TOPCON Healthcare

TERA
Dry Eye Imager

Rev. 1.0 06/11/2025
Cod. 890000024600

Thank you for choosing this product.

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

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

The original text of this manual is in English.

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CONTENTS

1 INTENDED USE

TERA Eye Dry Imager (hereinafter TERA) is a device for assessment of corneal properties and pupillary response. It provides measurements of corneal topography, curvature, aberrations, and pupillography to support clinical evaluations. The device is intended to be used by qualified healthcare professionals to aid in the diagnosis, monitoring, and management of corneal and pupillary disorders in adult patients..

1.1 INTENDED USERS

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

1.2 TYPES OF USE/REUSES

The device is designed for multiple patient, multiple use applications.

1.3 PLACE OF USE

Healthcare centers, optometry practices, eye hospitals, and other eye-care facilities.

1.4 PATIENT POPULATION

TERA is intended for use on the adult population.

Sex	No specifications
Age	Adult population
Medical Condition	• Various refractive conditions of the cornea, such as myopia, hyperopia, and astigmatism • Keratoconus • Various clinical conditions of the eyeball and surrounding areas such as dry eye, conjunctival hyperemia, and blepharitis

Table 1.1: Characteristics of the intended patient population

1.5 CONTRAINDICATIONS

There are no contraindications or side effects for the subject device.

1.6 CAUTIONS

The instrument should be used with caution in the following situations:

- Patients who are unable to sit upright or unable to place their head on the chin-rest and forehead rest of the instrument (with or without supplemental human or mechanical support).

Limited to corneal topography, the following cautions must be taken into account:

- Artificial tears instillation before image acquisition is not recommended, as the tear film produced can be inaccurately read as the cornea's topography.
- Patients with keratitis, conjunctivitis, or any other infectious disease, as well as in patients taking medications that cause hypersensitivity to light.
- Patients hypersensitive to light.
- Patients who have recently undergone photodynamic therapy

The use of the instrument is not recommended in the following cases:

- Acute infections of the eye.
- Recent ocular surgery (within 3 months).
- Only one functional eye (monocular).
- Poor fixation
- Nystagmus

1.7 LIMITATIONS

There are no restrictions on the use of the device, and the device does not require specific limitations.

1.8 RESIDUAL RISKS/UNDESIRABLE SIDE EFFECTS

There are no known residual risks or undesirable side effects.

1.9 GENERAL DESCRIPTION OF FUNCTIONS

TERA is a corneal analyzer with the following functions:

- Corneal topography and keratometry for diagnostic purposes
- Pupil measurements
- Assessment of the status of the Meibomian glands
- Tear meniscus height measurement
- Fluorescence imaging for contact lens fitting
- Ocular surface staining for diagnostic purposes
- Dynamic analysis of tear film stability and blink time
- Qualitative assessment of the status of the ocular redness
- Qualitative assessment of the status of the lipid layer flow
- Qualitative assessment of the blepharitis inflammation state
- Store and generate overviews of historical data of ocular properties for easy and comprehensive observation of changes and trends over time. This is especially useful for conditions such as dry-eye disease and keratoconus.

1.10 INTERACTION WITH THE PATIENT

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

- ABS Chinrest
- ABS Forehead rest

The chinrest and the forehead rest are the applied parts.

2 PRECAUTIONS

This electronic device is intended for use in professional healthcare settings, including health centers, optical stores, hospitals, and other eye care facilities, where the equipment and systems are managed by healthcare professionals.

Use and store the device in a suitable location under standard ambient temperature, humidity, and atmospheric pressure conditions, and avoid exposure to direct sunlight.

- To ensure proper functioning, install the instrument in a location not subject to vibrations
- Before operating the device, verify that the power cable is intact and securely connected to both the device and the mains outlet
- Use the recommended mains voltage
- When the unit is not used, disconnect the power supply, and protect it against sun and dust
- To obtain accurate and reliable measurements, keep the measuring cone clean and dust-free

2.1 ELECTROMAGNETIC COMPATIBILITY

This electronic device is a precision instrument intended for use in professional healthcare environments, including hospitals, physicians' offices, surgical centers, and limited care facilities, where equipment and systems are managed by healthcare professionals. This product complies with EMC standards (IEC 60601-1-2 4th Edition).

- ELECTRICAL MEDICAL DEVICES require special EMC precautions and must be installed and operated according to the EMC instructions provided in the accompanying documentation.
- The use of accessories and cables other than those supplied with the instrument, except cables sold by the equipment manufacturer as spare parts, may lead to an increase in emissions and reduce the devices or system's immunity.
- Any cables connected to USB and LAN ports must be less than 3 meters in length.
- The device should not be used adjacent to or stacked on other equipment; if adjacent or stacked use is inevitable, the equipment should be watched to verify proper operation in the configuration in which it will be used.

- Portable RF communication equipment should be used no closer than 30 cm to any part of the equipment, including specified cables. Otherwise, the degradation of equipment performance could result.

2.1.1 EM Emission

The TERA device fulfills the requirements of IEC 60601-1-2 4th Edition:

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

2.1.2 EM Immunity

The TERA device fulfills the requirements of IEC 60601-1-2 4th Edition:

Immunity Test	**Standard**	**Test Level**		
Electrostatic discharge (ESD)	IEC 61000-4-2	± 8kV contact, ± 15kV air		
Electrical fast transient/Burst	IEC 61000-4-4	±2kV, 100kHz repetition frequency		
Surges	IEC 61000-4-5	±1kV common mode, ±2kV differential mode		
Rated Power frequency magnetic field	IEC 61000-4-8	30 A/m		
Conducted disturbances induced by RF fields	IEC 61000-4-6	**Level**	**Frequency**	**Modulation**
		3V	150kHz–80MHz	1kHz 80% AM
		6V	6.765–6.795MHz	1kHz 80% AM
		6V	13.553–13.567MHz	1kHz 80% AM
		6V	26.957–27.283MHz	1kHz 80% AM
		6V	40.66–40.70MHz	1kHz 80% AM
Radiated RF EM fields	IEC 61000-4-3	**Level**	**Frequency**	**Modulation**
		3	80MHz ÷ 2700MHz	1kHz 80% AM
		27	380MHz ÷ 390MHz	18Hz 50% PM
		28	430MHz ÷ 470MHz	18Hz 50% PM
		9	704MHz ÷ 787MHz	217Hz 50% PM
		28	800MHz ÷ 960MHz	18Hz 50% PM
		28	1700MHz ÷ 1990MHz	217Hz 50% PM
		28	2400MHz ÷ 2570MHz	217Hz 50% PM
		9	5100MHz ÷ 5800MHz	217Hz 50% PM

Table 2.1: Immunity Test Standards and Test Levels

The TERA device is intended for use in an electromagnetic environment in which radiated RF interferences are controlled. The customer or the user of the device can help prevent electromagnetic interference by keeping a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.

For transmitters rated at a maximum output power not listed above the recommended separation distance d in meters (m) can be estimated using the equation applicable to

Table 2.2: Recommended separation distances between portable and mobile RF communication equipment and the device.

Rated max output of transmitter (W)	**Separation distance according to transmitter frequency (m)**		
	150 kHz **to 80** MHz $d = 1.2 \cdot \sqrt{P}$	**80** MHz **to** 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz **to 2.0** GHz $d = 2.3 \cdot \sqrt{P}$
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

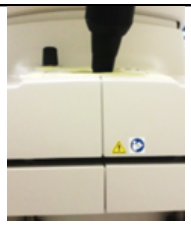
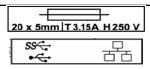
the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

3 SYMBOLS

This section provides an overview of the symbols used in the TERA User Manual and device labeling. These symbols are essential for understanding device operation and compliance requirements.

Symbol	Standard Reference	Description
	IEC 60417-5840	CLASS I DEVICE IN ACCORDANCE WITH 60601-1 APPLIED PART TYPE B
CE 0123	regulation (EU) 2017/745	Product in accordance with regulation (EU) 2017/745
Type A	EN ISO 19980	corneal topography according to ISO 19980:2021
	IEC 60417-5032	alternate current
	ISO 7010-M002	follow the instructions for use
	ISO 7010-W001	general warning
	ISO 7010-W027	optical radiation warning
	ISO 7010-W001	caution (general warning): to avoid injury caused by electric shock, do not open the cover. ask your dealer for service.

Symbol	Standard Reference	Description
	ISO 7010-W001	general warning: be careful not to hit the patient's eyes or nose with the instrument during operation. the patient may be injured.
	ISO 7010-W001	caution (general warning): to avoid damage from the motorized chinrest, be mindful of the patient while using the device
	EN ISO 15223-1 ISO 7000-3082	manufacturer
	EN ISO 15223-1 ISO 7000-2493	reference or model number
	EN ISO 15223-1 ISO 7000-0632	temperature limitation specifies the temperature limits to which the medical device can be safely exposed.
	EN ISO 15223-1 ISO 7000-2620	humidity limitation specifies the range of humidity to which the medical device can be safely exposed.
	EN ISO 15223-1 ISO 7000-2621	atmospheric pressure limitation specifies the range of atmospheric pressure to which the medical device can be safely exposed.
	EN ISO 15223-1 ISO 7000-0626	keep dry
	EN ISO 15223-1 ISO 7000-0621	fragile! handle with care
	ISO 780	this way up specifies the correct upright position of the package for transportation
	IEC 60417-5009	stand-by switch
	IEC 60417-5009	external ports and fuses

Symbol	Standard Reference	Description
	EN ISO 15223-1 ISO 7000-2498	serial number
	EN ISO 15223-1	medical device indication
	EN ISO 15223-1 ISO 7000-2497	manufacturing date yyyy-mm
	MedDO	Swiss authorized representative
	EN ISO 15223-1	unique device identifier
	EN ISO 15223-1	this symbol is solely applicable to ec member countries. to avoid potential negative consequences for the environment and possibly human health, this instrument should be disposed of (i) for eu member countries – in accordance with weee 2012/19/ue (directive on waste electrical and electronic equipment) or (ii) for all other countries, in accordance with local waste disposal and recycling laws.

Table 3.1: List of Symbols Used in TERA User Manual

These symbols help ensure proper device handling and compliance with medical safety standards. Always refer to the official documentation for detailed explanations.

4 SAFETY INSTRUCTIONS

4.1 GENERAL

- TERA should be used only for its intended purposes as detailed in this manual.
- Always keep this manual handy and close to the device.
- ⚠ The instrument can only be used by qualified personnel (eye specialists, ophthalmologists, opticians, and optometrists) after reading this user manual.
- For each clinical function, hazards have been identified from potential faults or misuse of the system. There are no unacceptable risks related to clinical functions; therefore, there is no Essential Performance for the device.
- The device is installed by the final user.
- The device must be connected to an appropriate power source; otherwise, its performance may be reduced.
- ⚠ Position the unit so that it is not difficult to disconnect the plug for connection to the supply main.
- ⚠ If the device has just been delivered or has undergone thermal shock, wait at least one hour before making measurements on patients.
- ⚠ If the device has been subjected to external forces (e.g., impact or dropping), it must be thoroughly checked before examining patients. To do this, refer to the related section in this manual. If necessary, send the device for repair.
- Remove all covering material (dust sheets) from the device before turning it on.
- ⚠ Run all the control functions (detailed in 12.7 Checking calibration section) before carrying out measurements on patients.
- ⚠ The physician or device user must inform the patient of the related safety instructions and ensure that they are observed.
- Use only genuine TERA accessories and spare parts.
- Turn off the device if it is not going to be used for an extended period.
- ⚠ Installation of unauthorized software on the device is not permitted.

- ⚠ 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.

- ⚠ To reduce the risk of electric shock or damage, keep the device away from water, moisture, and other liquids. Do not place containers filled with liquids on or near the device. If the device becomes wet, immediately disconnect it from the power supply and contact authorized service personnel.

- Unexpected or accidental shutdown of the device may cause loss of unsaved data or incomplete grading results.

4.2 ENVIRONMENT OF USE

- The device must be used in the environmental conditions as specified in this document.

- The least favorable environment is defined as the maximum temperature values within which the unit must operate while drawing maximum current. The environmental value is +40°C. Maximum current absorption occurs during topography acquisition.

- The maximum temperature of applied parts (chinrest and headrest) can exceed 41°C when the device is used at an ambient temperature close to 40°C. The device temperature does not exceed 48°C. Considering the examination duration, the patient's condition, and the parts that are in contact with the patient, there are no known contraindications regarding contact with the device.

- It is advisable to use the device in an unlit environment.

- Do not use the device near highly flammable materials or in areas at risk of explosion.

4.3 ELECTRICAL SAFETY

- ⚠ To avoid the risk of electric shocks, this equipment must only be connected to the supply mains with protective grounding.

- TERA has an on-board power supply unit installed. For connection to the supply mains, use only the manufacturer-approved cables provided with the device.

- Before performing maintenance on the device, turn it off and disconnect the power cable.

- Do not touch the LAN/USB ports contacts and the patient at the same time.

- ⚠ The device remains connected to the mains supply as long as the power cable is plugged in. Complete disconnection is only possible by removing the power cable from the outlet.

4.4 LED EMISSION SAFETY

- ⚠ **CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to the summed light of spatially overlapping light sources from this instrument when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2 J/cm2 after, 2:36 min for source 1, and 2:36 min for source 2, if all sources are operating concurrently as happens in "Inner acquisition mode". Although the risk of retinal injury at a cumulative exposure just exceeding 2,2 J/cm2 is low, as some patients may be more susceptible than others, caution is advised. Exposures exceeding the recommended maximum exposure (RME) of 10 J/cm2 (cumulative exposure duration exceeding 4,5 times the Group 1 limits) entail a significant risk of injury.**

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

- The LED groups comply with the emission limits for the Group 2 instruments of the ISO 15004-2:2024 standard.

4.5 INSTALLATION WITH EXTERNAL DEVICES OR IT NETWORK

- TERA complies with the CE marking requirements.

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

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

- A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular, such a Separation Device is required when a network

connection is made. The requirement for the Separation Device is defined in clause 16.5 of IEC 60601-1.

- In case a Multiple Socket Outlet is used to supply the system, a Medical Electrical System has been created, even if there is no signal connection to other equipment. This might lead to an increase in leakage current and grounding impedances. Therefore, a Multiple Socket Outlet should always be used with an isolation transformer, as described in clause 16.9 of IEC 60601-1.
- Note that the total grounding impedance, from each equipment in a system, should be maximum 0.2 Ohm measured to the grounding pin in the mains plug of the Multiple Socket Outlet.
- An external keyboard or another input device compatible with USB interfaces be connected to the device to enter text.
- Do not use mobile phones or other devices not compliant with the requirements of class B EMC near the TERA.
- ⚠ Every external device that has to be connected to TERA must have a USB connection cable with a maximum length of 3 m.
- TERA can be connected to an IT network to print reports and perform remote technical assistance.
- The TERA USB port must be connected to the printer with a USB or LAN interface. Ask the local distributor technical assistance for printer driver installation.
- The TERA can be connected to a Local Area Network (LAN) through the LAN connector. The network must have an Ethernet protocol (IEEE 802.3). Ask your local distributor for technical assistance and the TERA system administrator for network settings.
- ⚠ TERA can be connected to an external network folder to save PDF reports or to enable technical service interventions on the device.
- Connection of the TERA to a computer network that includes other equipment could result in previously unknown RISKS; identify, analyze, and control such RISKS (refer to IEC 60601-1).
- Subsequent changes to a computer network could introduce new RISKS and require new analysis.
- Changes to the computer network include:
  - Changes in computer or data network configuration
  - Connection of additional items to the computer network
  - Disconnecting items from the computer network
  - Update of equipment connected to the computer network
  - Upgrade of equipment connected to the computer network

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

- ⚠ Do not change the Ethernet settings of the “INTERNAL” or “RESERVED” adapter.

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

TERA is designed to operate exclusively on a secure and compliant network. For optimal performance and data protection, it must be connected to a network that meets the following requirements:

- ⚠ Access to the network must be restricted to authorized personnel.

- ⚠ Network configurations must comply with relevant cybersecurity standards (e.g., IEC 80001-1 or applicable regulations).

Failure to use a secure network may compromise the device’s functionality, data integrity, and patient safety.

4.6 TRANSPORT AND PACKAGING

- The device must be transported and stored in its original packaging.

- For storage and transport conditions, refer to "17 **Technical Specifications and Performance**" section.

- Carefully store the original packaging to use it if you need to transport the device.

- To move the device over short distances (without packaging) and to fit it in and remove it from the original packaging, grip the device with both hands, one on the front headrest arch and the other in the recessed niche at the back the device (in position with the locking system).

- ⚠ Use the Packing mode button before Tera transportation.

4.7 CLEANING

The main purpose of this paragraph is to list all the activities needed in order to carry out an efficient and systematic cleaning and disinfection during normal use, to ensure the device is correctly cleaned and disinfected.

- ⚠ Correct cleaning and disinfection procedures, together with adequate operating procedures, are essential to prevent the spread of infection or cross-contamination.

4.7.1 Recommended Products

The procedure must be carried out considering the requirements of both cleaning and disinfection. It takes as well into account the features of the product such as its sensitivity to specific substances and the choice of effective disinfecting products.

- ⚠ Be careful not to wet the device and clean it only as specified to prevent damage. Never use solvents or other abrasive agents.
- Do not clean the plastic parts with solvents such as benzene or similar products, as they may cause discoloring of the parts and degradation of the material.

We recommend to use the following products:

- Detergents - polyenzymatic solutions or neutral surfactant-based solutions.
- Disinfectants/decontaminating products - Surface-friendly disinfectants (containing or not containing aldehyde) or formaldehyde-free surface disinfectants-cleaners (e.g., Kohrsolin FF) alternatively you may use ethyl alcohol, 70 v/v, or isopropyl alcohol.
- Correct cleaning and disinfection procedures, together with adequate operating procedures, are essential to prevent the spread of infection or cross-contamination.

4.7.2 Hygiene and safety

The device is considered "noncritical" when its use is carried out on healthy skin, so that adequate cleaning, or low-level disinfection is considered sufficient. However, the patient's condition is transmissible by direct contact, or in case of exposure to body fluids, it is recommended to disinfect with a higher-level disinfectant after cleaning.

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

4.7.3 Procedure for cleaning and disinfection

Regularly clean the device removing dust using a soft cloth.

In case of more persistent surface dirt, use a soft cloth soaked with a rinse-free cleansing solution (we recommend using neutral, surfactant-based solutions and/or polyenzymatic solutions).

- The device comes with a dust cover to be used to protect it. Cover the TERA if it is not going to be used for an extended time.
- If there are permanent stains on the surface of the Placido disc, please contact your distributor for replacement.

4.7.4 Plexiglass cleaning procedures

It is important that the plexiglass in front of the cone is cleaned correctly according to the following instructions to prevent scratches and abrasions

Type of Cloth: Microfibre cloth such as the one supplied with the instrument, inside the calibrator box.

Type of solution: ethyl alcohol, 70 v/v, or isopropyl alcohol

Cleaning methods: Continuously folding the cloth to expose a clean part during the cleaning process helps to keep the dirty parts of the cloth away from the glass surface. It is also important to rub in a linear motion, as circular movements simply redistribute the dust, with the risk of causing scratches

4.8 SAFETY MEASUREMENTS CHECKING

- ⚠ It is recommended to check the calibration of the instrument when the device has been transported from one place to another and when it has suffered an impact or thermal shocks(refer to 12.7 Checking calibration section).
- ⚠ It is recommended to check the calibration every day when turning on the device using the instrument provided(refer to 12.7 Checking calibration section).
- The user of the device must check that the measurements provided by the device are plausible.
- It is advisable to visually check all the light sources before examining patients to make sure that they turn on properly.
- If the device frequently emits error signals, turn it off and contact technical support to have the device checked. Refer to Errors in measurements section (12.10.8.1).
- ⚠ In patients with blue eyes, the acquisition of pupillometry in mesopic lighting conditions can be difficult to accomplish. In this case, we suggest acquiring the mesopic data through dynamic pupillometry.
- ⚠ Contact lenses must not be worn by the patient during data acquisition.

4.9 PRIVACY AND CYBERSECURITY

- ⚠ When installing a new unit, the user MUST set his credentials to prevent unauthorized physical access to the device.
- ⚠ Make sure the USB devices you wish to connect to the instrument are secured against malware/viruses.
- ⚠ Patient data on USB devices can become corrupted when inserting them into computers for backup or transfer.
- ⚠ The use of antivirus software on computers is recommended, and it is the responsibility of the user.

- ⚠ To protect data exported to USB from unauthorized access, use dedicated USB data for storage.

- ⚠ Installation of any unapproved software, including drivers, could degrade the performance of the instrument and may void the instrument warranty.

4.9.1 Privacy

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

4.9.1.1 Definitions and application within this device

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

  Personal Data used with the device are:

  - Subject identification data: name, date of birth, gender, ID (according to the ID application policy of the clinic). Refer to the application settings section for further details on the management of subject identification data.

  - Subject physical/physiological data: subject's eyes biometric measurements, as acquired and stored during each examination and belonging to the subject. Refer to the application settings section for further details on the types of biometric measurements performed by the device.

- **Controller**: means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data. The controller is the representative of the clinic or hospital where the device is installed.

- **Processor**: means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the Controller. The processor is/are the person/s designed by the clinic or hospital to operate the device and use the results.

4.9.1.2 Device characteristics to support Data Protection

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

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

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

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

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

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

- **Right to Rectification or Erasure.** The controller and processor can, upon request from the data subject, rectify the subject's identification data. The controller and processor can, upon request from the data subject, erase permanently the subject's identification data and physical/physiological data. After erasure, no trace of the subject data is present on the device. Refer to the patient management section for details on how to rectify or erase patient data.

- **Right to restriction of processing.** The device application doesn't automatically process or transmit the subject data.

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

- **Right to object.** No automated processing of data subjects is performed in this device. The processing is performed on the decision of the processor.

- **Automated individual decision-making, including profiling.** No automated decision-making or profiling is performed on this device.

4.9.1.3 Privacy and Data Protection during assistance/support services

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

4.9.2 Privacy and Security options

The Privacy and Security options can be accessed at any time from the settings.

4.10 SAFETY INCIDENT – NOTICE TO THE USER AND/OR PATIENT

In case any serious incident occurs in relation to the device, please report it to the manufacturer, at the following addresses:

- Customer service (email address: service.hcs.it@topcon.com)
- Quality office (email address: quality.hcs.it@topcon.com)

5 PRODUCT WARRANTY AND RELIABILITY

5.1 SAFETY WARRANTY TERMS

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

5.2 VALIDITY CONDITIONS

- ⚠ The product warranty is valid only if the device is equipped with its original accessories.
- The product warranty is void in the event of loss or damage due to improper or incorrect use of the device.

5.3 REPAIRS AND SERVICE

- ⚠ If the device is opened by unauthorized staff, the manufacturer shall be held harmless from all liability, and the warranty shall be null and void.
- NOTE: Modifications or repairs to the product, especially where they require opening the device, may only be carried out by technical staff authorized by the manufacturer.

5.4 MAINTENANCE GUIDELINES

Regular maintenance should be performed following the guidelines in this manual. Users should not attempt repairs or maintenance beyond routine cleaning and care.

5.5 LIABILITY

The manufacturer is not liable for damages caused by fire, natural disasters, misuse, or negligence. The manufacturer is also not responsible for business losses resulting from the unavailability of the device.

5.6 LIFETIME

The lifetime is intended as the product's total life in use from the date of sale to the date of discard during which the manufacturer of the medical device guarantees the safe and effective use of the product through risk management, and the product can maintain its scope of application.

The estimated lifetime of the TERA device is 8 years.

- Modifications to the product or failure to follow the manufacturer's instructions may substantially reduce the expected lifetime and significantly increase the risks associated with the use of this device and are thus not permitted.

6 LEGAL PROVISIONS

6.1 REGULATORY COMPLIANCE

The TERA device complies with applicable medical device regulations, including REGULATION (EU) 2017/745 and IEC 60601-1 standards. It is classified as a Class IIa medical device.

6.2 CERTIFICATIONS AND STANDARDS

Standard	Description
IEC 60601-1	Class I type B continuous operation
IEC 60601-1-2	see Sections 2.1.1 and 2.1.2
ISO 15004-2	Group 2
ISO 19980	Type A

Table 6.1: Certifications and standards

6.3 DEVICE MODIFICATIONS

- Any modifications or repairs to the product must be performed by authorized personnel.
- Unauthorized modifications may result in safety risks and void regulatory compliance.

6.4 END-OF-LIFE DISPOSAL

At the end of its service life, the TERA must be disposed of in compliance with local environmental regulations. Electronic waste should be recycled properly to avoid environmental impact.

7 LIABILITY

7.1 GENERAL LIABILITY

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

7.2 EXTERNAL FACTORS

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

7.3 BUSINESS AND OPERATIONAL LIABILITY

The manufacturer is not liable for losses incurred due to unavailability of the device, including loss of revenue or business disruptions.

7.4 USER RESPONSIBILITY

It is the responsibility of the user to ensure that the device is used according to the prescribed guidelines and under appropriate conditions.

8 MAIN COMPONENTS

Table 8.1: Patient's side

Device View	Component Description
	1 Locking pins for chinrest paper 2 Chinrest 3 Placido disk 4 Forehead rest 5 Chinrest support

Table 8.2: User's side

Device View	Component Description
	1 Standby switch, Power Entry module, LAN/USB ports 2 Touchscreen display 3 Joystick with thumbwheel and button

9 PACKAGING CONTENT

9.1 ITEMS INCLUDED IN THE PACKAGE

The TERA is securely packaged with the following components and accessories to ensure proper installation and operation.

- TERA main device unit
- Power cables (compliant with EU and US/CA standards) - CODE 02
- USB drive with manuals and software
- Protective dust cover
- Calibration checking device - CODE 01
- Chinrest paper and pins

9.2 TRANSPORT AND SAFETY PRECAUTIONS

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

10 INSTALLING/UNINSTALLING THE SYSTEM

10.1 INSTALLATION PROCEDURE AND SETUP INSTRUCTIONS

The TERA system should be installed in a stable and suitable environment. Follow these steps for proper installation.

1. Unpack the device and ensure all components are present.
2. Place the device on a stable, flat surface.
3. Connect the device with the supplied power cord to a power source and ensure that it is properly grounded.
4. Press the power button and wait for the system to initialize.
5. Check that the touchscreen display is functioning correctly.
6. Run all the control functions (detailed in 12.7 Checking calibration section) before carrying out measurements on patients.

10.2 TROUBLESHOOTING STARTUP ISSUES

If the device does not start properly, check the power connections and refer to the troubleshooting section in the manual.

10.3 UNINSTALLATION PROCEDURE

If the system needs to be moved or stored, follow these steps to safely uninstall it.

1. Turn off the device and disconnect the power cable.
2. Carefully repack the device using the original packaging.
3. Secure all loose components to avoid damage during transport.
4. Store the device according with the storage enviromental conditions reported in section "17 **Technical Specifications and Performance**".

11 SETUP I-VIEWER (OPTIONAL)

11.1 INTRODUCTION

i-Viewer is an ophthalmic reviewing software that allows the examination data obtained with TERA to be reviewed on a PC. The software interacts via a network with the TERA to exchange data.

11.2 SYSTEM REQUIREMENTS

Ensure that the PC meets the following minimum requirements for installing i-Viewer:

- Windows 7, 8, 10, or 11 (32/64 bit)
- At least 2GB of RAM
- At least 4GB of free storage space
- Minimum screen resolution: 1280x1024

11.3 INSTALLATION PROCEDURE

1. Run the installer and follow the on-screen instructions.
2. Accept the terms and conditions to proceed with the installation.
3. Once installation is complete, restart the PC if required.

11.4 CONNECTING I–VIEWER TO TERA

Follow these steps to connect i-Viewer to the TERA device:

1. Ensure both the TERA and the PC are connected to the same network.
2. Enable the "i-Viewer Network" option in the TERA settings.
3. i-Viewer will automatically detect available TERA devices on the network.
4. Once connected, patient and examination data will sync between the devices.

12 OPERATING INSTRUCTIONS

12.1 POWERING ON THE DEVICE

To turn on the TERA, press and hold the power button until the startup screen appears. The device will initialize and be ready for use.

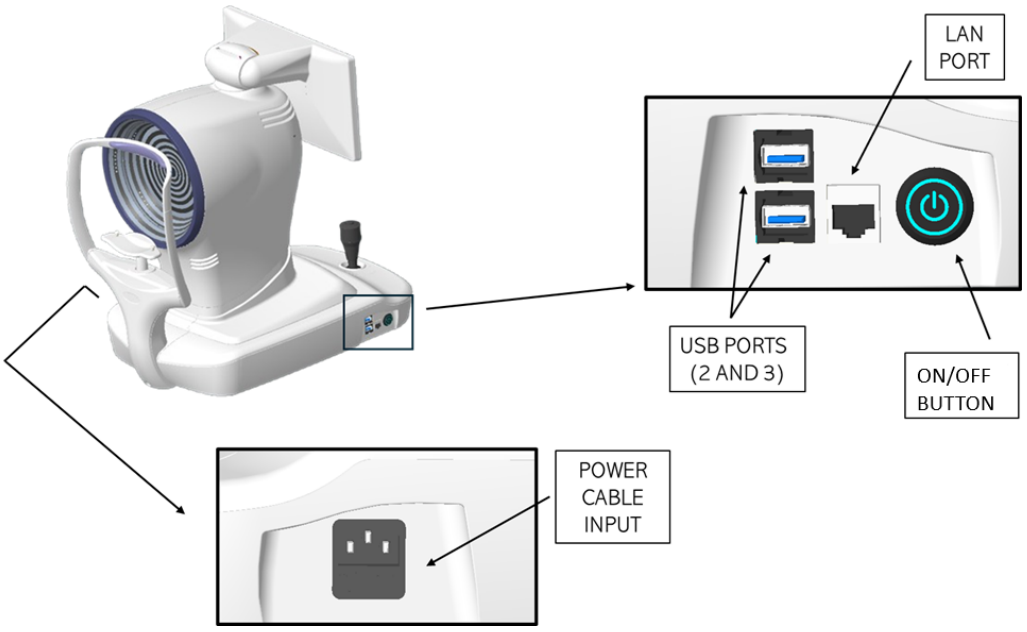


Figure 12.1: Device power on/off

12.2 SHUTTING DOWN THE DEVICE

To turn off the TERA, tap on the Menu button ☰ in the upper right corner of the application and tap on **Shutdown**.

The device will turn off on its own while ensuring data integrity.

12.3 USER LOGIN/LOGOUT

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

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

⚠ It is not necessary to disclose the user password to technical support staff.

User name and password are case-sensitive.

12.3.1 First login

When the on-board application is started the first time, the following prompt is shown. Insert the following credential and then tap "Login".

- User name: "superadmin"
- Password: "superpassword"

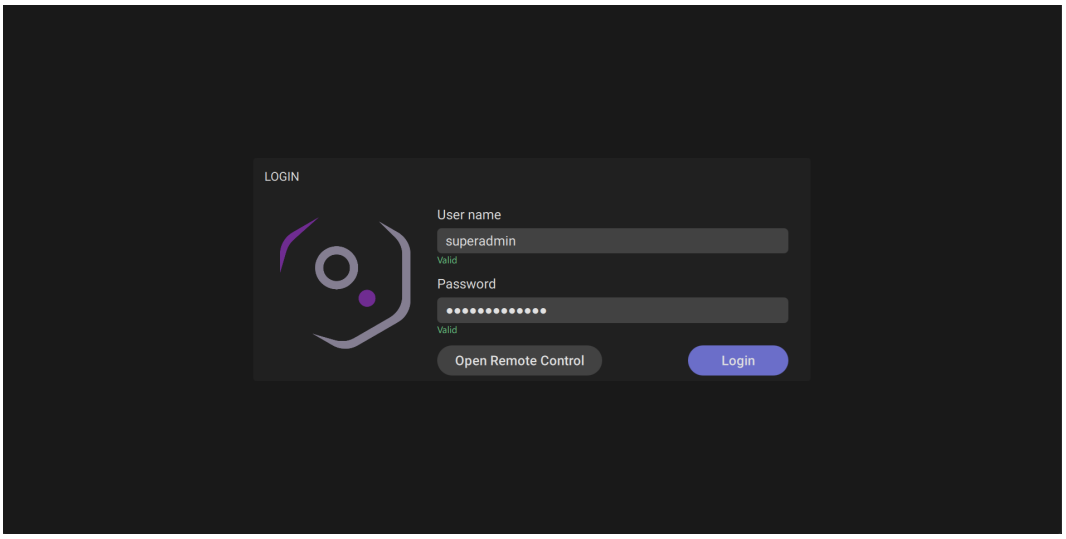


Figure 12.2: User login

After pressing the “Login” button with default credentials, you will be warned (Figure 12.3) that your password has expired and you will get redirect to a password change access to the Privacy and Security settings of the application (Figure 12.4), where you provide new login and password. By pressing Cancel, you choose not to proceed with the customization of the data protection options; the message will be prompted at the next startup.

