IDE Vision

MPSII 9001

Macular Pigment Screener

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Table of Contents

The MPS II 9001 must be used in accordance with the operating instructions.


Please read the instructions before attempting operation.using the device
The instructions in this manual are to be viewed as an accompaniment to correct training on this device.

The results of a test are only to be analysed by a suitably qualified person. Operation of the device does not require any medical qualification but it is the responsibility of the practice manager/owner to ensure that the device is used only by suitably trained personnel.

There are no contraindications arising from the use of this device.
WARNING - The device contains no user serviceable parts and no modification of this equipment is allowed.

Contact your sales agent for details of on-site training.

The information contained in this manual is subject to change without notice.

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Revision history

Release	Date	Change
Version 1.0	March 23	Initial Release IDE Vision MPS 9001

Warnings

Users should be familiar with and adhere to all warnings, cautions and instructions for use that are labelled on the MPSII device and included in the MPSII User Manual.

- The MPSII device and associated equipment are designed for use by personnel trained in the practice of undertaking examinations in optical vision. All personnel should be thoroughly familiar with the operation of the device prior to use and should follow good clinical practice when using the device.
- The MPSII device should not be used in the presence of flammable anaesthetic mixtures; with air; with oxygen or with nitrous oxide.
- Regular periodic maintenance of the MPSII device is recommended and as a minimum should be undertaken annually.
- Precautions for EMC safety should be observed. The MPSII complies with IEC60601-1-2:2015, however:
    - Electronic equipment in the vicinity of the MPSII device may affect its operation and potentially cause unpredictable operation of the device.
    - Wherever possible the MPSII device should be distanced from surrounding electromagnetic equipment and cables to this equipment in order to reduce possible electromagnetic interference.
    - The MPSII device is only approved for connection to a Windows based computer and not any other device
- When positioning the unit, ensure that access is available to the power On/Off switch located on the rear of the unit.
- Fluids should not be allowed to enter the device as this may result in damage to the system.
- User should be aware of the status of unit at all times during the procedure.
- Only qualified personnel should service the device and the unit cabinet should not be opened except by these personnel due to the risk of hazardous electrical shock. All service requirements should be referred to an MPSII authorised representative.
- Never attempt to service any part of the device when being operated by a patient. Disconnect and remove from patient environment before servicing.
- All equipment should be thoroughly cleaned after each use.

WARNING: Do not modify this equipment without authorization of the manufacturer.

WARNING: To avoid the risk of electric shock this equipment must only be connected to a mains supply with a protective ground.

Explanation of symbols used in manual and on the MPSII

Consult manual

WEEE Directive

Power Off (0)
Power On (1)

Type B Applied Part

CE mark

USB

Protective earth

AC Mains

Patient response button socket

Power connector socket
(MPS 9001)

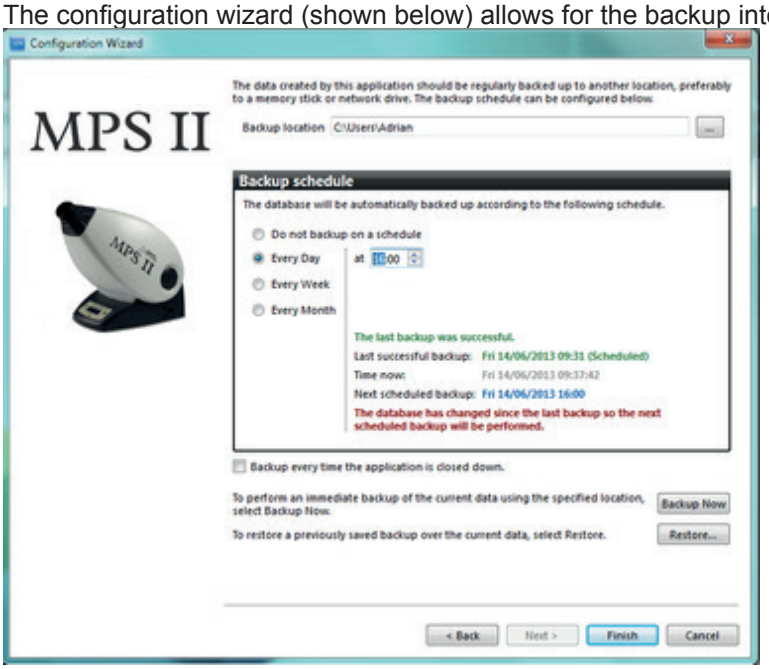
Date of manufacture
(The date will be adjacent to this symbol)

Height adjustment.
Pull and hold handle to release in order to raise or lower.

Database Warning

To reduce the possibility of data loss in the unlikely event of computer hard disk failure, it is strongly recommended that the database of patient records be backed up regularly either to a USB memory stick or other suitable removable media and kept off-site or in a suitable safe location.

The configuration wizard (shown below) allows for the backup interval and location to be set.



The default location is C:\users\login_name\ but can be any location on the PC.

It is good practice that a backup copy of the database is kept off-site or in a suitable fire safe location.

The database used in the MPS II software is based on the PostgreSQL database program.
The database structure ensures that each patient has an entry (called a record) in the database.

The patient's record holds all of their contact details and also a copy of every test they complete along with risk factor information and any supplementation recommended.

The database has inbuilt security to stop unauthorised access to the information contained within.

Every time a new test is performed the results (if saved) are attached to the patient's "record in the database".

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Acknowledgements

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IDE Vision Ltd. continuously improves the design processes of its equipment to minimise the negative impact on the environment and the communities in which the equipment is manufactured, shipped, and used.

This symbol on the product or on its packaging indicates that to preserve the environment, this product must be recycled after its useful life as required by law and must not be disposed of with your household waste. It is your responsibility to dispose of your waste electrical and electronic equipment by handing it over to a designated collection point for the proper recycling of such equipment. The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment. For more information about the authorised collection location nearest to you, please contact your local city office, your household waste disposal service or the agent from whom you purchased the product.

Instalation

The MPS II is designed to be connected to a suitable laptop or PC using a standard USB cable (supplied).

IT IS IMPORTANT THAT YOU DO NOT PLUG THE USB CABLE INTO THE COMPUTER UNTIL YOU HAVE INSTALLED THE MPS II SOFTWARE AND DRIVER.

The MPS II can be placed on any stable, flat surface or electric table.
The device should be set up to prevent rocking or tilting and to allow ventilation to the base and rear of the unit.

It is important that no parts of the unit should overhang the edge of the surface on which the MPS II is mounted.
Ensure that there is sufficient space in front of the unit for the patient to sit comfortably.

The MPS II is supplied with a universal input power supply meaning it does not need adjusting for different mains input voltages.
It is important not to substitute any other power supply for the one supplied. (for replacements contact your supplier or contact IDE Vision directly.)

The on/off switch for the device is on the back panel. Mains isolation of the device is also possible by disconnection of the power supply unit or by removal of the mains power cable..

The MPS II is supplied with a patient response button as an applied part for patient use.
The patient response button cable is connected into the rear of the unit and the button itself must be accessible to the patient.

It is not recommended to extend the supplied USB cable since communications between the PC/Laptop and MPS II may be unreliable.
It is not recommended that the USB cable is connected to a USB 3 port as this can cause connection issues.

See the Quick Start guide or relevant section of this manual for connection instructions or software instalation.

For a copy of the End User License Agreement (EULA) go to www.ide-vision.com.

The software once installed and running will display the status of the connected device at the bottom of the screen along with the name of the current operator (in this case operator1) and the date of the next scheduled backup.

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How to use this manual

This manual is written for use with the MPS II Macular Pigment Screener.

Throughout the manual there are references to MPS II or MPS 9001; All of these refer to the stand-alone MPS II unit which has the manufacturer's reference number MPS 9001.

If you have a laptop with touch pad or external mouse connected, you need to move the on-screen arrow cursor over the button/item you want to select and then press the left hand button.

In the event of software upgrades, up to date operational instructions will be installed at the same time as the software.

Updates of the software can be obtained from your agent or from www.ide-vision.com as and when released.

Some of the screen shots in this manual may be from different versions of software and may differ slightly from the software installed on your machine.

The information in this manual was correct at the time of publishing.
It is important that all of the literature and software supplied with the MPS II is kept in a safe place.

Use of the software
Throughout the software there are visual clues to help you operate the software and perform testing.
The on-screen controls will be colour coded to help you.The explanation is below.

 If a button is greyed out if it cannot be used.

 If a button is blue it is available for use and

 If a button is green it is the next button you should press to progress.

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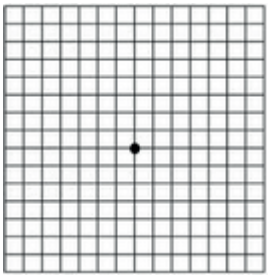
An Introduction to Macular Pigment

Age-related Macular Degeneration (AMD) affects hundreds of millions of people worldwide and reactive treatment accounts for billions in direct healthcare spending each year. This is despite the condition having a number of modifiable risk factors which can be proactively controlled to reduce the risk of developing the most advanced ('wet') form of the disease.

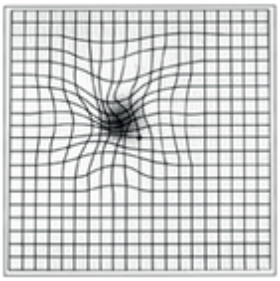
Macular pigment optical density (MPOD) is one such risk factor. Measured by the MPS II, MPOD indicates a person's level of protection against the high-energy visible (HEV) blue light known to be absorbed by the protective layer of macular pigment in front of the retina.

Increasingly prevalent in modern society, HEV blue light (380-500 nm) – emitted by cell phones, PCs, televisions, LED lighting and the sun – puts people with low MPOD at risk of developing AMD in the future.

There are ways to increase MPOD and reduce the threat of AMD if those at risk can be identified. Eye health supplements rich in the retinal carotenoids lutein (L) and zeaxanthin (Z) have been proven beneficial in raising MPOD, whilst purpose-designed lenses are also available to protect the wearer from the development of AMD.



Normal Amsler Grid



Amsler grid with AMD

MPOD and heterochromatic flicker photometry (HFP)

Macular pigment optical density (MPOD) is calculated by measuring how much blue light macular pigment (MP) absorbs. The MPS II uses the principle of heterochromatic flicker photometry (HFP) to provide an accurate calculation of the blue light absorption of MP. MPOD values are provided on a scale of 0-1 – the lower the value, the higher the level of blue light hitting the macula and, therefore, the higher the risk of developing AMD.

HFP requires patients to make flicker matches using two wavelengths of light, one of which (blue; 465nm) is absorbed by the macular pigment and another (green; 530nm) which is not. Flicker matches can be made at both the central and peripheral point in the retina.

The HFP method used by the MPS II obtains flicker matches in a unique way which makes the determination of the minimum flicker point relatively quick and easy, even for inexperienced observers. Patients are instructed to press a button as soon as flicker is detected, in contrast to the more conventional HFP approach where they are required to adjust a green-blue luminance ratio until flicker is minimised or eliminated.

The MPS II uses the principle of HFP in both of its test modes, based on supporting clinical evidence, of which there is a sample below:

- Makridaki M, Carden D and Murray IJ (2009) Macular pigment measurement in clinics: controlling the effect of the ageing media. Ophthalmic & Physiological Optics 29(3), 338-44

- Van der Veen RLP, Berendschot TTJM, Hendrikse F, Carden D, Makridaki M and Murray IJ (2009) A new desktop device for measuring macular pigment optical density based on a novel technique for setting flicker thresholds. Ophthalmic & Physiological Optics 29(2)

IDE-Vision website

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The MPS II is a computerised device for measuring a subject's macular pigment optical density.

It's purpose is to identify patients at risk of developing early stage AMD.

The MPS II uses low intensity light of specific wavelengths at calibrated intensities to gauge a patient's heterochromatic flicker response.
The patient looks into the device at the stimulus light and is asked to press a button when they see the light flicker.
The target background luminance is maintained at 250cdm^{-2} to significantly reduce detection by rods or short-wave cones.

The MPS II has an internal microprocessor used to control the light intensities and the test program sequence.

For full operation, the unit is connected to, and controlled from, a computer running one of the Microsoft Windows7™, Windows 8™, Windows 10™ or current Windows operating systems.

Once installed, you will immediately have the capability to carry out routine macular screening examinations on your patients.

From then on, your confidence with the unit will grow with every use and you will rapidly discover the simplicity of operation and the ease of obtaining valuable and accurate Macular Pigment Optical Density data.

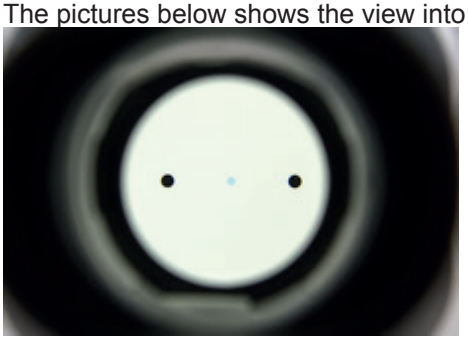
A database is included in the software that stores the MPOD results alongside the patient details.
Using the database, reports can be generated to monitor the way in which the patient's MPOD responds to supplementation.

