VISUAL SCREENER

USER MANUAL

VISIOLITE® 4K

CE

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FIM Medical

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1. Information regulatory

1.1. Safety Warnings

Do not use Visiolite® 4K in a non-medical setting.

Do not disassemble the device or work on internal components.

Do not use Visiolite® 4K in an explosive atmosphere or in the presence of anesthetic gases.

Use only the power supply and accessories supplied with the Visiolite® 4K to ensure performance and safety.

Visiolite® 4K should not be immersed or sprayed with liquid to be disinfected.

Visiolite® 4K must be placed on a flat and stable surface.

The Visiolite® 4K is a fragile optical device and must be transported in the FIM Medical trolley or, failing that, in its original packaging to protect it from vibrations and shocks.

Before putting Visiolite® into service 4K, please take the necessary time to ensure that the equipment is gradually adapted to the temperature and humidity conditions of use specified in paragraph 2.3.1, especially when transitioning from storage or transport to direct use, in order to ensure optimal operation and avoid any risk of damage.

1.2. Use planned

The Visiolite® 4K is a computerized vision device for screening visual disorders. The patient can be a child aged 5 years and over or an adult (male or female).

1.3. Operators planned

Visiolite® 4K must be used exclusively by healthcare professionals who are qualified to interpret the results and ensure compliance with hygiene and bacterial contamination rules. The delivery of results must always be accompanied by a medical explanation.

Visiolite® 4K should not be used for medical prescription purposes and can in no case give rise to a drug prescription or a pre or post surgical diagnosis. Only a specialized doctor can confirm and corroborate the results obtained with Visiolite® 4K by other examinations in order to prescribe a correction or surgical intervention.

1.4. Medical contraindications

Visiolite® 4K glare tests should not be performed on patients who are photosensitive, have recently taken photosensitizing medication (examples given in Table 1), have undergone eye surgery or trauma in the last 3 months, or suffer from one of the following pathologies: albinism, cystinosis , keratoconjunctivitis , ocular inflammation.

If in doubt, a doctor's advice is essential before carrying out a glare test.

If there is any discomfort or pain in the eye, the test should be stopped.

Table 1Non-exhaustive list of examples of photosensitizing drugs

Antibiotics	**Antifungals**	**Antidepressants**
Doxycycline Ciprofloxacin Levofloxacin Sulfamethoxazole	Griseofulvin Voriconazole	Amitriptyline Imipramine Sertraline
Antihistamines	**Non -steroidal anti- inflammatory drugs**	**Diuretics**
Diphenhydramine Promethazine	Ibuprofen Naproxen Piroxicam	Hydrochlorothiazide Furosemide
Drugs cardiovascular	**Drugs psychotropic drugs**	**Drugs antidiabetics**
Amiodarone Nifedipine Quinidine	Chlorpromazine Thioridazine	Glipizide Glibenclamide or glyburide

1.5. Benefits clinics and risks

The performance, multiplicity of visual tests and compliance with ISO 8596 of Visiolite® 4K ensure a qualitative clinical benefit in screening for different visual disorders for the patient.

There is no limitation on the number of examinations performed per patient with the Visiolite® 4K and therefore no risk associated with its use.

1.6. Incidents or risks of serious incidents

In the event of an incident or risk of a serious incident related to the device, healthcare professionals or users may make a declaration to the competent authorities of the Member State of the European Union. In all cases, the manufacturer must be notified as soon as possible in order to declare and process the materiovigilance case.

2. Technical information

2.1. Materials provided

Visiolite® 4K device :

- Removable front support
- IEC60601 Medical External Power Supply (Part No. Globtek GTM41060-2512)
- Microfiber cloth for cleaning glasses
- USB Type C to Type A Cable
- VisioWin® software (computerized version)
- Fact Sheet
- Remote control and CD input block (Only for remote control version)
- Optional: VisioClick®, a USB Type A to B cable, an Audio headset, a carrying case

2.2. Device Overview

Visiolite® 4K is a medical device for screening for various visual function disorders such as: ametropia, hyperopia, presbyopia, myopia, astigmatism, AMD, diplopia or dyschromatopsia.

The principle of the device is to display images to the patient (tests). Depending on what the patient perceives, it is possible to detect visual deficiencies.

The tests require the patient's visual function in near, far, intermediate and hyperopia (+1 δ) vision. Different distances are available for each vision depending on the configurations (see optical focal lengths in paragraph 2.3.1).

Tests can be performed using either monocular vision (right or left) or binocular vision. Limitations may apply to individual tests.

The Visiolite® 4K also allows visual tests to be carried out at different lighting levels:

- Photopic lighting (160 cd/m² adjustable on patient request to 80 cd/m²)
- Mesopic lighting (low brightness of 3 cd/m²)

The device operates in two control modes:

- Autonomous in remote controlled version
- Interface in computerized version

Designed to be as ergonomic as possible, the Visiolite® 4K is equipped with a head presence sensor that detects the positioning of the patient's forehead. Once the patient is correctly positioned, the examination can begin.

The Visiolite® 4K offers you the following advantages:

- Ergonomics of use and transport, in remote-controlled or computerized version
- Fast startup and execution
- Highly configurable and automatable
- Highly interfacable with major business software

The examination can be carried out independently by the patient using the VisioClick® accessory sold as an option. This automation accessory works using voice instructions broadcast via an audio headset to which the patient responds via a push button.

1	Removable forehead support and patient head presence detection zone
2	Retractable goggle for central visual field testing
3	Optics for distance and intermediate vision testing
4	LED series for peripheral visual field testing
5	Optics for near vision testing
6	Ergonomic nasal location
7	Non-slip weighted foot to ensure the stability of the device
8	Location of connectors and on/off switch
9	Remote control with 7'' touch screen (Only for the remote control version)
10	VisioClick® response box with headset support
11	Automated option: Headphones on their stand
12	Automated option: Single-use hygienic caps

2.3. Technical characteristics

2.3.1. Features of the computerized or remote-controlled Visiolite® 4K

<table>
<tr><td>Screen display</td><td colspan="4">TFT-LCD 5.46'' 4K 2160p (3840x2160)</td></tr>
<tr><td>Backlight type</td><td colspan="4">Double (2 x 12 LED)</td></tr>
<tr><td>Brightness levels</td><td colspan="4">Photopic 80 or 160 cd/m²
Mesopic 3 cd/m²</td></tr>
<tr><td>Focal lengths optics</td><td colspan="4">Depending on the versions:
<table>
<tr><td>Near vision</td><td>Intermediate vision</td><td>Distance vision</td></tr>
<tr><td>33.00 ± 0.25 cm
14.0 ± 0.1”
16.0 ± 0.1”</td><td>60.0 ± 0.5 cm
80.0 ± 0.5 cm
24.0 ± 0.2”</td><td>5.0 ± 0.1 m
20.0 ± 0.4 ft</td></tr>
</table>
Lenses for hyperopia: +1 diopter</td></tr>
<tr><td>Connectivity</td><td colspan="4">USB Type C / RJ45</td></tr>
<tr><td>Power supply unit</td><td colspan="4">Input: 100-240V AC / 50-60Hz / 0.6A
Output: 12V DC / 24W Max / 2.08A Globtek GTM41060-2512
Cable length : 2.99m</td></tr>
<tr><td>Protection level</td><td colspan="4">Medical with 2 levels of patient protection (2 x MOPP cf. EN60601-1)</td></tr>
<tr><td>Class electric</td><td colspan="4">II</td></tr>
<tr><td>Screen remote</td><td colspan="4">TFT-LCD 7'' 800x480 Capacitive touch</td></tr>
<tr><td>Cable remote</td><td colspan="4">USB Type C / Cable length: 2.10m</td></tr>
<tr><td>Remote control power supply</td><td colspan="4">5V DC / 2.5W Max / 500 mA</td></tr>
<tr><td>Storage temperature</td><td colspan="4">-10 to 60°C</td></tr>
<tr><td>Temperature of use</td><td colspan="4">15 to 35°C</td></tr>
<tr><td>Reference standards</td><td colspan="4">NF EN ISO 13485, EN 60601-1, EN 60601-1-2, IEC 60601-1-6, EN 62366-1, EN ISO 10993-1, EN ISO 10993-5, EN ISO 10993-10, NF EN ISO 14971, EN 62304/A1, EN ISO 15223-1, ISO 8596, ANSI Z80.21, NF EN ISO 15004-2</td></tr>
<tr><td>Class medical</td><td colspan="4">I</td></tr>
<tr><td>Safety class software</td><td colspan="4">A</td></tr>
<tr><td>GMDN Code</td><td colspan="4">65177</td></tr>
<tr><td>Part applied patient</td><td>Front support</td><td colspan="3">Type B</td></tr>
<tr><td>Dimensions</td><td>50x27x25cm</td><td>Visiolite® 4K packaged</td><td>19x13x4cm</td><td>Remote</td></tr>
<tr><td>Weight</td><td>4.5 kg</td><td>Visiolite® 4K alone</td><td>0.475 kg</td><td>Remote</td></tr>
</table>

2.3.2. VisioWin® software

Software VisioWin®	Minimum configuration	Recommended configuration
Operating system	Windows 7, 8 or 8.1	Windows 10 or 11
Processor	Pentium IV 2.8GHz	Intel Core i3 or higher
Architecture	64 bits	64 bits
Memory	2GB RAM	4GB RAM
Disk space	16GB	20GB
Graphics card	256MB	512MB
Resolution Monitor	1024x768	1920x1080

2.3.3. Features specific to VisioClick®

Tension	5VDC (via USB port)
Power	2.5W maximum
Output impedance	16 Ω - 32 Ω
Audio connector	3.5mm 3-pole stereo (TRS) audio jack
Headphone cable length	1.2 m
Frequency range	20 Hz - 20 KHz
Class medical	I
Safety class software	A
Part applied patient	Headphone earpiece bonnet Type BF
Material helmet bonnet	Non-woven polypropylene 35g/m² biocompatible
Dimensions	25x14x5cm Response box only (excluding support and headset)
Weight	0.475kg Case only 0.700 kg Cable , stand, headset included

2.4. Passivity electromagnetic

Visiolite® 4K meets the requirements of EN 60601-1-2 regarding electromagnetic compatibility of medical devices.

The electronic design of the Visiolite® 4K ensures the immunity of the display screen to surrounding electromagnetic disturbances.

The proximity of radiofrequency devices therefore does not affect the reliability of the display of visual impairment screening tests.

2.5. Symbols


Non-ionizing electromagnetic radiation (Wifi 2412 MHz - 2484 MHz)


CE marking MDR 2017/745


Type B applied part


Must not be disposed of as unsorted waste , but treated in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive


Consult the manual user

Device medical

Serial number


Manufacturer Identification


Date of manufacture


Do not reuse. Single use only.

Lot number

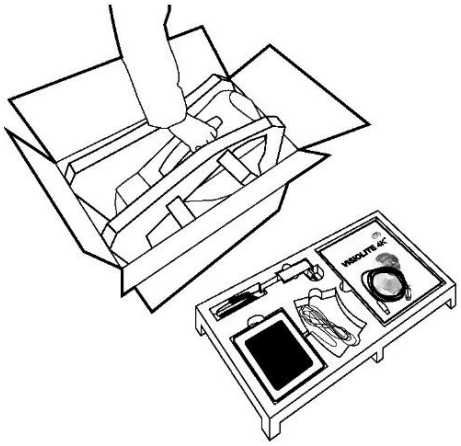
Storage temperature between -10 and 60°C


Deadline of use

3. Installation of Visiolite® 4K

3.1. Unpacking the device

To access the Visiolite® 4K , open the box and remove the compartmentalized foam tray which contains the equipment listed in paragraph 2.1.
Lift the Visiolite® 4K by the handle.



The cardboard, foam cushioning and cables must be kept for maintenance shipments.

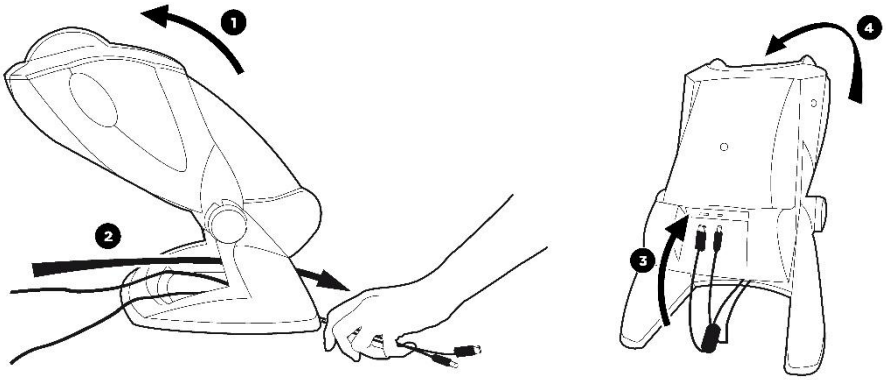
3.2. Connecting the cables

Tilt the appliance into the plug-in position.
Pass the cables through the back between the foot and the body of the Visiolite® 4K.

Computerized version:
Connect the Type C connector of the USB cable to the Visiolite® 4K then the power supply cable.

Connect the Type A connector of the USB cable to the PC where the VisioWin® software is installed

Remote controlled version:
Connect the Type C connector of the remote control cable to the Visiolite® 4K then the power supply cable.
The remote-controlled Visiolite® 4K is then ready for use.



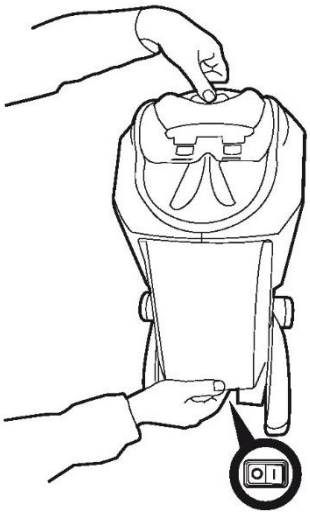
Use only the power supply and accessories supplied with the Visiolite® 4K to ensure performance and safety.

Visiolite® 4K must be placed on a flat and stable surface.

3.3. Computerized version: First start and access to the VisioWin® installer

The VisioWin® software download link is provided in the Information Sheet supplied with the device.

Once the Visiolite® 4K is connected to the PC, it is also possible to access the VisioWin® software installation executable file or the PDF version of the user manual by pressing the front support immediately after switching on the device. The Visiolite® 4K is then recognized as a mass storage device by Windows, which opens a folder in the file explorer.
Please note that the time to copy the installation file may be longer than by internet download.



3.4. Computerized version: Installation of VisioWin® software

Administrator rights are required to install VisioWin® software.

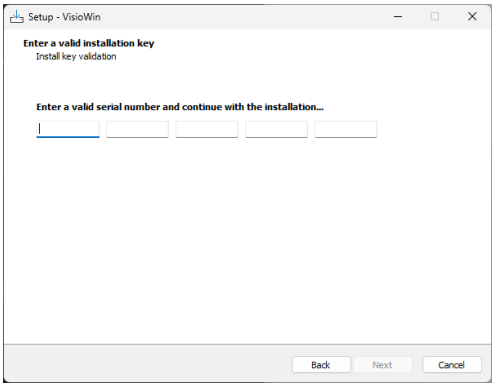
Run the retrieved SetupVisioWin.exe installation file as instructed in paragraph 3.3.

Select the language of the installation wizard.

VisioWin® software can be used under the license conditions to be read and approved.

If you should refuse these conditions up to 48 hours after installation, you have the possibility to return the device.

Enter the license key provided in the Information Sheet supplied with the device.



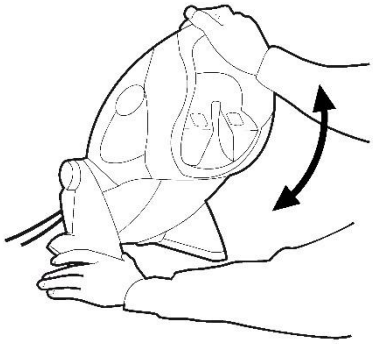
Select the installation folders for the software and database.

Once the installation is performed and completed, the Visiolite® 4K can be used using the VisioWin® software.

4. Using the computerized Visiolite® 4K

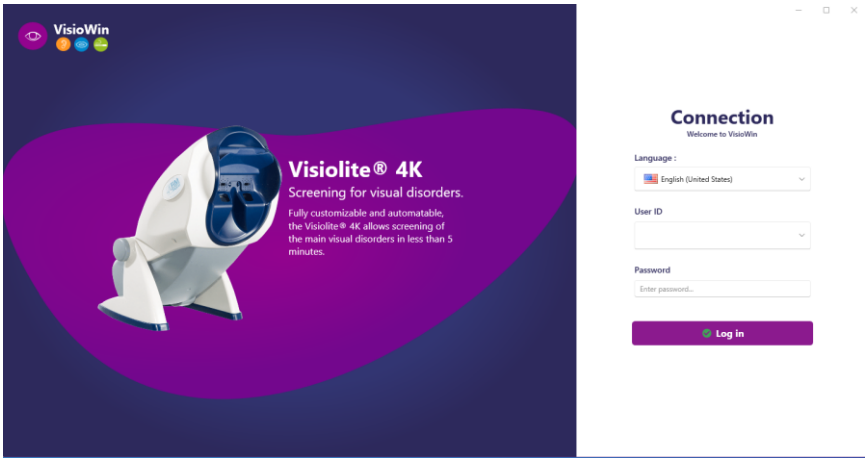
4.1. Tilt adjustment

Before using the Visiolite® 4K with a patient, adjust the tilt while holding the foot.



4.2. Starting the software VisioWin®

When starting, the VisioWin® software checks that all the technical prerequisites are met for optimal use of the functionalities.

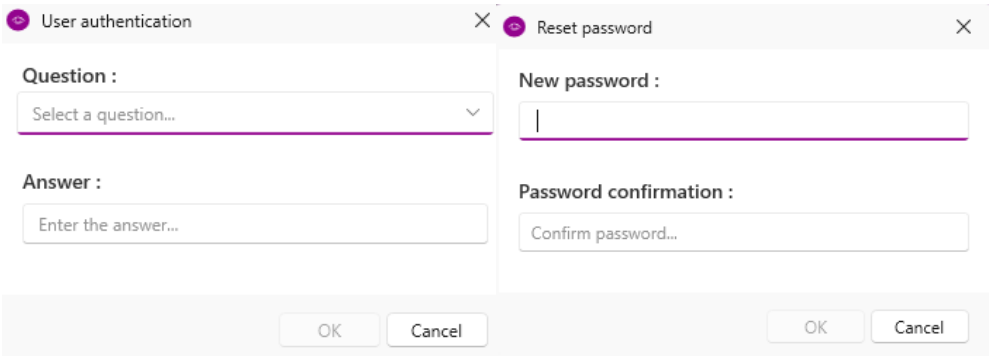


Access to the VisioWin® software is secured by a user authentication interface.

Choose the software interface language, select the username and enter the access password.

With the Windows user directory (LDAP) equivalence option detailed in paragraph 0, access to the software is possible with Windows login credentials.

If you forget your password, a verification question will allow you to set a new password.



4.3. VisioWin® Software Home Page

4.3.1. Interface Description user

VisioWin® software interface is divided into different areas:

(1) Identity of the patient who must undergo the examination

(2) Patient Window: View and navigate between patient data.

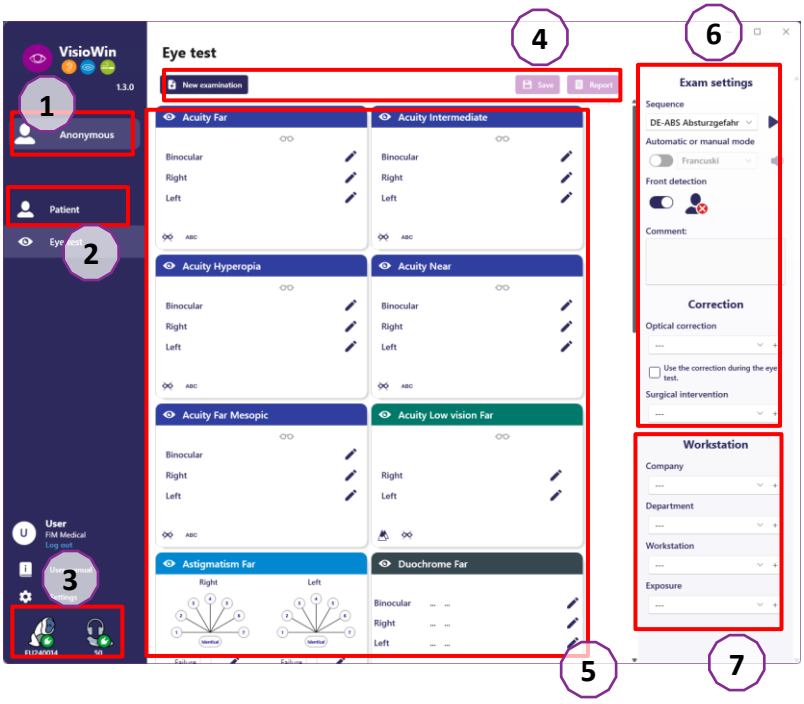
(3) Status bar: information relating to the hardware status of the Visiolite® 4K.

