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Assure Plus

Product Spec Sheet

Product 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), Age-Related Macular Degeneration (AMD) and Glaucoma as well as screening for Cardiovascular Disease (CVD) risks.

The SaMD can be installed either on a desktop computer or a server environment which has access to patients' retinal images. 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. **A web application mode:** This component allows users from within the intranet to view and manage patient records, and download reports on the browser.
5. **A sub user mode:** This component allows the administrator to create individual user profiles, granting users within the intranet the ability to access and utilise the software.

Intended Purpose:

Assure Plus is intended to classify the images collected from fundus cameras to screen for Diabetic Retinopathy (DR), Age-Related Macular Degeneration (AMD), Glaucoma 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.

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), Age-Related Macular Degeneration (AMD) and Glaucoma. It is not intended as a definitive tool for diagnosis.

Validation:

Using an image data pool of over 200,000 retinal images from various clinical settings, the Eyetelligence technical team has developed and validated the SaMD application (a convolutional neural network deep learning system for the automated detection process) across many ethnicities.

Algorithm Performance:

The performance of screening for referable DR (≥moderate nonproliferative DR and/or macular oedema), glaucoma suspect, and late-wet AMD have been published in peer reviewed journals (see references). A panel of 21 licensed ophthalmologists were recruited in the performance validation. Table below summarises the performance of the AI-based deep-learning model at screening for those diseases in independent validation image sets.

Measurement	Glaucoma suspect	Late-wet AMD	Referable DR
Validation set	8,000	3,850	8,000
Negative	6,463	706	6,532
Positive	1,537	3,144	1,468
Sensitivity	95.6%	98.0%	97.0%
Specificity	92.0%	94.0%	91.3%
Accuracy	92.9%	94.7%	92.4%

For CVD screening the AI has been validated against publicly available databases, like UKBioBank, and has been found to be very accurate (AUC=0.88 for risk score>10%) compared to WHO CVD calculators.

Regulatory Approval:

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

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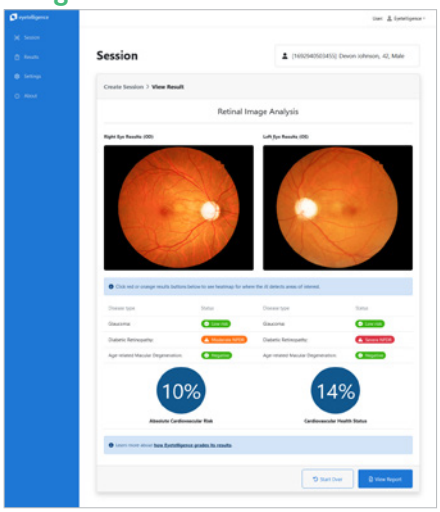
Hardware Requirement:

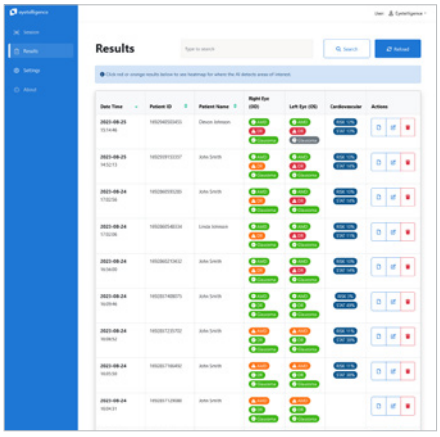
Assure Plus requires the following hardware and environment settings. It doesn't require access to a high performance computing facility such as a GPU.

- CPU: Quad-core 2.4 GHz or faster
- RAM: 8GB or above
- Hard Disk: 200GB available space, SSD
- OS: Windows 10/11, 64 bit

Image view:



Results view:



Patient Data Security

Assure Plus can be locally deployed and does not collect and send any patient identity and clinical information outside the SaMD users' desktop computer or server environment. When the application is installed in a server environment, all connections will be done via secure VPNs and only de-identified information will be shared.

The SaMD users need to ensure the patient information and other sensitive data is protected and secure.

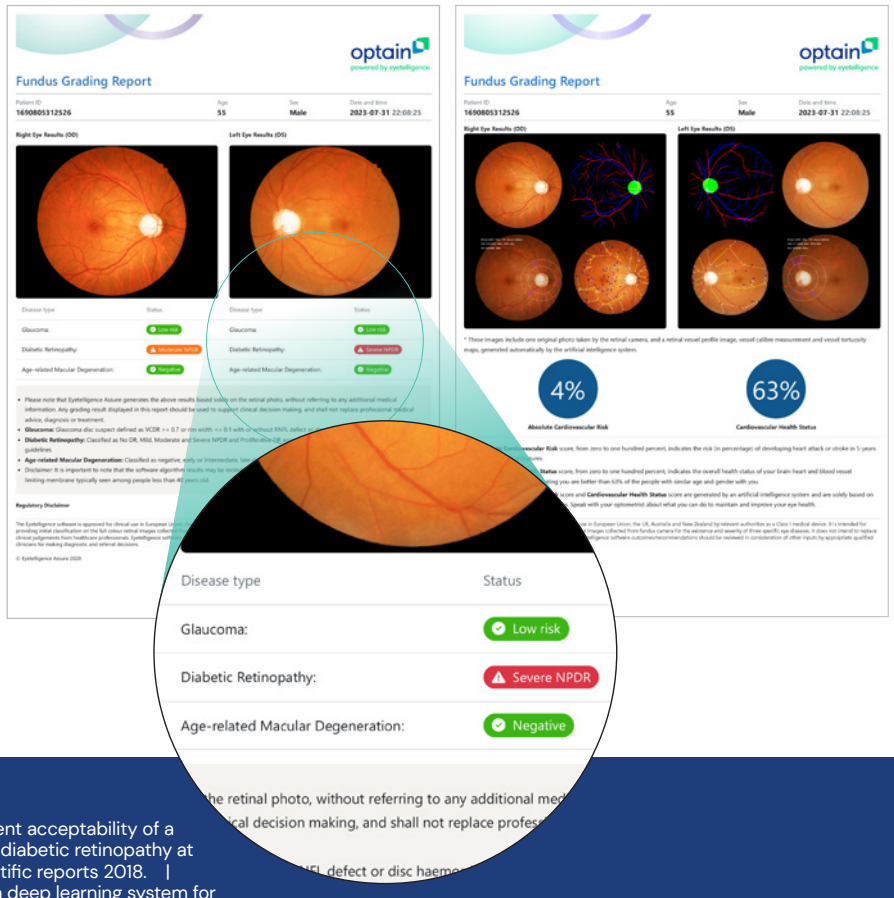
Compatibility:

Assure Plus AI algorithms were trained and validated using images taken from many different camera manufacturers. The algorithms are able to screen for the three referable eye diseases using fundus images from most global leading camera manufacturers.

System output:

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

Printed View:



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.

For more information please scan the QR code

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