KONAN MEDICAL

Visual Electrophysiology

EvokeDx®

EvokeDx® is the NextGen VEP+ERG instrument developed by Konan Medical and leading scientists in visual electrophysiology.

Its compact, all-in-one form factor features numerous market leading technologies including patented test conditions called isolated check visual evoked potentials (icVEP™) and powerful Fourier Analytics.

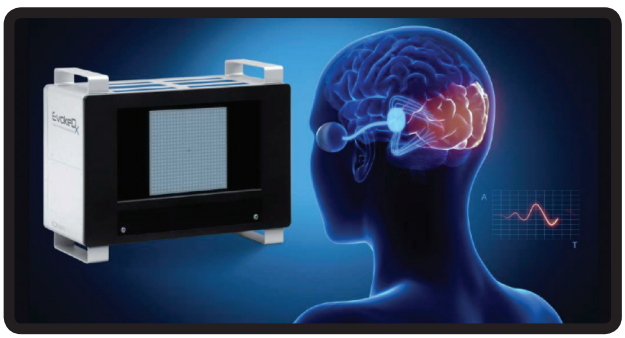
EvokeDx NextGen icVEP | VEP | ERG

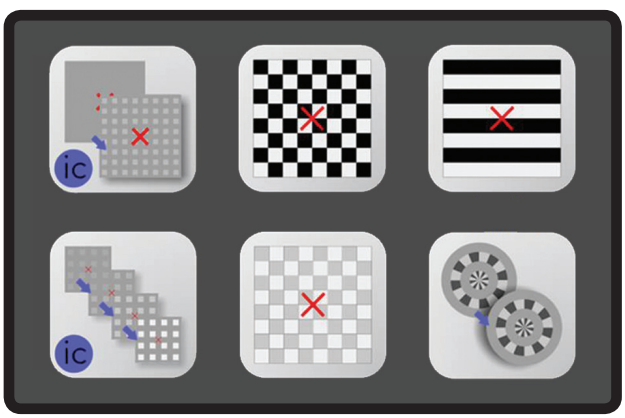
Clinical Benefits

Visual Evoked Potentials (VEPs) provide objective, quantitative information about the functional integrity of discreet visual pathways in a noninvasive manner.

This is new information that is complementary to the structural analysis obtained from technologies such as OCT and Fundus photography, and augments subjective information from standard visual acuity and perimetry.

Electroretinograms (ERGs) reflect the integrity of the optics, photoreceptors, bipolar cells and retinal ganglion cells. Clinically, ERGs may be useful when patients have abnormal VEPs to differentiate between retinal dysfunction and dysfunction occurring in the optic nerve, optic radiations and occipital cortex.



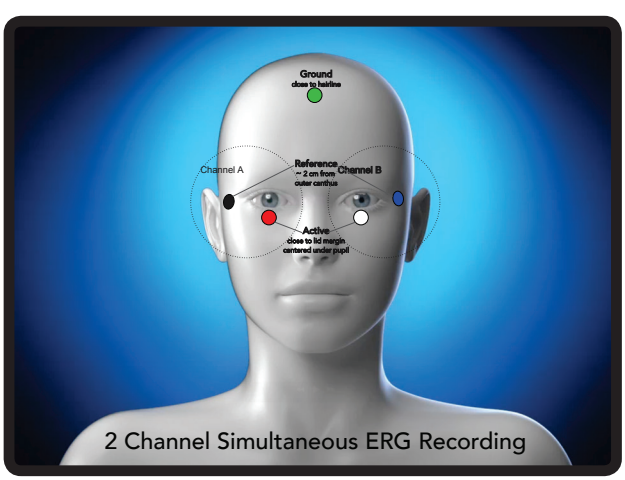


"Konan's EvokeDx is the most advanced electrodiagnostic device for use by eye care professionals I've ever seen. The myriad of testing options allows for the quantification of aspects of visual performance beyond anything else on the market."

