

MYOPIA EXPERT

700

Biometer

USER MANUAL



Thank you for choosing this product.

Please read the information in this manual carefully. You must be familiar with its contents to operate the device.

The manufacturer has a policy of continuous improvement of its products. Therefore, some instructions, specifications, and pictures in this manual may differ slightly from the product you purchased. The manufacturer also reserves the right to make any changes to this manual without notice.

The original text of this manual is in English.

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1. INTENDED USE

1.1 INTENDED USERS

MYOPIA EXPERT 700 is a corneal analyser with an integrated pupillographer and optical biometer.

The main applications are the following:

- Corneal topography for diagnostic purposes
- Measurement of Eye Axial thicknesses
- Fluorescence imaging for contact lens fitting
- Pupil measurements
- Store and generate overviews of historical data of ocular properties for easy observation of changes over time. For example, it is especially useful in the case of myopia.

Eye specialists, ophthalmologists, opticians, and optometrists. The instrument must be used by qualified personnel

1.2 LOCATION OF USE

Health centres, optician shops, eye hospitals, and other eye-care related facilities.

1.3 PATIENT POPULATION

Suitable also for children, seniors, or disabled people.

1.4 CONTRAINDICATIONS

After the examination, the patient may be slightly dazzled. It is recommended to advise the patient to wait a few minutes before driving or doing anything that requires perfect vision.

1.5 GENERAL DESCRIPTION OF FUNCTIONS

MYOPIA EXPERT 700 is a corneal analyser with integrated pupillographer and optical biometer with the following functions:

- Cornea image acquisition and topographic analysis
- Eye Axial Biometry
- Dynamic pupillometry acquisition: recording of a sequence of pupil images as the light conditions change. Static pupillometry acquisition in controlled light conditions (photopic, mesopic and scotopic)
- Fluorescein analysis: picture and/or video acquisition that allows checking contact lens positioning, or assessing cornea's artefacts and the lachrymal film (rupture time)
- Analysis of wave front corneal aberrations generated by the front surface of the cornea with Zernike analysis: information on the optical properties of the cornea and the optical problems that may affect sight
- Contact lens simulation: the software selects from a database the lens best suited to the eye and allows different lenses to be compared

1.6 INTERACTION WITH THE PATIENT

Patients do not control the device. They are positioned with their chin on the chinrest and their forehead against the forehead-rest, and they are asked to stay perfectly still and look at the fixation point with one eye. The device is entirely controlled by specialized personnel.

2. PRECAUTIONS

This electronic device is a precision unit, and it is intended to be used in a professional healthcare environment, including hospitals, physicians' offices, surgical centres, and limited care facilities, where equipment and systems are managed by healthcare professionals.

Use and store it in a suitable place at standard ambient temperature, humidity, and atmospheric pressure conditions and avoid exposure to direct sunlight.

- To ensure proper functioning, install the instrument in a place not subject to vibrations
- Connect all the cables correctly before use
- Use the recommended mains voltage
- When the unit is not used, disconnect the power supply, and protect it against sun and dust
- To obtain accurate and reliable measurements, keep the measuring cone clean and dust-free.

This product complies with EMC standards (IEC 60601-1-2 4th Edition).

- ELECTRICAL MEDICAL DEVICES require special EMC precautions and must be installed and activated per the EMC instructions provided in the accompanying documentation.
- The use of accessories and cables other than those supplied with the instrument, except cables sold by the equipment manufacturer as spare parts, may lead to an increase in emissions and reduce the device's or system's immunity.
- Any cables connected to USB and LAN ports must be less than 3 meters in length.
- The device should not be used adjacent to or stacked on other equipment; if adjacent or stacked use is inevitable, the equipment should be watched to verify proper operation in the configuration in which it will be used.
- Portable RF communication equipment should be used no closer than 30 cm to any part of the equipment, including specified cables. Otherwise, the degradation of equipment performance could result.

2.1 ELECTROMAGNETIC COMPATIBILITY

2.1.1 EM Emission

The MYOPIA EXPERT 700 device fulfills the requirements of IEC 60601-1-2 4th Edition:

Emission limit	Standard	Compliance
Conducted and radiated RF	CISPR 11	Class B
Harmonics distortion	IEC 61000-3:2	Class A
Voltage fluctuations/ flicker emissions	IEC 61000-3:3	Compliant

2.1.2 EM Immunity

The MYOPIA EXPERT 700 device fulfills the requirements of IEC 60601-1-2 4th Edition:

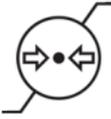
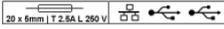
Immunity test	Standard	Test level		
Electrostatic discharge (ESD)	IEC 61000-4-2	± 8kV contact ± 15kV air		
Electrical fast transient/Burst	IEC 61000-4-4	±2kV 100kHz repetition frequency		
Surges	IEC 61000-4-5	±1kV common mode ±2kV differential mode		
Rated Power frequency magnetic field	IEC 61000-4-8	30 A/m		
Conducted disturbances induced by RF fields	IEC 61000-4-6	Level	Frequency	Modulation
		3V	150kHz÷80MHz	1kHz 80% AM
		6V	6,765MHz÷6,795MHz	1kHz 80% AM
		6V	13,553MHz÷13,567MHz	1kHz 80% AM
		6V	26,957MHz÷27,283MHz	1kHz 80% AM
		6V	40,66 MHz ÷ 40,70 MHz	1kHz 80% AM
Radiated RF EM fields	IEC 61000-4-3	Field (V/m)	Frequency	Modulation
		3	80MHz÷2700MHz	1kHz 80% AM
		27	380MHz÷390MHz	18Hz 50% PM
		28	430MHz÷470MHz	18Hz 50% PM
		9	704MHz÷787MHz	217Hz 50% PM

		28	800MHz÷960MHz	18Hz 50% PM
		28	1700MHz÷1990MHz	217Hz 50% PM
		28	2400MHz÷2570MHz	217Hz 50% PM
		9	5100MHz÷5800MHz	217Hz 50% PM

Recommended separation distances between portable and mobile RF communication equipment and the device			
The MYOPIA EXPERT 700 device is intended for use in an electromagnetic environment in which radiated RF interferences are controlled. The customer or the user of the device can help prevent electromagnetic interference by keeping a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output of transmitter (W)	Separation distance according to transmitter frequency (m)		
	150kHz to 80MHz $d = 1.2 \sqrt[3]{P}$	80MHz to 800MHz $d = 1.2 \sqrt[3]{P}$	800MHz to 2GHz $d = 2.3 \sqrt[3]{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>Note:</p> <p>(1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies</p> <p>(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			

3. SYMBOLS

Symbol	IEC Publication	Description
	IEC 60417-5840	CLASS I DEVICE IN ACCORDANCE WITH 60601-1 APPLIED PART TYPE B
		PRODUCT IN ACCORDANCE WITH DIRECTIVE 93/42/EEC
Type A	EN ISO 19980	CORNEAL TOPOGRAPHY ACCORDING TO ISO 19980:2012
	IEC 60417-5032	ALTERNATE CURRENT
	ISO 7010-M002	FOLLOW THE INSTRUCTIONS FOR USE
	ISO 7010-W001	GENERAL WARNING
	ISO 7010-W001	CAUTION (GENERAL WARNING): TO AVOID INJURY CAUSED BY ELECTRIC SHOCK, DO NOT OPEN THE COVER. ASK YOUR DEALER FOR SERVICE.
	ISO 7010-W001	GENERAL WARNING: BE CAREFUL NOT TO HIT THE PATIENT'S EYES OR NOSE WITH THE INSTRUMENT DURING OPERATION. THE PATIENT MAY BE INJURED.
	ISO 7010-W001	CAUTION (GENERAL WARNING): TO AVOID DAMAGE FROM THE MOTORIZED CHINREST, BE MINDFUL OF THE PATIENT WHILE USING THE DEVICE
	EN ISO 15223-1	MANUFACTURER

	EN ISO 15223-1	REFERENCE OR MODEL NUMBER
Group 2	EN ISO 15004-2	PRODUCT CLASSIFIABLE AS GROUP 2 IN ACCORDANCE WITH EN ISO 15004-2
	EN ISO 15223-1	TEMPERATURE LIMITATION Specifies the temperature limits to which the medical device can be safely exposed.
	EN ISO 15223-1	HUMIDITY LIMITATION Specifies the range of humidity to which the medical device can be safely exposed.
	EN ISO 15223-1	ATMOSPHERIC PRESSURE LIMITATION Specifies the range of atmospheric pressure to which the medical device can be safely exposed.
	EN ISO 15223-1	KEEP DRY Specifies a medical device that needs to be protected from moisture.
	ISO 7000 - 0621	FRAGILE! HANDLE WITH CARE
	ISO 780	THIS WAY UP Specifies the correct upright position of the package for transportation
	IEC 60417-5009	STAND-BY SWITCH
		EXTERNAL PORTS AND FUSES
	<p>This symbol is solely applicable to EC member countries.</p> <p>To avoid potential negative consequences for the environment and possibly human health, this instrument should be disposed of (i) for EU member countries – in accordance with WEEE 2012/19/UE (Directive on Waste Electrical and Electronic Equipment) or (ii) for all other countries, in accordance with local waste disposal and recycling laws.</p>	

3.1 DEVICE SAMPLE LABELING



4. SAFETY INSTRUCTIONS

4.1 GENERAL

- MYOPIA EXPERT 700 should be used only for its intended purposes, as detailed in this manual.
- Keep this manual handy and close to the device at all times.
-  The instrument can be used only by qualified personnel (eye specialists, ophthalmologists, opticians, and optometrists) after having read this user manual.
- For each clinical function, hazards have been identified from potential faults or misuse of the system. There are no unacceptable risks related to clinical functions, so there is no Essential Performance for the device.
- The device must be installed by qualified staff.
- The device must be connected to an appropriate power source; otherwise, its performance may be reduced.
-  Position the unit so that it is not difficult to disconnect the plug for connection to the supply line.
-  If the device has just been delivered or underwent thermal shock, wait at least one hour before making measurements on patients.
-  If the device has been affected by external forces (e.g., if it is hit or dropped), it must be thoroughly checked before examining patients. To do this, refer to the related section in this manual. If necessary, send the device in for repair.
- Remove all the covering material (dust sheet) from the device before turning it on.
-  Run all the control functions (detailed in the related section in this document) before carrying out measurements on patients.
- The physician or device user must inform the patient of the related safety instructions and ensure that they are observed.
- Use only genuine MYOPIA EXPERT 700 accessories and spare parts.
- Turn off the device if it is not going to be used for an extended period.
-  Unauthorized software installation in the device is not permitted.

4.2 ENVIRONMENT OF USE

- The device must be used in the environmental conditions, as specified in this document.
- The least favorable environment is defined as the maximum values of temperature for the unit within which it must operate, while the unit is drawing the maximum current. The environmental value is stated as +40°C. The maximum current absorption occurs during topography acquisition.
- The maximum temperature of applied parts (chinrest and headrest) can exceed 41°C when the device is used at an ambient temperature close to 40°C. The device temperature does not exceed 48°C. Considering the examination duration, the patient's condition, and the parts that are in contact with the patient, there are no known contraindications regarding contact with the device.
- It is advisable to use the device in an unlit environment
- Do not use the device near highly flammable materials or in areas at risk of explosion.

4.3 ELECTRICAL SAFETY

-  To avoid the risk of electric shocks, this equipment must only be connected to the supply mains with protective grounding.
- MYOPIA EXPERT 700 has an on-board power supply unit installed. For connection to the supply mains, use only the manufacturer-approved cables provided with the device.
- Before performing maintenance on the device, turn it off and disconnect the power cable.
- Do not touch the LAN/USB ports contacts and the patient at the same time.

4.4 LED EMISSION SAFETY



CAUTION - The light emitted from this device is potentially hazardous. The longer the duration of exposure, the higher the risk of ocular damage. Exposure to the device light when using it at maximum intensity will infringe the safety requirements after 60-minutes of use.

MYOPIA EXPERT 700 has a series of LEDs of various types and powers installed. All the characteristics are detailed in the Technical Specifications section in this manual.

The LED groups comply with the emission limits for the Group 2 instruments of the ISO 15004-2 standard.

4.5 INSTALLATION WITH EXTERNAL DEVICE OR IT NETWORK

MYOPIA EXPERT 700 complies with the CE marking requirements.

-  External equipment intended for connection to signal inputs/outputs on the Medical Electrical Equipment shall comply with the relevant product standard for such equipment, e.g., IEC 60950-1 or IEC 62368-1 for IT-equipment and the IEC 60601 for Medical Electrical Equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the requirements stated in clause 16 of IEC 60601-1. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e., at least 1.5 m from the patient support or shall be supplied via a Separation transformer to reduce the leakage current.

Any person who connects external equipment to the Medical Electrical Equipment has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements set in clause 16 of IEC 60601-1. If in doubt, contact a qualified medical technician or your local representative.

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular, such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in clause 16.5 of IEC 60601-1.

In case a Multiple Socket Outlet is used to supply the system, a Medical Electrical System has been created, even if there is no signal connection to other equipment. This might lead to an increase in leakage current and grounding impedances. Therefore, a Multiple Socket Outlet should always be used with an isolation transformer, as described in clause 16.9 of IEC 60601-1.

Note that the total grounding impedance, from each equipment in a system, should be maximum 0.2 Ohm measured to the grounding pin in the mains plug of the Multiple Socket Outlet.

- An external keyboard or another input device compatible with USB interfaces such as barcode or card readers can be connected to the device to enter text.
- Do not use mobile phones or other devices not compliant with the requirements of class B EMC near the MYOPIA EXPERT 700.
-  Every external device that has to be connected to MYOPIA EXPERT 700 must have a USB connection cable with a maximum length of 3 m.
- The purpose of the MYOPIA EXPERT 700 connection to an IT network is to print reports and perform remote technical assistance.
- The MYOPIA EXPERT 700 USB port must be connected to the printer with a USB or LAN interface. Ask the local distributor technical assistance for printer driver installation.
- The MYOPIA EXPERT 700 can be connected to a Local Area Network (LAN) through the LAN connector. The network must have an Ethernet protocol (IEEE 802.3). Ask your local distributor for technical assistance and the MYOPIA EXPERT 700 system administrator for network settings.

- The purpose of the MYOPIA EXPERT 700 connection is saving PDF reports on an external network folder or technical service intervention on the device.
-  Connection of the MYOPIA EXPERT 700 to a computer network that includes other equipment could result in previously unknown RISKS; identify, analyze, and control such RISKS (refer to IEC 60601-1:2005).
- Subsequent changes to a computer network could introduce new RISKS and require new analysis.
- Changes to the computer network include:
 - Changes in computer or data network configuration
 - Connection of additional items to the computer network
 - Disconnecting items from the computer network
 - Update of equipment connected to the computer network
 - Upgrade of equipment connected the computer network
- The term computer network used here corresponds to the term network/data coupling in IEC 60601-1:2005.
-  Do not change the Ethernet settings of the "INTERNAL" or "RESERVED" adapter.

If a specific configuration for the LAN network is needed, the settings can be modified accordingly on the "EXTERNAL" Ethernet adapter.

4.6 TRANSPORT AND PACKAGING

- The device must be transported and stored in its original packaging
- For storage and transport conditions, refer to the related section in this document
- Carefully store the original packaging to use it if you need to transport the device
- To move the device over short distances (without packaging) and to fit it in and remove it from the original packaging, grip the device with both hands, one on the front headrest arch and the other in the recessed niche at the back the device (in position with the locking system)
-  Fully unscrew the two locking screws and the semi-lock before use.
-  Lower the instrument to its minimum height using the joystick, then lock the MYOPIA EXPERT 700 using the instrument semi-lock and the two locking screws for transport.

4.7 CLEANING

- Regularly clean the device removing dust using a soft cloth. In the case of more persistent surface dirt, use a soft cloth soaked with water or alcohol (70% max).
-  Be careful not to wet the device and clean it only as specified to prevent damage. Never use solvents or other abrasive agents.
- Do not clean the plastic parts with solvents such as benzene or similar products, as they may cause discolouring of the parts and degradation of the material.
- The device comes with a dust cover to be used to protect it. Cover the MYOPIA EXPERT 700 if it is not going to be used for an extended time.
-  Before turning on the device, remove the cover. Never put the cover on when the device is on.
- If there are permanent stains on the surface of the Placido disc, please contact your distributor for replacement.

Before using the chinrest on another patient, clean the mounting brackets that come into contact with the forehead and chin using neutral detergents.

4.8 CHECKING THE MEASUREMENTS

-  It is recommended to check the calibration of the instrument when the device has been transported from one place to another and when it has suffered an impact or thermal shocks.
-  It is recommended to check the calibration every day when turning on the device using the instrument provided.
- The user of the device must check that the measurements provided by the device are plausible.
- It is advisable to visually check all the light sources before examining patients to make sure that they turn on properly.
- If the device frequently emits error signals, turn it off and contact technical support to have the device checked.
-  In patients with blue eyes, the acquisition of pupillometry in mesopic lighting conditions can be difficult to accomplish. In this case, we suggest acquiring the mesopic data through dynamic pupillometry.
-  Contact lenses must not be worn by the patient during data acquisition.

4.9 PRIVACY & CYBERSECURITY

-  When installing a new unit, the user **MUST** set his credentials to prevent unauthorized physical access to the device. To set up the log in access to the instrument and on-board data, refer to section 17.8.
-  Make sure the USB devices you wish to connect to the instrument are secured against malware/viruses.
-  Patient data on USB devices can become corrupted when inserting them into computers for backup or transfer.
-  The use of antivirus software on computers is recommended, and it is the responsibility of the user.
-  To protect data exported to USB from unauthorized access, use dedicated USB data for storage.
- Installation of any unapproved software, including drivers, could degrade the performance of the instrument and may void the instrument warranty.

4.9.1 Privacy



It is recommended that the operator understands the characteristics of this device concerning Data Protection.

4.9.1.1 Definitions and application within this device

Personal Data: means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Personal Data used with the device are:

- Subject identification data: name, date of birth, gender, ID (according to the ID application policy of the clinic). Refer to the application settings section for further details on the management of subject identification data.
- Subject physical/physiological data: subject's eyes biometric measurements, as acquired and stored during each examination and belonging to the subject. Refer to the application settings section for further details on the types of biometric measurements performed by the device.

Controller: means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.

The controller is the representative of the clinic or hospital where the device is installed.

Processor: means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the Controller.

The processor is/are the person/s designed by the clinic or hospital to operate the device and use the results.

4.9.1.2 Device characteristics to support Data Protection

Data Protection

The device provides by default encryption of data stored, to avoid unauthorized access to Personal Data.

The device provides by default technical measures to provide integrity, availability, and resilience of subject data by means of encryption, data integrity checksum, and redundancy.

The data can be accessed based on subject identification only within the application itself, which is protected by the login that can be configured by the Data Controller to grant confidentiality.

The subject's data are used within the device on-board application only for storage and identification purposes.

The Controller can apply an explicit pseudonymization rule to handle subject identification by using only ID subject identification and not using the subject's name, DoB, gender in the device.

Right of Access by the data subject

The controller and processor have access to data related to the subject, which can be stored on the device and can make the data available to the subject in the normal operating mode. The data can also be accessed in the form of a printable or electronic file (PDF or XML file).

Right to Rectification or Erasure

The controller and processor can, upon request from the data subject, rectify the subject's identification data.

The controller and processor can, upon request from the data subject, erase permanently the subject's identification data and physical/physiological data. After erasure, no trace of the subject data is present on the device.

Refer to the patient management section for details on how to rectify or erase patient data.

Right to restriction of processing

The device application doesn't automatically process or transmit the subject data.

Right to data portability

The controller and processor can provide to the data subject the data in the form of exported or printed reports or XML data file.

Right to object

No automated processing of data subjects is performed in this device. The processing is performed on the decision of the processor.

Automated individual decision-making, including profiling

No automated decision-making or profiling is performed on this device.

4.9.1.3 Privacy and Data Protection during assistance/support services

The device provides functionalities to assure Data Protection also during assistance/support services, to avoid disclosure of Personal Data to unauthorized personnel and ensure data integrity and availability.

Refer to section 17.8 for specific options

4.9.2 Privacy & Security options

When the on-board application is started the first time, the following prompt is shown.



By pressing the "OK" button, you get access to the Privacy & Security settings of the application, where you can define a login password and customize the level and type of data protection.

By pressing Cancel, you choose not to proceed with the customization of the data protection options; the message will be prompted at the next start up.

The Privacy and Security options can be accessed at any time from the settings. For the details on each option, refer to section 17.8.

PRIVACY AND SECURITY

In this section you can configure your data protection options within this device. The main option is the definition of the user password to access the device. For further details on the data protection options please refer to sections 4.9 and 17.8 of the user manual.

Use Password Login to operate the device

Configure Password



PASSWORD NOT CONFIGURED!

Auto LOG OFF / Screen Saver

Timeout [min]:



15



Hide Patient Details in reports and exported exam packages

Anonymize filenames of exported reports and exam packages

Password protect exported PDF reports (use login password)

Hide Patient Names and Disable Actions when in assistance mode

Close

5. PRODUCT WARRANTY AND RELIABILITY



The product warranty is valid only if all the instructions detailed in this document are followed.

The product warranty is void in the event of loss or damage due to improper or incorrect use of the device.

The product warranty is valid only if the device is equipped with its original accessories.



If the device is opened by unauthorized staff, the manufacturer shall be held harmless from all liability, and the warranty shall be null and void.

NOTE: Modifications or repairs to the product, especially where they require opening the device, may only be carried out by technical staff authorized by the manufacturer.

6. LEGAL PROVISIONS

93/42/EEC – 2007/47/EC	Class IIa medical device
IEC 60601-1	Class I type B continuous operation
IEC 60601-1-2	see EMC Table
ISO 15004-2	Group 2
UNI EN ISO 19980	Type A

7. LIABILITY

The manufacturer shall not be held liable for damages caused by fire, earthquakes, actions by third parties and other accidents, or negligence and misuse of the instrument by the user.

The manufacturer shall in no way be liable for damages caused by the user or by the unavailability of the device, such as a loss of profits or suspension of business.

8. MAIN COMPONENTS

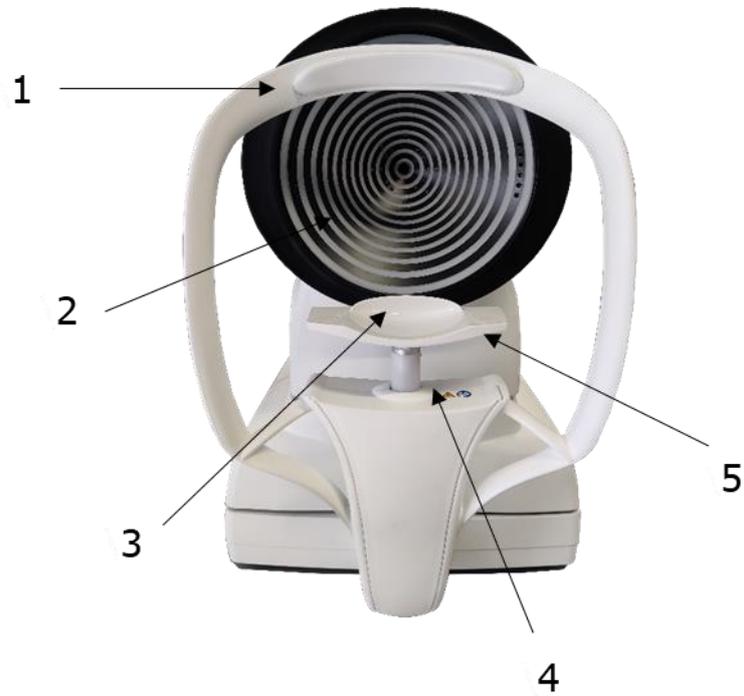


Fig. 1 Patient's side

1. FOREHEAD REST
2. PLACIDO DISK
3. CHINREST
4. Locking pins for chinrest paper
5. Chinrest monitor

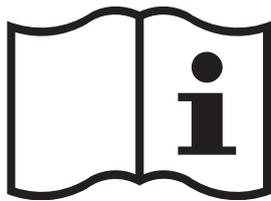
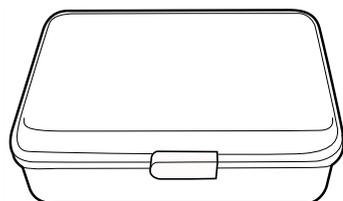


Fig.2 User's side

1. LCD DISPLAY WITH TOUCHSCREEN
2. JOYSTICK
3. STAND-BY BUTTON
Power connector (with fuse carrier)
2 x USB port
1x LAN port

NB: The parts in contact with the patient (applied parts) are the forehead rest and the chinrest in Acrylonitrile Butadiene Styrene resin (ABS).

9. STANDARD ACCESSORIES AND EQUIPMENT

<p>Calibration checking device</p> <p>  The calibration checking device shows the serial number of the instrument with which it is associated. To properly check calibration, the calibrator provided with the instrument must always be used. </p>	
<p>Power cable</p>	
<p>CD</p> <p>User Manual (English)</p>	
<p>User Manual (English)</p>	
<p>Accessories box containing:</p> <ul style="list-style-type: none"> • Touchscreen pen • Silicon cloth • Chinrest paper • Chinrest pins 	

10. INSTALLING/UNINSTALLING THE SYSTEM

MYOPIA EXPERT 700 is packed for shipping in a double cardboard box on a dedicated pallet with specially shaped cardboard parts inside, to help ensure the instrument is safely handled and transported.

 Keep the original packaging for future use. The system must always be handled/shipped in its original packaging, which is specifically designed to protect it against damages.

10.1 INSTALLING THE SYSTEM

Before installing the system, read the “Safety Instructions” in this manual. Fig. 3 shows the complete packaging of the instrument.



Fig. 3

Cut the extensible film and the packing straps. Open the outer box, as shown in Fig. 4.



Fig. 4

Remove the manual and the accessories from the dedicated spaces between the two pieces of cardboard.

The accessories are:

- “Essilor” box:
 - Calibration checking device
 - Chinrest paper
 - Chinrest pins

- Touchscreen pen
- Silicon cloth
- Power cable (European cable and Hospital Grade cable)
- MYOPIA EXPERT 700 dust cover
- MYOPIA EXPERT 700 user manual

Open the internal box and remove the specially shaped part that holds the instrument. Remove the Nylon cover.



Be careful when taking MYOPIA EXPERT 700 out of the box, gripping it by the chinrest arch and the base beside the joystick. The instrument can now be taken out of the package. The steps are illustrated in Fig. 5:



Fig. 5

Place the instrument on a flat surface.

 Completely unscrew the two locking screws and the semi-lock.

Connect the power cable provided. The instrument is now ready for use.

10.2 UNINSTALLING THE SYSTEM

Take the original packaging.

 Set the instrument to the minimum height using the joystick. Lock the device using the instrument semi-lock and the two locking screws for transportation.



Fig. 6

Insert the instrument in the box, as shown in Fig. 6, and place the Nylon cover on it.

Follow the step sequence shown in Fig. 7.



Fig. 7

Put the accessories in the dedicated spaces. Close the external box with strong packing tape or use extensible film and packing straps.

11. SETTING UP THE INSTRUMENT

11.1 GENERAL

Before connecting the device to external devices or IT Networks, please read the SAFETY INSTRUCTIONS.

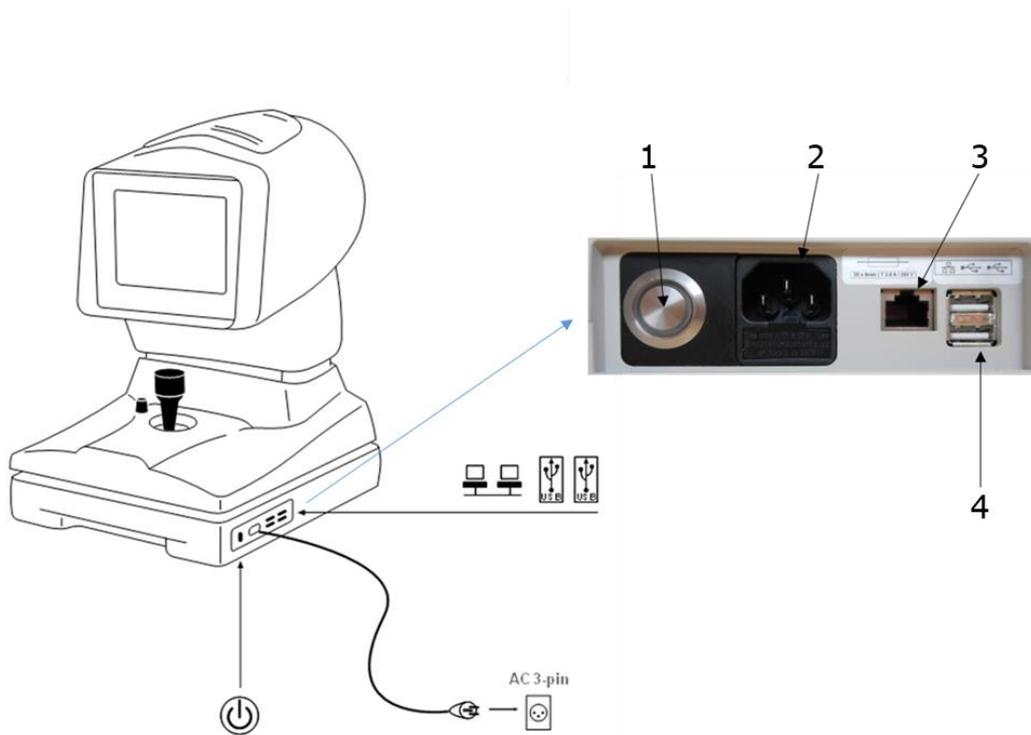


Fig.8

- | |
|--------------------|
| 1. STAND BY BUTTON |
| 2. POWER CONNECTOR |
| 3. LAN PORT |
| 4. USB PORT (2) |

11.2 POWER-ON PROCEDURE

Make sure the power cord provided is connected to the supply mains.

Press the standby button and wait for the system loading until the screen shown in Fig. 15 appears.

11.3 POWER-OFF PROCEDURE

 Press the stand-by button shown in Fig. 8. The device turns off automatically.

12. OPERATING INSTRUCTIONS

MYOPIA EXPERT 700 is designed to work in stand-alone mode. For this reason, all the software functions are automatically loaded when the device is turned on, enabling the user to control the device and guiding him or her through the various phases:

- Entering the patient's data
- Different acquisition modes
- Measures display and processing
- Lens selection

More information for each function and the description of all the settings and other functions available are provided in the following sections of this chapter, to which you should refer for further details.

To interact with the software, a touchscreen LCD display is used. To activate the button or the desired function, simply touch the screen at the command. The screen is highly sensitive. Gentle and slight pressure is required and strongly recommended.

12.1 USER LOGIN/LOGOUT

The user **MUST** configure the login password to access the device operations and stored data, in order to ensure confidentiality and integrity of personal data and avoid unauthorized access.

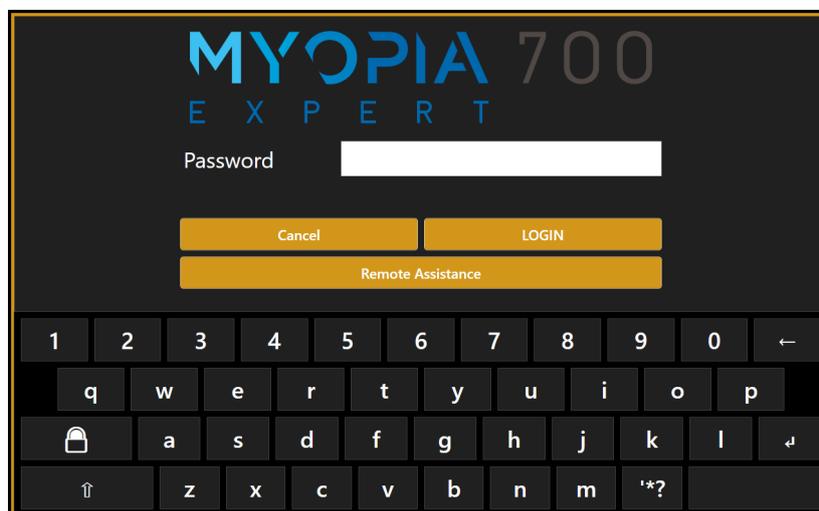


It is recommended to choose a strong password. It is recommended to keep a record of the password in a safe place.



It is not necessary to disclose the user password to technical support staff. Refer to section 12.1.3 for details.

Refer to section 17.8 on how to configure and manage the login access. If the user login password is configured and enabled, the login screen will be prompted at the start-up of the MYOPIA EXPERT 700 on-board application. The login screen is also prompted to allow access to the privacy and security settings (section 17.8).



Type the user password as configured to access the operations and data of the device.



If the password is forgotten or access problems are encountered, please contact assistance.

It is possible to get remote support by pressing on the button "Remote Assistance" if the device is connected to the internet.

12.1.1 User Logout

It is possible, at any time, to lock the device operations by accessing the main views of the applications and pressing on the lock button . The login screen will be prompted again.



12.1.2 Auto Logoff / Screen Saver

The device locks automatically if no user actions occur for a configurable amount of time. The MYOPIA EXPERT 700 screen saver is then shown.



To unlock, touch the device's screen. If the login password is configured and enabled, the user login password is requested.

To configure the screen saver timeout or enable/disable it refer to section 17.8.2.

12.1.3 Technician Support Staff Login

Technical staff can log into the device and on-board application without knowing the user password. The authorized technical staff know the technician password, which allows servicing the device having data protection features applied according to the privacy options in section 17.8.

To let the technical staff login correctly, firstly press the lock button.

12.2 OVERVIEW

Every working environment has the same screen layout. Below is shown a sample of the acquisition screen.

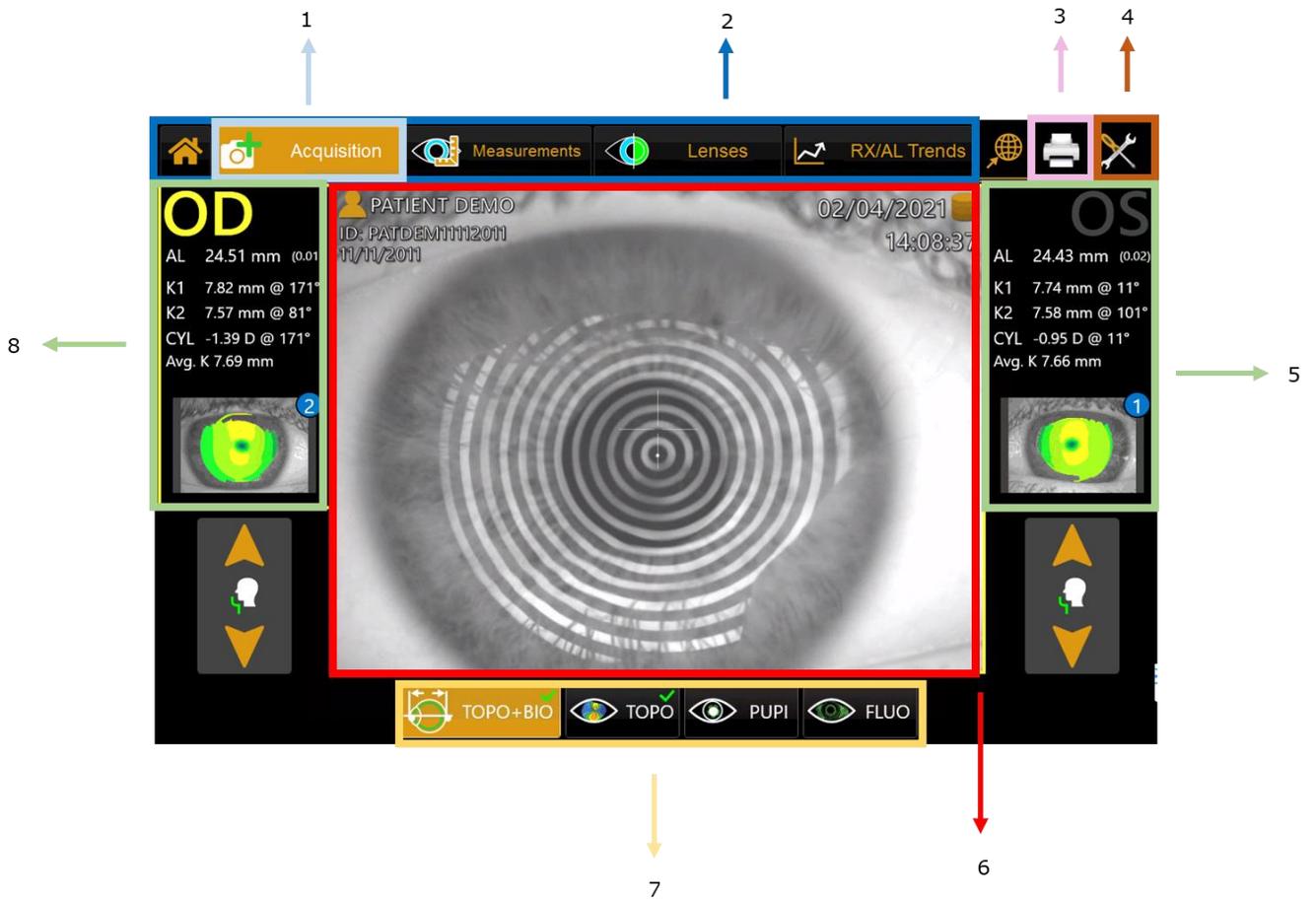


Fig.9

1. The active working area is highlighted in orange.
2. Main Menu
3. Print
4. Settings
5. Left - Eye Data
6. Live images from camera
7. The measurement selections are highlighted in orange.
8. Right - Eye Data

12.3 CHECKING CALIBRATION

 It is recommended to check the calibration of the device:

- Every day before starting patient examinations;
- When the device has been transported from one place to another;
- When it has suffered an impact or thermal shocks.

To check the calibration, turn on the device, and when asked to check the calibration, press START. The test patient is automatically created.