Contraindications

No contraindications are known for macular pigment tests.

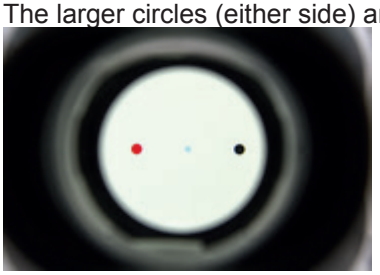
MPS II target

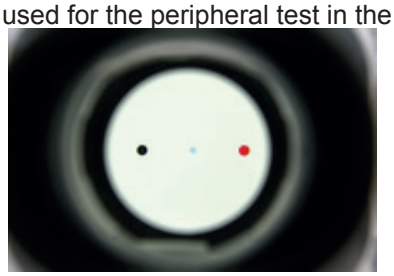
The MPS II target is the most important part of the unit and the lens and optics of the device should be kept clean and free from dust and debris by using the supplied dust cover when the unit is not in use.
The pictures below shows the view into the eyepiece –



Three circles are visible on a plain white background.
During a test, the central (smaller) target will light a blue-green colour and it is here flicker will be seen.

The larger circles (either side) are fixation targets used for the peripheral test in the Detailed mode.





The peripheral fixation targets light up red and the patient is instructed to look at them during peripheral testing whilst observing the central target through the side of the eye (not required in Standard mode).

It is important that the patient maintains fixation on the correct target during peripheral testing. If either of the red peripheral fixation targets is illuminated, then the patient should fixate on it. If neither of them is illuminated, the patient should look directly at the central target.

In both cases, the response to flicker in the central targets should be the same.

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Since MP lies within the foveal region other media changes, e.g. lens yellowing, will not affect the MP value.
Note that the initial blue/green ratio is pre-set by taking the age of the subject into account. The older the subject the further to the right the start point.

If a subject has been fitted with an intra-ocular lens (IOL), the eye may then appear much younger so the software automatically assumes an age of 20 when the IOL button has been selected (patient's form).

The MPS II first measures a patient's flicker sensitivity. This is used to normalise each subject as far as possible so that the starting flicker frequency is close to 30Hz. Some subjects still lie outside this normalisation process.

This affects the shape of the curve and hence the accuracy of measurement. if the sensitivity is too high the curve starts at a high value (> 30 Hz) and remains shallow. Too low a value, and the curve starts at a low value and is too deep (sometimes going below 5Hz) which may halt the test being run. Optimum sensitivity occurs when the minimum value falls between 20 Hz and 15 Hz.

In subjects with diabetic media yellowing, the error will be higher because their media appears older.

When lights are different in colour, it is difficult to say whether or not they are of equal intensity or luminance.
This device uses the well-known technique of heterochromatic flicker photometry (HFP) to identify the equal-luminance point of two flickering lights of different wavelengths.

Macular pigment absorbs selectively in the blue region of the visible spectrum, at 460nm, and is present only in the central 8 degrees of vision.
HFP is performed for central fixation where macular pigment is maximal.

A constant white background illuminance is used; blue and green light are alternately flickered. The blue light is chosen to match the absorbance of the macular.

In the MPS II, the equal luminance points are obtained by presenting the two lights at a series of different intensity ratios. The flicker frequency starts at a high rate where flicker cannot be detected (target appears a steady blue-green colour) and, for each blue-green intensity ratio, the flicker rate slowly reduces until the patient sees the flicker - at which point they press the response button.

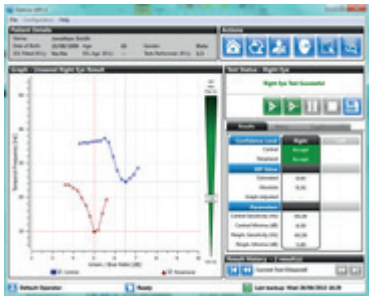
This process is repeated at different intensities to obtain the graph. The curve will have a minimum which corresponds to the equal luminance point for the blue/green target. The software calculates the MP value based on this minimum and the patient's age.

Standard test mode

The latest version of the MPS II software implements the Standard test mode algorithm from earlier versions.

Developed by one of the original inventors of the device, the algorithm interprets the validity of screening results.

Previous versions of the software have relied on the operator making subjective judgements on the result's validity. The new algorithm relieves the operator of this responsibility by automatically interpreting the results. Of course the Detailed test mode interface remains for the testing of diabetics, clinical research and teaching, but most will find the ease of use in Standard mode applicable to most test cases. A simple button click toggles between Standard and Detailed test modes (shown here, for comparison) –



The Standard test mode contains a subset of the Detailed test mode controls.
The macular index is calculated from the patient's age and the central run (a peripheral run is not needed).

The algorithm looks at the patient's response to the test and analyses the shape of the graph and the test values. There are three possible outcomes, clearly displayed below the graph (Accept, Caution and Reject) - see Appendix 3 - Confidence limits.

In most cases, the results will be accepted. In a few instances the results will be unacceptable (and the program ensures these cannot be saved as a valid result). When the Standard test mode algorithm produces a low, but acceptable result, the final decision is left to the operator.

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The Detailed Mode is used for patients where the Standard test mode is not suitable, people with diabetes for example.

For this test mode, two measurements are taken, one with the patient looking directly at the stimulus target (using the central region of the macular) with the light from the target passing THROUGH their macular pigment as in Standard Mode

For the second phase of this test, the patient fixates peripherally on a point 8° to the side of the stimulus light (so they are viewing the stimulus where macular pigment is known to be absent).

The patient responds to the stimulus flicker as before and once the test is finished, the central and peripheral results are then used to determine the patient's MPOD.

This is done by working out the ratio of the amount of blue light absorbed in the central region compared with the peripheral region. The greater the density, the more blue light is absorbed by the MP.

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There are three possible results given by the MPS II Software depending on which test you are running.

The Standard Mode test will give an age estimate.

The Detailed Mode test will give an age estimate, an absolute result and can also give a graph adjusted result under operator control.

These three terms are explained below.

MP-Estimate
This means that the peripheral part of the test has been estimated using the patient's age. The patient's MPOD level has been calculated from their central test result and the estimated peripheral. It is not an absolute measurement.

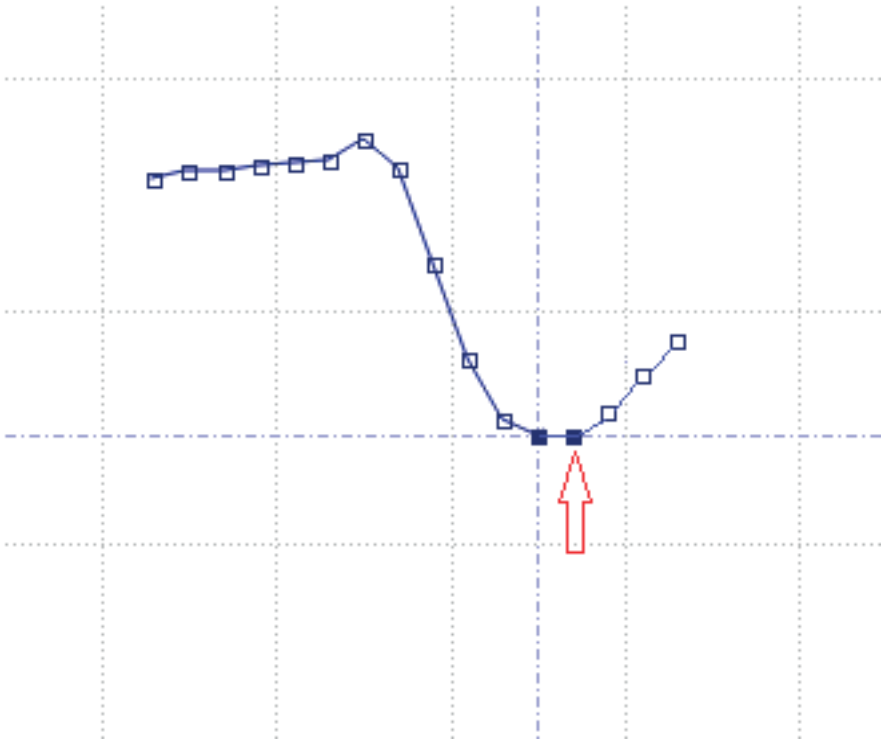
MP-Absolute
This is the full measurement where both parts of the test are undertaken by the patient and is the full measurement. There is no estimating in it. This test is necessary for patients with eye diseases or diabetes where we cannot estimate the peripheral result using their age. (Diabetics in particular have different age related results).

To calculate an absolute measurement we need to use the Detailed mode test and perform a central test (where the patient looks directly at the target) and then a peripheral test (where the patient looks at the red fixation point) and by comparing these two results we work out the patient's absolute MP level.

MP-Graph Adjusted
This is where the absolute result of a Detailed mode test is changed by moving the minimum point on the graph.

For example, if the patient's central test curve looked like the picture below, the software would pick the right hand point (arrowed) as the minimum, but you can see that there are two points at exactly the same intercept on the Y axis. The operator can move to the other point to see what affect it has on their MP level result. (In this example, the change will be minimal).

This new MP value is recorded alongside the calculated result in the database as adjusted as the operator has changed the result that the software originally calculated.



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Once an accepted test result has been given by the software, the patient will be eager to know the outcome of the test and to discuss any changes required in lifestyle and diet.

The actual MPOD score can be compared to national scales to ascertain the patient risk factor.

If the patient has recorded a score of >0.9 then it means that their MP is higher than the device can measure.
It is always a good idea to check the patient's eye to ascertain if there is a lens opacity issue (cataract) that may be contributing to the high MP score and if the lens is clear then the MP result is valid.

In these cases, if doing a Detailed Mode test, it is not possible to perform any more testing as the software does not have a central minimum point to calculate against.

Test modes best practice

For both of the tests - Standard and Detailed mode - it is important that the patient is informed of what to expect to enable them to perform the test correctly.

Below are some tips and tricks to help optimise a test.

- Put a trial lens in the front slot of the machine with the patient's distance Rx. If you do not have access to these use the patient's spectacles (near SV, varifocals or bifocals) or contact lenses (distance Rx with over-readers, multifocals or monovision near lens) but refrain from using tinted lenses.
    - The MPS II has a 5.00D lens within the optics, so a distance Rx will suffice and the heterochromatic flicker photometry (HFP) procedure is relatively insensitive to blur.
    - Remember to record the correction used in the Notes field.
- Occlude the eye not being tested using an eye patch.
- Perform in mesopic or scotopic lighting.
- Measure the right eye, then the left eye using Standard test mode only and save the results
- Inform the patient that the test requires concentration; however they should be encouraged to blink naturally. When flicker is detected on the central spot, it's 'finger on the buzzer' and speed is of the essence.
- Advise the patient that there will be a short familarisation test before the main test to check their response to flicker.
    - This sets the initial blue/green ratio and is recorded as squares on the graph. This takes approximately 30 seconds. Only if the responses are very inconsistent will an error message appear stating 'range too high' and 'start again'.
    - When this is over the middle spot will temporally go black. The patient must keep watching (don't let the patient move their head), as the second actual test will take place immediately the screen lights up again.
    - The flickering central light may appear slightly bleached out and/or leave an after image. Reassure the patient that this is just because you have been staring at it much like 'staring at the sun'
- Now the test has begun, watch the screen and if you see the patient pressing the button too quickly, or indeed losing concentration between responses, pause the test and remind the patient of the original instructions or restart the test, or repeat the test later.
    - The importance of constant communication cannot be over-emphasised.
    - Keep encouraging the patient with phrases like 'you're doing well', 'look for the flicker' and'you're nearly finished', as silence will cause the patient to question if they are performing the test correctly.

- On average, depending on MP, this measurement takes approximately 60 seconds to complete.
  - The repeatability of HFP measurements has previously been studied and amended scoring techniques have reduced the Standard Deviation(SD).
  - However, with the Standard test mode of a central-only measurement, any ‘noise’ in repeatability testing is minimised and thus measurements taken at different visits can be compared with confidence

- Only if coexisting pathology is present (diabetic maculopathy, AMD) should the Detailed test mode be used,i.e. taking central and peripheral measurements to achieve an absolute MP score. to do this:.
  - Perform the central measurement first.
  - Then inform the patient that they should be fixating at the top of the peripheral red target (left target for RE and vice-versa) and using their side vision to view the central blue flickering target. They will want to glance at this, but you must inform them to resist the temptation.
  - If they stare at the flickering target directly it forfeits the results, as all they are doing is performing a central measurement again.
  - Half-way during the test, ask the patient to re-fixate at the bottom of the red target from then on, but again only pressing the button when they see the flickering target. This prevents the flickering target from disappearing due to the Troxler effect. Blinking after pressing the button can also prevent this.

