TOPCON

ALADDIN HW3.0

User manual

Rev. 20 EN - 2023

Caution: Federal law restricts this device to sale by or on the order of an **optometrist**, **optician**, or an **ophthalmologist**.

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.

Accessibility and scope of the manual

Thank you for choosing this product.

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

Keep these instructions in a safe place close to the device. The manual must be at hand at all times. For a correct use of the instrument, read the instructions carefully.
The purpose of this manual is to inform the user as to all the device's functions, settings, safety, installation, maintenance, cleaning and storage instructions.

ALADDIN HW3.0

Product cod. 1240212

SW v.: 1.10.x

Manufacturer

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Contents

1 INTENDED USE

ALADDIN HW3.0 is intended for biometric determination of the following ocular measurements: axial length, corneal radius, corneal cylinder axis, anterior chamber depth, central corneal thickness, crystalline lens thickness, white-to-white (WTW) and pupil diameter of the human eye. ALADDIN HW3.0 also measures corneal topography.

For patients who are candidates for intraocular lens (IOL) implantation, ALADDIN HW3.0 also aids in the calculation of the appropriate IOL power and type to be implanted.

ALADDIN HW3.0 is intended for use by physicians and eye-care professionals and may only be used under the supervision of a physician.

1.1 Intended users

ALADDIN HW3.0 is intended for use by physicians and eye-care professionals (opticians, ophthalmologists) and may only be used under the supervision of a physician.

For surgery and intraocular lens implantation, the device can only be used under medical supervision. For the other applications, the device must be used by qualified personnel.

1.2 Places of use

The intended places of use are: health care centers, doctors' surgeries, operating theatres.

1.3 Contraindications

Patient could have a dazzle effect, after the exam, dues to the device lights, but it disappears in few minutes.

1.4 Description of functionalities

The ALADDIN HW3.0 is a combined device for the biometric measurements of ocular structures. The measurements assist in the determination of the appropriate power and type of intraocular lens.

Below a summary of the device functions:

OPTICAL BIOMETRY - Measurement of the following ocular structures by means of the low-coherence optical interferometry method:

- **Axial Length (AL)**: distance between the cornea and the inner limiting membrane.
- **Anterior Chamber Depth (ACD)**: distance between the anterior surface of the crystalline (anterior capsule) and the outermost stratum of the cornea (epithelium), measured along the central axis where the latter is biggest.
- **Central Corneal Thickness (CCT)**: distance between the outer stratum of the cornea (epithelium) and the inner stratum (endothelium) on the central axis.
- **Lens Thickness (LT)**: distance from the anterior surface of the crystalline lens (anterior capsule) and the posterior surface, measured along the central axis.

TOPOGRAPHY - Acquisition of the topographic map of the eye, through the reflection of 24 rings of the Placido disk at a distance of 80 millimeters from the eye. The following measurement are performed:

- **Keratometry (KER)**: measurement of the curvature of the anterior surface of the cornea. Includes all the basic functions of corneal topography (ketorefractive parameters and Zernike analysis).
- **White-to-White (WTW)** or corneal diameter: horizontal distance between the borders of the corneal limbus.

PUPILLOMETRY - It is performed with image analysis of the sequence of acquisition. The acquisition is performed with LEDs of different wavelengths. The device uses infrared LEDs to dilate the pupil and white LEDs to reproduce photopic light conditions and to contract the pupil. There are three modes:

- DYNAMIC Pupillometry acquisition in dynamic controlled light condition: mesopic → photopic → mesopic.
- PHOTOPIC Pupillometry acquisition in static photopic controlled light conditions.
- MESOPIC Pupillometry acquisition in static mesopic controlled light conditions.

IOL CALCULATION - Intraocular lens power calculation and suggestion made using the following formulae: Holladay 1, Haigis, Hoffer Q, SRK / T, SRK II, Camellin-Calossi, Shammas No history, Barrett Universal II. There are three modes:

- **IOL calculation**:Calculating the total spherical power for an intraocular lens to be implanted.
- **Toric IOL calculation**: Calculating the spherical equivalent power, cylinder power and placement axis for a toric intraocular lens to be implanted.
- **Post refractive IOL calculation**: Calculating intraocular lenses for patients who have undergone refractive surgery to correct myopia or hypermetropia.

The ALADDIN HW3.0 has an onboard PC with a dedicated software providing all the functionalities described above.

Please refer to the literature references listed in **19. Appendix: bibliography.**

1.5 Essential Performance

- **Keratometry (KER) Measurement**
- **Axial Length (AL) Measurement**
- **Anterior Chamber Depth (ACD), Central Corneal Thickness (CCT), Lens Thickness (LT) Measurement**

1.6 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.

The parts in contact with the patients are the followings:

- ABS chinrest
- Teflon forehead rest

2 PRECAUTIONS

This electronic instrument is a precision tool and it is intended to be used in professional healthcare environment including hospitals, physician's offices, surgical centers and limited care facilities, where equipment and systems are administered by healthcare professionals. Make sure to use it and keep it in a suitable place, at a normal temperature, humidity and atmospheric pressure out of direct sunlight.

- To ensure proper functioning, install the instrument in a vibration-free location.
- Connect all cables correctly before use.
- Use the recommended network voltage.
- When the instrument is not in use, turn off the power supply and protect it from the sun and from dust.
- To obtain accurate and reliable measurements, keep the measuring cone clean and free of dust.

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.
- Failure to follow warnings related to electromagnetic compatibility, can compromise the essential performance or basic safety of the device, affect the proper operation of the camera and software, false alarms, interruption of operations or wrong measurement.
- In presence of high level EMC disturbance (i.e. Electrostatic Discharge, Electrical fast transient/Burst) the device could stop working. In case, don't use on patient until the source of disturbance is removed.
- Care is exercised in design and manufacturing to minimize damage to devices under normal use. However, electronic devices are susceptible to many environmental stresses. The device may be affected by electrostatic discharge (ESD). In an environment likely to cause ESD, such as air conditioning, humidification, non-conductive floor coverings, synthetic clothing, discharge any charge collected on your body before touching the device.

The FDA labelling for some IOLs contain sizing based upon white-to-white measurements derived from studies in which this measurement is done with callipers. It is unknown whether the white-to-white measurement from this device yields results systematically biased compared to those from calliper measurements. Thus, sizing based upon white-to-white measurements from this device may not be consistent with those based upon measurements with callipers.

2.1 Electromagnetic compatibility

2.1.1 EM Emission

The ALADDIN HW3.0 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 ALADDIN HW3.0 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 ALADDIN HW3.0 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

Symbols	IEC publications	Description
	IEC 60417-5840	CLASS I DEVICE ACCORDING TO EN 60601-1 APPLIED PART TYPE B
CE		PRODUCT COMPLIANT WITH DIRECTIVE 93/42/EC
Type A	EN ISO 19980	CORNEAL TOPOGRAPHY ACCORDING TO ISO 19980:2005
	IEC 60417-5032	ALTERNATE CURRENT
	EN ISO 15223-1	REFERENCE OR MODEL NUMBER
	ISO 7010-M002	FOLLOW THE INSTRUCTIONS FOR USE
	ISO 7010-W001	GENERAL WARNING
	ISO 7010-W001	CAUTION (GENERAL WARNING): TO AVOID INJURY CAUSED BY ELECTRIC SHOCK, DO NOT OPEN THE COVER. ASK YOUR DEALER FOR SERVICE.
	ISO 7010-W001	GENERAL WARNING: BE CAREFUL NOT TO HIT THE PATIENT'S EYES OR NOSE WITH THE INSTRUMENT DURING OPERATION. THE PATIENT MAY BE INJURED.
	EN ISO 15223-1	MANUFACTURER
	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
	This symbol is solely applicable for EC member countries. To avoid potential negative consequences for the environment and possibly human health, this instrument should be disposed of (i) for EU member countries – in accordance with WEEE directive 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 Sample labelling on the device

4 SAFETY INSTRUCTIONS

4.1 General

- ALADDIN HW3.0 should be used only for its intended purposes as detailed in this manual.
- It must be installed by qualified personnel.
- 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 full biometry 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.
-  If the device has just been delivered or has been subjected to thermal shock, wait at least one hour before making measurements on patients.
- Keep this manual at hand close to the device at all times.
-  The physician or device user must inform the patient of the pertinent safety instructions and ensure that they are adhered to.
-  Connect the device to the supply mains using one of the cables supplied with the device
-  Position the unit so that it is not difficult to disconnect the plug for connection to the supply main.
-  Perform all the control functions (detailed in the relative section in this document) before carrying out measurements on patients. In addition, if software interface shows an "Initializing error" warning, don't go on with measurements. Also "Low repeatability of measure" warning originates a wrong IOL calculation.
-  Only personnel with the appropriate training and experience may use the device and interpret the results.
- Use of the device requires training and professional skills. The scholastic and cultural preparation of the user and the User Manual reading are enough as training.
- Turn off the device if it is not going to be used for a long period of time.
-  If external forces act on the device (e.g. if it is knocked or dropped), it must be thoroughly checked before proceeding to examine patients. To do this, refer to the relative section in this manual. If necessary, send the device in for repair.
- Use only original ALADDIN HW3.0 accessories and spare parts specific for this device.
- Remove all the covering (dust sheet) from the device before turning it on.
- Do not use the device close to highly inflammable materials or in areas with an explosion hazard.
-  Unauthorized installation of software in the device is forbidden.
-  After the examination, the patient may be slightly dazed. It is recommended to advise the patient to wait a few minutes before driving or performing actions that require perfect vision.

-  When operating the chinrest up/down switch, be careful not to pinch the patient's hand. The patient may be injured.

4.2 Electrical safety

-  To avoid risk of electric shock, this device must be connected to supply mains with protective earth.
- ALADDIN HW3.0 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.
- Maintenance activities must be done in absence of the patient.
- Fuse change can be done by the user by following the instructions and safety precautions described in this Manual.
- Do not touch the LAB/USB ports contacts and the patient at the same time.

4.3 LED emission safety

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

ALADDIN HW3.0 has a series of LEDs of various types and powers installed. All the characteristics are detailed in the Technical Specifications section in this manual.

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

4.4 Installation with external devices or IT Network

ALADDIN HW3.0 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.
- 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.
- When ALADDIN HW3.0 is installed in rooms for medical use, the PC and the connected printer must be powered by means of an IEC 60601-1 compliant insulating transformer.
- If ALADDIN HW3.0 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 close to ALADDIN HW3.0.
-  Every external device that has to be connected to ALADDIN HW3.0 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 installator must check that the system maintains basic safety and essential performance of the product in compliance with IEC 60601-1.

- The purpose of ALADDIN HW3.0 connection to an IT network is report printing and remote technical assistance.
- The ALADDIN HW3.0 USB port must be connected to printer with USB or LAN interface. Ask Topcon technical assistance for printer driver installation.
- The ALADDIN HW3.0 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 ALADDIN HW3.0 and network settings.
- The purpose of ALADDIN HW3.0 connection is saving PDF report on an external network folder or technical service intervention on the machine.
- Connection of ALADDIN HW3.0 to a computer network that includes other equipment could result in previously unidentified RISKS; identify, analyse, 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.
-  Do not change the Ethernet settings “Local Area Connection 2” adapter.
  If specific configuration for LAN network is needed in the settings can be modified accordingly on “Local Area Connection” Ethernet adapter.

4.5 Transport and packaging

- The device must be transported and stored in its original packaging.
- For the storage and transport conditions, refer to the relative section in this document.
- Carefully keep the original packaging in order to use it if you need to transport the device.
- To move the device for short distances (without packaging) and to insert 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 on the rear of the device (where the locking system is).
-  Completely unscrew the two locking screws and the semi-lock (Figure 2) before use.
-  Lower the instrument to its minimum height using the joystick, then lock ALADDIN HW3.0 using the semi-lock and the two locking screws for transportation (Figure 2).

4.6 Cleaning

- Regularly clean dust off the device using a soft cloth. For more persistent superficial dirt, use a soft cloth dampened with water or alcohol at maximum 70%.
-  Be careful not to get the device wet and clean it only as indicated to prevent damaging it. Never use solvents or other abrasive agents.
- The device comes with a dust cover to be used to protect it. Cover ALADDIN HW3.0 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.

4.7 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 patients to make sure that they come on properly.
- If the device frequently emits error signals, turn it off and contact technical support to have the device checked.
-  In patients with blue eyes, acquisition of pupillometry in mesopic lighting conditions can be difficult to accomplish. In this case, we suggest acquiring the mesopic data through dynamic pupillometry.
-  Contact lenses must not be worn by the patient during data acquisition.

4.8 Privacy & Cybersecurity

-  When performing the installation of a new unit the user MUST set his own credentials to prevent unauthorized physical access to the device. To set up the access login to the instrument operation and on-board data refer to section 13.7.
-  Make sure the USB devices you intend to connect to the instrument are secured against malware/viruses.
-  Patient data on USB devices can become corrupted when inserting into computers for backup or transfer.
-  The use of antivirus software on computers is recommended and it is responsibility of the user.
-  To protect data exported to USB from unauthorized access, use dedicated USB data for storage.
-  Installation of any unapproved software, including drivers, could degrade the performances of the instrument and may void the instrument warranty.

4.8.1 Privacy

 It is recommended that the operator understand the characteristics of this device in relation to Data Protection.

4.8.1.1 *Definitions and application within this device*

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

Personal Data used with the device is:

- Subject identification data: subject name, subject date of birth, subject gender, subject ID (according to the practise ID application policy). Refer to section 11.4 for further details on the management of subject identification data.
- Subject physical/physiological data: subject eyes biometric measurements, as acquired and stored in each examination belonging to the subject. Refer to section 1.4 for further details on the types of biometric measurements performed by the device.

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

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

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

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

4.8.1.2 *Device characteristics to support Data Protection*

Data Protection

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

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

The data can be accessed in relation to subject identification only within the application itself which is protected by login that can be configured by the controller to grant confidentiality.

The subject data it is used within the device on-board application only for storage and identification purpose. The controller can apply an explicit pseudonymisation rule to handle subject identification by using only ID subject identification and not using subject name, DoB, gender in the device.

Right of Access by the data subject

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

Right to Rectification or Erasure

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

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

Refer to section 11.4.2.2 for details on how to rectify or erase patient data.

Right to restriction of processing

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

Right to data portability

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

Right to object

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

Automated individual decision-making, including profiling

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

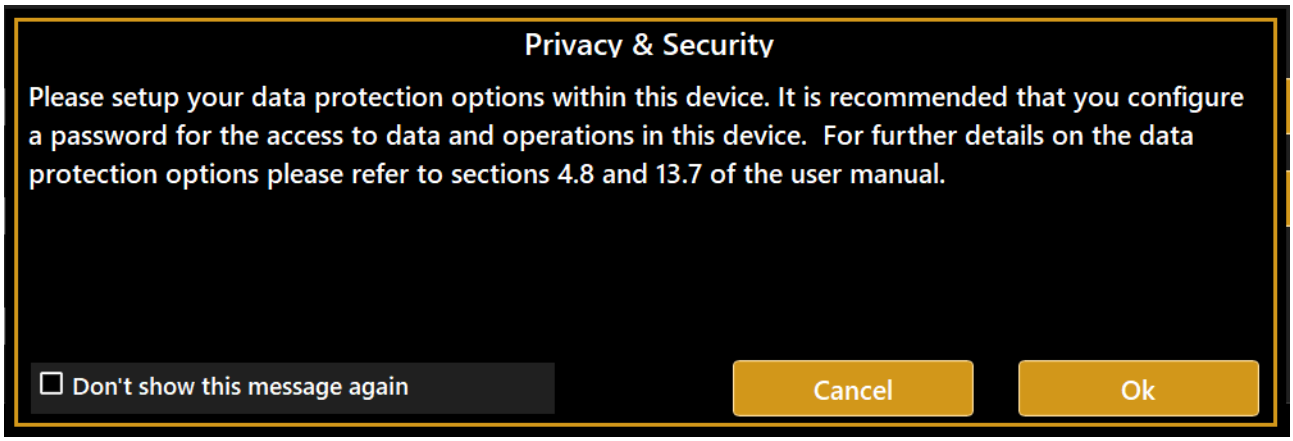
4.8.1.3 *Privacy and Data Protection during assistance/support services*

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

Refer to section 13.7 for specific options.

4.8.2 Privacy & Security options

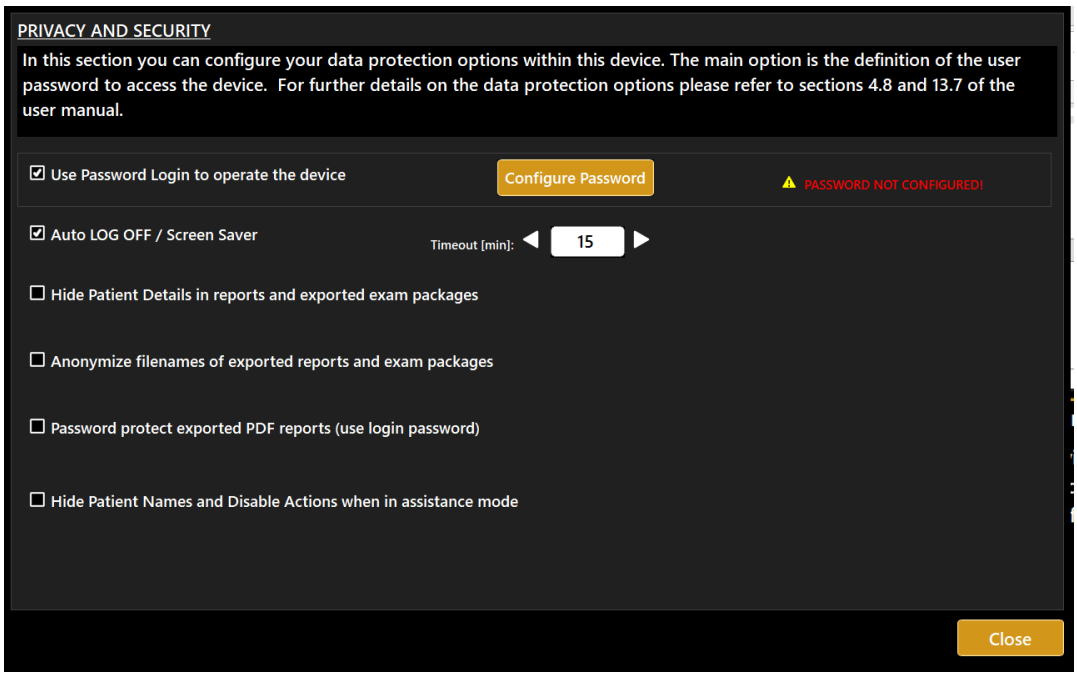
When the on board application is booted, the following prompt is shown.



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

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

The Privacy and Security options can be access at any time from the settings. For the details on each option refer to section 13.7.



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 personnel, the manufacturer is relieved of all responsibility and the warranty shall become null and void.
- **N.B.**: Modifications or repairs to the product, especially where they require opening the device, may only be carried out by technical personnel 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:	→	EMC
ISO 15004-2:	→	Group 2
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 MAIN COMPONENTS

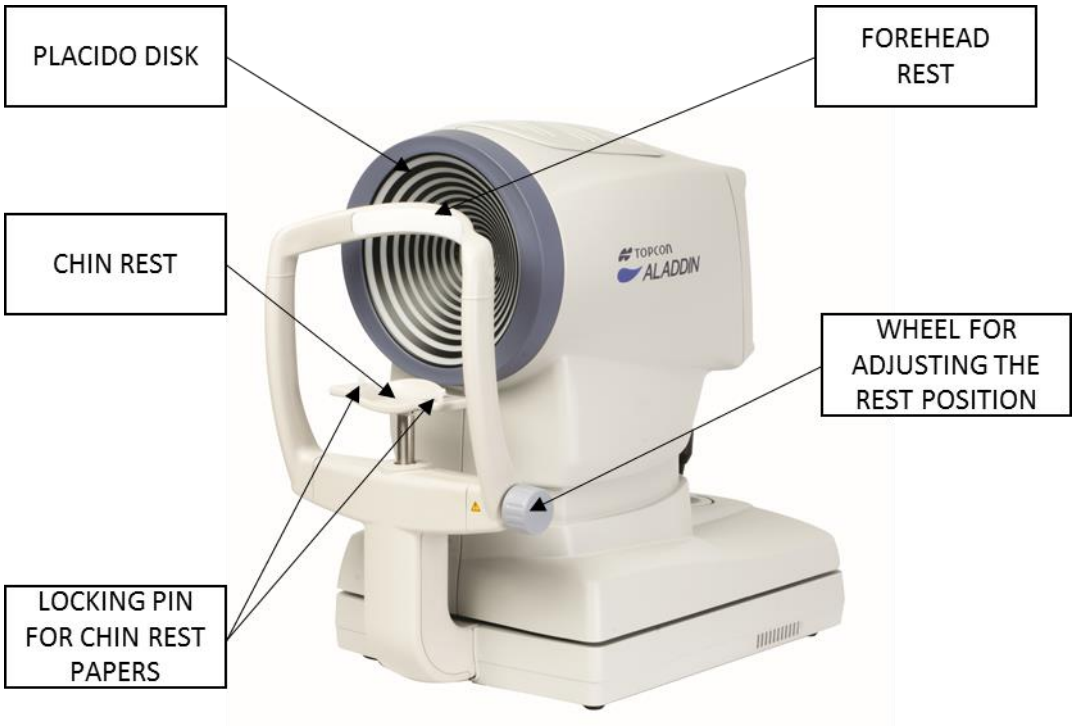


Figure 1 Patient's side

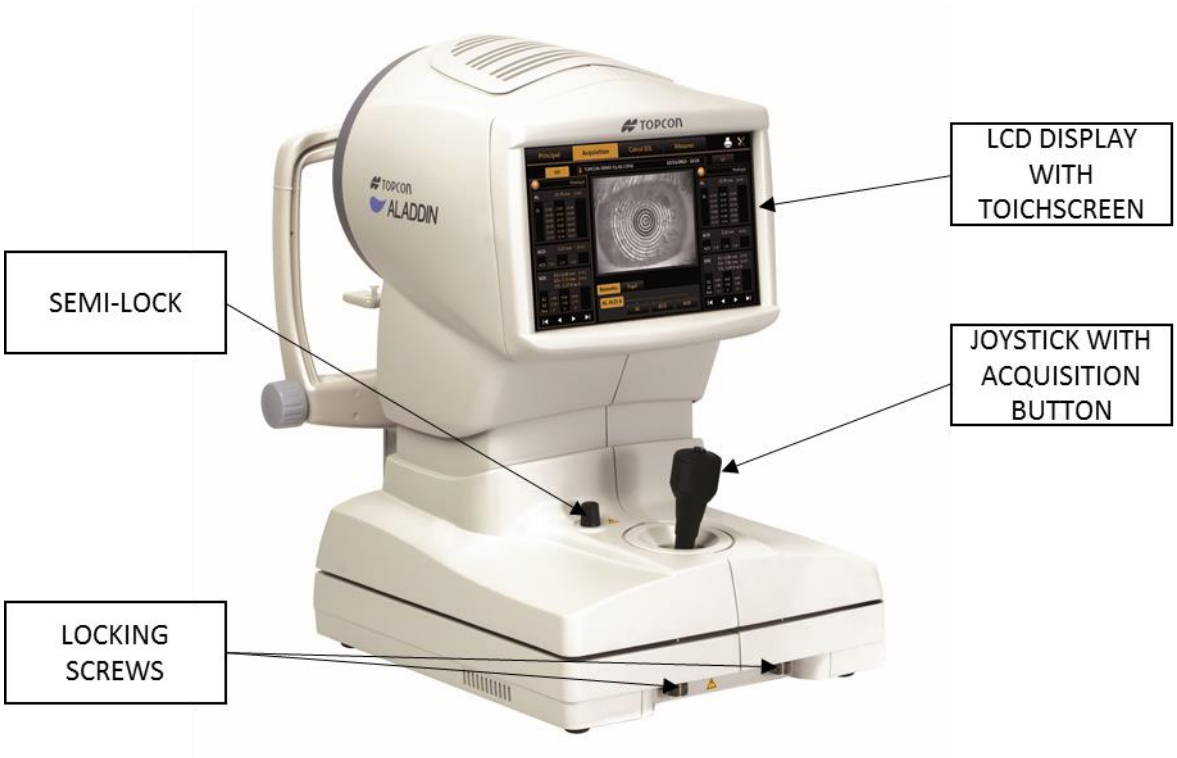


Figure 2 User's side

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)

8 INSTALLATION /UNINSTALLATION OF THE SYSTEM

ALADDIN HW3.0 is packed for shipping in a double cardboard box on a dedicated pallet with specially shaped cardboard parts inside to guarantee instrument safety during shipment.

Keep the original packaging for future use. The system must always be moved/shipped in its original packaging, which is specifically designed for damage protection.

8.1 Installing the system

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

Figure 3

Figure 3 shows the complete packaging of the instrument.
Cut the extensible film and the packing straps. Open the external box, and remove the wood panel as shown in Figure 4.

Figure 4

Remove the manual and the accessories from the dedicated spaces between the two pieces of cardboard (see Figure 5).

Figure 5

The accessories are:

- "Topcon" box:
  - calibration checking device
  - chin rest paper
  - chin rest pins
  - touchscreen pen
  - silicon cloth
- Power cable
- "Topcon" ALADDIN HW3.0 dust cover
- ALADDIN HW3.0 user manual

Open the internal box and remove the specially shaped cardboard that holds the instrument. The instrument can now be taken out of the package. The steps are illustrated in Figure 6.

Figure 6

Be careful when taking ALADDIN HW 3.0 out of the box gripping it by the chin rest arch and the base beside the joystick.

Remove the Nylon cover.

Place the instrument on a flat surface.

Completely unscrew the two locking screws and the semi-lock (Figure 2).

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

8.2 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 (Figure 2).

Figure 7

Place the Nylon cover over the instrument and insert it in the box, as shown in Figure 7.
Follow the sequence of steps shown in Figure 8.



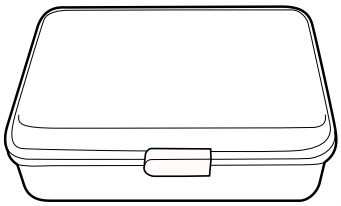





Figure 8

Put the accessories in the dedicated spaces. Position the wood panel with the shock absorbers in the lower part. Close the external box with strong packing tape or use extensible film and packing straps.

9 STANDARD ACCESSORIES AND EQUIPMENTS

Calibration checking device **The calibration checking device shows the serial number of the instrument with which it is associated. To properly check calibration, the calibrator provided with the instrument must always be used.**	
Power cable	
Manual	
Protective cover	
Accessories box containing: • Touchscreen pen • Silicon cloth • Chin rest paper • Chin rest pins	

10 SETTING UP THE INSTRUMENT

10.1 Connection modes

Before connect device to external devices or IT Network, please read paragraph 4.4.

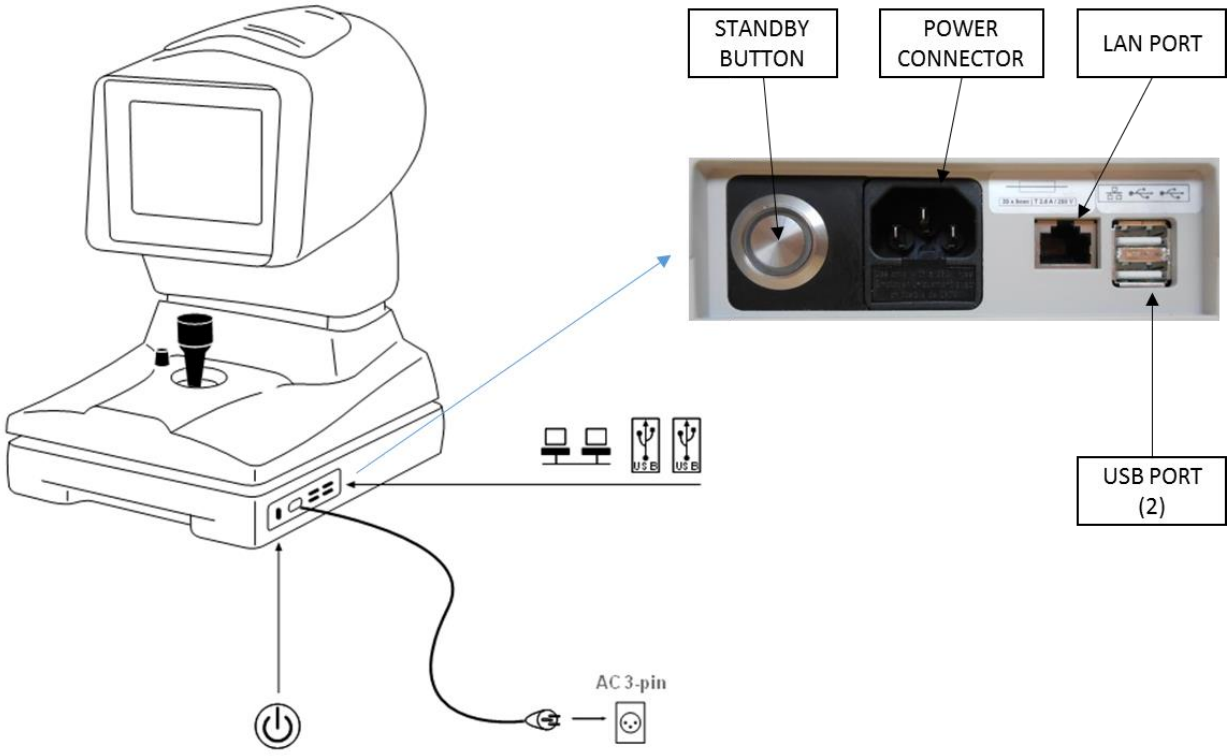


Figure 9

10.2 Power on procedure

Make sure the power cord provided is connected to the mains.
Press the stand-by button (see Figure 9) and wait for the system loading until the screen showed in Figure 16 appears.

11 OPERATING INSTRUCTIONS

ALADDIN HW3.0 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:

- Entry of patient data
- Acquisition of the various possible modes
- Display of measurements
- Selection of intraocular lenses

More information for each function and setting are provided in the following paragraphs.
To interact with the software, the LCD display with touchscreen is used. To activate the button or the desired function, simply touch the screen close to the command. The screen is highly sensitive. Minimum pressure is required, indeed advised.

11.1 User Login/Logout

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

 It is recommended to make a robust password choice. It is recommended to keep record of the password in a safe place.

 It is not necessary to disclose the user password to technical support staff. Refer to section 11.1.3 for details.

Refer to section 13.7 on how to configure and manager the login access. If the user login password is configured and enabled, the login screen will be prompted at the start-up of the Aladdin on-board application. The login screen is prompted also to allow access to the privacy and security settings (section 13.7).

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

If the password is forgotten or access problems are encountered please contact assistance.
It is possible to get remote support by pressing on the button “Remote Assistance” if the device is connected to internet. Refer to section 13.6.2 for further details on TeamViewer remote support.

11.1.1 User Logout

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

11.1.2 Auto LogOFF/ Screen Saver

The device locks automatically if no user actions occurs for a configurable amount of time. The Aladdin screen saver is then shown.

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

To configure the screen saver timeout or enable/disable it refer to section 13.7.2.

11.1.3 Technician Support staff Login

Technical staff can log into the device and on-board application without knowing the user password. The authorized technical staff knows the technician password which allows to do service on the device having data protection features applied according to privacy options of section 13.7.

To let the technical staff log in properly press on the lock button before.

11.2 Overview

Every working environment has the same screen layout. In Figure 10 a sample of the acquisition screen is shown.

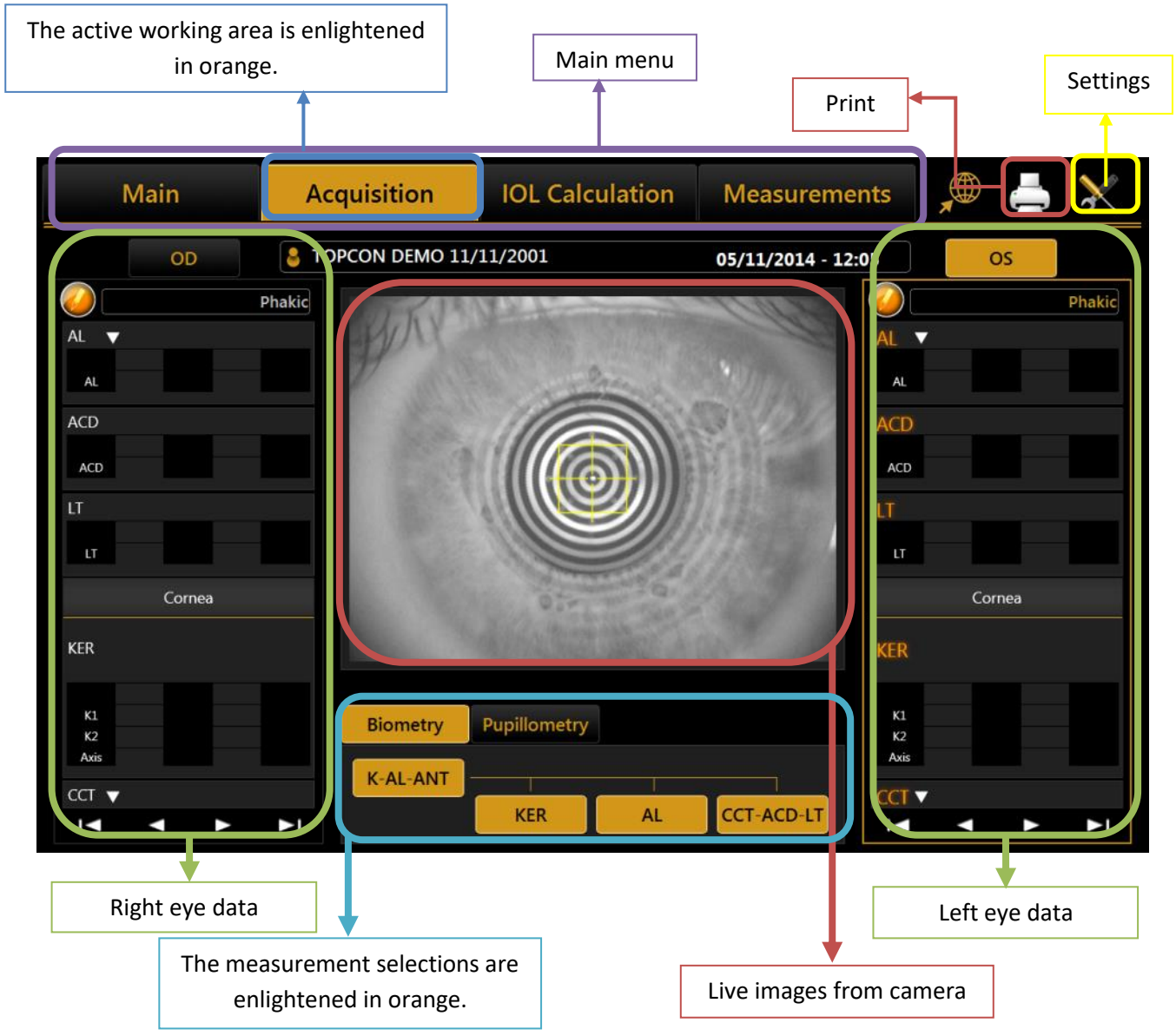


Figure 10

11.3 Checking the calibration

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.

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

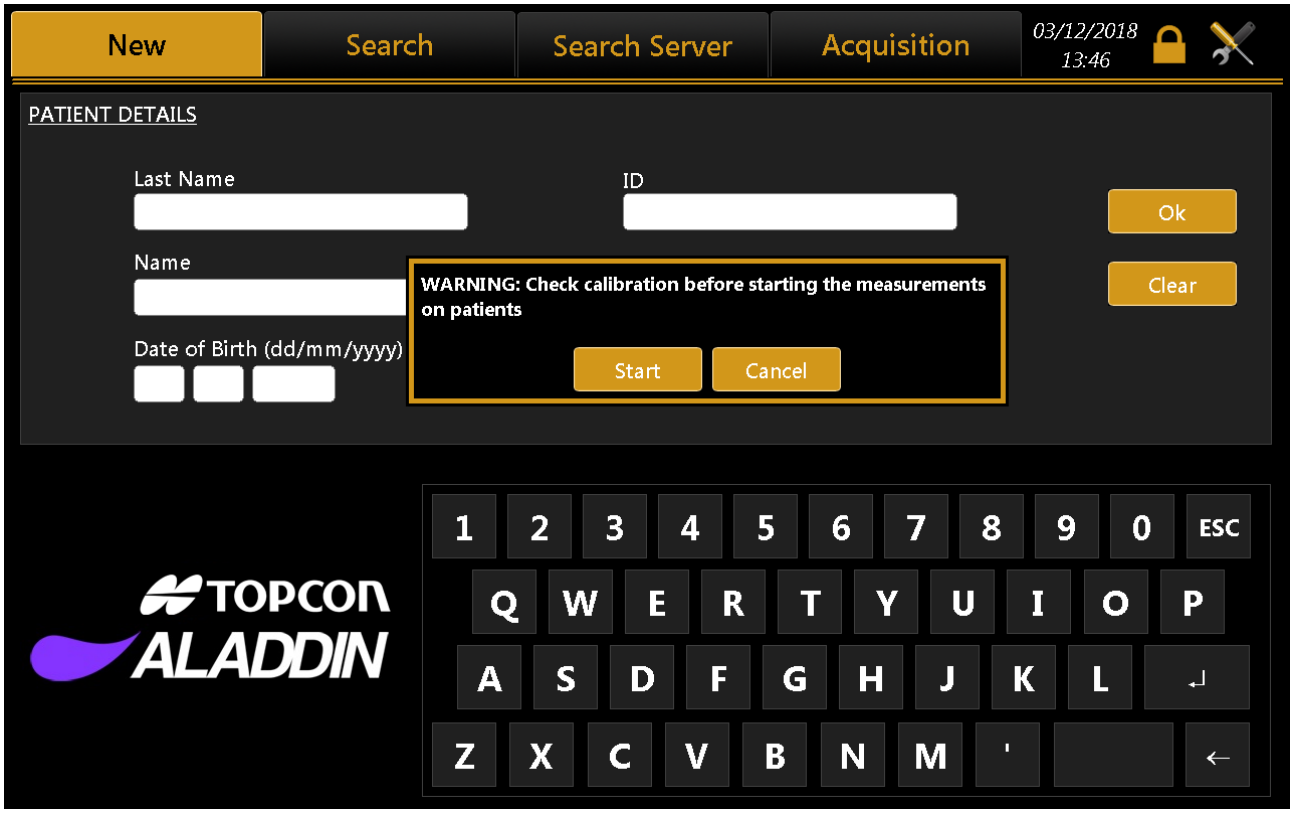


Figure 11

The next screen explains how to check calibration:

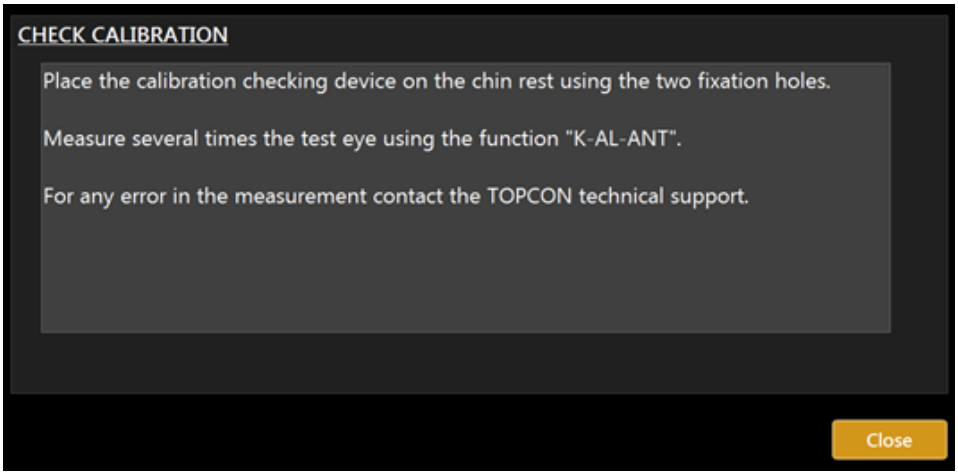
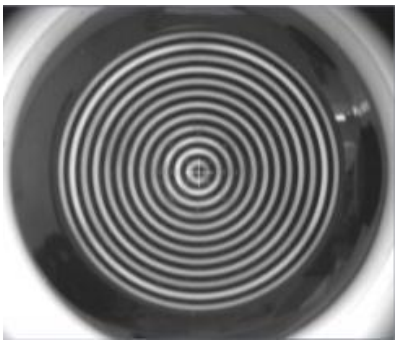


Figure 12

Set the calibration tool supplied with the device 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 (Figure 13).

CORRECT alignment



WRONG alignment

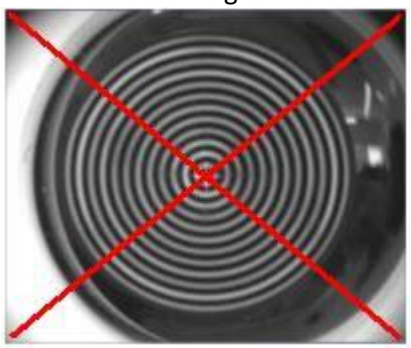


Figure 13

Now check and several times acquire the calibration checking device using the complete acquisition (K-AL-ANT). For details on this acquisition mode, see chapter 11.5.
If the calibration is ok, the "Valid" word will be display for all the measurements (Figure 14). If the measurements are incorrect, the words "Repeat" or "Not Valid" will be displayed besides the wrong measurement (Figure 15).

See table below for instructions.

MESSAGE	MEANING	WHAT TO DO
VALID	Good calibration	Click on "Main" to start a new examination. When asked, press Yes to save the "Calibration Check". NB: the "Valid" word must be displayed for ALL the measurements.
REPEAT	Acquisition failed: cannot check calibration	Acquire again until three times following these suggestions: • improve the environmental conditions (less light and no reflections on the sphere); • clean the sphere of the calibration tool; • make sure that the calibration tool is position correctly. If the calibration check is still not valid, do not take any patient measurement and contact Technical Support.
NOT VALID	Incorrect calibration	

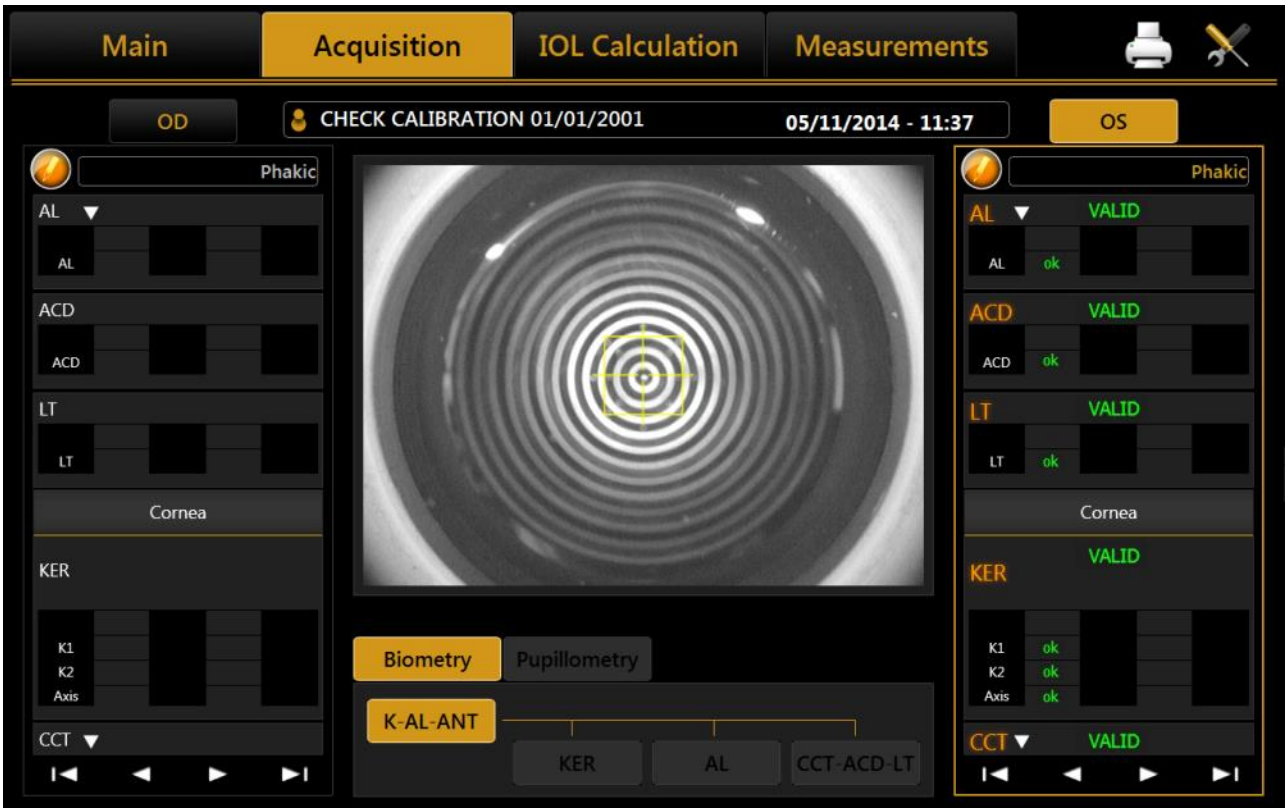


Figure 14

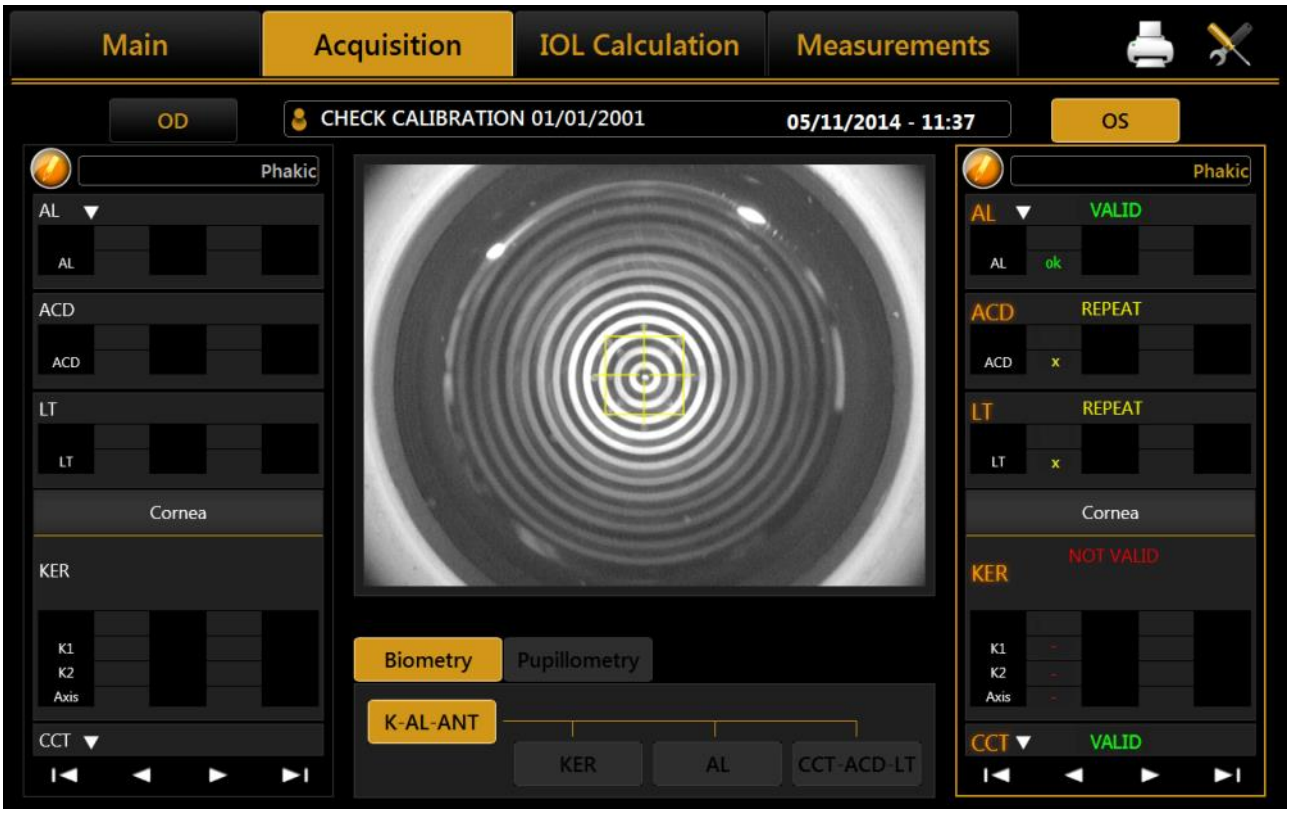


Figure 15

11.4 Patient entry/selection

When the instrument is turned on, the software displays the following screen. Before start examination, it is required to create a new patient or select a previously saved one from database.

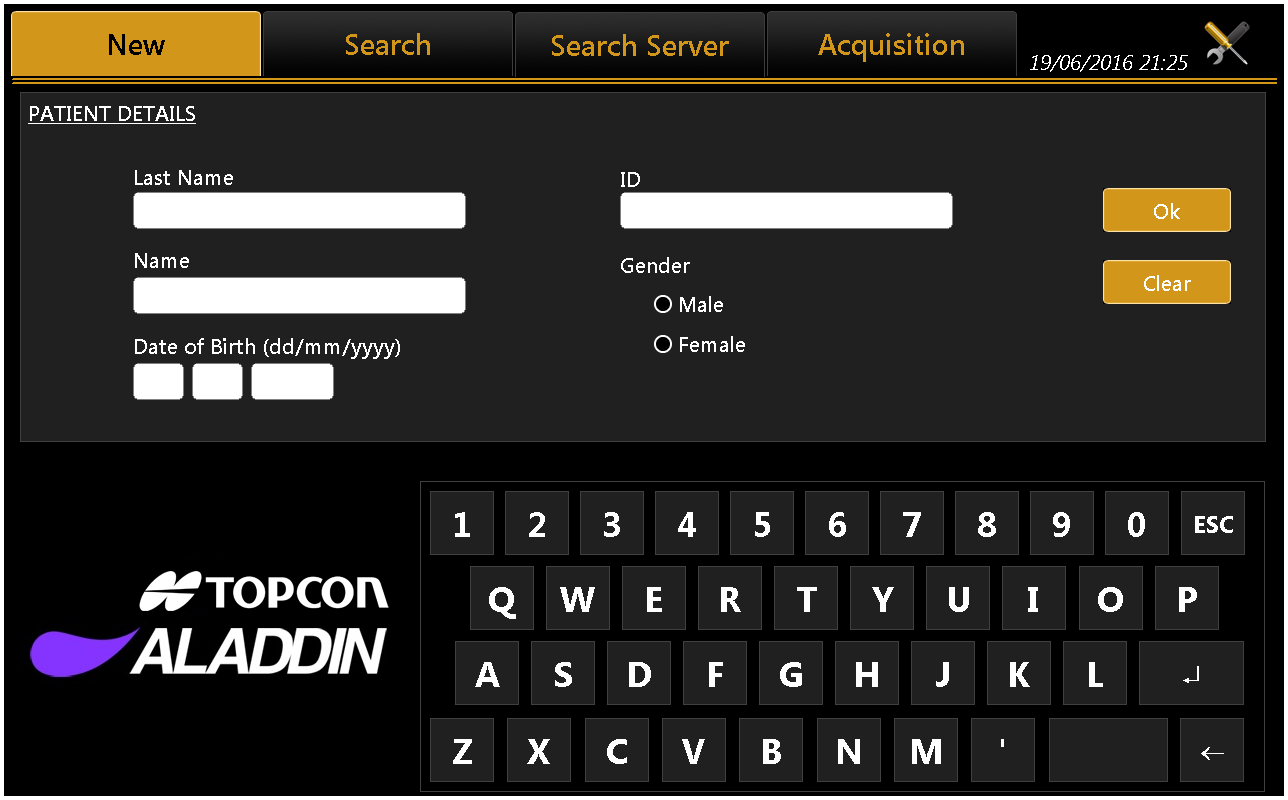


Figure 16

Figure 16 shows the section for creating a new patient, entering Last Name, Name and Birth Date as required fields (Gender and ID are optional). You can set from the settings environment to have only the ID as required field.

11.4.1 Creating a new patient

To create a new patient, select the **"New"** tab and enter the data using the on-screen keyboard. Once you have entered the new patient data, click on the **"Ok"** button or select the **"Acquisition"** tab to confirm the information and continue with the examination. If you want to empty all the fields click on the **"Clear"** button. Before going into the acquisition environment, additional information on the patient is required, in particular the presence and type of crystalline and the nature of the vitreous body (Figure 18).

An external keyboard or another input device compatible with "*keyboard wedge interface"* (USB Type A) such as barcode or card reader can be connected to the device to input text. The user must assure that the desired textbox is under focus before the input action.

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.

11.4.1.1 *Entering special characters*

A special character can be entered simply by touching and holding for a few seconds the corresponding letter as shown in Figure 17:

Figure 17

11.4.1.2 *Selecting crystalline and vitreous body type*

Once the patient identity record has been created, it is possible to select the type of cristallyne and vitreous body for each patient's eye, by pressing the "Acquisition" button (please see the following Figure 18)

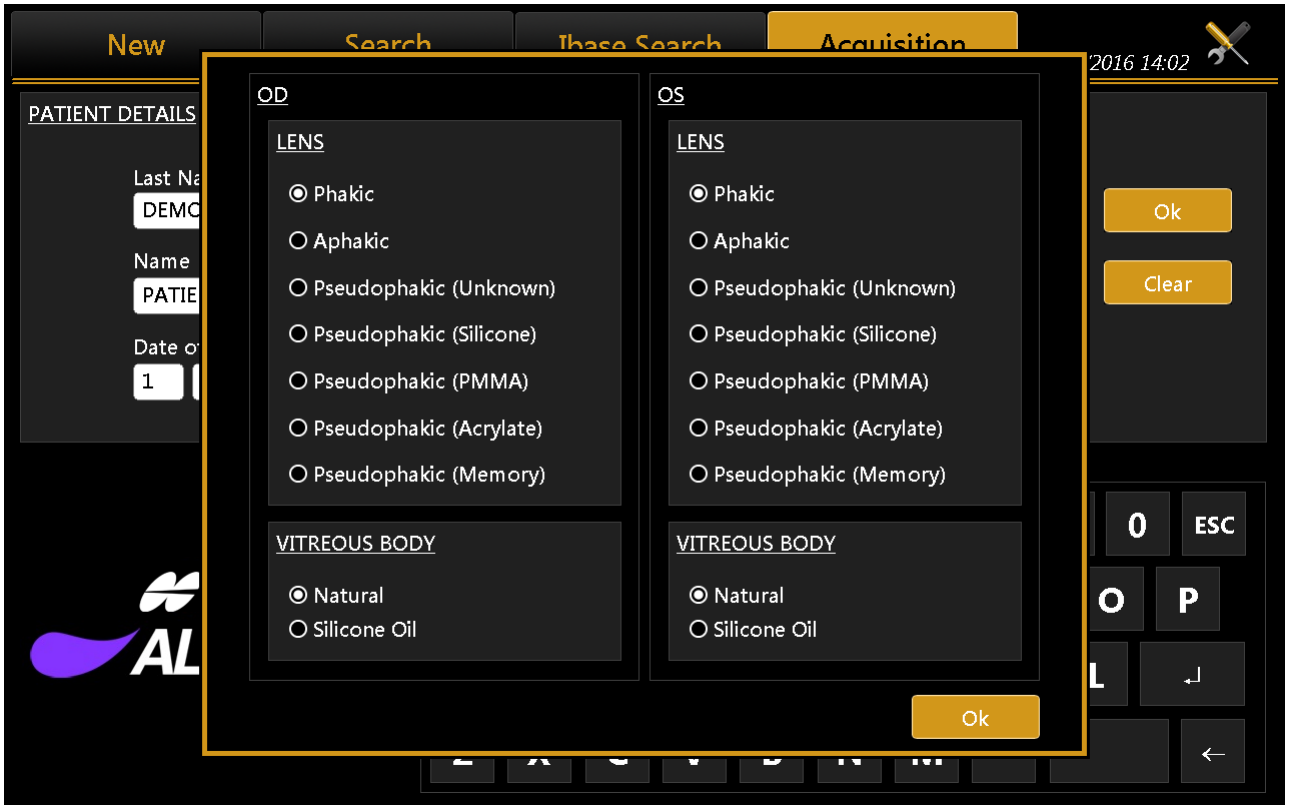


Figure 18

For each eye, select the type of crystalline currently present:

- **Phakic:** the patient has a natural crystalline lens.
- **Aphakic:** the patient does not have any crystalline lens from birth or as a result of surgery.
- **Pseudophakic:** the patient has an intraocular lens substituting the crystalline. In this case, it is very important to also detail the type of material used by the surgeon:

- **Unknown**
- **Silicon**
- **PMMA**
- **Acrylate**
- **Memory**

The measured axial eye length depends on the measuring mode selected. Depending on the measuring mode selected, ALADDIN HW3.0 corrects the measurement with a constant defined as follows.
ALADDIN HW3.0 device takes into consideration two conditions of the eye that can alter the measurement of axial length:

- Vitreous body filled of silicone oil
- Implant of intra ocular lens

The difference of the measurement is caused by a different group refraction index considered in the formula. According to bibliographic data, the calculations have been performed to assess the amount of correction that must be applied to correct the measurement in these special cases.

The correction data have been compared with predicate device assumptions and a table of corrections has been elaborated as follows:

The correction values (in mm) of the natural vitreous body

Phakic	0
Aphakic	0.21
Pseudophakic Unknown material	0.11
Pseudophakic Silicone IOL	0.12
Pseudophakic PMMA IOL	0.11
Pseudophakic Acrylic IOL	0.1
Pseudophakic Memory IOL	0.11

For the vitreous body you can choose between:

- **Natural:** the vitreous body has never been operated or treated such as to alter its composition.
- **Silicon Oil:** the vitreous body has been filled, even only partly, with silicon oil.

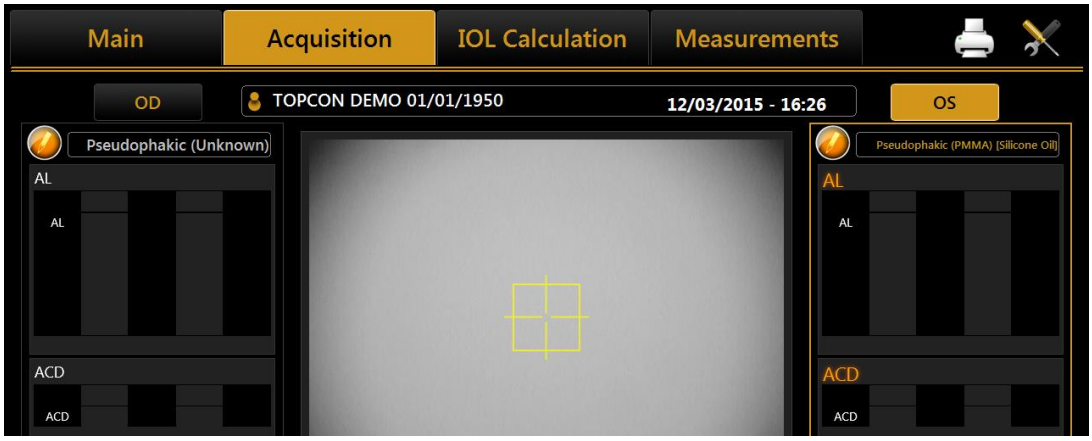
The correction values (in mm) of the vitreous body filled by Silicon Oil

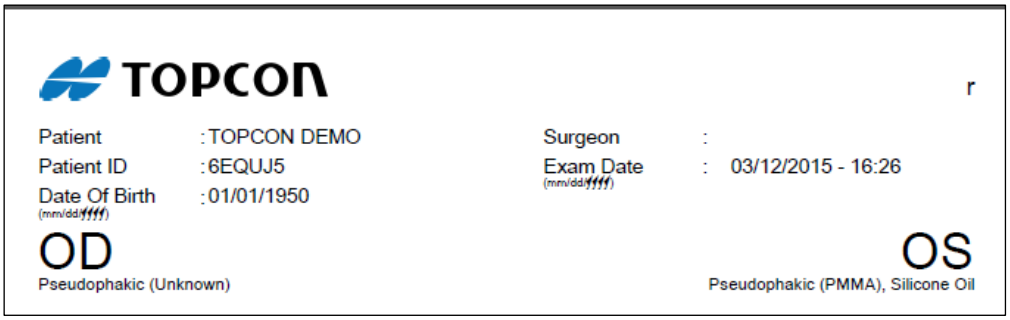
Phakic	-0.74
Aphakic	-0.86
Pseudophakic Unknown material	-0.75
Pseudophakic Silicone IOL	-0.74
Pseudophakic PMMA IOL	-0.75
Pseudophakic Acrylic IOL	-0.76
Pseudophakic Memory IOL	-0.75

All this information is required because, on the basis of the artificial materials and their optical properties present inside the eye, the instrument always corrects the measurements obtained to the most precise value possible.
Once this information has been entered, you can access the acquisition environment.

For more details on the acquisition environment see the dedicated section.

The vitreous body nature is expressed, if different from natural, in the acquisition view as well as in the output reports, as shown in the following figures. The lens nature is always reported.





11.4.2 Selecting or modifying a patient

On the input screen, click on the **"List"** tab to access all the patients included in the local database (see Figure 19).