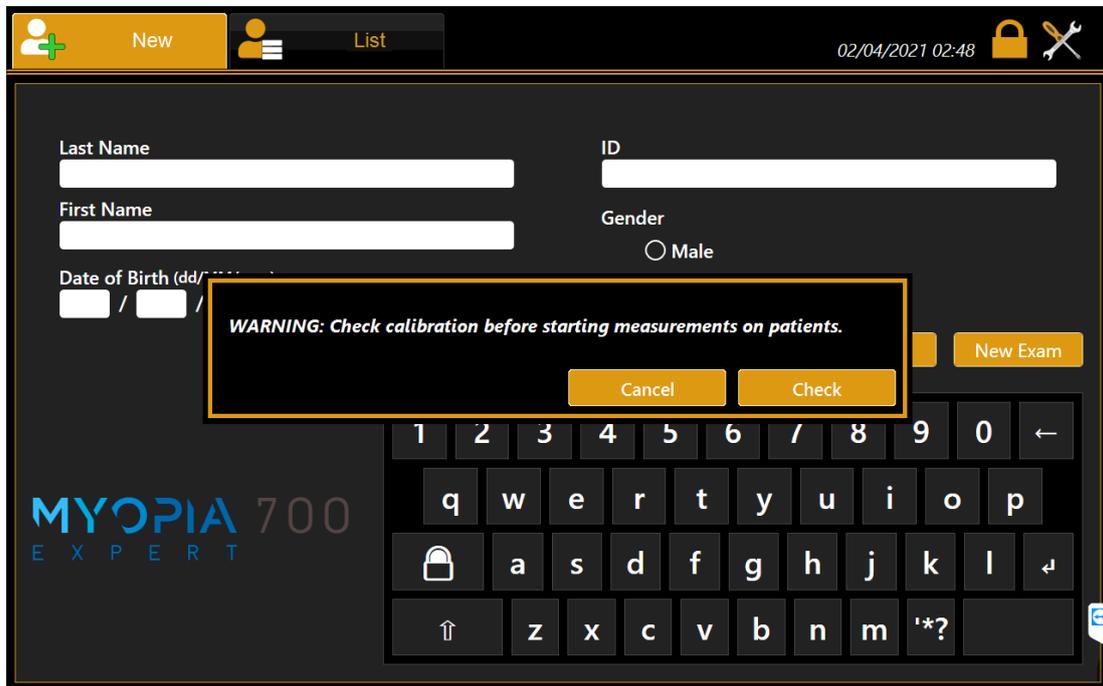


Fig. 10

The next screen explains how to check the calibration:

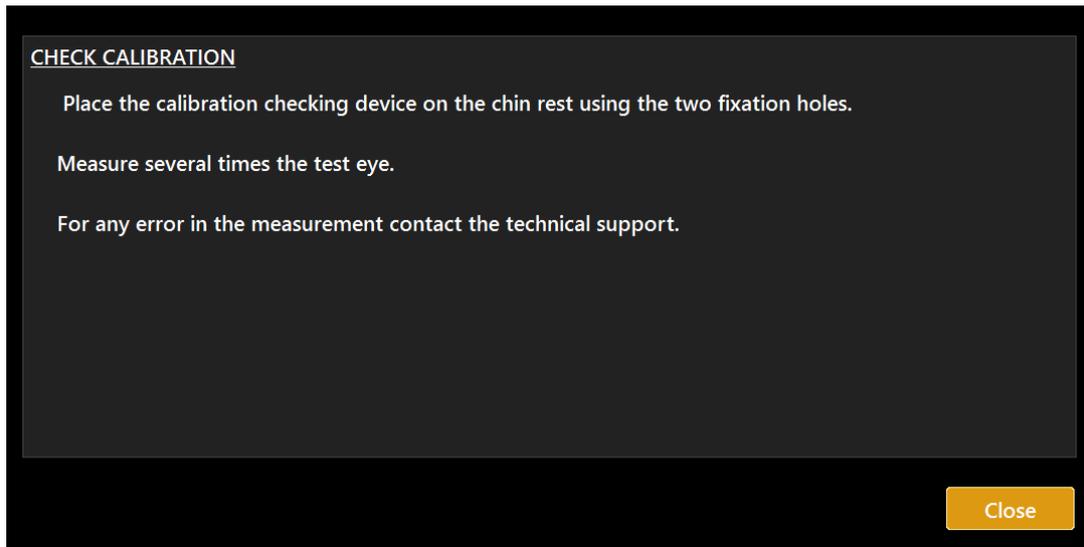
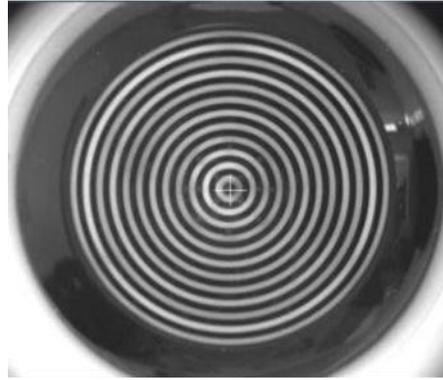


Fig. 11

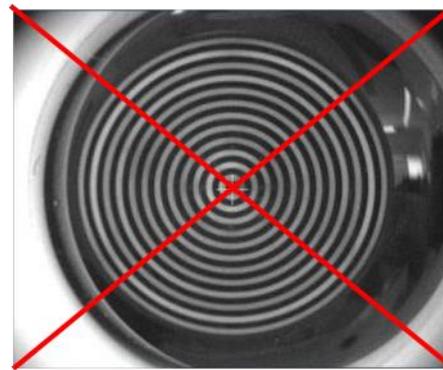
Set the calibration tool supplied with the device (Fig. 12) in the special holes in the chinrest and press until the tool is blocked on the device. Check that the calibration tool is perfectly aligned with the device. If the calibration tool is positioned correctly, all the rings of the Placido disk should be seen reflected in the center on the surface of the hemisphere (Fig. 13).



Fig. 12



CORRECT alignment



WRONG alignment

Fig.13

Now check and acquire several times the calibration checking device using the complete acquisition (Topography and Axial biometry). For details on this acquisition mode, see chapter 12.6.

If the calibration is ok, the "Valid" word will be displayed for all the measurements. If the measurements are incorrect, the words "Repeat" or "Not Valid" will be displayed beside the wrong measurement.

See the table below for instructions.

MESSAGE	MEANING	WHAT TO DO
OK	Good calibration	Click on "Main" to start a new examination. When asked, press Yes to save the "Calibration Check". NB: the "OK" word must be displayed for ALL the measurements.
REPEAT	Acquisition failed: cannot check the calibration	Acquire three more times following these suggestions: improve the environmental conditions (less light and no reflections on the sphere);

<p>ERROR</p>	<p>Incorrect calibration</p>	<p>clean the sphere of the calibration tool; make sure that the calibration tool is positioned correctly. If the calibration check is still not valid, do not take any patient measurement and contact Technical Support.</p>
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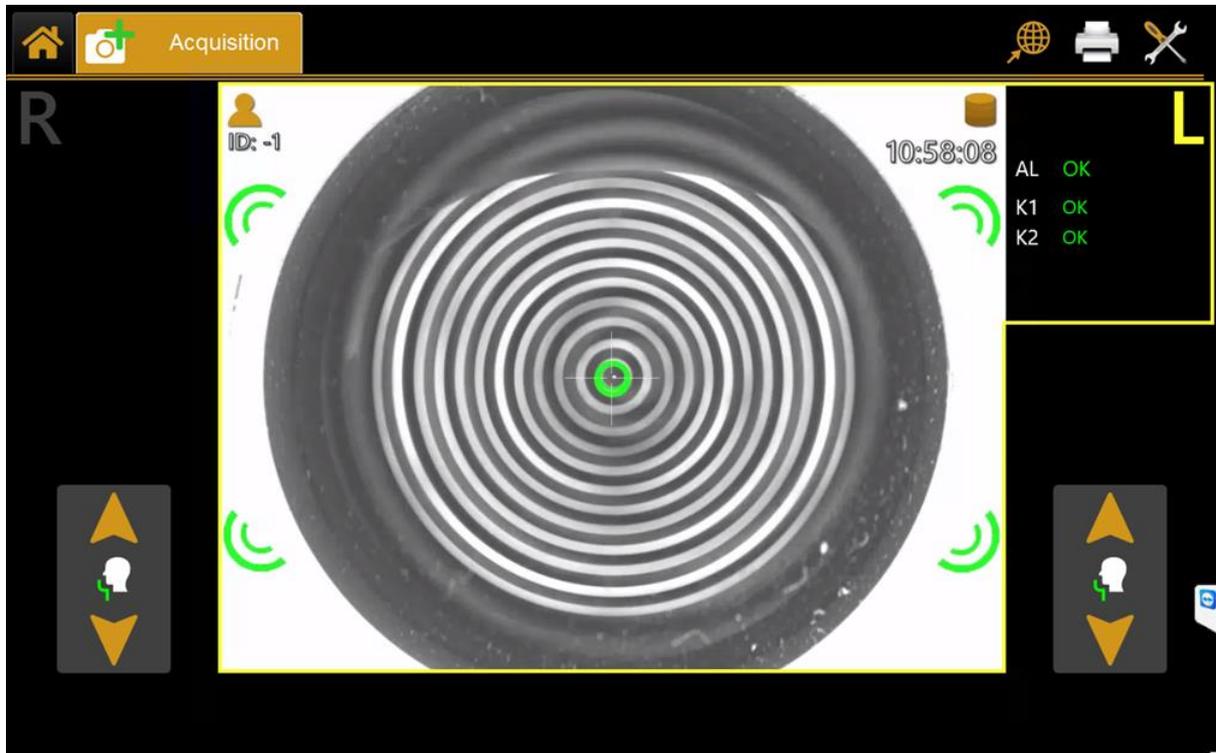


Fig. 14

12.4 ENTERING/ SELECTING A PATIENT

When the MYOPIA EXPERT 700 instrument is turned on, the software displays the following screen. To continue the examination, you must always enter a patient or select one from the database or server (if enabled).

The screenshot shows the software interface for entering patient information. At the top, there are two tabs: 'New' (selected) and 'List'. The date and time '02/04/2021 03:00' are displayed in the top right corner, along with a lock icon and a wrench icon. The main form contains the following fields and options:

- Last Name: Text input field
- First Name: Text input field
- Date of Birth (dd/MM/yyyy): Three separate text input fields for day, month, and year
- ID: Text input field
- Gender: Radio button options for 'Male' and 'Female'
- Buttons: 'Clear' and 'New Exam'

A virtual keyboard is overlaid on the bottom right of the screen, featuring a numeric keypad, a QWERTY layout, and a numeric keypad. The 'MYOPIA 700 EXPERT' logo is visible in the bottom left corner of the interface.

Fig. 15

Fig. 15 shows the section for creating a new patient, entering Last Name, Name and Birth Date (Gender and ID are optional).

12.4.1 Creating a new patient

To create a new patient, select the **"New"** tab and enter the data using the on-screen keyboard (MYOPIA EXPERT 700 only). Once you have entered the new patient data, tap on the **"New Exam"** button to confirm the information and continue with the examination. If you want to clear all the fields, tap on the **"Clear"** button.

If you only want to create the patient press on button **"Save"**.

A special character can be entered simply by touching and holding the corresponding letter (Fig.16)



Fig. 16

12.4.2 Selecting or editing a patient

On the input screen, tap on the **"List"** tab to access all the patients found in the database (Fig.17).

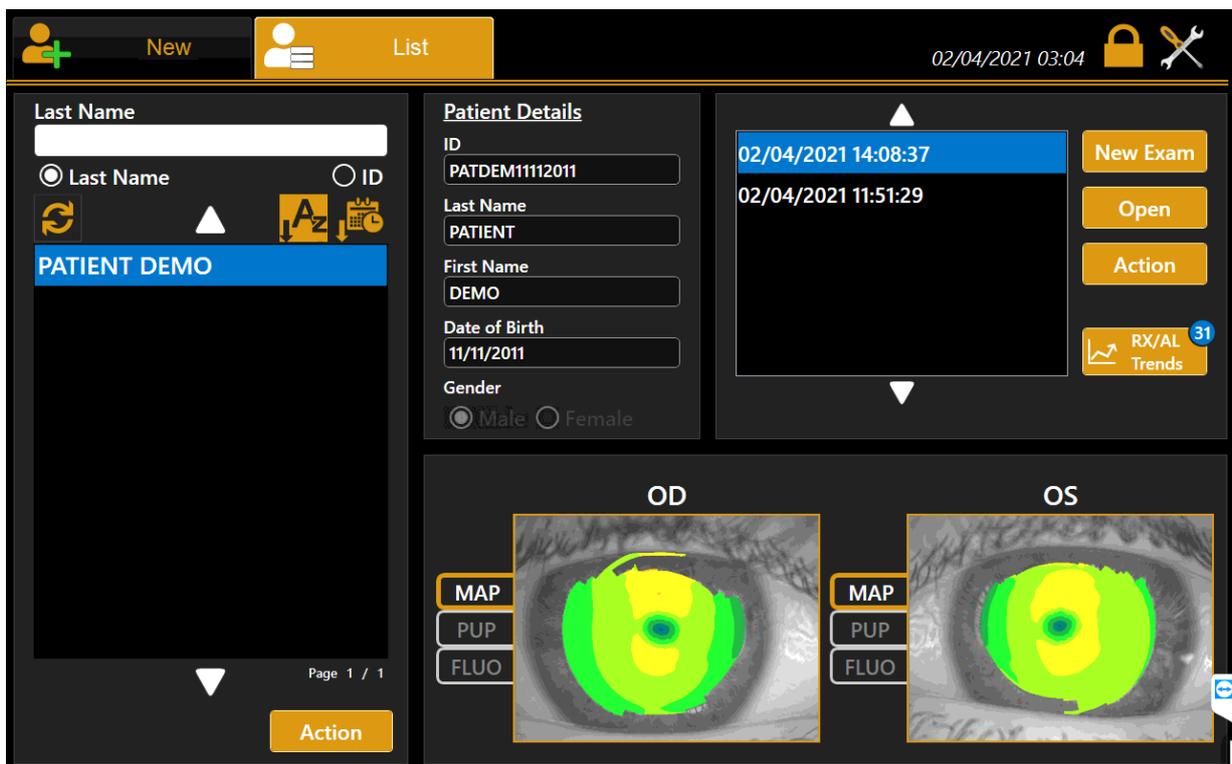


Fig. 17

On this screen, you can select a previously created patient and the examinations associated with him/her. The list can be viewed by **patient ID** or by **Last Name** (and name) selecting the corresponding radio button. If you type into the **"Last Name"** field, a search is done in the local database for patients with the corresponding surname or whose surname contains the selected key, same for patient ID. By pressing

the button on the right, the patient list is sorted alphabetically (A to Z) or by the last exam date (most recent first).

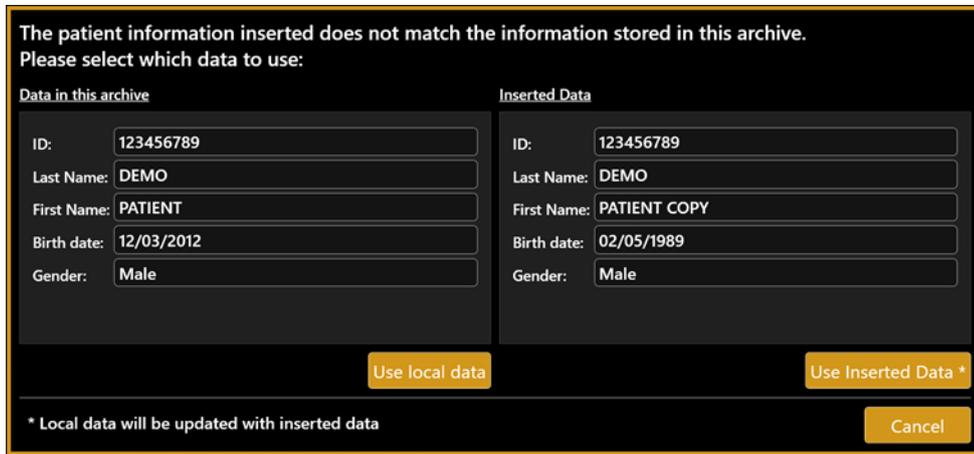
12.4.3 Patient data management

When you create a new patient, edit an already existing patient, or select a patient from a server (to create a new exam), the software performs a search on the local archive to check if these data already exist.

 This search is performed trying to match only the ID

If the ID entered, or selected from the server, matches the ID of an already existing patient, the software shows a message (see picture below) to prompt you to choose from the two options listed below:

- **“Use local data”** Maintain existing data (discard entered data)
- **“Use entered data”** Replace the already existing patient data with the data just entered.



The patient information inserted does not match the information stored in this archive.
Please select which data to use:

Data in this archive	Inserted Data
ID: 123456789	ID: 123456789
Last Name: DEMO	Last Name: DEMO
First Name: PATIENT	First Name: PATIENT COPY
Birth date: 12/03/2012	Birth date: 02/05/1989
Gender: Male	Gender: Male

Buttons: Use local data, Use Inserted Data *, Cancel

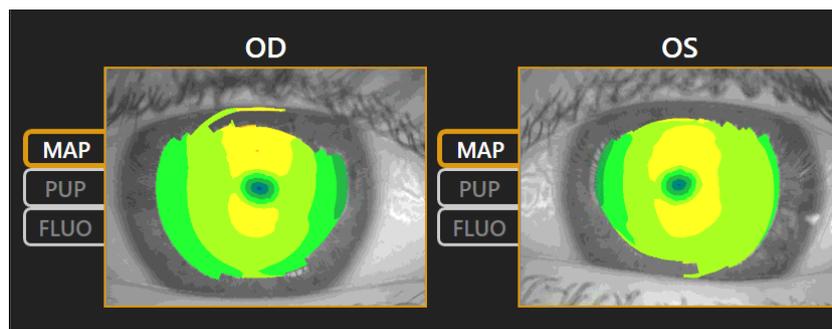
* Local data will be updated with inserted data

12.4.4 Open an examination or acquire data for the selected patient

In the left column, tap on a patient. The list of associated examinations will be displayed in the right list. In this list, you can access examinations or delete them, using the “Open” or “Delete” buttons.

By selecting an exam is possible to see the types of acquisition performed for both eyes and visualize a preview image for each type of acquisition. The acquisition type items in the column menu are enabled or disabled according to the acquisitions performed or not performed in the selected examination.

By double-tapping, in the preview image, the selected exam will be open to the related type of acquisition.



After selecting a patient, another examination can be carried out by pressing the **"New"** button. If you want to export a selected exam from the list of examinations associated with a patient, using the "Export Exam" button you can export the exam to a USB drive.

12.4.5 Managing the selected patient

From the list of patients, select the patient you want to manage and press the "Action" button. The application opens a form (Fig. 15) with three buttons, "Delete", "Export Patient" and "Cancel". Press "Delete" to delete the selected patient with all of his exams, press "Export Patient" if you want to export it with all of his exams (possibility to export to USB), or press "Cancel" to abort. From the list of patients, select the patient you want to edit, a form will be opened to editing it. Press "Ok" or "Cancel" to confirm or cancel the changes.

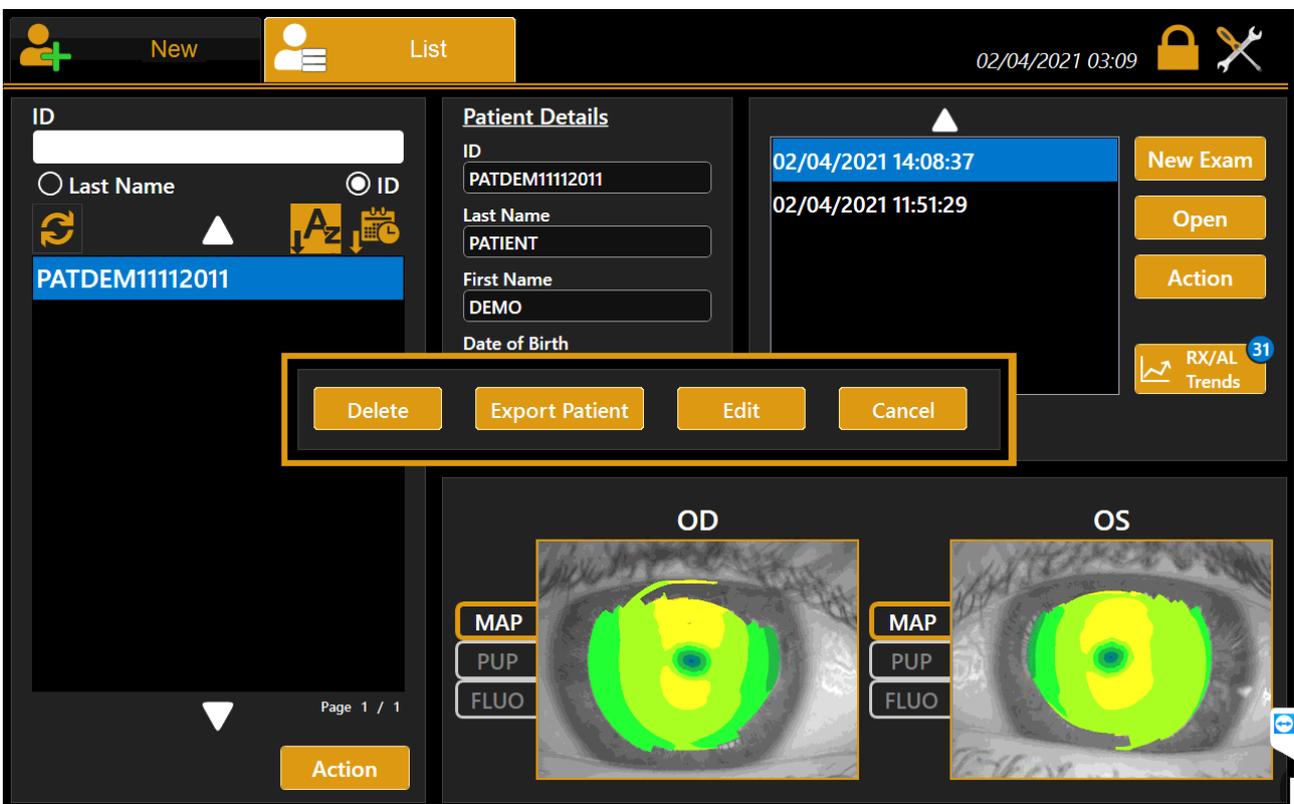


Fig. 18

12.4.6 Selecting a patient from Server

MYOPIA EXPERT 700 can be enabled to search patients from DICOM services (refer to DICOM configuration section):

DICOM Patient Root Query: search patient's details on enabled patient's archive server

DICOM Worklist Mode: get the list of patients and tasks in the waiting room.

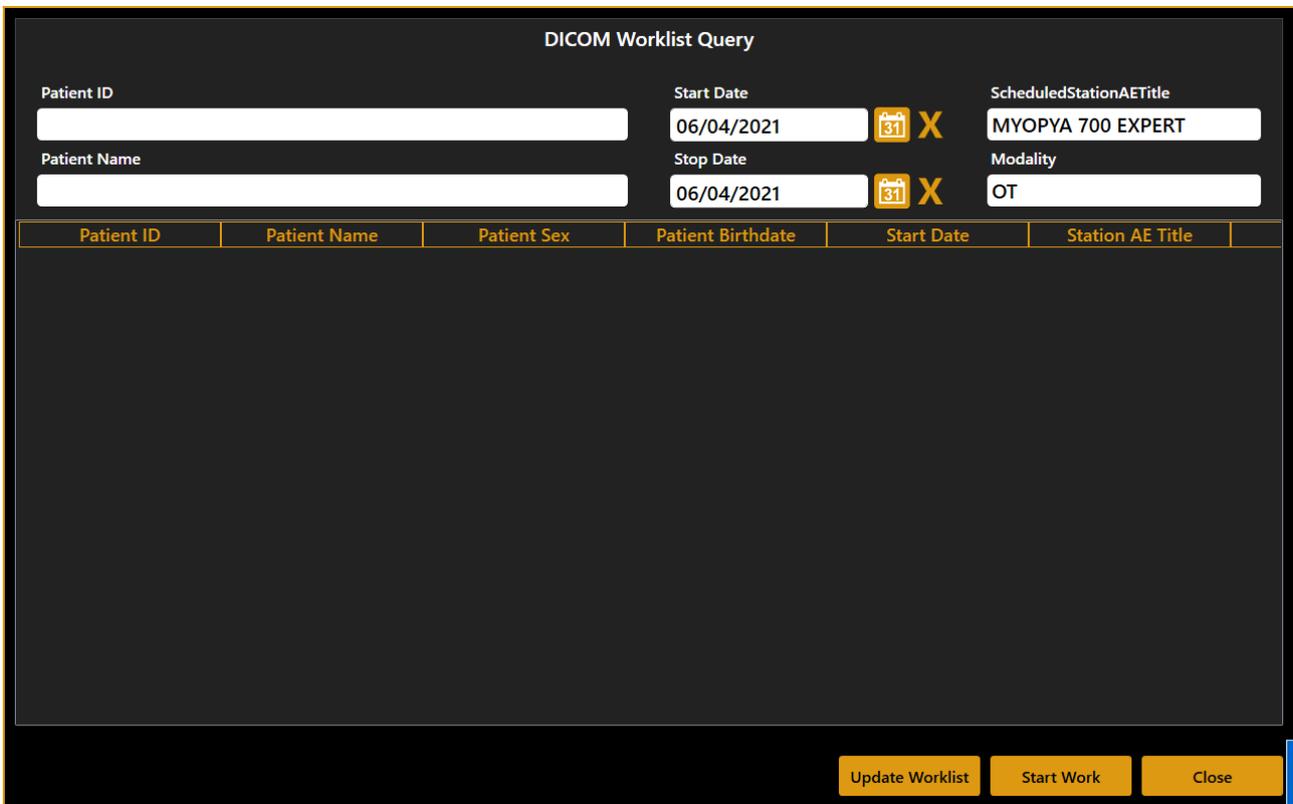
The user can search for a patient either by **surname** or by **id**. A list of patients will be created corresponding to the search criteria. Once selected a patient, the user can create a new examination in the standard mode by clicking on the Acquisition or OK button.

12.4.6.1 Start an exam from the Waiting Room

If DICOM Mode Worklist service is configured, MYOPIA EXPERT 700 can search for pending patient examinations in the waiting room. Pressing on the **“Waiting Room...”** button (Fig.19) shows a list of the pending worklists for the current day. The list can be filtered by one or more of the following criteria:

- Patient Name
- Patient ID
- Examination date range
- Scheduled Station Name (default is “MYOPIA EXPERT 700”) *
- Mode (default is “OT”) *

* = contact DICOM services administrator for details on these settings



DICOM Worklist Query

Patient ID:

Patient Name:

Start Date: 06/04/2021

Stop Date: 06/04/2021

ScheduledStationAETitle: MYOPYA 700 EXPERT

Modality: OT

Patient ID	Patient Name	Patient Sex	Patient Birthdate	Start Date	Station AE Title

Fig. 19

Each time the filtering criteria are changed, press **“Update Worklist”** to update the list of matching items.

Once the desired work is selected, press **“Start Work”** to start a new exam related to the selected work.

12.5 ACQUISITION ENVIRONMENT: GENERAL INSTRUCTIONS

12.5.1 Positioning the patient

The adequate positioning of the patient respect to the device is required to obtain correct measurements. A steady head position and the correct device-to-patient distance are obtained by resting the patient's head well against the chinrest and forehead band. The patient must look steadily at the fixation point in the center of the Placido disk.

The correct alignment with the patient's pupils can be visually checked by the operator referring to the two lines on the forehead supports (see the red arrows in Fig. 20).



Fig. 20

The joystick illustrated in Fig. 21 is the only part the user has to physically control during acquisition. The button on the top marked "Acquisition button" starts the acquisition of the various measurements.

The thumbwheel marked "Height Regulation" allows adjusting the instrument height according to the patient's position.

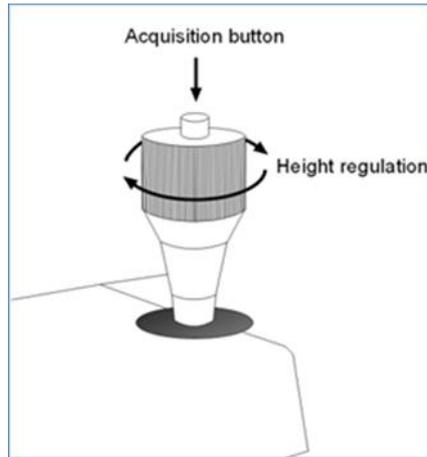


Fig. 21

The height of the chinrest can be regulated by the on-screen touch control if the joystick adjustment is not enough to achieve the correct position.



Fig. 22

The position of the chinrest must be both comfortable and correct, i.e., it must allow the person measuring to focus on the fixation LED correctly. Make sure the patient's forehead is well up against the forehead rest.

12.5.2 Description of the acquisition screen

Fig. 25 shows the acquisition screen:



Fig. 23

The acquisition window (Fig.23) has the following commands:

- *OD* and *OS*: these indicate the eye being acquired (the one highlighted in yellow); they are selected automatically, depending on the position to which you move the instrument.
- *TOPO+BIO*: gives access to the topographic and axial biometry section.
- *TOPO*: gives access to the topographic section.
- *PUPI*: gives access to the pupillometry section.
- *FLUO*: gives access to the fluorescein section.

12.5.3 Acquisition procedure

The Back-lighting of the Placido disk is automatically activated when you enter the acquisition environment. If the instrument is not used for a few minutes, the cone turns off; to turn it on again, just press the joystick button. To acquire the image or measurements in general, whatever mode you are in, simply proceed as follows:

- Align the live image in the center and focus, and then press the joystick button to start the acquisition.
- Move the instrument forward and backward (following the instructions of the red and blue arrows on the screen) to find the ideal focus.
- When the green indicators are displayed, press the joystick button again, and the system will automatically capture the required image and/or measurements. Do not move the joystick during acquisition, which lasts just a few seconds.

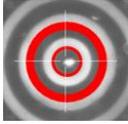
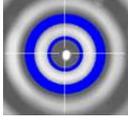
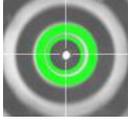
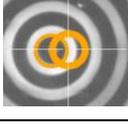
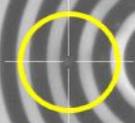
The Focusing and centering guidance system is composed of two aspects:

- Centering
- Focusing distance

The ideal **centering** condition is achieved when **matching the two circle aims** through horizontal and vertical movements, reaching the condition shown in the following picture.

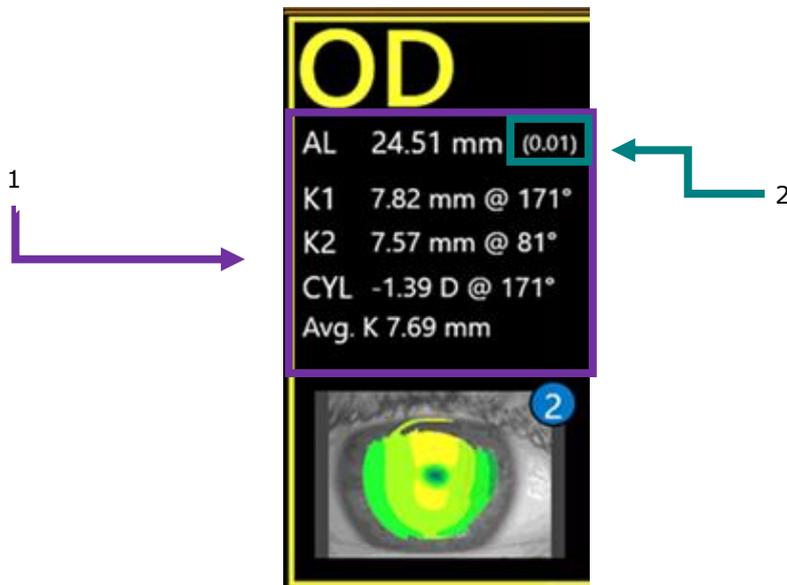
The two circles assume different colors depending on focusing position while the size of the circle connected to the aiming cross changes depending on the focusing distance from the ideal position. The ideal **focusing** condition is achieved by **following the 4 indicators** at the side of the viewport, which explain the needed movement in the "forward/backward" direction.



	<p>The red arrows indicate to move the instrument forwards towards the patient's eye.</p> <div style="display: flex; align-items: center;">  <div style="margin-left: 20px;"> <p>The centering condition is displayed in red</p> </div> </div>
	<p>The blue arrows indicate to move the instrument backward away from the patient.</p> <div style="display: flex; align-items: center;">  <div style="margin-left: 20px;"> <p>The centering condition is displayed in blue</p> </div> </div>
	<p>The green signs indicate that the ideal focus has been reached. Press the joystick button to start the automatic acquisition procedure.</p> <div style="display: flex; flex-direction: column; align-items: center;"> <div style="display: flex; align-items: center; margin-bottom: 10px;">  <div style="margin-left: 20px;"> <p>The centering condition is displayed in green. Press the joystick button to start the acquisition</p> </div> </div> <div style="display: flex; align-items: center;">  <div style="margin-left: 20px;"> <p>The centering condition is displayed in orange. Center better before pressing the joystick button to start the acquisition</p> </div> </div> </div>
	<p>The focusing or centering condition is very out of tolerance, and a better center and/or distance alignment is required</p>

DESCRIPTION OF RESULTS

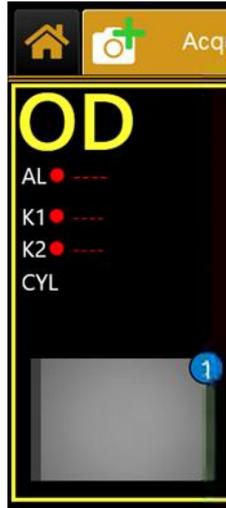
For each Biometry and Keratometry result, a dedicated section is present. In each section, the total result is shown together with the standard deviation between the single results (if more than one) and any warning or error marking (described in the following section).



1: Total Result
2: Standard deviation of total results

ERRORS IN MEASUREMENTS

Sometimes the measurement is taken in one of these conditions: bad focus, closed eyelid, tear film irregularity, high standard deviation in multiple measurements, movement, measurement not in range; in this case, a warning appears above the measurement.



ATTENTION: When the symbol  is shown above a measurement, it means that the software identified an error during the acquisition, which could be: bad focus, closed eyelid, tear film irregularity, high standard deviation in multiple measurements, movement, and measurement not in range.

The possible problems in acquisition are found in the software with the following methods:

Error cause	Identification
Closed eyelid	Missing ring reflection on the eye Placido Image, on the upper hemisphere of the cornea
Movement	Interlace pattern shown in acquired image
Broken Tear film	Missing ring reflection on the eye on Placido Image
Bad focus	Defocus of ring reflection on acquired image
High standard deviation on repetition	Big difference between repeated acquisitions
Measurement not in range	Output out of instrument range of measurement

 If a warning sign is shown above a measurement, it is recommended to make further acquisitions until reliable data is obtained.

12.6 TOPOGRAPHY + BIO

In the "TOPO+BIO" acquisition mode is performed in combination with the following acquisitions:

- **Topography**, same acquisition as described in the following paragraph
- **Axial Length**, measured through repeated interferometry scans (express eye Axial Length as **ultrasound equivalent value**, assuming the eye is phakic). For each acquisition, six individual interferometry scans are performed.



Fig.24

Note: Ultrasound biometrical instruments measure the axial length as the distance between the cornea and the inner limiting membrane because the sound waves are reflected at this membrane. To ensure that the measured values obtained with the MYOPIA EXPERT 700 are compatible with those obtained through acoustic axial length measurement, the system automatically adjusts for the distance difference between the inner limiting membrane and the pigmented epithelium. The displayed axial length values are thus directly comparable to those obtained by immersion ultrasound, and no re-calculation or correction factors are necessary. Nevertheless, deviations may occur between the displayed axial lengths and ultrasound readings (particularly in the applanation procedure).

12.7 TOPOGRAPHY

Topography is used to measure the corneal curvature. It is based on the reflection of the Placido disk on the eye at a controlled working distance for high precision measurement.

MYOPIA EXPERT 700 allows the user to acquire the corneal topography of the eye. The "Corneal Map" is obtained from the reflection of 24 rings of the Placido disk at a distance of 80 millimeters from the patient's eye. The position of the device, in relation to the patient's eye thus found, is used as a starting point for fine adjustments to be made in the corresponding measurement mode.

By selecting this mode, the acquisition environment shown in Fig. 25 appears.

Upon acquisition, the Keratometry result is shown, together with a preview of the corneal topography map.

The number of acquisitions performed is shown in the corner of the topography eye image.



Fig. 25

12.8 PUPILLOMETRY

Press the **"PUPI"** button to acquire the Pupillometry images.

By selecting this mode, the acquisition environment shown in Fig. 26 appears on the screen.

Press the joystick button to start the acquisition and press the button again to stop the acquisition; if the user does not interrupt the acquisition manually, the software automatically interrupts it when the sliding bar reaches the end. As already mentioned in the introductory sections, four types of acquisition can be performed:

- Dynamic pupillometry: variable light conditions
- Photopic controlled light conditions (Photopic)
- Mesopic controlled light conditions (Mesopic)
- Scotopic controller light conditions (Scotopic)

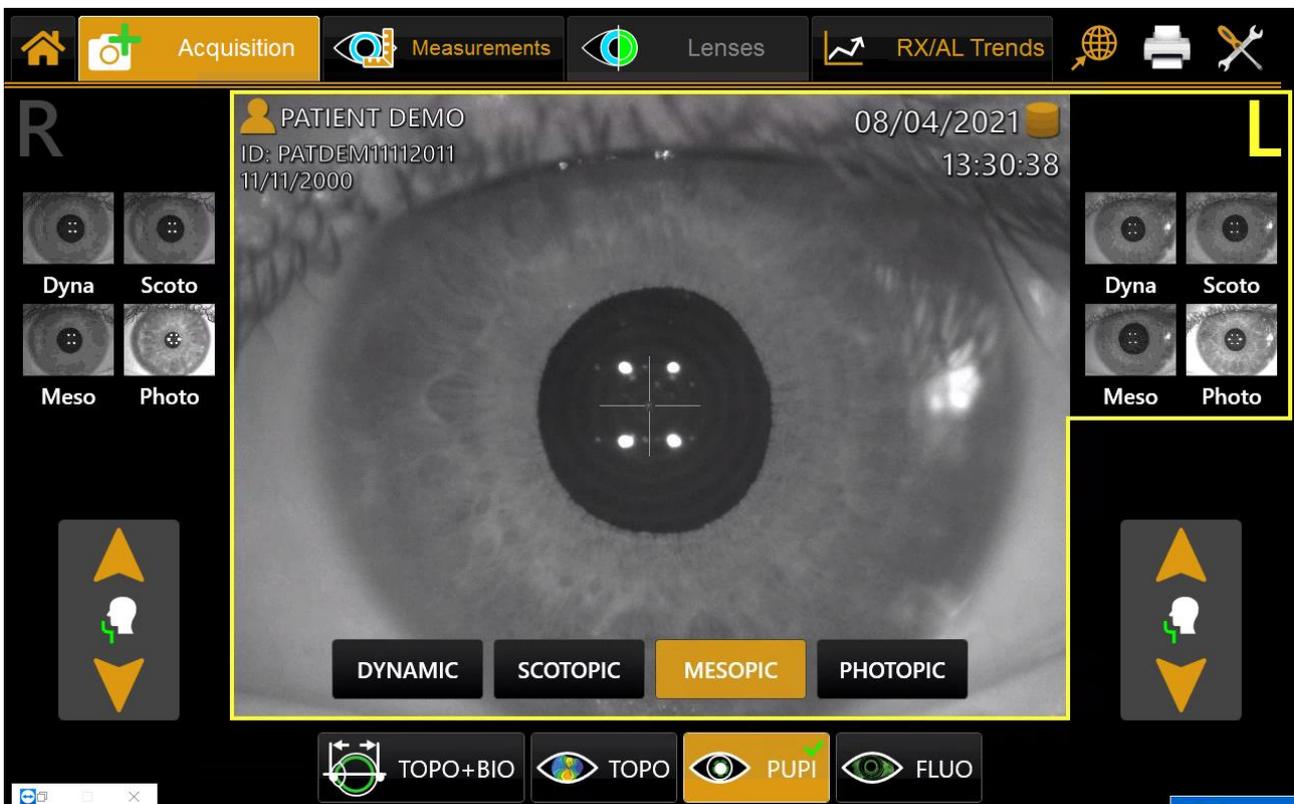


Fig. 26

In the case of dynamic pupillometry, recording of the state of the pupil is started, first in scotopic conditions, then photopic and then scotopic again. The data on the diameters measured are recorded and shown in the **"Measurements"** section.