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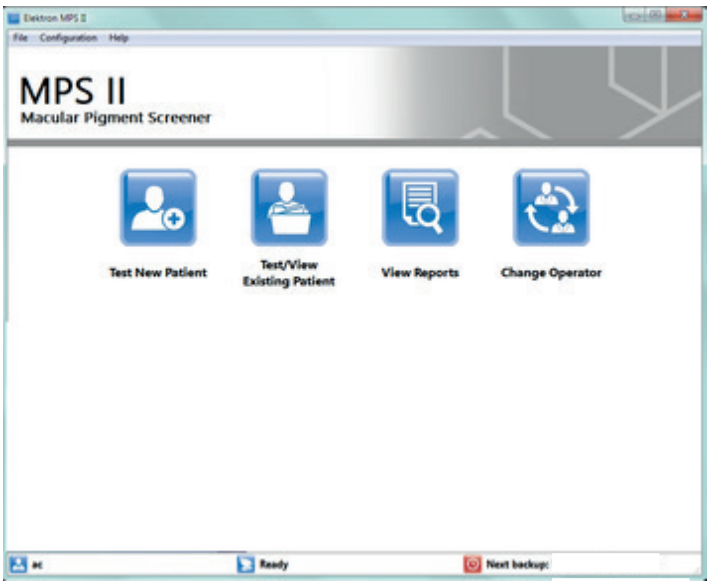
Start the program and wait until the main menu screen (shown below) is available–



You have two options here:-

If the patient has not been tested previously then you will need to click the New Patient icon to create a new record in the database.

If you have tested the patient before then you can select their record from the database by clicking the Test/View Existing Patient button.

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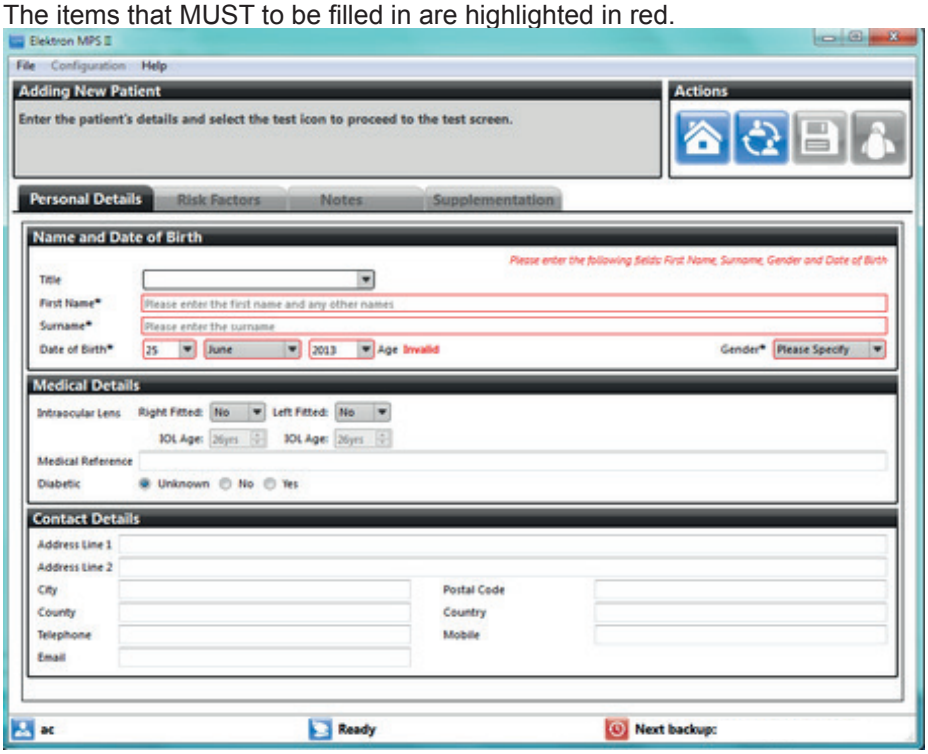
If the patient has never been tested on this device before then they will not exist in the database.
To create a new record select the **Test New Patient** button.

Test New Patient

The Adding New Patient entry screen will open with the **Personal Details tab selected**

The items that MUST to be filled in are highlighted in red.



To create a new record, the mandatory fields are:'First Name', 'Surname', 'Date of Birth' and 'Gender'. Selecting the 'Title' option to create a new record. Selecting the title will also set the gender, for exaple, selecting Mr will set gender as male.

You can see from the screen shot that the entry in the Age field is shown as invalid. This is because the age of the patient is under 1.

All other fields can be left blank, if required, or can be filled-in at a later date.

Once all of the required patient's details have been entered, the test button will highlight in green 

At this time you can also enter any risk factors relevant to the patient under the Risk Factors tab.

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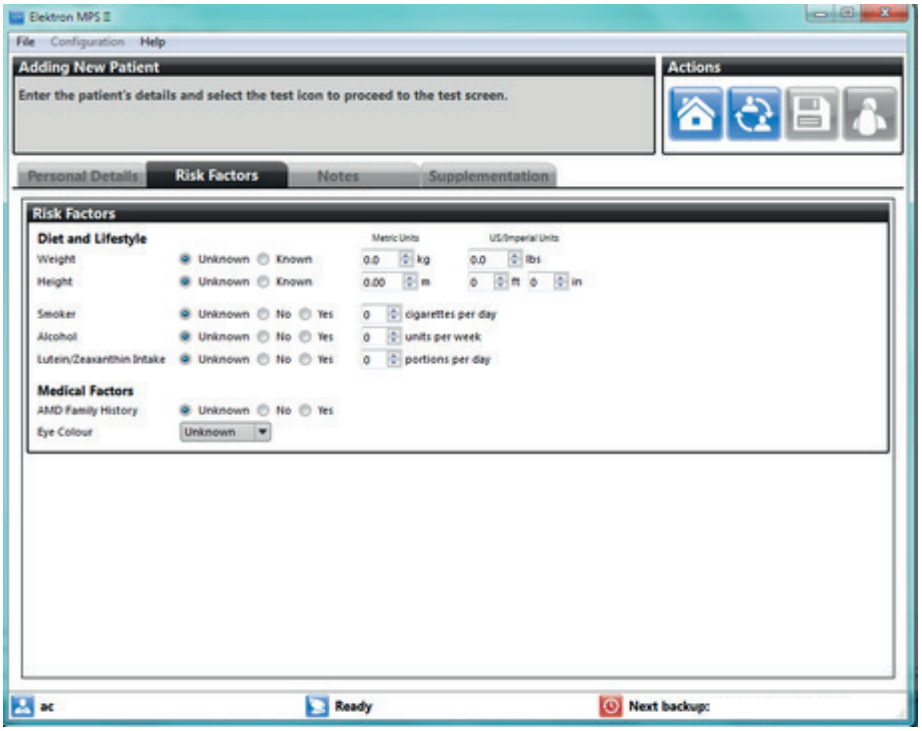

This gives you an opportunity to discuss the risk factors with a new patient.

There are also tabs for **Notes** and for **Supplementation. T**he Notes section allows you to enter details such as the refractive correction worn by the patient (i.e. whether they wore their own glasses) but it is normal to fill these in after the test.

Press the green test patient button  to create the record and go directly to the test screen or

Press the home button  to discard all changes made and return to the main menu screen.
(You will be prompted whether you want to discard the record you have just created)

It is also possible to save  the changes made but not test the patient at this time.

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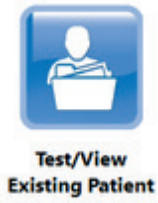
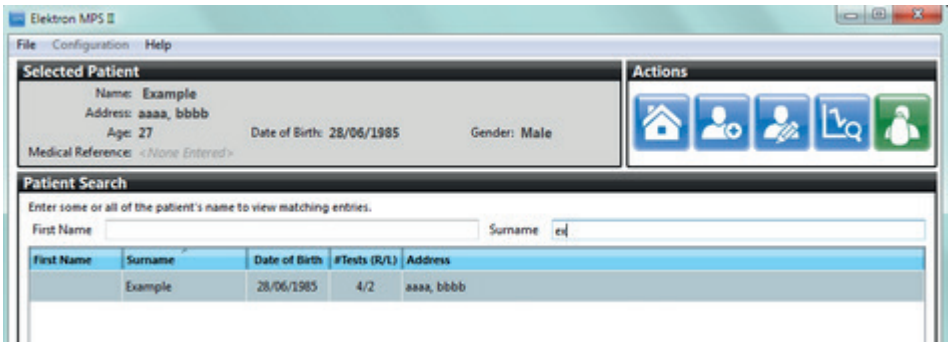
Selecting an existing patient

If the patient has previous tests stored in the database then select the Test/View Existing Patient button.
You will be presented with the database listing all patients in alphabetical order by surname.



To find a particular patient you can type their surname in the box provided in the Patient Search section - as you start to type the surname the records will filter to show all matching records.



When you have found the patient, click on the name to select the record.
You can then :-

 Test this patient

 Edit this patient's details in the database

 View the patient's previous test results

 Or if you realise that the patient is not in the database after all, you can add them by clicking the add new patient button (without having to go back to the main menu and start again)

 Or cancel and return to the main menu screen.

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The Standard test mode performs a central only test (through the patient's macular pigment) and uses their age to estimate their peripheral test result.

The measured centre and age-estimated peripheral are then used to derive the MPOD value.

This test can reliably and repeatably be used on the majority of the population as long as they do not have any pre-existing pathology (diabetic maculopathy, AMD).

In these cases the Detailed Mode test must be performed. It is also good practice to perform a detailed mode test on all new patients to ascertain that their lens is age-normal and therefore the age estimate used in the software is valid.

The details of the test can be found here

Standard test - summary

- Start the program (normally from the Desktop icon)
- Select New patient - Enter data onto the Patient's form or Existing patient - find them in the database
- Click the Test icon
- By default the Right eye is tested first, occlude the patient's other eye
- Instruct the patient on what to expect and how to perform the test.
- Start the test.
- Give the patient feedback during the test
- At the end of the test, check that the software has accepted the result for this eye.
- Occlude the patient's tested eye, press the swap eyes button and test the other eye.
- After testing both eyes, review the results with the patient.

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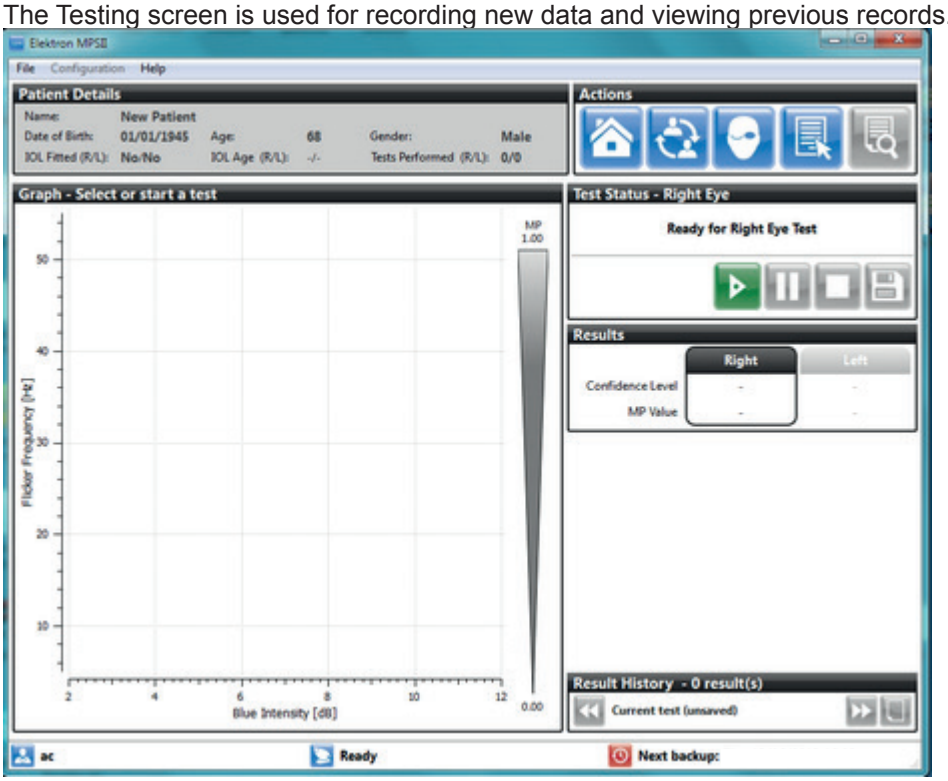
The Testing screen is shown and the RIGHT eye is selected by default.
The Testing screen is used for recording new data and viewing previous records.



If you wish to test the LEFT eye first then click the Change eye button. 

Make sure the patient is seated comfortably and has an occluder over the eye not being tested.

Give them the response button and ask them to look into the device adjusting the angle so that they can comfortably press their eye against the eyepiece.

The following are guideline instructions for the patient –

Please look into the eyepiece at the three target circles.
Fixate on the central circle (only look at the light, nowhere else).
The central target will light up a blue-green colour and will start to flicker.
Press and release the response button when you see the target start to flicker.
It is also a good idea to blink after pressing the button.
It will reset and repeat this test 5 or 6 times.
The central target will then dim and come back a slightly different colour, keep fixating on it
Again the target will start to flicker, press and release the response button as before.
The test will take approximately 1-2 minutes to complete.

The screen shows that the software is READY to test the RIGHT eye.

