



User Manual



Visiolite®

*Essential
Modulus
Master and Master-GT*



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1.Introduction

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1.1. List of supplied elements

The following elements should be found inside the packaging:

- Visiolite®
- External medical power plug IEC60601 (reference: GTM41060-2512 GLOBTEK manufacturing, UL certification: E175861)
- USB lead (for computerised versions only)
- Visiolite® software installation CD with user manual included (for computerised versions only)
- Driver remote control (for remote control versions only)
- Cloth for cleaning lenses
- Forehead rest
- Response forms CD (for remote control versions only)
- Information sheet

1.2. Presentation

We recommend reading these instructions thoroughly before use.

This user manual is intended for Visiolite® operators, whatever the chosen model (Essential, Modulus, Master or Master-GT).

Only a practitioner can direct a patient to an ophthalmologist in order to confirm the Visiolite® results obtained. The ophthalmologist will perform further tests to prescribe visual correction or surgical intervention.

The Visiolite® is a screening device designed by FIM for the exploration of visual function. The Visiolite® currently operates with two driving modes, depending on the model (refer § 1.4):

- Remote control version
- Computerised version

Designed for maximum ergonomics, the Visiolite® is equipped with a detector that detects the position of the patient's forehead. Once the patient is correctly positioned, the test begins.

The Visiolite® is designed to progressively adapt the patient to different light levels depending on the type of test performed. Tests can be performed on three light levels:

- High photopic
- Low photopic
- Mesopic

Depending on the version, the practitioner can parameter sequences in order to define which tests are to be performed systematically, depending on needs. The Visiolite® is equipped with several optical effects and mirrors to perform near (33cm/13inches), intermediate (60cm/23.6inches) and far (5m/16.4ft) vision tests. Tests can also be performed in monocular or binocular vision. For computerised versions, results are recorded directly onto the computer. For remote control versions, results are recorded on response forms.

Innovative solutions have considerably reduced the weight of the device and expanded the range of available tests requiring no operator manipulation of the device. The device also integrates the latest high technology: a

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lighting principle that preserves slide quality over time.

The Visiolite® offers the following assets:

- Compact size
- Light-weight equipment
- Portability
- Ergonomic use
- Quick testing
- Programming and automation to create test sequences according to patient risk
- Elimination of yellowing of slides
- Optimisation of computer connectivity
- Option of performing several visual acuity tests to avoid voluntary or involuntary memorising of optotypes
- Device set-up for vehicle-driver tests
- Performing visual tests with corrective or progressive lenses
- Performing tests in low photopic light for photo-sensitive patients
- Parametering test sequences to customise tests
- Performing far, near and intermediate vision tests

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1.3. Technical features

Technical features	
Storage temperature	0 - 50°C (32 - 122°F)
Operating temperature	15 - 35°C (59 - 95°F)
Humidity	75% maximum
Altitude of operation	< 2000m (6561.7ft)
External power plug	Input: 100-240VAC 50-60Hz 0.6A Output: 12VDC 2.08A (medical class)
Power supply	12VDC from an external power medical supply (refer § 1.1)
Power absorbed	24W
Standard	EN 60601-1, EN 60601-1-2
Medical class	Class I
Applied part	Type B
Marking	CE
Dimensions	50x27x25 cm (19.7x10.6x9.8 inches)
Weight	4.850 kg (10.7lb)

Optical features	
Lighting system	16 white LEDs and diffuser system
Lenses	Far vision: (5.0 ± 0.1)m (16.4 ± 0.3)ft Intermediate vision: (60.0 ± 0.5)cm (23.6 ± 0.2)inches Near vision: (33.00 ± 0.25)cm (13.0 ± 0.1)inches Hyperopia lenses: +1 dioptré
Lighting conditions (nominal values)	High photopic (160 candelas) Low photopic (80 candelas) Dusk mesopic (3 candelas) Conform to NF EN ISO 8596 standard

Test features	
Reactivity	Time between 2 neighbouring tests: 700ms Time to pass from one slide to another: 1 sec
Average test time	Routine test: 3 mins In-depth test: 5 mins

1.4. Visiolite® range models

ACUITY TESTS	ESSENTIAL	MODULUS	MASTER
Landolt rings	•	•	•
Numbers		•	•
Letters	•	•	•
Low vision letters		•	•
SUPPLEMENTARY TESTS			
Astigmatism	•	•	•
Red/green duochrome	•	•	•
Depth perception		•	•
Vertical and horizontal phorias	•	•	•
Fusion			•
Ishihara type colours test	•	•	•
Amsler grid		•	•
Contrast sensitivity			•
Hyperopia test (+1 dioptré)	•	•	•
Horizontal et vertical visual field	•	•	•
Glare sensitivity			• (GT option)
Glare resistance (educational test)			• (GT option)
DISTANCES			
Far vision 5m/16.4ft	•	•	•
Intermediate vision 60cm/23.6inches	•		•
Near vision 33cm/13.0inches	•	•	•
LIGHTING			
High photopic	•	•	•
Low photopic		•	•
Mesopic (night vision)	•		•
DRIVER MODE			
Computer		•	•
Remote control	•		•

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1.5. Serial number labels

Serial number labels display the following information:



CE marking Directive 93/42/EEC



Type B applied part



The device should not be discarded with general household waste. Return it to the manufacturer for disposal



Consult the accompanying documents

SN

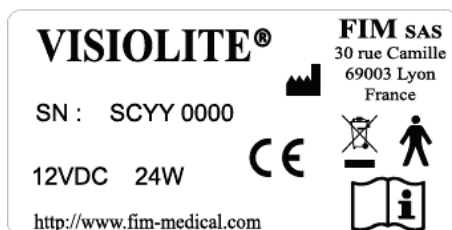
Serial number



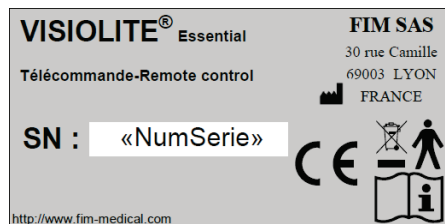
Manufacturer identification

1.6. Labelling

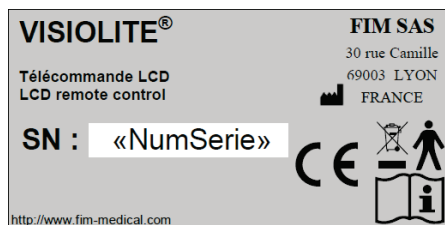
1.6.1. Visiolite® label



1.6.2. Essential remote control label



1.6.3. LCD remote control label



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1.6.4. Supplied external power plug label



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2.Safety

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2.1. General

CAUTION:

- Never dismantle or interfere with the device without the authorisation of the manufacturer. Only FIM After Sales Service and trained distributors are qualified to work on the equipment
- The Visiolite® should be returned regularly for annual maintenance to FIM After Sales or your distributor
- Use only the leads and power plugs supplied by FIM
- It is highly recommended to store and transport the Visiolite® at a temperature of 0 - 40°C (32 - 104°F). If a change in atmospheric conditions occurs, wait a while until there is no condensation on the optics before using the device
- Do not expose the device to vibrations or excessive shocks
- Do not wet the device. Protect it from all liquid projections. Never wash the Visiolite® under running water or spray directly with liquids
- If accidentally damaged (fall or shock), send the device to FIM After Sales Service, or to your distributor, if trained by FIM for maintenance
- If the device no longer maintains a stable position, or has degraded, return it to FIM After Sales Service, or to your distributor, if trained by FIM for maintenance
- If any elements of the device degrade, the device should be returned for checking, to FIM After Sales Service, or to your distributor, if trained by FIM for maintenance
- Repetitive visual defects appearing in every patient should signal a possible problem with the device
- The device should not be used in the presence of anaesthetic gases
- The Visiolite® remote controls should only be used with the device, and vice-versa
- If the device or its accessories degrade visibly, contact FIM After Sales Service or your distributor
- The device should sit on a flat and stable surface
- If a multi-adaptor is used, no other electrical device or multi-adaptor should be connected to the device
- The device should be positioned so as to leave the power plug free, in case of emergency

2.2. Operator

The Visiolite® is reserved for the use of health professionals.

For computerised versions, the operator must be trained in the basic rules of computers and shall take all precautions against the risk of software pirating, disclosure of confidential data, viral attacks or incorrect handling.

Particular care shall be taken to back up recorded data as often as possible, on a reliable support. FIM recommends daily back up.

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As a reminder to operators, the Visiolite® software is delivered with a licence contract stating the software conditions of use. This licence is granted for the installation and use at one work station. All new installations require the purchase of extra licences.

2.3. Medical contraindications

Patients suffering from the following medical contraindications are not permitted to perform vision tests:

- General contraindications: photosensitive persons should not perform screening tests in high photopic
- Contraindications related to glare: all photosensitising medication

All persons performing the glare test must be informed of the risks related to certain photosensitising medication. Ensure the patient does not suffer from the following pathologies (non-exhaustive list):

- albinism
- cystinosis
- keratoconjunctivitis
- surgery
- inflammation
- traumatism

Ensure the patient has not undergone refractive surgery less than three months previously.

Example of list (non-exhaustive) of photosensitising medications in France (see next page).

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Non-steroidal anti-inflammatories	Antibiotics	Cardiology - Angiology	Neurology - Psychiatry
Acide tiaprofénique Artotec (Diclofenac) Brexin Butazolidine Cycladol Diclofenac Feldene Ketoprofene Ketum (ketoprofene) Indocid (Indométhacine) Indocollyre (Indométhacine) Inflaced Mobic Nabucox Naprosyne (Naproxène) Nifluril Gélule Piroxicam (ketoprofene) Profenid (ketoprofene) Proxalyoc (Piroxicam) Surgam Topfena (ketoprofene) Voldal Voltarene (Diclofenac) XenidGén (Diclofenac) Zofora	Cyclines Doxy (Doxycycline) Doxycycline Granudoxy (Doxycycline) Lysocline Mestacine (Minocycline) Minocycline Minolis (Minocycline) Mynocine SpanorGén (Doxycycline) Tetralysal Tolexine (Doxycycline) Vibramycine (Doxycycline) Macrolides Disulone Pediazole Zithromax Quinolones Ciflox Decalogiflox Enoxor Logiflox Monoflocet (Ofloxacin) Negram Forte Noroxine Pipram fort Uniflox Sulphamides Adiazine	Antiarrhythmic Amiodarone Bi-tildiem (Diltiazem) Corbionax (genAmiodarone) Cordarone (Amiodarone) Deltazen (Diltiazem) Diacor (Diltiazem) Dilrene (Diltiazem) Diltiazem Monotildiem (Diltiazem) Serecor Tildiem (Diltiazem) Antihypertensives Co-renitec Furosemide Korec (Quinaprilchlorhyd.) Koretic (Quinaprilchlorhyd.) Lasilix (Furosemide) Logimax Logroton Moducron Moduretic Moex Piportyl Prestole Prinzide Renitec	Neuroleptics Largactil Modecate Moditen Neuleptil Nozinan Tercian Trilifan Zyprexa Antidepressants Floxyfral (Flutamide) Hypnotics Noctran Theralene Sedatives Mépronizine (Méprobamate) Tegretol
Allergology (anti-histamines)	Metabolism and Nutrition	Infectiology, Parasitology	Cancerology and Haematology
Algotropyl (Promethazine) Istamyl Fluisedal (Promethazine) Phenergan (Promethazine) Primalan RhinathiolPromethazine Theralene Toplexil Apaisyl	Oral Antidiabetics Amarel Daonil Hémidaonil Minidiab Hypolipidemics Lipanor Lodaless Zocor	Antituberculosis drugs Adiazine (Sulfamide) Rifater (Rifampicine) Antimalarials Quinimax (Pipotiazine) Quinine Savarine Antileprosy drugs Lamprene (Clofazimine) Disulone Systemic antivirals Cymevan Zelitrex	Eulexine (Flutamide) Flutamide Prostadirex (Flutamide) Otorhinolaryngology Oflocet (Ofloxacin) Gynaecology Duphaston (Dydrogesterone) Gastroenterohepatology Dipentum Rheumatology Neuriplege Quinisedine

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2.4. Precautions before tests

The device operates on the basis of binocular fusion. The operator must ensure the patient has adequate fusion to perform the test. Before all tests, the operator should ask the patient if he or she generally wears glasses or contact lenses. Photosensitive patients may perform the tests in low photopic, for more comfort during the tests.

