USER MANUAL

CA-800

CORNEAL ANALYZER

CE 0123

REV. 18 2023

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.: 1.6.x

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1 INTENDED USE

CA-800 is a corneal analyser with integrated pupillographer. The instrument acquires images of the cornea and analyses 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 analyser 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

1.1 Intended Users

Eye specialists, ophthalmologists, opticians and optometrists.

The instrument must be used by qualified persons.

1.2 Place of use

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

1.3 Contraindications

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

1.4 General description of functions

CA-800 is a corneal analyser 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 - Toric Intraocular lens calculation (Toric IOL).

i-MAP is an ophthalmic reviewing software which allows to review on PC the examination data obtained with CA-800. i-MAP software is able to interact via network with the CA-800 to exchange data.

1.5 Interaction with the patient

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

2 PRECAUTIONS

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

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.
- To obtain accurate and reliable measurements, keep the measuring cone clean and dust-free.

This product conforms to the EMC standard (IEC 60601-1-2 4th Edition).

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

2.1 Electromagnetic compatibility

2.1.1 EM Emission

The CA-800 device fulfills requirements of IEC 60601-1-2 4th Edition:

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

2.1.2 EM Immunity

The CA-800 device fulfills requirements of IEC 60601-1-2 4th Edition:

Immunity test	Standard	Test level		
Electrostatic discharge (ESD)	IEC 61000-4-2	± 8kV contact ± 15kV air		
Electrical fast transient/Burst	IEC 61000-4-4	±2kV 100kHz repetition frequency		
Surges	IEC 61000-4-5	±1kV common mode ±2kV differential mode		
Rated Power frequency magnetic field	IEC 61000-4-8	30 A/m		
Conducted disturbances induced by RF fields	IEC 61000-4-6	**Level**	**Frequency**	**Modulation**
		3V	150kHz÷80MHz	1kHz 80% AM
		6V	6,765MHz÷6,795MHz	1kHz 80% AM
		6V	13,553MHz÷13,567MHz	1kHz 80% AM
		6V	26,957MHz÷27,283MHz	1kHz 80% AM
		6V	40,66 MHz ÷ 40,70 MHz	1kHz 80% AM
Radiated RF EM fields	IEC 61000-4-3	**Field (V/m)**	**Frequency**	**Modulation**
		3	80MHz÷2700MHz	1kHz 80% AM
		27	380MHz÷390MHz	18Hz 50% PM
		28	430MHz÷470MHz	18Hz 50% PM
		9	704MHz÷787MHz	217Hz 50% PM
		28	800MHz÷960MHz	18Hz 50% PM
		28	1700MHz÷1990MHz	217Hz 50% PM
		28	2400MHz÷2570MHz	217Hz 50% PM
		9	5100MHz÷5800MHz	217Hz 50% PM

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

The 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.

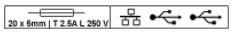
Rated maximum output of transmitter (W)	**Separation distance according to transmitter frequency (m)**		
	150kHz to 80MHz $d = 1.2 \cdot \sqrt{P}$	**80MHz to 800MHz** $d = 1.2 \cdot \sqrt{P}$	**800MHz to 2GHz** $d = 2.3 \cdot \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
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.

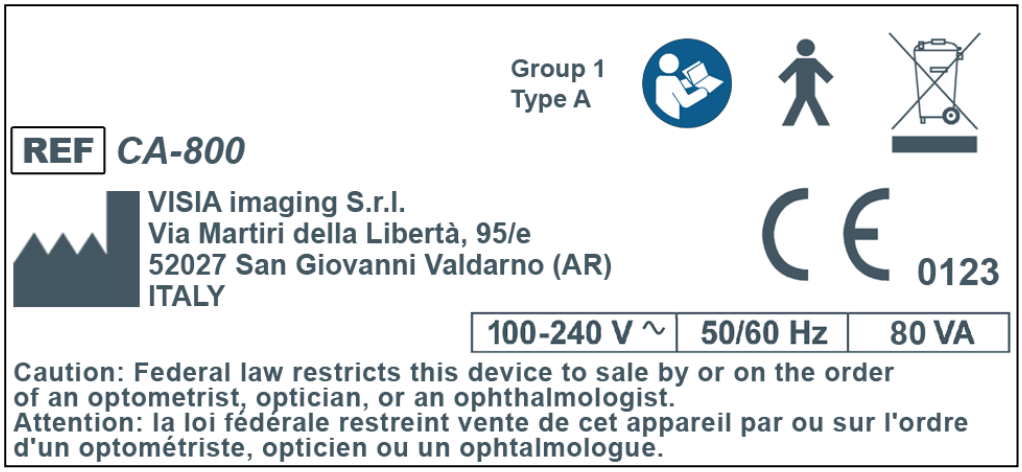
Note:
(1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies
(2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3 SYMBOLS

Symbol	IEC Publication	Description
	IEC 60417-5840	CLASS I DEVICE IN ACCORDANCE WITH 60601-1 APPLIED PART TYPE B
		PRODUCT IN ACCORDANCE WITH DIRECTIVE 93/42/EEC
Type A		CORNEAL TOPOGRAPHY ACCORDING TO ISO 19980:2012
	IEC 60417-5032	ALTERNATE CURRENT
	ISO 7010-M002	FOLLOW THE INSTRUCTIONS FOR USE
	ISO 7010-W001	GENERAL WARWING
	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 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.*
	IEC 60417-5009	STAND-BY SWITCH
		EXTERNAL PORTS AND FUSES
	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 2012/19/UE (Directive on Waste Electrical and Electronic Equipment) or (ii) for all other countries, in accordance with local disposal and recycling laws.	

3.1 Device sample labeling



4 SAFETY INSTRUCTIONS

4.1 General

- CA-800 should be used only for its intended purposes as detailed in this manual.
- Keep this manual at hand and close to the device at all times.
- ⚠ The instrument can be used only by qualified persons (eye specialists, ophthalmologists, opticians and optometrists) after having read this user manual.
- For each clinical function hazards have been identified from potential failures or misuse of the system. There are no unacceptable risks related to clinical functions, so there are no Essential Performance for the device.
- The device must be installed by qualified staff.
- The device must be connected to an appropriate power source, otherwise its performance may be reduced.
- ⚠ Position the unit so that it is not difficult to disconnect the plug for connection to the supply main.
- ⚠ If the device has just been delivered or underwent thermal shock, wait at least one hour before making measurements on patients.
- ⚠ If the device has been affected by external forces (e.g. if it is 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.
- Remove all the covering material (dust sheet) from the device before turning it on.
- ⚠ Run all the control functions (detailed in the relative section in this document) before carrying out measurements on patients.
- ⚠ The physician or device user must inform the patient of the related safety instructions and ensure that they are observed.
- Use only genuine CA-800 accessories and spare parts.
- Turn off the device if it is not going to be used for a long period of time.
- ⚠ Unauthorized software installation in the device is not permitted.

4.2 Environment of use

- The device must be used in the environmental conditions as specified in this document.
- The least favorable environment is defined as the maximum values of temperature for the unit 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.
- It is advisable to use the device in an unlit environment
- Do not use the device near highly flammable materials or in areas with an explosion risk.

4.3 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.

4.4 LED emission safety

The light emitted from this instrument is not potentially hazardous.

CA-800 has a series of LEDs of various types and powers installed. All the characteristics are detailed in the Technical Specifications section in this manual.

The LED groups comply with the emission limits for the Group 1 instruments of the standard ISO 15004-2.

4.5 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.
- An external keyboard or another input device compatible with “keyboard wedge interface” (PS/2) such as barcode or card readers can be connected to the device to input text.
- 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 near 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.
- After connection of external devices to the USB or LAN, the end installer must check that the system maintains basic safety and essential performance of the product in compliance with IEC 60601-1.
- 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.

4.6 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 locking screws 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 locking screws for transportation.

4.7 Cleaning

Regularly clean the device removing dust using a soft cloth. In the case of more persistent surface dirt, use a soft cloth soaked with water or alcohol (70% max).

⚠ Be careful not to wet the device and clean it only as indicated to prevent damaging it. Never use solvents or other abrasive agents.

- Do not clean the plastic parts with solvents such as benzene or similar products, as they may cause discoloring of the parts and decomposition of the material.
- 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.
- 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 the mounts that come into contact with the forehead and chin with neutral detergents.

4.8 Checking the measurements

⚠ The calibration must be checked when the device has been transported from one place to another and when it has suffered an impact or thermal shocks.

- ⚠ 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.

5 PRODUCT WARRANTY AND RELIABILITY

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

The product warranty is 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.

6 LEGAL PROVISIONS

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

ETL CLASSIFIED

C ETL US LISTED

Intertek

ETL Standards:

- Medical Electrical Equipment – Part 1: General Requirements For Basic Safety and Essential Performance [AAMI ES60601-1:2005+A1]
- Medical Electrical Equipment – Part 1: General Requirements For Basic Safety and Essential Performance [CSA C22.2#60601-1:2014 Ed.3]

7 LIABILITY

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

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

8 MAIN COMPONENTS

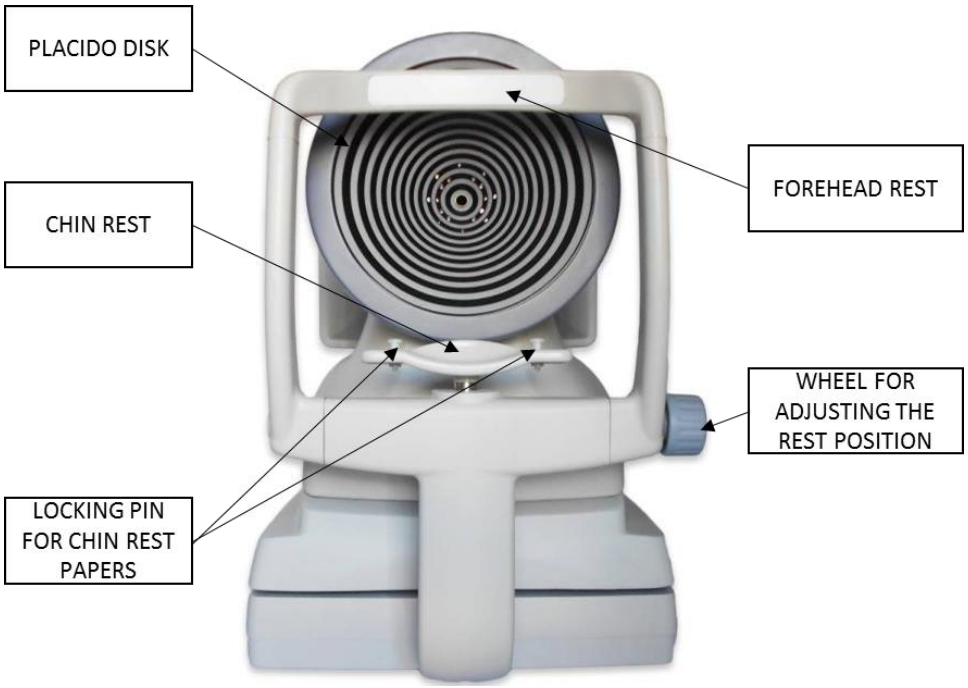


Fig. 1 Patient's side

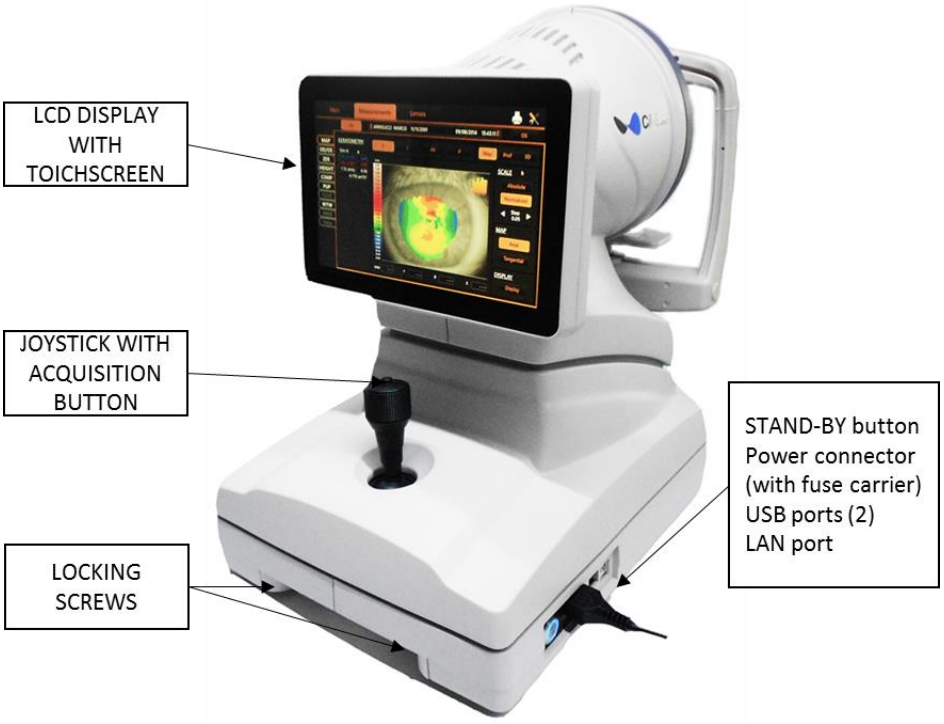
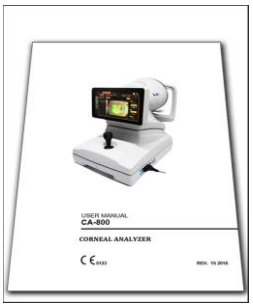
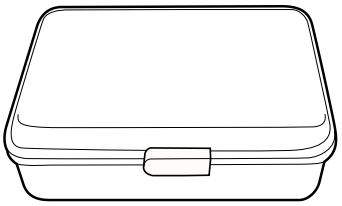


Fig. 2 User's side

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

9 PACKAGING CONTENT

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 cables (for EU and US)	
CD User Manual in 5 languages i-MAP 1.6.8 SW installer	
User Manual (English)	
Protective dust cover	

Accessories box containing: • Touchscreen pen • Silicon cloth • Chinrest paper • Chinrest pins	
Touchscreen pen	
Silicone cloth	
Chinrest paper	
Chinrest pin	
Silica gel salt sachet	

10 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.

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

10.1 Installing the system

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

Fig. 3

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

Fig. 4

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

The accessories are:

- **“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.

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

The instrument can now be taken out of the package. The steps are illustrated in Fig. 5:

Fig. 5

Place the instrument on a flat surface.

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

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

10.2 Uninstalling the system

Take the original packaging.

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

Fig. 6

Insert the instrument in the box, as shown in Fig. 6, and place the Nylon cover on it. Follow the step sequence shown in Fig. 7.

Fig. 7

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

11 SETTING UP THE INSTRUMENT

11.1 General

Before connect device to external devices or IT Network, please read SAFETY INSTRUCTION.

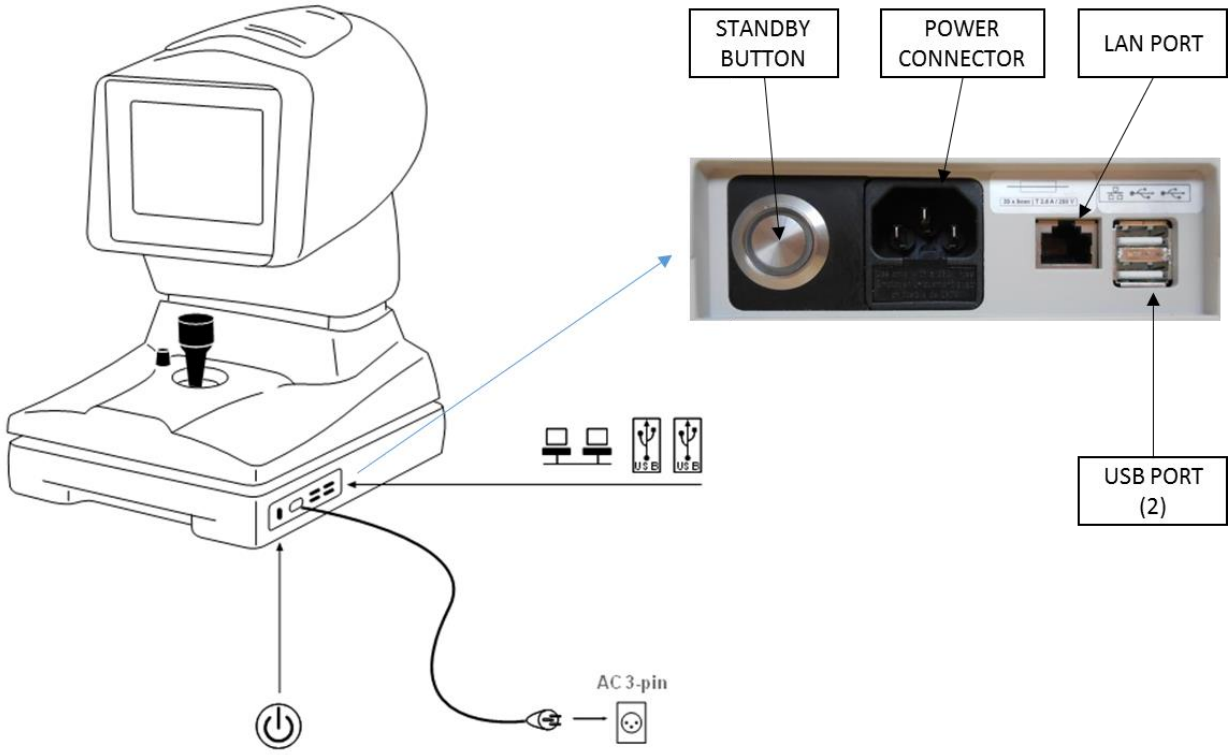


Fig. 8

11.2 Power on procedure

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

Press the stand-by button and wait for the system loading until the screen showed in Fig. 16 appears.

11.3 Power off procedure

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

12 SETUP i-MAP (optional)

12.1 Introduction

i-MAP is the reviewing application for examination data obtained with CA-800.

If desired, i-MAP can be installed in one or more PC which are connectable through network with CA-800 device. i-MAP replicates the same application interface and functionalities as the CA-800 on board application. The information provided in the following sections of this manuals apply equivalently (if not differently specified) to i-MAP application and CA-800 on board application.

On i-MAP it is not possible to directly perform examinations, New Exam action that is explained in the following sections of the user manual does not apply to i-MAP application.

12.2 i-MAP System Requirements

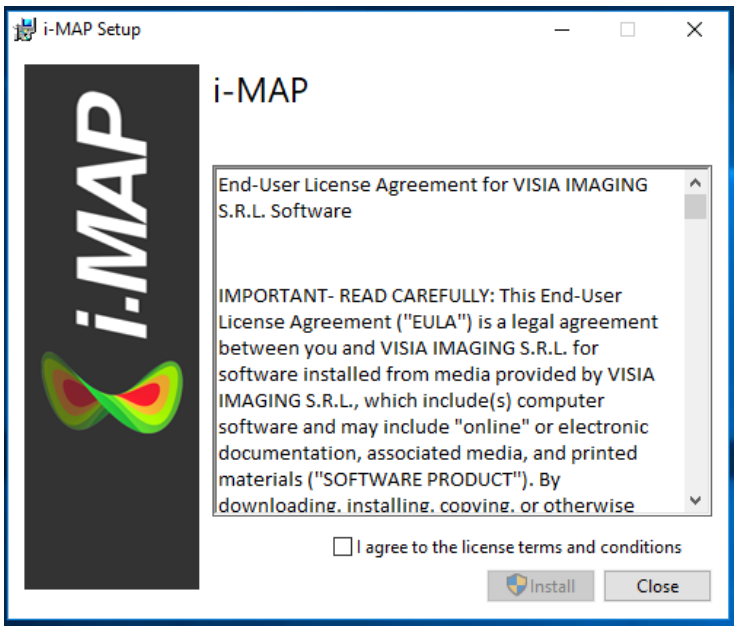
System requirements for i-MAP software:

- Operating System:
  - Windows 7 (32/64 bit)
  - Windows 8 (32/64 bit)
  - Windows 10 (32/64 bit)
  - Windows 11 (32/64 bit)
- SW dependencies, these are automatically installed with the application if not already present:
  - .Net Framework 4.5.2 or later
  - VC++ Runtime 2013
  - VC++ Runtime 2015
- RAM: At least 2GB
- HDD free space: we recommend at least 4GB free. Occupied space after installation is around 570MB (above mentioned SW dependencies not included), then the amount of free space determines the maximum size the archive of examinations.
- Screen resolution: min. 1280x1024

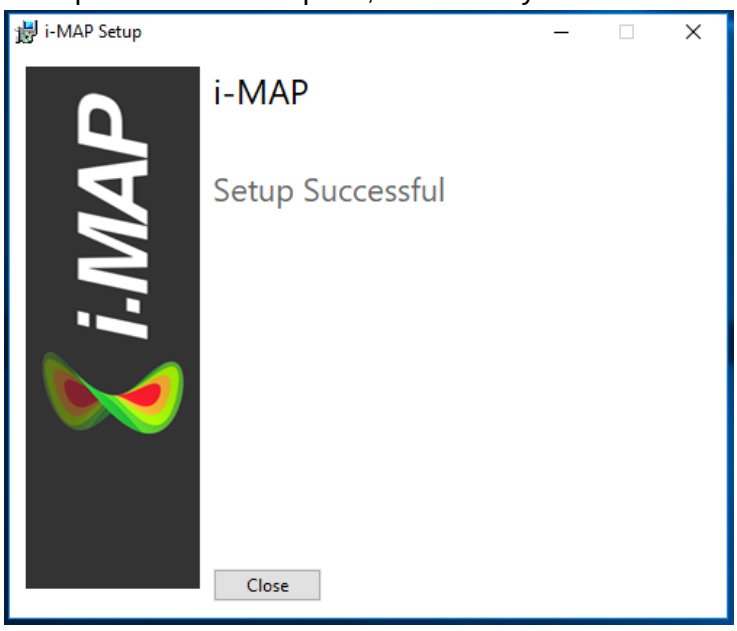
12.3 i-MAP Installation procedure

- Double-click on the installer file iMAPInstaller 1.X.X.exe

- Read the Disclaimer, accept the terms and conditions and press Install

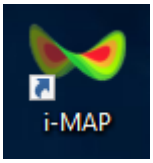


- Administrator privileges will be required
- Wait for the installation procedure to complete, at the end you can run i-MAP



12.4 Running the i-MAP Application

To run the application, double-click on the Desktop icon created after the installation or from the start menu.



Wait for the application to load.

When the application is loaded, you will see the following view, where you have the list of patients and exams currently accessible.

12.5 i-MAP Main View

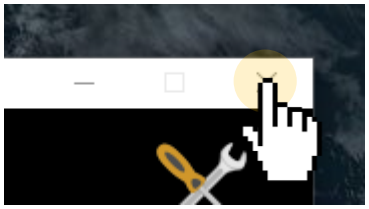
The picture below shows the main view of the application.

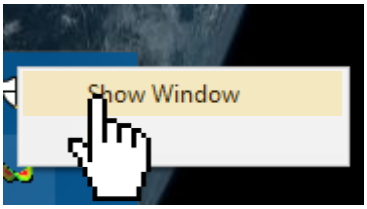
12.6 i-MAP Settings

Press on the Settings icon to access the settings of the application. See section 0 for explanation of settings.

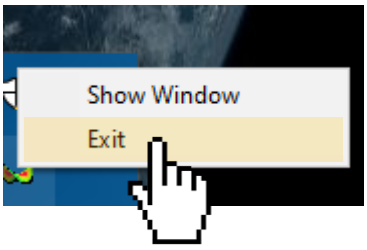
12.7 Closing the i-MAP Application

If pressing the title bar close button the application is minimized to taskbar, to show the application window again right-click on i-MAP icon in taskbar and select Show Window.





To completely close the application, go to **Settings** > **Admin** section and press **"Close App"** or from the taskbar icon select **"Exit"**.



12.8 Setup Connection between CA-800 and/or other i-MAP Network Instances

This section explains the basic configuration of a **i-MAP Network Instance** (an i-MAP Network Instance is a CA-800 device or an instance of i-MAP application installed on a PC) in the i-MAP network.

i-MAP network allows to interconnect i-MAP Network Instances in the practice LAN to share examination and patient data. Fig. 9 shows a possible arrangement of i-MAP network where several i-MAP Network Instances are connected.

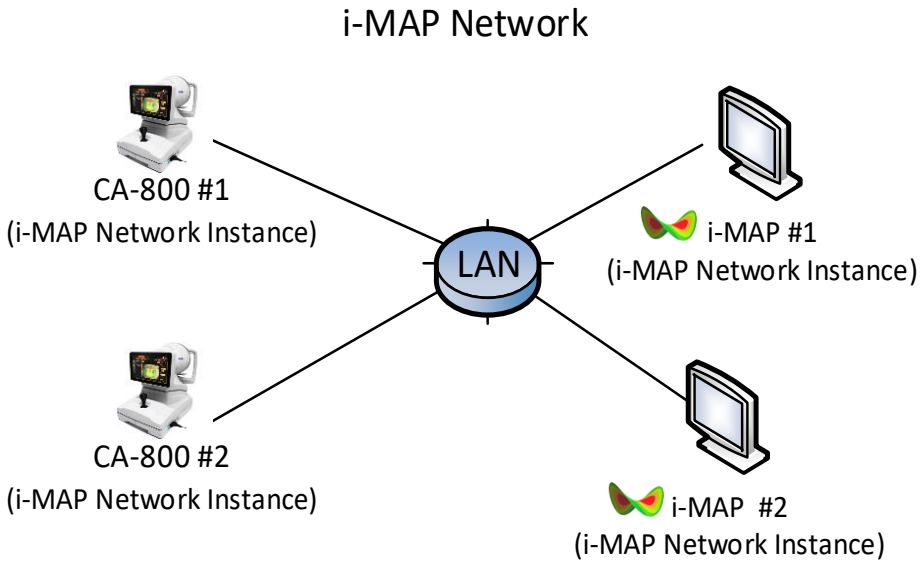
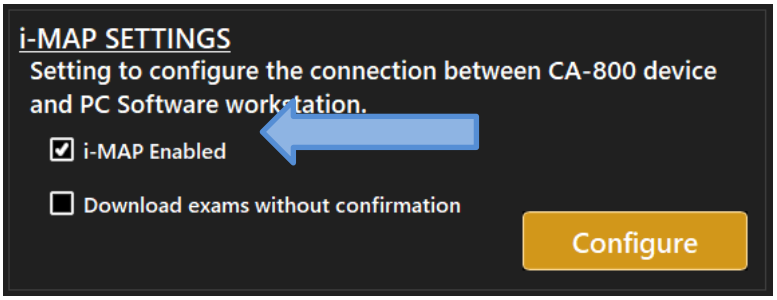


Fig. 9

12.8.1 Basic configuration

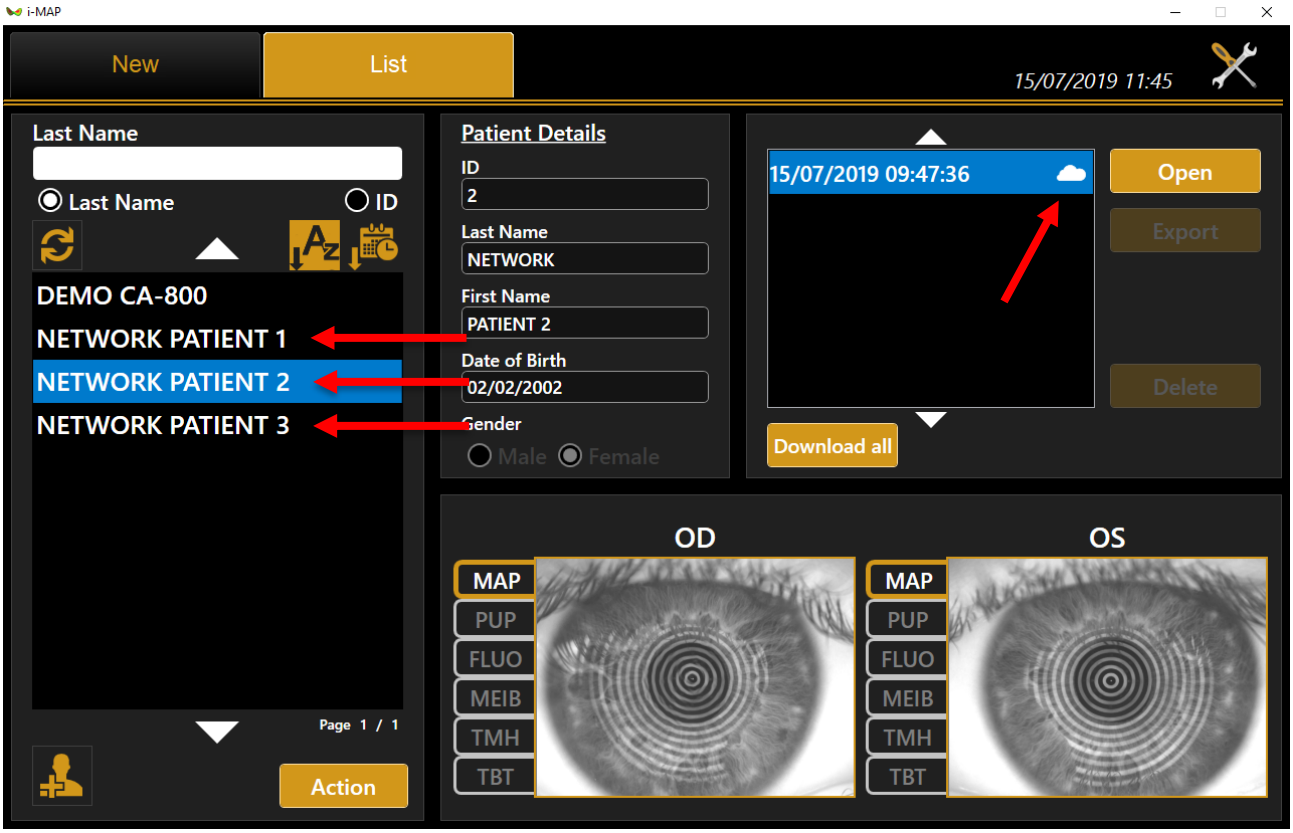
i-MAP allows connections between CA-800 devices and/or other i-MAP Network Instances in the same network. To do this first of all make sure that the "**i-MAP Enabled**" option is checked (go to the Setting->Connectivity section).



i-MAP automatically scans the network to find active i-MAP Network Instances (CA-800 or i-MAP), add them to its internal list and retrieve the patients and exam lists, uniting the local database with the other remote databases.

The resulting merged patients list can be viewed in the initial environment ("List" tab).

If a patient retrieved from the network contains valid exams, these will be inserted in the exams list and will be marked with a "**cloud**" icon as shown in the picture below.



Pressing the **"Open"** button when a remote exam is selected, i-MAP will download the exam. Once downloaded, i-MAP will automatically open the exam. Refer to section 13.4 for more details.

13 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:

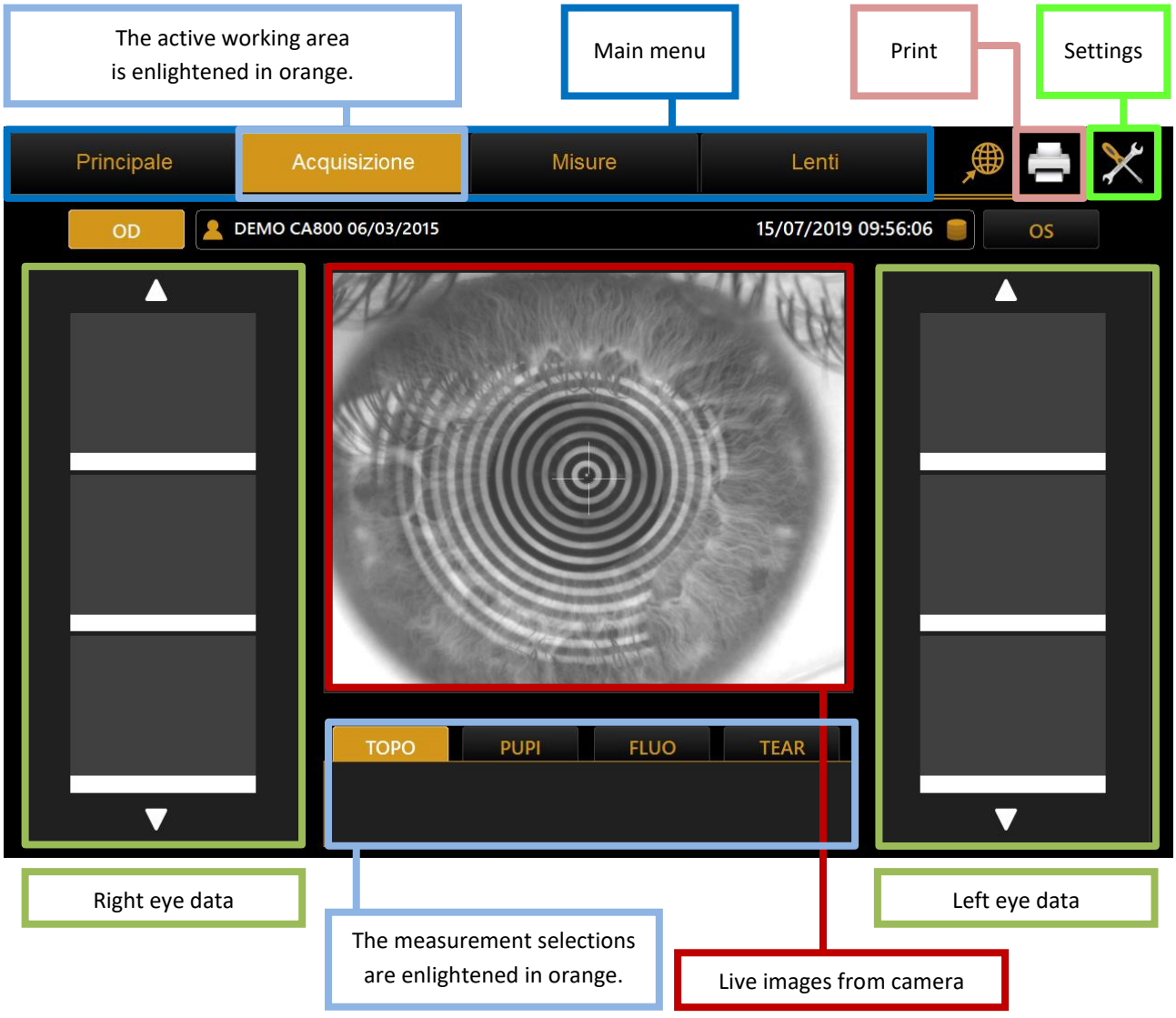
- Entering the patient's data
- Different acquisition modes
- Measures display and processing
- Lens selection

More information for each function and the description of all the settings and other functions available are 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.

13.1 Overview

This section does not apply to i-MAP application. Every working environment has the same screen layout. In Fig. 10 a sample of the acquisition screen is showed.



13.2 Checking calibration

This section does not apply to i-MAP application.

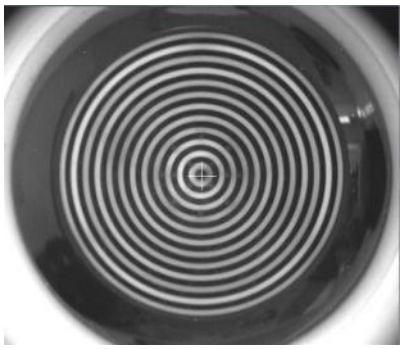
The calibration must be checked:

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

Insert the calibration tool provided with the device (Fig. 11) 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. 12).

Fig. 11

CORRECT alignment



WRONG alignment

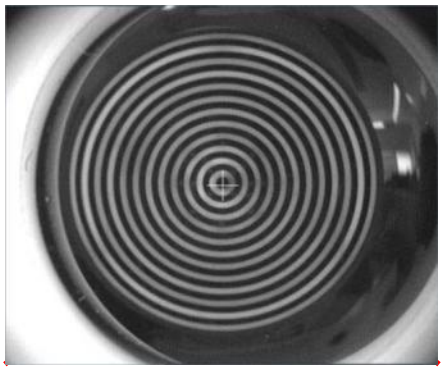


Fig. 12

To check calibration, turn the instrument on and go to settings, then select the Admin tab and press Check (Fig. 13).

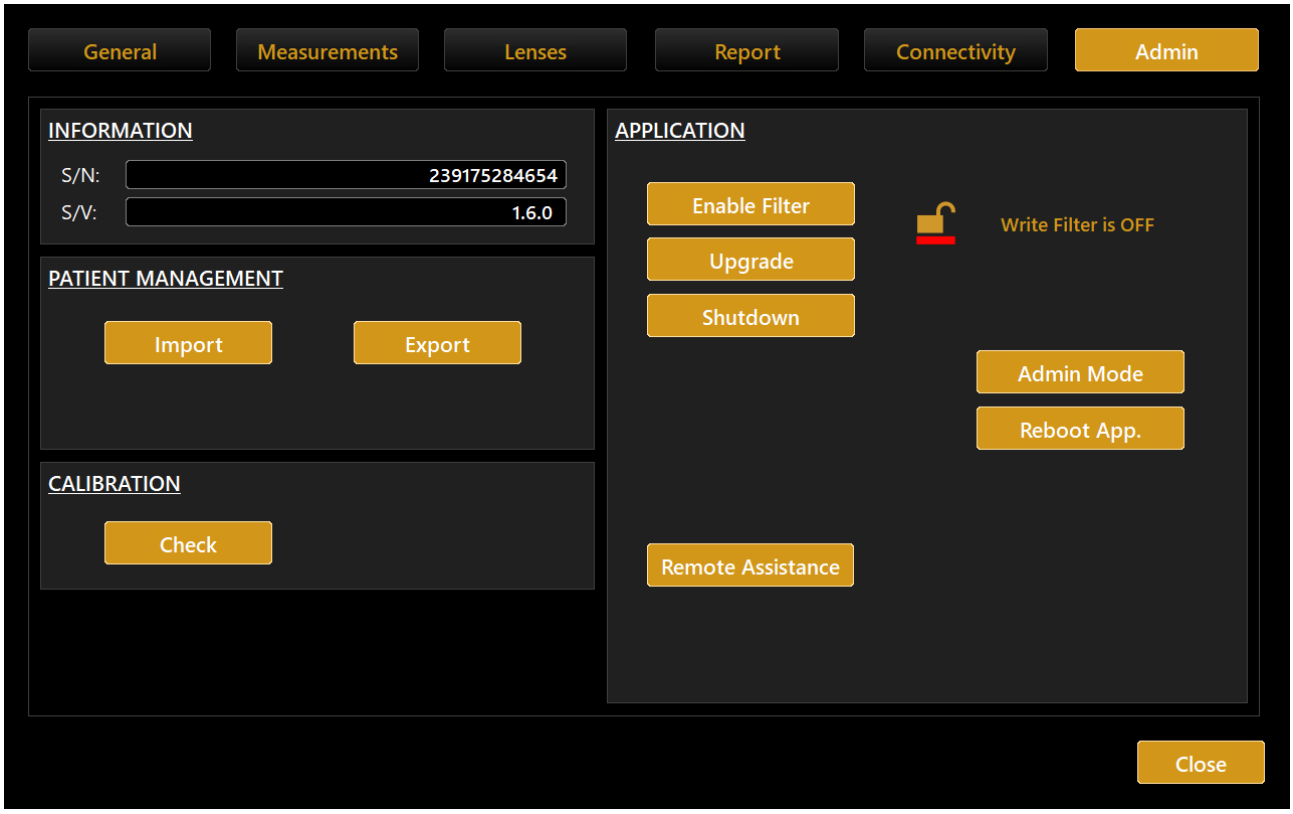


Fig. 13

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. 16). If calibration is not correct, the software will display the message “Calibration Check: NEGATIVE” (Fig. 17).

Fig. 14

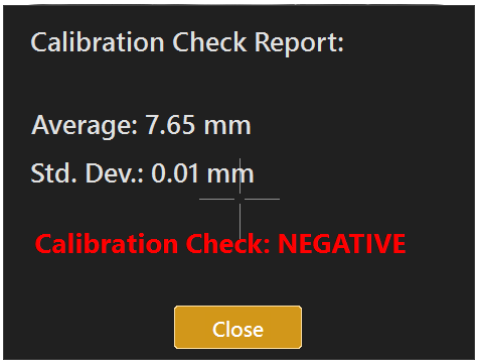


Fig. 15

13.3 Entering/selecting a patient

When the CA-800 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).

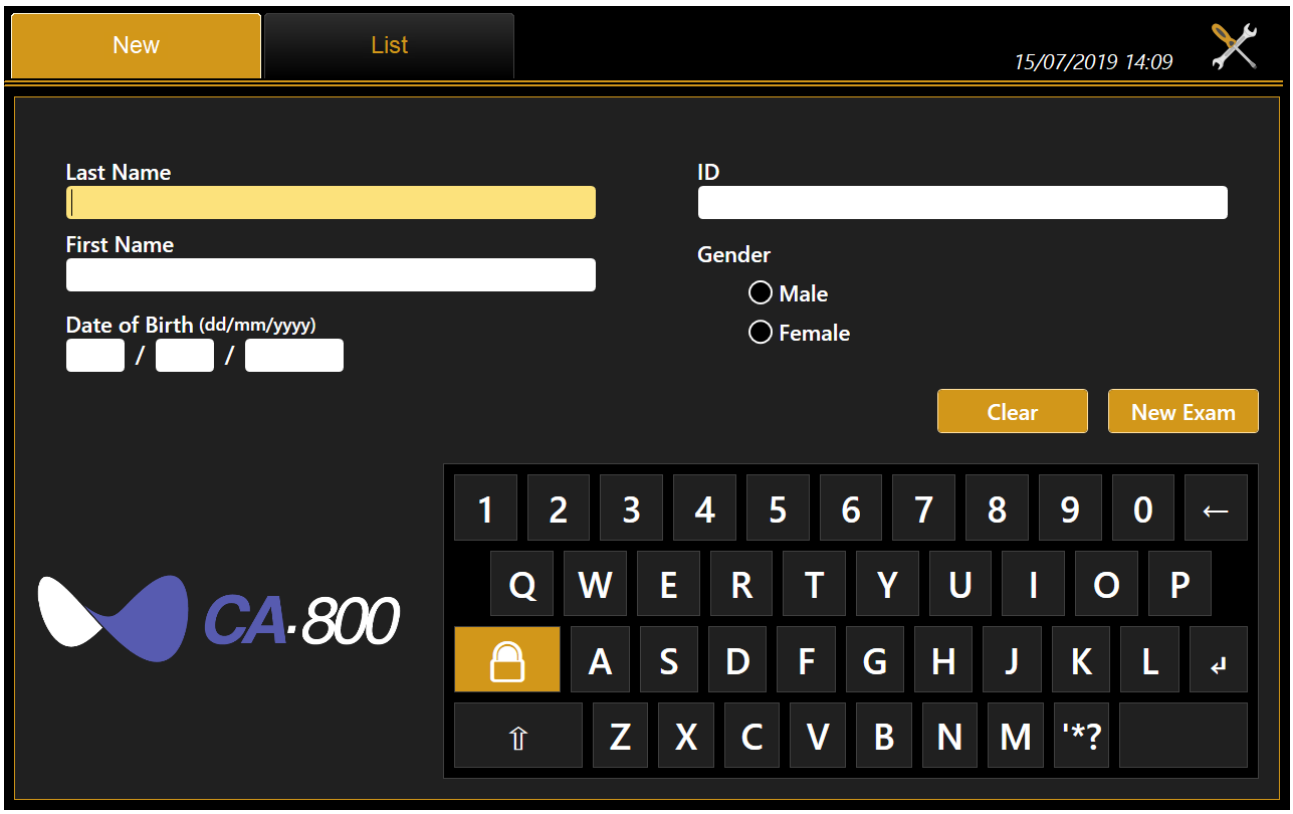


Fig. 16

Fig. 16 shows the section for creating a new patient, entering Last Name, Name and Birth Date (Gender and ID are optional).

13.3.1 Creating a new patient

To create a new patient, select the **"New"** tab and enter the data using the on-screen keyboard (CA-800 only). Once you have entered the new patient data, tap on the **"New Exam"** button to confirm the information and continue with the examination. If you want to clear all the fields tap on the **"Clear"** button.

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

A special character can be entered simply by touching and holding the corresponding letter (Fig. 17).

Fig. 17

13.3.2 Creating a new patient on i-MAP

To create a new patient, press on the “add patient” button or select the **“New”** tab and enter the data.

