

User Manual

Visiolite®

*Essential
Modulus
Master and Master-GT*



Contents

1. Introduction	6
1.1. List of supplied elements	7
1.2. Presentation	7
1.3. Technical features	9
1.4. Visiolite® range models	10
1.5. Serial number labels	11
2. Safety	12
2.1. General	13
2.2. Operator	14
2.3. Medical contraindications	14
2.4. Precautions before tests	16
2.5. Interpretation of results	16
3. Equipment and Installation	17
3.1. Installation procedure	18
3.1.1. Opening the box	18
3.1.2. Nomenclature	18
3.1.3. Connection	20
3.2. Operating systems	20
3.3. Hardware requirements	20
3.4. Software Installation (computerised version)	21
3.4.1. PC connection	22
3.4.2. Uninstallation	22
3.4.3. First run	22
3.4.1. Test before use	23
3.5. Procedure to stop the device	23
3.5.1. Software version	23
3.5.2. Essential remote control version	23
3.5.3. LCD remote control version	23
3.6. Backup/restore	23
3.6.1. Presentation	23
3.6.2. Backup	23
3.6.3. Restore	24
4. Use	25
4.1. Raise/lower Visiolite® body	26
4.2. Software use	26

4.2.1.	Description of menus	26
4.2.2.	Manual mode	27
4.2.3.	Semi-automatic mode	31
4.2.4.	Settings	31
4.2.5.	Database	38
4.3.	VisioClick® Use	40
4.3.1.	How it Works	40
4.3.2.	Running the Automation	40
4.3.3.	Vocal Instructions, Status Indicators and Buttons	41
4.3.4.	Automation Settings	42
4.3.5.	VisioClick® indicator in the status bar	42
4.4.	Essential remote control use	43
4.4.1.	Begin a test	43
4.4.2.	Binocular and monocular mode	44
4.4.3.	Visual field	44
4.4.4.	Standby	44
4.4.5.	Essential remote control response forms	44
4.5.	Master model LCD screen remote control use	45
4.5.1.	Keys	46
4.5.2.	Forehead presence	46
4.5.3.	Begin a test	46
4.5.4.	Choose a mode	47
4.5.5.	Perform a test	47
4.5.6.	Visual field	47
4.5.7.	Standby	47
4.5.8.	Remote control response form	48
5.	Tests Description	49
5.1.	Visual acuity test	50
5.2.	Contrast sensitivity test	52
5.2.1.	Purpose	52
5.2.2.	Patient instructions	52
5.3.	Duochrome test	53
5.3.1.	Purpose	53
5.3.2.	Definition	53
5.3.3.	Patient instructions	53
5.3.4.	Perception example	53
5.4.	Astigmatism test	54
5.4.1.	Purpose	54
5.4.2.	Definition	54
5.4.3.	Prerequisite	54
5.4.4.	Patient instructions	54
5.4.5.	Perception example	54
5.5.	Phorias test	55
5.5.1.	Purpose	55
5.5.2.	Definition	55
5.5.3.	Patient instructions	55

5.6. Depth perception test	56
5.6.1. Purpose	56
5.6.2. Interpretation limits	56
5.6.3. Definition	56
5.6.4. Patient instructions	56
5.7. Fusion test	57
5.7.1. Purpose	57
5.7.2. Definition	57
5.7.3. Patient instructions	57
5.8. Age-related macular degeneration (ARMD) / Amsler grid	57
5.8.1. Purpose	57
5.8.2. Definition	57
5.8.3. Patient instructions	57
5.8.4. Perception examples	57
5.9. Color perception test	58
5.9.1. Purpose	58
5.9.2. Definition	58
5.9.3. Patient instructions	58
5.10. External and central visual field test	59
Definitions	59
5.10.1. External visual field	59
5.10.2. Central visual field	60
5.10.3. Patient instructions	60
5.10.4. Significance of stimuli in the test window	61
5.10.5. Results	61
5.11. Glare sensitivity test (Master-GT version)	62
5.11.1. Purpose	62
5.11.2. Principle	62
5.11.3. Operator and patient instructions	62
5.12. Glare resistance test (Master-GT version)	63
5.12.1. Purpose	63
5.12.2. Principle	63
5.12.3. Patient instructions	63
6. Cleaning and Maintenance	65
6.1. Removable forehead rest cleaning	66
6.1.1. Remove forehead rest	66
6.1.2. Replace forehead rest	66
6.2. Clean the housing	66
6.3. Clean the lenses	66
6.4. Clean the peripheral field holes	66
6.5. List of generic bactericidal fungicidal products validated by FIM MEDICAL	67
6.6. Annual service	67
6.7. Guarantee	67

6.8	Lifetime	67
7.	Available accessories	68
7.1.	LCD remote control	69
7.2.	VisioClick®	69
7.3.	Trolley case	69
7.4.	Face cover	69
7.5.	Dust cover	69
8.	What To Do If?	70
8.1.	No noise when switched on	71
8.2.	Normal switch-on noise but screen light remains grey	71
8.3.	Error message appears at recording	71
8.3.1.	“Identification incomplete”	71
8.3.2.	“Operation must use updateable query”	71
8.4.	Patient identification file found but not the tests	71
8.5.	Visiolite® light does not come on	71
8.6.	Glare and motor drive seem weak	71

1. Introduction

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 MEDICAL 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 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
- Optimization of computer connectivity
- Option of performing several visual acuity tests to avoid voluntary or involuntary memorizing 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
- Creating/modifying test sequences
- Performing far, near and intermediate vision tests

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	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, EN 62366-1, EN ISO 10993-5, EN ISO 10993-10, NF EN ISO 14971, NF EN 62304/A1, NF EN 1041+A1, EN ISO 15223-1, ISO 8596, ANSI Z80.21, NF EN ISO 15004-2 :2007 §5.4.1.6, EN ISO 10993-1.
Medical class	Class I
Software security class	A
Electric class	Class II
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	<p><u>Depending of the version:</u></p> <p>Far vision: $(5.0 \pm 0.1)\text{m}/(16.4 \pm 0.3)\text{ft}$; $(20.0 \pm 0.4)\text{ft}$</p> <p>Intermediate vision: $(60.0 \pm 0.5)\text{cm}/(23.6 \pm 0.2)''$; $(80.0 \pm 0.5)\text{cm}/(31.5 \pm 0.2)''$; $(24.0 \pm 0.2)''$</p> <p>Near vision: $(33.00 \pm 0.25)\text{cm}/(13.0 \pm 0.1)''$; $(35.50 \pm 0.25)\text{cm}/(14.0 \pm 0.1)''$; $(16.0 \pm 0.1)''$</p> <p>Hyperopia lenses: +1 dioptre</p>
Lighting conditions (nominal values)	<p>High photopic (160 candelas)</p> <p>Low photopic (80 candelas)</p> <p>Dusk mesopic (3 candelas)</p> <p>Conform to NF EN ISO 8596 standard</p>

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

1.4. Visiolite® range models

	Essential	Modulus	Master
Acuity Tests			
Landolt Rings	•	•	•
Numbers		•	•
Letters	•	•	•
Low vision letters		•	•
Supplementary tests			
Astigmatism	•	•	•
Red/green duochrome	•	•	•
Depth perception		•	•
Vertical & horizontal phorias	•	•	•
Fusion			•
Ishihara type colours test	•	•	•
Amsler grid		•	•
Contrast sensitivity			•
Hyperopia test (+1 dioptre)	•	•	•
Horizontal & vertical visual field	•	•	•
Central 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	•		•

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



Storage condition



Do not reuse. Single use



Batch/lot number



Expiry date

2. Safety

2.1. General

CAUTION:

- Never dismantle or interfere with the device without the authorization of the manufacturer. Only FIM MEDICAL After Sales Service and trained distributors are qualified to work on the equipment
- The Visiolite® should be returned regularly for annual maintenance to FIM MEDICAL After Sales or your distributor
- Use only the leads and power plugs supplied by FIM MEDICAL
- It is highly recommended to store and transport the Visiolite® at a temperature of 0 -50°C (32 - 122°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 MEDICAL After Sales Service, or to your distributor, if trained by FIM MEDICAL for maintenance
- If the device no longer maintains a stable position, or has degraded, return it to FIM MEDICAL After Sales Service, or to your distributor, if trained by FIM MEDICAL for maintenance
- If any elements of the device degrade, the device should be returned for checking, to FIM MEDICAL After Sales Service, or to your distributor, if trained by FIM MEDICAL 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 MEDICAL 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 intended for the use only of health professionals (doctor, ophthalmologist, optician, medical secretary...) or by a person who have received training in conducting optical tests. Considering their level training, health professionals should have no trouble using the device. Results should only be interpreted by physicians who have undergone ophthalmology training. Operator should be aware of hygiene and bacterial contaminations rules. In case of doubt, please consult the user manual and/or FIM MEDICAL.

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 MEDICAL recommends daily back up.

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).

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) Proxalyc (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 Moducoren Moduretic Moex Piportyl Prestole Prinzide Renitec	Neuroleptics Largactil Modicate 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 Liponor Lodales 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

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

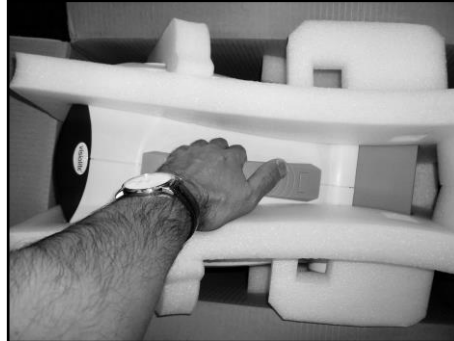
- Patient results should always be accompanied by an explanation from the practitioner
- The Visiolite® may not be used for medical treatment. It can under no circumstances be used as the basis for medication prescriptions, pre- or post-surgical diagnoses, or any other type of prescription
- The Visiolite® 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

3. Equipment and Installation

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.