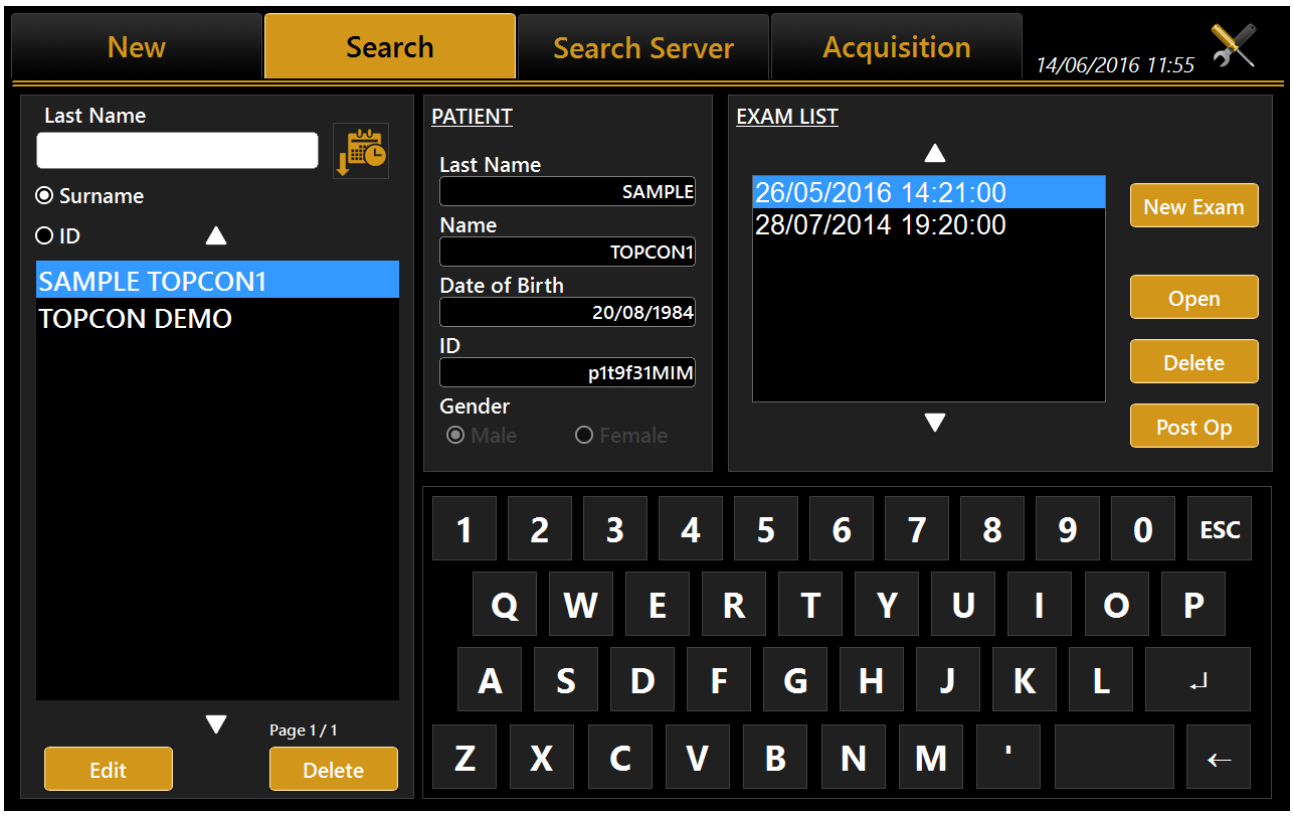


Figure 19

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).

11.4.2.1 *Open an examination or acquire data for the selected patient*

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

11.4.2.2 *Delete or edit the selected patient*

From the list of patients, select the exam you want to delete and press the "Delete" button. The program will ask you to confirm the choice.

Press "Edit" to change the name, surname or date of birth. This takes you back to the initial **"New"** tab. From here, you can edit the information you need to change and press **“Ok”** or “**Cancel”** to confirm or cancel the changes.

11.4.2.3 *Insert the Post-Op (after surgery) refraction data*

Through this function the user can update the data related to a single exam of the chosen patient. This means that if the patient has already undergone surgery, the new refractive status can be recorded as a main factor to personalize constants of the implanted IOL.

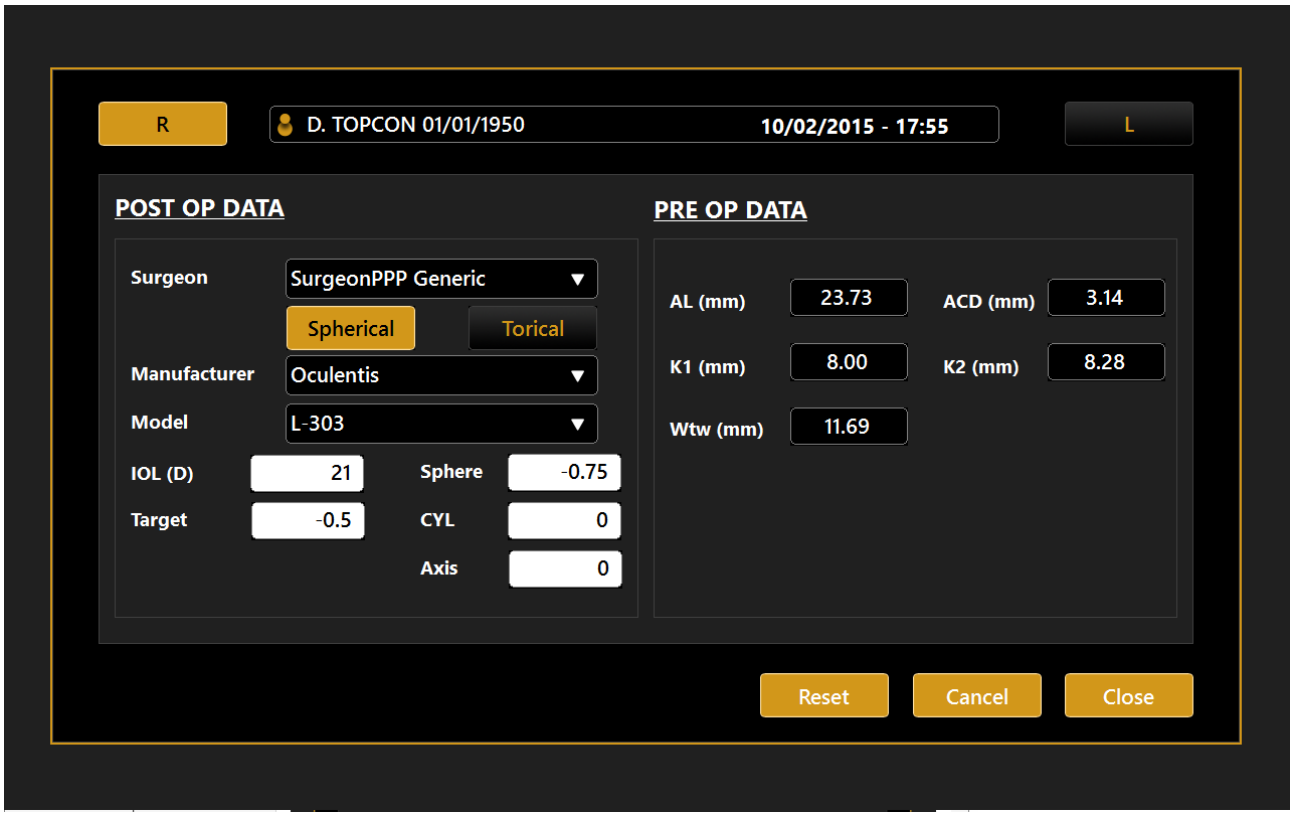


Figure 20

Opening the Post-Op section, the screen shown Figure 20 will be displayed.

In this section you can insert the Post-Op Data (IOL information plus actual refraction) in the meantime looking at the Pre Operative Data.

11.4.3 Selecting a patient from Server

Once enabled, Aladdin **IMAGEnet i-base's** integration from Aladdin'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 (Figure 21).

In the same way, ALADDIN HW3.0 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 (Figure 23). Once selected a patient, the user can create a new examination in the standard mode by clicking on the Acquisition or OK button button.

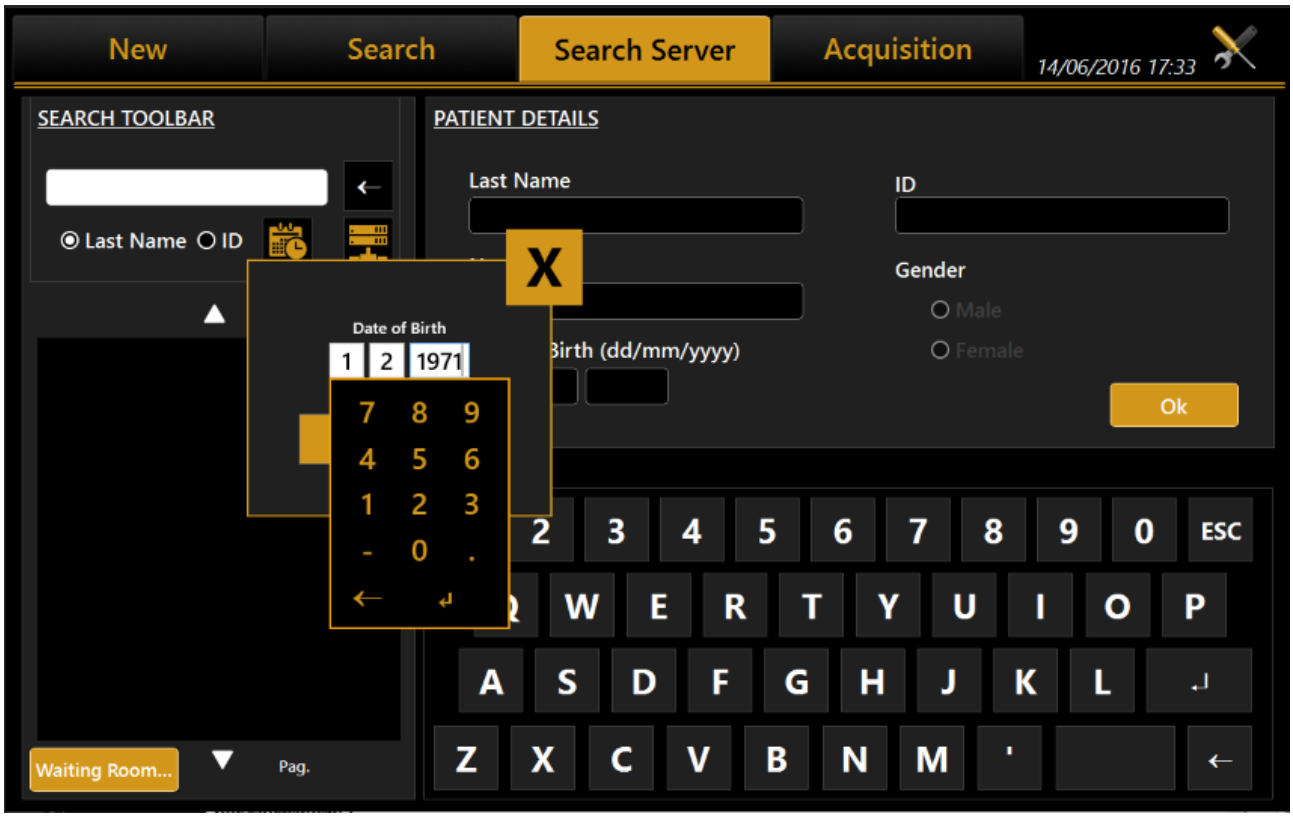


Figure 21

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.

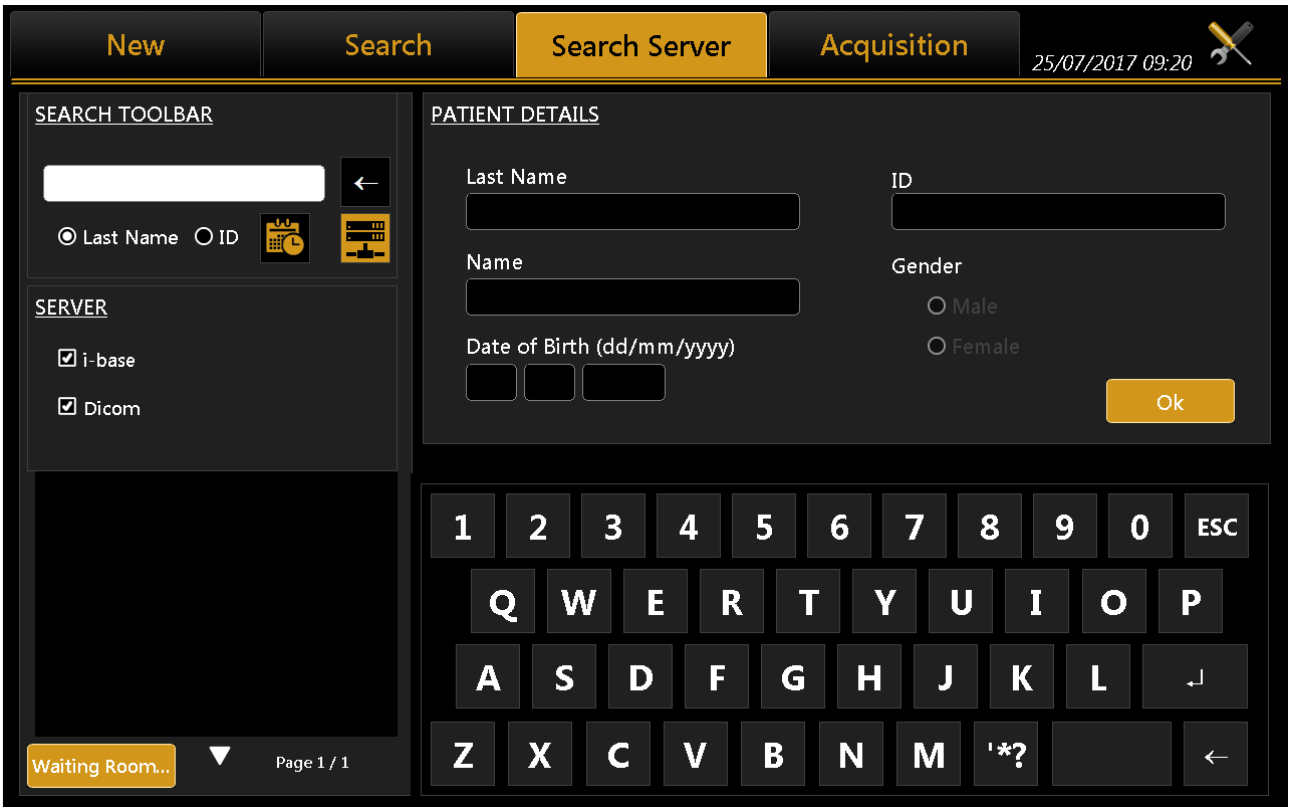


Figure 22

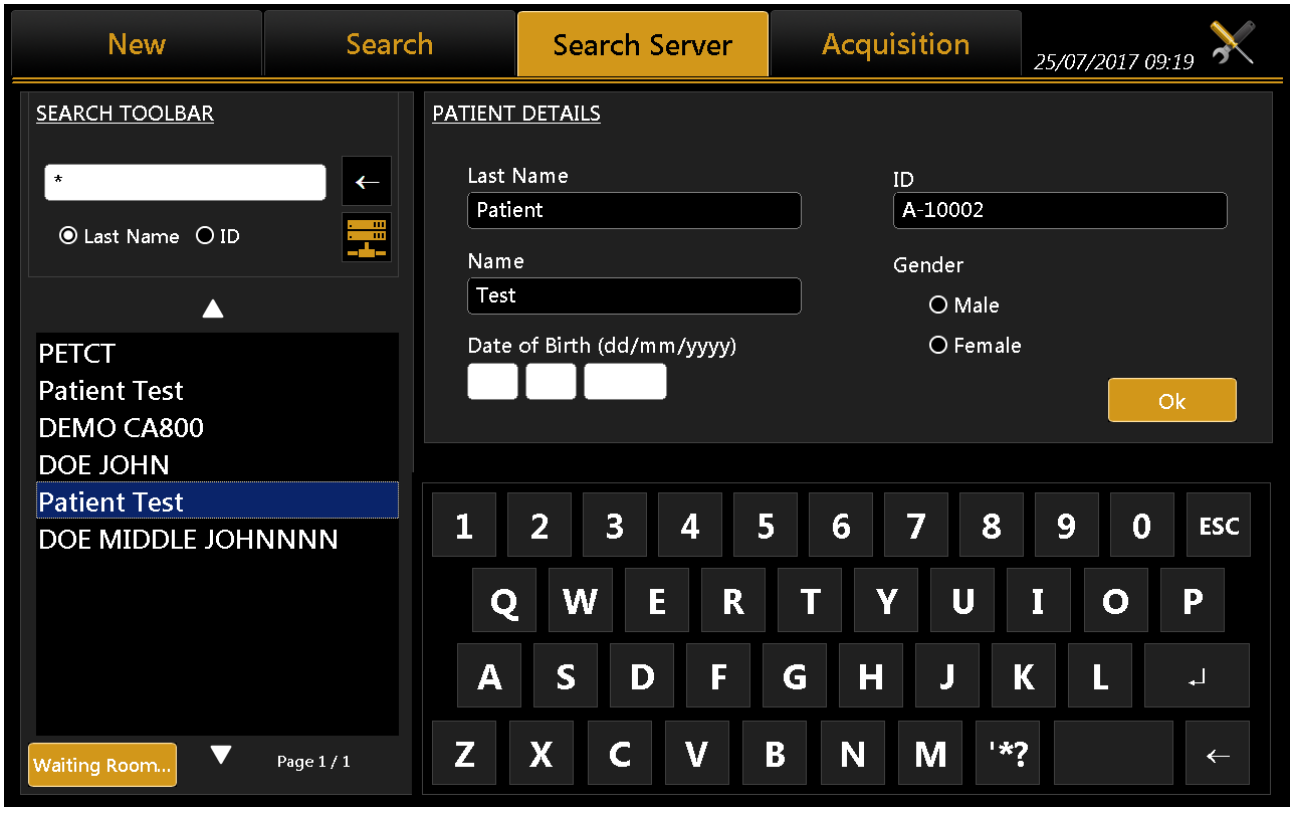


Figure 23

11.4.3.1 *Start an exam from the Waiting Room*

If DICOM Modality Worklist service is configured, ALADDIN HW3.0 is able to search for pending patient's examinations in the waiting room. Pressing on the "**Waiting Room…"** button (Figure 22) 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 "Aladdin")*
- Modality (default is "OT")*

* = contact DICOM services administrator for details on these settings

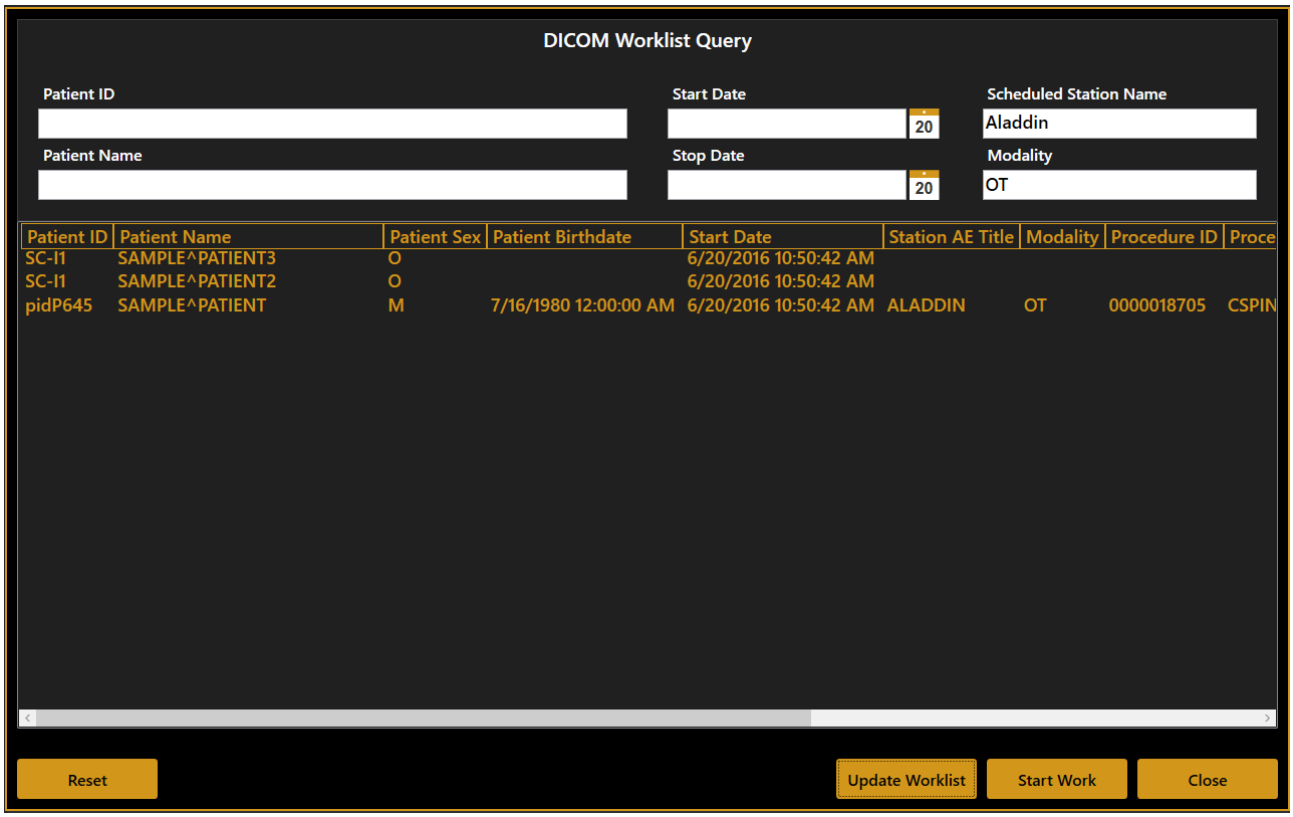


Figure 24

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.

11.5 Acquisition: general instructions

11.5.1 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. 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 Figure 25).

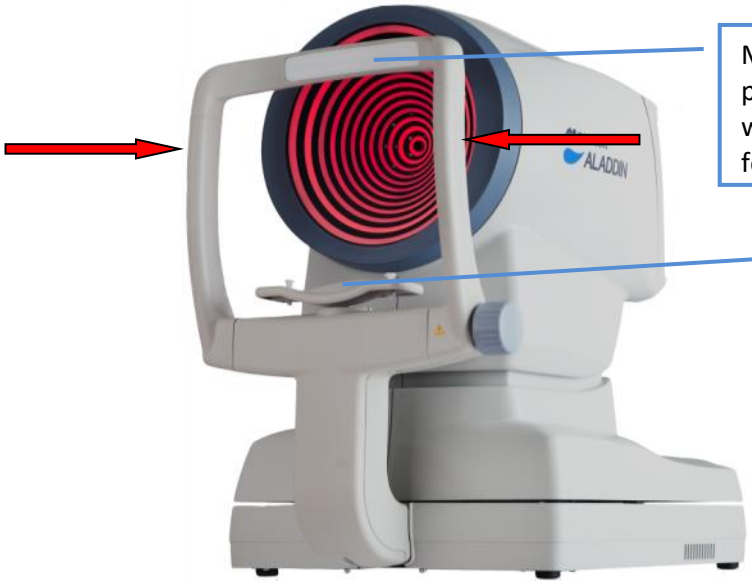
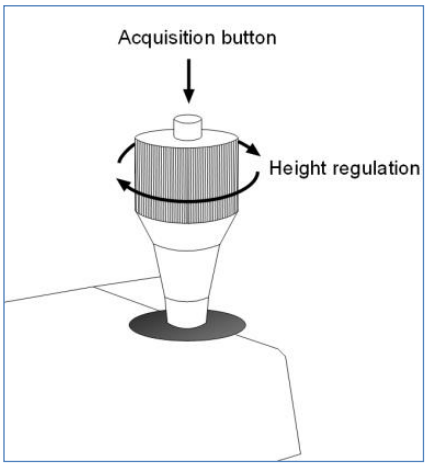


Figure 25

The working distance from the device to the eye is 80.0 mm. The software guides the operator in order to reach the ideal focus condition (see paragraph 11.6)



The joystick illustrated in Figure 26 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's height according to the patient's position.
If the adjuster on the joystick is not enough to achieve the correct position, move the knob on the chin rest for adjusting the height

Figure 26

11.5.2 Description of the Acquisition screen

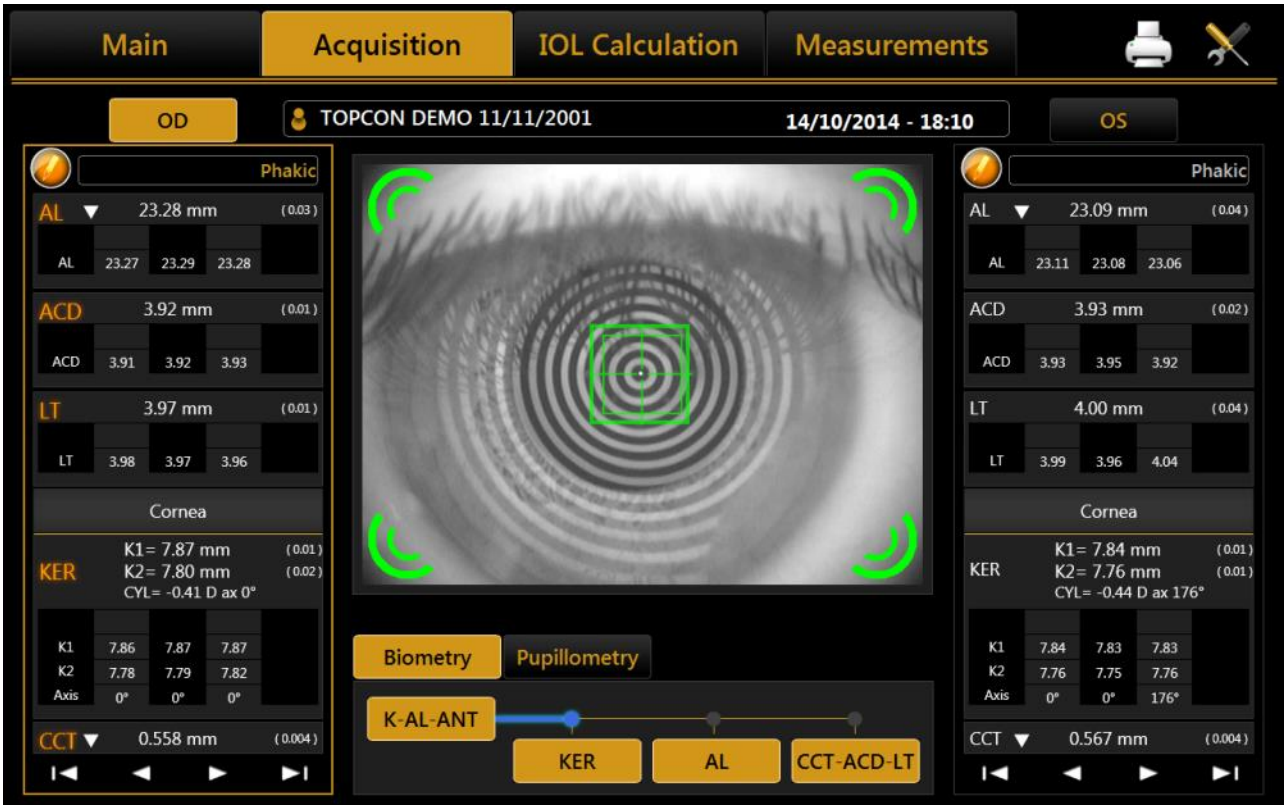


Figure 27

Figure 27 shows the acquisition screen from where all the operations to acquire the required measurements are performed.

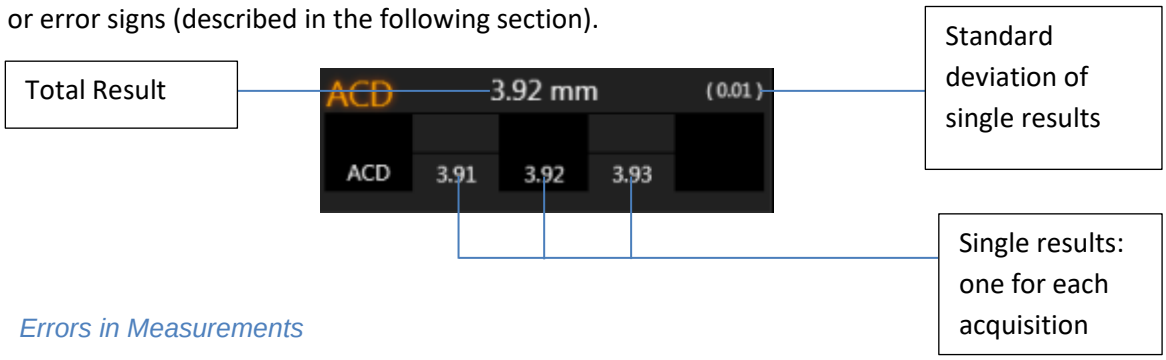
The acquisition window has the following commands:

- ***OD*** and ***OS***: indicate the eye being acquired (the one highlighted in yellow); they are normally selected automatically, depending on the position into which you move the instrument.
- ***Biometry:*** gives access to the biometric measurement section
- ***Pupillometry:*** gives access to the pupillometry section
- The  buttons at the bottom of the data frame for each eye serve to scroll the measurements, as some of these are hidden if more than four acquisitions are made per eye.
-  Modify the nature of the lens and vitreous body. The Axial Length will automatically be corrected depending on the new refractive index

When the acquisition is done, and the eye is selected: the correctly acquired measurements are displayed in white and incorrect measurements are displayed in red. See Figure 28.

11.5.2.1 *Description of results*

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



11.5.2.2 *Errors in Measurements*

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

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

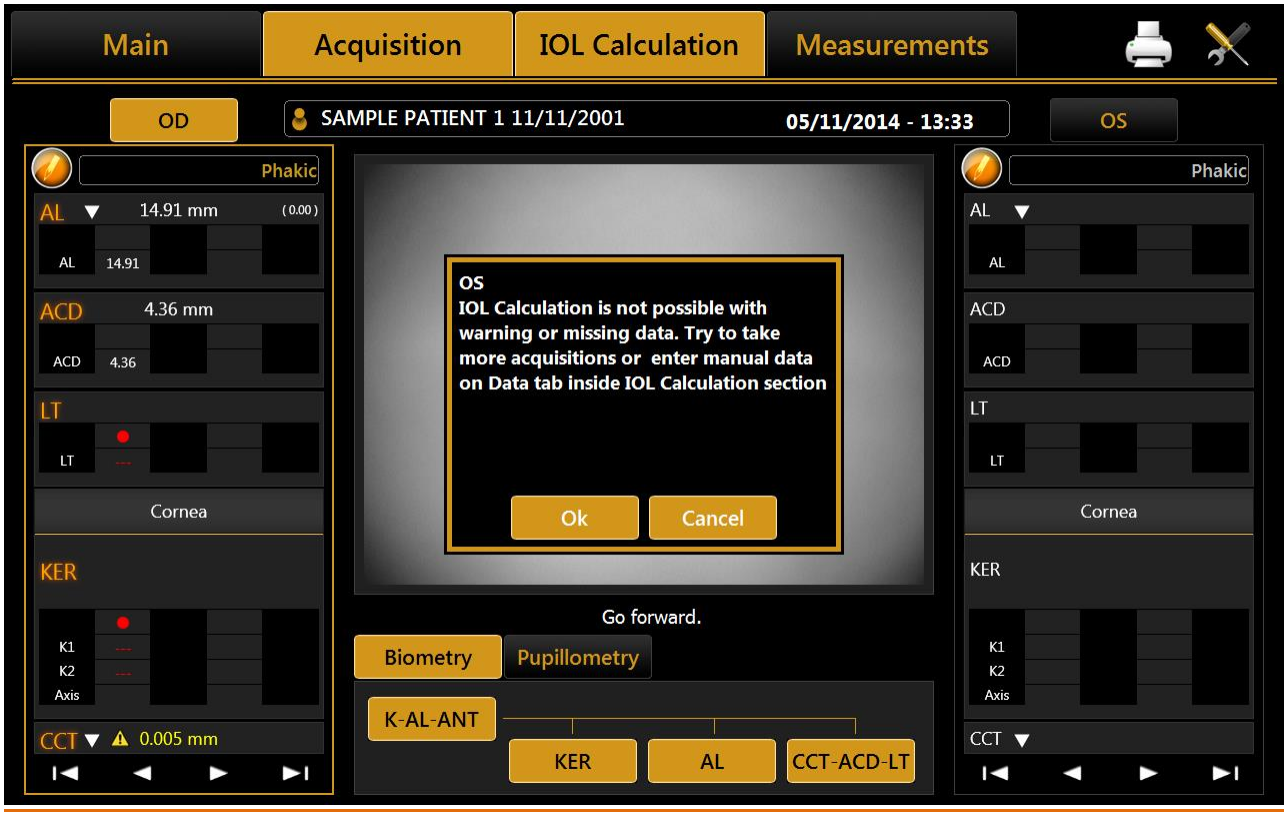


Figure 28

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

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

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

It is very important that the main types of measurement (KER-AL-ACD) taken are shown without a warning sign, otherwise it will not be possible to proceed to IOL Calculation with the current data (valid ACD is needed only if using *Haigis formula*).

Valid LT and CCT aren't needed to access IOL calculation as they are not used in any of the available formulas.

As shown in Figure 28, accessing IOL Calculation, an error window will be shown warning the user to reacquire the measurements or to manually enter a new set of data.

If the user proceeds with manual input (Figure 29), the software will pre-populate all the fields with acquired data, even those with error or warning signs. It is also possible to enter arbitrary data, if possible taken with other instruments.

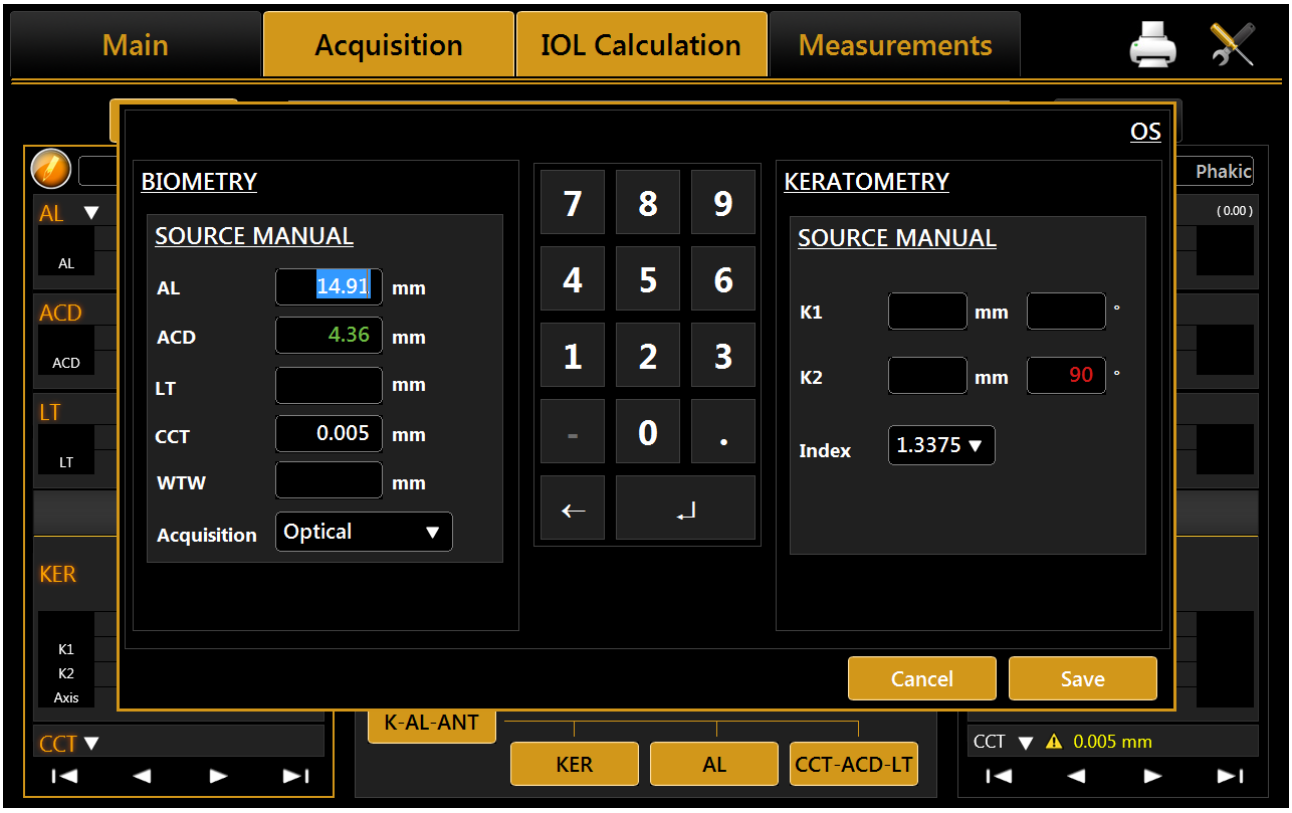


Figure 29

11.6 Biometry: acquisition procedure

There are two acquisition mode:

MODE	BUTTON	DESCRIPTION
FULL BIOMETRY ACQUISITION	K-AL-ANT	Perform the AL (Axial Length), CCT-ACD-LT sequence (Central Corneal Thickness, Anterior Chamber Depth and Lens Thickness) and KER (Keratometry) acquisitions in a full sequence measurement.
SINGLE ACQUISITION	KER	Perform KER (Keratometry) acquisition
	AL	Perform AL (Axial Length) acquisition
	CCT-ACD-LT	Perform CCT-ACD-LT sequence (Central Corneal Thickness, Anterior Chamber Depth and Lens Thickness)

WARNING: ***a valid LT result cannot be obtained without acquiring the patient's AL.***

WARNING: ***a standalone CCT-ACD-LT measurement cannot be performed without a valid AL result***

Backlighting 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.

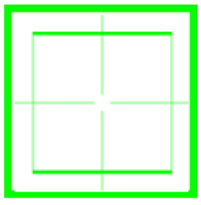
To acquire the image or measurements in general, whatever mode you are in, simply proceed as follows:

1. Align the live image in the center and focus, then press the joystick button to start the acquisition (you need to perform this step only the first time you acquire a patient eye).
2. Move the instrument forwards and backwards (following the indications of the red and blue arrows on the screen) to find the ideal focus. While you find the ideal focus achieve the central alignment by centering the two squared aims with vertical or horizontal movements.
3. When the green indicators are displayed and the two squares are centered (both green), press the joystick button again and the system will automatically capture the required image and/or measurements.
4. **Don’t move the joystick in the few seconds during the acquisition.**

Focusing and centering guidance system is composed of two aspects:

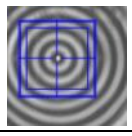
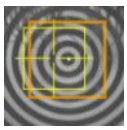
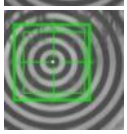
- Centering
- Focusing distance

Centering ideal conditions are achieved by **centering the two squared aims** by means of horizontal and vertical movements, reaching the condition of following picture:



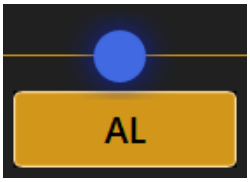
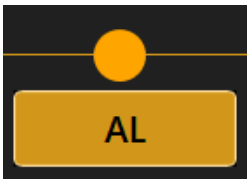
The two squares assume different colors depending on two aspects: focusing position and centering in tolerance.

Focusing ideal conditions are achieved by **following the 4 indicators** at the corners of the viewport, which explain the needed movement in the “forward/backward” direction.

	The red arrows indicate to move the instrument forwards towards the patient's eye.  The centering condition is displayed in red color
	The blue arrows indicate to move the instrument backwards away from the patient.  The centering condition is displayed in blue color
	The green signs indicate that the ideal focus has been reached. Press the joystick button to start the automatic acquisition procedure. In this situation the centering aims assume different colors, as follows:  The centering condition is out of tolerance and a better center alignment is required  The centering condition is displayed in green color, press the joystick button to start acquisition

At the end of the acquisition the measurements are displayed in the corresponding side windows (see Figure 27).

During the acquisition procedure, pulsating dots appear above the “KER”, “AL” and “CCT-ACD-LT” buttons to guide the user through the acquisition steps. They are explained in the following table:

	The system is waiting for the user click on acquisition button. Follow the guide for right centering and focusing, then click the joystick.
	The system is acquiring. Wait until it has finished.
	The system has finished the acquiring procedure.
	The system is acquiring or waiting for user input in a previous step of the acquisition sequence.

11.7 Full biometry acquisition (K-AL-CCT-ACD-LT)

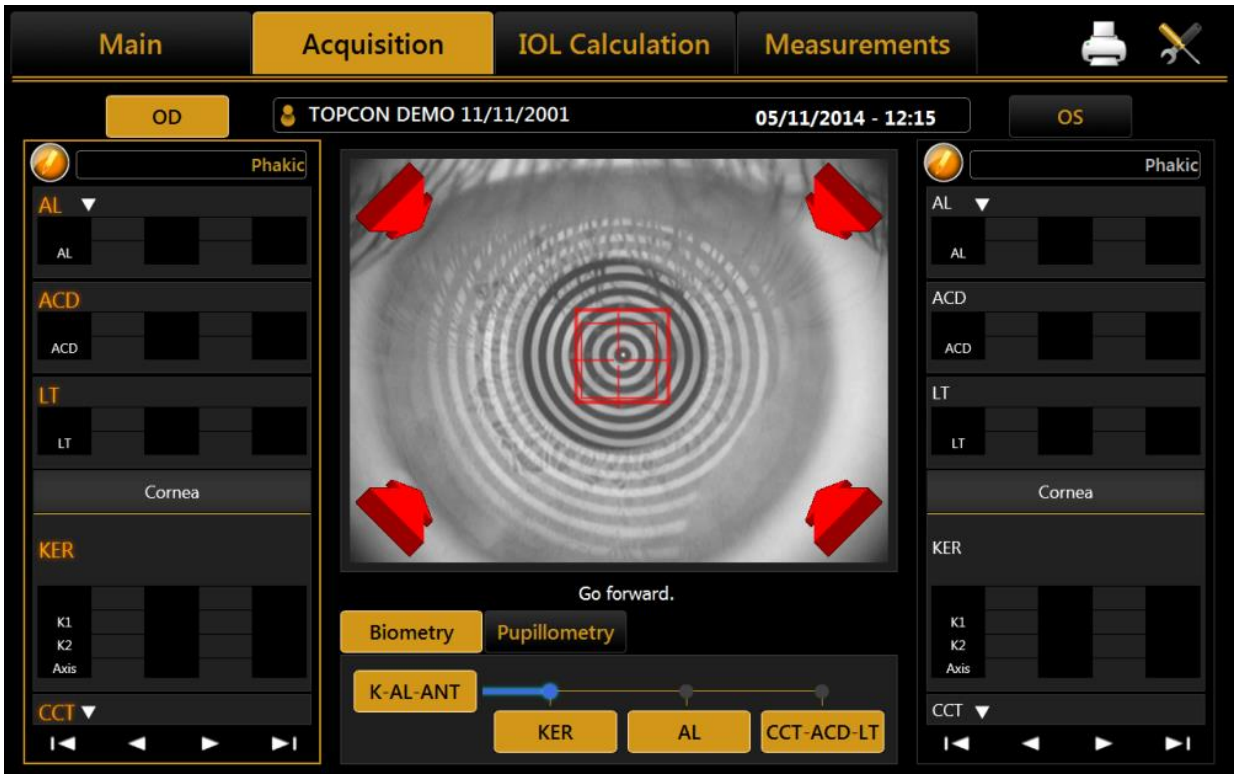


Figure 30

This is a special mode which successively performs all the measurements described in detail in the following paragraphs, specifically:

- Keratometry
- Axial Length
- Anterior Chamber Depth, Central Corneal Thickness and Lens Thickness
- Identification of Mesopic and Photopic pupil

Below the acquisition steps:

1. Press the joystick button a first time to start the procedure (Figure 30).
2. Find the ideal focus and achieve the central alignment as described in paragraph 11.6.
3. Press the joystick button to perform the Keratometry acquisition.
4. Next the system will automatically perform also the Axial Length acquisition (the progression of acquisition steps is shown in Figure 31, as described in paragraph 11.6).
5. Find the ideal focus and achieve the central alignment as described in paragraph 11.6.
6. Press the joystick button to perform the Anterior Chamber Depth, Central Corneal Thickness and Lens Thickness acquisition.
7. Wait few seconds for measurements calculation.
8. The measurements are displayed in the corresponding side windows (see Figure 27).
9. A new acquisition can be done.

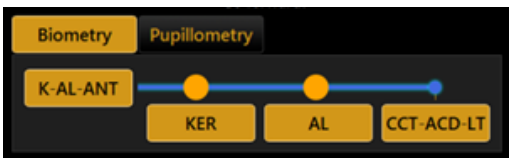


Figure 31

11.8 Acquisition of axial length measurements (AL)

Interpretation of axial length measurements. As a rule, an interference signal is produced if the measuring light is reflected by the retinal pigmented epithelium of the eye. This signal is utilized for axial length measurements.

Note: Ultrasonic biometrical instruments measure the axial length as the distance between the cornea and the inner limiting membrane, because the sound waves are reflected at this membrane. To ensure that the measured values obtained with the ALADDIN HW3.0 are compatible with those obtained through acoustic axial length measurement, the system automatically adjusts for the distance difference between the inner limiting membrane and the pigmented epithelium. The displayed axial length values are thus directly comparable to those obtained by immersion ultrasound, and no re-calculation or correction factors are necessary. Deviations may nevertheless occur between the displayed axial lengths and ultrasonic readings (particularly in the applanation procedure).

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

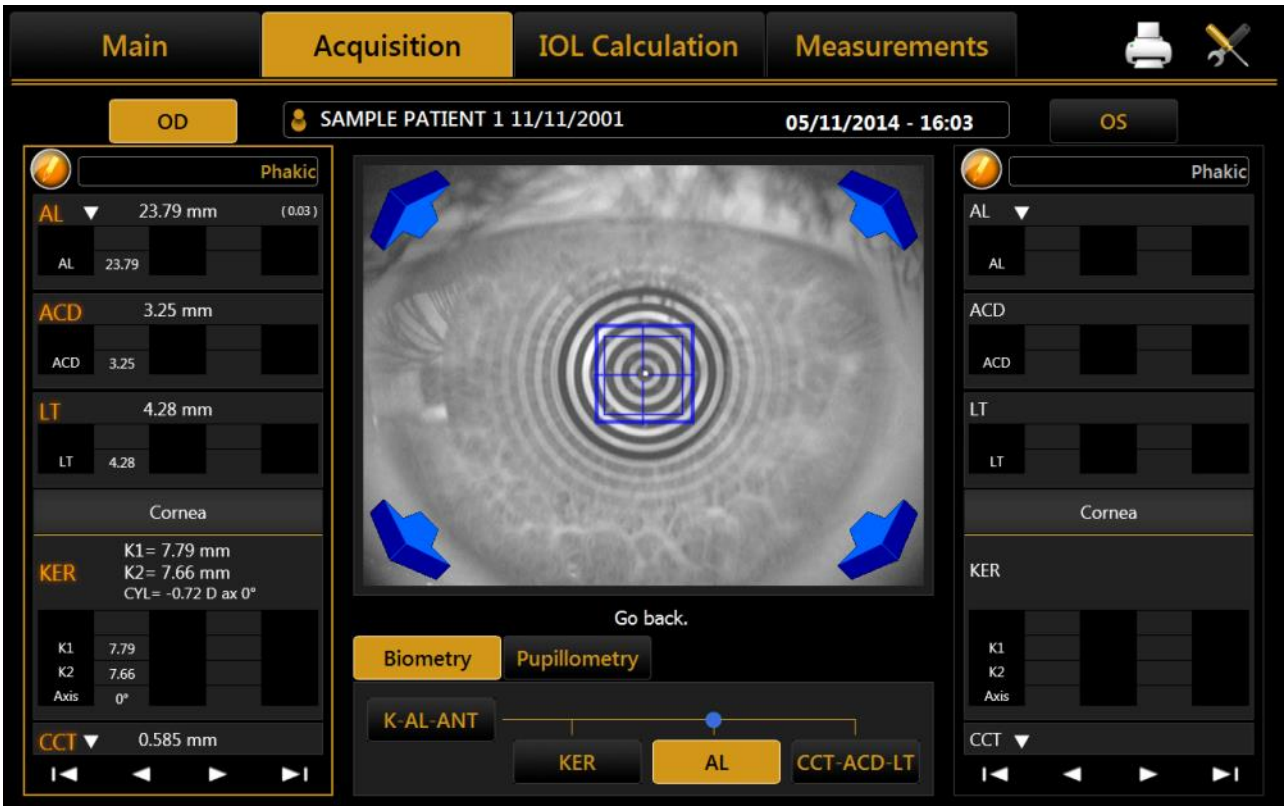


Figure 32

The side columns show the measurements performed for the two eyes (OD = right, OS = left).

For each acquisition, six measurements of the axial length are performed. The information displayed is the same as in the “full sequence” acquisition. The six measurements are reported as a group result in the collapsed view, to expand the view and see each single measurement press the arrow next to AL title to expand/collapse the view.

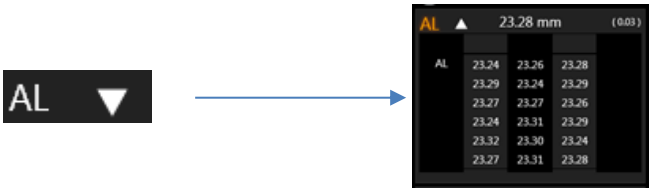


Figure 33

11.9 Acquisition of the anterior segment sections (CCT-ACD-LT)

The AL measurement must be performed before CCT-ACD-LT measurement in order to have a LT result without warning.

A standalone CCT-ACD-LT measurement cannot be perform without a valid AL result.

With this type of acquisition measurements about the sections of the anterior segment of the eye are taken using the interferometer system.

By selecting this mode, the acquisition environment appears as shown in Figure 34.

Press the joystick button and move the device according to the instructions of the automatic guidance system (red/blue arrows and centering aims) until ideal conditions have been reached (green icons and centered aims).

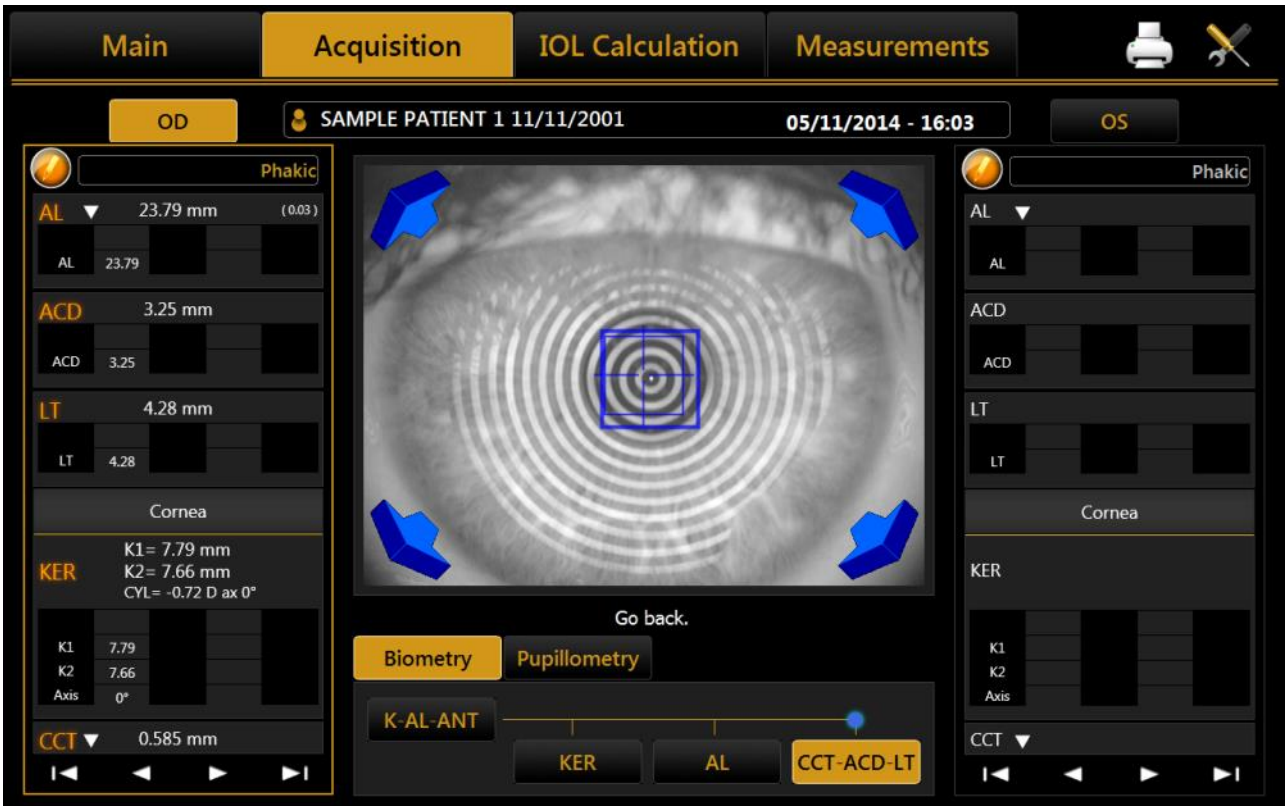


Figure 34

11.10 Keratometry acquisition (KER)

Keratometry 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 measurement precision.
ALADDIN HW3.0 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, serves as a starting point for fine adjustments to be made in the respective measurement mode.
By selecting this mode, the acquisition environment shown in Figure 35 appears.

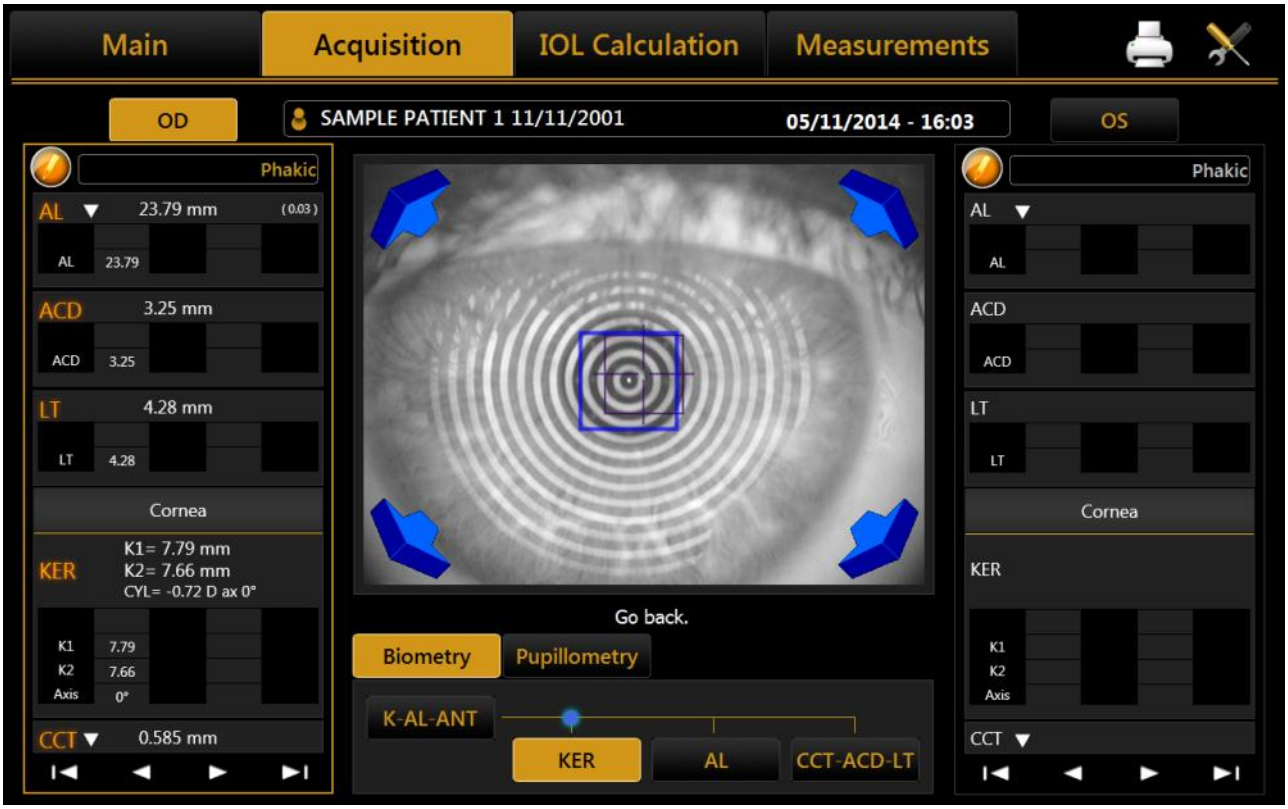


Figure 35

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 performs the standard calculation of 6,144 zero crossing points, identified at the 24 RINGS along the 256 semi-meridian.

In order to increase the measurement precision, interferometry is used to evaluate the corneal distance.

The keratometry data is evaluated in the left column, which is referring to the right eye.
This section has the same interactions as the “K-AL-CCT-ACD-LT” acquisition.

However, since it is not possible for the human eye to stay still, the images acquired manually in a range close to the optimum focus (which is the optimal operating range of the device) can be out-of-focus.

11.11 Pupillometry

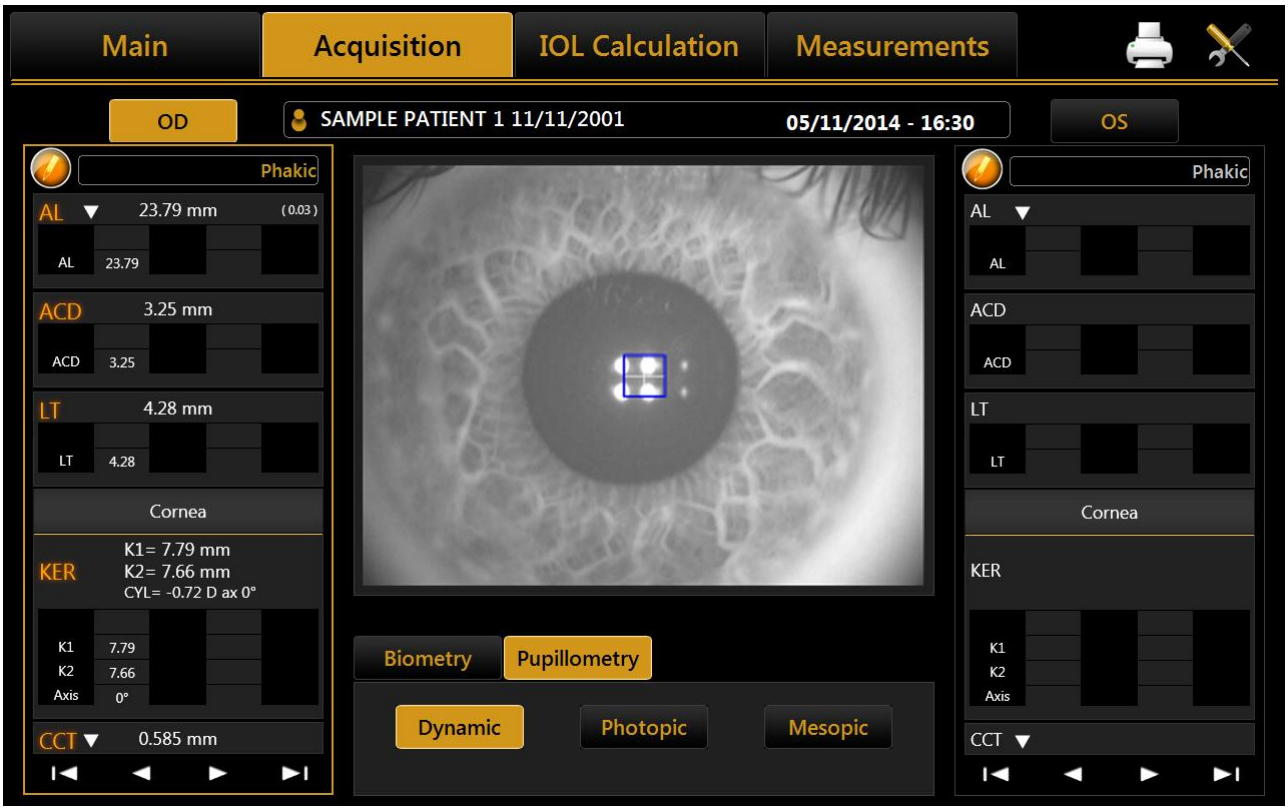


Figure 36

By selecting this mode, the acquisition environment shown in Figure 36 appears on the screen.
In order to acquire the pupillometry, first of all you need to center the blue rectangle, which is overlaid in the image on the reflection of the four LEDs, as shown in Figure 37.