Fig. 18 Shows the section for creating a new patient, entering Last Name, Name, Date of birth, Gender and ID. Some fields are mandatory and other optional depending of the **“Patient Required Fields”** option in the settings (refer to section 17.1 for details).

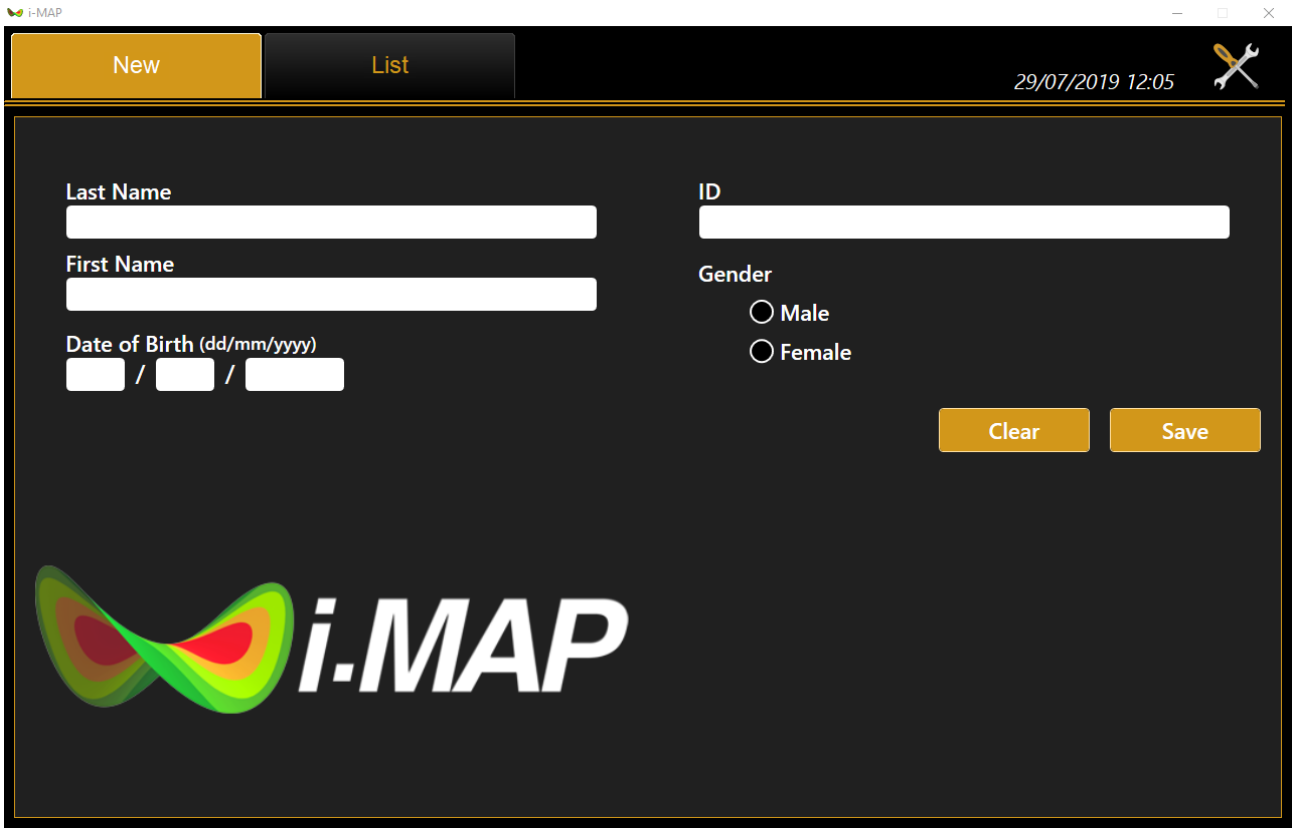


Fig. 19

13.3.3 Selecting or editing a patient

On the input screen, tap on the **"List"** tab to access all the patients found in the database (Fig. 20).

Fig. 20

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

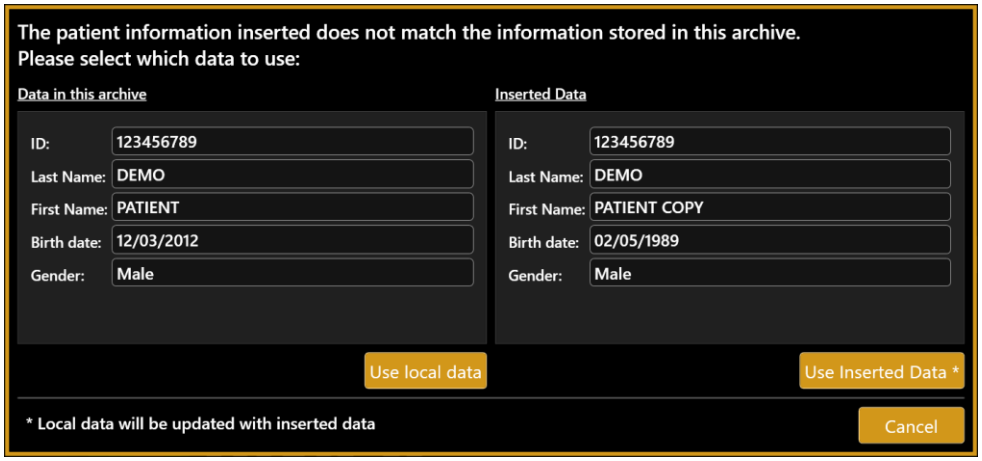
13.3.4 Patient data management

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

⚠ This search is performed trying to match only the ID

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

- **"Use local data"** Maintain existing data (discard inserted data)
- **"Use inserted data"** Replace the already existing patient data with the just typed one.

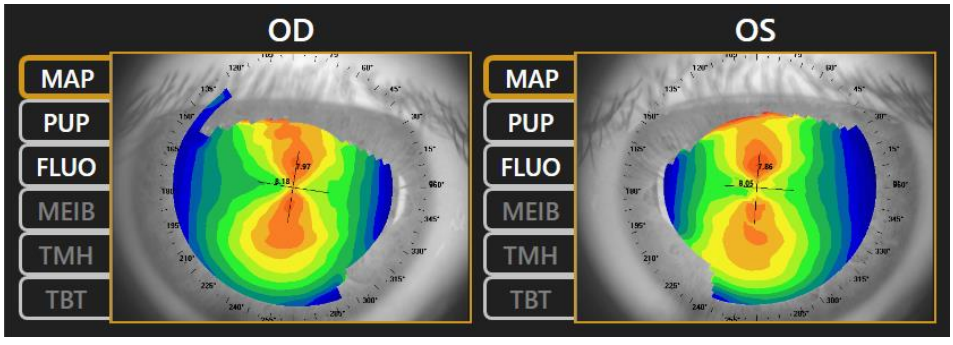


13.3.5 Open an examination or acquire data for the selected patient

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

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

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



After selecting a patient, another examination can be carried out by pressing the **"New"** button. If you want to export a selected exam from the list of examinations associated to a patient, using the "***Export Exam***" button you can choose the destination (USB or Corneal Analyzer). (Fig. 22)

13.3.6 Managing the selected patient

From the list of patients, select the patient you want to manage and press the **"Action"** button. The application opens a form (Fig. 15) with three buttons, **“Delete”**, **“Export Patient”** and **“Cancel”**. Press **“Delete”** to delete the selected patient with all of his exams, press **“Export Patient”** if you want to export it with all of his exams (possibility to export to USB[1] or to i-MAP instances or to Corneal Analyzer) 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. 21

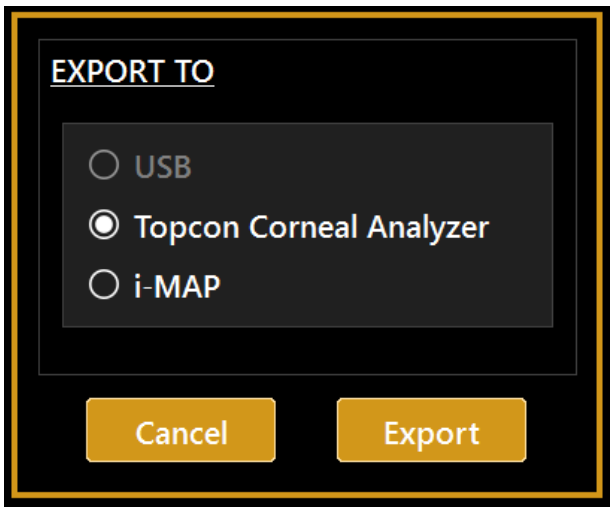


Fig. 22

[1] Selectable local folder in the case of i-MAP

13.3.7 Selecting a patient from Server [2]

Once enabled, CA-800 **IMAGEnet i-base's** integration from CA-800's settings panel (refer to IMAGEnet i-base configuration), it's possible to select a new patient from the patient list retrieved from IMAGEnet i-base or Corneal Analyzer (Fig. 24).

In the same way, CA-800 can be activated to search patients from DICOM services (refer to DICOM configuration section):

- **DICOM Patient Root Query**: search patient's details on enable patient's archive server
- **DICOM Modality Worklist**: get the list of patients and tasks in the waiting room

The user can search for a patient either by **surname**, by **id** or by **date of birth** (i-base only). A list of patients will be created corresponding to the search criteria (Fig. 23). Once selected a patient, the user can create a new examination in the standard mode by clicking on the Acquisition or OK button.

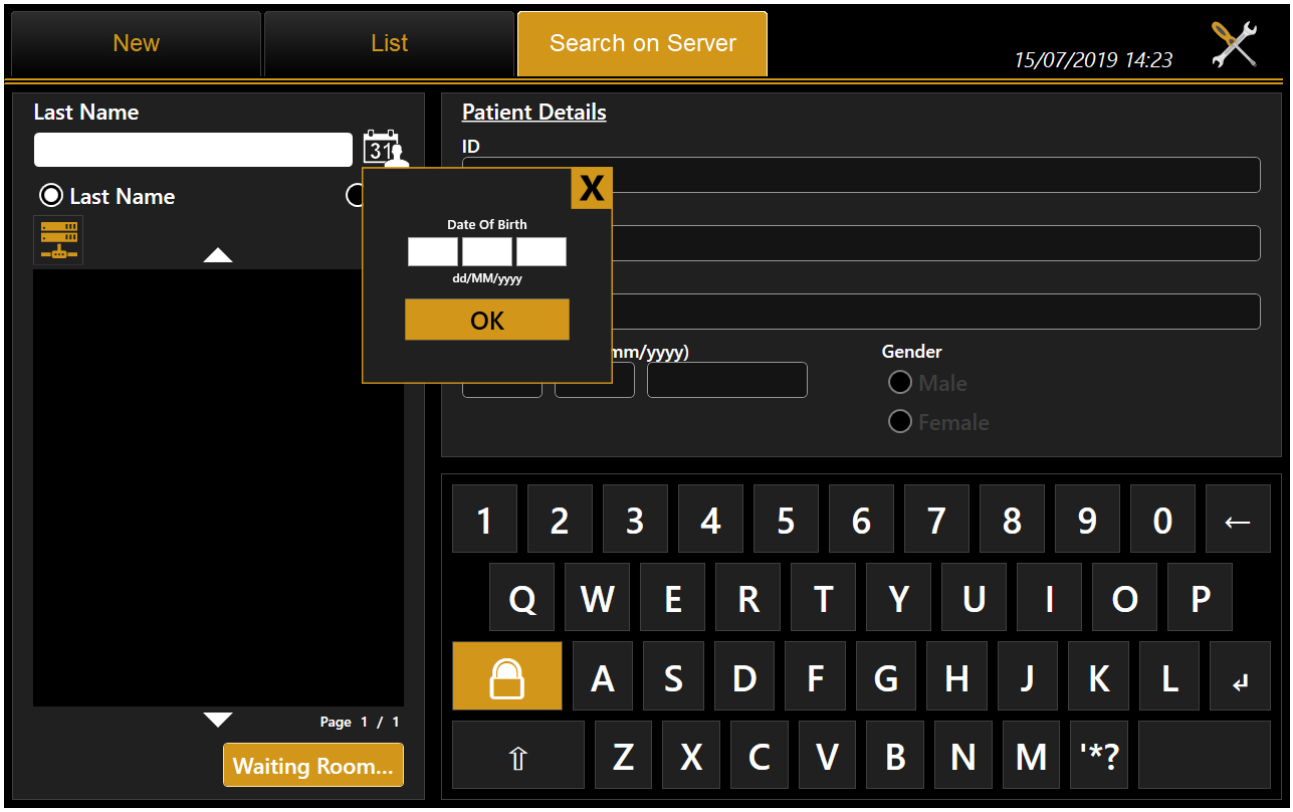


Fig. 23

The user can search from IMAGEnet i-base and/or DICOM sources at the same time by enabling/disabling the corresponding options using the server selection button.

[2] This section applies to CA-800 on-board software only

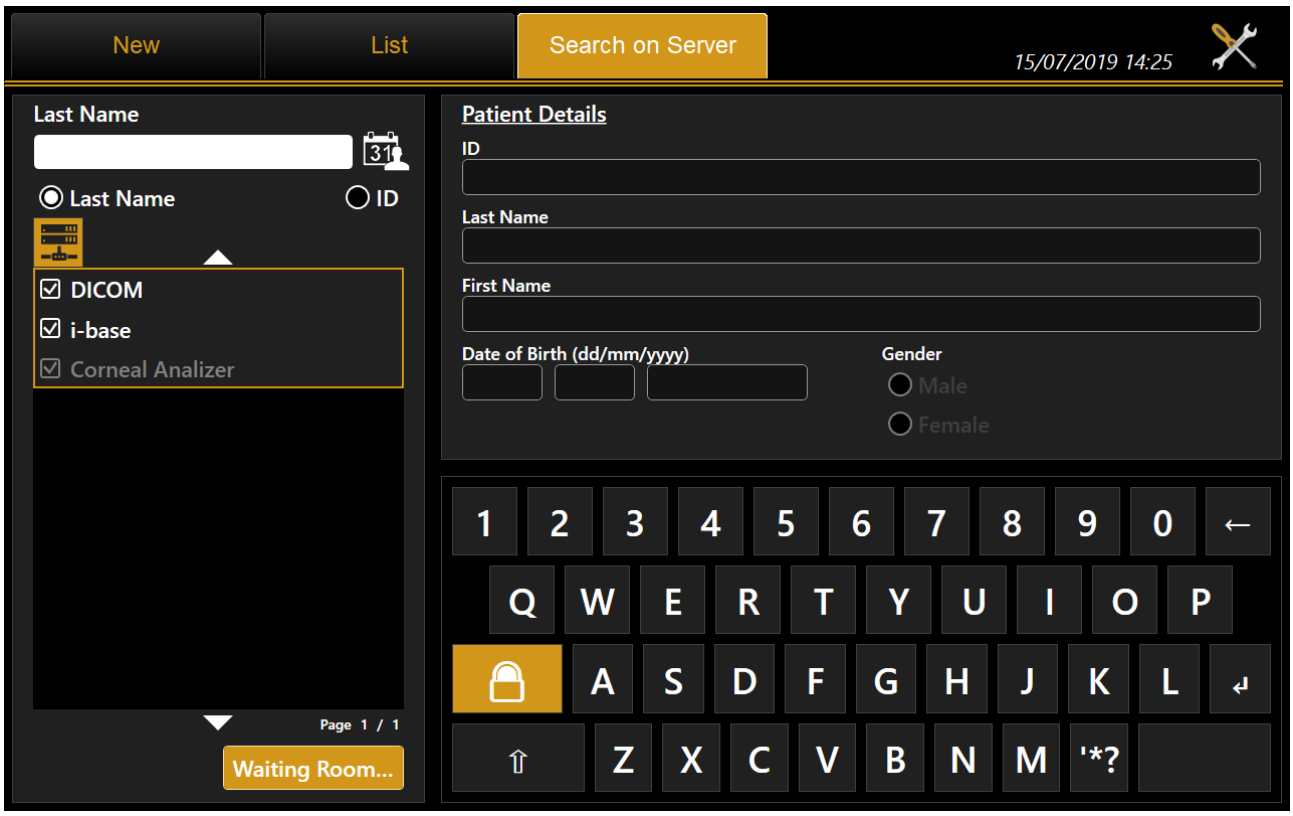


Fig. 24

13.3.7.1 Start an exam from the Waiting Room

If DICOM Modality Worklist service is configured, CA-800 is able to search for pending patient's examinations in the waiting room. Pressing on the **"Waiting Room…"** button (Fig. 25) shows a list of the pending worklists for the current day. The list can filtered by one or more of the other criteria:

- Patient Name
- Patient ID
- Examination date range
- Scheduled Station Name (default is "CA-800")*
- Modality (default is "OT")*

* = contact DICOM services administrator for details on these settings

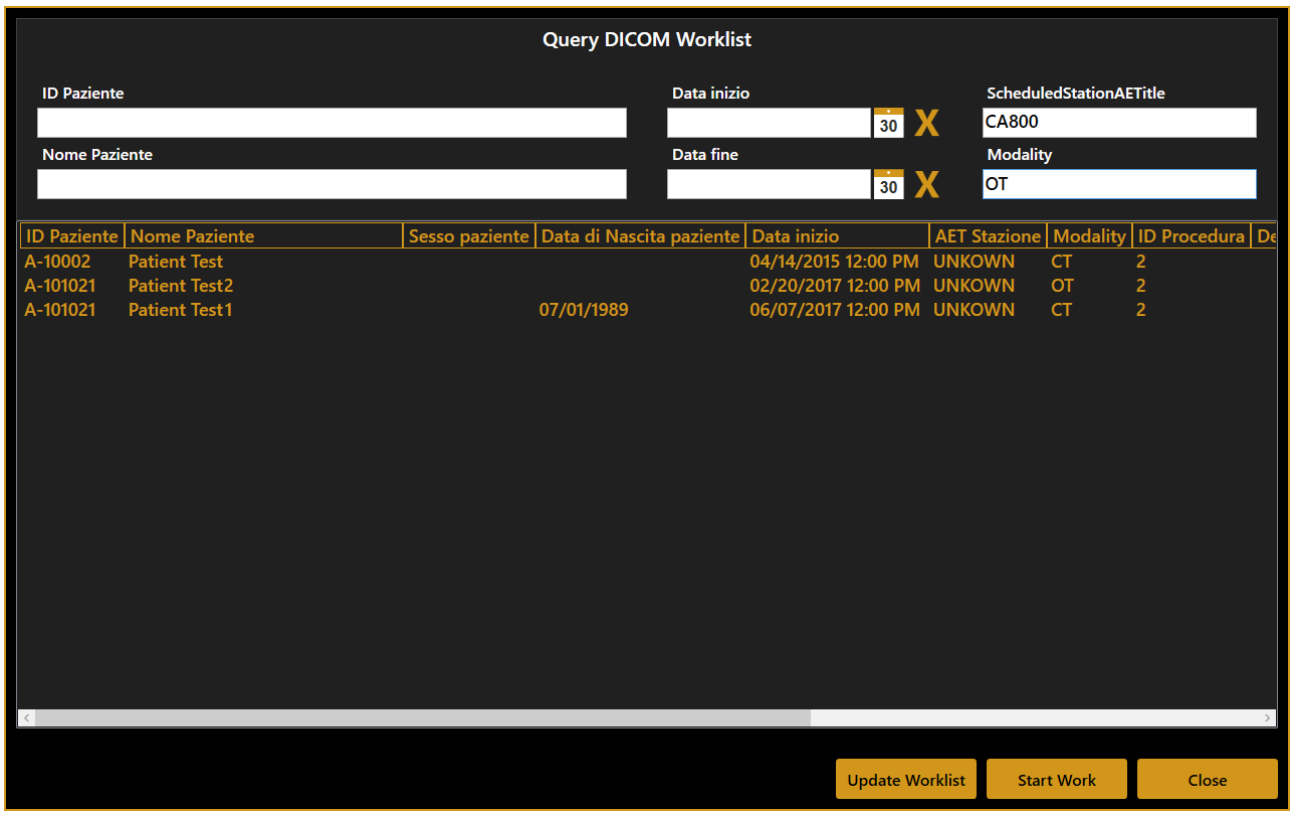


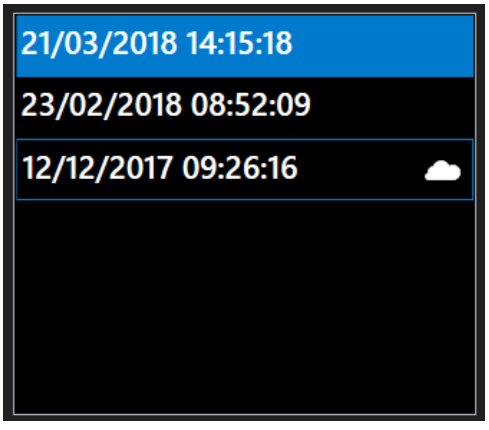
Fig. 25

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

Once the desired work is selected, press "**Start Work**" to start a new exam relative to the selected work.

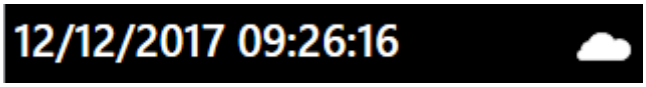
13.4 Local and Remote Exams

For the selected patient, the examinations list can contain local and/or remote exams (if i-MAP network is activated).

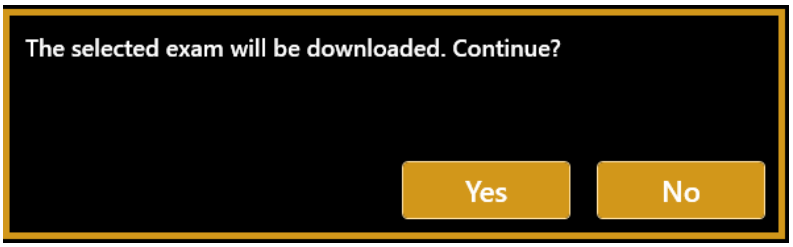


- **Local exams** are present in the local database of the considered CA-800 or i-MAP instance

- **Remote exams** are present in the database of another CA-800 or i-MAP instance and can be downloaded to the local database by pressing "**Open**" button. They are marked with the  **cloud icon**



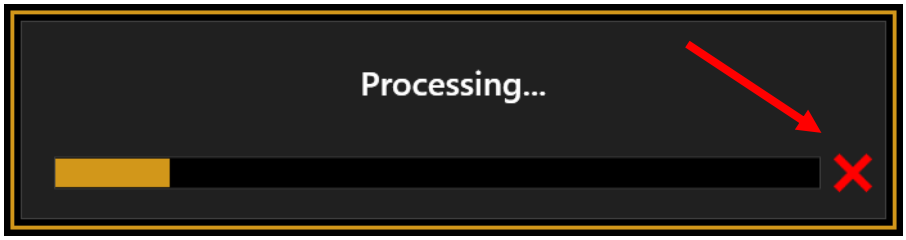
Once the **"Open"** button is pressed for a Remote Exam the following confirmation message is prompted



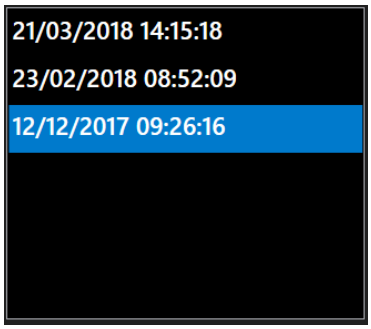
If pressing "**No**" no action is performed.
If pressing "**Yes**" the exam is downloaded to local database and then automatically open.

If you have checked the option **"Download exams without confirmation"** in the i-MAP Settings (see section 17.9.1) no confirmations will be asked, the exam will be downloaded automatically.

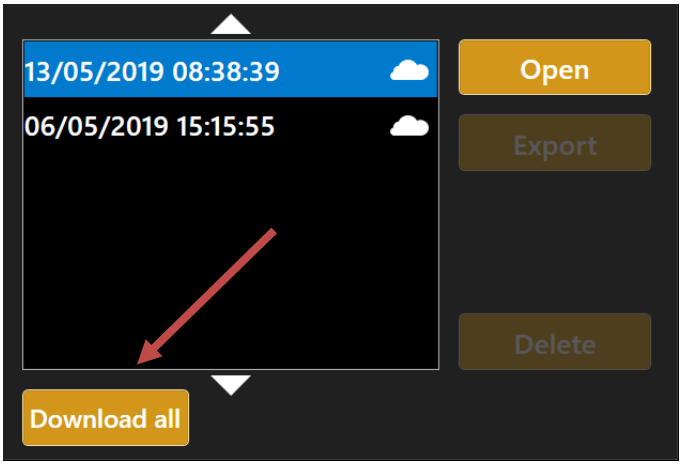
During loading message is possible to abort downloading operation before it's completed by pressing **X** button on the right side of the progress bar.



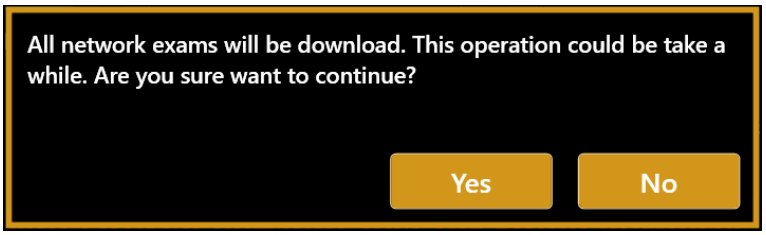
After a Remote Exam is downloaded it becomes a Local Exam and it is visualized accordingly in the exams list.



The button **"Download all"** allow you to download all network exams of selected patient.



The same confirmation message that prompted with **"Open"** button appear and then you can confirm and waiting the downloading process completed.



13.5 Acquisition environment: general instructions[3]

13.5.1 Positioning the patient

To obtain correct measurements it is necessary an adequate positioning of the patient relative to the device. A steady head position and the correct device-to-patient distance are obtained by resting the patient's head well against the chin rest and forehead band (see Fig. 28). The patient must look steadily at the fixation point in the center of the Placido disk.

A correct alignment with the patient's pupils can be visually checked by the operator referring to the two lines on the forehead supports (see the red arrows in Fig. 26).

Fig. 26

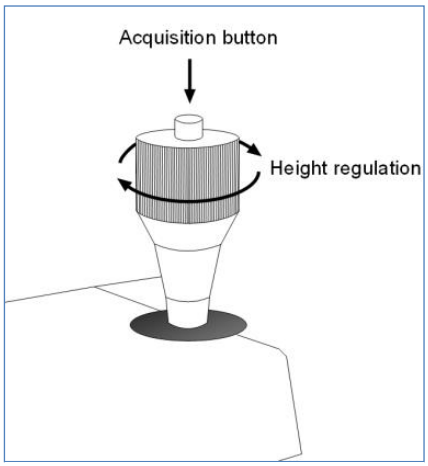


Fig. 27

The joystick illustrated in Fig. 27 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.

[3] This section applies to CA-800 only.

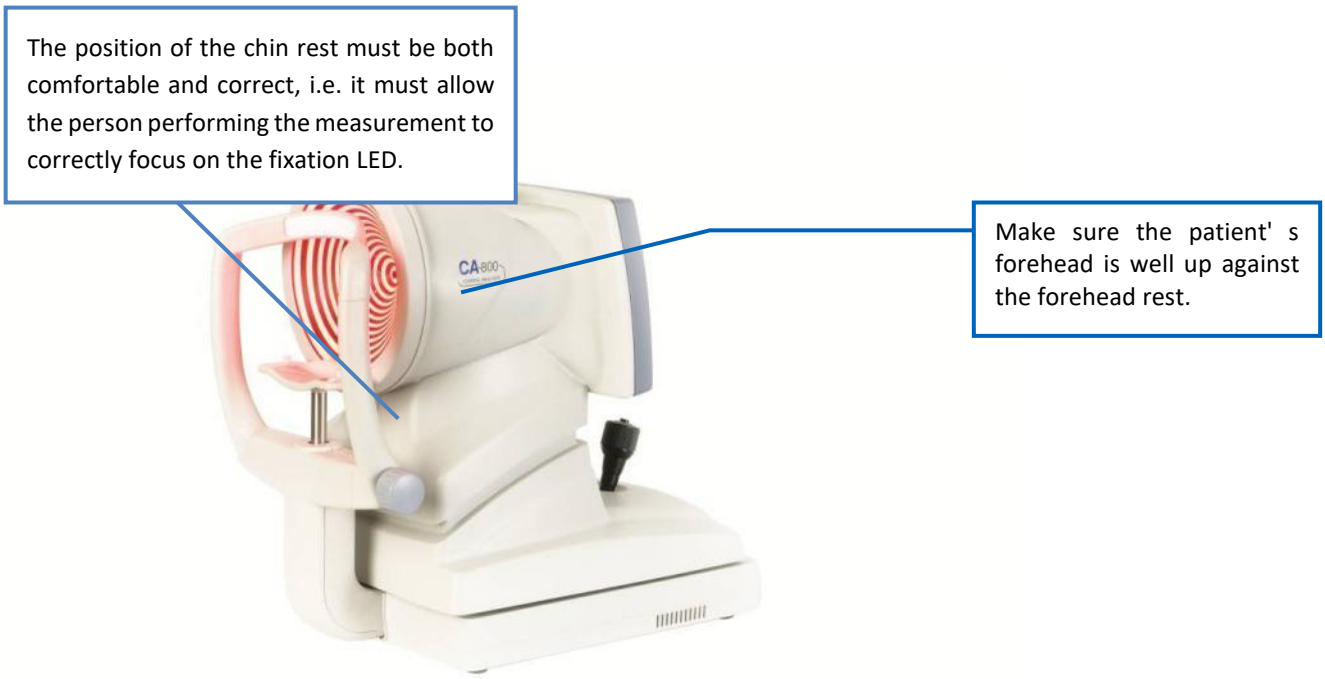


Fig. 28

13.5.2 Description of the acquisition screen

Fig. 29 shows the acquisition screen.

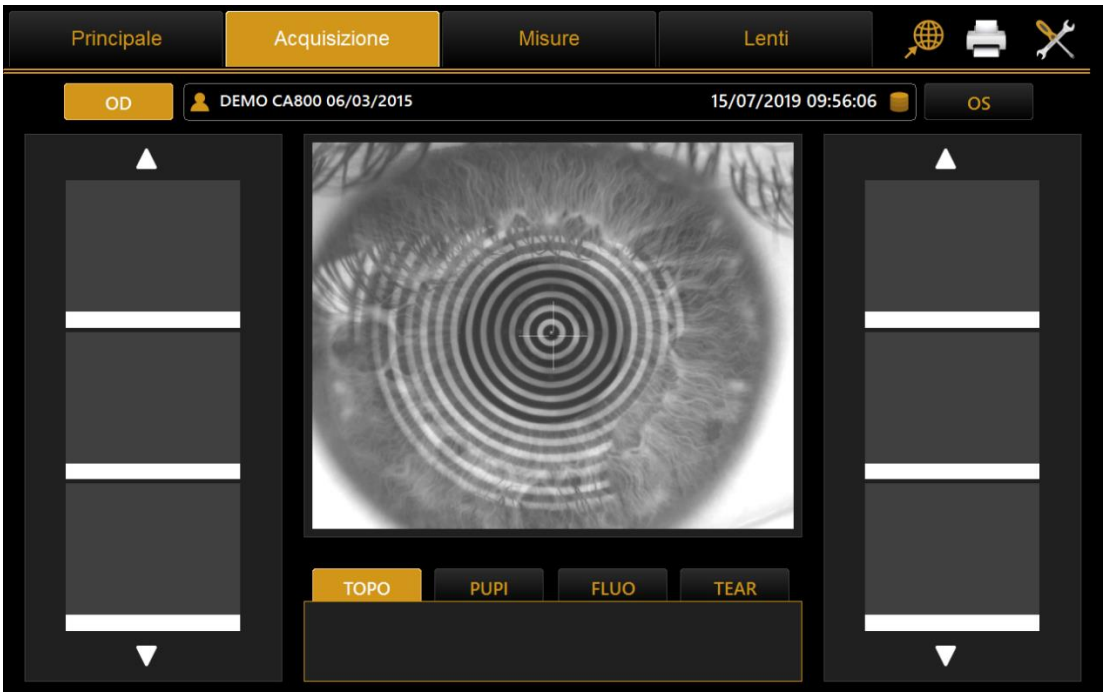


Fig. 29

The acquisition window (Fig. 29) 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.
- ***FLUO:*** gives access to the fluorescein section.
- ***TEAR:*** gives access to the Meibomian glands photography, Blink analysis, Tear break-up time analysis section.

13.5.3 Acquisition gallery

A preview of the acquired image is shown in the acquisition gallery (Fig. 30 for topography, pupillometry, Meibomian, TBT, fluorescein).

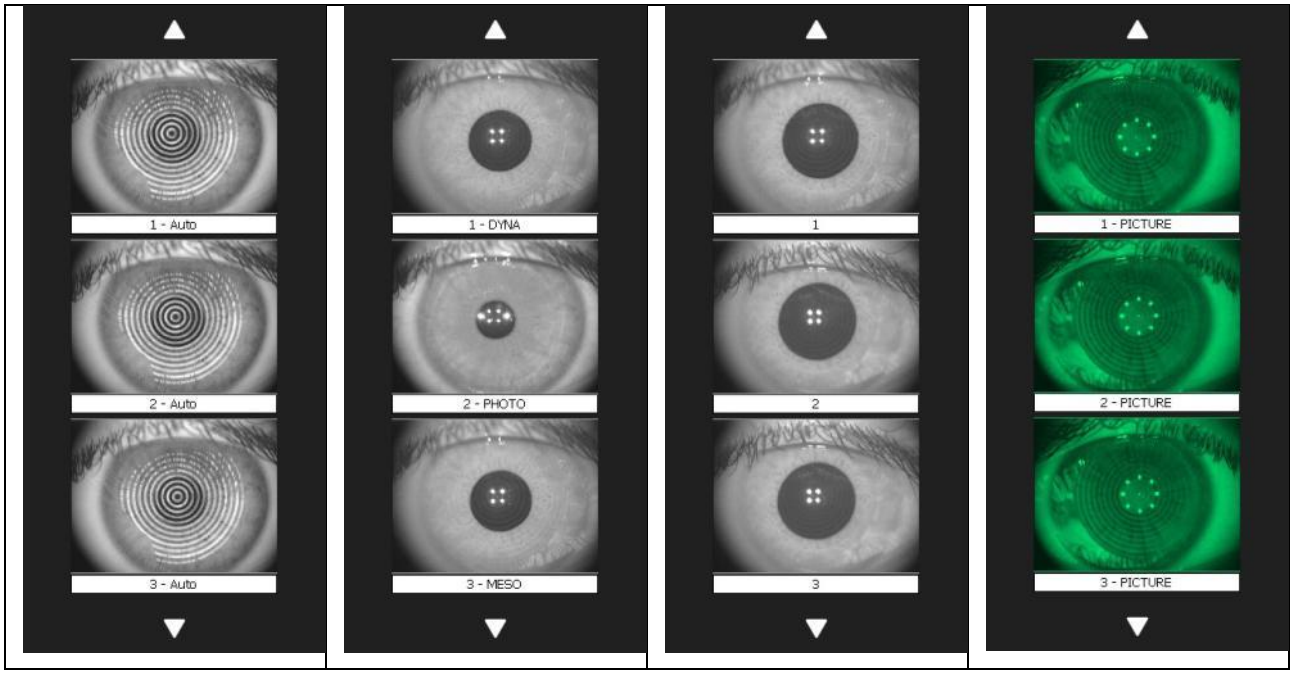


Fig. 30

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. 31).

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.

13.5.4 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.
	The centering condition is displayed in green color, press the joystick button to start acquisition

13.6 Topography[4]

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. 31 appears.

Fig. 31

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-meridians.

[4] This sections applies to CA-800 only.

13.7 Pupillometry[5]

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

By selecting this mode, the acquisition environment shown in Fig. 32 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. 32

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.

[5] This sections applies to CA-800 only.

13.8 Fluorescein[6]

Press the ***"FLUO"*** button to access the fluorescein analysis acquisition environment (Fig. 33).

You can select between picture and movie acquisition.

Fig. 33

[6] This section applies to CA-800 only.

13.9 TEAR[7]

Press the **TEAR** button to enter acquisition modalities for:

- Meibomian glands photography
- Tear Meniscus Height photography
- Blink analysis
- Tear break-up time analysis

13.9.1 Meibomian (MEIB)

By pressing MEIB button, the acquisition environment shown in Fig. 34 appears on the screen.

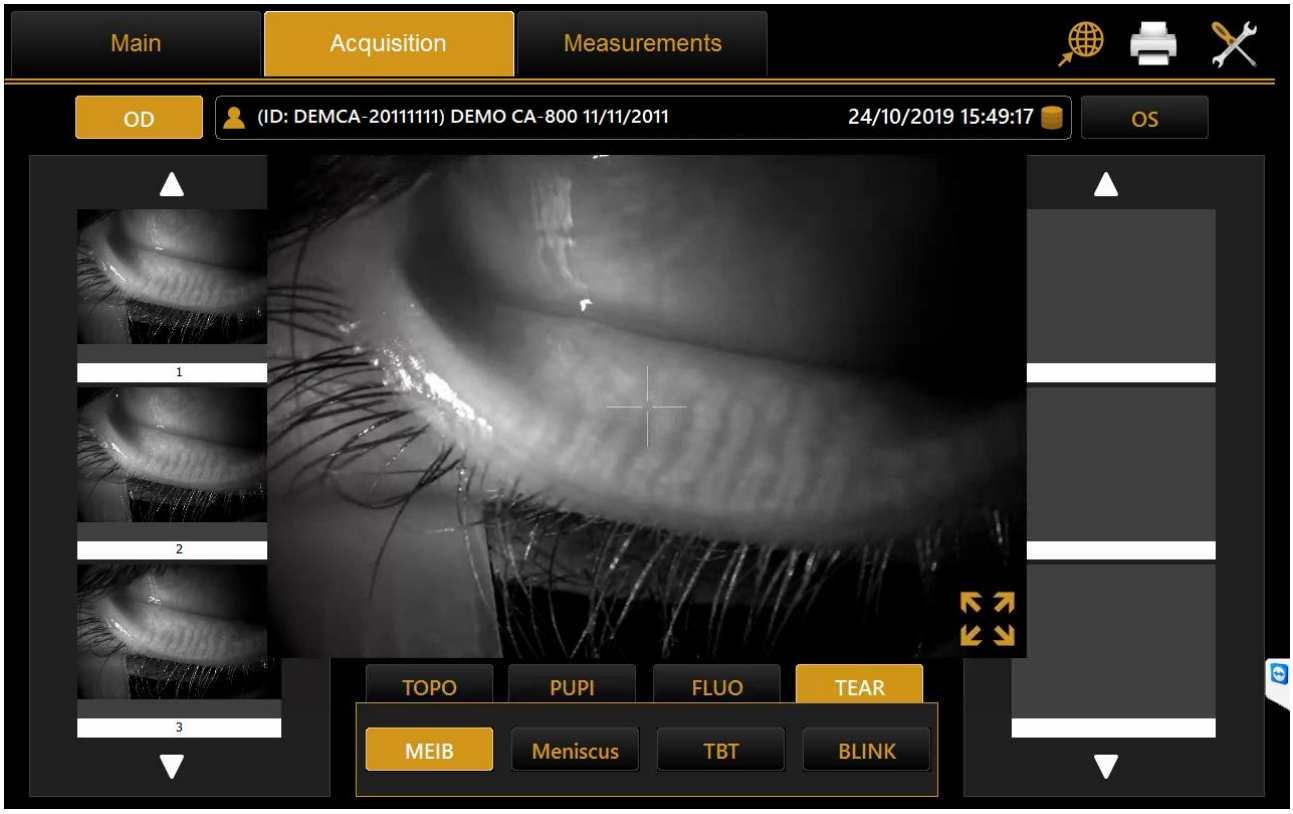


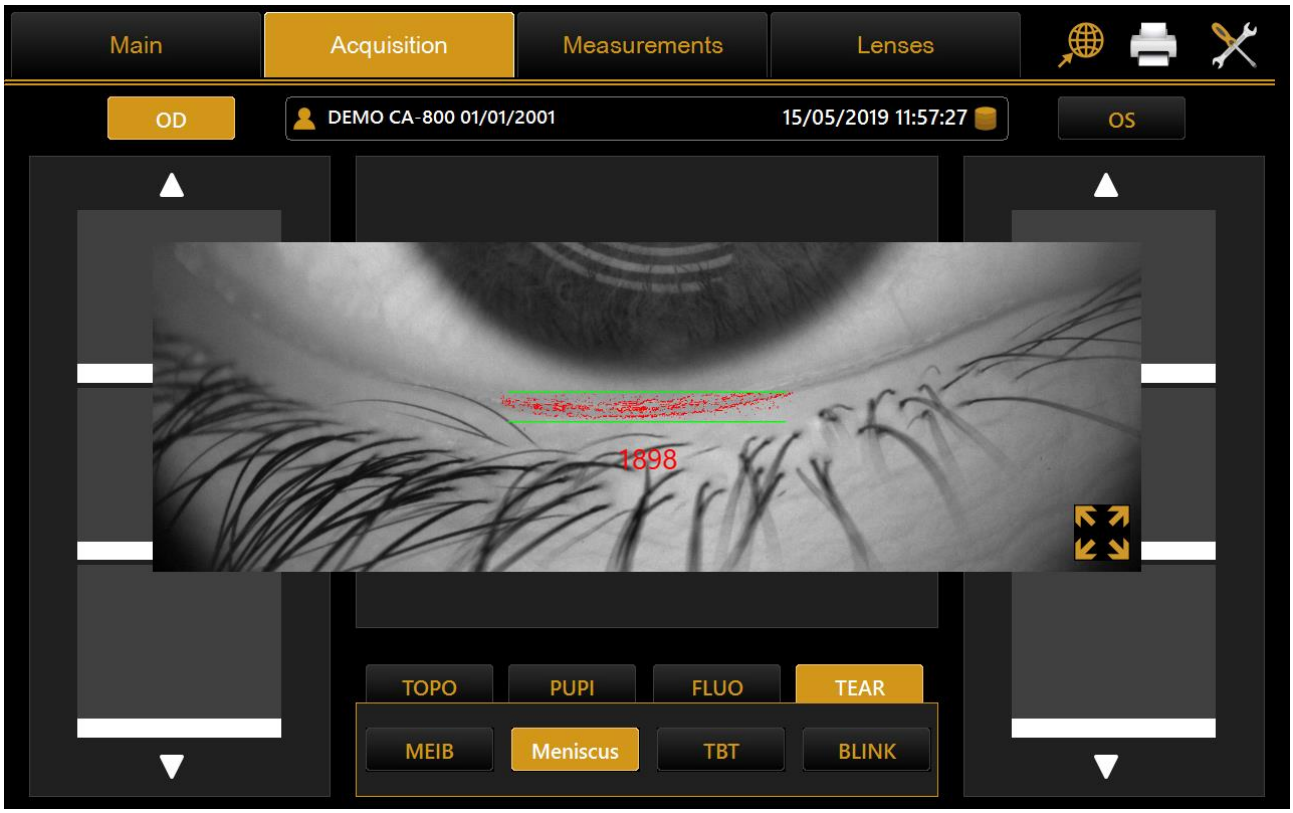
Fig. 34

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.

[7] This sections applies to CA-800 only.

13.9.2 Tear Meniscus Height (TMH)

This acquisition allows to get a picture of the tear meniscus height.



The application analyzes the center of the image and calculates the overlay number that is an indication of the focus. Bigger is the number and better is the focus. To take an acquisition just click the joystick button.

Attention: this feature is available only from CA-800 HW2.

13.9.3 Blink Analysis

By pressing “BLINK” button the acquisition environment switches to Blink Analysis mode. This acquisition allows to measure automatically the average IBI index (Inter-Blink Interval). To perform the blink analysis acquisition focus on the center of the four IR LEDs reflection barycenter (Fig. 35).