(4) Action buttons for creating and saving the examination.

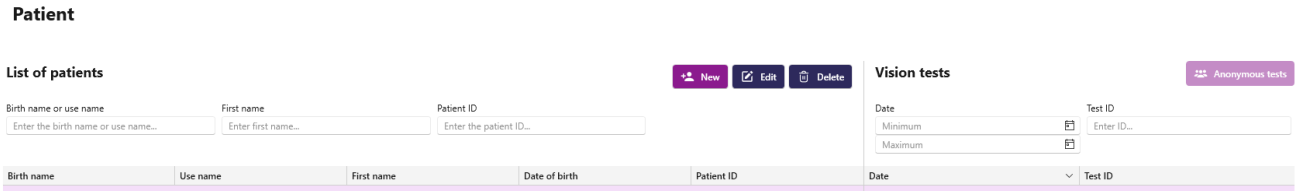
(5) Examination Window: Presentation of the tests that can be performed and work area relating to entering the results of each test.

(6) Settings for the examination in progress.

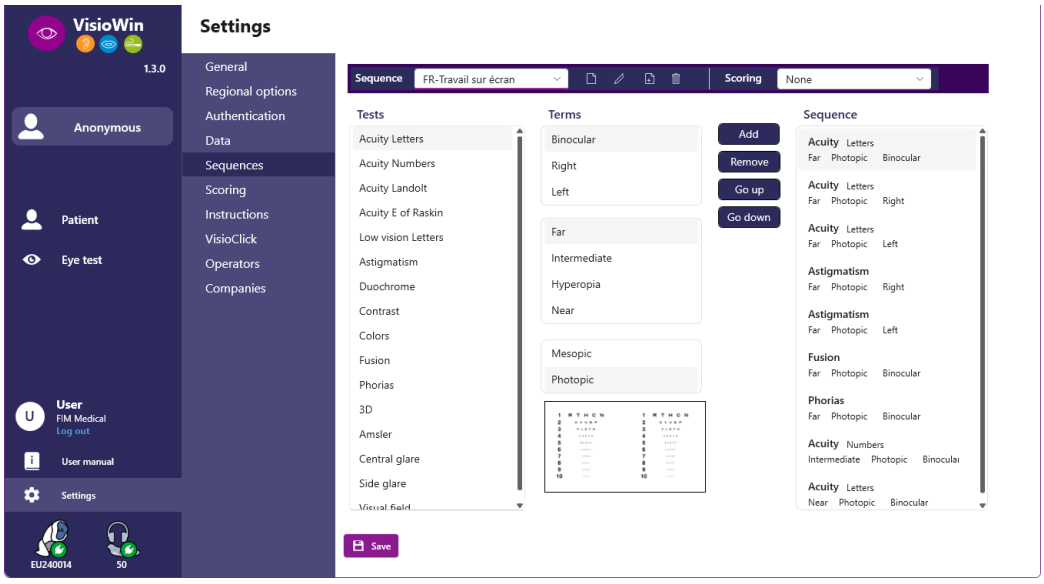
(7) Information relating to the workstation occupied by the patient performing the examination.



Presentation of the Patient Window:



A second side menu is available for software configuration with the possible presence of a contextual toolbar, for example for managing test sequences.



4.3.2. Description of icons

 Create or select a patient profile

 Show current review page

 Connected socket

 Plug disconnected

 Show manual user

 Access support options

 Access the settings pages

 Start a new exam with the selected patient

 Report

 The Visiolite® 4K is not connected or detected by the PC.

 The Visiolite® 4K is connected.

 The patient's forehead is not in contact with the device. Tests cannot be started.

 The patient's forehead is correctly positioned for proper performance of the tests.

 The VisioClick® is not connected or detected by the PC.

 The VisioClick® is connected but the audio headset is not properly plugged in. The voice instructions are not heard by the patient.

 The VisioClick® is connected and the headset is operational.

 Start a test.

 Start a test sequence.

automated mode :

 VisioClick® is connected , answer button released

 The VisioClick® is connected, answer button pressed

 The patient's forehead is not in contact with the device.

 The patient's forehead is in contact, response button pressed.

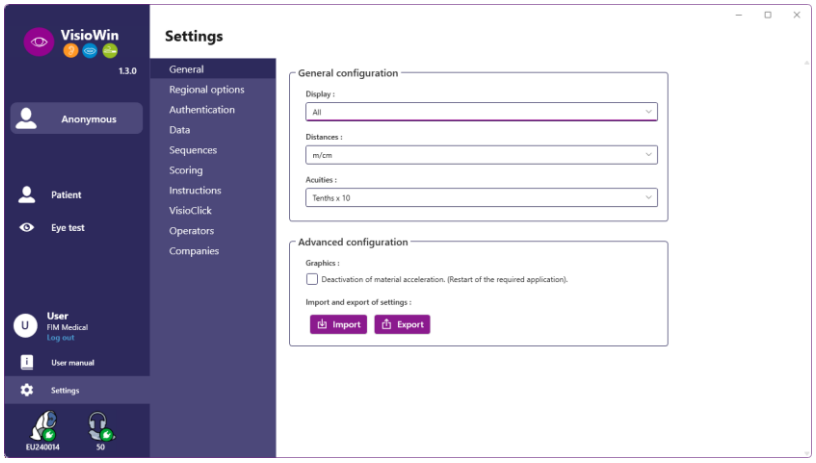
 Start the sequence by clicking the answer button.

 Pause the sequence by clicking the answer button.

 Restart the current test by clicking on the answer button.

4.4. Software Setup VisioWin®

4.4.1. Settings generals



Accessible from *Settings* in the side menu, the general settings allow you to define:

- The display mode of visual tests according to manual execution (see paragraph 4.6.2) or by sequence (see paragraph 4.6.3) of vision tests.
  For manual use and to display all available tests, select the *All option.*
  To limit the display to only the predefined tests in the sequences ; select *Sequences.*
- The unit of visual distances tested in metric (m/cm) or imperial (ft /in) system
- Visual acuity results unit LogMAR , MAR, Tenths, Tenths x10, Snellen 20ft or 6m

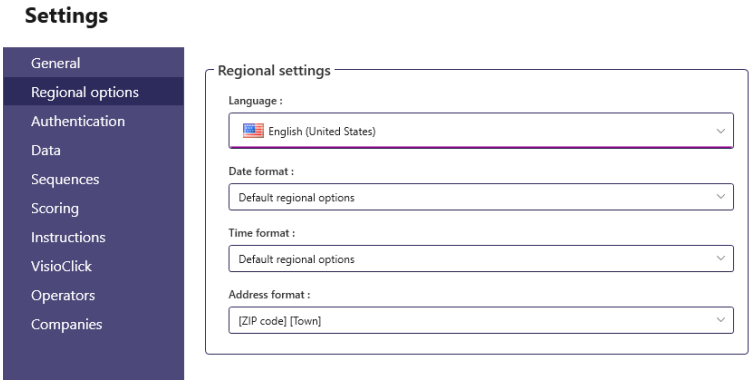
From the *General tab* , settings can be exported or imported to be replicated from or to another installation using the dedicated buttons.

The settings are saved in an encrypted secure format.

Submenus of the general settings allow management of regional, authentication and database settings.

4.4.2. Regional options

Regional options allow you to change the display language, date, time or address format. These settings are important for formatting the exam report.



VisioWin® software uses the regional settings of the Windows operating system by default.

4.4.3. Settings authentication

Authentication settings allow you to define the secure connection method to the software.

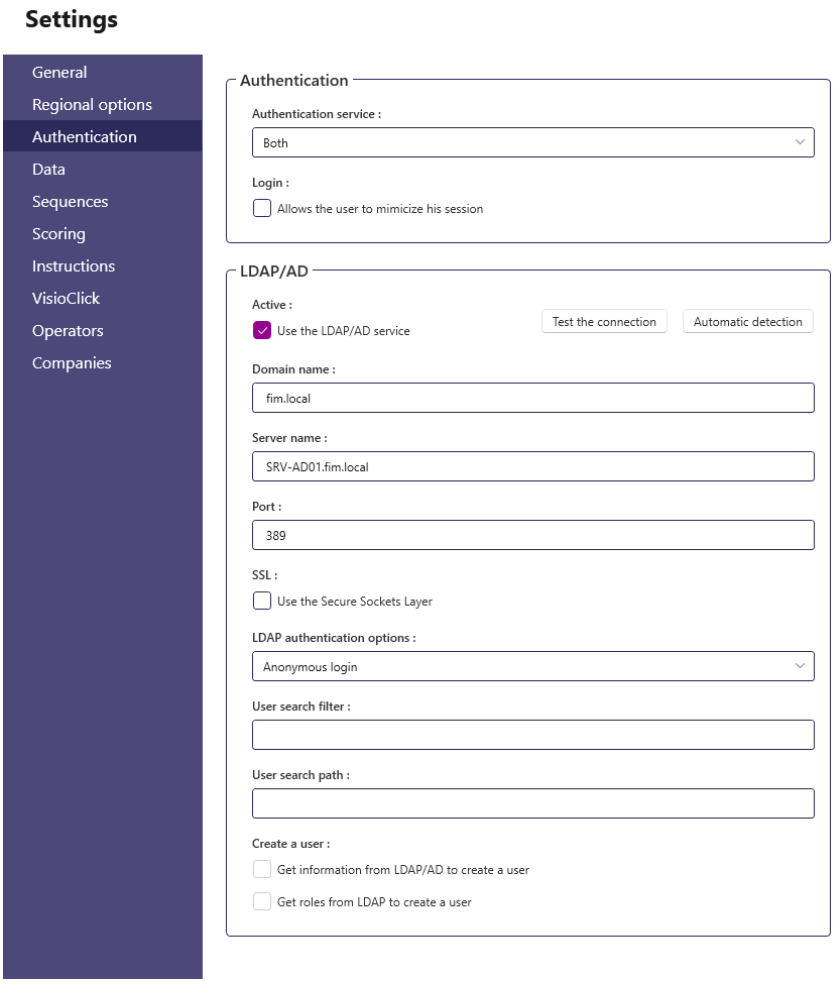
It is possible to disable password-protected access to the software by unchecking the *Use box a username and password.*

In order to ensure the protection of patient data, it is strongly recommended not to deactivate access control to the VisioWin® software by secure authentication.

Two authentication modes are possible and can be combined:

- Database: definition of an identifier and password for each user profile of the local database
- LDAP: Equivalence with the Windows User Directory (LDAP)

The LDAP service can be automatically configured and tested using the dedicated buttons.
Manual configuration using the current network settings is also possible.



See section 0to configure user profiles and manage access credentials.

4.4.4. Data

This tab gives you access to all settings related to the database and the interoperability of the VisioWin® software.

It is divided into four parts:

Database provider:

VisioWin® software works with a PostgreSQL database which can be local or remote.

The connection to the database and its integrity is tested when the software is started.

Database access settings can be changed and tested using the dedicated “Connection Test” button.

Automatic import:

Allows the operator to import patient data into VisioWin® software, view previous examinations performed, perform new tests and export them to the business software subsequently.

Automatic export:

Exporting data from VisioWin® software to the most widely used business software is possible, thus ensuring the interoperability of Visiolite® 4K.

ERM:

Data exchange mode with the EMR with a secure exchange protocol.

If you want EMR compatibility, make sure the box is checked. Login is done by entering the username and password you use when you normally log in to your business software.

Contact FIM Medical for further information.

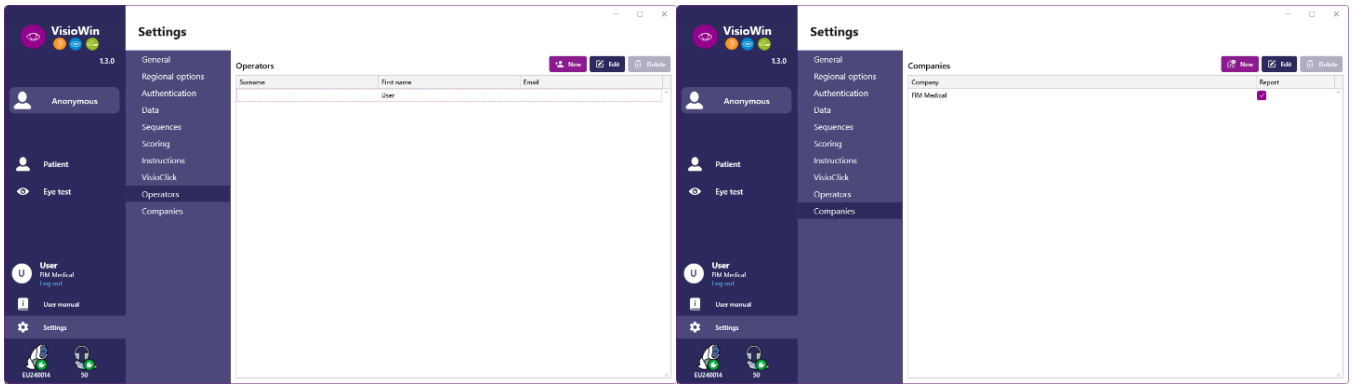
4.4.5. User Management

Profile directory management allows you to view, create and modify user profiles.

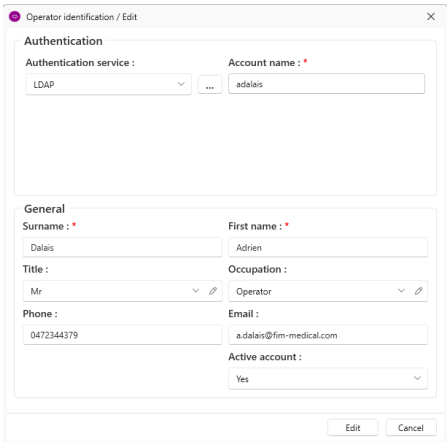
To add a new user, click *New*

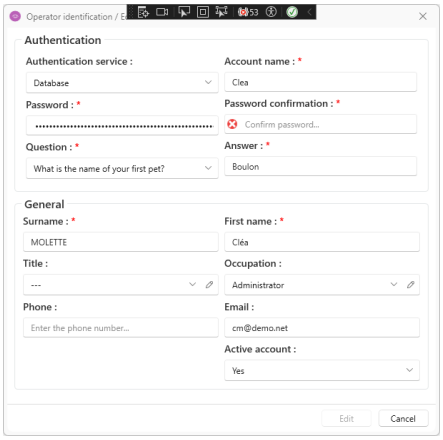
To edit the user profile: click *Edit*

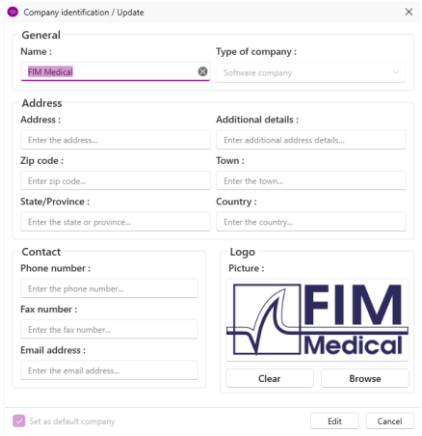
To delete the user profile: click *Delete*



The edit functionality allows you to edit all the information previously entered using the forms below.







Changing user information will apply to the profile

The password and verification question must be carefully defined for each user.

The authentication method can be adapted to each user profile (see paragraph 0).

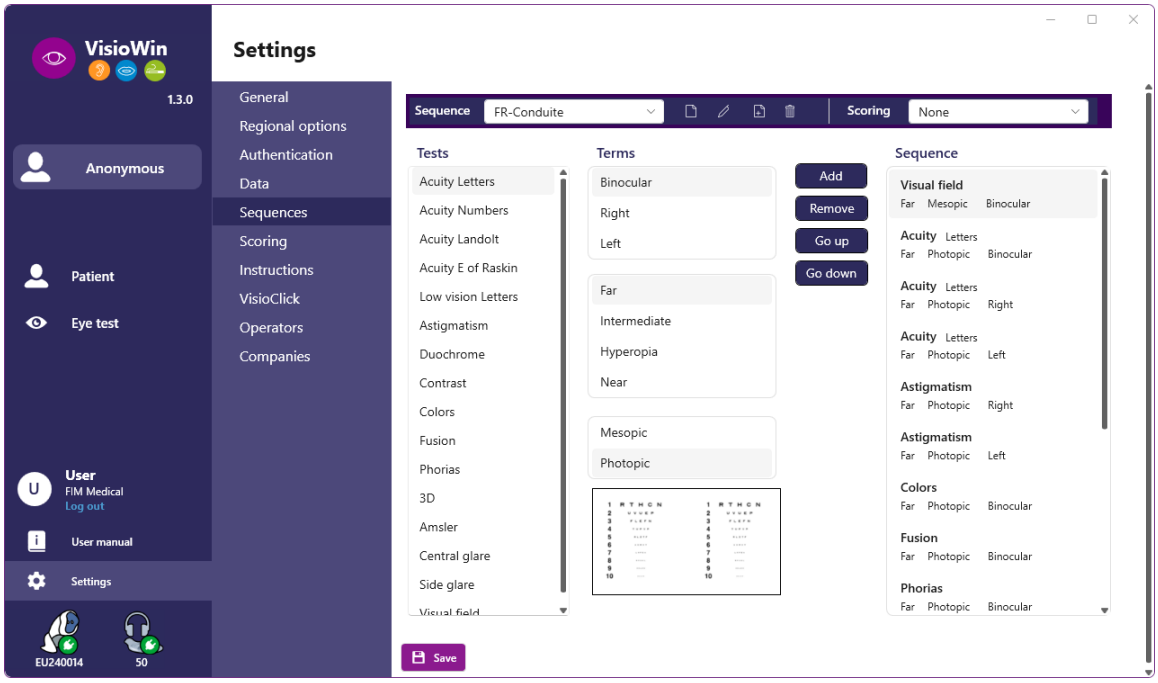
The company can be defined as that of the patient or the examiner, in which case the logo will be included in the examination report.

To ensure the protection of patient data, it is imperative that default passwords are changed in accordance with local recommendations regarding password length and complexity.

4.4.6. Editing sequences

By default, several sequences are available in VisioWin®, which can be modified or supplemented with new sequences.

- Create a new sequence
- Rename the sequence selected
- Clone the selected sequence
- Delete sequence selected



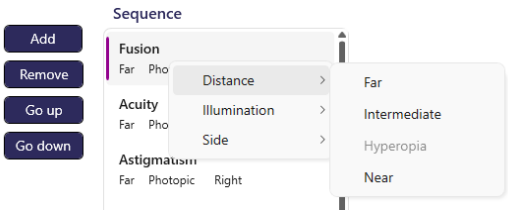
Click on the sequence creation button, select the first test to be carried out, the vision, distance and lighting conditions then validate by clicking on *Add*.

Repeat to add more tests.

The order of the tests in the sequence can be changed using the *Move Up* and *Move Down buttons*.

Use the *Remove button* to remove a test from the sequence.

The conditions of the added tests can be edited directly in the list by right-clicking.



Select scoring profile to apply to determine the success thresholds (see paragraph 4.4.7).

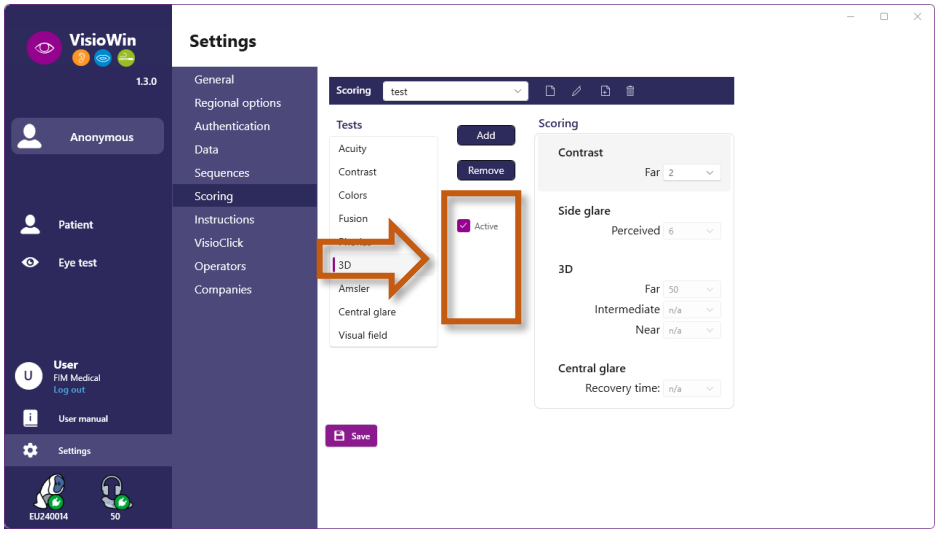
Click *Save* to validate the new sequence.

To create a new sequence it is also possible to start from an existing sequence which should be cloned and then modified.

4.4.7. Scoring parameters

Scoring profiles allow you to define success thresholds for each type of test.

Similar to Sequences, Scores can be created, renamed, cloned and deleted using the same context bar icons.



Use the *Add* and *Remove buttons* to complete the list of tests to which to apply the scores.

The scores must then be defined according to the scales of results expected for each test.

The unit of acuity 4.4.1).