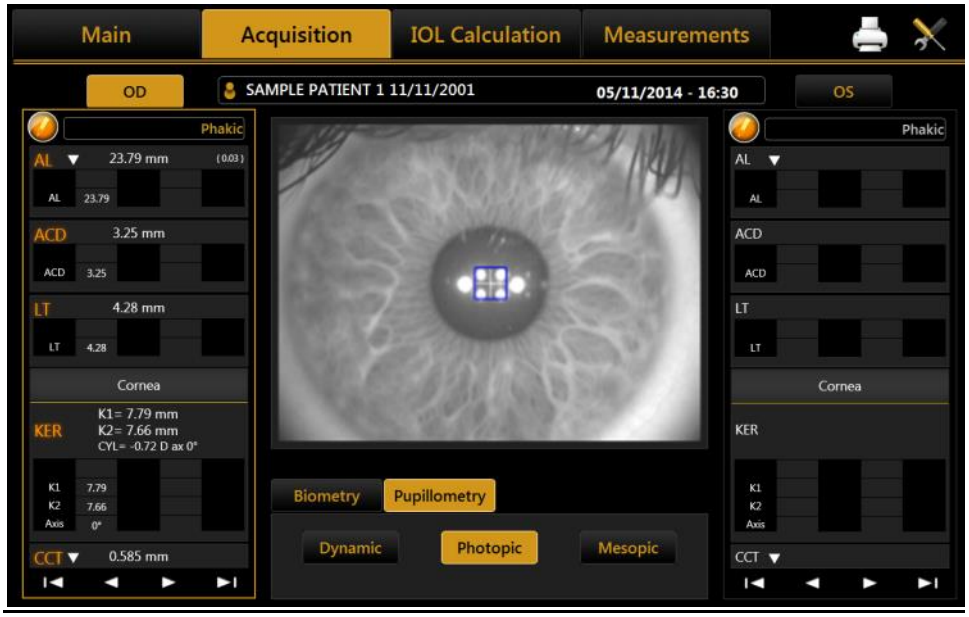
Press the joystick button to start the acquisition and press the button again to stop the acquisition.
As already mentioned in the introductory paragraphs, three types of acquisition can be performed:

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

In the case of the dynamic pupillometry, recording of the state of the pupil is started, first in mesopic conditions, then photopic and then mesopic again. The data on the diameters measured are recorded and shown in the **"Measurement"** 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 to which it is subjected. In the pupillometry acquisition in static controlled light conditions: photopic and mesopic, certain frames are saved, which you can 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. In this case, we suggest acquiring the mesopic data through dynamic pupillometry.*



Acquisition in photopic controlled light conditions

Figure 37

Acquisition in mesopic controlled light conditions

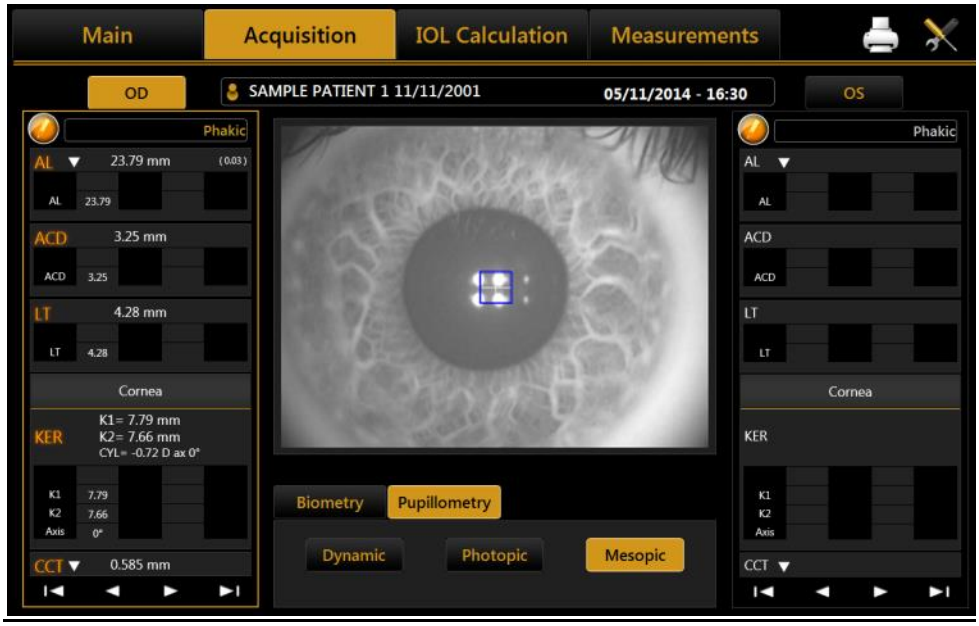


Figure 38

11.12 Report printing

After every measurement, you can print the corresponding report or print all the measurements made in the current exam. In the top-right corner of the screen, press on the  button.

As shown in Figure 39 you can now select from the left column which report to print and also with which surgeon preset (from the **"Surgeon"** box).

You can print directly to an external printer or a USB drive and also print to both simultaneously ("Both" option).

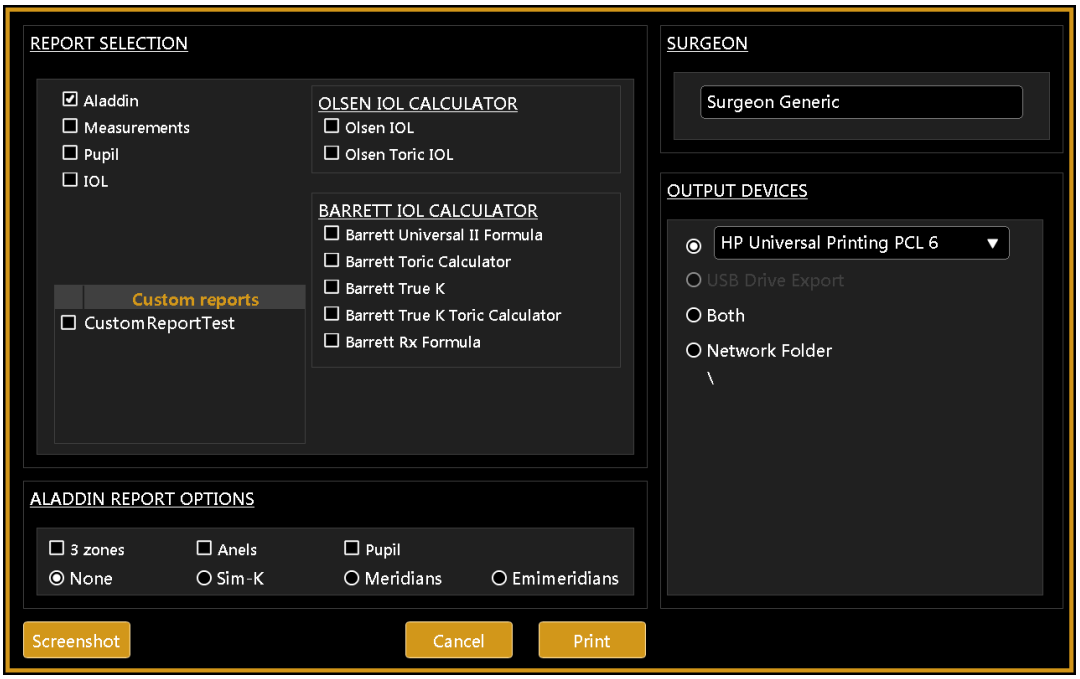


Figure 39

In addition to these two options you can select a network folder as destination of report to print. For network folder settings, see 13.5.1.

The "Aladdin Report Options" allow to define which overlay will be printed in the topography maps images of the "Aladdin". Refer to sections 12.1 and to 13.2 for details about this options.
By clicking on the Screenshot button (Figure 39) you can open the print screen preview and, as shown in Figure 40, send to print the document as represented in the preview.

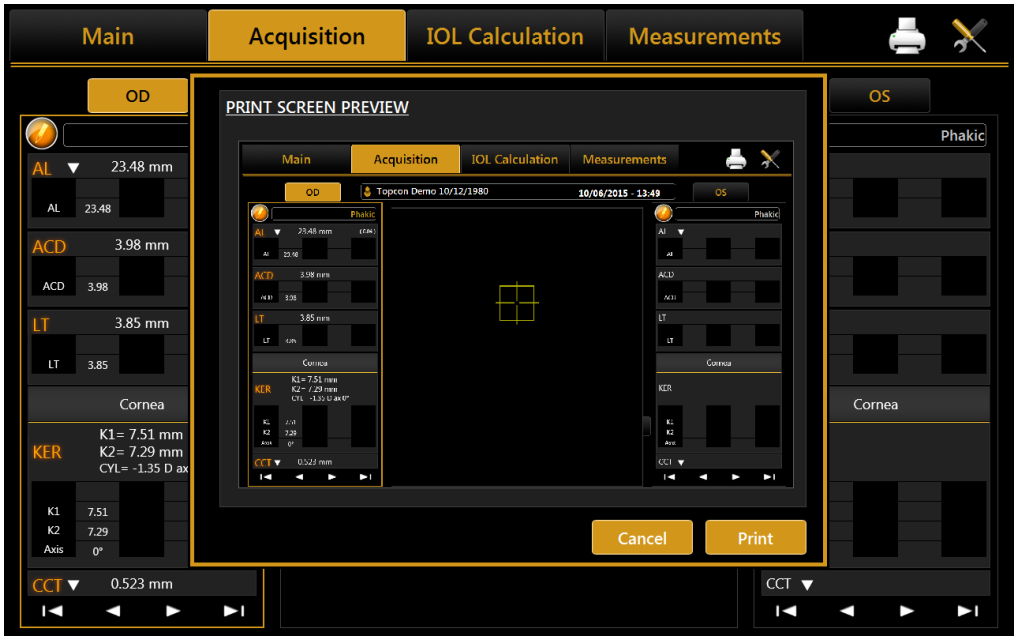
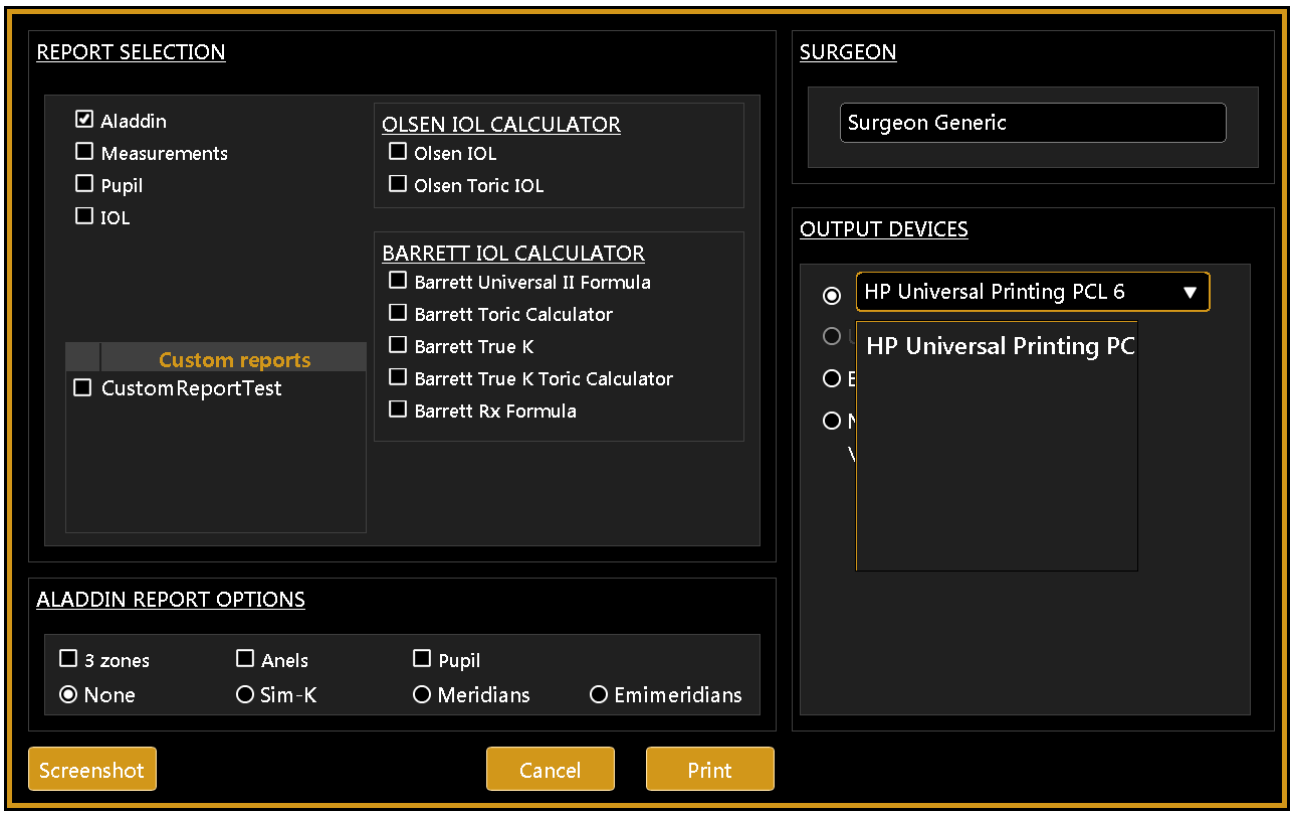


Figure 40

11.12.1 Available Printers

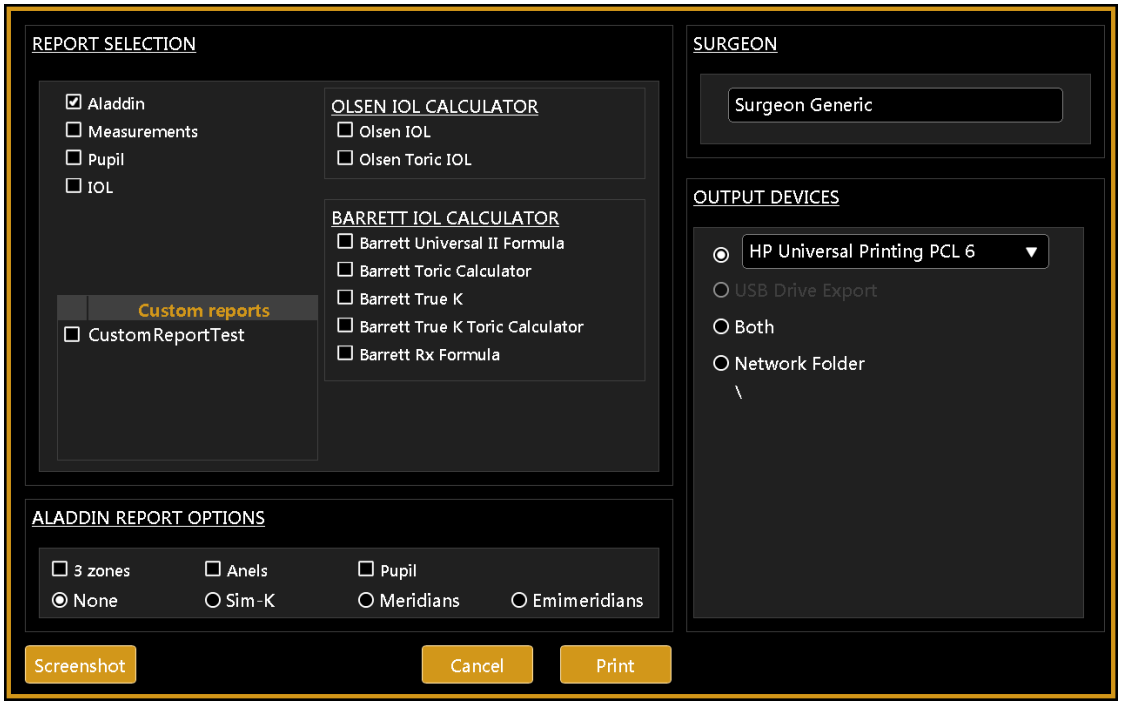
The printing form is showing a list of available printers. The available printers are the one installed on the Operating System. Refer to "Appendix: Installing an external printer" or ask to your technical support in order to have the desired printer installed.

The application pre-selects always the last used printer.



11.12.2 Custom Reports

If the unit has been provided with Customized Reports they will be available to be selected for printing or exporting in the Printing form. In order to obtain custom reports contact you technical assistance.



11.13 Data Exportation

After every measurement, you can export the corresponding reports or xml date made in the current exam.

In the top-right corner of the screen, press on the  button. The popup of Figure 41 is show where you can select one or more destinations for exportation.

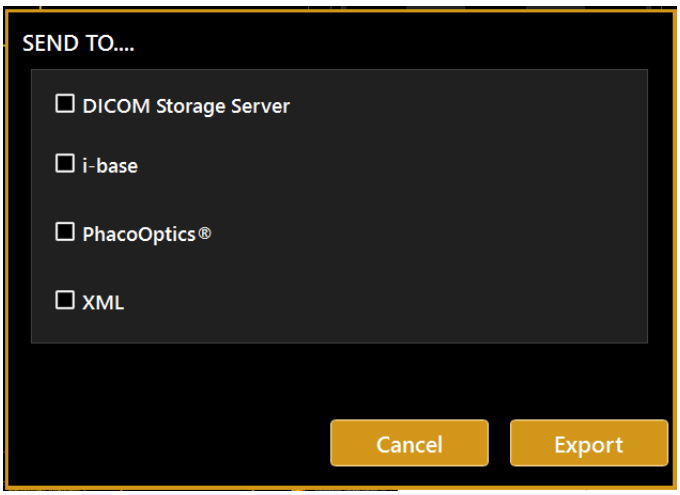
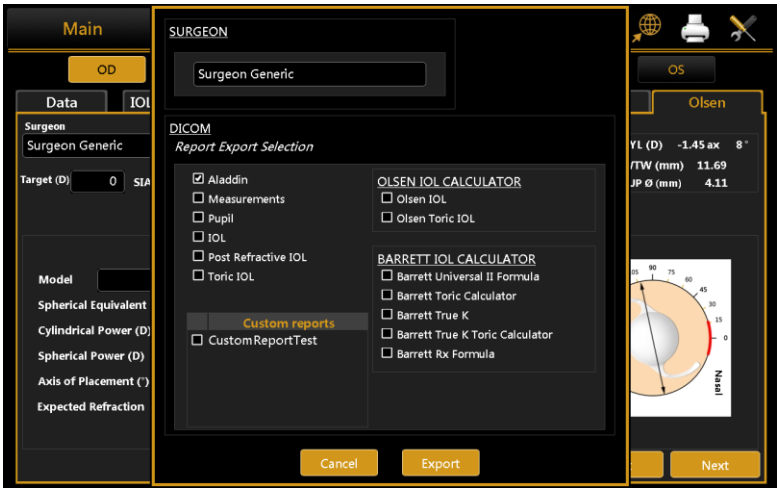


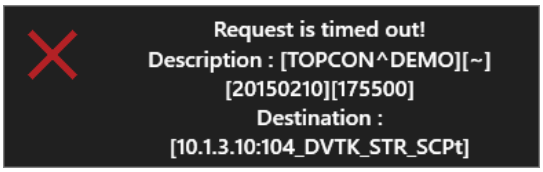
Figure 41

Currently available destinations are:

- **DICOM Storage SCP Server**, the selected reports are sent to the designed DICOM storage location according to prior defined settings. Refer to DICOM configuration for further details. Select the desired reports to save on the Storage location.

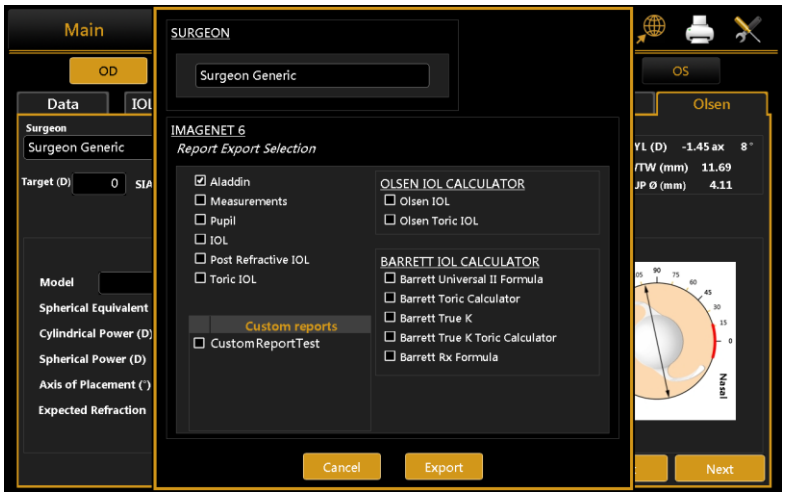


You will receive the confirmation message in case of successful or unsuccessful transfer.



If Storage Commitment is configured you will receive the confirmation message in case of successful or unsuccessful transfer.

- **IMAGEnet 6/IMAGEnet i-base**, the selected reports and data are sent to IMAGEnet i-base or IMAGEnet 6 if activated and configured from the settings. If both are enabled the destination is IMAGEnet 6.



- **PhacoOptics®:** http://www.phacooptics.net/, export biometry data in xml format to a network shared folder, to be imported in PhacoOptics® software. Refer to section 13.5 and to PhacoOptics® software instruction for further details on configuration.

- **XML:** create XML file with biometry data and IOL calculations (also images of the eye topography) that is exported to the configured network shared folder. Refer to section 13.5.

When the selection of the destination you can press "**Export**" to perform exportation of data to the destinations, or "**Cancel**" to just close.

11.14 IOL calculation

ALADDIN HW3.0 also includes a section for calculation of the intraocular lenses (IOL Calculation).

In order to perform the intraocular lens power calculation, the available power interval, the increments and the calculation constants must be provided for each type of formula and lens. These, however, do not depend solely on the type of lens and the calculation formula, but are also closely linked to the measuring technology and the surgical techniques used. **It is strongly recommended that the user optimize the IOL constants in clinical practice and the type of device used for acquisition of the biometric data.**

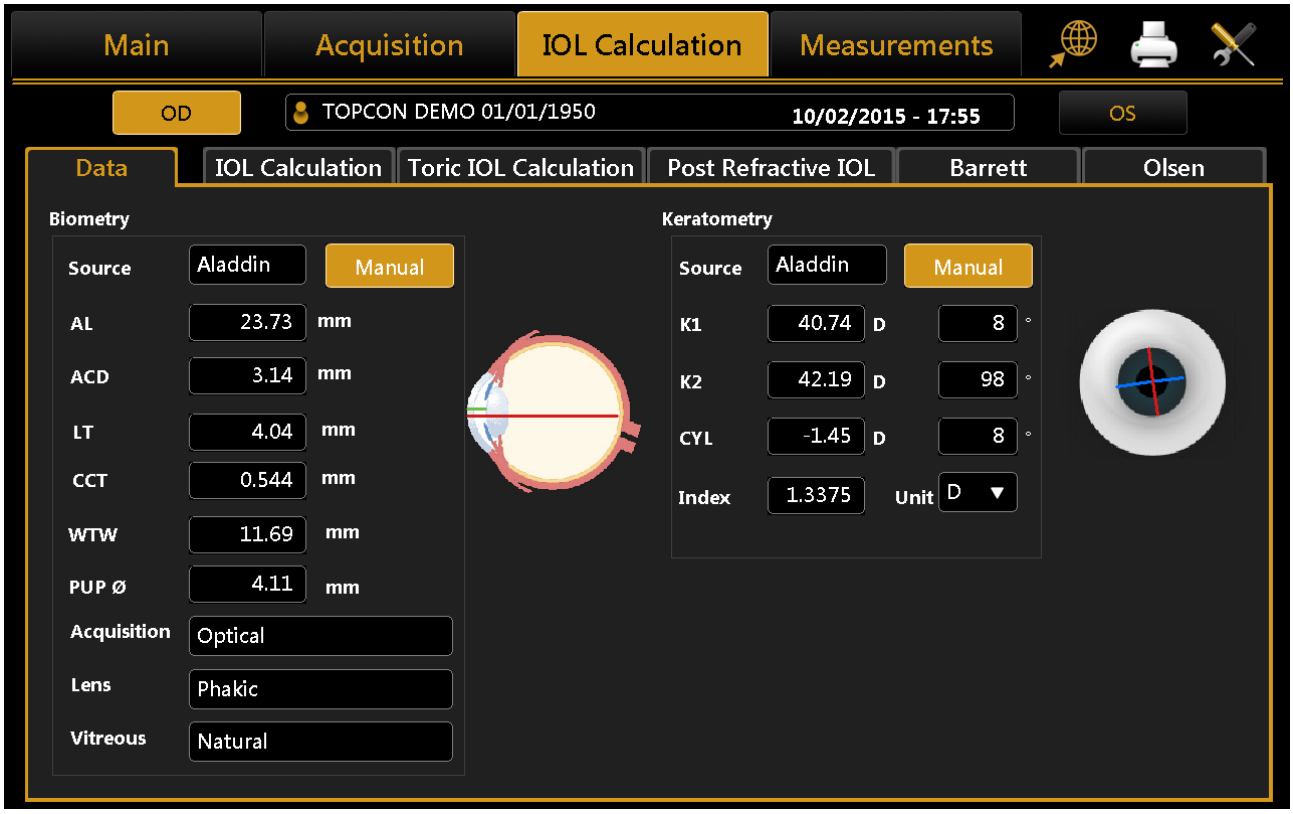


Figure 42

The screen has various sections, which we will explore in detail below:

- Data
- IOL Calculation
- Toric IOL Calculation
- Post Refractive IOL
- Barrett (Barrett IOL Calculator module)
- Olsen (Olsen IOL Calculator module)

The first time a surgeon enters in IOL Calculation, it will appear the panel shown in Figure 43 that contains the Disclaimer regarding the usage of the IOL Calculation. The Disclaimer will appear every time you enter in IOL Calculation or you want to print a IOL report, unless you check the box below before clicking the OK button. The Disclaimer is also replicated in the IOL settings (see 13.4.1), where you can even reactivate its appearance at every IOL usage.

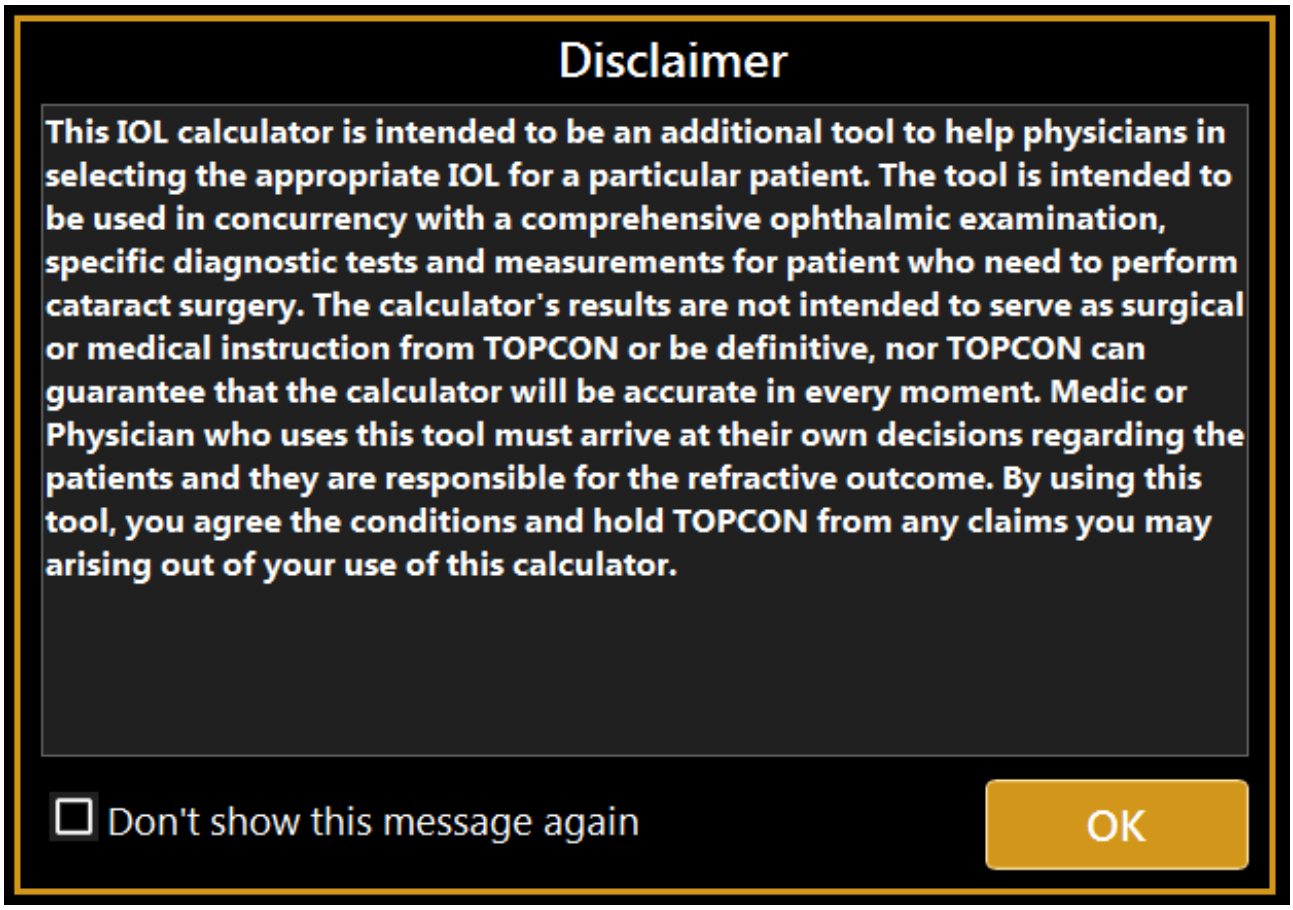


Figure 43

11.14.1 Data

In this section there is a summary of the measurements performed with the instrument.

The screen displayed for the "Data" tab is as shown in Figure 42. As you can see, it has two sections:

- **Biometry:** detailing the data on the ocular biometry
- **Keratometry:** detailing the patient's keratometric data

From the **"Source"** field (present in both the Biometry and Keratometry sections, Figure 42), you can choose to use the measurements of the **"Aladdin"** instrument as source, or to enter them manually by pressing the **"Manual"** button**.** In this case, a panel opens (Figure 44) where you can enter the data manually using the numeric keypad.

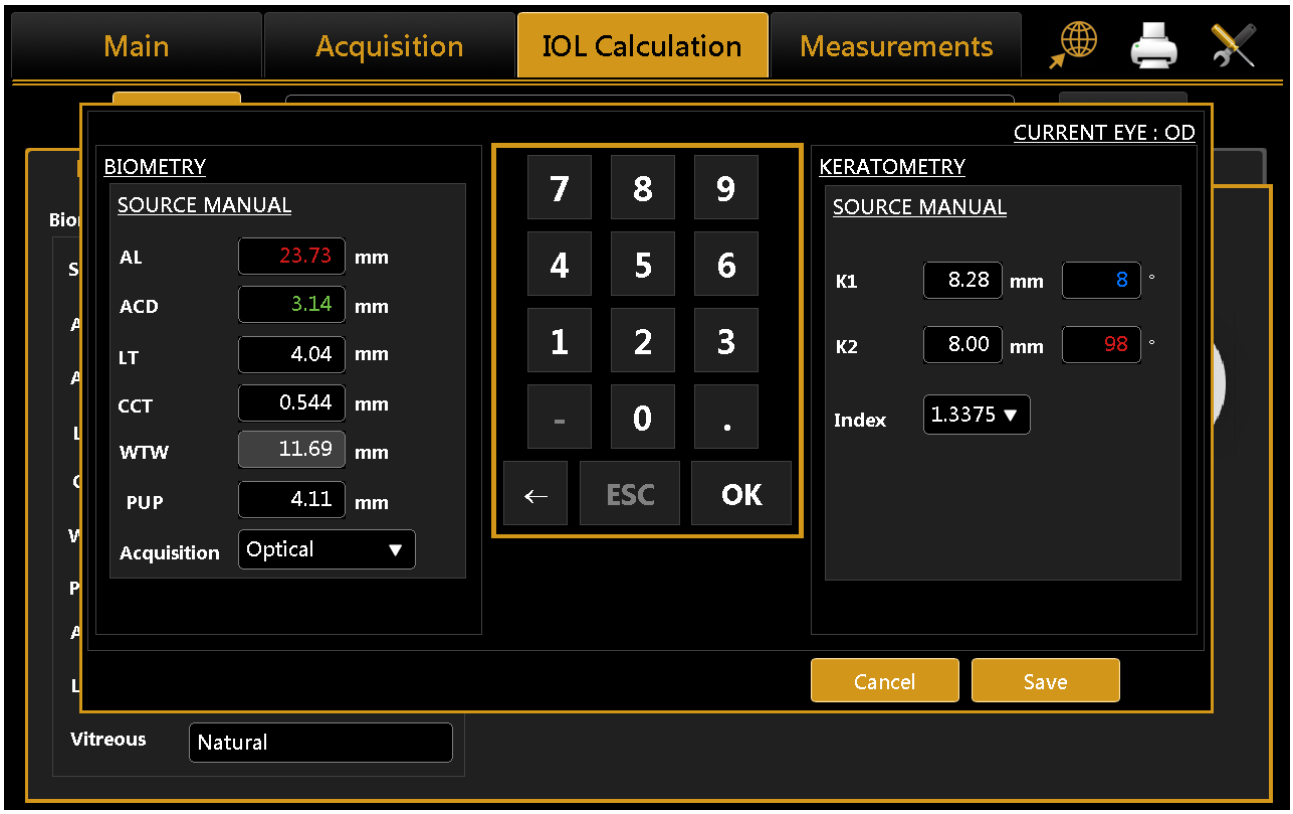


Figure 44

In Figure 44 (Manual Keratometry tab), you can enter values both in Diopters or Millimeters. The values will be automatically recognized according to a specific range. This range goes from 6.75mm to 9.64mm, (from 35Diopters to 50Diopters). Also every mm/D conversion from now on will be performed on the basis of the current index in this section.

In Figure 44 you can manually enter biometry data; knowing that an external instrument does not always work in Optical mode, you can also select acoustic measurement mode.

⚠	**WARNING:** *The responsibility for any data entered and checked manually lies exclusively on the user.*
	WARNING: *Using data from acoustic instruments also means that the constant of every IOL must be optimized for those kinds of instrument; at present, it is more common to find online only databases of lenses optimized for optical interferometry instruments.*

11.14.2 Spherical IOL calculation

The section where you process the data collected for the calculation of the best intraocular lens is divided into three main parts:

The **IOL Calculation** section is fundamental in calculating the total spherical power that will compensate the removal of the crystalline in cataract surgery. This calculation, depending on the case, will be sufficiently precise to guarantee the patient optimal vision.

In certain cases, however, if the corneal astigmatism exceeds a disturbance value, i.e. if faced with a medium or medium-high astigmatism, it is advisable to implant an intraocular lens that also takes this factor into account (refer to the following section).

In the **"Toric IOL Calculation"** section, a surgeon who has established, by means of topography, the need for an astigmatic correction, can use toric lens calculation. The calculation is made on the basis of the ideal spherical IOL and the patient's characteristics. The software then, on the basis of the corneal astigmatism, recalculates the one on the IOL plane, also considering the possible astigmatism induced by surgery.

The Toric IOL is thus chosen, which guarantees post-operation refraction with minimum residual astigmatism.

In the "**Post Refractive IOL**" section you can calculate the intraocular lenses for patients who have already had refractive surgery to correct myopia or hypermetropia.

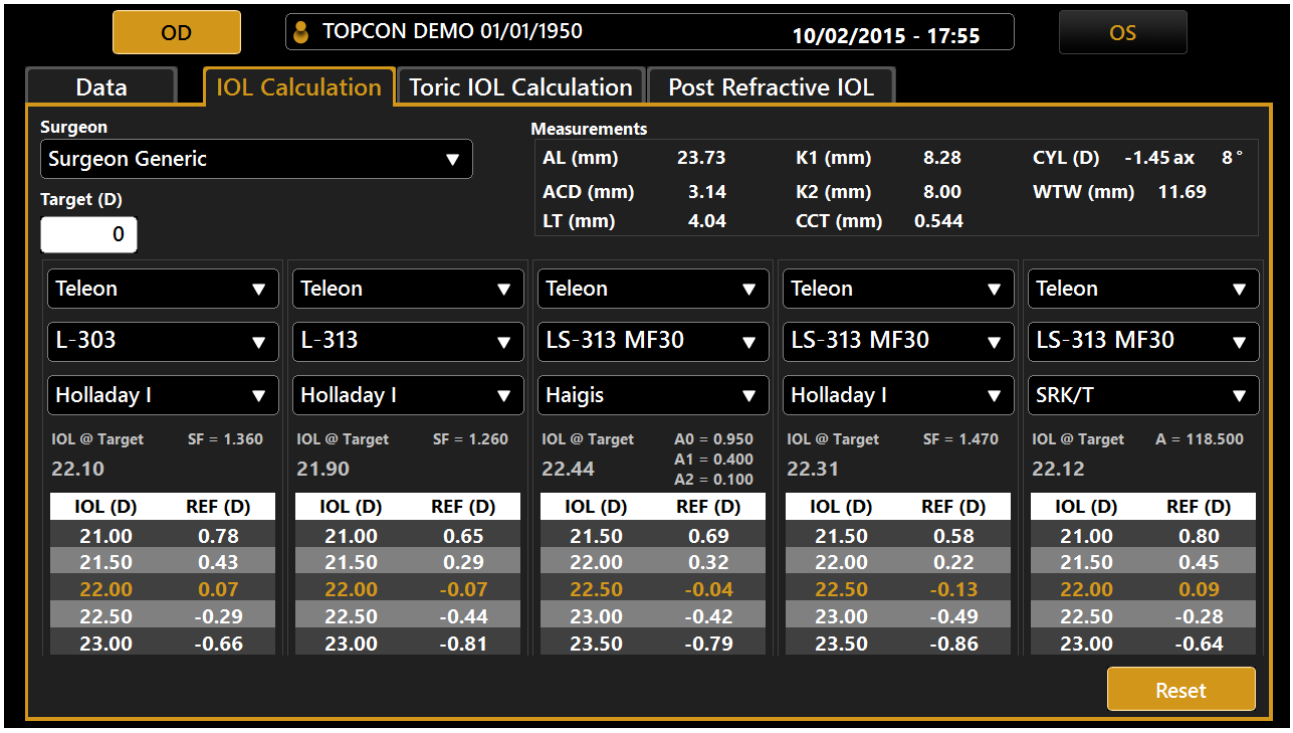


Figure 45

Figure 45 above shows the SW environment for entering data for the **"IOL Calculation"**.
In the ***"Surgeon"*** field, you can choose which surgeon will perform the IOL implant and any customization of the constants or preset of the preferred lenses and formulae will be applied on this basis.
In ***"Target"*** field the target refractive value for the Post-Op must be inserted.
The ***"Measurements"*** field summarizes the measurement data.

From the drop-down menu, select the IOL manufacturer and model, as well as the preferred formula with which to calculate the best lens.
Once this data has been entered, the most appropriate lens can be chosen at the discretion of the surgeon.

Pressing **“Reset”** will reset the initial preset conditions.

11.14.3 Toric IOL calculation

Toric IOL calculation is divided into two main steps. The first one consists on the calculation of the Spherical Equivalent Power; in the second one you can select the toric IOL that produce the best correction.

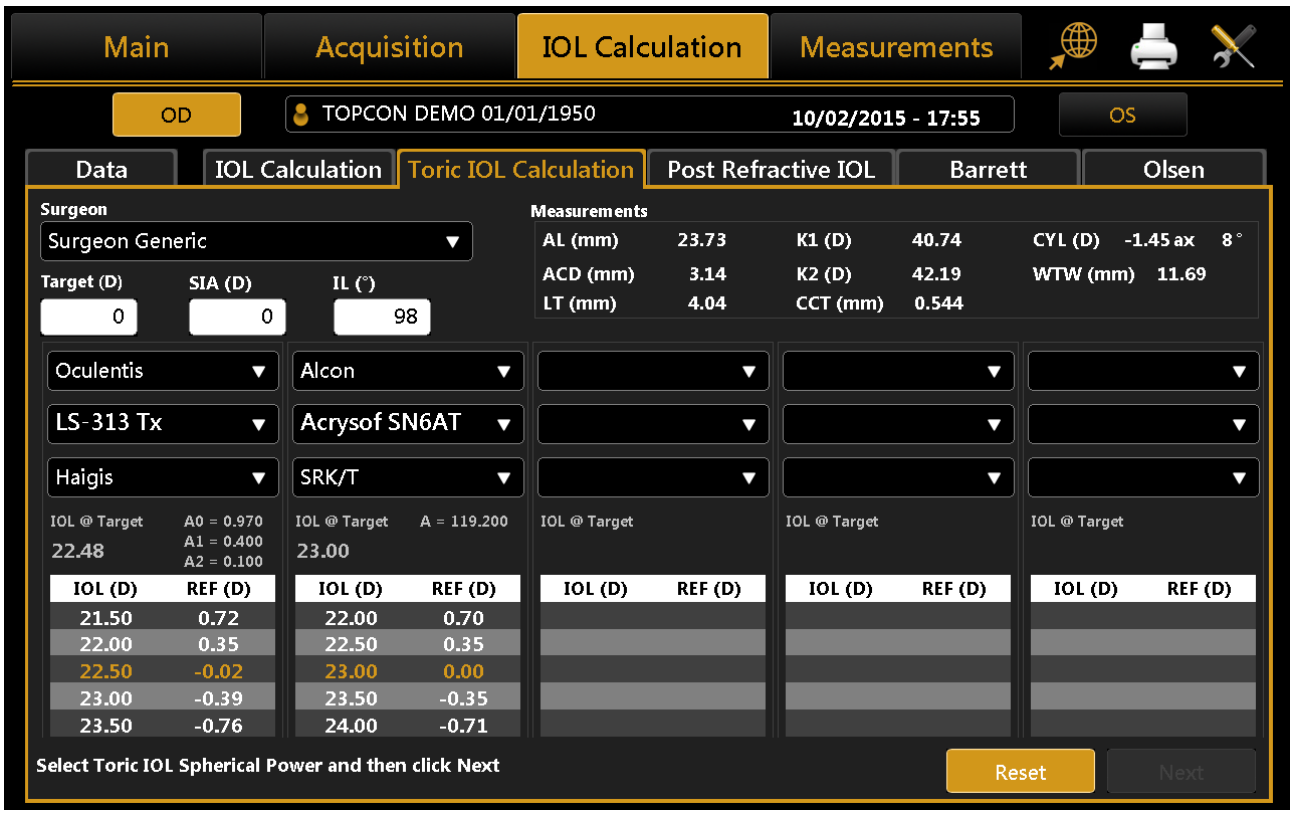


Figure 46

Figure 46 shows the first-step interface that has quite the same structure as the normal IOL calculation. The available toric lenses you can select come from a list of models whose calculation constants have been published by their manufacturer. The user can in case insert new toric manufacturers and/or models inside toric IOL settings section (see 13.4.3)

In addition to choosing the **"Target"**, you need to specify also the **"Surgical Induced Astigmatism (SIA)"** and **"Incision Location (IL)".** The former identify the astigmatism (in diopters) induced by the incision while the latter identify the surgical incision axis. After having selected the toric IOL model and one of the available formulas, a values table from which to choose the **Spherical Equivalent Power** is obtained. Once you choose a lens, pressing **"Next"** at the bottom right, you enter in the second-step of toric IOL calculation (Figure 47).

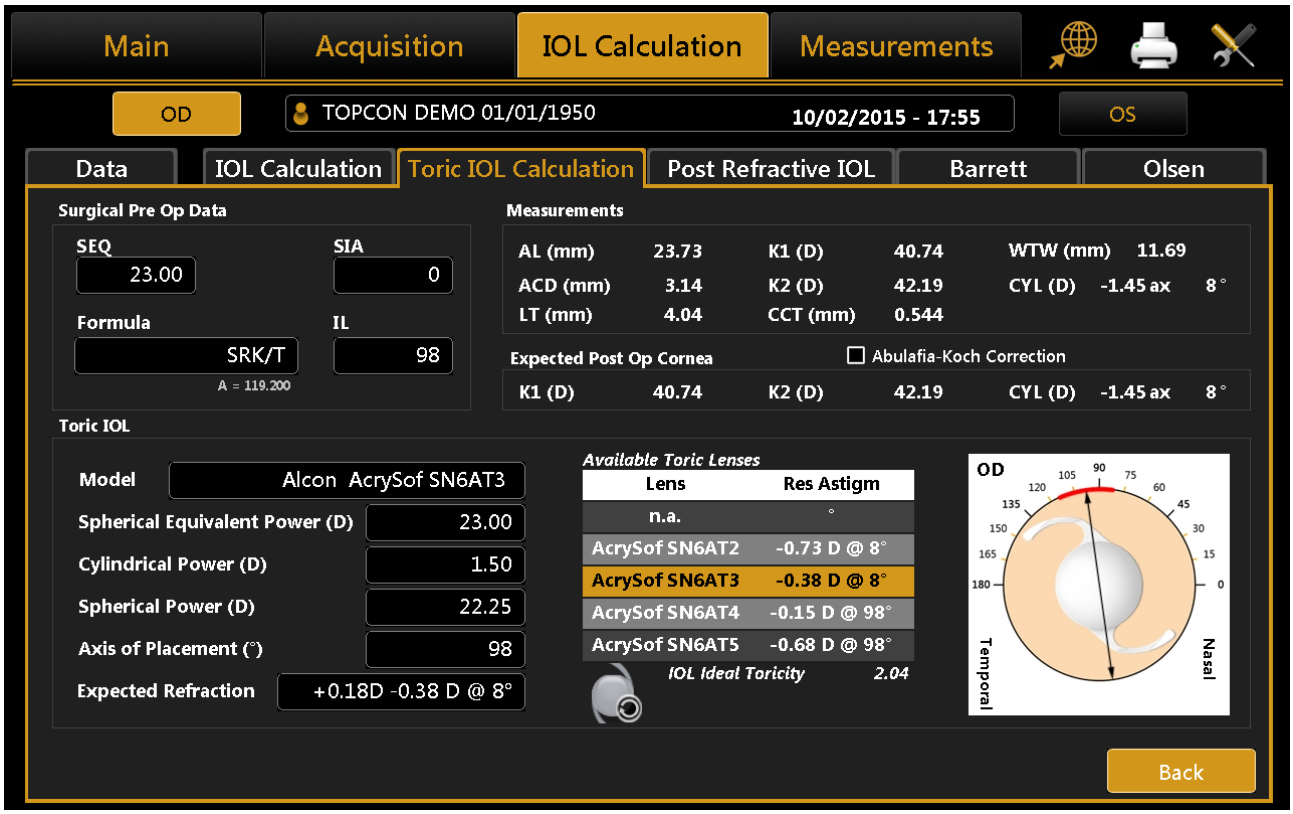


Figure 47

"Measures" and **"Surgical Pre Op Data"** frames summarize the values used in the first-step calculation.

"Expected Post Op Cornea" frame gives information about the post surgery patient eye Keratometry, taking into account the aforementioned SIA and IL.

If the option "**Abulafia-Koch correction**" is selected the astigmatism is corrected in the **"Expected Post Op Cornea"** by taking into account, together with SIA and IL, the nomogram-based correction. Refer to "*Abulafia A, Koch DD, Wang L, Hill WE, Assia EI, Franchina M, Barrett GD: New regression formula for toric intraocular lens calculation. – Journal of Cataract & Refractive Surgery, 2016 – Elsevier*". If the Toric IOL calculation is performed using the Abulafia-Koch Correction it is reported in the corresponding Toric IOL report.

As a result, the **"Toric IOL"** frame, immediately below, details the best toric lens computed automatically by the system for the manufacturer and model selected previously in the first-step.

From **"Available Toric Lenses"** table you can choose also a different cylinder value for the lens, based on the Residual Astigmatism you want to achieve (under-correction/overcorrection). In particular, the best toric lens value is shown in the central row and (if available) the ones that under-correct above the central row, the ones that overcorrect below.

At the right side, you can find an image that illustrates the ideal position of the IOL once the implant is in place and in red the incision location angle.

Under the table, the small icon opens the Toric Rotation Misalignment Simulator (Figure 48).

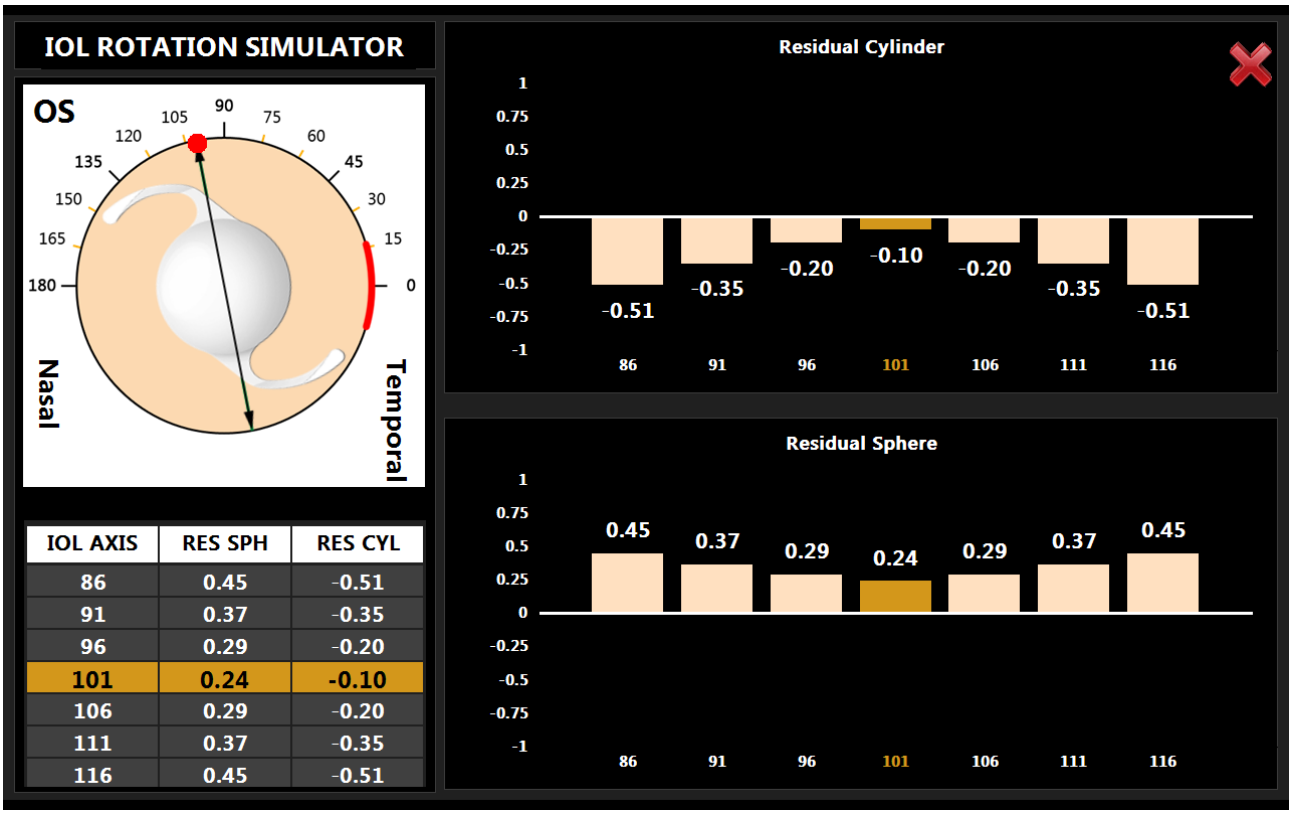


Figure 48

This simulation shows the impact of a wrong axis placement that can occur during surgery and how it affects the residual sphere and cylinder refraction of the patient. The simulator starts at the correct axis placement and displays in the left bottom table a series of misalignment angles close to the ideal one. Selecting a different row you can see the new residual sphere and cylinder at the selected axis.

In Figure 49 is shown the selection of a ten degrees misalignment, with the new axis selected in orange and the correct one in green.

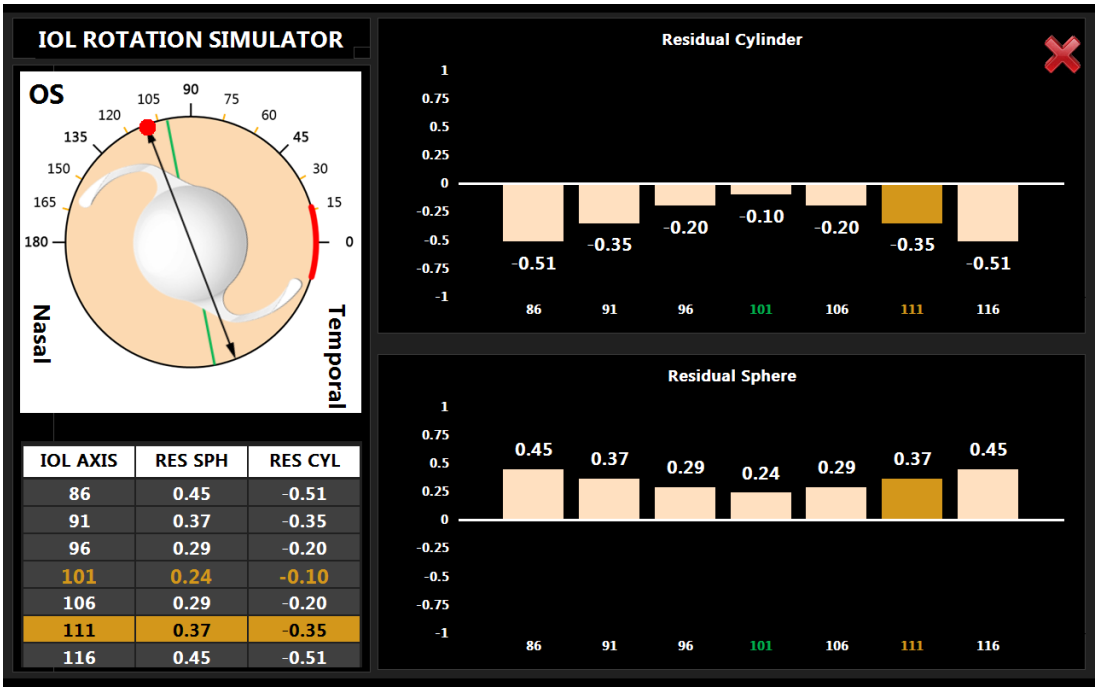


Figure 49

11.14.4 Post Refractive IOL calculation

In this section, you can calculate intraocular lenses also for patients who have undergone refractive surgery to correct myopia or hyperopia by using the Camellin-Calossi formula and the Shammas no-history formula (Figure 50).

These formulae are used with patients who have had prior refractive surgery. Each such patient is unique and results may vary widely. You should interpret all IOL power recommendations with caution.

In this environment, you need to manually enter certain fundamental data.

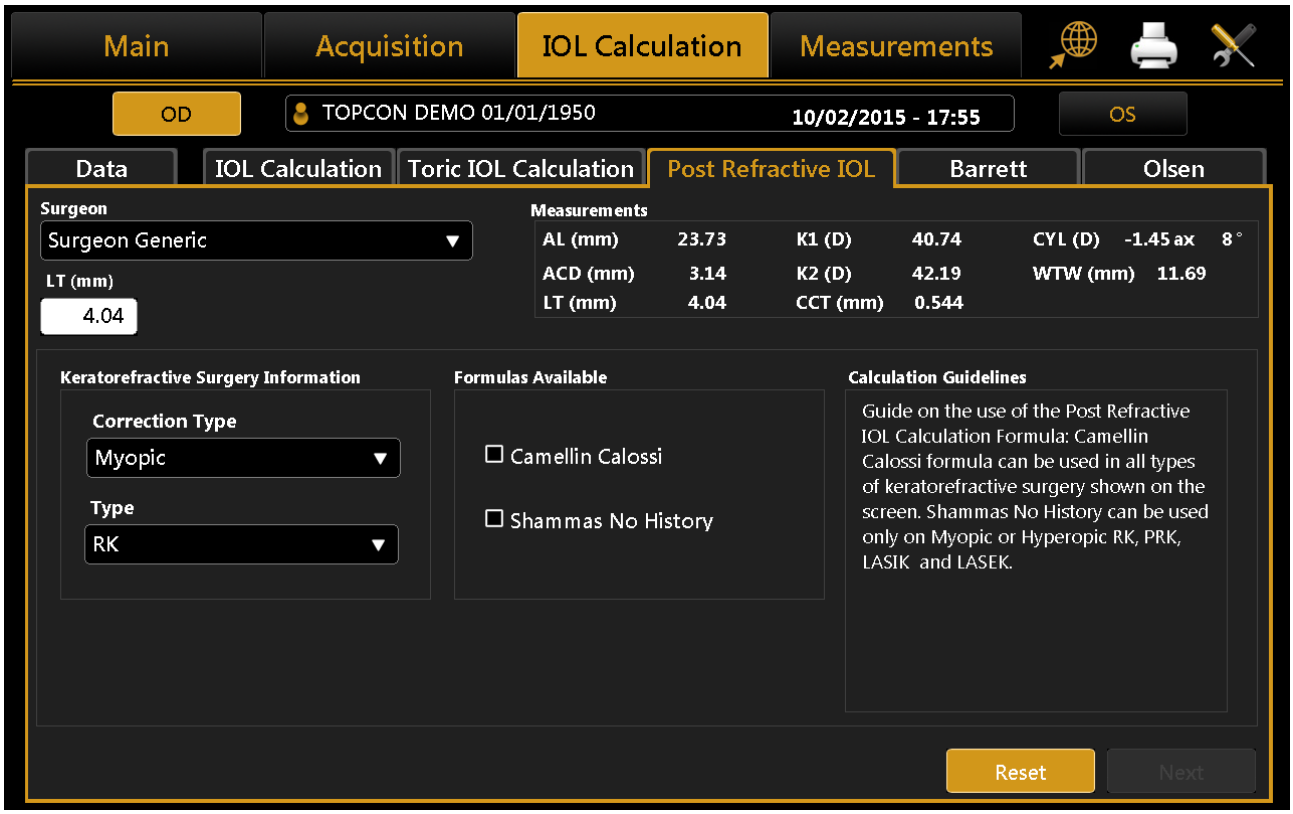


Figure 50

The first is the surgeon who performs the operation. As in IOL calculation, the constants may differ from one surgeon to another.

The second data is the "**LT"**, i.e. the crystalline lens thickness that can be modified manually.

Next, select the correction type between the options shown below:

- **Myopic**
- **Hyperopic**
- **Unknown**

If the correction type is unknown:

- it is not possible to select the surgery type
- it is not possible to choose the Shammas No-History formula
- to use the Camellin Calossi formula, you must insert in the Input Data the Pachimetry values and the optic zone diameter.

If the correction type is myopic or hyperopic, you have to select the surgery type performed on the patient from those listed:

1. **Radial Keratotomy (RK)**
2. **Photo Refractive Keratectomy (PRK)**

3. **Lasik**
4. **Lasek**
5. **LK**
6. **PTK**
7. **Unknown**

In case of **Radial Keratotomy, Photo Refractive Keratectomy, Lasik and Lasek** you need to insert in the **"Refractive Change"** frame the correct ametropia type and the correction factor obtained by the operation ("**SIRC")**.

In case of **LK, PTK or Unknown** only the Camellin Calossi formula is available and you need to insert the current **Pachymetric data** as well as the diameter of the optical zone to improve the accuracy of the final calculation (Figure 51).

The **Unknown** option must be selected every time that **you don't know the type of surgery** or **one of the associated information.**

For example if you know your patient has undergone Radial Keratotomy or Photo Refractive Keratectomy or Lasik or Lasek but you don't know the SIRC value, select **Unknown** and insert the pachimetry values.

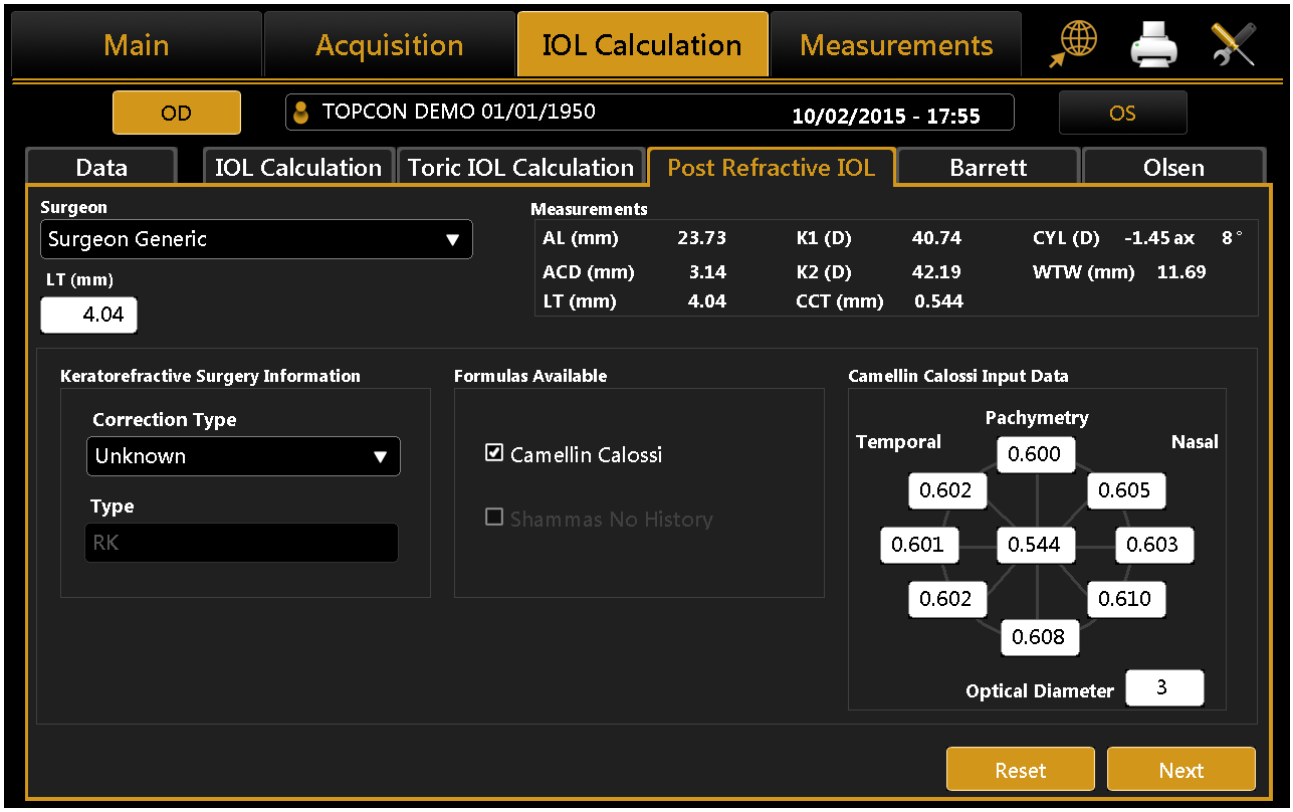


Figure 51

By pressing **"Next"** you move on to the final diagram of the calculation. Here you decide on the **"Target"** and select the lens make and model.

If you highlight the lens selected, the result is memorized and highlighted on the report.

