INSTRUCTIONS FOR USE

CORNEAL ANALYZER

CA-800 CORNEAL ANALYZER

CE 0123

REV. 10 2015

Thank you for choosing this product.

Please read the information in this manual carefully. You must be knowledgeable with its contents in order to work with the device.

The manufacturer has a policy of continuous improvement of its products, so it is possible that 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.

SW v.: 1.0.x

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Contents

1. INTENDED USE

1.1.Use:

CA-800 is a corneal analyzer with integrated pupillographer. The instrument acquires images of the cornea and analyzes its topography. The software selects the image with the best focus out of a sequence of images. In the image, the rings of the disc reflected by the illuminated cone are used to geometrically calculate the topographic map of the cornea. From the topographic map data, a set of parameter are processed for the measurements.

The main applications of the corneal analyzer are the following:

- Cornea measurements for diagnostic instruments
- Cornea and pupil measurements for application of contact lenses
- Fluorescence analysis for contact lens positioning
- Pupil measurements for the identification of specific pathologies

1.2.Users:

Eye specialists, ophthalmologists, opticians and optometrists.

The instrument must be used by qualified persons.

1.3.Facilities:

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

1.4.Positioning the patient

The patient must be positioned in such a way that the distance from the device to the eye is 83 mm.

A steady head position and the correct device-to-patient distance are promoted by resting the patient's head properly against the chin rest and forehead band.

Correct alignment with the patient's pupils can be visually inspected by the operator referring to the two lines on the forehead supports.

Fig. 1

The patient must be instructed to look permanently at the aiming point in the center of the Placido disk. The position of the device in relation to the patient's eye thus found is the starting point for fine measurement adjustments.

The patient does not use the controls.

The patient may be an elderly person, an invalid, or a child. In any case, the device is to be controlled by the aforementioned skilled staff.

1.5.Contraindications

There aren't any known contraindications to the use of the medical equipment.

2. INTRODUCTION

The intuitive and user-friendly software interface and the hardware, designed for patient comfort, make the CA-800 one of the most popular corneal analyzers on the market.
The instrument analyzes any type of corneal map: axial and instantaneous with 2D representation.
This instrument also allows you to simulate contact lenses and view the 3D map to analyze the wavefront corneal aberrations.

2.1.Notes:

This manual describes the CA-800 corneal analyzer, including its functions, basic operations, instrument cleaning, and instrument storage.
For best use of the instrument, carefully read the instructions provided.
Keep these instructions in a safe place.

3. PRECAUTIONS

This electronic instrument is a precision unit. Use and store it in a suitable place at normal 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 the sun and dust.
In order to obtain accurate and reliable measurements, keep the measuring cone clean and dust-free.
This product is in compliance with the EMC standards (IEC 60601-1-2:2007).

- ELECTROMEDICAL DEVICES require particular precautions for electromagnetic compatibility and must be installed and set up based on the EMC information provided in the documents attached.
- Portable RF communication instruments may interfere with medical devices.
- Using accessories and cables other than those provided with the instrument, except for the cables sold by the equipment manufacturer as spare parts, may result in increased emissions and may reduce the immunity of the device or system.
- The eventual cables connected to USB and LAN ports must be less than 3 meters length.
- The device must not be used in contact with other equipment.

If the device is to be used in contact with other instruments, check proper functioning in the required configuration.

3.1.EMC table

Emission-related aspects		
The CA-800 device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should make sure that it is used in the said environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The CA-800 device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The CA-800 device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3:2	Class A Compliant	The device can be used in all buildings, including domestic buildings and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3:3	Compliant	

Immunity-related aspects			
The CA-800 device is intended for use in the electromagnetic environment specified below. The customer or the user of the CA-800 device should make sure that it is used in the said environment.			
Immunity test	**EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be made of wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ Burst EN 61000-4-4	±2kV for power supply lines	±2kV for power supply lines	The quality of the power mains should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±1kV differential mode	±1kV differential mode	The quality of the power mains should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U T (60% dip in U_T) for 5 cycle 70% U T (30% dip in U_T) for 25 cycle < 5% U T (>95% dip in U_T) for 5 seconds	< 5% U T (>95% dip in U_T) for 0.5 cycle 40% U T (60% dip in U_T) for 5 cycle 70% U T (30% dip in U_T) for 25 cycle < 5% U T (>95% dip in U_T) for 5 seconds	The quality of the power mains should be that of a typical commercial or hospital environment. If the user requires continuous device operation during power mains interruptions, it is recommended that the device be powered using an uninterruptible power supply or a battery.
Power frequency magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a standard commercial or hospital environment.

Radio frequency immunity-related aspects

The CA-800 device is intended for use in the electromagnetic environment specified below. The customer or the user of the CA-800 device should make sure that it is used in the said environment.

Immunity test	**EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF EN 61000-4-6	3 V from 150kHz to 80MHz	3 V from 150kHz to 80MHz	**Portable and mobile RF communications equipment should not be used in the vicinity of the device, including its cables, unless the recommended separation distance calculated from the equation applicable to the frequency of the transmitter is observed.** Recommended separation distance $d = 1.2 \cdot \sqrt{P}$ from 150kHz to 80MHz $d = 1.2 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3 \cdot \sqrt{P}$ from 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF EN 61000-4-3	3 V from 80MHz to 2.5GHz	3 V from 80MHz to 2.5GHz	

The fixed RF transmitter field strength, as determined by an electromagnetic site survey, may be lower than the compliance level in relation to each frequency range.
Interference may occur in the vicinity of any equipment marked with the following symbol:

Recommended separation distances between portable and mobile RF communication equipment and the surgical Navigation device

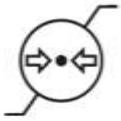
The CA-800 device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of device can help prevent electromagnetic interference by keeping a minimum distance between portable and mobile RF communication equipment (transmitters) 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 $d = 1.2 \cdot \sqrt{P}$	**80MHz to 800MHz** $d = 1.2 \cdot \sqrt{P}$	**800MHz to 2GHz** $d = 2.3 \cdot \sqrt{P}$
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

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.

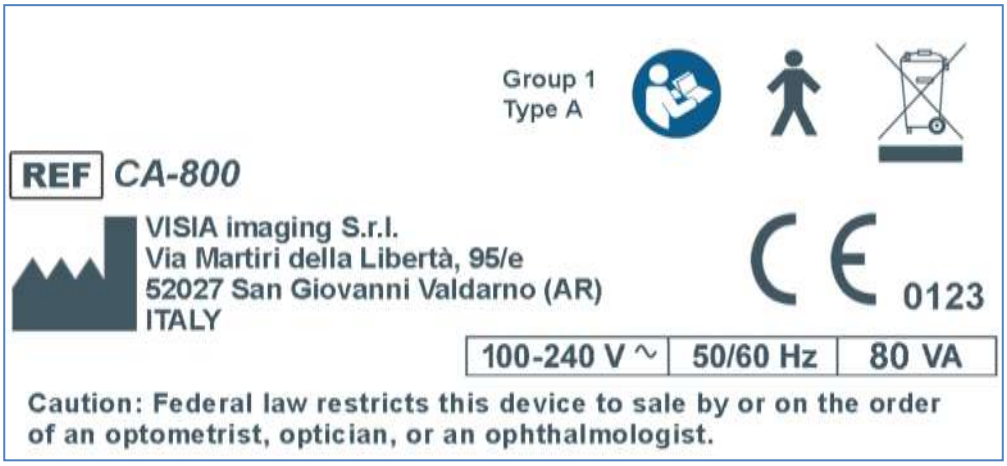
Note:
(1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

4. 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		CORNEAL TOPOGRAPHY ACCORDING TO ISO 19980:2005
	IEC 60417-5032	ALTERNATE CURRENT
	EN 60601-1	FOLLOW THE INSTRUCTIONS FOR USE
	EN ISO 15223-1	MANUFACTURER
	EN ISO 15223-1	REFERENCE OR MODEL NUMBER
Group 1	EN ISO 15004-2	PRODUCT CLASSIFIABLE AS GROUP 1 IN ACCORDANCE WITH EN ISO 15004-2
	EN 62471	PRODUCT CLASSIFIABLE AS EXEMPT GROUP IN ACCORDANCE WITH EN 62471
	EN ISO 15223-1	TEMPERATURE LIMITATION *Indicate the temperature limits to which the medical device can be safely exposed.*
	EN ISO 15223-1	HUMIDITY LIMITATION *Indicate the range of humidity to which the medical device can be safely exposed.*
	EN ISO 15223-1	ATHMOSPHERIC PRESSURE LIMITATION *Indicate the range of atmospheric pressure to which the medical device can be safely exposed.*
	EN ISO 15223-1	KEEP DRY *Indicates a medical device that needs to be protected from moisture.*
		HANDLE WITH CARE

	ISO 780	THIS WAY UP *Indicates correct upright position of the transport package.*
	This symbol is solely applicable for EC member countries. 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 (Directive on Waste Electrical and Electronic Equipment) or (ii) for all other countries, in accordance with local disposal and recycling laws.	

4.1.Device sample labeling



5. SAFETY INSTRUCTIONS

5.1.General

- CA-800 should be used only for its intended purposes as detailed in this manual.
- It must be installed by qualified staff.
- 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 to be operating in, while the unit is consuming 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 environmental temperature close to 40°C. The device temperature doesn't exceed 48°C anyway. Considering the examination duration, the patient condition and the parts that are in contact with the patient, there aren't any known contraindications about to the contact with the device.
- 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 main.

-  If the device has just been delivered or underwent thermal shock, wait at least one hour before making measurements on patients.
- Keep this manual at hand and close to the device at all times.
-  The physician or device user must inform the patient of the related safety instructions and ensure that they are observed.
-  Run all the control functions (detailed in the relative section in this document) before carrying out measurements on patients.
-  Only duly trained and experienced staff may use the device and interpret the results obtained.
- Turn off the device if it is not going to be used for a long period of time.
- It is advisable to use the device in an unlit environment
-  If the device has been affected by external forces (e.g. if it is knocked or dropped), it must be thoroughly checked before examining patients. To do this, refer to the relative section in this manual. If necessary, send the device in for repair.
- Use only genuine CA-800 accessories and spare parts.
- Remove all the covering material (dust sheet) from the device before turning it on.
- Do not use the device in the vicinity of highly flammable materials or in areas with an explosion risk.
-  Unauthorized software installation in the device is not permitted.
-  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.

5.2. Electrical safety

-  To avoid the risk of electric shocks, this equipment must only be connected to supply mains with protective ground.
- CA-800 has an on-board power supply unit installed. For connection to the 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.

5.3.LED emission safety

CA-800 has a series of LEDs of various types and powers installed. All the characteristics are detailed in the "SPECIFICATIONS" section.
The device falls within class 1 according to EN 60825-1.
All sources are classifiable as EXEMPT GROUP according to EN 62471.

5.4.Installation with external devices or IT Network

CA-800 complies with the CE marking requirements.

-  Before connecting an external device, such as a computer, printer, monitor, keyboard, mouse or other devices, make sure that they comply with the EN 60950-1 standard and have the CE marking.

- Connecting electrical equipment to the device actually results in the creation of medical equipment, and may jeopardize safety.
- When CA-800 is installed in rooms for medical use, the PC and the connected printer must be powered using an IEC 60601-1 compliant insulating transformer.
- If CA-800 is installed in rooms for medical use without a computer, it is not necessary to use an insulating transformer.
- Do not use mobile phones or other devices not compliant with the requirements of class B EMC in the vicinity of CA-800.
- Every external device that has to be connected to CA-800 must have a connection cable (USB or LAN) with a maximum length of 3 m.

The purpose of CA-800 connection to an IT network is report printing and remote technical assistance.
The CA-800 USB port must be connected to printer with USB or LAN interface. Ask Topcon technical assistance for printer driver installation.
The CA-800 can be connected to a Local Area Network (LAN) through the LAN connector. The network must have Ethernet protocol (IEEE 802.3). Ask Topcon technical assistance and the system administrator for CA-800 and network settings.
The purpose of CA-800 connection is saving PDF report on an external network folder or technical service intervention on the machine.
Connection of CA-800 to a computer network that includes other equipment could result in previously unidentified 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 computer network
- Disconnecting items from computer network
- Update of equipment connected to computer network
- Upgrade of equipment connected to computer network

The term computer network used here corresponds to the term network/data coupling in IEC 60601-1:2005.

6. TRANSPORT AND PACKAGING

- The device must be transported and stored in its original packaging.
- For storage and transport conditions, refer to the relative section in this document.
- Carefully store the original packaging, in order 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 recess at the rear of the device (in position with the locking system).

Completely unscrew the two transportation locks and the semi-lock before use.

Lower the instrument to its minimum height using the joystick, then lock CA-800 using the instrument semi-lock and the two “instrument locking devices” for transportation.

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 indicated to prevent damaging it. Never use solvents or other abrasive agents.
- The device comes with a dust cover to be used to protect it. Cover CA-800 if it is not going to be used for a long period of time.
-  Before turning on the device, remove the cover. Never put the cover on when the device is on.

8. PACKAGE CONTENTS

- Power cable
- Manual
- Dust cover
- Accessory for calibration check

 **NOTE: keep the original packaging to store or transport the device.**

9. CHECKING THE MEASUREMENTS

-  It is absolutely essential to check calibration 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 measurements 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 the patients, to make sure that they illuminate properly.
- In the event of frequent error signals, turn the device off and contact the technical support to have it inspected.

10. PRODUCT WARRANTY AND RELIABILITY

- The product warranty is valid only if all the instructions detailed in this document are followed.
- The product warranty is forfeited in the event of loss or damage due to improper or incorrect use of the device.
- The product warranty is valid only if it is equipped with its original accessories.
- If the device is opened by unauthorized staff, the manufacturer is relieved of all responsibility and the warranty will become 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.

11. LEGAL PROVISIONS

93/42/EEC – 2007/47/EC:	→	Class IM medical device
EN 60601-1:	→	Class I type B continuous operation
EN 60601-1-2:	→	EMC
EN 15004-2:	→	Group 1
EN 62471:	→	All the sources are “EXEMPT GROUP”
UNI EN ISO 19980	→	Type A

12. USE AND MAINTENANCE

NOTE: the manufacturer shall provide, upon request, circuit diagrams. the 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.

12.1. Use

As the CA-800 Corneal Analyzer is an electronic instrument for medical purposes, it must be used by experienced and qualified staff.

12.2. Maintenance

To assure safety and performance of the equipment, it is advisable not to perform any operations other than those indicated below. For detailed information, please follow the instructions.

12.2.1. Calibration check

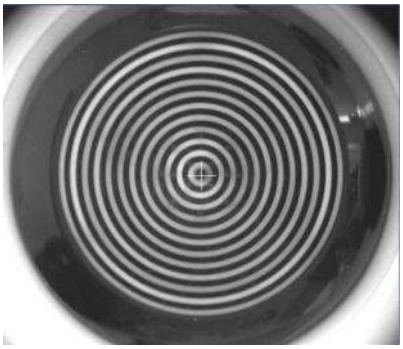
Calibration must be checked if the device was transported from one place to another and if it suffered an impact or thermal shocks.

Check the device calibration every day before starting patient examinations.

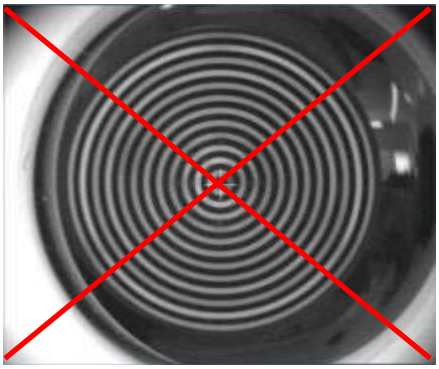
Insert the calibration tool provided with the device (Fig. 2) in the special holes in the chin rest and press until the tool is blocked on the device. Check that the calibration tool is perfectly aligned with the device. If

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. 3).

Fig. 2



CORRECT alignment



WRONG alignment

Fig. 3

To check calibration, turn the instrument on and go to settings, then select the Admin tab and press Check (Fig. 4).

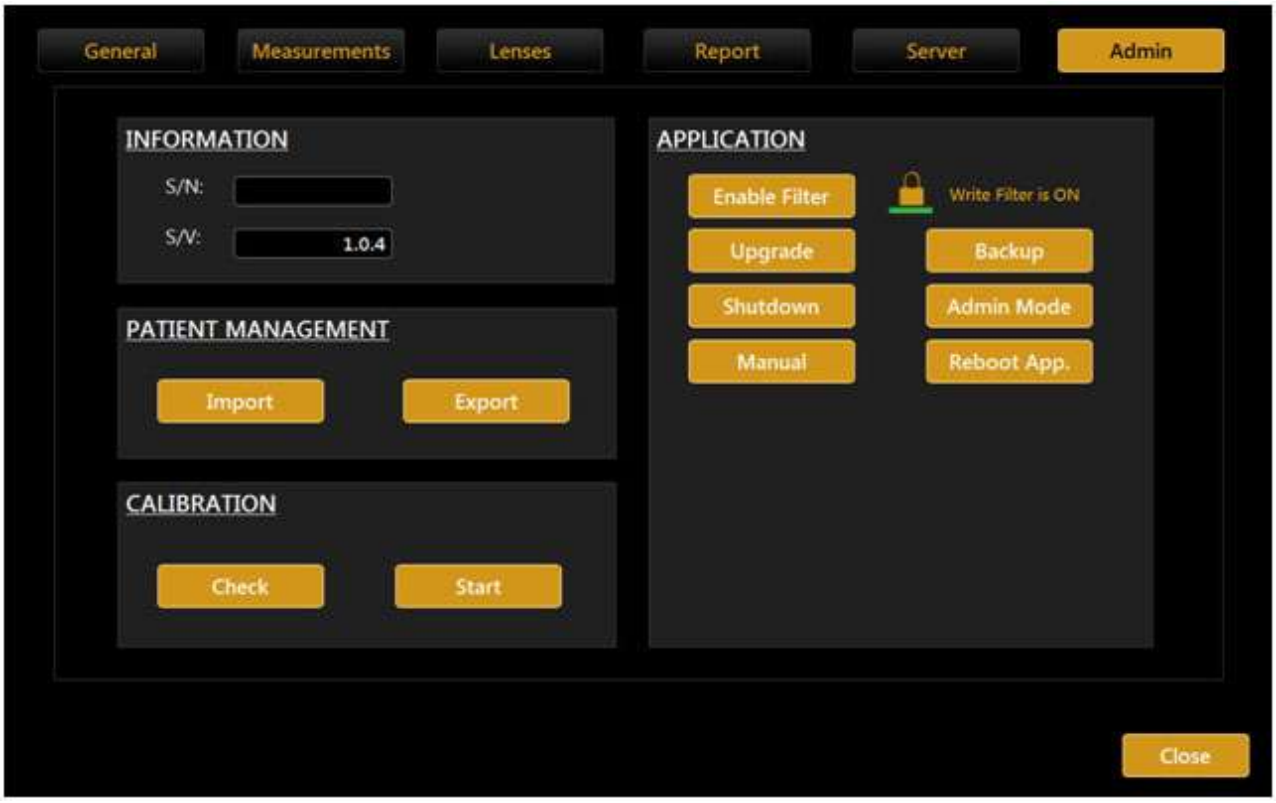


Fig. 4

After acquiring the 8 mm sphere eight times, at the end of the acquisitions the calibration check is complete and, if calibration is correct, the software will display the message “Calibration Check: POSITIVE” (Fig. 5).

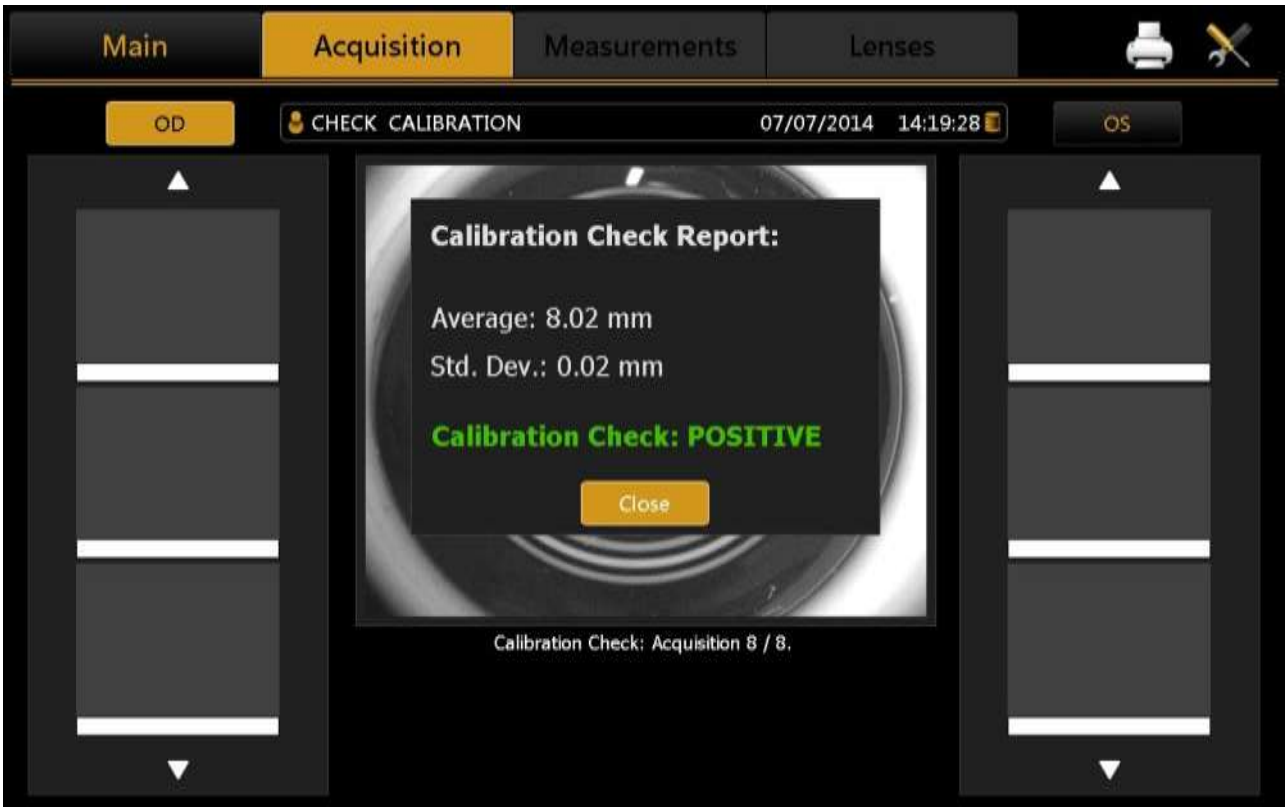


Fig. 5

If calibration is not correct, the software will display the message “Calibration Check: NEGATIVE” (Fig. 6).

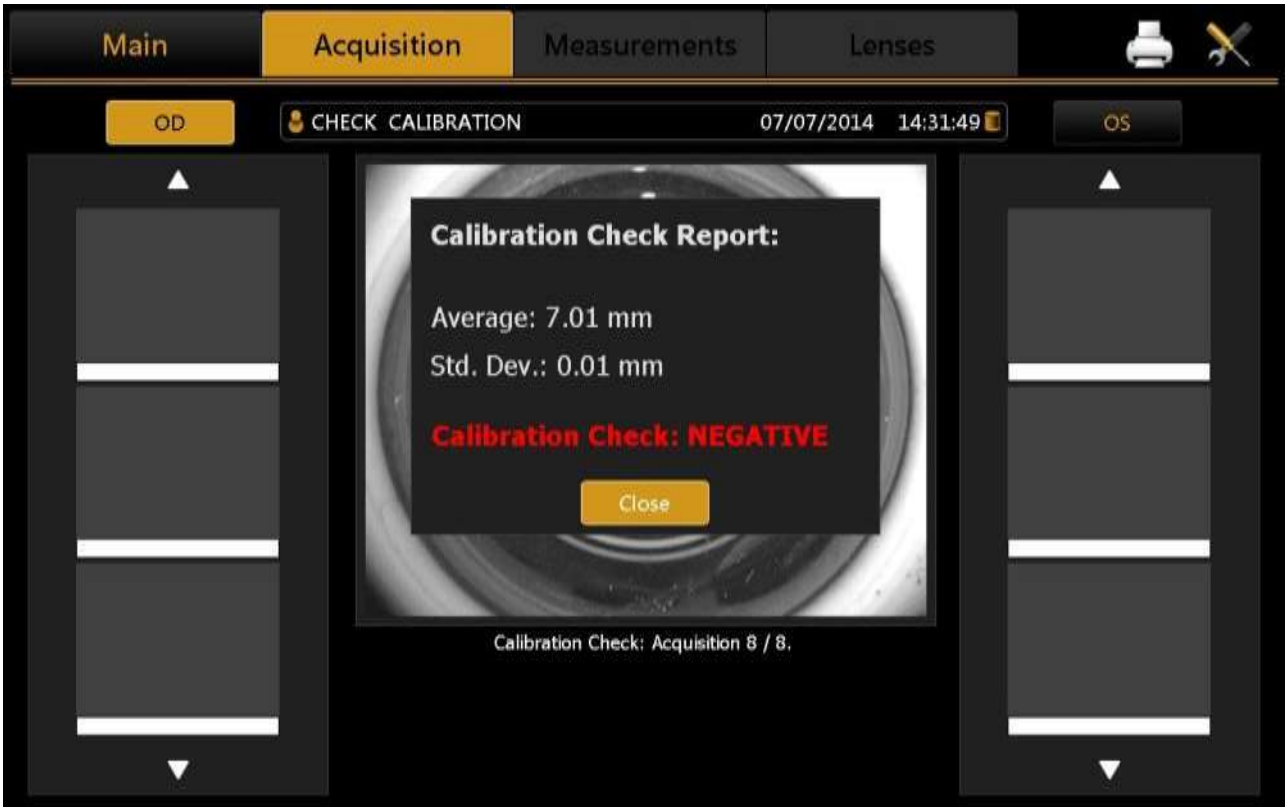


Fig. 6

12.2.2. Cleaning

Do not clean the plastic parts with solvents such as benzene or similar products, as they may cause discoloring of the parts and decomposition of the material.
If the instrument is dirty, clean the surface with a dry cloth.
If there are permanent stains on the surface of the Placido disc, please contact Topcon Support for replacement.
Before using the chin rest on another patient, clean and disinfect the mounts that come into contact with the forehead and chin with neutral detergents.

13. 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 unavailability of the device, such as a loss of profits or suspension of business.
The manufacturer shall not be held liable for damages caused by use of the device for purposes other than those described in this instruction manual.
The manufacturer shall not be held liable for the result of the diagnoses performed with this device.