Attention: Check the *Active box* so that the selected scoring profile is applied during the exam.

4.4.8. Test Statement Parameters

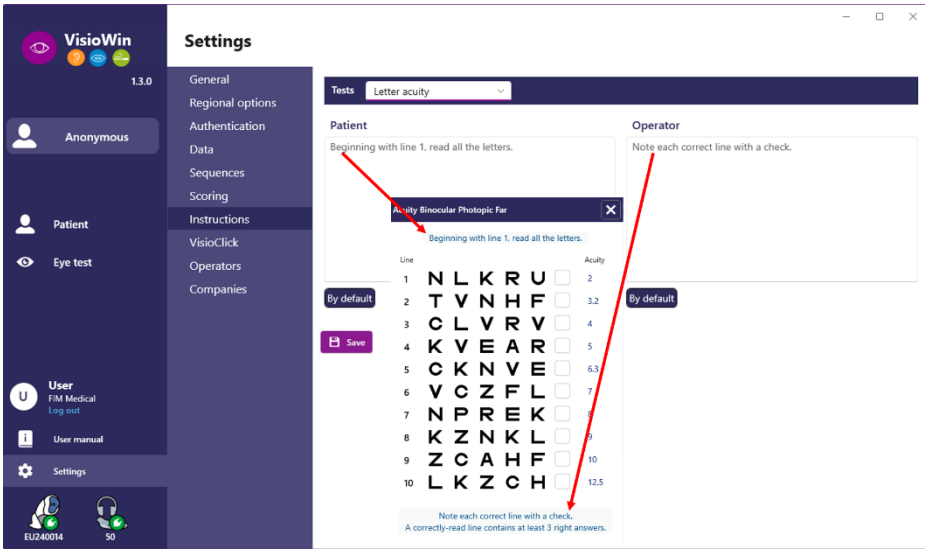
The instructions visible in the test tiles are customizable in the *Instructions tab.*

Patient field corresponds to the instruction to be given to the patient for the execution of the test.

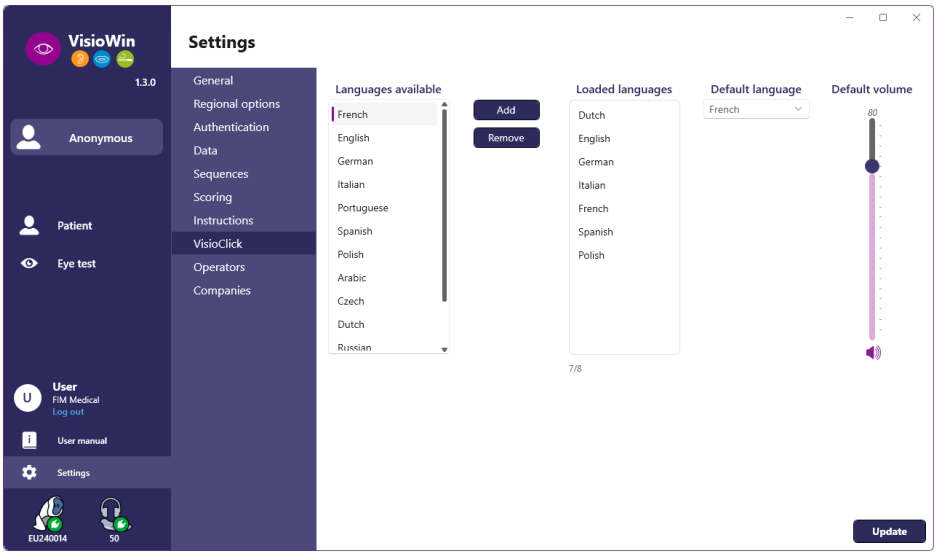
Operator field corresponds to the instruction for entering the result.

Select the test to modify, make the reformulations in the input fields then save.

It is possible to restore the default wording by clicking on *Default.*



4.4.9. VisioClick® Settings



VisioClick® automation settings page allows you to do the following:

- Change the language preselection for voice instructions:
- Add a language from the list of available languages by clicking *Add.*
- Remove a language from the list of loaded languages by clicking *Remove.*
- Select the language to be broadcast by default in the headset
- Set default headset volume

Click *Update* to validate the new configuration to be applied.

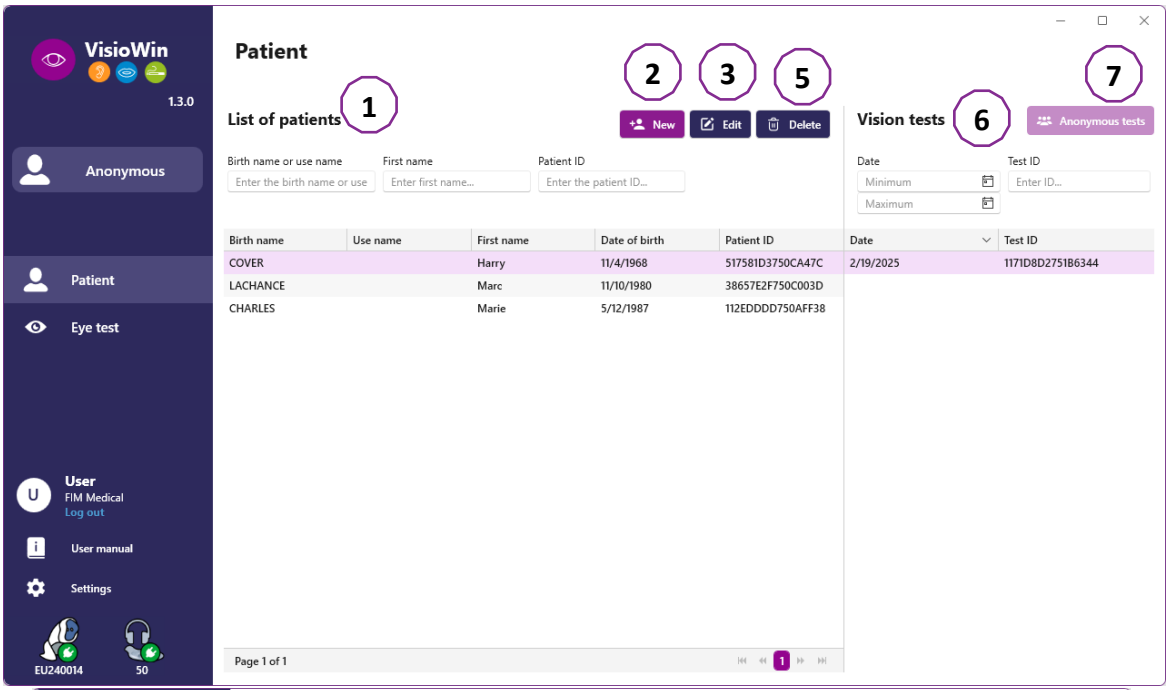
4.5. Patient profile management

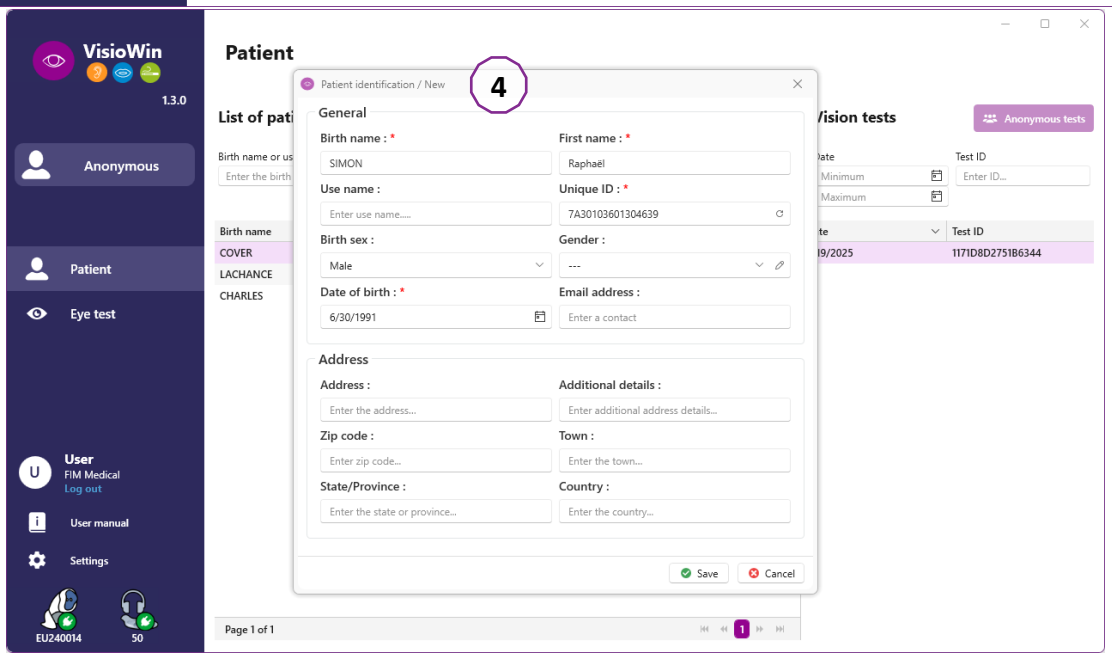
4.5.1. Patient profile management (excluding third-party software interface)

To save the results of an examination in the local database of the PC (excluding third-party software), it is necessary to first create a patient profile or select an existing patient.

From the side menu, click on the patient icon to access the patient profile viewing interface. The search fields (1) allow you to filter the database to select an existing profile. Click on *Edit* to edit the profile of the selected patient (3).

Click on *New* (2) to create a new profile using the input form (4).





Delete (5) allows you to permanently delete the selected patient.
Vision tests (6) allows you to view the history of examination results for the selected patient.
Anonymous tests (7) displays reviews taken without an assigned patient

4.5.2. Patient profile management (third-party software interface)

When your EMR box is checked (see paragraph 4.4.1.3.), to save the results of an examination in the database of your EMR (third-party software), it is necessary to select an existing patient in the database of your EMR.

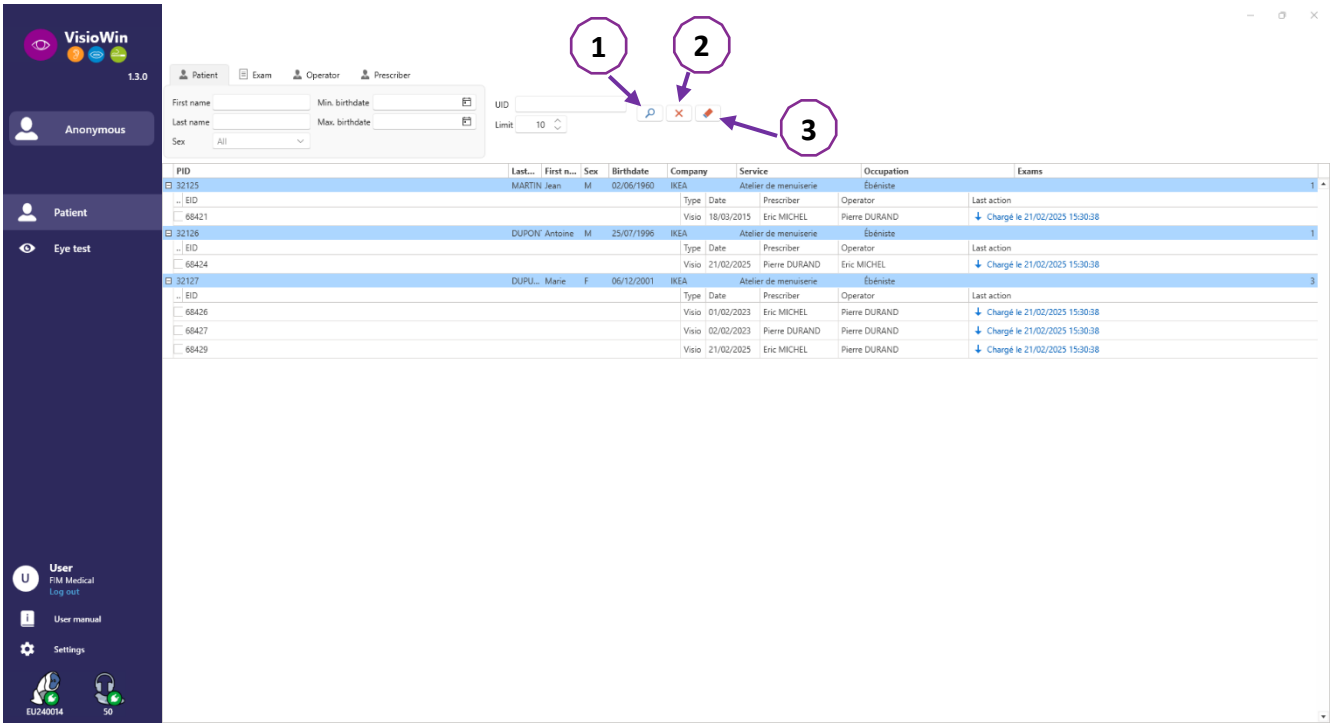
From the side menu click on the patient icon to access the patient profile viewing interface.

It is possible to sort the data by using different filters:

- Patient
- Examination carried out
- Operator
- Practitioner

After entering the necessary information to best sort the database, click (1).

At any time you can cancel the applied filter by clicking on (2) or clear the filter by selecting (3).



4.6. Conducting a new exam

4.6.1. Precautions of use

The operation of the device is based on binocular fusion. The operator must ensure that the patient has sufficient fusion to perform the examination.

Before any examination, the patient should be asked if he or she usually wears optical correction.

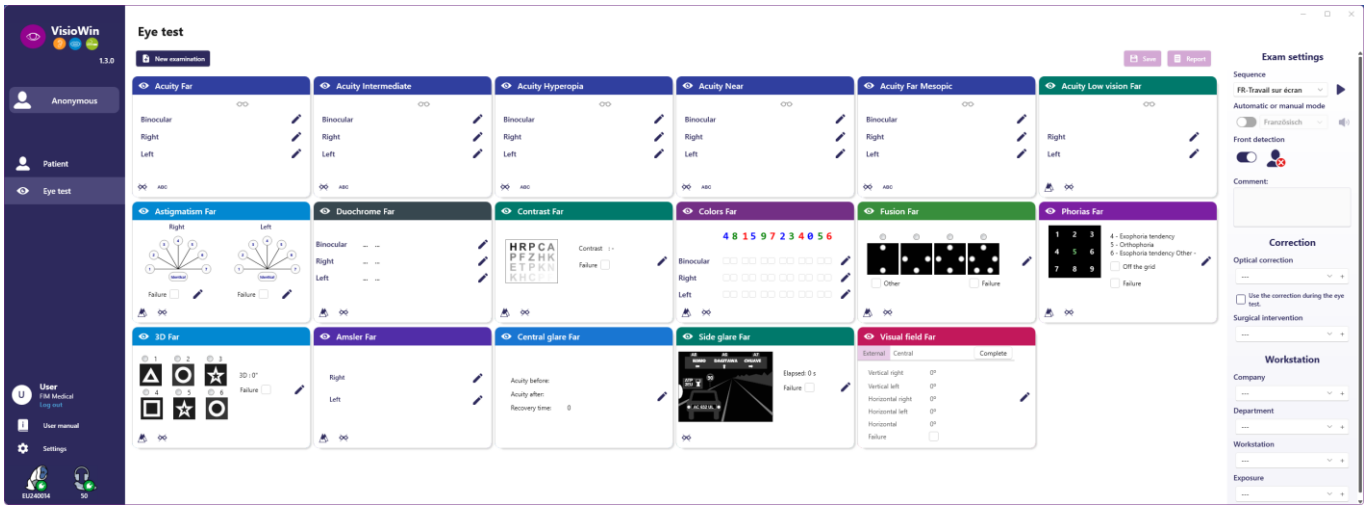
For photosensitive patients the light level can be reduced at any time during a test.

The examination should be carried out in a suitable environment, ensuring that the patient is not bothered by a light source outside the device.

In the case of a glare test, in accordance with the contraindications set out in paragraph 1.4, the user must inform the patient of the progress of the test and will take care to ensure that there is no persistent discomfort at the end of the test.

4.6.2. Performing a visual test

Visual tests are available on the *Exam page* and represented by thumbnails.



Each vignette corresponds to a visual aptitude for which different test conditions can be modified: optotype model, vision, distance or lighting conditions.

Click on the icons in the lower left corner of the thumbnails to vary the test conditions.

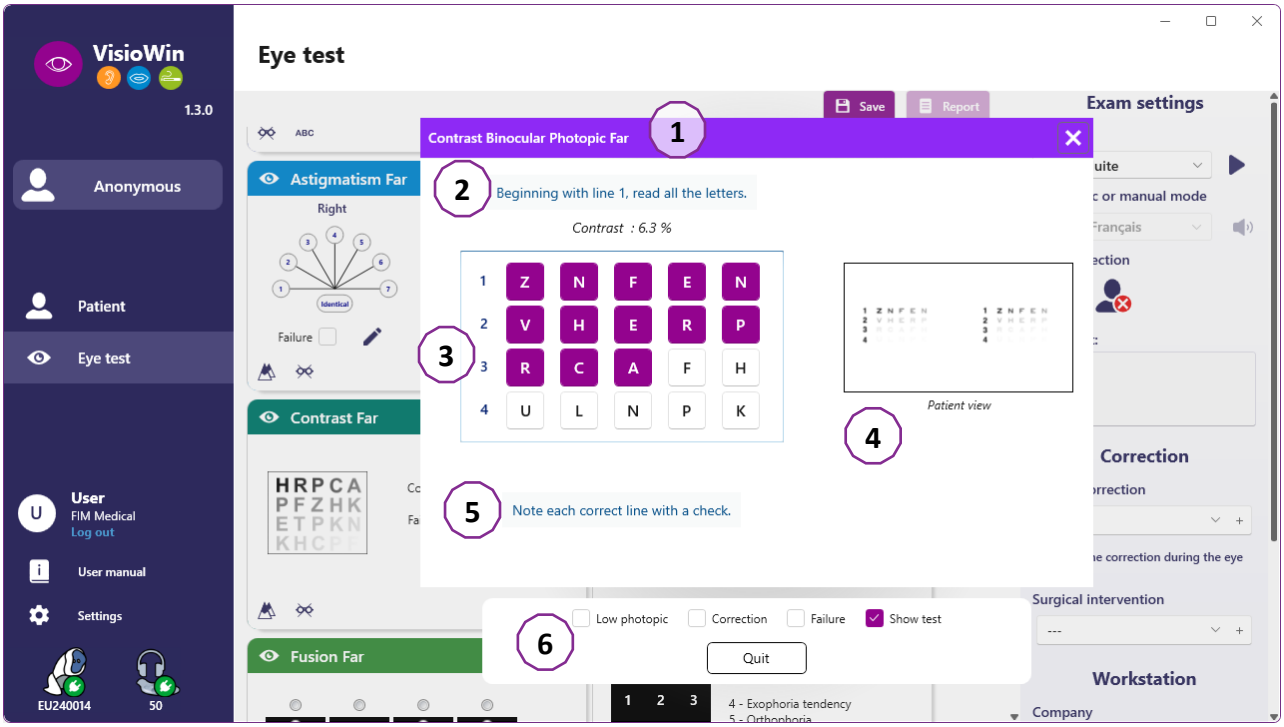
- Distance vision
- Intermediate vision
- Second intermediate vision
- Near vision
- No optical correction
- Wearing optical correction
- ABC Letters FIM or SLOAN
- 123 Numbers
- E of Raskin
- FIM Symbols
- Landolt rings with 4 orientations
- Landolt rings with 8 orientations

The icon allows you to launch a test manually in the appropriate viewing mode.

Visual tests can be performed spontaneously and in a targeted manner provided that the display of all tests is activated in the general settings (see paragraph 4.4.1) or in a sequenced manner according to a predefined order in the sequence editor (see paragraph 0).

From the review page toolbar, it is possible to:

- Start a test sequence previously selected from the drop-down menu
- Access the sequence editor
- Switch to automated mode (see paragraph 0)
- Add a comment that will be transcribed in the review report
- Add a test to the current sequence
- Enable / Disable Detection frontal



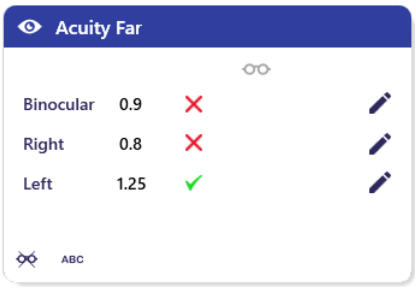
To run the test a double command window is displayed in the foreground.

The upper window (1) allows you to view the instruction to be given to the patient for the execution of the test (2), to also view the optotypes (3) or the slide (4) displayed in the Visiolite® 4K and to enter the result perceived by the patient. For the operator, the instruction for entering the result is indicated at the bottom of this window (5).

Once the patient's perceived result is entered, the acuity is calculated or a trend can be indicated.

In the lower window (6), several additional options can be activated:

- Reduced light intensity for photosensitive people
- Wearing corrective lenses
- Test Failed
- Preview of the test as displayed in the Visiolite® 4K and seen by the patient
- The *Previous* and *Next buttons* scroll through the tests in the thumbnail or sequence.