The software will guide you with what to press by highlighting the next step button in Green.
The screen shot below shows that we are ready to start the test as the Start test button  is the only green button on screen

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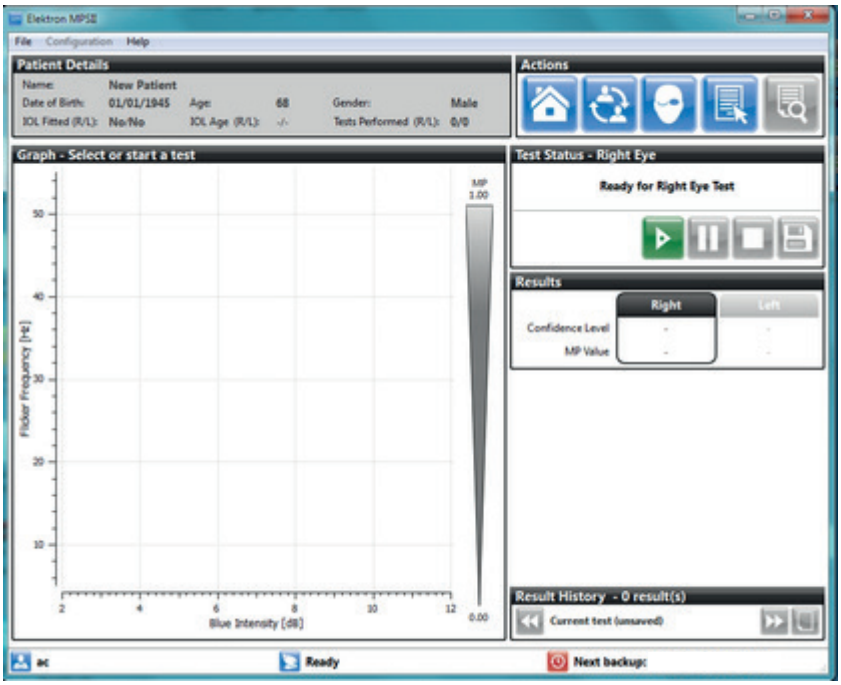

Press the start test button when the patient is ready.

The first phase of the test checks the patient's flicker response and records this on the screen.
A set of five results completes this phase.
Note that there may be more than 5 presentations if the initial spread is too high. The test will not continue if the patient's responses are too fast or too slow.

If the patient has an acceptable flicker threshold, the measurement phase of the test will follow.
At this point the central target dims and resets a slightly different colour.
It is important that the patient does not think this is the end of the test and that they continue to look into the instrument.

The on-screen graph will mark the patient's responses as blue squares, moving from left to right as the test progresses.
Note that the first central test point is not used or displayed on the graph. The graph will start with the second point.

A "best fit" curve will be drawn between the points as they are drawn.
Note: you can pause and restart the test or stop it altogether using the controls in the test status box at any point during the test.

Restart, Pause and Stop.

As the test progresses, give the patient feedback and encouragement.

Ideally, the plotted graph will follow a downward curve with a clearly defined minimum.
Standard mode analysis looks at the shape of this curve and test values for its result.
The result is calculated from the curve minimum and the patient's age peripheral result .

The patient can be told to relax once the test is complete.

The test will be analysed by the software and the confidence level will be presented on the screen as a colour code.
The three possible results are

Accept

Caution

Reject

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Accept gives you the all clear that the data is acceptable and the software can determine the minima.
A caution tells you that the software can determine a minima but is not happy with the cleanliness of the data - a re-test is advisable.
A reject must always be redone, as no result can be determined from the data.
(More details can be seen in Appendix 3 Confidence Limits section)

The result will appear in the results box on the right hand side of the screen.

If the other eye is to be tested (and we recommend this on an initial consultation) then press the change eyes button Move the occluder to the patient's tested eye and reposition them ready for the second eye test.

Once the test is complete, the **Save** button will become available.
At this point, either save the data by pressing the save button (only one eye to be tested) or test the other eye by pressing the change eyes button
It is also possible to retest the current eye.
A test report for the patient can be generated as a PDF for printing by pressing the Generate Report button. you will be prompted to save the file and then it will be displayed in your default PDF viewer.

If Save is chosen after both eyes have been tested then both results will be saved at the same time, it is not necessary to save them individually, although if only testing one eye, this can be saved on its own.

If you press the Home , Edit patient or Swap patient you will be prompted that you have not saved and asked whether you wish to save or discard the test.

Note that once saved, the results cannot be deleted.

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Detailed test mode

The Detailed Test Mode is used where patients have a pre-existing pathology, such as diabetic maculopathy or where there is an unknown element such as an IOL as it allows you to perform a central test (through the patient's macular pigment) and then a "baseline" peripheral test, where the patient fixates on a point that is outside their macular pigment and observes the flickering target from the "corner of their eye".

The measured central and peripheral results are then used to derive the MPOD value.

This test can reliably and repeatably be used on the majority of the population but many patients will need some practice to perform the peripheral part of the test.

If the patient does not have any pre-existing pathology (diabetic maculopathy, cataract, AMD) and you have previously ascertained that their age estimate matched the absolute measurement then the Standard Test Mode can be used for all subsequent testing.

The details of the test are here

Detailed test - summary

- Start the program (normally from the Desktop icon)
- Select New patient - Enter data onto the Patients form or Existing patient - find them in the database
- Click the Test icon
- By default the Right eye is tested first, occlude the patient's other eye
- Instruct the patient on what to expect and how to perform the test.
- Start the central part of the test.
- Review the results and then proceed with the peripheral test.
- Review the peripheral result and then occlude the patient's tested eye and test the other eye
- After testing both eyes, review the results with the patient

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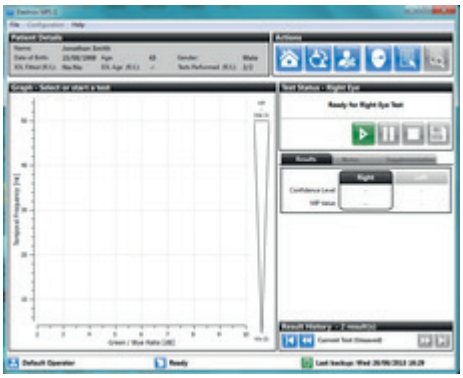
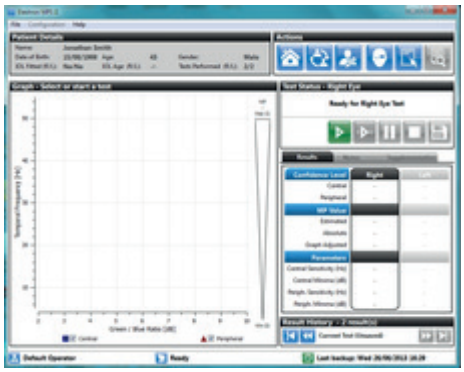
Please refer to the Standard Mode details section (Standard Test) to find out how to select a patient

Press the Test patient button  to go to the testing screen.

Press the switch to Detailed Mode button  to change from Standard Mode (Left) to Detailed Mode (Right).





The testing screen is shown and the RIGHT eye is selected by default.
The Testing screen is used for recording new data and viewing previous records.

To change to the left eye press the swap eyes button 

Make sure the patient is seated comfortably and has an occluder over the eye not being tested.

The following are guideline instructions for the patient –

Please look into the eyepiece at the three target circles.
Fixate on the central circle (only look at the light, nowhere else).
The central target will light up a blue-green colour and will start to flicker.
Press and release the response button when you see the target start to flicker.
It is also a good idea to blink after pressing the button.
It will reset and repeat this test 5 or 6 times.
The central target will then dim and come back a slightly different colour, keep fixating on it
Again the target will start to flicker, press and release the response button as before.
The test will take approximately 1-2 minutes to complete.

The screen shows that the software is READY to test the RIGHT eye.

The software will guide you with what to press by highlighting the next step button in Green.
The screen shot below shows that we are ready to start the test as the Start test button  is the only green button on screen

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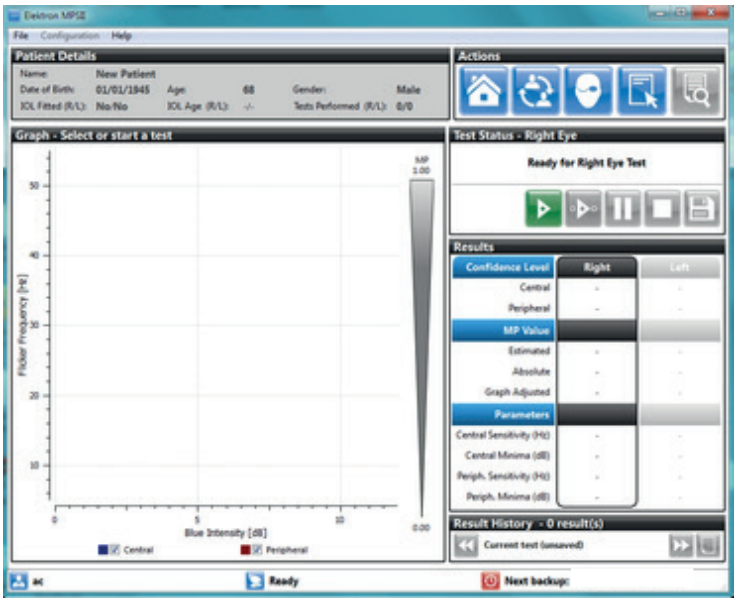

If this is the Patient's first time on the instrument it is a good idea to give them some practice. (Perform a test, but do not save the result)
Press the Start test button when the patient is ready.

The first phase of the test checks the patient's flicker response and records this on the screen.
A set of five results completes this phase.
Note that there may be more than 5 presentations if the initial spread is too high. The test will not continue if the patient's responses are too fast or too slow.
If the patient has an acceptable flicker threshold, the measurement part of the test will start.

At this point the central target dims and reset a slightly different colour.
It is important that the patient does not think this is the end of the test and that they continue to look into the instrument.

The on-screen graph will mark the patient's responses as blue squares, moving from left to right as the test progresses.

Note that the first central test point is not used or displayed on the graph. The graph will start with the second point.

A "best fit" curve will be drawn between the points as they are drawn.

Note: you can pause and restart the test or stop it altogether using the controls in the test status box at any point during the test.

Restart, Pause and Stop.

As the test progresses, give the patient feedback and encouragement.

Ideally, the plotted graph will follow a downward curve with a clearly defined minimum.
When the central test is finished, the patient can sit sit back. the software will show the confidence limits of the central test

The test will be analysed by the software and the confidence level will be presented on the screen as a colour code.
The three possible results are

Accept

Caution

Reject

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Accept gives you the all clear that the data is acceptable and the software can determine the minima.

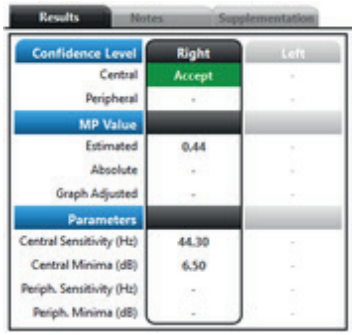
A caution tells you that the software can determine a minima but is not happy with the cleanliness of the data - a re-test is advisable.

A reject must always be redone, as no result can be determined form the data.

It is possible to retest the central or peripheral parts of the test, discarding the data collected for that part of the test but keeping the other part.

for example, if the central test was acceptable, but the peripheral advised caution, then you can retest the peripheral only while keeping the data from the central test.
(More details can be seen in Appendix 3 Confidence Limits section)

The results section below shows that the central test is acceptable and that an estimated MPOD value based on the central measurement is 0.44



Once the central test has been completed satisfactorily the peripheral test button  will become active (and coloured green)

Give the patient the new instructions for performing the peripheral test.

> ***For the second part,***
>
> ***Please look into the eyepiece again.***
> ***Fixate on the red circle that illuminates to the left or right of the central circle (only look at the red light, nowhere else).***
> ***The Central target will light up a blue/green colour as before and start to flicker,***
> ***Respond to the flicker of the central target by Pressing and releasing the response button but without looking directly at it.***
> ***It is also a good idea to blink after pressing the button.***
> ***It will reset and repeat this test 5 or 6 times.***
> ***The central target will then dim and come back a slightly different colour, keep fixating on the red target to the side.***
> ***Again the central target will start to flicker, press and release the response button as before.***
> ***The test will take approximately 1-2 minutes to complete.***

Press the Peripheral Test button when the patient is ready.
The patient's responses will be displayed on the same graph as the central test as red triangles.

As with the central test, there is a flicker threshold test to start before the main test starts.
The messages in the test status box tell you which phase of the test is being performed.

At the end of the Peripheral test, the confidence limits are displayed along with the MPOD value.
The Peripheral and central results are combined to produce an **absolute** MPOD value and this is displayed below the estimated value.

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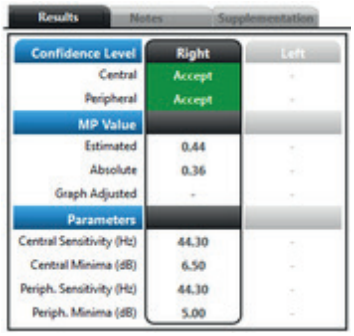

If the other eye is to be tested (and we recommend this on an initial consultation) then press the change eyes button Move the occluder to the patient's tested eye and reposition them ready for the second eye test.

