

VISION SCREENING



USER MANUAL VISIOLITE® 4K



CE



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1. Introduction – Visiolite® 4K

The Visiolite® 4K is intended to explore visual function and screen for visual disorders.

The **important symbols** used in these instructions are shown below:



WARNING: Indicates conditions or practices which, if not avoided can cause danger to the patient and user and/or environment.



CAUTION: Indicates conditions or practices that could result in damage to the equipment.



NOTE: Indicates important information about the use of the device.

2. Instructions for your safety



WARNING: Do not disassemble the device or work on internal components.

WARNING: Do not open the device or insert object in it.

WARNING: Do not use any power supply or accessories other than those provided with the device, as this may compromise its performance and safety.



CAUTION: Do not store or use the device outside the environmental conditions specified in the technical characteristics.

CAUTION: Do not immerse the device in liquid or expose it to spraying.

CAUTION: Do not use the device if it shows any visible signs of damage.

3. Electromagnetic compatibility

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

Its electronic design ensures robust immunity to surrounding electromagnetic disturbances.

As a result, the presence of radio frequency equipment does not affect the reliability of visual screening tests.

4. Clinical information

Intended use

The Visiolite® 4K is intended for the evaluation of visual function and the screening of visual impairments.

Device users



CAUTION: The Visiolite® 4K must be used exclusively by trained healthcare professionals who are qualified to interpret the results and ensure compliance with hygiene and bacterial contamination rules. **Test results must always be communicated with appropriate medical interpretation.**

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

Patient population

The Visiolite® 4K can be used to perform visual acuity tests on patients older than 5 years old who can understand and follow test instructions.

Contraindications

Glare tests with the Visiolite® 4K should not be performed on patients who are photosensitive, have recently taken photosensitizing medications (examples listed in Table 1), have undergone eye surgery or experienced ocular trauma within the past 3 months, or suffer from any of the following conditions: albinism, cystinosis, keratoconjunctivitis, or ocular inflammation.

If there is any doubt, medical advice is essential before conducting a glare test.

If the patient experiences discomfort or eye pain, the test must be immediately discontinued.

For photosensitive persons, a low photopic mode can be used.

Table 1: *Non-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

Limitations of use

The patient cannot understand and follow test instructions.

Clinical benefits

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

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

Adverse effects and potential side effects

In the event of an incident or a risk of a serious incident related to the device, healthcare professionals or users may file a report with the competent authorities of the European Union Member State. In all cases, the manufacturer must be informed as soon as possible in order to report and handle the medical device vigilance case.

5. Technical description

Materials provided

Equipment included with the Visiolite® 4K device:

- Removable front support
- External IEC60601 medical power supply unit (Globtek reference GTM41060-2512 or UE Electronic reference UES24LCP-120200SPA)
- Microfiber cloth for cleaning the lenses
- USB Type C to Type A cable
- VisioWin® software V02.00.00 (Computerized version)
- Information sheet
- Remote control (Remote-controlled version only)
- Optional: VisioClick®, a USB Type A to Type B cable, an audio headset, a transport cover

Device presentation

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

The device works by displaying images to the patient (tests). Depending on what the patient perceives, it is possible to screen for visual impairments.

The tests assess the patient's visual function in near vision, distance vision, intermediate vision and under a hyperopia condition (+1δ). Different distances are available for each type of vision depending on the configurations.

The tests can be carried out either in monocular vision (right or left), or in 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 at the patient's request to 80 cd/m²)
- Mesopic lighting (low brightness of 3 cd/m²)

The device operates in two control modes:

- Standalone in the remote-controlled version
- Interfaced in the computerized version

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

The Visiolite® 4K offers you the following advantages:

- Ergonomics of use and transport, in the remote-controlled or computerized version
- Fast start-up and execution
- Highly configurable and automatable
- Highly interoperable with major business software

The examination can be performed independently by the patient using the optional VisioClick® accessory. This automation accessory operates using voice instructions delivered via an audio headset, to which the patient responds via a push button.



1. Removable forehead support and patient head-presence detection area
2. Retractable eyecup for the central visual field test
3. Optics for distance and intermediate vision tests
4. LED arrays for the peripheral visual field test
5. Optics for near vision tests
6. Ergonomic nasal position
7. Weighted non-slip base to ensure device stability
8. Location of connectors and ON/OFF switch
9. Remote control with 7" touchscreen (Remote-controlled version only)
10. Automated option: VisioClick® response unit with its headset holder
11. Automated option: Audio headset on its holder
12. Automated option: Single-use hygienic covers



6. Technical characteristics

Features of the Visiolite® 4K

Display screen	TFT-LCD 5.46" 4K 2160p (3840x2160)			
Backlight type	Double (2 x 12 LEDs)			
Brightness levels	Photopic 80 or 160 cd/m ² Mesopic 3 cd/m ²			
Optical focal lengths	Depending on the versions:			
	Near vision	Intermediate vision	Distance vision	
	33.00 ± 0.25 cm 14.0 ± 0.1" 16.0 ± 0.1"	60.0 ± 0.5 cm 80.0 ± 0.5 cm 24.0 ± 0.2"	5.0 ± 0.1 m 20.0 ± 0.4 ft	
	Lenses for hyperopia: +1 diopter			
Connectivity	USB Type C / RJ45			
Power supply unit	Input: 100-240V AC / 50-60Hz / 0.6A Output: 12V DC / 24W Max / 2.08A Cable length: 2.99m			
Level of protection	Medical with 2 levels of patient protection (2 x MOPP cf. EN60601-1)			
Electric class	II			
Remote control screen	TFT-LCD 7" 800x480	Remote control screen		
Remote control cable	USB Type C / Cable length: 2.10m			
Remote control power supply	5V DC / 2.5W Max / 500 mA	Remote control power supply		
Storage temperature	-10 to 60°C	Storage temperature		
Operating temperature	15 to 35°C	Operating temperature		
Reference standards	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			
Medical class	I			
Software security class	A			
GMDN Code	65177			
Patient applied part	Forehead support			
Dimensions	50x27x25cm	Visiolite® 4K packaged	19x13x4cm	Remote control
Weight	4,5 kg	Visiolite® 4K alone	0,475 kg	Remote control












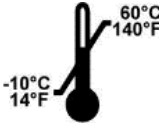

Hardware requirements for VisioWin® software

VisioWin® Software	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-bit	64-bit
Memory	2GB of RAM	4GB of RAM
Disk space	16GB	20GB
Graphics card	256MB	512MB
Monitor Resolution	1024x768	1920x1080

Specific characteristics of VisioClick®

Voltage	5VDC (via USB port)		
Power	2.5W maximum		
Output impedance	16 Ω - 32 Ω		
Audio connector	3.5mm 3-pole stereo (TRS) audio jack		
Headset cable length	1.2 m		
Frequency range	20 Hz - 20 KHz		
Medical class	I		
Software security class	HAS		
Patient applied part	Headset earpiece cover	Type BF	
Headset cover material	Non-woven polypropylene 35g/m ² biocompatible		
Dimensions	25x14x5cm	Response unit only (excluding holder and headset)	
Weight	0.475kg	Response unit only	0.700 kg Cable, holder, headset included

7. Symbols

	<p>CE marking according to Medical Device Regulation (UE) 2017/745</p>		<p>Instructions for use</p>
	<p>Type B applied part</p>		<p>Non-ionizing electromagnetic radiation (WiFi 2412 MHz - 2484 MHz)</p>
	<p>Must not be disposed of with unsorted waste, but treated in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive</p>		<p>Manufacturer Identification</p>
	<p>Medical Device</p>		<p>Date of manufacture</p>
	<p>Batch Number</p>		<p>Use-by date</p>
	<p>Serial Number</p>		<p>Storage temperature from -10 to 60°C</p>
	<p>Unique Device Identifier</p>	<p>(11)XXXXXX</p>	<p>UDI Identification - Date of manufacture</p>
<p>(01)XXXXXXXXXXXXXXXXXX</p>	<p>UDI Identification - Unique product identification number</p>	<p>(10)XXXXXX</p>	<p>UDI Identification - Batch number</p>

8. Installing the Visiolite® 4K

Unpacking the device



NOTE: The box and cables should be retained for maintenance.

To access the Visiolite® 4K, open the box and remove the compartmentalized foam tray that contains the equipment.

Lift the Visiolite® 4K by the handle.



Connecting the cables



WARNING: Do not use any power supply or accessories other than those provided with the device, as this may compromise its performance and safety.

Tilt the device into the connection position.

Route the cables through the back between the base and the body of the Visiolite® 4K.

Computerized version:

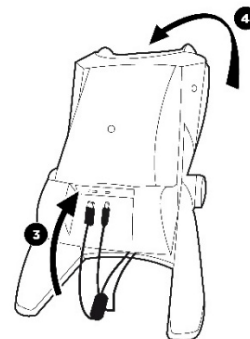
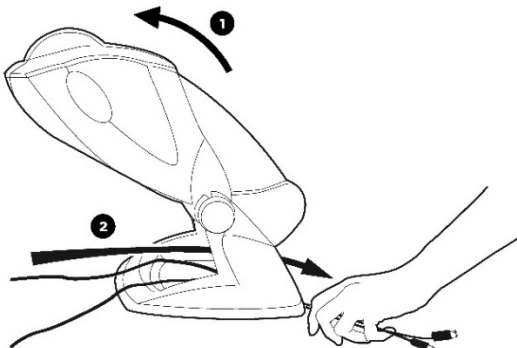
Connect the Type C connector of the USB cable to the Visiolite® 4K, then connect the power supply cable.

Connect the Type A connector of the USB cable to the PC on which the VisioWin® software is installed.

Remote controlled version:

Connect the Type C connector of the remote control cable to the Visiolite® 4K, then connect the power supply cable.

The remote-controlled Visiolite® 4K is then ready for use.

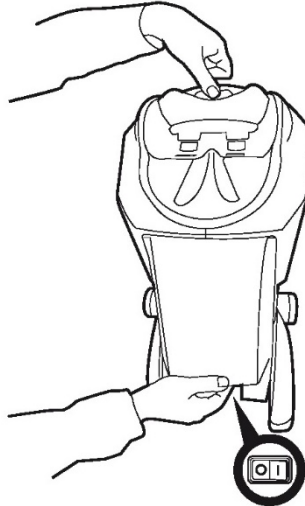


Computerized version: First start and 4K to the VisioWin® installer

The download link for the VisioWin® software is available 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 forehead support immediately after turning on the device. The Visiolite® 4K is then recognized by Windows as a mass storage device, which opens a folder in File Explorer.

Please note that the time required to copy the installation file may be longer than via internet download.

**Computerized version: Installation of VisioWin® software**

NOTE: Administrator rights are required to install the VisioWin® software.

Run the SetupVisioWin.exe installation file you have retrieved.

Select the language of the installation wizard.

The VisioWin® software is usable under the license conditions, which must be read and approved.

If you were to 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 the database.

Once the installation has been completed, the Visiolite® 4K can be used with the VisioWin® software.

9. Preliminary explanations to the patient

Adjusting the device



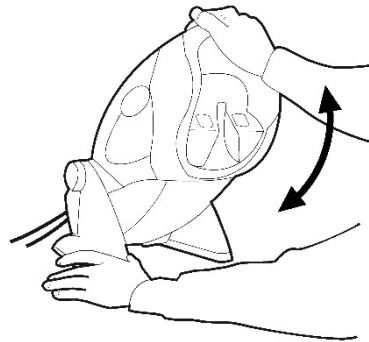
CAUTION: The Visiolite® 4K must be placed on a flat, stable surface.

CAUTION: The Visiolite® 4K must be transported only when fully folded. Fold the device down to the lowest position at the base before transport.

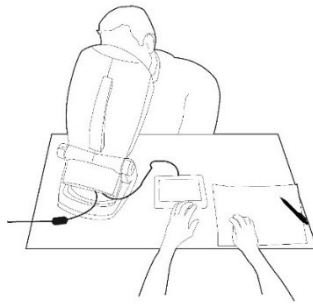
It is important to check that the patient is in the correct position before starting an examination, as this is the key to a successful examination.

We recommend that the patient sits with his or her back straight, facing the machine, and that the machine is tilted so that it rests on the forehead.

Before using the Visiolite® 4K with a patient, adjust the inclination while holding the base.



10. Using the remote-controlled Visiolite® 4K



Carrying out a remote-controlled examination

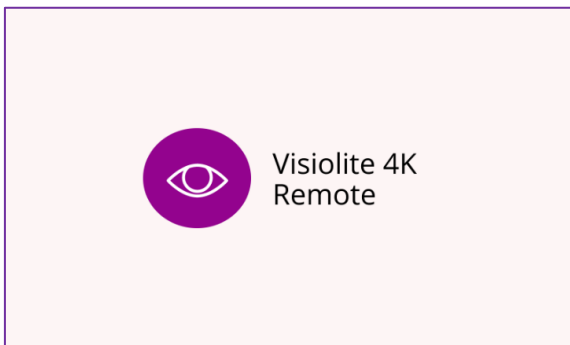
Remote control start

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

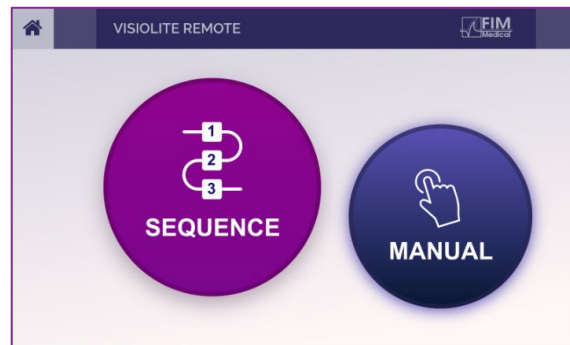
Turn on the remote-controlled Visiolite® 4K using the ON/OFF switch.

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

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



Remote control startup screen

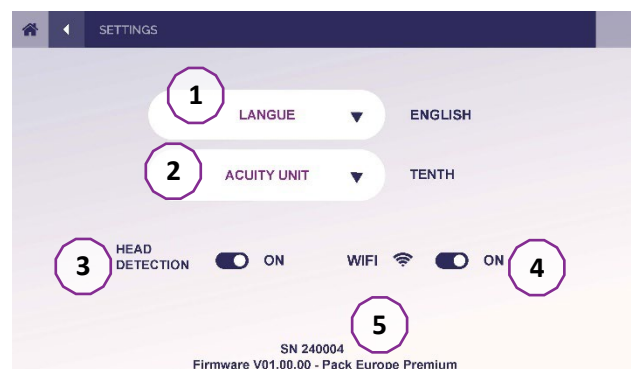


Remote Control Home Page

Remote control setup

The remote control settings are accessible via the  button located in the lower left corner of the remote control home page.

- (1) Choice of interface language
- (2) Choice of unit of visual acuity results LogMAR, Tenths, Tenths x10, Snellen 20ft or 6m
- (3) Enable or disable forehead detection
- (4) If you activate this function, the tests will be displayed in the device only if the patient's forehead is in contact with the forehead support of the Visiolite® 4K
- (5) Enable or disable the WIFI function
- (6) Remote control information



Using the response block

The response block can be downloaded from the link provided in the Information Sheet supplied with the device.

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

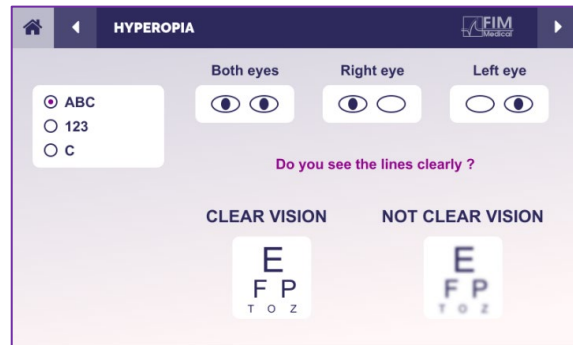
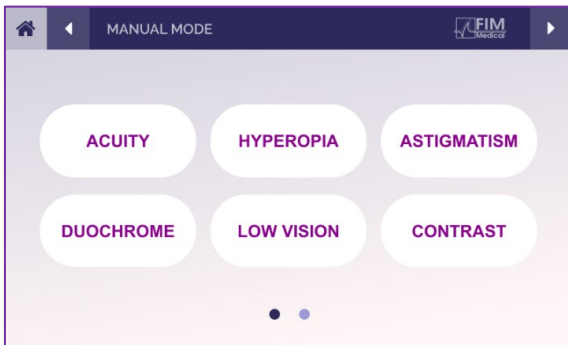
The response form is a detailed document for recording test results. It includes fields for patient identification (Name, Date of Birth, Gender, Risk), test date, and time. It also has checkboxes for optical correction (None, Glasses, Lenses) and eye surgery. The main section contains various test results for: Distance vision (Far, Intermediate, Near, Low), Astigmatism, Hypermetropia (+1 diopter), Duochrome/Anisometropia, Stereoscopic vision, Phorias, Fusion, Dychromotropics, and Anisler. Each test result is recorded in a grid format with checkboxes for 'Failed' or 'Passed' and specific values.

Using the remote control in manual mode

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

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

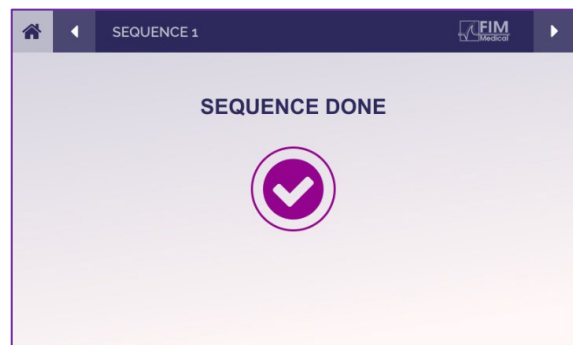
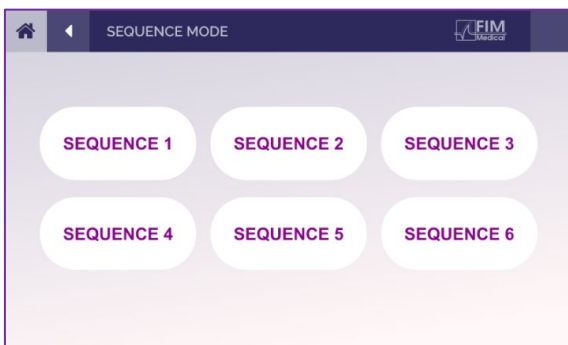
The instruction to be given to the patient is also visible on the test page.