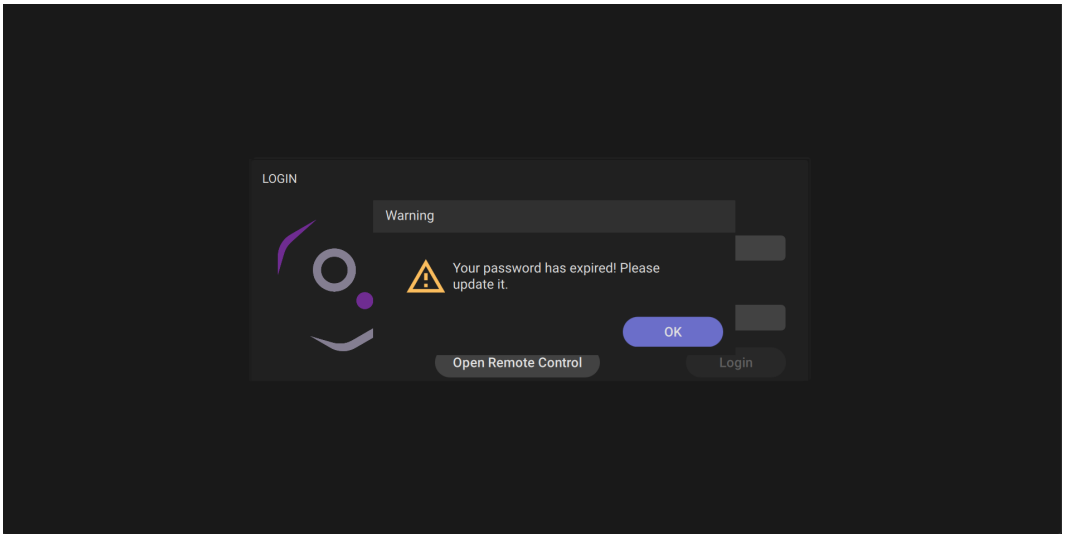


Figure 12.3: Password expired

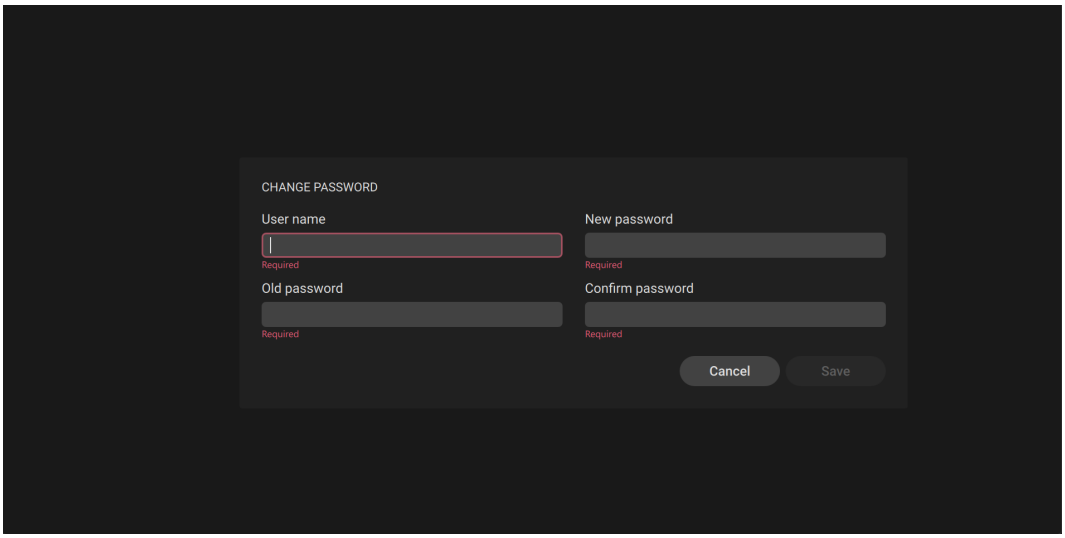


Figure 12.4: Password Change Forced

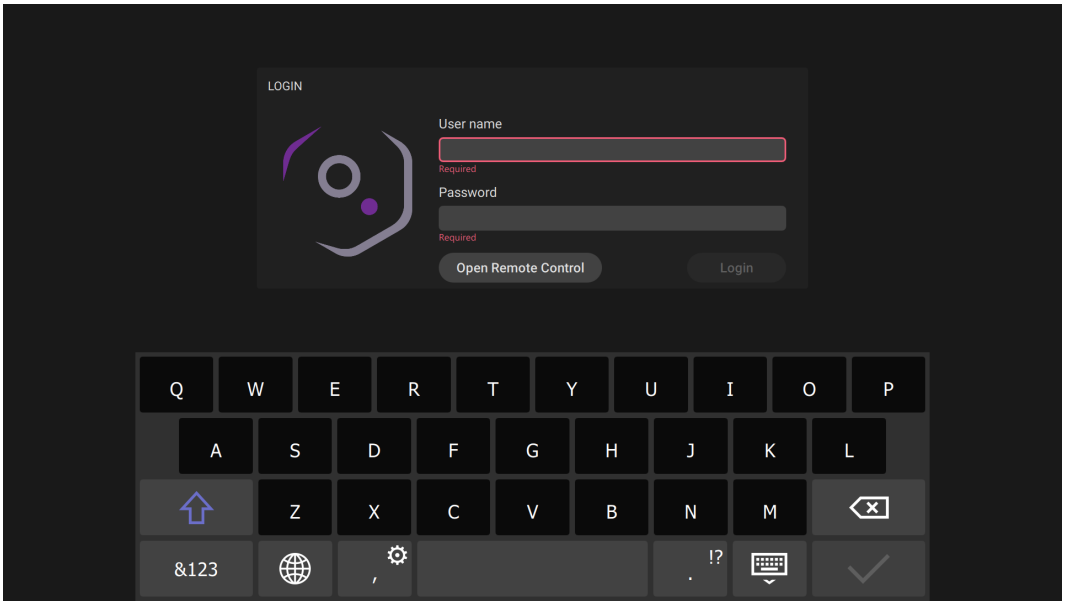


Figure 12.5: User login

If the user login password is configured and enabled, the login screen will be displayed at startup of the TERA on-board application.

⚠ If the password is forgotten or access problems are encountered, please contact technical support.

12.3.2 User Logout

The user can block device operation at any time by pressing the user button and selecting the logout option.

Figure 12.6: User logout

The login screen will be displayed.

12.3.3 Technician Support staff Login

Technical staff can log into the device and on-board application without knowing the user password. Authorized technical staff know the technician password, which allows servicing the device with data protection features applied according to the privacy options of the Setting-Admin section.

12.4 OPTIONS MENU

Tap on Menu button ☰ in the upper right corner of the application to open the **Menu** option lists. The available operation for the user are:

- **Settings:** tap to open settings. Settings are detailed explained inside Chapter 15.
- **About:** tap to view TERA device infos such as: including serial number, software and hardware version numbers, and current connection status.
- **Shutdown:** tap to turn off TERA The device will turn off on its own while ensuring data integrity.

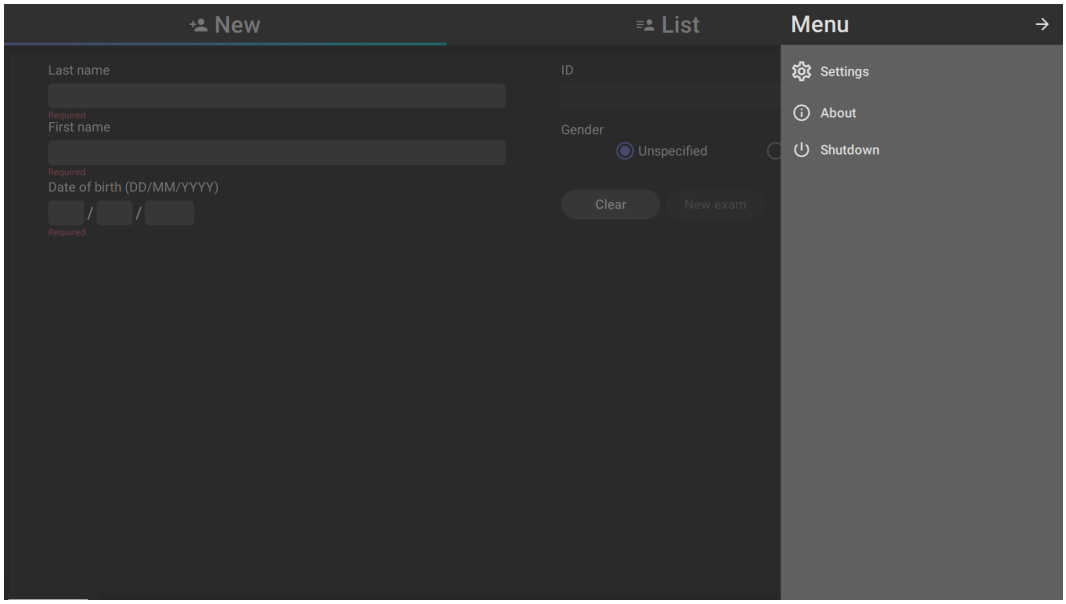


Figure 12.7: Option Menu

12.5 SCREEN LOCKER

If the device remains inactive for a certain amount of time, the screen lock menu appears (Figure 12.8). Enter the password to unlock the device. The screen lock feature can be disabled, and the timeout duration adjusted, from the Settings menu.

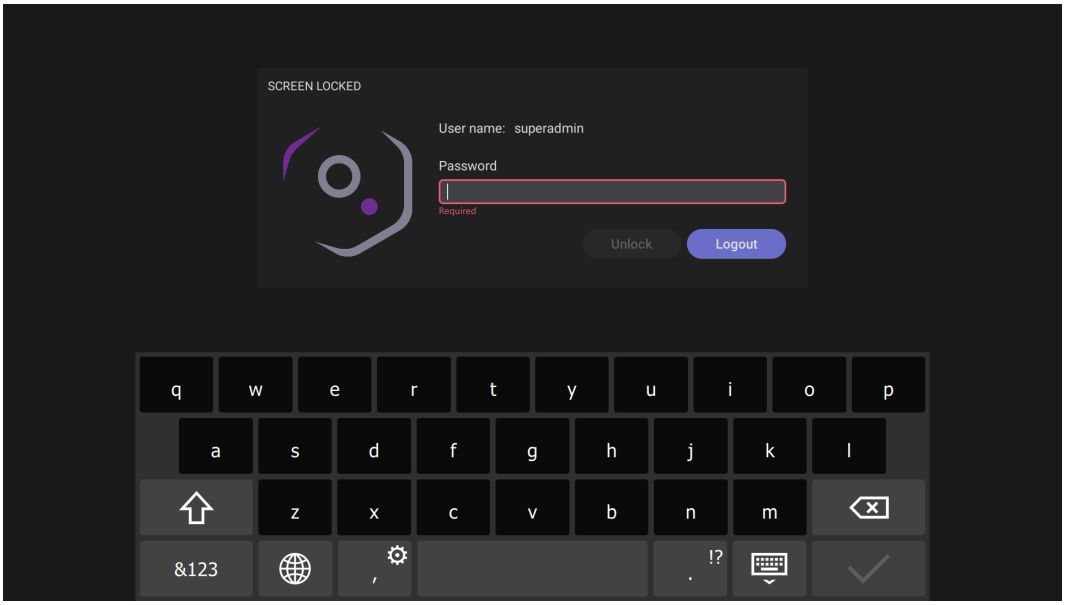


Figure 12.8: Screen lock view

12.6 USER INTERFACE OVERVIEW

The TERA features a touchscreen interface that allows users to navigate through menus, configure settings, acquisition and review measurement data. Every working environment has the same screen layout. Below is shown a sample of the acquisition screen, Figure below provides a description of all the user interface elements.

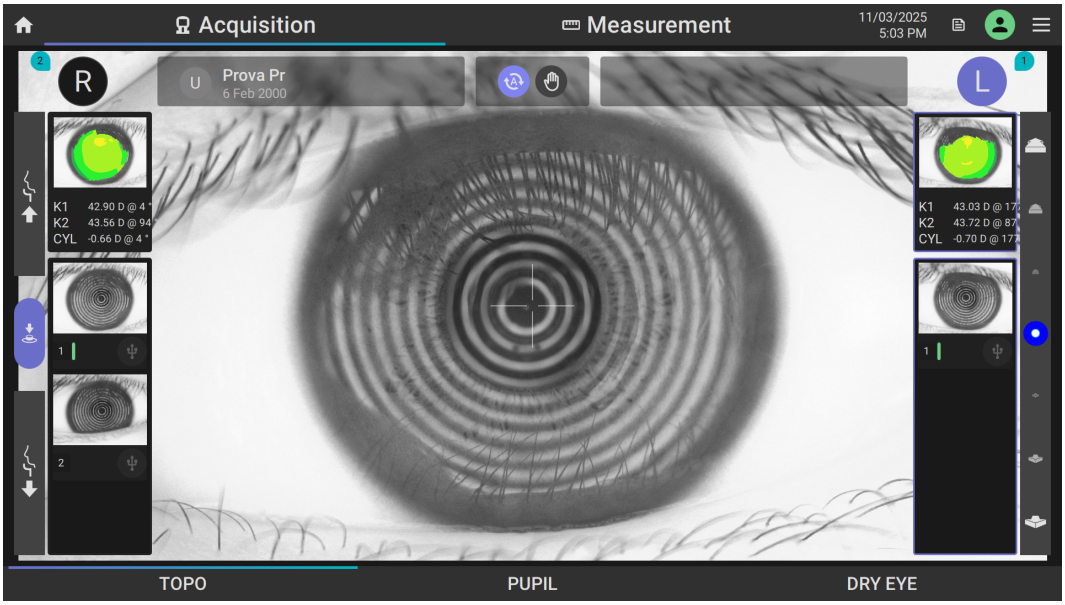


Table 12.1: Overview

#	Acquisition screen description
1	The user interface clearly indicates which environment the user is working in. The active work area is highlighted.
2	The main tab is always displayed at the top of the screen.
3	The date/time indicator, user management button and Menu button are always visible on the main tab of all the environments.
4	Acquired eye data are displayed in the acquisition environment. Left eye data are displayed on the right side of the screen. Right eye data are displayed on the left side of the screen.
5	The controls for adjusting the chinrest position, the live image focus and the joystick button are always visible in the acquisition environment.
6	The controls for selecting the acquisition mode are always visible in the acquisition environment. The active acquisition mode is highlighted.
7	The live image is always visible in the acquisition environment. It is positioned in the center of the screen.

12.7 CHECKING CALIBRATION

⚠ It is recommended to check the calibration of the device:

- Every day before starting patient examinations;
- When the device has been transported from one place to another;

- When it has suffered an impact or thermal shocks

To check the calibration, turn on the device and, when asked to check the calibration (Figure 12.9), perform the procedure. The test patient is automatically created.

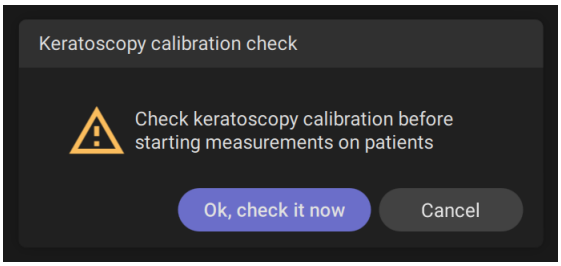


Figure 12.9: Check calibration start message

The next screen explains how to check the calibration:

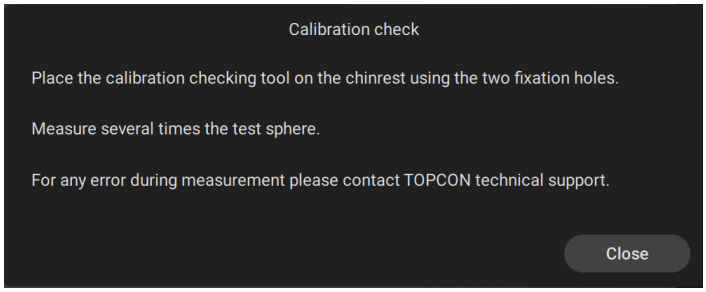
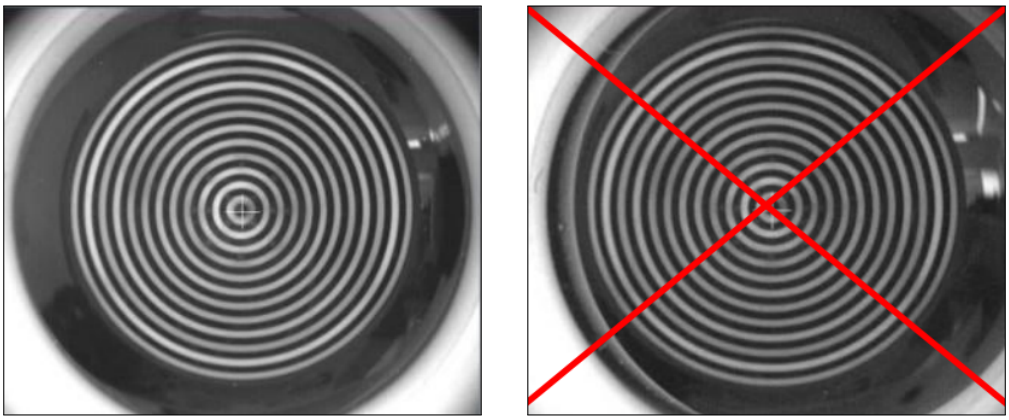


Figure 12.10: Check calibration explain

Insert the calibration tool supplied with the device (Figure 12.11) in the special holes in the chinrest and press until the tool is blocked on the device. Check that the calibration tool is perfectly aligned with the device. If the calibration tool is positioned correctly, all the rings of the Placido disk should be seen reflected in the center on the surface of the hemisphere (Figure 12.12).

Figure 12.11: Check calibration tool



(a) CORRECT alignment **(b)** WRONG alignment

Figure 12.12: Check calibration tool alignment

Perform the calibration procedure by acquiring the calibration check tool several times (Figure 12.13). The acquisition mode is Topography. For details on this acquisition mode, see §12.10.

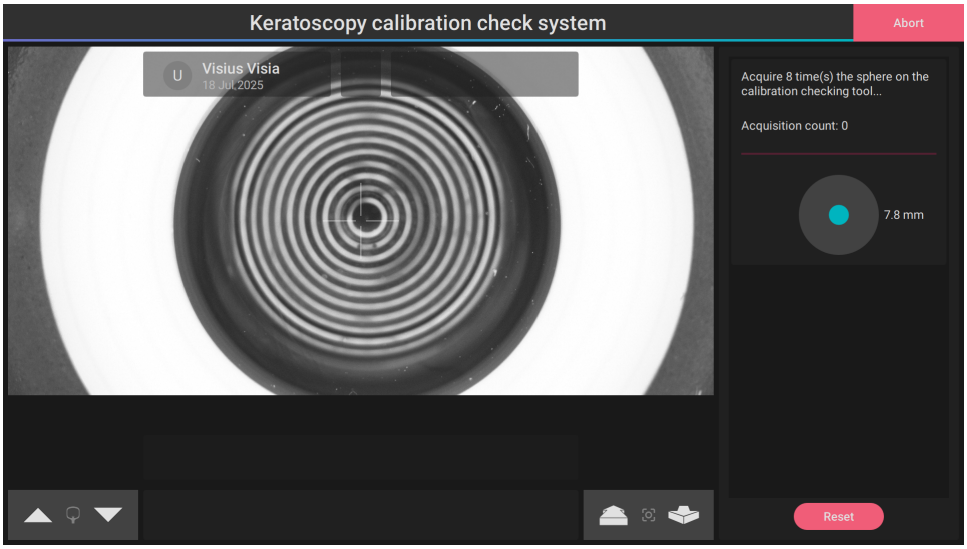
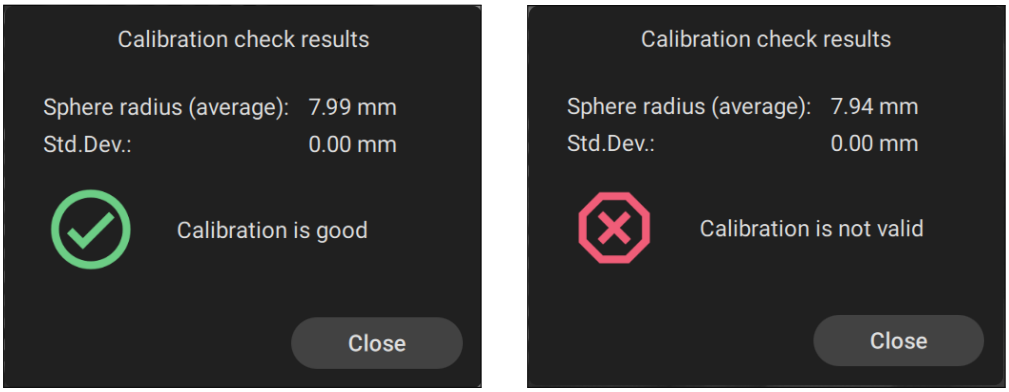


Figure 12.13: Check calibration environment

The acquisition count is updated step by step. The check calibration result will be displayed at the end of the acquisition sequence (Figure 12.14):

- Valid: acquisition and calibration are successful
- Repeat: acquisition failed, calibration cannot be checked
- Invalid/Error: calibration is not successful



(a) Valid **(b)** Not valid

Figure 12.14: Check calibration result

12.8 ENTERING/SELECTING A PATIENT

When the TERA is turned on, after the user logs in, the software displays the following screen (Figure 12.15). The user can choose to create a new patient or select an existing one.

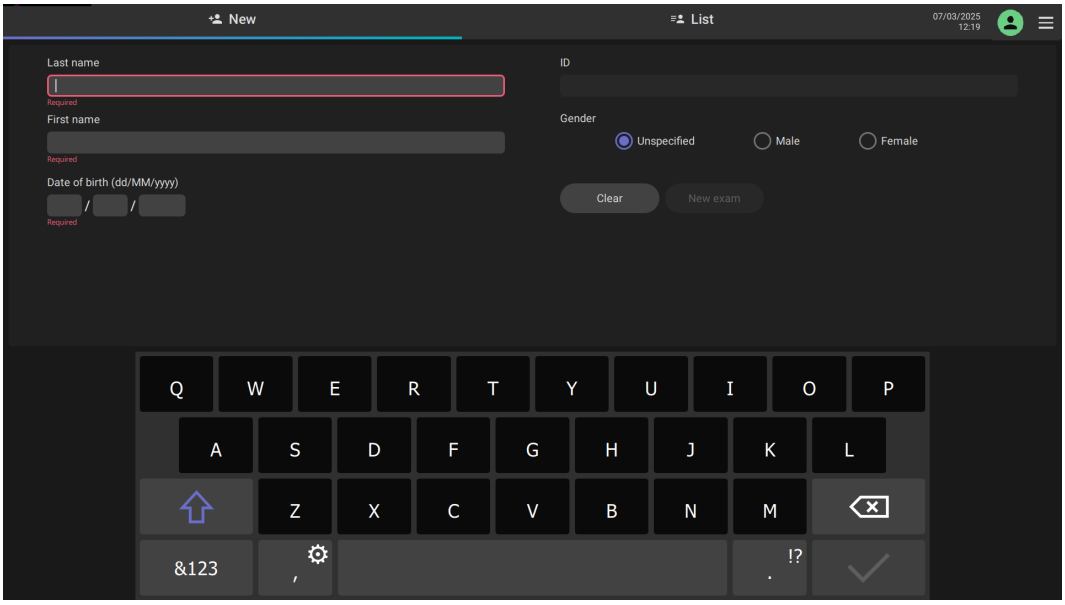


Figure 12.15: New patient creation panel

12.8.1 Creating a new patient

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

Tap on "New Exam" button to confirm the information and continue with the examination. Tap Clear button to clear all patient fields.

A special character can be entered by touching and holding the corresponding letter (Figure 12.16)

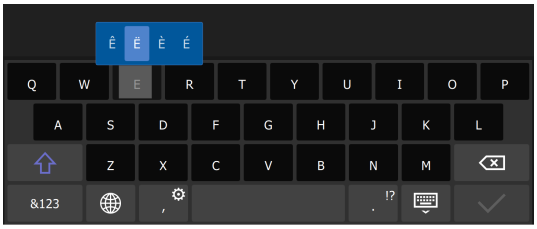


Figure 12.16: Keyboard special character

12.8.2 Selecting or editing a patient

To select or edit an existing patient, tap the **List** tab (Figure 12.17).

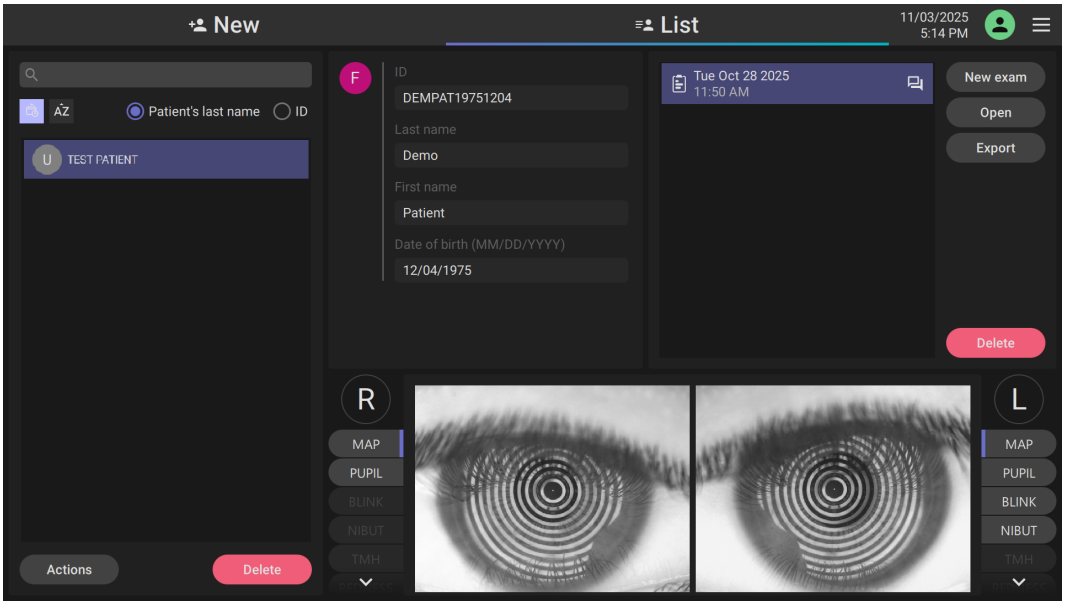


Figure 12.17: Patient list

On this environment, the user can select a previously created patient and the exams associated with him/her. The patient list can be viewed by patient ID or by Last Name (and name) selecting the corresponding option. The patient list can be sorted alphabetically (AZ option) or by date (calendar option).

-  Calendar icon representing scheduling.
-  AZ icon representing alphabetical sorting.

Once the calendar button is selected, you can change the order of the exams by tapping on it (the possible orders will be from the oldest exam to the most recent, and from the most recent to the oldest). Once the AZ button is selected, you can change the alphabetical order by tapping on it (the filtering occurs either from A to Z or from Z to A).

The list of patients can be scrolled. By typing in the search text box, the patient list is automatically updated to show matching patients.

To edit a patient's data, press the Actions button and then the Edit button (Figure 12.18). Make the changes (Last name, First name, Date of birth, Gender) and tap Save to confirm them. Tap Close to end editing without saving the changes.

12.8.3 Selecting or creating an exam

Once a patient is selected, all the previous exams are shown in a list on the right side. The user can open an existing exam by selecting it and tapping **Open** to access the measurement environment (see 13); otherwise, the user can create a new exam by tapping the **New Exam** button.

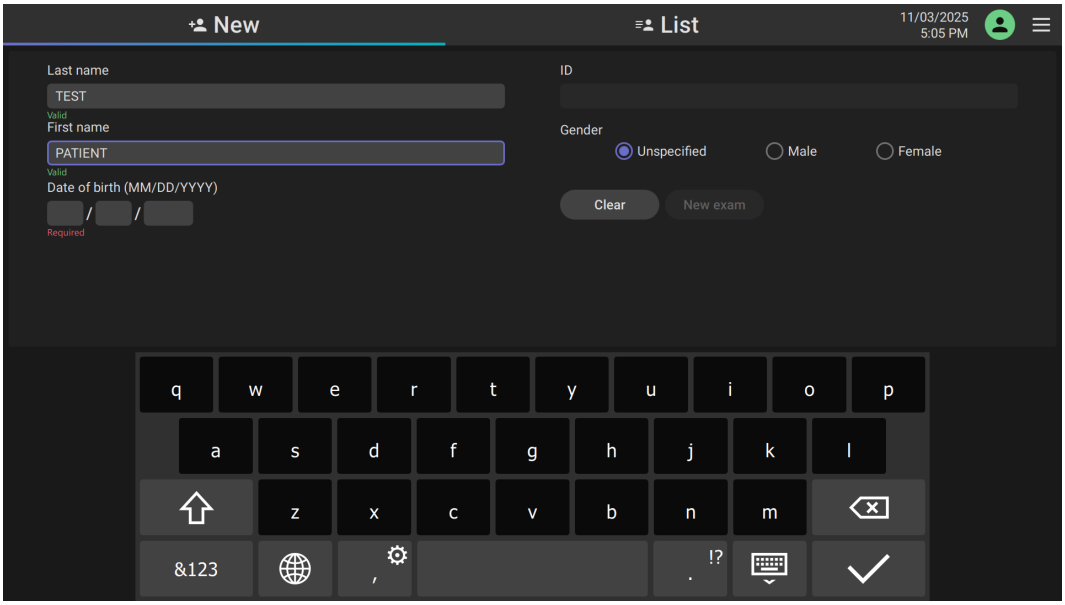


Figure 12.18: Patient edit

12.8.4 Patient data management

When a new patient is created or an existing patient is edited, the application scans the archive to check if this data already exists.

⚠ The scan is performed trying to match only the patient ID.

If the entered patient ID matches an existing patient ID, the conflict must be handled through a notification that the application will display on the screen indicating that the patient's ID already exists.

12.8.5 Open an examination or acquire data for the selected patient

By accessing the List environment, the list of patients is located in the left column. By tapping on a patient, the list of associated exams will be displayed in the right list. In this list, the user can access or delete the exams, using the **Open** or **Delete** buttons.

By selecting an exam is possible to see the types of acquisition performed for both eyes and visualize a preview image for each type of acquisition. The acquisition type items in

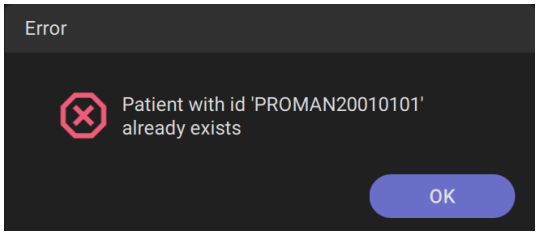


Figure 12.19: Patiend ID already exists

the column menu are enabled or disabled according to the acquisitions performed or not performed in the selected examination.

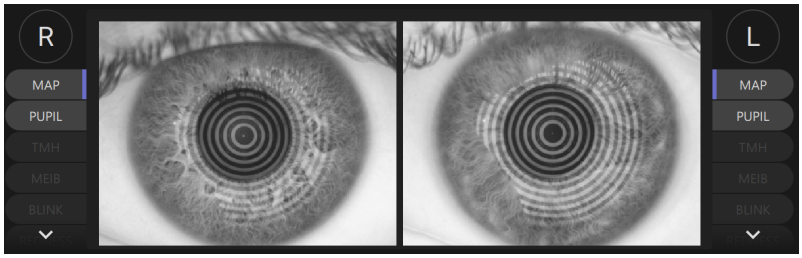


Figure 12.20: Exam preview

After selecting a patient, another examination can be carried out by pressing the **New Exam** button. To export the selected exam in the list of exams associated with a patient, tap the **Action** button and then the **Export** button. You can export the exam to a USB drive.

12.8.6 Managing the selected patient

To manage an existing patient, select the patient to manage from the patient list and tap the "Actions" button (Figure 12.21). The application opens a menu with **Export** and **Edit** buttons. Tap **Export** button to export the selected patient with all exams to the TERA viewer. Tap **Edit** to modify anagraphical data. Tap **Delete** button to delete the selected patient and all the exams.

12.8.7 Managing the selected patient exam

To manage an existing exam, select the patient and the exam to manage from the patient list and exams list, the press the **Actions** button (Figure 12.22). Tap **Delete** button to delete the selected exam.

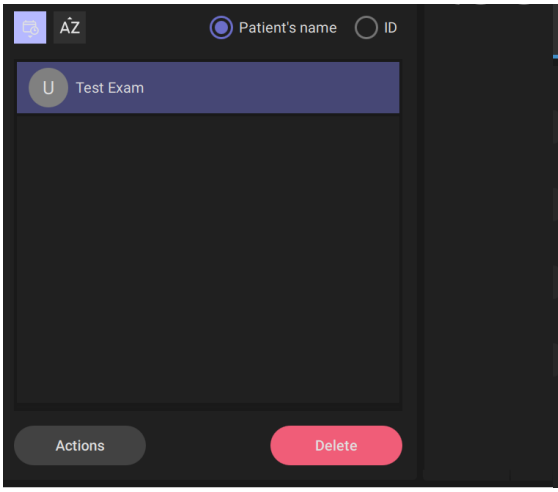


Figure 12.21: Patient management actions

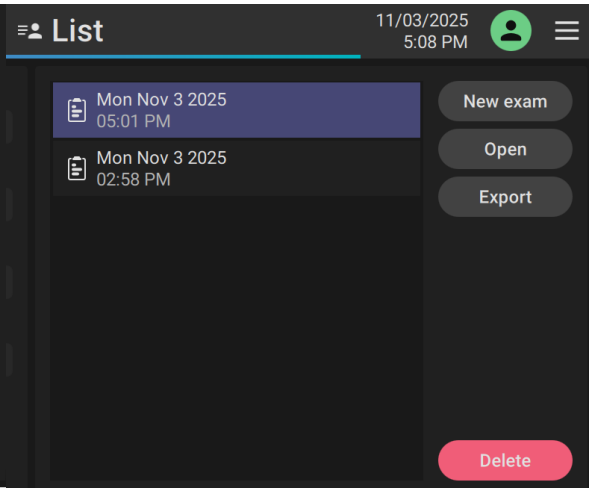


Figure 12.22: Patient exam management actions

12.9 DRY EYE QUESTIONNAIRES

Once a new exam is created, the user has the possibility to fill in different predefined Questionnaires: DEQ5 and OSDI6 to Dry Eye disease.

The user can select the Questionnaire to be filled in or he can skip and start the exam acquisition by clicking the button Proceed to acquisition, as shown in Figure 12.23.

Only one type of questionnaire can be chosen.