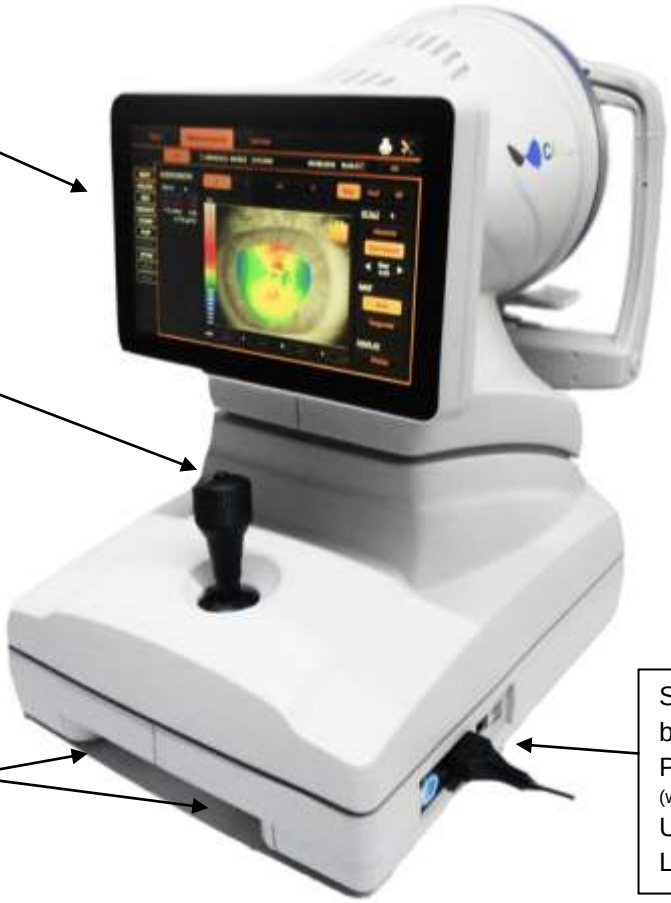
14. WARNING LABELS AND PLATES

In order to safely use the instrument and prevent risks to the operator and other persons as well as damage to the device, the instruction manual provides a description of the safety warning labels and plates on the instrument body.
Carefully read the PRECAUTIONS and SAFETY RULES as well as the manual and observe the instructions contained therein.

15. COMPONENTS

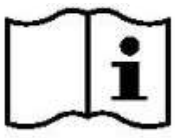
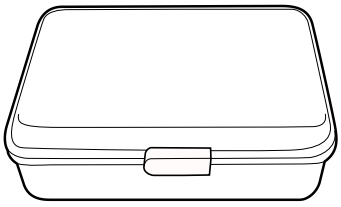
15.1. Main parts

NB: The parts in contact with the patient (**applied parts**) are the head rest in Teflon and the chin rest in acrylonitrile butadiene styrene resin (ABS)



16. CA-800 STANDARD ACCESSORIES

The following accessories are included in the package:

•	Calibration checking device **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.**	
•	Power cable	
•	Manual	 
•	Touchscreen pen, silicon cloth, chin rest paper and chin rest pins	

17. INSTALLING/UNINSTALLING THE SYSTEM

CA-800 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.

Two special warning labels are applied on the outside of the cardboard box. Please check them as described below before accepting the instrument on delivery, or accept it only with reserve.

If the circle on the label, shown below, is white, this means that the instrument has not been tilted during handling. If it is red, the instrument may have been damaged during transport.

If the white rectangle on the label shown above is red in the middle, this means that the instrument may have been damaged by shocks during transport.

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.

17.1. Installing the system

Before installing the system, read the “Safety Instructions” in this manual.

Fig. 7 shows the complete packaging of the instrument.

Cut the extensible film and the packing straps. Open the outer box as shown in Fig. 8.

Fig. 7

Fig. 8

Remove the manual and the accessories from the dedicated spaces between the two pieces of cardboard
The accessories are:

- "Topcon" box:
  - calibration checking device
  - chin rest paper
  - chin rest pins
  - touchscreen pen
  - silicon cloth
- Power cable (European cable and Hospital Grade cable)
- CA-800 dust cover
- CA-800 user manual

Open the internal box and remove the specially shaped part that holds the instrument. Remove the Nylon cover. The instrument can now be taken out of the package. The steps are illustrated in Fig. 9 .

Fig. 9

Be careful when taking CA-800 out of the box gripping it by the chin rest arch and the base beside the joystick.

Place the instrument on a flat surface.

Completely unscrew the two transportation locks and the semi-lock.

Connect the power cable provided.

The instrument is now ready for use.

17.2. 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 "instrument locking devices" for transportation.

Fig. 10

Insert the instrument in the box, as shown in Fig. 10, and place the Nylon cover on it.

Follow the step sequence shown in Fig. 11.

Fig. 11

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

17.3. Connection modes

18. OPERATING INSTRUCTIONS

CA-800 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 is provided in the following paragraphs of this chapter, to which you should refer for further details.

To interact with the software, the LCD display with touchscreen 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.

18.1. General description of functions

CA-800 is a corneal analyzer with the following functions:

- Cornea image acquisition and topographic analysis;
- 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 movie acquisition that allow to check the contact lens positioning, or to assess cornea's artifacts and the lachrymal film (rupture time);
- Analysis of wavefront 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;
- Optional - Oculentis Intraocular lents calculation (Toric IOL).

18.1.1. General instructions

The follow icons provide access to functions commons to various working environments:

Access to the "Settings" section, described in detail in the dedicated paragraph.

Direct printing of the report or saving a PDF file based on the options selected in the print section.

18.2. Checking calibration

See **12.2.1- Calibration check**.

18.3. Entering/selecting a patient

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

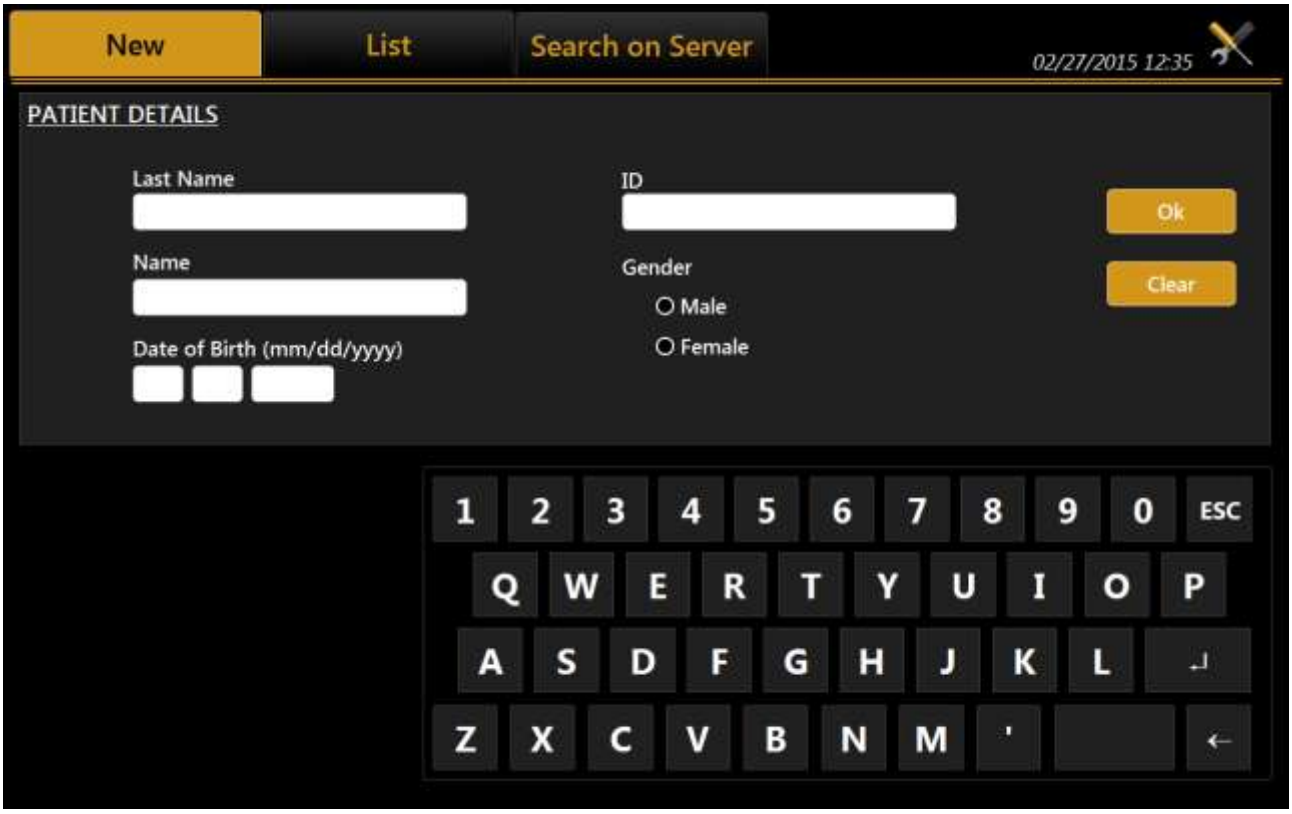


Fig. 12

Fig. 12 shows the section for creating a new patient, entering Last Name, Name and Birth Date (Gender and ID are optional).

18.3.1. Creating a new patient

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

A special character can be entered simply by touching and holding the corresponding letter (Fig. 13).

Fig. 13

18.3.2. Selecting or editing a patient

On the input screen, tap on the **"List"** tab to access all the patients found in the database (Fig. 14).

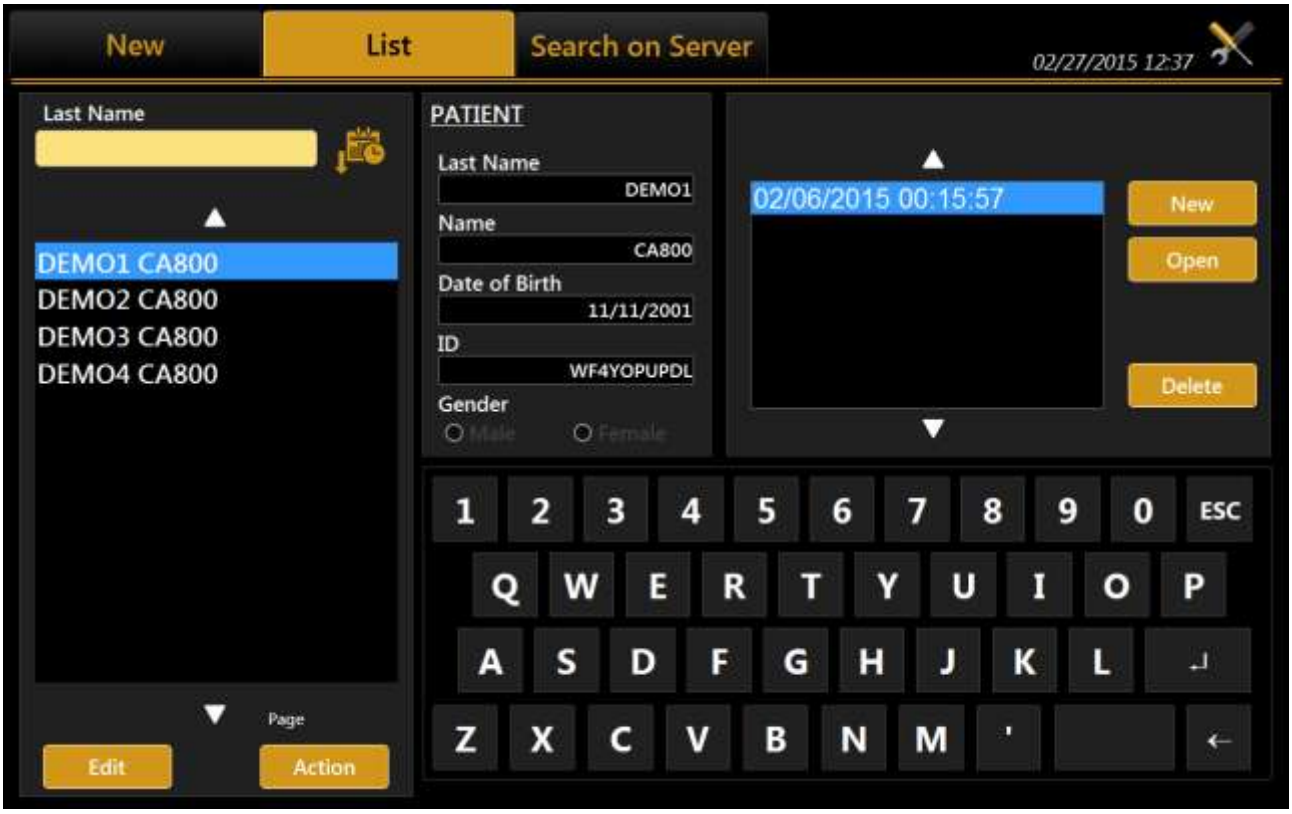


Fig. 14

On this screen you can select a previously created patient and the examinations associated with him/her.
If you edit the **"Last Name"** field, a search is done in the database for patients with the corresponding surname or whose surname contains the selected key. By pressing the arrow button on the right, the field and the search are canceled.

18.3.3. Open an examination or acquire data for the selected patient

In the left column, tapping on a patient in the **"Exam List"** frame, the list of associated examinations will be displayed. In this list, you can access examinations or delete them, using the "Open" or "Delete" buttons.
After selecting a patient, another examination can be carried out by pressing the **"New"** button.

18.3.4. 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" and "Cancel". Press "Delete" to delete the selected patient with all of his exams, press "Export" if you want to export it with all of his exams 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.

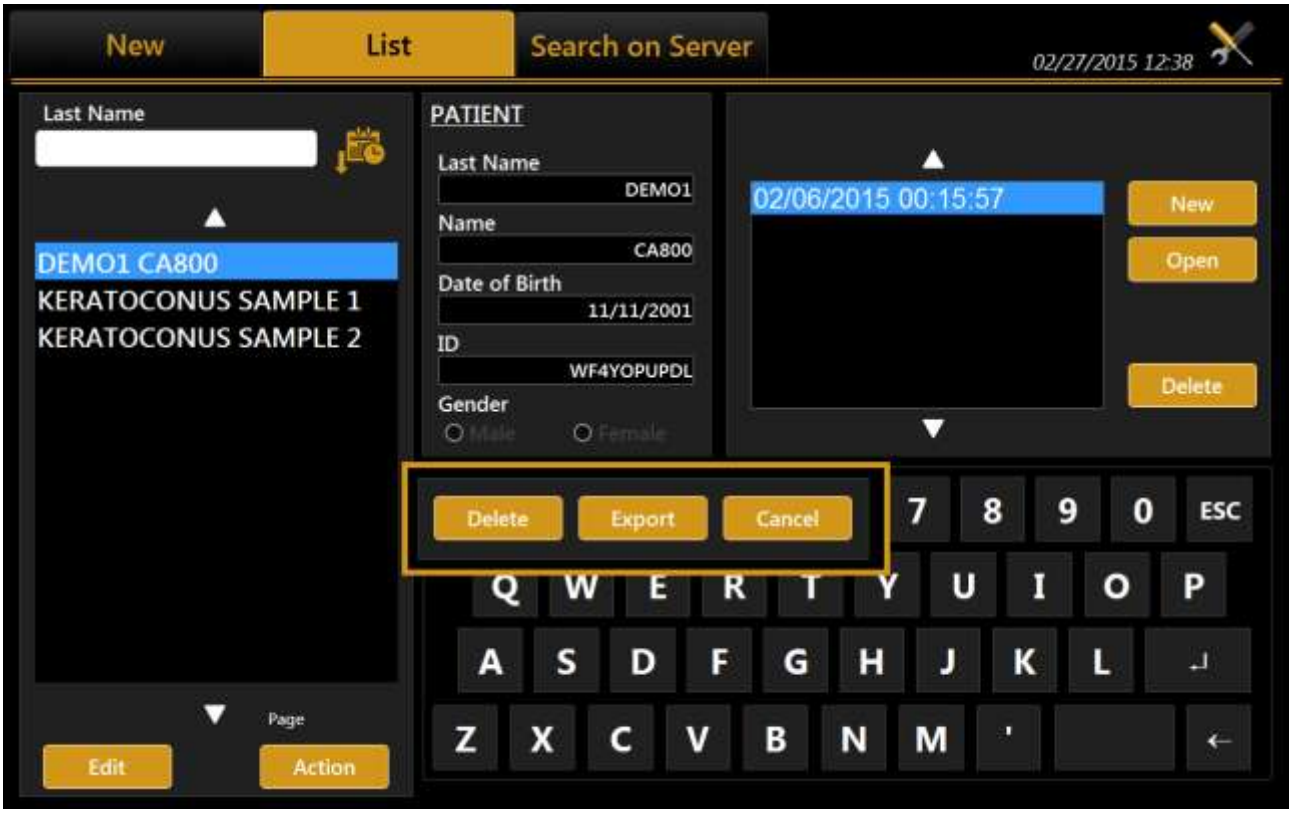


Fig. 15

18.3.5. Selecting a patient from Server List

After enabling the CA-800 Server List integration using the CA-800 settings panel (see Server List configuration), you can select a new patient from the patient list retrieved from the IMAGEnet i-base or Corneal Analyzer (Fig. 16). The user can search for a patient either by surname or by ID (only if you have selected IMAGEnet i-base as active server). A list of patients corresponding to the search criteria will be created. After selecting a patient, the user can create a new examination in standard mode by tapping on the “Ok” button.

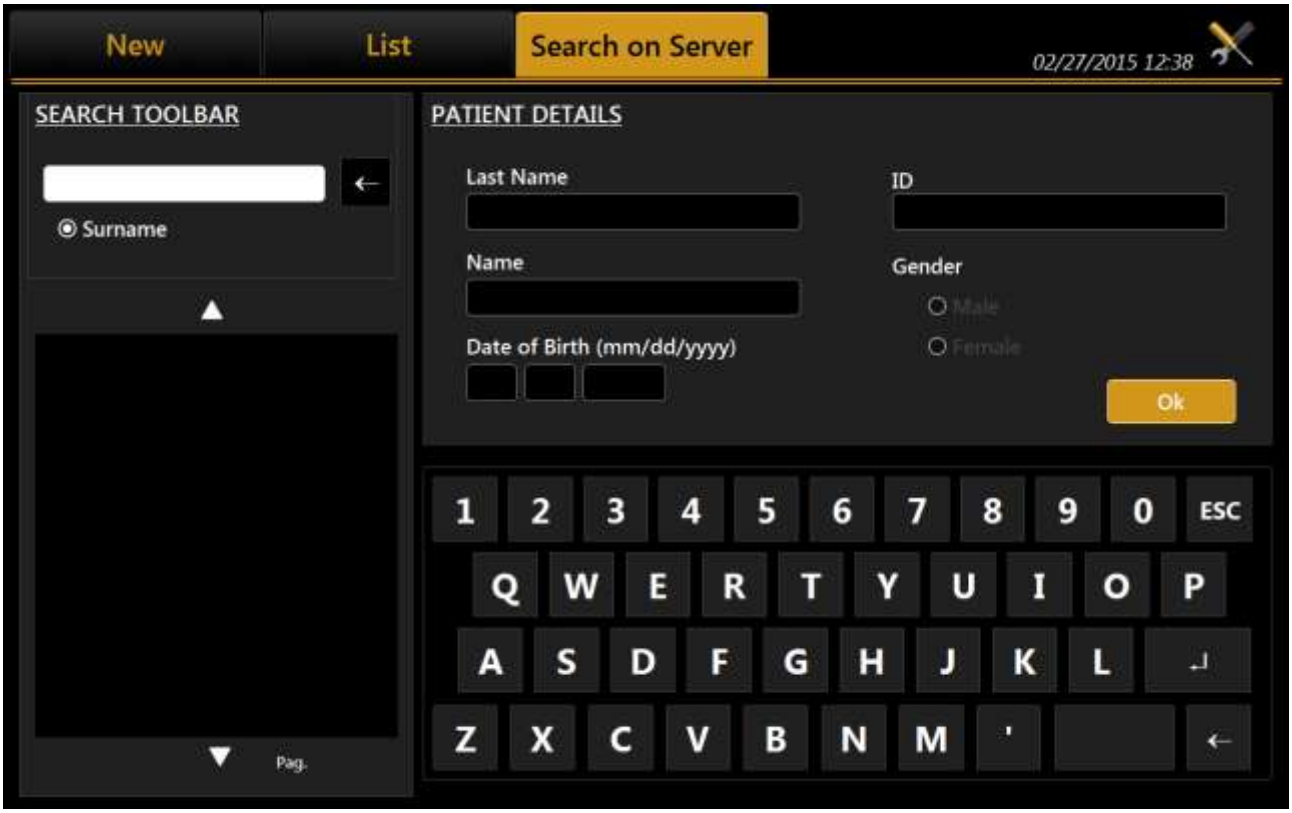


Fig. 16

18.4. Acquisition environment: general instructions

Fig. 17 shows the acquisition screen.

Fig. 17

The joystick illustrated in Fig. 18 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 thumb wheel marked "Height Regulation" allows you to adjust the instrument height according to the patient's position.

On the chin rest there is also a knob for adjusting the height, if the adjuster on the joystick is not enough to achieve the correct position.

To perform the acquisition, position the patient with his/her chin on the chin rest and forehead on the forehead rest. This is the correct position for performing the examination.

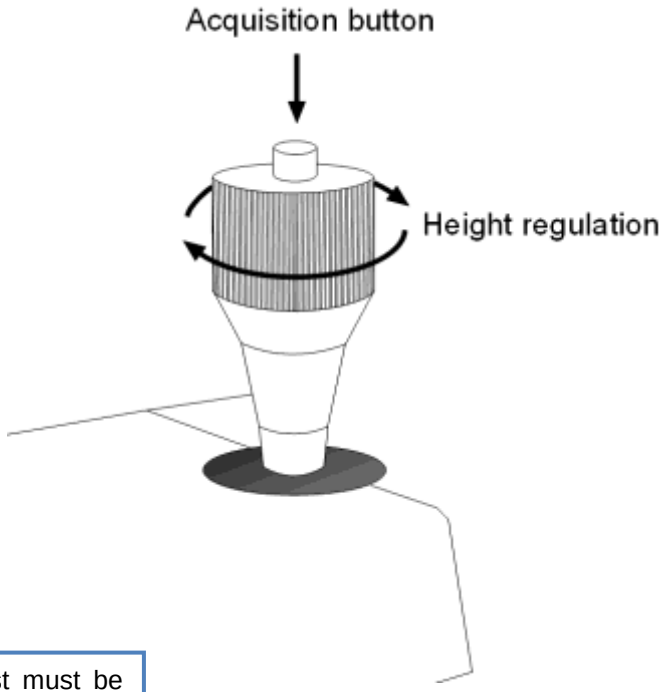


Fig. 18

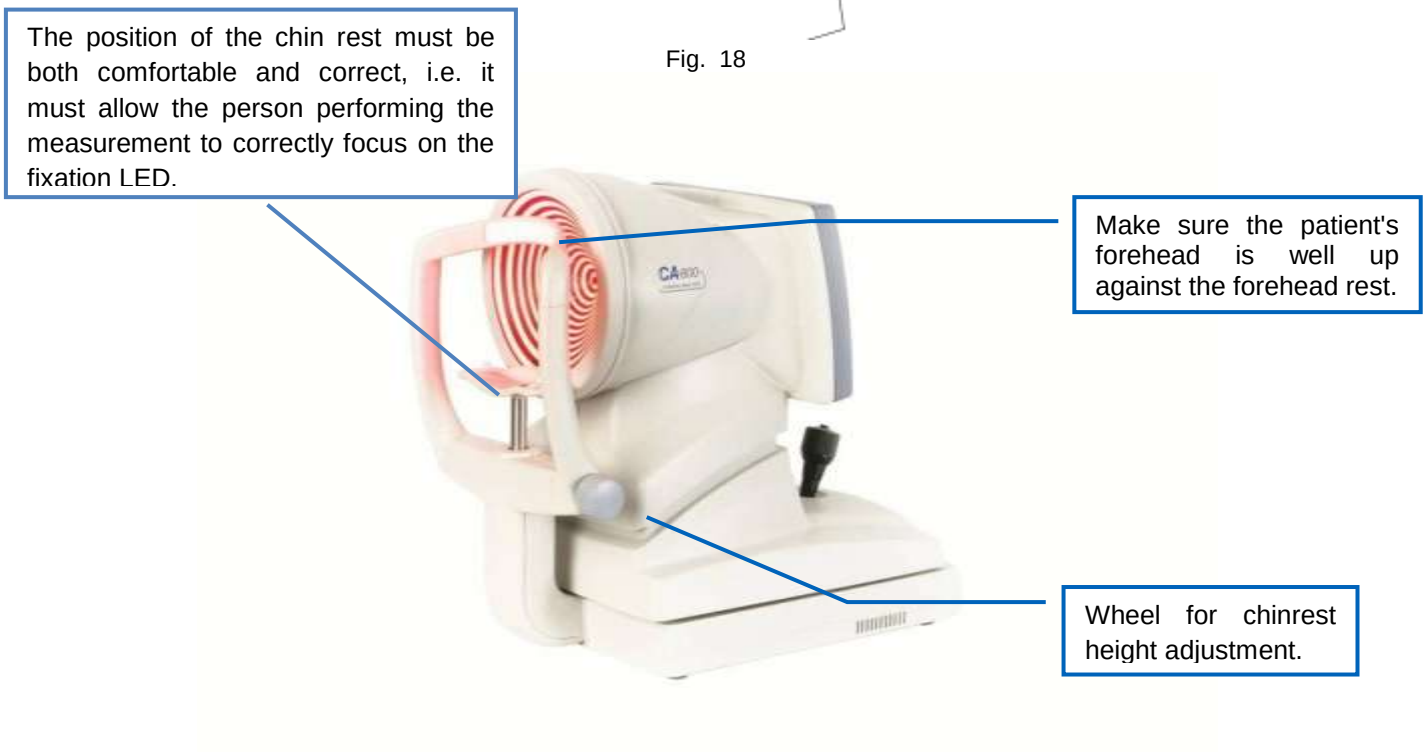


Fig. 19

18.4.1. Description of the acquisition screen

The acquisition window (Fig. 17) 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:*** gives access to the topographic section.

- ***PUPI:*** gives access to the pupillometry section.
- ***EXTRA:*** gives access to the meibomian section.
- ***FLUO:*** gives access to the fluorescein section.

18.4.2. Acquisition gallery

A preview of the acquired image is shown in the acquisition gallery (Fig. 20 for topography, pupillometry, meibomian and fluorescein, respectively).

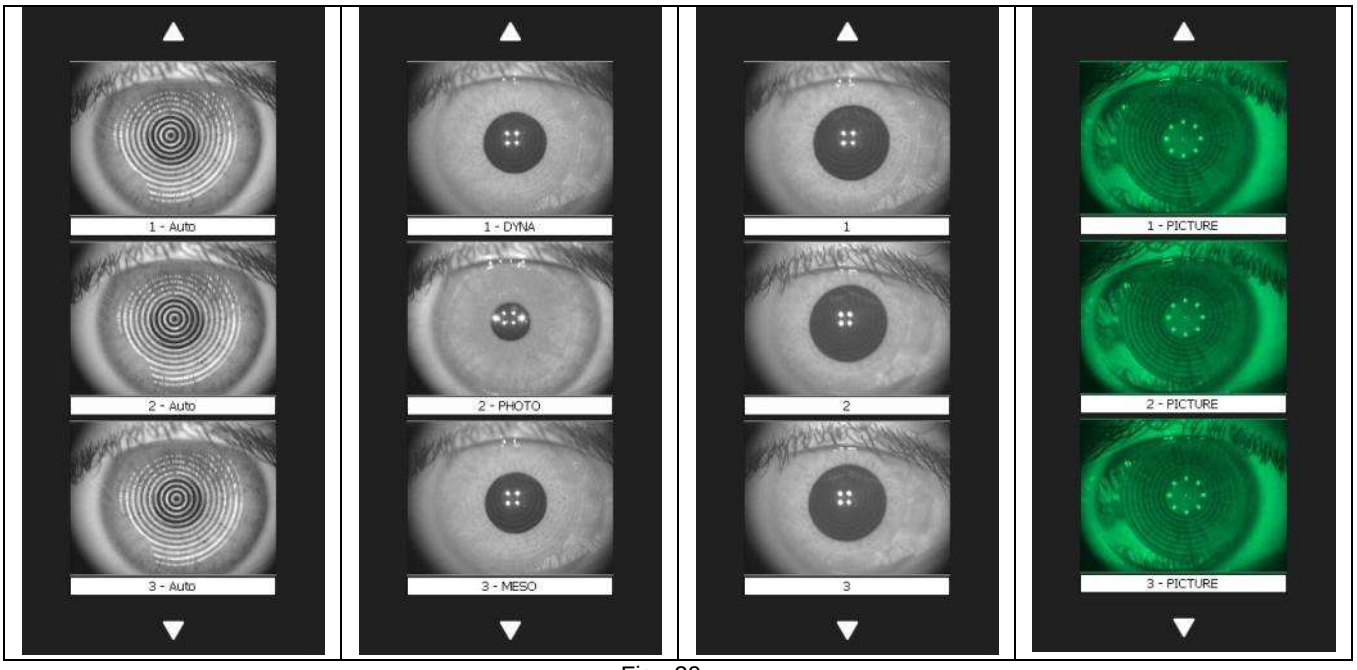


Fig. 20

The images are numbered progressively and each of them is associated with the eye it refers to and the type of acquisition.