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

Using the remote control in sequence mode

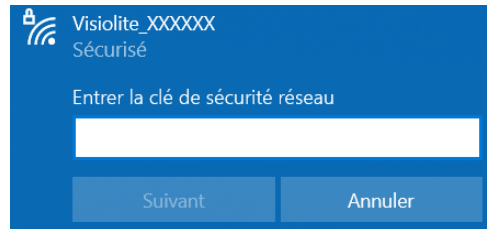
Sequence mode gives access to all pre-recorded sequences on the remote control.



Webapp WiFi Access Settings

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

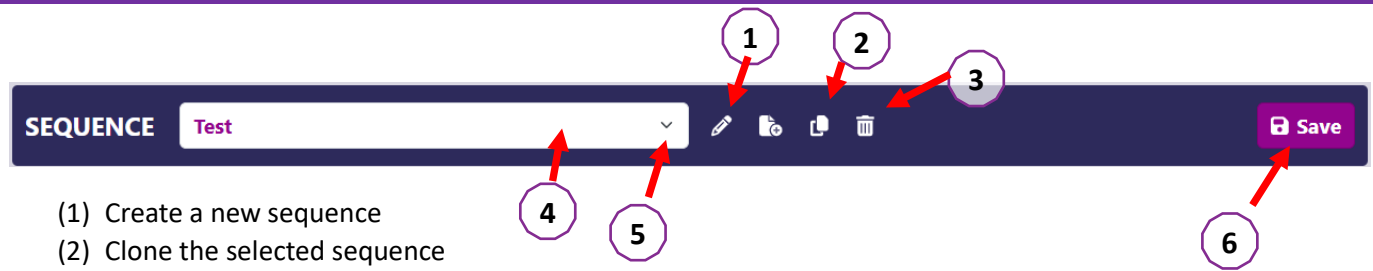
Enter the Wi-Fi password located on the back of the device.



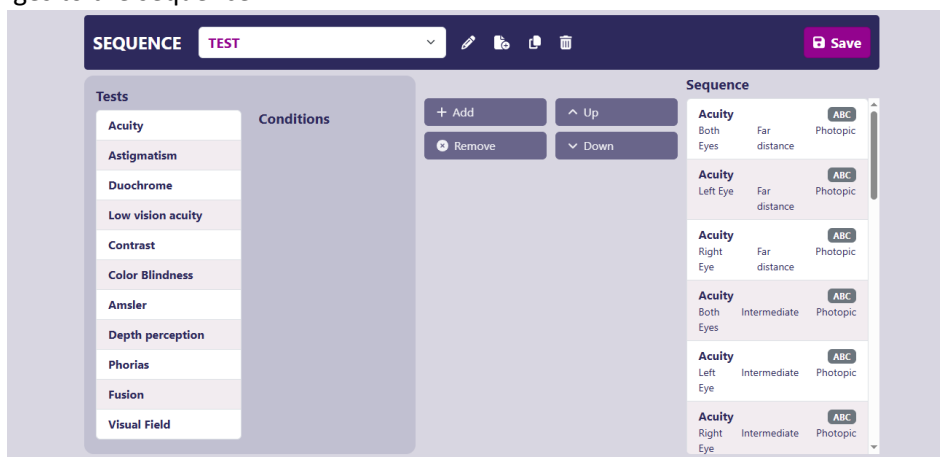
Once connected to Wi-Fi, open your internet browser and enter the following address in the address bar to access the Visiolite® Remote Webapp interface:

remote.local

Editing sequences via the Webapp



- (1) Create a new sequence
- (2) Clone the selected sequence
- (3) Delete the 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 confirm 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.

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	DE Edition	DE Premium	UK Edition	UK Premium	US Junior	DE 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 +1δ	•	•	•	•			•	•	•	•	•
ABC hyperopia +1δ (Display one by one)									•	•	
Hyperopia +1δ							•	•			
Hyperopia +1δ (Display one by one)							•	•			
Landolt hyperopia (4 positions) +1δ	•	•	•	•	•	•	•	•			•
Mesopic					•	•					

Table 2: Configurations for special test packs

Test Pack – Special Tests	<i>Europe Edition</i>	<i>Europe Premium</i>	<i>US Edition</i>	<i>US Premium</i>	<i>DE Edition</i>	<i>DE Premium</i>	<i>UK Edition</i>	<i>UK Premium</i>	<i>US Junior</i>	<i>DE Junior</i>	<i>DMV</i>
Full field of vision	•	•	•	•	•	•	•	•	•	•	•
Red/Green Duochrome	•	•			•	•	•	•			
Fusion	•	•	•	•	•	•	•	•	•	•	•
Phorias	•	•	•	•			•	•	•	•	•
Child phorias									•	•	
Standard color perception							•	•			
Child color perception							•	•			
Traffic light perception	•	•	•	•	•	•	•	•			•
Reliefs					•	•					
Child reliefs	•	•	•	•	•	•	•	•		•	•
Glare resistance									•	•	
Glare sensitivity	•	•	•	•	•	•	•	•			•
Contrast sensitivity – ABC									•	•	
Contrast sensitivity – Landolt (x8)											•

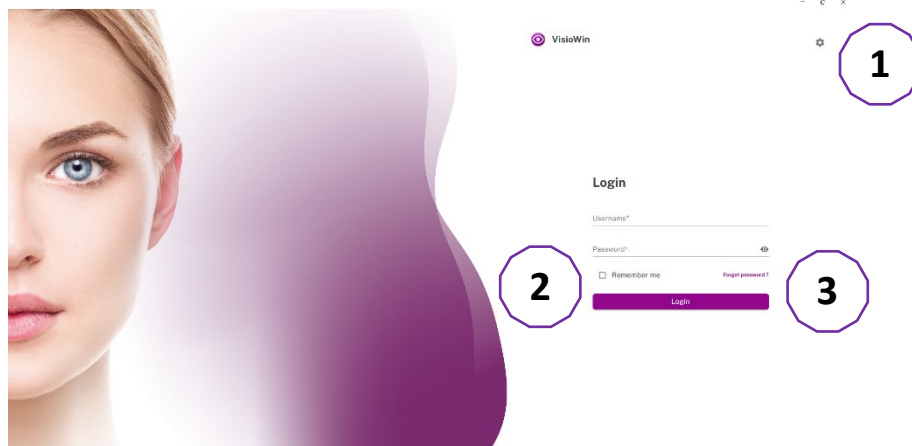
11. VisioWin® Software first connection

When using the VisioWin® software for the first time, you will be prompted to complete the following steps:

Select your language and accept the Terms of Use

Upon launching the software, enter the activation key. This key can be found on the information sheet provided with your device. Then select your preferred language. Please read the General Terms and Conditions of Use (available via the orange link), and accept them to continue.

VisioWin® Software Login Page





1. Interoperability Settings: Settings that ensure communication between VisioWin® and your business software (EMR). This tab is detailed in the Interoperability section of the software settings.
2. Remember Me: Enables automatic login to the operator’s session during future uses of the software.
3. Forgot Password: Allows password recovery in case of loss. To create a new password, you will need to answer the security question you defined when creating your account.

← **Forgot Password**

What was the name of your first pet?

Answer*

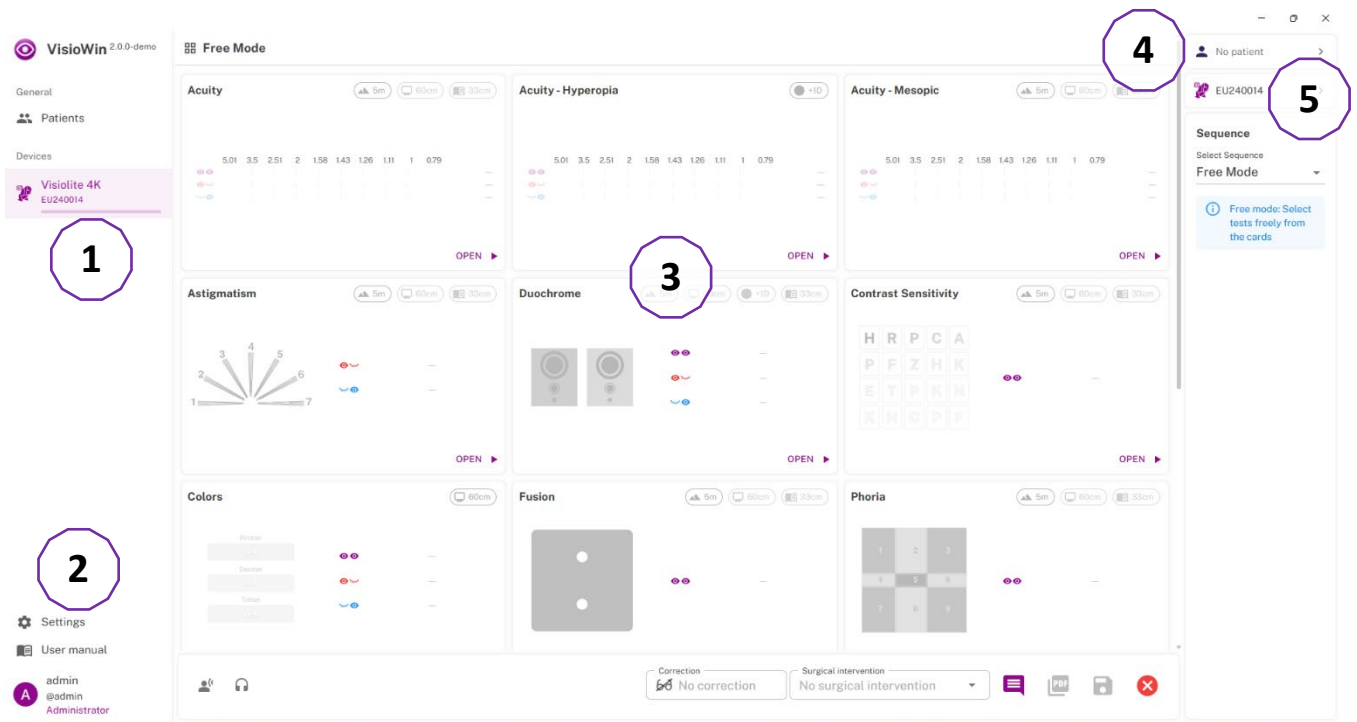
New password* 

Confirm password* 

CONFIRM
















12. VisioWin® Software Home page

User interface description



1. **Navigation menu:** Access to the connected vision screener, examination window and access to previous examinations.
2. **Settings:** User profile, software settings, user manual.
3. **Examination window:** Access to the tests available.
4. **Patient profile:** Create a new patient and display the patient’s information.
5. **Device information:** Displays connected device along with its associated information.

Description of the icons

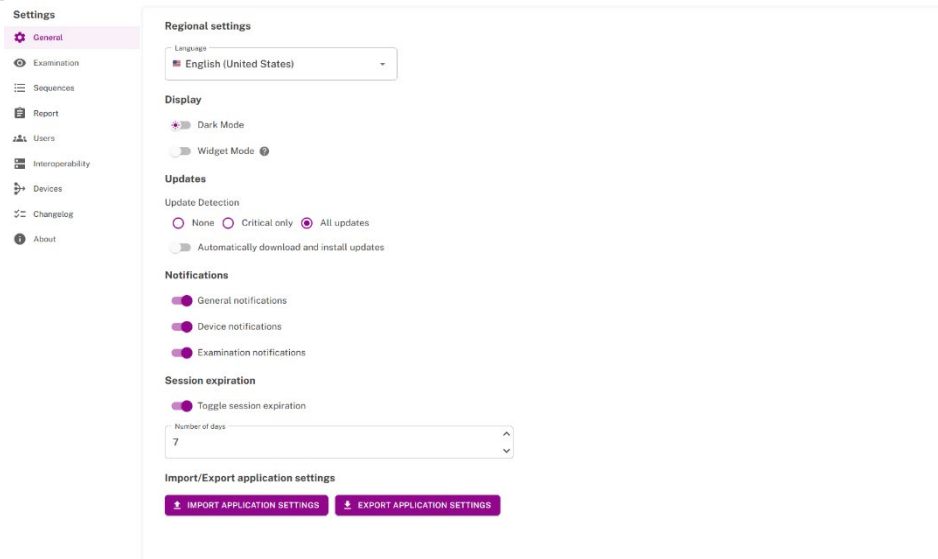
-  Create new profiles (Users, patients, etc.)
-  Access settings
-  View user manual
-  Edit profiles (Users, patients, etc.)
-  Delete the selected profiles (Users, patients, etc.)
-  User profile
-  Delete
-  No device connected
-  Device connected
-  VisioClick® headset connected
-  VisioClick® headset connected
-  The patient forehead is in contact with the device and thus is detected
-  The patient forehead is not in contact with the device and thus is not detected
-  Patient profile
-  Play Button

VisioWin® Software settings

General



NOTE: If you do not check the “Automatically download and install updates” box, when the software starts VisioWin® a window information will appear to inform you of availability of an update.
NOTE: If you wish to update, you will have to click on the “Update” button that will appear at the top right corner of your VisioWin® software



The general options are divided into 6 sections:

Regional Settings:

Allows you to change the display language.

Display Settings:

Enables you to choose between light mode and dark mode, and to activate or deactivate the widget mode (when enabled, the software appears as a shortcut in the lower-right corner of your screen, allowing you to monitor the progress of the test while using other applications).

Updates:

Allows you to choose your preferences regarding automatic updates of the VisioWin® software.

Notifications:

Choose whether you want to receive notifications from the software, the connected device, or during ongoing tests.

Session Expiration:

Enable or disable session expiration to control whether the user session automatically expires after a period of inactivity, and specify the number of days before the session is terminated.

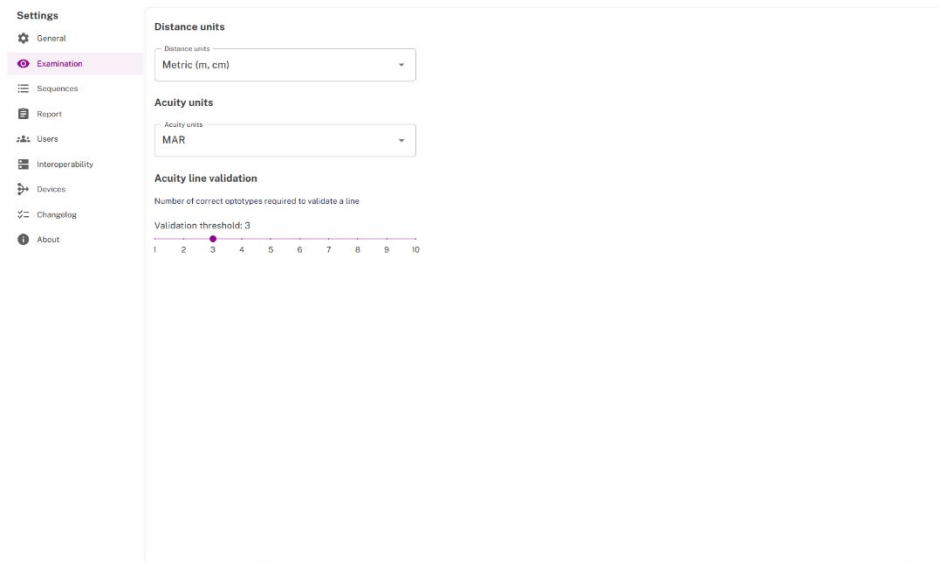
IMPORT/EXPORT Application Settings:

Import: Allows the operator to import the VisioWin® software parameters.

Export: Allows the operator to export the VisioWin® software parameters.

By default, VisioWin® uses the regional settings of the Windows operating system.

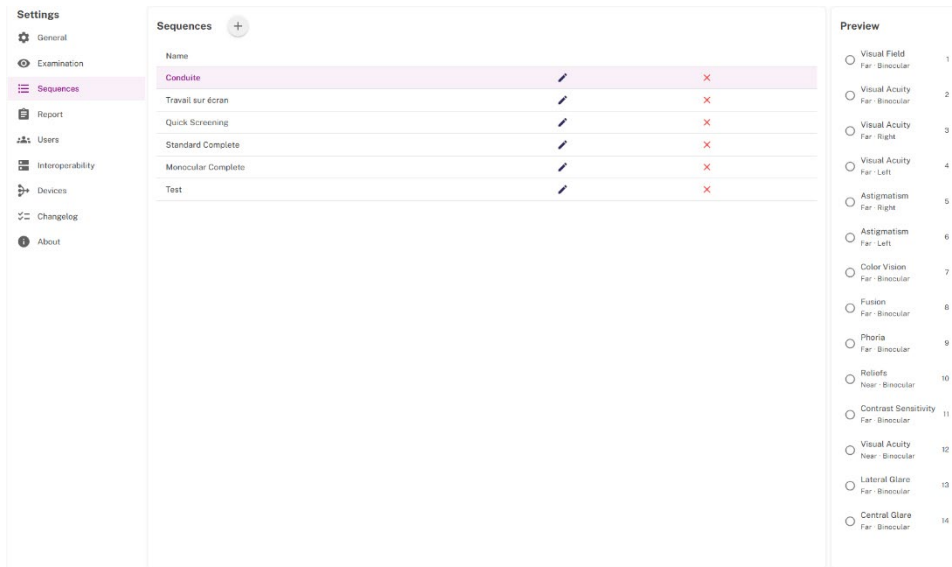
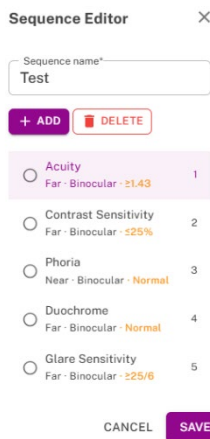
Examination



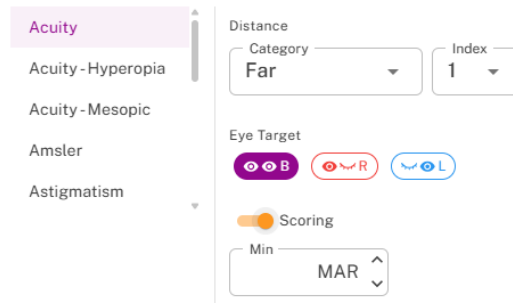
Accessible from Settings in the side menu, examination configurations allow you to define:

- The unit of the visual distances tested in metric (m/cm) or imperial (ft/in) system
- The unit of visual acuity results LogMAR, MAR, Tenths, Tenths x10, Snellen 20ft or 6m
- The number of correctly identified optotypes required to validate a test line.

