Request for Information:
Impaired Driving Technologies – Eye Tracking As An Indicator of Impairment.
Agency/Docket Number: NHTSA-2020-0102
Document Number: 2020-24951
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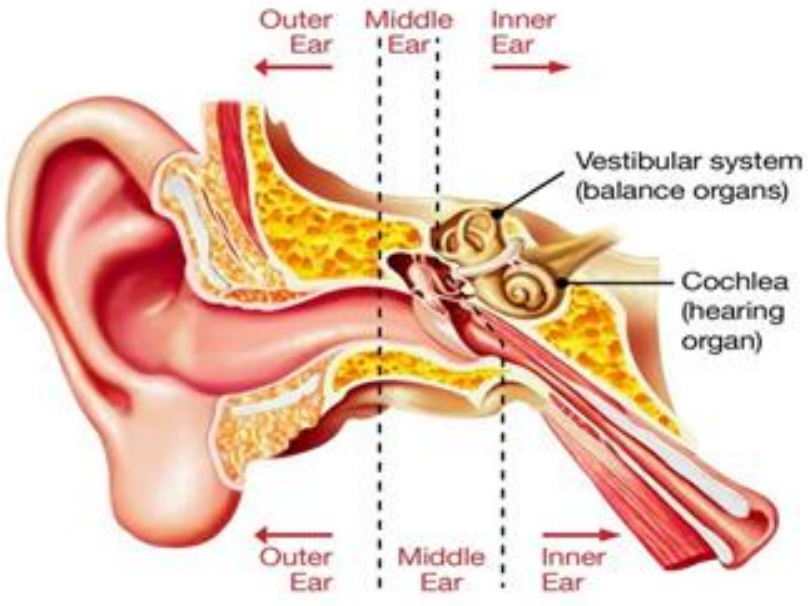
My background in eye tracking started at the University of Florida College of Medicine when I entered graduate school in the Department of Physiology in 1969.

I was very much interested in space medicine, especially zero-gravity and its effect on human physiology. For me it came down to understanding the ***Sense of Balance***:

End-organ receptors for gravity and movement 

are located in our inner ears, bilaterally. These receptors are working 24/7 from birth to death. They connect though the brain to our muscles that control movement, including those that move our eyes so we can maintain acute vision while we move in three-dimensional space.



Because we are only aware of balance when the system is impaired, i.e. sea sickness, car sickness, space sickness, dizziness, vertigo, double-vision, etc., it is called the 'System of Silent Elegance'.

Abnormal eye movements and pupil physiology are also related to reactions to prescriptions that have warnings about these medications causing drowsiness/driving /dizziness, etc. Also abnormal eye signs can be caused by abuse of over-the-counter medications, medical conditions like vertigo, dizziness, even brain

tumors/strokes/infarcts. Later in this RFI response, I will show pilot data on how possibly fatigue factors into 'impairment'.

The use of eye movements and pupil size/reactivity for medical applications has existed and evolved for centuries. The acute/immediate neurological evaluation of these physiologies is standard of care ranging from points of injury by EMT's (i.e., brain injuries, concussion, stroke, etc.) and ER protocols to the chronic testing related to ongoing issues of vertigo and dizziness, including sports related return-to-play/return-to-work issues.

As part of my desire to be a Mission Specialist at NASA, early in my graduate education I was awarded a scholarship to its Bio-Space Technology Training Program, held at the NASA Wallops Island, Virginia rocket launching facility.

It was that experience which sparked my interest in advancing the technology and methodology of using eye movements and pupil reactions as biometrics to study neurological impairment.

Two issues were known to be important in advancing the technology. One was the issue of 'fixation', which is the change in eye movements that occur when a subject has visual input versus being tested in 'total darkness' with no visual input at all. When vision is allowed, the brain tries to fixate on what it sees, and therefore diminishes or totally inhibits certain types of eye movements. The more the visual input, the greater the effect.

The other pertains to the control of the amount of ambient light that impinges on the eye which controls the size of the individual's pupils and their reactivity.

As examples, people will exhibit eye movements similar in some respects to those exhibited during alcohol intoxication when that person is stationary looking at a moving environment, i.e., on a train watching the scenery pass by (optokinetic nystagmus). Another example is measuring pupil size in a brightly lit room (pupils normally are smaller the brighter the ambient light).

