optain
powered by eyetelligence

Camera and Assure Plus

Product Spec Sheet

Camera Description:

The camera captures fundus images automatically, achieved by auto alignment, auto focus, and auto voice interaction. It features split focusing technology and 15 mega pixels resolution for HD images, with 50° field of view.

Assure Plus Description:

Assure Plus is a Software as a Medical Device (SaMD) product which deploys a collection of clinically validated Artificial Intelligence (AI) based algorithms to provide a classification or grading on the retinal images, collected through fundus camera, for Diabetic Retinopathy (DR), as well as screening for Cardiovascular Disease (CVD) risks.

The SaMD is installed in a tablet which can be connected to the camera through WiFi or Ethernet. It does not require instant access to the Internet or access to high computing capacity such as GPU.

Assure Plus includes the following components.

1. Models: This component is the fundamental package for image grading algorithms stored in the local computer folder.
2. Assure Plus: This component is the main application of this product and provides the application package for user interface and operations including Session, Results and Settings sections.
3. Database: This component is used to store data and settings for the software. The database file is stored in the local computer folder.
4. Camera server: This component is used to connect to the camera.

Intended Purpose:

Assure Plus is intended to classify the images collected from fundus cameras to screen for Diabetic Retinopathy (DR), and CVD risks in patients/consumers. Assure Plus reports are intended to be subsequently verified and certified by a qualified healthcare professional who will make a clinical diagnosis based on a range of inputs not limited to Assure Plus reports.

Camera and Assure Plus connection:

The camera and the tablet need to join the same network. Then the Connect Camera button on the Assure Plus software is used to connect to the camera.

Caution:

Assure Plus is intended to provide information along with other inputs to the appropriate clinicians about the patients' likelihood of suffering from Diabetic Retinopathy (DR) , glaucoma and AMD. It is not intended as a definitive tool for diagnosis.

Assure Plus Regulatory Approval:

- Australia: TGA Class I
- Europe: CE Class I
- UK: MHRA Class I
- NZ: Medsafe Class I

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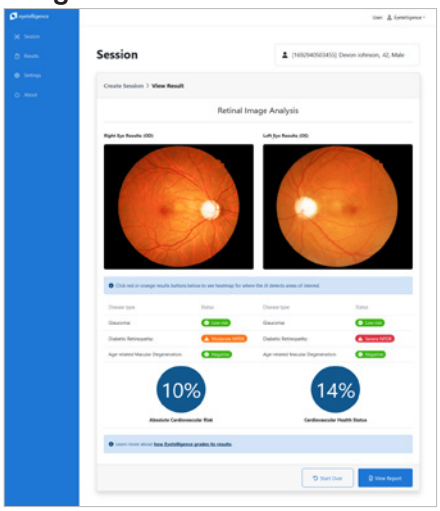
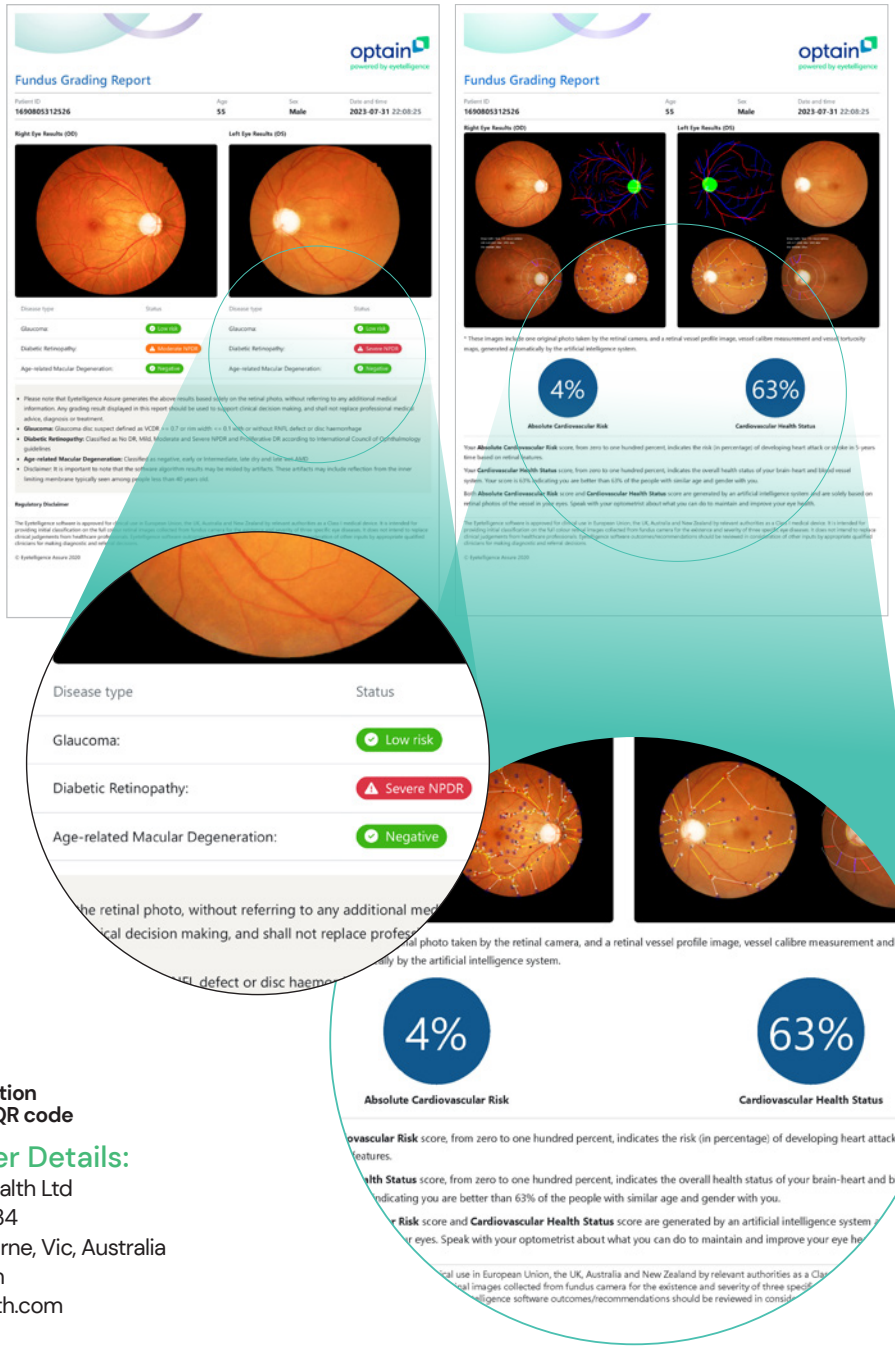
System output:

