

MONA GLC

v.1.0.0

INSTRUCTIONS FOR USE

Description of MONA GLC

MONA GLC is a software product developed by MONA.health that incorporates artificial intelligence-based algorithms to evaluate ophthalmic images of the retina to predict the need for referral for primary open angle glaucoma (POAG) screening. MONA GLC is not intended to provide information to be used to take decisions with diagnostic or therapeutic purposes.

For example, following a positive result from MONA GLC, patients should undergo a comprehensive standard-of-care POAG screening without the use of MONA GLC, using established medical devices and procedures. As with any screening tool, false negative results may occur. Therefore, individuals who receive a result indicating no need for referral for POAG screening should be encouraged to undergo repeat evaluation in accordance with applicable national or local screening guidelines. MONA GLC is intended to support entry into, and not replace, established POAG screening workflows.

MONA GLC uses an application where users upload color fundus images that meet the requirements specified in the indications for use.. The application transmits the captured images to a secure server for subsequent analysis using deep learning (DL) algorithms, which yields a score that the software then thresholds to create a binary label for the need for referral for POAG screening.

The results support the healthcare provider decide whether to refer for further screening using standard-of-care clinical procedures. MONA GLC does not rule out the presence of unscreened diseases. If MONA GLC is inconclusive, individuals should be referred to an ophthalmologist.

Intended purpose and indications for use

MONA GLC is an artificial intelligence software intended to evaluate ophthalmic images from fundus cameras to predict the need for referral for primary open angle glaucoma (POAG) screening.

MONA GLC is indicated for use by healthcare providers to identify adult individuals who may require referral into POAG screening pathways, by making use of a software solution with an interface and artificial intelligence models. MONA GLC is indicated for use with two fundus images per individual, one from the left eye and one from the right eye. These images should be of good quality, in-focus, unaltered* , centered on the optic disc with a 45-degree field of view and captured using a color fundus camera. (* original camera exports, no screenshots or images with annotations).

Note: MONA GLC is not intended to provide information to be used to take decisions with diagnosis or therapeutic purposes, but rather to support referral into established POAG screening pathways in accordance with standard clinical practice. MONA GLC does not rule out the presence of unscreened diseases. If MONA GLC is inconclusive, individuals should be referred to an ophthalmologist.

Clinical Benefit

MONA GLC is an artificial intelligence-based technology that enables a simple and accessible method to identify individuals who may require referral into primary open-angle glaucoma (POAG) screening pathways within the field of ophthalmology.

Performance Characteristics

MONA GLC demonstrates performance in predicting the need for referral into primary open-angle glaucoma (POAG) screening pathways, with a sensitivity of >85% and a specificity of >85%. The software has demonstrated an overall accuracy of >96% in a large evaluation population (n = 11,952).

Contraindications

MONA GLC is not intended to be used on images from:

- individuals under 18 years of age
- individuals with prosthetic eyes
- individuals contraindicated for imaging with the fundus imaging system used to obtain retinal images

Warnings and recommendations

The following warnings/precautions are listed for MONA GLC








- MONA GLC is not intended to provide information to be used to take decisions with diagnosis or therapeutic purposes.
- If the individual reports sight problems, a negative screening result should not be the basis for not referring the individual to a qualified physician.
- The wearing of contact lenses, spectacles or other vision-correcting devices by the person under examination during image acquisition will negatively impact device performance or may even inhibit device operation at all.
- MONA GLC is only designed to predict the need for referral for primary open angle glaucoma (POAG) screening. It is not intended to predict any other ophthalmic diseases or any other systemic diseases. Individuals should not rely on MONA GLC for referral for any other disease screenings.
- MONA GLC is also not intended to follow the progress of primary open angle glaucoma (POAG) or to manage progress update reports.
- Individuals who get a result indicating the need for referral for primary open angle glaucoma (POAG) screening should be immediately referred to an ophthalmologist for further screening, diagnosis and treatment.
- Individuals who get the result of no need for referral for primary open angle glaucoma (POAG) screening should be strongly encouraged to test again in a time period according to the guidelines applicable in his/her respective country.
- If MONA GLC is not able to generate a result on an individual due to the poor quality of the images, the individual may be retested immediately after pharmacologic dilation. If dilation is not possible or if MONA GLC still does not generate a result, the individual should be referred to an ophthalmologist for evaluation since the individual may have vision threatening primary open angle glaucoma (POAG), or other abnormalities including cataract.
- MONA GLC is designed to work with two fundus images per individual, one from the left eye and one from the right eye. These images should be of good quality, in-focus, unaltered* , centered on the optic disc with a 45-degree field of view and captured using a color fundus camera (* original exports of the camera, no screenshots or images with annotations).
- MONA GLC has limitations that the user should be aware of:

- MONA GLC performs computerized interpretation of retinal images therefore MONA GLC will miss the need for referral for primary open angle glaucoma (POAG) screening, in some cases (false negatives), and erroneously flag the need for referral for primary open angle glaucoma (POAG) screening, in others where there is none (false positives).
- The user is responsible for ensuring that the images submitted (input) to MONA GLC for an individual are correct and correspond to that individual in order to avoid mistaken identity with respect to MONA GLC results.
- Individuals should be advised to immediately report to an ophthalmologist if they experience vision loss, blurred vision, floaters or any other symptom as these symptoms require the immediate attention of an ophthalmologist.

Best-practice tips and precautions

- The user should ensure that the computer on which MONA GLC is being installed, meets the minimum requirements as set out in the MONA GLC Engineering Manual.
- To prevent unauthorized access to the patient data on MONA GLC (data input and results), it is strongly recommended that the computer on which MONA GLC is installed be password-protected (using a strong password); free of viruses and malware; with anti-virus software and firewall installed and activated; and updated with the latest security patches.

Description of Symbols used on the product MONA GLC software label

Symbol	Description
	Medical Device
	Manufacturer
	Date of Manufacture
	CE Marking
	Unique Device Identifier
	Consult Instructions for use
	Follow instructions for use

Incident reporting

In case any serious incident occurs in relation to MONA GLC, this should be reported to your MONA.health representative (or info@mona.health) and the component authority of your country.

Manufacturer contact details

MONA GLC
V1.0.0
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MONA.health can supply a hard copy of the instruction for use within 7 calendar days of receiving a request from the user.