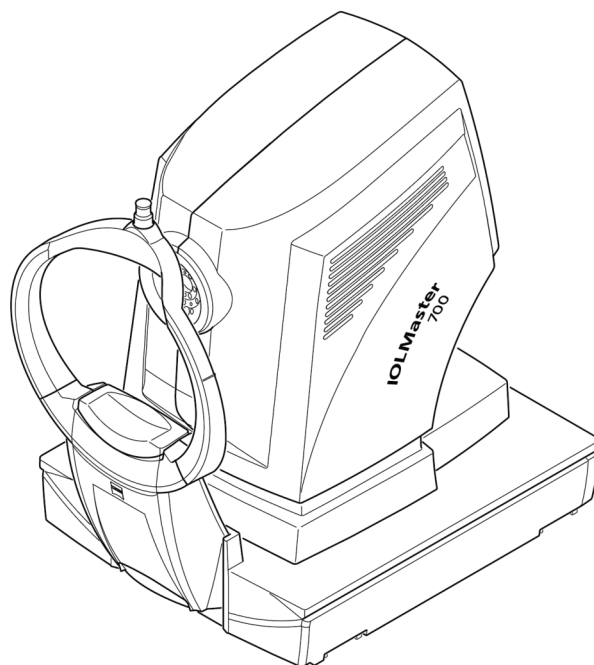


IOLMaster 700

Software release 1.90

Documentation set



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Content

User manual IOLMaster 700

[000000-1932-169-GA-en-GB-180924]

1

Appendix

IOLMaster 700 - License activation

[000000-1932-169-KurzGA01-GB-200618]

IOLMaster 700

Software release 1.90

Instructions for use

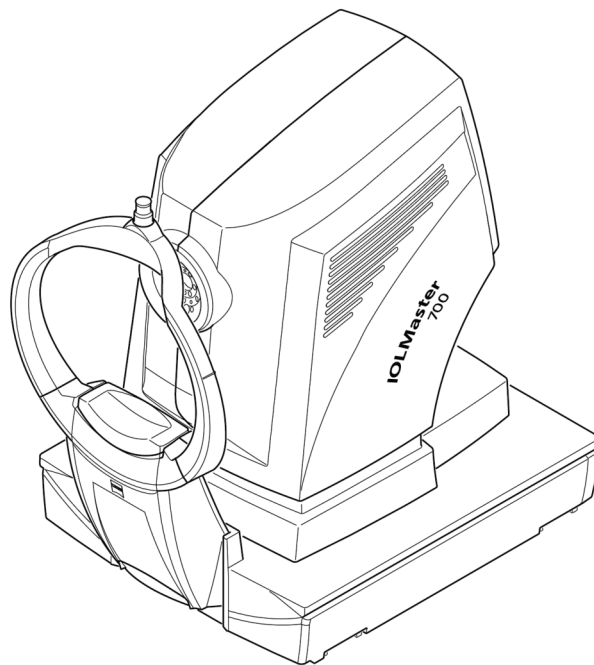


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1 Notes on the instructions for use

1.1 Product name

The IOLMaster 700 is referred to as the "device" in these instructions for use.

1.2 Scope of application

The present instructions for use apply to the IOLMaster 700 with software version 1.90 and the following marking:

- Reference number: 1932-169

1.3 Purpose and storage of the documentation

These Instructions for Use explain the safety features, functions and performance parameters of the device. They contain instructions on the safe use of the device and identify measures for its care and maintenance.

Correct operation of the device is imperative for its safe and successful function.

Action

- ▶ Read these Instructions for Use before setting up and using the device the first time.
- ▶ Keep the Instructions for Use accessible for all users at all times.
- ▶ Pass the Instructions for Use to future owners of the device.

1.4 Questions and comments

Action

- ▶ If you have any questions or comments concerning these instructions for use or the device itself, please contact ZEISS Service.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

1.5 Conventions in this document

Certain types of information are specially marked in this document for better recognition.

1.5.1 Conventions in all text areas

- This is a list.
 - This is a second level list.

This is a cross-reference: Conventions in this document [▶ 7].

This is **highlighted text**.

This is `software code or program text`.

Names of software dialogs, fields or menus, and software messages are marked by quotation marks:

- "View" menu.
- "Do you want to save the settings?"

The steps in menu and file paths are separated by slashes:

- "File / Save as"
- "My documents / Documents"

Keys, buttons, knobs, levers and other operating controls are marked by square brackets:

- [START] key
- [Next] button

1.5.2 Conventions in a course of action

WARNING!

This is warning information about hazards that can cause death or severe injuries if not avoided.

The warning message names the possible consequences.

- This is a measure with which hazards can be prevented.

CAUTION!

This is warning information about hazards that can cause injuries if not avoided.

The warning message names the possible consequences.

- This is a measure with which hazards can be prevented.

NOTE

This is warning information about hazards that can cause property damage if not avoided.

The warning message names the possible consequences.

- This is a measure with which hazards can be prevented.

Prerequisite

- ☒ This is a requirement that must be met before the start of a sequence of actions.

Action

1. This is a command.
2. **CAUTION! This is a warning message about hazards that can occur during a single action.** This is a command.
⇒ This is the result of a sequence of actions.

1.6 Applicable documents

Documents

Instructions for use of components and accessories

2 Safety notes

2.1 Intended user profile

The device may only be installed, operated, used, and maintained by persons who have been properly trained or who have the required knowledge and experience to do so. Please also adhere to the national qualification guidelines applicable in your country.

Persons who operate the device must have knowledge of basic ophthalmic examination and diagnosis methods.

It is recommended that operators of the device have the following skills:

2.1.1 Technicians or personnel performing measurements with the IOLMaster 700

- The user performs medical (eye) history and screening procedures.
- The user provides patient instructions during measurement procedures.
- The user observes acoustic and optical warning signals and displays on medical devices.
- The user is familiar with the use of computers and computer interfaces (USB, Ethernet, DVI, display port).
- The user is familiar with the Microsoft Windows operating system and applications based on it.
- The user performs cleaning and calibration procedures on medical devices.

2.1.2 Physician's assistants, nurses or other personnel performing data processing

In addition to the skills required for performing measurements, the user should have knowledge of pathological factors that influence measurement quality, in particular:

- Cataract-related light scattering of optical media
- Corneal opacity-related light scattering of optical media
- Optimization of device settings, to minimize pathological factors that influence measurement quality

- Handling of standard measurement protocols and measurement results in optics/optometry such as refraction values (sphere, cylinder, axis), ophthalmometer values (corneal radii), eye length, anterior chamber depth, WTW, corneal thickness and lens thickness.
- Evaluation of the quality of readings with the aid of information provided in the instructions for use

2.1.3 Evaluation of measurement data

Evaluation of measurement data should be performed by physicians (e.g. ophthalmologist, cataract surgeon, refractive surgeon) using the instructions provided in these instructions for use.

Users should not rely solely on measurements made using the IOLMaster 700 in making decisions regarding the calculation and implantation of intraocular lenses or other therapeutic procedures, but should rely on their own expertise and judgment.

2.2 Intended field of application

This device may only be set up, operated and used for the specified purpose and according to national regulations, consistent with the applicable industry standards and occupational safety and accident prevention regulations.

2.2.1 Intended use

The device is to be used only for the visualization and measurement of eye structures such as axial length, anterior chamber, eye lens, retina, pupil and for the determination of corneal curvature and thickness, white-to-white distance (WTW) of the human eye and calculation of the required intraocular lens.

The Option Reference Image may only be used in conjunction with the IOLMaster 700 to capture images in which sclera vessels in the vicinity of the limbus are discernible in combination with the superposition of principal meridian of corneal curvature measurement.

2.2.2 Instructions and precautions to avoid measuring errors

- Measurement through contact lenses produces incorrect results. Intraocular lenses should not be calculated on the basis of such measurements.
- The wearing of rigid or soft contact lenses may have an effect on the surface geometry of the cornea and thus the optical state of the eye. Therefore, for measurements conducted on wearers of contact lenses using IOLMaster 700, a rest period should be observed from the time the contact lens is removed to the time of measurement. The required duration of the time from removal of the lens to the time of measurement may vary individually and must be determined by a qualified physician.
- Avoid the use of eye drops prior to measurement, as they may lead to incorrect results, in particular in the measurement of corneal curvature. The use of tear fluid substitute may also impact the measured keratometry values.
- Do not perform any contact measurements or examinations in which the eye is touched. They may result in incorrect readings, particularly for axial length and corneal curvature measurements. Contact measurements or examinations should only be performed after the patient has been measured with the IOLMaster 700.
- Patients who are unable to sit upright in front of the device or patients with forehead or chin injuries which prevent the head from being supported on the forehead / chin rest, should not be examined with the device.
- Poor measurement result quality can be expected in the following categories of patient:
 - The patient is unable to steadily fixate the fixation light with the eye under examination (e.g. in the case of nystagmus, extremely poor visual acuity, lack of concentration, tremor or shortness of breath).
 - The patient is unable to follow the instructions of the user.
 - Patients with deficient specular reflection of the cornea for keratometry measurements (e.g. distortion of the tear film, scarring or caustic burn of the cornea).
 - Patients with complete or partial coverage of the cornea, caused by palpebral fissure which is closed or too small.
- In patients with morphological changes of the retinal anatomy in the region of the fovea (e.g. retinal detachment, edema, staphyloma), the axial length measurement result may be erroneous and thus is not usable or only of limited use for IOL calculation.

- In the case of low transparency of the optical media of the eye (e.g. corneal opacities, dense cataract, opacity of the posterior capsule, hemorrhage in the vitreous body) it may be difficult to measure biometric parameters of the cornea, anterior chamber, lens or axial length.
- Axis and refractive power values of the IOLMaster 700 may not be used for patients with irregular corneal astigmatism, in particular for toric IOLs.
- Correct detection of boundary layers in the B-scan should be checked with particular care during measurement, especially when measuring very long eyes, eyes with dense cataracts, pseudophakic or aphakic eyes, eyes with any kind of pathology. Despite various plausibility checks, measuring errors cannot be excluded in individual cases.
- In patients with rotary nystagmus it is not possible to take a reliable reference image for the digitally marked alignment of toric intraocular lenses.

2.3 Responsibilities and duties of the responsible organization

Operating personnel

The device may only be operated by instructed and trained personnel.

- ▶ Restrict access to the device to authorized operating personnel.
- ▶ Ensure that the operating personnel have been trained and instructed.
- ▶ Ensure that the operating personnel have read and understood the instructions for use.
- ▶ Keep the instructions for use available at all times for the operating personnel.
- ▶ To facilitate access for the entire operating personnel: If necessary, request further copies of the instructions for use from ZEISS.
- ▶ Define the required skills for handling the device and provide information on who is authorized for which activities.
- ▶ Define rules for reporting errors and damage, and provide information on these (Notification to manufacturers and authorities [▶ 14]).
- ▶ Regularly check compliance with the national laws and regulations concerning accident prevention and occupational health.

Safety inspections

- ▶ To prevent any reduction in device safety due to aging and wear: Have regular safety inspections performed in accordance with the applicable national regulations for this device. Safety inspections may be carried out only by the manufacturer or persons authorized by the manufacturer.
- ▶ Keep within the prescribed deadlines.
- ▶ Perform the inspections to the prescribed extent.

The following safety inspections and checks should be performed as a minimum for the device:

- Check the presence of the instructions for use
- Visual inspection of the device and its accessories for damage, as well as legibility of markings and labels
- Leakage current test
- PE conductor check
- Check the ventilation slits of the device. They should not be covered or obstructed.
- Functional check of all switches, buttons, connectors and control lamps on the device
- Performing a calibration test

Service life

The development, production and maintenance of the device, together with associated risks, are based on an expected service life of eight years, assuming that the device is operated and maintained as prescribed in these instructions for use.

Changes to the product

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

Accessories and additional equipment

- ▶ If you want to connect accessories or additional equipment to the device: Contact your ZEISS representative [▶ 7].

Additional equipment connected to medical electrical equipment must comply with the corresponding IEC or ISO standards (e.g. IEC 60950-1 for data processing equipment).

Furthermore all configurations must comply with the normative requirements for medical systems (see IEC 60601-1-1 or section 16 of IEC 60601-1).

If you connect additional devices to medical electrical systems, you are a system configurer and are thus responsible for ensuring that the system complies with the normative requirements for systems.

Local laws take precedence over the above normative requirements.

2.3.1 Notification to manufacturers and authorities

If a serious incident affecting the user, patient or another person occurs in connection with this medical device, the responsible organization or person responsible must report this incident to the manufacturer or seller of the medical product.

In member states of the European Union, the responsible organization or person must report serious incidents to their competent authority. In all other countries, comparable rules apply where national legislation so requires.

2.4 Responsibilities and duties of the operator

Electrical safety

- ▶ Switch the device off every time before disconnecting it from the power supply or if you are not going to use the device for any length of time. Also disconnect the device from the power supply before cleaning surfaces or accessories.
- ▶ Insert the power plug only into a power outlet that has a functioning protective earth connection.
- ▶ Use only cables and plugs which are in perfect working condition.
- ▶ Connect the device only to a power supply that corresponds to the values specified on the rating plate.
- ▶ Do not use multiple sockets.
- ▶ Do not use extension cables.
- ▶ Do not touch the device when your body is charged electrostatically and the unit is not grounded.
- ▶ Observe the instructions regarding electromagnetic compatibility (EMC).
- ▶ Set the device up so that the power cable can be disconnected from the power supply quickly and without any supplementary means.
- ▶ Connect the device using the power cable intended for use with the device. If the device is mounted to an instrument table qualified by Carl Zeiss Meditec, it will be powered through this table.
- ▶ Perform the electrical installation in conformance to IEC 60364-7-710 or the applicable national regulations. This includes the integration of a ground fault circuit interrupter (GFCI).
- ▶ Do not touch the patient and the connections of the device simultaneously.

Live parts are accessible inside the device. If you remove the housing, you are exposed to the risk of an electric shock.

- ▶ Never open the device!

Ambient conditions

- ▶ Make sure that the installation requirements and the operation of the device meet the following requirements:
 - Low vibration
 - Clean environment
 - Avoid extreme mechanical loads
- ▶ Do not operate or store the supplied devices in environmental conditions other than those prescribed.
- ▶ Operate the device only on a table with an even table top to allow for ventilation at the bottom of the device. Make sure that no papers or other objects have been placed under the device.
- ▶ Do not operate the supplied devices, when powered by electricity,
 - on easily inflammable materials,
 - in explosion risk areas (e.g. combustible mixture of anesthetic, cleaning or disinfecting agents with air, oxygen or nitrous oxide).
- ▶ Do not store or use this device in damp areas. Do not expose the device to water splashes, dripping or sprayed water.
- ▶ Ensure that no liquids can enter the device.

Decommissioning

- ▶ If one of the following events should occur, disconnect the cable from the power supply, label the device clearly as being out of service and report the problem to the ZEISS Service:
 - Defective sensor for right / left detection (right / left labeling may be incorrect)
 - Electric shocks
 - Penetration of substances
 - Frequently occurring error messages
 - Faults that cannot be remedied based on the information provided in these instructions for use

Symbols and labels

- ▶ Observe the symbols and labels attached to the device.

Transport

- ▶ Transport the unit over long distances (e.g. move, return for repair, etc.) only in original packaging or special return packaging.
- ▶ Contact your dealer or ZEISS Service.
- ▶ To lift the device, use only the recessed grips provided at the bottom of the head rest and at the base of the device. Never lift the device by the measuring head or by the head rest itself.

2.5 Risks due to optical radiation

The light emitted by this device is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this device when operated at maximum intensity will exceed the safety guideline after 27 min. As the respective light source (illumination of the reference image) is only switched on for 0.5 seconds during measurement, this corresponds to more than 3000 measurements of the same eye.

- ▶ Do not extend the length of use of the device for the eye examinations unnecessarily.

2.6 Software installation

- ▶ Install only software authorized by Carl Zeiss Meditec in this device.
- ▶ Activate the user administration (administrator rights required) in order to prevent access to the device and readings by unauthorized persons.
- ▶ Assign the appropriate access rights to the persons authorized to use the device.
- ▶ Note that a forgotten administrator password can only be recovered by ZEISS Service!
- ▶ Ensure that the assigned passwords are protected from unauthorized access. Unauthorized persons may under no circumstances use the service password. This will invalidate the safety warranty for the medical device IOLMaster 700.

2.7 Network connection

28. The IOLMaster 700 can be included into an Ethernet network to perform the following applications:

- Print
- DICOM export or import
- PDF file export to a shared network drive

Use a network isolator (cut-off voltage of at least 4 kV) when connecting the device to a LAN. Connect the device only to private networks which are protected from public networks (the internet) by measures which meet the latest technical requirements (e.g. firewalls)!

Connecting the unit to an IT network that includes other devices could lead to unforeseen risks for patients, users and third parties. The responsible organization should determine, analyze, evaluate and manage these risks by taking appropriate measures. (IEC 80001-1:2010 includes instructions on addressing these risks.) Similarly, subsequent changes to the IT network can lead to new risks and therefore require additional analysis:

- Changes to the IT network configuration
- Connection additional elements in the IT network
- Removal of elements from the IT network
- Updates or upgrades of devices that are connected to the IT network
- The configuration and network settings should only be changed by a network administrator with experience.

2.8 Maintenance measures

Maintenance procedures (maintenance and repairs) which are not specified in these instructions for use may only be carried out by persons authorized by Carl Zeiss Meditec and solely according to the service instructions issued by Carl Zeiss Meditec. For planning and implementing these maintenance and care procedures please contact ZEISS Service or your local dealer.

2.9 Product-specific risks

Responsibility of the operator

Users should not rely solely on measurements made using the IOLMaster 700 in making decisions regarding the calculation and implantation of intraocular lenses or other therapeutic procedures, but should rely on their own expertise and judgment.

Maintain stable fixation. Unstable fixation can lead to measuring errors and the calculation of incorrect IOL refractive powers.

Check the correct position of all measurement marks. In case of incorrect positioning, there is a risk of measuring errors. This can lead to the calculation of incorrect IOL refractive powers.

When editing values, the user is responsible for the correctness and precision of the values, especially when entering keratometry values manually.

The IOL calculation is valid only if the biometric measurement was correct, an appropriate IOL calculation formula was selected and the IOL constants were optimized for the specific application in advance.

Using IOL constants

Subject to the lens type, the constants must be defined and entered prior to using the IOLMaster. Your IOLMaster does not have its own constants; they are physician-specific and contingent on individual circumstances. In particular the diagnostic and surgical methods may result in differing corrective factors for calculation. The constants should thus be subjected to regular review and refinement.

Special remarks on phakic or piggy-back IOLs or pseudophakic eyes

When measuring phakic IOLs and piggy-back IOLs, the measurement of anterior chamber depth and lens thickness will be inaccurate and may not be used for IOL calculation.

When measuring pseudophakic eyes, the measurement of anterior chamber depth and lens thickness may be inaccurate depending on the intraocular lens - especially in case of PMMA-IOL. The measurement marks should be checked very carefully to ensure correct positioning.

Artifacts in OCT scans

Occasionally, the following artifacts may be visible in the cross-sectional images (OCT measurement):

- Saturation of A-scans may lead to continuous or broken lines in axial direction in the B-scan.
- Tissue may appear thicker than it really is due to secondary signals, especially beside saturated A-scans.
- In rare cases, mirror images may appear (especially in the fixation check scan).

3 Description of the device

3.1 Package check list








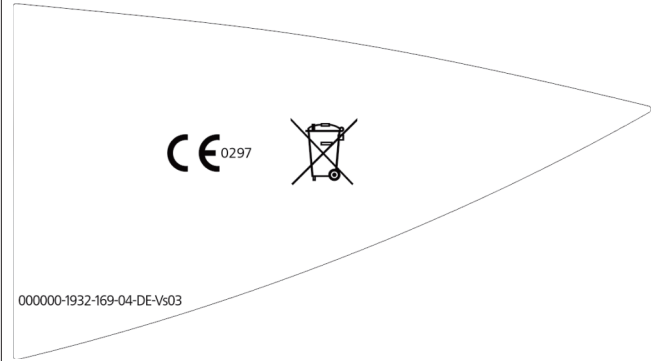


The device is delivered fully assembled in foam packaging.

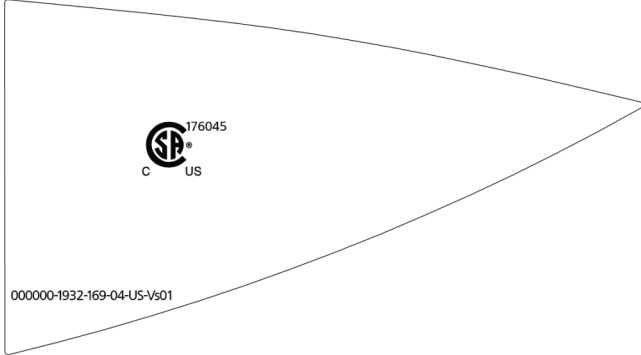


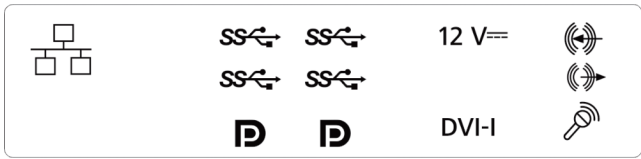







The enclosed accessory box contains the following components:

- Power supply cable
- Documentation set
- Dust cover
- Operator interface composite cable
- Stray light protective cover
- USB drive with IOL constants

The external monitor is supplied in a separate box (original packaging).

3.2 Device marking

Labels	Explanation
	IOLMaster 700 type label
	 Manufacturer
	 AC voltage
	 Applied part type B
	IP20 Ingress protection rating for housing (protected against solid foreign bodies of 12.5 mm in diameter and larger, no protection against penetration of water)
	Identification label with unique device identification code (Unique device identification label) IOLMaster 700
	REF Catalog number / part number
	SN Serial number
	 Date of manufacture
	 UDI (01)04049471092080(11)YYMMDD(21)XXXXXXXXXX Unique device identification code (data matrix and plain text)
	CE approval label and disposal advice for EU
	 0297 EU conformity symbol with identification number of notified body
	 Disposal advice for EU

Labels	Explanation
	Approval label for Canada
	"Disconnect device from the power supply before opening" information label
	"Observe user manual" information label
	Connector panel for version 1
	Connector panel for version 2
	Fuse identification label
	Label for marking the device as a medical device
	Country of origin label (for specific countries only depending on national regulations)
	IOLMaster 700 type label - software update set vs. 1.90
	 <p>Manufacturer</p>
	 <p>Catalog number / part number</p>

3.3 Structure of the device

3.3.1 View from physician's side

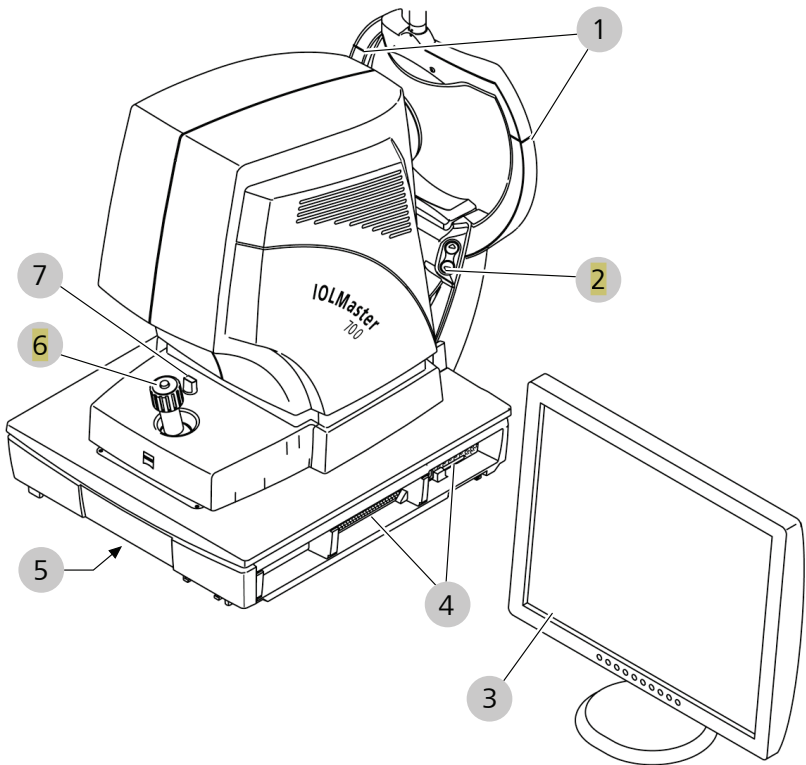


Figure 1: Device design, view from the physician's side

6.	1	Canthus marks (indicate patient eye level needed for optimum measurement)	2	Height adjustment of chin rest
	3	External touch screen monitor (used as input device, for observing the patient eye and for displaying the readings)	4	Connector panel [► 24]
7.	5	Grip (physician's side) for lifting the device	6	Joystick with release button (for moving the measuring head in X, Y and Z direction, height adjustment by turning)
	7	Knob for locking the measuring head		

3.3.2 View from patient’s side

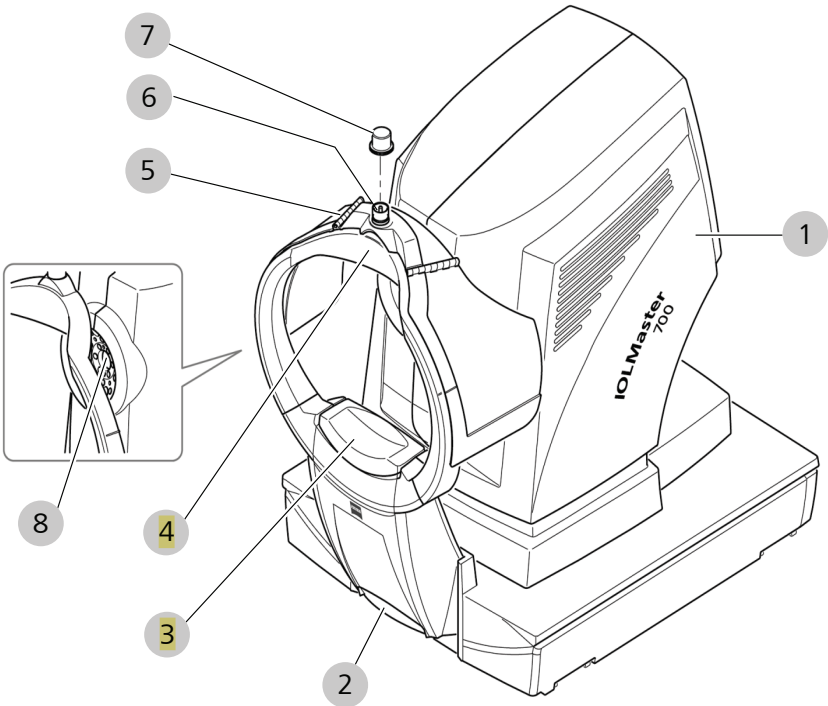


Figure 2: Device design, view from the patient's side

6.

1	Measuring head	2	Recessed grip (patient's side) for lifting the device
3	Patient chin rest (applied part)	4	Patient forehead rest with integrated forehead sensor (applied part)
5	Stray light protective cover	6	Holder for stray light protective cover
7	Cap nut	8	Laser beam exit aperture

3.3.3 Connector panel of IOLMaster 700

The connector panel of IOLMaster 700 is available in two versions.
Version 1:

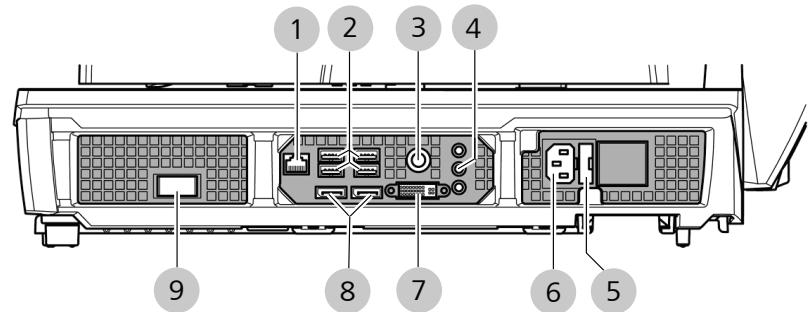


Figure 3: Connector panel of IOLMaster 700 (version 1)

1	Network port	2	4 USB ports (version 3.0)
3	Power supply of external monitor (12 V)	4	Audio port for external monitor
5	Power supply fuse	6	Power supply plug (~)
7	Signal port for external monitor	8	2 display ports
9	Standby button		

Version 2:

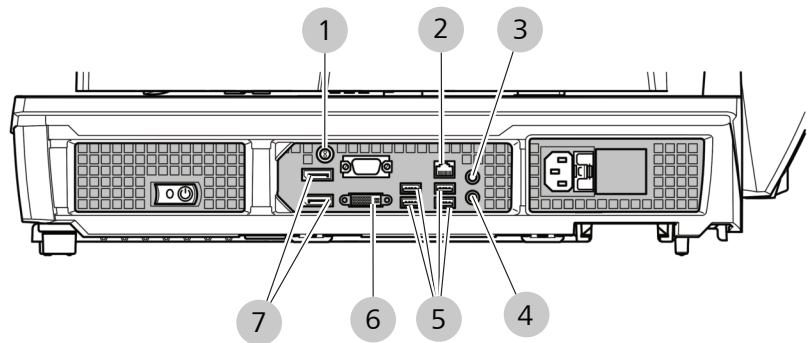


Figure 4: Connector panel of IOLMaster 700 (version 2)

1	Power supply of external monitor (12 V)	2	Network port
3	Audio port (line in)	4	Audio port (line out)
5	4 USB ports (version 3.1)	6	DVI connection
7	2 display ports		

3.3.4 Connector panels of the touch screen monitors

The connector panel of your touch screen monitor corresponds to one of the following versions.

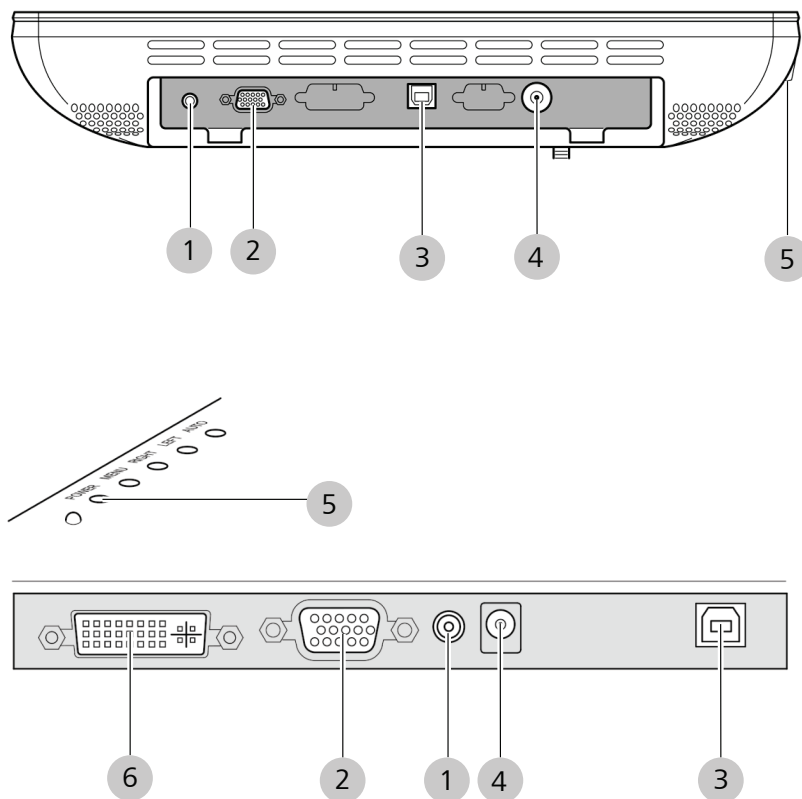


Figure 5: Connector panels of the touch screen monitors

1	Audio port (line in)	2	VGA port
3	USB port	4	Power supply (DC IN)
5	On / off button	6	DVI-D port

3.3.5 Operator interface composite cable

The operator interface composite cable is available in two versions.

Version 1:

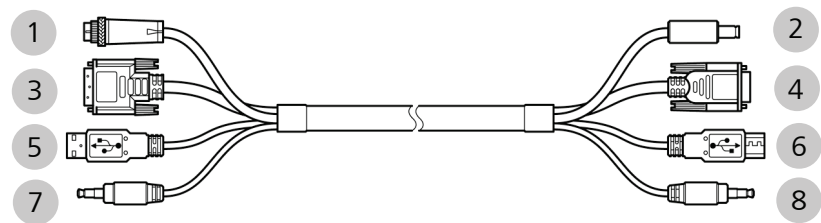


Figure 6: Operator interface composite cable (version 1)

1	DC power connection on device	2	DC power connection on monitor
3	DVI port on device	4	VGA port on monitor
5	USB port on device	6	USB port on monitor
7	Audio port (line in) on device	8	Audio port (line in) on monitor

Version 2:

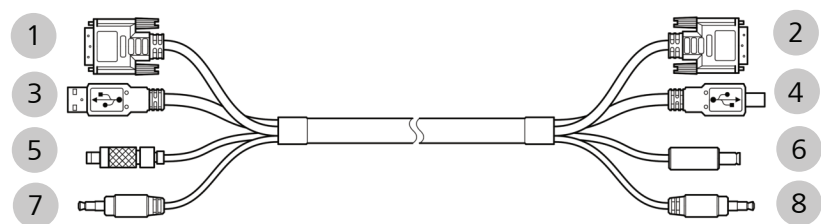


Figure 7: Operator interface composite cable (version 2)

1	DVI-D port on device	2	DVI-D port on monitor
3	USB (type A) port on device	4	USB (type B) port on monitor
5	DC power connection on device	6	DC power connection on monitor
7	Audio port (line in) on device	8	Audio port (line in) on monitor

3.4 Functional description

1. The device is a combined biometry instrument for the visualization of eye structures and acquisition of data of the human eye required for the calculation of an intraocular lens to be implanted.

The device is capable of consecutive measurement of the following eye parameters in one session: axial length, corneal curvatures, corneal thickness, anterior chamber depth, lens thickness and white-to-white distance. All measurements are non-contact, providing excellent patient comfort.

The corneal curvature is determined by measuring the distance between reflected light spots projected onto the cornea.

1. The corneal thickness, anterior chamber depth, lens thickness and axial length measurements are based on an interference optical method known as partial coherence interferometry (PCI). The one-dimensional coherence interferometry method is known as an A-scan and the two-dimensional method is called a B-scan (Optical Coherence Tomography, OCT). This enables biometric measurements along the visual axis of both procedures to be compared to each other.

This is also the reason why existing formulae and constants can be used for IOL calculation (see chapter Comparability of IOLMaster 700 with IOLMaster 500 for calculation of IOL refractive powers [► 220]).

The white-to-white distance and pupil diameter are determined from the image of the iris.

Depending on the brightness, the pupil size can fluctuate greatly during measurement. The readings may not be used to plan further treatment.

The measurement procedure is automated, so that the operator is only required to adjust the device to the patient's eye and initiate the measurement. For this reason the complex biometry of the eye can rapidly be acquired using the IOLMaster 700, but should be undertaken with the greatest of care and attention to detail.

Extensive integrated safety features (independent redundant hard and software safety features) ensure maximum safety for both the patient and operator during use and operation of the IOLMaster 700.

The control program for the computer in the device base runs on Microsoft Windows. An external touch screen monitor is used to observe the patient's eye and to display the readings. The device is

8. controlled using the touch screen monitor and the joystick on the device base. Optionally, the device can be operated (e.g. patient data input) using a keyboard, a mouse and the joystick on the device base.

3.4.1 Total Keratometry (optional license)

Total Keratometry (TK) is the ZEISS marketing name of a feature that conceptually resembles total corneal power (TCP) values.

The purpose of Total Keratometry (TK) is to determine the refractive power of the human cornea expressed in a toric model consisting of three parameters (TK1, TK2, Talpha). TK can be compared with keratometry when calculating intraocular lenses (IOL). Therefore, TK can be used for IOL calculation instead of conventional keratometry (see section Notes on IOL calculation [► 104] for detailed instructions on IOL calculation with Total Keratometry). Moreover, TK overcomes certain systematic weaknesses of keratometry by reducing model assumptions (i.e. the assumption of a constant anterior/posterior corneal surface ratio and a constant central corneal thickness implied by the keratometric index).

Restrictions, however, apply to formulae designed to calculate IOL power for eyes having undergone corneal refractive surgery, thereby compensating for the changed ratio between anterior and posterior corneal surface curvatures. Another restriction applies to formulae that have been designed to overcome known systematic weaknesses of keratometry with respect to corneal astigmatism. Using TK values in such formulae would compensate these systematic differences twice and therefore should be avoided to prevent overcorrection. Post-laser vision correction (LVC) formulae (e.g. Haigis-L, Barrett True-K) and toric formulae with a dedicated model or nomogram addressing the astigmatism of the IOL (e.g. Barrett Toric) are applicable examples to consider.

Technically, TK values are calculated via the toric lens model using the toric curvature of the anterior corneal surface based on keratometry and the toric curvature of the posterior corneal surface based on optical coherence tomography (OCT). The posterior corneal surface values are an intermediate step of determining TK, but are also displayed to the user.

The "Total Keratometry" (TK) license includes the following functions:

- Measurements of total corneal refractive power TK taking into account the readings from the posterior corneal surface (in contrast to model assumptions in keratometry)
- Measurements of the radius of curvature of the posterior corneal surface

The same values as for conventional keratometry ($R1 \mid K1$, $R2 \mid K2$, $R \mid SE$, ΔK) are available for both, whereby the TK measured values are denoted with $TR1 \mid TK1$, $TR2 \mid TK2$, $TR \mid TSE$, ΔTK and measurements of the posterior corneal surface with $PR1 \mid PK1$, $PR2 \mid PK2$, $PR \mid PSE$, ΔPK . The TK measured values are equivalent to the keratometry of eyes in which the measurements of the posterior corneal surface correspond to the Gullstrand model.

4 Installation

4.1 Installation safety

WARNING!

Electrical hazard

The use of unsuitable power cables could result in electric shock.

- ▶ Ensure that the power supply connector is suitable and certified for the local connection.
- ▶ Observe the following specifications when replacing the supplied power cable:
 - Protective earth conductor resistance maximum 0.1 Ω
 - Local certification of the power cable for connection to medical devices
 - Device plug C13 conforming to IEC 60320
 - Cross-section at least 0.75 mm² / AWG 18 ; Hospital Grade design for specific countries (e.g. USA, Canada) (For cables > 2.5 m the cross-section must be increased to 1.5 mm²).

WARNING!

Electrical hazard due to connecting additional devices

If other system components are connected to the instrument table than those described in this manual, a non-medically-rated system is created in accordance with IEC 60601-1. There is a risk of electrical shock.

- ▶ No components other than the system components described should be connected.
- ▶ If any changes are made to the system, ensure that the safety requirements as per IEC 60601-1 are met.
- ▶ The power supply connections of the instrument table must only be used for supplying power to the IOLMaster 700. Use of the power supply connections as a multiple socket is prohibited.

WARNING!

Fire hazard from faulty electrical installation

Fire can occur due to faults in the electrical installation.

- ▶ Ensure that the electrical installation conforms to IEC 60364-7-710.
- ▶ For USA and Canada only: Use only NEMA 5-15P power plugs for single-phase power systems with 120 V AC.
- ▶ Ensure that the power consumption data on the type plate are met when selecting overcurrent protection.

CAUTION!

Mechanical hazard while carrying the device

Improper lifting and setting down of the device may result in the hands and fingers being crushed.

- ▶ When lifting and carrying the device, use only the recessed grips on the head rest and base of the device provided for this purpose.
- ▶ Ensure that no parts of the body (fingers, hands), or objects, are beneath the device when lowering it.

4.2 Prepare for installation

NOTE

Mechanical hazard

Improper lifting may damage the device.

- ▶ To lift the device, use only the recessed grips provided at the bottom of the head rest and on the base of the device.

Action

1. Remove the device and the monitor from the packaging and put them onto a table.
2. Unpack the accessories.
3. Remove the shipping brace. To do this, turn the joystick to the right (one turn) to raise the measuring head and pull out the plastic plate which is located between the device base and the measuring head (pull to patient side).
4. Remove the blue protective cover from the chin rest.

4.3 Connect the device

WARNING!

Electrical hazard due to connecting additional devices

Faults in the electrical installation may cause an electric shock.

- ▶ Ensure that the power is supplied to the monitor only via the composite cable operator interface through the IOLMaster 700. If other DC power supply units are used, there is a risk of the patient touching live device parts.
- ▶ Do not connect the monitor directly via the power supply plug to the power supply network.
- ▶ Only set up additional monitors connected via the device's display port connectors outside the patient environment and connect them via an isolating transformer.
- ▶ Only use devices that comply with IEC 62368-1 or IEC 60950-1 as additional monitors.
- ▶ Use a network isolator (cut-off voltage of at least 4 kV) when connecting the device to a LAN.
- ▶ Use a USB isolator (at least 4 kV cut-off voltage; with USB cable) when connecting external USB devices with separate power supply to the device. The USB isolator may not be powered by a separate power supply.

Action

1. Connect the external touch screen monitor to the IOLMaster 700 using the operator interface composite cable [▶ 26]. To do this, plug the appropriately labeled connectors into the ports of the IOLMaster 700 and the touch screen monitor.
2. Optional: connect the keyboard.
3. Optional: connect the mouse.
4. Optional: connect the network cable including network isolator [▶ 229].
5. Optional: connect the USB drive with the IOL constants.
6. Connect the power cable.

When the device is connected to the power supply, the indicator light on the standby button flashes blue.

4.4 Installing the stray light protective cover for the Reference Image Option

The stray light protective cover for the Reference Image Option is fastened to the head rest.

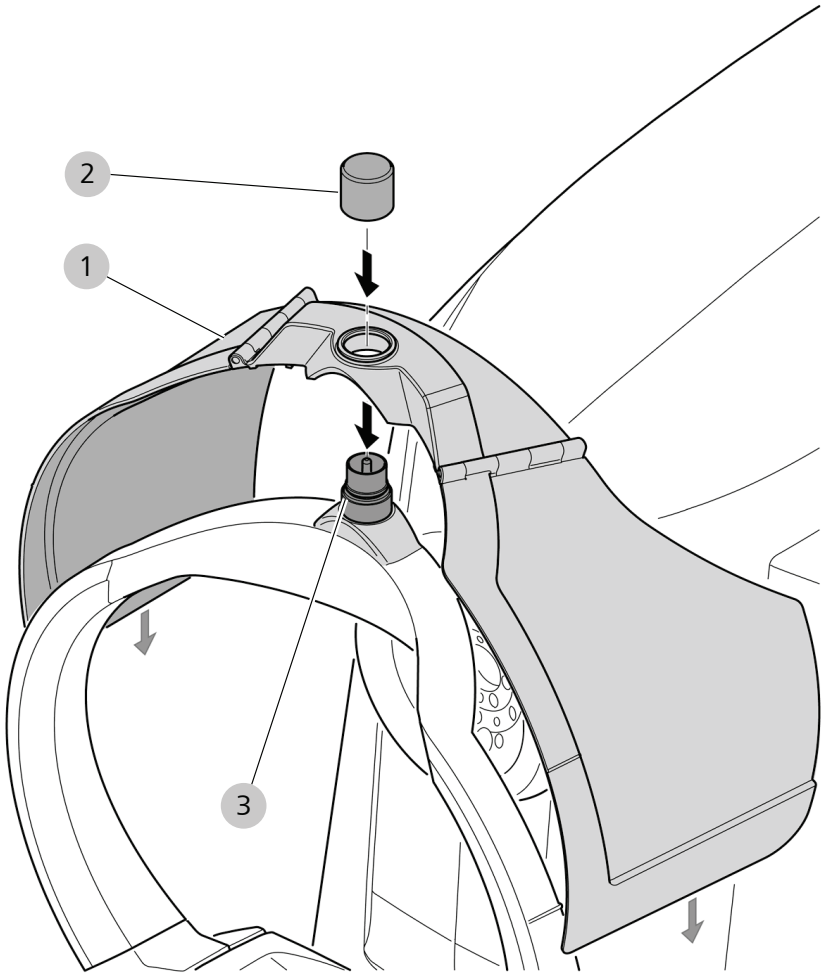


Figure 8: Installing the stray light protective cover for the Reference Image Option

1	Stray light protective cover	2	Cap nut
3	Holder for stray light protective cover		

Action

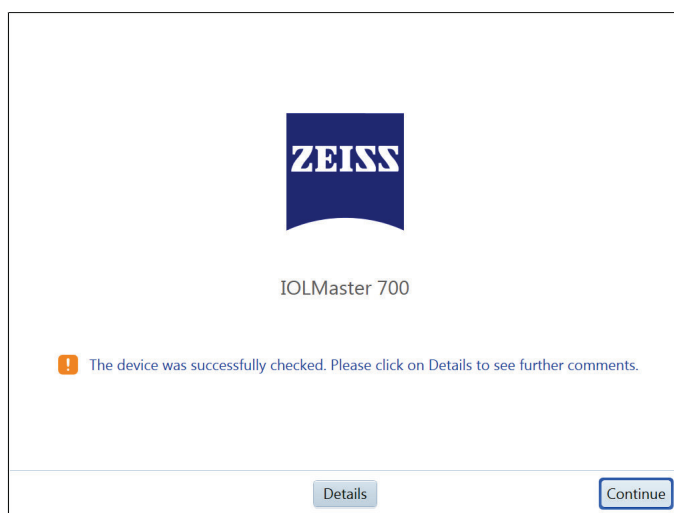
1. Remove the cap nut of the holder.
2. Apply the stray light protective cover.
3. Fasten the stray light protective cover by screwing on the cap nut.

5 Daily startup

5.1 Switch the device on

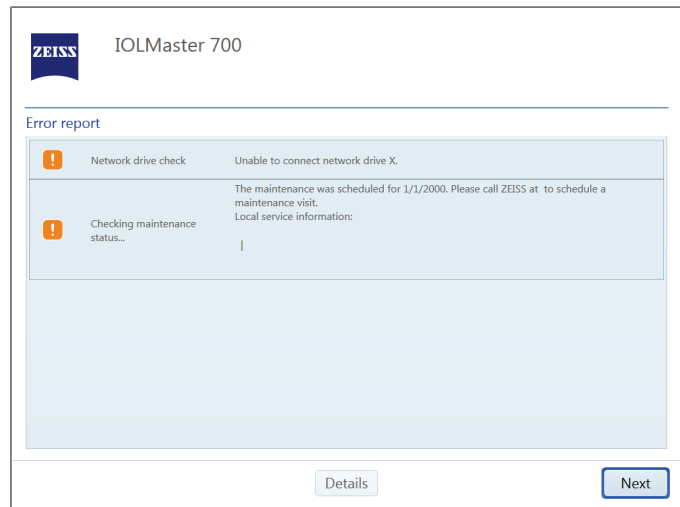
Action

1. Check if the device is connected to the power supply.
⇒ The indicator light on the standby button flashes blue.
2. Switch the device on using the standby button [▶ 24].
⇒ During operation the indicator light of the standby button is continuously blue.
3. During initial operation switch on [▶ 25] the monitor.
⇒ A wizard starts for adjusting the monitor settings.
4. After switching on, the software will be launched automatically, and a self-test carried out.



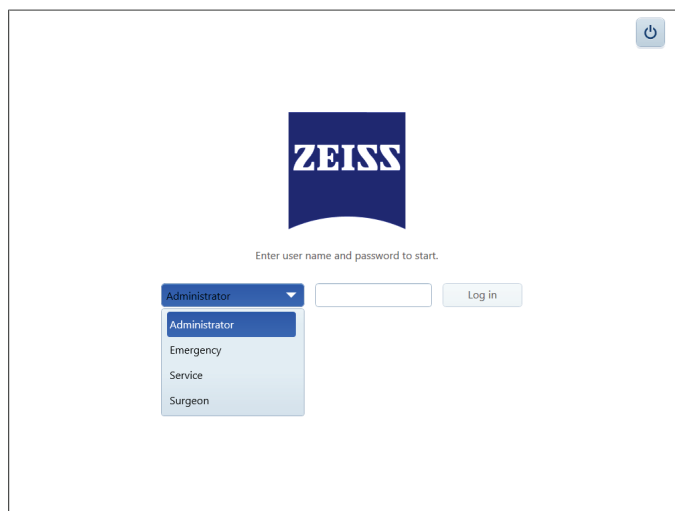
⇒ The start window of the software will open.

5. Tap the [Details] button.



⇒ The device status overview will be displayed.

6. Tap the [Continue] button.



⇒ A window to log into the device will open.

7. Select one of the following users: Administrator, Emergency, Service, Surgeon.
8. Enter the password and tap the [Log in] button.

TIP: The following users are already available when the device is started for the first time: Administrator, Emergency, Service, Surgeon. When starting the device for the first time, log in as Administrator. In User Management you can then add other users.

6 Before every use

6.1 Preparation safety

Prior to using the device, the user must ensure that it is in a good condition and fully functioning. Furthermore, the user must follow the instructions in the instructions for use. The following inspections must be carried out each working day prior to use:

Action

- ▶ Visual inspection of device, power cable and accessories to ensure that they are present and intact. If parts are missing or damage is visible, the device should not be used and should be taken out of service.
- ▶ Check the ventilation slits of the device. They should be covered or obstructed.
- ▶ Perform the calibration test.

6.2 Calibration test

CAUTION!

Risk due to measuring errors

Measurements on patients with an improperly calibrated device can be erroneous and result in the calculation of incorrect IOL powers.

- ▶ Check the calibration of the device daily before carrying out measurements on patients.
- ▶ Do not perform any measurements on patients if the calibration test failed.
- ▶ Remove the device from service, if the calibration test repeatedly failed. In this event, contact ZEISS Service.

Set values and tolerances are included in the device software and will be automatically compared with the measured calibration test values and saved within the device.

6.2.1 Calibration test - start window

After successfully logging in, the "Calibration test" dialog is displayed. In this dialog, the device calibration status can be checked.

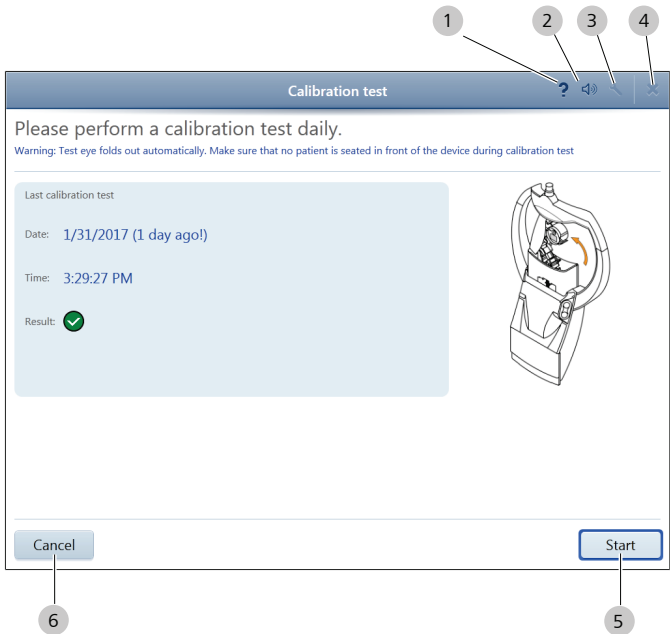






Figure 9: Calibration test - start window

Item	Icon/Name	Explanation
1	 Help	Opens the online help for the current screen.
2	 Speaker	Use the [Volume] button to display a slide control for adjusting the volume.
3	 Settings	Opens the "Settings" dialog. This function is deactivated during the calibration test.
4	 Close	Opens a menu with options for logging out the current user or switching the device off. This function is deactivated during the calibration test.
5	Start	Starts the calibration test.
6	Cancel	The calibration test is canceled. The application software can then be started by tapping the [OK] button. Alternatively, use the [Shut down] button to quit the software and switch off the device.

6.2.2 Calibration test – step 1

While "Initializing hardware..." is displayed, the device will be prepared and the test tool holder in the chin rest compartment will rise up automatically.

During the first of three steps, the coarse alignment of the measuring head is performed. The reflective pattern of the six LED test marks must be in the center of the cross hairs and focused. The traffic light (in the upper left corner of the live image), the directional arrows for joystick adjustment (in the center bottom of the live image) and the centering cross serve as adjustment tools. Checking the required procedure steps is supported by the description on the left side and the graphical representation on the right side of the display.

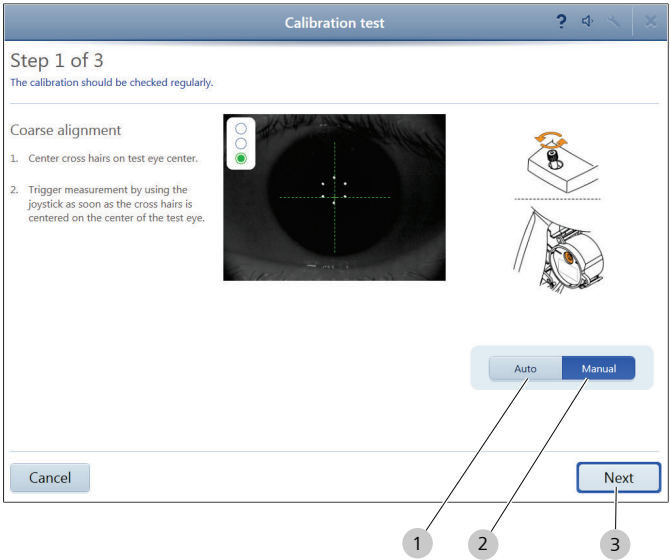








Figure 10: Calibration test – step 1

Item	Icon/Name	Explanation
1	"Auto" measuring mode	As soon as the device is adjusted correctly, the measurement is triggered automatically.
2	"Manual" measuring mode	The measurement is triggered manually by pressing the button on the joystick.