Visualization of scoring

During and after the exam, the result is reported in the corresponding test sticker.

scoring parameter is active, the validation or not of the predefined criterion is indicated respectively by a green check mark or a red cross.

Once all tests are completed, click *Save* to save the exam results to the database.

Click *Report* in the navigation bar to view the exam report.

4.6.3. Using test sequences

For greater ease of use, the display of tests on the examination page can be restricted to only the tests in the sequence selected in the toolbar. This setting is to be made in the general settings described in paragraph 4.4.1.

To start a sequence, select the appropriate sequence from the toolbar drop-down menu and then click the icon ▶.

The tests can be chained in the order predefined in the sequence settings (see paragraph 0), use the *Next* and *Previous buttons* to navigate through the sequence.

During and at the end of the sequence, the result is reported in the corresponding test thumbnail.

Once the sequence is complete, click on *Report* in the navigation bar to view the exam report.

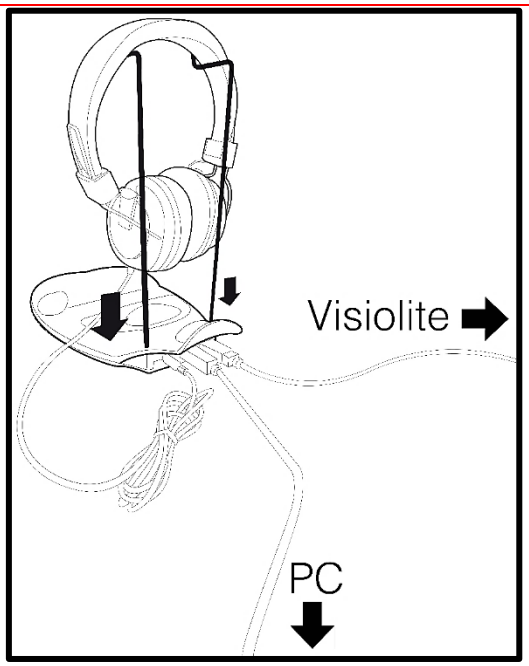
4.6.4. Autorun with VisioClick®

Avoid using the VisioClick® in a noisy environment that prevents you from properly understanding the spoken instructions given by the audio headset.

The glare sensitivity test is not possible with the VisioClick®.

Although the VisioClick® device gives the patient a certain autonomy, a healthcare professional must always be present in the immediate vicinity to ensure that the examination goes smoothly.

For reasons of hygiene and biocompatibility, it is mandatory to use single-use hygienic caps from the FIM Medical brand.
These earcups have been specifically developed by FIM Medical to meet the biocompatibility constraints of ISO 10993 materials and to guarantee perfect sound transmission in compliance with IEC 60645-1.



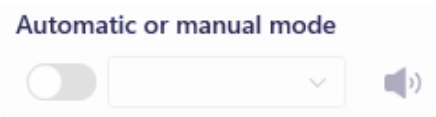
Position the metal helmet holder in the two holes of the VisioClick®.

Connect the USB cable of the Visiolite® 4K, Type A connector on the VisioClick®, Type C on the Visiolite® 4K.

Connect the USB cable of the VisioClick®, Type B connector on the VisioClick®, Type A on the PC.

Connect the headset jack connector to the VisioClick®.

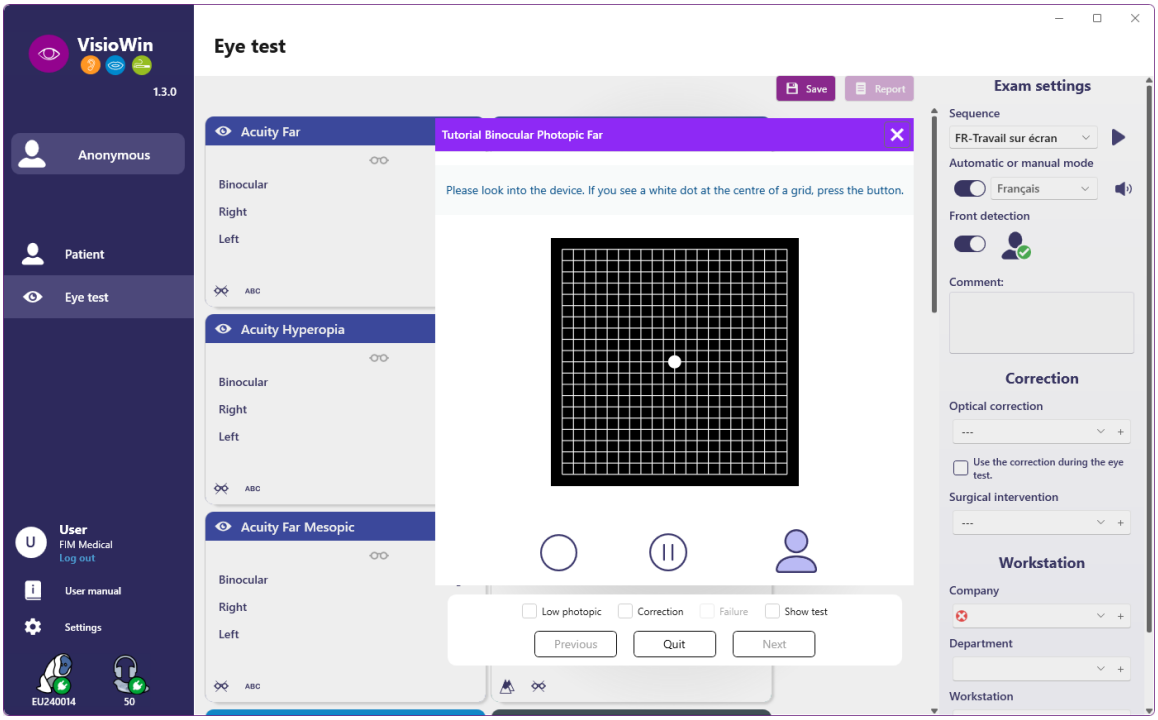
Once all connections have been made correctly, the VisioClick® and the headset should appear as detected in the VisioWin® software status bar.



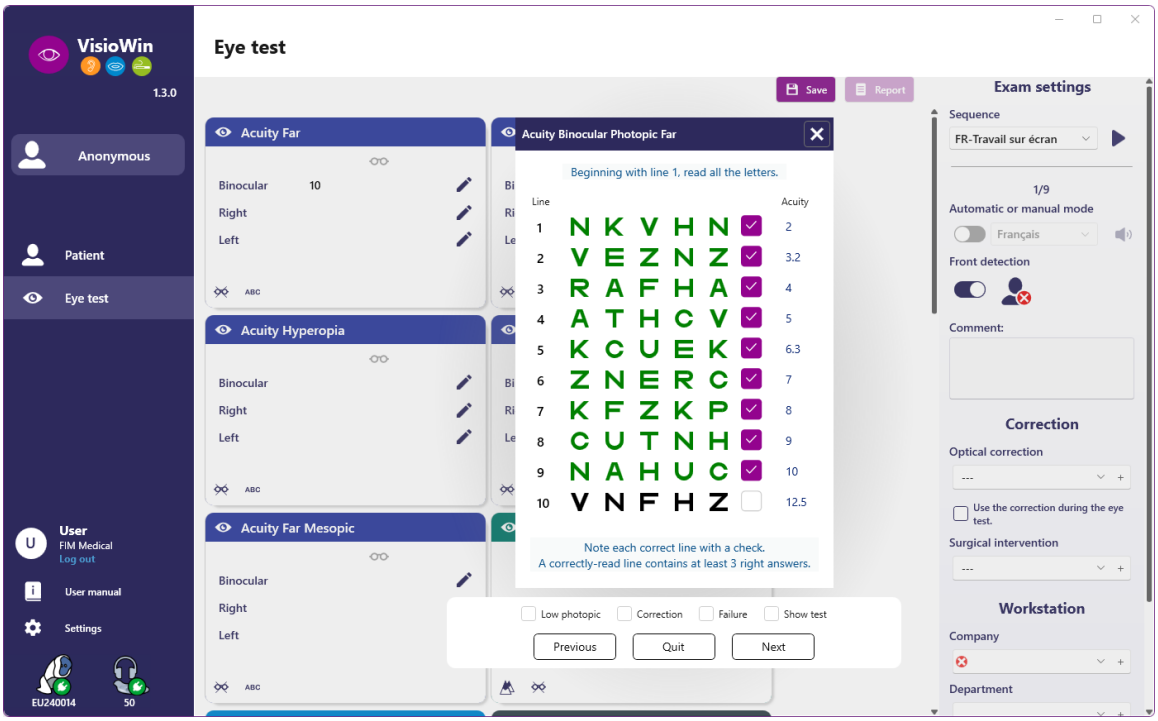
To use automatic mode from the review page, slide the button from *Manual* to *Auto* in the toolbar.
Select the voice prompt language and adjust the volume with the slider (see paragraph 0for default settings).

Click on the ▶ toolbar icon to start the sequence in automatic mode.

The sequence begins with a test of understanding the vocal instructions.



Tests can also be run selectively in automatic mode.



Refer to paragraph 0for more details on the automatic mode icons.

Note: If the headset is accidentally disconnected, the examination is interrupted and the patient is notified.

4.7. Visualizing the results of examination

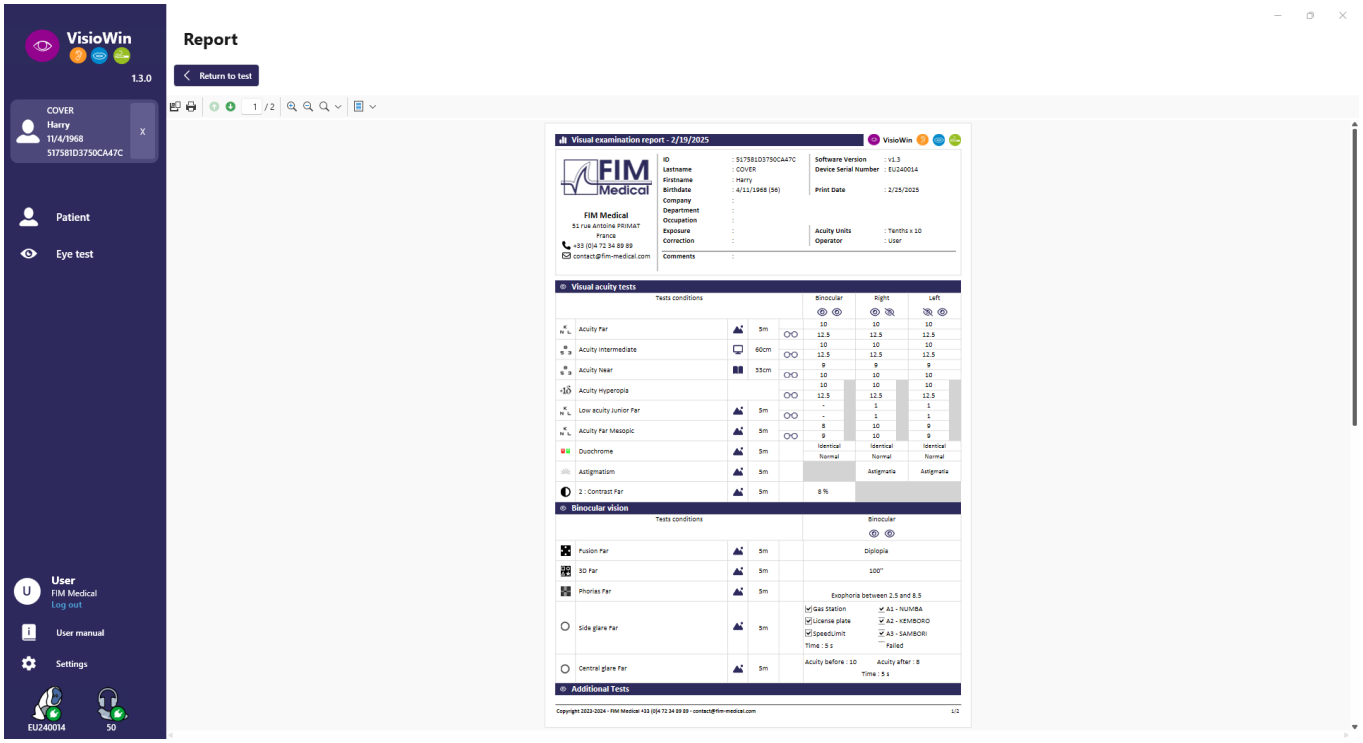
4.7.1. Review report

Once the exam is completed the results by clicking the Save button, the exam will be saved in PDF format. The exams can then be printed or exported to third-party software.

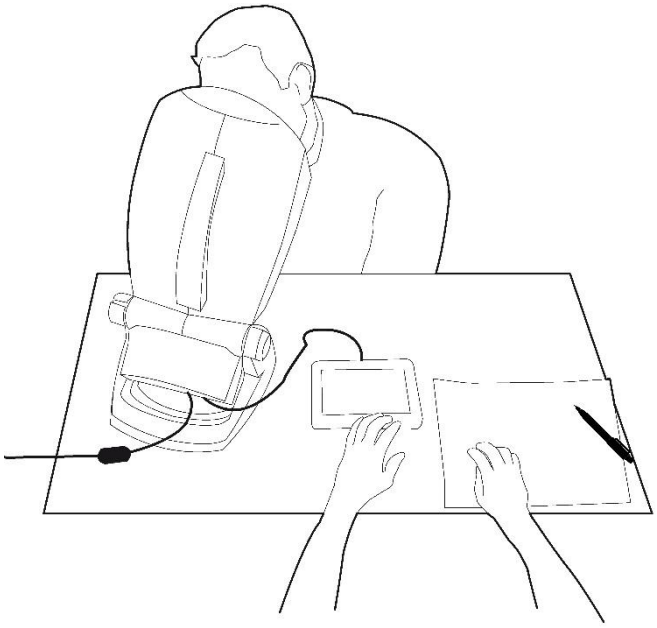
Click on *Report* to access the PDF report viewer.

Gateway software allows you to export results in PDF format to most third-party software.

Contact FIM Medical for further information on Gateway software features.



5. Using the remote-controlled Visiolite® 4K



5.1. Performing a remote-controlled examination

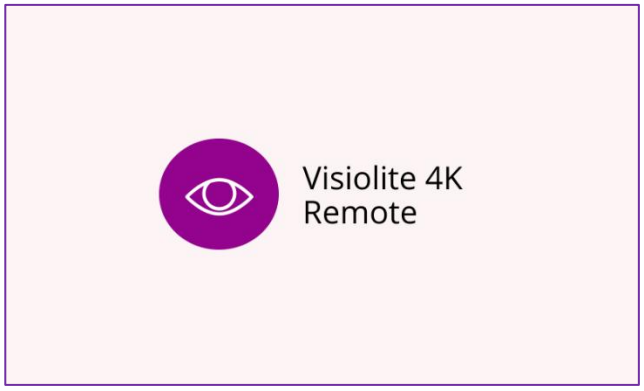
5.1.1. Remote control start

Connect the Visiolite® 4K with the power supply and connect the remote control to the Visiolite® 4K using the USB type C cable.

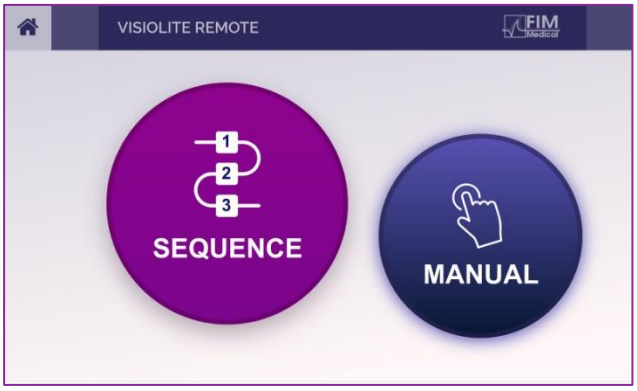
Switch on the remote-controlled Visiolite® 4K using the on/off switch.

The remote control then turns on automatically. A start-up screen is displayed while the home page initializes.

The remote control's touch interface then provides access to the various functions.



Remote control start screen

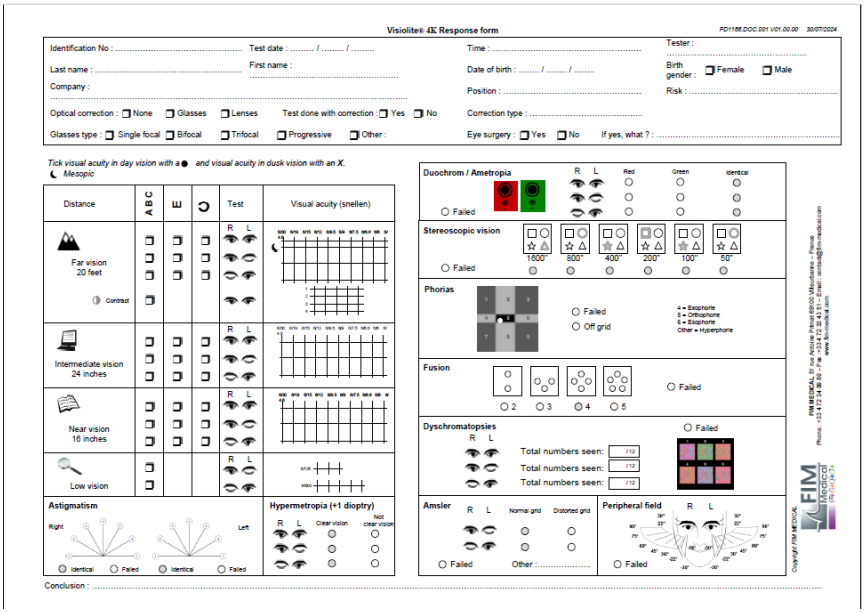


Remote Control Home Page

5.1.2. Using the response block

The answer block can be downloaded from the link provided in the Information Sheet supplied with the unit.

The results of the various tests carried out manually or in sequence can be reported by hand on the answer block.

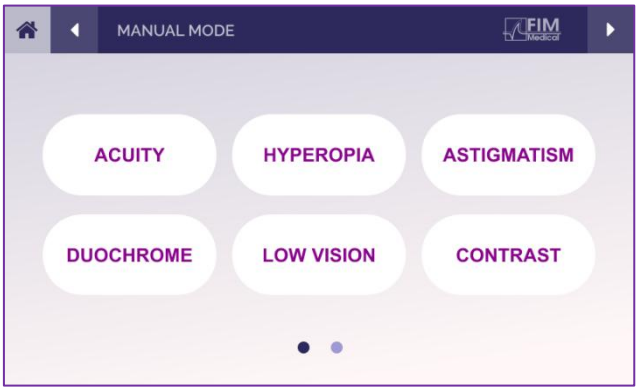


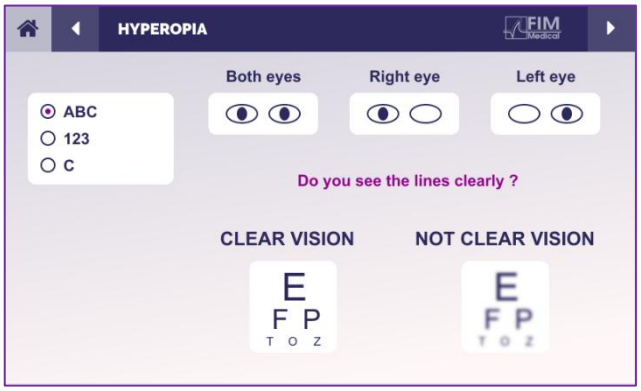
5.2. Using the remote control in manual mode

Manual mode gives access to all the tests available on the remote control.

Select a test and test conditions via the touch interface to control the slides to be displayed to the patient.

The instruction to be given to the patient is also visible on the test page.



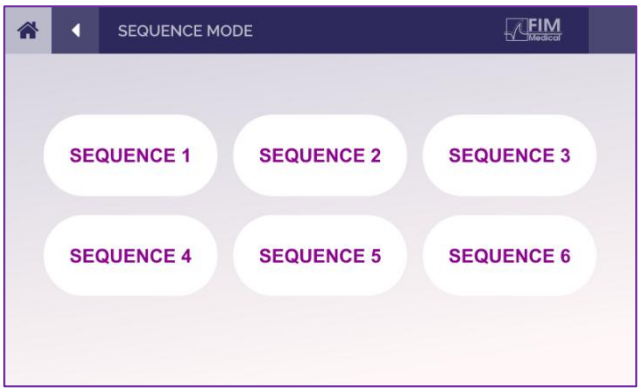


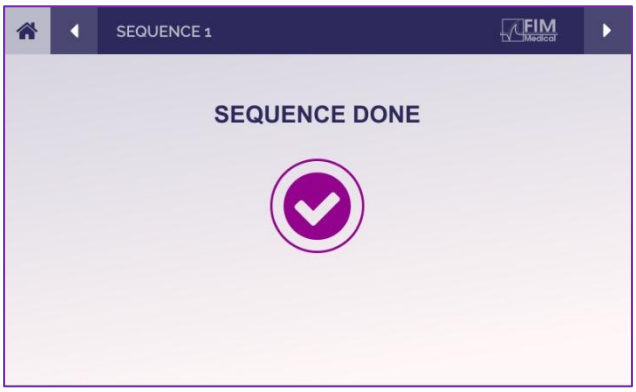
Report the result perceived by the patient on the response block.