In 1992, I was the first to develop and to file with the FDA a means for enhanced technology for eye movement testing using invisible infrared illumination in a digital video image processing methodology for vestibular applications.

Device Classification Name	Nystagmograph
510(K) Number	K925111
Device Name	HOUSE INFRARED/VIDEO ELECTRONYSTAGMOGRAPH SYSTEM
Applicant	EYE DYNAMICS, INC. 2291 205TH STREET, SUITE 203 Torrance, CA 90501
Applicant Contact	Ronald A Waldorf
Correspondent	EYE DYNAMICS, INC. 2291 205TH STREET, SUITE 203 Torrance, CA 90501
Correspondent Contact	Ronald A Waldorf
Regulation Number	882.1460
Classification Product Code	GWN
Date Received	10/09/1992
Decision Date	03/23/1994
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Neurology
510k Review Panel	Neurology
Type	Traditional

Until this new image processing technology was developed, eye movements were evaluated by applying electrodes to the skin surrounding the eyes and recording the small electrical dipole (approx.. ½ mvolt) that exists between the eye's cornea and retina.

With infrared video technology, no electrodes are needed as the camera's output is coupled to digital image processing to evaluate eye movements and pupil size/reactivity – even with eyes open in total darkness as a means for controlling the influences of activity in the visual field of the subject as well as the amount (if any) of ambient light effecting pupil size.

Any eye device that is going to be used for this type of application should meet the existing medical standards for the safety of infrared illumination on the eye. These are defined in the American National Standards Institute 'Procedures for Testing Basic Vestibular Function'. ANSI/ASA S3.45-2009

The document is included in the response as Attachment2_ANSI.

The FDA approval for the enhanced technology was granted in 1994 just as the Drug Recognition Expert program was gaining traction nationally. InfraRed/Video Nystagmography, now known as Video Nystagmography or 'VNG' has become the worldwide standard of care methodology for vestibular assessment.

While I was developing the technology and using it in clinical applications at places like the House Ear Institute and Clinic (Los Angeles, CA), I heard a radio interview about law enforcement programs that used 'eyes' to help determine if someone was driving under the influence.

The radio station put me in touch with the authors of the study which led to my introduction to Dr. Marcelline Burns of the Southern California Research Institute (SCRI).

The Southern California Research Institute, established in 1973, was a nonprofit organization affiliated with the University of California – Los Angeles which "studied human skills performance, psychomotor behavior and cognitive skills as they are affected by pharmacological, physical and psychosocial variables".

The SCRI conducted research studies which were sponsored by the National Highway Traffic Safety Administration (NHTSA) to determine the best methods of detecting impaired drivers using field sobriety tests. Under the guidance of the National Highway Traffic Administration, the Southern Research Institute conducted a battery of tests to determine the best standardized processes for evaluating a driver's impairments after consuming alcohol and the best methods to establish probable cause for a DUI or drunken driving arrest. The tests which were standardized are called the Standardized Field Sobriety Test (SFST).

After showing SCRI my medical eye tracking technology, I was introduced to Sgt. Dick Studdard, LAPD (now retired) in 1987. From that meeting has evolved not just a life-long friendship and respect for what he has accomplished, but also the evolution of the science of impairment which has important applications on our highways and workplaces. For me, it also resulted in being granted the following patents related to 'eyes' and neurological impairment:

	PAT. NO.	**Title**
1.	**7,798,643**	'System for analyzing eye responses to automatically track size, location, and movement of the pupil.'
2.	**7,614,745**	'System for analyzing eye responses to automatically determine impairment of a subject.'
3.	**7,357,507**	'Image-based system to observe and document eye responses.'
4.	**7,338,166**	'Image-based system to observe and document eye responses having a reflective protractor for measurement of stimulus position.'
5.	**5,137,345**	'Apparatus for monitoring physiological data to detect drug impairment.'

6. **9,101,312** 'System for the physiological evaluation of brain function.'
7. **8,668,337** 'System for the physiological evaluation of brain function.'