- Dr. Paul Harris
Professor, Southern College of Optometry

Key Features

- Portable, cutting-edge technology with a small footprint and competitive pricing
- Low cost electrodes save thousands in annual operating costs
- Dual channel, integrated amplifier enables bilateral ERGs, cutting test time in half
- Organic LED stimulus display eliminates undesired luminance artifacts found in LCD and LED displays
- Integrated OLED display calibration precisely maintains contrast and luminance values over time
- Online features include real-time remote support and automatic software updates



Key Features

Operator Aspect

Touch Screen UX
Intuitive icons
Step-by-step workflows
Simplified operation

16 Test Conditions + Visual Acuity
Patented Isolated Check VEP
Conventional and novel VEP
ERG & ETDRS/Pediatric visual acuity @ 65cm

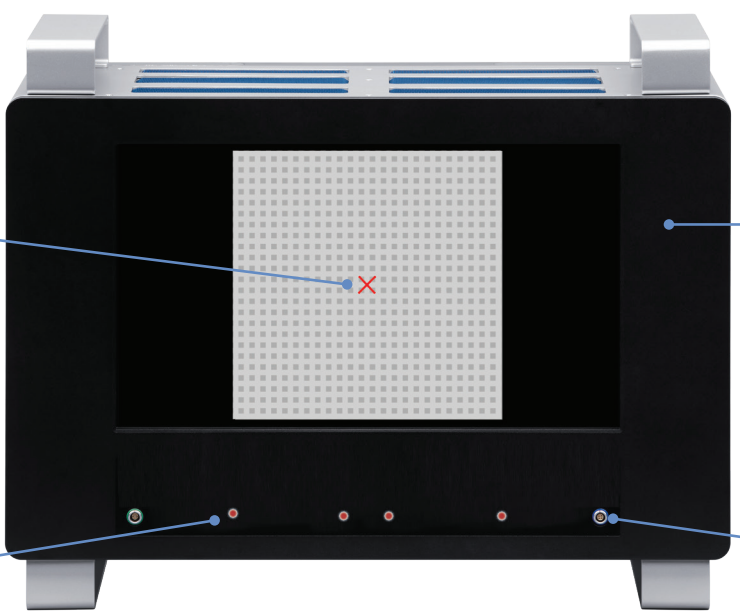
Adult / Pediatric Mode
Child friendly video fixation targets

Channel Selector
Single channel VEP
Dual channel ERG

Patient Aspect

Organic LED Stimulus Display
Eliminates unwanted luminance artifacts and delivers a greater level of precision than conventional LCD/LED systems

Infra-Red Gaze Tracker
Monitors patient fixation, distance and compliance



Integrated Dual Channel Amplifier
Enables simultaneous bilateral ERG recording

Robust VEP I ERG Leads
Low-cost electrodes save thousands in annual operating costs

USA Reimbursement: CPT 95930 & 92275

Konan visual electrophysiology offers remarkable value both clinically and financially.

