VISUAL SCREENING

USER MANUAL

VISIOLITE® ACCESS

CE

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Table of Content

1. Introduction

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

Device users

CAUTION: The Visiolite® Access 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® Access 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® Access by other examinations in order to prescribe a correction or surgical intervention.

Patient population

The Visiolite® Access can be used to perform visual acuity tests on patients older than 3 years old who can understand and follow test instructions.

Contraindications

Glare tests with the Visiolite® Access 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 and, multiplicity of visual tests of Visiolite® Access ensure an indirect qualitative clinical benefit in screening for different visual disorders for the patient.

Adverse effects and potential side effects

Visiolite® Access does not generate adverse effects or side-effects related to its use.

5. Technical description

Materials provided

Equipment included with the Visiolite® Access device:

- Visual system on its adjustable base
- Touchscreen Control Panel
- DVI video cable
- IEC60601 Medical External Power Supply (Part No. UE Electronic UES24LCP-120200SPA)
- USB Stick including the control panel configuration file, the user manual and the response form
- Information sheet
- Plastic pouch containing 10 biocompatible forehead rests

Device presentation

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

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

The tests require the patient's visual function in near, far, intermediate and hyperopia vision. Different distances are available for each vision depending on the configurations (see optical focal lengths in paragraph 6).

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

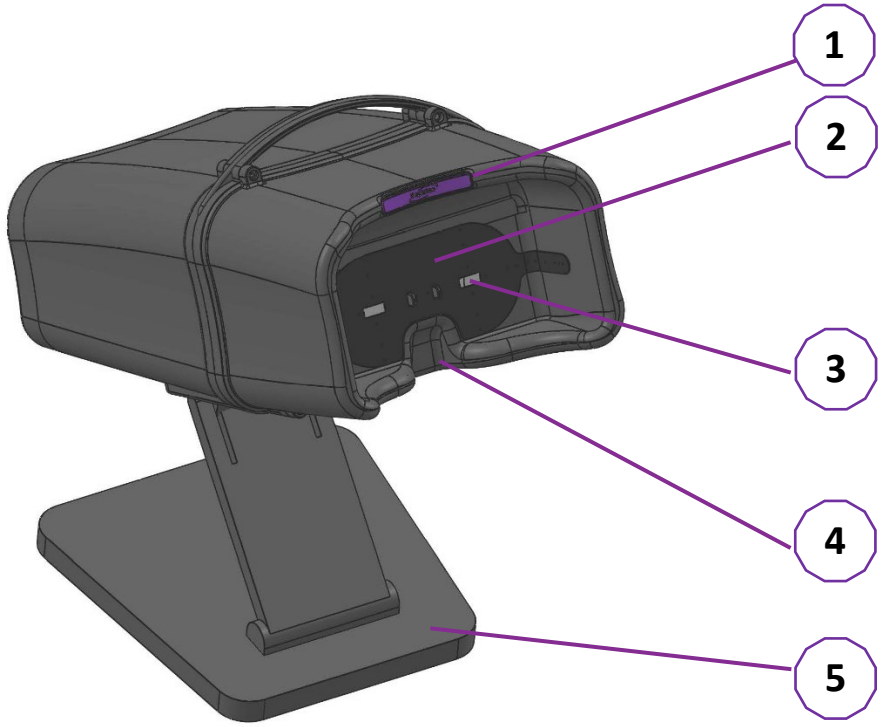
The Visiolite® Access also allows visual tests to be carried out at different lighting levels:

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

The device operates with a control panel.

The Visiolite® Access offers you the following advantages:

- A simplified and intuitive user experience
- Operation with the highest level of cybersecurity and data protection
- Mobility for use in portable or on-the-go settings



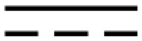
1 Removable forehead rest
2 LED for visual field testing
3 Anti reflective glass window
4 Ergonomic nasal location
5 Base to ensure stability, adjust height and tilt
6 Control panel
7 USB port for firmware setup/update and data export
8 On/off switch
9 DVI video cable
10 Power supply adapter

6. Technical characteristics

Features of the Visiolite® Access

Internal display	**TFT-LCD 5.46'' 2K 1440p (2560x1440)**			
Backlight type	Single (1 x 14 LED)			
Brightness levels	Photopic 80 or 160cd/m² Mesopic 3 cd/m²			
Optical distances	The device includes 6 optical lenses: Near vision: 35cm (14'') Intermediate vision: 60cm (24'') / 81cm (32'') Far vision: 6m (20 ft) Hyperopia: +1δ / +1.5δ			
Connectivity	USB Type A			
Video cable	DVI	Length: 1m		
Touchscreen	**TFT-LCD 7'' 1024x600**	**Capacitive touch**		
Control panel power supply	12V DC / 24W / 2A Max			
Power supply unit	Input: 100-240V AC / 50-60Hz / 0,6A Output: 12V DC / 24W / 2,08A Max Cable length: 2,99m	UE Electronic UES24LCP-120200SPA		
Protection level	Medical with 2 levels of patient protection (2 x MOPP cf. EN60601-1)			
Electric class	II			
Storage temperature	-10 to 60°C			
Temperature of use	15 to 35°C			
Regulatory standards	MDR 2017/745, ISO 10993-1, EN 62366-1:2015/A1:2020, EN ISO 15223-1:2021, EN ISO 20417:20216			
Security standards	ISO 10993-1, EN 60601-1, EN 60601-1-2, IEC 60601-1-6, ANSI Z80.36, EN ISO 15004-2			
Medical class	Class I (rule 13), MDR 2017/745 Annex VIII			
EMDN code	Z12120120 - INSTRUMENTS FOR THE ASSESSMENT OF VISUAL FUNCTIONALITY			
GMDN code	65177 - Vision physiology/eye movement analysis system			
Part applied	Front Support	Type B		
Dimensions	42 x 22,5 x 24,5 cm	Packaged	40 x 20 x 22 cm	Visual system only
Weight	4,5 kg	Packaged	3,5 kg	Visual system only
Year of CE marking	2025			

7. Symbols

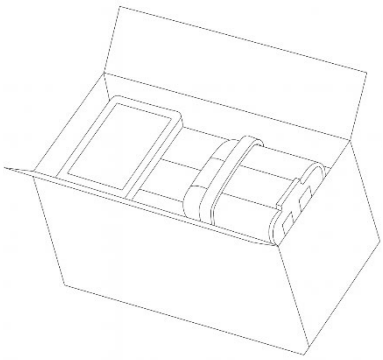
CE	CE marking according to Medical Device Regulation (UE) 2017/745		Instructions for use
	Type B applied part		Direct current
	Must not be disposed of with unsorted waste, but treated in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive		
MD	Medical Device		Manufacturer Identification
LOT	Batch Number		
SN	Serial Number		Date of manufacture
	Storage temperature from -10 to 60°C		
UDI	Unique Device Identifier	(11)XXXXXX	UDI Identification - Date of manufacture
(01)XXXXXXXXXXXXXX	UDI Identification - Unique product identification number	(10)XXXXXX	UDI Identification - Batch number