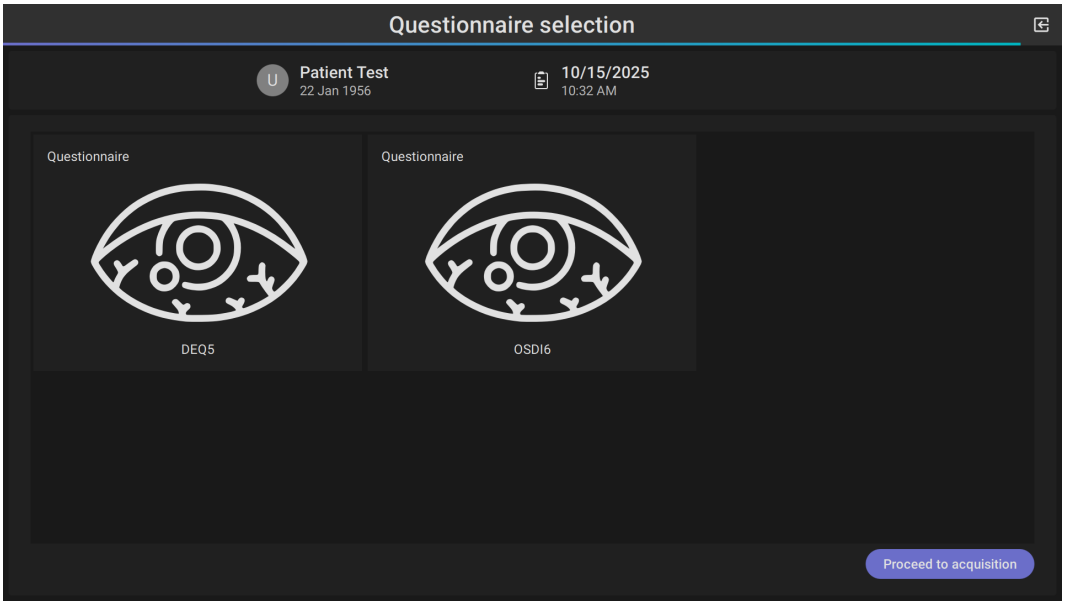


Figure 12.23: Dry eye questionnaire selection

Once a Questionnaire has been filled in and saved, it won't be possible to change it and it will be linked to the single executed exam.

The icon  on the exam list means that a Questionnaire associated to that exam has been previously filled in and the related data can be shown.

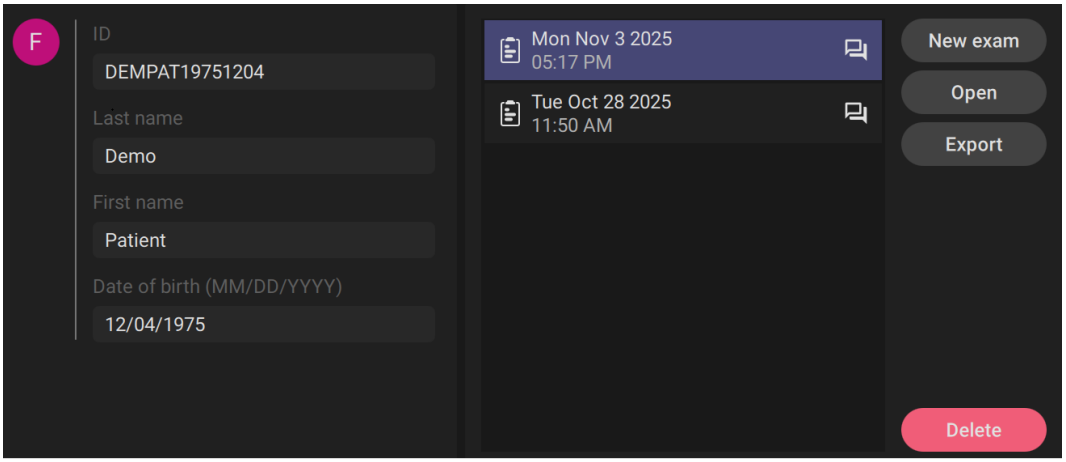


Figure 12.24: Questionnaire icon in the exam list

12.9.1 DEQ5 questionnaire

For the DEQ5 Questionnaire, the user shall reply to five different questions, shown in the following pictures.

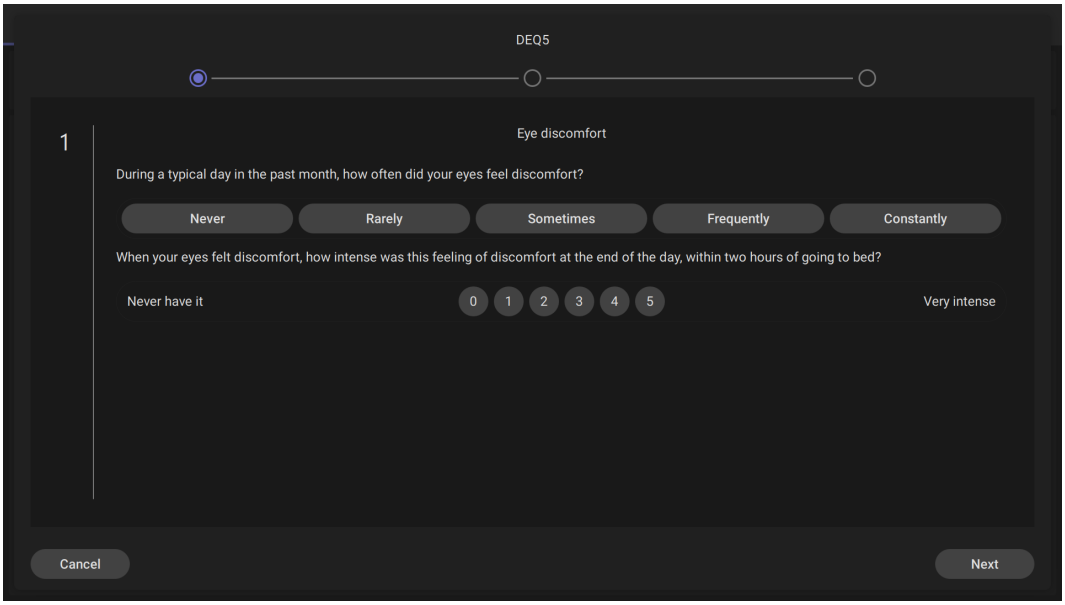


Figure 12.25: DEQ5 - Eye discomfort

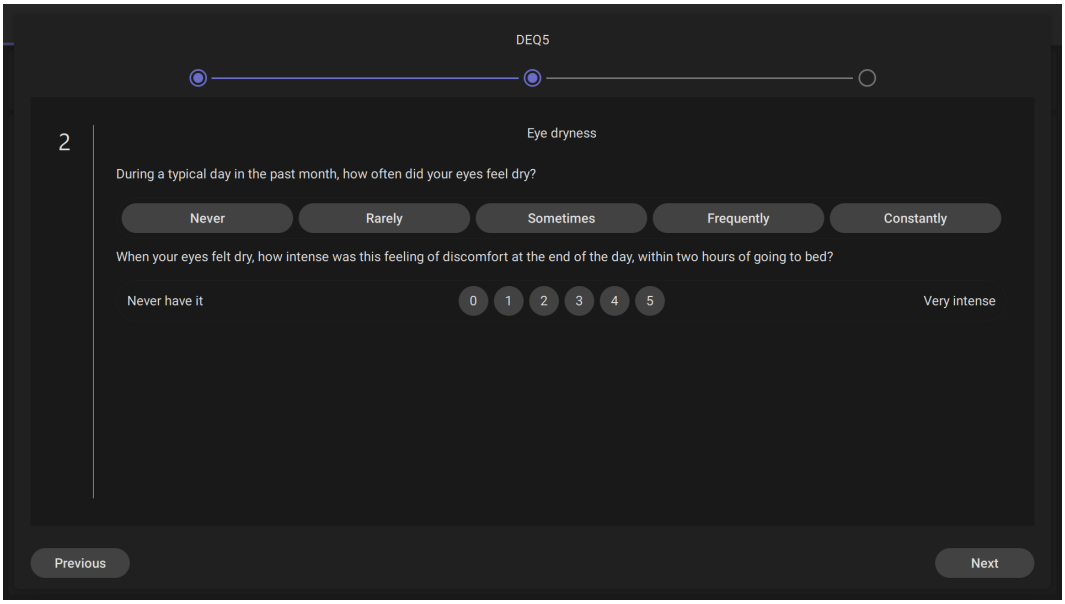


Figure 12.26: DEQ5 - Eye dryness

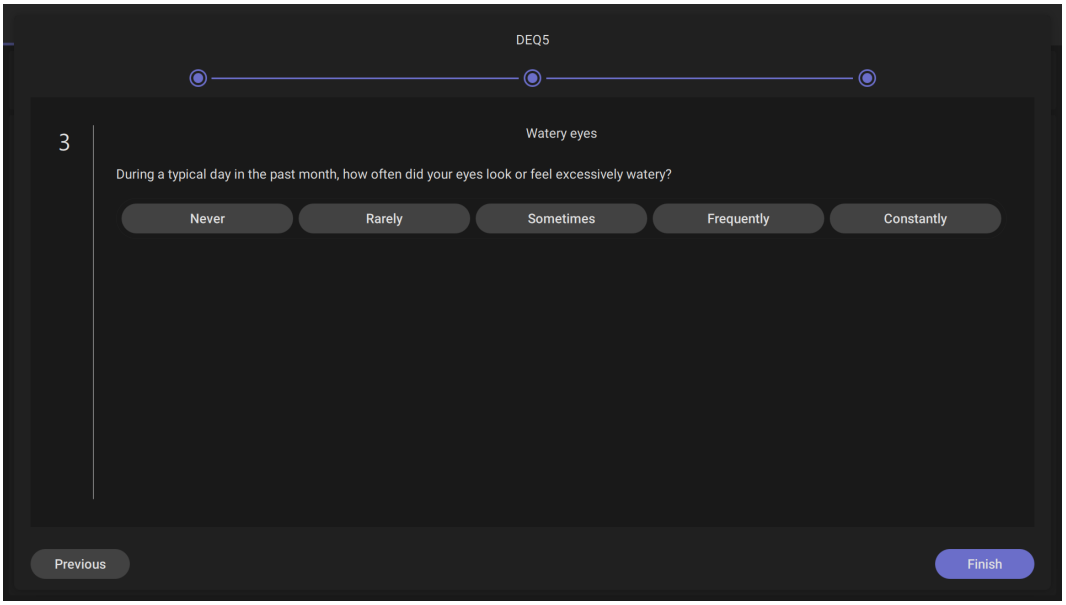


Figure 12.27: DEQ5 - Eye watery

12.9.2 OSDI6 questionnaire

For the OSDI6 Questionnaire, the user shall reply to different questions, shown in the following pictures.

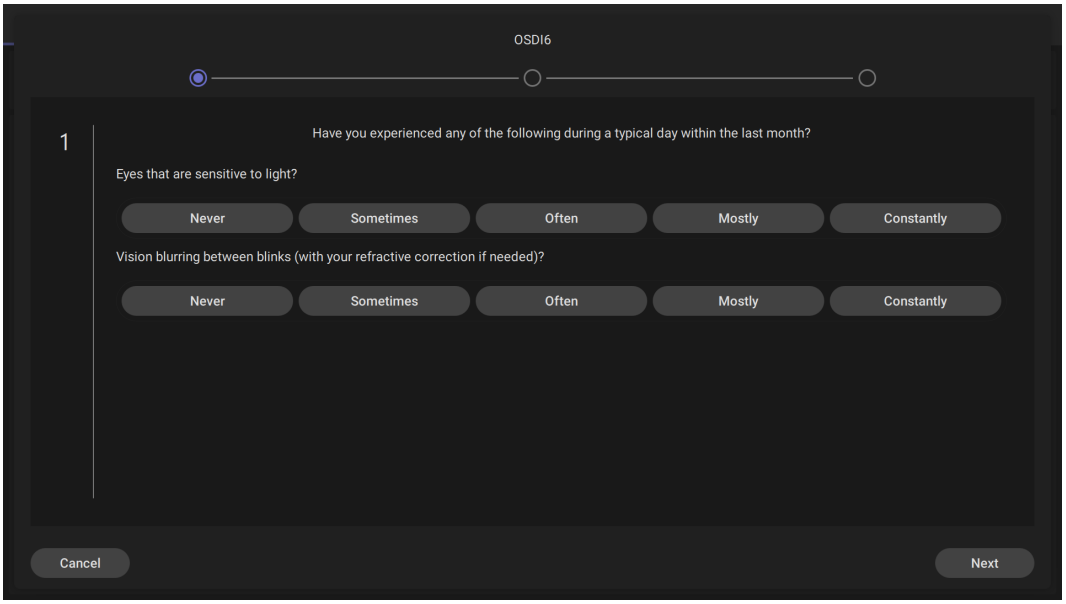


Figure 12.28: OSDI6 - Experiences

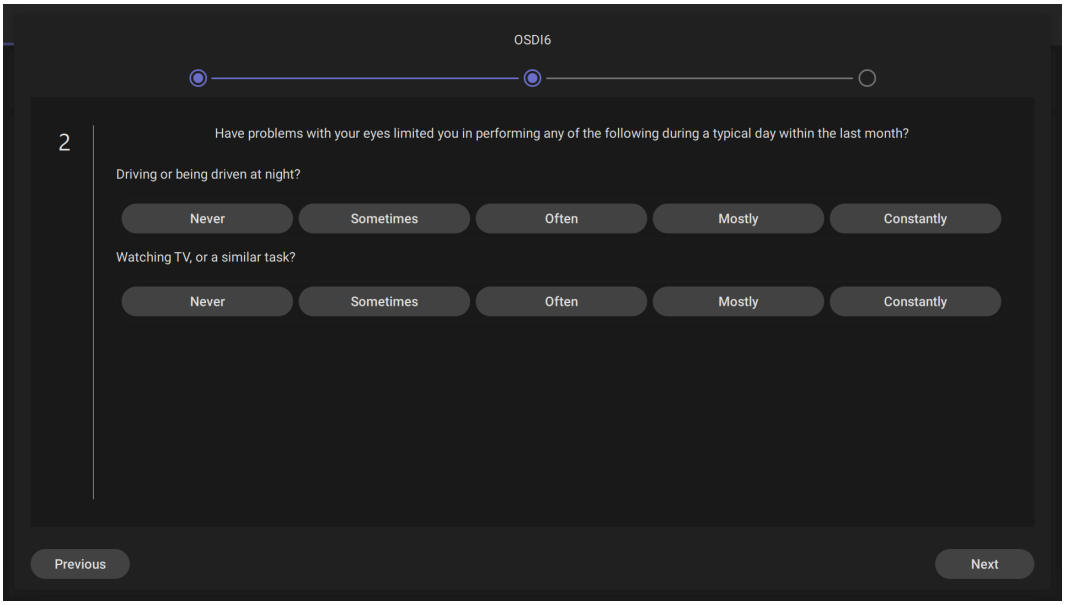


Figure 12.29: OSDI6 - Problems

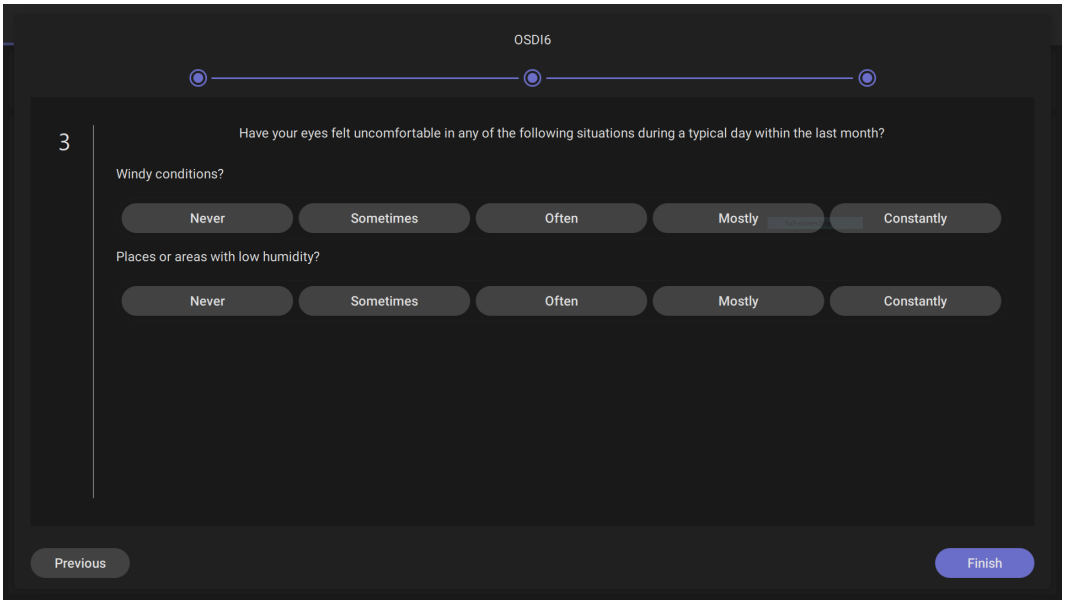


Figure 12.30: OSDI6 - Felt uncomfortable

12.10 ACQUISITION ENVIRONMENT: GENERAL INSTRUCTIONS

12.10.1 Positioning the patient

The adequate positioning of the patient respect to the device is required to obtain correct measurements. A steady head position and the correct device-to-patient distance are obtained by resting the patient's head well against the chinrest and forehead band (Figure 12.31). This is how a correct positioning can be achieved:

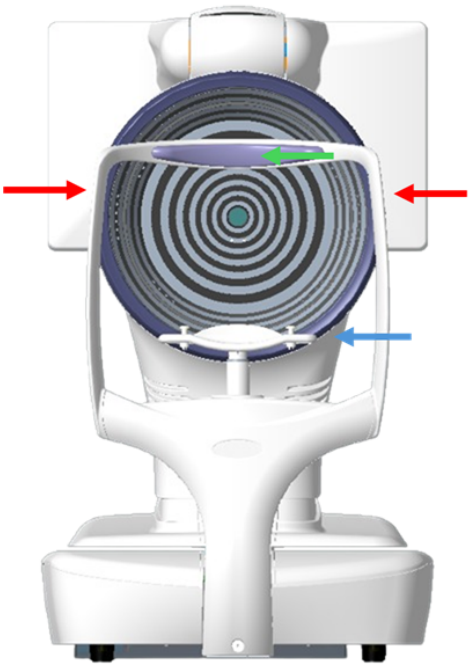


Figure 12.31: Patient positioning

1. The patient's forehead must stand well up against the forehead rest (green arrow).
2. The patient's eye must be aligned with the two lines on the forehead supports (see the red arrows).
   User can achieve the correct alignment regulating the chinrest height (blue arrow) by using the on-screen touch control (Figure 12.33)
3. The patient must steadily fixate on the target point at the center of the Placido disk.

The joystick illustrated in Figure 12.32 is one of the parts the user can physically control during acquisition. The button on the top marked "Acquisition button" starts the acquisition of the various measurements. The thumbwheel marked "Height Regulation" allows adjusting the instrument height according to the patient's position.

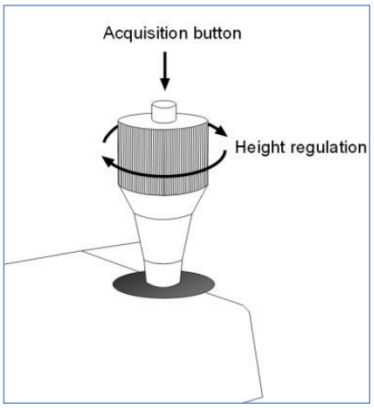


Figure 12.32: Joystick

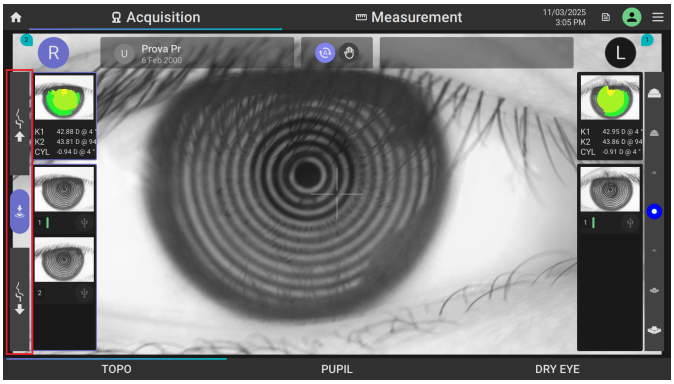


Figure 12.33: Chinrest height (red control)

12.10.2 Alignment and Focus

The TERA device features a motorized base and chin rest. Manual alignment mode is always available via the joystick and the corresponding controls in the acquisition environment.

12.10.2.1 Automated Alignment

The device automatically detects and tracks the patient's eye. The motorized base moves automatically, guided by the autofocus system to reach the optimal focus position. Once optimal focus is achieved, the system acquires the best possible image (this feature is not be available for all acquisition types). The environments where the automated alignment is available are listed below:

- TOPO(Topography)
- PUPIL(Pupillometry)
- NIBUT(Non-Invasive Break-Up Time)

12.10.2.2 Manual Alignment

The user manually tracks the patient's eye to position the acquisition. The motorized base is controlled manually using the joystick or touchscreen interface. The image is acquired using either the joystick button or touchscreen controls. Manual alignment provides greater control over device positioning, allowing quick intervention in challenging acquisition scenarios (e.g., high keratoconus), and suits the preferences of experienced operators. The environments where only manual alignment is enabled are listed below:

- Blink
- TMH(Tear Meniscus Height)
- Redness

- Bleph(Blephratis)
- Lipid(Lipid layer Thickness)
- MEIB(Meibomian Glands)
- FLUO(Fluorescein)
- Lissamine

12.10.3 Description of the acquisition screen

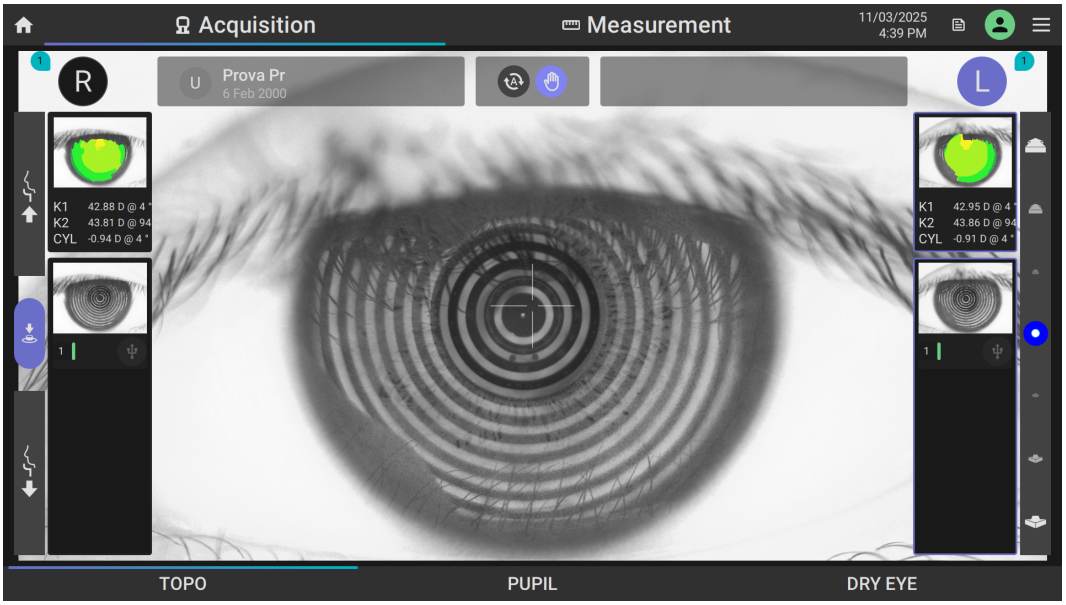


Figure 12.34: Acquisition screen

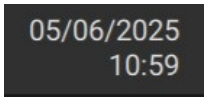
TOP BAR: the top bar provides information and user actions available during the current acquisition session.

HOME: tap to close the exam and return to the patient's list.

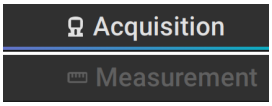
MENU: tap to open options menu (See Section 12.4).

CREDENTIALS: tap to manage user credentials.

EXPORT: tap to open export panel (see Section 14)



DATE TIME: current date time



TAB SWITCH: tap to switch between acquisition and measurement environments (see Chapter 13 for details about measurements)

BOTTOM BAR: using the bottom bar tabs user can switch between all the acquisition systems:

- **TOPO**: Provides access to the topography acquisition section (12.10.9).
- **PUPIL**: Provides access to the pupillometry acquisition section. (12.10.8)
- **DRY EYE**: Opens the dry eye acquisition section, including:

  BLINK: Blink behavior analysis (12.10.10)

  NIBUT: Not invasive tear break-up time analysis (12.10.11)

  TMH: Tear meniscus height (12.10.12)

  REDNESS: Redness evaluation (12.10.13)

  BLEPH: Blepharitis documentation (12.10.14)

  LIPID: Lipid layer thickness (12.10.15)

  MEIB: Meibomian glands imaging and analysis (12.10.16)

12.10.3.1 Acquisition gallery

A preview of the acquired images is shown in the acquisition gallery. For example, in Figure 12.35, the different galleries used for TOPO, TMH, PUPIL, REDNESS and BLEPH acquisitions type are shown.

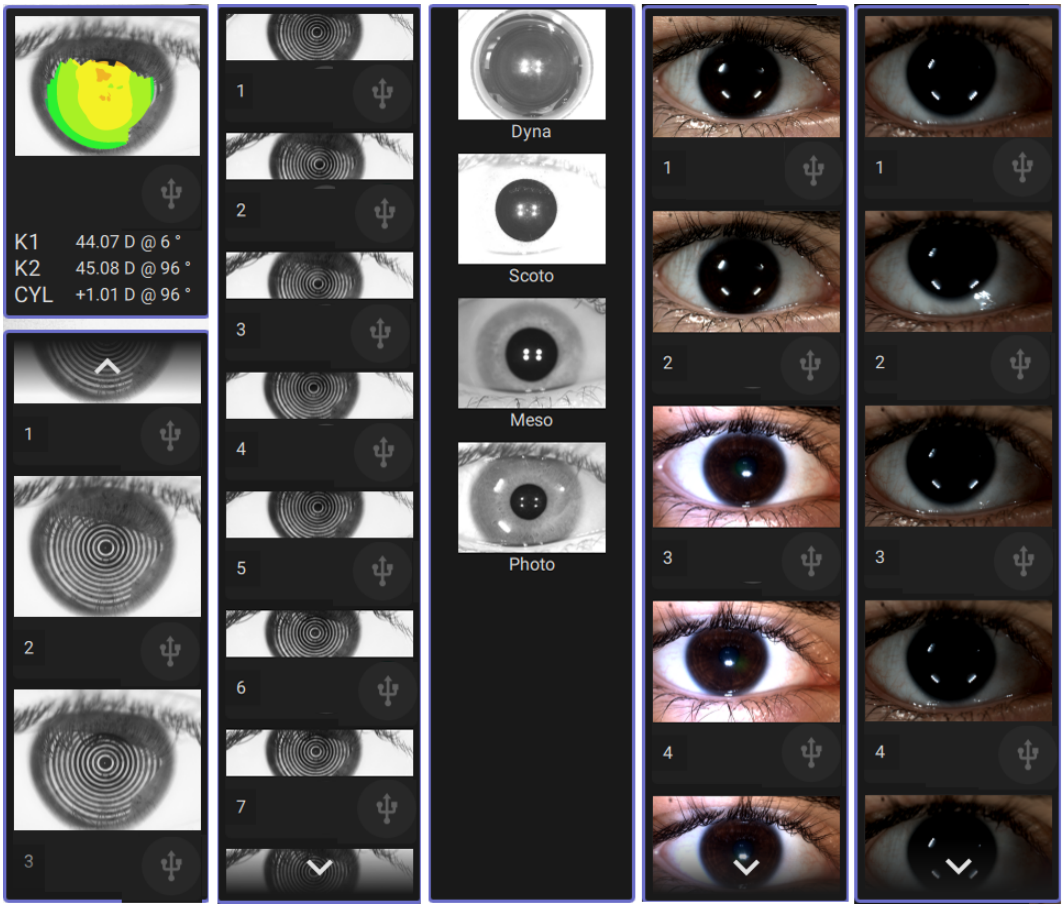


Figure 12.35: Some examples of acquisition gallery

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

For each element in the gallery, in addition to the acquisition index, there are buttons to export into an usb driver.

Selecting the enlarge button, the environment in Figure 12.36 is shown. The selected gallery item is displayed. The central bottom arrows allow you to scroll through the gallery items, the **Remove** button deletes the item from the gallery and the **Close** button back to the Acquisition environment.

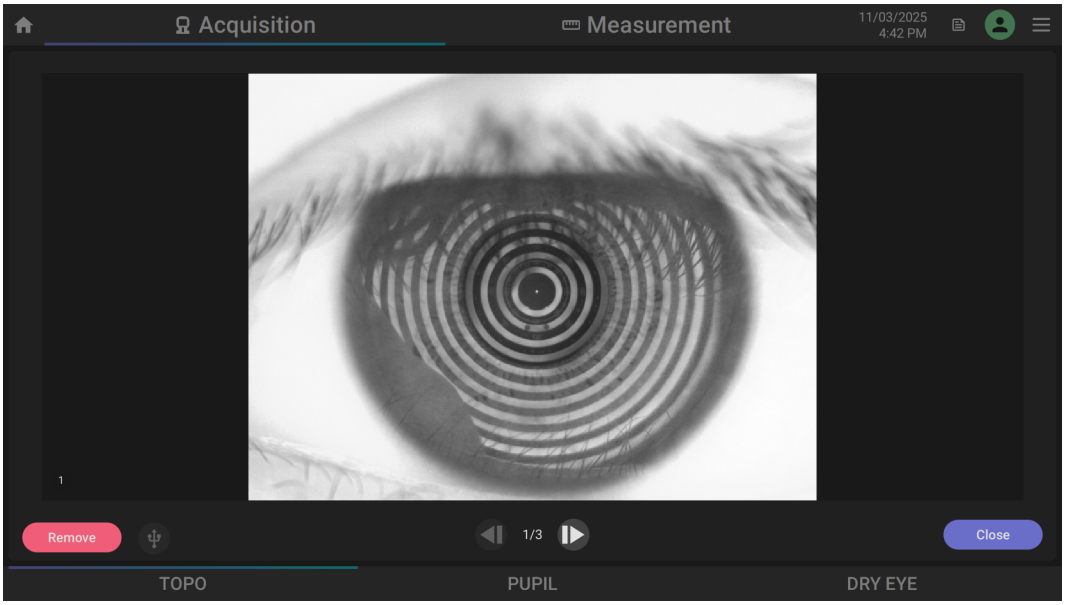


Figure 12.36: Gallery item viewer

When the number of acquisitions made exceeds the number of positions available in the gallery, arrow buttons are available to scroll through the images.

12.10.4 Acquisition side

The highlighted eyeside buttons (12.38 and 12.37) indicates the eye being acquired. Tapping on it to moves the motorized base to the corresponding eye. The eye-side label can be configured in the settings to display the native language or as "OD/OS," which always shows "OD" for the right eye and "OS" for the left eye.)

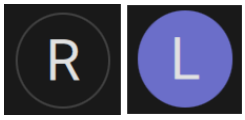


Figure 12.37: Eye side selection (native languages)

Figure 12.38: Eyeside selection (OD/OS)

12.10.5 Acquisition type

The available acquisition mode are video or photo. The acquisition mode can be selected directly from the acquisition environment (Figure 12.39). Some environment does not allows video acquisition type and so this selection is not shown.

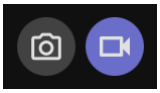
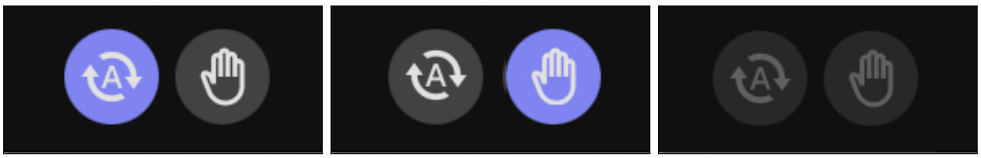


Figure 12.39: Acquisition type: video or photo

12.10.6 Acquisition mode

The available acquisition mode are manual (Section 12.10.6.1) and automatic (Section12.10.6.2). The acquisition mode can be selected directly from the acquisition environment, if both modes are available.



(a) Automatic selected (b) Manual selected (c) Manual available only

12.10.6.1 Manual acquisition procedure

To acquire an image or measurement, regardless of the acquisition mode, follow these steps:

- Select the manual acquisition type from the acquisition environment.
- Align the live image in the center of the screen and adjust the focus. Then, press the joystick button to begin the acquisition.
- In the TOPO(Topography), PUPIL(Pupillometry) and NIBUT(Non-Invasive Break-Up time) Environment you can move the instrument forward or backward according to the red and blue arrows displayed on the screen to achieve optimal focus. Instead in the other environment like Blink, TMH(Tear Meniscus Height), REDNESS, BLEPH(Blepharitis), LIPID(Lipid layer thickness), MEIB(Meibomian Glands), FLUO(Fluorescein) and LISSAMINE this guide arrows are not shown.
- When the green indicators appear, press the joystick button again. The system will then automatically capture the required image and/or measurements. **Do not move the joystick during the acquisition, which lasts only a few seconds.**

The **focusing** and **centering** assistance system consists of two elements:

- Centering
- Focusing

Optimal **centering** is achieved by aligning the two circular aiming indicators through precise horizontal and vertical movements. The circles change color depending on the focusing position, and the size of the circle linked to the aiming cross varies based on the distance from the ideal focal plane.

Optimal **focusing** is guided by four indicators located on the edges of the viewport. These indicators suggest the necessary forward or backward movement to reach the correct focus.