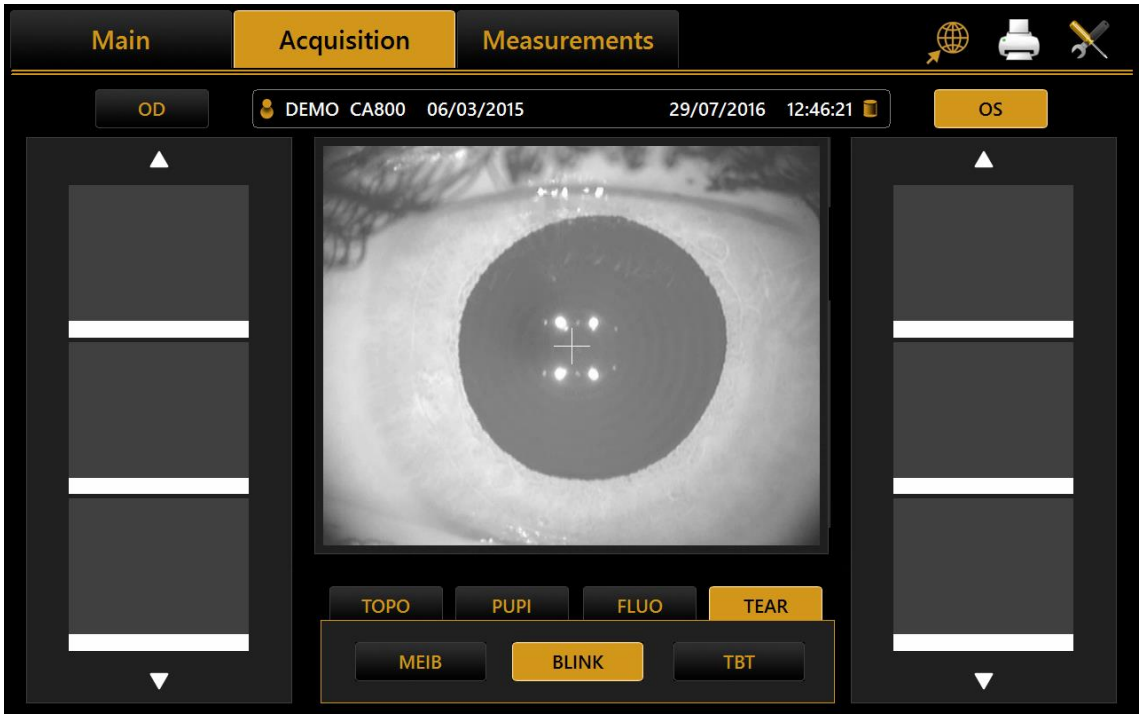


Fig. 35

Click in the joystick and leave the patient to his natural blinking behaviour. Assure the patient doesn’t move out of focus. When the patient will blink the device automatically recognizes the blink. (Fig. 36)

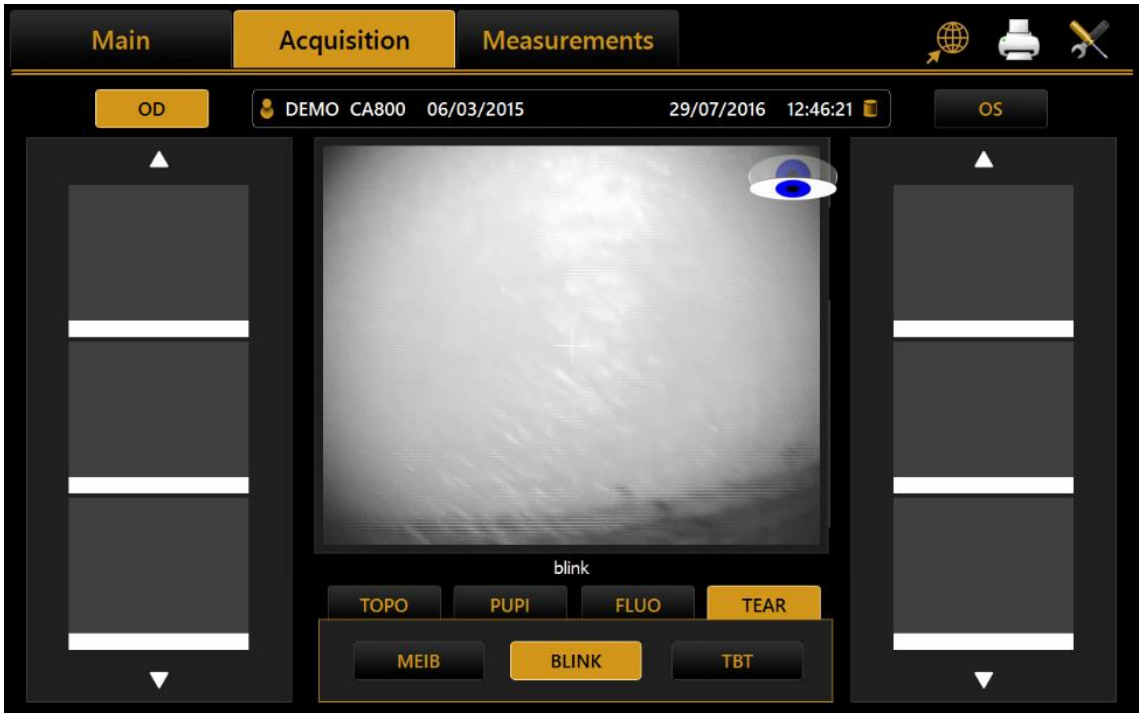


Fig. 36

During the acquisition, below the live image, are updated in real time (Fig. 37):

- **Time (s):** time passed since the begin of the acquisition (Max. duration of acquisition is 5 minutes).
- **#blink:** number of detected blinks since the begin of the acquisition
- **#blink/min:** average number of blinks per minute
- **Avg. IBI(s):** average Inter-Blink Interval, average time between consecutive blinks.

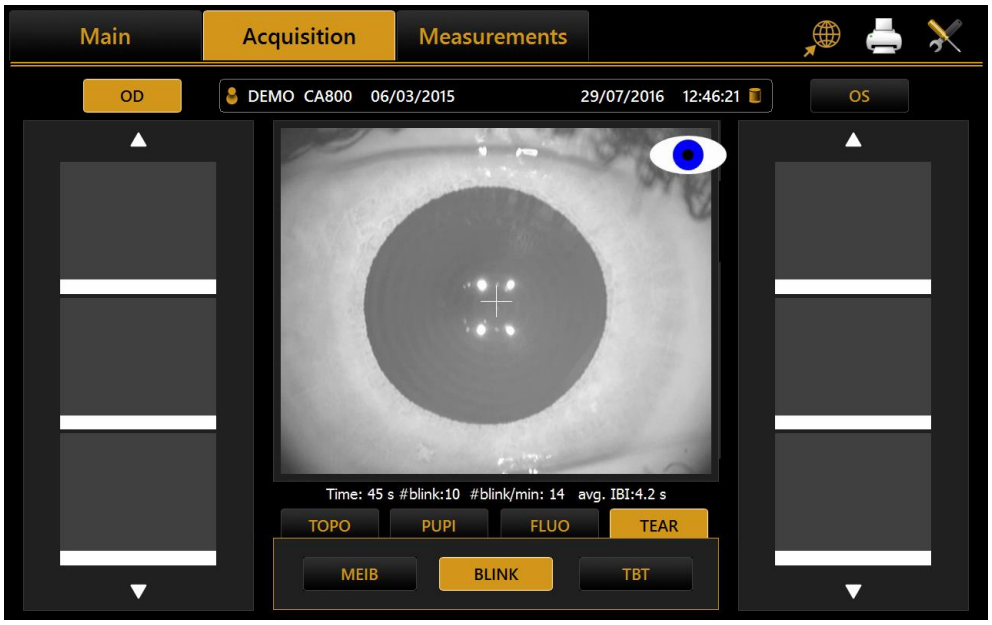


Fig. 37

Click on the joystick to stop the acquisition. The summary of analysis is reported in the message. (Fig. 38)

Fig. 38

Only one acquisition is maintained, which is valid for both eyes, so the last acquisition performed overwrites the previous one. No image is shown in the side galleries.

13.9.4 Break-Up Time (TBT)

By pressing the **"TBT"** button the acquisition environment switches as shown in Fig. 39, to TBT acquisition mode.

This acquisition allows to analyze the tear Break-Up Time (TBT) and to detect and localize the broken sectors of the corneal surface.

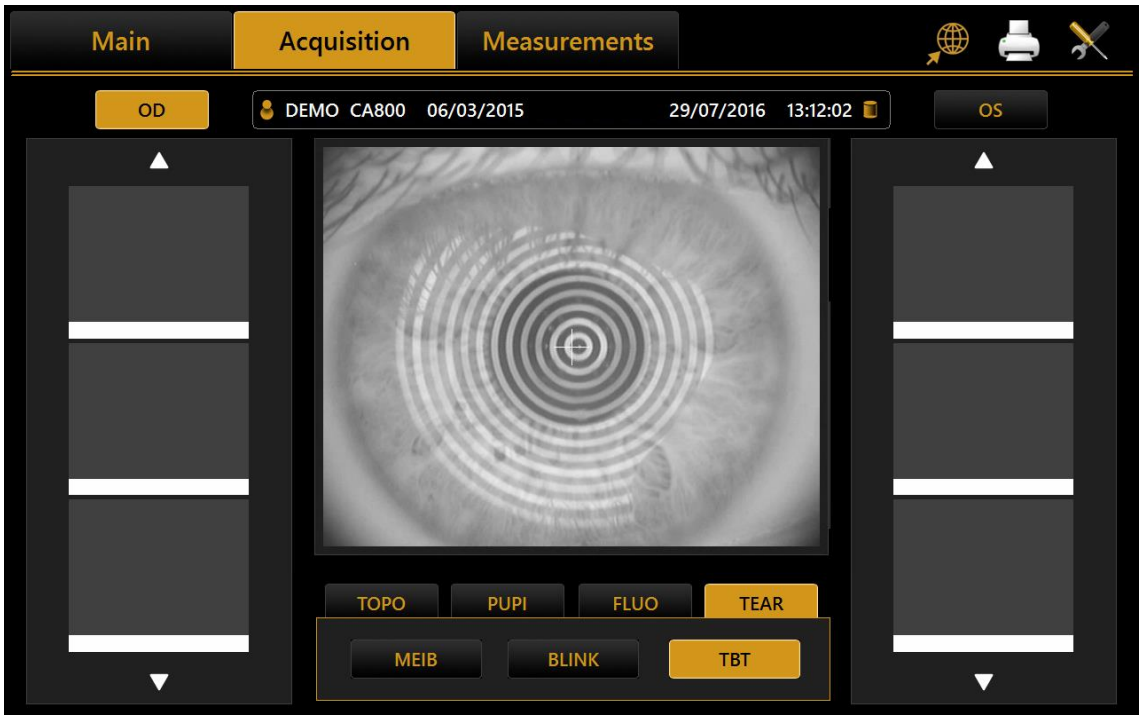
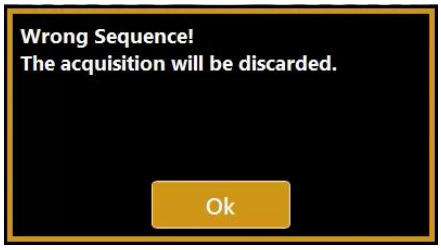


Fig. 39

The acquisition is performed by the following sequence:

1. Align to center of the rings
2. Click the joystick to activate the focusing guide, follow the focusing arrows until the green marks are shown and the message "FOCUS IS OK: ASK PATIENT TO BLINK" (Fig. 40)
3. Ask the patient to blink in order to "reset" the tear film conditions
4. The blink is automatically detected by the device and the analysis of the Tear Film behavior starts. During the Tear Film analysis the area of Placido rings is divided in polar sectors and analyzed. The sectors where significant variations are detected are colored with a green/yellow/red scale depending on the amount of variation (Fig. 41).
5. The acquisition is stopped if another blink occurs or if the joystick is pressed again
6. If a second blink occurs within 5 seconds since the previous blink the TBT analysis is restarted
7. Maximum duration of the acquisition is 30 seconds
8. When the acquisition stops the popup message "Wrong Acquisition Sequence! The acquisition will be discarded." is shown if the acquisition sequence hasn't been performed correctly
9. The summary map (time-wise coloring) of the broken sector is overlaid for 2 seconds to the live image (Fig. 42)



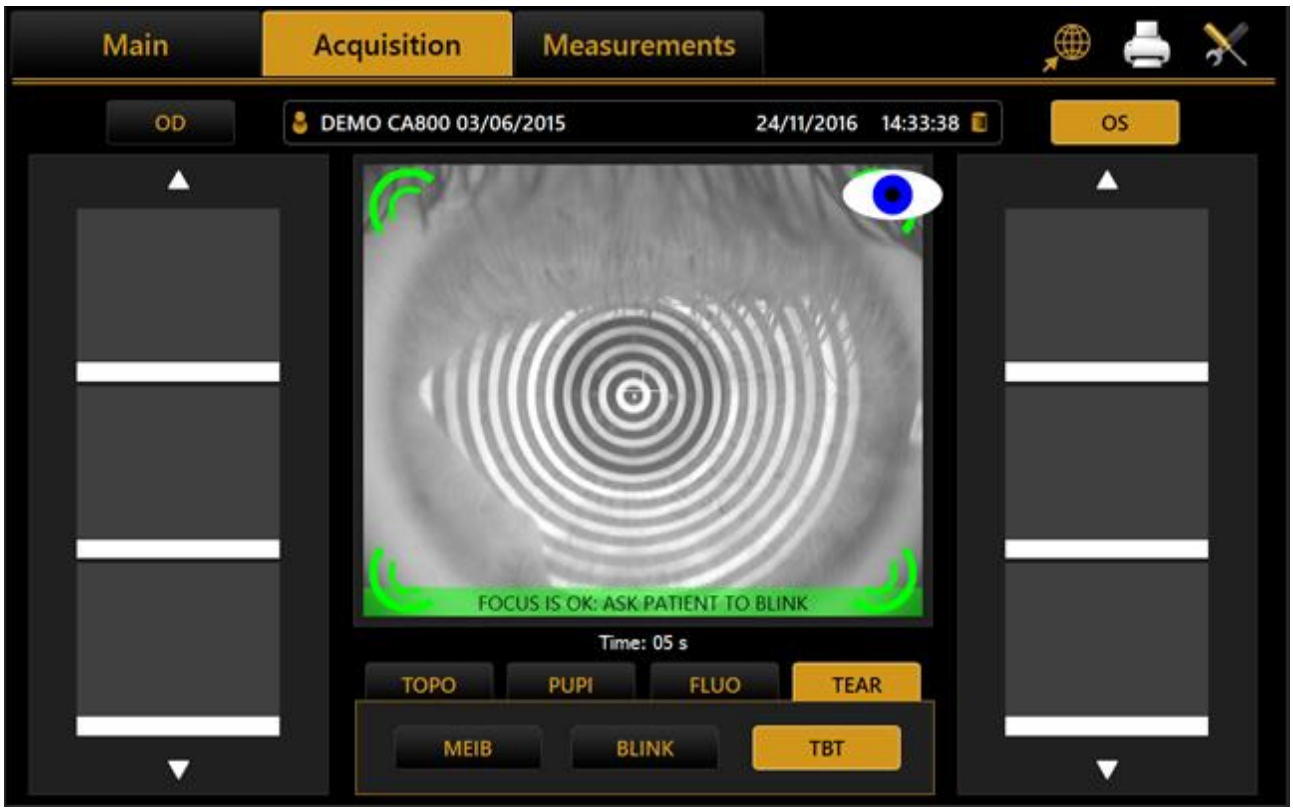

Main
Acquisition
Measurements
OD
DEMO CA800 03/06/2015
24/11/2016 14:33:38
OS
FOCUS IS OK: ASK PATIENT TO BLINK
Time: 05 s
TOPO
PUPI
FLUO
TEAR
MEIB
BLINK
TBT

Fig. 40

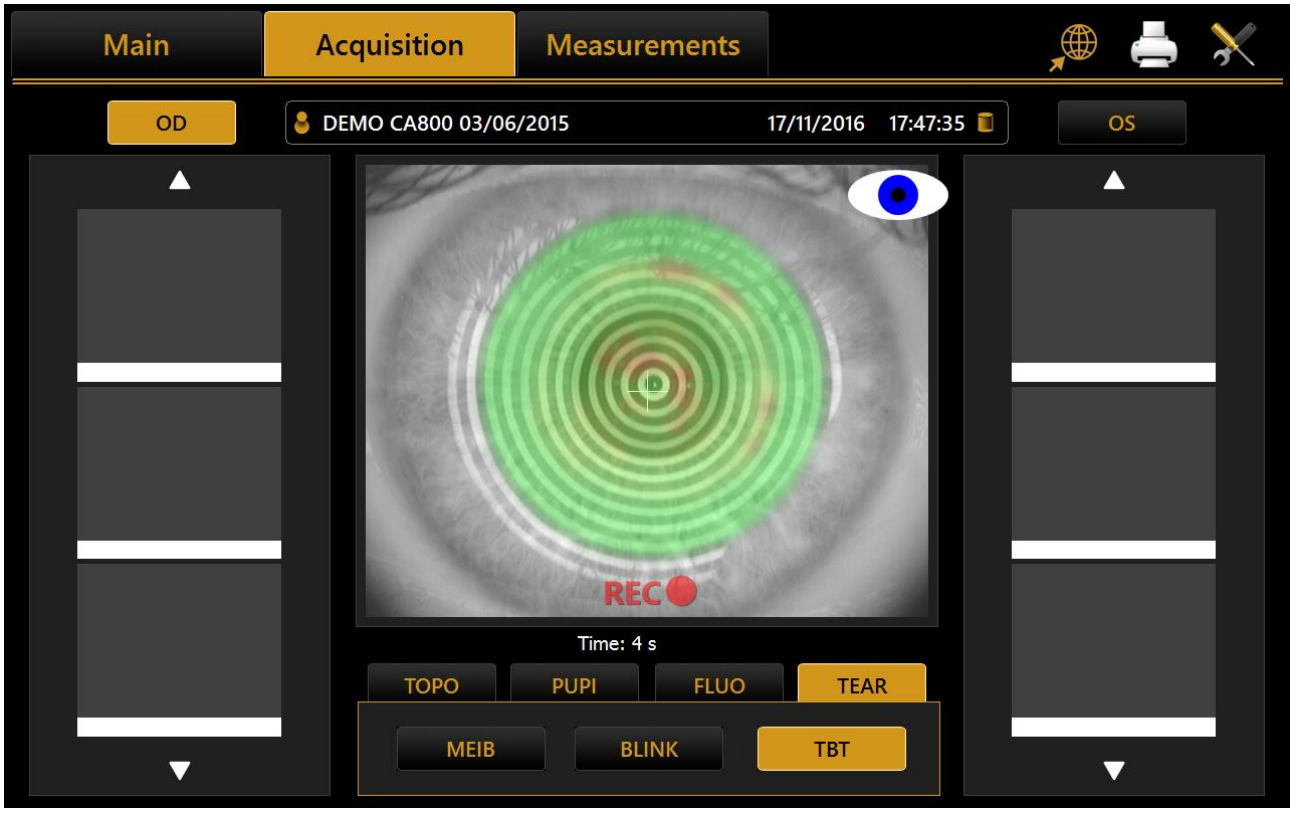

Main
Acquisition
Measurements
OD
DEMO CA800 03/06/2015
17/11/2016 17:47:35
OS
REC
Time: 4 s
TOPO
PUPI
FLUO
TEAR
MEIB
BLINK
TBT

Fig. 41

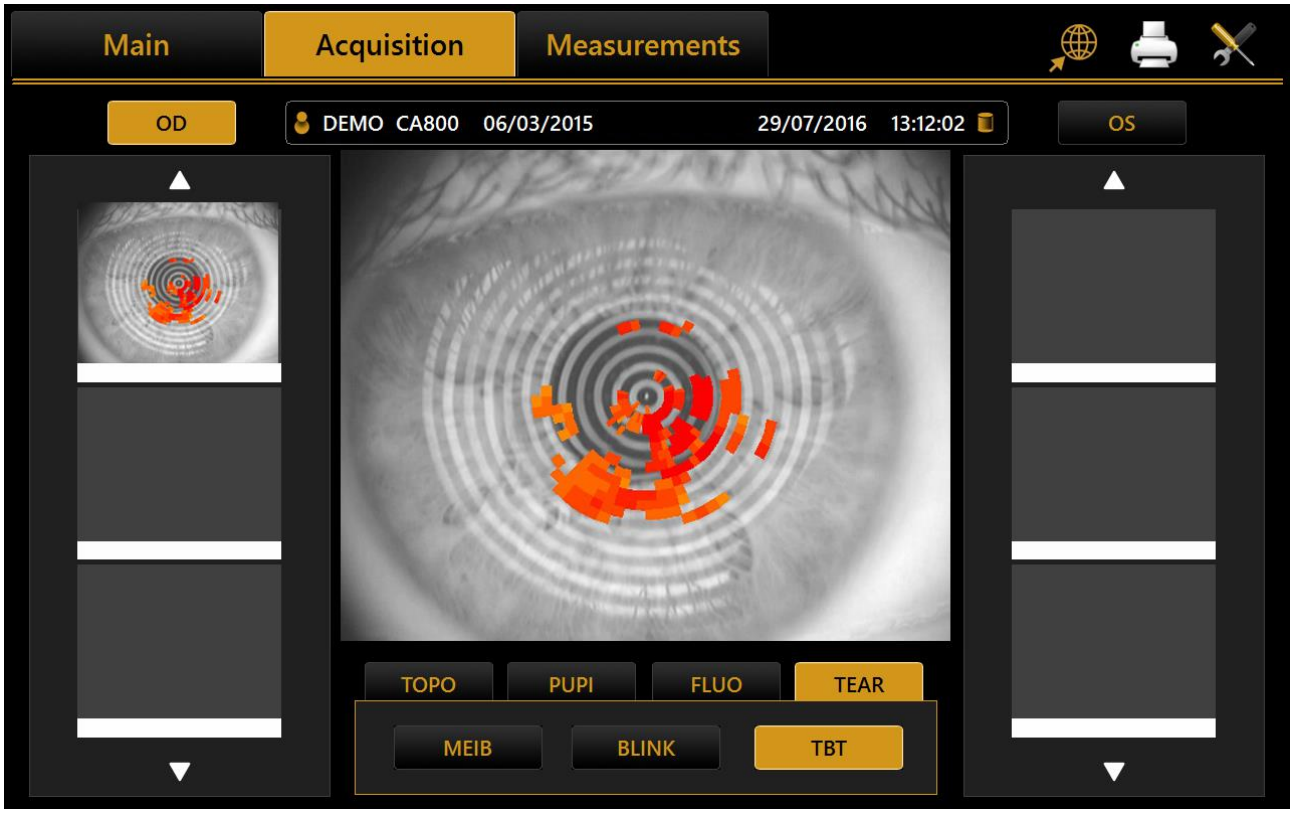


Fig. 42

If necessary, starting from SW V.1.6.8, it is possible to disable the live-view detection (i.e. overlapping green/yellow/red colored scale layout) during the TBT acquisition.

To do this, access the Measurements settings and disable the "Live-view TBT" tab inside the “MAP OPTION” window (see Paragraph 17.2).

14 MEASUREMENTS

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

There are 11 types of measurement sections:

- **MAP**: Topography Map
- **OD/OS**: (or R/L) Right to Left side by side Topography Map review
- **ZER:** Zernike Analysis
- **HEIGHT:** Altimetric Map
- **COMP:** Topography Map comparison of two different exams of the same patient
- **PUP:** Pupillometry
- **FLUO:** Flourescein acquisitions review
- **WTW:** White to White review
- **MEIB:** Meibomian glands acquisitions review
- **TMH:** Tear Meniscus Heights analysis
- **TBT:** Tear Breakup Time and Blink acquisitions review

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

14.1 MAP – Topography Map

The environment displayed is shown in Fig. 43.

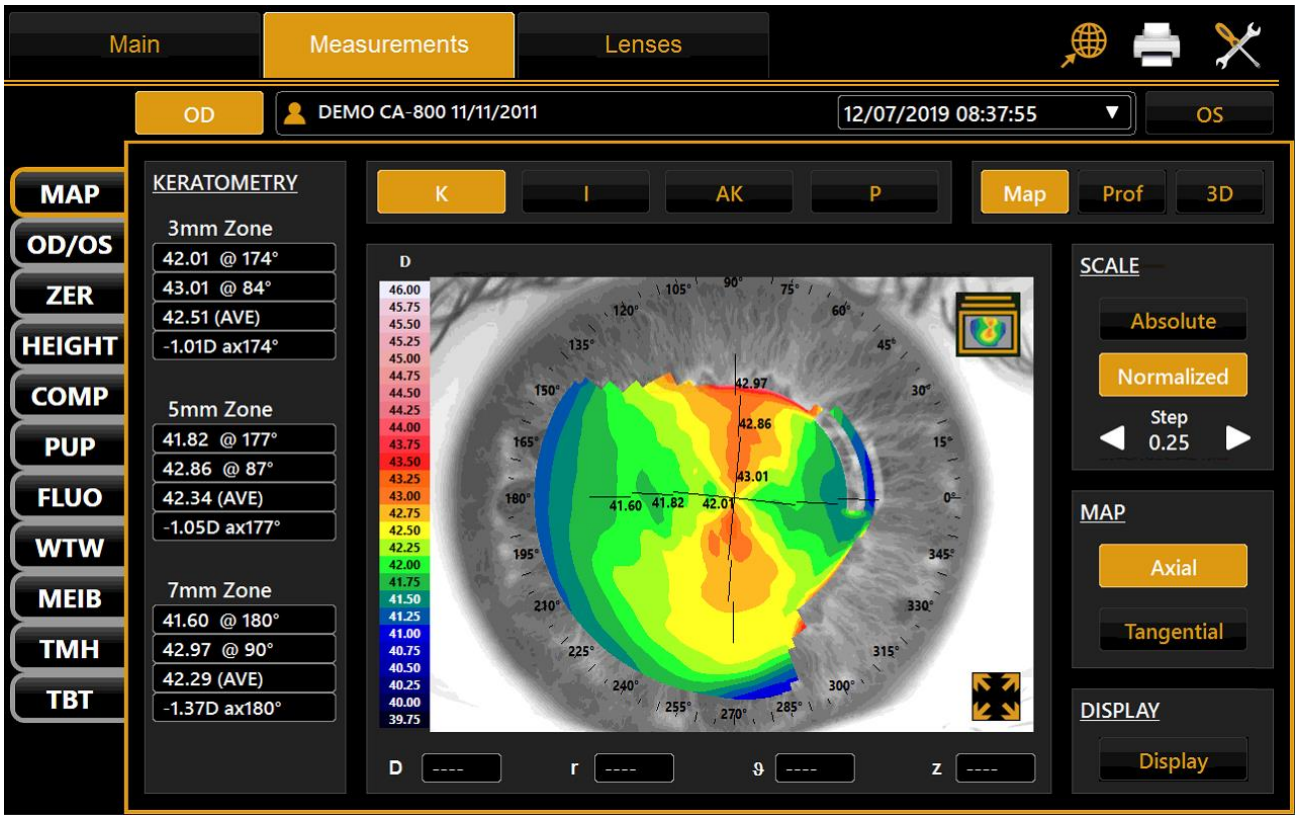


Fig. 43

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

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

- ***Absolute*** or ***Normalized***: absolute scale or standardized scale with related step.
- ***Axial*** or ***Tangential***: axial map or tangential map.

- ***Display***: allows you to choose whether to display or not the image of the eye, the map, the rings, the numeric values and transparency.

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

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

14.1.1 Topographic map indexes

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

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

14.1.2 Keratometry

Press the ***"K"*** button to display the keratometric data on the 3 mm, 5 mm and 7 mm zones, as shown in Fig. 43.

14.1.3 Keratorefractive indexes

Press ***"I"*** button to view the keratorefractive indexes (Fig. 44):

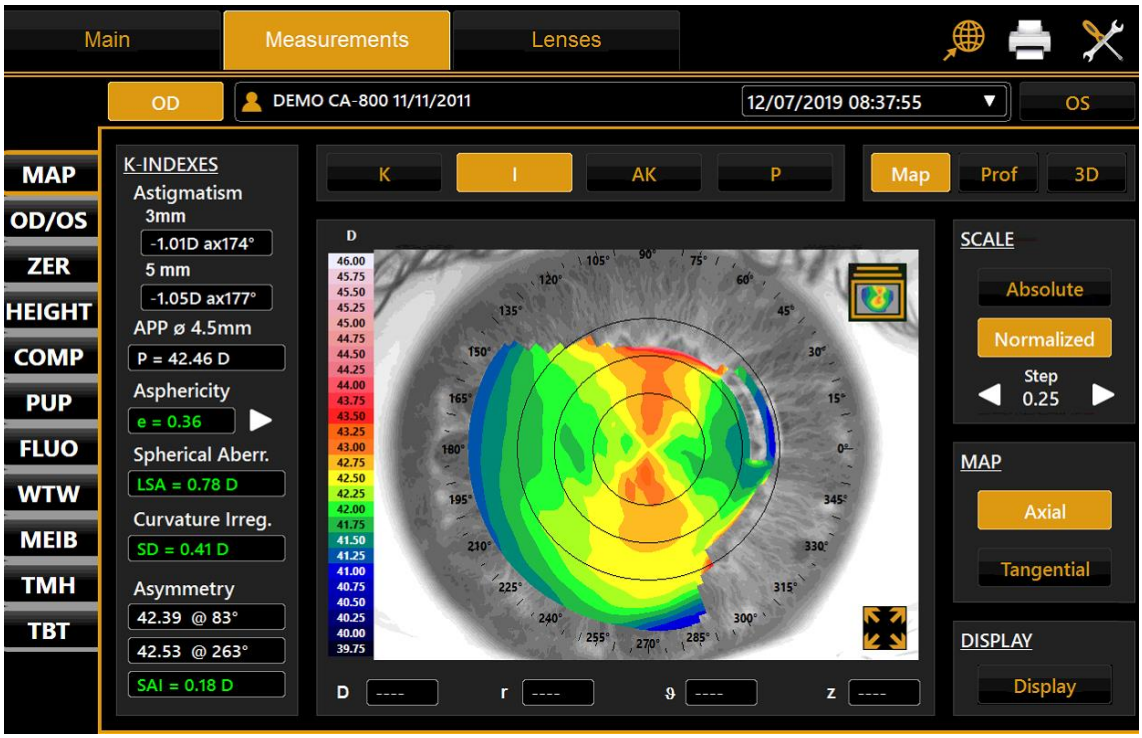


Fig. 44

- **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

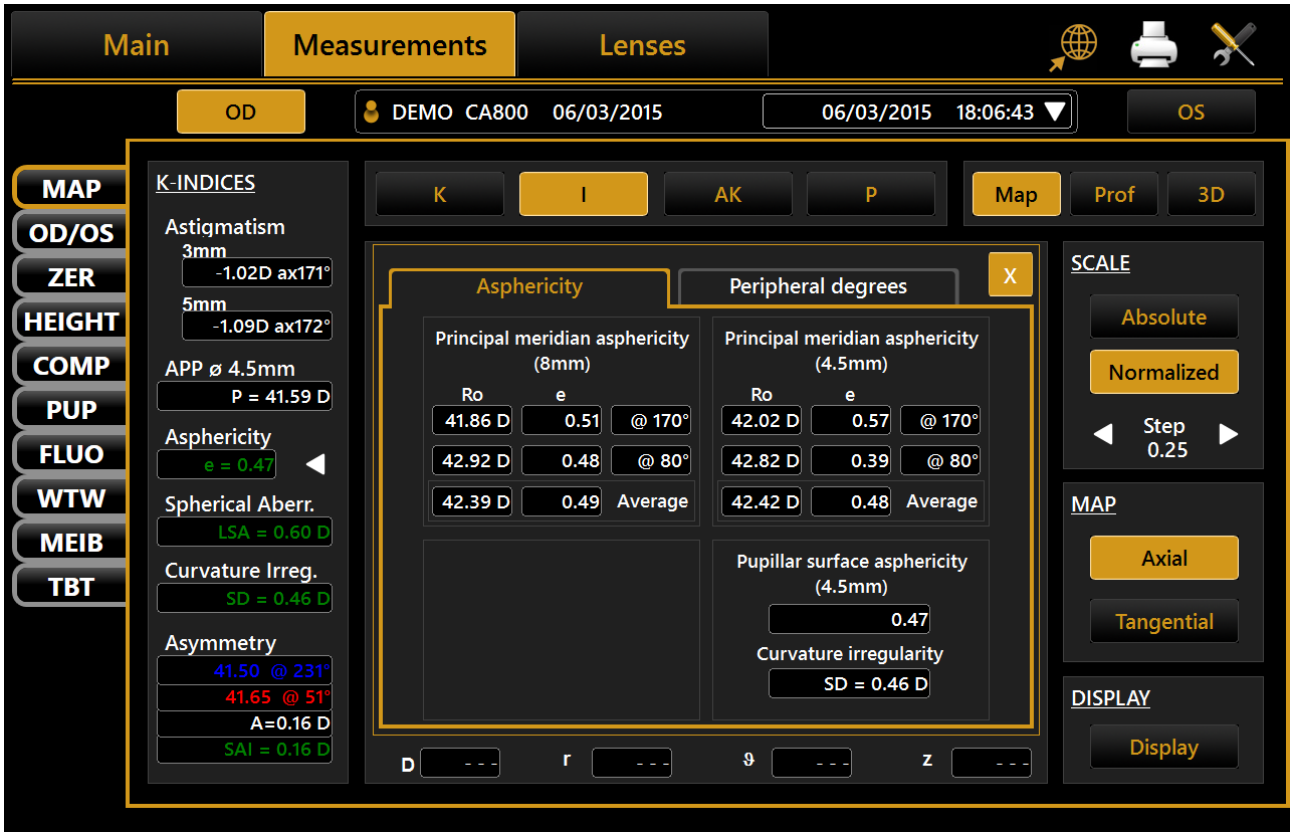


Fig. 45

As you can see from (Fig. 45) 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 Fig. 46).

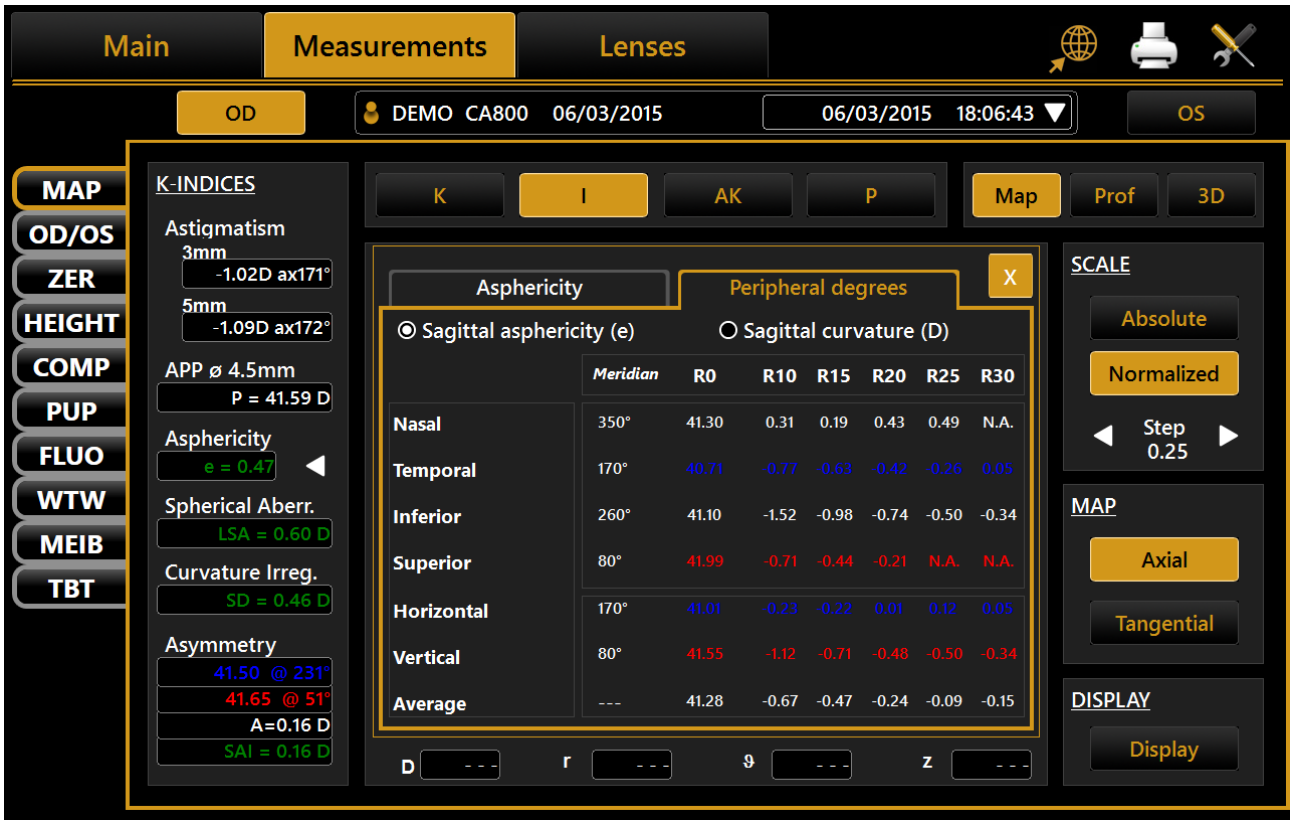


Fig. 46

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.

14.1.4 Keratoconus

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

The KC shows the following informations (Fig. 47):

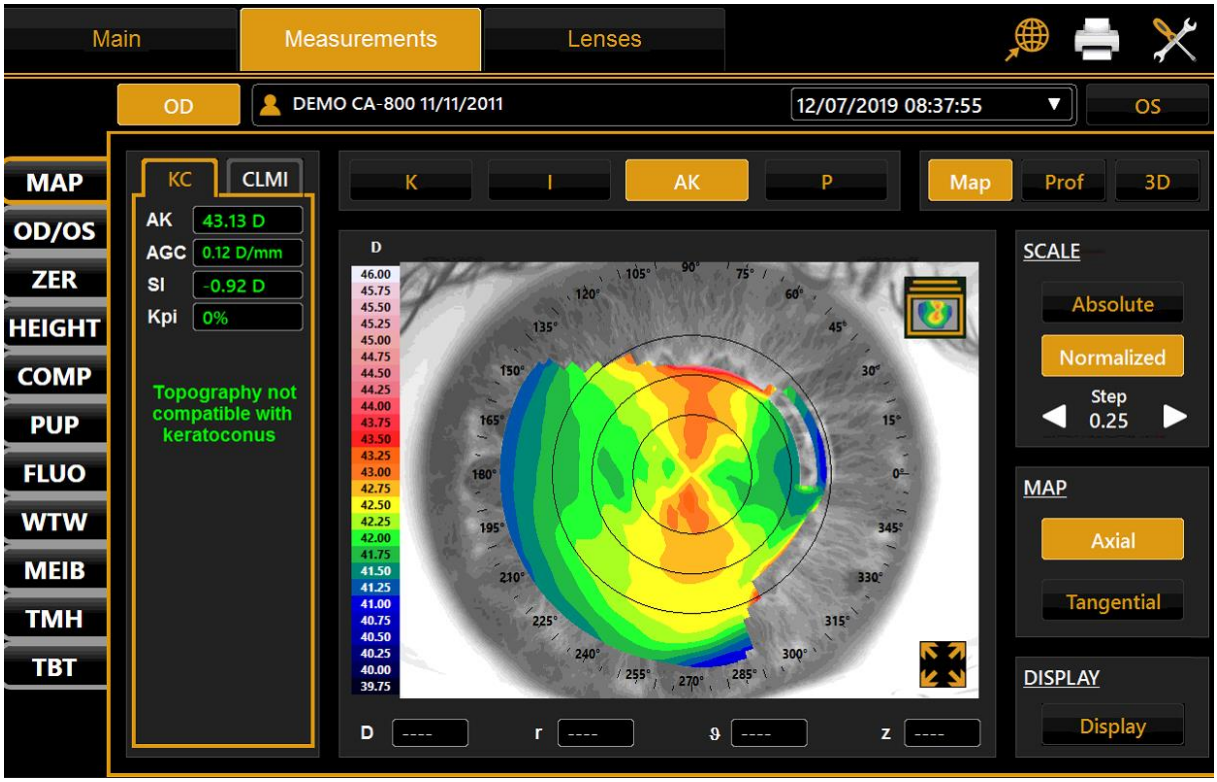


Fig. 47

- ***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 centred 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 barycentre of the keratoconus in relation to the centre of the map

- ***RND***: circularity factor of the keratoconus

The CLMI shows the following informations (Fig. 48):

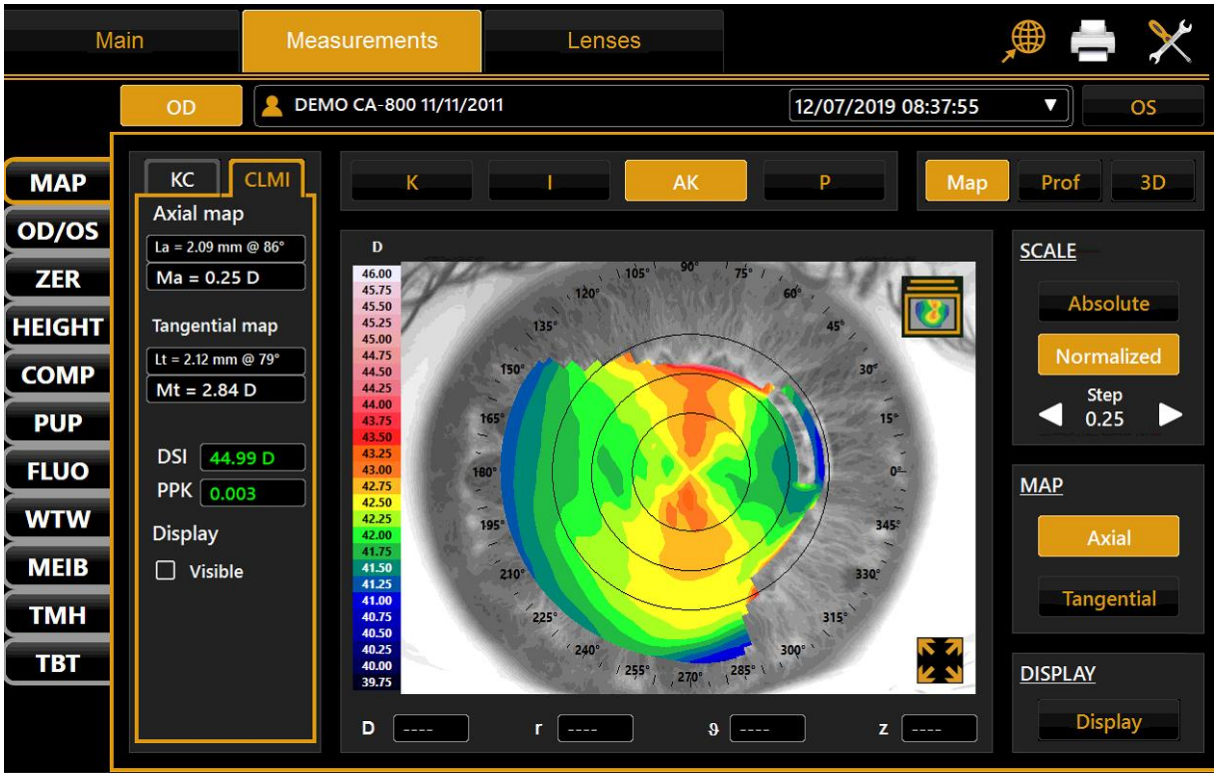


Fig. 48

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

14.1.5 Pupil

Press the ***"P"*** button to open the pupil indexes (Fig. 49):

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

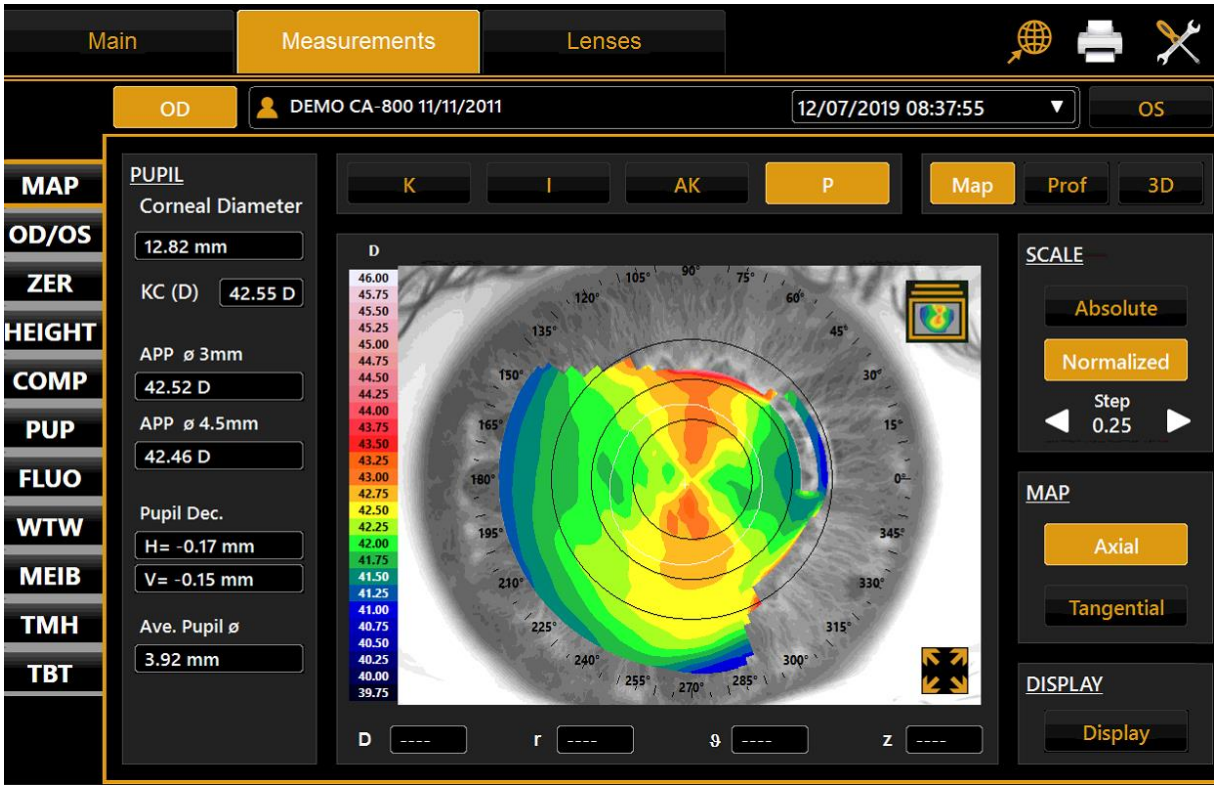


Fig. 49

14.1.6 Gallery

Press the icon at the top right of the map to enter the gallery (Fig. 50).