Sequences

Add step



CANCEL **ADD**

From this section, you can access all previously saved sequences in the software, modify or delete them, and preview the tests included in each sequence.

To create a new sequence:

- Click the **+** button.
- Enter a name for the new sequence and select the test to be performed by clicking on the ADD button.
- Choose the testing distances, select the eye(s) to be tested, and specify whether scoring should be applied.
- Click the ADD button, then repeat the process to include additional vision tests and their parameters.
- You can rearrange the order of the different tests in your sequence by selecting and moving manually a test into the desired position.
- To remove a test from the sequence, select the test to be removed and click on DELETE button.
- Click SAVE to confirm.

Report

This section allows you to customize your reports by including elements such as your logo, contact details, the content to be displayed, available previews, and footer information, among others.

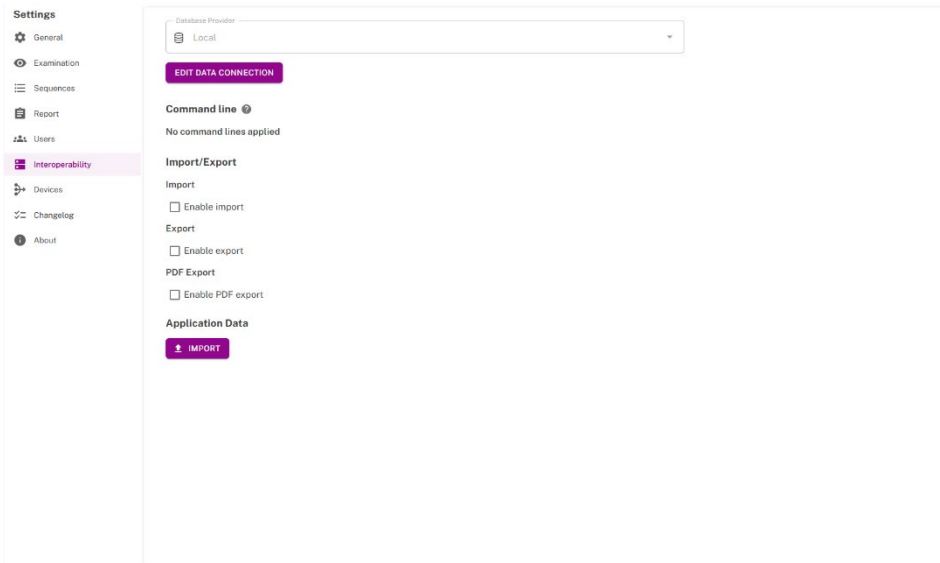
Users



CAUTION: To ensure the protection of patient data, it is strongly recommended not to disable secure authentication access control to the VisioWin® software.

Displays the list of users already registered, and lets you add new users. You also have access to LDAP, a protocol that allows different systems to connect to a centralized directory containing user identifiers and information, in order to authenticate users, assign appropriate access rights, and allow them to manage their own passwords.

Interoperability

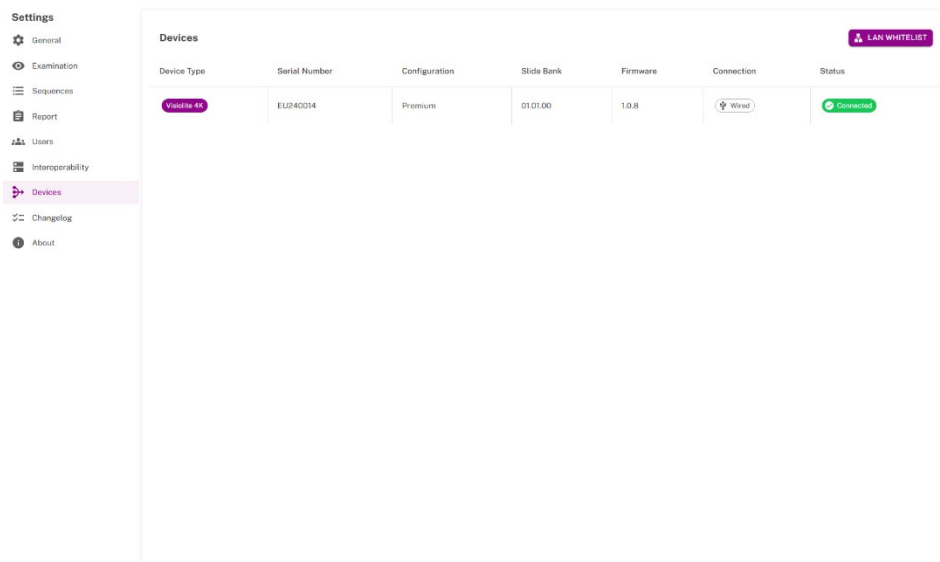


Selects the database supplier: local (directly on the software), remote (External database in PostgreSQL) or no database.

VisioWin® will then automatically perform the necessary presetting to facilitate data exchange. Available options:

- Enable import: allows patient files to be imported from your EMR.
- Enable export: exports patient data and results to your EMR.
- Enable PDF export: saves examination reports in PDF format.

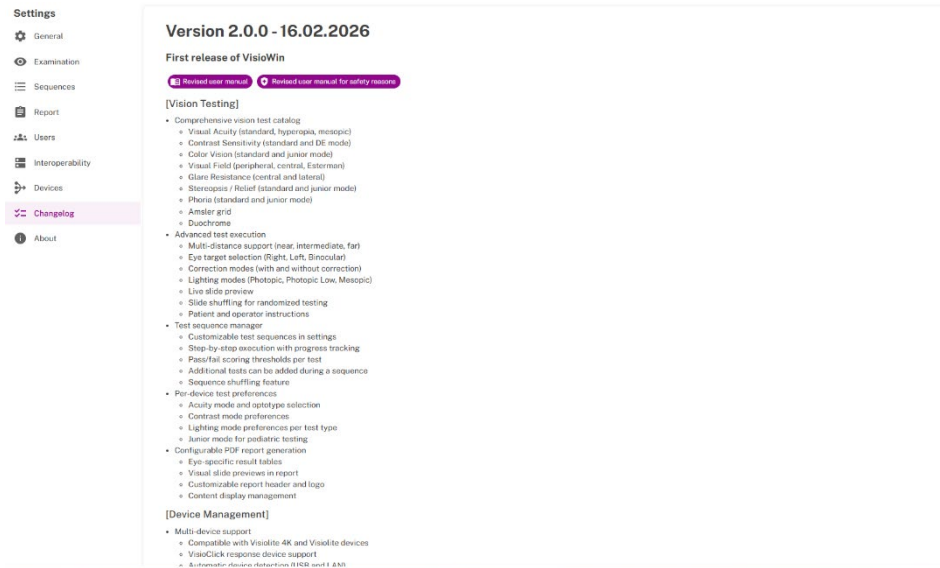
Devices



Displays the list of all currently connected devices along with their associated information (model, serial number, device version, etc.).

Click this LAN WHITELIST button to display the serial numbers of the devices authorized on the LAN connection.

Changelog



Version 2.0.0 - 16.02.2026

First release of VisioWin

Revised user manual for safety reasons

[Vision Testing]

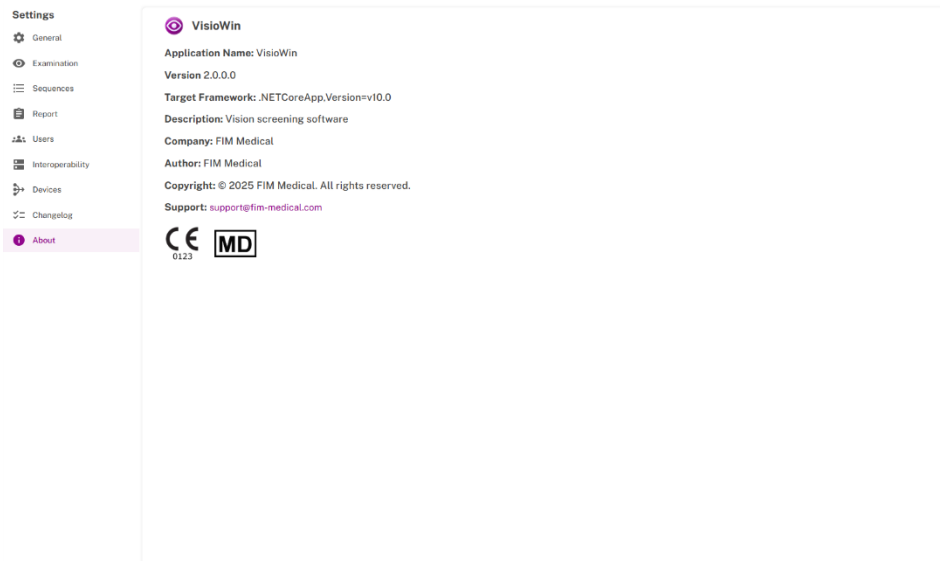
- Comprehensive vision test catalog
 - Visual Acuity (standard, hyperopia, myopic)
 - Contrast Sensitivity (standard and DE mode)
 - Color Vision (standard and junior mode)
 - Visual Field (peripheral, central, Esterman)
 - Glare Resistance (central and lateral)
 - Stereopsis / Relief (standard and junior mode)
 - Phoria (standard and junior mode)
 - Amster grid
 - Duochrome
- Advanced test execution
 - Multi-distance support (near, intermediate, far)
 - Eye target selection (Right, Left, Binocular)
 - Correction modes (with and without correction)
 - Lighting modes (Photopic, Photopic Low, Mesopic)
 - Live slide preview
 - Slide shuffling for randomized testing
 - Patient and operator instructions
- Test sequence manager
 - Customizable test sequences in settings
 - Step-by-step execution with progress tracking
 - Pass/fail scoring thresholds per test
 - Additional tests can be added during a sequence
 - Sequence shuffling feature
- Per-device test preferences
 - Acuity mode and optotype selection
 - Contrast mode preferences
 - Lighting mode preferences per test type
 - Junior mode for pediatric testing
- Configurable PDF report generation
 - Eye-specific result tables
 - Visual slide previews in report
 - Customizable report header and logo
 - Content display management

[Device Management]

- Multi-device support
 - Compatible with Visiolite 4K and Visiolite devices
 - VisioClick response device support
 - Automatic device detection (HSR and I ANI)

Displays all of the elements modified or added during an update.

About



VisioWin

Application Name: VisioWin

Version 2.0.0.0

Target Framework: .NETCoreApp,Version=v10.0

Description: Vision screening software

Company: FIM Medical

Author: FIM Medical

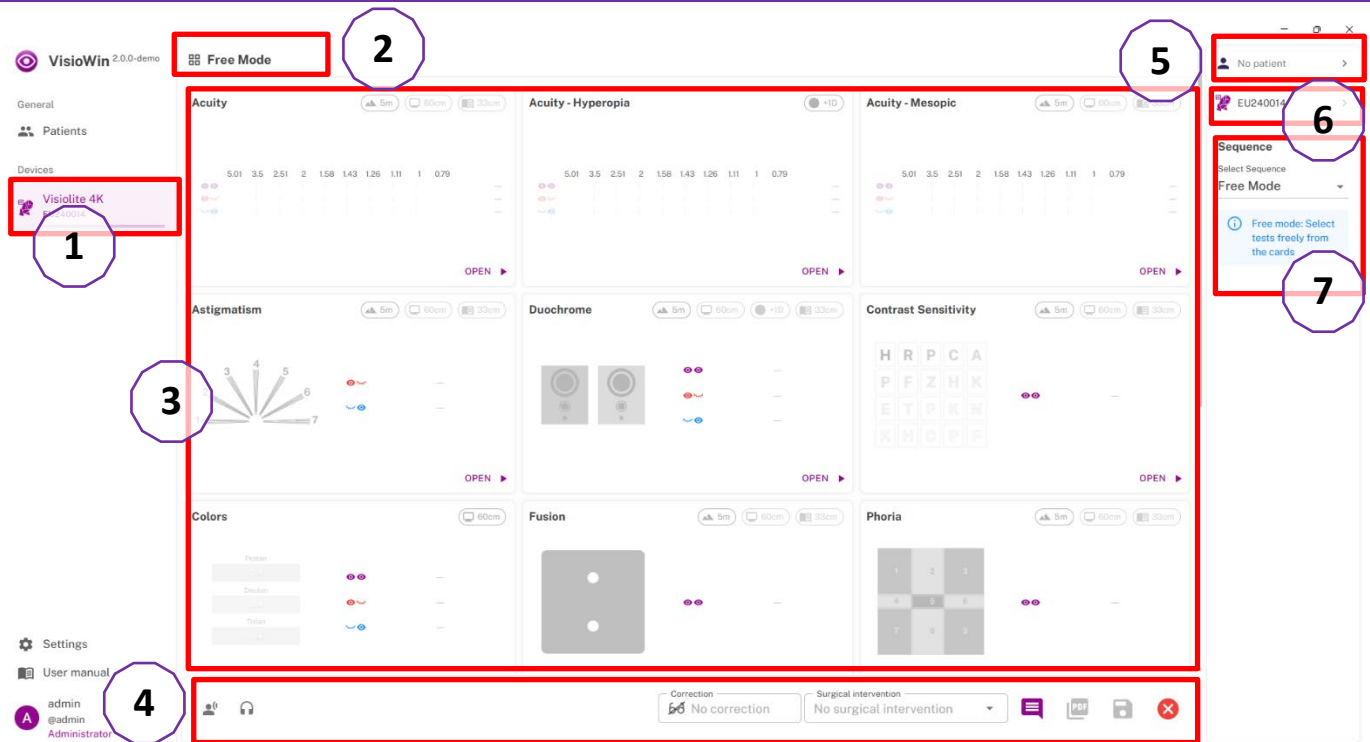
Copyright: © 2025 FIM Medical. All rights reserved.

Support: support@fim-medical.com

CE 0123 MD

Displays software information.

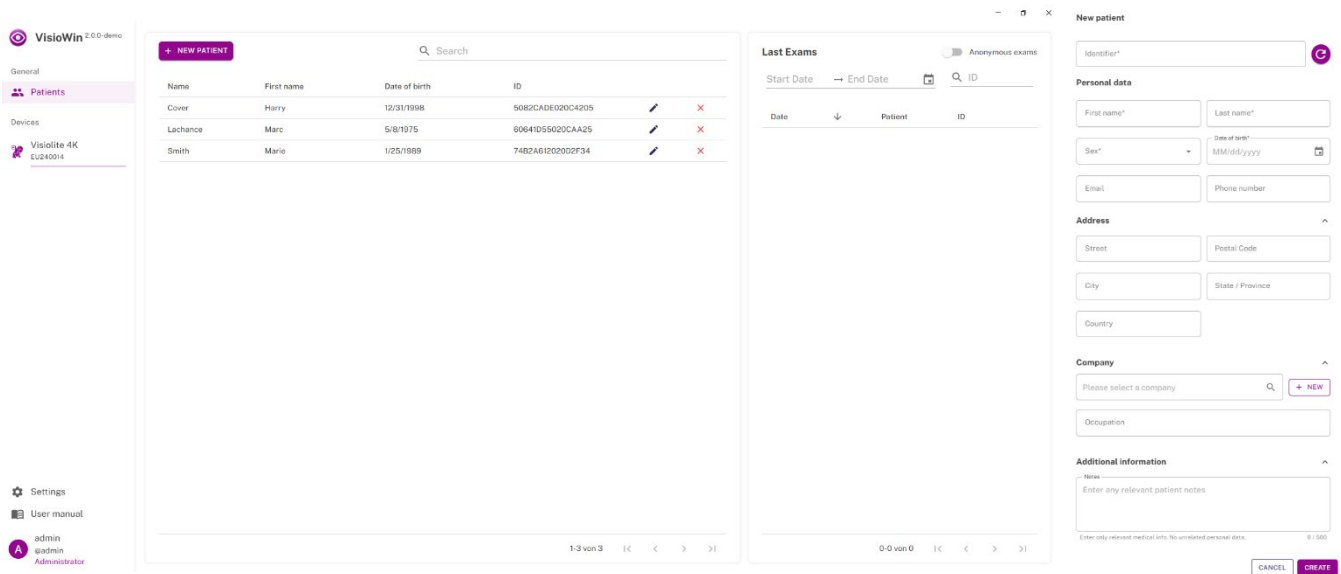
Examination window



1. **Navigation menu:** Provides access to the connected vision screener and the examination window.
2. **Examination name:** Displays *Free Mode* when accessing all available tests, or the name of the selected test sequence.
3. **Examination window:** Displays and provides access to the available tests.
4. **Toolbar:** Provides access to test settings, comments, patient clinical information, report generation, and saving the current test.
5. **Patient profile:** Displays patient information.
6. **Device information:** Displays the connected device and its associated information.
7. **Sequence settings menu:** Allows selection, launch and monitoring of a test sequence.