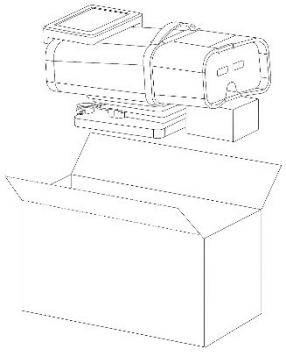
8. Installing the Visiolite ® Access

Unpacking the device

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

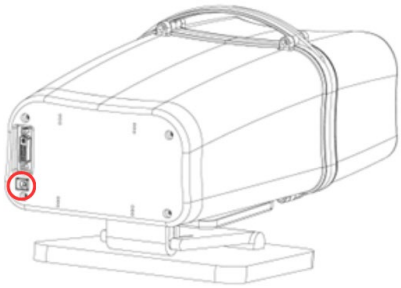
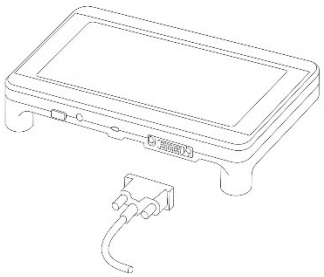
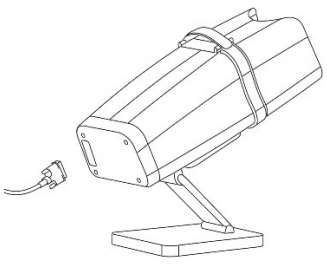
To access the Visiolite® Access, open the box and lift the Visiolite® Access by the handle.





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.

Connecting the Power cable:	***Connecting the Control Panel:***	
On the back of the device, connect the power cable to the point indicated by the red circle.	Connect the DVI cable to the Control Pnael and to the back of the device.	
		

Control panel's firmware installer

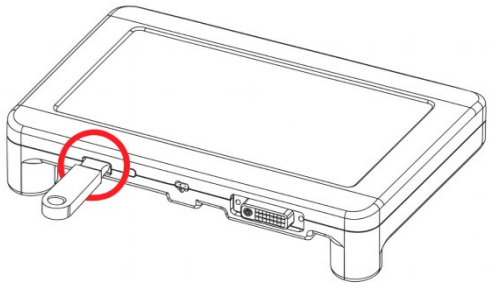
When you purchase a Visiolite® Access, you will find a USB key in the box.

This USB key will contain the firmware installer, as well as your pre-recorded sequences (if you would like to have additional sequences at a later date, please contact FIM Medical).

The first time you use the Visiolite® Access, you will need to insert the USB key into the USB port on the control panel (circled in red on the display).

A window will open asking if you wish to proceed with the software update. Once you have given your consent, the control panel will update and record your pre-recorded sequences automatically.

This operation may take a few minutes.



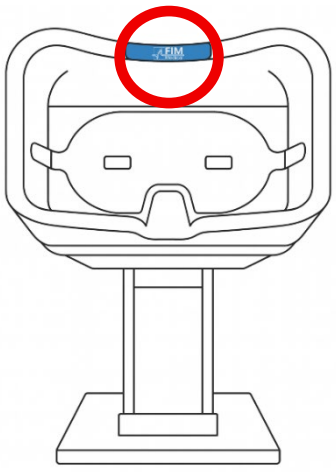
Control panel's Removable forehead rest

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.

CAUTION: If the FIM Medical logo on the removable forehead rest begins to fade, it is recommended to replace the forehead rest.

The box also contains a pouch of removable forehead rest.

Before using the appliance, it is necessary to install the removable forehead rest by inserting it in the dedicated place on the front of the device.



Check that the FIM Medical logo remains clearly visible. Replace the forehead rest if the logo starts to fade.

Firmware Version: V01.00.00

9. Preliminary explanations to the patient

Adjusting the device

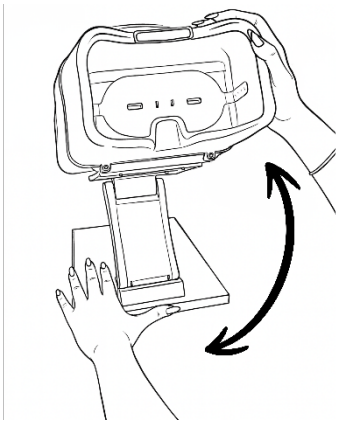
CAUTION: The Visiolite® Access must be placed on a flat, stable surface.

CAUTION: The Visiolite® Access 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.

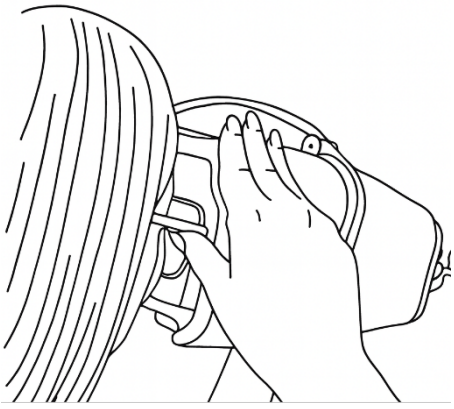
Before using the Visiolite® Access with a patient, adjust the inclination while holding the base.



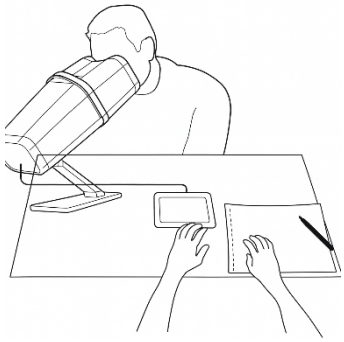
Special Case: Patients with Progressive, Bifocal, or Multifocal Lenses

During near vision testing, it is important to ensure that the patient is viewing through the correct part of their prescription lenses.

1) Instruct the patient to slightly adjust the position of their glasses (for example, by lifting them with their thumbs) so that the reading portion of the lenses is aligned with the eyepiece.
2) Confirm that the patient is comfortable and that the test view is not obstructed by the frame or by the wrong lens area.