5.3. Using the remote control in sequence mode

Sequence mode gives access to all the sequences pre-recorded on the remote control.

Click the next/previous arrows located in the upper corners of the screen to move forward or backward through the test sequence.

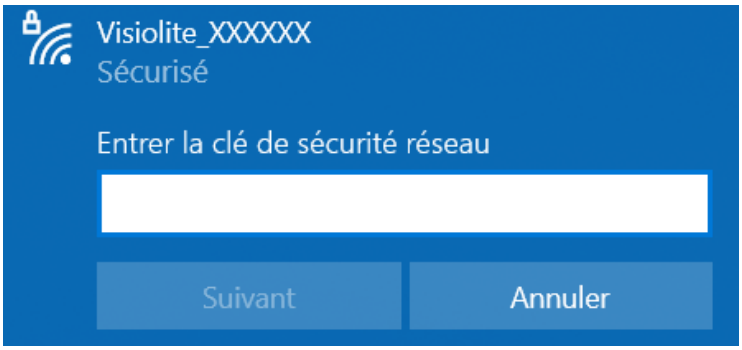




5.4. Webapp Wifi Access Settings

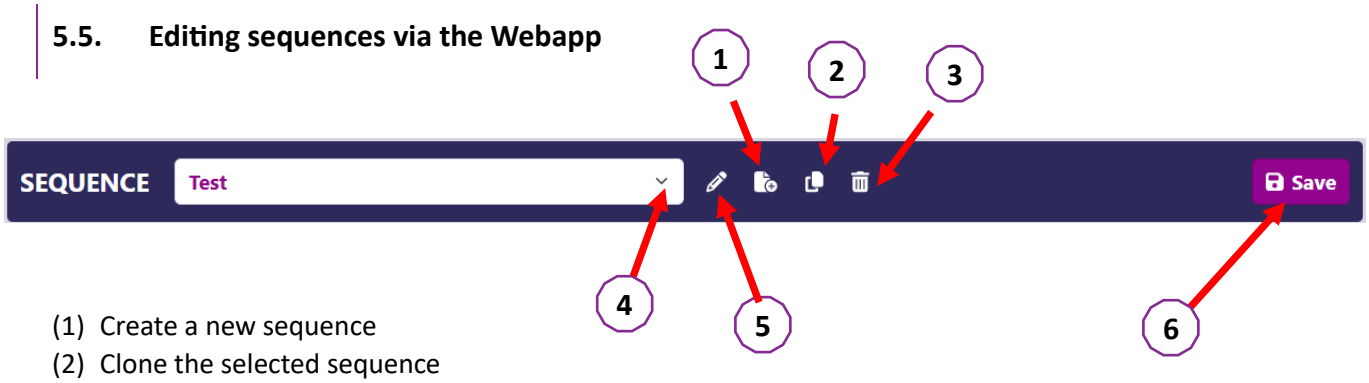
Select the Wifi network named according to the serial number of the remote control.

Enter the Wifi password found on the back of the device.

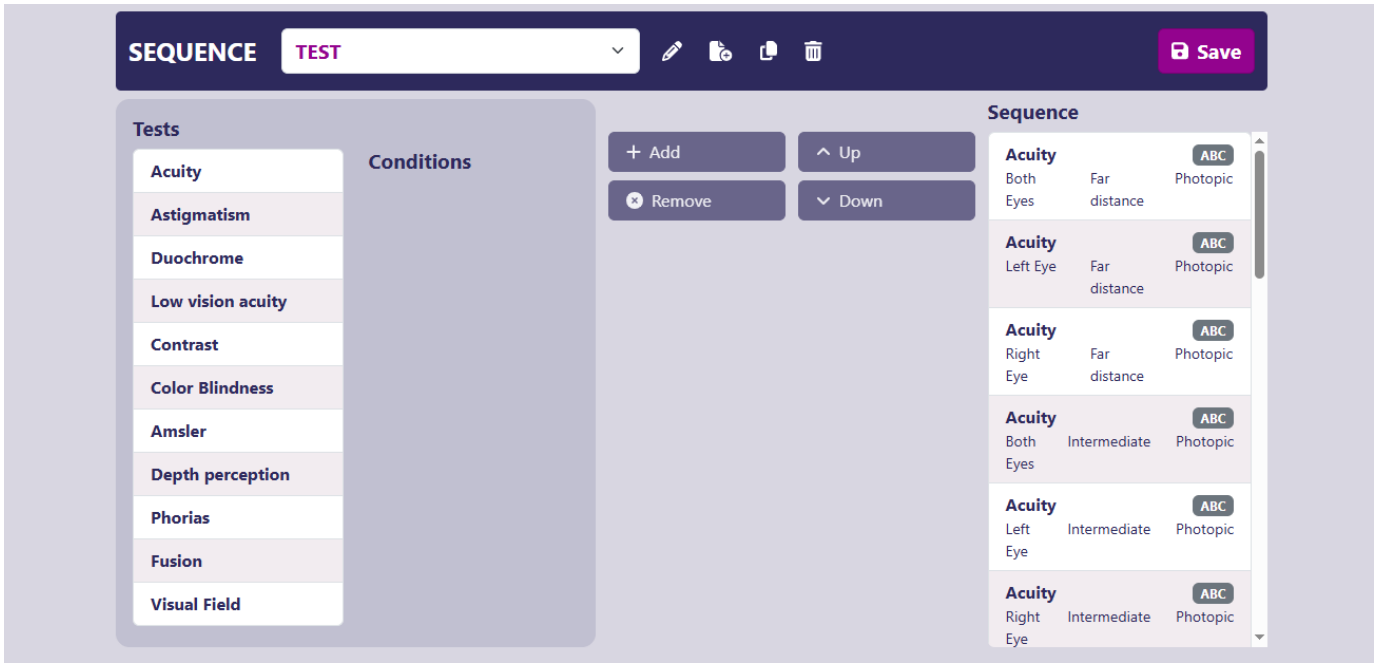


Once connected to Wifi, the Visiolite® Remote Webapp interface will be accessible to you in your internet browser.

5.5. Editing sequences via the Webapp



(1) Create a new sequence
(2) Clone the selected sequence
(3) Delete selected sequence
(4) Choose the desired sequence from the drop-down list
(5) Rename the selected sequence
(6) Save changes to the sequence



Click on the sequence creation button, select the first test to be carried out, the vision, distance and lighting conditions then validate by clicking on “Add”.

Repeat to add more tests.

The order of the tests in the sequence can be changed using the “Move Up” and “Move Down” buttons.

Use the “Remove” button to remove a test from the sequence.

6. Description of the tests

6.1. Test Library

The Visiolite® 4K is configured with a test library, also called a test pack.

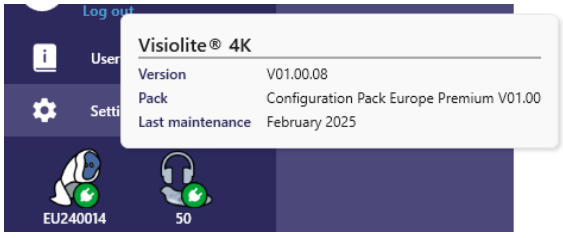
Table 1: Configurations for visual acuity test packs

Test Pack – Visual Acuity	*Europe Edition*	*Europe Premium*	*US Edition*	*US Premium*	*OF Edition*	*DE Premium*	*UK Edition*	*UK Premium*	*US Junior*	*FROM Junior*	*DMV*
Acuity – ABC	•	•	•	•		•	•	•		•	
Acuity – SLOAN Letters									•		
Acuity – ABC (Letter by letter display)										•	
Acuity – SLOAN Letters (Display one by one)									•		
Acuity – Iso- acuity letters											•
Acuity – 123	•	•		•	•	•		•	•		•
Acuity – Raskin's E					•	•	•	•		•	
Acuity – Raskin 's E (Display one by one)										•	
Acuity – Landolt (4 positions)	•	•	•	•			•	•			•
Acuity – Landolt (8 positions)					•	•				•	
Acuity – Landolt (8 pos.) (Display one by one)										•	
Acuity – Symbols									•	•	
Acuity – Symbols (Display one by one)									•	•	
Amsler	•	•	•	•	•	•	•	•			
Astigmatism	•	•	•	•	•	•	•	•	•	•	
Low vision – ABC (monocular)	•	•	•	•			•	•		•	•
Low vision – Landolt (8 pos.) (monocular)					•	•					
Low vision – ABC (binocular)										•	
Low Vision – SLOAN Letters									•		
Low Vision – Symbols									•	•	
ABC hyperopia $^{+1\delta}$	•	•	•	•			•	•	•	•	•
ABC Hyperopia $^{+1\delta}$ (Display one by one)									•	•	
Hyperopia E $^{+1\delta}$							•	•			
Landolt hyperopia (4 positions) $^{+1\delta}$							•	•			
Mesopic	•	•	•	•	•	•	•	•			•
Mesopic Landolt (8 positions)					•	•					

Table 2: Configurations for special test packs

Test Pack – Special Tests	*Europe Edition*	*Europe Premium*	*US Edition*	*US Premium*	*OF Edition*	*DE Premium*	*UK Edition*	*UK Premium*	*US Junior*	*FROM Junior*	*DMV*
Visual field complete	•	•	•	•	•	•	•	•	•	•	•
Duochrome red/green	•	•			•	•	•	•			
Merger	•	•	•	•	•	•	•	•	•	•	•
ABC hyperopia +1δ	•	•	•	•			•	•	•	•	•
ABC Hyperopia +1δ (Display one by one)									•	•	
Hyperopia E +1δ							•	•			
Landolt hyperopia (4 positions) +1δ							•	•			
Mesopic	•	•	•	•	•	•	•	•			•
Mesopic Landolt (8 positions)					•	•					
Phorias	•	•	•	•	•	•	•	•		•	•
Childhood Phorias									•	•	
Standard color perception	•	•	•	•	•	•	•	•			•
Child's color perception									•	•	
Traffic light perception											•
Reliefs	•	•	•	•	•	•	•	•			•
Child reliefs									•	•	
Glare resistance		•		•		•		•			•
Sensitivity to glare		•		•		•		•			•
Contrast sensitivity - ABC	•	•	•	•			•	•			•
Contrast sensitivity – Landolt (x8)					•	•					

The test pack activated in the device is visible in the main side menu.



6.2. Acuity tests visual

6.2.1. Purpose and presentation of the test

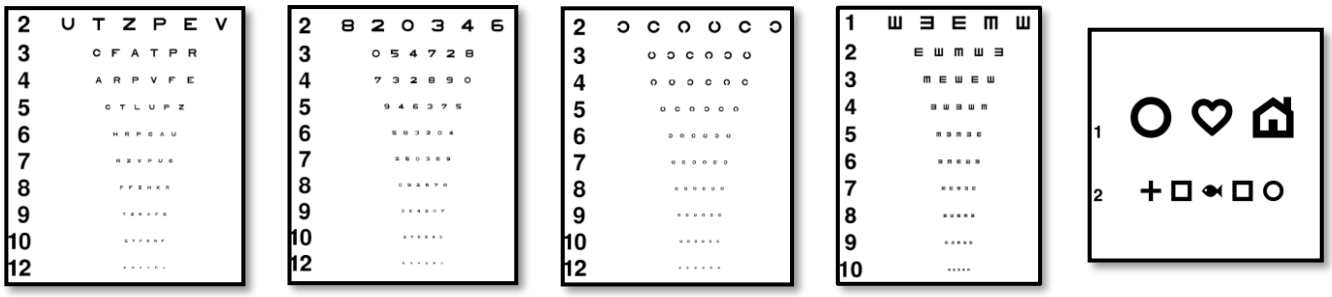
The visual acuity test is the starting point of any eye examination. It ensures that a patient has the correct correction and assesses their ability to decipher information from everyday life. During an examination, we generally aim to achieve a visual acuity of 10/10, or even 12/10. This will enable the subject to decipher information from everyday life such as the name of a street on a plaque or articles in a newspaper. The test is performed in different ways: monocularly , binocularly , from a distance, in an intermediate, from near, with compensation, without compensation, in a photopic or mesopic environment. These different acuities will provide us with information about a patient's visual abilities.

Among these tests we find the following within the Visiolite® 4K:

- ✓ Acuity visual from afar
- ✓ Acuity visual intermediate
- ✓ Acuity close -up visual
- ✓ It is also possible to blur a patient's eye by one diopter in order to assess a tendency towards hyperopia.
- ✓ Mesopic visual acuity to test patient's vision at dusk
- ✓ Low vision to assess a subject's ability to drive and testing monocular visual acuities of 0.5/10 and 1/10

The various tests offered allow the assessment of two types of visual acuity: recognition acuity, also called morphoscopic acuity , and resolution acuity. It may be useful to test both in order to assess certain specific problems. The optotypes used are as follows :

- ✓ The letters
- ✓ The numbers
- ✓ The Landolt Rings
- ✓ Raskin's E's
- ✓ The symbols



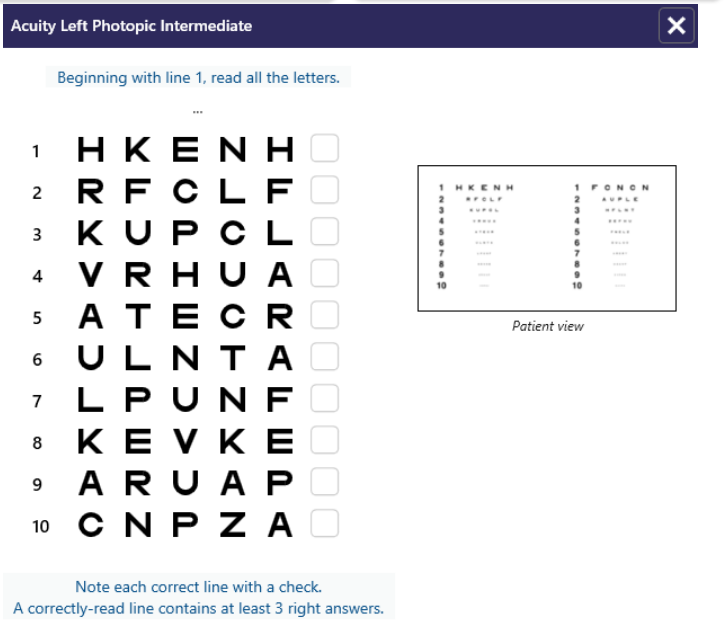
6.2.2. Running the test

- ✓ It is interesting to start with the raw visual acuities of the weaker eye in order to avoid any memorization phenomenon. Then the acuities of the second eye and then the binocular acuities can follow.
- ✓ This test must first be carried out in distance vision, then in near vision and possibly in intermediate vision.
- ✓ You can then perform the same procedure to measure the patient's compensated acuities.

6.2.3. Interface Description VisioWin®

The visual acuity tests are split into as many vignettes as there are distance situations (near, intermediate, far) and lighting (photopic/mesopic) to be tested.

Click on the symbols at the bottom left of the thumbnail to vary the test conditions: with/without correction, optotype model (ABC/123/C/E/Symbols).



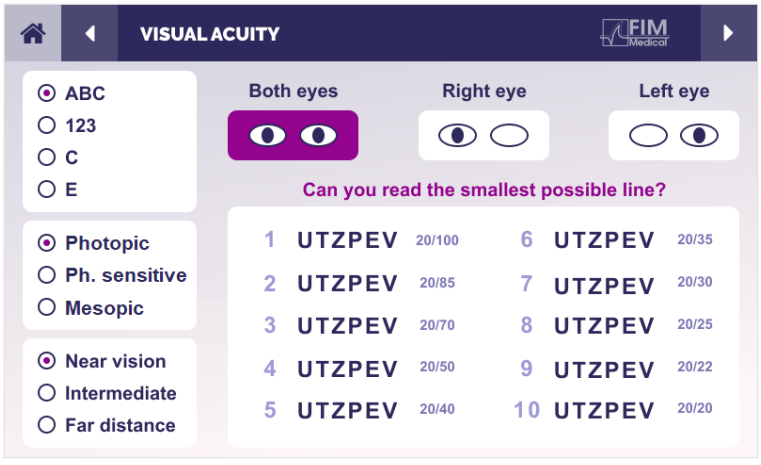
In the response entry window, click on the box to the right of the line to validate the acuity if at least 3 optotypes have been successfully recognized by the patient.

It is also possible to validate or invalidate the perception of an optotype with a left or right click on the optotype respectively.
The perceived optotype is then colored green, the unrecognized one red.

It is not imperative to validate all optotypes independently, validating the optotype with the lowest acuity automatically validates all previous ones.

The unit of the result is to be defined in the general parameters (see paragraph 4.4.1).

6.2.4. Interface Description Remote



The remote control interface allows you to view the conditions of the current test:

- Optotype type poster
- Display brightness level
- Viewing distance
- Viewing mode requested
- Question to ask
- Optotypes displayed

State the question and note the perceived result on the response form.

6.2.5. Instructions to give to the patient

Depending on the type of optotype selected, ask the following question:

- Letters: “On the smallest possible line, read all the letters”
- Numbers: “On the smallest possible line, read all the numbers”
- Landolt : "On the smallest possible line, say on which side the opening of the ring is located."
- Raskin 's E : "On the smallest possible line, say in which direction the letter E is oriented"
- Symbols: “On the smallest possible line, identify the symbols”

6.3. Contrast sensitivity test

6.3.1. Purpose and presentation of the test

This test can detect a decrease in contrast sensitivity that may reflect damage to the retina due to diseases such as cataracts, chronic glaucoma or diabetic retinopathy. A decrease in contrast sensitivity may also occur after corrective eye surgery.

The test is based on the MARS contrast sensitivity test. The test offers 20 different contrast levels that decrease according to the distribution below. Contrast sensitivity is expressed as a percentage, with 100% being the highest contrast and 1.2% being the lowest. In order not to discriminate between subjects, the presentation of the optotypes is done at an acuity level of 2/10. The tables below represent the different contrasts, expressed as a percentage, used in the test.

1	H	R	P	C	A
2	P	F	Z	H	K
3	E	T	P	K	N
4	K	H	C	P	F

1	100	80	63	50	40
2	32	25	20	16	12,5
3	10	8	6,3	5	4
4	3.2	2.5	2	1.6	1.2

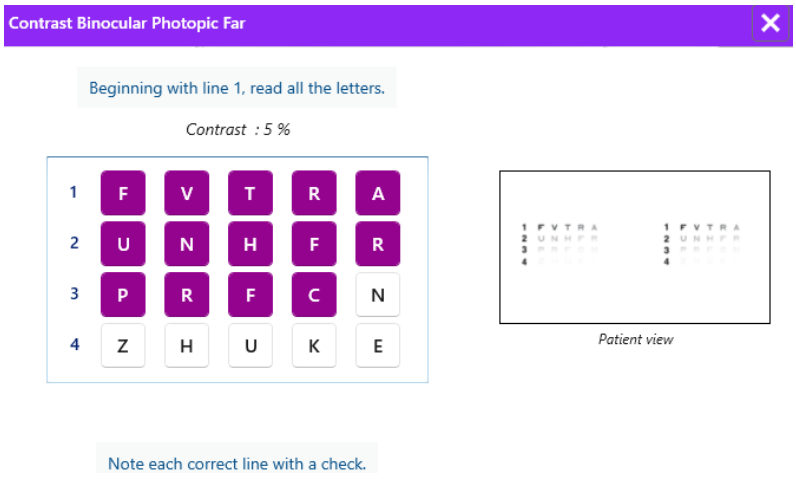
6.3.2. Running the test

- ✓ This test is done binocularly.
- ✓ This test is recommended for distance vision.
- ✓ This test should be performed with patient compensation.
- ✓ This test is recommended in high photopic but can also be carried out in low photopic.
- ✓ The patient must have visual acuity of at least 2/10.

6.3.3. Interface Description VisioWin®

The thumbnail shows the contrast gradient as seen by the patient and the exam result as a percentage.

The viewing distance can be changed.

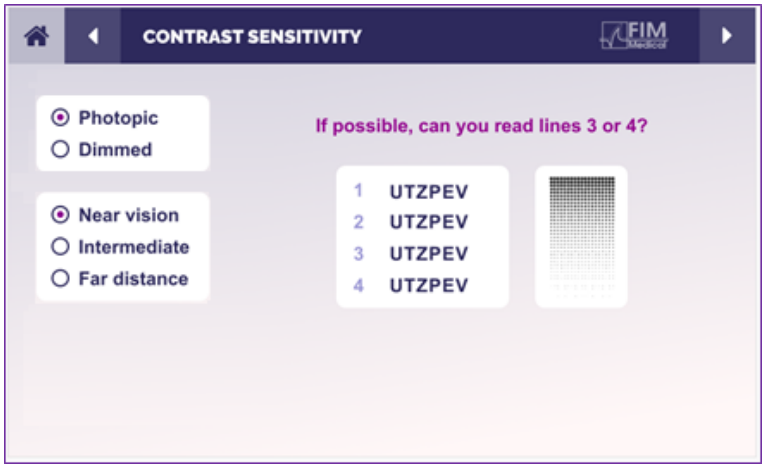


In the response entry window, click on the optotypes correctly recognized by the patient.

