ALADDIN

User manual

CE 0123

Product cod. 1240211
ALADDIN HW2.0

Rev. 23 - 2016

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

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.

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

The original text of this manual is in English.

SW v.: 1.5.x

Manufacturer

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Contents

1 Intended Use

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

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

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

1.1 Description of functionalities

Aladdin is a combined device for the measurement of various parameters used in the application of intraocular lenses.

The instrument can work in two different modes:

1. Consecutive acquisition of all the measurements available on the eye
2. Individual acquisitions for each type of measurement

Aladdin includes six types of measurement in a single instrument.

- Axial length(AL)
- Corneal topography
- Keratometry(KER)
- Corneal diameter (white-to-white)
- Pupillometry
- Anterior chamber depth (ACD)

Axial length is the distance between the cornea and the inner limiting membrane. It is measured with a low-coherence interferometry system with a super luminescent diode. The measuring range goes from 15 mm to 38 mm

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 measuring precision.

Aladdin 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 millimetres from the patient's eye. The position of the device in relation to the patient’s eye serves as the starting point to make adjustments in the respective measurement modes. With the acquisition of the corneal topography, the **Corneal Diameter can be determined**. The Corneal Diameter is also known as "white- to- white" distance.

The **pupillometry** is performed with LEDs of different wavelengths. In particular, the instrument uses infrared LEDs to dilate the pupil and white LEDs to reproduce photopic light conditions and to contract the pupil (dynamic pupillometry).

ACD (anterior chamber depth) is the distance between the anterior surface of the crystalline (anterior capsule) and the outermost stratum of the cornea (epithelium), measured along the optical axis where the latter is biggest. This measurement is performed using the reflection principle of a slit light projected onto the anterior surfaces of the eye.

Caution should be practised when using the device's ACD measurement for any given intraocular lens calculation because of the high variability of this measurement.

The ACD measurement is the distance between corneal epithelium and the crystalline lens surface.

Aladdin has an onboard PC with the dedicated software that provides all the functionalities described.

The information obtained from the measurements can be used for various applications, for example: Cataract operations, IOL calculation, IOL toric calculation and post lasik calculation.
The intraocular lens power suggestion is made using scientifically recognised formulae: Holladay 1, Haigis, Hoffer Q, SRK / T, SRK II, Camellin-Calossi, Shammas No history.

The Haigis, HofferQ, Holladay, SRK® II and SRK®/T formulae are implemented in the software.
Please refer to the following literature references on the formulae (in case of specific questions please contact Visia Imaging):

- Haigis: http://www.augenklinik.uni-wuerzburg.de/uslab/ioltxt/haid.htm
- HofferQ: HOFFER KJ: The Hoffer Q formula: A comparison of theoretic and regression formulas. J Cataract Refract Surg, 19:700-712, 1993; ERRATA 20:677, 1994
- Reply: Errata in printed Hoffer Q formula. Journal of Cataract & Refractive Surgery, Volume 33, Issue 1, Pages 2-3, January 2007, Authors:Kenneth J. Hoffer, MD
- Holladay: HOLLADAY JT, PRAGER TC, CHANDLER TY, MUSGROVE KH, LEWIS JW, RUIZ RS: A three-part system for refining intraocular lens power calculations. J Cataract Refract Surg, 14:17-24, 1988
- SRKII: RETZLAFF J: A new intraocular lens calculation formula, Am Intra-Ocular Implant Soc J 6:148-152, 1980
- SRK/T: RETZLAFF J, SANDERS DR, KRAFF MC: Development of the SRK/T intraocular lens implant power calculation formula. J Cataract Refract Surg 16 (3):333-340, 1990

Correction of corneal radii/corneal refraction after corneal refractive surgery:

- HOLLADAY JT: IOL calculations following RK. Refract Corneal Surg 5(3):203, 1989
- HOFFER KJ: Intraocular lens power calculation for eyes after refractive keratotomy. J Refract Surg 11:490:493, 1995

Calculation of phakic implants:

- vd HEIJDE GL, FECHNER PU, WORST JGF: Optische Konsequenzen der Implantation einer negativen Intraokularlinse bei myopen Patienten. Klin MB1 Augenheilk 192:99-102, 1988
- HOLLADAY JT: Refractive power calculations for intraocular lenses in the phakic eye. Am J Ophthalmol 116:63-66, 1993
- HAIGIS W: Biometry in complicated situations, 9th Conv. of DGII 1995, Rochels et al (Hrsg.), Springer, 17-26, 1996

Relations between ultrasound and optical biometer calculation constants:

- RETZLAFF J, SANDERS DR, KRAFF MC (1990): Lens Implant Power Calculation - A manual for ophthalmologists & biometrists, 3rd edition, Slack Inc, Thorofare NJ, USA
- HAIGIS W, LEGE B, MILLER N, SCHNEIDER B: Comparison of immersion ultrasound biometry and partial coherence interferometry for IOL calculation according to Haigis, Graefes Arch Clin Exp Ophthalmology (2000) 238:765-773

- HOLLADAY, JT: International intraocular lens implant registry 2003. J Cataract Refract Surg (2003) 29:176-197
- HAIGIS W: Relations between optimized IOL constants. Symposium on Cataract, IOL and Refractive Surgery of the American Society of Cataract and Refractive Surgery (ASCRS), Philadelphia, PA, USA, June 1-5, 2002, Abstracts, p.112, 2002

Intraocular lens power calculation AFTER corneal refractive surgery:

- Camellin-Calossi: M. Camellin, MD; A. Calossi, Optom "A new formula for intraocular lens power calculation after refractive Corneal Surgery", Journal of Refractive Surgery, vol. 22 Feb. 2006.
  This formula is for use in 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.
- Shammas No-history: SHAMMAS H.J., SHAMMAS M.C: "No-history method of intraocular lens power calculation for cataract surgery after myopic laser in situ keratomileusis", J Cataract Refract Surg 2007; 33:31–36 Q 2007 ASCRS and ESCRS.
- Shammas No-history: SHAMMAS H.J., SHAMMAS M.C., GARABET A., KIM J.H., SHAMMAS A. , LABREE L.: Correcting the Corneal Power Measurements for Intraocular Lens Power Calculations After Myopic Laser In Situ Keratomileusis" - American Journal of Ophthalmology (Impact Factor: 4.02). 10/2003; 136(3):426-32.
- Shammas No-history: SHAMMAS H.J., SHAMMAS M.C., HILL W.E.: Intraocular lens power calculation in eyes with previous hyperopic laser in situ keratomileusis" - J Cataract Refract Surg 2013; 39:739–744 Q 2013 ASCRS and ESCRS.

Toric IOL calculation:

- HB Fam, KL Lim: Meridional analysis for calculating the expected spherocylindrical refraction in eyes with toric intraocular lenses. Journal of Cataract & Refractive Surgery, 2007 - Elsevier
- N Alpins: Astigmatism analysis by the Alpins method. Journal of Cataract & Refractive Surgery, 2001 - Elsevier
- G Savini, KJ Hoffer, M Carbonelli, P Ducoli: Influence of axial length and corneal power on the astigmatic power of toric intraocular lenses - Journal of Cataract & …, 2013 - Elsevier
- JT Holladay, TV Cravy, DD Koch: Calculating the surgically induced refractive change following ocular surgery. - Journal of Cataract & Refractive Surgery, 1992 – Elsevier
- 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

1.2 Users

Users: medical staff, opticians, ophthalmologists.

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.

1.3 Positioning the patient

The patient must be positioned in such a way that the distance from the device to the eye is 80 mm.
A steady head position and the correct device-to -patient distance is promoted by resting the patient's head well against the chin rest and forehead band.
A correct alignment with the patient's pupils can be visually checked by the operator referring to the two lines on the forehead supports.

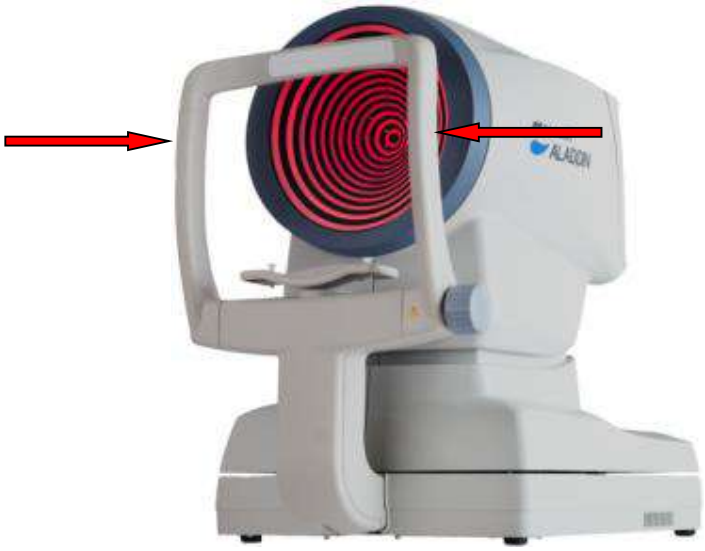


Figure 1

It is necessary to tell the patient to look steadily at the fixation point in the center of the Placido disk. The position of the device in relation to the patient's eye thus found is a starting point for fine measurement adjustments.
The patient does not use the controls.
The patient may be an elderly person, an invalid, or a child. In any case the device is to be controlled by the aforementioned specialized personnel.

1.4 Places of use

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

1.5 Contraindications

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

2 Accessibility and scope of the manual

Keep these instructions in a safe place close to the device. The manual must be at hand at all times. For best 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.

3 Introduction

3.1 Main characteristics

ALADDIN is a multifunction medical device used for the detection of various biometric parameters, particularly useful for the calculation of spherical, toric or personalized intraocular lenses. It records a wide range of parameters, which are acquired by using different techniques.

Optical Biometry: by means of the low-coherence optical interferometry method, ALADDIN executes axial length measurements (between 15 and 38mm).

Anterior chamber depth: slit light projection - by projecting a slit of certain characteristics onto the eye, you can determine the length of the optical axis of the anterior chamber, a very important measurement for the calculation of IOL.

Topography: the device acquires a topographic map of the patient of approximately 6,200 points using a 24-ring Placido disk to show the description of the corneal surface. This measurement also provides a Keratometry at 3mm, 5mm and 7mm 7mm (or at 2,4,6 mm depending on the settings) with the respective corneal astigmatism.

Pupillometry: for an accurate calculation of intraocular lenses, the instrument has a set of LEDs onboard that allows a measurement of Photopic, Mesopic and Dynamic pupillometry.

White-to-White: as a result of the corneal topography and by means of an internal software algorithm, a white-to-white value can be obtained, i.e. the corneal diameter recorded at the limbus.

The software can give suggestions for the choice of intraocular lens based on several different formulae.

Similarly, a database of intraocular lenses is also implemented. Before the calculation is made, the data for the desired lens must be entered.

ALADDIN also covers all the basic functions of corneal topography for recording some keratorefractive parameters.

4 Precautions

This electronic instrument is a precision tool. 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 3rd 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.
- Portable RF communication instruments may interfere with medical devices.
- 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 must not be used in contact with other devices.
  If use of the device in contact with other instruments is unavoidable, check that the device works properly in the required configuration.

Caution should be practised when using the device's ACD measurement for any given intraocular lens calculation because of the high variability of this measurement.

The ACD measurement is the distance between corneal epithelium and the crystalline lens surface.

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.

4.1 EMC table

Emission issues		
ALADDIN is intended for use in the electromagnetic environment specified below. The customer or user must ensure that it is used only in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guide**
RF emissions CISPR 11	Group 1	ALADDIN uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in neighbouring electronic devices.
RF emissions CISPR 11	Class B	ALADDIN is suitable for use in all residential buildings and those directly linked to a low-voltage supply network that supplies residential buildings.
Harmonic Emissions IEC 61000-3-2	Class A Compliant	The device can be used in all buildings, including residential buildings and those connected to the low-voltage mains network that supplies residential buildings.
Emissions of voltage fluctuations/flicker IEC 61000-3-3	Compliant	

Immunity issues			
ALADDIN is intended for use in the electromagnetic environment specified below. The customer or user must ensure that it is used only in such an environment.			
Immunity issues	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment - guide**
Electrostatic discharge (ESD) EN 61000-4-2	± 6kV on contact ± 8kV in air	± 6kV on contact ± 8kV in air	The floors must be wood, cement or ceramic. If the floors are covered with synthetic material, relative humidity must be at least 30%.
Transients/fast electric Trains EN 61000-4-4	±2kV power supply lines	±2kV power supply lines	The power supply should be typical of a commercial environment or hospital.
Surge EN 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV common mode	The power supply should be typical of a commercial environment or hospital.
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	< 5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	The power supply should be typical of a commercial environment or hospital. If the user requires the device to operate continuously even during a power cut, we recommend powering the device with an uninterruptable power supply (UPS) or a battery.

Power frequency magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields must have levels characteristic of a typical commercial or hospital environment.

Immunity aspects at RF

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device must ensure that it is used only in such an environment.

Portable and mobile RF communication devices must be used no closer to any part of the device, including the cables, than the recommended separation distance, calculated from the equation applicable to the frequency of the transmitter.

Immunity test	**Test level EN 60601-1-2**	**Compliance level**	**Electromagnetic environment – guide** Recommended separation distance (where *P* is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m)).
Conducted RF EN 61000-4-6	3 Vrms from 150kHz to 80MHz	3 Vrms from 150kHz to 80MHz	$d = 1.2 \cdot \sqrt{P}$ from 150kHz to 80MHz
Radiated RF EN 61000-4-3	3 V/m from 80MHz to 2.5GHz	3 V/m from 80MHz to 2.5GHz	$d = 1.2 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3 \cdot \sqrt{P}$ from 800 MHz to 2.5 GHz

Field strengths from fixed RF transmitters, as determined in an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:

Recommended separation distance between portable and mobile radio communication devices and the ALADDIN device

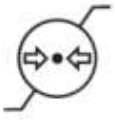
ALADDIN is intended for use in an electromagnetic environment in which radiated RF disturbances are under control. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between mobile and portable RF communication devices (transmitters) and the ALADDIN device as recommended below, according to the maximum output power of the radio communication devices.

Maximum nominal output power of the transmitter (W)	**Separation distance according to the frequency of the transmitter (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 with maximum output powers not listed above, the recommended separation distance d in meters (m) can be calculated using the equation applicable to the frequency of the transmitter, where P is the nominal maximum output power of the transmitter in Watts (W) according to the transmitter manufacturer.

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

5 Symbols

Symbols	IEC publications	Description
	IEC 60417-5840	CLASS I DEVICE ACCORDING TO EN 60601-1 APPLIED PART TYPE B
		PRODUCT COMPLIANT WITH DIRECTIVE 93/42/EC
Type A	EN ISO 19980	CORNEAL TOPOGRAPHY ACCORDING TO ISO 19980:2005
	IEC 60417-5032	ALTERNATING CURRENT
	ISO 7010-W001	GENERAL WARNING
	EN ISO 15223-1	REFERENCE OR MODEL NUMBER
	ISO 7010-M002	FOLLOW THE INSTRUCTIONS FOR USE
	EN ISO 15223-1	MANUFACTURER
Group 1	EN ISO 15004-2	PRODUCT CLASSIFIABLE AS GROUP 1 IN ACCORDANCE WITH EN ISO 15004-2
	EN 62471	PRODUCT CLASSIFIABLE AS EXEMPT GROUP IN ACCORDANCE WITH EN 62471
	EN ISO 15223-1	TEMPERATURE LIMITATION *Indicate the temperature limits to which the medical device can be safely exposed.*
	EN ISO 15223-1	HUMIDITY LIMITATION *Indicate the range of humidity to which the medical device can be safely exposed.*
	EN ISO 15223-1	ATHMOSPHERIC PRESSURE LIMITATION *Indicate the range of atmospheric pressure to which the medical device can be safely exposed.*

	EN ISO 15223-1	KEEP DRY *Indicates a medical device that needs to be protected from moisture.*
		HANDLE WITH CARE
	ISO 780	THIS WAY UP *Indicates correct upright position of the transport package.*
	This symbol is solely applicable for EC member countries. To avoid potential negative consequences for the environment and possibly human health, this instrument should be disposed of (i) for EU member countries – in accordance with WEEE (Directive on Waste Electrical and Electronic Equipment) or (ii) for all other countries, in accordance with local disposal and recycling laws.	

5.1 Labeling on the device

6 Safety instructions

6.1 General

- ALADDIN 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.
- 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 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.

6.2 Electrical safety

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

6.3 LED emission safety

The light emitted from this instrument is not potentially hazardous.

ALADDIN has a series of LEDs of various types and powers installed. All the characteristics are detailed in the Technical Specifications section in this manual.
The LED groups comply with the emission limits for the Group 1 instruments of the standard UNI EN ISO 15004-2.

All sources are classifiable as EXEMPT GROUP according to EN 62471.

6.4 Installation with external devices or IT Network

ALADDIN 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.
- When ALADDIN 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 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.
- Every external device that has to be connected to ALADDIN must have a connection cable (USB or LAN) with a maximum length of 3 m.

The purpose of ALADDIN connection to an IT network is report printing and remote technical assistance.

- The ALADDIN USB port must be connected to printer with USB or LAN interface. Ask Topcon technical assistance for printer driver installation.
- The ALADDIN 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 and network settings.
- The purpose of ALADDIN connection is saving PDF report on an external network folder or technical service intervention on the machine.
- Connection of ALADDIN to a computer network that includes other equipment could result in previously unidentified RISKS; identify, analyze, and control such RISKS (refer to IEC 60601-1:2005).
- Subsequent changes to a computer network could introduce new RISKS and require new analysis.

- Changes to the computer network include:
  - Changes in computer or data network configuration
  - Connection of additional items to computer network
  - Disconnecting items from computer network
  - Update of equipment connected to computer network
  - Upgrade of equipment connected to computer network
  - The term computer network used here corresponds to the term network/data coupling in IEC 60601-1:2005.

6.5 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 transportation locks and the semi-lock (Figure 10) before use.
-  Lower the instrument to its minimum height using the joystick, then lock ALADDIN using the instrument semi-lock and the two “instrument locking devices” for transportation (Figure 10).

6.6 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 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.

6.7 Package contents

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

 NB: keep the original packaging for storage or transport of the device.

6.8 Checking the measurements

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

-  Check the measurements every day when turning on the device using the instrument provided.
- The user of the device must check that the measurements provided by the device are plausible.
- It is advisable to visually check all the light sources before examining 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.

6.9 Cybersecurity

-  When performing the installation of a new unit the user MUST set his own credentials to prevent unauthorized physical access to the device.
-  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.

7 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.

8 Legal provisions

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

9 Components

9.1 Main Body

Figure 2

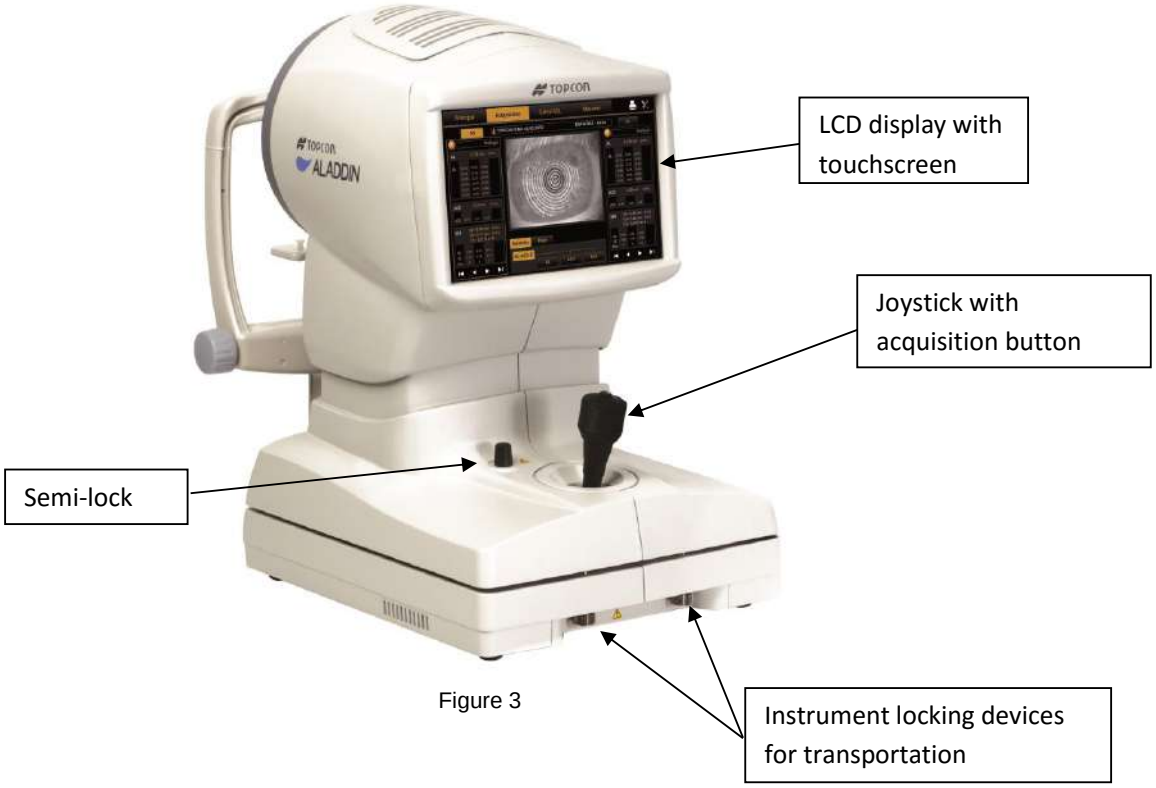


Figure 3

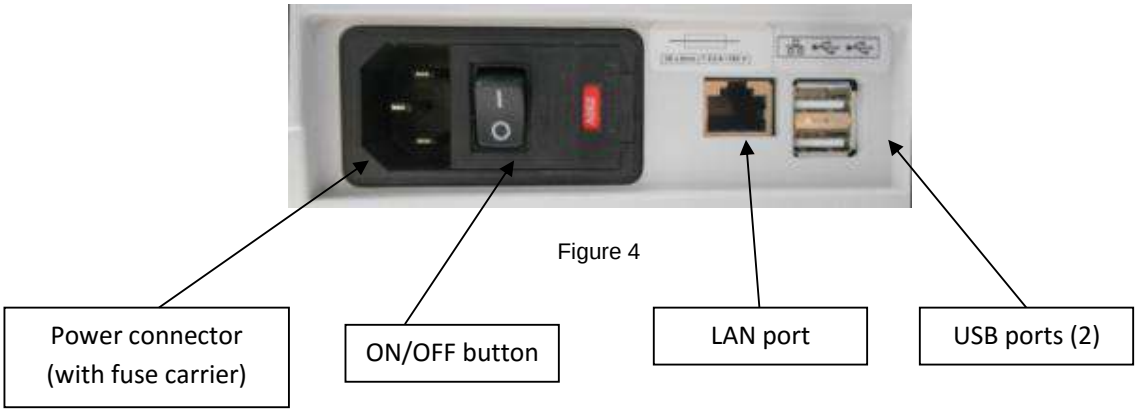


Figure 4

9.2 Other components

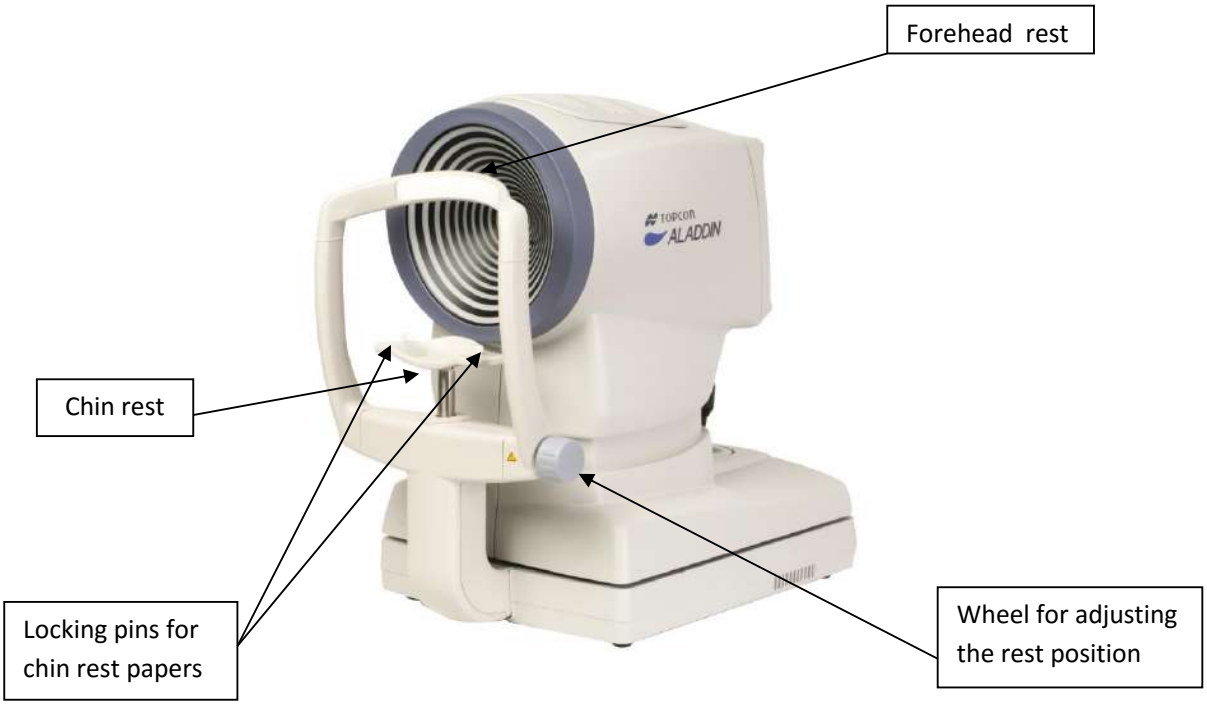


Figure 5

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)

10 Installation /uninstallation of the system

ALADDIN 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.

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

If the circle on the label shown below is white, it means that the instrument has been handled without tipping. If it is red, the instrument may have been damaged during shipping.

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

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.

10.1 Installing the system

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

Figure 6

Figure 6 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 7.

Figure 7

Remove the manual and the accessories from the dedicated spaces between the two pieces of cardboard (see Figure 8).

Figure 8

The accessories are:

- "Topcon" box:
  - calibration checking device
  - chin rest paper
  - chin rest pins
  - touchscreen pen
  - silicon cloth
- Power cable
- "Topcon" ALADDIN dust cover
- ALADDIN 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 9.

Figure 9

Be careful when taking ALADDIN HW3.0 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 transportation locks and the semi-lock (Figure 10).

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

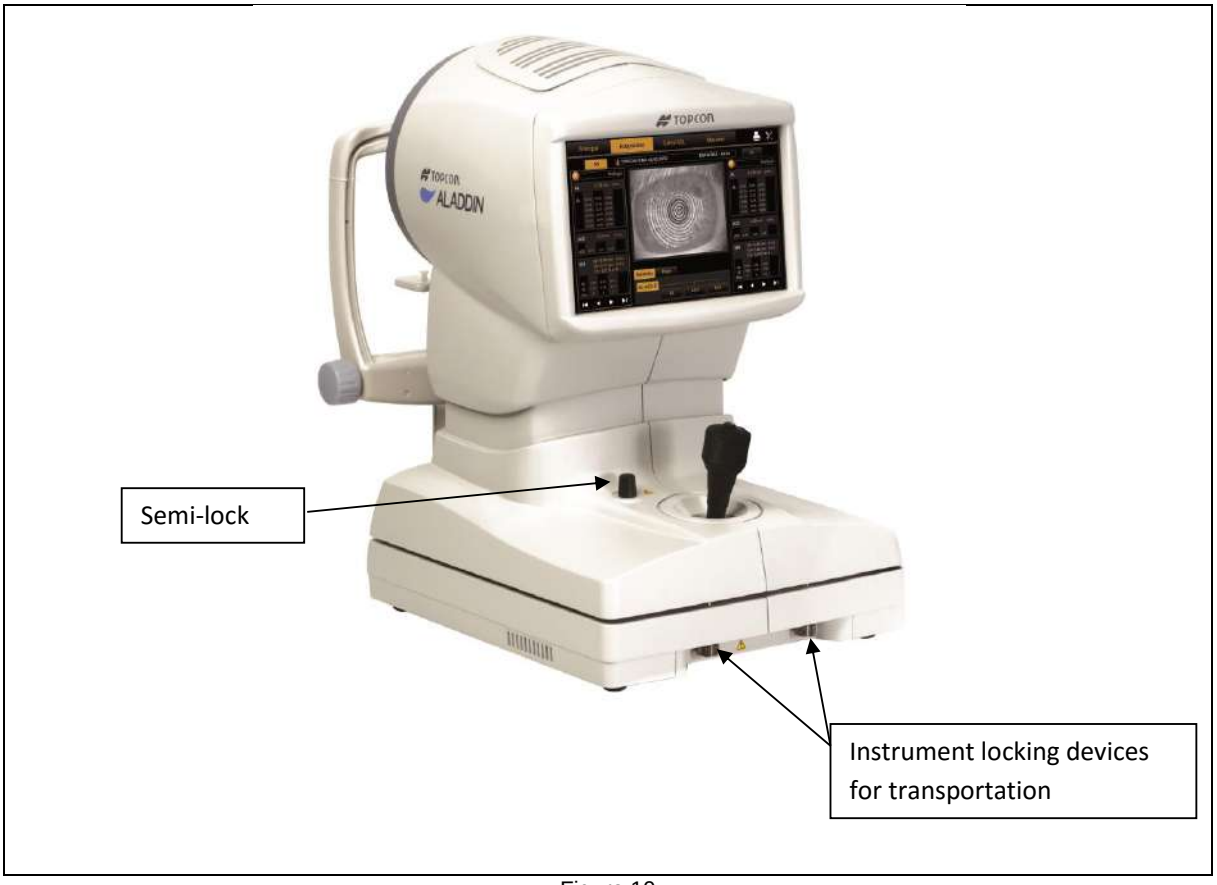


Figure 10

10.2 Uninstalling the system

Take the original packaging.

Set the instrument to the minimum height using the joystick. Lock the device using the instrument semi-lock and the two "instrument locking devices" for transportation (Figure 10).

Figure 11

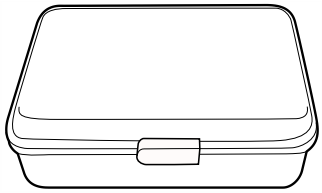
Place the Nylon cover over the instrument and insert it in the box, as shown in Figure 11.
Follow the sequence of steps shown in Figure 12.

Figure 12

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.

11 ALADDIN accessories and equipment

11.1 Standard equipment

•	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	
•	Touchscreen pen silicon cloth chin rest paper chin rest pins	

12 Setting up the instrument

12.1 Connection modes

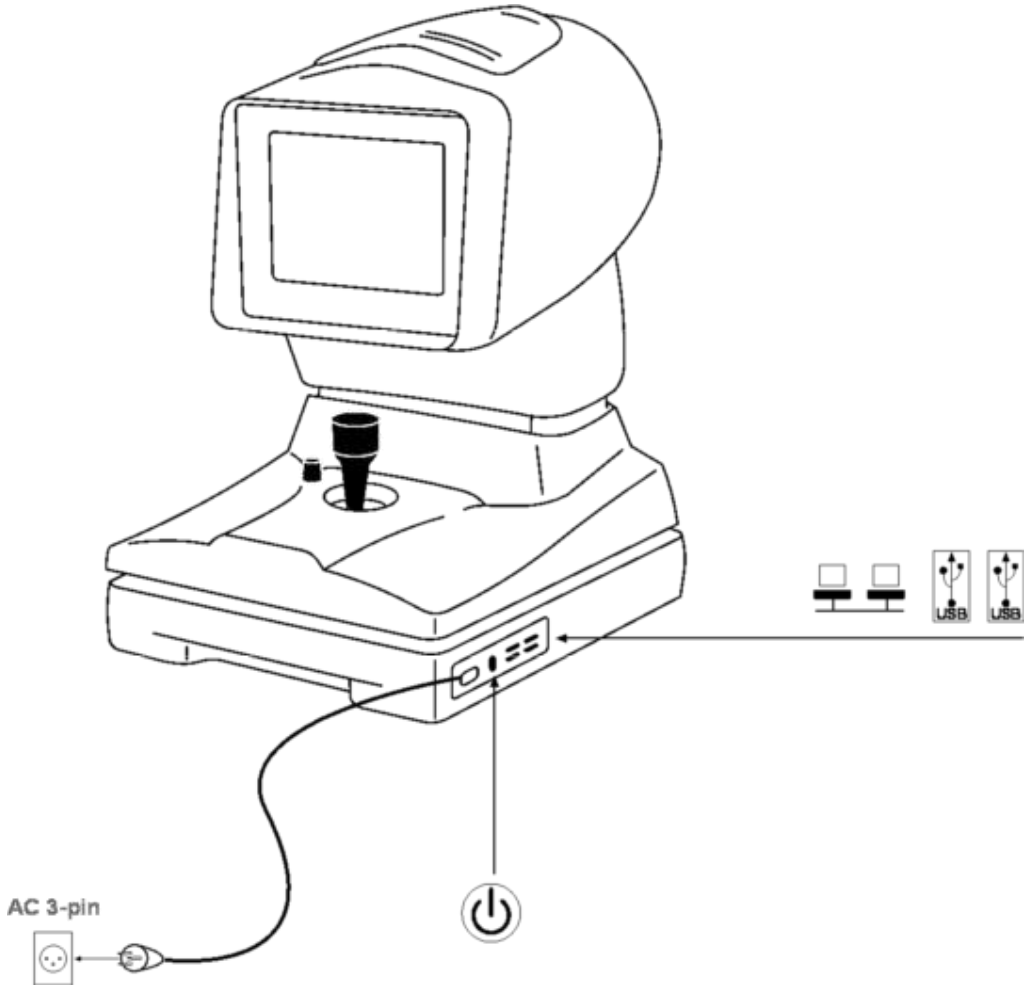


Figure 13

13 OPERATING INSTRUCTIONS

ALADDIN 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 the description of all the settings and other functions included is provided in the following paragraphs of this chapter, to which we refer you for further details.

To interact with the software, the LCD display with touchscreen is used. To activate the button or the desired function, simply touch the screen close to the command. The screen is highly sensitive. Minimum pressure is required, indeed advised.

13.1 General description of functionalities

The Aladdin device has the following functionalities:

- Cornea image acquisition and topographic analysis.
- Measurement of the eye's axial length.
- Measurement of the anterior chamber depth with the slit projection method.
- White-to-White measurement.
- Dynamic pupillometry acquisition: recording of a sequence of images of the pupil in varying light conditions. Acquisition of the static pupillometry in controlled light conditions (photopic and mesopic).
- Analysis of the wavefront aberrations generated by the front surface of the cornea with Zernike analysis: information on the cornea's optical properties and on the optical problems that can hinder vision.
- Intraocular lenses (IOL and Toric IOL) calculation, both BEFORE and AFTER refractive surgery (by means of the Camellin-Calossi and Shammas No History formulae).

Refer to the literature related to the Camellin-Calossi formula (in case of specific questions please contact Visia Imaging):

- Camellin-Calossi: M. Camellin, MD; A. Calossi, Optom “A new formula for intraocular lens power calculation after refractive Corneal Surgery”, Journal of Refractive Surgery, vol. 22 Feb. 2006.

Refer to the literature related to the Shammas No History formula (in case of specific questions please contact Visia Imaging):

- Shammas No-history: Shammas H.J., Shammas M.C:“No-history method of intraocular lens power calculation for cataract surgery after myopic laser in situ keratomileusis”, J Cataract Refract Surg 2007; 33:31–36 Q 2007 ASCRS and ESCRS.

- Shammas No-history: Shammas H.J., Shammas M.C., Garabet A., Kim J.H., Shammas A. , LaBree L.: Correcting the Corneal Power Measurements for Intraocular Lens Power Calculations After Myopic Laser In Situ Keratomileusis" - American Journal of Ophthalmology (Impact Factor: 4.02). 10/2003; 136(3):426-32.
- Shammas No-history: Shammas H.J., Shammas M.C., Hill W.E.:Intraocular lens power calculation in eyes with previous hyperopic laser in situ keratomileusis" - J Cataract Refract Surg 2013; 39:739–744 Q 2013 ASCRS and ESCRS.

These formulae are for use in 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.

13.1.1.1 General instructions

On the various screens displayed by the software there are symbols that provide access to certain functions available in several working environments.

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

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

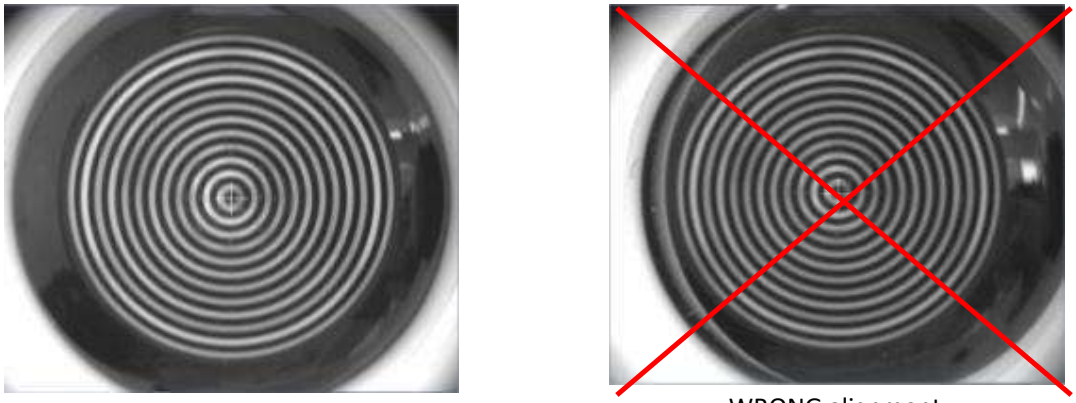
13.2 Checking the calibration

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 calibration of the device every day before starting patient examinations.

Set the calibration tool supplied with the device (Figure 14) 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 15).

Figure 14



CORRECT alignment WRONG alignment

Figure 15

To check the calibration, turn on the instrument, and when asked to check the calibration, press Start (Figure 16) and then press Close (Figure 17).

