

"Eyenuk Inc.'s AI-based diabetic retinopathy screening software EyeArt™ tested with portable smartphone-based imaging device in new study indicating potential for highly sensitive yet cost-effective mass retinal screening"

A new study <u>published in the international 'Eye' journal (Springer Nature)</u> demonstrated very high sensitivity for detecting any diabetic retinopathy (95.8%) and sight-threatening diabetic retinopathy (99.1%) using <u>EyeArt</u>[™] automated screening software with <u>Remidio Fundus on</u> <u>Phone</u> system.

LOS ANGELES, CA, March 12, 2018 -- Eyenuk, Inc., a leading developer of advanced clinically supported artificial intelligence (AI) enabled solutions to identify diseases via retinal image analysis, today announced the publication of a study using Eyenuk's EyeArt[™] screening software on retinal images acquired with the <u>Remidio Fundus on Phone</u> (FOP) system, an FDA 510k registered fundus camera which combines a smartphone with patented optics. The study demonstrated very high sensitivity for detecting both any diabetic retinopathy (DR) and sight-threatening diabetic retinopathy (STDR), indicating potential for enabling highly sensitive yet cost-effective mass retinal screening.

The research, conducted at <u>Madras Diabetes Research Foundation</u> (MDRF) in Chennai, India, was <u>published in the international 'Eye' journal (Springer Nature)</u> by Dr. R. Rajalakshmi and her colleagues from MDRF. The study investigators chose Eyenuk's EyeArt™ AI screening software to analyze retinal images of individuals with diabetes taken with a Remidio Fundus on Phone system. The EyeArt™ screening software results were compared to independent blinded grading by retinal specialists to evaluate the diagnostic efficacy. Sensitivity for detecting any DR and STDR was 95.8% and 99.1% respectively, while specificity was 80.2% and 80.4% respectively. The study authors noted that some non-DR retinal lesions like drusen, RPE atrophic patch, a retinal telangiectatic vessel at macula, RPE hypertrophy, tessellated fundus and retinal vein occlusion were the causes of false positives.

"We are very encouraged by this study demonstrating impressive sensitivity and specificity using EyeArt[™] with images from this novel smartphone-based fundus imaging system. This is especially notable given that our AI system was never trained on images captured by the Remidio FOP system, suggesting the robustness and broad applicability of our software algorithms", stated Kaushal Solanki, Founder & CEO of Eyenuk, Inc. "We look forward to converting these impressive results into real-world clinical practice by eventually making EyeArt[™] available for mass diabetic retinopathy screening in conjunction with a lower-cost portable high-quality fundus imaging device like the Remidio system."

According to the <u>World Health Organization</u> (WHO), there are nearly 285 million visually impaired people worldwide. As many as 80% of those cases could have been avoided with early detection. With 90% of those affected living in low-income areas, an effective, accessible, affordable, and easy-to-use screening system is critical for early detection of eye diseases such as diabetic retinopathy, which if untreated may lead to blindness. Combining

Press Release



EyeArt[™] automated AI-based screening software with an affordable camera, such as the one offered by Remidio, may provide greater and less expensive access to eye screening around the world, and potentially reduce the incidence of blindness caused by diabetic retinopathy.

Until recently, diabetic retinopathy could only be detected by trained ophthalmologists and retina specialists who examine the back of the eye (retina) or by retinal color photography taken using expensive retinal cameras. Moreover, these retinal photographs had to be interpreted by trained eye doctors. Recently, advanced technologies like Remidio FOP that combine smartphones with sophisticated optics, have enabled cost-effective and high-quality retinal imaging that was not previously possible with basic smartphone attachments. Artificial intelligence, a simulation of intelligence by a software/machine, is a specialized field based on teaching the machine, via numerous examples, to accurately interpret the images. With recent advances in AI, pioneering tools like EyeArt™ can now be used to grade retinal images of people with diabetes to determine which patients have any retinopathy, or have sight-threatening retinopathy requiring urgent referral to an ophthalmologist.