Item	Icon/Name	Explanation
3	Next	Tap the [Next] button to change to the second step of the calibration test.
	 Traffic light function	The traffic light (in the upper left corner of the live image) and the directional arrows for joystick adjustment (in the center bottom of the live image) serve as adjustment tools.
	 Right directional arrow	
	 Left directional arrow	
	 Directional arrow to front or back	
	 Directional arrow counterclockwise: downward movement	
	 Directional arrow clockwise: upward movement	

6.2.2.1 Raise the test tool holder

The test tools [► 40] supplied with the device are for verifying that the device is serviceable and properly calibrated.

Measurements can be performed on the test eye the same as on a human eye. The test eye is also ideal for practicing operation of the IOLMaster 700.

The supplied scale is to be used for checking the WTW measurement.

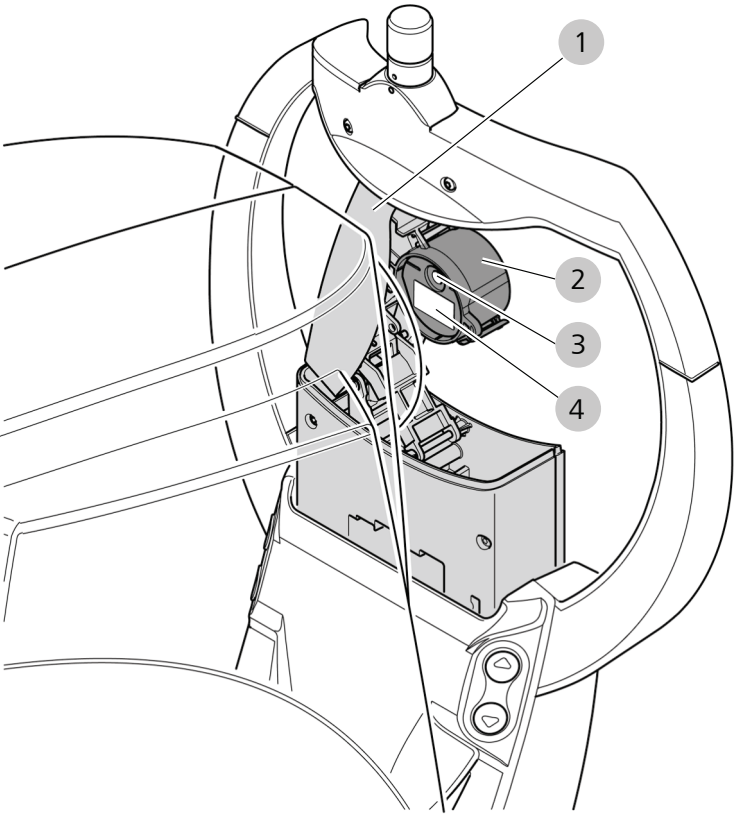


Figure 11: Raise the test tool holder

1	Opened chin rest	2	Test tool holder
3	Test eye for biometry and keratometry	4	WTW scale

⚠ CAUTION!

Mechanical risk from moving parts

Facial injuries may be caused by the chin rest rising and the test eye folding open.

- Prior to tapping the [Start] button, ensure that no person is in front of the head rest.

Action

1. Tap the [Start] button.
 - ⇒ The chin rest folds open and the test tool holder integrated under the chin rest automatically rises.
2. Perform the measurements on the test tools as described below. **NOTE! Handle the test tools with care and protect them against scratches. Avoid unnecessary touching of the test tools.**
 - ⇒ The readings will be compared with the set values saved in the device software and automatically evaluated. Upon completion of measurements, the test tool holder will automatically retreat into its case.

6.2.2.2 Check axial length measurement and keratometer

The test eye is for verifying the axial length measurement tool (AL) and the keratometer (R).

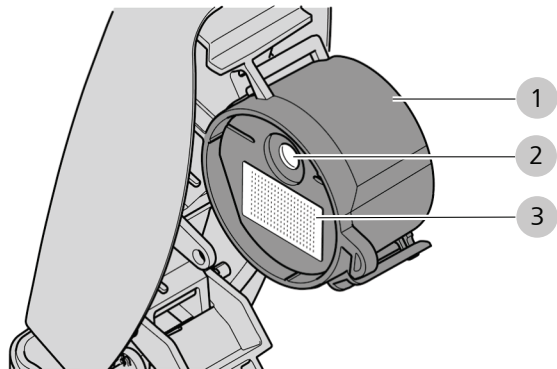


Figure 12: Test eye and WTW scale on test tool holder

1	Test tool holder	2	Test eye for biometry and keratometry
3	WTW scale		

Action

- The measurements should be taken in the same way as for a human eye (see section Software description [► 49])!
 - ⇒ If the readings from the test tool are within the set values and tolerances saved in the device, the device is properly calibrated.
- Tap the [Help] button (question mark) in the upper right corner of the screen to open the online help on the current screen.

6.2.3 Calibration test – step 2

In step 2 of the calibration test, the OCT scan and keratometer calibration is checked.

Use the adjustment tools seen in step 1 to focus the reflective pattern of the 18 LEDs. Additionally to the live image, the horizontal (to the right of the central live image) and vertical (on the bottom of the central live image) OCT scan is also shown. In each image, an adjustment area is proposed (shown in green). If the measuring beam is orthogonally reflected, a yellow dot is displayed within the green rectangular of the adjustment area in the horizontal and vertical OCT scan image. As in step 1, measurement is triggered automatically or manually by pressing the joystick button.

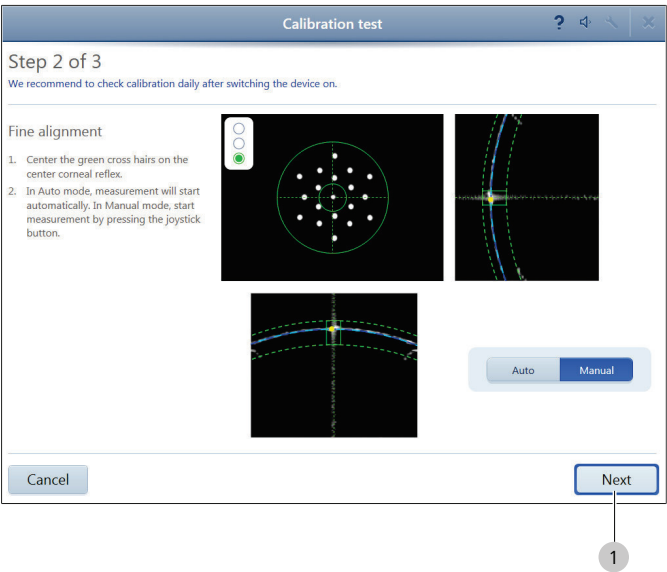


Figure 13: Calibration test – step 2

Item	Icon/Name	Explanation
1	Next	Tap the [Next] button to change to the third step of the calibration test.

6.2.4 Calibration test – step 3

In step 3 of the calibration test, the calibration of white-to-white measurement is checked by measuring a line raster.

For help in performing the required procedure steps see also the description on the left side and the graphical representation on the right side of the display. As shown, the joystick is turned counter-clockwise (downwards) until the line raster is displayed within the live image. The line raster should completely fill the live image and be as focused as possible prior to triggering the measurement by pressing the button on the joystick manually.

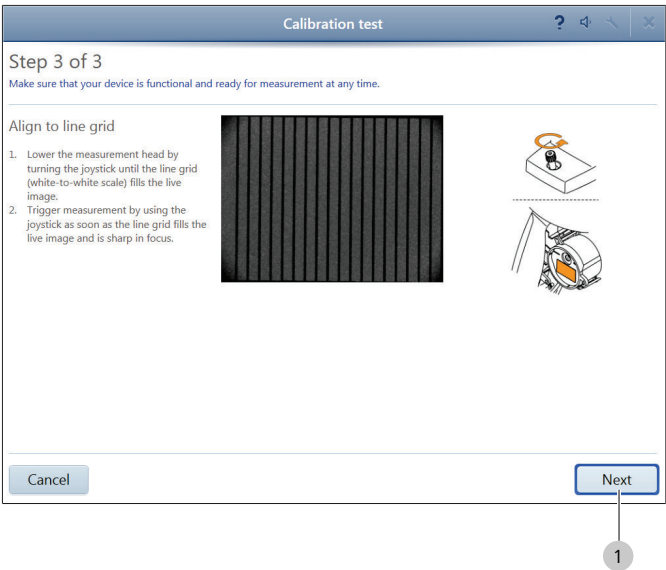


Figure 14: Calibration test – step 3

Item	Icon/Name	Explanation
1	Next	Tap the [Next] button to complete the calibration test.

6.2.5 Results of the calibration test

The results of the calibration test will be shown in an overview. If one or several steps of the calibration test fail, repeat the calibration test or contact ZEISS Service.

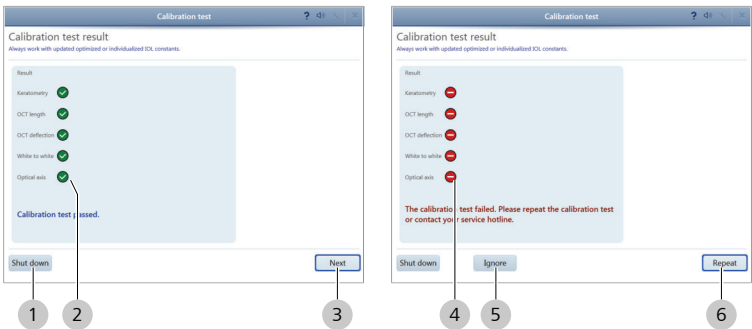




Figure 15: Calibration test passed (left) and failed (right)

Item	Symbol	Explanation
1	Shut down	The software will be terminated automatically and the device will be set to standby mode.
2	 Calibration test passed.	The calibration test for the respective measured value was passed.

Item	Symbol	Explanation
3	Next	The "Calibration test" dialog window will be closed. The test tool holder retreats into its case in the chin rest and the application will be started.
4	 Calibration test failed.	The calibration test for the respective measured value failed.
5	Ignore	Starts the application despite the failed calibration test.
6	Repeat	Repeat the calibration test.

Empty page, for your notes

7 Operation

7.1 Operation safety

CAUTION!

Mechanical hazard from moving parts

Injuries may be caused by the instrument table lowering.

- ▶ When lowering the instrument table, always ensure that no objects or body parts are within the movement range of the tabletop.
- ▶ Read the instructions for use of the instrument table and follow its warning instructions.

CAUTION!

Mechanical risk from falling parts

The patient may injure him / herself or the device may be damaged.

- ▶ Instruct the patient not to touch the device with his / her hands.
- ▶ Instruct the patient not to use the device as a support or an aid when standing up.

CAUTION!

Mechanical risk from moving parts

Head or facial injuries may be caused.

- ▶ Adjust the height of the motorized chin rest only when in direct visual contact with the patient.
- ▶ Make sure that no objects or body parts are put through the head rest.
- ▶ Ensure that the automatic calibration test is terminated before the patient touches the head rest.

CAUTION!

Risk arising from incorrect operation

The use of unsuitable IOL constants can lead to the calculation of incorrect IOL powers.

- ▶ Use only constants optimized for optical biometry for calculating options for intraocular lens power to be implanted using the device readings.
- ▶ Use only suitable lens constants in case of IOL calculation with ultrasound applanation readings.
- ▶ Review and refine regularly the IOL constants used.

 **CAUTION!**

Risk due to measuring errors

Unstable fixation can lead to measuring errors and the calculation of incorrect IOL refractive powers.

- ▶ Check that the patient fixates correctly and the fovea is visible in the fixation check scan.
- ▶ Repeat the measurement in case of doubt or check the measuring results by using alternative methods, if necessary.

 **CAUTION!**

Risk due to measuring errors

Measuring errors cannot be precluded if the measurement marks are incorrectly positioned, this can lead to the calculation of incorrect IOL refractive powers.

- ▶ Check the correct position of the measurement marks.
- ▶ Repeat the measurement in case of doubt or check the measuring results by using alternative methods, if necessary.
- ▶ Perform a particularly detailed examination of the measurement marks when examining pseudophakic eyes. In these cases the measurement of anterior chamber depth and lens thickness may be inaccurate depending on the intraocular lens and especially with PMMA-IOL.

 **CAUTION!**

Risks arising from operation

Changing prematurely to the other eye during the measurement may result in inaccurate measurements.

- ▶ Do not change to the other eye during measurement.

Deviations from the target refraction by the IOLMaster 700 itself are minimized by appropriate handling of the device. In particular the following procedure steps must be carried out:

- ▶ Position the patient's eye to the level of the canthus marks on the head rest [▶ 22] using the chin rest height control.

WARNING! Head or facial injuries may be caused.

- ▶ Ensure that the patient correctly fixates with the eye to be examined.

CAUTION! Measuring errors cannot be precluded if the eye is not firmly fixated. This can lead to the calculation of incorrect IOL refractive powers.

- ▶ Ensure that the device is precisely focused for keratometry, biometry or white-to-white measurement.
- ▶ Observe the adjustment aids and instructions displayed on the device during measurement.
- ▶ Use the biometry formulae properly.
- ▶ Use only adjusted IOL constants.

CAUTION! The use of unsuitable IOL constants can lead to the calculation of incorrect IOL powers.

Action

TIP: A detailed description of the user interface of the device is provided in the online help. Tap the [Help] button (question mark) in the upper right corner of the screen to open the online help on the current screen.

7.2 IOL database

Constants must be pre-determined for calculation of lens power based on IOLMaster measurement. Only lens constants which have been optimized for the IOLMaster should be used. The IOL constants of the lens manufacturer can be used, but these are usually less suitable.

You can enter your own constants on the basis of experience, or make use of third party data. The IOL Con Website (<https://iolcon.org>) by Steinbeis Vision Research publishes optimized constants for the calculation of intraocular lenses with the IOLMaster. These lens constants are provided as benchmarks for IOLMaster users free of charge from a steadily growing surgical database. They are not determined, validated, verified or otherwise confirmed and checked by Carl Zeiss Meditec for correctness and suitability for use for IOL, but are based solely on statistical data from users. A USB drive with the current database at the time of manufacture is included with your device. This database can be installed as required.

If the USB drive should no longer be available, you can download your IOL constants from the IOL Con Website (<https://iolcon.org>) or from the ZEISS website (<https://www.zeiss.com/meditec/int/resource-center/cataract-services/optimized-lens-constants.html>). Copy your file with IOL constants to your own USB drive and then import them into the IOLMaster.

If you wish to use this data, please follow the installation steps described in section "Software description / Settings / Advanced settings / IOL management [▶ 155]".

NOTE! The USB drive should not be inserted or removed while the system is starting up or shutting down or when the LED on the USB drive is lit.

7.3 Backup data

The IOLMaster 700 is equipped with a data backup function via a network or USB connection.

NOTE! IOLMaster 700 does not perform automatic data backup. Data backup is the responsibility of the user.

- ▶ Connect an external storage device and perform a data backup.

TIP: Information on the use of the external data backup is to be found in section Software description / Settings / Maintenance [▶ 192].

Action

7.4 Exporting raw data

In addition to the backup function, the IOLMaster 700 is equipped with a raw data export feature (anonymized or not anonymized) via a network or USB connection.

Action

- Connect an external storage device and export the raw data after each measurement.

TIP: In order to ensure sufficient speed for raw data transfer, we recommend to use external storage media via the network or USB 3.0 connection.

TIP: Information on raw data export can be found in the software description chapter in Settings / Advanced settings / Measurement [► 166].

7.5 Switching off the device

NOTE

Data loss

Data loss can occur if the device is disconnected prematurely from the power supply.

- Unplug the power supply or switch off the main room switch only when the blue indicator light in the standby button is flashing.

Action

1. When all measurements have been completed, exit the program by tapping the [Close] button in the upper right corner of the display and by selecting [Shut down] in the drop-down menu or by pressing the standby button.

NOTE! The device may not be switched on again until the indicator light of the standby button flashes.

NOTE! If the device is switched off at the standby button while in operation, the program will quit automatically and the device put into standby mode. Wait until the device is in standby mode (indicator light on button flashing) before pulling the power supply plug or switching off at the main room switch.

2. Disconnect the power plug if you are not going to be using the device for any length of time.

NOTE! If the device is unplugged or switched off at the main room switch while the device is still running, the program cannot quit and the operating system cannot be shutdown properly; this can lead to loss of saved data and/or defects in the device's control software. This does not present a hazard to patients or the operator.

8 Software description

8.1 General operating instructions

The operating system of the device's control computer works in the background. For safety reasons, it is not accessible to the user.

NOTE! No attempt should be made to tamper with the operating system! In particular, deactivation of the Microsoft Windows firewall is not permitted!

Microsoft Windows operating conventions apply to the user interface of the software of the IOLMaster 700. This includes the use of a touch screen or an optional USB keyboard and USB mouse, the use of icons, working with dialogs and menus, confirming by touching buttons on the screen or by clicking on the buttons using the optional USB mouse, etc.

NOTE! The system does not support all key combinations of Microsoft Windows. The special Microsoft Windows keys that exist on some keyboards are ineffective.

In rare cases, Microsoft Windows error messages may appear on the LC display. This may be the case, for instance, if the program flow is affected (mostly by external disturbances, e.g. cell phones). The device does not support the submission of automatically generated problem reports to Microsoft! Multiple safety mechanisms in the device's hardware and software ensure that there is no risk of injury.

The program can be controlled by:

- Tapping buttons on the screen with your fingers.
- Clicking on buttons or icons (using the cursor) using the optional USB mouse.

Measurements are triggered by pressing the button on the joystick.

8.1.1 Touch screen operation

Action

- ▶ Tap the buttons or icons on the screen to open menus or dialogs or to start a measurement.
- ▶ Enter the required data using the on-screen keyboard.

The on-screen keyboard is used to fill out the text boxes. It appears automatically as soon as the cursor is inserted into a text box.



Figure 16: On-screen keyboard

Item	Name	Explanation
1	ABC	Switches the keyboard layout from numerals and special characters to letters.
2	123	Switches the keyboard layout from letters to numerals and special characters.
3	Hide on-screen keyboard	Hides the on-screen keyboard again.
4	Language	When a key is pressed, the keyboard layout switches to the next language. All installed languages will be shown consecutively.
	Menu with special characters	Touch and hold a character to bring up a menu with all the special characters (umlauts, etc.) belonging to this character. The desired special character can be selected by tapping it.

8.1.2 Operation using the optional USB keyboard and mouse

Action

- ▶ Move the cursor by moving the mouse as desired.
- ▶ Click the buttons or icons on the screen to open menus or dialogs or to start a measurement.
- ▶ Enter the required data using the USB keyboard.

8.2 Patient

This dialog window will appear upon starting the software and successful login. The “Patient” dialog window enables the user to select, search, create, edit or delete patient data records.

8.2.1 Patient / Measurements

An overview of all measurements of the selected patient, grouped by date of measurement, is displayed.

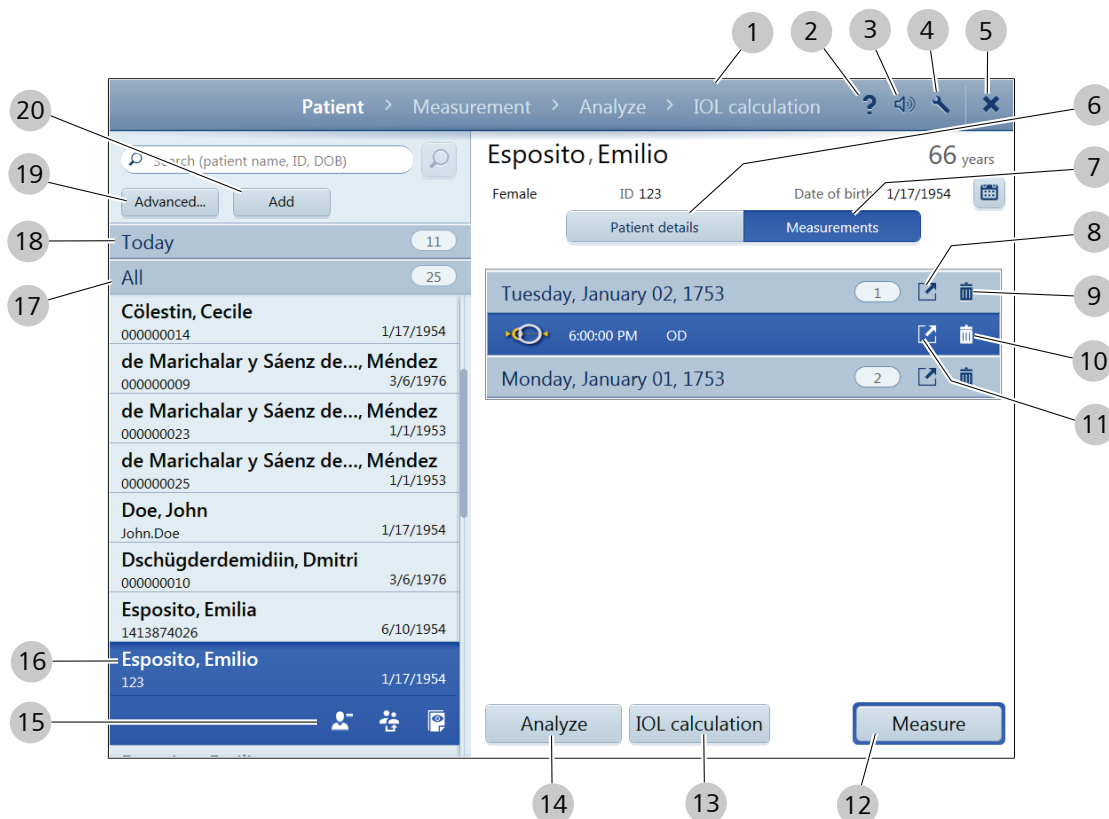












Figure 17: Patient / Measurements


Item	Icon/Name	Explanation
1	Workflow toolbar	Displays the workflows and the current position.
2	 Help	Use the [Help] button to open the online help for the current screen.
3	 Speaker	Use the [Volume] button to display a slider for adjusting the volume.
4	 Settings	Use the [Settings] button to open the "Settings" [▶ 141] dialog.
5	 Close	Use the [Close] button to open a menu with options for logging out the current user or switching off the device.

Item	Icon/Name	Explanation
6	Patient details	An overview of patient details will be displayed.
7	Measurements	An overview of all measurements of the selected patient, grouped by date of measurement, is displayed.
8	Export	Use this button to export all measurements of a selected patient on the selected day. The export (including PDF) can be configured in the "Advanced settings / Export" dialog.
9	Delete	Use this button to delete all measurements of a patient on the selected day.
10	Delete	Use this button to delete the selected measurement. To delete a patient data record completely, tap the small triangle at the right-hand side of the patient name on the left side of the list. A context menu (see 15) will be displayed. By tapping the "Delete" menu entry and confirming the query in the following window, the selected patient data record with all measurement data will be deleted.
11	Export	Use this button to export the selected measurement. The export (including PDF) can be configured in the "Advanced settings / Export" dialog.
12	Measure	Use this button to open the "Perform measurement" [► 60] dialog and perform a new measurement.
13	IOL calculation	Use this button to open the "IOL calculation" [► 84] dialog window and perform or edit the calculation of intraocular lenses for the selected measurement.
14	Analyze	The analysis of the selected measurement is started.

Item	Icon/Name	Explanation
15	 Delete	<p>The “Delete” menu entry will only be displayed if the patient data is saved on the device and not on the DICOM server. By tapping the “Delete” menu entry and confirming the query in the following window, the selected patient data record with all measurement data will be deleted.</p>
	 Merge	<p>The “Merge” menu entry will only be displayed if the patient data is saved on the device and if the DICOM network has been deactivated in the Settings / Network [► 181] dialog. The “Merge” menu item is used to merge several patient data records.</p> <p><i>Action</i></p> <ul style="list-style-type: none"> ▶ Select a patient and tap the “Merge” menu entry in the context menu. A dialog will be opened to search for other data records for merging. ▶ Enter the search string in the “Search” input field. Parts of the patient name, ID, or date of birth may be entered into the search. The search is started by tapping the magnifying glass or [Enter] key. The search can be reset by tapping the  button. ▶ In the list box with the search results, select the data records which you want to merge with the previously selected patient. Using the [Compare] button will display an overview showing the difference between the data records. ▶ Tap the [Merge] button to merge the selected data records. A text input field will be displayed to enter the reason for merging the data. ▶ Enter the reason for merging the data in the text input field. If you activate the checkbox “Define this text as default text”, the text entered will be used in every merge of patient data. ▶ Tap [Merge]. All data records will be saved under the name of the patient who was selected first.
	 Exam	<p>The “Exam” menu entry is used to display the examination data of the patient.</p> <ul style="list-style-type: none"> ▶ Select a patient and tap the “Exam” menu entry in the context menu. A dialog with the list of examinations will be opened. ▶ Select an examination and tap [Reassign]. A dialog opens in which the patient can be searched to which the examination is to be assigned. ▶ Enter the search string in the “Search” input field. Parts of the patient name, ID, or date of birth may be entered for the search. The search is started by tapping the magnifying glass or [Enter] key. The search can be reset by tapping the  button. ▶ Select the patient from the search results to whom the selected procedure is to be assigned. By tapping on [Details], further information on this patient will be displayed. ▶ Tap [Reassign] to assign the exam data to the selected patient. A text input field will be displayed to enter the reason for merging the data. ▶ Enter the reason for reassignment of data in the text input field. If you activate the checkbox “Define this text as default text”, the text entered will be used in every reassignment of patient data. ▶ Now tap [Reassign]. All procedures will be saved under the name of the selected patient.

Item	Icon/Name	Explanation
16	Selected patient	The selected patient is highlighted in blue. Next to the patient's name, there is a small blue triangle with which the context menu 15 can be opened to edit the patient data.
17	All / Search results	<p>The "All" list box will be displayed if the DICOM network is disabled in the network settings. The list box can be expanded by tapping it. All existing patient data is displayed at the outset in the "All" list box. If a simple search has been performed, only the search results will be displayed.</p> <p>The "Search results" list box will be displayed if the DICOM network is enabled in the network settings. The list box can be expanded by tapping it. The "Search results" list box displays the results of the simple search.</p>
18	Today	This list box will be displayed if the DICOM network is enabled in the network settings. The list box can be expanded by tapping it. The "Today" list box displays the patients scheduled for examination or treatment on the current day. This patient data is imported, for example, from the worklist of your clinic's information system.
19	Advanced	The "Search" [► 57] dialog will be opened to enter advanced search criteria.
20	Add	<p>New patient data can be entered. The following information is obligatory:</p> <p>Last name, first name: Use the screen keyboard to enter the last and first name of the patient in the text boxes provided.</p> <p>Gender: Select the patient's gender in the "Gender" drop-down box.</p> <p>Date of birth: Open the "Date" selection box and select the patient's day, month, and year of birth. Confirm with [OK]. The patient's age and date of birth will be displayed on the screen.</p> <p>The  symbol may be displayed in the patient data (e.g. name). This serves as a placeholder for characters that cannot be displayed.</p>

8.2.2 Patient / Patient details

 **CAUTION!**

Risk arising from incorrect operation

All details on lens state and vitreous body state are coupled with the measurement. If parameters are not correctly selected before measuring, the axial length or corneal refractive power of the device cannot be correctly determined. This can lead to the calculation of incorrect IOL refractive powers.

- ▶ Select the correct parameters for the patients **prior to** measurement. The values of axis length do not take into account any change of parameters after the measurement.
- ▶ In case of a gas-filled eye, wait after a vitrectomy until the eye has filled with aqueous humor, otherwise it will not be possible to measure the axis length correctly.

An overview of patient details will be displayed. It is recommended that the patient’s refraction and visual acuity data, if known, be entered or selected in the respective boxes.



Figure 18: Patient / Patient details

Item	Icon/Name	Explanation
1	Sphere	Optional fields for the input of refraction parameters.
	Cylinder	
	Axis	

Item	Icon/Name	Explanation
2	Lens state	<p>Drop-down list for selecting the lens state. The correct selection of lens state is mandatory for exact axial length measurement.</p> <p>The following states may be selected:</p> <ul style="list-style-type: none"> ■ Phakic (natural lens) ■ Aphakic (no lens) ■ Pseudophakic (IOL, material: acrylate) ■ Phakic IOL (artificial lens in addition to natural lens) ■ Piggyback IOL (two IOLs) ■ Piggyback IOL silicone (two IOLs, material: silicone) ■ Pseudophakic PMMA (IOL, material: PMMA) ■ Pseudophakic silicone
3	Vitreous body state	<p>Drop-down list for selecting the vitreous body state.</p> <p>The following states may be selected:</p> <ul style="list-style-type: none"> ■ Vitreous body (normal state) ■ Silicone oil (eye filled with silicone oil after retinal surgery) ■ Post-vitrectomy (eye filled with aqueous humor after vitrectomy)
4	Visual acuity	<p>Drop-down list for selecting the visual acuity. The visual acuity values are shown in the data format which has been determined under "Advanced settings / Parameters, units" [► 152].</p>
5	LVC	<p>Drop-down list for selecting the LVC state. The right choice is essential to obtain a correct formula proposal.</p> <p>If this mandatory entry is not wanted, the "Untreated" LVC default value can be entered under "Advanced settings / Parameters, units" [► 152].</p> <p>The following states may be selected:</p> <ul style="list-style-type: none"> ■ Untreated (untreated eye) ■ LASIK (laser-in-situ keratomileusis) ■ LASEK (laser-epithelial keratomileusis) ■ PRK (photorefractive keratectomy) ■ RK (radial keratotomy)
6	Study ID (optional)	<p>Individually identifiable study ID, e.g. to identify study patients or pathologies. All previously entered study IDs are displayed as a drop-down list.</p>

8.3 Advanced search

Tap the [Advanced] button to display the "Search" dialog window. Additional search criteria can be entered here.

For a search of patient data stored on the device the [All patients] option button must be selected with the DICOM network enabled.

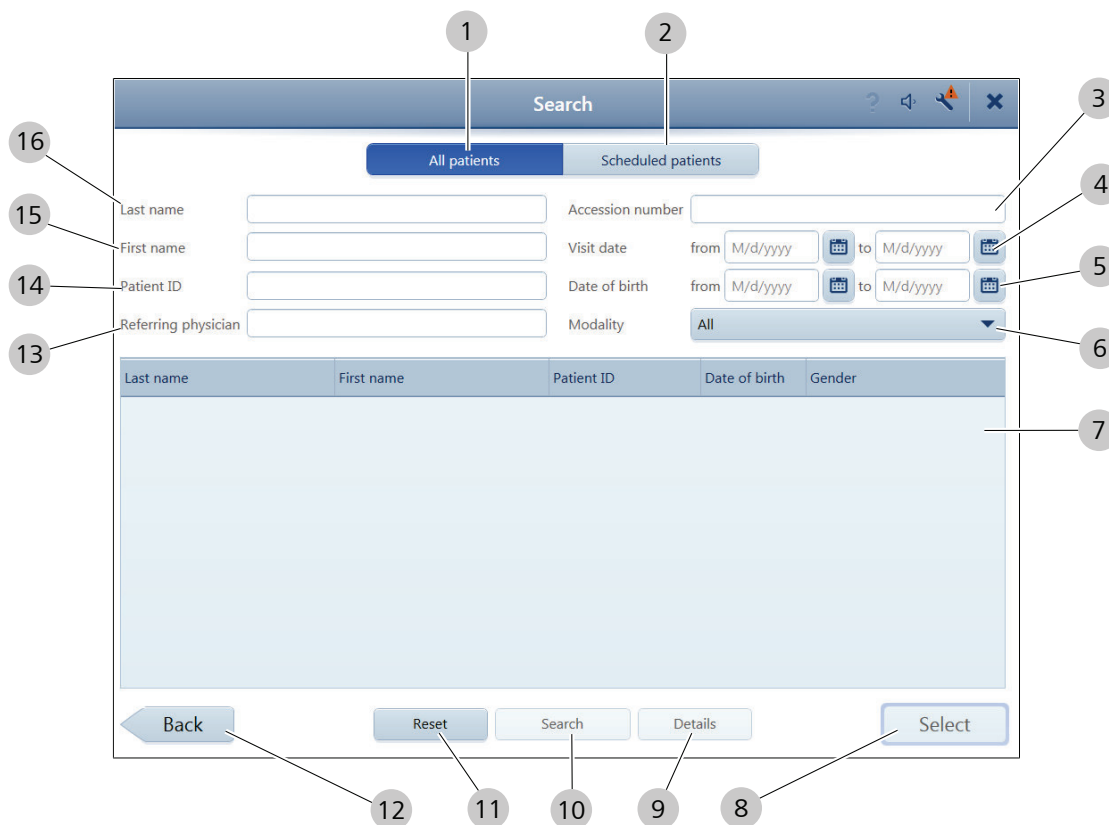


Figure 19: Advanced search

Item	Icon/Name	Explanation
1	All patients (only visible if DICOM network has been enabled)	Search of all patient data stored on the device.
2	Scheduled patients (only visible if DICOM network has been enabled)	Search of the Modality worklist (MWL) of your clinic's information system (see "Advanced MWL search" [► 58]).
3	Accession number	Entering character strings. Only patients whose accession number contains the entered character string will be included in the search.
4	Visit date	Once the "Visit date from / to" selection boxes have been expanded, the starting and ending date of a period can be selected. Search of patients whose date of visit lies within this period.
5	Date of birth	Once the "Date of birth from / to" selection boxes have been expanded, the starting and ending date of a period can be selected. Search of patients whose date of birth lies within this period.

Item	Icon/Name	Explanation
6	Modality	The type of treatment is selected using the "Modality" drop-down list.
7	Search results	All patient data that satisfy the given search criteria will be shown in the "Search results" list box.
8	Select	Returns to the "Patient" [▶ 50] dialog window. The patient data selected in the "Search results" list box will be imported to the "All" list box in the "Patient" [▶ 50] dialog window.
9	Details	Displays the details of an entry in the modality worklist (MWL) of your clinic's information system (only visible if the [Scheduled patients] option button is enabled).
10	Search	By tapping the [Search] button, the search will be started.
11	Reset	The [Reset] button is used to delete all entered search criteria.
12	Back	The [Back] button closes the "Patient" [▶ 50] dialog window without accepting the search results.
13	Referring physician	Entering character strings. Search of patients the name of whose referring physician contains the entered character string.
14	Patient ID	Entering numbers. Search of patients whose patient ID contains the entered numeric string.
15	First name	Entering character strings. Search of patients whose first name contains the entered character string.
16	Last name	Entering character strings. Search of patients whose last name contains the entered character string.

8.4 Advanced MWL search

The "Search" (MWL) dialog window will appear after tapping the [Advanced] button when the DICOM network has been enabled. Additional search criteria can be entered here. Both the DICOM network and the [Scheduled patients] option button must be enabled for the advanced MWL search in the modality worklist (MWL) of your clinic's information system.

The screenshot shows the 'Advanced MWL search' interface. At the top, there is a 'Search' header with icons for search, help, settings, volume, and close. Below the header are two tabs: 'All patients' (labeled 1) and 'Scheduled patients' (labeled 2). The 'Scheduled patients' tab is active. Below the tabs are search filters: 'Last name' (labeled 16), 'First name' (labeled 15), 'Patient ID' (labeled 14), 'Scheduled Station AE Title' (labeled 13, with 'Nithin' entered), 'Procedure ID' (labeled 4), 'Accession number' (labeled 5), and 'Modality' (labeled 6, with 'All' selected in a dropdown). Below the filters is a table of results (labeled 7) with columns: Last name, First name, Patient ID, Date of birth, and Gender. The table contains three rows: 'jack ripper' (Patient ID 858, Date of birth 4/13/1993, Male), 'manju all' (Patient ID 722, Date of birth 2/21/1989, Male), and 'Patient 3' (Patient ID 713, Date of birth 1/31/2004, Male). At the bottom, there are buttons: 'Back' (labeled 12), 'Reset' (labeled 11), 'Search' (labeled 10), 'Details' (labeled 9), and 'Select' (labeled 8).

Figure 20: Advanced MWL search

Item	Name	Explanation
1	All patients (only visible if DICOM network has been enabled)	Search of all patient data stored on the device (see section "Advanced search" [► 57]).
2	Scheduled patients (only visible if DICOM network has been enabled)	Search of the modality worklist (MWL) of your clinic's information system.
3	All	The period in which the treatment date of the sought patient lies is selected using the "All" drop-down list. The following states may be selected: <ul style="list-style-type: none"> ■ Today: The treatment date is the current day. ■ Tomorrow: The treatment date is the following day. ■ Week: The treatment date was within the last week. ■ Time span: The selection boxes "from / to" will be displayed. The starting and ending date of the period can now be selected. Search of patients whose date of visit lies within this period.
4	Procedure ID	Entering numbers. Search of patients whose procedure ID contains the entered numeric string.
5	Accession number	Entering character strings. Only patients whose accession number contains the entered character string will be included in the search.

Item	Name	Explanation
6	Modality	The type of treatment is selected using the "Modality" drop-down list.
7	Search results	All patient data that satisfy the given search criteria will be shown in the "Search results" list box.
8	Select	Returns to the "Patient" [► 50] dialog window. The patient data selected in the "Search results" list box will be imported to the "All" list box in the "Patient" [► 50] dialog window.
9	Details	Displays the details of an entry in the modality worklist (MWL) of your clinic's information system (only visible if the [Scheduled patients] option button is enabled).
10	Search	By tapping the [Search] button, the search will be started.
11	Reset	The [Reset] button is used to delete all entered search criteria.
12	Back	The [Back] button closes the "Patient" [► 50] dialog window without accepting the search results.
13	Scheduled Station AE Title	Entering character strings. Only patients whose Scheduled Station AE Title contains the entered character string will be included in the search.
14	Patient ID	Entering numbers. Search of patients whose patient ID contains the entered numeric string.
15	First name	Entering character strings. Search of patients whose first name contains the entered character string.
16	Last name	Entering character strings. Search of patients whose last name contains the entered character string.

8.5 Measure

8.5.1 Take measurements

General information

After selecting or editing the patient data in the "Patient" [► 50] dialog window and tapping the [Measure] button, the "Measurement" dialog window will open. When using the MWL function the patient ID is displayed instead of "Measure" text in the dialog window.

The IOLMaster 700 measures the eye structures, corneal curvature, pupil diameter and white-to-white distance and visualizes the results as a longitudinal (axial) section of the eye. Additionally, a reference image is captured for the digitally marked alignment of toric intraocular lenses (ZEISS Cataract Suite markless).

Observe the information and instructions in the section "Instructions and precautions to avoid measurement errors" [► 11].

Measurement

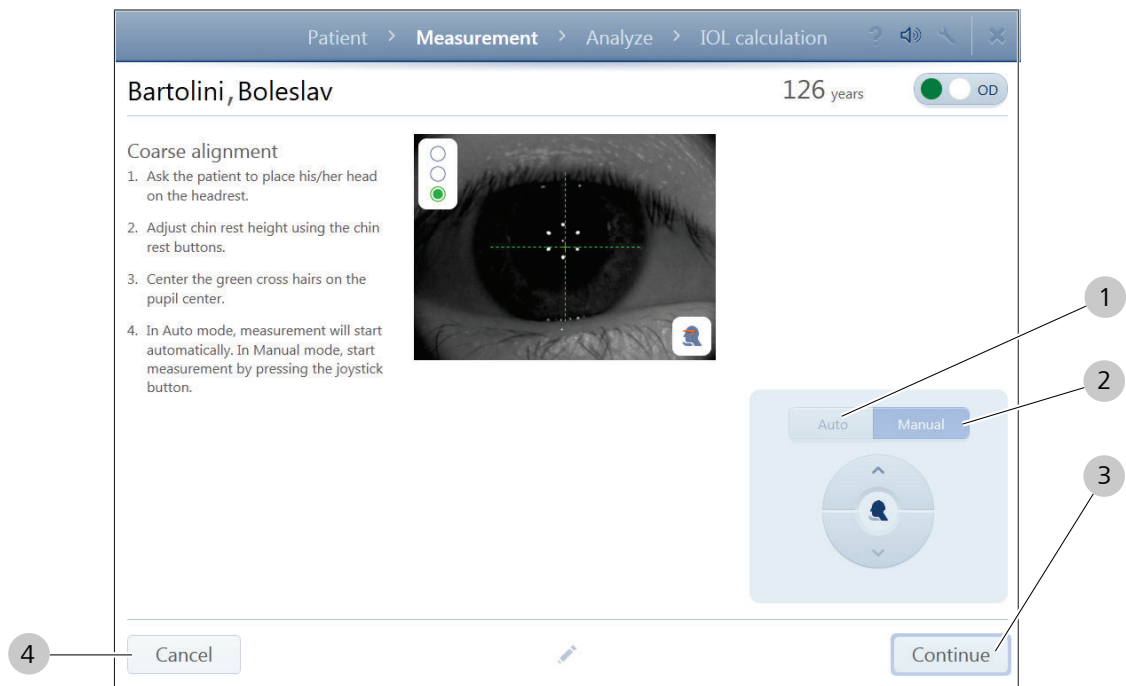


Figure 21: Measurement - Coarse alignment

Item	Name	Explanation
1	Auto	As soon as the device is adjusted correctly, the measurement is triggered automatically. The measurement can also be triggered manually.
2	Manual	The measurement is triggered manually by pressing the button on the joystick.
3	Continue	Tap the [Continue] button to change to the second step of the measurement.
4	Cancel	The measurement procedure is canceled. The "Quality check" [▶ 68] dialog window will be displayed.

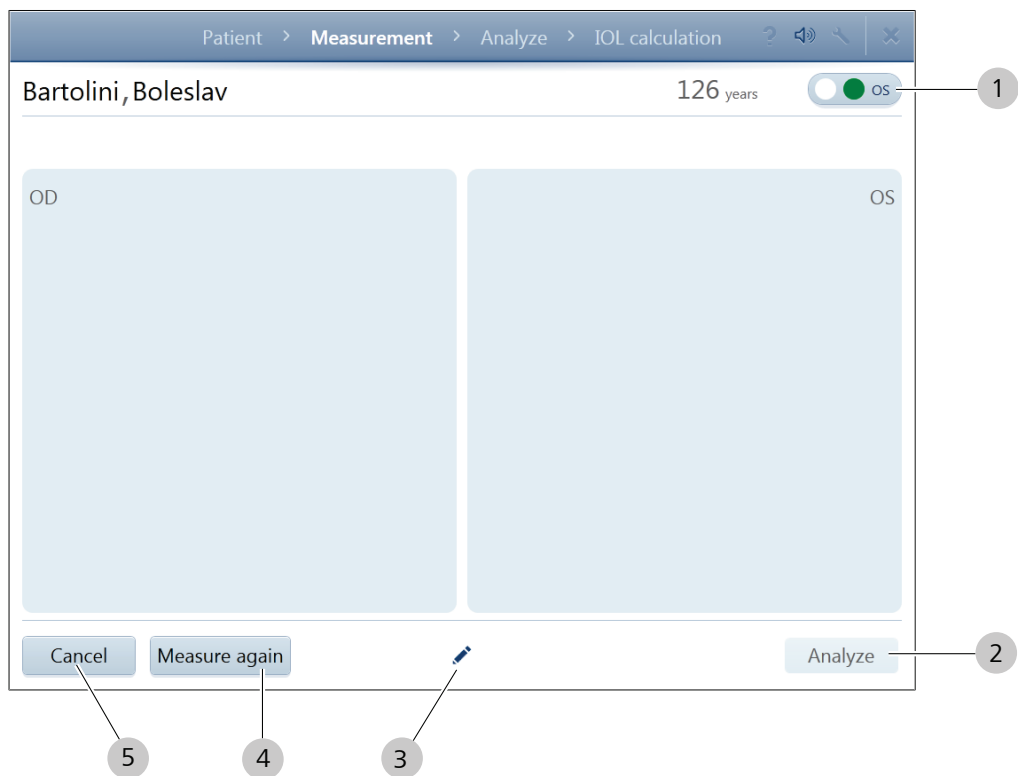











Figure 22: Overview of measurement procedure

Item	Name	Explanation
1	OD / OS	Overview of measurement procedure with all previously performed steps for the left (OS) and right (OD) eye.
2	Analyze	The analysis of the current measurement will be started.
3	Pen	Use this button to add information or notes on the patient or examination.
4	Measure again	The current measurement will be rejected. You can repeat this measurement.
5	Cancel	<p>The following query will be displayed: "All measured data will be deleted. Do you really want to quit the current measurement?"</p> <ul style="list-style-type: none">■ [No]: The "Measurement" dialog window will open with an overview of all completed measurements.■ [Yes]: The current measurement will be rejected and the "Patient" [► 50] dialog window will open.

Adjustment tools

Symbol	Explanation
OD/OS	<p>The position of the device in relation to the eye to be measured is highlighted in green and bold.</p> <ul style="list-style-type: none"> ■ OD: lat. oculus dexter, right eye ■ OS: lat. oculus sinister, left eye <p>By determining the position of the measuring head, the device automatically detects which eye will be measured.</p>
Marks on the head rest	<p>The marks on the head rest are for approximate vertical adjustment of the device in relation to the patient. These marks should be on the same height as the patient's eye canthus.</p>
	<p>Warning symbol which is shown in the bottom right of the live image if the patient's forehead is not rested on the head rest so that a stable working distance cannot be ensured.</p>
	<p>Buttons with arrows for chin rest height adjustment. Tap the arrows to move the chin rest up or down. Alternatively, the chin rest height can be adjusted directly on the head rest using the arrow keys.</p>
	<p>The traffic light (in the upper left corner of the live image) serves to find the optimum measurement position. The green light indicates that the device is correctly aligned and the measurement can be triggered. In Automatic mode, the measurement is triggered as soon as the traffic light shows the green signal. The yellow light means that the alignment of the device is sufficient for measurement but not optimal. In order to achieve good measuring results, the device should be aligned more precisely prior to measurement. In Automatic mode, measurement is not triggered as long as the traffic light is yellow. The red light indicates that the device is not correctly aligned and the measurement will not be triggered. First, the device must be correctly aligned.</p>
	<p>Right directional arrow for measuring head adjustment (at the bottom of the live image)</p>
	<p>Left directional arrow for measuring head adjustment (at the bottom of the live image)</p>
	<p>Directional arrow to front or back for measuring head adjustment (at the bottom of the live image)</p>
	<p>Directional arrow anti-clockwise downwards for measuring head adjustment (at the bottom of the live image)</p>
	<p>Directional arrow clockwise upwards for measuring head adjustment (at the bottom of the live image)</p>

Symbol	Explanation
Centering cross	The centering cross (green) in the live image may also be used for adjusting. The required steps are shown on the left side of the screen.
	This symbol is displayed in the live image of the "Measurement" dialog window. The patient should blink shortly before the measurement. This spreads the tear film regularly over the cornea so that the cornea surface reflects the light evenly.

Trigger measurement

CAUTION!

Risk due to measuring errors

If you trigger measurement on yellow or red traffic light you have to expect increased deviations of the measurement results. This can lead to the calculation of incorrect IOL refractive powers.

- ▶ Avoid measurements on yellow or red traffic lights.
- ▶ Compare the results of several measurements including other measurement methods in such cases.

If the adjustment is correct, measurements are triggered automatically upon selecting [Auto] as soon as the traffic light is on green.

Upon tapping the [Manual] button, measurements are triggered manually by pressing the button on the joystick. The joystick button should only be pressed if the traffic light is on green.

Manually triggering a measurement is possible by pressing the joystick button at any time, independent of the traffic light color and automatic mode.

In rare cases it is possible that the green traffic light display for an optimum measurement setting cannot be reached, e.g. in the case of very uncooperative patients. In these cases measurement can also be triggered if the traffic light is on yellow or red by pressing the joystick button.

Measurement procedure

CAUTION!

Risk due to measuring errors

In the case of poor fixation biometric values cannot be correctly determined by the device. This can lead to the calculation of incorrect IOL refractive powers.

- ▶ Ask the patient whether he/she can see the red fixation light. Ask the patient to look only at the red fixation light.
- ▶ Check the measurement results (e.g. by repeated measurements and / or alternative methods of measurement), if in doubt, whether the patient is able to maintain a stable fixation of the fixation light.

As with the calibration test, the measurement involves three steps (see section "Application guidelines" [▶ 93]).

Step1: Coarse alignment

The measuring head is coarsely adjusted. The reflective pattern of the six LED test marks must be in the center of the cross hair and focused. A WTW image is captured here to detect the iris edge (limbus). In particular, ensure that the visible right and left edge of the iris is not disturbed by reflections from lamps and windows. Instruct the patient to look steadily at the fixation light in the center and ensure that the device head is aligned as accurately as possible. The validity of the WTW measurement depends on this check of correct recognition of the iris edge.

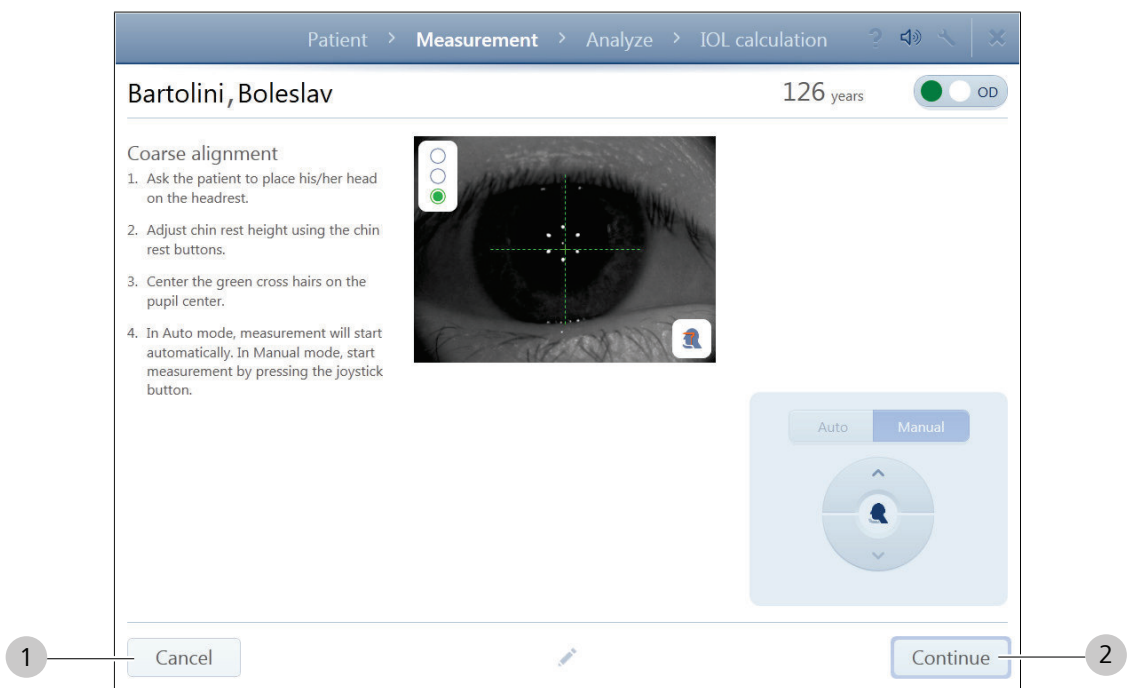


Figure 23: Measurement - Coarse alignment

Item	Name	Explanation
1	Cancel	The dialog window will be closed.
2	Continue	Tap the [Continue] button to start the next step of the measurement procedure. If the "Auto" option has been selected for triggering the measurement, it is not necessary to touch the [Continue] button. By pressing the joystick button you can also proceed with the next measurement step.

Step 2: Fine alignment

For fine adjustment, the reflective pattern from 18 LED test marks is focused using the adjustment tools. Additionally to the live image, the horizontal (to the right of the central live image) and vertical (on the bottom of the central live image) OCT scan is also shown. In each image, an adjustment area is proposed (green rectangle). If the alignment is correct, a yellow dot is displayed within the green rectangular of the adjustment area in the horizontal and vertical OCT scan image. Measurement is triggered automatically or manually depending on the selection made earlier.