For topography, you can tap on a preview image to select or deselect it. The selected images are displayed normally, while those not selected are dark (Fig. 21).

To calculate the topographic map, the software automatically selects the best image for each eye.

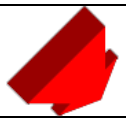
The arrow buttons in the gallery frame for each eye are used to scroll the images, as some of these are hidden if more than three acquisitions per eye are made.

18.4.3. Acquisition procedure

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 forwards and backwards (following the indications 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 red arrows indicate to move the instrument forward towards the patient's eye.
	The blue arrows indicate to move the instrument backward, away from the patient.

18.5. 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.

CA-800 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. 21 appears.

Fig. 21

In this mode, the topographic map of the cornea is acquired.

Knowing the distance of the corneal apex, with a precision of microns, at the time of acquisition of the topographical image, the software applies to each of the 256 zero crossing, identified for each of the 24 RINGS, a correction factor given by the ratio between correct mean value and mean radius of the ring.

Concerning the calculation, the software calculates, as standard, 6,144 zero crossing points, identified at the 24 RINGS along the 256 semi-meridian.

18.6. Pupillometry

Press the ***“PUPI”*** button to acquire the Pupillometry images.

By selecting this mode, the acquisition environment shown in Fig. 22 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 paragraphs, four types of acquisition can be performed:

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

Fig. 22

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 different light conditions applied. In the static pupillometry acquisition made in controlled light conditions (photopic, mesopic and scotopic) certain frames are saved and can be display by scrolling the associated gallery in the Pupil → Measurements section.

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

18.7. Meibomian

Press the **EXTRA** button to acquire the meibomian gland images.

By selecting this mode, the acquisition environment shown in Fig. 23 appears on the screen.

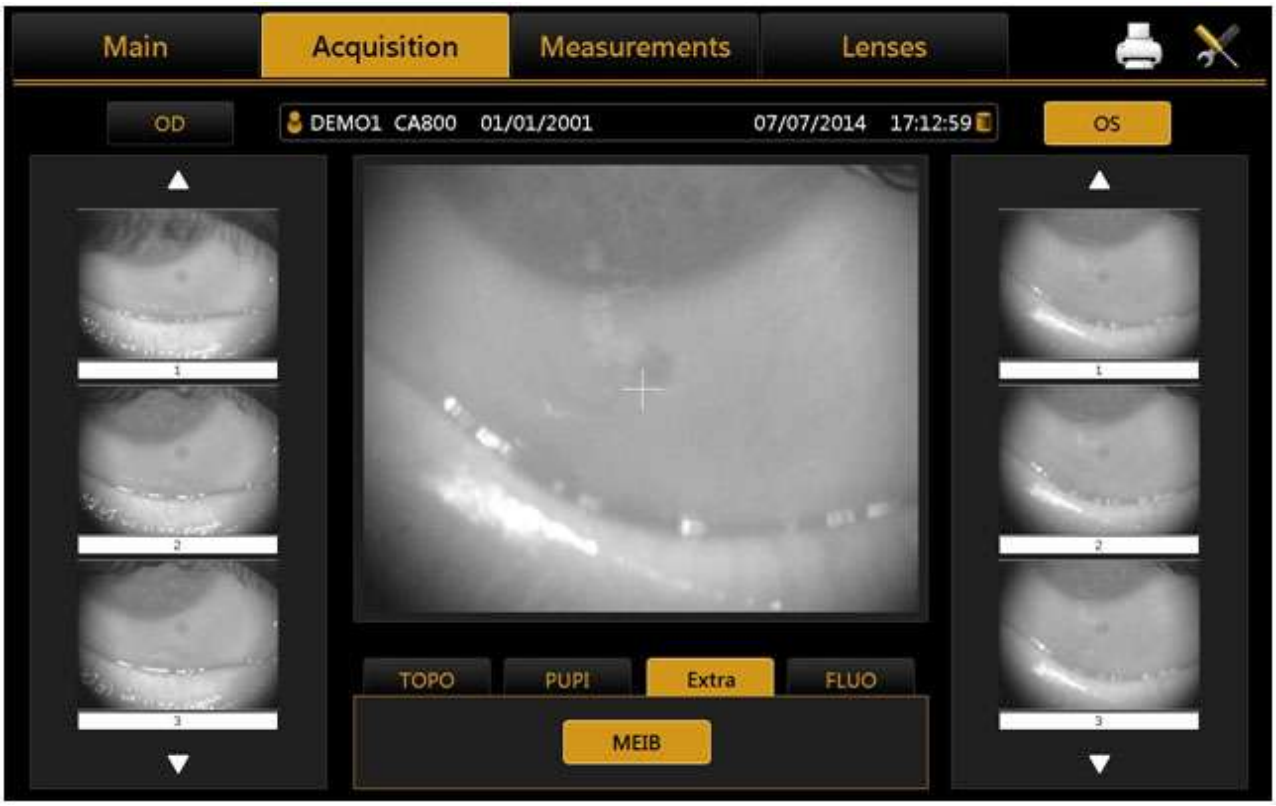


Fig. 23

In this section the user can take pictures of the meibomian gland. The images will be displayed in the gallery and in the **Measurements** tab.

18.8. Fluorescein

Press the ***"FLUO"*** button to access the fluorescein analysis acquisition environment (Fig. 24).
You can select between picture and movie acquisition.

Fig. 24

18.9. Measurements

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

There are four types of measurement.

- **MAP**: Keratometry
- **ZER:** Zernike Analysis
- **ALTIM:** Altimetric
- **PUP:** Pupillometry

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

18.9.1. MAP-Topographic map

The environment displayed is shown in Fig. 25.

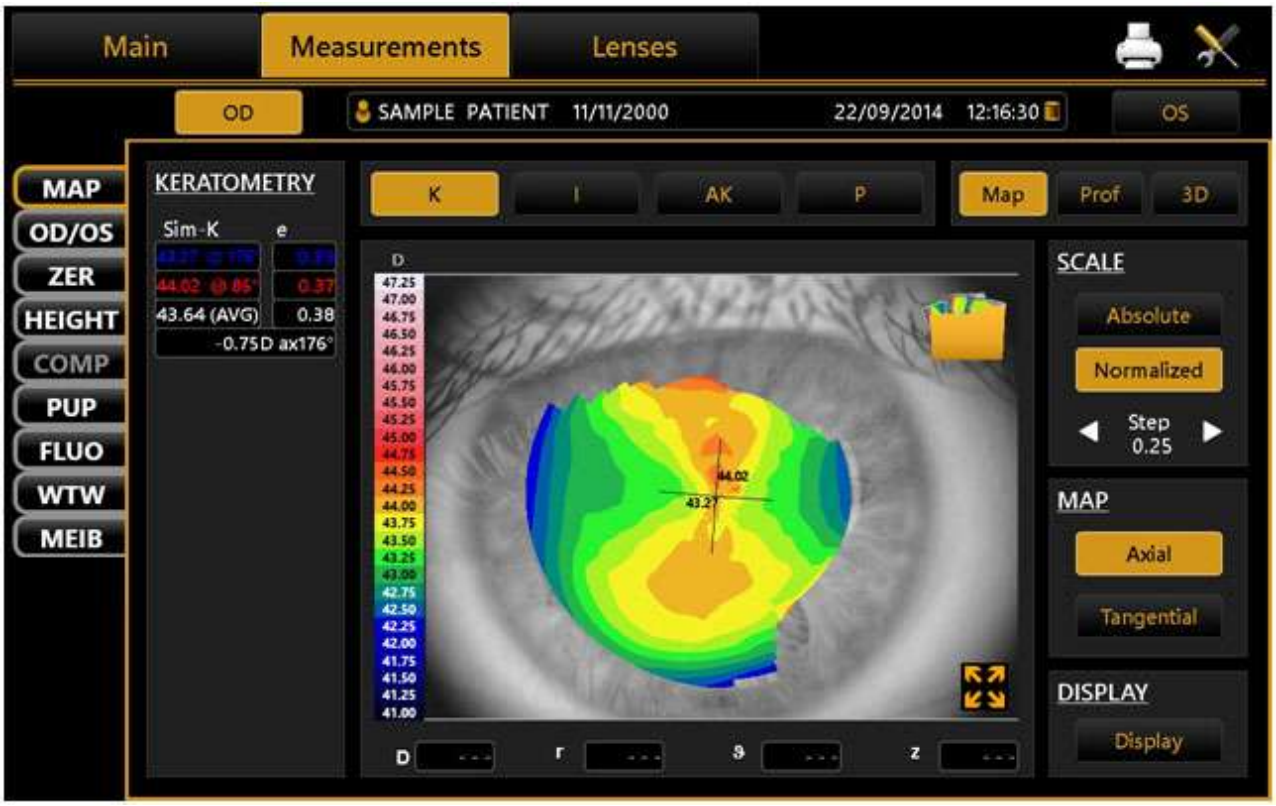


Fig. 25

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)

18.9.1.1. 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

18.9.1.2. Keratometry

Press the ***"K"*** button to display the keratometric data on the 3 mm, 5 mm and 7 mm zones, as shown in Fig. 25.

18.9.1.3. Keratorefractive indexes

Press the ***"I"*** button to view the keratorefractive indexes (Fig. 26):

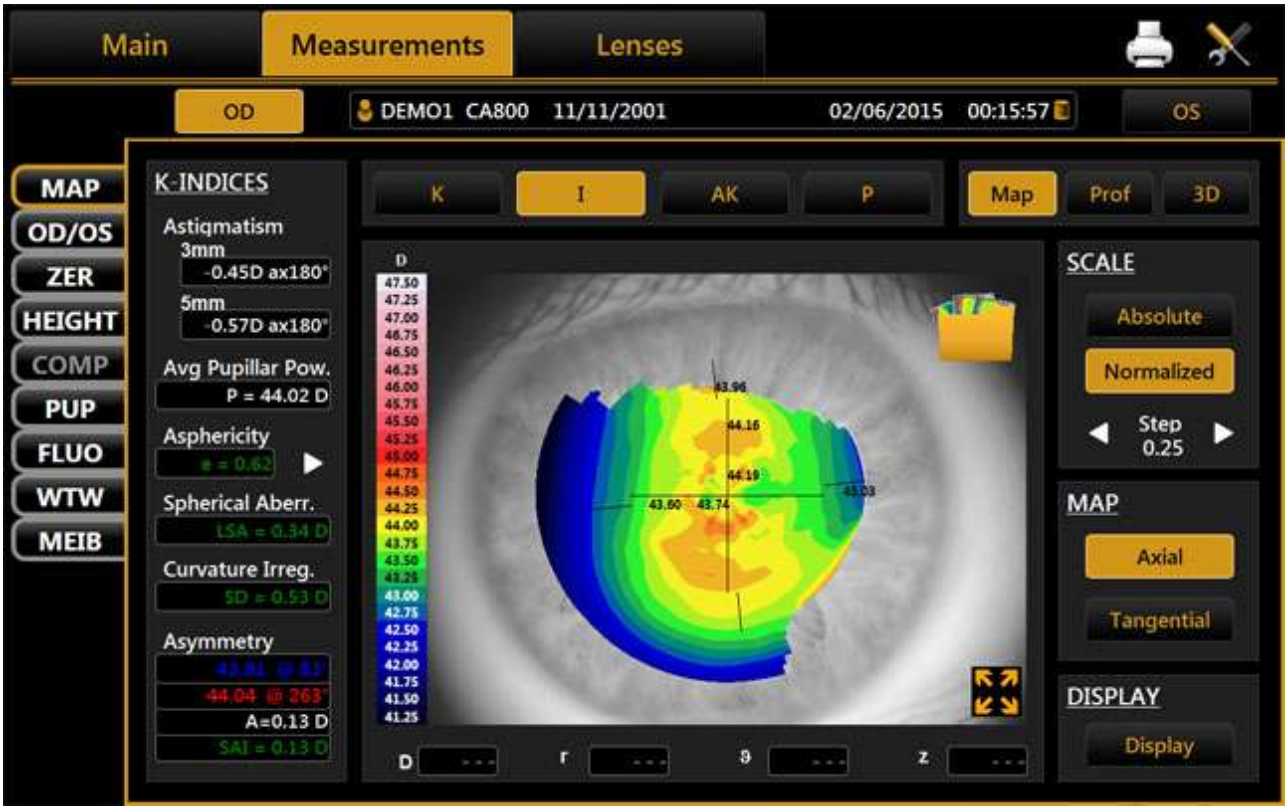


Fig. 26

- **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 by two tabs' (Asphericity and Peripheral degrees) which specify the corneal asphericity.

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

Asphericity

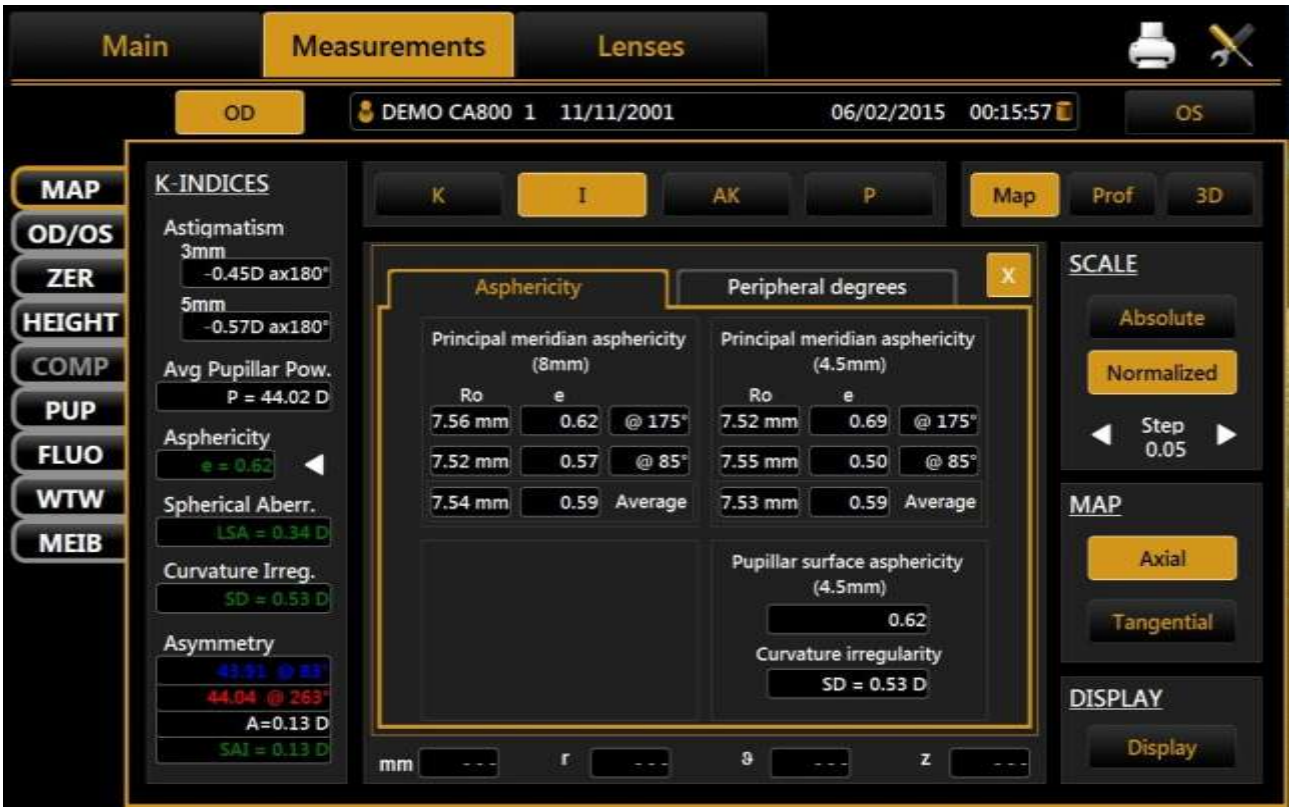


Fig. 27

As you can see from (Fig.27) the panel is divided into four parts.

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

- in the first line you can read the apical radius (Ro) and the asphericity (e) along the flattest meridian (@);
- in the second line there are the same parameters calculated along the steepest meridian; in the third line there are the average values of the apical radius and of 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 as pupillar surface (4.5mm) and the surface irregularity (SD).

The last parameter measures the difference between the current cornea curvature and 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 Figure 28).

Fig. 28

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 respectively the average between nasal and temporal parameter values and between inferior and superior parameter values.

The last row contains the general parameter averages.

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

18.9.1.4. Keratoconus

Press the ***"KC"*** button to open Keratoconus screening, this section is divided into two tabs: KC and CLMI.
The KC shows the following information (Fig. 29):

Fig. 29

- ***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 reference.
- ***SI***: difference between the average power of two circular zones centered on the vertical axis of the ruler and placed in the lower hemisphere and in 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 a 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, ø***: polar coordinates (mm, °) 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. 30):

Fig. 30

- ***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.

18.9.1.5. Pupil

Press the ***"P"*** button to open the pupil indexes (Fig. 31):

- **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 decentralization from the optical axis.
- **Avg Pupil Ø:** Mean diameter of the pupil.

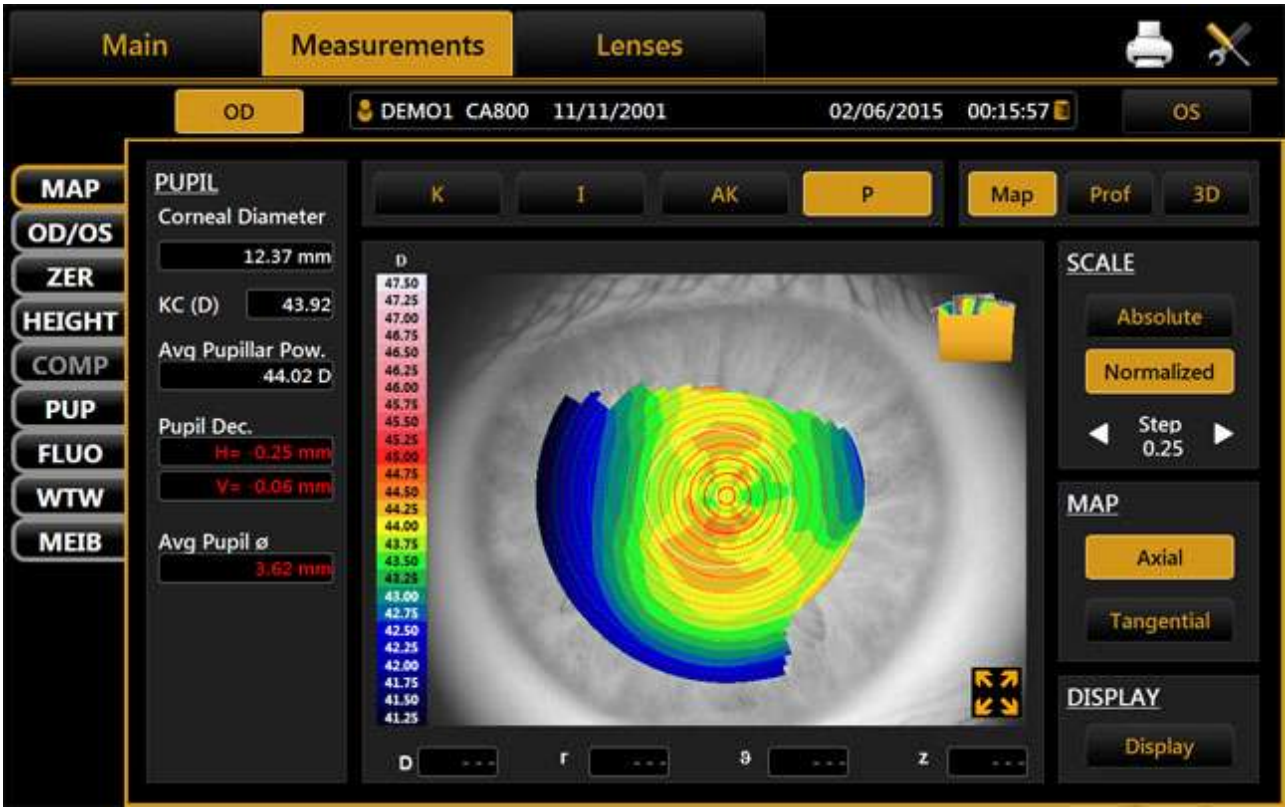


Fig. 31

18.9.1.6. Gallery

Press the icon at the top right of the map to enter the gallery (Fig. 32).

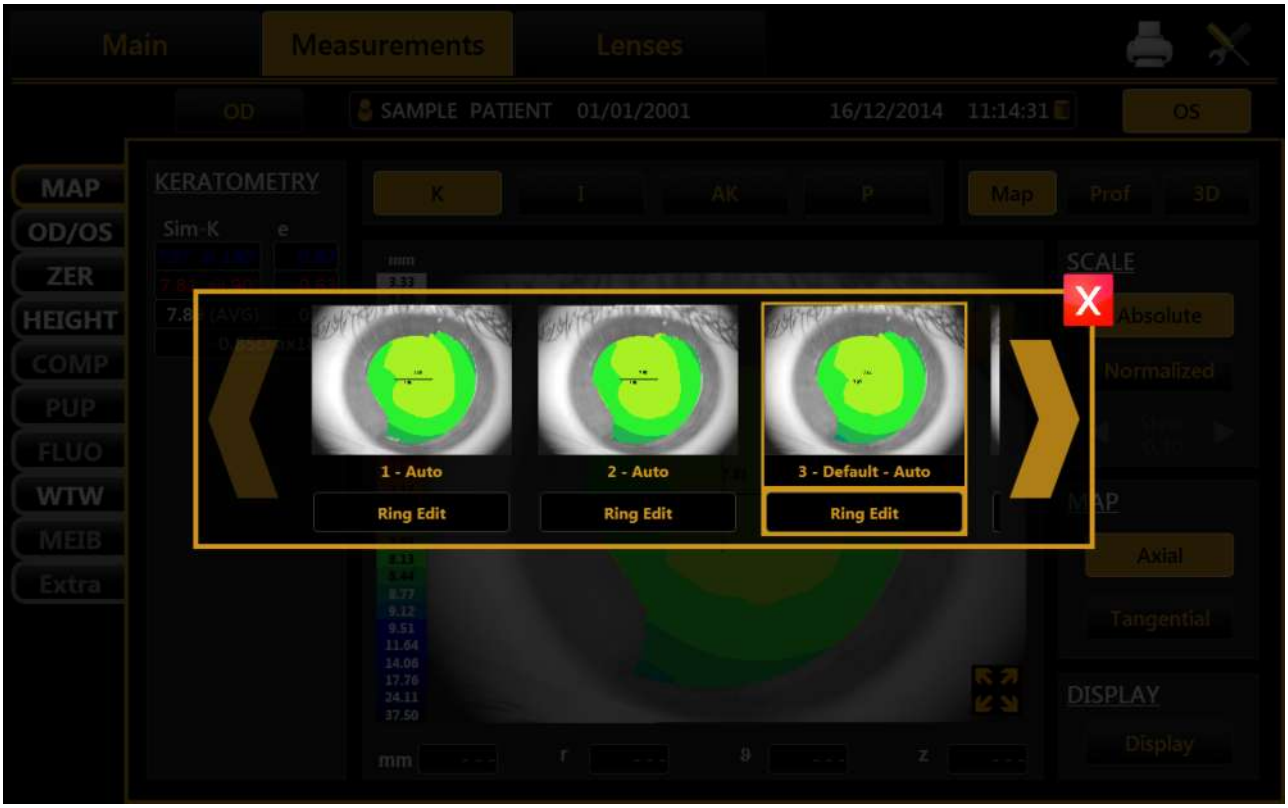


Fig. 32

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

18.9.1.7. Full screen mode

From the map environment (Fig. 25) you can access full screen mode (Fig. 33) 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.

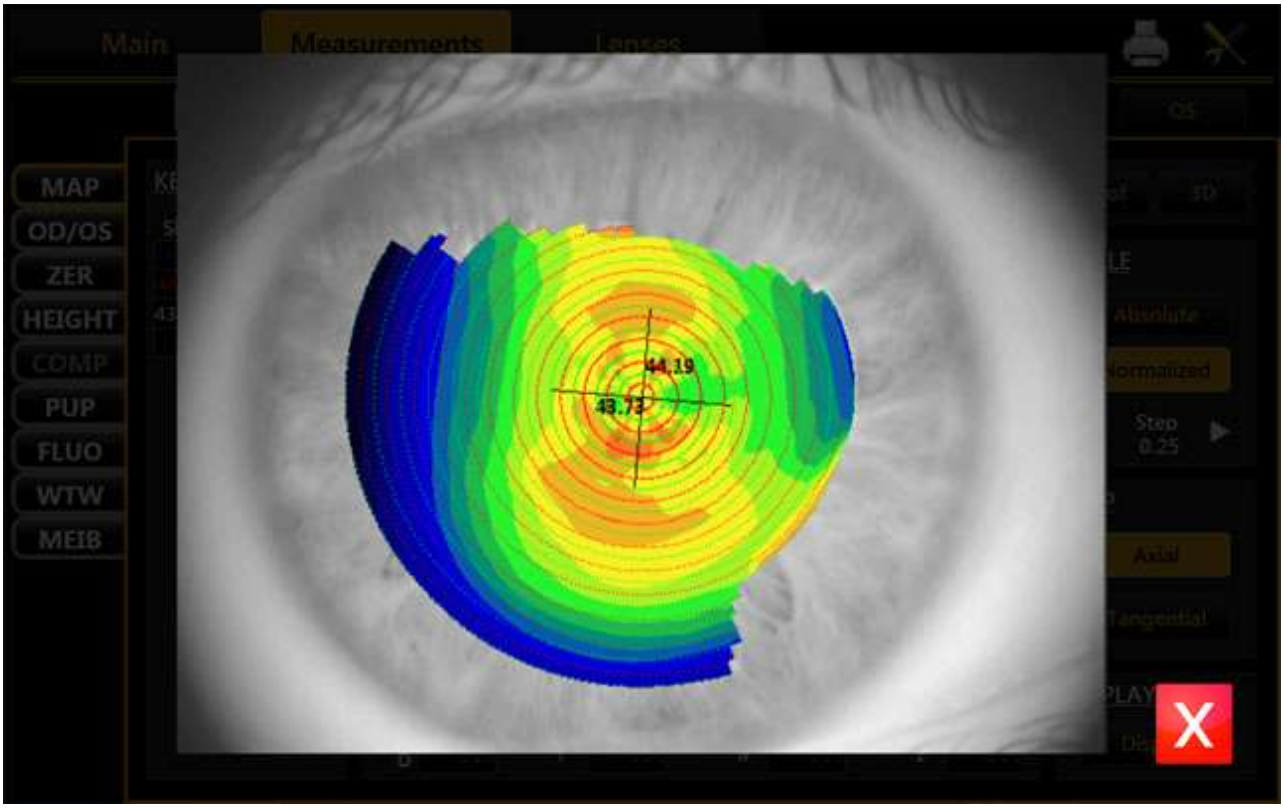


Fig. 33

18.9.1.8. 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. 34).