The patient should be placed in an environment adapted to tests. Ensure there is no intense lighting that may reflect on the Visiolite® optics, particularly for the glare test, where strong lateral light sources would disrupt the test. Do not place the device near a window. For the glare test, the user must inform the patient of the test procedure. During the test, always explain to the patient which optotypes he or she is in the process of studying (eg: number of lines, letters, etc.).

The medical personnel must ensure the patient is calm when performing the test and that he or she has understood the aim of the screening. The operator controls the Visiolite® back-lighting, which progressively increases in intensity to enable the patient to become accustomed to the light levels. The operator may drive the Visiolite® in low photopic for patient comfort. The operator should ensure the patient leaves the room safely after performing the glare test (no visual problems, headache or fatigue).

2.5. Interpretation of results

- Patient results should always be accompanied by an explanation from the practitioner
- The Visiolite® may not be used for medical treatment. It can under no circumstances be used as the basis for medication prescriptions, pre- or post-surgical diagnoses, or any other type of prescription
- The Visiolite® may not be used to determine the aptitude of an individual to perform a certain task. This can only be established by the doctor responsible for the tests, in conjunction with other medical expertise
- The Visiolite® is a screening device for visual problems. Only an ophthalmologist is qualified to confirm Visiolite® results, in conjunction with other tests, to prescribe correction or surgical intervention

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3. Equipment and Installation

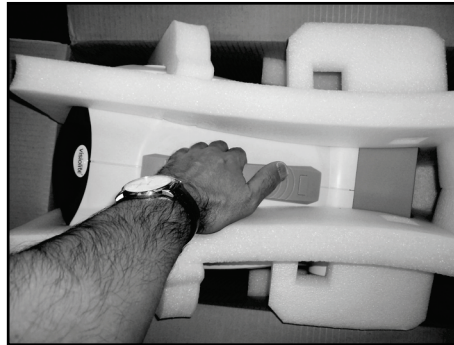
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3.1. Installation procedure

3.1.1. Opening the box

After removing the compartment containing the accessories, lift the Visiolite® by the handle as indicated below.

We strongly advise conserving all the original packaging of the Visiolite® for maintenance operations.



3.1.2. Nomenclature



1 Body

The Visiolite® body contains all the functional elements.

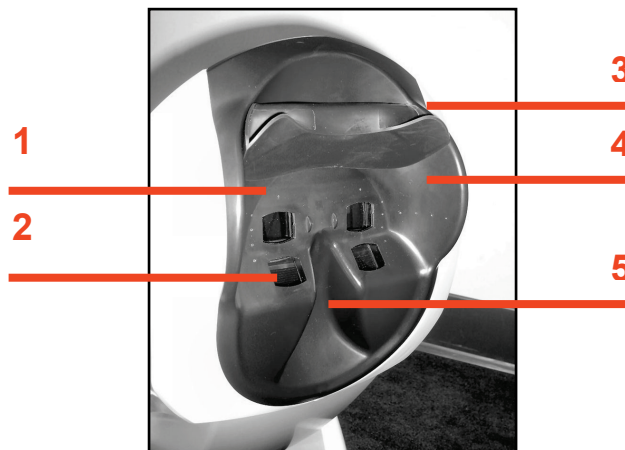
2 Mask

Far and near vision lenses are integrated into the mask, which is adapted to the average patient morphology.

3 Base

The Visiolite® base is ballasted to ensure stability of the instrument whatever the inclination of the body.

The elastomer gum coating prevents the Visiolite® slipping, and avoids scratching the table surface.



Face mask

1 Far vision lenses

2 Near vision lenses

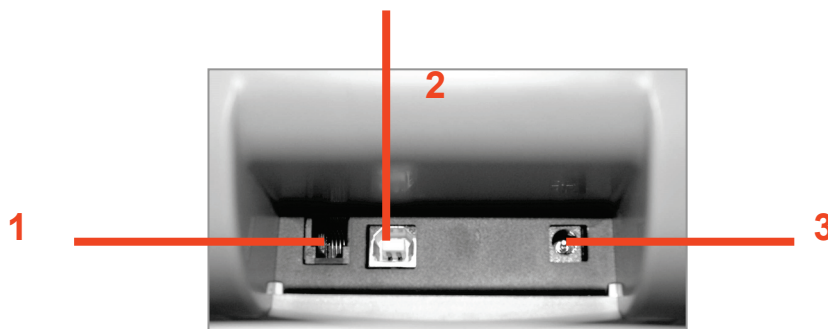
3 Removable forehead rest piece

A removable elastomer piece is positioned on the forehead rest. An electro-sensitive sensor indicates the patient's forehead is in contact with the forehead rest, via a Visiolite® light display. When the forehead is correctly positioned on the forehead rest, the patient should not feel any discomfort.

4 Peripheral field

A number of small holes are visible around the lenses. These light guides are for the visual peripheral field test.

5 Nose position



Back – Connection support

1 RS232 connector lead or remote control

2 USB lead

3 Power supply

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3.1.3. Connection



- Incline the device to the connection position.
- Thread the leads via the back of the Visiolite® between the base and the body.
- Firstly connect the control leads (USB lead or remote control) then the mains adaptor lead.
- Reposition the Visiolite® to work mode, taking care not to jam the leads.
- Plug the mains adaptor into the wall socket.
- **Caution, for computerised versions:**
- Do not connect the Visiolite® to the computer before the software is installed (refer § 3.2).

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3.2. Operating systems

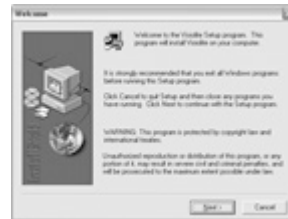
Windows XP, Windows Vista, Windows 7

3.3. Software Installation (computerised version)

For computerised versions, the operator must be in possession of the administration rights on the workstation to be installed. From the CD Rom root directory, run the "Setup.exe" file; not necessary if it is set-up for automatic running.



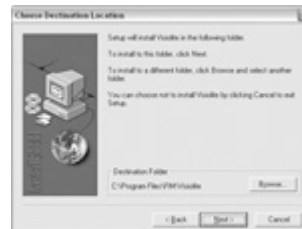
1. Temporary Welcome Screen



2. Recommendation Screen

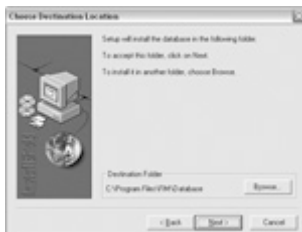


3. Enter company name and serial number



4. Enter software installation destination

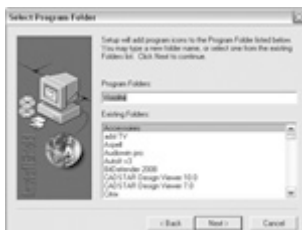
from the back of the CD jacket



5. Enter data base destination



6. Select Typical installation



7. Validate Next



8. Validate Finish



An icon is placed on the Windows desktop to run the software.

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3.3.1. PC connection

After installation, use the USB lead to connect the Visiolite® to the PC. If installation is correct, the device should immediately be recognised.

If not, disconnect the Visiolite® and manually run drivers installations found on the CD in **“Drivers”** directory. Double click on CP210xVCPInstaller.exe and follow the instructions.

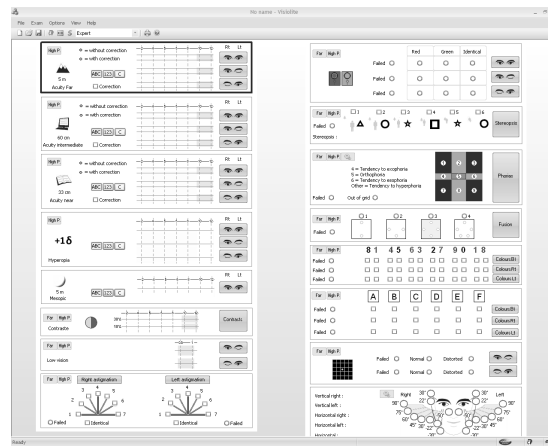
Then connect the Visiolite® which should be immediately recognised by the operating system.

3.3.2. Uninstallation

To uninstall Visiolite® go to the “Start” menu, “Control Panel”, “Add/Remove program”. Uninstall the Visiolite® software and the drivers “Silicon laboratories CP210x USB to UART bridge”.

3.3.3. First run

The following screen appears:



A light on the bottom right of the screen indicates whether the Visiolite® is correctly connected:

- Grey light: no connection
- Red light: searching
- Green light: connection established

If there is a connection problem, the light goes to grey again: check in Windows Device Manager that the device has, in fact, been recognised. This appears in the Ports section (COM and LPT) under the name CPS10x USB to UART Controller.



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3.3.1. Test before use

Check that the Visiolite® is driven by the software and the tests displayed are those desired.

Initially a small red or green symbol representing a head appears at the bottom right of the screen:

- Green if the patient's forehead is correctly positioned against the forehead rest
- Otherwise grey

Tests are exposed only if the forehead is detected by the sensor.

Click on any key and check that the Visiolite® motor starts and displays the correct test.

3.4. Procedure to stop the device

3.4.1. Software version

To stop the Visiolite® safely, close the software and disconnect by unplugging the power plug at the back of the device.

3.4.2. Essential remote control version

To stop the Visiolite® safely, wait a moment until the device goes on standby (remote-control LEDs off). Then unplug the leads.

3.4.3. LCD remote control version

To stop the Visiolite® safely, press on the "Distance" key for 3 secs. The device and the remote control will switch off. Then unplug the leads.