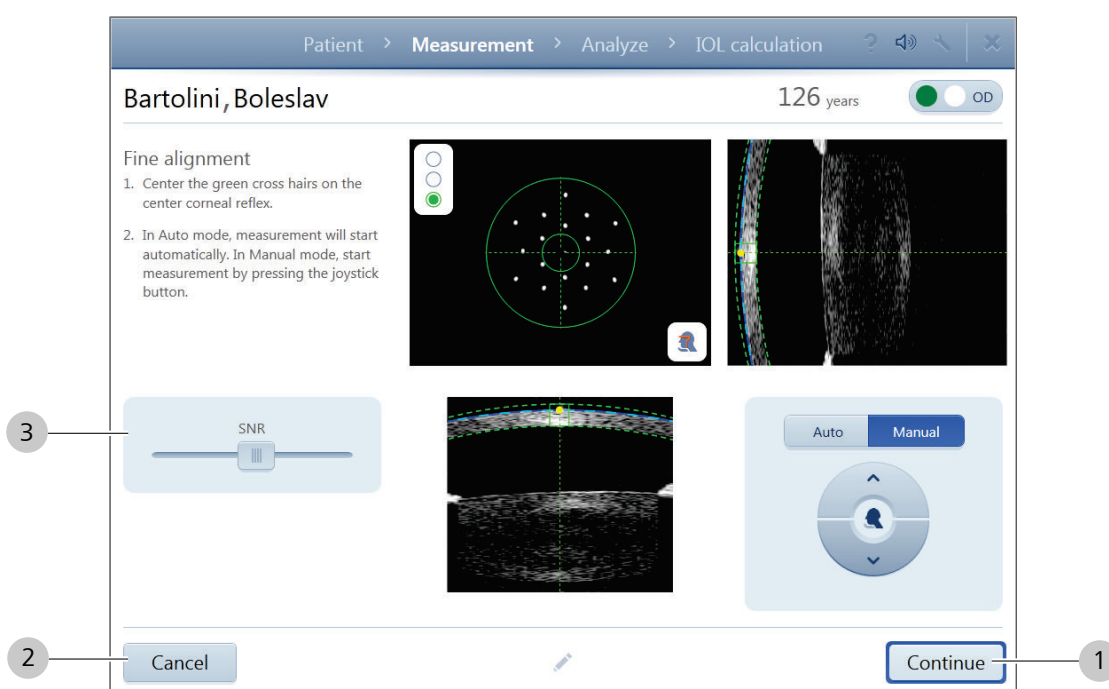


Figure 24: Measurement - fine alignment

Item	Name	Explanation
1	Continue	Tap the [Continue] button to start the next step of the measurement procedure. If the "Auto" option has been selected for triggering the measurement, it is not necessary to touch the [Continue] button. By pressing the joystick button you can also proceed with the next measurement step.
2	Cancel	The dialog window will be closed.
3	SNR slider	During measurement, in some cases, the SNR slider can correct the contrast of the OCT live image resulting in improved eye structure presentations, especially on the posterior lens surface. This function is not needed normally, however, it can be used if automatic detection of the eye structures using measurement marks failed. At the beginning of each measurement, the position of the SNR slider will be reset to the default value.

Step 3: Fixation check scan

For fine adjustment, the reflective pattern from 18 LED test marks is focused using the adjustment tools. Additionally to the live image, the horizontal (to the right of the central live image) and vertical (on the bottom of the central live image) OCT scan is also shown. In each image, an adjustment area is proposed (green rectangle). If the measuring beam is correctly aligned, a yellow dot is displayed within the green rectangular of the adjustment area in the horizontal and vertical OCT scan image. Measurement is triggered automatically or manually depending on the selection made earlier.

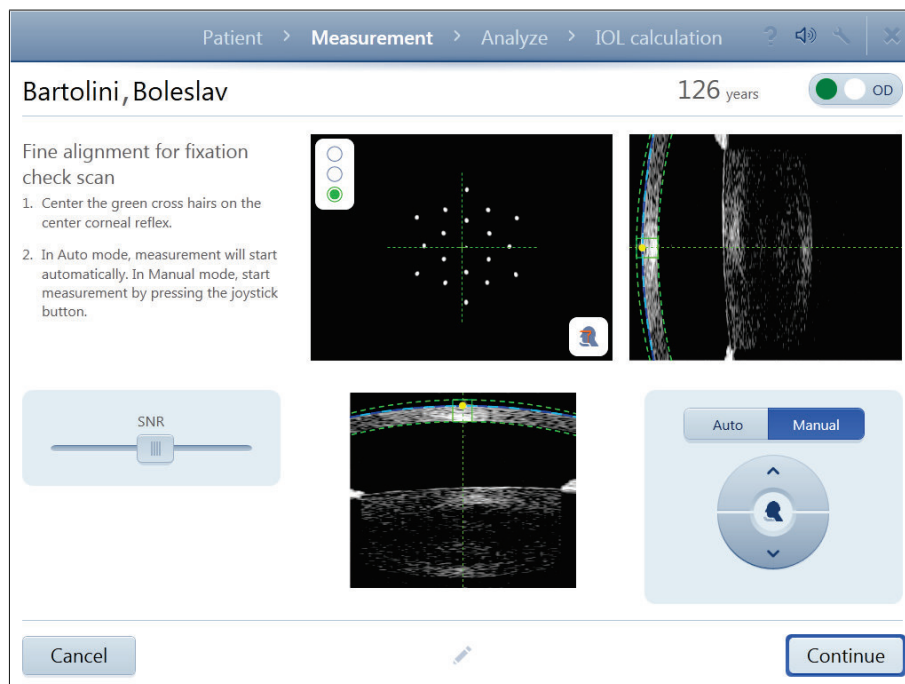


Figure 25: Measurement - Fixation check scan

End measurement

You can repeat the current measurement or measure the other eye after moving the measuring head to the other eye using the joystick.

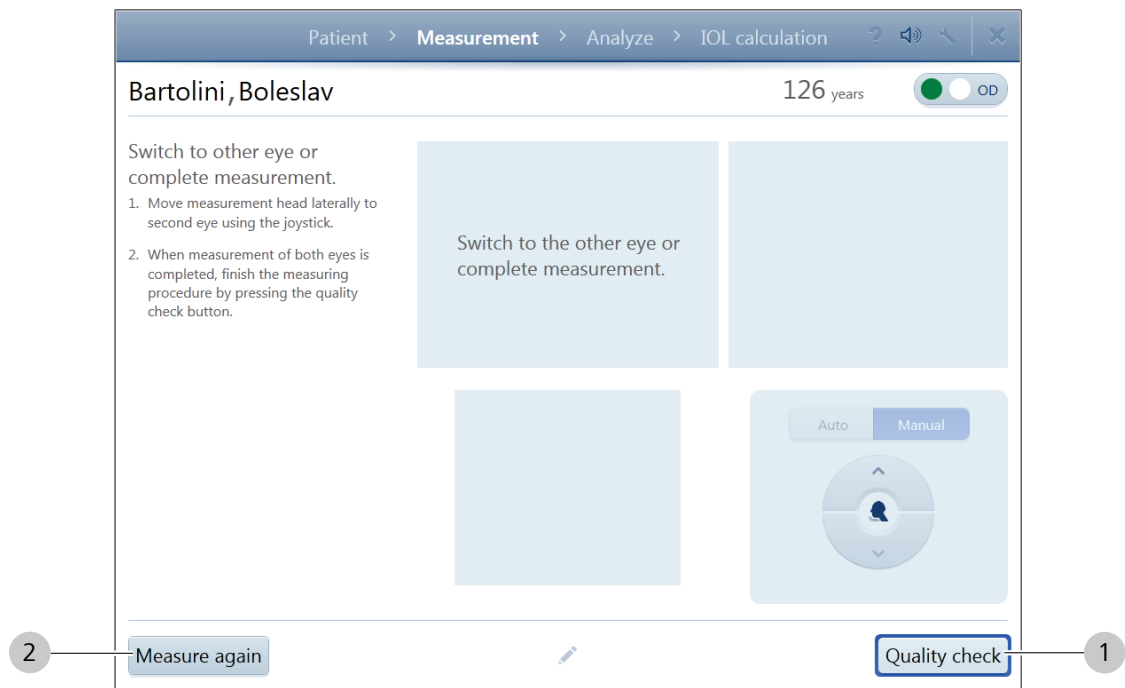


Figure 26: Measurement - change side

Item	Name	Explanation
1	Quality check	Tap this button to display an overview of the currently terminated measurement which helps the user to check the quality of measurement.
2	Measure again	The measurement will be repeated.

8.5.2 Quality check

The “Quality check” dialog allows the user to evaluate the quality of the measurement.

When measuring both eyes, it is not recommended to perform the quality check until both eyes have been measured so that data of both eye can be printed on one printout.

The following information is displayed:

- Captured images
- Measurement marks shown as an overlay on the images
- Signal quality indicators (green, yellow or red)
- Warnings

All elements are relevant to evaluate measurement quality. In addition to the general appearance of the images the user should check whether there are distorted or missing parts in the keratometry image, whether the eyelid was closed in one of the images, whether the foveal pit is missing, or whether unusual morphologies are present in the fixation check scan. Details for assessing the individual images are given below.

The correct positioning of the measurement marks in the images must be checked. Details for assessing the individual images are given below. The indicators for signal quality may indicate a decreased signal quality. The user must take into account all elements in order to decide whether a measure can be accepted, as explained in detail below.

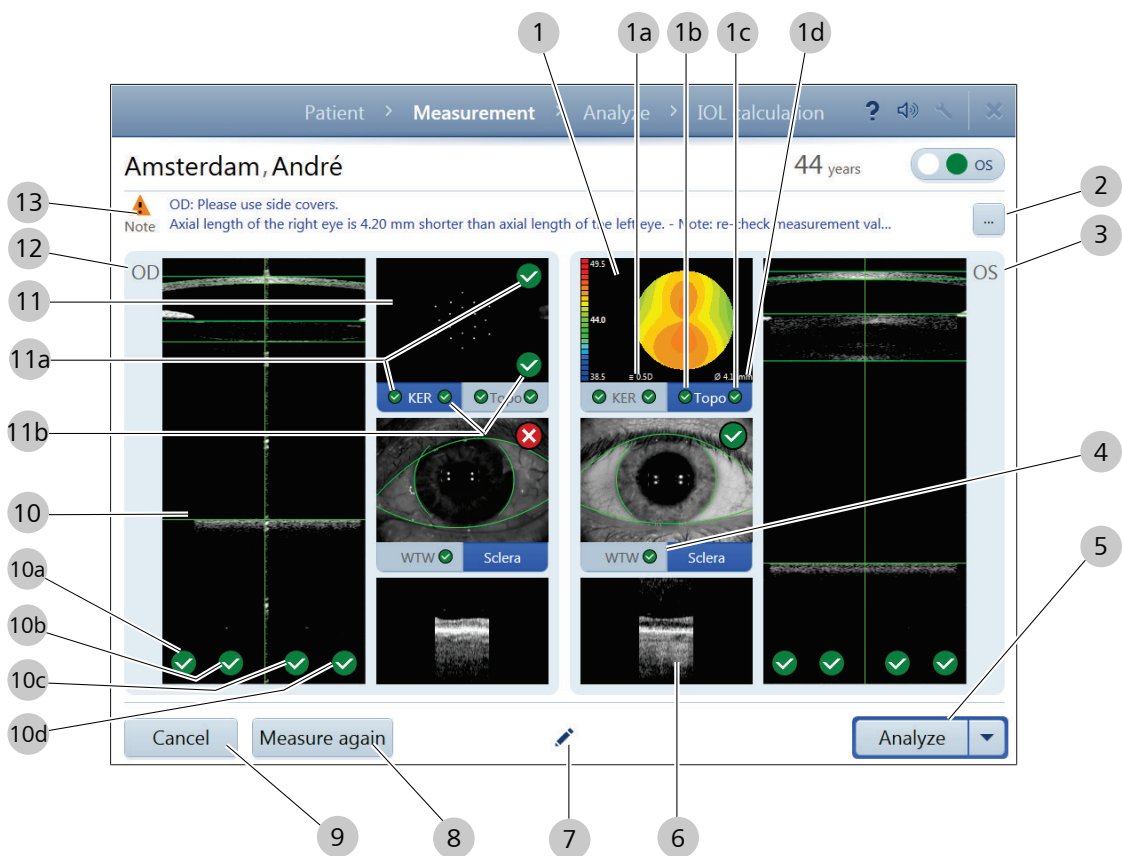


Figure 27: Quality check




Pos.	Name	Explanation
1	Central Topography	Depending on user settings, either the Total Axial Power Map or Anterior Axial Power Map will be displayed.
1a	Increment	Increment for the color scale for Central Topography
1b	Anterior Axial Power Map quality indicator	Indicates measurement quality for the calculation of the Anterior Axial Power Map

Pos.	Name	Explanation
1c	Total Axial Power Map quality indicator	Indicates measurement quality for the calculation of Total Axial Power Map
1d	Central Topography diameter	Diameter of Central Topography Map
2	...	This button will be displayed if the space for notes is not sufficient. After tapping on the button, the complete note will be displayed.
3	OS	Images for the left eye are displayed on the right side of the display.
4	White-to-White/ Sclera	The corneal diameter is determined using the WTW image. In the WTW image, the user must check that the measuring marks are positioned exactly at the edges of the pupil to the iris and the iris to the sclera. The sclera image is used as a reference image for the digitally marked implantation of toric IOL using the ZEISS Cataract Suite markerless system.
5	Analyze	Drop-down list for selecting the next procedure step (Analyze, IOL calculation or start of patient manager).
6	Fixation	Central 1 mm scan on the retina. This is used to check the correct fixation of the patient during measurement.
7	Pen	Use this button to add information or notes on the patient or examination.
8	Measure again	The measurement will be repeated.
9	Cancel	The measurement procedure is canceled.
10	Biometry scan	Used to generate the measured values for CCT (central corneal thickness), ACD (anterior chamber depth), LT (lens thickness) and AL (axial length).
10a	CCT signal quality indicator	Indicates signal quality for the measured value CCT (central corneal thickness)
10b	ACD signal quality indicator	Indicates signal quality for the measured value ACD (anterior chamber depth)
10c	LT signal quality indicator	Indicates signal quality for the measured value LT (lens thickness)
10d	AL signal quality indicator	Indicates signal quality for the measured value AL (axial length)
11	Keratometry	The corneal curvature radii are calculated from the keratometry image. The user must check whether all 18 points are clearly visible in the keratometry image.
11a	Keratometry signal quality indicator	Indicates signal quality for Keratometry measurement values
11b	TK signal quality indicator	Indicates signal quality for Total Keratometry measurement values

Pos.	Name	Explanation
12	OD	Images for the right eye are displayed on the left side of the display.
13	Note	In this area, notes on special eye structures (e.g. long eye) or image capture conditions (e.g. ambient lighting) are displayed.

Signal quality indicators

Each indicator of signal quality refers to an individual measured value (e.g. axis length) or a group of measured values (e.g. keratometry). Each indicator can have the following states:

Symbol	Explanation
 Signal quality OK	A green indicator indicates that the signal quality is OK.
 Signal quality marginal	A yellow indicator indicates that the signal quality of the measurement is impaired. This indication is based on consistency and image quality tests. Measured values with borderline signal quality will appear with an exclamation mark in the IOL calculation window and on printouts.
 Measurement failed	A red indicator indicates that there is no measured value. Failed measurements will appear with three hyphens (---) in the IOL calculation window and on printouts.

The indicators for signal quality should only be used to assess the suitability of a measurement. Prior to applying or rejecting a measurement, the user must check all quality indicators in the "Quality check" window using the images and measuring marks (as described below). This applies to measurements in which all signal quality indicators are green, as well as to those with one or more yellow indicators. If the check of images and measuring marks shows that they are OK, but one or several yellow signal quality indicators are yellow, it is recommended to repeat the measurement prior to any final clinical decision.

NOTE! A green signal quality indicator is no guarantee for the accuracy and reliability of the measurement. The user is responsible for checking the measurement as described.

If repeatedly no measurement values are displayed for axial length, check whether the optical surfaces are contaminated on the device side facing the patient. If there are signs of dirt, clean the optical surfaces as described in section Cleaning [► 210].

Biometry scan

CAUTION!

Risk due to measuring errors

Measuring errors cannot be precluded if the measurement marks are incorrectly positioned, this can lead to the calculation of incorrect IOL refractive powers.

- ▶ Check the correct position of the measurement marks.
- ▶ Repeat the measurement in case of doubt or check the measuring results by using alternative methods, if necessary.
- ▶ Perform a particularly detailed examination of the measurement marks when examining pseudophakic eyes. In these cases the measurement of anterior chamber depth and lens thickness may be inaccurate depending on the intraocular lens and especially with PMMA-IOL.

CAUTION!

Risk due to measuring errors

Due to wrongly detected lens surfaces, the anterior chamber depth and lens thickness are often not reliable, especially with phakic or piggyback IOLs.

- ▶ Do not use values for anterior chamber depth or lens thickness from measurements with phakic IOLs or piggyback IOLs for IOL calculation.
- ▶ Instead, use an IOL calculation formula in these cases that does not integrate the anterior chamber depth and / or lens thickness, e.g. SRK/T, Hoffer Q or Holladay 1. The axial length should be considered when selecting the formula.

The following measured values are determined from the OCT scan (OD is shown on the left and OS on the right of the "Quality check" dialog window):

- CCT (central corneal thickness)
- ACD (anterior chamber depth)
- LT (lens thickness)
- AL (axial length)
- PCS (posterior corneal surface)
- TK
- Total Axial Power Map

The signal quality indicators relate to these measured values.

NOTE! Check the correct position of the measurement marks. If the position is incorrect, there is a risk of measuring errors.

The measuring marks for OCT measurements are correctly positioned, if a green line is located at each surface:

- Green line on the anterior surface of the cornea
- Green line on the posterior surface of the cornea

- Green line on the anterior surface of the lens
- Green line on the posterior surface of the lens
- Green line at the beginning of retinal signal



B scan CCT ✓ ACD ✓ LT ✓ AL ✓

Figure 28: Example of correct position of the measurement marks



B scan CCT ✓ ACD ✓ LT ✓ AL ✓

Figure 29: Example of missing measurement mark for retina signal, discard this measurement

In the white-to-white image, a set of green lines must be on the edge of the pupil to the iris, and a set of green lines must be on the edge of the iris to the sclera.

When measuring aphakic eyes, anterior chamber depth and lens thickness will not be determined.

Keratometry

CAUTION!

Risk due to measuring errors

Distorted or blurred light points can lead to measurement errors for corneal curvature, posterior corneal surface (PCS), Total Keratometry (TK) and Central Topography. This can lead to the calculation of incorrect IOL refractive powers.

- ▶ Make sure that the light points in the images are not deformed.
- ▶ Make sure that no points are missing in the keratometry image.
- ▶ Make sure that the patient has his/her eyes wide open.
- ▶ Repeat the measurement or check the results, if necessary, with alternative measurement methods in the case of deformed or blurred light points.

See also section “Notes on keratometry” [► 94].

The corneal curvature radii are determined from the keratometry image (OD is shown on the upper left side and OS on the upper right side of the quality check screen).

The user must check whether all 18 points are clearly visible in the keratometry image. If one of the points has blurry edges, is distorted, not round or missing, the measurement must be checked and repeated.

The user must check that the patient has his/her eyes wide open.

Please note that the keratometry only includes reliable data from all three zones (i.e. all 18 points) if the keratometry signal quality indicator is green.

White-to-white (WTW)

See also section “Notes on white-to-white measurement” [► 99].

The corneal diameter is determined from the WTW image (OD is shown in the center on the left and OS in the center on the right of the quality check screen layout).

In the WTW image, the user must check that the measuring marks are positioned exactly at the edges of the pupil to the iris and the iris to the sclera. Each set of measuring marks must be exactly positioned on these edges. If iris and pupil edges are not detected correctly, the measurement should be discarded and repeated.

Check the correct position of the measurement marks. If the position is incorrect, there is a risk of measuring errors.

Fixation

See also section "Notes on fixation check" [► 99].

⚠ CAUTION!

Risk due to measuring errors

Unstable fixation can lead to measuring errors and the calculation of incorrect IOL refractive powers.

- Check that the patient fixates correctly and the fovea is visible in the fixation check scan.
- Repeat the measurement in case of doubt or check the measuring results by using alternative methods, if necessary.

The fixation check scan is used to evaluate correct fixation of the patient during measurement. A central 1 mm scan of the retina will be performed (OD is shown on the lower left side and OS on the lower right side of the quality check screen layout).

Good fixation is shown by a depression in the center, the so-called foveal pit. If the foveal pit (see image on the right) is clearly discernible, the patient has fixated properly during the scan. If it cannot be detected correctly (see image on the left), the patient has either not properly fixated or the morphology of the fovea is unusual. In this case, measurement should be repeated and the patient be instructed to fixate on the fixation light in the device. If the patient cannot fixate during several measurements the user should verify if there may be another problem with the patient which requires special examination.

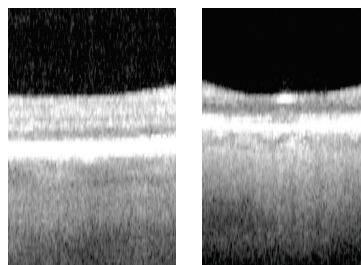


Figure 30: Insufficient (left) and correct (right) fixation

Sclera

The sclera image is used as a reference image for the digitally marked implantation of toric IOL using the ZEISS Cataract Suite markerless system.

The signal quality indicator of the sclera image is also dependent of the quality indicator of the keratometry.

In the "Advanced settings / Measurement" [► 166] dialog area you can enter the value of corneal astigmatism which determines a clinical indication of this application. If the defined value is reached, a sclera image is automatically triggered.

To capture a good sclera image, it is important that the patient open his/her eyes wide, the lighting in the room is not too bright and the vessels in the patient's eye can be recognized (no sclera image is captured if vessels cannot be recognized). The stray light protective cover can be used to reduce the influence of ambient lighting on image quality.

Enlarged view of images

Tap the images in the "Quality check" window to enlarge them. Individual images can be additionally zoomed in or out using the touch screen functions. The images are arranged in a row. From left to right, you see the biometry scans (0°, 30°, 60°, 90°, 120° and 150°), the fixation check scan, three keratometer measurements, the Anterior Axial Power Map, the Total Axial Power Map, followed by a sclera image and a white-to-white image, first of the right and then of the left eye.



Figure 31: Enlarged view of images

By horizontally arranging the A-scans of scan pattern which has not been captured horizontally, the B-scan proportions in the Quality check may appear distorted, i.e. cornea and lens appear too flat. A very small section of the retina appears as a larger area. This representation does not have any influence of the plausibility check of biometric parameters along the visual axis.

8.6 Analyze

In the "Analyze" dialog window, B-scans, more images and measured values are displayed to support the user in evaluating the measurement. In this window, the user must check whether the measured values are plausible and consistent for both eyes (if both OD and OS were measured).

By tapping on the [Analyze] button in the "Measurement" dialog window, the "Analyze" dialog window will be opened after measurement and prior to IOL calculation. The "Analyze" dialog window can also be opened after IOL calculation.

The images of biometric scans, keratometry, Central Topography, WTW and sclera as well as the fixation check scans are displayed separately for the right and left eye. The following information is shown in the "Analyze" dialog window:

- Captured images
- Measurement marks shown as an overlay on the images
- Signal quality indicators (green, yellow or red)
- Warnings
- Measured values
- Standard deviation (SD) values of several individual measurements

All elements are relevant to evaluate measurement quality. In addition to the general appearance of the images the user should check whether there are distorted or missing parts in the keratometry image, whether the eyelid was closed in one of the images, whether the foveal pit is missing, or whether unusual morphologies are present in the fixation check scan. Details for assessing the individual images are given below.

The correct positioning of the measurement marks in the images must be checked. Details for assessing the individual images are given below.

The indicators for signal quality may indicate a decreased signal quality. The user must take into account all elements in order to decide whether a measure can be accepted, as explained in detail below.

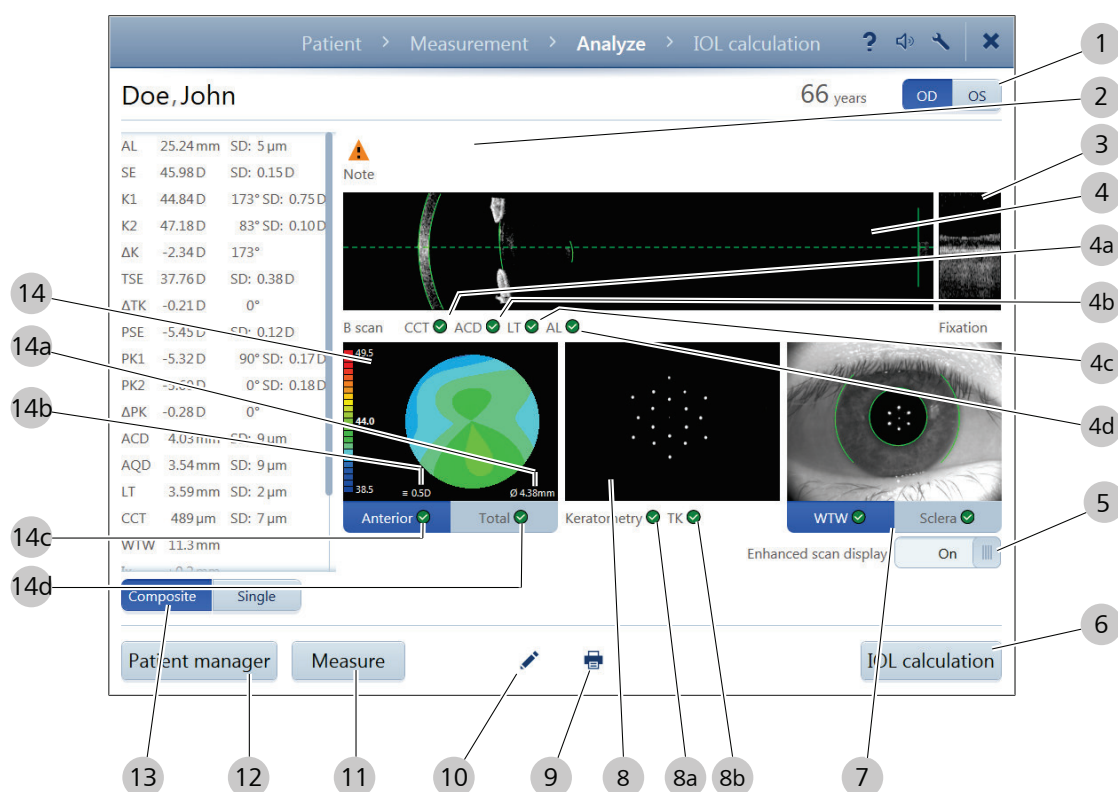





Figure 32: Analyze

Item	Name	Explanation
1	OD / OS	Tap the [OD / OS] button to alternate between the Analyze display of the right ([OD], Latin: oculus dexter) and left ([OS], Latin: oculus sinister) eye.
2	Note	In this area, notes on special eye structures (e.g. long eye) or image capture conditions (e.g. ambient lighting) are displayed.
3	Fixation	Central 1 mm scan on the retina. This is used to check the correct fixation of the patient during measurement.
4	B-scan	Calculates the measured values for CCT (central corneal thickness), ACD (anterior chamber depth), LT (lens thickness) and AL (axial length), in the quality check image OD is displayed on the left and OS on the right.
4a	CCT signal quality indicator	Indicates signal quality for the measured value CCT (central corneal thickness)
4b	ACD signal quality indicator	Indicates signal quality for the measured value ACD (anterior chamber depth measured from the anterior corneal surface to the anterior lens surface)
4c	LT signal quality indicator	Indicates signal quality for the measured value LT (lens thickness)
4d	AL signal quality indicator	Indicates signal quality for the AL measured value (anterior chamber depth measured from the anterior corneal surface to the RPE)

Item	Name	Explanation
5	Enhanced scan display	Select a higher scan resolution by using the [Enhanced scan display] option button. If the option button is enabled, three single images of biometric scans are superimposed at 0°, 30°, 60°, 90°, 120° and 150° showing more details in the scan as compared to the display if the function is disabled.
6	IOL calculation	Tap this button to open the "IOL calculation" [► 84] dialog window and perform or edit the calculation of the intraocular lens.
7	White-to-White/ Sclera	The corneal diameter is determined using the WTW image. In the WTW image, the user must check that the measuring marks are positioned exactly at the edges of the pupil to the iris and the iris to the sclera. The sclera image is used as a reference image for the digitally marked implantation of toric IOL using the ZEISS Cataract Suite markerless system.
8	Keratometry	The corneal curvature radii are calculated from the keratometry image. The user must check whether all 18 points are clearly visible in the keratometry image.
8a	Keratometry signal quality indicator	Indicates signal quality for Keratometry measurement values
8b	TK signal quality indicator	Indicates signal quality for Total Keratometry measurement values
9	Print	Tap the [Print] button to print out biometric data and analysis for the selected eye. In the "Advanced settings / Printout" [► 170] dialog area you can define the print layout.
10	Pen	If you have entered notes for the measurement or IOL calculation previously, these will be displayed here. They can only be read.
11	Measurement	Use this button to open the "Measurement" [► 60] dialog window and perform a new measurement.
12	Patient manager	Use this button to open the "Patient" [► 50] dialog window.
13	Composite / Single	Tap the [Composite/Single] button to define the display of measured values. Use the [Composite] option to display measured values as the non-arithmetic average of single measurements. Use the [Single] option to display measurement values as single measured values and additionally the corresponding composite value in bold.
14	Central Topography	Depending on user settings, either the Total Axial Power Map or Anterior Axial Power Map will be displayed.
14a	Central Topography diameter	Diameter of Central Topography Map
14b	Increment	Increment for the color scale for Central Topography
14c	Anterior Axial Power Map quality indicator	Indicates measurement quality for the calculation of the Anterior Axial Power Map
14d	Total Axial Power Map quality indicator	Indicates measurement quality for the calculation of Total Axial Power Map

Signal quality indicators

Each indicator of signal quality refers to an individual measured value (e.g. axis length) or a group of measured values (e.g. keratometry). Each indicator can have the following states:

Symbol	Explanation
 Signal quality OK	A green indicator indicates that the signal quality is OK.
 Signal quality marginal	A yellow indicator indicates that the signal quality of the measurement is impaired. This indication is based on consistency and image quality tests. Measured values with borderline signal quality will appear with an exclamation mark in the IOL calculation window and on printouts.
 Measurement failed	A red indicator indicates that there is no measured value. Failed measurements will appear with three hyphens (---) in the IOL calculation window and on printouts.

The indicators for signal quality should only be used to assess the suitability of a measurement. Prior to applying or rejecting a measurement, the user must check all quality indicators in the "Analysis" window using the images and measuring marks (as described below) check. This applies to measurements in which all signal quality indicators are green, as well as to those with one or more yellow indicators. If the check of images and measuring marks shows that they are OK, but one or several yellow signal quality indicators are yellow, it is recommended to repeat the measurement prior to any final clinical decision.

NOTE! A green signal quality indicator is no guarantee for the accuracy and reliability of the measurement. The user is responsible for checking the measurement as described.

Explanation of measured values:

The following measured values are determined from the OCT scan (OD is shown on the left and OS on the right of the "Quality check" dialog window):

- CCT (central corneal thickness in μm)
- ACD (anterior chamber depth in mm, measured from anterior corneal surface to anterior lens surface)
- LT (lens thickness in mm)
- AL (axial length in mm, measured from the anterior corneal surface to the RPE)

- PCS (posterior corneal surface)
- TK (Total Keratometry)

When measuring aphakic eyes, anterior chamber depth and lens thickness will not be determined.

NOTE! When measuring pseudophakic eyes, the measurement of anterior chamber depth and lens thickness may be inaccurate depending on the intraocular lens - especially in case of PMMA-IOL. The measurement marks should be checked very carefully to ensure correct positioning.

Corneal curvatures can be displayed in diopters (D) or as radii in mm. These settings can be changed under "Advanced settings / Parameters, units" [► 152].

Designation	Explanation
Keratometry	
KER R1/K1 R2/K2	Corneal radii (R1/K1, R2/K2) of the two main section directions
KER R/SE	Mean value of corneal radii (R/SE in mm/D)
KER Cylinder (ΔK)	Corneal astigmatism (ΔK difference between corneal radii in the two main section directions) in diopters (D)
WTW image	
WTW diameter	Corneal diameter (white-to-white)
WTW center	Center coordinates of the limbus in relation to the visual axis (vector from limbus center to vertex)
Pupil diameter	Pupil diameter
Pupil center	Center coordinates of the pupil in relation to the visual axis (vector from pupil center to vertex)

The distance between the pupil center (P_x , P_y) from the corneal vertex (highest point of the cornea with fixation to device fixation light, also known as 1st Purkinje reflex), also referred to as CW-chord or Chang-Waring chord, can be used to evaluate the axis symmetry of the eye (deviation of optical axis from visual axis). The axis symmetry of the human eye is often described using the kappa angle. However, contradictory definitions of kappa angle can be found in the literature [1]. In addition, depending on definition and device technology, accurate measurement is not possible or only approximatively, which makes consistency and the clinical benefit of the kappa angle questionable. Cross-device consistency and clinical utility of the CW-chord is described in detail under [1] [► 233], [2] [► 233], [3] [► 233].

Further information on clinical markers for centering in refractive treatments and devices can be found in the following references: [1] [► 233], [2] [► 233], [3] [► 233]

Fixation

CAUTION!

Risk due to measuring errors

Unstable fixation can lead to measuring errors and the calculation of incorrect IOL refractive powers.

- ▶ Check that the patient fixates correctly and the fovea is visible in the fixation check scan.
- ▶ Repeat the measurement in case of doubt or check the measuring results by using alternative methods, if necessary.

The fixation check scan is used to evaluate correct fixation of the patient during measurement. A central 1 mm scan of the retina will be performed (OD is shown on the lower left side and OS on the lower right side of the quality check screen layout).

Good fixation is shown by a depression in the center, the so-called foveal pit. If the foveal pit (see image on the right) is clearly discernible, the patient has fixated properly during the scan. If it cannot be detected correctly (see image on the left), the patient has either not properly fixated or the morphology of the fovea is unusual. In this case, measurement should be repeated and the patient be instructed to fixate on the fixation light in the device. If the patient cannot fixate during several measurements the user should verify if there may be another problem with the patient which requires special examination.

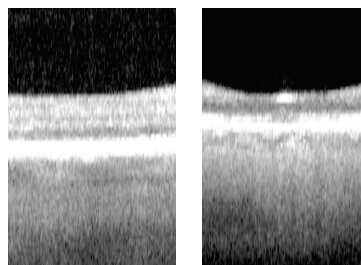


Figure 33: Insufficient (left) and correct (right) fixation

Sclera

The sclera image is used as a reference image for the digitally marked implantation of toric IOL using the ZEISS Cataract Suite markerless system.

The signal quality indicator for the sclera image (OD in the center on the left, OS in the center on the right) is dependent on the keratometry quality indicator.

In the "Advanced settings / Measurement" [▶ 166] dialog area you can enter the value of corneal astigmatism which determines a clinical indication of this application. If the defined value is reached, a sclera image is automatically triggered.

To capture a good sclera image, it is important that the patient open his/her eyes wide, the lighting in the room is not too bright and the vessels in the patient's eye can be recognized (no sclera

image is captured if vessels cannot be recognized). The stray light protective cover can be used to reduce the influence of ambient lighting on image quality.

The display of measured values can be adjusted to your needs in "Advanced settings / Analyze".

Enlarged view of images

For improved evaluation of the measurement quality you can tap the desired image to open an enlarged presentation.

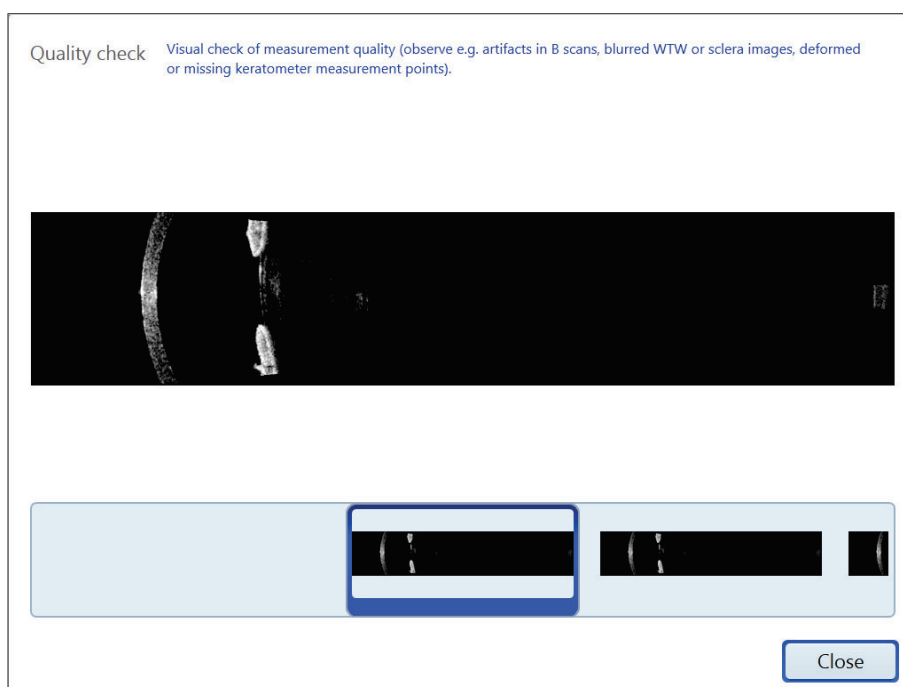


Figure 34: Enlarged view of images

8.7 IOL calculation

CAUTION!

Risk arising from incorrect operation

The use of unsuitable IOL constants can lead to the calculation of incorrect IOL powers.

- ▶ Use only constants optimized for optical biometry for calculating options for intraocular lens power to be implanted using the device readings.
- ▶ Use only suitable lens constants in case of IOL calculation with ultrasound applanation readings.
- ▶ Review and refine regularly the IOL constants used.

CAUTION!

Risk arising from incorrect operation

If an incorrect LVC mode has been selected this may lead to the calculation of incorrect IOL refractive powers.

- ▶ Use the Haigis Suite and Barrett Suite with LVC mode myopic only for eyes which were previously treated by LASIK, PRK or LASEK for myopia. Use the LVC mode Hyperopic for eyes which were previously treated by LASIK, PRK or LASEK for hyperopia.
- ▶ Do not use the Haigis Suite to calculate IOLs for eyes that were treated by RK. Use the Barrett Suite instead.
- ▶ Use only the corneal radii measured with the IOLMaster 700 for Haigis Suite with LVC mode myopic or hyperopic.

CAUTION!

Risk due to measuring errors

Due to wrongly detected lens surfaces, the anterior chamber depth and lens thickness are often not reliable, especially with phakic or piggyback IOLs.

- ▶ Do not use values for anterior chamber depth or lens thickness from measurements with phakic IOLs or piggyback IOLs for IOL calculation.
- ▶ Instead, use an IOL calculation formula in these cases that does not integrate the anterior chamber depth and / or lens thickness, e.g. SRK/T, Hoffer Q or Holladay 1. The axial length should be considered when selecting the formula.

CAUTION!

Risk arising from incorrect operation

For determining the human corneal refractive power Total Keratometry (TK) uses a toric model which measures both the anterior and posterior corneal surface. However, some IOL calculation formulae use nomograms to model the posterior corneal surface or compensate for the change in relationship of the anterior and posterior corneal surface following refractive surgery. If these formulae were to be used for IOL calculation with TK by means of manual transfer to IOL calculation software (including the application software of the IOLMaster 700), this would result in double compensation and thus the calculation of incorrect IOL refractive powers.

- ▶ In eyes **without** prior corneal surgery (in particular without refractive laser treatment) use only IOL calculation formulae which are integrated into the IOLMaster 700 application software when calculating **non-toric IOLs** with TK instead of Keratometry (e.g. Haigis, Holladay 1/2, SRK/T, Hoffer Q, Barrett Universal II with TK). The Barrett Universal II formula (part of the Barrett Suite) should not be used directly with TK. If you select TK to calculate non-toric IOLs in the Barrett Suite, the

application software will automatically use the formula "Barrett Universal II with TK", a variant of the Barrett Universal II formula designed for use with TK.

- ▶ Please note that there may be discrepancies in the suggested spherical IOL refractive power between keratometry and TK. The reasons for this are deviations in the individual eye from the Gullstrand model and measurement noise.
- ▶ For the calculation of **toric IOLs** for eyes **without** previous surgery (in particular without refractive laser treatment) of the cornea use only the Haigis-T or "Barrett Toric with TK" IOL calculation formulae. In the application software of the IOLMaster 700 the Haigis-T formula is provided as part of the Haigis Suite, and the "Barrett Toric with TK" formula is provided as part of the Barrett Suite.
- ▶ IOL calculation formulae using a nomogram for modeling the posterior corneal surface like the Barrett Toric Calculator should not be used directly with TK. Using the Barrett Toric Calculator together with TK would lead to a double correction and thus to an incorrect calculation of the corneal refractive power. The Barrett Toric Calculator, available as Barrett Toric in the Barrett Suite in the application software of the IOLMaster 700, does not allow IOL calculations with TK. Instead, the calculation is performed using the "Barrett Toric with TC" formula, which was developed for use with TK.
- ▶ Also, please observe that differences may arise in the suggested toric IOL refractive power between keratometry and TK. The reasons for this are deviations in the individual eye from the Gullstrand model and measurement noise. Because the astigmatism of the posterior corneal surface often deviates from the Gullstrand model, differences in particular in the cylinder and axis are to be anticipated.
- ▶ In eyes **with** prior corneal surgery (in particular refractive laser treatment), IOL calculation with TK should be used only with the latest generation formulae. In the IOLMaster 700 application software these are the Haigis (Haigis Suite with LVC mode "none"), the Holladay 2 and the "Barrett True-K with TK" (part of Barrett Suite) formulae. Older generation formulae (SRK/T, Holladay 1 and Hoffer Q) requiring a so-called "double K-correction" are not suitable for IOL calculation with TK **with** prior corneal surgery.

- ▶ TK must not be used with established IOL calculation formulae which were developed for classic keratometry values for eyes **with** prior refractive surgery. This includes in particular the Haigis-L (part of Haigis Suite) and Barrett True-K formulae (part of Barrett Suite). Using TK with these formulae would lead to a double correction and thus to an incorrect calculation of the corneal refractive power.
- ▶ Use of standard formulae for IOL calculation (including TK) is currently not recommended for eyes which have been treated with the ReLEx® smile or DMEK procedures.

After selecting the measured data of a patient in the "Patient / Measurements" [▶ 51] dialog window or after Quality check [▶ 68] of a measurement, tap the [IOL calculation] button to open the "IOL calculation" dialog window.

The biometric measured values for the right eye (OD) are displayed on the left side of the display and for the left eye (OS) on the right side of the display.

For each eye, the IOL calculation is made separately. For better orientation, the measured values of the selected eye are displayed on a white background, the data of the other eye are greyed out. Additionally, the selected eye is shown in bold and green letters in the upper right corner of the display.

Beneath the measured values, the lens state and LVC state are shown for each eye.

The following IOL calculation formulae are available on the IOLMaster 700:

- SRK/T [4] [▶ 233]
- Hoffer Q [5] [▶ 233]
- Holladay I [6] [▶ 233]
- Holladay II [7] [▶ 233],[8] [▶ 233],[9] [▶ 233]
- Haigis [10] [▶ 233]
- Haigis T [11] [▶ 233]
- Haigis L [12] [▶ 233],[13] [▶ 233],[14] [▶ 233]
- Haigis TL
- Barrett Universal II [15] [▶ 234]
- Barrett Universal II with TK [21] [▶ 234]
- Barrett Toric [16] [▶ 234],[17] [▶ 234]
- Barrett Toric with TK [21] [▶ 234]
- Barrett True-K [18] [▶ 234]
- Barrett True-K with TK [22] [▶ 234]

Tap the “Measured values” dialog area on the right or left side of the screen to alternate between the eyes.

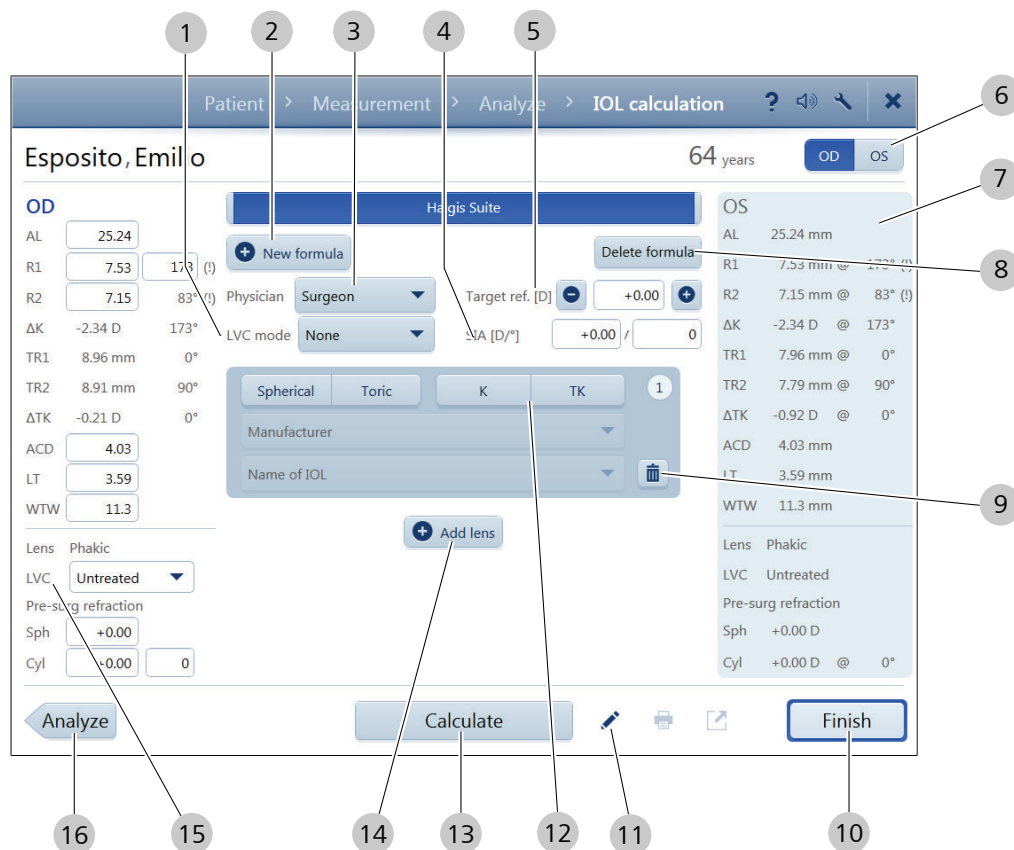


Figure 35: IOL calculation

Item	Name	Explanation
1	LVC mode	In the “LVC mode” drop-down list you can select if the patient had refractive corneal surgery prior to treatment (select “myopic” or “hyperopic” ablation profile) or not (None).
2	New formula	Tap [+ New formula] to select the calculation formulae to be applied. Haigis Suite (including Haigis, Haigis-L, Haigis-T and Haigis-TL), Barrett Suite (including Barrett Universal II, Barrett Universal with TK, Barrett-Toric, Barrett Toric with TK, Barrett True-K and Barrett True-K with TK), Holladay 1, Holladay 2, Hoffer®Q, SRK®/T and Multifomula are proposed for selection. The selection of the formula from the Haigis and Barrett Suite is done automatically depending on the selected IOL and the LVC status of the eye.
3	Physician	Select the user in the “Physician” drop-down list. Either intraocular lenses and their constants have already been entered for this user or they can be created or imported in “Advanced settings / IOL management” [▶ 155].

Item	Name	Explanation
4	SIA [D/°]	SIA is the surgically induced astigmatism during treatment. When working with SIA, the value for surgically induced astigmatism [D] (which is expected post-surgery) may be entered in the "SIA [D / °]" input field together with the axis [°]. The axis marks the position of the incision. The entered SIA value will be considered in the IOL calculation and affects the IOL refractive power. The SIA value and the axis can be entered separately for each eye. If values are entered only for one eye, these will not be automatically applied to the other eye! It is recommended to perform the IOL calculation with and without SIA to check the difference for the IOL calculation result. Should the IOL calculation be performed without SIA, "0" must be entered in both fields.
5	Target ref. [D]	The target refraction can be set individually for both eyes. The selected settings will be saved when starting IOL calculation and will be applied to all future calculations.
6	OD/OS	Tap the [OD / OS] button to alternate between the analysis display of the right and left eye: <ul style="list-style-type: none"> ■ OD: lat. oculus dexter, right eye ■ OS: lat. oculus sinister, left eye
7	Measured values	If a measurement value is marked with (!), it is an uncertain value which is marked as "uncertain" in the Quality check and in the Analyze screen. The user should check values marked with (!) very carefully and repeat the measurement if required.
8	Delete formula	Tap [Delete formula] to hide selected formulae so that they are not used for intraocular lens power calculation.
9	Delete	Tap this button to delete selected intraocular lenses from the selection list.
10	Finish	Tapping this button closes the IOL calculation and opens the "Patient" ► 50 dialog window.
11	Pen	Tap this button to enter special comments on IOL calculation. Use the on-screen or external keyboard to enter your comments. The comments you enter will be printed, but not stored in the database. When exiting the "IOL calculation" dialog window, the entries will not be stored.
12	K / TK (optional)	K: calculation based on Keratometry values TK: calculation based on Total Keratometry values
13	Calculate	Tap the [Calculate] button to start IOL calculation. According to the calculation formula, the selected intraocular lenses will be calculated. After selecting the calculation formula (Haigis Suite, Barrett Suite, Hoffer®Q, Holladay 1, Holladay 2, SRK®/T or Multiformula) the calculation results will be displayed.
14	+ Add lens	Tap [+ Add lens] to select intraocular lenses for calculation. Intraocular lenses should be manually created (IOL manager, see "Advanced settings / IOL management" ► 155) for each user or imported (Start ULIB import). An intraocular lens manufacturer can be selected from the drop-down list with the names of manufacturers. Then an intraocular lens is selected from the drop-down list with the names of IOLs. Tap [Spherical/Toric] to assign an IOL type. The intraocular lenses are numbered in the selection list.

Item	Name	Explanation
15	LVC	In this drop-down list the LVC state can be selected.
16	Analyze	This button opens the “Analyze” [► 77] dialog window.

Ensure that the lens selection is not changed and the selected lenses displayed in the usual order.

The measurement values can be edited by tapping the appropriate field. Edited values are marked with an *. If the IOL calculation window is closed, the entries in edited fields will be canceled. When re-starting the IOL calculation, the measured values are displayed in these fields.

Edited values cannot be saved. However, they are shown in the IOL calculation printout and will be marked with an *.

CAUTION! When editing values, the user is responsible for the correctness and precision of the values, especially when entering keratometry values manually.

Edited measurement values appear with an asterisk (*) in the printout of the lens calculation and the lens calculation is no longer based on the IOLMaster 700 measurement values!

Edited measurement values are not stored in the database of the IOLMaster 700. Edited measurement values are deleted when closing the IOL calculation window; they may be replaced by values determined by the device when you reopen the IOL calculation window. When you reopen the IOL calculation window, the edited readings must be entered again.

CAUTION! The IOL calculation is valid only if the biometric measurement was correct, an appropriate IOL calculation formula was selected and the IOL constants were optimized for the specific application in advance.

With certain combinations of “LVC state” and “LVC mode” entries, the Haiqis Suite does not provide an IOL calculation result.