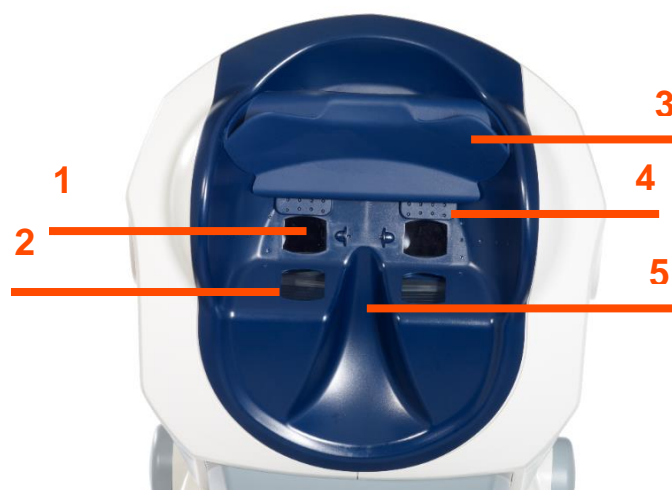
2 Mask

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

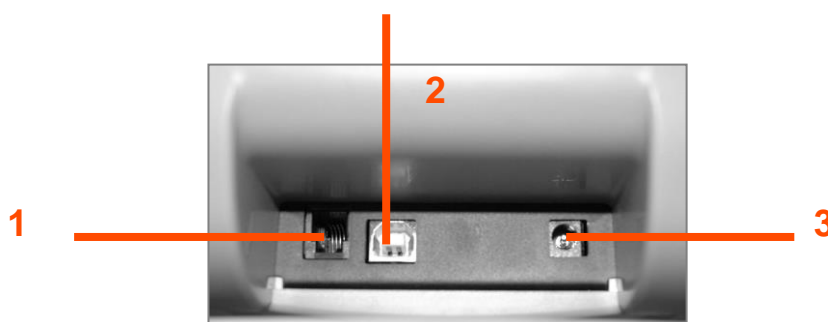
3 Removable forehead rest piece

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

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).

3.2. Operating systems

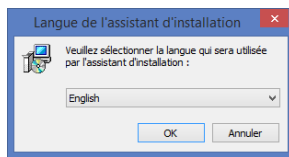
Windows 7, Windows 8.xx, Windows 10, Windows 11.

3.3. Hardware requirements

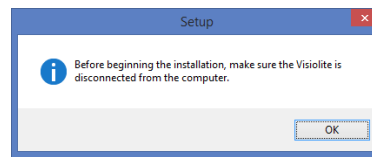
- Processor 2GHz or more
- 1 Go RAM
- 1 Go hard drive
- Graphic card 64Mo
- Display minimum resolution 1024x768

3.4. Software Installation (computerised version)

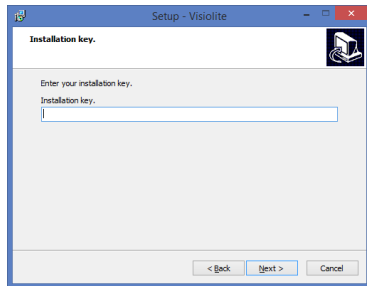
For computerised versions, the operator must have administration rights on the workstation.
From the CD Rom root directory, run the "SetupVisiolite.exe" file; not necessary if it is set-up for automatic running.



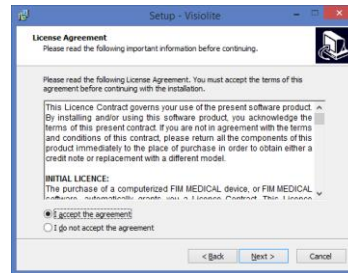
1. Temporary Welcome Screen



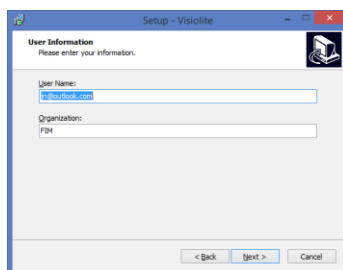
2. Recommendation Screen



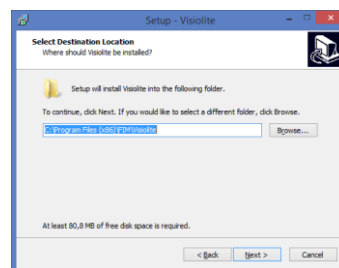
3. Enter serial number
from the back of the CD jacket



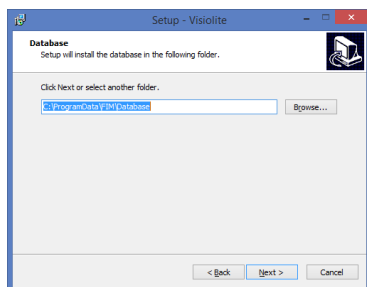
4. License agreement



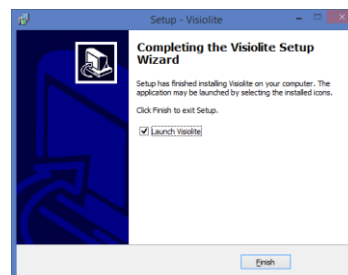
5. User information



6. Enter software installation destination



7. Enter database destination



8. Validate Finish



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

3.4.1.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.

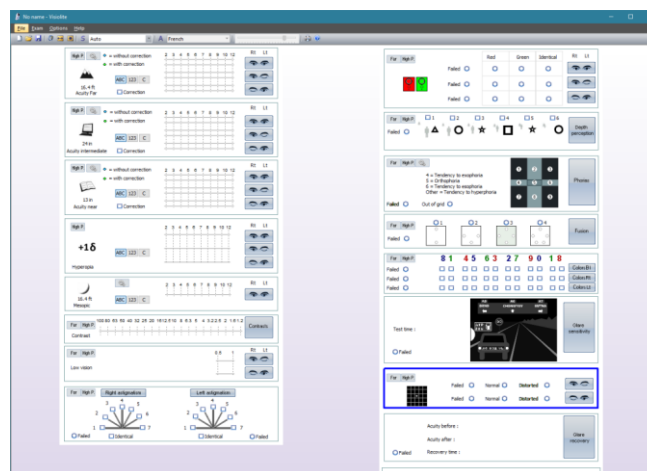
3.4.2.Uninstallation

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”.

Caution: Before uninstalling the driver, ensure that no software is using it.

3.4.3.First run

The following screen appears:

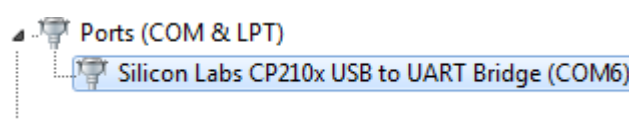


A light on the bottom right of the screen indicates whether the Visiolite® is correctly connected:



- 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 **Silicon Laboratories** CPS10x USB to UART Bridge.



3.4.1. 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.

3.5. Procedure to stop the device

3.5.1. Software version

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

3.5.2. 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.

3.5.3. 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.

3.6. Backup/restore

3.6.1. Presentation

The backup/restore function protects users against loss of data and configurations in the event of a computer breakdown.

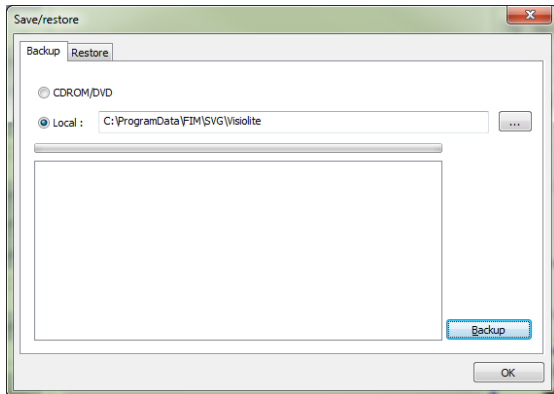
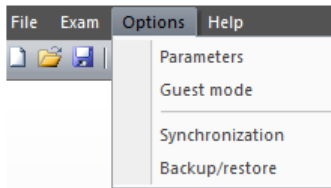
This function also accelerates and facilitates use in a pool of several Visiolite® devices.

3.6.2. Backup

Backup enables recovery of all the elements required for Visiolite® function. Elements backed up:

- Data base
- Configuration files
- Sequences
- Instructions
- Scoring
- Executable files

To backup, go to the **Options** menu then **Backup/restore**.



Choose backup mode:

- In a directory
- On a CD/DVD (*caution: the Windows burning tool must be installed*)

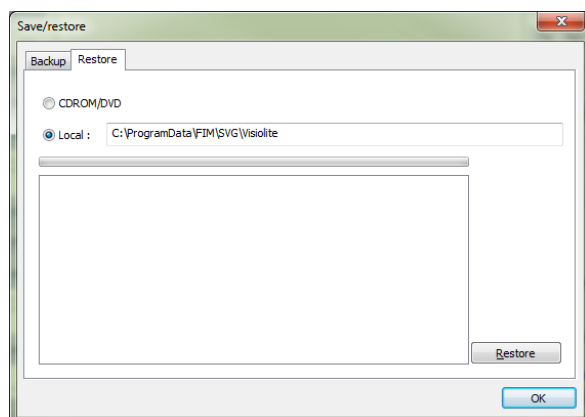
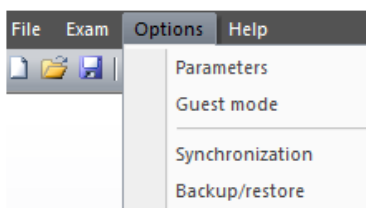
Click on **Backup**.

3.6.3.Restore

Restore enables recovery of the backed up files of all the elements required for the Visiolite® software.
Elements restored:

- Database
- Configuration files
- Sequences
- Instructions
- Scoring
- Executable files (except executable Visiolite itself).

To perform a restore, go to the **Options** menu then **Backup/restore**.



Click on the **Restore** tab.

Choose backup mode:

- Then a directory
- Then a CD/DVD

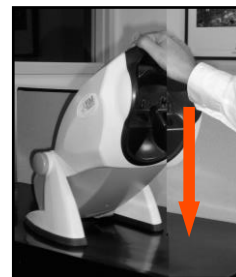
Click on **Restore**.