Dr. V. Mohan, Chairman, <u>Dr. Mohan's Diabetes Specialities Centre</u> and Director, MDRF said, "One out of 5 Indians with diabetes are at risk for developing diabetic retinopathy. Given the alarming increase in the number of people with diabetes and shortage of trained retinal specialists, computer-based analysis using artificial intelligence of the retinal photographs, taken using sleek and user-friendly smartphone-based cameras would reduce the burden of the health systems in screening for sight-threatening retinopathy. Use of artificial intelligence to analyze retinal images is a significant development and it fits in well with the current trend of using telemedicine to reach the remote underserved parts of the country especially the rural areas where specialized healthcare is often non-existent", said Dr. Mohan.

Dr. R. Rajalakshmi, Head-Medical Retina, Dr. Mohan's Diabetes Specialities Centre and MDRF said, "Regular retinal screening for all people with diabetes is still an unmet need in most countries especially in poor developing countries. Automated artificial intelligence software along with smartphone-based retinal imaging can be a promising initial tool for mass retinal screening". She added that smartphone retinal color photography combined with an automated detection system can ideally result in models with potential for cost-effective routine clinical use by the primary care physicians.

Dr. Anand Sivaraman, CEO of <u>Remidio Innovative Solutions Pvt. Ltd</u>., said, "The simplicity achieved by combining smartphones with our patented optics has resulted in Remidio Fundus On Phone to be priced at 1/5th to 1/10th of any traditional desktop retinal imaging system, delivering high quality relevant images repeatedly with high sensitivity and specificity exceeding 92% and 98% when clinically validated. The use of artificial intelligence like EyeArt™ in screening the images from the Remidio Fundus on Phone device, now enables large scale public health screening for eye health among the 400 million affected by Diabetes, globally."



Press Release ABOUT EYENUK, INC.

Evenuk, Inc., headquartered in Los Angeles, California, is an AI diagnostic company focused on quickly and accurately identifying patients suffering from potentially blinding eye diseases and chronic diseases at the point of care. Using computer vision and machine learning expertise, the company is developing a portfolio of products based on its proprietary retinal image analysis technology combined with deep learning to identify and track the progression of diseases including diabetic retinopathy, glaucoma, age-related macular degeneration, risk of stroke, cardiovascular risk, and Alzheimer's disease. EyeArt[™] development was partially supported by prestigious <u>National Eye Institute (NEI/NIH)</u> grants (EB013585, EY026864, EY027241). EyeArt[™] has received <u>CE Marking</u> and <u>Health Canada approval</u>, and is commercially available in the European Union and in Canada. In the United States, EyeArt[™] is limited by federal law to investigational use only and is not available for sale. For more information, visit www.eyenuk.com.

ABOUT MADRAS DIABETES RESEARCH FOUNDATION:

<u>Madras Diabetes Research Foundation</u> (MDRF), a unique 100% nonprofit research centre exclusively devoted for advanced research on diabetes and its complications, was established in 1996. Madras Diabetes Research Foundation is recognized by the Indian Council of Medical Research (ICMR) as "ICMR Centre for Advanced Research on Diabetes"

ABOUT REMIDIO INNOVATIVE SOLUTIONS PVT LTD:

<u>Remidio</u> is an innovative medical device company that seeks to create Healthcare Access by combining simplicity of product design with cutting edge technology and sustainable business model innovations. Remidio uses principles of Design Thinking and involves key stakeholders during the product development process – clinicians, patients, and health workers, with a view to designing product solutions that are simple to use, clinically relevant, reliable and scalable. Remidio's CE marked and FDA 510k registered retinal imaging devices have helped screen and impact more than 7.5 million patients in 15 countries globally, as a result of increased access provided by the ease of use and affordability of Remidio's patented optics on the smartphone platform.

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