Contrast sensitivity is then progressively calculated as responses are received and transcribed into the test thumbnail in the background.

It is not imperative to validate all letters independently, validating the optotype with the lowest contrast will automatically validate all previous ones.

6.3.4. Interface Description Remote



The remote control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Question to ask
- Optotypes displayed

State the question and note the perceived result on the response form.

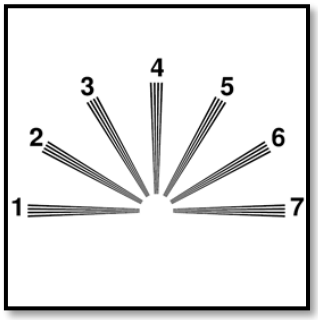
6.3.5. Instructions to give to the patient

Ask the following question: “Read the last letter you can see on line 4 or 3. ”

6.4. Astigmatism test

6.4.1. Purpose and presentation of the test

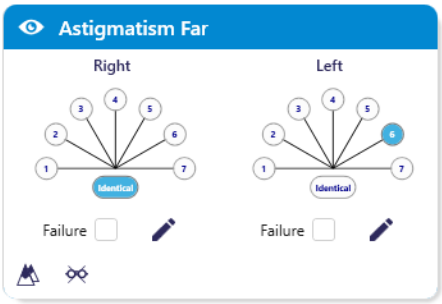
This test is used to detect a defect of astigmatism in a patient. Astigmatism is due to a bad relationship between the power of the eye and its length. The vision of the astigmatic will then be distorted in a particular direction. If the astigmatism is too great, the patient will have poor acuity at all distances. This type of defect can be compensated with astigmatic lenses.
This test consists of seven meridians, each spaced 30° apart. Each axis is represented by three lines to increase the sensitivity of the test. The numbers on the lines are presented at an acuity of 2/10.



6.4.2. Running the test

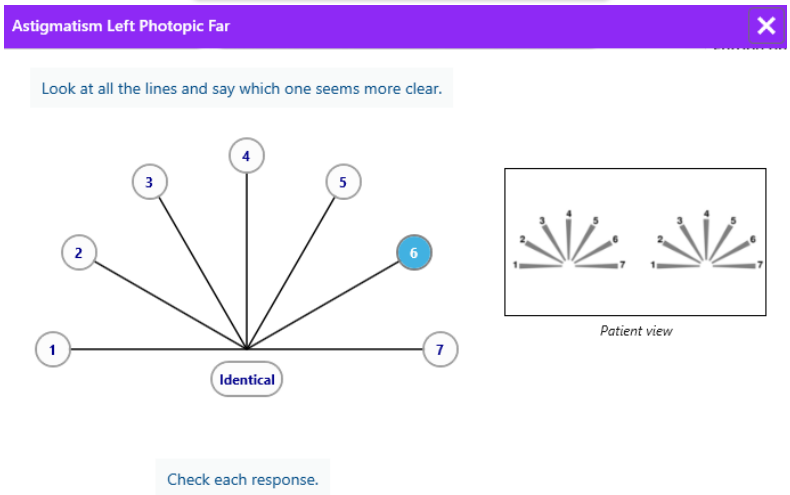
- ✓ This test is performed monocularly.
- ✓ This test should preferably be performed in distance vision in order to limit accommodation.
- ✓ The patient may or may not wear their compensation depending on what you want to test.
- ✓ This test is usually done in a photopic environment.

6.4.3. Interface Description VisioWin®



The thumbnail shows the meridian axes of each eye, with numbers for each axis.

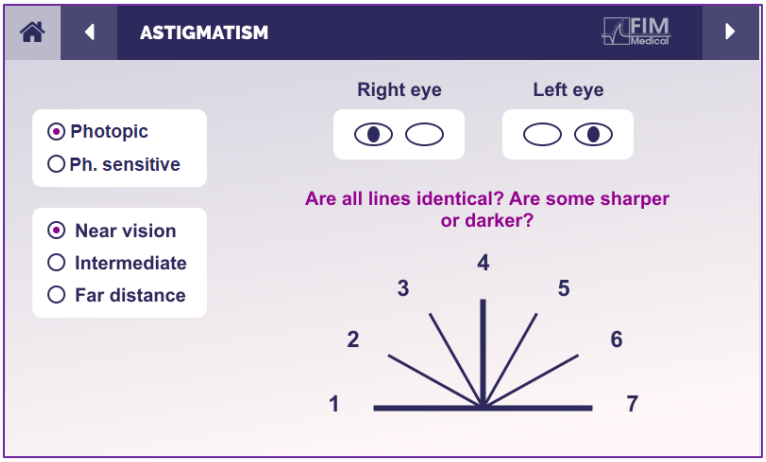
The viewing distance can be changed.



In the response entry window, click on the line or lines perceived most clearly by the patient.
Click on identical if the patient does not distinguish a difference.

The number of the line entered then turns blue.

6.4.4. Interface Description Remote



The remote control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Viewing mode requested
- Question to ask
- Optotypes displayed

State the question and note the perceived result on the response form.

6.4.5. Instructions to give to the patient

Ask the following question: “Look at all the lines, are they the same?”

If the answer is no: “Do one or more lines appear sharper or darker to you?”

“If so, which ones ? ”

6.5. Visual field test complete

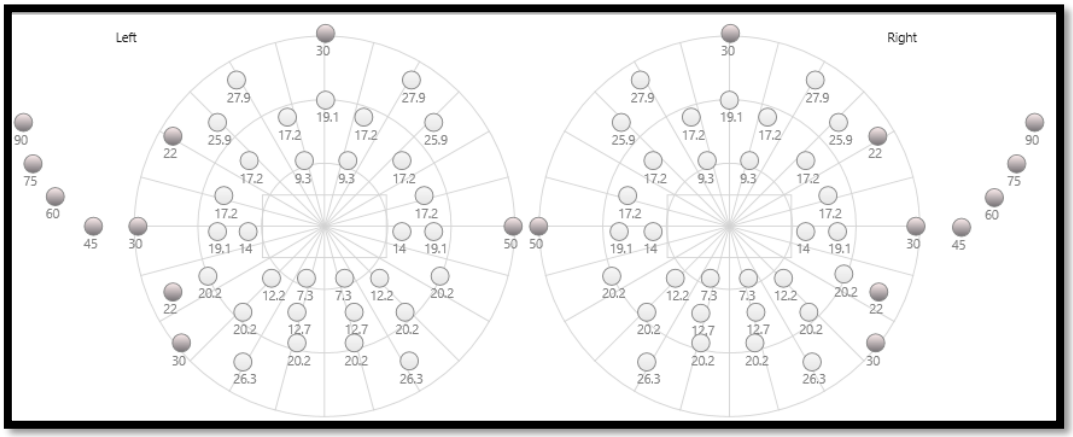
6.5.1. Purpose and presentation of the test

The visual field can highlight various vision disorders. It is essential for diagnosing vision holes due to scotomas, optic nerve damage or directly at the level of the cerebral cortex. The table below shows us the extent of the visual field measurable by the Visiolite® 4K. The values are not symmetrical, particularly because of the relief of the nose. At the binocular level, the horizontal fields will be added, giving a common area for both eyes of 120° surrounded by two crescents of monocular vision of 30° called half-moon fields. The total horizontal binocular field tested is therefore 180°.

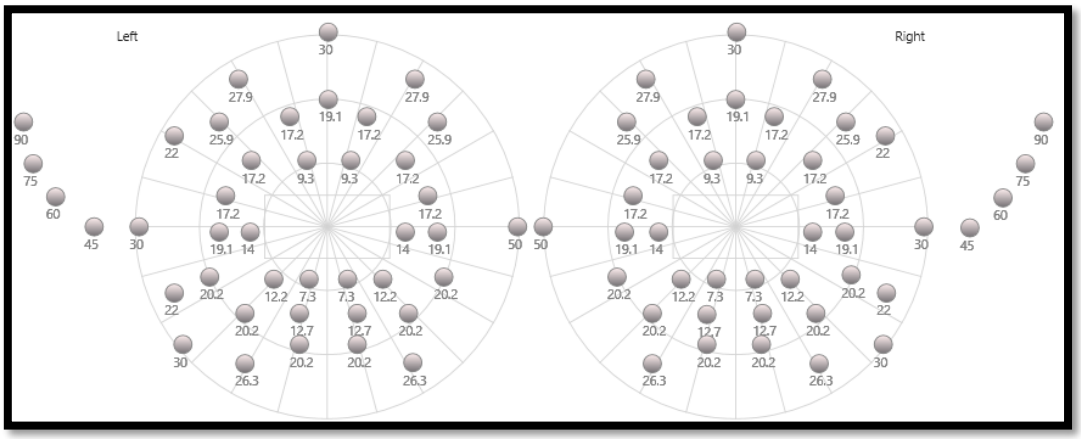
The visual field test can be broken down into two parts: the central field test and the peripheral field test. The first tests the central 30° of vision while the second tests the rest of the visual field. The peripheral field is assessed using a procedure similar to a static Goldman test, while the central field is controlled using an Esterman grid.

Monocular	Beaches	Binocular	Beaches
Nasal	50°	Horizontal	180°
Temporal	90°	Vertical	60°
Superior	30°		
Lower	30°		

Visual field extent tested by Visiolite® 4K



The peripheral field is tested using 20 light stimuli (represented here by the dark dots)



The central field is tested using 64 light stimuli (represented here by the dark dots)

Center field test is not available with remote control version

The peripheral field is tested using 10 diodes per eye. They are arranged as follows:

- ✓ Nasal: 50°
- ✓ Temporal: 30°, 45°, 60°, 75°, 90°
- ✓ High: 22°, 30°
- ✓ Low: 22°, 30°

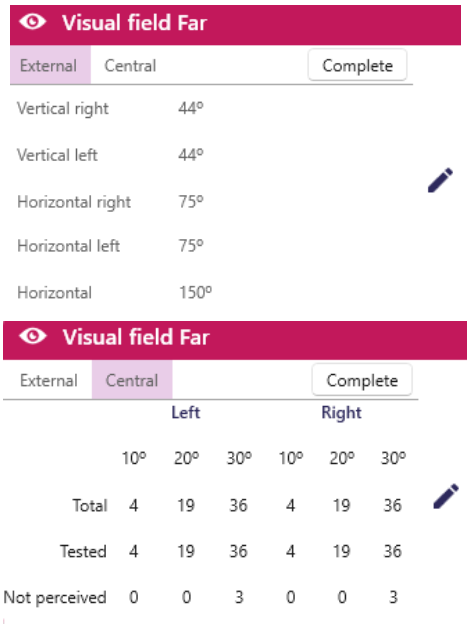
The central field will test the central 30° of vision using 32 diodes per eye. They are arranged in the manner of an Esterman grid , which will give more importance to low vision as well as the horizon line.

Perimetry is performed here in static mode, which implies that the stimulus will be activated for a short time during which the patient must be able to see it. The duration of activation of the light stimulus is of the order of 200 ms.

6.5.2. Running the test

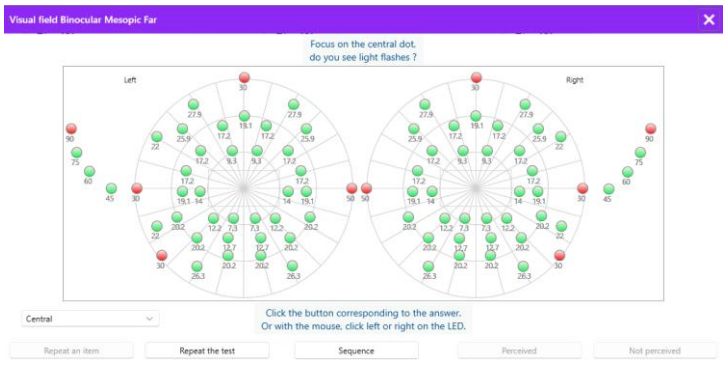
- ✓ This test is performed monocularly.
- ✓ The patient is not wearing his correction.

6.5.3. Interface Description VisioWin®



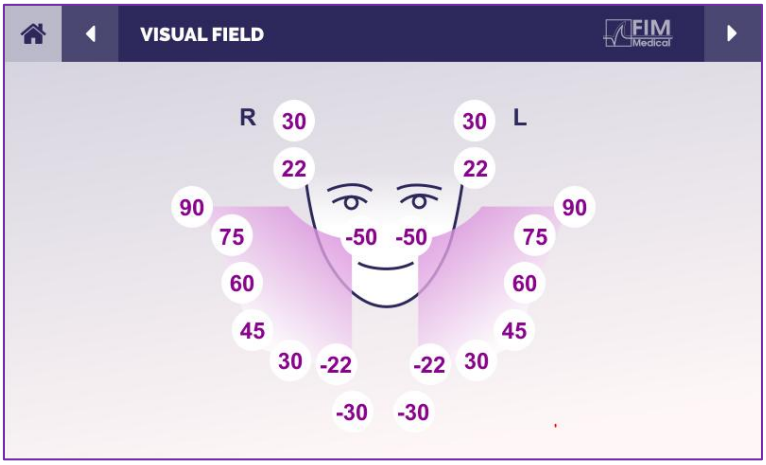
The visual field thumbnail is split into three tabs to test the peripheral and central field independently or in combination:

- A first tab dedicated to the peripheral field showing the extent of the peripheral field measured during the test: vertical and horizontal axis of each eye as well as the complete horizontal axis.
- A second tab dedicated to the central field with the number of diodes perceived for each eye according to the angular extent.
- A third tab to launch the complete test combining peripheral and central field



The input window maps all test points.
It is possible to perform the test manually by selectively clicking on the points to be tested.
Then click the left mouse button to validate the perception of light stimuli, the right mouse button to invalidate. The points then turn green or red respectively.
Test points can follow a predefined display sequence by clicking *Sequence.* Validate or invalidate the perception of stimuli using the *Perceived* and *Not Perceived buttons.*
It is also possible to *Stay One Point* and *Restart the test.*

6.5.4. Interface Description Remote



The remote control interface allows you to view the different diodes in the peripheral field as well as the corresponding angles.

Press the different circles to light up the associated diode and note on the response form whether the patient perceived the light emitted by the diode.

The central peripheral field test is not available in the remote-controlled version.

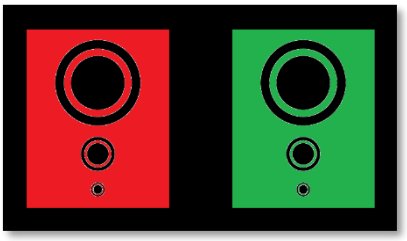
6.5.5. Instructions to give to the patient

Ask the following question: “Look straight ahead and fixate on the central point. From what side do you see " appear the little light?

6.6. Duochrome test

6.6.1. Purpose and presentation of the test

Also called the bichrome test or red-green test, this test is used to confirm a patient's hyperopia. It is based on the chromatic dispersion of the eye. The latter being an optical system, it breaks down light like a prism. Green wavelengths are therefore more deviated than red ones. Depending on the ease of reading on a red or green background, it is possible to know the patient's ametropia. If the patient is hyperopic, the green wavelengths will be closer to the retina, whereas if the patient is myopic, the red wavelengths will be closer to the retina. This test can nevertheless be distorted by the patient's accommodation, hence its majority use to detect hyperopia.

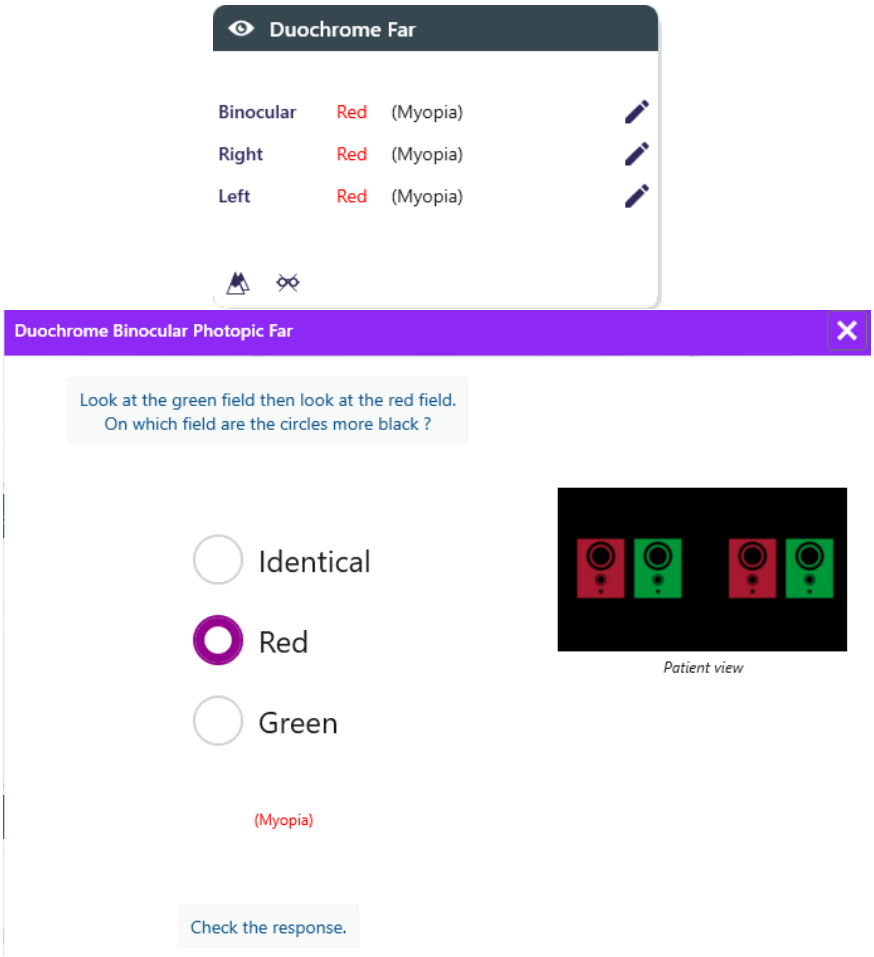


This test is based on the maximum transmission of the eye within the red and green wavelengths. These are 620 nm for red and 535 nm for green. These are therefore the wavelengths used for the colors in this test. Thus the dioptric interval between these two values is 0.5 δ. The circular figures on the tests allow the patient to compare their vision on a red background and on a green background.

6.6.2. Running the test

- ✓ This test is done monocularly then binocularly.
- ✓ This test can be performed with or without compensation depending on what you are looking for: ametropia in the patient or a check of their compensation.
- ✓ This test is to be carried out using photopic imaging.
- ✓ This test is recommended for distance vision in order to limit as much as possible the accommodation used by the patient.

6.6.3. Interface Description VisioWin®

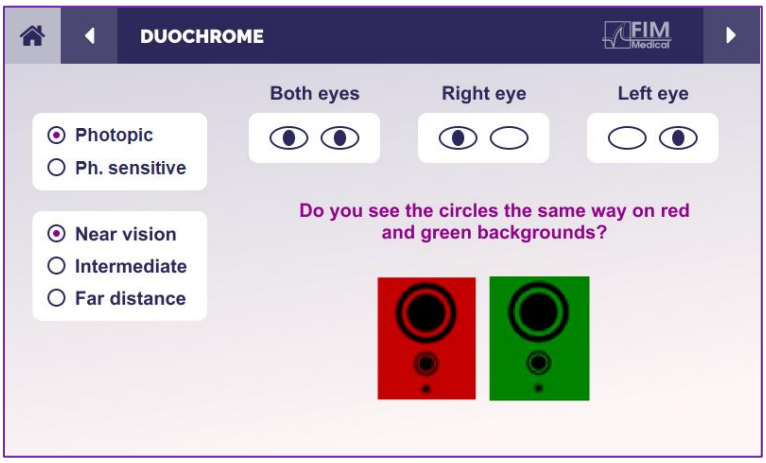


The vignette shows the color best perceived by the patient and a possible hyperopic or myopic tendency.

The viewing distance can be changed.

In the response entry window, click on the color that you perceive best. Click on identical if the patient does not distinguish a difference.

6.6.4. Interface Description Remote



The remote control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Viewing mode requested
- Question to ask

State the question and note the perceived result on the response form.

6.6.5. Instructions to give to the patient

Ask the following question: “Do you see the circles in the same way in the red figure and the green figure?”

If the answer is no: "Are they sharper or darker on one of the 2 colors?"

6.7. Relief test – Stereoscopy

6.7.1. Purpose and presentation of the test

This test is useful to check the quality of stereoscopic vision which is essential for good binocular vision. It is this acuity which allows for depth vision and comparison of the proximity of objects between them. A problem with stereopsis can reveal certain disorders such as anisometropia , amblyopia, strabismus or image suppression problems. The average stereoscopic threshold of the population is around 40 arc seconds (''), and any acuity greater than 60'' can highlight a binocular vision problem.