Button/Indicator	Meaning	Button/Indicator	Meaning
	Activate or deactivate patient's forehead detection. Turns green when the patient's forehead is detected. Turns red when the patient's forehead is not detected.		Comment area
	Turns on if the MVA is activated. Allows access to MVA settings (selection of language and volume)		Generates an examination report in PDF format
	Choose whether the patient is wearing corrective lenses and specify the type.		Save an exam.
	Choose whether the patient has undergone a surgical procedure and specify the type.		Reset exam





Patient profile management (excluding third-party software interface)



You can create a patient profile or select a specific patient profile for an examination.

If no patient is selected, the examination will be carried out anonymously.

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

Button	Meaning
	Filter the database to select an existing profile
	Create a new patient
	Edit the profile of the selected patient
	Delete the profile of the selected patient

When you select a patient, you will be able to view the history of that patient's exam results in the right window.

The window on the right can also be used to view previous examinations in anonymous mode, and to filter results according to various criteria.

To create a new patient profile, fill in the required information.

13. Conducting an exam



WARNING: Follow the cleaning directions for the device and the removable forehead rest mentioned in the Cleaning and disinfection section to avoid risk of cross-contamination.

Precautions for use

The equipment works on the basis of binocular fusion. The operator must ensure that the patient has sufficient fusion to carry out the examination.

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

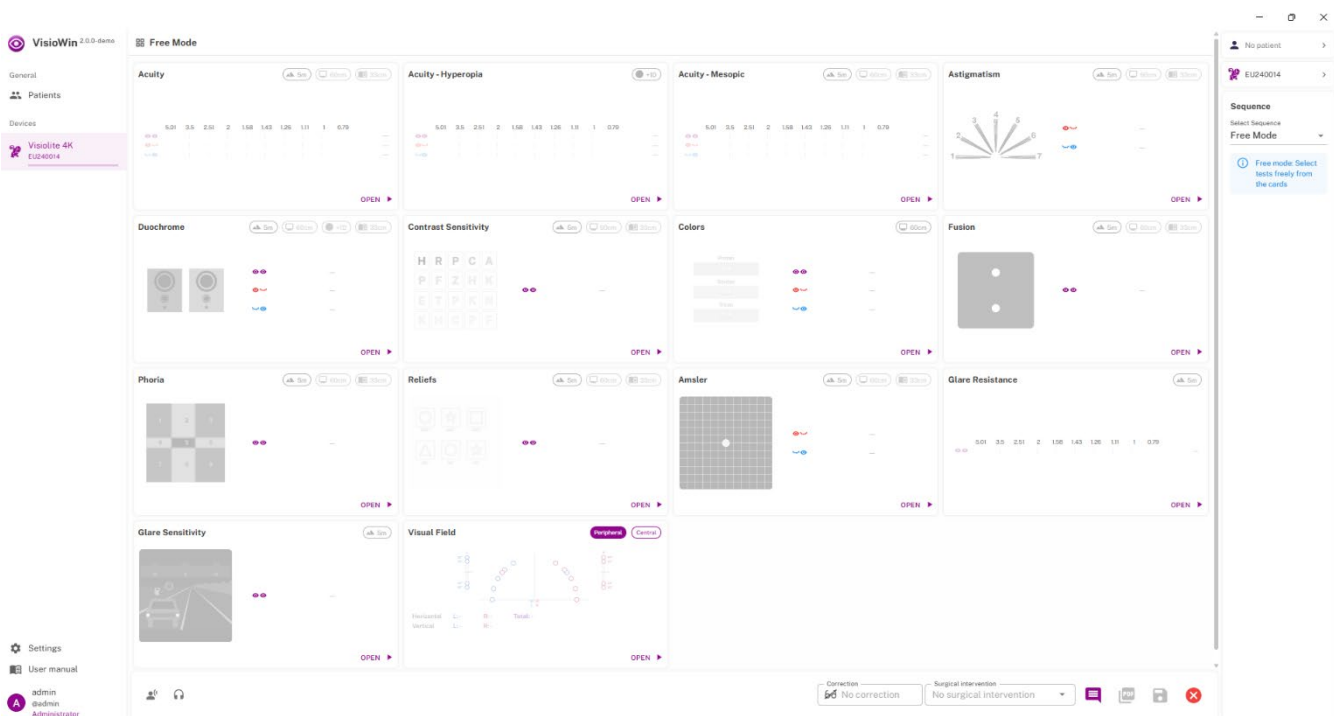
For photosensitive patients, the light level can be reduced at any time during the examination.

The examination should be carried out in an appropriate environment, ensuring that the patient is not obstructed by a light source external to the machine.

In the case of a glare test, the user must inform the patient of the test procedure and ensure that there is no persistent discomfort at the end of the test.

Once an examination is completed, operator must clean the device, especially the parts in contact with the patient

Selecting a test



Visual tests are available on the Examination window and are represented by thumbnails.

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

To launch a specific test, click on the OPEN button on the bottom right corner of the thumbnail.

Test interface

The interface includes the following elements:

- 1:** Distance selection (5m, 60cm, 33cm)
- 2:** Eye selection (Binocular, Right eye, Left eye)
- 3:** Correction status (Without correction, With correction)
- 4:** Main optotype grid with columns for Line, Optotypes, and Acuity
- 5:** Control buttons (EU, A, refresh, light)
- 6:** Preview window showing the current test line
- 7:** Instructions panel for patient and operator
- 8:** Navigation buttons (PREVIOUS, CLEAR, Failed, NEXT)

Although each test serves a different purpose, they all share a similar interface, presented as follows:

1. Choose the distance to be tested:

	Far Vision		Near Vision
	Intermediate Vision		

2. Choose the eye to be tested

	Binocular		Left eye
	Right eye		

3. Choose whether the patient is wearing corrective lenses during the test or non. (To be indicated first in the Toolbar of the Examination window before launching a test).

	The patient is not wearing corrective lenses		The patient is wearing corrective lenses
--	--	--	--

4. View of the optotypes

5. This section is divided into 4 parameters:

Pack selection:

Choose the pack to be applied to the test.

Each Pack has its own specific set of tests and optotypes to be used during the examination.

Optotype selection:



Choose the optotypes to be used during the test.

	Letters or SLOAN		Landolt 4 positions
	Numbers		Landolt 8 positions
	Raskin's E		FIM symbols

Start over:

Restarts the test from the beginning.

photopic:

	High photopic: Normal light output		Low photopic: Halves the light output of the Visiolite® 4K.
---	------------------------------------	---	---

6. See how the test is shown in the Visiolite® 4K.

7. View the instructions provided to the patient for performing the test, as well as the instructions for the user on how to proceed.

8. This section is divided 3 propositions:


Navigation:

The Previous and Next buttons allow you to scroll through the tests in the thumbnail or in the sequence.

Clear:

Deletes the results recorded during the test.

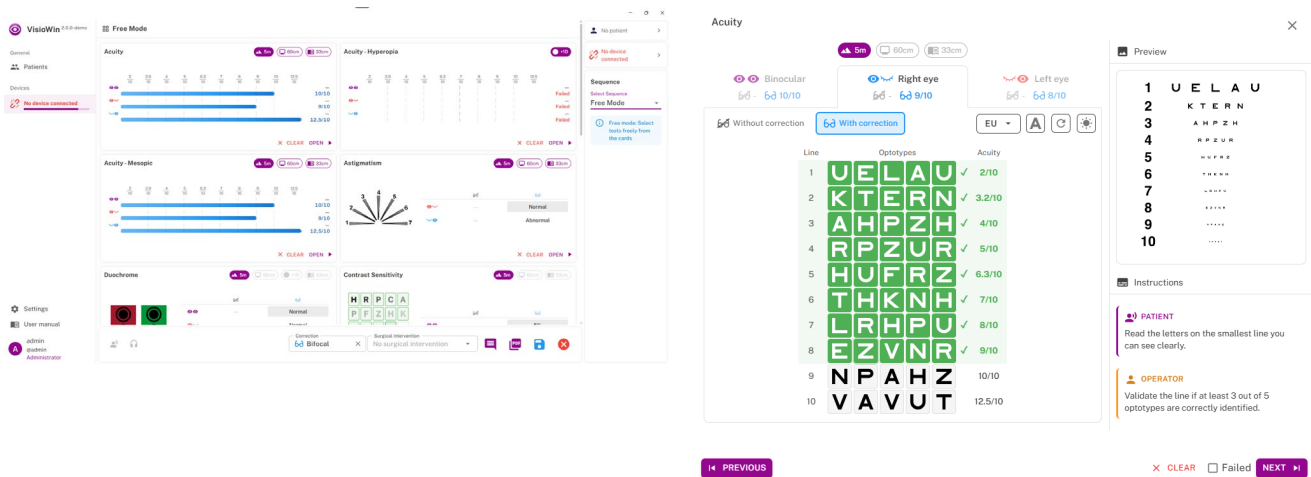
Failed:



NOTE: A justification comment is required for any failed test. It must be entered in the comment section located in the toolbar of the Examination window.

Check this box if the patient cannot see anything or did not understand the instructions.

Manual Mode



- Select the test you want to start and click OPEN.
- Follow the instructions provided for each test to ensure it is performed correctly.
- Click NEXT or CLOSE, if applicable, to navigate through the tests.
- Repeat the process for any other tests you wish to perform.
- Once the examination is complete, fill in the comment section if necessary.
- Click SAVE.
- You can then generate the examination report, by clicking on the PDF button.

Thumbnail presentation



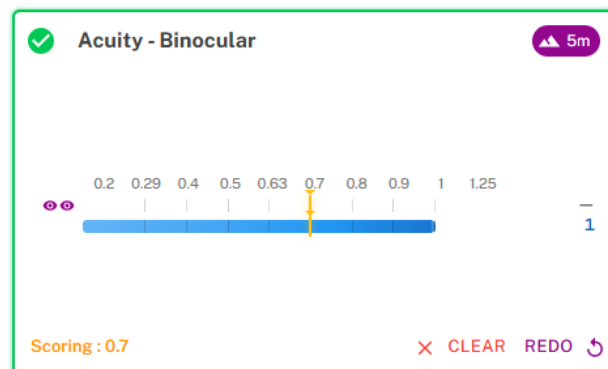
During and after the examination, the result is reported in the thumbnail of the corresponding test.

At the top-right corner of the thumbnail, the icons indicate the distance used during the test.

The distance(s) used are highlighted.

If several distances were used, you can switch between far, intermediate, and near vision by clicking the corresponding distance icon.

The selected icon will then be fully highlighted in purple.



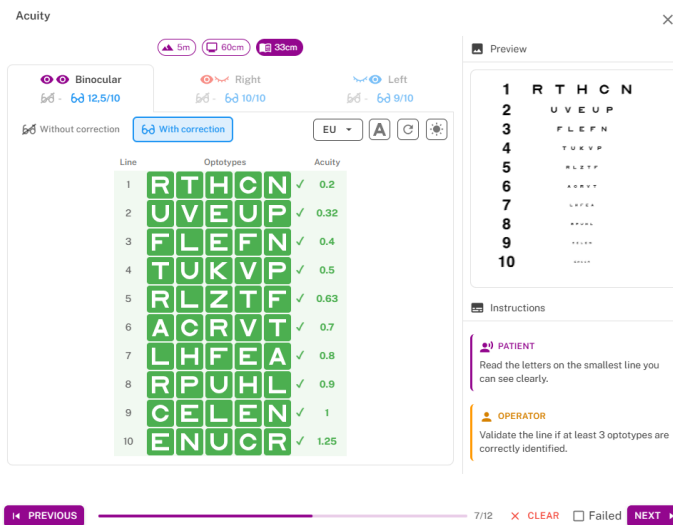
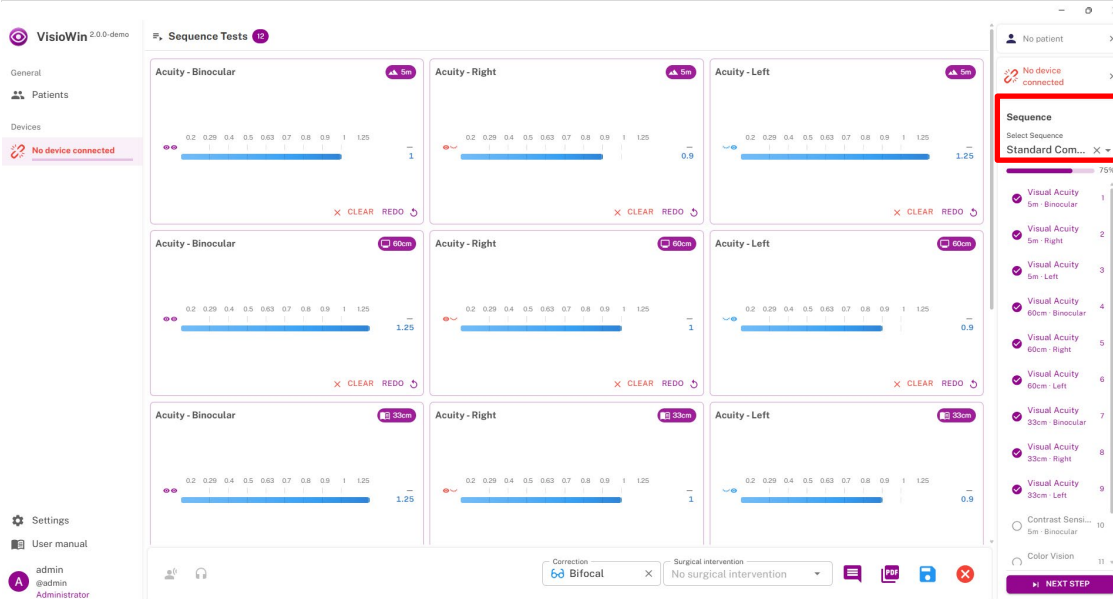
Visualization of scoring

If a scoring parameter is enabled, it is shown in the bottom-left corner of the thumbnail. Scored results are marked with a yellow indicator for easier identification.

Test Sequences



NOTE: Only the tests included in the selected sequence will appear in the Examination window.



- Select the sequence you wish to use for the examination from the drop-down menu highlighted in red. The tests included in the sequence will appear below in chronological order.
- Follow the instructions provided for each test in order to perform the test correctly.
- Use the NEXT STEP or the PREVIOUS button to navigate through the tests in the sequence.
- You can monitor the progress of the examination using the progress bar located below the red box. A progress bar also appears in the bottom section of each test.
- You can restart an individual test, if necessary, by clicking the “REDO” button.
- Once the examination is complete, fill in the comment section if necessary.
- Click the SAVE button.
- You can then generate the examination report.

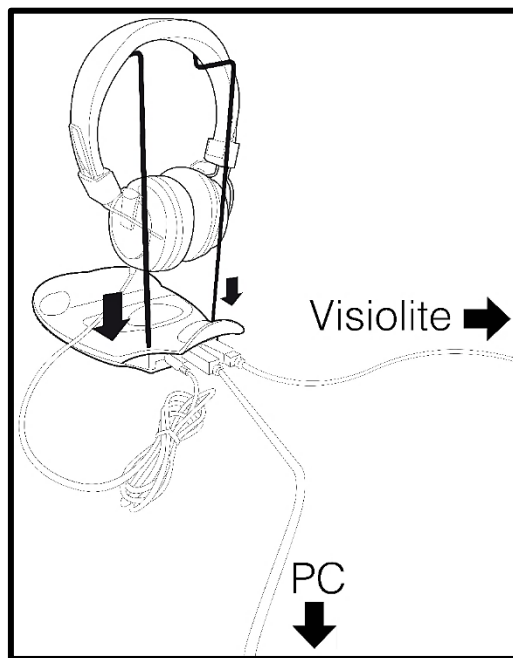
Automated mode with VisioClick®



WARNING: For hygiene and biocompatibility reasons, it is essential to use FIM Medical single-use hygienic ear covers with the Audiolyser® ADL Connect headphones.
WARNING: Single-use ear covers must be used for every examination and replaced between each patient.



NOTE: Avoid using the VisioClick® in a noisy environment that prevents proper understanding of the spoken instructions given through the audio headset.
NOTE: Glare sensitivity testing cannot be performed with VisioClick®.
NOTE: Although the VisioClick® device provides the patient with a certain level of autonomy, a healthcare professional must always remain in the immediate vicinity to ensure that the examination runs smoothly.



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

Connect the Visiolite® 4K USB cable: Type A connector to the VisioClick®, Type C connector to the Visiolite® 4K.

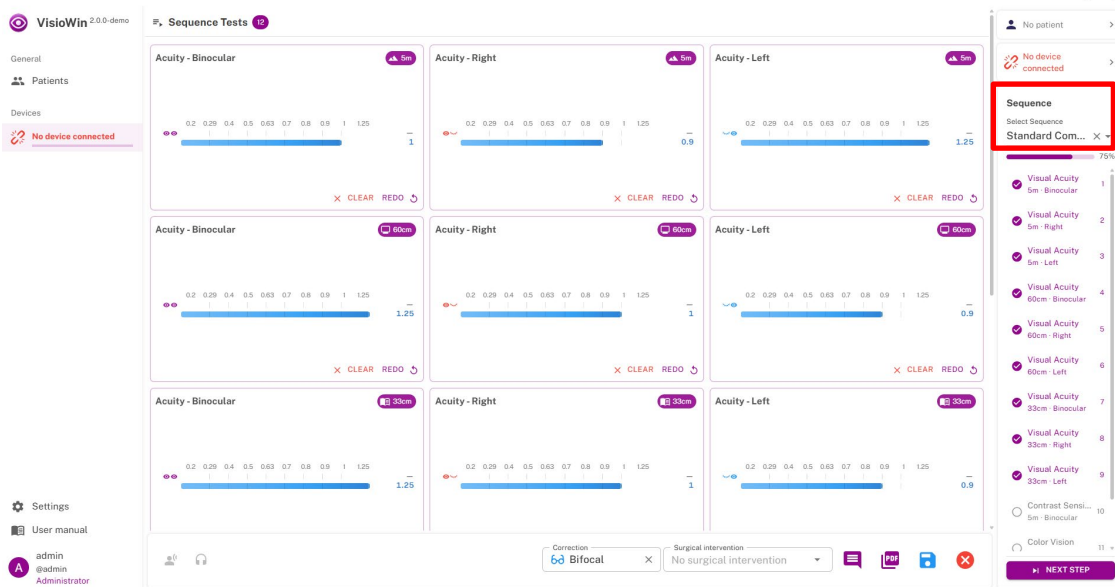
Connect the VisioClick® USB cable: Type B connector to the VisioClick®, Type A connector to the PC.