From that meeting with Dick Studdard, aka 'Sgt. Nystagmus', and with input from the likes of the Dr. Burns, and the opportunity to talk to thought-leaders from NHTSA, IACP, their DRE TAP Committee, etc., I began to configure the medical technology for law enforcement applications.

While VNG has evolved to be the global clinical standard, the use of this technology in law enforcement settings has been anecdotal and mainly based on the ergonomics of how a device could be used.

Early prototypes were used in applications ranging from training to field sobriety check points, to field-use, and for educating judges, juries, prosecuting attorneys, etc.

Part of this technology is that when a 'dark iris' individual's eyes are illuminated with invisible, safe, infrared illumination, their monochrome-lit pupils are observable on the device monitor in high-contrast, making it much easier to determine pupil size in the manner specified in the impairment protocols (total darkness, dim light, bright light, standard illumination, etc.)

This allows for an easier, more accurate assessment by the officer, with the ability to store the video of the suspects eye responses for later review and evidence.

Also, by having the video evidence, it can be determined if the 'eye sign' portion of the DRE/ARIDE/SFST protocols were administered correctly. If not, the ability to enhance and audit this important training and certification component of the programs is possible.

And, the technology can allow for remote/expert evaluations (in real-time, video streaming) as well. Finally, it would be beneficial in the education of judges, juries, prosecutors, etc., in the scientific value of 'eyes'.

> **As Dick Studdard has been quoted …"If a picture is worth a thousand words, what's a video worth?"**

Ocular Data Systems, Inc. (Pasadena, CA) is now the owner of the technology and know-how related to infrared/video eye tracking and its applications. The current product for law enforcement application is the DAX Evidence Recorder (https://dax.oculardatasystems.com/). DAX only records what the officer is seeing in response to the subject's performance of the eye tests administered by the officer. Examples of DAX Evidence Recorder videos can be found at https://dax.oculardatasystems.com/videos/

Currently, the DRE 'Voice of the Customer' is …"just give us video and audio. No numbers like pupil size, etc. are needed or desired since the opinion of the trained/certified DRE officer is the heart and soul of the program. Devices that would provide 'numbers' would complicate the program".

I have to admit that I initially pushed back on not having 'numbers' for the DRE application. I, and most of my clinical colleagues, use the numbers during clinical eye testing.

Ocular Data Systems learned to listen to 'the voice of the customer' and have designed the DAX to be an easy to use, light-weight, durable, inexpensive system. It is non-invasive and the recording system is optimized to observe and store the eye responses as well as subject and officer audio.

Since no analysis is required from the system, it also kept Ocular from having to do any conventional clinical trial research. Basically, when the eye moved did the DAX screen display that movement accurately? Did DAX record the audio? Was the DAX data saved/stored?

That part of the product development was easy. Over the past several years, DAX has been used by numerous Agencies/Certified Individuals:

- 34% of Drug Recognition Expert State Coordinators
- 30% of State Police segment
- 16% of Major Metro Police Departments

One specific application is by Officer Don Decker, DRE and Dr. Jack Richman (former DRE TAP Committee Member):

> *"Obviously we used the DAX for the HGN Study. Jack tells me it should be finished by the end of the month, and hopefully going out to be published.*
>
> *I did use it a few times during the Harvard/MGH Cannabis study. That one is still ongoing. I'll be back there for a while in the spring, and I'm hoping to get some more DAX videos from it.*
>
> *I have used it numerous times during Alcohol workshops, and as you know it proves invaluable being able to replay what the students saw, or thought they saw. Also as you know, I've used it numerous times during field certifications, which is great for the student and instructors alike. We have been able to replay the videos for the students. and several times have been able to see what they were not sure of during the actual testing. This definitely helps them out, and makes them better DREs". (Don Decker, DRE - personal communication).*

In a recent White Paper entitled "Countering Drug-Impaired Driving" from the Rand Corporation (see Attachment3_Rand):

> *"Law enforcement officers need additional tools to enhance their ability to collect evidence to detect drug-related*

impairment. Such tools would include conducting rigorous research to establish standardized, DUID specific observational field tests that more law enforcement officers can be trained to use…There is also a need to further develop and validate the DUID specific training received by law enforcement.