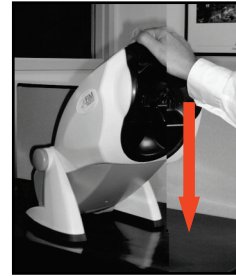
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4. Use

4.1. Raise/lower Visiolite® body



- Hold the base of the Visiolite® with one hand.
- With the other hand, raise the body of the device without forcing.



- Press gently on the upper part of the Visiolite®.

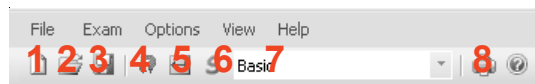
Comment: It is recommended to place the patient's hands on the test table and avoid placing the fingers into the inclination system.

4.2. Software use

4.2.1. Description of menus

4.2.1.1. Tool bar

Use the tool bar to run the other software functions.



1 New file

5 Positioning

2 Open

6 Run a sequence

3 Record

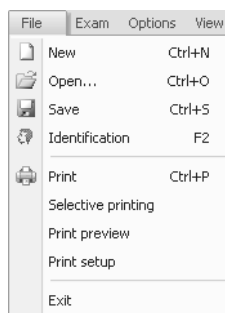
7 List of sequences

4 Identification

8 Print

4.2.1.2. Menu bar

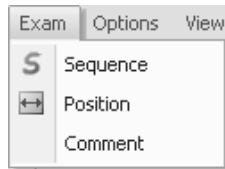
Use the drop-down menus to perform other actions not available from the main screen.



3 new actions:

- Selective printing
- Print preview
- Print set-up

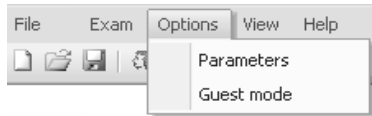
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1 new action:

- Add a comment

Comments can be input by the operator and printed and recorded with the test in the data base.



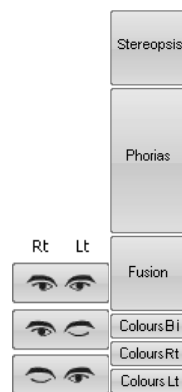
1 new action:

- Host mode

Use **guest mode** to parameter interfacing of the Visiolite® with external software, in order to exchange data.

4.2.2. Manual mode

The Visiolite® can be driven from the main screen. Use the command keys to choose a test and input patient response.









Command Keys

4.2.2.1. Choice of distance

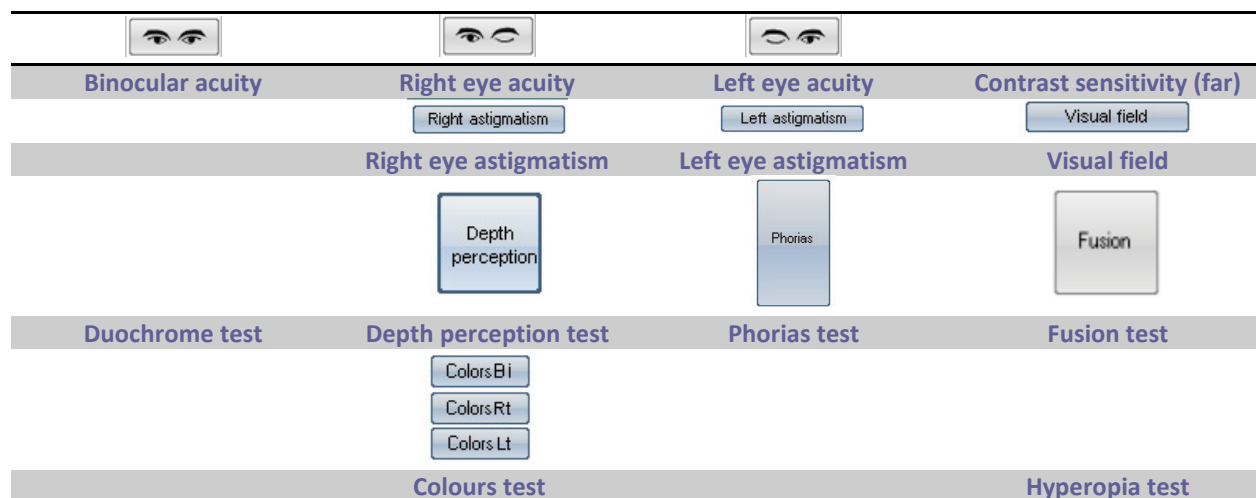
Far Vision

Intermediate Vision

Near Vision

High P.  5 m Acuity Far	◇ = without correction ◇ = with correction ABC 123 C <input type="checkbox"/> Correction	-2 -4 -5 -6 -8 -10 -12 Rt Lt 
High P.  60 cm Acuity intermediate	◇ = without correction ◇ = with correction ABC 123 C <input type="checkbox"/> Correction	-2 -4 -5 -6 -8 -10 -12 Rt Lt 
High P.  33 cm Acuity near	◇ = without correction ◇ = with correction ABC 123 C <input type="checkbox"/> Correction	-2 -4 -5 -6 -8 -10 -12 Rt Lt 

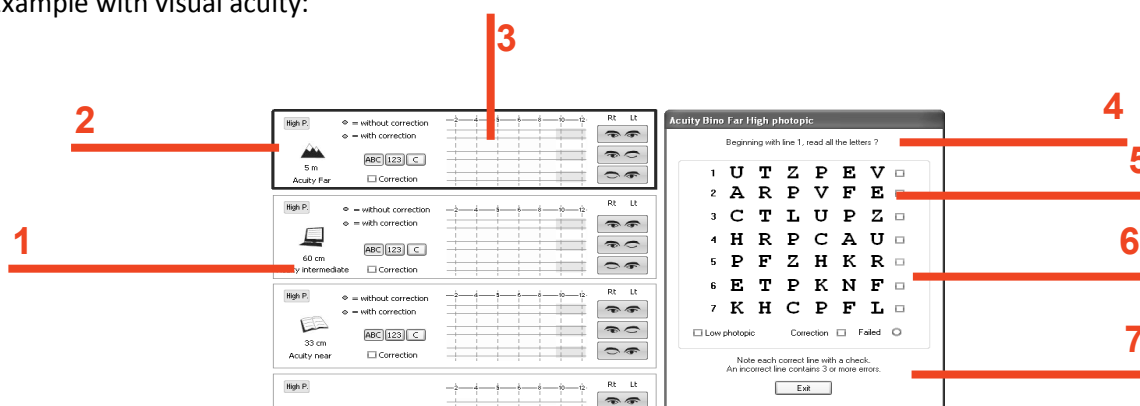
4.2.2.2. Command keys



4.2.2.3. Patient response

As soon as the command key is pressed, the device positions itself on the corresponding test and a window appears, to input patient responses.

Example with visual acuity:



1 Test choice

2 Lighting choice

- High Ph. – daylight
- Low Ph. – low daylight
- Mesopic Ph. – dusk light

3 Patient response

4 Patient instruction

5 Expected responses

6 Boxes to check

7 Operator instruction

In this example, the operator reads the instructions to the patient. The window gives the expected responses and the operator checks the boxes when the line of letters has been read.

4.2.2.4. Grey areas

Grey areas give an indication of the optimum response but cannot in any case determine normality or aptitude

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for a specific occupation or to perform a certain task.

These areas cannot be used for an individual's interest or for discrimination purposes.

Only the conclusions of the doctor responsible, in conjunction with other medical expertise, and depending on the task, can establish aptitude.

As this is a screening test, the results cannot in any case be used for medical treatment, pre-or post-surgical diagnosis, or for any sort of prescription.

4.2.2.5. Peripheral field

- Ask the patient to focus on the central dot.

Peripheral field stimuli can be scanned manually or semi-automatically.

In both cases, the operator must have the patient response before proceeding to the following stimulus.

4.2.2.5.1. Manual mode

- Click on the desired stimulus and wait for the patient response.
- If the patient responds correctly, click "Validate".

If the patient does not respond correctly, the stimulus flashes for the time pre-set in visual field parametering and goes to red.

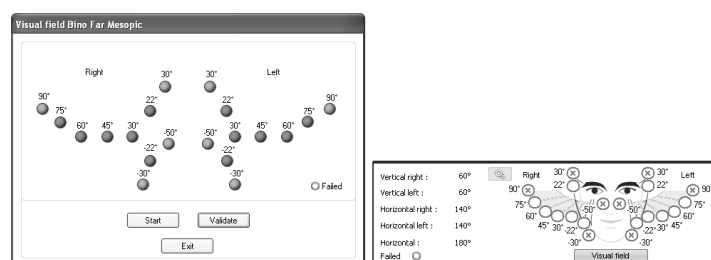
The angles tested will appear on the response form.

4.2.2.5.2. Semi-automatic mode

- Click "Start".

The program activates the stimuli from the outside to the inside of the field, until the limits can be defined.

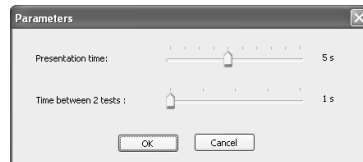
- When the patient responds correctly, click "Validate" or press on the space bar.



Presentation time of the luminous stimulation, as well as the time between two tests can be parametered as follows:

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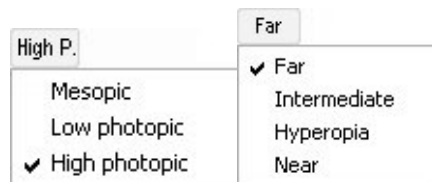
- Click the Parameters key



- Set the time

4.2.2.6. Settings

For all tests, lighting and optical mode can be adjusted by clicking on the following keys:



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4.2.3. Automatic mode

The Visiolite® software can pre-program tests.

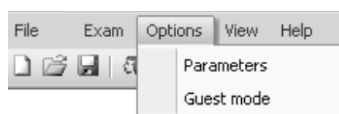
4.2.3.1. Use of sequences

To use a sequence, proceed as follows:

- Choose the desired sequence in the list of sequences in the tool bar.
- Click “S” on the tool bar or press the keyboard “Space” bar.
- Use the space bar to go from test to test.

4.2.4. Parametering

The software can be parametered as follows:

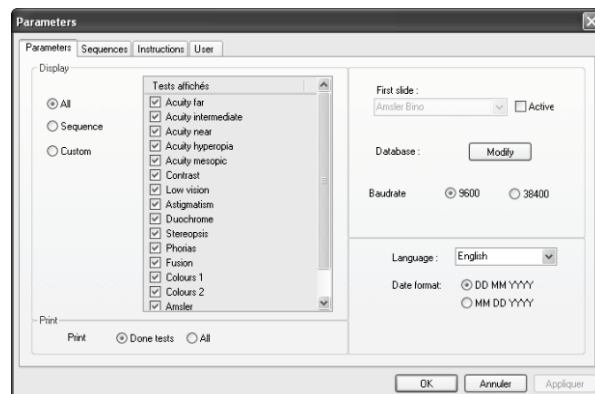


- Click “Options” menu.
- Click “Parameters”.

4.2.4.1. Display and print parameters

- Click “Parameters” tab.

