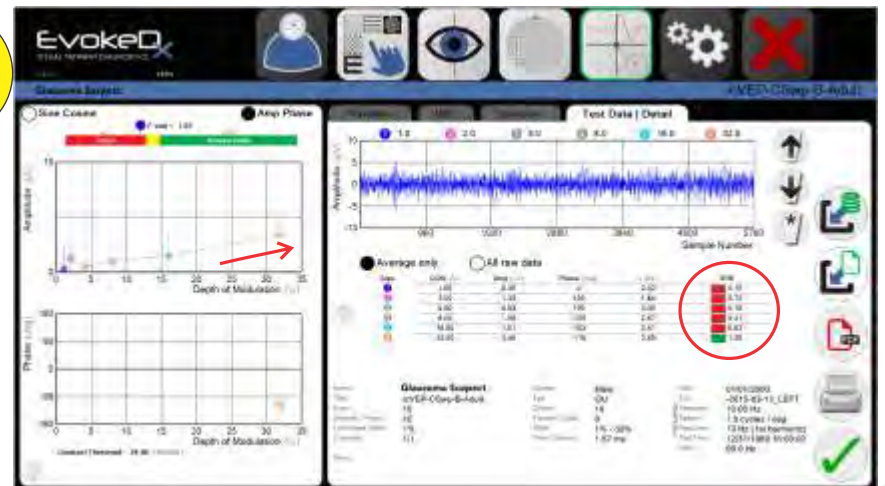
In a glaucoma suspect patient, as the DOM increases, the signal only bounces around in the noise until the last step (largest luminance changes = 32%). The SNR again describes clearly that the patient has no real response from DOM +/- 1% to +/- 32%). Fstat is insignificant.

Non-Signficant Response

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EvokeDx Test Library

Just as OCT and visual fields each come standard with a variety of test strategies allowing the physician to explore a particular suspected condition or disease, EvokeDx provides a battery of test strategies to explore visual pathway and retinal deficiencies with both novel and ISCEV standard methods.

Using simple, single-step targeted tests, to broad patterned and uniform fields sweeps to understand when functions exit the noise and become significant, EvokeDx has you covered.


Test Strategy Library
a wide variety of test strategies to explore patient conditions: patented icVEP, ISCEV and novel VEP, ERG. Expert System coming soon.

icVEP!

ISOLATED CHECK VEP STRATEGIES

Konan's patented isolated check VEP (icVEP) is a steady state, low contrast stimulus pattern that is thought to target the magnocelluar ON (bright) or OFF (dark) pathways.[3]

Featuring *"Very Short Interval Testing"*, the icVEP-LC stimulus is presented as 10 short 2 second runs (instead of a single, long run), enabling simplifed data collection and easing the test burden to the patient.
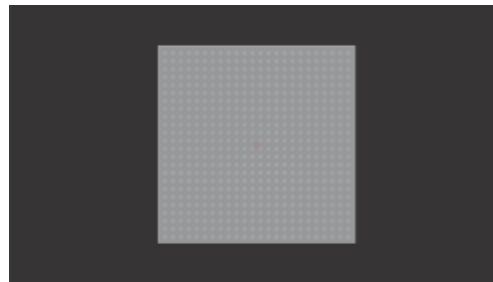
Available as LC (single low contrast DOM) and DOM Sweep (Dark / Bright: 1 to 32% DOM).

"EvokeDx is powerful, simplified, and objective assessment of the visual pathway"

OLED: What's the Big Deal?

ISCEV 2012 standards for PERG testing suggest that "*nearly all current liquid crystal display (LCD) stimulators present a brief luminance artifact during pattern reversal, rendering them unsuitable for PERG recording.*" Such artifacts contaminate the visual evoked response as a flash ERG inadvertently performed with the intended steady state response.

EvokeDx utilizes a cutting edge, linearized organic light emitting diode (OLED) display to eliminate the luminance artifact, avoiding an unwanted skewed response. Additionally, OLED benefits EvokeDx with microsecond timing (10x faster than standard LCDs) providing an additional measure of timing precision.

Calibration in a word: CRITICAL

Since proper responses are reliant on precision brightness of the depth of modulation, calibration and linearization of the monitor over the range of brightness values used in the tests is required. Each EvokeDx system is individually delivered with date-stamped, factory calibration and linearization.
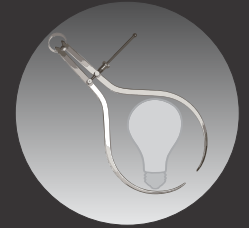
We go further however ... monitor characteristics may change over time. We record the last calibration date and provide a proprietary, one-button calibration reassesment tool to keep EvokeDx at peak performance over time.