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.

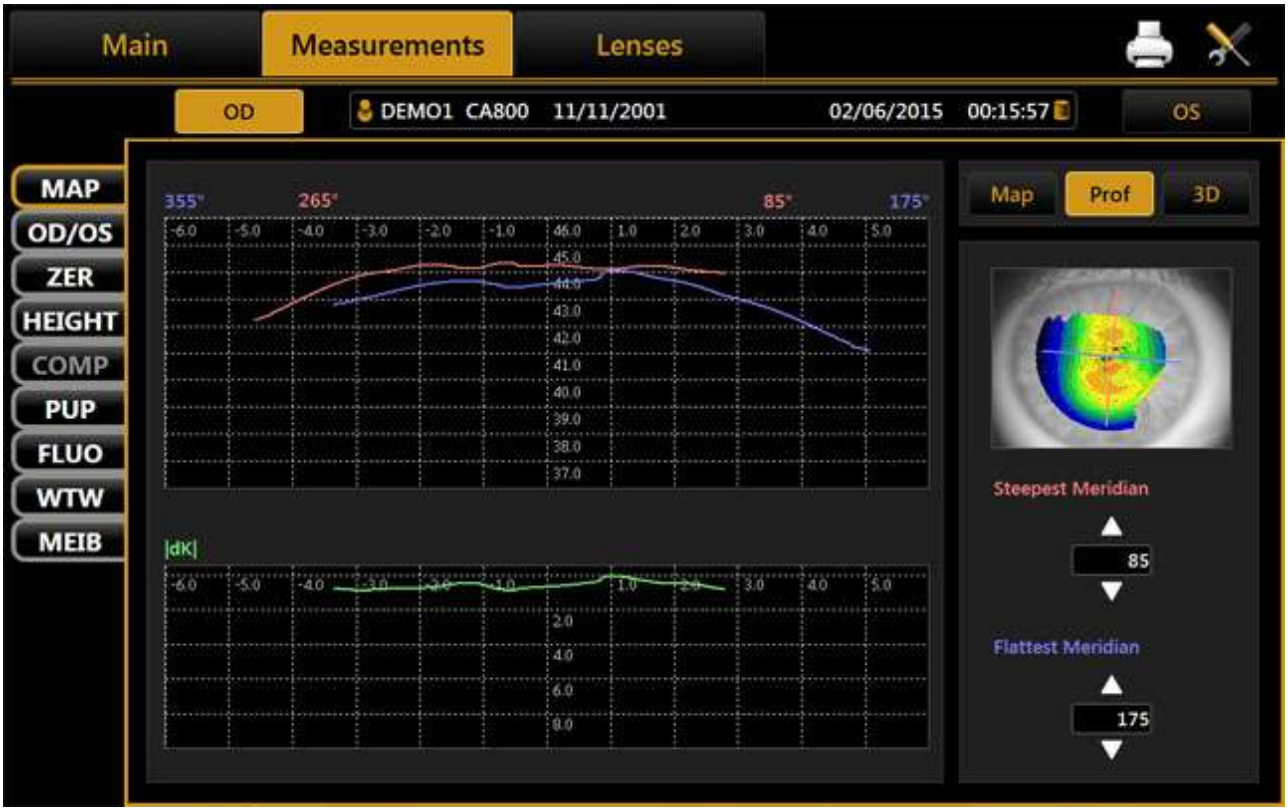


Fig. 34

18.9.1.9. 3D

Press the ***"3D"*** button to view the 3D map of the keratometric data (Fig. 35):

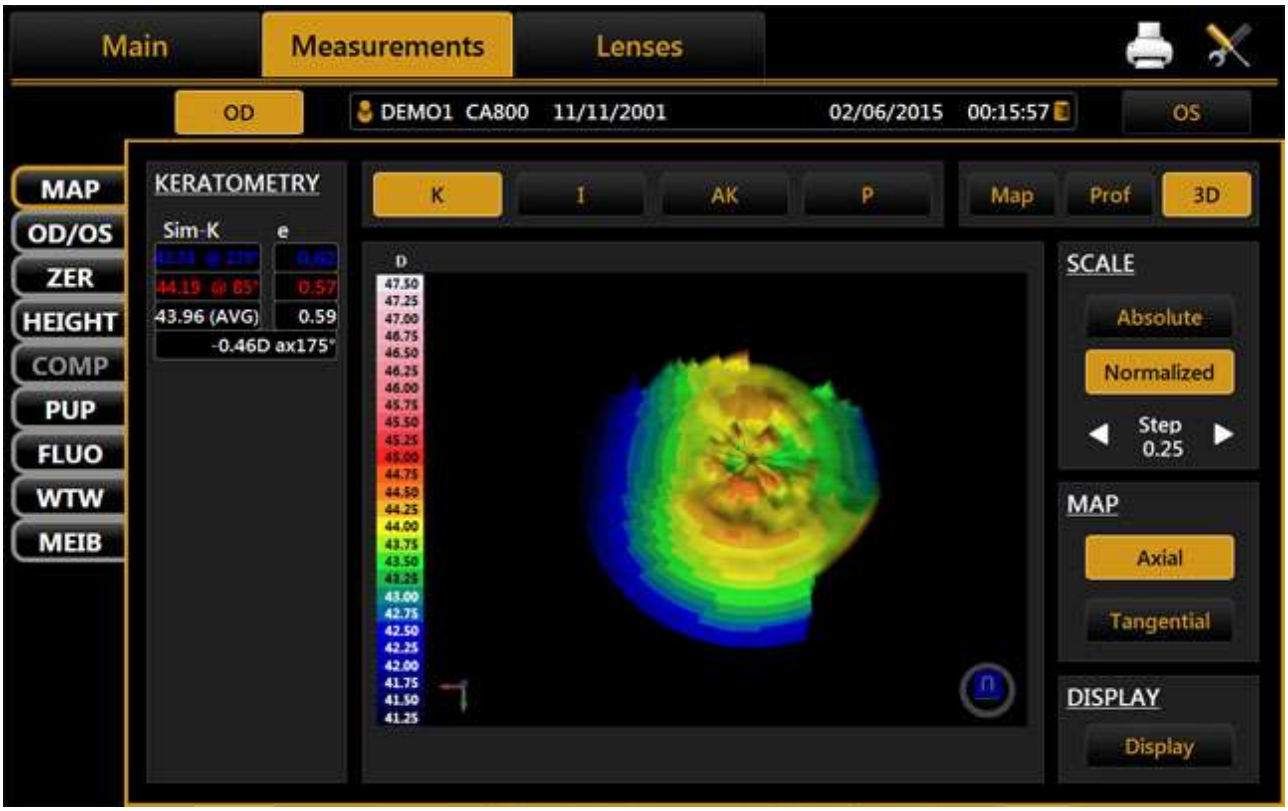


Fig. 35

18.9.1.10. Edit ring

In this section the user can edit the 24 rings in order to improve the topographic map (Fig. 36).

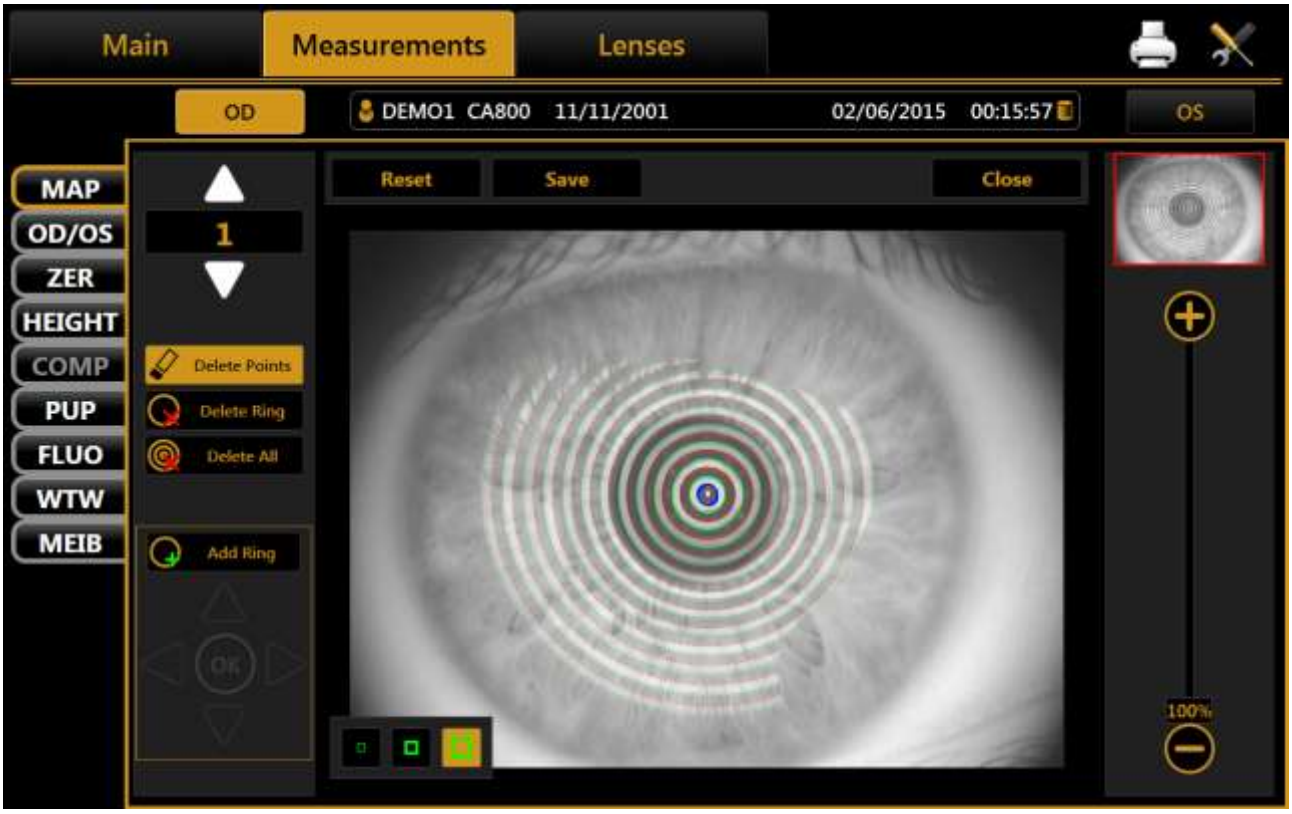


Fig. 36

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 slide 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:
  - **"Delete Points"**, to delete parts of the selected ring;
  - **"Delete Ring"**, to delete all of the selected ring;
  - **"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.

18.9.2. OD/OS

In this section you can compare the OD and the OS data on the same screen (Fig. 37):

Fig. 37

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.

18.9.3. ZER - Zernike

The Zernike module provides a comprehensive view of the wavefront 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. 38).

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.

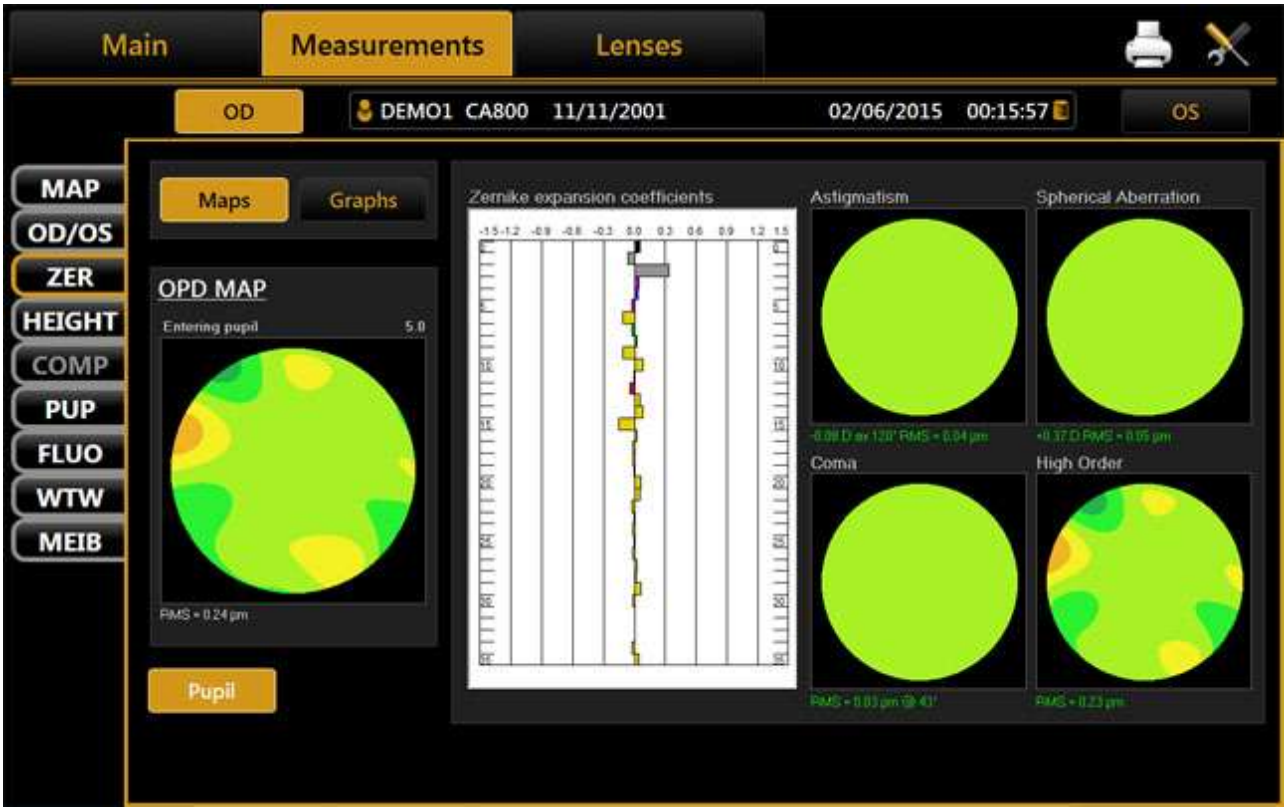


Fig. 38

Tap on ***"Graphs"*** at the top left to display the vision quality summary (Fig. 39). This section displays:

- **Zernike Coefficient pyramid**: represents the numerical value of each coefficient by means of a gray scale; the greater the coefficient, the greater the color contrast with the pyramid background.
- **Point Spread Function**: represents the intensity of the wavefront in the retina.
- **Spot Diagram**: represents the spatial distribution of the wavefront over the retina.
- **Visus/Visus Low Contrast:** represents the patient's real vision with high and low contrast.

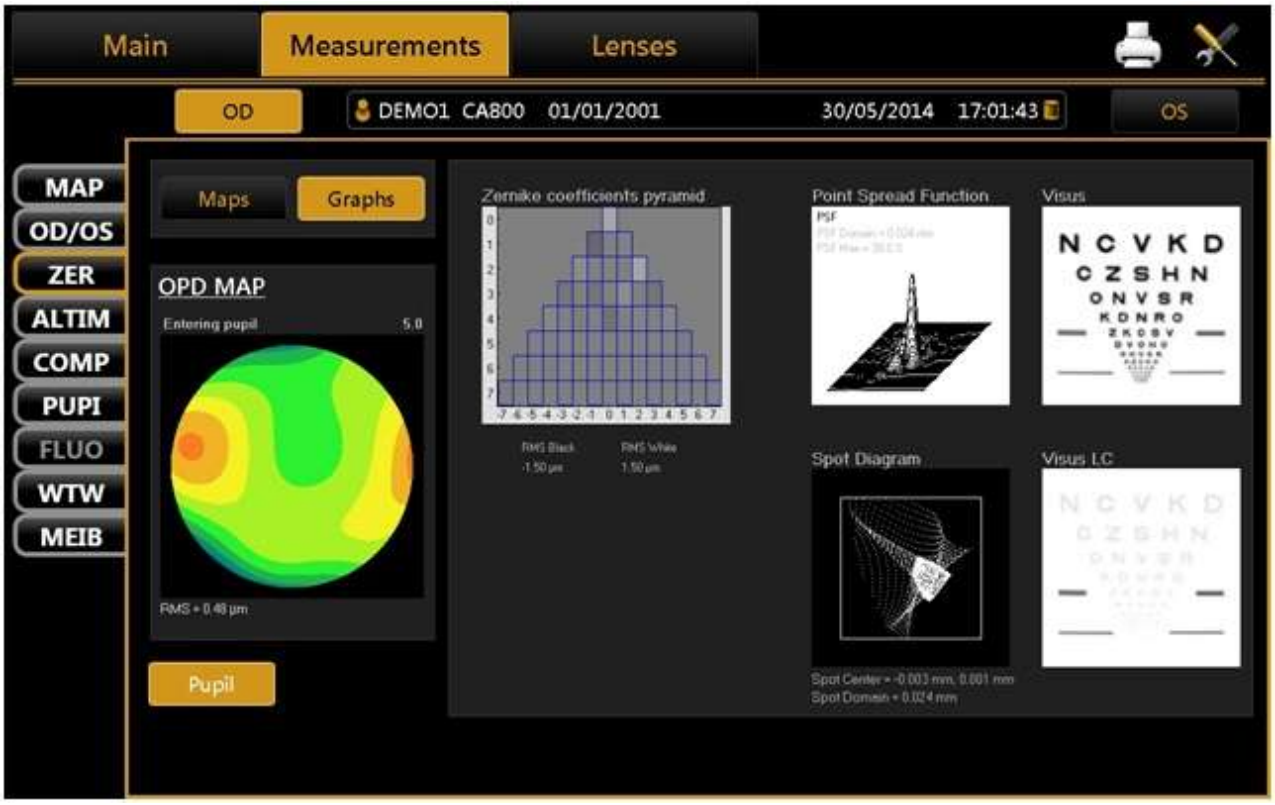


Fig. 39

The data displayed refers only to the component induced by the anterior surface of the cornea, not by the eye entire optical system.

Press the ***"Maps"*** button to return to the maps display.

The ***"Pupil"*** button opens a panel (Fig. 40) where you can select the diameter of the pupil (in a range between 2 mm and 7.5 mm) to see how the aberrations change as the pupil diameter varies.

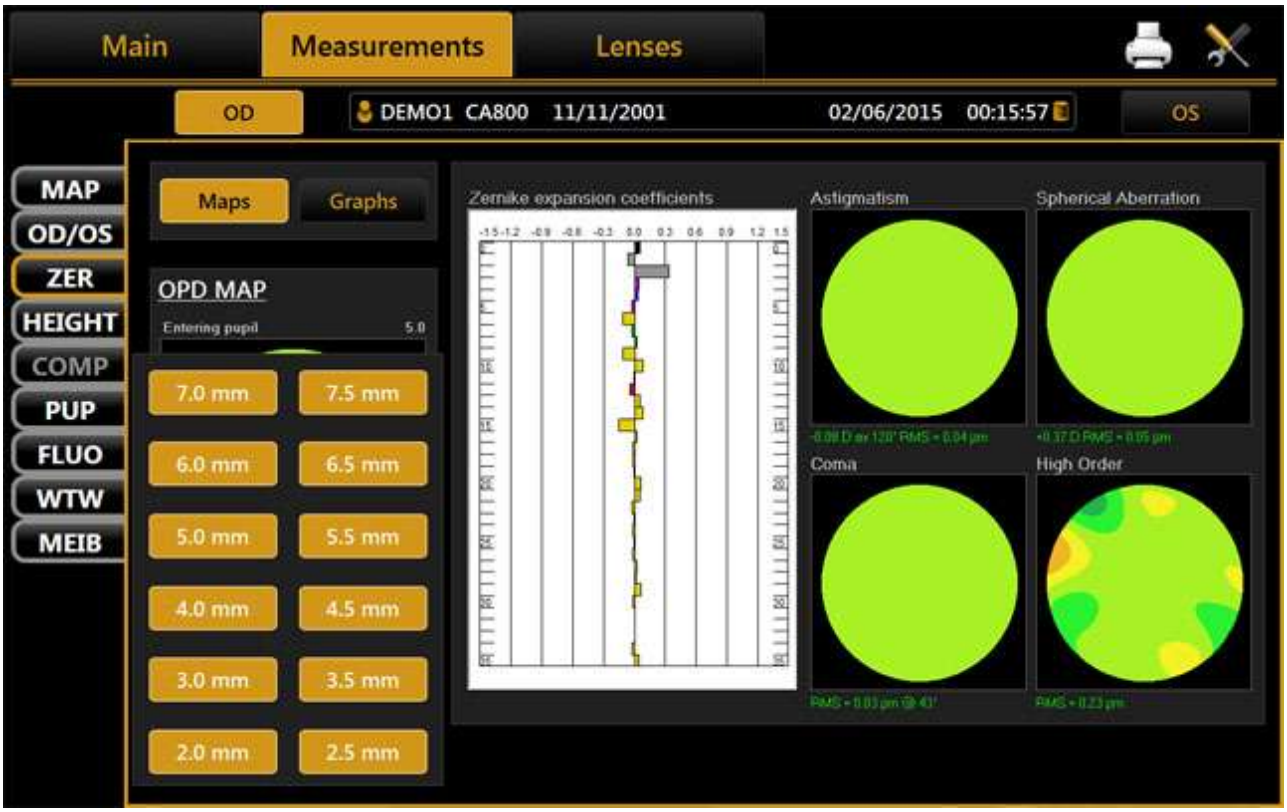


Fig. 40

18.9.4. HEIGHT

"Height" environment allows the user to compare the patient's cornea with a reference surface (Fig. 41):

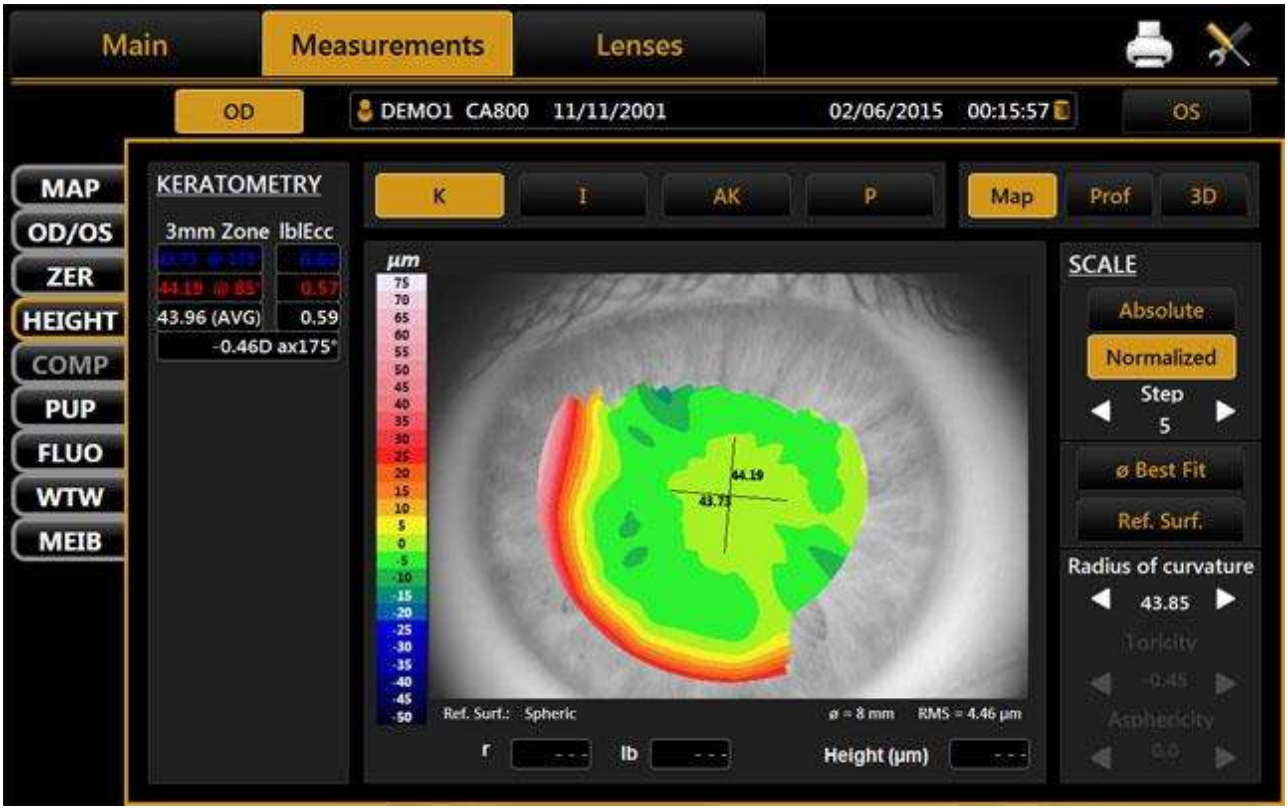


Fig. 41

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:
  - ✓ **Spherical**: the user can change the ***"Radius Flat"***.
  - ✓ **Aspherical**: the user can change the ***"Radius Flat"*** and ***Asphericity"***.
  - ✓ ***Asphero – Toric***: the user can change the "Radius Flat", "Toricity" and "Asphericity".
  - ✓ ***Differential***: the user can select the image of another exam of the same patient to compare it with the current exam (Fig. 42).

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.