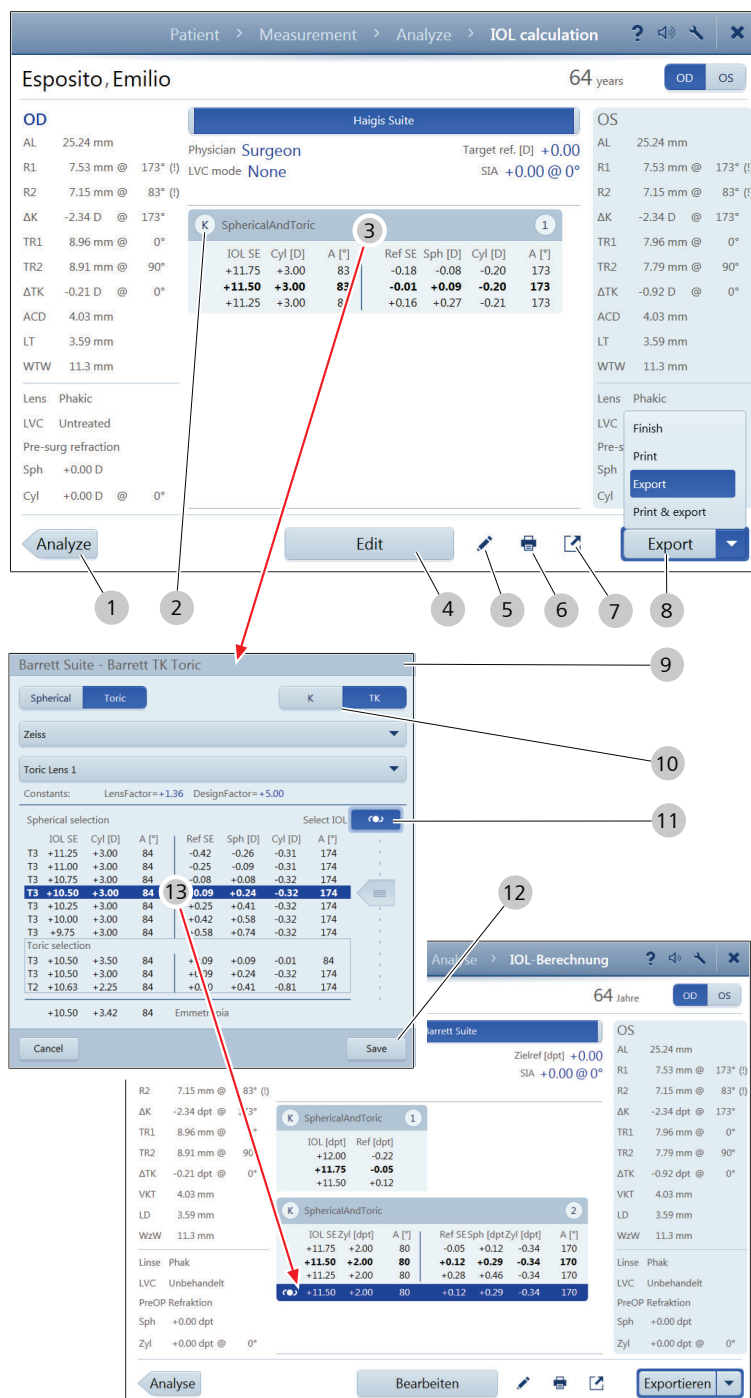


Figure 36: IOL calculation

Item	Name	Explanation
1	Analyze	This button opens the “Analyze” [► 77] dialog window.
2	K or TK (optional)	K: display of IOL calculation based on Keratometry values TK: display of IOL calculation based on Total Keratometry values

Item	Name	Explanation
3	Result of IOL calculation	By tapping on the results, the detailed view for this lens will be opened.
4	Edit	Tap this button to edit information on IOL calculation.
5	Pen	Tap this button to enter special comments on IOL calculation. Use the on-screen or external keyboard to enter your comments. The comments you enter will be printed, but not stored in the database. When exiting the "IOL calculation" dialog window, the entries will not be stored.
6	Print	Tap this button to print out biometric data, the IOL calculation and the analysis on an overview sheet. In the "Advanced settings / Printout" [► 170] dialog area you can define the print layout or individually defined printouts.
7	Export	Tap this button to export biometric data, the IOL calculation and the analysis on an overview sheet. In the "Advanced settings / Export" [► 172] dialog area you can define the export composition.
8	Finish	Drop-down list for selecting the "Finish", "Print", "Export" or "Print & export" functions. Here the data for both eyes can be printed or exported. After closing the IOL calculation, the "Patient" [► 50] dialog window will be opened.
9	Formula	Display of the selected IOL calculation formula
10	K / TK (optional)	K: display of IOL calculation based on Keratometry values TK: display of IOL calculation based on Total Keratometry values
11	IOL selection	IOL selection for reference image printout and export to Zeiss Cataract Suite. A blue bar will be displayed to select the IOL (13).
12	Save	Settings will be saved and the selected lens will be displayed in the "IOL calculation" window.
13	Selected IOL	The selected IOL will be highlighted with a blue bar. The bar can be scrolled vertically using the scroll bar at the side.

8.8 Application guidelines

The Application Guidelines section gives useful tips on how to operate the IOLMaster 700, as well as how to assess the quality of the data collected. Techniques and methods of operation of the device are described that may contribute to data quality of improvements (see also section “Measurement” [► 60]).

8.8.1 Notes on OCT measurement (CCT, ACD, LT, AL)

The IOLMaster 700 uses Swept Source Biometry for measuring the distances in the eye. A measurement is made from the epithelium of the cornea to the RPE, and then calibrated to immersion ultrasound.

How to adjust the device

As a rule the adjustment aid indicates the optimum measurement setting by a green traffic light. The vertical and horizontal OCT scans are shown in the live image. In each image, an adjustment area is proposed (green rectangle). If the alignment is correct, a yellow dot is displayed within the green rectangle of the adjustment area in the horizontal and vertical OCT scan image.

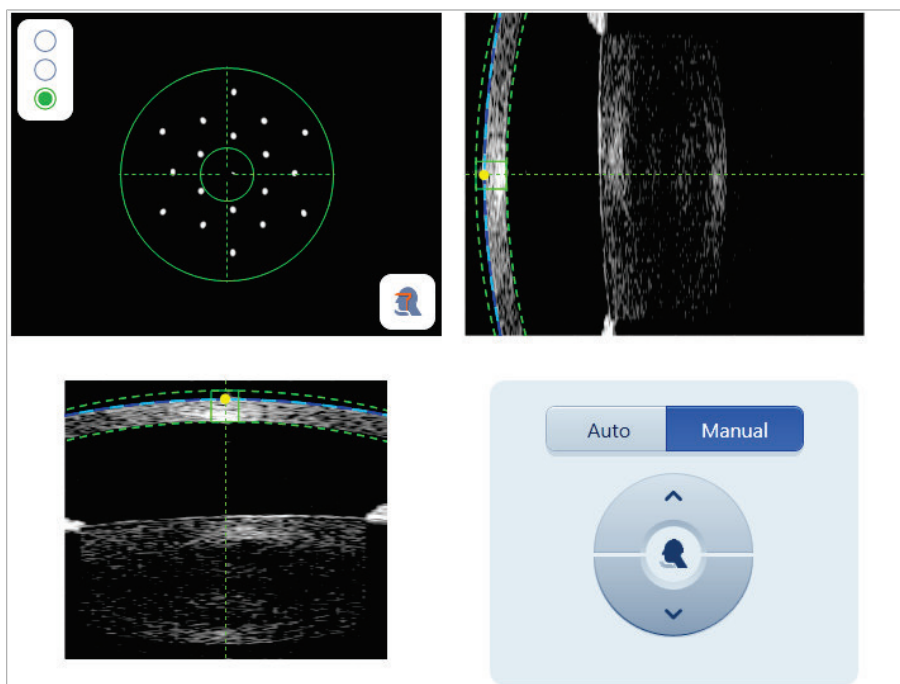


Figure 37: Measurement setting

Misadjustments

Measurement while patient is wearing contact lenses

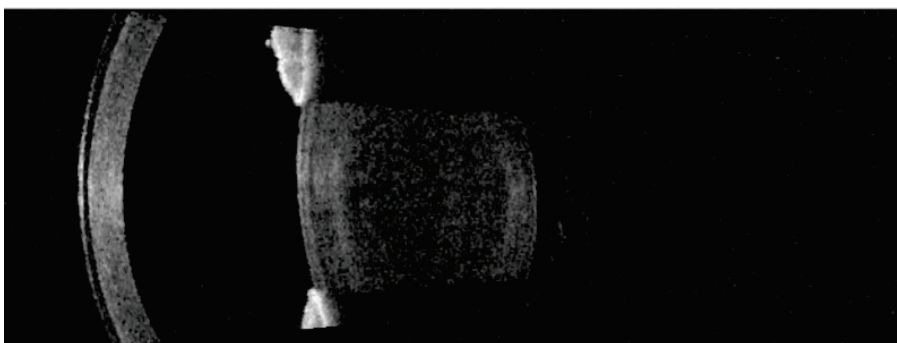


Figure 38: Measurement while patient is wearing contact lenses

Error	Measurement has been made while patient is wearing contact lenses. Keratometry, AL, ACD and CCT are incorrect.
Remedy	Repeat the measurement no earlier than two weeks after the first measurement in case of soft contact lenses and three weeks in case of rigid contact lenses to avoid the falsification of the measured values. Observe the section "Instructions and precautions to avoid measurement errors" [► 11].

8.8.2 Notes on keratometry

CAUTION!

Risk due to measuring errors

Pressure to the eyeball leads to a deformation of the cornea. Thus the corneal curvature can not be determined correctly and this may result in the calculation of incorrect IOL refractive powers.

- When raising of the upper eyelid, ensure that no pressure is exerted on the eye.

How to adjust the device

As a rule the adjustment aid indicates the optimum measurement setting by a green traffic light. In some cases (e.g. keratoconus, keratoglobus, corneal lesions) it may not be possible to achieve the green traffic light for optimum measurement setting. In such cases the Automatic function must be temporarily disabled. However, now ensure that the setting is correct. Ask the patient to relax and look at the fixation light. If the patient cannot see the fixation light, he or she should look straight ahead into the device.

TIP: The peripheral measuring marks will be invisible to the patient (infrared light).

When adjusting the device, make sure that all six peripheral points are visible and located in the field between the two auxiliary circles, as closely as possible to the center of the display. The images of the measuring marks on the display must be optimally focused by

varying the distance between patient and device. The images of the measuring marks should be circular or ellipsoid. To improve the reflectivity of the cornea, it is advisable to ask the patient to close and open the eyes several times. This replenishes the tear film and improves the imaging of the measuring marks (on a regular cornea).

Note

Depending on the reflectivity of the cornea, the image of the fixation light may be barely visible or not visible at all. This is irrelevant for the calculation of the corneal radii, as the position of the fixation light will not be evaluated.

Measuring errors

The "Measuring error" message has two basic causes:

- The results of the internal single measurements vary by more than 0.05 mm (very rare, defocused device).
- The measuring marks are either indiscernible or not recognized as such.
- Deformed keratometer points are not included in the evaluation.

The possible reasons for this are described below.

Misadjustments

Defocused device

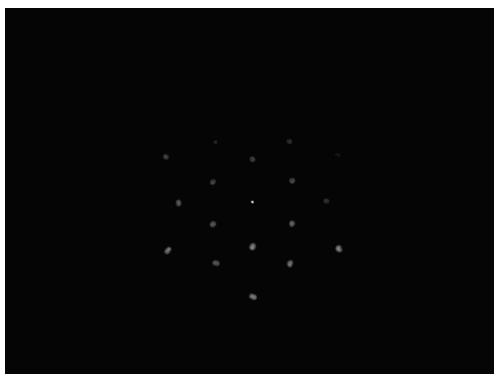


Figure 39: Defocused device

Error

The images of the measuring marks are too large, because the device is defocused. No measured value can be calculated.

Remedy

A measurement can be retaken after correcting the focus adjustment to minimize the peripheral mark size. Sometimes, with exactly adjusted focus, small circles (like haloes) may be visible around the eighteen peripheral measuring points. In this case, focusing is optimum.

Concealed measuring marks

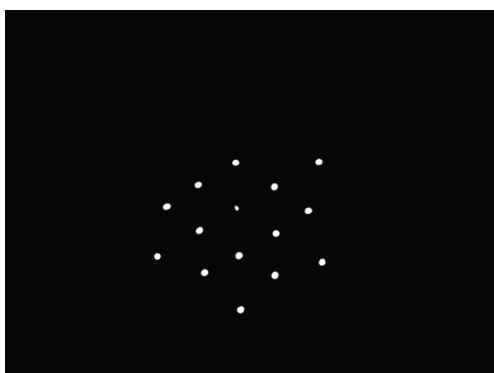


Figure 40: Concealed measuring marks

Error

This error may also occur if the patient closed his/her eye or did not open it wide enough. This is particularly the case with a restless or anxious patient.

Remedy

Ask the patient to open his or her eyes wide and repeat the measurement. If measurement is still not possible, gently lift the upper eyelid, as is usual in tonometry.

Other findings

Pseudophakic eyes

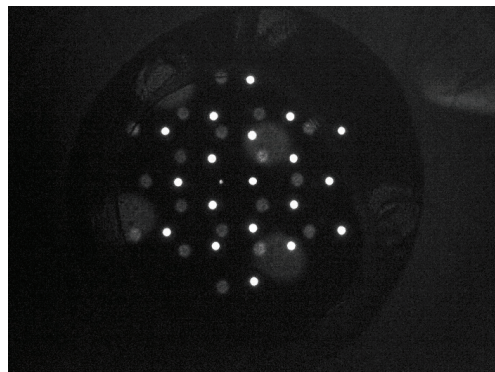


Figure 41: Pseudophakic eyes

Error

In the measurement of pseudophakic eyes, beside reflex images from the cornea, secondary images of the measuring marks from the anterior side of the IOL may be visible. The reflections from the IOL are fainter and lack definition.

Remedy

Move the device approximately 1 mm away from the patient's eye (defocusing) and take the measurement. The images produced at the cornea will now be slightly larger, while the artifacts of the IOL will become fainter, and will not be identifiable as measuring points; a measurement is then possible. If this procedure is not successful, the corneal curvature cannot be measured.

Dry eye

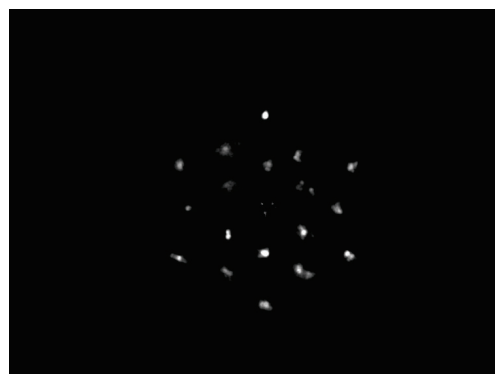


Figure 42: Dry eye

Error

If the tear film is suddenly interrupted, the reflectivity of the cornea will be greatly reduced at these points and the cornea will scatter the light more strongly. If a measuring mark is projected onto this area, the otherwise circular or ellipsoid image of the measuring mark will become irregular. Irregular marks and/or multiple reflections will form. In this case, a precise measurement of the corneal curvature will not be possible. The results will fluctuate or the "Measuring error" message will be displayed.

Remedy

Ask the patient to blink several times or close the eyes for a few seconds by repeated opening and closing of the eye, to replenish the tear film of the cornea. Take the measurement immediately afterwards.

Alternatively, rapid drying of the tear film can be eliminated by known therapies. However, no tear fluid substitute should be used on the day of measurement.

NOTE! In case of an interrupted tear film or dry eyes, significant deviations of the keratometry values may occur in repeated measurements.

Irregularities of the corneal surface (scars)

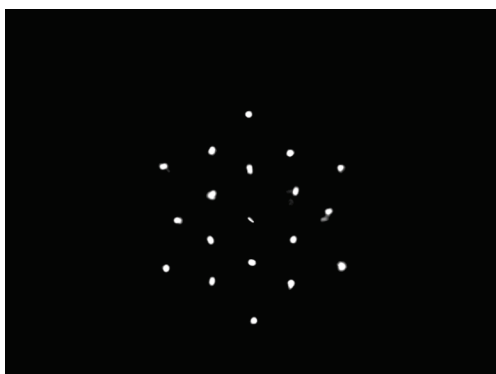


Figure 43: Irregularities of the corneal surface (scars)

Error

Scars and local irregularities on the corneal surface impair the imaging quality of the measuring marks. Depending on the extent and location of the artifacts, measuring errors may occur.

Remedy

Position the measuring mark adjacent to, above or below the scar by slightly displacing the device relative to the eye, then take a measurement. In such cases, it is advisable to repeat the measurement several times. Depending on the degree of irregularity, fluctuations or measuring errors may occur.

NOTE! Keratometry is not possible with the IOLMaster in patients who have had keratoplasty.

8.8.3 Notes on Central Topography

4. Central Topography of IOLMaster 700 (Anterior Axial Power Map and Total Axial Power Map) is based on the telecentric keratometry of the anterior corneal surface and OCT-based imaging of the posterior corneal surface.

Good keratometry and OCT corneal thickness measurement values are required for establishing the Anterior Axial Power Map and Total Axial Power Map.

Action

- ▶ Make sure that the patient has his/her eyes wide open.
- ▶ Ensure correct fixation.
- ▶ Observe the quality indicator display.

Central Topography measures the Anterior Axial Power and Total Axial Power of the central cornea. It can be used in cataract applications to evaluate the total symmetry of the central corneal form. With IOLMaster 700, it is not possible to measure the peripheral cornea, evaluate local anomalies or evaluate further aspects of the corneal form.

- ▶ Check the measurement results using other diagnostic methods if you are in doubt and if you intend to implant multifocal or toric IOL.
- ▶ Use appropriate devices and methods for your clinical diagnoses.

8.8.4 Notes on white-to-white measurement

How to adjust the device

As a rule the adjustment aid indicates the optimum measurement setting by a green traffic light. Arrows will show how the joystick must be moved in order to reach the optimum measurement position. In some cases it is possible that the green traffic light display for an optimum measurement setting cannot be reached. Confirm that the setting is correct. Ask the patient to relax and look at the red fixation light. Focus on the iris, not on the light spots. Adequate room lighting will facilitate the detection of iris structures. Avoid direct exposure of the eye and device front panel to extraneous light. In particular, ensure that the visible right and left edge of the iris is not disturbed by reflections from lamps and windows. If the iris structure is not discernible, focus on the edge of either iris or pupil. Serious defocusing will result in incorrect data. After the image has been taken, the operator should check in the quality check display that the software has correctly detected the edge of the iris and the pupil. If the circle segments drawn in the image do not define the iris or pupil correctly, the measurement must be repeated.

8.8.5 Notes on fixation check scan

Evaluation of fixation and the morphology of the fovea

The fixation check scan is used to evaluate correct fixation of the patient during measurement. A central 1 mm scan of the retina will be performed (OD is shown on the lower left side and OS on the lower right side of the quality check screen layout).

Good fixation is shown by a depression in the center, the so-called foveal pit. If the foveal pit (see image on the right) is clearly discernible, the patient has fixated properly during the scan. If it cannot be detected correctly (see image on the left), the patient has either not properly fixated or the morphology of the fovea is unusual. In this case, measurement should be repeated and the patient be instructed to fixate on the fixation light in the device. If

the patient cannot fixate during several measurements the user should verify if there may be another problem with the patient which requires special examination.

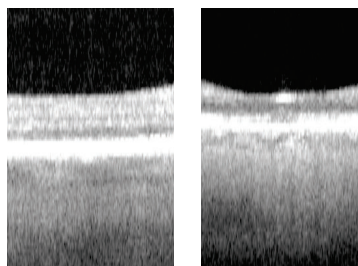


Figure 44: Insufficient (left) and correct (right) fixation

Examples of unusual morphology of the fovea

It may be the case that no depression in the center, the so-called foveal pit, can be seen although the patient confirms to have correctly fixated after repeated measurement. In these cases, the fundus of the patient should be examined using other diagnostic methods, for example a retina OCT. Some examples of unusual morphologies of the fovea are shown below.

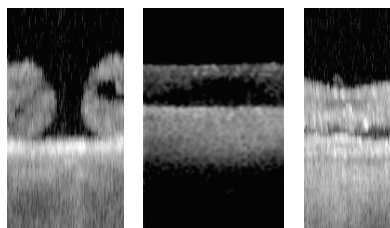


Figure 45: Examples of unusual morphology of the fovea

8.8.6 Notes on images for the reference image

Evaluation of reference image quality

The following notes refers to ambient lighting conditions of the location where the device is installed.

Ambient and room illumination of device location

Minimize variations of ambient lighting conditions e.g. due to the time of the day or room lighting conditions. Darker room lighting conditions minimize the risk of unwanted reflections or stray light in the reference image and thus enhance quality. Never expose the device to direct sunlight. Avoid ceiling illumination in the area directly above or near the device.

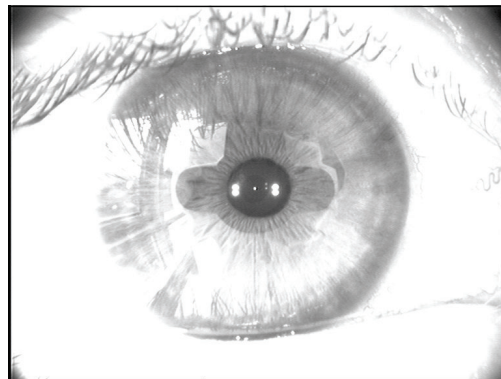


Figure 46: Ambient illumination too bright

Error

Error message: "Please check ambient illumination." The ambient illumination is too bright, e.g. due to a large window on a sunny day.

Remedy

Decrease ambient illumination e.g. by switching off or dimming the room lighting or by lowering shutters etc.

Stray light from local light sources or lateral sunlight

Lateral illumination from local light or reflection sources or from lateral illumination when the sun is low can lead to local reflections or stray light in the sclera.

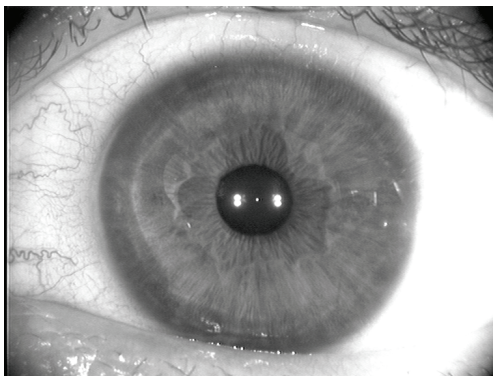


Figure 47: Lateral illumination

Error

Error message: "Please use side covers." Lateral illumination generates local reflections in vessels near the limbus. Accurate detection of vessels near the limbus is not possible.

Remedy

Correct adjustment of the side covers on the head rest prevents reflections in the sclera effectively.

The following information refers primarily to the operation of the device.

Eye is not correctly centered

Lateral decentration of the reference image can lead to erroneous evaluations of the reference image quality.

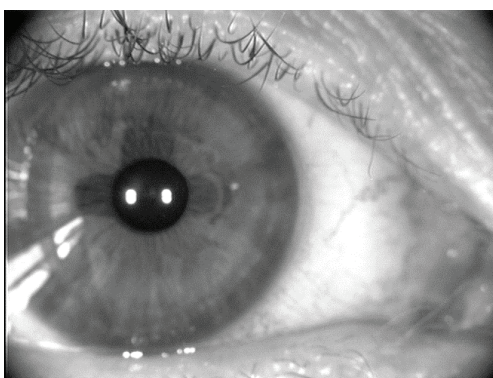


Figure 48: Lateral decentration

Error

Error message: "Improve device centration." The limbus is not within the limbus area shown in the eye template. Accurate detection of vessels near the limbus is not possible.

Remedy

Ensure that the centering of the eye or the purkinje reflections in the pupil area are in the center of the viewing window, so that the entire area of the limbus is clearly visible.

The following information refers primarily to characteristics of the patient's eye.

Palpebral aperture too small

It may be difficult for some patients to open the eye sufficiently wide. Palpebral apertures which are too small prevent accurate detection of vessels near the limbus.

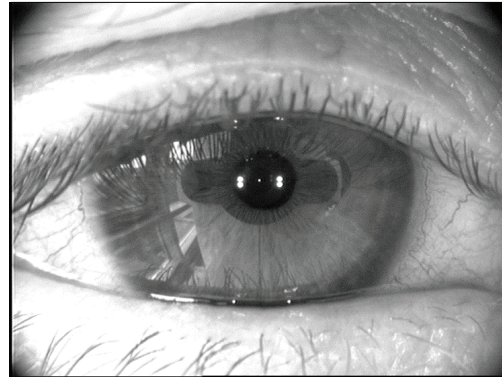


Figure 49: Palpebral aperture too small

Error

Error message: "Ask patient to blink and open the eye wider." The area in which vessels near the limbus can be detected may be too small. Accurate detection of vessels near the limbus is not possible.

Remedy

Encourage the patient to open his/her eye as wide as possible. Try to support opening of the eye with a finger by slightly pulling the area of the eyebrows and upper eyelids, but without applying any pressure to the eyeball, while operating the device with the other hand.

Excessive eye movements prevent images of sufficient quality from being obtained

In some cases, eyes may move considerably during image capture. Excessive eye movements prevent sufficient quality of the reference image.

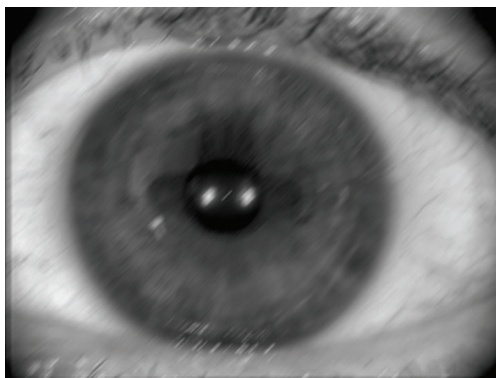


Figure 50: Strong eye movements

Error

Error message: "Unstable fixation." The area in which vessels near the limbus can be detected is not in focus. Accurate detection of vessels near the limbus is not possible.

Remedy

Repeat the measurement and ask the patient to focus on the central fixation light. Instruct the patient to blink shortly before the measurement, to produce a continuous tear film. This will improve the reflectivity of the cornea.

Few vessels near the limbus

In some cases the eye may have not enough vessels near the limbus which prevents detection of a sufficient number of vessels.

Error

Error message: "Not enough vessels near the limbus have been found." Not enough vessels in the area in which vessels near the limbus can be detected. Accurate detection of vessels near the limbus is not possible.

Remedy

Patient is possibly not suitable for adjustment of intraocular lens using scleral vessels near the limbus. Treat the patient by means of manual marking.

8.8.7 Notes on IOL calculation

See also section "IOL calculation" [► 84].

IOL calculation formulae

When calculating IOL different formulae can be used, involving various measuring parameters in the calculation of the IOL refractive powers. When selecting the IOL calculation formula, the type of IOL to be calculated (non-toric or toric) and the type of keratometry (Keratometry or Total Keratometry) is important.

The various different formulae are not applicable to all measured values of IOLMaster 700. Some formulae, for example, do not allow calculation with manually modified values (Haigis-L). Other formulae do not allow TK calculation (Barrett Universal II). In the software, such calculations are locked and an alternative is proposed if possible.

Precautions when using Total Keratometry for IOL calculation

(Formulae not named here will not allow TK values to be used in IOL calculation in the software)

Normal eyes

- In eyes without prior corneal surgery (in particular without refractive laser treatment) use only IOL calculation formulae which are integrated into the IOLMaster 700 application software when calculating non-toric IOLs using TK instead of Keratometry:
 - Haigis (part of the Haigis Suite)
 - Holladay 1
 - Holladay 2
 - SRK/T
 - Hoffer Q
 - Barrett Universal II with TK
- The Barrett Universal II formula (part of the Barrett Suite) should not be used with TK. When choosing TK for non-toric IOL calculation in the Barrett Suite, the device will automatically select the "Barrett Universal II with TK" formula.

Astigmatic eyes

- For the calculation of toric IOLs in eyes without prior corneal surgery (in particular without refractive laser treatment), use only the following formulae:
 - Haigis-T
 - Barrett Toric with TK

The Haigis-T formula is provided in the IOLMaster 700 software as part of the Haigis Suite, the "Barrett Toric with TK" formula is part of the Barrett Suite.

- IOL calculation formulae using a nomogram for modeling the posterior corneal surface like the Barrett Toric Calculator should not be used with TK. Using the Barrett Toric Calculator with TK input would result in double compensation and thus the calculation of incorrect IOL refractive power. The Barrett Toric Calculator, provided as Barrett Toric within the Barrett Suite of the IOLMaster 700, will not allow the calculation with TK. The calculation will be performed with the "Barrett Toric with TK" formula.

Post LVC eyes

- In eyes with prior corneal surgery (in particular refractive laser treatment), TK for IOL calculation should be used only with the latest generation formulae. In the IOLMaster 700 software these are the Haigis (Haigis Suite with LVC mode "none"), the Holladay 2 and the "Barrett True-K with TK" formulae.
- Older generation formulae requiring a so-called "double K correction" (SRK/T, Holladay 1 and Hoffer Q) are not suitable for TK IOL calculation with prior corneal surgery.
- TK should not be used with established IOL calculation formulae which were developed for classic keratometry values in eyes with prior refractive surgery, such as Haigis-L (part of Haigis Suite) and Barrett True-K (part of Barrett Suite). The use of TK with these formulae would result in double compensation and thus the calculation of incorrect IOL refractive powers.

Use of Keratometry (K) and Total Keratometry (TK) values in IOL calculation formulae with IOLMaster 700

Formula	Non-astigmatic eyes	Astigmatic eyes	Post LVC eyes
Hoffer Q	K / TK	-	-
SRK/T	K / TK	-	-
Holladay 1	K / TK	-	-
Holladay 2	K / TK	-	TK
Haigis	K / TK	-	TK
Haigis-T	-	K / TK	-
Haigis-L	-	-	K
Haigis-TL	-	-	K
Barrett Universal II	K	-	-
Barrett Toric	-	K	-
Barrett True-K	-	-	K
Barrett True-K with TK	-	-	TK
Barrett TK Universal II	TK	-	-
Barrett Toric with TK	-	TK	-

Formula	Permissible with IOLMaster 700 after
Haigis-L	Myopic and hyperopic LASIK/PRK/LASEK
Haigis-TL	Myopic and hyperopic LASIK/PRK/LASEK
Haigis with TK	Myopic LASIK/LASEK/PRK
Holladay 2 with TK	Myopic LASIK/LASEK/PRK
Barrett True-K	Myopic and hyperopic LASIK/LASEK/PRK and RK
Barrett True-K with TK	Myopic and hyperopic LASIK/PRK/LASEK

Haigis Suite and Holladay 2 can be used only with a phakic anterior chamber depth. For any other lens status, no IOL calculation is performed.

Use of standard formulae for IOL calculation is currently not recommended for eyes which have been treated with the ReLEx® smile procedure.

8.8.7.1 Application instructions for Haigis Suite

The Haigis Suite is a combination of four formulae:

- **Haigis**
- **Haigis-L** for cases after laser refractive surgery (LASIK, LASEK, PRK) and only with IOLMaster 700 Keratometry (K)
- **Haigis-T** for toric lens calculation
- **Haigis-TL** for toric IOL calculation in cases after laser refractive surgery and only with IOLMaster 700 Keratometry (K)

Depending on the selected lens (i.e. toric and/or non-toric IOL) Haigis or Haigis-T will be used. Haigis-T is used for toric IOL, Haigis is used for non-toric IOL.

Depending on the LVC state set in the patient manager, the LVC mode selected in IOL calculation and the selected IOL type, Haigis-L, Haigis-TL or Haigis with TK will be applied.

8.8.7.1.1 Spheric IOL calculation with Haigis Suite (Haigis formula)

Action

1. In the patient manager, set the LVC state of the patient to "Untreated":

The screenshot shows the 'Patient' tab in the IOL calculation software. The patient is 'Esposito, Emilio', 64 years old, female, ID 123, born 1/17/1954. The 'LVC' (Lens Vault Control) state is set to 'Untreated' and is highlighted with a red box. The 'OD' (Ocular Dominance) and 'OS' (Ocular Status) tabs are visible, showing 'Spherical' and 'K' (Keratometry) settings. The 'Analyze' button is visible at the bottom.

2. Select "Haigis Suite" in the IOL calculation.
3. Select "Spherical".
4. Select "K" (Keratometry) or "TK" (Total Keratometry).
5. The default setting for LVC mode is "None". Do not change this setting in the IOL calculation.
6. LVC state should already have been set to "Untreated" (Step 1). You can adjust the LVC state after measurement, if required. Ensure that the LVC mode is consistent.

The screenshot shows the 'IOL calculation' tab. The 'Haigis Suite' formula is selected and highlighted with a red box. The 'LVC mode' is set to 'None' and is highlighted with a red box. The 'Spherical' and 'K' (Keratometry) settings are visible. The 'LVC' state is set to 'Untreated' and is highlighted with a red box. The 'Calculate' button is visible at the bottom.

7. Tap [Calculate].

Patient > Measurement > Analyze > IOL calculation

Esposito, Emilio 64 years OD OS

Haigis Suite

Physician Surgeon LVC mode None Target ref. [D] +0.00 SIA +0.00 @ 0°

OD

AL 25.24 mm

R1 7.53 mm @ 173° (I)

R2 7.15 mm @ 83° (I)

ΔK -2.34 D @ 173°

TR1 8.96 mm @ 0°

TR2 8.91 mm @ 90°

ΔTK -0.21 D @ 0°

ACD 4.03 mm

LT 3.59 mm

WTW 11.3 mm

Lens Phakic

LVC Untreated

Pre-surg refraction

Sph +0.00 D

Cyl +0.00 D @ 0°

OS

AL 25.24 mm

R1 7.53 mm @ 173° (I)

R2 7.15 mm @ 83° (I)

ΔK -2.34 D @ 173°

TR1 7.96 mm @ 0°

TR2 7.79 mm @ 90°

ΔTK -0.92 D @ 0°

ACD 4.03 mm

LT 3.59 mm

WTW 11.3 mm

Lens Phakic

LVC Untreated

Pre-surg refraction

Sph +0.00 D

Cyl +0.00 D @ 0°

Analyze Edit Export

K SphericalAndToric 1

IOL [D] Ref [D]

+11.75 -0.15

+11.50 +0.03

+11.25 +0.20

Spherical IOLs with Haigis

⇒ The results of IOL calculation with the Haigis formula will be displayed. The type of IOL calculation is shown by K (Keratometry) or TK (Total Keratometry) ahead of the IOL name.

8. Tap [Export].

Date of calibration test: by: Result: 12.00 mm

Date of measurement: 1/1/1753 n: 1.3375 CVD: 12.00 mm

! IOL calculation

OD right OS left

Eye status

LS: Phakic VS: Vitreous body VA: ---

Ref: +0.00 D +0.00 D @ 0°

LVC: Untreated LVC mode: -

Target ref.: plano SIA: +0.00 D @ 0°

Target ref.: ---

Biometric values

AL: 25.24 mm SD: 5 μm

ACD: 4.03 mm SD: 9 μm

LT: 3.59 mm SD: 2 μm

WTW: 11.3 mm

R: 7.34 mm (I) SD: 24 μm R1: 7.53 mm @ 173°

ΔK: -2.34 D @ 173° R2: 7.15 mm @ 83°

TR: 8.94 mm SD: 90 μm TR1: 8.96 mm @ 0°

ΔTK: -0.21 D @ 0° TR2: 8.91 mm @ 90°

K Zeiss SphericalAndToric

- Haigis -

A0: -0.070 A1: +0.210 A2: +0.163

IOL (D) Ref (D)

+12.00 -0.32

+11.75 -0.15

+11.50 +0.03

+11.25 +0.20

+11.00 +0.37

+11.54 Emmetropia

Spherical IOLs with Haigis

⇒ The report of IOL calculation with the Haigis formula will be displayed.

8.8.7.1.2 Toric IOL calculation with Haigis Suite (Haigis-T formula)

Action

1. In the patient manager, set the LVC status of the patient to "Untreated".
2. Select "Haigis Suite" in the IOL calculation.
3. Select "Toric".
4. Select "K" (Keratometry) or "TK" (Total Keratometry).
5. The default setting for LVC mode is "None". Do not change this setting in the IOL calculation.
6. LVC state should already have been set to "Untreated" (Step 1). You can adjust the LVC state after measurement, if required. Ensure that the LVC mode is consistent.

The screenshot shows the IOLMaster 700 software interface for a patient named Emilio Esposito, 64 years old. The interface is divided into OD (Ocular Dominant) and OS (Ocular Subordinate) sections. The Haigis Suite is selected, and the LVC mode is set to 'None'. A red box highlights the 'Do not change' instruction. The LVC status is set to 'Untreated'.

Parameter	OD Value	OS Value
AL	25.24	25.24 mm
R1	7.53	7.53 mm @ 173° (t)
R2	7.15	7.15 mm @ 83° (t)
ΔK	-2.34 D	-2.34 D @ 173°
TR1	8.96 mm	7.96 mm @ 0°
TR2	8.91 mm	7.79 mm @ 90°
ΔTK	-0.21 D	-0.92 D @ 0°
ACD	4.03	4.03 mm
LT	3.59	3.59 mm
WTW	11.3	11.3 mm
Lens	Phakic	Phakic
LVC	Untreated	Untreated
Pre-surg refraction	Sph +0.00	Sph +0.00 D
	Cyl +0.00	Cyl +0.00 D @ 0°

⇒ Haigis-T is used for toric IOLs.

7. Tap [Calculate].

Patient > Measurement > Analyze > IOL calculation

Esposito, Emilio 64 years OD OS

Haigis Suite

Physician Surgeon LVC mode None Toric IOL with Haigis-T

Target ref. [D] +0.00 SIA +0.00 @ 0°

K SphericalAndToric

IOL SE	Cyl [D]	A [°]	Ref SE	Sph [D]	Cyl [D]	A [°]
+11.75	+3.00	83	-0.18	-0.08	-0.20	173
+11.50	+3.00	83	-0.01	+0.09	-0.20	173
+11.25	+3.00	83	+0.16	+0.27	-0.21	173

Lens Phakic LVC Untreated Pre-surg refraction Sph +0.00 D Cyl +0.00 D @ 0°

Analyze Edit Export

⇒ The results of IOL calculation with the Haigis-TL formula will be displayed. The type of IOL calculation is shown by K (Keratometry) or TK (Total Keratometry) ahead of the IOL name.

8. Tap [Export].

Date of calibration test: by: Result: Date of measurement: 1/1/1753 n: 1.3375 CVD: 12.00 mm

OD right IOL calculation OS left

Eye status

LS: Phakic VS: Vitreous body Ref: +0.00 D +0.00 D @ 0° VA: --- LVC: Untreated LVC mode: - SIA: +0.00 D @ 0° Target ref.: plano

Biometric values

AL: 25.24 mm SD: 5 µm ACD: 4.03 mm SD: 9 µm LT: 3.59 mm SD: 2 µm WTW: 11.3 mm R: 7.34 mm (!) SD: 24 µm R1: 7.53 mm @ 173° ΔK: -2.34 D @ 173° R2: 7.15 mm @ 83° TR: 8.94 mm SD: 90 µm TR1: 8.96 mm @ 0° ΔTK: -0.21 D @ 0° TR2: 8.91 mm @ 90°

K Zeiss SphericalAndToric

- Haigis Toric - A0: -0.070 A1: +0.210 A2: +0.163

IOL SE	IOL Cyl	IOL axis	Ref SE	Ref Sph	Ref Cyl	Ref Axis
+12.00	+3.00	83°	-0.36	-0.26	-0.20	173°
+11.75	+3.00	83°	-0.18	-0.08	-0.20	173°
+11.50	+3.00	83°	-0.01	+0.09	-0.20	173°
+11.25	+3.00	83°	+0.16	+0.27	-0.21	173°
+11.00	+3.00	83°	+0.34	+0.44	-0.21	173°
+11.49	+3.29	83°				Emmetropia

Toric IOL with Haigis-T

⇒ The report of IOL calculation with the Haigis-L formula will be displayed.

8.8.7.1.3 Toric IOL calculation with Haigis Suite (Haigis-TL formula)

Action

1. In the patient manager, set the LVC state of the patient to "LASIK", "LASEK" or "PRK".
2. Select "Haigis Suite" in the IOL calculation.
3. Select "Toric".
4. Select "K" (Keratometry).
5. Select "Myopic" or "Hyperopic" in the LVC mode.

The screenshot shows the 'IOL calculation' window for patient 'Cölestin, Cecile'. The 'Haigis Suite' formula is selected. The 'LVC mode' is set to 'Myopic'. The 'Spherical' option is set to 'Toric'. The 'LVC' is set to 'LASIK'. The 'Calculate' button is at the bottom right.

⇒ Haigis-TL will be used for toric IOLs.

6. Tap [Calculate].

The screenshot shows the 'IOL calculation' window with the results of the calculation. The 'Haigis Suite' formula is selected. The 'LVC mode' is set to 'Myopic'. The 'Spherical' option is set to 'Toric'. The 'LVC' is set to 'LASIK'. The 'Calculate' button is at the bottom right.

⇒ The results of IOL calculation with the Haigis-TL formula will be displayed. The type of IOL calculation is shown by K (Keratometry) ahead of the IOL name.

7. Tap [Export].

Date of calibration test: 3/1/2017
by: n: 1.3375
Result: CVD: 12.00 mm

! [OD] Only valid for myopic LASIK/LASEK/PRK! Do not use after RK or hyperopic treatments.

OD right				IOL calculation				OS left			
Eye status											
LS: Phakic				VS: Vitreous body				LS: Phakic			
Ref: +0.00 D @ 0°				VA: ---				Ref: ---			
LVC: LASIK				LVC mode: Myopic				LVC: ---			
Target ref.: plano				SIA: +0.00 D @ 0°				Target ref.: ---			
Biometric values											
AL: 25.24 mm		SD: 5 µm		AL: ---				AL: ---			
ACD: 4.03 mm		SD: 9 µm		ACD: ---				ACD: ---			
LT: 3.59 mm		SD: 2 µm		LT: ---				LT: ---			
WTW: 11.3 mm				WTW: ---				WTW: ---			
R: 7.34 mm (I)		SD: 24 µm		R: ---				R: ---			
ΔK: -2.34 D @ 173°				R1: 7.53 mm @ 173°				R1: ---			
TR: 8.94 mm		SD: 90 µm		R2: 7.15 mm @ 83°				R2: ---			
ΔTK: -0.21 D @ 0°				TR1: 8.96 mm @ 0°				TR1: ---			
				TR2: 8.91 mm @ 90°				TR2: ---			
Zeiss SphericalAndToric											
- Haigis-L Toric -											
A0: -0.070 A1: +0.210 A2: +0.163											
IOL SE	IOL Cyl	IOL axis	Ref SE	Ref Sph	Ref Cyl	Ref Axis					
+13.75	+2.50	83°	-0.41	-0.33	-0.16	173°					
+13.50	+2.50	83°	-0.23	-0.15	-0.16	173°					
+13.25	+2.50	83°	-0.06	+0.02	-0.16	173°					
+13.00	+2.50	83°	+0.12	+0.20	-0.17	173°					
+12.75	+2.50	83°	+0.29	+0.38	-0.17	173°					
+13.17	+2.73	83°	Emmetropia								
Zeiss SphericalAndToric											
- Haigis-L -											
A0: -0.070 A1: +0.210 A2: +0.163											
IOL (D)	Ref (D)										
+13.75	-0.39										
+13.50	-0.21										
+13.25	-0.03										
+13.00	+0.14										
+12.75	+0.32										
+13.20	Emmetropia										

(I) Borderline value
(*) Value was edited manually
--- No value measured

⇒ The report of IOL calculation with the Haigis-L formula will be displayed.

8.8.7.1.4 IOL calculation for patients after laser refractive surgery with the Haigis Suite (Haigis-L formula)

Action

1. In the patient manager, set the LVC state of the patient to "LASIK", "LASEK" or "PRK".

The screenshot shows the 'Patient' tab in the software. The patient list on the left includes Cölestin, Cecile. The main panel shows her details: Female, ID 000000014, Date of birth 1/17/1954. The 'Measurements' tab is active, showing OD and OS eye data. The 'LVC' dropdown menu is open, and 'LASIK' is selected and highlighted with a red box. Other options include 'Untreated', 'LASEK', 'PRK', 'RK', and 'LASIK' (repeated).

2. Select "Haigis Suite" in the IOL calculation.
3. Select "Spherical".
4. Select "Myopic" or "Hyperopic" in the LVC mode.
5. Select "K" (Keratometry).

The screenshot shows the 'IOL calculation' tab. The 'Haigis Suite' formula is selected. The 'LVC mode' dropdown is set to 'Myopic' (highlighted with a red box). The 'Spherical' option is selected under the 'SphericalAndToric' dropdown (highlighted with a red box). The 'K' option is selected under the 'K' dropdown (highlighted with a red box). The 'LVC' dropdown is also set to 'LASIK' (highlighted with a red box). The 'Calculate' button is visible at the bottom.

⇒ Haigis-L will be used for spherical IOLs.

6. Tap [Calculate].

Patient > Measurement > Analyze > IOL calculation

Cölestin, Cecile 64 years OD OS

Haigis Suite

OD

AL 25.24 mm Physician Surgeon Target ref. [D] +0.00

R1 7.53 mm @ 173° (I) LVC mode Myopic SIA +0.00 @ 0°

R2 7.15 mm @ 83° (I) Only valid for myopic LASIK/LASEK/PRK! Do not use after RK or hyperopic treatments.

ΔK -2.34 D @ 173°

TR1 8.96 mm @ 0°

TR2 8.91 mm @ 90°

ΔTK -0.21 D @ 0°

ACD 4.03 mm

LT 3.59 mm

WTW 11.3 mm

Lens Phakic

LVC LASIK

Pre-surg refraction

Sph +0.00 D

Cyl +0.00 D @ 0°

OS

AL 25.24 mm

R1 7.53 mm @ 173° (I)

R2 7.15 mm @ 83° (I)

ΔK -2.34 D @ 173°

TR1 7.96 mm @ 0°

TR2 7.79 mm @ 90°

ΔTK -0.92 D @ 0°

ACD 4.03 mm

LT 3.59 mm

WTW 11.3 mm

Lens Phakic

LVC LASEK

Pre-surg refraction

Sph +0.00 D

Cyl +0.00 D @ 0°

K SphericalAndToric 1

IOL SE Cyl [D] A [°] Ref SE Sph [D] Cyl [D] A [°]

+13.50 +2.50 83 -0.23 -0.15 -0.16 173

+13.25 +2.50 83 -0.06 +0.02 -0.16 173

+13.00 +2.50 83 +0.12 +0.20 -0.17 173

K SphericalAndToric 2

IOL [D] Ref [D]

+13.50 -0.21

+13.25 -0.03

+13.00 +0.14

Spherical IOLs with Haigis-L

Analyze Edit Export

⇒ The results of IOL calculation with the Haigis-L formula will be displayed. The type of IOL calculation is shown by K (Keratometry) ahead of the IOL name.

7. Tap [Export].

Date of calibration test: by: Result:		Date of measurement: 3/1/2017 n: 1.3375 CVD: 12.00 mm	
[OD] Only valid for myopic LASIK/LASEK/PRK! Do not use after RK or hyperopic treatments.			
OD right		OS left	
IOL calculation			
Eye status			
LS: Phakic VS: Vitreous body		LS: Phakic VS: Vitreous body	
Ref: +0.00 D +0.00 D @ 0°		Ref: --- VA: ---	
LVC: LASIK LVC mode: Myopic		LVC: --- LVC mode: ---	
Target ref.: plano SIA: +0.00 D @ 0°		Target ref.: --- SIA: ---	
Biometric values			
AL: 25.24 mm SD: 5 µm		AL: ---	
ACD: 4.03 mm SD: 9 µm		ACD: ---	
LT: 3.59 mm SD: 2 µm		LT: ---	
WTW: 11.3 mm		WTW: ---	
R: 7.34 mm (I) SD: 24 µm R1: 7.53 mm @ 173°		R: --- R1: ---	
ΔK: -2.34 D @ 173° R2: 7.15 mm @ 83°		ΔK: --- R2: ---	
TR: 8.94 mm SD: 90 µm TR1: 8.96 mm @ 0°		TR: --- TR1: ---	
ΔTK: -0.21 D @ 0° TR2: 8.91 mm @ 90°		ΔTK: --- TR2: ---	
Zeiss SphericalAndToric			
- Haigis-L Toric -			
A0: -0.070 A1: +0.210 A2: +0.163			
IOL SE	IOL Cyl	IOL axis	Ref SE Ref Sph Ref Cyl Ref Axis
+13.75	+2.50	83°	-0.41 -0.33 -0.16 173°
+13.50	+2.50	83°	-0.23 -0.15 -0.16 173°
+13.25	+2.50	83°	-0.06 +0.02 -0.16 173°
+13.00	+2.50	83°	+0.12 +0.20 -0.17 173°
+12.75	+2.50	83°	+0.29 +0.38 -0.17 173°
+13.17	+2.73	83°	Emmetropia
Zeiss SphericalAndToric			
- Haigis-L -			
A0: -0.070 A1: +0.210 A2: +0.163			
IOL (D)	Ref (D)		
+13.75	-0.39		
+13.50	-0.21		
+13.25	-0.03		
+13.00	+0.14		
+12.75	+0.32		
+13.20	Emmetropia		
(I) Borderline value (*) Value was edited manually --- No value measured			
Comment			

⇒ The report of IOL calculation with the Haigis-L formula will be displayed.

8.8.7.2 Application instructions for Barrett Suite

Note: The screens from section Application instructions for Haigis Suite [► 107] are applicable as well for the Barrett Suite application. Barrett Suite is a combination of three or five (if Total Keratometry license is activated) formulae:

- Barrett Universal II
- Barrett True-K for cases after laser refractive surgery (LASIK, LASEK, PRK) and RK
- Barrett Toric for toric lens calculation
- Barrett Universal II with TK (if Total Keratometry license is enabled)
- Barrett Toric with TK for toric lens calculation (if Total Keratometry license is enabled)
- Barrett True-K with TK for eyes after refractive surgery (LASIK, LASEK, PRK, if Total Keratometry license is enabled)

Depending on the selection of the keratometry type (Keratometry or Total Keratometry) the classic Barrett formula or the "Barrett with TK" formula will be selected.

Depending on the selected lens (i.e. toric and/or non-toric IOL) Barrett Universal II or Barrett Toric will be used. Barrett Toric is used for toric IOL, Barrett Universal II is used for spherical IOL.

Toric and non-toric IOL as well as Keratometry- and Total Keratometry-based calculations can be calculated simultaneously and can be re-calculated any time.

Depending on the LVC state set in the Patient manager, and on the LVC mode selected in IOL calculation, Barrett True-K will be applied.

The functionality corresponds to the information given for the Haigis Suite [► 107]. However, please observe the following difference:

- Barrett Suite additionally allows the calculation of spherical IOLs with prior RK (observe the restrictions described in the following concerning toric IOL and hyperopic ablation profiles).
- Barrett Suite allows the use of manually entered K values in pre-op LVC state (observe the restrictions described in the following concerning hyperopic ablation profiles).
- The Barrett Suite does not allow the calculation of toric IOLs in connection with a pre-op LVC state.

NOTE! The Barrett Suite uses own lens constants which are managed by the Lens manager, as with all other formula. Note that the design factor (DF) is not included in all lenses of the IOL constants import. If necessary, contact the lens manufacturer.

NOTE! When using the Barrett True-K formula after refractive corneal surgery, Dr. Barrett recommends entering the optional values pre-Lasik ref. and post-Lasik ref. (refraction before and after refractive corneal surgery) if known. These optional values cannot be entered into IOLMaster 700. In these cases, use the Barrett True-K online calculator (http://www.apacrs.org/barrett_true_K_universal_2).

8.8.8 Information on printouts

8.8.8.1 General information

1 Patient **Cölestin Cecile**

2 Date of birth **1/17/1954** Gender **Female**

3 Patient ID **000000014**

4 Physician **Surgeon** Operator **Surgeon**

5 Date of calibration test: by: Result: CVD: 12.00 mm

Date of measurement: 3/1/2016 n: 1.3375

This IOL calculation contains values that were edited manually.

OD right		IOL calculation		OS left	
SphericalAndToric - Barrett Universal II		SphericalAndToric - Barrett TK Universal II		SphericalAndToric - Barrett TK Universal II	
Eye status					
LS: Phakic Ref: -2.25 D -0.75 D @ 34° LVC: Untreated (*) Target ref.: -0.25 D		VS: Vitreous body VA: 20/25 LVC mode: - SIA: +1.50 D @ 178°		LS: Phakic Ref: +0.00 D +0.00 D @ 0° LVC: Untreated (*) Target ref.: plano SIA: +0.00 D @ 0°	
Biometric values					
AL: 25.24 mm SD: 5 µm ACD: 4.03 mm SD: 9 µm LT: 3.59 mm SD: 2 µm WTW: 11.3 mm		AL: 25.24 mm SD: 5 µm ACD: 4.03 mm SD: 9 µm LT: 3.59 mm SD: 2 µm WTW: 11.3 mm		AL: 25.24 mm SD: 5 µm ACD: 4.03 mm SD: 9 µm LT: 3.59 mm SD: 2 µm WTW: 11.3 mm	
SE: 45.98 D (I) SD: 0.15 D K1: 44.84 D @ 173° ΔK: -2.34 D @ 173° TSE: 37.76 D SD: 0.38 D TK1: 37.66 D @ 0° ΔTK: -0.21 D @ 0°		SE: 45.98 D (I) SD: 0.15 D K1: 44.84 D @ 173° ΔK: -2.34 D @ 173° TSE: 42.85 D SD: 0.80 D TK1: 42.39 D @ 0° ΔTK: -0.92 D @ 0°		SE: 45.98 D (I) SD: 0.15 D K1: 44.84 D @ 173° ΔK: -2.34 D @ 173° TSE: 42.85 D SD: 0.80 D TK1: 42.39 D @ 0° ΔTK: -0.92 D @ 0°	
K Zeiss SphericalAndToric		TK Zeiss SphericalAndToric		K Zeiss SphericalAndToric	
- Barrett Universal II - LF: +1.36 DF: Default IOL (D) Ref (D) +12.50 -0.56 +12.25 -0.39 +12.00 -0.22 +11.75 -0.05 +11.50 +0.12 +11.68 Emmetropia		- Barrett TK Universal II - LF: +1.36 DF: Default IOL (D) Ref (D) +11.50 -0.59 +11.25 -0.42 +11.00 -0.25 +10.75 -0.08 +10.50 +0.09 +10.63 Emmetropia		- Barrett Universal II - LF: +1.36 DF: Default IOL (D) Ref (D) +12.25 -0.39 +12.00 -0.22 +11.75 -0.05 +11.50 +0.12 +11.25 +0.28 +11.68 Emmetropia	
+12.00 -0.22		+10.63 Emmetropia		+10.75 -0.08	
(I) Borderline value (*) Value was edited manually --- No value measured					
Comment					

6

7

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IOLMaster 700 Version 1.80 Report dated 6/12/2018 5:12 AM; created by Surgeon Page 1 of 7

Item	Explanation
1	Patient data
2	User data

Item	Explanation
3	Date of calibration test
4	Date of measurement
5	Warnings from internal plausibility checks
6	Comments which the users entered in the "IOL calculation" window or after measurement
7	Software version

8.8.8.1.1 Non-toric IOL calculation

Patient: Cölestin Cecile

Date of birth: 1/17/1954 Gender: Female

Patient ID: 000000014

Physician: Surgeon Operator: Surgeon

Clinic or practice information

Date of calibration test: by: Result: CVD: 12.00 mm

Date of measurement: 3/1/2016 n: 1.3375

This IOL calculation contains values that were edited manually.