EvokeDx analytics open the door to new insights in visual electrophysiology

NextGen Technologies

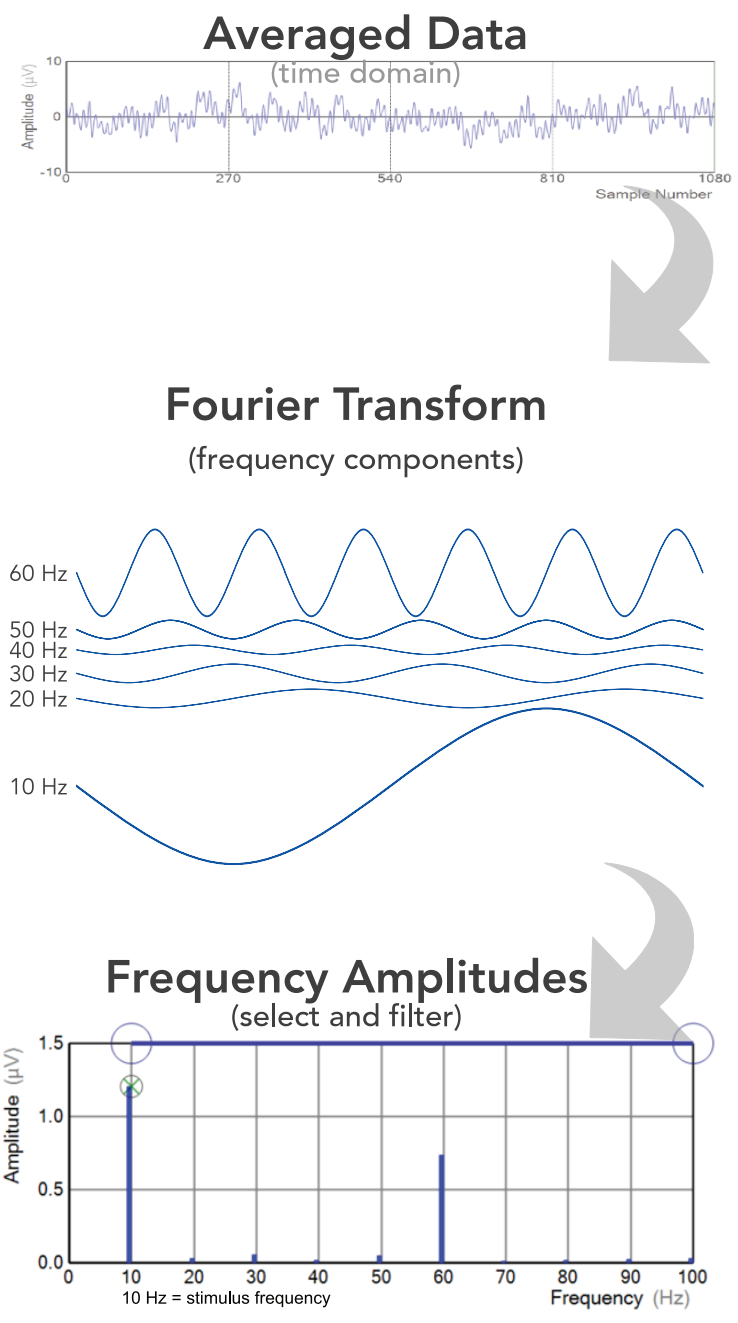
Fourier Analytics

EvokeDx leverages powerful Fourier Analytics by converting the time-domain EEG response to the frequency-domain, using a signal processing technique called a discrete Fourier Transform. Well known in other physical and biological fields such as spectral domain OCT, Fourier Analytics provide a rich, statistical assessment of the composition of the entire VEP/ERG waveform.

The Fourier Transform decomposes the complex and repetitive time-based waveform into a spectrum of sinusoidal functions referred to as 'frequency components'. Once isolated, these components are statistically assessed in multiple ways to provide a clear and detailed view of the response to a given stimulus.

Conversely, time-domain analytics measure just two or three points in time, (e.g. the N75 & P100) and provide only latency and amplitude values. While peak time latencies provide some measure of function, amplitudes are known to be affected by factors such as age and anatomy, and are therefore highly variable between healthy individuals.

Fourier analytics are the key to revealing new insight into measured responses that are simply not possible with early generation time-domain technologies.



KonanCare

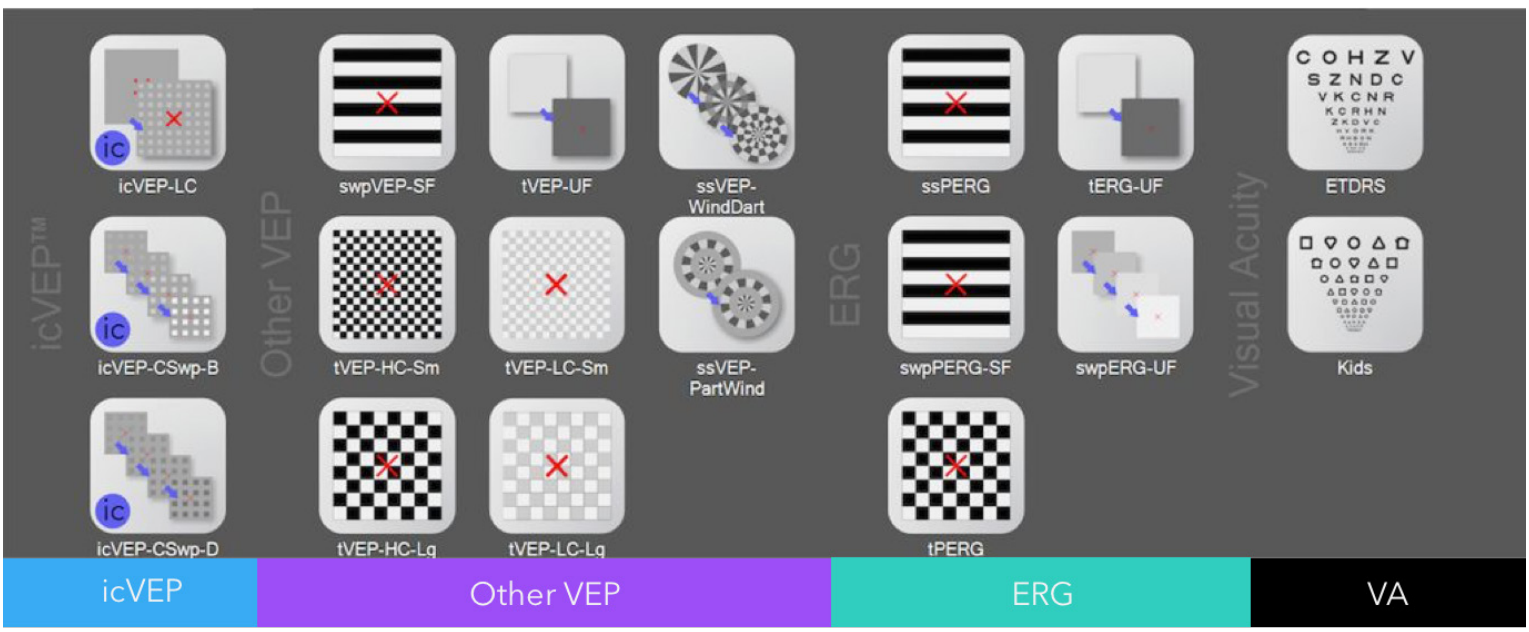
EvokeDx comes with one year of extra protection through the highest priority support system.