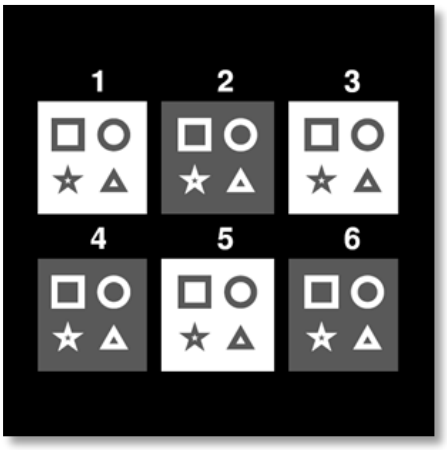


Image seen by the left eye

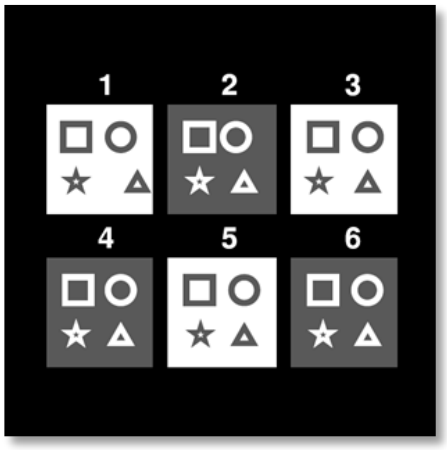


Image seen by the right eye

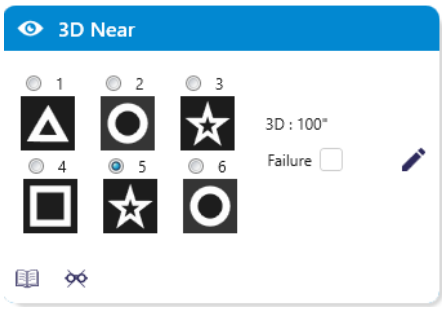
This test consists of six vignettes, each containing four shapes. On each vignette, one of the shapes is shifted only on one eye: the consequence is that the shape thus shifted appears in relief for the subject. This is due to the fact that the brain will try to merge these two almost identical images. The greater the difference between the position of a shape on the right eye and on the left eye, the greater the impression of relief will be. Fixation disparities are expressed in seconds of arc (''), equivalent to 1/3600th ^{of} a degree. They are as follows on this test :

- ✓ Vignette 1: The offset of the triangle position between the right eye and the left eye is 1600''
- ✓ Vignette 2: The offset of the circle position between the right eye and the left eye is 800''
- ✓ Thumbnail 3: The offset of the star position between the right eye and the left eye is 400''
- ✓ Vignette 4: the offset of the position of the square between the right eye and the left eye is 200''
- ✓ Vignette 5: the offset of the star position between the right eye and the left eye is 100''
- ✓ Vignette 6: the offset of the position of the circle between the right eye and the left eye is 50''

6.7.2. Running the test

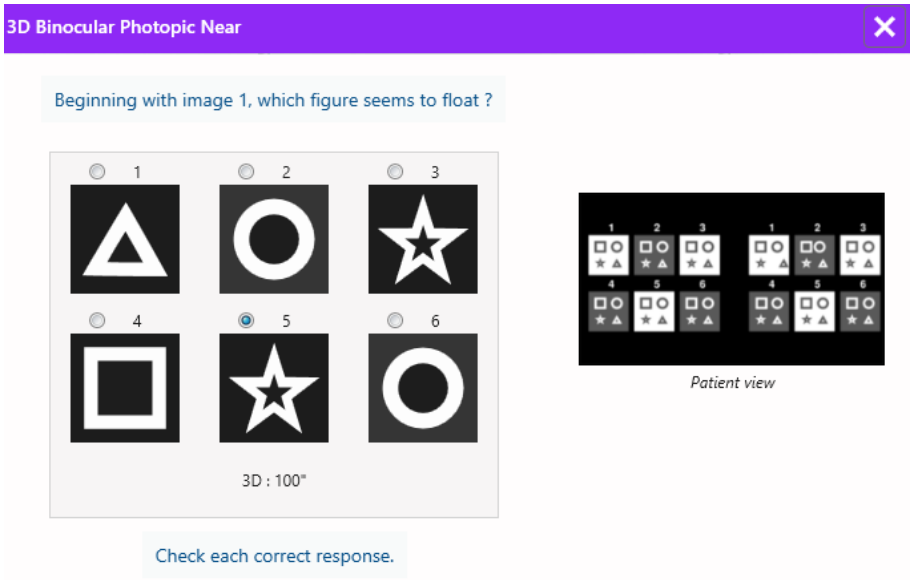
- ✓ This test is done binocularly.
- ✓ This test is recommended for distance vision as well as near vision.
- ✓ This test should be performed with patient compensation.
- ✓ This test is to be carried out using photopic imaging.

6.7.3. Interface Description VisioWin®



The thumbnail shows the geometric shapes in relief perceived by the patient and the corresponding level of shift in arc seconds ('').

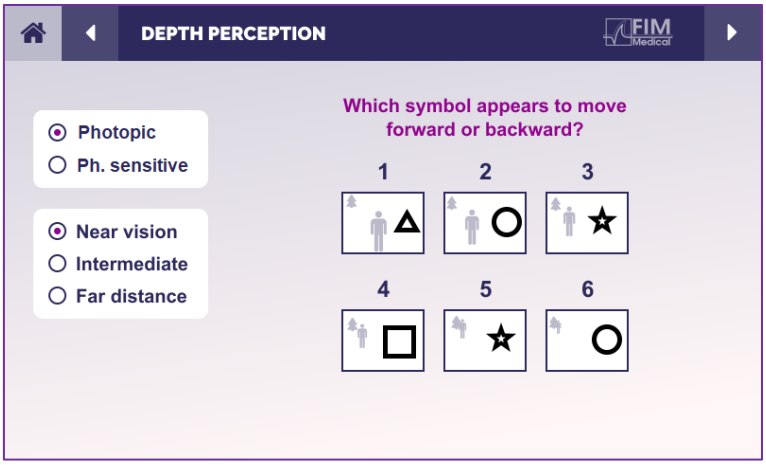
The viewing distance can be changed.



In the response entry window, click on the geometric shapes perceived as offset, “in relief”, by the patient.

It is not imperative to check all the boxes independently, validating the shape with the lowest emphasis will automatically validate all the previous ones.

6.7.4. Interface Description Remote



The remote control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Question to ask
- Forms geometric in relief

State the question and note the perceived result on the response form.

6.7.5. Instructions to give to the patient

Ask the following question: “Starting from figure number 1, which drawing seems to be moving forward or backward relative to the others?”

6.8. Phoria test

6.8.1. Purpose and presentation of the test

The phoria test is used to highlight the tendency of an eye to deviate from its binocular fixation position in the absence of a fusional stimulus. We also speak of heterophorias or dissociated phorias, which are measured in prismatic diopters (Δ). There are several forms :

- ✓ Esophoria denotes a crossing of the visual axes in front of the fixed object.
- ✓ An exophoria causes these axes to cross behind this object.
- ✓ A D/L or L/R hyperphoria when one eye is deviated vertically relative to the other.
- ✓ Incyclophoria or excyclophoria when one eye tends to turn slightly on itself along its anteroposterior axis.

However, it is not abnormal for a subject not to be orthophoric. Indeed, there are categories in which the majority of the population is found without this representing a problem for them.

- ✓ The majority of subjects are between 0 Δ and 2 Δ of exophoria in distance vision.
- ✓ The majority of subjects fall between 0 Δ and 6 Δ of exophoria in near vision.

A poorly compensated phoria can subsequently result in significant visual fatigue, diplopia or even the neutralization of the image in one eye. This test allows for complete dissociation of the two eyes by not proposing any fusion lock between the two.

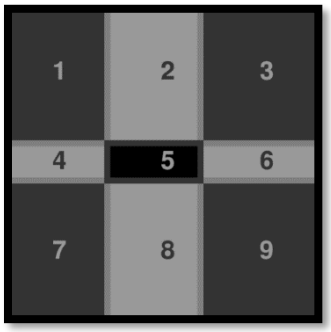


Image seen by the left eye

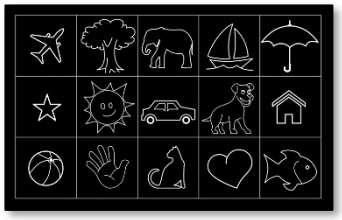


Image seen by the left eye (Child-friendly variant)

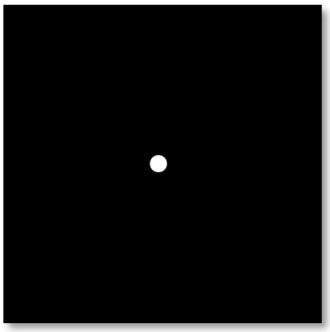


Image seen by the right eye

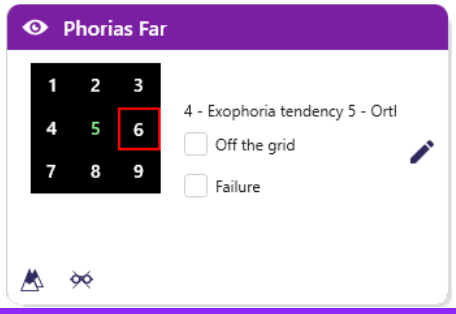
This test, which assesses a patient's heterophorias, is composed of two images. The first represents a grid of nine boxes while the second is only composed of one point. This grid will allow the value of the phorias to be framed as follows:

- ✓ Horizontally :
  - Phorias greater than 9 Δ.
  - Phorias between 3 Δ and 9 Δ.
  - Phorias less than 3 Δ.
- ✓ Vertically :
  - Phorias greater than 9 Δ.
  - Phorias between 1 Δ and 9 Δ.
  - Phorias less than 1 Δ.

6.8.2. Running the test

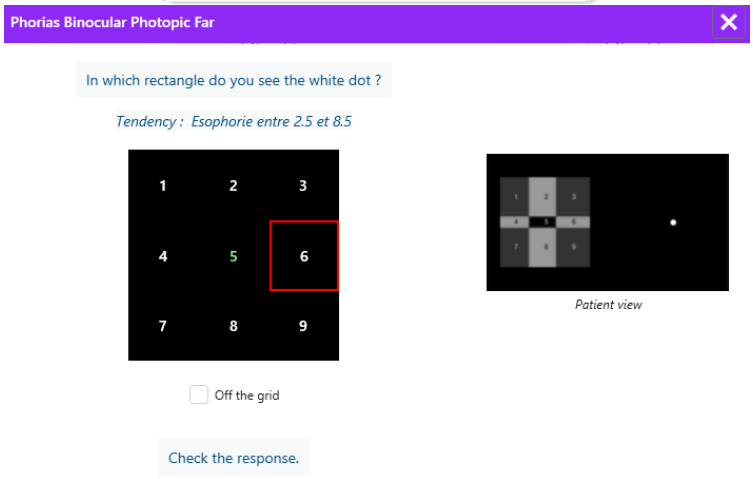
- ✓ This test is done binocularly.
- ✓ This test should be performed with patient compensation.
- ✓ This test can be performed photopic and possibly mesopic.
- ✓ This test should be performed when monocular acuities are approximately the same. If the difference is too great, this test will have no diagnostic value.

6.8.3. Interface Description VisioWin®



The thumbnail shows the grid of nine boxes displayed to the patient and the trend associated with the result entered.

The viewing distance can be changed.

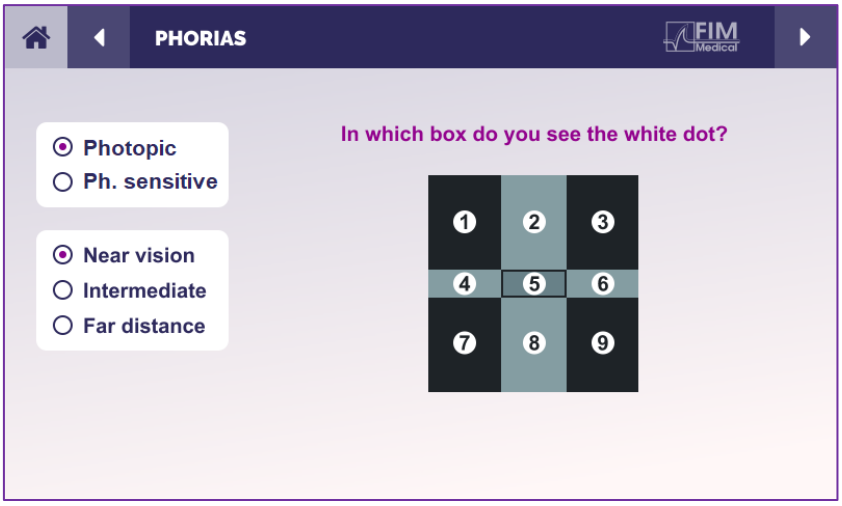


In the response entry window, click on the box in which the patient sees the white dot.

The trend related to the result is visible above the input grid.

Check the *Off-grid box* if the patient does not perceive the white dot.

6.8.4. Interface Description Remote



The remote control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Question to ask

State the question and note the perceived result on the response form.

6.8.5. Instructions to give to the patient

Ask the following question: “In which box do you see the white dot?”

The movement of the point is often fleeting or non-existent (orthophoria): questioning must prepare the patient to indicate the location of the point at the moment of its appearance.

To make this test more sensitive, the Visiolite® 4K presents the grid and the point successively with a slight time delay.

6.9. Fusion test

6.9.1. Purpose and presentation of the test

The purpose of this test is to check the patient's binocular vision. It is known as the Worth test. It will allow us to know if the patient's brain is able to fuse the images from the right eye with those from the left eye. Fusion requires good visual acuity in each eye. Fusion disorders can be more or less advanced, from a disparity of fixation to the complete suppression of one of the two images. They are also often responsible for significant visual fatigue when working on a screen.

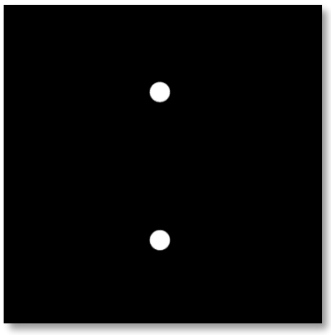


Image seen by the left eye

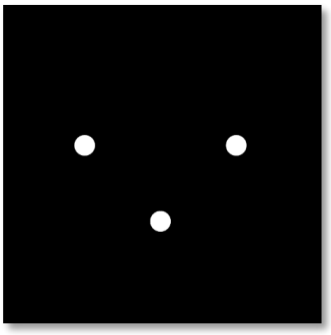


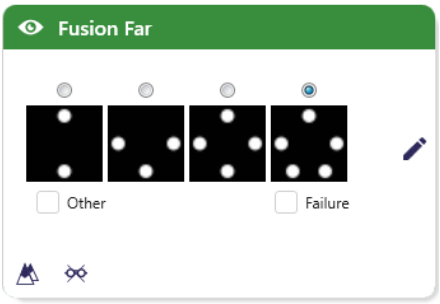
Image seen by the right eye

This test consists of two different images. The one for the left eye contains two points while the one for the right eye contains only three points. The fusion must be done using the lower point that is common to both images.

6.9.2. Running the test

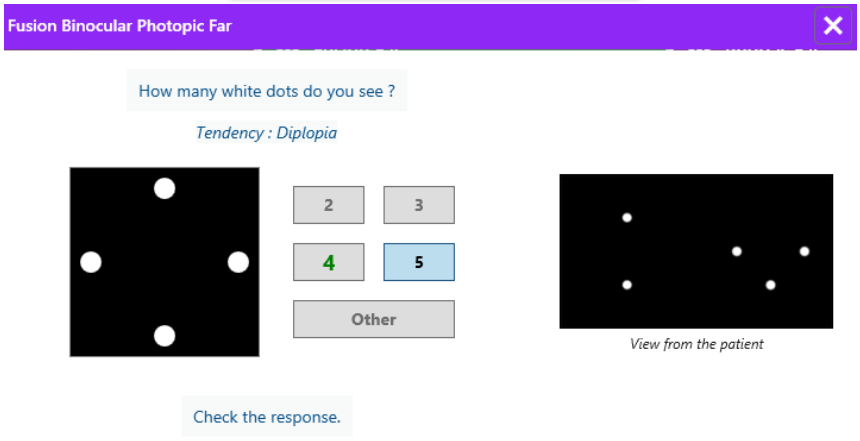
- ✓ This test is done binocularly.
- ✓ This test should be performed with patient compensation.
- ✓ This test must be performed photopic.

6.9.3. Interface Description VisioWin®



The vignette presents the 4 results perceptible by the patient.

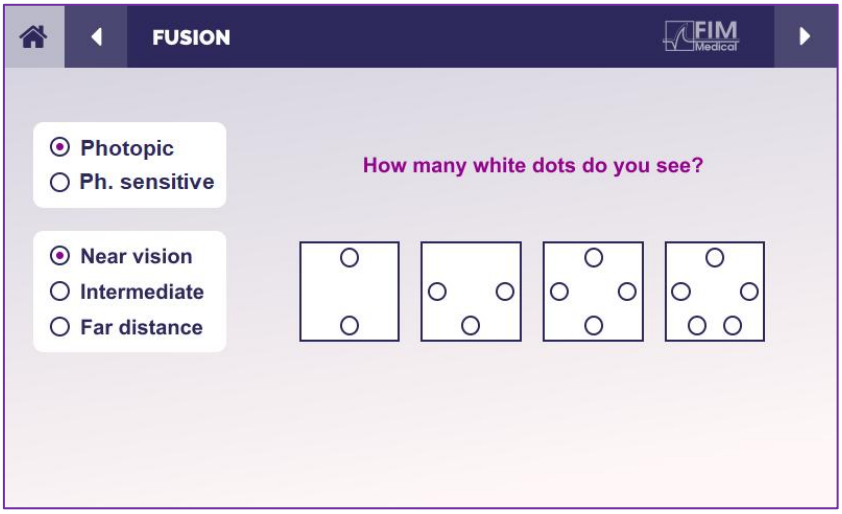
The viewing distance can be changed.



In the response entry window, click on the number of points received by the patient.

The trend related to the result is visible above the input boxes.

6.9.4. Interface Description Remote



The remote control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Question to ask

State the question and note the perceived result on the response form.

6.9.5. Instructions to give to the patient

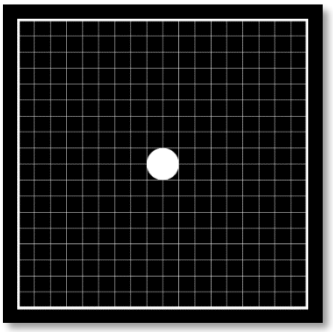
Ask the following question: “How many white dots do you see?”

6.10. Amsler Grid Test

6.10.1. Purpose and presentation of the test

The Amsler grid is a test that can highlight vision disorders related to retinal problems and more specifically to damage to the macula. This test is intended to control the central 20° of the retina. It is used in particular to highlight Age-Related Macular Degeneration (AMD), a disease that mainly affects people **over 50 years old.** It is an essential test because it can detect the following pathologies:

- ✓ A glaucoma
- ✓ A scotoma
- ✓ Damage to the optic nerve
- ✓ AMD
- ✓ A metamorphopsia
- ✓ A loss of the peripheral field or central field

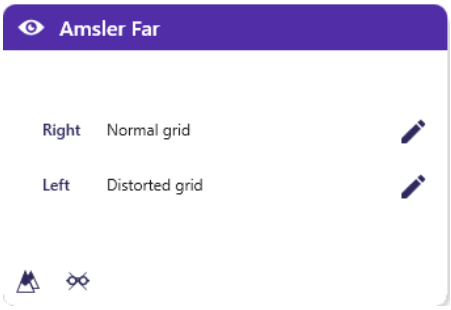


This test was developed by a Swiss ophthalmologist named Marc Amsler. It is presented in the form of a square grid viewed at an angle of 20°. Each row and each column is composed of 20 tiles and there is a fixation point in the center of the grid. The latter will allow the patient's gaze to be fixed in order to be able to control their visual field. We have opted for a white grid on a black background, but different versions exist.

