



EyeArt v2.1.0

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# EyeArt Artificial Intelligence (AI) Eye Screening System

## Indications for Use

*The EyeArt system is intended for use by healthcare providers to screen for diabetic retinopathy in patients with diabetes via computerized analysis of colored images of the retina.*

## Warnings

- The EyeArt System is intended to screen only for diabetic retinopathy (DR). EyeArt is not indicated for any other retinal, ophthalmic or any other systemic disease(s). It does not take the place of a regular eye examination for purposes of assessing the presence of age-related macular degeneration, glaucoma, cataract, anterior segment diseases, peripheral retinal diseases, or other possibly vision threatening conditions.
- The EyeArt system does not treat DR. A healthcare provider should review the EyeArt system's results and if necessary, advise patients for referral to an eye care provider for follow-up care.
- The EyeArt system does not diagnose or treat diabetes – it is only for use in people already diagnosed with diabetes.
- The EyeArt system has limitations and therefore it is possible that in some cases EyeArt might miss retinopathy (false negative) or indicate presence of retinopathy where there is none (false positive).
- The EyeArt system uses the presence of surrogate markers for detecting the presence of clinically significant diabetic macular edema (CSDME).
- The EyeArt system is designed to work with good quality retinal color images with sufficient field of coverage. Do not use the EyeArt system with images of other tissues or random objects for evaluation. Refer to the EyeArt photography manual for minimum requirements for good quality retinal images.
- In some cases, if the images are of poor quality or without sufficient field of coverage, the EyeArt system provides an *Ungradable* output. In such cases, fundus photography and EyeArt analysis may be retried. If the EyeArt system's outcome of *Ungradable* persists after retrying, the patient may have vision threatening diabetic retinopathy, or other abnormalities and should be referred to an eye care provider.
- If the EyeArt system is unable to perform screening, it raises a *Technical Error*. In such cases, analysis by the EyeArt system may be retried after checking internet connectivity. If the error persists, it is recommended that the images be manually graded by trained personnel or the patient be referred to an eye-care provider.
- If the patient experiences vision loss, blurred vision, floaters or any other symptoms, he/she should be immediately brought to attention of an eye care provider.
- The user is responsible for uploading and labeling the images appropriately to avoid any patient-data mismatch by the EyeArt system. Please ensure that all the images submitted for a patient belong to that patient.
- A mydriatic agent like tropicamide (1.0% solution) may be administered to some patients who are unable to dilate. Refer to the respective label of the mydriatic agent for contraindications, warnings and precautions.

## Precautions

- The user should ensure that the computer on which the EyeArt system is being installed, meets the minimum requirements as set out in the EyeArt user manual.
- To prevent unauthorized access to the patient data on the EyeArt system (data input and results), it is strongly recommended that the computer on which the EyeArt system is installed be password-protected (using a strong password); free of viruses and malware; with anti-virus software and firewall installed and activated; and updated with the latest security patches. It is also recommended that the local database created by the EyeArt system be periodically backed-up (refer to the EyeArt user manual).
- It is recommended that retinal photographers undergo training according to the EyeArt photography manual prior to using the EyeArt system.

\*EyeArt has been cleared for sales as a Class IIa medical device by EU and as a Class 2 medical device by Health Canada. In the United States, EyeArt is limited by federal law to investigational use. This document is not applicable to the United States. v1\_20190411