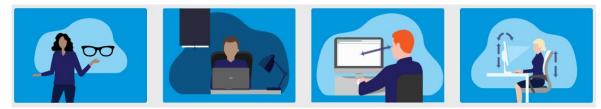


Eyeonic Visual Field Test

User Manual



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Eyeonic provides accurate, convenient and secure online assessment of your peripheral vision



Welcome,

The Eyeonic team wish you a warm welcome to the online Eyeonic Visual Field Test.

Visual field testing is critical for modern eyecare. It involves the assessment of a person's peripheral vision, one eye at a time. It detects and monitors diseases of the eye like glaucoma. Glaucoma is common, affecting 76 million people globally, in all populations of the world. People are often unaware of their glaucoma until it is advanced, however if detected early treatment can be given to save sight. And yet, 50% in the most developed countries and 90% in the least developed countries do not know they have glaucoma.

Until recently, visual field testing required dedicated, expensive machines that can only be accessed at an eyecare clinic. This means poorer and more remote regions could not access visual field testing. Even in wealthy regions, the inconvenience of attending an eyecare clinic means many people do not check their eyes leading to more severe visual problems later.

Through its revolutionary technology, the Eyeonic Visual Field Test allows anyone to test their visual field on any computer.

All that is required is a stable internet connection. By improving access to visual field testing, Eyeonic hopes that its technology means easier visual field testing and earlier detection of glaucoma globally. Visual field machines are large, bulky, expensive and difficult to use and maintain; in comparison computers and the internet are cheaper and widely available.

Visual field testing is often not fun. Using the older machines, people find the test stressful, uncomfortable, and often feel out of control. The online Eyeonic visual field test has been designed to be a more comfortable and enjoyable experience, while still accurate. User's love it –84% of users strongly prefer it to conventional visual field machines.

Eyeonic Pty Ltd was founded in 2020 by Ophthalmic specialist Professor Simon Skalicky. Supported by experts at Microsoft it has been designed rigorously to ensure smooth functionality and integrity of data. It uses premium artificial intelligence and mathematical formulae. The Eyeonic team is committed to the scientific process. Several papers published in international Ophthalmology journals have critically evaluated the online Eyeonic Visual Field test and found it to be safe, consistent, reliable and accurate in diagnosing eye disease like glaucoma. A network of global experts continues to research the technology, ensuring its ongoing success.

We hope you enjoy the experience as much as we did bringing the technology to life.

The information provided has been developed to support you in successfully setting up and performing the Eyeonic Visual Field Test. Please read the instructions carefully before commencing your visual field test.

the Eyeonic team



Note: the symbols below denote critical information.

Caution	Consult instructions for use/user manual
Manufacturer	Lot number The Eyeonic Visual Field Test Lot Number is made up of the software version number and release date.
Date of manufacture	MD Medical Device
UK Conformity Assessment Marking	



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Ensure you are using the correct User Manual and always refer to the latest e-IFU on the Eyeonic website.

1 Intended Use

The Eyeonic Visual Field Test is an online visual field test intended to be used to perform visual field testing and detect visual field changes, as an aid to supplement but not replace clinical judgement in monitoring or screening for primary, secondary, open or closed angle glaucoma.

Small luminous points (spots) are displayed in various random positions and the patient's response is recorded, these are used as an aid to clinical evaluation and ancillary investigations in the monitoring or detection of glaucoma by a clinician (i.e. ophthalmologist). As a standalone device the Eyeonic Visual Field Test is not intended to diagnose or rule out eye disease like glaucoma.

The Eyeonic Visual Field Test is intended to be used in supervised clinical settings and homeuse on a standard laptop or desktop personal computer. For these people (who are not performing the test under a clinician's directions) the test advises them to see a clinician to determine if they have any eye condition. The test does not attempt to specifically diagnose any condition on its own - rather directs the individual to further assessment by a clinician.

2 Indications for Use

- Glaucoma patients and suspects who undergo regular monitoring.
- People whom the clinician (Optometrist or Ophthalmologist) is suspicious for diagnosing glaucoma, based on optic disc appearance, intraocular pressure and optic nerve scan (e.g. Optical Coherence Tomography).
- Ancillary assessment for other disorders of vision that can cause visual field changes such as certain retinopathies, non-glaucomatous optic neuropathies, or central nervous system visual pathway disorders.