It is important to note that Ocular considers DAX to be a 'Sole-Source' device based on the company's patents. For full disclosure, I am including in Attachment4_SoleSource a copy of the letter Ocular provides with each quote.

ADMISSIBILITY

As important as the technology is in gathering the 'evidence', the admissibility of such is also of importance.

In 1995, Ocular sought legal advice from Steven Talpins, Esq. from Rumberger, Kirk & Caldwell (Miami Florida). Steve has great expertise in this field. A brief bio:

Stephen Talpins is an advocate, consultant and trial attorney who represents clients and works with stakeholders in the commercial (premises and products liability), substance abuse (alcohol and drugs), correctional (criminal justice) and public (government and non-profit) sectors. In January 2011, Stephen was named one of the "20 People to Watch" by The Century Council.

Stephen is the Co-Founder, Chairman of the Board and Chief Executive Officer of the National Partnership on Alcohol Misuse and Crime (NPAMC), an inclusive non-profit public-private partnership based in Washington, DC that is committed to identifying, developing, and promoting criminal justice programs that improve public safety, reduce recidivism and change lives for offenders who misuse alcohol. He also is the Vice President of the Institute for Behavior and Health. Stephen previously worked as the Vice President of Industry Relations for Alcohol Monitoring Systems, Incorporated (AMS), manufacturer of an ankle bracelet that detects alcohol use transdermally.

Stephen formerly served as National Director of Public Policy for Mothers Against Drunk Driving (MADD), Director of the National District Attorneys Association – American Prosecutors Research Institute's National Traffic Law Center (NTLC), a National Highway and Traffic Safety Administration (NHTSA) and National Association of Prosecutor Coordinators (NAPC) Prosecutor Fellow and as an Assistant State Attorney with the Miami-Dade County (Florida) State Attorney's Office.

He is a frequent lecturer and the author of several articles, monographs and a book chapter. In addition to being named one of the 20 People to Watch, he has received numerous awards and commendations including the National Commission Against Drunk Driving (NCADD) Adjudication Award for Outstanding Prosecution, Citizens Against Drug Impaired Driving (C.A.N.D.I.D.) Award for Outstanding DRE Achievement, and MADD Florida Outstanding Prosecutor Award.

His opinion regarding the admissibility of videotape evidence is posted on Ocular's website at:
https://dax.oculardatasystems.com/grant-support/

He concludes….."Experienced defense attorneys routinely and aggressively challenge the admissibility of virtually every type of evidence in DUI cases. At times, they have convinced judges to suppress even the most commonly accepted evidence. Nonetheless, I believe that 'DAX' recordings should easily withstand legal challenges, especially if 'the company' prepares for them in advance by educating prosecutors and providing legal support when necessary."

The first legal test case of infrared/video eye evidence was quoted from the book – 'Drunk Driving Defense', Sixth Edition (2005), by Lawrence Taylor and Steven Oberman, Aspen Publishing. Page 273…

"Also, Counsel should be aware that the technology now exists for videotaping nystagmus tests. This would, of course, provide an objective and verifiable record of the defendant's performance

on the test. The EM/1 is an instrument developed by Eye Dynamics, Inc. of Torrance, California. Designed to be operated by a Drug Recognition Expert (DRE), it has a separate video camera for each eye and records on videotape smooth pursuit, nystagmus, pupil size and reaction, and eyelid tremor. It has already been used successfully in court". See State v. Rosasco, No. TD 92-02-006 (County of Yavapai, Ariz. 1992)

This case centered on the fact that a suspect was arrested and failed the eye tests. The suspect said it was because he had myasthenia gravis, a neurological disease – which was the cause of his nystagmus. As Dick Studdard lives in Prescott, the equipment was allowed to test the subject. The new recordings did not show any nystagmus or other eye signs related to the neurological condition. The defense attorney's motion to have the video excluded was denied. The suspect pled guilty.