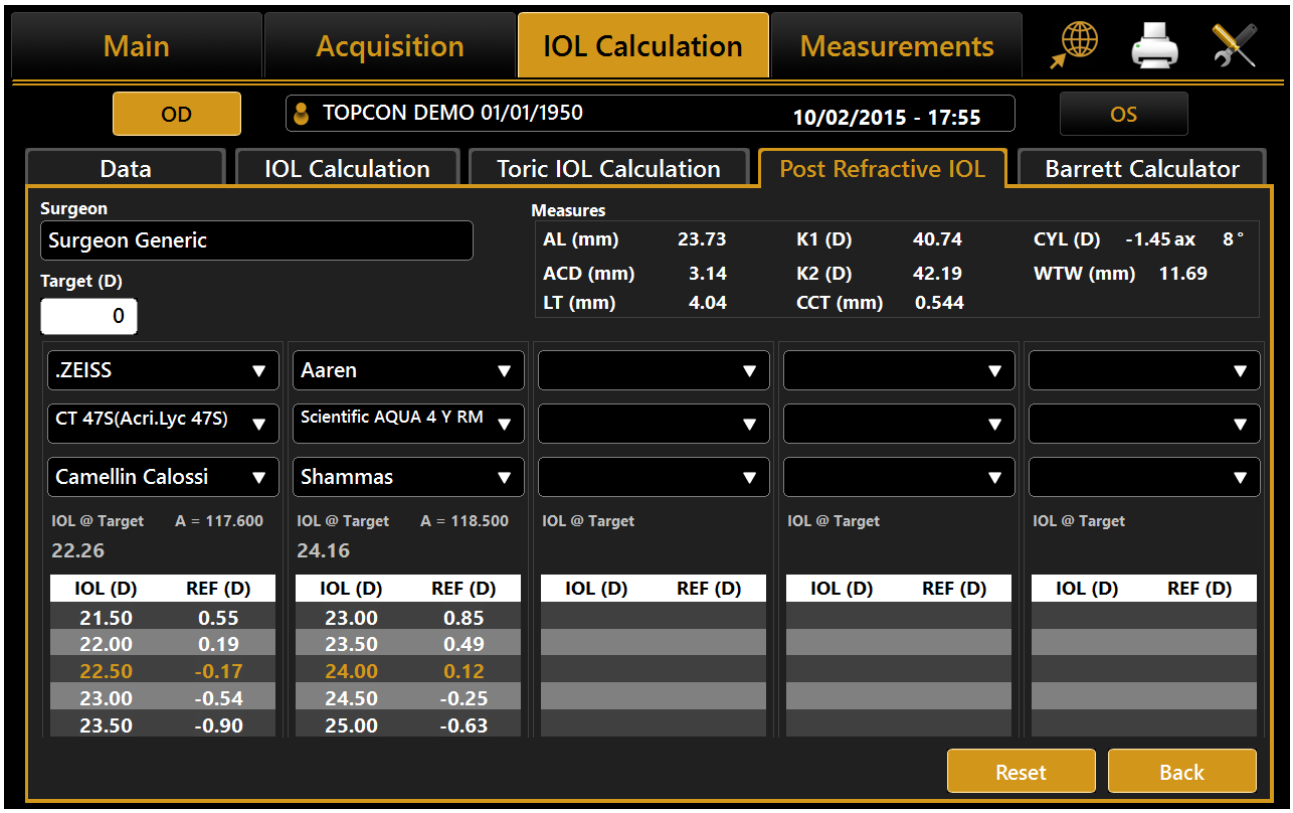


Figure 52

The final result of the Post-Op calculation is shown in Figure 52 with the suggested lenses highlighted in yellow in each table.

11.14.5 Barrett Calculator

Barrett Calculator is an optional module: ask your distributor for details.

The Barrett Calculator integrates the Barrett IOL Calculator v1.05. The calculation methods are the following:

- **Universal Formula II**: Barrett Universal II Formula v1.05, for alle yes regardless of axial length
- **Toric Calculator:** Barrett Toric Calculator v1.05, for correction of pre-existing corneal astigmatism with Toric IOLs
- **True K:** Barrett True K Formula v1.05, for eyes with prior myopic or hyperopic LASIK/PRK/RK
- **True K Toric:** Barrett True-K Toric Calculator v1.05, for eyes with prior myopic or hyperopic LASIK/PRK/RK and corneal astigmatism
- **Rx Formula:** Barrett Rx Formula v1.05, for IOL exchange and piggy back IOLs based on refraction after cataract surgery

All the formulas are based on the *Barrett Universal II Formula*.

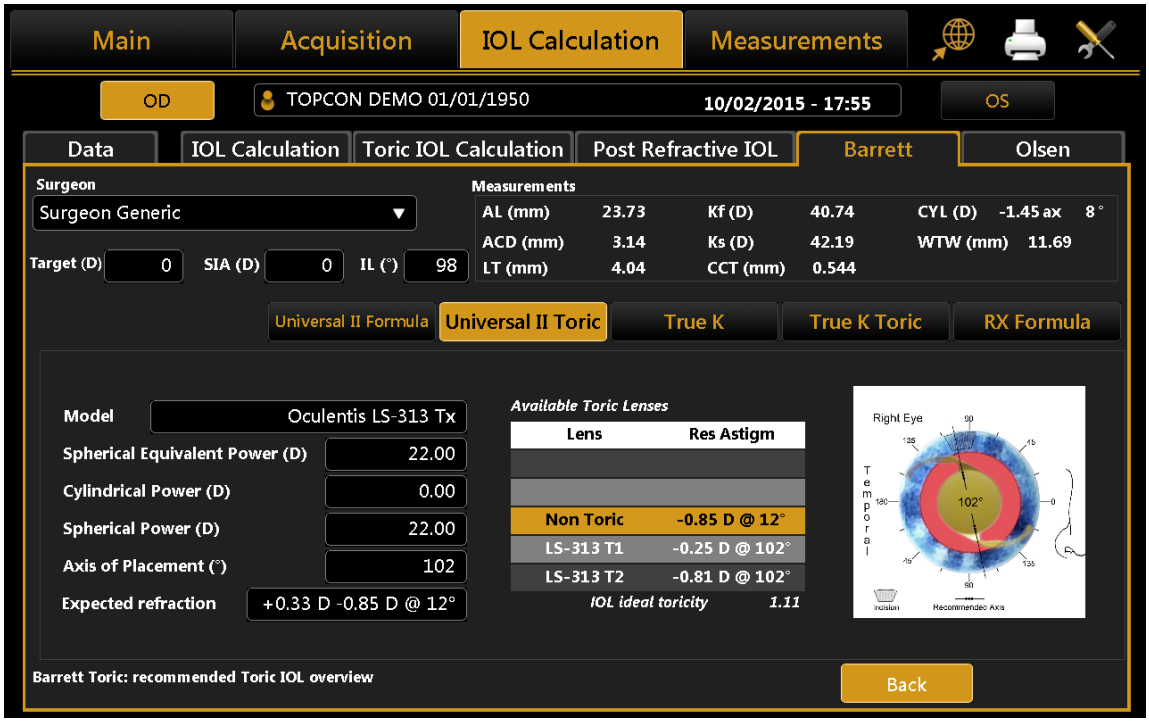
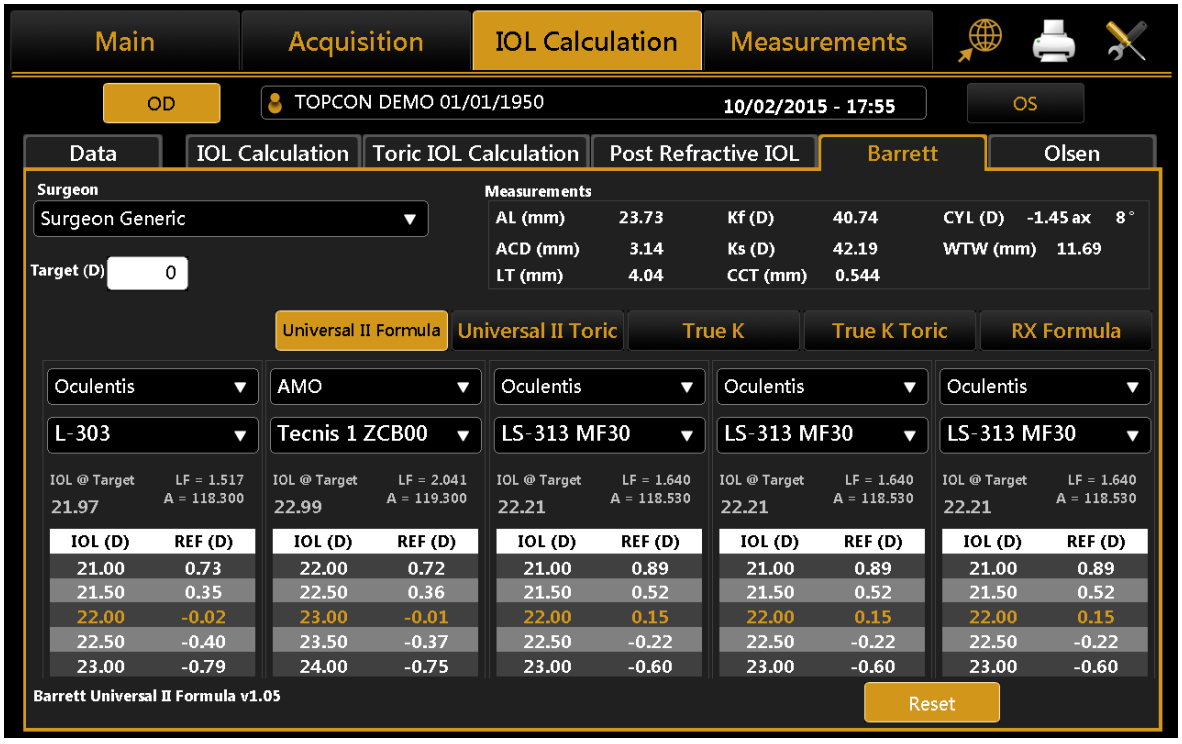


Figure 53

11.14.5.1 *Universal Formula II (Barrett)*

Barrett Universal II Formula v1.05, for all yes regardless of axial length.



In the ***"Surgeon"*** field, you can choose which surgeon will perform the IOL implant and any customization of the constants or presetting of the preferred lenses will be applied on this basis.

In ***"Target"*** field the target refractive value for the Post-Op must be inserted.
The ***"Measurements"*** field summarizes the measurement data.
From the drop-down menu, select the IOL manufacturer and model with which to calculate the best lens.
Once this data has been entered, the most appropriate lens can be chosen at the discretion of the surgeon. The latter is highlighted in orange. Once selected, the lens will be memorized as the preferred one and will be shown highlighted on the report printout.

Pressing **"Reset"** will reset the initial preset conditions.

11.14.5.2 *Toric Calculator (Barrett)*

Barrett Toric Calculator v1.05, for correction of pre-existing corneal astigmatism with Toric IOLs.

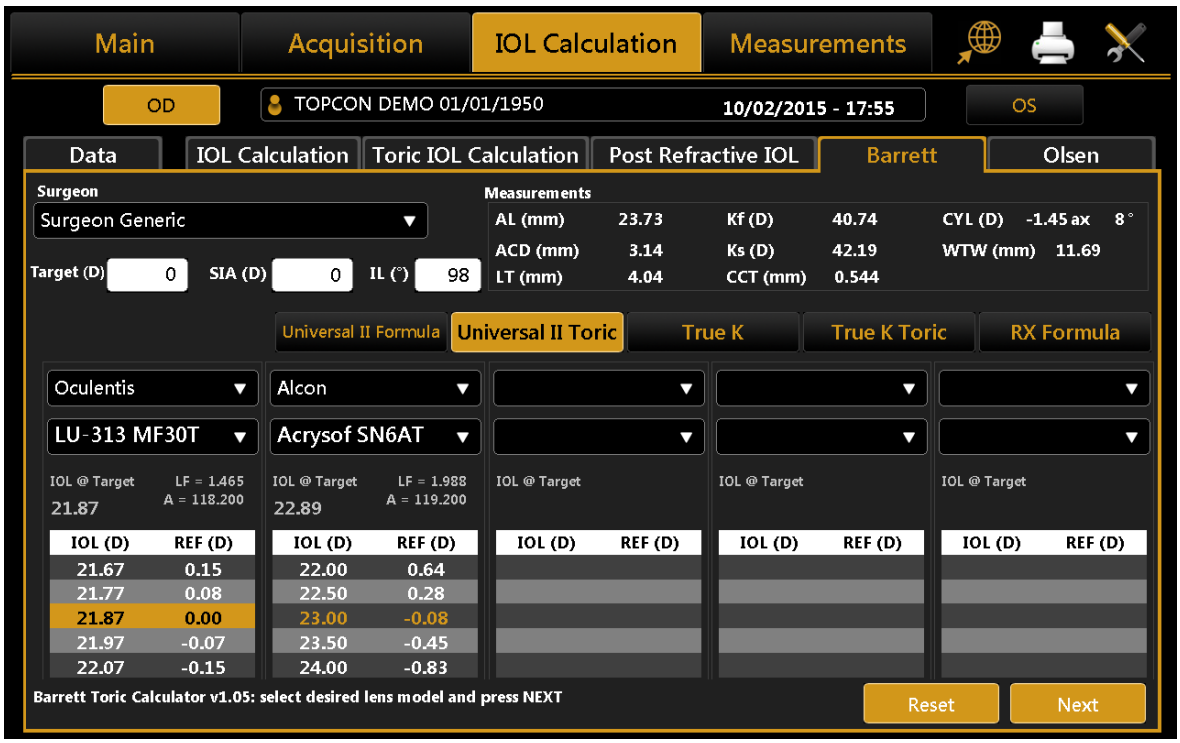


Figure 54

Toric Calculator (Barrett) is divided into two main steps. The first one consists on the calculation of the Spherical Equivalent Power; in the second one you can select the toric IOL that produce the best correction.

Figure 60 shows the first-step interface that has quite the same structure as the spherical IOL calcualtion. The available toric lenses you can select come from a list of models whose calculation constants have been published by their manufacturer. The user can in case insert new toric manufacturers and/or models inside toric IOL settings section (see 13.4.3)

In addition to choosing the **"Target"**, you need to specify also the **"Surgical Induced Astigmatism (SIA)"** and **"Incision Location (IL)".** The former identify the astigmatism (in diopters) induced by the incision while the latter identify the surgical incision axis.

After having selected the toric IOL model, a values table from which the **Spherical Equivalent Power** is obtained. Once you choose a lens, pressing **"Next"** at the bottom right, you enter in the second-step of toric IOL calculation (Figure 55).

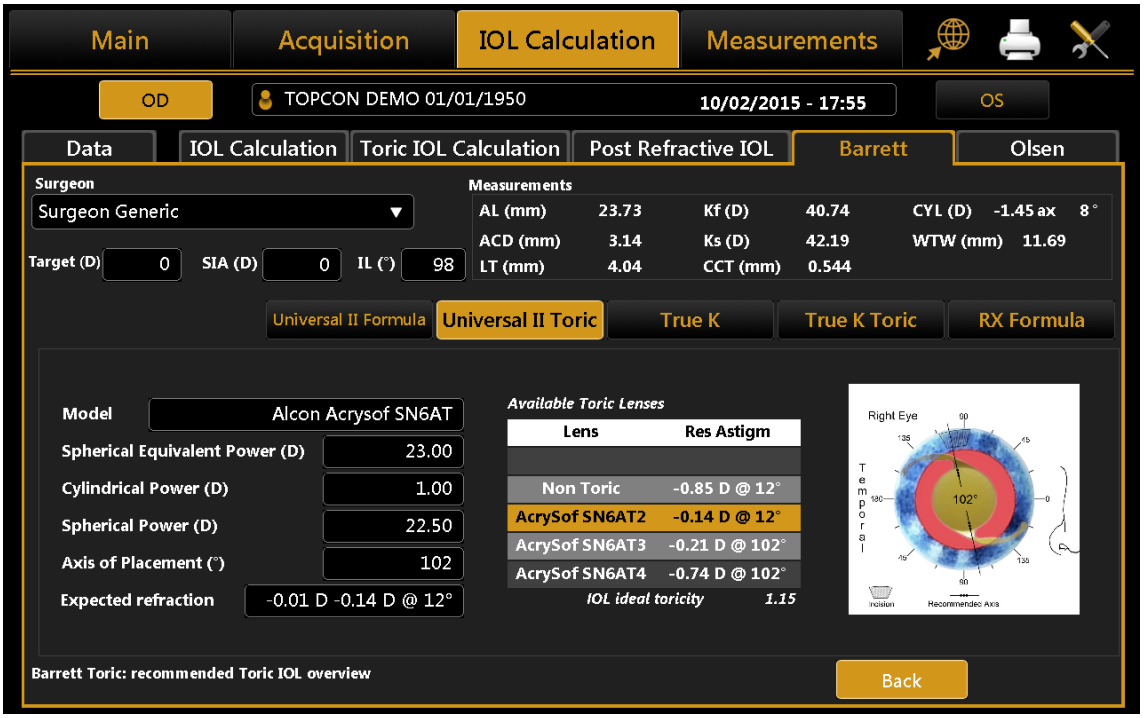


Figure 55

As a result, the **"Toric Calculator"** frame, immediately below, details the best toric lens computed automatically by the system for the manufacturer and model selected previously in the first-step.

From **"Available Toric Lenses"** table you can choose also a different cylinder value for the lens, based on the Residual Astigmatism you want to achieve (under-correction/overcorrection). In particular, the best toric lens value is shown in the central row and (if available) the ones that under-correct above the central row, the ones that overcorrect below.

At the right side, you can find an image that illustrates the ideal position of the IOL once the implant is in place and the incision location angle.

11.14.5.3 *True K (Barrett)*

Barrett True K Formula v1.05, for eyes with prior myopic or hyperopic LASIK/PRK/RK.

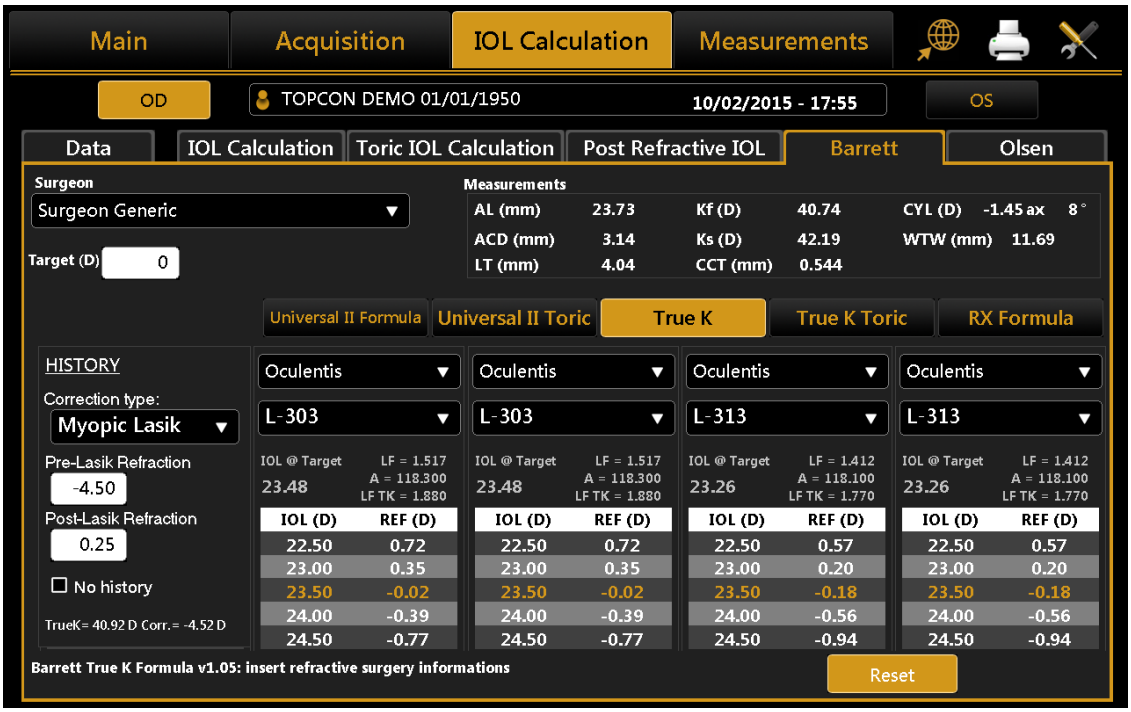


Figure 56

In ***"Target"*** field the target refractive value for the cataract Post-OP must be inserted.
The ***"Measurements"*** field summarizes the measurement data.

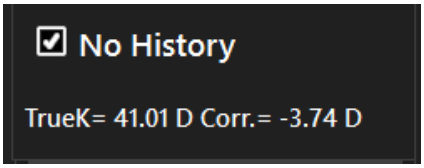
In the "***HISTORY"*** section select the correction type performed in the preceeding Refractive Surgery:

- **Myopic Lasik**
- **Hyperopic Lasik**
- **Radial Keratotomy**

Insert the measured Refraction (**Pre-Lasik Ref., in diopters**) before the Refractive Surgery and the measured Refraction (**Post-Lasik Ref., in diopters**) after the Refractive Surgery, accordingly the selected correction type.

Pre-Lasik Ref. must be negative for Myopic Lasik and Radial Keratotomy corrections, while must be positive for Hyperopic Lasik.

Otherwise select "**No History**" if pre and post refractive surgery measurements are not available in order to obtain an estimate of the correction amount based on the correction type and the eye biometry data.



From the drop-down menu, select the IOL manufacturer and model with which to calculate the best lens. Once this data has been entered, the most appropriate lens can be chosen at the discretion of the surgeon. The latter is highlighted in orange. Once selected, the lens will be memorized as the preferred one and will be shown highlighted on the report printout.

Pressing **"Reset"** will reset the initial preset conditions.

11.14.5.4 *True K Toric (Barrett)*

Barrett True-K Toric Calculator v1.05, for eyes with prior myopic or hyperopic LASIK/PRK/RK and corneal astigmatism.

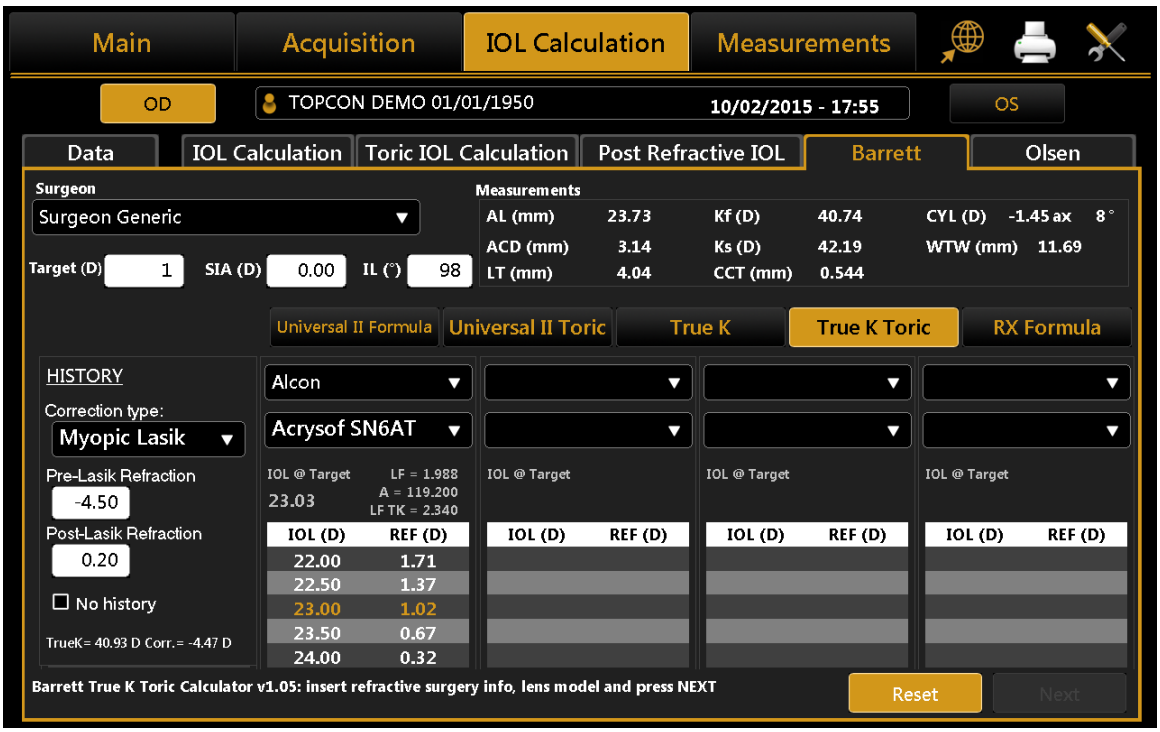


Figure 57

True K Toric Calculator (Barrett) is divided into two main steps. The first one consists on the calculation of the Spherical Equivalent Power; in the second one you can select the toric IOL that produce the best correction.

Figure 57 shows the first-step interface that has quite the same structure as the spherical IOL calcualtion. The available toric lenses you can select come from a list of models whose calculation constants have been published by their manufacturer. The user can in case insert new toric manufacturers and/or models inside toric IOL settings section (see 13.4.3)

In addition to choosing the **"Target"**, you need to specify also the **"Surgical Induced Astigmatism (SIA)"** and **"Incision Location (IL)".** The former identify the astigmatism (in diopters) induced by the incision while the latter identify the surgical incision axis.

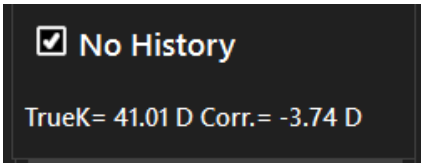
In the "***HISTORY"*** section select the correction type performed in the preceeding Refractive Surgery:

- **Myopic Lasik**
- **Hyperopic Lasik**
- **Radial Keratotomy**

Insert the measured Refraction (**Pre-Lasik Ref., in diopters**) before the Refractive Surgery and the measured Refraction (**Post-Lasik Ref., in diopters**) after the Refractive Surgery, accordingly the selected correction type.

Pre-Lasik Ref. must be negative for Myopic Lasik and Radial Keratotomy corrections, while must be positive for Hyperopic Lasik.

Otherwise select "**No History**" if pre and post refractive surgery measurements are not available in order to obtain an estimate of the correction amount based on the correction type and the eye biometry data.



After having selected the toric IOL model, a values table from which the **Spherical Equivalent Power** is obtained. Once you choose a lens, pressing **"Next"** at the bottom right, you enter in the second-step of True K toric IOL calculation (Figure 58).

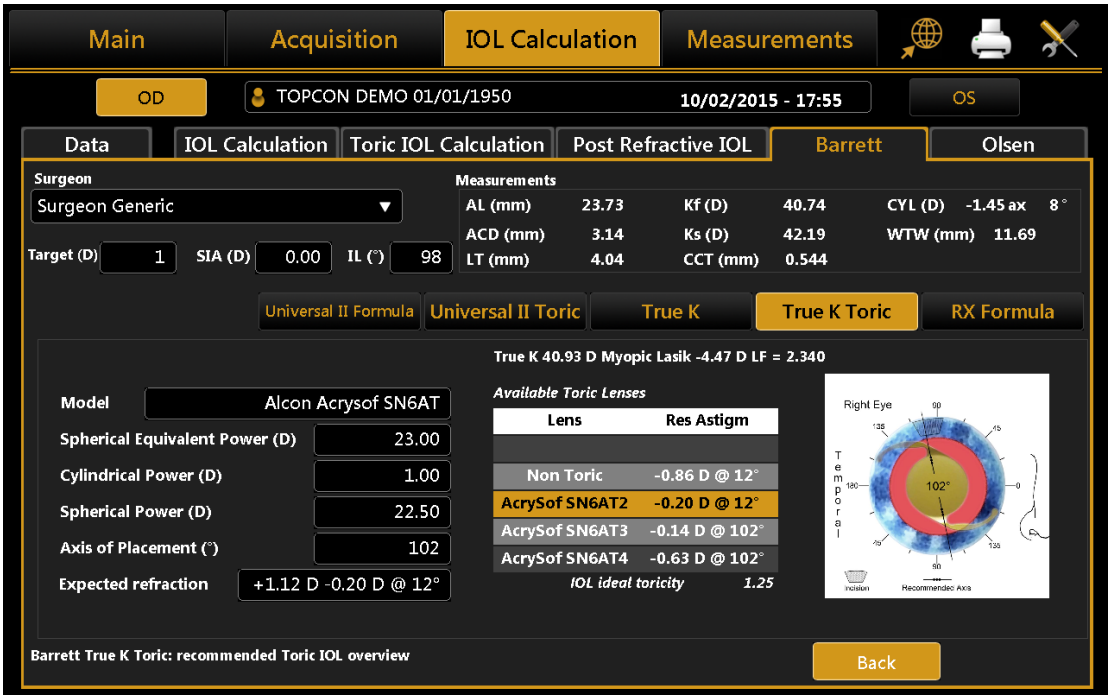


Figure 58

As a result, the **"True K Toric"** frame, immediately below, details the best toric lens computed automatically by the system for the manufacturer and model selected previously in the first-step.

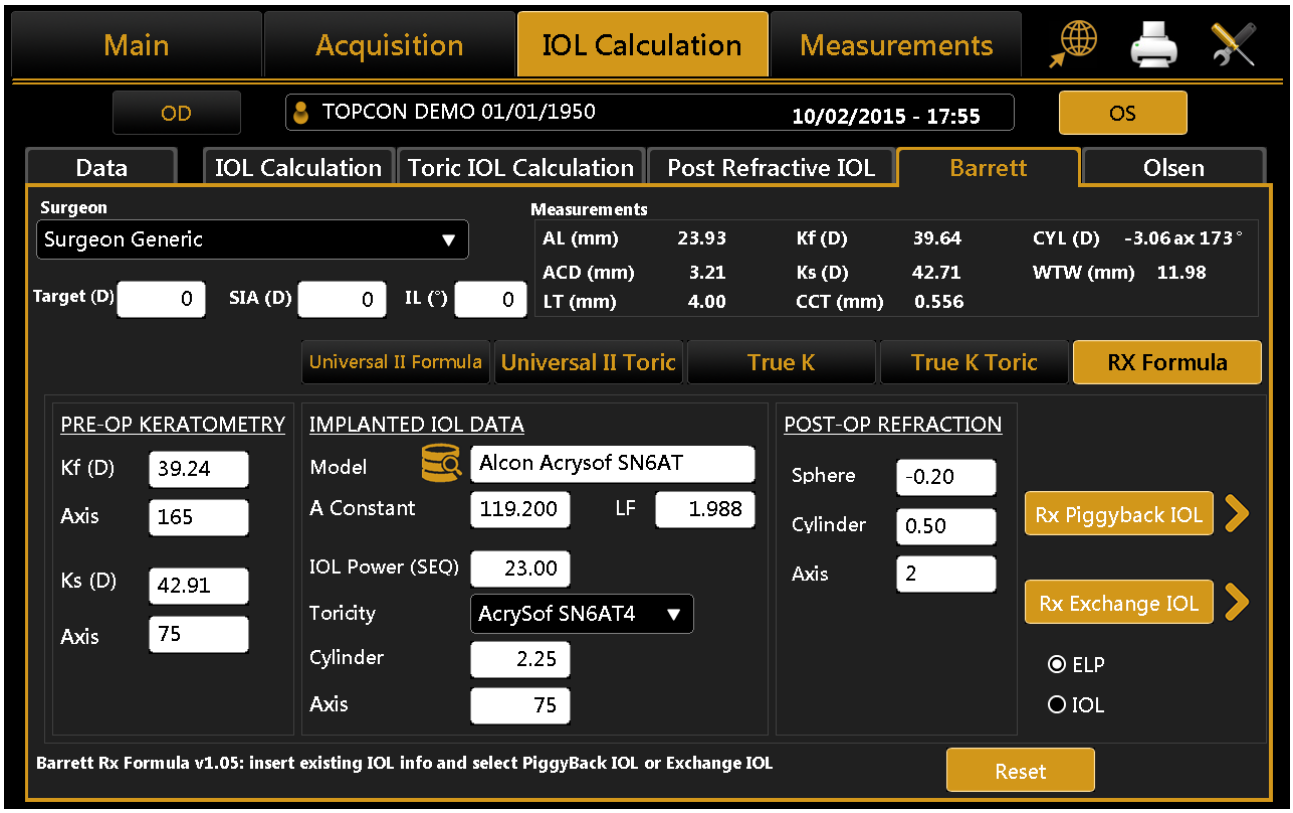
From **"Available Toric Lenses"** table you can choose also a different cylinder value for the lens, based on the Residual Astigmatism you want to achieve (under-correction/overcorrection). In particular, the best toric lens

value is shown in the central row and (if available) the ones that under-correct above the central row, the ones that overcorrect below.

At the right side, you can find an image that illustrates the ideal position of the IOL once the implant is in place and the incision location angle.

11.14.5.5 *RX Formula (Barrett)*

Barrett Rx Formula v1.05, for IOL exchange and piggy back IOLs based on refraction after cataract surgery.



RX Formula (Barrett) is divided into two main steps. The first one consists in inserting all the information regarding the current situation of the patient's eye.

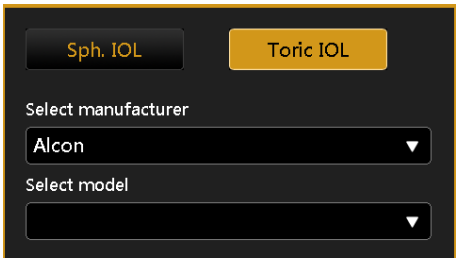
The ***"Measurements"*** field summarizes the measurement data achieved in the current exam, and they represent the current eye biometry.

In ***"Target"*** field the target refractive value for the new surgery Post-OP must be inserted. In addition to choosing the **"Target"**, you need to specify also the **"Surgical Induced Astigmatism (SIA)"** and **"Incision Location (IL)".** The former identify the astigmatism (in diopters) induced by the incision while the latter identify the surgical incision axis.

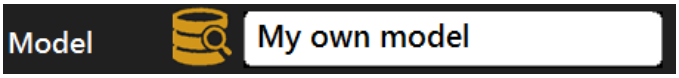
In the section "***PRE-OP KERATOMETRY***" you can insert the Keratometry data that was measured before the first cataract surgery.

In the section "***IMPLANTED IOL DATA***" you can insert information about the IOL implanted in the first cataract surgery:

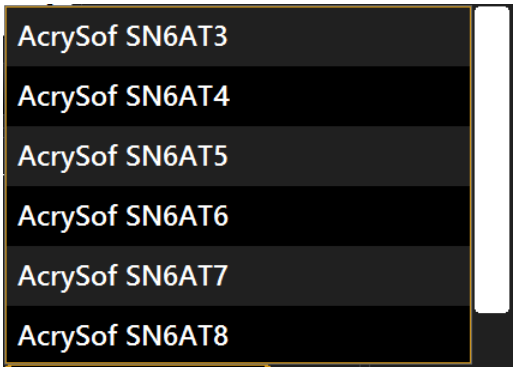
- **Model**: allows to insert the implanted IOL model:
  - selecting from the on-board database of Spheric IOL or Toric IOL lenses, by using the button  which opens the selection list



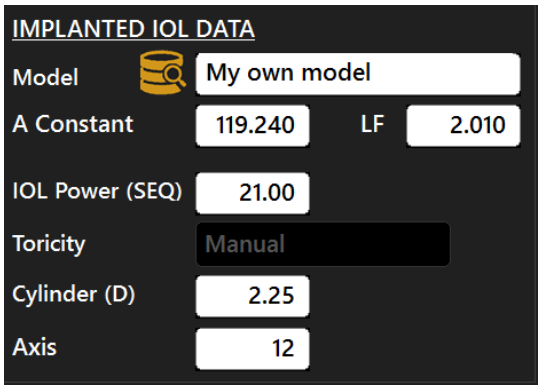
  - Inserting manually the description of the implanted IOL



- **A Constant/ LF:** are the calculations constants used for the calculation performed to select the power of the IOL implanted in the first cataract surgery, are filled automatically if the lens model is selected from the on-board archive or must be inserted manually for manually inserted models.
  Adjust the appropriate Lens Factor/A Constant for IOL by subtracting 0.25 mm from Lens Factor "bag" constant if IOL in sulcus.
- **IOL Power (SEQ):** is the spherical Equivalent power of the Implanted IOL
- **Toricity:** is the cylinder value selection list for the toricity of the implanted IOL, it's automatically populated with a list of cylinder values and submodels if the implanted IOL information has been selected from the on board database



  Otherwise if the IOL model information has been inserted manually, this list is locked to "Manual" and the cylinder value must be inserted manually



- **Cylinder:** is the cylinder value of the implanted IOL which can be inserted manually or selected from the Toricity list if available
- **Axis:** is the axis of placement of the implanted toric IOL

In the section "***POST-OP REFRACTION***" you can insert information about the refraction measured after the first cataract surgery during which the Implanted IOL described in the "Implanted IOL data" was applied.

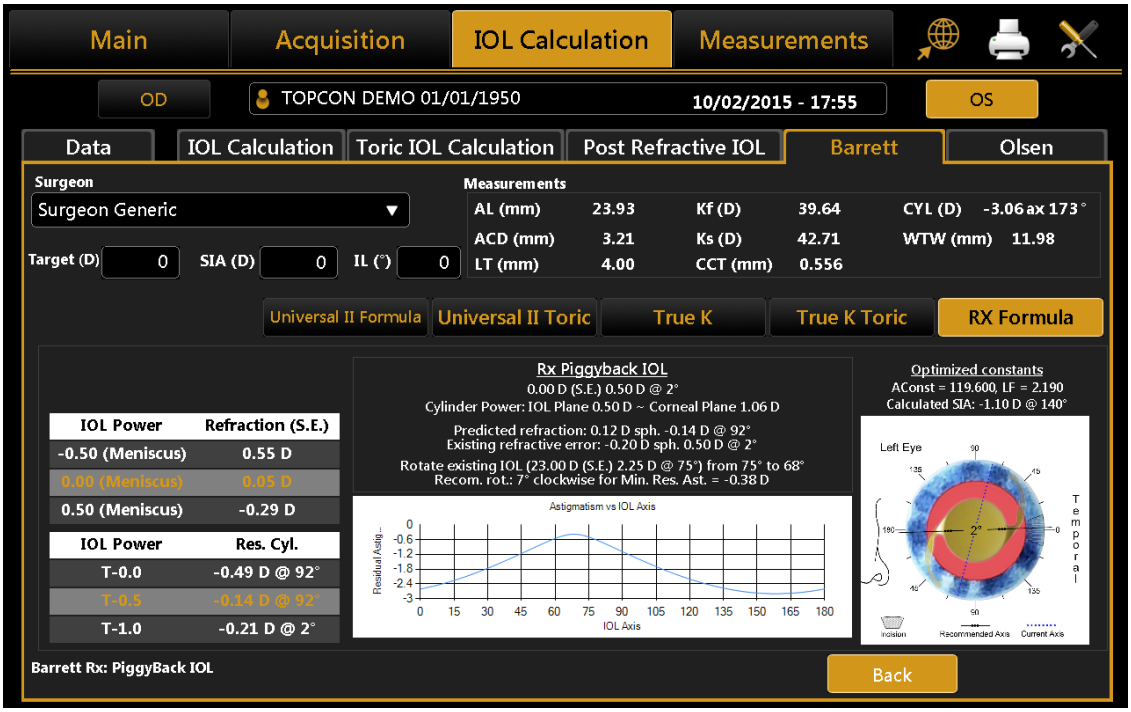
All the mentioned values are required to proceed in the second step of the RX Formula. Then it's possible to proceed to the second step using one of the two available options:

- **Rx Piggy Back IOL**
- **Rx Exchange IOL**

Choose between the two options:

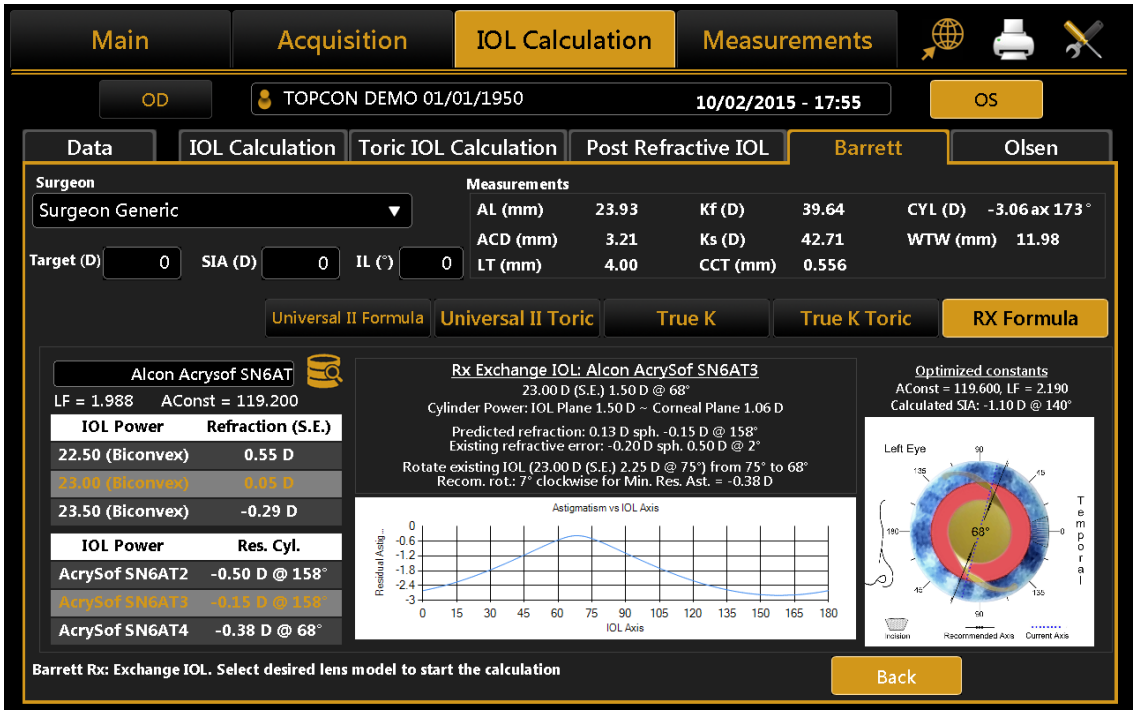
- **ELP(default)** if an error in the predicted ELP is assumed
- **IOL** for Post Lasik, RK or Low Diopters IOL where predicted ELP is unreliable

The recommended IOL/Piggy Back IOL and Refractive Outcome are calculated according the Barrett Universal II Formula and Barrett Toric Calculator.



The recommended TORIC IOL and Axis alignment for the targeted refractive outcome is displayed. The axis that provides the minimum astigmatism for the existing IOL is calculated as well as the rotation in degrees from the current axis of the existing implanted IOL.

The SIA and Optimised Lens Factor/A Constant are provided according to the pre and post op Keratometry and the refractive outcome.



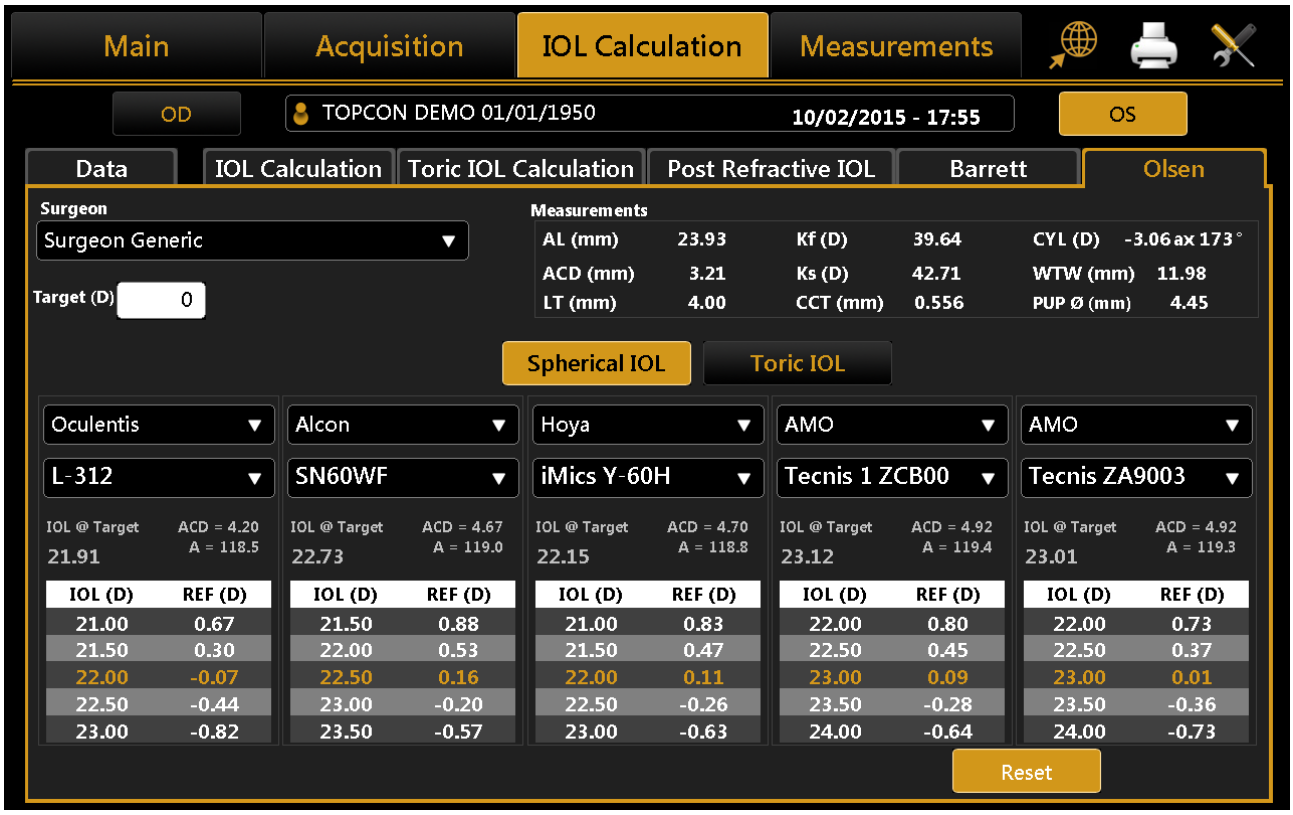
11.14.6 Olsen Calculator

Olsen Calculator is an optional module: ask your distributor for details.

The Dr. Olsen's formula is based on standard paraxial ray tracing using standard keratometry of the anterior surface of the cornea and optical biometry of the eye. The IOL power calculation methodology using ray tracing and improved algorithms to predict the position of the IOL inside the eye is intellectual property protected by international law. It includes a toric calculator which is based on a proprietary method to account for the non-measured posterior surface of the cornea.

11.14.6.1 *Olsen Spherical IOL (Dr. Olsen formula)*

Olsen Spherical IOL calculator performs calculations of spherical IOLs using the Dr. Olsen's formula.

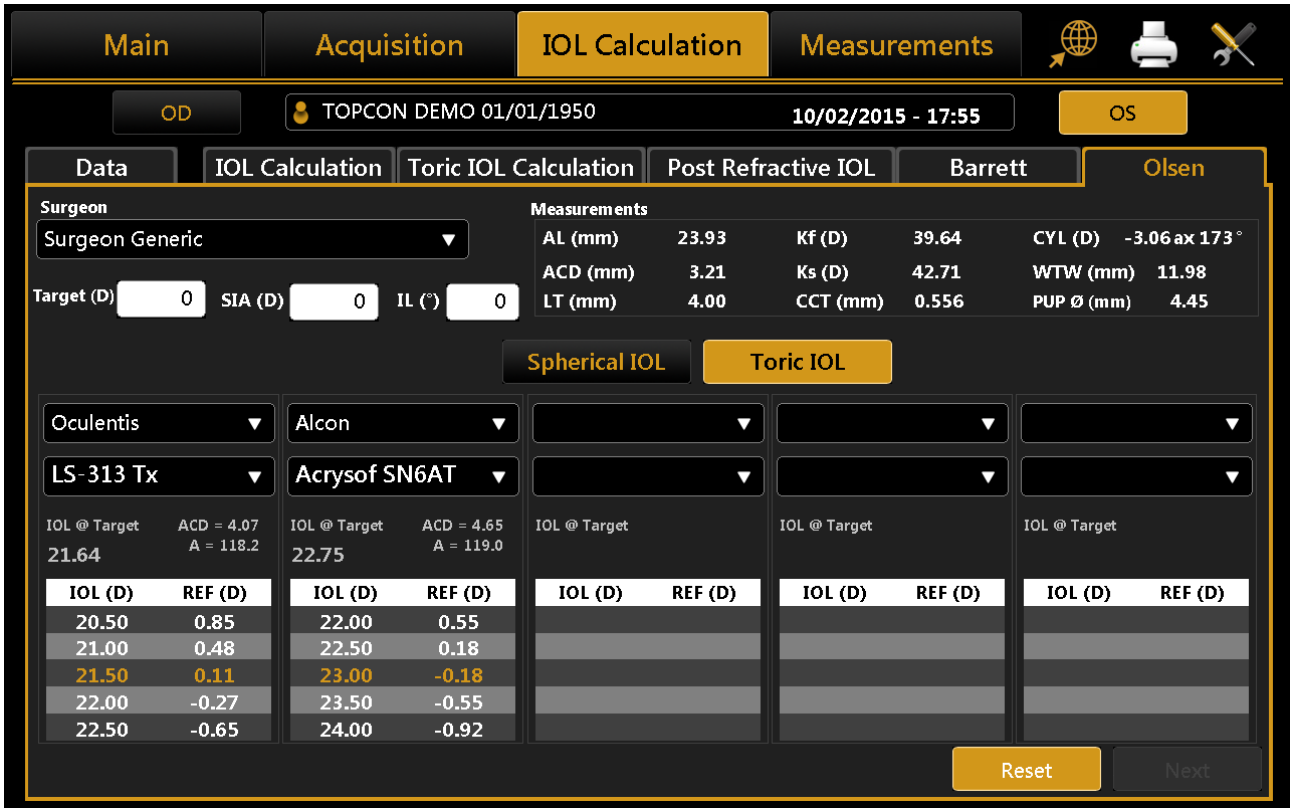


In the ***"Surgeon"*** field, you can choose which surgeon will perform the IOL implant and any customization of the constants or presetting of the preferred lenses will be applied on this basis.
In ***"Target"*** field the target refractive value for the Post-Op must be inserted.
The ***"Measurements"*** field summarizes the measurement data.
From the drop-down menu, select the IOL manufacturer and model. The available lenses you can select come from a list of models whose calculation constants and optical parameters have been validated. The user can in case insert new manufacturers and/or models inside IOL settings section (see 13.4.3).
Once this data has been entered, the most appropriate lens can be chosen at the discretion of the surgeon. The latter is highlighted in orange. Once selected, the lens will be memorized as the preferred one and will be shown highlighted on the report printout.
Pressing **"Reset"** will reset the initial preset conditions.

11.14.6.2 *Olsen Toric IOL (Dr. Olsen formula)*

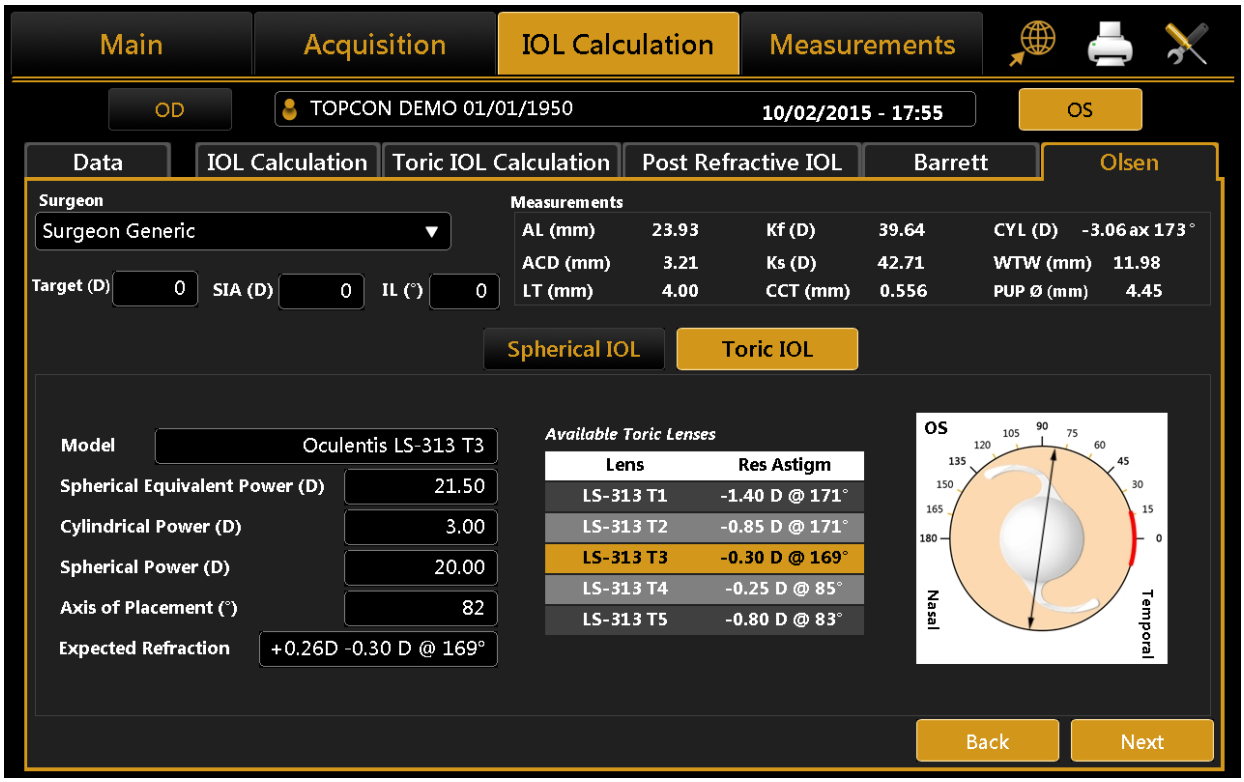
Olsen Toric IOL Calculator (based on Dr. Olsen's formula) is divided into two main steps. The first one consists on the calculation of the Spherical Equivalent Power; in the second one you can select the toric IOL that produce the best correction.

The first-step interface has quite the same structure as the spherical IOL calcualtion. The available toric lenses you can select come from a list of models whose calculation constants and optical parameters have been validated. The user can in case insert new toric manufacturers and/or models inside toric IOL settings section (see 13.4.3).



In addition to choosing the **"Target"**, you need to specify also the **"Surgical Induced Astigmatism (SIA)"** and **"Incision Location (IL)".** The former identify the astigmatism (in diopters) induced by the incision while the latter identify the surgical incision axis.

After having selected the toric IOL model, a values table from which the **Spherical Equivalent Power** is obtained. Once you choose a lens, pressing **"Next"** at the bottom right, you enter in the second-step of toric IOL calculation.



As a result, the **"Toric Calculator"** frame, immediately below, details the best toric lens computed automatically by the system for the manufacturer and model selected previously in the first-step.

From **"Available Toric Lenses"** table you can choose also a different cylinder value for the lens, based on the Residual Astigmatism you want to achieve (under-correction/overcorrection). In particular, the best toric lens value is shown in the central row and (if available) the ones that under-correct above the central row, the ones that overcorrect below.

At the right side, you can find an image that illustrates the ideal position of the IOL once the implant is in place and the incision location angle.

11.15 Data saving

After performing some acquisitions and eventual IOL calculations, in order to save the data from the examination, click on the “Main” button. As shown in Figure 59, the software will ask the user to confirm the action.

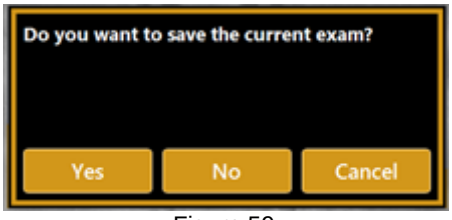
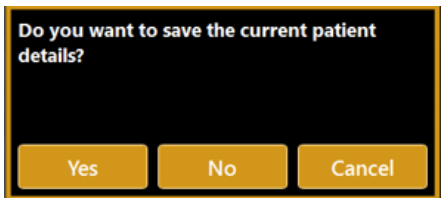


Figure 59

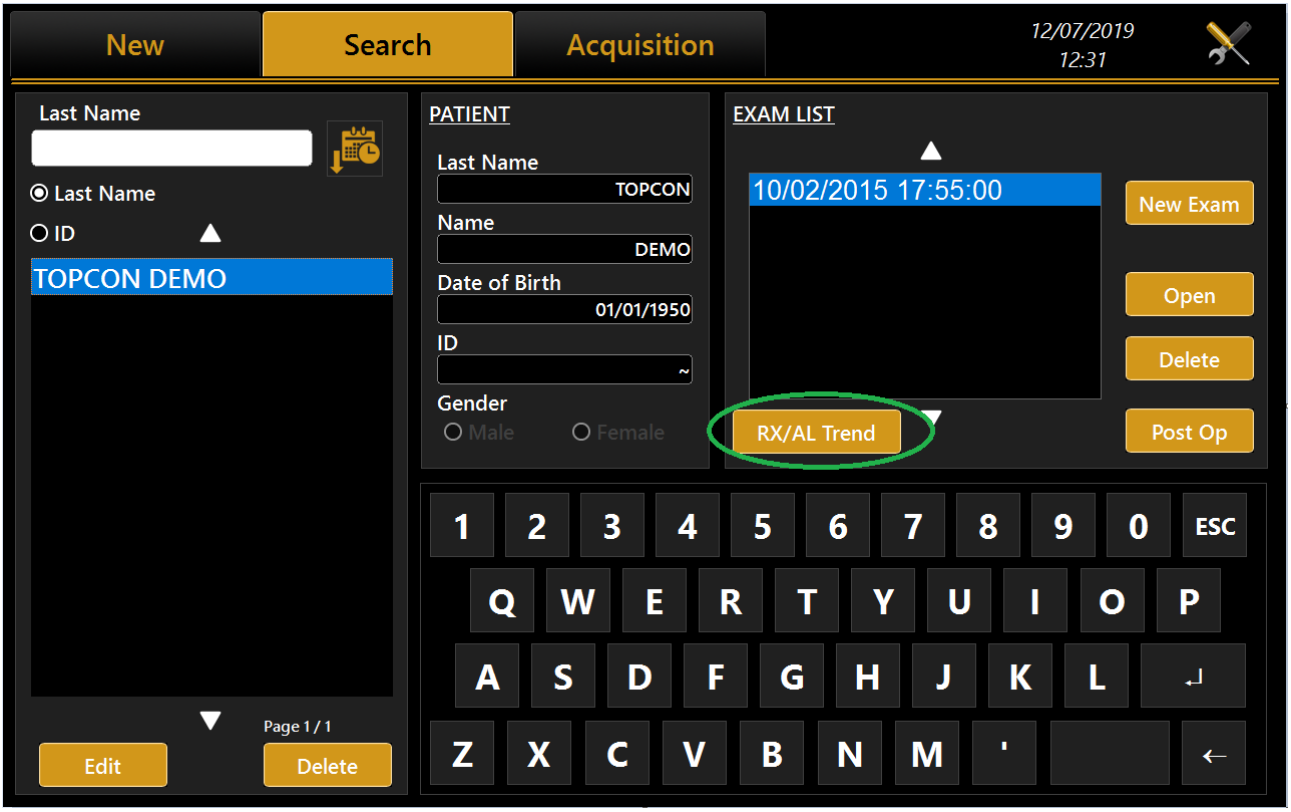
If you want to save the data of the patients without doing an acquisition, you have to press the “main” button when you are in the “acquisition” panel. The system will ask you if you want to save the current patient’s details.



11.16 RX/AL Trend Function

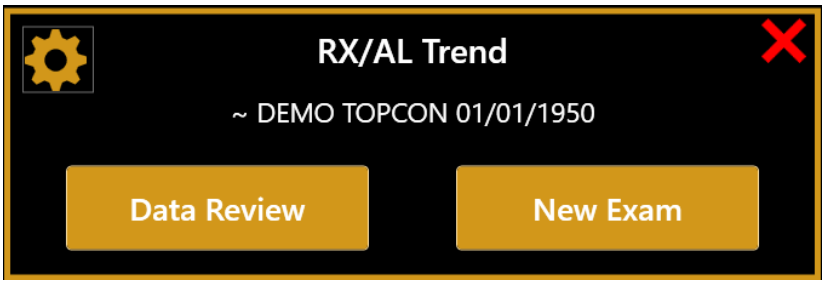
If enabled from the settings (see section 13.6) the RX/AL Trend Function can be accessed from the patient list view.

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



By pressing the RX/AL Trend button you access the two main actions for the selected patient:

- **Data Review**, access to the RX/AL Trend data overview section
- **New Exam**, proceed with a new examination



11.16.1 RX/AL Trend Action Window

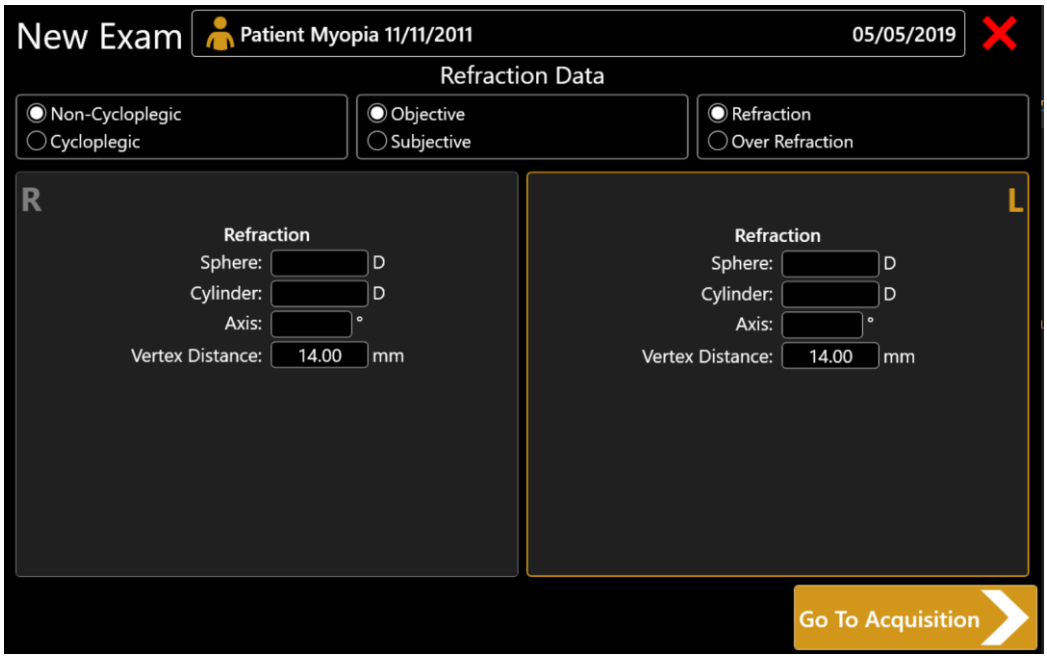
The RX/AL Trend Action Window provides access to the two main actions if a patient is selected from the list.

If no patient is selected the two actions are disabled.

