PRODUCT INFORMATION

EyeArt INDICATIONS 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.

HOW DOES EyeArt WORK

1. EyeArt operator captures images of the retina using an indicated fundus camera.
2. These images are submitted to the EyeArt analysis engine by an operator using the EyeArt client.
3. EyeArt analyzes the images for signs of more than mild diabetic retinopathy (mtmDR) and vision-threatening diabetic retinopathy (vtDR) using an ensemble of deep learning networks.
4. EyeArt provides quality or more than mild DR and vision-threatening DR outputs with follow up instructions for care.

HOW CAN I GET EyeArt TO WORK IN MY CLINIC?

- EyeArt is indicated for use with Canon CR-2 AF and Canon CR-2 Plus AF.
- EyeArt operator will need a comprehensive training session by an Eyenuk certified trainer
- EyeArt will work with existing computers and internet connection.
- EyeArt is designed to interface with electronic health record systems.

EyeArt INPUT

2 color images with 45 degrees (field of view) per eye – 1 optic nerve head centered, and 1 macula centered.

EyeArt RESULTS

EyeArt results are at eye-level and can be output as a PDF report or in XML or JSON formats.

EASY TO INTERPRET RESULTS

- Negative for more than mild DR in both eyes. Return for retinal imaging within 12 months.
- More than mild DR detected in *<left/right/both>* eye(s). Refer to an eye care professional for evaluation.
- Vision-threatening DR detected in *<left/right/both>* eye(s). Refer to an eye care professional for evaluation (with preferential scheduling if possible).
- Ungradable images detected. Refer to an eye care professional for evaluation. Patient may have underlying vision-threatening DR and/or other abnormalities.

PATIENT DATA PROTECTION

- Patient data protection and privacy as per HIPAA and GDPR.
- HIPAA processes audited by independent third parties.

QUALITY MANAGEMENT SYSTEM

- ISO 13485 certified. Quality management system is compliant with FDA Quality Systems regulations.
- Regular internal and third-party audits.