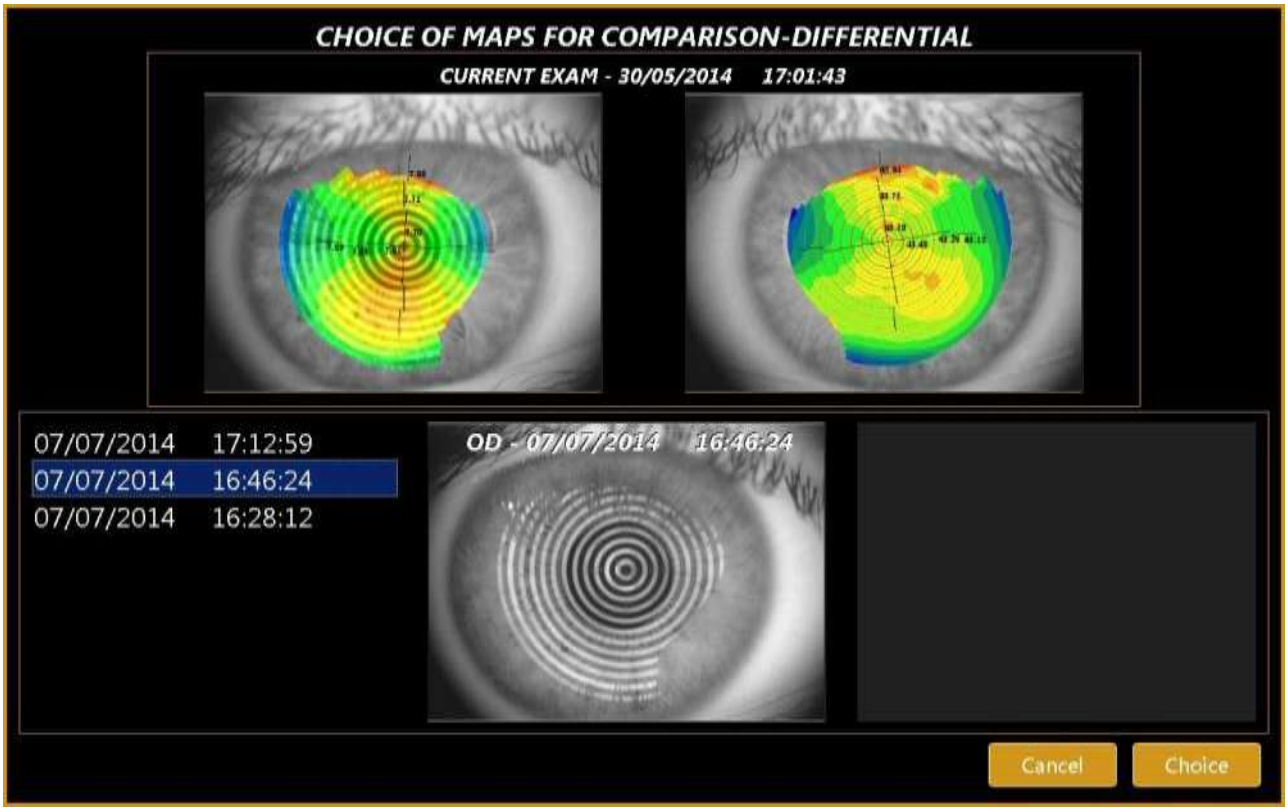


Fig. 42

18.9.4.1. Profile

Press the ***"Profile"*** button to view the curvature profile along the steep meridian or the flat meridian (Fig. 43).

Fig. 43

It is possible to scale the graph with the ***"50µm"***, ***"10µm"*** and ***"5µm"*** buttons found under the graph.
Press the ***"Close"*** button to go back to the topographic map.

18.9.4.2. 3D

Press the ***"3D"*** button to view the 3D map of the altimetric data (Fig. 44).

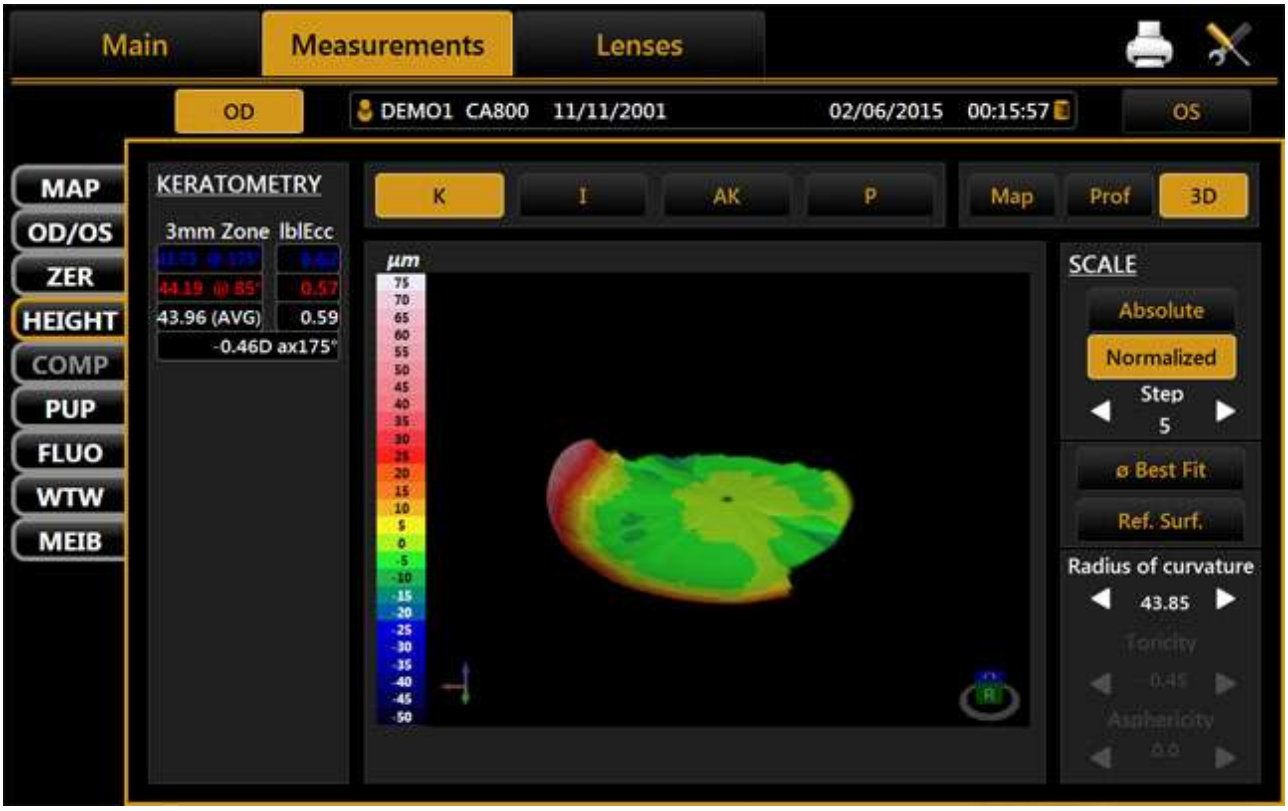


Fig. 44

18.9.5. COMP - Comparison

Comparison mode allows the user to compare the current exam data with the data of another exam for the same patient (Fig. 45).

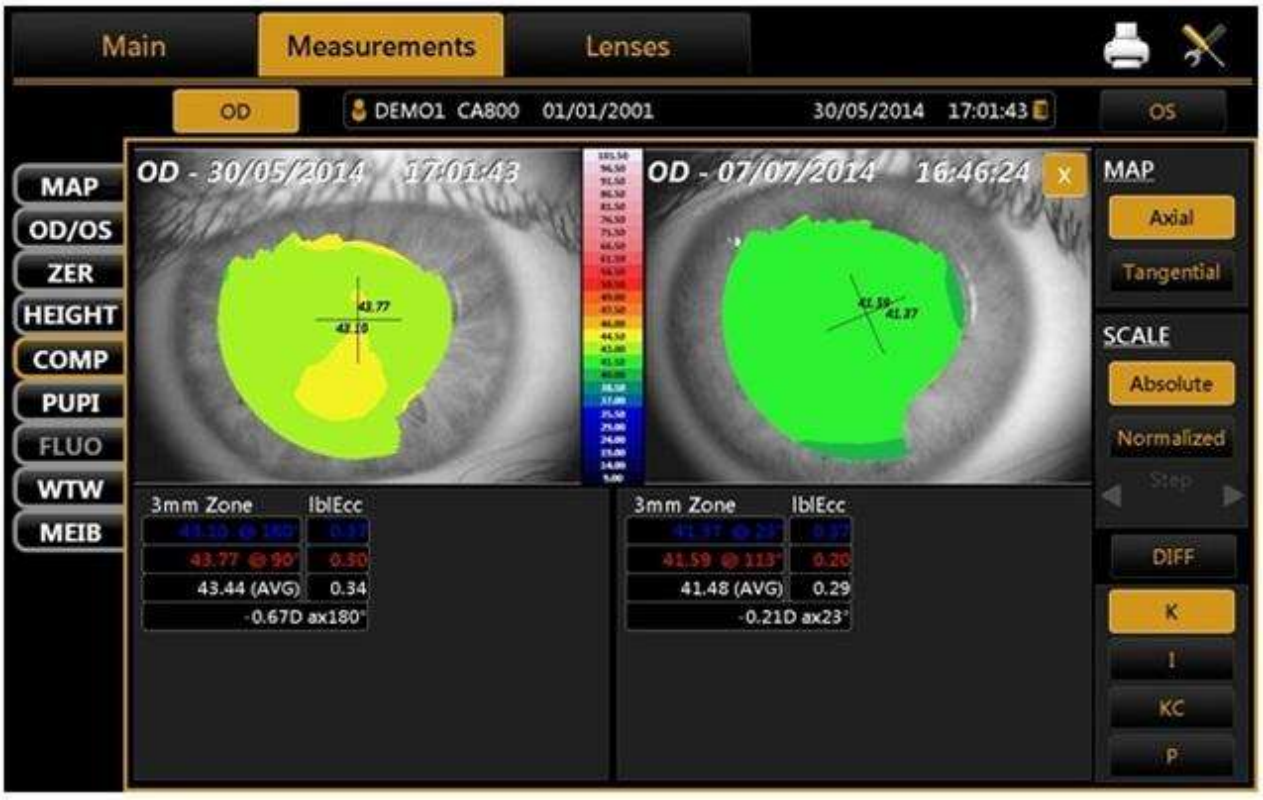


Fig. 45

When you select the ***"COMP"*** button, the interface shown in Fig. 46 appears and the software allows you to choose in a list of exams for the patient currently selected.

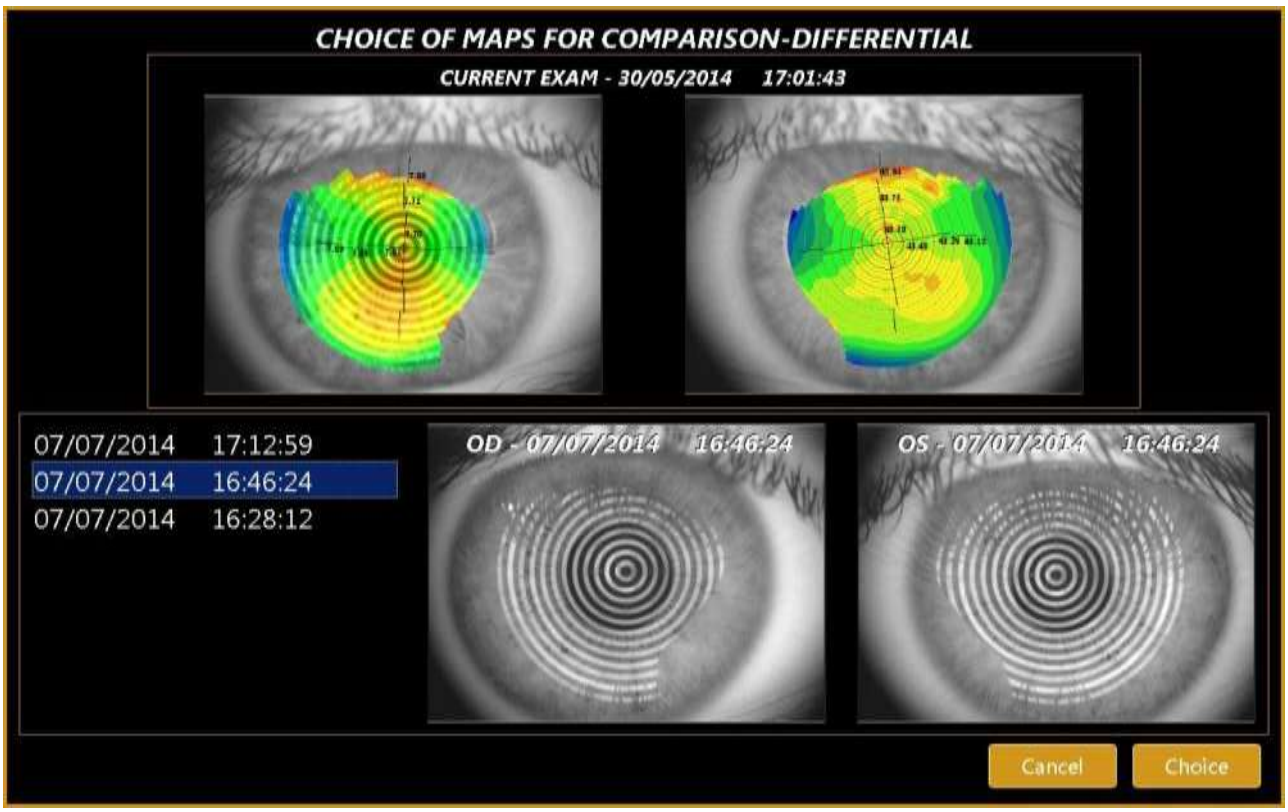


Fig. 46

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 relative 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.

18.9.5.1. Differential

By tapping the ***"DIFF"*** button in comparison mode, the user switches to differential mode (Fig. 47).

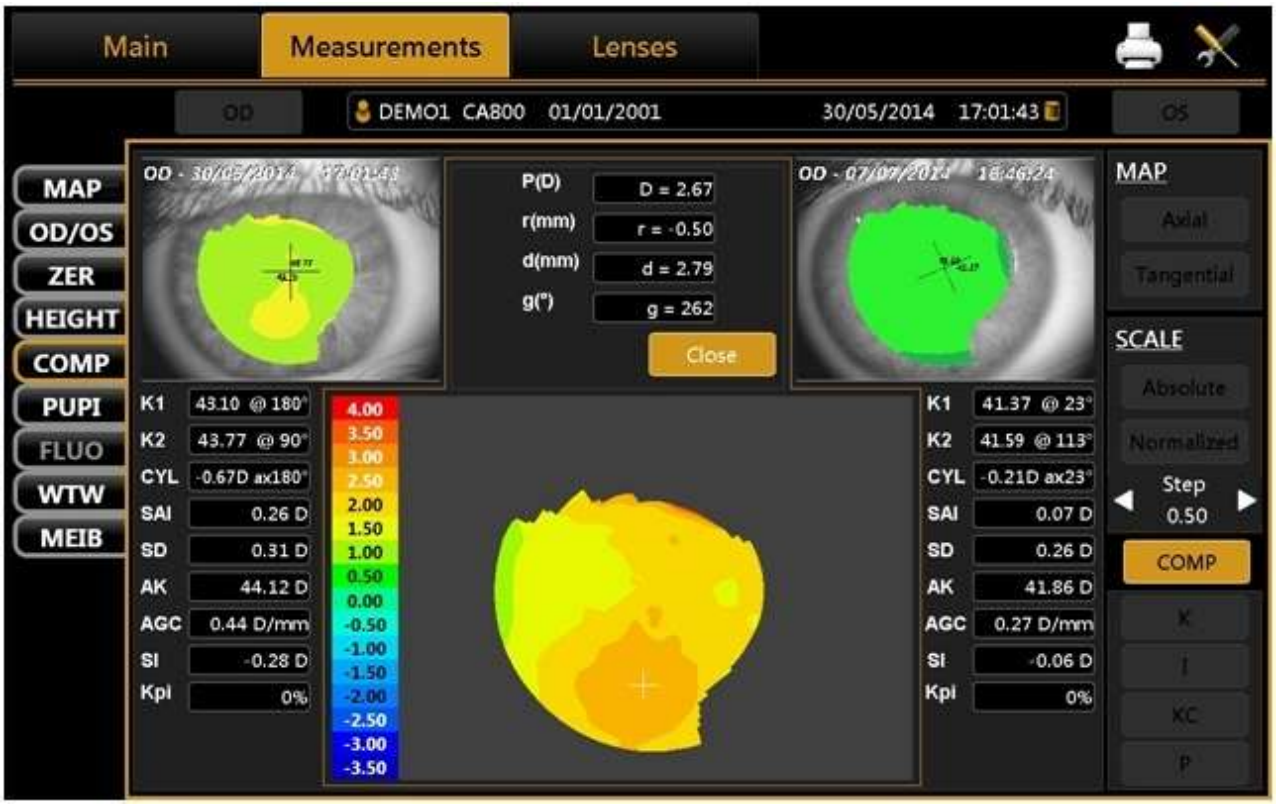


Fig. 47

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 there are four differential values that 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 center of the image;
- ***g***: is the angle of the cursor from the base line.

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.

18.9.6. 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. 48).

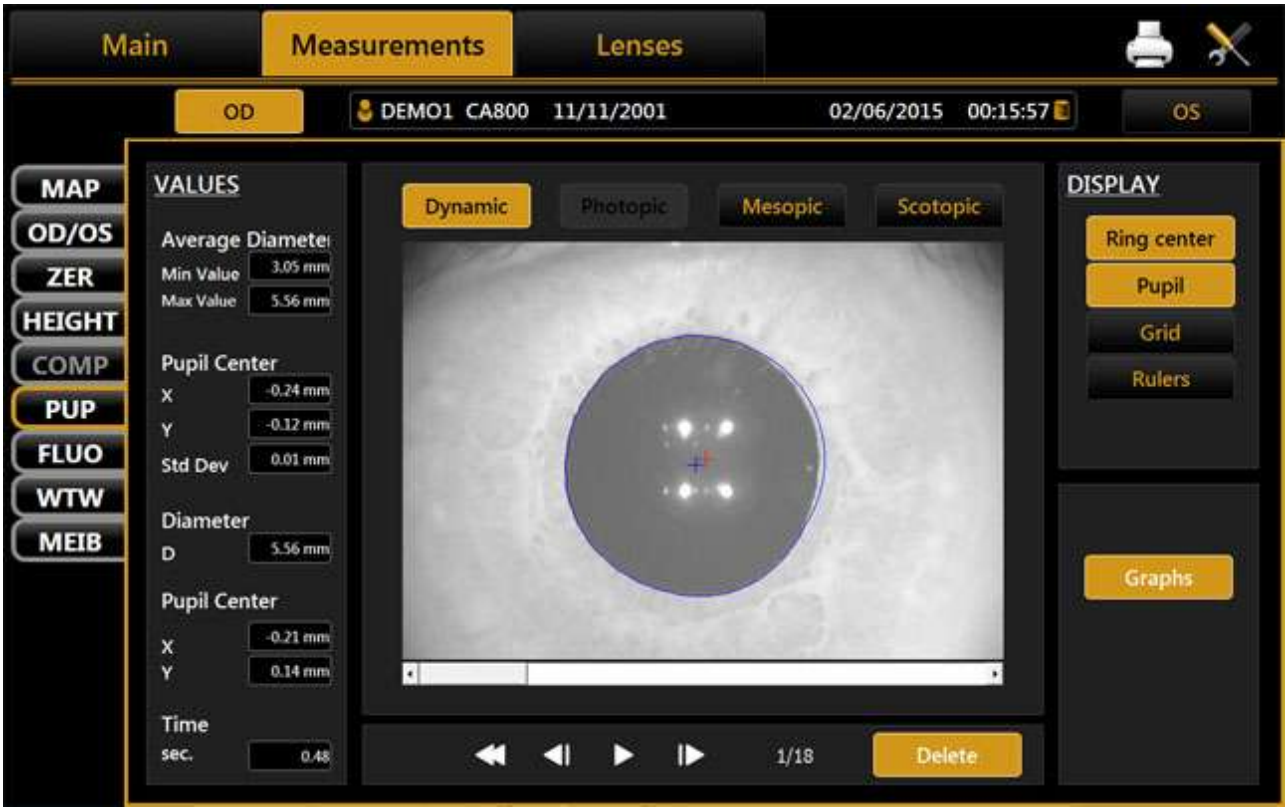


Fig. 48

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.

18.9.6.1. 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

18.9.6.2. 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.

18.9.6.3. Dynamic

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.

18.9.6.4. 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.

18.9.6.5. 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.

18.9.6.6. Graphs

In this section, three types of graph are displayed:

- ***Decentralization*** (Fig. 49)
- ***Latency*** (Fig. 50)
- ***Statistics*** (Fig. 51)

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.

Decentralization

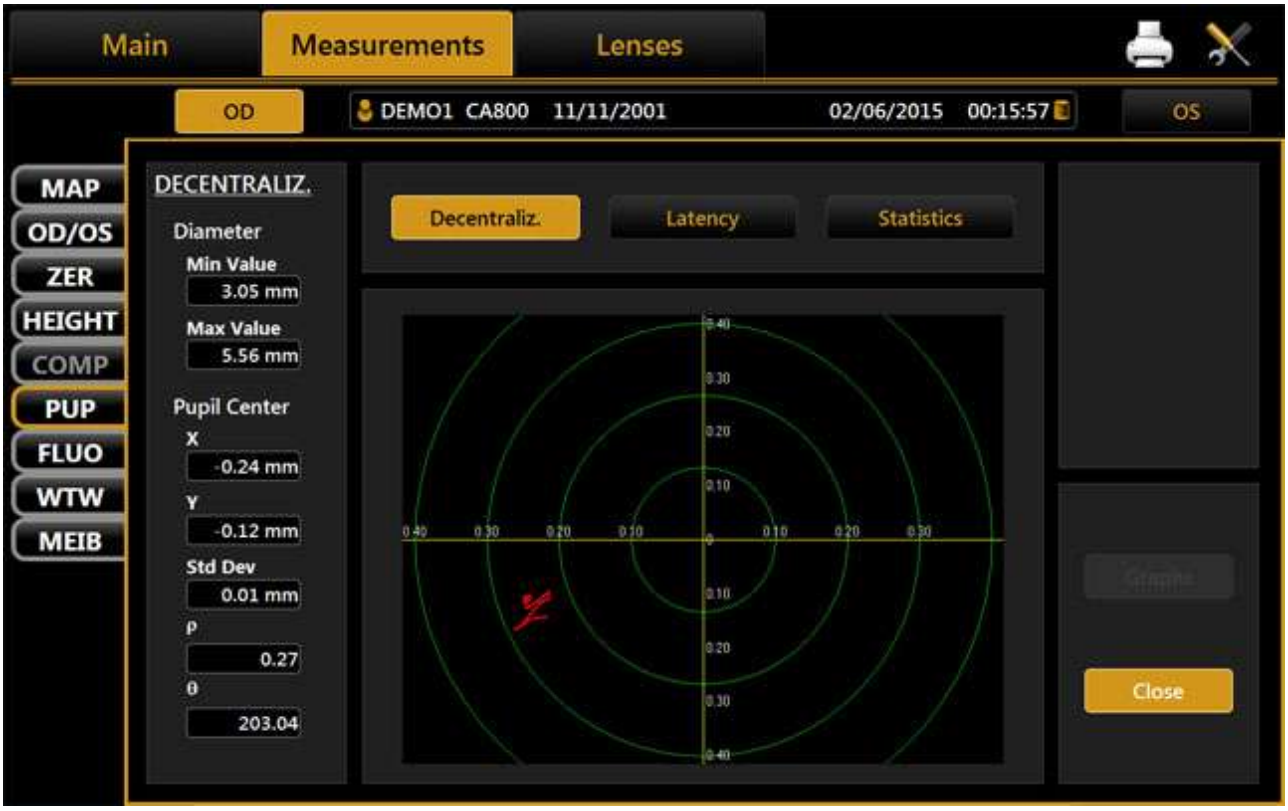


Fig. 49

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

Latency

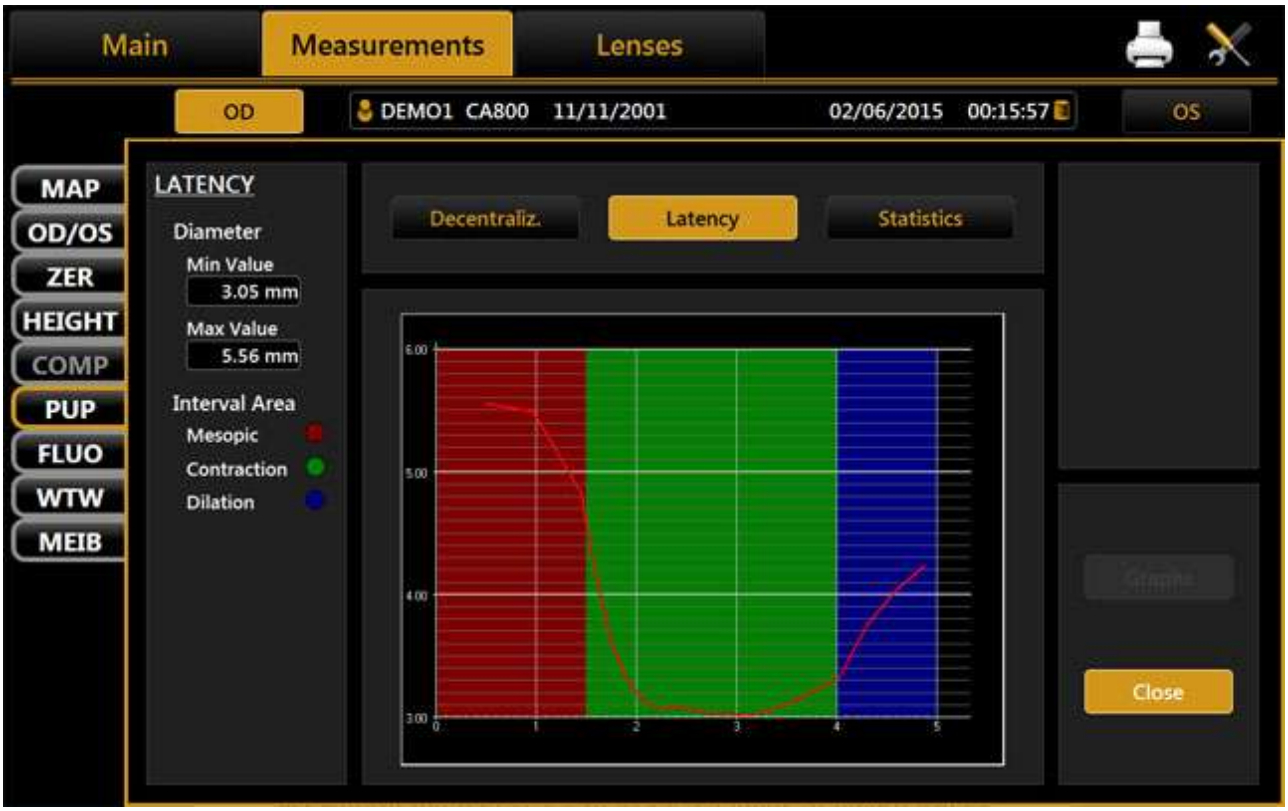


Fig. 50

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 in 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

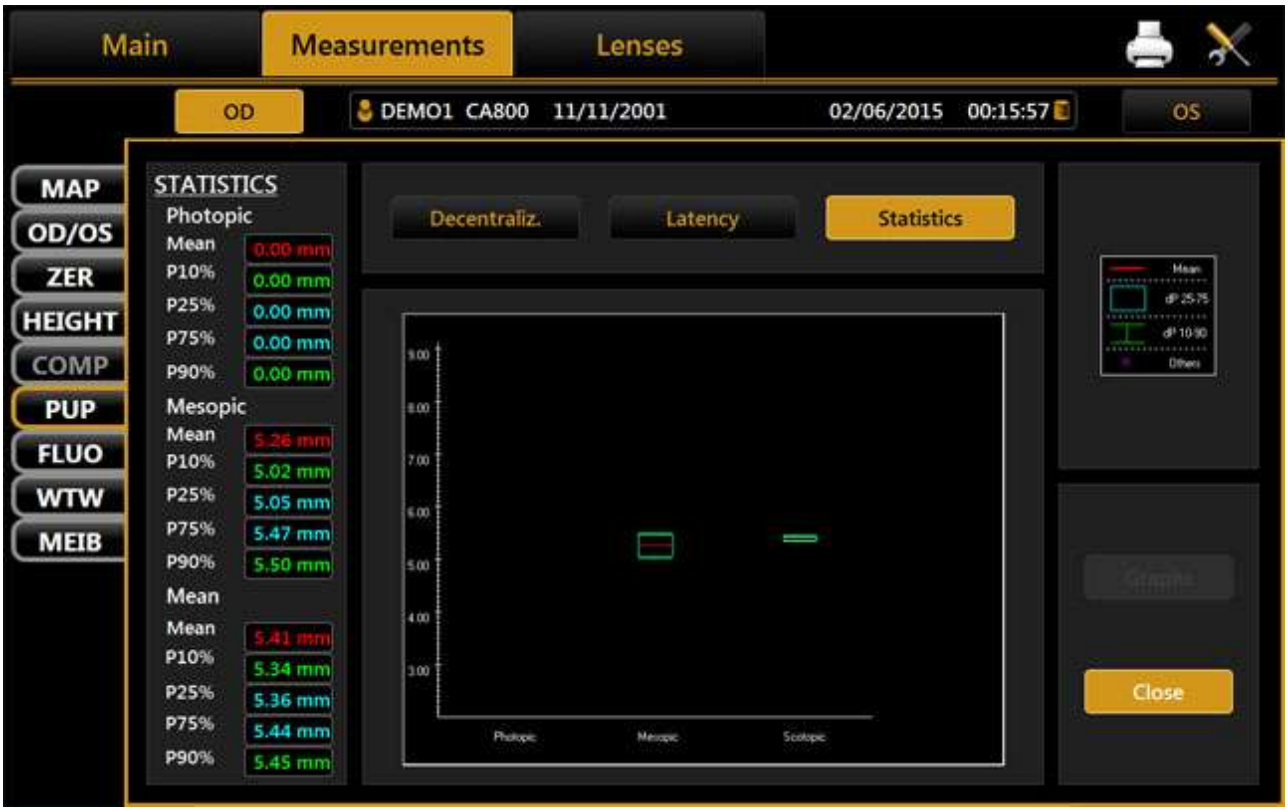


Fig. 51

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 line represents the average value of the sample, the blue frame the value interval between the 25% and 75% percentiles, the green line the value interval between the 10% and 90% percentiles, and the red circle the values outside this interval.

