MPS II User Manual

The MPS II is a world leader in macular pigment density measurement

by Elektron Technology UK Ltd.
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1 MPS II

1.1 Introduction

The MPS II / MPS 9000 must be used in accordance with the operating instructions. Please read the instructions before attempting operation.

The instructions in this manual are to be viewed as an accompaniment to correct training on this equipment.

The results of a test are only to be analysed by a suitable qualified person, and it is the responsibility of the practice manager/owner to ensure that only suitably trained personnel are operating this equipment.

Contact your sales agent for details of on-site training.
1.1.1 Elektron Company notices

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### Revision History

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<tr>
<td>Version 1.00</td>
<td>24/6/13</td>
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<td>Spelling and grammatical corrections and some formatting changes</td>
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<td>Version 1.2</td>
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<td>Added graph estimate information in Detailed Mode test</td>
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1.1.1.2 Important warnings

**WARNING**
This unit must be connected to an earthed mains supply

**WARNING**
Hazardous voltages are present inside the electrical enclosures of this unit. No user-serviceable parts inside

**WARNING**
This equipment is not suitable for use in an oxygen rich environment

**WARNING**
This equipment should be kept dry at all times
1.1.1.3  **Explanation of symbols used in manual and on instrument**

Definition of symbols used in the manual and on the instrument.

- **WARNING**
- Consult manual
- WEEE Directive
- Power Off (0)
- Power On (1)
- Type B Applied Part
- Hazardous voltage
- CE mark
- USB
- Protective earth
- AC Mains
1.1.1.4 Database warning

To reduce the possibility of 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 on 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 MP test is performed the results (if saved) are attached to the patient’s “record” card.
1.1.1.5 Acknowledgements

Microsoft, Windows, Windows 7™ and Windows 8™ are registered trademarks of Microsoft Corporation.

Elektron Technology UK Ltd. continuously improves the design processes of its equipment to minimize 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 authorized 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.
1.2 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 MPS9000; both of these refer to the stand-alone MPS II unit which has the manufacturer’s reference number MPS9000 or MPS1000.

Throughout this manual there will be references to laptop or PC where PC stands for Personal Computer.

It does not matter which computer you have as the software is the same.

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 (when available).

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.

- Greyed out if they cannot be used.

- Blue if they are available for use and

- Green if they are the next button you should press to progress.
1.3 An Introduction to Macular Pigment

Age-related Macular Degeneration (AMD) is the most common cause of vision loss in people over 50 and its prevalence increases with age. There is a growing awareness of the disease, the need to measure the risk of getting it and how to take preventative action.

As the World's population ages, the condition is expected to become more prevalent creating a heavy financial burden on health care services. It is safe to say that if the entire population lived to 100 years, we would all exhibit varying levels of macular degeneration.

Given that there is no cure for AMD, it is vital to prevent the disease for as long as possible through diet, lifestyle and optimising Macular Pigment Levels – the internal sunscreen for the eyes.

The macula is the central and most sensitive part of the retina at the back of the eye and macular pigment acts as an antioxidant that protects the retina from the potentially damaging effects of blue light – if the density of this pigment is reduced then the retina is made more vulnerable and more likely to gradually deteriorate. By catching those with low levels of macular pigment, the MPS II makes it possible to reduce their risk of long-term vision loss. People with AMD experience severely distorted vision and find it very hard to read and recognise faces.

Eventually the condition can lead to total blindness. The density of the macular pigment has been shown to be linked to diet and to other lifestyle factors, including smoking.

The scientifically proven technique for measuring the density of macular pigment, heterochromatic flicker photometry (HFP), has been available for over 30 years. The new MPS II uses the same technology, but takes it to the next stage by refining it and making it available in a more accessible package thanks to advances in LED lighting.

The approach adopted by the MPS II is far easier for patients to use than earlier versions of the technology. Unlike conventional methods, where observers have to set the point where flicker disappears (or minimised), the measurement consists of a series of button presses in response to the onset of flicker, which makes it far easier for the subject to take the test and for the Optical Practitioner to accurately determine the flicker thresholds and optical density.

Visit our Website for more up to date information regarding clinical papers and developments in the Prevention, Detection and Treatment of AMD.

Elektron healthcare Website
1.4 MPS II testing

The MPS II is a computerised instrument 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 instrument 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 the Microsoft Windows8™, or Windows 8™ operating system.

The MPS II is easy to use and does not require advanced computer literacy for its operation.

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 data.

A powerful database is included in the software that stores the macular pigment results alongside the patient details. using the database, reports can be generated to monitor the patient’s progress after supplementation.
1.4.1 MPS II target

The MPS II target is the most important part of the unit and the lens and optics of the instrument 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 these. 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.
1.4.2 Testing strategy

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 the subject has been fitted with an Intra-Ocular Lens, the eye may then appear much younger so the software automatically assumes an age of 20 when the IOL button has been ticked (patient’s form).

The MPS II first measures the 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. Too high a sensitivity and the curve starts at a high value (> 30 Hz) and remains shallow. Too low a value, and the curve starts at a low value (< 30 Hz) and is too deep (sometimes below 5Hz) which may halt the 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.
1.4.3 Standard test

The latest version of the MPS II software implements the Standard mode algorithm from version 4.