OD right **IOL calculation** **OS** left

SphericalAndToric - Barrett Universal II **SphericalAndToric - Barrett TK Universal II**

Eye status

LS: Phakic VS: Vitreous body Ref: -2.25 D -0.75 D @ 34° VA: 20/25

LVC: Untreated (*) LVC mode: - SIA: +1.50 D @ 178° Target ref.: -0.25 D

AL: 25.24 mm SD: 5 µm ACD: 4.03 mm SD: 9 µm LT: 3.59 mm SD: 2 µm WTW: 11.3 mm

SE: 45.98 D (!) SD: 0.15 D K1: 44.84 D @ 173° ΔK: -2.34 D @ 173° K2: 47.18 D @ 83° TSE: 37.76 D SD: 0.38 D TK1: 37.66 D @ 0° ΔTK: -0.21 D @ 0° TK2: 37.87 D @ 90°

Zeiss SphericalAndToric **Zeiss SphericalAndToric** **Zeiss SphericalAndToric** **Zeiss SphericalAndToric**

- Barrett Universal II - **- Barrett TK Universal II -** **- Barrett Universal II -** **- Barrett TK Universal II -**

LF: +1.36 DF: Default IOL (D) Ref (D) IOL (D) Ref (D) IOL (D) Ref (D) IOL (D) Ref (D)

+12.50 -0.56 +11.50 -0.59 +12.25 -0.39 +11.25 -0.42

+12.25 -0.39 +11.25 -0.42 +12.00 -0.22 +11.00 -0.25

+12.00 -0.22 +11.00 -0.25 +11.75 -0.05 +10.75 -0.08

+11.75 -0.05 +10.75 -0.08 +11.50 +0.12 +10.50 +0.09

+11.50 +0.12 +10.50 +0.09 +11.25 +0.28 +10.25 +0.25

+11.68 Emmetropia +10.63 Emmetropia +11.68 Emmetropia +10.63 Emmetropia

+12.00 -0.22 +10.75 -0.08

(!) Borderline value (*) Value was edited manually --- No value measured

Comment

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Item	Explanation
1	Corneal vertex distance in mm (CVD)
2	Refractive index
3	If an IOL was highlighted for export in the detailed view, it will be displayed here.
4	Eye status: Lens status (LS), vitreous body status (vitreous state, VS)

Item	Explanation
5	Manifest refraction
6	Corneal status: After laser correction (LVC)
7	Target refraction
8	Surgically induced astigmatism (SIA)
9	Composite values: Axis length (AL), anterior chamber depth (ACD), lens thickness (LT) with a standard deviation (SD)
10	White-to-white measurement
11	Composite values: K flat, K steep, cylinder
12	Composite values: TK flat, TK steep, Total Cylinder
13	Calculation results for Keratometry (K)
14	Calculation results for Total Keratometry (TK)
15	Spherical IOL
16	Formulae used and corresponding IOL constants used
17	IOL calculation results, recommended values are highlighted
18	If an IOL was highlighted for export in the detailed view, the calculation results of this IOL will be displayed here.

8.8.8.1.2 Non-toric IOL calculation formula - 4 in 1 (multi formula)

Here, up to four different IOL calculation formulae for an IOL model are compared with each other.

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18

Patient: de Marichalar y Sáenz de Tejada Méndez

Date of birth: 1/1/1953 Gender: Female

Patient ID: 000000025

Surgeon: Surgeon Operator: Surgeon

Clinic or practice information

Date of calibration test: 1/1/1973 by: 1.3375 Result: CVD: 12.00 mm

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[OS] SRK® is a trademark of CTI (Computational Technology Inc.) Hoffer® Q is a trademark of Kenneth Hoffer.

OD right **IOL calculation** **OS left**

SphericalAndToric - Hoffer® Q

Eye status

LS: Phakic VS: Vitreous body
Ref: +0.00 D +0.00 D @ 0° VA: ---
LVC: Untreated LVC mode: -
Target ref.: -0.25 D SIA: +1.50 D @ 178°

LS: Phakic VS: Vitreous body
Ref: +0.00 D +0.00 D @ 0° VA: ---
LVC: Untreated LVC mode: -
Target ref.: plano SIA: +1.00 D @ 35°

Biometric values

AL: 25.24 mm SD: 5 µm
ACD: 4.03 mm SD: 9 µm
LT: 3.59 mm SD: 2 µm
WTW: 11.3 mm

AL: 25.24 mm SD: 5 µm
ACD: 4.03 mm SD: 9 µm
LT: 3.59 mm SD: 2 µm
WTW: 11.3 mm

SE: 45.98 D (!) SD: 0.15 D K1: 44.84 D @ 173°
ΔK: +2.34 D @ 83° K2: 47.18 D @ 83°
TSE: 37.76 D SD: 0.38 D TK1: 37.66 D @ 0°
ΔTK: +0.21 D @ 90° TK2: 37.87 D @ 90°

SE: 45.98 D (!) SD: 0.15 D K1: 44.84 D @ 173°
ΔK: +2.34 D @ 83° K2: 47.18 D @ 83°
TSE: 42.85 D SD: 0.80 D TK1: 42.39 D @ 0°
ΔTK: +0.92 D @ 90° TK2: 43.31 D @ 90°

Zeiss SphericalAndToric **Zeiss SphericalAndToric** **Zeiss SphericalAndToric** **Zeiss SphericalAndToric**

- Haigis -
A0: -0.070 A1: +0.210 A2: +0.163
IOL (D) Ref (D)
+23.50 -0.58
+23.25 -0.39
+23.00 -0.21
+22.75 -0.02
+22.50 +0.17
+22.73 Emmetropia

- Hoffer® Q -
pACD: +5.01
IOL (D) Ref (D)
+12.00 -0.58
+11.75 -0.41
+11.50 -0.25
+11.25 -0.08
+11.00 +0.08
+11.12 Emmetropia

- Haigis -
A0: -0.070 A1: +0.210 A2: +0.163
IOL (D) Ref (D)
+16.50 -0.43
+16.25 -0.25
+16.00 -0.07
+15.75 +0.11
+15.50 +0.28
+15.90 Emmetropia

- Hoffer® Q -
pACD: +5.01
IOL (D) Ref (D)
+11.50 -0.25
+11.25 -0.08
+11.00 +0.08
+10.75 +0.24
+10.50 +0.40
+11.12 Emmetropia

Zeiss SphericalAndToric **Zeiss SphericalAndToric** **Zeiss SphericalAndToric** **Zeiss SphericalAndToric**

- Holladay 2 -
ACD: +1.250
IOL (D) Ref (D)
+8.75 -0.73
+8.50 -0.50
+8.25 -0.28
+8.00 -0.05
+7.75 +0.17
+7.94 Emmetropia

- SRK®/T -
A const.: 118.50
IOL (D) Ref (D)
+13.50 -0.63
+13.25 -0.47
+13.00 -0.32
+12.75 -0.16
+12.50 -0.01
+12.48 Emmetropia

- Holladay 2 -
ACD: +1.250
IOL (D) Ref (D)
+8.50 -0.50
+8.25 -0.28
+8.00 -0.05
+7.75 +0.17
+7.50 +0.40
+7.94 Emmetropia

- SRK®/T -
A const.: 118.50
IOL (D) Ref (D)
+13.00 -0.32
+12.75 -0.16
+12.50 +0.14
+12.00 +0.29
+12.48 Emmetropia

(!) Borderline value (*) Value was edited manually --- No value measured

Comment
[OU]: 4 formulas (3K / 1TKP); [OD]: lvc.myopic, target refraction: -0.25; [OS]: target refraction plano, SIA values, refractivesurgerystate: undefined, and a sel...

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Item	Explanation
1	Corneal vertex distance in mm (CVD)
2	Refractive index
3	If an IOL was highlighted for export in the detailed view, it will be displayed here.

Item	Explanation
4	Eye status: Lens status (LS), vitreous body status (vitreous state, VS)
5	Manifest refraction
6	Corneal status: After laser correction (LVC)
7	Target refraction
8	Surgically induced astigmatism (SIA)
9	Composite values: Axis length (AL), anterior chamber depth (ACD), lens thickness (LT) with a standard deviation (SD)
10	White-to-white measurement
11	Composite values: K flat, K steep, cylinder
12	Composite values: TK flat, TK steep, Total Cylinder
13	Calculation results for Total Keratometry (TK)
14	Spherical IOL
15	Formulae used and corresponding IOL constants used
16	IOL calculation results, recommended values are highlighted
17	If an IOL was highlighted for export in the detailed view, the calculation results of this IOL will be displayed here.
18	Calculation results for Keratometry (K)

8.8.8.1.3 Toric IOL calculation

1 Patient: Cölestin Cecile

2 Date of birth: 1/17/1954 Gender: Female

3 Patient ID: 000000014

4 Physician: Surgeon Operator: Surgeon

5 Date of calibration test: by: Result: CVD: 12.00 mm

6 Date of measurement: 3/1/2016 n: 1.3375

7 This IOL calculation contains values that were edited manually.

8 **OD** right eye **OS** left eye

9 IOL calculation

10 SphericalAndToric - Haigis Toric

11 Eye status

12 LS: Phakic VS: Vitreous body

13 Ref: -2.25 D -0.75 D @ 34° VA: 20/25

14 LVC: Untreated (*) LVC mode: -

15 Target ref.: -0.25 D SIA: +1.50 D @ 178°

16 Target ref.: plano LVC mode: -

17 SIA: +0.00 D @ 0°

18 Biometric values

19 AL: 25.24 mm SD: 5 µm

20 ACD: 4.03 mm SD: 9 µm

LT: 3.59 mm SD: 2 µm

WTW: 11.3 mm

SE: 45.98 D (I) SD: 0.15 D K1: 44.84 D @ 173°

ΔK: -2.34 D @ 173° K2: 47.18 D @ 83°

TSE: 37.76 D SD: 0.38 D TK1: 37.66 D @ 0°

ΔTK: -0.21 D @ 0° TK2: 37.87 D @ 90°

Zeiss SphericalAndToric

- Haigis Toric -

A0: -0.070 A1: +0.210 A2: +0.163

IOL SE	IOL Cyl	IOL axis	Ref SE	Ref Sph	Ref Cyl	Ref Axis
+12.25	+5.00	85°	-0.54	-0.40	-0.28	175°
+12.00	+5.00	85°	-0.37	-0.22	-0.29	175°
+11.75	+5.00	85°	-0.19	-0.05	-0.29	175°
+11.50	+5.00	85°	-0.02	+0.13	-0.29	175°
+11.25	+5.00	85°	+0.16	+0.31	-0.30	175°
+11.47	+5.42	85°				Emmetropia
+11.75	+5.00	85°	-0.19	-0.05	-0.29	175°

Zeiss SphericalAndToric

- Haigis Toric -

A0: -0.070 A1: +0.210 A2: +0.163

IOL SE	IOL Cyl	IOL axis	Ref SE	Ref Sph	Ref Cyl	Ref Axis
+16.50	+1.00	90°	-0.44	-0.34	-0.19	0°
+16.25	+1.00	90°	-0.26	-0.16	-0.19	0°
+16.00	+1.00	90°	-0.08	+0.02	-0.19	0°
+15.75	+1.00	90°	+0.10	+0.20	-0.19	0°
+15.50	+1.00	90°	+0.28	+0.37	-0.19	0°
+15.89	+1.27	90°				Emmetropia
+16.00	+1.00	90°	-0.08	+0.02	-0.19	0°

(I) Borderline value (*) Value was edited manually --- No value measured

Comment

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Item	Explanation
1	Corneal vertex distance in mm (CVD)
2	Refractive index
3	If an IOL was highlighted for export in the detailed view, it will be displayed here.
4	Vitreous body status (VS)

Item	Explanation
5	Lens state (LS)
6	Manifest refraction
7	Corneal status: After laser correction (LVC)
8	Target refraction
9	Surgically induced astigmatism (SIA)
10	Composite values: Axis length (AL), anterior chamber depth (ACD), lens thickness (LT) with a standard deviation (SD)
11	White-to-white measurement
12	Composite values: K flat, K steep, cylinder
13	Composite values: TK flat, TK steep, Total Cylinder
14	Calculation results for Keratometry (K)
15	Toric IOL
16	Formulae used and corresponding IOL constants used
17	IOL calculation results, recommended values are highlighted
18	If an IOL was highlighted for export in the detailed view, the calculation results of this IOL will be displayed here.
19	Calculation results for Total Keratometry (TK)
20	Implantation axis

8.8.8.2 Analysis report

Clinic or practice information

Patient: Cölestin, Cecile

Date of birth: 1/17/1954 Gender: Female

Patient ID: 000000014

Physician: Surgeon Operator: Surgeon

Date of calibration test: by: Result: 12.00 mm

Date of measurement: 3/1/2016 n: 1.3375 CVD:

OD
right

LS: Phakic
Ref: -2.25 D -0.75 D @ 34°

AL: 25.24 mm SD: 5 µm
CCT: 489 µm SD: 7 µm
ACD: 4.03 mm SD: 9 µm
LT: 3.59 mm SD: 2 µm

VS: Vitreous body
VA: 20/25

WTW: 11.3 mm
P: 5.2 mm

ix: +0.2 mm ly: +0.0 mm
CW-Chord: 0.2 mm @ 121°

SE: 45.98 D SD: 0.15 D
K1: 44.84 D @ 173° SD: 0.75 D
K2: 47.18 D @ 83° SD: 0.10 D
ΔK: -2.34 D @ 173°

TK1: 37.66 D @ 0° SD: 0.38 D
TK2: 37.87 D @ 90° SD: 1.02 D
ΔTK: -0.21 D @ 0° SD: 0.75 D

B scan

Fixation

Anterior axial power

(!) Borderline value

Keratometry

(*) Value was edited manually

White to white

--- No value measured

Comment

IOLMaster 700

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Item	Explanation
1	Eye status: Lens state, vitreous body state, LVC state, manifest refraction, visual acuity
2	Composite values: Axis length (AL), anterior chamber depth (ACD), lens thickness (LT) with a standard deviation (SD)
3	White-to-white and pupil diameter

Item	Explanation
4	Shift of the corneal apex towards iris center (lx, ly) and pupil center (px, py) in X and Y direction, Chang-Waring Chord (CW-chord, "Angle Kappa")
5	Composite-K, flat meridian K, steep meridian K, cylinder K
6	Composite-TK, flat meridian TK, steep meridian TK, cylinder TK
7	Extended or single B-scan image (bird's eye view of a horizontal scan)
8	Extended or single fixation check image ~ 1 mm of horizontal retina scan
9	White-to-white image
10	Keratometry raw image
11	Image for Central Topography, Total Axial Power Map or Anterior Axial Power Map depending on user settings and availability

8.8.8.3 Biometric data

Patient	Cölestin Cecile			Clinic or practice information																																																								
Date of birth	1/17/1954	Gender	Female																																																									
Patient ID	000000014																																																											
Physician	Surgeon	Operator	Surgeon																																																									
Date of calibration test:		by:	Result:																																																									
Date of measurement: 3/1/2016		n: 1.3375	CVD: 12.00 mm																																																									
																																																												
<div style="display: flex; justify-content: space-between;"> <div> OD right </div> <div>Biometric values</div> <div> OS left </div> </div>																																																												
Eye status																																																												
<div style="display: flex; justify-content: space-between;"> <div> LS: Phakic Ref: -2.25 D -0.75 D @ 34° LVC: LASIK </div> <div> VS: Vitreous body VA: 20/25 </div> <div> LS: Phakic Ref: +0.00 D +0.00 D @ 0° LVC: LASEK </div> <div> VS: Vitreous body VA: 20/60 </div> </div>																																																												
Biometric values																																																												
<div style="display: flex; justify-content: space-between;"> <div> AL: 25.24 mm CCT: 489 µm ACD: 4.03 mm LT: 3.59 mm </div> <div> SD: 5 µm SD: 7 µm SD: 9 µm SD: 2 µm </div> <div> AL: 25.24 mm CCT: 489 µm ACD: 4.03 mm LT: 3.59 mm </div> <div> SD: 5 µm SD: 7 µm SD: 9 µm SD: 2 µm </div> </div>																																																												
<table border="1" style="width: 100%; text-align: center;"> <thead> <tr> <th>AL</th> <th>CCT</th> <th>ACD</th> <th>LT</th> <th>AL</th> <th>CCT</th> <th>ACD</th> <th>LT</th> </tr> </thead> <tbody> <tr><td>25.24 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td><td>25.23 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td></tr> <tr><td>25.23 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td><td>25.23 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td></tr> <tr><td>25.24 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td><td>25.23 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td></tr> <tr><td>25.23 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td><td>25.23 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td></tr> <tr><td>25.24 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td><td>25.23 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td></tr> <tr><td>25.24 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td><td>25.23 mm</td><td>489 µm</td><td>4.03 mm</td><td>3.59 mm</td></tr> </tbody> </table>					AL	CCT	ACD	LT	AL	CCT	ACD	LT	25.24 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm	25.24 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm	25.24 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm	25.24 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm
AL	CCT	ACD	LT	AL	CCT	ACD	LT																																																					
25.24 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm																																																					
25.23 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm																																																					
25.24 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm																																																					
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25.24 mm	489 µm	4.03 mm	3.59 mm	25.23 mm	489 µm	4.03 mm	3.59 mm																																																					
Corneal values																																																												
<div style="display: flex; justify-content: space-between;"> <div> SE: 45.98 D (!) K1: 44.84 D @ 173° K2: 47.18 D @ 83° ΔK: -2.34 D @ 173° </div> <div> SD: 0.15 D SD: 0.75 D SD: 0.10 D </div> <div> SE: 45.98 D (!) K1: 44.84 D @ 173° K2: 47.18 D @ 83° ΔK: -2.34 D @ 173° </div> <div> SD: 0.15 D SD: 0.75 D SD: 0.10 D </div> </div>																																																												
<div style="display: flex; justify-content: space-between;"> <div> SE: 45.98 D SE: 45.98 D SE: 45.98 D </div> <div> ΔK: -2.34 D @ 173° ΔK: -2.34 D @ 173° ΔK: -2.34 D @ 173° </div> <div> SE: 45.98 D SE: 45.98 D SE: 45.98 D </div> <div> ΔK: -2.34 D @ 173° ΔK: -2.34 D @ 173° ΔK: -2.34 D @ 173° </div> </div>																																																												
<div style="display: flex; justify-content: space-between;"> <div> TSE: 37.76 D TK1: 37.66 D @ 0° TK2: 37.87 D @ 90° ΔTK: -0.21 D @ 0° </div> <div> SD: 0.38 D SD: 1.02 D SD: 0.75 D </div> <div> TSE: 42.85 D TK1: 42.39 D @ 0° TK2: 43.31 D @ 90° ΔTK: -0.92 D @ 0° </div> <div> SD: 0.80 D SD: 0.63 D SD: 0.55 D </div> </div>																																																												
<div style="display: flex; justify-content: space-between;"> <div> TSE: 38.74 D TSE: 38.36 D TSE: 37.76 D </div> <div> ΔTK: -1.33 D @ 0° ΔTK: -1.00 D @ 96° ΔTK: -0.04 D @ 0° </div> <div> TSE: 42.39 D TSE: 42.39 D TSE: 42.39 D </div> <div> ΔTK: --- ΔTK: --- ΔTK: --- </div> </div>																																																												
White-to-white and pupil values																																																												
<div style="display: flex; justify-content: space-between;"> <div> WTW: 11.3 mm P: 5.2 mm </div> <div> Ix: +0.2 mm CW-Chord: 0.2 mm @ 121° </div> <div> WTW: 11.3 mm P: 5.2 mm </div> <div> Ix: +0.2 mm CW-Chord: 0.2 mm @ 121° </div> </div>																																																												
Reference image																																																												
<div style="display: flex; justify-content: space-between;"> <div>Image stored</div> <div>Image stored</div> </div>																																																												
<div style="display: flex; justify-content: space-between;"> <div>(!) Borderline value</div> <div>(*) Value was edited manually</div> <div>--- No value measured</div> </div>																																																												
<div style="border: 1px solid black; height: 30px; width: 100%;"></div>																																																												
																																																												

Item	Explanation
1	Eye status: Lens state, vitreous body state, manifest refraction, visual acuity, LVC state
2	Composite values: Axis length (AL), anterior chamber depth (ACD), lens thickness (LT) with a standard deviation (SD)
3	Average values: AL, ACD, LT of the 3 scans of 6 meridians

Item	Explanation
4	Composite-K, flat meridian K, steep meridian K, cylinder K
5	3 average K-values of 5 single measurements (K)
6	Composite-TK, flat meridian TK, steep meridian TK, cylinder TK
7	3 average TK-values of 5 single measurements (TK)
8	White-to-white diameter (WTW), pupil diameter (P)
9	Shift of the corneal apex towards iris center (lx, ly) and pupil center (px, py) in X and Y direction, Chang-Waring Chord (CW-chord, "Angle Kappa")
10	Reference image status: "Image saved" or "No image"

8.8.8.4 Reference Image

8.8.8.4.1 Keratometry axis

Patient: Cölestin Cecile

Date of birth: 1/17/1954 Gender: Female

Patient ID: 000000014

Physician: Surgeon Operator: Surgeon

Date of calibration test: by: Result: CVD: 12.00 mm

Date of measurement: 3/1/2016 n: 1.3375

This IOL calculation contains values that were edited manually.

OD right Reference image

Eye status

LS: Phakic VS: Vitreous body LVC: Untreated (*)

Ref: -2.25 D -0.75 D @ 34° VA: 20/25

Biometric values

AL: 25.24 mm	SE: 45.98 D (!)	TSE: 37.76 D
ACD: 4.03 mm	K1: 44.84 D @ 173°	TK1: 37.66 D @ 0°
LT: 3.59 mm	K2: 47.18 D @ 83°	TK2: 37.87 D @ 90°
NTW: 11.3 mm	ΔK: -2.34 D @ 173°	ΔTK: -0.21 D @ 0°
P: 5.2 mm		

lx: +0.2 mm ly: +0.0 mm

W-Chord: 0.2 mm @ 121°

SphericalAndToric - Barrett Universal II -

IOL (D) Ref (D)

+12.00 -0.22

90°

180°

0°

270°

Steep axis K2

(!) Borderline value (*) Value was edited manually --- No value measured

Comment

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Item	Explanation
1	Eye status: Lens state, vitreous body state, LVC state, manifest refraction, visual acuity
2	Composite values: Axis length (AL), anterior chamber depth (ACD), lens thickness (LT) with a standard deviation (SD)

Item	Explanation
3	White-to-white diameter (WTW), pupil diameter (P)
4	Shift of the corneal apex towards iris center (lx, ly) and pupil center (px, py) in X and Y direction, Chang-Waring Chord (CW-chord, "Angle Kappa")
5	Composite-K, flat meridian K, steep meridian K, cylinder K
6	Composite-TK, flat meridian TK, steep meridian TK, cylinder TK
7	Axis according to the TABO scheme
8	If no IOL was selected in the detailed view and "Keratometry" as default in the printing settings, the steep corneal axis of Keratometry is displayed here.
9	Temporal
10	Nasal

8.8.8.4.2 Total Keratometry axis

Patient: de Marichalar y Sáenz de Tejada Méndez

Date of birth: 1/1/1953 Patient ID: 000000025 Gender: Female

Physician: Surgeon Operator: Surgeon

Clinic or practice information

Date of calibration test: by: Result: Date of measurement: 1/1/1973 n: 1.3375 CVD: 12.00 mm

OD right Reference image

Eye status

LS: Phakic Ref: +0.00 D +0.00 D @ 0° VS: Vitreous body LVC: Untreated

Biometric values

AL: 25.24 mm ACD: 4.03 mm LT: 3.59 mm WTW: 11.3 mm P: 5.2 mm

SE: 45.98 D (!) K1: 44.84 D @ 173° K2: 47.18 D @ 83° ΔK: +2.34 D @ 83°

TSE: 37.76 D TK1: 37.66 D @ 0° TK2: 37.87 D @ 90° ΔTK: +0.21 D @ 90°

ix: +0.2 mm Px: +0.1 mm iy: +0.0 mm Py: -0.1 mm

90° 180° 0° 270°

Steep axis TK2

(!) Borderline value (*) Value was edited manually --- No value measured

Comment [OU]: 4 form las (3K / 1TKP); [OD]: lvc.myopic, target refraction: -0.25; [OS]: target refraction plano, SIA values, refractivesurgerystate: undefined, and a sel...

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Item	Explanation
1	Eye status: Lens state, vitreous body state, LVC state, manifest refraction, visual acuity
2	Composite values: Axis length (AL), anterior chamber depth (ACD), lens thickness (LT) with a standard deviation (SD)
3	White-to-white diameter (WTW), pupil diameter (P)

Item	Explanation
4	Shift of the corneal apex towards iris center (lx, ly) and pupil center (px, py) in X and Y direction, Chang-Waring Chord (CW-chord, "Angle Kappa")
5	Composite-K, flat meridian K, steep meridian K, cylinder K
6	Composite-TK, flat meridian TK, steep meridian TK, cylinder TK
7	Axis according to the TABO scheme
8	If no IOL was selected in the detailed view and "Total Keratometry" as default in the printing settings, the steep corneal axis of Total Keratometry is displayed here.
9	Temporal
10	Nasal

8.8.8.4.3 IOL implantation axis

Patient: Cölestin Cecile

Date of birth: 1/17/1954 Gender: Female

Patient ID: 000000014

Physician: Surgeon Operator: Surgeon

Clinic or practice information

Date of calibration test: by: Result:
Date of measurement: 3/1/2016 n: 1.3375 CVD: 12.00 mm

This IOL calculation contains values that were edited manually.

OD right Reference image

Eye status
LS: Phakic VS: Vitreous body LVC: Untreated (*)
Ref: -2.25 D -0.75 D @ 34° VA: 20/25

Biometric values

AL: 25.24 mm	SE: 45.98 D (I)	TSE: 37.76 D
ACD: 4.03 mm	K1: 44.84 D @ 173°	TK1: 37.66 D @ 0°
LT: 3.59 mm	K2: 47.18 D @ 83°	TK2: 37.87 D @ 90°
WTW: 11.3 mm	ΔK: -2.34 D @ 173°	ΔTK: -0.21 D @ 0°
P: 5.2 mm		

IC: +0.2 mm Iy: +0.0 mm
CW-Chord: 0.2 mm @ 121°

SphericalAndToric
- Haigis Toric -

IOL SE IOL Cyl IOL axis Ref SE Ref Sph Ref Cy Ref Axis
+11.75 +5.00 85° -0.19 -0.05 -0.29 175

90° 180° 270° 0° 85°

(I) Borderline value (*) Value was edited manually --- No value measured

Comment

IOLMaster 700 Version 1.80 Report dated 6/12/2018 5:11 AM; created by Surgeon

ZEISS

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Item	Explanation
1	Eye status: Lens state, vitreous body state, LVC state, manifest refraction, visual acuity
2	Composite values: Axis length (AL), anterior chamber depth (ACD), lens thickness (LT) with a standard deviation (SD)
3	White-to-white diameter (WTW), pupil diameter (P)

Item	Explanation
4	Shift of the corneal apex towards iris center (lx, ly) and pupil center (px, py) in X and Y direction, Chang-Waring Chord (CW-chord, "Angle Kappa")
5	If an IOL was selected in the detailed view, it will be displayed here including the formula used and the calculation results.
6	Composite-K, flat meridian K, steep meridian K, cylinder K
7	Composite-TK, flat meridian TK, steep meridian TK, cylinder TK
8	Axis according to the TABO scheme
9	If an IOL was selected in detailed view, the corresponding implantation axis will be displayed here.
10	Temporal
11	Nasal

8.8.8.5 Corneal data report

Patient		Cölestin Cecile		Clinic or practice information
Date of birth	1/17/1954	Gender	Female	
Patient ID	000000014			
Physician	Surgeon	Operator	Surgeon	
Date of calibration test:		by:		Result:
Date of measurement: 3/1/2016		n:	1.3375	CVD: 12.00 mm
<div style="display: flex; justify-content: space-between;"> <div> <p>OD right</p> </div> <div> <p>OS left</p> </div> </div>				
Corneal values				
Eye status				
LS: Phakic Ref: -2.25 D -0.75 D @ 34° LVC: LASIK		VS: Vitreous body VA: 20/25		LS: Phakic Ref: +0.00 D +0.00 D @ 0° LVC: LASEK
Corneal values				
SE: 45.98 D (!) K1: 44.84 D @ 173° K2: 47.18 D @ 83° ΔK: -2.34 D @ 173°		SD: 0.15 D SD: 0.75 D SD: 0.10 D		SE: 45.98 D (!) K1: 44.84 D @ 173° K2: 47.18 D @ 83° ΔK: -2.34 D @ 173°
SE: 45.98 D SE: 45.98 D SE: 45.98 D		ΔK: -2.34 D @ 173° ΔK: -2.34 D @ 173° ΔK: -2.34 D @ 173°		SE: 45.98 D SE: 45.98 D SE: 45.98 D
Total Keratometry				
TSE: 37.76 D TK1: 37.66 D @ 0° TK2: 37.87 D @ 90° ΔTK: -0.21 D @ 0°		SD: 0.38 D SD: 1.02 D SD: 0.75 D		TSE: 42.85 D TK1: 42.39 D @ 0° TK2: 43.31 D @ 90° ΔTK: -0.92 D @ 0°
TSE: 38.74 D TSE: 38.36 D TSE: 37.76 D		ΔTK: -1.33 D @ 0° ΔTK: -1.00 D @ 96° ΔTK: -0.04 D @ 0°		TSE: 42.39 D TSE: 42.39 D TSE: 42.39 D
Corneal back surface values				
PSE: -5.45 D PK1: -5.32 D @ 90° PK2: -5.60 D @ 0° ΔPK: -0.28 D @ 0°		SD: 0.12 D SD: 0.17 D SD: 0.18 D		PSE: -5.46 D PK1: -5.42 D @ 76° PK2: -5.50 D @ 166° ΔPK: -0.08 D @ 166°
PSE: -33.98 D PSE: -32.73 D PSE: -31.60 D		ΔPK: -0.64 D @ 66° ΔPK: -0.59 D @ 69° ΔPK: -0.55 D @ 71°		PSE: -5.46 D PSE: -5.46 D PSE: -5.46 D
Other values				
CCT: 489 μm WTW: 11.3 mm P: 5.2 mm		SD: 7 μm lx: +0.2 mm ly: +0.0 mm CW-Chord 0.2 mm @ 121°		CCT: 489 μm WTW: 11.3 mm P: 5.2 mm
		lx: +0.2 mm ly: +0.0 mm CW-Chord 0.2 mm @ 121°		
(j) Borderline value (*) Value was edited manually --- No value measured				
Comment				

Item	Explanation
1	Eye status: Lens state, vitreous body state, manifest refraction, visual acuity, LVC state
2	Composite-K, flat meridian K, steep meridian K, cylinder K
3	3 average K-values of 5 single measurements (K)
4	Composite-TK, flat meridian TK, steep meridian TK, cylinder TK
5	3 average TK-values of 5 single measurements (TK)

Item	Explanation
6	Composite-PK, flat meridian PK, steep meridian PK, cylinder PK
7	3 average PK-values of 5 single measurements (PK)
8	Composite value of central corneal thickness (CCT)
9	White-to-white diameter (WTW), pupil diameter (P)
10	Shift of the corneal apex towards iris center (lx, ly) and pupil center (px, py) in X and Y direction, Chang-Waring Chord (CW-chord, "Angle Kappa")

8.8.9 Export reference image for ZEISS Cataract Suite markerless

Export measurements (including reference image and calculated target axis of toric IOLs) for ZEISS Cataract Suite markerless directly after IOL calculation [► 84]. If you do not need the calculated target axis of toric IOLs, you can export the measurement in the "Patient / Measurements" [► 51] dialog window.

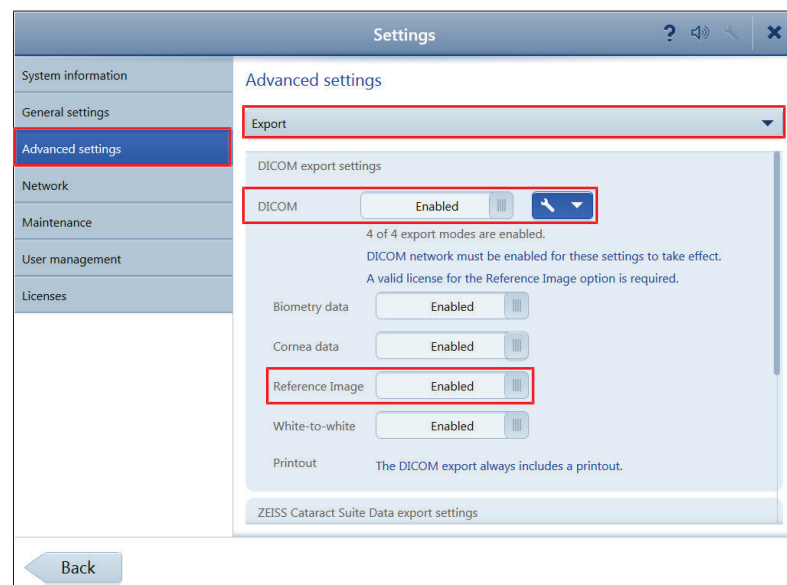
In general, there are three ways to export the reference image for the ZEISS Cataract Suite markerless from IOLMaster 700:

- Via a network / FORUM
- Via USB
- Via ZEISS EQ Mobile Cloud Instance:

8.8.9.1 Export reference image via network / FORUM

Action

1. Configure the following settings in the "Advanced settings / Export" dialog window:
 - Set the [DICOM] option button to "Enabled".
 - Tap on the wrench on the right side of the [DICOM] option button to display further setting options.
 - Set the [Reference Image] button on "Enabled".

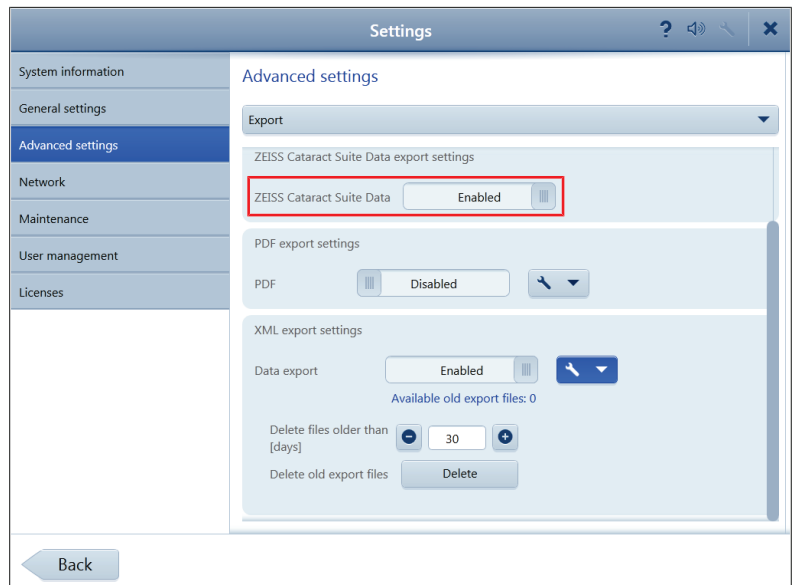


2. Tap [Export] in the "IOL calculation" [► 84] dialog window.

8.8.9.2 Export reference image via USB

Action

1. Configure the following settings in the "Advanced settings / Export" dialog window:
 - Set the [ZEISS Cataract Suite data] option button to "Enabled".



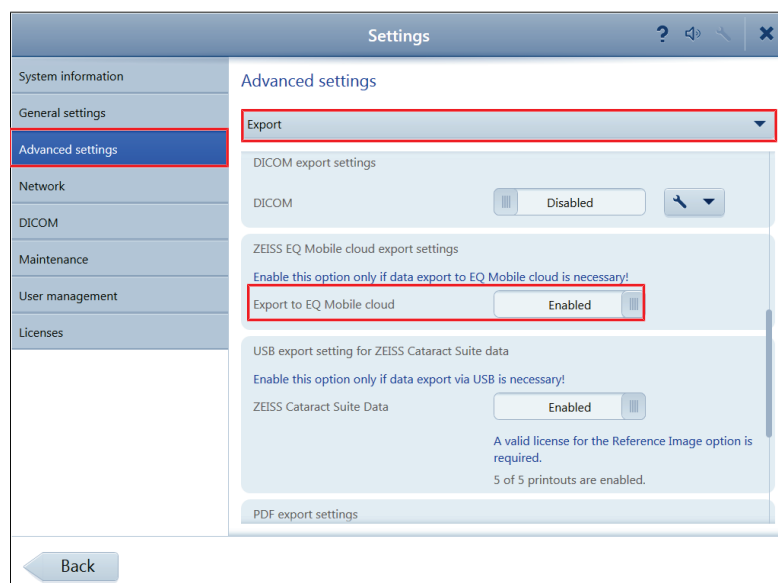
2. Connect a USB drive to the device.
3. Tap [Export] in the "IOL calculation" [► 84] dialog window.
 - ⇒ A .upt file is saved on the USB drive together with the measured values and reports. The files can be read with CALLISTO eye.

8.8.9.3 Export reference image via ZEISS EQ Mobile Cloud

This export function is available if the ZEISS EQ Mobile option has been purchased and installed. For more information on the configuration of EQ Mobile Cloud on your IOLMaster 700, see section 8.9.5. Also observe the installation instructions of the ZEISS EQ Mobile Cloud.

Action


1. Configure the following settings in the "Advanced settings / Export" [▶ 172] dialog window:
 - Set the [Export to EQ Mobile Cloud] option button to "Enabled".



2. Tap [Export] in the "IOL calculation" [▶ 84] dialog window.

8.9 Settings

8.9.1 Menu bar

Tap the  button in the upper right corner of the display to open the "Settings" dialog window. The menu bar to enable various adjustment options is located on the left side of the dialog window. The dialog of the selected setting option is displayed on the right side in the work area of the dialog.

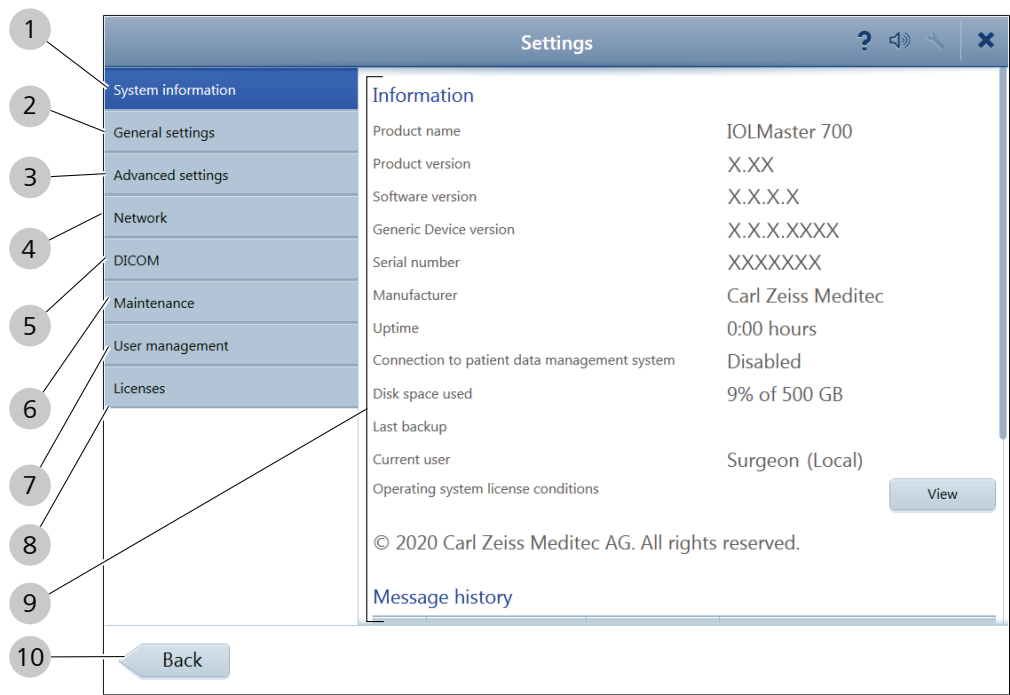


Figure 51: Settings - menu bar

Pos.	Icon/Name	Explanation
1	System information	Opens a window displaying system information (start window after opening the "Settings" dialog).
2	General settings	Opens a window for specifying general device settings.
3	Advanced settings	Opens a window for specifying advanced system settings.
4	Network	Opens a window for specifying network settings.
5	DICOM	Opens a window for specifying DICOM settings.
6	Maintenance	Opens a window for specifying maintenance settings.
7	User management	Opens a window for configuring user management.
8	Licenses	Opens a window for displaying existing licenses and activating new licenses.

Pos.	Icon/Name	Explanation
9	Working range	Displays the dialog for the selected setting option.
10	Back	Closes the "Settings" dialog. All modified settings will be automatically saved.

8.9.2 System information

This dialog window opens by tapping the [System information] button. It shows important system information.

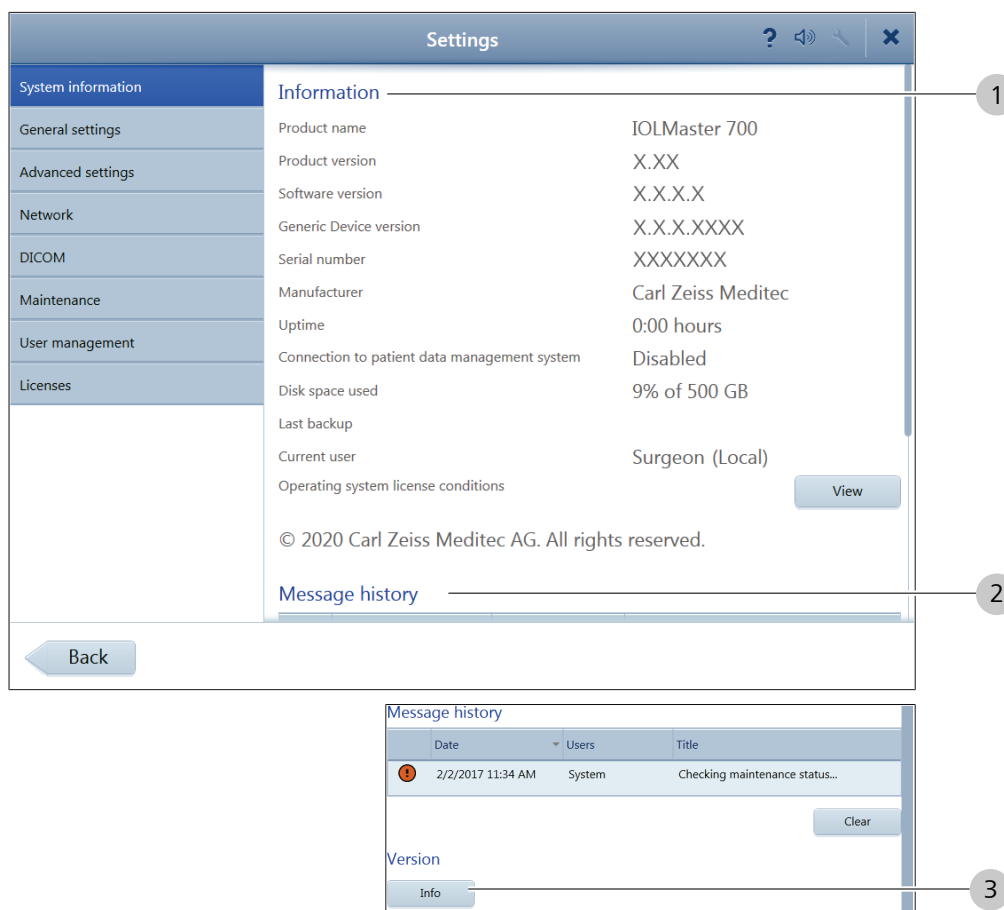






Figure 52: System information

Pos.	Icon/Name	Explanation
1	"Information" dialog area	
	This area displays important information about the device software.	
2	"Message history" dialog area	
	List of system messages	This area contains an overview of all system messages (e.g. network connection errors).
	 Warning	"Warning" symbol in message overview
	 Error	"Error" symbol in message overview
	 Serious error	"Serious error" symbol in message overview
	 Information	"Information" symbol in message overview
3	"Version" dialog area	
	Information	Tap the [Information] button to open "Version" dialog, where you can see information about ZEISS IOLMaster700 – SWEPT Source Biometry and localization.

The "Version" dialog window opens by tapping the [Info] button.

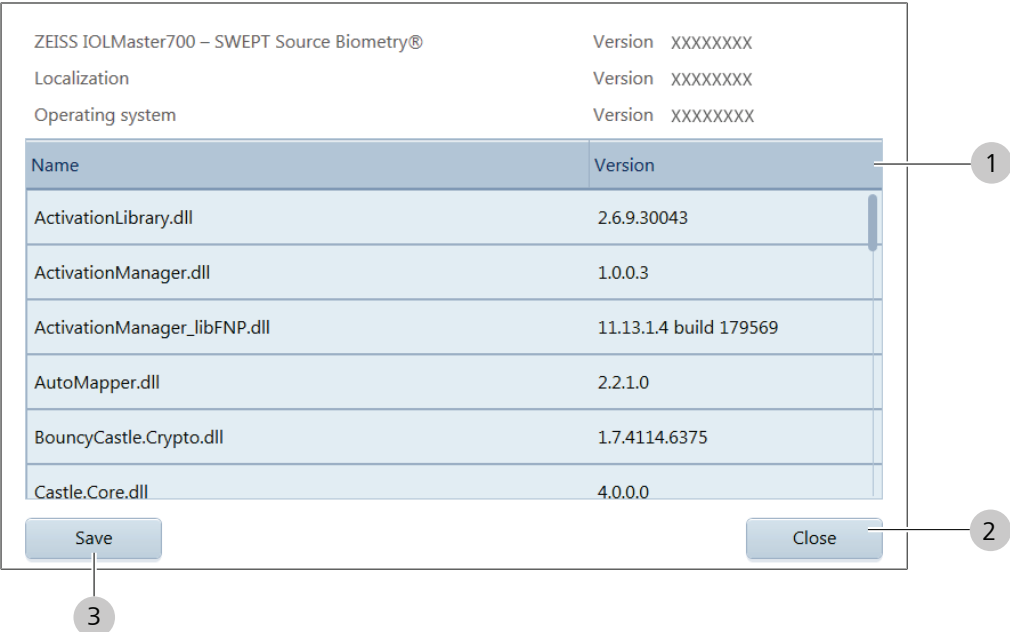


Figure 53: System information - Version

Pos.	Name	Explanation
1	Name / Version	This list box displays the dynamic program libraries with version numbers.
2	Close	Closes the "Version" dialog area.
3	Save	Saves all version information in a log file.

8.9.3 General settings

Tap the [General settings] button to open this dialog window. All general device and software settings can be made here.

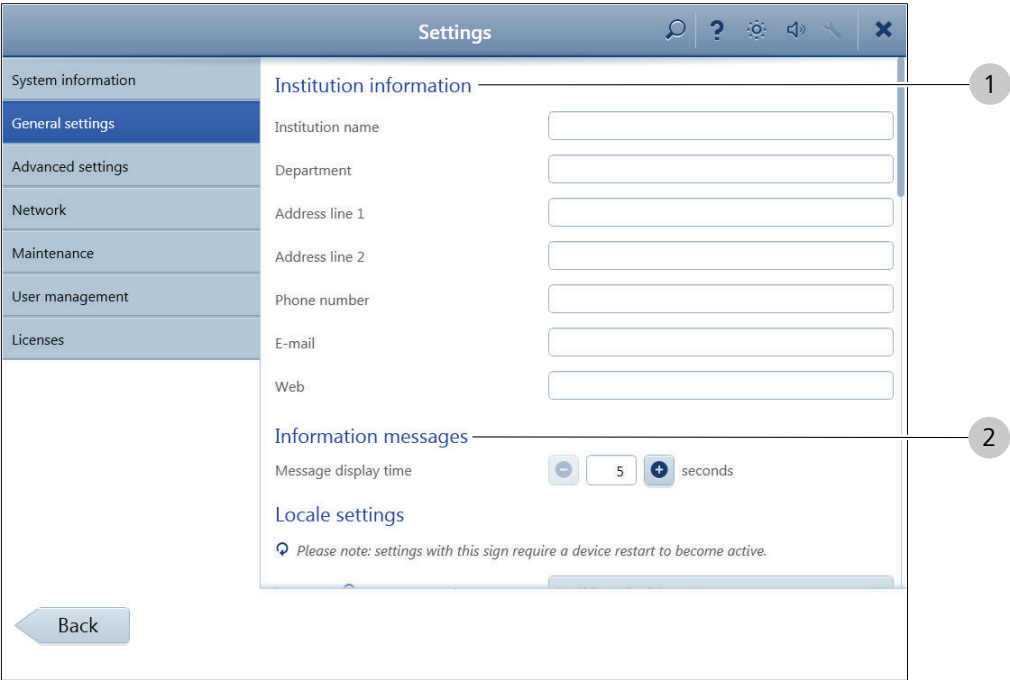


Figure 54: General settings 1

Item	Name	Explanation
1	"Institution information" dialog area	
	Institution name	Input field for entering the name of the institution / clinic / practice that is to appear in the reports.
	Department	Input field for entering the name of the department that is to appear in the reports.
	Address line 1; Address line 2	Input field for entering the address to appear in the reports.
	Phone number	Input field for entering the telephone number to appear in the reports.
	E-mail	Input field for entering the e-mail address to appear in the reports.
	Web	Input field for entering the web address to appear in the reports.
2	"Information messages" dialog area	
	Message display time	Input field for setting the display time of system messages (in seconds). The time can be increased/reduced in one second increments with the [+] and [-] buttons.

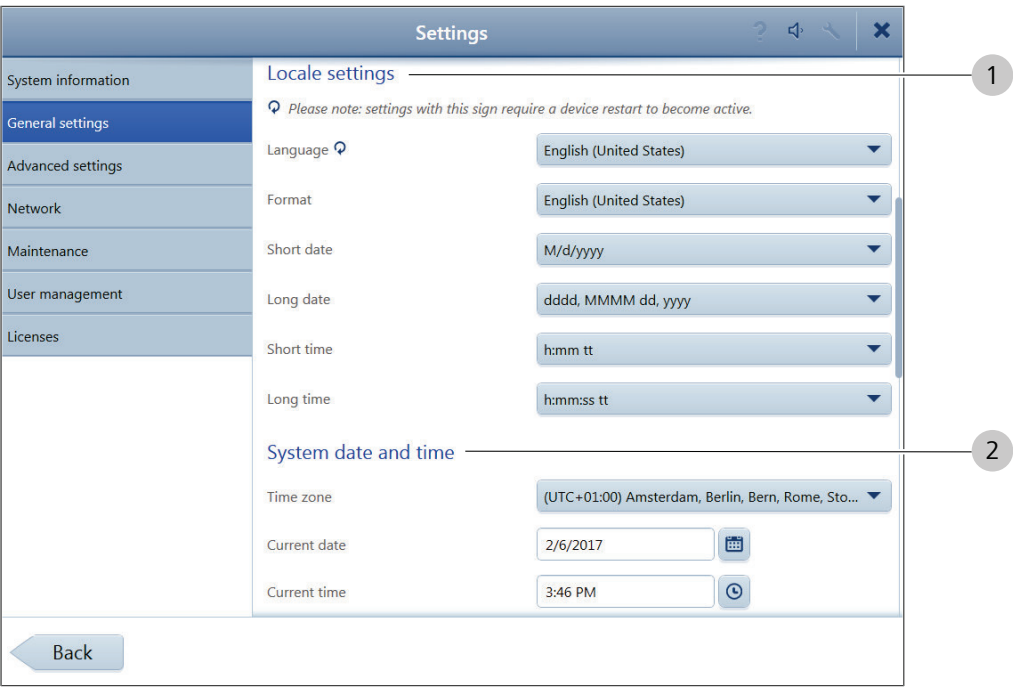


Figure 55: General settings 2

Item	Name	Explanation
1	"Locale settings" dialog area	
	Language	Drop-down list for selecting the language.
	Format	Drop-down list for selecting the regional format settings.
	Date (long / short)	Drop-down lists for selecting the display format for the date.
	Time (long / short)	Drop-down lists for selecting the display format for the time.
	When changing the language, a restart of the device is required. To acknowledge the message, press [OK].	
2	"System date and time" dialog area	
	Time zone	Drop-down list for selecting the current time zone.
	Current date	The current date can be selected after the expanding the "Current date" selection box.
	Current time	The current time can be selected after the expanding the "Current time" selection box.