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

18.9.7. FLUO - Fluorescein

The fluorescein module (Fig. 52) allows you to assess the physical condition of the cornea and to verify the contact lens position and fitting towards the cornea.

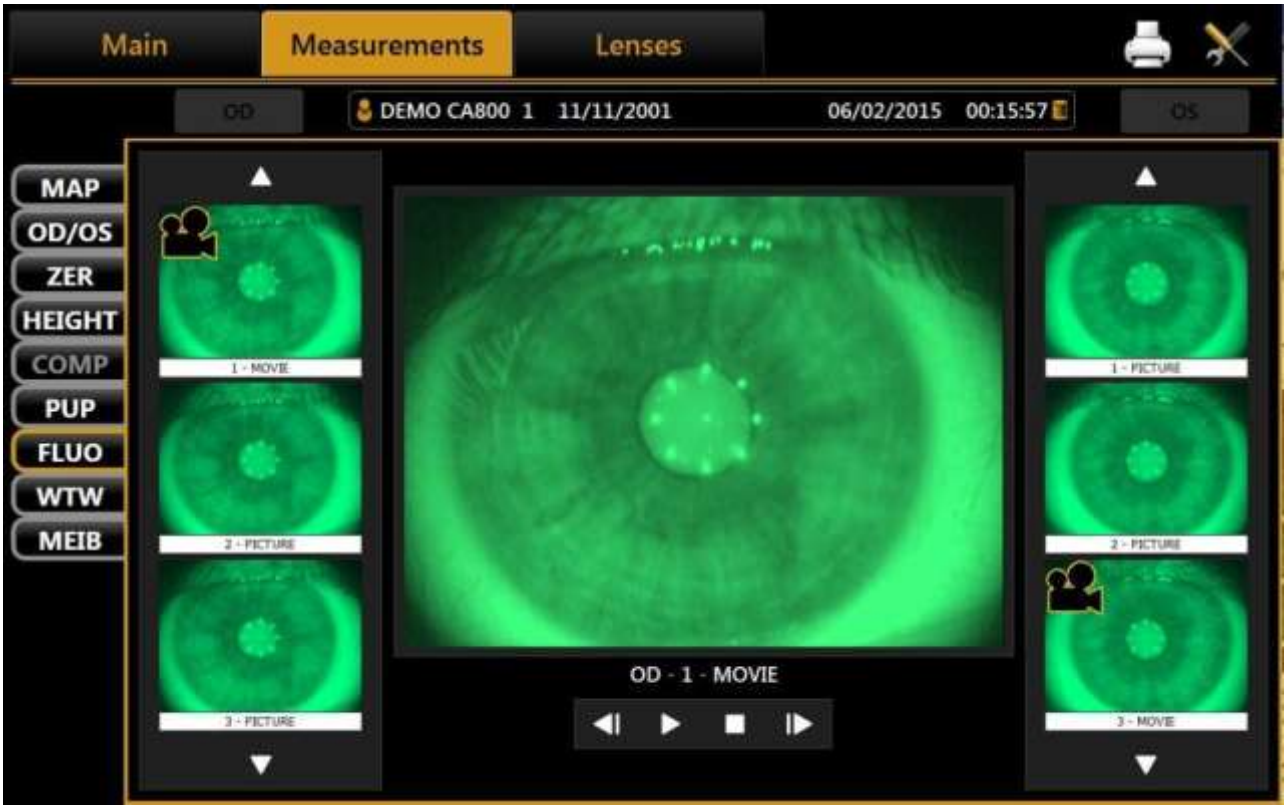


Fig. 52

The pictures and movies 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 movie, its reproduction starts automatically.

Depending on the selection, the eye the picture or movie refers to will be highlighted.

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

18.9.8. WTW - White to White

The White to White section allows you to view the value of the corneal diameter calculated from limbus (Fig. 53).

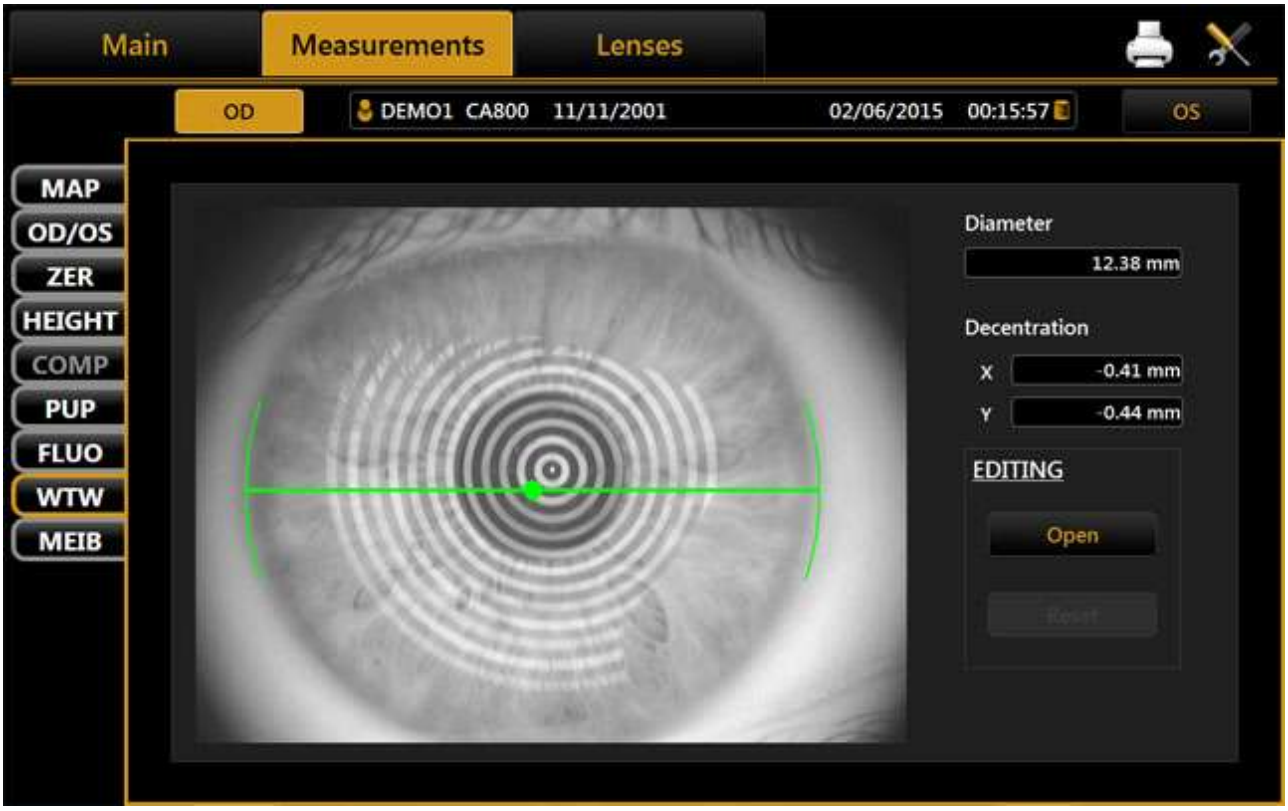


Fig. 53

Tapping on the **Open** button in the **Edit** menu (Fig. 54), the user can manually reposition positional indicators in order to refine the diameter measurements.

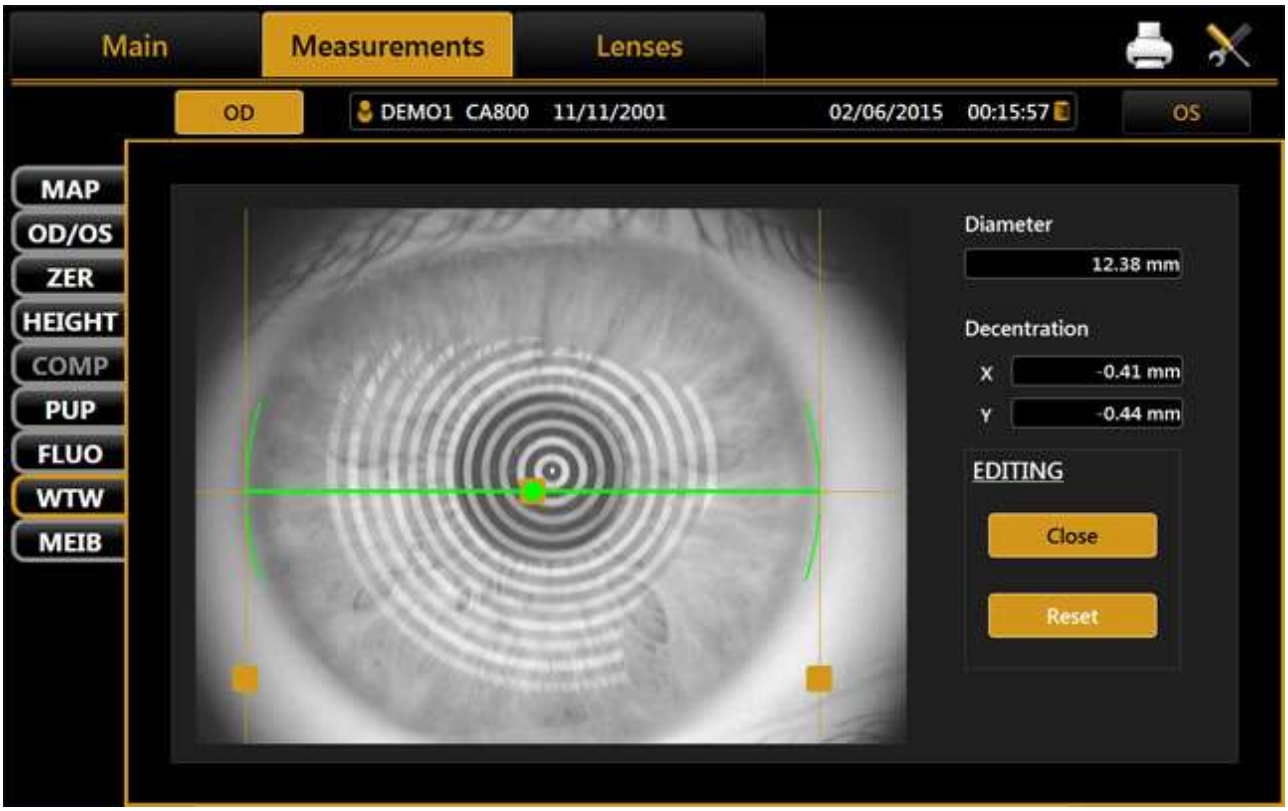


Fig. 54

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

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

By changing the indicators position also values of corneal diameter and 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.

18.9.9. MEIB - Meibomian

In the meibomian section, the user can check all the images that have been taken in the meibomian gland acquisition section (Fig. 55).

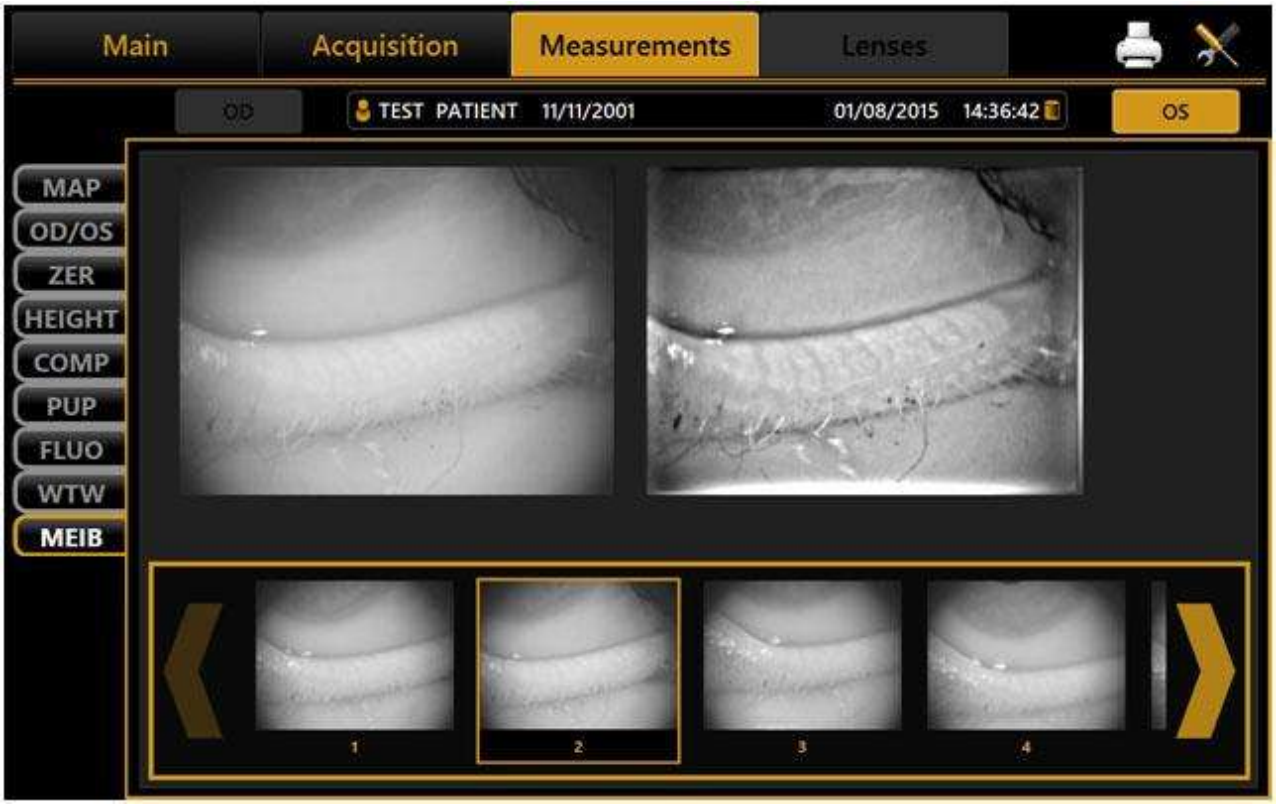


Fig. 55

18.10. 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. 56).

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 screen-shot of the current view.

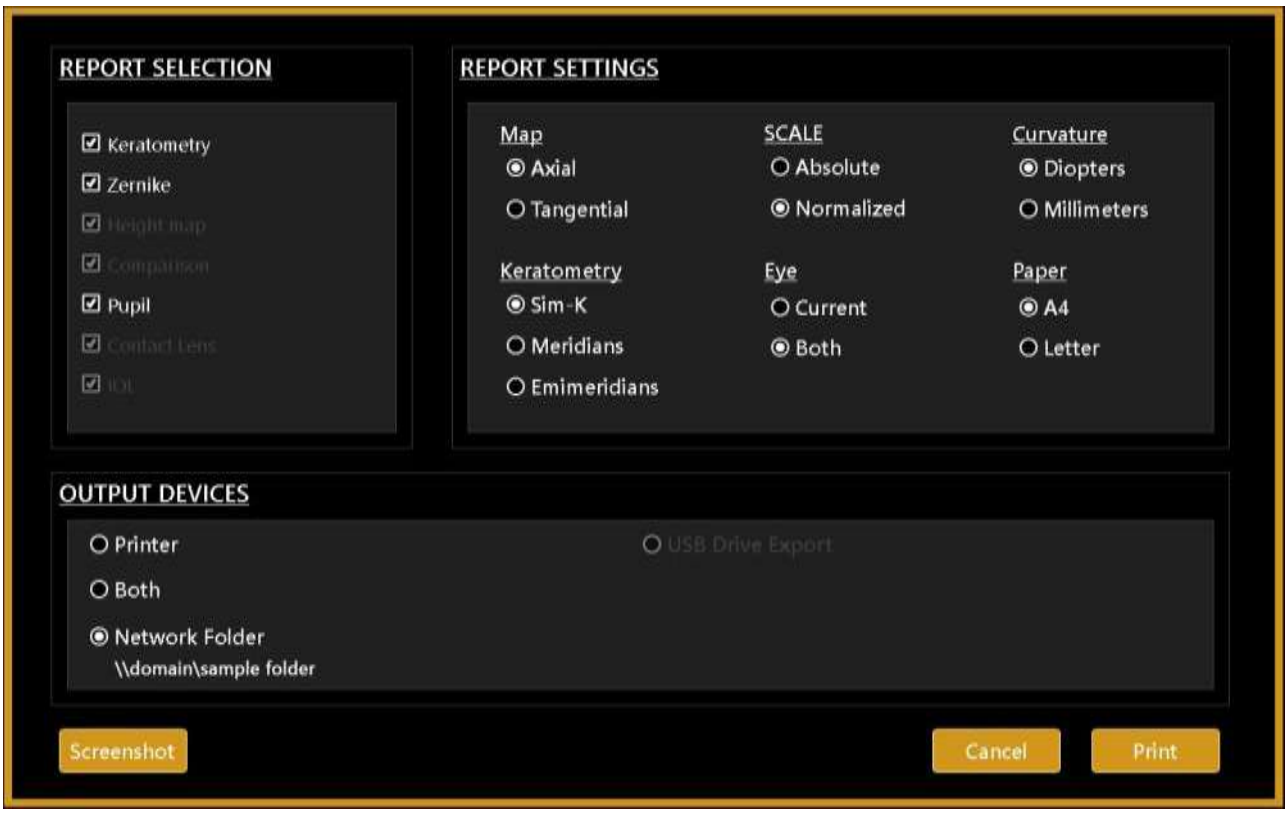


Fig. 56

18.11. 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. 57, 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.

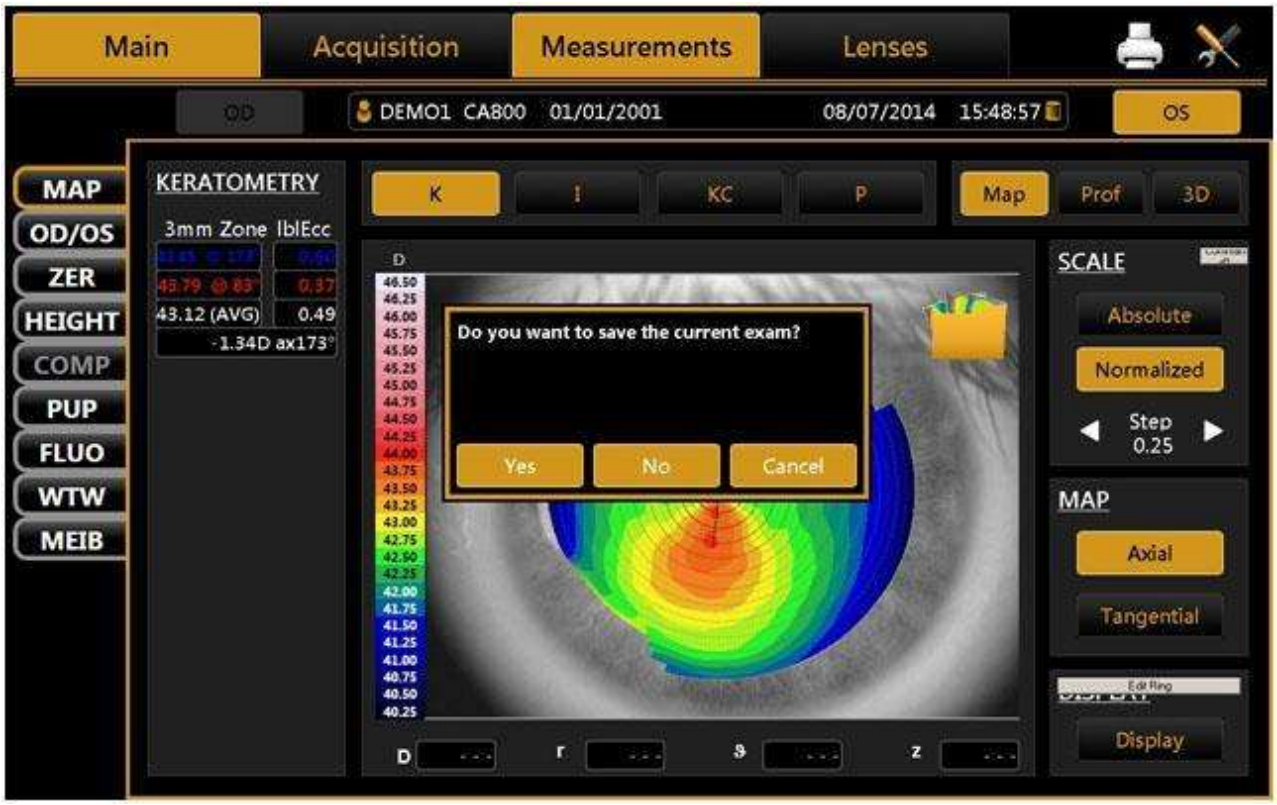


Fig. 57

18.12. Lenses

The lenses module has two sections:
Contact Lenses: simulate contact lens fitting.
Intraocular Lenses, that simulate the intraocular lenses positioning and calculation of lenses parameters.

18.12.1. Contact Lenses

The contact lenses module (Fig. 58) simulates contact lens positioning.

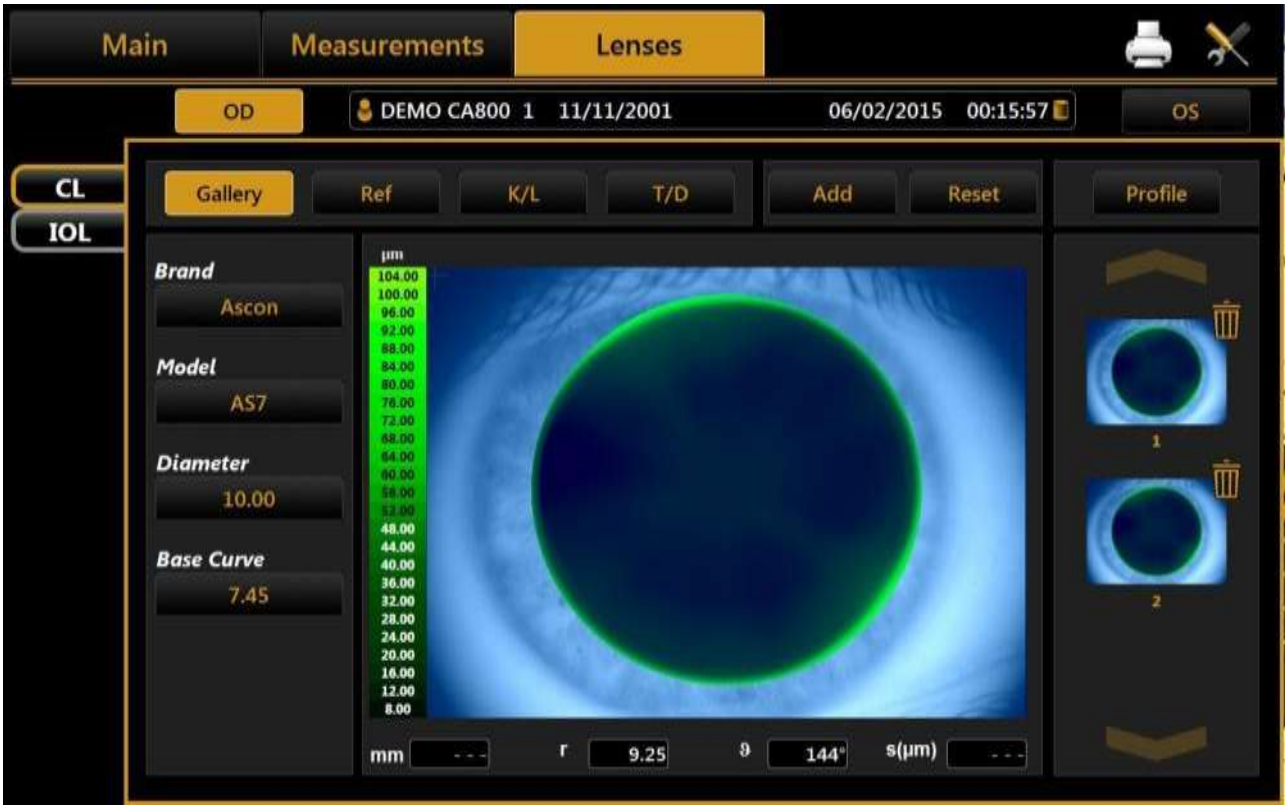


Fig. 58

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**

18.12.1.1. Gallery

From this section, is possible to select the brand, the model, the diameter and the base curve of the lenses (Fig. 58) and to add the favorite ones to the gallery on the right.
To add the favorite 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 "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.

18.12.1.2. Ref

In the ref section the user can see the sphere, the cylinder, the axis and the VD of the selected lens (Fig. 59).

