

## 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.

## 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 history of macular edema, moderate non-proliferative retinopathy, severe non-proliferative retinopathy, proliferative retinopathy, or retinal vascular (vein or artery) occlusion. Patients with a history of macular edema or retinopathy other than mild (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 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. 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 color 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 and Canon CR-2 Plus AF 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.