Figure 12.40: Acquisition centering and focusing

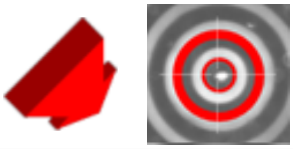
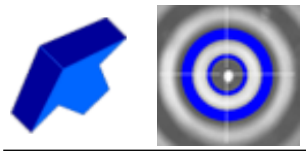
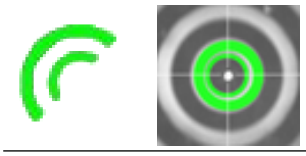
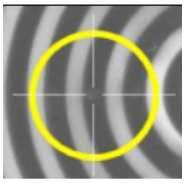
	**Red arrows:** Move the instrument forward toward the patient's eye. The centering indicators appear red.
	**Blue arrows:** Move the instrument backward away from the patient. The centering indicators appear blue.
	**Green indicators:** The ideal focus has been reached. Acquisition is performed automatically.
	**Out of tolerance:** The focus or centering is significantly off. Improve distance and/or centering alignment.

Table 12.2: Visual indicators for manual focus and centering guidance

12.10.6.2 Auto acquisition procedure

Select automatic acquisition type from acquisition environment. Before starting the automatic acquisition, move the instrument until the patient's eye is clearly visible in the live image. Use the joystick or the touchscreen controls (chinrest commands, focus slide, alignment by dragging in live) to do this.

In the TOPO(Topography), PUPIL(Pupillometry) and NIBUT(Non-Invasive Break-Up time) Environments the automatic acquisition can be started by:

- pressing the joystick button
- tap virtual joystick command in the acquisition environment
- tap in the center of the eye in the live image
- drag the center of the eye towards the crosshair at the center of the live image and drop

The automatic acquisition procedure handles eye alignment, focus and selection of the best image. Once the image is acquired, it is added to the image gallery.

12.10.7 Acquisition adjust

The acquisiton adjust button (Figure 12.41) allows user to adjust acquisition luminance condition. Some environment requires specifics light condition for a correct acquisition, so this selection is not shown(the selection is available only in TMH, REDNESS, BLEPH, LIPID, MEIB and FLUO). Tapping on this button shows the acquisition adjust panel

Figure 12.41: Acquisition adjust button

Using the slider (Figure 12.42), the user can increase or decrease image luminace for the acquisition. By selecting **AUTO**, the system will automatically determine the optimal image luminance. In FLUO and MEIB environments the auto determination of the best image luminance is not provided, and a slider for luminance adjust is provided (Figure 12.42), tapping the  will reset the default value. The user can also adjust the diaphragm settings using the diaphragm control buttons in the TMH, REDNESS, BLEPH, MEIB and FLUO environments (Figure 12.44), or manually increase or decrease the lights power in the LIPID Environment (Figure 12.45).

Figure 12.42: Brightness adjust slider

Figure 12.43: Brightness adjust slider (MEIB and FLUO)

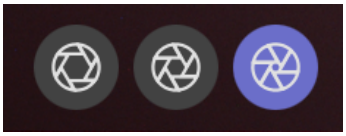


Figure 12.44: Diaphram aperture button group

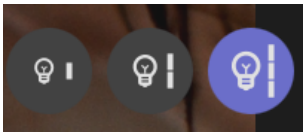


Figure 12.45: Lights power button group

12.10.8 Topography/Keratoscopy

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

TERA allows the user to acquire the corneal topography of the eye. The "Corneal Map" is obtained from the reflection of 22 + 2 rings of the Placido disk at a predefined distance from the patient's eye. The position of the device, in relation to the patient's eye thus found, is used as a starting point for fine adjustments to be made in the corresponding measurement mode.

By selecting TOPO acquisition mode, the acquisition environment in Figure 12.46 is shown.

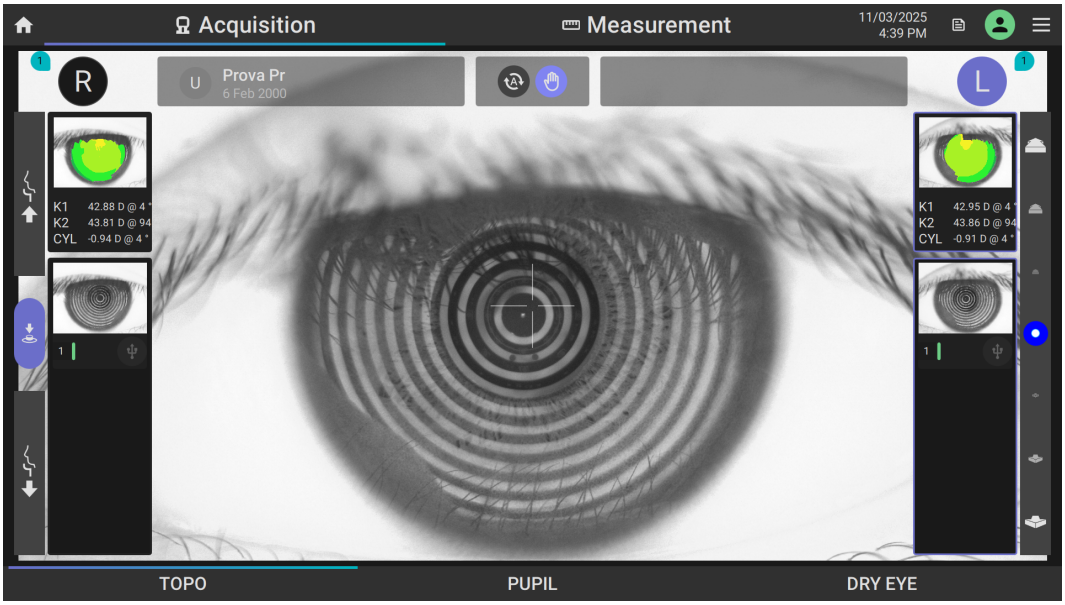


Figure 12.46: Topography acquisition environment

This type of acquisition allows both manual (12.10.6.1) and automatic (12.10.6.2) acquisition procedures.

After the acquisition, the keratometry results are updated on the acquired eye side. The best acquisition with the calculated data is shown at the top.

12.10.8.1 Errors in mesurements

Sometimes the measurement is taken in one of these conditions: bad focus, closed eyelid, tear film irregularity, movement, measurement not in range; in this case, a dotted line is shown in location of keratoscopy values (Figures 12.47 and 12.48)

ATTENTION: when the measurement results are not complete, it means that the software identified an error during the acquisition, which could be: bad focus, closed eyelid, tear film irregularity, high standard deviation in multiple measurements, movement, and measurement not in range.

Figure 12.47: invalid measurement (eyelid)

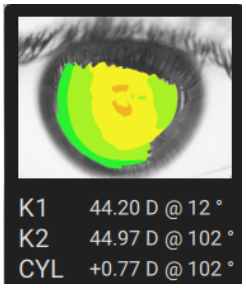


Figure 12.48: Successful measurement

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

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

Table 12.3: Errors in measurements

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

12.10.9 Pupillometry

By selecting PUPI acquisition mode, the acquisition environment in Figure 12.49 is shown.

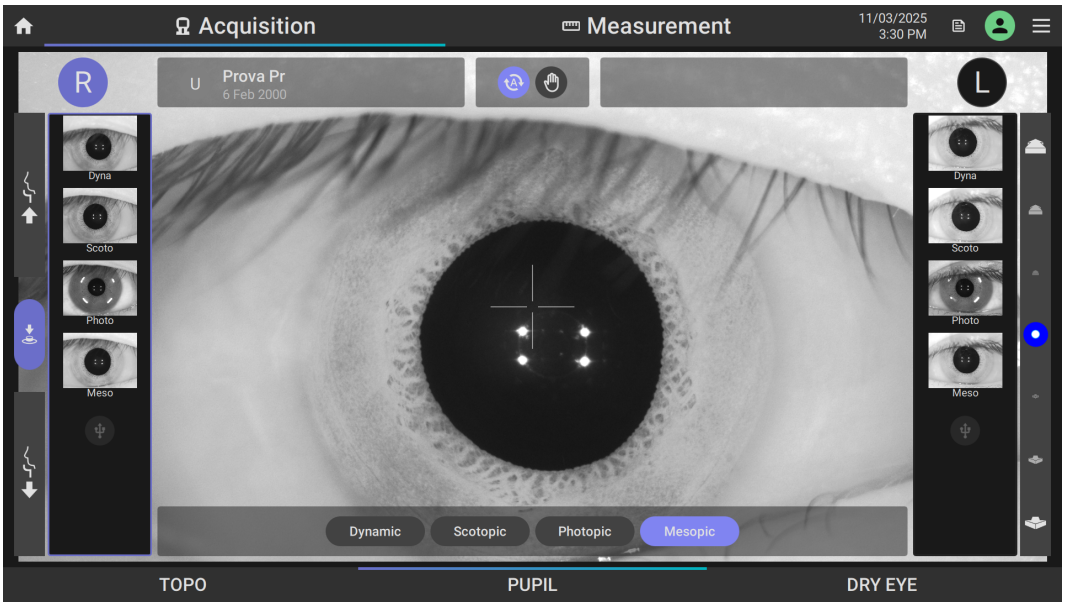


Figure 12.49: Pupillometry acquisition environment

This type of acquisition allows both manual (12.10.6.1) and automatic (12.10.6.2) acquisition procedures.

Once the acquisition has started, if the user does not manually stop it(by tapping on virtual joystick icon or pressing on the physical joystick button), it is automatically stopped when

the time limit is reached(end of the scroll bar). The time limit depends from the chosen pupillometry aquisition type.

There are four types of pupillometry acquisition available:

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

Dynamic pupillometry acquisition records the behavior of the pupil as the light conditions change. It starts with scotopic conditions, then photopic and finally scotopic again.

Static pupillometry acquisition records the behavior of the pupil in controlled light conditions (photopic, mesopic and scotopic).

⚠**WARNING**: if the patient has blue eyes, pupillometry acquisition under mesopic lighting conditions may be difficult to achieve

12.10.10 Blink

By selecting BLINK acquisition mode, the acquisition environment in Figure 12.50 is shown.

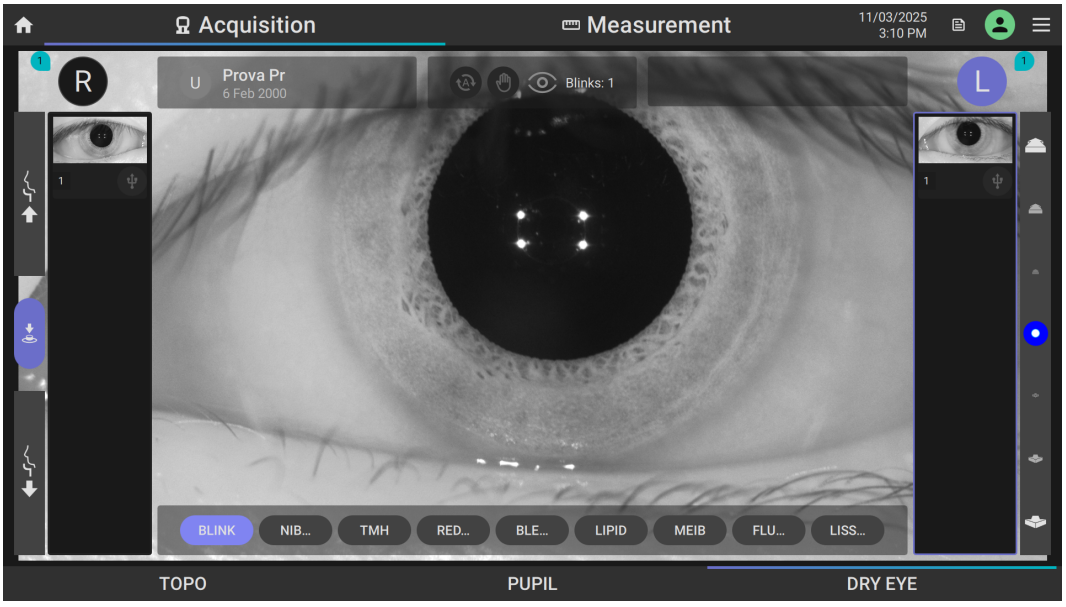
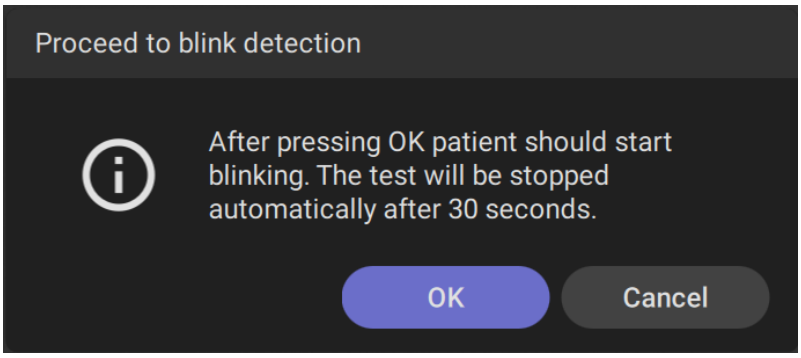


Figure 12.50: Blink acquisition environment

This type of acquisition only allows manual (12.10.6.1).

This acquisition allows measuring the average IBI index (Inter-Blink Interval) automatically. The acquisition precedure is the following:

1. Center the four bright points on the barycenter of the pupil.
2. Bring the four bright dots into focus.
3. Ask to the patient to keep a stable position.
4. Click in the joystick button.
5. The application will shown the following pop-up:



6. Tap the "OK" Button, and leave the patient to his natural blinking behavior leave the patient to his natural blinking behavior
7. Blinks are automatically recognized and counted.
8. Acquisition is stopped:
   - Clicking on the joystick's button or tapping the joystick's icon on the acquisition screen.
   - Reaching the time limit (30 seconds). The progression time is diplayed on screen from a progress bar.
9. A summmary of analysis is displayed as popup message where are shown the **Blink count**, **Mean**, and the **Standard deviation**.

12.10.11 NIBUT

This acquisition allows analyzing the tear NIBUT and detecting and localizing the broken sectors of the corneal surface. By selecting NIBUT acquisition mode, the acquisition environment in Figure 12.52 is shown.

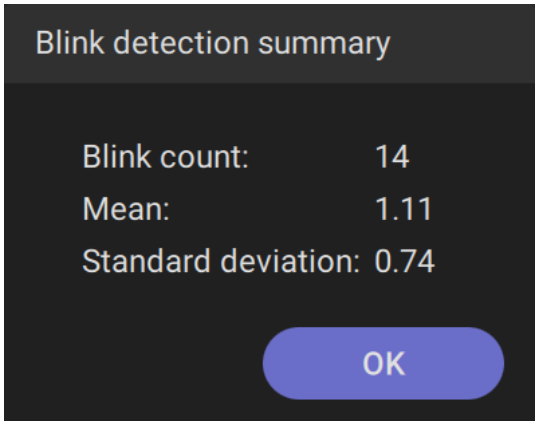


Figure 12.51: Blink summary analysis

Figure 12.52: Break-Up Time (NIBUT) acquisition environment

This type of acquisition allows both manual (12.10.6.1) and automatic (12.10.6.2) acquisition procedures.

The acquisition is performed by the following sequence:

1. Align the patient's eye (center of the rings) with the crosshair in the center of the live image in automatic or manual mode.

2. Focus the eye image (automatically or manually) until the green marks appear (Figures 12.53 and 12.54.)

Figure 12.53: eye focusing

Figure 12.54: eye focused

3. Ask the patient to blink in order to "reset" the tear film conditions.
4. The blink is automatically detected by the device, and the NIBUT analysis starts. During NIBUT analysis, the area of Placido rings is divided into polar sectors and analyzed. The sectors where significant variations are detected are colored with a green/yellow/red scale depending on the amount of variation (Figure 12.55).Green indicates that no sector break has been detected. When a sector begins to break, the intensity of the yellow color represents the degree of the break. Red indicates that the sector is definetely broken.

Figure 12.55: NIBUT analysis on going

5. The acquisition is successfully performed if one of the following events occurs once at least 5 seconds have elapsed from the start of the video acquisition (i.e., from the first detected blink):
   - A second blink is recognized by the device
   - The joystick button is pressed
   - The touchscreen joystick button is pressed by the user
   - The acquisition reaches its maximum duration (30 seconds)

6. If the acquisition ends within 5 seconds, it is considered invalid. If it ends due to a blink, it can restart with a new blink. Otherwise, the acquisition is terminated, considered invalid and is not saved. See error messages in the section 12.10.11.1.
7. Maximum duration of the acquisition is 30 seconds.
8. If the acquisition sequence ends successfully, the summary map (temporary coloring) of the interrupted sector is superimposed on the live image for a few seconds (Figure 12.56).

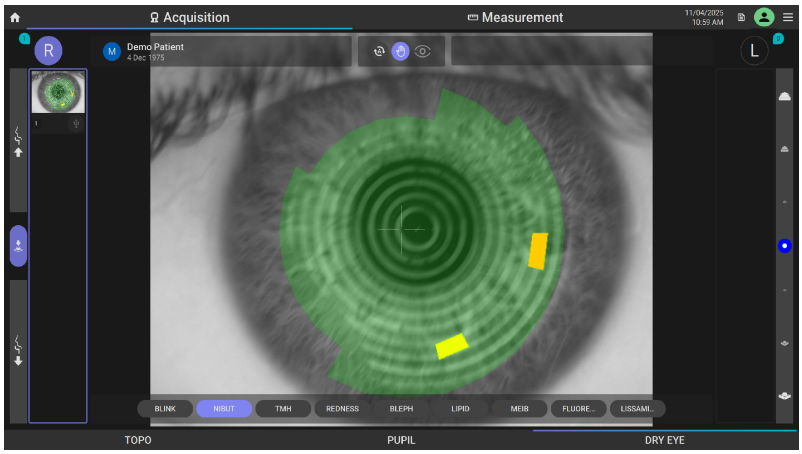


Figure 12.56: Summary map

12.10.11.1 *NIBUT error messages*

A NIBUT acquisition may be considered invalid, and therefore interrupted and not saved, due to the following reasons:

- If the acquisition ends within the first 5 seconds, be it through the pression of the acquisition button or by leaving the ideal focus, the following error message will be shown:

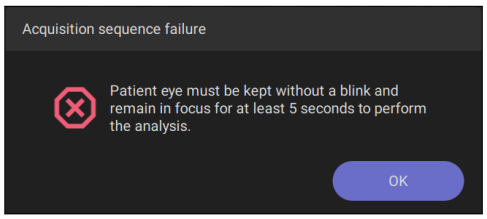


Figure 12.57: Acquisition interruption before 5 seconds error message

- If the acquisition ends before the first blink has been performed, be it through the pression of the acquisition button or by leaving the ideal focus, the following error message will be shown

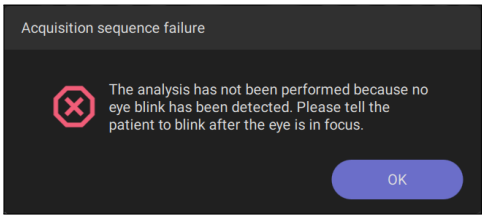


Figure 12.58: Acquisition interruption before performing the first blink error message

12.10.12 Tear Meniscus Height

By selecting TMH acquisition mode, the acquisition environment in Figure 12.59 is shown.

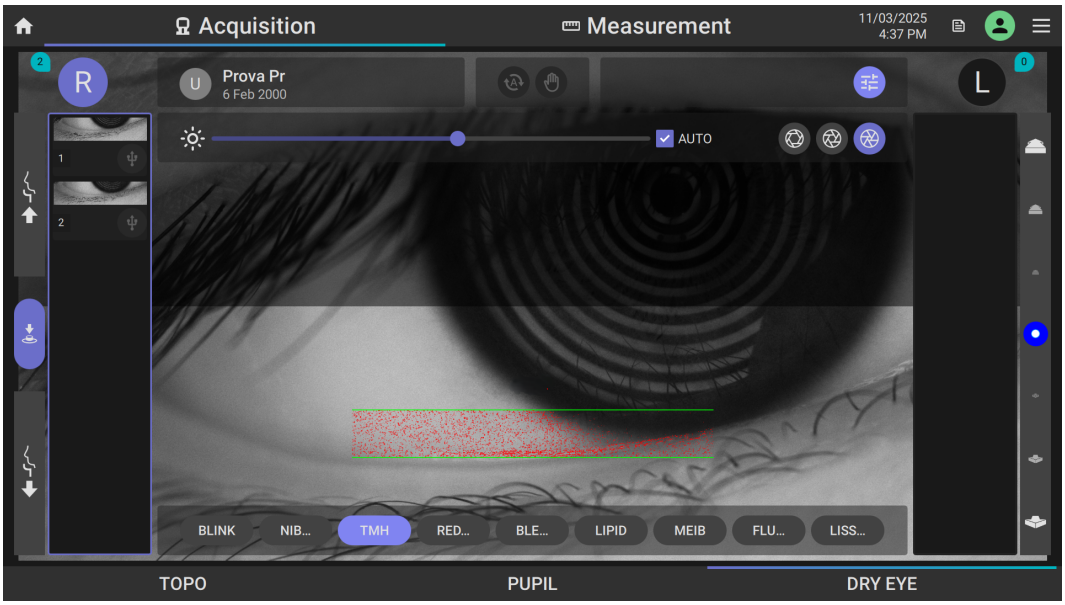


Figure 12.59: Tear meniscus height acquisition environment

This type of acquisition does not allow either manual or automatic acquisition procedures.

To assist in TMH acquisition, the environment provides some visual aids to help the user perform an accurate measurement. Two parallel green lines help to center and locate the tear meniscus, while the focused areas within them are highlighted with red dots.

This acquisition allows the measuring of the tear meniscus profile. The acquisition precedure is the following:

1. Align the lower eyelid with the reference region
2. By looking at the value displayed in red, move the base until the highest focus is found.

3. Press either the physical, or the on-screen acquisition button

The device will automatically perform a short-depth scan around the current position and select the best-focused image.

At any time, the user can:

1. Take control using the joystick to assist or correct the scan.
2. Trigger a manual capture via the physical acquisition button, or the on-screen acquisition button.

12.10.13 Redness

By selecting REDNESS acquisition mode, the acquisition environment in Figure 12.60 is shown.

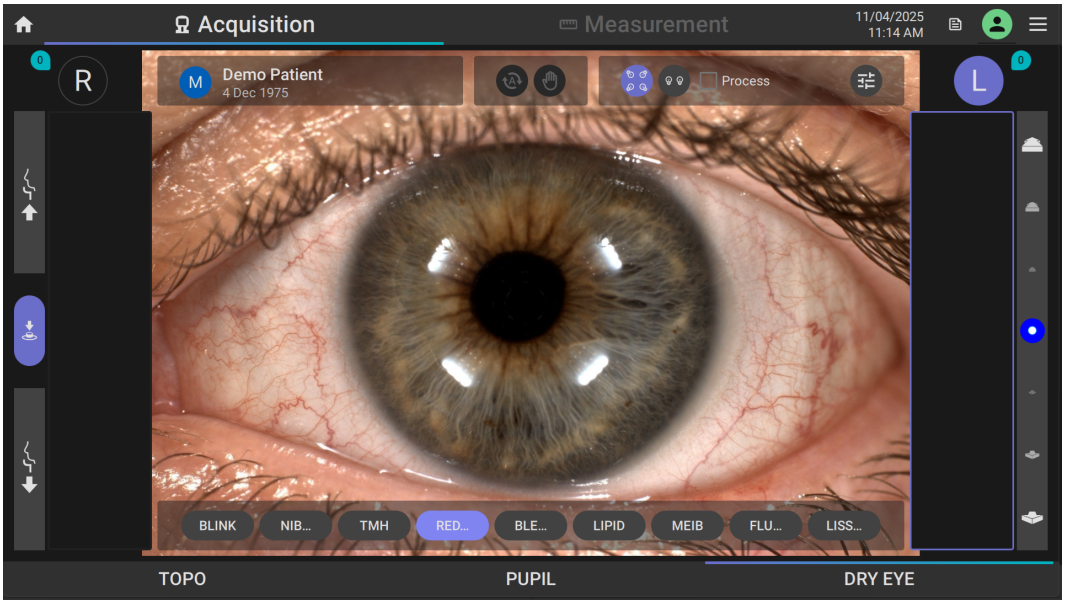


Figure 12.60: Redness acquisition environment

This type of acquisition only allows manual (12.10.6.1) acquisition procedure.

The acquisition procedure is the following:

1. Select the acquisition mode (**external** or **inner**) using the button in the acquisition panel.

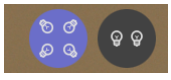


Figure 12.61: Redness acquisition mode: external or inner lights

- **External:** uses the four external white LEDs.

- **Inner:** uses the two inner white LEDs.

2. Move the joystick until the eye's surface and its surrunding areas appears both centered and in focus. Use the LED reflections as a reference for centering. Then adjust the focus by moving the joystick forward or backward until optimal focus is achieved. In case, use 12.10.7 to adjust acquisition conditions.

3. Once the image is centered and properly focused, press the joystick button to acquire the image.

CAUTION — The light emitted from this instrument is potentially hazardous. Exposure to the summed light of spatially overlapping light sources from this instrument when operated at maximum intensity will potentially exceed the Group 1 exposure limit of 2,2 J/cm2 after, 2:36 min for source 1, and 2:36 min for source 2, if all sources are operating concurrently as happens in "Inner acquisition mode". Although the risk of retinal injury at a cumulative exposure just exceeding 2,2 J/cm2 is low, as some patients may be more susceptible than others, caution is advised. Exposures exceeding the recommended maximum exposure (RME) of 10 J/cm2 (cumulative exposure duration exceeding 4,5 times the Group 1 limits) entail a significant risk of injury.

	*"Inner acquisition mode"*: **source 1** and **source 2** operate concurrently.

Table 12.4: Inner acquisition mode caution

12.10.14 Blepharitis

By selecting BLEPH acquisition mode, the acquisition environment in Figure 12.62 is shown.

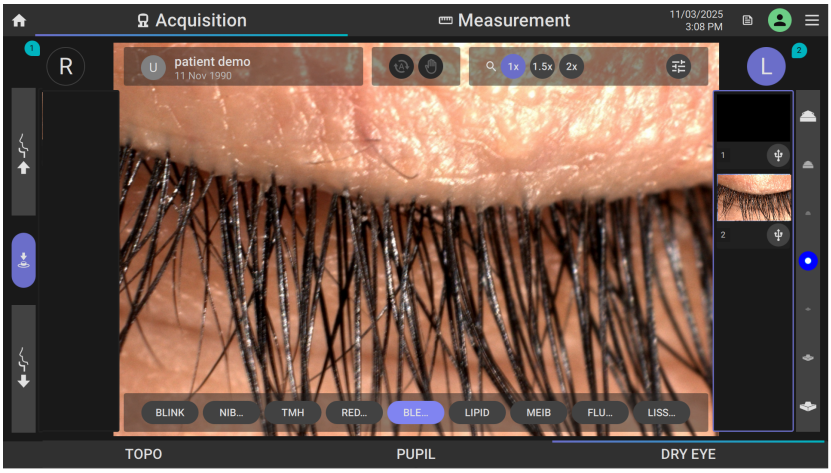


Figure 12.62: Blepharitis acquisition environment

This type of acquisition only allows manual (12.10.6.1) acquisition procedures.

The acquisition procedure is the following:

1. Move the joystick until the part of eyelid you want to acquire is centered. Then adjust the focus by moving the joystick forward or backward until optimal focus is achieved. In case, adjust acquisition conditions (12.10.7). Use the zoom button group for a close-up view or zoom out for a wider view of the acquisition environment..

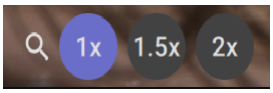


Figure 12.63: Zoom buttons

2. Once the image is centered and properly focused, press the joystick button to acquire the image.

12.10.15 Lipid Layer Thickness

By selecting LIPID acquisition mode, the acquisition environment in Figure 12.64 is shown.

This type of acquisition only allows manual (12.10.6.1) acquisition procedure.

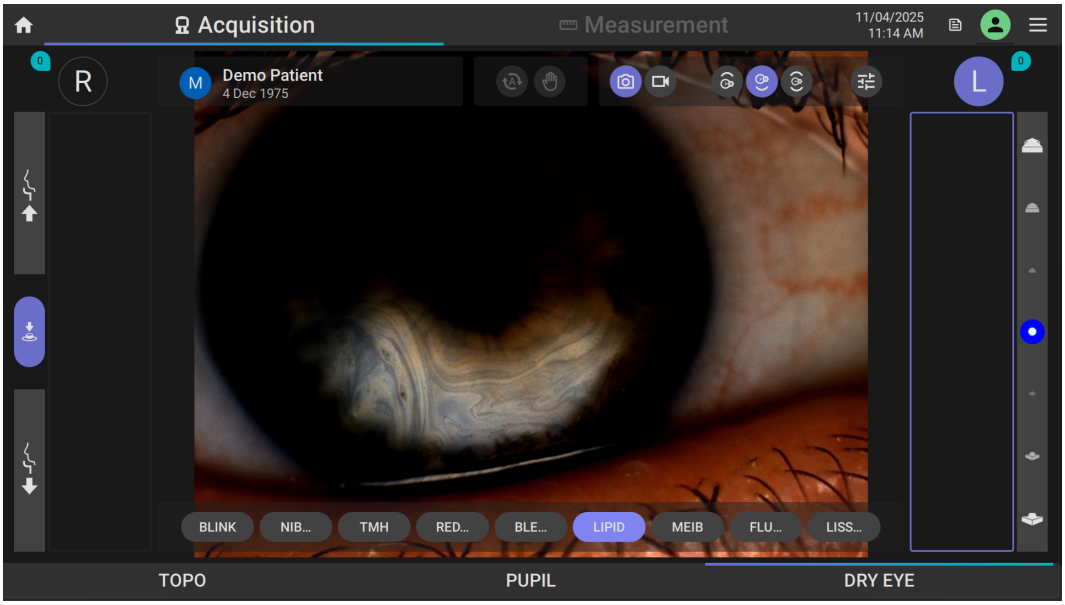


Figure 12.64: Lipid layer thickness acquisition environment

This type of acquisition allows both video and photo acquisition type.

The acquisition procedure is the following:

1. Select the acquisition lights mode (Figure 12.65 **upper**, **lower** or **both**) using the button in the acquisition panel.

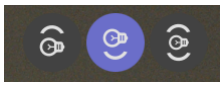


Figure 12.65: Light acquisition mode: user can activate upper, lower or both the white lights

2. Select the acquisition type between video or photo.

3. Move the joystick until the image appears both centered and in focus. Use lights reflections as a reference for centering. Then adjust the focus by moving the joystick forward or backward until optimal focus is achieved. In case, adjust acquisition conditions (12.10.7). Ask the patient to blink to reset and generate the lipid layer film again.

4. Once the image is centered and properly focused, press the joystick button to acquire the image or the video.

5. Maximum duration of the acquisition is 30 seconds.

12.10.16 Meibomian glands

By selecting MEIB acquisition mode, the acquisition environment in Figure 12.66 is shown.

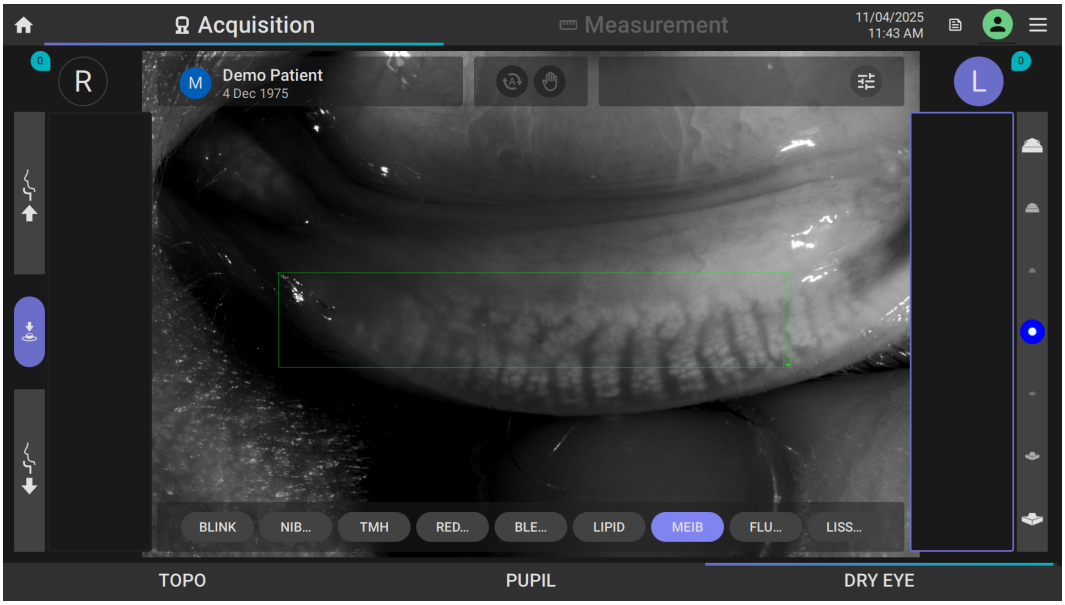


Figure 12.66: Meibomian acquisition environment

To ensure good contrast and quality of the acquired images, before taking the acquisitions it is advisable to turn off the lights in the room (or at least to dim them as much as possible).

Before starting the acquisition, the upper and lower eyelids should be properly inverted to visualize the patient's meibomian glands.

The MEIB acquisition environment contains two visual aids to help the user perform an accurate acquisition:

1. **A green rectangle** helps centering the meibomian glands.
2. **A green vertical bar** displays a focus score to assist in capturing the sharpest image.

Press either the physical, or the on-screen acquisition button to start a new scan.
The device will automatically perform a short-depth scan around the current position and select the best-focused image from the scan.

At any time, the user can:

1. Take control using the joystick to assist or correct the scan.
2. Trigger a manual capture via the physical acquisition button, or the on-screen acquisition button.

The Exposure slider allows you to manually adjust the brightness of the live image.

12.10.16.1 *Meibomian glands acquisition procedure*

Meibomian gland imaging requires the patient's eyelids to be everted. This can be done by one person who everts the eyelid while simultaneously operating the TERA to center the image, focus, and acquire. Alternatively, meibomian gland imaging can be performed by two people: one person everts the eyelids and another person acquires images with the TERA.