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®.

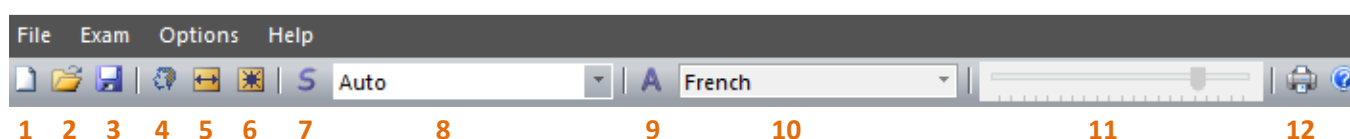
Comment: It is recommended to place the patient's hands on the test table and avoid placing the fingers into the inclination system.

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.

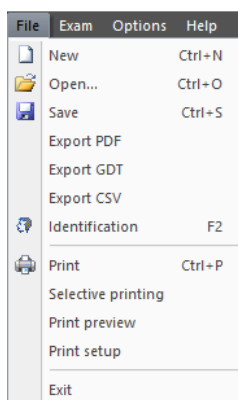


1 New file	7 Run a sequence
2 Open	8 List of sequences
3 Sage	9 Automatic mode
4 Identification	10 Automation language
5 Positioning	11 VisioClick® volume adjustment
6 Light	12 Print

Note: elements 9, 10 & 11 involve using a Visioclick®

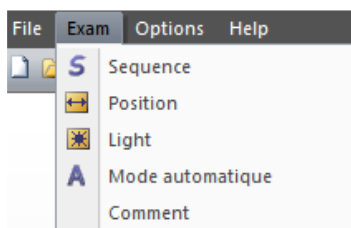
4.2.1.2. Menu bar

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



Functions:

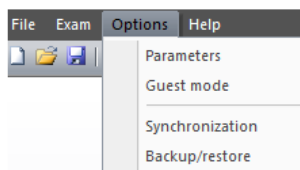
- Manage a test
- Access identification
- Export
- Print



Functions:

- Run the chosen sequence
- Positioning of patient
- Light
- Automatic mode
- Add a comment

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



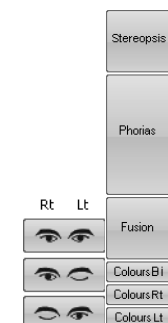
Functions:

- Parameters
- Configuration of guest mode
- Synchronization
- Backup/restore

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.	Icons	Legend	2	3	4	5	6	7	8	9	10	12	Rt	Lt
5 m	Acuity Far	<input type="checkbox"/> = without correction <input checked="" type="checkbox"/> = with correction												
60 cm	Acuity intermediate	<input type="checkbox"/> = without correction <input checked="" type="checkbox"/> = with correction												
33 cm	Acuity near	<input type="checkbox"/> = without correction <input checked="" type="checkbox"/> = with correction												

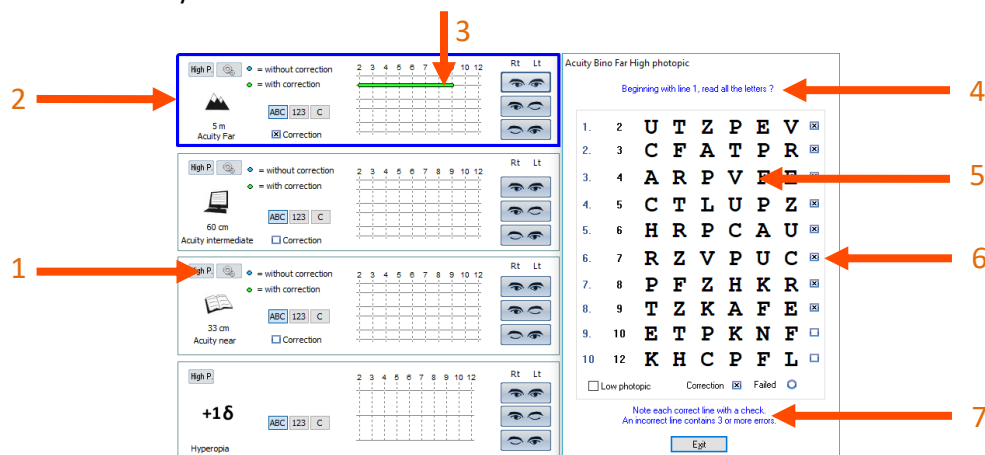
4.2.2.2. Command keys

Binocular acuity	Right eye acuity	Left eye acuity
Visual field	Right astigmatism	Left astigmatism
Visual field	Right eye astigmatism	Left eye astigmatism
ColorsBi	Depth perception	Phorias
ColorsRt		
ColorsLt		
Colours test	Depth perception test	Phorias test
Glare sensitivity	Glare recovery	Contrastes
Glare sensitivity test	Central glare test	Contrast sensitivity
Fusion		
Fusion test		

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 Checkboxes

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 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 during a time configured in visual field settings, then goes to red.

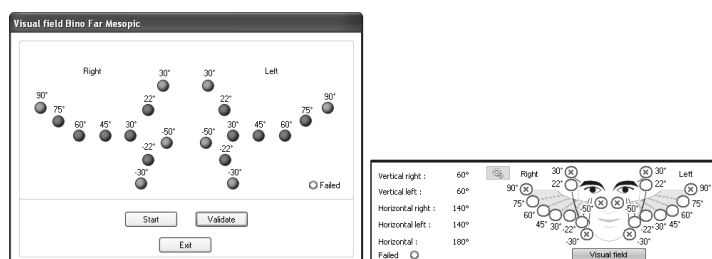
The angles tested will appear on the response form.

4.2.2.5.2. Semi-automatic mode

- Click “Start”.

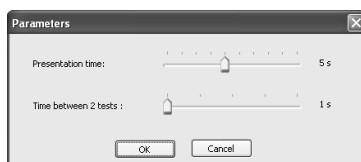
The program activates the stimuli from the outside to the inside of the field, until the limits can be defined.

- 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 configured as follows:

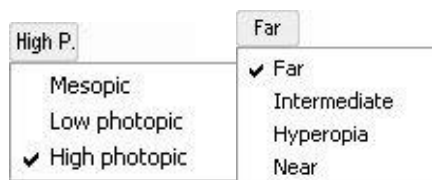
- Click the Parameters key



- Set the time

4.2.2.6. Settings

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



4.2.3.Semi-automatic mode

The Visiolite® software can pre-program tests.

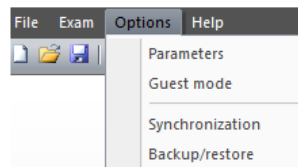
4.2.3.1. Use of sequences

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.Settings

The software can be configured as follows:

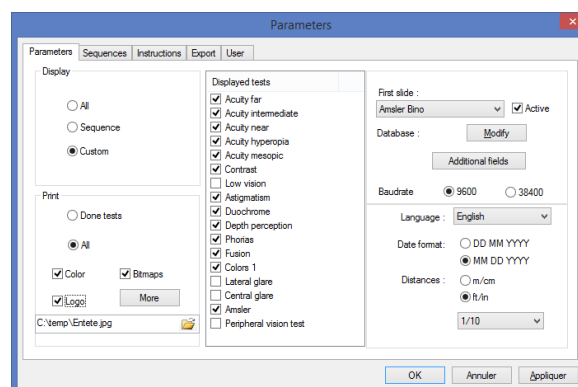


- Click “Options” menu.
- Click “Parameters”.

4.2.4.1. Display and print parameters

- Click “Parameters” tab.

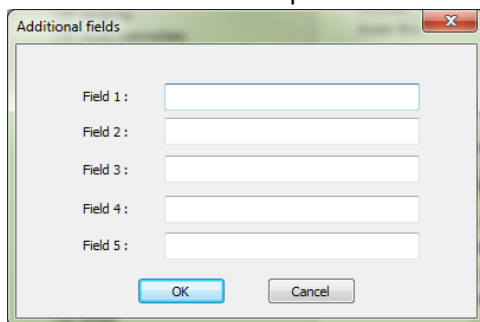
The following window appears:



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

Add additional fields required for identification in the database.

1. Click on the button to open the window to add fields.



2. Click on the OK button to validate and close the window.

CAUTION: Choice of fields is definitive. A backup performed with these fields should always be opened with these same fields. The name can be changed but it cannot be destroyed.

➤ Choice of distances unit (m/cm or ft/in)

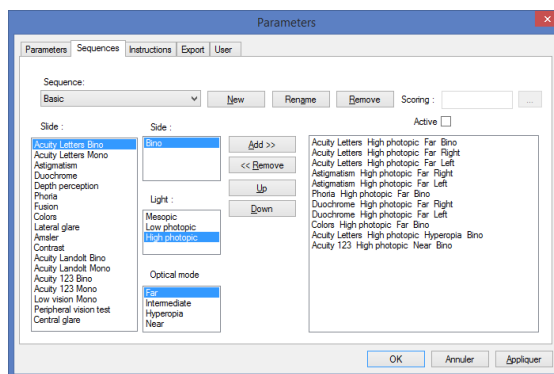
➤ Choice of type of visual acuity:

1. Tenth
2. Snellen 16.4ft
3. Snellen 6m

4.2.4.2. Sequences setting

➤ 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 lists “side”, “light” and “optical mode” to set 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.

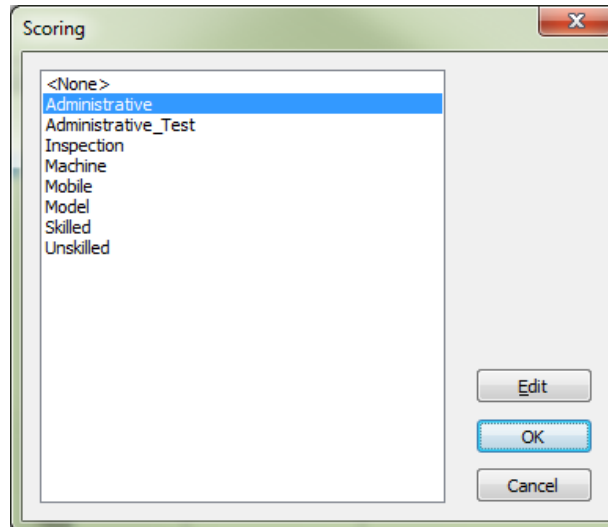
Once established, click “OK” so that the sequence appears in the scroll-down list, accessible from the tool bar.