10. Using the Visiolite® Access



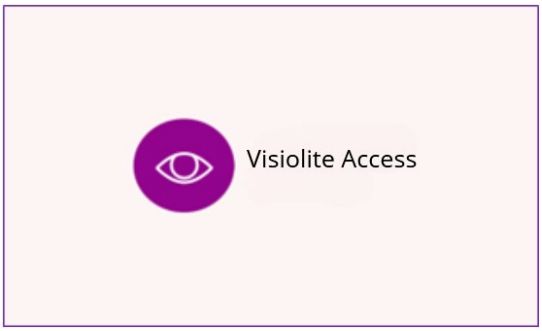
Starting up the control panel

Plug in the Visiolite® Access with the power supply and connect the control panel to the Visiolite® Access using the DVI cable.

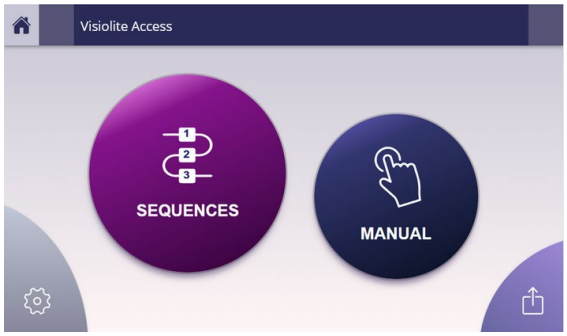
Switch on the Visiolite® Access control panel using the on/off switch.

The control panel will then switch on automatically. A start-up screen will be displayed while the home page is being initialized.

You can then use the control panel's touch interface to access the various functions.



Control panel start-up screen

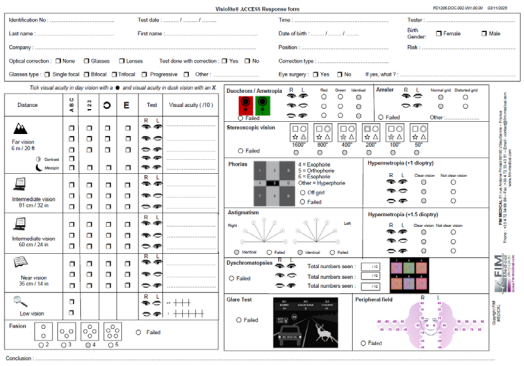


Control panel home page

Use of the response form

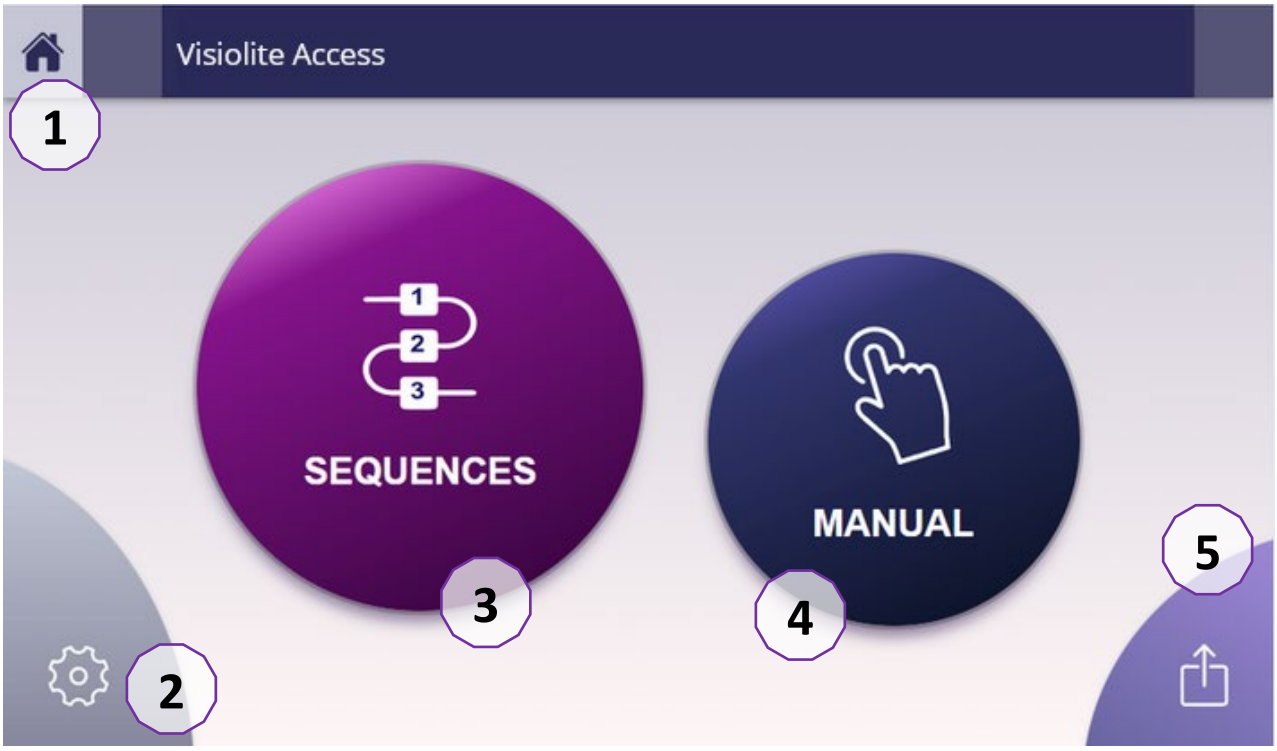
The response block can be downloaded from the link provided in the Information Sheet supplied with the device.