For the dynamic acquisition, a sequence of images is recorded and allows you to "review" the evolution of the pupil through the various light conditions applied. In the static pupillometry acquisition made in controlled light conditions (photopic, mesopic, and scotopic) specific frames are saved. They can be displayed by scrolling the associated gallery in the Pupil → Measurements section.

WARNING: With blue eyes, the acquisition of pupillometry in mesopic lighting conditions can be difficult to accomplish.

12.9 FLUORESCHEIN

Press the "**FLUO**" button to access the fluorescein analysis acquisition environment (Fig. 27).

You can select between picture and movie acquisition.

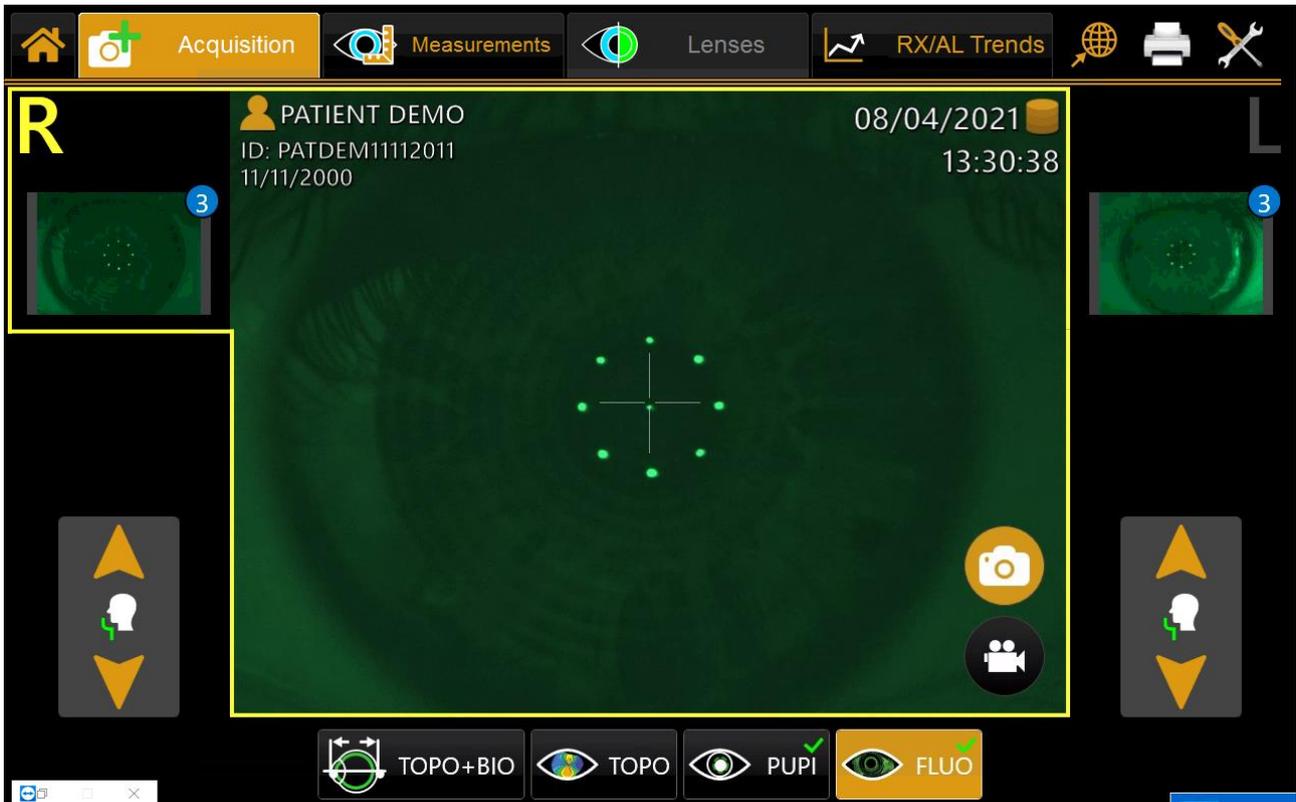
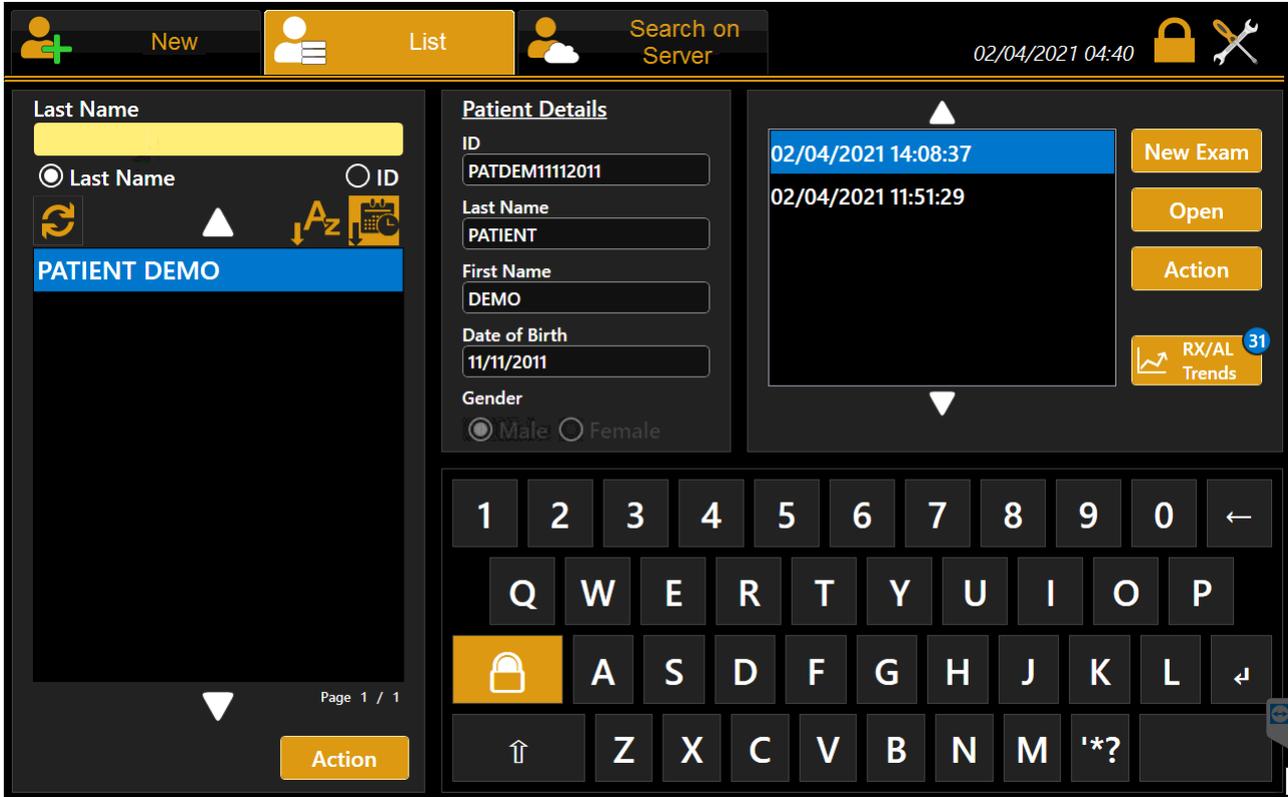


Fig. 27

13. RX/AL TRENDS FUNCTION

The RX/AL Trend function allows reviewing the progression of the biometry value of the selected patient over time, based on the data present in the local archive, with the possibility to add further data manually.



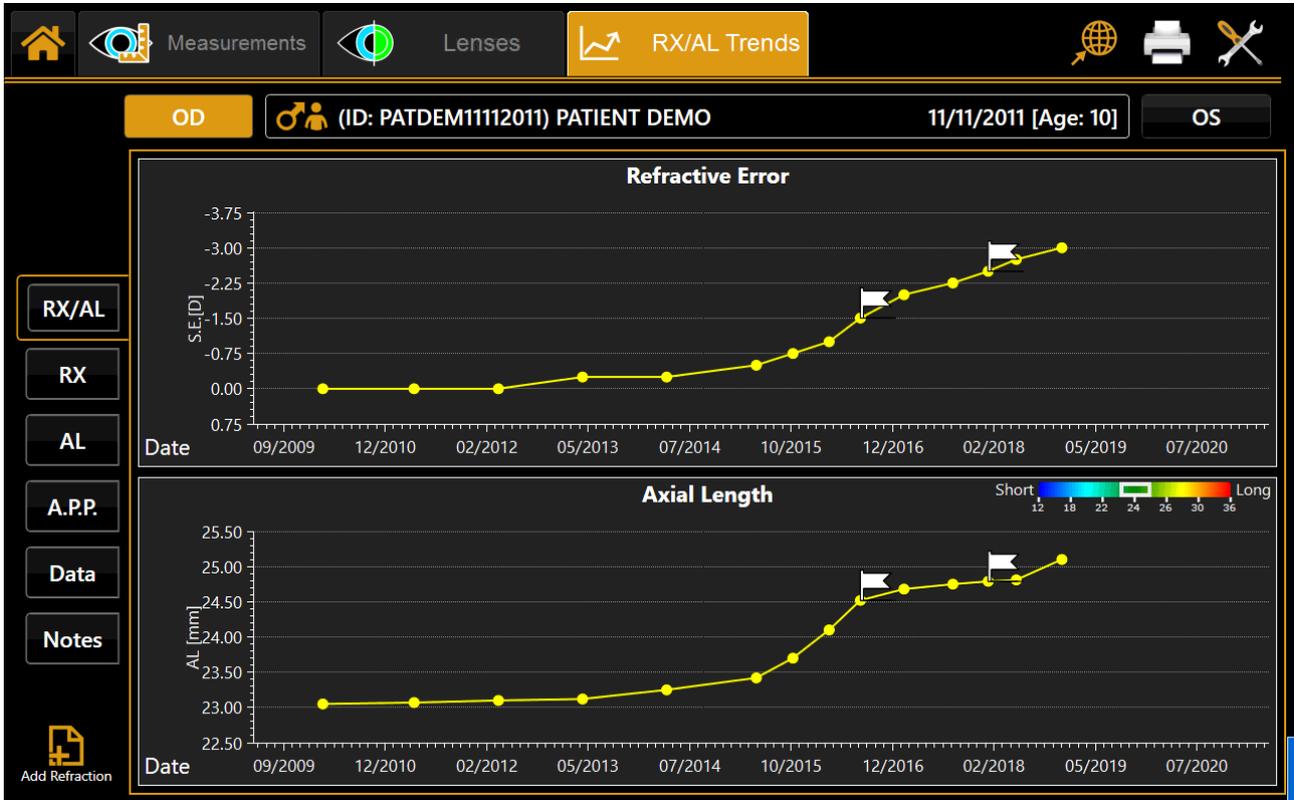
By pressing the RX/AL Trend button, it is possible to access the Data Review, the RX/AL Trend data overview section for the selected patient.

The number inside the blue circle over the "RX/AL Trends" button shows the current number of exams containing manually entered data (or imported from Excel file).

N.B. In the list, only the exams containing acquisitions done with the device are shown, the rest can be visualized from the "Data Review" section of the "RX/AL Trends" module.

13.1 DATA REVIEW

The data present in the Data Review section is provided by examinations directly performed with MYOPIA EXPERT 700 and stored onboard together with manual data eventually imported or added.



BASELINE

Starting condition of the trend profiles. It can be changed on the fly to any examination date.

MONTH BASE

Window period for Variation profile calculation

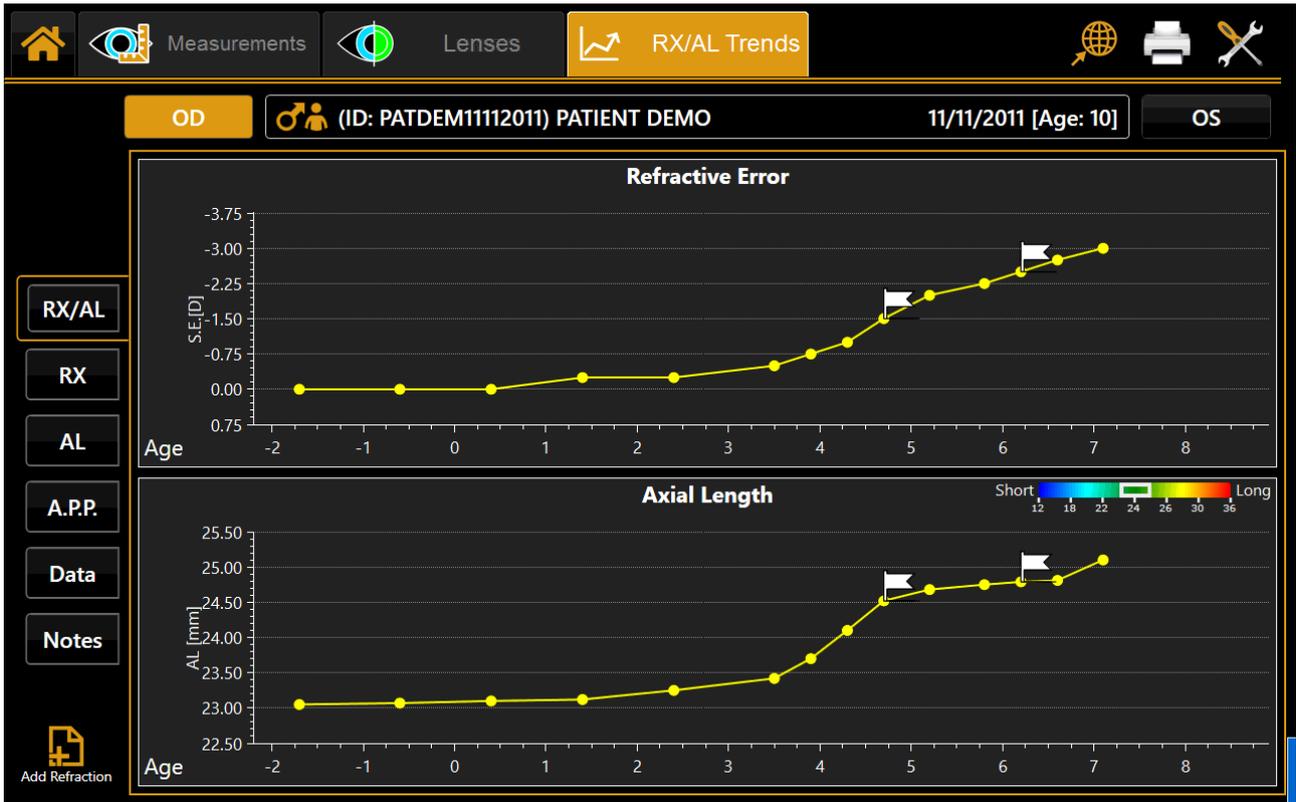
NOTES

Notes can be added/edited in relation to each single examination date and reviewed.

	Date	RX SE [D]	AL [mm]	A.P.P. [D]	Note
RX/AL	03/02/2018	-2.50	25.89		
RX	04/04/2018	-2.75			Note
AL	05/06/2018	-2.75			
A.P.P.	07/09/2018	-3.00	26.09		
Data	20/12/2018	-3.00	26.10		
Notes	31/01/2019	-3.00	26.12		
	14/03/2020				

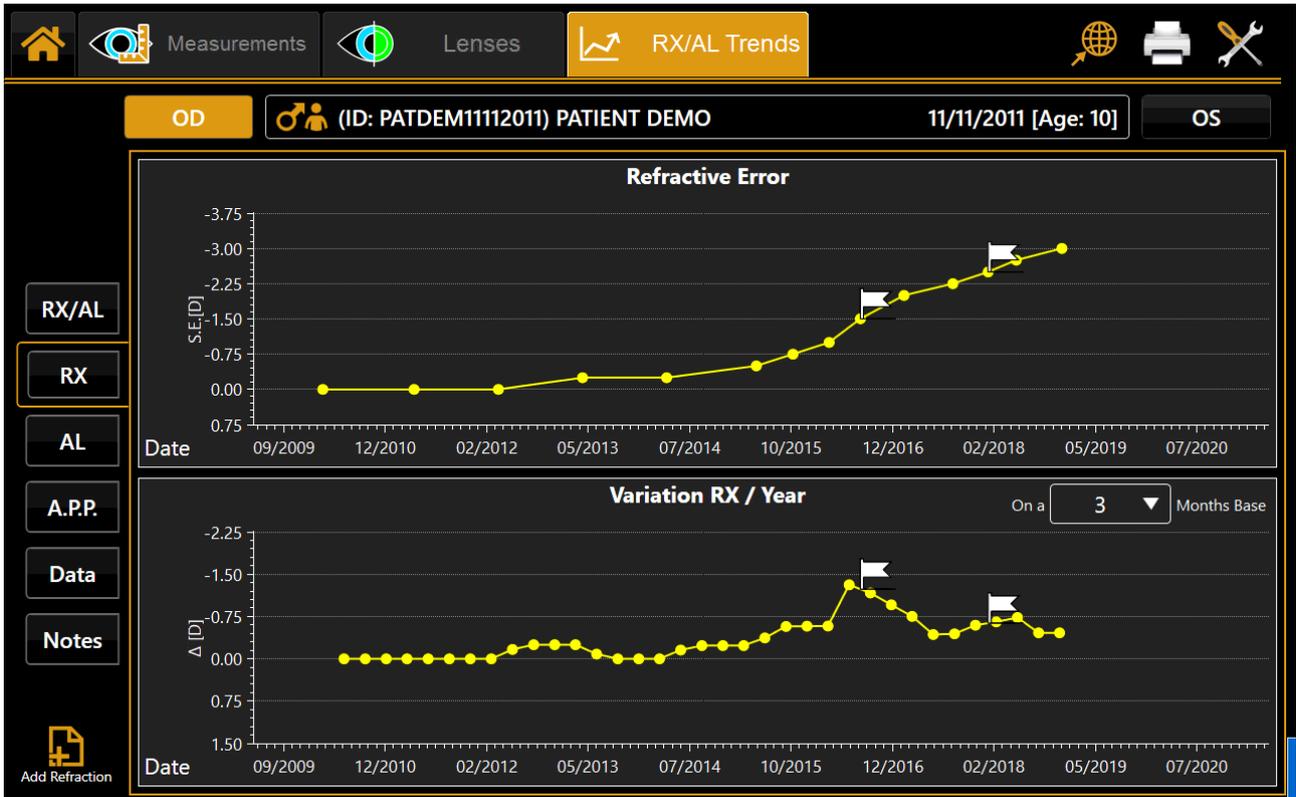


RX/AL, Refraction & Axial Length trend: Combined trend view with Refraction error S.E. and Axial Length.



RX, Refraction trend: Refraction S.E. absolute value (at reference Vertex Distance) trend and yearly variation (on 3,6,12 months' basis).

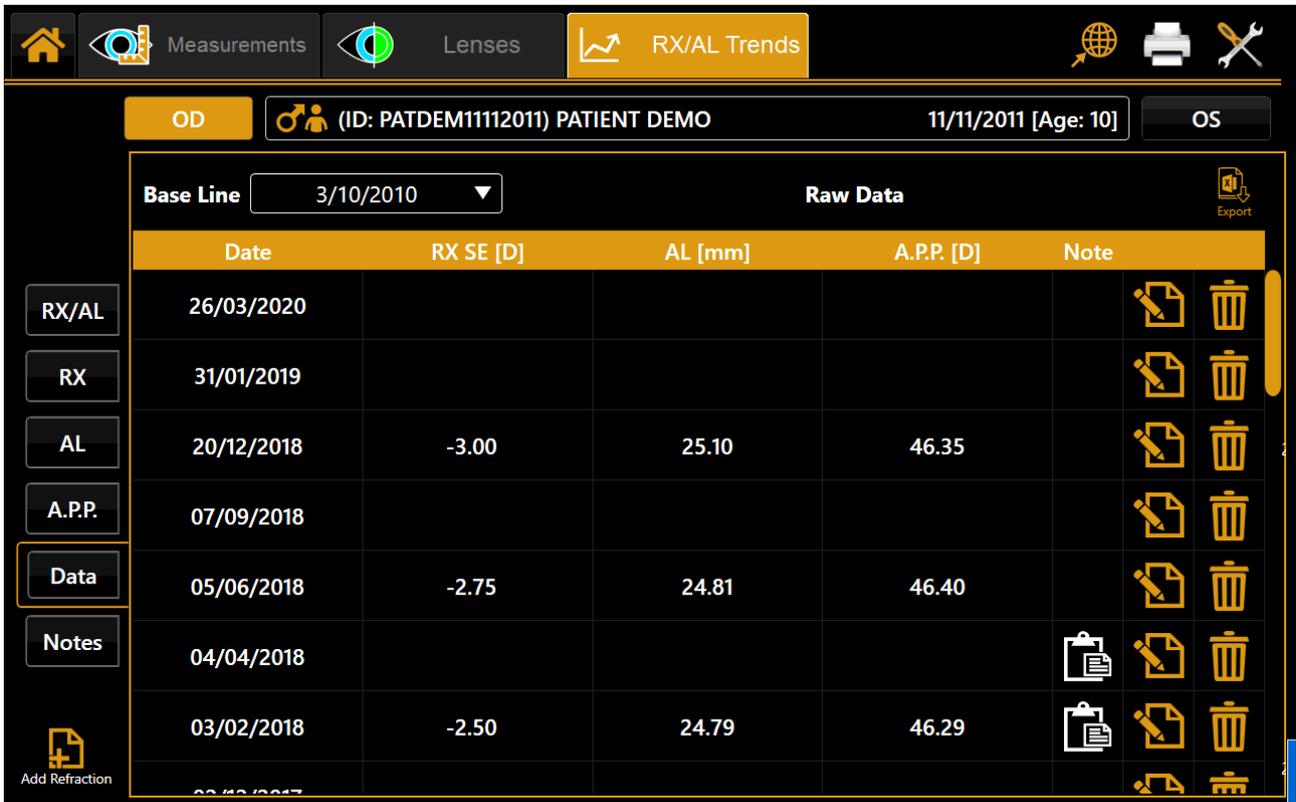
AL, Axial Length trend: Absolute Value trend and yearly variation (on 3,6,12 months' basis).



A.P.P., Average Pupillar Power: (calculated on a circle of 4.5mm diameter) Absolute Value trend and yearly variation (on 3,6,12 months' basis).

DATA

Raw data table review and management (edit, delete).



OD (ID: PATDEM11112011) PATIENT DEMO 11/11/2011 [Age: 10] OS

Base Line 3/10/2010 Raw Data Export

	Date	RX SE [D]	AL [mm]	A.P.P. [D]	Note		
RX/AL	26/03/2020						
RX	31/01/2019						
AL	20/12/2018	-3.00	25.10	46.35			
A.P.P.	07/09/2018						
Data	05/06/2018	-2.75	24.81	46.40			
Notes	04/04/2018						
	03/02/2018	-2.50	24.79	46.29			
	02/12/2017						

Add Refraction

General action buttons:

- **Import Button:** Import data from the template sheet for the current patient only.
- **Add Button:** Add data manually by filling the form.

Per-row action buttons:

- **Edit Button:** Edit data of the selected row, show edit form with current values

Edit Exam Demo Patient 10/03/2010

Non-Cycloplegic
 Cycloplegic

Objective
 Subjective

Refraction
 Over Refraction

OD Refraction

Sphere 0.00 D
Cylinder 0.00 D
Axis 0 °
VD 0.00 mm

OS Refraction

Sphere [] D
Cylinder [] D
Axis [] °
VD 14.00 mm

Note

Close Save

- **Delete Button:** Delete the selected row

13.1.1 Report & Screenshot

To create a report of the RX/AL Trend, press the print icon in the top main bar and check the RX/AL Trend report.



A binocular report with:

- Refraction and Axial Length absolute and yearly variation charts
- Data table
- Notes list

SCREENSHOT: create a report page with the current view



Available output destinations:

- Printer (as in the main printing form of the application)
- USB drive export
- Network Shared folder

14. MEASUREMENTS

All measurements performed during the examination can be reviewed in detail in the "Measurements" section.

There are 12 types of measurement section.

- **MAP:** Topography Map
- **OD/OS:** (or R/L) Right to Left side by side Topography Map review
- **ZER:** Zernike Analysis
- **HEIGHT:** Altimetric Map
- **COMP:** Topography Map comparison of two different exams of the same patient
- **PUP:** Pupillometry
- **FLUO:** Fluorescein acquisitions review
- **WTW:** White to White review

To which various environments correspond. They are described in detail in the following sections.

14.1 MAP- TOPOGRAPHY MAP

The environment displayed is shown in Fig. 28.

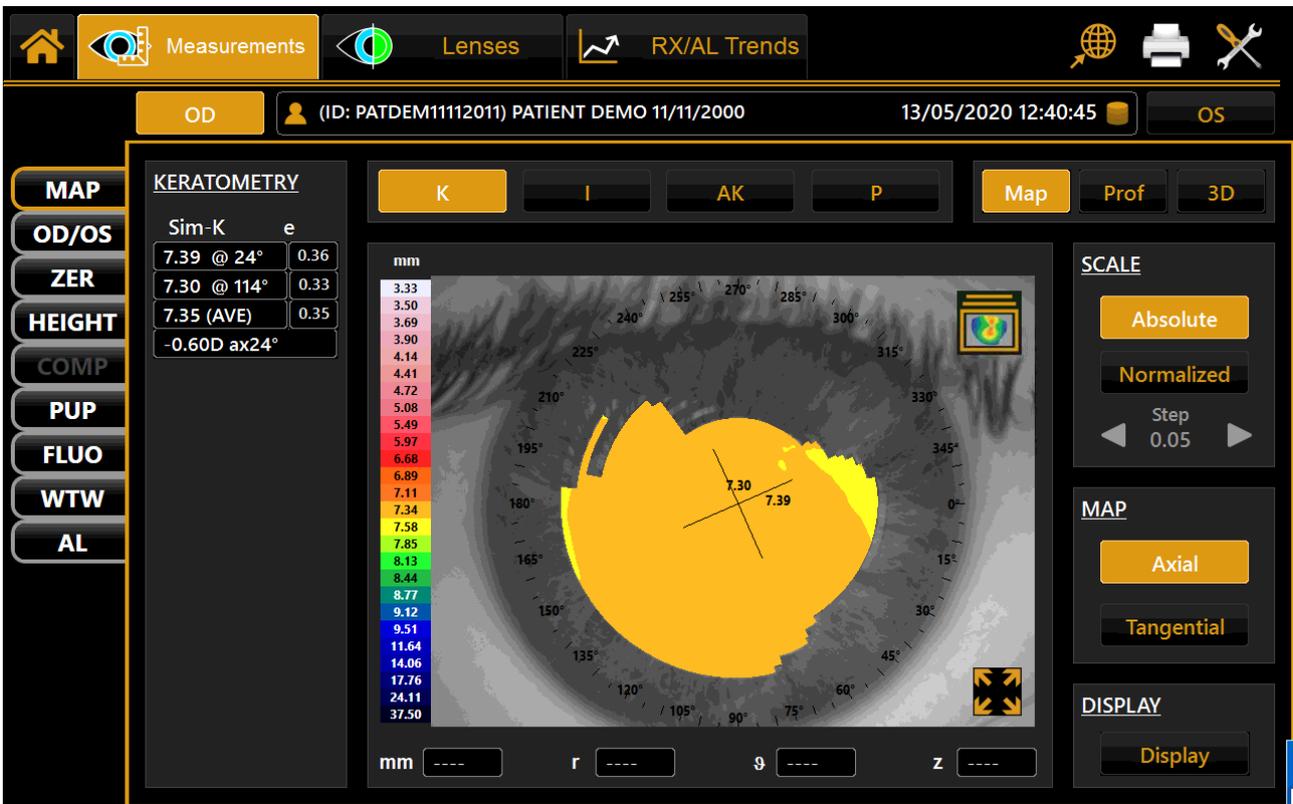


Fig. 28

Tap on the "OD" or "OS" buttons to display the map of the right or left eye. The "OD" and "OS" buttons are only active if the keratometry of the eye in question has been acquired.

In the right column, you can select the following options:

- **Absolute** or **Normalized**: absolute scale or standardized scale with related step.
- **Axial** or **Tangential**: axial map or tangential map.
- **Display**: allows you to choose whether to display or not the image of the eye, the map, the rings, the numeric values, and transparency.

Press on any point on the map to display the following information:

- Diopters (D)
- Radius (r)
- Meridians (θ)
- Altimetry (z)

14.1.1 Topographic map indexes

The diagnostic indexes can be selected with the following buttons (at the top, above the map):

- *K*: Keratometry
- *I*: Keratorefractive indexes
- *KC*: Keratoconus
- *P*: Pupil

14.1.2 Keratometry

Press the "**K**" button to display the keratometric data on the 3 mm, 5 mm, and 7 mm zones, as shown in Fig. 28.

14.1.3 Keratorefractive indexes

Press the "**I**" button to view the keratorefractive indexes (Fig. 29):



Fig. 29

- Astigmatism: Astigmatism at 3 and 5 mm
- Pupil Avg: Average pupil power for a pupil of 4.5 mm
- Asphericity: Asphericity of the cornea at 8 mm diameter. Pressing the arrow will open a more detailed set of data. Refer to the corneal asphericity section below for more details.
- Spherical Aberration: Longitudinal spherical aberration of a 4.5mm diameter cornea area

- Curvature Irregularity: Irregularity of curvature calculated on the standard deviation of the instantaneous readings for a 4.5mm diameter cornea area
- Asymmetry + SAI: Asymmetry between the most curved hemisphere and the flattest one, calculated for a 4.5mm diameter cornea area and a SAI (Surface Asymmetry Index), which represents the surface asymmetry index of the 4.5mm diameter cornea area.

Corneal asphericity

The window is composed of two tabs (Asphericity and Peripheral degrees), which specify the corneal asphericity.

The Corneal Asphericity window could also be invoked from the Corneal Height Map environments. In this case, as in the topographic map, the user should choose the Asphericity Corneal menu item.

Asphericity

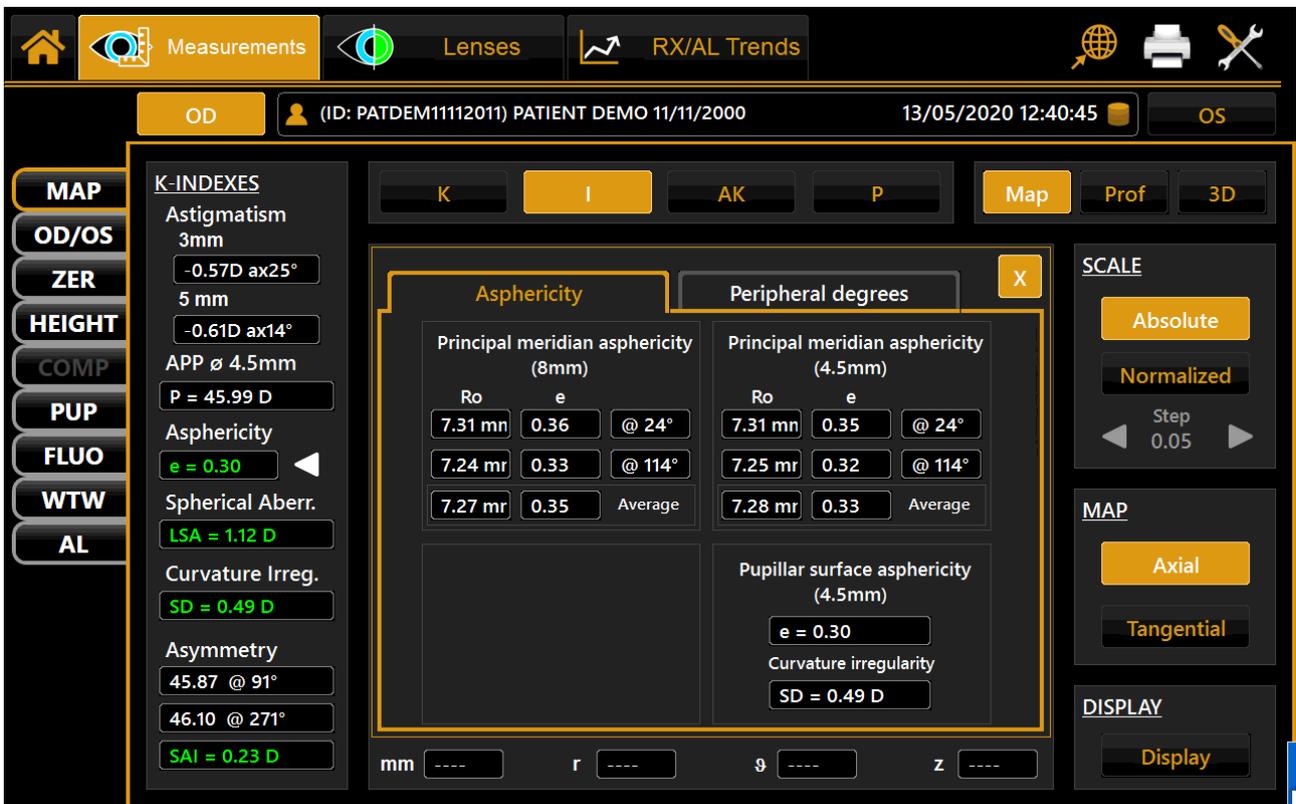


Fig. 30

As you can see from Fig.30, the panel is divided into four parts.

The top-left rectangle (Principal meridian asphericity (8mm)) contains three rows:

- In the first row you can read the apical radius (Ro) and the asphericity (e) along the flattest meridian (@);
- In the second row, there are the same parameters calculated along the steepest meridian; in the third row, there are the average values of the apical radius and the asphericity. The parameter calculations are based on a circular area centered in the center of the rings with diameter= 8mm.

The top right rectangle (Peripheral degrees) contains the same parameters as in the top left one, but the diameter of the circular area is 4.5mm.

The bottom right rectangle contains two parameters: the corneal asphericity referred to the pupillary surface (4.5mm) and the surface irregularity (SD).

The last parameter measures the difference between the current cornea curvature and the related aspherical best fit surface. In every panel, curvature and asphericity values are formatted according to the settings chosen with the items Curvature and Asphericity present in the settings environment.

Peripheral degrees

The table describes the corneal asphericity at the different peripheral degrees (see Fig. 31).

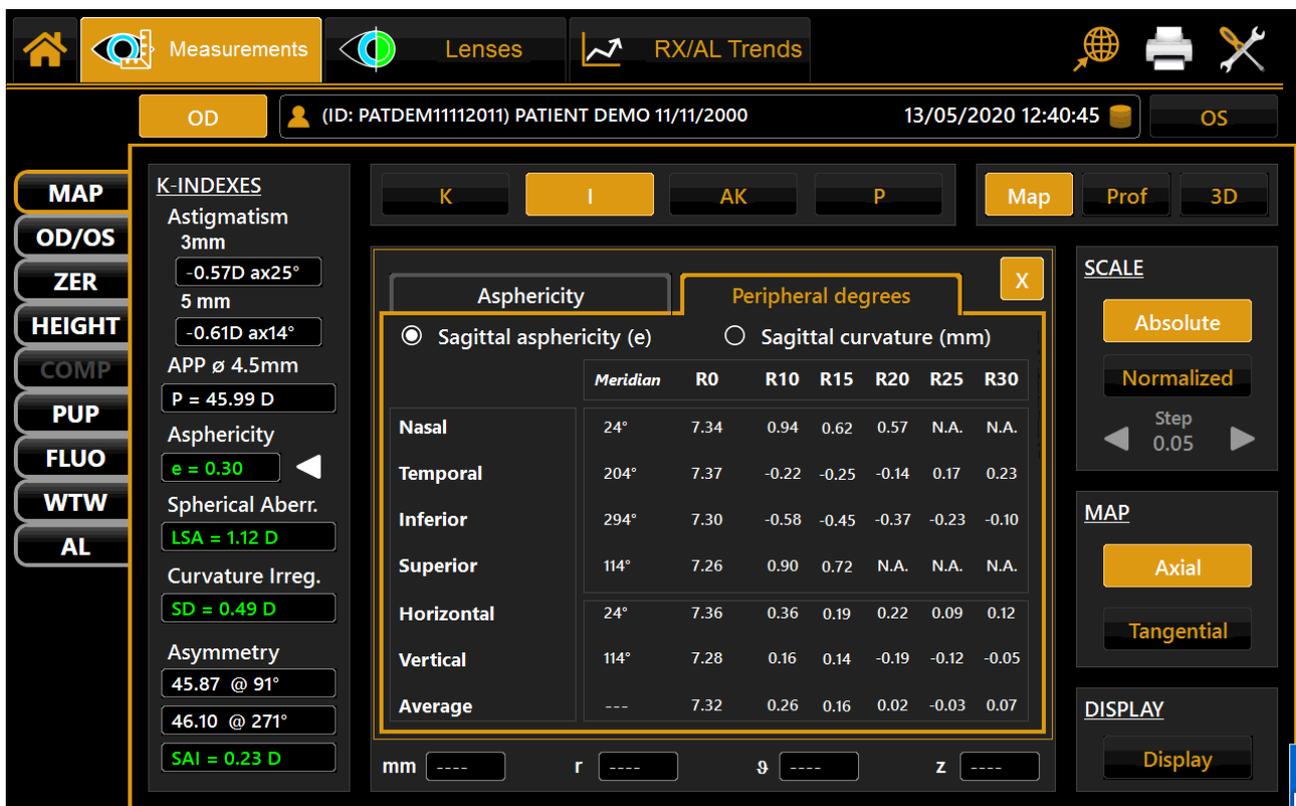


Fig.31

The first four rows of the table describe the parameter values examined along the nasal, temporal, inferior, and superior emimeridian. The next two rows (horizontal and vertical) represent the average between nasal and temporal parameter values and between inferior and superior parameter values, respectively.