Developed by Leading Experts

EvokeDx is the product of world-class experts with decades of experience corroborated by multi-center NIH studies and other clinical research conducted with glaucoma, amblyopia, MS, macular degeneration, retinitis pigmentosa, diabetic retinopathy, traumatic brain injury and others. [2,3,4]

SBIR Glaucoma investigation, Phase I (Columbia) and Phase II (Yale, Hamilton Eye University. TN, and University of Alabama Optometry), reported 94% and 92% accuracy respectively in separating glaucomatous from non-glaucoma patients using the patented icVEP protocol.

An independent assessment in June 2013 in Beijing (TongRen and YouYi) report equivalent findings using icVEP: "high accuracy demonstrates the value as an aid in the diagnosis of open angle Glaucoma."[6] EvokeDx has not been the subject of a FDA 510(k) submission for diagnosis of glaucoma.

1. US Patent 06966650 Method and Apparatus for and Automated Procedure to Detect and Monitor Early-stage Glaucoma.
2. Victor, JD, Mask J. A new statistic for steady-state evoked potentials, Electroencephalogy Clin Neurophysiol, 1991, 78:378-388.
3. Zemon V,Tsai JC, et al, Novel electrophysiological instrument for rapid and objective assessment of magnocellular deficits associated with glaucoma, Doc. Ophthalmol, 2008, 17:233-243.
4. Kim D. Zemon V, Saperstein A, Butler B, Javitt D, Dysfunction of early-stage processing in schizophrenia: harmonic analysis, Schizophr. Res, 2005, 76:55-65.
5. FDA 510(k) K081591. This device is used as a tool for assessment of visual function. It cannot be used as a definitive diagnostic indicator. The configuration and interpretation of the test shall be made by users based upon their knowledge and understanding of VEPs in response to stimuli. **Diagnosis of a patient is the responsibility of a licensed physician.**
6. Detailed results available on request from Konan Medical USA, Inc.

Gaze Tracking

EvokeDx utilizes a sophisticated IR gaze tracker to assist the operator in assuring that the patient is positioned correctly and remains fixated / attentive during the test. A graphical heat map provides the operator with real-time feedback on deviation of gaze from center and test distance.

The video windows provide a live display assuring that the patient is properly positioned vertically and horizontally with the center of the stimulus pattern along with an indicator of distance.
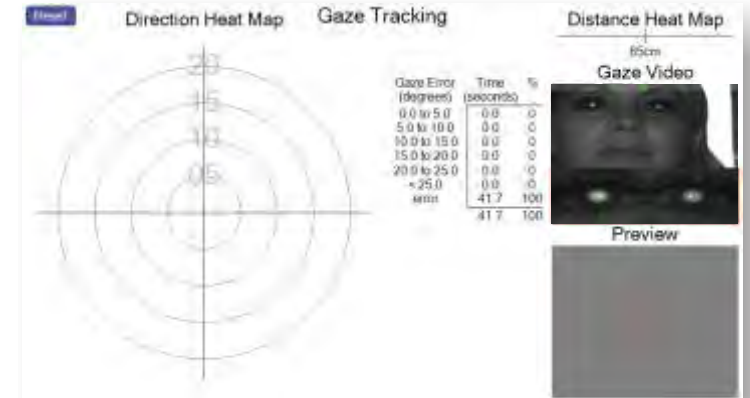
Which is Better, 1 or 2 (Channels)?

ONE BUTTON SELECTION OF SIMULTANEOUS BILATERAL TEST RECORDING

Select a two channel recording to simultaneously compare two separate responses to the exact same stimuli, e.g. record and compare right and left eye ERG responses to the same stimuli at the same time.

A 5 lead electrode assembly is used: two active, two reference, one ground.

2 Channel Simultaneous ERG Recording
5 lead cable

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Why "Runs"

VERY SHORT INTERVAL TESTING -
SIMPLIFIED COMPLIANCE | POWERING STATISTICS

It is no secret that neuro-affected conditions increase with age. EvokeDx test strategies are uniquely administered by concatenating a series of **very short** *"runs"*. Each run is only about 2 to 10 seconds, and is a substantially easier task for young and older patients to maintain attention.

2s

10s

Statistically, a series of runs with same conditions may offer a significant advantage over a single long run in which the recorded responses changes / diminshes over time. Attention, blinking, corneal hydration, fixation, and patient overall satisfaction with testing is enhanced using the EvokeDx very short interval *"Run"* strategy.

Electrodes

WHY NOT ONLY PROPRIETARY?
FLEXIBILITY IN CHOICE OF DISPOSABLE ELECTRODES

EvokeDx electrode cables use snap fitting, very low-cost, industry-standard EEG disposables. Available from Konan or independently. There are a wide variety of shapes, and features to select from. We provide a starter kit of some of our favorites.