Assure Plus generates decision support reports in machine readable (CSV), rendered screen views and print out format (PDF).

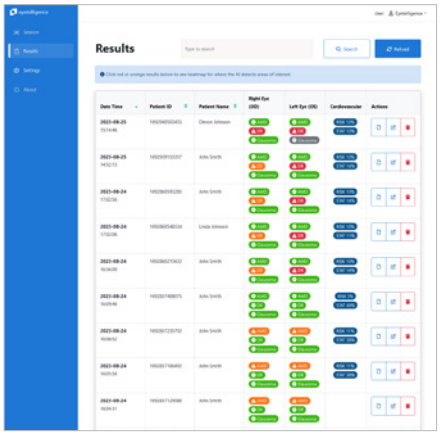
Image view:



Printed View:



Results view:



For more information please scan the QR code

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References:

Keel S, Lee P, Scheetz J, et al He M. Feasibility and patient acceptability of a novel artificial intelligence-based screening model for diabetic retinopathy at endocrinology outpatient services: a pilot study. Scientific reports 2018. | Li Z, He Y, Keel S, Meng W, Chang RT, He M. Efficacy of a deep learning system for detecting glaucomatous optic neuropathy based on color fundus photographs. Ophthalmol 2018: In press. | Ting DSW, Cheung CY, Lim G, et al He M, Wong TY. Development and Validation of a Deep Learning System for Diabetic Retinopathy and Related Eye Diseases Using Retinal Images From Multiethnic Populations With Diabetes. Jama 2017; 318(22): 2211-23. | Lin Z, Shi D, Zhang D, Shang X, He M, Ge Z. Camera Adaptation for Fundus-Image-Based CVD Risk Estimation. InInternational Conference on Medical Image Computing and Computer-Assisted Intervention 2022 Sep 16 (pp. 593-603). Cham: Springer Nature Switzerland.

Regulatory Disclaimer

The Eyetelligence software is approved for clinical use in the European Union (CE mark) and Australia and included in the ARTG, the TGA 's register of therapeutic goods, as a Class I medical device. It is intended for the assessment of the retinal vascular system and to screen for microvascular health issues of the body, based on full colour fundus photos that are generated from a fundus camera. The Eyetelligence system outcomes are intended to be subsequently verified and certified by a qualified medical/eye care professional who will make a clinical decision based on a range of inputs not limited to Eyetelligence outcomes.