Developed by one of the original inventors of the instrument, 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 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 the two modes (shown below, for comparison) –

The Standard mode contains a subset of the Detailed 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 mode algorithm produces a low, but acceptable result, the final decision is left to the operator.
1.4.4 Detailed Test Mode

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

For this test, 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 the 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 Macular Pigment Optical Density.

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.
1.4.5 **Explanation of terms**

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

The Standard 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 MP 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 perform a central test (where patient looks directly at the target) and then a peripheral test (where the patient looks at the red fixation point) and by comparing these 2 results we work out the patient’s MP level.

**MP-Graph Adjusted**
This is where the Absolute result of a detailed 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 2 points at exactly the same point 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.
2 Installation

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

It is not recommended to extend the supplied cable since communications between the PC/Laptop and MPS II may be unreliable.

See the Quick Start guide or Appendix 1 for connection instructions.
See the Quick Start guide or Appendix 2 for software installation instructions.

See the End User License Agreement (EULA) in Appendix 8 for full detailsof the license on the software.
(this is the same license agreement that is agreed when installing the software.)
**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 software once installed and running will display the status of the connected instrument at the bottom of the screen along with the name of the current operator (in this case AC) and the date of the next scheduled backup.

The MPS II can be placed on any stable, flat surface or electric table.
The instrument should be located 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 has an internal power supply unit. The power supply is universal and does not need adjusting for different mains voltages, but it is important to check that the correctly rated fuses are being used (see Appendix 1 or the label on the rear of the unit).

The patient response button is connected into the rear of the unit and must be accessible by the patient. The on/off switch for the instrument is on the back panel.
3 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 full aperture (or reduced aperture) trial lens in the front slot of the machine with the reading 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 patient’s Notes.

- Occlude the eye not being tested using an eye patch. Perform in mesopic or scotopic lighting. Measure the right eye, then the left eye with a central measurement only (ie Standard mode) and save the results.

- Inform the patient that this test requires concentration; however they should be encouraged to blink naturally. When you detect flicker on the central spot, it’s ‘finger on the buzzer’ and speed is of the essence.

- There will be a short familiarisation 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’.

- 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) then take the central and peripheral measurements (ie Detailed mode). 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, pause it and get them to look 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.
4 Selecting a Patient

Start the program and wait until the Main Menu screen is shown –

You have 2 options here:-

- If the patient is new to this test then you will need to create a New Patient in the database.

- If you have tested the patient before then you can select their record from the database, so select the Test existing patient button.
4.1 Create a New Patient

If the patient has never been tested on this instrument before then they will not exist in the database. Select the Test New Patient button.

Test New Patient

The Patient entry screen will be displayed. The items that MUST to be filled in are highlighted in red.

You have to enter, at least, the patient’s First name, Surname, Date of birth and Gender to create a new record. Selecting the title will also set the gender, for example, selecting Mr will set gender as male.

You can see from the screen shot that the age 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 other relevant Risk Factors the patient has by clicking on the Risk Factors tab.
This gives you an opportunity to discuss the risk factors with a new patient.

There are also tabs for **Notes** and also for **Supplementation**, the Notes 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 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 original screen. (you will be prompted whether you want to discard the record)

It is also possible to SAVE  the changes made but not test the patient at this time.
4.2 Select Existing Patient

If the patient has previous tests stored in the database then select the Test 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 name in the search box - as you start to type the surname in the search box the records will clear to show all matching records.

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

- Test this patient
- Edit this patients details in the database
- View the patients 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 starting again)
- Or cancel and return to the Main menu
5 Standard Test Mode

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.

The details of the test are here.
5.1 Standard 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 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.
5.2 Standard Test - Sequence

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.

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 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.

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

Ideally, the patient’s 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
---|---|---
![Accept](image1) | ![Caution](image2) | ![Reject](image3)

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.
(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.

![Results](image4)

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 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.
5.3 Patient Instructions

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.

6 Detailed Test Mode

The Detailed Test Mode is used where patient's have a pre-existing pathology, such as diabetic maculopathy and allows you to perform a central test (through the patient's macular pigment) and then a 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, AMD) then the Standard Test Mode can be used

The details of the test are here
6.1 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
6.2 Detailed Test - Sequence

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.
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.

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

Ideally, the patient’s 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 

<table>
<thead>
<tr>
<th>Accept</th>
<th>Caution</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Accept" /></td>
<td><img src="image" alt="Caution" /></td>
<td><img src="image" alt="Reject" /></td>
</tr>
</tbody>
</table>

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

![Results Table]

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.

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.
6.3 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 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.

6.4 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 second one of these, and you can choose the other to see what difference this will make.

To alter the graph cursor position you must first have completed a full 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.
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.

6.5 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.

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.

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 data range by clicking on either the start or end date the 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.

The start and end dates of the report can be selected.

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.

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 form a particular operator. 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.
7 Viewing Previous Record Data

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 meaning of the buttons is explained below.

Move to the first patient record and display the data

Move to the previous patient record and display the data

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

Move to the last patient record - this will be the one we have not completed yet.

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.
8 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.

![Configuration Wizard screenshot](image)

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.

The third screen allows you to enter details about your practice. 
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).
Appendix 1 - MPS II Installation

The MPS9000 / 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 and 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 0.75mm² cross sectional area (the supplied power lead meets this specification).