The last row contains the general parameter averages.

The first two columns show the analyzed meridian and the apical radius along that meridian. The subsequent rows (R10, R15, R20, R25, R30) indicate the eccentricity value or the sagittal radius at the various peripheral degrees.

14.1.4 Keratoconus

Press the "AK" button to open Keratoconus screening; this section is divided into two tabs: KC and CLMI.

The KC shows the following information (Fig. 32):

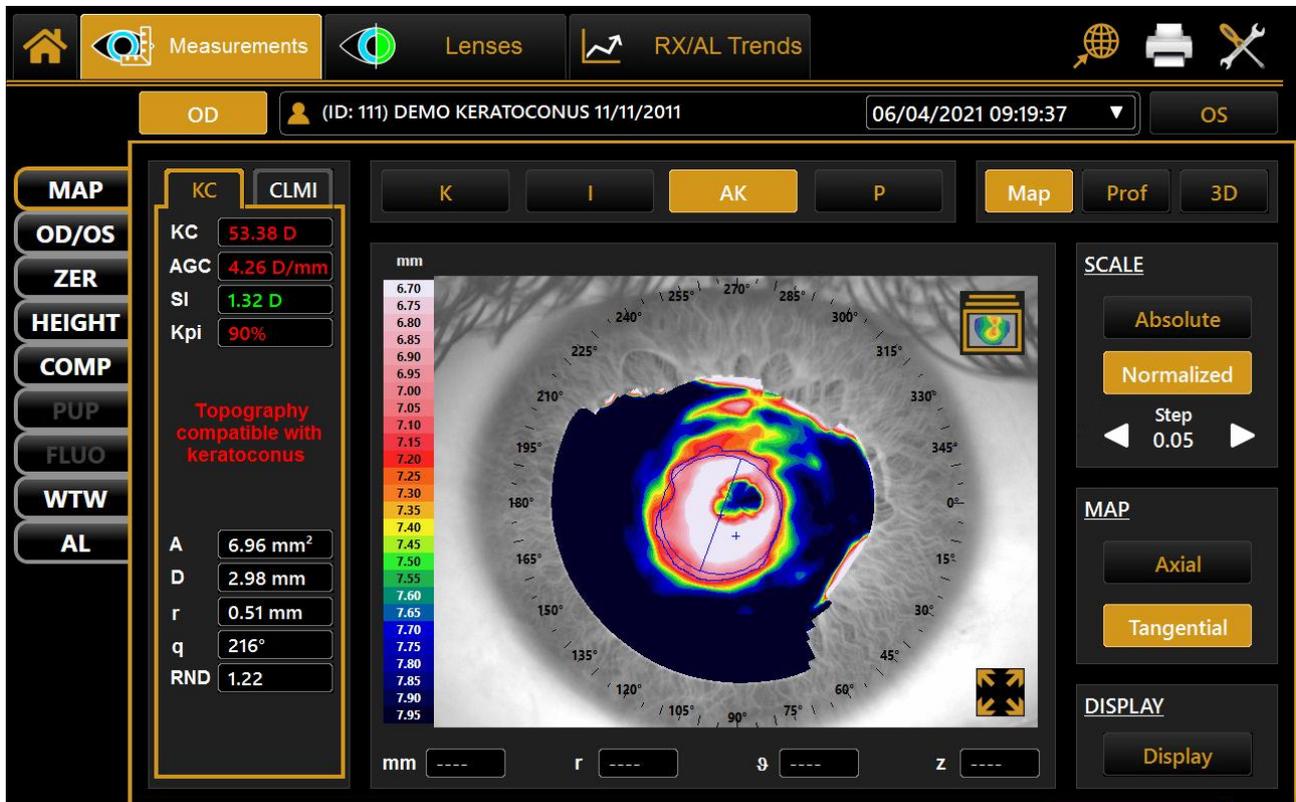


Fig. 32

- **AK:** Apical curvature

Represents the power of the cornea at its apex

- **AGC:** apical gradient of curvature

Represents the average variations per unit of length of the corneal power, taking the apical power as a reference.

- **SI:** the difference between the average power of two circular zones centered on the vertical axis of the ruler and placed in the lower hemisphere and the upper hemisphere of the cornea, respectively.
- **Kpi:** Keratoconus diagnosis probability index.

Based on the combined evaluation of the first three indexes with the probability index, three different possibilities result: topographic picture not compatible with keratoconus (green); suspected keratoconus (yellow); topographic picture compatible with keratoconus (red).

If the topographic picture is compatible with keratoconus or indicates suspected keratoconus, the numerical values of the geometric parameters of the cone are shown at the bottom of the panel. These are:

- A : area of the keratoconus (mm^2)
- D : average diameter of the keratoconus (mm)
- r, \varnothing : polar coordinates (mm, $^\circ$) of the barycenter of the keratoconus in relation to the center of the map
- RND : circularity factor of the keratoconus

The CLMI shows the following information (Fig. 33):

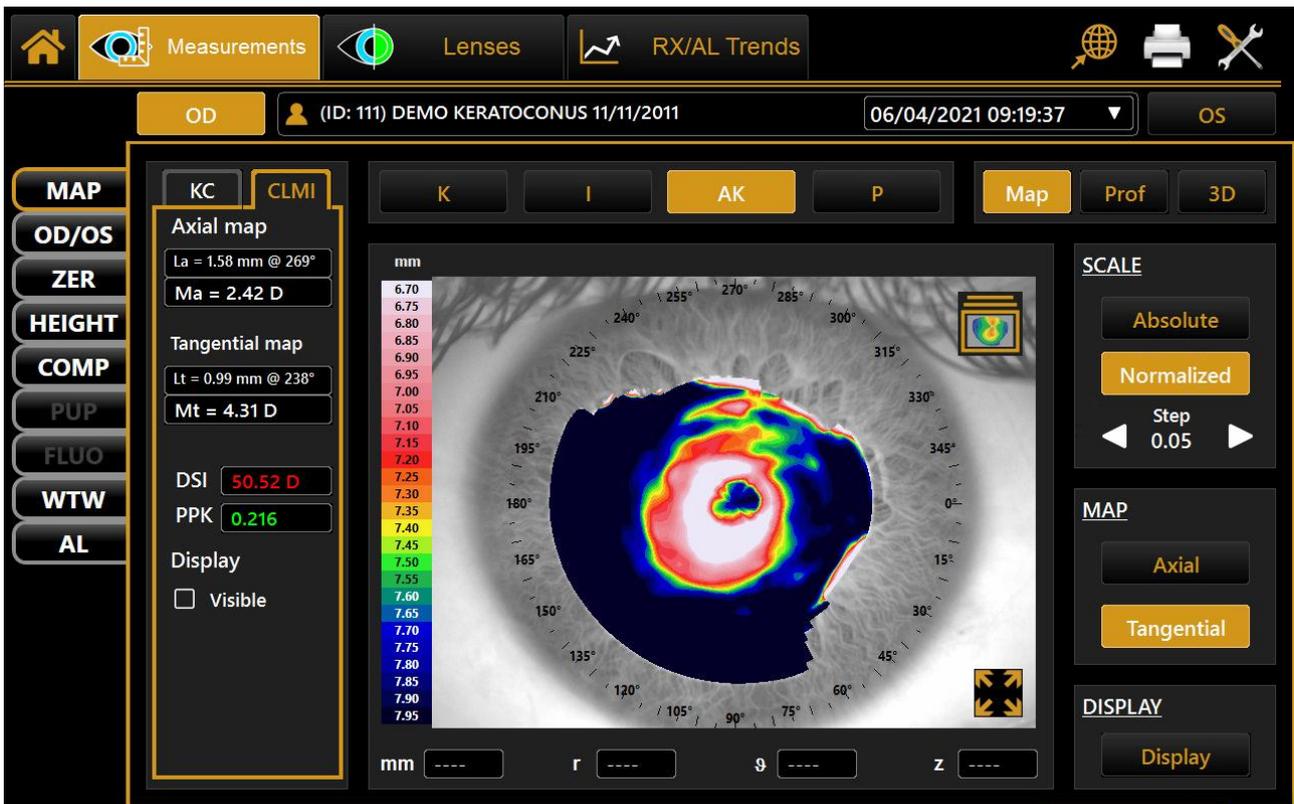


Fig. 33

- *Axial map CLMI*: Cone Location and Magnitude Index based on the axial map.
- *Tangential map CLMI*: Cone Location and Magnitude Index based on the tangential map.
- *DSI*: Differential Sector Index.
- *PPK*: Percent Probability Keratoconus.
- *Display CLMI*: allows you to choose whether the CLMI map must be shown or not.

14.1.5 Pupil

Press the "P" button to open the pupil indexes (Fig.34):

- **Corneal Diameter**: represents the diameter of the patient's cornea in mm.
- **KC**: KC represents the central keratometry in diopters.
- **Avg Pupil Power**: Average pupil power for a pupil of 4.5 mm.

- Pupil Dec.: Pupil decentration from the optical axis.
- Avg Pupil Ø: Mean diameter of the pupil.

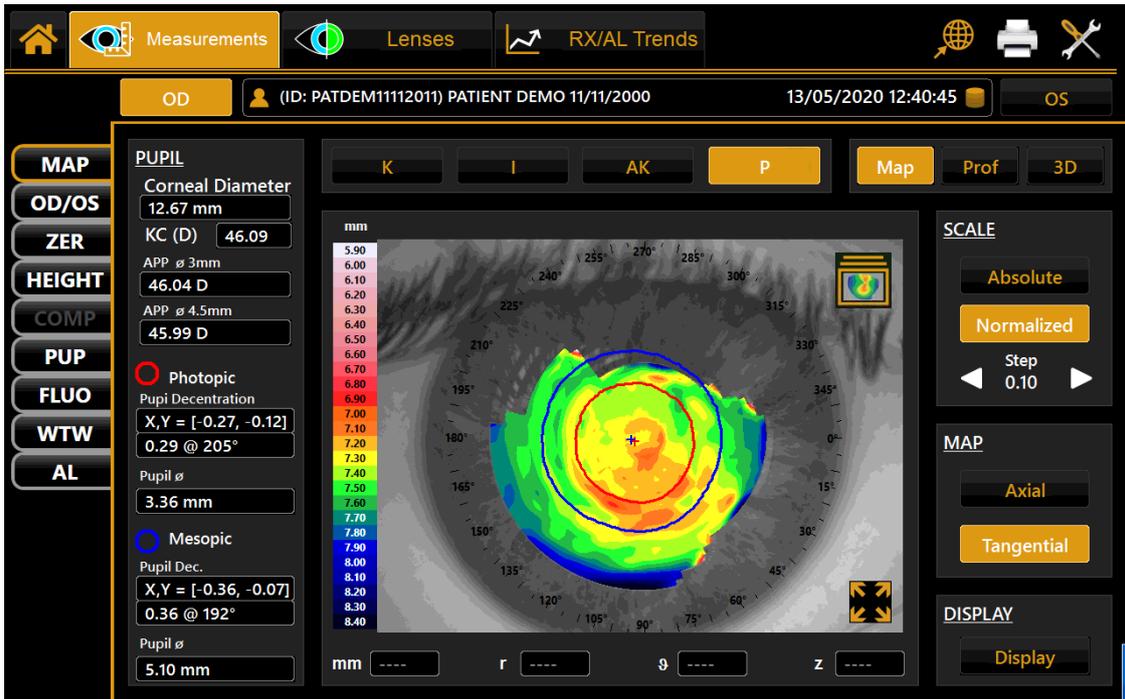


Fig. 34

14.1.6 Gallery

Press the icon at the top right of the map to enter the gallery (Fig.35).

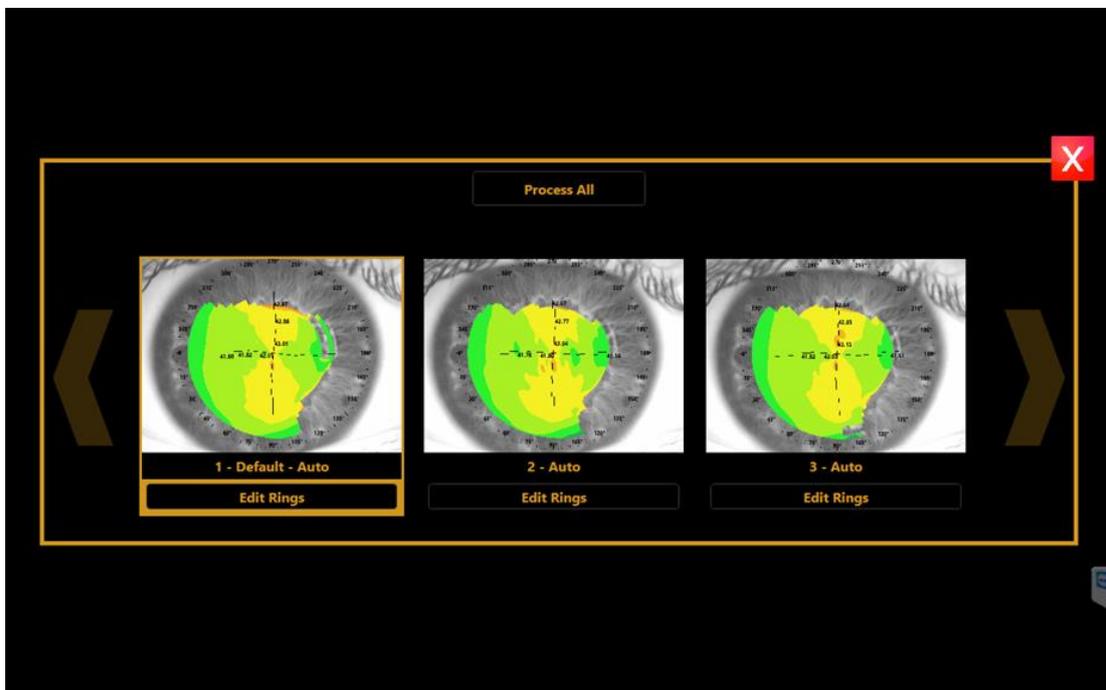


Fig. 35

From the gallery, you can change the default image for all the acquisitions made.

14.1.7 Full-screen mode

From the map environment (Fig.38), you can access full-screen mode (Fig.36) by pressing the button positioned at the bottom right corner of the image. To close the environment, tap on the **X** button at the bottom right corner.

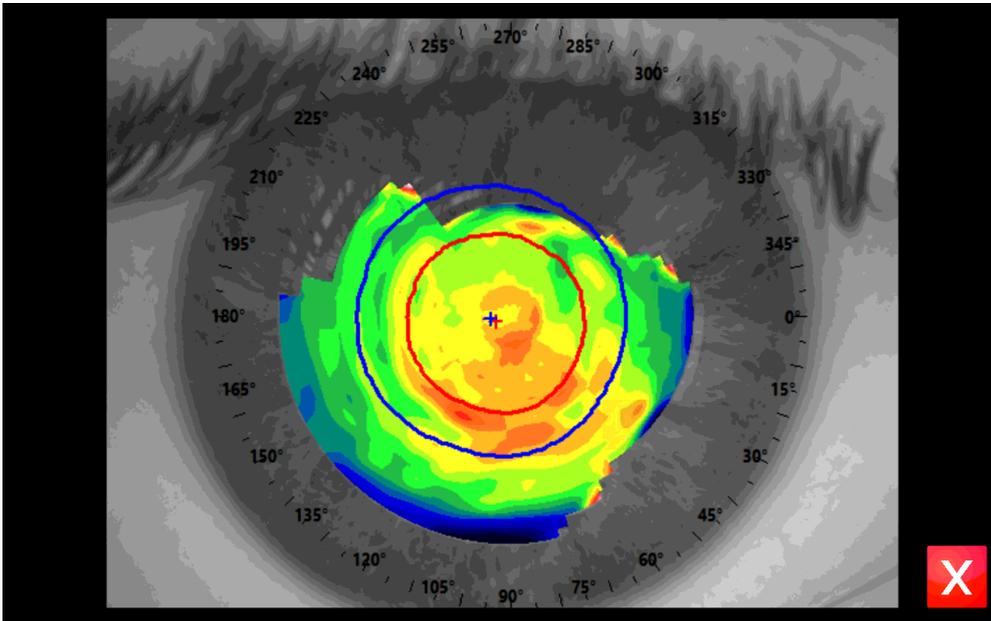


Fig. 36

14.1.8 Profile

Press the **"Profile"** button to view the curvature profile along the most curved meridian and the flattest meridian (red and blue). The difference is displayed in green (Fig.37).

By pressing the arrow buttons, you can change the flattest and the most curved meridians.

The graph will be modified accordingly. Press the **"Map"** button to go back to the topographic map.

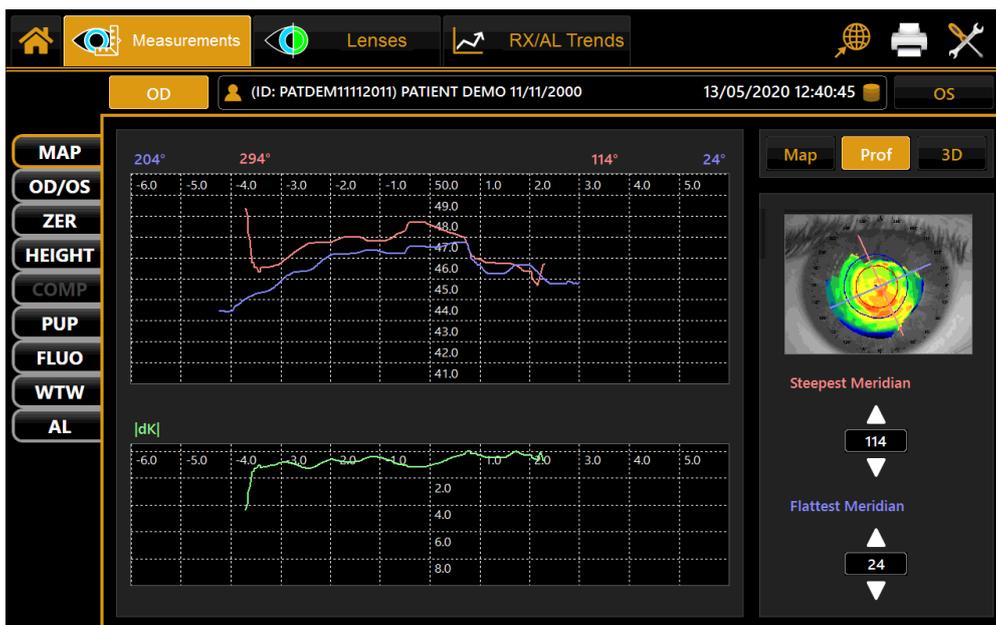


Fig.37

14.1.9 3D

Press the "3D" button to view the 3D map of the keratometric data (Fig.38):

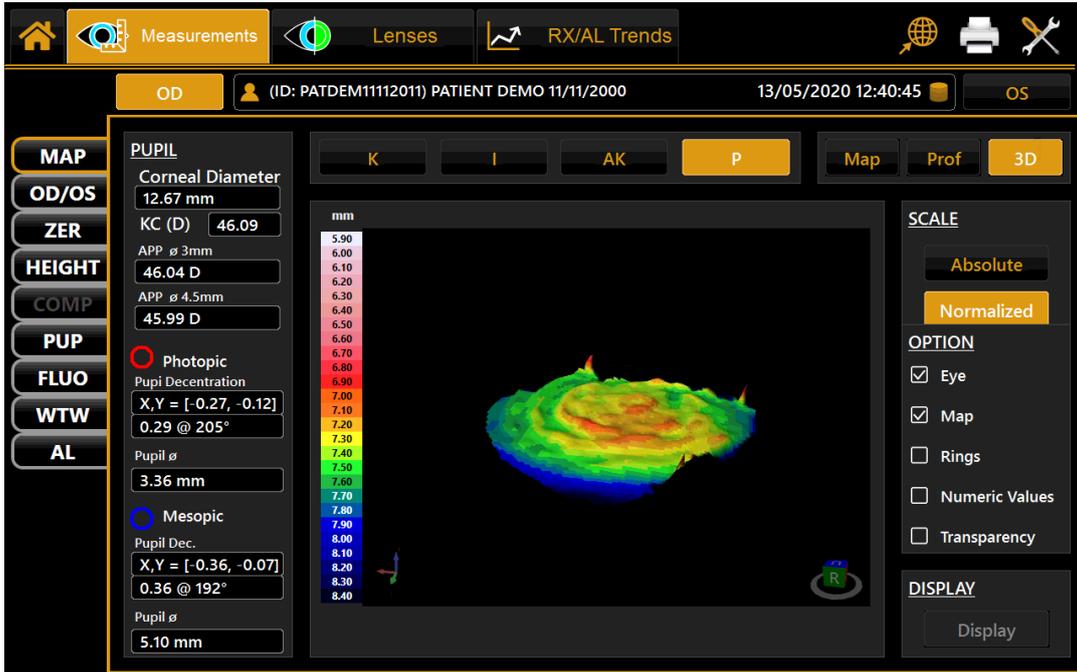


Fig. 38

14.1.10 Edit Rings

In this section, the user can edit the 24 rings in order to improve the topographic map (Fig.39).

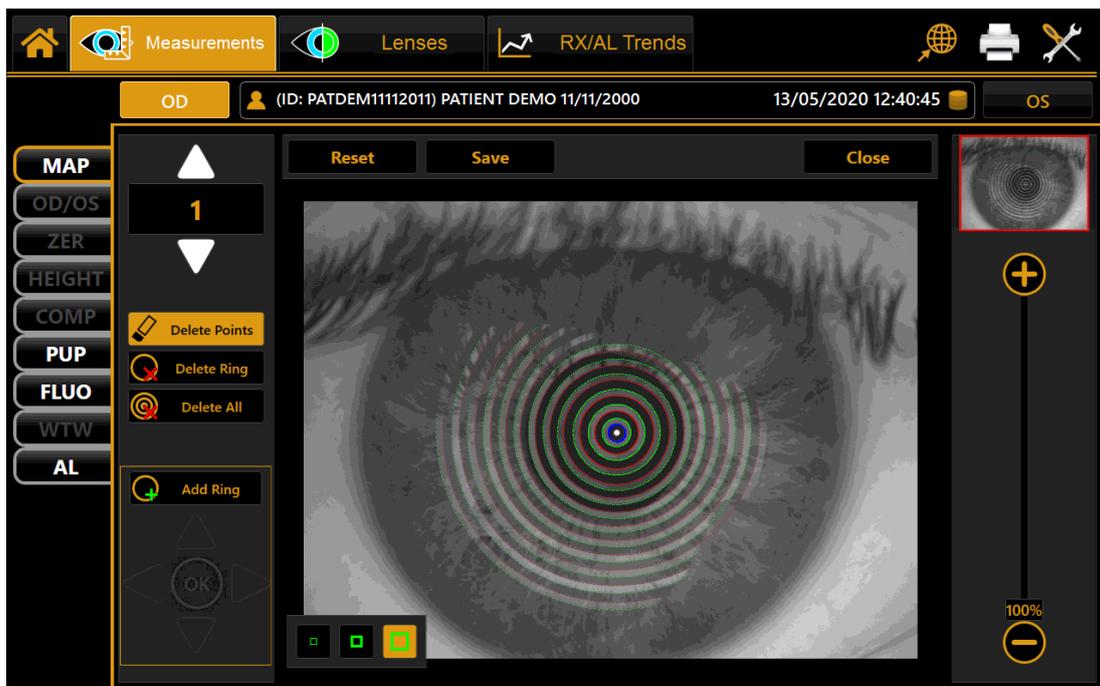


Fig. 39

On the right, the navigation tools are available:

- At the top, the thumbnail of the image with a red rectangle inside is displayed. This shows the current position within the image; it is possible to drag it and move it to see different parts of the image.
- At the bottom, there is a zoom slider that allows the user to zoom from 100% to 1000%.

The editing tools are found on the left:

- From the top area, you can select the ring you wish to edit;
- In the central area, three buttons are available:
 1. "Delete Points", to delete parts of the selected ring;
 2. "Delete Ring", to delete all of the selected rings;
 3. "Delete All", to delete all the 24 rings.

"Add Ring", to choose where the selected ring will be added in the image;

- The four arrows and the central button available at the bottom are active only when the "Add Ring" button is enabled. These allow the user to move the cursor and to confirm the position.

At the top of the image, there are three buttons:

- "Reset", to reset the original rings;
- "Save", to save all the changes made by the user;
- "Close", to close the environment.

14.2 OD/OS

In this section you can compare the OD and the OS data on the same screen (Fig 50):

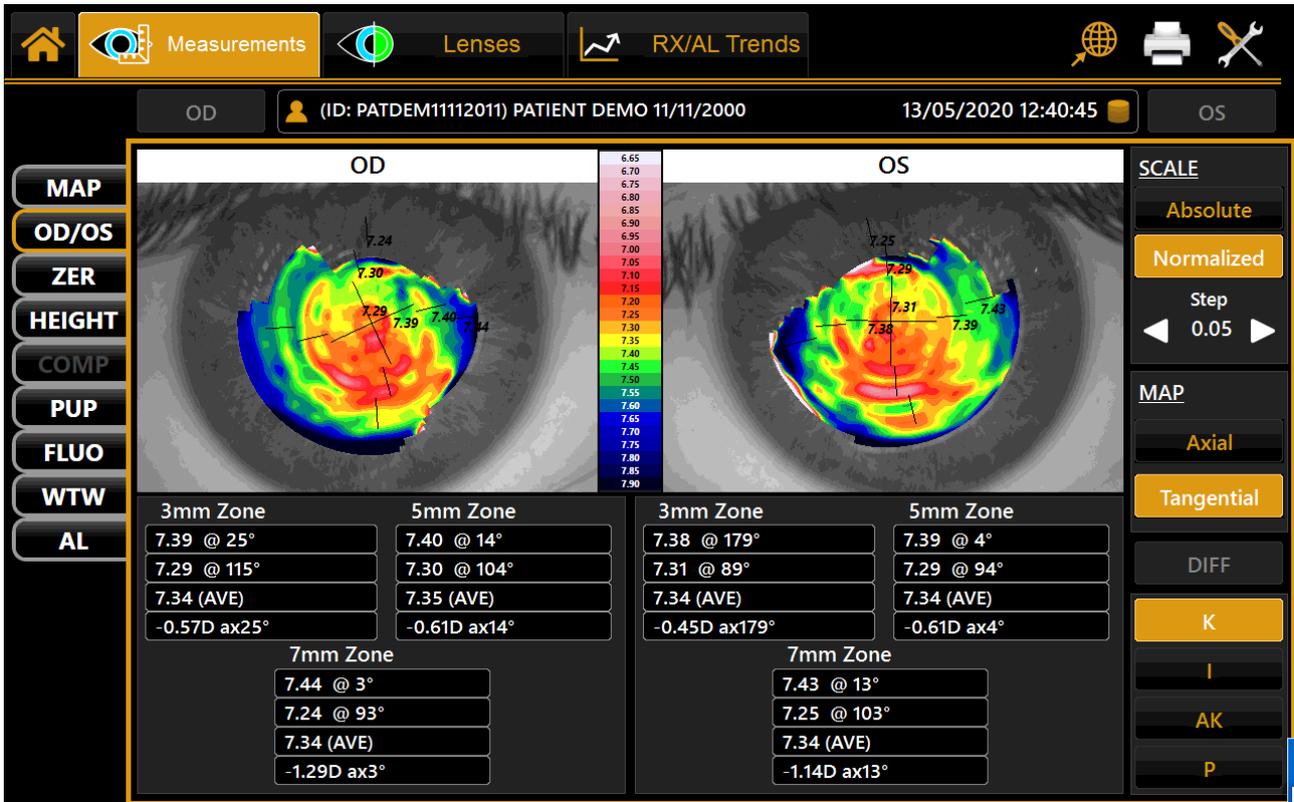


Fig. 40

As in the "Map" section, you can switch between the "K", "I", "KC" and "P" tabs.

The "DIFF" button is disabled because the "difference map" is allowed only with the same eye.

14.3 ZER-ZERNIKE

The Zernike module provides a comprehensive view of the wave front aberrations generated by the front surface of the cornea. The results of the Zernike axis are illustrated by means of numerical indexes and graphic representations.

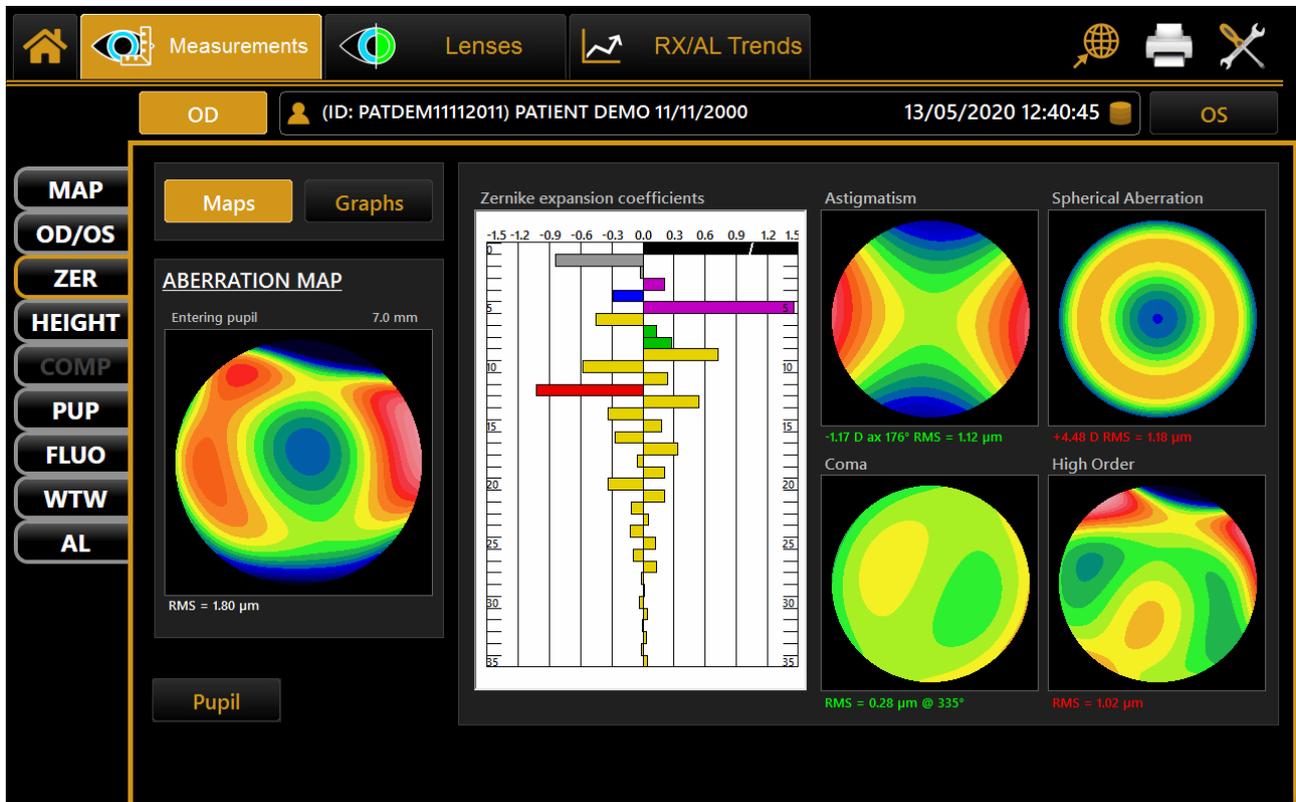


Fig. 41

Tap on the **"OD"** or **"OS"** buttons to view the results of the Zernike analysis for the right or left eye.

On the left, the OPD Map is detailed, representing the total aberration that corresponds to the sum of all the aberration components and the RMS value. This allows you to quantify the deviation with respect to an ideal wavefront. On entering the module, the aberration map is displayed (**"Maps"** section):

- Histograms of the Zernike expansion coefficients: each histogram represents the weight of the corresponding polynomial.
- Primary aberrations map:
 - Astigmatism: the map, the magnitude in diopters, the axis and the RMS value are displayed
 - Spherical aberration: the map, the quantity of longitudinal spherical aberration in diopters and the RMS value are displayed
 - Coma: the map, the RMS value, and the direction are displayed
 - High Order: all the components of an order higher than the primaries are grouped; the map and the RMS value are displayed.

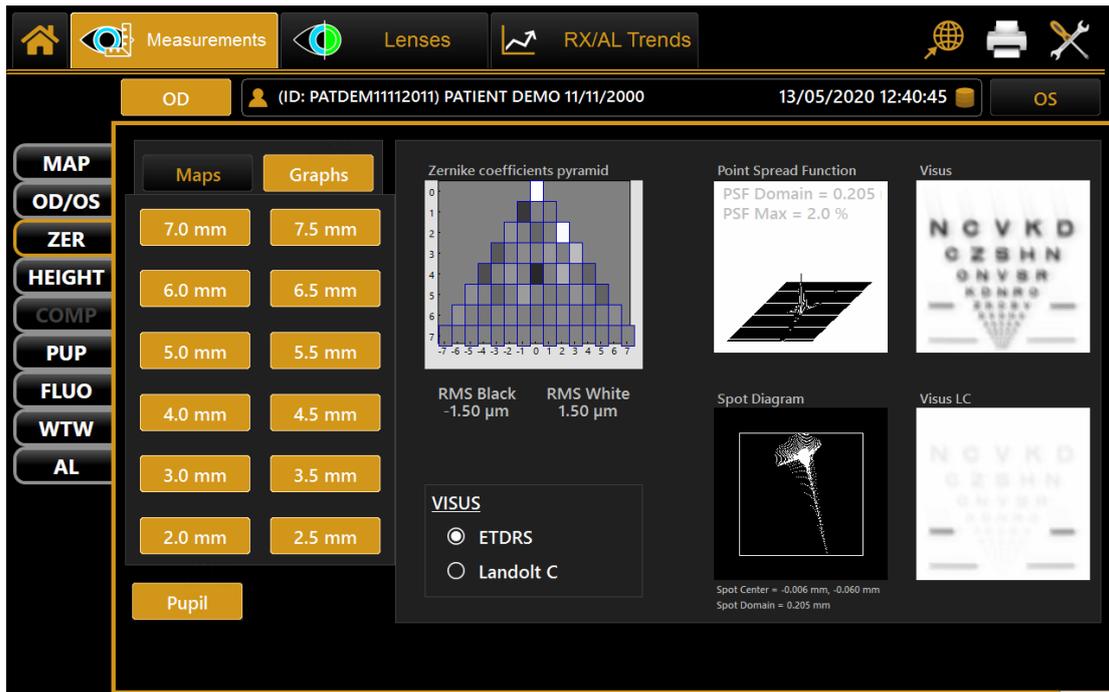
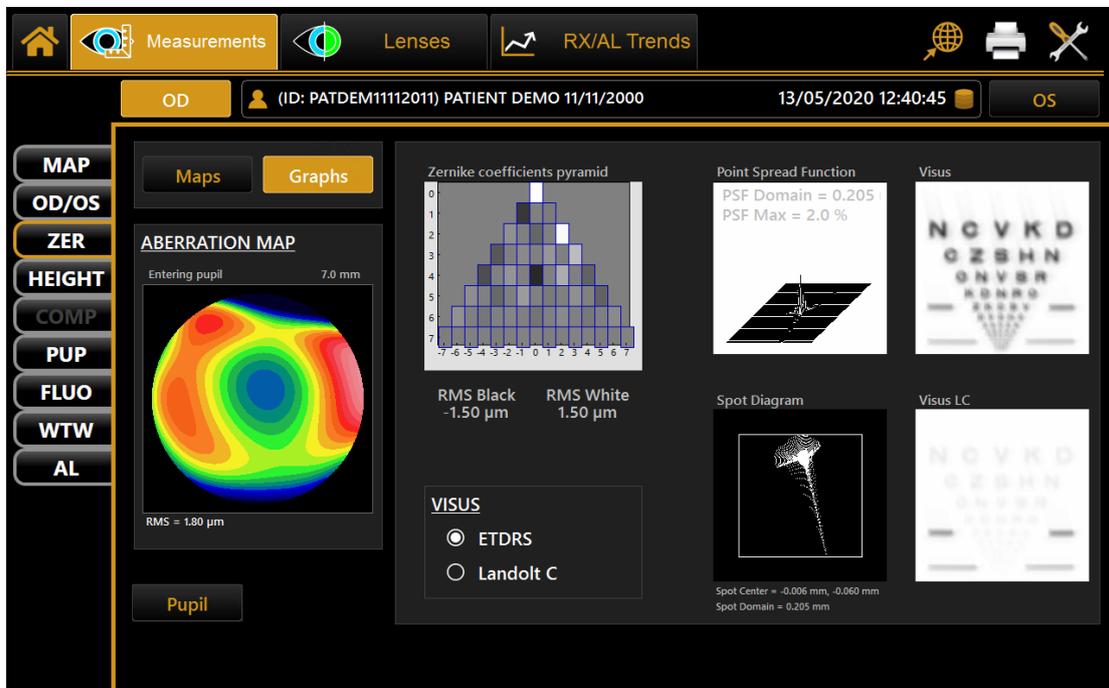


Fig. 43

It is possible to switch between **ETDRS** and **Landolt C** Visus simulation view.



14.4 HEIGHT

“Height” environment allows the user to compare the patient’s cornea with a reference surface (Fig.44):



Fig. 44

In the right column, it is possible to:

- Choose between the “Absolute” and “Normalized” scale, with the possibility to change the normalized scale step.
- Choose the “Best Fit Diameter” and select the best fitting diameter in the range from 3mm to 8mm.
- Choose the “Reference Surface” and select the following surfaces:
 1. Spherical: the user can change the “Radius Flat”.
 2. Aspherical: the user can change the “Radius Flat” and “Asphericity”.
 3. Asphero – Toric: the user can change the “Radius Flat”, “Toricity” and “Asphericity”.
 4. Differential: the user can select the image of another exam of the same patient to compare it with the current exam (Fig.45).

By tapping on any point of the map, the software will provide the following information:

- *r*: the distance of the point from the center of the image in polar coordinates.
- *lb*: the angle of the distance *r*.
- *Height*: the distance between the patient’s cornea point and the reference surface point.