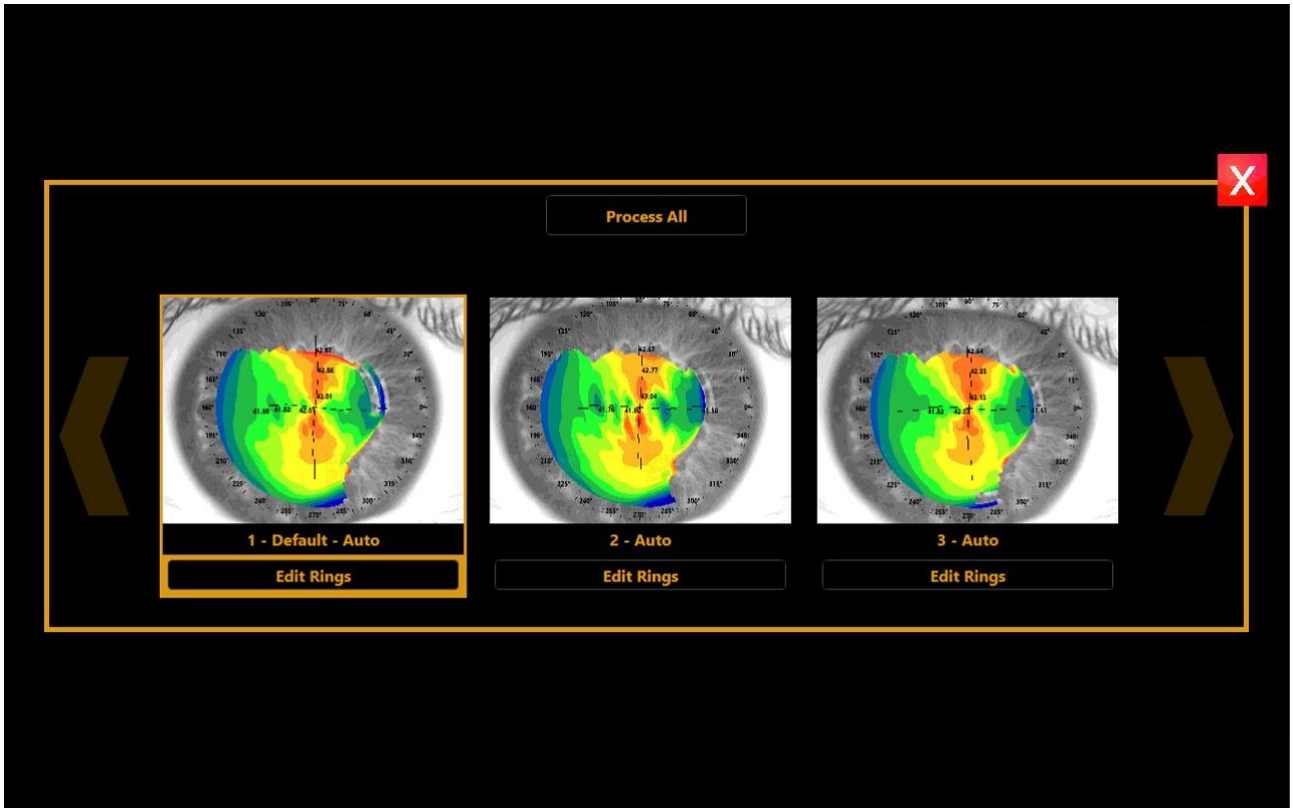


Fig. 50

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

14.1.7 Full screen mode

From the map environment (Fig. 43), you can access full screen mode (Fig. 51) 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.

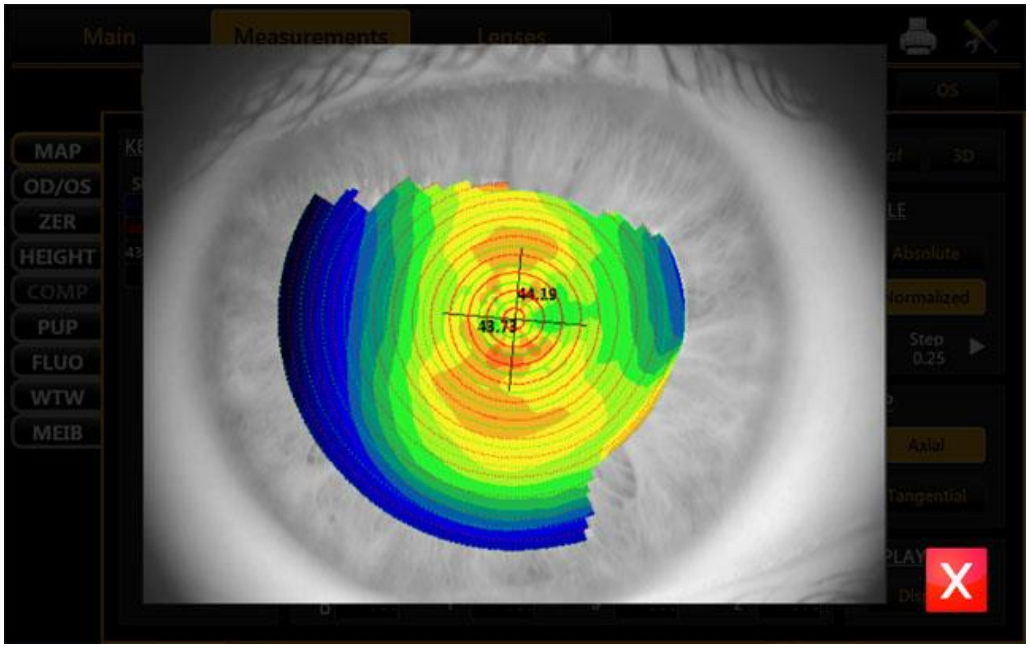


Fig. 51

14.1.8 Profile

Press the ***"Profile"*** button to view the curvature profile along the most curved meridian and the flattest meridian (red and blue). The difference is displayed in green (Fig. 52).

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.

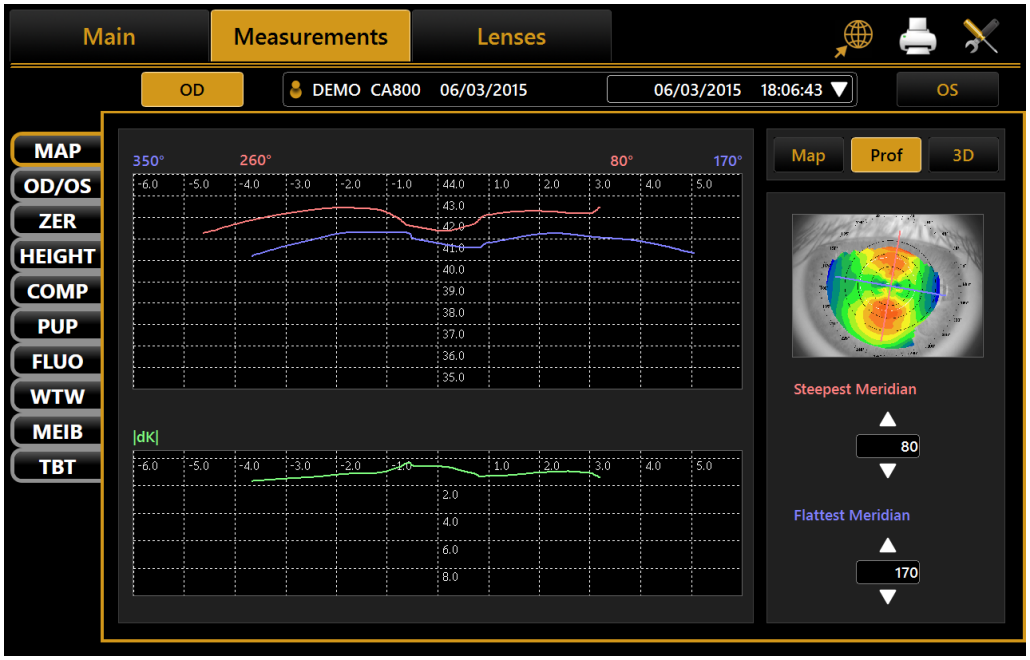


Fig. 52

14.1.9 3D

Press the ***"3D"*** button to view the 3D map of the keratometric data (Fig. 53):

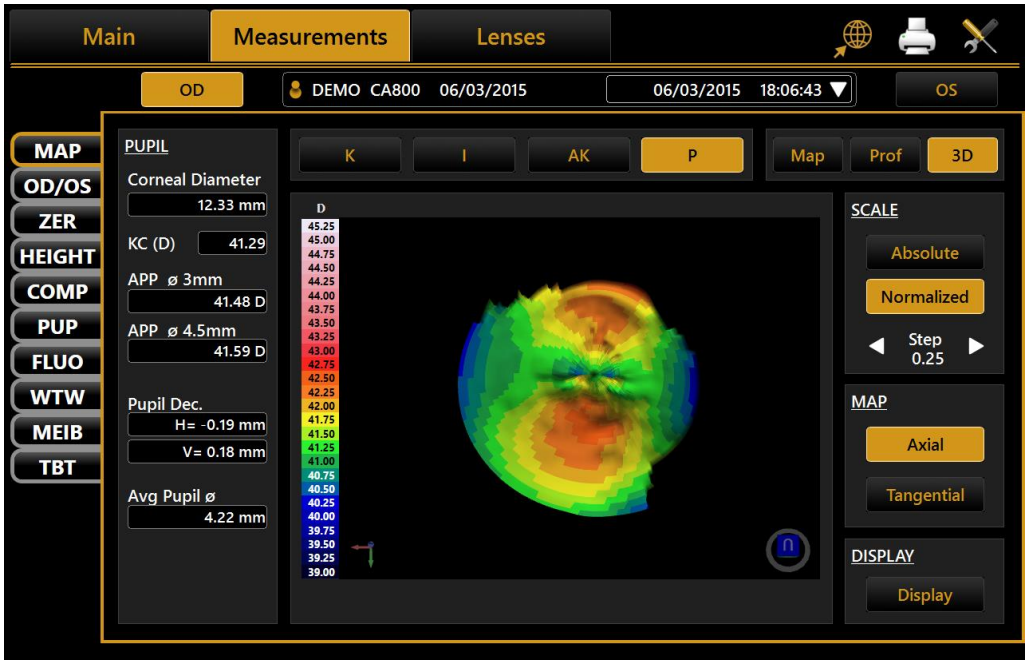


Fig. 53

14.1.10 Edit Rings

In this section the user can edit the 24 rings in order to improve the topographic map (Fig. 54).

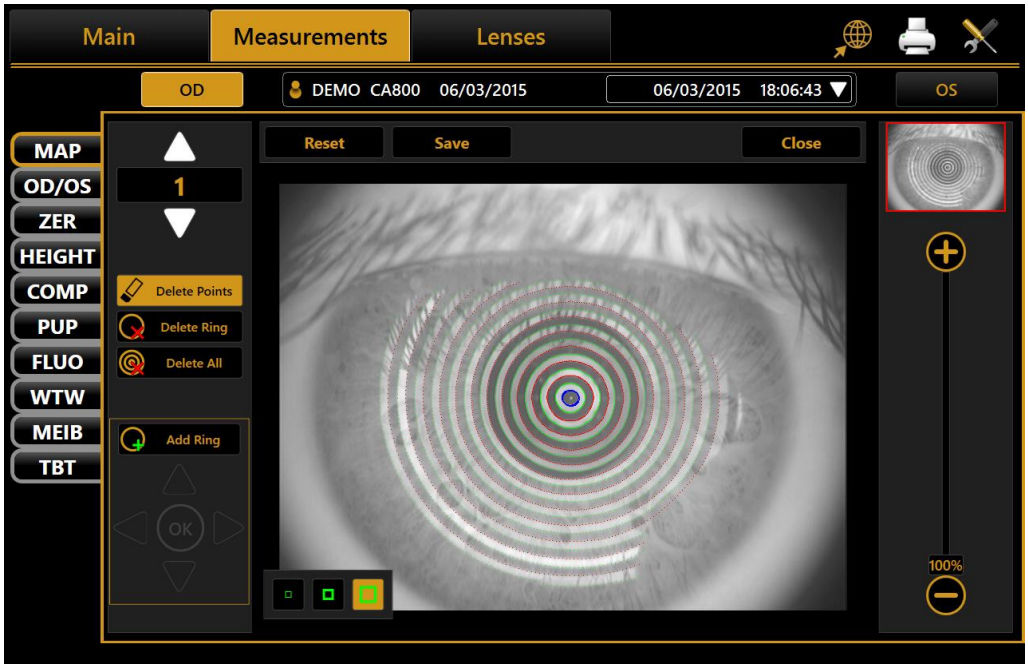


Fig. 54

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.

14.2 OD/OS

In this section you can compare the OD and the OS data on the same screen (Fig. 55):

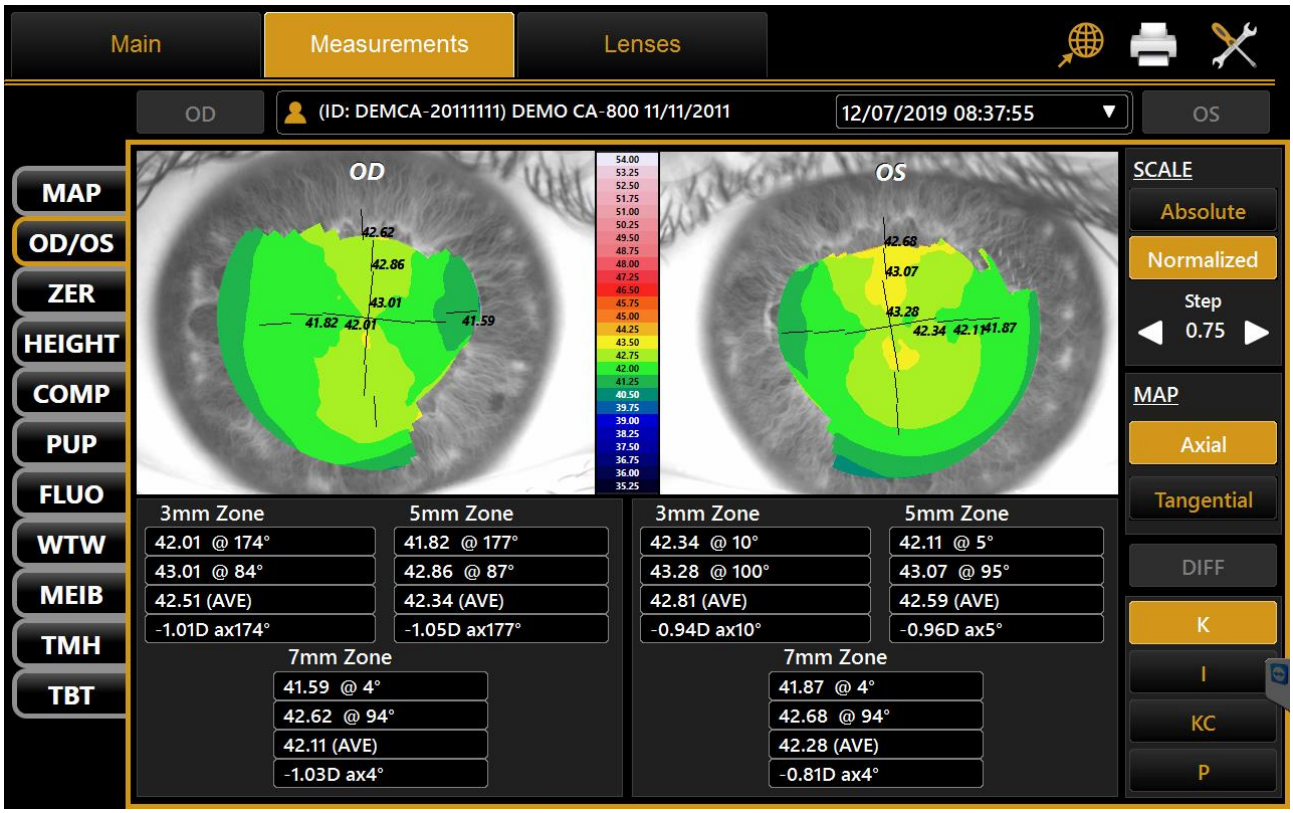


Fig. 55

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

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

14.3 ZER- Zernike

The Zernike module provides a comprehensive view of the 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.

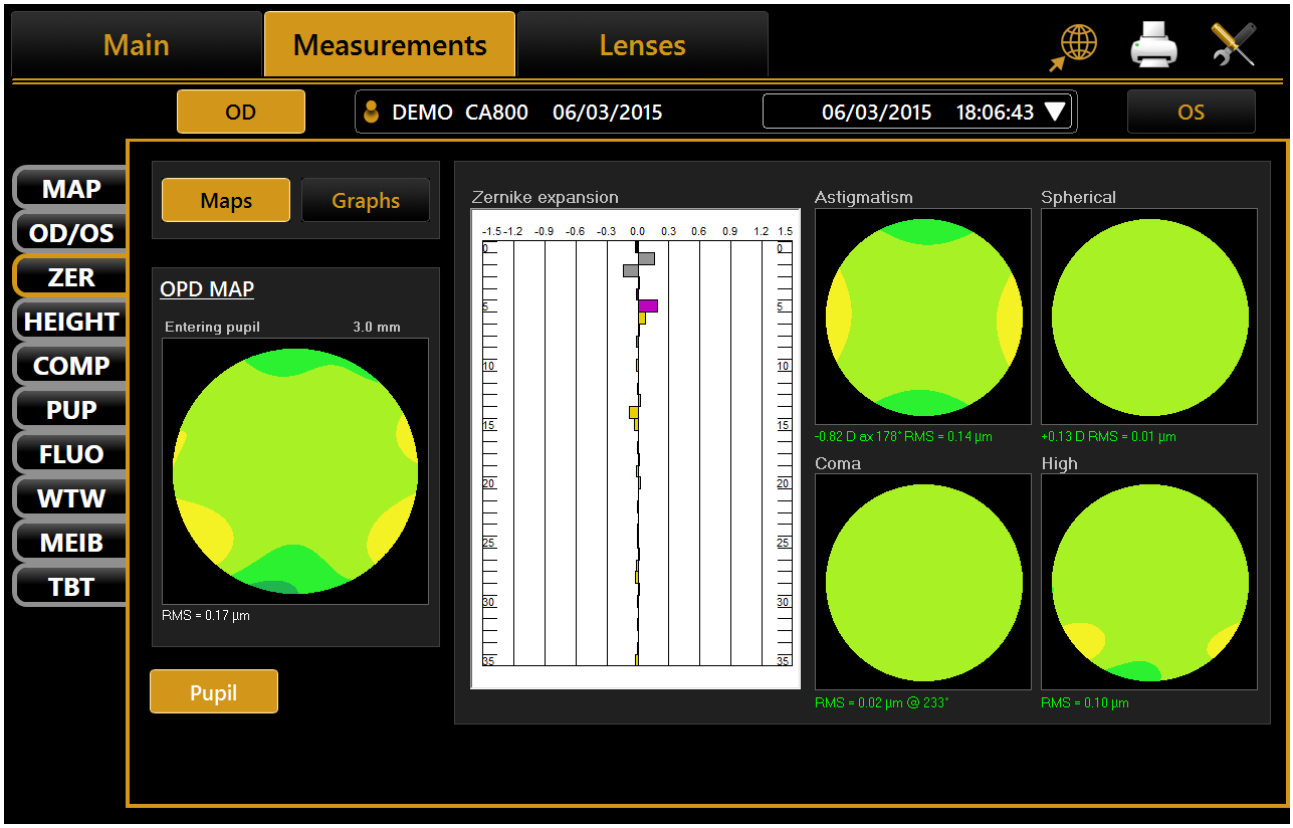


Fig. 56

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.

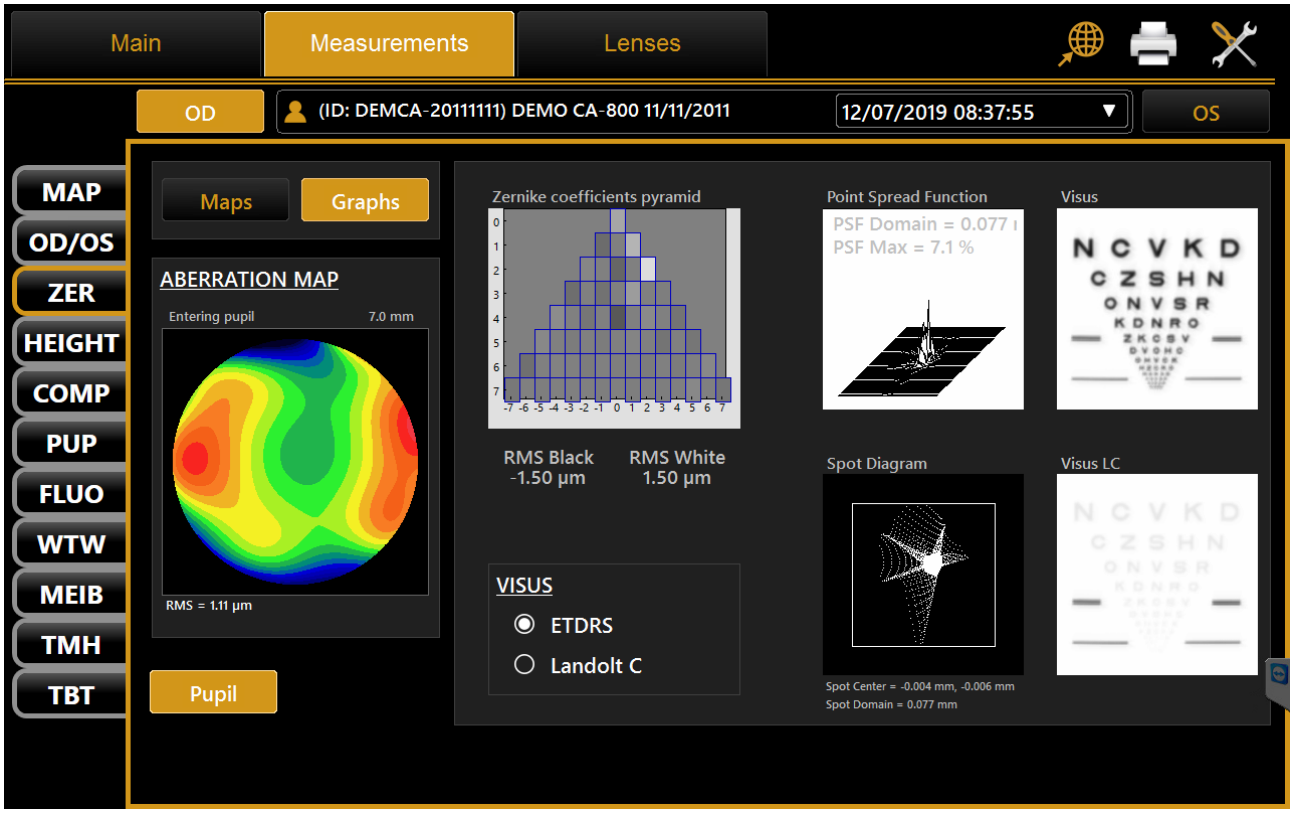


Fig. 57

Tap on ***"Graphs"*** at the top left to display the vision quality summary (Fig. 58). 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.

The data displayed refer 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. 58) 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.

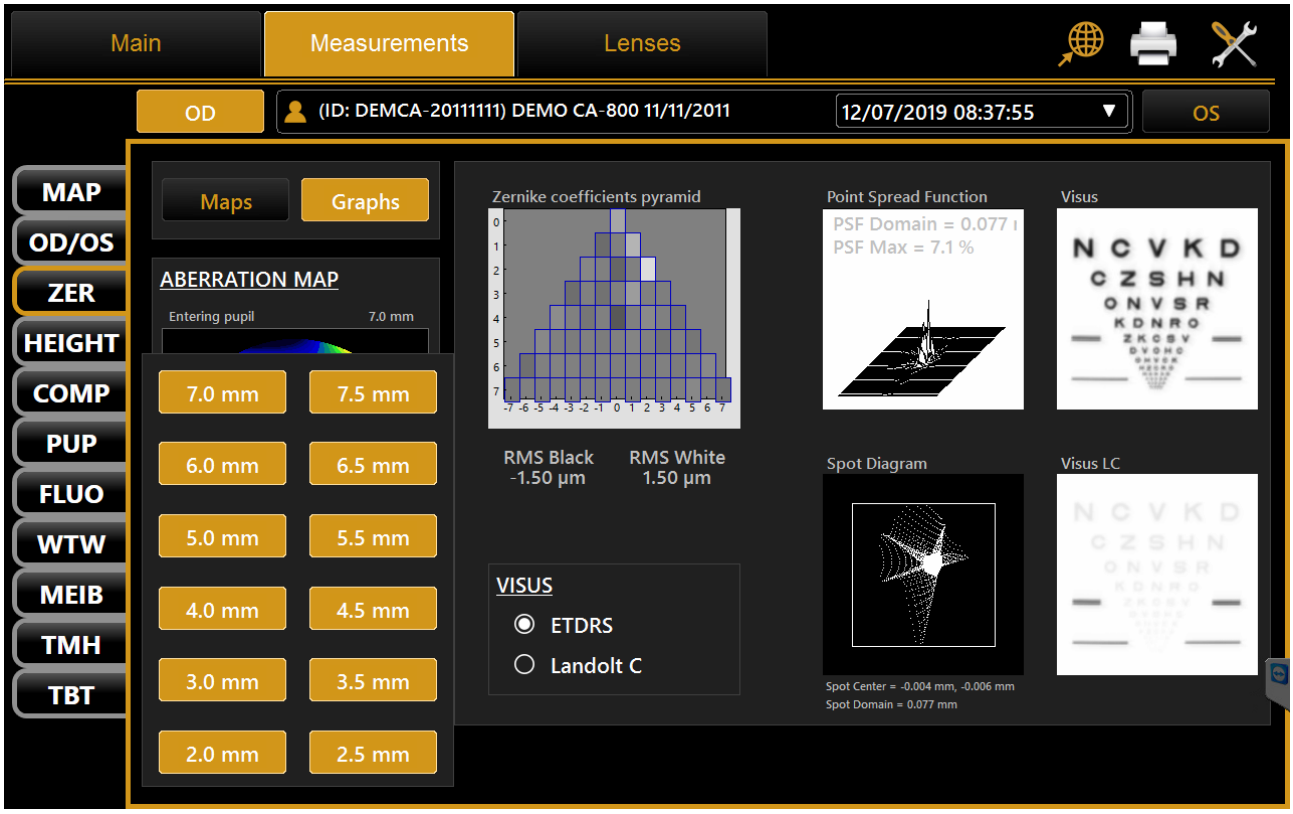
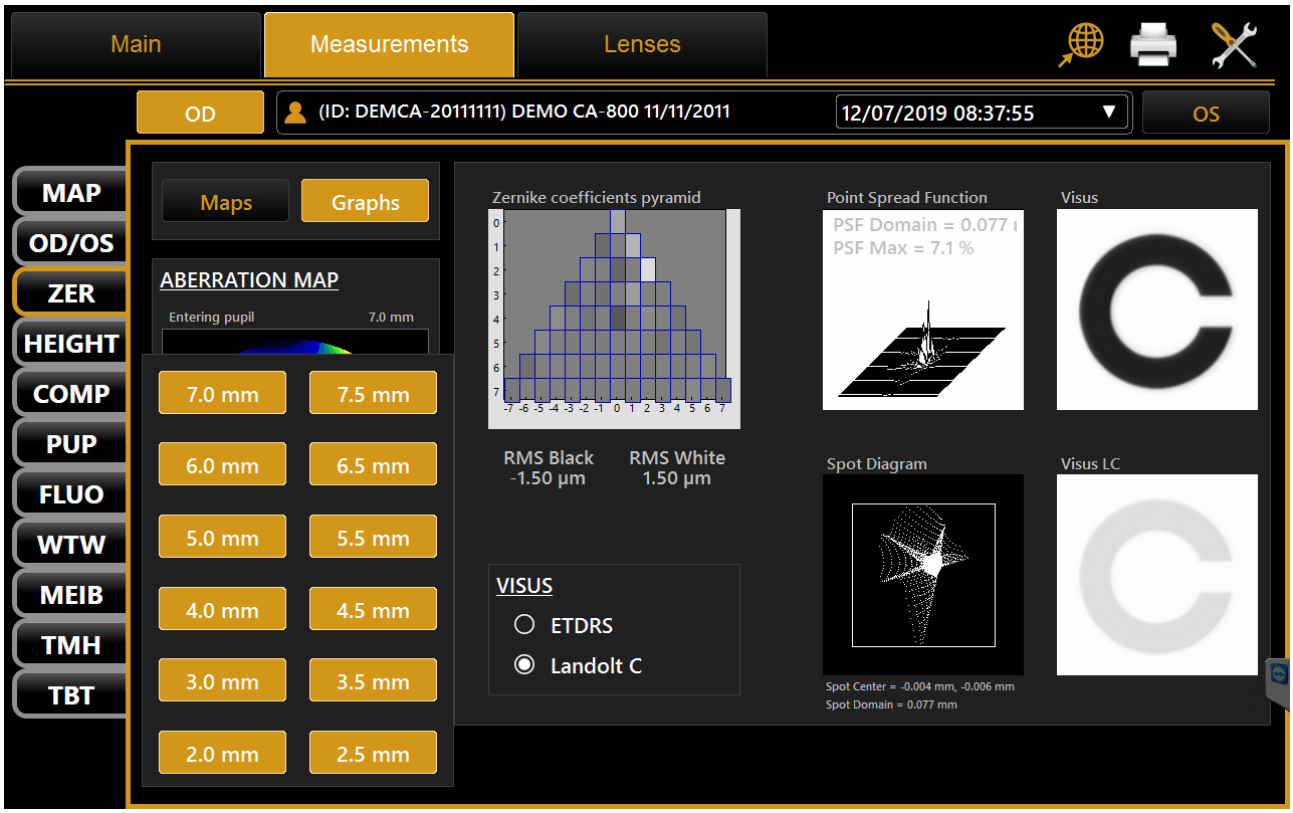


Fig. 58

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



14.4 HEIGHT

"Height" environment allows the user to compare the patient's cornea with a reference surface (Fig. 59):

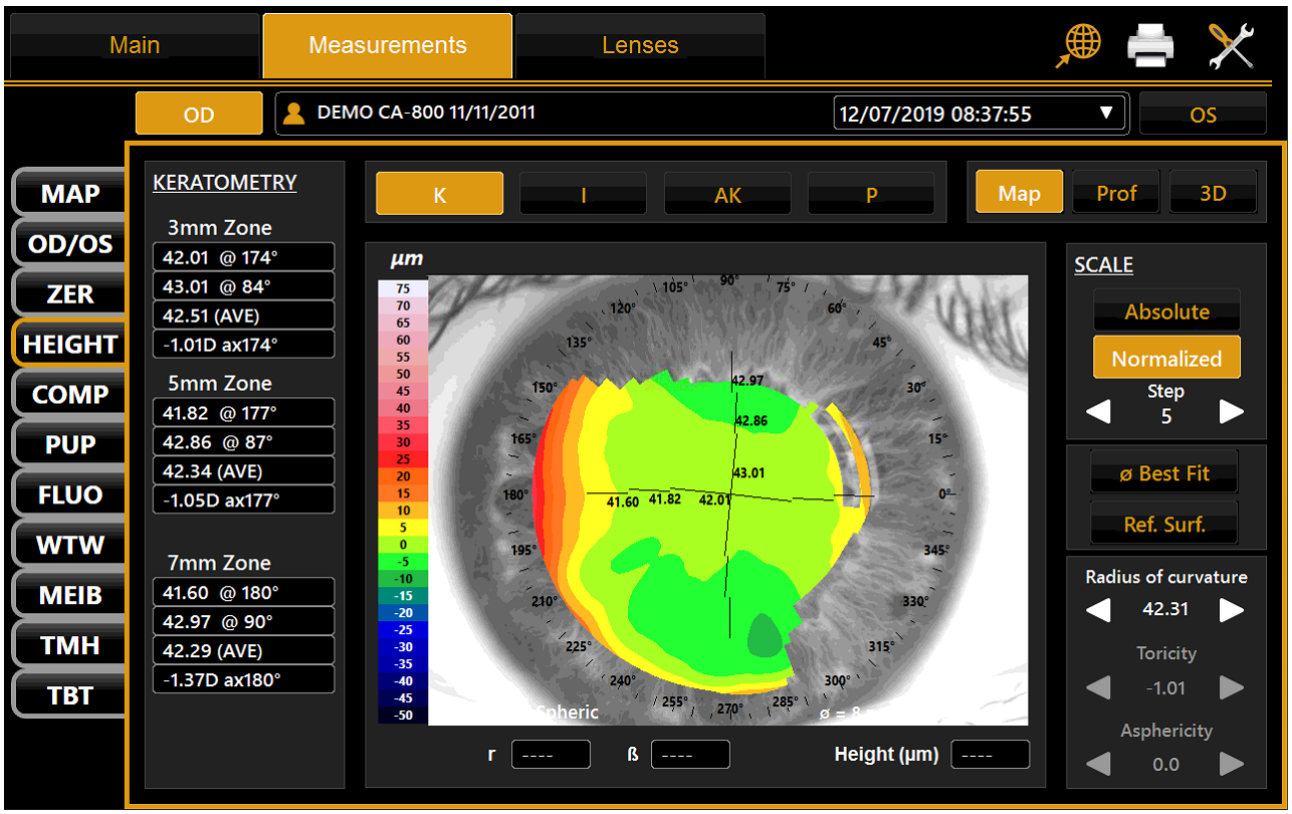


Fig. 59

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. 60).

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.
- ***Ib***: 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.

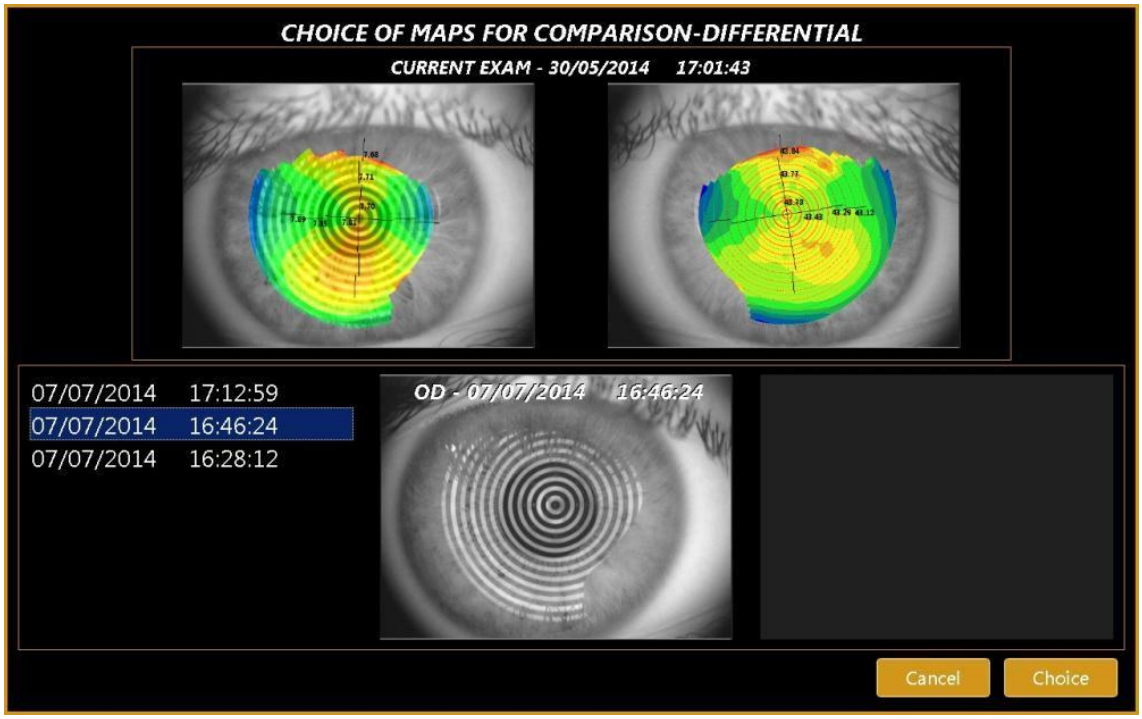


Fig. 60

14.4.1 Profile

Press the ***"Profile"*** button to view the curvature profile along the steep meridian or the flat meridian (Fig. 61).

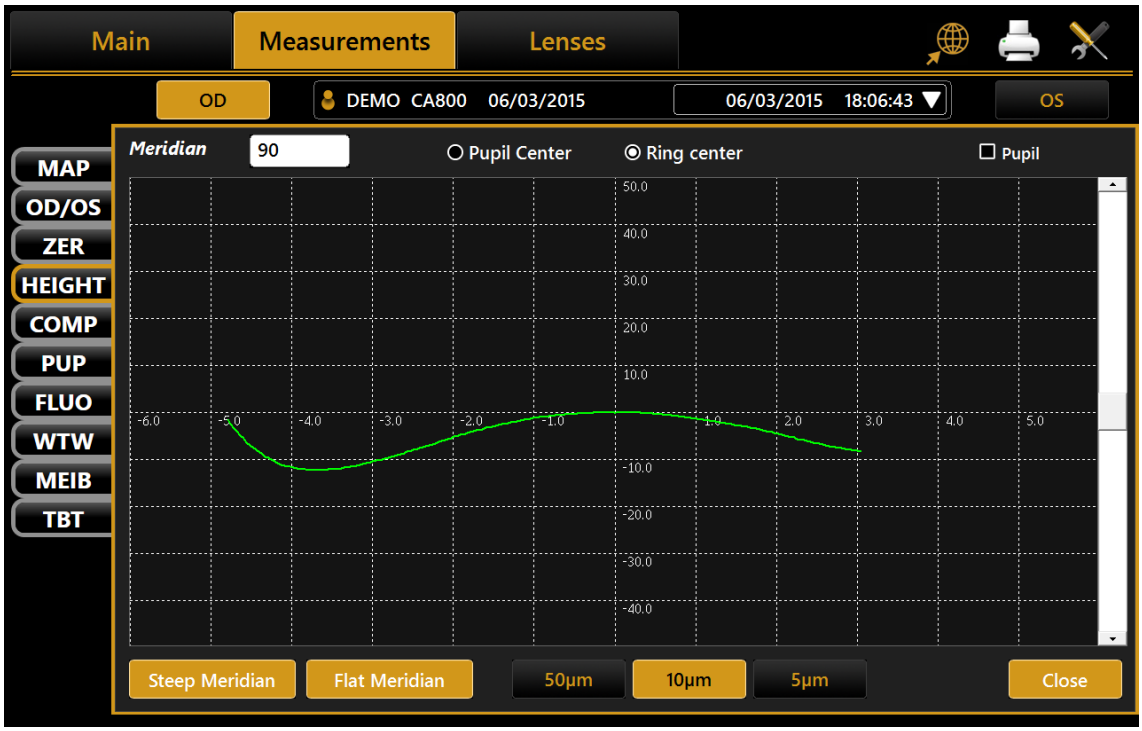


Fig. 61

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.

14.4.2 3D

Press the ***"3D"*** button to view the 3D map of the altimetric data (Fig. 62).

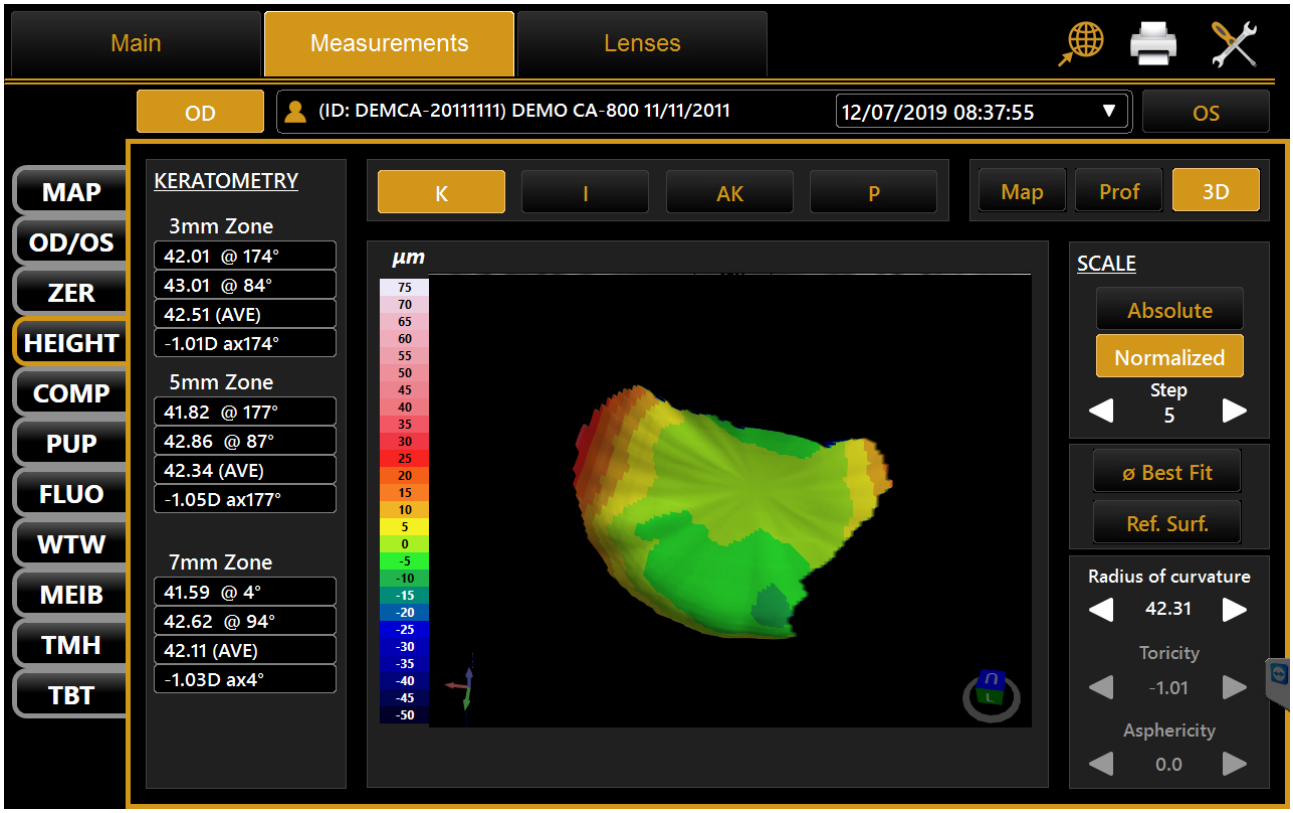


Fig. 62

14.5 COMP- Comparison

Comparison mode allows the user to compare the current exam data with the data of another exam for the same patient (Fig. 63).