*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
Check that the MPS II has the correct rating of fuse for your mains voltage by pulling out the drawer under the mains input connector and reading the rating from the top of the fuses. The correct rating is specified in the specification section and on the back panel of the unit. Connect the supplied mains lead from the mains input connector on the rear of the MPS II unit to the mains supply wall socket.

4 Accessories
If the unit is located on an electric table, the table should be connected to the mains supply using a suitable mains lead and the MPS II should be powered from the power outlet at the top of the table.

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 requirements of the EMC European Directive 2004/108/EC, but it does emit radiation and if it causes 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. This equipment complies with the EMC requirements of EN 60601-1-2 (Class B) which are appropriate for Medical devices, however it should not be placed in close proximity to sensitive equipment or close to strong sources of EM fields.

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 80% (non-condensing) and at a pressure between 700 and 1060 mbar.
For storage and transport the ambient temperature must be between -20 and 50 degrees Celsius, the humidity between 10% and 80% (non-condensing) and pressure between 500 and 1060 mbar.

8 Electrical connections
The picture below shows the connections on the back panel of the instrument.
It is important that the correct rating of fuse is used in the MPS II as damage may occur. The rating is shown below the Mains Inlet Socket. The instrument must be earthed.

9 Laptop or PC
Connect the mains lead supplied with the laptop/PC to a suitable mains power supply. 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 ‘rectangular’ end of the USB lead goes to a spare USB port on your PC and the other end (the ‘square’ end) goes into the USB port on the back of the MPS II.
Appendix 2 - Software Installation

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 by clicking the links above.

The Laptop or PC must have either a Windows 7™ or Windows 8™ operating system on it.

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
10.1 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. 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-5.xx.xx.exe program to start the installation.
5. Depending on the PC’s UAC (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.
10.2 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.
10.3 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
11 Appendix 3 - Confidence Limits

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.

![Graph - Right eye result from 05/06/2013 11:24:41](image)

**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 coloured coded Orange.

![Graph - Left eye result from 05/06/2013 11:24:41](image)
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**

**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.

![Graph - Left eye result from 06/06/2013 08:45:40](image)

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**
12 Appendix 4 - Example data

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

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.
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.
Appendix 5 - Technical Specification

1 TYPE
Computerised 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 external control)
Mains input connector (IEC320)
Patient response button

5 ELECTRICAL SPECIFICATION
Mains input voltage: 100-240 Vac, universal input
Fuses: 2 off 20mm x 5mm IEC 60127-2 high breaking capacity
Fuse rating: 240Vac T0.5AH250V, 110VAC T1AH250V
Frequency 50/60 Hz
Power consumption: 15 VA
Power input connector: IEC 320 socket

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 3048 m (0 to 10,000 ft)
Storage .................................................. 0 to 12,192 m (0 to 40,000 ft)

10 ACCESSORIES AND DETACHABLE PARTS
The MPS II is supplied with the following accessories and detachable parts:
USB Flash Drive containing installation software for PC
Mains cable (country specific)
Dust cover
Patient Response Button (PRB)
Replacement fuses for alternate voltage

11 OPTIONAL EXTRAS
Electric Table (without top)
Custom made top with printer carrier
V shaped table top
Inkjet Printer

12 LIST OF SPARE PARTS
Occluder
Operating Manual
Dust Cover
Mains Cable Replacement
Patient response Button
Replacement fuses

13 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 Directive 93/42/
EEC (as amended). Any modifications to the equipment may affect the compliance with
the directive and referenced standards.
14 Appendix 6 - Maintenance and Warranty

Regular Inspection
Maintenance
Cleaning
Preventative Maintenance
Replacement Parts
Spare Lenses
Repairs and Re-calibration
Warranty

14.1 Regular Inspection

Inspect the equipment 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 at the back of the instrument and the cable of the patient response button.

14.2 Maintenance

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.

14.3 Cleaning

The equipment is housed in an enclosure that can be wiped clean as required. This is done with the unit disconnected from the supply.

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 moulding removed (see next paragraph). Use a clean air supply of air – e.g. aerosol can, designed for this purpose.

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. Since the patient is likely to be in contact with the eyepiece, there might be a possibility of allergenic reactions in some patients. The material has been selected to be is “Evoprene” which is a thermoplastic elastomer rather than natural rubber.
To remove the eyepiece, 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.

14.4 Preventative maintenance

Every six months it is recommended that the mains lead should be inspected and replaced if there is any sign of damage to the insulation etc.

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.

14.5 Replacement parts

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Part number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dust cover</td>
<td>SUN9303</td>
</tr>
<tr>
<td>USB A-B cable</td>
<td>WIR5121</td>
</tr>
<tr>
<td>Eyepiece assembly</td>
<td>MPS9000-328</td>
</tr>
<tr>
<td>Software CD</td>
<td>SUN5900*</td>
</tr>
<tr>
<td>T0.5AH250 HBC fuse</td>
<td>FUS1226</td>
</tr>
<tr>
<td>T1AH250V HBC fuse</td>
<td>FUS1227</td>
</tr>
<tr>
<td>Manual</td>
<td>MAN2000</td>
</tr>
</tbody>
</table>
14.6 Spare lenses

The following are available for the MPS II as optional extras—

- MF OPT7001: Lens +1D 1.502 Index
- MF OPT7002: Lens +2D 1.502 Index
- MF OPT7003: Lens +3D 1.502 Index
- MF OPT7004: Lens +4D 1.502 Index

14.7 Repairs and Recalibration

The MPS II contains no user serviceable parts except for replaceable external items (fuses).