Connect the headset jack plug to the VisioClick®.



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

Launching an examination in automated mode with VisioClick®



- Select a test sequence
- Click on the VisioClick headset button, and choose to activate MVA, volume and language.
- Click on the Play button.

14. Description of tests

Visual acuity tests

Purpose and presentation of the test:

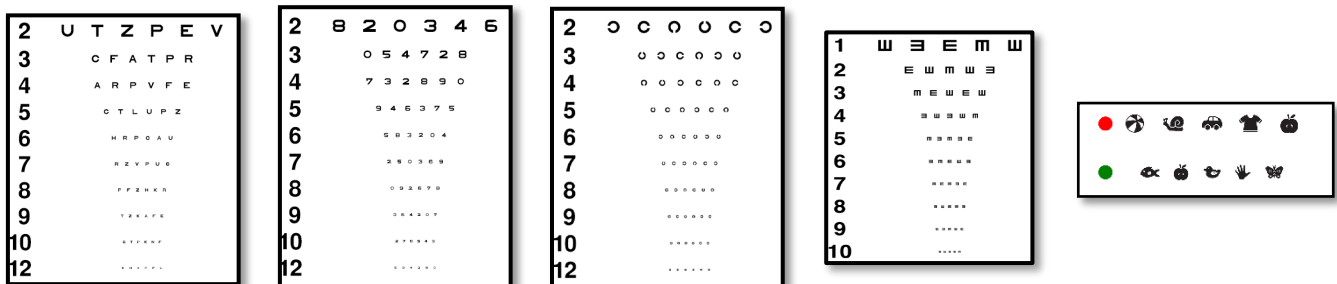
The visual acuity test is the starting point for any eye examination. It ensures that a patient has the correct correction and assesses his or her ability to decipher everyday information. During an examination, the aim is generally to achieve visual acuity of 10/10 or even 12/10. This will enable the subject to decipher everyday information such as the name of a street on a sign or articles in a newspaper. The test is carried out in a variety of ways: monocularly, binocularly, at a distance, intermediately, at close range, with compensation, without compensation, in a photopic or mesopic environment. These different acuities will tell us about a patient's visual abilities.

These tests include the following within Visiolite® 4K:

- Distance visual acuity
- Intermediate visual acuity
- Near visual acuity
- It is also possible to blur a patient's eye by one diopter in order to assess a tendency towards hyperopia.
- Visual acuity in a mesopic environment to test the patient's vision at twilight
- Low vision to assess a subject's aptitude for driving, testing monocular visual acuity at 0.5/10 and 1/10.

The various tests on offer assess two types of visual acuity: recognition acuity, also known as 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:

- Letters
- Numbers
- Landolt rings
- Raskin E's
- DAVL Symbols



Execution of the test:

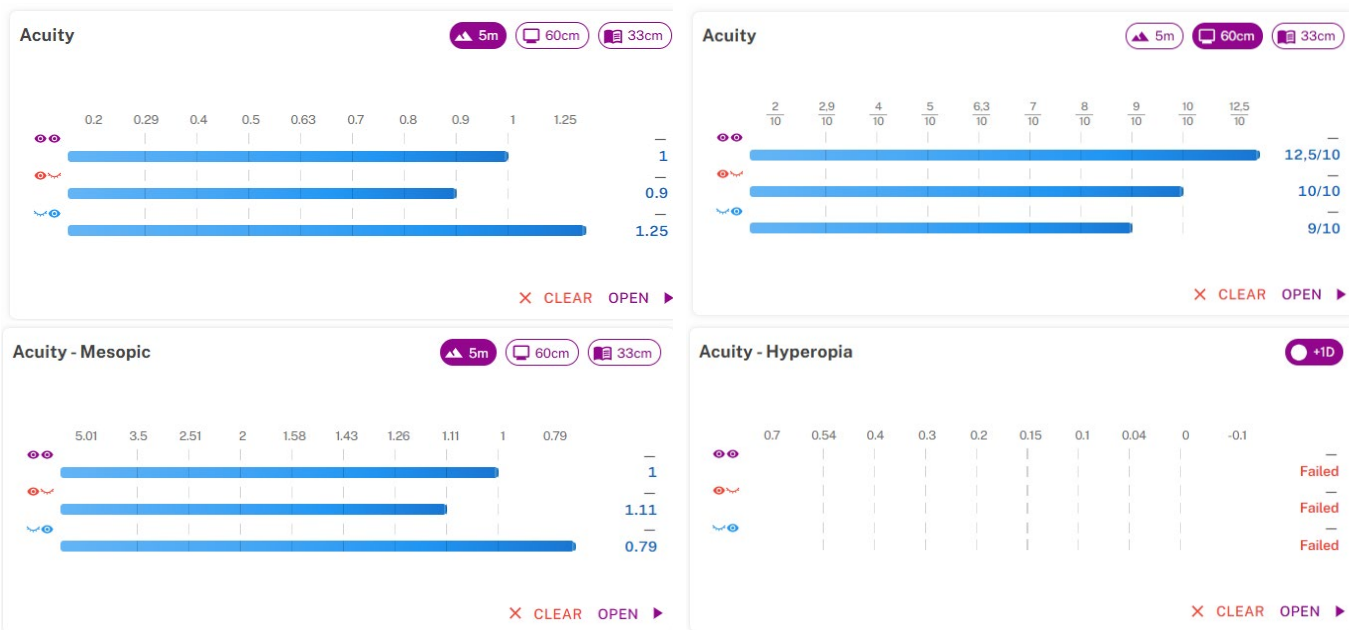
It is a good idea to start with the gross visual acuity of the weaker eye in order to avoid any memory effect. This can be followed by the acuity of the second eye and then the binocular acuity.

This test should first be performed for distance vision, then for near vision and possibly for intermediate vision.

You can then use the same procedure to measure the patient's compensated acuity.

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

Description of the VisioWin® interface



Visual acuity tests are divided into as many thumbnails as there are combinations of viewing distance (near, intermediate, distance) and lighting (photopic/mesopic) to be tested.

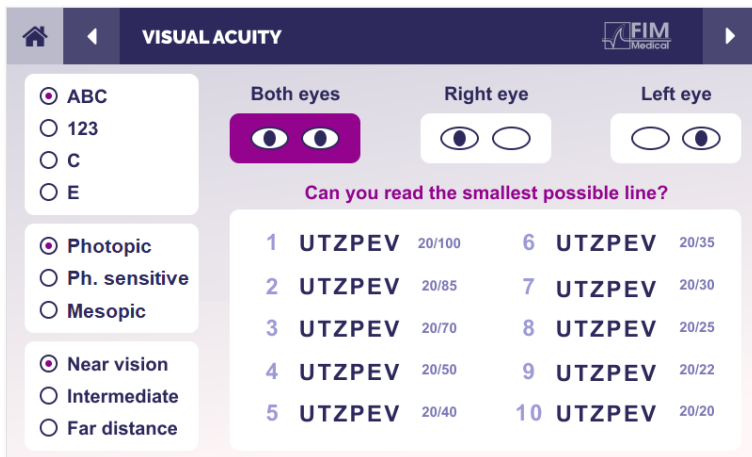
In the response entry window, click on the box to the right of the line to validate the acuity if the minimum validation threshold of optotypes have been successfully recognized by the patient.

It is also possible to validate or invalidate the perception of an optotype with a click or a double-click on the optotype respectively. The perceived optotype is then coloured green, the unrecognized one stays white.

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 and validation threshold are to be defined in the examination section of VisioWin® settings.

Description of the Remote-Control interface



The remote-control interface allows you to view the test conditions currently being performed:

- Type of optotype displayed
- Display brightness level
- Viewing distance
- Vision mode being tested
- Question to ask
- Optotypes displayed

Read the question aloud and record the patient’s response on the answer form.

Instructions to give to the patient

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

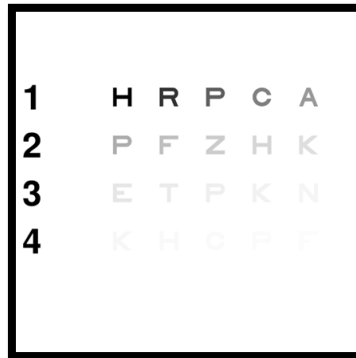
- Letters: “Read the letters on the smallest line you can see clearly.”

Contrast sensitivity test

Purpose and presentation of the test

This test reveals a drop in contrast sensitivity, which may reflect damage to the retina caused by diseases such as cataracts, chronic glaucoma or diabetic retinopathy.

Reduced contrast sensitivity can also occur after eye repair surgery.



The test is based on the MARS contrast sensitivity test. The test offers 20 different levels of contrast which 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. To avoid discriminating between subjects, the optotypes are presented at an acuity level of 2/10.

The tables below show the different contrasts, expressed as a percentage, used in the test.

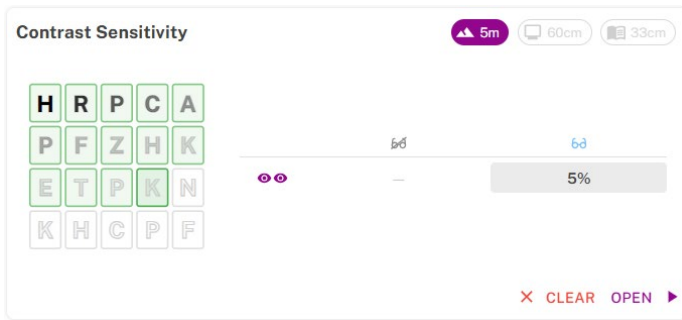
1	H	R	P	C	A
2	P	F	Z	H	K
3	E	T	P	K	N
4	K	H	C	P	F

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

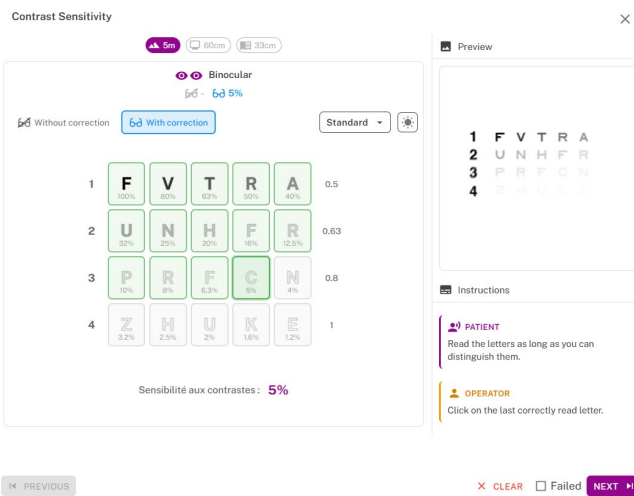
Execution of the test:

- This test is performed binocularly.
- This test is recommended for distance vision.
- This test must be carried out with the patient's compensation.
- This test is recommended for high phototics but can also be performed for low phototics.
- The patient must have a visual acuity of at least 2/10.

Description of the VisioWin® interface



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

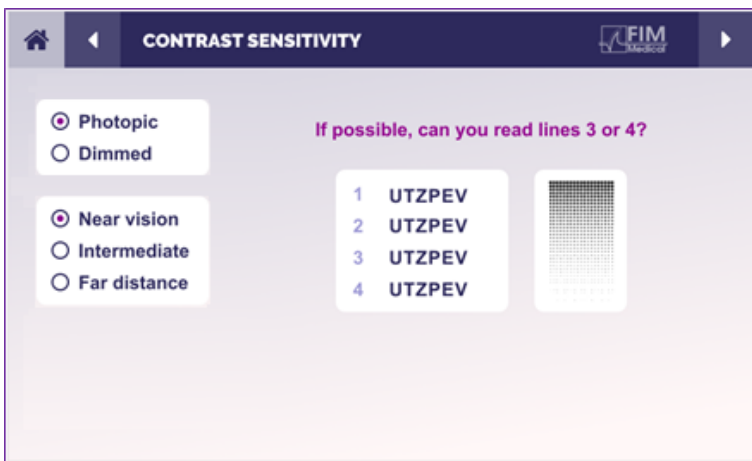


In the response entry window, click on the optotypes correctly recognized by the patient.

Contrast sensitivity is then gradually 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.

Description of the Remote-Control interface



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

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

Read the question aloud and note the perceived result on the response form.

Instructions to give to the patient

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

- Letters: "Read the letters as long as you can distinguish them."

Astigmatism test

Purpose and presentation of the test

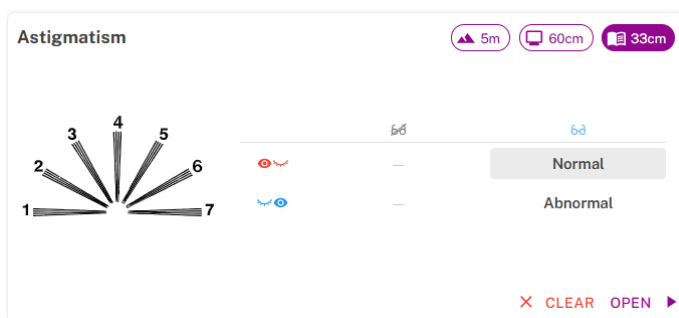
This test is used to detect an astigmatism defect in a patient. Astigmatism is caused by an incorrect relationship between the power of the eye and its length. The astigmatic person's vision will then be distorted in a particular direction. If the astigmatism is too great, the patient will have poor acuity at any distance. This type of defect can be compensated for with astigmatic lenses.

This test consists of seven meridians, each spaced 30° apart. Each axis is represented using three lines to increase the test's sensitivity. The numbers on the lines are presented at an acuity of 2/10.

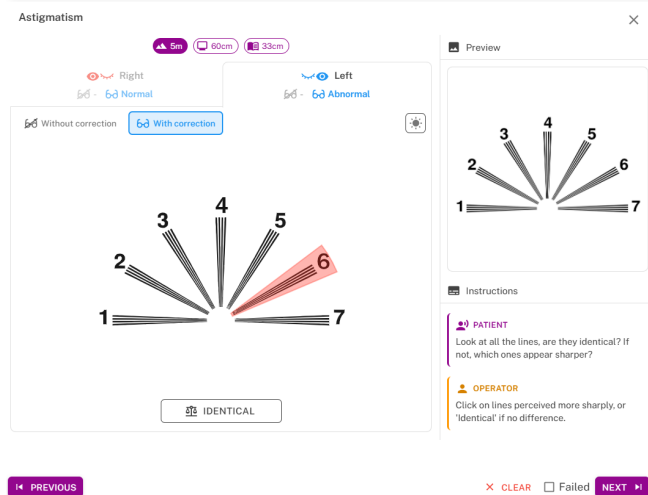
Execution of the test:

- This test is performed monocularly.
- This test should preferably be performed at a distance in order to limit accommodation.
- The patient may or may not be wearing compensation depending on what you wish to test.
- This test is generally performed in a photopic environment.

Description of the VisioWin® interface



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

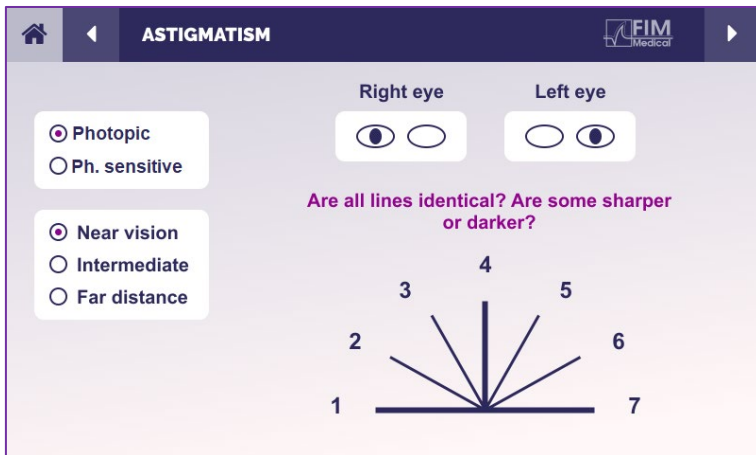


In the response entry window, click on the line or lines perceived most clearly by the patient.

Click on Identical if the patient does not distinguish a difference.

The number of the line entered is then coloured red if abnormal or green when identical.

Description of the Remote-Control interface



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

Read the question aloud and note the perceived result on the response form.

Instructions to give to the patient

Ask the following question: “Look at all the lines, are they identical? If not, which ones appear sharper?”

Full visual field test

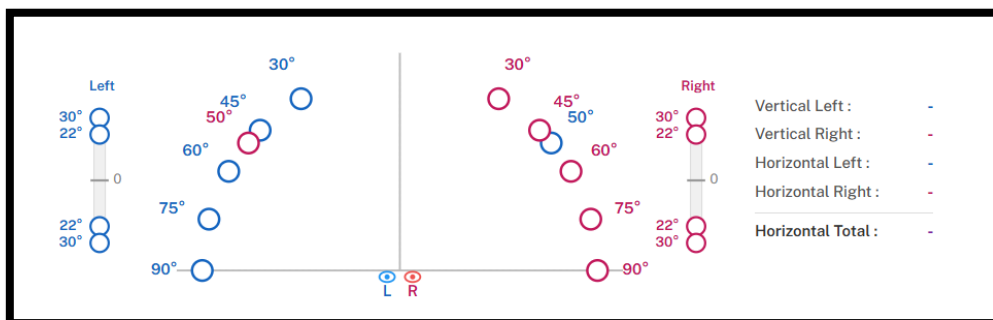
Purpose and presentation of the test

The visual field makes it possible to highlight various vision disorders. It is essential for diagnosing blind spots caused by scotomas, damage to the optic nerve, or issues directly at the level of the cerebral cortex. The table below shows the extent of the visual field measurable by the Visiolite® 4K. The values are not symmetrical, notably due to the shape of the nose. At binocular level, the horizontal fields add up, 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°.