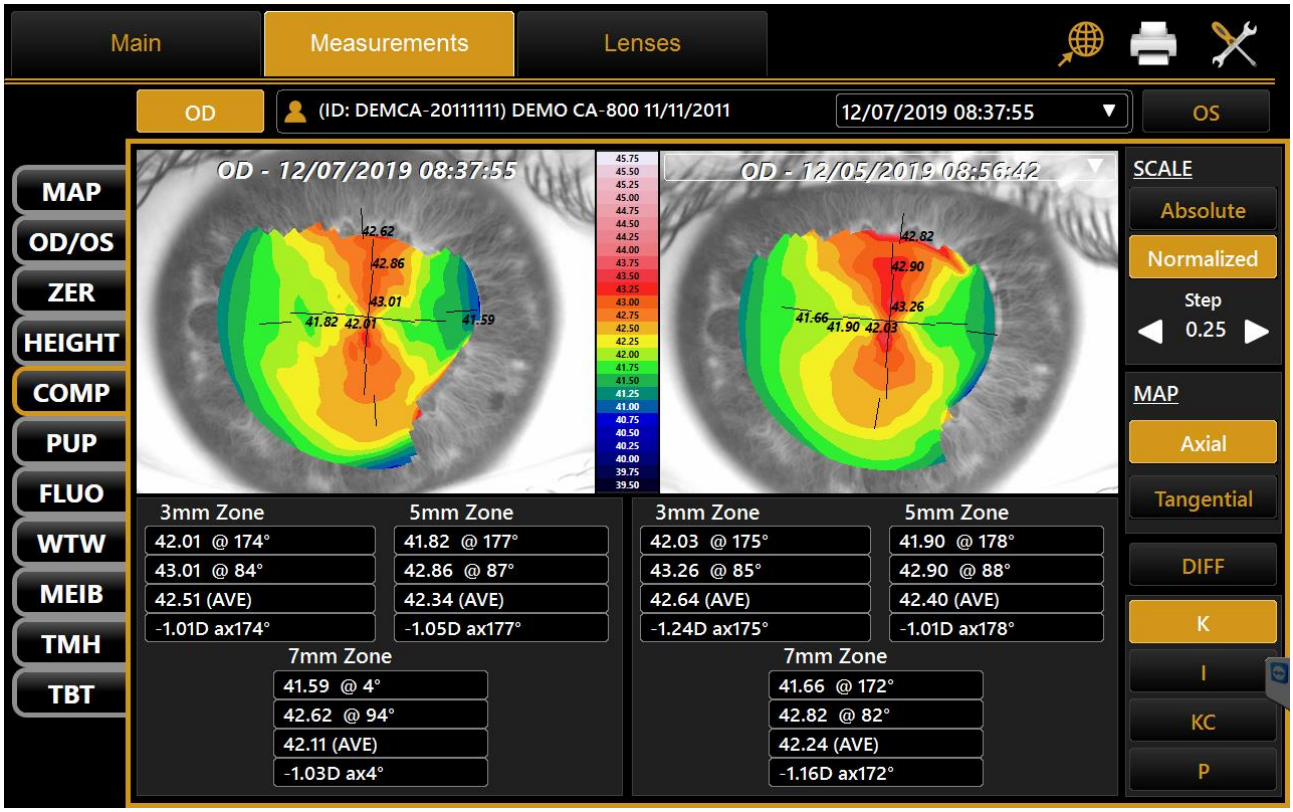


Fig. 63

When you select the ***"COMP"*** button, the interface shown in Fig. 64 appears and the software allows you to choose in a list of exams for the patient currently selected.

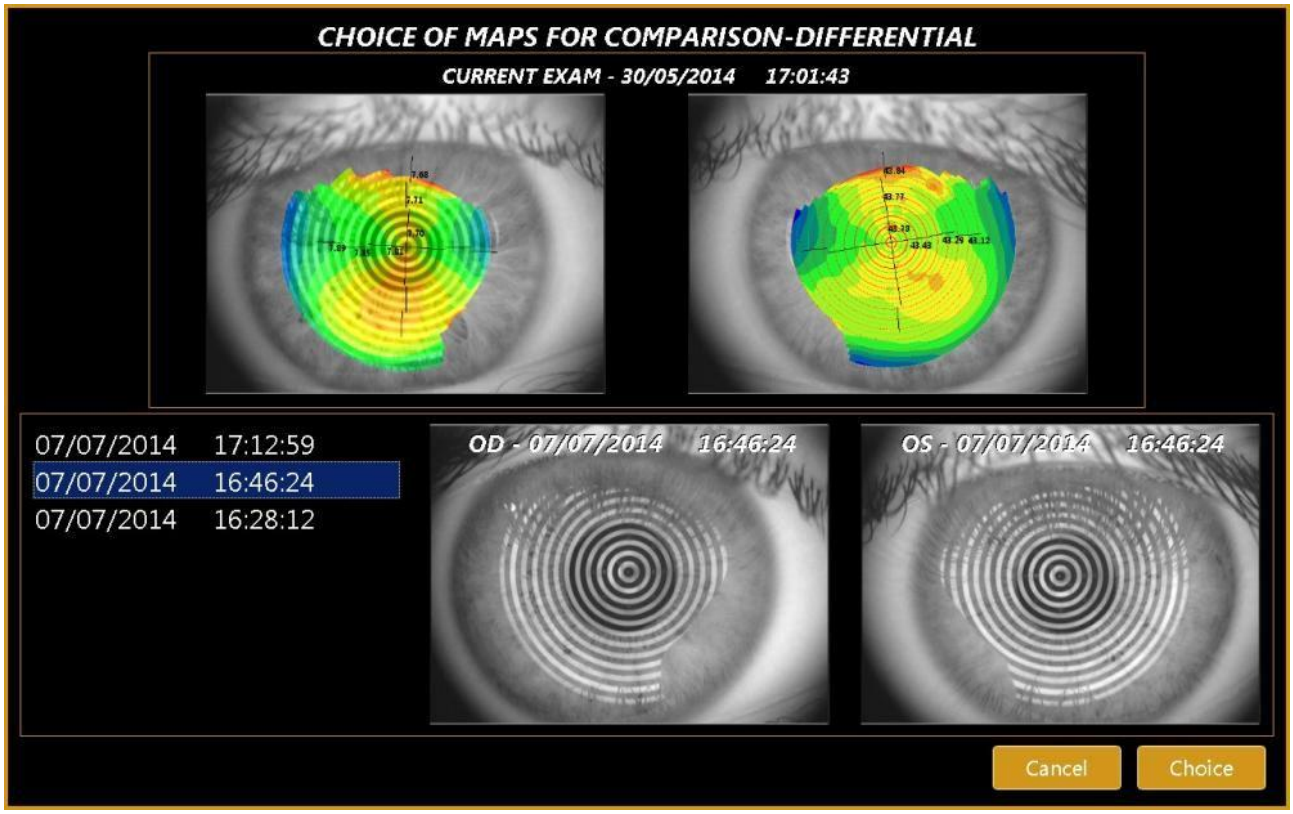


Fig. 64

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.

14.5.1 DIFF- Differential

By tapping the “DIFF” button in comparison mode, the user switches to differential mode (Fig. 65).

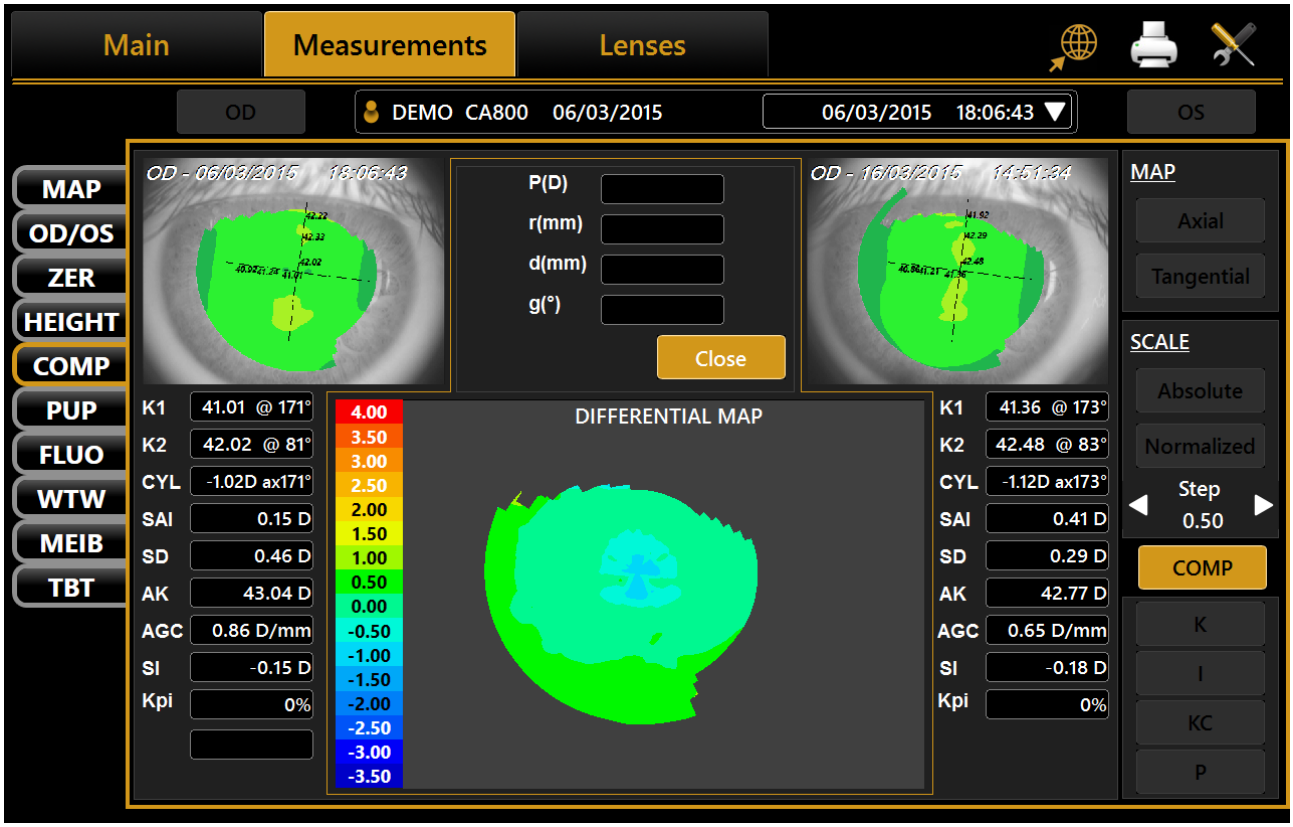


Fig. 65

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.

14.6 PUP- Pupillometry

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

Normally, if pupillometry is acquired, the software switches to dynamic mode (Fig. 66).

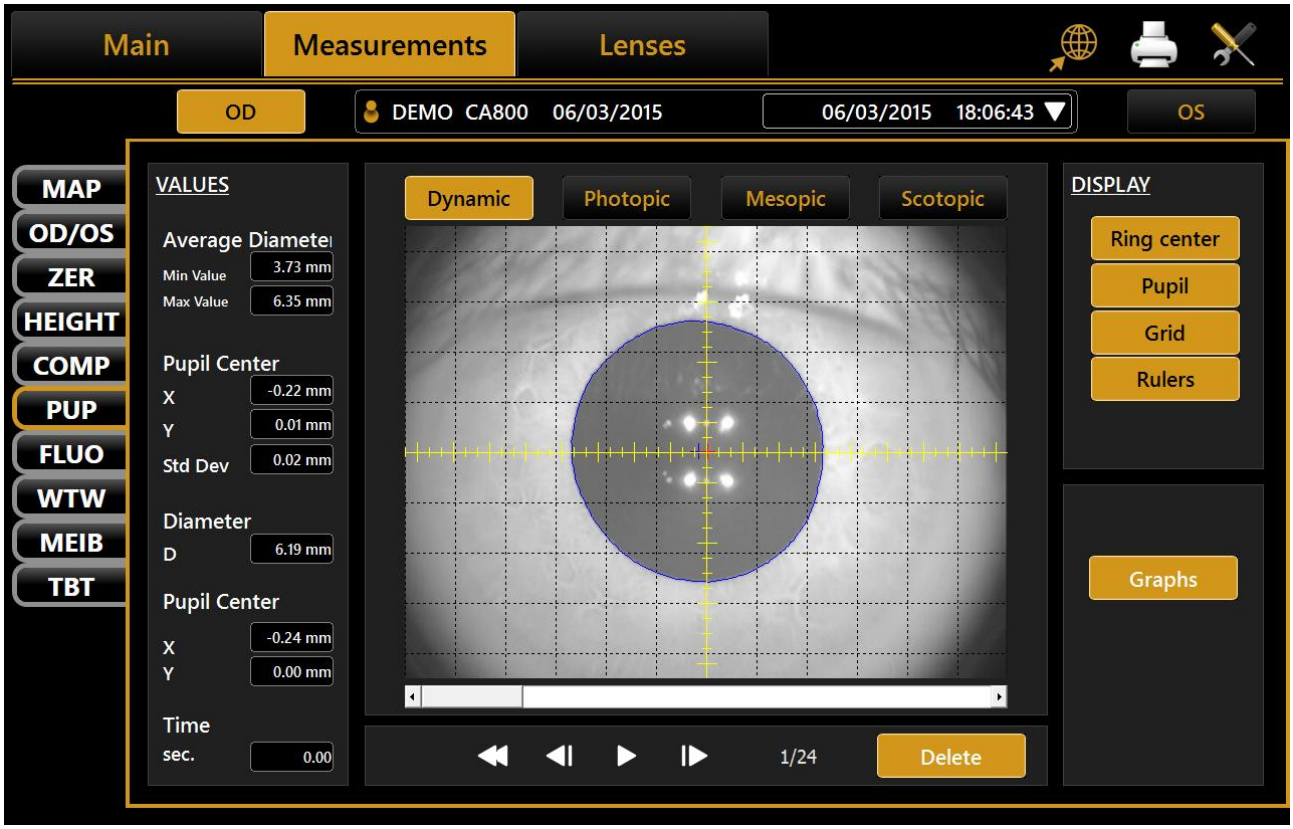


Fig. 66

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

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

14.6.1 Display

- **Ring Center:** Shows the position of the fixation point (i.e. the red cross follows the corneal vertex, while the blue cross the pupil center)
- **Pupil:** Shows the blue ring, which highlights the pupil edges
- **Grid:** Shows an overlaid grid (each grey grid equals to 1mm)
- **Rulers:** Shows calibrated rulers (small marks equal to 0.25mm while big marks equal to 0.75mm)

14.6.2 Sequences

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

- Dynamic
- Photopic
- Mesopic

- Scotopic

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

14.6.3 Dynamic

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

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

14.6.4 Photopic, Mesopic, Scotopic

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

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

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

14.6.5 Functions

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

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

14.6.6 Graphs

In this section, three types of graph are displayed:

- ***Decentration*** (Fig. 67)
- ***Latency*** (Fig. 68)
- ***Statistics*** (Fig. 69)

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

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

Decentration

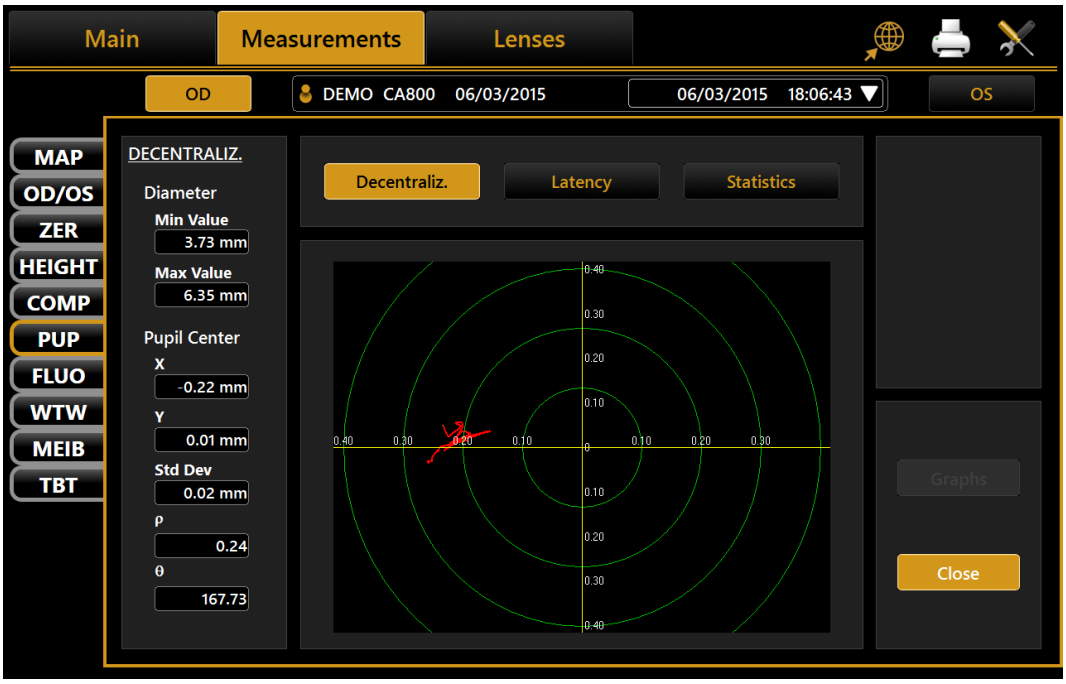


Fig. 67

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

Latency

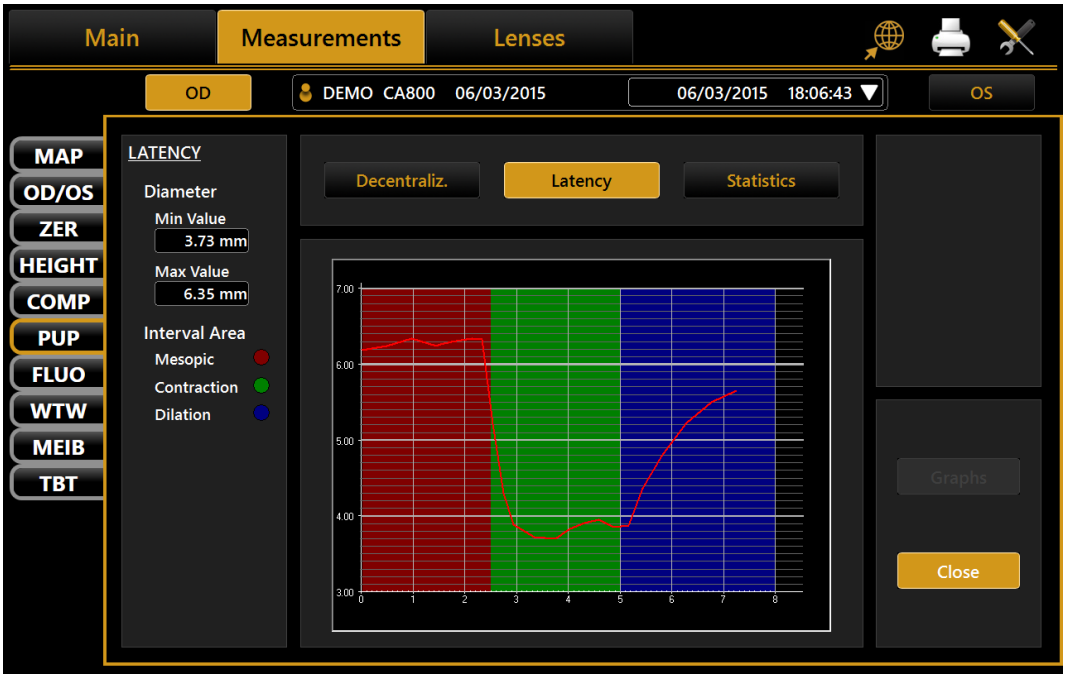


Fig. 68

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

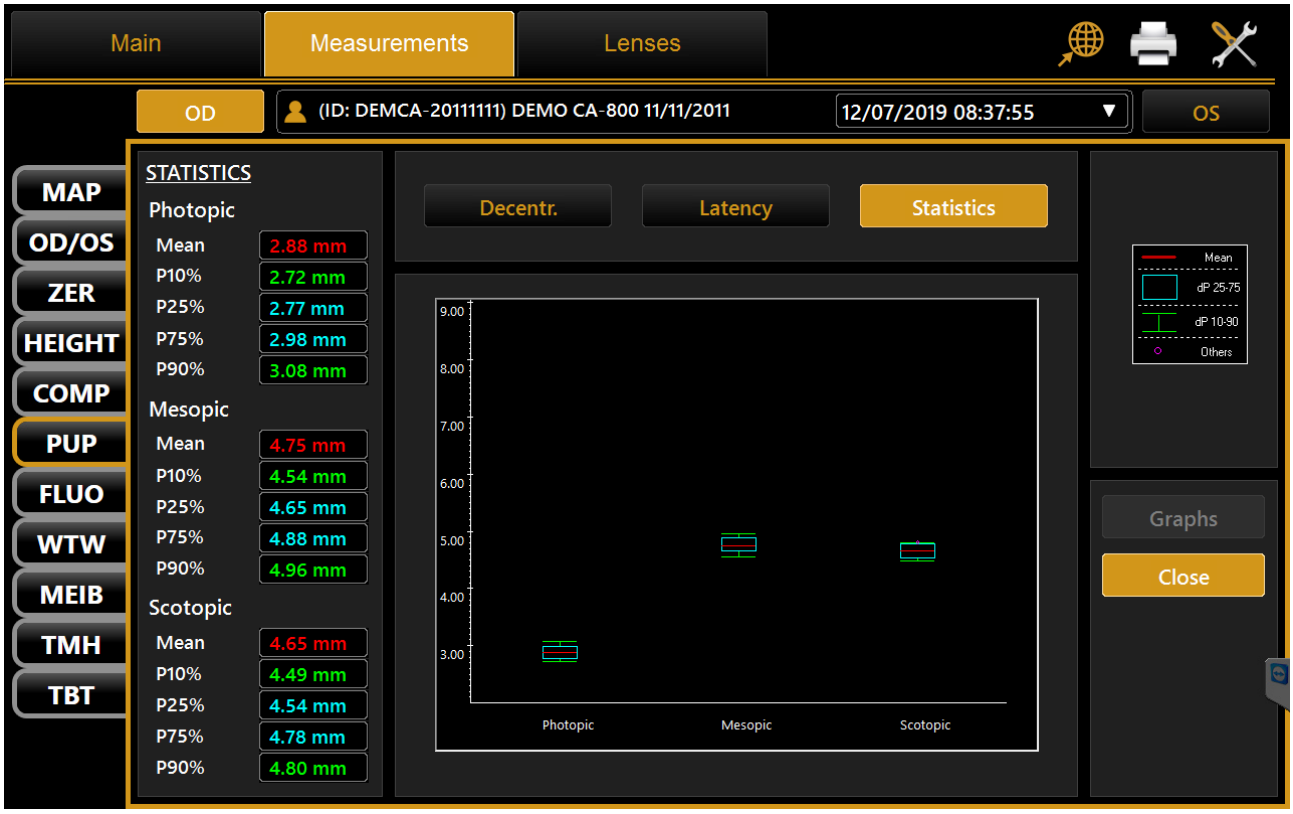


Fig. 69

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.

14.7 FLUO – Fluorescein

The fluorescein module (Fig. 70) allows you to assess the physical condition of the cornea and to verify the contact lens position and fitting towards the cornea.

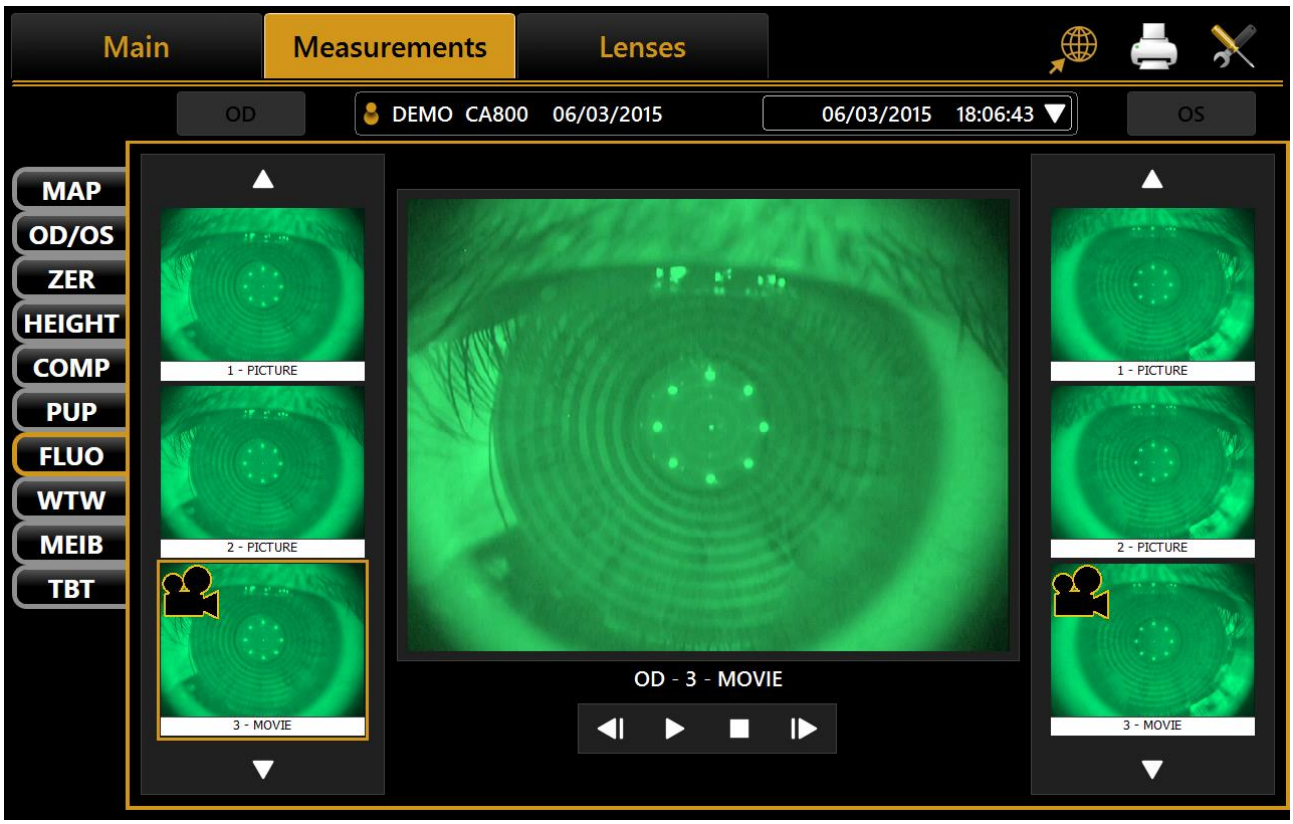


Fig. 70

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 and the eye, the picture or the movie which 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.

14.8 WTW – White To White

The White to White section allows you to view the value of the corneal diameter calculated from limbus (Fig. 71).

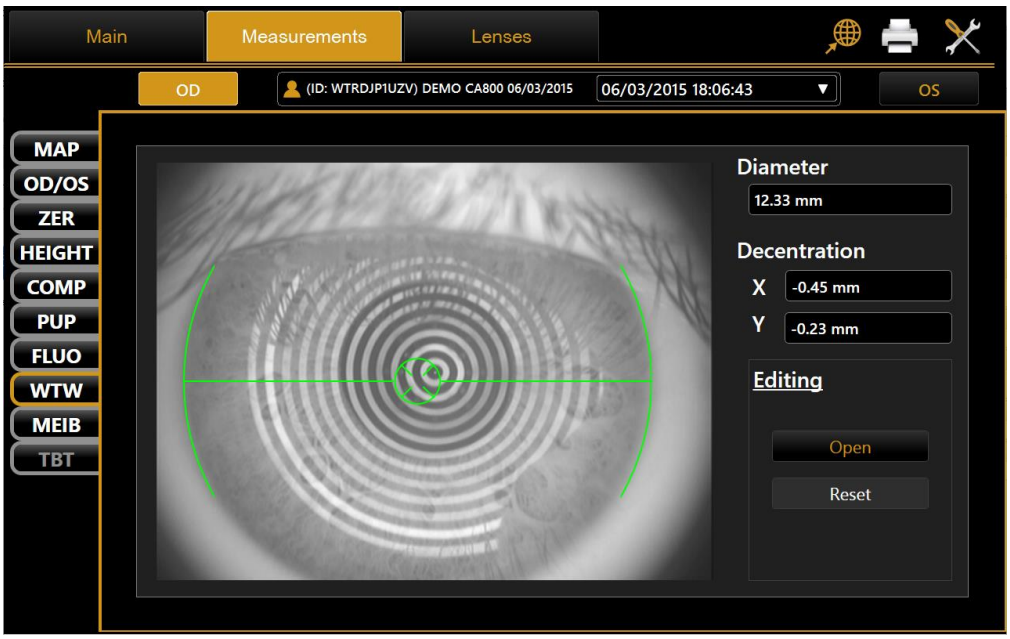


Fig. 71

Tapping on the **Open** button in the **Edit** menu (Fig. 72), the user can manually reposition positional indicators in order to refine the diameter measurements.

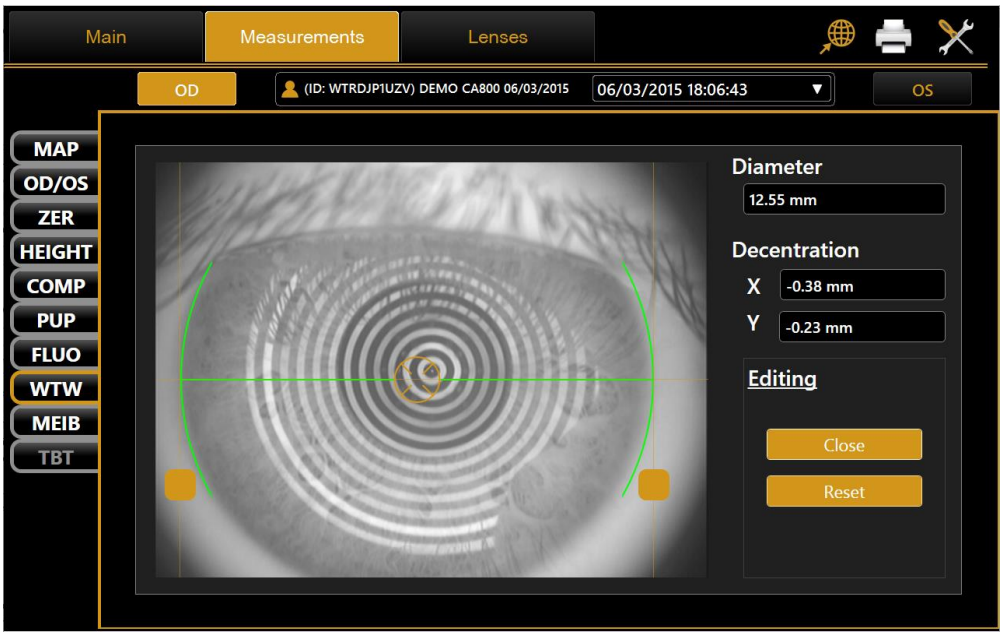


Fig. 72

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

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

By changing the 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.

14.9 MEIB – Meibomian Glands

In the Meibomian section, the user can check all the images that have been taken in the Meibomian gland acquisition section. It is also possible to change type and level of enhancement. (Fig. 74).

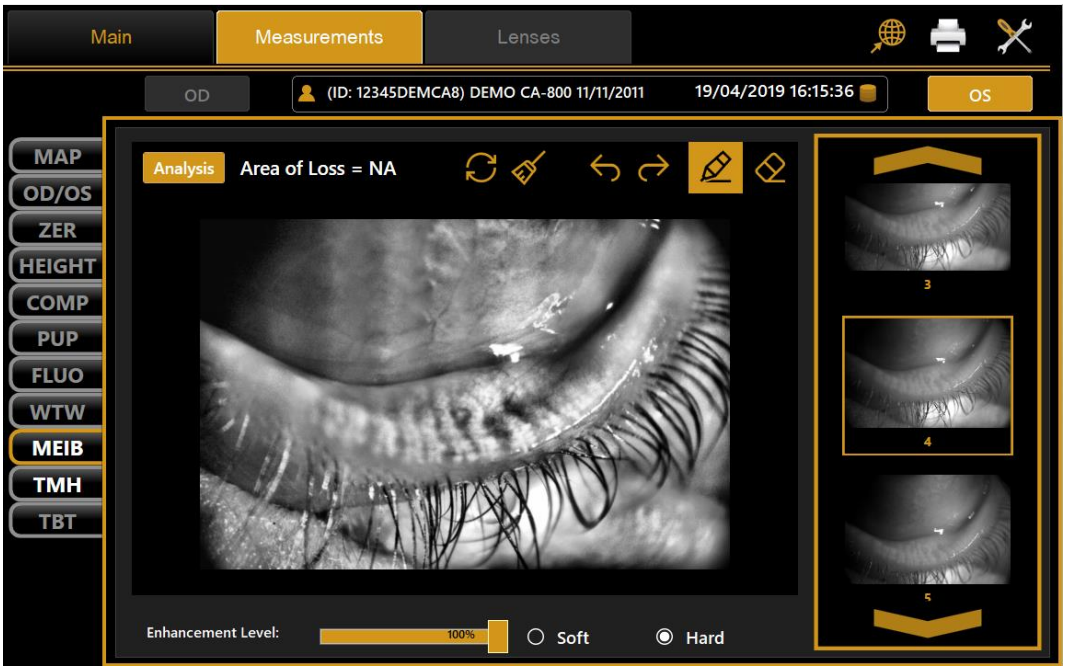
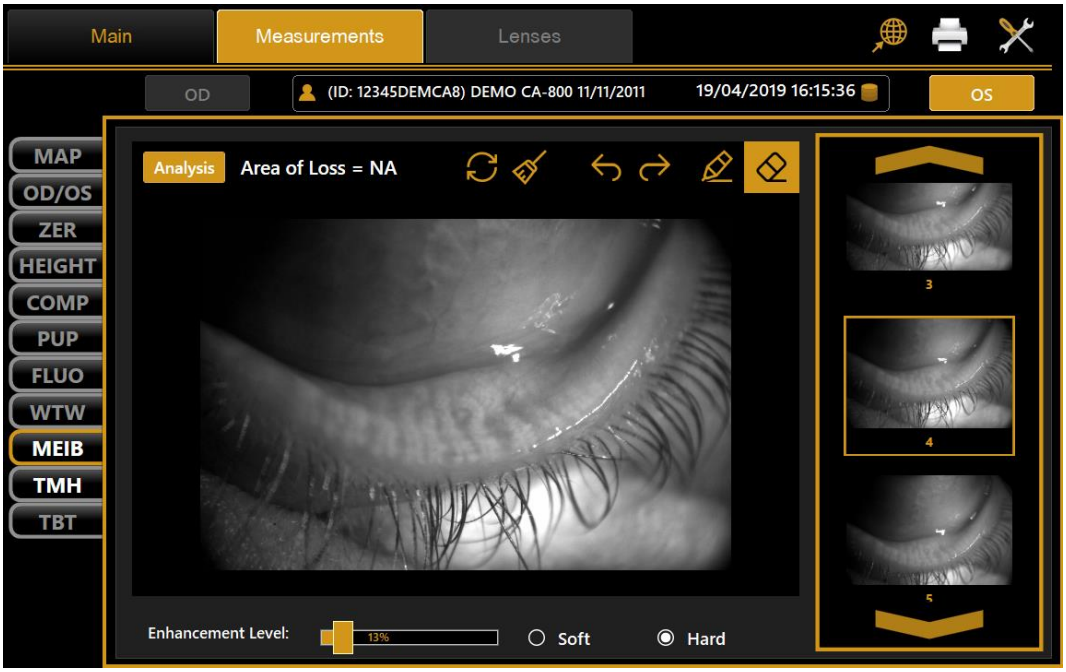
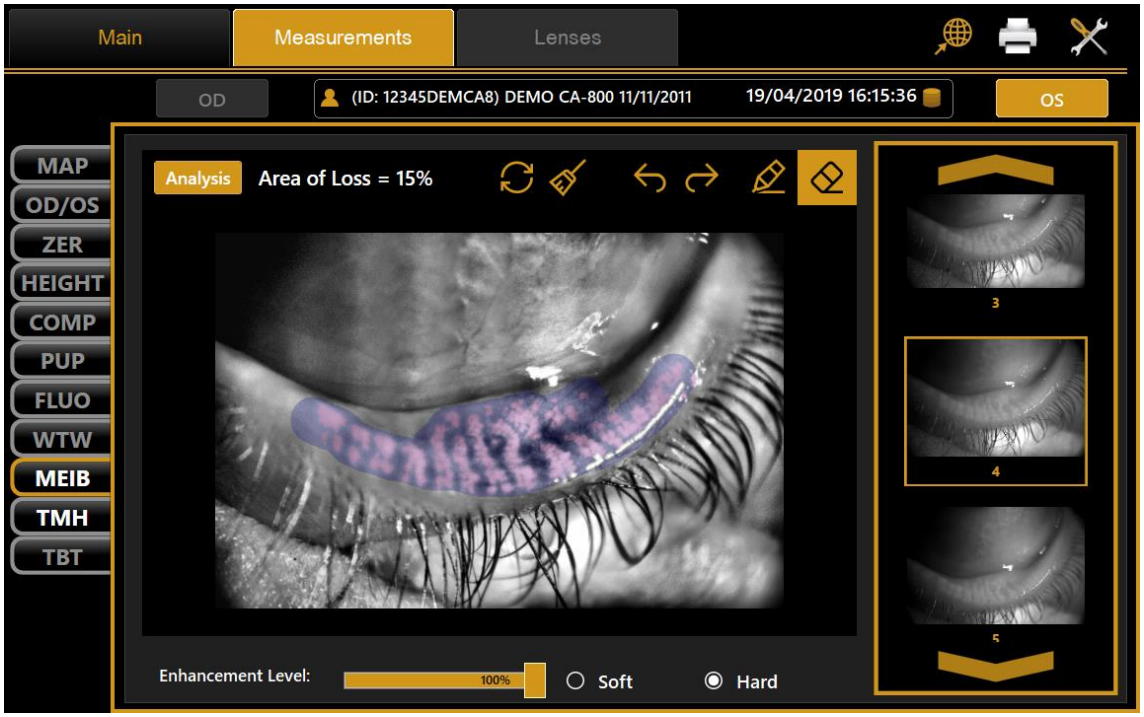


Fig. 73



14.9.1 Meibomian glands analysis



With the **"Analysis"** button activated (as in picture above), the user is allowed to draw with the finger, the area used for the analysis.

Once completed, result area will be colored in:

- **Blue:** the area not covered by the glands
- **Pink:** the processed area covered by the glands

Upper to the image there is the **"Area of Loss"** that represents the percentage of the area not covered by the glands with respect to the entire area.

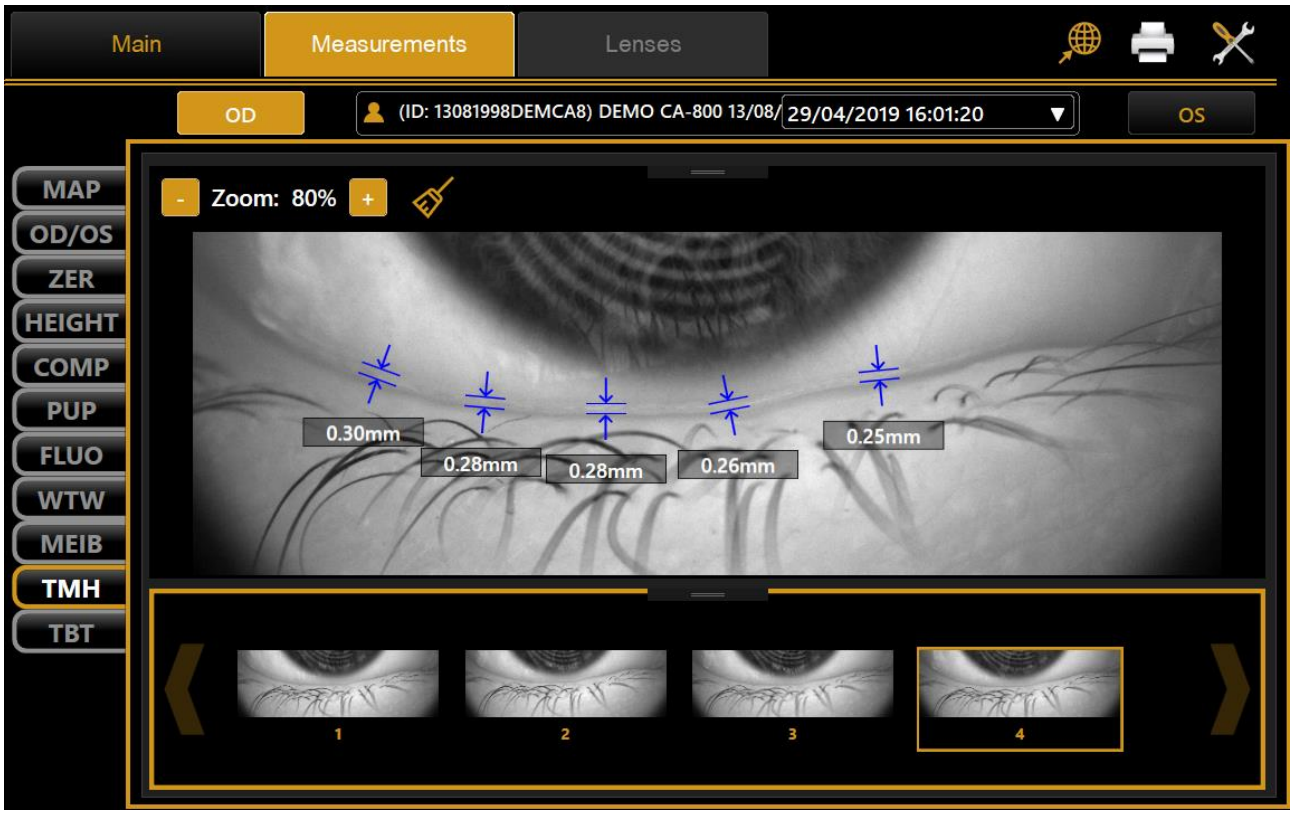
There also some function buttons listed below:

Analysis	**Analysis**: Enable or disable analysis
	**Pencil (Add function)**: Let able to add a specific zone to the area of interest. The area can be added by "painting" it with a finger, exactly like the pencil of every painting software.
	**Eraser (Remove function)**: Let able to remove a specific zone from the area of interest. The area can be removed by "painting" the zone to remove with a finger, exactly like the rubber of every painting software.
	**Reload**: It cancels the last modifies and re-load the last persisted map (the persisting is done when the exam is saved)
	**Clean**: It empties the area of interest
	**Cancel action**: It cancels the last modify
	**Restore action**: It restores the last canceled modify

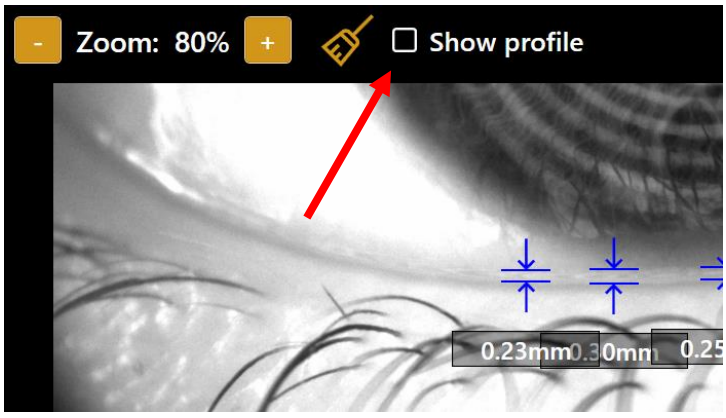
14.10 TMH – Tear Meniscus Height

In the TMH section, the user can check all the images that have been taken in the Meniscus acquisition

The view shows the calibers add from the user, showing the position, the angle and the height of the tear meniscus expressed in millimeters. It is possible to start a processing to create a profile of the entire meniscus.



The user can zoom in and zoom out the image using the zoom function button in the upper left side of the window.