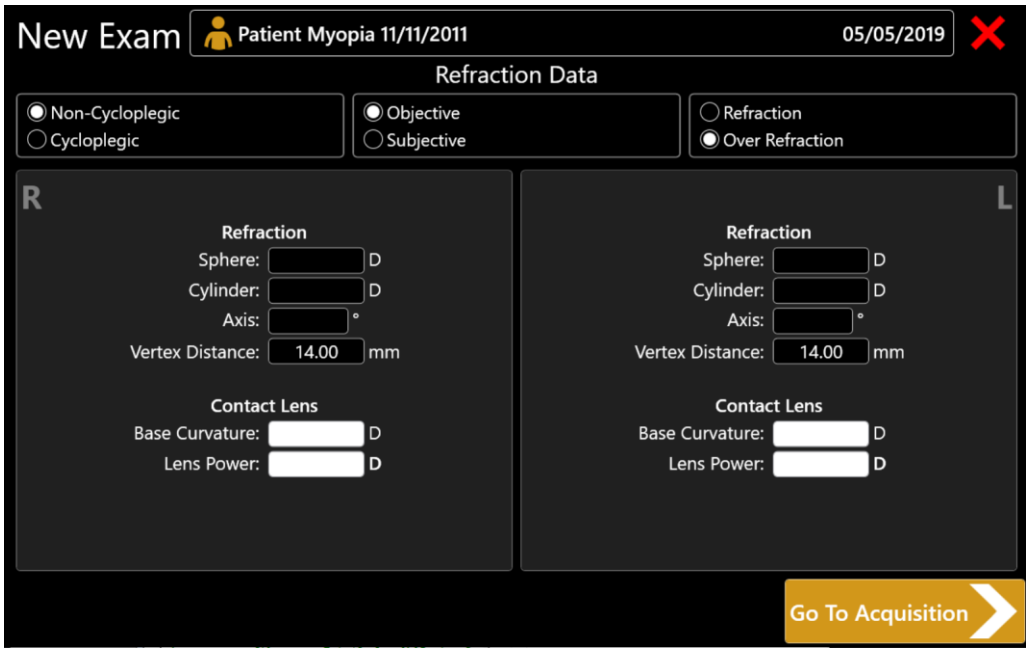
The windows provides also access to the RX/AL Trend function specific options. Other options such as Cylinder notation or Display unit depend on the general settings of the Aladdin application.

11.16.2 New Exam Action

You can enter the current refraction measurement data before performing the biometry acquisitions. The data is not compulsory to proceed with acquisition, you can update them afterward in Data Review section.



If you select Over Refraction option you are prompted also the input of the Contact Lens data.



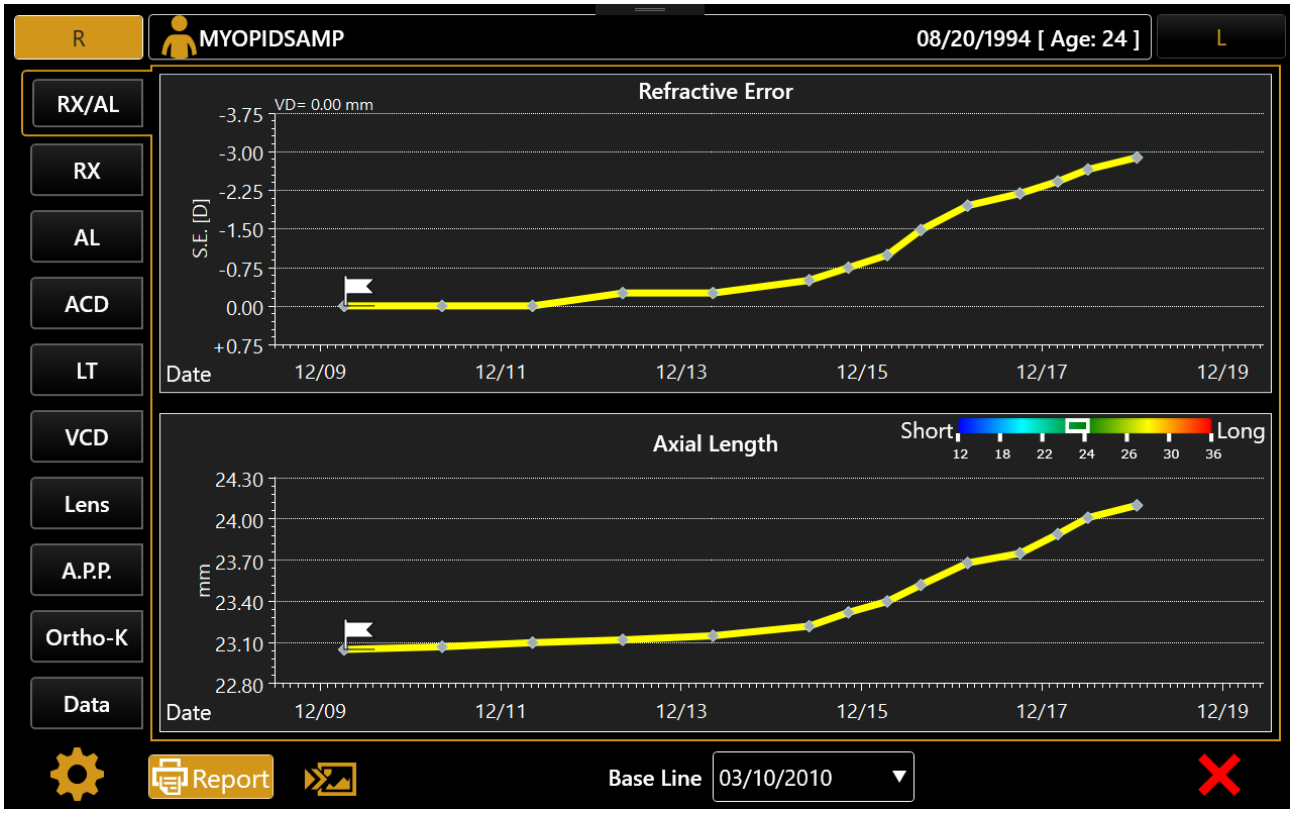
When pressing on Go to Acquisition a new examination session will be activated and Aladdin will be ready for acquisition.

Using this function it is possible to perform the following acquisition flow:

1. Measure Subjective/Objective Refraction externally
2. Input Refraction Data in the form
3. Perform Topography and Biometry acquisition on Aladdin

11.16.3 Data Review

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



BASELINE

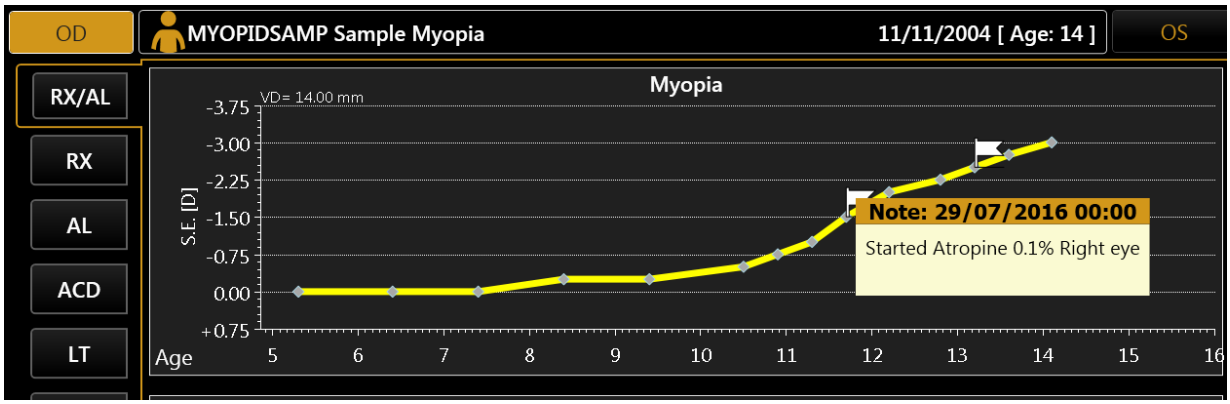
Starting condition of the trend profiles. Can be changed on the fly to any examination date.

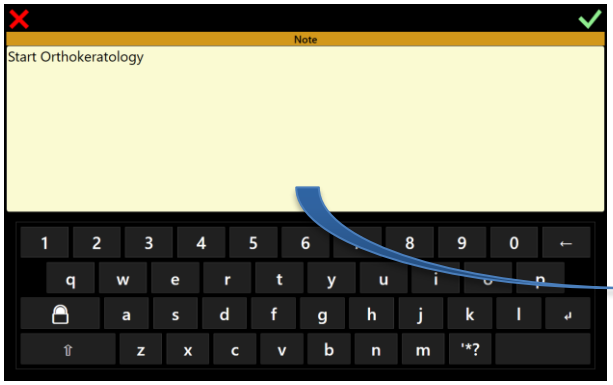
MONTH BASE

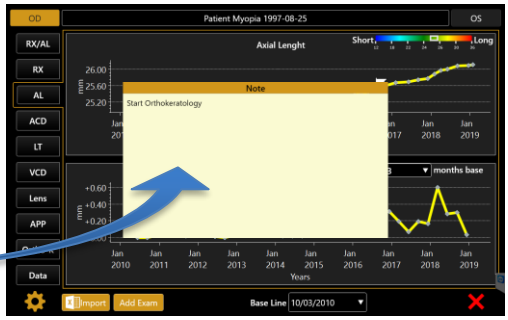
Windowing period for Variation profile calculation.

NOTES

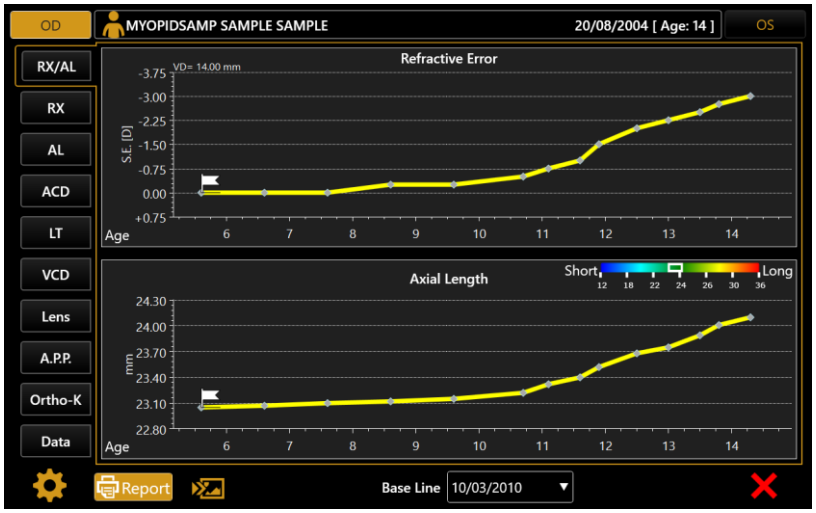
Notes can be added/edited in relation to each single examination date and reviewed.


OD
MYOPIDSAMP Sample Myopia
11/11/2004 [Age: 14]
OS
RX/AL
RX
AL
ACD
LT
Myopia
VD= 14.00 mm
S.E. [D]
-3.75
-3.00
-2.25
-1.50
-0.75
0.00
+0.75
Age
5
6
7
8
9
10
11
12
13
14
15
16
Note: 29/07/2016 00:00
Started Atropine 0.1% Right eye

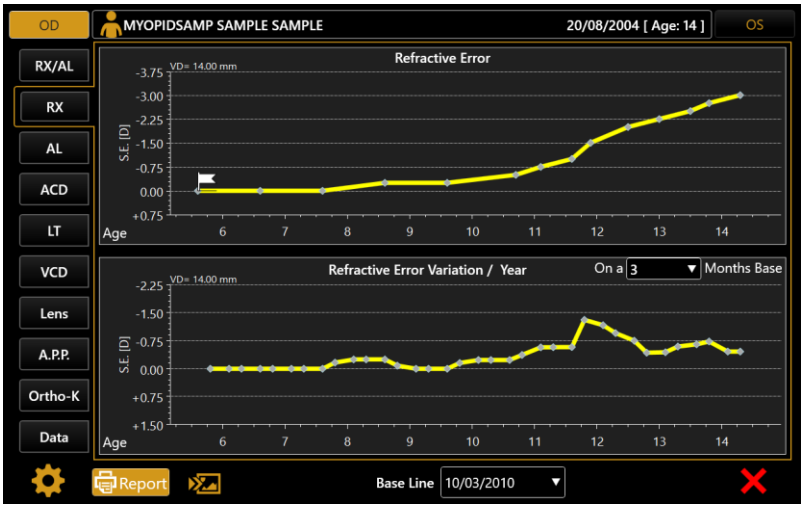

Note
Start Orthokeratology


Patient Myopia 1997-08-25
Axial Lenght
Note
Start Orthokeratology
months base
Years
Import
Add Exam
Base Line 10/03/2010

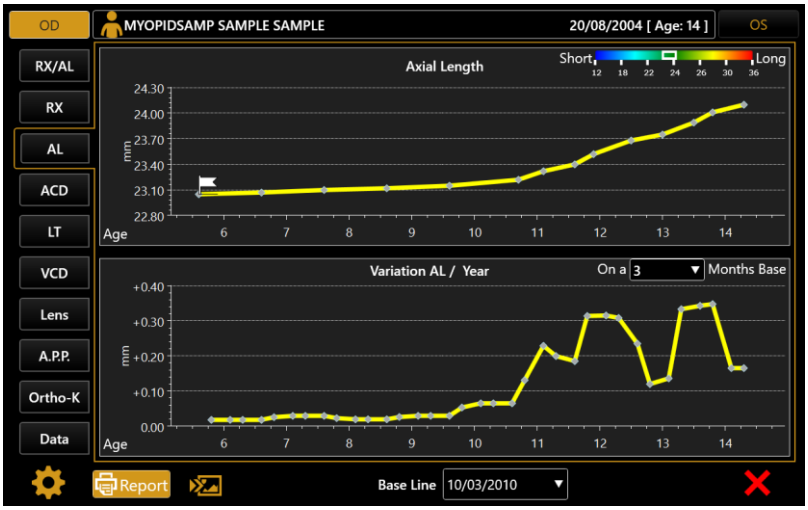
RX/AL: Refraction & Axial Length trend: Combined trend view with Refraction error S.E. and Axial Length.



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



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



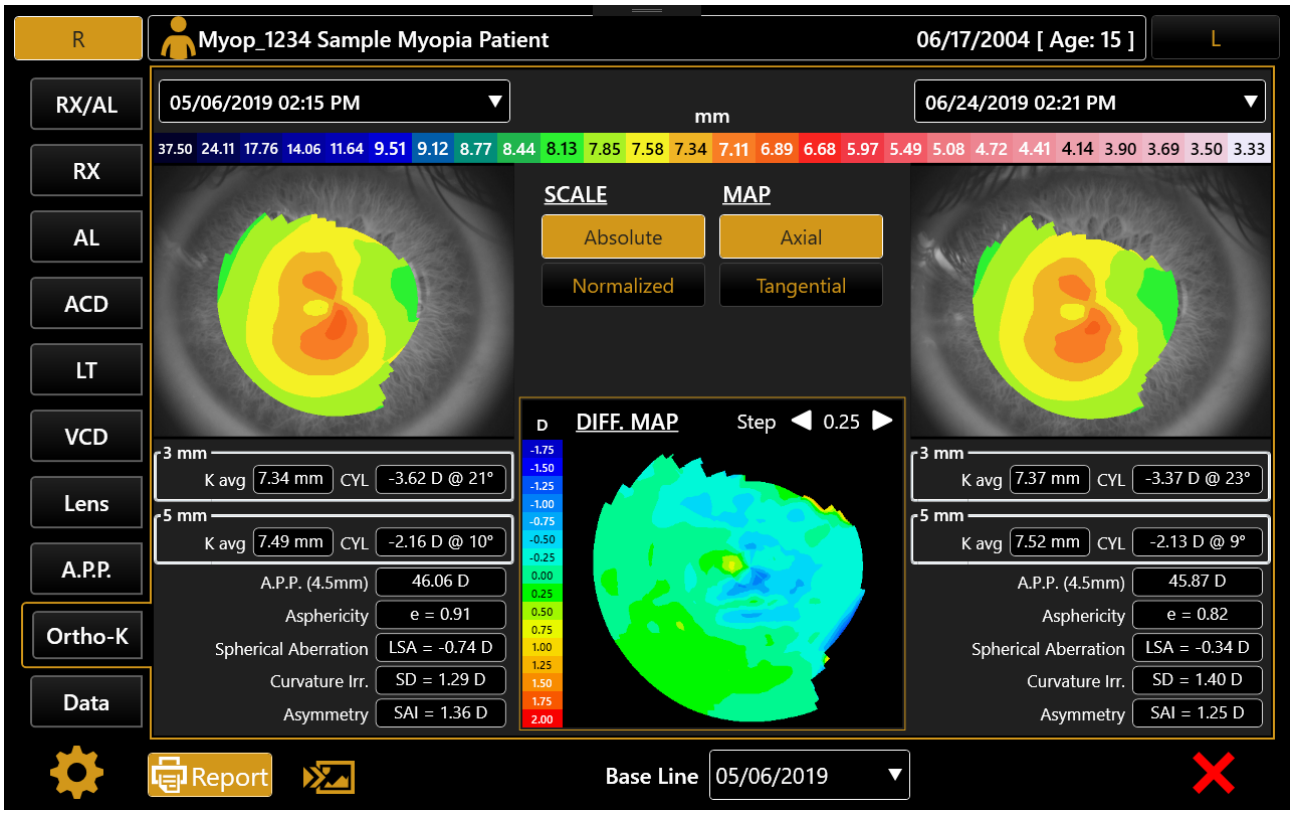
Other Trends:

For other biometry values the absolute value trend and the yearly variation are shown (if the data is available):

- ACD, Anterior Chamber Depth
- LT, Lens Thickness
- VCD, Vitreous Chamber Depth
- APP, Average Pupillar Power (4.5mm diameter)
- Lens Power: estimated from biometry data and refraction data if available

Ortho-K section

View to compare Topography map between two different examinations. Available only for examination performed directly with Aladdin. Compare variations of Kerato-refractive indexes. Useful to verify effects of Ortho-K application.

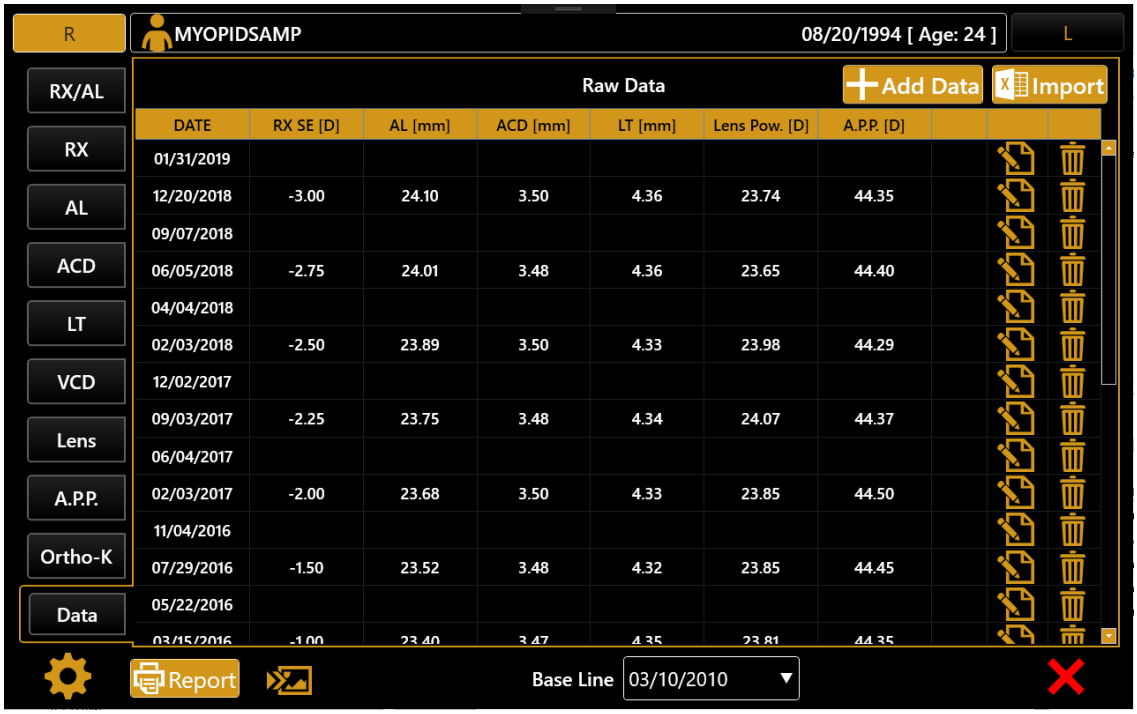


KERATO REFRACTIVE INDEXES

- 3mm and 5mm Keratometry
- Average Pupillar Power (4.5mm diameter pupil size)
- Asphericity
- Spherical Aberration (Longitudinal Spherical Aberration LSA)
- Curvature Irregularity (SD, Corneal Power std. deviation)
- Asymmetry (SAI index)

DATA

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

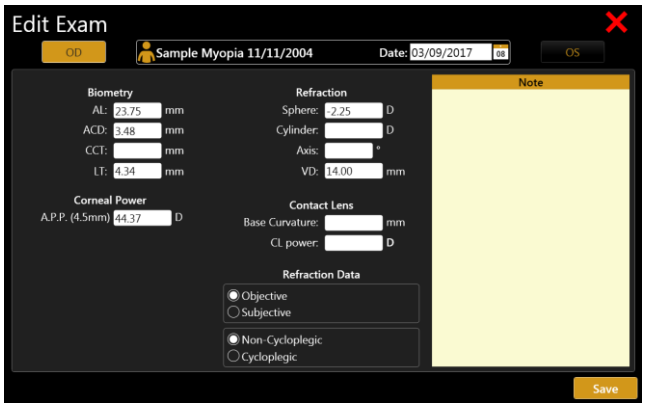


Import Button: Import data from template sheet for the current patient only.

Add Button: Add data manually by filling the form.

ROW Buttons

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



Delete Button: Delete the selected row

REPORT & SCREENSHOT

REPORT: Create Report with:

- Refraction and Axial Length trend
- Data table
- Notes

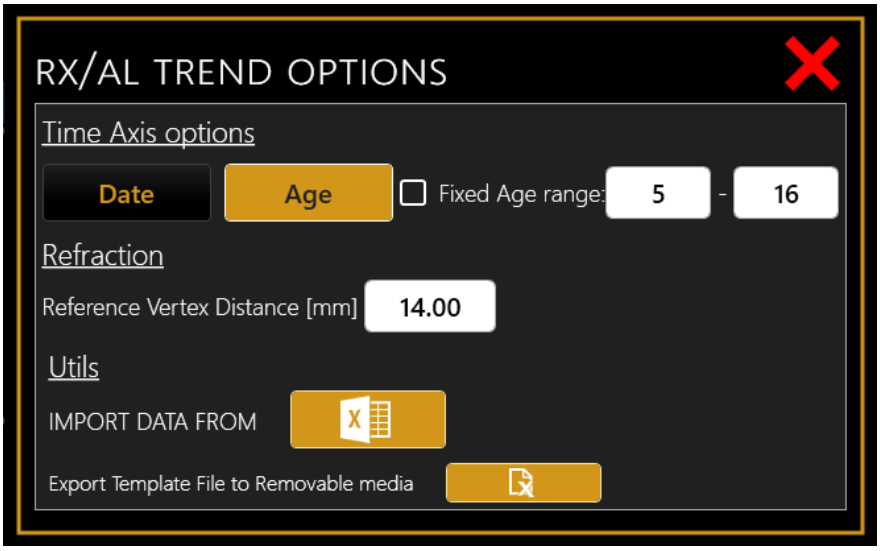
SCREENSHOT: create a report page with the current view

Available output destinations:

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

11.16.4 RX/AL Trend Option

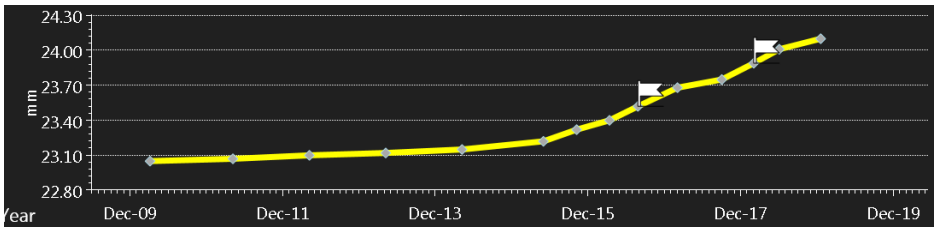
By pressing on the settings icon you get access to the RX/AL Trend related options.



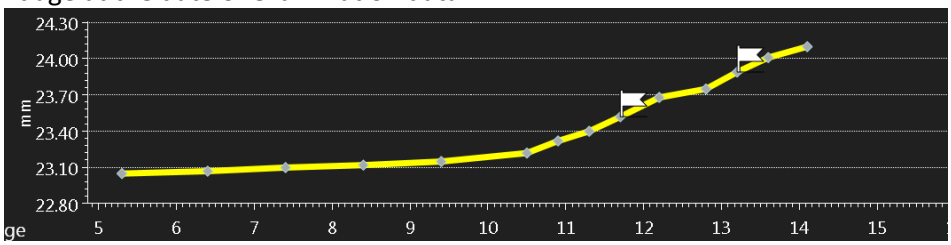
Time Axis Options

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

- Date, calendar date of examination data



- Age, patient age at the date of examination data



If the Age option is selected for the Time Axis, the Fixed age range can be enabled/disabled and configured.

If the fixed age range is enabled at the least the age range defined by the two related values will be visualized in the time axis. Data eventually exceeding such range will be shown as well.

Refraction Options

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

Utils

- **Import data from** predefined sheet template file. A dialog to select a file from connected USB pen drive will be shown.
  In this action can be imported data for:
  - The currently active patient (will be matched by ID)
  - Another patient already existing in Aladdin archive (will be matched by ID)
  - A patient not present in the Aladdin archive (a new patient will be created if at least ID and date of Birth are specified in the sheet, otherwise the data will be ignored)

- **Export**: create on the connected USB drives an empty sheet template file, to be filled externally and used for importation of previous/already existing data.

DATA IMPORT TEMPLATE SHEET

IMPORTANT: Do not alter the structure of the sheet!

Patient					Examination		Refraction/OverRefraction						Over Refraction Info		Biometry				Note
ID	LastNam	Name	DoB	Gender	Eye		Rx VD [mm]	Rx Sphere [D]	Rx Cyl [D]	Rx Cyl Axis [deg]	Rx type	Eye Status	Lens Power SE [D]	Base Curve [mm]	AL [mm]	ACD [mm]	LT [mm]	APP [D]	Test note
PatientID			25/05/1937	M	Dx	10/07/19	12.00	-2.62	0.00	0.00	Subjective	Normal	-2.00		25.67	4.00	3.48	44.37	Note: Only First Test Note for same Patient/Exam date is imported
PatientID			25/05/1937	F	Sx	10/07/19	0.00	-4.37	-0.25	172.00	Objective	Cycloplegia							not imported

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

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

Each row of the can contain data for:

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

REQUIRED DATA (for each row)

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

IMPORTATION RULES

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

EXAMPLE

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

Patient					Examination		Refraction/OverRefraction						Over Refraction Info		Biometry				Note
ID	LastNam	Name	DoB	Gender	Eye		Rx VD [mm]	Rx Sphere [D]	Rx Cyl [D]	Rx Cyl Axis [deg]	Rx type	Eye Status	Lens Power SE [D]	Base Curve [mm]	AL [mm]	ACD [mm]	LT [mm]	APP [D]	Test note
PatientID			25/05/1937	M	Dx	10/07/19	12.00	-2.62	0.00	0.00	Subjective	Normal	-2.00		25.67	4.00	3.48	44.37	Note: Only First Text Note for same Patient/Exam date is imported
PatientID			25/05/1937	F	Sx	10/07/19	0.00	-4.37	-0.25	172.00	Objective	Cycloplegia							not imported

DATA DESCRIPTION

- Patient Identification

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

- Eye Examination identification
  Eye identification and Exam date

Examination	
Eye	Date
Dx	07/05/2019
Sx	07/05/2019

- Refraction Measurement Data

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

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

- Biometry Data

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

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

12 MEASUREMENTS

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

There are four types of measurement.

- **KER**: Keratometry
    - **ZER:** Zernike Analysis
- **AL:** Axial length
- **ANT:** Anterior Segment sections: CCT,ACD,LT
- **PUP:** Pupillometry

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

12.1 Topographic map (KER)

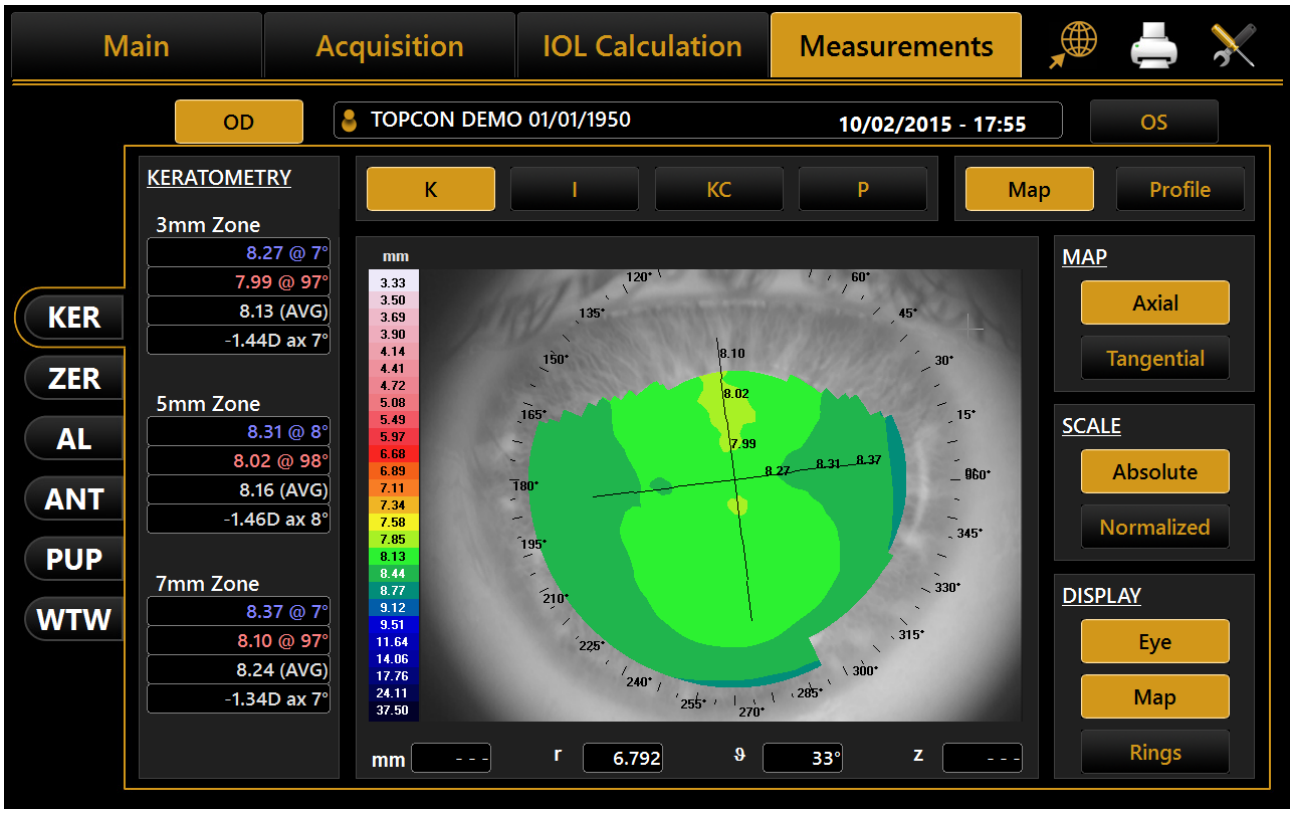


Figure 60

The environment displayed is shown in Figure 60.

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

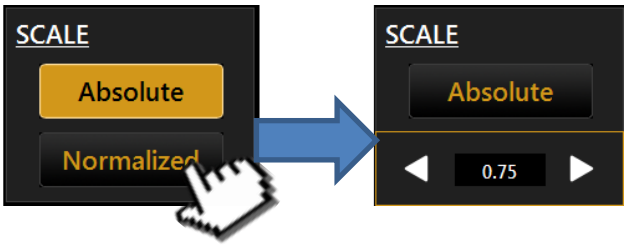
In the right column, you can select the following options:

- ***Axial*** or ***Tangential***: axial map or tangential map
- ***Absolute*** or ***Normalized***: absolute scale or standardized scale
- ***Eye, Map, Rings***: to display the image of the eye, the map, the rings

Pressing on any point on the map displays the following information:

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

The Scale buttons allow to switch between Absolute and Normalized (adjustable) scale color steps. When Normalized is pressed the button is replaced with controls that allows to adjust the color step for the current topography map. Minimum step size is 0.25 D or 0.05 mm depending on the selected measure unit.



Refer to section 13.2 for more settings relative to the topographic map representation.
The buttons at the screen top show the topographic map indices (see following paragraphs for details):

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

12.1.1 Keratometry

Press the ***"K"*** button to display the keratometric data on the 3 mm, 5 mm and 7 mm zones, as shown in Figure 60 (by settings the zones can be set to 2,4,6 mm).

12.1.2 Keratorefractive indices

Press the ***"I"*** button to view the keratorefractive indices:

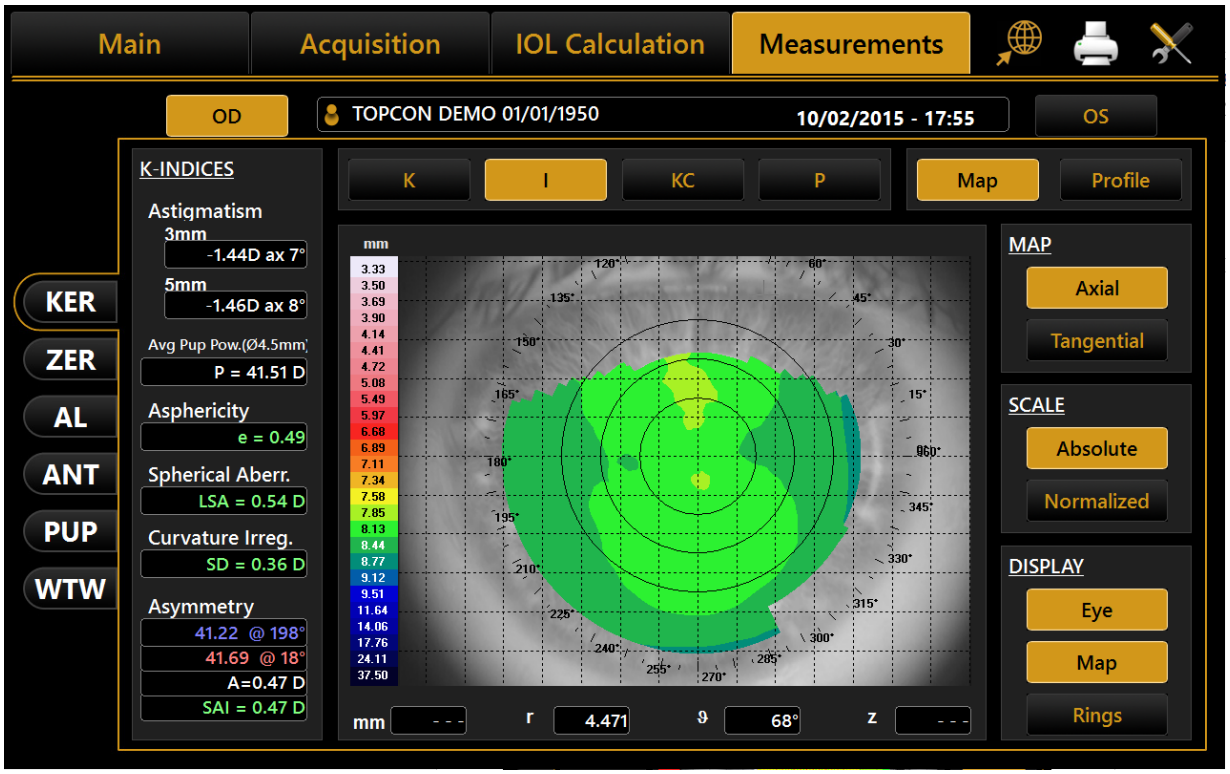


Figure 61

- **Astigmatism:** Astigmatism at 3 and 5 mm (or 2 and 4 mm)
- **Pupil Avg:** Average pupil power for a pupil of 4.5 mm
- **Asphericity:** Asphericity of the cornea at 8 mm diameter
- **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 4.5mm diameter cornea area and an **SAI** (Surface Asymmetry Index) that represents the surface asymmetry index of the 4.5mm diameter cornea area.

12.1.3 Keratoconus

Press the ***"KC"*** button to open Apex keratometry with the following information:

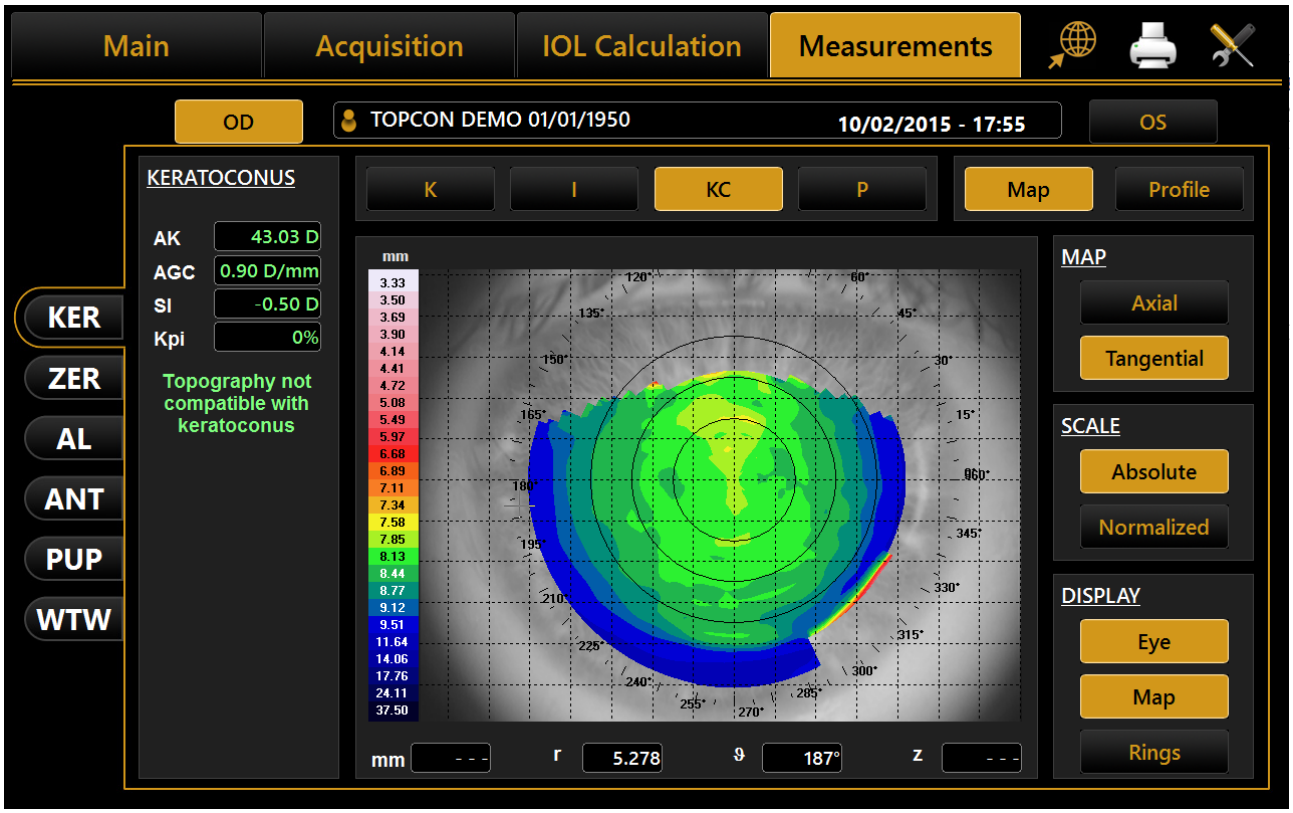


Figure 62

- ***AK***: Apical curvature.
  Represents the power of the cornea in its apex
- ***AGC***: apical gradient of curvature.
  Represents the corneal power average variations (per unit of length), taking the apical power as reference.
- ***SI***: difference between the average power of two circular zones centered in 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 indices with the probability index, there are three different possibilities: 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 (mm²)
- *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*

12.1.4 Pupil

Press the ***"P"*** button to open the pupil's indices:

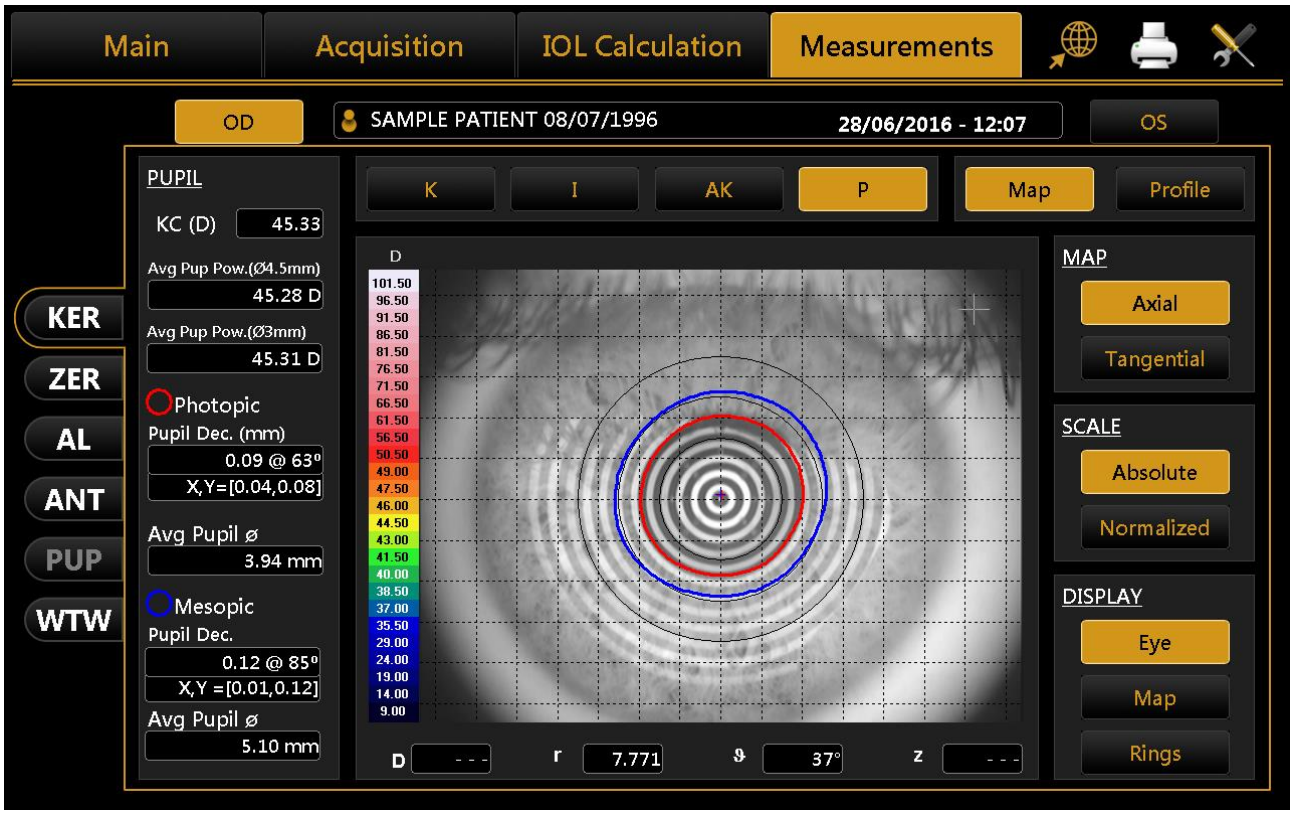


Figure 63

- **KC:** KC represents the central keratometry in diopters
- **Avg Pupil Power:** Average pupil power for a pupil of 4.5 mm and 3.0 mm
- **Photopic(red outline)**
  - **Pupil Dec.:** Pupil decentration in polar and cartesian coordinates from the cornea vertex
  - **Avg Pupil Ø:** Mean diameter of the pupil
- **Mesopic(blue outline)**
  - **Pup Dec.**: Pupil decentration in polar and cartesian coordinates from the cornea vertex
  - **Avg Pupil Ø:** Mean diameter of the pupil

12.1.5 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 (Figure 64).

By pressing the arrow buttons, you can vary the flattest and the most curved meridians.
The graph will be modified accordingly.
Pressing the ***"Map"*** button, you go back to the topographic map.

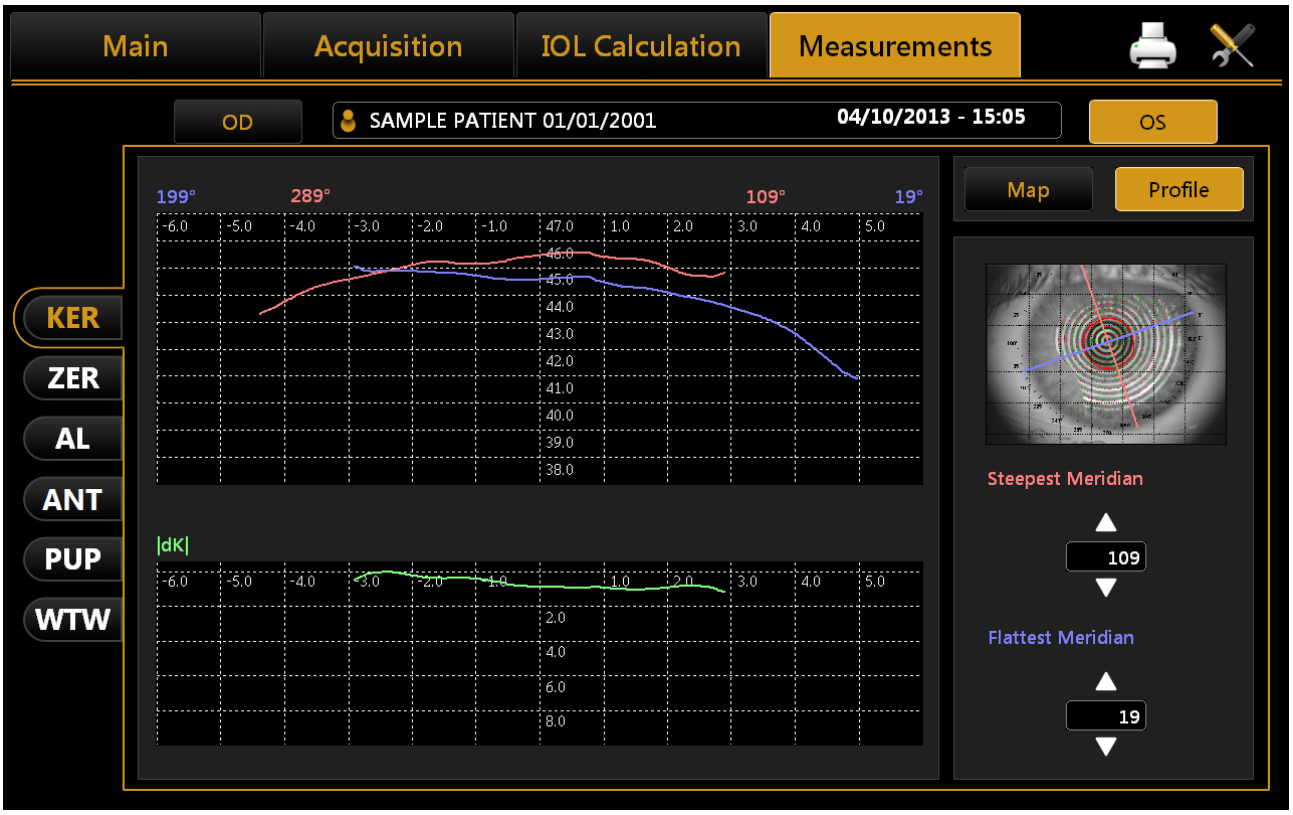


Figure 64

12.2 Zernike

The Zernike module provides a comprehensive view of the wave front aberrations generated by the front surface of the cornea. The results of the Zernike axis are illustrated by means of numerical indices and graphic representations (Figure 65).

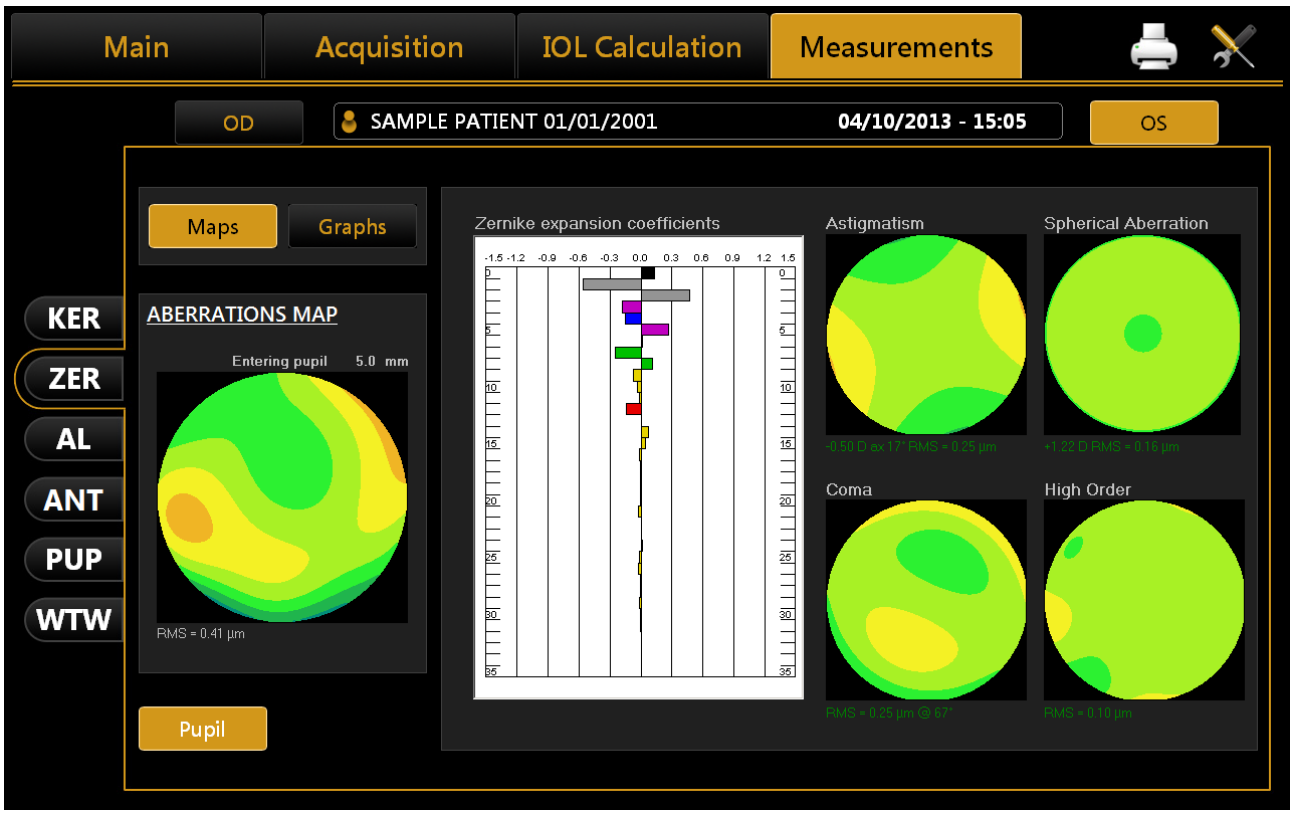


Figure 65

Click on the ***"OD"*** or ***"OS"*** buttons to view the results of the Zernike analysis for the right or left eye.
On the left the Aberrations 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 aberrations 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 a higher order than the primaries are grouped; the map and the RMS value are displayed.

Click on ***"Graphs"*** at the top left to display the vision quality summary (Figure 66).
This section displays:

- **Zernike Coefficient pyramid**: represents the numerical value of each coefficient by means of a grey scale; the greater the coefficient, the greater the color contrasts with the pyramid's background.

- **Point Spread Function**: represents the intensity of the wave front in the retina.
- **Spot Diagram**: represents the spatial distribution of the wave front over the retina.
- **Visus/Visus Low Contrast:** represent the patient's real vision at high and low contrast.

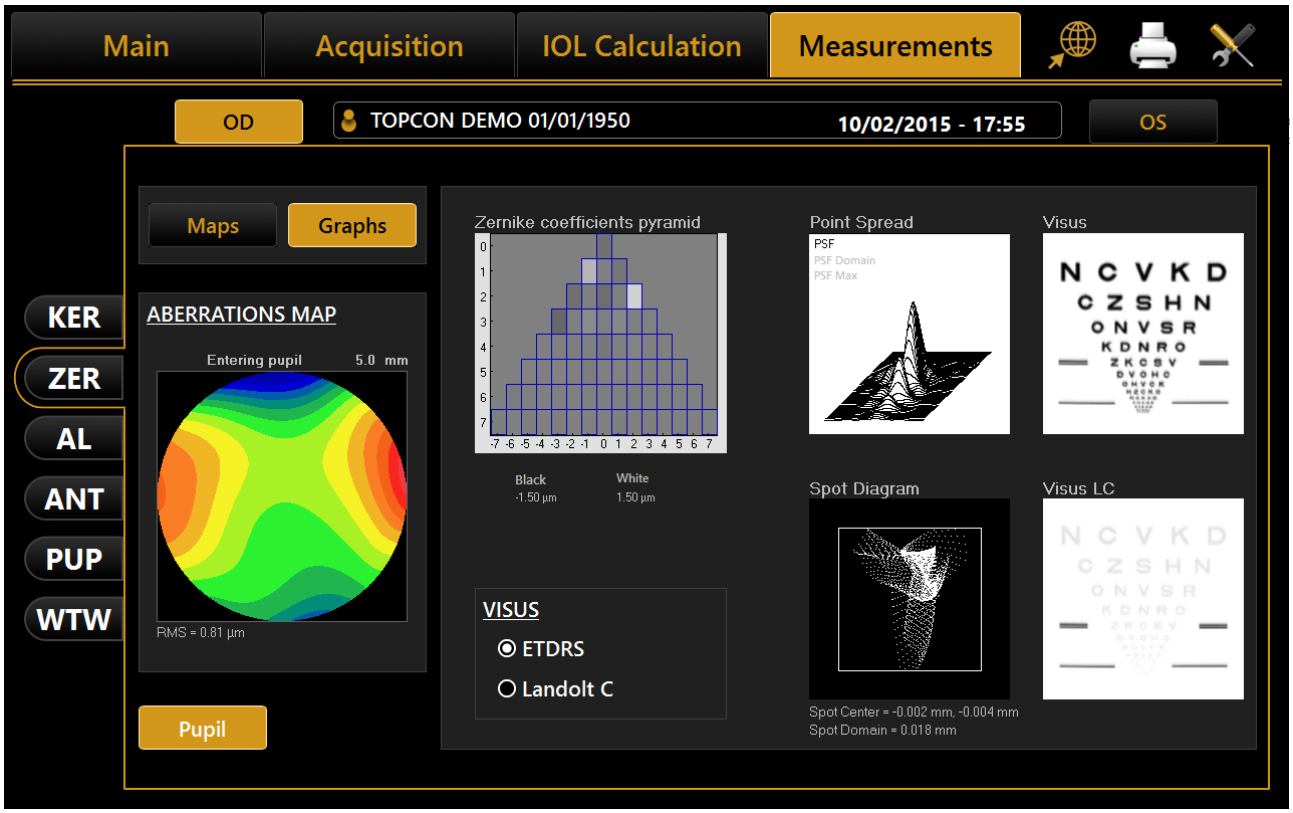


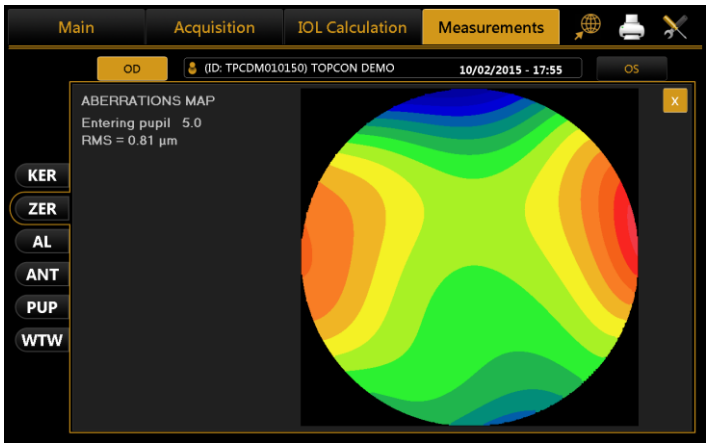
Figure 66

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

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

The ***"Pupil"*** button opens a panel (Figure 67) 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 with the variation of the pupil diameter.

Double click on each images (except Visus simulation) to review the chart enlarged.



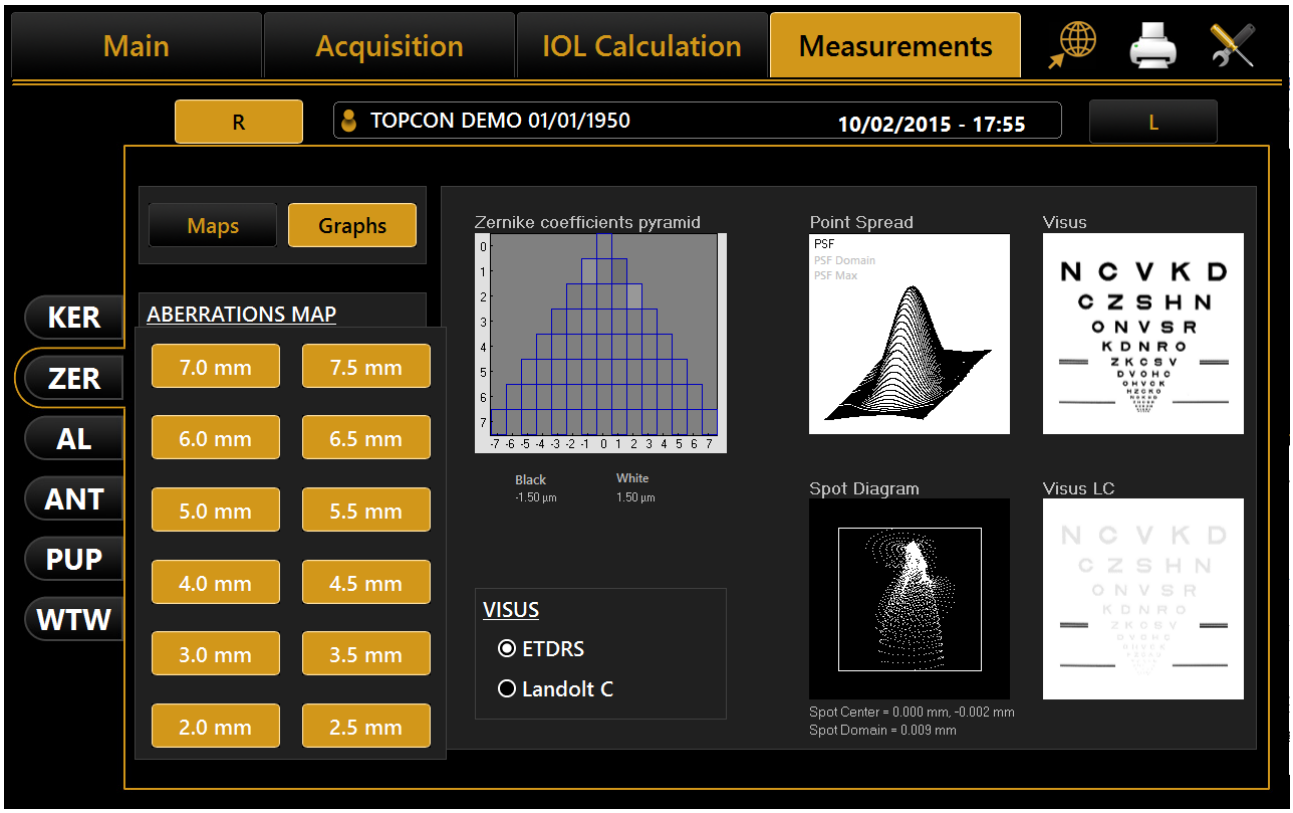
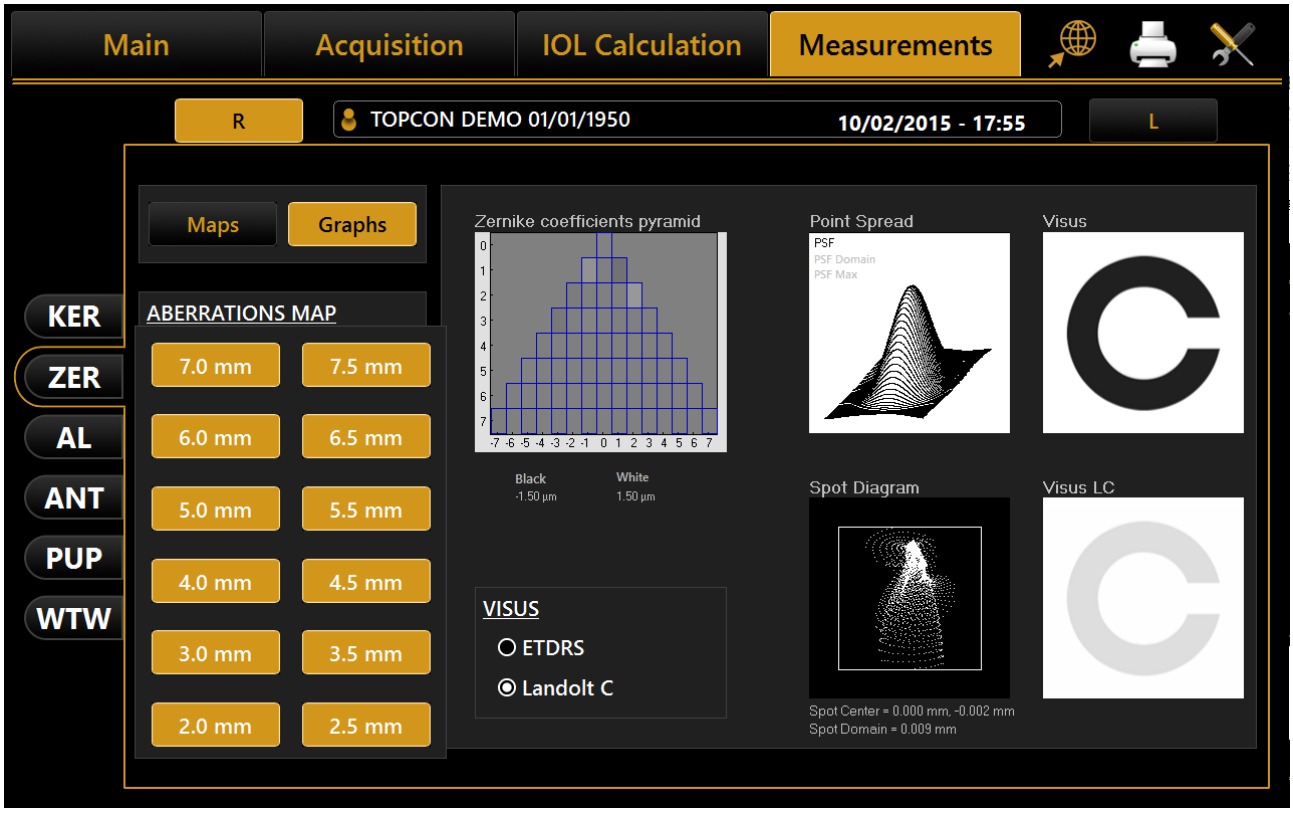


Figure 67

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



12.3 Axial Lenght (AL)

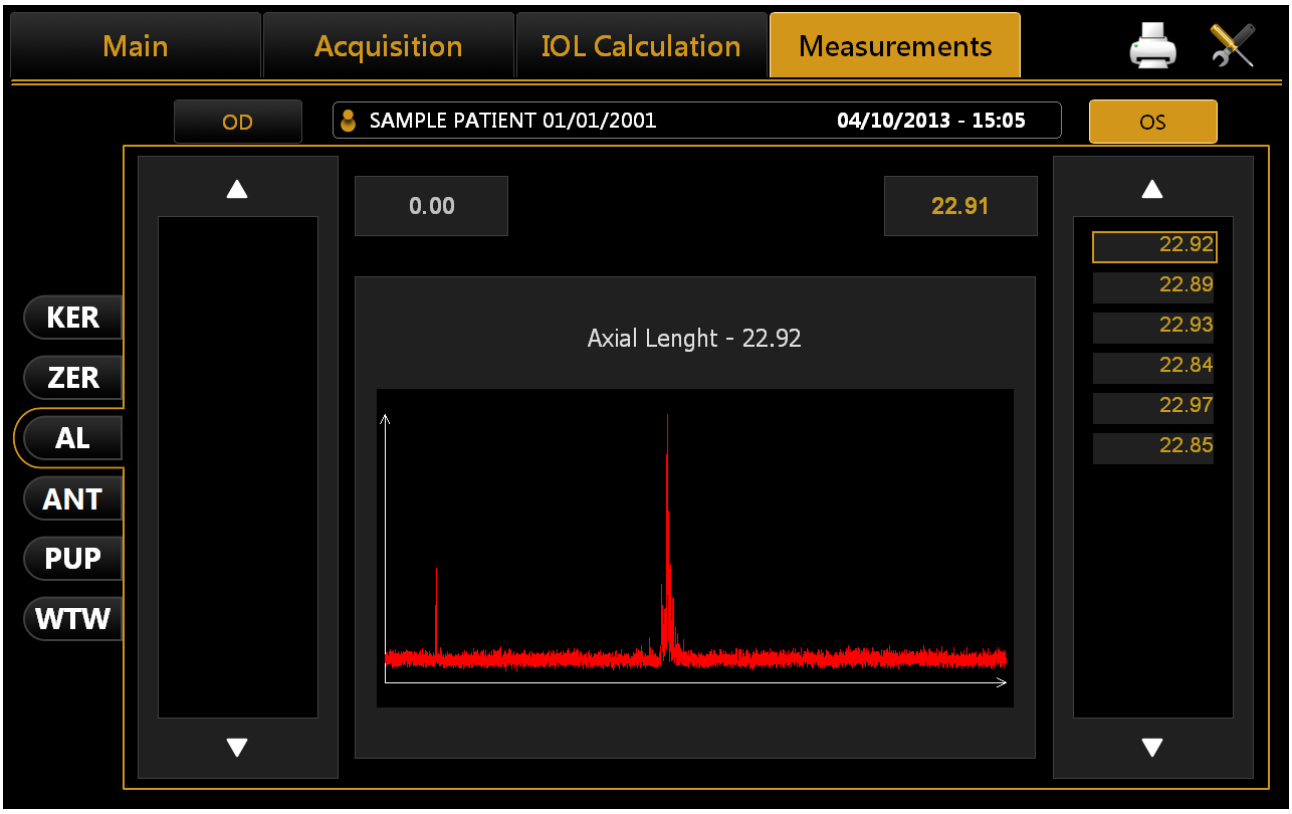


Figure 68

Figure 68 shows an axial length measurement.