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 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 for more details of this.

In case of difficulty please contact your supplier.

14.8 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.

Please note that Elektron Technology reserves the right to alter the specification of the hardware or software at any time without notification.
15 Appendix 7 - Troubleshooting

This chapter 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 –

- 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.
Appendix 8 - Software License Agreement

IMPORTANT NOTICE: PLEASE READ CAREFULLY BEFORE INSTALLING THE SOFTWARE

This licence agreement (Licence) is a legal agreement between you (Licensee or you) and ELEKTRON TECHNOLOGY UK LIMITED (English company number 04949934) of Broers Building, JJ Thomson Avenue, Cambridge CB3 0FA (Licensor, us or we).

The following terms are used in this Licence:

- The MPS II computer software and the data supplied with the software, any Maintenance Release and the associated media (Software);
- Software that corrects faults, add functionality or otherwise amends or upgrades the Software which we may supply to you from time to time (Maintenance Release);
- printed materials and online or electronic documentation we supply to you in connection with the Software (Documentation);
- the Macular Pigment Screener portable device provided by the Licensor (MPS Device), and PC refers to a personal computer.

We may also make available to you open-source software (as defined by the Open Source Initiative (http://opensource.org) or the Free Software Foundation (http://www.fsf.org) (Open-Source Software) when we supply you with the Software. Use of Open-Source Software is subject to the relevant third party licence terms, and such Open-Source Software remains the property of the relevant licensors.

We licence use of the Software and Documentation to you on the basis of and subject to the terms of this Licence. We do not sell the Software or Documentation to you. Except in respect of any elements licensed from third parties, we remain the owner of the Software and Documentation at all times.

OPERATING SYSTEM REQUIREMENTS: THIS SOFTWARE REQUIRES A PERSONAL COMPUTER WITH WINDOWS 7™ or WINDOWS 8™ OPERATING SYSTEMS.

IMPORTANT NOTICE TO ALL USERS:

- BY INSTALLING, COPYING OR OTHERWISE USING THE SOFTWARE OR CLICKING ON THE "ACCEPT" BUTTON BELOW YOU AGREE TO THE TERMS OF THIS LICENCE WHICH WILL BIND YOU AND YOUR EMPLOYEES.
- IF YOU DO NOT AGREE TO THE TERMS OF THIS LICENCE, WE WILL NOT LICENSE THE SOFTWARE AND DOCUMENTATION TO YOU AND YOU MUST DISCONTINUE THE INSTALLATION PROCESS NOW BY CLICKING ON THE "CANCEL" BUTTON BELOW THE DISPLAYED LICENCE AGREEMENT. IN THIS CASE YOU MUST RETURN ANY MEDIA ON WHICH THE SOFTWARE IS STORED AND ALL ACCOMPANYING DOCUMENTATION TO THE LICENSOR.

You should print a copy of this Licence for future reference.

1. GRANT AND SCOPE OF LICENCE

1.1 In consideration of you agreeing to abide by the terms of this Licence, the Licensor hereby grants to you a non-exclusive, non-transferable licence to use the Software and the Documentation and any Maintenance Release which we make available to you on and subject to the terms of this Licence.

1.2 You may:

(a) install and use the Software for your personal purposes (if you are a consumer) or your internal business purposes (if you are a business):

(i) only on one PC; and

(ii) only in conjunction with the MPS Device together with which the Software was provided to you;

(b) make up to one copy of the Software for back-up purposes only, provided you comply with the provisions in condition 2(f);

(c) use any Documentation in support of the use permitted under condition 1.2.

1.3 Unless agreed otherwise by the Licensor in writing, the Software may not be used or
installed on more than one PC, and may not be used to process data captured by, or to communicate with, more than one MPS Device (and that MPS Device must, unless agreed otherwise by the Licensor in writing, be the one together with which the Software was provided to you).

2. RESTRICTIONS

Except as expressly set out in this Licence or as permitted by any local law, you undertake:

(a) not to copy the Software or Documentation except where such copying is incidental to normal use of the Software or where it is necessary for the purpose of back-up or operational security, nor use the Software on more than one PC;
(b) not to rent, lease, sub-license, loan, translate, merge, adapt, vary or modify the Software or Documentation;
(c) not to make alterations to, or modifications of, the whole or any part of the Software nor permit the Software or any part of it to be combined with, or become incorporated in, any other programs;
(d) not to disassemble, de-compile, reverse engineer or create derivative works based on the whole or any part of the Software nor attempt to do any such things except to the extent that (by virtue of section 296A of the Copyright, Designs and Patents Act 1988) such actions cannot be prohibited because they are essential for the purpose of achieving inter-operability of the Software with another software program, and provided that the information obtained by you during such activities:
   (i) is used only for the purpose of achieving inter-operability of the Software with another software program;
   (ii) is not disclosed or communicated without the Licensor's prior written consent to any third party to whom it is not necessary to disclose or communicate it; and
   (iii) is not used to create any software which is substantially similar to the Software;
(e) to ensure that any licence key we provide to you is kept confidential and is not disclosed to any third party;
(f) to keep all copies of the Software secure and to maintain accurate and up-to-date records of the number and locations of all copies of the Software;
(g) to supervise and control use of the Software and ensure that the Software is used by your employees and representatives in accordance with the terms of this Licence;
(h) to include our copyright notice on all entire and partial copies of the Software in any form;
(i) not to provide, or otherwise make available, the Software in any form, in whole or in part (including, but not limited to, program listings, object and source program listings, object code and source code) to any person, other than your employees, without prior written consent from us;
(j) not to use the Software via any communications network or by means of remote access.

