

## 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 diabetic retinopathy. EyeArt is indicated for use with Canon CR-2 AF, Canon CR-2 Plus AF, and Topcon NW400 cameras.

## CONTRAINDICATIONS

The clinical trial validating EyeArt did not include the following patients who met the specified criteria. Therefore, EyeArt is contraindicated for use on such patients.

- Patients with persistent visual impairment in one or both eyes. Patients complaining of decreased vision should be referred to an eye care specialist;
- Patients with a known history of macular edema, retinal vascular occlusion, or retinopathy from any cause should be referred to an eye care specialist.;
- Patients with a history of ocular injections, laser treatment of the retina, or intraocular surgery (other than uncomplicated cataract surgery);
- Patients who are contraindicated for fundus photography (for example, have hypersensitivity to light).

## WARNINGS

- EyeArt is only indicated to detect diabetic retinopathy. It is not intended to detect concomitant diseases, other ophthalmic diseases, or other systemic diseases. Patients should not rely on EyeArt for detection of any other disease.
- Patients with a known history of diabetic retinopathy should follow up with their eye care providers for evaluation. Patients who have been previously told by their eye care providers that they require eye care follow-up should be advised to continue that follow-up with eye care per the eye care providers' recommendations.
- Patients with an EyeArt result indicating diabetic retinopathy should be immediately referred to an eye care professional for further screening and treatment that is consistent with the recommendations of appropriate professional societies. In cases where EyeArt does not provide a detection result, the patient should always be immediately retested or referred to an eye care professional. In cases where EyeArt does not detect the presence of referable disease, the patient should be strongly encouraged to test again at an appropriate point in the future.
- Patients should be informed that EyeArt does not treat retinopathy and that their images are analyzed to determine whether further examination is needed by an eye care professional. Physicians should review EyeArt results and advise patients of recommended referrals to an eye care professional for evaluation and potential treatment.
- If EyeArt 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 of the pupil. If dilation is not possible or if EyeArt still does not generate a detection result, such a patient should be referred to an eye care professional for evaluation since the patient may have vision-threatening diabetic retinopathy, or other abnormalities including cataract.
- EyeArt is not intended for use in screening for diabetes mellitus – it is only for use on people already diagnosed with diabetes mellitus.
- EyeArt is designed to work with good quality, in-focus, disc- and macula-centered retinal fundus images. Do not use EyeArt with other images of the retina, other tissue, or random objects.
- EyeArt is only intended to be used with images acquired with the Canon CR-2 AF, Canon CR-2 Plus AF, and Topcon NW400 cameras. Refer to the FDA cleared User's Manuals of the cameras for relevant contraindications, warnings, and precautions.
- The user is responsible for ensuring that the images submitted (input) to EyeArt for a patient are correct and correspond to that patient in order to avoid mistaken identity with respect to EyeArt results.
- The performance of EyeArt in pregnant patients has not been determined. Women with diabetes mellitus who become pregnant should receive eye examination early and closely in the course of the pregnancy because the disease can progress rapidly, therefore more frequent evaluations for diabetic retinopathy by an eye care provider should be considered by their health care providers.
- Please be aware that use of EyeArt may result in false negatives and false positives. EyeArt may fail to detect more than mild or vision-threatening diabetic retinopathy when it exists (false negative) or may erroneously indicate that it exists when in reality it does not (false positive).