3 Contraindications

- Very unstable seizure activity
- Uncontrolled vertigo
- Severe loss of central vison and visual acuity below 6/48 (20/160)
- Significant cognitive impairment resulting in inability to perform test correctly



4 Precautions

- Ensure the computer used for testing is adequately powered to complete the test and you have internet access.
- Users with cognitive impairment, or unfamiliar with using a computer may not be suitable to perform the Eyeonic Visual Field Test unsupervised. Consult your clinician if you have concerns.
- If you are not comfortable following instructions in English, you may not be suitable to perform the Eyeonic Visual Field Test unsupervised. Consult your clinician if you have concerns.
- Users with postural issues of the back and neck (e.g., severe scoliosis, kyphosis) may find it difficult to maintain their head in position for the duration of the test and may not be suitable to complete the test unsupervised.
- Ensure your screen is clean before performing the test.

5 Warnings

- If you have unstable epilepsy or uncontrolled vertigo consult your clinician before completing the Eyeonic Visual Field Test.
- Self-diagnosis based on Eyeonic Visual Field Test results is dangerous, always consult your clinician.
- Visual field testing alone should not be used to diagnose eye disease, rather it should be interpreted in the context of clinical examination and other tests.
- A normal visual field test does not exclude glaucoma as up to 40% of the optic nerve must be damaged before a perimetry test shows any abnormality. Always consult your clinician regardless of a positive or negative Eyeonic Visual Field Test result.
- Only severe glaucoma is symptomatic. Early detection requires visual field tests to be completed regularly, every 1-2 years or as prescribed by your clinician.
- Risk factors for glaucoma include a family history of glaucoma, high eye pressure, African
 or Asian descent, age > 50, diabetes, high or low blood pressure or obstructive sleep
 apnoea. If you have one or more risk factors, you should consider regular visual field
 tests to detect early signs of glaucoma every 1-2 years or as prescribed by your clinician.
- Ensure the distance between your eyes and the computer monitor is set to the correct distance. Sitting too far away from or too close to the monitor can lead to inaccurate results.
- Do not share your password and login details with anyone else.



- Should the application cease mid-test (e.g., power outage) the user can check to see how much progress was saved by reviewing their last saved visual field test. They can then restart the test once the power or internet issue has been resolved.
- The test is best performed in an indoor, undisturbed, quiet environment, in a darkened room.
- The device has been extensively clinically evaluated, however not vigorously in the following sub-groups, among whom it should be used with caution:
 - Individuals with secondary glaucoma or closed angle glaucoma
 - Individuals having undergone recent ocular surgery.
 - Children or adults under the age of 40

Studies are underway to evaluate the device within these populations.

- The device can be used by patients in clinic or at home. For optimal home use prior training in a supervised in-clinic setting is strongly recommended.
- The clinical evidence does not verify the performance of the device on curved monitors.

6 Equipment requirements

The Eyeonic Visual Field Test is an online software web application, installation is not required however access to the internet is required.

The web application can be accessed on any device connected to the internet, namely smartphones, tablets or personal computers, but the testing strategy cannot be performed on a smartphone and is best performed on a computer monitor.

Minimum equipment requirements for using the application on a computer:

- Desktop or laptop computer with speakers
- A computer mouse and/or keyboard
- A webcam is recommended however not necessary (it is necessary for the binocular Driving Vision Test).
- Access to the internet
- Antivirus software installed on your computer
- Up-to-date operating system, either:



- Windows 10 version 21H2 or later; or
- MacOS 12 (Montery) or later
- Sufficient system resources:
 - Available storage space: minimum 4GB
 - System memory (RAM): minimum 4GB, recommended 8GB
- Web browser Google Chrome, Mozilla Firefox, or Safari

Minimum equipment requirements for using the application on a tablet computer or iPad:

- Android tablet or Apple iPad with speakers and touchscreen
- A user-facing camera is recommended however not necessary (it is necessary for the binocular **Driving Vision Test**).
- Access to the internet
- Antivirus software installed on your device
- Up-to-date operating system, either:
 - Android 12 or later; or
 - Apple iOS 15 or later
- Sufficient system resources:
 - Available storage space: minimum 4GB
 - System memory (RAM): minimum 4GB, recommended 8GB
- Web browser Google Chrome, Mozilla Firefox, or Safari



7 Who can use the Eyeonic Visual Field Test?

If you can use a computer, you can use this software web application. You do not need permission to perform the visual field test. Even if you see well, it may detect a problem and save your sight.