4.2.4.2.1. Scoring:

For each sequence, an active Scoring can be added. Scoring fixes the minimum and maximum limits for one or several tests, defined by either the user or by default in the software.

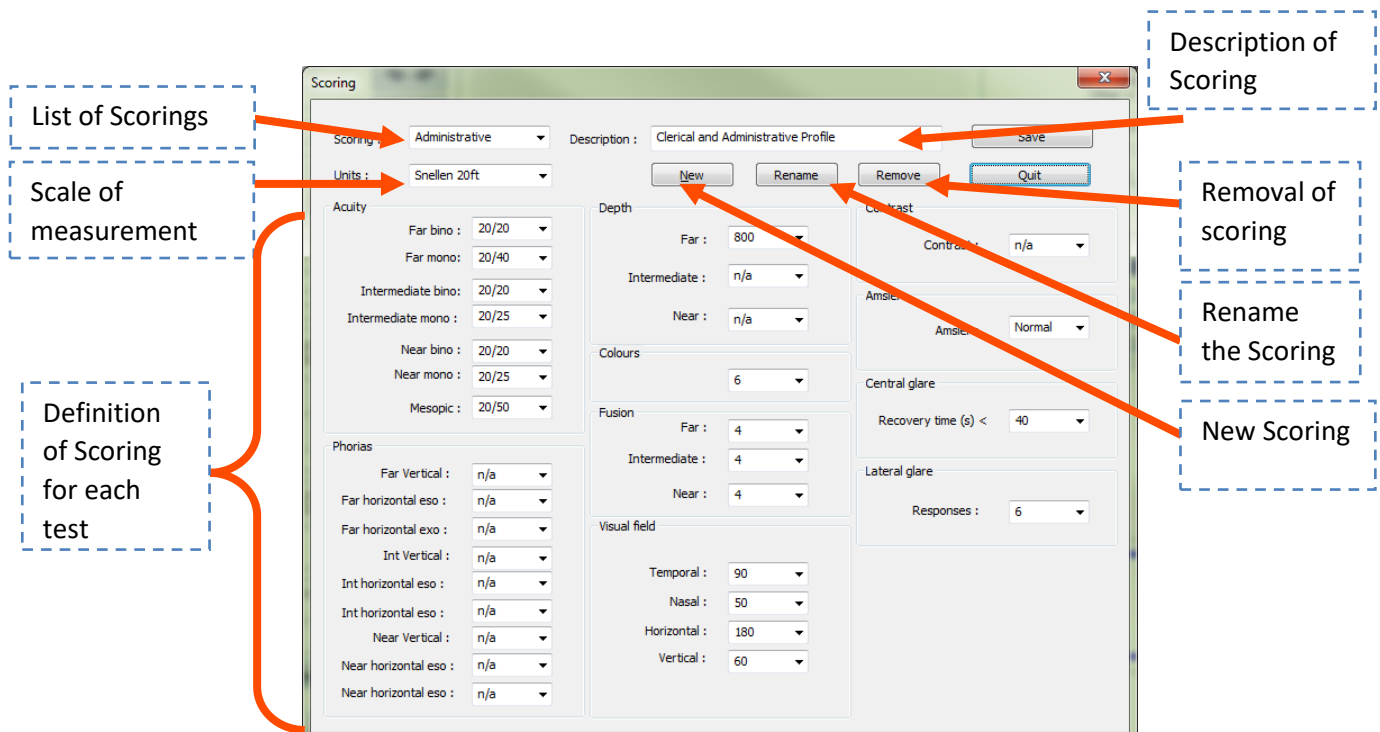
To choose a Scoring, select the sequence chosen in the scrolling list. Then click on the **Active** box.

Click on the ... button to choose the Scoring.



Use the below window to create or edit Scoring.

To edit, create or delete a Scoring, click on the **Edit** button, which opens the Scoring management console.



Use the **OK** button to validate the screen.

4.2.4.3. VisioClick® Settings

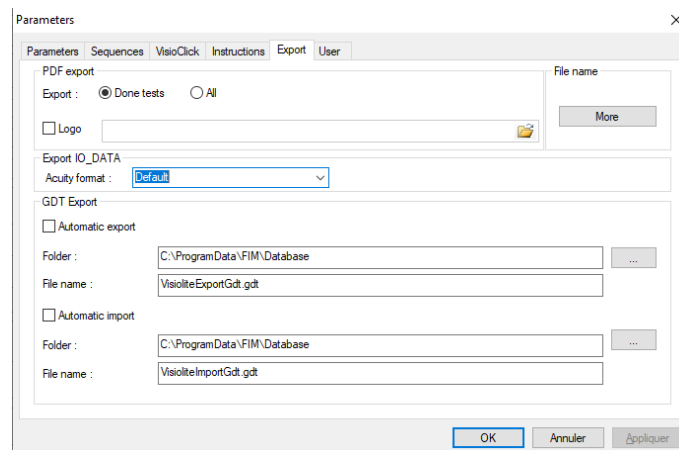
Refer 4.3. VisioClick® Use.

4.2.4.4. Export settings

4.2.4.4.1. Presentation

Export mode exists in several formats to create a file readable by software other than the Visiolite®. Possible exports:

- PDF (Adobe® format)
- GDT (Specific format)
- CSV (Export compatible with Excel)
- Io_Data (Guest mode export)



Only PDF and GDT exports require configuration.

4.2.4.4.2. PDF export

PDF export

Export : ☒ Done tests ☐ All

☐ Logo

File name

More

For PDF export, configure only what the software exports:

- Tests done
- All the tests

The logo that will appear on the PDF file can also be chosen (*e.g. your company logo*).

Click on the **Advanced** button to open a window to parameter:

- Automatic recording (*defined if the recording in PDF is done at the same time as another, standard recording*)
- The backup folder (*define the PDF file recording folder*)
- Name of the file (*define the file name: possibility of using global variables such as:*
 - *[First name]*
 - *[Last name]*
 - *[Date]*
 - *[Time]*
 - *[ID]*

Export

Automatic recording

☒ No

☐ Guest mode

☐ Always

Backup folder

☒ Database

☐ Other ...

File format

☒ VisioliteExport

☐ Fields ...

OK Cancel

4.2.4.4.3. GDT export

The screenshot shows a 'GDT Export' dialog box with two sections. The top section is for 'Automatic export' and the bottom for 'Automatic import'. Each section has a 'Folder' field with a browse button ('...') and a 'File name' field. The 'Folder' fields are set to 'C:\ProgramData\FIM\Database'. The 'File name' fields are 'VisioliteExportGdt.gdt' and 'VisioliteImportGdt.gdt' respectively. Both 'Automatic' checkboxes are unchecked.

GDT export is an export in a specific format. In the configuration of this format, you can choose:

- If the export is done automatically
- The folder of the exported file
- The name of the GDT file exported
- If the import is done automatically
- The folder of the imported file
- The name of the imported GDT file

Note: Do not begin to configure an export if you are not sure of the format used.

4.2.4.4.4. Io_Data export

The screenshot shows the 'Export IO_DATA' configuration dialog box. It has a dropdown menu for 'Acuity format' with a list of options: 'Default', '1/10', 'Snellen 20ft', and 'Snellen 6m'. The 'Default' option is selected. Below this is a 'GDT Export' section with an unchecked 'Automatic export' checkbox.

Io_Data export is an interaction mode with other software.

Acuity format function allows you to choose the acuity type in the export.

- Default
- Tenth
- Snellen 20ft
- Snellen 6m

Please, leave the **Default** choice unless it is necessary. Only an IT engineer is able/authorized to configure this mode.

4.2.4.5. Instructions setting

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.

4.2.4.6. Operator setting

Select the “User” tab to fill the user information. These fields can be printed out.

Relevant fields:

- First name, last name
- Occupation
- Address
- Post code, town
- Telephone number
- Fax number

4.2.5.Database

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

4.2.5.1. Patient identification

- Click "Identification" key.

The following window appears:

The 'Identification' window is a form for entering patient data. It includes the following fields and controls:

- Last name:** Text field with a red asterisk and a search button (...).
- First name:** Text field with a red asterisk.
- Date of birth:** Text field with a red asterisk.
- Age:** Text field with a red asterisk, value '0'.
- Id number:** Text field with a red asterisk and an 'Auto' button.
- Gender:** Radio buttons for 'Male' and 'Female', both with red asterisks.
- Optical correction:** Radio buttons for 'None', 'Glasses', and 'Lenses', all with red asterisks.
- Type:** Dropdown menu.
- Surgery:** Dropdown menu.
- Company:** Text field.
- Position:** Text field.
- Job spec.:** Text field.
- Notes:** Text area.
- Operator:** Dropdown menu with a search button (...).
- Test with correction:** Check box.
- Legend:** Red asterisk = required field.
- Buttons:** 'OK', 'Modify', and 'Cancel' at the bottom.

Fields with a red asterisk are required for recording.

Note: Additional fields created during configuration of the software are placed in this window. Up to five additional fields may be added.

4.2.5.2. Recording

Use "Record" to store the test in progress if all the required 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".

The following screen appears:

The 'Open' window is used for searching and managing recorded tests. It includes the following elements:

- Search section:**
 - By name:** Text field.
 - By ID:** Text field.
 - Between:** Check box.
 - Date range:** Two date pickers (e.g., 07/04/2009 and 08/04/2009).
 - Search button:** To execute the search.
- Buttons on the right:**
 - New exam:** To create a new test.
 - Load exam:** To load an existing test.
 - Erase:** To delete a test.
 - Quit:** To exit the window.

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 identification screen is automatically completed.