The second legal case came about from an earlier version of DAX, called HawkEye, which was used as part of a DRE evaluation in a double homicide in Houston, Texas: *Petty v. Texas (6/12/2014 NO. 01-12-00902-CR & NO. 01-12-0093-CR). (See Attachment5_PettyCase)*

"Arresting Officer Egdorf transported Appellant to the hospital where a blood sample was drawn. The officer then transported Appellant to the police station. There, Officer Egdorf again administered the HGN test to Appellant. Officer Egdorf used a piece of equipment known as a HawkEye to make a close-up video recording of Appellant's eyes while the HGN test was administered. Appellant again exhibited all six clues of intoxication. In addition, Officer Egdorf observed that Appellant's eyes showed a lack of convergence when he brought a stimulus in toward Appellant's nose. This also indicated to Officer Egdorf that Appellant was intoxicated.

The trial court judgments were affirmed by the Appellate court, which included the use of eye video's specialized for HGN/Pupil observation and documentation.

*According to Officer Egdorf, the arresting officer (personal communication), the video evidence of the eyes **was essential** in the convection of this driver.*

Workplace Application of using eyes as the initial impairment screening protocol, has evolved with the technology.

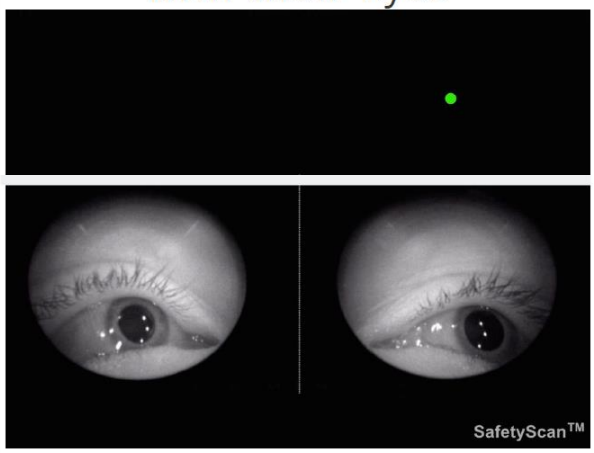
In workplace settings, the video technology is linked to sophisticated virtual reality/eye tracking headset hardware to provide digital information about the workers eye movements and pupil size/reactivity 80 times a second.

ONE SIMPLE APP

Completed: MVP Windows App

ONE SIMPLE TEST

Employee Follows Dot with their Eyes



Headset tracks their Eyes

The worker simply looks into the VR headset and, in the darkness of headset they see a simple green dot which moves under computer control to the right or to the left and can get brighter as well as being perceived as coming to the tip of the workers nose.

The computerized test protocol, which mimics the eye tests done by law enforcement, provides a stream of data to Ocular's proprietary machine learning / artificial intelligence software.

What is unique to Ocular is how it analyzes these data to come to a Low Risk or High Risk Assessment of real-time impairment.

An earlier version of SafetyScan (known as the EPS System) was included in a Transportation Research Board project entitled "Fitness-For-Duty in the Transit Workplace" (October, 1996 #TCRP F1).

This project explored the feasibility of using fitness-for-duty testing. A Summary of the 115 page Final Report is attached to this RFI.
Attachment6_Batelle

In conclusion, they state:

"The most sensitive test detected impairment in 79% of subjects at 0.08% BAC, 62.5% of subjects at 0.06% BAC, 38.46% of subjects at 0.04% and 19.35% of subjects at 0.02 BAC. These results suggest that one of the tests is especially promising as a fitness-for-duty assessment tool based upon the use of alcohol as the stressor."

That test was the EPS. The summary graph below not only shows that the EPS (FFD-01) had the best detection rate of any of the technologies chosen.

Equally important, the rate of detection follows the time course of alcohol metabolism.