1. To acquire images of the Meibomian glands, select the MEIB button (Meibomian) on the Acquisition screen (Figure 12.66).

2. Disinfect the support surfaces (chin rest and forehead rest).

3. Select the upper or lower eyelid of the OD (right eye) or OS (left eye). The selected eye is automatically highlighted, based on the device position.

4. Carefully evert the eyelid and ensure that the full extent of the Meibomian glands is visible across the entire nasal-to-temporal length of the eyelid.

    - For the **lower** eyelid: evert slightly below the lash line using a cotton swab, finger, or eyelid everter. Ensure the tool does not block the inner eyelid surface.

    - For the **upper** eyelid: evert at the top of the tarsal plate, again using a cotton swab, finger, or other tool, ensuring the view is unobstructed.

5. Center and focus the area of interest manually using the joystick or touchscreen. **NOTE:** Ensure the glands are fully visible and centered inside the target box. Use the focus bar to confirm the image is sharp and of good quality.

6. Capture the image using the joystick button or touchscreen. Check the image quality:

    - If defects are present (e.g., blur, misalignment, obstruction, incomplete eversion, overexposure), reacquire the image.

    - If the full eyelid length is not visible, acquire additional images—one nasal and one temporal—by repeating steps 6–8.

7. Repeat steps 5–8 to capture the remaining eyelid images (upper and lower eyelids of both eyes), if needed.

12.10.17 Fluorescein

By selecting FLUO acquisition mode, the acquisition environment in Figure 12.67 is shown.
⚠ This type of acquisition requires instilling a small amount of ocular fluorescein into the eye.

Figure 12.67: Fluoreiscein acquisition environment

This type of acquisition only allows manual (12.10.6.1) acquisition procedure.

This type of acquisition allows both video and photo acquisition type.

The acquisition procedure is the following:

1. Select the acquisition type between video or photo.
2. Move the joystick until the image looks focused and centered, using the LEDs reflections as reference.
3. Once the image is centered and focused, click on the joystick button to acquire an image or to start recording a video. In the case of video recording, the process will stop either when another joystick button is pressed or when the preset maximum video duration is reached, whichever comes first. In case, use 12.10.7 to adjust acquisition conditions.
4. Maximum duration of the video acquisition is 15 seconds.

12.10.18 Lissamine

By selecting LISSAMINE acquisition mode, the acquisition environment in Figure 12.68 is shown.

⚠ This type of acquisition requires instilling a small amount of ophtalmic lissamine green into the eye.

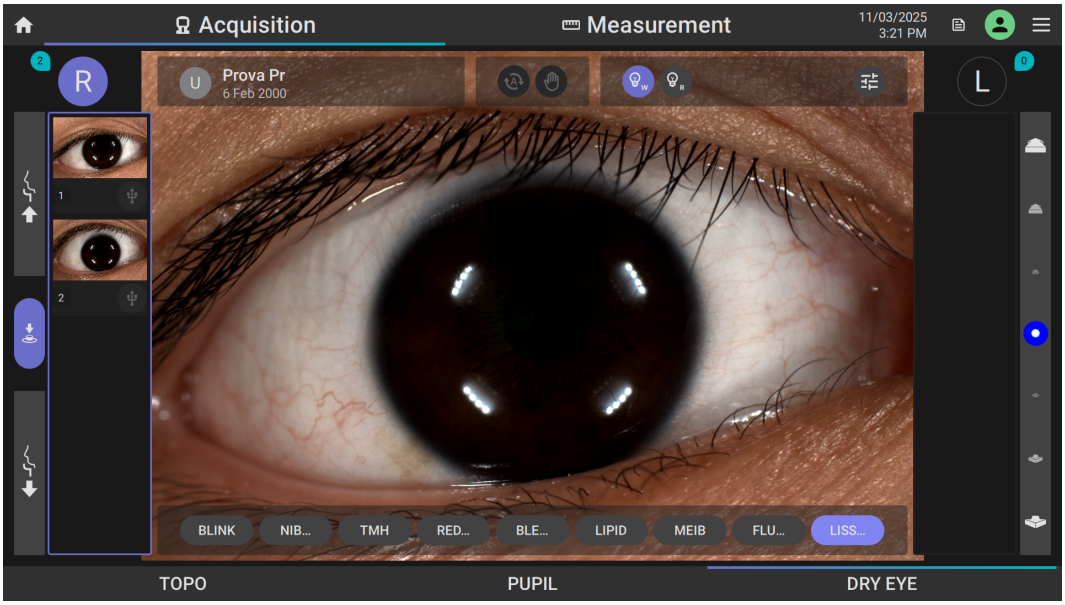


Figure 12.68: Lissamine acquisition environment

This type of acquisition only allows manual (12.10.6.1) acquisition procedure.

This type of acquisition allows photo acquisition type.

The acquisition procedure is the following:

1. Select the acquisition lights mode (Figure 12.69) **W** (white light) or **R** (red light) in the acquisition panel.

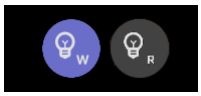


Figure 12.69: Light acquisition mode: user can activate W or R lights

2. Move the joystick until the image appears both centered and in focus. Use lights reflections as a reference for centering. Then adjust the focus by moving the joystick forward or backward until optimal focus is achieved. In case, adjust acquisition conditions (12.10.7). Ask the patient to not blink.

3. Once the image is centered and properly focused, press the joystick or virtual joystick button to acquire the image.

12.10.19 Saving acquisition

After completing some acquisitions, in order to save the data from the examination, tap on the home button. As shown in 12.70, the software will prompt the user to confirm the action.

By tapping the **Save** button, the application will save the acquisition data and exit the acquisition environment.

By tapping the **Discard** button, the application will not save the acquisition data and will exit the acquisition environment.

By tapping the **Cancel** button, the application will remain on the acquisition environment.

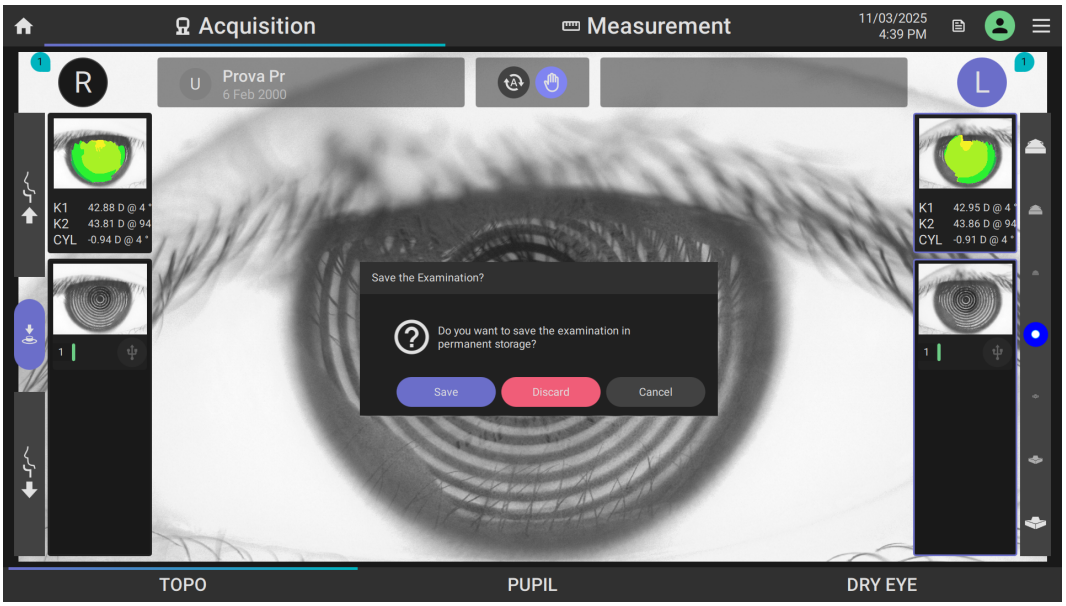


Figure 12.70: Acquisition saving

12.11 ACQUISITION LIMIT WARNING

When the maximum number of acquisition is reached, a warning message pops out (Figure 12.71). The maximum number of acquisitions can be adjusted from the Settings menu.

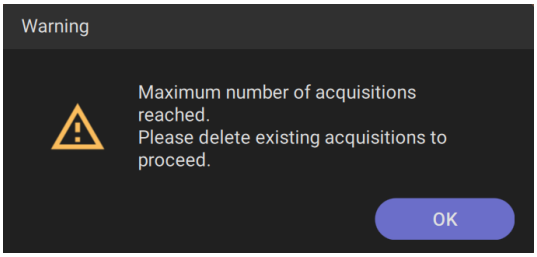


Figure 12.71: Acquisition limit pop up

13 MEASUREMENTS

13.1 MEASUREMENT OVERVIEW

All measurements performed during the examination can be reviewed in detail in the "Measurements" section. Measurements environment can be reached from patient list (see Section 12.8.3) or directly from live acquisition environment, selecting the Measurement tab in the top bar. The TERA provides comprehensive analysis tools for each measurement type, enabling detailed evaluation of corneal topography, pupillometry, fluorescein imaging, and tear film dynamics.

All measurement types are listed in the left tab. The user can switch between sections by tapping the desired one. Available sections are highlighted, and the current section is marked by a colored line.

Figure 13.1: Measurement sections list

- MAP: Topography Map
  - OD/OS: (or R/L) Right to Left side by side Topography Map review
  - ZER: Zernike Analysis
  - COMP: Topography Map comparison of two different exams of the same patient
  - WTW: White to White review
- PUP: Pupillometry
- BLINK: Blink acquisitions review
- NIBUT: Nibut acquisitions review
- TMH: Tear Meniscus Heights analysis
- REDNESS: Redness analysis review
- BLEPH: Blepharitis analysis review
- LLT: Lipid layer thickness analysis review
- MEIB: Meibomian glands acquisitions review
- FLUO: Fluorescein acquisitions review
- LISSAMINE: Lissamine acquisitions review
- QUEST: Questionnaires review

13.2 MAP – TOPOGRAPHY MAP

The topography map environment provides comprehensive corneal surface analysis with multiple visualization options and diagnostic indices.

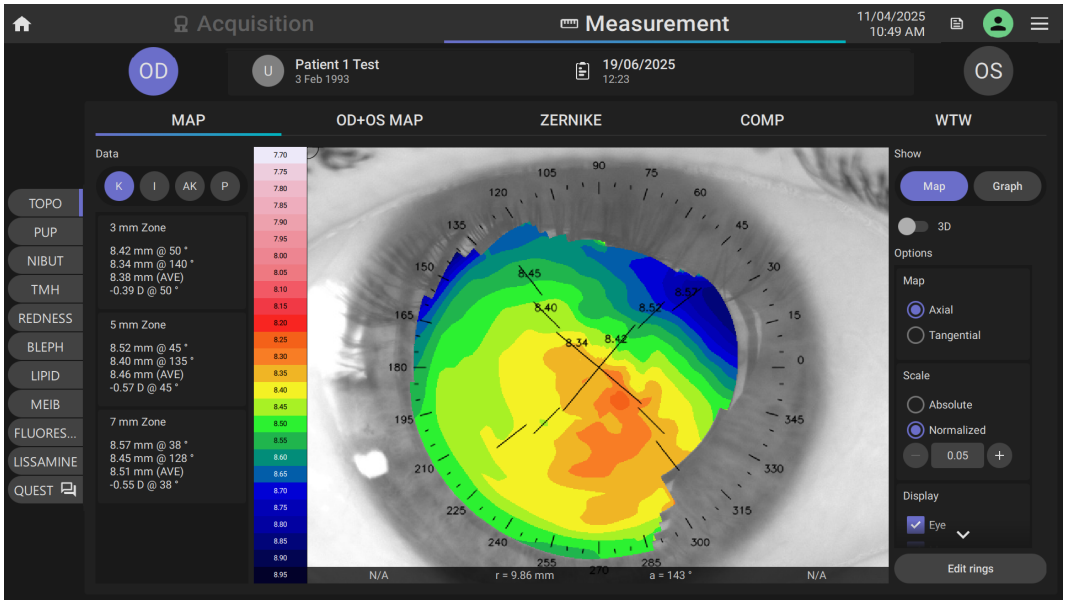


Figure 13.2: Main topography map display interface

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

13.2.1 Map Display Options

In the right column, the user can adjust the display options.

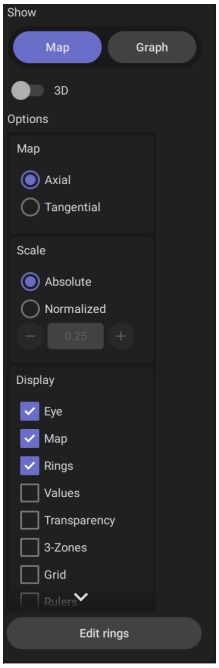


Figure 13.3: Control panel for topography map visualization

- **Show** – This option defines how the topography map is represented. **Map** displays the two-dimensional topography map. **Graph** provides the curvature profile along different directions (see Section 13.2.3). Activating the **3D** mode shows the topography map as a three-dimensional surface (see Section 13.2.4).
- **Map**
  - Axial. Displays the axial curvature map.
  - Tangential. Displays the tangential curvature map.
- **Scale**
  - Absolute. Uses a fixed color scale for curvatures value
  - Normalized. Uses a normalized scale with related curvature step value.
- **Display** Provides additional options for visualization (expandable menu).
- **Edit rings** Tap to open the rings editor environment (See section 13.2.5)

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

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

13.2.2 Topographic Map Indices

The diagnostic indices can be selected with the following buttons (on the top left column):

- 

K: Keratometry
- 

I: Keratorefractive indices
- 

KC: Keratoconus analysis
- 

P: Pupil

13.2.2.1 Keratometry

Press the "K" button to display the keratometric data on the 3 mm, 5 mm and 7 mm zones.

13.2.2.2 Keratorefractive Indices

Press "I" button to view the keratorefractive indices:

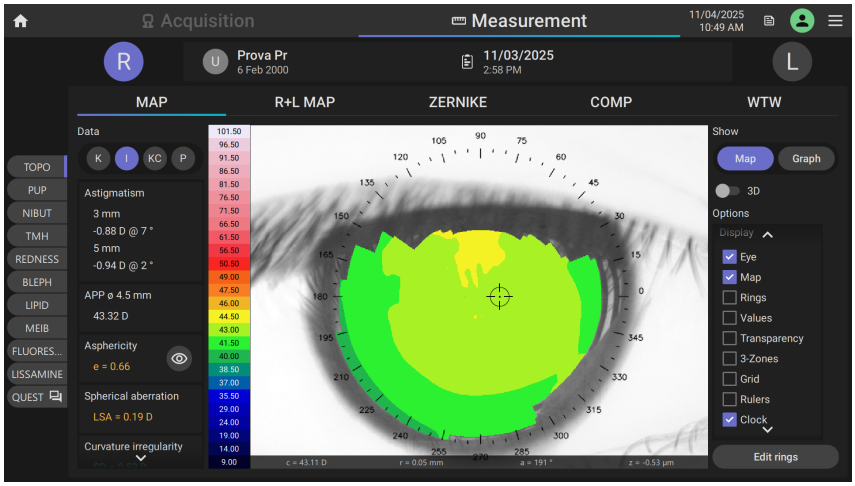


Figure 13.4: Keratorefractive indices display

- Astigmatism: Astigmatism at 3 and 5 mm
- Pupil Avg: Average pupil power for a pupil of 4.5 mm
- Asphericity: Asphericity of the cornea at 8 mm diameter. Pressing the button with eye icon will open a more detailed set of data
- Spherical Aberration: Longitudinal spherical aberration of a 4.5mm diameter cornea area
- Curvature Irregularity: Irregularity of curvature calculated on the standard deviation of the instantaneous readings for a 4.5mm diameter cornea area
- Asymmetry + SAI: Asymmetry between the most curved hemisphere and the flattest one, calculated for a 4.5mm diameter cornea area and a SAI (Surface Asymmetry Index) which represents the surface asymmetry index of the 4.5mm diameter cornea area

CORNEAL ASPHERICITY The window is composed by two tabs (Asphericity and Peripheral degrees) which specify the corneal asphericity. The Corneal Asphericity window could be invoked also from Corneal Height Map environments.

Figure 13.5: Asphericity analysis panel

ASPHERICITY TAB The panel is divided into four parts:

- The top-left rectangle (Principal meridian asphericity 8mm) contains three lines showing apical radius (Ro) and asphericity (e) along the flattest and steepest meridians, plus average values

- The top right rectangle (Principal meridian asphericity 4.5mm) contains the same parameters for a 4.5mm circular area

- The bottom rectangle contains corneal asphericity referred to pupillar surface (4.5mm) and surface irregularity (SD)

PERIPHERAL DEGREES TAB The table describes the corneal asphericity at the different peripheral degrees. The first four rows describe parameter values along the nasal, temporal, inferior and superior emimeridian. The next two rows represent averages between nasal/temporal and inferior/superior values respectively.

Figure 13.6: Peripheral degrees analysis table

13.2.2.3 Keratoconus Analysis

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

Figure 13.7: Keratoconus screening KC tab

KC TAB The KPI tab shows the following information:

- AK: Apical curvature - Represents the power of the cornea at its apex
- AGC: Apical gradient of curvature - Represents the average variations per unit of length of the corneal power

- SI: Difference between average power of two circular zones centred on the vertical axis
- Kpi: Keratoconus diagnosis probability index

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

If keratoconus is detected, the following geometric parameters are shown:

- A: area of the keratoconus (mm^2)
- D: average diameter of the keratoconus (mm)
- ρ, ϕ: polar coordinates (mm, °) of the barycentre
- RND: circularity factor of the keratoconus

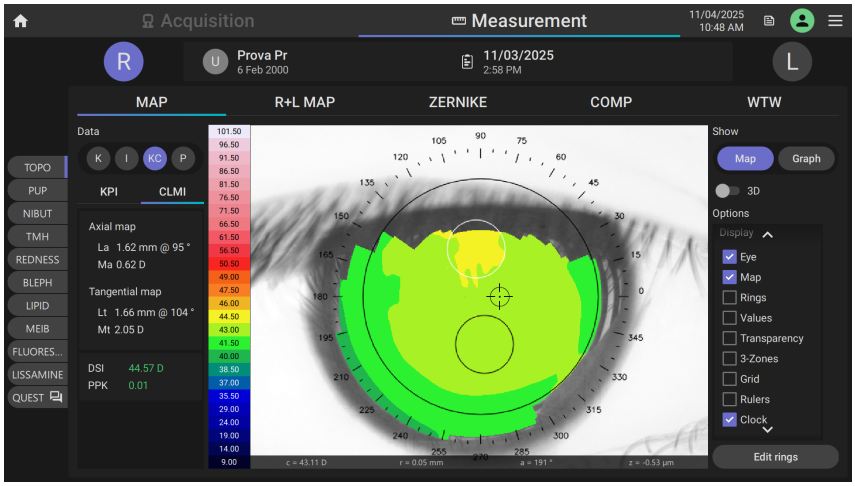


Figure 13.8: CLMI analysis tab

CLMI TAB The CLMI tab shows the following information:

- Axial map CLMI: Cone Location and Magnitude Index based on the axial map
- Tangential map CLMI: Cone Location and Magnitude Index based on the tangential map
- DSI: Differential Sector Index
- PPK: Percent Probability Keratoconus

13.2.2.4 Pupil Indices

Press the "P" button to open the pupil indices:

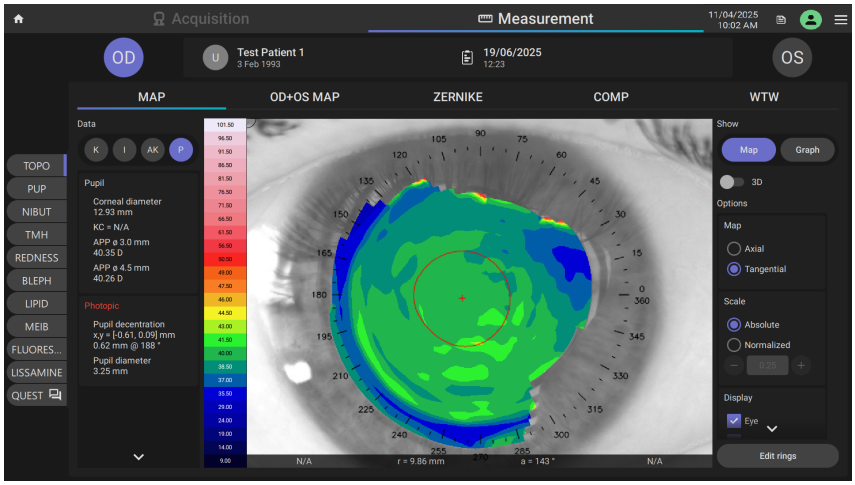


Figure 13.9: Pupil indices display

- Corneal Diameter: represents the diameter of the patient's cornea in mm
- KC: KC represents the central keratometry in diopters
- Avg Pupil Power (APP): Average pupil power inside the 3.0 mm pupil
- Avg Pupil Power (APP): Average pupil power inside the 4.5 mm pupil
- Pupil Decentration: Pupil decentration from the optical axis
- Pupil diameter: average pupil diameter

13.2.3 Profile View (Graph)

Press the "Graph" button to visualize the curvature profile along the most curved meridian and the flattest meridian (red and blue). The difference is displayed in green.

Figure 13.10: Curvature profile along principal meridians

By pressing the +/- buttons, user can change the flattest and the steepest meridians. The graph will be modified accordingly. Press the "Map" button to go back to the topographic map.

13.2.4 3D View

Press the "3D" button to view the 3D map of the keratometric data:

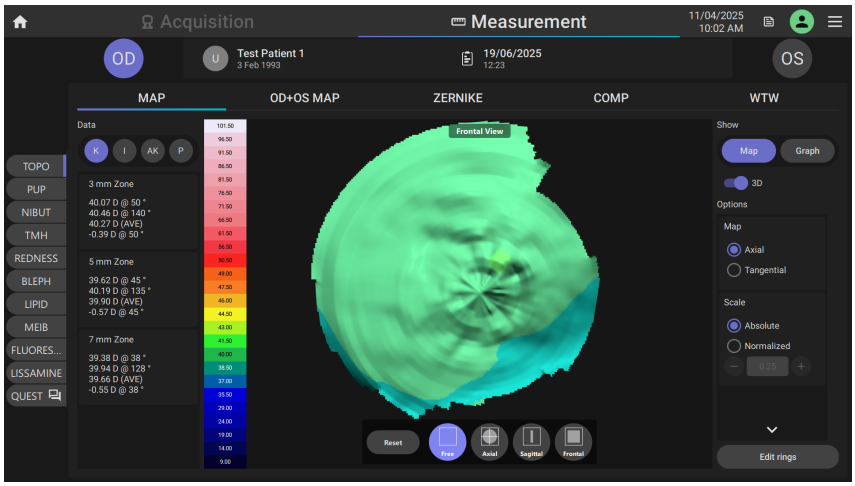


Figure 13.11: 3D topographic map visualization

The user can rotate and explore the 3D surface using the touchscreen, assisted by the buttons in the bottom bar:

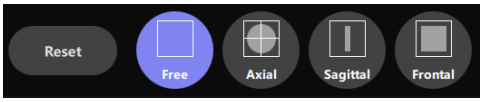


Figure 13.12: 3D visualization commands.

- Reset: resets the 3D view to the default orientation.
- Free: Enables free navigation, allowing rotation and movement in any direction.
- Axial: only allows rotations along axial line.
- Sagittal: only allows rotations along sagittal line.
- Frontal: only allows rotations along frontal line.

13.2.5 Edit Rings

Clicking on the command button, the view changes and the editing environment is displayed. In this section the user can edit all the rings in order to improve the topographic map.

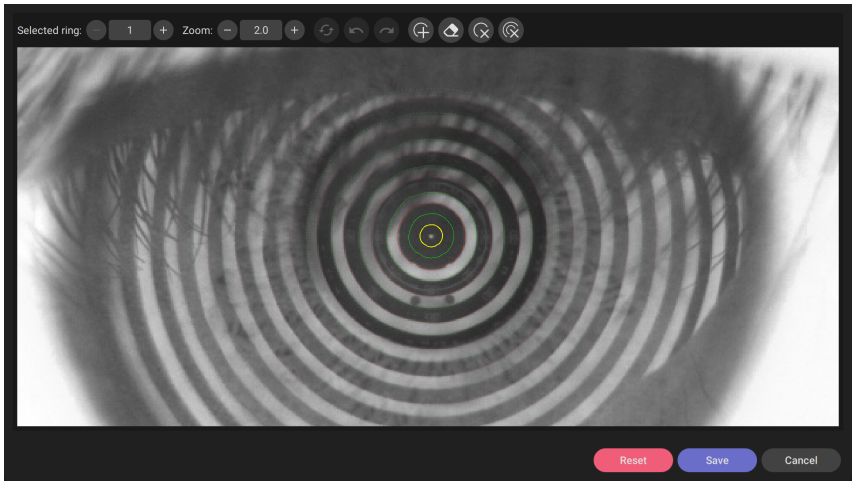
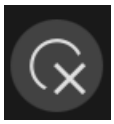
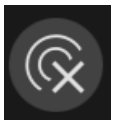
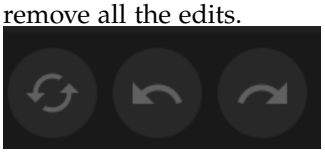


Figure 13.13: Ring editing interface

On the top bar, the navigation and editing tools are available.

Figure 13.14: Edit rings toolbar

#	Edit rings procedure description
1	Select the desired rings to be edited using the ring spin box. Selected rings are highlighted in yellow as an overlay on the topography map. 
2	Once the ring is selected, the user can perform the following operations: • **Add ring**: Tap the *Add Ring* button in the control bar, then tap on the topographic image to add a ring at that location. The new ring appears in yellow.  • **Delete ring**: Tap the *Delete Ring* button to remove the selected ring.  • **Eraser**: Tap the *Eraser* button, then tap on the map to remove parts of the selected ring inside the marked area.  • **Delete all rings**: Tap the *Delete All Rings* button to remove all rings. You can also place a new ring center using the *Center Placement* tool. When a new center is placed, the rings are automatically re-detected. 
3	Use the time arrow buttons to UNDO or REDO the last operation, or completely remove all the edits. 
4	Press **Save** to confirm the changes, or press **Reset** to discard all modifications. Press **Close** to close the environment.

13.3 OD/OS COMPARISON

In this section you can compare the OD and the OS data on the same screen. This section is available only if at least an acquisition for each eye (OD/OS) exists.

Figure 13.15: Side-by-side comparison of right and left eye topography

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

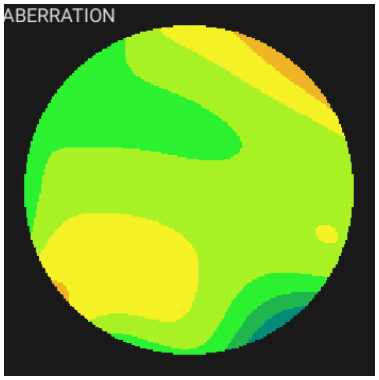
13.4 ZER – ZERNIKE ANALYSIS

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

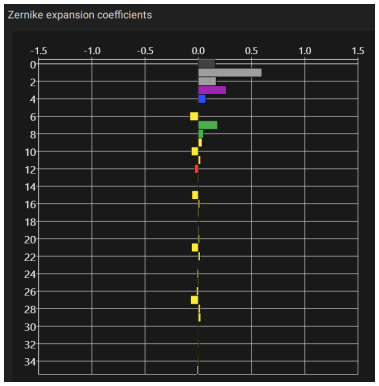
Figure 13.16: Zernike analysis main interface

Tap on the "R" or "L" buttons to view the results of the Zernike analysis for the right or left eye. On entering the module, the aberration maps are displayed ("Maps" section).

13.4.1 Aberration Maps

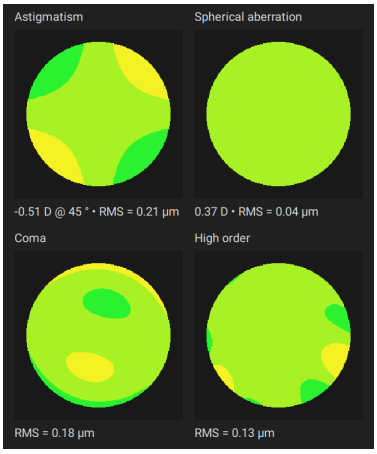


Aberration: this map shows the total wavefront aberration that corresponds to the sum of all the aberration components. The total RMS value is shown under the map. User can select the diameter of the pupil where all aberration maps are calculated. Pupil range is between 2 mm and 7.5 mm.



Zernike expansion coefficients histogram: each histogram bar represents the weight of the corresponding polynomial. Each primary aberration coefficient has its own color. Gray for Prism components, red for Sphere component, purple for Astigmatism components, green for Coma components, while all the High Order components are yellow colored.

- **Astigmatism**: the map, the magnitude in diopters, the axis and the RMS value are displayed.
- **Spherical aberration**: the map, the quantity of longitudinal spherical aberration in diopters and the RMS value are displayed.
- **Coma**: the map, the RMS value and the direction are displayed.
- **High Order**: all the components of an order higher than the primaries are grouped; the map and the RMS value are displayed.



13.4.2 Vision Quality Graphs

Tap on "Graphs" on the top bar to display the vision quality summary (Figure 13.17).The data displayed refer only to the component induced by the anterior surface of the cornea, not by the eye entire optical system.

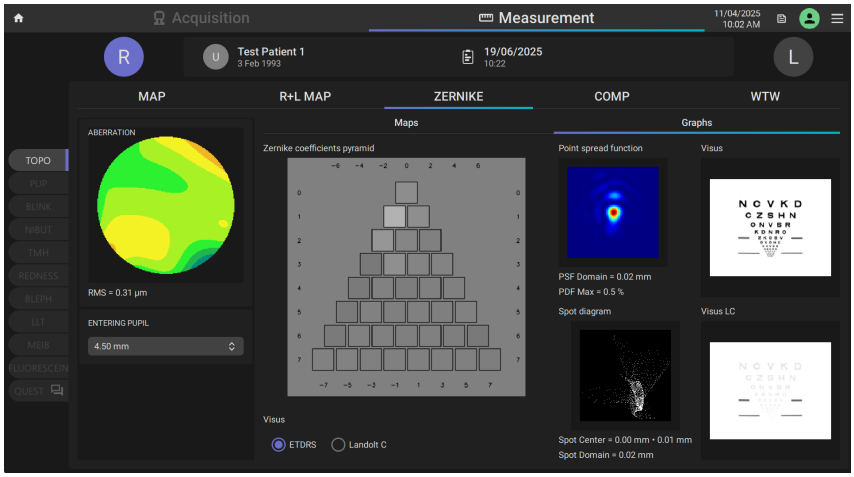
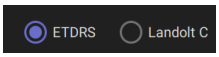
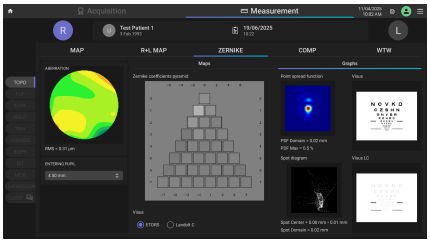


Figure 13.17: Vision quality graph main interface

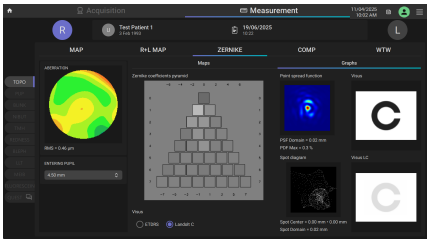
This section displays:

- Zernike Coefficient pyramid: represents the numerical value of each coefficient by means of a gray scale
- 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 LC: simulate the patient's real vision with high and low contrast. User cans switch between ETDRS and Landolt C Visus simulation view (Figure (13.18) using the Visus mode buttons 



(a) ETDRS



(b) LANDOLT

Figure 13.18: Zernike vision quality analysis graphs

13.5 COMP – COMPARISON

Comparison mode allows the user to compare the current exam data with the data of another exam for the same patient. Data always refer to the same eye.

Figure 13.19: Comparison interface showing two examinations

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

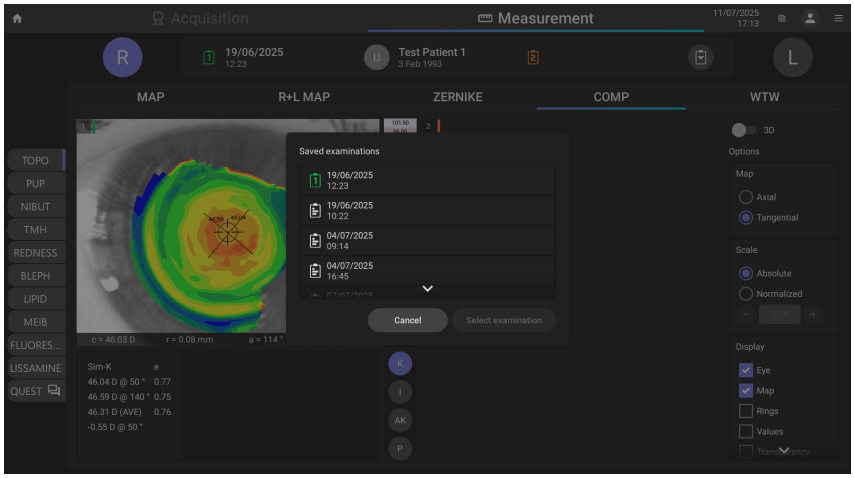


Figure 13.20: Exam selection for comparison

Figure 13.21: map indexes selection

In comparison mode, it is still possible to switch between the Topographic Map Indices tabs using the map indexes selection; The user can also use map options as in the single exam view (see section 13.2.1). Selected options are applied to both the maps.