In this screen you can select and display the interferometric graph for each measurement and from the left and right columns the measurements performed for the right eye and left eye, respectively. The measurements highlighted in yellow are the ones used to calculate the average axial length and are acceptable with respect to signal/noise. Those highlighted in red are those discarded by the system, for being unacceptable. It is always advisable to repeat a discarded measurement carefully.

12.4 Anterior Segment Sections (ANT, CCT-ACD-LT)

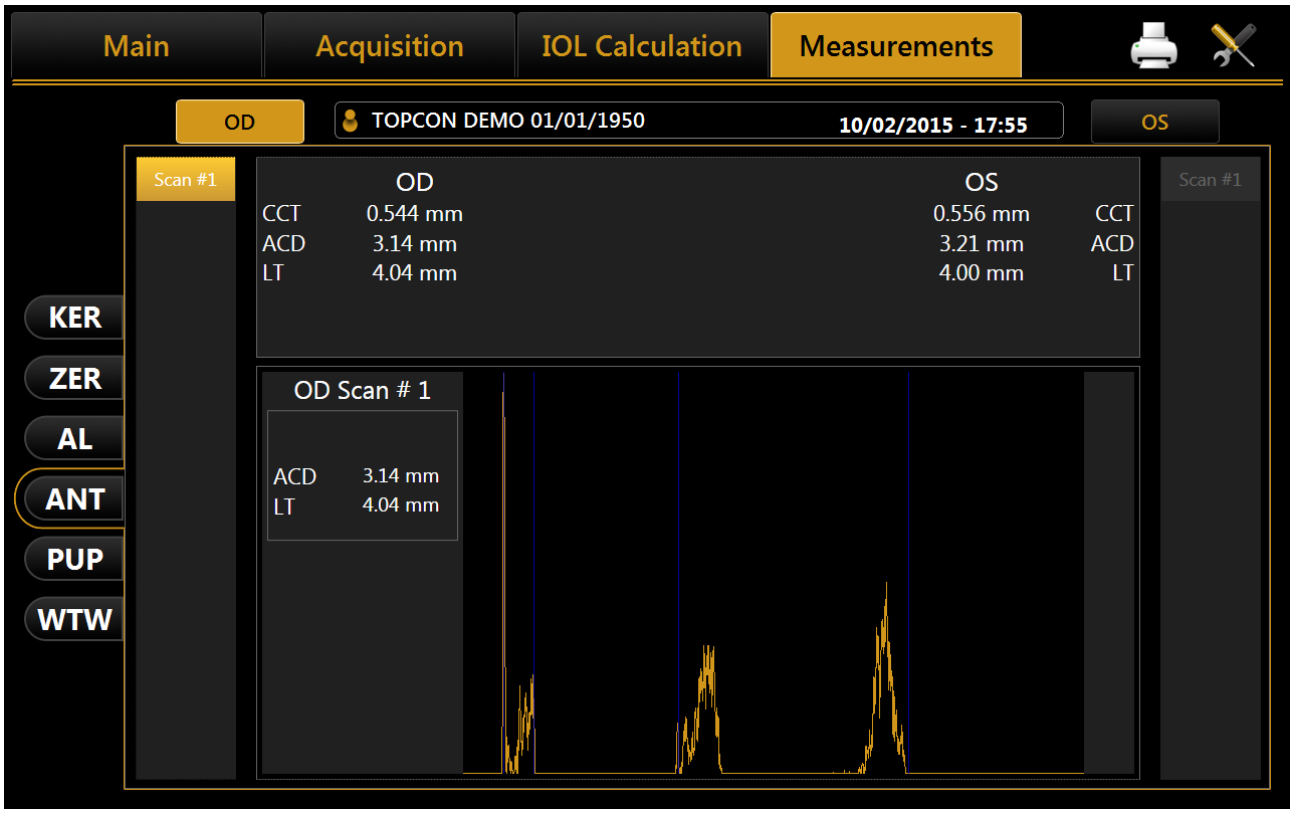


Figure 69

Figure 69 gives an example of ANT (Anterior Segment Section) measurements.
In this screen you can select and display the interferometric graph for each measurement and from the left and right columns the measurements performed for the right eye and left eye, respectively.
As for the axial length, if the instrument does not record good quality signal, or if the data is inconsistent, the acquisition is discarded.

On the top-central section the over-all values for both eyes are reported, while in the column at the left side of the interferometric graph the results for the selected acquisition are reported.

LT results are always with warning signs if the AL measurement for the same eye is not present.

12.5 Pupillometry (PUP)

The pupillometry module allows displaying and analyzing the dynamic and static pupillometry (pupil images acquired in controlled light conditions).

Normally, if the pupillometry is acquired, the software goes into dynamic mode (Figure 70).

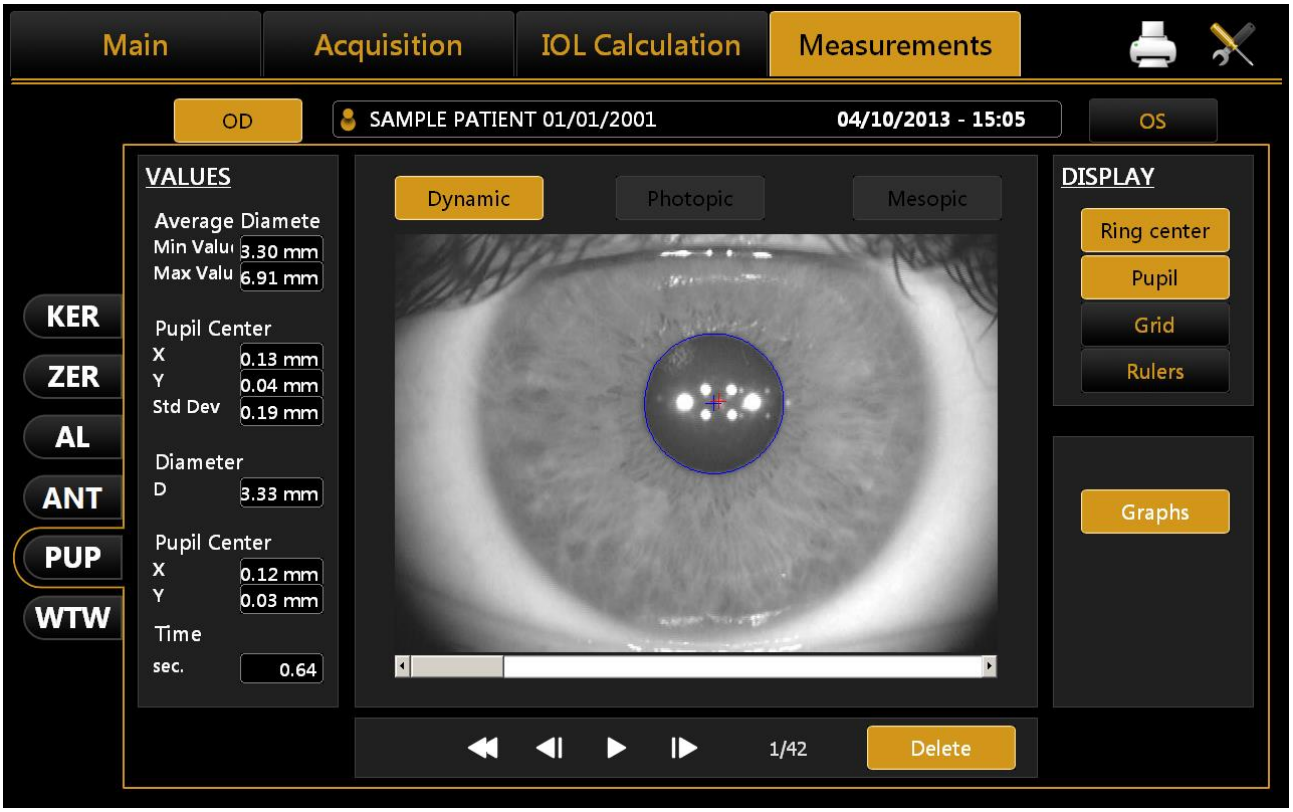


Figure 70

Click on ***"OD"*** or ***"OS"*** to display the pupillometry of the right or left eye, respectively.
With the patient's eye in view, buttons are located below the home screen. These buttons are used to navigate between the acquired frames. The current frame is shown next to the buttons.

Below a summary of the functions available on this screen:

Display

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

Sequences

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

- **Dynamic** Clicking 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

- **Photopic, Mesopic** By clicking on the *"Photopic"*, *"Mesopic"* buttons static pupillometry acquisitions will be displayed, with the following information:
  - **Value of the average pupil diameter measured in all the images acquired during the sequence.**

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

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

Delete

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

Graphs

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

12.5.1 Graphs

In this section three types of graph are displayed:

- ***Decentration*** (Figure 71)
- ***Latency*** (Figure 72)
- ***Statistics*** (Figure 73)

In all these graphs you can select which eye you want to analyze by clicking on **"OD"** or **"OS"**.

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

Decentration

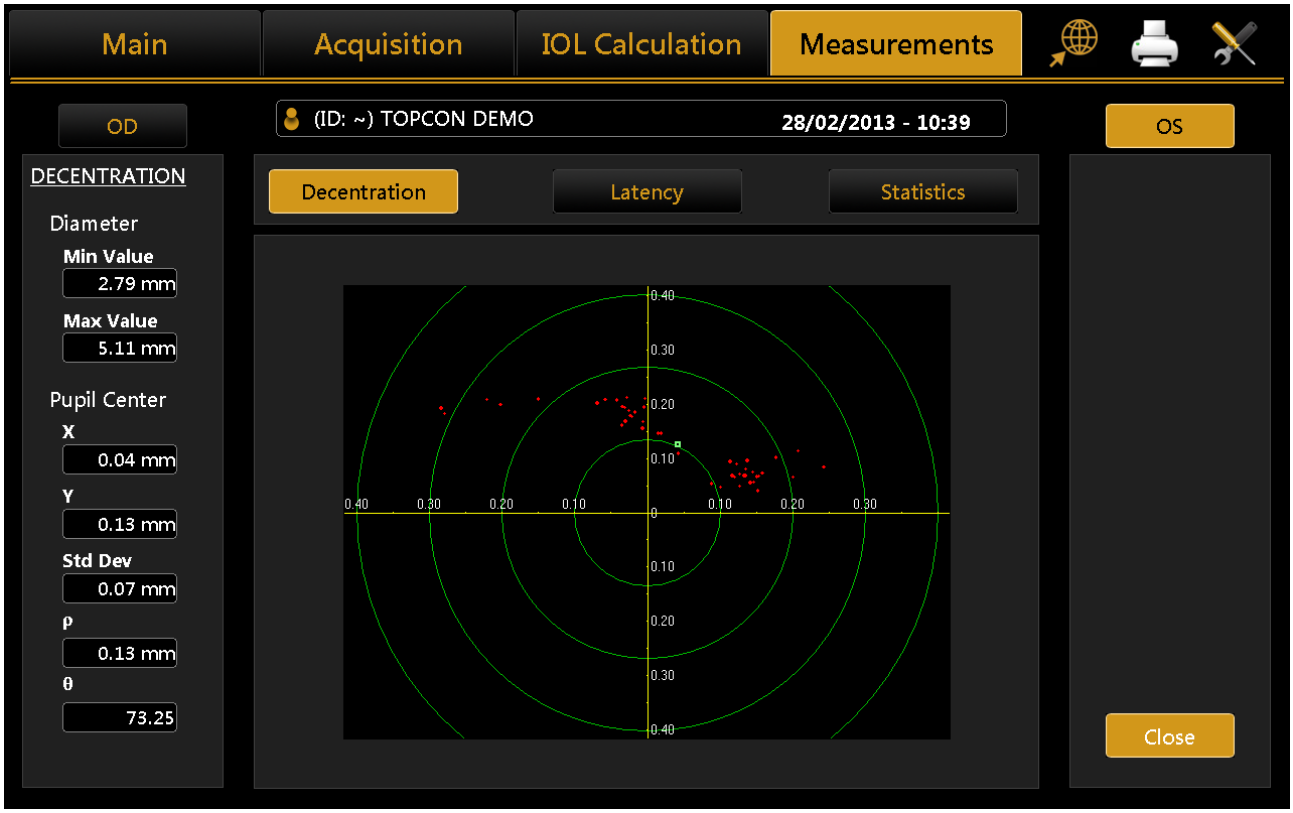


Figure 71

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

Latency

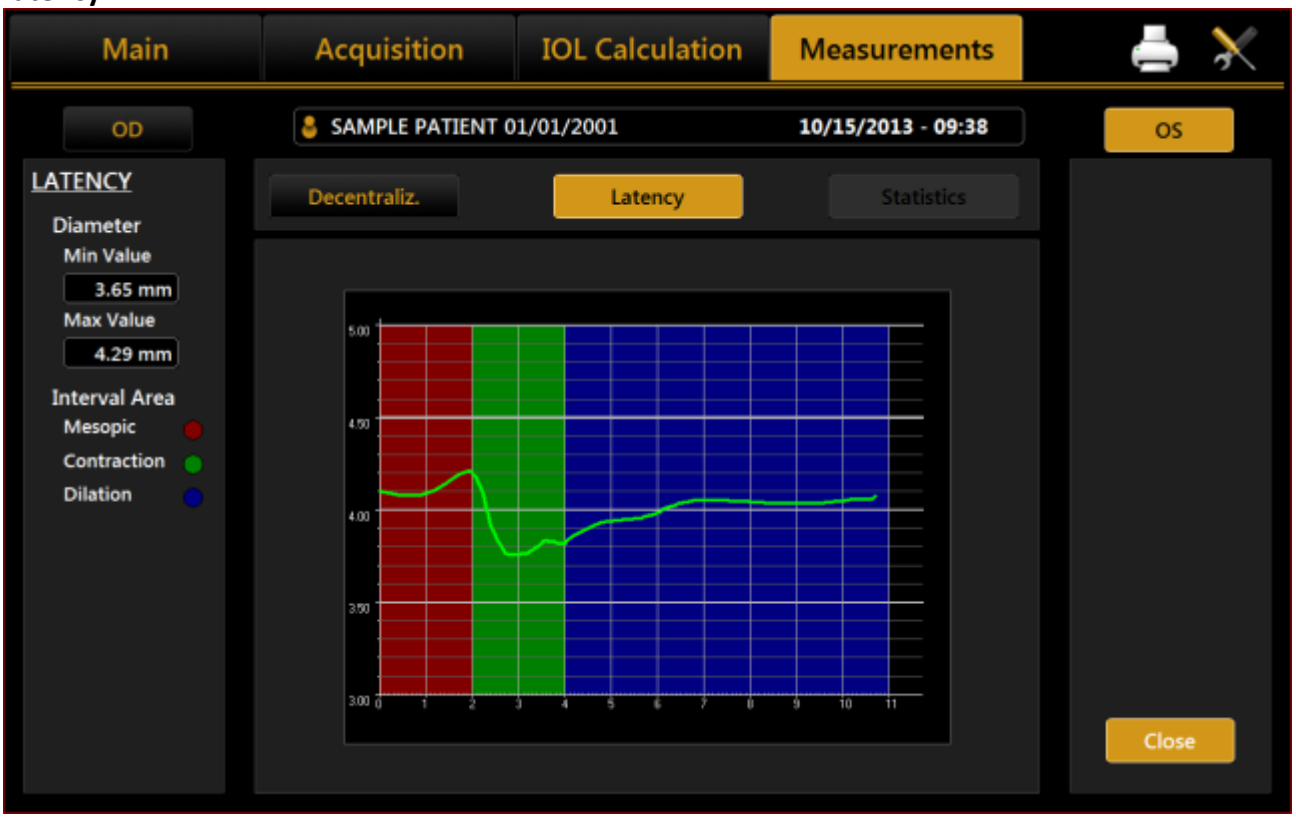


Figure 72

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

Taking into account that dynamic pupillometry consists of acquiring various images in variable light conditions, from mesopic to photopic and back to mesopic, 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 mesopic 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.

Remember that these graphs are only available if the acquisition of the dynamic pupillometry has been performed.

Statistics

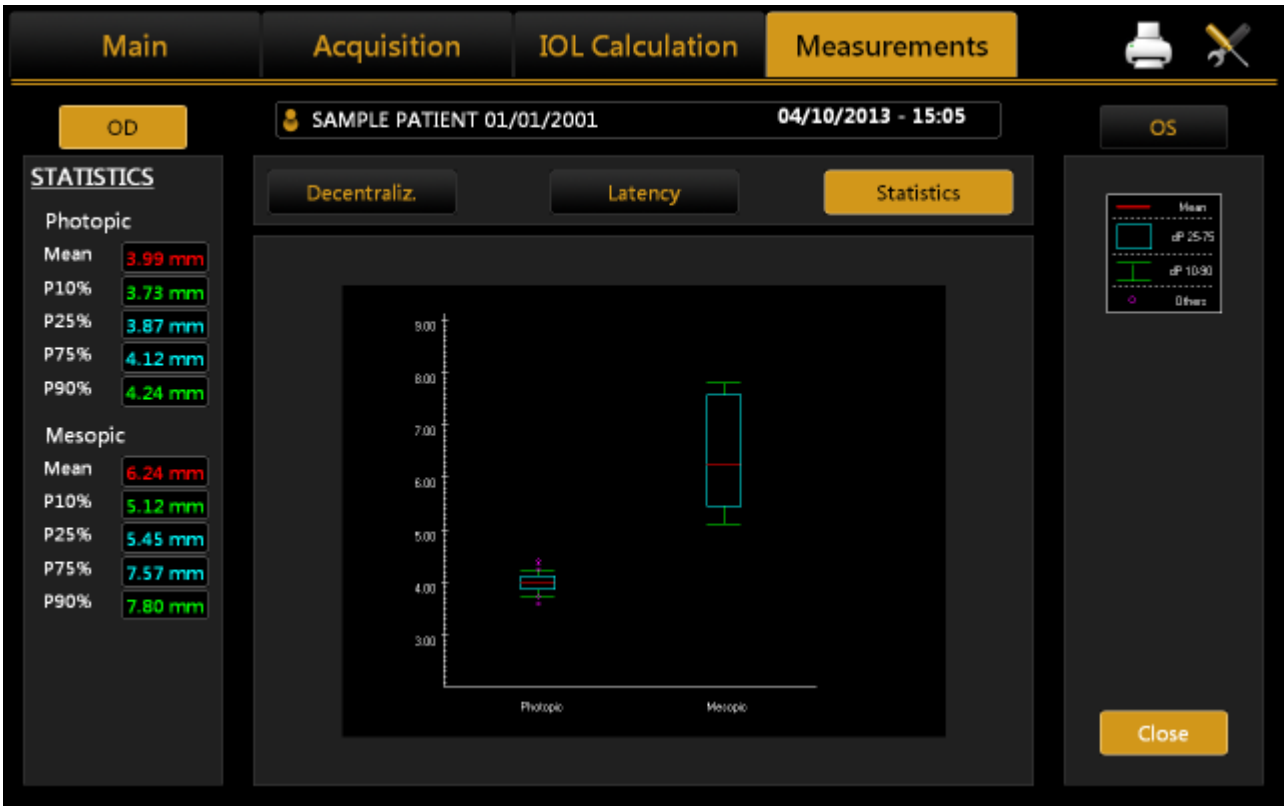


Figure 73

The graph represents the static value of the percentile of the sample for each acquisition in 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 or mesopic conditions.

12.6 White To White (WTW)

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

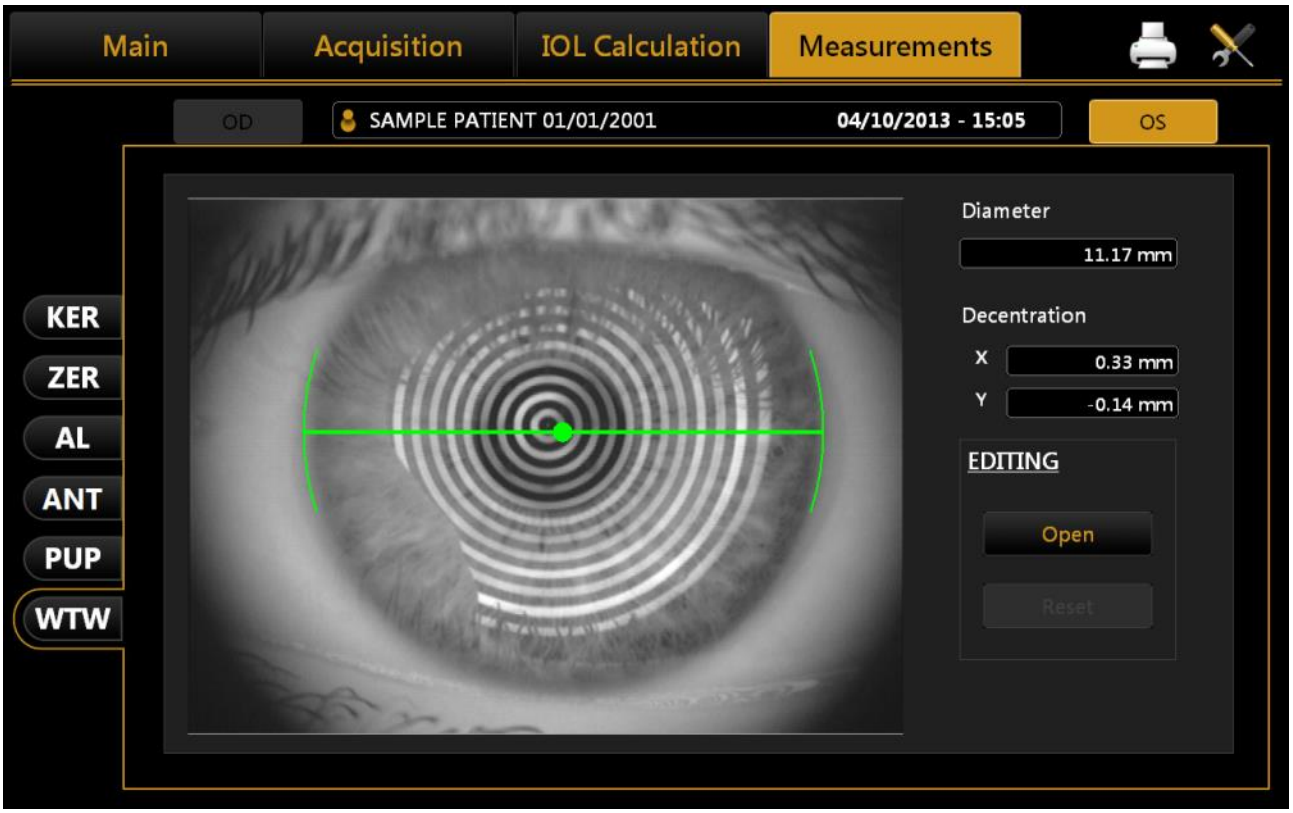


Figure 74

Clicking on the **Open** button in the **Edit** menu, the user can manually reposition positional indicators in order to refine the diameter measurements.

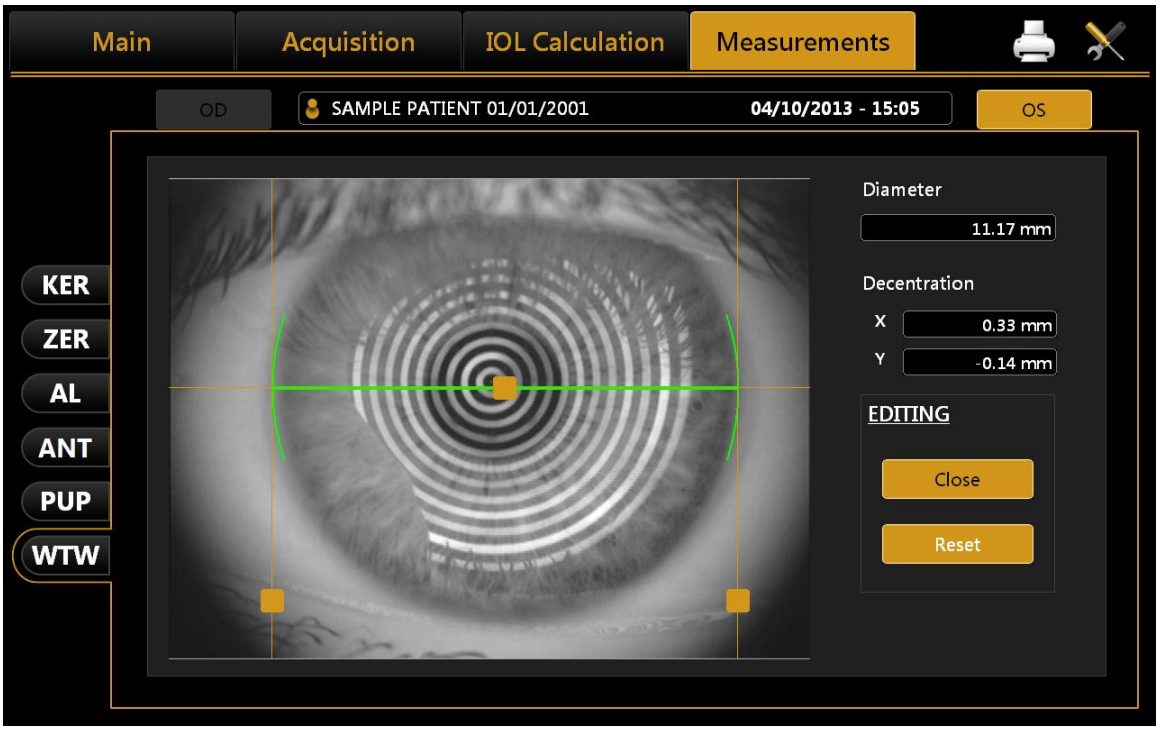


Figure 75

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 restores all values to the ones obtained by the automatic calculations of system.

13 SETTINGS

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

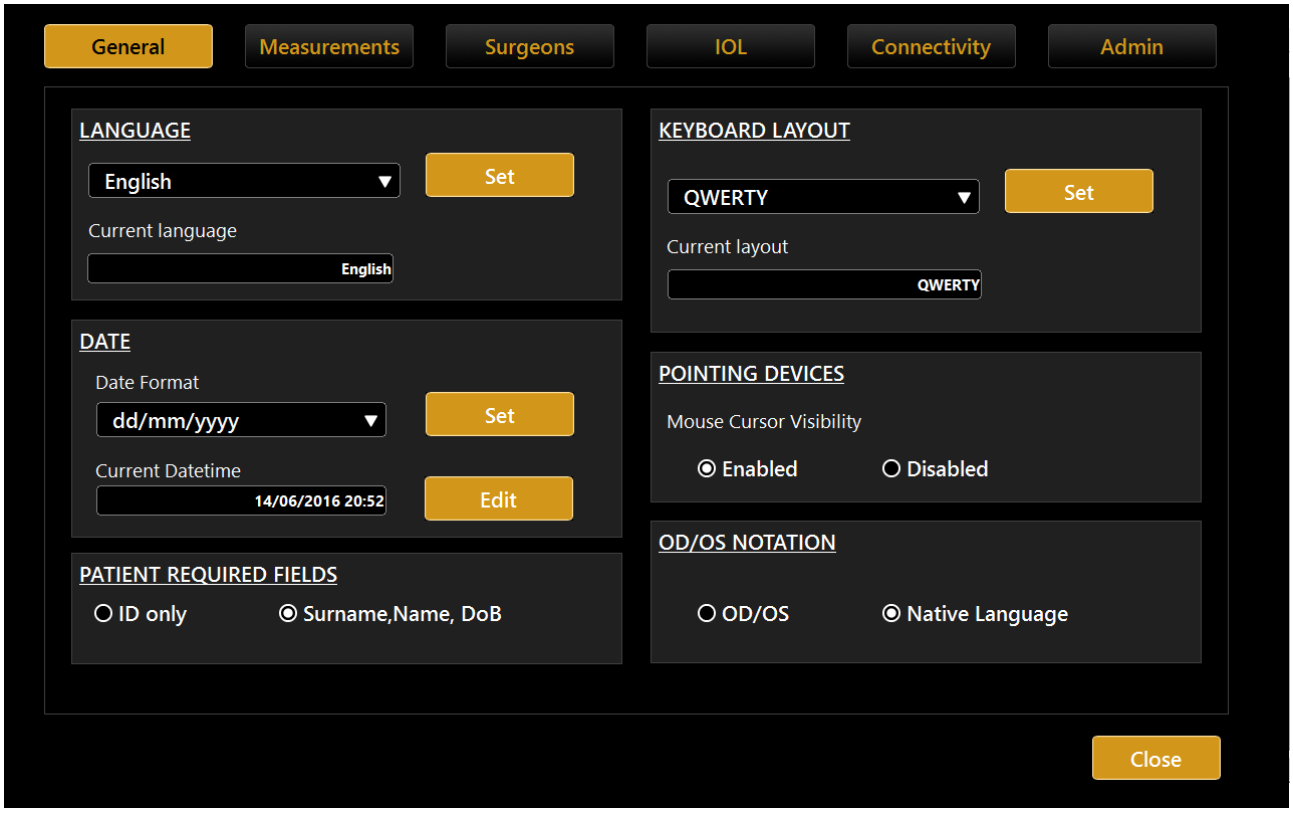


Figure 76

The settings screen is divided into the following categories.

- General
- Measurements
- Surgeons
- IOL
- Connectivity
- Admin

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

13.1 General

Refer to Figure 76:

Language: The first time the program is started, the default language set is English and the keyboard layout is "QWERTY".

To change the language settings, select the desired language from those that appear by clicking on the ↓ button, press ***"Set"*** to set automatic start with the chosen language. It is suggested 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 update of the layout in the personal details window **("Main").**

Date: Choose the desired date format and press on the **"Set"** button. You can also set the current system date and time by clicking on the "Edit" button.
Pointing Devices: Toggles the mouse cursor (on or off).
OD/OS Notation: Toggles between two different notations, OD/OS will show the Latin notation to indicate which eye is being acquired. The native language will depend on the words for left and right.
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).

13.2 Measurements

The acquisition settings panel allows you to set parameters for display of the corneal map, the printout and acquisition and display of the pupillometry.

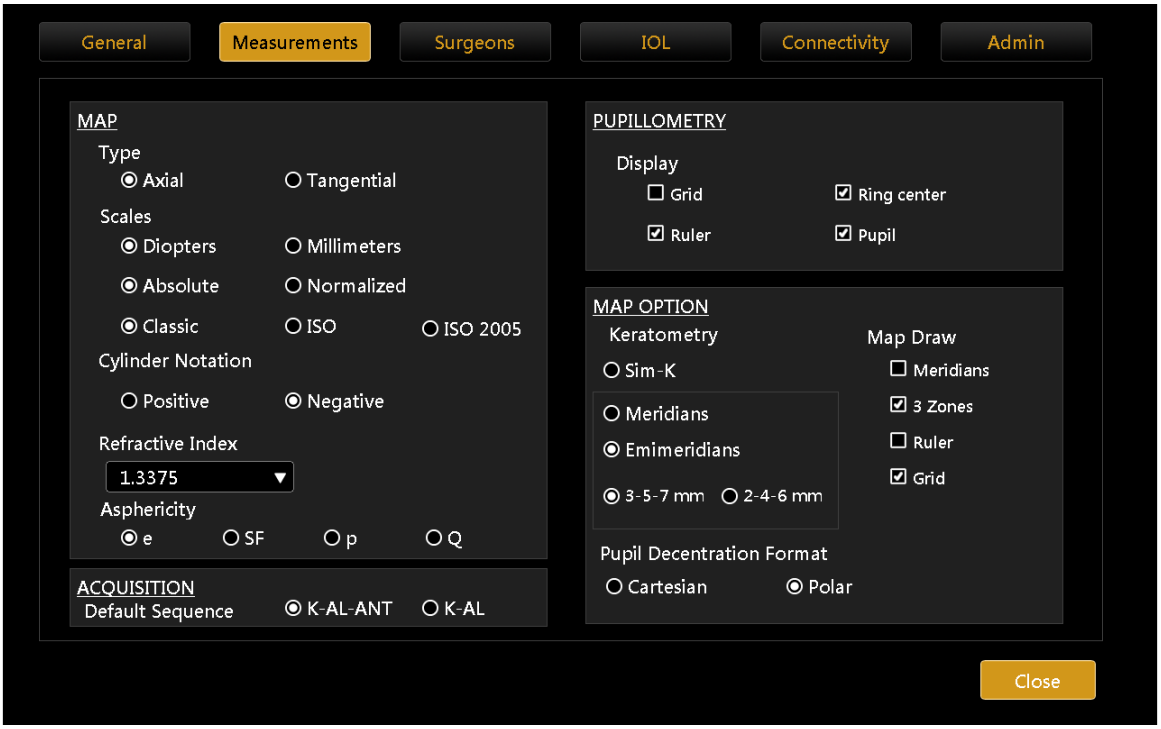


Figure 77

13.2.1 Map

Type
Select a map type:

- ***Axial***
- ***Tangential***

Scales
Select a scale measure:

- ***Diopters***
- ***Millimeters***

Select a scale type:

- ***Absolute***
- ***Normalized***

Select a scale color map (*see paragraph 13.2.5 for details*):

- ***Classic***
- ***ISO***[1]
- ***ISO 2005***[2]

Cylinder Notation

Select the type of cylinder notation:

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

Refractive Index

Select the refractive index to work with. You can choose from 5 indices:

- 1.3315
- 1.3320
- 1.3360
- 1.3375
- 1.3380

Be careful because changing the index will result in a differently calculated Keratometry and Topographic Map. Change this value at your discretion.

Asphericity

Select an asphericity unit of measure:

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

13.2.2 Acquisition

Select the default Biometry sequence acquisition:

- **K-AL-ANT:** the default acquisition sequence is Keratometry->Axial Length->Anterior Segment (CCT-ACD-LT)
- **K-AL:** the default acquisition sequence is Keratometry->Axial Length. Anterior Segment (CCT-ACD-LT) can be performed by pressing on the relative button

13.2.3 Pupillometry

Select one or more items with which to personalise the display of the pupil images:

- ***Grid***
- ***Ruler***
- ***Ring center***: the center of the pupil (in blue) and the fixation point (in red) will be displayed
- ***Pupil***: the outline of the pupil will be displayed in blue

[1] ISO 19980:2012(en) Ophthalmic instruments — Corneal topographers
[2] ISO 19980:2005(en) Ophthalmic instruments — Corneal topographers

13.2.4 Map Option

Map Design

Select one or more items with which to personalise the map display:

- ***Meridians***
- ***3 Zones***
- ***Ruler***
- ***Grid***

Keratometry

Select one of the keratometric indices:

- ***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*

Pupil decentration format

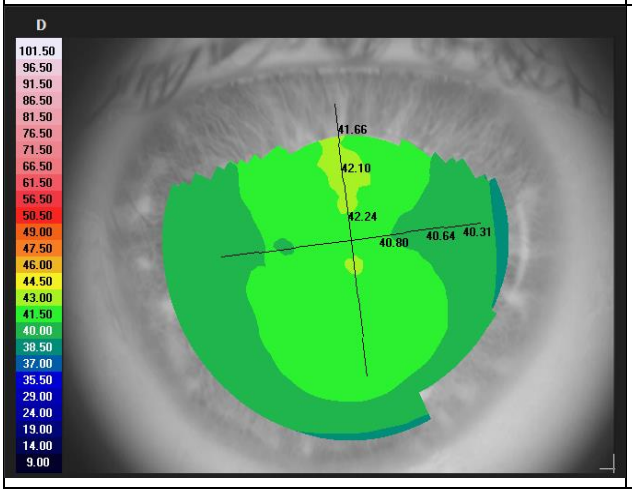
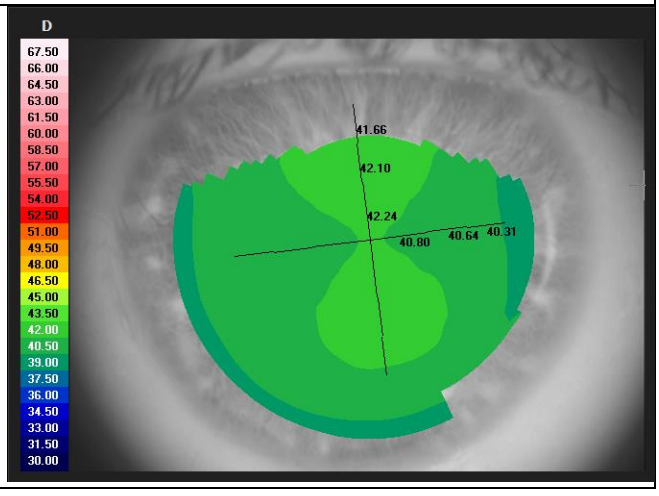
Display the pupil center decentration in Cartesian or polar coordinates in the application and Aladdin report

- Cartesian
- Polar

13.2.5 Topography Map Color scale description

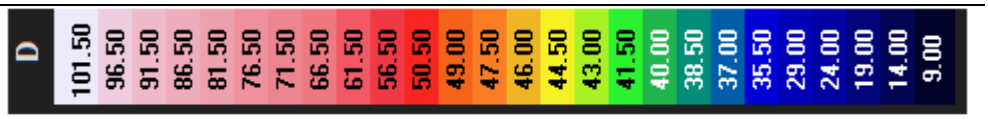
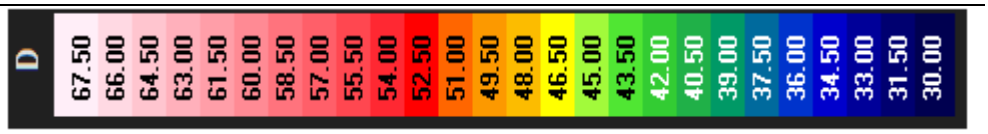
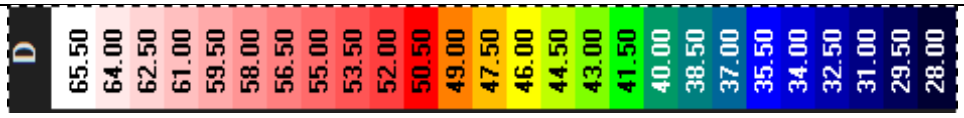
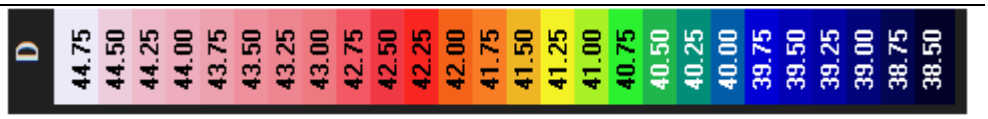
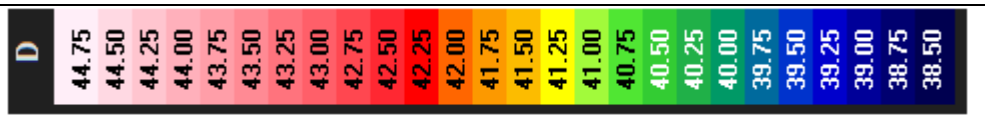
Previous software versions have always used the same color scale for Topography maps (absolute and normalized), this is called “Classic” color scale. This software version introduces the possibility to switch the scale to the ISO[3] and ISO 2005[4] color scale, by going to Measures section of the settings. The color scale option selected affects any topographic map drawing in the ALADDIN HW3.0 application and in the printed reports (also the custom ones).

The Classic and ISO absolute color scale are shown in the following figure for the same topography map.

Classic	ISO
	

[3] ISO 19980:2012(en) Ophthalmic instruments — Corneal topographers

[4] ISO 19980:2005(en) Ophthalmic instruments — Corneal topographers

Absolute scale	**Classic**	
	ISO	
	ISO 2005	
Normalized (adjustable) scale	**Classic**	
	ISO	
	ISO 2005	

13.3 Surgeons

The **"Surgeons"** panel allows you to create different user profiles.

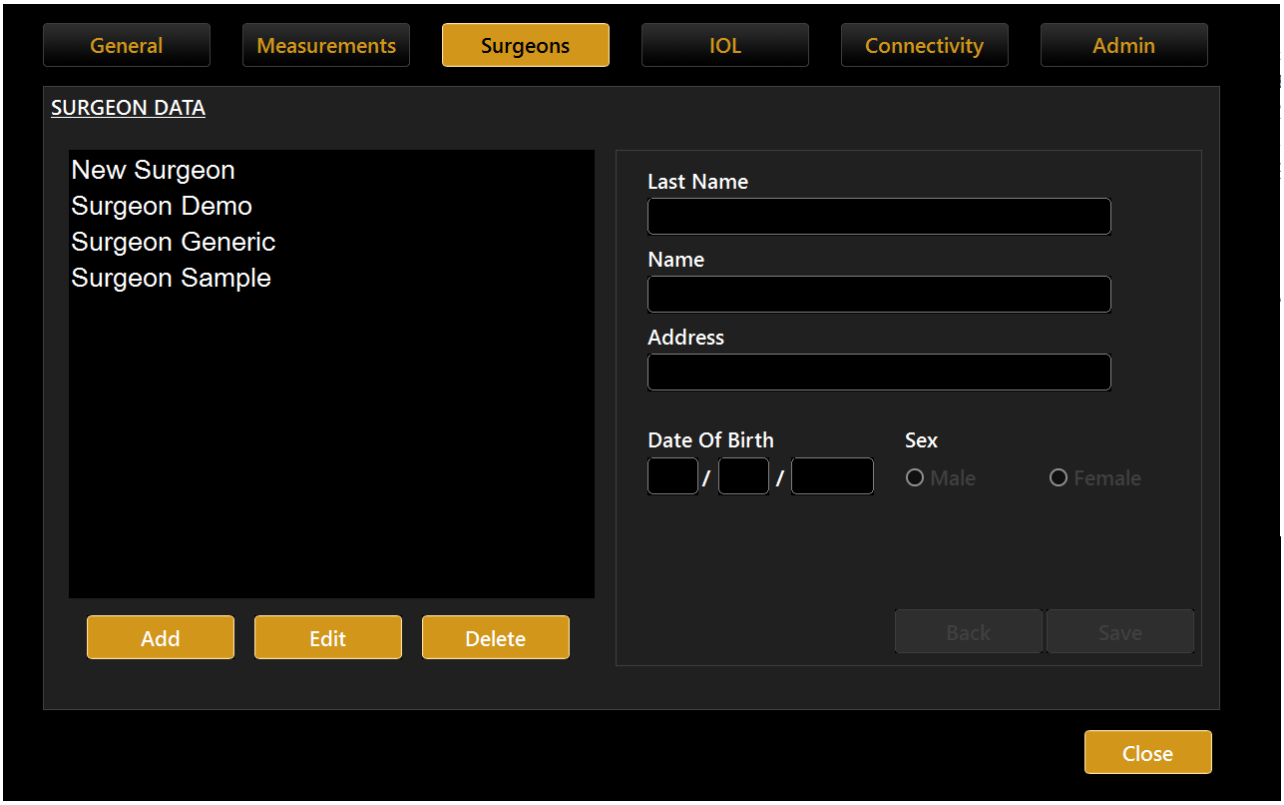


Figure 78

Select the surgeon in the left column to display the data.
Press the **"Edit"** button to modify the data entered.

Press the **"Add"** button to add a new surgeon.
Once you have entered/modified the data, press the **"Back"** or **"Save"** buttons, respectively, to cancel or save the data.

13.4 IOL

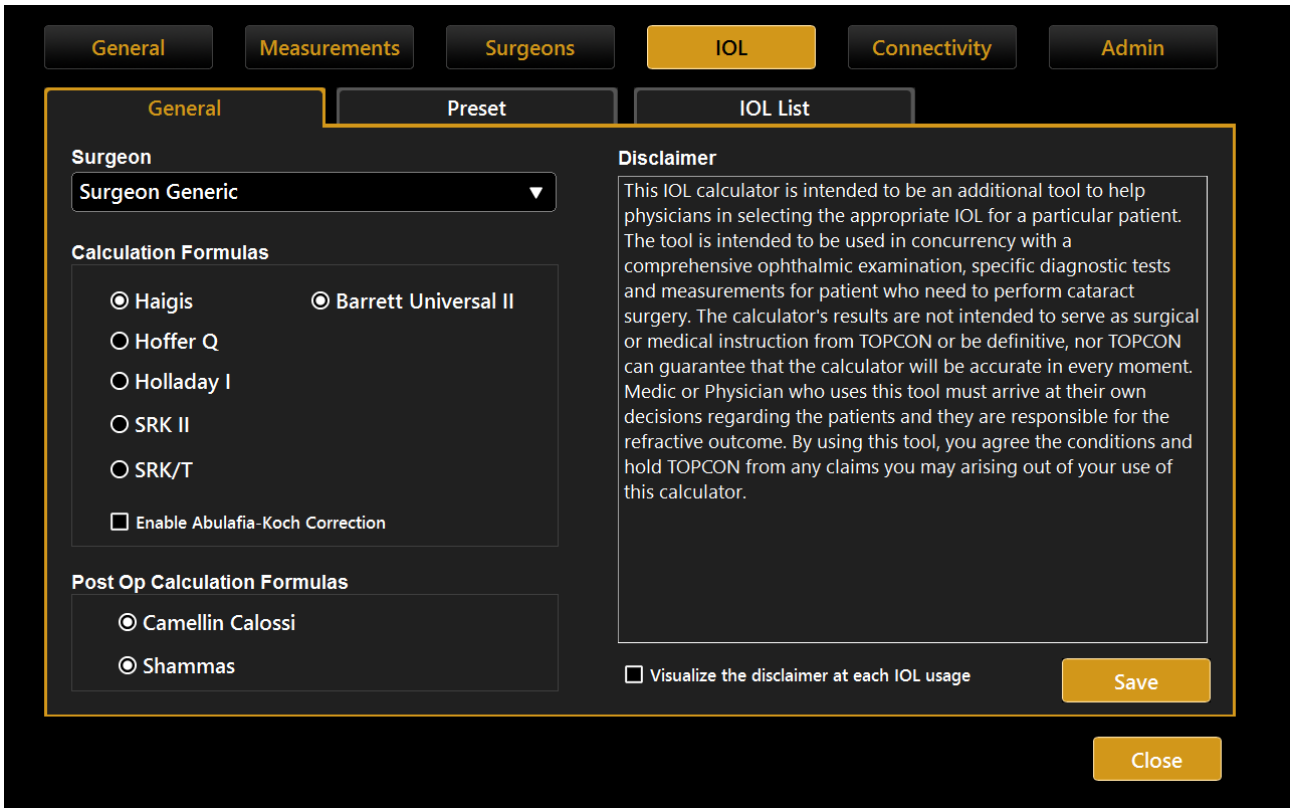


Figure 79

Here you can configure various options and presets for the IOL environment (Figure 79) associated with the surgeon selected, divided into three different environments described in detail below:

- General
- Preset
- IOL list

13.4.1 General

General environment (Figure 79) displays the terms and conditions of use of the IOL calculation section and lets you choose which formulas will be activated. You can reactivate the appearance of the Disclaimer for the selected surgeon at every IOL usage by checking the box below it and then saving.

13.4.2 Preset

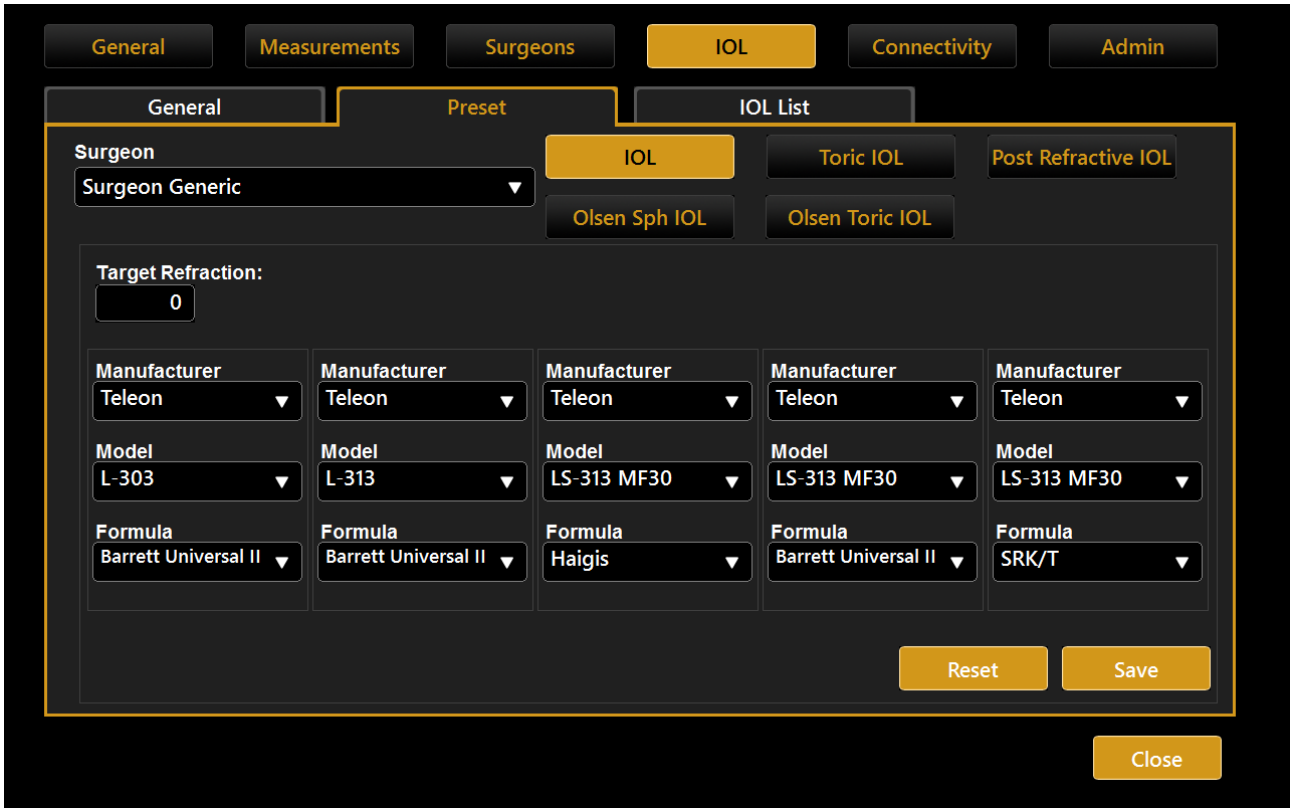


Figure 80

Preset environment (Figure 80) is composed of 5 main sections, where each surgeon can set:

- Under **"IOL"** the preset for the **IOL Calculation** (included the Barrett Universall II spherical section of Barrett module)
- Under **"Toric"** the preset for the **Toric IOL Calculation** (included the Barrett Universall Toric and True K toric section of Barrett module)
- Under **"Post Refractive IOL"** the preset for the **Post Refractive IOL** (included the Barrett TrueK section of Barrett module)
- Under **"Olsen Sph. IOL"** the preset for **Olsen Spherical IOL** calculation section of Olsen module
- Under **"Olsen Toric IOL"** the preset for **Olsen Toric IOL** calculation section of Olsen module

Clicking on **"Save"** button the selected settings are saved. This function will be particularly useful during the IOL calculation, when each setting is reloaded each time as preset.
Pressing the **"Reset"** button, previous selections are reset, deleting all presets associated with the surgeon.

"IOL" and "Post Refractive IOL" sections have the same screen, the "Toric" one is presented in Figure 81.

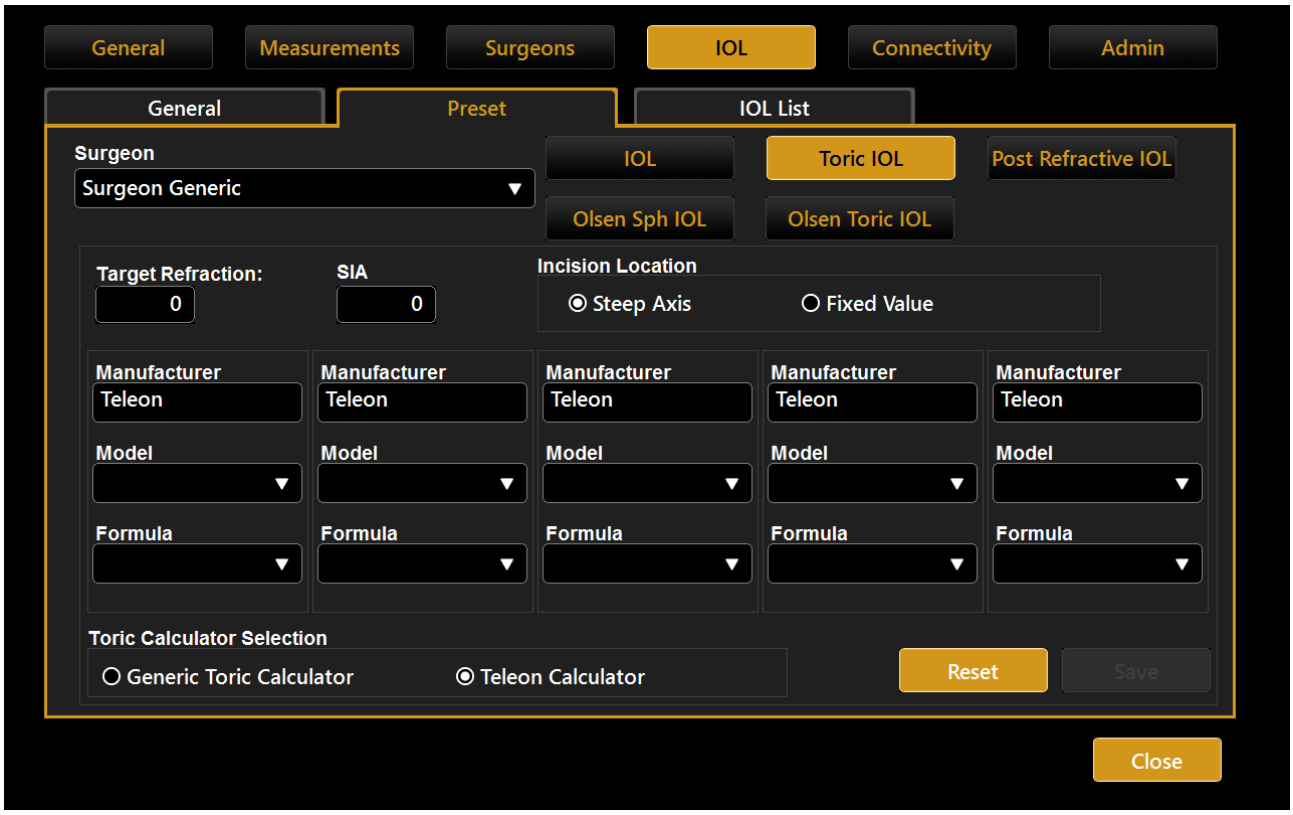


Figure 81

Toric preset uses a different set of lenses (with only toric ones) and requires some additional settings with respect to “IOL” and “Post Refractive IOL” sections.

In particular, you can specify the “Surgical Induced Astigmatism (SIA)” induced by the surgeon and the “Incision Location” used during the surgery. You can decide to set the “Incision Location” at the Steep Axis of the Keratometry or at a Fixed Value to be specified.

The “Toric Calculator Selection” is to choosen between:

- “Generic Toric Calculator”, that allows to define the lenses preset from a fully customizable collection of models and manufacturers.
- “Teleon Calculator”, that allows to limit the collection of available lenses to Teleon manufacturer only. In this case the manufacturer selection is locked both in the preset set-up and in the Toric IOL calculation environments.
  With the Teleon Toric Calculator option selected you have access to the additional following functionalities:
  - Review the Toric IOL alignment image with the specific Teleon aspect also in the Toric calculation interface
  - Print the Teleon specific order forms also using the Barrett Universal II Toric Calculator (if activated)
  - Get the Lentis Comfort Toric (LS-313MF15Tx) Plausibility Checkup Report printed out together with the Order Form

This setting is per Surgeon.

In the “Olsen Sph. IOL” and “Olsen Toric IOL” preset the formula is locked to Olsen formula.

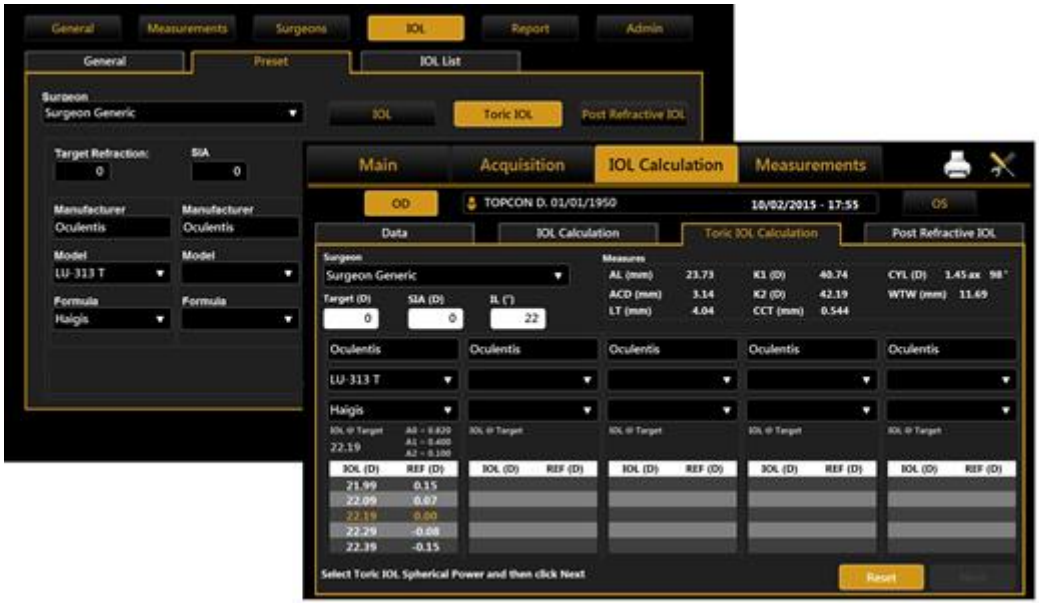


Figure 82

13.4.3 IOL list

In this section (Figure 83) you can manage IOL spherical and torical lenses list. You can change the available manufacturers and models by adding, deleting or editing them.
For each lens you can display and edit the constants used in each formula.
The two main environments, the “Spherical” and the “Torical” ones, can be selected clicking on the corresponding button and have a similar layout.