The following window appears:

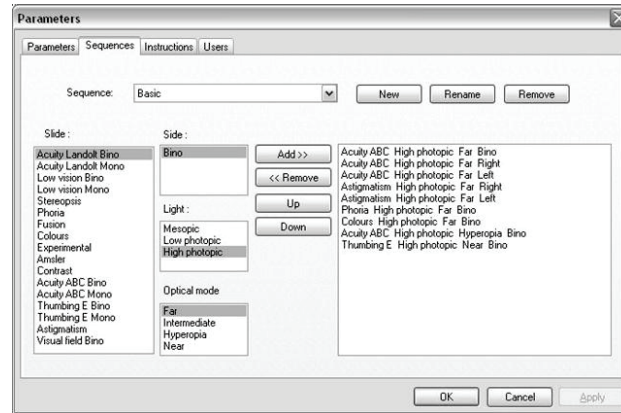


- Parameter display and print modes.
- Choose the first test to appear when the software is run.
- If necessary, change the data base path.

4.2.4.2. Parametering sequences

- Click “Sequences” tab.

The following screen appears:



Firstly, create a new sequence by clicking “New”.

The name of this list can be modified at any time by clicking “Rename”.

Unwanted sequences can also be deleted.

The left-hand column named “Slide” contains a list of tests the Visiolite® can perform.

Use the three centre lists to set all the parameters for each test.

Use “Add” or “Remove” to choose the tests you wish to program in each sequence.

“Up” or “Down” keys set the order of tests to be performed.

The right-hand column indicates the tests list and order of the created sequence.

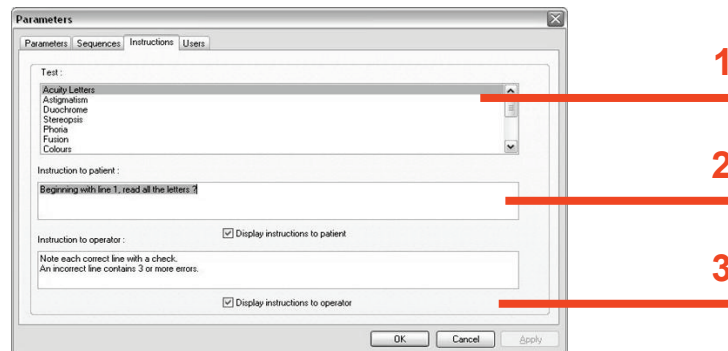
Once established, click “OK” so that the sequence appears in the scroll-down list, accessible from the tool bar.

4.2.4.3. Parametering instructions

Each test window has two instruction fields: one for the patient and one for the operator. These instructions can be modified.

- Click “Instructions” tab.

The following window appears:



1 Tests

2 Patient instruction

3 Operator instruction

- Select a test from the top window then set the operator and patient instructions.

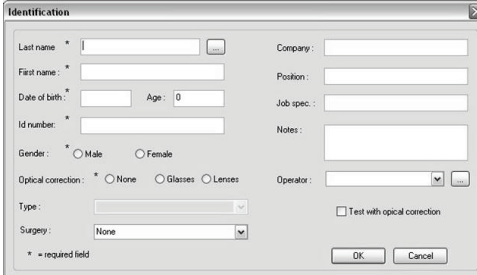
4.2.5. Data base

Patient data (first name, surname ...) as well as the tests are stored in a data base.

4.2.5.1. Patient identification

- Click "Identification" key.

The following window appears:



The image shows the 'Identification' dialog box with the following fields:

- Last name: * (compulsory)
- First name: *
- Date of birth: *
- Age: 0
- Id number: *
- Gender: * (Male, Female)
- Optical correction: * (None, Glasses, Lenses)
- Type: *
- Surgey: *
- Company: *
- Position: *
- Job spec: *
- Notes: *
- Operator: *
- Test with optical correction: *

Fields with a red asterisk are compulsory for recording.

4.2.5.2. Recording

Use "Record" to store the test in progress if all the compulsory identification fields have been filled in.

If the operator attempts to exit the software without recording a test, an alert appears.

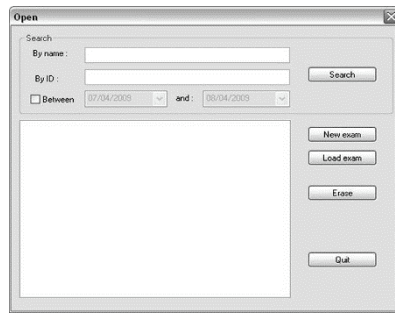
4.2.5.3. Recover a file

To locate patient data already recorded, proceed as follows:

- Click "Open".

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The following screen appears:



In the "Name" box, type the first letters of the patient's surname.

- Click "Search".

The list of names starting with these letters appears.

- Select the patient.
- Click "New exam".

The data is automatically entered into the identification screen.

Patient search can also be carried out by identification number or by recording date.

4.2.5.4. Recall a test

To view a previous test, or to print it, the operator can recall a file (refer § 4.2.5.3). Proceed as seen previously: a small + sign is displayed beside the patient surname, indicating the tests were performed. Click on the + sign.

A list of dates and times is displayed.

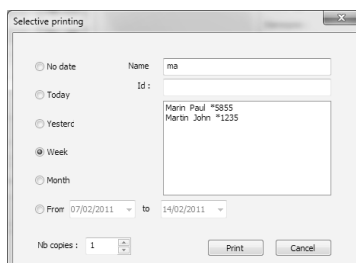
- Double click on one of the dates, or click "Load exam" to display the test performed.

4.2.5.5. Print

- Simply click "Print" to print out test results.

4.2.5.6. Selective printing

Use selective printing (File menu, Selective printing) to print tests according to the following criteria:



- No criteria
- Today
- Yesterday
- Week
- Month
- Manual selection
-

4.3.

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4.4. Essential remote control use

The Visiolite® Essential remote control is ergonomic and very user-friendly. Each key of the remote control corresponds to a test, and each key is associated with a light for the test displayed in the Visiolite®.



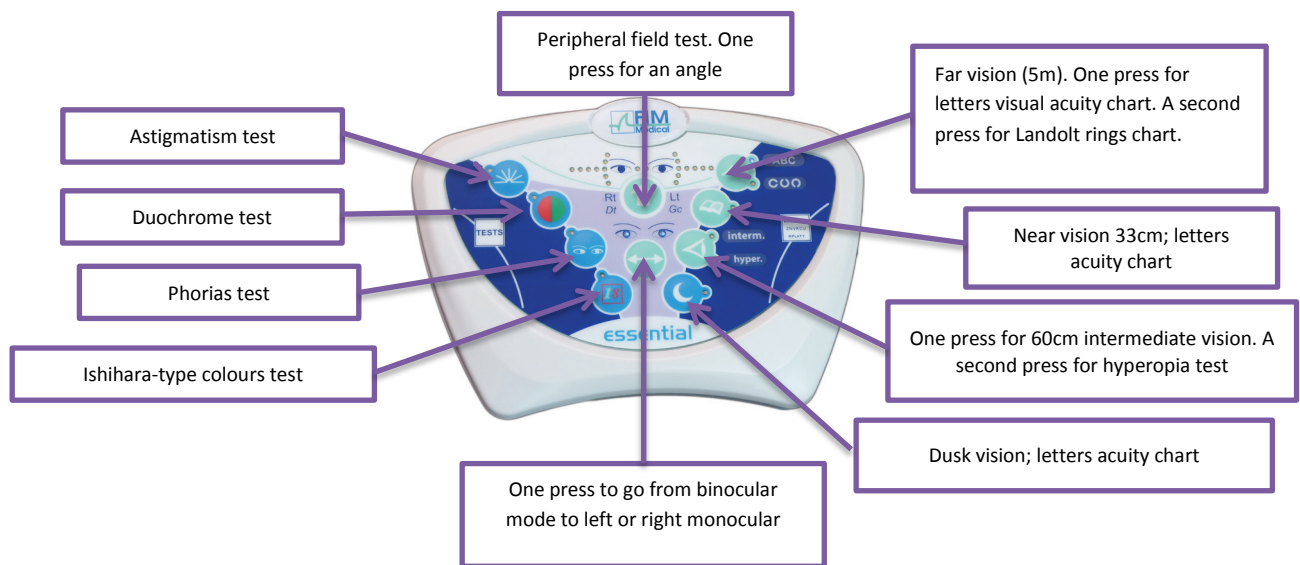
The remote control lead connector is an RJ11 type. Click the connector into the intended socket.

To unplug the lead, push down on the tongue and slowly pull out the lead. The Essential remote control should not be connected to the Visiolite® Essential.

Reminder: The Essential remote control should only be connected to the Visiolite® Essential.

As soon as the RJ11 lead and the mains are connected, the Visiolite® initialises in a few seconds, and automatically positions itself on the far vision (5m) visual acuity test in binocular mode. The Visiolite® is ready to use.

The right side of the remote control is for visual acuity tests. The left part is for extra tests.



4.4.1. Begin a test

To begin a test, simply click on the test you would like to perform.

Example: visual acuity test in near vision (33 cm).



One press on this key positions the Visiolite® on the near vision acuity chart. A light beside the key lights up to confirm your test choice.

4.4.2. Binocular and monocular mode

At any moment the test allows, you can switch from binocular mode to monocular mode by clicking on the following key:

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Binocular



Left monocular

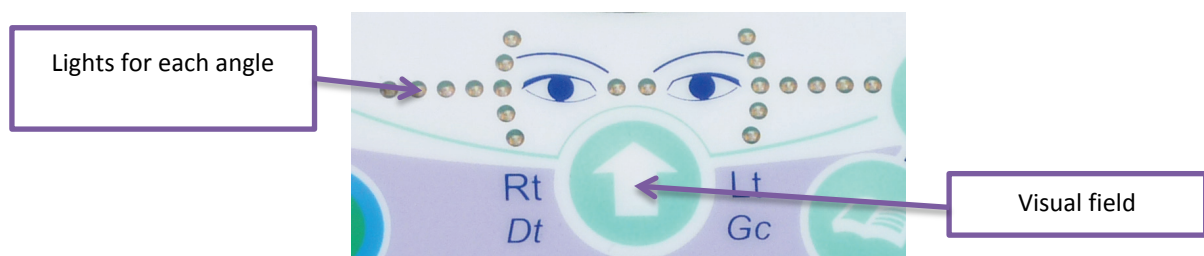


Right monocular

The lights above the keys indicate the mode selected.

4.4.3. Visual field

To begin a visual field test, press on the key indicated below. A first light representing an angle lights up. Then each press tests the next angles, which is represented by a light. As such, the horizontal and vertical fields are tested. The test begins by testing the extremities.



4.4.4. Standby

After several minutes without use, the Visiolite® remote control goes on standby mode. To reactivate, press any remote control key, or touch the Visiolite® forehead rest.

4.4.5. Essential remote control response forms

The form is required to note the results given by the patient. This is only supplied with the remote control, on the CD-ROM supplied with the Visiolite®, and can be printed as required.

If a copy is given to the patient or a third party, photocopy the original.

The form is composed of three parts:

- Patient identification
- Doctor conclusions and comments
- Tables or boxes to check according to patient response

The grey areas on the response form indicate the optimum response but cannot in any case determine normality or aptitude for a specific occupation or to perform a certain task. These areas cannot be used for an individual's interest or for discrimination purposes.