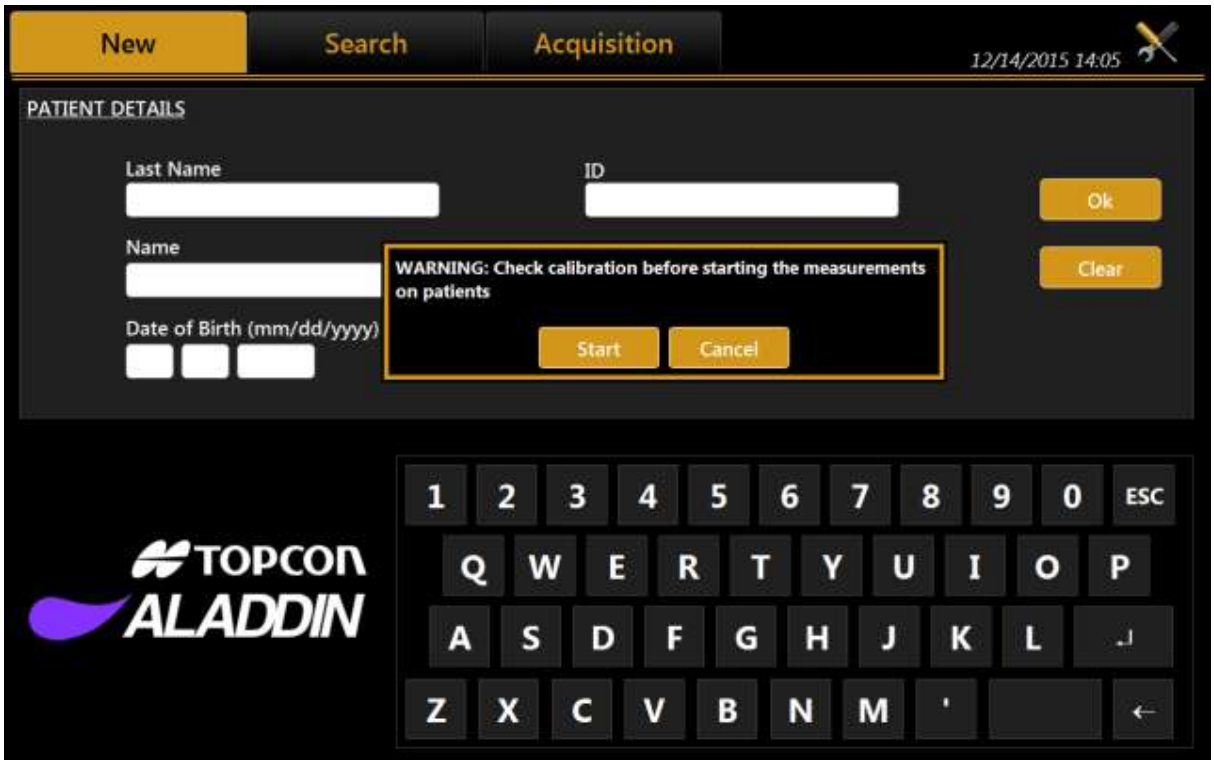


Figure 16

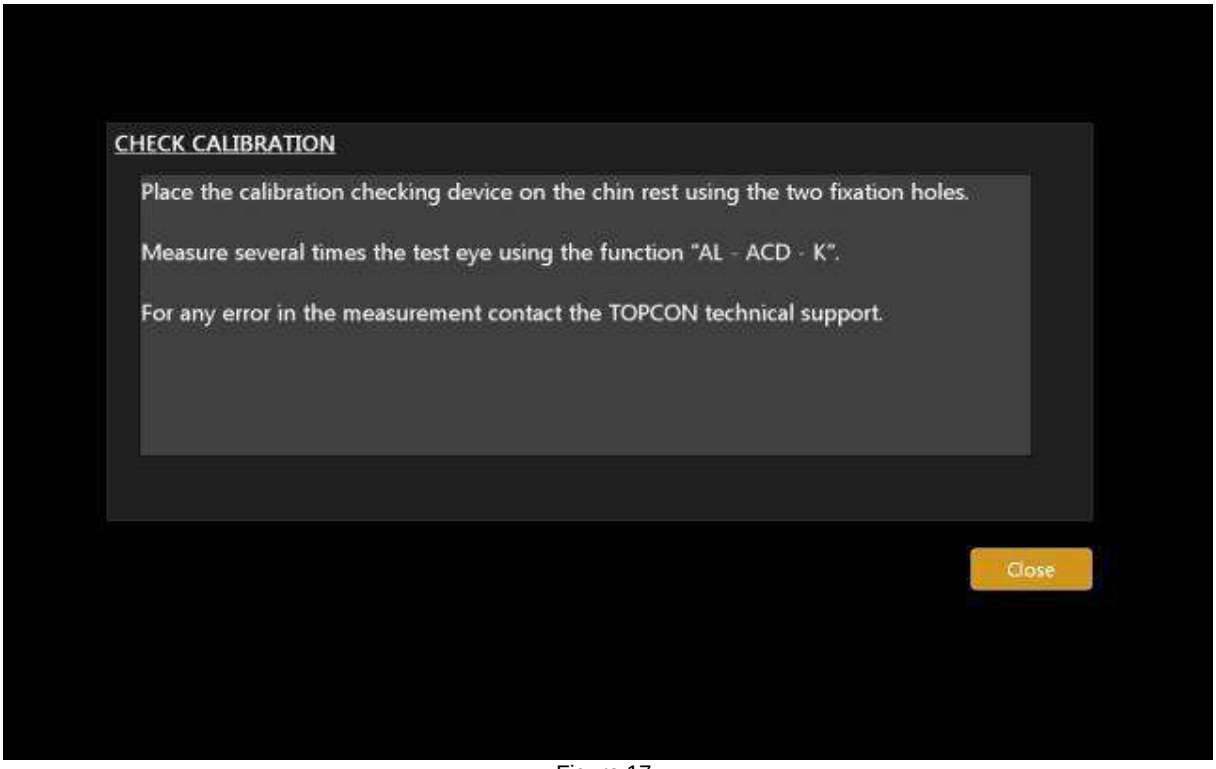


Figure 17

To check the calibration, turn on the instrument and, when asked to check the calibration, press OK. By pressing ok, the test patient is automatically created. Now check and several times acquire the calibration checking device using the complete acquisition (AL-ACD-K), in check calibration is not possible to acquire the single measurements. If the calibration is ok, the "Valid" word will be display for all the three measurements (Figure 18).

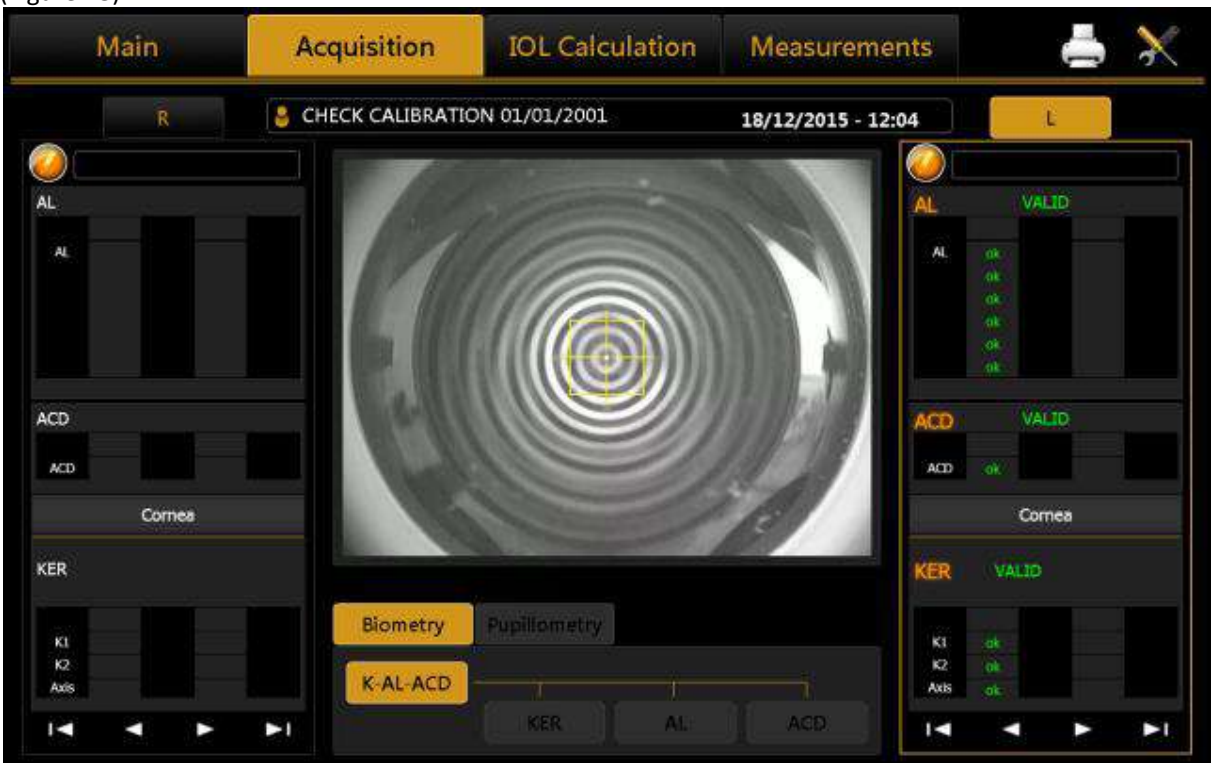


Figure 18

If the measurements are incorrect, the words “Repeat” or “Not Valid” will be displayed besides the wrong measurement (Figure 19).

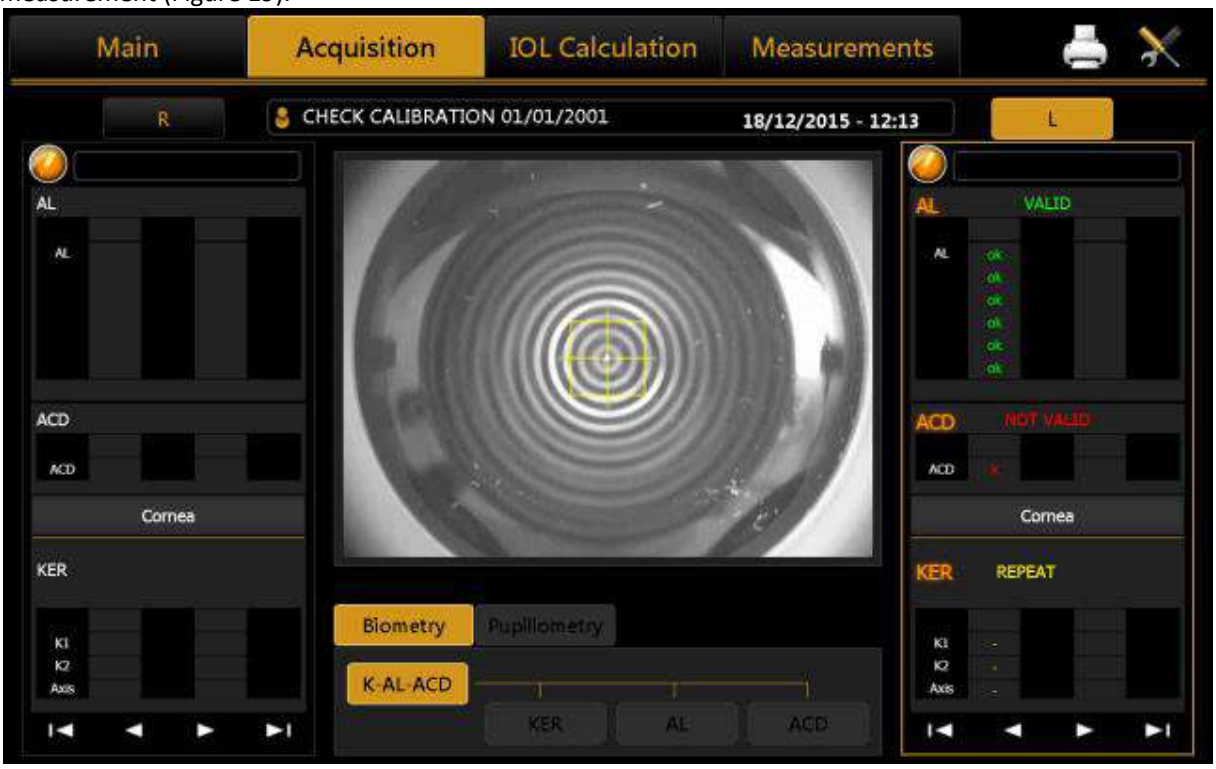


Figure 19

VALID	Good calibration, your device is ok
REPEAT	Bad acquisition, you must repeat
NOT VALID	Incorrect calibration, call the assistance

If the calibration goes wrong, try acquiring at least two or three times more with this tips:

- improving the environmental conditions (less light and no reflections on the sphere);
- cleaning 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 Topcon Technical Support to have the Aladdin instrument checked.

To complete the measurements, check that all the measurements are valid, click on **“Main”** to start a new examination, and when asked, press Yes to save the current “Calibration Check”.

13.3 Patient entry/selection

When the instrument is turned on, the software displays the following screen. To continue the examination, you always need to enter a patient or select one from those on file.

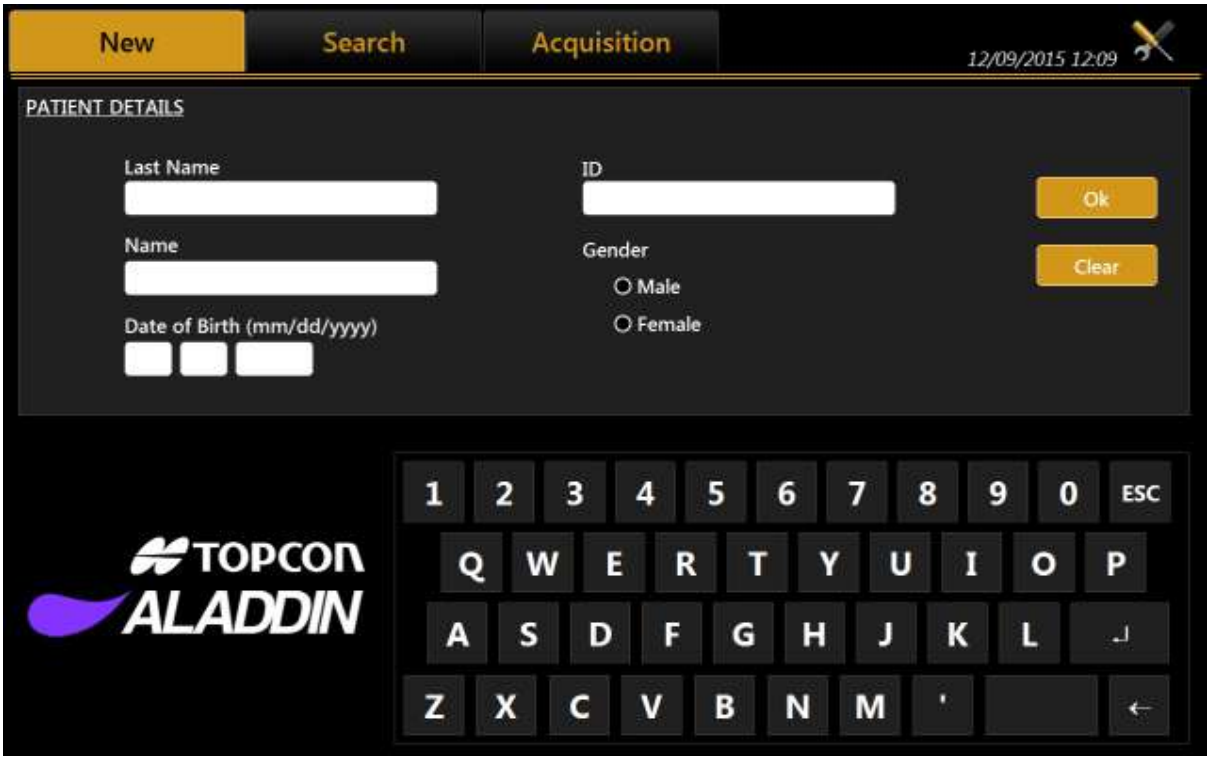


Figure 20

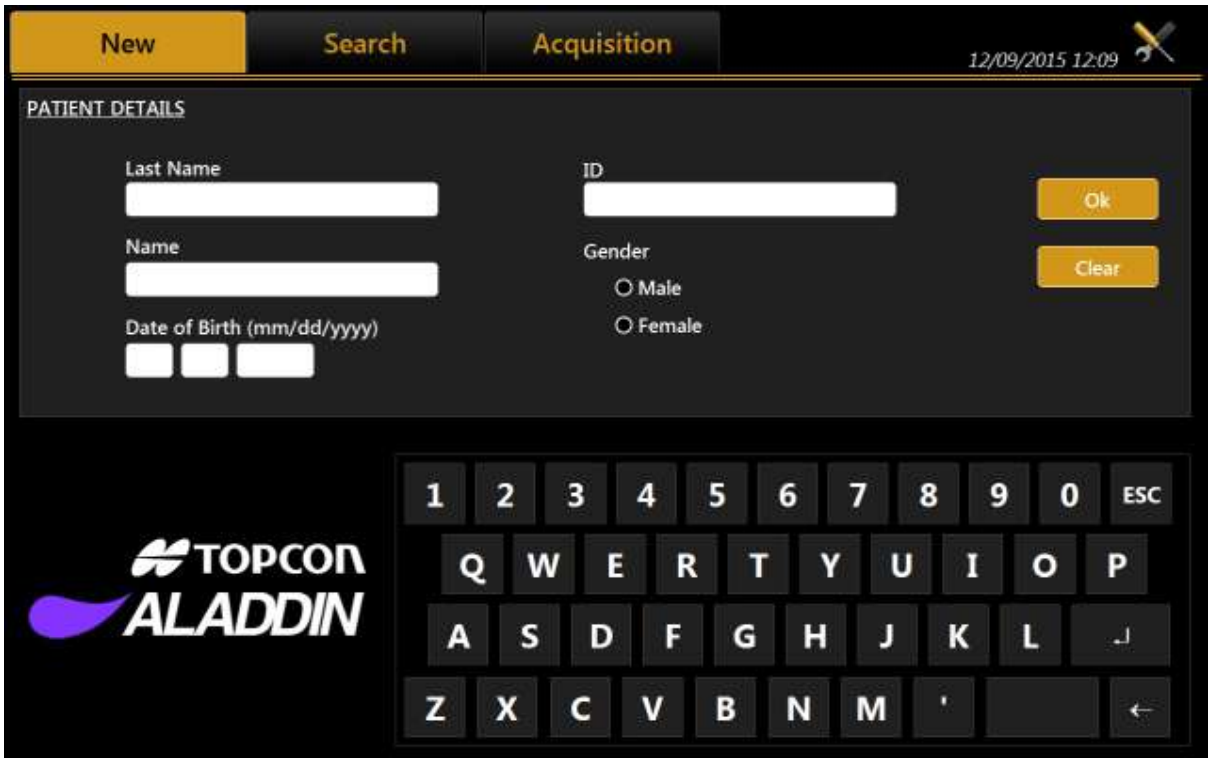


Figure 20 shows the section for creating a new patient, entering Last Name, Name and Birth Date as required

fields (Gender and ID are optional). You can set from the settings environment to have only the ID as required field.

13.3.1 Creating a new patient

To create a new patient, select the **"New"** tab and enter the data using the on-screen keyboard. 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 22).

An external keyboard or another input device compatible with "*keyboard wedge interface*" (PS/2) 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.

13.3.1.1 Entering special characters

A special character can be entered simply by touching and holding the corresponding letter as shown in Figure 21:

Figure 21

13.3.1.2 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 humor for each patient's eye, by pressing the "Acquisition" button (please see the following Figure 22)

Figure 22

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 corrects the measurement with a constant defined as follows.
Aladdin 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:

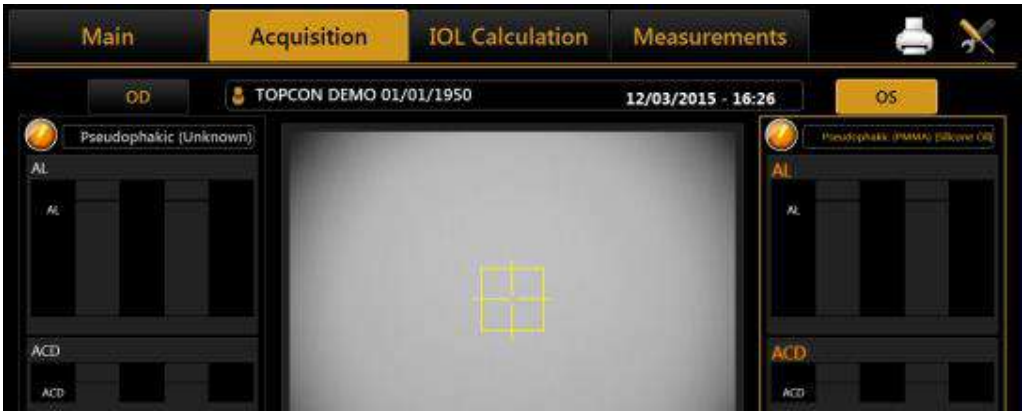
- **Natural:** the vitreous body has never been operated or treated such as to alter its composition.
- **Silicon Oil:** the vitreous body has been filled, even only partly, with silicon oil.

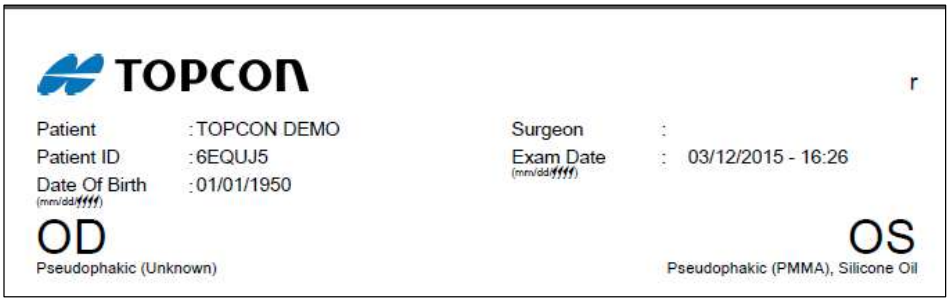
The correction values (in mm) of the vitreous body filled by Silicon Oil

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.





13.3.2 Selecting or modifying a patient

On the input screen, click on the **"List"** tab to access all the patients included in the database (see **Errore. L'origine riferimento non è stata trovata.**).

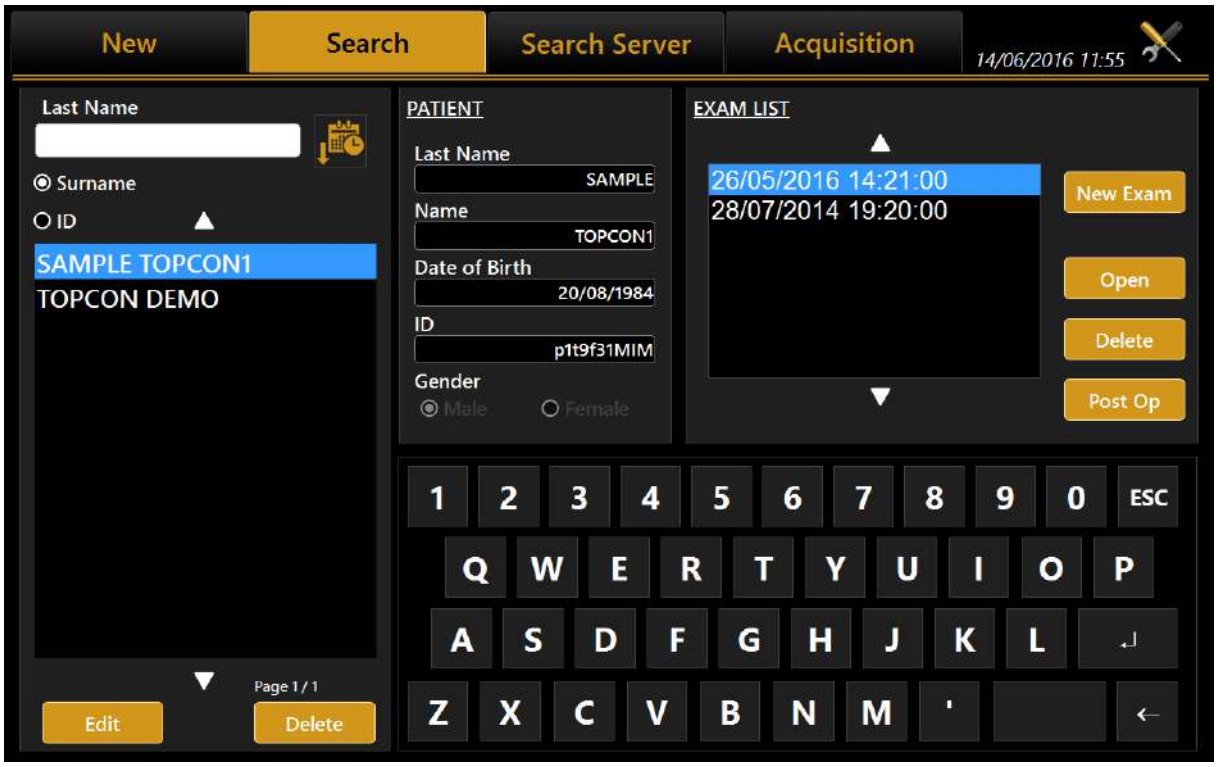


Figure 23

On this screen you can select a previously created patient and the examinations associated with him/her.

The list can be viewed by **patient ID** or by **Last Name** (and name) selecting the corresponding radio button.

If you type into the **"Last Name"** field, a search is done in the local database for patients with the corresponding surname or whose surname contains the selected key, same for patient ID.

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

13.3.2.1 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.

13.3.2.2 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.

13.3.2.3 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.

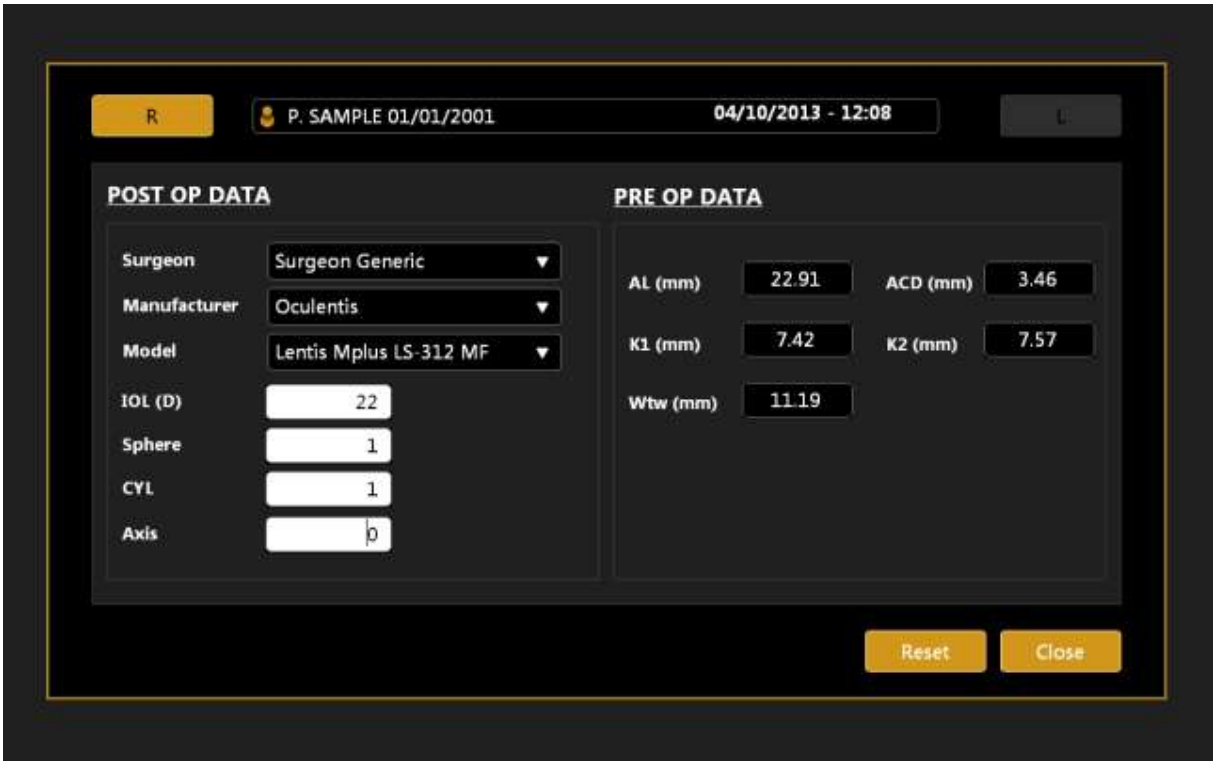


Figure 24

Opening the Post-Op section, the screen shown Figure 24 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.

13.3.3 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 25).

In the same way, Aladdin 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). Will be created a list of patients corresponding to the search criteria (Figure 27). Once selected a patient, the user can create a new examination in the standard mode by clicking on the Acquisition or OK button button.

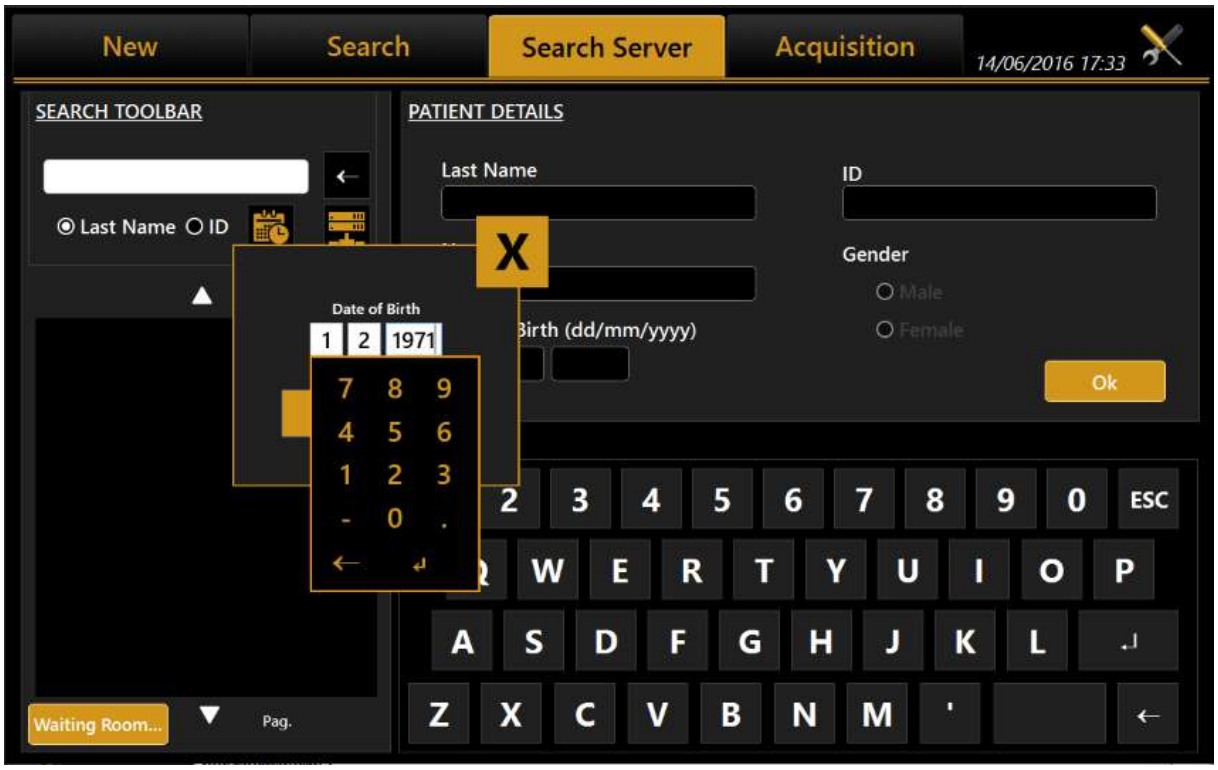


Figure 25

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.

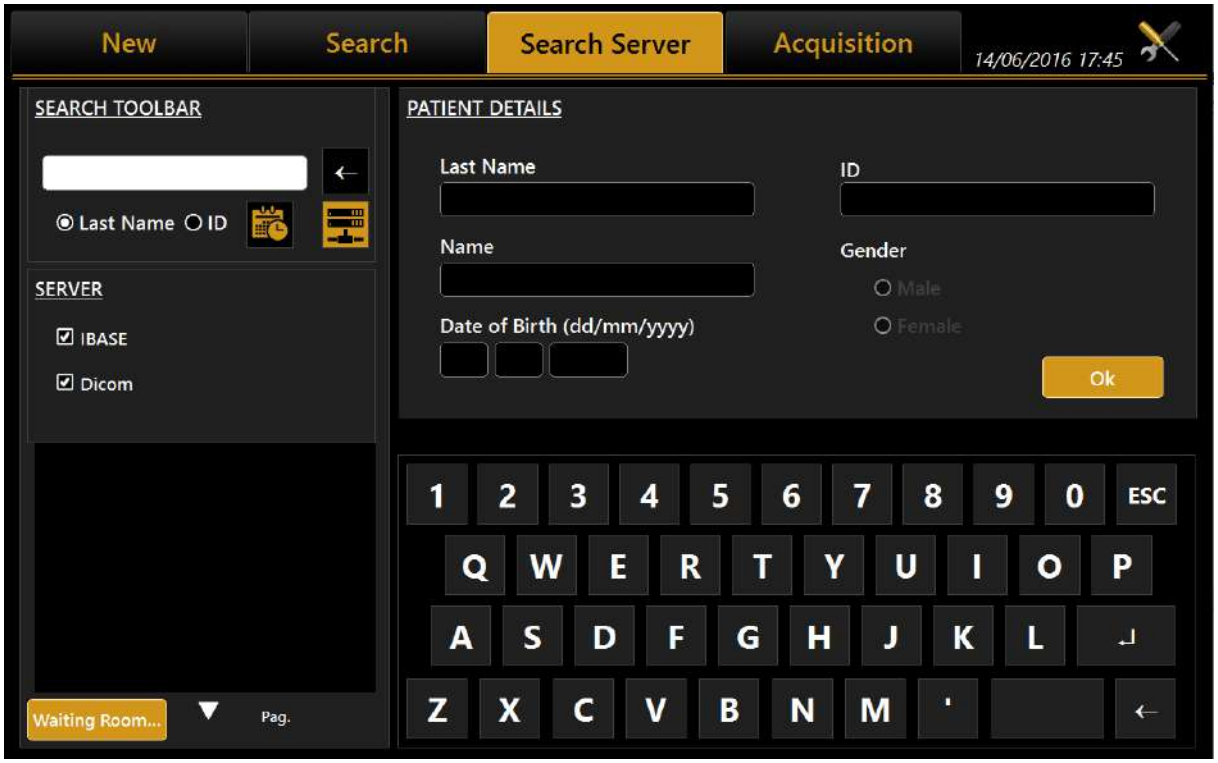


Figure 26

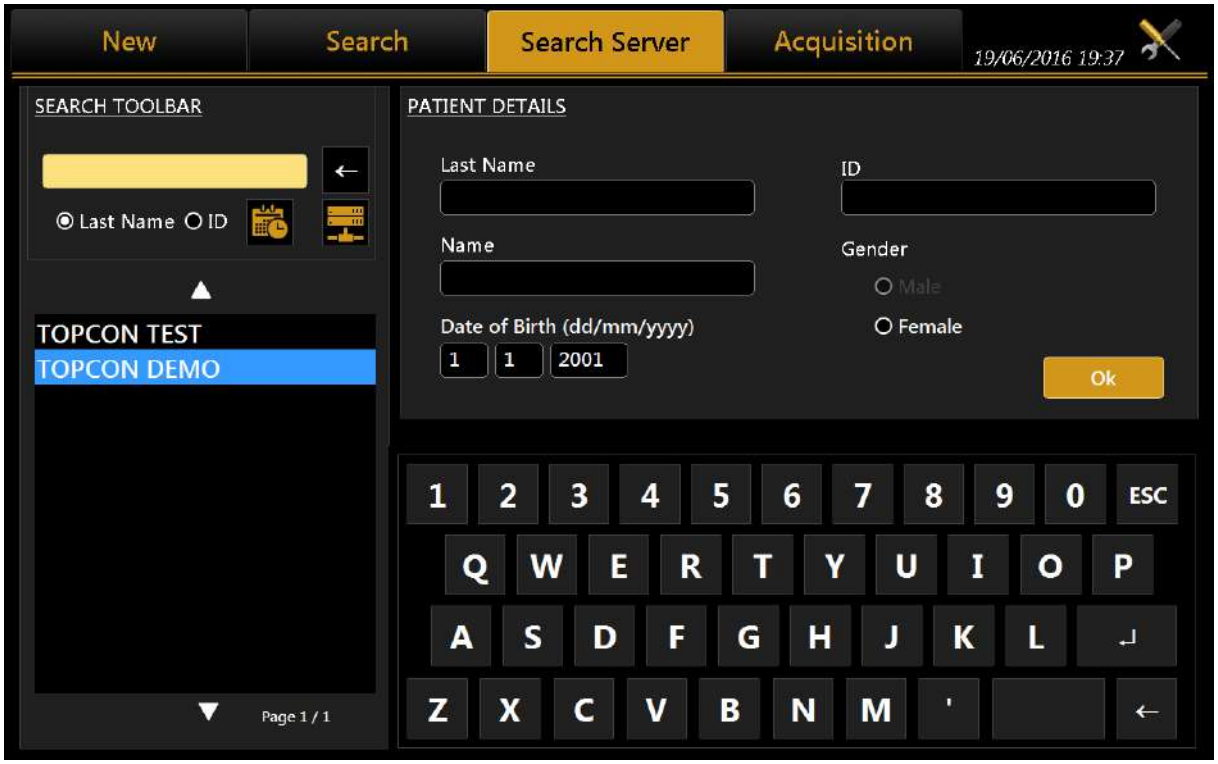


Figure 27

13.3.3.1 Start an exam from the Waiting Room

If DICOM Modality Worklist service is configured, Aladdin is able to search for pending patient's examinations in the waiting room. Pressing on the "**Waiting Room…"** button (Figure 26) 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

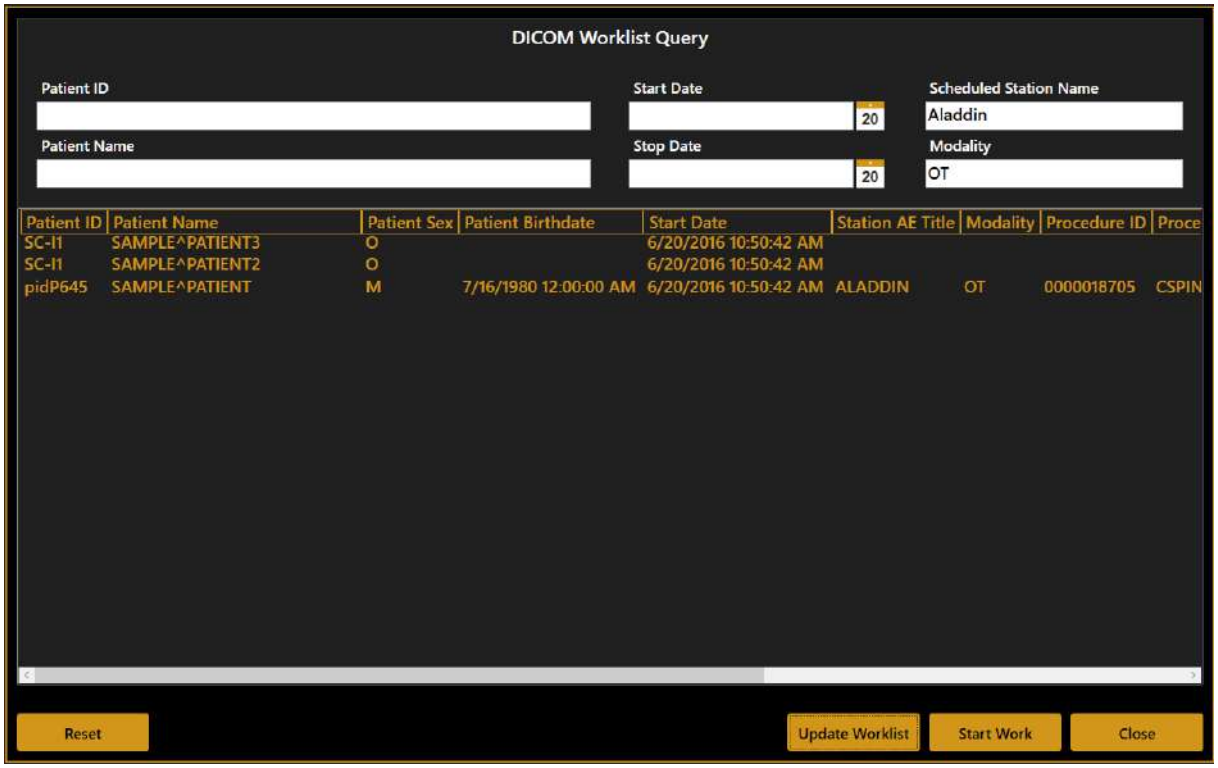


Figure 28

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

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

13.4 Acquisition environment: general instructions

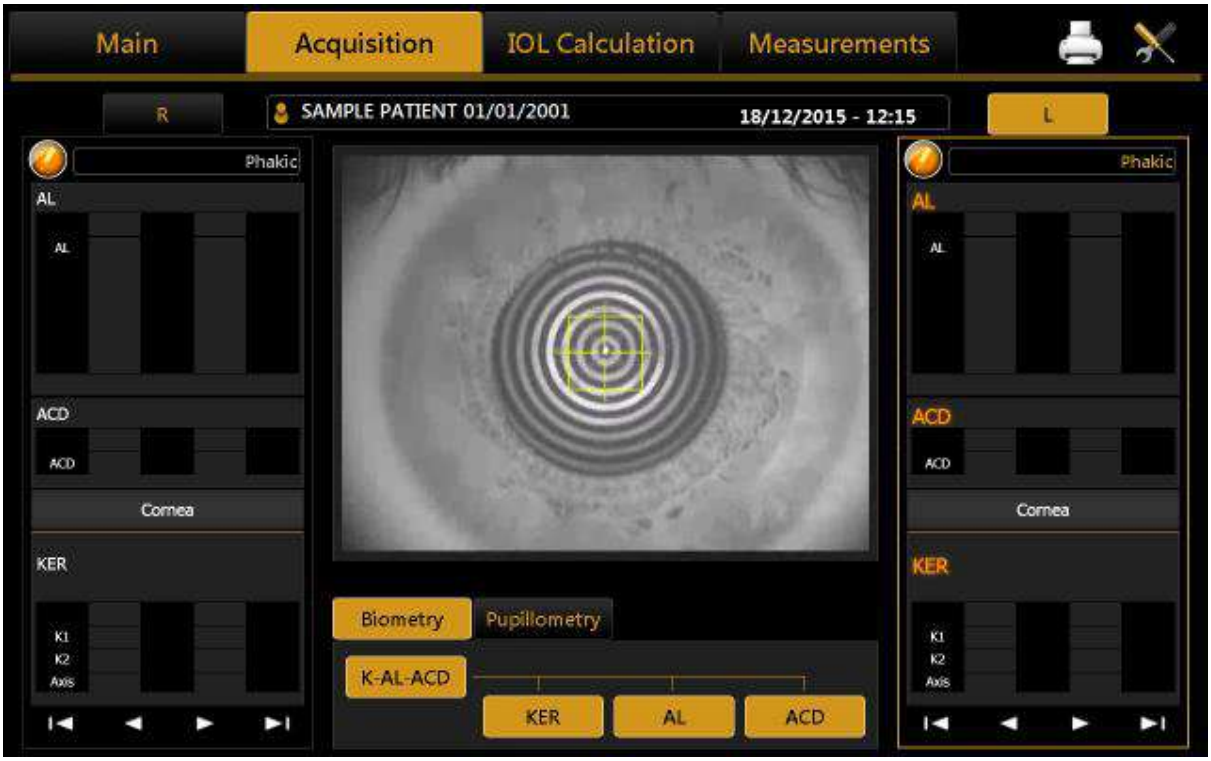


Figure 29

Figure 29 shows the acquisition screen.