3. INTELLECTUAL PROPERTY RIGHTS

3.1 You acknowledge and agree that all intellectual property rights in the Software and the Documentation throughout the world belong to us, that rights in the Software are licensed (not sold) to you, and that you have no rights in, or to, the Software or the Documentation other than the right to use them in accordance with the terms of this Licence.

3.2 You acknowledge that you have no right to have access to the Software in source code form or in unlocked coding or with comments.

4. LIMITED WARRANTY

4.1 We warrant that:

(a) the media on which the Software is stored and distributed is (at the time it is supplied) free from defects in design, material and workmanship under normal use;
(b) the Software will, when properly used and on an operating system for which it was designed, perform substantially in accordance with the functions described in the Documentation; and
(c) that the Documentation correctly describes the operation of the Software in all material respects,

for a period of 90 days from the date of installation of the Software (Warranty Period). If a defect in the media occurs during the Warranty Period, we will replace it free of charge if you return it to the Licensor with (so far as you are able) a documented example of such defect or error.

4.2 If, within the Warranty Period, you notify us in writing of any defect or fault in the Software as a result of which it fails to perform substantially in accordance with the Documentation, we will, at our sole option, either repair or replace the Software, provided that you make available all the information that may be necessary to help us to remedy the defect or fault, including sufficient
information to enable us to recreate the defect or fault.

4.3 The warranty does not apply:
(a) if the defect or fault in the Software results from you having amended the Software;
(b) if the defect or fault in the Software results from you having used the Software in
contravention of the terms of this Licence.

4.4 We are not obliged to provide any Maintenance Releases. Unless agreed otherwise by us
in writing, we have no obligation to support the Software on more than one PC, or in respect of more
than one MPS Device.

4.5 Any Open-Source Software we provide to you may be used according to the terms and
conditions of the specific licence under which the relevant Open-Source Software is distributed, but
is provided "as is" and expressly subject to the disclaimer in condition 5.7.

5. LIMITATION OF LIABILITY

5.1 You acknowledge that the Software has not been developed to meet your individual
requirements, and that it is therefore your responsibility to ensure that the facilities and functions of
the Software as described in the Documentation meet your requirements. Neither we nor our
suppliers warrant that the functions contained in the Software will meet your requirements or that the
operation of the Software will be uninterrupted or error-free.

5.2 We only supply the Software and Documentation for internal use by your business, and you
agree not to use the Software or Documentation for any re-sale purposes.

5.3 We shall not under any circumstances whatever be liable to you, whether in contract, tort
(including negligence), breach of statutory duty, or otherwise, arising under or in connection with the
Licence for:
(a) loss of profits, sales, business, or revenue;
(b) business interruption;
(c) loss of anticipated savings;
(d) loss or corruption of data or information;
(e) loss of business opportunity, goodwill or reputation; or
(f) any special, indirect or consequential loss or damage, even if we were aware of the
circumstances in which any such loss or damage could arise at the time we supplied the Software to
you.

5.4 Other than the losses set out in condition 5.3 and in condition 5.5 (for which we are not
liable), our maximum aggregate liability under or in connection with this Licence whether in contract,
tort (including negligence) or otherwise, shall in all circumstances be limited to GBP1,500. This
maximum cap does not apply to condition 5.6.

5.5 You agree that in entering into this Licence, either you did not rely on any representations
(whether written or oral) of any kind or of any person other than those expressly set out in this
Licence or (if you did rely on any representations, whether written or oral, not expressly set out in this
Licence) that you shall have no remedy in respect of such representations and (in either case) we
shall have no liability in any circumstances otherwise than in accordance with the express terms of
this Licence.

5.6 Nothing in this Licence shall limit or exclude our liability for:
(a) death or personal injury resulting from our negligence;
(b) fraud or fraudulent misrepresentation;
(c) any other liability that cannot be excluded or limited by English law.

5.7 This Licence sets out the full extent of our obligations and liabilities in respect of the supply
of the Software and Documentation. Except as expressly stated in this Licence, there are no
conditions, warranties, representations or other terms, express or implied, that are binding on us.
Any condition, warranty, representation or other term concerning the supply of the Software and
Documentation which might otherwise be implied into, or incorporated in, this Licence whether by
statute, common law or otherwise, is excluded to the fullest extent permitted by law.

5.8 All references to "we" or "us" in this condition 5 shall, for the purposes of this condition 5
and condition 9.6 only, be treated as including all employees, subcontractors and suppliers of us, all
of whom shall have the benefit of the exclusions and limitations of liability set out in this condition 5,
in accordance with condition 9.6.