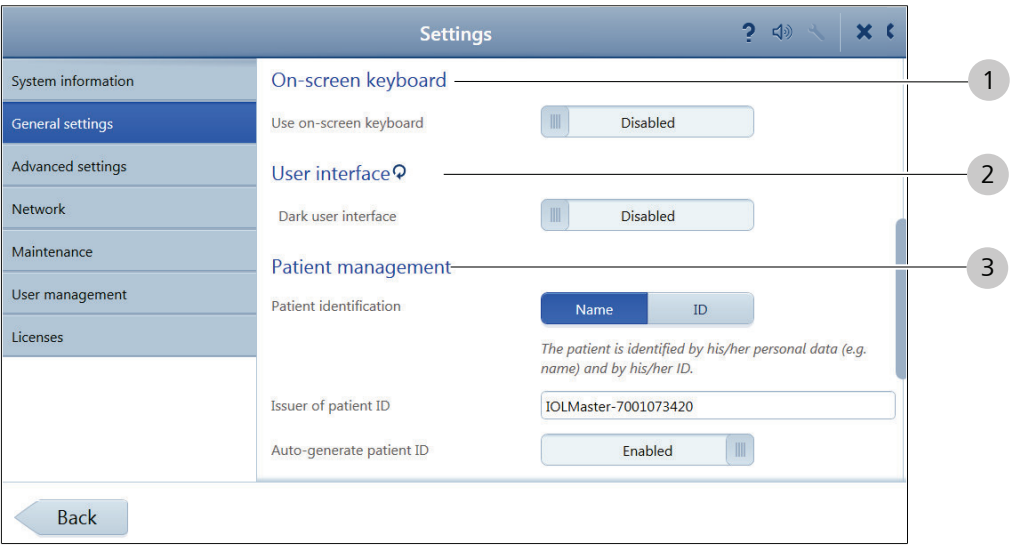


Figure 56: General settings 3

Item	Name	Explanation
1	"On-screen keyboard" dialog area	
	Use on-screen keyboard	This option button is used to enable or disable the on-screen keyboard.
2	"User interface" dialog area	
	Dark user interface	This option button is used to enable or disable a darkened user interface.
3	"Patient management" dialog area	
	Patient identification	In the [Name] button setting the patient is identified by his/her personal data (e.g. name) and an ID. In the [ID] button setting the patient is identified by ID and Gender only. Additional personal data is optional.
	Issuer of patient ID	This input field is for entering the initials of the person creating the patient ID (issuer).
	Auto-generate patient ID	This option button is used for enabling and disabling the automatic assignment of a patient ID.

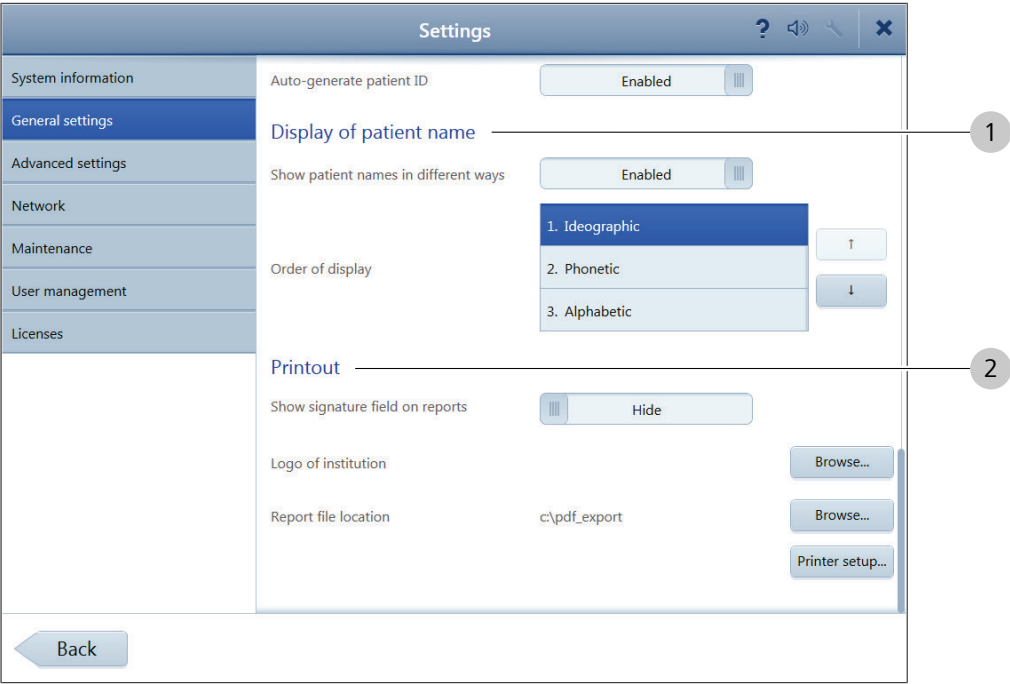


Figure 57: General settings 4

Item	Name	Explanation
1	"Display of patient name" dialog area	
	Show patient names in different ways	This option button is used to enable/disable the display of the patient name in different ways. Activation of the option [Show patient names in different ways] enables a choice between ideographic, phonetic and alphabetic notation.
	Order of display	This list box is only displayed when the option [Show patient names in different ways] is enabled. The order of display can be selected with the arrow keys. Only the first two entered patient names are displayed in each case.

Item	Name	Explanation
2	"Printout" dialog area	
	Show signature field on reports	This option button is used to enable/disable the display of the signature field on reports.
	Logo of institution	The [Browse] button opens a window for choosing a logo of the institution in JPG format that is to appear on reports. After selecting the desired folder, the window is closed by tapping the [Select] button; the name of the selected logo will be displayed on the screen. The [Cancel] button closes the window without importing the logo.
	Report file location	The [Browse] button opens a window for selecting the storage location for reports in PDF format. After selecting the desired folder, the window is closed by tapping the [Select] button; the selected folder will be displayed on the screen as the storage location. The [Cancel] button closes the window without changing the storage location.
	Printer setup	The [Printer setup] button opens a window for selecting and setting up a printer (see "Printer setup"). [▶ 149]

8.9.3.1 Printer setup

Navigate to "Settings / General / Printer setup". The dialog for printer configuration contains functions for setting up, editing and deleting printers.

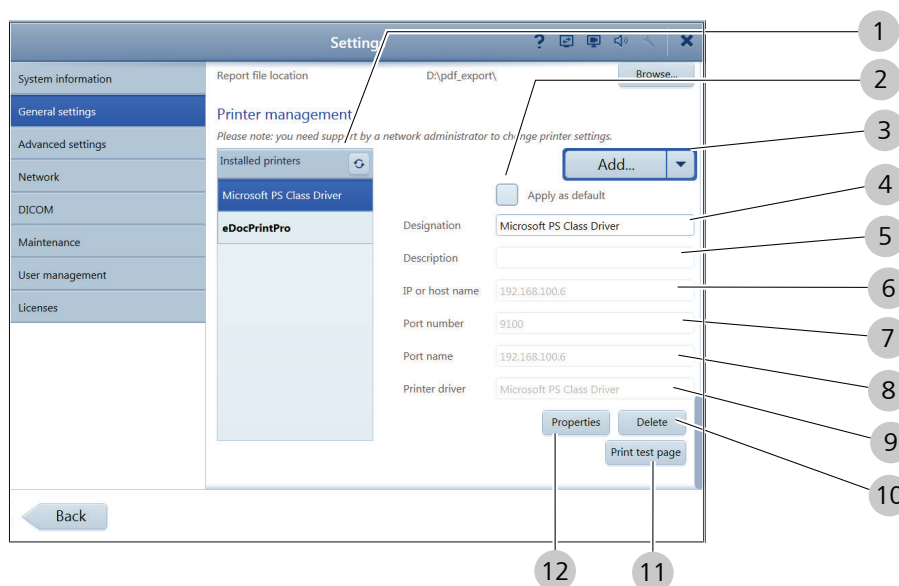


Figure 58: Printer setup

Item	Name	Explanation
Printer setup		
1	"List of installed printers" list box	The printers currently installed in the system are displayed in the "List of installed printers" list box. A printer can be selected by tapping it. The selected printer is highlighted in blue.
2	Set as default	If this checkbox is enabled, the printer currently selected is set as the default print.
3	Add	Tap the [Add] button to open a dialog window for adding a new printer.
4	Designation	Name of printer
5	Description	Description of the printer (optional)
6	IP or host name	IP or host name of printer
7	Port number	Port number of printer
8	Port name	Port name of printer
9	Printer drivers	Selected printer driver
10	Delete	Tap the [Delete] button to delete the currently selected printer from the "List of installed printers" list box.
11	Print test page	Tap the [Print test page] button to print a test page.
12	Properties	Tap the [Properties] button to display the dialog for changing the printer settings for the printer currently selected. For example, the paper size can be specified here.

8.9.4 Advanced settings

This dialog window is opened by tapping the [Advanced settings] button. The current user-specific settings can be displayed, entered and changed here.

8.9.4.1 Select setting

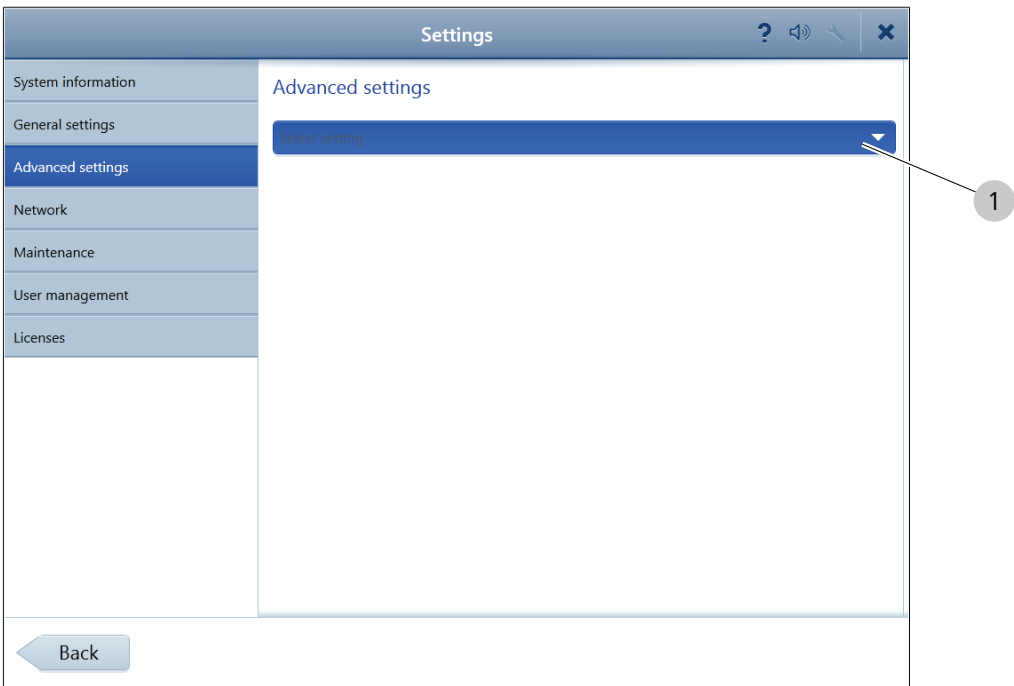


Figure 59: Select setting

Item	Name	Explanation
1	Select setting	Select the following settings using the drop-down list "Select setting": <ul style="list-style-type: none">■ Parameters, units■ Workflow■ IOL management■ Measurement■ Analyze■ Printout■ Export■ IOL calculation

8.9.4.2 Parameters, units

The advanced setting option "Parameters, units" can be opened using the drop-down list in the "Advanced settings" dialog window.

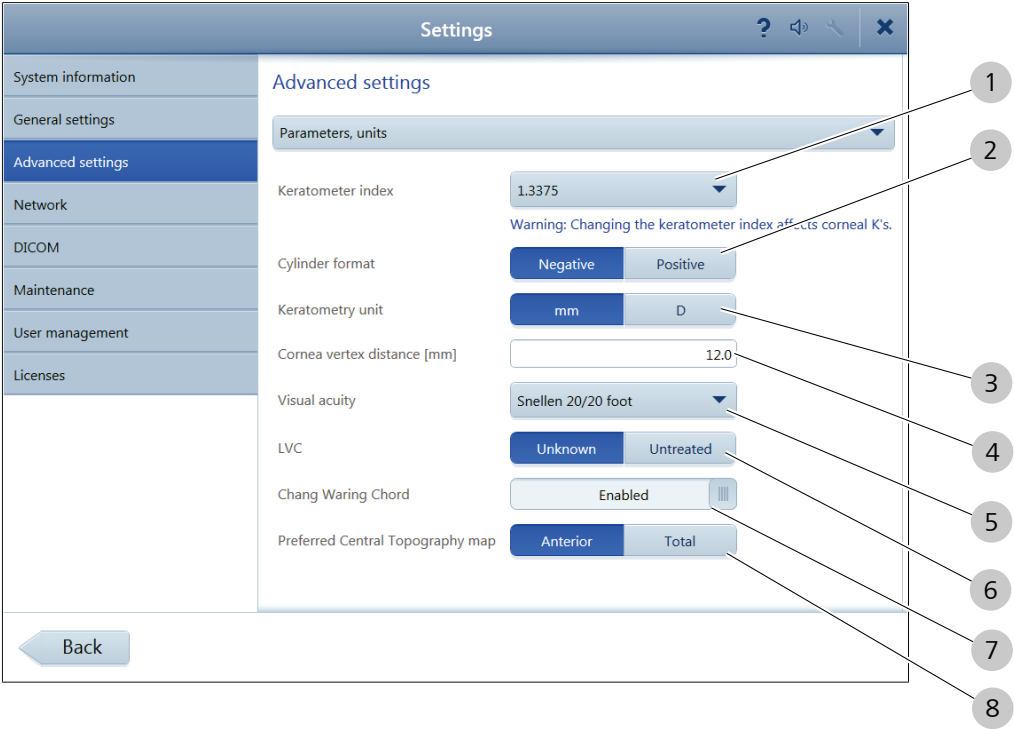


Figure 60: Parameters, units

Pos.	Name	Explanation
Parameters, units		
1	Keratometer index	The refractive index is selected using the "Keratometer index" drop-down list.
2	Cylinder format	This option button is used to enter the cylinder value in negative or positive notation.
3	Keratometry unit	Tap this option button to define the keratometry unit. On selecting "mm", the corneal radii are displayed. On selecting "D", the corneal K's are displayed. Use the formula $D = (n-1)/R$ (keratometry index n) to convert the corneal radii (R) to corneal K's (D).
4	Cornea vertex distance [mm]	In the "Cornea vertex distance [mm]" input field the cornea vertex distance (distances between spectacles back side and corneal front side) is entered in millimeters. Typical values are approx. 12 mm for spectacles correction and 0 mm for contact lens correction. The cornea vertex distance is related to the pre-surgery subjective refraction and should be adjusted to each patient individually. It can be entered as a decimal figure using the on-screen or external keyboard.

Pos.	Name	Explanation
5	Visual acuity	The "Visual acuity" drop-down list allows selection of regional notation for refractive power (visual acuity) in Decimal, Snellen 20/20 foot, Snellen 6/6 meter or LogMAR.
6	LVC	This option button is used to preselect the LVC state in the patient manager. In eyes with no prior refractive surgery, no further entries are necessary. The physician is responsible for the correctness of entered data.
7	Chang Waring Chord	Using this option button, the display of the shift of the corneal apex towards pupil center (Px, Py) in X and Y direction or Chang-Waring Chord (CW-chord, "Angle Kappa") will be determined.
8	Preferred Central Topography Map	This option button determines how the Central Topography is displayed by default in the "Measurement" and "Analysis" dialog windows and in the printouts.

8.9.4.3 Workflow

The advanced setting option "Workflow" can be opened using the drop-down list in the "Advanced settings" dialog window.

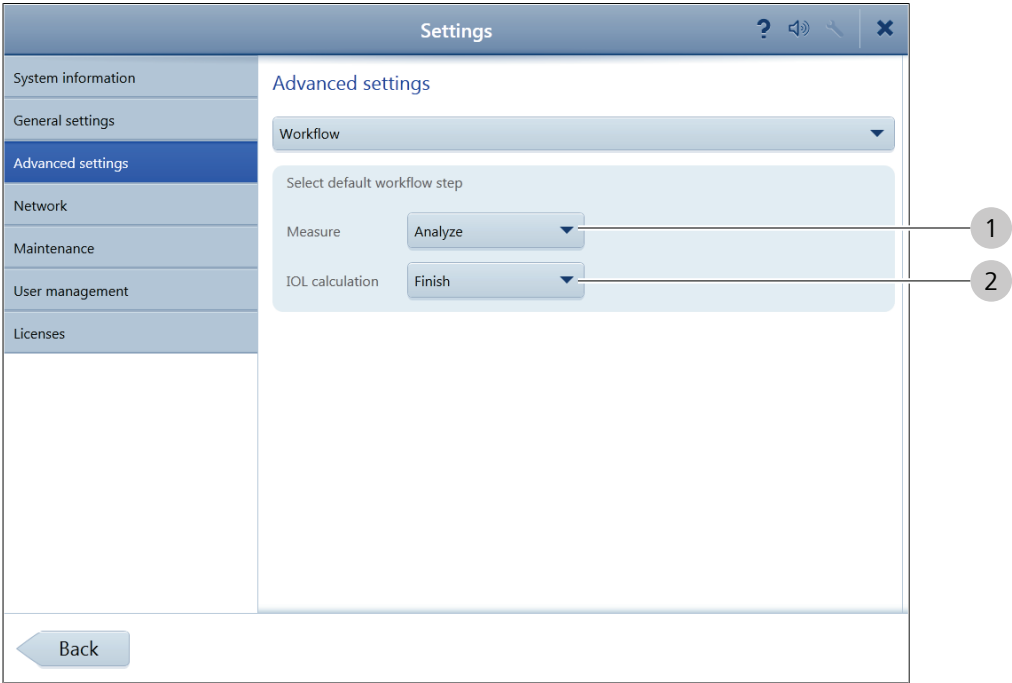


Figure 61: Workflow

Item	Name	Explanation
Workflow		
1	Measurement	In the "Measure" drop-down list the workflow for the "Measure - Quality check" [► 68] dialog window is defined. You can select whether the measurement is followed by analysis of images or the IOL calculation.
2	IOL calculation	In the "IOL calculation" drop-down list the workflow for the "IOL calculation" [► 84] dialog window is defined. You can select whether IOL calculation is terminated without printing ("Finish") or the results are printed ("Print").

8.9.4.4 IOL management

The advanced setting option "IOL management" can be opened using the drop-down list in the "Advanced settings" dialog window.

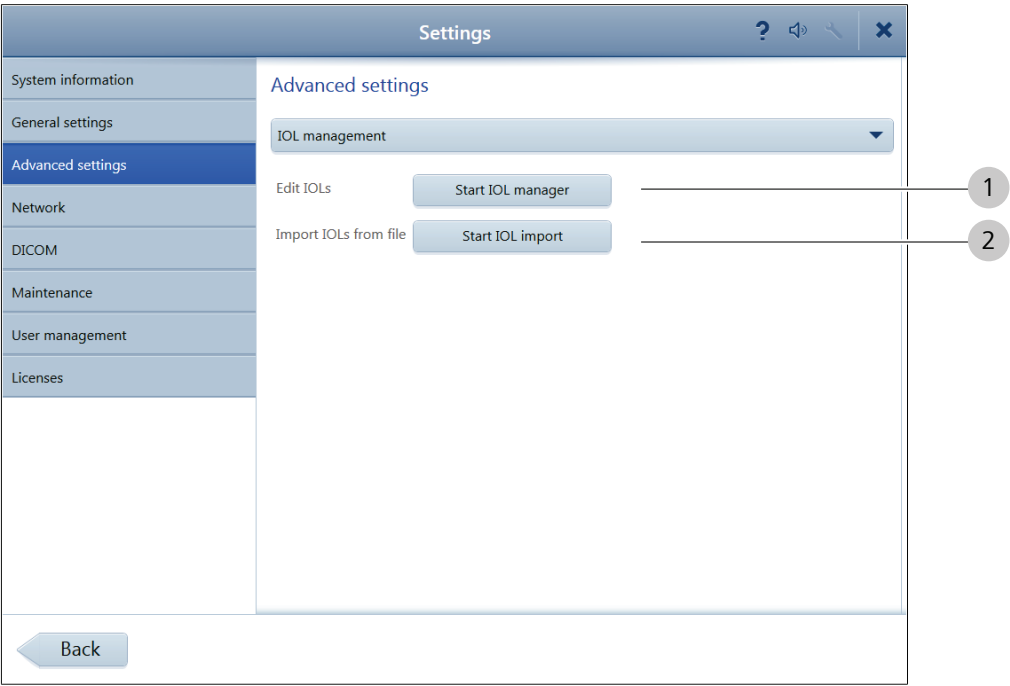


Figure 62: IOL management

Item	Name	Explanation
IOL management		
1	Start IOL manager	This button starts the IOL manager. In the IOL manager user-specific intraocular lenses and their constants can be generated and edited (see "Lens manager").
2	Start IOL import	Tap this button to start a dialog in which intraocular lenses and their constants can be imported from the IOL constants list and edited (see "Import of IOL constants").

8.9.4.4.1 Lens manager

CAUTION!

Risk arising from incorrect operation

The refractive power of the IOL calculation for toric lenses will be issued in spherical equivalent according to the standard. When selecting the appropriate IOL refractive power based on the label of the IOL manufacturer this may cause confusion between sphere (Sph) and spherical equivalent (SE).

- ▶ Be careful when selecting the appropriate IOL refractive power on the label of the IOL manufacturer. Some manufacturers use two different formats (spherical refractive power (Sph) and spherical equivalent (SE)) on their labels when describing the refractive power of toric lenses. If this is the case, clarify with the manufacturer of toric lens which refractive power notation should be used.
- ▶ If you perform the IOL calculation using the device software of IOLMaster 700, select the IOL using the spherical equivalent of the toric lens refractive power indicated on the label of the IOL manufacturer. If in doubt, ask the IOL manufacturer how to identify this value on the label.

CAUTION!

Risk arising from incorrect operation

In case of errors during the input of IOL data, inexistent IOL or IOL with a high residual refraction may be shown as optimum IOL.

- ▶ Check all manually entered IOL parameters carefully. Carl Zeiss Meditec AG does not accept any liability for the correctness and suitability of parameters.
- ▶ When selecting the IOL to be implanted, consider the expected residual refraction. In case of an unusually high expected residual refraction check the IOL selection and the manually entered or imported IOL parameters.
- ▶ When calculating toric IOL, ensure the displayed cylinder value in D beside the toric marking.

Constants subject to the lens type must be defined and entered prior to using the IOLMaster 700. Your IOLMaster 700 does not have its own constants; they are physician-specific and contingent on individual circumstances. In particular the diagnostic and surgical methods may result in differing corrective factors for calculation. The constants should thus be subjected to regular review and refinement.

The lens manager is started using the [Start lens manager] button in the "Advanced settings - IOL management" [▶ 155] dialog window.

Make sure that you are logged in as user or surgeon if you want to make changes in the lens manager. An administrator cannot make changes in the lens manager.

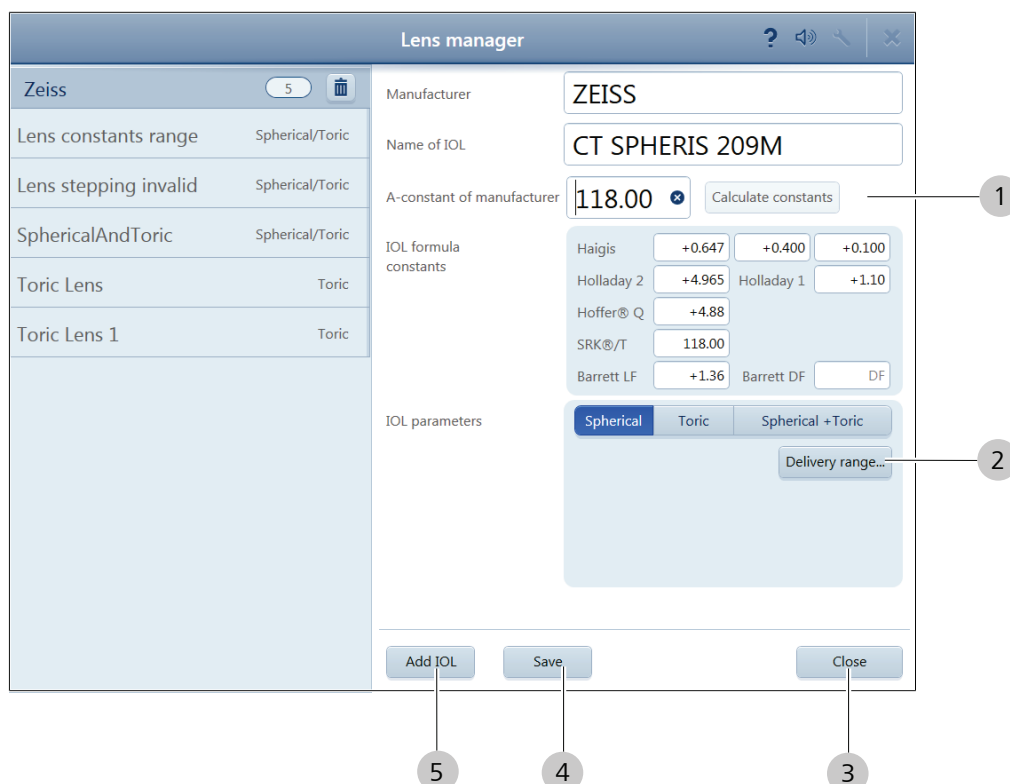


Figure 63: Lens manager

Item	Name	Explanation
1	Calculate constants	Tap the [Calculate constants] button to determine the different IOL formula constants for various calculation formulae (Haigis Suite, Holladay 1, Holladay 2, Hoffer®Q, SRK®/T, Barrett Suite). Note that all constants are calculated from the SRK/T constant. If not SRK/T constant has been entered, the manufacturer's constant will be used.
2	Delivery range	Tapping the [Delivery range] button displays a new window for the Definition of delivery ranges [► 158].
3	Close	Tap the [Close] button to close the lens manager.
4	Save	Tap the [Save] button to save the entered intraocular lens into the user-specific selection list.
5	Add IOL	Tap the [Add IOL] button to open an input area where you can enter the Manufacturer, Name of IOL and A-constant of manufacturer. These data can be entered using the on-screen or external keyboard. Using the [Spherical / Toric / Spherical+Toric] buttons you can enter the IOL type. Additionally, the notation with SE (Spherical equivalent) or Sph (Sphere) must be selected for toric IOL. In the SE range or Sphere range and Cylinder range input area the delivery

Item	Name	Explanation
		range of the intraocular lens is entered using the on-screen or external keyboard. Tap the [SE step size] buttons (0.25/0.5) or [Sphere step size] (0.25/0.5) and [Cylinder step size] buttons (0.5/0.75) to enter the power steps in which the intraocular lens can be delivered.

8.9.4.4.1.1 Definition of delivery ranges

For lenses with regular cylinder gradations over the entire delivery range

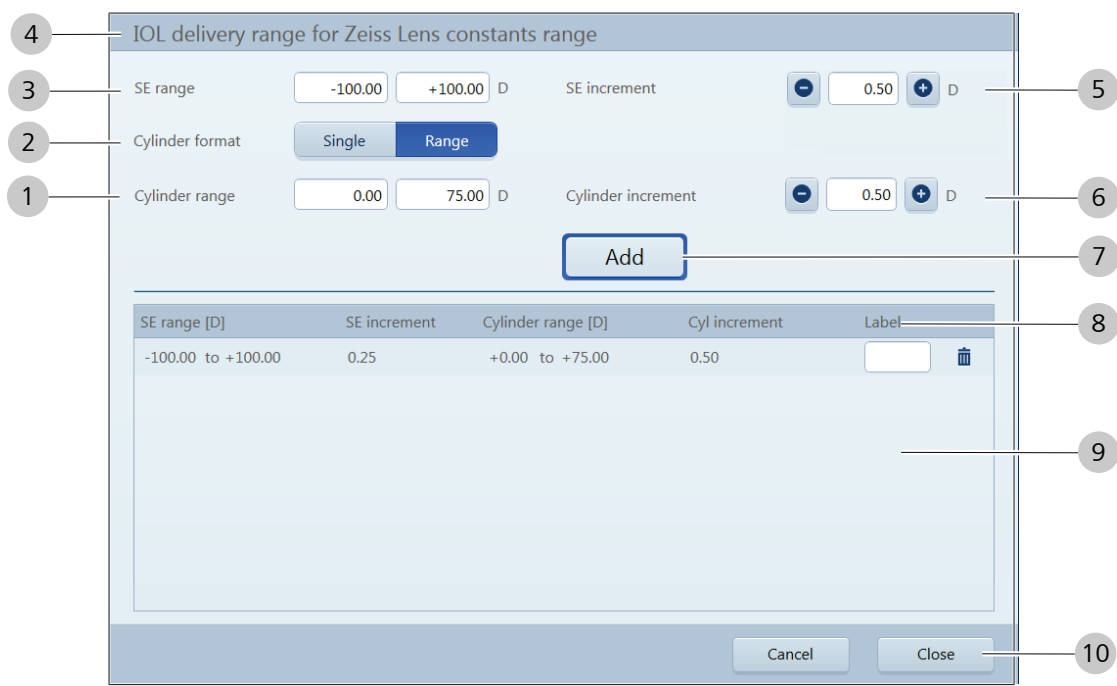


Figure 64: Definition of delivery ranges (cylinder format: range)

Item	Name	Explanation
1	Cylinder range	Enter the cylinder range
2	Cylinder format	Select the cylinder format "Range" for lenses with irregular cylinder gradations over the entire delivery range
3	SE range	Enter the delivery range
4	IOL name	Name of the IOL
5	SE increment	Enter the increment for the increment for spherical equivalent (or sphere)
6	Cylinder increment	Definition of cylinder increment
7	Add	Add the definitino for delivery range and cylinder range to IOL

Item	Name	Explanation
8	Label	Individual delivery or cylinder ranges can be marked with individual labels. The labels will be shown in the software interface and in printouts.
9	List	IOL specification list
10	Close	The window will be closed. After closing, the settings must be saved in the following window.

For lenses with irregular cylinder gradations over the entire delivery range

IOL delivery range for Zeiss Lens constants range

SE range

+34.00

+100.00

D

SE increment

-

0.50

+

D

Cylinder format

Single

Range

Cylinder

5.25

D

Add

SE range [D]	SE increment	Cylinder range [D]	Cyl increment	Label
+34.00 to +100.00	0.50	+1.00	---	T2 <div></div>
+34.00 to +100.00	0.50	+1.50	---	T3 <div></div>
+34.00 to +100.00	0.50	+2.25	---	T4 <div></div>
+34.00 to +100.00	0.50	+3.00	---	T5 <div></div>
+34.00 to +100.00	0.50	+3.75	---	T6 <div></div>
+34.00 to +100.00	0.50	+4.50	---	T7 <div></div>
+34.00 to +100.00	0.50	+5.25	---	T8 <div></div>

Cancel

Close

1

2

3

Figure 65: Definition of delivery ranges (cylinder format: Single)

Item	Name	Explanation
1	Cylinder format	Select the cylinder format "Single" for lenses with regular cylinder gradations over the entire delivery range
2	Cylinder	Enter the cylinder step
3	Label	Individual delivery ranges or cylinder steps can be marked with individual labels. The labels will be shown in the software interface and in printouts.

8.9.4.4.2 Import of IOL constants

A USB drive with the current IOL constants database at the time of manufacture is included with your device. The database is based on the IOL Con website (iolcon.org - Steinbeis Vision Research). This database can be installed as required. By importing the constants from the USB drive you accept the liability disclaimer specified in this section.

- The file is provided "as is" without any express or implied warranty. No warranty is given for the file's suitability for a particular purpose and the data's freedom from errors.
- The file provides IOL constants that are taken directly from third party websites or other publicly available sources.
- In addition, the file contains IOL design factors and some lens factors that are not publicly available and therefore cannot be verified by the user. Such parameters are either provided or calculated directly by Carl Zeiss Meditec AG ("CZM") or come from the non-public part of the Barrett Calculators ASCRS website ("Non-Public Parameters").
- CZM does not guarantee the accuracy of constants and non-public parameters adopted from third parties. Furthermore, the customer expressly acknowledges that CZM is not responsible for these constants and non-public parameters, nor has it validated, verified or otherwise confirmed that they are suitable for IOL implantation.
- The customer carries sole responsibility for checking the validity and accuracy of any constants and non-public parameters he wishes to import ("imported constants"). This also includes checking that the values of the imported constants match those listed in the respective manufacturer information. CZM's liability for personal injury or damage to property (e.g. caused by the transmission of computer viruses) resulting from the upload and subsequent use of the imported constants is limited to gross negligence and intent.
- Not all products, services or offers are approved or offered in every market and approved labeling and instructions may vary from one country to another. For country specific product information, see the appropriate country website.
- The customer assumes unlimited liability for the use of Imported Constants including use by other surgeons and clinical personnel. CZM is not liable for consequential damages resulting from the use of this data.

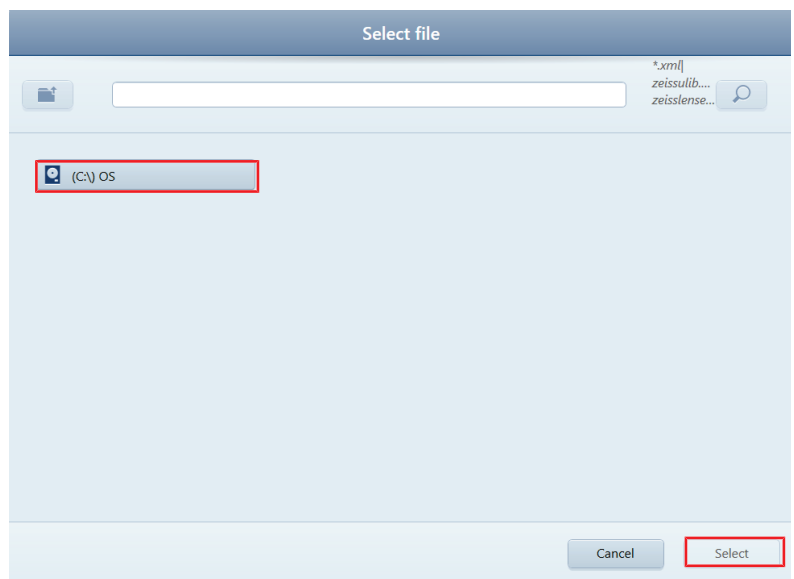
NOTE! The USB drive should not be inserted or removed while the system is starting up or shutting down or when the LED on the USB drive is lit.

Import of IOL constants

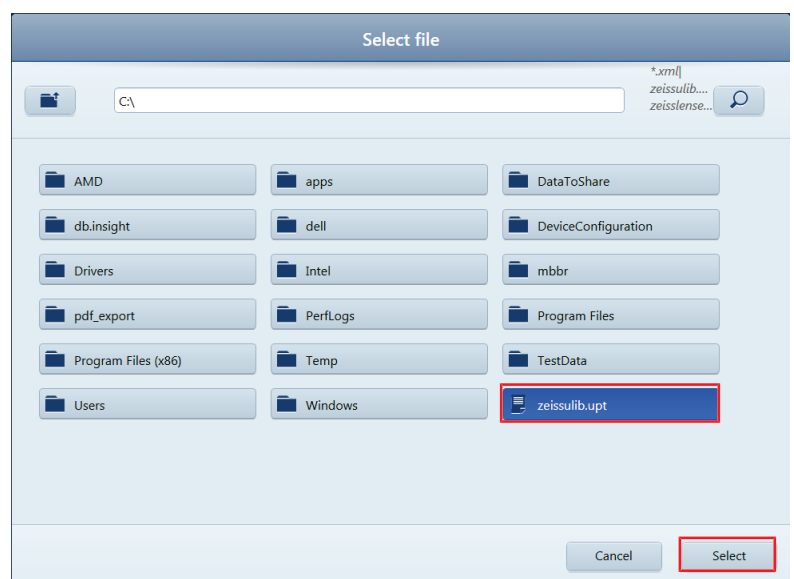
The IOL constants import is started using the [Start ULIB import] button in the "Advanced settings / IOL management" [▶ 155] dialog.

Action

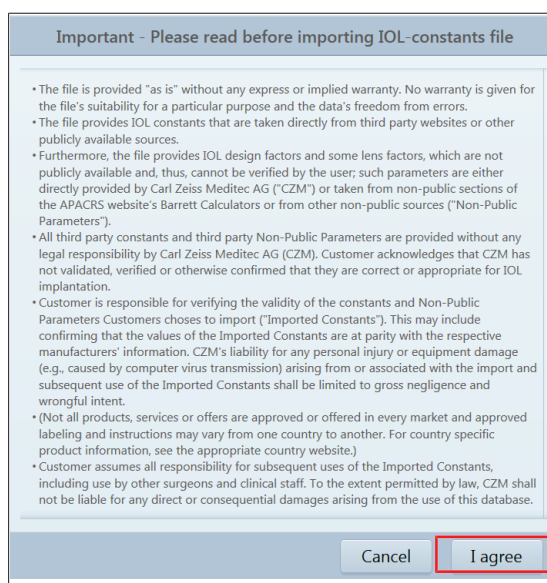
1. When the message is displayed that no IOL constants were found in the IOL constants database after starting the IOL constants import, check if the USB drive with the IOL constants database has been plugged into the device.
2. Select the folder assigned to your USB drive. Then tap on [Select].



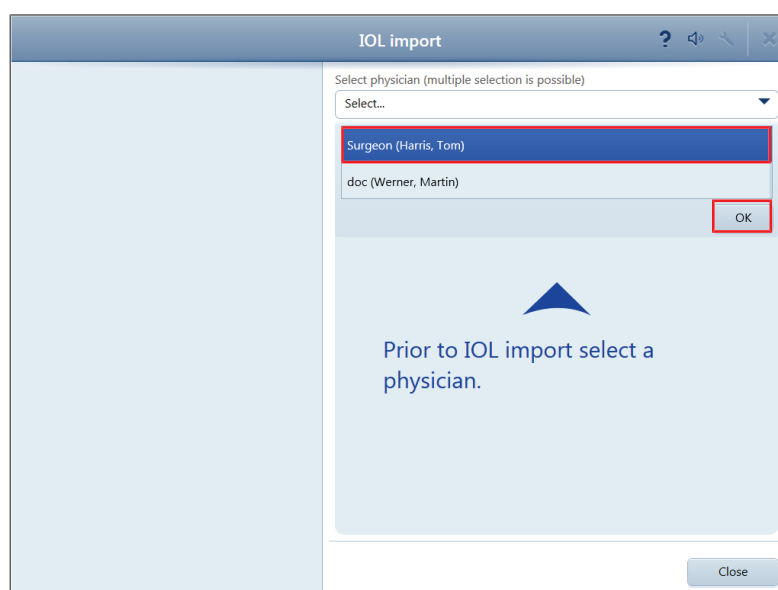
3. Select the file to be imported (files from IOL Con have the file extension .xml, files from the ZEISS website have the file extension .upt). Then tap on [Select].



4. Tap on [I agree] to accept the liability disclaimer.



5. Select a physician. Then tap on [OK].



6. Use the "Ethnicity" drop-down list to select the intraocular lenses according to different regions. Tap [Import all] to import all available intraocular lenses. Tap [Import] beside the

manufacturer's name to import intraocular lenses of this manufacturer. Tap [Import] beside the lens name to import this intraocular lens.

7. If a lens with the same data is exists in your import directory, the lens will not be imported. If a lens with the same name but different data already exists in your import directory (data conflict), the following dialog box is displayed.

- ⇒ Select [Keep] or [Skip] to keep the existing lens data.
- ⇒ Select [Replace] to overwrite the existing lens data.
- ⇒ Select [Create new IOL] to save the new lens data under a different lens name.
- ⇒ Select [Skip all] to keep existing lens data in all data conflicts.

8. Tap [Close] to finish the IOL constants import.

Updating the IOL database

The IOL constants file is made available without an explicit or implicit warranty. The suitability of the file for an intended purpose or error-free functioning of the data included in this file cannot be guaranteed. These IOL constants are made available without a legal liability by Carl Zeiss Meditec (CZM). Upon installation, the user acknowledges that Carl Zeiss Meditec has not defined, validated or verified these IOL constants and delivery ranges, nor confirms in any way that they are correct or suitable for use with IOL. It is the user's responsibility to verify the validity of imported constants and their delivery ranges.

The constants should be checked at regular intervals to ensure that they are consistent with the data on the website.

Addresses: <https://www.zeiss.com/meditec/int/resource-center/cataract-services/optimized-lens-constants.html> or
<http://www.iolcon.org>

Note that the Barrett Suite constants are not included in the IOL constants database. For lenses which are available in the Barrett Online Calculator, the constants should be checked at regular intervals to ensure that they are consistent.

Addresses: http://www.apacrs.org/barrett_universal2/ or
<http://www.ascrs.org/barrett-toric-calculator>

For all other lenses the lens factor of the Barrett Suite is based on the SRK/T constant.

Download the IOL data only from the address specified and using a separate PC connected to the Internet and a USB drive. Transfer the data from the PC to the IOLMaster 700 using a USB drive.

NOTE! Do not use a network-connected IOLMaster 700 for the download.

The download of IOL constants from the ZEISS website is possible as follows:

- Access the website
<https://www.zeiss.com/meditec/int/resource-center/cataract-services/optimized-lens-constants.html>
and select "Download ZEISS IOLMaster Constants".
- Confirm that you have read the instructions and agree with them.
- Tap [ZEISS IOLMaster 700] to start the download of the IOL constants file.
- Save the file (do not select "Open") on a USB drive.
- Plug the USB drive into the IOLMaster 700.
- Perform the next steps as described above.

The USB drive should not be inserted or removed while the system is starting up or shutting down or when the LED on the USB drive is lit.

8.9.4.5 Measurement

The advanced setting option "Measurement" can be opened using the drop-down list in the "Advanced settings" dialog window.

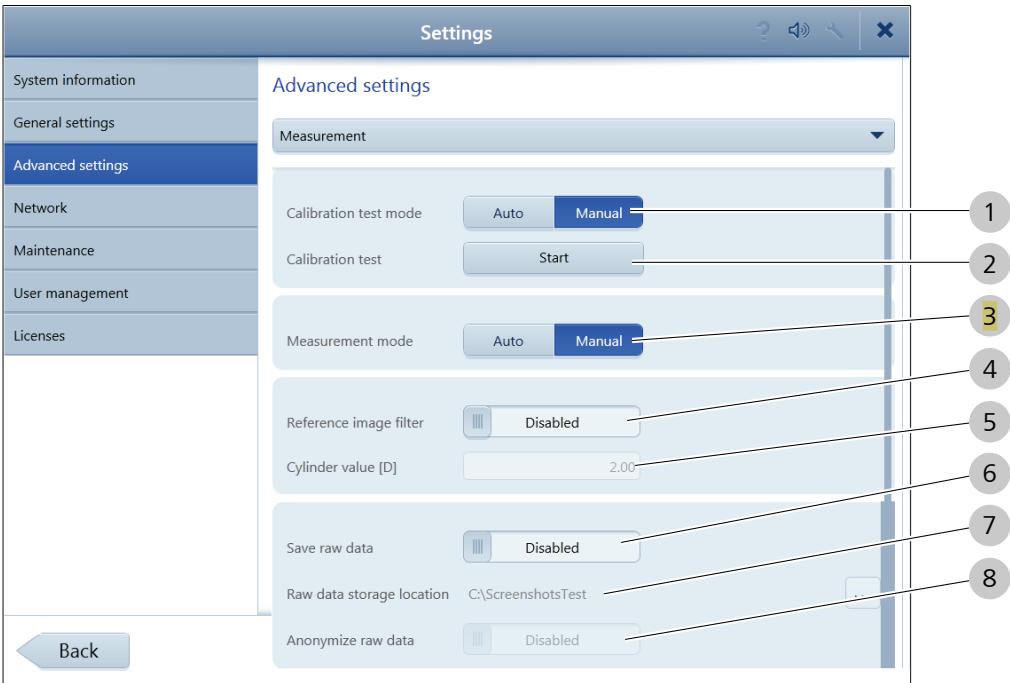


Figure 66: Measurement

Item	Name	Explanation
Measurement		
1	Calibration test mode	Tap this option button to select [Auto] to automatically trigger a calibration test after correct adjustment of the device to the eye, or [Manual] to trigger a calibration test when pressing the joystick button.
2	Calibration test	This button opens the "Calibration test" [► 35] dialog window. Here, a calibration test can be performed at any time.
9. 3	Measurement mode	Tap this option button to select [Auto] to automatically trigger a measurement after correct adjustment of the device to the eye, or [Manual] to trigger a measurement when pressing the joystick button.
4	Reference image filter	This option button allows to determine whether the "Reference image filter" function will be enabled or disabled. If a filter is enabled, the corneal astigmatism value can be set above which a reference image is to be saved. This is done in the "Cylinder value [D]" input field. If the filter is disabled, a reference image is always saved.

Item	Name	Explanation
5	Cylinder value [D]	In the "Cylinder value [D]" input field the value of corneal astigmatism will be defined from which a clinical indication for the implantation of a toric intraocular lens shall be supported. The value can be entered as a decimal figure with the [D] (diopter) unit using the on-screen or external keyboard. If the measured corneal astigmatism is above the preset value, the reference image is not discarded, but tested for signal quality, and stored.
6	Save raw data	This option button allows to determine whether the external saving of raw data will be enabled or disabled.
7	Raw data storage location	To switch to the storage location use the [...] button. In this window the external storage location for raw data can be selected and confirmed by tapping [Select]. The storage is done through storage on an external USB 3.0 hard disk.
8	Anonymize raw data	This option button allows to determine whether patient data will be anonymized (Enabled) or saved together with personal data (Disabled). The patient ID will be saved in any case.

8.9.4.6 Analyze

The advanced setting option "Analyze" can be opened using the drop-down list in the "Advanced settings" dialog window.

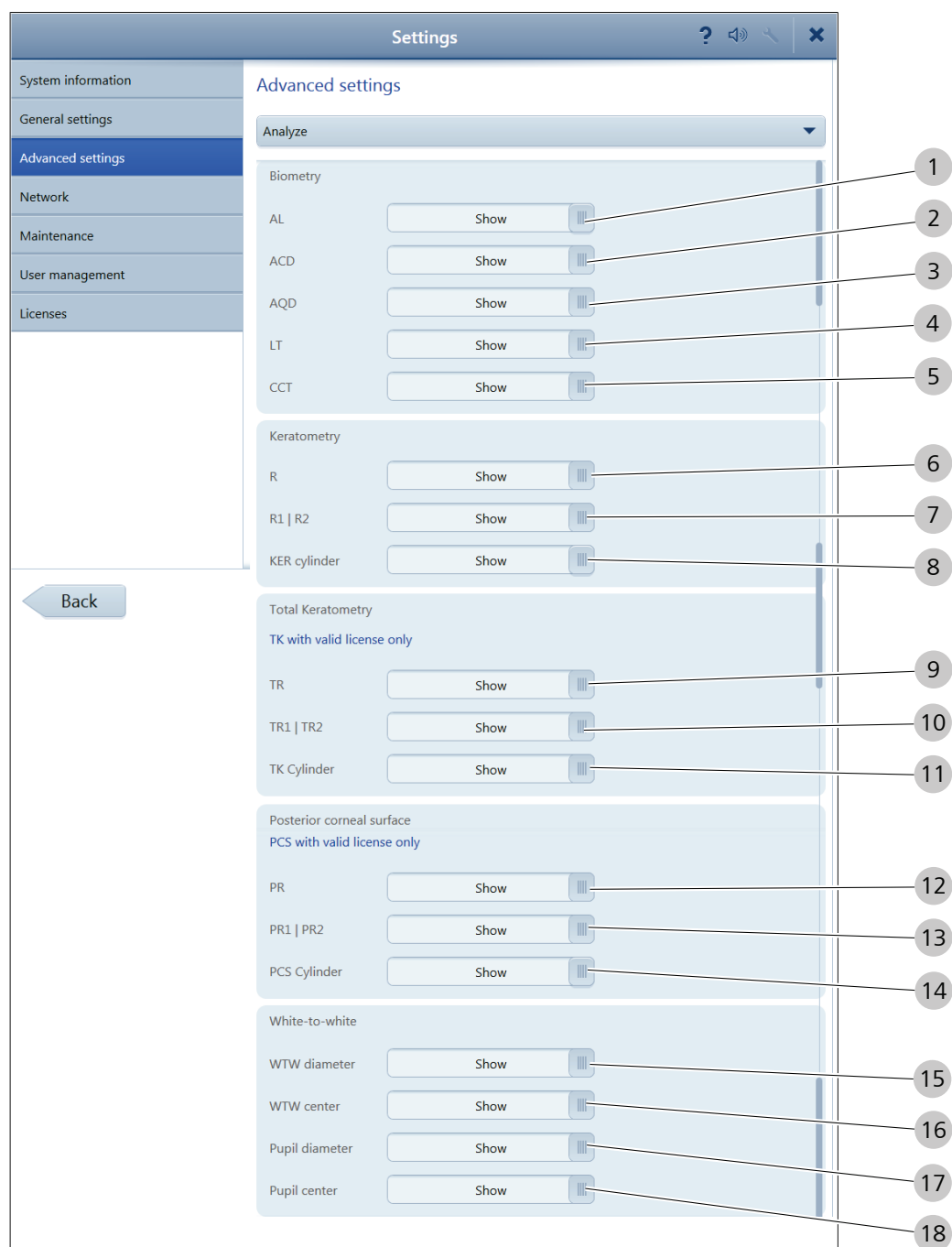


Figure 67: Analyze

Item	Name	Explanation
Analyze		
1	AL	This option button will be used to determine whether the axial length will be displayed or not.
2	ACD	This option button will be used to determine whether the anterior chamber depth (measured from anterior corneal surface to anterior lens surface) will be displayed or not.
3	AQD	This option button will be used to determine whether the interior anterior chamber depth (measured from posterior corneal surface to anterior lens surface) will be displayed or not.
4	LT	This option button will be used to determine whether the lens thickness will be displayed or not.
5	CCT	This option button will be used to determine whether the central corneal thickness will be displayed or not.
6	R	This option button will be used to determine whether the mean value of corneal radii will be displayed or not.
7	R1 R2	This option button will be used to determine whether the corneal radii will be displayed in the two main section directions or not.
8	KER cylinder	This option button will be used to determine whether the corneal astigmatism (difference between corneal radii in the two main section directions) will be displayed or not.
9	TR	This option button will be used to determine whether the mean value of Total Keratometry will be displayed or not.
10	TR1 TR2	This option button will be used to determine whether the Total Keratometry values will be displayed in the two main section directions or not.
11	TK cylinder	This option button will be used to determine whether the Total Keratometry astigmatism (difference between corneal radii in the two main section directions) will be displayed or not.
12	PR	This option button will be used to determine whether the mean value of corneal radii of the posterior corneal surface will be displayed or not.
13	PR1 PR2	This option button will be used to determine whether the corneal radii of the posterior corneal surface will be displayed in the two main section directions or not.
14	PCS cylinder	This option button will be used to determine whether the astigmatism of the posterior corneal surface (difference between corneal radii in the two main section directions) will be displayed or not.
15	WTW diameter	This option button will be used to determine whether the corneal diameter (white-to-white) will be displayed or not.
16	WTW center	This option button will be used to determine whether the center coordinates of the cornea or iris related to the corneal vertex will be displayed or not.

Item	Name	Explanation
17	Pupil diameter	This option button will be used to determine whether the pupil diameter will be displayed or not.
18	Pupil center	This option button will be used to determine whether the center coordinates of the pupil related to the corneal vertex will be displayed or not.

8.9.4.7 Printout

The advanced setting option "Printout" can be opened using the drop-down list in the "Advanced settings" dialog window.