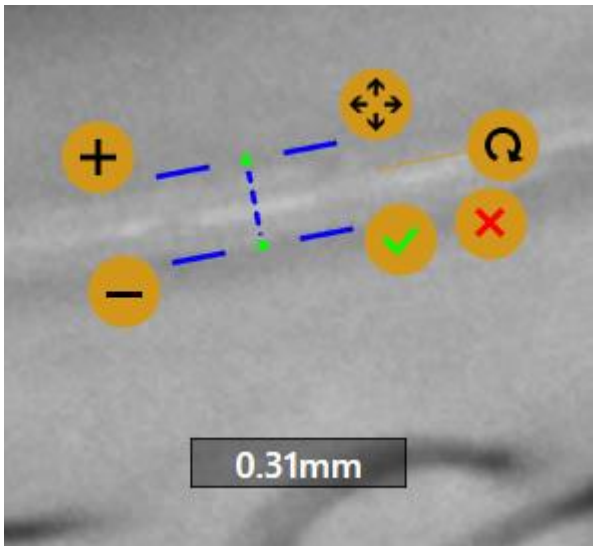


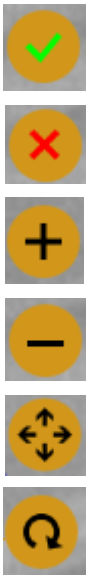
14.10.1 Tear Meniscus Height Calibers

The user is able to add calibers to measure the height of the tear meniscus simply by tapping the image where he wants to add it.

Once added the application selects the calibers just added and enter the “edit” mode (see picture below).

In this mode some function are shown:





Confirm and close the edit mode

Remove the caliber

Make the caliber height bigger

Make the caliber height smaller

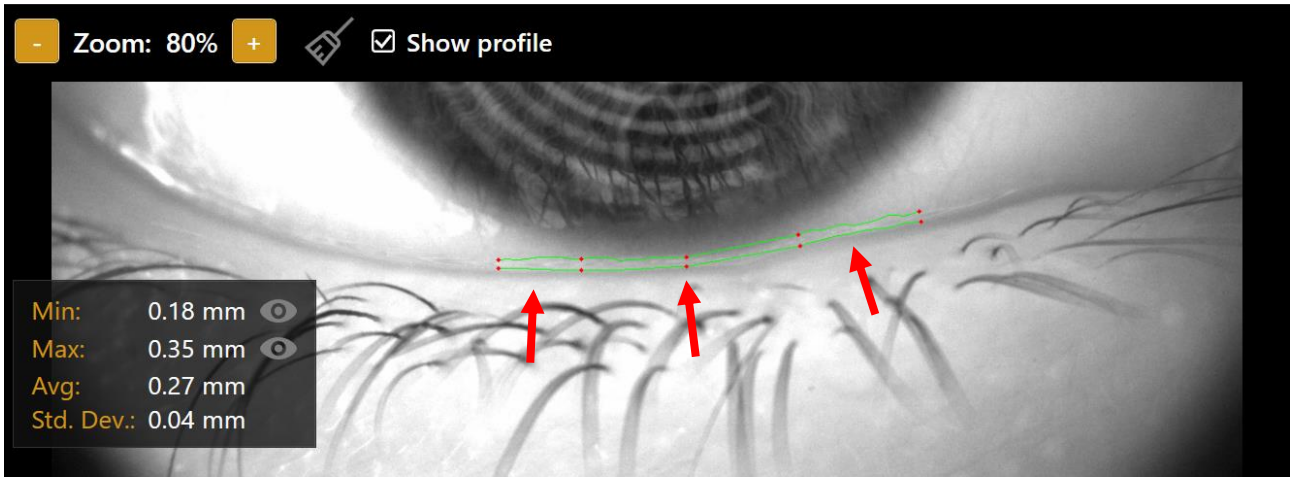
Dragging the button, the caliber is dragged too

Dragging the button, the caliber is rotated

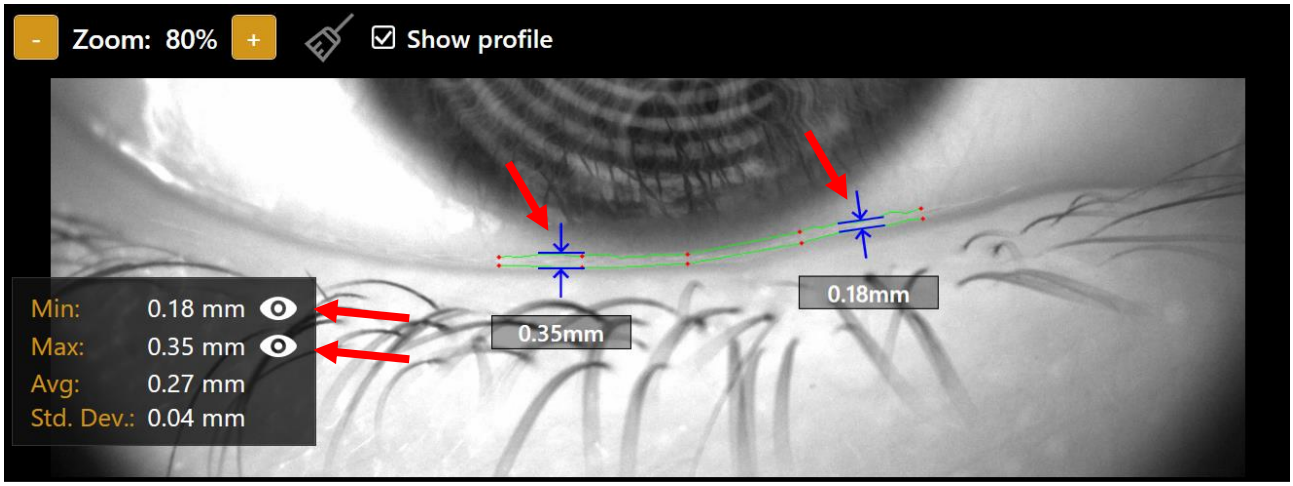
It is possible to edit already added calibers by selecting them.

14.10.2 Tear Meniscus Height Profiles

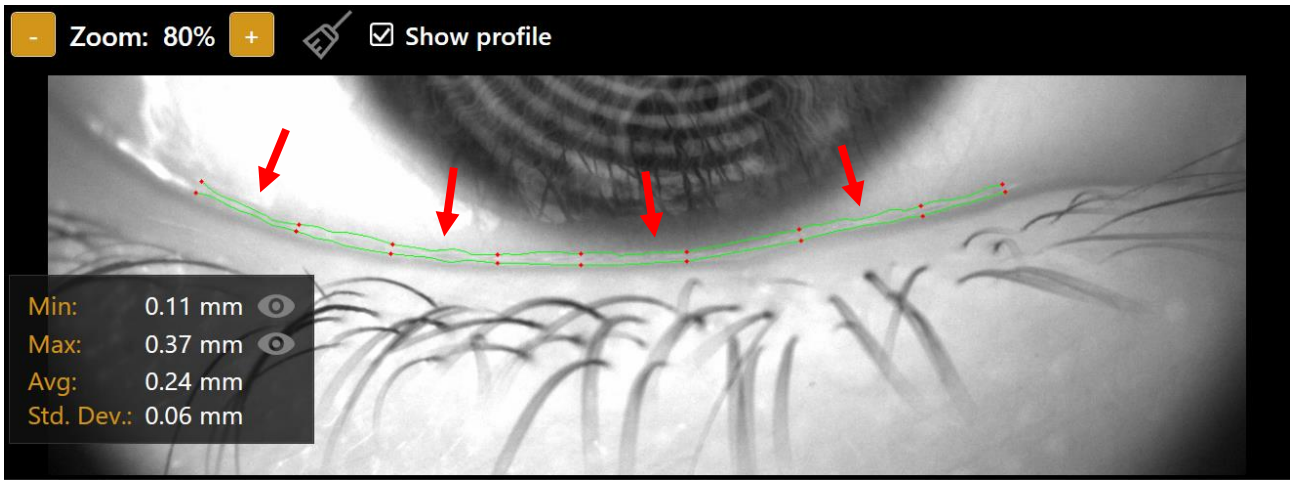
Once you have manually positioned a reasonable number of height calibers on tear meniscus, you can check **"Show profile**" to perform tear meniscus profile drawing automatically.



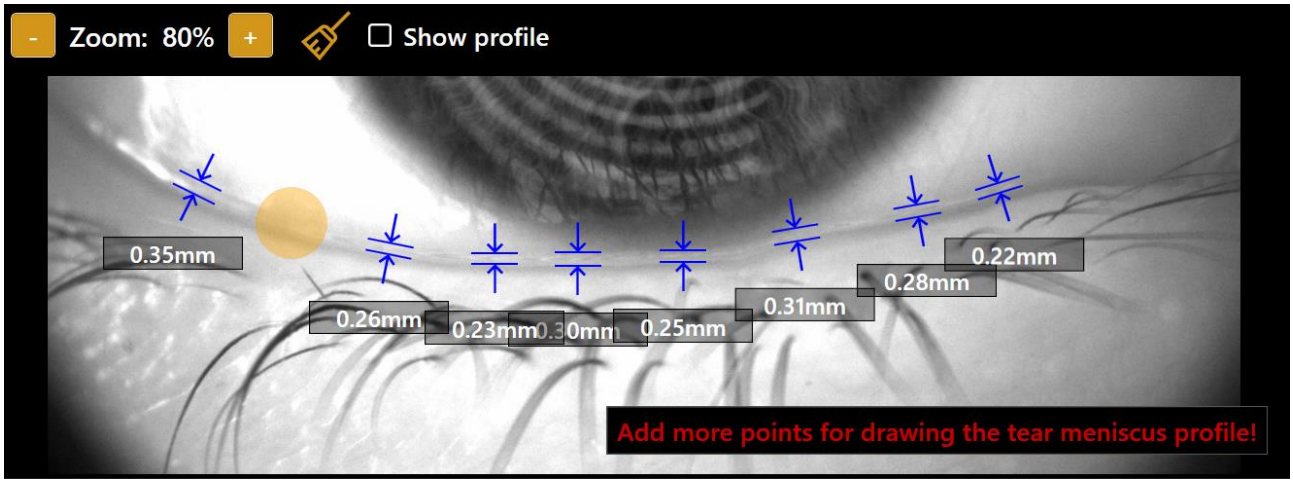
In the bottom left angle of the measurement screen, a table with the profile data will be displayed and it's possible to show the minimum and the maximum profile height found simply by checking eye's controls at the side of min. and max. values of the table.



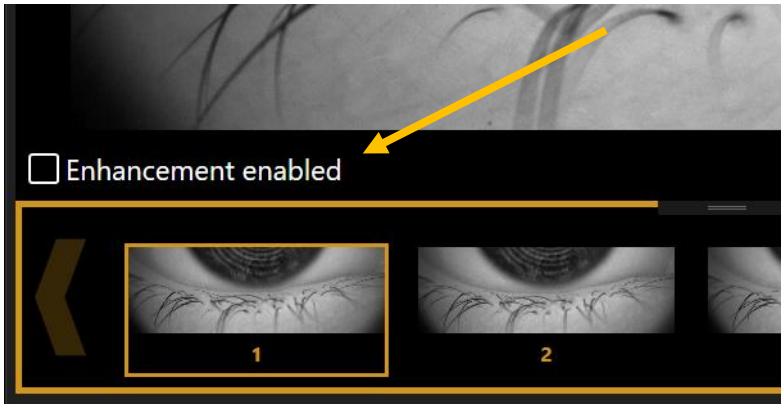
By unchecking **"Show profile"** option, height calibers will be displayed again and you can add more points or edit the existing ones, to perform a different profile length calculation.



To perform an accurately profile drawing, application notifies with a blinking message and animated circle control, the point where it is necessary another height profile control.



By clicking **"Enhancement enabled"** in the bottom-right side of the measurement screen is also possible to increase acquisition image contrast to show a bit more accurately the tear meniscus profile.



14.11 TBT – Tear Film Breakup Time analysis

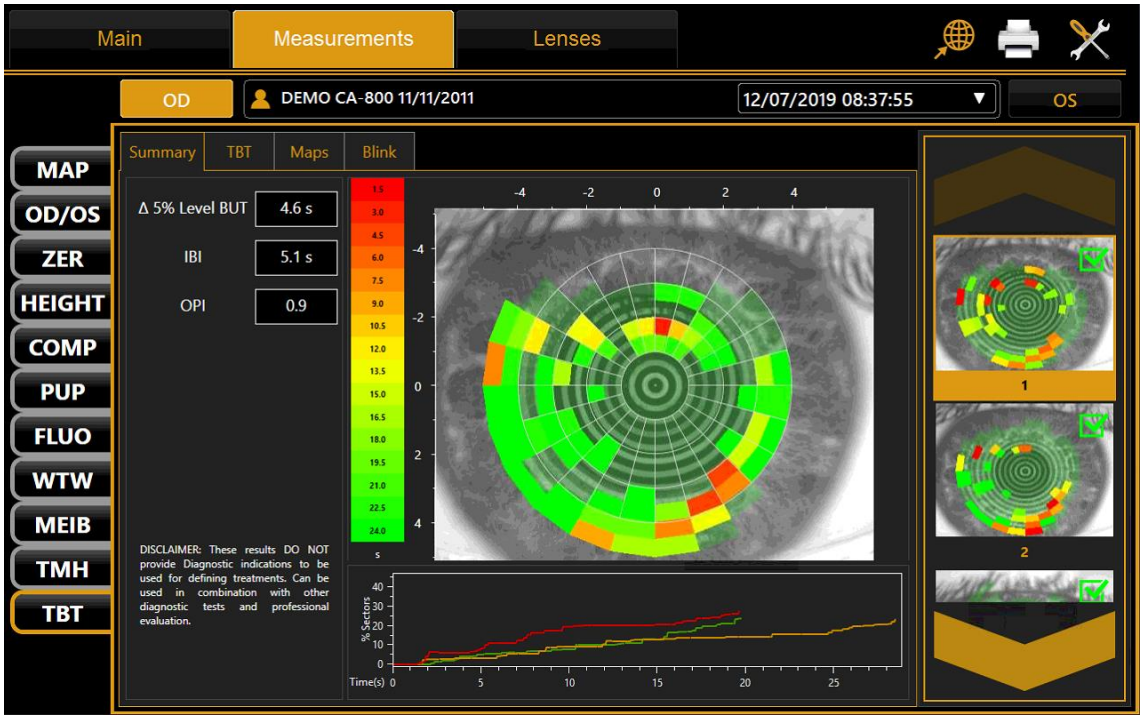
In the TBT section is possible to review the results of the TBT and Blink analysis. The section is composed of 4 views, described in the following paragraphs. On the right column a gallery showing all the acquisition performed for the current eye. By clicking on each element of the gallery the data of the corresponding acquisition are shown in the each view.

DISCLAIMER: The results DO NOT provide Diagnostic indications to be used for defining treatments. Can be used in combination with other diagnostic tests and professional evaluation.

14.11.1 Summary

Among all the acquisitions performed the values are reported as follows:

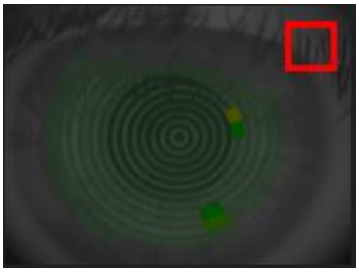
- **Δ 5% Level TBT** (Tear Film Break Up Time): average of 5% Level TBT measured in each acquisition
- **IBI** (available if BLINK acquisition is performed): average Inter-Blink Interval
- **OPI (Ocular Protection Index)**: available if IBI is available, is the rate between Δ 5% Level TBT and IBI



The sector maps shows, for each sector in which a breakup has been detected, the color-coded breakup time in seconds where reddish colors represent sectors that broke a short time after the blink and green sectors that broke after a longer time after the blink. For each sector the breakup time is average among all the acquisitions. Sectors not colored didn't break in any acquisition.

The plot shows by time the current percentage of broken sectors for each acquisition.

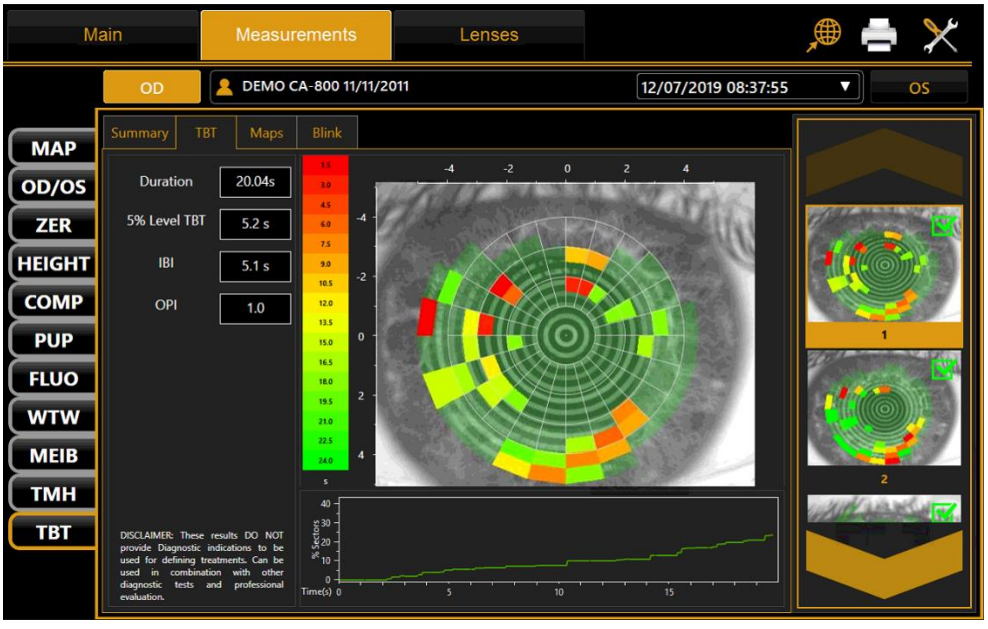
It is possible to exclude a single acquisition from the summary overview and average indexes by unchecking the acquisition image from the gallery. The exclusion/inclusion will affect also the relative TBT report.



14.11.2 TBT

By switching to the TBT view the results of TBT analysis and OPI index can be reviewed for each single acquisition. The following values are reported for the selected acquisition:

- **5% Level TBT:** the first time at which the percentage of breakup sectors arrived to the level of 5% (PLEASE NOTE: ">" than the total duration of the acquisition will be reported as a result if the 5% level TBT do NOT occur within the duration of the acquisition)
- **Duration:** the duration of the TBT analysis interval for the selected acquisition
- **OPI (Ocular Protection Index)**: available if IBI is available, is the rate between 5% Level TBT(of the selected acquisition) and IBI



The sector maps show, for each sector in which a breakup has been detected, the color-coded breakup time in seconds where reddish colors represent sectors that broke a short time after the blink and green sectors that broke after a longer time after the blink. Sectors not colored didn't break in the current acquisition.

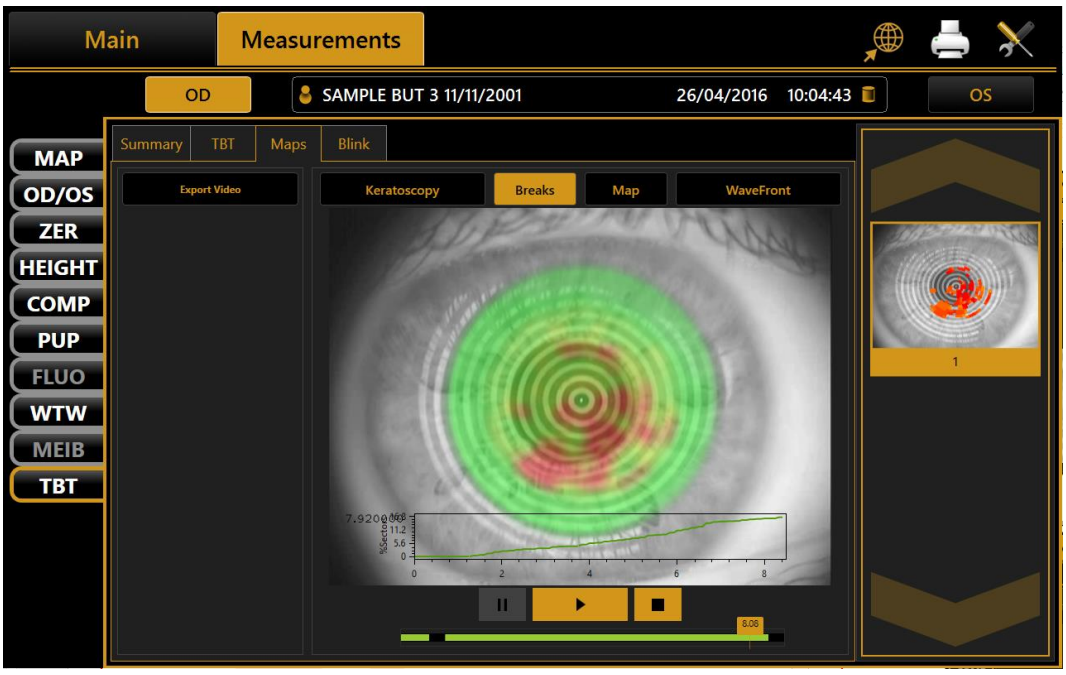
The plot shows by time the current percentage of broken sectors for the current acquisition.

14.11.3 Maps

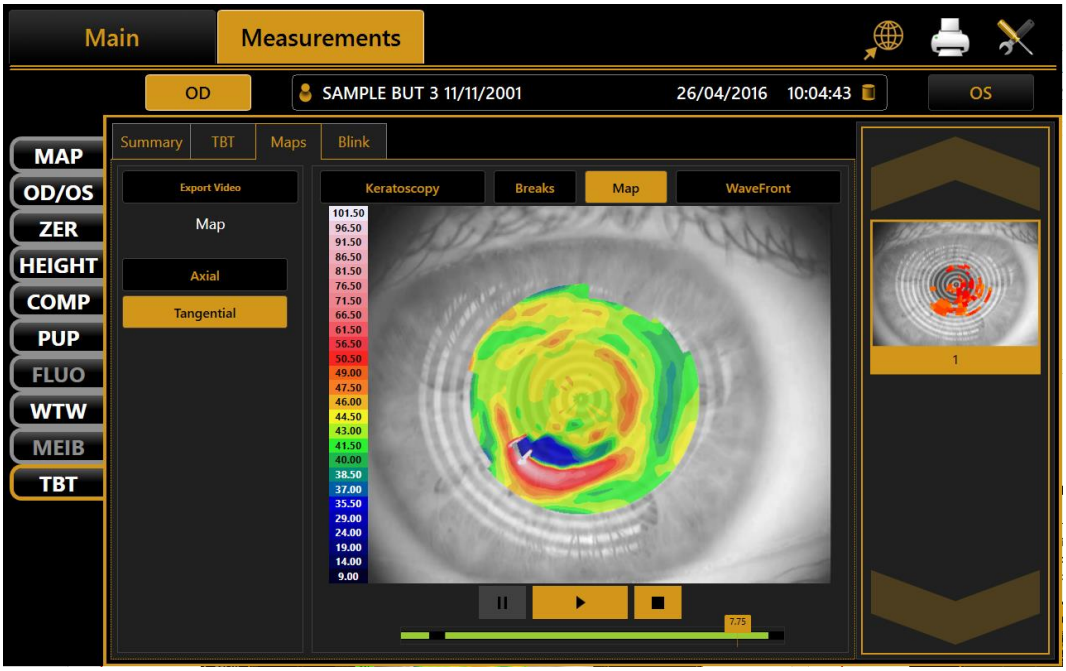
Switching to Maps view it is possible to review the behavior of the Tear Film during time for each single acquisition. In this view is possible to play a video with overlaid informations inf 4 options:

Keratoscopy: play the video with no overlay drawing

- **Break**: play the video with time-wise evolution of the breakup sectors. The overlaid plot is the by time percentage of breakup sectors.



- **Map**: play the video with time-wise evolution of topography map in Axial and Tangential values (absolute scale).

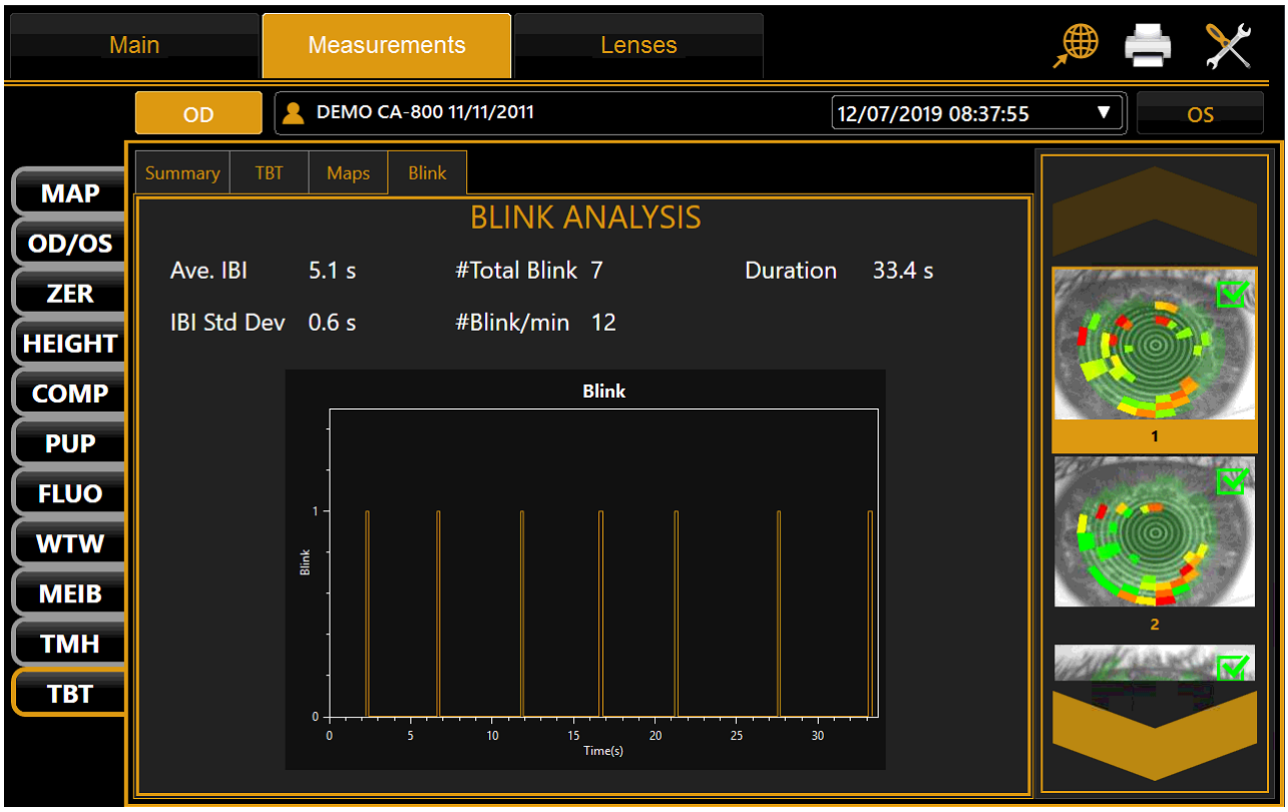


- **Wavefront**: play the video with time-wise evolution of aberration Zernike components. Selectable between full OPD, Astigmatism, Spherical aberration, Coma, High Order. The overlaid plot is the by time RMS residuals (in microns) for the selected components.

14.11.4 Blink

The content of this view is available only if a BLINK acquisition was performed. The Values reported are:

- **IBI Average:** average Inter-Blink Interval, used to calculated the OPI index
- **IBI std. Dev:** standard deviation of the Inter-Blink Interval values
- **#Total Blink:** total number of blinks during acquisition
- **Duration:** total duration of the time range analyzed
- **#Blink/min:** average number of blinks per minute



15 REPORT PRINTING & SAVING

15.1 Report printing

- In the measurements section, the user can print all the measurements made in the current exam.
- In the top-right corner of the screen, press on the  button to open the report printing panel (Fig. 74).
- 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***[8]: 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.

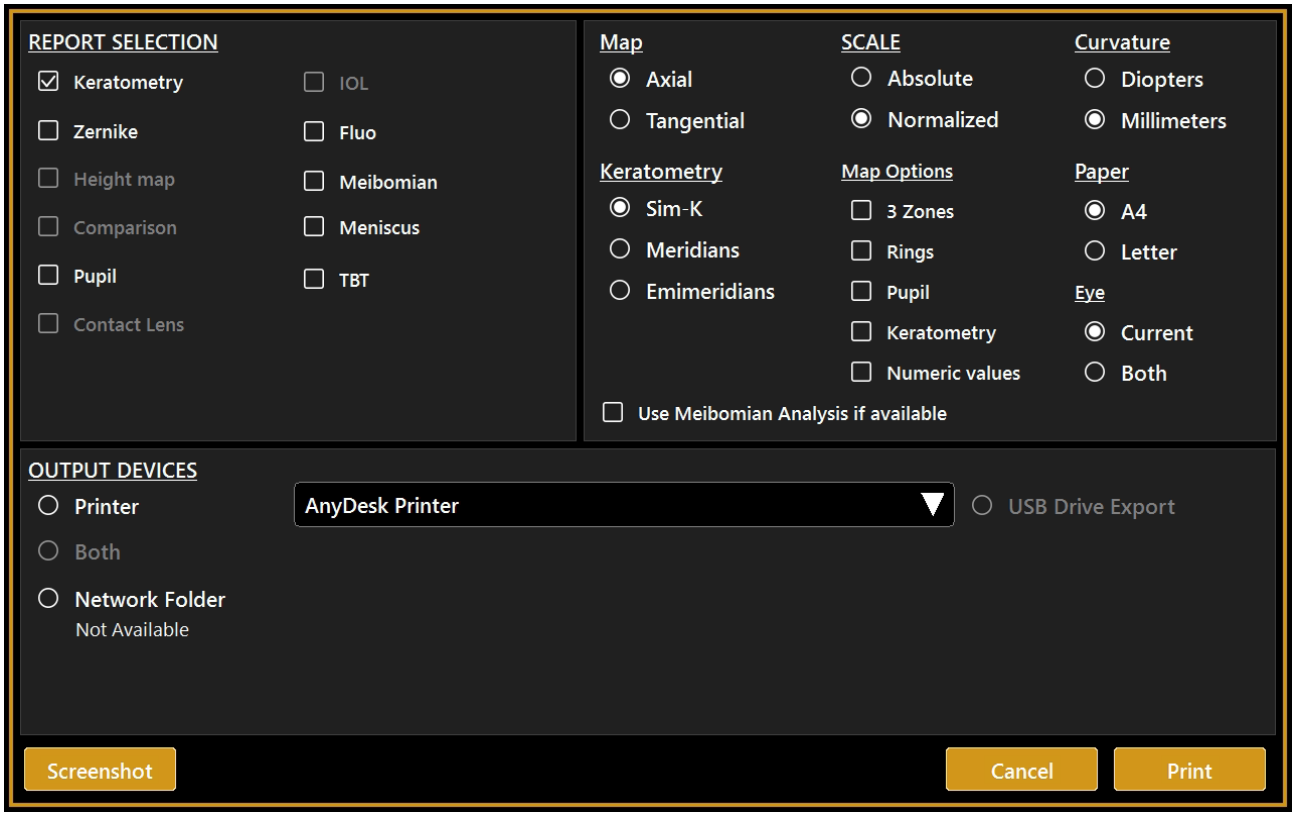


Fig. 74

[8] Different options between USB or folder selection are present on CA-800 or i-MAP respectively

15.2 Saving the examination data

After completing some acquisitions, in order to save the data from the examination, tap on the home button. As shown in Fig. 75, 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.

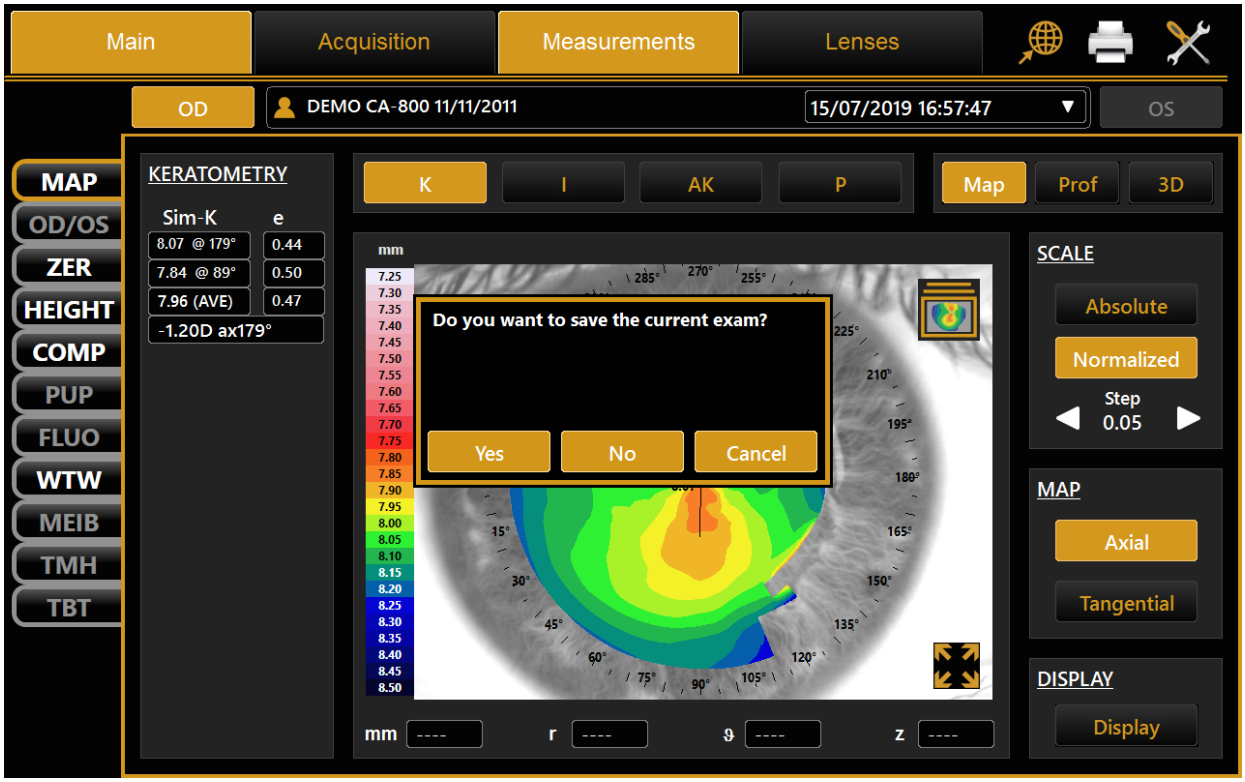


Fig. 75

16 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.

16.1 Contact Lenses

Note: This function calculates the difference between the patient's corneal shape measured by CA-800 and the shape of the contact lens provided by the lens manufacturer under the setting which you set up in advance, and visualizes the calculation results.

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

The contact lenses module (Fig. 76) simulates contact lens positioning.

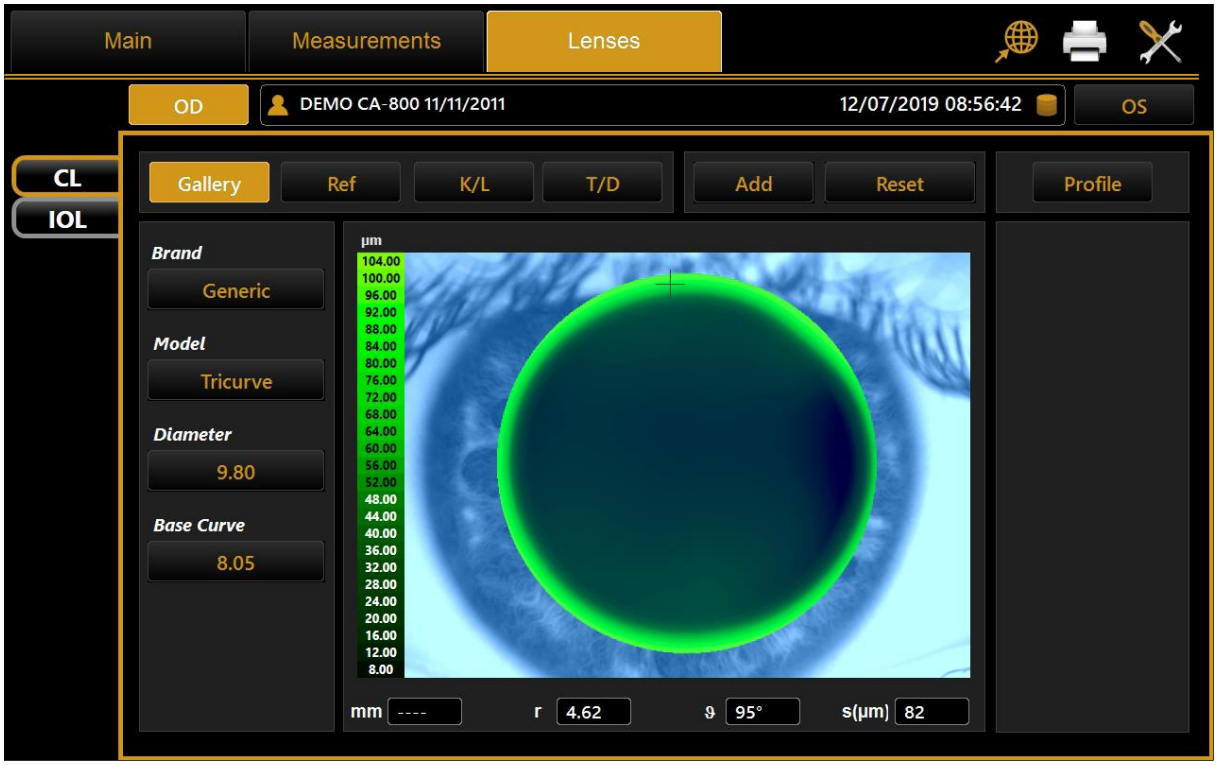


Fig. 76

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

There are four main sections in the contact lenses module:

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

16.1.1 Gallery

From this section, is possible to select the brand, the model, the diameter and the base curve of the lenses (Fig. 76) 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.

16.1.2 Ref

In the ref section the user can see the sphere, the cylinder, the axis and the VD of the selected lens (Fig. 77).

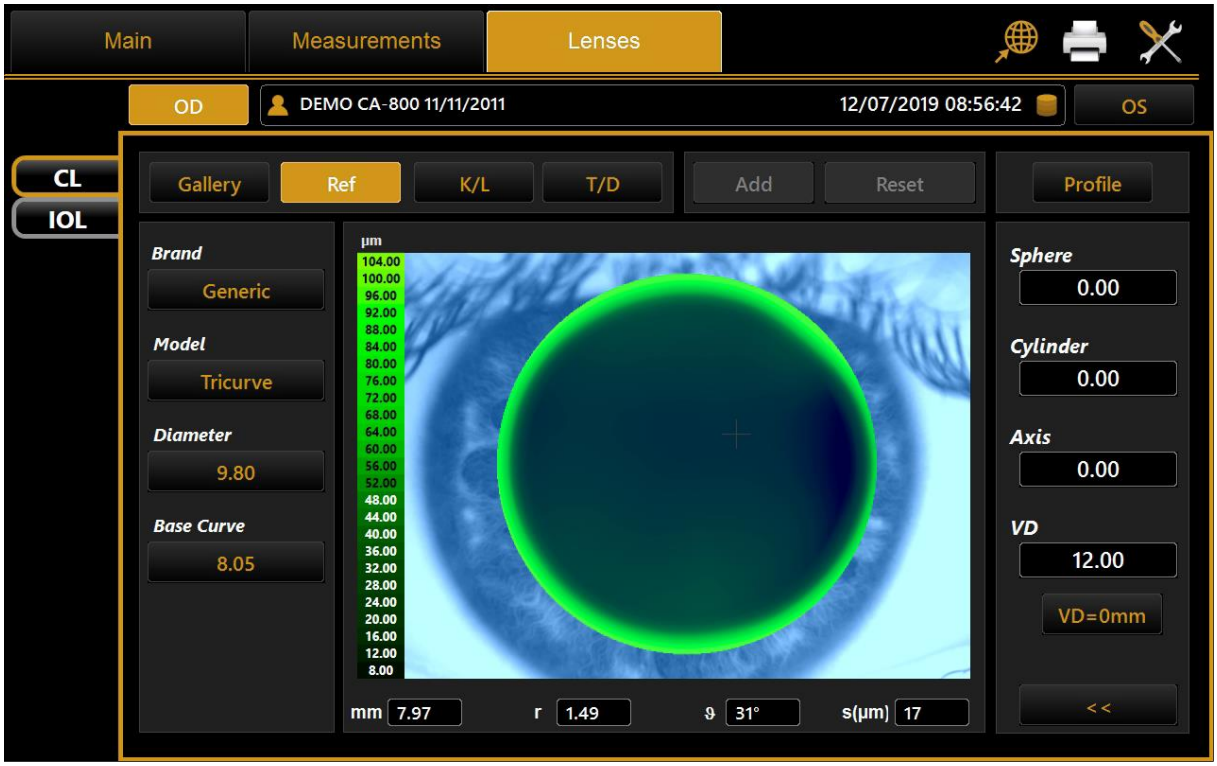


Fig. 77

In this section it is also possible to edit these values by pressing the button found under the values: a tab will appear (Fig. 78) and the user will be able to edit the values by pressing the relative arrows found at the right of the value.

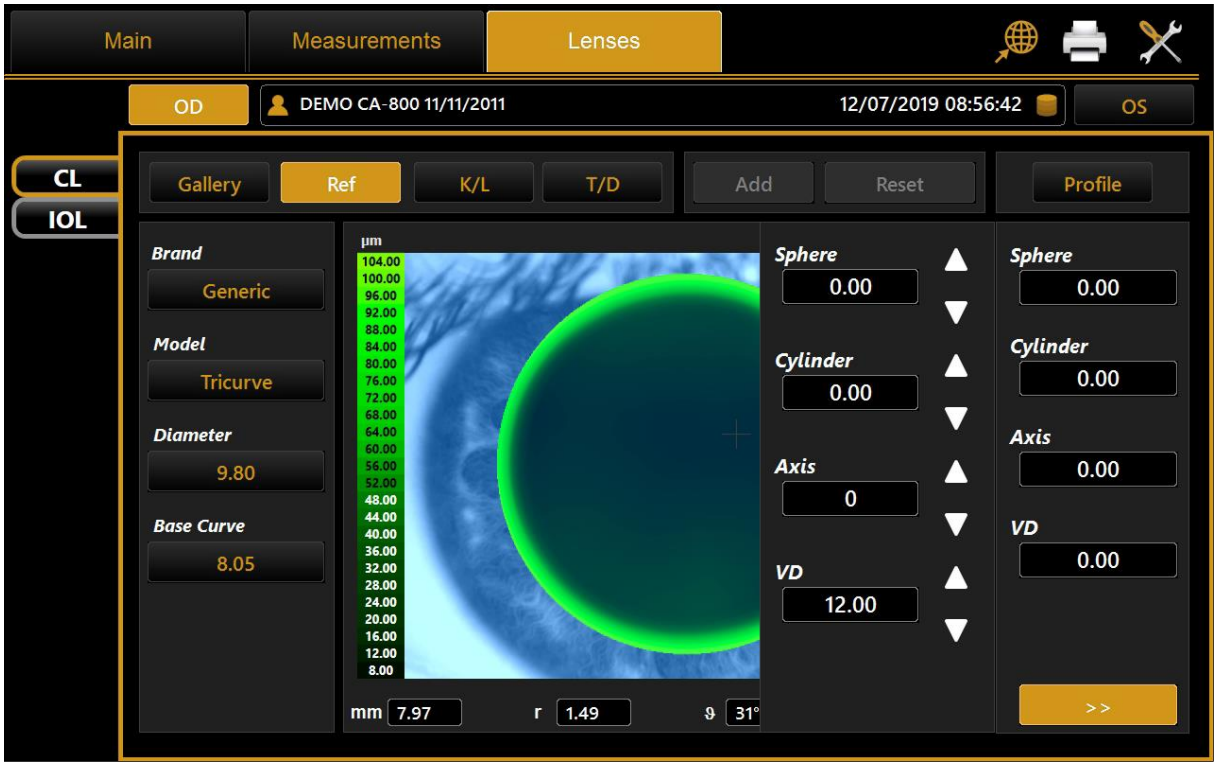


Fig. 78

16.1.3 K/L

This section displays information about the patient's eye (Fig. 79) and namely:

- Keratometric data.
- Corneal diameter

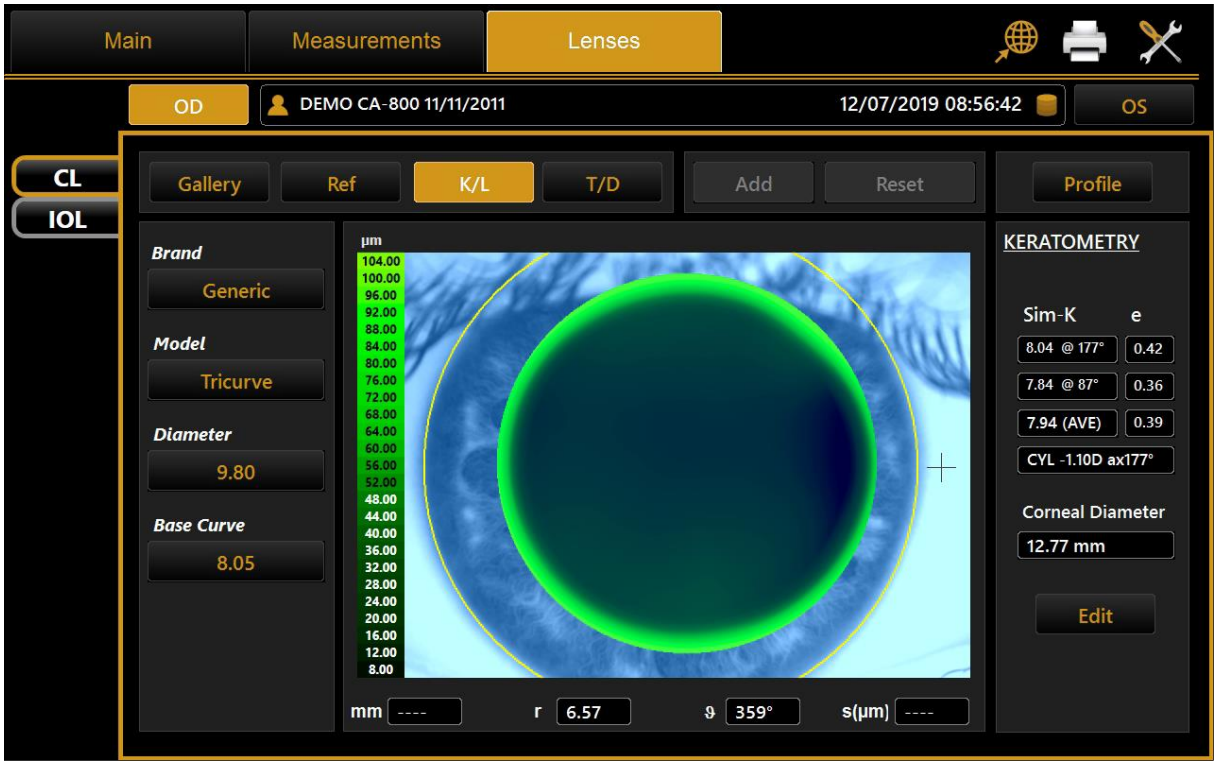


Fig. 79

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.