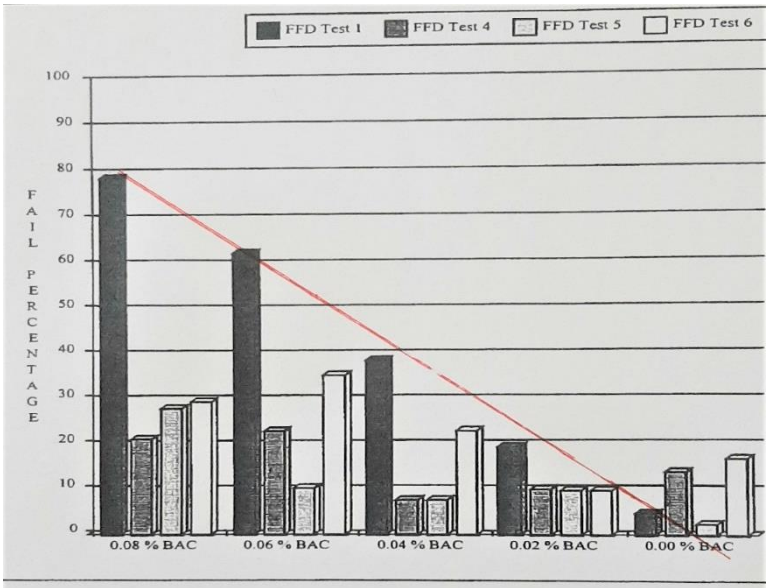


Figure 6-11. Fail Percentages at Various BACs for All FFD Tests

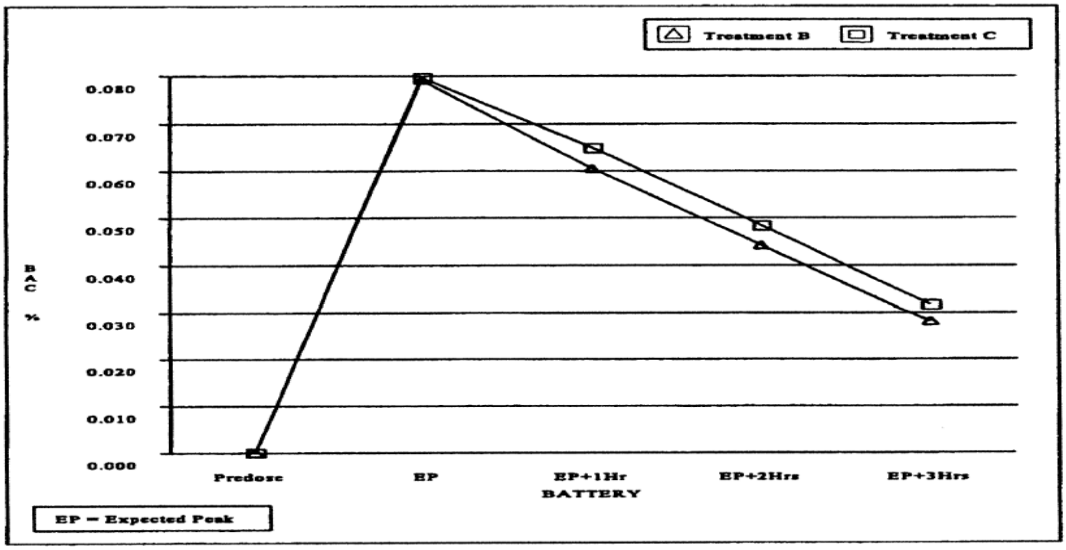


Figure 6-5. Average Peak BACs for the Alcohol Treatments

What is unique about Ocular's solution and covered under the following issued patents is knowing how to analyze these involuntary oculomotor and/or pupillary responses into **Yes/No** (*Low Risk/High Risk*) results .

United States Patent 7,614,745
http://www.freepatentsonline.com/7614745.html
System for analyzing eye responses to automatically determine impairment of a subject
Waldorf, et al. November 10, 2009

1. An impairment determination system for automatically determining impairment of a subject based on pupil responses during administration of a test protocol to said subject, as recorded in a time-wise sequence of digital images of at least one of the subject's eyes taken during administration of said test protocol to said subject, comprising: digital image processing means for identifying a location of a pupil of at least one of said subject's eyes in a plurality of said digital images in said sequence of digital images; pupil size means for computing a size of said pupil in said plurality of said digital images in said sequence of digital images; and impairment determining means, responsive to said location of a pupil and said size of said pupil in said plurality of said digital images in said sequence of digital images, for automatically determining whether said subject is impaired, comprising: stimulus means for recording a position of a stimulus target, used to direct movement of said subject's eyes, with respect to each digital image in said time-wise sequence of digital images, comparison means for contrasting said tracked eye movement in said sequence of digital images with said position of a stimulus target, and pattern means for identifying a departure of said tracked eye movement in said sequence of digital images with said position of a stimulus target against at least one predetermined pattern, representative of eye movement of said subject corresponding to a priorly administered stimulus protocol.