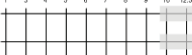


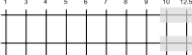



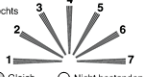
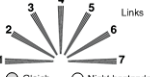
Only the conclusions of the doctor responsible, in conjunction with other medical expertise, can establish aptitude. As this is a screening test, the results cannot in any case be used for medical treatment, pre-or post-surgical diagnosis, or for any sort of prescription.

The response form gives the operator the expected response, and also to adapt the questions to ask the patient, depending on the type of test.




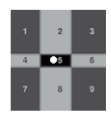
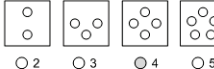



Visiolite® Antwortformular

ID Nummer :	Testdatum : / /	Zeist :	Untersucher :
Nachname :	Vorname :	Geburtsdatum : / /	Geschlecht : <input type="checkbox"/> Weiblich <input type="checkbox"/> Männlich
Firma :	Position :		Risiko :
Sehhilfe : <input type="checkbox"/> Nein <input type="checkbox"/> Brille <input type="checkbox"/> Linsen		Test mit sehhilfe : <input type="checkbox"/> Ja <input type="checkbox"/> Nein	
Typ brille : <input type="checkbox"/> Normal <input type="checkbox"/> Bifokal <input type="checkbox"/> Trifokal <input type="checkbox"/> Progressiv <input type="checkbox"/> Andere :		Augen-Op : <input type="checkbox"/> Ja <input type="checkbox"/> Nein Wenn ja, weiche ? :	

Kontrast-Sehtest Graue bereiche = erwarteten antworten
Markieren sie normale Ergebnisse mit einem ● und ergebnisse von tests unter abgedunkelter umgebung mit X.

Abstand	ABC	E Raskin	1 2 3	Landolt ringe	Test	Szhschärfe (/10)
 Ferne 5 m ● Visus 2.5 ● Visus 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	
 PC-Abstand 60 cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	
 Leseabstand 33 cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	
 Sehtest ohne brille	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	
Astigmatismus rechts  1 2 3 4 5 6 7 links  1 2 3 4 5 6 7					Blendempfindlichkeit : <input type="checkbox"/> Nicht bestanden Widerstand gegen die blendung : Recovery-zeit : <input type="checkbox"/> Nicht bestanden	

Zusammenfassung :

Fehrsichtigkeit  <input type="checkbox"/> Nicht bestanden	Tiefenwahrnehmung  <input type="checkbox"/> Nicht bestanden	Hyperopi (+1 dioptrin) R L Besser Schlechter 	Phorie 4 = Exophorie 5 = Orthophorie 6 = Esophorie Andere = Hyperphorie  <input type="checkbox"/> Nicht bestanden <input type="checkbox"/> Außerhalb des gitters
Fusion  <input type="checkbox"/> Nicht bestanden		Dyschromatopsie (rot grün schwäche) <input type="checkbox"/> Nicht bestanden 	
Amsler R L Normales gitter Verzerres gitter  <input type="checkbox"/> Nicht bestanden		Peripherie  <input type="checkbox"/> Nicht bestanden	

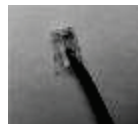
FIM MEDICAL 30 rue Camille - 69003 LYON - France
Phone : +33 4 72 34 88 88 - Fax : +33 4 72 34 43 51 - Email : contact@fim-medical.com
www.fim-medical.com
Copyright FIM MEDICAL

4.5. Master model LCD screen remote control use

The Visiolite® LCD remote control has a micro-controller to choose from 7 operating modes.

The remote control lead connector is an RJ11 type; insert it into the intended socket. To unplug the lead, push down on the tongue and slowly pull out the lead.

Reminder: the remote control should only be connected to the Visiolite®.



As soon as the RJ11 plug and the mains are connected, the remote control LCD screen lights up and displays a mode of use for the Visiolite®. The Visiolite® is ready for operation after a few seconds of initialisation.

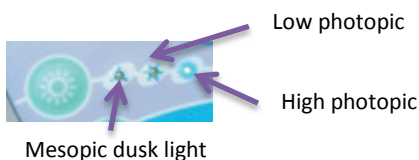
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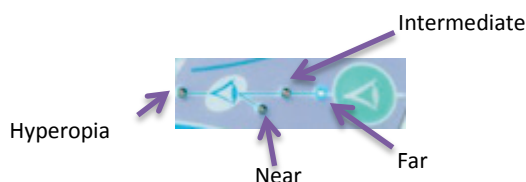
4.5.1. Keys

At any time during a test, lighting and distance may be modified:

- Lighting



- Distance

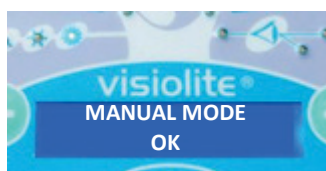


4.5.2. Forehead presence

A blinking light indicates the patient's forehead is not in contact with the forehead rest.

4.5.3. Begin a test

As soon as it is switched on, the last mode used appears.



Use MANUAL mode to scroll through all the tests proposed. However, no patient profile would justify a test as complete as this. It is thus preferable to use programmed tests.

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4.5.4. Choose a mode

To scroll through the tests of the selected mode, use the left and right arrows. Go from one mode to another by pressing on the right or left arrow.



To select the displayed mode, click "OK".

4.5.5. Perform a test

Once the mode is chosen, go from one test to another with the right key, which displays the following test. Return to the previous test by pressing on the left key.



4.5.6. Visual field

When the remote control displays the visual field test, press "OK". Use the right and left arrows to change lighting. To exit the test, press "OK" again.



20 horizontal and vertical visual field LEDs

4.5.7. Standby

After several minutes without use, the Visiolite® remote control goes on standby mode. To reactivate, press any remote control key, or touch the Visiolite® forehead rest.

4.5.8. Remote control response form

The form is required to note the results given by the patient. This is only supplied with the remote control, on the CD-ROM supplied with the Visiolite®, and can be printed as required.

If a copy is given to the patient or a third party, photocopy the original.

The form is composed of three parts:

- Patient identification
- Doctor conclusions and comments
- Tables or boxes to check according to patient response

The grey areas on the response form indicate the optimum response but cannot in any case determine normality or aptitude for a specific occupation or to perform a certain task. These areas cannot be used for an individual's interest or for discrimination purposes.



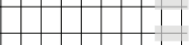


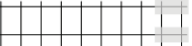






Only the conclusions of the doctor responsible, in conjunction with other medical expertise, can establish aptitude. As this is a screening test, the results cannot in any case be used for medical treatment, pre-or post-surgical diagnosis, or for any sort of prescription.

The response form gives the operator the expected response, but also to adapt the questions to ask the patient, depending on the type of test.


Visiolite® Antwortformular


ID Nummer :	Testdatum : / /	Zeist :	Untersucher :
Nachname :	Vorname :	Geburtsdatum : / /	Geschlecht : <input type="checkbox"/> Weiblich <input type="checkbox"/> Männlich
Firma :	Position :	Risiko :	
Sehhilfe : <input type="checkbox"/> Nein <input type="checkbox"/> Brille <input type="checkbox"/> Linsen		Test mit sehhilfe : <input type="checkbox"/> Ja <input type="checkbox"/> Nein	
Typ brille : <input type="checkbox"/> Normal <input type="checkbox"/> Bifokal <input type="checkbox"/> Trifokal <input type="checkbox"/> Progressiv <input type="checkbox"/> Andere :		Augen-Op : <input type="checkbox"/> Ja <input type="checkbox"/> Nein Wenn ja, weiche ? :	

ⓘ Kontrast-Sehtest Graue Bereiche = erwarteten Antworten
Markieren sie normale Ergebnisse mit einem ● und ergebnisse von tests unter abgedunkelter umgebung mit X.

Abstand	ABC	E Raskin	1 2 3	Landolt ringe	Test	Schzschärfe (/10)
 Ferne 5 m ● Visus 2.5 ● Visus 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	
 PC-Abstand 60 cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	
 Leseabstand 33 cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	
 Sehtest ohne brille	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	


Astigmatismus


rechts  1 2 3 4 5 6 7
● Gleich ☐ Nicht bestanden


links  1 2 3 4 5 6 7
● Gleich ☐ Nicht bestanden

Blendempfindlichkeit :
☐ Nicht bestanden


Widerstand gegen die blendung :
Recovery-zeit :
☐ Nicht bestanden

Fehrsichtigkeit 
☐ Nicht bestanden


Tiefenwahrnehmung 
☐ Nicht bestanden


Hyperopi (+1 dioptrin)
R L Besser Schlechter

☐ ☐

Phorie
4 = Exophorie
5 = Orthophorie
6 = Esophorie
Andere = Hyperphorie
☐ Nicht bestanden
☐ Außerhalb des gitters

Fusion

☐ Nicht bestanden

Dyschromatopsie (rot grün schwäche)
☐ Nicht bestanden

Amsler R L Normales gitter Verzerrtes gitter

☐ Nicht bestanden

Peripherie

☐ Nicht bestanden

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5. Tests Description

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5.1. Visual acuity test

Visual acuity is a criterion for quality of vision; the power of the eye to distinguish detail.

Visual acuity is determined by the identification of black symbols on a white background, called optotypes.

The Visiolite® uses several different visual acuity charts that:

- Vary the optotypes so as to avoid voluntary or involuntary memorisation
- Test illiterate persons
- Test persons who only recognise numbers
- Test morphoscopic vision (recognition of shapes)
- Test the power of separation (recognition of a detail)
- Test low vision (less than 1/10th)

Different charts test binocular and monocular vision.

The choice and shape of symbols is rigorously defined to increase efficiency of optotype identification.

An acuity test, or chart, contains 8 levels of visual acuity (8 lines).

A level of visual acuity is represented by 6 distinct optotypes grouped on the same line.

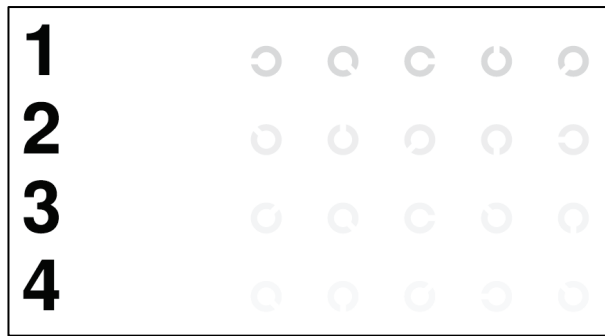
The different levels of acuity presented constitute the acuity scale.

A number corresponding to the level of visual acuity expressed in tenths: 0.5 to 12.5 is represented on the left of each line.

A level of visual acuity is validated when 4 of the 6 optotypes of this acuity are correctly identified.