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



11. Visiolite® Control Panel Home Page

User Interface Description



1 **Home menu:** Access the Home page

2 **Settings:** Control panel General settings

3 **Sequence:** Access all sequences recorded on the control panel

4 **Manual:** Access to all tests that can be performed on the control panel

5 **Export:** Test results export settings

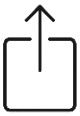
Description of the icons


Home menu


Access General settings

Access to all recorded sequences


Access to all tests available


Export settings


Move to the left / back button

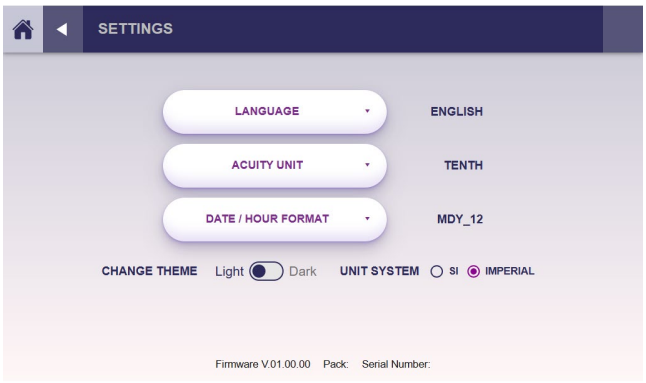

Move to the right


Save button

Control Panel settings

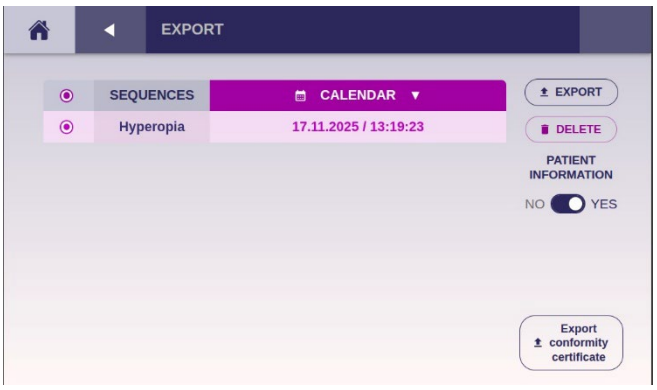
NOTE: The control panel firmware can only be updated via a USB key.

General



The settings allow you to change the display language, the date and time format, the unit of visual distances tested in metric (m/cm) or imperial (ft/in) and the unit of visual acuity results LogMAR, Tenths, Tenths x10 or Snellen 20ft.

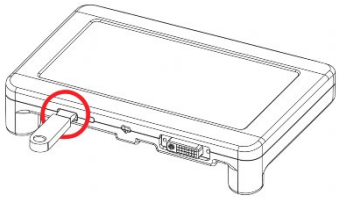
Export



Calendar: Filter the exams by date.

Delete: Erase the selected exam(s).

Export: Exporting data from the control panel is done directly and exclusively to a USB key. This can be inserted into the USB port on the control panel circled in red.



Patient information: Enables selection of whether a patient identification page is exported and added to the report. This page can then be completed manually by the user/operator with the patient's details.

Export conformity certificate: Enables the exporting of the device's manufacturing conformity certificate.

12. 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 test is completed, operator must clean the device, especially the parts in contact with the patient

Manual Mode

To launch a test in manual mode,

- On the home page, select *Manual*.
- Choose the test you wish the patient to take
- Configure the test parameters generally found on the right of the screen to meet your needs
- Read the Instruction to be read to the patient
- Enter the patient's answer on the response form.

Sequence Mode

To launch a test in manual mode,

- On the home page, select *Sequence*.

A window will open, from which the Visiolite® Access will follow the tests in the recorded sequence in order.

- Read the Instruction to be read to the patient
- Click on the screen to mark the patient's response (if applicable) or enter the patient's answer on the response form.
- Go through the entire protocol by clicking on ▶. At any time during the examination, you can go back by clicking on ◀.

For ‘photosensitive’ patients, you can lower the brightness in the device by clicking on ‘Photopic low’ (Reduces the light in the Visiolite® Access by half).

- Once the exam is complete, click on the *Save* button

Description of tests

Visual acuity tests

✓ ***Purpose and presentation of the test:***

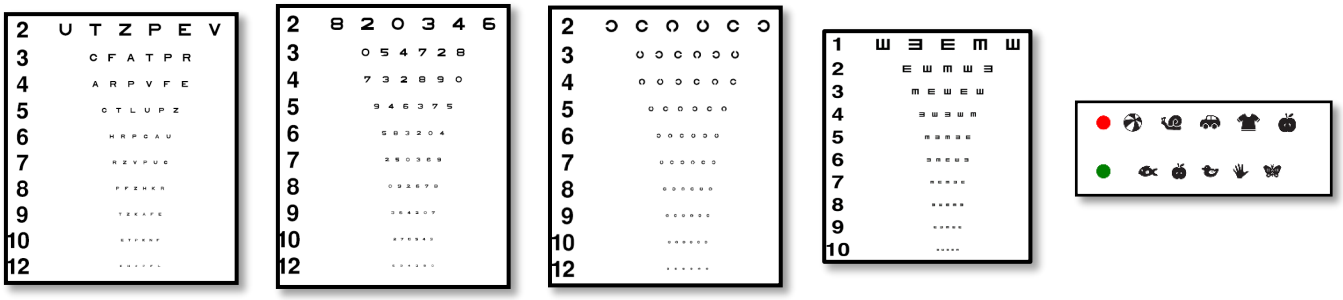
The visual acuity test is the starting point for any eye examination. It ensures that a patient has the correct correction and assesses his or her ability to decipher everyday information. During an examination, the aim is generally to achieve visual acuity of 10/10 or even 12/10. This will enable the 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® Access:

- 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.

In Sequence mode:

Firmware Version: V01.00.00

In the window for entering responses, click on the box to the right of the line to validate the acuity if at least 3 optotypes have been successfully recognised by the patient.

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

The unit of the result is defined in the general settings.

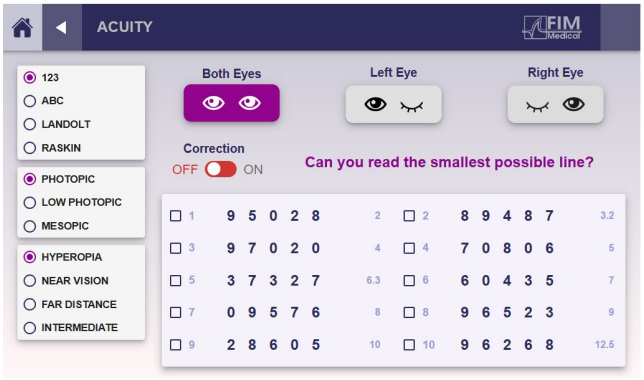
In Manual mode:

Note down on the response form the answers given by the patient.

It is not necessary to validate all the optotypes independently. Validate the acuity if at least 3 optotypes have been successfully recognised by the patient.

The unit of the result is defined in the general settings.

✓ ***Control panel interface description:***



The control panel interface displays the current test conditions:

- Type of optotype displayed
- Display brightness level
- Vision distance
- Mode of vision required
- Question to be asked
- Optotypes displayed

State the question and record the result on the answer form.

✓ ***Instructions to be given to the patient:***

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

- Letters: ‘On the shortest line possible, read all the letters.’

- Numbers: ‘On the shortest line possible, read all the numbers.’

- Landolt: ‘On the shortest possible line, say which side the ring opening is on.’

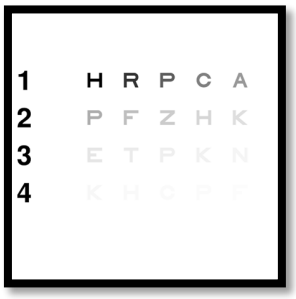
- Raskin's E: ‘On the shortest line possible, say which way the letter E is pointing.’