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 that tests were recorded. 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. VisioClick® Use

The Visiolite® automation module uses the VisioClick® to perform tests or test sequences in a fully automated way.

Refer to the "VisioClick® User Manual" for connection.

4.3.1. How it Works

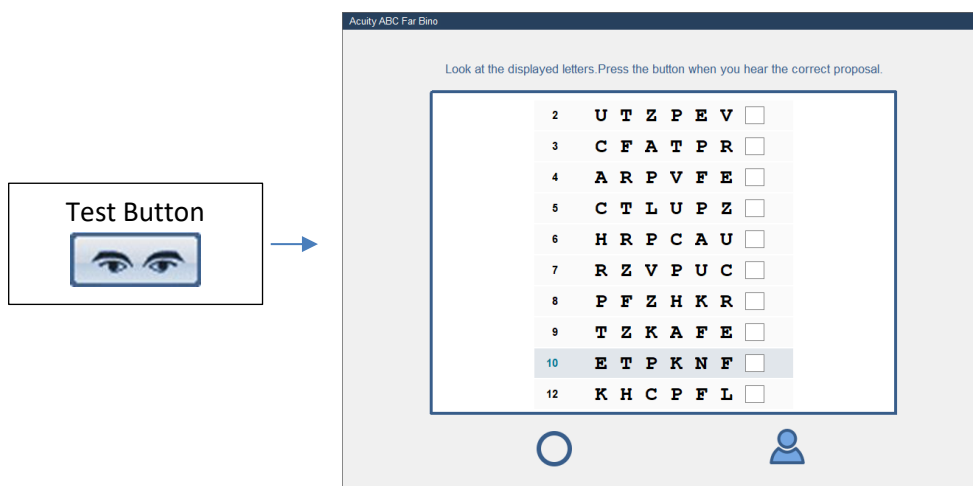
The operator activates the automation, selects a language and adjusts the volume in the toolbar, then runs the automation. The automation module starts tests and manages voice instructions for the patient who responds with the answer button.

4.3.2. Running the Automation

When the Automation button on the toolbar is pressed, any action to launch a test or sequence will go through the automatism. Two modes are then possible:

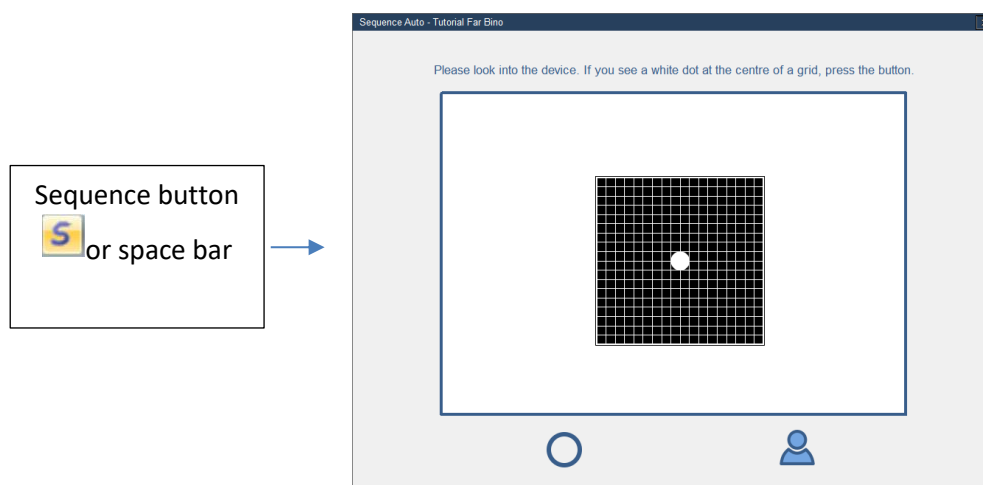
4.3.2.1. Test Mode

The operator clicks on a test, e.g. Binocular Visual Acuity button. The automation module will perform an automatic binocular visual acuity test.



4.3.2.2. Sequence Mode

The operator clicks on the Sequence button (or space bar). The automation module will perform the entire sequence automatically, test by test.



4.3.3. Vocal Instructions, Status Indicators and Buttons

Vocal Instructions

A large text area displays the current vocal instruction in the software language (which may differ from the vocal instructions language).

VisioClick® Status Indicator



VisioClick® not detected



VisioClick® detected, button released



VisioClick® detected, button pressed

Note: if there is loss of communication with the VisioClick® (failure, removal...) a dialog box informs the operator and the automated system is stopped.

Visiolite Status Indicator



Visiolite not detected



Visiolite detected, patient not detected



Visiolite detected, patient detected

Play/Pause/Replay button (sequence mode only)



1 click => start the sequence



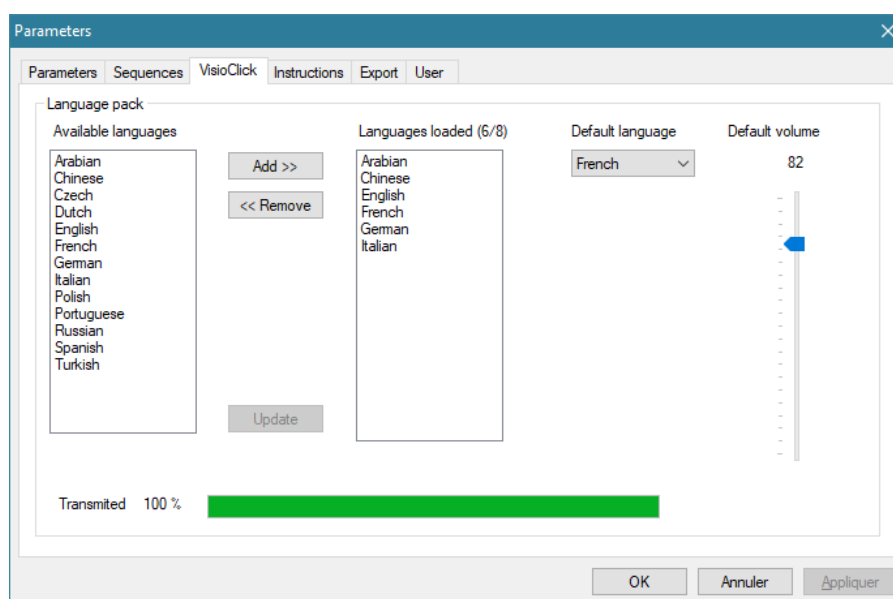
1 click => pause



1 click -> restart current test

4.3.4.Automation Settings

Modify automation settings with VisioClick® in this window.



4.3.4.1.1. Language Pack

VisioClick® is delivered with a number of preloaded languages. Other languages are available on the computer. Add or remove them from this window.

Select languages to add or remove, and use the "Add" and "Remove" buttons. Then click "Update" to update the VisioClick®.

4.3.4.1.2. Default Language

The default language is the one used by VisioClick® when it is switched on. Select the default language and click "Update".

4.3.4.1.3. Default Volume

The default volume is the one that VisioClick® uses when it is switched on. Set the default volume and click "Update".

4.3.5.VisioClick® indicator in the status bar



VisioClick® not detected



VisioClick® detected, Jack not detected



VisioClick® detected, Jack detected

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®.



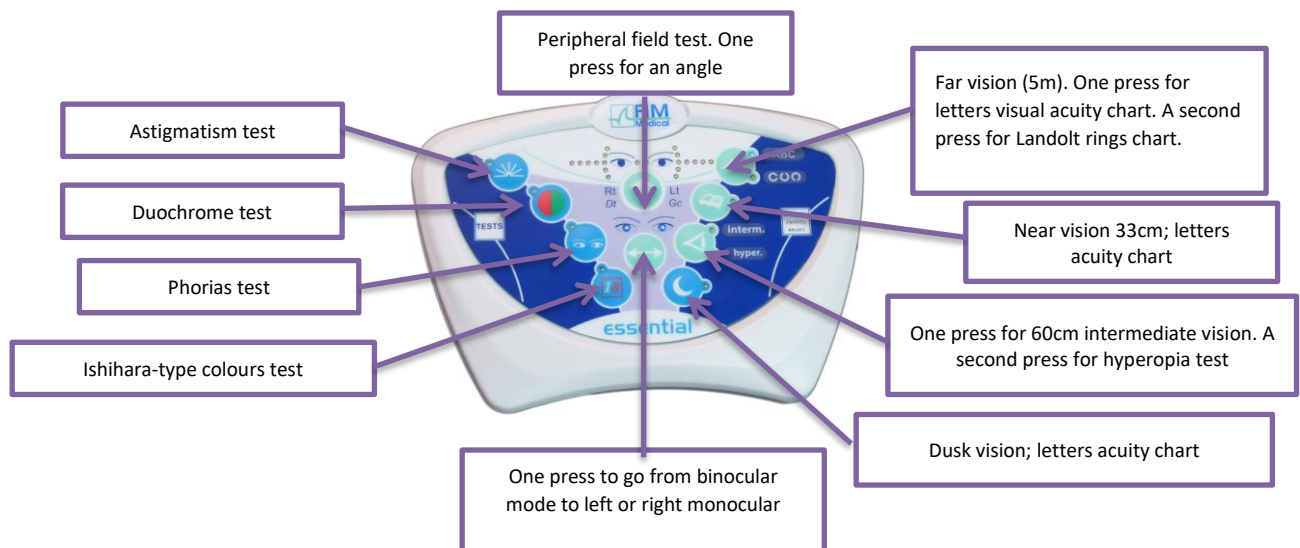
The remote control lead connector is an RJ11 type. Click the connector into the intended socket.

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.

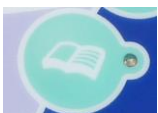
The right side of the remote control is for visual acuity tests. The left part is for extra tests.