	Binocular Acuity	Monocular Acuity 1	Monocular Acuity 2
Numbers	Zahlen 3 2 3 8 4 9 0 4 8 2 0 3 4 6 5 7 3 2 8 9 0 6 9 4 6 3 7 5 7 5 8 3 2 0 4 8 0 9 2 6 7 8 10 2 7 6 5 4 3 12.5 6 3 4 9 8 0	Zahlen 3 8 3 4 2 6 9 4 0 2 4 3 8 5 5 4 5 2 0 6 8 6 7 6 9 2 8 0 7 9 8 3 2 0 7 8 3 6 7 5 4 2 10 5 3 4 6 7 9 12.5 8 9 3 4 0 6	Zahlen 3 2 7 6 3 8 5 4 8 2 7 9 3 0 5 2 5 3 0 4 8 6 6 2 5 3 7 4 7 5 8 0 4 2 6 8 3 9 6 5 4 7 10 6 0 2 7 9 8 12.5 9 6 4 8 3 0
Landolt	Landolt ringe 3 ㄥㄥㄥㄥㄥㄥㄥㄥ 4 ㄥㄥㄥㄥㄥㄥㄥㄥ 5 ㄥㄥㄥㄥㄥㄥㄥㄥ 6 ㄥㄥㄥㄥㄥㄥㄥㄥ 7 ㄥㄥㄥㄥㄥㄥㄥㄥ 8 ㄥㄥㄥㄥㄥㄥㄥㄥ 10 ㄥㄥㄥㄥㄥㄥㄥㄥ 12.5 ㄥㄥㄥㄥㄥㄥㄥㄥ	Landolt ringe 3 ㄥㄥㄥㄥㄥㄥㄥㄥ 4 ㄥㄥㄥㄥㄥㄥㄥㄥ 5 ㄥㄥㄥㄥㄥㄥㄥㄥ 6 ㄥㄥㄥㄥㄥㄥㄥㄥ 7 ㄥㄥㄥㄥㄥㄥㄥㄥ 8 ㄥㄥㄥㄥㄥㄥㄥㄥ 10 ㄥㄥㄥㄥㄥㄥㄥㄥ 12.5 ㄥㄥㄥㄥㄥㄥㄥㄥ	Landolt ringe 3 ㄥㄥㄥㄥㄥㄥㄥㄥ 4 ㄥㄥㄥㄥㄥㄥㄥㄥ 5 ㄥㄥㄥㄥㄥㄥㄥㄥ 6 ㄥㄥㄥㄥㄥㄥㄥㄥ 7 ㄥㄥㄥㄥㄥㄥㄥㄥ 8 ㄥㄥㄥㄥㄥㄥㄥㄥ 10 ㄥㄥㄥㄥㄥㄥㄥㄥ 12.5 ㄥㄥㄥㄥㄥㄥㄥㄥ
Raskin	Raskin 1 ME3MEW 3 W3WEM3 5 MWEM3E 7 3EW3MW 10 EM3WE3	Raskin 1 E3MW3M 3 MWEM3W 5 3EMWEM 7 MW3EW3 10 E3WM3E	Raskin 1 WEM3EM 3 3MEW3W 5 E3MEWM 7 WM3WE3 10 3EW3ME
Low vision Specific aptitude test for vehicle driving		Dämmerungssehen rechtes Auge 0.5 VFZ 1 NTHLC	Dämmerungssehen linkes Auge 0.5 UPN 1 KFCZU

5.2. Contrast sensitivity test



Contrast sensitivity test

5.2.1. Purpose

Demonstrates a decrease in contrast sensitivity. Contrast sensitivity is typically a retinal function and a decrease can indicate an alteration of the retina. It is also decreased in certain diseases such as cataracts and chronic glaucoma.

Decrease in contrast sensitivity is physiological in night vision.

Two acuity levels are available in binocular: 2.5 or 4.

For each test, the contrast decreases with each line, from 20 to 5 % like this:

20
10
7
5
Contrast in %

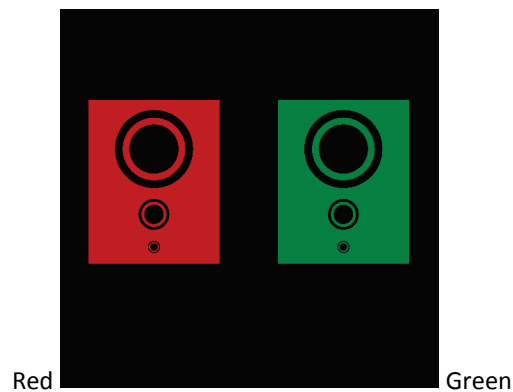
5.2.2. Patient instructions

"From the first line, read all the letters".

- Check the response

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5.3. Duochrome test



5.3.1. Purpose

Demonstrates a deficiency of far, intermediate or near vision.

5.3.2. Definition

Black shapes are presented on both red and green backgrounds.

Clearer vision (or blacker) on a red or green background indicates ametropia.

5.3.3. Patient instructions

“Are the black circles clearer, or blacker, in the green or the red, or are they the same?”

➤ Note the response on the response form.

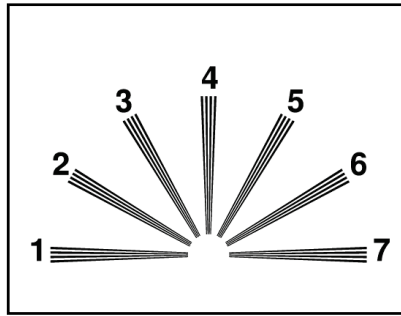
5.3.4. Expected responses

- Similar perception on both backgrounds indicates normal far vision
- Clearer, or blacker, vision on the red background indicates a myopic tendency
- Clearer, or blacker, vision on the green background indicates a hyperopic tendency or presbyopia of near vision. If this is noted with far vision, a hyperopia test is indicated

5.3.5. Perception example



5.4. Astigmatism test



5.4.1. Purpose

Astigmatism is an important source of eye strain, particularly in intense conditions or poor lighting (screen work or night driving with glare from oncoming vehicle lights).

5.4.2. Definition

The astigmatism test is composed of an astigmatic dial with 7 branches numbered from 1 to 7.

5.4.3. Prerequisite

This test should be performed in monocular mode.

The operator should look at each of the branches consecutively.

5.4.4. Patient instructions

Are some of the lines blacker or clearer?"

- Note the responses on the response form.

5.4.5. Expected responses

If the patient perceives some branches less clear, or greyer, than others, the eye is probably astigmatic.

Normally all the branches should be perceived in the same way. A branch that is clearer in direction 4 indicates vertical or direct astigmatism. On the contrary, if the branches are clearer in directions 1 and 7, this indicates horizontal or inverse astigmatism. These directions indicate different optical strength in the particular meridian, as the corneal astigmatism is toric, rather than perfectly spherical.

A 'clearer in directions 1, 4 and 7' response is thus impossible, and the Visiolite® operator is alerted by a question mark. Generally, in these cases, after repeating the test with clear instructions, the response would be interpreted as 'identical'.

"Oblique" astigmatism also exists and is more difficult to correct, sometimes persisting despite correction. In this case, the response would be given in either the 2 or 3 meridian, or the 5 and 6. A simultaneous response: 2, 3, 5, 6 is impossible.

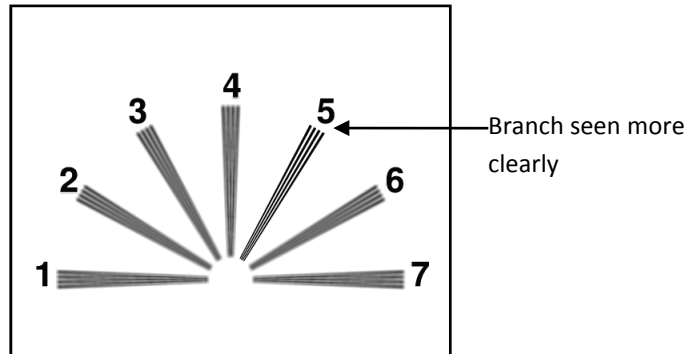
Sometimes a meridian astigmatism is only detected by varying focal length. Astigmatism could thus be tested in near vision, or after addition of the hyperopia lens in far vision. Of course, detection for astigmatism in near or intermediate vision is useless, if it is present in far vision.

Lastly, this device only screens "regular" astigmatisms. Other, "irregular" astigmatisms, notably on corneal scars,

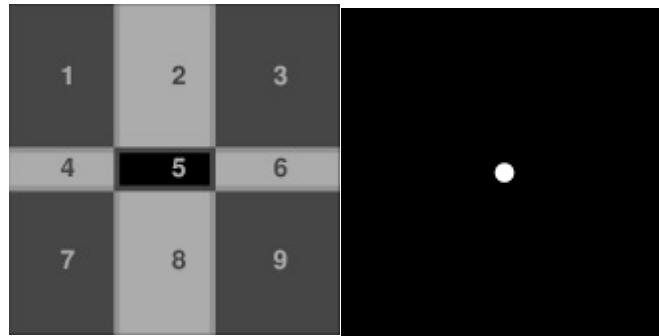
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are screened by ophthalmologists.

5.4.6. Perception example



5.5. Phorias test



5.5.1. Purpose

The phorias test checks parallelism of the ocular axes at physiological rest.

All phorias (heterophoria) translate as eye strain (asthenopia), notably in intense conditions (screen work).

Eventually heterophoria, coupled with fatigue, can become diplopia (double vision). This test is particularly interesting for screening latent heterophorias.

5.5.2. Interpretation limits

This test is only significant when visual acuity in the right and left eyes is practically identical. This test cannot be interpreted if there are large differences in acuity between the two eyes. In this case, the heterophoria would not be due to eye strain, as the better eye takes over and becomes dominant.

5.5.3. Definition

A grid containing 9 areas numbered from 1 to 9 is presented to the left eye, while a white dot is presented to the right eye. Without neutralisation of one of the images by the brain, the two images should superimpose.

Localisation of the white dot on one of the numbered zones of the grid qualifies the type of phoria of the patient:

The grid is sized so as to reveal an esophoria of 2 dioptries, an exophoria of 3 dioptries and a hyperphoria of 1 dioptre.

5.5.4. Patient instructions

“In which direction is the dot moving?”

- Note the area number on the response form.

5.5.5. Expected responses

The white dot is seen in:

- Area 5: the ocular axes are parallel (orthophoria)
- Area 4: the ocular axes have a tendency to diverge horizontally (exophoria)

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- Area 6: the ocular axes have a tendency to converge horizontally (esophoria)
- Area 2 or 8: the ocular axes have a tendency to diverge vertically (hyperphoria)



If the white dot or the grid is not perceived, the brain has neutralised one of the images.

If the dot is perceived outside of the grid, the heterophoria is over 9 dioptres.

With this test, the Visiolite® can completely dissociate the two eyes, indirectly performing a well-known test, the cover test, but more easily and accurately. As such, when the patient attempts to dissociate the dot and the grid, their convergence function will be used. The dot will move in the opposite direction to that of the heterophoria. This direction is noted.

The yellow arrows can be used to ⁽¹⁾: drag-and-drop the arrow in the grid. A right-pointing arrow indicates initial movement of the dot (and thus of the eyeball) from inside to out— ESOPHORIA. A left-pointing arrow indicates initial movement of the dot from outside to inside— EXOPHORIA.