The joystick illustrated in Figure 30 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.
On the chin rest there is also a knob for adjusting the height if the adjuster on the joystick is not enough to achieve the correct position.

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

The button  is available in both eye columns; its function is to modify the nature of the lens and Vitreous body during the examination. The Axial Length will automatically be corrected depending on the new refractive index.

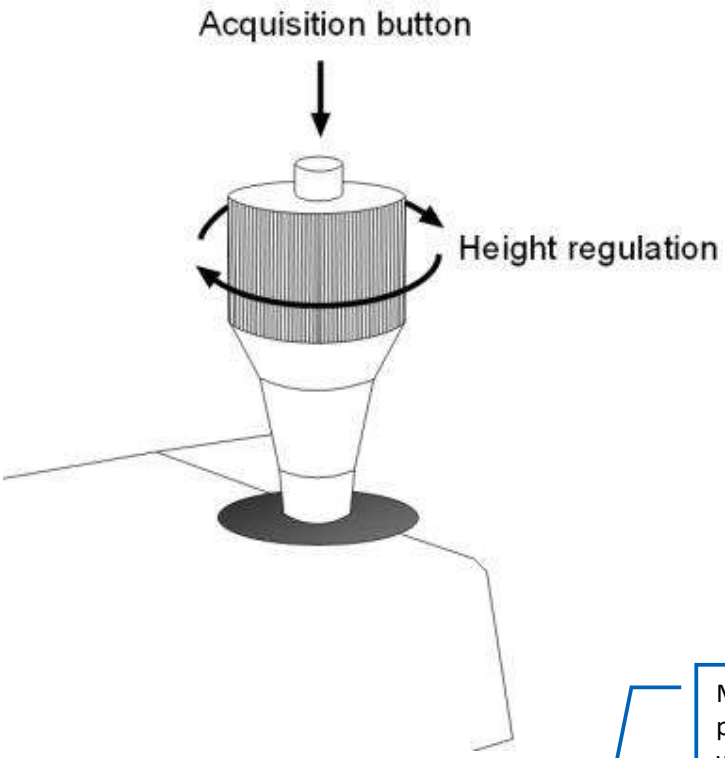


Figure 30

13.4.1 Description of the Acquisition screen

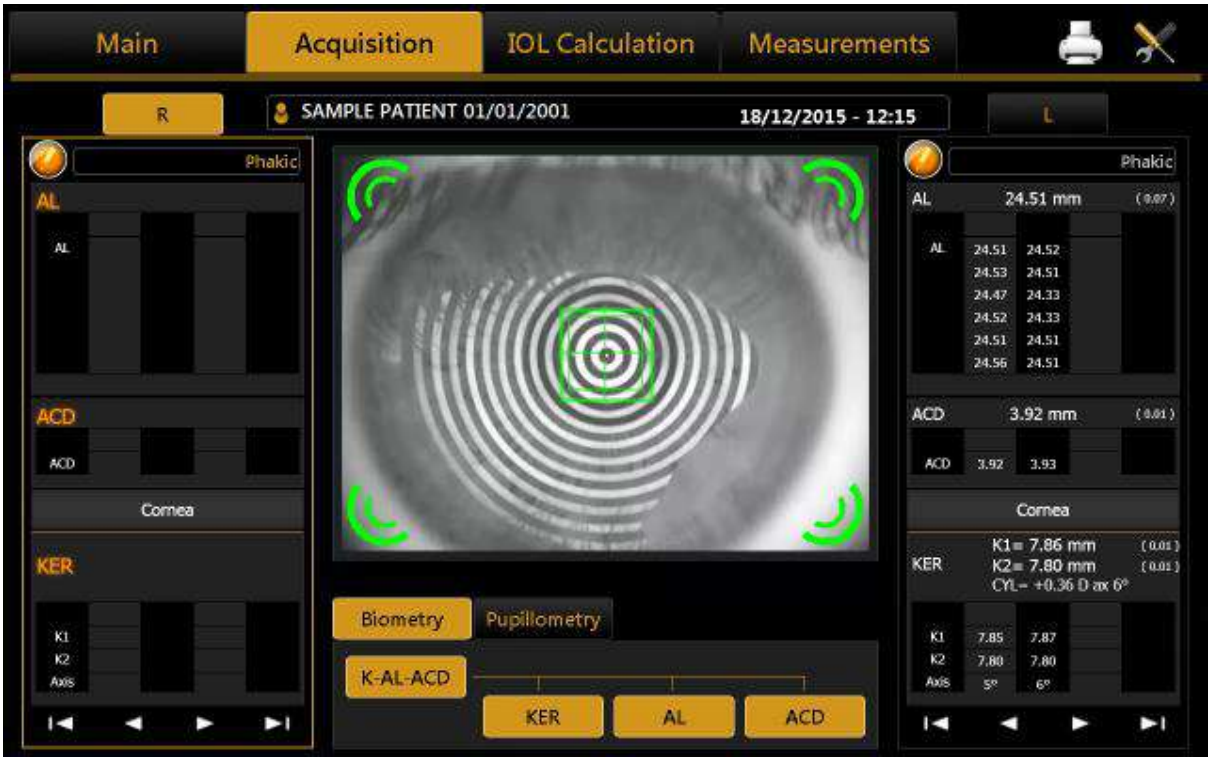


Figure 31

Figure 31 shows the acquisition screen from where all the operations to acquire the required measurements are performed.

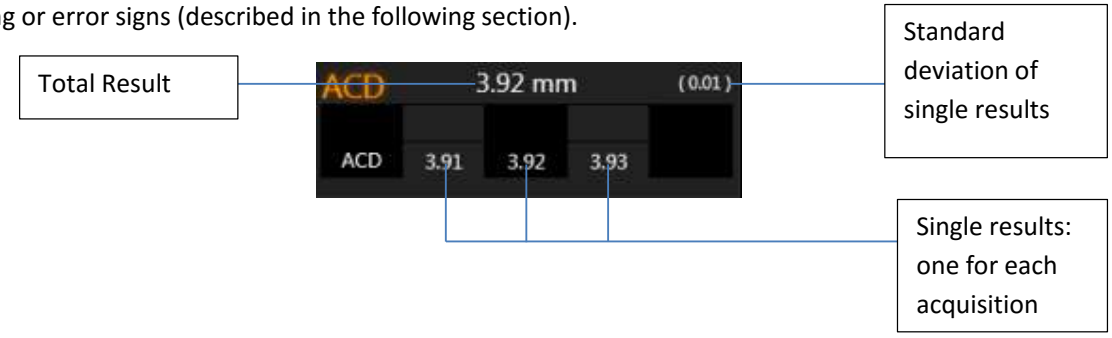
The acquisition window has the following commands:

- ***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.

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 32.

13.4.1.1 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).



13.4.1.2 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 are bad focus, closed* eyelid*, tear film irregularity, high standard deviation in multiple measurements, movement, measurement not in range.*

Figure 32

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*).

Caution should be practised when using the device's ACD measurement for any given intraocular lens calculation because of the high variability of this measurement.

The ACD measurement is the distance between the corneal epithelium and the crystalline lens surface.

As shown in the figure above, 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 manual input (Figure 33), 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.

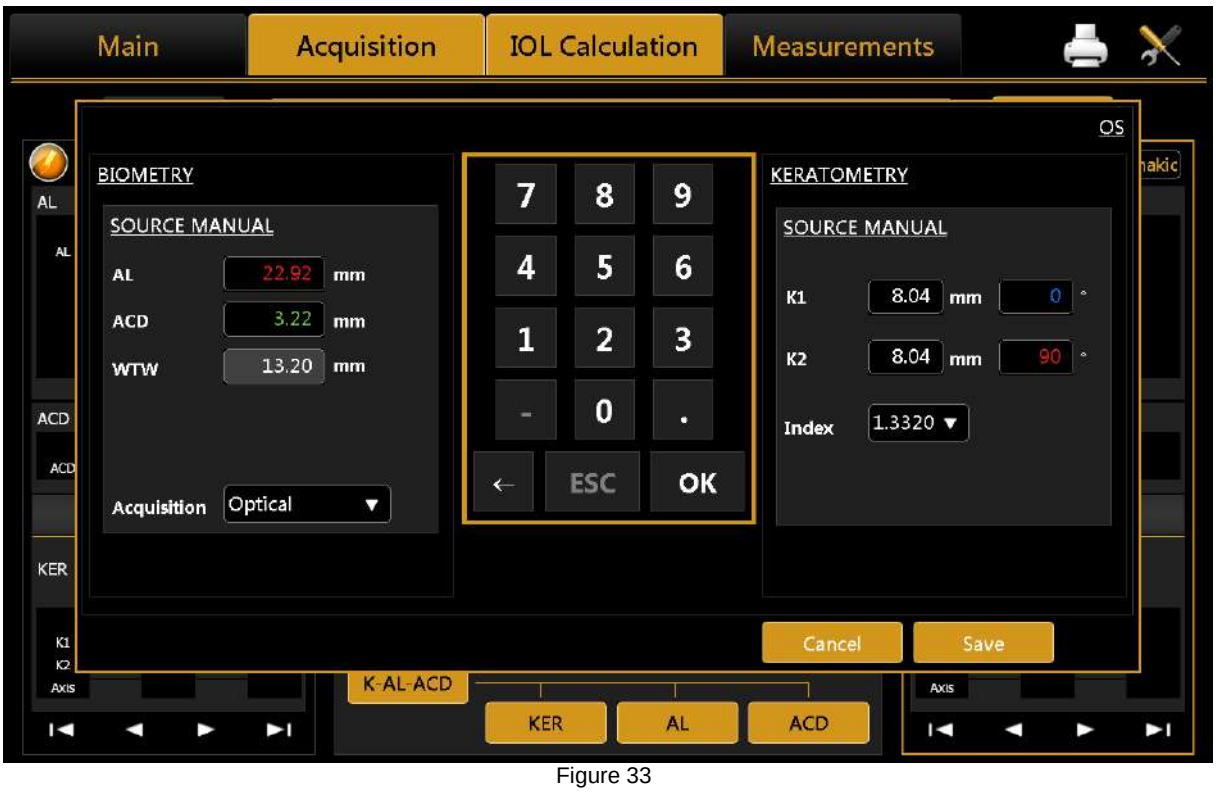


Figure 33

13.4.1.3 Biometry

Selecting the "Biometry" button, you can perform the axial length, anterior chamber depth and keratometry acquisitions either individually or in a full "AL-ACD-K" measurement, where the instrument executes all the measurements in sequence, i.e.

- Axial Length
- Anterior Chamber Depth
- Keratometry

To perform the measurements individually, simply click on one of the “AL” (axial length), “ACD” (anterior chamber depth) or “KER” (keratometry) buttons.

WARNING: ***a correct ACD measurement cannot be made without acquiring the patient's keratometry.***

Caution should be practised when using the device’s ACD measurement for any given intraocular lens calculation because of the high variability of this measurement.

The ACD measurement is the distance between corneal epithelium and the crystalline lens surface.

13.4.1.4 Pupillometry

Selecting the "Pupillometry" button gives access to the environment for the acquisition of the following measurements:

- Dynamic pupillometry
- Photopic pupillometry
- Mesopic pupillometry

13.5 Full biometry acquisition (K-AL-ACD)

Figure 34

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

- Axial length measurement
- Anterior chamber depth

- Acquisition of the topographic map with all associated measurements
- Identification of Mesopic and Photopic pupil

13.5.1 Acquisition procedure

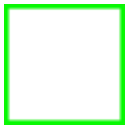
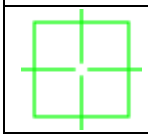
Backlighting of the Placido disk is automatically activated when you enter the acquisition environment. If the instrument is not used for a few minutes, the cone turns off; to turn it on again, just press the joystick button.
To acquire the image or measurements in general, whatever mode you are in,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

1. Align the live image in the center and focus, then press the joystick button to start the acquisition.
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:

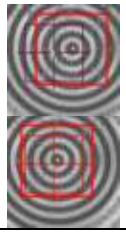
- Centering
- Focusing distance

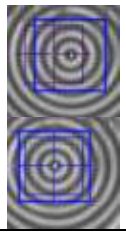
Centering ideal conditions are achieved by **centering the two squared aims** by means of horizontal and vertical movements.
The squared aims are the following:

	**Ideal Centering Marker**, represents the ideal axis of alignment, matching the center of rings in the Placido image of the eye
	**Current Centering Marker**, represents the current axis of alignment , matching the center of the viewport

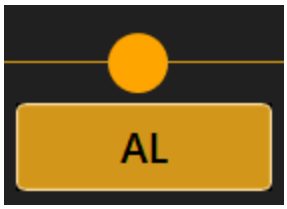
The two squares assume different colors depending on two aspects: focusing position and centering in tolerance.

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. In this situation the centering aims assume different tones of red color, as follows:  The centering condition is out of tolerance (**Ideal Centering Marker** and **Current Centering Marker** have different tones) The centering condition is in tolerance (**Ideal Centering Marker** and **Current Centering Marker** have the same tone)

	The blue arrows indicate to move the instrument backwards away from the patient. In this situation the centering aims assume different tones of blue color, as follows:  The centering condition is out of tolerance(**Ideal Centering Marker** and **Current Centering Marker** have different tones) The centering condition is in tolerance (**Ideal Centering Marker** and **Current Centering Marker** have the same tone)
	The green icons 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 (**Ideal Centering Marker** is orange and **Current Centering Marker** is yellow) The centering condition is in tolerance (**Ideal Centering Marker** and **Current Centering Marker** are both green)

During the acquisition procedure, pulsating signals appear above the “KER”, “AL” and “ACD” buttons to guide you through the several 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.

13.5.2 Further adjustments for the anterior chamber depth

Caution should be practised when using the device's ACD measurement for any given intraocular lens calculation because of the high variability of this measurement.

The ACD measurement is the distance between corneal epithelium and the crystalline lens surface.

At the end of the automatic acquisition of K-values and axial length, ACD must be acquired manually following the alignment procedure.

Figure 35

The slit is turned on, and the central alignment of the slit on the corneal apex can be performed.

Follow the instructions of the red and blue arrows until optimum acquisition conditions have been reached and the software will automatically capture the image for the measurement.

13.6 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 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 36 appears.

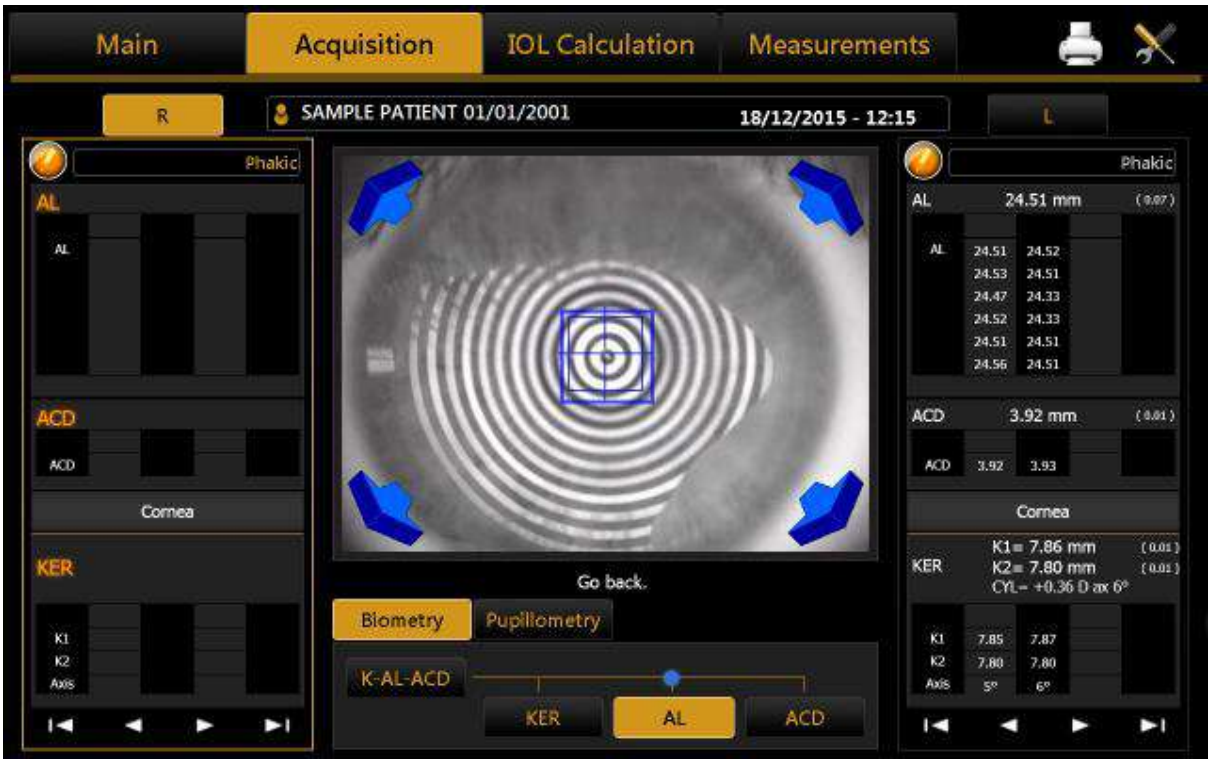


Figure 36

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 “K-AL-ACD” acquisition.

13.7 Acquisition of the anterior chamber measurement (ACD)

The anterior chamber depth may only be measured on phakic eyes! ACD measurements of pseudophakic eyes result in measuring errors and/or incorrect readings. The readings for pseudophakic eyes do not reflect the anterior chamber depth.

The keratometer measurement must be performed before anterior chamber depth measurement.

Caution should be practised when using the device’s ACD measurement for any given intraocular lens calculation because of the high variability of this measurement.

The ACD measurement is the distance between corneal epithelium and the crystalline lens surface.

Fine adjust the device, so that:

- the fixation point is displayed in optimum focus in the square on the screen (only the fixation point should be within the square, not the other image details),
- no reflections must be in the image of the cornea (can cause interference), otherwise the reading will be incorrect,
- the anterior crystalline lens is optimally visible. As a rule, the image of the fixation point will lie between the images of the cornea and the crystalline lens. It should be close to (but not within) the optical section of the crystalline lens.

By selecting this mode, the acquisition environment appears as shown in Figure 37.
Press the joystick button and move the device according to the instructions of the automatic guidance system (red and blue arrows) until ideal conditions have been reached (green icons).

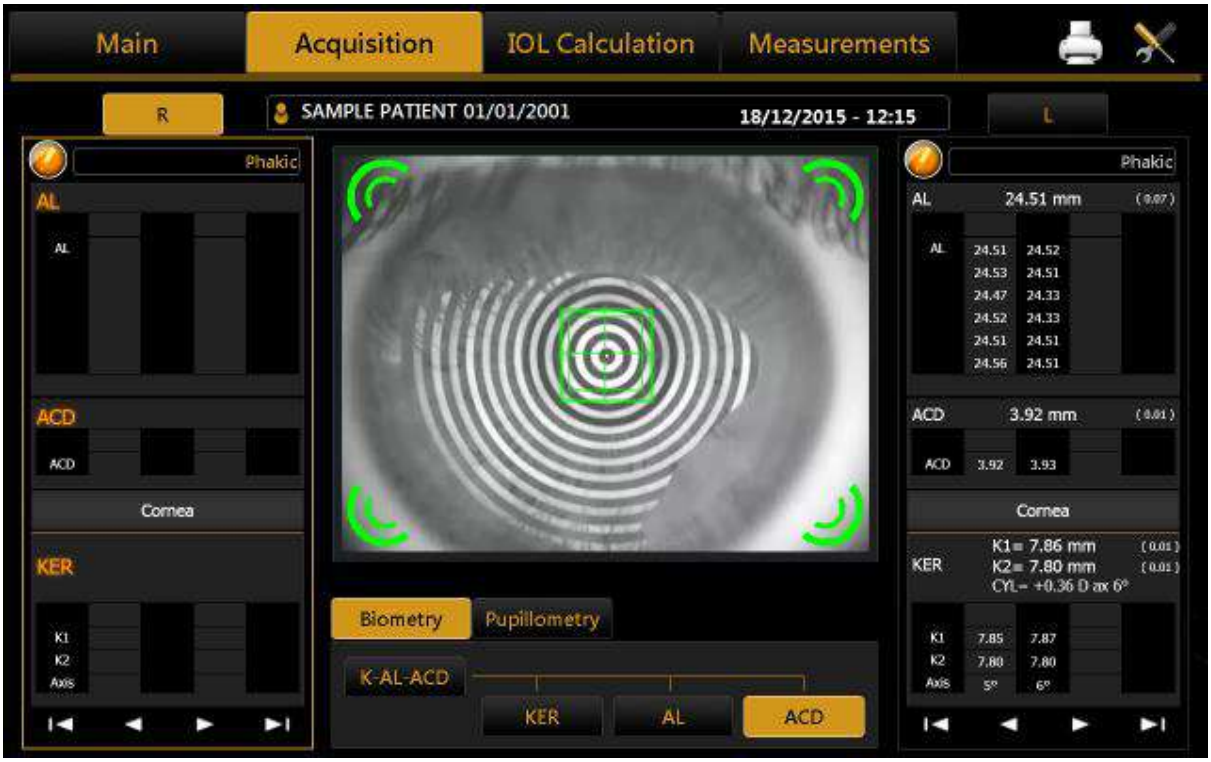


Figure 37

The acquisition proceeds by projecting a slit light beam onto the cornea (Figure 38).

Figure 38

Follow the instructions of the red and blue arrows until optimum acquisition conditions have been reached and the software will automatically capture the image for the measurement.
In these conditions, the instrument records the anterior chamber depth.

13.8 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 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 39 appears.

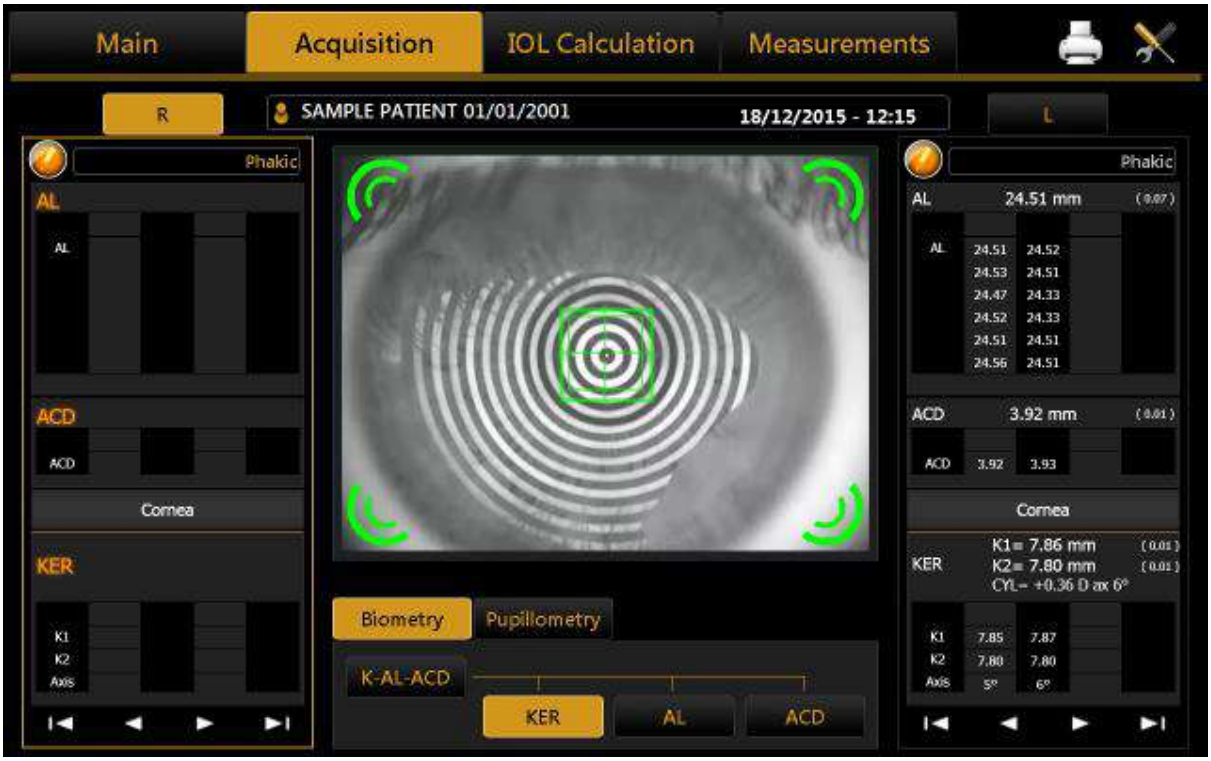


Figure 39

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 right column, which is referring to the left eye.
This section has the same interactions as the “K-AL-ACD” 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.

13.9 Acquisition of the dynamic, photopic, mesopic pupillometry

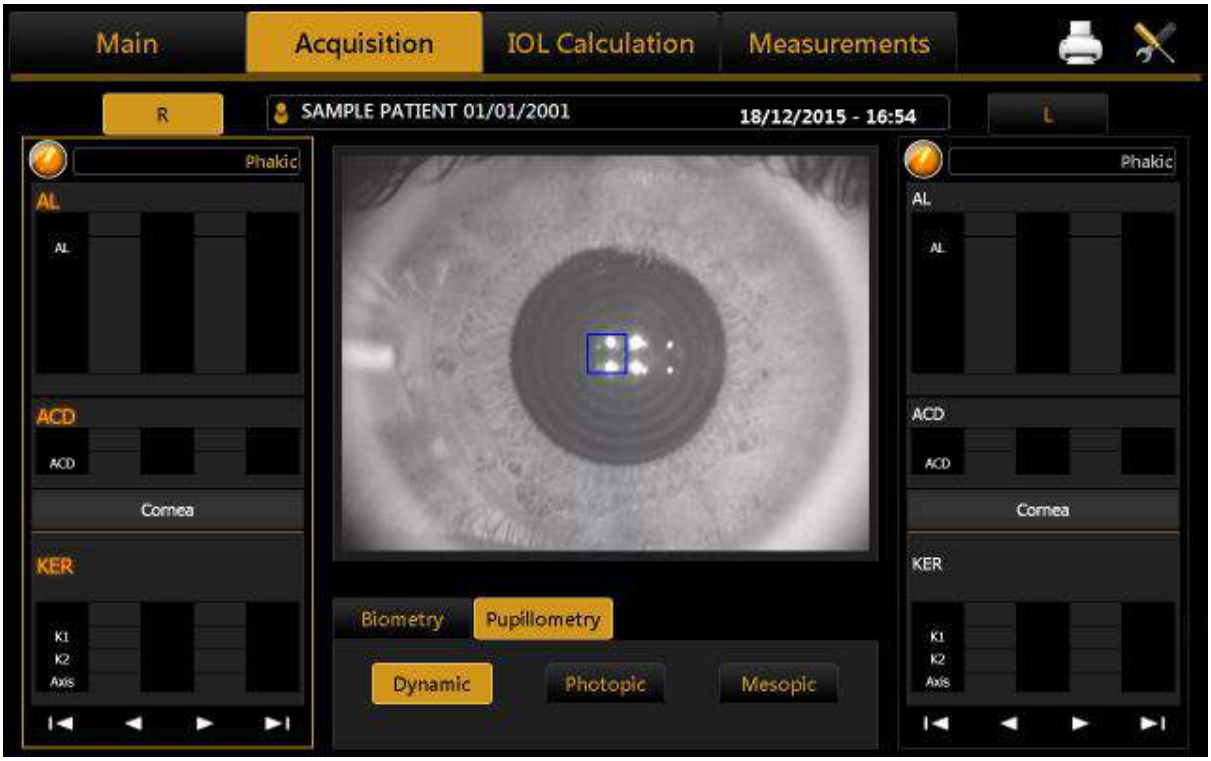


Figure 40

By selecting this mode, the acquisition environment shown in Figure 40 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 41.

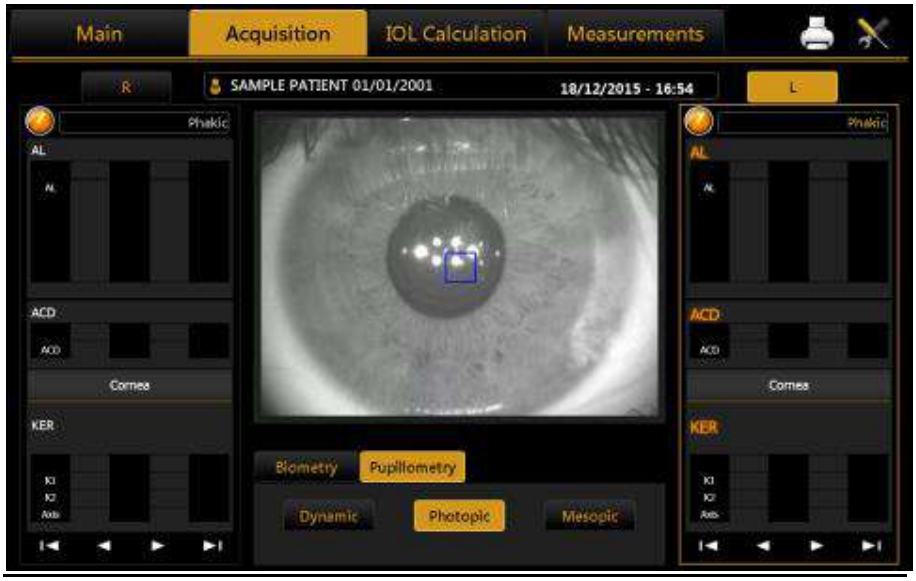
Press the joystick button to start the acquisition and press the button again to stop the acquisition.
As already mentioned in the introductory paragraphs, three types of acquisition can be performed:

- 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.

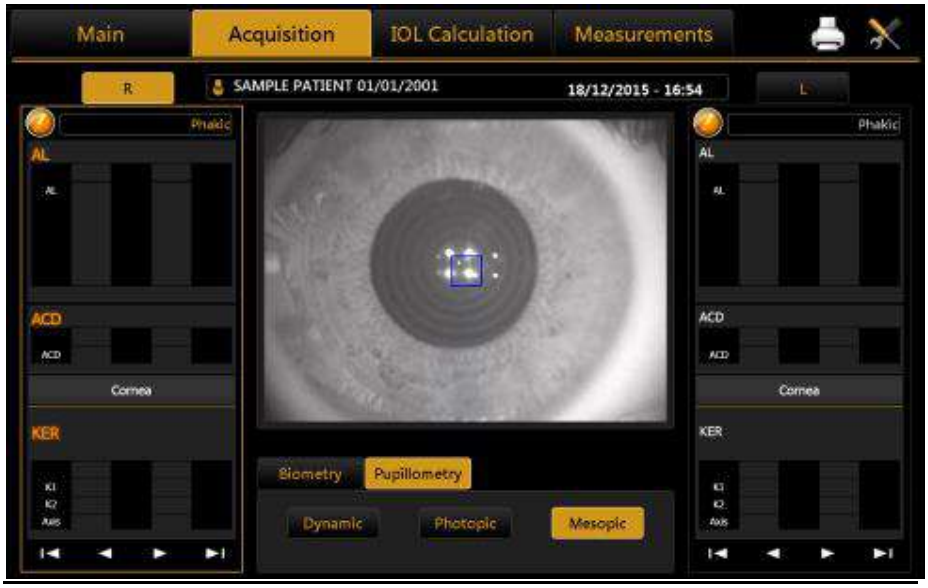
For the dynamic acquisition, a sequence of images is recorded and allows you to "review" the evolution of the pupil through the various different light conditions to which it is subjected. In the pupillometry acquisition in static controlled light conditions: photopic and mesopic, certain frames are 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 41



Acquisition in mesopic controlled light conditions

Figure 42

13.10 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 43 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.

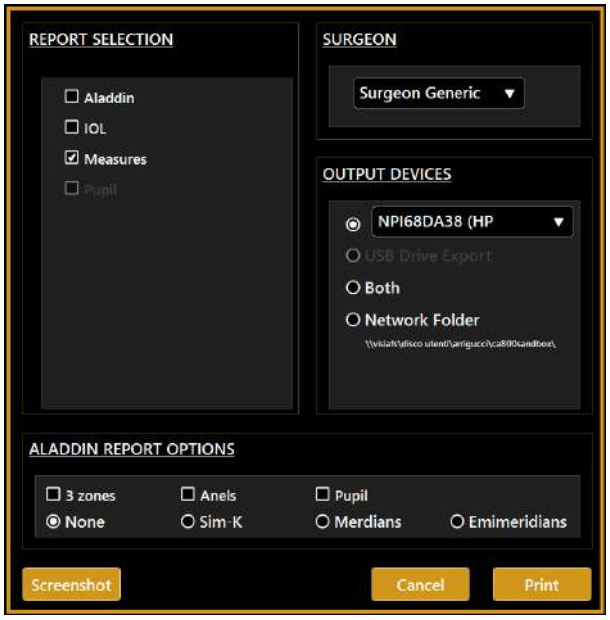


Figure 43

In addition to these two options you can select a network folder as destination of report to print. For network folder settings, see 13.15.5.1.

The "Aladdin Report Options" allow to define which overlay will be printed in the topography maps images of the "Aladdin". Refer to sections 13.13.1 and to 13.15.2 for details about this options.
By clicking on the Screenshot button (Figure 43) you can open the print screen preview and, as shown in Figure 44, send to print the document as represented in the preview.

