RETINA-AI Galaxy

	RETINA-AI Health, Inc. 2925 Richmond Ave, Suite 1200 Houston TX 77098 https://www.retinahealth.ai/	REF	**0001**	**[Placeholder for UDI]**
		LOT	**1.0.1**	

INDICATIONS FOR USE

RETINA-AI Galaxy is indicated for use by healthcare providers to automatically detect more than mild diabetic retinopathy (mtmDR) 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. RETINA-AI Galaxy is indicated for use with CenterVue DRSPlus, Next Sight Nexy, Crystalvue NFC-700, Topcon NW400, and CenterVue DRS cameras in primary care settings.

Rx only	Federal law restricts this device to sale (or use) on the order of a licensed practitioner.
	Read and understand instructions for use before using this product.

CONTRAINDICATIONS

- ⚠ 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

- ⚠ RETINA-AI Galaxy 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 RETINA-AI Galaxy for detection of any other disease.
- ⚠ Patients with a RETINA-AI Galaxy 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 RETINA-AI Galaxy does not provide a detection result, the patient should always be immediately retested or referred to an eye care professional. In cases where RETINA-AI Galaxy 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 RETINA-AI Galaxy 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 RETINA-AI Galaxy results and advise patients of recommended referrals to an eye care professional for evaluation and potential treatment.
- ⚠ If RETINA-AI Galaxy 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 RETINA-AI Galaxy 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.
- ⚠ RETINA-AI Galaxy is not intended for use in screening for diabetes mellitus – it is only for use on people already diagnosed with diabetes mellitus.
- ⚠ RETINA-AI Galaxy is designed to work with good quality, in-focus, disc- and macula-centered retinal color images. Do not use RETINA-AI Galaxy with other images of the retina, other tissue, or random objects.
- ⚠ RETINA-AI Galaxy is only intended to be used with images acquired with the CenterVue DRSPlus, Next Sight Nexy, Crystalvue NFC-700, Topcon NW400, and CenterVue DRS cameras. Refer to the FDA cleared User's Manuals of the cameras for relevant contraindications, warnings, and precautions. Pharmacologic dilation (mydriasis) using a Tropicamide 1.0% solution may be required to capture sufficient quality images in some patients. Refer to the FDA approved label of Tropicamide 1.0% for relevant contraindications, warnings, and precautions.
- ⚠ The user is responsible for ensuring that the images submitted (input) to RETINA-AI Galaxy for a patient are correct and correspond to that patient in order to avoid mistaken identity with respect to RETINA-AI Galaxy results.

RETINA-AI Galaxy (v1.0.1) performance at detecting more than mild diabetic retinopathy (mtmDR)			
Camera	**Sensitivity**	**Specificity**	**Imageability**
CenterVue DRSPlus	95.0% [90.7%-98.3%]	82.8% [79.0%-86.1%]	99.2% [98.4%-99.9%]
Crystalvue NFC-700	89.2% [84.1%-94.0%]	82.5% [78.7%-86.0%]	99.2% [98.6%-99.7%]
Topcon NW400	87.3% [81.8%-92.4%]	83.2% [79.8%-86.3%]	96.5% [94.9%-98.1%]
CenterVue DRS	88.2% [82.5%-93.6%]	85.3% [81.9%-88.7%]	94.0% [91.8%-96.2%]
Next Sight Nexy	83.6% [77.3%-89.5%]	82.6% [79.1%-85.9%]	99.2% [98.4%-99.9%]
RETINA-AI Galaxy (v1.0.1) performance at detecting vision-threatening diabetic retinopathy (vtDR)			
Camera	**Sensitivity**	**Specificity**	**Imageability**
CenterVue DRSPlus	97.1% [90.0%-100.0%]	84.0% [80.4%-87.1%]	99.2% [98.4%-99.9%]
Crystalvue NFC-700	88.2% [74.0%-97.6%]	88.1% [85.2%-90.8%]	99.2% [98.6%-99.7%]
Topcon NW400	93.9% [83.9%-100.0%]	94.8% [93.0%-96.5%]	96.5% [94.9%-98.1%]
CenterVue DRS	94.1% [84.2%-100.0%]	85.0% [81.9%-87.9%]	94.0% [91.8%-96.2%]
Next Sight Nexy	94.1% [84.0%-100.0%]	90.9% [88.5%-93.2%]	99.2% [98.4%-99.9%]

RETINA-AI Galaxy (v1.0.1) clinical performance testing summary

The clinical trial in which the RETINA-AI Galaxy was tested prospectively enrolled 397 people age 22 or above who had diabetes but had not been previously diagnosed with more than mild diabetic retinopathy. ClinicalTrials.gov ID: NCT04774822. The population was representative including for example median age 53.2 years, age range 22.3 to 84.9 years; 0.5% American Indian or Alaska Native, 2.3% Asian, 20.3% Black or African American, 67.5% White, and 9.4% Other races; 48.8% were Hispanic/Latino; 61.6% were female, 38.4% male; 3.6% had Type I diabetes and 96.4% had Type II diabetes. Exact demographics varied slightly by camera and were nearly identical across all 5 cameras. To obtain the clinical performance results, the diagnostic output of the RETINA-AI Galaxy was compared to the assessment of American Board of Ophthalmology-certified ophthalmologists who are also fellowship-trained retina specialists.

Area Under the Receiver Operator Characteristic Curve (AUC) was as follows for mtmDR. On DRSPlus AUC = 0.97 [0.95-0.98]; on Crystalvue AUC = 0.93 [0.90-0.95]; on Nexy, AUC = 0.91 [0.88-0.94]; on Topcon AUC = 0.95 [0.93-0.97]; on DRS AUC = 0.95 [0.93-0.97]. For vtDR AUCs are as follows. on DRSPlus AUC = 0.97 [0.95-0.99]; on Crystalvue AUC = 0.91 [0.85-0.97]; on Nexy AUC = 0.94 [0.88-0.98]; on Topcon AUC = 0.96 [0.92-0.99]; on DRS AUC = 0.97 [0.94-0.99]