- DAVL Symbols: ‘On the shortest line possible, identify the symbols.’

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

✓ ***Performing 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 photopics but can also be performed for low photopics.
- The patient must have a visual acuity of at least 2/10.

In Sequence mode:

In the window for entering responses, click on the optotypes correctly recognised by the patient.

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

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

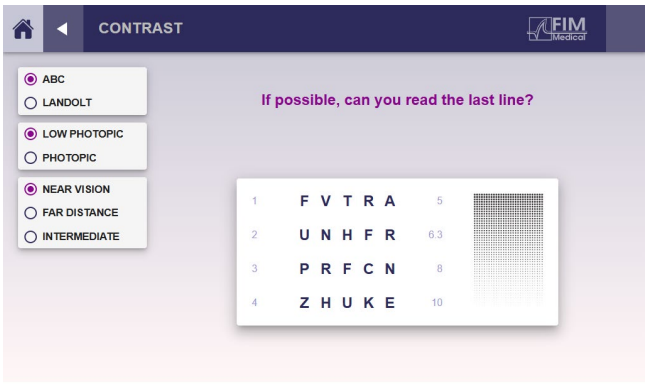
In Manual mode:

Note down on the response form the answers given by the patient.

It is not necessary to validate all the optotypes independently. Validate the test if at least 3 optotypes have been successfully recognised by the patient.

✓ ***Control panel interface description:***

Firmware Version: V01.00.00



The control panel interface shows the current test conditions:

- Display brightness level
- Viewing distance
- Question to be asked
- Optotypes displayed

Say the question and note the result on the answer form.

✓ ***Instructions to be given to the patient***

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

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.

✓ ***Performance 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.

In Sequence mode:

In the window for entering responses, click on the line or lines that the patient perceives more clearly.

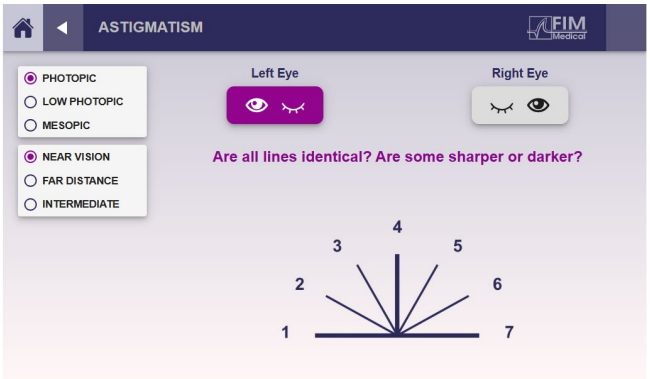
Click on identical if the patient cannot see any difference.

The number of the line entered is then coloured blue.

In Manual mode:

Note down on the response form the answer given by the patient.

✓ ***Control panel interface description:***



The control panel interface shows the current test conditions:

- Display brightness level
- Viewing distance
- Mode of vision required
- Question to be asked
- Optotypes displayed

State the question and record the result on the answer form.

✓ ***Instructions to be given to the patient***

Ask the following question: "Look at all the lines, are they identical?

If not: "Does one or more of the lines look sharper or darker to you?

"If so, which ones?

Full visual field test

✓ ***Purpose and presentation of the test***

The visual field is used to identify various vision disorders. It is essential for diagnosing gaps in vision due to scotomas, damage to the optic nerve or directly to the cerebral cortex. The table below shows the extent of the visual field measurable by Visiolite® Access. The values are not symmetrical, in particular because of the relief of the nose. At binocular level, the horizontal fields are added together, giving a zone common to 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 broken down into two parts: analysis of the central field and analysis of the peripheral field. The first tests the central 30° of vision, while the second tests the rest of the visual field. The peripheral field is assessed using a procedure similar to a static Goldman test, while the central field is checked using an Esterman grid.

Monocular	Slots	Binocular	Slots
Nasal	30°	Horizontal	180°
Temporal	90°	Vertical	90°
Superior	45°		
Inferior	45°		

The central field is tested using 32 light stimuli

The central field will test the central 30° of vision using 16 diodes per eye. They are arranged in the manner of an Esterman grid, giving greater importance to low vision and the horizon line.

Perimetry is performed here in static mode, which means that the stimulus will be activated for a short time during which the patient must succeed in seeing it. The light stimulus is activated for around 200 ms.

✓ ***Performing the test***

- This test is performed monocularly.

- The patient does not wear the correction.

In Sequence mode:

In the window, select which stimulus you want to test and click on it to activate the stimulus

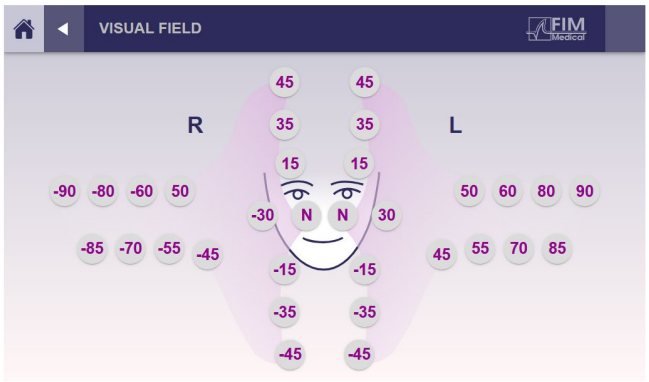
Click on the green tick if the patient sees the stimulus

Click on the red cross if the patient does not see the stimulus

In Manual mode:

Note down on the response form the answer given by the patient.

✓ ***Control panel interface description:***



The control panel interface shows the different diodes in the peripheral field and their corresponding angles.

Press on 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.

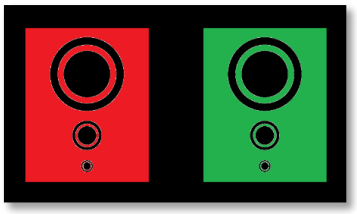
✓ ***Instructions to be given to the patient***

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.

✓ ***Performing 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.

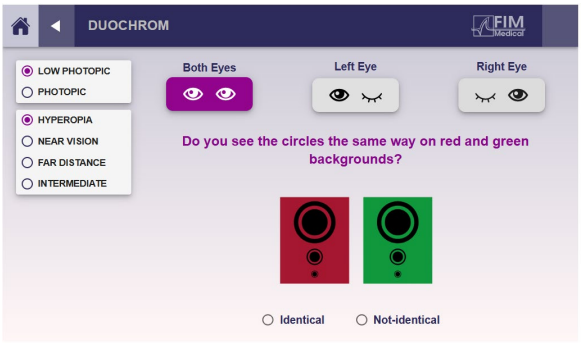
In Sequence mode:

In the window for entering responses, click on the colour best perceived.
Click on identical if the patient does not see any difference.