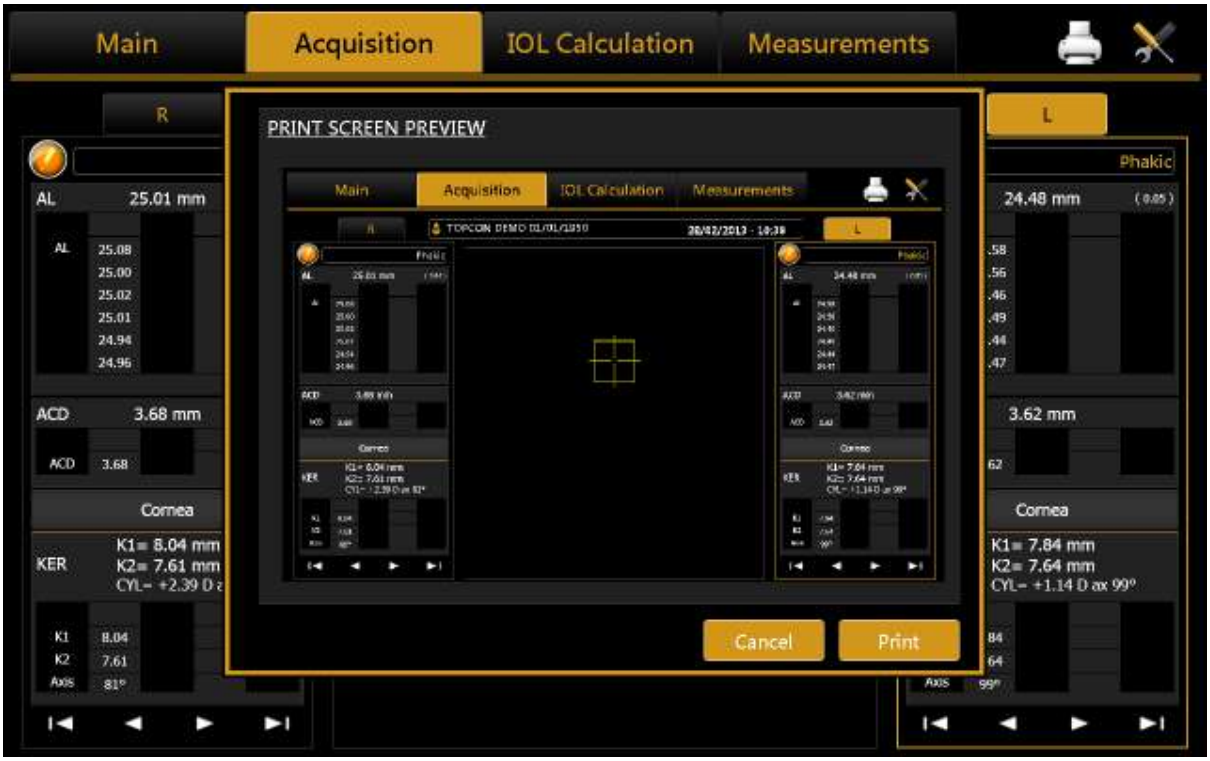
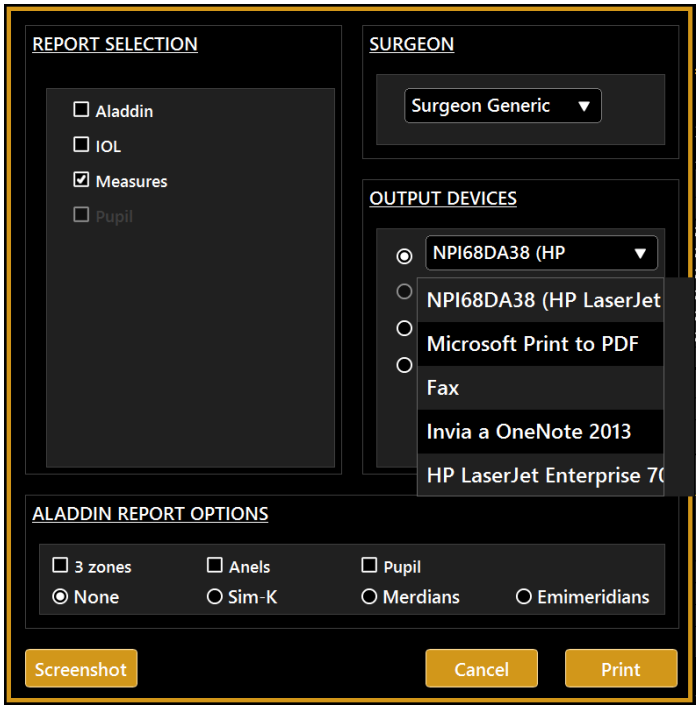


Figure 44

13.10.1 Available Printers

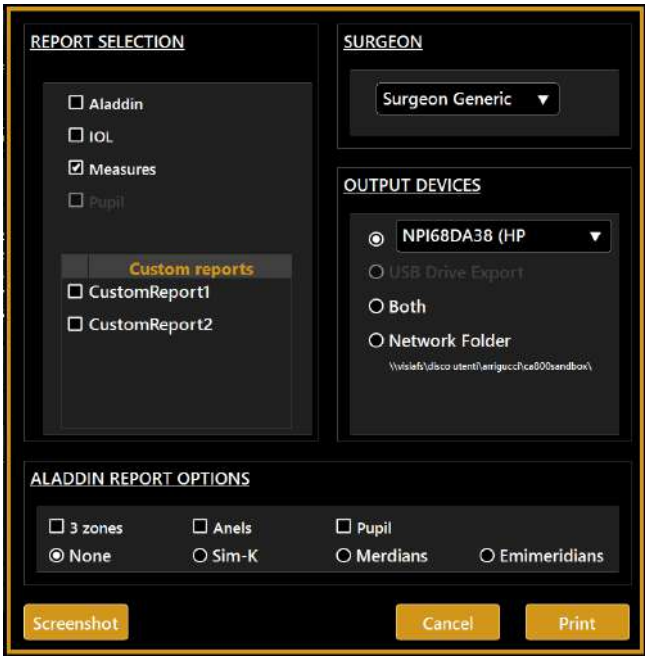
The printing form is showing a list of available printers. The available printers are the one installed on the Operating System. Refer to “Appendix: Installing an external printer” or ask to your technical support in order to have the desired printer installed.

The application pre-selects always the last used printer.



13.10.2 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.



13.11 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 45 is show where you can select one or more destinations for exportation.

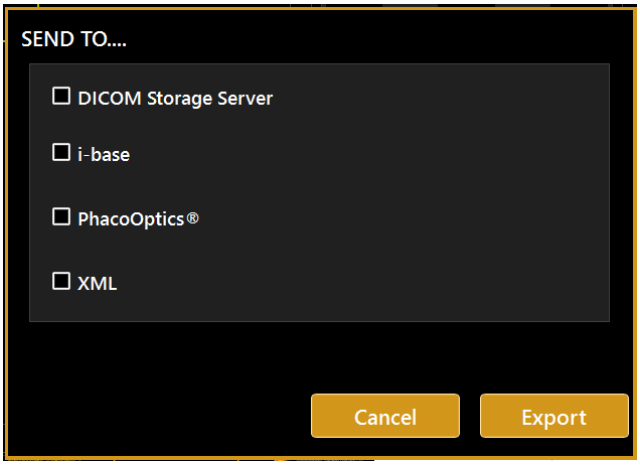


Figure 45

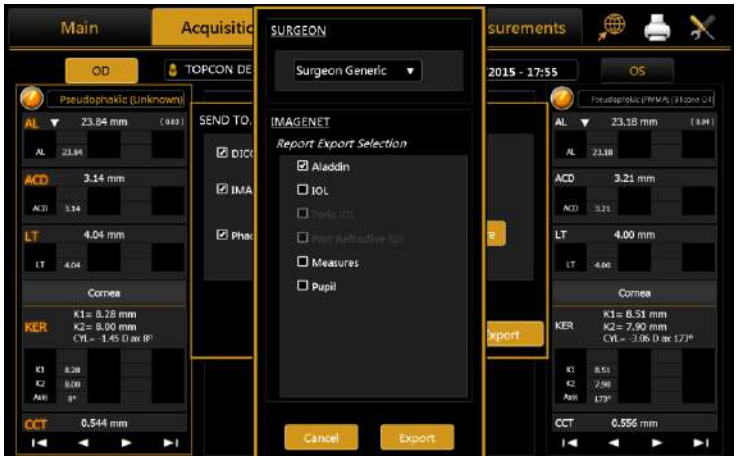
Currently available destinations are:

- **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 13.15.5 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 13.15.5.

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

13.12 IOL CALCULATION

ALADDIN 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.**

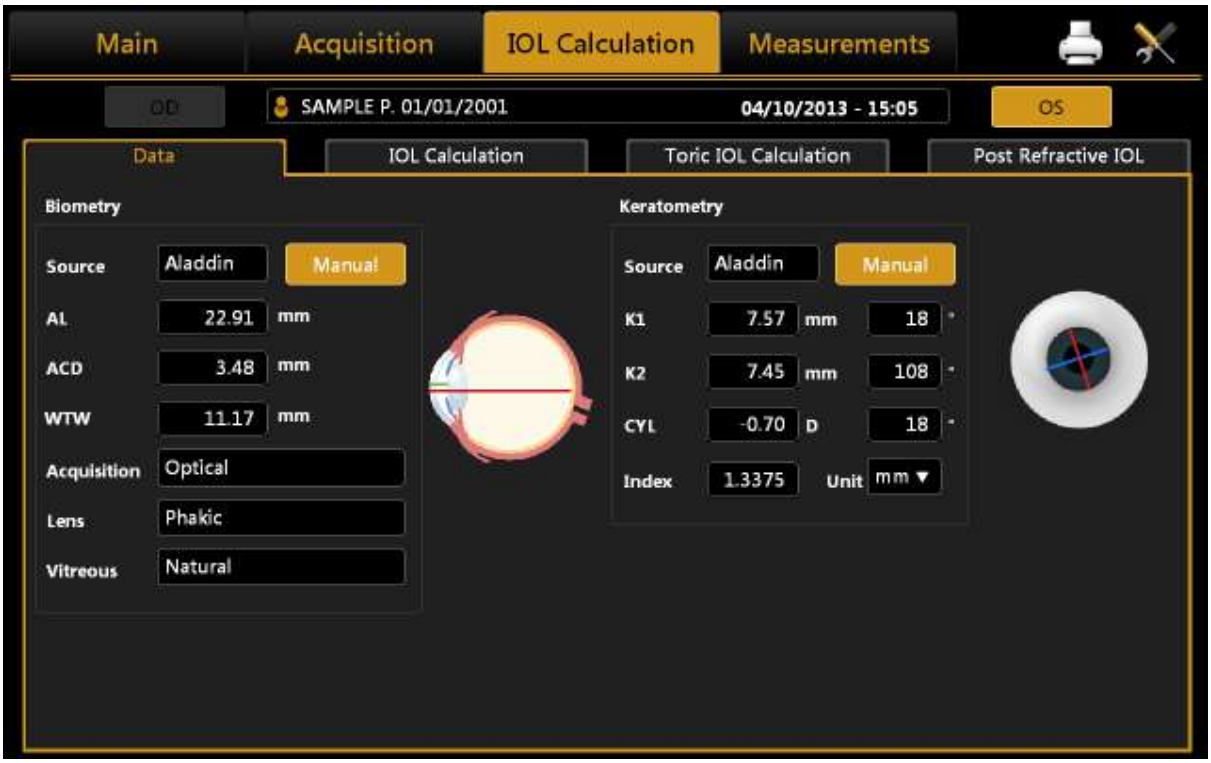


Figure 46

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

- Data
- IOL Calculation
- Toric IOL calculation
- Post Refractive IOL Calculation

Caution: The Toric IOL Calculation function is not available for the US market.

The first time a surgeon enters in IOL Calculation, it will appear the panel shown in Figure 47 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 13.15.4.1), where you can even reactivate its appearance at every IOL usage.

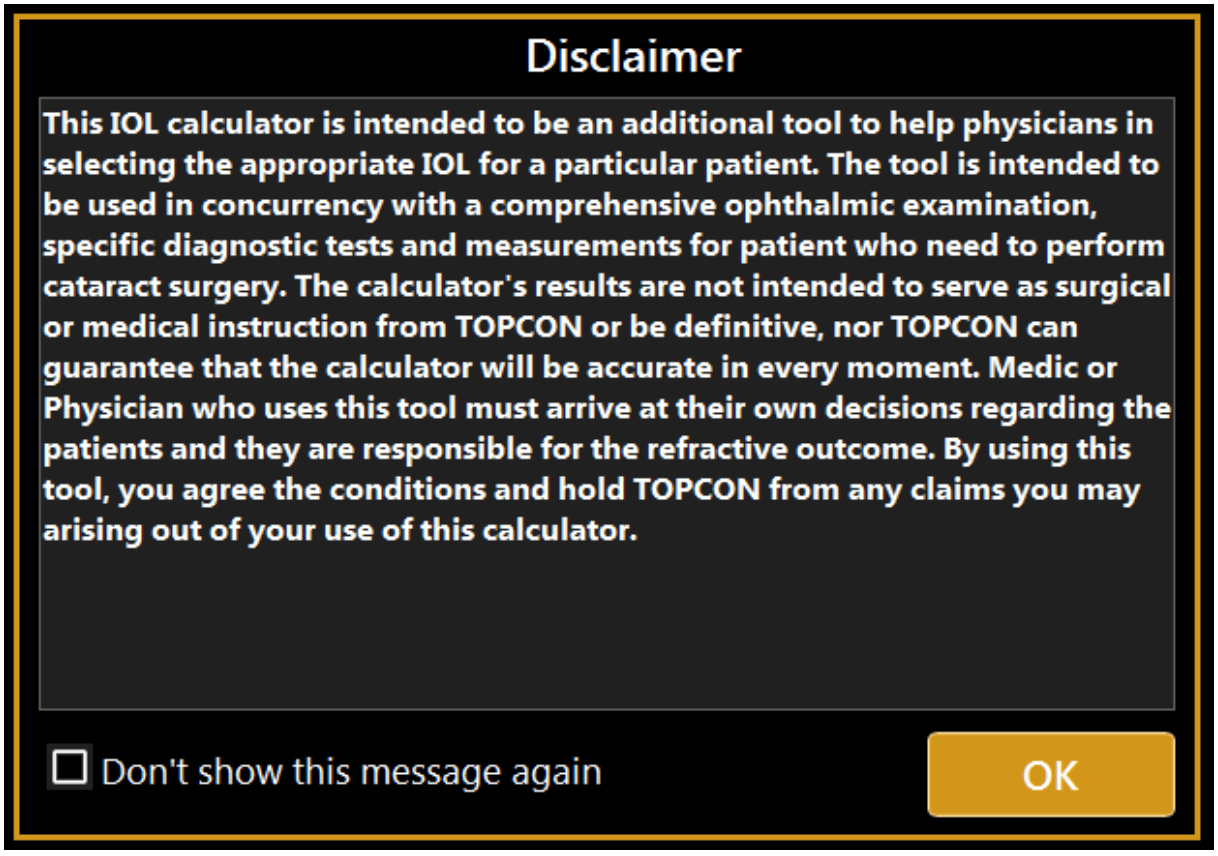


Figure 47

13.12.1 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 46. 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 46), 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 48) where you can enter the data manually using the numeric keypad.

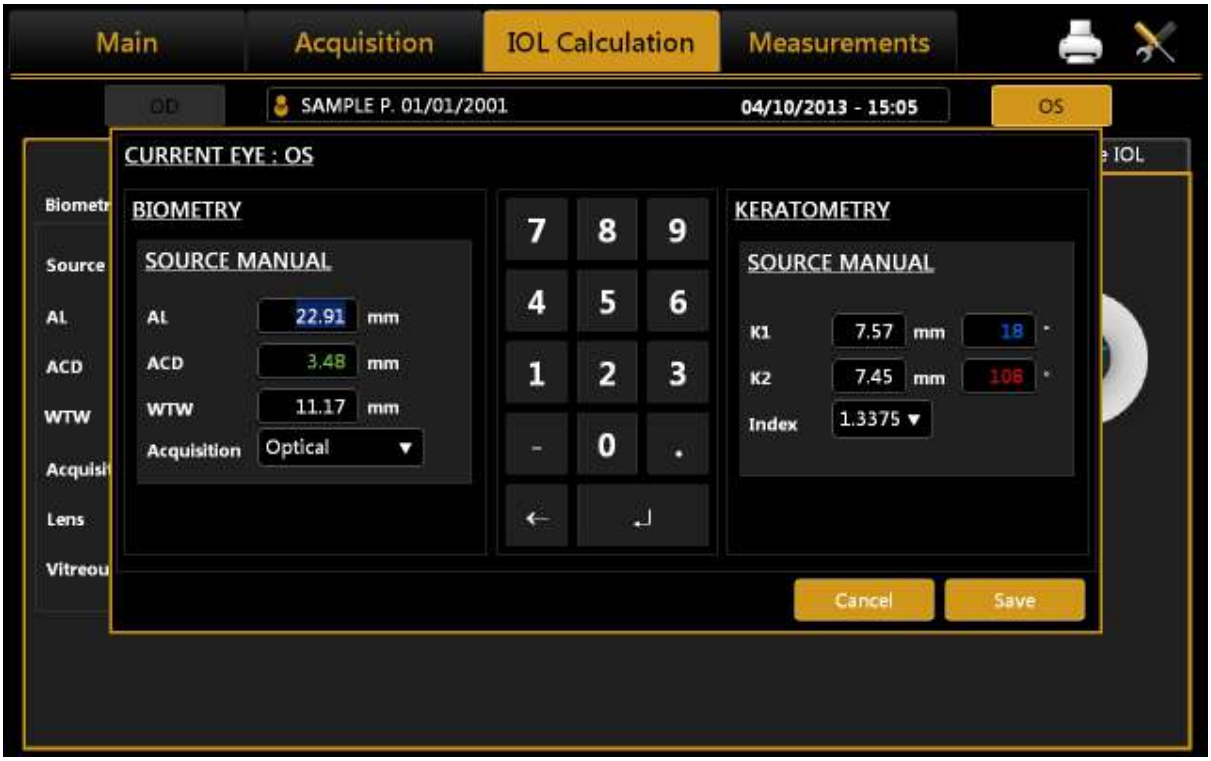


Figure 48

In Figure 48 (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 48 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.*

13.12.2 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 a topography, the need for an astigmatic correction, can confidently use the Oculentis 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.

Caution: The Toric IOL Calculation function is not available for the US market.

Finally, 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.

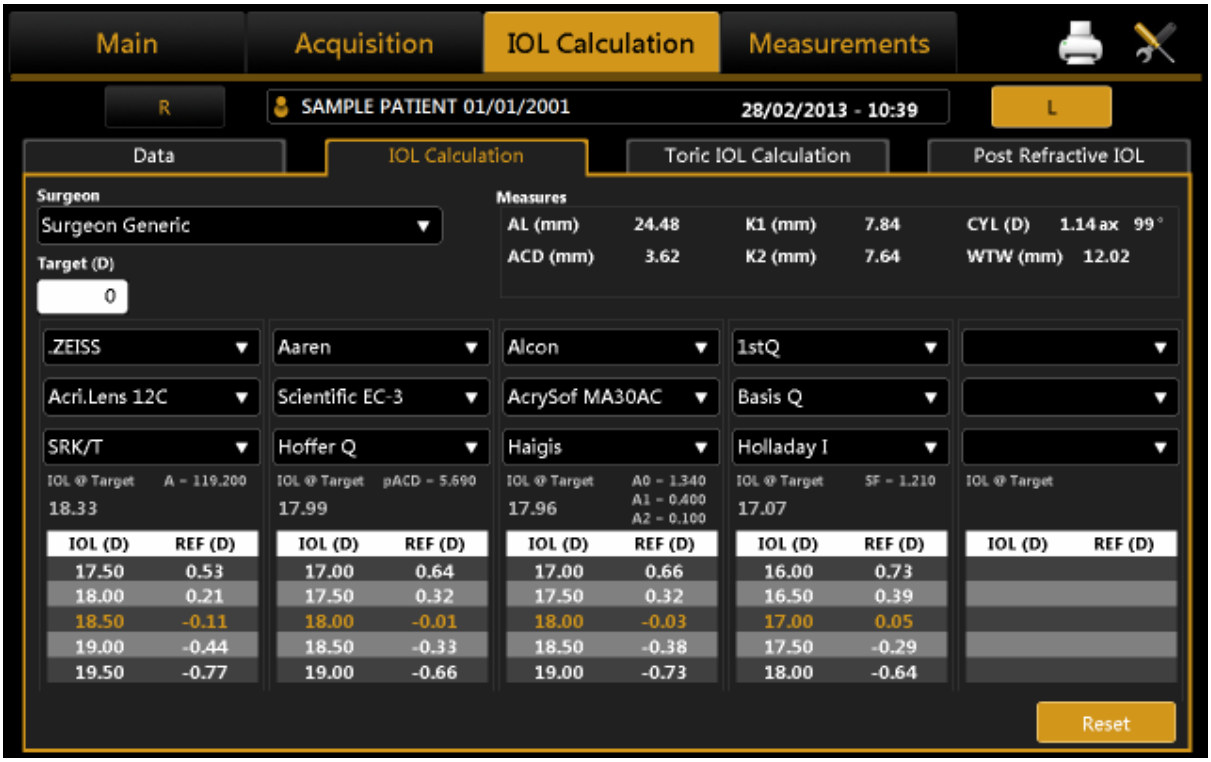


Figure 49

Figure 49 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 presetting 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. 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.

13.12.3 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.

Caution: The Toric IOL Calculation function is not available for the US market.

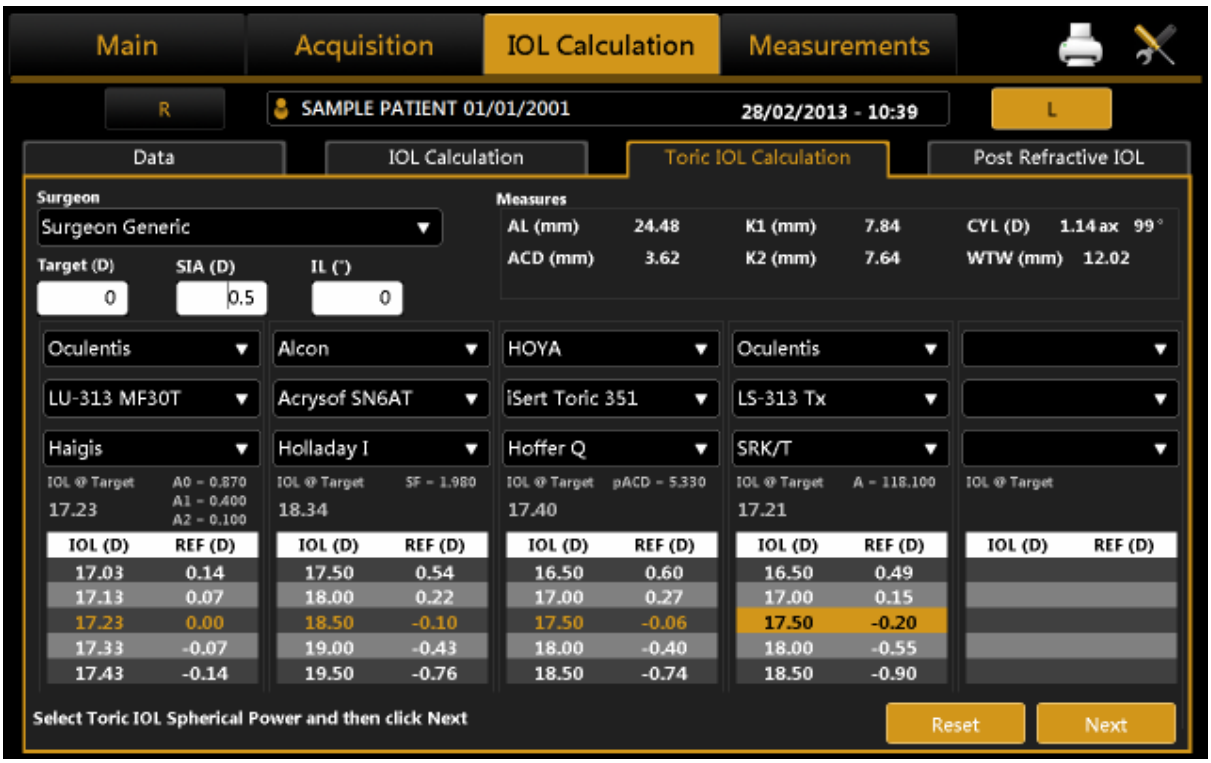


Figure 50

Figure 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 13.15.4.3).

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 48).

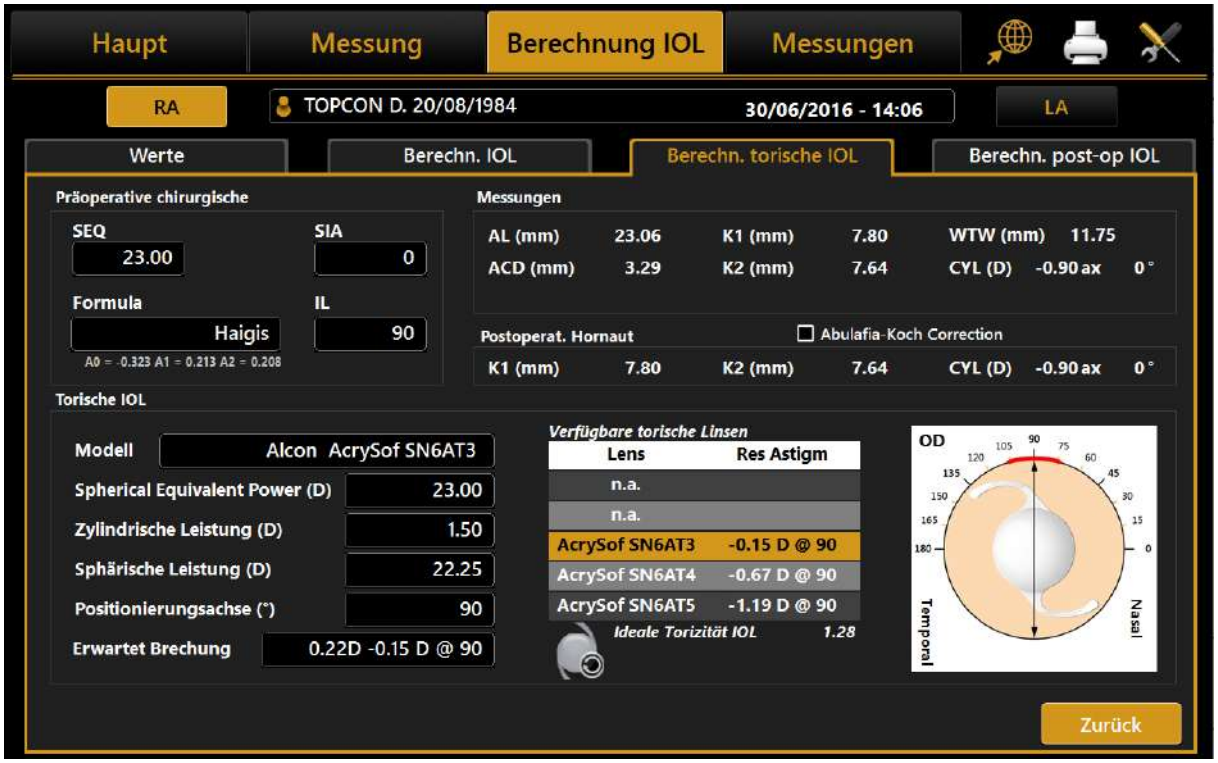


Figure 51

"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 spherical and 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 52).

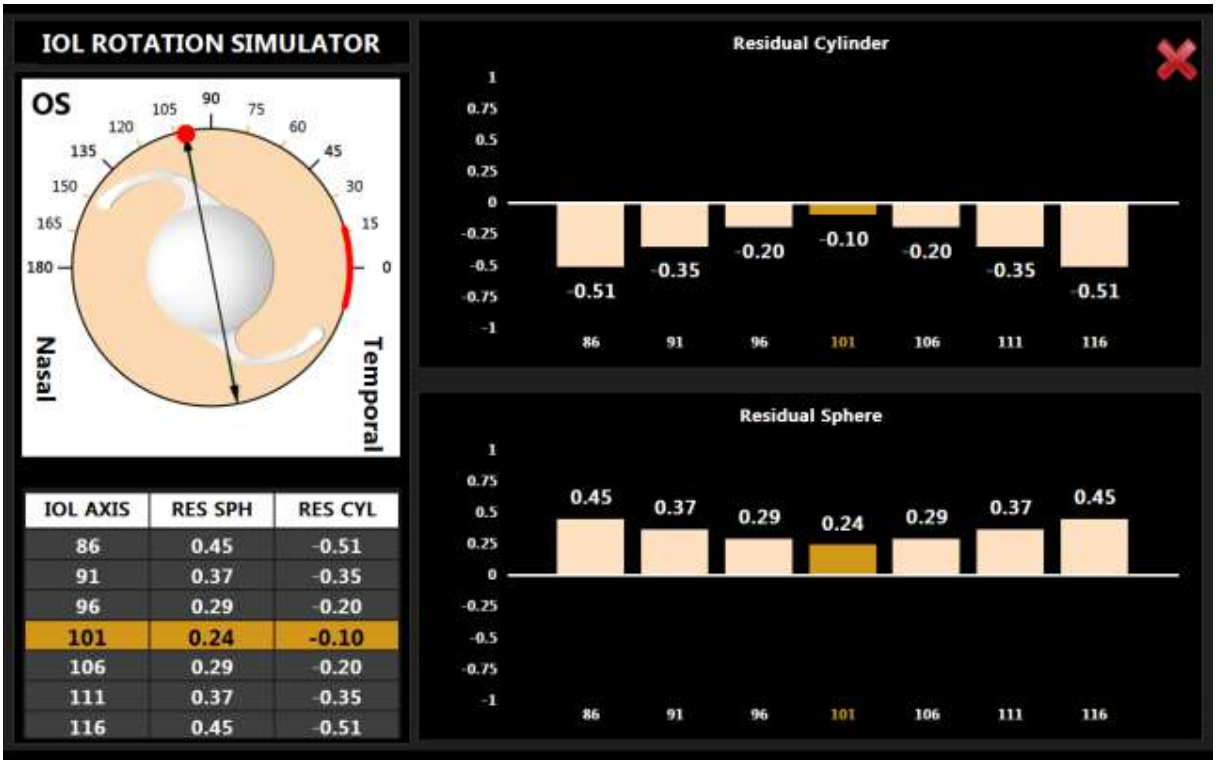


Figure 52

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

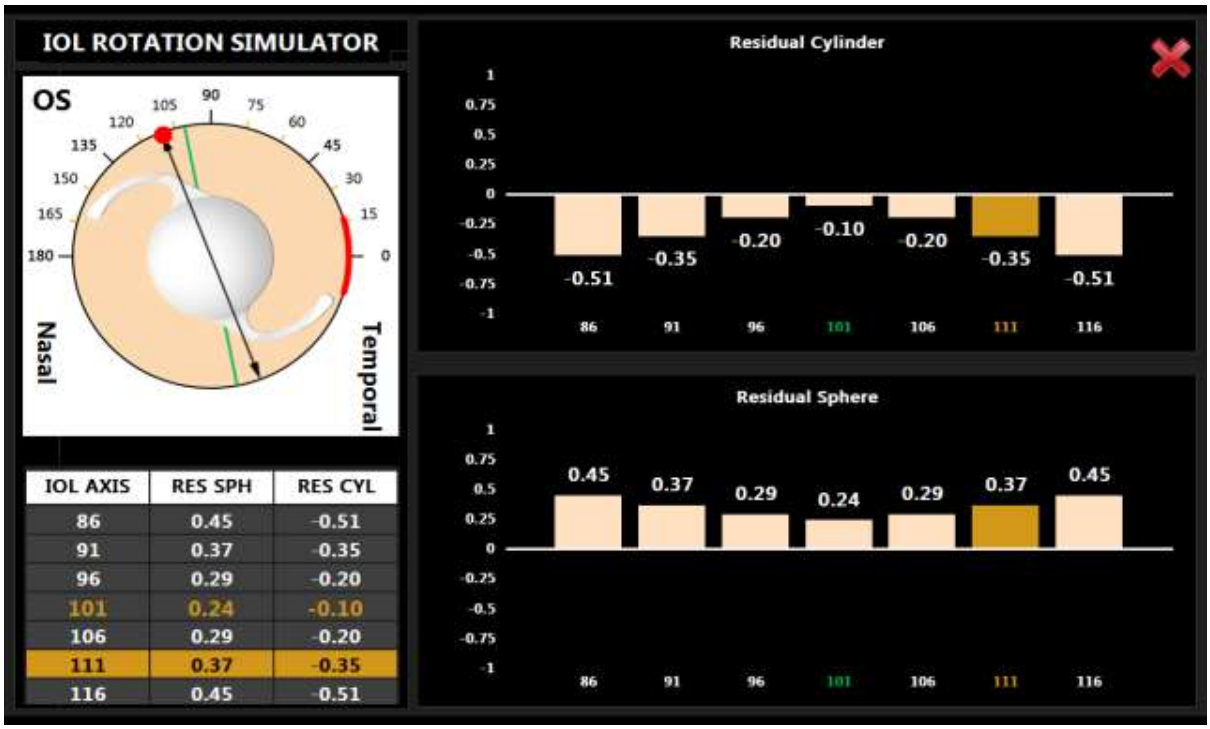


Figure 53

13.12.4 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 54).

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.

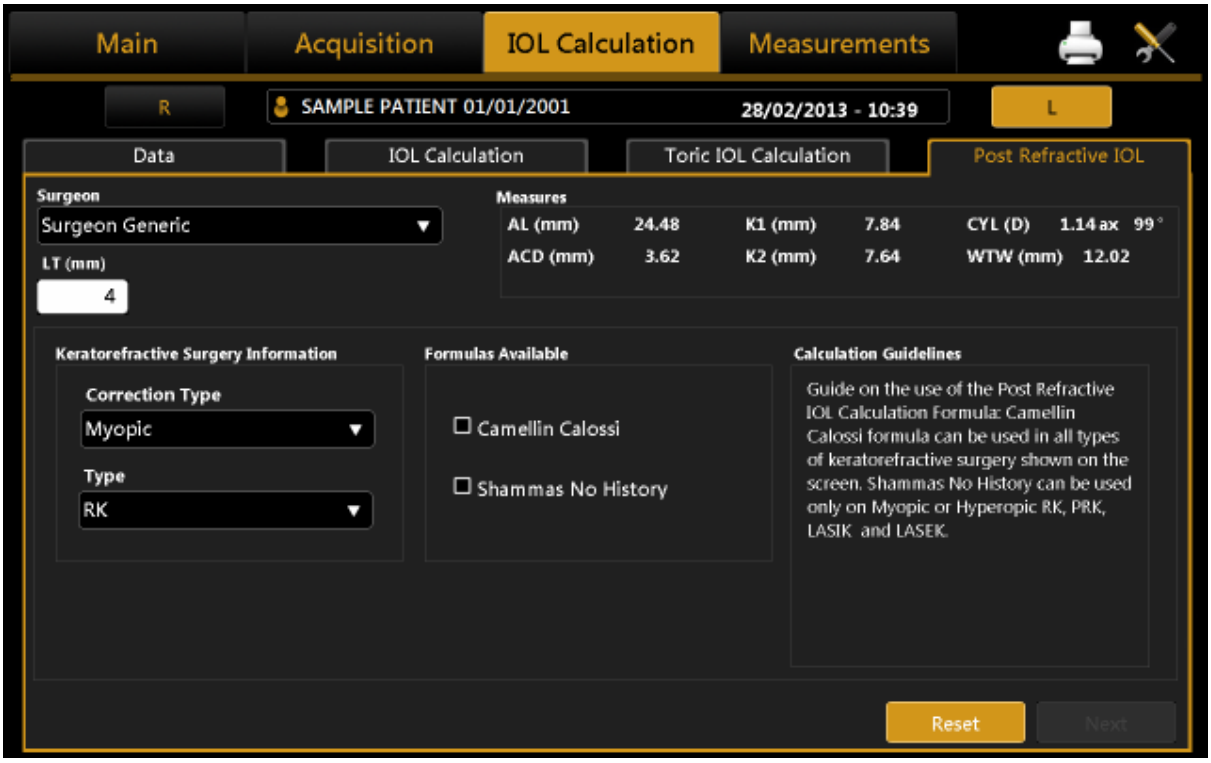


Figure 54

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.
Next, select the correction type between the option shown below:

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

If the correction type is unknown:

- it won't be 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 55).

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.

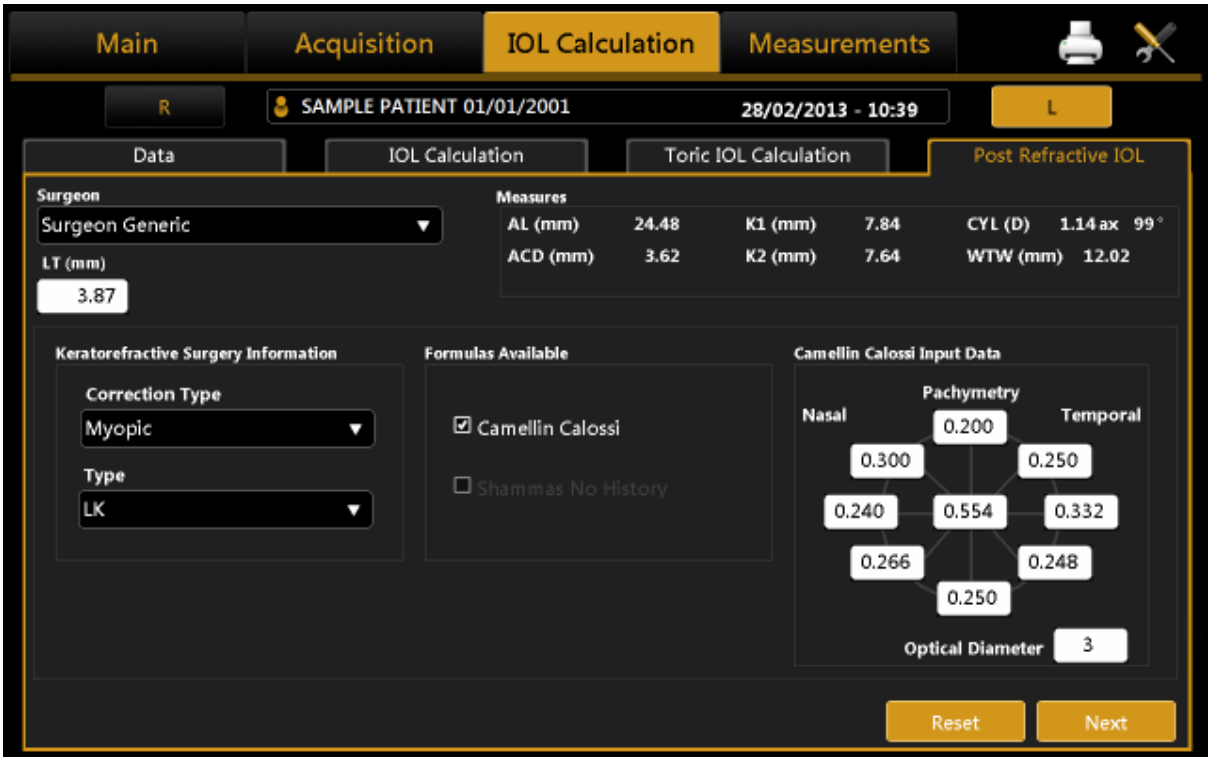


Figure 55

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.

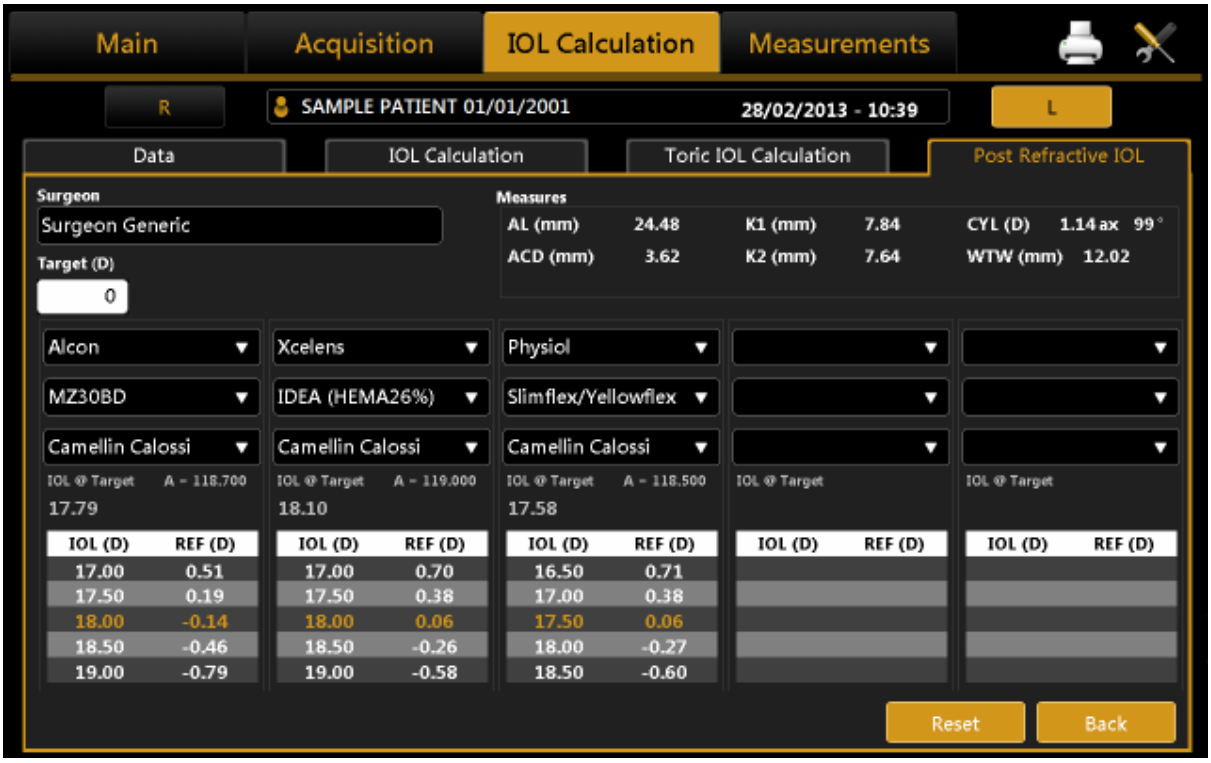


Figure 56

The final result of the Post-Op calculation is shown in Figure 56 with the suggested lens highlighted in yellow.