In the altimetric mode, it is still possible to see the “K”, “I”, “KC” and “P” tabs.

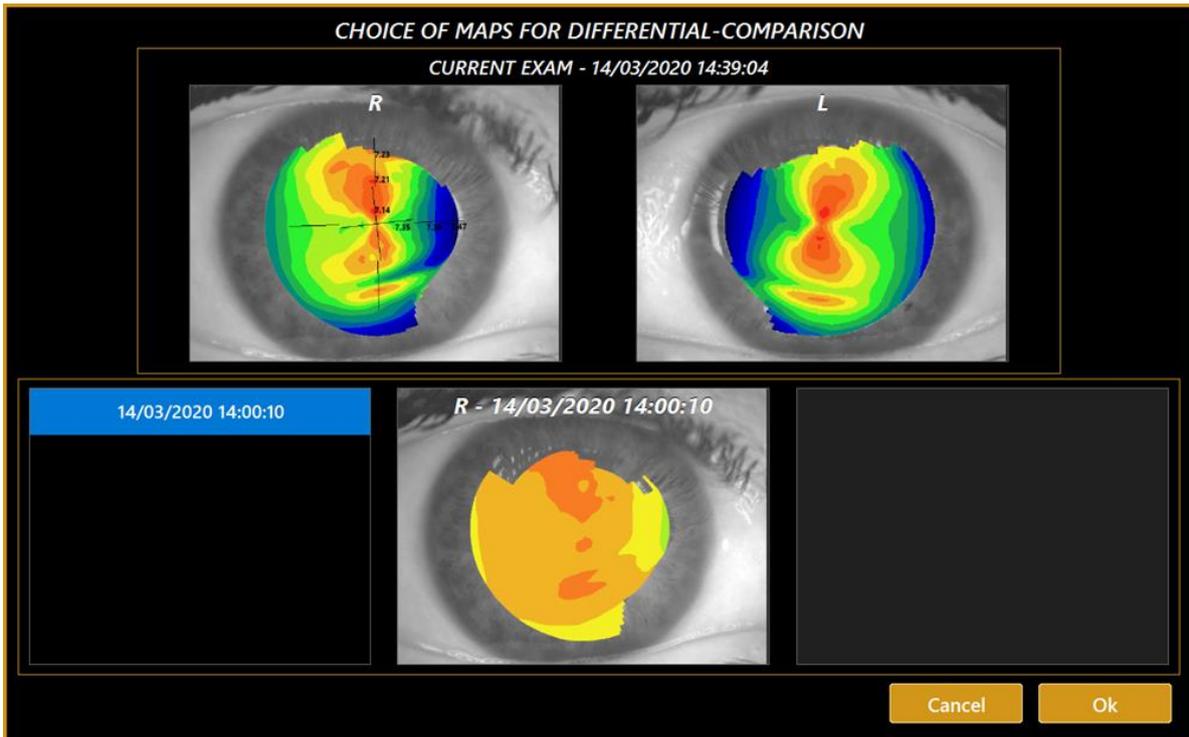


Fig. 45

14.4.1 Profile

Press the "Profile" button to view the curvature profile along the steep meridian or the flat meridian (Fig.56).

It is possible to scale the graph with the "**50 μ m**", "**10 μ m**" and "**5 μ m**" buttons found under the graph.

Press the "**Close**" button to go back to the topographic map.

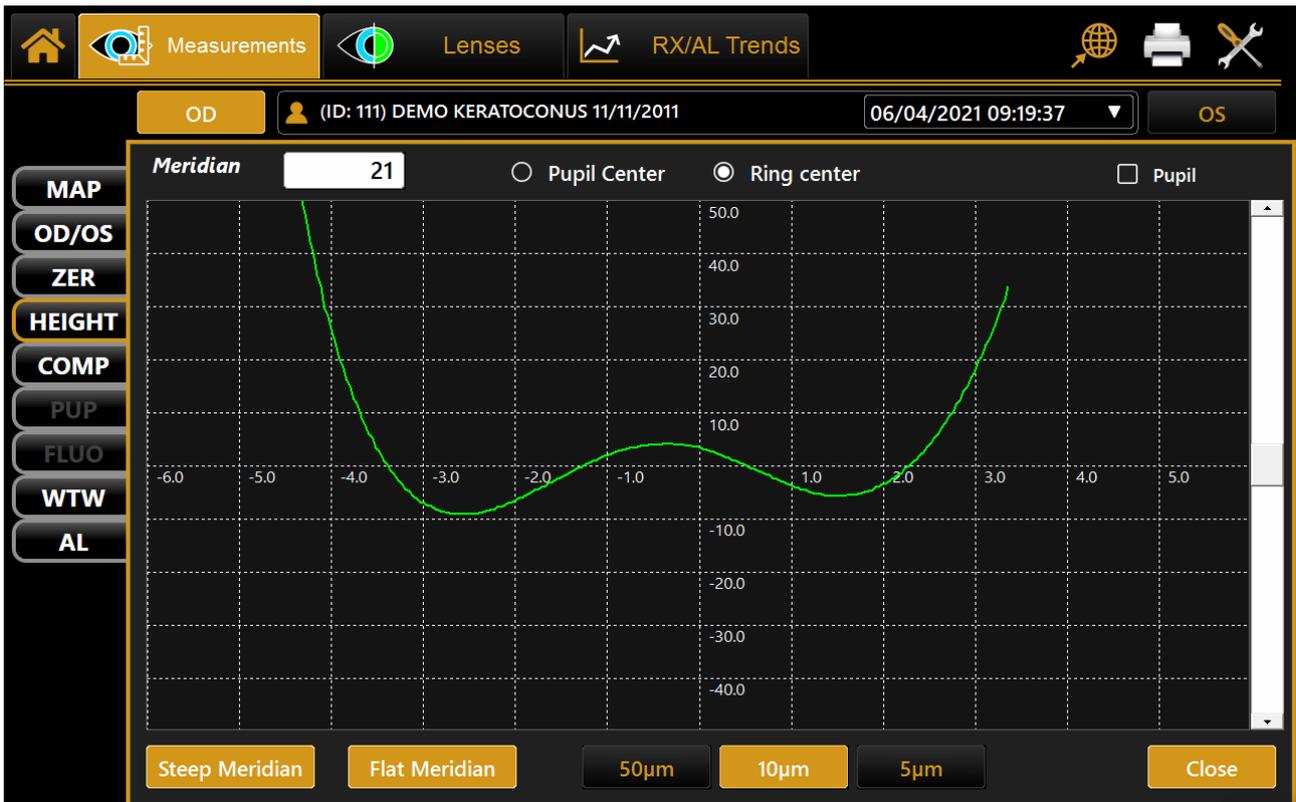


Fig. 46

14.4.2 3D

Press the "3D" button to view the 3D map of the altimetric data (Fig.47).

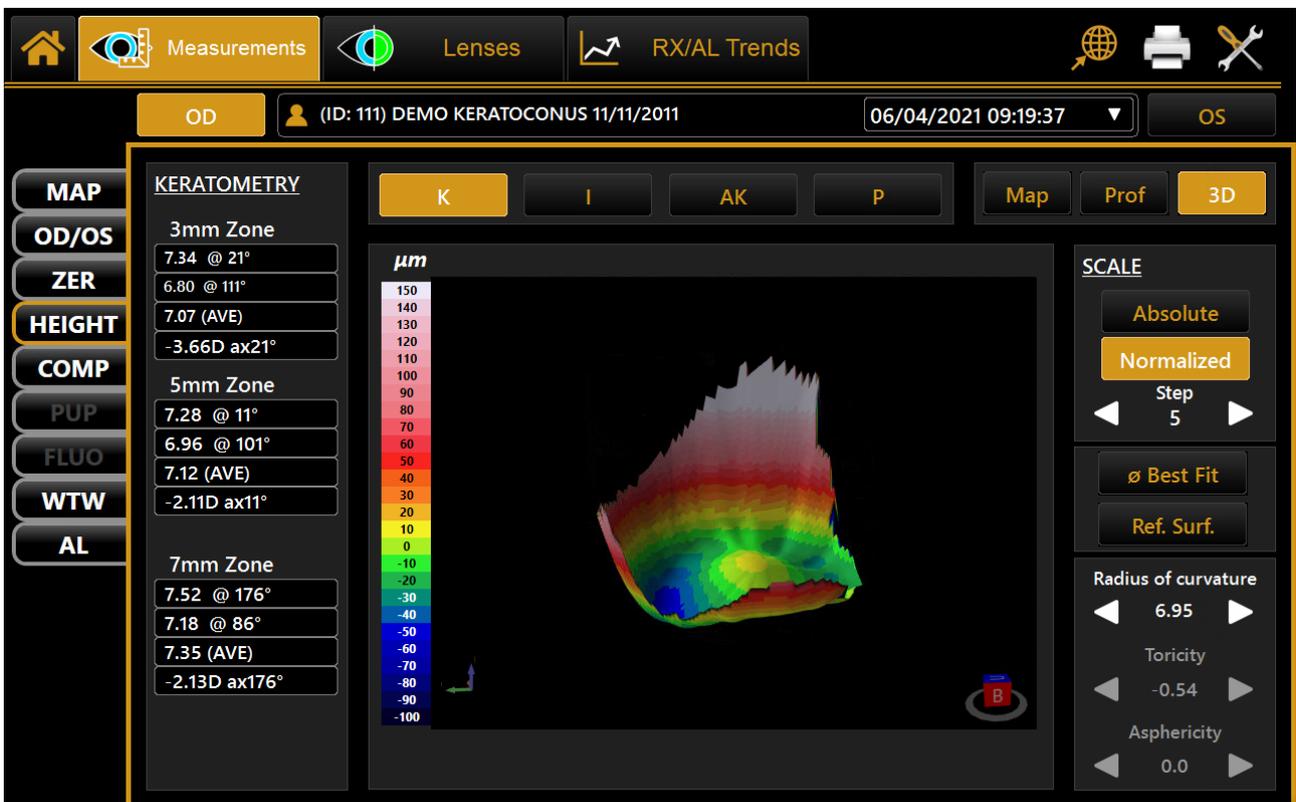


Fig. 47

14.5 COMP- COMPARISON

Comparison mode allows the user to compare the current exam data with the data of another exam for the same patient (Fig.48).



Fig. 48

When you select the **"COMP"** button, the interface shown in Fig.49 appears, and the software allows you to choose in a list of exams for the patient currently selected.

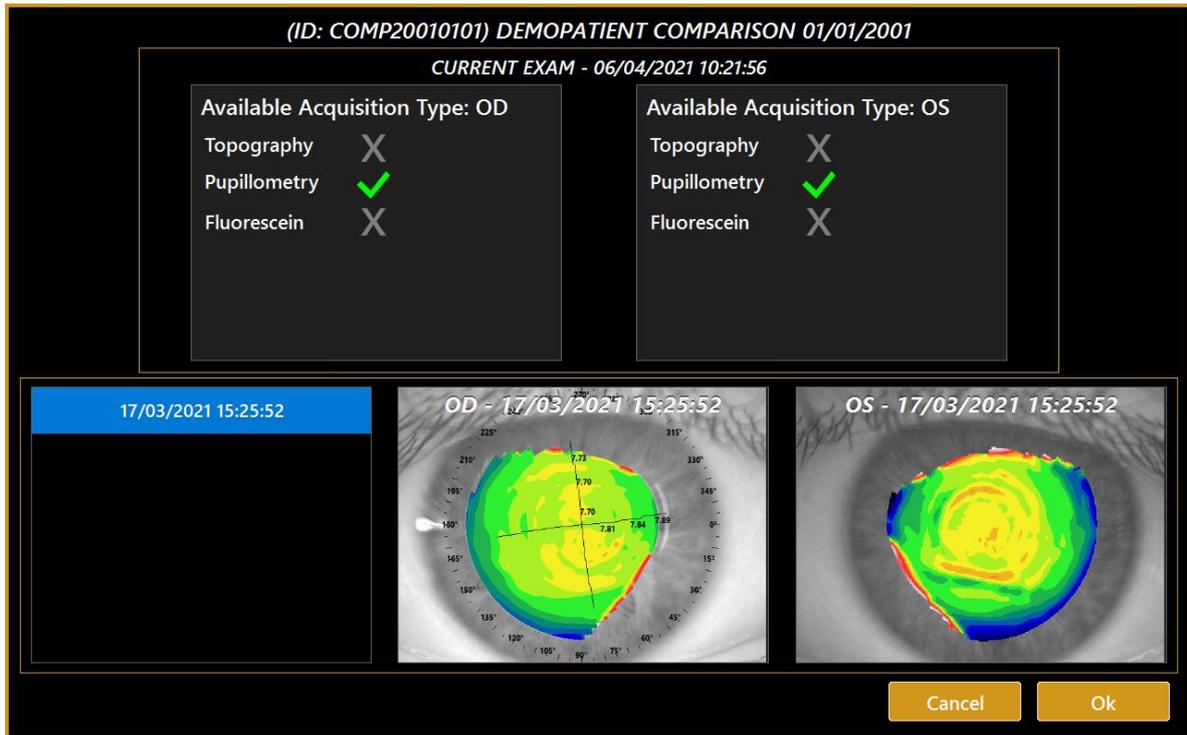


Fig. 49

In comparison mode, it is still possible to see the “K”, “I”, “KC” and “P” tabs; in addition, it is possible to select the “DIFF” button (see the related paragraph).

The user can also change:

- MAP: it is possible to choose between axial and tangential.
- SCALE: it is possible to choose between absolute and normalized; for the normalized map, the user can set the step.

It is possible to change the comparison exam by tapping on the “X” button at the top right corner of the comparison exam map.

14.5.1 DIFF-Differential

By tapping the "DIFF" button in comparison mode, the user switches to differential mode (Fig.50).

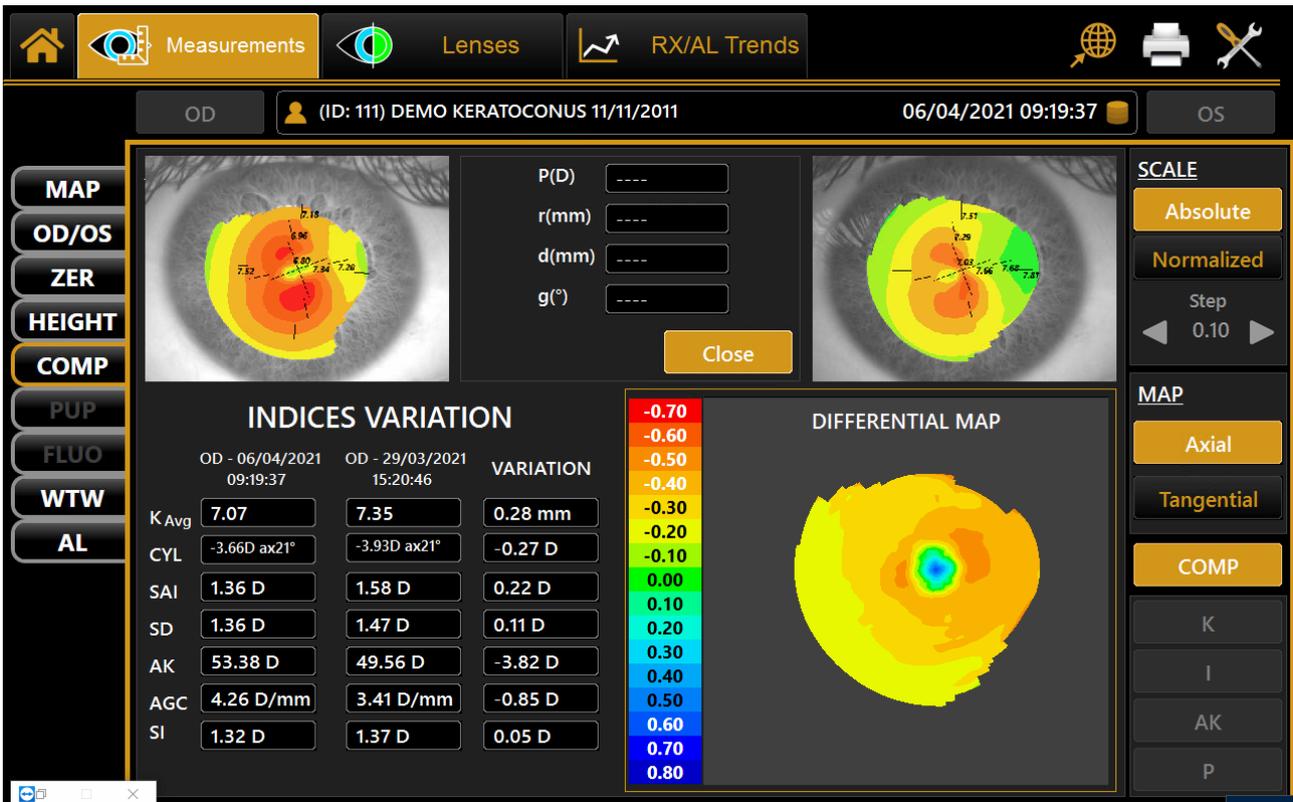


Fig. 50

In this section, it is possible to see the differential map between the current exam and the exam selected by the user.

Under the maps found at the top left and top right, there are the main indexes of the respective maps.

Above the differential map, four differential values appear after tapping on the differential map:

- **P:** is the difference between the dioptric power;
- **r:** is the difference between the radii of curvature;
- **d:** is the distance of the cursor from the centre of the image;
- **g:** is the angle of the cursor from the baseline.

The user can change the step of the differential map by tapping on the two arrows next to the step label.

Press the "COMP" button to go back to comparison mode.

14.6 PUP-PUPILLOMETRY

The pupillometry module allows the user to display and analyze the dynamic and static pupillometry (pupil images acquired in controlled light conditions).

Normally, if pupillometry is acquired, the software switches to dynamic mode (Fig.51).

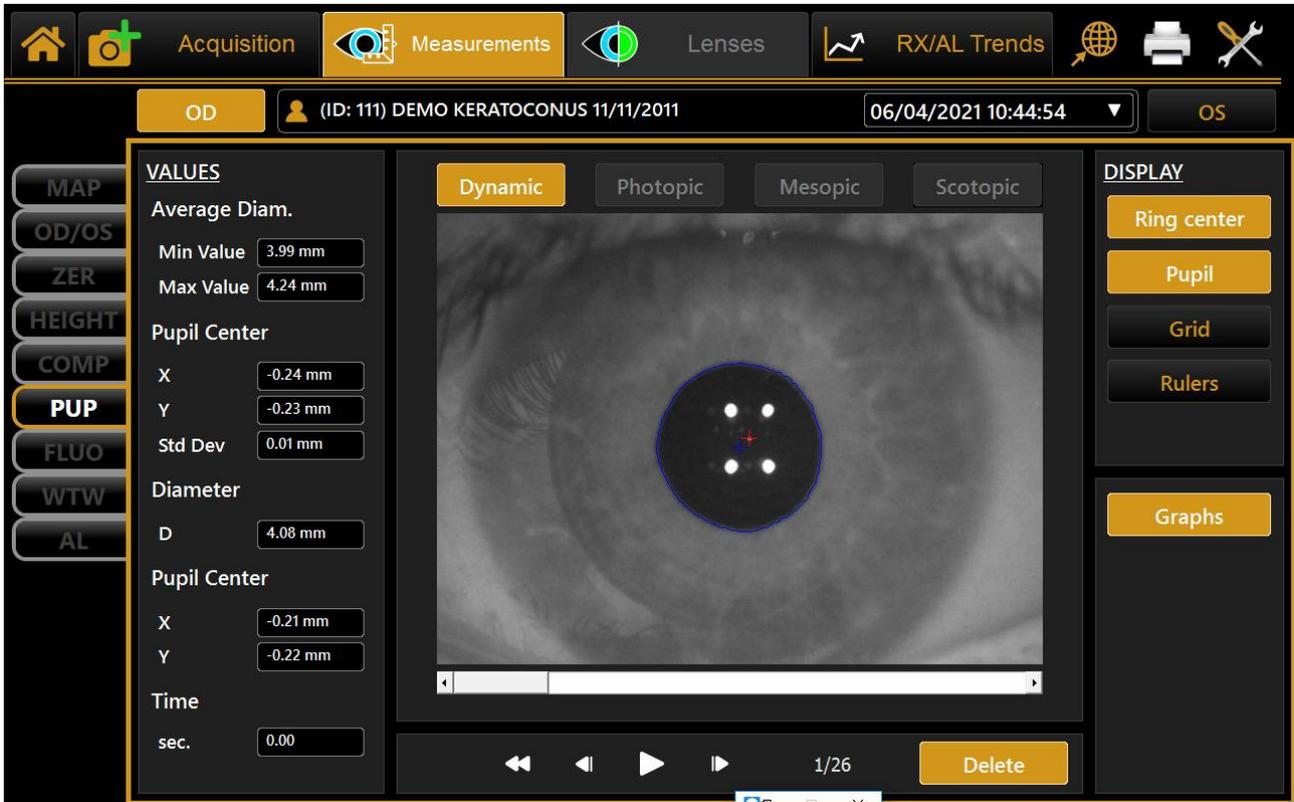


Fig. 51

Tap on "OD" or "OS" to display the pupillometry of the right or left eye, respectively.

With the patient's eye in view, the buttons will be located below the home screen. These buttons are used to navigate between the acquired frames. The current frame is shown next to the buttons.

14.6.1 Display

- Ring Center: Shows the position of the fixation point
- Pupil: Shows the blue ring, which highlights the pupil edges
- Grid: Shows an overlaid grid
- Rulers: Shows calibrated rulers

14.6.2 Sequences

The user can select the sequence of images to be displayed using the buttons at the top:

- Dynamic
- Photopic

- Mesopic
- Scotopic

The active buttons are those for which at least one acquisition is available.

14.6.3 Dynamic

By tapping on the **"Dynamic"** button to display the dynamic pupillometry in the left column, the following information will also be displayed:

- Average: Value of the maximum and minimum pupil diameter measured in all the images acquired during the sequence.
- Pupil Center: Cartesian coordinates of the average pupil center and its standard deviation.
- Diameter: Pupil diameter for the frame selected.
- Pupil Center (frame): Cartesian coordinates of the center of the pupil for the frame selected.

14.6.4 Photopic, Mesopic, Scotopic

By tapping on the **"Photopic"**, **"Mesopic"**, **"Scotopic"** buttons, static pupillometry acquisitions will be displayed with the following information:

- Value of the average pupil diameter measured for all the images acquired during the sequence.

The other information is the same as that already described for dynamic pupillometry.

14.6.5 Functions

Graphs

Press the **"Graphs"** button to display the graphs relating to the pupil. This function is explained in the next paragraph.

Delete

Pressing the **"Delete"** button, the system deletes the current pupillometry frame and the data it contains.

14.6.6 Graphs

In this section, three types of graphs are displayed:

- Decentration (Fig.52)
- Latency (Fig.53)
- Statistics (Fig.54)

In all these graphs, you can select the eye you wish to analyze by tapping on **"OD"** or **"OS"**.

The **"Close"** button closes the graphs.

Decentration:

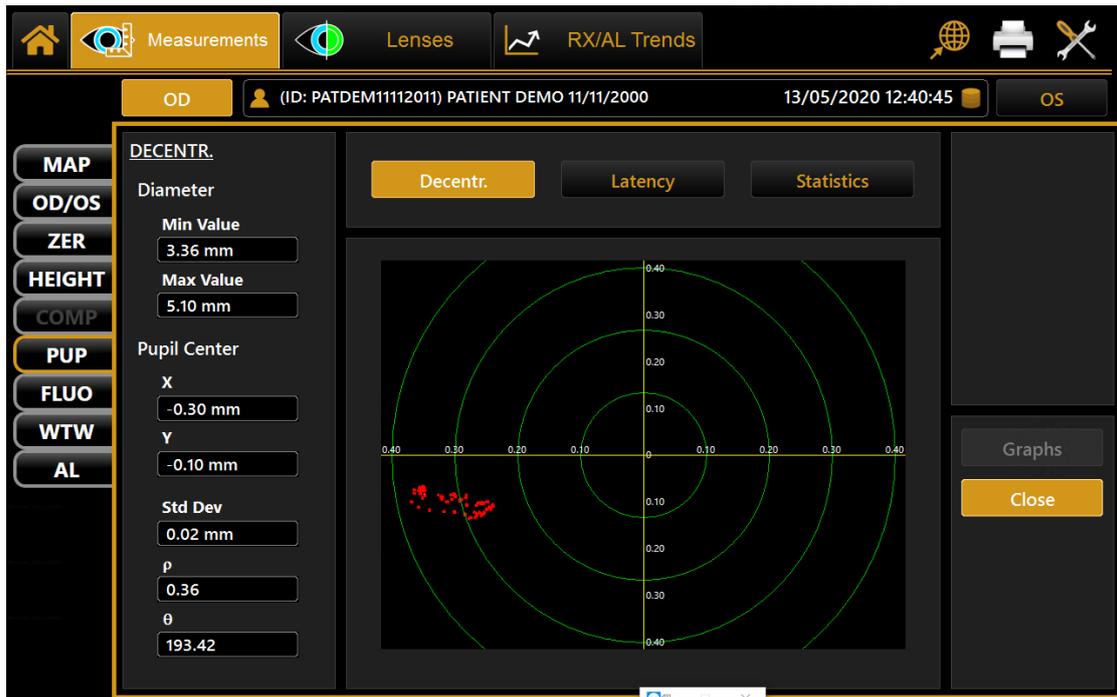


Fig. 52

The green concentric circles identify the decentration of the pupil center with respect to the fixation point. The red line, on the other hand, represents the coordinate variations during the acquisition of dynamic pupillometry.

Latency:

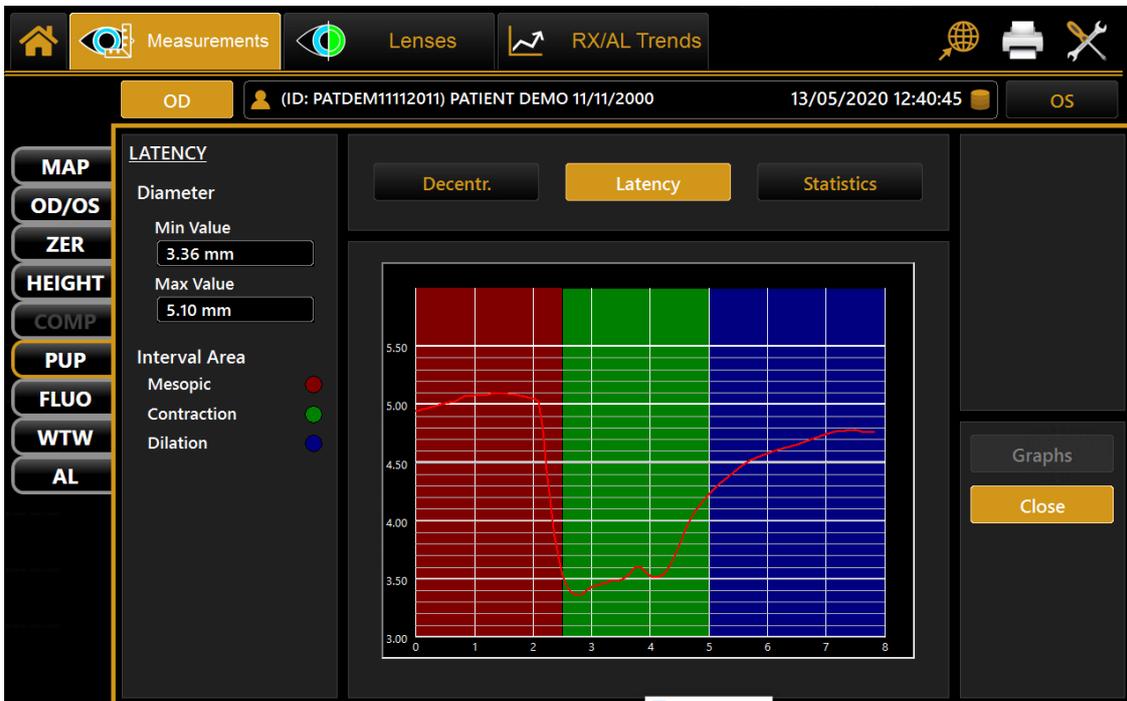


Fig. 53

The graph shows the time in seconds on the abscissa and the pupil diameter in mm on the ordinate, in a scale standardized based on the maximum and minimum value recorded. The progression of the pupil diameter over time is represented in the following.

Taking into account that dynamic pupillometry consists of acquiring various images under variable light conditions, from scotopic to photopic and back to scotopic, on the **"Settings"** screen, you can set the acquisition times for each mode (explained later). The left column shows the key to the graph.

- Red: for acquisition in scotopic light conditions.
- Green to indicate the pupil contraction phase following a change in brightness brought about by the LEDs coming on.
- Blue: for the pupil dilation phase following the change from LEDs on to LEDs off.

NB: These graphs are only available if dynamic pupillometry has been acquired.

Statistics:

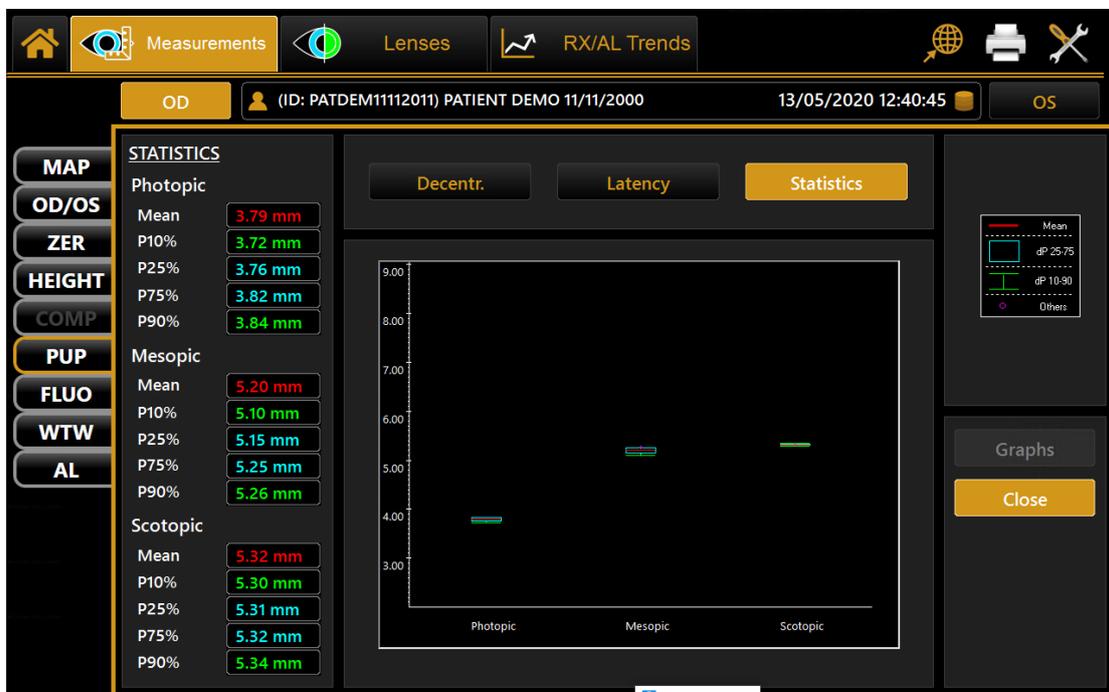


Fig. 54

The graph represents the percentile static value of the sample for each acquisition under controlled light conditions.

As indicated in the key on the right-hand side and by the values detailed on the left, the red row represents the average value of the sample, the blue frame the value interval between 25% and 75%, the green row the value interval between the 10% and 90%, and the red circle the values outside this interval.

The graph is displayed only if the images of the pupil have been acquired in photopic, mesopic or scotopic conditions.

14.7 FLUO-FLUORESCHEIN

The fluorescein module (Fig.55) allows you to assess the physical condition of the cornea and to verify the contact lens position and fitting towards the cornea.

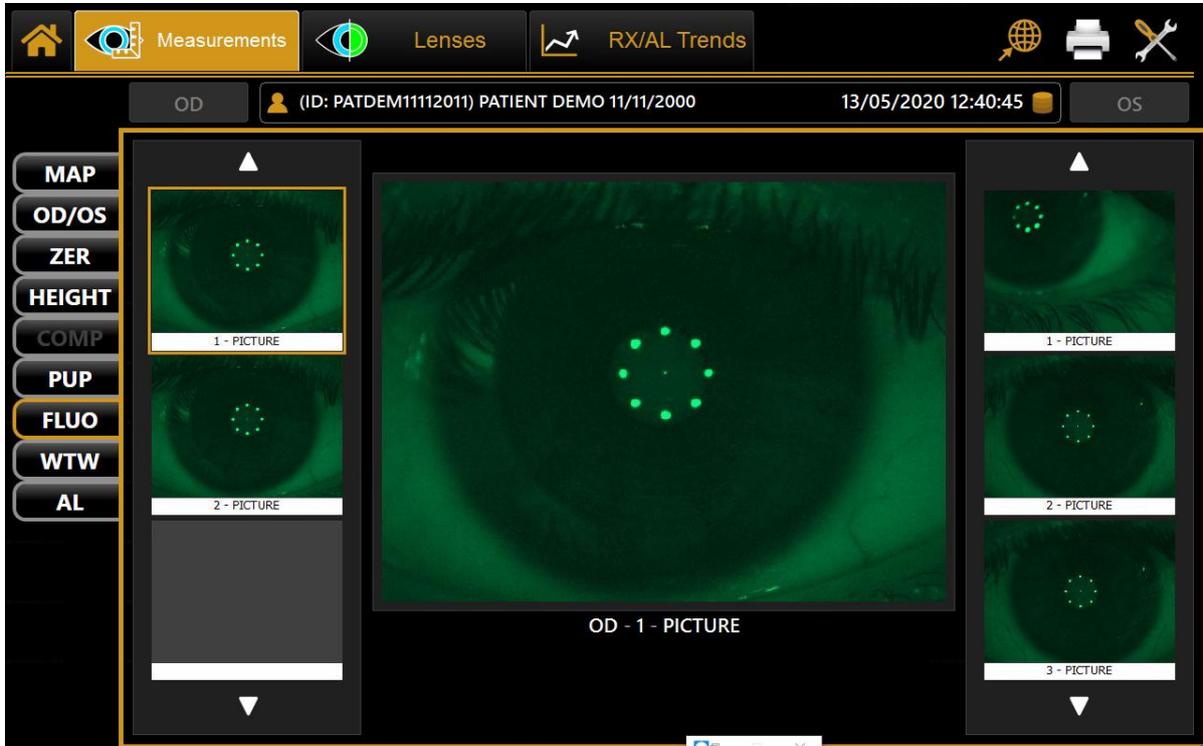


Fig. 55

The pictures and videos acquired can be viewed in the gallery.

When the fluorescein module is started, the first acquisition in the gallery is displayed in the main window.

Tapping on a picture, this is displayed in the main window.

Tapping on a video, it is played automatically.

Depending on the selection and the eye, the related picture or video will be highlighted.

The two numbers on the bottom right indicate the number of the image displayed in the main window and the total number of images in the gallery.

14.8 WTW – WHITE TO WHITE

The White-to-White section allows you to view the value of the corneal diameter calculated from the limbus (Fig.56).

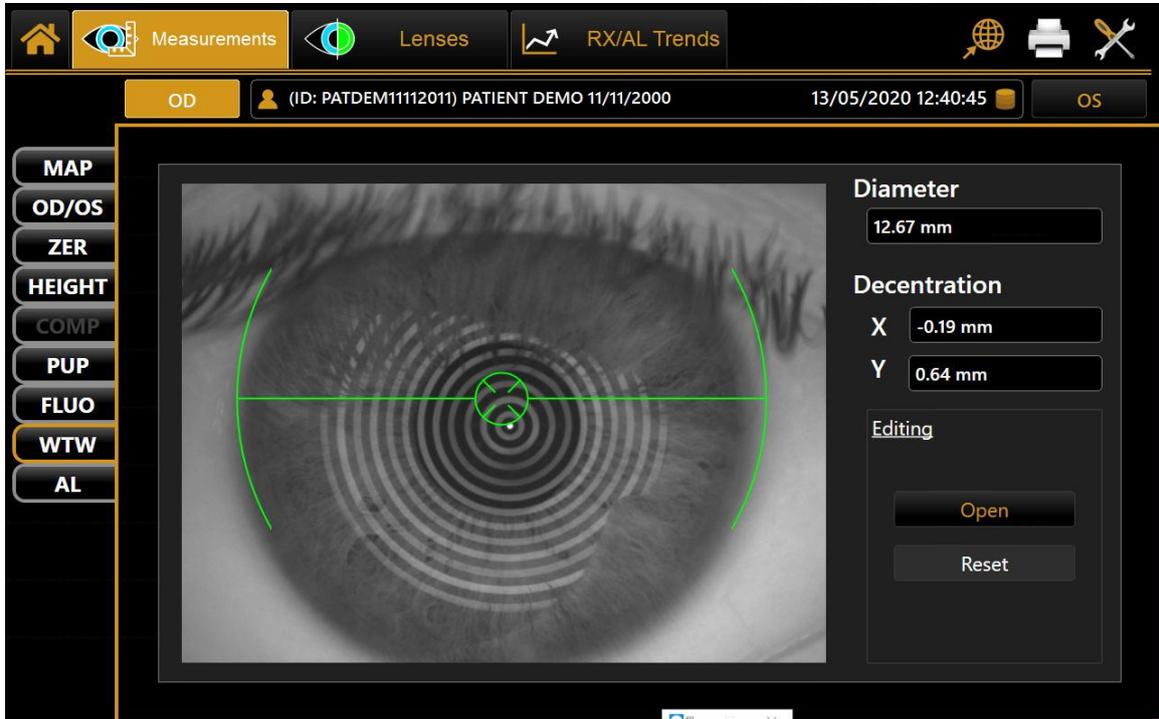


Fig.56

Tapping on the **Open** button in the **Edit** menu (Fig.57), the user can manually reposition the positional indicators in order to refine the diameter measurements.