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:



Binocular



Left monocular

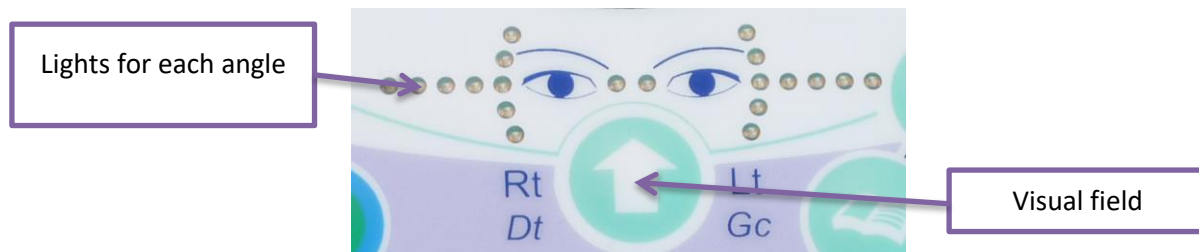


Right monocular

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.

QUESTIONS

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®.

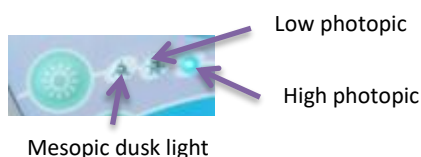
As soon as the RJ11 plug and the mains are connected, the remote control LCD screen lights up and displays a mode of use for the Visiolite®. The Visiolite® is ready for operation after a few seconds of initialisation.



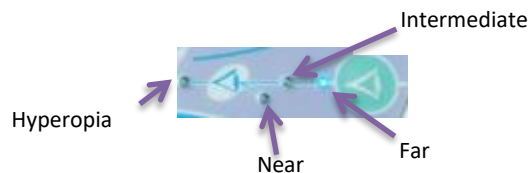
4.5.1.Keys

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

- Lighting



- Distance

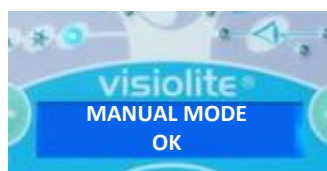


4.5.2.Forehead presence

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

4.5.3.Begin a test

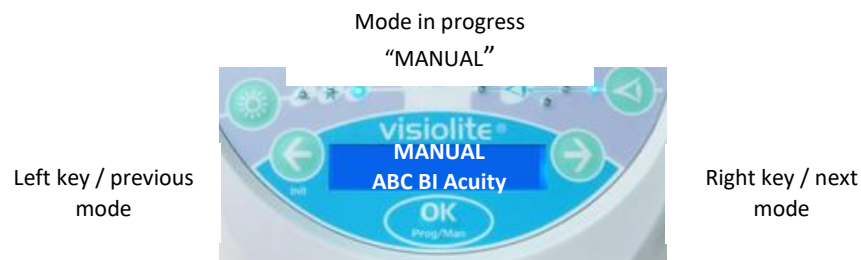
As soon as it is switched on, the last mode used appears.



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.

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 Essential Form

Identification No: _____ Test date: ____/____/____ Time: ____/____/____ Tester: _____
 Last name: _____ First name: _____ Date of birth: ____/____/____ Gender: ☐ Female ☐ Male
 Company: _____ Position: _____ Risk: _____
 Optical Correction: ☐ None ☐ Glasses ☐ Lenses Test done with correction: ☐ Yes ☐ No
 Glasses type: ☐ Single focal ☐ Bifocal ☐ Trifocal ☐ Progressive ☐ Other: _____
 Eye surgery: ☐ Yes ☐ No Eyes, what?: _____
 Comments: _____

(Only areas = tested responses)

Distance	A	B	C	Test	Visual Acuity (10°)
 Far Vision 5m	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	2 4 5 6 8 10 12
 Intermediate vision 40cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	2 4 5 6 8 10 12
 Near Vision 33 cm	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	R L 	2 4 5 6 8 10 12

* Check visual acuity in vision of day with a ● and visual acuity in night vision with a X.

Amesbury

☐ Failed

R	L	Red	Green	Identical
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Hypertropia (H) display

☐ Failed

R L Clear Vision

Hyperopia

☐ Failed

4 = Esophoria
5 = Orthophoria
6 = Exophoria
Other = Hyperphoria

☐ Failed ☐ Off grid

1	2	3
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	5	6
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	8	9
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Dyschromatopsia

☐ Failed

R L

Peripheral field

Right eye Left eye

Conclusion: _____

5. Tests Description

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 several levels of visual acuity (several 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: 2, 3, 4, 5, 6, 7, 8, 9, 10, 12 (depending on the equipment) 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.

Letters

Binocular Acuity

2	U T Z P E V
3	C F A T P R
4	A R P V F E
5	C T L U P Z
6	H R P C A U
7	R Z V P U C
8	P F Z H K R
9	T X E A F E
10	E T P E N F
12	K A P P F L

Monocular Acuity 1

2	K R U C T N
3	V Z A U J F
4	Z N V K C U
5	R P L V F T
6	J K N T U P
7	T N F E P R
8	F V T K Z A
9	A J R A L U
10	T U J P F U
12	K A P J A A

Monocular Acuity 2

2	C H V F R L
3	A Z R H U J
4	K C L R H E
5	A U J T P H
6	N J V R Z K
7	L F A V C J
8	J E L H V E
9	K A E R T H
10	E T A P E Y
12	V A L A C A

Numbers

2	8 2 0 3 4 6
3	0 5 4 7 2 8
4	7 3 2 8 9 0
5	9 4 6 3 7 5
6	8 0 3 2 0 4
7	2 5 0 3 6 9
8	0 3 2 4 7 9
9	0 4 4 2 0 7
10	8 7 0 5 4 0
12	4 7 7 7 0 0

2	8 7 2 9 3 0
3	3 2 8 5 9 7
4	2 5 3 0 4 8
5	6 2 5 3 7 4
6	8 0 4 2 6
7	4 2 5 9 0 3
8	0 3 0 5 4 7
9	2 7 1 4 6 0
10	0 0 4 7 0 0
12	0 0 0 0 0 0

2	0 2 4 3 8 5
3	3 8 0 9 4 2
4	4 5 2 0 6 8
5	7 6 9 2 8 0
6	9 8 3 2 0 7
7	5 2 8 4 0 0
8	0 0 5 5 4 2
9	4 2 8 6 3 7
10	9 3 4 6 9 9
12	0 0 0 0 0 0

Landolt

2	0 0 0 0 0 0
3	0 0 0 0 0 0
4	0 0 0 0 0 0
5	0 0 0 0 0 0
6	0 0 0 0 0 0
7	0 0 0 0 0 0
8	0 0 0 0 0 0
9	0 0 0 0 0 0
10	0 0 0 0 0 0
12	0 0 0 0 0 0

2	0 0 0 0 0 0
3	0 0 0 0 0 0
4	0 0 0 0 0 0
5	0 0 0 0 0 0
6	0 0 0 0 0 0
7	0 0 0 0 0 0
8	0 0 0 0 0 0
9	0 0 0 0 0 0
10	0 0 0 0 0 0
12	0 0 0 0 0 0

2	0 0 0 0 0 0
3	0 0 0 0 0 0
4	0 0 0 0 0 0
5	0 0 0 0 0 0
6	0 0 0 0 0 0
7	0 0 0 0 0 0
8	0 0 0 0 0 0
9	0 0 0 0 0 0
10	0 0 0 0 0 0
12	0 0 0 0 0 0

Low vision
Specific aptitude
test for vehicle
driving

0.5	U P N
1	K F C Z U

0.5	V F Z
1	N T H L C

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.

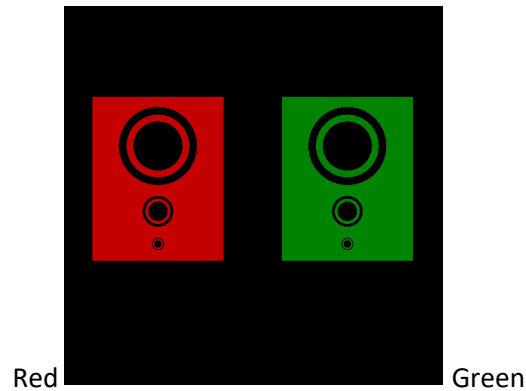
The acuity level of this test is constant (3.2 /10). Only the contrast decreases with each letter, from 100 to 1.2 %.

5.2.2. Patient instructions

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

- Check the response

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.

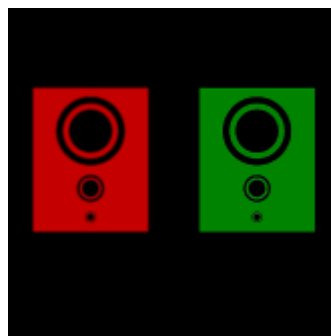
Clearer vision (or blacker) on a red or green background indicates ametropia.

5.3.3. Patient instructions

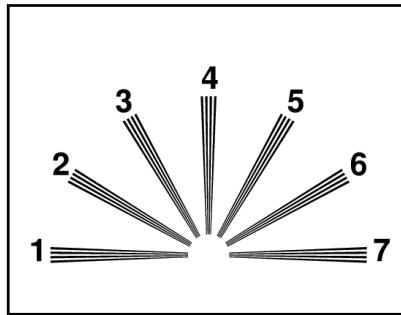
“Are the black circles clearer, or blacker, in the green or the red, or are they the same?”

- Note the response on the response form.

5.3.4. 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.

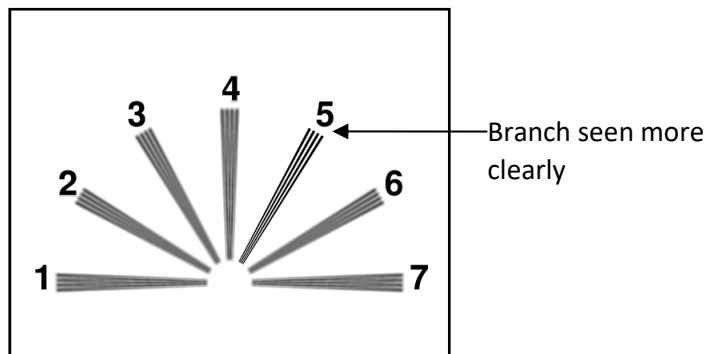
The operator should look at each of the branches consecutively.