Once the test is complete, the **Save** button will become available.
At this point, either save the data by pressing the save button (only one eye to be tested) or test the other eye by pressing the change eyes button
It is also possible to retest the current eye.

If Save is chosen after both eyes have been tested then both results will be saved at the same time, it is not necessary to save them individually, although if only testing one eye, this can be saved on its own.

If you press the Home , Edit patient or Swap patient buttons without saving you will be prompted that you have not save and asked whether you wish to save or discard the test.

Note that once saved, the results cannot be deleted.

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Patient instructions peripheral

For the second part,

Please look into the eyepiece again.
Fixate on the red circle that illuminates to the left or right of the central circle (only look at the red light, nowhere else).
The Central target will light up a blue/green colour as before and start to flicker,
Respond to the flicker of the central target by pressing and releasing the response button but without looking directly at it.
It is also a good idea to blink after pressing the button.
It will reset and repeat this test 5 or 6 times.
The central target will then dim and come back a slightly different colour, keep fixating on the red target to the side.
Again the central target will start to flicker, press and release the response button as before.
The test will take approximately 1-2 minutes to complete.

Graph estimate

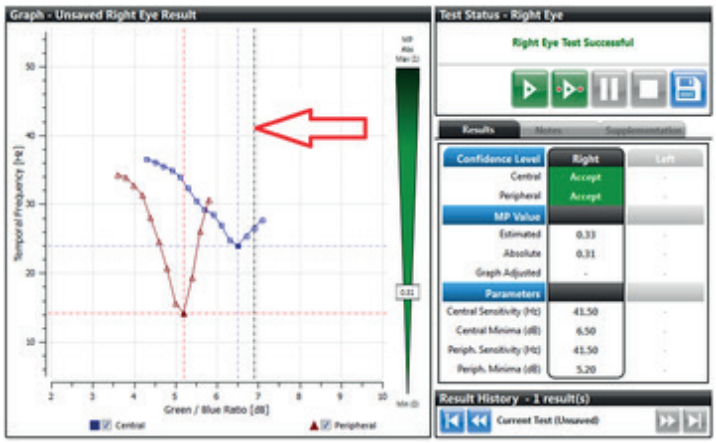
Sometimes it may be necessary to adjust the minimum value chosen by the software - for example if there are 2 points at the bottom of the graph at exactly the same level.

It is unlikely that the software will allow a completely different minimum to be accepted as it will always advise caution when there are more than one possible minima.

In the case where there are 2 points at the minimum the software will pick the lower of these (they may look identical in value but the software is working to a higher resolution than can be displayed on the graph) and you can choose the other to see what difference this will make.

To alter the graph cursor position you must first have completed an absolute measurement using both central and peripheral measurements.

You can then move your mouse pointer over the graph curves, you will see a vertical line follows your cursor over the curve.(arrowed below)



If you left click you will see a pink dot appear on the central (blue) curve (arrowed below).
This denotes the newly chosen minimum point

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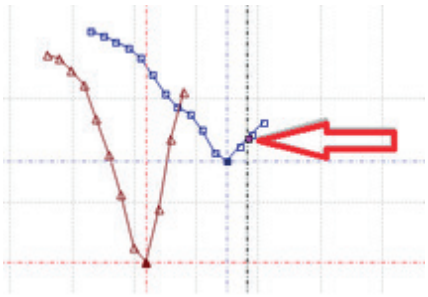
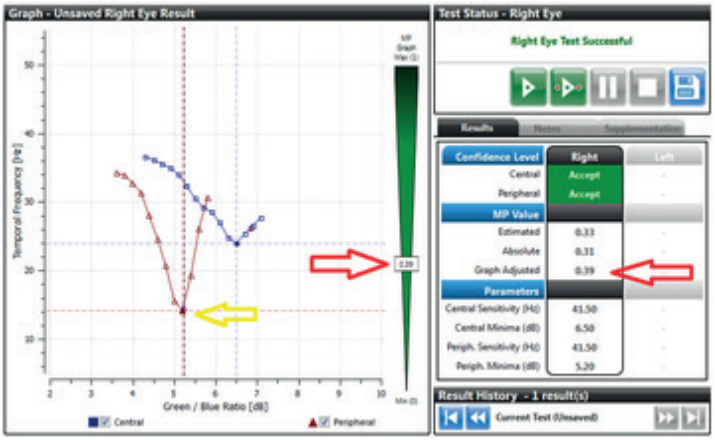


If you now do the same on the peripheral (red) curve but this time, hold down the SHIFT button when you left click. A pink triangle will be shown in the new minimum position.(yellow arrow below)

The graph estimate reading will be displayed in the table and also the value on the slider will change.(red arrows below)



You can move and click on the graphs as many times as you like and the graph estimate value will change every time.

Test reports

There are a number of reports that are available from the software.

These are
1. End of test report - showing the results of the test just performed.
2. Patient time line report - giving details of a patient's previous results
3. Practice report - giving results of all tests performed in a specific time-frame. This report can also be run for individual operators.

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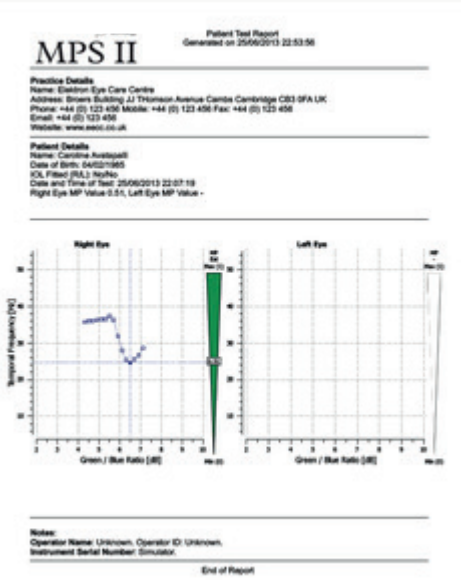
Test report

1. The end of test report

This is available at the end of a test by pressing the report button on the test screen 
A typical report might look like this –



The patient's details are shown, along with the practice details and the graphs and MPOD values recorded for both eyes.

The test report is generated as a PDF file and you will be prompted to save it before it is displayed in the computer's default PDF viewer.
From here it can be viewed, resized, printed or saved in another location.

All of the standard controls available with your PDF viewer are available.
(more information on this is available from the help file of your PDF viewer).

The results from both eyes (if tested together) are on the same printout.

2. The Patient time-line report

This is accessed from the main menu by pressing the View Reports button 
The report displays all of a patient's tests in a specified date range in graph and table format.

By default the date range is the previous year from today's date.

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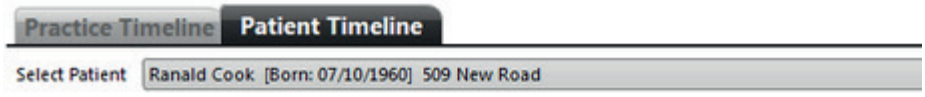
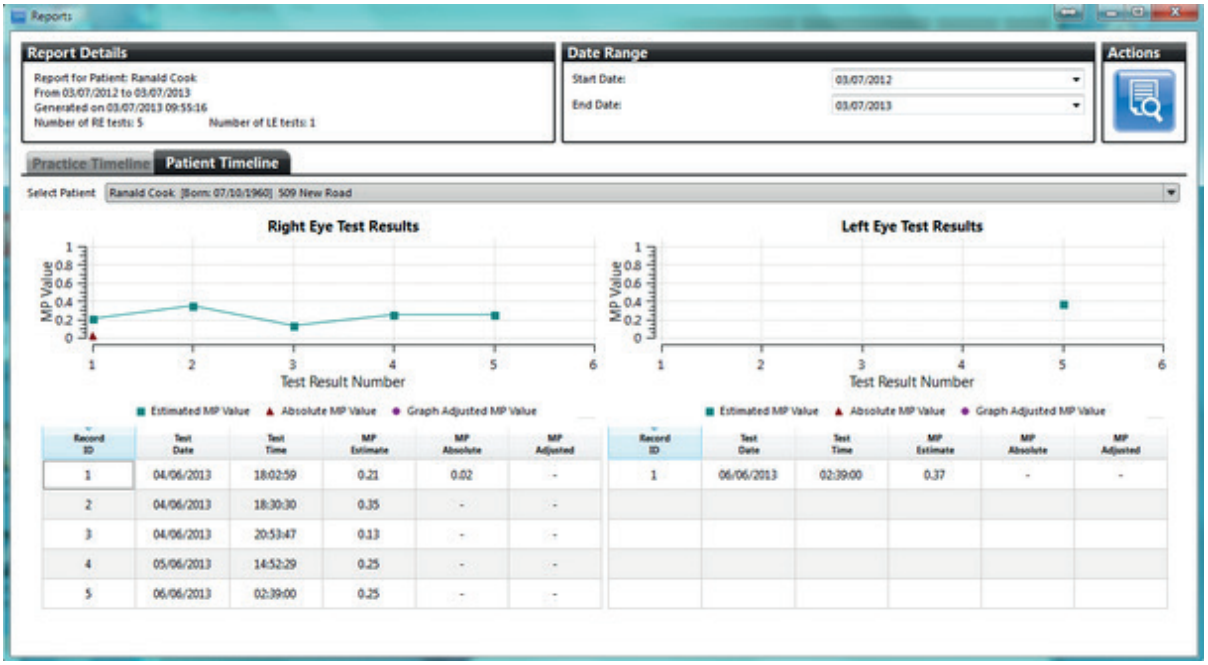
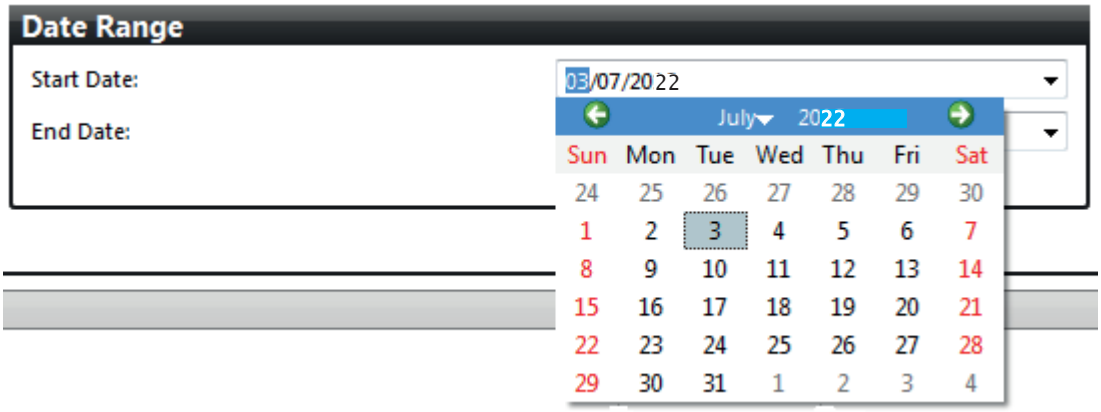
Click the Patient Time line tab and select the patient by using the drop down list.



The report will be displayed as below.



You can change the date range by clicking on either the start or end date in the date range box.
A calendar will be displayed.



You can change the month by clicking the small triangle next to the month and selecting the required month from the drop down list.
Alternatively you can click the left and right arrows at the top of the box to move one month at a time.

You must click on a day of the month to close the calendar and set the date.

The start and end dates of the report can be changed as required.

The report can be saved as a PDF by pressing the Save and View Report button 
You will be prompted to save the file and it will then be displayed in your default PDF viewer.

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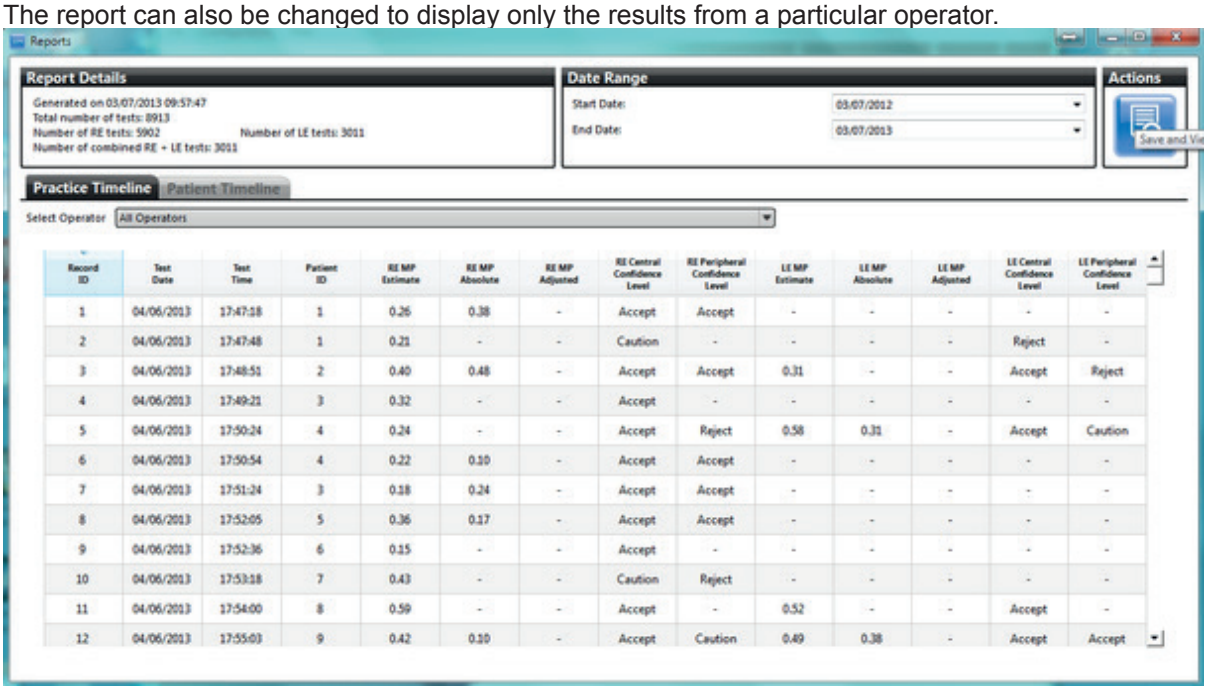
3. Practice time-line report

This report is also accessed from the main menu by pressing the View Reports button 
It displays all of the tests performed by all operators for a specified date range.
By default the date range is the previous year from today's date.