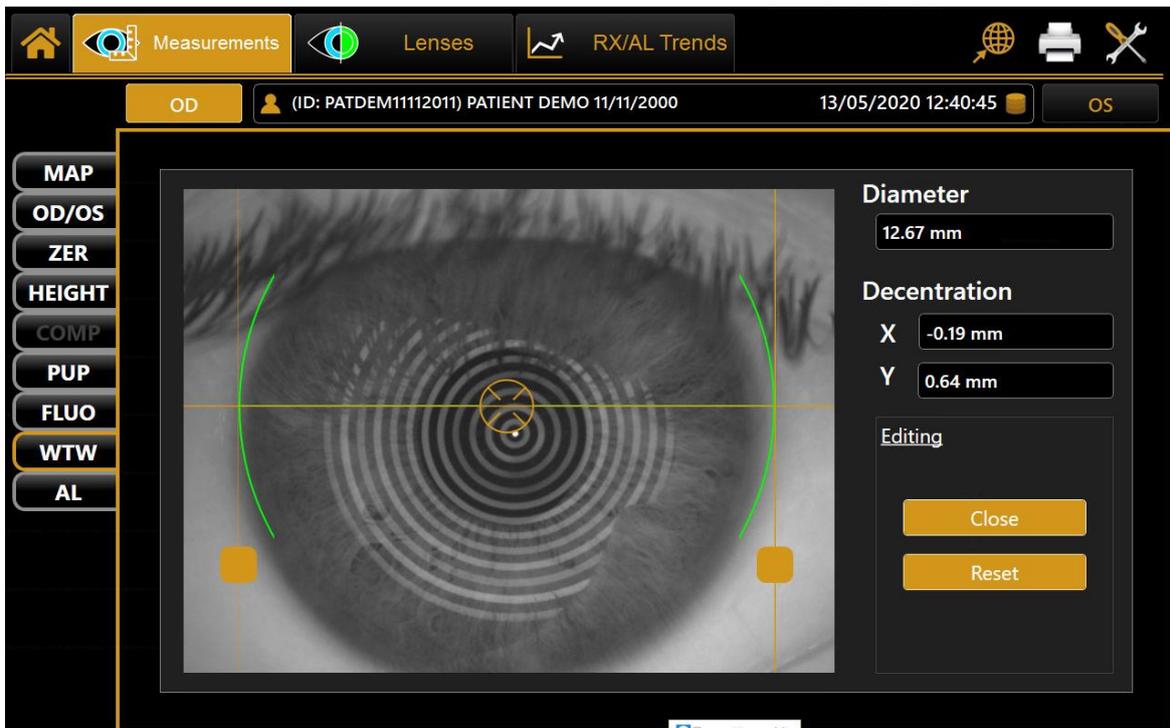


Fig. 57

Next to the image, obtained by automatic white to white calculation, you can see:

- Corneal diameter.
- Decentration: deviation from the center of the iris with respect to the fixation point

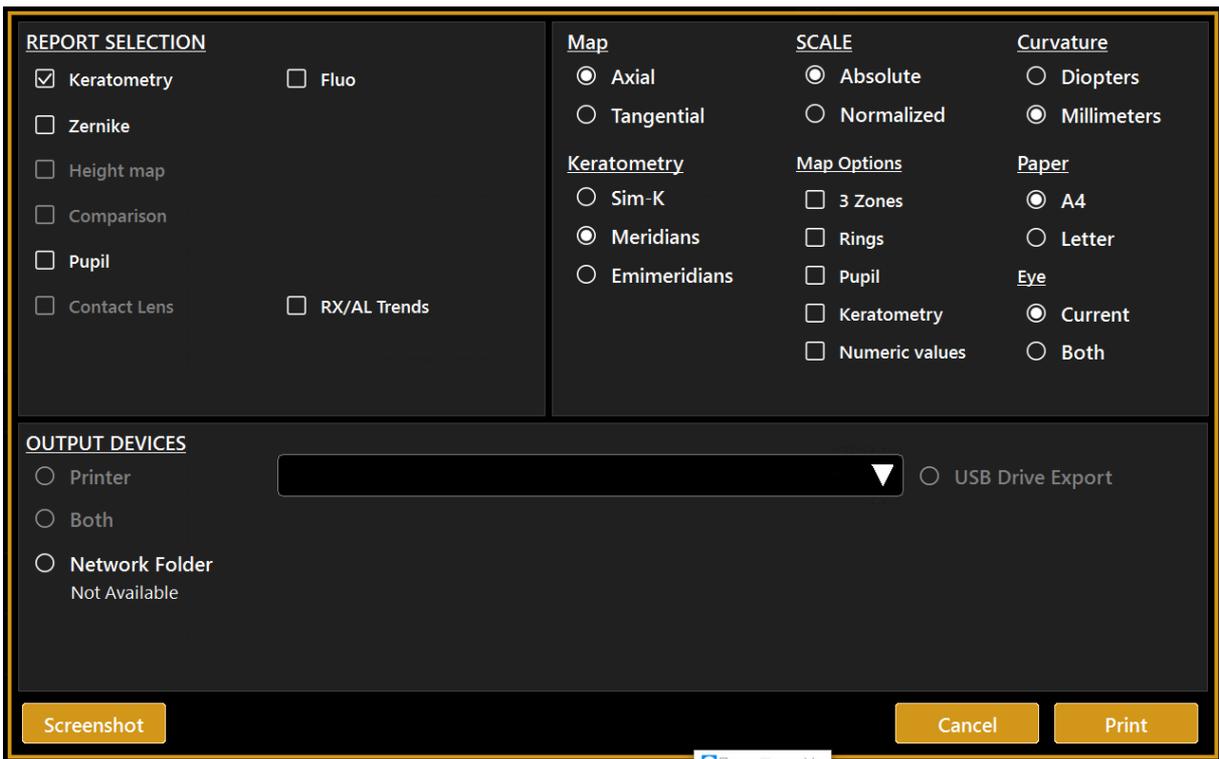
By changing the position of the indicators also the values of corneal diameter and the offset of the visual axis x and y are updated. The Reset button resets all the values to the ones obtained by the automatic system calculations.

15. REPORT PRINTING & SAVING

15.1 REPORT PRINTING

- In the measurements section, the user can print all the measurements made in the current exam.
- In the top-right corner of the screen, press on the  button to open the report printing panel (Fig.58).
- Three sections are available in the report printing panel:
 - *Report selection*: the user can select the type of report he/she wants to print; the height map, comparison, and contact lens report are available only in the related sections.
 - *Report settings*: the user can change the settings for report printing.
 - *Output devices*: the user can choose where he/she wants to export the selected report; both options refer to printer and USB drive export.

It is also possible to take a screenshot of the current view.



The screenshot shows a dark-themed report printing panel with the following sections:

- REPORT SELECTION**:
 - Keratometry
 - Zernike
 - Height map
 - Comparison
 - Pupil
 - Contact Lens
 - Fluo
 - RX/AL Trends
- Map**:
 - Axial
 - Tangential
- SCALE**:
 - Absolute
 - Normalized
- Curvature**:
 - Diopters
 - Millimeters
- Keratometry**:
 - Sim-K
 - Meridians
 - Emimeridians
- Map Options**:
 - 3 Zones
 - Rings
 - Pupil
 - Keratometry
 - Numeric values
- Paper**:
 - A4
 - Letter
- Eye**:
 - Current
 - Both
- OUTPUT DEVICES**:
 - Printer (with a dropdown menu)
 - Both
 - Network Folder (Not Available)
 - USB Drive Export

At the bottom, there are three buttons: **Screenshot**, **Cancel**, and **Print**.

Fig. 58

15.2 SAVING THE EXAMINATION DATA

After completing some acquisitions, in order to save the data from the examination, tap on the home button. As shown in Fig.59, the software will prompt the user to confirm the action.

If the user presses the **"Cancel"** button, the software will remain on the current screen.

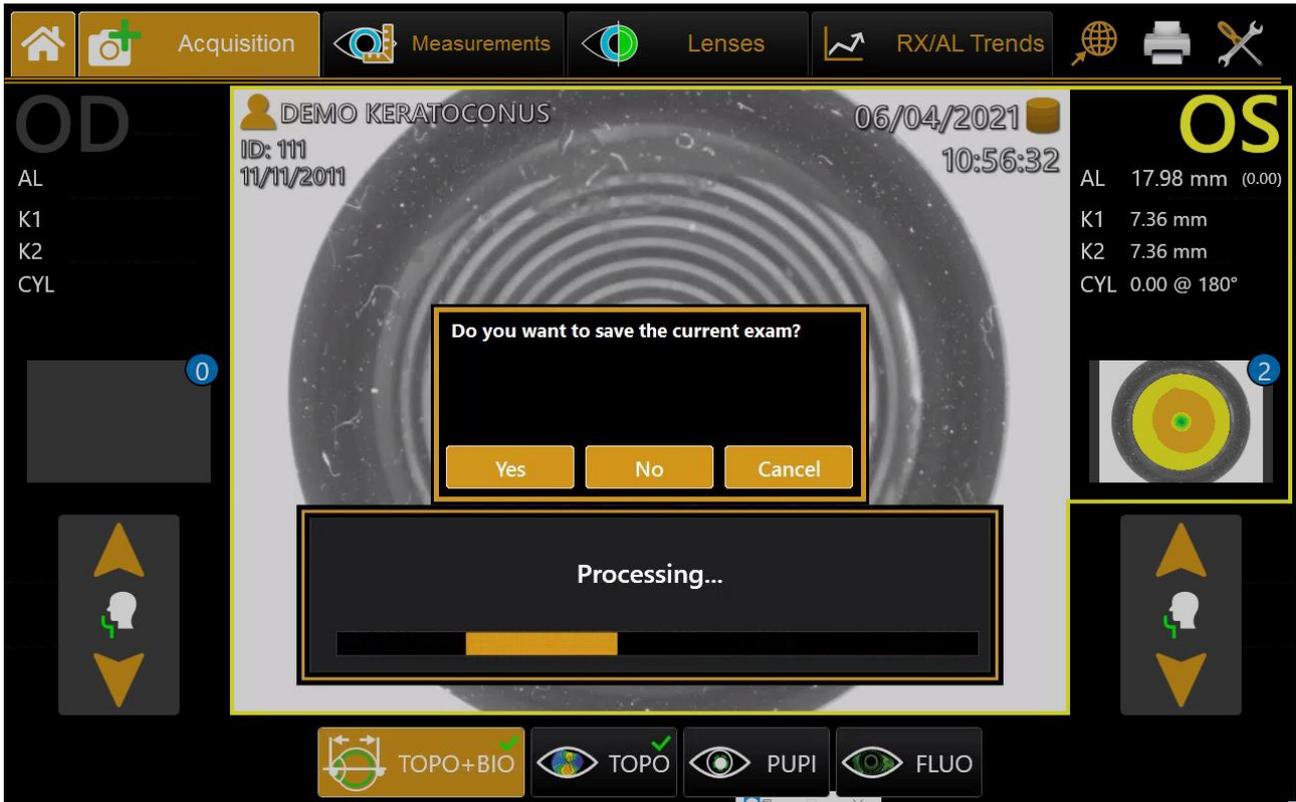


Fig. 59

16. LENSES

Contact Lenses: simulate contact lens fitting.

16.1 CONTACT LENSES



Note: This function calculates the difference between the patient's corneal shape measured by MYOPIA EXPERT 700 and the shape of the contact lens provided by the lens manufacturer under the setting which you set up in advance, and visualizes the calculation results.

Please note that this result does not represent the patient's actual status when he or she wears contact lenses.

The contact lens module (Fig.60) simulates contact lens positioning.

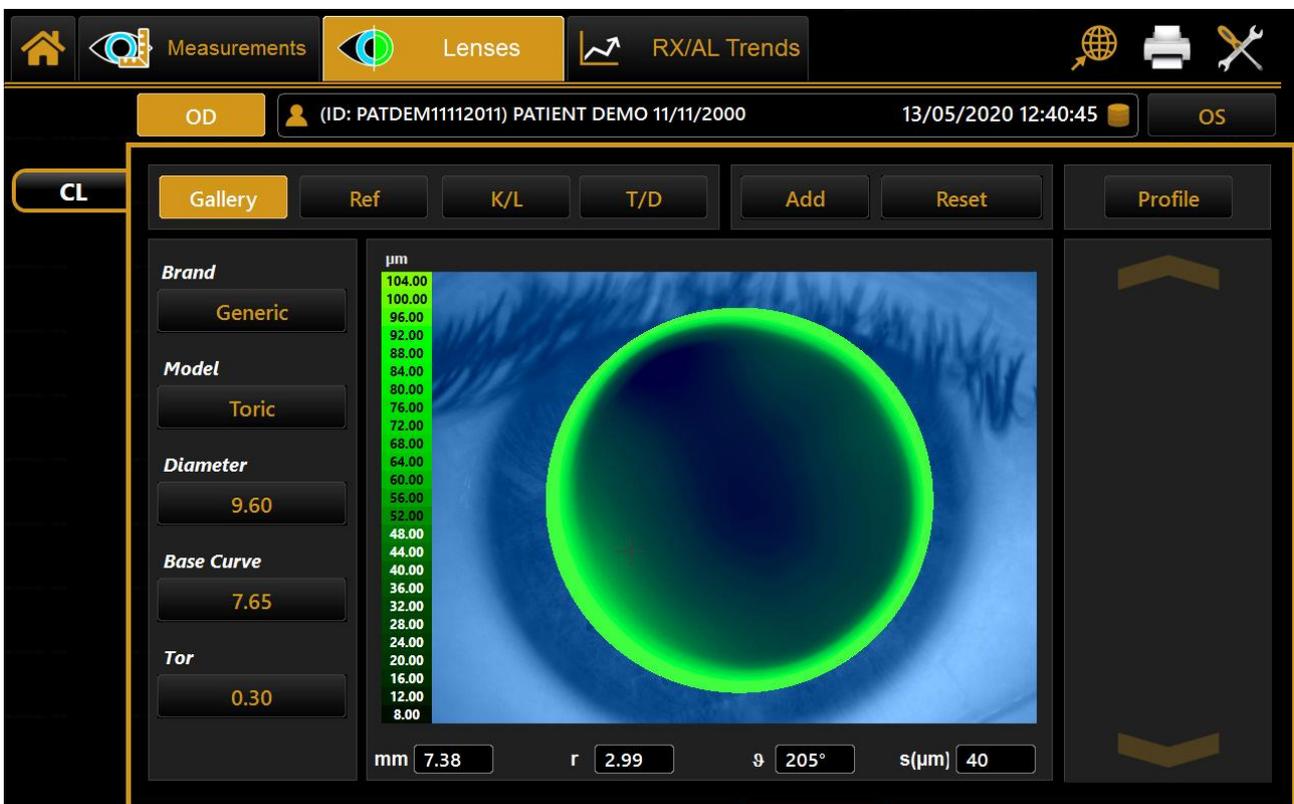


Fig. 60

Tap on the **"OD"** or **"OS"** button to view the lens in the right or left eye.

There are four main sections in the contact lenses module:

- Gallery
- Ref
- K/L
- T/D

16.1.1 Gallery

From this section, it is possible to select the brand, the model, the diameter, and the base curve of the lenses (Fig.61) and to add the favourite ones to the gallery on the right.

To add the favourite lenses, press the "Add" button. To cancel all the lenses shown in the gallery, press the "Reset" button. Instead, if you want to delete a single lens, you must tap on the "Recycle Bin" icon.

If more than three lenses are shown in the gallery, it is possible to scroll them using the arrows above and under the gallery.

16.1.2 Ref

In the ref section, the user can see the sphere, the cylinder, the axis, and the VD of the selected lens (Fig.61).

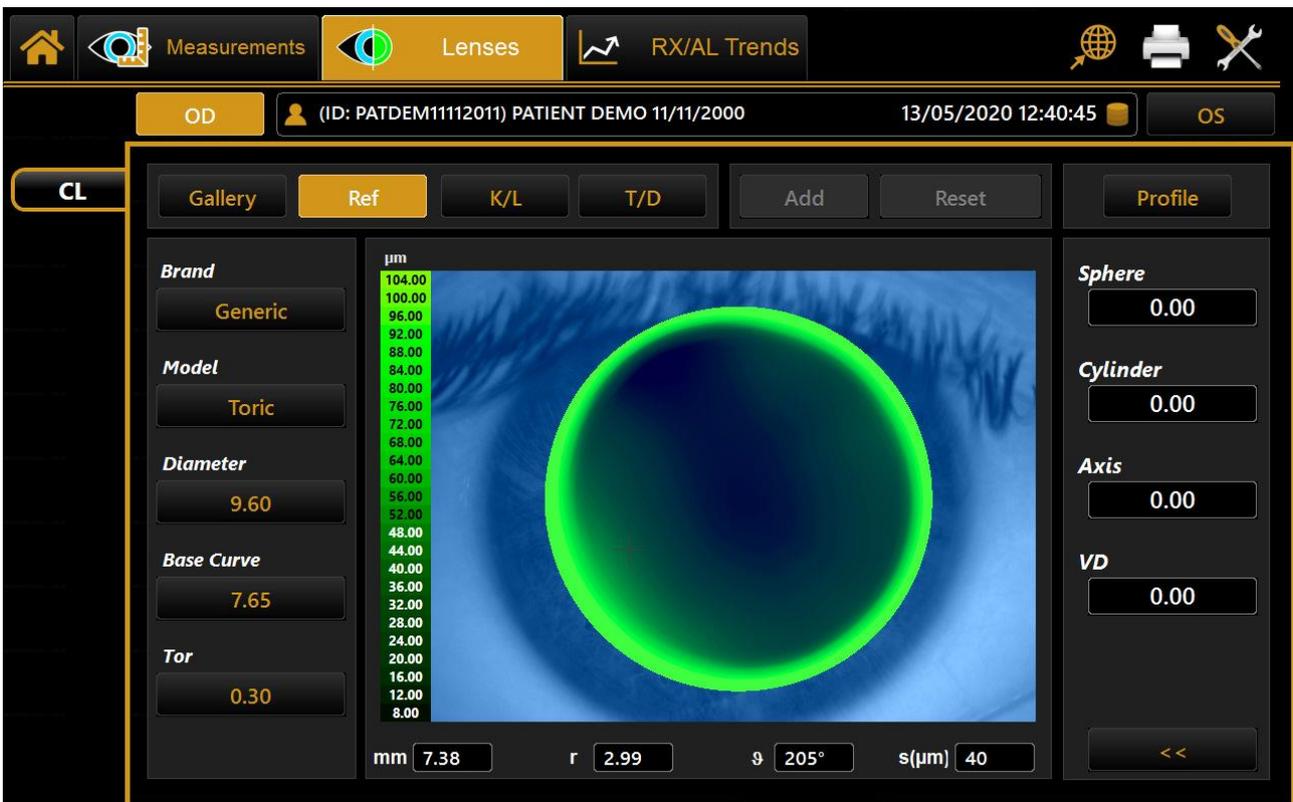


Fig. 61

In this section, it is also possible to edit these values by pressing the button found under the values: a tab will appear (Fig.62), and the user will be able to edit the values by pressing the related arrows found at the right of the value.

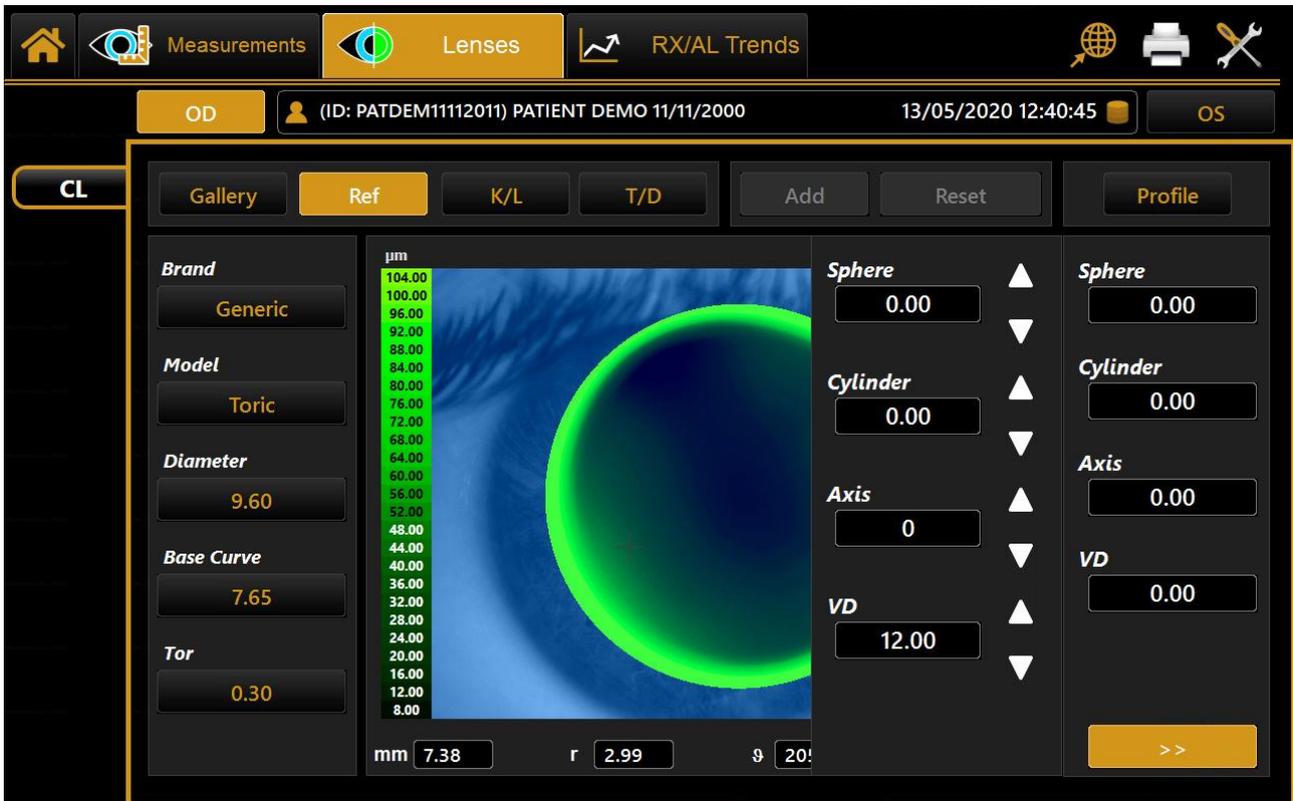


Fig. 62

16.1.3 K/L

This section displays information about the patient's eye (Fig.63) and namely:

- Keratometric data.
- Corneal diameter

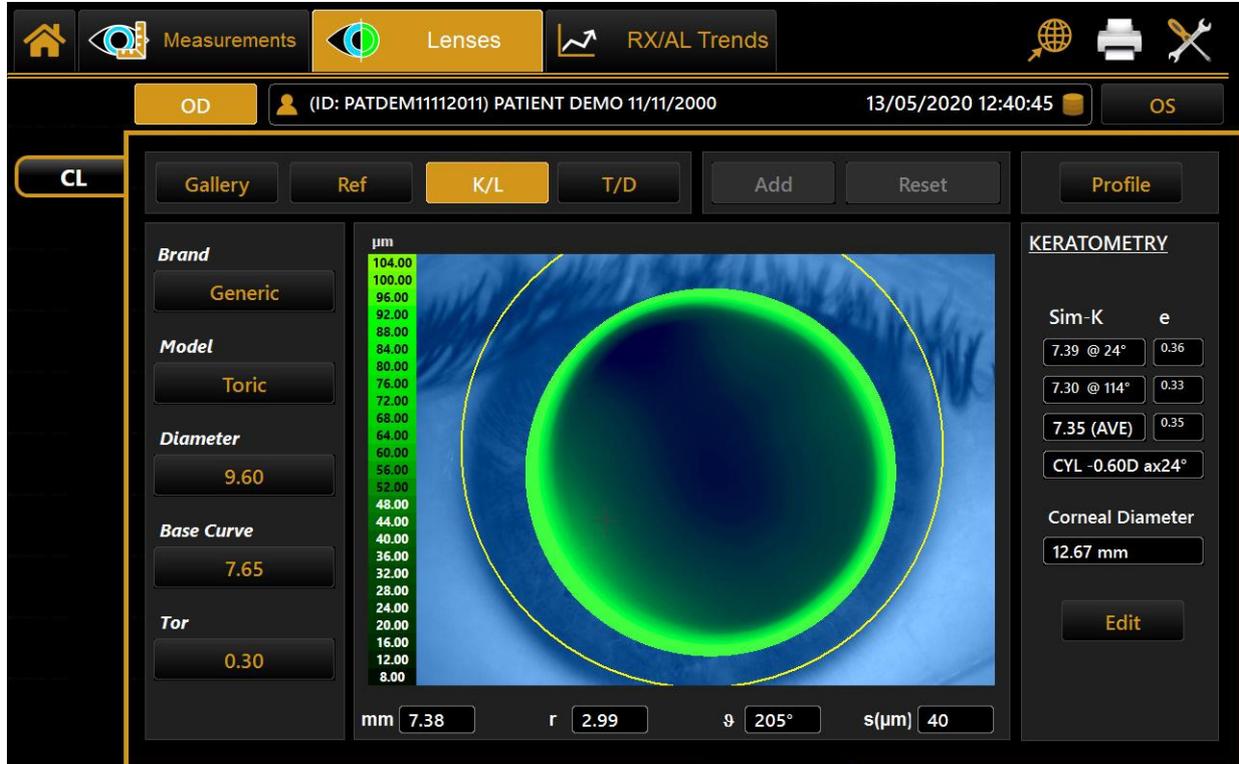


Fig. 63

In this section, it is also possible to edit the limbus by tapping on the **"Edit"** button. By pressing this button, the user will be required to select three points of the limbus; after selecting these points, the limbus line will be created.

16.1.4 T/D

This section displays the tilting and decentration of the selected lens (Fig.64).

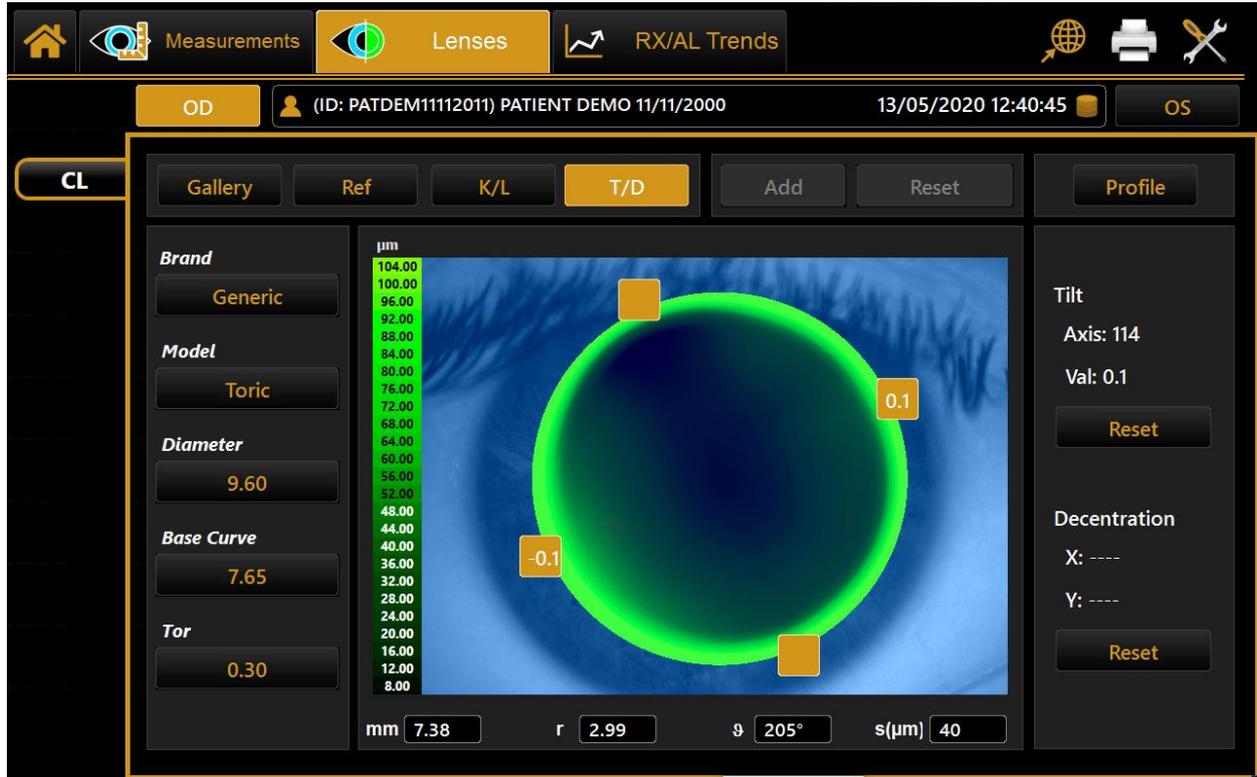


Fig. 64

The user can edit the tilt values by tapping on the yellow squares found around the lens, and the decentration values by dragging (using their fingers) the lens to the desired position.

16.1.5 Profile

In the profile section, the user can see the distance between the selected lens and the patient's cornea in a graph (Fig.65).

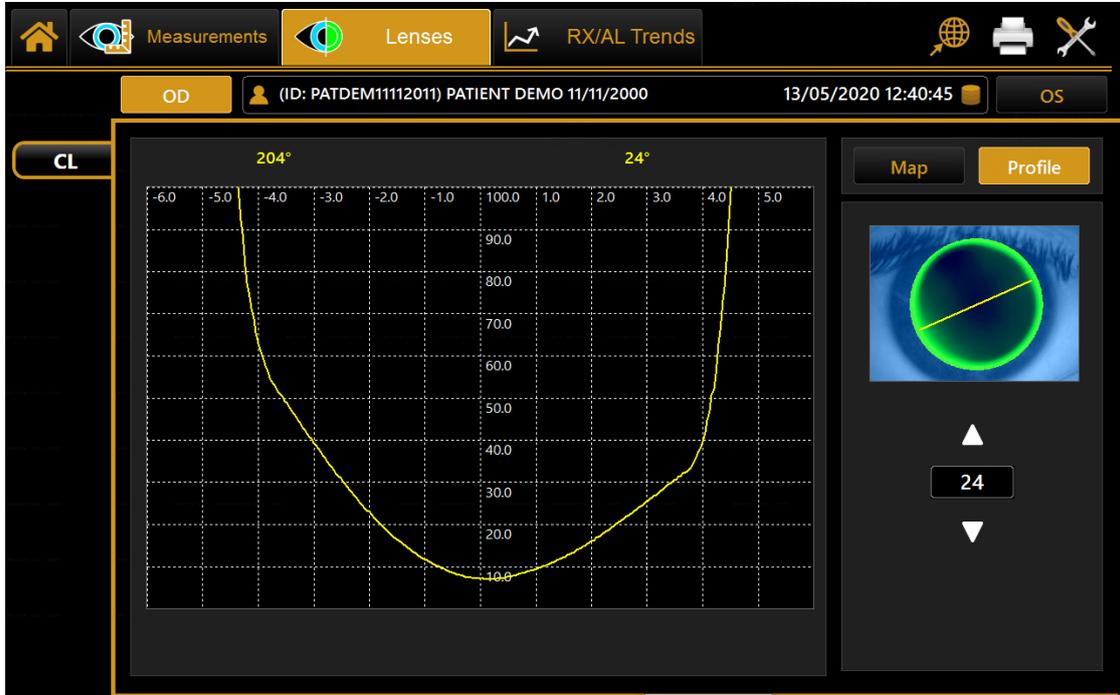


Fig. 65

The user can select the meridian where the distance is displayed by tapping on the arrows found above and under the meridian value.

17. SETTINGS



To access the “Settings” section, press the button:

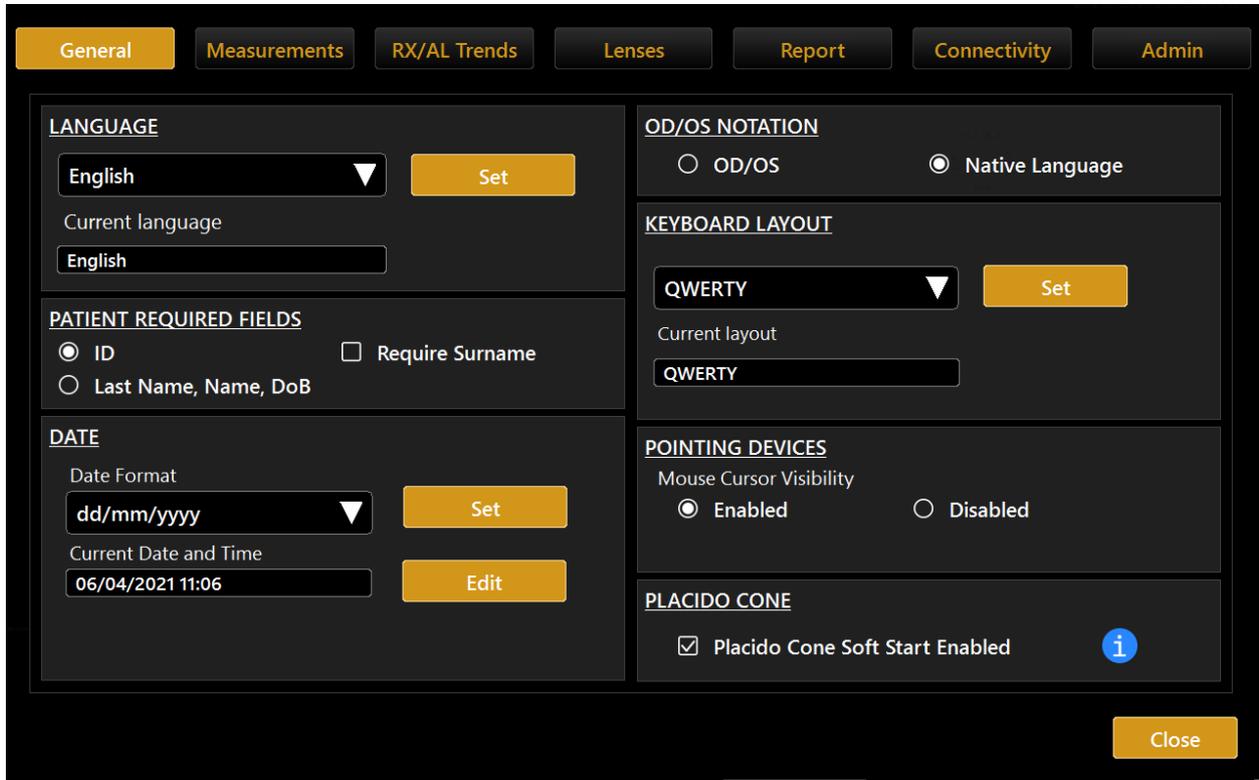


Fig.66

The settings screen is divided into the following categories:

- General
- Measurements
- RX/AL Trends
- Lenses
- Report
- Connectivity
- Admin

From each setting environment, you can close and return to the previous activity by selecting the “**Close**” button.

17.1 GENERAL

Refer to Fig.66:

- **Language:** The first time the program is started, the default language is set to English, and the keyboard layout is "QWERTY". To change the language settings, select the desired language from those that appear by tapping on the  button, press "Set" to set the chosen language for automatic starting. It is recommended to reboot the device to apply all the settings.
- **Keyboard Layout:** To change the keyboard layout, select the desired layout, and press "Set". You can display the updated layout in the personal details window ("Main").
- **Date:** Choose the desired date format and press the "Set" button. You can also set the current system date and time by tapping on the "Edit" button.
- **Pointing Devices:** Toggles the mouse cursor on or off.
- **OD/OS Notation:** To select how to indicate the eye being acquired in two different notations. The option OD/OS shows the Latin notation. The local language option shows the terms used for the left and right in the language set for the device.
- **Patient Required Fields:** Toggles between two different options of required fields for the creation of new patient's details. With ID only the ID is the only required field to insert when creating a patient. With this option, the patient list is by default shown by ID (can be changed to Surname and Name in the patient list view). If you select the option "Require Surname" (available only with the "ID Only" working mode), the software requires the surname when entering the patient's details.

17.2 MEASUREMENTS

The acquisition settings panel allows you to set the parameters for displaying the corneal map and acquiring and displaying fluorescein and pupillometry (Fig.67).

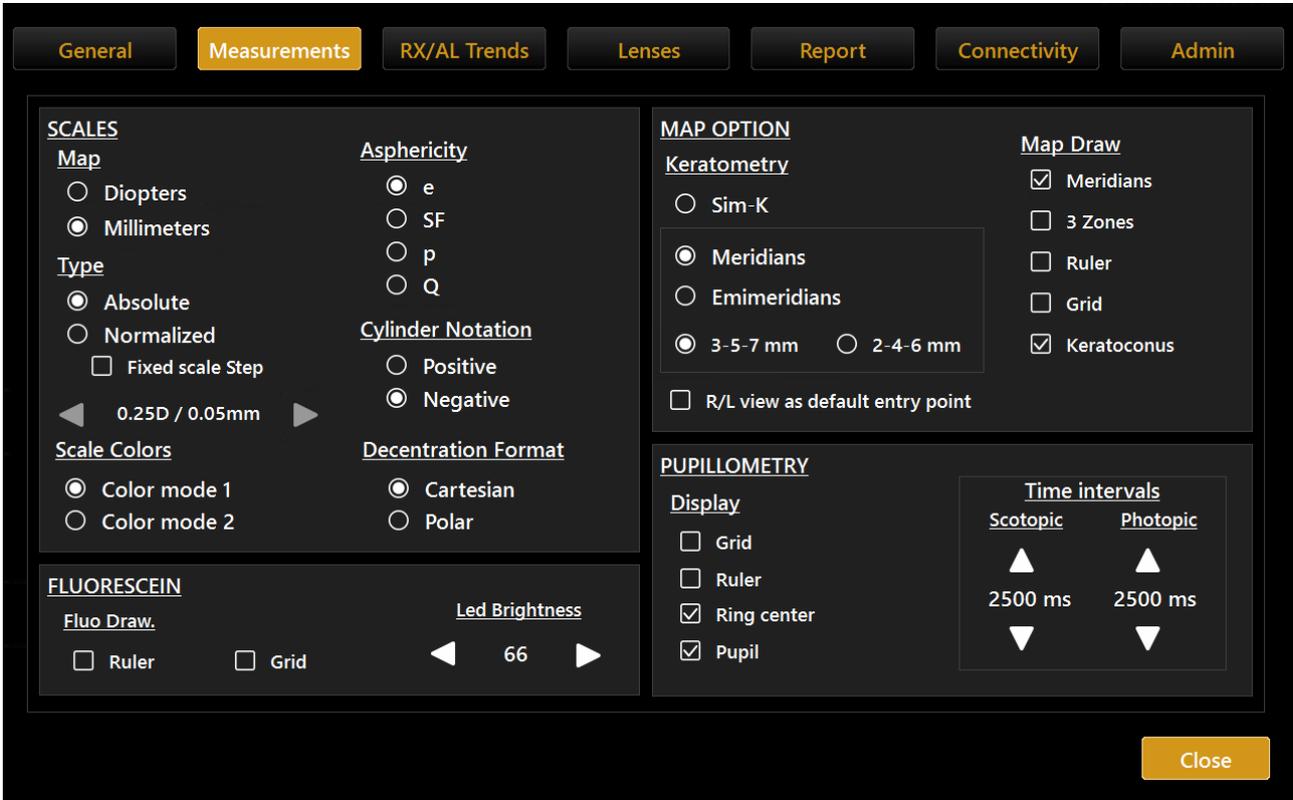


Fig. 67

17.2.1 Scales

Map

Select a unit of measure:

- Diopters
- Millimeters

This option is activated both for the acquisition screen and for the topographic map.