13.13 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
- **ACD:** Anterior chamber depth
- **PUP:** Pupillometry

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

13.13.1 TOPOGRAPHIC MAP (KER)

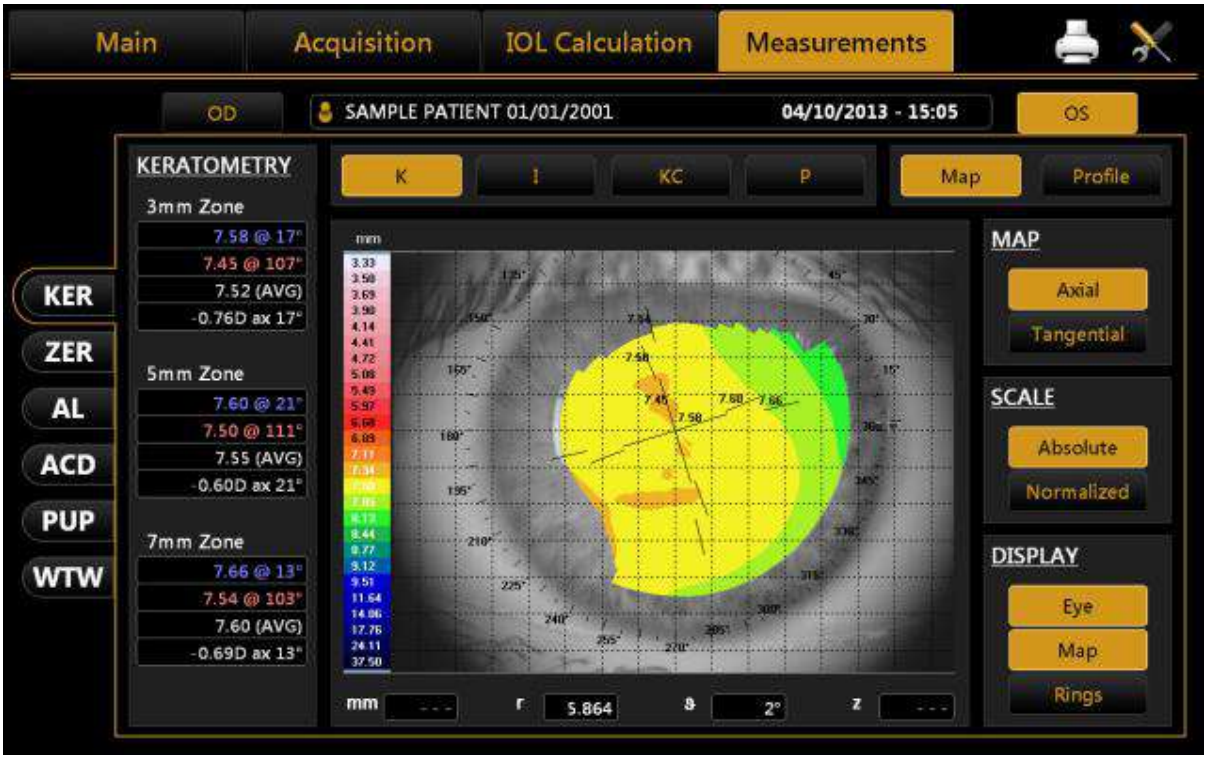


Figure 57

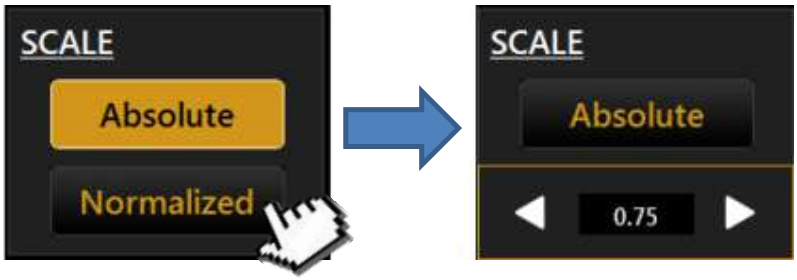
The environment displayed is shown in Figure 57.
Click on the ***"OD"*** or ***"OS"*** buttons to display the map of the right or left eye. The R and L buttons are only active if the keratometry of the eye in question has been acquired.
In the right column, you can select the following options:

- ***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 13.15.2 for more settings relative to the topographic map representation.

13.13.1.1 Topographic map indices

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

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

13.13.1.2 Keratometry

Press the ***"K"*** button to display the keratometric data on the 3 mm, 5 mm and 7 mm zones, as shown in Figure 57 (by settings the zones can be set to 2,4,6 mm).

13.13.1.3 Keratorefractive indices

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

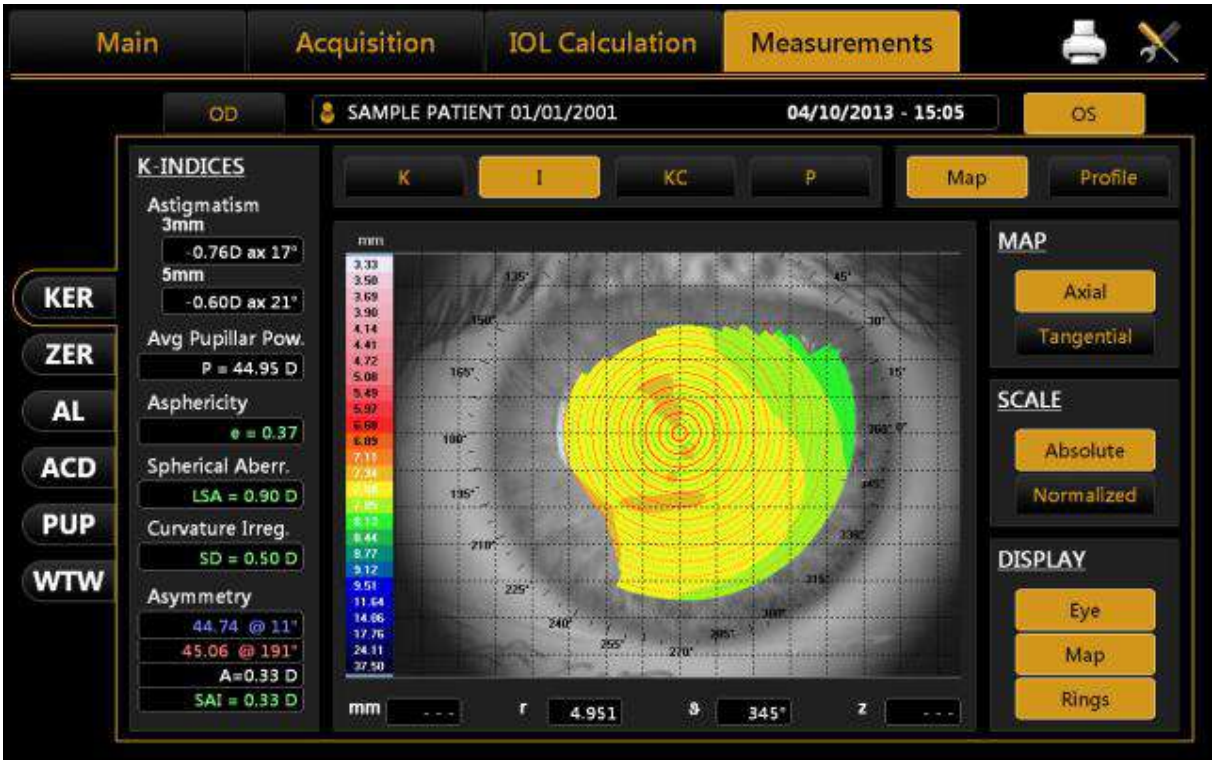


Figure 58

- **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.

13.13.1.4 Keratoconus

Press the ***"KC"*** button to open Keratoconus screening with the following information:

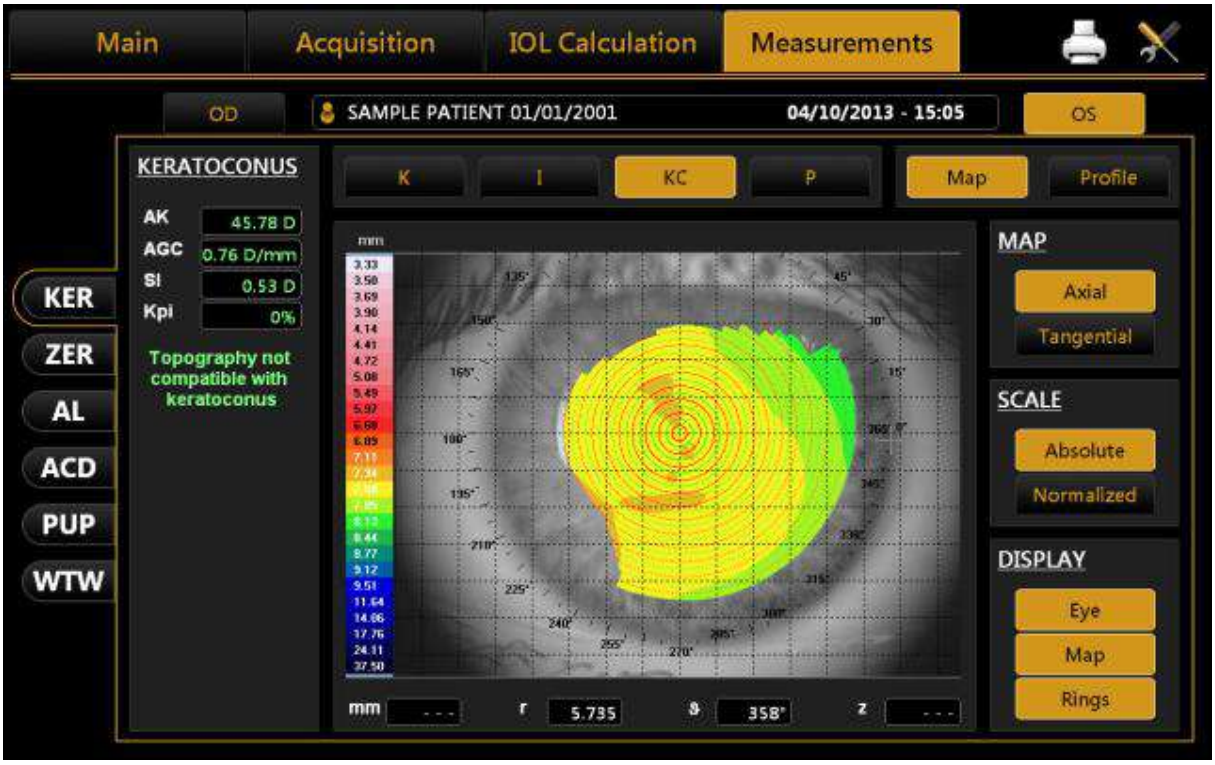


Figure 59

- ***AK***: Apical curvature.
  Represents the power of the cornea in its apex
- ***AGC***: apical gradient of curvature.
  Represents the average variations per unit of length of the corneal power, taking the apical power as reference.
- ***SI***: difference between the average power of two circular zones centered 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

13.13.1.5 Pupil

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

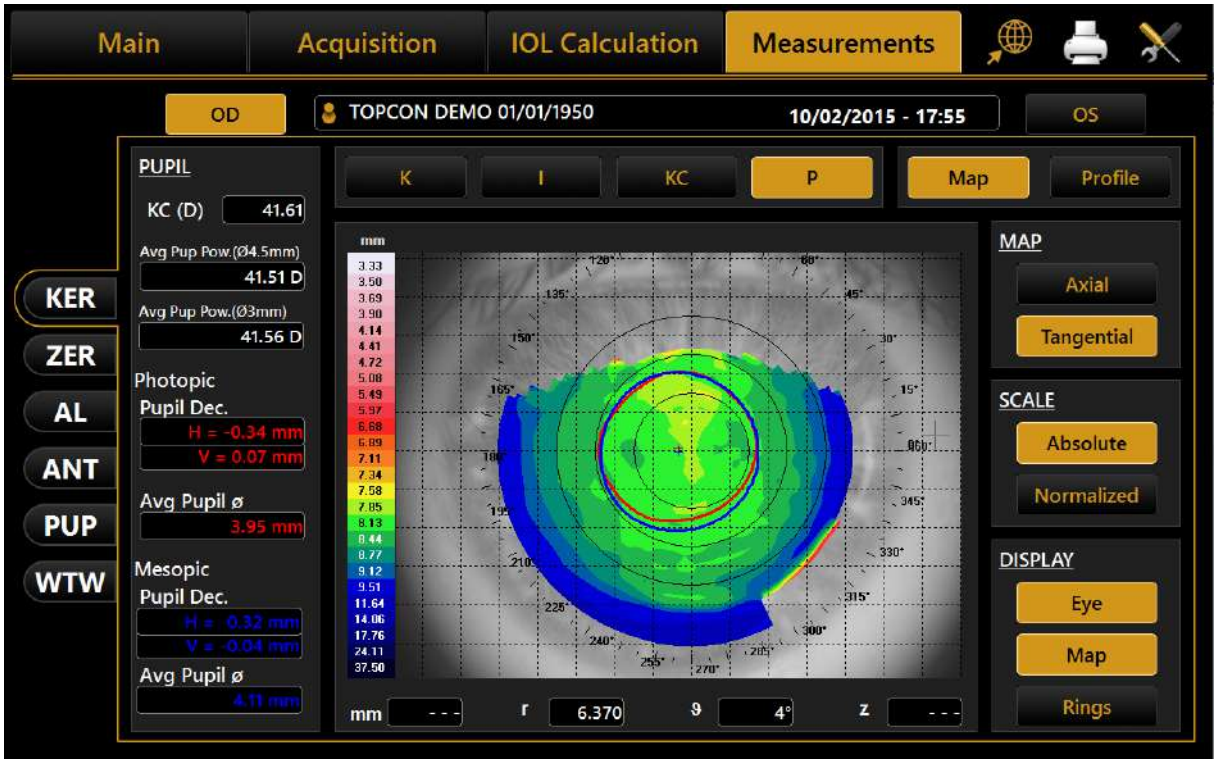


Figure 60

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

13.13.1.6 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 61).

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.

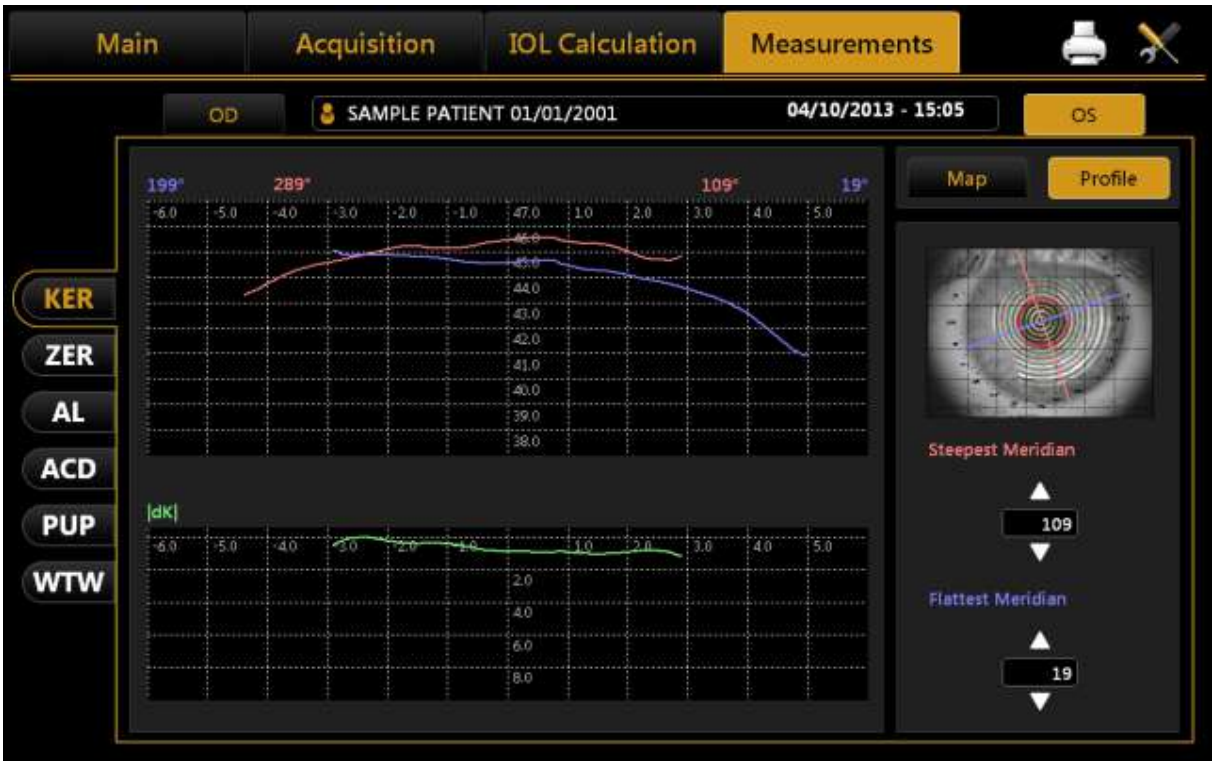


Figure 61

13.13.2 Zernike

The Zernike module provides a comprehensive view of the wavefront aberrations generated by the front surface of the cornea. The results of the Zernike axis are illustrated by means of numerical indices and graphic representations (Figure 62).

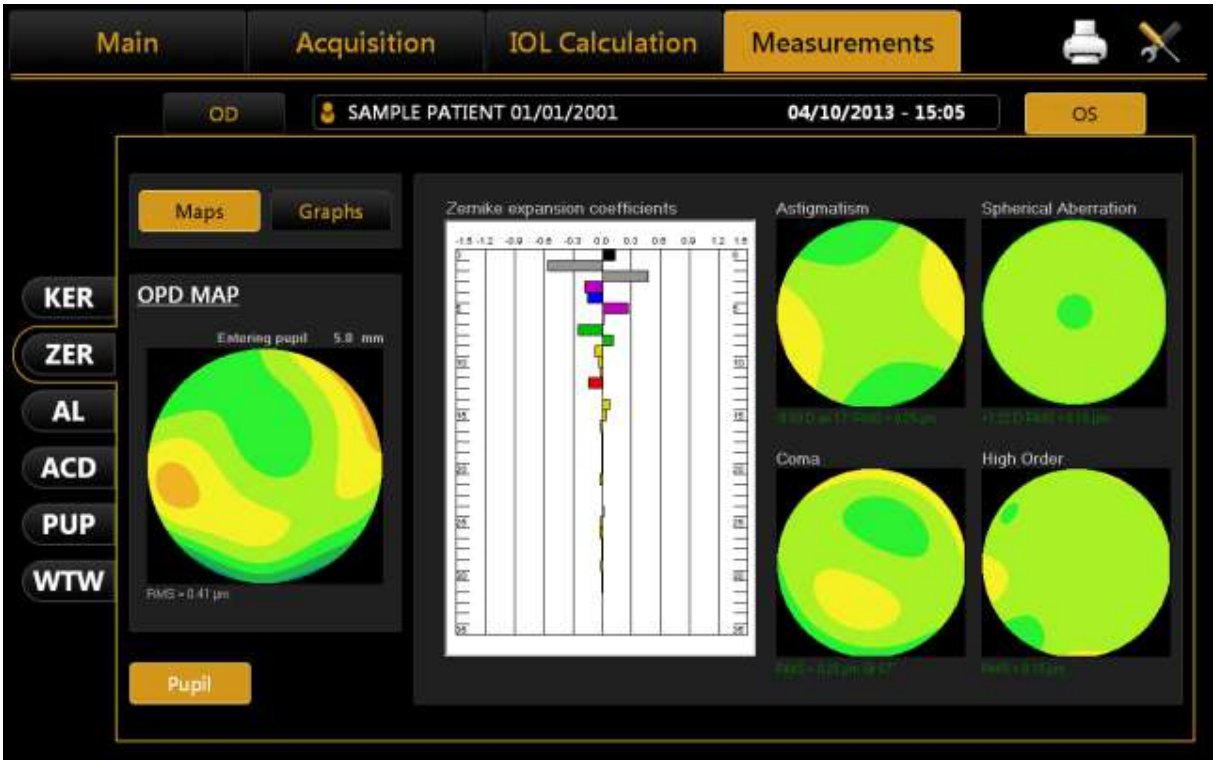


Figure 62

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 OPD Map is detailed, representing the total aberration that corresponds to the sum of all the aberration components and the RMS value. This allows you to quantify the deviation with respect to an ideal wavefront.
On entering the module, the 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 63).
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 contrast with the pyramid's background.
- **Point Spread Function**: represents the intensity of the wavefront in the retina.

- **Spot Diagram**: represents the spatial distribution of the wavefront over the retina.
- **Visus/Visus Low Contrast:** represent the patient's real vision at high and low contrast.

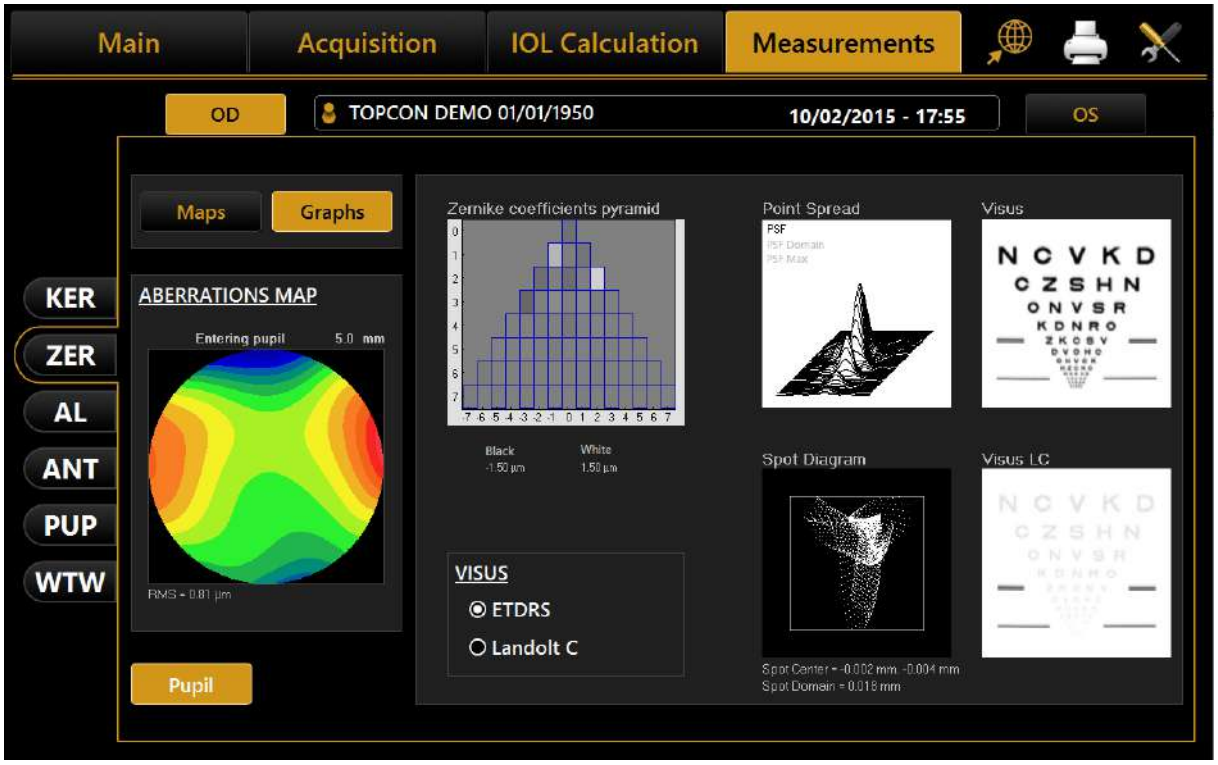


Figure 63

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 64) 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.

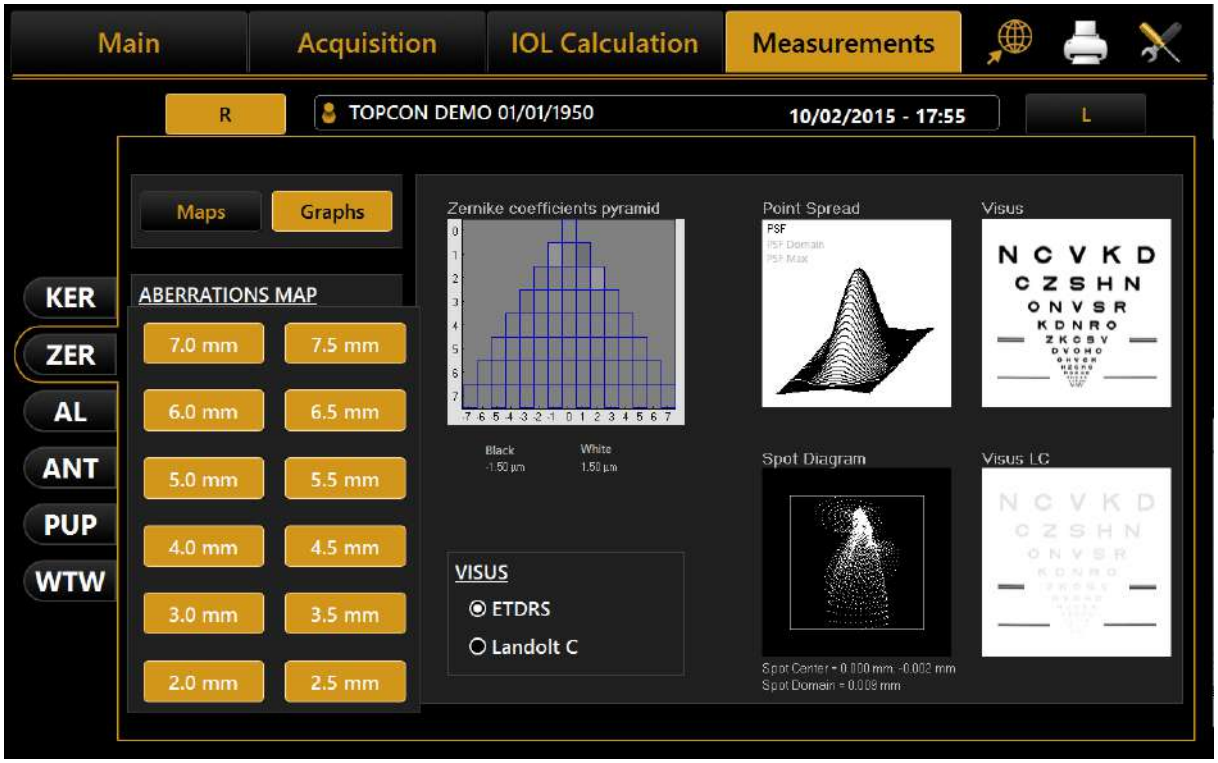
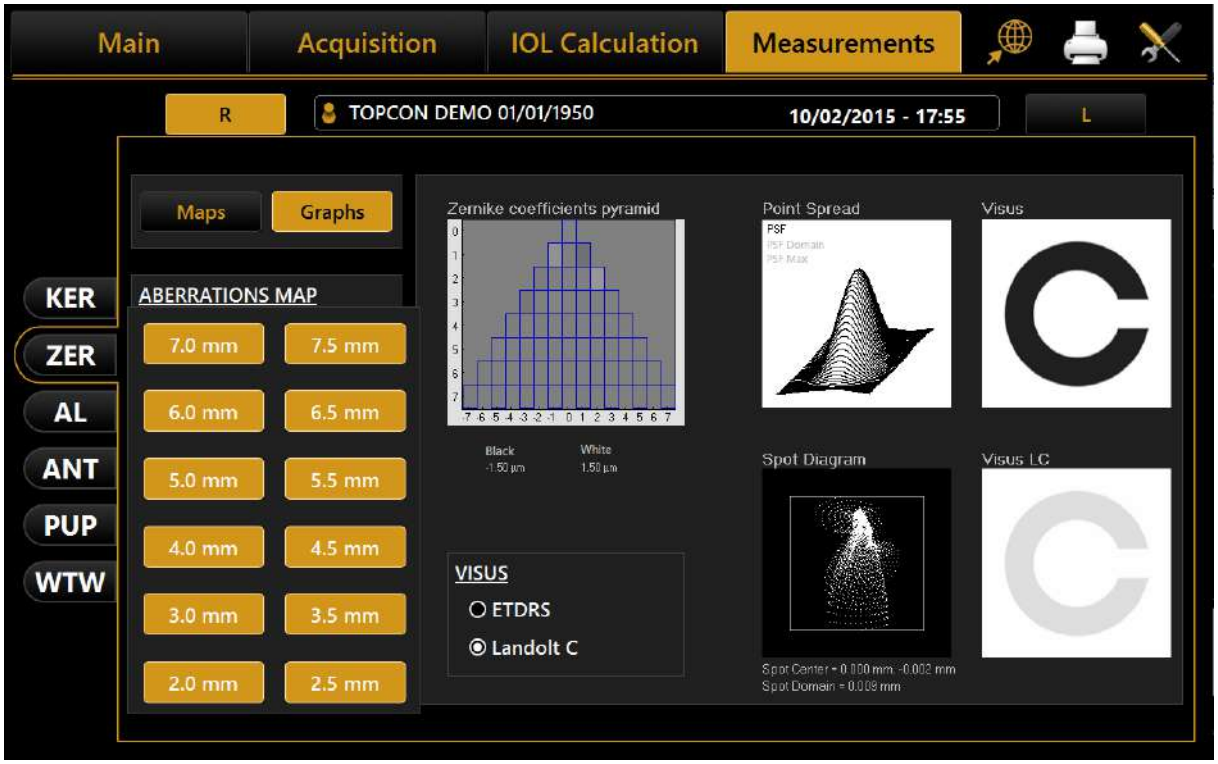


Figure 64

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



13.13.3 AXIAL LENGTH (AL)

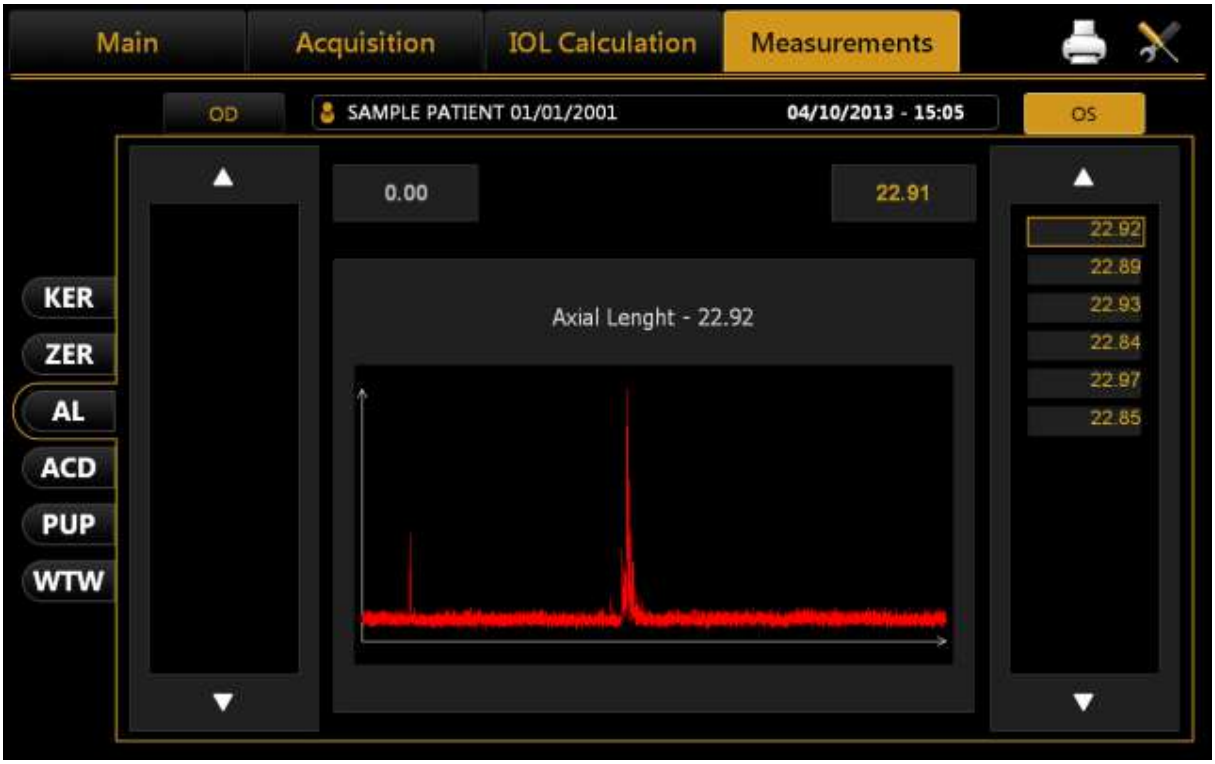


Figure 65

Figure 65 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.

13.13.4 ANTERIOR CHAMBER DEPTH (ACD)

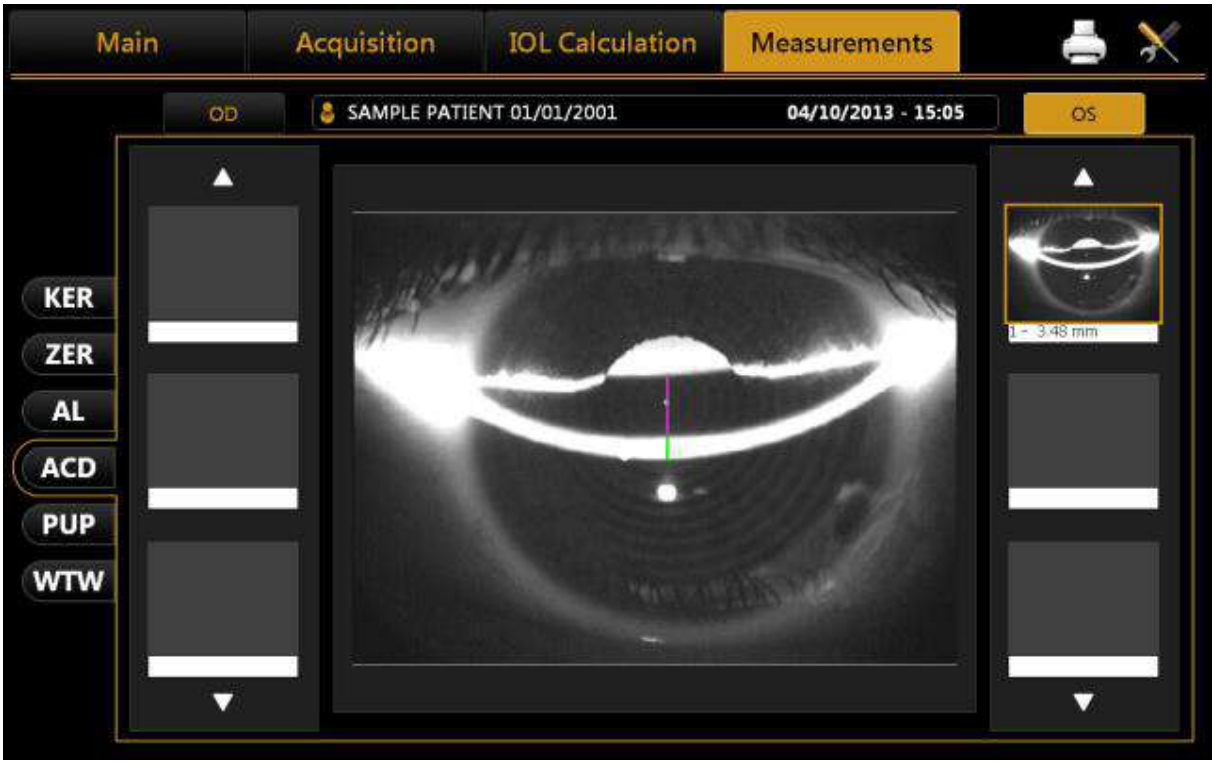


Figure 66

Figure 66 gives an example of ACD (Anterior Chamber Depth) measurement.

Looking at the image in the centre of the screen, you can see that three different reflections are present. From the bottom, the first reflection is the slit's point of origin and is irrelevant for calculation purposes. The second half-moon-shaped reflection is the reflection of the light slit on the first corneal surface. The third reflection is divided into crystalline reflection - you can see that this reflection has a high thickness - and iris reflection. The latter is also irrelevant for calculation purposes.
As for the axial length, if the instrument does not record good quality reflections, or if the data is inconsistent, the acquisition is discarded.

Caution should be practised when using the device's ACD measurement for any given intraocular lens calculation because of the high variability of this measurement.

The ACD measurement is the distance between corneal epithelium and the crystalline lens surface.

13.13.5 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 67).