United States Patent 7,798,643
http://www.freepatentsonline.com/7798643.html
System for analyzing eye responses to automatically track size, location, and movement of the pupil
Waldorf, et al. September 21, 2010

1. *A pupil tracking system for automatically determining pupil responses, as recorded in a time-wise sequence of digital images of at least one of the subject's eyes, comprising: digital image processing means for identifying a location of a pupil of at least one of said subject's eyes in a plurality of said digital images in said sequence of digital images, comprising: center point determining means for identifying a darkest spot in the pupil of said eye, pupil geometry determining means for ensuring said pupil satisfies a minimum shape configuration, comprising: region-growing means for applying a region-growing procedure to said identified darkest spot of said pupil to expand the boundaries of said pupil to include regions of equivalent decreasing darkness; and pupil size means for computing a size of said pupil in said plurality of said digital images in said sequence of digital images.*

An example of how SafetyScan (or equivalent technology) could be used in the workplace is:

> *A person is hired by a school bus company. As part of the hiring process, a Post-Offer Drug Screen is required which includes a SafetyScan Screen.*
>
> *When all the results come back from the Post-Offer testing, including any MRO input, etc., and the company determines that worker is fit-for-duty, then the SafetScan Screen taken on that Post-Offer Visit becomes that workers Baseline Neurological Performance.*
>
> *Now, whenever the company policy dictates, the driver could be SafetyScan tested and results immediately compared to the persons Baseline Neurological Performance.*

Ocular has used SafetyScan in various clinical studies, the most recent if being a state-funded, IRB-approved, clinical trial at the University of Colorado entitled the “Observational Study of Driving Impairment in Occasional versus Heavy Marijuana Users”. Ashley Brooks-Russell and Michael J. Kosnett. Findings are soon to be published.

Ocular also plans to submit to the recently released SBIR Solicitation from the Department of Transportation, Request for Proposals. The following represent two of the applications that eye tracking technology can address:

21-FM2: Readiness Assessment Technology

NHTSA estimates that in 2017, 91,000 police-reported crashes involved drowsy drivers. These crashes led to an estimated 50,000 people injured and nearly 800 deaths. However, there is broad agreement across the traffic safety, sleep science, and public health communities that this is an underestimate of the impact of drowsy driving. (NHTSA Traffic Safety Facts, Drowsy Driving, October 201711). Drowsy driving's impact is even more pronounced among commercial vehicle drivers. Commercial vehicle drivers face many challenges that can increase fatigue including increased driving hours per day, nighttime driving, and health-related issues such as untreated obstructive sleep apnea.

An objective quantifiable measure, which can serve as a Readiness Assessment Technology, is needed to assess a driver's alertness *before* driving a commercial motor vehicle (CMV). Such a measure could be used to identify and mitigate driver fatigue. This project directly supports the Federal Motor Carrier Safety Administration's (FMCSA) strategic objective to produce safer commercial drivers, carriers, and vehicles described in FMCSA's Annual Modal Research Plan (AMRP)12. Additionally, the Readiness Assessment Technology developed through this process could potentially be useful to other Department of Transportation agencies. The technology could be applied to other modes as well as non-commercial drivers to address operator alertness.

The success of the Readiness Assessment Technology will rely on the product's ability to produce reliable, accurate and timely results when measuring driver readiness. Production of the end product must also be technically feasible and cost effective to produce. Additionally, the technology must comply with important security requirements such as confidentiality, integrity, privacy and security. Once successfully developed, the Readiness Assessment Technology will be marketable to prospective buyers such as CMV drivers and carriers who are challenged by drowsy driving and are interested in increasing driver safety. Overall, the results of this project will have strong potential to contribute to the overall reduction of crashes due to commercial drivers' alertness, thus furthering the strategic objectives set out in the FMCSA's 2020 AMRP.

Ocular has pilot-data showing the value of eye tracking related to issue of fatigue. See Appendix7_Fatigue. Done in conjunction with Circadian Technologies (Boston, MA), the EPS Device which was known at that point as 'SafetyScope' was used in a 'Proof of Concept' study where the subjects remained awake for 24 hours. Besides being tested with SafetyScope, subjects were evaluated on a

driving simulator test, a performance vigilance test, and EEG and EMG recordings were made.