6. TERMINATION

6.1 Without prejudice to our other rights and remedies, we may terminate this Licence
immediately by written notice to you if you commit a material or persistent breach of this Licence
which you fail to remedy (if remediable) within 14 days after the service of written notice requiring you
to do so.

6.2 Upon termination for any reason:
(a) all rights granted to you under this Licence shall cease;
(b) you must cease all activities authorised by this Licence; and
(c) you must immediately delete or remove the Software from all computer equipment in your
possession and immediately destroy or return to us (at our option) all copies of the Software then in
your possession, custody or control and, in the case of destruction, certify to us that you have done
so.

6.3 Any provision in this Licence which expressly or by implication is intended to come into or
continue in force on or after termination of this Licence shall remain in full force and effect.

7. NOTICES
7.1 Any notice required to be given under this Licence shall be in writing. If you are sending
notice, it shall be delivered personally, or sent by pre-paid first-class post or recorded delivered or by
commercial courier or by email to martinreeves@elektron-technology.com. If we are giving notice,
we may do so by posting it on our website at www.elektron-technology.com or, if we have your
contact details, we may either post it (in a manner set out above) or we may email you. If you are
posting notice to us, please send it for the attention of the Company Secretary, Elektron Technology
PLC at Broers Building, 21 JJ Thomson Avenue, Cambridge CB3 0FA.

7.2 Any notice shall be deemed to have been duly received:
(a) if delivered personally, when left at the address and for the contact referred to in condition
7.1, or for the contact at the address referred to by you in any communication you send to us;
(b) if sent by pre-paid first-class post or recorded delivery, at 9,00am on the third working day
after posting (if posted from within the UK) or on the seventh working day after posting (if posted
from outside of the UK);
(c) if delivered by commercial courier, on the date and at the time that the courier's delivery
receipt is signed;
(d) if posted on our website, 12 hours after it is uploaded; or
(e) if sent by email, 24 hours after it is sent.

8. EVENTS OUTSIDE OUR CONTROL
8.1 We will not be liable or responsible for any failure to perform, or delay in performance of,
any of our obligations under this Licence that is caused by an Event Outside Our Control. An Event
Outside Our Control is defined below in condition 8.2.

8.2 An Event Outside Our Control means any act or event beyond our reasonable control,
including without limitation failure of public or private telecommunications networks or electricity
supply.

8.3 If an Event Outside Our Control takes place that affects the performance of our obligations
under this Licence:
(a) our obligations under this Licence will be suspended and the time for performance of our
obligations will be extended for the duration of the Event Outside Our Control; and
(b) we will use our reasonable endeavours to find a solution by which our obligations under this
Licence may be performed despite the Event Outside Our Control.

9. OTHER IMPORTANT TERMS
9.1 We may transfer our rights and obligations under this Licence to another organisation, but
this will not affect your rights or our obligations under this Licence.
9.2 You may only transfer your rights or your obligations under this Licence to another person if
we agree in writing.
9.3 We may require you to, and you agree to, permit us (and/or our contractors and agents) to
inspect and have access to any premises (and to the computer equipment located there) at or on
which the Software is being kept or used, and have access to any records kept in connection with
this Licence, for the purposes of ensuring that you are complying with the terms of this Licence,
provided that we provide reasonable advance notice to you of such inspections, which must take
place at reasonable times.
9.4 This Licence and any document expressly referred to in it constitute the entire agreement
between you and us and supersede all prior agreements, arrangements and understandings between
you and us. You acknowledge that you have not relied on any statement, promise or representation
made or given by or on behalf of the us which is not set out in this Licence or any document
expressly referred to in it.

9.5 If we fail to insist that you perform any of your obligations under this Licence, or if we do not enforce our rights against you, or if we delay in doing so, that will not mean that we have waived our rights against you and will not mean that you do not have to comply with those obligations. If we do waive a default by you, we will only do so in writing, and that will not mean that we will automatically waive any later default by you.

9.6 It is agreed that it is intended to confer a benefit on us and the third parties referred to in conditions 5.8 and 9.3 by making the exclusions and limitation of liability available to them in accordance with this Licence, provided that the rights of such third parties under this licence shall only be enforceable by us on their behalf. We owe no duty to them to enforce such rights and we may conduct or compromise any relevant proceedings as we see fit.

9.7 Except as provided in condition 9.6, a person who is not a party to this Licence shall not have any rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Licence, but this does not affect any right or remedy of a third party which exists, or is available, apart from that Act.

9.8 Each of the conditions of this Licence operates separately. If any court or competent authority decides that any of them are unlawful, invalid or unenforceable, the remaining conditions will remain in full force and effect. If any invalid, unenforceable or illegal provision of this Licence would be valid, enforceable and legal if some part of it were deleted, the provision shall apply with the minimum medication necessary to make it legal, valid and enforceable.

9.9 No variation of this Licence shall be effective unless it is in writing and signed by us.

9.10 This Licence, its subject matter and its formation (and any non-contractual disputes or claims) are governed by and construed in accordance with English law. We both agree to the exclusive jurisdiction of the courts of England and Wales.