You do not require any training or qualification to use Eyeonic Visual Field Test, the test has been designed to be interactive and will guide you through the visual field test with easy to follow, clear instructions.

If you need regular visual field tests (e.g. for glaucoma), you can use the Eyeonic Visual Field Test, You can give permission to your clinician to view the results.



Users with cognitive impairment or unfamiliar with using a computer may not be suitable to perform the Eyeonic Visual Field Test unsupervised.

Consult your clinician if you have concerns.

8 Registration

Registration to the Eyeonic Visual Field Test is easy, using any electronic device with access to the internet open the Eyeonic website <u>https://eyeonic.com</u> and click on the **REGISTER** button located at the top right of the screen.

You will need to provide your first name, last name and a valid email address.

You are required to set a unique password; this must meet the criteria defined below:

- At least **8 characters** or more, and
- Contain at least 1 number digit, and
- Contain at least one UPPERCASE letter, and
- Contain at least one lowercase letter, and
- Contain at least one **special character**, for example: ! @ # \$ %

Select **NO** when asked "Are you a clinician" from the dropdown box.

You will need to select a **gender** and provide a **date of birth.** You have the option of uploading a **profile picture**. By clicking **REGISTER**, you agree to our **terms and conditions** and **privacy policy**,



DO NOT share your password and login details with anyone else.



9 Logging in

Once you have registered and set up your Eyeonic Visual Field Test account login to get started.

Using any electronic device with access to the internet open the Eyeonic website <u>https://eyeonic.com</u> and click on the **LOGIN** button located at the top right of the screen enter your credentials and click **CONTINUE**.

If you forget your password, click on the **FORGOT PASSWORD** and follow the prompts to reset.

10 Appointing your clinician(s)

Your primary clinician is your main clinician i.e. ophthalmologist, optometrist, physician, or other healthcare provider, they are responsible for setting your visual field testing schedule/frequency, the test type and reviewing your test results.

Once you have logged into the Eyeonic Visual Field Test, click on the **YOUR CLINICIANS** button located at the top of the screen.

- **Step 1:** In the Search for clinicians **ADDRESS** field start typing your address. Click on the address when it appears in the dropdown results.
- **Step 2:** Use the **Show Clinicians within** dropdown box to expand or reduce the search field.
- **Step 3:** A list of available clinicians will show, based on the results you may refine the search by adjusting the search field as per step 2.
- Step 4: Click the blue SELECT CLINICIAN button to select your clinician.

What if my regular treating clinician is not available?

If you cannot find your clinician, it may be that they have not yet joined the Eyeonic family. Invite your clinician to join Eyeonic by clicking on the **INVITE A CLINICIAN YOU KNOW TO JOIN THE SITE**.

Simply enter their name and email address, click **INVITE** and they will automatically receive an email invitation to join Eyeonic.

Can I add extra clinicians?

You can nominate up to three additional clinicians, as per Steps 1 to 4 above. These are automatically appointed within Eyeonic Visual Field Test as "secondary clinicians".

The first clinician added is automatically assigned as your "primary clinician".



A **primary clinician** is your ophthalmologist, optometrist, physician, or other healthcare provider responsible for reviewing your tests.

How do I update/change my primary clinician?

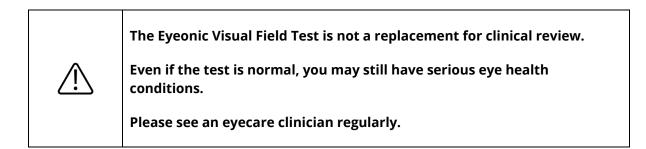
To make a nominated secondary clinician your primary clinician click on the blue **MAKE PRIMARY** button located beside the nominated clinician.