13.4.3.1 *IOL Spherical List*

The **“Spherical”** layout is shown in Figure 83.
On the left side you can find the list of manufacturers, in the center their related spherical models while in the right side the calculation constants of the selected lens.

Figure 83

List of functions for IOL manufacturer column:

- **Add:** add a new manufacturer not present in the current list
  - Insert the manufacturer name
  - Insert the model name
  - Insert the kind of formula and constant
  - Insert the value of the constant, “Hoffer Q pACD” in the case below (other constants will automatically be converted).

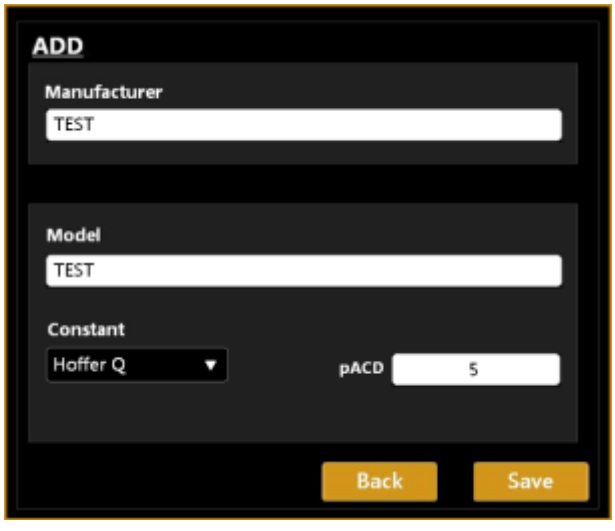


Figure 84

- **Edit:** edit the name of the current manufacturer in the list
- **Delete:** delete a manufacturer. Please note that this function will also delete every IOL associated to the current manufacturer.

List of functions for IOL model column:

-  **Add:** add a new IOL model to the current manufacturer:
  - Insert the model name
  - Insert the kind of formula and constant
  - Insert the value of the constant, "Haigis A0" in the case below (other constants will automatically be converted).

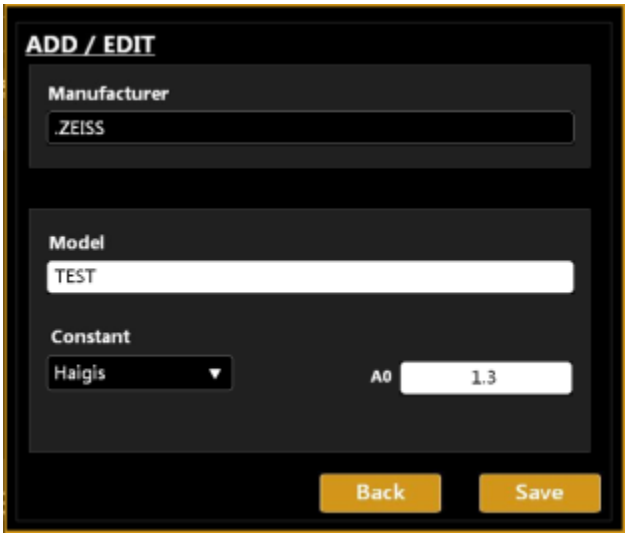


Figure 85

-  **Edit:** edit the name of the current IOL
-  **Delete:** delete the selected IOL
-  **Calculation Constants History:** gives information on any change of calculation constants or optical advanced parameters values as shown in Figure 86.
  The possible sources of edit are "Manual" (constants values changed manually by the user), "ULIB" (constants values changed after an ULIB update) and "Restore" (constants values restored by the user to a previous version). To restore a previous version you need to select the version to be restored and then click on the yellow right-arrow and then click on save button.

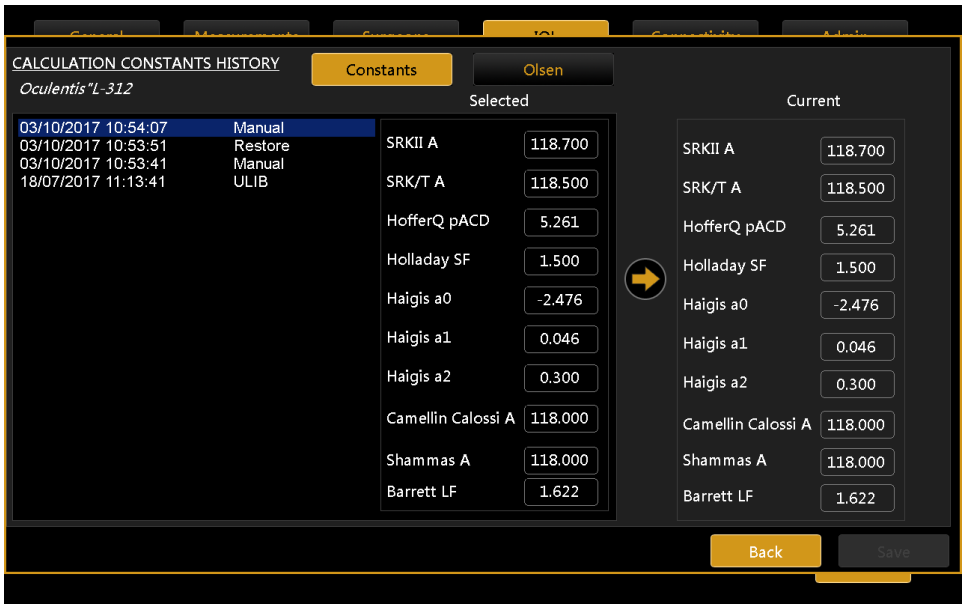
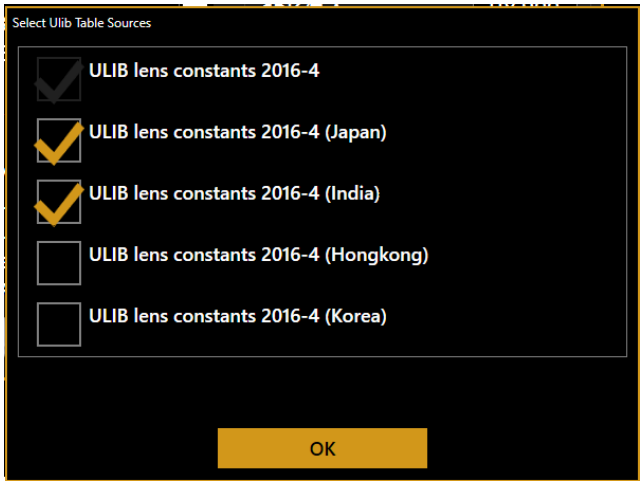


Figure 86

With the "**Ulib**" button you can import .zip files of ULIB (User Group for Laser Interference Biometry) format. Download the file and copy it to the root (main card) of an empty FAT32-formatted USB pen

1. Insert the USB pen in the ALADDIN HW3.0 device.
2. Click on the ***"Ulib"*** button on the "IOL list" panel.
3. Select which data to import among the list of source tables available in the downloaded package.

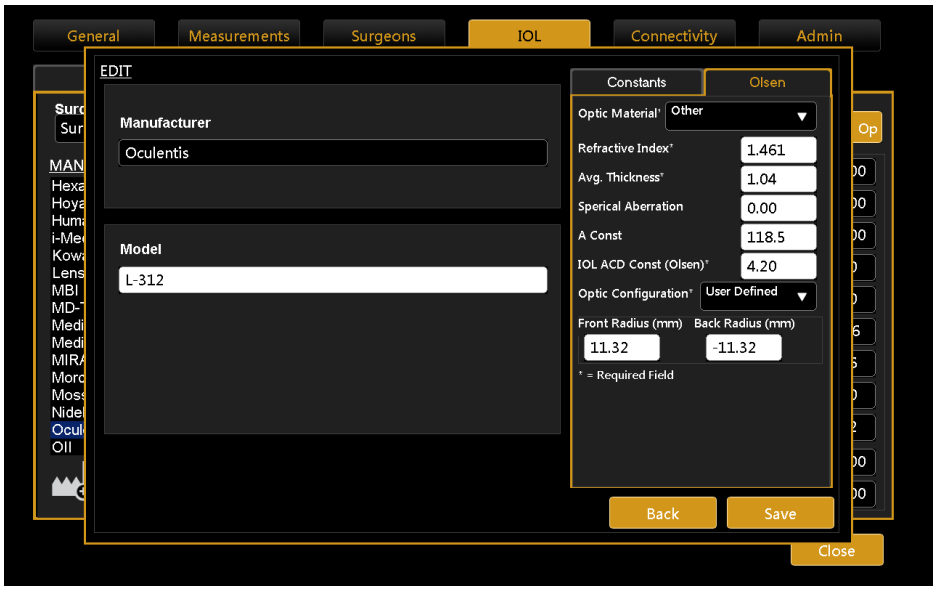


13.4.3.2 *IOL Spherical model Advanced paremeters (Olsen)*

To use an IOL model with the Olsen formula, advanced optical parameters for the IOL model must be defined.

Advanced IOL model parameters are not contained in the Ulib database and they will not be changed or added to any IOL model when performing the Ulib update. Aladdin by default provides these parameters for a subset of the IOL models. The user, accordingly to his knowledge and needs, can edit these parameter or add them for a model that didn't have them by default.

To edit or insert the advanced IOL parameters for an existing (or newly created) IOL model select the desired IOL model and press the edit button  .



Optic Material and Refractive index: the user can select the optic material that correspond to the selected IOL model to get the Refractive index field value filled automatically. Otherwise, the user can select “Other” from the list to specify a different refractive index. The refractive index value is used in the Olsen formula to perform the IOL calculations. It doesn’t affects other formulae.

Aladdin provides standard refractive index values for the following materials:

- Acrylic
- Hydrophobic Acrylic
- PMMA
- Hydrophilic Acrylic
- Silicone
- Collamer
- HEMA

It is recommended to obtain the exact value from the manufacturer; this information is usually provided in the IOL model datasheet.

Avg. Thickness, Front Radius and Back Radius: these values must be specified with respect to the same IOL power. It is recommended to specify these values with respect to an average IOL power value of 22D.

Spherical Aberration: [optional] the spherical aberration value must be provided by the manufacturer according to the spherical aberration correction applied to the IOL model. Typical values are -0.27 µm for a full correction. Zero value is for a model that does not add or subtract the spherical aberration to the eye. If the value is left empty, a 0.1 µm value of spherical aberration add to the eye is assumed.

A Const: optimized A Const value used for SRK/T formula on the selected IOL model. Can be inserted to get the IOL ACD Const (Olsen) automatically calculated from this value if a directly optimized value for IOL ACD Const (Olsen) is not available.

IOL ACD Const (Olsen constant): if a directly optimized value for IOL ACD Const (Olsen) is available can be inserted and used without the need of inserting a corresponding A Const value.

Optic Configuration: this value is to indicate the relationship between the front IOL curvature and the back IOL curvature. Available values in the list are:

- Biconvex 1:1, front radius is positive back radius is negative
- Biconvex 2:1, front radius is positive back radius is negative
- Biconvex 3:1, front radius is positive back radius is negative
- Biconvex 1:2, front radius is positive back radius is negative
- Biconvex 1:3, front radius is positive back radius is negative
- PlanoConvex, front radius is 0 back radius is negative
- ConvexoPlano, front radius is positive back radius is 0
- ConvexoConcavo, front and back radius are positive values

13.4.3.3 *IOL Torical List*

The **"Torical"** layout is shown in Figure 87.

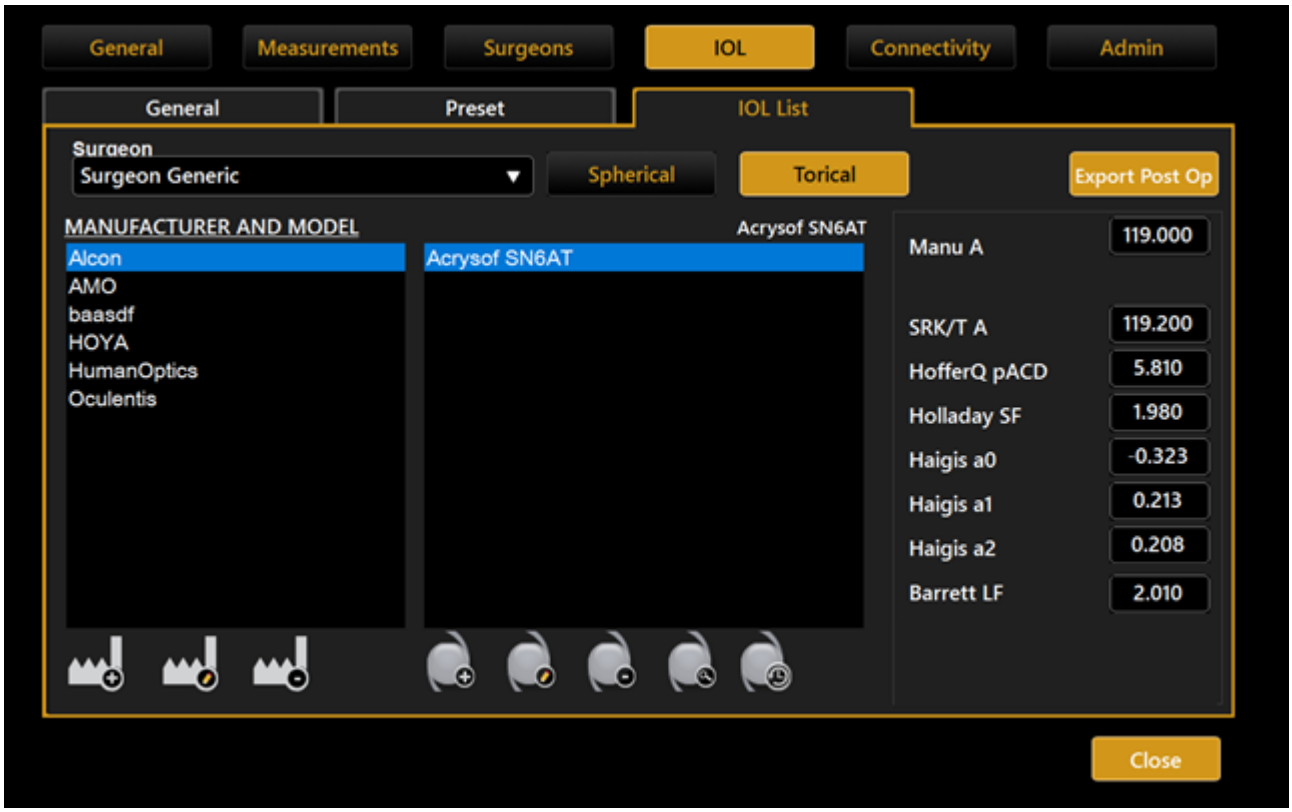


Figure 87

List of functions for IOL manufacturer column:

- **Add:** add a new manufacturer not present in the current list
  - Insert the manufacturer name
  - Insert the model name
  - Insert the kind of formula and constant
  - Insert the value of the constant, “Hoffer Q pACD” in the case below (other constants will automatically be converted)
  - Define the “Sphere Power Range”, inserting the minimum, the maximum and the step of the spherical power of the lens
  - Choose the “Cylinder Definition” of the lens, with “Sub models” or “Cylinder Range Based”.
    - If you select “Sub models” (Figure 88) you can add a list of sub models each of them with a different cylinder value of Toricity, using the IOL button under the table (add, edit and delete).
    - If you select “Cylinder Range Based” (Figure 89), you have to insert the minimum, the maximum and the step of the cylinder value in order to define the toricity range of the lens.

Figure 88

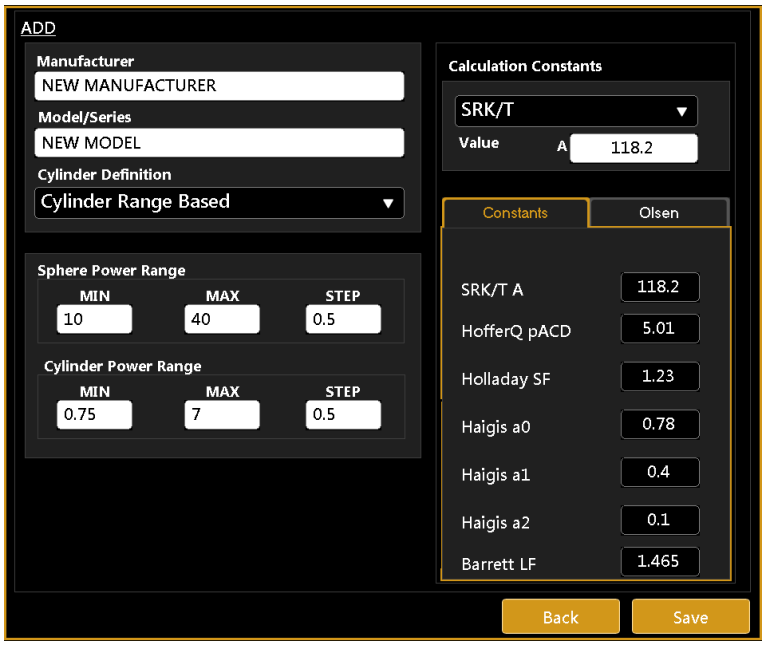


Figure 89

- **Edit:** edit the name of the current manufacturer in the list
- **Delete:** delete a manufacturer. Please note that this function will also delete every IOL associated to the current manufacturer.

List of functions for IOL model column:

- **Add:** add a new IOL model to the current manufacturer, with the same procedure described in the "Add Toric Manufacturer" section above.
- **Edit:** edit the name and the properties of the current IOL
- **Delete:** delete the selected IOL
- **View Properties:** visualize properties, calculation constants and list of sub models of the lens (or cylinder range)
- **Calculation Constants History:** gives information on every change of calculation constants values. The layout is similar to the one in Figure 86.
  The possible sources of edit are "Manual" (constants values changed manually by the user) and "Restore" (constants values restored by the user to a previous version). To restore a previous version you need to select the version to be restored and then click on the yellow right-arrow and then click on save button.

13.4.3.4 *IOL Toric model Advanced paremeters (Olsen)*

Refer to section 13.4.3.2 for details.

13.5 Connectivity

This panel (Figure 90) allows you to configure all the settings relative to network connectivity with external softwares or storage destinations.

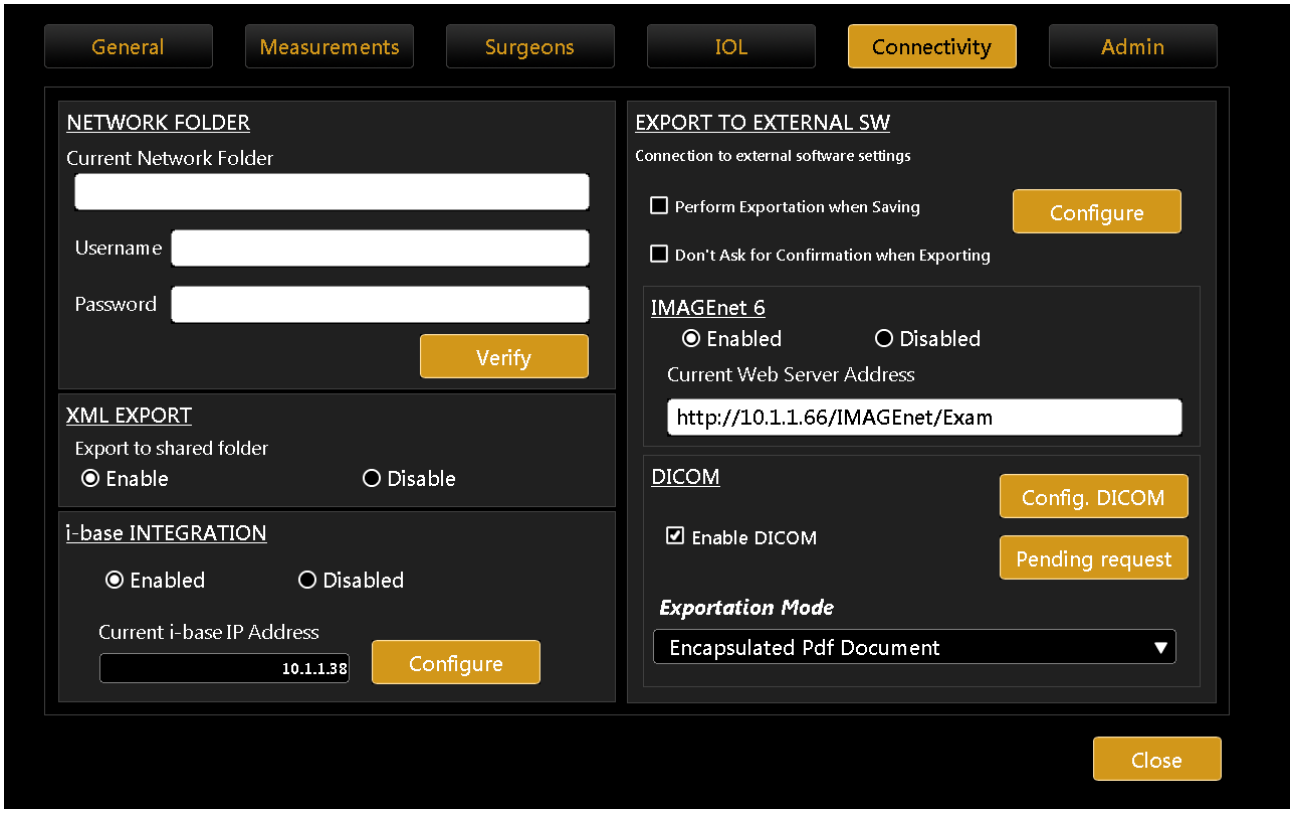


Figure 90

13.5.1 Network folder configuration

The "NETWORK FOLDER" panel allows the user to configure and use a remote network folder to store ALADDIN HW3.0 reports.
That resource will then become selectable as a destination in the report's print form.

In order for ALADDIN HW3.0 to be able to connect to the remote network folder, you must configure ALADDIN HW3.0 setting the correct access credentials for the remote resource.

Configuration parameters:

- ***Network folder path*:** the path to access the network folder location (without trailing backslashes)
  eg.
  \\10.0.0.81\path_to\AladdinSandbox
  \\TopconNetwork\path_to\AladdinSandbox
- ***Username*:** specify the domain name if needed
  eg.
  TopconDomain\username
- ***Password*:** for the specified username

When you click on the “Configure” 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 is reported as shown in Figure 91. Connection failure may be due to unreachable resource path or to wrong credentials.

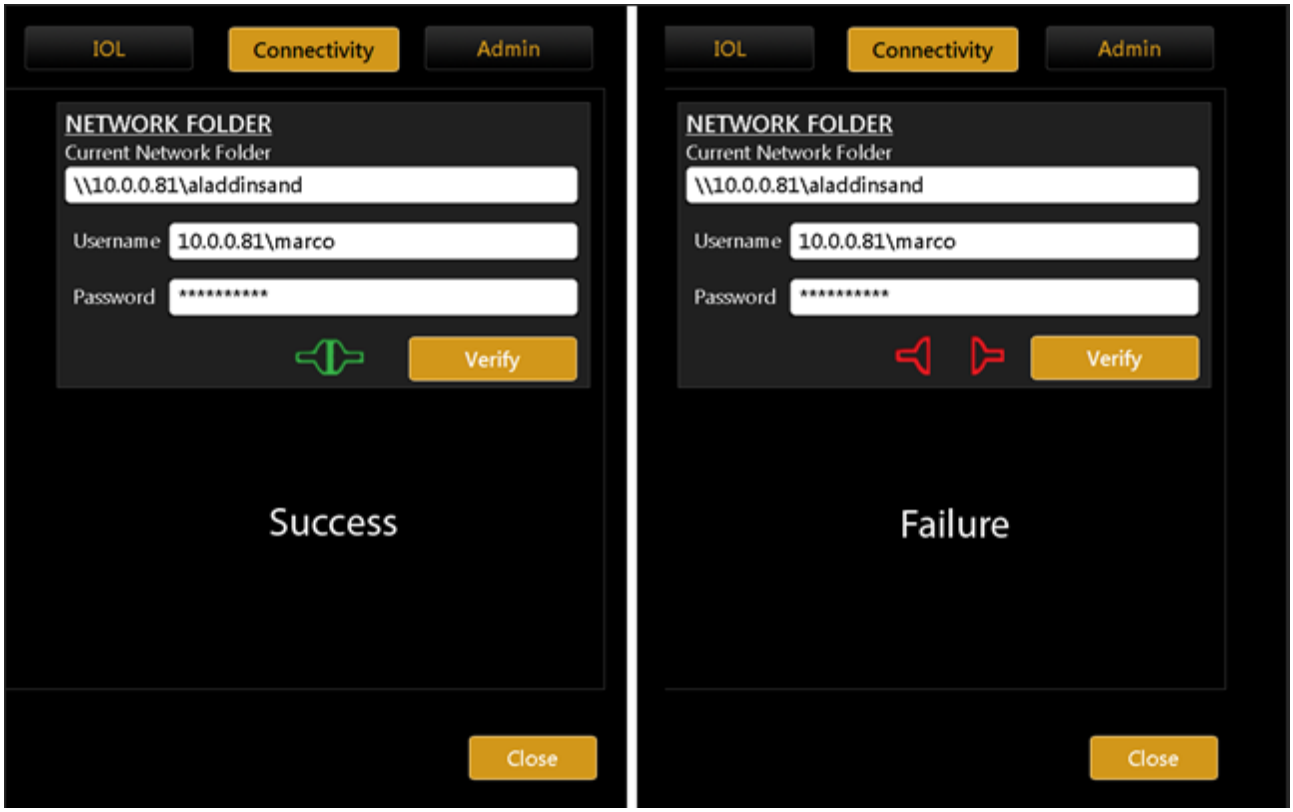


Figure 91

13.5.2 XML Export

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

13.5.3 IMAGEnet i-base software

ALADDIN HW3.0 can receive and transfer data to Topcon IMAGEnet i-base through a wireless or LAN network. IMAGEnet i-base is activated by clicking on the Enabled Option and by providing the IP address of the machine we want to connect to. By clicking on the Configure button (Figure 94) the user is presented with a list of IP Addresses of the machines running IMAGEnet i-base software that are reachable from ALADDIN HW3.0. Once selected the proper IP(Figure 92), ALADDIN HW3.0 is ready to exchange data with IMAGEnet i-base machine.

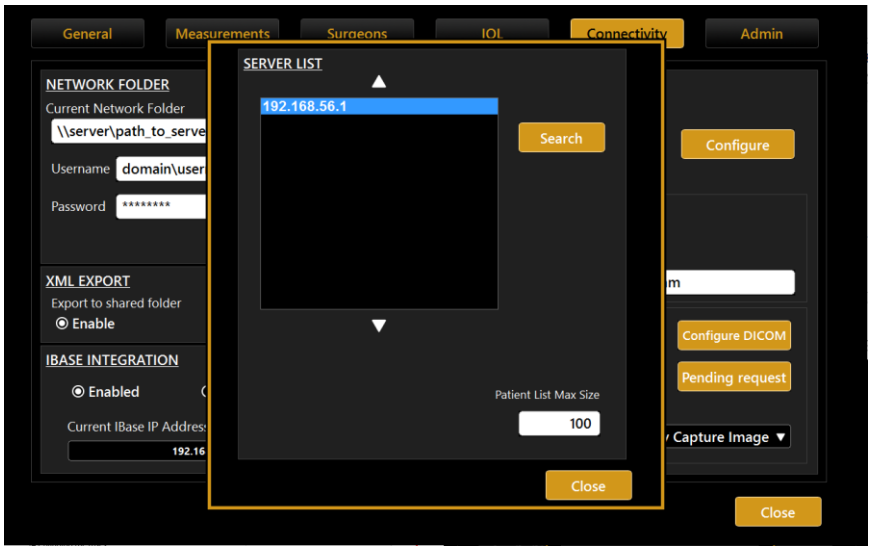


Figure 92

13.5.4 IMAGEnet 6 Server software

ALADDIN HW3.0 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, ALADDIN HW3.0 is ready to exchange data with the IMAGEnet 6 Server machine (Figure 93).

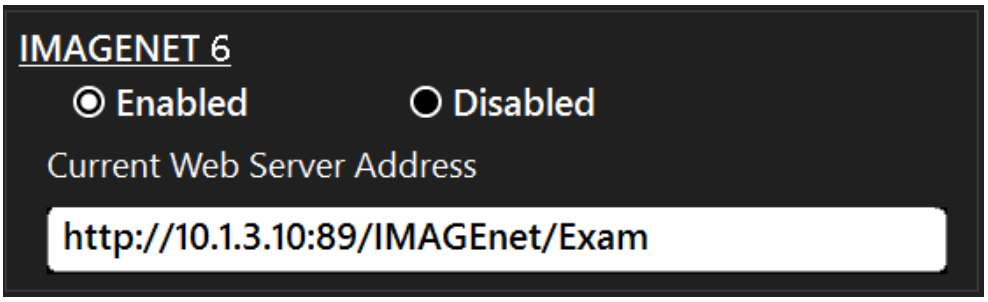


Figure 93

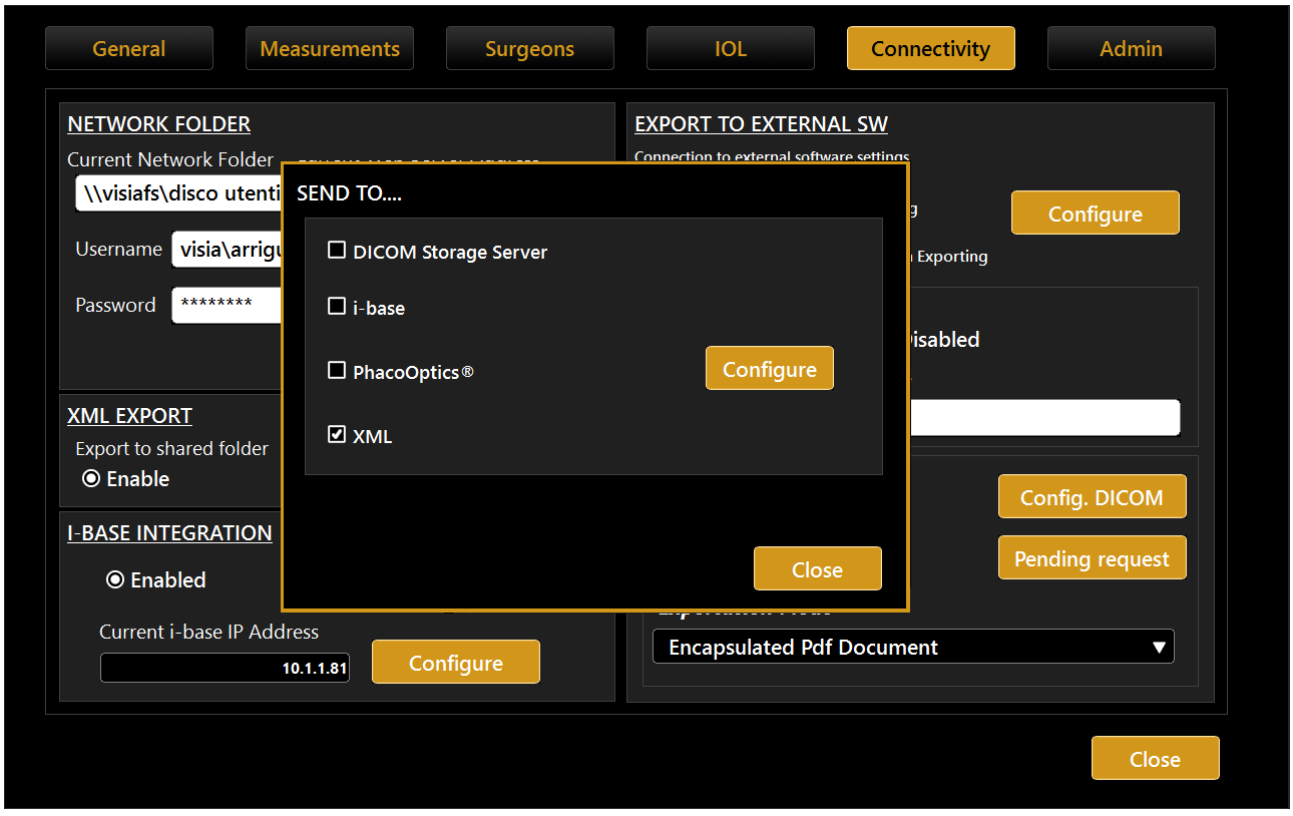
13.5.5 Export to External Software settings

In this panel it is possible to control two main aspects of the device behaviour 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

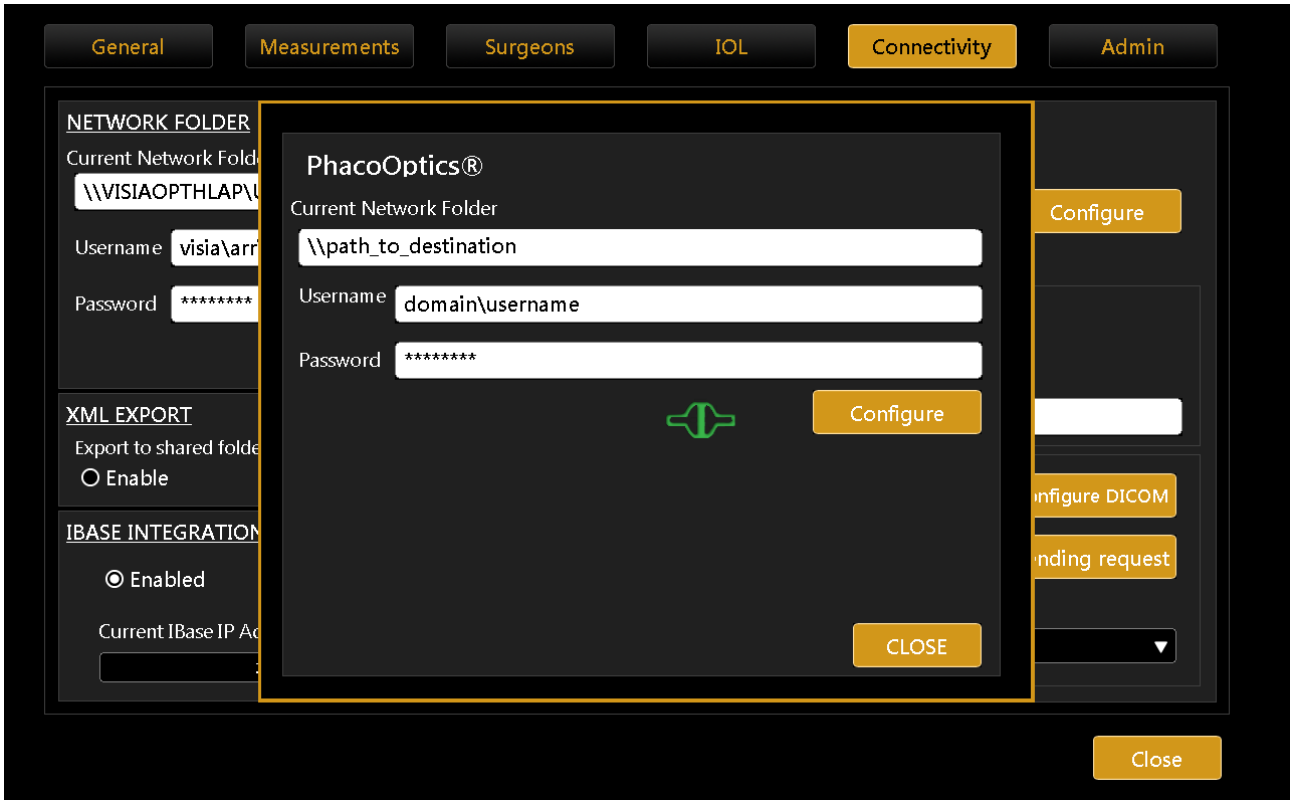
It is also possible to access configuration ("Configure" button) of the other external software destinations which are not present in the other panels of this section.

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



PhacoOptics®: http://www.phacooptics.net/

In order to get exam data to exported to PhacoOptics® software, running on an external PC, it is necessary to configure a network path and access credentials for the target of exportation. Refer to PhacoOptics® manuals on how to get the data exported from ALADDIN HW3.0 inside the application.



13.5.6 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:

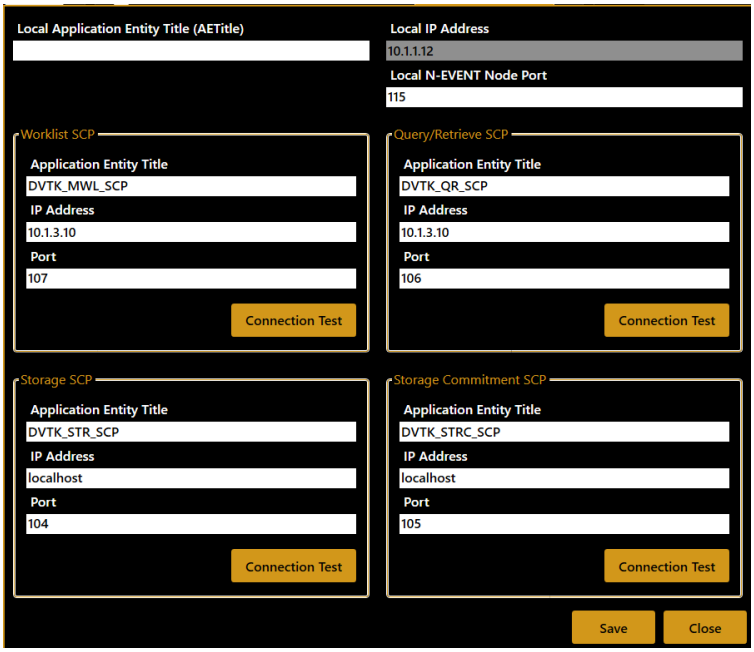
- **Modality Worklist**, The DICOM Modality Worklist service provides a list of imaging procedures that have been scheduled for performance by the acquisition device.
- **Patient Root Query,** This enables the device to find patient's details from a DICOM server.
- **Storage,** The DICOM Store service 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 ALADDIN HW3.0 is describe in detail in its **DICOM Conformance Statement**. Visit http://www.topconmedical.com/conformance.cfm to download it.

13.6 Admin

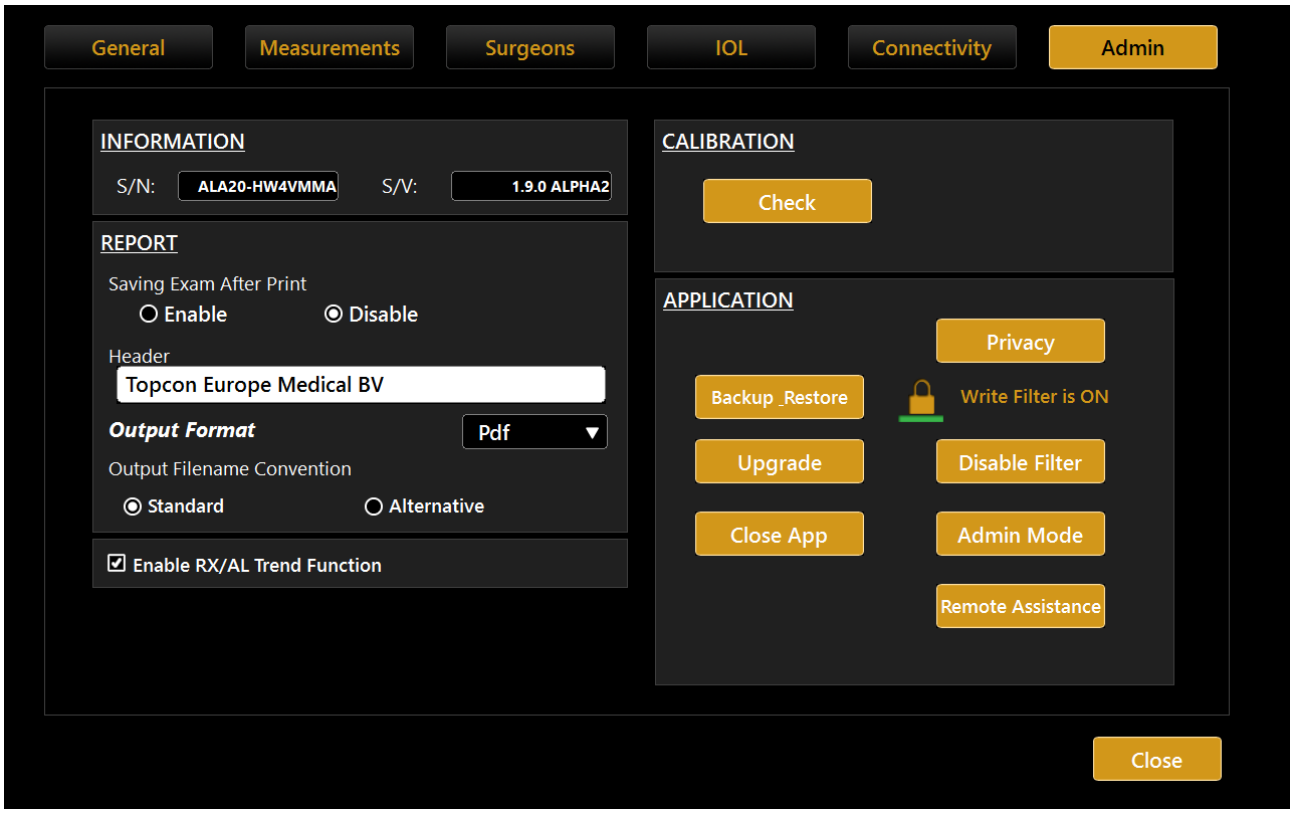


Figure 94

This is the instrument's administration panel (Figure 94).

It provides certain information on the system: serial number (S/N) and software version (S/V).
The ***"Check"*** button starts the calibration check procedure.

- **Check the calibration**

  See the paragraph describing the procedure Checking the calibration.

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

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

The "**Enable RX/AL Trend Function**" gives access to the function for reviewing biometry data over time in charts from the exam list view. See section 11.16 for further details.

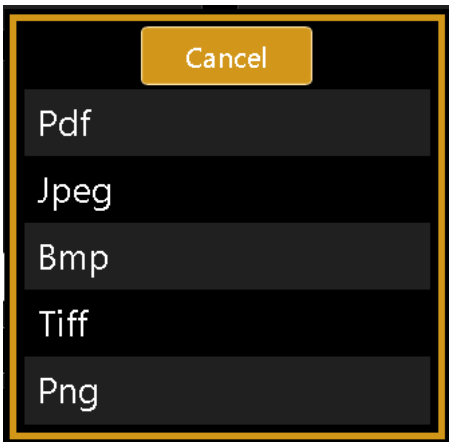
The "Application" frame manages the behaviour of the integrated software:

- ***Upgrade*** → Updates the integrated software
- ***Backup*** → Starts the backup procedure on a USB driver
- **Close App** → Closes the application
- **Privacy** → Refer to section 13.7

13.6.1 Report

In the "Report" panel of Admin section it is possible to set a Custom header for all the reports, as well as setting the output format of reports exported to network folder. The available formats are: Pdf, Jpeg, Bmp, Tiff, Png.

It is also possible to set the automatic saving of the exam after printing.



Output filename convention

Option to choose between two filename conventions for the reports exported to network folder:

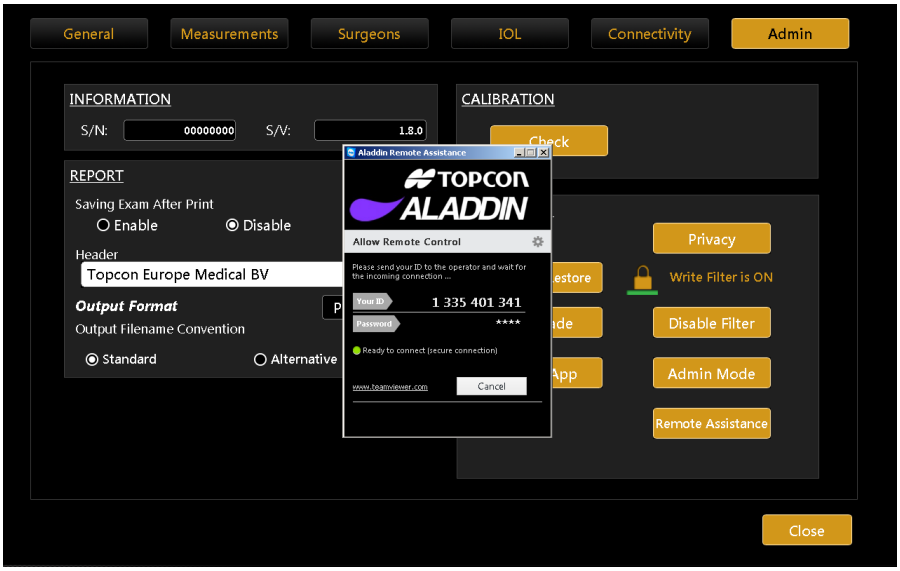
- Standard:
  patientID[_patientSurname][_patientName][_patientDoB]_reportName[_eyelabel]_ExamDateTime[_progressiveNumbert].extension
- Alternative:
  patientID[_patientDoB]_Aladdin_eyelabel[_progressiveNumber].extension

  eyelabel is:
  - R, right eye
  - L, left eye
  - B, both eyes
  - N, no eye related

13.6.2 Remote Assistance

In case you need remote Assistance the ALADDIN HW3.0 application integrates Teamviewer QS (Quick Support) pre-installed.

- There is NO NEED to disable the Write Filter protection
- Ensure to have available internet access for your ALADDIN HW3.0 unit
- Go to Settings -> Admin and press "Remote Assistance".
- Wait for the Teamviewer 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 Teamviewer window or press “Remote Ass. OFF”

If you get one of the following windows please check your internet connection to ALADDIN HW3.0 or contact your IT staff.

13.6.3 Updating the integrated software

In this section is described the software upgrade procedure from one version to the following version.
To update the software, perform the following operations:

1. Unpack the update packet in the root (main card) of an empty FAT32-formatted USB external drive.
2. Switch on the ALADDIN HW3.0.
3. Cancel the calibration check (Figure 95).

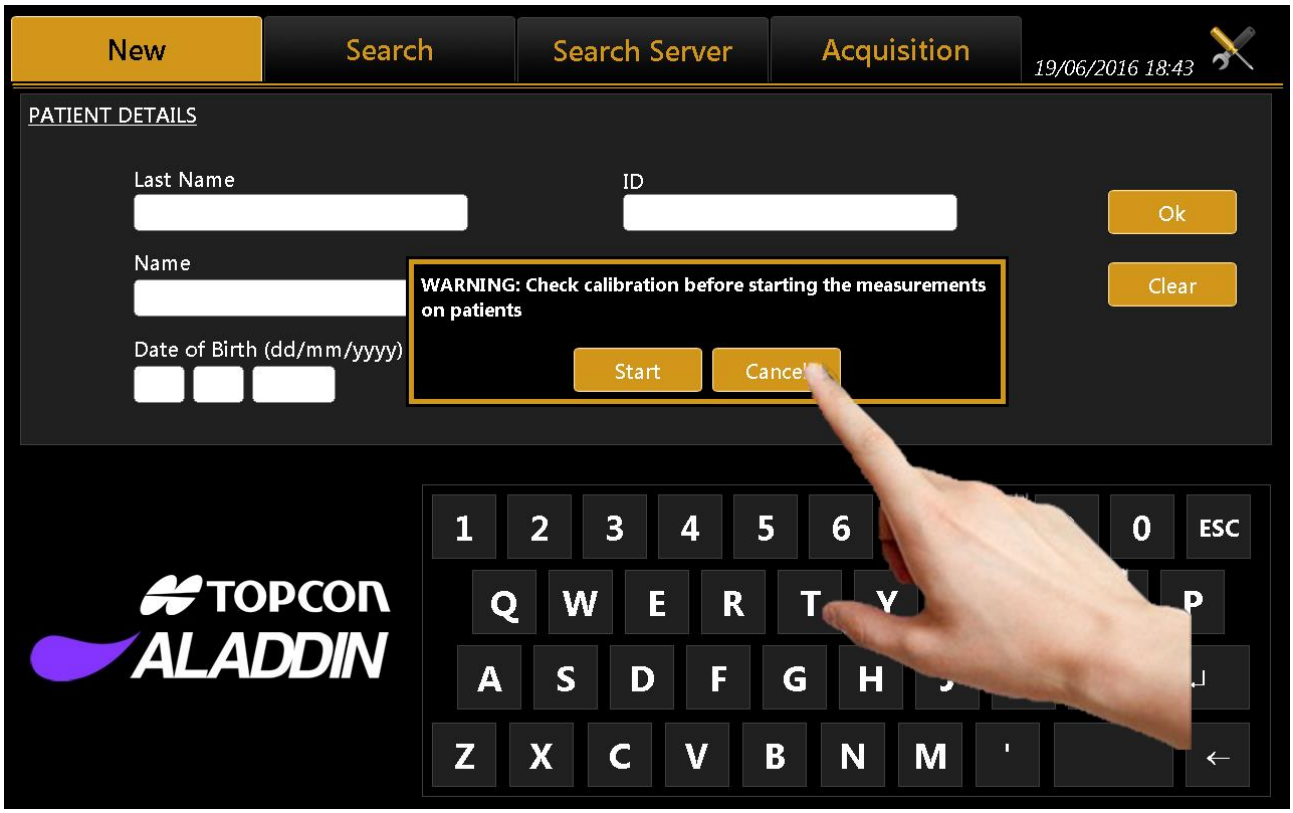


Figure 95

4. Click on the settings icon (Figure 96).

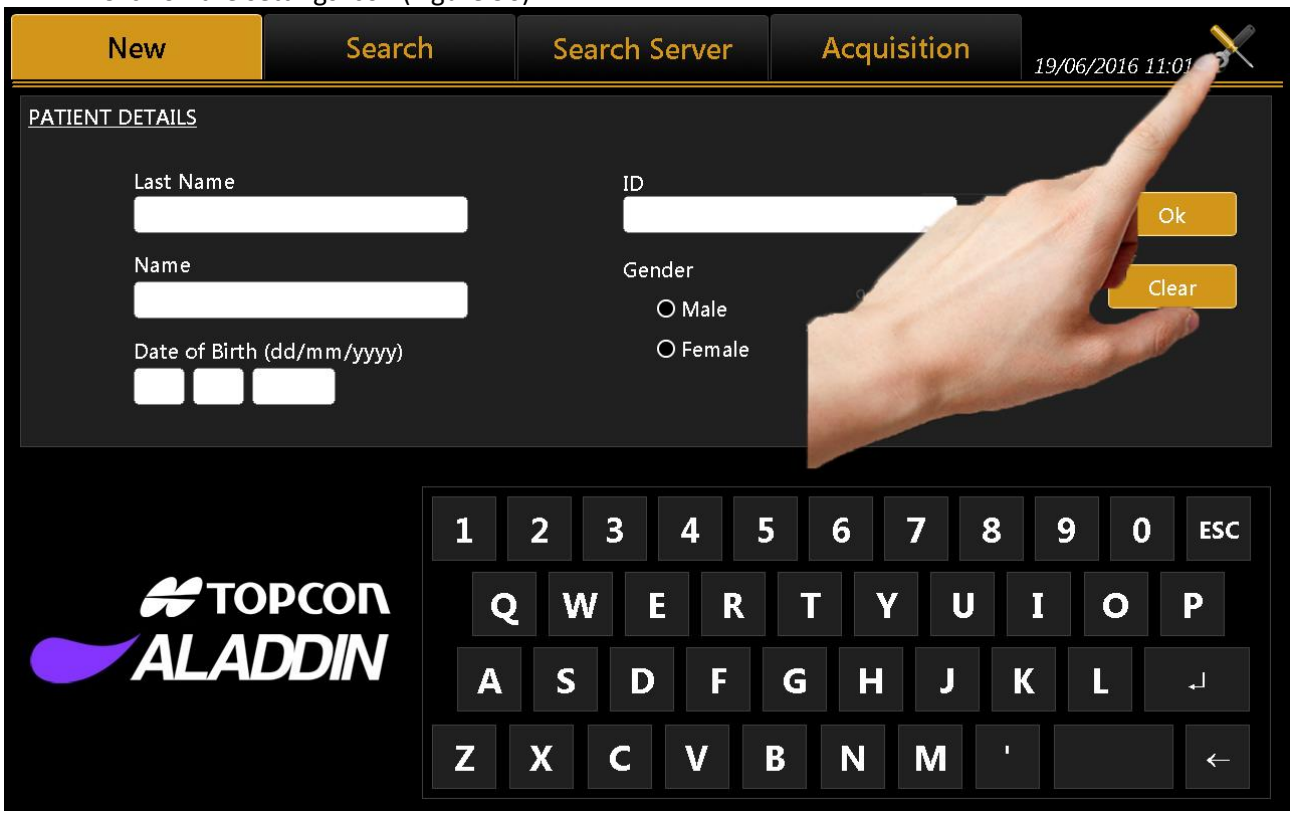


Figure 96

5. Click on the "**Admin**" tab (Figure 97).

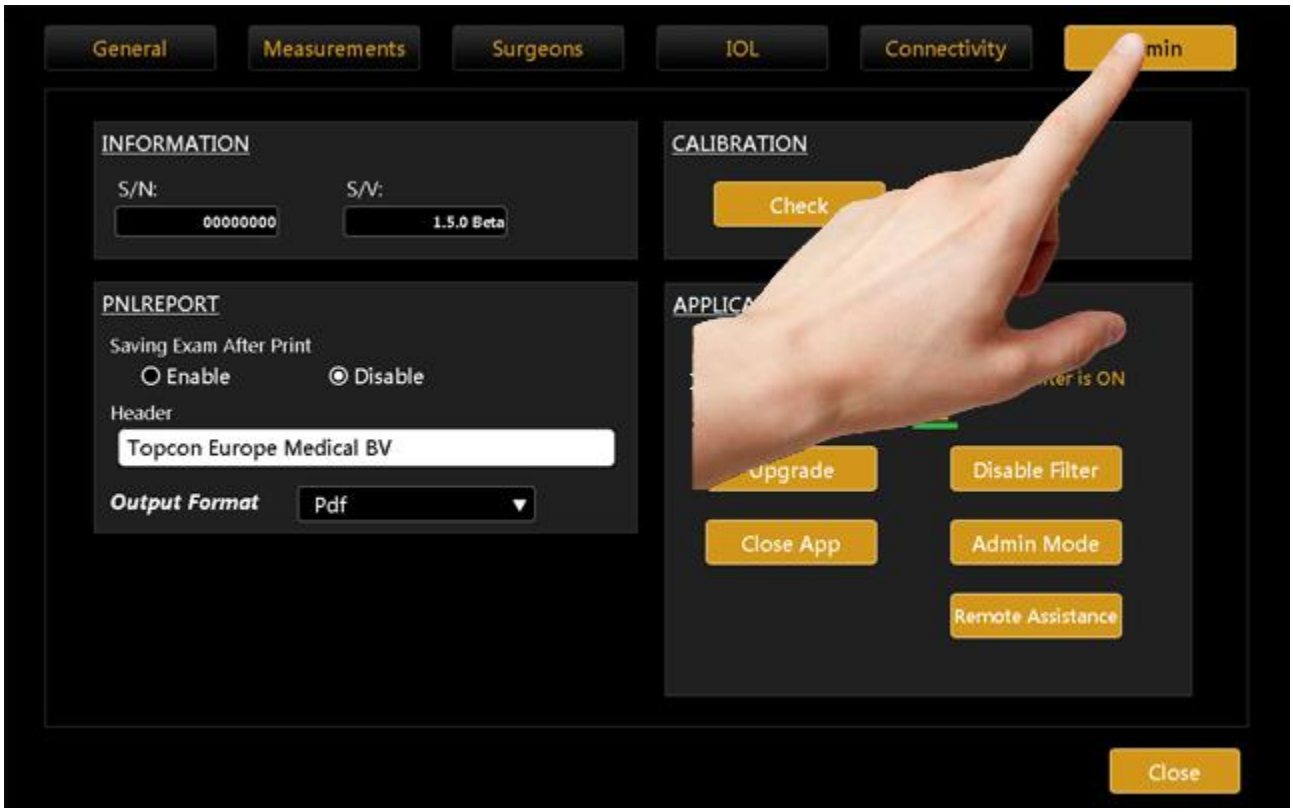


Figure 97

6. Insert the USB stick with the "*Aladdin upgrade*" files in one of the USB ports (Figure 98).

Figure 98

7. Click on the "**Upgrade**" button (Figure 99).

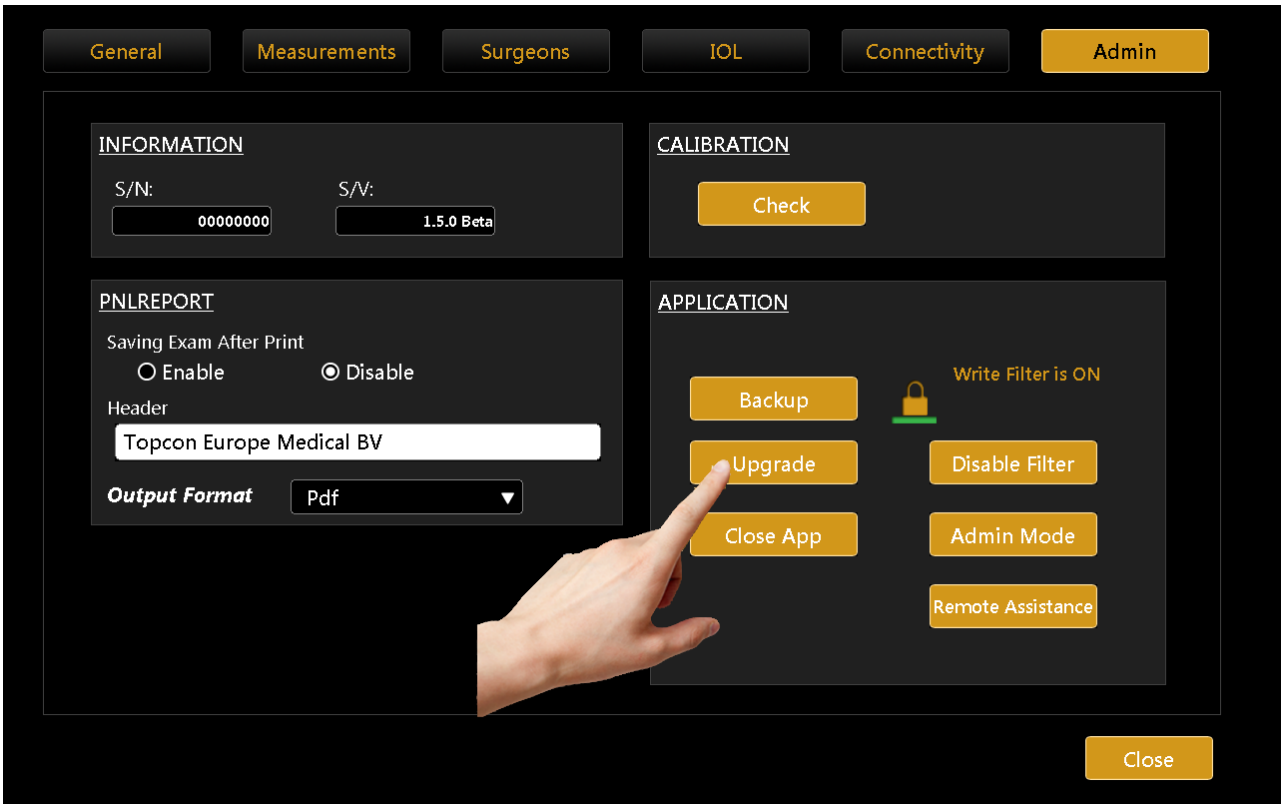


Figure 99

8. Click on "**Ok**" to reboot the system and start the upgrade (Figure 100).

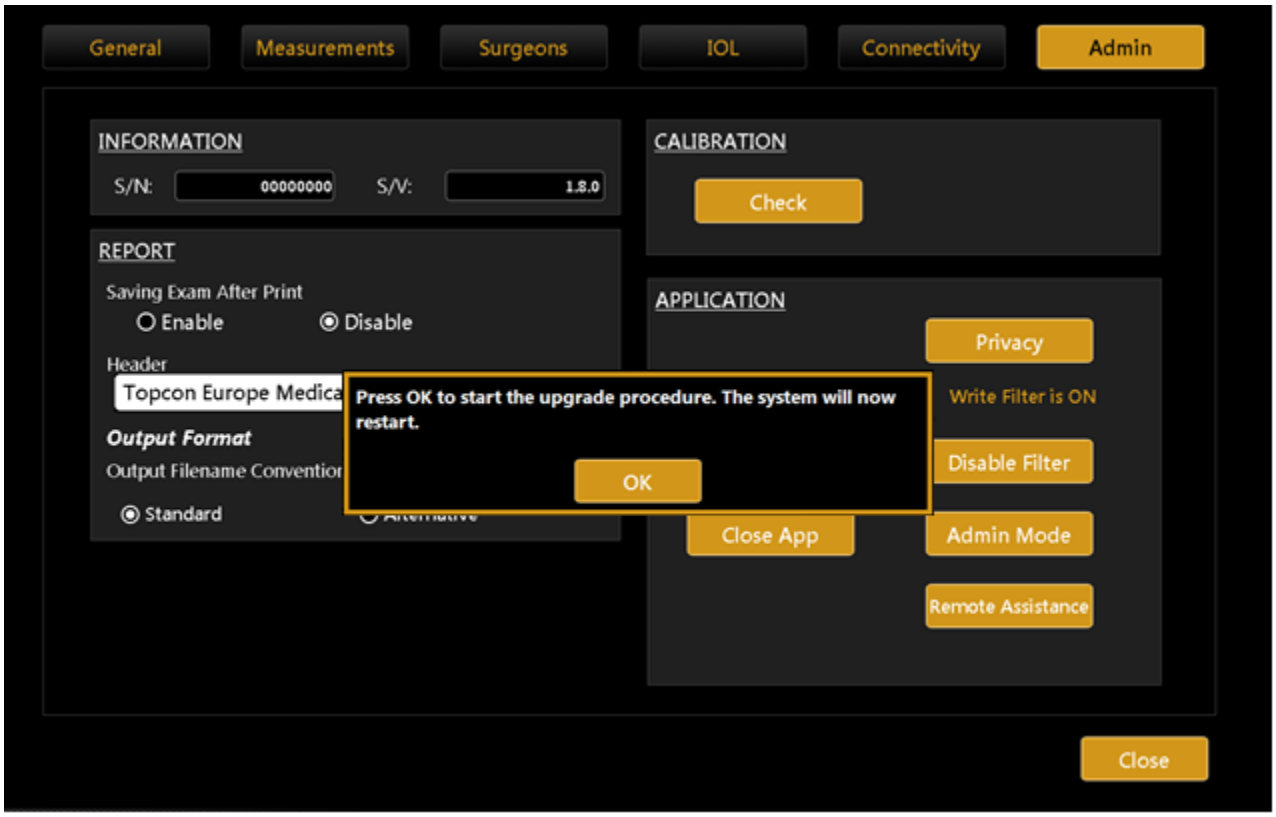


Figure 100

9. After the upgrade you will see the message of Figure 101 on the screen.

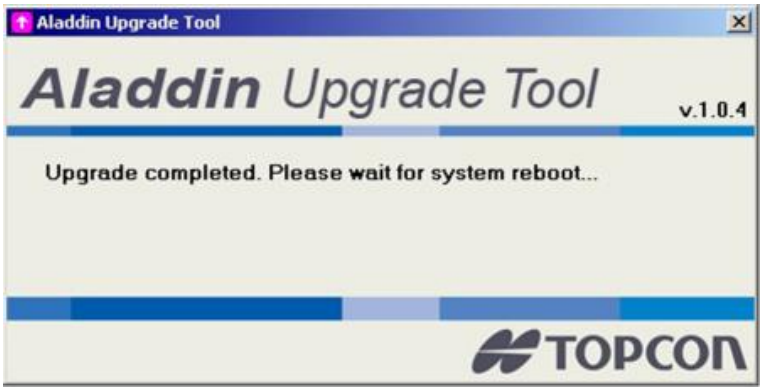


Figure 101

10. The system will reboot and starts the "*Aladdin application*".

11. After restart, the software updates the system; this operations could take some minutes please don't restart machine during this procedure (Figure 102).