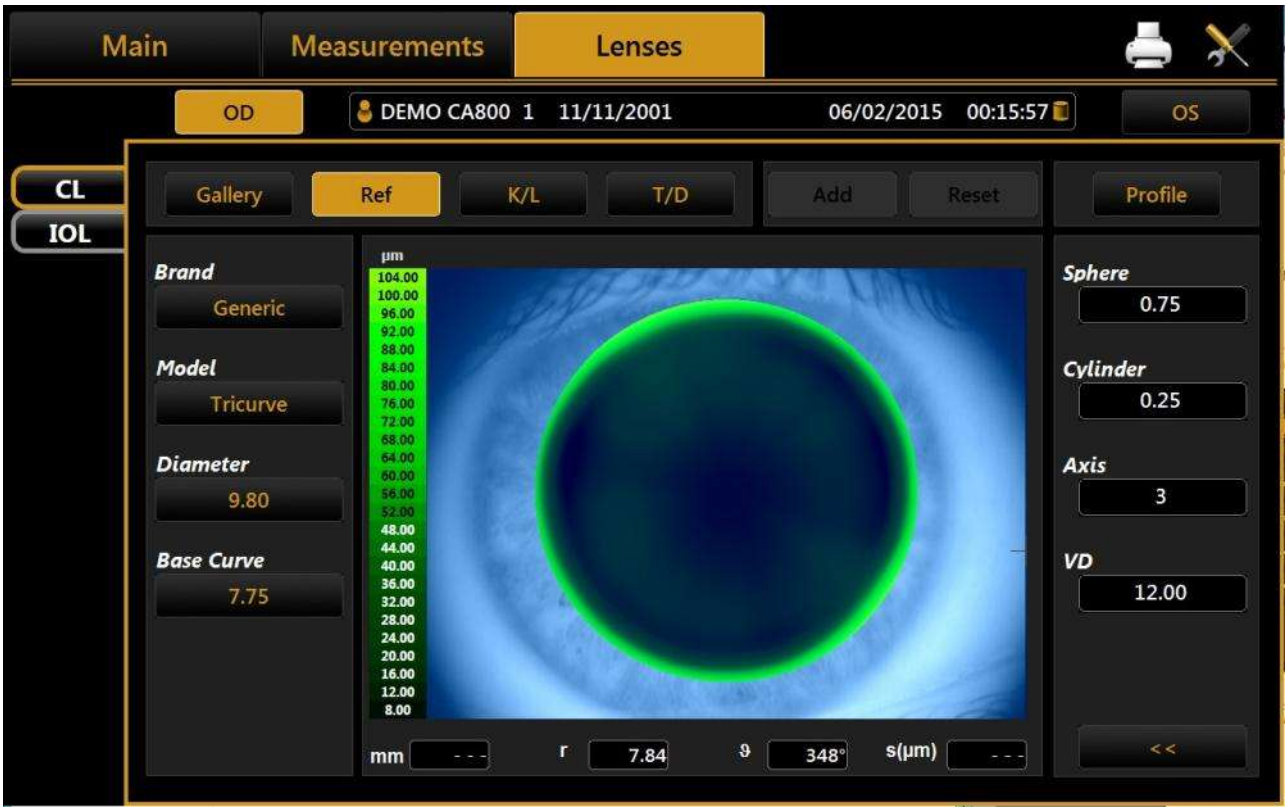


Fig. 59

In this section it is also possible to edit these values by pressing the button found under the values: a tab will appear (Fig. 60) and the user will be able to edit the values by pressing the relative arrows found at the right of the value.

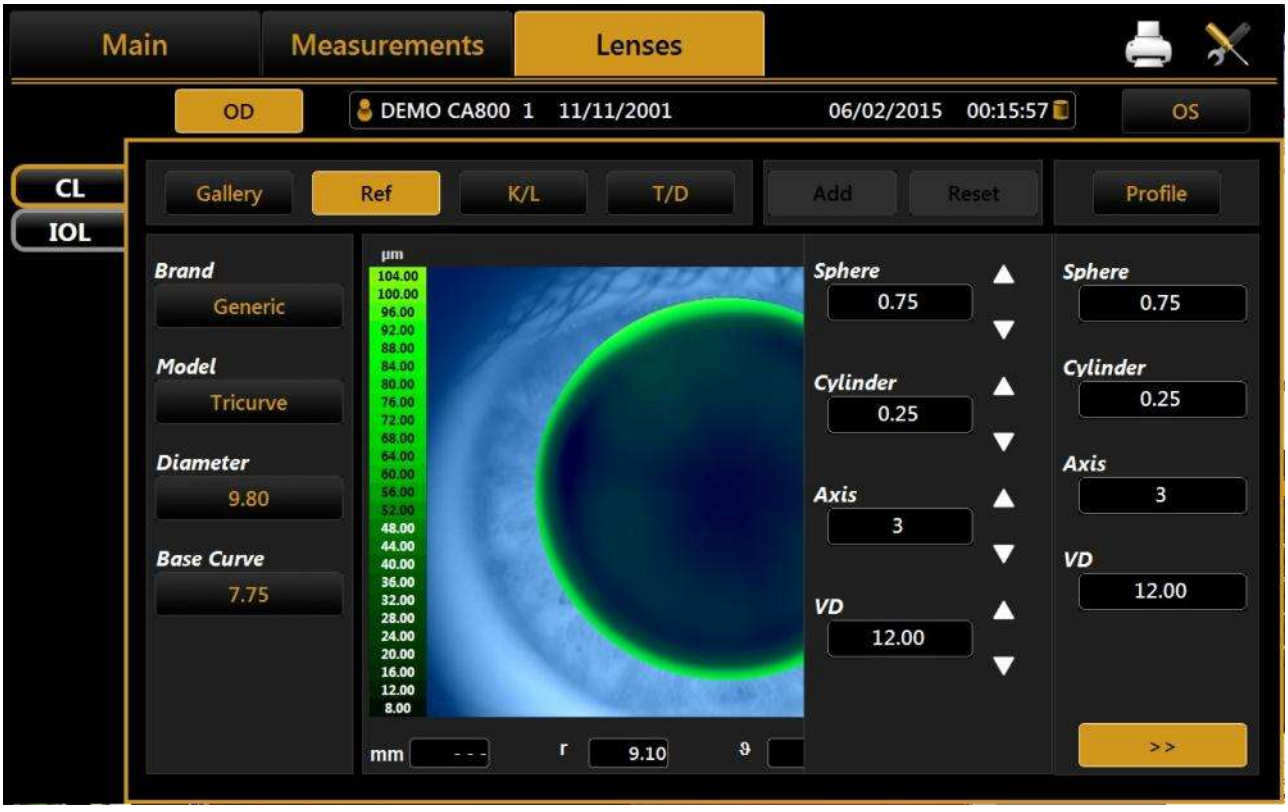


Fig. 60

18.12.1.3. K/L

This section displays information about the patient's eye (Fig. 55), and namely:

- ***Keratometric data.***
- ***Corneal diameter***

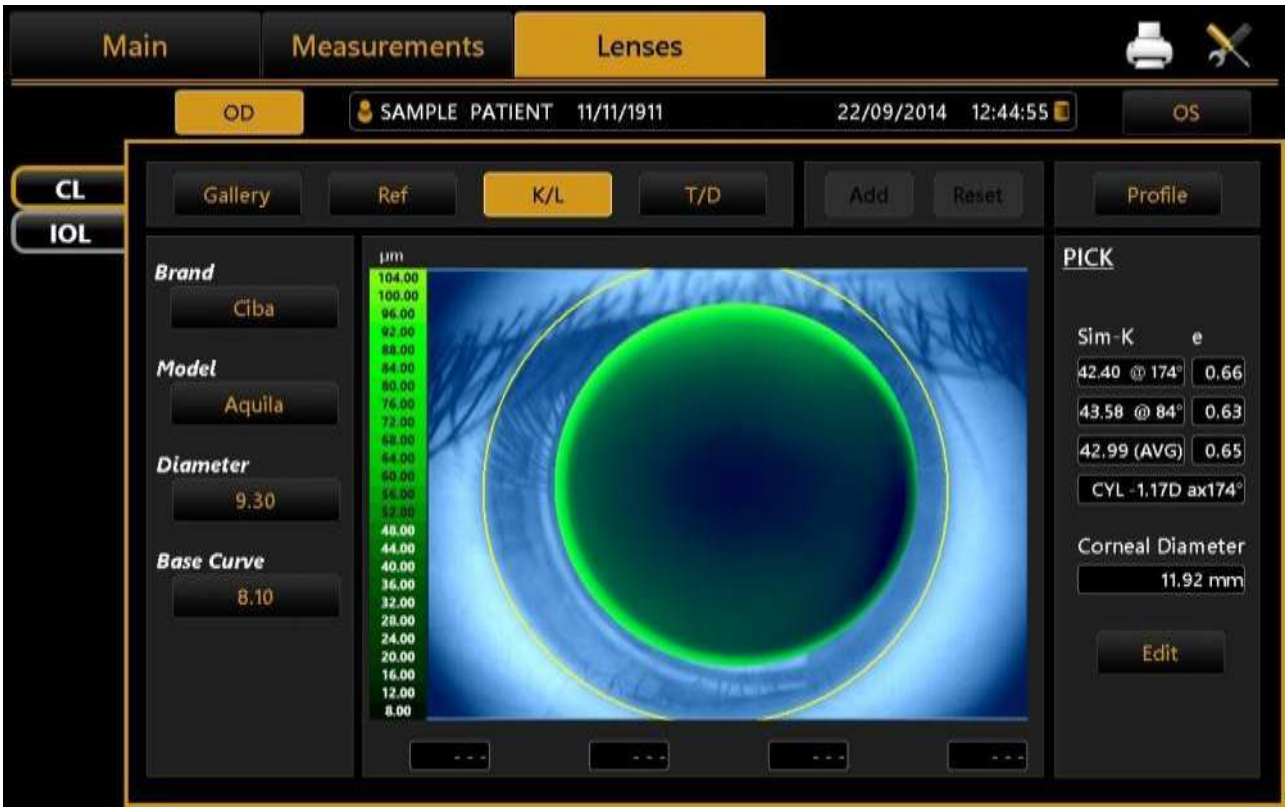


Fig. 61

In this section it is also possible to edit the limbus by tapping on the ***"Edit"*** button. 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.

18.12.1.4. T/D

This section displays tilting and decentralization of the selected lens (Fig. 62).

Fig. 62

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

18.12.1.5. Profile

In the profile section, the user can see the distance between the selected lens and the patient's cornea in a graph (Fig. 63).

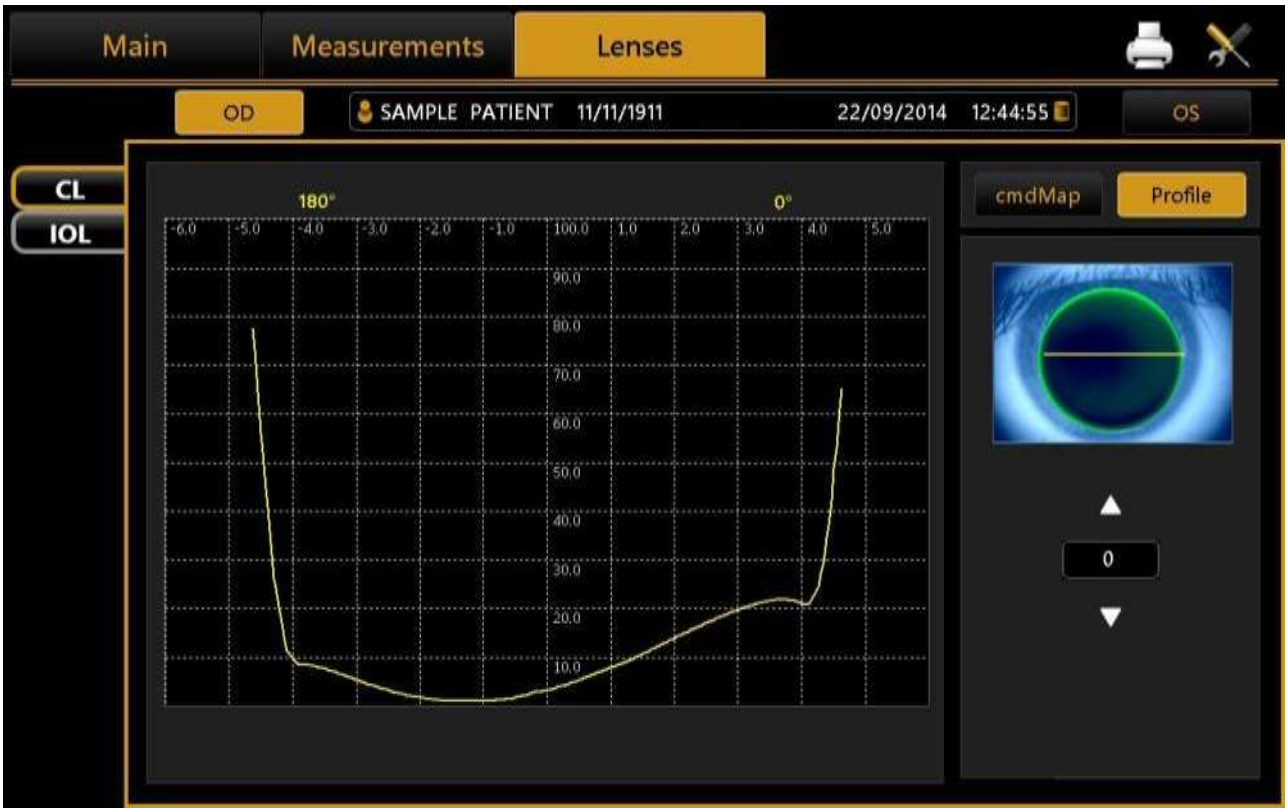


Fig. 63

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

18.12.2. Optional: Oculentis Intraocular Lenses calculation (toric IOL)

The Toric IOL software module is the tool to calculate Oculentis Toric intraocular lenses.
The first window (Fig.64) shows the "Summary of Corneal Data", the second one shows report the biometry data on the left, and the pre-operative data on the right (Fig. 65)

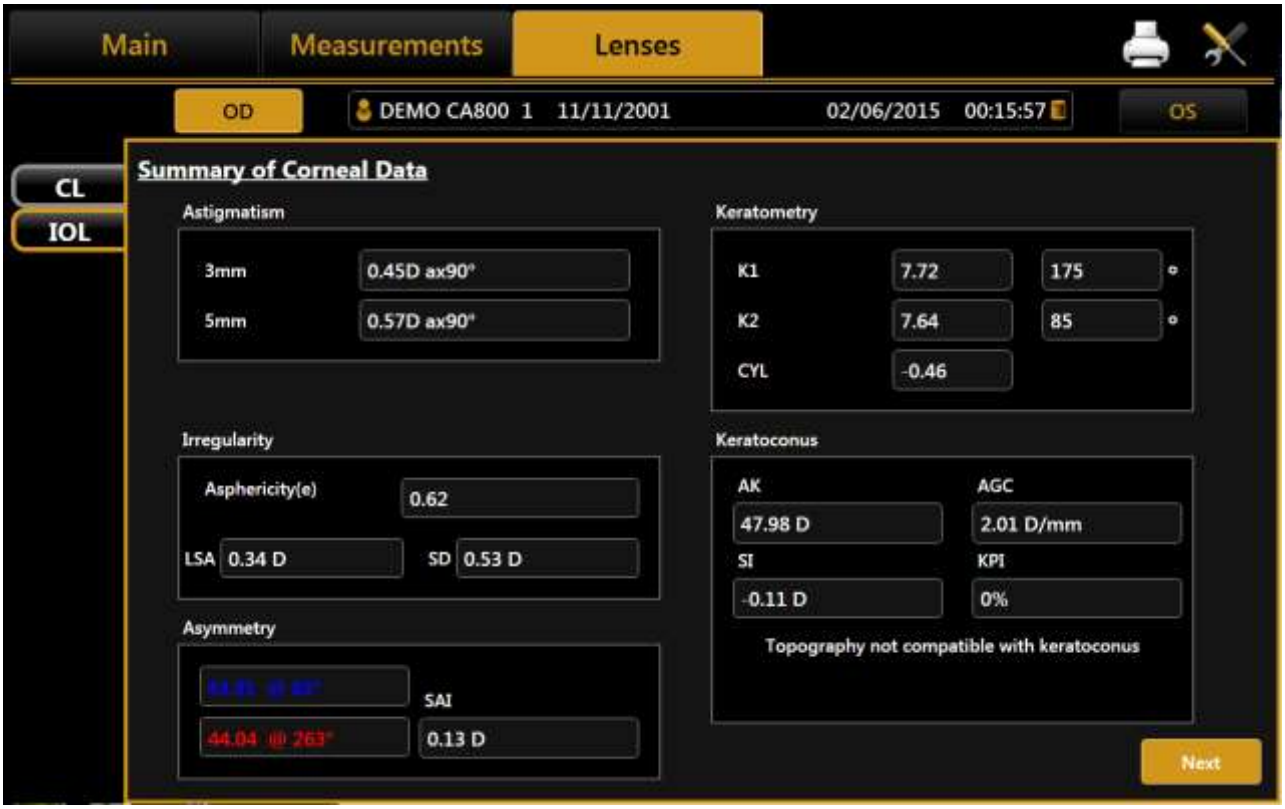


Fig. 64

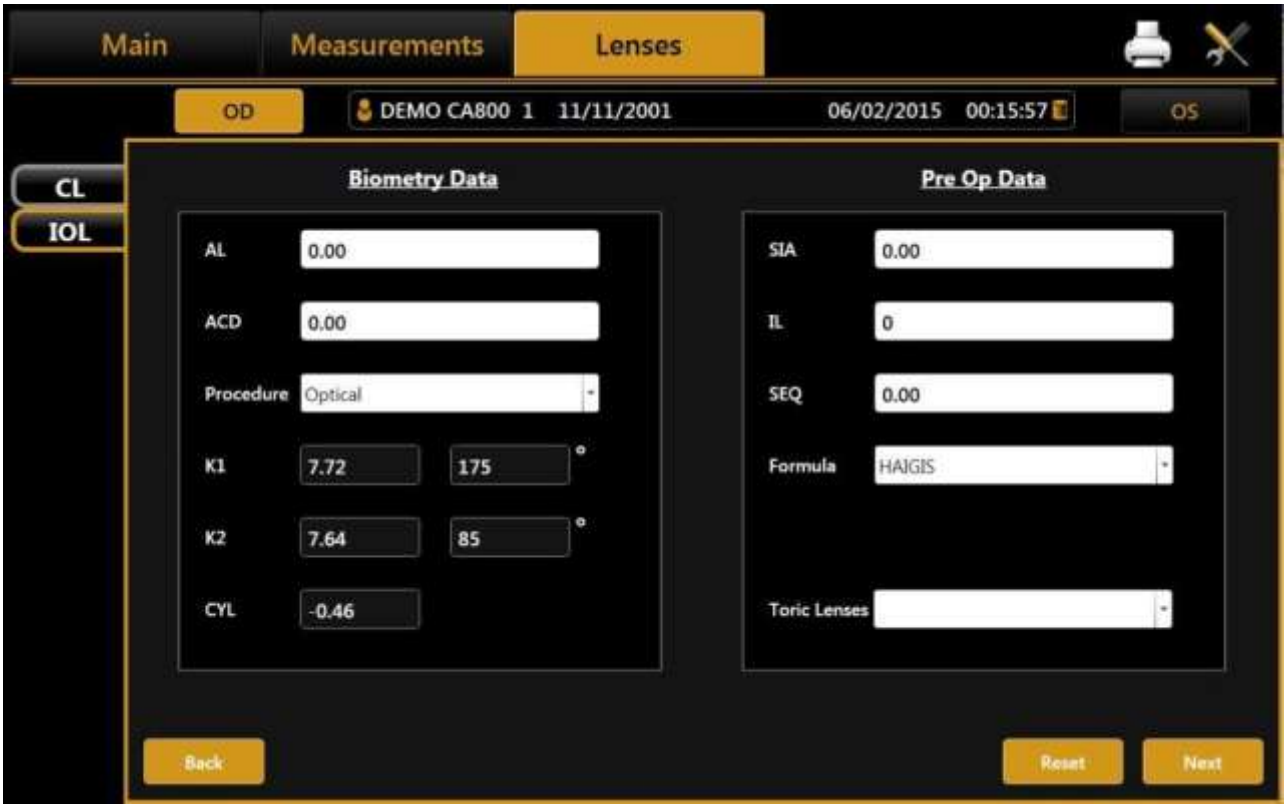


Fig. 65

Tap on the **"OD"** and **"OS"** buttons to go from the right to the left eye and vice versa.

Tap on the **"Reset"** button to erase all the data that have been insert by the user.

18.12.2.1. Summary of Corneal Data

In this section the user can review the corneal data of current eye. There are a few numbers of sub-sections, for example “Astigmatism”, “Irregularity”, “Asymmetry”, “Keratometry” and “Keratoconus”.

18.12.2.2. Biometry Data

In this section the user can enter the following data:

- **Axial Length (AL)**;
- **Anterior Chamber Depth (ACD)**;
- The acquisition procedure, choosing between **“Optical”** and **“Acoustical”**;
- **K1** value: the software enters this value automatically, but the user may edit it;
- **K2** value: the software enters this value automatically, but the user may edit it;
- **Cylinder value (CYL)**.

18.12.2.3. Pre Op Data

In this section the user can enter the following data:

- **Surgically Induced Astigmatism (SIA)**;
- **Incision Location (IL)**;
- **Spherical Equivalent (SEQ)**;
- The formula used by the software to calculate Oculentis Toric IOL between **Haigis**, **Hoffer Q**, **SRK II**, **SRK T** and **Holladay I**;
- **Toric Lenses,** among those available.

The toric lenses available are the following:

- **LS – 313 Tx**;
- **LU – 313 T (X)**;
- **LU – 313 Ty (X)**;
- **LU – 313 MF30T (X)**;
- **LU – 313 MF30TY (X)**;
- **LU – 313 MF30T**;
- **LU – 313 MF30TY**;
- **LU – 313 MF20T;**
- **LU – 313 MF20TY;**
- **LU – 313 MF15T**;
- **LU – 313 MF15TY**.

18.12.2.4. IOL Calculation results

Once all the **Biometry Data** and **Pre Op Data** are provided, it is possible to tap on the **"Next"** button to access the second step for toric calculation (Fig. 66).

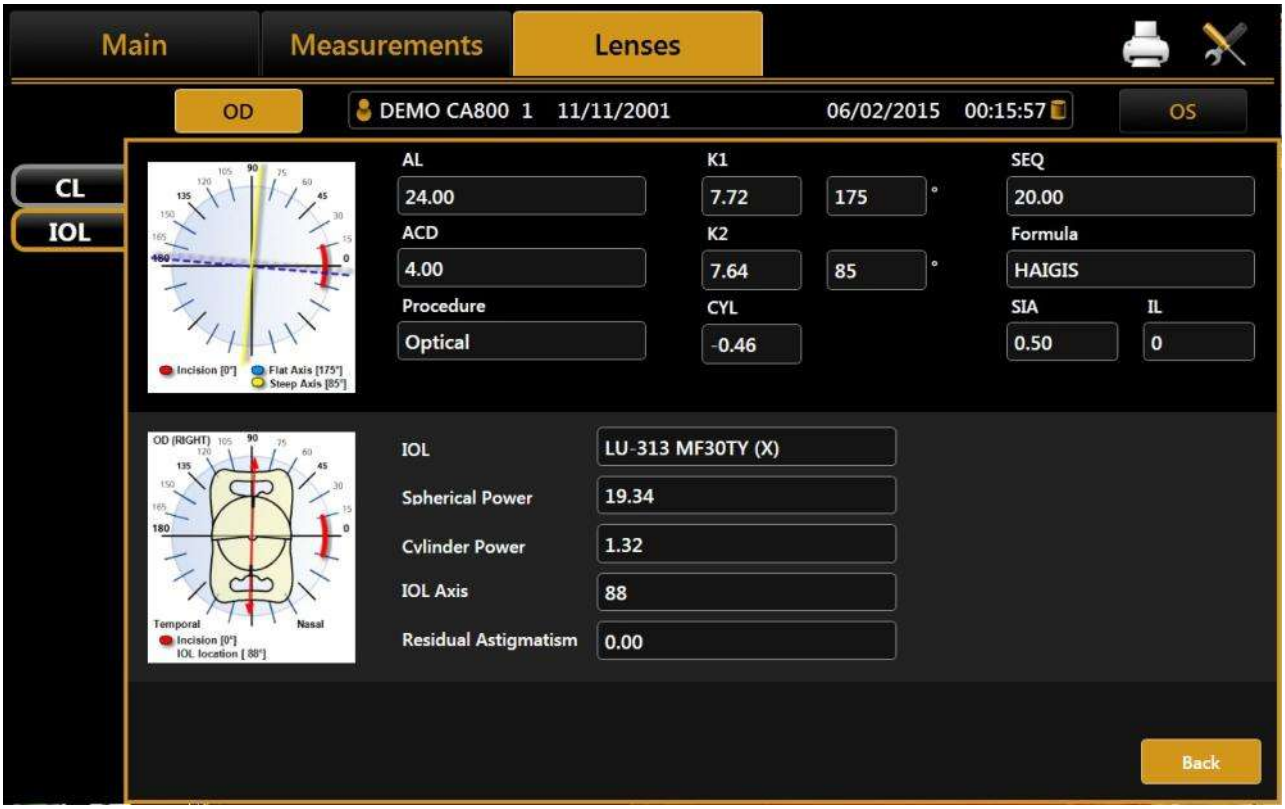


Fig. 66

In the second step, the software provides a summary of the data entered by the user and further information:

- **Spherical Power**;
- **Cylinder Power**;
- **IOL Axis**;
- **Residual Astigmatism**.

18.13. Settings

To access the ***"Settings"*** section, press the  button.

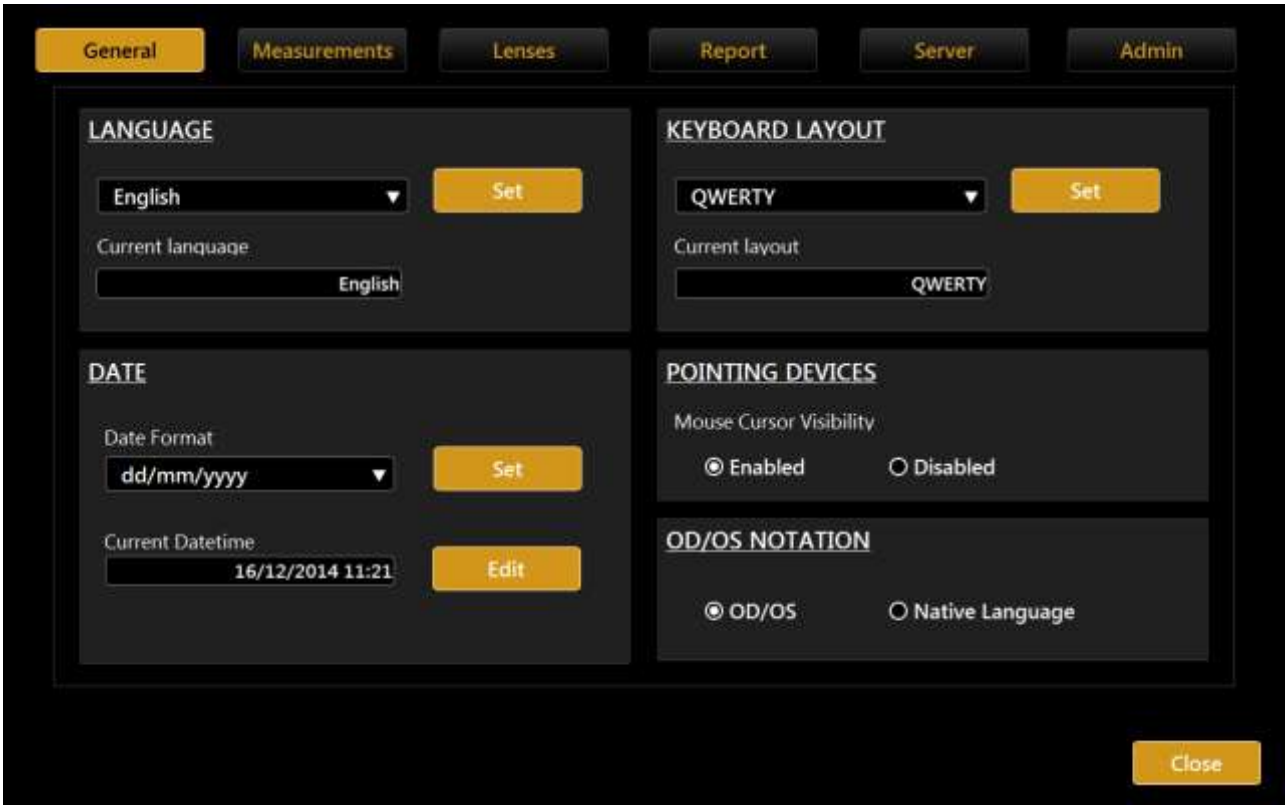


Fig. 67

The settings screen is divided into the following categories.