➡ Caution

Dot movement is often fleeting, or non-existent (orthophoria): the questions should prepare the patient to indicate the movements of the dot in relation to the grid as soon as the test is presented and before the dot comes to rest⁽²⁾.

To render this test more sensitive, the Visiolite® presents the grid and the dot successively, with a slight time difference.

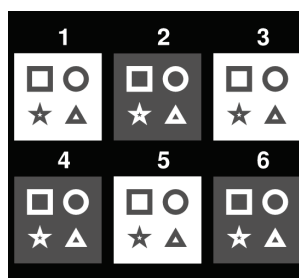
➡ Caution

This test cannot be interpreted if there is an important difference between the two eyes. Also, ensure the patient does not close an eye during the test.

(1)Tick “dynamic phorias” option in the set-up parameters so that the arrows appear.

(2)When the dot does not move, simply click on the area where it is seen in the grid.

5.6. Depth perception test



5.6.1. Purpose

To qualify depth perception acuity.

This test can be useful, for example, for forklift operators who require precise docking of loads, or for perception of distances in vehicle driving.

5.6.2. Interpretation limits

Depth perception results from the brain integrating two slightly differently-positioned images. This test is only possible if both eyes have identical, or nearly identical, visual acuity and normal convergence (at least normal fusion). This test is impossible when there is an important difference in acuity between the two eyes, or disparity of fixation. However, total absence of depth perception acuity cannot be deduced so easily. Physiologically, even with low acuity in one eye, even to the point of simple light perception, and normal acuity in the other eye, depth perception vision is made through cerebral compensation. In theory, only one-eyed individuals cannot have depth perception vision.

5.6.3. Definition

Depth perception is screened with 6 separate, numbered boxes. Each box contains 4 shapes: a square, a circle, a star and a triangle.

For each box, one of the shapes has a binocular horizontal disparity, expressed in arcseconds (1 arcsecond = $1^\circ/3600$). This causes a stereoscopic parallax in relation to the three other shapes in the box. Consequently, this shape should be perceived by the patient in front of, or behind, the three other shapes. The value of binocular disparity is different for each box: large for the first box and decreasing by half for each consecutive box.

Normal depth perception acuity should perceive the disparities of all the tests.

Box	1	2	3	4	5	6
Disparity (in arcseconds)	1600"	800"	400"	200"	100"	50"
Expected responses	Triangle	Circle	Star	Square	Star	Circle

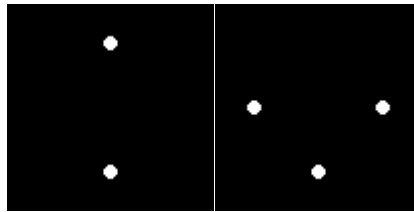
5.6.4. Patient instructions

"Certain shapes seem to be behind or in front of the others; give the answer for groups 1 to 6".

- Note responses on the response form.

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5.7. Fusion test



5.7.1. Purpose

To check binocular vision.

Fusion is the ultimate phase in binocular vision. As for phorias, fusion requires good visual acuity in each eye. In the case of phoria anomaly, fusion can be obtained by stimulating the oculomotor muscles, which will correct the phorias. Failure of this test signifies anatomical impossibility of convergence, which is found in extreme cases of strabismus.

A fusion problem (which can range from fixation disparity to suppression of one of the two images) can be an important source of eye strain during screen work. The patient should see four dots for the test to be successful.

5.7.2. Definition

A group of white dots is presented to the patient with different patterns for each eye.

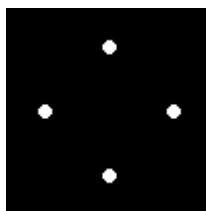
5.7.3. Patient instructions

“How many white dots can you see?”

- Note the response on the response form.

5.7.4. Expected responses

- 4 points perceived indicates fusion: the brain correctly superimposes the two images coming from each of the eyes
- 2 points perceived indicates suppression: the brain neutralises the image coming from the right eye
- 3 points perceived indicates suppression: the brain neutralises the image coming from the left eye
- 5 points perceived indicates diplopia: the brain is unable to correctly superimpose the two images coming from each eye



Normal perception

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5.8. Age-related macular degeneration (ARMD) / Amsler grid

5.8.1. Purpose

Screening for central visual field deficiency.

5.8.2. Definition

The test is composed of a grid on a black background with a central white dot.

The user should focus on the central white dot.

5.8.3. Prerequisite

This test must be performed in monocular mode.

5.8.4. Patient instructions

“Are the horizontal and vertical lines perfectly straight?”

“Are any of the areas deformed?”

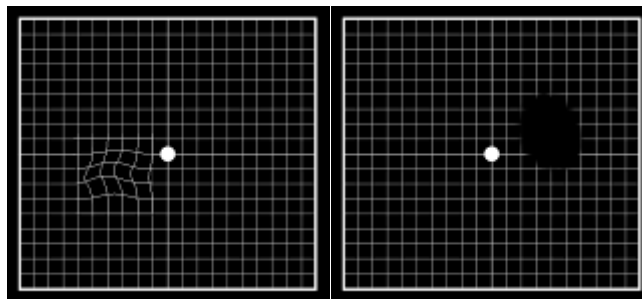
“Do any holes or black areas appear inside the grid?”

➤ Note the response on the response form.

5.8.5. Expected responses

- Distortion of lines, or metamorphopsia, could be associated with age-related macular degeneration
- An area in which the lines disappear is associated with macular scotoma (blind spot)

5.8.6. Perception examples



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5.9. Colour perception test

5.9.1. Purpose

Chromatic deficiency screening. As well as exploration of congenital dyschromatopsias (as in the Ishihara-type tables), this test offers the possibility of exploring acquired dyschromatopsias.

These tests are particular in that they screen problems of colour vision in shaded areas and in the blue-yellow axis. These areas are not explored with the classical Ishihara test, which only explores the red-green axis, essentially affected in congenital deficiencies of colour vision.

The blue-yellow axis is predominantly affected in acquired dyschromatopsias, in particular those of toxic origin, of which this is an early sign. Moreover, this test is more sensitive due to the presentation of shades of colours close to neutral, allowing for device luminosity, calibrated for this type of test (high photopic mode).

5.9.2. Definition

The test presented is a pseudo-isochromatic of the Ishihara type.

Colour perception is checked using 6 distinctly numbered boxes.

Each box, or plate is composed of a matrix of dots of variable height, shade and colour.

Areas of similarly-coloured dots are defined to form numbers. A number composed of two digits appears in each box. Colours are chosen so that an abnormality in the perception of colours makes it difficult to recognise certain numbers.

The total tests present 12 lines of chromatic confusion in the three axes:

- Protan (red)
- Deutan (green)
- Tritan (blue-yellow)

In all the six numbers presented, each number indicates a line of confusion.

E.g: within the number 81, failure to recognise the digit 8 indicates a tritan (blue) type deficiency, characteristic when the cones of the superficial layer of the retina are affected.

Failure to recognise the digit 1 indicates a deficiency of the deutan (green) type, which may be seen when the deep layers of the cones of the retina are affected, as the "4" of 45 tends to indicate a deficiency of the protan (red) type, when the same deep layers are affected.

These screening findings are summarised in the table on the following page.

5.9.3. Prerequisite

This test should be performed in high photopic mode. However, if the patient tested is blinded (blue-eyed people are subject), it can be performed in medium photopic mode, but never in low photopic mode.

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Important note

The test should be performed in MONOCULAR vision. It requires acuity of at least 8/10. If acuity is lower, any abnormality of colour vision should be confirmed in intermediate or near vision (if the patient has a better acuity at these distances).

5.9.4. Patient instructions

“Read the coloured numbers in each box”.

- Note the response on the response form.

Reading grid expressed in terms of tendency:

Box 1		Box 2		Box 3		Box 4		Box 5		Box 6	
8	1	4	5	6	3	2	7	9	0	1	8
tritan	deutan	protan	tritan	deutan	protan	tritan	deutan	protan	tritan	deutan	protan

5.9.5. Interpretation limits

Responses do not constitute a formal diagnosis, merely a trend.

All types of abnormality can be present in the same patient, each abnormality expressed more or less completely.

As such, for example, expression of a protan type deficiency can range from a simple abnormality with confusion of shades in the red-green axis (protanomaly) to complete blindness to the colour red (protanopsia).

Responses are expressed as tendencies and conclusions are not drawn on one test only.

Only the repetition of tests during successive examinations can confirm or invalidate this tendency, in particular with exposure to solvents, or in the presence of a progressive pathology such as diabetes.

This test should be interpreted with caution in patients over 40 years of age, for who colour vision can be altered normally.

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5.10. Horizontal and vertical visual field test

5.10.1. Definition

5.10.1.1. Horizontal temporal field

10 stimuli sweep the horizontal visual field to the right and left of the patient's eyes.

Angles swept: 90°, 75°, 60°, 45°, 30°.

➡ **Caution: this test should be performed in binocular vision.**

5.10.1.2. Horizontal nasal field

2 stimuli test the nasal field.

Angles tested: 50°.

➡ **Caution: this test should be performed in monocular vision.**

To test an eye, the patient should cover or close the other eye. The stimulus that tests the right eye is located on the patient's left, and vice-versa.

5.10.1.3. Vertical field

8 stimuli sweep the vertical visual field above and below the patient's eyes.

Angles swept: 30°, 22°, -22°, -30°.

5.10.2. Purpose

Measures aptitude for vehicle or engine driving. An appreciation of the amplitude of the horizontal and vertical visual field is required by certain laws (road rules).

5.10.3. Patient instructions

"While focussing on the central dot, do you see light flashes in your visual field?"

➤ Note the response on the response form.

➡ **Caution: if the patient wears glasses, the frames may alter the visual field.**

5.10.4. Limits

This test is not intended to completely explore the visual field.

Its main aim is to determine certain aptitudes; it does not serve to establish a diagnosis even if, in certain cases, screening is successful. Specialist diagnostic tests exist for this purpose (Goldman perimeter, etc ...).

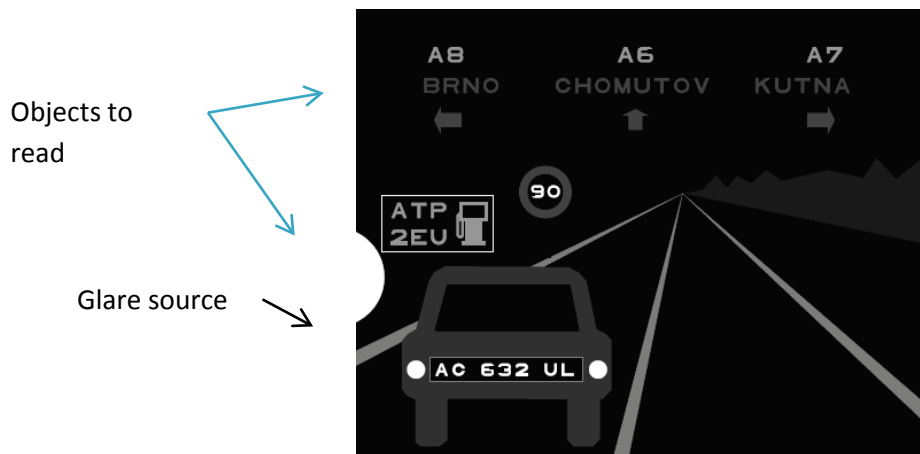
We thus restrict ourselves to pronouncing only normal visual fields. An abnormal result should be carefully interpreted, particularly for the nasal visual field (the shape of the nose could impede visibility of the light signal). In the lateral visual field, the patient's glasses frames may be a hindrance.