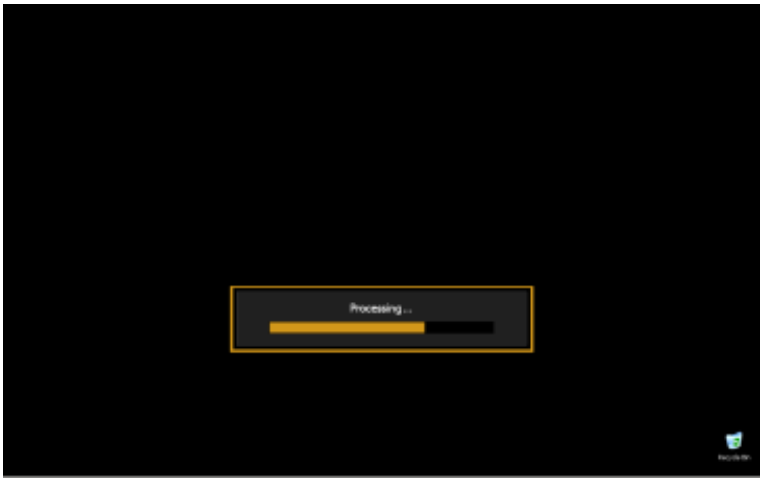


Figure 102

12. If you see the message of Figure 103, please switch off your ALADDIN HW3.0 and turn it on again. Your ALADDIN HW3.0 should now work fine.

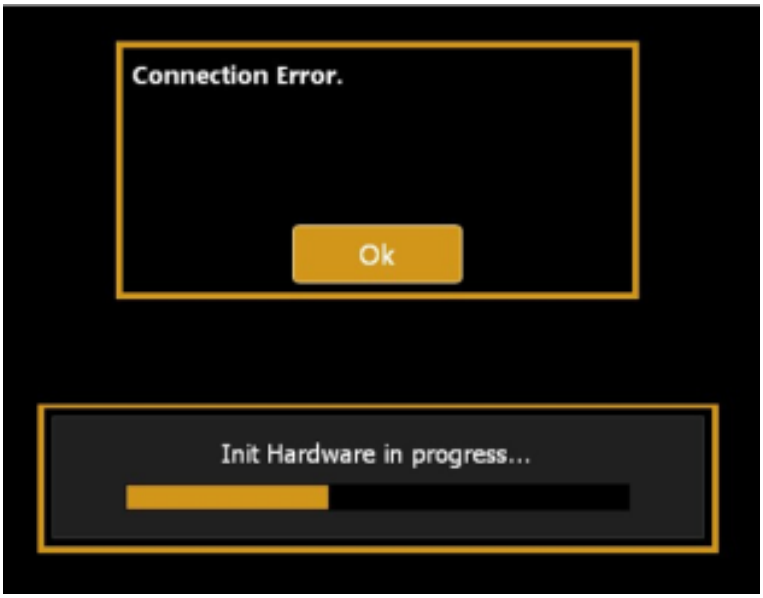


Figure 103

13. Your ALADDIN HW3.0 is upgraded. Please check in the settings, "**Admin**" tab if the S/V is now the new one (Figure 104).

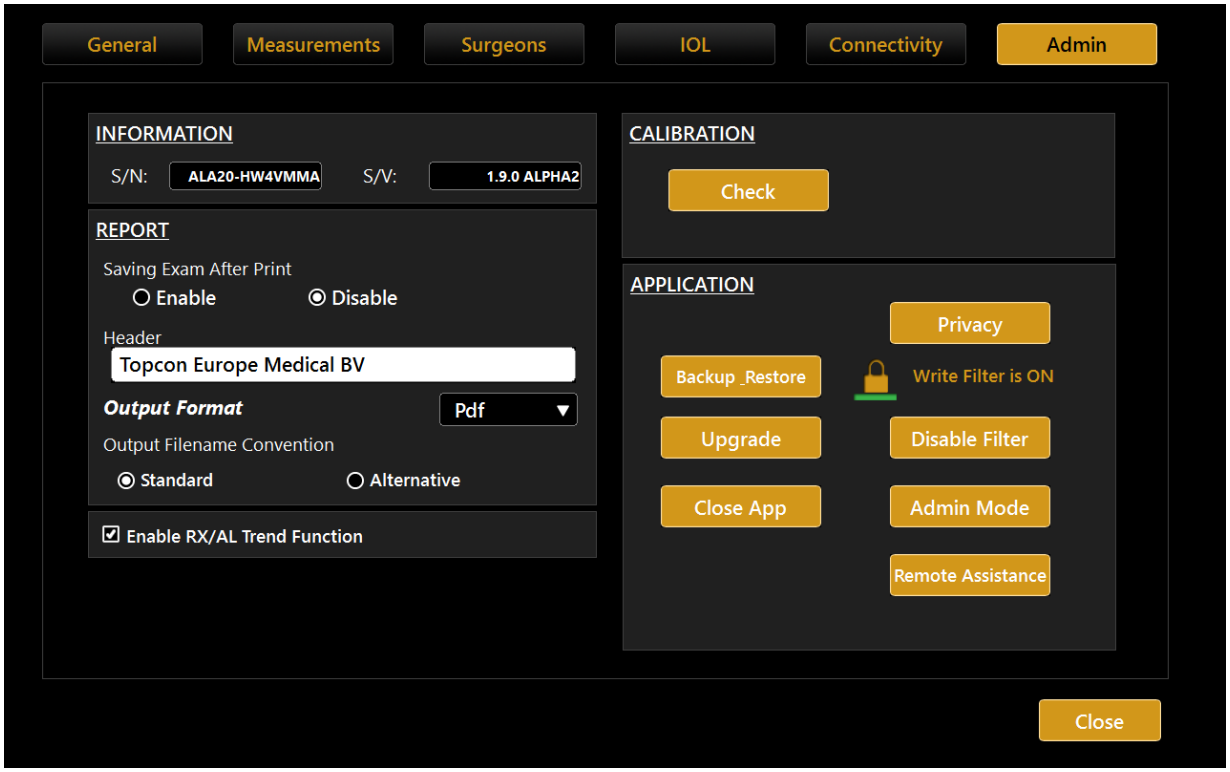


Figure 104

13.6.4 Backup & Restore

It's recommended to perform a backup to have a safety copy of every patient stored data. Depending on the expected size of the entire archive, we suggest to use an external USB drive or have available enough space on a designed network shared folder.
Pressing on the "Backup _Restore" button the Backup and Restore utility is opened.
It is possible to use an external USB drive or a network shared folder to backup and restore data.

Backup Contents
With this utility it is possible to backup:

- ***Local Exams archive:*** *the complete list of patients and exams that are currently stored in the local database of the machine*
- **Surgeon's presets and IOL collections:** *Surgeons list with all the data associated with each one, such as default IOL lens presets, IOL collections (customized constants or manually added IOL models)*
- **Application user settings:** *interface settings such as visualization options, display units, scales, network settings, report header*
- **Machine calibration:** *internal calibration parameters of the machine to be stored for safety.*

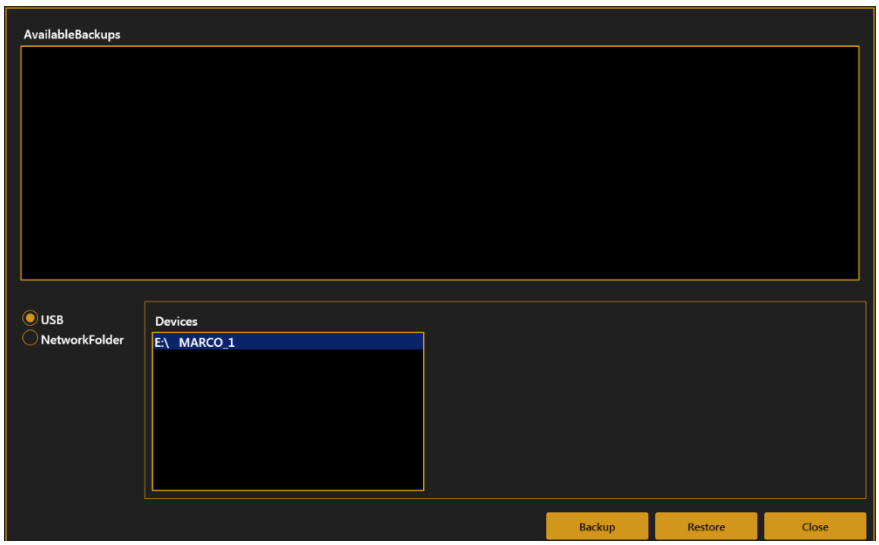
  The machine calibration can be restored only by the technician to the same device from which the backup was made.

Backup Procedure

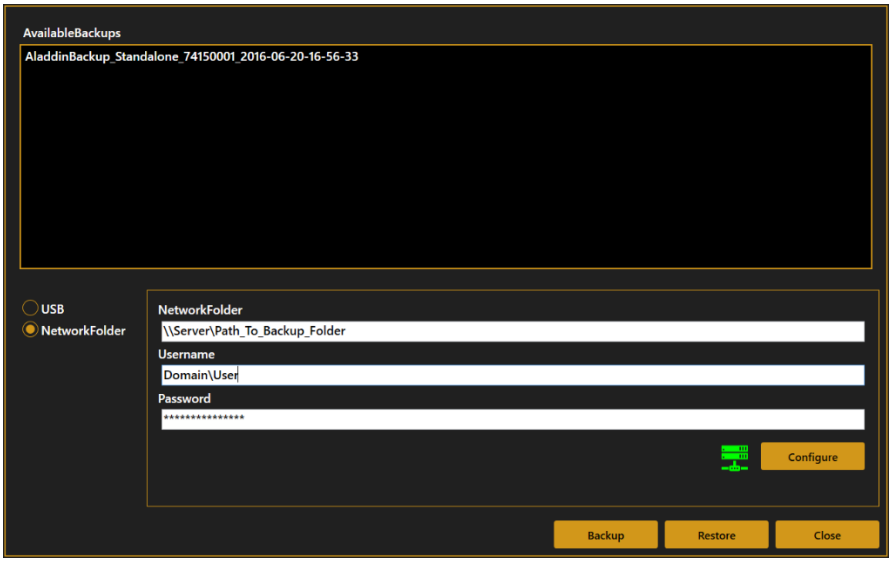
To perform the backup connect the desired USB external storage device or switch to Network Folder option.

1. Select the desired destination:

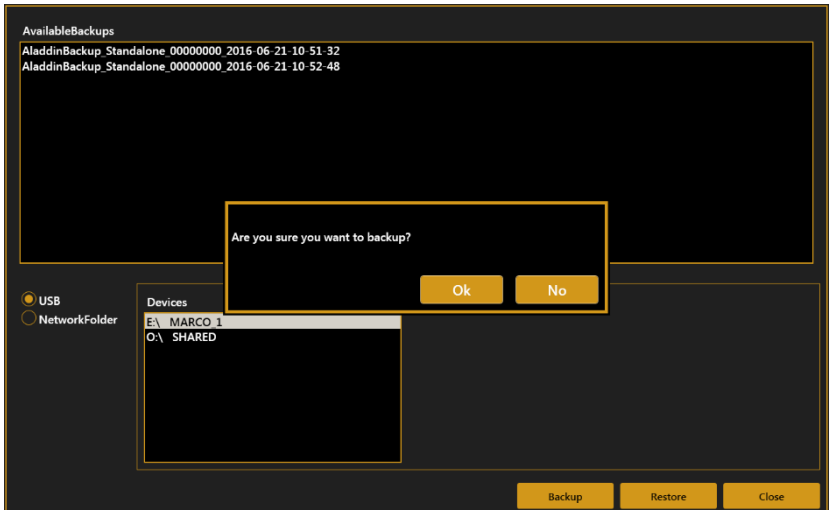
   - USB, select the desired partition from the list of the available



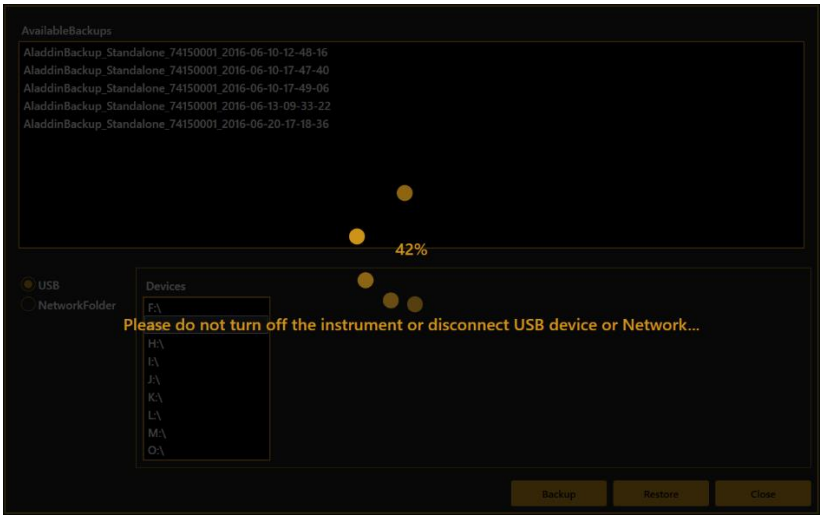
   - Network folder, define (if not already defined) the desired network shared folder destination, check the connectivity.



2. Press “Backup” button, wait for the procedure to complete. Press “OK” to confirm the operation or “No” to do not perform the backup.



Do not turn off the device or unplug the power supply and ethernet cable while performing this operation. Do not unplug USB devices if USB is the backup destination. This may take several minutes depending on the exam archive size.



3. After the procedure is completed, a new entry appears in the list of available backup data with the following naming convention:

AladdinBackup_Standalone_<*device serial number*>_<*backup date*>

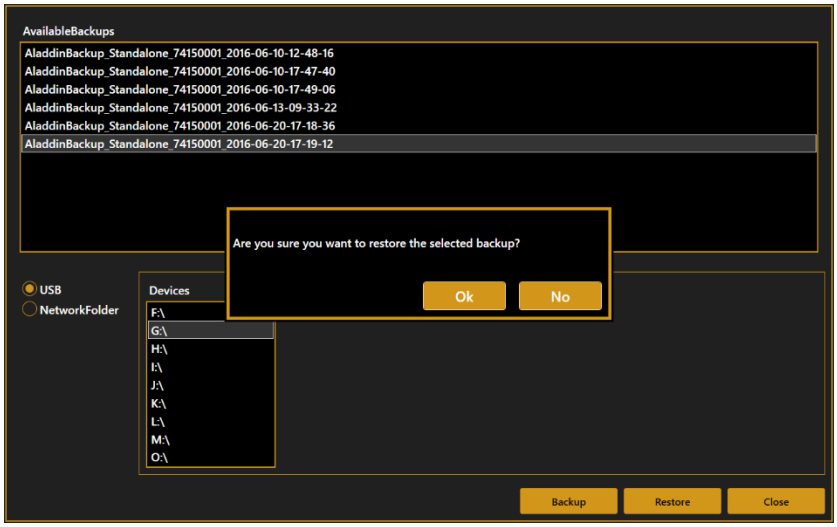
Restore Procedure

The machine calibration backup CANNOT be restored to a different machine from the original one.

If attempting to restore a different machine backup to the current machine the calibration restore is skipped. Ask to technical assistance in order to restore the calibration.

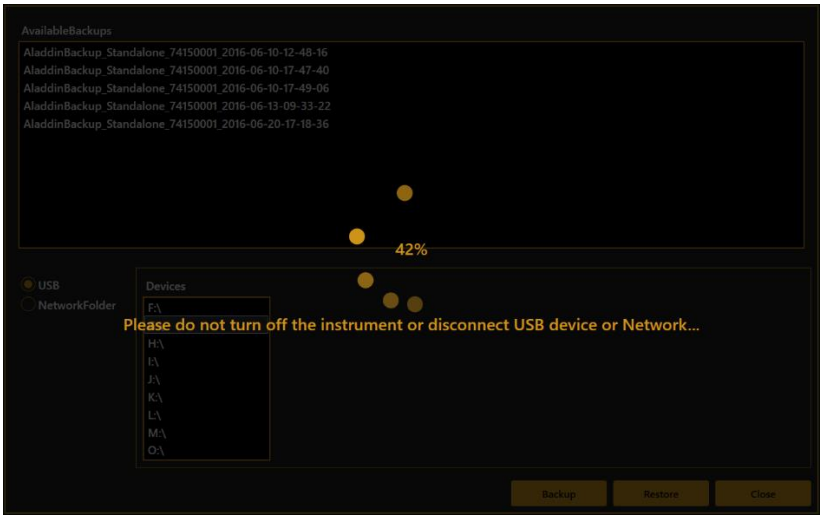
1. Select the source of the backup image to restore (USB or Network Folder). Navigate the list of detected backup images available at the selected source.

2. Select from the list the backup image you want to restore and press “Restore” button.
   Press “OK” to confirm the operation.



3. The Restore procedure starts.

Do not turn off the device or unplug the power supply and ethernet cable while performing this operation. Do not unplug USB devices if USB is the backup source.



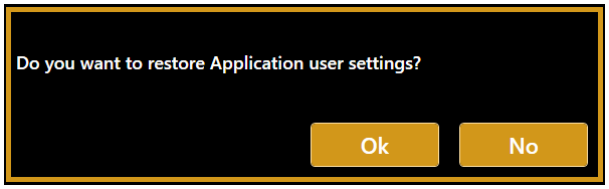
4. In sequence, it is prompted to confirm if restoring or not each kind of backup content.
   Press “OK” if you want to restore the content or press “No” to skip the restore of the mentioned content.
   (1) *Restore machine calibration files*.

   The calibration can be restored only to the device from which the backup was made originally.

   This operation is allowed only to authorized technicians. Contact your distributor for assistance. The machine calibration restore is skipped if the procedure is performed by the user.

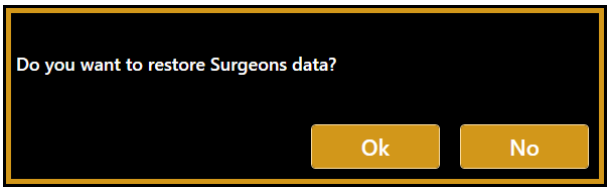
   (2) Restore Application User Settings.

   The current content on the machine will be overwritten.



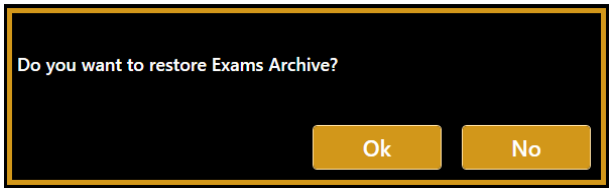
   (3) Restore Surgeons settings.

   The current content on the machine will be overwritten.



   (4) Restore Local Exams archive.

   The backup content will be added to the current content if not already present. This may take several minutes depending on the number of exams in the archive.



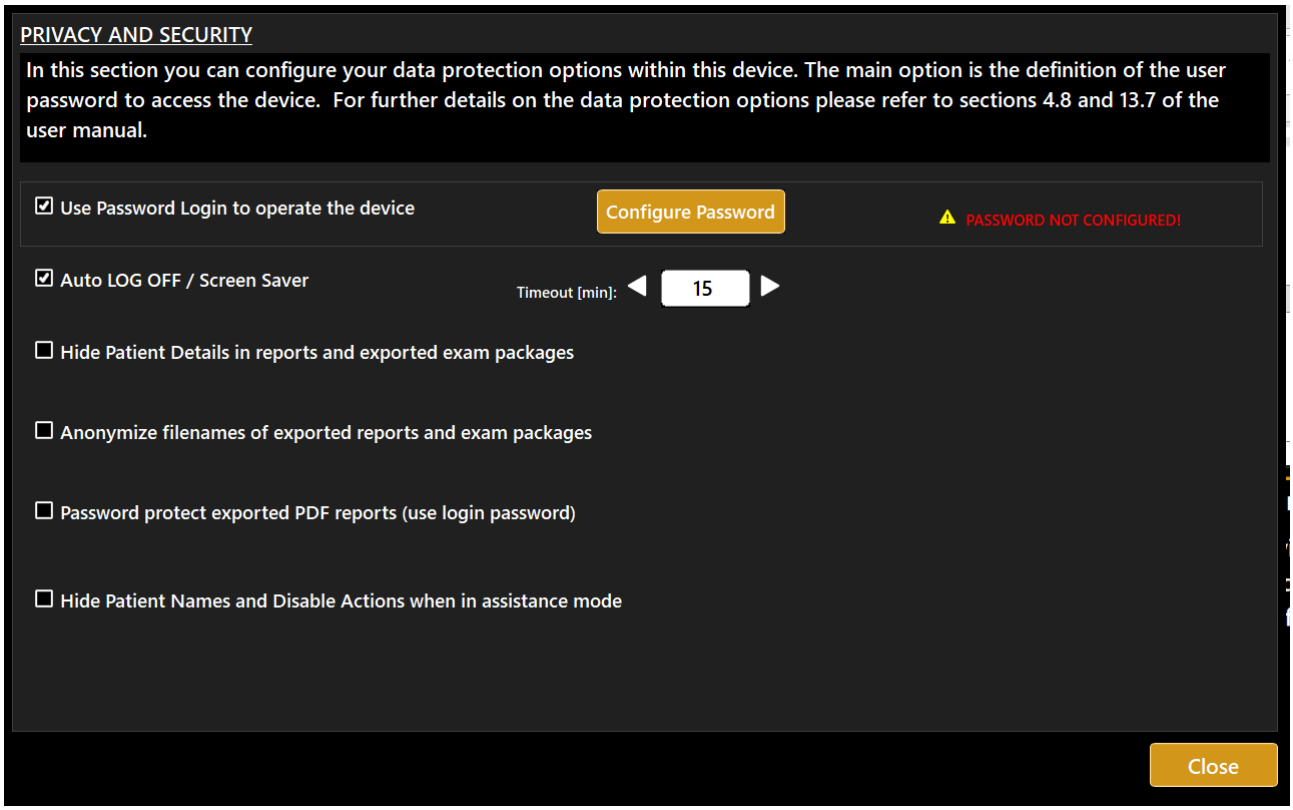
13.6.5 Shut down

Press the ***"Close App"*** button to close the application and return to the Windows desktop. You will be asked to confirm this operation.

Press the stand-by button to shut down the device.

13.7 Privacy & Security Settings

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



13.7.1 Password protected Login

The options allows to protect with password the access to the Aladdin on-board application operations and data. By default the option is enabled but requires the password to be configured.

When the option is enabled and the password configured the login is prompted when (refer to section 11.1):

- the Aladdin on-board application starts
- the auto log OFF timeout occurs (if enabled)
- the lock button in the main top bar is pressed

Press on “Configure Password” button to define the preferred password.

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

It is recommended to apply a password aging policy.

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

13.7.2 Screen Saver / Auto Log OFF

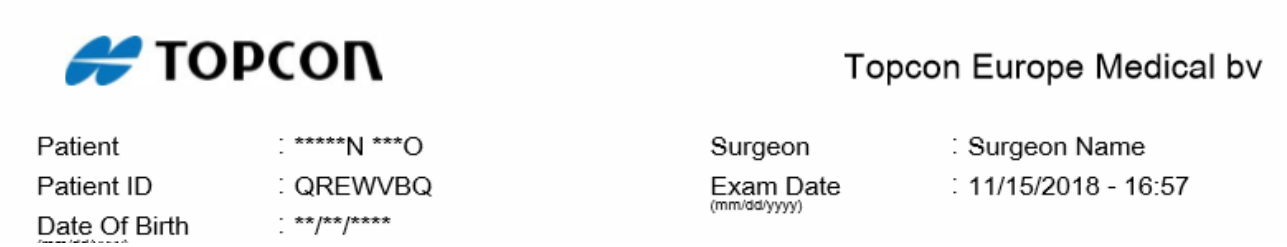
The option allows to set automatic locking of the Aladdin on-board after a configurable timeout.

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

When no interaction with the device is performed during the timeout the screen saver will be displayed. When the screen saver is closed the login screen (if enabled and configured) will be displayed.

13.7.3 Hide Patient Details in reports and exported exam packages

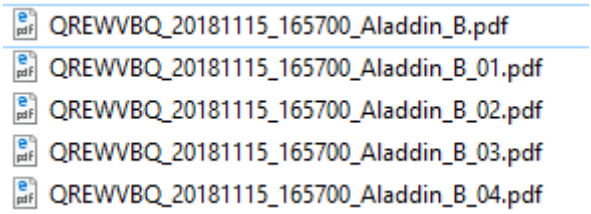
The option, if enabled, allows to mask the patient details in the header of the printed or exported reports. Only the used patient ID will be reported normally.



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

13.7.4 Anonymize filenames of exported reports and exam packages

If the option is selected the report output filename convention will be forced to be the alternative one, refer to section 13.6.1 for further details.



13.7.5 Password protect exported PDF reports

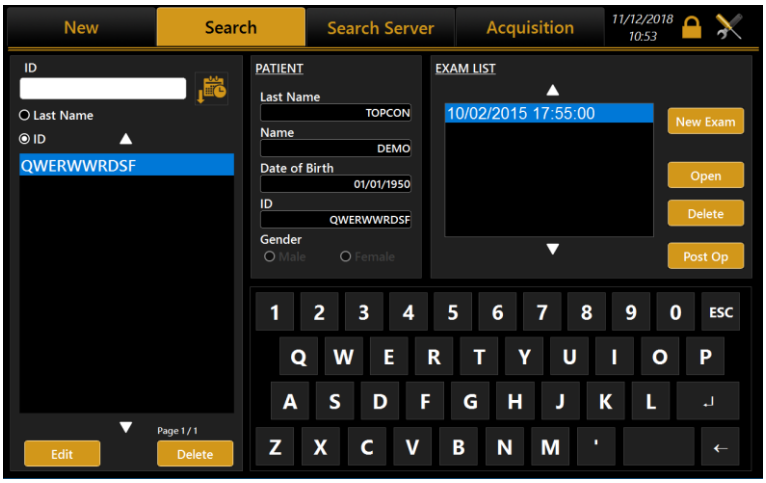
This option is available if the login password is enabled and configured. If this option is enabled the PDF reports exported to network shared folder will be accessible only by typing the user password as defined to access the Aladdin on-board application.

13.7.6 Hide Patient Names and Disable Actions when in assistance mode

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

User Mode

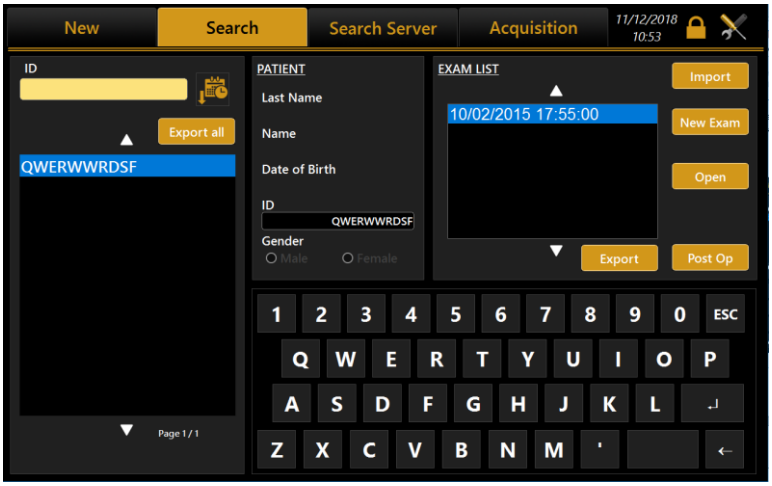
In normal user mode the patient details and related actions are regularly accessible.



Technician Mode

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

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



14 CHANGING THE FUSES

Step 1
Open the fuse box cover using a screwdriver

Step 2
Take out the fuse box (use a screwdriver to release it)

Step 3
Remove the blown fuse from its seat and replace it with an identical one, as indicated in the table below and on the instrument label.

Step 4
Push the fuse box carefully back into position

Figure 105

It is mandatory to use fuses only with the indicated characteristics

The use of undersized fuses can cause the interruption of power to the device during normal working conditions. In this case there is no risk to the user, nor for the patient, but the device turns off at inopportune moments, and this can cause data loss

The use of oversized fuses can lead to damage to the internal electronics of the device due to current overload for non-interruption by fuses. In this case you do not identify risks to the patient, but on the user or damage to the device and then stop working and possible data loss.

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

15 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			
FEATURE	**MEASUREMENT METHOD**		**LIGHT SOURCE**
Corneal topography - Keratometry	Placido disk		Red LED Type1 and Type 2
	Keratometry conus	24 rings equally distributed in a 43D sphere	
	Analysed points	Over 100,000 points	
	Measured points	Over 6,000 points	
	Corneal coverage	Up to 9.8 mm on a sphere of 8mm radius (42.2 diopters with n=1.3375)	
	Focusing system	Guided focus	
Pupillometry	Image analysis		Infrared and white light LED
AL	Low-coherence interferometry on optical fiber		Sled @ 830nm
ACD			
CCT			
LT			

OPTICAL RADIATIONS				
FEATURE	**LIGHT SOURCE**		**WAVELENGHT**	**POWER ON EYE**
Central fixation LED	Yellow green LED		572 nm	< 0.01 mW
Illumination of Placido disk for topographic analysis	Red LED Type1		633 nm	<0.02 mW
	Red LED Type2		615 -630 nm	<0.02 mW
Pupillometric analysis	White LED	Blue	473 nm	0.03 cd
		Green	532 nm	0.005 cd
		Red	630 nm	0.008 cd
	IR LED		780 nm	<0.4 mW
AL measurement	Sled		830 nm	< 0.7 mW
	IR LED (crown)		770 nm	< 0.1 mW
CCT-ACD-LT measurement	Sled		830 nm	< 0.7 mW
	Red LED Type1		633 nm	<0.02 mW
	Red LED Type2		615 -630 nm	<0.02 mW

CAUTION - The light emitted from this device is potentially hazardous. The longer the duration of exposure, the higher the risk of ocular damage. Exposure to the device light when using it at maximum intensity will infringe the safety indication after a 60-minutes use. ALADDIN HW3.0 has a series of LEDs of various types and powers installed. All the characteristics are detailed in the Technical Specifications section in this manual. The LED groups comply with the emission limits for the Group 2 instruments according to the standard ISO 15004-2.

INFORMATION ON MEASUREMENTS				
MEASURE		**MEASURING RANGE**	**DISPLAY RESOLUTION**	**IN VIVO REPEATABILITY**
Keratometry	Curve radius	5.00 – 12.00 mm	0.01 mm	±0.02 mm
	Curve Radius in Diopter (D) (n=1.3375)	28.00 - 67.50 D	0.01 D	±0.12 D
Axial Length		15.00 – 38.00 mm	0.01 mm	±0.016 mm
Anterior Chamber Depth		1.50 – 6.50 mm	0.01 mm	±0.04 mm
Central Corneal Thickness		0.300 – 0.800 mm	0.001 mm	±0.02 mm
Lens Thickness	Phakic eye	1.50 – 6.50 mm	0.01 mm	±0.06 mm
	Pseudo-phakic eye	0.50 – 3.50 mm	0.01 mm	±0.06 mm
Pupil dimension		0.50 – 10.00 mm	0.01 mm	±0.05 mm
Limbus (White-To-White)		8.00 – 14.00 mm	0.01 mm	±0.05 mm

ENVIRONMENTAL CONDITIONS			
	IN USE	**STORAGE**	**TRANSPORT**
Temperature	10 - 40° C	-20 - 70° C	-20 - 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		<100 VA
Fuse	**Type**	20 x 5 mm
	Value	T 2.5 A L 250 V anti-surge

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

ON-BOARD PC SPECIFICATIONS	
Operating system	WINDOWS 10 64bit
Processor	Intel® Celeron®
RAM	4GB
Hard disk	At least 500GB SATA + mSATA SSD 32GB
External connections	LAN integrated, 2x USB

16 PERFORMANCE TESTS

BRIEF SUMMARY OF PERFORMANCE TESTS AND RESULTS

A prospective, single site clinical study comparing the performance of the ALADDIN HW3.0 with LENSTAR LS 900 was conducted in 66 eyes (1 eye for each enrolled subject). This study evaluated the agreement and precision in the subsequent endpoints:

Data Type	All Devices
Quantitative Measurements	• Axial Length (AL) • Cylinder Axis (AX) • Anterior Chamber Depth (ACD) • Lens Thickness (LT) • Central Corneal Thickness (CCT) • White-to-white distance (WTW) • Keratometry at the flattest meridian (K1_D) • Keratometry at the steepest meridian (K2_D)

The related unit of measurements are:

- Axial length: millimeters;
- Cylinder Axis: degrees;
- Anterior Chamber Depth: millimeters;
- Lens Thickness: millimeters;
- Central Corneal Thickness: millimeters;
- White-to-white distance: millimeters;
- Keratometry: diopters.

Analysis of Agreement

The measurements for the Agreement analysis arise from the first three acceptable measurement types acquired from each device.

For each endpoint (AL, AX, ACD, LT, CCT, WTW, K1_D, K2_D), the analysis of agreement was performed for every ALADDIN HW3.0 unit per LENSTAR LS 900 unit configuration for each operator separately.

The analysis was carried out estimating the mean difference, its standard deviation, 95% Limits of Agreement, Bland-Altman scatter and difference plot using Bland-Altman method for multiple observations on an individual (Bland and Altman, 1999).

The overall analysis of agreement is reported in the table below.

The endpoint means with their standard deviations were provided too.

Details about the Bland-Altman analysis: model terms were estimated via REML assuming exchangeable replications and a device * subjects interaction term.

The agreement between instruments is summarized in Table 1:

Table 1.

Agreement between ALADDIN HW3.0 and LENSTAR LS 900.

	ALADDIN HW3.0		LENSTAR LS 900		Agreement parameters			
Endpoint	**ALADDIN Mean**	**ALADDIN SD**	**LENSTAR Mean**	**LENSTAR SD**	**Difference Mean**	**Difference SD**	**Lower LoA**	**Upper LoA**
AL[mm]	24.04	1.43	24.05	1.43	-0.010	0.024	-0.058	0.038
AX [°]	76.73	78.26	76.56	77.56	0.174	6.176	-12.177	12.525
ACD[mm]	3.67	0.38	3.67	0.39	0.004	0.040	-0.076	0.085
LT[mm]	3.67	0.27	3.65	0.27	0.021	0.054	-0.088	0.129
CCT[mm]	0.555	0.035	0.555	0.035	0.000	0.004	-0.008	0.008
WTW[mm]	12.27	0.34	12.30	0.36	-0.032	0.068	-0.167	0.103
K1[D]	43.16	1.43	43.17	1.44	-0.010	0.105	-0.221	0.201
K2[D]	44.26	1.52	44.26	1.53	-0.006	0.178	-0.362	0.349

Note to the Table 1:

- data in table concern the summarized comparison produced by 3 operators using 3 different Aladdin and 3 different Lenstar LS 900 units.

The results of the study demonstrate that the Axial Length (AL), Cylinder Axis (AX), Anterior Chamber Depth (ACD), Lens Thickness (LT), Central Corneal Thickness (CCT), White-to-white distance (WTW) and Keratometry (K1_D and K2_D) measurements of the ALADDIN HW3.0 are substantially equivalent to those of the predicate device.

Analysis of Precision

The measurements for the Precision analysis arise from the first three acceptable measurement types acquired from each device.

Analysis of precision, for each endpoint, will be performed on ALADDIN and LENSTAR separately using a REML method for repeated measures within subject including the subsequent terms: device identifier (A1, A2, A3 for ALADDIN and L1, L2, L3 for LENSTAR), operator identifier (1, 2 and 3), subject identifier (1 to 66) and every two-way interactions and the three-way interaction; a standard variance component matrix will be used as covariance structure of R-side matrix. The related results will be used to estimate: - the repeatability SD as the square root of model MSE; the repeatability limit as repeatability SD multiplied by 2.8; the repeatability coefficient of variation as (repeatability SD / mean) multiplied 100; - the reproducibility SD as the square root of (device variance component estimate + operator variance component estimate + device*subject variance component estimate + operator*subject variance component estimate + device*operator variance component estimate + device*operator*subject variance component estimate + model MSE); the reproducibility limit as reproducibility SD multiplied by 2.8; the reproducibility coefficient of variation as (reproducibility SD / mean) multiplied 100.

Variance component estimates were provided for every model term.

To assess if the variability of repeated measures within a subject is fairly constant across the range of results:

1) plot of the standard deviation of repeated results within eye (vertical axis) versus the mean of repeated results (horizontal axis) was provided for each endpoint;

2) Spearman correlation coefficients and related *p*-values for hypothesis H_0: $\rho_{Spearman} = 0$ between mean and standard deviation were provided for each endpoint.

Analysis described in previous point 1 and 2 was provided for ALADDIN HW3.0 and LENSTAR LS 900 separately.

Details about REML analysis: model terms will be estimated by using sum of squares.

The results of the analysis of repeatability and reproducibility are summarized in Table 2:

Table 2
Repeatability and reproducibility.

DEVICE	Endpoint	Overall Mean	REPEATABILITY			REPRODUCIBILITY		
			SD	Limit	% COV	SD	Limit	% COV
ALADDIN HW3.0	**AL[mm]**	24.04	0.020	0.056	0.084	0.024	0.068	0.100
ALADDIN HW3.0	**AX [°]**	76.73	2.859	8.004	3.726	2.918	8.170	3.803
ALADDIN HW3.0	**ACD[mm]**	3.67	0.026	0.073	0.708	0.026	0.074	0.721
ALADDIN HW3.0	**LT[mm]**	3.67	0.031	0.086	0.833	0.032	0.090	0.878
ALADDIN HW3.0	**CCT[mm]**	0.555	0.005	0.013	0.837	0.005	0.013	0.858
ALADDIN HW3.0	**WTW[mm]**	12.27	0.066	0.184	0.536	0.066	0.186	0.541
ALADDIN HW3.0	**K1_D [D]**	43.16	0.077	0.217	0.179	0.082	0.230	0.191
ALADDIN HW3.0	**K2_D [D]**	44.26	0.121	0.339	0.274	0.127	0.355	0.286
LENSTAR LS 900	**AL[mm]**	24.05	0.014	0.040	0.059	0.015	0.041	0.061
LENSTAR LS 900	**AX [°]**	76.56	5.304	14.852	6.928	5.312	14.873	6.938
LENSTAR LS 900	**ACD[mm]**	3.67	0.036	0.100	0.974	0.036	0.102	0.991
LENSTAR LS 900	**LT[mm]**	3.65	0.052	0.145	1.418	0.053	0.147	1.440
LENSTAR LS 900	**CCT[mm]**	0.555	0.004	0.011	0.722	0.004	0.011	0.726
LENSTAR LS 900	**WTW[mm]**	12.30	0.065	0.183	0.532	0.066	0.184	0.533
LENSTAR LS 900	**K1_D [D]**	43.17	0.114	0.320	0.265	0.118	0.329	0.272
LENSTAR LS 900	**K2_D [D]**	44.26	0.186	0.522	0.421	0.191	0.535	0.432

Note to Table 2:

- Repeatability includes variation due to measurement error;
- Reproducibility includes variations due to the device, the operator, the interaction between device and subject, the interaction between operator and subject, the interaction between device and operator, the interaction between device, operator and subject, and measurement errors;
- Repeatability % COV = (Repeatability SD / abs(overall mean))*100;
- Reproducibility % COV = (Reproducibility SD / abs(overall mean))*100.

The result of the repeatability and reproducibility study demonstrate that ALADDIN HW3.0 is substantially equivalent for both repeatability and reproducibility to the predicate device.

The analyses of reproducibility and repeatability shows that ALADDIN HW3.0 and LENSTAR LS 900 performances are substantially equivalent for the assessed endpoints.

17 DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY/ *Dichiarazione di conformità:*

Manufacturer/*Fabbricante:*

Name/*Nome*: VISIA imaging S.r.l.

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

Name of device/*Nome del dispositivo*:

BIOMETER and CORNEAL ANALYSER integrated

Marca/*Brand*: **TOPCON**

Model/*Modello*: **ALADDIN**

I, the undersigned, hereby declare that the aforementioned devices comply with Directive 93/42/EEC (implemented in Italy by Legislative Decree no. 46/97) and subsequent amendments and additions (Directive 2007/47/EC – implemented in Italy by Legislative Decree no. 037/10) for Class IIa equipment.

Io, sottoscritto, con la presente dichiaro che i dispositivi specificati sopra sono conformi alla Direttiva 93/42/CEE (recepita in Italia con D.Lgs 46/97) e successive modifiche e integrazioni (Direttiva 2007/47/CE – recepita in Italia con D.Lgs 037/10) per i dispositivi di Classe IIa.

Alessandro Foggi
Managing director
Legal representative

18 APPENDIX A: INSTALLING AN EXTERNAL PRINTER

18.1 Getting drivers and transferring them to ALADDIN

It is recommended to download the latest drivers for the printer and this should be done through an external PC. Download the latest drivers in the Technical Support section of the printer manufacturer site.
Download the drivers, which usually come in a zipped folder. Unzip it and keep the *.inf* file somewhere easily accessible (for example "C:\Drivers"). Copy them to the root directory of an USB FAT32 formatted pen driver that will later be connected to the ALADDIN USB port.
Now go back to ALADDIN and disable the "Write Filter" carrying out the following steps:

18.2 Disabling the Write Filter

1. Disable the **Write Filter** in the **Admin** tab of **Settings** panel and Confirm.
   Settings→Admin→ Disable Filter
   Press OK
2. The machine will restart automatically.

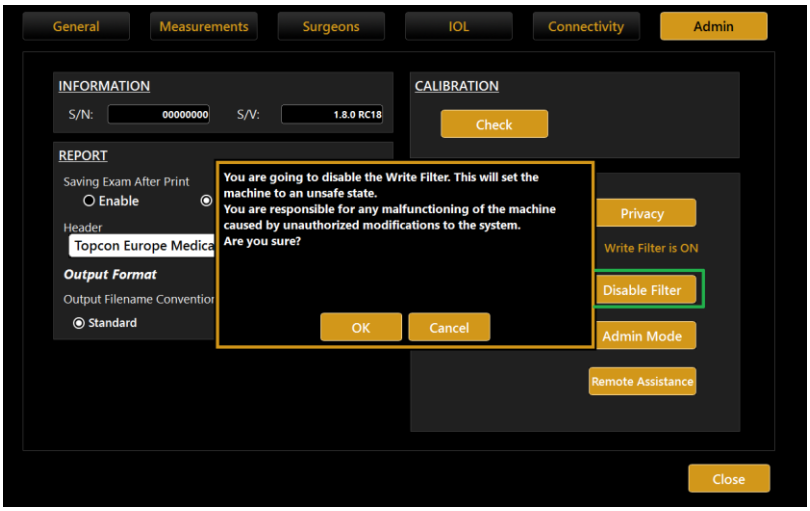


Figure 106

3. Upon restarting, the Aladdin application will warn about the unsafe state of the system.

   Press Cancel to avoid the restarting of the machine.

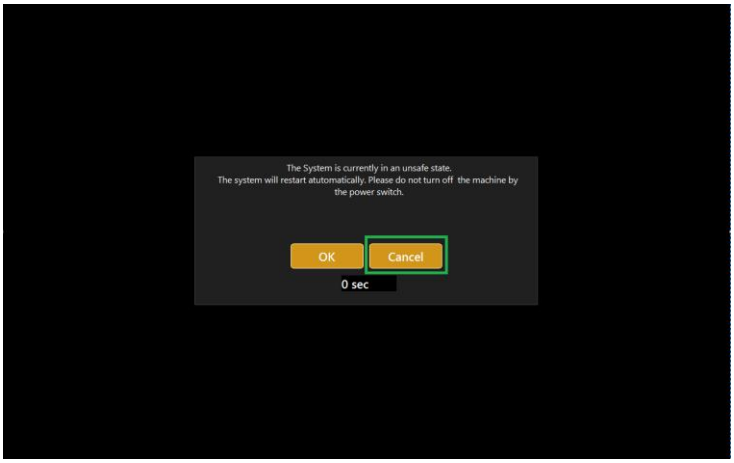


Figure 107

4. Close the Aladdin application:
   Settings→Admin→ Close App
   Press OK
5. You will have access to the Desktop of the machine.
6. Connect the USB pen with the downloaded drivers to Aladdin.

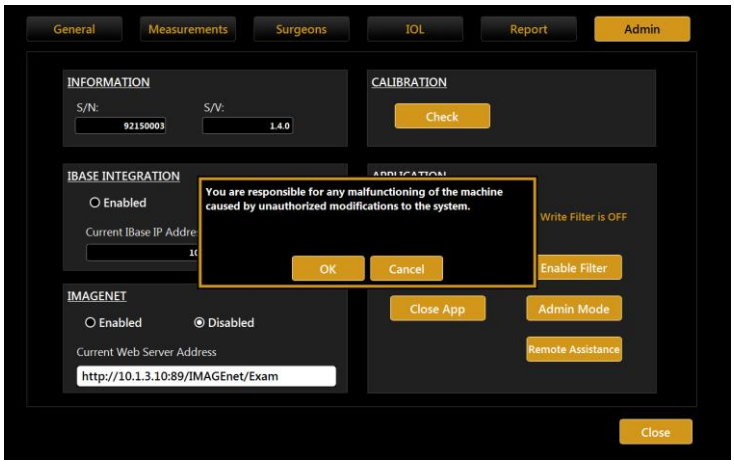


Figure 108

18.3 Installing a local printer (USB)

The following instructions are for a Windows 10 system.

Close the software using the procedure explained before in step 2. Right click on the Windows start button and select Control Panel.

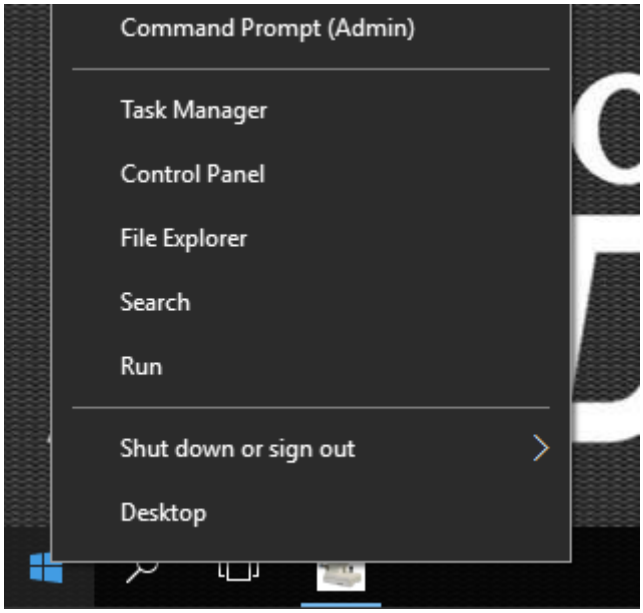
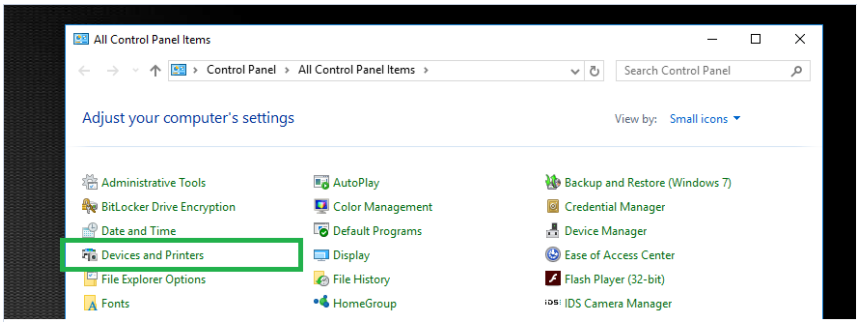


Figure 109

In the control Panel select "**Devices and Printers**".



Select the **Add Printer** function.

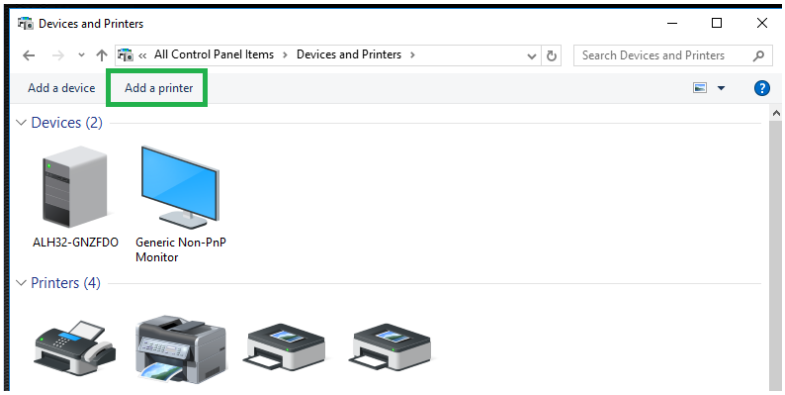


Figure 110

The **Add Printer Wizard** will appear. The printer could be automatically detected. If yes follow the steps, if not press on “The printer that I want isn’t listed”.

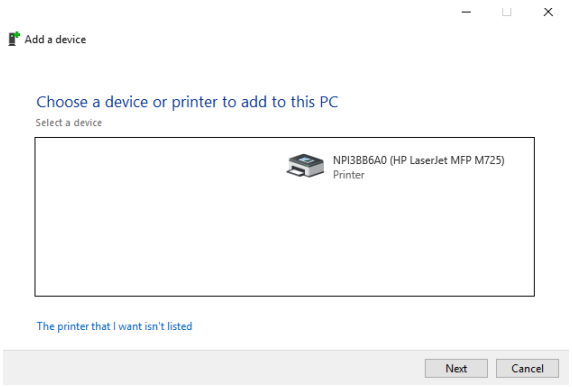


Figure 111

Select “**Add a local printer or network printer with manual settings**”. Click **Next**.

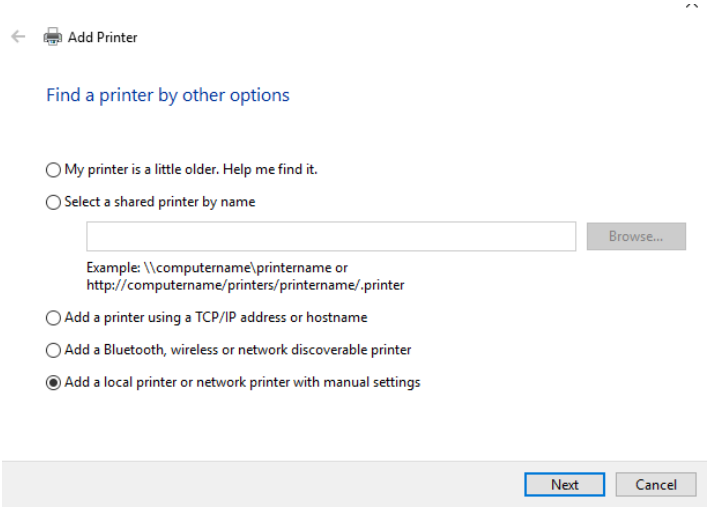
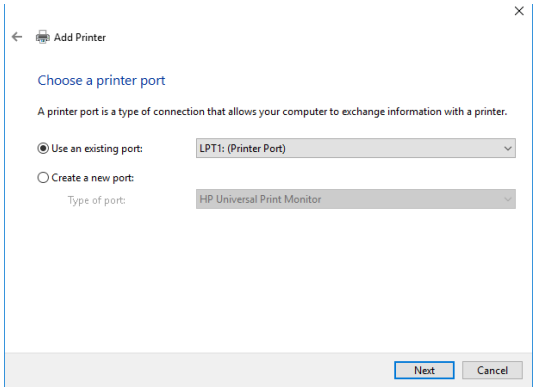


Figure 112

Press **Next** to the following screen.



You now need to identify the make and model of the printer. Click on the **Have Disk...** button.

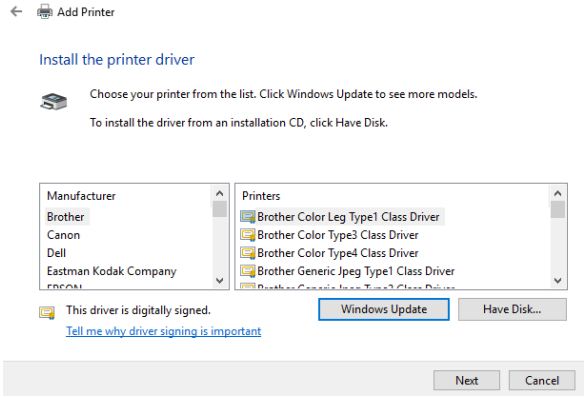


Figure 113

Click the **Browse** button and select the folder where you extracted the drivers (.inf file) for this printer. Once you've done that, click **OK**.

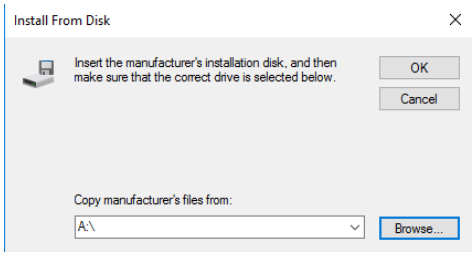


Figure 114

Select your printer model from the **Printers** list and then click the **Next** button.

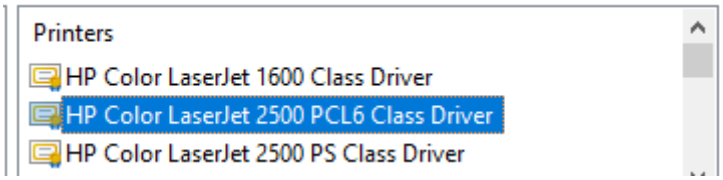


Figure 115

It is now very important to re-enable the Write Filter. Follow the instructions under **"Re-Enabling the Write Filter"**, otherwise there is the risk of damaging the device.

18.4 Installing a network printer (LAN)

Do not change the Ethernet settings of "**Local Area Connection 2**" or "**Reserved**" adapter.
If specific configuration for LAN network is needed it the settings can be modified accordingly on "**Local Area Connection**" or "**External**" Ethernet adapter.

Connect ALADDIN to an external network through the LAN port using an Ethernet cable. Go to control panel and select devices and printers, refer to previous section. The printer could be automatically detected. If yes follow the steps, if not press on "The printer that I want isn't listed".

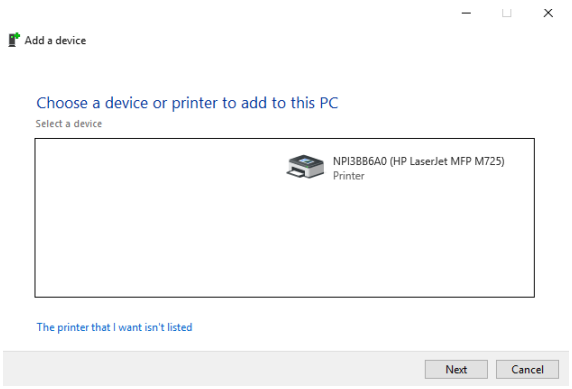


Figure 116

Select "**Add a printer using a TCP/IP address or hostname"**, and then select "Standard TCP/IP Port" from the **Type of port** drop-down menu. Click **Next**.

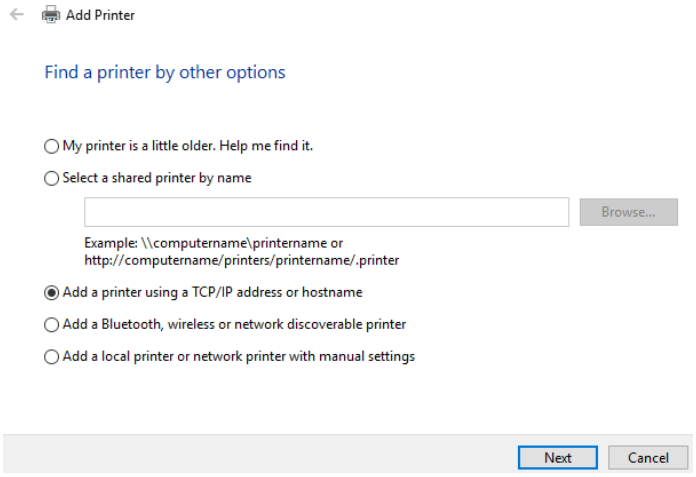


Figure 117

Enter the **Printer Name or IP address** in the "Printer Name" textbox. **Port Name** will automatically be entered. You can leave the default. Click **Next**. There will be a small delay while your computer configures the port.

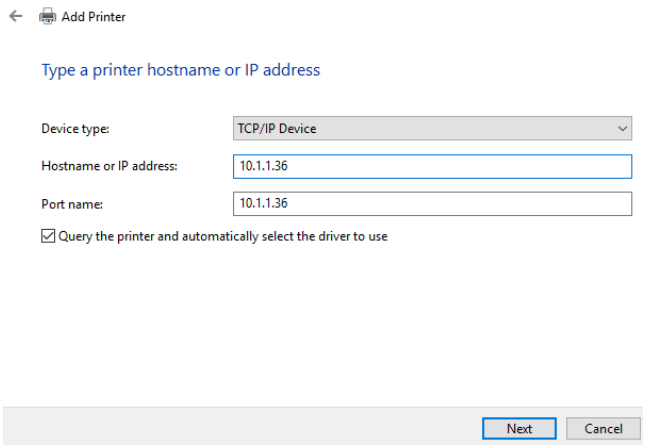


Figure 118

From here on, follow the steps for automatic driver selection or select manually the drivers as described for **"Installing a local printer (USB)".**

18.5 Re-Enabling the Write Filter

1. Open the Aladdin application.
2. The system will warn about the unsafe state.
3. Wait for the automatic restart or press OK.
4. The system will restart enabling the write filter.
5. Once restarted, the system will be in a safe state.

OR

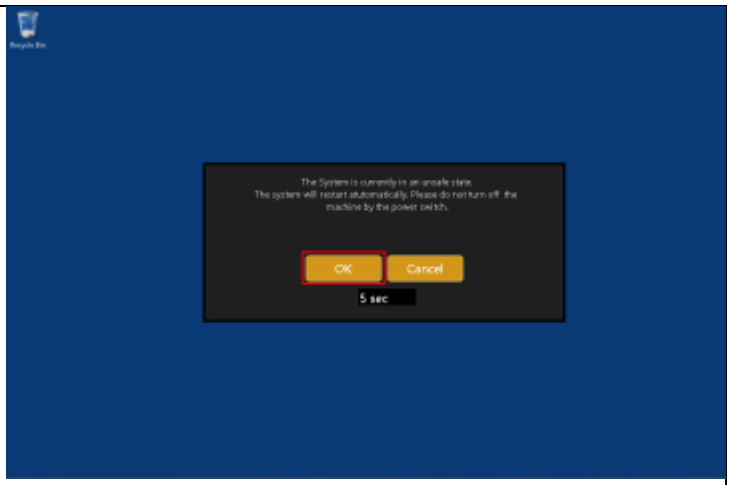


Figure 119

1. From inside the application if already open go to:

Settings→Admin→ Enable Filter

2. After restarting the system will be in a safe state.

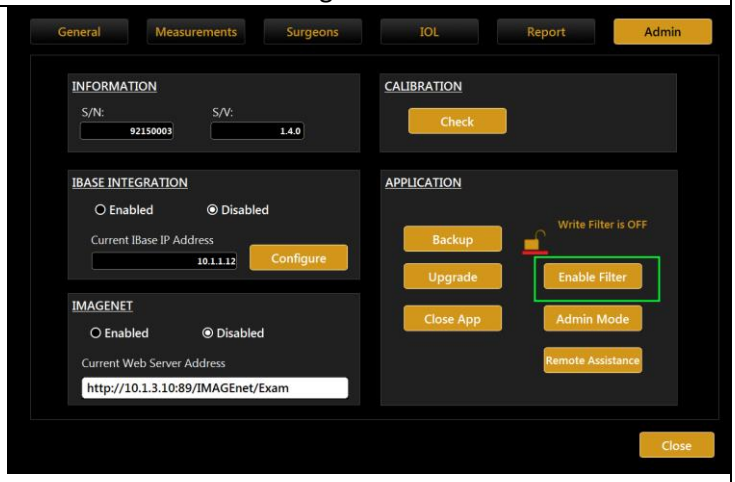


Figure 120

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ALADDIN HW3.0

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

- Product name: Aladdin HW3.0
- Software version and Serial Number: 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

Aladdin HW3.0

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