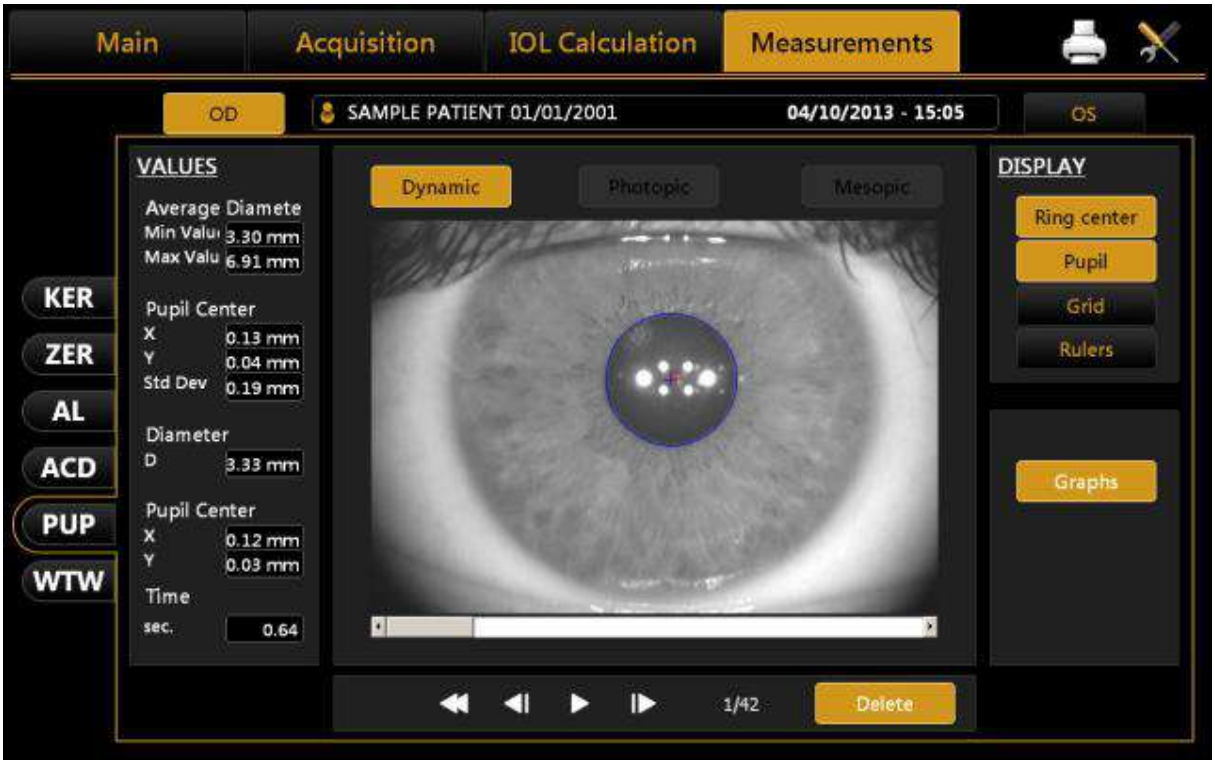


Figure 67

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.

13.13.5.1 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

13.13.5.2 Sequences

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

- **Dynamic**
- **Photopic**
- **Mesopic**

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

13.13.5.3 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

13.13.5.4 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.

13.13.5.5 Functions

Graphs

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

Delete

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

13.13.5.6 Graphs

In this section three types of graph are displayed:

- ***Decentralization*** (Figure 68)
- ***Latency*** (Figure 69)
- ***Statistics*** (Figure 70)

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.

Decentralization

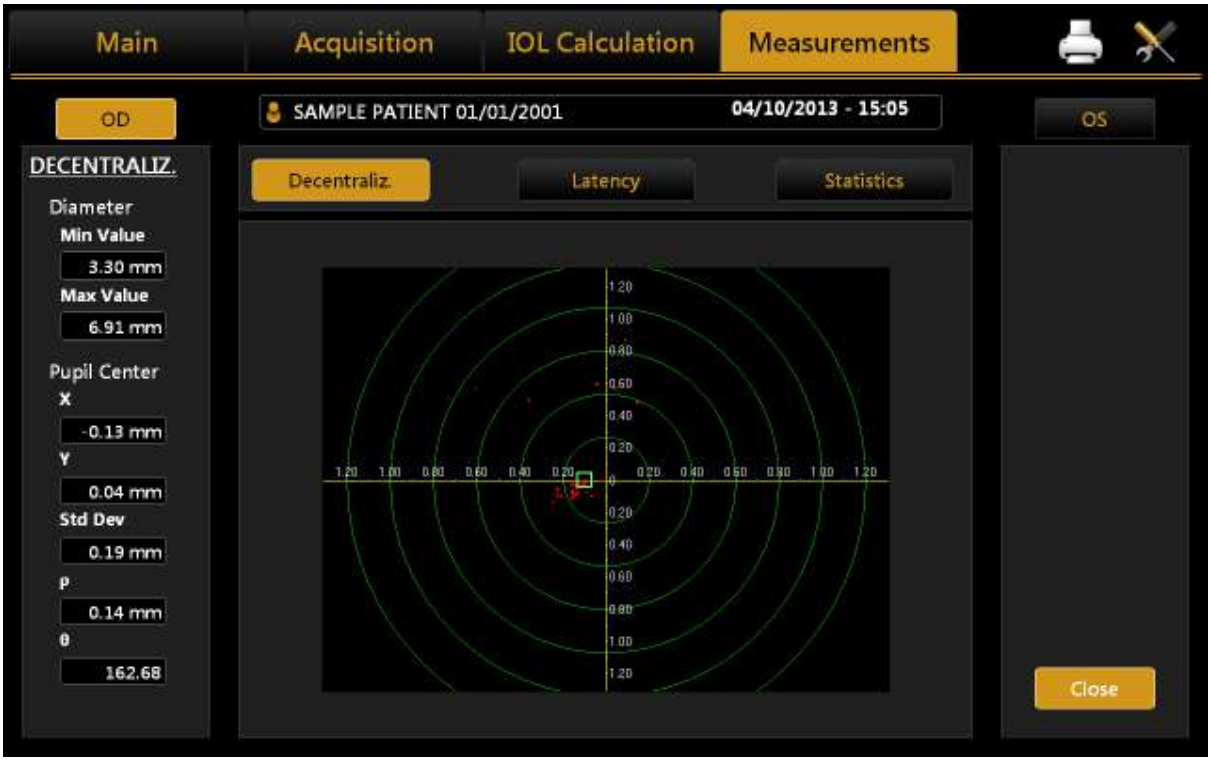


Figure 68

The green concentric circles identify the decentralization 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

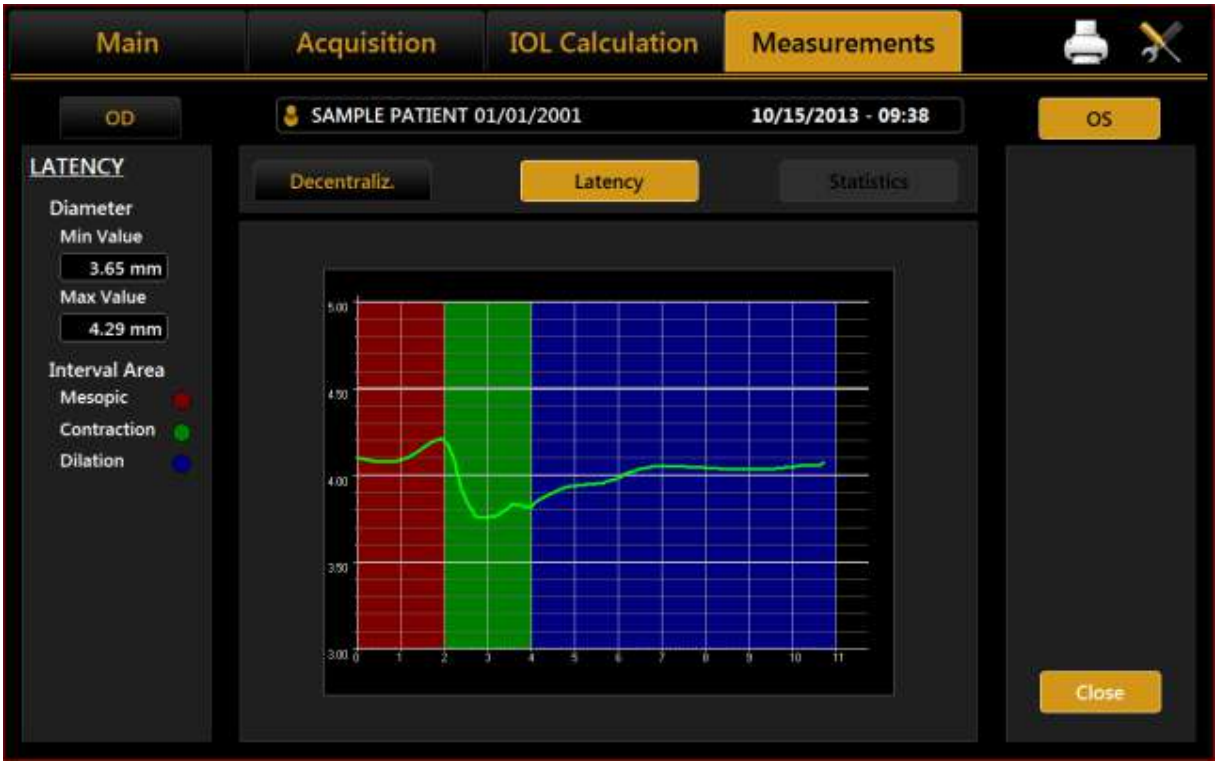


Figure 69

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

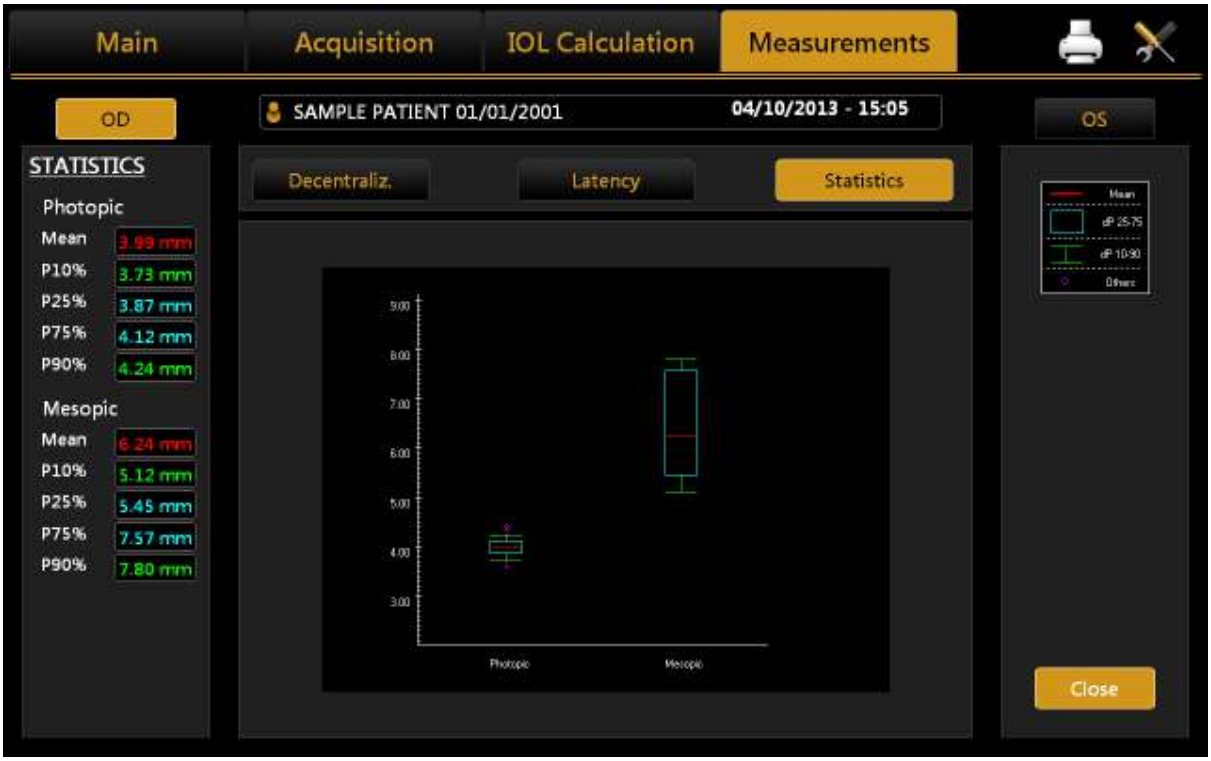


Figure 70

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.

13.13.6 WHITE TO WHITE

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

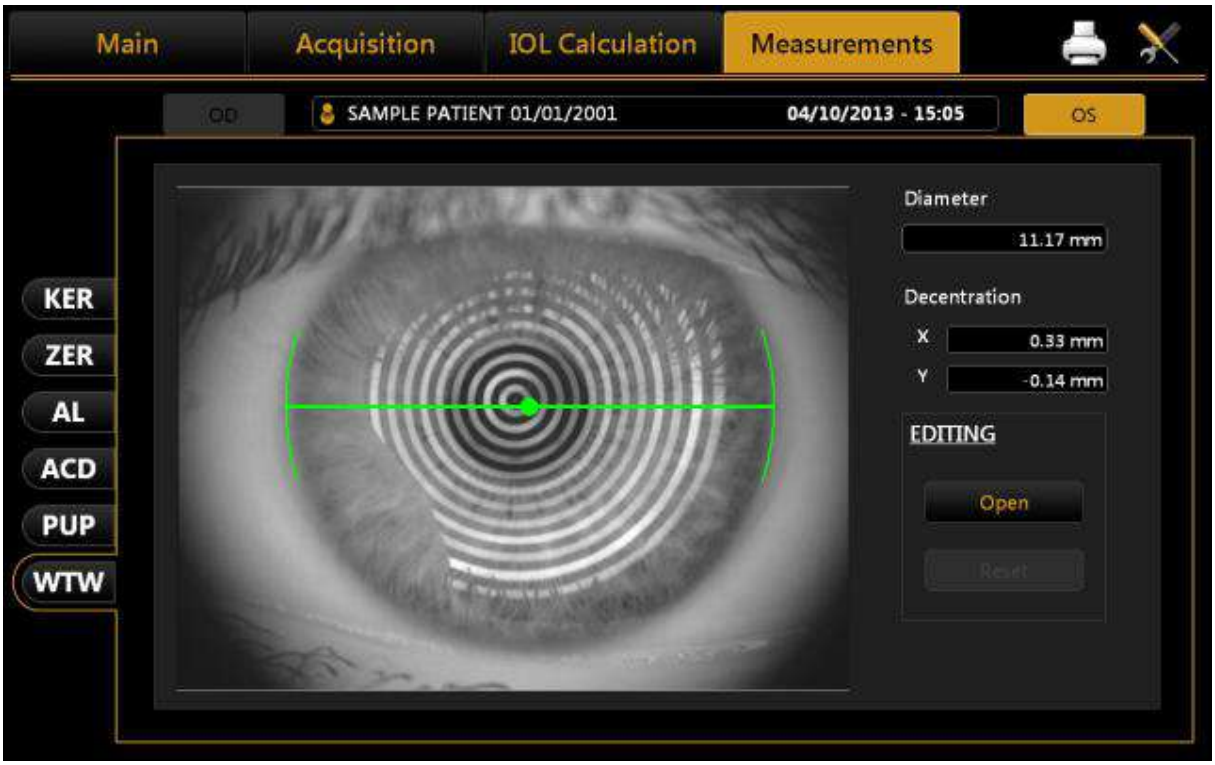


Figure 71

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

Figure 72

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

- **Corneal diameter**;

- **Decentralisation**: 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.

13.14 EXAMINATION DATA SAVING

After performing some acquisitions and eventual IOL calculations, in order to save the data from the examination, click on the home button. As shown in Figure 73, the software will ask the user to confirm the action.

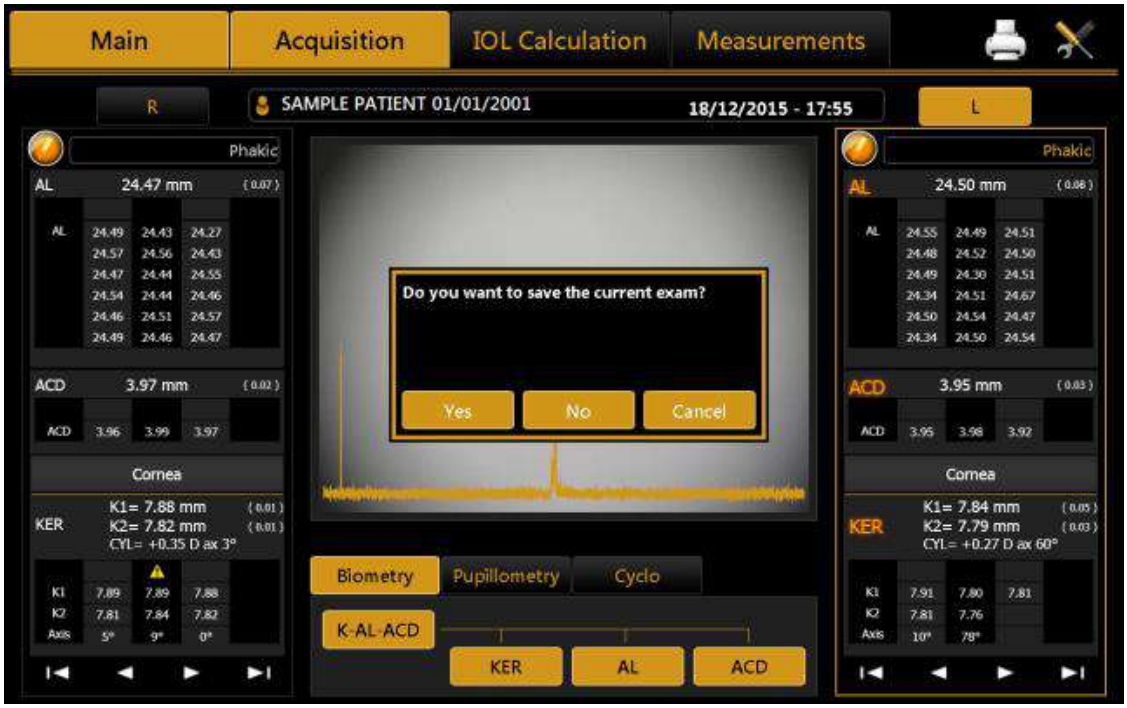
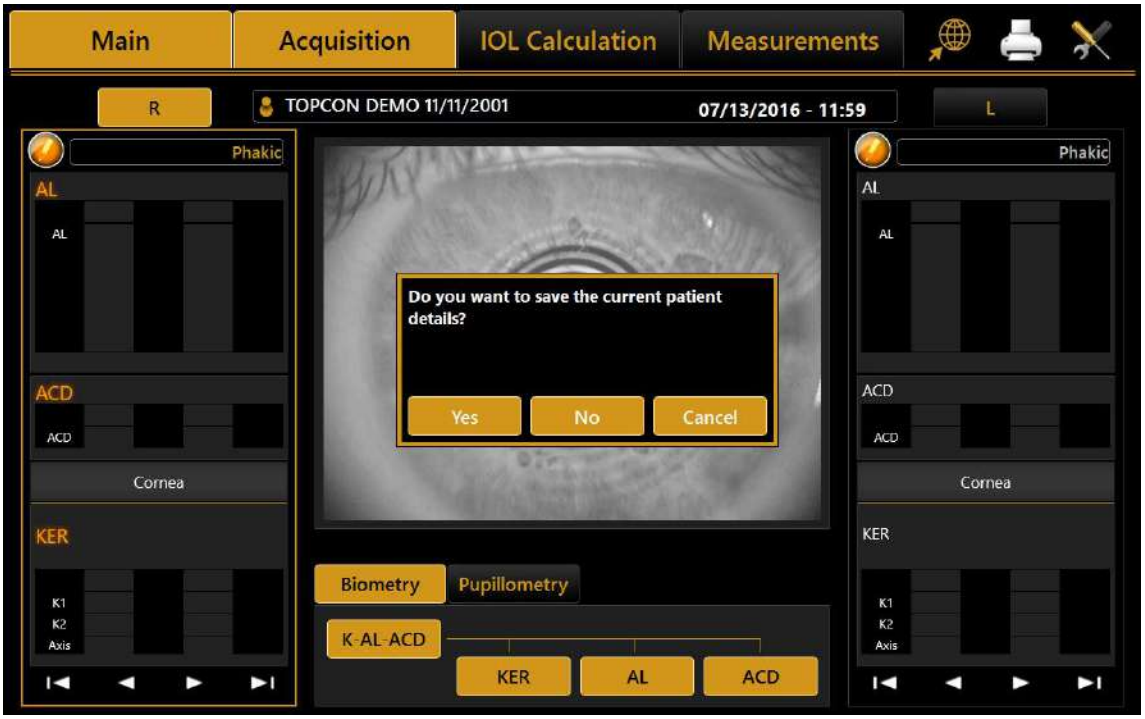


Figure 73

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.



13.15 SETTINGS

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

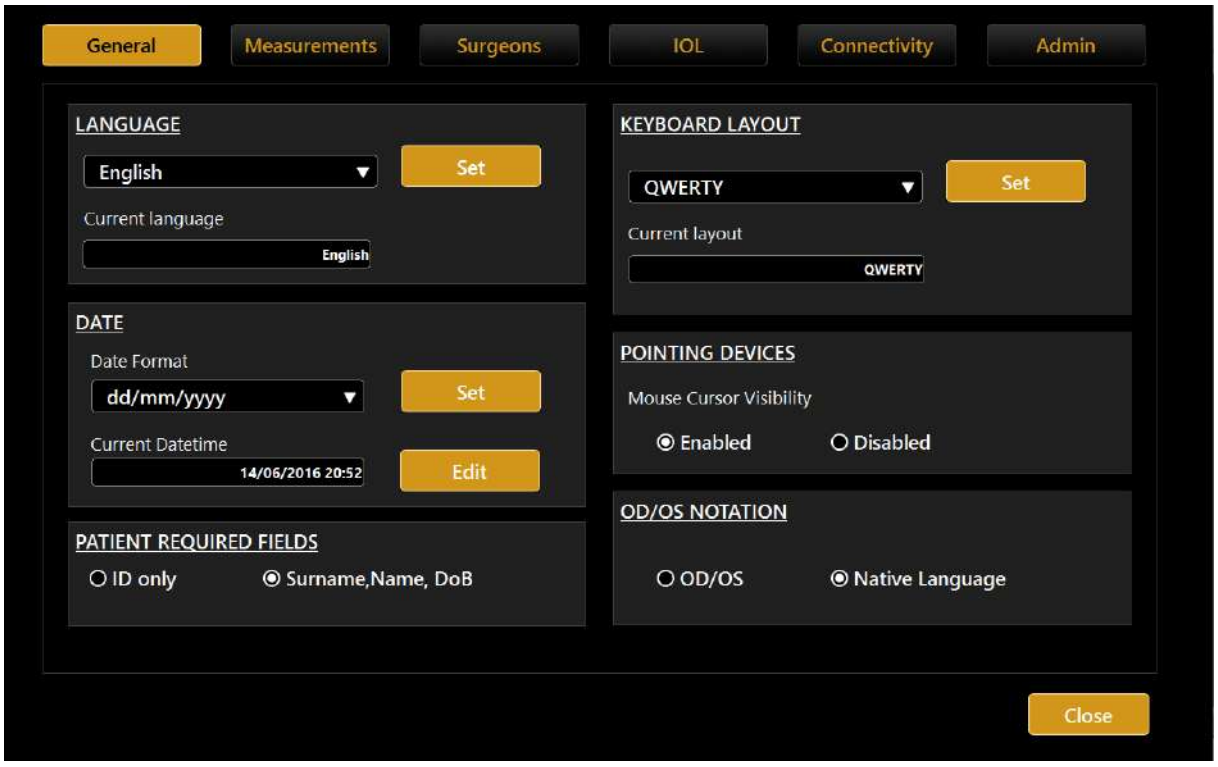


Figure 74

The settings screen is divided into the following categories.

- General
- Measurements
- Surgeons
- IOL
- Report
- Admin

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

13.15.1 General

Refer to Figure 74:

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).

13.15.2 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 (**Errore. L'origine riferimento non è stata trovata.**).

13.15.2.1 Scales

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:

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

Cylinder Notation

Select the type of cylinder notation:

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

Figure 75

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

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

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***

Acquisition

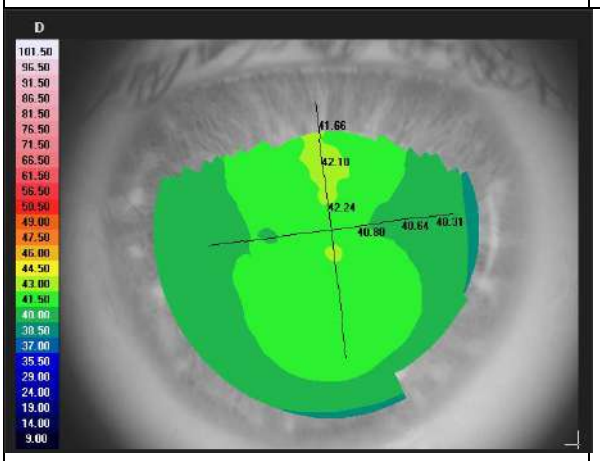
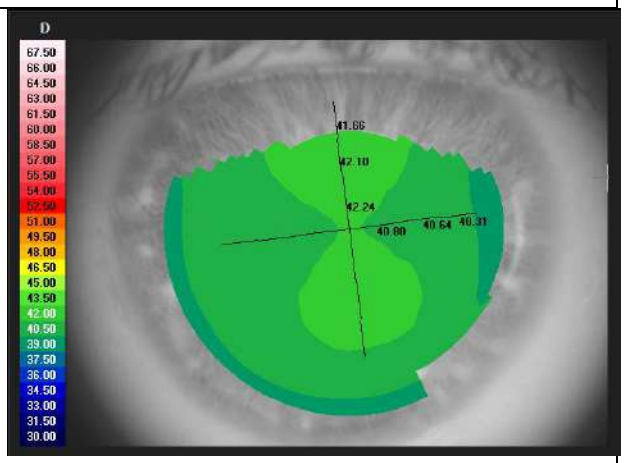
Select the default Biometry sequence acquisition:

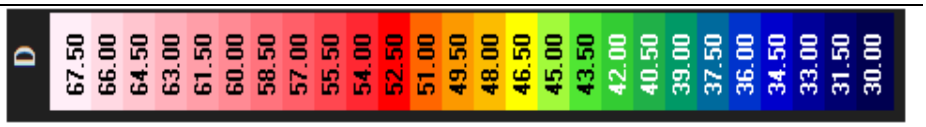
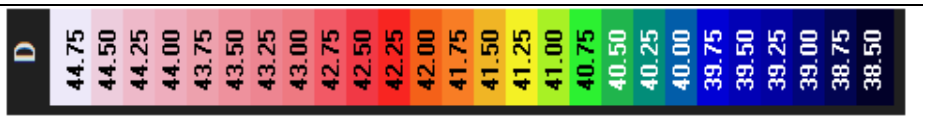
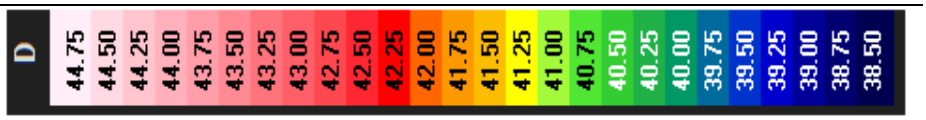
- **K-AL-ANT:** the default acquisition sequence is Keratometry->Axial Length->Anterior Segment (ACD)
- **K-AL:** the default acquisition sequence is Keratometry->Axial Length. Anterior Segment (ACD) can be by pressing on the relative button

13.15.2.2 Topography Map Color scale

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] color scale and ISO2005[4] color scale, by going to Measures section of the settings. The color scale option selected affects any topographic map drawing in the Aladdin application and in the printed reports (also the custom ones).

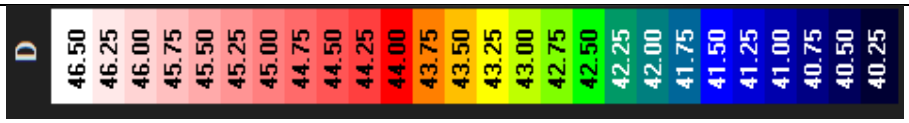
The Classic and ISO absolute color scale are shown in the following figure for the same topography map.

Classic	ISO
	

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

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

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

	ISO 2005	

13.15.2.3 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*

13.15.2.4 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

13.15.3 Surgeons

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

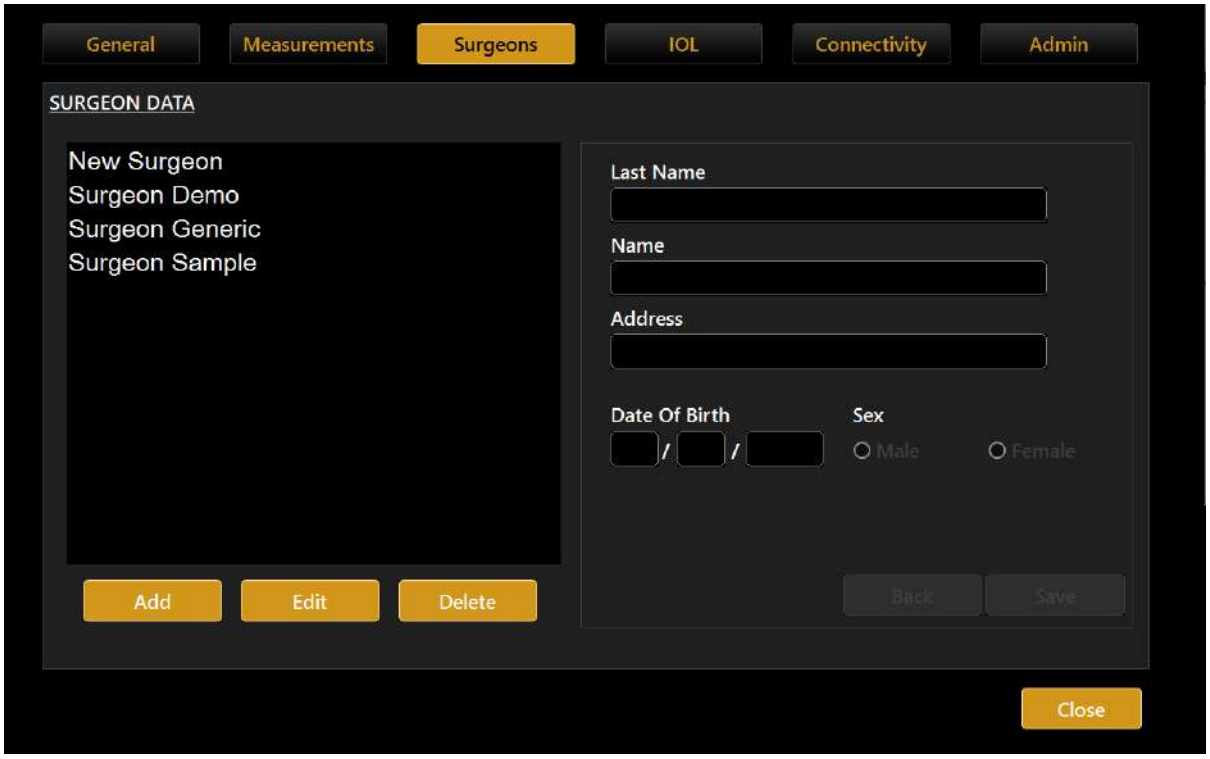


Figure 76

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.

13.15.4 IOL

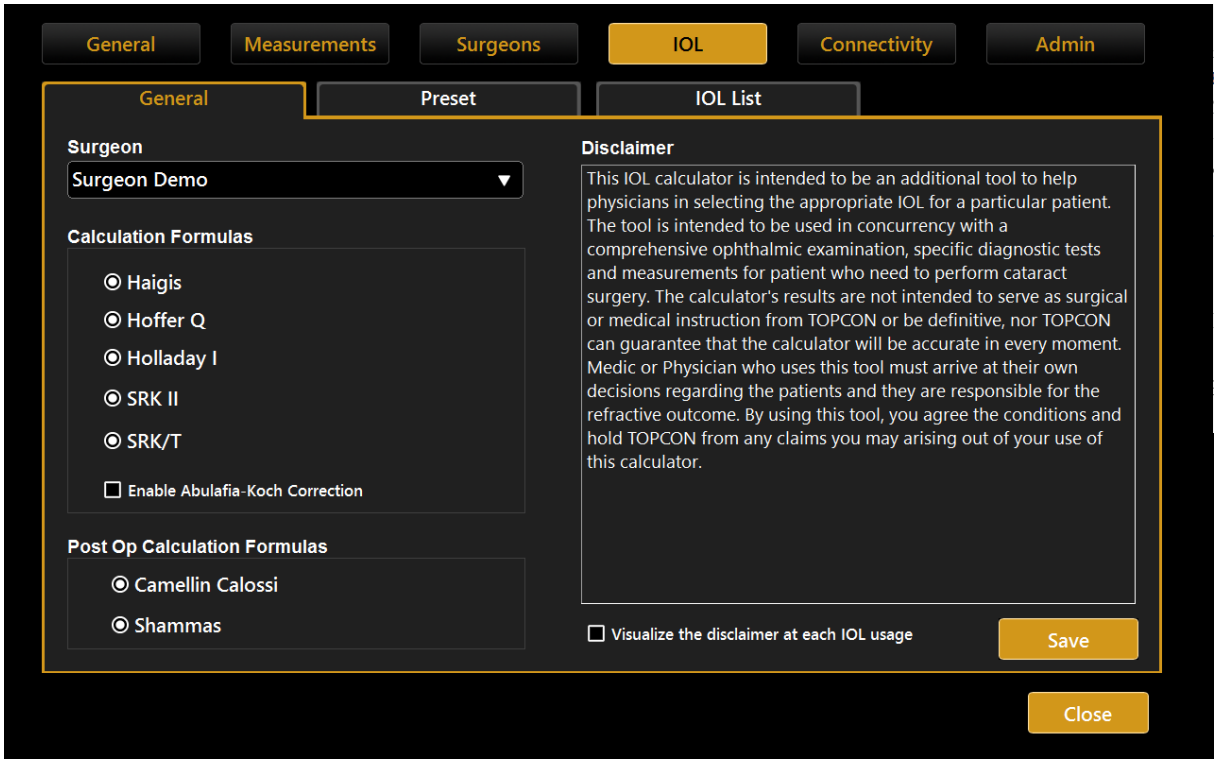


Figure 77

Here you can configure various options and presets for the IOL environment (**Errore. L'origine riferimento non è stata trovata.**) associated with the surgeon selected in the "**Last Name**" section, divided into three different environments described in detail below:

- General
- Preset
- IOL list

13.15.4.1 General

General environment (Figure 77)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.

Caution: The Toric IOL Calculation function is not available for the US market.

13.15.4.2 Preset

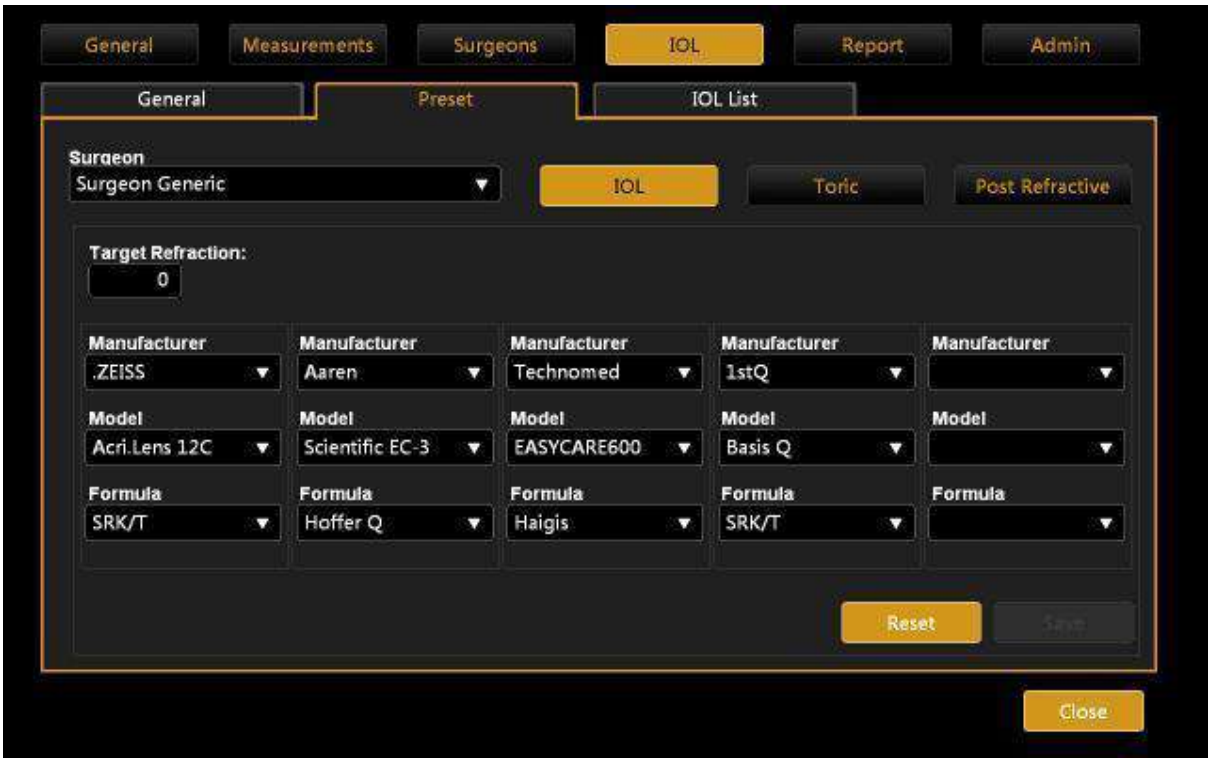


Figure 78

The screen presented is as shown in **Errore. L'origine riferimento non è stata trovata.**.

Each surgeon can set:

- Under **"IOL"** the preset for the **IOL Calculation**
- Under **"Toric"** the preset for the **Toric IOL Calculation**
- Under **"Post Refractive"** the preset for the **Post Refractive IOL**

By clicking on **"Save"** the selected settings are saved. This function will be particularly useful during the IOL calculation, when the settings are reloaded each time as preset.
By pressing the **"Reset"** key, 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 79.

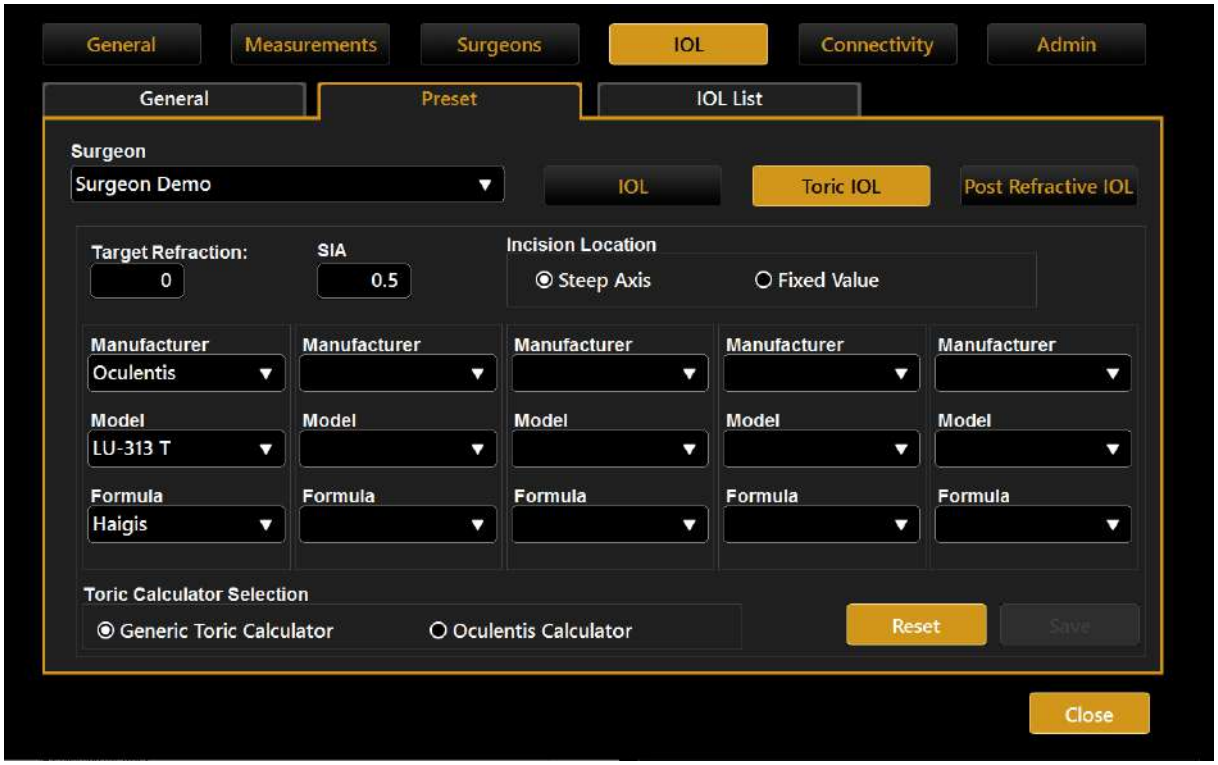


Figure 79

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 choose between:

- “Generic Toric Calculator”, that allows to define the lenses preset from a fully customizable collection of models and manufacturers.
- “Oculentis Calculator”, that allows to limit the collection of available lenses to Oculentis manufacturer only. In this case the manufacturer selection is locked both in the preset set-up and in the Toric IOL calculation environments.