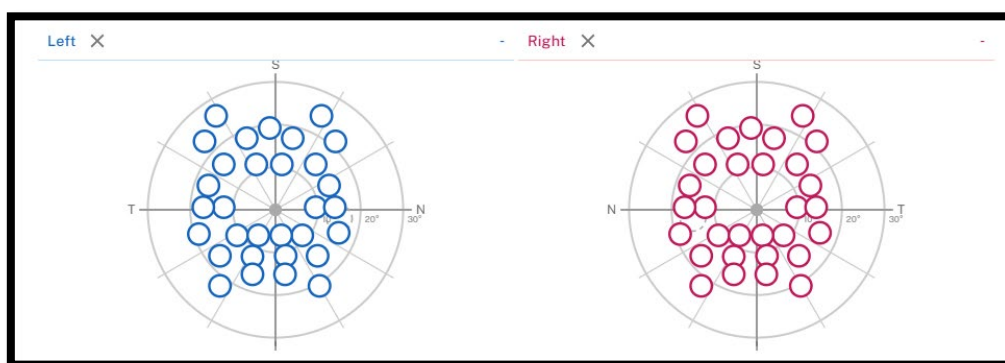
The visual field examination can be divided into two parts: analysis of the central field and analysis of the peripheral field. The first tests the central 30° of vision, whereas the second tests the rest of the visual field. The peripheral field is evaluated using a procedure similar to a static Goldman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

Monocular	Monocular	Monocular	Monocular
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



The central field is tested using 64 light stimuli

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°

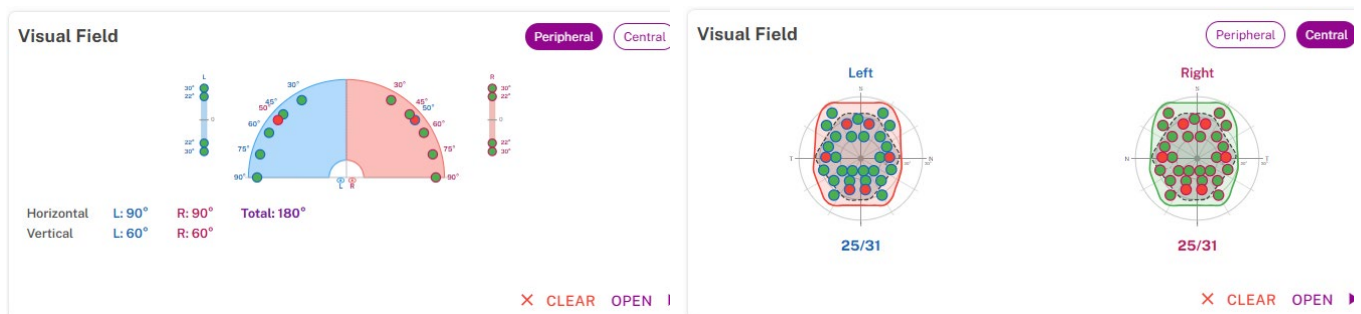
The central field will test the central 30° of vision using 32 diodes per eye. They are arranged in the manner of an Esterman grid, which gives more importance to lower vision and to the horizon line.

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

Execution of the test:

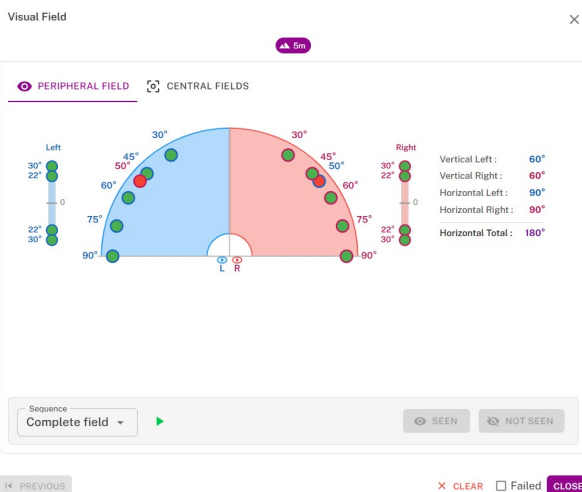
- This test is performed monocularly.
- The patient is not wearing his correction.

Description of the VisioWin® interface



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 presenting 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.



The input window maps all test points.

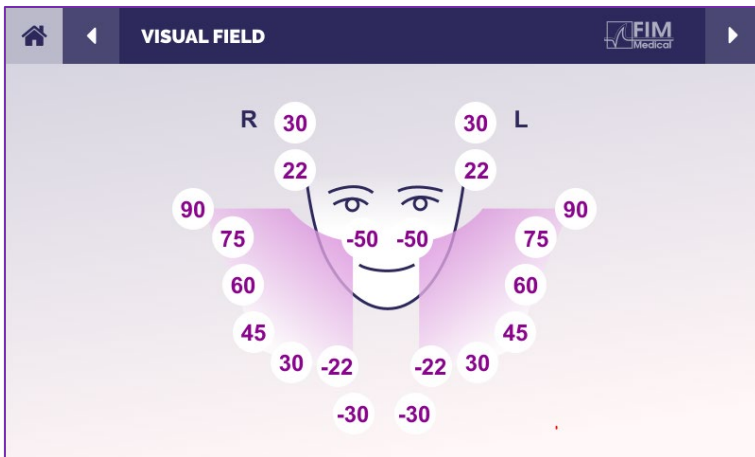
It is possible to perform the test manually by selectively clicking on the points to be tested.

Then click a mouse button/SEEN button to confirm the perception of light stimuli, and the NOT SEEN button to cancel. The points will then turn green or red respectively.

Test points can follow a predefined display sequence by clicking Sequence. Confirm or cancel the perception of stimuli using the SEEN and NOT SEEN buttons.

It is also possible to Reset a point and to Restart the test, by either reselecting the concerned stimulus or clicking the CLEAR button to restart the entire test.

Description of the Remote-Control interface



The remote-control interface allows you to view the different peripheral field diodes and 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.

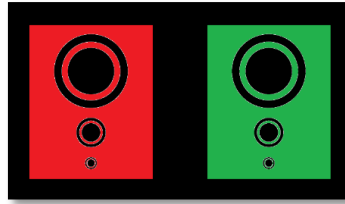
Instructions to be given to the patient

Ask the following question: "Look straight ahead and stare at the central point. On which side do you see the little light appearing?"

Duochrome test

Purpose and presentation of the test

Also known as the bichromatic test or the red-green test, this test is used to confirm a patient's hyperopia. It is based on the chromatic dispersion of the eye. As the eye is an optical system, it breaks down light like a prism. Green wavelengths are therefore deviated more than red ones. Depending on how easy it is to read against a red or green background, it is possible to determine the patient's ametropia. If the patient is hypermetropic, the green wavelengths will be closer to the retina, whereas if the patient is myopic, the red wavelengths will be closer to the retina. However, this test can be distorted by the patient's accommodation, which is why it is mainly used to detect hypermetropia.

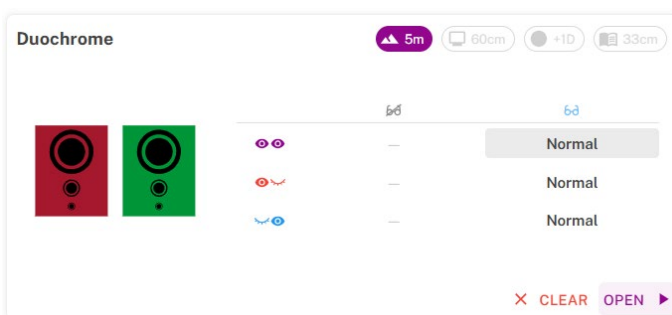


This test is based on the eye's maximum transmission within the red and green wavelengths. These are 620 nm for red and 535 nm for green. These are the wavelengths used for the colours in this test. The dioptric interval between these two values is 0.5 δ . The circular figures on the tests allow the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

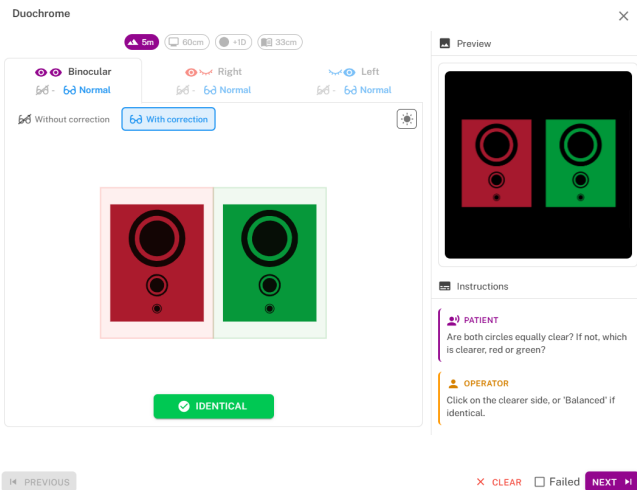
Execution of the test:

- This test is performed monocularly and 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 on compensation.
- This test should be performed photopically.
- This test is recommended for distance vision in order to limit the patient's accommodation as much as possible.

Description of the VisioWin® interface



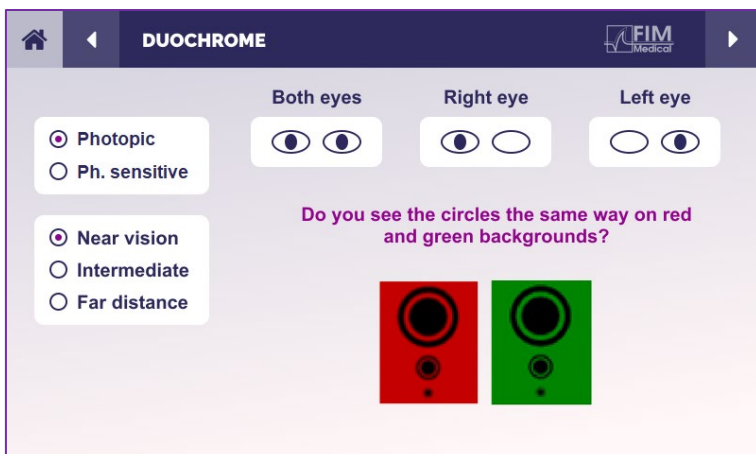
The thumbnail shows the color best perceived by the patient and a possible hyperopic or myopic tendency.



In the response entry window, click on the color that is perceived best.

Click on Identical if the patient does not distinguish a difference.

Description of the Remote-Control interface



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

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

Ask the following question: "Are both circles equally clear?"

If not: "Which one is clearer red or green?"

Relief Test

Purpose and presentation of the test

This test is useful for checking the quality of stereoscopic vision, which is essential for good binocular vision. It is this acuity which enables relief vision and the comparison of the proximity of objects to each other. A problem with stereopsis may reveal certain disorders such as anisometropia, amblyopia, strabismus or image suppression problems. The average stereoscopic threshold for the population is around 40 seconds of arc (‘’), and any acuity above 60’’ may indicate a binocular vision problem.

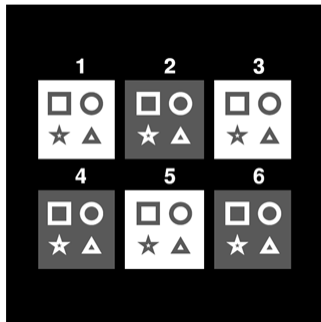


Image seen by the left eye

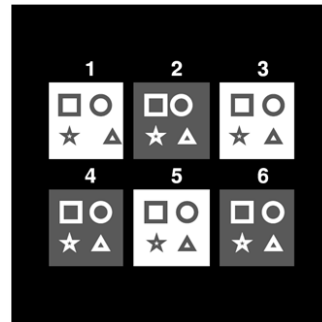


Image seen by the right eye

This test consists of six vignettes, each containing four shapes. In each thumbnail, one of the shapes is shifted to one eye only: the result is that the shifted shape appears in relief to the subject. This is because the brain will try to merge these two virtually identical images. The greater the difference between the position of a shape in the right eye and the left eye, the greater the impression of relief. Fixation disparities are expressed in seconds of arc (‘’), equivalent to 1/3600th of a degree. They are as follows for this test:

Vignette	Shape	Shift between right and left eyes
1	Triangle	1600'
2	Circle	1600''
3	Star	400'
4	Square	200''
5	Star	100'
6	Circle	50''

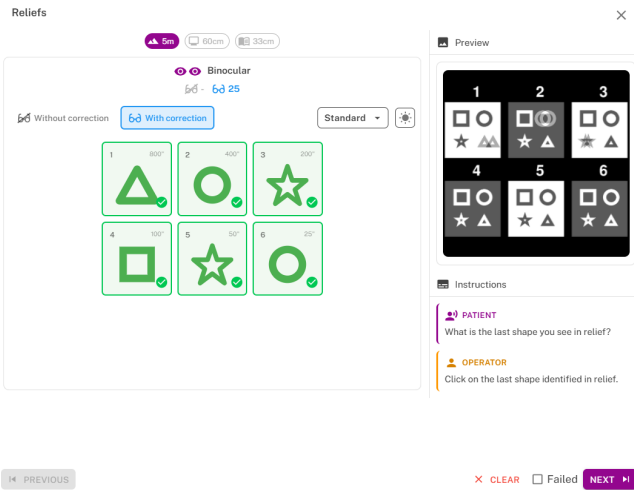
Execution of the test:

- This test is performed binocularly.
- This test is recommended for both distance and near vision.
- This test must be carried out with the patient's compensation.
- This test should be performed photopically.

Description of the VisioWin® interface



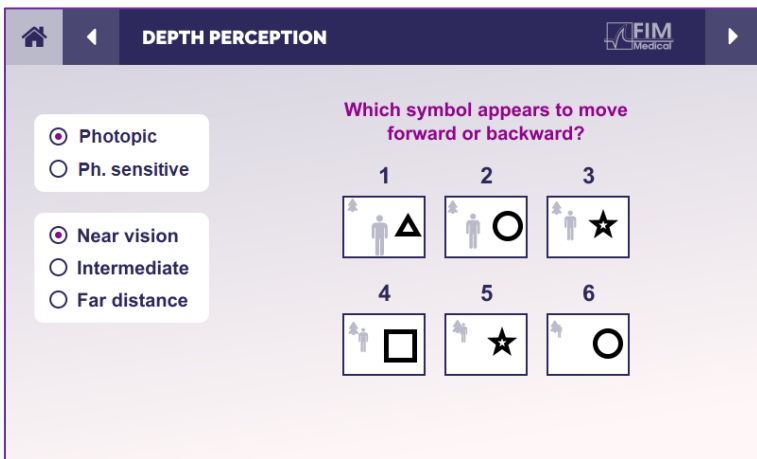
The thumbnail shows the geometric shapes (standard or junior) perceived in relief by the patient and the corresponding shift level in arc seconds (").



In the response entry window, click on the geometric shapes perceived as shifted, "in relief", by the patient.

It is not necessary to tick all the boxes independently; selecting the shape with the lowest relief level automatically validates all previous ones.

Description of the Remote-Control interface



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

- Display brightness level
- Viewing distance
- Question to ask
- Geometric shapes in relief

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

Ask the following question: "What is the last shape you see in relief?"

Phoria test

Purpose and presentation of the test

The phoria test shows the tendency of an eye to deviate from its binocular fixation position in the absence of a fusional stimulus. It is also known as heterophoria or dissociated phoria, and is measured in prism dioptres (Δ). There are several forms:

- An esophoria denotes a crossing of the visual axes in front of the fixed object.
- An exophoria causes these axes to cross behind the object.
- L/R or R/L hyperphoria when one eye is deviated vertically from the other.
- Incyclophoria or excyclophoria when one eye tends to turn slightly on itself along its anterior-posterior axis.

However, it is not abnormal for a subject not to be orthophoric. In fact, there are categories into which the majority of the population fall without this representing a problem for them.

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

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

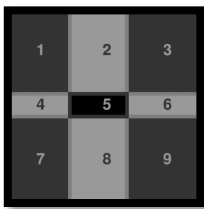
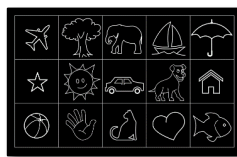


Image seen through the left eye



*Image seen through the left eye
(Child-friendly variant)*

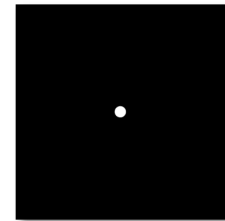


Image seen through the right eye

This test, used to assess a patient's heterophoria, consists of two images. The first is a grid of nine squares, while the second consists of a single dot. This grid will allow the value of the phoria to be framed as follows:

Horizontally:

- Phories greater than 9 Δ .
- Phories between 3 Δ and 9 Δ .
- Phories less than 3 Δ .

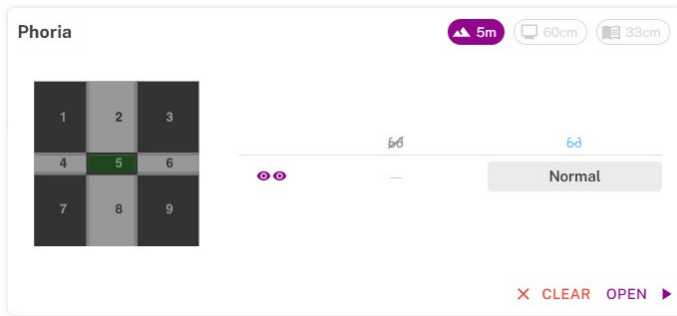
Vertically:

- Phories greater than 9 Δ .
- Phories between 1 Δ and 9 Δ .
- Phories less than 1 Δ .