As with the patient time line, the start and end dates can be changed by clicking on the date.
The report can also be changed to display only the results from a particular operator.



Record ID	Test Date	Test Time	Patient ID	RE MP Estimate	RE MP Absolute	RE MP Adjusted	RE Central Confidence Level	RE Peripheral Confidence Level	LE MP Estimate	LE MP Absolute	LE MP Adjusted	LE Central Confidence Level	LE Peripheral Confidence Level
1	04/06/2013	17:47:18	1	0.26	0.38	-	Accept	Accept	-	-	-	-	-
2	04/06/2013	17:47:48	1	0.21	-	-	Caution	-	-	-	-	Reject	-
3	04/06/2013	17:48:51	2	0.40	0.48	-	Accept	Accept	0.31	-	-	Accept	Reject
4	04/06/2013	17:49:21	3	0.32	-	-	Accept	-	-	-	-	-	-
5	04/06/2013	17:50:24	4	0.24	-	-	Accept	Reject	0.58	0.31	-	Accept	Caution
6	04/06/2013	17:50:54	4	0.22	0.10	-	Accept	Accept	-	-	-	-	-
7	04/06/2013	17:51:24	3	0.18	0.24	-	Accept	Accept	-	-	-	-	-
8	04/06/2013	17:52:05	5	0.36	0.17	-	Accept	Accept	-	-	-	-	-
9	04/06/2013	17:52:36	6	0.15	-	-	Accept	-	-	-	-	-	-
10	04/06/2013	17:53:18	7	0.43	-	-	Caution	Reject	-	-	-	-	-
11	04/06/2013	17:54:00	8	0.59	-	-	Accept	-	0.52	-	-	Accept	-
12	04/06/2013	17:55:03	9	0.42	0.10	-	Accept	Caution	0.49	0.38	-	Accept	Accept

The report can be saved as a PDF by clicking the Save and View Report button  You will be prompted to save the file and it will then be displayed in your default PDF viewer.

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It is possible to view a patient's result history in two ways.

1. At the start or end of a test, where the Result History (below) is displayed on the lower right corner of the testing screen or
2. From the main menu, without performing a test.

From the main menu, select a patient as normal in the test/view existing patient screen 

Select the patient and then click the View Patient Results button 

This will take you to the test screen but will display their most recent test result.

The patient's previous records can be viewed by using the controls at the bottom of the screen in the Result History section.
The example below shows that the patient has 10 previous records in the database. Use the **Switch Eyes** button to see the graph results from the other eye

There are four buttons that are used to move between records –

The button functions are explained below.

 Move to the first record and display the data

 Move to the previous record and display the data

 Move to the next record and display the data
(it is shown greyed out here as we are at the last record)

 Move to the last record - if you are viewing at the start or end of a test this will be today's date.

The last button is used to move to a new patient record, ready for recording data.

Note that the screen must be on a new patient record to record data (the last two buttons above will be greyed out).
Also note that the record count reflects the number of visits regardless of whether a single or both eyes were tested.

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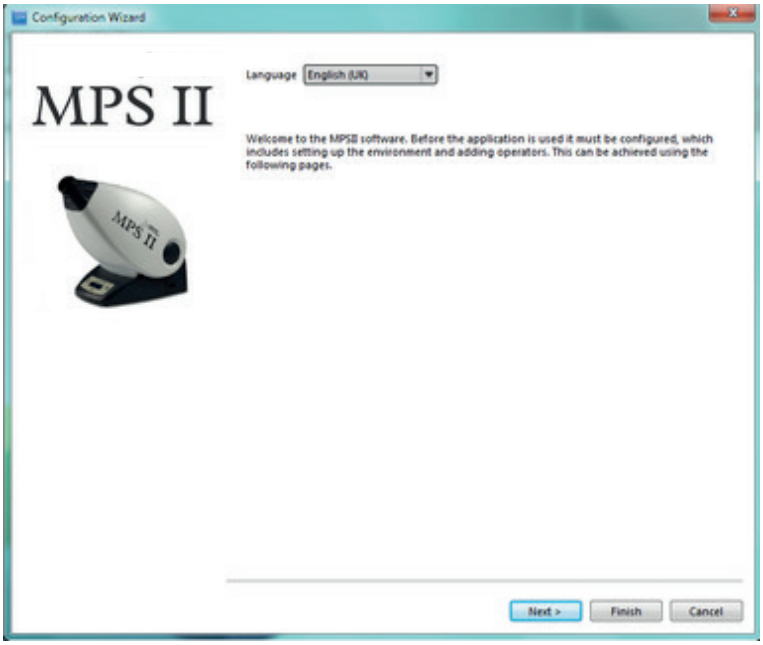
Configuration wizard

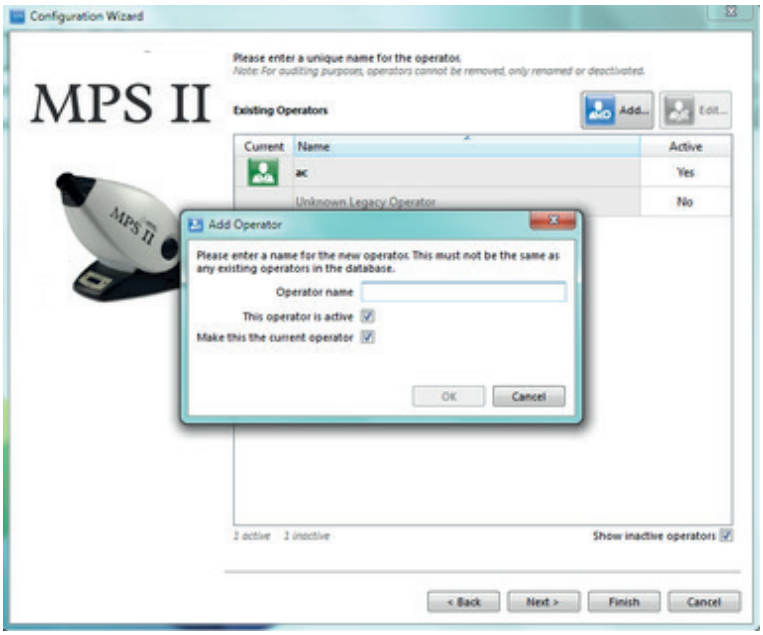
The Configuration wizard runs automatically the first time the software is used after a clean installation.

It guides the installer through changing the software language, adding users and setting a backup strategy.

It can also be run at any time by clicking the Configuration link on the main menu (home) page.



The first screen allows you to change the displayed language.
NOTE : THE LANGUAGE WILL CHANGE IMMEDIATELY SO IF YOU CANNOT READ THE LANGUAGE YOU SELECT **DO NOT** PRESS THE NEXT BUTTON AS YOU MAY NOT BE ABLE TO NAVIGATE BACK



The second screen allows you to view, select and add new operators.
NOTE : you cannot delete operators, you can only make them inactive.

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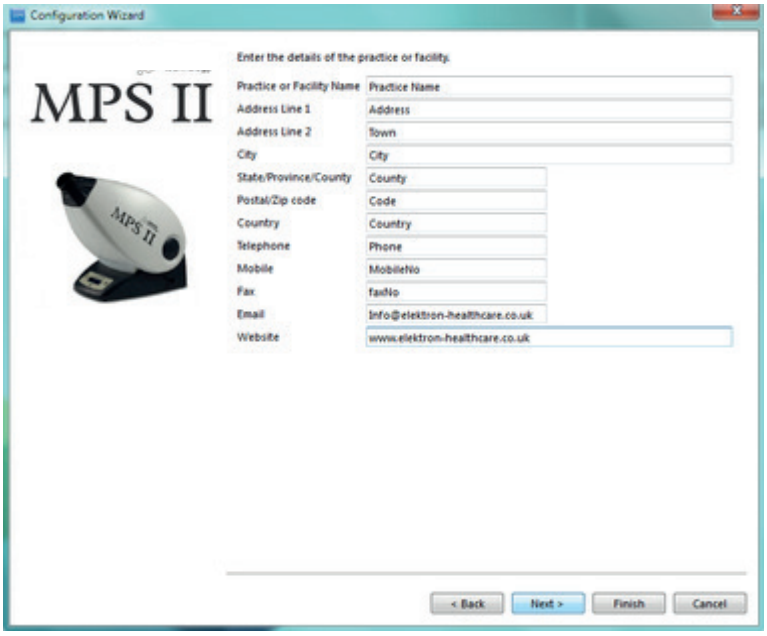
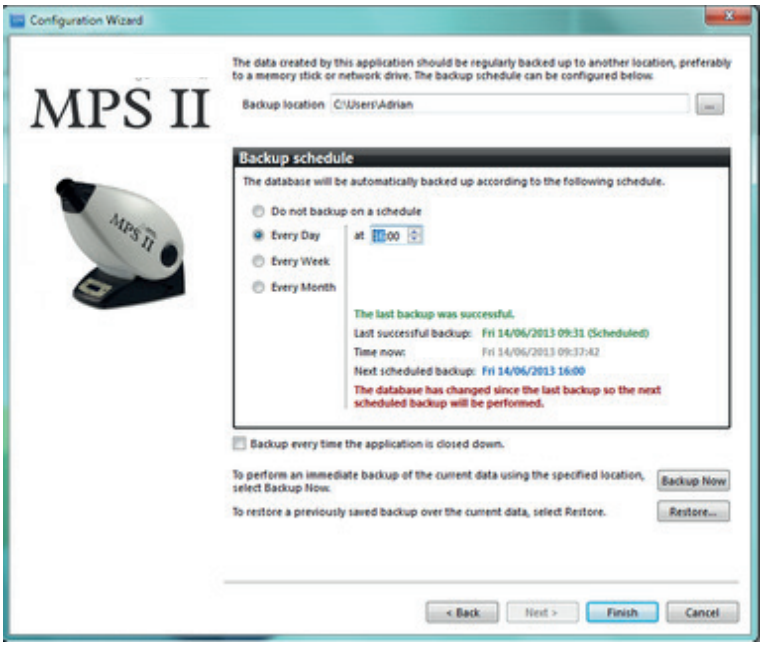


The third screen allows you to enter details about your practice or office.
These details will appear on the patient copy of the test report



The final screen allows you to set up an automatic backup strategy for the database files.
You can select to backup at certain intervals or every time the software is closed down.

The location of the backup can be any folder on the machine or network (if attached to a network).

The MPS 9001 / MPS II must be used in accordance with the operating instructions. Please read the instructions before attempting operation.

1 Location

The electrical installation of the room where the MPS II is to be operated must comply with local electrical regulations. The unit must be protected from ingress of liquids, flammable liquids and gasses..

2 Mains supply*

The mains supply required is 15 VA at 100 to 240 Volts AC. An IEC approved mains lead must be used with conductors of at least 0.75mm^2 cross sectional area (the supplied power lead meets this specification). The MPS II must be installed in such a way as not to impede the isolation. For the MPS 9001 only the supplied external power supply should be used.

*For USA/Canada - The supplied Hospital grade mains cable must be used but grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "Hospital Only" or "Hospital Grade". Outside of the hospital environment the Hospital grade mains cable must be used and connected to a grounded (Earthed) outlet to maintain grounding of the equipment.

3 Power connection

MPS 9001 - Connect the supplied mains power lead between the mains input connector on the external power supply of the MPS II unit and the mains supply wall socket.
NOTE - only the supplied power lead should be used.

4 Accessories

The supplied part patient response button should be connected to the rear panel socket marked with the words "Response button" or the  symbol.

5 Safety

Ensure the leads do not trail on the floor and are not subject to abrasion on sharp edges. Use only laptops, computers, printers and monitors that conform to EN60950.

6 EMC

The MPS II conforms to the current requirement requirements of the standard EN 60601-1-2 (Class B) for Electromagnetic disturbances (EMC) but it may emit radiation and may cause interference with other items of equipment, position it further away or try a different orientation. Do not operate transmitters or mobile telephones in close proximity to the equipment.