This setting is per Surgeon.

Figure 80

13.15.4.3 IOL list

In this section (Figure 81) 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.

13.15.4.3.1 IOL Spherical List

The **“Spherical”** layout is shown in Figure 81.

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 81

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).

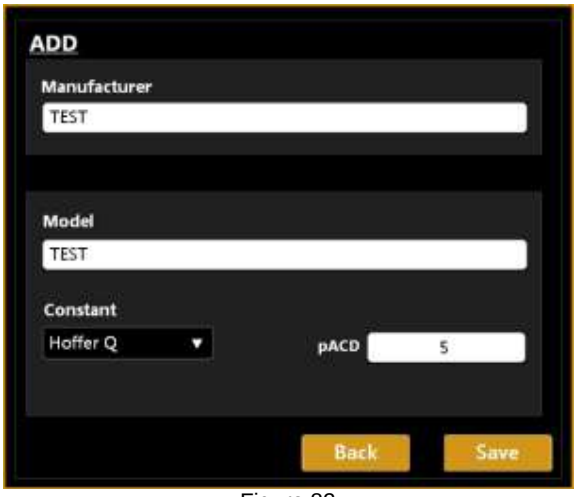


Figure 82

- **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).

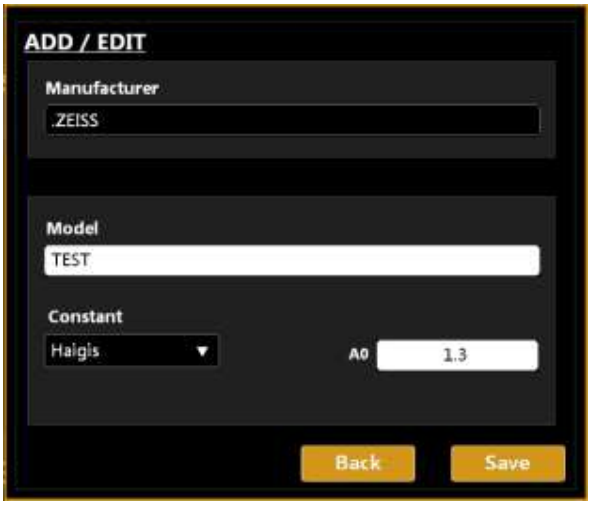


Figure 83

-  **Edit:** edit the name of the current IOL
-  **Delete:** delete the selected IOL
-  **Calculation Constants History:** gives information on every change of calculation constants values as shown in Figure 84.
  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.

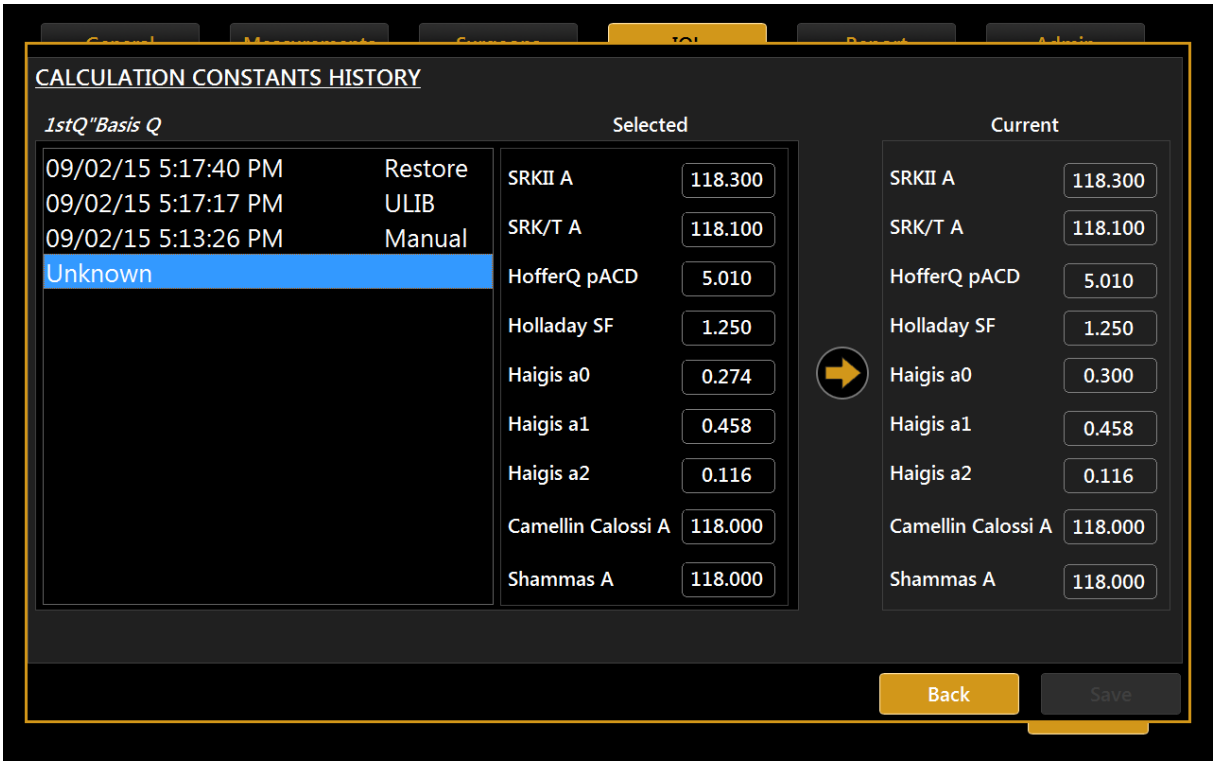


Figure 84

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 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.

13.15.4.3.2 IOL Torical List

The **"Torical"** layout is shown in Figure 85.

Figure 85

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 86) 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 87), 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 86

Figure 87

-  **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 84.
  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.

13.15.5 Connectivity

This panel (Figure 88) allows you to configure all the settings relative to network connectivity with external softwares or storage destinations.

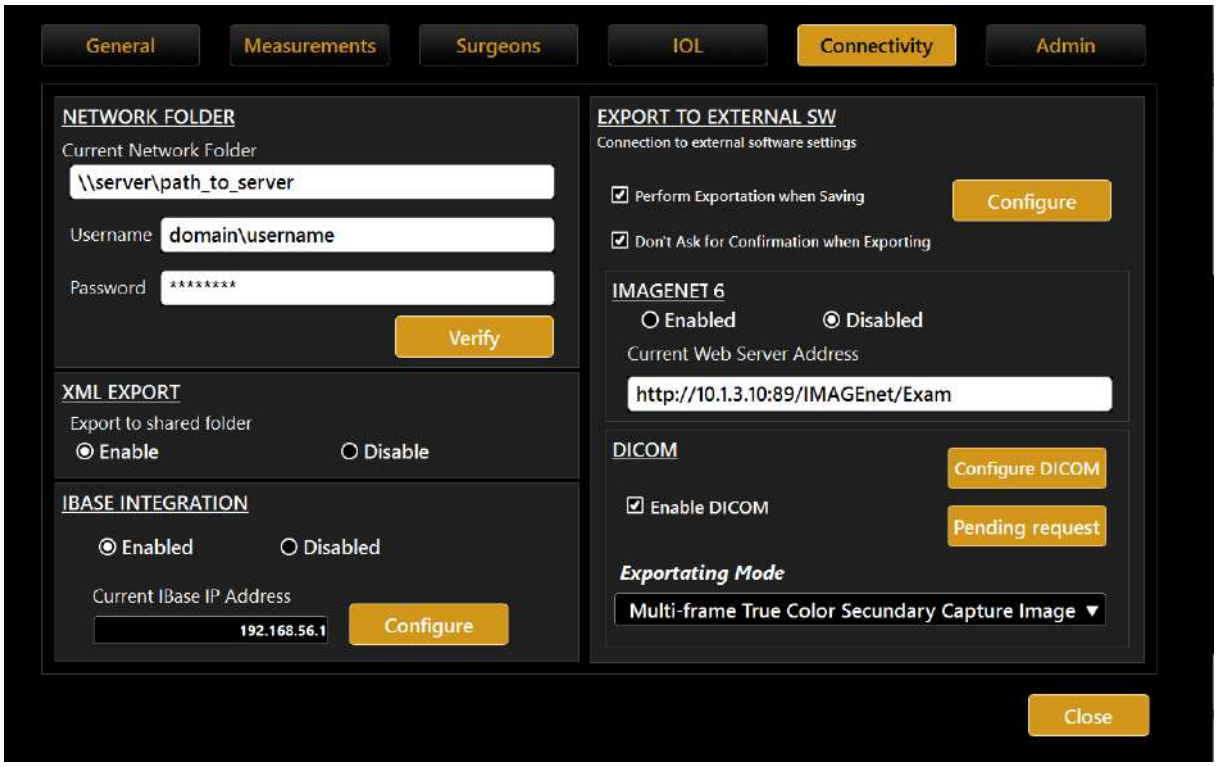


Figure 88

13.15.5.1 Network folder configuration

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

In order for Aladdin to be able to connect to the remote network folder, you must configure Aladdin 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 89. Connection failure may be due to unreachable resource path or to wrong credentials.

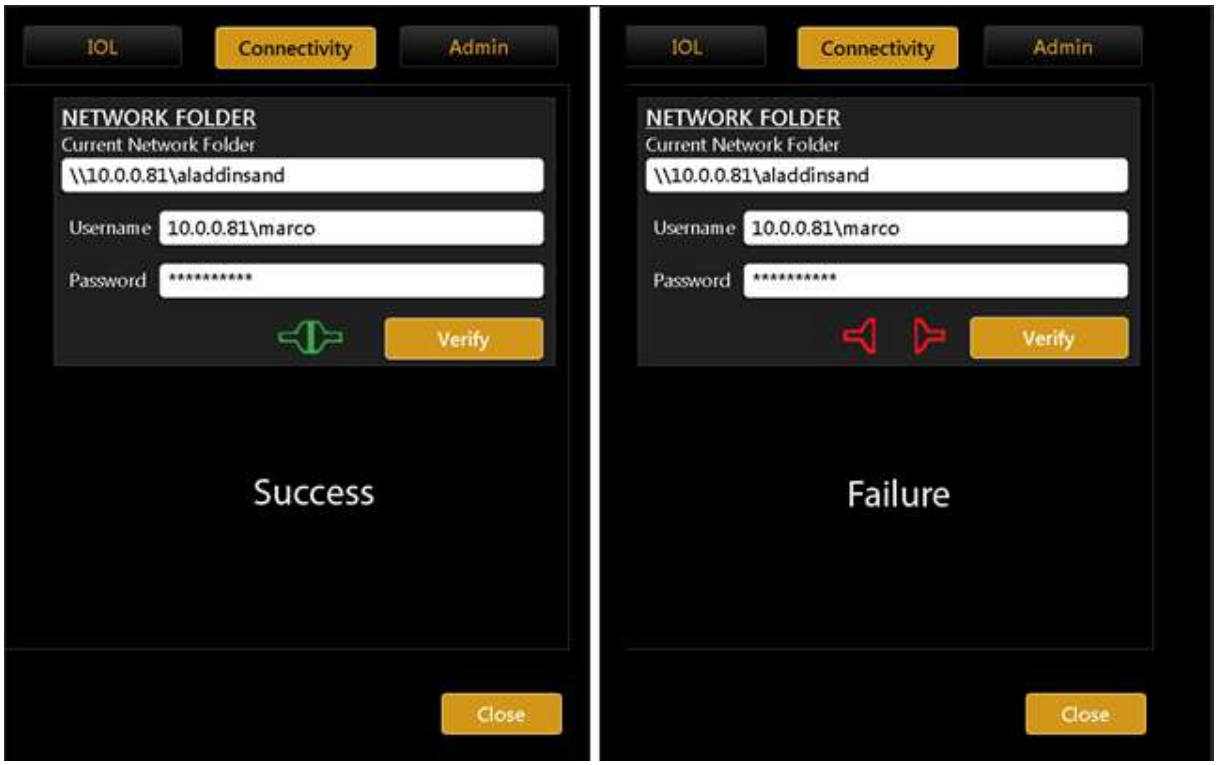


Figure 89

13.15.5.2 XML Export

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

13.15.5.3 IMAGEnet i-base software

Aladdin 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 88) the user is presented with a list of IP Addresses of the machines running IMAGEnet i-base software that are reachable from Aladdin. Once selected the proper IP(Figure 90), Aladdin is ready to exchange data with IMAGEnet i-base machine.

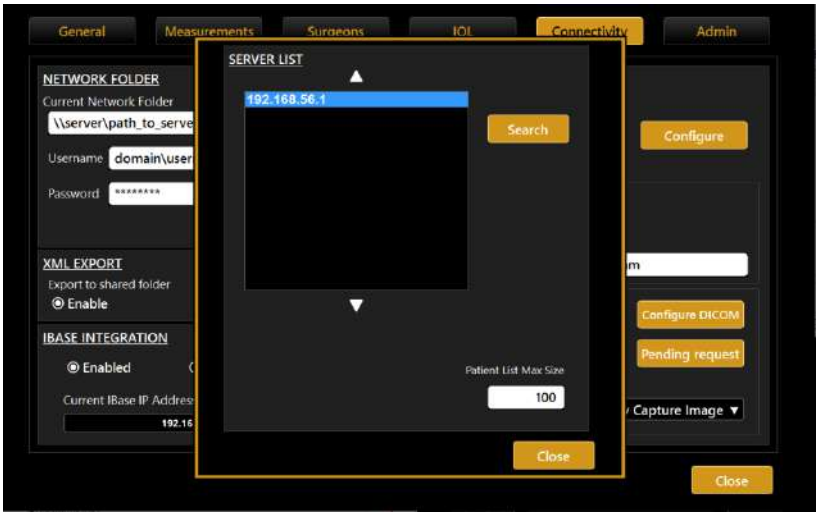


Figure 90

13.15.5.4 IMAGEnet 6 Server software

Aladdin 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 is ready to exchange data with the IMAGEnet 6 Server machine (Figure 91).

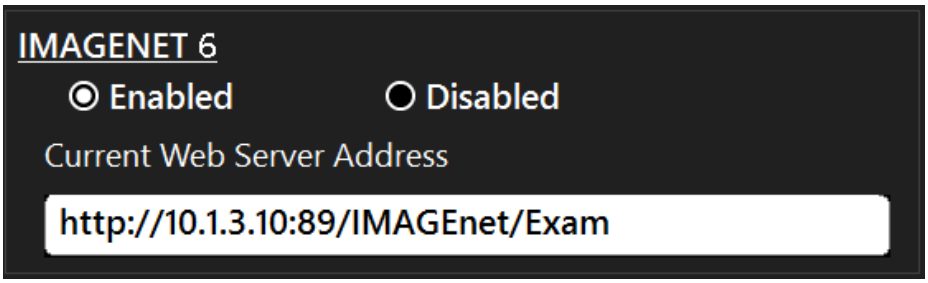


Figure 91

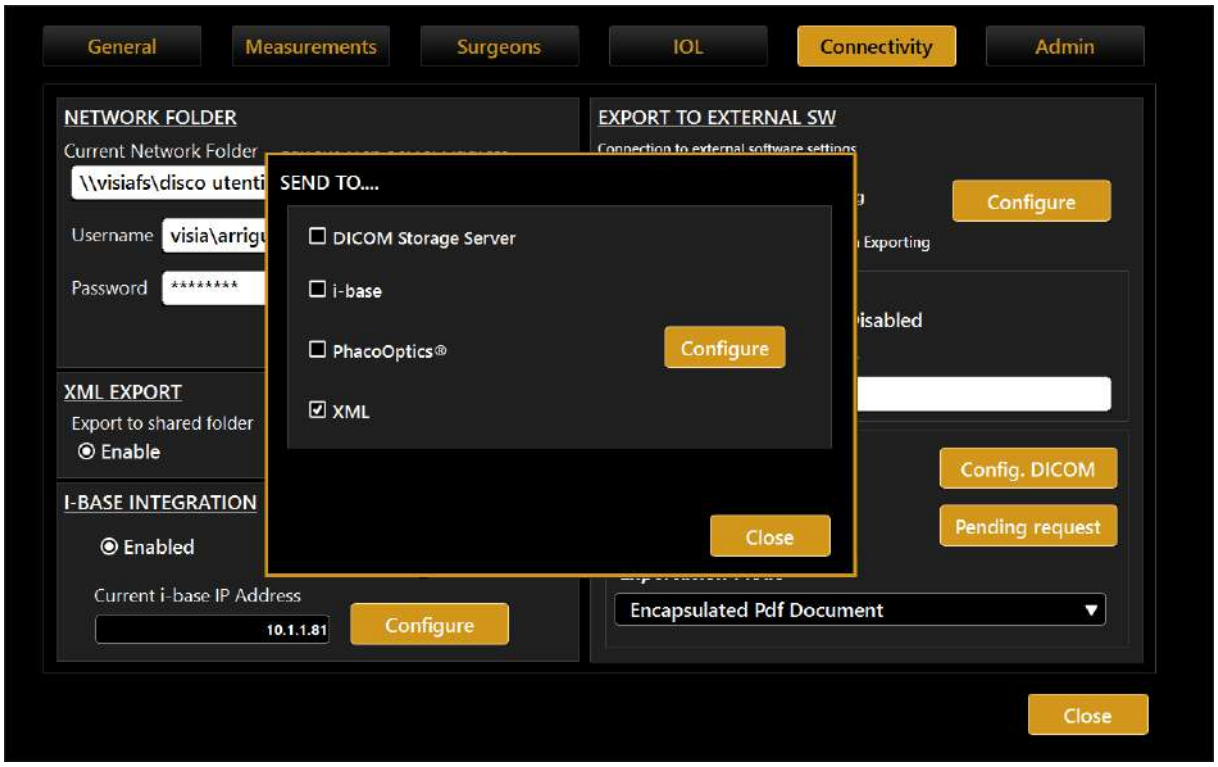
13.15.5.5 Export to External Software settings

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

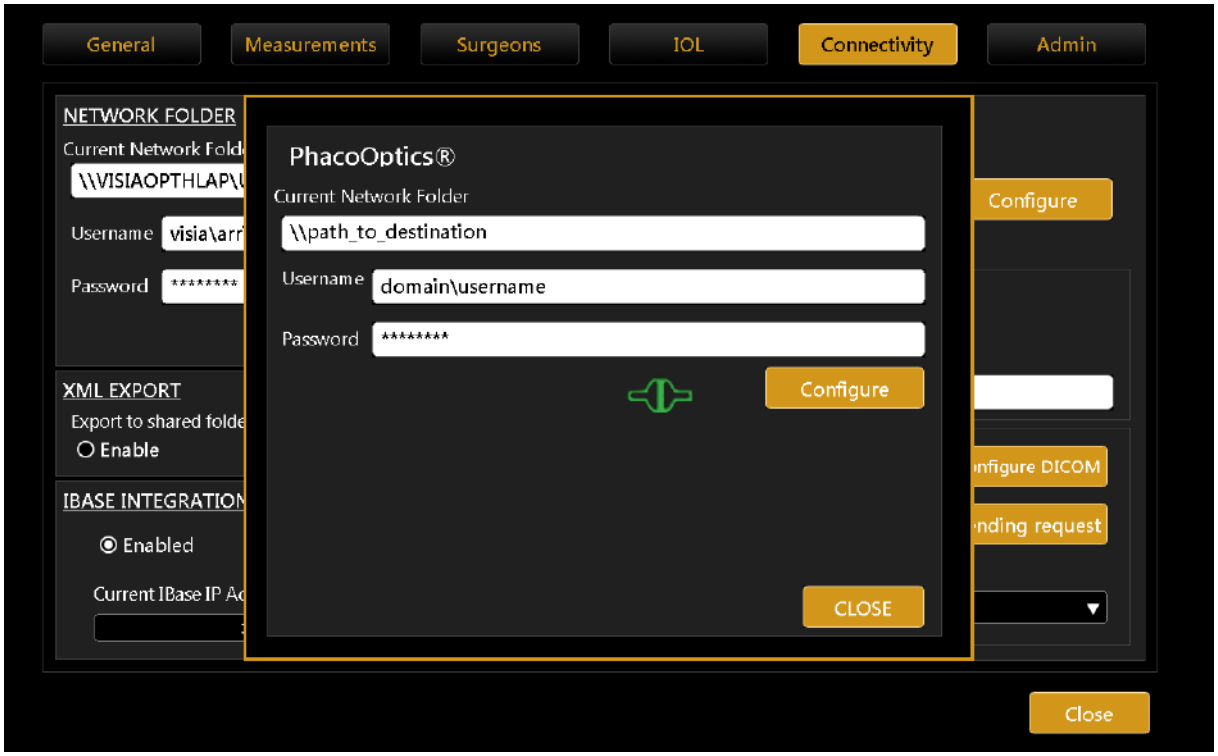
It is also possible to access configuration ("Configure" button) of the other external software destinations which are not present in the other panels of this section.

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 inside the application.



13.15.5.6 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:

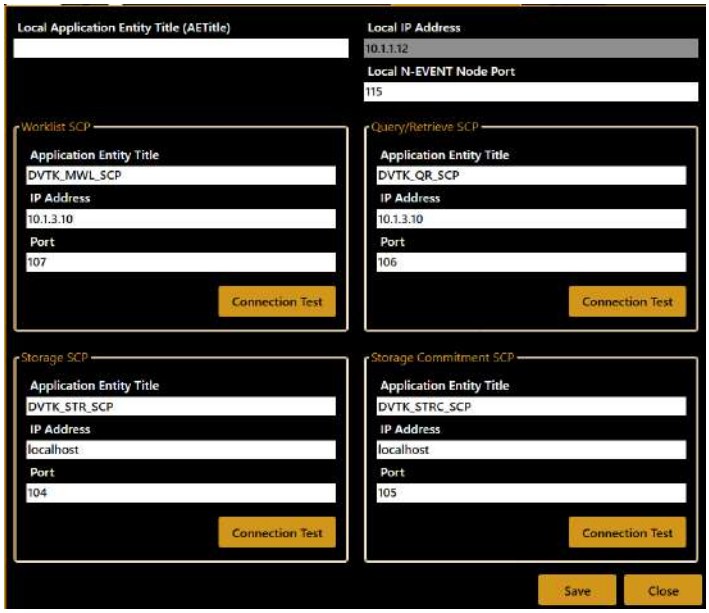
- **Modality Worklist**, The DICOM Modality Worklist service provides a list of imaging procedures that have been scheduled for performance by the acquisition device.
- **Patient Root Query,** This enables the device to find patient's details from a DICOM server.
- **Storage,** The DICOM Store service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

13.15.6 Admin

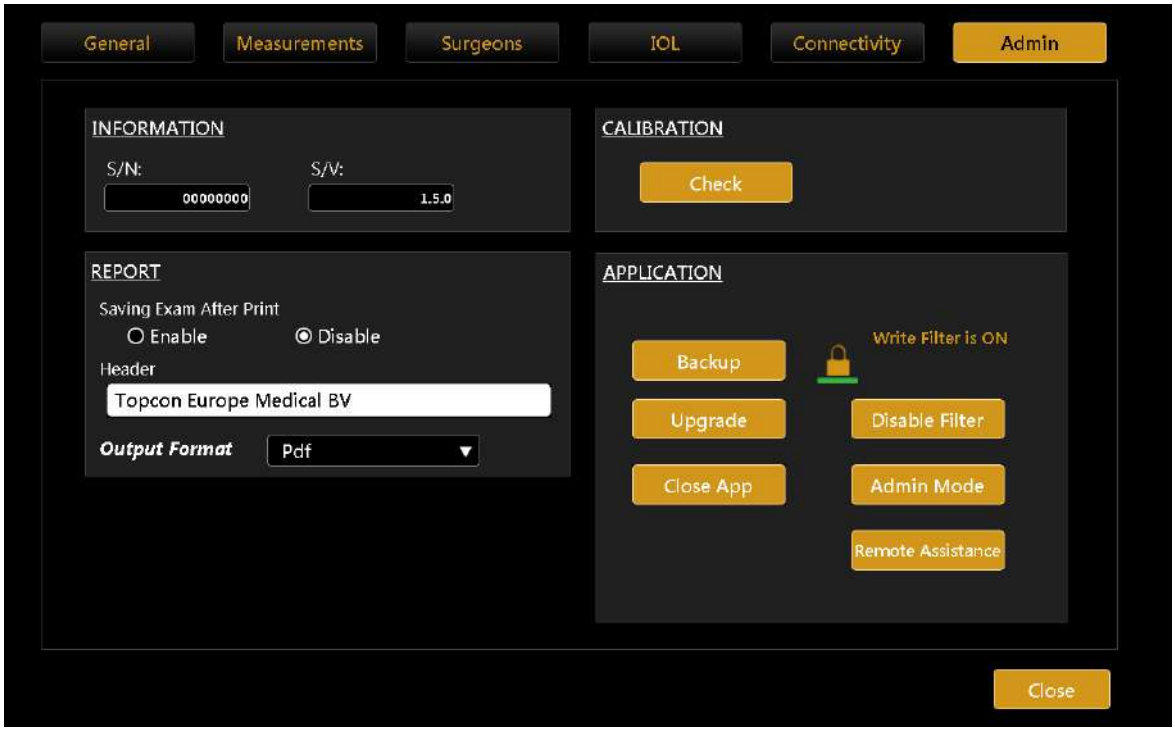


Figure 92

This is the instrument's administration panel (Figure 92).

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.

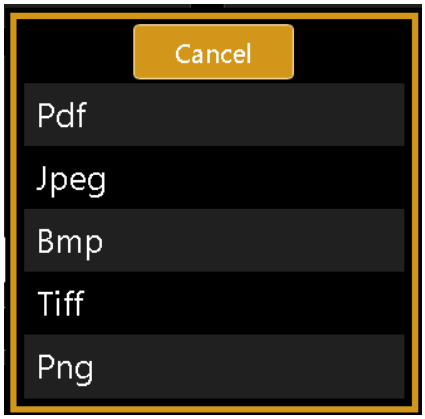
The "Application" frame manages the behavior of the integrated software:

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

13.15.6.1 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.



13.15.6.2 Remote Assistance

In case you need remote Assistance the Aladdin 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 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 or contact your IT staff.

13.15.6.3 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.
3. Cancel the calibration check (Figure 93).

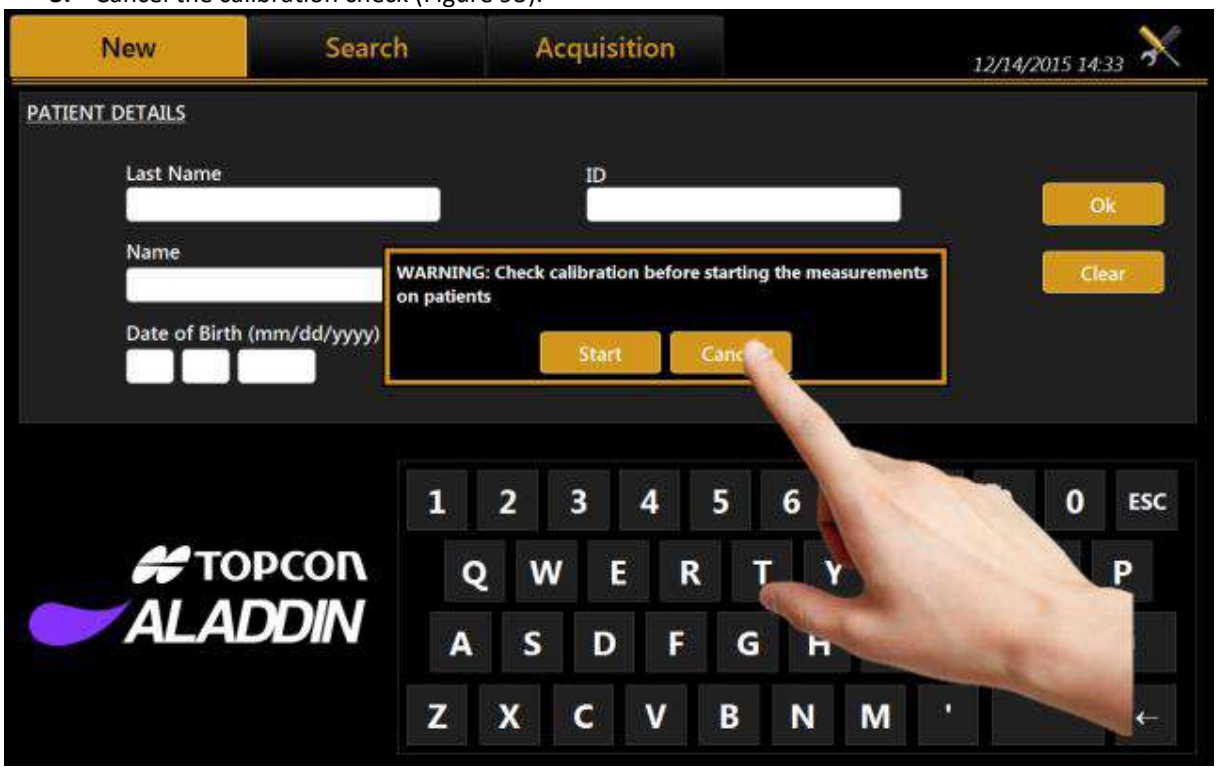


Figure 93

4. Click on the settings icon (Figure 94).

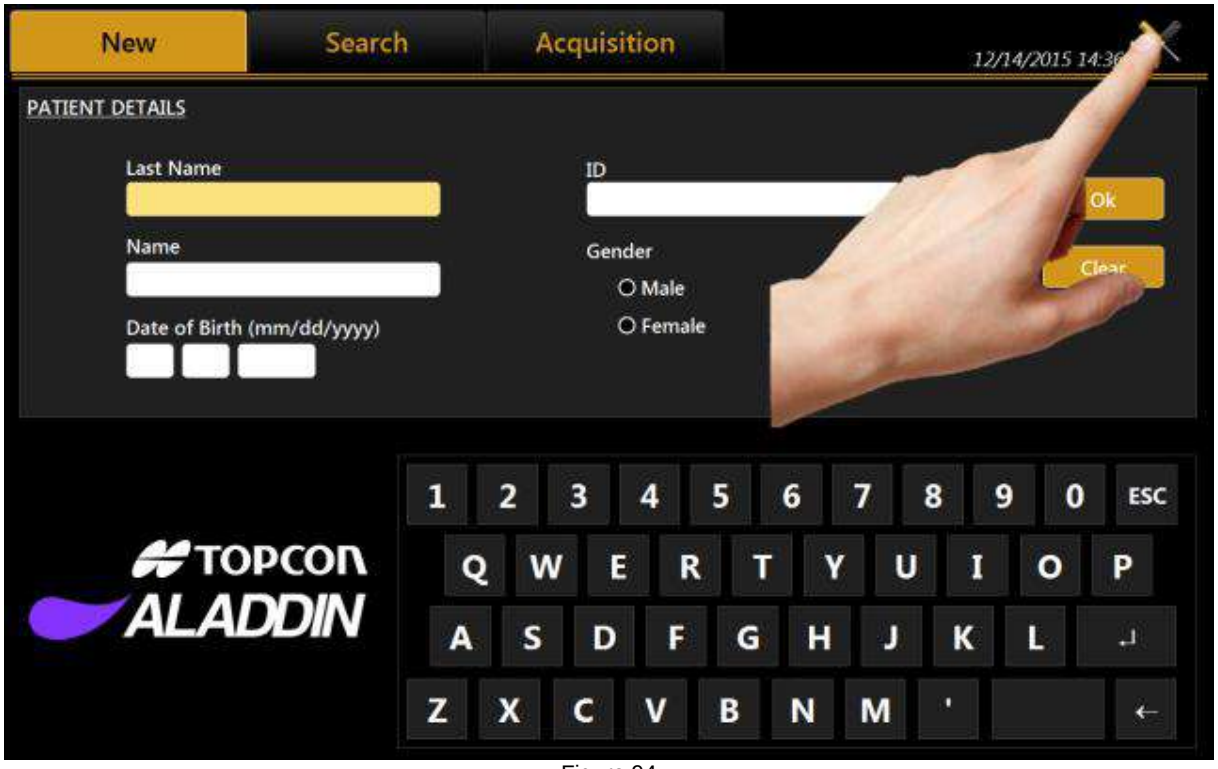


Figure 94

5. Click on the "**Admin**" tab (Figure 95).

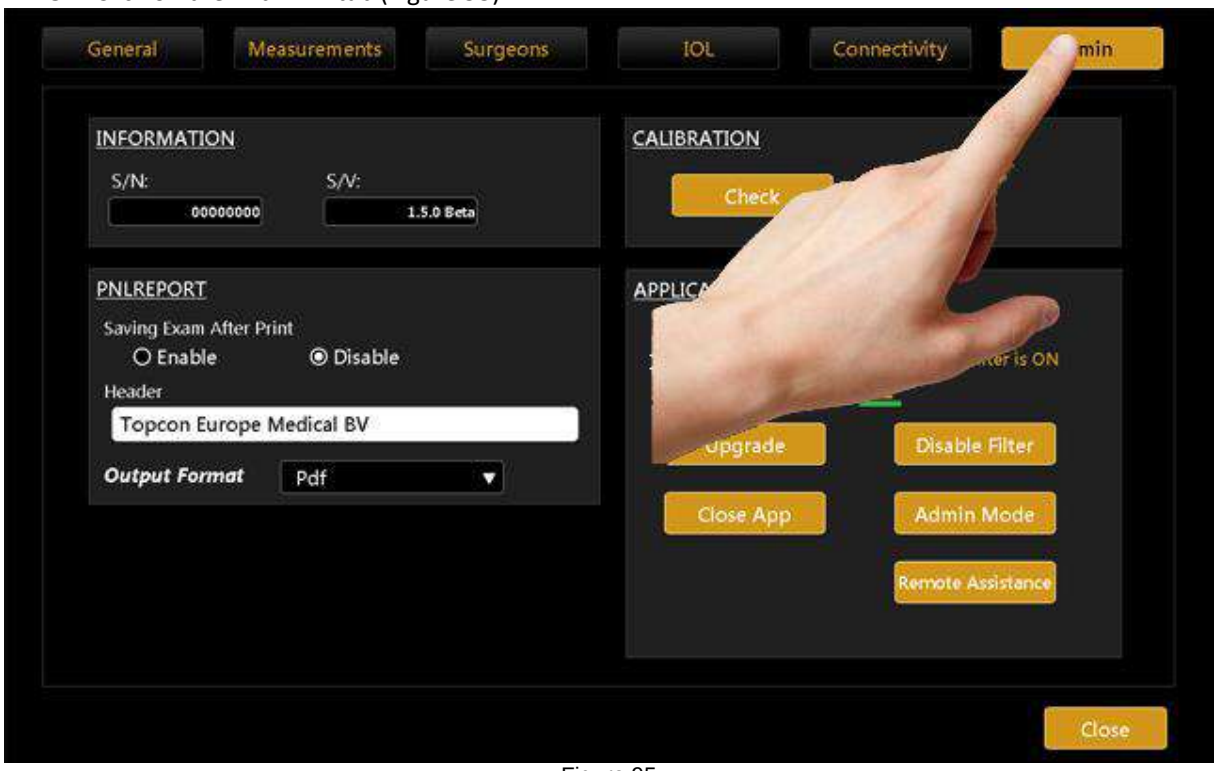


Figure 95

6. Insert the USB stick with the "*Aladdin upgrade*" files in one of the USB ports (Figure 96).

Figure 96

7. Click on the "**Upgrade**" button (Figure 97).

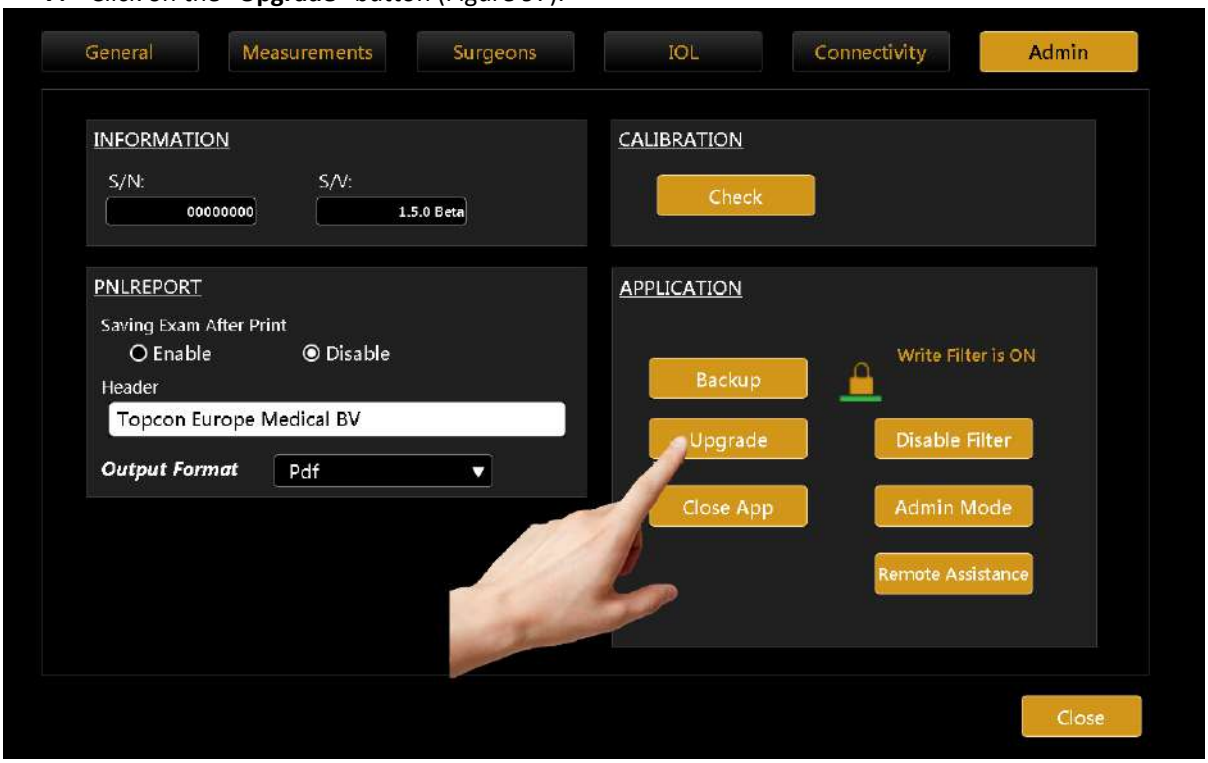


Figure 97

8. Click on "**Ok**" to reboot the system and start the upgrade (Figure 98).

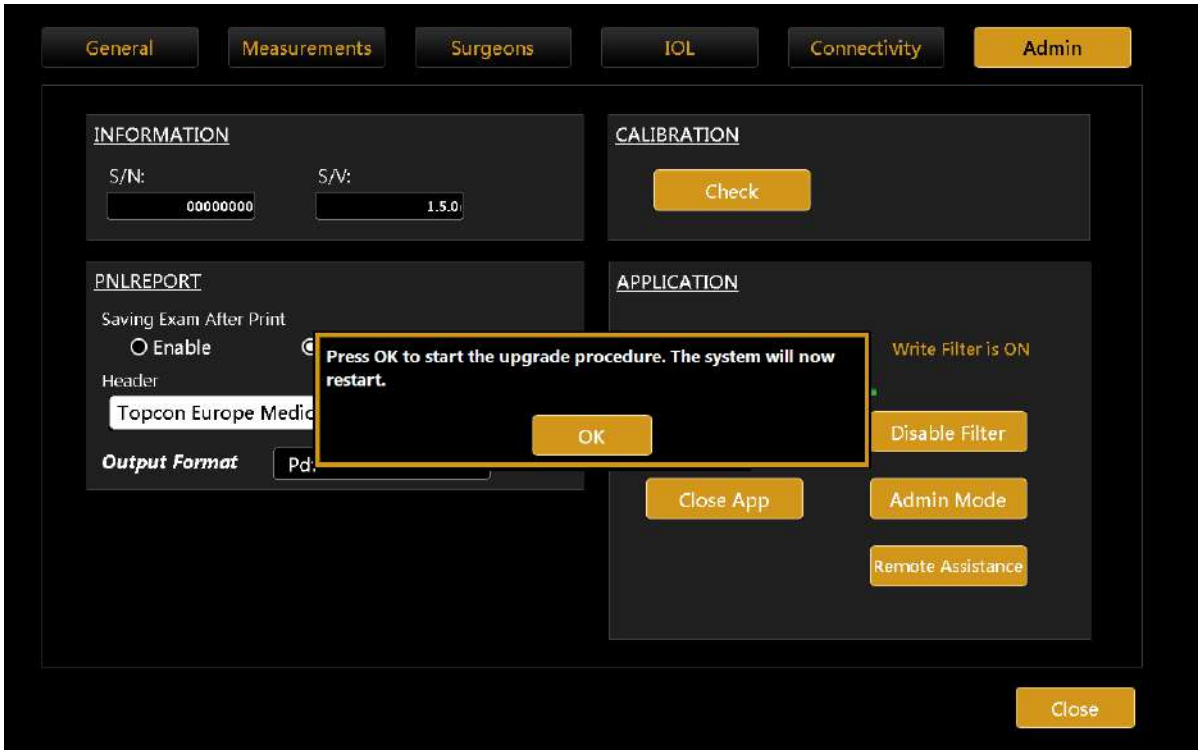


Figure 98

9. After the upgrade you will see the message of Figure 99 on the screen.

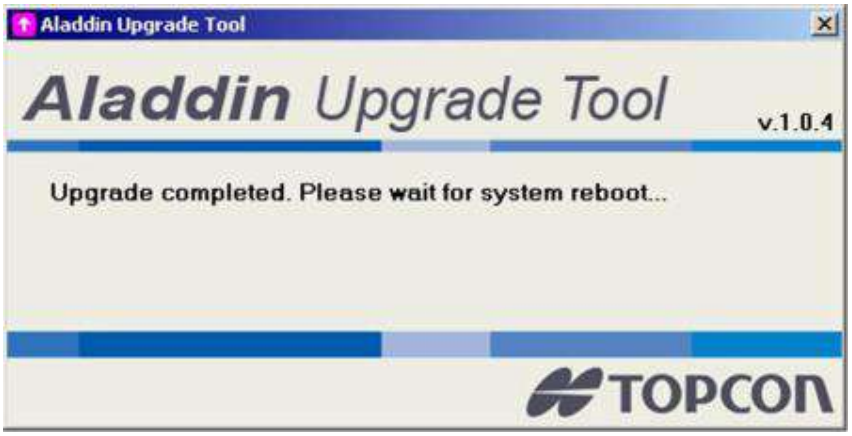


Figure 99

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 100).

