



EyeArt[®] AI System

for **Automated** Diabetic Retinopathy Testing



INSTANTANEOUS RESULTS



FULLY AUTONOMOUS



DILATION TYPICALLY NOT NEEDED



HIPAA COMPLIANT



NO SPECIALIST NEEDED AT POINT-OF-CARE



SUPPORTS EMR INTEGRATION



REIMBURSED BY MEDICARE

The *EyeArt* AI system is the **only** FDA-cleared artificial intelligence (AI) technology for detection of both more than mild and vision-threatening diabetic retinopathy (DR) and enables rapid, onsite DR testing in convenient settings:

Primary Care

**Diabetes Care /
Endocrinology**

Eye Care

**Community / Rural
Health & FQHC**

EyeArt AI System Workflow



Capture two color retinal images per eye
(*optic nerve centered and macula centered*)



Upload images to the secure *EyeArt* AI system for analysis in the cloud



Download the *EyeArt* Report
(*takes less than 30 seconds to process*)



Engage, triage, and educate patient at the point-of-care, referring when indicated by the report

INDICATION FOR USE

EyeArt is indicated for use by healthcare providers to automatically detect more than mild diabetic retinopathy and vision-threatening diabetic retinopathy (severe non-proliferative diabetic retinopathy or proliferative diabetic retinopathy and/or diabetic macular edema) in eyes of adults diagnosed with diabetes who have not been previously diagnosed with more than mild diabetic retinopathy. *EyeArt* is indicated for use with Canon CR-2 AF and Canon CR-2 Plus AF cameras in both primary care and eye care settings.

EyeArt[®] AI System

Clinical Validation

In a **landmark prospective multi-center pivotal clinical trial**, the *EyeArt* AI System was compared against the rigorous ETDRS* reference standard for the detection of more than mild diabetic retinopathy (mtmDR) and vision-threatening DR (vtDR). This study enrolled 915 patients at 15 primary care and eye care sites. The reference standard was provided by the Wisconsin Fundus Photograph Reading Center (FPRC) with adjudicated grading where each case was graded by 2 independent graders and disagreements were adjudicated by a senior grader.

*ETDRS = Early Treatment Diabetic Retinopathy Study

EyeArt AI System Performance

	mtmDR	vtDR
Sensitivity	96%	92%
Specificity	88%	94%

% of Patients with AI Diagnostic Results

(Imageability)

First attempt without dilation	90%
Dilation when needed	97%

	Dilation	Imaging	Human Reading
EyeArt AI System	Only When Needed ~10%	2-field Fundus (4 images)	None
ETDRS Reference	Required for all	4-wide field Stereoscopic (20 images)	Multiple Expert Graders at Wisconsin FPRC

Other Key Scientific Publications

- **BMJ Ophthalmology** - the *EyeArt* AI System demonstrated **100% sensitivity** for detection of moderate, severe, and proliferative DR in the largest AI prospective study in the world (n = 30,405)¹
- **Diabetes Technology and Therapeutics** - in over 100,000 consecutive encounters, the *EyeArt* AI System demonstrated **91.3% sensitivity** and **91.1% specificity** for detection of DR in the largest healthcare AI study in the world (n = 101,710)²
- **BMJ Ophthalmology** - **100% sensitivity** for detection of vision-threatening DR in the UK Moorfields Eye Hospital Study (n = 1,257)³

¹ P. Heydon, C. Egan, L. Bolter, R. Chambers, J. Anderson, S. Aldington, I. M. Stratton, et al. "Prospective Evaluation of an Artificial Intelligence-Enabled Algorithm for Automated Diabetic Retinopathy Screening of 30 000 Patients." *British Journal of Ophthalmology*, June 30, 2020.

² M. Bhaskaranand, C. Ramachandra, S. Bhat, J. Cuadros, M. G. Nittala, S. R. Sadda, and K. Solanki. "The Value of Automated Diabetic Retinopathy Screening with the EyeArt System: A Study of More Than 100,000 Consecutive Encounters from People with Diabetes." *Diabetes Technology & Therapeutics* 21, no. 11 (August 2019).

³ A. Olvera-Barrios, T. FC Heeren, K. Balaskas, R. Chambers, L. Bolter, C. Egan, A. Tufail, and J. Anderson. "Diagnostic Accuracy of Diabetic Retinopathy Grading by an Artificial Intelligence-Enabled Algorithm Compared with a Human Standard for Wide-Field True-Colour Confocal Scanning and Standard Digital Retinal Images." *British Journal of Ophthalmology*, May 5, 2020.



5850 Canoga Avenue
Suite 250
Woodland Hills, CA 91367

☎ 1 818 835 3585

✉ eyeart@eyenuk.com

🌐 www.eyenuk.com

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