7 Ambient temperature and humidity

The equipment should only be operated if the ambient temperature is between 10 and 35 degrees Celsius and the humidity is between 30% and 90% (non-condensing) and at a pressure between 700 to 1060 mbar. (70 to 106 kPa)

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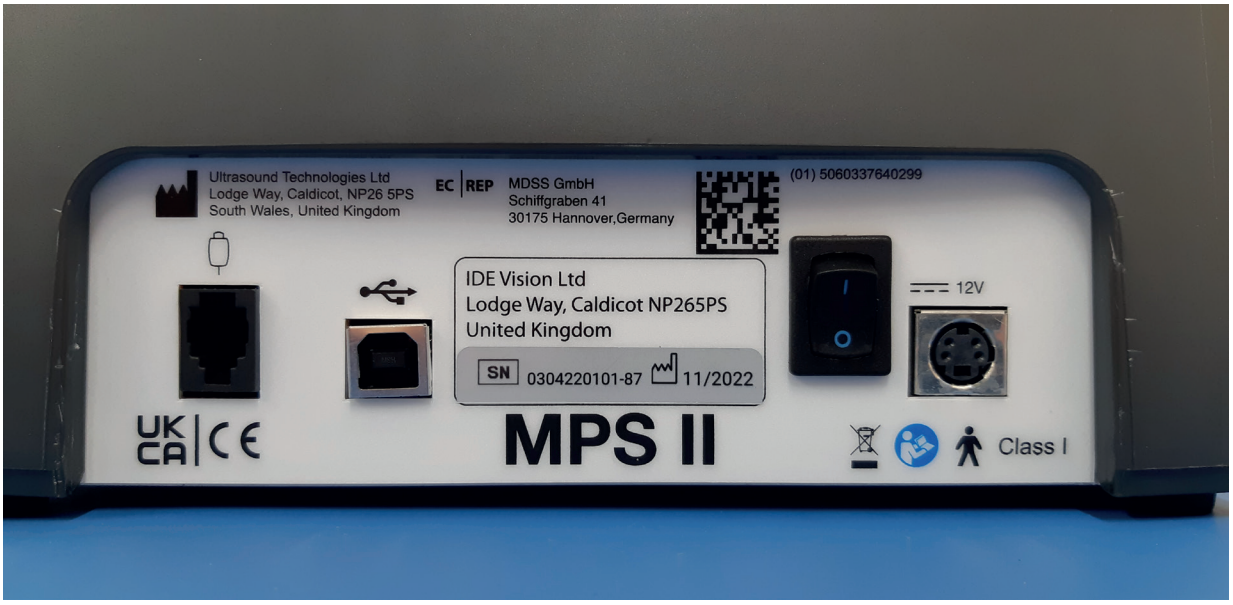
8 Electrical connections MPS 9001

The picture below shows the connections on the back panel of the instrument. **Only the supplied mains cable and power supply should be used.**

9 Laptop or PC

After installing the software (see the Quick Start guide), connect the USB data cable (supplied) between the USB interface connector on the rear of the MPS II device and a spare USB port on the computer. The Windows operating system will detect the device when it is powered on and will load the appropriate drivers.



The software and drivers need to be loaded on the computer before the MPS II is connected to a PC.

There are two sets of instructions for –

- Installing on a new PC, or
- Updating an existing copy of the software

Choose the section you need within this manual...

The Laptop or PC must have either a Windows 7 or later operating system.

The specification of the PC should meet or exceed the following :-

1 gigahertz (GHz) or faster 32-bit (x86) or 64-bit (x64) processor

1 gigabyte (GB) RAM (32-bit) or 2 GB RAM (64-bit)

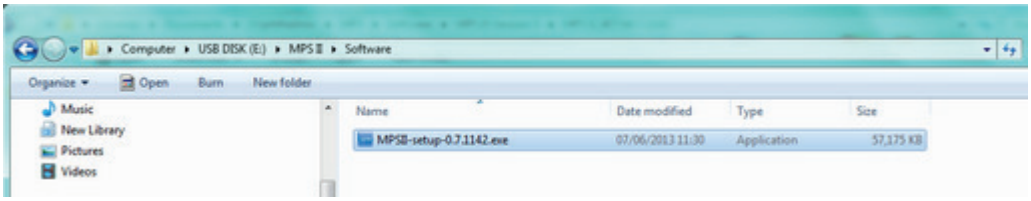
2 GB available hard disk space (32-bit) or 3 GB (64-bit)

At least one unused USB port.

Additional requirements to use certain features: Adobe PDF reader XI

Installation on a new PC

1 Place the supplied MPS II USB Flash drive into a USB port on the computer.
2 If you are prompted for an action, select OPEN FOLDER TO VIEW FILES
3 if you are not prompted, then open MY COMPUTER from the start menu and select the drive letter for the flash drive.
4 Open the SOFTWARE folder, it should look similar to the screenshot below.



The MPS II Vx.xx file name will differ, depending on the software version number.

4 Double click on the MPSII-setup.exe program to start the installation.
5 Depending on the PC's User Account Control setting, you may see a Windows security message - answer YES
6 The language selection window will appear, select your language and click OK
7 Click Next
8 Read and Accept the license agreement and click Next
9 Select the destination folder (it is recommended to leave as the default) and click Next
10 Select a Start Menu folder (it is recommended to leave as the default) and click Next
11 Check the create a desktop icon tick box and click Next
12 Click Install to begin the installation. This will take a few minutes to complete.
13 When completed click the Finish button.
14 The software is now ready to run from the desktop icon.
15 When first run, the Configuration Wizard will run. Details can be found in the configuration wizard section

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Updating an existing installation

It is recommended that the existing database be backed-up before updating an existing installation.

Follow the instructions in the previous section Installation on a New PC

The main difference in a software upgrade is that the patient database is NOT overwritten and will be imported into the new software for immediate use.

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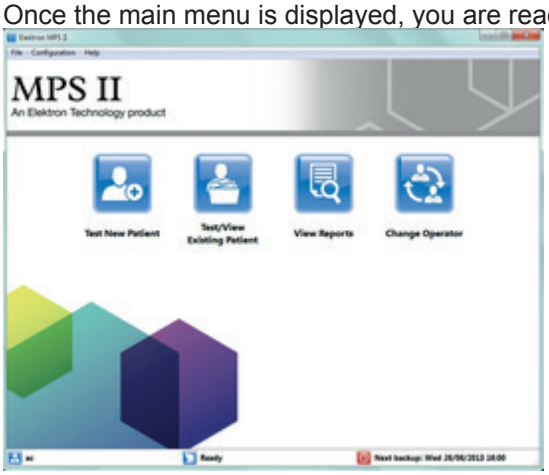
Starting the Program

The software can be started from the desktop icon or from the standard Windows program menu (accessed via the Start button).
Double Click the desktop icon to start –

IMPORTANT NOTICE - PLEASE READ
When you first run the software after installation, you will be required to run through the configuration wizard. This will only happen the first time you run the software.

Once the main menu is displayed, you are ready to operate the software



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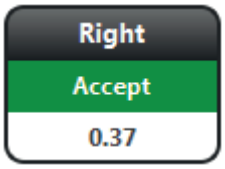
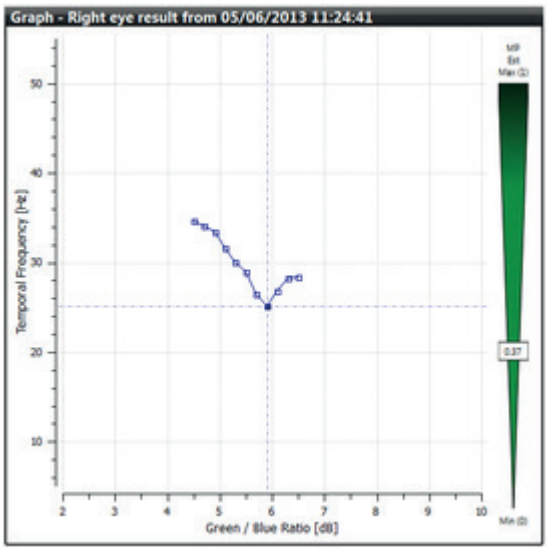
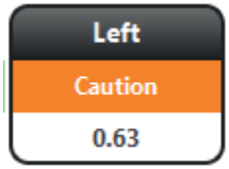
There are three possible test results, shown below the graph –

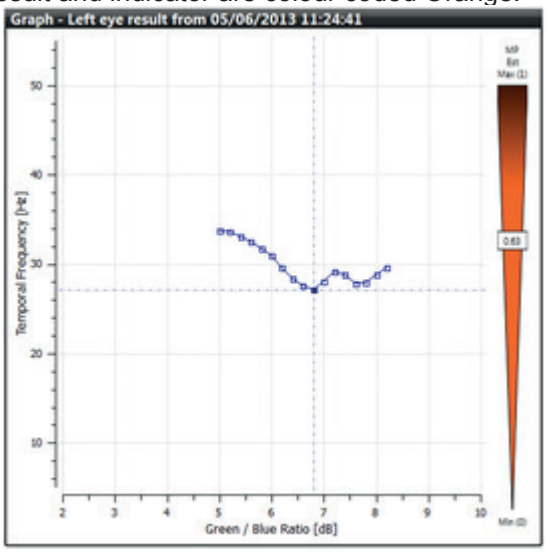
Accept
The result has been analysed. The result of the analysis is acceptable.
An example is shown below. The data show a distinct minimum at an acceptable flicker rate, and so the confidence limits on the data are good. You can see that the result is colour coded green and also the MPOD vertical indicator is also coloured green.





Accept with caution
The result has been analysed and the analysis recommends caution. The graph requires investigation.
An example is shown below. The data show a very poor minimum (at an acceptable flicker rate), and so caution is advised.
Again you can see the result and indicator are colour coded Orange.





If a caution is advised, then check the following –

Slightly noisy data	*Suggest Subject blinks frequently – say after each button press*
Shallow graph	*Suggest Subject presses button as soon as flicker is seen*

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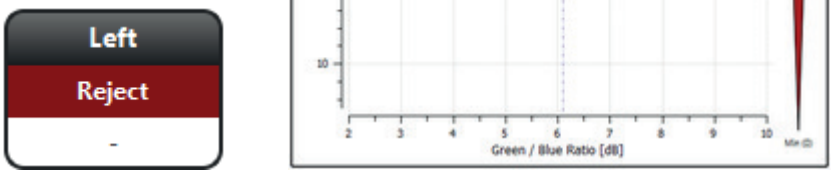
Reject
The result has been analysed and the analysis has rejected the result. The test must be repeated.
An example is shown below. The data show a well-defined minimum, but there is an unusual bump before it.
Here the colour coding is Red for reject.



If a reject occurs, then check the following –

Possible IOL	*Check with Subject for IOL or Tint or entered age*
Minimum same as start	*Check with Subject for IOL or Tint or entered age*
Result reads 0	*Check Subject for IOL or Tint or entered age*
Data Too Noisy	*Suggest Subject blinks frequently – say after each button press*
Too few data points	*Suggest Subject blinks frequently – say after each button press*
Minimum same as end	*Suggest Subject blinks frequently – say after each button press*
Flicker too high	*Advise Subject to wait until flicker is seen*

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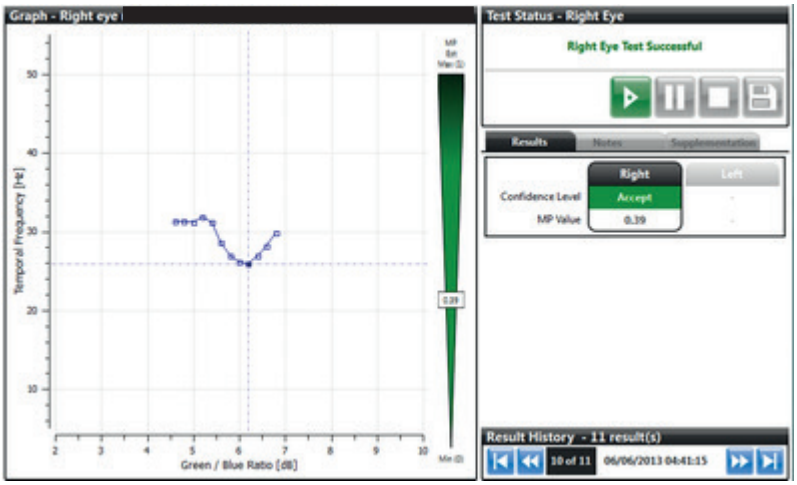
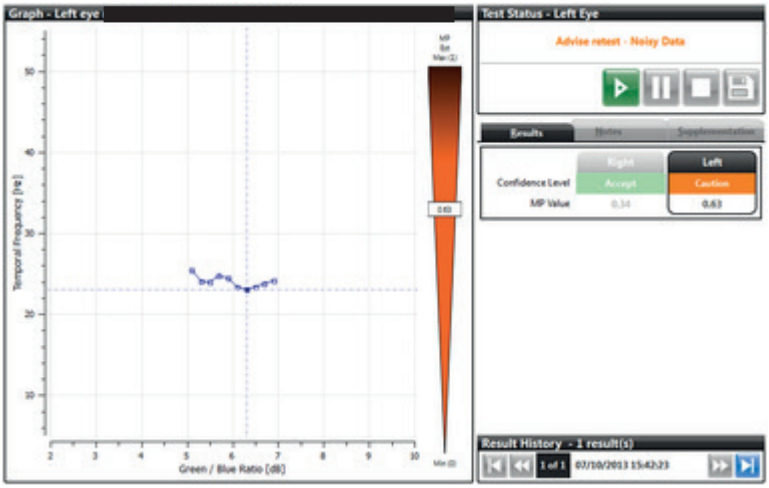
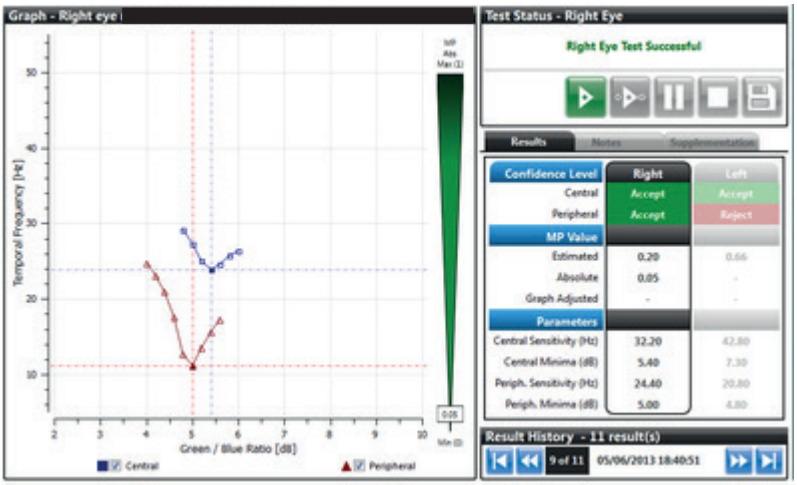
The screenshots below show some sample data. they provide examples of the different confidence accept, caution



This is a result taken in Standard mode.
Data is acceptable, shown by the green area below the graph.