Type

Select a scale type:

- Absolute
- Normalized

Fixed scale Step: define a fixed step size for the normalized color scale

Asphericity

Select an asphericity unit of measure:

- e
- SF
- p
- Q

Cylinder Notation

Select a notation for cylinder calculation:

- Positive
- Negative

Scale Colors

Select between two color scales options:

- Color Mode 1



(Absolute scale)

- Color Mode 2



(Absolute scale)

Decentration Format

Select a decentration format:

- Cartesian
- Polar

17.2.2 Fluorescein

Fluo Draw

Select one or more items to customize the fluorescein display:

- Ruler
- Grid

Led Brightness

Select the led power in a range from 1 to 15.

17.2.3 Pupillometry

Display

Select one or more items to customize the pupillometry display:

- Grid
- Ruler
- Ring center
- Pupil

Time intervals

Select the time intervals, in a range from 500ms to 5000ms, of the scotopic and the photopic phase during the pupillometry acquisition.

17.2.4 Map Option

Map Draw

Select one or more items to customize the map display:

- Meridians
- Zones
- Ruler
- Grid

Keratometry

Select one of the keratometric indexes:

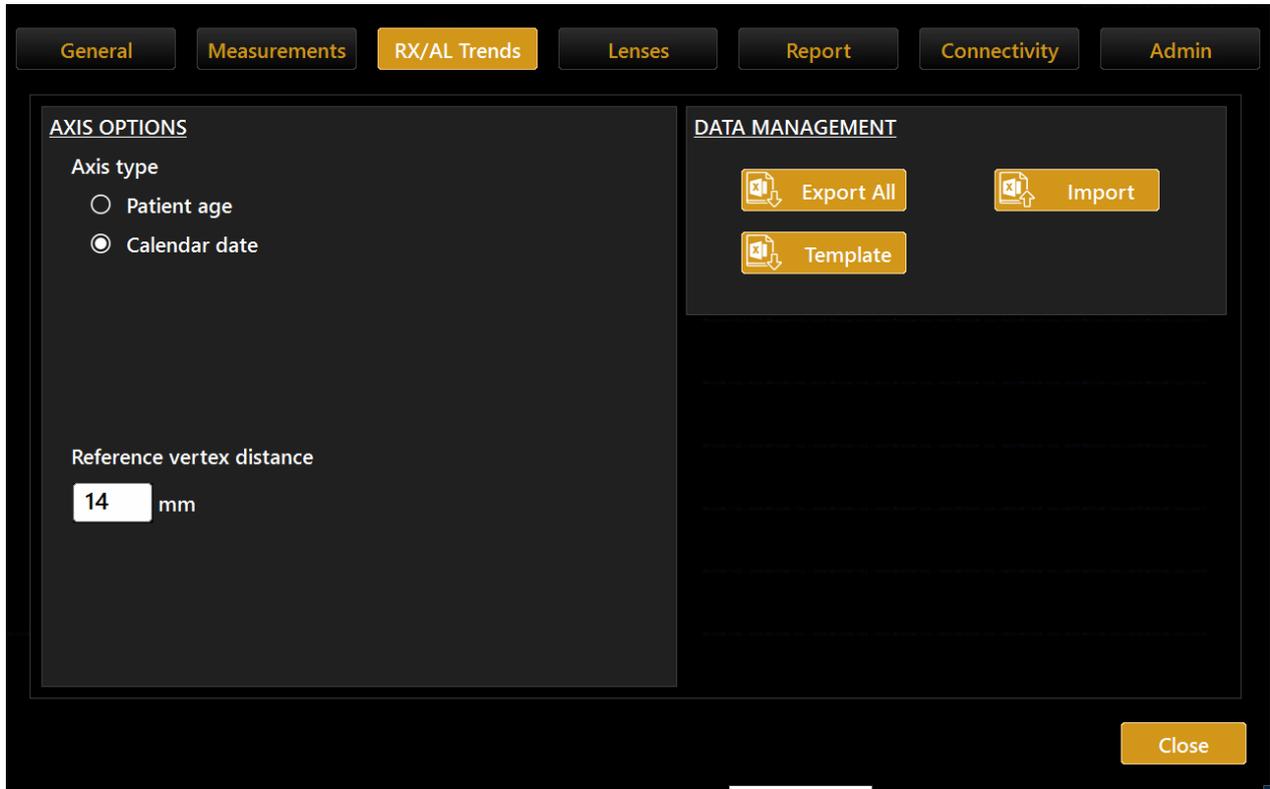
- Sim-K
- Meridians
- Emimeridians
- **3-5-7 mm or 2-4-6 mm**, selects the 3 Zones diameters to which the Meridians or Emimeridians values are displayed

R/L view as a default entry point:

Option to enter automatically in the R/L topography view instead of the MAP topography view when accessing the Measurements environment

17.3 RX/AL TREND OPTIONS

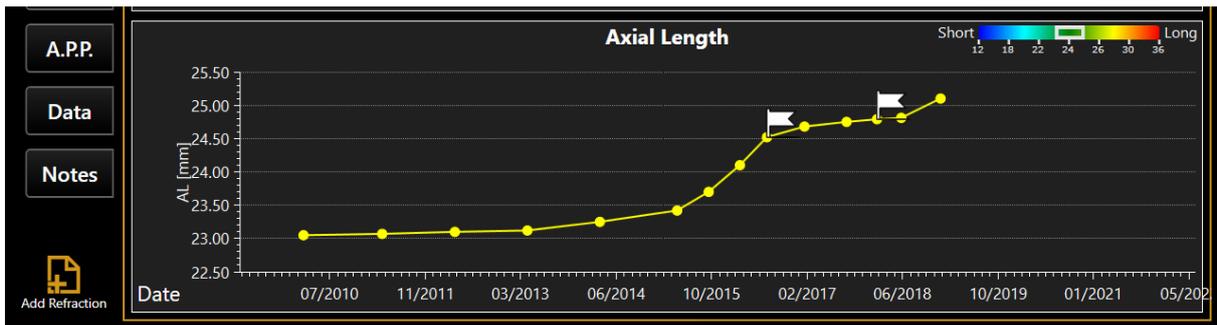
By pressing on the settings icon, you get access to the RX/AL Trend related options.



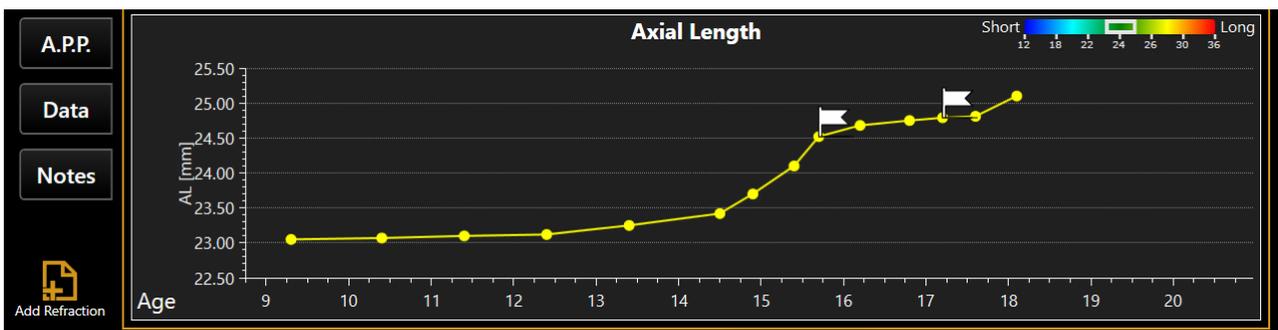
Time Axis Options

The charts shown in the Data Review section can have the time axis visualized by:

- Date, calendar date of examination data



- Age, patient age at the date of examination data



If the Age option is selected for the Time Axis, the Fixed age range can be enabled/disabled and configured. If the fixed age range is enabled, at least the age range defined by the two related values will be displayed in the time axis. Data eventually exceeding such range will be shown as well.

Refraction Options

The reference vertex distance value will determine the vertex distance (VD) to which all the refraction data will be shown in the charts (transposed if input VD was different).

Data Management:

- **Import data from** predefined sheet template file. A dialog to select a file from a connected USB pen drive will be shown.

In this action can be imported data for:

- The currently active patient (will be matched by ID)
- Another patient already existing in the archive (will be matched by ID)
- A patient not present in the archive (a new patient will be created if at least ID and date of Birth are specified in the sheet; otherwise, the data will be ignored)
- **Export template:** create on the connected USB drives an empty sheet template file, to be filled externally and used for the importation of previous/already existing data.
- **Export** data of all patients within an Excel file of the same format as the template used to import data

DATA IMPORT TEMPLATE SHEET

IMPORTANT: Do not alter the structure of the sheet!

Patient				Examination				Refraction/Overrefraction				Over Refraction info			Biometry				Note
ID	LastName	Name	DOB	Gender	Eye	Rx VD (mm)	Rx Sphere (D)	Rx Cyl (D)	Rx Cyl Axis (Deg)	Rx type	Eye Status	Lens Power SE (D)	Base Curve (mm)	AL (mm)	ACD (mm)	LT (mm)	APP (D)	Test note	
PatientID			25051997	M	Rx	10/07/19	12.00	-2.62	0.00	Subjective	Normal	-2.00		25.67	4.00	3.48	64.37		
PatientID			25051997	F	Lx	10/07/19	0.00	-4.37	-0.25	172.00	Objective								Note: Only First Test Note for each Patient/Exam date is imported and reported

This sheet is to be used for importing a set of data automatically into the RX/AL Trend data collection.

The sheet can be arranged to contain data for different patients and both Right and Left eye.

Each row of the can contain data for:

- Patient identification
- Eye examination data identification
- Biometry data
- Refraction Data
- Note belonging to the examination date

REQUIRED DATA (for each row)

- **Patient ID:** patients already present in the archive will be matched by this field
- **Patient Date of Birth:** required to import patients who are not already existing in the archive
- (if the DoB is not specified the patient will not be created and the related data ignored)
- **Examination Eye** (right or left only accepted values)
- Examination Date

IMPORTATION RULES

- If the compulsory data is not provided the single sheet row will be ignored
- Patients not already present in the archive
- The Dates (patient DoB and Exam Date) will be parsed according to the **Date Format** selected in the settings of the application. Not compatible dates will cause the row to be ignored.
- If in relation to a single examination date/patient ID there is more than one row (typically two for each Exam Date of a patient for Right and Left eye):
 - Only the first occurrence for each eye will be imported
 - Only the note (if present) of the first occurrence will be imported

EXAMPLE

Data for one Examination date of Patient with a date for both Right and Left eye

Patient					Examination		Refraction/Overrefraction				Over Refraction Info		Biometry				Note	
ID	LastNam	Name	DoB	Gender	Eye	Rx VD (mm)	Rx Sphere (D)	Rx Cyl (D)	Rx Cyl Axis (Deg)	Rx type	Eye Status	Lens Power SE (D)	Base Curve (mm)	AL (mm)	ACD (mm)	LT (mm)	APP (D)	Text note
PatientID		20051931	M	01	R	10/0715	0.00	-2.52	0.00	0.00	Subjective	-2.00		25.67	4.00	3.40	44.37	Note: Skip First Test Note for each PatientExam date to imported
PatientID		20051931	F	01	L	10/0715	0.00	-4.37	-0.25	172.00	Objective							not imported

DATA DESCRIPTION

- Patient Identification

Patient				
ID	Surname	Name	DoB	Gender
Patient ID	Surname	Name	11/11/2011	M
Patient ID	Surname	Name	11/11/2011	M

- Eye Examination identification:
 - Eye identification and Exam date

Examination	
Eye	Date
Rx	07/05/2019
Lx	07/05/2019

- Refraction Measurement Data

Refraction/OverRefraction						Contact Lens	
Rx VD	Rx Sphere	Rx Cyl	Rx Cyl Axis	Rx type	Eye Status	Lens Power SE	Base Curve
12	-2.22	0	0				
12	-2.80	0	0				

- Vertex Distance in mm relative to the refraction measurement
- Refraction measurement in preferred notation (positive cylinder notation or negative cylinder notation)
- Rx type:
 - Subjective or Objective
 - Eye status: condition at the moment of refraction measurement
 - Cycloplegia or Normal
 - Contact Lens data (in case of Over Refraction measurement)
 - Lens Power SE in Diopters
 - Base Curve of contact lens in mm
- Biometry Data

Biometry			
AL	ACD	LT	APP
25.02	3.6	4.02	45.2
25.15	3.8	4.2	44.7

- Axial Length [mm]
- Anterior Chamber Depth (Epithelium to Anterior Capsule) [mm]
- Crystalline Lens Thickness [mm]APP (Average Pupillary Power) [D]:
- Corneal Power in the entrance pupil optical zone

17.4 LENSES

It allows you to manage your lens database (Fig.68).

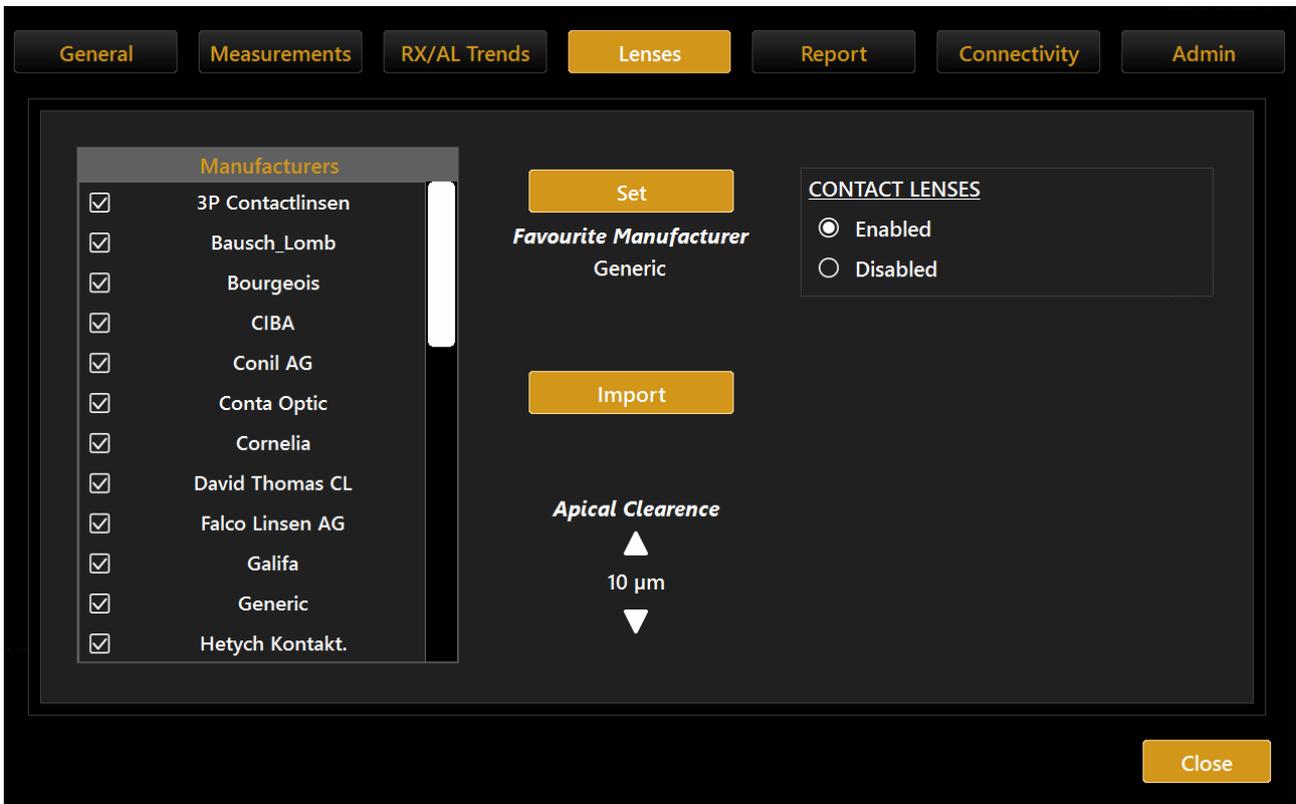


Fig.68

A brand list is displayed to the left.

Tap on the **"Import"** button to add new manufacturers to the database. You can import new manufacturers using a USB pen-drive.

Check the manufacturers you want to include in the list of available lenses for the contact lens fitting module.

Select the desired brand and press **"Set"** to set the favorite manufacturer. When you enter the lenses module, this will be the default manufacturer.

Set the apical clearance using the up/down arrows.

17.5 REPORT

Clinical Information

It allows the user to edit the header and the logo that will be printed at the top of the report page (Fig.69).

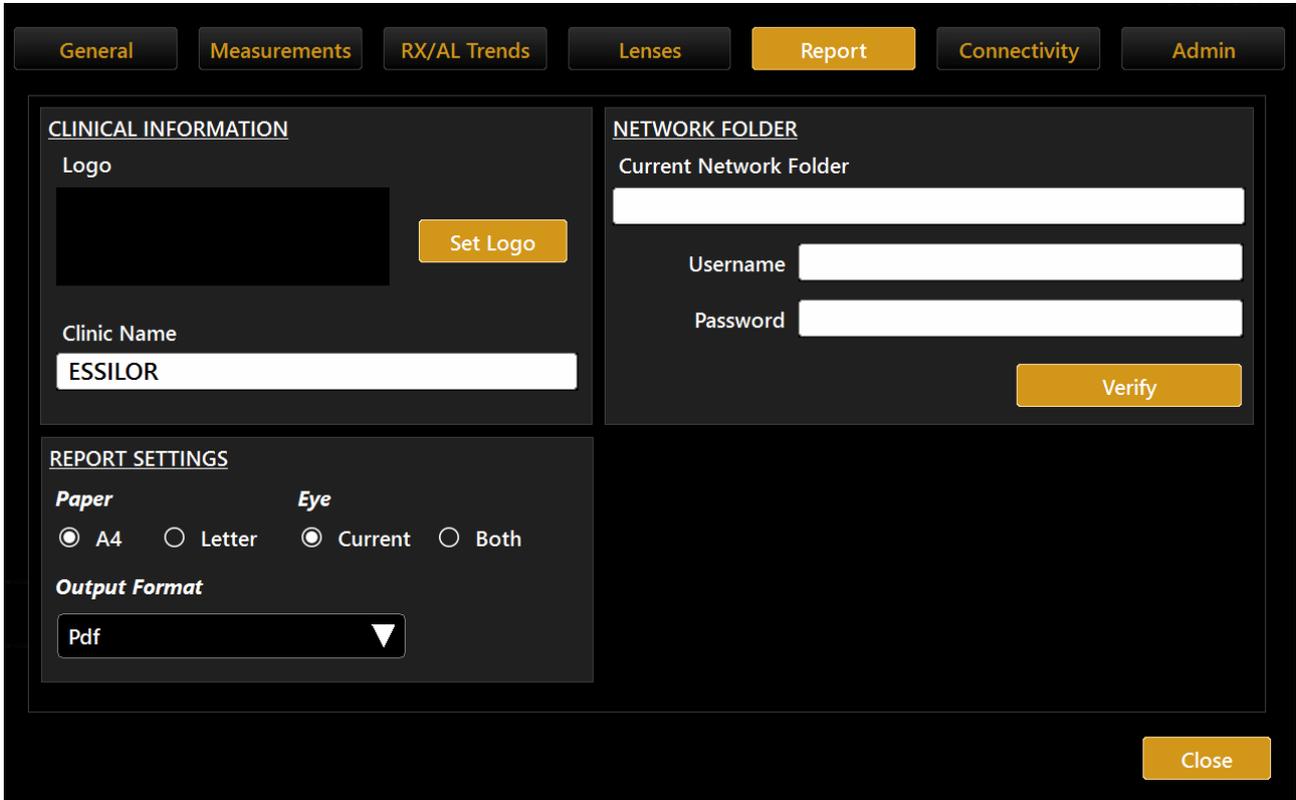
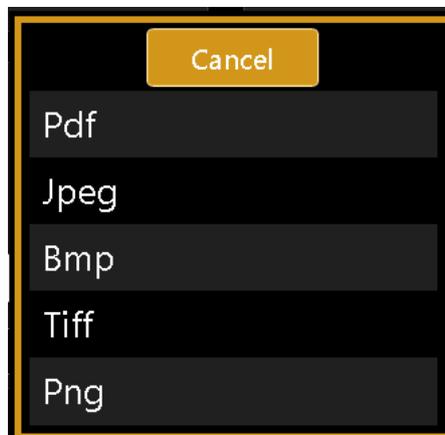


Fig.69

17.5.1 Report Settings

It allows the user to set the default paper type and to choose whether the report will be for one eye or both.

It is possible to set the output format of reports exported to a network folder. The available formats are Pdf, Jpeg, Bmp, Tiff, Png.



17.5.2 Network Folder

It allows the user to configure and use a remote network folder to store MYOPIA EXPERT 700 reports.

This resource will then become selectable as the destination in the report print form.

To allow MYOPIA EXPERT 700 to connect to the remote network folder, you must configure the MYOPIA EXPERT 700 settings with the correct access credentials for the remote resource.

Configuration parameters:

- *Network folder path*: the path to access the network folder location (without trailing backslashes)

e.g.,

\\server\path_on_server

- *Domain name (optional) and user name*: user name associated to an optional domain name that have the authorization to access to a specified network folder path



Note: if the specified network folder is part of another computer, the computer name must be entered as the domain before the user name

e.g.,

domain name\user name

- *Password*: for the specified user name

Tapping on the "**Verify**" button, the system starts searching for the network resource. This procedure may take some time, depending on the network. Failure or success to connect to the network resource will be reported, as shown in Fig.70, and Fig.71. A connection failure may be due to an unreachable resource path or to wrong credentials.

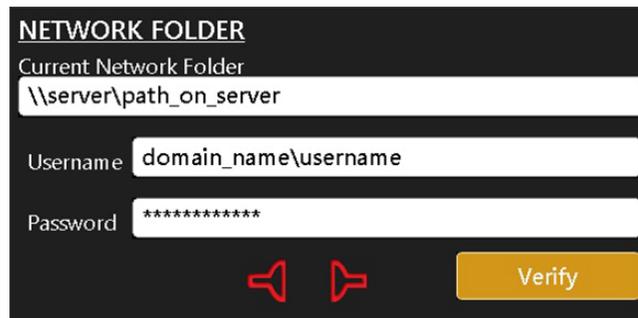


Fig. 70

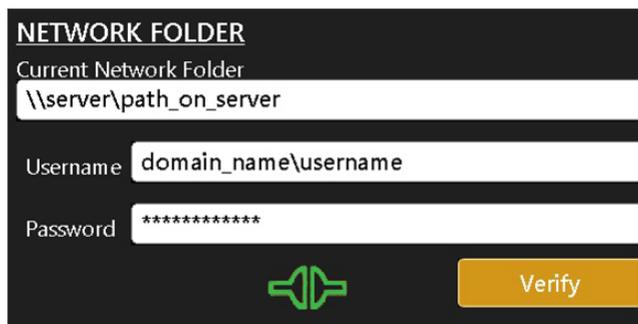
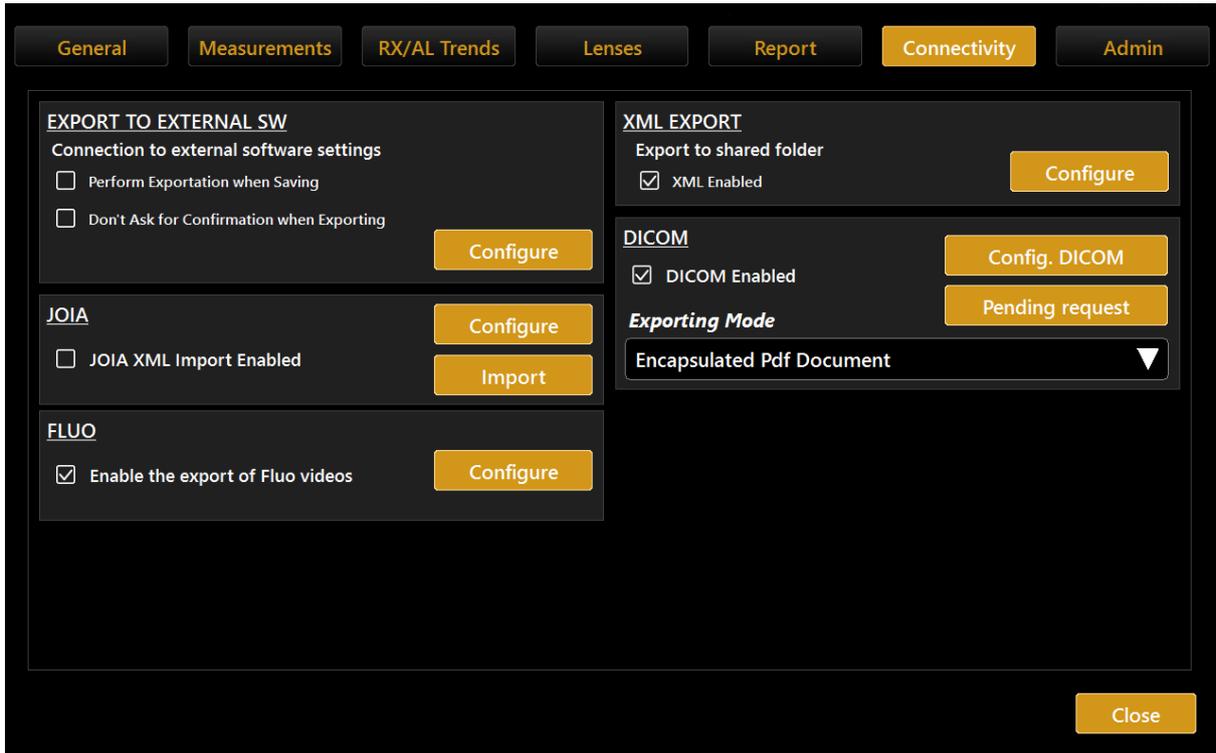


Fig. 71

17.6 CONNECTIVITY



17.6.1 Server List

17.6.2 Export to External Software settings

In this panel, it is possible to control two main aspects of the device behavior in relation to the exportation function.

17.6.3 XML Export

Enables/Disables the XML option for exporting XML data of the exam to the network folder by the export window.

17.6.4 DICOM

The DICOM panel of the Connectivity section allows setting the needed parameters for the connections to the available DICOM services.

The available services are:

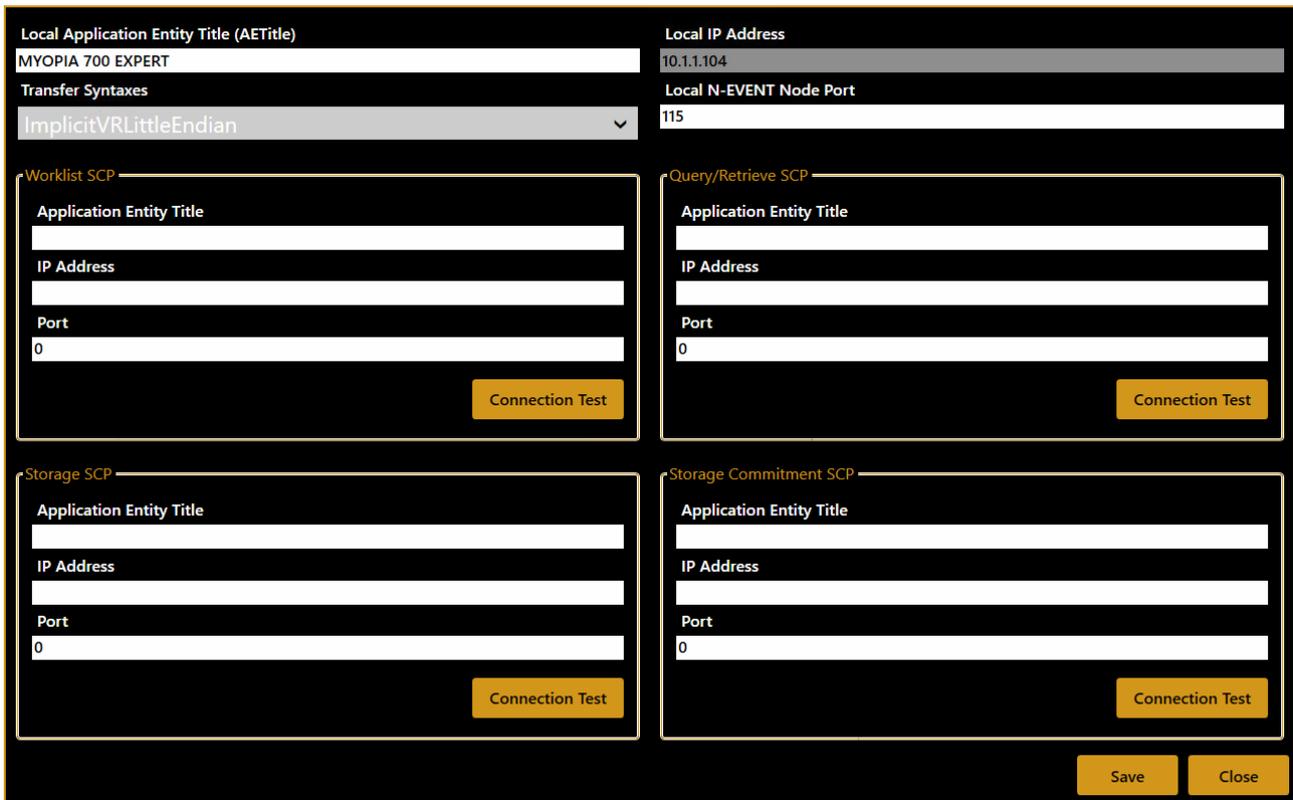
- Worklist Mode, The DICOM Worklist Mode provides a list of imaging procedures that have been scheduled for performance by the acquisition device.
- Patient Root Query, this enables the device to find the patient's details from a DICOM server.
- Storage, The DICOM Store service is used to send images or other persistent objects (structured reports, etc.) to picture archiving and communication systems (PACS) or workstations.
- Storage Commitment the DICOM Storage Commitment service is used to confirm that an image has been permanently stored by a device.

For each service, the needed parameter is:

- Remote Application Entity (AE) title
- Remote IP address
- Remote connection port

The “**Local Application Entity title**” is the identifier name through which the device presents itself to the servers.

The “**N-EVENT Report node port**” is the port at which the device can receive N-EVENT REPORTS for storage commitments (default is 115).



The screenshot shows a configuration window with the following fields and sections:

- Local Application Entity Title (AETitle):** MYOPIA 700 EXPERT
- Local IP Address:** 10.1.1.104
- Local N-EVENT Node Port:** 115
- Transfer Syntaxes:** ImplicitVRLittleEndian
- Worklist SCP:** Application Entity Title, IP Address, Port (0), Connection Test
- Query/Retrieve SCP:** Application Entity Title, IP Address, Port (0), Connection Test
- Storage SCP:** Application Entity Title, IP Address, Port (0), Connection Test
- Storage Commitment SCP:** Application Entity Title, IP Address, Port (0), Connection Test
- Buttons:** Save, Close

The connectivity to the defined server can be tested using the “C-ECHO” function activated by the related “**Connection Test**” button. The result of the connection test is shown by the green or red icon.



The screenshot shows the configuration for an Application AE:

- Application AE:** WL_SCP_AE_TITLE
- IP Address:** 10.1.1.30
- Port:** 107
- Connection Test:** Button with a red error icon (a red 'X' over a red signal icon).

In order to configure the full DICOM workflow properly, it could be necessary to perform some operations or configurations on the server’s side. In order to do this, contact the System Administrator.

The DICOM module of MYOPIA EXPERT 700 is described in detail in its **DICOM Conformance Statement**. For more information, refer to your local distributor.

17.7 ADMIN

This is the device administration panel (Fig. 72).

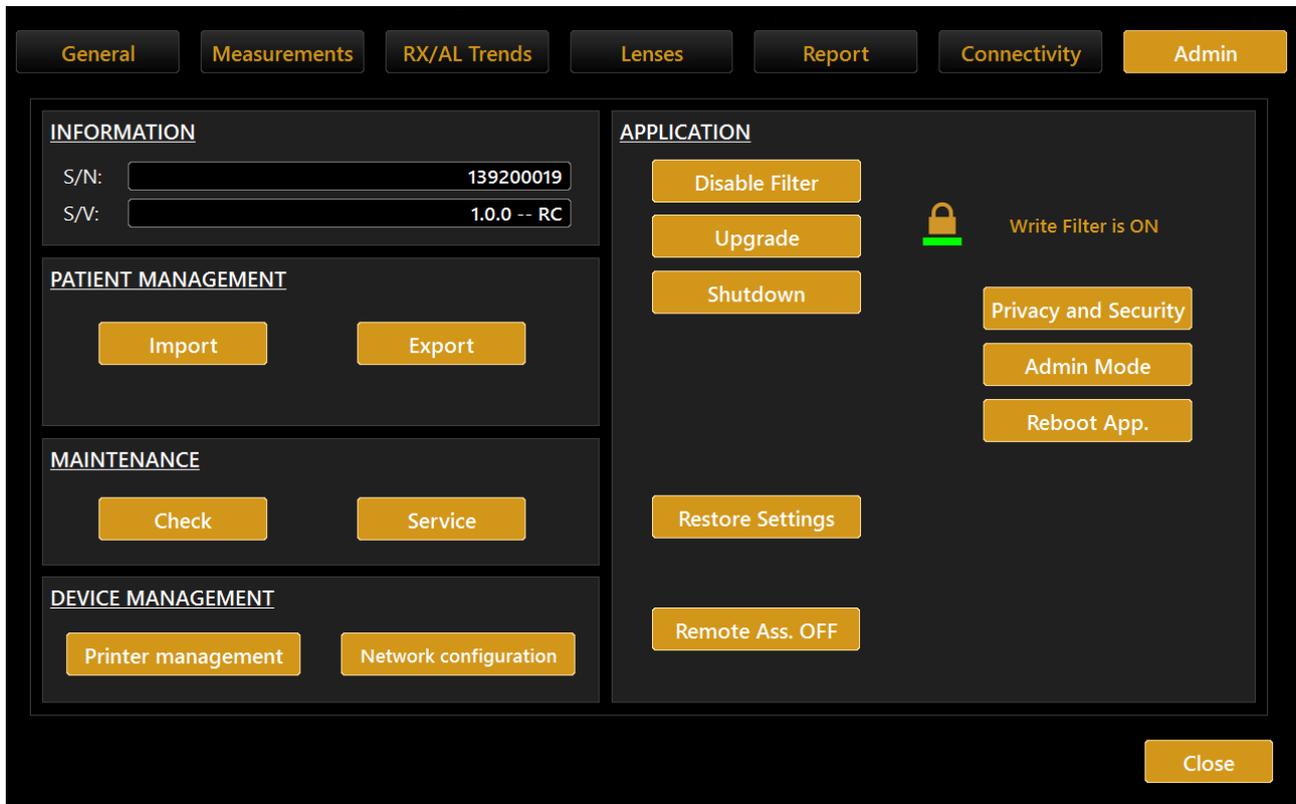


Fig.72

It provides information on the system, such as a serial number (S/N) and software version (S/V).

The "**Check**" button starts the calibration check procedure.

Checking calibration

See the section on the procedure.



It is recommended to check the calibration when the device has been transported from one place to another and if it suffered an impact or thermal shocks.



It is recommended to check the calibration every day when turning on the device.

The "**Application**" frame manages the behavior of the integrated software:

- **Upgrade:** Updates the integrated software
- **Shutdown:** Power off the machine
- **Reboot App:** Reboot the application
- **Privacy:** Refer to section 17.8

17.7.1 Remote Assistance

In case you need remote assistance, the MYOPIA EXPERT 700 application integrates Team Viewer QS (Quick Support) pre-installed.

There is NO NEED to disable the Write Filter protection

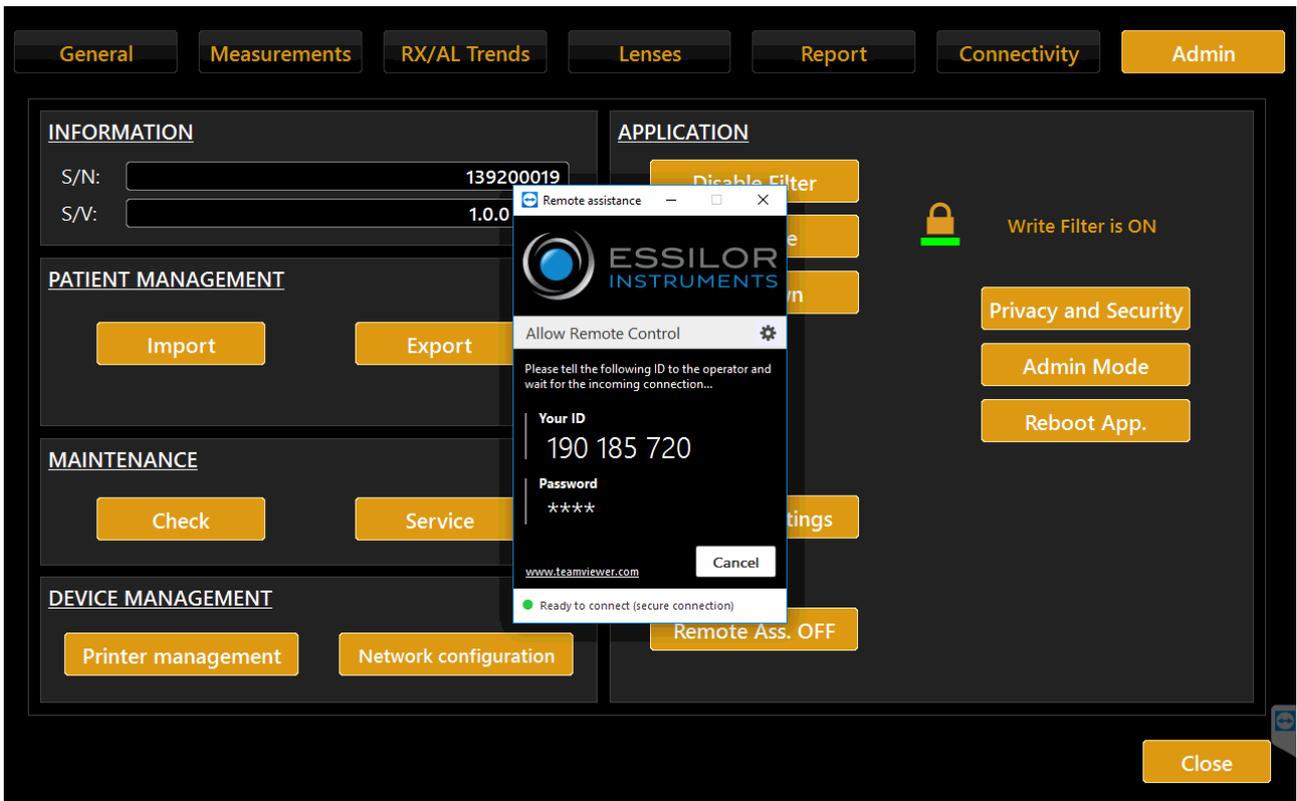
Ensure to have internet access available for your MYOPIA EXPERT 700 unit

Go to Settings > Admin and press "Remote Assistance".