In Manual mode:

Note down on the response form the colour best perceived given by the patient.

✓ ***Control panel interface description:***



The control panel interface shows the different diodes in the peripheral field and their corresponding angles.

Press on 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.

✓ ***Instructions to be given to the patient***

Ask the following question: "Do you see the circles in the same way in the red and green figures?

If not: "Are they sharper or darker on one of the 2 colours?

Firmware Version: V01.00.00

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.

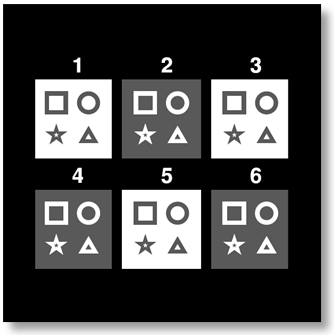


Image seen by the left eye

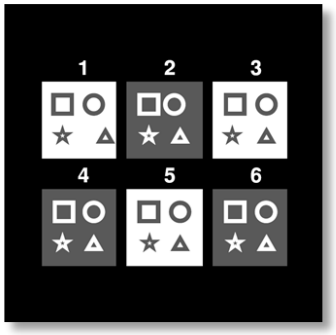


Image seen by the right eye

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"

✓ ***Performing 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.

In Sequence mode:

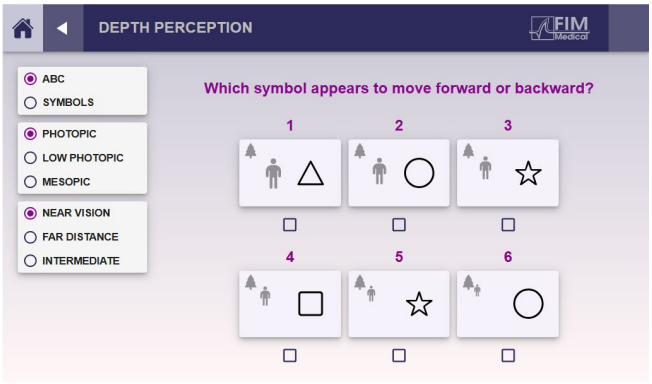
In the window for entering responses, click on the geometric shapes that the patient perceives as shifted, or ‘in relief’.

It is not necessary to tick all the boxes independently; validating the shape with the least relief will automatically validate all the previous ones.

In Manual mode:

Note down on the response form the geometric shapes that the patient perceives as shifted, or ‘in relief’

✓ ***Control panel interface description:***



The control panel interface shows the current test conditions:

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

Say the question and note the result on the answer form.

✓ ***Instructions to be given to the patient***

Ask the following question: 'Starting with figure number 1, which drawing seems to be moving forwards or backwards in relation to the others?'

<u>Phoria test</u>

✓ ***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.

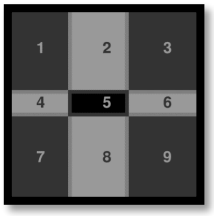


Image seen through the left eye

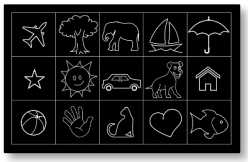


Image seen through the left eye

(Child-friendly variant)

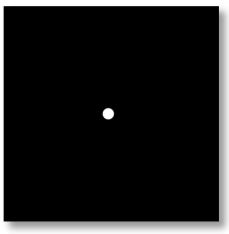


Image seen through the right eye

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.

✓ ***Performing 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.

In Sequence mode:

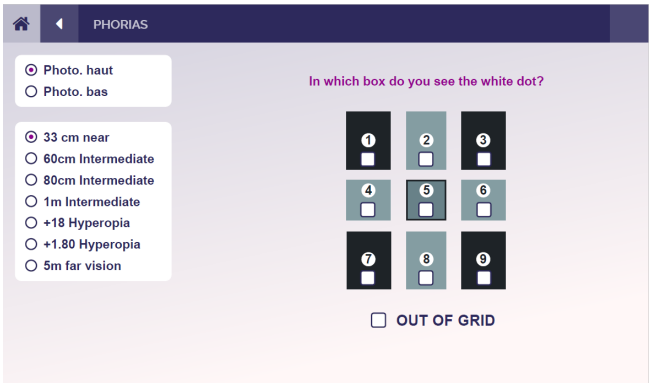
In the window for entering responses, click on the box in which the patient perceives the white dot.

The tendency linked to the result is visible above the input grid.

In Manual mode:

Note down on the response form the box in which the patient perceives the white dot.

✓ ***Control panel interface description:***



The control panel interface shows the current test conditions:

- Display brightness level

- Viewing distance

- Question to be asked

State the question and note the result on the answer form.

✓ ***Instructions to be given to the patient***

Ask the following question: "In which square do you see the white dot?

The movement of the dot is often fleeting or non-existent (orthophoria): the questioning should prepare the patient to indicate the location of the dot when it appears.

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

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.

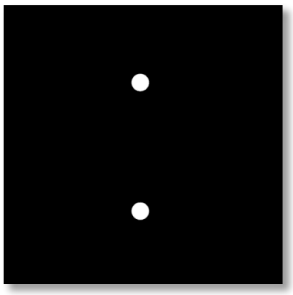


Image seen through the left eye

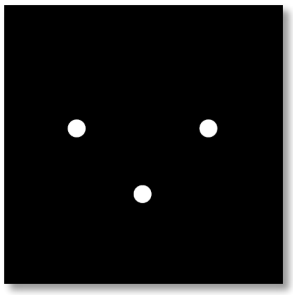


Image seen through the right eye

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.

✓ ***Performing the test***

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

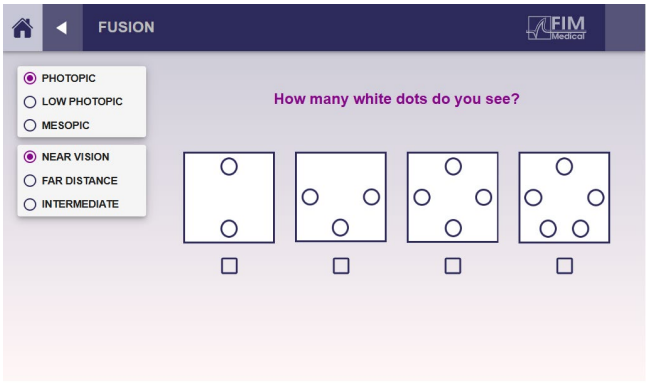
In Sequence mode:

- In the window for entering responses, click on the number of points perceived by the patient.