13.6 WTW – WHITE TO WHITE

The White to White section allows you to view the value of the corneal diameter calculated from limbus. Next to the image, obtained by automatic white to white calculation, you can see:

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

Figure 13.22: White to white measurement interface

13.6.1 Manual Editing

User can manually edit the diameter and the offset of the automatic calculated white to white.

#	White to white edit procedure description
1	Tap **Edit** button to activate the positional indicators on the image (Figure 13.22)
2	Change centering and size of white to white using the positional indicators. By changing the indicators position also values of corneal diameter and the x and y offsets are updated.
3	Press **Save** to save the current values. Press **Reset** to reset all the values to the ones obtained by the automatic system calculations.

Figure 13.23: White to white manual editing interface

13.7 PUP – PUPILLOMETRY

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

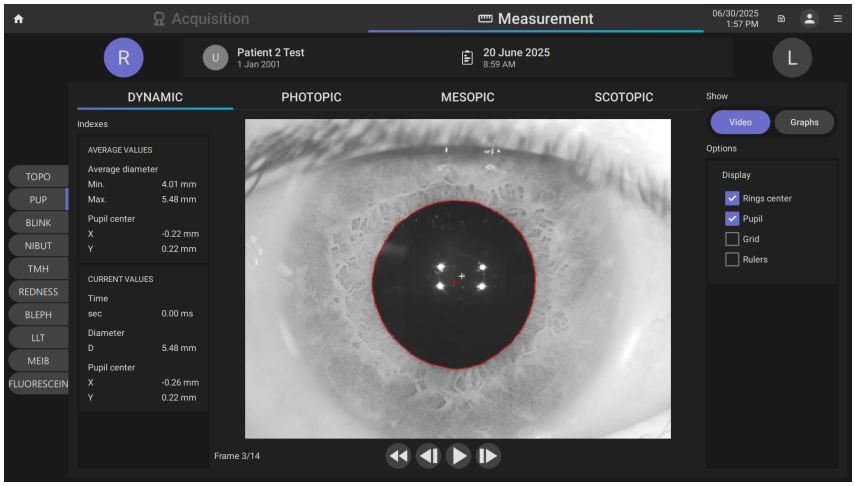


Figure 13.24: Pupillometry analysis interface

Normally, if pupillometry is acquired, the software switches to dynamic mode. Tap on "R" or "L" to display the pupillometry of the right or left eye, respectively.

13.7.1 Display Options

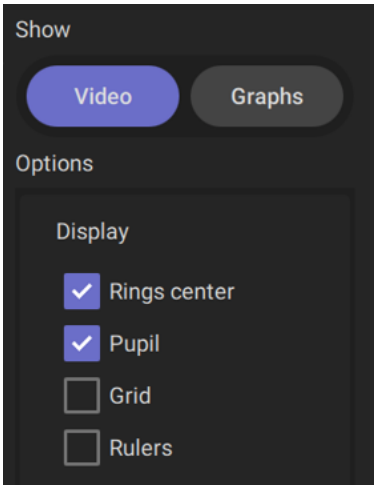


Figure 13.25: Pupil display options

- Press the "Graphs" button to display the graphs relating to the pupil. This function is explained in the next paragraph.
- Ring Center. Shows the position of the fixation point (i.e. the white cross follows the corneal vertex, while the red cross the pupil center)
- Pupil. Shows the red ring, which highlights the pupil edges
- Grid. Shows an overlaid grid (each grey grid equals to 1mm)
- Rulers. Shows calibrated rulers (small marks equal to 0.25mm while big marks equal to 0.75mm)

13.7.2 Sequences

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

- Dynamic
- Photopic
- Mesopic
- Scotopic

13.7.2.1 Dynamic Pupillometry

Tapping on the "Dynamic" button, Dynamic pupillometry acquisitions will be displayed in video with the following information table:

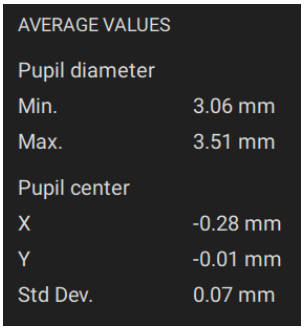


Figure 13.26: Dynamic average values table

- Pupil diameter: Value of the maximum and minimum pupil diameter measured in all the images acquired during the sequence
- Pupil Center: Cartesian coordinates of the average offset between pupil center and fixation and its standard deviation

13.7.2.2 Photopic, Mesopic, Scotopic

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

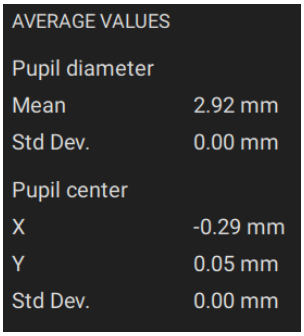


Figure 13.27: Photopic, Mesopic, Scotopic average values table

- Pupil diameter: average and standard deviation for all the image acquired during the selected static sequence
- Pupil Center: cartesian coordinates of the average offset between pupil center and fixation and its standard deviation during the selected static sequence

13.7.3 Pupil video analysis

The user can control the pupil video reproduction by using the video player buttons located below the video sequence.

Each button has a different function:

-  Rewind : brings the Pupillometry video back to the beginning while also stopping it.
-  Previous Frame: brings the Pupillometry video back to the previous frame.
-  Play / Stop: starts or stops playback of the selected Pupillometry video. If paused, it resumes from the current position.
-  Next Frame: moves the Pupillometry video forward to the next frame.

On the left column, data for current frame of the video are shown:

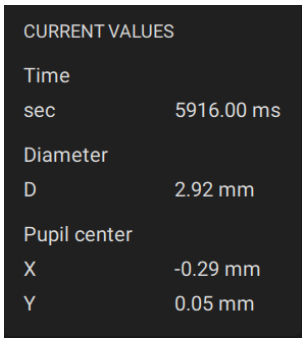


Figure 13.28: Current frame values table

- Time: Milliseconds from video start for the frame selected
- Diameter: Pupil diameter for the frame selected
- Pupil Center: offset between pupil center and fixation for the frame selected

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

13.7.4 Graphs

Tap **Graphs** to open Graphs section. In this section, three types of graph are displayed:

- Decentration
- Latency
- Statistics

⚠ Decentration and latency graphs are only available if dynamic pupillometry has been acquired. Statistics graph is available only when all Mesopic, Photopic and Scotopic pupillometry have been acquired.

In all these graphs you can select the eye you wish to analyze by tapping on "OD" or "OS". Tap **Video** to go back to the video section

13.7.4.1 Decentration Graph

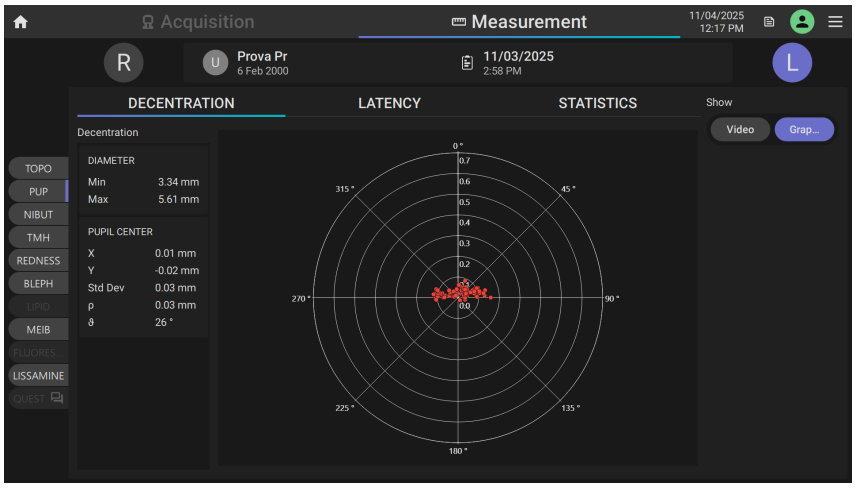


Figure 13.29: Pupil decentration analysis

The white concentric circles identify the decentration of the pupil center with respect to the fixation point. The red dots represent all the pupil center coordinates of all frames of the dynamic pupillometry.

13.7.4.2 *Latency Graph*

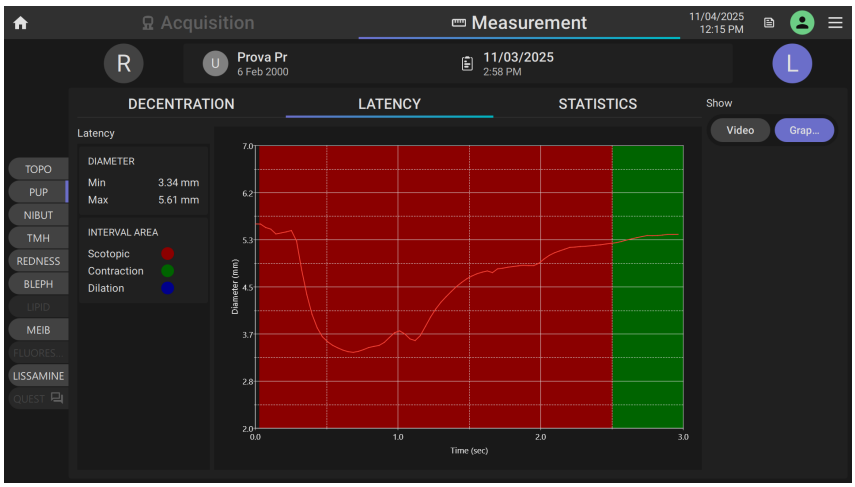


Figure 13.30: Pupil response latency analysis

The graph shows the time in seconds on the abscissa and the pupil diameter in mm on the ordinate, in a scale standardized based on the maximum and minimum diameter values recorded.

13.7.4.3 *Statistics Graph*

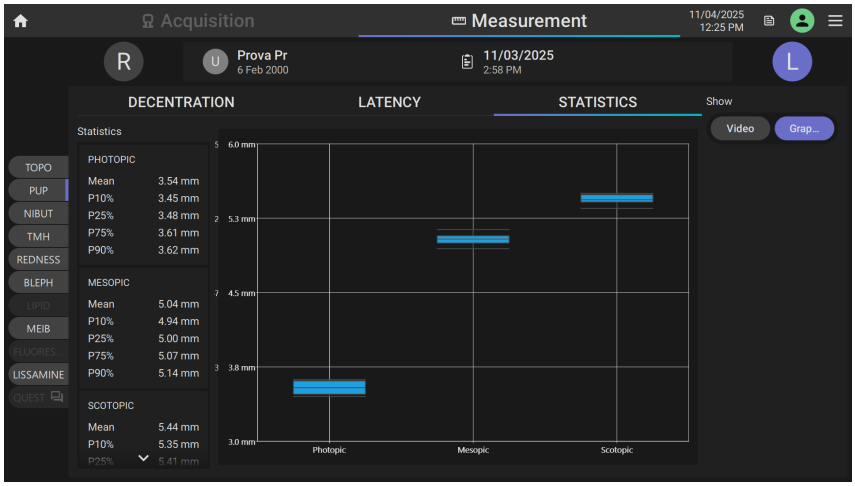


Figure 13.31: Pupil size statistics

The graph and the tables show the statistic distribution of pupil diameter values for each acquisition under controlled light conditions.

PHOTOPIC	
Mean	3.54 mm
P10%	3.36 mm
P25%	3.51 mm
P75%	3.57 mm
P90%	3.67 mm

The table shows the pupil diameters at different percentile levels. Mean is the average diameter of all the frames. P10% and P90% mark the upper and lower values around the mean containing 80% of the values in the frame buffer. P25% and P75% mark the upper and lower values around the mean containing 50% of the values. All percentile values are shown in the graph as gray lines, with a blue box highlighting the range between P25% and P75%.

13.8 NIBUT – NON-INVASIVE BREAK-UP TIME

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

- ⚠ DISCLAIMER: The results of any individual test cannot be used alone for diagnosis. They should always be interpreted in the context of symptoms, other relevant diagnostic tests and driver assessments, before applying professional judgment to diagnose or plan treatment.

13.8.1 Summary

This tab shows cumulative results of all the acquisition performed for the selected eye:

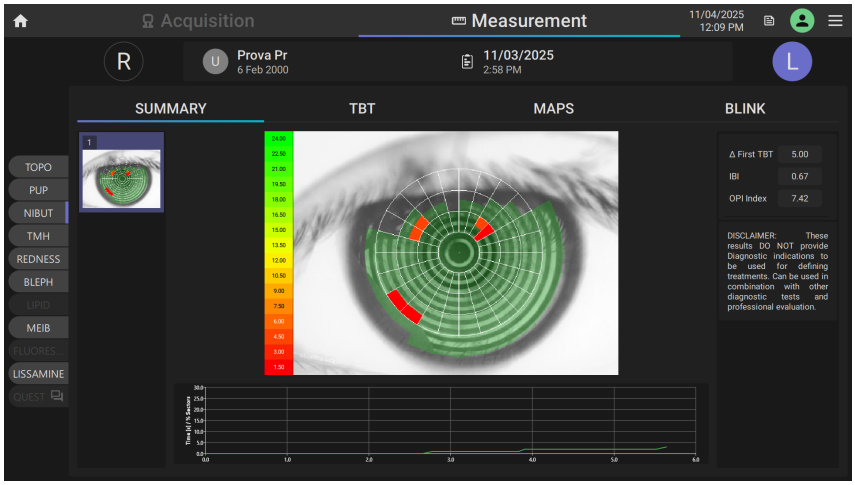


Figure 13.32: Nibut summary view

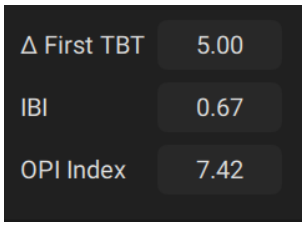
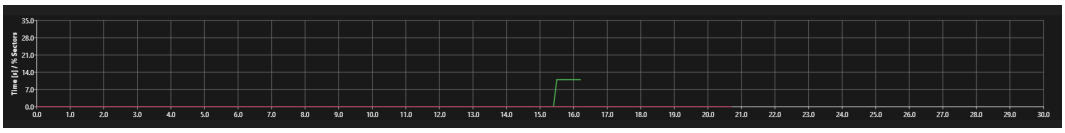


Figure 13.33: Summary values table

- **Δ First TBT** (Tear Film Break-Up Time): average of First TBT for all the valid acquisition. First TBT is the time of first occurrence of a valid sector break.
- **IBI** (available if BLINK acquisition has been performed): average Inter-Blink Interval
- **OPI index** (Ocular Protection Index): available only if IBI is available, it's the ratio between First TBT and IBI

The overlay map shows the average break-up map across acquisitions. For a detailed explanation of an single break-up map, refer to the TBT section.

The plot shows time on the x-axis against the percentage of broken sectors at that time. In case of multiple acquisitions, graphs of each acquisition are drawn.



13.8.2 TBT

By switching to the TBT view the results of TBT analysis and OPI index can be reviewed for each single acquisition.

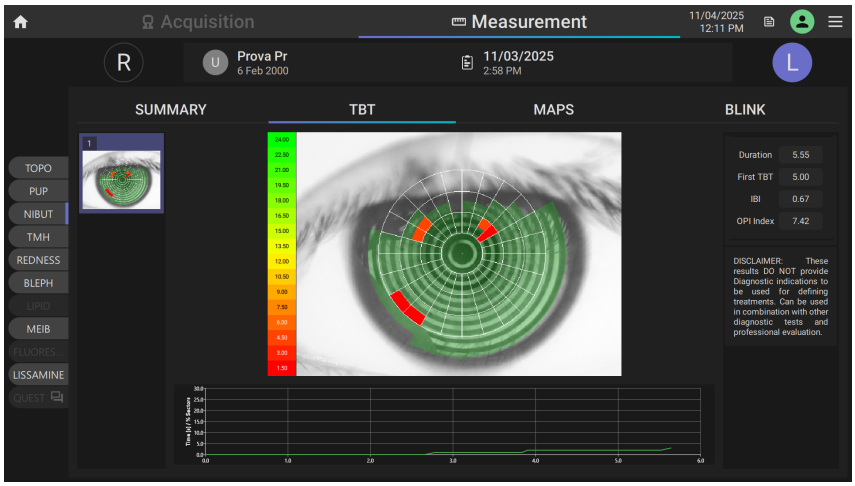


Figure 13.34: Single TBT acquisition analysis

The following values are for the selected acquisition:

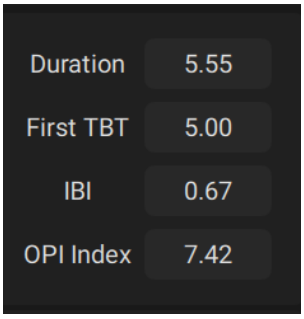
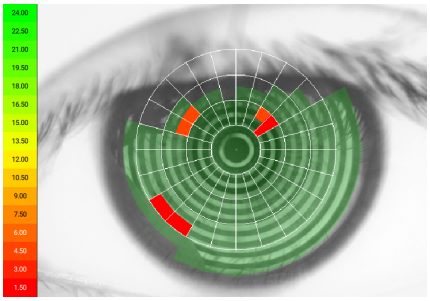


Figure 13.35: Single acquisition values table

- **Duration**: the duration of the TBT analysis interval for the selected acquisition
- **First TBT** (Tear Film Break-Up Time). First TBT is the time of first occurrence of a valid sector break.
- **IBI** (available if BLINK acquisition has been performed): average Inter-Blink Interval
- **OPI index** (Ocular Protection Index): available only if IBI is available, it's the ratio between First TBT and IBI

The overlay map shows the break-up time of each sector:



All the detecetd sector are marked by a green opaque overlay. The color of each sector represents the time at which the tear film broke in that region. The color scale provides the correspondence between color and break-up time. Break-up time is calculated in seconds from initial blink. Sectors not colored didn't break in the current acquisition.

13.8.3 Maps

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

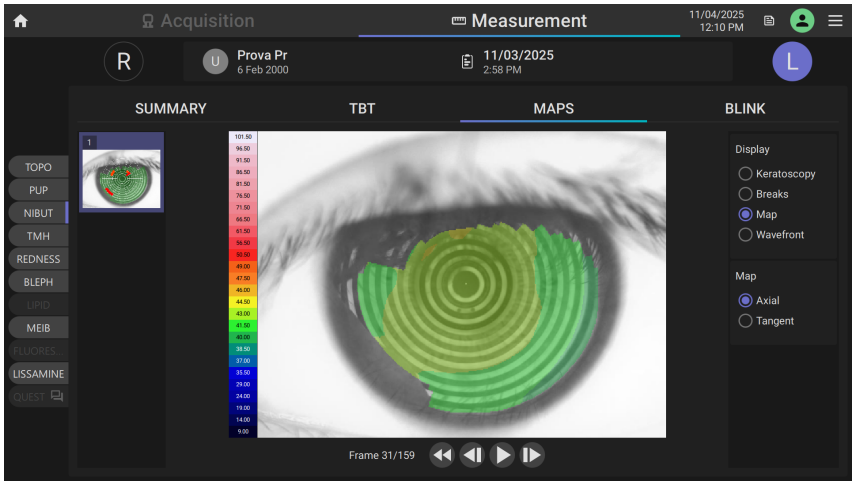


Figure 13.36: TBT maps view with video playback options

- Keratoscopy: play the video with no overlay drawing

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

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

- Wavefront: play the video with time-wise evolution of aberration Zernike components. Selectable between full OPD, Astigmatism, Spherical aberration, Coma, High Order.

13.8.4 Blink

The content of this view is available only if a BLINK acquisition was performed

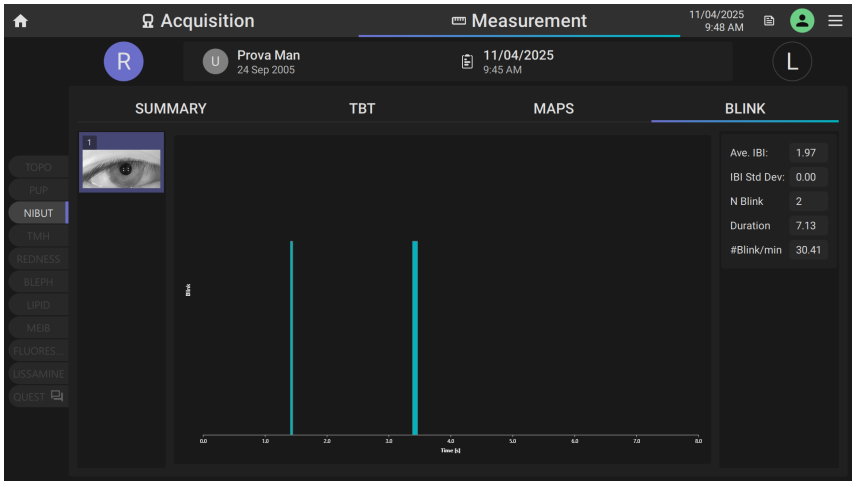
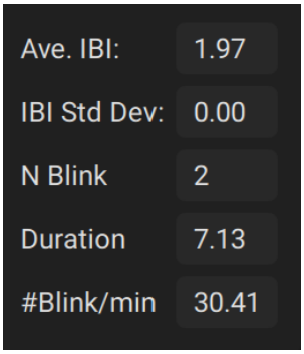


Figure 13.37: Blink analysis results

The Values reported are:



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

The graph illustrates the blinks detected during the acquisition process. Each blink is represented as a bar, where the position indicates the timing of the blink and the bar's length corresponds to its duration.

13.9 TMH – TEAR MENISCUS HEIGHT

In the TMH section, the user can check all the images that have been taken in the Meniscus acquisition. Furthermore, this section allows the user to draw and review the profile of the tear meniscus.

- ⚠ DISCLAIMER: The results of any individual test cannot be used alone for diagnosis. They should always be interpreted in the context of symptoms, other relevant diagnostic tests and driver assessments, before applying professional judgment to diagnose or plan treatment.

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

- Zoom in: decreases the current zoom percentage by 10%
- Zoom out: increases the current zoom percentage by 10%
- 67% Current zoom percentage: indicates the magnification level at which the image is currently being displayed.

Tapping the Analyse button (ANALYSE) toggles the application into Analysis mode, enabling the user to insert, adjust, or remove calipers to accurately draw the tear meniscus profile.

13.9.1 Tear Meniscus Height Calipers

Upon enabling the Analysis mode, the user can add calipers to measure the height of the tear meniscus by simply tapping on the desired location in the image. Once added, the application automatically selects the newly placed calipers and switches to Edit mode.

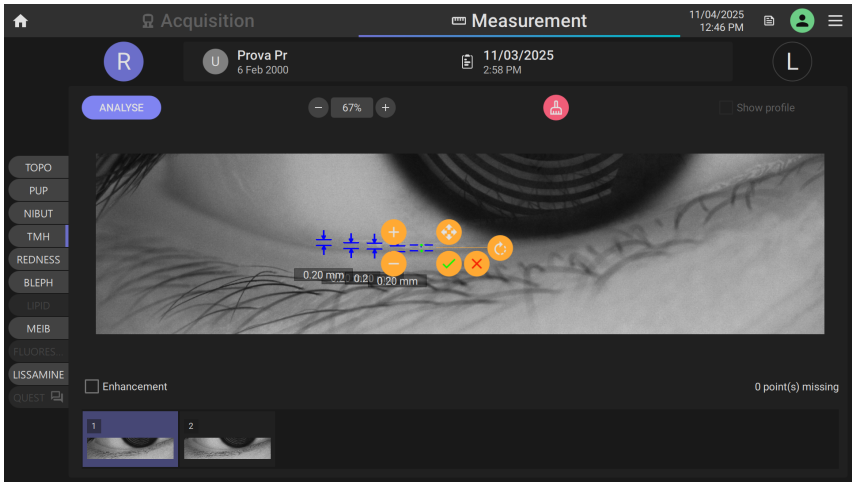


Figure 13.38: Tear meniscus height caliper editing

In this mode, the following functions are shown:

- Confirm and close the edit mode
- Remove the caliper
- Increase/Decrease the caliper's height from upper
- Increase/Decrease the caliper's height from bottom

- Dragging the button, the caliper is dragged too
- Dragging the button, the caliper is rotated

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

By pressing the brush button( ), all the calipers that have been previously inserted will be removed. This function is only available when the Check Profile option is disabled.

13.9.2 Tear Meniscus Height Profiles

Once you have manually positioned at least five calipers on tear meniscus, you can check "Show profile" to perform tear meniscus profile drawing automatically.

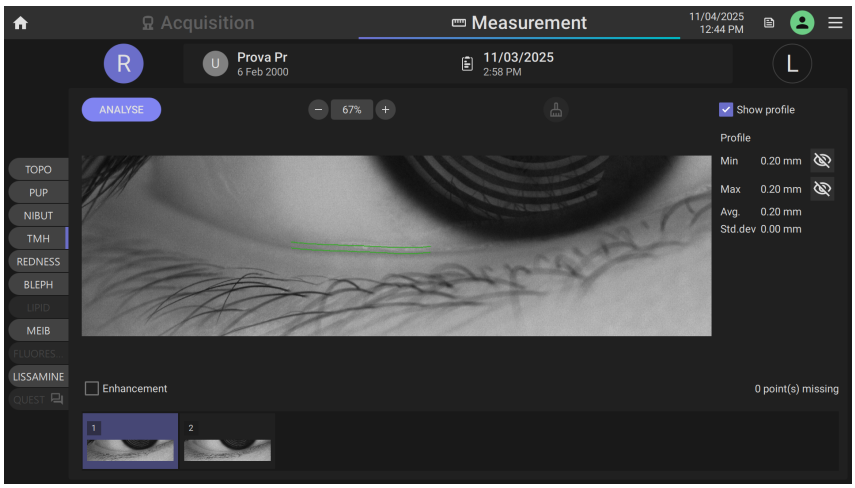


Figure 13.39: Tear meniscus height profile analysis

By flagging the check box: "Show profile", the following data appears in the upper-right corner of the screen: Min, Max, Avg, and Std. Dev. The eye-shaped buttons next to the Min and Max values allow you to toggle the visibility of the minimum and maximum profile height calipers.

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

By clicking on “Enhancement enabled” at the bottom left of the measurement screen, you can also increase the contrast of the captured image of the tear meniscus.

13.10 REDNESS – REDNESS

In the redness section, user can review all images captured during the redness acquisition session. Each image can be assessed, allowing users to assign a severity grade for redness.

- ⚠ DISCLAIMER: The results of any individual test cannot be used alone for diagnosis. They should always be interpreted in the context of symptoms, other relevant diagnostic tests and driver assessments, before applying professional judgment to diagnose or plan treatment.

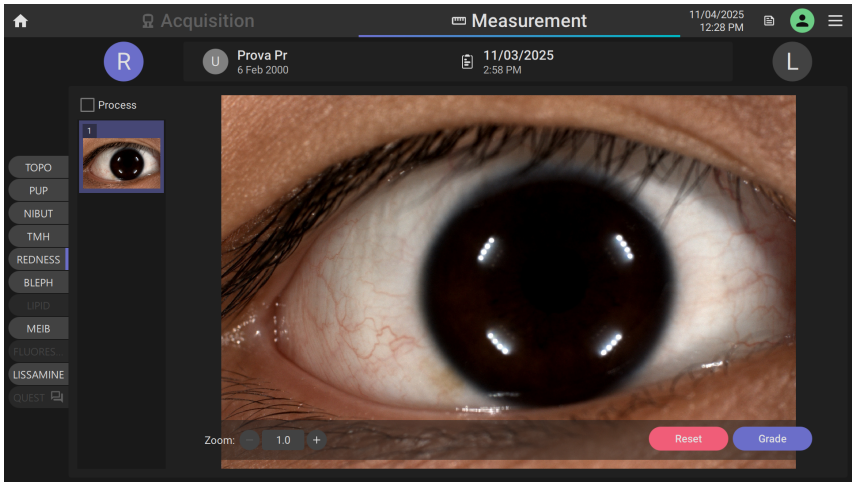
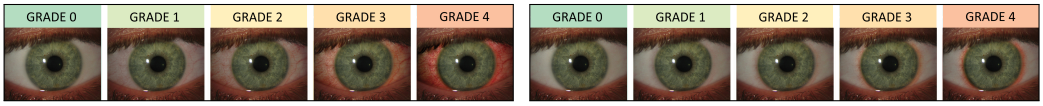


Figure 13.40: redness analysis interface

The acquired images are displayed in the scrollable gallery on the left side. Upon accessing the Redness measurement section, the first image in the gallery is automatically loaded and shown.

Tap the 'Process' checkbox to toggle between the original image and the automatically processed version, where saturated areas are replaced with the original scleral texture. Tap 'Report' to generate the redness analysis report.

REDNESS GRADING PROCEDURE User can perform an assesment based on the grading scale. User can select grading scale type in the Settings, the available redness grading scales are Jenvis [1] (Figure 13.41) and Efron [2] (Figure 13.42).

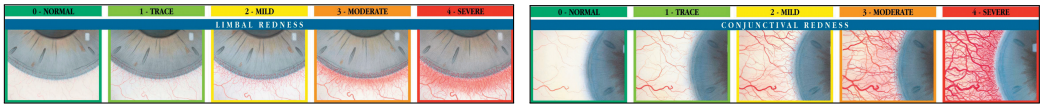


(a) Jenvis bulbar scale **(b)** Jenvis limbal scale

Figure 13.41: Jenvis scale

1 Jenvis, D. R., et al. (2007). The development and validation of the Jenvis Dry Eye Questionnaire. *Optician*, 233(6091), 16–21.

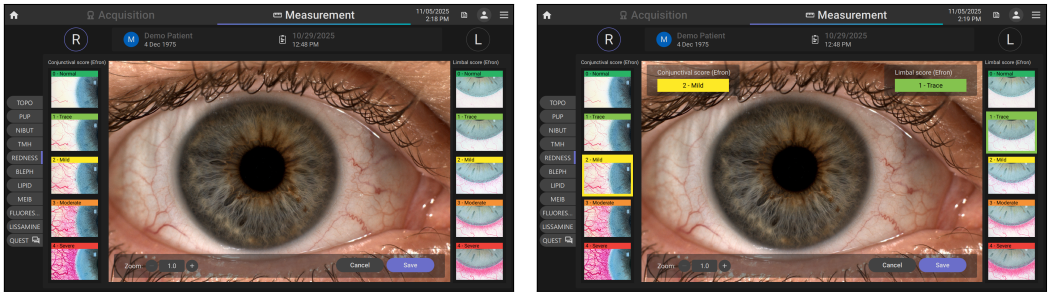
2 Efron, N., Morgan, P. B., & Katsara, S. S. (2001). Validation of grading scales for contact lens complications. *Ophthalmic and Physiological Optics*, 21(1), 17–29.



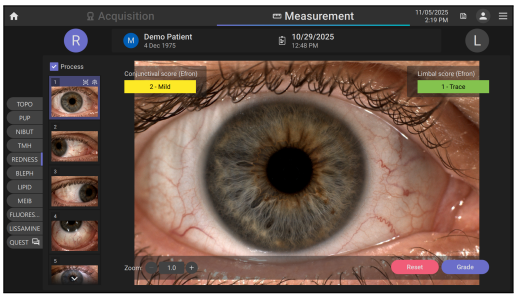
(a) Efron limbal scale **(b)** Efron conjunctival scale

Figure 13.42: Efron scale

Tap on **Grade** button to assign a redness severity score to the selected image. The score levels for the selected scale will appear on the right and left side (Figure 13.43a) Select limbal and/or bulbar grade (Figure 13.43b). Press **Save** to assign the selected grading or **Cancel** to refuse current changes (Figure 13.43c).



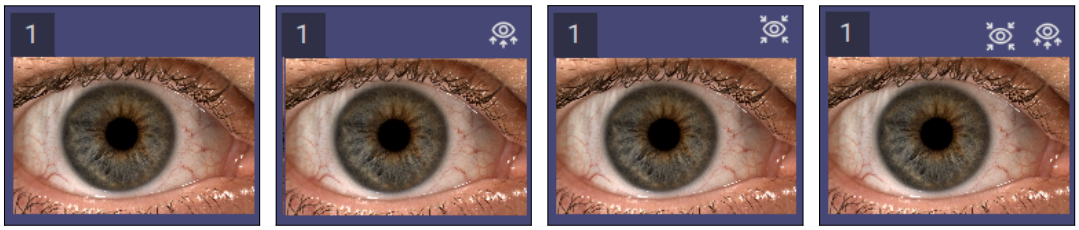
(a) Before grading **(b)** Grading images



(c) After grading

Figure 13.43: Example of redness grading using the Efron scale

Graded images are marked by a small label on their preview. The assigned grade is displayed in the colored tag positioned at the top-left corner of the image. Press **Reset** to reset all the assigned gradings.



(a) No score assigned **(b)** Limbal score assigned **(c)** Bulbar score assigned **(d)** Both scores assigned

Figure 13.44: Symbols used to specify how and which images have been used for grading

13.11 BLEPH – BLEPHARITIS

In the Blepharitis section, user can review all the images captured during the blepharitis acquisition session. Each image can be assessed, allowing users to assign a severity grade for blepharitis.

- ⚠ DISCLAIMER: The results of any individual test cannot be used alone for diagnosis. They should always be interpreted in the context of symptoms, other relevant diagnostic tests and driver assessments, before applying professional judgment to diagnose or plan treatment.

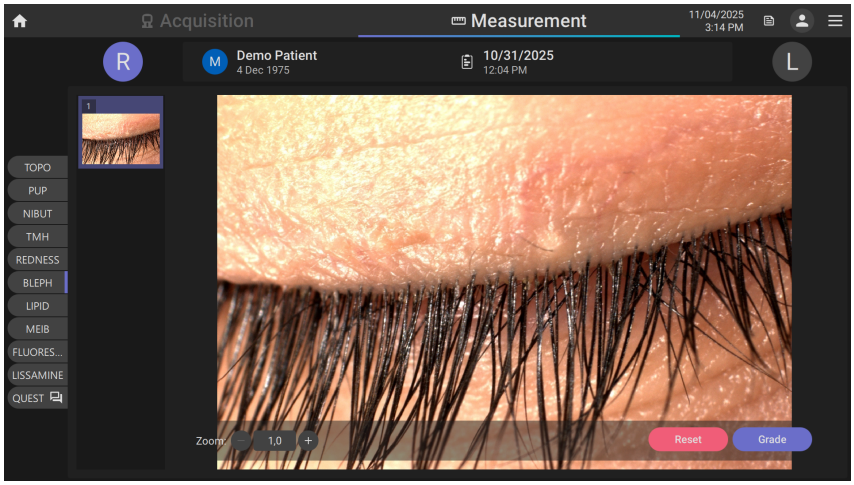


Figure 13.45: bleph analysis section

The acquired images are displayed in the scrollable gallery on the left side. When the blepharitis module is activated, the first image in the gallery is automatically loaded and shown.