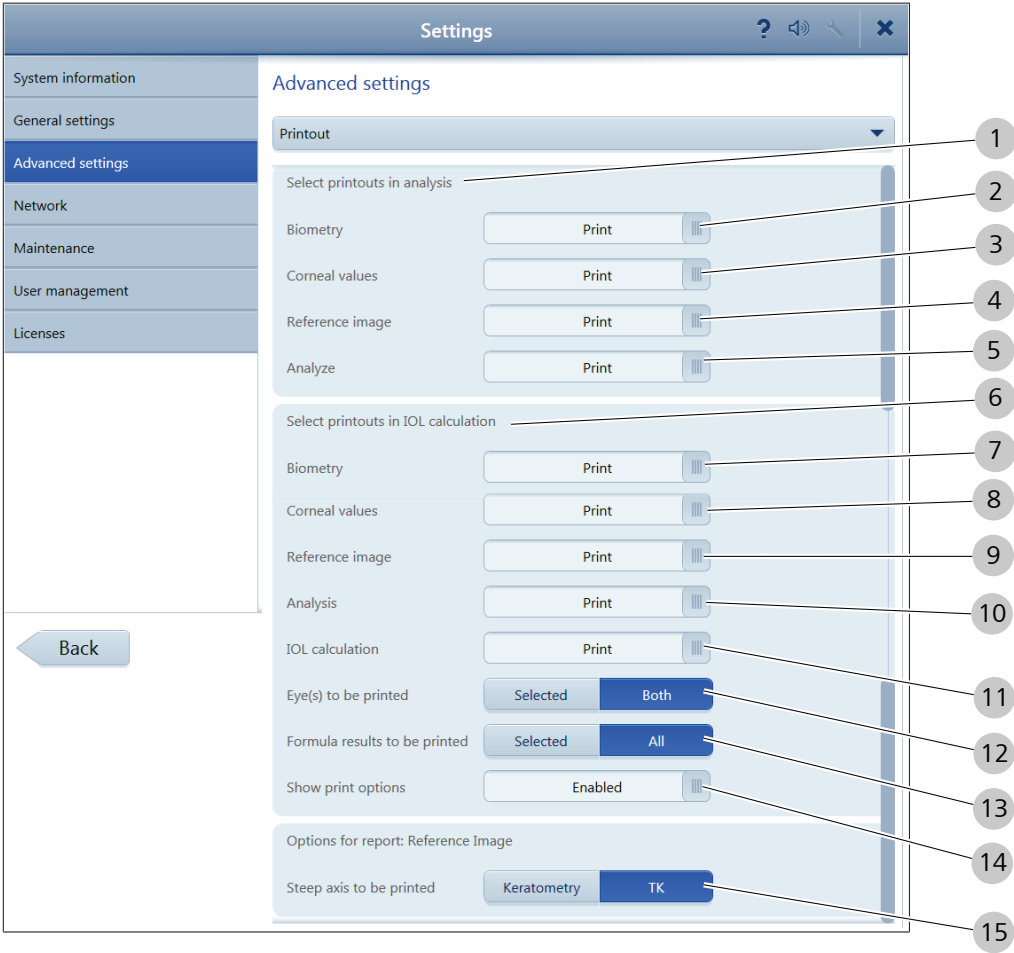


Figure 68: Printout

Item	Name	Explanation
Printout		
1	Select printouts in analysis	The printout of the analysis is automatically created by using this window and cannot be disabled.
2	Biometry	This option button will be used to determine whether the measurement value analysis will be printed (Print) or not (Do not print).
3	Corneal values	This option button will be used to determine whether the analysis of the corneal values will be printed (Print) or not (Do not print).
4	Reference image	This option button will be used to determine whether the analysis will be printed (Print) or not (Do not print) together with the Option Reference Image.
5	Analyze	This option button will be used to determine whether the analysis of the intraocular lens calculation will be printed (Print) or not (Do not print).
6	Select printouts in IOL calculation	The printout of the IOL calculation is automatically created by using this window and cannot be disabled.
7	Biometry	This option button will be used to determine whether the intraocular lens calculation will be printed (Print) or not (Do not print).
8	Corneal values	This option button will be used to determine whether the corneal values will be printed (Print) or not (Do not print).
9	Reference image	This option button will be used to determine whether the calculation of a toric intraocular lens will be printed (Print) or not (Do not print) together with the Option Reference Image.
10	Analyze	This option button will be used to determine whether the analysis of the intraocular lens calculation will be printed (Print) or not (Do not print).
11	IOL calculation	This option button will be used to determine whether the IOL calculation will be printed (Print) or not (Do not print).
12	Eye(s) to be printed	This option button will be used to select which eye or whether both eyes are to be printed.
13	Formula results to be printed	This option button will be used to select if the results of the selected formula or of all formula in the selection bar will be printed.
14	Show print options	This option button will be used to select whether the selection of print options will be displayed (enabled) or not (disabled) when printing via the printer icon. The above options will be used as default.
15	Steep axis to be printed	This option button will be used to define which axis (Keratometry or Total Keratometry (TK)) will be printed in the Reference Image printout if none was selected for IOL in the detailed view.

8.9.4.8 Export

The advanced setting option "Export" can be opened using the drop-down list in the "Advanced settings" dialog window. The settings of this dialog can be made by all users and are valid for all users of the device.

The advanced setting option "Export" can be used to enable the desired export functions. The settings are valid for exports from the "Patient / Measurements" [► 51] and "IOL calculation" [► 84] dialog windows.

The advanced setting option "IOL calculation" can be opened using the drop-down list in the "Advanced settings" dialog window.

Settings for IOL calculation export

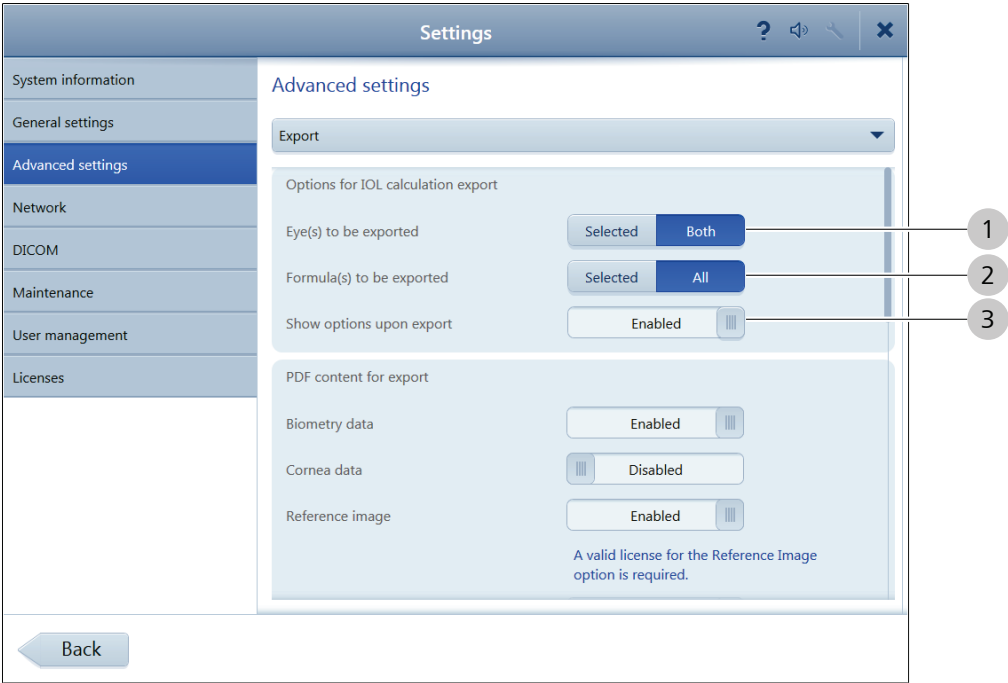


Figure 69: Settings for IOL calculation export

Pos.	Name	Explanation
Settings for IOL calculation export		
1	Eye(s) to be exported	Use this option button to determine whether the data is exported for the selected eye or for both eyes.
2	Formula(e) to be exported	Use this option button to determine whether the data is exported fro the selected formula or for all formulae.
3	Display export options	Use this option button to determine whether the export settings are displayed prior to the export of the IOL calculation.

PDF content for export

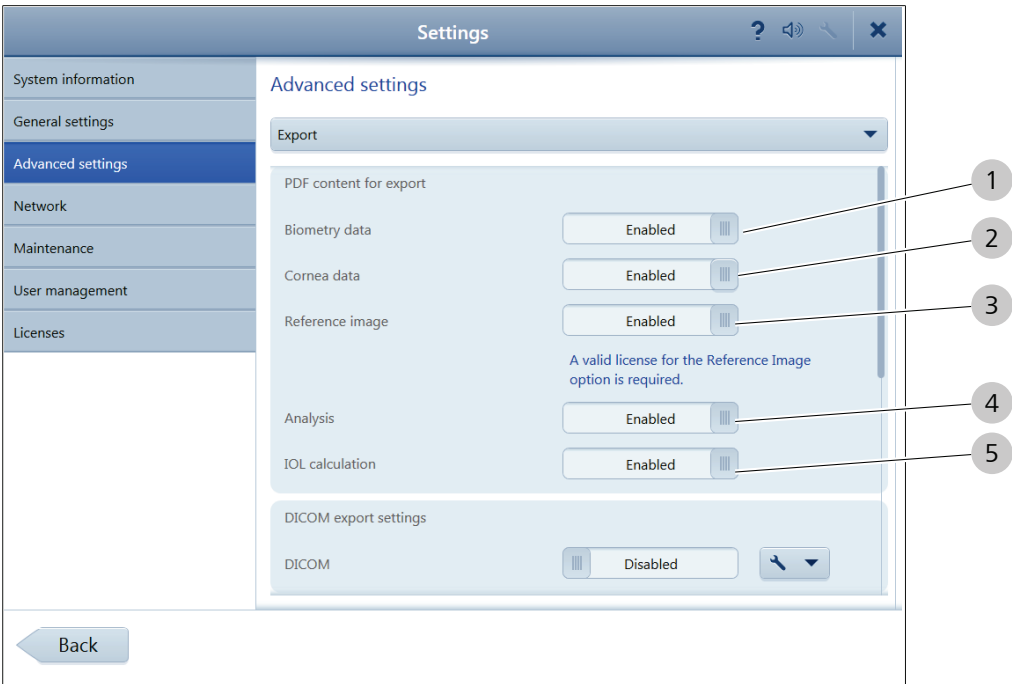


Figure 70: PDF content for export

Pos.	Name	Explanation
PDF content for export		
1	Biometry data	Use this option button to determine whether the biometry data will be exported (enabled) or not (disabled).
2	Cornea data	Use this option button to select whether the corneal data will be exported (enabled) or not (disabled).
3	Reference image	Use this option button to select whether the Reference Image will be exported (enabled) or not (disabled).
4	Analyze	Use this option button to select whether the analysis data will be exported (enabled) or not (disabled).
5	IOL calculation	Use this option button to select whether the IOL calculation will be exported (enabled) or not (disable).

DICOM export settings

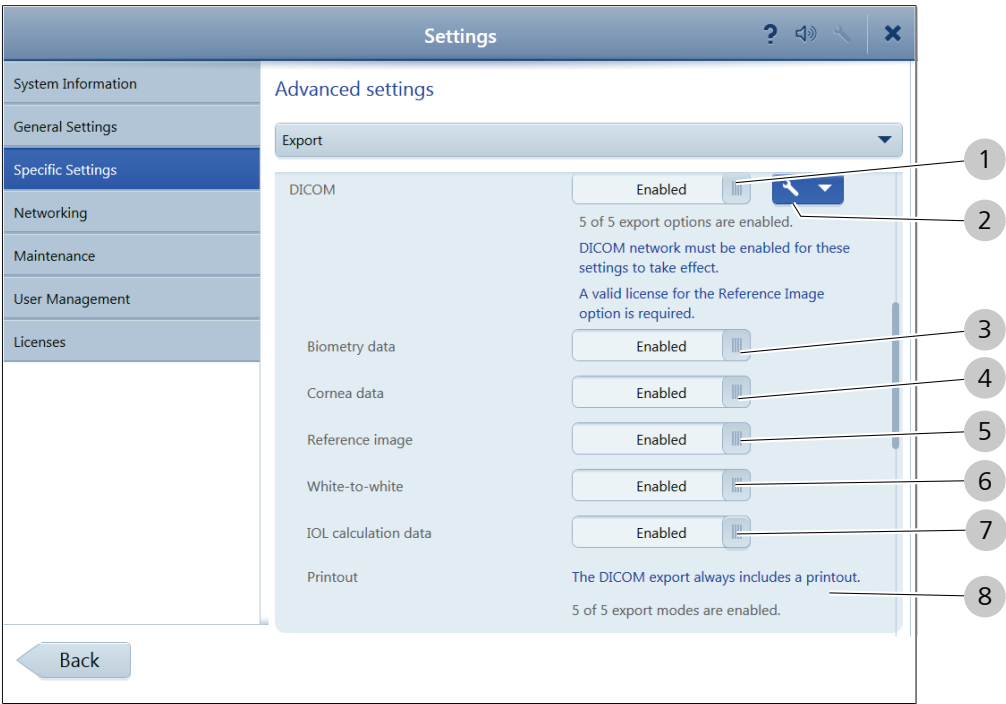


Figure 71: DICOM export settings

Pos.	Name	Explanation
DICOM export settings		
1	DICOM	Use this option button to select whether data will be exported into the clinic's IT system (enabled) or not (disabled).
2	Wrench	Tap the wrench to display further option buttons for more details on data to be exported.
3	Biometry data	Use this option button to enable or disable the export of biometry data.
4	Cornea data	Use this option button to enable or disable the export of corneal data.
5	Reference image	Use this option button to enable or disable the export of Reference Images.
6	White-to-white	Use this option button to enable or disable the export of white-to-white data.
7	IOL calculation data	Use this option button to enable or disable the export of IOL calculation data. Note: It is not possible to export toric IOL, IOL calculated using a Barrett formula and IOL calculated using TK.
8	Printout	The printout is always included in DICOM export.

ZEISS Cataract Suite Data export settings

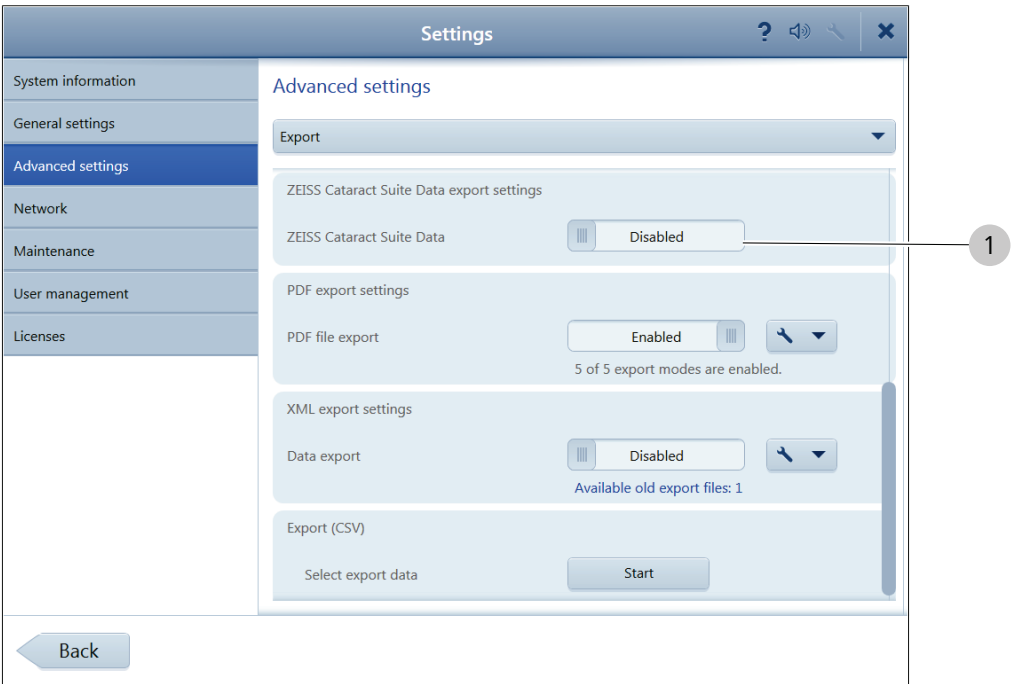


Figure 72: ZEISS Cataract Suite Data export settings

Pos.	Name	Explanation
ZEISS Cataract Suite Data export settings		
1	ZEISS Cataract Suite Data	Use this option button to enable or disable the export of data on a storage medium (e.g. a USB drive).

ZEISS EQ Mobile Cloud export settings

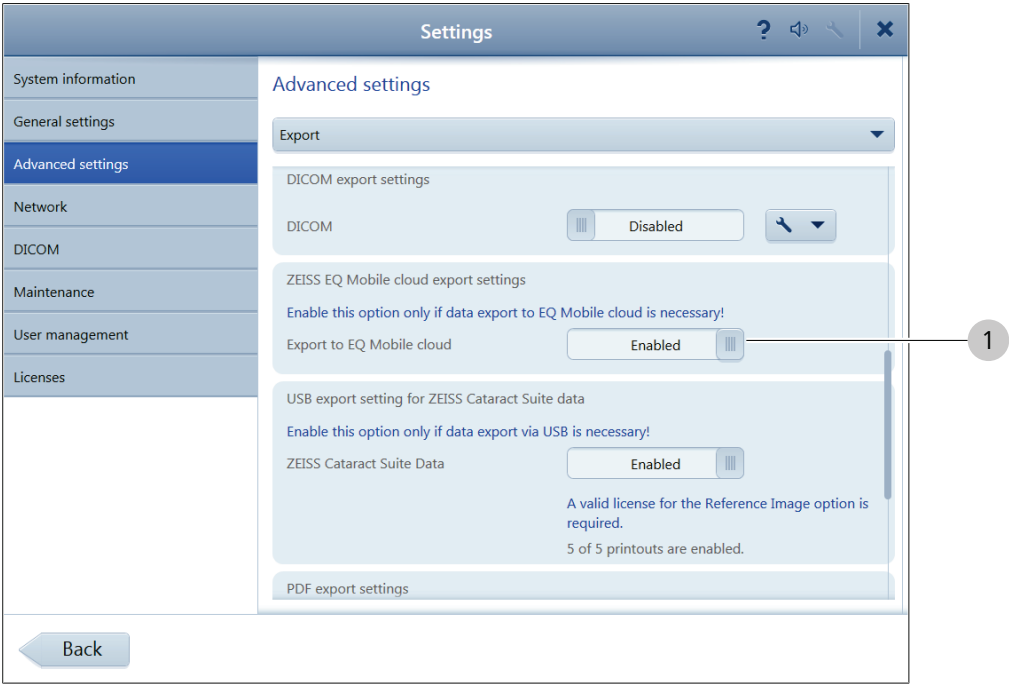


Figure 73: ZEISS EQ Mobile Cloud export settings

Pos.	Name	Explanation
ZEISS EQ Mobile Cloud export settings		
1	Export to EQ Mobile Cloud	Use this option button to enable or disable the export of data to ZEISS EQ Mobile Cloud.

PDF export settings

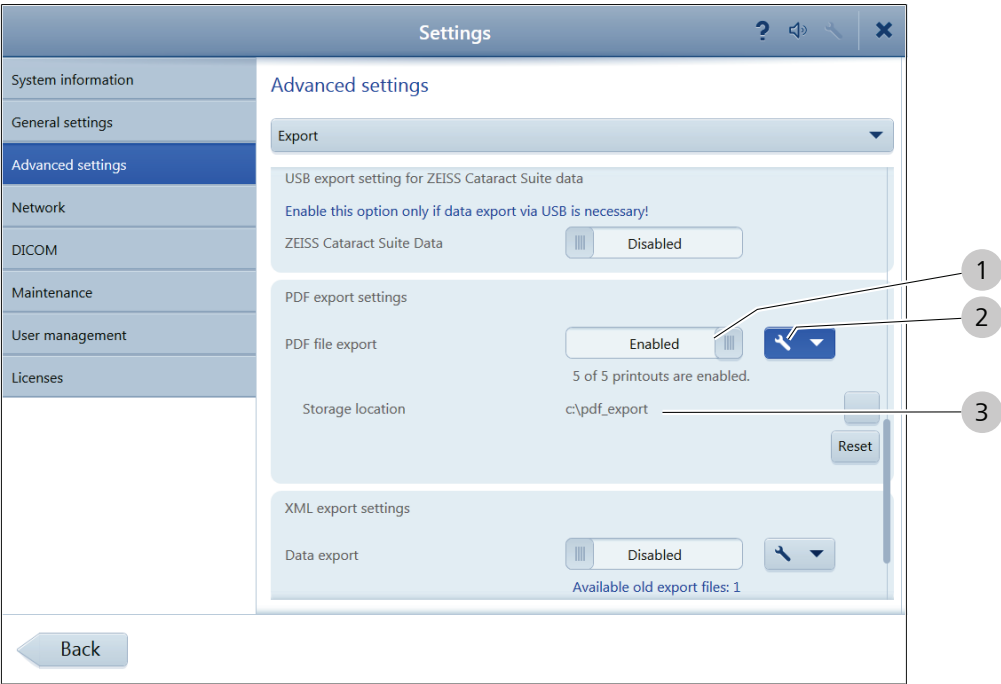


Figure 74: PDF export settings

Pos.	Name	Explanation
PDF export settings		
1	PDF file export	Use this option button to export electronic printouts as PDF files. This function works independently of paper printouts.
2	Wrench	After tapping the wrench, further setting options for PDF export will be displayed.
3	Storage location	The [...] button opens a window for selecting the storage location for PDF export. After selecting the desired folder, the window is closed by tapping the [Select] button; the selected folder will be displayed on the screen as the storage location. Use the [Reset] button to reset the storage location to the default value. If the "pdf_export" local folder is selected, it can be accessed from any PC within the local network as a shared folder by using the following credentials: user name: Customer, password: Customer.

XML export settings

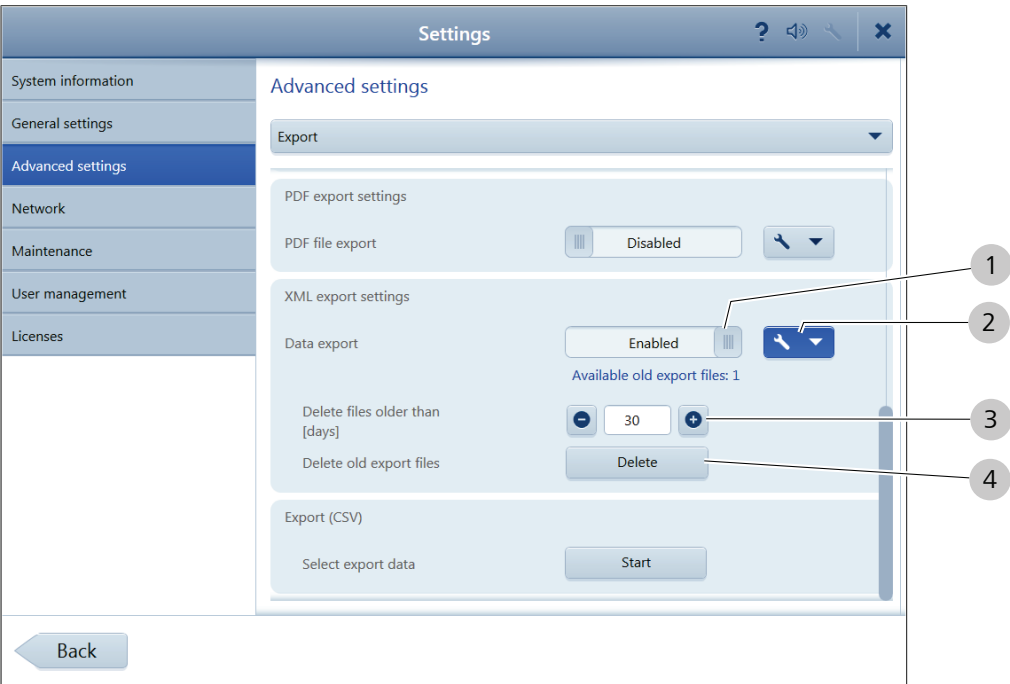


Figure 75: XML export settings

Pos.	Name	Explanation
XML export settings		
1	Data export	Use this option button to enable or disable XML data export. XML data will be exported to the local "Export" folder. This folder can be accessed from any PC within the local network as a shared folder by using the following credentials: user name: Customer, password: Customer.
2	Wrench	After tapping the wrench, further setting options for data export will be displayed.
3	Delete files older than [days]	Using the [-] and [+] buttons allows to change the data of deletion between 0 and 365 days. The default setting is 30 days.
4	Delete old export files	The [Delete] button allows to delete all export reports which are older than the selected period of time.

Export (CSV)

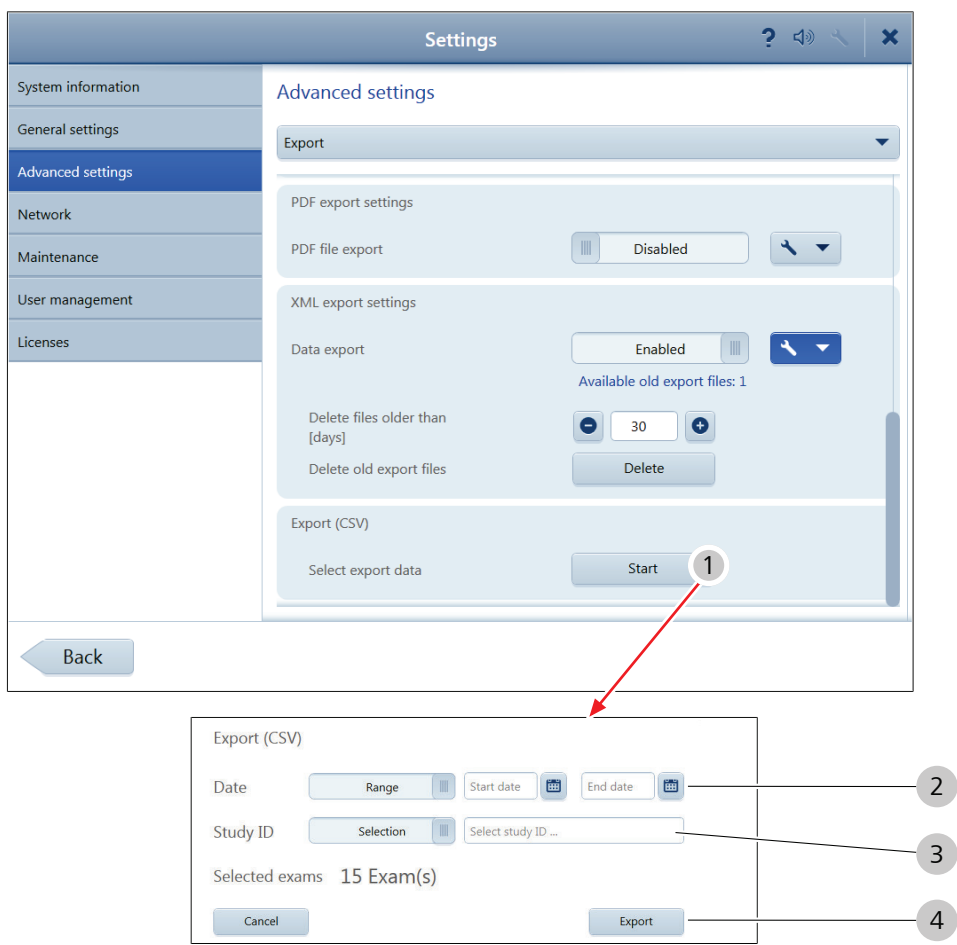


Figure 76: Export (CSV)

Pos.	Name	Explanation
Export (CSV)		
1	Select export data	The [Start] button opens a window for selecting the options for export data.
2	Date	Use this option button to determine whether all data (all) on the device or only data in a defined date range (range) shall be exported.
3	Study ID	Use this option button determine whether all data (all) on the device or only patients with a selected study ID (selection) will be exported.
4	Export	This button starts the export.

8.9.4.9 IOL calculation

The advanced setting option "IOL calculation" can be opened using the drop-down list in the "Advanced settings" dialog window.

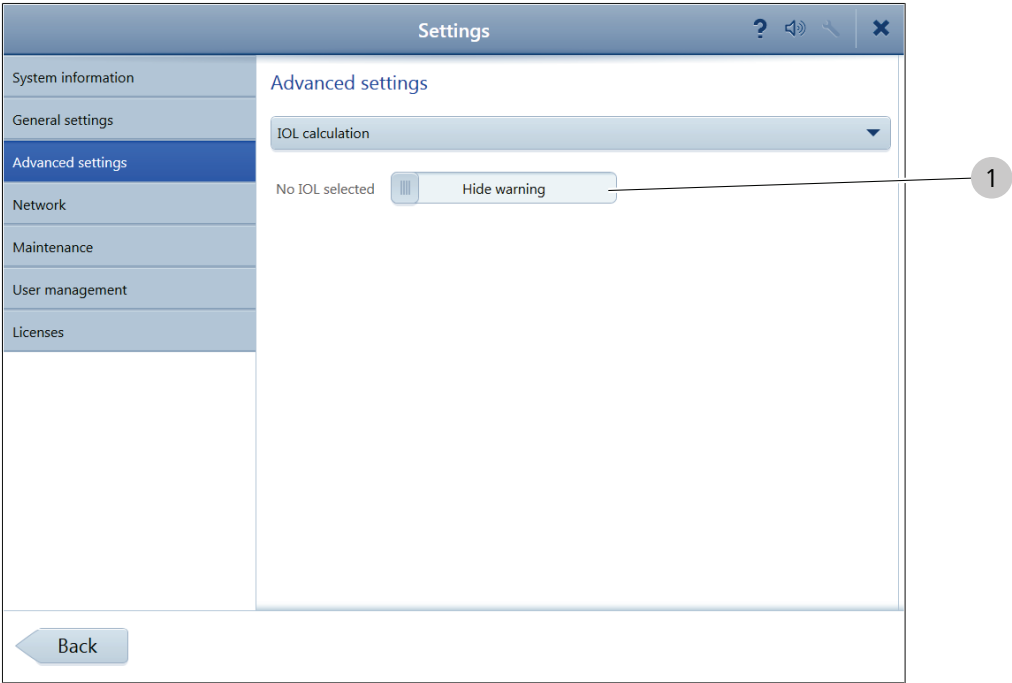


Figure 77: IOL calculation

Item	Name	Explanation
IOL calculation		
1	No IOL selected	This option button allows to determine whether a warning will be displayed (Show warning) or not (Do not show warning) when leaving the "IOL calculation" window while no IOL was selected.

8.9.5 Network

This dialog is opened by clicking the [Network] button. The current network settings can be displayed and changed here.

NOTE! Configuration and network settings may only be changed by an experienced network administrator.

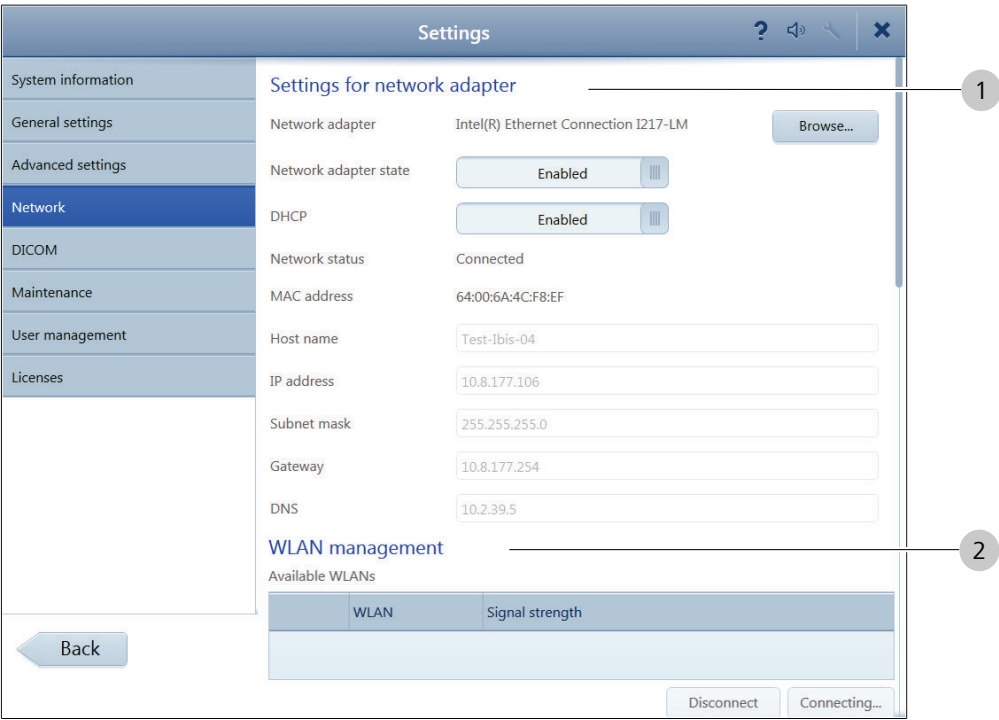


Figure 78: Network 1

Item	Name	Explanation
1	"Settings for network adapter" dialog area	In this area, the current settings for network configuration such as DHCP status, IP address, subnet mask, gateway, DNS, MAC address, host name and network status are displayed.
	Network adapter	Information field to display the selected network interface board. The [Browse] button opens a window for selecting the network interface board.
	Network adapter state	Option button for enabling/disabling the selected network interface board. When this function is enabled, you can configure the IP address, subnet mask, DNS, gateway, and domain for the network interface board.
	DHCP	Option button for enabling/disabling the DHCP. If DHCP has been enabled, the IP address, subnet mask and gateway are retrieved from the DHCP server. The following boxes will then be greyed out.
	Network status	Information field for displaying the network status.
	MAC address	Information field for displaying the MAC address.
	Host name	Information field for displaying the host name.

Item	Name	Explanation
	IP address	Input field for entering the IP address. This field must only be filled out if DHCP has been disabled.
	Subnet mask	Input field for entering the subnet mask. This field must only be filled out if DHCP has been disabled.
	Gateway	Input field for entering the gateway. This field must only be filled out if DHCP has been disabled.
	DNS	Input field for entering the DNS address.
2	"WLAN management" dialog area	
	Available WLANs	List box for displaying all available WLANs, their names and signal strength.
	Disconnect	This button is used to disconnect the WLAN selected previously in the "Available WLANs" list box.
	Connecting...	This button is used to connect the WLAN selected previously in the "Available WLANs" list box.

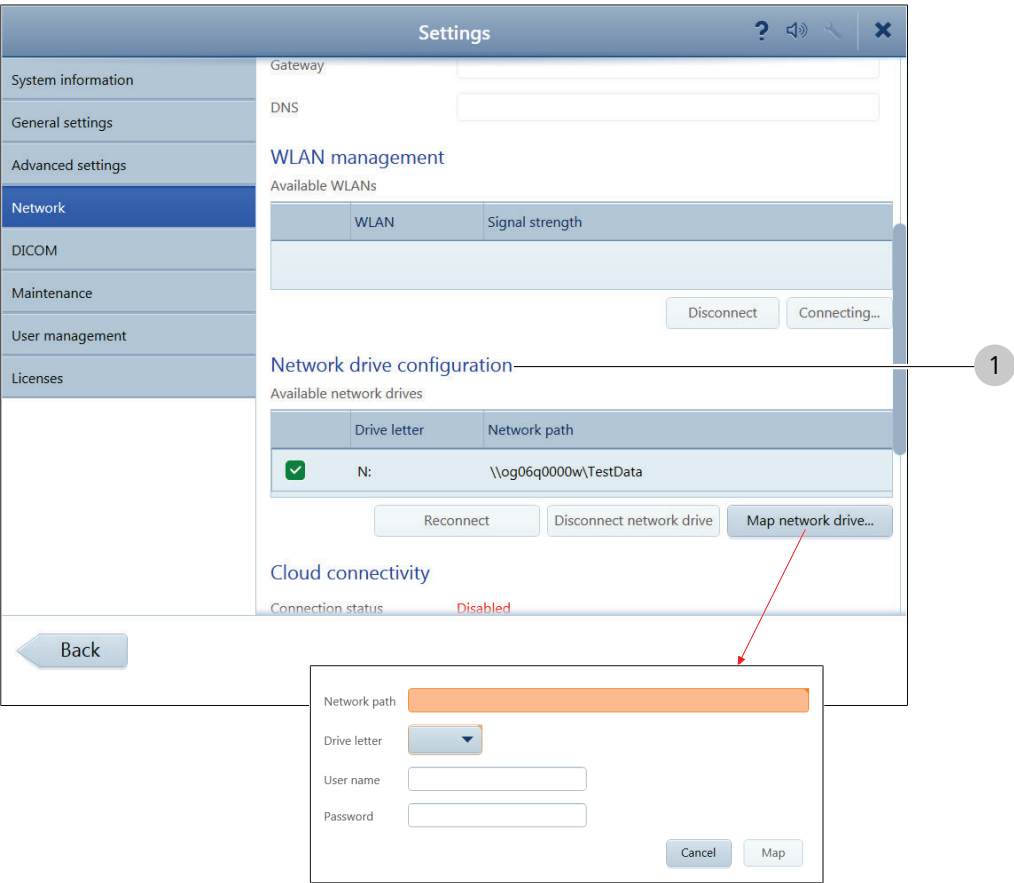


Figure 79: Network 2

Item	Name	Explanation
1	"Network drive configuration" dialog area	
	Available network drives	All existing network drives are displayed in this list box with the drive letter and network path.
	Reconnect	This button is used to reconnect the network drive selected in the "Available network drives" list box.
	Disconnect network drive	This button is used to disconnect the network drive selected in the "Available network drives" list box.
	Map network drive ...	This button is used to map a new network drive. A dialog opens in which the network path, drive letter, user name and password can be entered. The network drive is mapped by tapping the [Map] button. The new network drive will be displayed in the "Available network drives" list box.

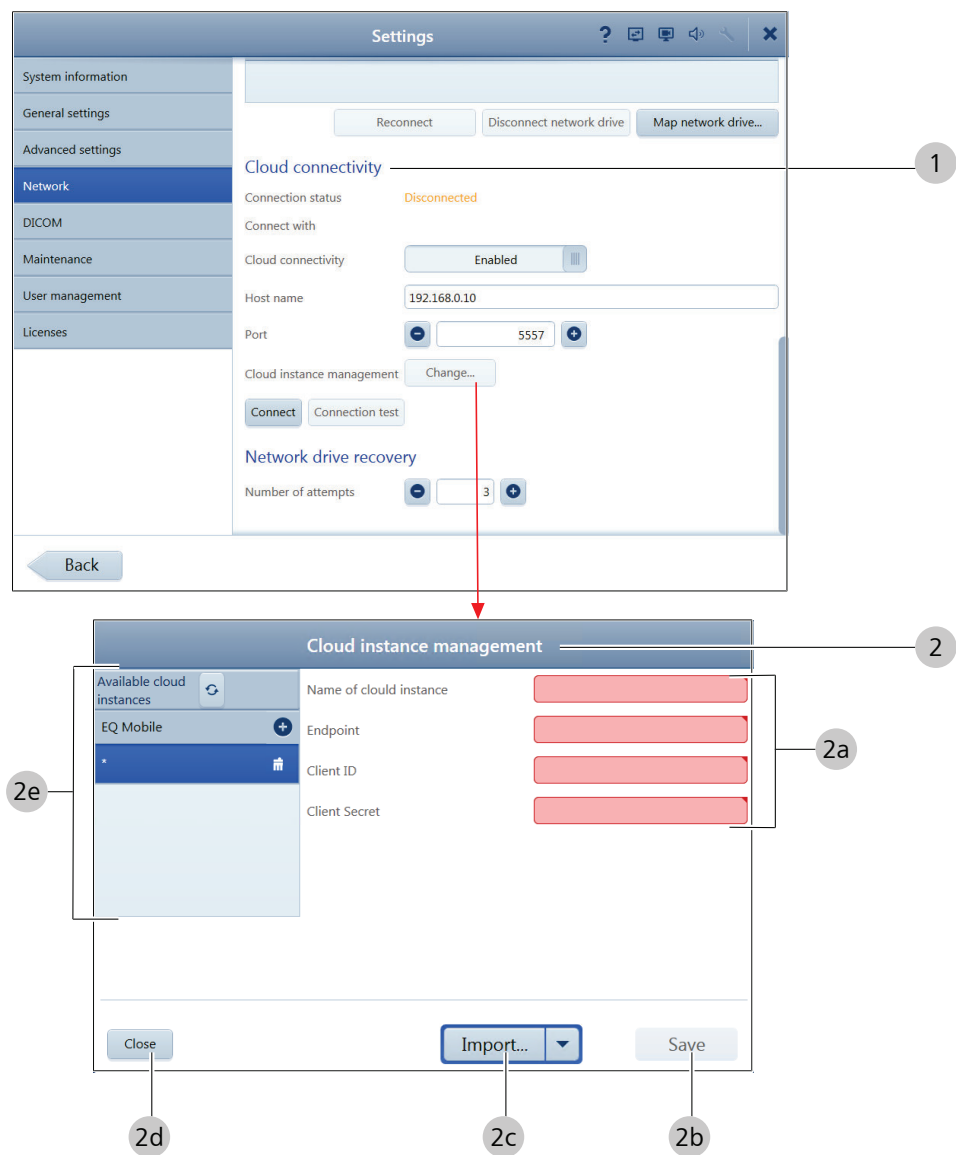


Figure 80: Network 3

Item	Name	Explanation
1	"Cloud connectivity" dialog area	
	Connection status	Information field for displaying the cloud connectivity of the device.
	Connect with	Information field for displaying the name of the cloud application with which the device is connected for patient data export.
	Cloud connectivity	Use this option field to enable or disable the cloud connectivity for patient data export. If the option field is enabled, patient data will be exported to the configured cloud instance of the cloud application. If the option field is disabled, no patient data will be exported to the configured cloud instance of the cloud application. For detailed instructions, refer to the cloud connectivity setup manual.

Item	Name	Explanation
	Host name	Input field for entering the host name or IP address of the transfer software used for cloud connectivity. This field only needs to be filled in if the transfer software has been activated on a remote computer.
	Port	Input field for entering the port which is monitored by the transfer software for cloud connectivity on patient data export requests. This field must only be filled in if the transfer software has been enabled on a remote computer.
	Cloud Instance Management	Use this button to open a dialog for modifying the EQ Mobile Cloud settings.
	Connect	Use this button to establish a connection to the EQ Mobile Transfer Software and cloud instance.
	Connection test	Use this button for testing the connection.
2	Cloud instance management	
2a	Name of cloud instance Endpoint Client ID Client Secret	Cloud instance management parameters for establishing a connection between IOLMaster and EQ Mobile Cloud. These parameters will be set automatically when uploading the configuration file which you received by email when you purchased the ZEISS EQ Mobile option
2b	Save	Use this button to save the EQ Mobile cloud instance configuration.
2c	Import	Use this button to import the EQ Mobile cloud instance configuration file from a USB drive. You have received the configuration file when you purchased the ZEISS EQ Mobile option.
2d	Close	Use this button to close the dialog.
2e	Available cloud instances	This list shows all available EQ Mobile cloud instances under "EQ Mobile".

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8.9.6 DICOM

This dialog is opened by clicking the [DICOM] button. The current DICOM settings can be displayed and changed here.

NOTE! DICOM settings may only be configured and changed by an experienced network administrator.

Settings

Please note: settings with this sign require a device restart to be enabled.

Connection configuration

DICOM network ☐ Enabled

Local application entity

Station name

Local AE title

Port

Remote application entity

☐ Use the DICOM storage configuration for Query / Retrieve / Storage Commitment

	Service	AE title	Host name	Port
?	Modality Worklist	CZMAMWL	ogvmforum40.dejem.zeiss.org	11119
?	Storage	CZMA	ogvmforum40.dejem.zeiss.org	11119
?	Retrieve	CZMA	ogvmforum40.dejem.zeiss.org	11119

Back

Figure 81: DICOM 1

Item	Name	Explanation
1	"Connection configuration" dialog area	
	DICOM network	Option button for enabling/disabling the DICOM network communication. When the DICOM network is enabled, the connection must be configured in the following boxes.
2	"Local application entity" dialog area	
	Station name	Input field for entering the station name.
	Local AE title	Input field for entering the local AE title.
	Port	Input field for entering the port number. The port number can be changed using the [+] and [-] buttons.

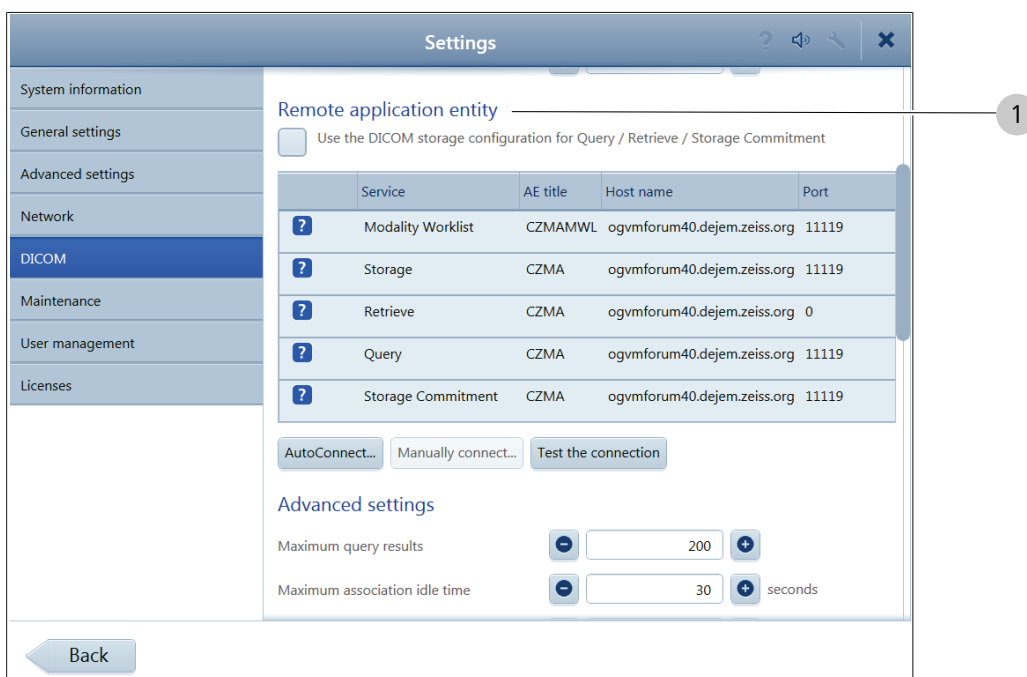


Figure 82: DICOM 2

Item	Name	Explanation
1	"Remote application entity" dialog area	
	Use the DICOM storage configuration for Query / Retrieve / Storage Commitment.	If this button is enabled, only the DICOM services MWL and Storage must be configured. The settings for the DICOM services Retrieve, Query and Storage Commitment are retrieved from Storage. Observe the note displayed below the table.
	"Remote application entity" list box	This list box contains an overview of all remote application entities including AE title, Host name and Port.
	AutoConnect...	Use the AutoConnect™ button for performing an automatic configuration. All detected DICOM servers are displayed in a list. The desired DICOM server is selected by clicking [Select] and the connection will be automatically configured. The AutoConnect™ function only works with ZEISS FORUM Servers from FORUM version 3.0. Observe the note displayed below the table.
	Manually connect...	This button is used for configuring the DICOM services manually. To do this, select the desired service and tap the [Manually connect...] button. A window will open in which the service can be enabled/disabled. The values must be entered manually in the "AE title", "Host name" and "Port" input fields.
	Test the connection	This button is used for testing the connections to the individual services. The results of the test connection are shown in a new window. By clicking the [See details] button, the details of the test connection results can be displayed.

Note on the "Retrieve" service

Currently, the IOLMaster 700 does not support the "Retrieve" service. Please make sure that this service is not enabled. To do this, tap the [Manually connect...] button and disable the "Retrieve".

<input checked="" type="checkbox"/>	MWL	CZMAMWL	ForumServer.inblt10.zeiss.o...	11119
<input checked="" type="checkbox"/>	Storage	CZMA	ForumServer.inblt10.zeiss.o...	11119
<input checked="" type="checkbox"/>	Retrieve	CZMA	ForumServer.inblt10.zeiss.o...	11119
<input checked="" type="checkbox"/>	Query	CZMA	ForumServer.inblt10.zeiss.o...	11119
<input checked="" type="checkbox"/>	Storage Commitment	CZMA	ForumServer.inblt10.zeiss.o...	11119

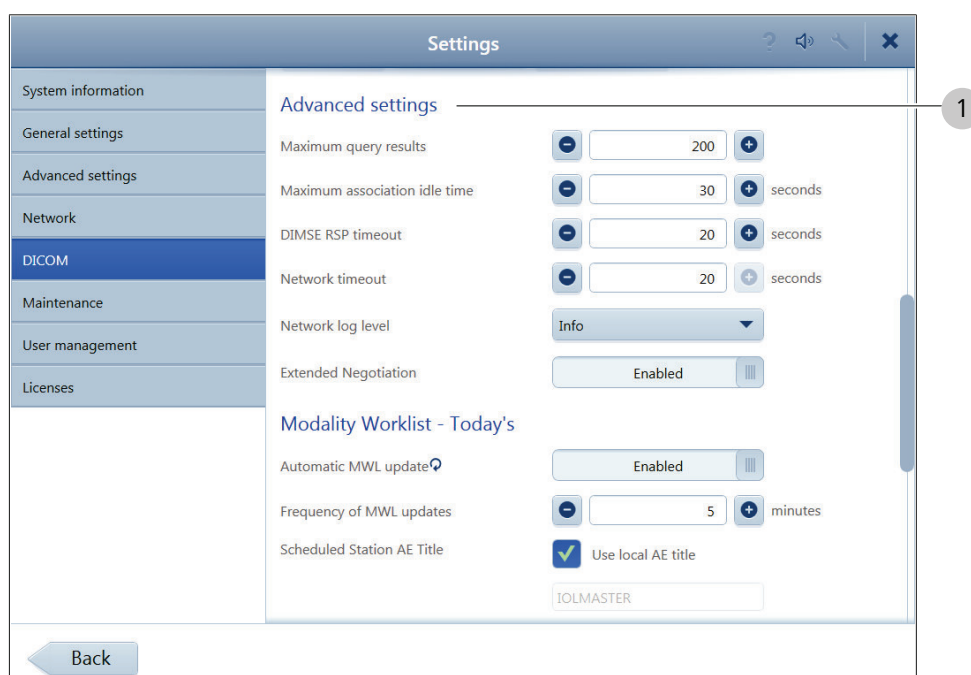


Figure 83: DICOM 3

Item	Name	Explanation
1	"Advanced settings" dialog area	
	Maximum query results	The maximum query results can be entered in the "Maximum query results" input field. The value can be changed using the [+] and [-] buttons.
	Maximum association idle time	The "Maximum association idle time" configures the time within which the association is kept open after any request / response communication. The value (in seconds) can be changed using the [+] and [-] buttons.
	DIMSE RSP timeout	The "DIMSE RSP timeout" configures the maximum time in which the system waits for a specific response from the server to a prior request. The value (in seconds) can be changed using the [+] and [-] buttons.
	Network timeout	The "Network timeout" (in seconds) after which the search should be aborted can be entered in this input field. The value can be changed using the [+] and [-] buttons.

Item	Name	Explanation
	Network log level	The log level of the network services can be set in this drop-down list. The following modes are possible: <ul style="list-style-type: none"> ■ Debug ■ Info ■ Warning ■ Error
	Extended Negotiation	The Extended Negotiation is the negotiation of an advanced feature set between client and server which is required for complete FORUM communication. If this option button has been enabled, communication with Extended negotiation will be put into operation.

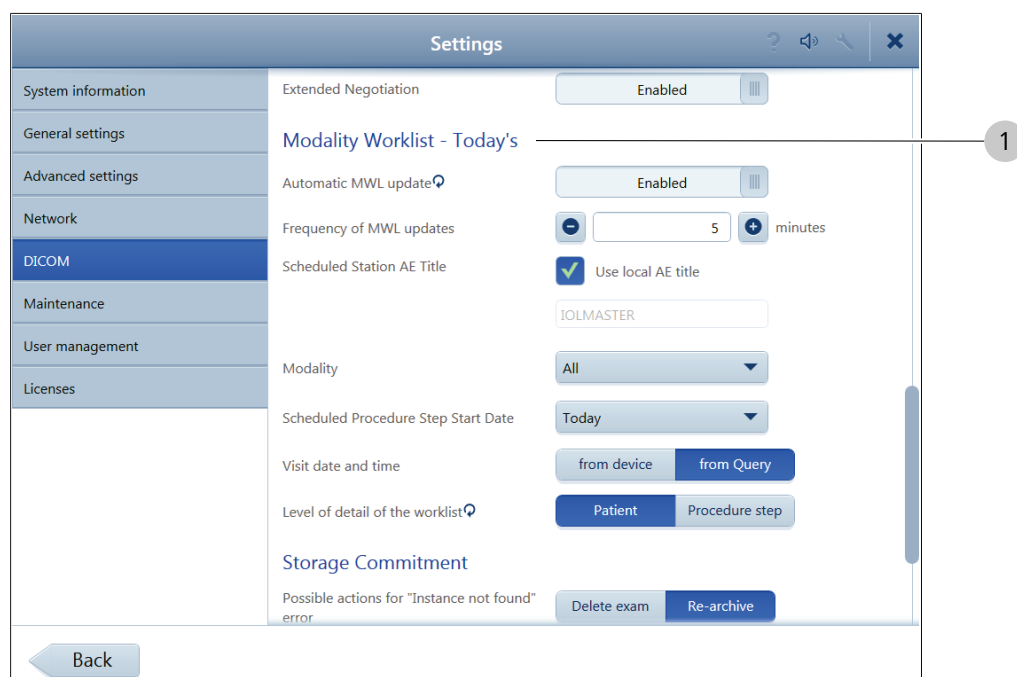


Figure 84: DICOM 4

Item	Name	Explanation
1	"Modality Worklist - Today's" dialog area	
	Automatic MWL update	This option button is used to specify whether or not the modality worklist is to be automatically updated.
	Frequency of MWL updates	If the [Automatic MWL update] option button has been enabled, the update frequency can be specified in the [Frequency of MWL updates] input field. The number entered specifies the update frequency in minutes. It can be changed using the [+] and [-] buttons.
	Scheduled Station AE Title	This MWL query parameter defines for which device the scheduled patient orders are to be queried. The default value is the AE title of the local device (Local AE title). If the parameter is not set (empty string), orders for all devices will be queried.