In Manual mode:

- Note down on the response form the number of points perceived by the patient.

✓ ***Control panel interface description:***



The control panel interface shows the current test conditions:

- Display brightness level
- Viewing distance
- Question to be asked

State the question and note the result on the answer form.

✓ ***Instructions to be given to the patient***

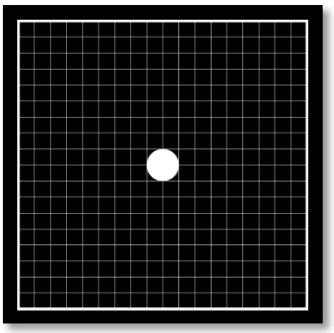
Ask the following question: "How many white dots can you see?

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.

✓ ***Performing the test***

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

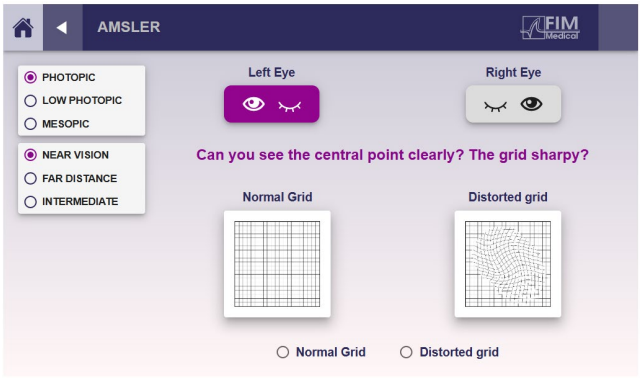
In Sequence mode:

- In the window for entering responses, tick whether the patient perceives the grid as normal or distorted.

In Manual mode:

- Note down on the response form whether the patient perceives the grid as normal or distorted.

✓ ***Control panel interface description:***



The remote control interface shows the current test conditions:

- Display brightness level
- Vision mode required
- Viewing distance
- Question to be asked

State the question and note the result on the answer form.

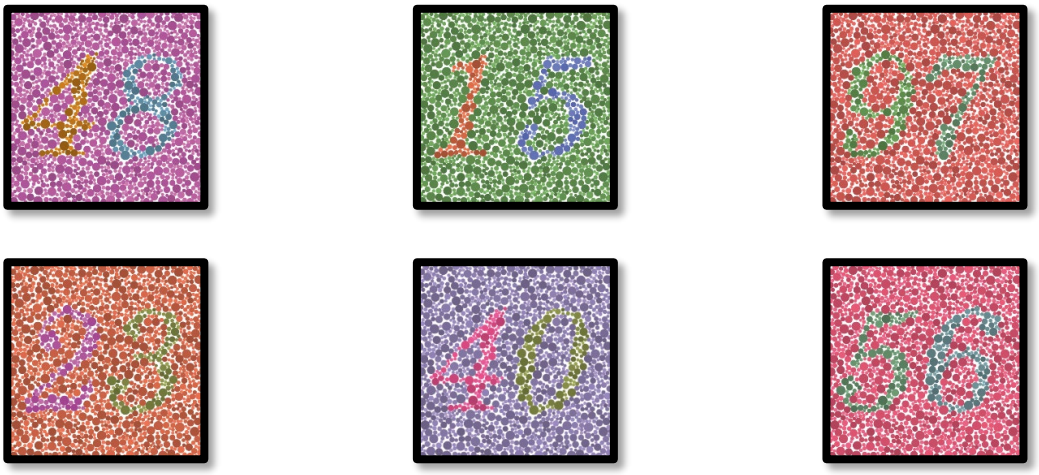
✓ ***Instructions to be given to the patient***

Ask the following question: "Can you see the central point clearly? Is the grid clear?

<u>Colour perception test</u>

✓ ***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.

✓ ***Performing 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.

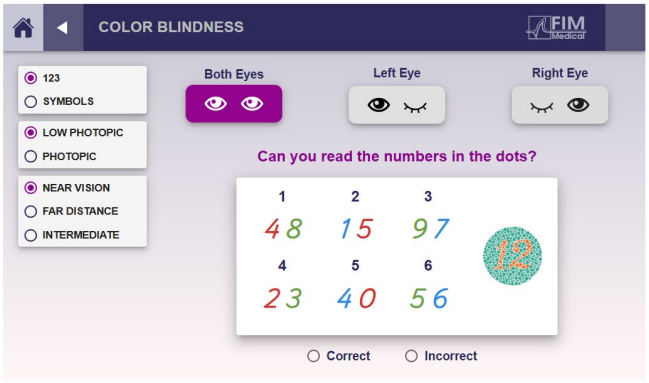
In Sequence mode:

- Tick the Correct box if the patient recognises all the digits correctly.
- Tick the Incorrect box if the patient does not recognise all the digits correctly.

In Manual mode:

- Note down on the response form all the digits recognised correctly or incorrectly by the patient.

✓ ***Control panel interface description:***



The remote control interface shows the current test conditions:

- Display brightness level
- Vision mode required
- Viewing distance
- Question to be asked

State the question and note the result on the answer form.

✓ ***Instructions to be given to the patient***

Ask the following question: 'Starting with figure number 1, read the figures in the discs.

Glare sensitivity test

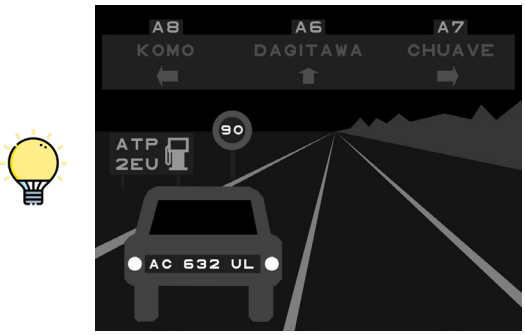
NOTE: The Visiolite® Access glare tests must not be carried out on photosensitive patients who have recently taken photosensitising medication.

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

✓ ***Performing 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.