BLEPHARITIS GRADING PROCEDURE User can perform an assessment of blepharitis severity using the Efron grading scale [3] (Figure 13.46). Tap on the **Grade** button to assign a blepharitis severity score to the selected image. Press **Save** to confirm the selected grading or **Cancel** to discard current changes.

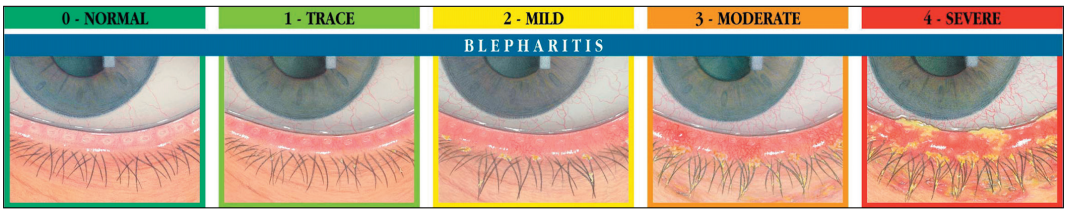
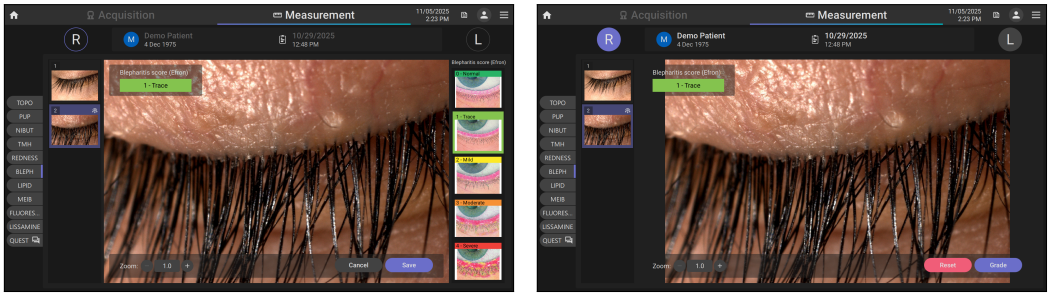


Figure 13.46: Efron blepharitis grading scale

The grading interface displays the selected image and the available Efron scale levels on the sides (Figure 13.47a). Once a grade is selected, it is visually applied to the image (Figure 13.47b).

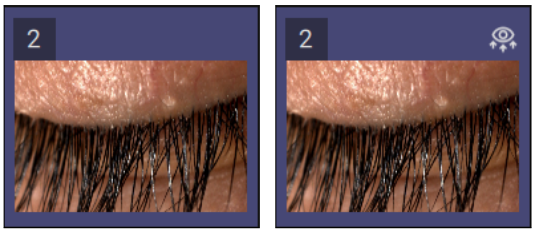


(a) Grading images **(b)** After grading

Figure 13.47: Example of blepharitis grading using the Efron scale

Graded images are marked by a small label on their preview. The assigned grade is displayed in a colored tag positioned at the top-left corner of the image. Press **Reset** to remove all assigned gradings.

3 Efron, N., Morgan, P. B., & Katsara, S. S. (2001). Validation of grading scales for contact lens complications. *Ophthalmic and Physiological Optics*, 21(1), 17–29.



(a) No score assigned **(b)** Score assigned

Figure 13.48: Symbols used to indicate graded and non-graded images

13.12 LIPID – LIPID LAYER THICKNESS

In the LIPID section, the user can review all images and videos captured during the LLT acquisition session. Each image can be assessed to assign a severity grade to the observed lipid layer pattern.

- ⚠ DISCLAIMER: The results of any individual test cannot be used alone for diagnosis. They should always be interpreted in the context of symptoms, other relevant diagnostic tests, and professional clinical judgment.

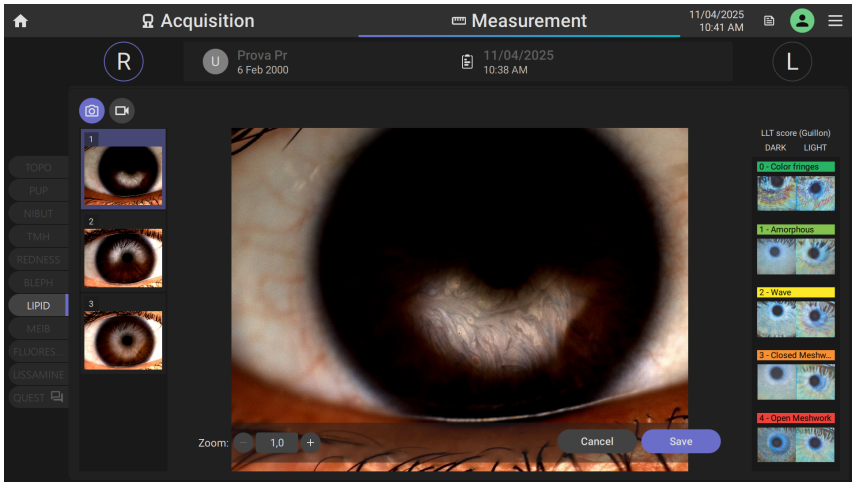


Figure 13.49: LIPID analysis section

The acquired images are displayed in the scrollable gallery on the left side. Upon accessing the LLT measurement section, the first image in the gallery is automatically loaded and displayed. Tap **Report** to generate the LLT analysis report.

LIPID LAYER THICKNESS GRADING Tap on **Grade** to assign a grading to the selected image based on the Guillon scale [4] (Figure 13.50). Press **Save** to confirm the selected grade or **Cancel** to discard the changes.

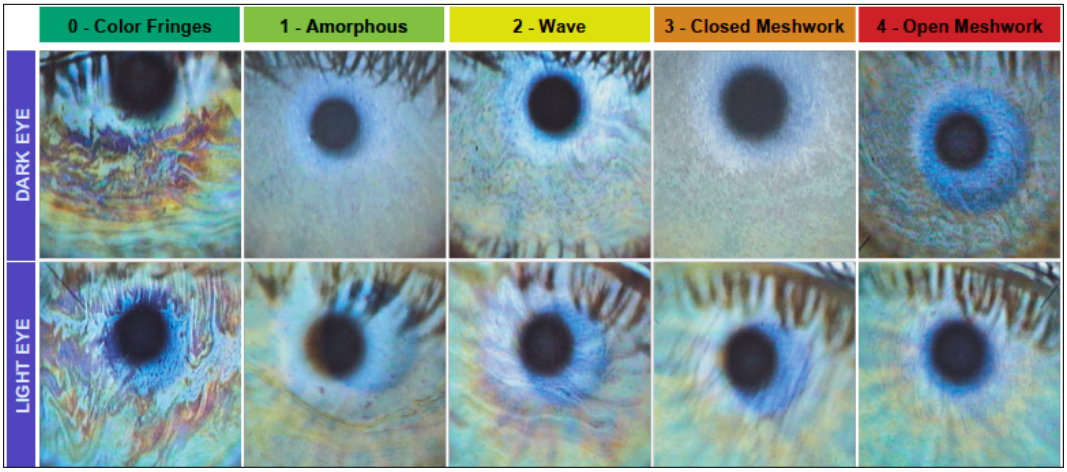
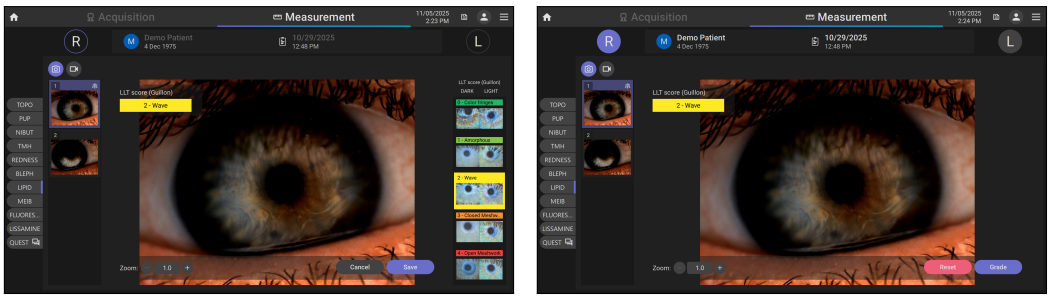


Figure 13.50: Guillon lipid layer grading scale

The grading interface displays the selected image together with the available Guillon scale levels on the sides (Figure 13.51a). Once a grade is selected, it is visually applied to the image (Figure 13.51b).

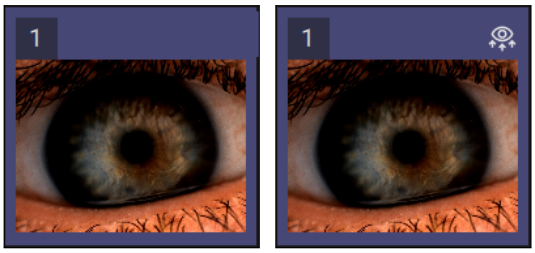


(a) Grading image **(b)** After grading

Figure 13.51: Example of LLT grading using the Guillon scale

Graded images are marked by a small label on their preview. The assigned grade is displayed in a colored tag positioned at the top-left corner of the image. Press **Reset** to remove all assigned gradings.

4 Guillon, M. (1998). Use of the Tearscope Plus in the routine contact lens fitting practice. *Contact Lens and Anterior Eye*, 21(Suppl 1), S31–S40.



(a) No score assigned **(b)** Score assigned

Figure 13.52: Symbols used to indicate graded and non-graded LLT images

13.13 MEIB – MEIBOMIAN GLANDS

In the Meibomian section, the user can check all the images that have been taken in the Meibomian gland acquisition section. It is also possible to change type and level of enhancement. Each image can be assessed, allowing users to assign a severity grade for the area of loss.

- ⚠ DISCLAIMER: The results of any individual test cannot be used alone for diagnosis. They should always be interpreted in the context of symptoms, other relevant diagnostic tests and driver assessments, before applying professional judgment to diagnose or plan treatment.

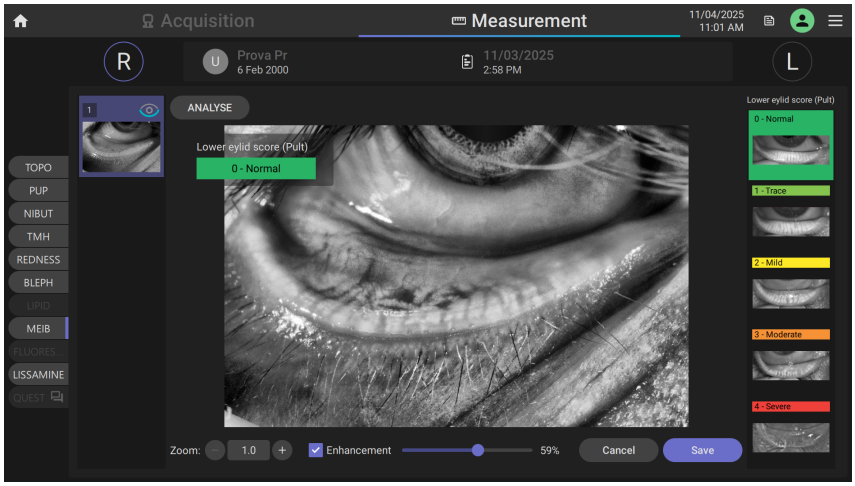


Figure 13.53: Meibomian gland analysis section

13.13.1 Meibomian Glands Analysis

With the "Analysis" button activated, the user is allowed to draw with the finger, the area used for the analysis.

Once completed, result area will be colored in:

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

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

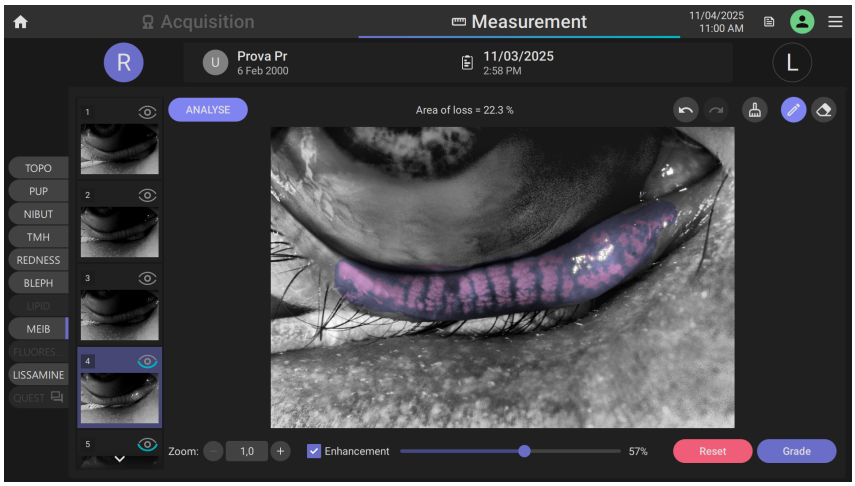


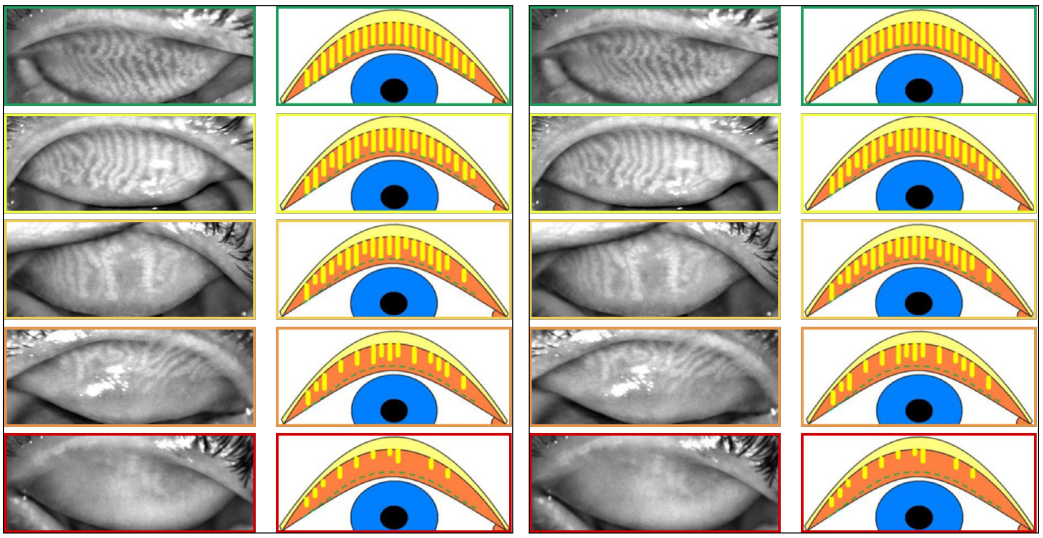
Figure 13.54: Meibomian glands analysis

The list of function buttons related to Analysis is provided below:

- ANALYSE Analyse: Enable or disable analysis
- Pencil (Add function): Let able to add a specific zone to the area of interest. The area can be added by "painting" it with a finger, exactly like the pencil of every painting software
- Eraser (Remove function): Let able to remove a specific zone from the area of interest. The area can be removed by "painting" the zone to remove with a finger, exactly like the rubber of every painting software
- Clean: It empties the area of interest
- Cancel action: It cancels the last modify
- Restore action: It restores the last canceled modify

MEIBOMIAN GLANDS GRADING Tap on **Grade** to assign a grading to the selected image based on the Pult [5] grading scale (Figure 13.55).

5 Pult, H., & Riede-Pult, B. H. (2012). Non-contact meibography: Keep it simple but effective. *Contact Lens and Anterior Eye*, 35(2), 77–80.



(a) Pult lower lid scale (b) Pult upper lid scale

Figure 13.55: Pult scale

When pressing **Grade**, a popup window appears (Figure 13.56), forcing the user to specify whether the evaluation refers to the upper or lower eyelid (Figures 13.57a, 13.57c and 13.57b).

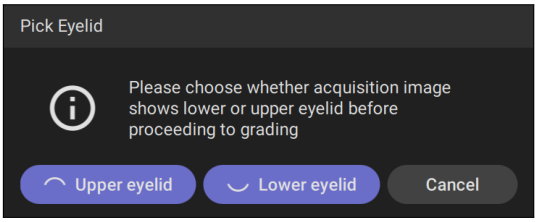
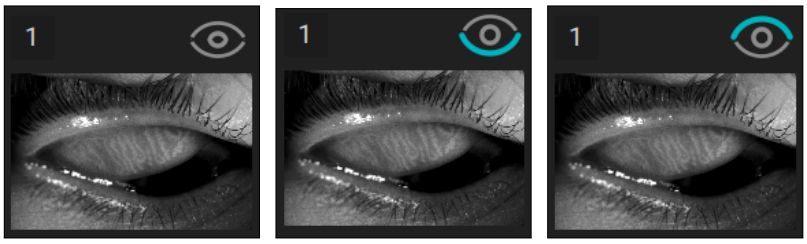


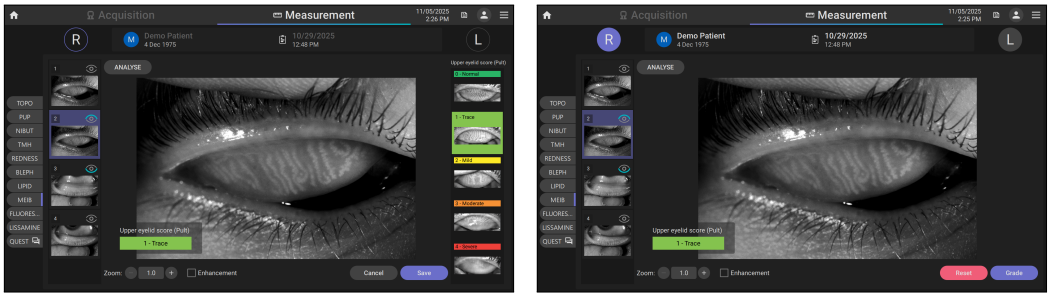
Figure 13.56: Popup window for eyelid selection before grading



(a) Eyelid to be selected (b) Lower lid selected (c) Upper lid selected

After confirming the selection, the corresponding grading scale is displayed for score assignment (Figure 13.57d). Press **Save** to assign the selected grading or **Cancel** to discard

current changes Once a grade is selected, it is shown onto the image (Figure 13.57e). Press **Reset** to remove all assigned gradings.



(d) Grading image **(e)** After grading

Figure 13.57: Example of Meibomian grading using the Pult scale

13.14 FLUO – FLUORESCEIN

The fluorescein module allows the assessment of the corneal surface integrity and the evaluation of contact lens positioning and fitting relative to the cornea.

- ⚠ DISCLAIMER: The results of any individual test cannot be used alone for diagnosis. They should always be interpreted in the context of symptoms, other relevant diagnostic tests and driver assessments, before applying professional judgment to diagnose or plan treatment.

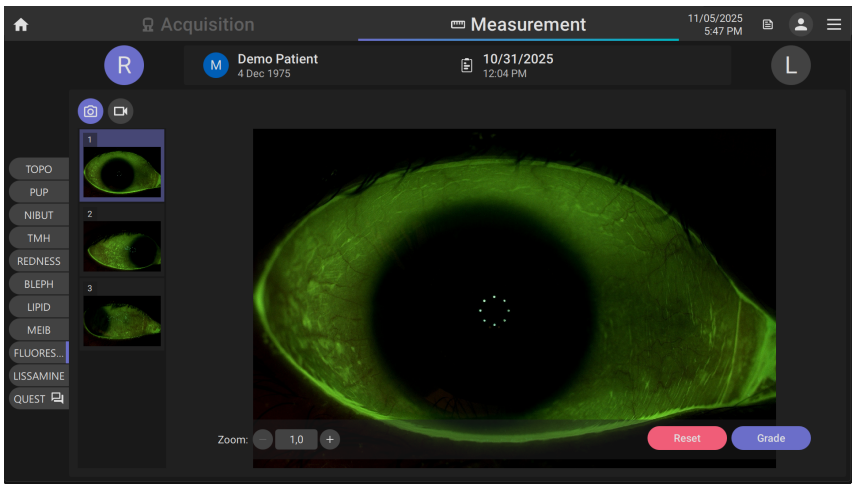
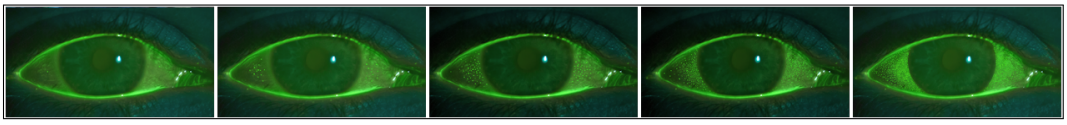


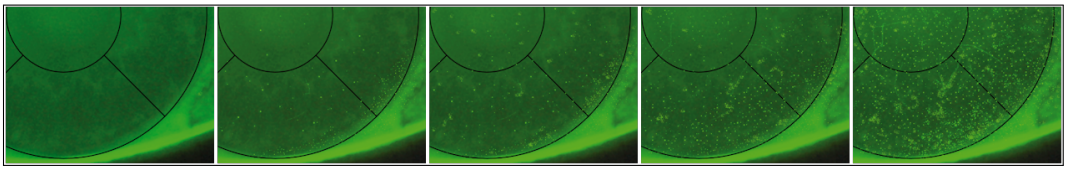
Figure 13.58: Fluorescein analysis interface

All acquired pictures and videos are displayed in the scrollable gallery on the left side. When the fluorescein module is opened, the first acquisition in the gallery is automatically displayed in the main view. Tap on a picture to display it in the main window, or tap on a video to start its playback. Depending on the selection and the eye, the corresponding picture or video is highlighted in the gallery.

FLUORESCEIN GRADING Tap on **Grade** to assign a grading to the selected image based on the Jenvis grading scale (Figure 13.59). The Jenvis [6] scale allows separate evaluation of *conjunctival* and *corneal* staining.



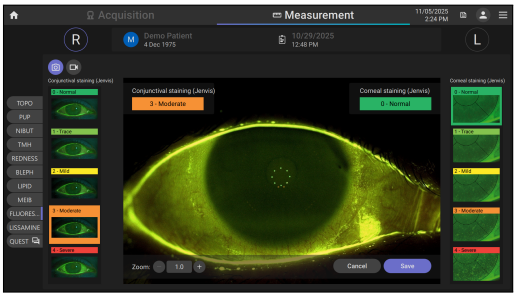
(a) Jenvis conjunctival scale



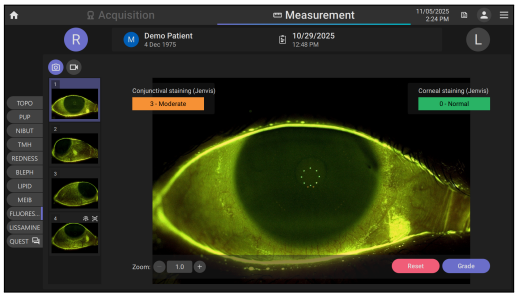
(b) Jenvis corneal scale

Figure 13.59: Jenvis fluorescein grading scale

The score levels for the selected scale will appear on the right and left side 13.60a) Select conjunctival and/or corneal staining and press **Save** to assign the selected grading or **Cancel** to refuse current changes.



(a) Grading image

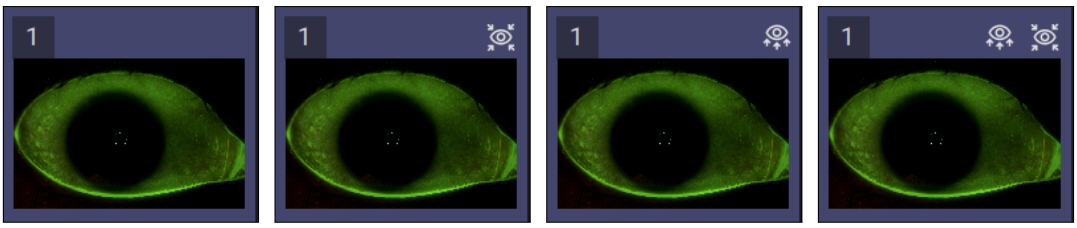


(b) After grading

Figure 13.60: Example of fluorescein grading using the Jenvis scale

6 Jenvis, D. R., et al. (2007). The development and validation of the Jenvis Dry Eye Questionnaire. *Optician*, 233(6091), 16–21.

Graded images are marked with a small label on their preview (Figure 13.61). The assigned grade is displayed in the colored tag positioned at the top-left corner of the image. Press **Reset** to clear all the assigned gradings (Figure 13.60b).



(a) No score assigned **(b)** Conj. score assigned **(c)** Corneal score assigned **(d)** Both scores assigned

Figure 13.61: Symbols used to indicate conjunctival and corneal fluorescein grading results

13.15 LISSAMINE — LISSAMINE

The lissamine module allows you to properly assess devitalized dry cells over the corneal and conjunctival eye surface.

- ⚠ DISCLAIMER: The results of any individual test cannot be used alone for diagnosis. They should always be interpreted in the context of symptoms, other relevant diagnostic tests and driver assessments, before applying professional judgment to diagnose or plan treatment.

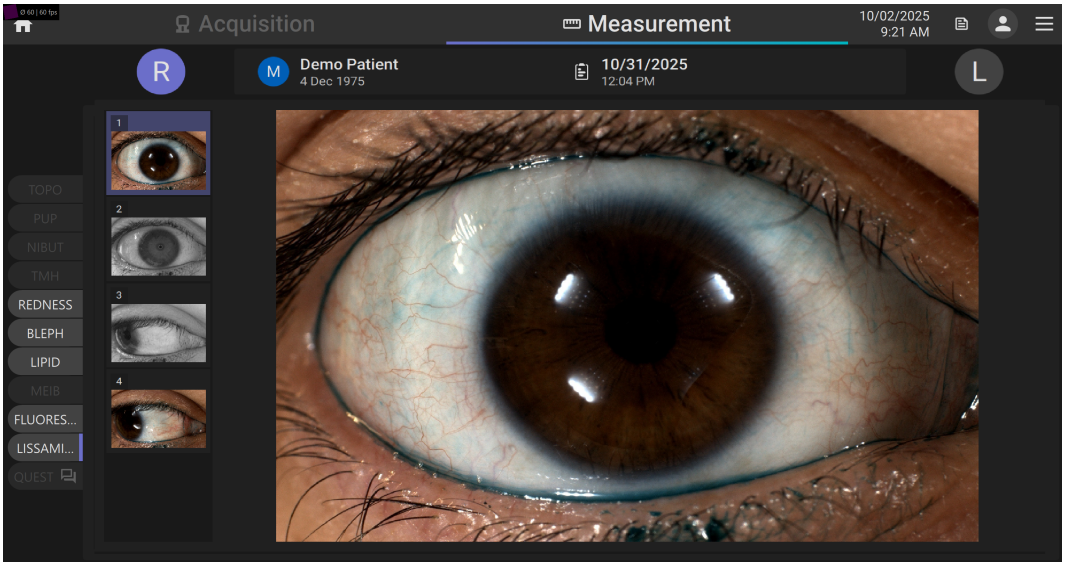


Figure 13.62: Lissamine analysis interface - White light

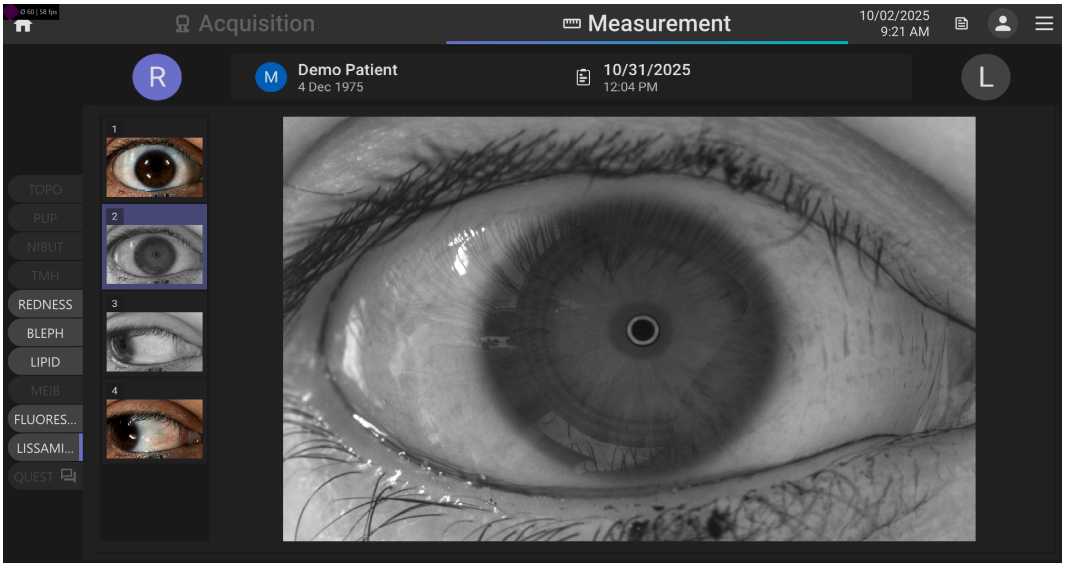


Figure 13.63: Lissamine analysis interface - Red light

The pictures acquired can be viewed in the gallery. When the Lissamine module is started, the first acquisition in the gallery is displayed in the main window. The gallery can contain both images captured using white (Figure 13.63) and red 13.62) lights.

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

Depending on the selection and the eye, the picture which refers to, will be highlighted. The number at the top left indicate the number of the image displayed in the main window.

13.16 QUEST – QUESTIONNAIRES

The Questionnaires module allows you to review the questionnaire answers.

If more than one Questionnaire type has been filled in, it's possible to select the Questionnaire type for which the user wants to review the answers by clicking on the icons on the right side of the window.

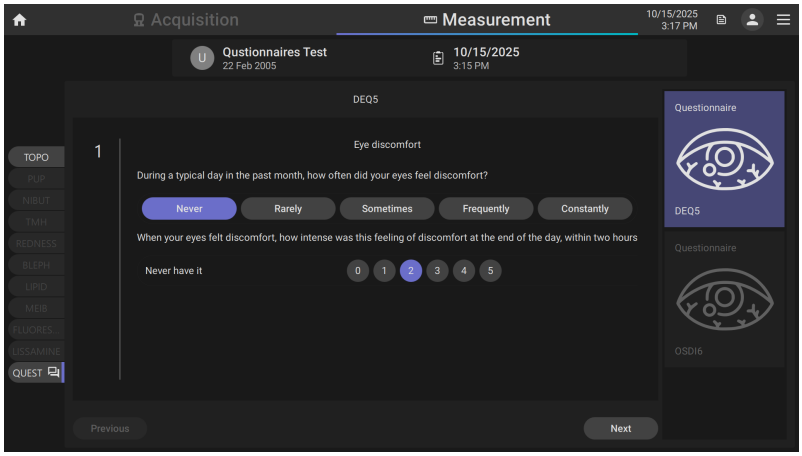


Figure 13.64: Questionnares review - DEQ5

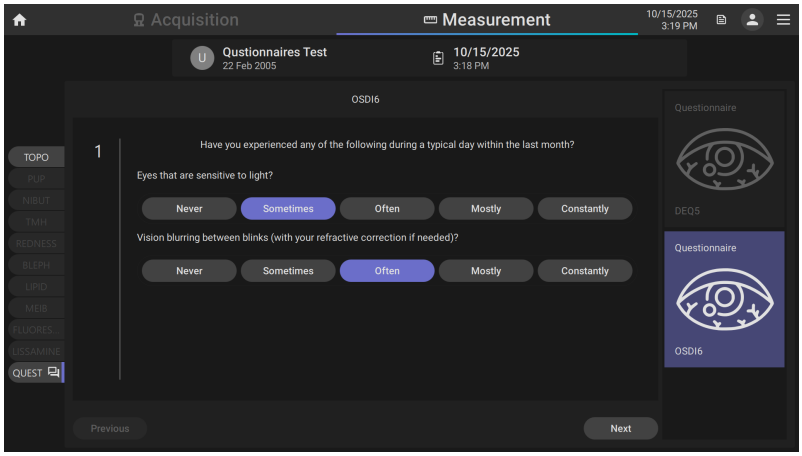


Figure 13.65: Questionnares review - OSDI6

14 REPORT EXPORT

14.1 GENERATING A REPORT

The TERA allows users to generate detailed reports of measurement results, which can be printed or saved digitally.

14.2 CONFIGURE THE REPORT

In the measurements section, the user can export all the measurements made in the current exam. In the top-right corner of the screen, press  to open the report generator panel (Fig. 14.1).