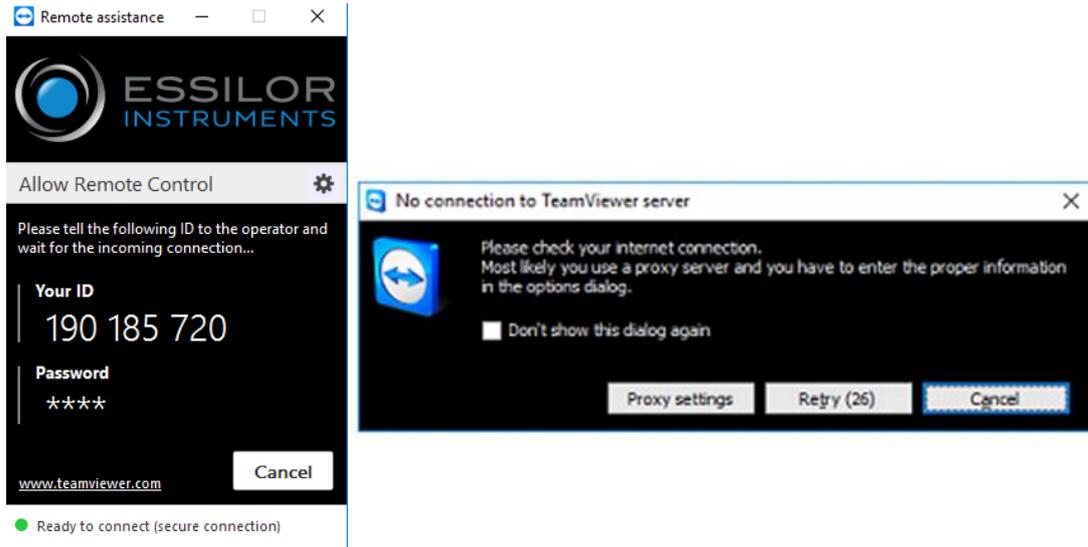
Wait for the Team Viewer Window to open

Communicate to the Remote Operator the ID shown under "Your ID" and wait for the incoming connection

The password is masked; the operator knows it already.



To turn off manually the Remote Assistance, you can close the Team Viewer window or press "**Remote Ass. OFF**". If you get one of the following windows, please check your internet connection to MYOPIA EXPERT 700 or contact your IT staff.

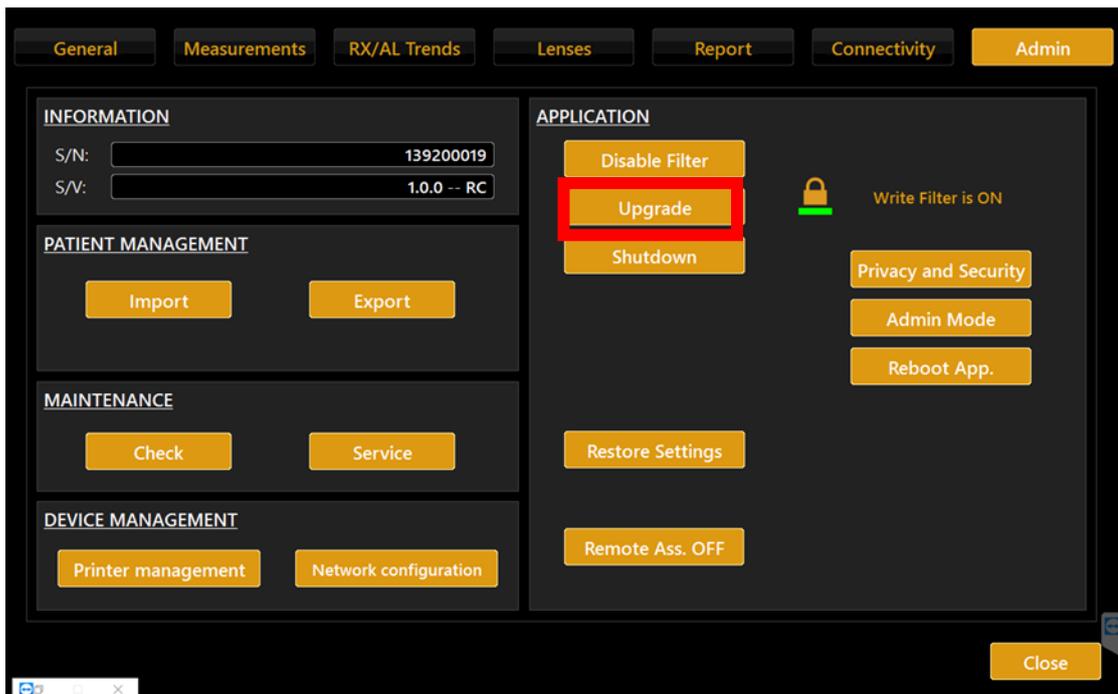


17.7.2 Updating the integrated software

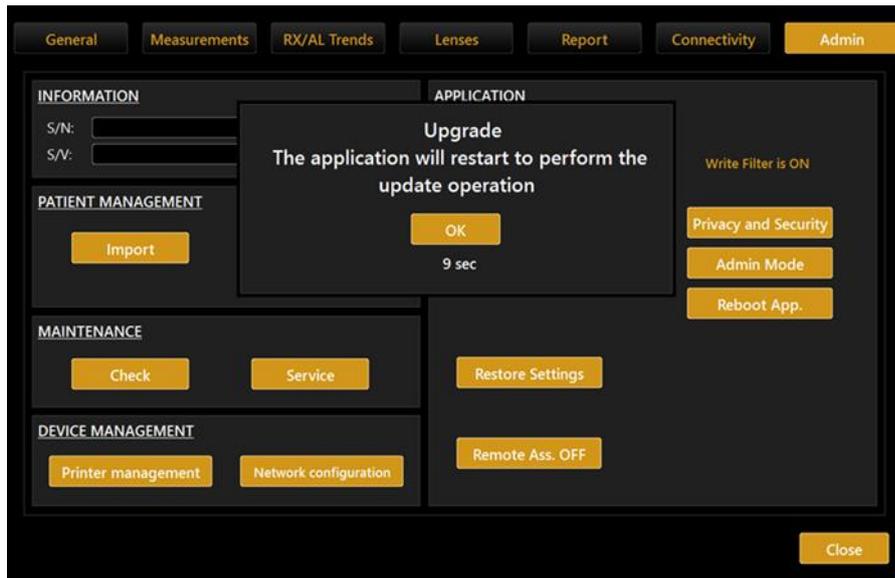
This section describes the software upgrade procedure from one version to the next version.

To update the software, perform the following operations:

1. Put the upgrade package in the root (main card) of an empty FAT32-formatted USB external drive.
2. Switch on the MYOPIA EXPERT 700.
3. Click on the settings icon
4. Click on the “Admin” tab
5. Insert the USB stick with the “MYOPIA EXPERT 700 upgrade” files in one of the USB ports.
6. Click on the “Upgrade” button.



- Click on **“Ok”** to reboot the system and start the upgrade.



- After the upgrade completed, the system will reboot and starts the "MYOPIA EXPERT 700 application".
- If you see the message shown in Fig. 73, please switch off your MYOPIA EXPERT 700 and turn it on again. Your MYOPIA EXPERT 700 should now work fine.

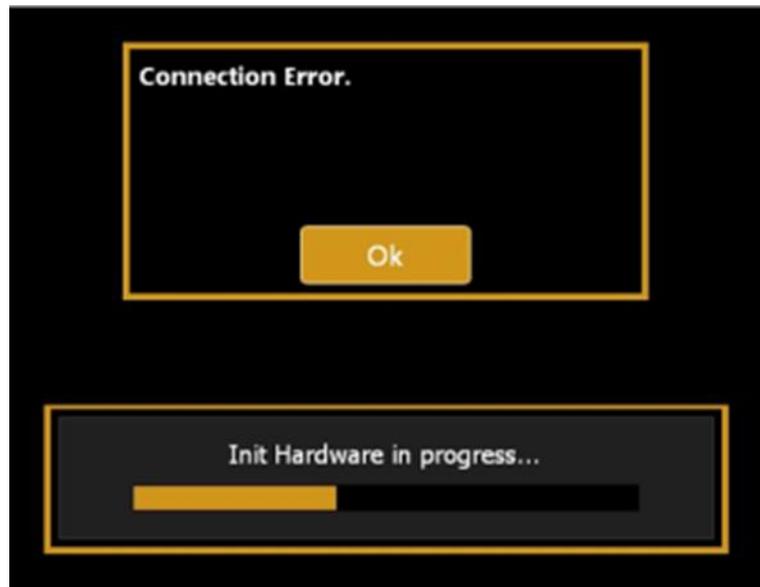


Fig. 73

- Your MYOPIA EXPERT 700 is upgraded. Please check in the settings, **“Admin”** tab if the S/V is now the new one.

17.7.3 Patients Management

With “**Import**” and “**Export**” buttons, users can respectively import and export the entire patient’s examinations data to the USB drive.

1. System. This operation may take some minutes: do not restart the machine during this procedure.
2. Your MYOPIA EXPERT 700 is now upgraded.

17.7.4 Printer management and Network configuration

The “Printer management” and the “Network configuration” buttons open, respectively, the printer management and the network configuration panels of Windows that allow to manage the printers and the network properties of the device.

N.B.

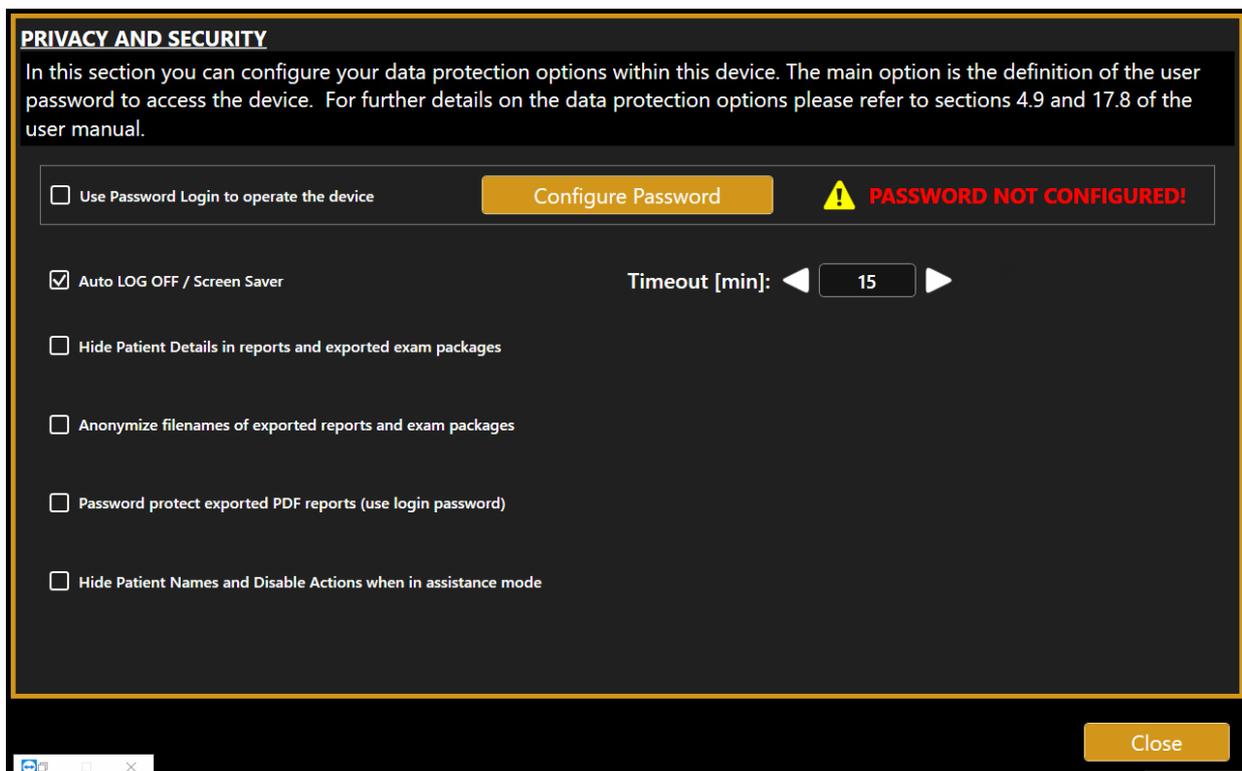
For detailed information on how to manage printers and network properties, follow the general instructions of Windows 10.

17.7.5 Shutdown

Press the “**Shutdown**” button to switch off the device.

17.8 PRIVACY & SECURITY SETTINGS

 If the password login is kept enabled and a password has already been defined, it is necessary to input the defined login password to operate the device.



PRIVACY AND SECURITY

In this section you can configure your data protection options within this device. The main option is the definition of the user password to access the device. For further details on the data protection options please refer to sections 4.9 and 17.8 of the user manual.

Use Password Login to operate the device Configure Password  **PASSWORD NOT CONFIGURED!**

Auto LOG OFF / Screen Saver Timeout [min]: ◀ 15 ▶

Hide Patient Details in reports and exported exam packages

Anonymize filenames of exported reports and exam packages

Password protect exported PDF reports (use login password)

Hide Patient Names and Disable Actions when in assistance mode

Close

17.8.1 Password protected Login

The options allow protecting with a password the access to the MYOPIA EXPERT 700 on-board application operations and data. By default, the option is enabled but requires the password to be configured.

When the option is enabled, and the password configured the login is prompted when:

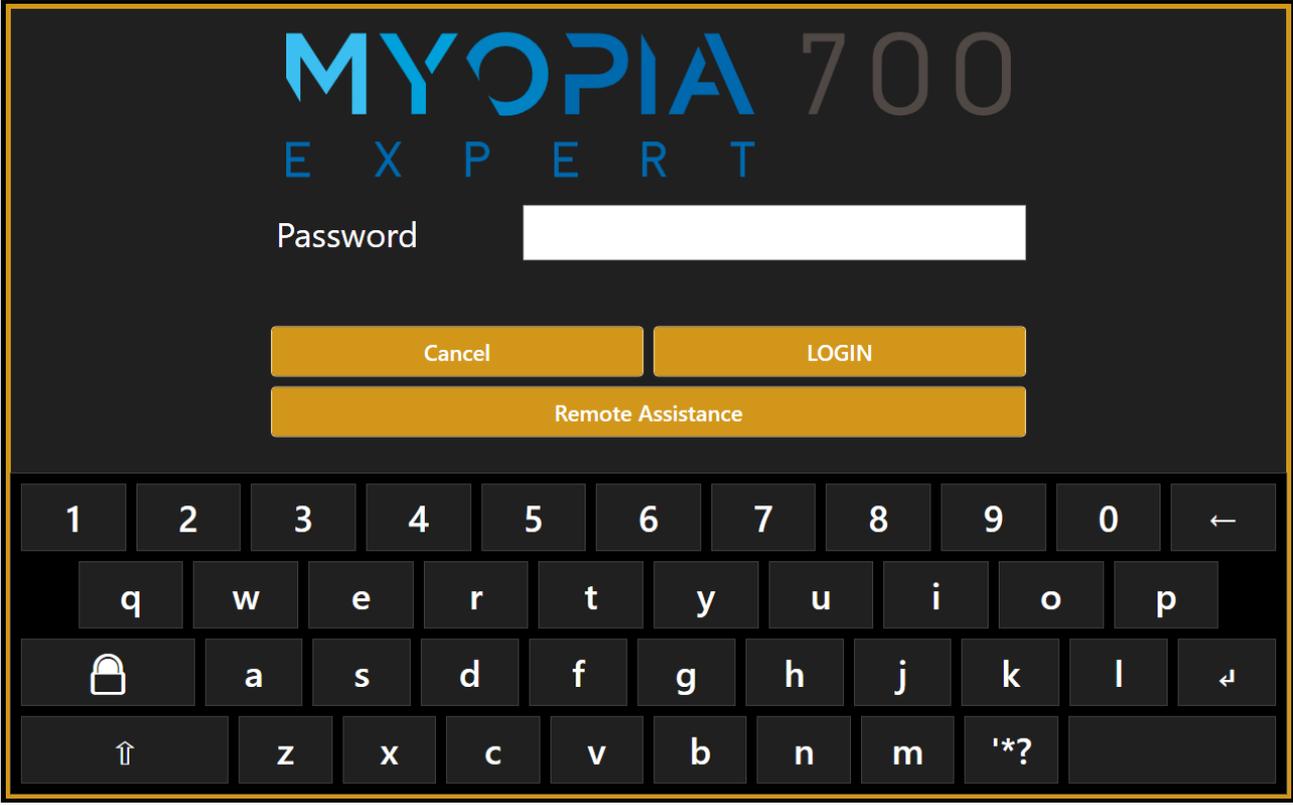
- the MYOPIA EXPERT 700 on-board application starts
- the auto Log OFF timeout occurs (if enabled)
- the lock button in the main top bar is pressed

Press on the "Configure Password" button to define the preferred password.

 It is recommended to use a strong password. The password is case-sensitive. No password strength checks are applied.

 It is recommended to apply a password aging policy.

Type the desired password in the password field and type it again in the confirm password field.



17.8.2 Screen Saver / Auto Log OFF

The option allows setting automatic locking of the MYOPIA EXPERT 700 on-board after a configurable timeout.

By default, the option is enabled with the timeout set to 15 minutes.

When no interaction with the device is performed during the timeout, the screen saver will be displayed.

When the screen saver has closed, the login screen (if enabled and configured) will be displayed.



17.8.3 Hide Patient Details in reports and exported exam packages

The option, if enabled, allows masking the patient details in the header of the printed or exported reports. Only the used patient ID will be reported regularly.



ESSILOR

Patient Information			
Patient	P****T D**O	Gender	M
Patient ID	PATDEM11112011	Exam Date	13/05/2020 (dd/mm/yyyy)
Date of Birth	**/**/****		

If, for assistance reasons, the exam data is exported, the patient details will be replaced with indications of the source device; only the patient ID will be maintained.

17.8.4 Anonymize filenames of exported reports and exam packages

If the option is selected, the report output filename convention will be forced to be the alternative one.

-  PATDEM11112011_R__13_05_2020__12_40__CORNEAL_MAP.pdf
-  PATDEM11112011_R__13_05_2020__12_40__CORNEAL_MAP_01.pdf
-  PATDEM11112011_R__13_05_2020__12_40__CORNEAL_MAP_02.pdf
-  PATDEM11112011_R__13_05_2020__12_40__CORNEAL_MAP_03.pdf

17.8.5 Password protect exported PDF reports

This option is available if the log in password is enabled and configured. If this option is enabled, the PDF reports exported to the network shared folder will be accessible only by typing the user password as defined to access the MYOPIA EXPERT 700 on-board application.

17.8.6 Hide Patient Names and Disable Actions when in assistance mode

The options, used in combination with a password-protected login, allows making the patient details and related actions non-accessible when interacting with the MYOPIA EXPERT 700 on-board application in technician/service mode. To switch the application to technician mode, press on the lock button to lock the application. Let the technician staff log in to the application with the technician password; the Application will switch to Technician Mode. To switch the application back to user mode, press again the lock button and enter the user password.

User Mode

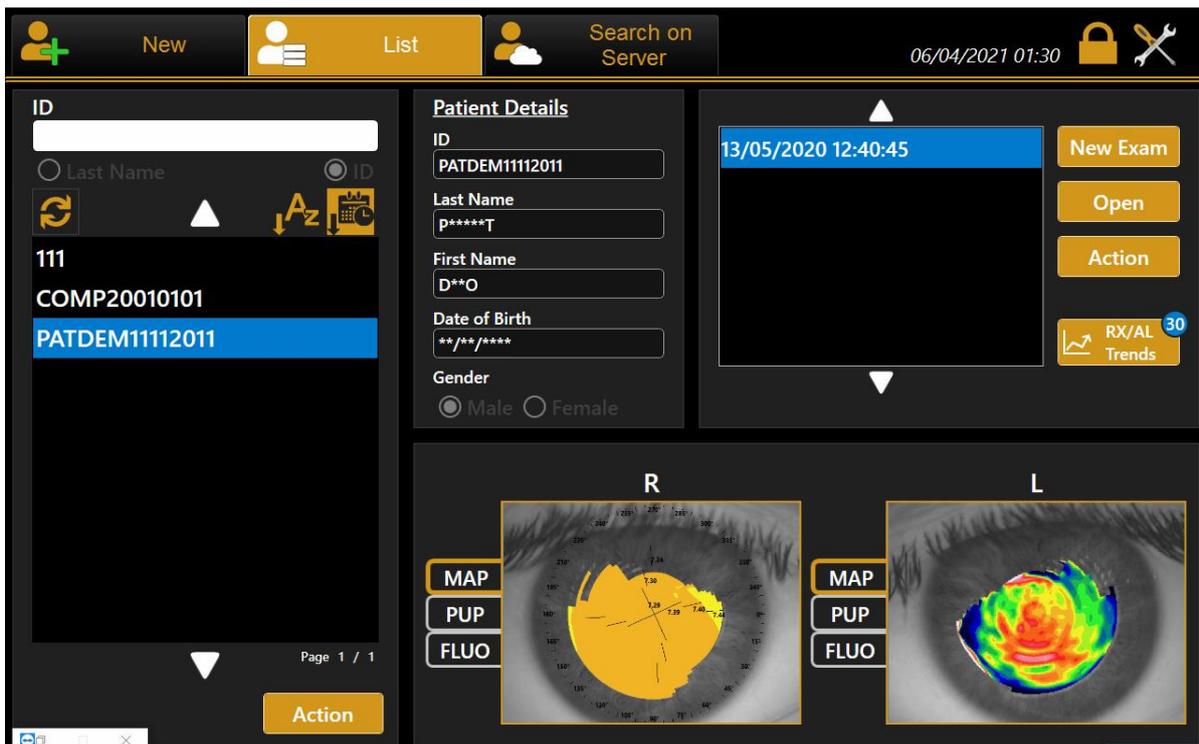
In standard user mode, the patient details and related actions are regularly accessible.



Technician Mode

In technician Mode, the patient details are not accessible, and delete/edit actions are not available.

When exporting exam packages in this mode, the patient details are automatically anonymized.



18. MYOPIA EXPERT 700 TROUBLESHOOTING

Problem	Solution
The external body of the MYOPIA EXPERT 700 is broken	Contact Technical Service
The MYOPIA EXPERT 700 display is broken	Contact Technical Service
The MYOPIA EXPERT 700 cannot be moved with the joystick	Completely unscrew the two locking screws and the semi-lock. If the problem persists, contact Technical Service
The MYOPIA EXPERT 700 doesn't move properly with the joystick	Contact Technical Service
The MYOPIA EXPERT 700 display is black	Check that the MYOPIA EXPERT 700 device is on. Check that the power cables are properly connected. If the problem persists, contact Technical Service.
The MYOPIA EXPERT 700 power cord is connected correctly, but the device doesn't boot up	Contact Technical Service
After switching on the MYOPIA EXPERT 700, only a blue screen appears	Contact Technical Service
The MYOPIA EXPERT 700 is on, but the on-board application is not active	Turn off the device from the stand by switch and turn it on again. If the problem persists, contact Technical Service
After a few minutes when switched on, the MYOPIA EXPERT 700 restarts	Contact Technical Service
One or both USB external ports don't work	Contact Technical Service
The MYOPIA EXPERT 700 boots up and the on-board application is started, but no touch operation is possible	Contact Technical Service
The acquisition is not taken automatically when doing the calibration check.	Check that the calibration checking device is positioned correctly, and it is clean. Use the provided cloth for proper cleaning. If the problem persists contact Technical Service.
Calibration check has failed	Repeat the measurement. If the problem persists, contact Technical Service.

Cannot perform acquisitions using the joystick button.	If the problem persists, contact Technical Service.
The switch from right to the left eye and vice versa doesn't work.	Contact Technical Service.
The MYOPIA EXPERT 700 restarts when clicking on the joystick button	Contact Technical Service.
Some lights in the MYOPIA EXPERT 700 do not turn on when making the related acquisition.	Check that the proper acquisition type is selected. If the problem persists, contact Technical Service.
The standard deviation after an acquisition session is higher than 0.16 D	Repeat the measurement. If the problem persists contact Technical Service.
Cannot insert new patient's details	Contact Technical Service
Cannot view previously saved examinations	If the problem persists, contact Technical Service.
Cannot save new examination data	Contact Technical Service
Cannot print Reports	Check that some reports are selected, the correct printer is selected and that the printer is working properly. If the problem persists, contact Technical Service.
Cannot export Reports to Network	Check that the LAN cable is connected correctly and the designed destination is reachable. If the problem persists, contact Technical Service.
The reports printed layout is not correct	Check the page layout settings in the MYOPIA EXPERT 700 on-board application and the printer.
The map image is not shown in the measurements section	Check that at least one acquisition has been performed, and the map is enabled visualization settings. If the problem persists, contact Technical Service.
Generic Software error	Contact Technical Service.

19. MYOPIA EXPERT 700 TECHNICAL SPECIFICATIONS



No modification of this equipment is allowed.

NOTE: The manufacturer shall provide, upon request, circuit diagrams, list of components, descriptions, calibration instructions, or other information that will assist the technical assistance personnel in the repair of parts of the device specified by the manufacturer as repairable by the technical support staff.

NOTE: For the isolation of the device from the supply mains, the device is provided with a removable power cable.

GENERAL INFORMATION			
FUNCTION	FEATURES		LIGHT SOURCE
Corneal topography and Keratometry	Keratoscopic Cone	24 rings equally distributed on a 43D sphere	Red LED Type1 and Type 2
	Analyzed points	Over 100.000	
	Measured points	Over 6.000	
	Corneal Coverage	Up to 9.8 mm on a sphere of radius 8mm (42.2 diopters with $n = 1.3375$)	
	Focus System	Guided focus	
Pupillometry	Integrated		Infrared and white light LED
Axial Biometry	Low-coherence interferometry on optical fiber		Sled @ 820nm
Fluorescence	Integrated		Blue LED

OPTICAL RADIATIONS SPECIFICATIONS						
Light Source	Feature	Assistance Panel Control	Peak (nm)	Bandwidth (nm)	Power/ Luminous Intensity	
					At the source	On eye
Cone Red LED Backlight Ring 3 and 4 PCB	Illumination of Placido disk for topographic analysis	Cone	633	16	<180 mcd	<0.02 mW
Cone Red LED Backlight Ring 2 PCB		Cone	633	16	<180 mcd	<0.02 mW
Cone Red LED Backlight Central PCB		Internal Cone	622	17	< 112.5 mcd	<0.01 mW
Cone Central IR LED	<i>For technical assistance only</i>	NIR leds	780	30	< 100 mW/sr	
Cone White LED	Pupillometric analysis	White leds	--	--	< 1100 mcd	
Yellow green Fixation LED	Central fixation LED	Fixation	572	15	<360 mcd	<0.01mW
Cone Blue led	Fluorescein analysis	Blue leds	475	25	<900 mcd	0.207mW
Cone IR LED 940	Pupillometric analysis	Infrared	940	45	<20 mW/sr	<0.03mW
SLED Interferometer	Axial Biometry acquisition	SLED	820	25	<2.5mW	< 0.7 mW

 **CAUTION** - The light emitted from this device is potentially hazardous. The longer the duration of exposure, the higher the risk of ocular damage. Exposure to the device light when using it at maximum intensity will infringe the safety indication after a 60-minutes use. MYOPIA EXPERT 700 has a series of LEDs of various types and powers installed. All the characteristics are detailed in the Technical Specifications section in this manual. The LED groups comply with the emission limits for the Group 2 instruments according to the standard ISO 15004-2.

INFORMATION ON MEASUREMENTS					
MEASUREMENTS		MEASURING RANGE	DISPLAY RESOLUTION	IN REPEATABILITY	VIVO
Keratometry	Curve radius	5.00 – 12.00 mm	0.01 mm	±0.02 mm	
	Curve Radius in Diopter (n=1.3375) (D)	28.00 - 67.50 D	0.01 D	±0.12 D	
Axial Length		15.00 – 36.00 mm	0.01 mm	±0.027 mm	
Pupil dimension		0.50 – 10.00 mm	0.01 mm	N/A	
Limbus (White-To-White)		8.00 – 14.00 mm	0.01 mm	±0.05 mm	

ENVIRONMENTAL CONDITIONS						
	IN USE		STORAGE		TRANSPORT	
Temperature	Min	Max	Min	Max	Min	Max
		10°C	40°C	-20°C	70°C	-20°C
Relative humidity	8-75% (non condensing)		8-75% (non condensing)		8-75% (non condensing)	
Atmospheric pressure	800-1060 hPa		700-1060 hPa		700-1060 hPa	

ELECTRICAL DATA		
Power supply	AC 100-240V 50/60 Hz	
Power consumption	100 VA	
Fuse	Type	20 x 5 mm
	Value	T 2.5 A L 250 V anti-surge

MECHANICAL SPECIFICATIONS		
	Device	Device Packaged
Width	320mm	600mm
Height	490mm	800mm
Length	470mm	710mm
Weight	18 kg	29kg

ON-BOARD SPECIFICATIONS	PC
	SN 158xxxxxx
Operating system	WINDOWS 10 64bit
Processor	Intel
RAM	4GB
Hard disk	At least 500GB
External connections	LAN integrated, 2x USB

20. DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY / Dichiarazione di conformità

Manufacturer / Fabricante: VISIA imaging S.r.l.

Address / Indirizzo: Via Martiri della Libertà, 95/e
52027 San Giovanni Valdarno (AR)
ITALY

Name of device / Nome del dispositivo: **INTEGRATED DEVICE CORNEAL ANALYZER AND OCULAR BIOMETER**

Brand / Marca: **ESSILOR**

Model / Modello: **MYOPIA EXPERT 700**

I, the undersigned, hereby declare under my sole responsibility that the aforementioned devices comply with the Directive 93/42/EEC (implemented in Italy by Legislative Decree n. 46/97) with Annex II excl. (4) and subsequent amendments and additions (Directive 2007/47/CE – implemented in Italy by Legislative Decree n. 037/10) for **Class IIa** equipment.

*Io, sottoscritto, sotto la mia sola responsabilità, con la presente dichiaro che i dispositivi specificati sopra sono conformi alla Direttiva 93/42/CEE (recepita in Italia con D.lgs 46/97) secondo l'allegato II escluso (4) e successive modifiche e integrazioni (Direttiva 2007/47/CE recepita in Italia con D.lgs 037/10) per i dispositivi di **Classe IIa**.*

Ing. -----
Managing director
Legale rappresentante

Place/Luogo: Via Martiri della Libertà 95/e
San Giovanni V.no (AR) – ITALY

21. CHANGING THE FUSES



WARNING: Do not perform the following operation in the presence of the patient.



Step 1

Open the fuse box cover using a screwdriver



Step 2

Take out the fuse box (use a screwdriver to release it)



Step 3

Remove the blown fuse from its seat and replace it with an identical one, as shown in the table below and on the instrument label.



Step 4

Push the fuse box carefully back into position

Fuse type	Fuse value
20 x 5 mm	T 2.5 A L 250 V anti-surge

The latest version of the user manual in the appropriate language is available on a web space. Upon request, a paper version can be provided for free.

- en The complete user manual is available on a web space. To access it, please scan the QR code below using a dedicated application.
- fr Le manuel utilisateur complet est disponible sur un espace web. Pour y accéder veuillez scanner le QR code ci-dessous à l'aide d'une application dédiée.
- ar لتتمكن من الوصول إليه، يُرجى مسح رمز الاستجابة السريعة أدناه باستخدام تطبيق مخصص لذلك.
- be Поўная інструкцыя карыстальніка даступна ў інтэрнэт-прасторы. Каб атрымаць доступ, адсканіруйце QR-код ніжэй пры дапамозе спецыяльнай праграмы.
- bg Пълното ръководство за потребителя е достъпно на уеб пространство. За достъп, моля, сканирайте QR кода по-долу с помощта на специално предназначено приложение.
- cs Celá uživatelská příručka je k dispozici na webu. Pro přístup k ní oskenujte níže uvedený QR kód pomocí specializované aplikace.
- da Den komplette brugermanual findes på et websted. Du får adgang til den ved at scanne QR-koden nedenfor ved hjælp af en dertil beregnet applikation.
- de Die vollständige Bedienungsanleitung ist auf einem Speicherplatz verfügbar: Für den Zugriff darauf scannen Sie bitte untenstehenden QR-Code mittels einer dafür vorgesehenen Anwendung.
- el Το πλήρες εγχειρίδιο χρήσης διατίθεται σε έναν ιστοχώρο. Για να μεταβείτε σε αυτόν, σαρώστε τον παρακάτω κωδικό QR μέσω μιας ειδικής εφαρμογής.
- es El manual de uso completo está disponible en la web. Para acceder, escanee el código QR que se encuentra a continuación con la ayuda de una aplicación.
- et Täielik kasutusjuhend on saadaval veebis. Juurdepääsuks palun skannige allolevat QR-koodi, kasutades selleks spetsiaalselt rakendust.
- fi Täydellinen käyttöohje on käytettävissä verkossa. Avaa käyttöohje skannaamalla QR-koodi asianmukaisella sovelluksella.
- hr Potpuni korisnički priručnik dostupan je na webu. Da biste mu pristupili, skenirajte QR-kod u nastavku namjenskom aplikacijom.
- hu A teljes használati útmutató megtalálható a webes felületen. A hozzáféréshez, kérjük, olvassa le a lenti QR-kódot a megfelelő alkalmazás használatával.
- id Panduan pengguna yang lengkap tersedia di web space. Untuk mengaksesnya, silakan pindai kode QR berikut dengan menggunakan aplikasi khusus.
- it Il manuale utente completo è disponibile su uno spazio Web. Per accedervi, scansionare il codice QR seguente mediante un'applicazione dedicata.
- ja ユーザーマニュアル完全版はウェブサイト内で閲覧いただけます。そちらにアクセスするには、専用アプリケーションを使用して以下のQRコードをスキャンしてください。
- ko 완전한 사용자 매뉴얼이 웹사이트에 있습니다. 전용 앱을 사용해 아래의 QR 코드를 스캔하면 접근할 수 있습니다.
- lt Išsamas naudotojo vadovas ieškokite interneto svetainėje. Kad jį atvertumėte, specialia programėlę nuskaitykite toliau pateiktą QR kodą.
- lv Pilnā lietotāja instrukcija ir pieejama tīmeklī. Lai tai piekļūtu, lūdzu, noskenējiet tālāk redzamo QR kodu, izmantojot tam paredzētu lietojumprogrammu.

ms	Manual pengguna yang lengkap boleh didapati di ruangan web. Untuk akses, sila imbas kod QR di bawah menggunakan aplikasi yang berkenaan.
nl	De volledige gebruikershandleiding is beschikbaar op een website. U kunt de handleiding bereiken door de QR-code hiernaast te scannen met een geschikte applicatie.
no	Den komplette brukerhåndboken er tilgjengelig på et webområde. For å få tilgang, må du skanne QR-koden nedenfor ved hjelp av en dedikert applikasjon.
pl	Kompletna instrukcja użytkownika jest dostępna na stronie internetowej. Aby uzyskać dostęp, zeskanuj poniższy kod QR przy użyciu dedykowanej aplikacji.
pt	O manual do utilizador completo está disponível num espaço web. Para aceder, queira digitalizar o QR code seguinte com a ajuda de uma aplicação dedicada.
pt (brazil)	O manual do usuário completo está disponível na área web do cliente. Para acessar, scanear o código QR abaixo usando a respetiva aplicação.
ro	Versiunea integrală a manualului de utilizare este disponibilă pe un site web. Pentru a-l accesa, scanați codul QR de mai jos cu ajutorul unei aplicații dedicate.
ru	Полное руководство пользователя доступно на сайте. Чтобы получить к нему доступ, сканируйте QR-код ниже с помощью специального приложения.
sk	Celý používateľský manuál je dostupný na internete. Aby ste sa k nemu dostali, naskenujte QR kód nižšie pomocou na to určenej aplikácie.
sl	Celoten uporabniški priročnik je na voljo na spletnem mestu. Za dostop do njega skenirajte spodnjo kodo QR z uporabo namenske aplikacije.
sr	Potpuno korisničko uputstvo je dostupno na vebu. Da biste mu pristupili, skenirajte QR kôd u nastavku pomoću namenske aplikacije.
sv	Den fullständiga handboken finns på en plats på Internet. Skanna QR-koden nedan med en lämplig app för att få åtkomst till den.
th	มีคู่มือผู้ใช้ฉบับสมบูรณ์ให้ที่เว็บไซต์ เพื่อเข้าถึงข้อมูล กรุณาสแกนรหัส QR ด้านล่างนี้โดยใช้แอปพลิเคชันเฉพาะงาน.
tr	Kullanma kılavuzunun tamamı internette bulunmaktadır. Kılavuza erişmek için, bu amaca yönelik bir uygulama kullanarak aşağıdaki QR kodunu taratın.
uk	Повний посібник користувача доступний на сайті. Щоб отримати до нього доступ, скануйте QR-код нижче за допомогою спеціального додатку.
vi	Cẩm nang hướng dẫn sử dụng hoàn chỉnh hiện có trên không gian web. Để truy cập, vui lòng quét mã QR bên dưới sử dụng ứng dụng chuyên dụng.
zh	操作手册全文可在一个网络空间内查询。如要访问该空间，请使用一个专门的应用软件扫描QR条码。



MYOPIA 700

EXPERT

Please specify the following when contacting your local supplier regarding questions about this product:

- Product name: MYOPIA EXPERT 700
- Software version: as written in the Settings > Admin section
- Period of use: Please provide the date of installation
- Defective condition: Please provide as many details as possible.

MYOPIA EXPERT 700

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MANUFACTURER

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