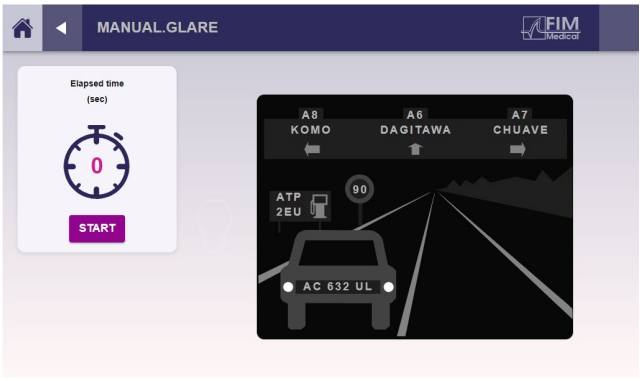
In Sequence mode:

- A timer is located on the left-hand side of the screen click on start to record the time taken by the patient to complete the test
- In the response input window, left-click on the elements perceived by the patient.
- If you make a mistake, click on the item again to deactivate it.
- Activated items are coloured green.
- All items containing letters or numbers can be clicked.

In Manual mode:

- A timer is located on the left-hand side of the screen click on start to record the time taken by the patient to complete the test
- Note down on the response form all the elements perceived by the patient.

✓ ***Control panel interface description:***



The control panel interface shows the current test conditions:

- Display brightness level
- Vision mode required
- Viewing distance
- Question to be asked

State the question and note the result on the answer form.

✓ ***Instructions to be given to the patient***

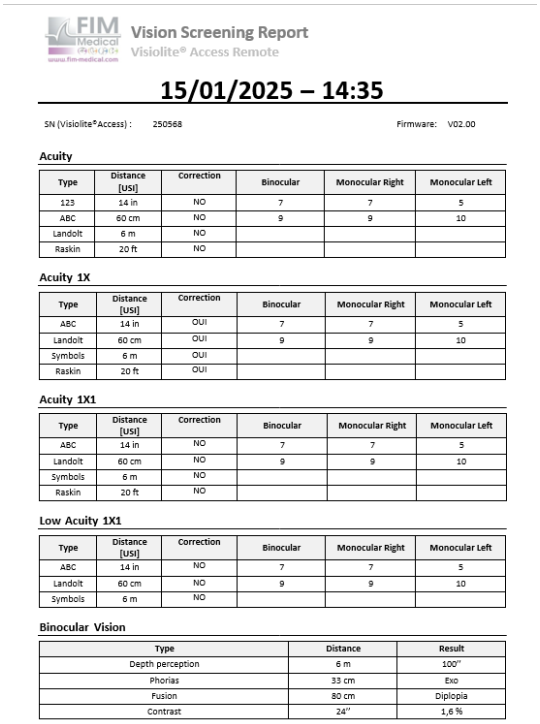
Ask the following question: 'Read all the information in the scene, if possible starting as close as possible to the light source'.

13. Displaying results

Once the examination has been completed and saved, it will be visible in the ‘Export’ tab.

A report will automatically be generated and you will be able to export it to a USB key (as seen in the ‘Control Panel settings’ section).

The report will take the following form:



Vision Screening Report
Visiolite® Access Remote

15/01/2025 – 14:35

SN (Visiolite®Access) : 250568 Firmware: V02.00

Acuity

Type	Distance [USI]	Correction	Binocular	Monocular Right	Monocular Left
123	14 in	NO	7	7	5
ABC	60 cm	NO	9	9	10
Landolt	6 m	NO			
Raskin	20 ft	NO			

Acuity 1X

Type	Distance [USI]	Correction	Binocular	Monocular Right	Monocular Left
ABC	14 in	OUI	7	7	5
Landolt	60 cm	OUI	9	9	10
Symbols	6 m	OUI			
Raskin	20 ft	OUI			

Acuity 1X1

Type	Distance [USI]	Correction	Binocular	Monocular Right	Monocular Left
ABC	14 in	NO	7	7	5
Landolt	60 cm	NO	9	9	10
Symbols	6 m	NO			
Raskin	20 ft	NO			

Low Acuity 1X1

Type	Distance [USI]	Correction	Binocular	Monocular Right	Monocular Left
ABC	14 in	NO	7	7	5
Landolt	60 cm	NO	9	9	10
Symbols	6 m	NO			

Binocular Vision

Type	Distance	Result
Depth perception	6 m	100''
Phorias	33 cm	Exo
Fusion	80 cm	Diplopia
Contrast	24''	1,6 %

14. Maintenance of the Visiolite® Access

Cleaning and disinfection

WARNING: The removable forehead rest and plastic parts of the Visiolite® Access 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® Access:

- Clorox® Healthcare Bleach
- Clorox® Disinfecting Wipes
- Oxivir Excel® Wipes
- Bactinyl® Disinfecting Wipes
- Sani-Cloth® Bleach / Plus / HB / AF3
- Sani-Cloth Active wipes
- Super Sani-Cloth®
- Formula 409®
- Virex® Plus
- Sterimed® 100
- PURELL® Healthcare Surface Disinfecting Wipes
- Mikrozid® AF wipes
- Bactinyl®
- 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 anti-reflective glass window with wet wipes or disinfectant liquids.

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

CAUTION: If the FIM Medical logo on the removable forehead rest begins to fade, it is recommended to replace the forehead rest.

Periodic maintenance

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

CAUTION: Maintenance of Visiolite® Access 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® Access at 5 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® Access 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.

15. Troubleshooting and error messages

Issue	Probable cause	Solution
Visiolite® Access does not turn on	Power supply fault	Ensure the power cable is securely connected to the device and power source. If using a power strip, try connecting the power supply directly to a wall outlet. Verify that the outlet provides power (test with another device).
The test seen by the patient is different from that displayed in the Control Panel.	DVI video cable may be damaged or improperly connected	Turn off the Visiolite® Access Unplug the power and DVI cable Reconnect the DVI cable securely Plug in the power and restart the device If it persists, test with another DVI cable
Test display is distorted or inconsistent.	DVI connection or display issue	See above. Also check for signs of screen or graphics controller failure.
Stains are visible on the tests.	Optical or display contamination, possibly due to dust, fingerprints, or other residues	Gently clean the anti-reflective glass window using a dry microfiber cloth. Avoid using alcohol or wet wipes, which may damage the coating. Rotate the optical barrel through all test distances several times. This may help dislodge internal dust particles.
The test display flickers. The colors of the tests appear abnormal. The brightness is not uniform or too low.	Damaged or unstable screen display	Turn off the Visiolite® Access, unplug the power supply. Leave the Visiolite® Access at rest for several hours before plugging it back in.
The tests appear blurry	The optics are foggy	Clean the anti-reflective glass window with a microfiber cloth.
The tests results can’t be found for export.	The date and time parameters may be incorrectly configured.	Open the control panel and check the system date and time. Correct if needed. Ensure storage media (e.g., USB) is properly inserted and recognized
The control panel is not working correctly or crashes.	Corrupted firmware installation	Insert the USB stick delivered with the device. Run the initial firmware setup to restore factory settings

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

Firmware Version: V01.00.00