THIRD PARTY LICENSE INFORMATION

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Developed using D2XX Drivers from Future Technology Devices International Limited. (http://www.ftdichip.com/Firmware/vnc2toolchain/License.txt)

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Version 2.1, February 1999

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[This is the first released version of the Lesser GPL. It also counts as the successor of the GNU Library Public License, version 2, hence the version number 2.1.]

Preamble

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When we speak of free software, we are referring to freedom of use, not price. Our General Public Licenses are designed to make sure that you have the freedom to distribute copies of free software (and charge for this service if you wish); that you receive source code or can get it if you want it; that you can change the software and use pieces of it in new free programs; and that you are informed that you can do these things.

To protect your rights, we need to make restrictions that forbid distributors to deny you these rights or to ask you to surrender these rights. These restrictions translate to certain responsibilities for you if you distribute copies of the library or if you modify it.

For example, if you distribute copies of the library, whether gratis or for a fee, you must give the recipients all the rights that we gave you. You must make sure that they, too, receive or can get the source code. If you link other code with the library, you must provide complete object files to the recipients, so that they can relink them with the library after making changes to the library and recompiling it. And you must show them these terms so they know their rights.

We protect your rights with a two-step method: (1) we copyright the library, and (2) we offer you this license, which gives you legal permission to copy, distribute and/or modify the library.

To protect each distributor, we want to make it very clear that there is no warranty for the free library. Also, if the library is modified by someone else and passed on, the recipients should know that what they have is not the original version, so that the original author's reputation will not be affected by problems that might be introduced by others.

Finally, software patents pose a constant threat to the existence of any free program. We wish to make sure that a company cannot effectively restrict the users of a free program by obtaining a restrictive license from a patent holder. Therefore, we insist that any patent license obtained for a version of the library must be consistent with the full freedom of use specified in this license.

Most GNU software, including some libraries, is covered by the ordinary GNU General Public License. This license, the GNU Lesser General Public License, applies to certain designated libraries, and is quite different from the ordinary General Public License. We use this license for certain libraries in order to permit linking those libraries into non-free programs.
When a program is linked with a library, whether statically or using a shared library, the
combination of the two is legally speaking a combined work, a derivative of the original library. The
ordinary General Public License therefore permits such linking only if the entire combination fits its
criteria of freedom. The Lesser General Public License permits more lax criteria for linking other
code with the library.

We call this license the "Lesser" General Public License because it does Less to protect the
user's freedom than the ordinary General Public License. It also provides other free software
developers Less of an advantage over competing non-free programs. These disadvantages are the
reason we use the ordinary General Public License for many libraries. However, the Lesser license
provides advantages in certain special circumstances.

For example, on rare occasions, there may be a special need to encourage the widest possible
use of a certain library, so that it becomes a de-facto standard. To achieve this, non-free programs
must be allowed to use the library. A more frequent case is that a free library does the same job as
widely used non-free libraries. In this case, there is little to gain by limiting the free library to free
software only, so we use the Lesser General Public License.

In other cases, permission to use a particular library in non-free programs enables a greater
number of people to use a large body of free software. For example, permission to use the GNU C
Library in non-free programs enables many more people to use the whole GNU operating system, as
well as its variant, the GNU/Linux operating system.

Although the Lesser General Public License is Less protective of the users’ freedom, it does
ensure that the user of a program that is linked with the Library has the freedom and the wherewithal
to run that program using a modified version of the Library.

The precise terms and conditions for copying, distribution and modification follow. Pay close
attention to the difference between a "work based on the library" and a "work that uses the library". The
former contains code derived from the library, whereas the latter must be combined with the
library in order to run.

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TERMS AND CONDITIONS FOR COPYING, DISTRIBUTION AND MODIFICATION

0. This License Agreement applies to any software library or other program which contains a notice
placed by the copyright holder or other authorized party saying it may be distributed under the terms
of this Lesser General Public License (also called "this License"). Each licensee is addressed as
"you".

A "library" means a collection of software functions and/or data prepared so as to be conveniently
linked with application programs (which use some of those functions and data) to form executables.

The "Library", below, refers to any such software library or work which has been distributed under
these terms. A "work based on the Library" means either the Library or any derivative work under
copyright law: that is to say, a work containing the Library or a portion of it, either verbatim or with
modifications and/or translated straightforwardly into another language. (Hereinafter, translation is
included without limitation in the term "modification").

"Source code" for a work means the preferred form of the work for making modifications to it. For
a library, complete source code means all the source code for all modules it contains, plus any
associated interface definition files, plus the scripts used to control compilation and installation of
the library.

Activities other than copying, distribution and modification are not covered by this License; they
are outside its scope. The act of running a program using the Library is not restricted, and output
from such a program is covered only if its contents constitute a work based on the Library
(independent of the use of the Library in a tool for writing it). Whether that is true depends on what
the Library does
and what the program that uses the Library does.

1. You may copy and distribute verbatim copies of the Library's complete source code as you
receive it, in any medium, provided that you conspicuously and appropriately publish on each copy
an appropriate copyright notice and disclaimer of warranty; keep intact all the notices that refer to
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Library.

You may charge a fee for the physical act of transferring a copy, and you may at your option offer
warranty protection in exchange for a fee.