6.10.2. Running the test

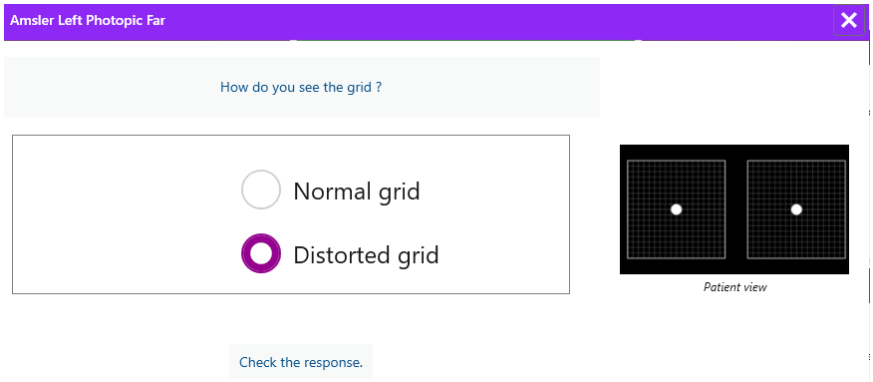
- ✓ This test is done monocularly.
- ✓ This test should be performed with patient compensation.
- ✓ This test must be performed in photopic mode

6.10.3. Interface Description VisioWin®



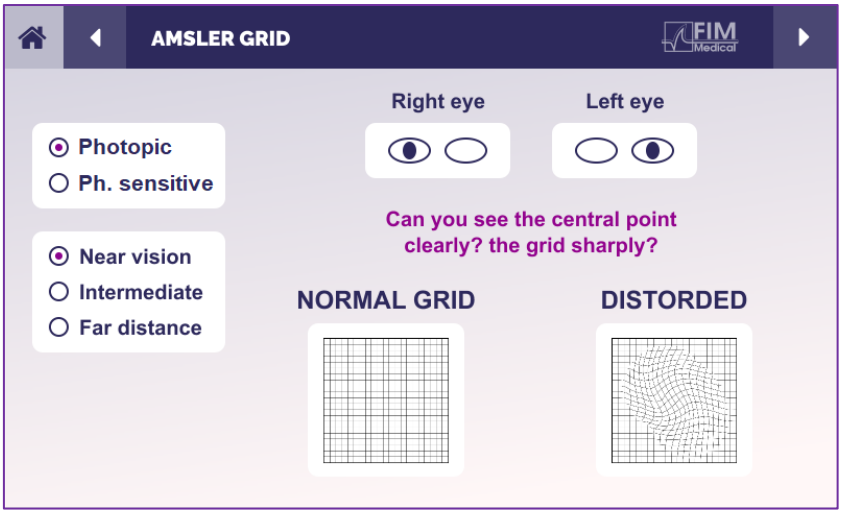
The thumbnail shows the results for each eye tested.

The viewing distance can be changed.



In the response entry window, check whether the patient perceives the grid as normal or distorted.

6.10.4. Interface Description Remote



The remote control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing mode requested
- Viewing distance
- Question to ask

State the question and note the perceived result on the response form.

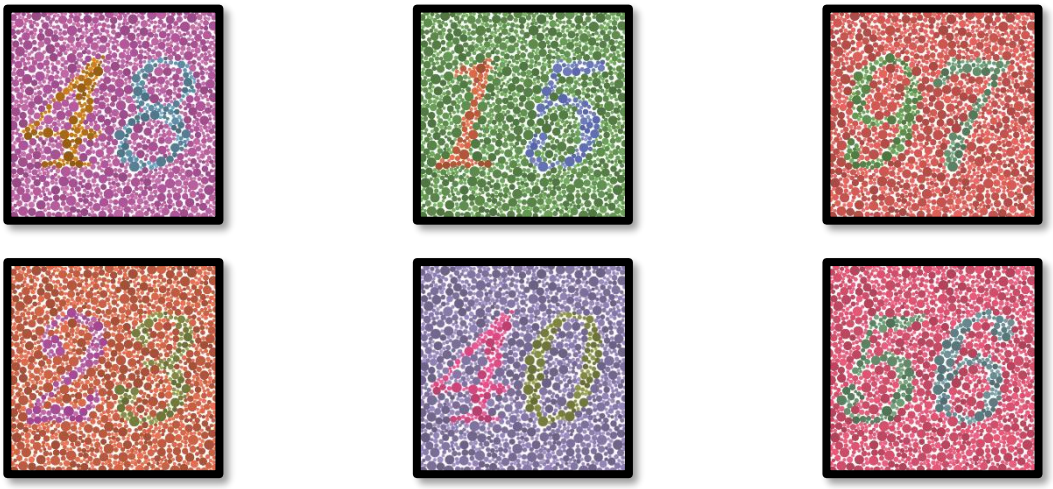
6.10.5. Instructions to give to the patient

“ Can you see the central point clearly? Is the grid clear ? »

6.11. Color perception test

6.11.1. Purpose and presentation of the test

This color perception test, consisting of a set of pseudo-isochromatic plates, allows the detection of color vision abnormalities, and mainly Protan , Deutan and Tritan type dyschromatopsias. Reading the numbers on all the plates allows us to know the state of a subject's color perception and can reveal difficulties in recognizing certain numbers and therefore certain colors.



The color perception test is based on the vision of pseudo-isochromatic plates (PIC). The test consists of six plates of numbers using the principle of color confusion lines in the CIE- xy ("International Commission on Illumination") diagram.

The background and pattern hues are strategically chosen on a confusion line, so the pattern is visible to a normal subject, but not to a subject with a color deficiency. All of these tests allow for the solicitation of 12 chromatic confusion lines in the three axes: Protan , Deutan and Tritan.

Each test is made up of a mosaic of points of different colors, shades and dimensions.

Each board has 3 different shades (one for the background, one for the 1st number and another for the 2nd number).

Each shade is itself composed of several nuances.

6.11.2. Running the test

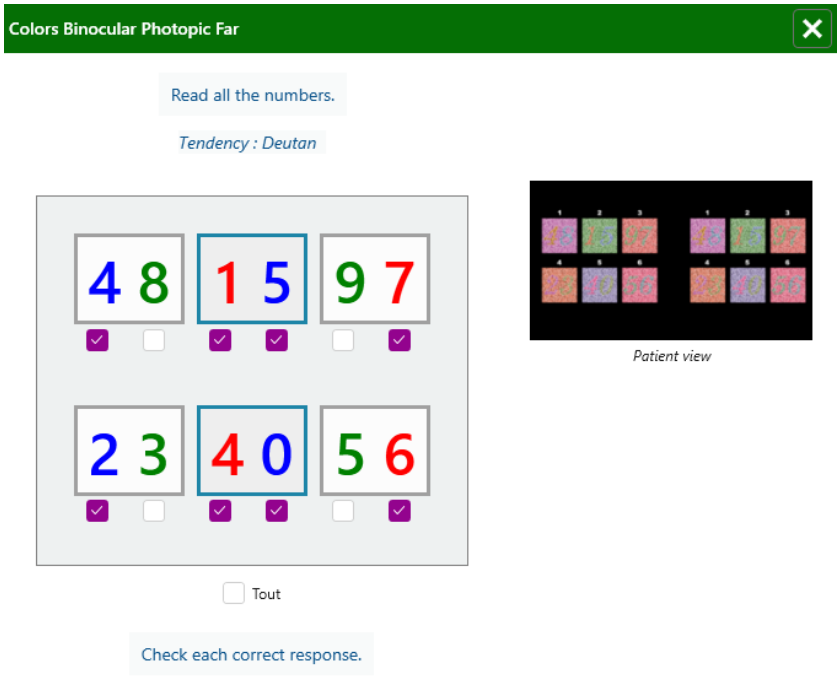
- ✓ This test is done binocularly , but can also be done monocularly.
- ✓ This test should be performed with patient compensation.
- ✓ This test must be performed photopic.

6.11.3. Interface Description VisioWin®

The thumbnail shows the color numbers to be identified by the patient for each vision mode.

The check boxes represent the numbers perceived or not by the patient.

The viewing distance can be changed.



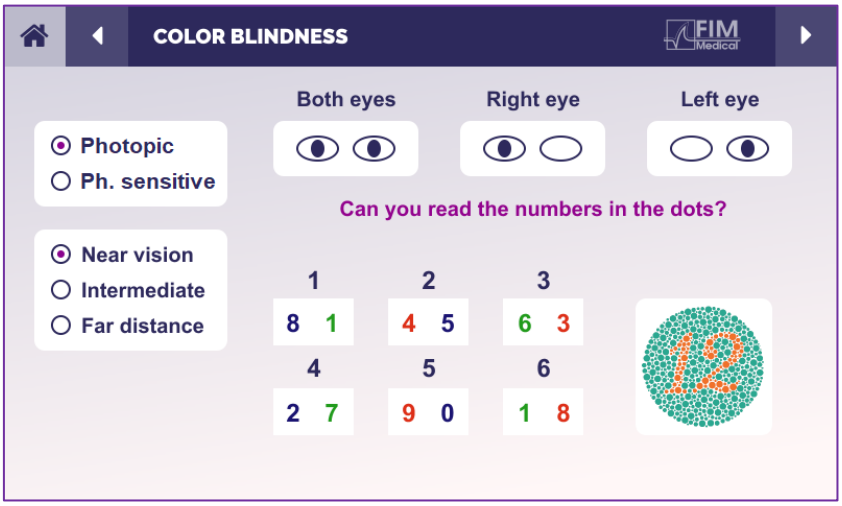
Patient view

In the response entry window, check the boxes corresponding to the numbers correctly recognized by the patient.

Check the *All box* if the patient correctly recognizes all the numbers.
Otherwise it is necessary to check all the boxes independently.

The trend related to the result is visible above the input grid.

6.11.4. Interface Description Remote



The remote control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing mode requested
- Viewing distance
- Question to ask

State the question and note the perceived result on the response form.

6.11.5. Instructions to give to the patient

Ask the following question: “Starting from figure number 1, read the numbers in the dots”

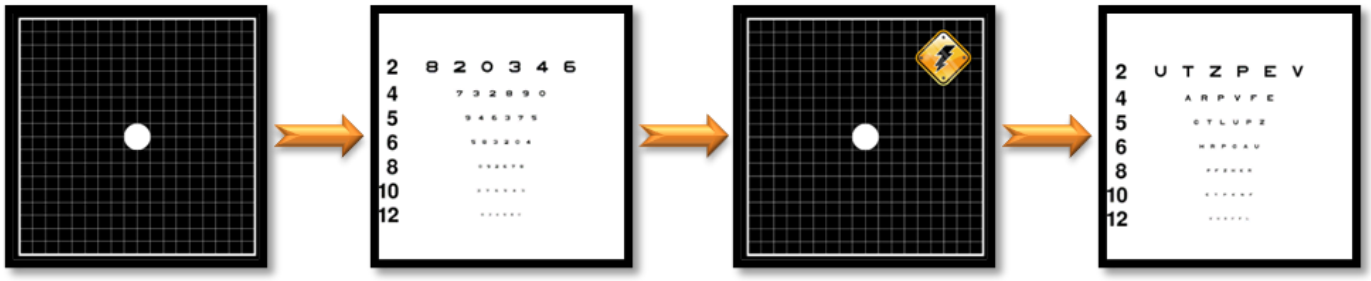
6.12. Glare resistance test

Visiolite® 4K glare tests should not be performed on photosensitive patients who have recently taken photosensitizing medication.
Medical contraindications to performing this test are detailed in paragraph 1.4

This test is not available with the remote control version.

6.12.1. Purpose and presentation of the test

The central glare test is used to check the recovery time of a subject's central vision after intense glare. Some pathologies lengthen this time, and it is therefore possible to find certain macular deficiencies in the patient with this test. It will be essential to carefully check all the contraindications of this test in order not to trigger adverse reactions in the patient. It will also be important to warn the patient about the relatively high intensity of the light.



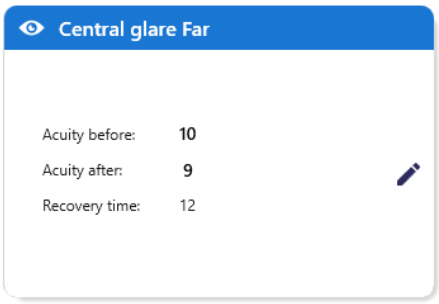
This test uses various other tests from Visiolite® 4K. It consists of four steps:

Etape 1. The Amsler grid is presented to the patient under mesopic illumination (3 cd/m²).
Etape 2. An acuity test with numbers is then presented in a mesopic environment.
Etape 3. The patient is then dazzled by a light of 3 lux.
Etape 4. An acuity test with letters is finally presented in a mesopic environment.

6.12.2. Running the test

- ✓ This test is done binocularly.
- ✓ This test is performed in distance vision.
- ✓ This test should be performed with patient compensation.
- ✓ This test must be performed mesopically.

6.12.3. Interface Description VisioWin®



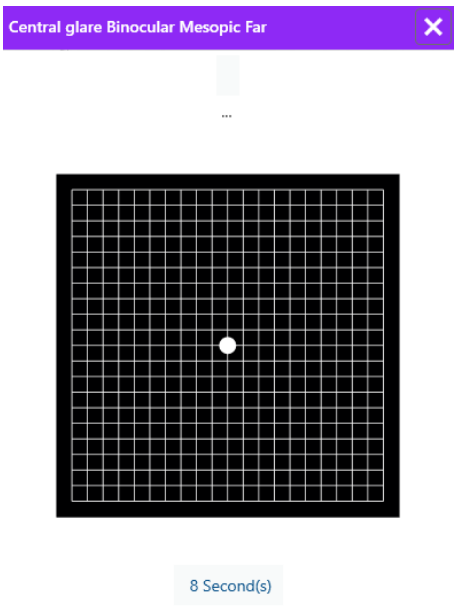
The vignette shows the acuity results before and after glare as well as the recovery time required for the patient to read the smallest line of optotypes after glare.

Viewing, distance or lighting conditions cannot be changed for this test.

The acuity results entry window is described with the test instructions below.

6.12.4. Instructions to give to the patient

Step 1 – Patient adaptation



The Amsler grid is displayed in mesopic brightness for a duration of 10 seconds.

Step 2 – Acuity Before glare

Ask the patient to read the optotypes from the smallest possible line.

Check the line to validate the acuity if at least 3 optotypes have been recognized.

Step 3 – Dazzle

Ask the patient to focus his gaze on the central glare point.

The Amsler grid is displayed for the entire 10 second glare duration.

The aim of this step is to cause a scotoma.

Step 4 – Acuity after recovery

Ask the patient to read the optotypes on the smallest possible line as soon as his visual perception capacity is recovered.
A countdown measures the recovery time.

Check the line to validate the acuity if at least 3 optotypes have been recognized. The optotypes displayed are different from step 2 to prevent any memorization by the patient.

6.13. Glare sensitivity test

Visiolite® 4K glare tests should not be performed on photosensitive patients who have recently taken photosensitizing medication.
Medical contraindications to performing this test are detailed in paragraph 1.4

This test is not available in a remote-controlled or automated version with VisioClick®.

6.13.1. Purpose and presentation of the test

Glare is when there is too much light for the eye to tolerate. This phenomenon reduces the subject's comfort and visual performance and can continue over time, even after the glare has stopped.

The purpose of this test is to reveal problems with light sensitivity by presenting a night driving scene where the patient will have to decipher as much information as possible. The more sensitive the patient is, the more diffuse the light will appear to him and the more difficulty he will have in reading information close to the light source.
This test will therefore allow us to highlight the visual capacities of a dazzled subject. It will be essential to carefully check all the contraindications of this test in order not to trigger adverse reactions in the patient. It will also be important to warn the patient about the relatively high intensity of the light.

This test represents a classic night driving scene. It consists of six objects that the patient will have to decipher. It includes :

- ✓ A license plate
- ✓ A sign information
- ✓ A speed limit sign
- ✓ Three panels directional

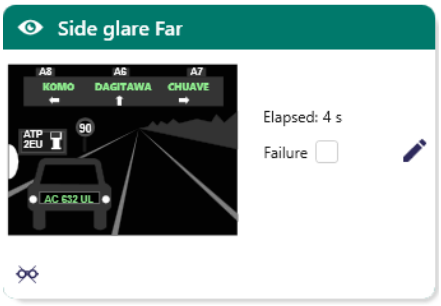
The different optotypes of the scene are formed of letters as well as random numbers. They are presented under a visual acuity between 3/10 and 4/10. The contrast levels are varied and the different objects are positioned in such a way as to recreate a potentially real situation.

The glare source is caused by a light diode placed on the left.

6.13.2. Running the test

- ✓ This test is done binocularly.
- ✓ This test is performed in distance vision.
- ✓ This test should be performed with patient compensation.
- ✓ This test is performed mesopically.
- ✓ The patient must have visual acuity of at least 4/10 in order to be able to read the various information.

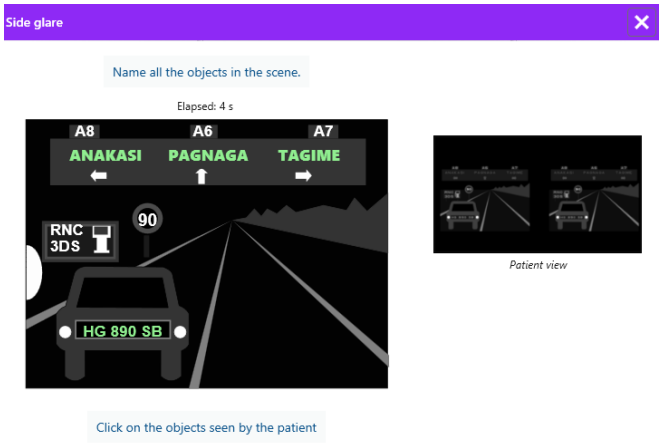
6.13.3. Interface Description VisioWin®



The thumbnail shows the driving situation displayed to the patient, the visual elements perceived are colored green.

The test completion time is also visible.

Viewing, distance or lighting conditions cannot be changed for this test.



In the response entry window, left-click on the elements perceived by the patient.
If you make a typing error, clicking the item again will deactivate it.

Activated elements are colored green.

All items with letters or numbers can be clicked.

6.13.4. Instructions to give to the patient

Ask the following question: “Read all the information in the scene, if possible starting from the one closest to the light source.”

7. Visiolite® 4K Maintenance

7.1. Cleaning

7.1.1. Disinfection of the front support and plastics

The removable forehead support and plastic parts of the Visiolite® 4K must be cleaned after each use with a soft cloth soaked in 70% isopropyl alcohol or a bactericidal/virucidal wipe from the following references approved by FIM Medical :

Bactinyl® Wipes disinfectants scented
Clorox® Healthcare Bleach
Sani-Cloth® Bleach / Plus / HB / AF3
Super Sani-Cloth®
Formula 409®
Virex® Plus
Mikrozid® AF Wipes
Mikrozid® Universal wipes premium
Oxivir Excel® wipes

Visiolite® 4K should not be immersed or sprayed with liquid.

Optical lenses should never be cleaned with wet wipes or other disinfectant liquids.

7.1.2. Cleaning the optics

The optical lenses on the front of the Visiolite® 4K must be cleaned regularly using the microfibre cloth supplied with the device (see paragraph 2.1).

Regular use of microfiber cloths does not alter the anti-reflective treatment.

Do not apply strong pressure to the lenses during this operation.

7.2. Periodic maintenance

Annual maintenance of the Visiolite® 4K is recommended for verification and calibration of the display screen and glare LEDs.

Only FIM Medical and its authorized distributors are authorized to carry out maintenance.

7.3. Support from the software Visiowin

From the side menu click on the icon *Help* to access maintenance information for VisioWin® software or Visiolite® 4K.

Information tab the following system information is available:

- Specifications computer hardware
- System Properties Windows operating system
- Information about Windows user account permission levels
- Database Properties
- VisioWin® software and Visiolite® 4K (Visioclick®) firmware versions

In the event of technical difficulties, this page will allow you to gather essential information for efficient and rapid support by the FIM Medical support team or your authorized distributor.

7.4. Disposal

In accordance with the WEEE directive, used electronic devices must be treated separately from household waste. The devices must be deposited in specific collection sites (waste disposal centres). For more information, you can contact FIM Medical or your authorized distributor.

7.5. Guarantee

Under the contractual warranty, only repairs are covered. The warranty will only be applicable if the normal and usual conditions of use of the device have been respected. During the annual maintenance, a certain number of preventive operations are carried out; the revision cannot constitute a guarantee of coverage of breakdowns that may occur after this revision.

The device East 2 year warranty.

7.6. Lifetime

FIM Medical estimates the lifespan of Visiolite® 4K at 10 years subject to proper compliance with cleaning conditions (paragraph 7.1), maintenance (paragraph 7.2) and environmental conditions (paragraph 2.3.1).

No liability for the lack of performance of the device can be attributed to FIM Medical in the event of non-compliance by the user with the maintenance recommendations and conditions of use.

7.7. Problem Solving

Issue	Probable cause	Solution
Visiolite® 4K does not turn on	Default power supply electric	Check the correct electrical connection of the Visiolite® 4K, a green indicator light should be visible on the power supply unit. If using a power strip, plug the power supply directly into a wall outlet.
Visiowin® software interface is not displayed correctly	Zoom level too high	Set zoom to 125% maximum
The Visiolite® 4K is shown as offline in VisioWin.	Visiolite® 4K is not detected or recognized by the PC	Turn off the Visiolite® 4K, move the USB connection cable to another available port on the PC.
The test seen by the patient is different from that displayed in VisioWin®. Test display is distorted or inconsistent.	The integrity of data stored in the device's internal memory is compromised.	Turn off the Visiolite® 4K, unplug the power supply. Reconnect the power supply and restart the Visiolite® 4K.
Stains are visible on the tests. The test display flickers. The colors of the tests appear abnormal. The brightness is not uniform or too low.	The screen display East damaged.	Turn off the Visiolite® 4K, unplug the power supply. Leave the Visiolite® 4K at rest for several hours before plugging it back in.
The tests appear blurry	The optics are foggy	Clean the mask optics with a microfiber cloth.
An error message is displayed when starting VisioWin®	The Windows directory where the software data is stored is not read/write accessible. The database is not read/write accessible.	Check with your network administrator for security permissions assigned to the Windows user account.

If the problem persists, or for any other problem, contact FIM Medical or your authorized distributor.

For quick troubleshooting, it will be helpful to provide system information or event logs available from the VisioWin® help page (see paragraph 7.3).