16.1.4 T/D

This section displays tilting and decentration of the selected lens (Fig. 80).

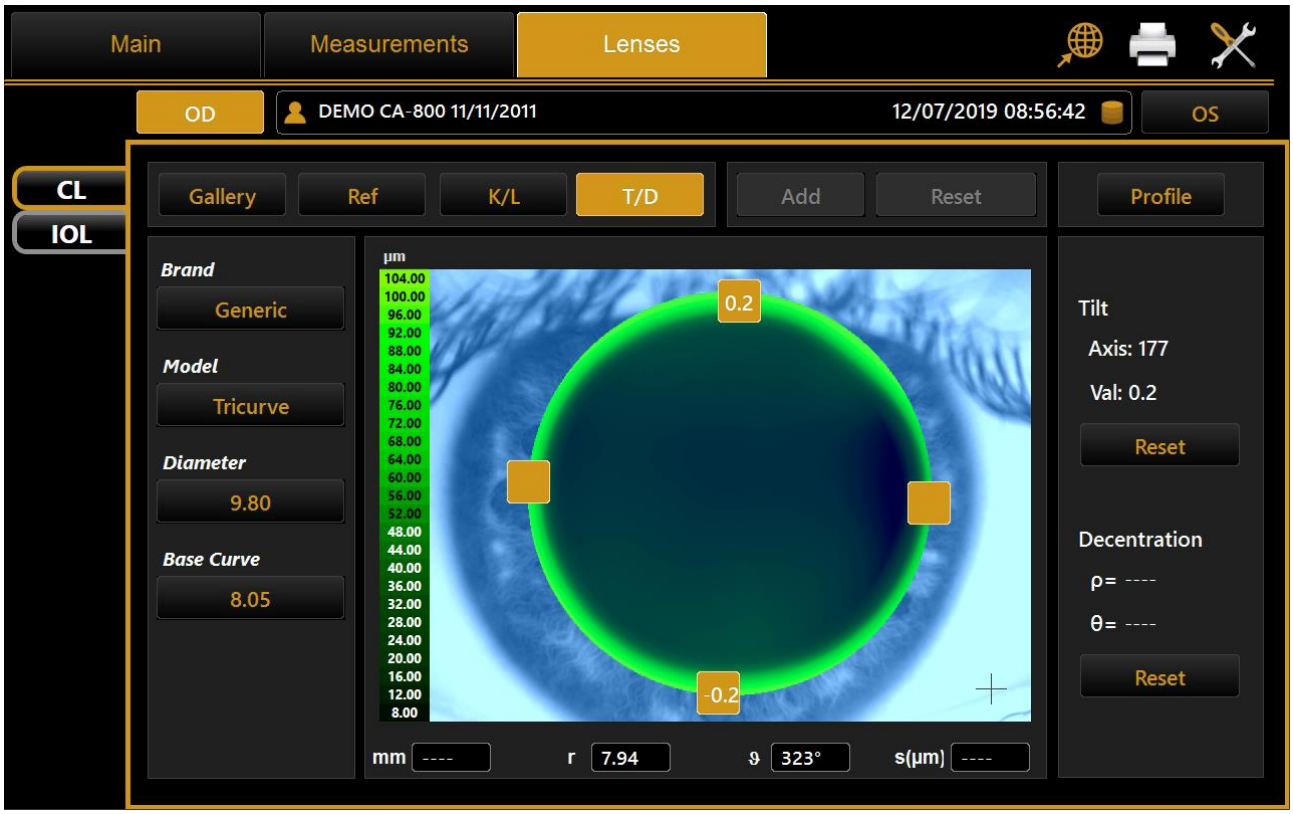


Fig. 80

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

16.1.5 Profile

In the profile section, the user can see the distance between the selected lens and the patient's cornea in a graph (Fig. 81).

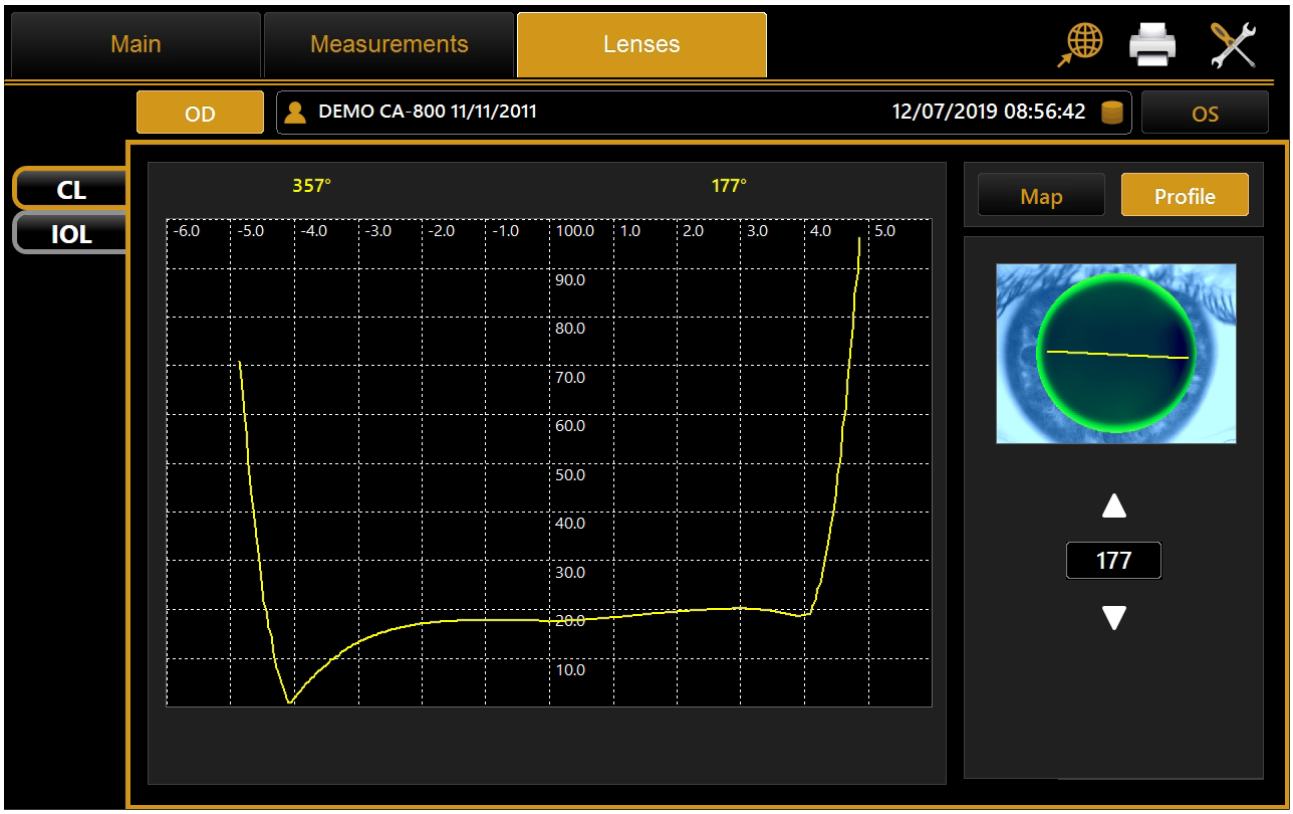


Fig. 81

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

16.2 Optional: Toric Intraocular Lenses calculation (toric IOL)

The Toric IOL software module is the tool to calculate 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)

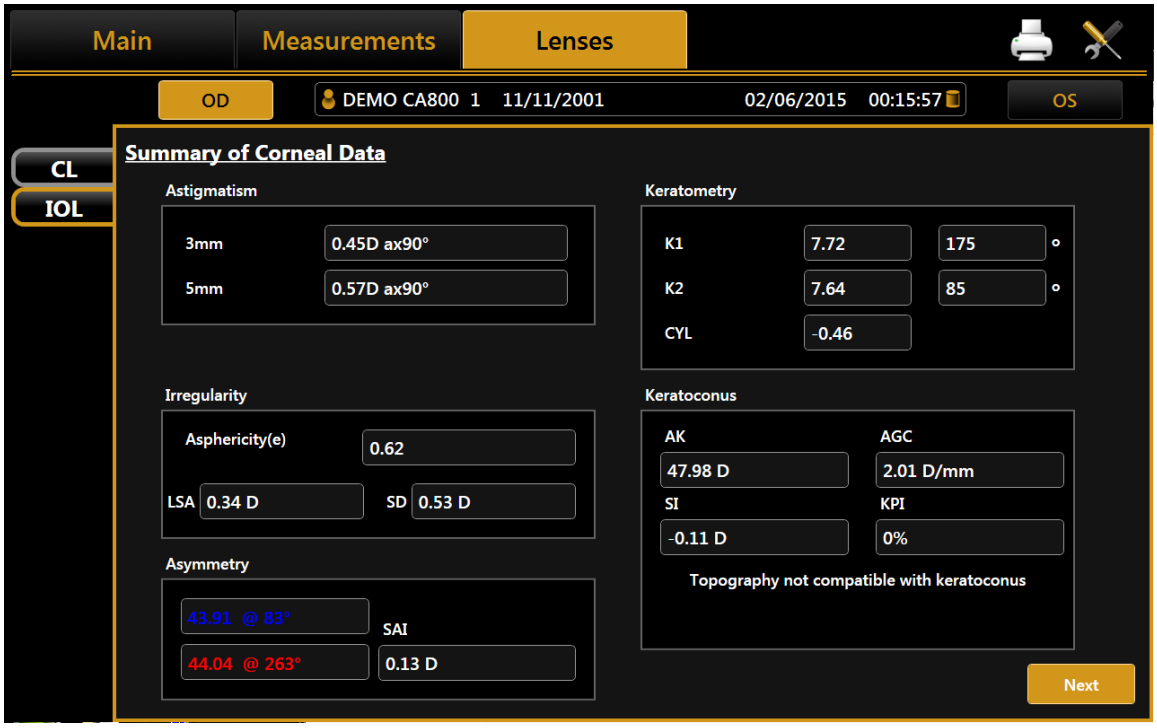


Fig. 82

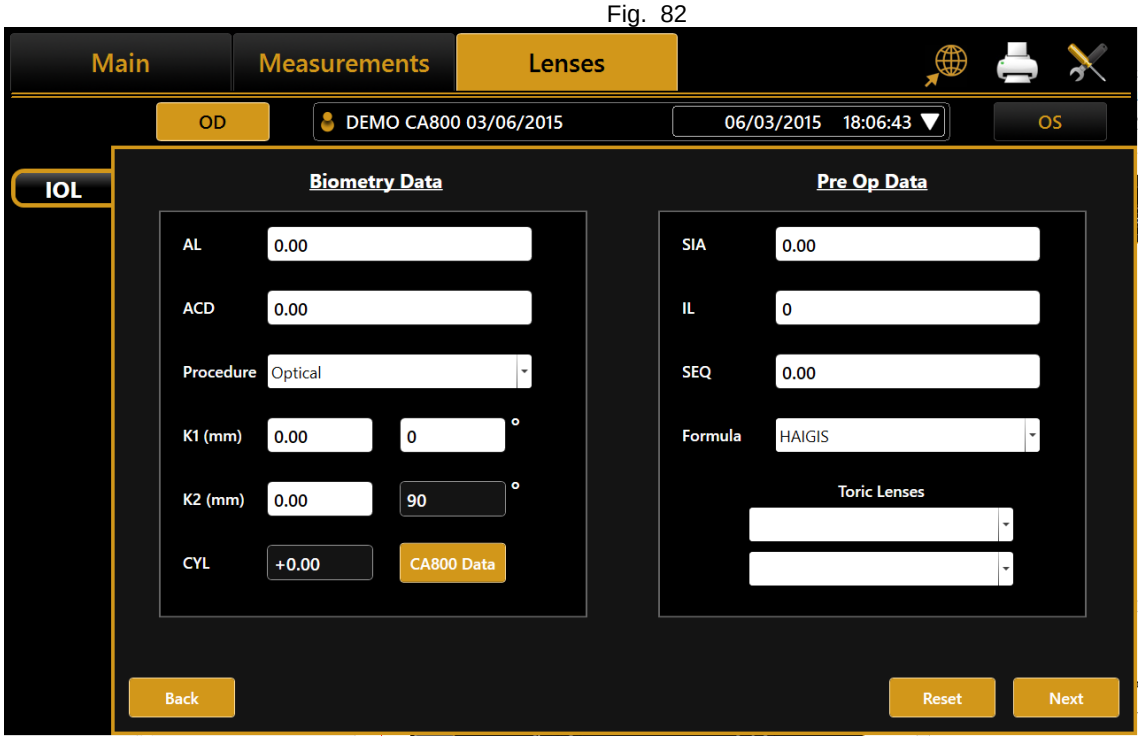


Fig. 83

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.

16.2.1 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”.

16.2.2 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: can be automatically filled from data measured by CA-800 using “CA-800 Data” button
- **K2** value: can be automatically filled from data measured by CA-800 using “CA-800 Data” button
- Cylinder value (CYL).

16.2.3 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 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:

- Oculentis LS – 313 Tx
- Oculentis LU – 313 T
- Oculentis LU – 313 TY
- Oculentis LU – 313 MF30T (X)
- Oculentis LU – 313 MF30TY (X)
- Oculentis LU – 313 MF30T
- Oculentis LU – 313 MF30TY
- Oculentis LU – 313 MF20T
- Oculentis LU – 313 MF20TY
- Oculentis LU – 313 MF15Tx
- Oculentis LU – 313 MF15T
- Oculentis LU – 313 MF15TY
- Alcon Acrysof SN6AT
- Hoya iSert Toric 351
- AMO Tecnis ZCTx
- HumanOptics Torica –aA Standard
- HumanOptics Torica –aA Extended
- HumanOptics Torica –aA Special
- HumanOptics Torica –aAY Standard
- HumanOptics Torica –aAY Extended
- HumanOptics Torica –aAY Special
- Rayner RayOne RA0610T

16.2.4 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. 84).

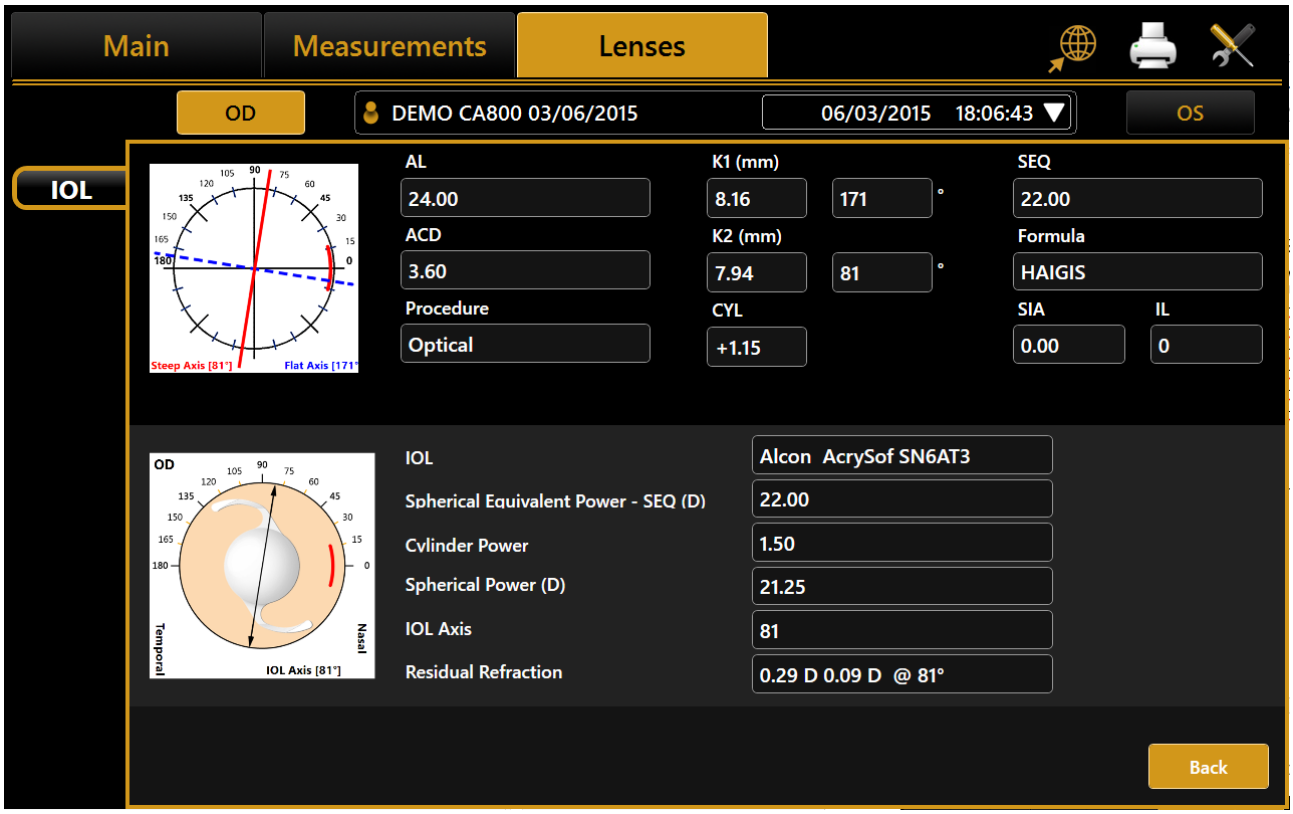


Fig. 84

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.

17 SETTINGS

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

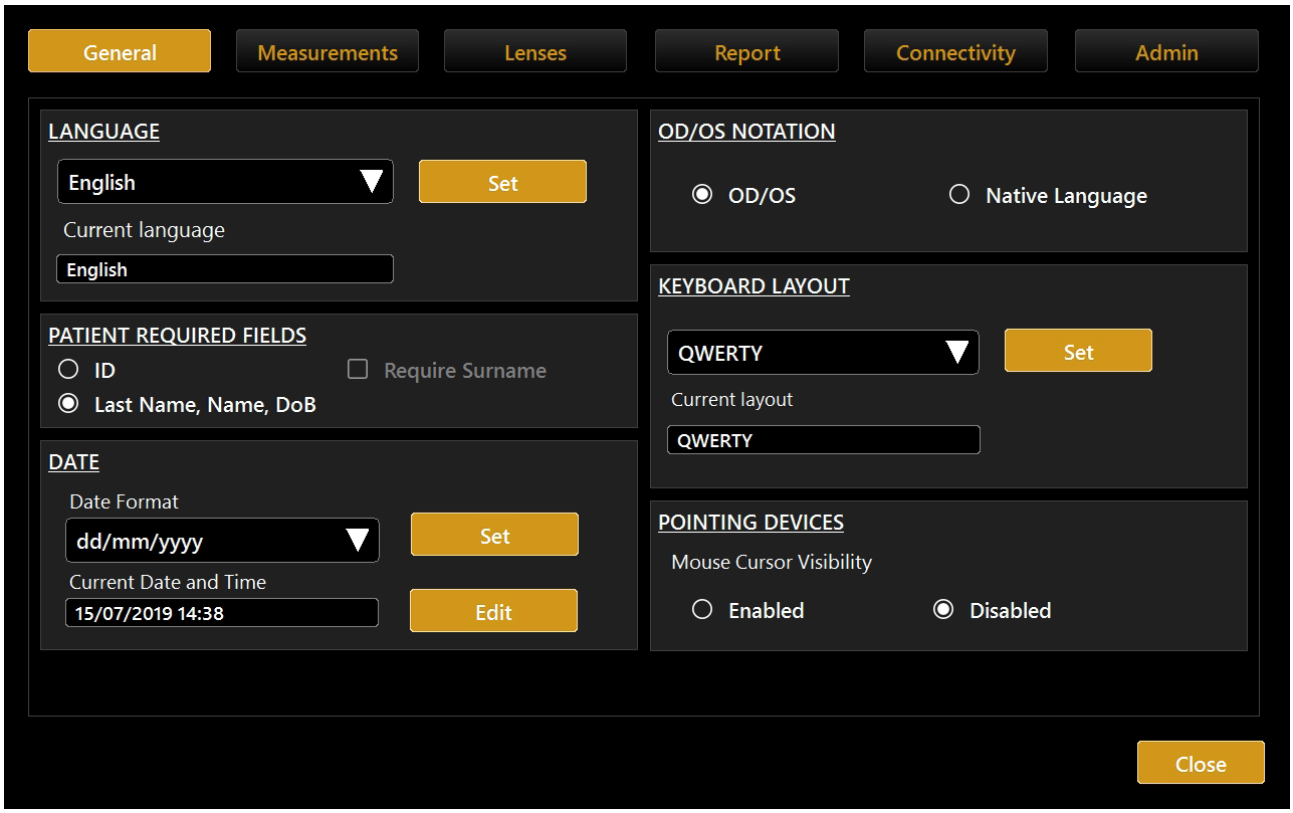


Fig. 85

The settings screen is divided into the following categories.

- General
- Measurements
- Lenses
- Report
- Connectivity
- Admin

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

17.1 General

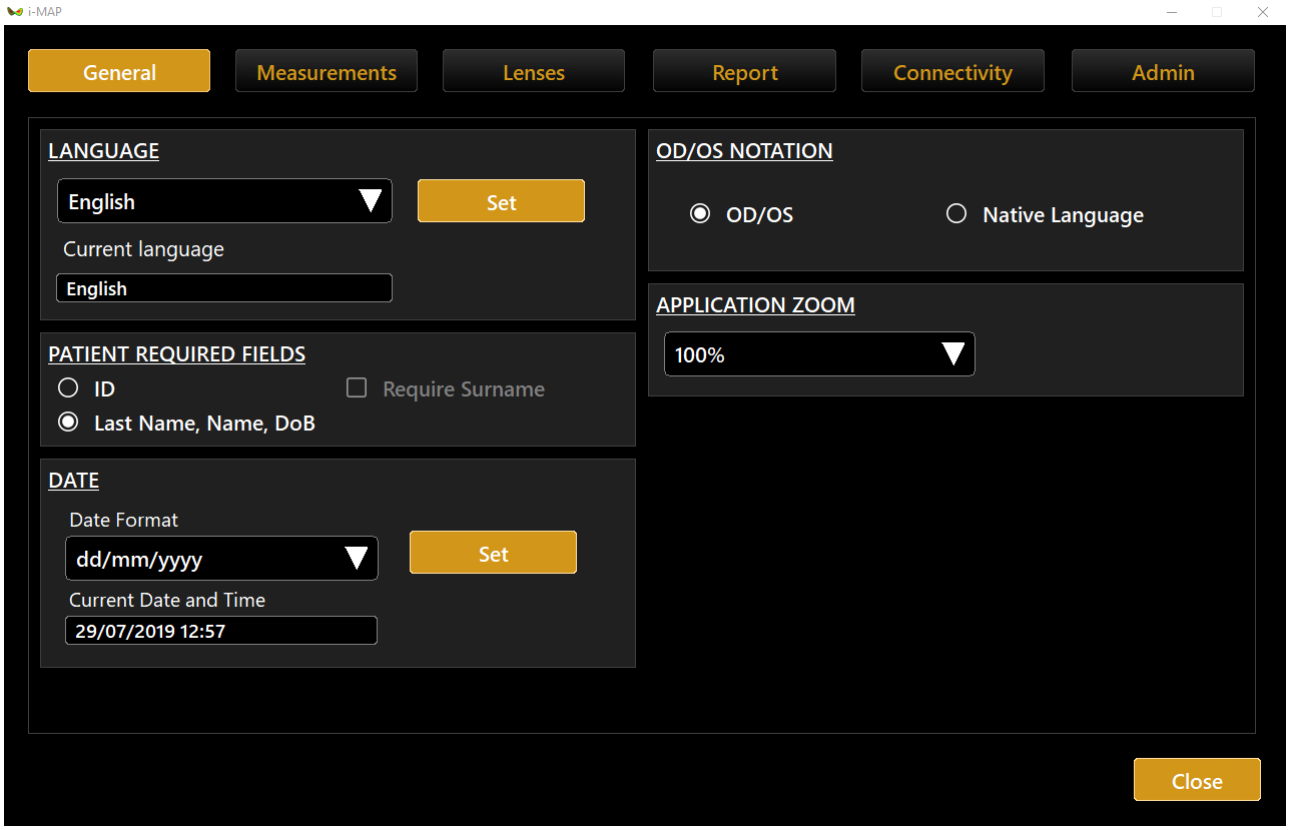
Refer to Fig. 85:

- **Language:** The first time the program is started, the default language is set to English and the keyboard layout is "QWERTY". To change the language settings, select the desired language from those that appear by tapping on the ⇓ button, press ***"Set"*** to set the chosen language for automatic starting. It is recommended to reboot the device to apply all the settings.
- **Keyboard Layout:** To change the keyboard layout, select the desired layout and press ***"Set".*** You can display the updated layout in the personal details window **("Main").**

- **Date:** Choose the desired date format and press the “Set” button. You can also set the current system date and time by tapping on the “Edit” button.
- **Pointing Devices:** Toggles the mouse cursor on or off.
- **OD/OS Notation:** To select how to indicate the eye being acquired in two different notations. The option OD/OS shows the Latin notation. The local language option shows the terms used for the left and right in the language set for the device.
- **Patient Required Fields:** Toggles between two different options of required fields for creation of new patient’s details. With ID only the ID is the only required field to insert when creating a patient. With this option the patient list is by default shown by ID (can be changed to Surname and Name in the patient list view). If you select the option “Require Surname” (available only with the “ID Only” working mode), the software requires the surname when entering the patients details.

17.1.1 i-MAP Application window size option[9]

On i-MAP it is possible to change the window size to factor different from 100% (**Application Zoom**). Choose the desired size factor and reboot the application to get the new factor applied.



[9] Not available in CA-800 on-board application

17.2 Measurements

The acquisition settings panel allows you to set the parameters for displaying the corneal map and acquiring and displaying fluorescein and pupillometry (Fig. 86).

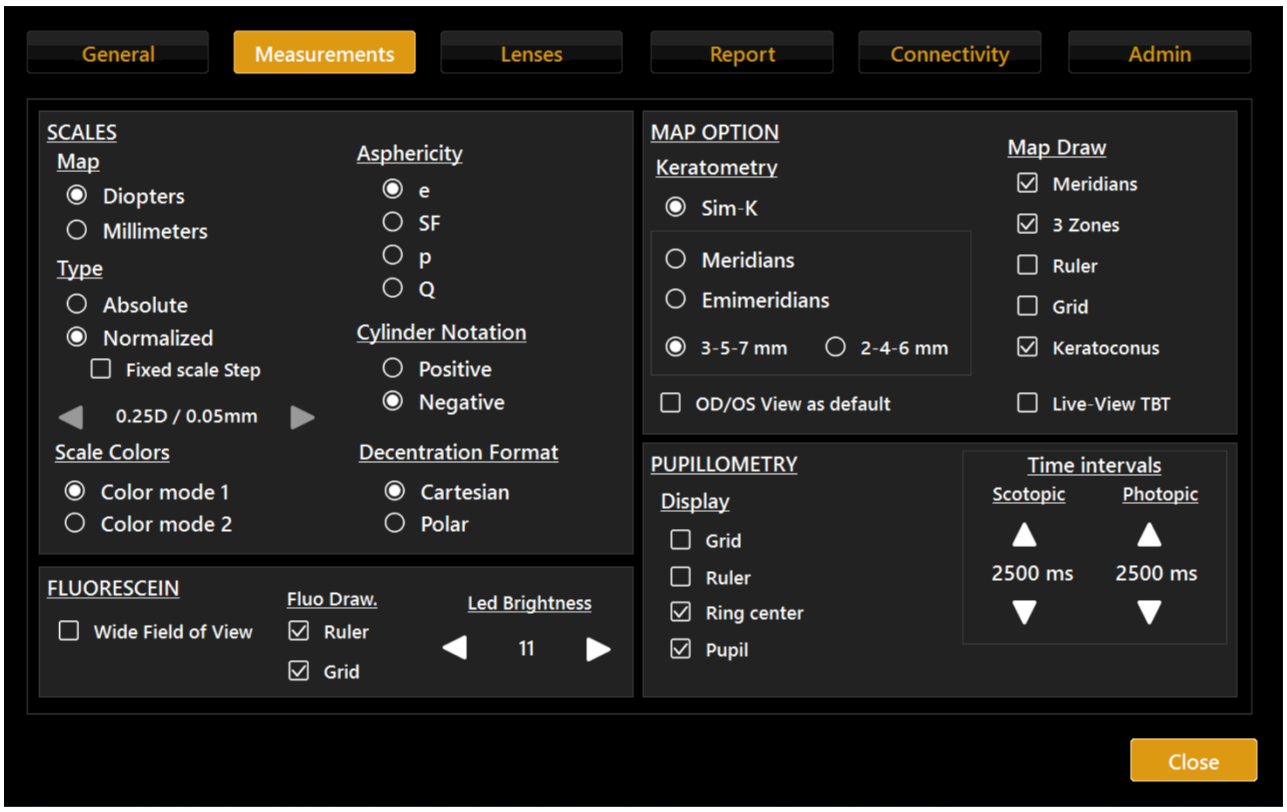


Fig. 86

17.3 Scales

Map

Select a unit of measure:

- Diopters
- Millimeters

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

Type

Select a scale type:

- Absolute
- Normalized

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

Asphericity

Select an asphericity unit of measure:

- e
- SF
- p
- Q

Cylinder Notation

Select a notation for cylinder calculation:

- Positive
- Negative

Scale Colors

Select between two color scales options:

- Color Mode 1

(Absolute scale)

- Color Mode 2

(Absolute scale)

Decentration Format

Select a decentration format:

- Cartesian
- Polar

17.4 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 0 to 11.

17.5 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.

17.6 Map Option

Map Draw

Select one or more items to customize the map display:

- Meridians
- Zones
- Ruler
- Grid

Keratometry

Select one of the keratometric indexes:

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

Live-view TBT

Option to disable the live-view detection (i.e. overlapping green/yellow/red coloured scale layout) during the TBT acquisition (PLEASE NOTE: available starting from SW V.1.6.8).

OD/OS view as default entry point:

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

17.7 Lenses

Allows you to manage your own lenses database (Fig. 87).

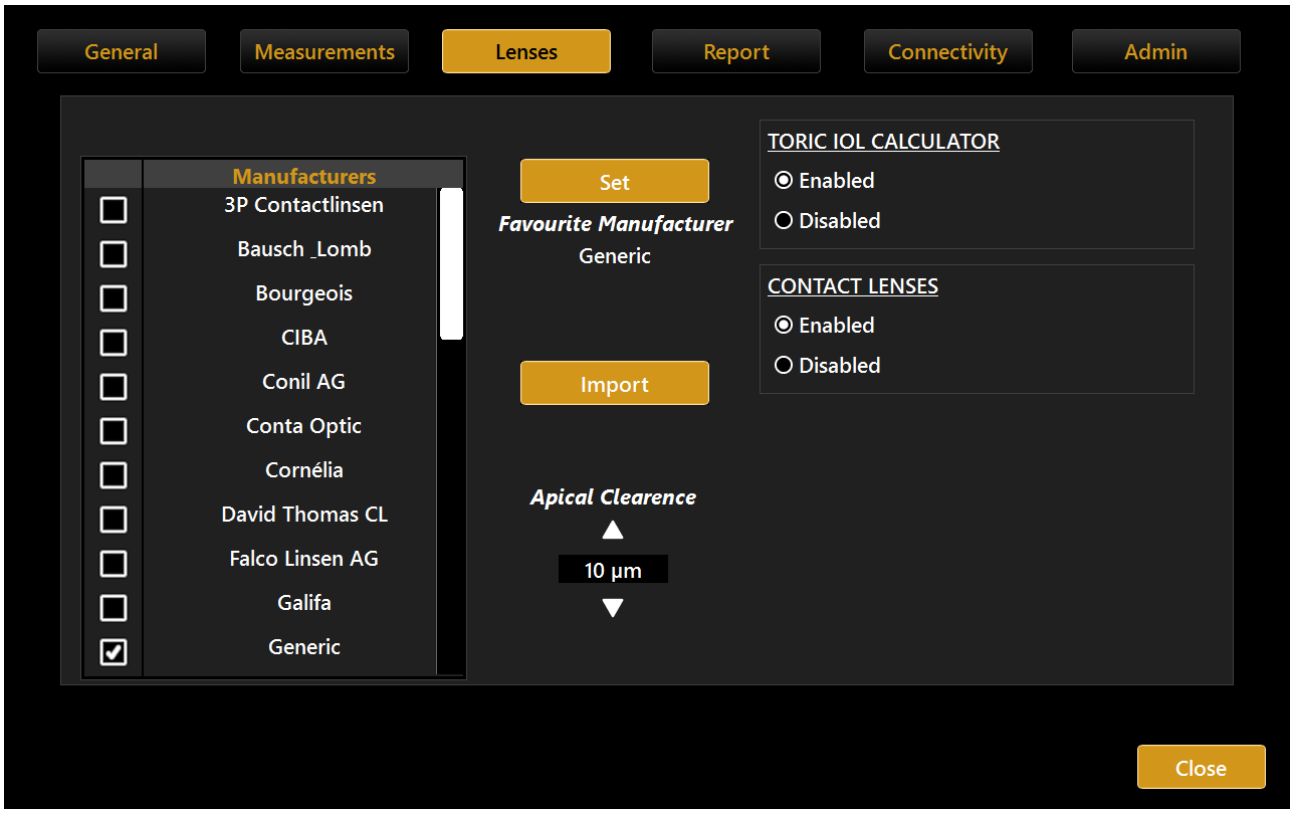


Fig. 87

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 (**Toric IOL Calculation**).

17.8 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. 88).

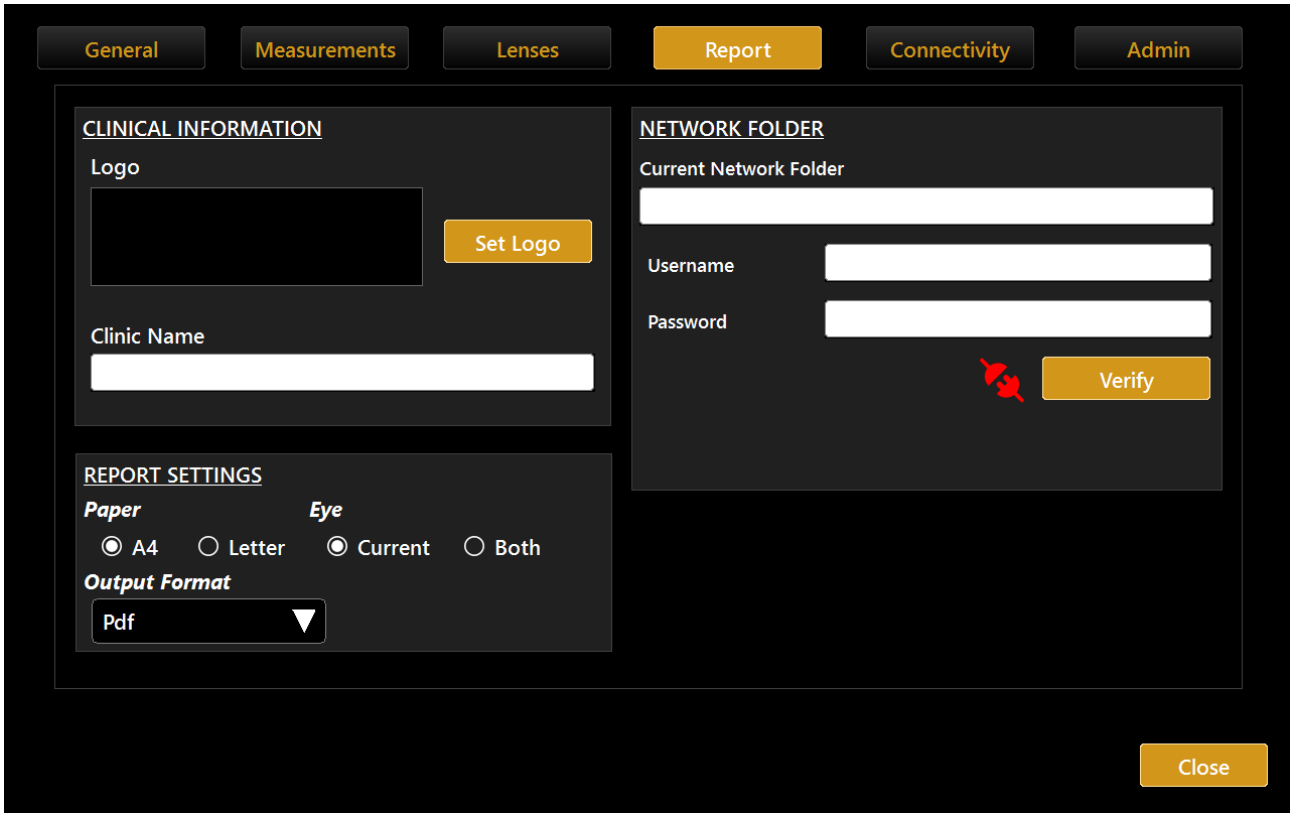
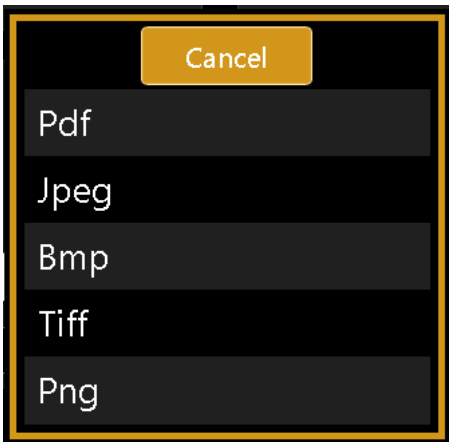


Fig. 88

17.8.1 Report Settings

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

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



17.8.2 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

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

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

e.g.,

domain_name\user name

- ***Password***: for the specified user name

Tapping on the ***"Verify"*** button, the system starts searching for the network resource. This procedure may take some time, depending on the network. Failure or success to connect to the network resource will be reported as shown in Fig. 89 and Fig. 90. A connection failure may be due to an unreachable resource path or to wrong credentials.

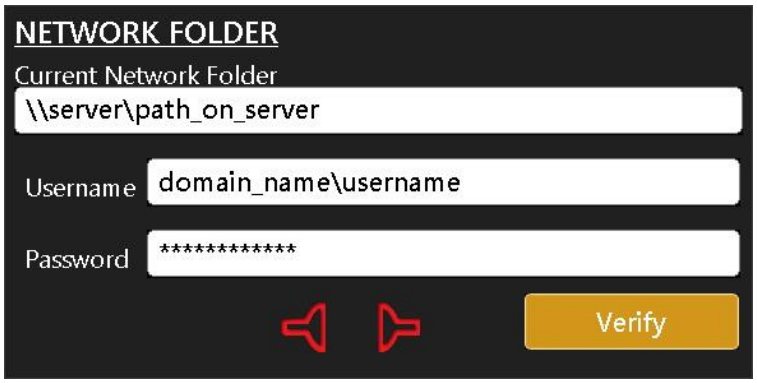


Fig. 89

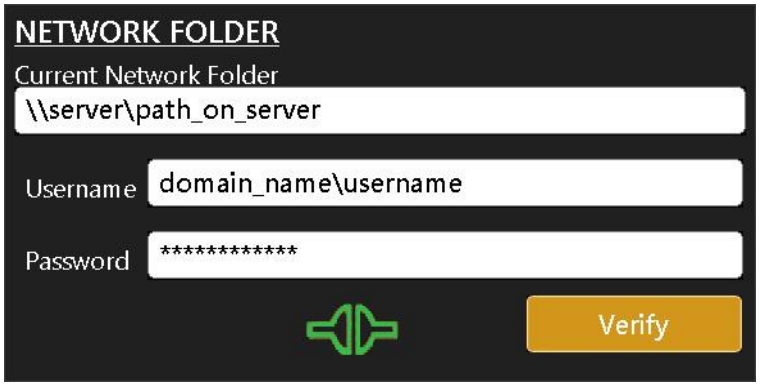
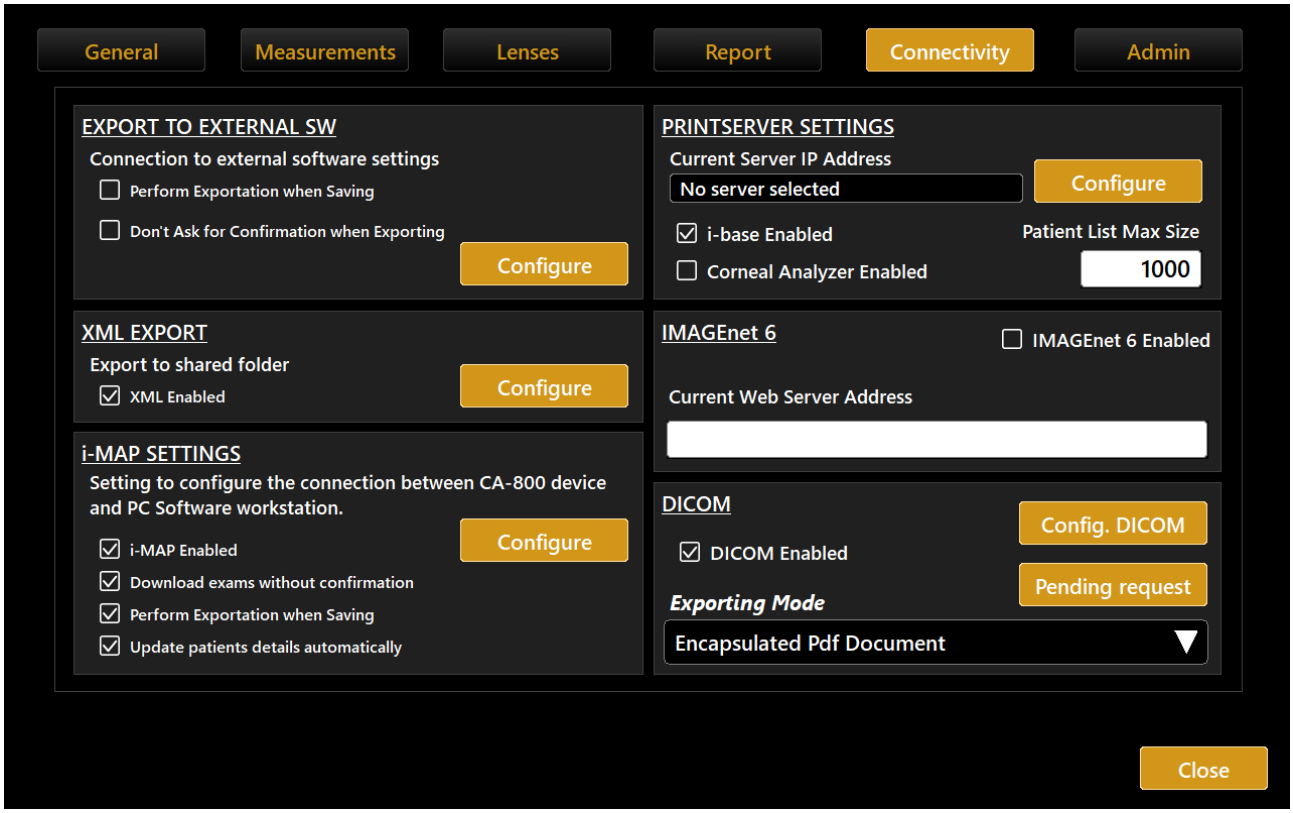


Fig. 90

17.9 Connectivity



17.9.1 i-MAP Settings

In this section it is possible to enable and configure the connection of the current **i-MAP Network Instance**.