- White-gloved installation and initial training
- Remote training support
- Remote technical support
- Priority service call back
- Software updates

icVEP™ Isolated-Check Visual Evoked Potentials

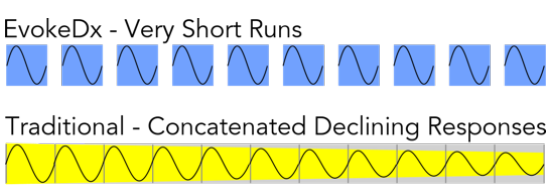
EvokeDx uniquely features icVEP, a patented test strategy based upon studies designed to emphasize contributions to the VEP selectively from the ON or OFF subdivisions of the magnocellular neural pathways[1].

Luminance of the checks varies sinusoidally in time such that the pattern smoothly appears and then disappears. The low contrast bright-check pattern, is thought to emphasize the M-ON pathway. icVEP tests are designed to assess low contrast processing in the visual system, which are deficient in various disorders.



EvokeDx Very Short Runs:

- Short sequences ~ 2 to 6 seconds (compare to 30 to 60 seconds continuous for traditional method)
- Easier to keep patient attention
- Easier for the the technician to manage patient
- Reduced need for repeat entire test
- Mathematical advantages in averaging response



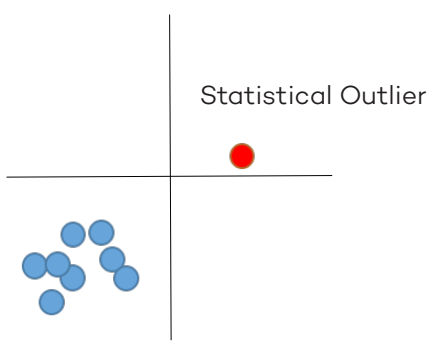
Visual electrophysiology data is contaminated by:

- loss of fixation (patterned tests)
- blinking (loss of stimulus)
- other muscle activity near active sensor sites

Outlier Analysis

At the end of each series of runs, a statistical outlier analysis is run and for individual runs that are significantly different from the other runs.

EvokeDx application automatically prompts the technician to repeat and replace any of the short individual run(s) that were statistically different, rather than starting the test over from the start.



[1] Zemon, V., & Gordon, J. (2006). Luminance-contrast mechanisms in humans: visual evoked potentials and a nonlinear model. Vision Research, 46(24), 4163-4180.

Specifications

EvokeDx Stimulus			
Resolution	1920 x 1080	Patterns	Patented isolated-check, checkerboard, gratings, windmill-dartboard, uniform field
Frame rate	60 Hz	Temporal functions	Sine wave, square 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 amplifier meets or exceeds ISCEV and FDA regulatory requirements			
Channels	One or Two		
Gain	20,000		
Common Mode Rejection Ratio	> 120 dB		
Ohm Isolation Voltage	1.5 kV		
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 definition of difference between two samples and confidence 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		

Distributed By

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