How do I remove clinician(s)?

Simply click on the blue **REMOVE CLINICIAN** button beside the clinician you wish to remove.



Please ensure you have selected your clinician correctly. The name of your selected clinician will flash in green at the top of the screen when you select them. You can check your selected clinicians by visiting "Your Clinicians" tab in the header.



11 Test setup

The Eyeonic Visual Field Test has been designed to provide you with the necessary instructions when you are logged in and using the software.

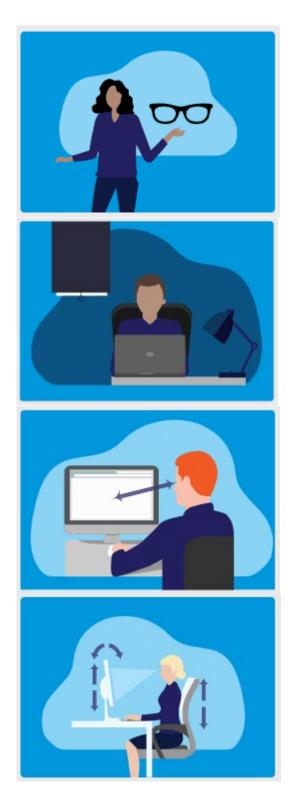
It takes 3-6 minutes per eye to complete the Eyeonic Visual Field Test. Prior to setting up ensure you have enough time to complete the Eyeonic Visual Field Test.



Ensure your computer sound and camera are turned on before commencing Test Setup.

Login to your Eyeonic account and select the appropriate visual field test. You will be presented with the Test Setup page, which includes instructions on setting up:





We will test **one eye** at a time; **close** the other eye firmly.

If you use **eye glasses** for reading, put them on.

Darken your room (complete darkness is not required).

Avoid lights shining directly on the screen or in your eyes.

Sit at the recommended distance from the screen, face-on. The suggested distance will vary between different devices, but is usually 40-55cm.

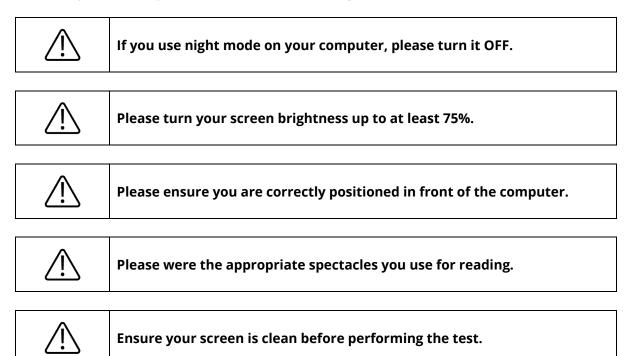
Alter your **seat** or **screen** height, or **tilt screen** for comfortable seating.

Sounds will guide you; turn on **speakers** or use **earphones** to hear.

It is recommended that you watch the setup video provided on this page prior to commencing your test.



When you are ready to commence click on the **Begin Visual Field Test** button.



12 Taking the Eyeonic Visual Field Test



Step 1: Close your eye and keep the eye being tested open. You may use your hand to cover your eye if required.

Step 2: Click the left button on your computer mouse to commence the test.



Step 3: Focus on the spinning gold star at all times.

Step 4: Click the left button on your mouse when the target appears on your screen.

The test will conduct a few initial test points to familiarise you with the targets.

To find your physiological blind spot, you will be tested with smaller, dark targets over a predetermined grid. The blind spot location is indicative of your position relative to the screen.

You may be asked to move forward or backward, until the blind spot has been found in the correct location.



During the test, each location in your peripheral vision will be assessed for sensitivity. Occasionally small, dark spots will be shone in the blind spot to assess for fixation accuracy.

Throughout the test sound is used to guide you. A positive, reassuring noise is produced every time you click at a correct time – like the noise when finding a coin on a computer game and a negative sound, like the noise when an error occurs when using computers or computer games, is produced when you click at an incorrect time. Verbal cues will also guide and encourage you during the test.

During the test, the fixation target may move to maximise the sampling area.



A progress bar under the fixation target will give you a sense of how far along the test you have progressed. On completion of the test you will be advised to click the mouse to access their results or perform further testing.