Execution of the test:

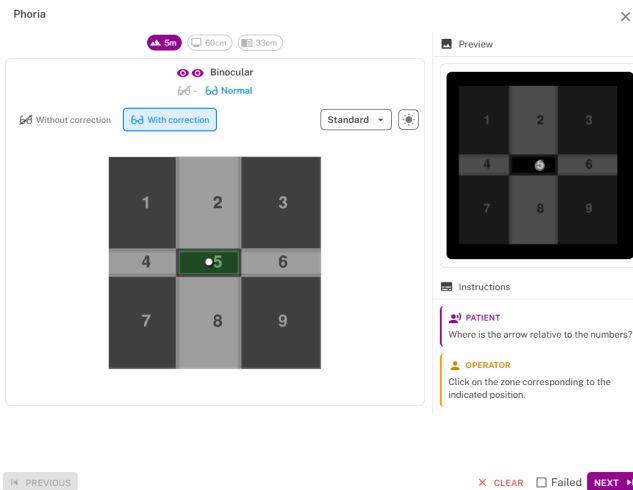
- This test is performed binocularly.
- This test must be performed with the patient's compensation.
- This test can be performed photopically and possibly mesopically.
- This test should be performed when monocular acuity is approximately the same. If the difference is too great, this test will have no diagnostic value.

Description of the VisioWin® interface



The thumbnail displays the 9-square grid shown to the patient and the trend associated with the entered result.

The viewing distance can be changed.

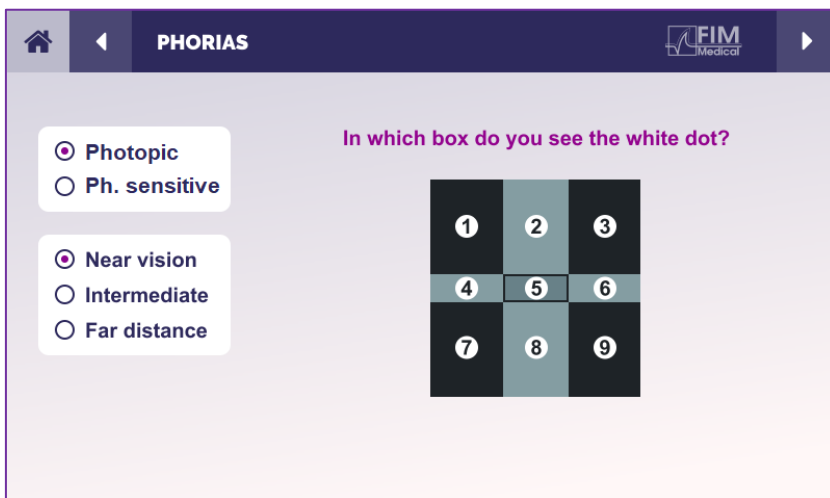


In the response entry window, click on the box in which the patient perceives the white dot.

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

Tick the Out of grid box if the patient does not perceive the white dot.

Description of the Remote-Control interface



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

- Display brightness level
- Viewing distance
- Question to ask

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

Ask the following question: "Where is the arrow relative to the numbers?"

Fusion test

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 determine whether the patient's brain is able to fuse images from the right eye with those from the left. Fusion requires good visual acuity in each eye. Fusion problems can be more or less advanced, ranging from a disparity in fixation to the complete suppression of one of the two images. They are also often responsible for significant visual fatigue when working on a computer screen.

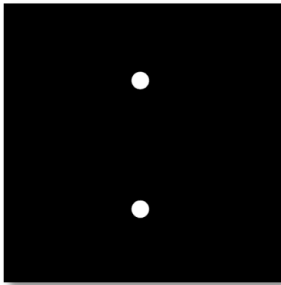


Image seen through the left eye

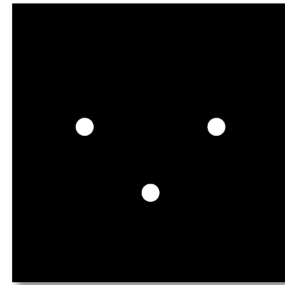


Image seen through the right eye

This test consists of two different images. The image for the left eye contains two dots, while the image for the right eye contains only three dots. The lower point, which is common to both images, must be fused.

Execution of the test:

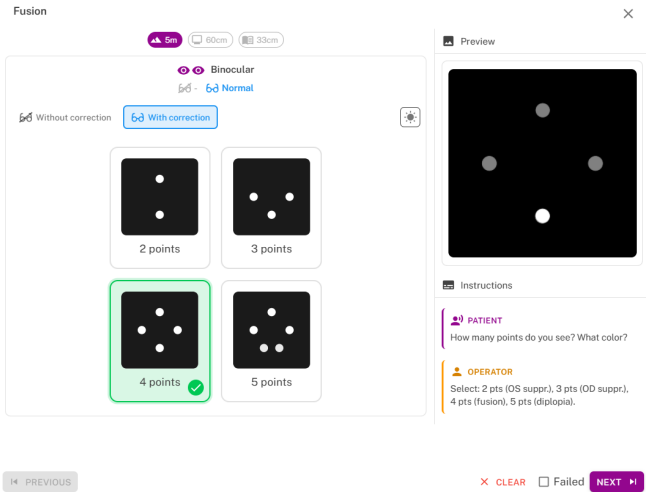
- This test is performed binocularly.
- This test must be performed with the patient's compensation.
- This test must be performed photopically.

Description of the VisioWin® interface



The thumbnail indicates whether fusion is possible or not.

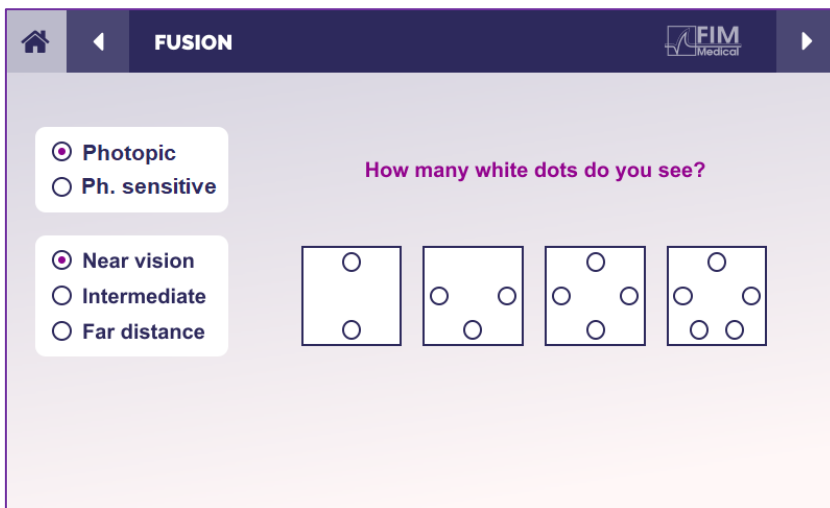
The viewing distance can be changed.



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.

Description of the Remote-Control interface



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

- Display brightness level
- Viewing distance
- Question to ask

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

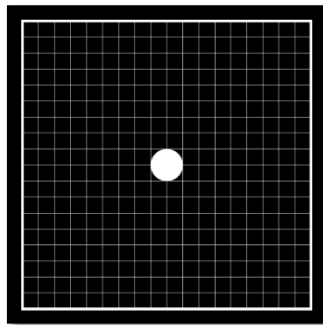
Ask the following question: "How many points do you see? What colour?"

Amsler grid test

Purpose and presentation of the test

The Amsler grid is a test used to identify vision problems linked to retinal problems and, more specifically, damage to the macula. The purpose of this test is to check the central 20° of the retina. In particular, it is used to detect Age-related Macular Degeneration (AMD), a disease that mainly affects people aged over 50. It is an essential test because it can detect the following pathologies:

- Glaucoma
- Scotoma
- Optic nerve damage
- AMD
- Metamorphopsia
- Peripheral or central field loss



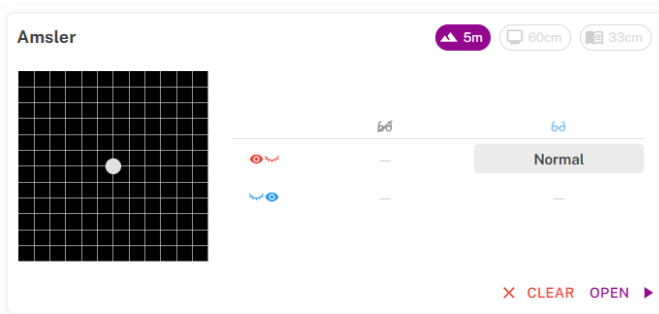
This test was developed by a Swiss ophthalmologist called Marc Amsler. It takes the form of a square grid viewed at an angle of 20°. Each row and column is made up of 20 squares and there is a fixation point in the centre of the grid. This will enable the patient's gaze to be fixed in order to control his visual field. We opted for a white grid on a black background, but different versions are available.

This test was developed by a Swiss ophthalmologist called Marc Amsler. It takes the form of a square grid viewed at an angle of 20°. Each row and column is made up of 20 squares and there is a fixation point in the centre of the grid. This will enable the patient's gaze to be fixed in order to control his visual field. We opted for a white grid on a black background, but different versions exist.

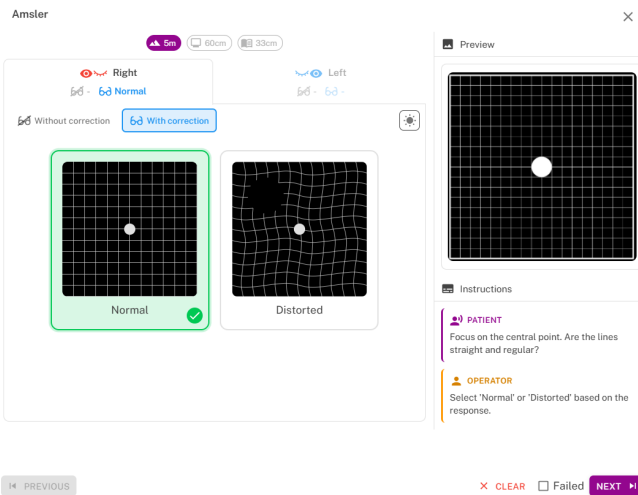
Execution of the test:

- This test is performed monocularly.
- This test must be performed with the patient's compensation.
- This test should be performed photopically.

Description of the VisioWin® interface

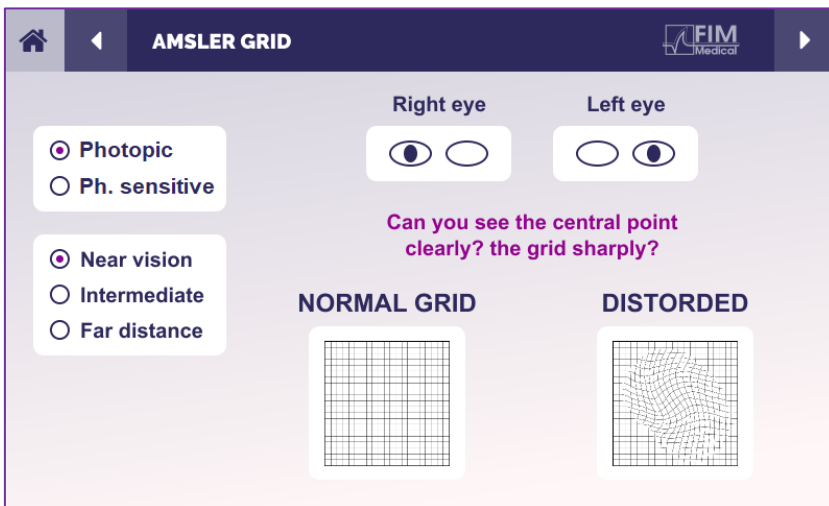


The thumbnail shows the results for each eye tested. The viewing distance can be changed.



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

Description of the Remote-Control interface



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

Read the question aloud and note the perceived result on the response form.

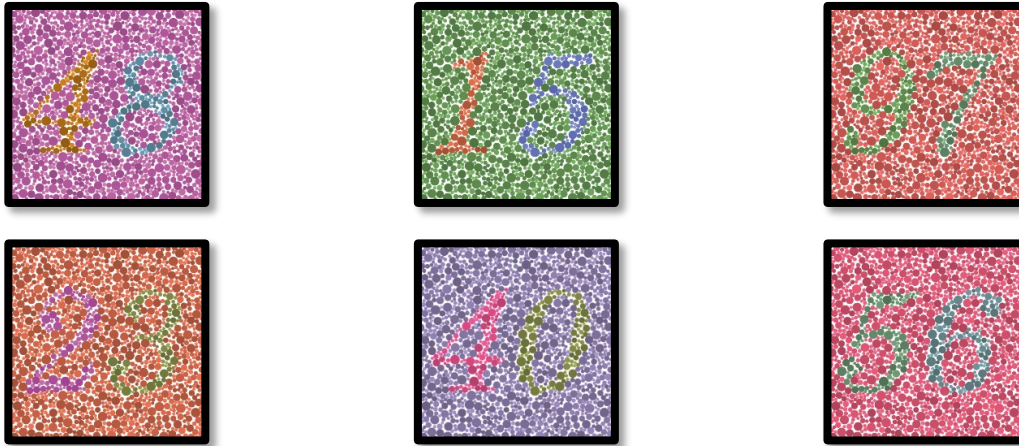
Instructions to be given to the patient

Ask the following question: "Focus on the central point. Are the lines straight and regular?"

Colour perception test

Purpose and presentation of the test

This colour perception test, consisting of a set of pseudo-isochromatic charts, is used to screen for abnormalities in colour vision, principally dyschromatopsias of the Protan, Deutan and Tritan types. By reading the numbers on all the charts, we can determine the state of a subject's colour perception and may reveal difficulties in recognising certain numbers and therefore certain colours.



The colour perception test is based on the vision of pseudo-isochromatic plates (PIC). The test consists of six number plates using the principle of colour confusion lines in the CIE-xy diagram (Commission Internationale de l'Eclairage).

The background and pattern colours are strategically chosen on a line of confusion, so that the pattern is visible to a normal subject, but not to a subject with a colour deficiency. Together, these tests make it possible to solicit 12 lines of chromatic confusion in the three axes: Protan, Deutan and Tritan.

Each test consists of a mosaic of dots of different colours, shades and dimensions.

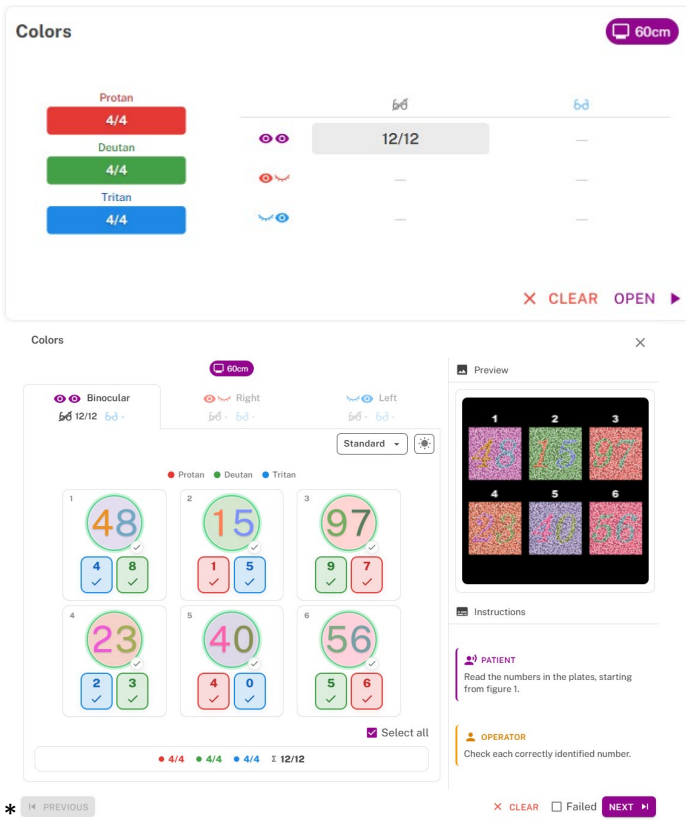
Each panel has 3 different shades (one for the background, one for the 1st digit and another for the 2nd digit).

Each shade is itself made up of several nuances.

Execution of the test:

- This test is performed binocularly, but can also be performed monocularly.
- This test must be performed with the patient's compensation.
- This test must be performed photopically.

Description of the VisioWin® interface



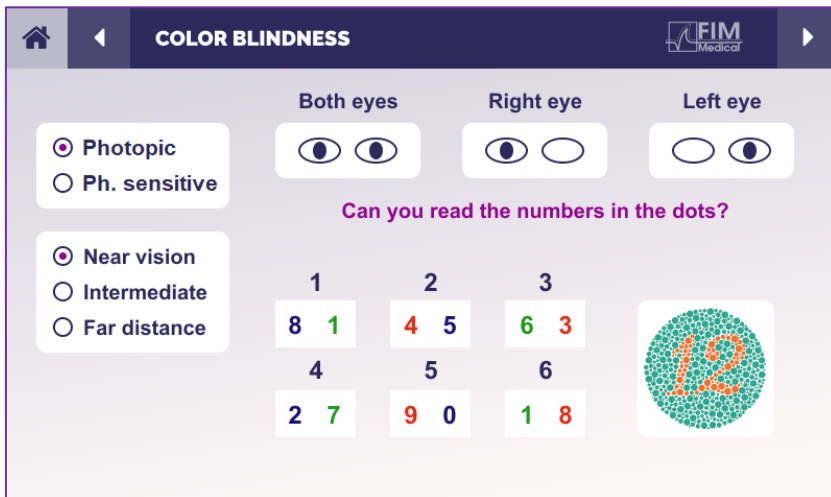
The thumbnail shows the colored numbers to be identified by the patient for each vision mode. The check boxes represent the numbers perceived or not perceived by the patient. The viewing distance can be changed.

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

Tick all boxes individually or the circle containing the numbers to validate both.

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

Description of the Remote-Control interface



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

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

Ask the following question: "Read the numbers in the plates, starting from figure 1."