5.4.4.Patient instructions

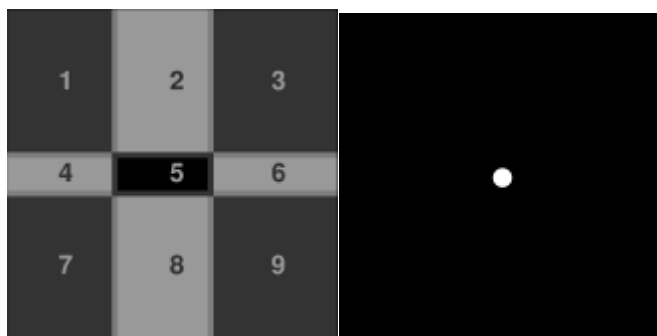
Are some of the lines blacker or clearer?"

- Note the responses on the response form.

5.4.5.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.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 neutralization of one of the images by the brain, the two images should superimpose.

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

5.5.3.Patient instructions

“In which direction is the dot moving?”

- Note the area number on the response form.

➡ 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.

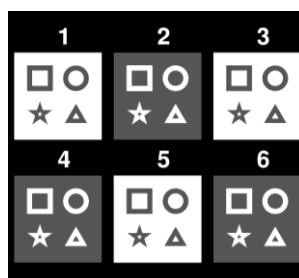
➡ Caution

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. 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.

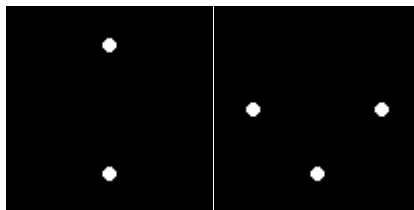
Box	1	2	3	4	5	6
Disparity (in arcseconds)	1600"	800"	400"	200"	100"	50"
Expected responses	Triangle	Circle	Star	Square	Star	Circle

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.
- Validate the check box on the software if the correct shape has been perceived

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. Failure of this test signifies anatomical impossibility of convergence, which is found in extreme cases of strabismus. 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.

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

5.8.1.Purpose

Screening for central visual field deficiency.

5.8.2.Definition

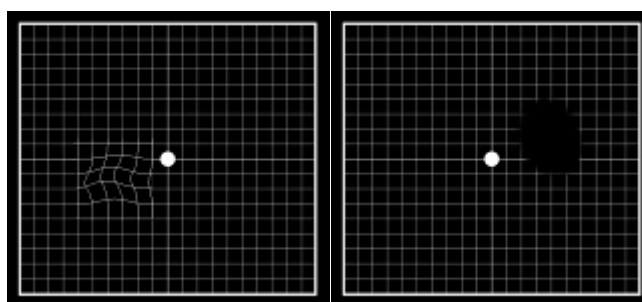
The test is composed of a grid on a black background with a central white dot. The user should focus on the central white dot.

5.8.3.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.

5.8.4.Perception examples



5.9. Color 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 color 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 colors 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. Color perception is checked using 6 distinctly numbered boxes. Each box, or plate is composed of a matrix of dots of variable height, shade and color. Areas of similarly-colored dots are defined to form numbers. A number composed of two digits appears in each box. Colors are chosen so that an abnormality in the perception of colors makes it difficult to recognize 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.

5.9.3.Patient instructions

“Read the colored numbers in each box”.

- Note the response on the response form.

5.10. External and central visual field test

The Visiolite offers two types of visual field tests: external and central visual fields.

Definitions

5.10.1. External visual field

Area from temporal horizontal field to nasal horizontal field for each eye, and from left temporal to right temporal for both eyes. Area of vertical field.

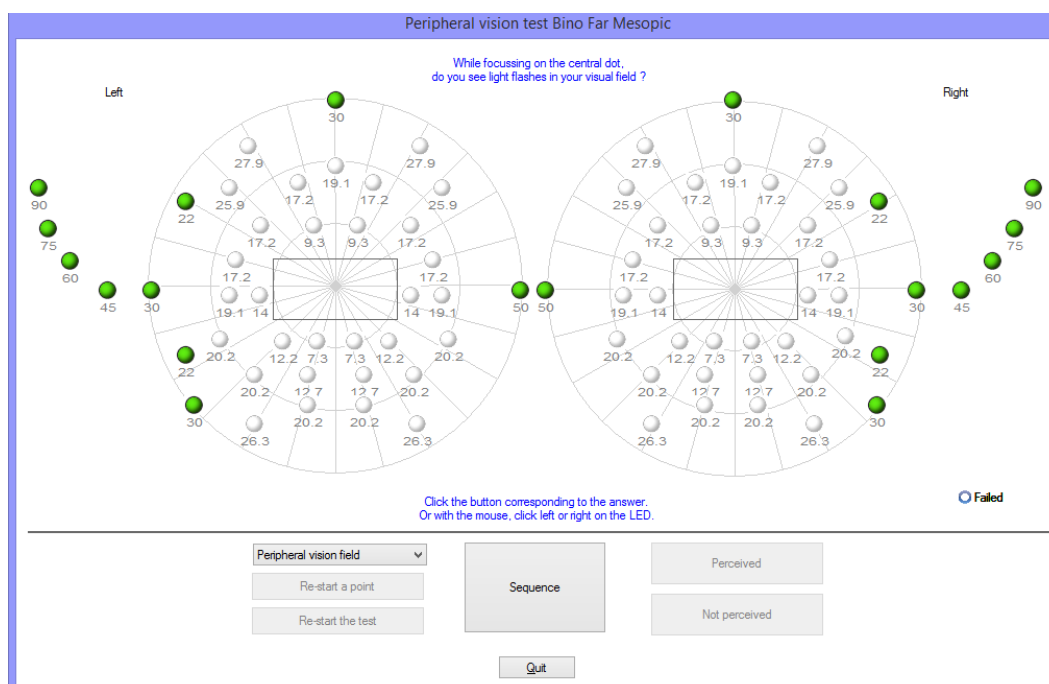
Horizontal field features

Angles tested on temporal side	90°, 75°, 60°, 45°, 30°
Angles tested on nasal side	50°
Total for one eye	140°
Total binocular	180°

Vertical field features

Angles tested	30°, 22°, -22°, -30°.
---------------	-----------------------

Arrangement of external field stimuli



5.10.1.1. Purpose

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

5.10.1.2. Use in manual mode

Select the test from the list. Click on the stimulus to test.

Click the «detected» or «not detected» button depending on whether the patient detects the stimulus or not.

5.10.1.3. Use in automatic mode

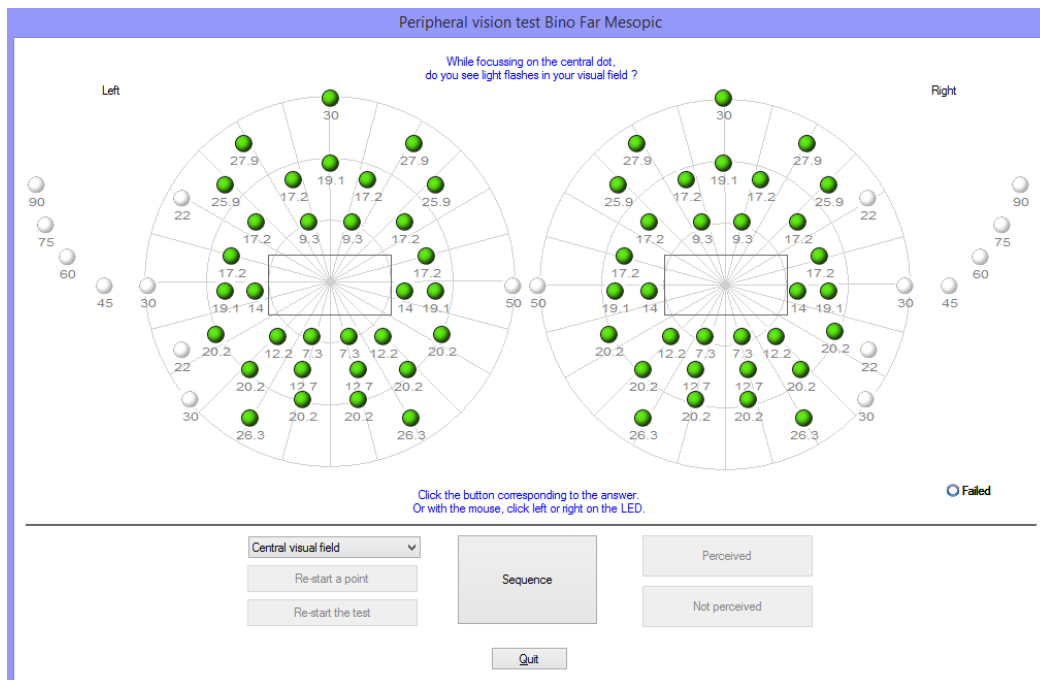
Select the test from the list, then click «sequence» to run the automatism. When the patient responds, click the «detected» button. If the patient does not detect the stimulus, click the «not detected» button.

NB: The sequence of the external field test is semi-random. The programme tests firstly the points furthest from the eye, then closest to it. The test stops when the visual field area of each eye is measured.

5.10.2. Central visual field

- Detects visual defects in a given radius (10°, 20°, 30°).

Arrangement of central field stimuli



5.10.2.1. Purpose

Measures aptitude for vehicle or engine driving. An evaluation of the amplitude of the integrity of the central visual field is required by certain laws (road rules).

5.10.2.2. Use

Select the test from the list and click «sequence» to run the automatism. When the patient responds, click the «detected» button. If the patient does not detect the stimulus, click the «not detected» button.





