



EyeArt v2.1.0

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EyeArt Artificial Intelligence (AI) Eye Screening System

Intended Use Statement

The EyeArt System is intended to detect signs of diabetic retinopathy including diabetic macular edema in patients with diabetes using computerized analysis of colored images of the retina.

Warnings

- The EyeArt system is only designed to detect diabetic retinopathy. It is not intended to detect concomitant diseases, other ophthalmic diseases, or other systemic diseases. Patients should not rely on the EyeArt system for detection of any other disease.
- Patients with an EyeArt result should be immediately referred to an eye-care provider for further diagnosis and treatment or strongly encouraged to test again based on the management guidelines and recommendations of appropriate professional societies.
- If the EyeArt system is not able to generate a detection result on a patient due to poor quality of images, such a patient may be retested immediately after pharmacologic dilation. If dilation is not possible or if the EyeArt system still does not generate a detection result, such a patient should be referred to an eye care provider for evaluation since the patient may have vision threatening diabetic retinopathy, or other abnormalities including cataract.
- The EyeArt system is designed to work with good quality, in-focus, retinal color images. Do not use the EyeArt system with other images of the retina, other tissue, or random objects.
- The user is responsible for ensuring that the images submitted (input) to the EyeArt system for a patient are correct and correspond to that patient in order to avoid mistaken identity with respect to EyeArt results.

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).
- The user should read and understand this user manual completely before proceeding to use the EyeArt Device.
- The user should be familiar with the general use of a personal computer running one of the operating systems