If at any point throughout the test you need to pause click the **space bar** on your keyboard. To resume the test click the **space bar** on your keyboard again.

To exit the test click the **backspace** on your keyboard.

Step 5: Once you have completed your test your results will be emailed to you if you have not assigned a clinician. If you have assigned a clinician, they will receive your results to review and advise next steps for example, schedule an appointment or your next visual field test date.



If you are unable to complete the test for any reason, please attempt to restart and reperform the test. If then you are unable to complete the test for any reason, immediately contact your clinician.

13 Viewing your results

To access your results and view any change over time with progression analysis click the **Results** button located at the top of the screen.

At any time, you can change your clinicians without losing previous data for serial monitoring. If your clinician has set a test frequency for you, you will receive email notification from Eyeonic when your next test is due.



You may find it difficult to interpret the results without a clinician – we encourage you to involve a clinician in the interpretation of your visual field test.

What if I have not appointed a primary clinician?

You will receive an email advising you of your test result. You will not be able to review your results without first checking this email.

Should your test result be normal based on the Glaucoma Hemifield Test, the email will advise you of the normal result, but also the importance of regular reviews with an eye healthcare professional.

Should your test result be abnormal, you will be advised to promptly seek an eye healthcare professional for review.

14 Billing

The Eyeonic Visual Field Test is a token based system.

When performing the Eyeonic Visual Field Test at home, each Visual Field Test costs one token per eye, a full Visual Field Test (both eyes) will cost two tokens.

All new users will be supplied with one free token on completing your registration, but further testing may require purchase of tokens.

To purchase tokens:

Step 1: Click on the **BILLING** button at the top of your screen.

Step 2: Click on the blue **PURCHASE** button beneath the number of tokens you would like to purchase.

If you perform the Eyeonic Visual Field Test on a clinic computer you will not be charged, rather the clinician will be billed. Likewise if you have assigned a Primary Clinician, and perform a test a scheduled by your clinician, then testing will be generally covered by their subscription.

15 Cleaning and reuse

The Eyeonic Visual Field Test is an online software web application, no cleaning, disinfection, packaging or re-sterilisation requirements apply to the device itself.

The computer monitor and webcam should be kept clean and wiped with a lint free cloth prior to performing the Eyeonic Visual Field Test to ensure that dust or dirt build up does not affect the display.



There are no maximum number of allowable reuses for the Eyeonic Visual Field Test. It is recommended that the test be performed as scheduled, and too frequent use does not necessarily result in more accurate detection.



Your Eyeonic account should not be used by anyone else. DO NOT allow another person to complete testing on your behalf.



16 Troubleshooting

I can't remember my password. How do I login?

Click on the link **FORGOT PASSWORD?** when you are in the login screen. Enter your email address and click **Continue**. You will receive an email with detail on resetting your password. Follow the links in your email account to change the password.

I don't have a webcam on my computer. Can I still perform the test?

The standard Visual Field Test will still work without a webcam, although may not be as accurate. Don't worry, the reduction in accuracy is small and unlikely to be greatly influential.

I have not received my results yet, what should I do?

Check your junk mail folder, if your results have not been received within 30 minutes of completing your test contact the Eyeonic team as detailed in Section 16.

My screen froze while I was performing my test, should I do it again?

If your screen freezes while you are in the middle of a test press refresh and begin again. Ensure your internet connection is stable.

Can I perform the Eyeonic Visual Field Test on a smartphone or tablet?

The Eyeonic Visual Field Test is accessible from any device. You cannot perform the Eyeonic Visual Field Test on your smartphone but can perform most protocols on tablet devices. If you attempt to commence the Eyeonic Visual Field Test on a smartphone, you will be prompted to use a computer or tablet.

Are there any requirements for computers e.g. screen size?

The online Eyeonic Visual Field Test will work on all computer types and sizes, laptop or desktop.

Does it matter if I test my left or right eye first?

No it does not matter which eye you test first.



17 Technical Support

For technical support you can email us at support@eyeonic.com or complete our online customer service form by clicking on the **CONTACT US** button located at the bottom of the screen while using the Eyeonic Visual Field Test.

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