Plotted against the average circadian rhythm graph of alertness, SafetyScope detected levels of fatigue that almost always occurred after midnight, through the 'wee-hours' of the morning. Note that the number of tests that were invalid - as the person could not complete the test or keep their eyes open in the dark internal environment of the device.

Accidents like Exon Valdez, Chernobyl, the Challenger Disaster, Bhopal in India, all had human fatigue-related issues that occurred during these wee hours.

I believe that more research into the issue of human fatigue based on oculomotor and pupillary research should continue as it seems to represent a fairly 'easy' screening solution to this very important aspect of human impairment/readiness.

Also, SafetyScan could be configured for the following application which would extend the interlock concept (which is limited to alcohol only) to one of safety and impairment – along with the ability to identify the user using iris identification. Identification of the driver is one of the major drawbacks of current interlock technology.

21-NH2: Ignition Interlock Device Data-Integrated Mobile Device App

Driving under the influence of alcohol is a serious problem, with alcohol-impaired drivers involved in 29% of all motor vehicle crash fatalities in 2017 (NHTSA, 2018)Rauch et al., 2010) Zador, Ahlin, Rauch, Howard & Duncan, 201114. Recidivism is of particular concern, given that individuals with a history of alcohol-impaired driving violations are more likely than those without such a history to drive while intoxicated (DWI) in the future (15. One effective sanction for reducing recidivism among DWI offenders is ignition interlock devices (IIDs)—devices installed in vehicles to prevent alcohol-impaired individuals from starting their vehicles. The effect of IIDs is further enhanced when offenders' IID performance is closely monitored and they are provided with frequent feedback. Unfortunately, this is often absent despite being a key factor in offenders' success on IIDs because of time-, cost-, or other logistical-constraints of the sanctioning agent/agency (16).

To address this limitation, this SBIR project aims to provide a time- and cost-effective approach to close monitoring and frequent feedback by developing an IID data-integrated mobile device application (app) to be used in conjunction with IIDs. Mobile device apps have become a common, easily-accessible, and widely-used approach to help individuals monitor and change a range of health and safety behaviors (Burke et al., 2011Bricker et al., 2014Juarascio et al., 2015Hoeppner et al., 201717; 18; 19; 20). However, to date, no app has been designed specifically for IID-sanctioned DWI offenders, despite their high risk for recidivism and the availability of IID data offering critical insight into their drinking and driving patterns.

The goal of this IID data-integrated mobile device app is (1) to enhance the effectiveness of IIDs at reducing recidivism while the IID is on the vehicle and (2) to retain that benefit once the IID is removed from the vehicle. To achieve this, the app would need to be able to "communicate" seamlessly with IIDs to capture and monitor offenders' IID performance in real-time and analyze overall patterns. The app would then utilize a variety of evidence-based approaches to behavior modification, including: providing frequent, immediate, detailed and tailored feedback; highlighting desirable/undesirable behavior; identifying and increasing users' awareness of their patterns of behavior, particularly their high-risk days/times and; preemptively offering reminders and alternatives prior to high-risk days/times. In addition, this approach will also address logistical and financial barriers to close monitoring and frequent feedback (e.g., time- and cost-constraints) by shifting the burden of this enhanced level of monitoring and feedback away from the sanctioning agents/agencies.

Finally, another important federal application for eye technology that would be germane to this NHTSA/DOT Request for Information is from the Food & Drug Administration (Attachment8_FDA).

In 2017 the FDA published non-binding guidance regarding 'Evaluating Drug Effects on the Ability to Operate a Motor Vehicle. Guidance for Industry". The purpose of the guidance is to assist pharmaceutical sponsors in the evaluation of the effects of psychoactive drugs on the ability to operate a motor vehicle. Specifically, this guidance addresses the FDA's current thinking regarding FDA-regulated drugs for which such evaluation may be needed2and the types of studies that such an evaluation entails during clinical trials.

I hope this information is helpful and I look forward to doing what I can to move the science of impairment forward. Thanks. R-

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