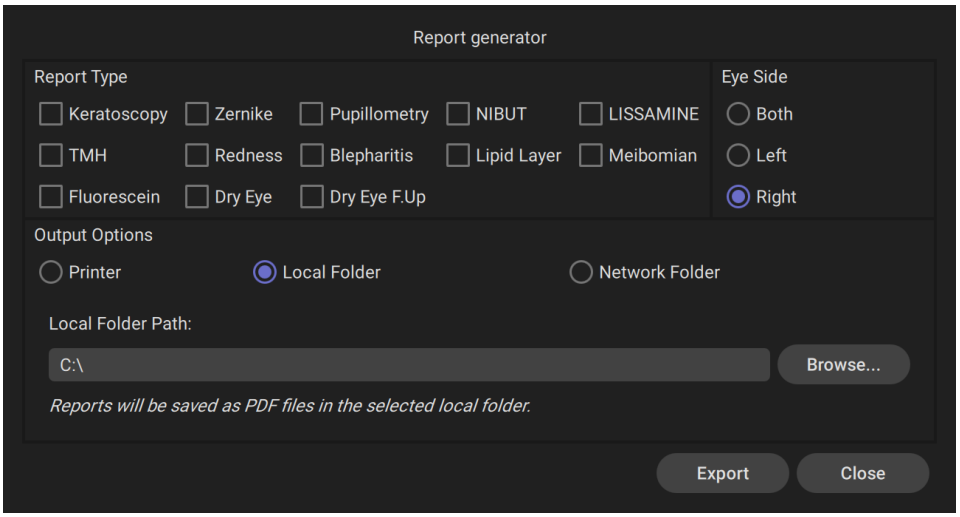


Figure 14.1: report generator panel

Three sections are available in the report generator panel:

- **REPORT TYPE** The user can select the type of report to print. Only acquisitions with valid measurements allow report generation. Some report types require some further condition to be available:

  Meibomian report is available only if upper or lower eyelid has been assigne to at least one image.

Dry Eye report is available only if a NIBUT acquisition has been performed in addition to MEIB or TMH one.

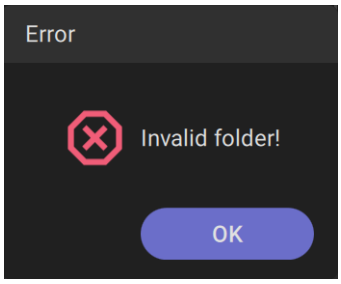
Dry Eye Follow Up report is available only if there exists another exam with an available Dry Eye report. More details about Dry Eye Follow up report are provided in the dedicated section.

- **EYE SIDE:** the user can select which eye will be included in the report.
- **OUTPUT OPTIONS:** the user can choose where to exporting the selected report; the available options are printer and USB drive.
  - **Printer:** Prints the selected reports directly using the connected printer. The list of available printers is displayed. Press *Refresh* to update the printer list.
  - **Local folder:** Exports the selected reports to a local folder (for example, a USB drive). Press *Browse...* to select the destination folder.
  - **Network folder:** Exports the selected reports to a network folder. The user can type the network path manually or press *Browse...* to select one.

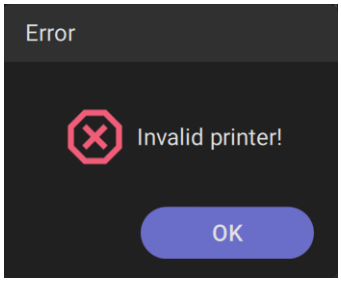
14.3 EXPORT THE REPORT

Once the export type, side, and destination have been selected, tap *Export* to confirm the reports export. Tap *Close* to cancel all the operation and close the panel.

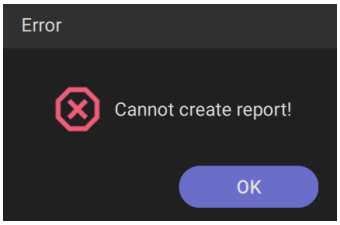
14.4 REPORT EXPORT FAILURES



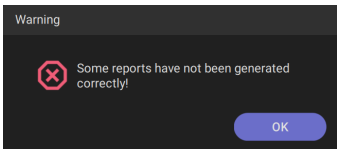
Invalid folder: the selected folder is not accessible or does not exist. Check the path and permissions, then try again.



Invalid printer: the selected printer is unavailable or disconnected. Verify the connection and refresh the printer list before retrying.



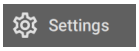
Invalid report: the selected report cannot be generated due to missing or corrupted measurement data.



Invalid report warning: one of the reports selected cannot be generated due to missing or corrupted measurement data.

15 SETTINGS

15.1 INTRODUCTION

To access the Settings environment select the button in the top-right corner  Then select the menu item 

The settings screen is divided into the following categories:

- General
- Acquisition
- Measurements
- Connectivity
- Admin

To exit the Settings environment select the button in the top-right corner 

15.2 GENERAL

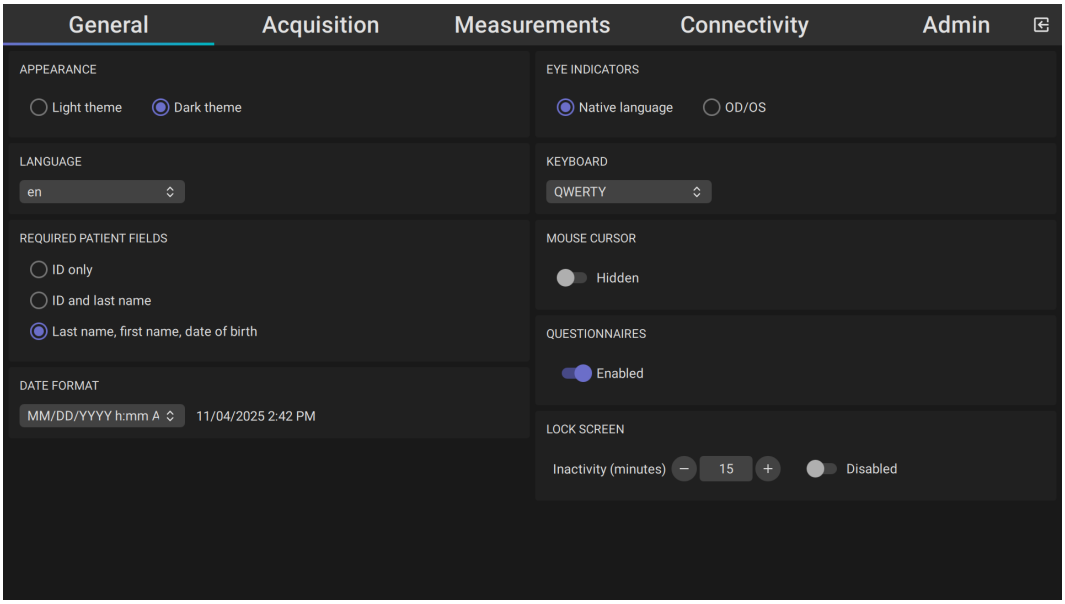


Figure 15.1: Settings - General

Referring to Figure 15.1:

- *APPEARANCE*: To choose the appearance of the application, select the Light or Dark theme.
- *LANGUAGE*: default language is English. To change the language settings, select the desired language from those that appear in the languages list. After selection, the language is updated automatically.
- *REQUIRED PATIENT FIELDS*: different options of required fields for the creation of new patient. If the required fields are not set, a new patient cannot be created. Toggle between three different mandatory field options for creating new patient data:
  - ID only: The ID is the only mandatory field to enter when creating a patient. With this option, the patient list is displayed by default by ID (it can be changed to Last Name and First Name in the patient list view).
  - ID and Last Name: The mandatory fields are ID and Last Name.
  - Last Name, First Name, Date of Birth: The mandatory fields are Last Name, First Name, and Date of Birth.
- *DATE FORMAT*: the available formats are:
  - MM/DD/YYYY h:mm AP
  - DD/MM/YYYY hh:mm

  - YYYY/MM/DD h:mm AP

- *EYE INDICATOR*: the setting allows to select how to indicate the eye being acquired in two different notations. The option OD/OS shows the Latin notation. The local language option shows the terms used for the left and right in the language set for the device.
- *KEYBOARD*: the setting allows to select the keyboard layout. The available layouts are:
  - QWERTY
  - AZERTY
- *MOUSE CURSOR*: toggles the mouse cursor on or off.
- *QUESTIONNAIRES*: toggle between enabling or disabling the predefined Questionnaires.
- *LOCK SCREEN*: toggle to enable the screen lock when the inactivity timer runs out. Select the inactivity time using the spin box.

15.3 ACQUISITION

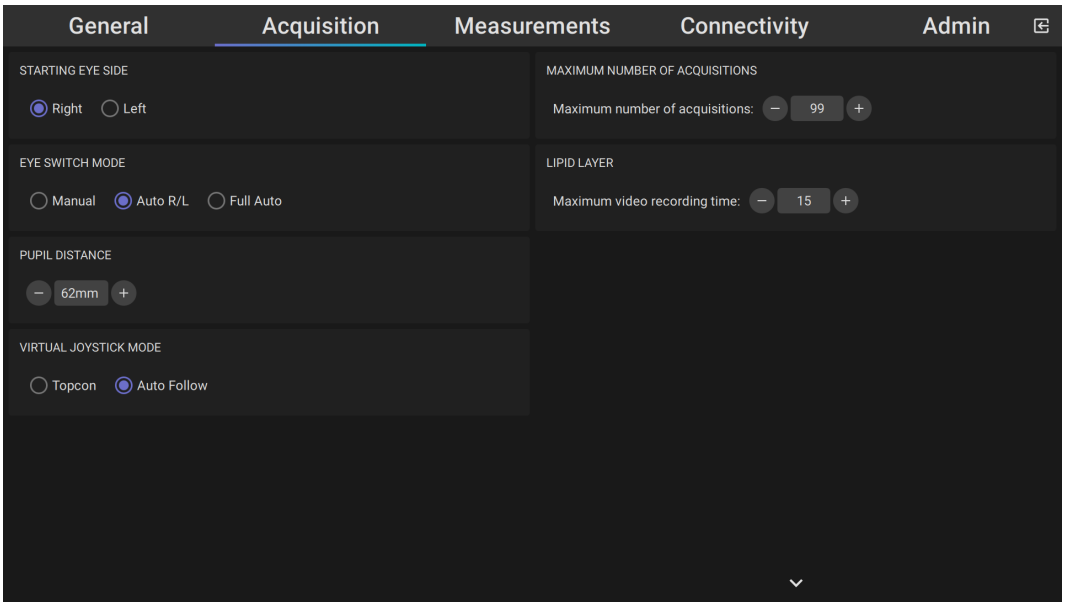


Figure 15.2: Settings - Acquisition

Referring to Figure 15.2:

- *STARING EYE SIDE*: the user can select the starting eye side when entering the acquisition environment.

- *EYE SWITCH MODE*: manages eye switch mode during the acquisition in TOPO acquisition type.

  - Manual: the user should moves manually the motorized base to switch eye side.

  - Auto R/L: eye switching is automatic. This option only manages eye switching, it does not perform acquisition. Automatic eye switching only occurs if the opposite eye has no previous acquisitions.

  - Full Auto: eye switching is automatic. This option manages both eye switching and acquisition. Automatic eye switching only occurs if the opposite eye has no previous acquisitions.

- *PUPIL DISTANCE*: distance used to perform Auto Eye Switch in both R/L and Full modes.

- *VIRTUAL JOYSTICK MODE*: virtual joystick management mode in the live section of the touchscreen.

  - Topcon:

    * tap: the selected point moves to the center of the live image

    * drag and drop: while dragging, the current position of your finger determines the direction of movement of the motorized base. The speed of movement is proportional to the distance of your finger from the center of the image. After drop the motorized base stops.

  - Auto follow:

    * tap: the selected point moves to the center of the live image

    * drag and drop: dragging the starting point in the live image. The direction of the movement is that of the finger, and also the speed. After drop the motorized base stops.

- *MAXIMUM NUMBER OF ACQUISITIONS*: represents the maximum number of acquisitions allowed for an exam. It includes all acquisition types. The + and - buttons allow you to change the value.

- *LIPID LAYER*: represents the allowed maximum length in seconds of recorded movies for the Lipid Layer acquisition type. The + and - buttons allow you to change the value.

15.4 MEASUREMENTS

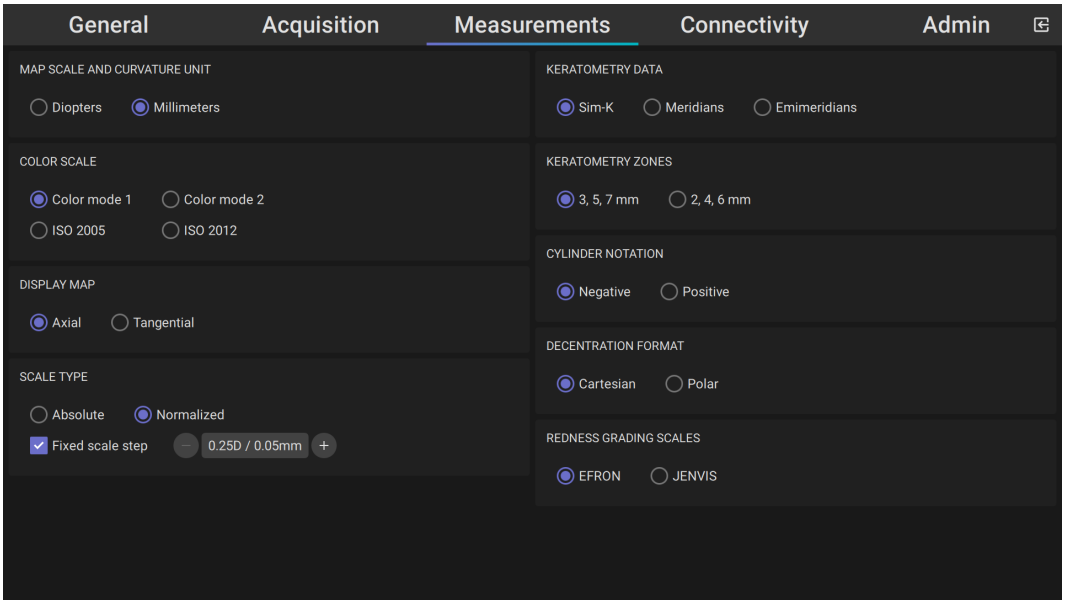


Figure 15.3: Settings - Measuremments

Referring to Figure 15.3:

- *MAP SCALE AND CURVATURE UNIT*: select a unit of measure. This option is activated both for the acquisition screen and for the topographic map.
  - Diopters
  - Millimiters
- *COLOR SCALE*: select between four color scales options.
  - Color mode 1 (Absolute scale)

Figure 15.4: Color Mode 1

  - Color mode 2 (Absolute scale)

Figure 15.5: Color Mode 2

  - ISO 2005: according to the ISO 19980:2005 Color specification
  - ISO 2012: according to the ISO 19980:2012 Color specification

- *DISPLAY MAP*: determines the map that is displayed when accessing the Measurement - TOPO environment.
  - Axial
  - Tangential
- *SCALE TYPE*: select scale type.
  - Absolute
  - Normalized

  Fixed scale Step: define a fixed step size for the normalized color scale.
- *KERATOMETRY DATA*: select one of the keratometric indexes.
  - Sim-K
  - Meridians
  - Emimeridians
- *KERATOMETRY ZONES*: selects the 3 Zones diameters to which the Meridians or Emimeridians values are displayed.
  - 3, 5, 7 mm
  - 2, 4, 6 mm
- *CYLINDER NOTATION*: select a notation for cylinder calculation.
  - Positive
  - Negative
- *DECENTRATION FORMAT*: select a decentration format.
  - Cartesian
  - Polar
- *REDNESS GRADING SCALE*: select a redness grading scale.
  - Efron
  - Jenvis

15.5 CONNECTIVITY

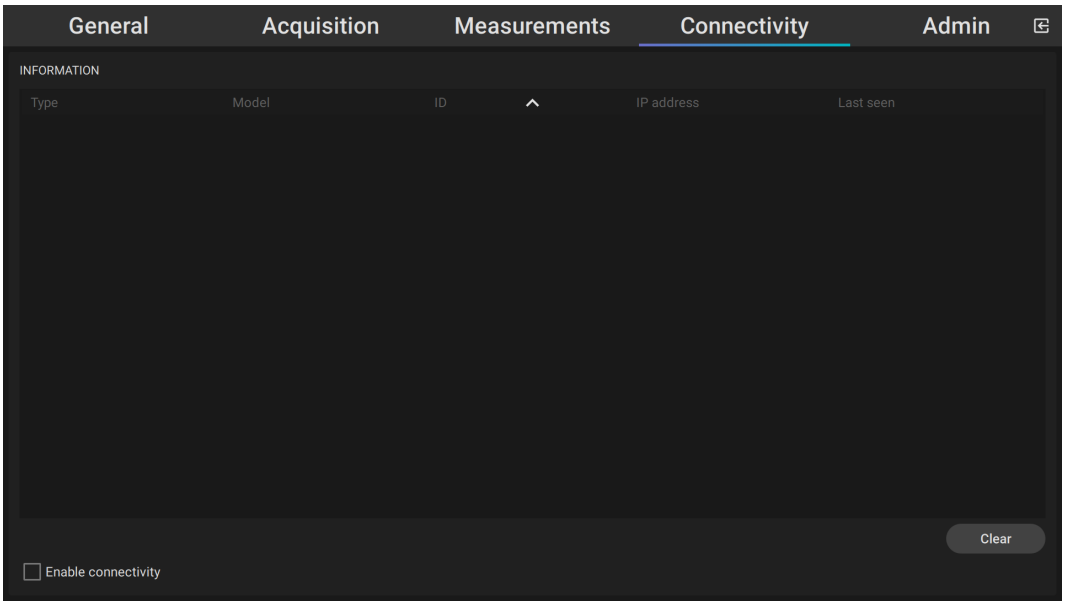


Figure 15.6: Settings - Connectivity

15.6 ADMIN

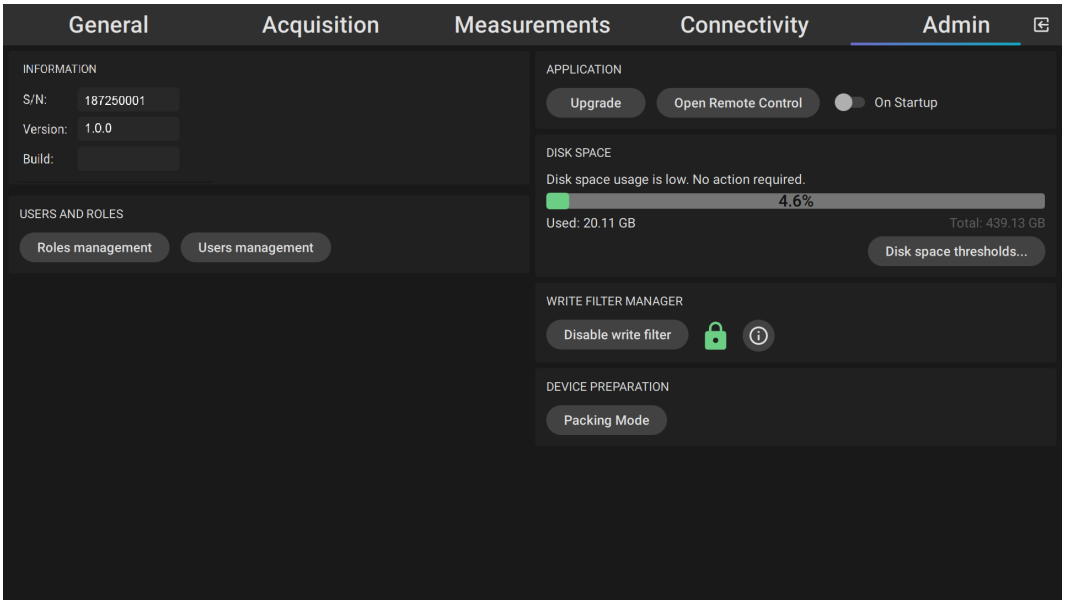


Figure 15.7: Settings - Admin

Referring to Figure 15.7:

- *INFORMATION*: provides information on the system.
  - S/N: device serial number
  - Version: software application version
  - Build: software build version
- *USERS AND ROLES*: allows to manage application roles and users.
- *APPLICATION*: manages the behavior of the integrated software.
  - Upgrade: update the integrated software (see 15.7)
  - Remote connection
    - Open Remote Control command (see 15.8)
    - Remote connection on startup option
- *DISK SPACE*: provides information on disk space usage.
  - Description of current disk space usage and suggested actions.
  - Colored bar indicating the percentage of used disk space compared to the total space.
    - Green: disk space usage is low
    - Yellow: disk space usage is not low
    - Red: disk space usage is very high
  - Disk space used
  - Disk space total
- *UWF FILTER MANAGER*: allows you to manage Write Filter protection.
  - Enable Uwf: enable Write Filter protection
  - Disable Uwf: disable Write Filter protection
  - Write Filter protection status
    -  Write Filter protection enabled
    -  Write Filter protection disabled
- *DEVICE PREPARATION*: allows you to move the motorized base to the rest position.

15.7 UPGRADE INTEGRATED SOFTWARE

This section describes the software upgrade procedure. To perform a secure and proper update procedure, the following warnings must be taken in account:

- ⚠ Before using a USB key for software updates, ensure that it has been scanned with up-to-date antivirus software on a trusted computer to prevent malware introduction.

- ⚠ Do not use USB keys with signs of tampering or damage, as they may compromise the integrity of the update process.

- ⚠ Install only software updates obtained directly from the manufacturer or authorized distributors. Updates from unverified sources may compromise the device's functionality and safety.

- ⚠ Perform software updates only in a secure and controlled environment to minimize risks of interruption or unauthorized access.

- ⚠ Ensure the device is connected to a reliable power source during the update process.

- ⚠ Do not power off the device during the update process.

The following steps are required to complete the procedure:

1. Copy the upgrade file in the root (main folder) of an empty FAT32-formatted USB external drive.

2. Switch on TERA device

3. Access to Settings environment

4. Tap on Admin tab

5. Insert the USB stick with the TERA update file into one of the USB ports

6. Tap on Upgrade button in APPLICATION section. Figure 15.8 will be shown

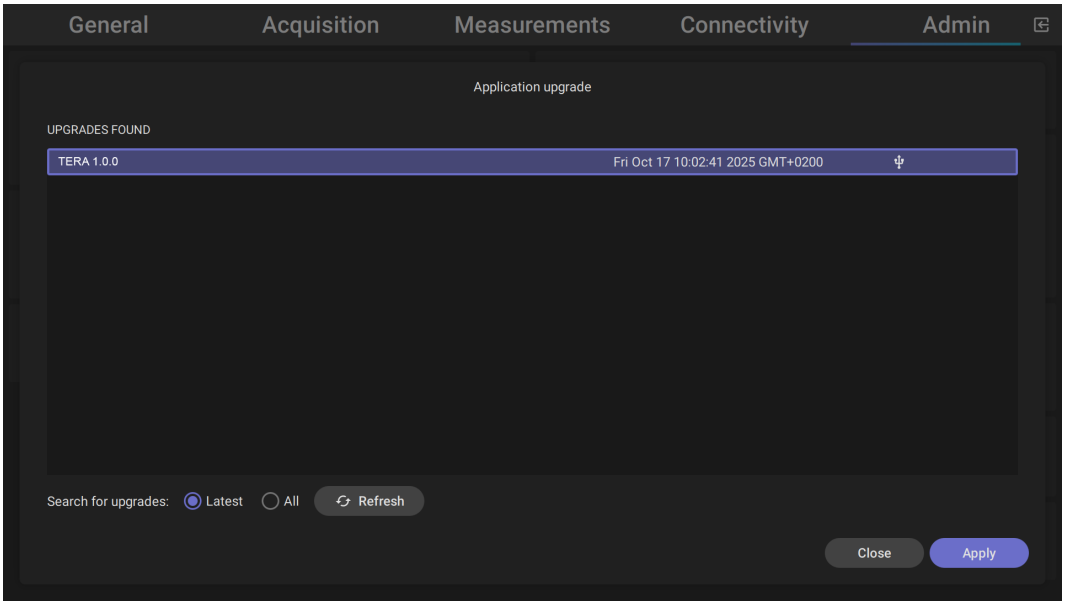
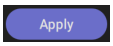
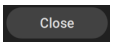


Figure 15.8: Upgrade environment

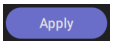
7. Select the TERA software version you want to install from the UPDATES FOUND list.

8. If no upgrades are found, press the Refresh button or remove and reinsert the USB stick.

9. Tap on 

button to start upgrade procedure, tap on 

button to stop it.

10. After tap on 

button, the upgrade procedure starts. The device is rebooted and the upgrade progression is shown, see Figure 15.9.

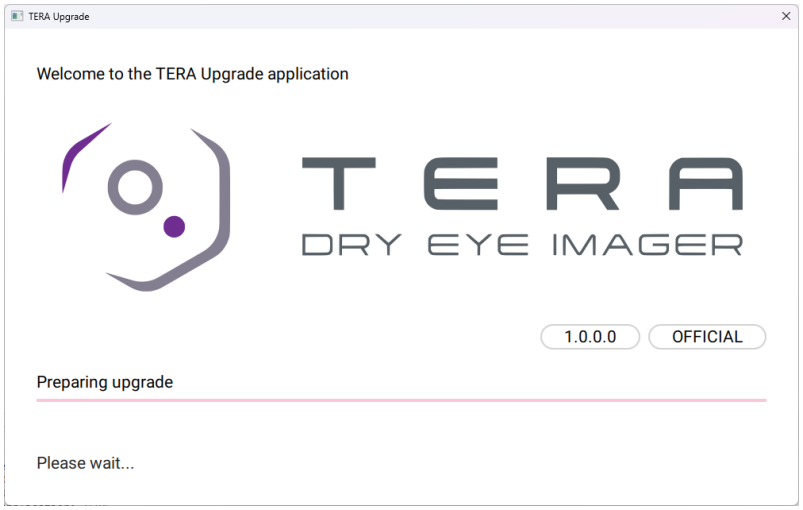


Figure 15.9: Upgrade progress

11. The upgrade procedure ends with a new loading of the TERA application.
12. Access to Settings environment, select Admin tab and check if the Version value is correctly updated.

15.8 REMOTE CONNECTION

If remote assistance is needed, the TERA application integrates Teamviewer QS (Quick Support) pre-installed.

Information and tips for managing remote connections:

- There is NO NEED to disable the Write Filter protection
- Ensure to have internet access available for your TERA unit
- Access to Settings environment, select Admin tab and press Open Remote Control button
- Wait for the Team Viewer Window to open
- Communicate to the Remote Operator the ID shown under “Your ID” and wait for the incoming connection
- The password is masked, the operator knows it already
- To turn off manually the Remote Assistance, you can close the Team Viewer window or press “Close Remote Control” button.

If you get one of the following windows (Figure 15.10), please check your internet connection to TERA or contact your IT staff.

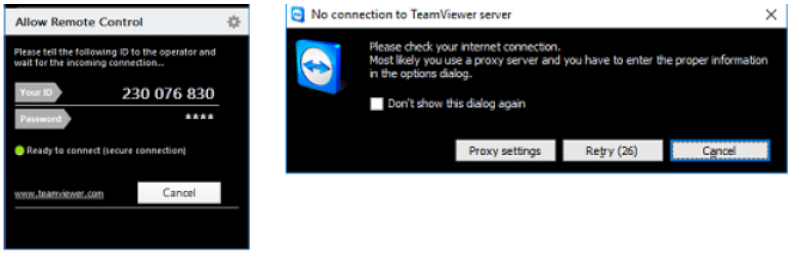


Figure 15.10: Remote connection error

16 TROUBLESHOOTING

16.1 COMMON ISSUES AND SOLUTIONS

This section provides solutions for common issues that may arise while using the TERA.

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

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

Table 16.1: Troubleshootings

16.2 TECHNICAL SUPPORT

If issues persist, contact technical support for assistance. Provide the model number and a description of the problem.

17 TECHNICAL SPECIFICATIONS AND PERFORMANCE

⚠ No modification of this equipment is allowed.

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

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

17.1 GENERAL

Table 17.1: General Specifications

Function	Features
Corneal topography and Keratometry	**Keratoscopic Cone:** 22+2 rings equally distributed on a 43 D sphere **Analysed points:** Over 100 000 **Measured points:** Over 6 000 **Corneal Coverage:** Up to 9.5 mm on a sphere of radius 8 mm **Focus System:** Manual and/or semi-automatic guided focus
Pupillometry	Integrated
Blepharitis Assessment	Integrated
Fluorescein	Integrated
Lissamine	Integrated
IBI index (Inter-Blink Interval)	Integrated
Break-Up Time (TBT)	Integrated
Meibomian Glands	Integrated
Tear meniscus	Integrated
Redness	Integrated
Lipid Layer Assessment	Integrated

17.2 INFORMATION ON MEASUREMENT

Table 17.2: Measurement Ranges and Technical Specifications

Measure	Measuring Range	Display Resolution	In Vivo Repeatability
Keratometry – Curve radius	5.00 – 12.00 mm	0.01 mm	±0.02 mm
Keratometry – Radius in Diopter (D) (n=1.3375)	28.00 – 67.50 D	0.01 D	±0.12 D
Pupil dimension	2.00 – 10.00 mm	0.01 mm	N/A
Limbus (White-To-White)	8.00 – 15.00 mm	0.01 mm	±0.05 mm
IBI Index	0.2 – 20.0 s	0.1 s	N/A
Break-Up Time (TBT)	0.5 – 30.0 s	0.1 s	N/A
Meibomian Glands area of loss	1 – 100 %	1 %	N/A
Tear Meniscus Height	0.10 – 1.00 mm	0.01 mm	N/A

17.3 ENVIRONMENTAL CONDITIONS

Table 17.3: Environmental Conditions

Parameter	In Use	Storage	Transport
Temperature	10 °C to 40 °C	−20 °C to 70 °C	−20 °C to 70 °C
Relative humidity	8 % to 75 % (non-condensing)	8 % to 75 % (non-condensing)	8 % to 75 % (non-condensing)
Atmospheric pressure	800 hPa to 1060 hPa	700 hPa to 1060 hPa	700 hPa to 1060 hPa

17.4 ELECTRICAL DATA

Table 17.4: Electrical Characteristics

Parameter	Value
Power supply	100 V to 120 V / 200 V to 240 V (±10 %), 50 Hz to 60 Hz
Power consumption	100 V A
Fuse Type	5 mm x 20 mm, ceramic, time-lag
Fuse Value	T 3.15 A H 250 V anti-surge

17.5 MECHANICAL SPECIFICATIONS

Table 17.5: Mechanical Characteristics

Parameter	Device	Device packaged
Width	332 mm	600 mm
Height	555 mm	850 mm
Length	552 mm	800 mm
Weight	19.0 kg	38.0 kg

17.6 ON-BOARD PC COMPONENTS SPECIFICATIONS

Table 17.6: Integrated PC Specifications

Parameter	Value
Operating system	Windows 11 IoT Enterprise LTSC
Processor	Intel N97
RAM	8 GB
Hard disk	At least 500 GB
External connections	1× USB 3.0, 1× USB 2.0, 1× 1GB Ethernet

17.7 LIGHT SOURCE DESCRIPTION

Table 17.7: Light Source Specifications

Light Source	Feature	Peak (nm)	BW (nm)	ISO 15004-2:2024 Safety Class	LEDs
Cone – Red LED Backlight Central Board	Illumination of Placido disk for topographic analysis	628	16	GROUP 1	98
Cone – Red LED Backlight Lateral Board	Illumination of Placido disk for topographic analysis	628	16	GROUP 1	66
Cone – Red LED Backlight Lateral Board	Illumination of Placido disk for topographic analysis	628	16	GROUP 1	66
Central Cone IR 940 LED	Pupillometric analysis, IBI index	950	42	GROUP 1	4
Internal Ring Blue LED	Fluorescein assessment	463	30	GROUP 1	8
External Ring Blue LED	Fluorescein assessment	463	30	GROUP 1	8
Cone Top Front White LED	Lipid layer assessment	–	–	GROUP 1	66
Cone Bottom Front White LED	Lipid layer assessment	–	–	GROUP 1	39
Cone Bottom Lateral White LED	Redness assessment	–	–	GROUP 1	8
Cone Top Lateral White LED	Redness assessment	–	–	GROUP 1	8
Right Lateral IR LED	Meibomian glands assessment	940	42	GROUP 1	6
Left Lateral IR LED	Meibomian glands assessment	940	42	GROUP 1	6
Yellow-Green Fixation LED	Central fixation LED	575	22	GROUP 1	1
Cone Frontal White LED	Redness and iris assessment	–	–	GROUP 2	2

NOTE: On request, the manufacturer can provide the user with graph showing the relative spectral output of the instrument between 305 nm and 1100 nm when the instrument is operating at maximum light intensity.

18 MAINTENANCE

The TERA device does not require preventive or regular maintenance.

Replacement of fuses, if necessary, it is an extraordinary maintenance's activity. The replacement must be performed as outlined in the section 18.2

Further maintenance and care procedures above and beyond those specified in this section (maintenance, safety inspections and repairs) may only be carried out by persons authorized by Visia Imaging S.r.l. and solely according to the service instructions issued by Visia Imaging S.r.l. For planning and implementing these maintenance and care procedures please contact Visia Imaging S.r.l. customer service or your local dealer.

18.1 FUSE REPLACEMENT

WARNING: Do not perform the following operation in the presence of the patient.
Before commencing the fuse replacement procedure, ensure that the device is powered off and disconnected from the electrical supply.

18.2 STEPS TO REPLACE A FUSE

Table 18.1: Step 1: Open Fuse Box Cover

Instructions	Illustration
1 Open the fuse box cover using a screwdriver	

Table 18.2: Step 2: Remove Fuse Box

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

Table 18.3: Step 3: Replace Fuse

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

Table 18.4: Step 4: Reinstall Fuse Box

Instructions	Illustration
4 Push the fuse box carefully back into position.	

Table 18.5: Fuse Specifications

Fuse type	Fuse value
20 × 5mm	T 3.15 A H 250 V anti-surge

19 END-USER LICENSE AGREEMENT

19.1 LICENSE TERMS

This End-User License Agreement (EULA) outlines the permitted usage of the TERA software. By using the software, the user agrees to the following terms.

19.2 SCOPE OF LICENSE

The license grants the user a non-transferable, non-exclusive right to use the software solely for operating the TERA device.

19.3 RESTRICTIONS

- The user may not modify, reverse-engineer, or distribute the software.
- The license may not be transferred to a third party without prior written consent.
- The software must only be used in accordance with the intended purpose of the TERA.

19.4 TERMINATION

Failure to comply with these terms will result in the termination of the license, requiring the user to cease all use of the software.

19.5 GOVERNING LAW

This agreement is governed by the laws of the country where the TERA was purchased.