2. You may modify your copy or copies of the Library or any portion of it, thus forming a work
based on the Library, and copy and distribute such modifications or work under the terms of Section
1 above, provided that you also meet all of these conditions:

   a) The modified work must itself be a software library.

   b) You must cause the files modified to carry prominent notices stating that you changed the
files and the date of any change.

   c) You must cause the whole of the work to be licensed at no charge to all third parties under the
   terms of this License.

   d) If a facility in the modified Library refers to a function or a table of data to be supplied by an
   application program that uses the facility, other than as an argument passed when the facility is
   invoked, then you must make a good faith effort to ensure that, in the event an application does not
   supply such function or table, the facility still operates, and performs whatever part of its purpose
   remains meaningful.

(For example, a function in a library to compute square roots has a purpose that is entirely well-
defined independent of the application. Therefore, Subsection 2d requires that any application-
supplied function or table used by this function must be optional: if the application does not supply
it, the square root function must still compute square roots.)

These requirements apply to the modified work as a whole. If identifiable sections of that work are
not derived from the Library, and can be reasonably considered independent and separate works in
themselves, then this License, and its terms, do not apply to those sections when you distribute
them as separate works. But when you distribute the same sections as part of a whole which is a
work based on the Library, the distribution of the whole must be on the terms of this License, whose
permissions for other licensees extend to the entire whole, and thus to each and every part
regardless of who wrote it.

Thus, it is not the intent of this section to claim rights or contest your rights to work written entirely
by you; rather, the intent is to exercise the right to control the distribution of derivative or collective
works based on the Library.

In addition, mere aggregation of another work not based on the Library with the Library (or with a
work based on the Library) on a volume of a storage or distribution medium does not bring the other
work under the scope of this License.

3. You may opt to apply the terms of the ordinary GNU General Public License instead of this
License to a given copy of the Library. To do this, you must alter all the notices that refer to this
License, so that they refer to the ordinary GNU General Public License, version 2, instead of to this
License. (If a newer version than version 2 of the ordinary GNU General Public License has
appeared, then you can specify that version instead if you wish.) Do not make any other change in these notices.

Once this change is made in a given copy, it is irreversible for that copy, so the ordinary GNU General Public License applies to all subsequent copies and derivative works made from that copy.

This option is useful when you wish to copy part of the code of the Library into a program that is not a library.

4. You may copy and distribute the Library (or a portion or derivative of it, under Section 2) in object code or executable form under the terms of Sections 1 and 2 above provided that you accompany it with the complete corresponding machine-readable source code, which must be distributed under the terms of Sections 1 and 2 above on a medium customarily used for software interchange.

If distribution of object code is made by offering access to copy from a designated place, then offering equivalent access to copy the source code from the same place satisfies the requirement to distribute the source code, even though third parties are not compelled to copy the source along with the object code.

5. A program that contains no derivative of any portion of the Library, but is designed to work with the Library by being compiled or linked with it, is called a "work that uses the Library". Such a work, in isolation, is not a derivative work of the Library, and therefore falls outside the scope of this License.

However, linking a "work that uses the Library" with the Library creates an executable that is a derivative of the Library (because it contains portions of the Library), rather than a "work that uses the library". The executable is therefore covered by this License. Section 6 states terms for distribution of such executables.

When a "work that uses the Library" uses material from a header file that is part of the Library, the object code for the work may be a derivative work of the Library even though the source code is not. Whether this is true is especially significant if the work can be linked without the Library, or if the work is itself a library. The threshold for this to be true is not precisely defined by law.

If such an object file uses only numerical parameters, data structure layouts and accessors, and small macros and small inline functions (ten lines or less in length), then the use of the object file is unrestricted, regardless of whether it is legally a derivative work. (Executables containing this object code plus portions of the Library will still fall under Section 6.)

Otherwise, if the work is a derivative of the Library, you may distribute the object code for the work under the terms of Section 6. Any executables containing that work also fall under Section 6, whether or not they are linked directly with the Library itself.

6. As an exception to the Sections above, you may also combine or link a "work that uses the Library" with the Library to produce a work containing portions of the Library, and distribute that work under terms of your choice, provided that the terms permit modification of the work for the customer's own use and reverse engineering for debugging such modifications.

You must give prominent notice with each copy of the work that the Library is used in it and that the Library and its use are covered by this License. You must supply a copy of this License. If the work during execution displays copyright notices, you must include the copyright notice for the Library among them, as well as a reference directing the user to the copy of this License. Also, you must do one of these things:

a) Accompany the work with the complete corresponding machine-readable source code for the Library including whatever changes were used in the work (which must be distributed under Sections
1 and 2 above); and, if the work is an executable linked with the Library, with the complete machine-
readable "work that uses the Library", as object code and/or source code, so that the user can
modify the Library and then relink to produce a modified executable containing the modified Library.
(It is understood that the user who changes the contents of definitions files in the Library will not
necessarily be able to recompile the application to use the modified definitions.)

b) Use a suitable shared library mechanism for linking with the Library. A suitable mechanism is
one that (1) uses at run time a copy of the library already present on the user's computer system,
rather than copying library functions into the executable, and (2) will operate properly with a modified
version of the library, if the user installs one, as long as the modified version is interface-
compatible with the version that the work was made with.

c) Accompany the work with a written offer, valid for at least three years, to give the same user
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