Glare resistance test

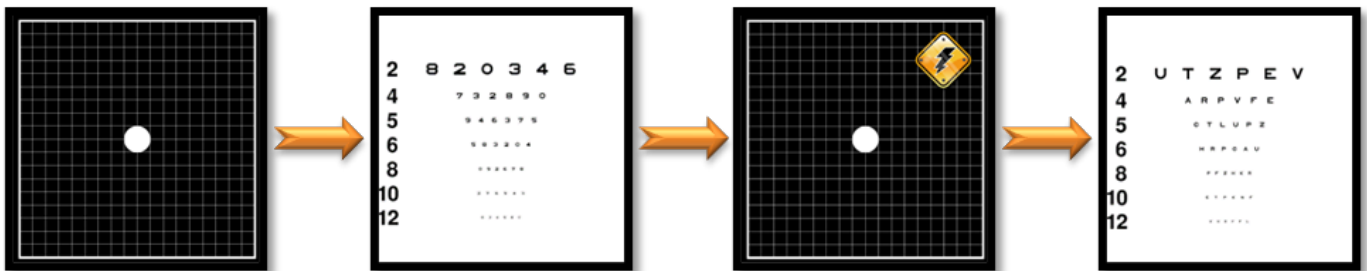


NOTE: The glare resistance test must not be carried out on photosensitive patients who have recently taken photosensitising medication.

NOTE: Medical contraindications to carrying out this test are detailed in the section on contraindications.

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 conditions lengthen this time, so this test can be used to detect certain macular impairments in the patient. It is essential to carefully check all contraindications for this test to avoid triggering adverse reactions in the patient. It is also important to clearly warn the patient about the relatively high intensity of the light.



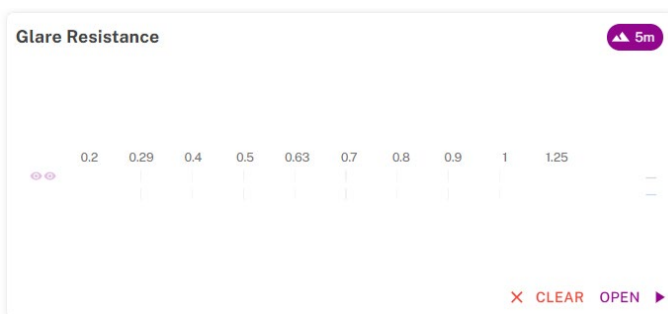
This test uses several other Visiolite® 4K tests. It consists of four steps:

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

Execution of the test:

- ✓ This test is performed binocularly.
- ✓ This test is performed in distance vision.
- ✓ This test must be performed with the patient wearing their correction.
- ✓ This test must be performed under mesopic conditions.

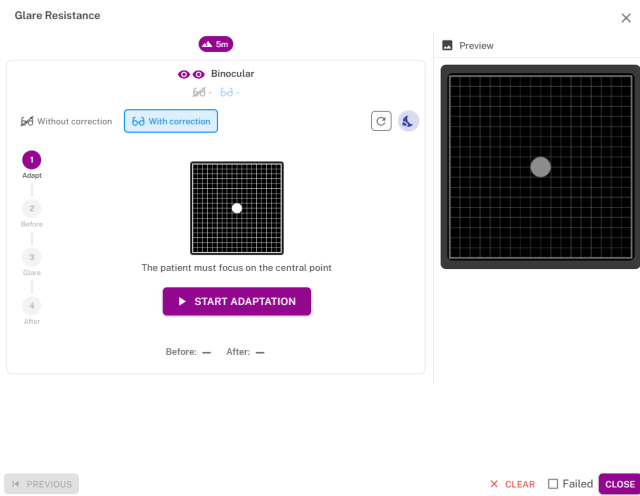
Description of the VisioWin® interface



The thumbnail 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.

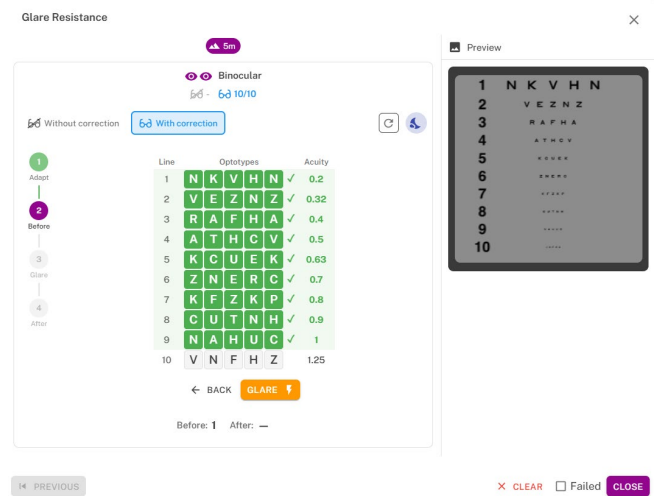
Instructions to be given to the patient

Step 1 – Patient Adaptation



The Amsler grid is displayed at mesopic brightness for 10 seconds.

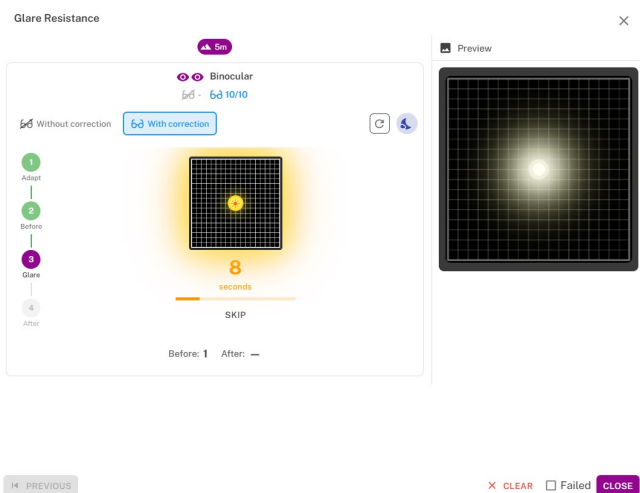
Step 2 – Acuity before glare



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

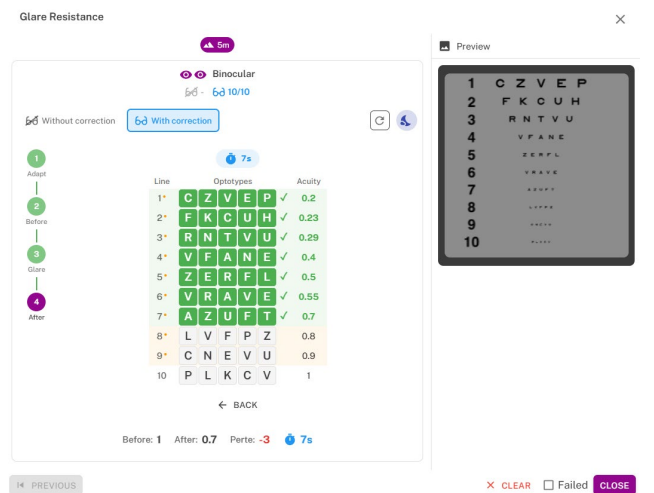
Click on the line to validate the acuity if the minimum validation threshold of optotypes have been successfully recognized by the patient.

Step 3 – Glare



Click on the GLARE button.
Ask the patient to focus their gaze on the central glare point.
The Amsler grid is displayed throughout the 10-second glare duration.
The objective of this step is to induce a scotoma.

Step 4 – Acuity after recovery



Ask the patient to read the optotypes on the smallest line possible as soon as their visual perception has recovered.

A countdown measures the recovery time.
Check the line to validate the acuity if the minimum validation threshold of optotypes have been successfully recognized by the patient.
The optotypes displayed are different from step 2 to prevent the patient from memorizing them.

Glare sensitivity test



NOTE: The glare sensitivity test must not be carried out on photosensitive patients who have recently taken photosensitising medication.

NOTE: Medical contraindications to carrying out this test are detailed in the section on contraindications.

Purpose and presentation of the test

Glare corresponds to an excessive light input that the eye cannot tolerate. This phenomenon reduces both comfort and visual performance, and may persist over time even after the glare has ceased.

The purpose of this test is to reveal problems of light sensitivity by presenting a nighttime driving scene where the patient must identify as much information as possible. The more sensitive the patient is, the more the light will appear diffuse and the more difficulty they will have reading information located near the light source. This test therefore makes it possible to highlight the visual capacities of a subject exposed to glare. It is essential to carefully verify all contraindications to avoid triggering adverse reactions in the patient. It is also important to clearly warn the patient about the relatively high intensity of the light.



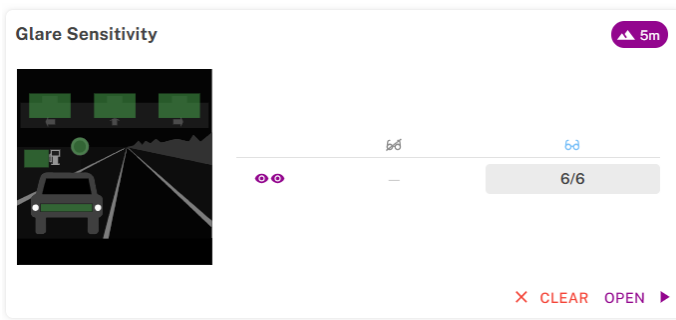
This test represents a nighttime driving scene with a glare source generated by a light-emitting diode positioned on the left-hand side. The scene is composed of six objects that the patient must identify. Each object contains optotypes formed by random letters and/or numbers.

Information to be identified	Contrast level	Decimal visual acuity level
Direction signs	30%	0,32
Information sign	60%	0,32
Speed limit	100%	0,4
License plate	100%	0,4

Execution of the test:

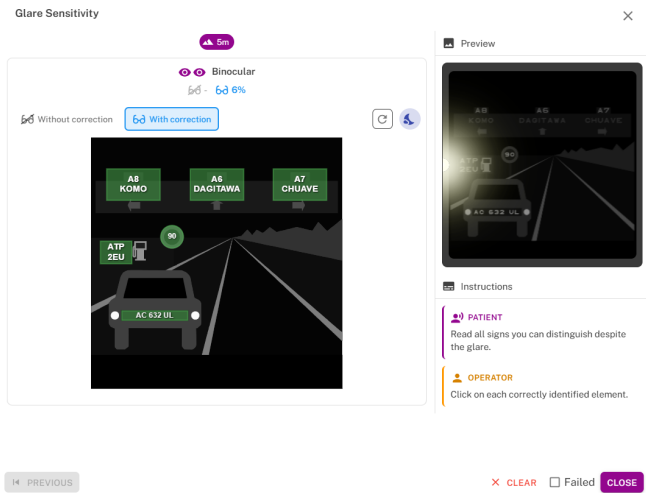
- This test is performed binocularly.
- This test is performed at a distance (The vision, distance and lighting conditions cannot be modified for this test.)
- This test must be performed with the patient's compensation.
- This test is performed mesopically.
- The patient must have visual acuity of at least 4/10 in order to be able to read the various information.

Description of the VisioWin® interface



The thumbnail shows the driving scene displayed to the patient; the visual elements perceived are highlighted in green.

The viewing, distance or lighting conditions cannot be modified for this test.



In the response entry window, left-click on the elements perceived by the patient.

In case of an input error, click again on the element to deactivate it.

The selected elements are highlighted in green.

All elements containing letters or numbers can be clicked.

Instructions to be given to the patient


Ask the following question: "Read all the signs you can distinguish despite the glare."

15. Displaying results



Visualizing the results examination

Review report

Once the exam is completed, click the *Save button* to save the exam results in PDF format. Exams can then be printed or exported to third-party software.

Click on  to access the PDF report viewer.


Vision Examination Report
2/15/2026

Tests and conditions		●●	●●	●●
Acuity	5m	12.5	9	12.5
	60cm	12.5	10	9
	33cm	12.5	10	9
Acuity Mesopic	60cm	12.5	10	9
	33cm	12.5	10	9
Acuity Hyperopia	5m	12.5	10	9
	+1D	12.5	10	12.5
Astigmatism	5m	—	 Normal	 Abnormal
Amsler	33cm	—	Normal	Normal
Color Vision	60cm	12/12	8/12	8/12

Tests and conditions		●●
Contrast	5m	5%
Duochrome	5m	Normal
Stereopsis	33cm	25"
Phoria	5m	Normal
	33cm	Normal

Tests and conditions		●●
Fusion	5m	4/4
	33cm	4/4
Glare Acuity	5m	10
Glare Lateral	5m	6/6

Visual field
Peripheral

 VisioWin 2.0.0
1 / 2

16.Maintenance of the Visiolite® 4K

Cleaning and disinfection



WARNING: The removable forehead rest and plastic parts of the Visiolite® 4K must be cleaned after each use with a damp cloth and a generic bactericidal-fungicidal product.

WARNING: FIM Medical has validated the use of the following pre-soaked wipes or cloths for the decontamination of the Visiolite® 4K:

- Clorox® Healthcare Bleach
- Clorox® Disinfecting Wipes
- Oxivir Excel® Wipes
- Bactynyl® Disinfecting Wipes
- Sani-Cloth® Bleach / Plus / HB / AF3
- Sani-Cloth Active wipes
- Super Sani-Cloth®
- Formula 409®
- Virex® Plus
- Sterimed® 100PURELL® Healthcare Surface Disinfecting Wipes
- Mikrozid® AF wipes
- Bactynyl®
- Oxivir Excel® Wipes
- Super Sani-Cloth®
- Mikrozid® Universal wipes premium
- Mikrozid® AF Wipes
- Mikrozid® Sensitive wipes premium
- Aseptonet® Biocide
- Anios® Quick wipes
- Anios® Excel wipes
- Incidin™ Alcohol Wipe
- ICB® France Klorxitol
- Wipes containing ethanol
- Wipes impregnated with 70% isopropyl alcohol
- Sanicloth® Bleach / Plus / HB / AF3
- Clorox® Healthcare Bleach
- Formula 409®
- Virex® II 256



CAUTION: The device must be cleaned using pre-soaked wipes or cloths only, as direct spraying may allow liquid to enter the housing and damage sensitive electronic components.

CAUTION: Do not immerse the device in liquid or expose it to spraying.

CAUTION: Do not clean the optical lenses with wet wipes or disinfectant liquids.

CAUTION: The optical lenses must be cleaned regularly using the supplied microfiber cloth, which is safe for the anti-reflective coating.

Periodic maintenance

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



CAUTION: Maintenance of Visiolite® 4K can only be carried out by FIM MEDICAL or a distributor if they have been authorized by FIM MEDICAL for maintenance.

Warranty

The device is guaranteed for 2 years.

Under the terms of the contractual warranty, only repair services are covered.

The warranty applies only if the device has been used under normal and intended conditions.

Please note that during annual maintenance, a number of preventive operations are performed. However, this revision does not constitute a guarantee against potential malfunctions that may arise after the service has been completed.

Service life

FIM Medical estimates the service life of Visiolite® 4K at 10 years subject to proper compliance with cleaning conditions, maintenance and environmental conditions.

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.

How to return a defective device



CAUTION: The Visiolite® 4K must be transported only when fully folded. Fold the device down to the lowest position at the base before transport.

In case of a defective device, please contact FIM Medical for support.

Before returning the device, please clean and disinfect it, as explained in the section “Cleaning and disinfection”.

When sending a device for service, it should be shipped in its original packaging

Disposal of the device

In accordance with the WEEE directive 2012/19/EU, used electronic devices must be treated separately from household waste. The devices must be deposited in specific collection sites (waste disposal centers). For more information, you can contact FIM Medical or your authorized distributor.



This symbol specifies that this device is considered as an electrical equipment and must not be disposed as a common garbage. This type of equipment can have potential effects on the environment and human health.

User information**Incident Reporting**

If a serious incident occurs in relation to the use of the device, it shall be promptly reported to the Manufacturer using the contacts below and to the Competent Authority of the country where the incident occurred.

Other User Assistance Information

For other information and requests of technical support, please contact your local distributor using the contacts below.

**MANUFACTURER:
FIM MEDICAL**

51 rue Antoine Primat
69100 Villeurbanne
FRANCE
Tel: +33 4 72 34 89 89 - Fax:
+33 4 72 33 43 51
contact@fim-medical.com
www.fim-medical.com

**TECHNICAL ASSISTANCE /
LOCAL DISTRIBUTOR
(Contacts and/or company's stamp)****Other information****User manual in paper format**

A paper version of these instructions for use is available upon request in accordance with the procedure explained on the accompanying sheet in the case.

Declaration of conformity

The present device is classified as a medical device class I according to the European Regulation MDR 2017/745. The device has been designed in accordance with the requirements of the IEC 60601-1.

17. Troubleshooting and error messages

Issue	Probable cause	Solution
The Visiolite® 4K does not turn on	Power supply fault	Check that the Visiolite® 4K is properly connected to the mains. If necessary, plug the power supply unit directly into a wall outlet.
The VisioWin® software interface is not displayed correctly	Zoom level too high	Set the zoom to a maximum of 125%.
The Visiolite® 4K is shown as offline in VisioWin®	The Visiolite® 4K is not detected or recognized by the PC	Switch off the Visiolite® 4K, then move the USB connection cable to another available USB port on the PC.
The test seen by the patient is different from the one displayed in VisioWin®. The test display is distorted or inconsistent.	The integrity of the data stored in the device's internal memory is compromised.	Switch off the Visiolite® 4K, unplug the power supply unit, wait a few seconds, then reconnect the power supply and restart the Visiolite® 4K.
Spots are visible on the tests. The test display shows abnormal marks. Brightness is not uniform or is too low.	The display screen is damaged.	Switch off the Visiolite® 4K, unplug the power supply unit, and contact FIM Medical or your authorized distributor. If the device has been stored in a cold environment, leave the Visiolite® 4K at rest for several hours before reconnecting it.
The tests appear blurry	The optics are fogged up	Clean the mask optics using a microfiber cloth.
An error message appears when starting VisioWin®	The Windows directory where the software data is stored is not accessible. The database is not accessible in read/write mode.	Check with your network administrator the security permissions assigned to the Windows user account.
Connection problem with the Webapp	Network profile set to "Public"	Set the WiFi network to "Private" mode, then restart the remote control.

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