This is an example of where the software advises a retest due to noisy data.



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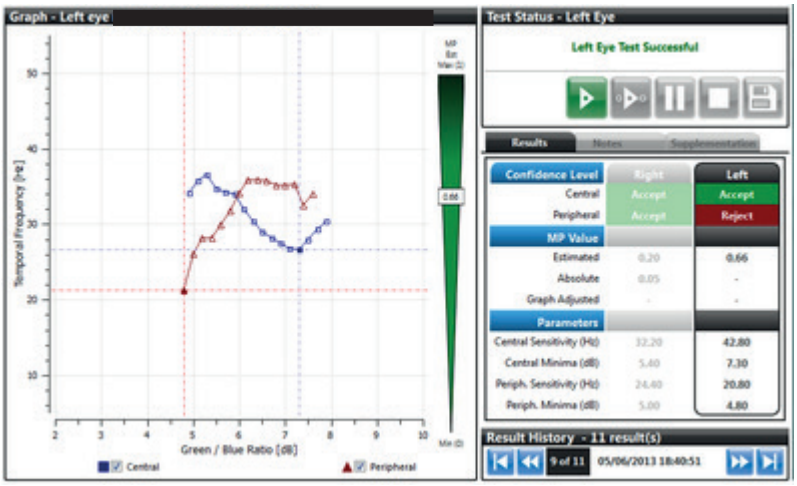
Example data

This is an example of the detailed mode accept screen for data. You can see that both the central and peripheral test have been accepted.



This is an example of a detailed mode reject.
The central test data has been accepted but the peripheral data is rejected as it does not conform to the expected results.
You can see in this case that the software has given an estimated MPOD result based on the central reading but not an absolute reading as the peripheral data is rejected.

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1 TYPE
Computer controlled device capable of measuring the Macular Pigment Optical Absorption Density
Chart distance: 17 cm. Background luminance: 250cdm^{-2}

2 STIMULI
LEDs with spectral outputs of 470nm and 530nm
Angular subtense: 1 degree (central), 3 degrees (peripheral fixation) Luminance: 100 – 1000 cdm^{-2}

3 FIXATION TARGETS
Diffused red LEDs with broad spectral output of 625 – 675 nm

4 INPUTS / OUTPUTS
USB 1.1 Type B connector (for control)
Mains input connector.
Patient response button connector.

5 ELECTRICAL SPECIFICATION
Mains input voltage: 100-240 Vac, universal input.
Frequency 50/60 Hz
Power consumption: 15 VA
Power supply input connector: IEC 320-C14 socket.
Power lead Fuse (where applicable) F 1 A, 250V

6 DIMENSIONS
300 x 230 x 300 - 350 (variable) (L x D x H) mm

7 WEIGHT
4.5 kg

8 CLASSIFICATION
Mains operated Class 1
Type B Applied Part. Continuous operation
Equipment not suitable for use in presence of flammable anaesthetic mixtures with air or oxygen or nitrous oxide.
Ordinary equipment without protection against ingress of water

9 ENVIRONMENT
Temperature:
Operating . . . . . 10° to 35°C (41° to 95°F)
Storage. . . . . –20° to 50°C (–4° to 122°F)

Relative humidity:
Operating. . . . . 30% to 80% (non-condensing)
Storage. . . . . 10% to 90% (non-condensing)

Maximum vibration:
Operating . . . . . 0.9 GRMS using a random-vibration spectrum that simulates shipment by air
Storage. . . . . 1.3 GRMS using a random-vibration spectrum that simulates shipment by truck

Maximum shock:
Operating . . . . . 1.52 m/sec (60 inches/sec) (less than or equal to a pulse width of 2 ms)
Storage. . . . . 2.03 m/sec (80 inches/sec) (less than or equal to a pulse width of 2 ms)

Altitude:
Operating . . . . . 0 to 2000 m (0 to 6,561 ft)
Storage. . . . . 0 to 12,192 m (0 to 40,000 ft)

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10 ACCESSORIES AND DETACHABLE PARTS

The MPS II is supplied with the following accessories and detachable parts:

- Quick Start guide - overview of installation and operation.
- User manual
- Occluder.
- Mains power supply and cable (country specific)
- Dust cover.
- Patient Response Button (PRB)
- USB A-B Cable 1.8 metres.
- Trial lens holder

11 LIST OF SPARE PARTS

Occluder
Operating Manual
Dust Cover
Mains Cable Replacement
Main power adaptor
Patient response Button
Trial lens holder
USB A-B Cable
Eyepiece assembly.

12 EC DECLARATION OF CONFORMITY

When used for the intended application this equipment is considered to be a Class I Medical Device and complies with the requirements of the Medical Devices Regulation 2001/83/EC (as amended).
Any modifications to the equipment may affect the compliance with the directive and referenced standards.

WARNING - No modification of this equipment is allowed.

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Table 1: Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The MPSII device is intended for use within the electromagnetic environment specified below. The customer or the operator of the MPSII device should ensure that it is only used within such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The MPSII device uses AC Power for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 2: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MPSII device is intended for use within the electromagnetic environment specified below. The customer or the operator of a MPSII should ensure that it is used within such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 seconds	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the MPSII device requires continued operation during power mains interruptions, it is recommended that the MPSII device be powered from an uninterruptible power supply.
Note: Ut is the a.c. mains voltage prior to application of the test level.			

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Table 3: Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The MPSII device is intended for use within the electromagnetic environment specified below. The customer or the operator of a MPSII should ensure that it is used within such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment Guidance
			Portable and mobile RF communications equipment should be no closer to any part of the MPSII device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended Separation Distance
Conducted RF	3 Vrms	3 Vrms	d = 1.2 √ P
IEC 61000-4-6	150 kHz to 80 MHz		
Radiated RF	3 V/m	3 V/m	d = 1.2 √ P 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz		d = 2.3 √ P 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b
			Interference may occur in the vicinity of equipment marked with the following symbol.
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and/or people.			
a. Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MPSII device is used exceeds the applicable RF compliance level above, the MPSII device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MPSII device. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

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Table 4: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the MPSII device

The MPSII device is intended for use in the electromagnetic environment specified below. The customer or the user of the MPSII device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MPSII device as recommended below, according to the maximum output power of the communications equipment.			
	Separation Distance According to Frequency of Transmitter m		
Read Maximum Output Power of Transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
W	d = 1.2 √ P	d = 1.2 √ P	d = 2.3 √ P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	3.8	3.8	7.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distances d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and/or people.			

Before any maintenance or cleaning is undertaken, it is important that the mains cable is removed from the wall socket, isolating the unit from any power. The equipment can also be isolated from the mains by removing the detachable mains cable.

The unit should not be maintained or serviced while in use by a patient.

Cleaning

It is important that the device is disconnected from the mains power supply by removal of the mains cable from the wall socket before any maintenance or cleaning work is undertaken.

Housing

The housing may be kept clean by wiping with a damp cloth. Do not use abrasive cleaners. Do not allow liquid to enter the MPS II.

Lens

The lens can be cleaned with any suitable lens cleaning cloth or sterile wipe. Abrasive cleaners must not be used.

Target Screen

The target screen may, in time, have deposits of dust - depending on the environment it is used in. Small debris can be “blown clear” of the target screen by blowing into one of the 2 holes that are located on either side of the lens with the eyepiece removed (see next paragraph).
Use a clean air supply of air – e.g. aerosol can, designed for this purpose.
It is important not to insert anything into the holes to touch the circuit board inside.

Eyepiece

The eyepiece could transfer contamination or infection from one person to another.
The eyepiece can be removed for cleaning/disinfection. Replacement eyepieces are available should the surface become damaged or discoloured.

Since the patient is likely to be in contact with the eyepiece, there might be a possibility of allergenic reactions in some patients.
The eyepiece material has been selected to be a low risk for allergenic reactions, it is made from a thermoplastic elastomer rather than natural rubber.

To remove the eyepiece assembly, gently squeeze inwards on the 2 sides and pull the eyepiece away from the unit (see below).

The eyepiece, and any adjacent areas that could come into contact with the patient, should be kept clean using a damp cloth followed by a suitable antiseptic wipe.

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It is recommended that you regularly inspect the equipment casing, response button casing and cables before use.

If any damage is found the equipment should not be used before it has been inspected by a competent person.

Particular attention should be paid to the

- Mains cable to the power supply unit.
- Power input at the back of the instrument.
- Cable of the patient response button.

The connected computer should be maintained in accordance with the manufacturer's instructions.
This includes hardware and software maintenance.

The operating system should be kept up to date with any patches and software upgrades.

The MPS II user software should be kept up to date with any patches and upgrades.
Upgrades will be made available from the manufacturer and sales agent's websites.

Replacement parts

There are NO user serviceable parts in the MPS II. The following replacement spare parts are available from your supplier –

Item	Part number
Dust cover	OP-0170-DP-100032
USB A-B cable	WIR5121
Eyepiece assembly	OP-0170-SA-100012
Slot in lens holder	OP-0170-DP100100
Software Flash Drive	*
Power supply	OP-0170-DP-200007
User manual	TO-016314-UM
Mains cable (country specific)	Quote country for part number

* The software part number will change with every version of software. Contact your supplier for the latest part number.

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Repairs and calibration

The MPS II contains no user serviceable parts.

The unit must only be serviced by an appropriately qualified person.

The Manufacturer will make available, on request and at its discretion, circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist Service Personnel to repair those parts of the MPS II that are designated by the Manufacturer as repairable by Service Personnel.

Calibration
It is recommended that the MPS unit has a calibration check at least once every 2 years to ensure it is within acceptable limits.
It is of course possible to check it more frequently if required.

Please contact your supplier or agent for information about calibration and servicing.

In case of difficulty please contact the manufacturers via email using service@ide-vision.com

Warranty

If, within 24 months from the date of installation, any defect is discovered in the instrument in respect of material or workmanship and reasonably within our control, we undertake to make good the defect at our own expense, provided notice is given to us as soon as it is discovered and that the instrument is immediately forwarded to our works, carriage paid, in the original packaging and with security seals unbroken.
If the original packaging is not available, then please contact your service representative to request packaging.

The MPS II has an expected lifetime of 7 years if used in accordance with the instructions and serviced by suitably qualified personnel at the recommended intervals.

Please note that IDE Vision Ltd. reserves the right to alter the specification of the hardware or software at any time without notification.

This section deals with any problems or error messages you may get whilst connecting the MPS II to a PC. In most cases there is a simple solution.
If the connection status message is NOT reading READY when starting the software then the MPS II is not communicating –

If you see NOT CONNECTED , then please try the following –

- Check that the MPS II device is powered
- Check that the USB cable between the MPS II device and the laptop/Computer is plugged in firmly at both ends

If any of the connections were loose, you will have to wait until the software detects the MPS II device.

If none of the above fixes the problem, then try unplugging the USB cable, power cycling the MPS II and re-connecting the USB cable.

There are various error messages that can be displayed with respect to the databases. Make a note of them as your service provider may need them to help you.

It is always good practice to keep a backup of the database in a safe location to minimise data loss in the event of a hard drive failure / computer loss.

In the event of a database error, the last backup can be restored with minimal loss of data.

EC	REP	MDSS GmbH Schiffgraben 41 30175 Hannover, Germany

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