5.10.3. Patient instructions

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

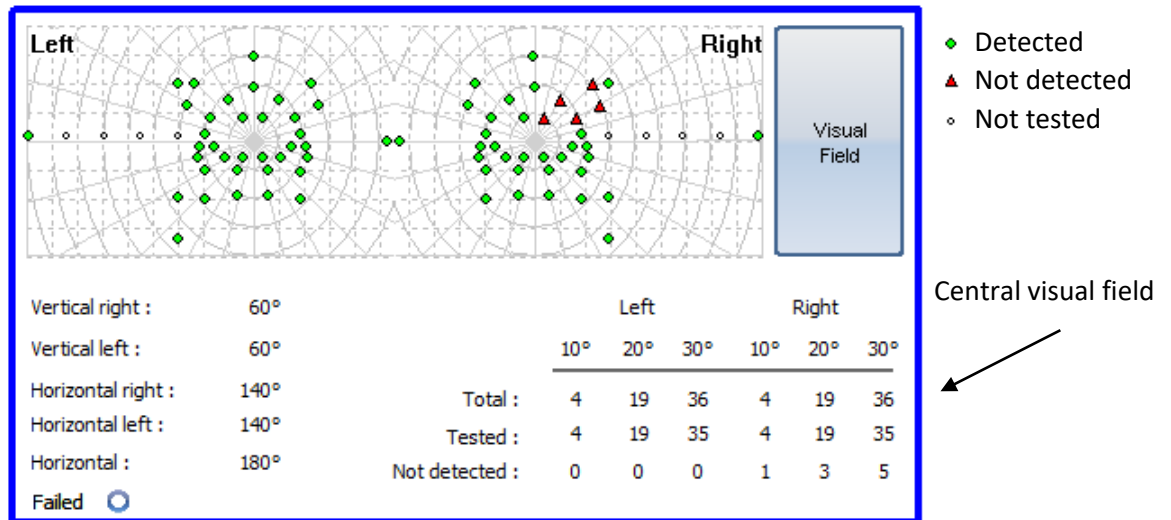
➤ Note the response on the response form.

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

5.10.4. Significance of stimuli in the test window

-  Detected
-  Not detected
-  Not tested
-  Not part of the sequence

5.10.5. Results

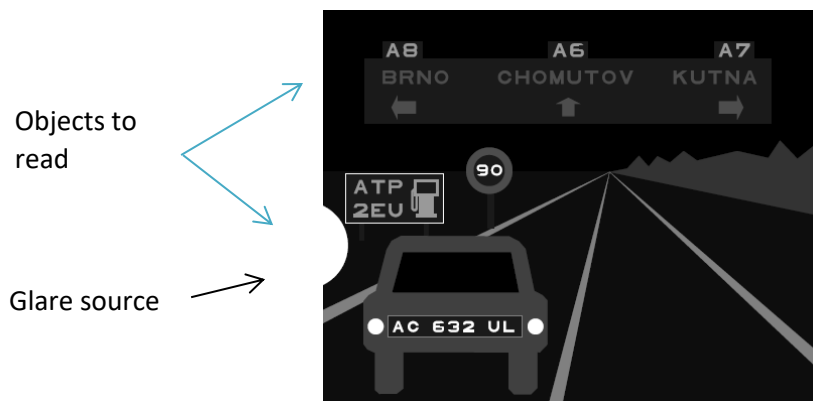


5.11. Glare sensitivity test (*Master-GT version*)

- ➡ **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

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

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 § 0. This test measures the recovery time of the patient's vision when submitted to a high source of light.

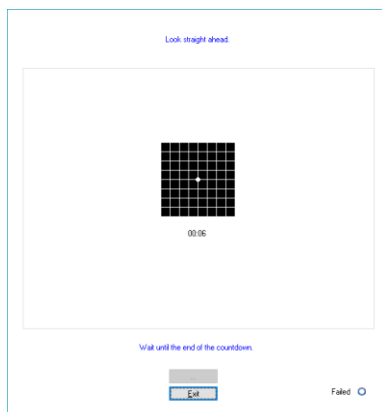
5.12.2. Principle

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.

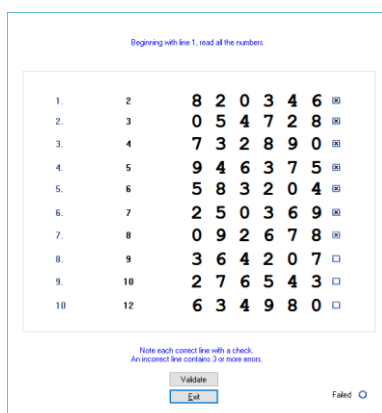


5.12.3. Patient instructions

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



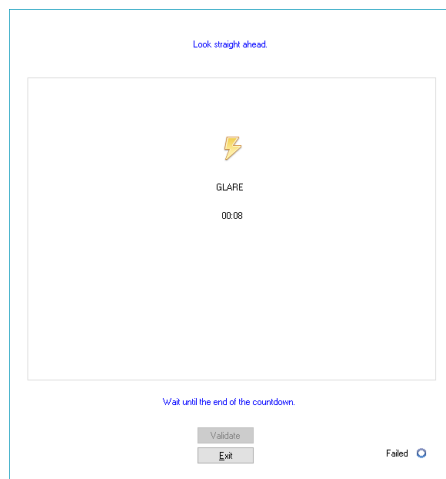
Patient adaptation in mesopic light over ten seconds.



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

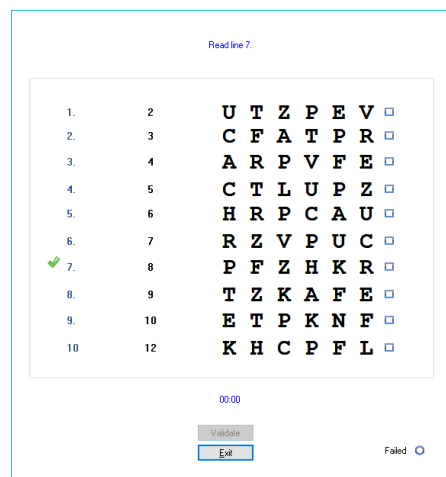
The operator notes the best patient acuity.

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



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.

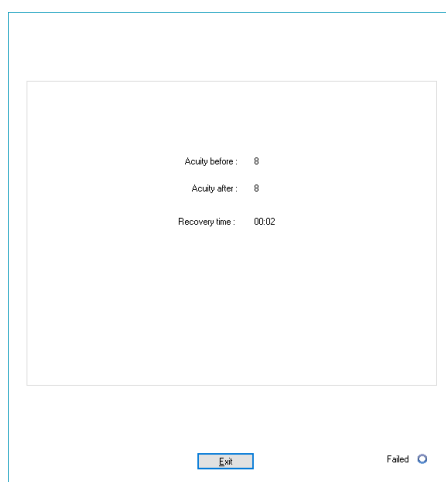


Final test phase.

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 memorization of the first test performed.

The operator notes the best acuity.

Note: Do not continue longer than two minutes.



Results.

6. Cleaning and Maintenance

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 MEDICAL 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.

6.5. List of generic bactericidal fungicidal products validated by FIM MEDICAL

Due to the wide range of brands and references of decontamination wipes available on the market, the company FIM MEDICAL has validated some references for its products that will not alter the aspect or the resistance of the housing plastics of its devices.

The company FIM MEDICAL validates the use of the following wipes or cloths for the decontamination of its products:

- Isopropyl alcohol 70 %
- Bactynil® Disinfectant wipes
- Clorox® Healthcare Bleach
- Super Sani Cloth®
- Mikroqid® AF wipes
- Mikroqid® Universal wipes premium

6.6. Annual service

The manufacturer recommends carrying out an annual check of the device by the manufacturer or its authorized distributors.

Maintenance is recommended every 3 years to maintain device performance.

Standard annual maintenance operations:

- ▶ Complete cleaning and functional test.
 - ▶ Calibration of LEDs for glare test (with Luxmeter and its support). These LEDs are located on the motherboard and can be setup with the TestVisiolite software.

Maintenance operations every 3 years:

- ▶ Change collapsible mirror belt
- ▶ Change band

Only FIM Medical or its approved distributors are authorized to carry out annual checks on its Visiolite® devices.

6.7. Guarantee

Within the framework of the contractual guarantee of two years, 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.

6.8. Lifetime

The lifetime of the VISIOLITE® is determined at 8 years on the condition that the user carries out the required maintenance as outlined in the above maintenance section.

FIM Medical will not be held liable for any degradation of performance in the case of failure to carry out these required maintenances.

7. Available accessories

7.1. LCD remote control

The company FIM MEDICAL has developed a remote control that enables the Visiolite® to be driven in a simplified manner without the use of software and a computer. With the remote control you can switch visual tests and control parameters.

Should you require a remote control, please contact the company FIM MEDICAL or your distributor.

7.2. VisioClick®

The company FIM MEDICAL has developed the VisioClick® box in order to automate the VISIOLITE® vision device. The functional principle of this device is to give vocal instructions to the patient via an audio headset, take the responses into account via a push button and relay the communication between the PC and the FIM MEDICAL screening device.

Should you require a VisioClick®, please contact the company FIM MEDICAL or your distributor.

7.3. Trolley case

The company FIM MEDICAL has developed a padded trolley case for transportation of the Visiolite®.

Should you require a trolley, please contact the company FIM MEDICAL or your distributor.

7.4. Face cover

FIM MEDICAL has specifically developed single-use hygienic face covers for use with the Visiolite®.

Caution: These single-use hygienic face covers must be replaced systematically between each patient. If the covers are not changed and reused between two patients, there is a risk of cross-contamination (bacterial or viral) when they come into contact with the face.

If you would like to purchase the single-use hygiene covers, please contact FIM MEDICAL or your distributor. Different packs are available.

7.5. Dust cover

FIM MEDICAL has developed a protective cover for the Visiolite®.

If you would like to purchase a trolley case, please contact FIM MEDICAL or your distributor.

8. What To Do If?

8.1. No noise when switched on

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

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

- Check USB connection and driver installation.

8.3. Error message appears at recording

8.3.1. *"Identification incomplete"*

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

8.3.2. *"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.

8.4. Patient identification file found but not the tests

- Click "+" on the left of the patient's name in the "Open" dialogue box.

8.5. Visiolite® light does not come on

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

8.6. Glare and motor drive seem weak

- Check you are using the recommended power plug.



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



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