Refer to section 12.8 for Basic configuration and usage of **i-MAP network**.

- "**i-MAP Enabled**": this option activates/de-activates the connectivity of the current CA-800 or i-MAP to participate in the i-MAP Network. If enabled this instance will be discoverable by other instances. If disabled this instance will be disconnected from i-MAP network.
- "**Download exams without confirmation**": this option, if checked, allows to download remote exams without further confirmation message when pressing "Open" button in the exams list
- "**Perform Exportation when Saving**": [10]this option, if checked, allows to get a new exam (or a modified one) exported automatically to the defined "**Export destinations**" (see following section)
- "**Update patients details automatically**": this option, if checked, allows to automatically update patients details when search patients over the network, checking if somewhere, these details were changed.
- "**Configure**" button allows to open **i-MAP Settings panel**

17.9.2 Customize i-MAP network instances behaviors (i-MAP Settings panel)

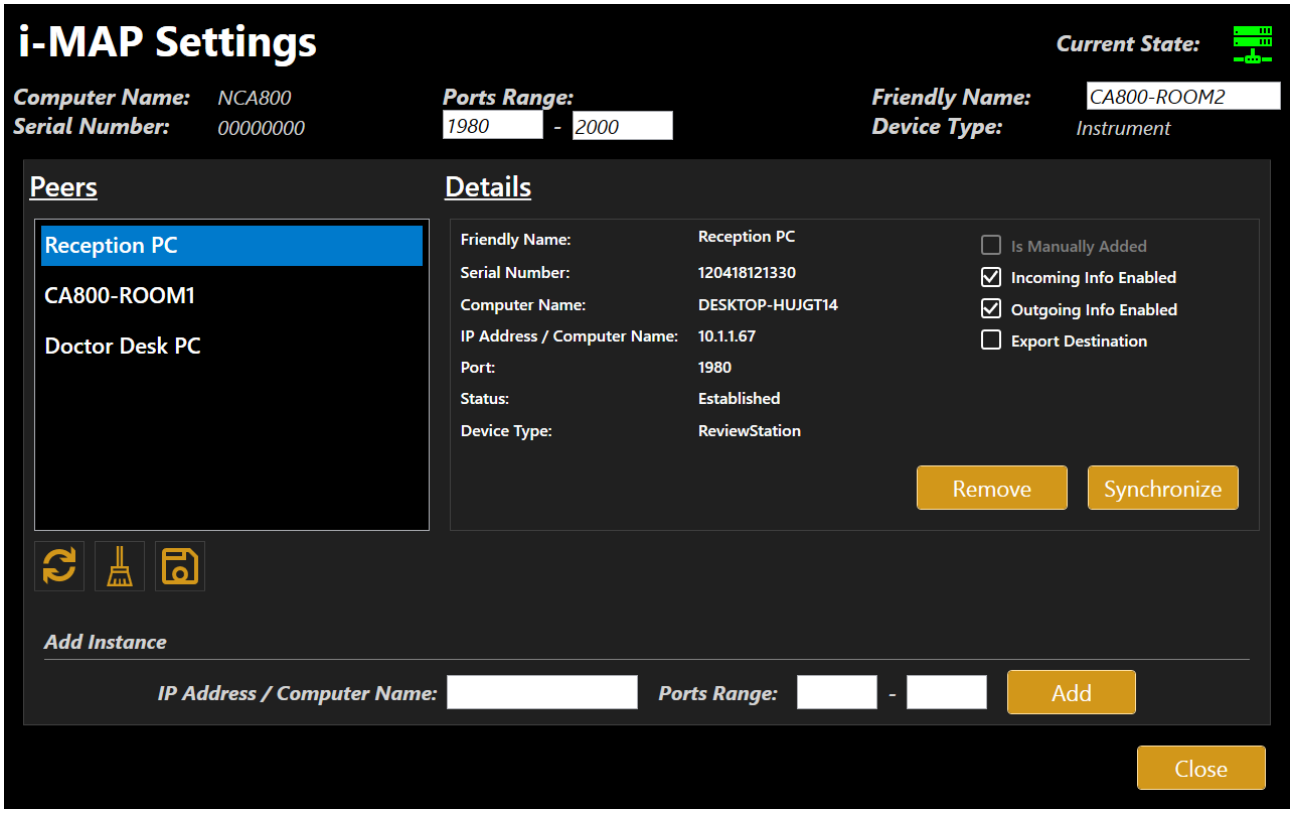
i-MAP Setting panel allow to customize the connectivity parameters for the current i-MAP Network Instance and its behavior in relation to the other i-MAP Network instance connected.

[10] This option is available only for CA-800

The top bar of the panel gives access to information of the local i-MAP Network instance (“this i-MAP Network instance”).

- **Ports Range**: allows to edit the port range which this i-MAP Network instance can use for the i-MAP Network connectivity service. The default ports range is from 1980 to 2000. Depending on the LAN configuration it could be necessary to refer to network administration staff
- **Friendly Name**: shows and allows to edit the friendly Name with which this i-MAP Network instance shows itself to the other instances. By default the value is the Computer Name.
- **Serial Number**: is the serial number of the CA-800 device (if this i-MAP Network instance is a CA-800) or the automatically generated SN at the time of installation in case of i-MAP SW instance.

As shown in the picture below, if you select an i-MAP network instance you can customize the relation behaviors and save the new configuration.



You can choose from which instance receive the data or to which instance send data by simply checking or unchecking the “**Incoming info Enabled**” and “**Outgoing Info Enabled**” check boxes.

The “**Export Destination**” option allows the user to export to one or more network entities when saving an exam or choose to export it, in order to stay up synchronized.

If you set one of these check boxes or set a custom ports range or change the friendly name, you have to press the “**Save**” button.

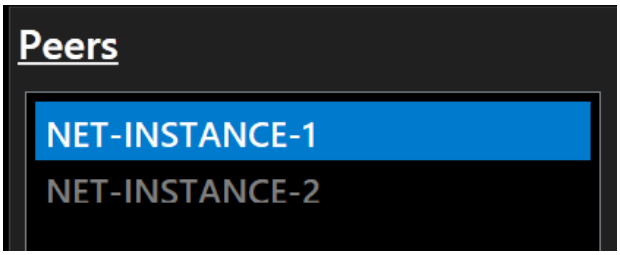
“**Save**” icon button in order to save this information.

“**Rescan**” icon button starts a new search of network instances on the network.

"**Clean**" icon button, cleans the current saved list (if present) and start a new search on the network.

"**Synchronize**" button allows to download new examination data from the selected instance to the local archive.

If a network instance was saved with a custom configuration and it's not more reachable will be shown in the list with a grey text color.



In the top-right corner there are some icons that allow the user to know if the application is connected.

The possible icons are:

Connected icon

Disconnected icon

Connecting animated icon

Manual configuration of and i-MAP network instance

When and i-MAP network instance (CA-800 or i-MAP application instance) is not automatically discovered, it is possible to add it manually by using the "Add Peer Manually" panel.

The first text box allows to insert the address of the i-MAP network instance you want to manually add (IP address or machine Name).

It is necessary to insert a port range in order to know on which port try to connect to.

17.9.3 Server List

Allows the user to enable or disable the server list and to set the maximum number of patients in the list when receiving results from Topcon Print Server.

It is possible to select between the corneal analyser and the ibase server and to set the ibase IP address.

17.9.4 Export to External Software settings

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

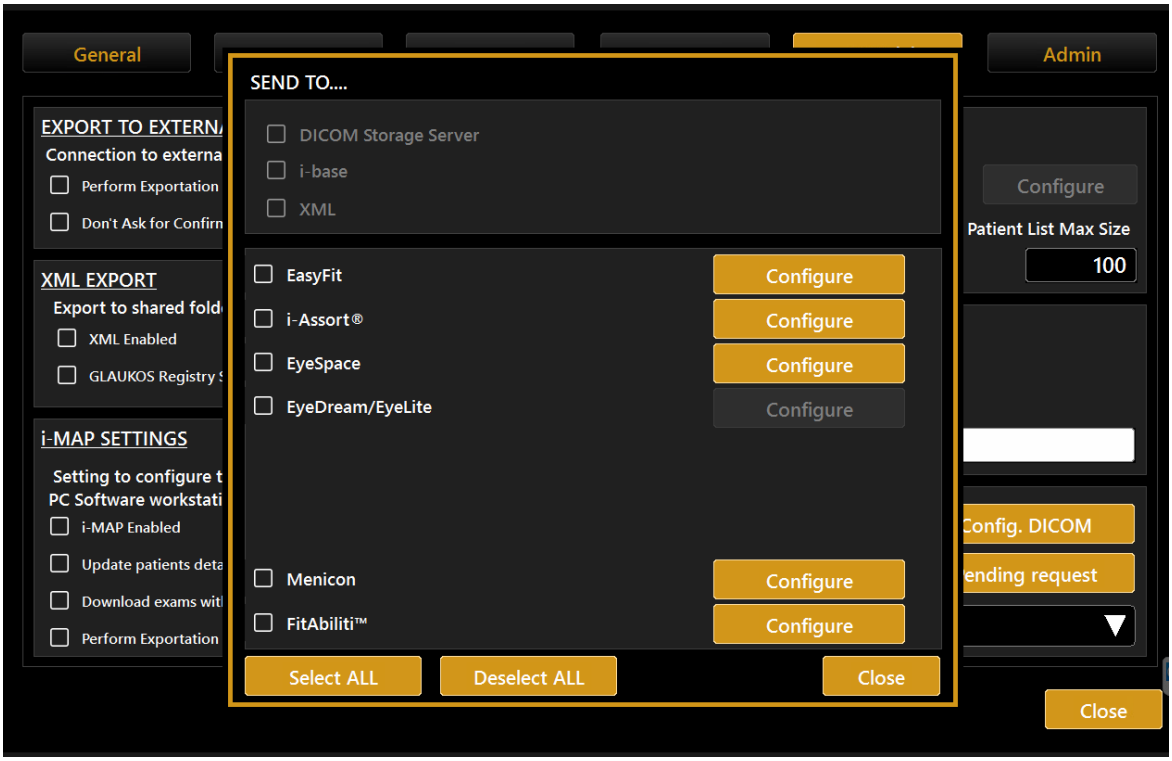
"*Perform Exportation when Saving*", allows to be prompted automatically the exportation form once saving a new or existing exam.

"*Don't ask for Confirmation when Exporting*", allows to skip the selection of targets when performing the exportation while saving or when pressing on the export button.

In this panel there is the possibility to choice between some external software, for example **EasyFit® (NLK EasyFit)**, **i-Assort®, EyeSpace™, EyeDream (No7 Contact Lenses)**, **Menicon and FitAbiliti™**.

It is also possible to access configuration (**"Configure"** button) of the other external software destinations which are not present in the other panels of this section.

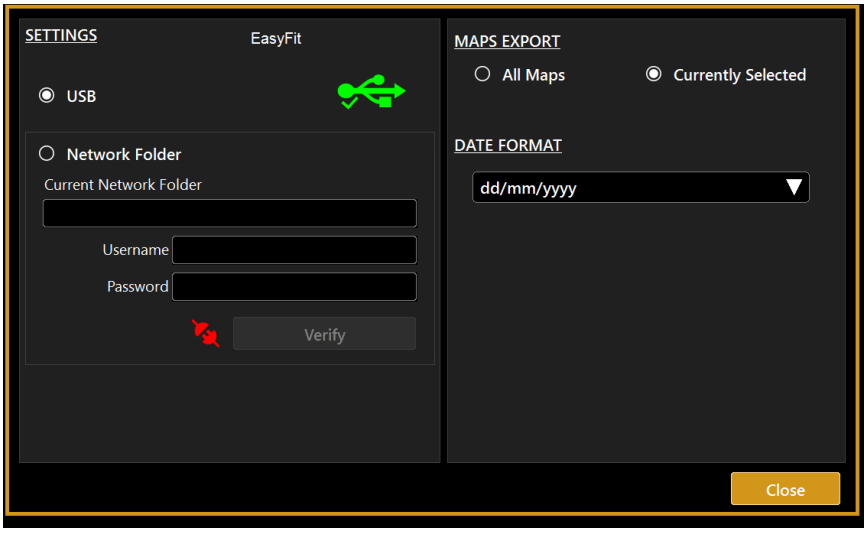
By activating the checkbox of an export destination, this is included in the targets of the exportation function.



EasyFit® (NLK EasyFit)

Exportation to EasyFit® it is an XML file with patient details and topography data that can be exported to USB pen drive or Network Shared Folder.

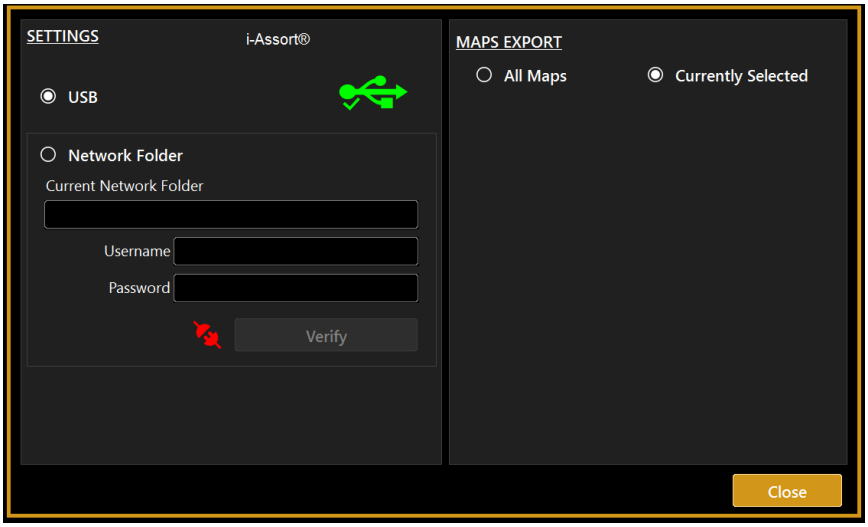
It can be chosen to export only the currently selected topography acquisition for each eye or all the acquisitions performed.



i-Assort®

Exportation to i-Assort® it is an XML file with patient details and topography data that can be exported to USB pen drive or Network Shared Folder.

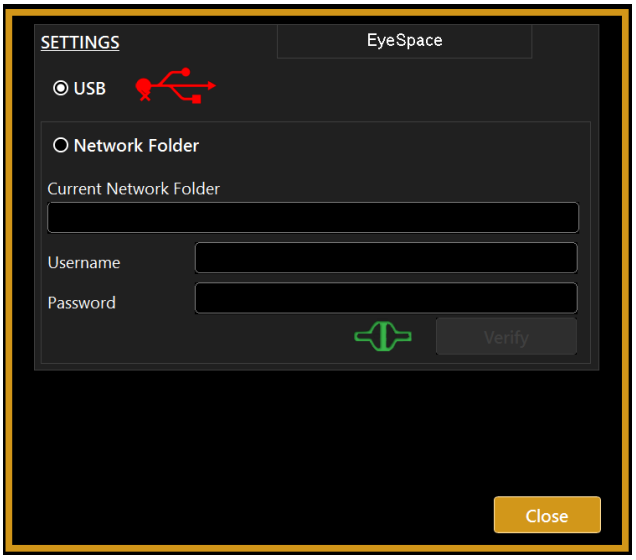
It can be chosen to export only the currently selected topography acquisition for each eye or all the acquisitions performed.



EyeSpace™

Exportation to EyeSpace™ it is a file with patient details and topography data that can be exported to USB pen drive or Network Shared Folder.

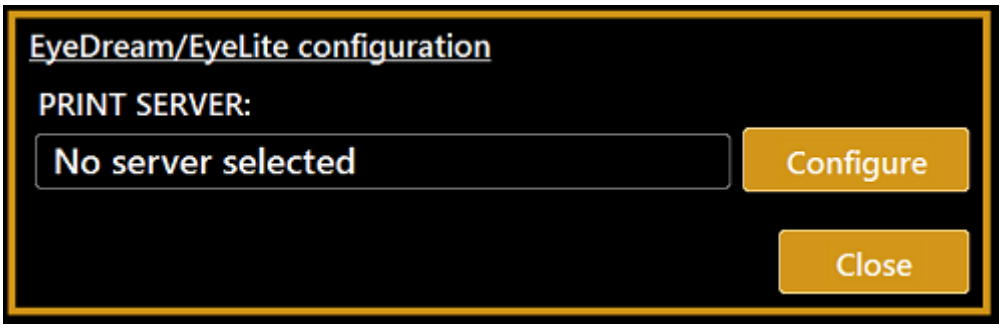
It is exported the currently selected topography acquisition for each eye.



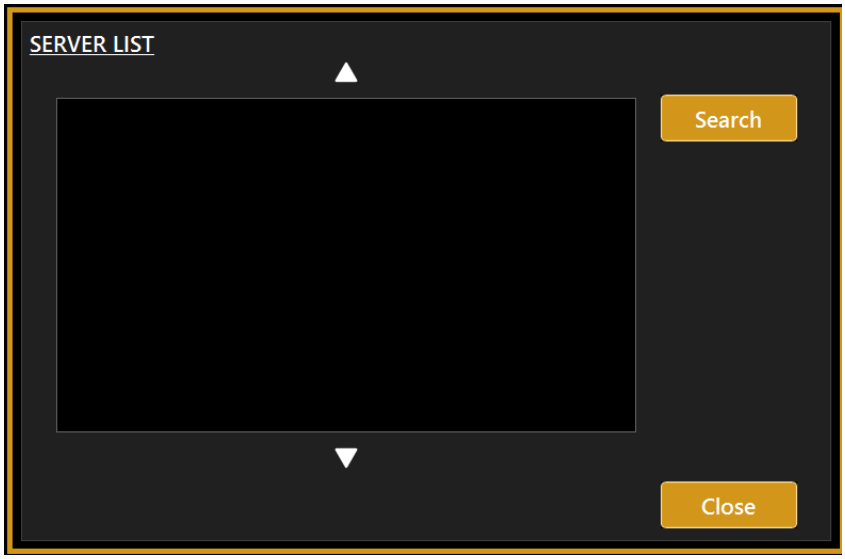
EyeDream/EyeLite (No7 Contact Lenses)

Exportation to EyeDream/EyeLite is performed through the network in combination with Topcon Print Server application(version 2.1.0.0 or later).

The Topcon Print Server application must be installed on the same PC station where the EyeDream/EyeLite software is installed.

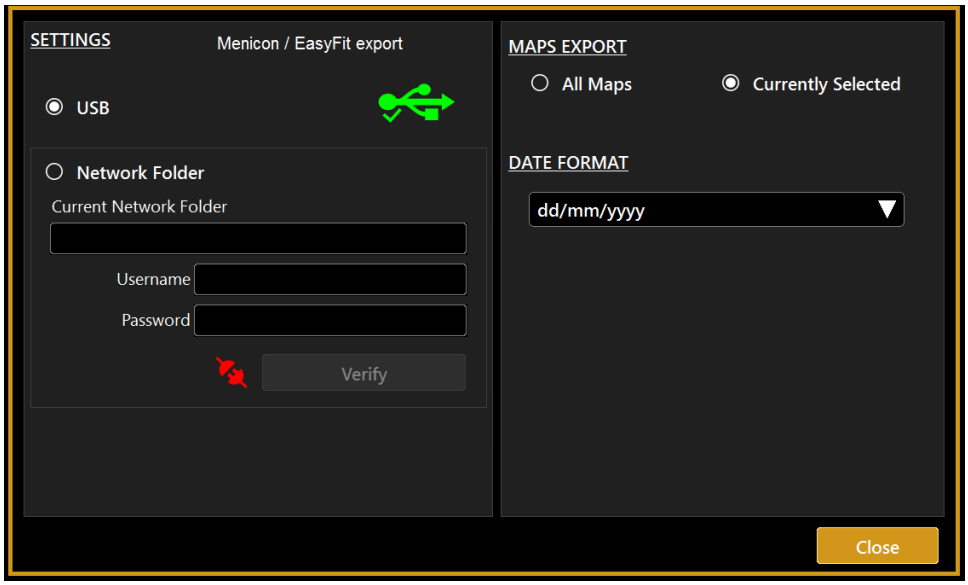


To match the CA-800 with the desired Topcon Print Server press on Configure button to search for the available Topcon Print Server instances in the local network. Select the desired IP and Close.



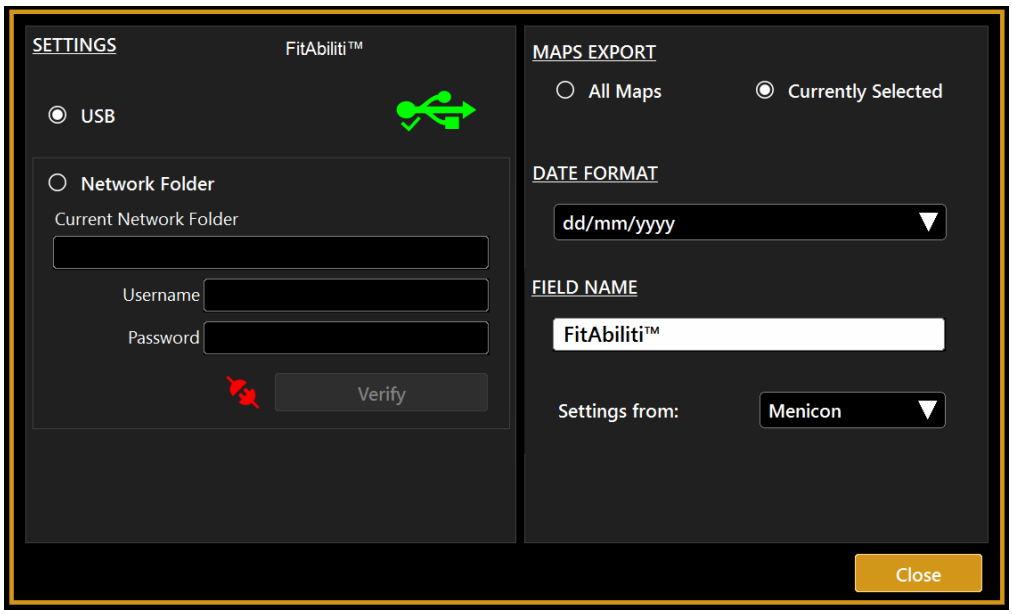
Menicon

Exportation to Menicon it is an XML file with patient details and topography data that can be exported to USB pen drive or Network Shared Folder.
It can be chosen to export only the currently selected topography acquisition for each eye or all the acquisitions performed.



FitAbiliti™

Exportation to FitAbiliti™ it is an XML file with patient details and topography data that can be exported to USB pen drive or Network Shared Folder.
It can be chosen to export only the currently selected topography acquisition for each eye or all the acquisitions performed.



17.9.5 XML Export

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

17.9.6 IMAGEnet 6 Server software

CA-800 can receive and transfer data to **Topcon IMAGEnet 6** Server through a wireless or LAN network. IMAGEnet 6 Server is activated by clicking on the Enabled Option and by providing the IP address of the external server we want to connect to. Once we have selected the proper IP, CA-800 is ready to exchange data with the IMAGEnet 6 Server machine (Fig. 91).

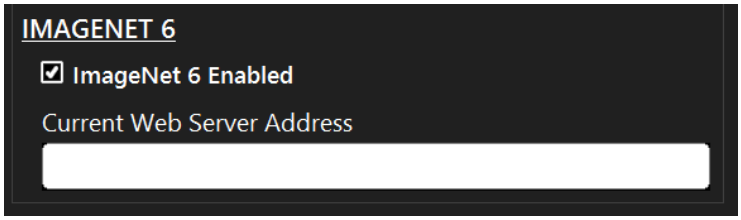


Fig. 91

17.9.7 DICOM

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

The available services are:

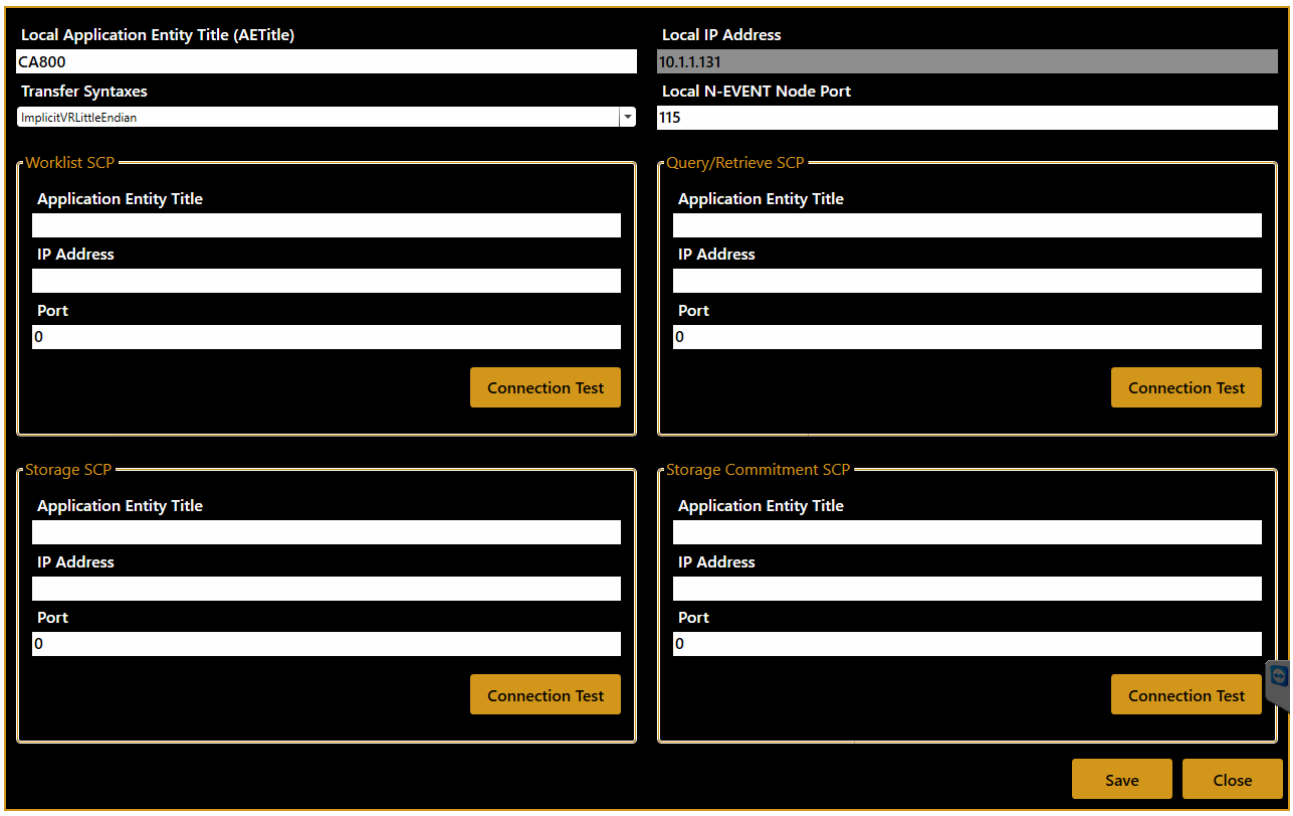
- **Modality Worklist**, The DICOM Modality Worklist service provides a list of imaging procedures that have been scheduled for performance by the acquisition device.
- **Patient Root Query,** This enables the device to find patient's details from a DICOM server.
- **Storage,** The DICOM Store service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

For each services the needed parameter are:

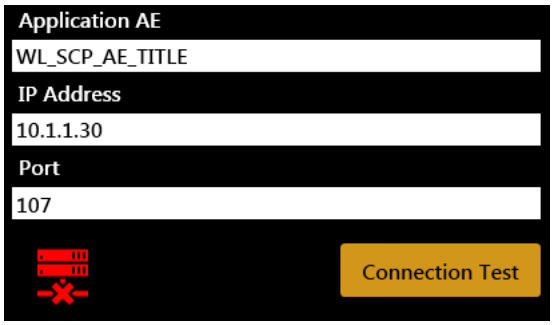
- Remote Application Entity (AE) title
- Remote IP address
- Remote connection port

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

The **"*N-EVENT Report node port*"** is the port at which the device is able to receive N-EVENT REPORTS for storage commitments (default is 115).



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



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

The DICOM module of CA-800 is describe in detail in its **DICOM Conformance Statement**. For more information refer to your local distributor.

17.10 Admin

This is the instrument administration panel (Fig. 92).

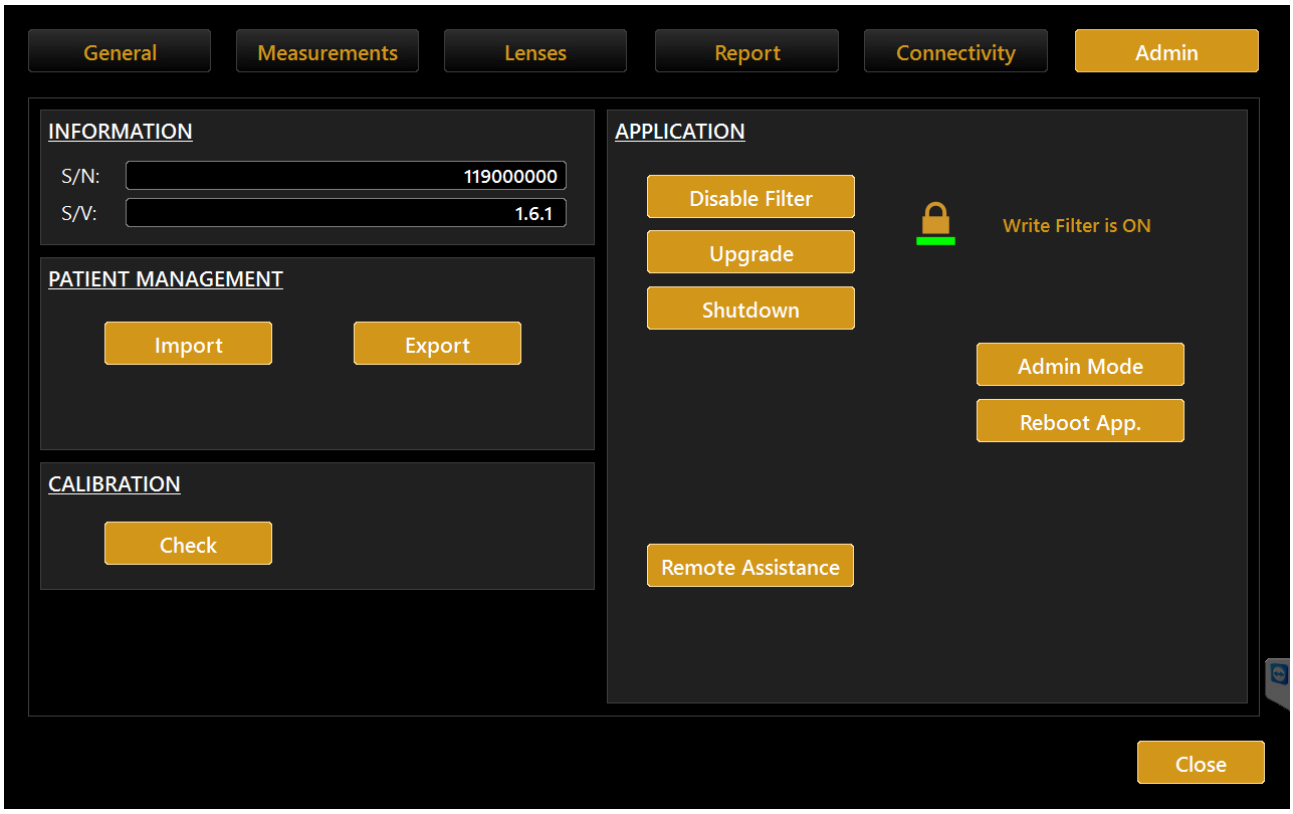


Fig. 92

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 behaviour of the integrated software:

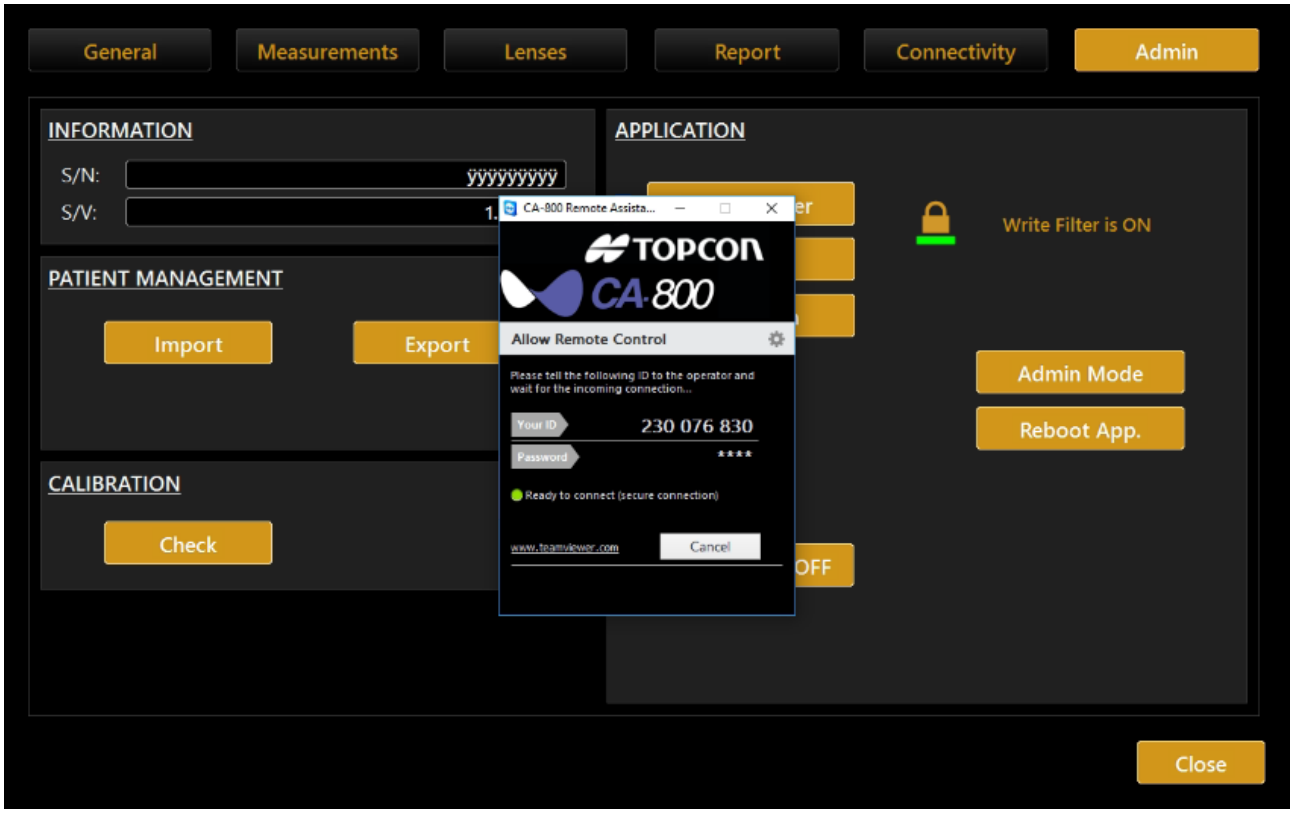
- **Upgrade**: Updates the integrated software
- **Shutdown**: Power off the machine
- **Reboot App**: Reboot the application

17.10.1 Remote Assistance[11]

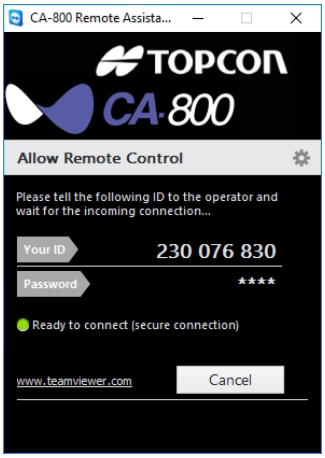
In case you need remote Assistance the CA-800 application integrates Team Viewer QS (Quick Support) pre-installed.

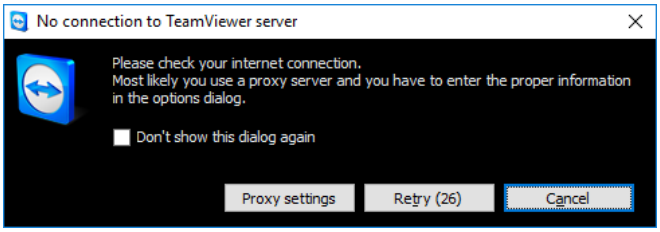
- There is NO NEED to disable the Write Filter protection
- Ensure to have available internet access for your CA-800 unit
- Go to Settings > Admin and press "Remote Assistance".

- Wait for the **Team Viewer** Window to open
- Communicate to the Remote Operator the ID shown under **"Your ID"** and wait for the incoming connection
- The password is masked, the operator knows it already



To turn off manually the Remote Assistance you can close the Team Viewer window or press **"Remote Ass. OFF"**. If you get one of the following windows please check your internet connection to CA-800 or contact your IT staff.





17.10.2 Patients Management

With **"Import"** and **"Export"** buttons, users can respectively import and export the entire patient's examinations data to USB drive (or selectable folder in case of i-MAP). In i-MAP it is also possible to change the location of data storage.

17.10.3 Updating the integrated software[11]

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. 93).

Fig. 93

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.

17.10.4 Shutdown[11]

Press the ***"Shutdown"*** button to switch off the device.

[11] This applies to CA-800 only.

18 CA-800 TROUBLESHOOTING

Problem	Solution
The external body of the CA-800 is broken	Contact TOPCON Technical Service
The CA-800 display is broken	Contact TOPCON Technical Service
The CA-800 cannot be moved with the joystick	Completely unscrew the two locking screws and the semi-lock. . If the problem persists, contact TOPCON Technical Service
The CA-800 doesn't move properly with the joystick	Contact TOPCON Technical Service
The CA-800 display is black	Check that the CA-800 device is on. Check that the power cables are properly connected. If the problem persists contact TOPCON Technical Service.
The CA-800 power cord is properly connected but the device doesn't boot up	Contact TOPCON Technical Service
After switch on the CA-800, only a blue screen appears	Contact TOPCON Technical Service
The CA-800 is on but the on-board application is not active	Turn off the device from the stand by switch and turn it on again. If the problem persists, contact TOPCON Technical Service
After a few minutes when switched on, the CA-800 restarts	Contact TOPCON Technical Service
One or both USB external ports don't work	Contact TOPCON Technical Service
The CA-800 boots up and the on-board application is started but no touch operation is possible	Contact TOPCON Technical Service
The acquisition is not taken automatically when doing calibration check.	Check that the calibration checking device is properly positioned and it is clean. Use the provided cloth for proper cleaning. If the problem persists contact TOPCON Technical Service.
Calibration check has failed	Repeat the measurement. If the problem persists contact TOPCON Technical Service.
Cannot perform acquisitions using the joystick button.	If the problem persists contact TOPCON Technical Service.
The switch from right to left eye and vice versa doesn't work.	Contact TOPCON Technical Service.
The CA-800 restarts when clicking on the joystick button	Contact TOPCON Technical Service.
Some lights in the CA-800 do not turn on when doing the relative acquisition.	Check that the proper acquisition type is selected. If the problem persists contact TOPCON Technical Service.

The standard deviation after an acquisition session is greater than 0.16 D	Repeat the measurement. If the problem persists contact TOPCON Technical Service.
Cannot insert new patient's details	Contact TOPCON Technical Service
Cannot view previously saved examinations	If the problem persists contact TOPCON Technical Service.
Cannot save new examination data	Contact TOPCON Technical Service
Cannot print Reports	Check that some reports are selected, the correct printer is selected and that the printer is properly working. If the problem persists contact TOPCON Technical Service.
Cannot export Reports to Network	Check that the LAN cable is properly connected and the designed destination is reachable. If the problem persists contact TOPCON Technical Service.
The reports printed layout is not correct	Check the page layout settings in the CA-800 on-board application and in the printer.
The map image is not shown in the measurements section	Check that at least one acquisition has been performed and the map is enabled visualization settings. If the problem persists contact TOPCON Technical Service.
Generic Software error	Contact TOPCON Technical Service.

19 CA-800 TECHNICAL SPECIFICATIONS

⚠ No modification of this equipment is allowed.

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.

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

GENERAL INFORMATION			
FUNCTION	FEATURES		LIGHT SOURCE
Corneal topography and Keratometry	Keratoscopic Cone	24 rings equally distributed on a 43D sphere	Red LED Type1 and Type 2
	Analyzed points	Over 100.000	
	Measured points	Over 6.000	
	Corneal Coverage	Up to 9.8 mm on a sphere of radius 8mm (42.2 diopters with n = 1.3375)	
	Focus System	Guided focus	
Pupillometry	Integrated		Infrared and white light LED
Fluorescence	Integrated		Blue LED
Meibomian imaging	Integrated		Infrared side leds

OPTICAL RADIATIONS				
FEATURE	**LIGHT SOURCE**		**WAVELENGHT**	**15004-2**
Central fixation LED	Yellow green LED		572 nm	Group 1
Illumination of Placido disk for topographic analysis	Red LED Type1		633 nm	
	Red LED Type2		615 -630 nm	
Pupillometric analysis	White LED	Blue	473 nm	
		Green	532 nm	
		Red	630 nm	
	IR LED		940 nm	
Fluorescein analysis	Blue LED		475 nm	
Meibomian imaging	IR LED		940 nm	

INFORMATION ON MEASUREMENTS					
Measure		**unit of meas.**	**Min**	**Max**	**precision**
Corneal Topography	Radius of curvature	mm	3.3	37.5	+- 0.03 mm
	Radius of curvature D (n=1.3375)	D (diopters)	9.00	101.5	+- 0.16
Pupillometry		mm	0.5	10	+- 0.05 mm

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

ELECTRICAL DATA		
Power supply		AC 100-240V 50/60 Hz
Power consumption		80 VA
Fuse	**Type**	20 x 5 mm
	Value	T 2.5 A L 250 V anti-surge

MECHANICAL SPECIFICATIONS	
Width	320mm
Height	490mm
Length	470mm
Weight	15 kg

ON-BOARD PC SPECIFICATIONS	**SN 75xxxxxx**	**SN 119xxxxxx**
Operating system	WINDOWS 8 Embedded	WINDOWS 10 64bit
Processor	AMD G-T56N	Intel
RAM	2GB	4GB
Hard disk	At least 500GB	
External connections	LAN integrated, 2x USB	

20 CHANGING THE FUSES

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

Step 1

Open the fuse box cover using a screwdriver

Step 2

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

Step 3

Remove the blown fuse from its seat and replace it with an identical one, as 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

21 End-User License Agreement for VISIA imaging S.r.l. Software

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CA-800

Corneal Analyzer

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

- **Product name:** CA-800
- **Software version:** as written in Settings > Admin section
- **Period of use:** Please inform us of the date of installation.
- **Defective condition:** Please provide us with as much detail as possible.

CA-800
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