A velcro placement band and electrode keepers are available as a convenience but not a requirement for use of EvokeDx. We will offer additional accessories in our on-line store. Quality, value, and convenience are always our priorities.

More Thoughtful Design Features

SOUND, SIGHT, ANIMATION, AND SUPPORT - ALL TO SIMPLIFY USE

Auditory Testing Cues

Pleasing auditory cues help instruct and enforce good patient compliance to each short run. The cues are intuitive, complementary and pleasing to the patient.

A soft high tone indicates the initiation of a run and *"pay attention"*. A soft low tone indicates run complete and *"relax"*. A double low tone indicates test complete.
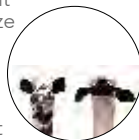
Pediatric Attention Animations

Selecting Pediatric test strategies adds a user-controlled animation preceding each short run.

As the patient becomes engaged in the content (easily assessed on gaze tracker), the test instantly replaces the animation.

fun, friendly, important

Visual Acuity: ETDRS and Pediatric

High spatial frequency tests require adequate acuity to produce a response. Both Sloan letter ETDRS and Pediatric *"Konan Kids"* optotypes are included to screen acuity.

The acuity charts are precisely rendered on the OLED display calibrated to a 65 cm test distance. An enlarged view is shown to the operator to verify patient answers.

Where are the Wires, Bits, Parts, and Pieces?

Early VEP/ERG systems were laboratory / experimental devices pushed into the clinical setting. We broke the mold to eliminate a collection of pieces, cables, tower PCs, and monitors somehow stuck together on a buggy or cart.

Assembly is: **open one box**, **set in place**, **plug in**, **go**. An optional rugged case may be used for easy transport to multiple locations.
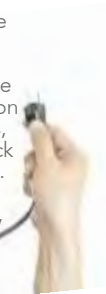
KonanCare Remote Support

Included with EvokeDx is one year of integrated, on-request support. We expect to earn your interest in continuing this convenient service into after-warranty periods.

Using our in-application web-connect feature, we can provide advanced training, technical support, or case review.

Virtual | Efficient | Expert

EvokeDx: The Next Generation

VISUAL ELECTRO-PHYSIOLOGY: EYE CARE | NEUROLOGY | RESEARCH

Specifications

EvokedDx Stimulus			
Resolution	1920 x 1080	Patterns	Patented isolated check, checkerboard, gratings, uniform field, windmill and windmill dartboard
Frame Rate	60 Hz	Temporal Functions	Square wave, sine wave, superimposed two sinusoid
Grey level	8 bit resolution	Sweep display	Up to 10 steps with variable contrast, spatial frequency, and temporal frequency
Gamma Correction	Software	Timing control	Synchronized image refresh with stimulus frame rate

Data Acquisition			
Analog - Digital Conversion	16 bit resolution	Data-timing Control	Synchronous stimulus - acquisition timing decreases the variability in the response measures
Sampling Rate	600 S/s, synchronous	Gamma Correction	Software
Electrodes	3 and 5 with disposable AgCl		

Signal Amplification	Proprietary meets or exceeds ISCEV - International Society for Clinical Electrophysiology of Vision and FDA regulatory requirements		
Channels	One or Two	Filters	Bandwidth 0.5 to 100 Hz
Gain	20,000	Input Range	+/- 6 mV
Common Mode Rejection Ratio	> 120 dB	Input Impedence	2 X 1012
Ohm Isolation Voltage	1.5 kV	CMRR	> 120 dB
Power Supply	+8 to +15 VDC	Power Supply	+8 to +15 VDC

Data Processing		Data Analysis	
Steady-state Response	Spectrum analysis	$T2_{CIRC}$	Digital Fourier Transform driven statistical analysis reducing complex waveform to amplitude and phase angle
Transient Response	Artifact removal	F_{STAT}	Statistical de nition of difference between two samples and con dence interval
Digital Filters	Low, high, even/odd, notch	MSC	Magnitude Squared Coherence estimates evoked response signal compared to frequency response noise

System Hardware			
Integrated Operator Computer	22" touchscreen	Power	100-240 VAC; 50/60 Hz; 5.5 A; isolation transformer included
IR Eye Monitoring Camera	770-950 nm (ISO grp)	WiFi / Bluetooth	Printing, EMR network communications, secure support
Dimensions	20.7 x 9.5 x 16.4 inches W x D x H (52.6 x 41.6 x 16.2 cm)	Weight	50 lbs (22.7 kgs)

Regulatory			
USA	FDA 510(k) K081591 clearance [5]		

Distributed by:

Konan Medical USA, Inc., 15 Marconi, Ste. A., Irvine, CA 92618 USA

+1 (949) 521-7730

sales@KonanMedical.com | www.KonanMedical.com

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