- ***General***
- ***Measurements***
- ***Lenses***
- ***Report***
- ***Server***
- ***Admin***

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

18.13.1. General

Refer to Fig. 67:

- **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.

18.13.2. Measurements

The acquisition settings panel allows you to set the parameters for displaying the corneal map and acquiring and displaying fluorescein and pupillometry (Fig. 68).

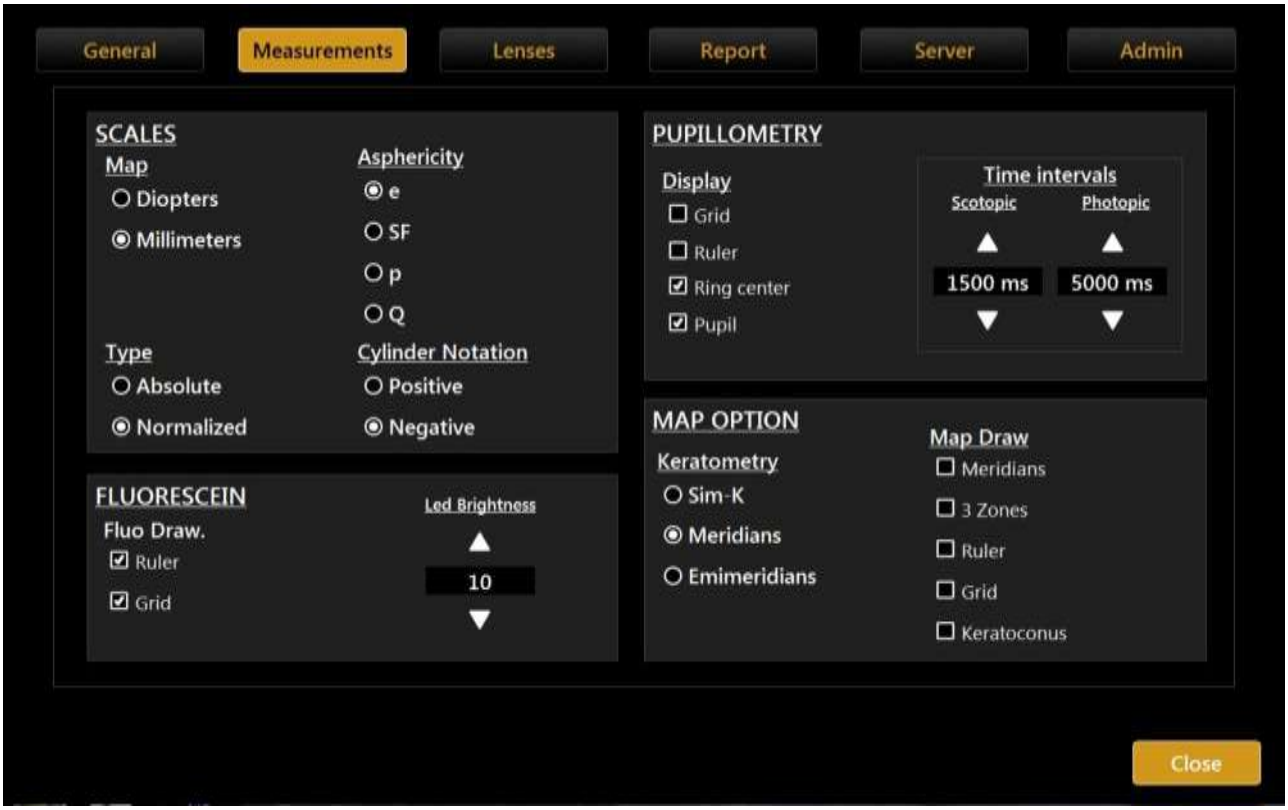


Fig. 68

18.13.2.1. 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***

Asphericity

Select an asphericity unit of measure:

- ***e***
- ***SF***
- ***p***
- ***Q***

Cylinder Notation

Select a notation for cylinder calculation:

- ***Positive***
- ***Negative***

18.13.2.2. Fluorescein

Fluo Draw

Select one or more items with to customize the fluorescein display:

- ***Ruler***
- ***Grid***

Led Brightness

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

18.13.2.3. Pupillometry

Display

Select one or more items with 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.

18.13.2.4. 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***

18.13.3. Lenses

Allows you to manage your own lenses database (Fig. 69).

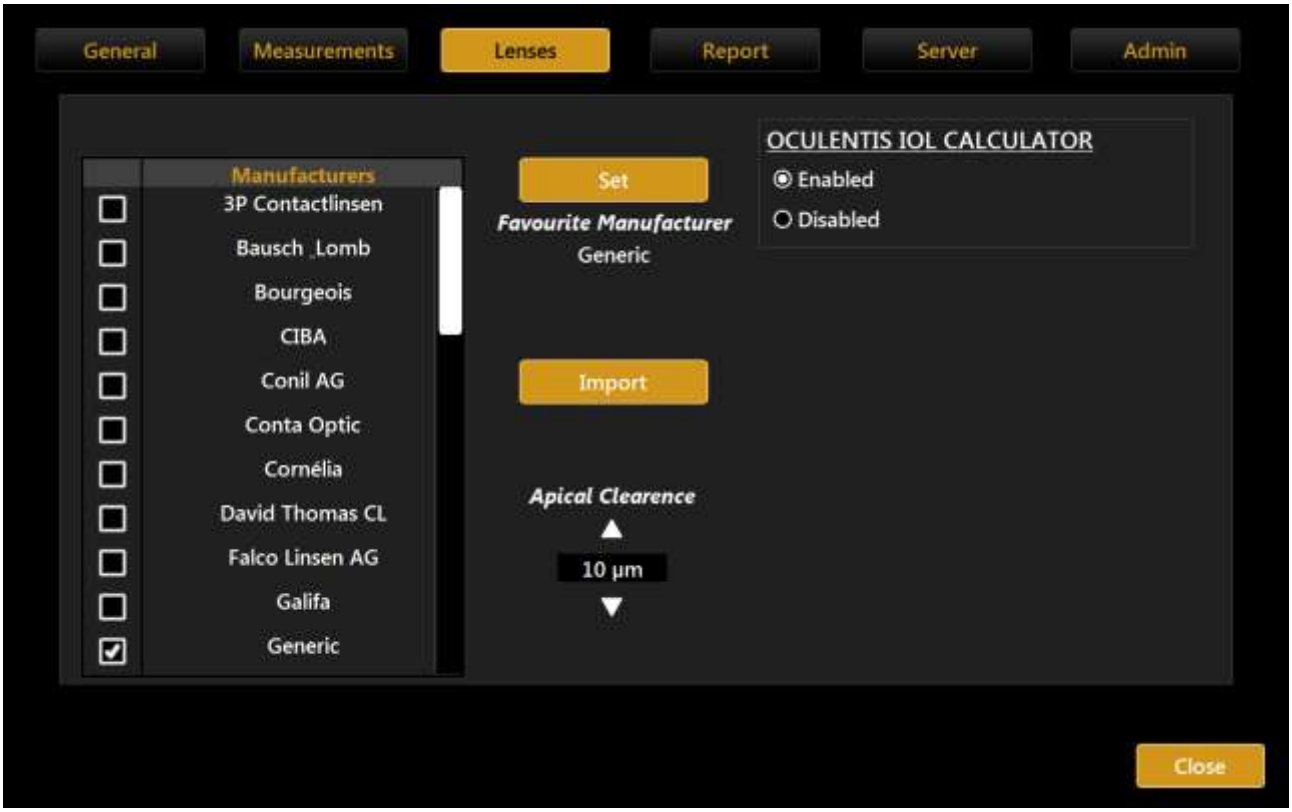


Fig. 69

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 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.

The right panel allows you to enable or disable the optional feature for the intraocular toric lenses calculation (Oculentis Toric IOL Calculation).

18.13.4. Report

Clinical Information

Allows the user to edit the header and the logo that will be printed at the top of the report page (Fig. 70).

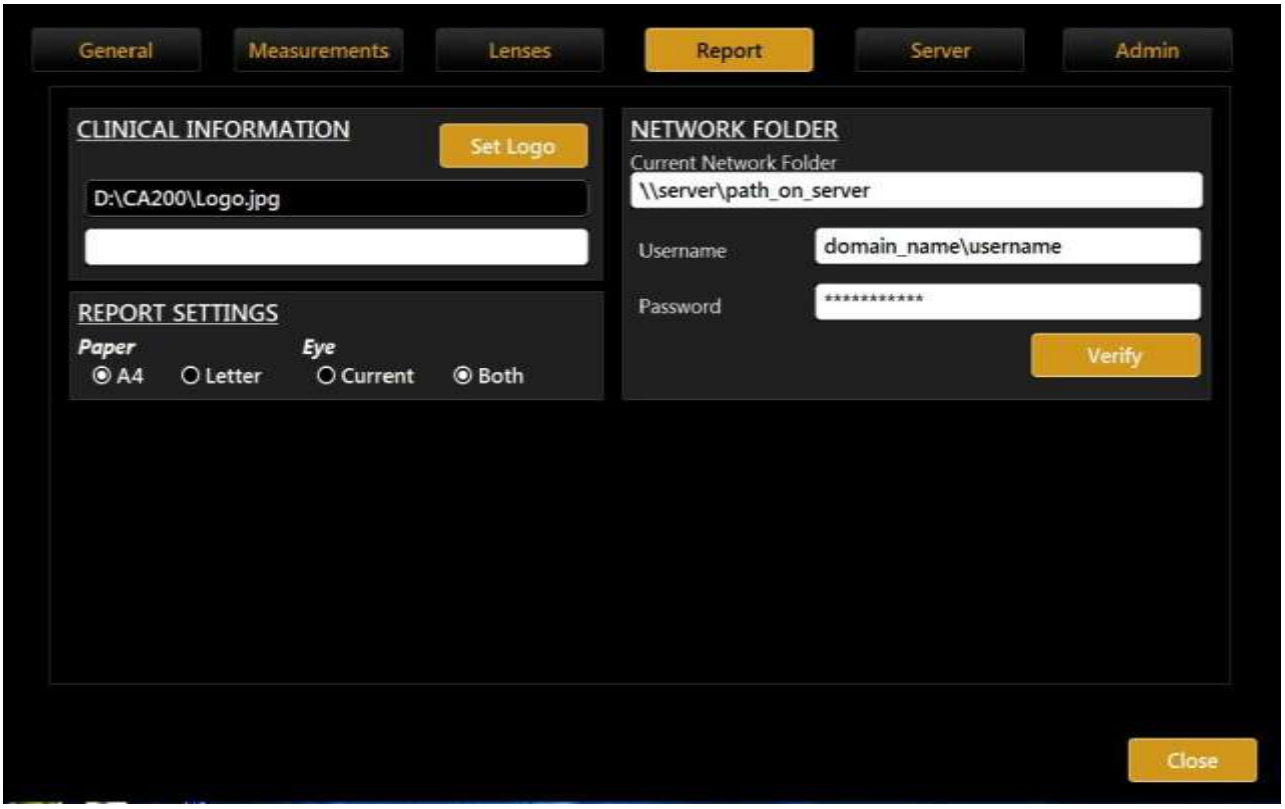


Fig. 70

Report Settings

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

Network Folder

Allows the user to configure and use a remote network folder to store CA-800 reports.

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

To allow CA-800 to connect to the remote network folder, you must configure the CA-800 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
- ***User name***: specify the domain name if needed
  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. 71 and Fig. 72. A connection failure may be due to an unreachable resource path or to wrong credentials.

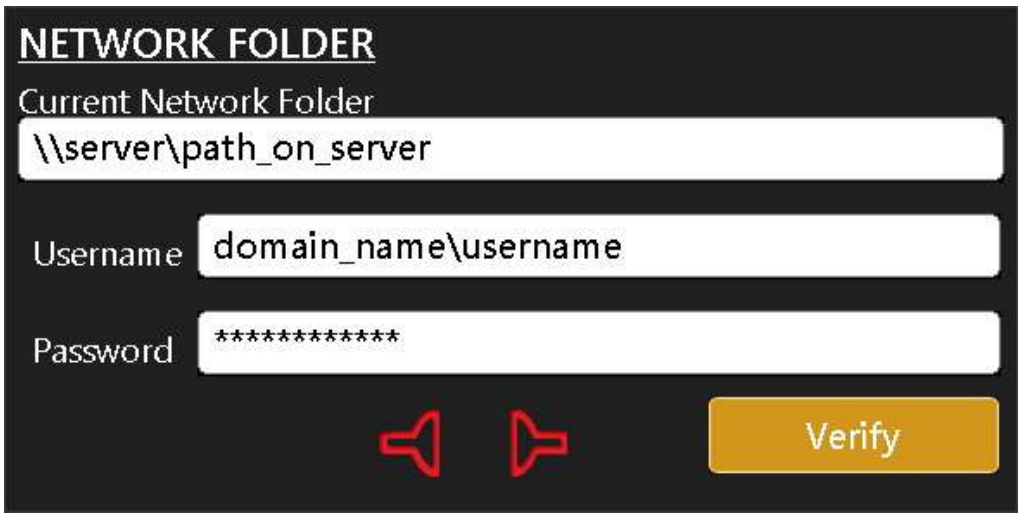


Fig. 71

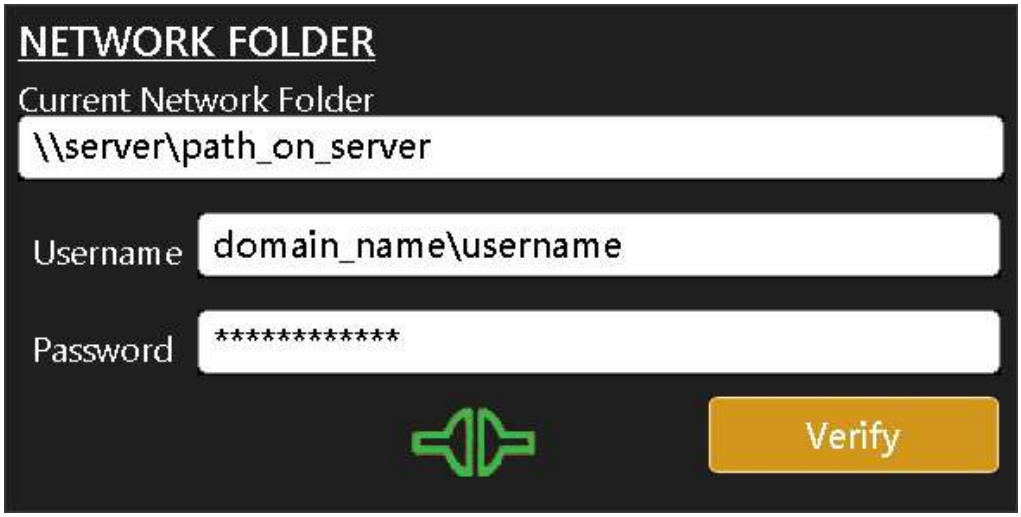


Fig. 72

18.13.5 Server

Server List

Allows the user to enable or disable the server list and to set the maximum number of patients in the list.
It is possible to select between the corneal analyzer and the ibase server and to set the ibase IP address.

18.13.6 Admin

This is the instrument administration panel (Fig. 73).

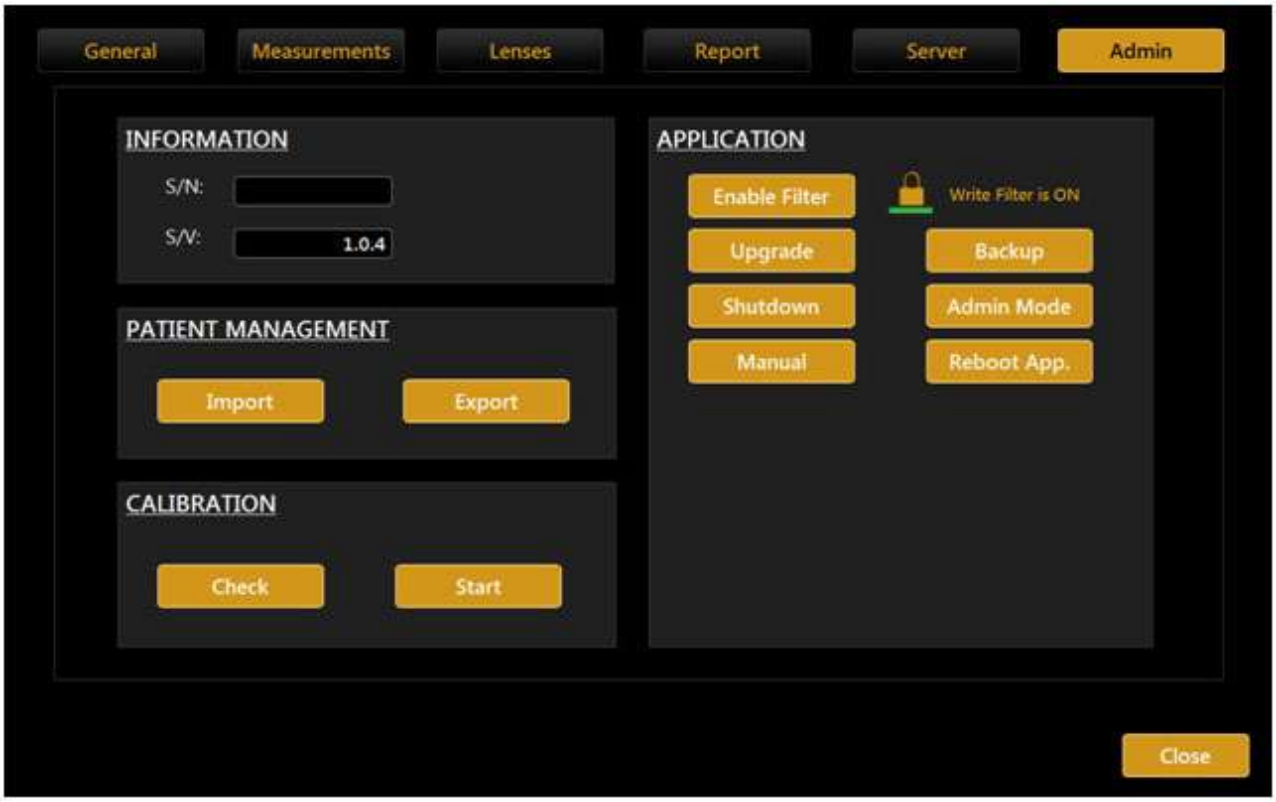


Fig. 73

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

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

Checking calibration

See the paragraph on the procedure.

Calibration must be checked if the device was transported from one place to another and if it suffered an impact or thermal shocks.

Check the measurements every day when turning on the device.

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

Upgrade → Updates the integrated software

Backup → Starts the backup procedure on a USB driver

Shut Down → Power off the machine

Manual → Opens the device manual

Reboot App. → Reboot the application

18.13.4.1. Manual

Directly from the CA-800 software, it is possible to open the instrument manual (Fig. 74).

From this environment, you can browse the manual:

- using the arrows at the top left, you can move to another page;
- using the plus and minus buttons, you can zoom in/out the page;
- using the double-arrow button, you can auto zoom to the page size;
- using the button at the top right, you can return to default zoom of 100%.

To close the manual, just press the **"Close"** button.

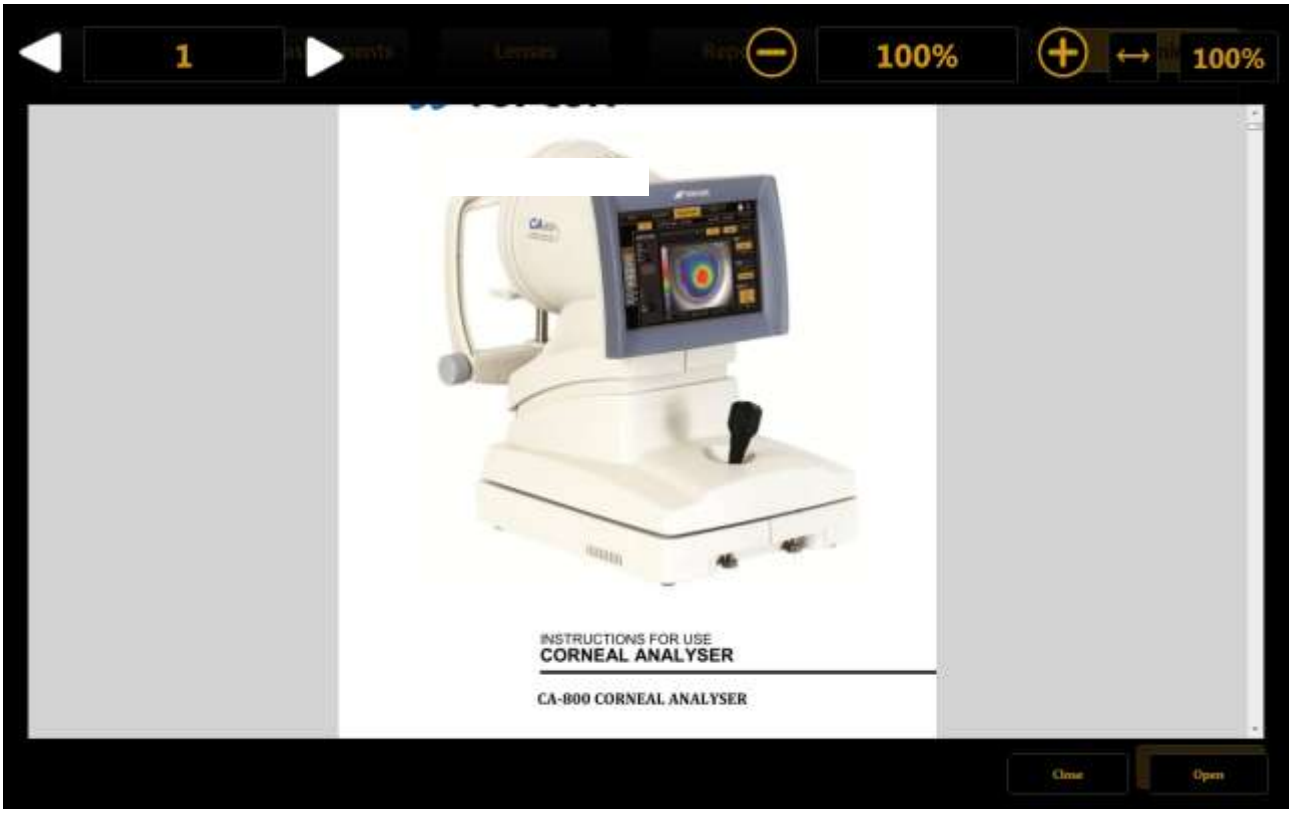


Fig. 74

18.13.4.2 Patients Management

With "Import" and "Export" buttons, users can respectively import and export the entire patient's examinations data to USB drive.

18.14. Updating the integrated software

This section describes the software upgrade procedure.

To update the software, perform the following operations:

1. Unpack the update package in the root (main card) of an empty FAT32-formatted USB external drive.
2. Switch on CA-800.
3. Tap on the settings icon.
4. Tap on the "**Admin**" tab.
5. Insert the USB stick with the "CA-800 *upgrade*" files into one of the USB ports (Fig. 75).

Fig. 75

6. Tap on the "**Upgrade**" button.
7. Tap on "**Ok**" to reboot the system and start the upgrade procedure.

8. The system will reboot and start the *"CA-800 application"*.
9. After restarting, the software updates the system; this operation may take some minutes: do not restart the machine during this procedure.
10. Your CA-800 is now upgraded.

18.15. Backup

It is recommended that you perform a backup to have a safety copy of every patient's data stored. Depending on the expected size of the entire archive, we suggest that you use an external USB disk rather than a USB pen with lower storage space:

1. Insert the empty and FAT32-formatted USB drive into the CA-800 device.
2. Tap on the ***"Backup"*** button.
3. Wait until the procedure has been completed.

18.16. Shutdown

Press the ***"Shutdown"*** button to close the application and go back to the Windows desktop. You will be prompted to confirm this operation.

Press the stand-by button to shutdown the device.

19. TROUBLESHOOTING

Problem	Solution
Calibration check has failed	Repeat the measurement, and if the problem persists, contact TOPCON Technical Service to have the instrument re-calibrated
The standard deviation after an acquisition session is greater than 0.12 D	Repeat the measurement
The CA-800 display is black	Check that the CA-800 device is on Check that the power cables are properly connected

20. SPECIFICATIONS

Technical Specifications	
Keratoscopic Cone	24 rings equally distributed on a 43D sphere
Points Analyzed	over 100.000
Points Measured	Over 6.200
Cornea 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
Fluorescence	Integrated
Output Ports	USB, LAN

Range and Accuracy of measurements				
Corneal Topography	**units of meas.**	**Min**	**Max**	**precision**
Radius of curvature	mm	3.3	37.5	+- 0.02 mm
Radius of curvature D (n=1.3375)	D (diopters)	9.00	101.5	+- 0.12

Pupillometry	**units of meas.**	**Min**	**Max**	**precision**
Pupillometry	mm	0.5	10	+- 0.05 mm

Environmental conditions	
Operation:	
Temperature	10 - 40° C
Relative humidity	8-75% (no condensate)
Atmospheric pressure	700-1060 hPa

Storage:	
Temperature	0 - 45° C
Relative humidity	8-75% (no condensate)
Atmospheric pressure	700-1060 hPa

Transport	
Temperature	-20 - 70° C
Relative humidity	8-75% (no condensate)
Atmospheric pressure	700-1060 hPa

Electrical specifications	
Power source	AC 100-240V 50/60 Hz
Power consumption	80 VA

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

Mechanical specifications	
CA-800	width:320mm height:490mm length:470mm weight:15 Kg

Optical radiations

Central fixation LED	
Source:	Yellow green LED
Wavelength:	572 nm
Power on patient's eye:	<0.01 mW

Illumination of Placido disk for topographic analysis	
Source:	Red LED Type 1
Wavelength:	633 nm
Power on patient's eye:	<0.02 mW
Source:	Red LED Type 2
Wavelength:	615-630 nm
Power on patient's eye:	<0.02 mW

Pupilometric analysis			
Source:	White LED		
	Blue	Green	Red
Wavelength:	473 nm	532 nm	630 nm
Power on patient's eye:	0.03 cd	0.005 cd	0.008 cd
Source:	IR LED		
Wavelength:	940 nm		
Power on patient's eye:	0.3 mW		
Source:	Red LED Type 1		
Wavelength:	633 nm		
Power on patient's eye:	<0.02 mW		
Source:	Red LED Type 2		
Wavelength:	615-630 nm		
Power on patient's eye:	<0.02 mW		

Fluorescein analysis	
Source:	Blue
Wavelength:	475 nm
Power on patient's eye:	0.207 mW

Onboard PC	
Operating system	WINDOWS 8 Embedded
Processor	AMD G-T56N
RAM	2GB
Hard disk	At least 250 GB
External connections	LAN integrated, 2x USB

21. CHANGING THE FUSES

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 indicated 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