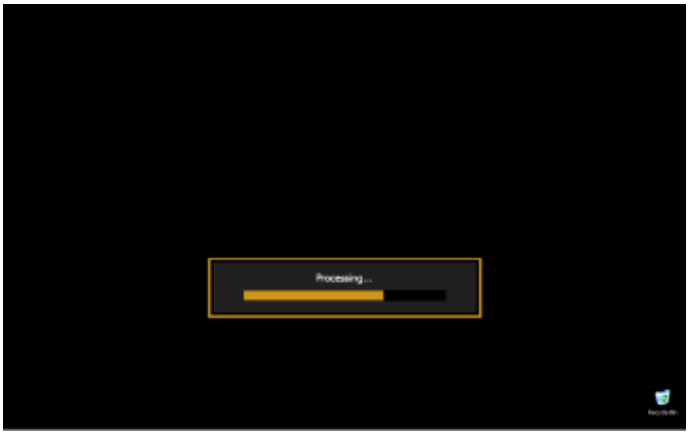


Figure 100

12. If you see the message of Figure 101, please switch off your Aladdin and turn it on again. Your Aladdin should now works fine.

Figure 101

13. Your Aladdin is upgraded. Please check in the settings, "**Admin**" tab if the S/V is now the new one (Figure 102).

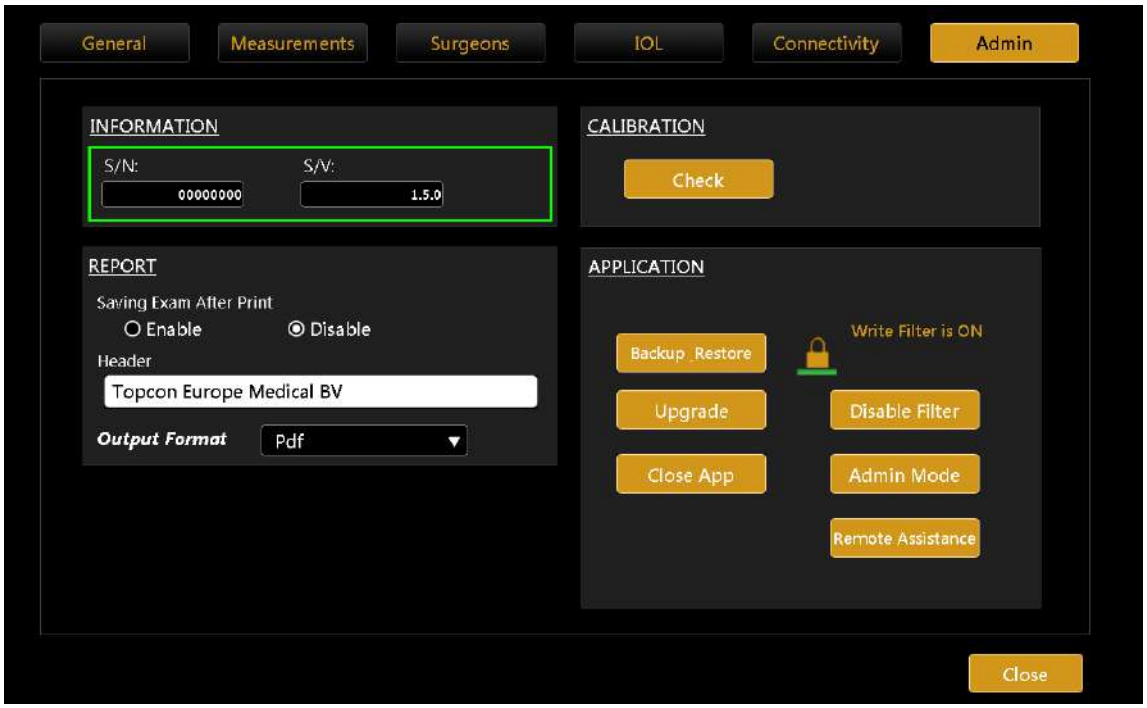


Figure 102

13.15.6.4 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.*

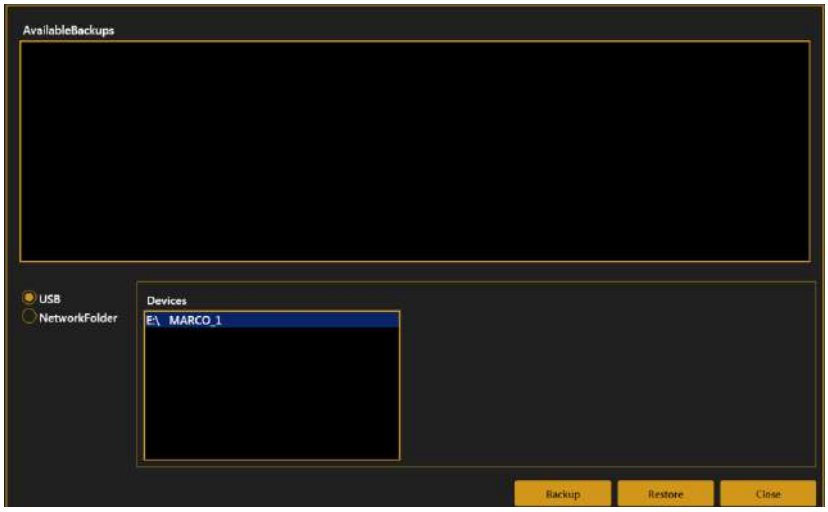
  The machine calibration can be restored only by the technician to the same device from which the backup was made.

Backup Procedure

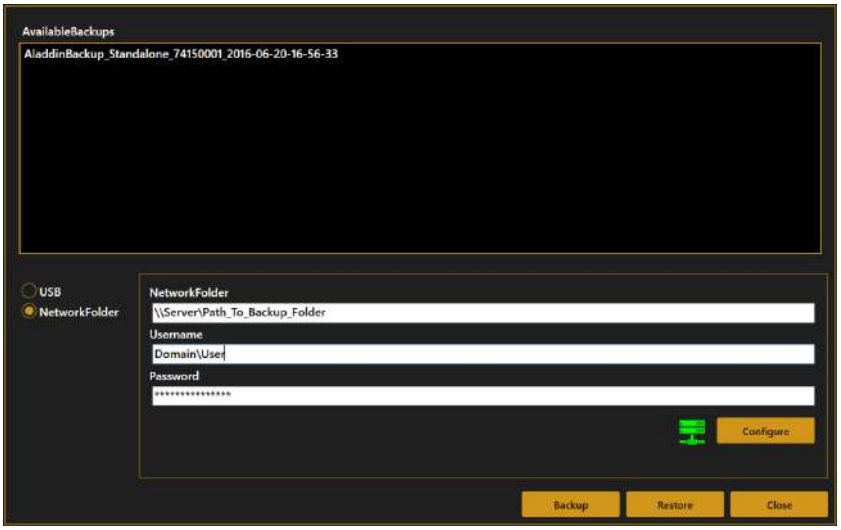
To perform the backup connect the desired USB external storage device or switch to Network Folder option.

1. Select the desired destination:

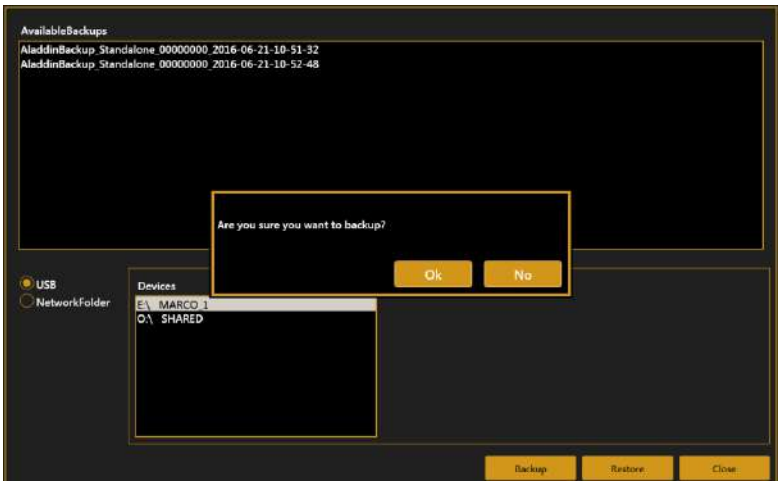
   - USB, select the desired partition from the list of the available



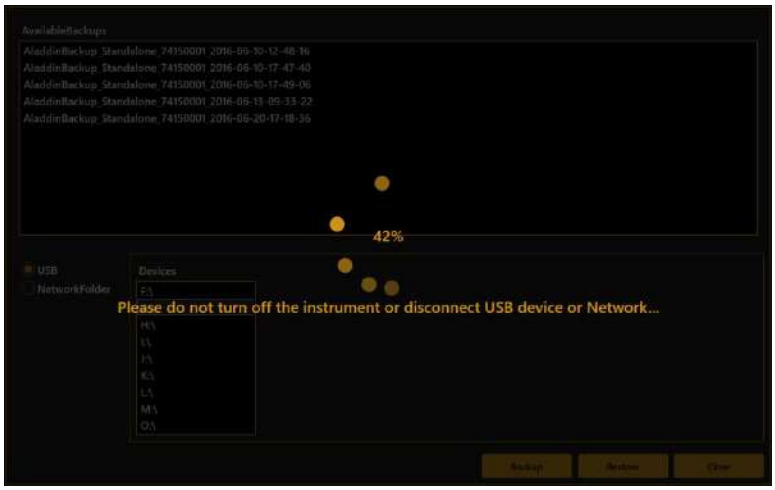
   - Network folder, define (if not already defined) the desired network shared folder destination, check the connectivity.



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*>

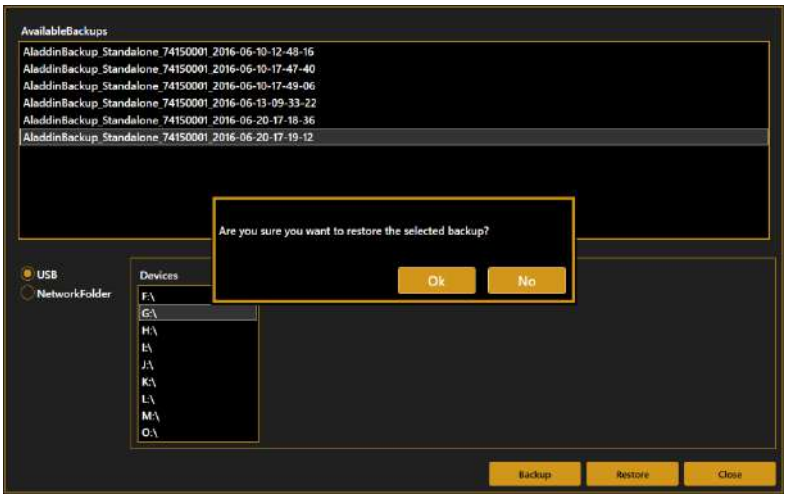
Restore Procedure

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.

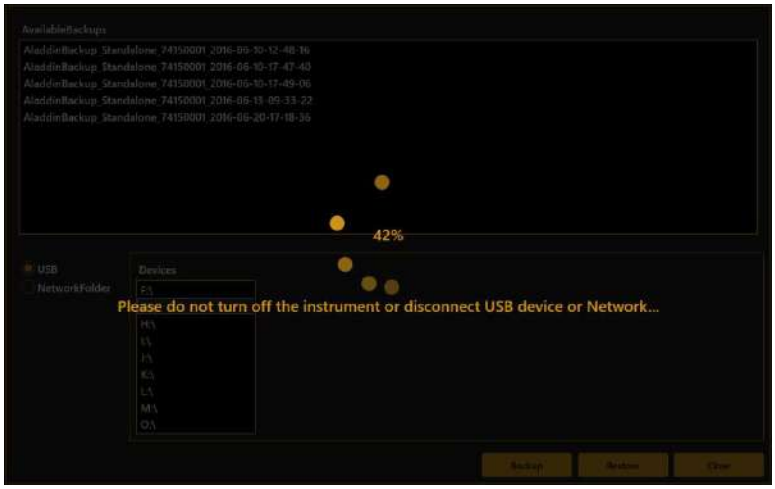
1. Select the source of the backup image to restore (USB or Network Folder). Navigate the list of detected backup images available at the selected source.

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.

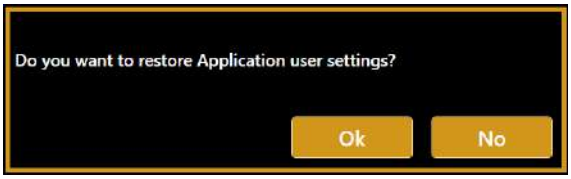
   (1) *Restore machine calibration files*.

   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.

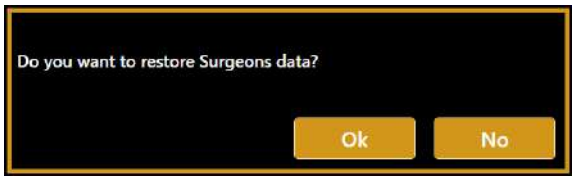
   (2) Restore Application User Settings.

   The current content on the machine will be overwritten.



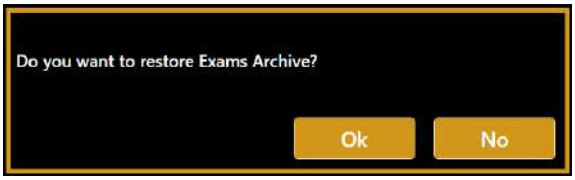
   (3) Restore Surgeons settings.

   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.



13.15.6.5 Closing the software

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

14 Operating voltage and fuse change

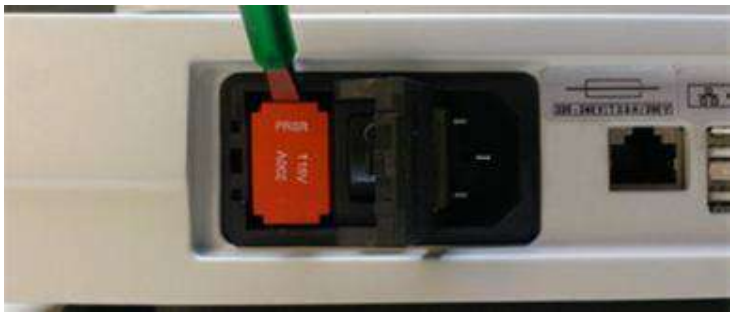
14.1 Changing the operating voltage

Step 1

Open the fuse box cover using a screwdriver

Step 2

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



Step 3

Make sure the fuses stay in the correct position

Step 4

Rotate the fusebox 180° so the 115V text is on the left side and put it back in the black fuse box

Step 5

Push the red fuse box carefully back into position

Step 6

Close the black cover again and check if 115V is displayed in the opening

14.2 Changing the fuse

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.

The procedure to change the fuse is very similar to changing the voltage, except that in Step 3 you also need to remove the blown fuse from its seat and replace it with an identical one as indicated in the following table and on the instrument label:

Power supply voltage	Fuse type	Fuse value
220 – 240 V	20 x 5 mm	2.5 A 250 V antisurge

After replacing the fuse, continue with step 5, of course without turning the fuse box, and step 6 and check that the desired voltage is indicated.

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 mains power, the device has a master switch that removes all power from the device, and a plug connection to high voltage which performs the same function as the previous one.

15.1 General

Corneal topography	
Keratometry conus	24 rings equally distributed in a 43D sphere
Points analyzed	Over 100,000 points
Points measured	Over 6,200 points
Corneal coverage	Up to 9.8 mm on a sphere of 8mm radius (42.2 dioptres with n=1.3375)
Focusing system	Guided focus

Pupillometry	
Measuring method	Image analysis
Light source	Infrared and white light LED

Axial length	
Measuring method	Low-coherence interferometry on optical fiber
Light source	SLED @ 830nm
Axial length range	From 15mm up to 38mm

Anterior chamber	
Measuring method	Slit light projection
Light source	Blue LED

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)

15.2 Electrical data

Power supply	*AC 100-240V 50/60 Hz*
Power consumption	*<150 VA*
Onboard fuses	*2x T2.5°*

Device Class for EN 60601-1	*Class I*

15.3 Optical radiation

1) Axial length measurement

Source:	Sled	
Wavelength	830	nm
Power on patient's eye:	< 0.6	mW

Source:	IR LED (crown)	
Wavelength:	770	nm
Power on patient's eye:	< 0.1	mW

2) Central fixation LED

Yellow green

Source:	LED	
Wavelength:	572	nm
Power on patient's eye:	<0.01	mW

3) Illumination of Placido disk for topographic analysis

Source:	Red LED Type1	
Wavelength:	633	nm
Power on patient's eye:	<0.02	mW

Source:	Red LED Type2	
Wavelength:	615 -630	nm
Power on patient's eye:	<0.02	mW

4) Pupilometric analysis

Source:			White LED	
	Blue	Green	Red	
Wavelength:	473	532	630	nm
Power on patient's eye:	0.03	0.005	0.008	cd

Source:	IR LED	
Wavelength:	780	nm
Power on patient's eye:	<0.4	mW

5) ACD measurement

Source:	Blue LED	
Wavelength:	473	nm
Power on patient's eye:	<0.07	mW

Caution should be practised when using the device's ACD measurement for any given intraocular lens calculation because of the high variability of this measurement.

The ACD measurement is the distance between corneal epithelium and the crystalline lens surface.

The light emitted from this instrument is NOT hazardous. It is classified ad Group 1 of ISO 15004-2.

15.4 Performance Testing

BRIEF SUMMARY OF PERFORMANCE TESTS AND RESULTS

A prospective, single site clinical study comparing the performance of the ALADDIN with IOL Master was conducted in 63 eyes (1 eye for each enrolled subject). This study evaluated the agreement, repeatability and precision in the subsequent endpoints:

Data Type	All Devices
Quantitative Measurements	• Axial Length • Anterior Chamber Depth • Radii of curvature of flattest and steepest meridian • Axis of the flat meridian • White to white distance

The agreement between instruments is summarized in Table 1:

Table 1.

Agreement between ALADDIN and IOL Master.

	ALADDIN		IOL Master		Agreement parameters			
Endpoint	Mean	SD	Mean	SD	Difference	Difference SD	lower LoA	upper LoA
acd	3.417830688	0.679989056	3.31952381	0.650987552	0.0983069	0.116363197	-0.1344195	0.33103327
al	23.70365079	1.703971867	23.68846561	1.710252709	0.0151852	0.027245176	-0.0393052	0.06967554
ax for 0.00<=cyl<=0.75	88.18518519	94.49566422	87.53947368	92.10832857	2.0765015	9.975699862	-17.874898	22.0279012
ax for 0.75<cyl<=1.50	77.48101266	115.8921525	76.05882353	114.2054185	0.9400949	3.261808332	-5.5835217	7.46371159
ax for 1.50<cyl	40.82758621	92.30826382	39.96428571	103.2499472	0.8218912	2.093718248	-3.3655453	5.00932767
k1	42.93549692	2.400645881	43.01523003	2.415238617	-0.0797331	0.154802285	-0.3893377	0.22987146
k2	43.90205198	2.589996595	43.99521136	2.600533074	-0.0931594	0.186267212	-0.4656938	0.27937504
wtw	12.28312169	0.525703699	12.32291005	0.557496798	-0.0397884	0.118840715	-0.2774698	0.19789307

Note to the Table 1:

- axis results are summarized by the subsequent classes of cylinder: 0.00≤cylinder≤0.75; 0.75<cylinder≤1.50; 1.50<cylinder.
- data in table concern the comparison producing the worst mean difference for al detected in the study.

The results of the study demonstrate that the axial length, corneal radius, anterior chamber depth and the "white-to-white" measurements of the Aladdin are substantially equivalent to those of the predicate device.

To evaluate repeatability and reproducibility, for each endpoint (AL, ACD, AX, K1, K2, WTW), analysis of precision was performed for ALADDIN and IOLMaster separately using a factorial ANOVA models for repeated measures within subject including the subsequent term: device identifier (A1, A2, A3 for ALADDIN and I1, I2, I3 for IOLMaster), operator identifier (1, 2 and 3), subject identifier (1 to 63) and every two-way interactions; a standard variance component matrix was used as covariance structure of R-side matrix. The related results

were used to estimate: - the reproducibility SD as the square root of model MSE; the reproducibility limit as reproducibility SD multiplied by 2.88; the reproducibility coefficient of variation as (reproducibility SD / mean) multiplied 100; - the repeatability SD as the square root of (device variance component estimate + operator variance component estimate + device*subject variance component estimate + operator*subject variance component estimate + model MSE); the repeatability limit as repeatability SD multiplied by 2.88; the repeatability coefficient of variation as (repeatability SD / mean) multiplied 100.
Variability of repeated measures within a subject was assessed before ANOVA modeling to guarantee that it is fairly constant across the range of results, as proved:

- plotting the standard deviation of repeated results with eye versus the mean of repeated results (data not shown);
- estimating the Spearman correlation coefficient between the standard deviation of repeated results with eye versus the mean of repeated results (data not shown).

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

TABLE2
Repeatability and reproducibility.

DEVICE	Endpoint	Overall Mean	REPEATABILITY			REPRODUCIBILITY		
			SD	Limit	% COV	SD	Limit	% COV
ALADDIN	acd	3.397248677	0.027579116	0.079427855	0.811807407	0.519528412	1.496241828	15.29262241
ALADDIN	al	23.69804821	0.018530025	0.053366472	0.078192199	0.129821027	0.373884559	0.547813162
ALADDIN	ax for 0.00<=cyl<=0.75	86.90250329	5.519759822	15.89690829	6.351669529	13.3944358	38.57597511	15.41317602
ALADDIN	ax for 0.75<cyl<=1.50	75.94121105	2.224842528	6.407546481	2.929690608	5.955000696	17.150402	7.841593008
ALADDIN	ax for 1.50<cyl	75.94121105	1.728735737	4.978758923	2.276413179	4.843085162	13.94808527	6.377413653
ALADDIN	k1	42.9413081	0.086388248	0.248798153	0.201177494	0.418268114	1.204612167	0.974046046
ALADDIN	k2	43.90794572	0.110161562	0.3172653	0.250892089	0.507055765	1.460320604	1.154815505
ALADDIN	wtw	12.27800118	0.065896179	0.189780996	0.536701196	0.264318617	0.761237618	2.152782146
IOLMaster	acd	3.327983539	0.048812637	0.140580394	1.46673312	0.241207692	0.694678153	7.247863133
IOLMaster	al	23.69269841	0.018705725	0.053872489	0.078951435	0.082094224	0.236431364	0.346495879
IOLMaster	ax for 0.00<=cyl<=0.75	88.66187221	7.444327655	21.43966365	8.39631227	15.80848015	45.52842284	17.83007708
IOLMaster	ax for 0.75<cyl<=1.50	75.96493239	2.164421305	6.233533358	2.849237453	16.539422	47.63353535	21.77244351
IOLMaster	ax for 1.50<cyl	75.96493239	1.867818382	5.379316939	2.45879029	5.710886052	16.44735183	7.517792582
IOLMaster	k1	43.0005842	0.082012189	0.236195103	0.190723429	0.330063483	0.950582831	0.767579067
IOLMaster	k2	43.99408476	0.093346514	0.268837961	0.212179694	0.53105056	1.529425614	1.20709537
IOLMaster	wtw	12.30152851	0.092008195	0.264983602	0.747941161	0.445406739	1.282771408	3.620743053

Note to Table 2:

- Repeatability includes variation due to measurement error;
- Reproducibility includes variations due to device, operator, interaction between device and subject, interaction between operator and subject, and measurement error;
- 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 is substantially equivalent for both repeatability and reproducibility to the predicate device.

Agreement study and reproducibility and repeatability study prove that ALADDIN performances are substantially equivalent to the predicate device ones for the assessed endpoints.

15.5 Information on measurements

1) Anterior chamber depth

Measuring range	1.5 – 5.5	mm
Display resolution	0.01	mm
Repeatability in live mode	±0.1	mm

2) Axial length

Measuring range	15 - 38	mm
Display resolution	0.01	mm
Repeatability in live mode	±0.016	mm

3) **Corneal Topography/Keratometry** (radius and axes of the main meridians)

Curve Radius (mm)

Measuring range	3.3 -37.5	mm
Display resolution	0.01	mm
Repeatability in live mode	±0.02	mm

Diopter Curve Radius (D) (n=1.3375)

Measuring range	9.0 -101.5	D
Display resolution	0.01	D
Repeatability in live mode	±0.12	D

4) Limbus (WTW)

Measuring range	6 – 18	mm
Display resolution	0.01	mm
Repeatability in live mode	±0.05	mm

5) Pupil dimension

Measuring range	0.5 – 10	mm
Display resolution	0.01	mm
Repeatability in live mode	±0.05	mm

15.6 Environmental conditions

	For operation:	***Storage:***	***Transport:***
Temperature	10-40° C	0-40° C	0-40° C
Relative humidity	8-75% (non condensing)	8-75% (non condensing)	8-75% (non condensing)
Atmospheric pressure	700-1060 hPa	700-1060 hPa	500-1060 hPa

15.7 Mechanical Specifications

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

15.8 Other Specifications: Onboard PC component specifications

	Hardware 1.0	**Hardware 2.0**
Operating system	*WINDOWS XP Embedded*	*WINDOWS 7 Embedded*
Processor	*Intel Atom N270*	*AMD G-T56N*
RAM	*1GB*	*2GB*
Hard disk	*160GB*	*250GB*
External connections	*LAN integrated, 2 xUSB*	*LAN integrated, 2 xUSB*

16 Declaration of conformity

DECLARATION OF CONFORMITY/ *Dichiarazione di conformità:*

Manufacturer/*Fabbricante* :

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

Address/*Indirizzo* : Via C.E. Gadda, 15 – 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

17 Appendix: Installing an external printer

17.1 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:

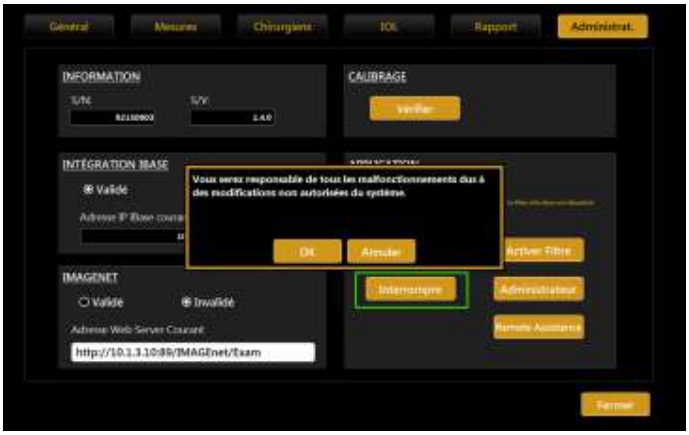
17.2 Disabling the Write Filter

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.

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

   Press Cancel to avoid the restarting of the machine.

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.



17.3 Installing a local printer (USB)

The following instructions are for a Windows XP system. On Windows 7 machines follow similar steps.

Close the software using the procedure explained before in step 2. From the ALADDIN Windows **Start** menu, select **Settings** then **Printers and Faxes**.

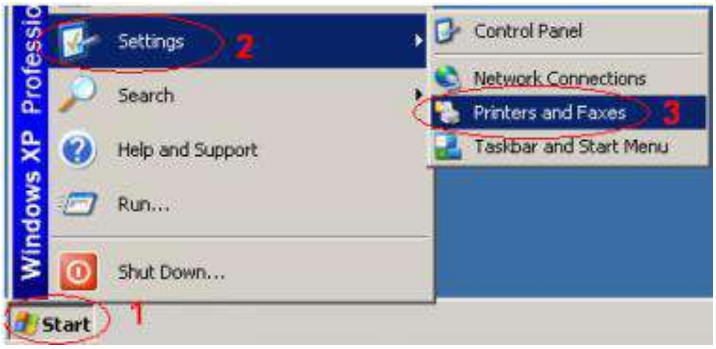


Figure 103

Double-click the **Add Printer** icon (or "File"→ "Add Printer").

Figure 104

The **Add Printer Wizard** will appear. Click **Next**.

Figure 105

Select "**Local printer attached to this computer"** and make sure that the **Automatically detect and install my Plug and Play printer** checkbox is not checked. Click **Next**.

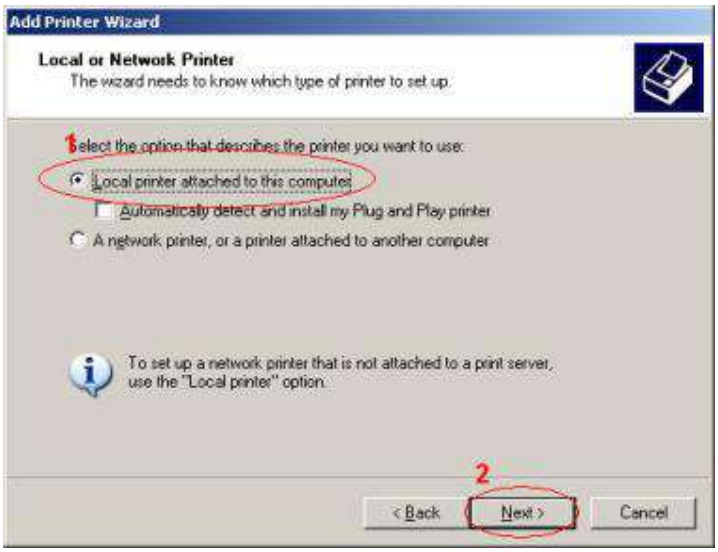


Figure 106

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

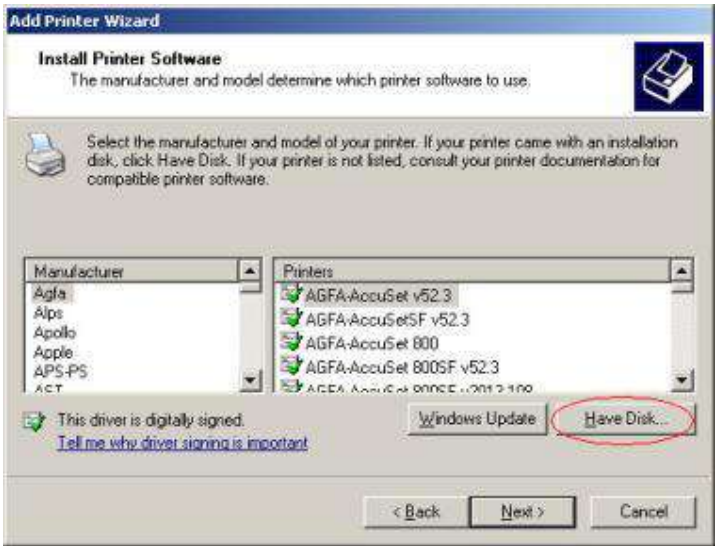


Figure 107

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 108

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

Figure 109

Select if you want to make this printer the default. Click **Next** and then **OK** and the procedure is finished.

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.

17.4 Installing a network printer (LAN)

Connect ALADDIN to an external network through the LAN port using an Ethernet cable.

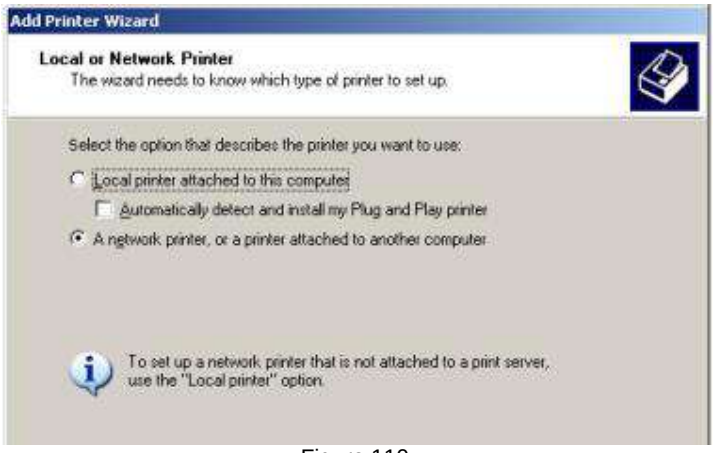


Figure 110

This time, select **"A network printer, or a printer attached to another computer"**

Now select "**Create a new port"**, then select "Standard TCP/IP Port" from the **Type of port** drop-down menu. Click **Next**.

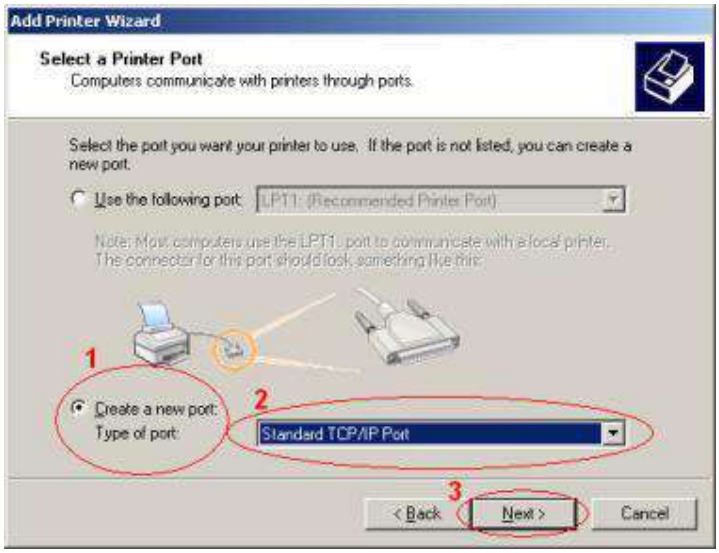


Figure 111

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.

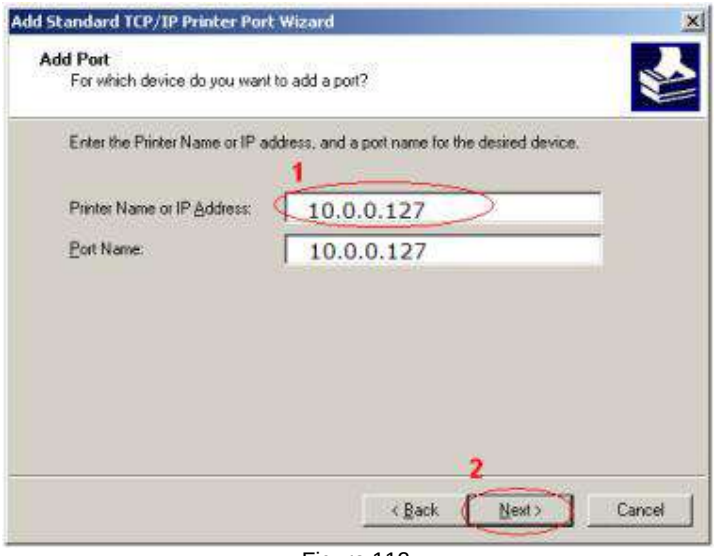


Figure 112

From here on, follow the same procedure as described for **"Installing a local printer (USB)"**

17.5 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

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.