5.11. Glare sensitivity test (*Master-GT version*)

➡ **Caution:** The glare sensitivity test may hold risks for the patient. Don't forget to take into account any medical contraindications (refer § 2.3).

5.11.1. Purpose

The glare sensitivity test provides rapid screening by simulating the disturbance caused by lights when passing a vehicle at night.



Glare sensitivity test

The optotypes are designed so that the patient is not able to guess the words without reading them. Words chosen are either:

- **random letters**
- **or names of Czech Republic towns**

The size of characters is acuity: 3.2/10 and 4/10 so as not to render this test more difficult.

The positioning of objects in the driving scene is important. These are positioned in several places with different contrasts, so as to simulate the difficulties in vehicle-driving conditions.



Different angles of positioning of objects to identify

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5.11.2. Principle

A driving scene composed of different objects and different contrasts is displayed.

The glare source comes from the left-hand side of the scene. The patient names the objects seen closest to the light source and the operator notes the responses.

5.11.3. Operator and patient instructions

“Name each element that you see in the scene”.

- Click on the objects seen

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5.12. Glare resistance test (*Master-GT version*)

➡ **Caution:** The glare resistance test may hold risks for the patient. Don't forget to take into account any medical contraindications (refer § 2.3).

5.12.1. Purpose

The glare resistance test is only for information. It is secondary to the sensitivity test presented in § 5.11. This test measures the recovery time of the patient's vision when submitted to a high source of light.

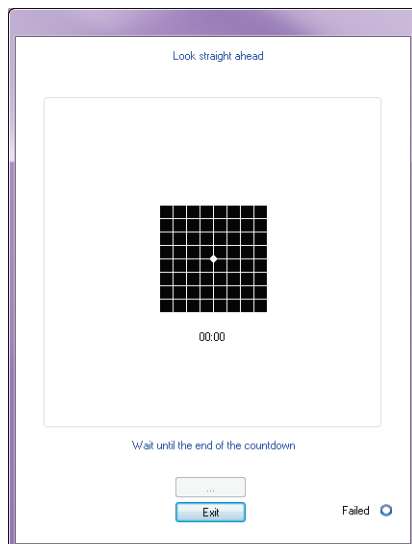
5.12.2. Principle

This test requires a precise protocol, integrated in this option. After a few seconds of adaptation, the software presents firstly a visual acuity test based on the "Binocular Mesopic Letters". The patient is blinded for 10 seconds. The device then displays a visual acuity test based on the "Binocular Mesopic Numbers". The aim is to measure the recovery time of the patient's visual acuity.

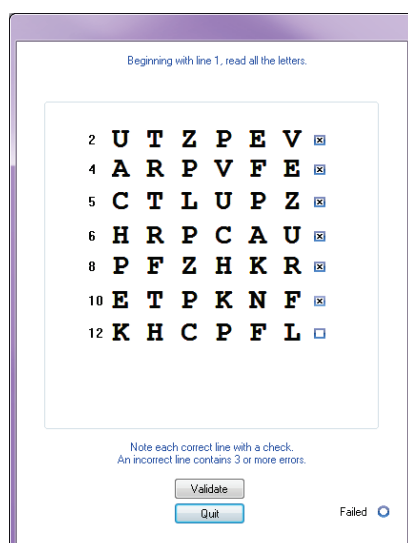
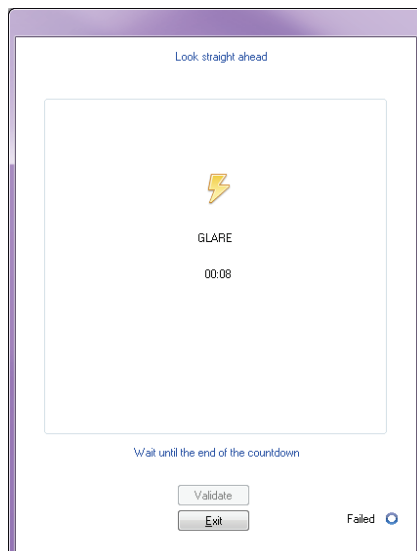
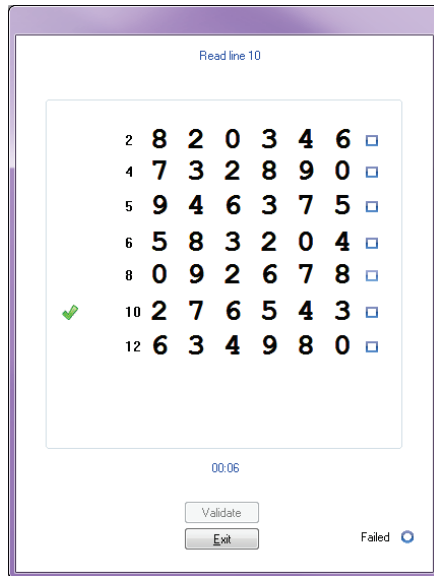


5.12.3. Patient instructions

Instructions are given by the software over the course of the test. Series of screens displayed by the Visiolite®:



Patient adaptation in mesopic light over ten seconds.



The Amsler grid is used on the patient so as to induce a scotoma. The glare lasts for 10 seconds.

The operator should insist that the patient focus on the central circle.

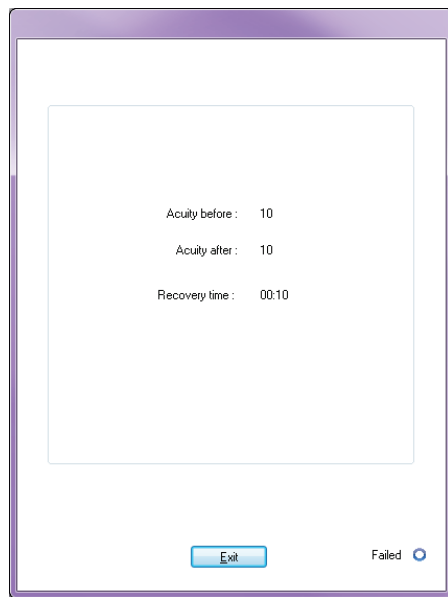
Final test phase.

The patient's visual acuity is evaluated on the basis of numbers presented in mesopic light. The aim is to measure the recovery time and to avoid memorisation of the first test performed.

The operator notes the best acuity.

Note: Do not continue longer than two minutes.

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Display of results.

Measurement of visual acuity in mesopic light after period of patient adaptation.

The operator notes the best patient acuity.

Note: If the patient demonstrates difficulty with a line, it is preferable to directly choose the line above.

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6. Cleaning and Maintenance

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6.1. Removable forehead rest cleaning

For hygienic measures, all the Visiolite® surfaces in contact with the skin (housing, mask, forehead rest) should be disinfected after each test. The removable forehead rest should systematically be cleaned after each use with a damp cloth and a bactericide solution. FIM MEDICAL recommends the use of Bactinyl® 5M.

If the forehead rest is damaged (ripped, etc...), contact your distributor or FIM for a replacement.

- **Caution: Never sterilise the Visiolite® or its accessories.**
- **Caution: Never wash the Visiolite® under running water or directly spray it with any sort of liquid.**

6.1.1. Remove forehead rest

- Simply pull it off.

6.1.2. Replace forehead rest

- Press on it.
- Clips located at the bottom.

6.2. Clean the housing

The Visiolite® housing can be cleaned with a damp cloth and a bactericide solution. FIM MEDICAL recommends the use of Bactinyl® 5M.

6.3. Clean the lenses

To avoid scratches, the external surface of the lenses should be regularly cleaned with a soft wipe used for glasses.

Do not press down on the lenses.

- **Caution: DO NOT use a bactericide solution to clean the lenses, as this will remove the anti-reflective coating.**

6.4. Clean the peripheral field holes

- Do not clean.
- Remove dust with a soft cloth.

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6.5. Annual service

Different forms of maintenance to keep the Visiolite® in an optimal operational state are recommended.

During annual servicing, the following operations are performed by FIM After Sales Service, or by your distributor (if trained by FIM personnel for maintenance):

- Checking device general functions
- Cleaning optics
- Checking and cleaning tests band
- Checking and minor repairs of mechanical and electronic elements
- Checking and calibration of central and lateral LEDs (only for Master-GT version)

This maintenance can be requested by the customer or by FIM if preventive operations are deemed necessary for correct functioning of the device.

6.6. Guarantee

Within the framework of the contractual guarantee of one year, only repairs are covered. The guarantee is only applicable if normal and usual conditions of use are respected. During annual servicing, a certain number of preventive operations are performed; breakdowns following annual service are not covered by the guarantee.

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7. What To Do If?

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7.1. No noise when switched on

- Check it is plugged into the power supply.
- Check the light on the power plug is on.

7.2. Normal switch-on noise but screen light remains grey

- Check USB connection and driver installation.

7.3. Error message appears at recording

7.3.1. “Identification incomplete”

Fields marked with a red asterisk in the identification panel are compulsory for recording.

7.3.2. “Operation must use updateable query”

This message is due to a problem of writing access rights on that computer. The administrator must give all tree structure rights, where the data base is found, to the operator.

7.4. Patient identification file found but not the tests

- Click “+” on the left of the patient’s name in the “Open” dialogue box.

7.5. Visiolite® light does not come on

- Check power supply connection.
- Check the patient’s forehead position on the forehead rest.

7.6. Glare and motor drive seem weak

- Check you are using the recommended power plug.

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8. Declaration of Conformity

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EC DECLARATION OF CONFORMITY

<u>Name</u>	<u>Version</u>	<u>Device Description</u>
VISIOLITE®	Master	Computerised, remote controlled visual function testing equipment
VISIOLITE®	Modulus	Computerised visual function testing equipment
VISIOLITE®	Essential	Remote controlled visual function testing equipment

The devices conform to the following standards:

EN 60601-1:2006/AC: 2010: Medical electrical equipment - Part 1: General requirements for basic safety.

EN 60601-1-2:2007/AC: 2010: Medical electrical equipment - Part 1-2: General requirements for basic safety - Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-1-6:2007/AC: 2010: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

EN ISO 10993-1:2009/AC: 2010: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

NF EN ISO 14971:2009: Medical devices - Application of risk management to medical devices.

I the undersigned, Marie-Ange DEREI, President of the F.I.M. company, located at 30 rue Camille 69003 LYON-FRANCE, assure and declare that the medical devices listed above belong to class I (rule 12) and satisfy the provisions of annex VI of directive 93/42/EEC, amended by directive 2007/47/EC.

Lyon, 31 July 2012,

Marie-Ange DEREI

President




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*Thank you for reading this manual.
If you require further information please don't
hesitate to contact us.*



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