Another 510(k) for Neuro Kinetics:
FDA Clears Faster, Easier to Use I-Portal® and VEST™ Software

PITTSBURGH, PA. September 20, 2018: Neuro Kinetics, Inc. (NKI), announced today that they received another 510(k) clearance from the United States Food and Drug Administration (FDA) for important efficiency features to its I-Portal® and VEST™ software. These new features make collecting clinical quality OVRT (Oculomotor, Vestibular, and Reaction Time) data faster and easier, and reduce analysis time on all of NKI’s clinical platforms: the I-Portal® NOTC (Neurotologic Testing Centers), I-Portal® VNG, and I-PAS™ (I-Portal® Portable Assessment System).

All NKI systems run I-Portal® and VEST™ software. I-Portal® captures and calculates the eye-tracking and position data, working symbiotically with VEST™, which controls the test stimuli. VEST also analyzes the data, provides tools for managing the results, and stores patient and test information in an organized and accessible database.

The clearance enables commercial use of NKI’s automatic, pupil threshold detection algorithm so I-Portal can automatically and seamlessly track a patient’s pupil without the test operator constantly adjusting the threshold manually. This makes testing more efficient and enhances the consistency and quality of the collected data.

The VEST™ component of the clearance adds three major enhancements. The first is an “Indication of Analysis Validity” that automatically lets the operator know when data collection is at risk of not being clinically useful and gives the clinic the option to quickly rerun the test without excessively inconveniencing the patient. The second component is the “Enhanced Data Acquisition/Artifact Detection” feature that compares both threshold and collected values to determine the validity of each point. Data points, e.g., a blink, are tagged as not valid and excluded in the default calculation of the output variables, e.g., gain or peak velocity. The third is called Eye Selection, which allows a test operator or downstream reviewer to select the superior eye for analysis. At times data can only be collected well on one eye. Rather than compromising the whole test session, one eye is frequently sufficient to produce important, critical data for a timely clinical evaluation.

Lastly, NKI updated the default parameter settings in VEST to more closely reflect current clinical practice. The operator now only has to review the variables for confirmation rather than completing detailed, time-consuming analyses for each test, saving important chunks of valuable clinic time.

As always, the user has the option of accepting or rejecting the recommendations made by the new VEST features and to alternatively analyze data manually.
Bottom line... these changes mean less clinic time testing and analyzing, without sacrificing NKI’s superior data quality.

To learn more about NKI, please visit [https://neuro-kinetics.com](https://neuro-kinetics.com).

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ABOUT NKI

The Science to See™

Neuro Kinetics, Inc. (NKI) is the leader in clinical eye tracking and non-invasive neuro-otologic and neuro-functional testing. Research shows that abnormal eye responses can help to diagnose more than 200 diseases and medical conditions. With 22 issued patents and over 150 installations, NKI’s FDA cleared I-Portal® devices are sold to physical therapists, audiologists, ENT’s, neurotologists, neuro-ophthalmologists, neurologists, and chiropractors around the globe. The company's cleared diagnostic platforms include the I-PAS® (I-Portal® Portable Assessment System), I-Portal® NOTC (Neuro-Otologic Test Center), I-Portal® VNG, (Video Nystagmography) and I-Portal® VOG (Video Oculography), along with related accessories, software, training and support services.

I-Portal systems have been in use for over a decade by prominent university and federal laboratories for vestibular and concussion clinical studies. Concussions, a form of mild Traumatic Brain Injury (mTBI), are an increasing public health concern. The absence of an objective diagnostic device has made health care practitioners eager for a device that can measure concussion symptoms acutely and over time with speed, precision and reliability. Recent third-party research initially indicates a battery of OVRT (oculomotor, vestibular, and reaction time) tests, in combination with NKI’s I-Portal devices, can support a more accurate diagnosis of mTBI (concussion) symptom measurement both acutely and during convalescence. NKI is actively working toward gaining clearance for its I-Portal® systems as an aid in the diagnosis of concussion based on this and other research.