Item	Name	Explanation
	Modality	This MWL query parameter defines for which device type (Modality) the scheduled patient orders are to be queried. The default value is "All". (All device types will be queried).
	Scheduled Procedure Step Start Date	This MWL query parameter queries only patient orders scheduled for a specific date. The default value is "Today", other possible values are "Tomorrow", "Week" or "All".
	Visit date and time	If the button is set to "from device", the device automatically sets the date and time of the visit during an examination. If the button is set to "from Query", the date and time information from the Modality Worklist response during an examination is used to determine the date and time of the visit.
	Level of detail of the worklist	If this button is set to "Patient", the device will display the demographic data of the scheduled patient with the time for the earliest procedure step scheduled today in the Scheduled patients' list for "Today". If this button is set to "Procedure step", the device will display the demographic data of the scheduled patient with the procedure steps scheduled today in the Scheduled patients' list for "Today".

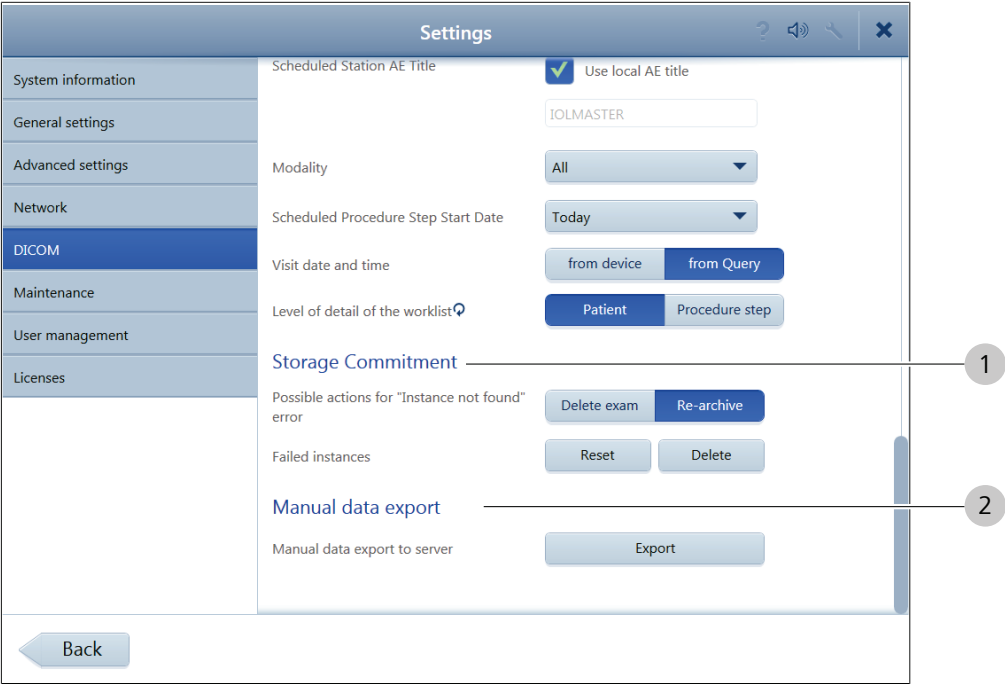


Figure 85: DICOM 5

Item	Name	Explanation
1	"Storage Commitment" dialog area	
	Possible actions for "Instance not found" error	The reaction of the device to all data for which the error message "Instance not found" was returned by the server during transmission to the Storage commitment DICOM service can be set here. If the "Re-archive" option has been enabled, the system will attempt to re-archive the data; otherwise the instance will be deleted.
	Failed instances	The [Reset] button is used to re-archive data that has not been confirmed as archived by the Storage Commitment DICOM service. The [Delete] button is used to delete data that has not been accepted by the Storage Commitment DICOM service.
2	"Manual data export" dialog area	
	Manual data export to server	By clicking the [Export] button, the measurement data can be exported manually to a server.

8.9.7 Maintenance

NOTE

Data loss possible

After backed up data has been restored, the IOLMaster 700 will reflect the status at the time of backup. All patients and lenses newly registered and measurements made and all other settings made since this time will be irretrievably lost!

- Back up your data regularly.

This dialog is opened by clicking the [Maintenance] button. A configuration wizard for checking and modifying the software settings can be launched here. The patient database can be backed up on an external drive for subsequent retrieval. Software updates can be carried out.

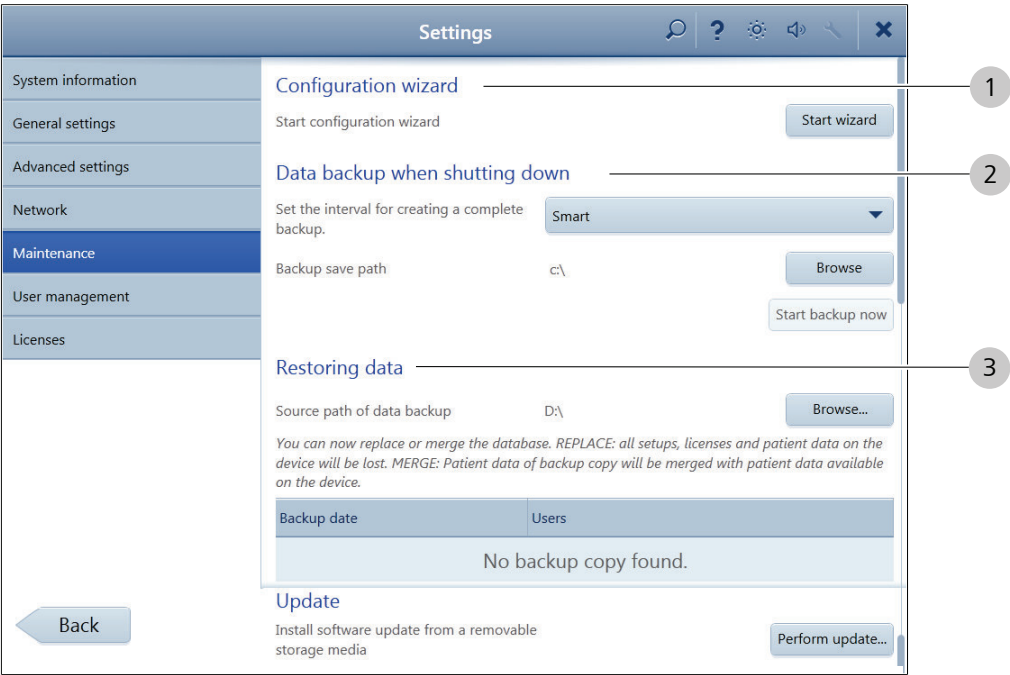


Figure 86: Maintenance 1

Pos.	Name	Explanation
1	"Configuration wizard" dialog area	
	Start configuration wizard	The [Start wizard] button launches the configuration wizard. The configuration wizard guides the user in a few steps through the device configuration process.
2	"Data backup when shutting down" dialog area	
	Drop-down list to select the interval for creating a complete backup	Tap the entry in the list to define the interval between two complete backups. When selecting [Smart] a daily backup will be performed. All changes since the last backup will be saved which saves storage space and time compared to a complete backup.
	Backup save path/ Browse	The [Browse] button opens a window for selecting the drive for data backup. After selecting the desired drive, the window is closed by tapping the [Select] button; the selected drive will be displayed on the screen as the storage location. The [Cancel] button closes the window without changing the storage location.
	Start backup now	The [Start backup now] button starts the data backup.

Pos.	Name	Explanation
3	"Restoring data" dialog area	
	Source path of data backup/Browse	The [Browse] button opens a window for selecting the options for data backup. After selecting the desired data backup the window will be closed by tapping the [Select] button. The selected path with the data backup file will be displayed on the screen. The [Cancel] button closes the window without selecting a data backup.
	List box with data backups	All data backups in the selected folder are displayed in this list box, together with the time of backup and name of the user who created the backup.
	Start restore	By tapping the entry in the data backup list more details of the data backup are displayed. The [Start restore] button is displayed. If you tap this button and confirm the query in the following window by tapping on [Restore], the data restore will be started using the selected data backup. For this purpose, the application will be restarted.
	Merge	The patient data of the selected backup will be merged with the current patient data on the device.
	Replace	The licenses and patient data on the device will be replaced by the selected data backup.

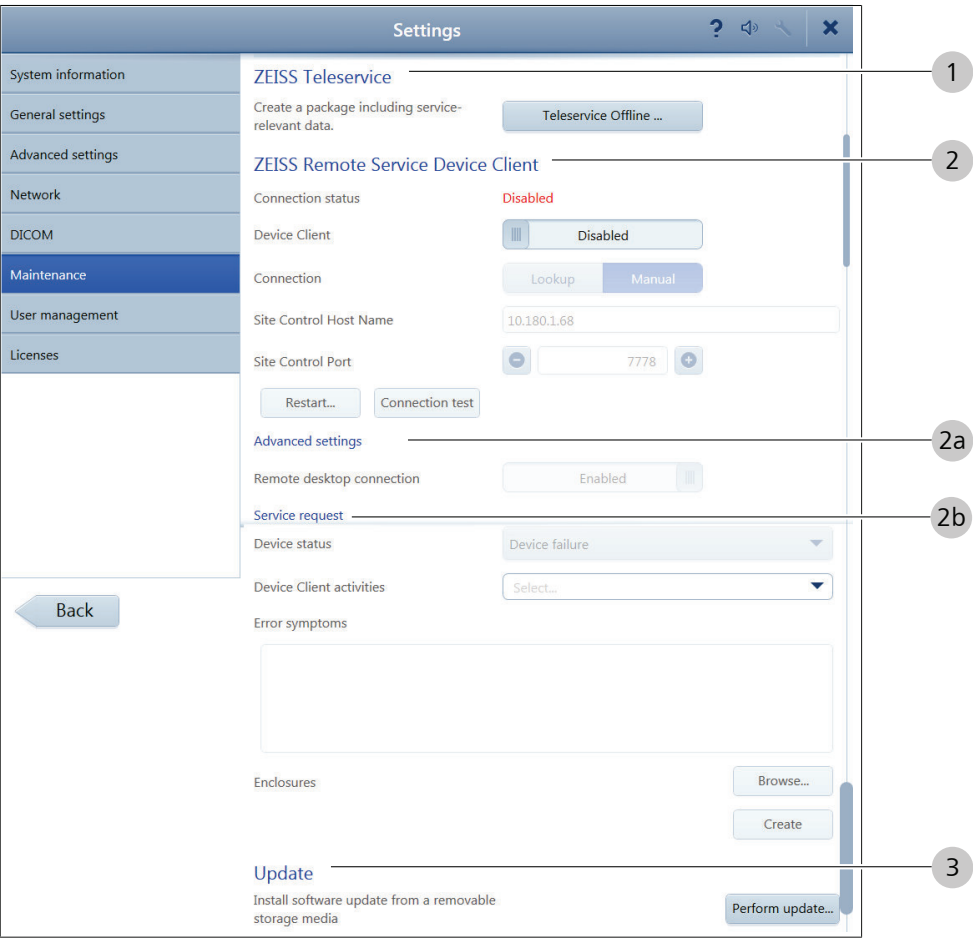


Figure 87: Maintenance 2

Pos.	Name	Explanation
1	"ZEISS Teleservice" dialog area	
	Create a package with service-related files.	Use the [Teleservice Offline] button for opening the offline remote maintenance tool. In the event of problems, a file package with log files and screenshots of the occurring problem can be created, exported to an external network drive or USB drive and sent by e-mail to ZEISS Service.
2	"ZEISS Remote Service Device Client" dialog area	
	Connection status	Information field for displaying the connection status with ZEISS Remote Service.
	Device client	If this button is enabled, the device client on the device will be enabled to communicate with ZEISS Remote Service. If this button is disabled, the device client will not be enabled on the device.

Pos.	Name	Explanation
	Connection	<p>If this option button is set to [Lookup], the device will automatically search for the ZEISS Remote Service - Site Control to communicate with the local network.</p> <p>If the [Manual] option button is enabled, the device connects to the ZEISS Remote Service - Site Control using the host name entered in the "Site Control Host Name" entry field in the local network.</p>
	Site Control Host Name	Input field for the host name of the ZEISS Remote Service - Site Control which is hosted on the local network.
	Site Control Port	Input field for entering the port number. The ZEISS Remote Service - Site Control is ready for communication with the device client. The port number can be changed using the [+] and [-] buttons.
	Restart...	The [Restart] button restarts the ZEISS Remote Service Device Client.
	Connection test	Use this button to test the connection with ZEISS Remote Service - Site Control. The results of the test are shown in a new window.
2a	Advanced settings	
	Remote desktop connection	<p>If this button is enabled, the ZEISS service employee can establish a remote connection via the ZEISS Remote Service for diagnosis, repair and troubleshooting if the system should show an unexpected malfunction.</p> <p>If this button is disabled, the ZEISS service employee cannot establish a remote connection via the ZEISS Remote Service.</p>
2b	Service request	
	Device state	<p>Drop-down list to select a general description of the device problem for a service request. The following states are possible:</p> <ul style="list-style-type: none"> ■ Device failure ■ Impaired use ■ No negative effects
	Device Client activities	Drop-down list to select the Device Client activities for a service request. You can select one or more actions for a service request, which are then executed together with the service request.
	Error symptoms	Input field for entering detailed error symptoms for a service.
	Enclosures	The [Browse] / [Create] buttons are used to select / create a file which will be sent together with a service request for troubleshooting. Use the [Send] button for starting the service request via the ZEISS Remote Service.
3	"Update" dialog area	
	Install software update from a removable storage media	Clicking the [Perform update] button closes the application and launches the update wizard. This wizard guides the user through the individual software update steps.

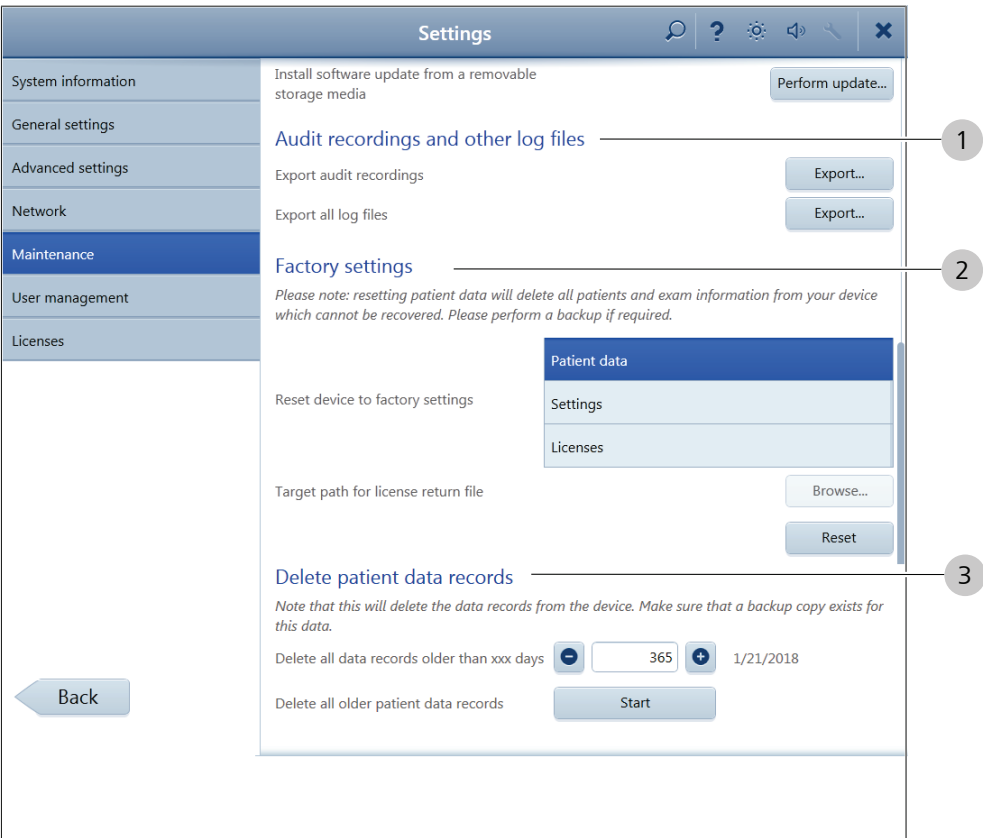


Figure 88: Maintenance 3

Pos.	Name	Explanation
1	"Audit recordings and other log files" dialog area	
	Export audit recordings	The [Export] button opens a window for selecting the folder for backing up audit recordings. After selecting the desired folder the window must be closed by tapping the [Select] button and the files will be exported. Upon successful completion of the export, the corresponding message will be displayed.
	Export all log files	The [Export] button opens a window for selecting the folder for backing up log files. After selecting the desired folder the window must be closed by tapping the [Select] button and the files will be exported. Upon successful completion of the export, the corresponding message will be displayed.

Pos.	Name	Explanation
2	"Factory settings" dialog area	
	Reset device to factory settings	Select whether patient data, licenses or settings will be reset.
	Target path for license return file/ Browse...	When tapping on [Browse...] in the "Target path for license return file", a window will be opened to select the target path for the license return file. Select the desired folder, then tap [Select]. The window will be closed. Click [Cancel] to close the window without selecting a folder.
	Reset	Tap [Reset] to reset the selected data to factory settings.
3	"Delete patient data records" dialog area Note that this will delete part of the data records from the device. Make sure that a backup copy exists for this data.	
	Delete all data records older than xxx days	This input field is used to specify the age in days from which the data records are deleted. The number can be changed using the [+] and [-] buttons.
	Delete all older patient data records	Tap the [Start] button to start the delete process.

8.9.7.1 Software update

This dialog will be opened on tapping the [Perform update] button in the "Maintenance" dialog window and enables you to update the software on your device. For this purpose you will need a storage medium with a software update.

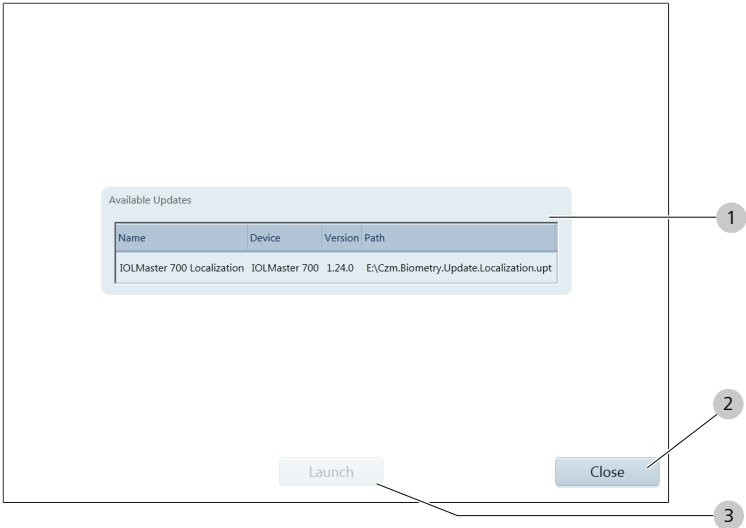


Figure 89: Software update

Item	Icon/Name	Explanation
1	Available updates list box	The "Available updates" list box displays all software updates that have been found. In addition, further information such as the name and version of the update will be displayed.
2	Close	Tap the [Close] button to close the dialog window.
3	Launch	Tap the [Launch] button to install the update highlighted in the list.

8.9.8 User management

This dialog window is opened by tapping the [User management] button. The "User management" dialog is used for creating, changing, managing and deleting users.

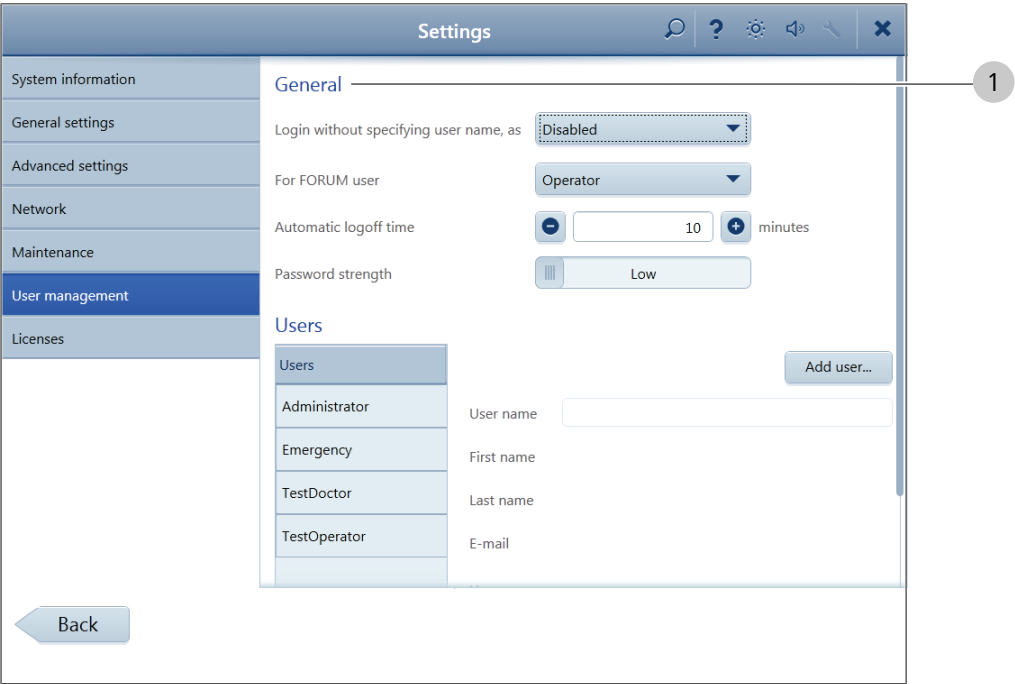


Figure 90: General

Item	Name	Explanation
1	"General" dialog area	
	Login without specifying user name, as	<p>The "Login without specifying user name, as" contains the following entries:</p> <ul style="list-style-type: none"> ■ Disabled: Each user must log in with user name and password. ■ Physician: User login is disabled. Each user is automatically assigned to the "Physician" user group. ■ Operator: User login is disabled. Each user is automatically assigned to the "Operator" user group.
	For FORUM user	<p>The "For FORUM user" drop-down list contains the following entries:</p> <ul style="list-style-type: none"> ■ Disabled: FORUM users cannot log in. ■ Physician: If the FORUM user logs in for the first time, he/she will be assigned to the database of the "Physician" user group. In subsequent logins this user can be selected from a drop-down list in the login window. ■ Operator: If the FORUM user logs in for the first time, he/she will be assigned to the database of the "Operator" user group. In subsequent logins this user can be selected from a drop-down list in the login window.
	Automatic logoff time	This input field can be used to enter the time in minutes after which a user is automatically logged off when the screen has not been touched.
	Password strength	<p>This option button is used to specify the criteria for the password check.</p> <ul style="list-style-type: none"> ■ Low: No requirements are imposed on the password. ■ High: The password must consist of at least 6 characters from at least two of the three following categories: <ul style="list-style-type: none"> – Upper case letters (A-Z) – Lower case letters (a-z) – Numbers (0 to 9)

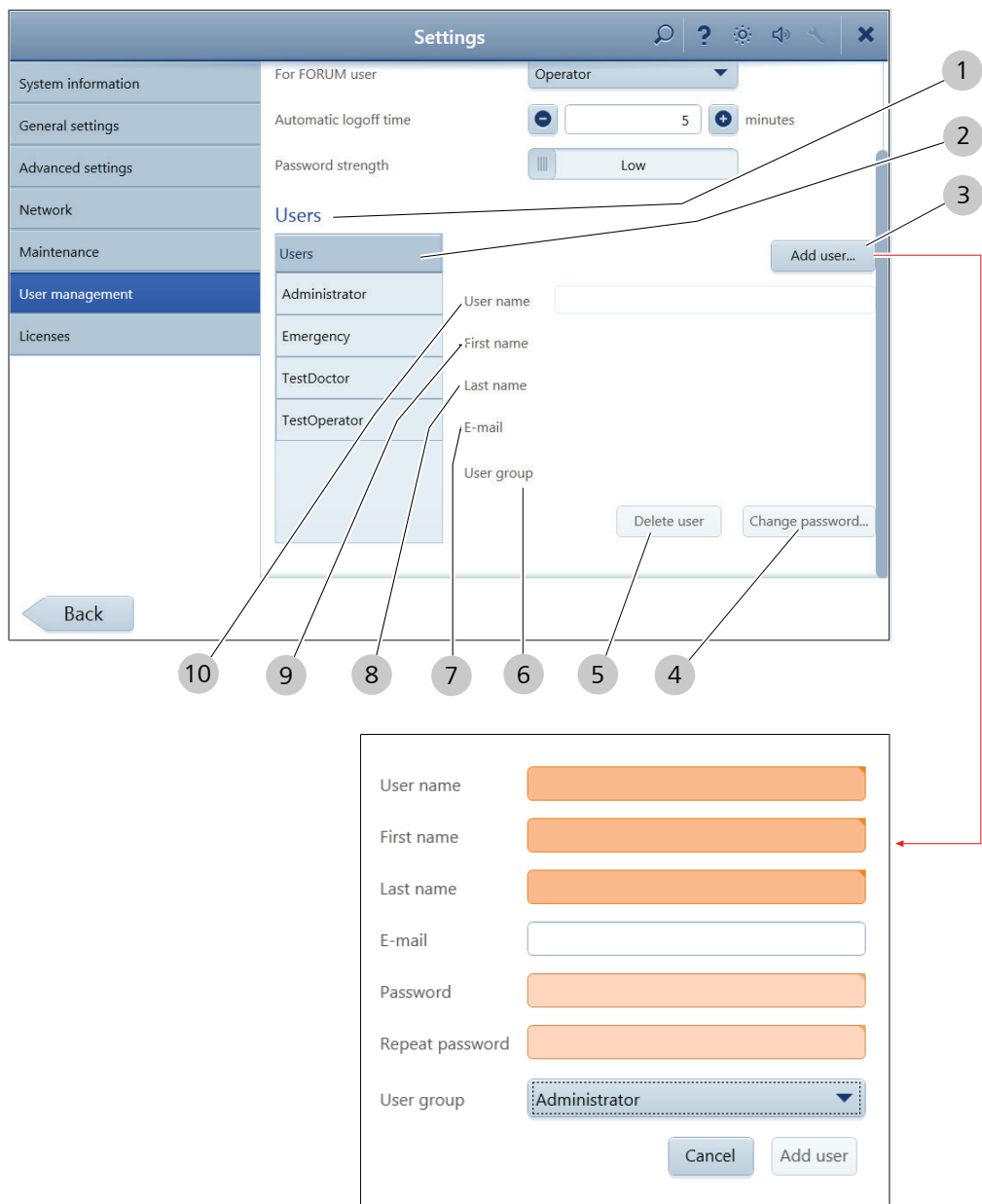


Figure 91: Users

Item	Name	Explanation
1	"Users" dialog area	
2	"Users" list box	The "Users" list box contains all existing users. The list can be scrolled down vertically using the scroll bar at the side. A user can be selected by tapping the respective entry. The data of the selected user is displayed in the adjacent input fields and can be edited there.

Item	Name	Explanation
3	Add user...	<p>Tapping the [Add user] button opens a dialog window for entering a new user. The "User name", "First name", "Last name", "E-mail", "Password", "Repeat password" and "User group" fields must be filled out or selected.</p> <p>Tapping the [Add user] button closes the dialog and adds the new user to the user list.</p> <p>[Cancel] closes the dialog window without adding the new user to the list.</p>
4	Change password	<p>Tapping the [Change password] button opens a dialog window for issuing a new password for the selected user. The new password must be entered in the input fields "New password" and "Repeat password". The new password must then be confirmed by tapping the [Reset password] button again.</p>
5	Delete user	<p>The selected user will be deleted. The deletion must be confirmed in the following dialog by tapping the [Delete user] button.</p>
6	User group	<p>The assignment of the selected user to one of the user groups (e.g. Physician, Administrator, Operator) can be changed with the aid of the "User group" drop-down list.</p>
7	E-mail	Input field for editing the e-mail address of the selected user.
8	Last name	Input field for editing the last name of the selected user.
9	First name	Input field for editing the first name of the selected user.
10	User name	Input field for editing the user name.

8.9.9 Licenses

This dialog window is opened by tapping the [Licenses] button. It allows you to activate licenses for additional software options.

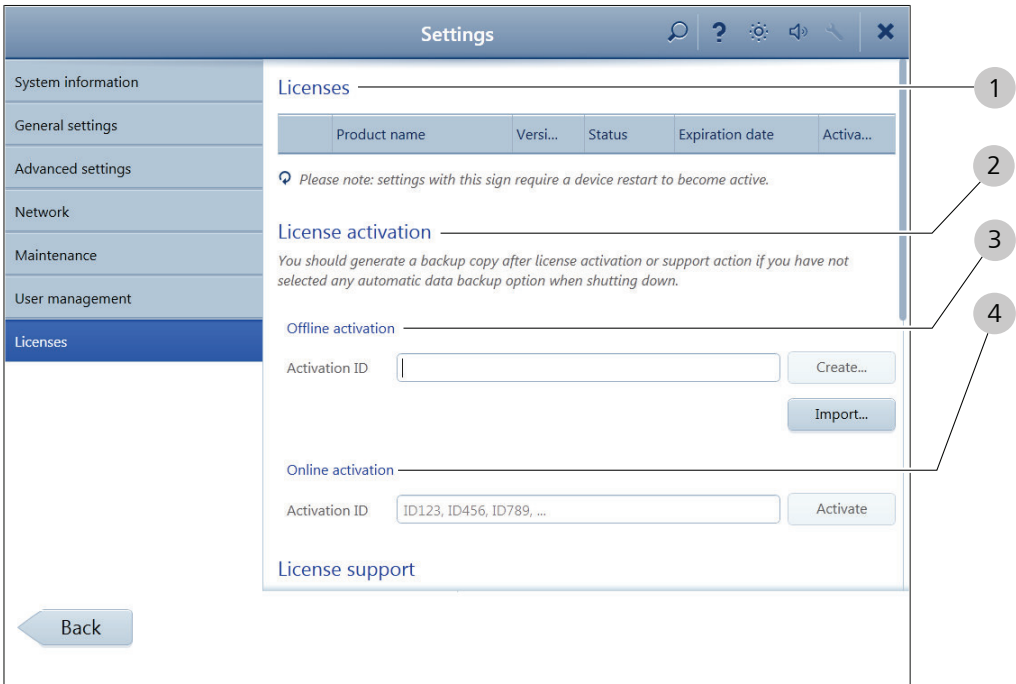


Figure 92: License activation

Item	Name	Explanation
1	"Licenses" dialog area	
	"Licenses" list box	<p>The following information on licenses already activated on the device is shown in the "Licenses" list box.</p> <ul style="list-style-type: none">■ Product name■ Version■ Status (Enabled/Disabled/Invalid)■ Expiration date■ Activation ID <p>A license can be selected by tapping it. Further details are displayed.</p>
2	"License activation" dialog area	<p>You should generate a backup copy after license activation or other license actions if you have not selected any automatic data backup option when shutting down the device.</p>

Item	Name	Explanation
3	Offline activation	The offline activation enables you to activate a new license on your device without network connection.
	Activation ID	Enter the activation ID received from ZEISS Service in this input field.
	Create	Connect an external storage medium to your device and tap [Create]. A requirement file will be created on the external storage medium. Submit this requirement file to ZEISS Service. You will receive an activation file from ZEISS Service.
	Import	Connect an external storage medium containing the activation file to your device and tap [Import]. A confirmation of the successful activation of the license will be displayed.
4	Online activation	The online activation enables you to activate a new license on your device online.
	Activation ID/ Activate	Enter the activation ID received from ZEISS Service in this input field and tap [Activate].

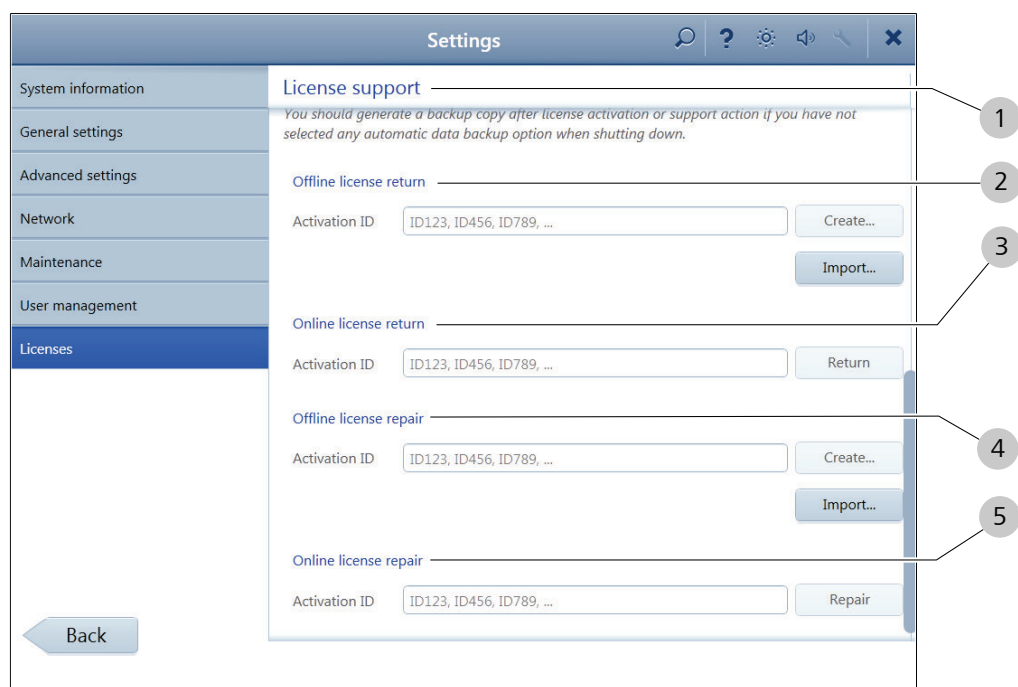


Figure 93: License support

Item	Name	Explanation
1	"License support" dialog area	
2	Offline license return	Offline license return is used to return a license on your device without network connection.
	Activation ID	Enter the activation ID received from ZEISS Service in this input field.
	Create	Connect an external storage medium to your device and tap [Create]. A requirement file will be created on the external storage medium. Submit this requirement file to ZEISS Service. You will receive a reply file from ZEISS Service.
	Import	Connect an external storage medium containing the reply file to your device and tap [Import]. A confirmation of the successful return of the license will be displayed.
3	Online license return	If your device has a network connection, you can return the activated license of your device using the online license return function.
	Activation ID	Enter the activation ID received from ZEISS Service in this input field and tap [Activate].
	Return	Tap [Return]. A confirmation of the successful return of the license will be displayed.

Item	Name	Explanation
4	Offline license repair	Use the offline license repair to restore invalid licenses without a network connection.
	Activation ID	Enter the activation ID received from ZEISS Service in this input field.
	Create	Connect an external storage medium to your device and tap [Create]. A repair requirement file will be created on the external storage medium. Submit this repair requirement file to ZEISS Service. You will receive a repair reply file from ZEISS Service.
	Import	Connect an external storage medium containing the repair reply file to your device and tap [Import]. A confirmation of the successful repair of the license will be displayed.
5	Online license repair	If your device has a network connection, you can restore an invalid license using the online license repair function.
	Activation ID	Enter the activation ID received from ZEISS Service in this input field.
	Repair	Tap on [Repair]. A confirmation of the successful repair of the license will be displayed.

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9 Cleaning and disinfection

9.1 Safety when cleaning and disinfecting the device

WARNING!

Electrical hazard due to penetration of moisture

The penetration of moisture into the device may cause an electric shock.

- ▶ Prevent moisture from penetrating the device or keyboard.
- ▶ Disconnect the power cable from the power supply before cleaning or disinfecting the device.

CAUTION!

Biological hazard due to cross-contamination

In case of no or inadequate disinfection of the device, the patient may be infected with germs.

- ▶ Parts with which the patient has come into contact during the examination (chin rest, forehead rest) should be cleaned with a disinfectant approved for the purpose.
- ▶ Observe the exposure times prescribed by the disinfectant manufacturer.

NOTE

Damage due to improper cleaning and disinfection

Some cleaning agents and disinfectants may have an adverse effect on plastic components. Damage caused by such disinfectants is not covered by our warranty.

- ▶ Observe the national disinfection regulations.
- ▶ Use only disinfectants approved by the manufacturer for the treatment of plastics and painted surfaces. The surfaces of the device have been tested and are guaranteed to resist frequent treatment with alcoholic disinfectants and cleaning agents (e.g. isopropyl alcohol up to 99.5 % and ethanol up to 96 %) over a long period.
- ▶ Do not use aggressive (e.g. acetone) or abrasive cleaning agents.

9.2 Cleaning

Action

- ▶ Do not use acetone and acetone-based cleaners to clean the device.
 - ⇒ These cleaning agents may damage the surfaces of the devices.
- ▶ All parts of the device casing may be wiped with a moist but not drip-wet cloth.
- ▶ Wipe off any marks or stains with distilled water, to which a drop of household detergent has been added.
- ▶ To clean the monitor and the keyboard, commercially available cleaning cloths for computers and monitors should be used.
- ▶ Use a commercial lens cleaning tissue (moist or dry) for cleaning the optical surfaces on the patient's side.
- ▶ Remove dust from optical surfaces by means of a fine brush.
- ▶ When not in use, cover the device to protect it from dust using the dust cover provided.

9.3 Disinfection

Instrument parts that are routinely in contact with the patient, i.e. the forehead rest and chinrest, should be disinfected before each examination. These parts are not removable.

We recommend wipe disinfection, since the optical components could be adversely affected by spraying. Please note that only the forehead rest and chinrest should be disinfected, not any of the optical components of the device.

Action

- ▶ In case of coarse contamination (e.g. makeup or dirt stains), remove visible stains on the forehead rest and chinrest with a soft cloth, moistened with a mild detergent or 70 % isopropyl alcohol solution.
- ▶ Then use another soft cloth, moistened with 70 % isopropyl alcohol solution, and thoroughly wipe the surfaces of the forehead rest and the chinrest.
- ▶ Allow the surfaces to dry completely, before the patient comes in contact with it.

10 Maintenance

10.1 Testing electrical safety

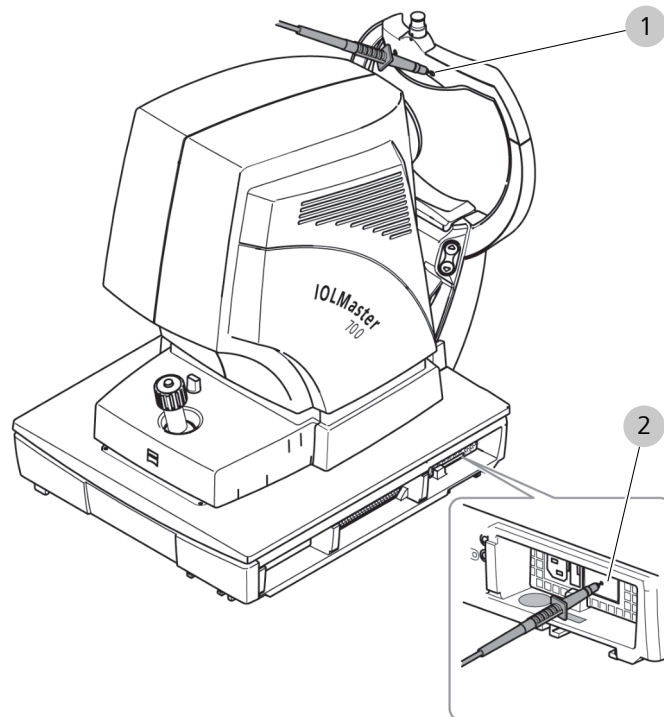


Figure 94: Testing electrical safety

1	Measurement point at head rest (screw)	2	Measuring point on connector panel
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⚠ WARNING!

Electrical hazard due to aging and wear

The electrical safety of the device may decrease with age and wear.

- ▶ Obtain information on the relevant regulations in your country regarding electrical equipment inspections. These must be adhered to!
- ▶ Unless otherwise regulated by local legal provisions: Have preventive maintenance carried out on your device serviced by by ZEISS Service or have an electrical safety inspection according to IEC 62353 performed by a qualified technician annually. When performing the inspection, observe the service instructions issued by Carl Zeiss Meditec and/or the following instructions.

Action

1. Perform a visual inspection of all components and cables to ensure they are in proper condition.
2. Check the protective earth conductor resistance. To do this, connect the device to the measuring instrument using the power cable. To perform a measurement, press the measuring tip to the measurement points shown in the figure.
⇒ The measured value may not exceed 0.3 Ω .
3. If there are doubts about the effectiveness of the insulation (such as multiple triggering of the fault circuit interrupter or other protective devices in the physician's practice, or traces of liquid on the device which suggest the penetration of liquid), measure the insulation resistance with a test voltage of 500 V.
⇒ The measured value may not be less than 2 M Ω .
4. After successful measurement, the device leakage current must be measured. Preferably, the differential current method should be used. The device is in its operating state. Press the measuring tip onto the measurement points again.
⇒ The measured value may not exceed 0.5 mA.
5. The test is concluded by a function check. This should be performed by a person who is familiar with the application.
6. Note down all measured values.

10.2 Replacing the fuses

NOTE

Electrical hazard due to incorrect fuse

Inserting an incorrect fuse may damage the device.

- ▶ Disconnect from the power supply before changing the fuse!
- ▶ Only use fuses which meet the specifications given on the sign containing fuse markings.

The fuse compartment with the fuse cartridge and the two fuses is located at the right-hand side of the device power input [► 24].

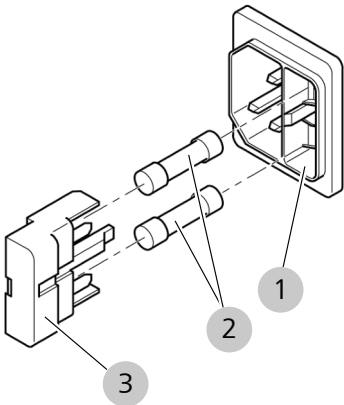


Figure 95: Replacing the fuses

1	Fuse compartment	2	Fuse
3	Fuse carrier		

Action

1. Remove the fuse carrier with fuse by pressing gently on the snap-in clip.
2. Replace the defective fuse.
3. Reinsert the fuse carrier with fuse. Ensure that the fuse carrier snap-in clip is correctly positioned.

Empty page, for your notes

11 Troubleshooting

11.1 Errors (no messages)

The following troubleshooting tables list possible problems encountered in the operation of the IOLMaster 700 together with the appropriate remedies. Should problems persist, please contact ZEISS Service.

11.1.1 Problems with the electric system

Fault	Cause	Remedy
Indicator light in standby button is not lit.	Power plug is not connected. Indicator light is defective. Power input fuse has been triggered, short circuit in the device	<ul style="list-style-type: none"> ▶ Ensure that the power plug is connected to the power supply. ▶ Replace the fuses [► 213]. ▶ If the indicator light is not lit, contact ZEISS Service.
After connecting the power cable, the indicator light does not flash.	Indicator light is defective.	▶ Contact ZEISS Service.
Shortly after being switched on, device switches off again.	Power supply unit is defective.	▶ Contact ZEISS Service.

11.1.2 Monitor problems

Fault	Cause	Remedy
The device switches on, but no screen display appears.	The required cables are not plugged in. Cable is defective. Monitor is defective.	▶ Check if the power supply cable and the touch screen cable are correctly plugged in. If yes, contact ZEISS Service.
After the device has booted up, it cannot be operated.	The required cables are not plugged in. Driver problems	▶ Check if the USB cable is plugged in. If yes, contact ZEISS Service.

11.1.3 Problems with the flexible optical measuring head

Fault	Cause	Remedy
The measuring head may be difficult to move or cannot be moved at all.	Shipping brace has not been removed. Locking mechanism has not been released.	► Check if the shipping brace [► 30] has been removed or the locking mechanism [► 22] has been released. If yes, contact ZEISS Service.

11.2 Service information

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

12 Technical specifications

12.1 Essential performance

The essential performance feature of the IOLMaster 700 is the measuring accuracy of the device required for calculating a patient-specific IOL.

Provided the measuring accuracy is not compromised, switching off or shutting down the device does not represent an unacceptable risk to a patient, user or third party and is therefore permissible

12.2 Compliance

This declaration shall be rendered invalid if changes are made to the device without the manufacturer's authorization.

12.2.1 The device fulfils the requirements of the following standards

- IEC 60601-1
- IEC 60601-1-2
- IEC 60825-1
- IEC TR 60601-4-2

12.2.2 Device classification

The device is classified as follows:

- Protection class: 1
- Type of protection: IP 20
- UMDNS No. 18-014

12.2.3 Classification of the device according to IEC 60825-1

- Laser class 1
- In device (not accessible): 3B

12.3 Electrical data

	Value
Rated voltage	100 V to 240 V AC (±10%)
Frequency	50 / 60 Hz
Power consumption during operation	120 VA
Power consumption in standby mode	1 W
Fuses	2xT3.15 A/H 250V 5x20 mm
Battery type / manufacturer	CR 2032 / Renata

12.4 Dimensions and weights

	Value
Footprint of basic unit	439 mm x 389 mm
Max. height of basic unit (measuring head)	563 mm
Weight of basic unit	27 kg
Dimensions of external monitors (W x H x D)	364 mm x 322 mm x 206 mm 350 mm x 305 mm x 220 mm

12.5 Measurement ranges and standard deviation of repeatability on the human eye

Calculation of standard deviation (SD) of repeatability using clinical data [19] [▶ 234] with three repeat measurements on IOLMaster 700. The value is based on a population (n=50) of cataract eyes.

	Value
Axial length	
Range	14 mm to 38 mm
Resolution of display	0.01 mm
SD of repeatability	5 µm
Pupil diameter	
Range	1 mm to 12 mm
Resolution of display	0.1 mm

12.5 Measurement ranges and standard deviation of repeatability on the human eye

	Value
Keratometer	
Range	5 mm to 11 mm
Resolution of display	0.01 mm
SD of repeatability SE	0.09 D
SD of repeatability Cylinder axis > 0.75 D	3.8°
Anterior chamber depth	
Range	0.7 mm to 8 mm
Resolution of display	0.01 mm
SD of repeatability	7 µm
Lens thickness	
Phakic eye range	1 mm to 10 mm
Pseudophakic eye range	0.13 mm to 2.5 mm
Resolution of display	0.01 mm
SD of repeatability	6 µm
Central corneal thickness	
Range	0.2 mm to 1.2 mm
Resolution of display	1 µm
SD of repeatability	2.5 µm
White-to-white	
Range	8 mm to 16 mm
Resolution of display	0.1 mm
SD of repeatability	111 µm

12.6 Comparability of IOLMaster 700 with IOLMaster 500 for calculation of IOL powers

IOL powers for each eye have been calculated using the SRK/T formula and corneal radii and axial length values of a population (n=105) of cataract eyes (see [20] [► 234]) measured with IOLMaster 700 (software version 1.50 and software version 1.14) and IOLMaster 500. On average the IOL refraction should not vary by more than 0.1 D.

Furthermore, the population mean values for cataract eyes for axial length, anterior chamber depth and corneal radii for two typical sets of constants each (A and B) have been calculated using the Haigis formula to determine whether the difference in IOL refractive power is more than 0.1 D (see [20] [► 234]).

The following tables show the results of the described IOL calculation using the IOLMaster 700 and IOLMaster 500 data and their difference (IOLMaster 700 with software version 1.50 versus IOLMaster 700 with software version 1.14 and IOLMaster 700, software version 1.50 versus IOLMaster 500) and the following basic IOL data:

- SRK/T formula with typical A constant A = 118.5
- Haigis formula with A set of constants: a0 = 1,3; a1 = 0,4; a2 = 0,1
- Haigis formula with B set of constants: a0 = 0.286; a1 = 0.175; a2 = 0.158

IOL refractive powers calculated with data of IOLMaster 700 (software version 1.50) and IOLMaster 500 and their difference [20] [► 234]

	(n=103)	Unit	IOLMaster 700 software version 1.50	IOLMaster 500 keratometry	Difference
1.	IOL power with SRK/T formula	D	19.85	19.85	0.00
2.	IOL power with Haigis formula (set of constants A)	D	19.99	19.96	0.03
3.	IOL power with Haigis formula (set of constants B)	D	19.39	19.38	0.01

IOL refractive powers calculated with data of IOLMaster 700 (software version 1.50) and IOLMaster 700 (software version 1.14) and their difference [20] [▶ 234]

	(n=103)	Unit	IOLMaster 700 software version 1.50	IOLMaster 700 software version 1.14	Difference
1.	IOL power with SRK/T formula	D	19.85	19.85	0.00
2.	IOL power with Haigis formula (set of constants A)	D	19.99	19.99	0.00
3.	IOL power with Haigis formula (set of constants B)	D	19.39	19.39	0.00

12.7 Optical data

	Value
Illumination for WTW measurement	
Source	LED
Wavelength	860 nm / 880 nm
Delivered power	< 500 µW
Illumination for OCT	
Source	Tunable laser
Wavelength range	1035 nm to 1080 nm
Maximum power output	1.67 mW
Illumination for keratometer measurement	
Source	LED
Wavelength	950 nm
Delivered power	< 500 µW
Green illumination for sclera images	
Source	LED
Wavelength	520 nm

	Value
Delivered power	< 100 µW
Max. exposure time per eye and day	27 min (corresponding to approx. 3000 measurements)
Fixation lamp	
Source	LED
Wavelength	660 nm
Delivered power	< 1 µW

12.8 Ambient conditions

	Value
Ambient conditions for operation	
Temperature	+10 °C to +35 °C
Relative humidity	30 % to 80 % (non condensing)
Altitude	up to 3,000 m above sea level
Ambient conditions for storage and transport in original packaging	
Temperature	-20 °C to +60 °C
Relative humidity	10 % to 90 % (non condensing)

12.9 Electromagnetic compatibility

Special electromagnetic compatibility (EMC) requirements apply to this device. The following factors can cause electromagnetic interference:

- Portable and mobile RF communications equipment in the vicinity of the device.
- Other devices placed in the vicinity of the device or stacked with the device.
- Accessories, cables and spare parts that are not specified in these instructions for use and not sold by ZEISS as spare parts.

When operating the device, observe the following EMC precautions.

- Follow the instructions for use.
- Observe the restrictions and instructions in this chapter.

12.9.1 Ambient conditions for intended use

The IOLMaster 700 is intended for use in professional healthcare facilities with regard to electromagnetic compatibility. These include in particular hospitals and medical practices, including those connected to the public power supply (e.g. in residential areas).

The IOLMaster 700 is not intended for operation in the following environments:

- Home health care (e.g. residential accommodation, nursing homes)
- Outdoor environments
- Other special environments (e.g. military facilities, heavy industry, facilities for medical treatment or diagnosis with high-power devices. These include in particular high-frequency surgical devices, short-wave therapy equipment and MRI devices.)

12.9.2 Restrictions on essential performance

The essential performance feature of the IOLMaster 700 is the measuring accuracy of the device required for calculating a patient-specific IOL.

If this measuring accuracy is compromised, e.g. due to strong electromagnetic interference (above the permissible level indicated below) on the device, there is a risk of incorrect calculation of IOL powers.

Provided the measuring accuracy is not compromised, switching off or shutting down the device due to electromagnetic interference does not represent an unacceptable risk to a patient, user, or third party and is therefore not a restriction of essential performance.

CAUTION!

Hazard from electromagnetic interference

Using IOLMaster 700 in direct proximity to other devices or stacked together with other devices can result in unforeseen interference with device operation.

- ▶ With the exception of device combinations described in these instructions for use (e.g. combination with instrument table), using IOLMaster 700 in direct proximity to other devices or stacked together with other devices should be avoided.
- ▶ If it is nonetheless necessary to operate the device in the aforementioned manner, IOLMaster 700 and the other devices should be observed to check for intended operation of the arrangement used.
- ▶ Do not use portable HF communications equipment (including peripheral devices such as antenna cable and external antennas) within a radius of 30 cm around the IOLMaster 700, including cables specified by the manufacturer. Otherwise, deterioration in the performance of the IOLMaster 700 is to be anticipated.

CAUTION!

Hazard from electromagnetic radiation

The use of accessories, all types of transducers and cables not specified in these instructions for use or not sold by Carl Zeiss Meditec as replacement parts may result in higher electromagnetic emissions or reduced immunity of the device and thus in faulty operation.

- ▶ Purchase spare parts (including spare cables) solely from Carl Zeiss Meditec or dealers authorized by Carl Zeiss Meditec.
- ▶ Ensure that any optional IT accessories (e.g. printers) meet the Class B CISPR 32 requirements.

Relevant accessories and cables:

- Power supply cable (2.50 m)
- Operator interface composite cable
- USB mouse and keyboard
- Network cable (1.50 m)
- Patch cable, crossover (5.00 m)
- Network isolator
- Instrument table

No regular inspections or maintenance are required in order to maintain electromagnetic compatibility (EMC). If obvious damage to the device is detected (e.g. housing or cables), remove the device immediately from service, label it clearly as being out of service, and contact ZEISS Service. It may still be possible to operate a damaged IOLMaster 700, but there could be increased emissions and/or decreased immunity.

The following guideline applies only to the accessories specified for and delivered with the device from Carl Zeiss Meditec.

Electromagnetic emission

Emitted interference	Standard	Compliance
Conducted emission	CISPR 11	Group 1, Class B
Radiated emission	CISPR 11	Group 1, Class B
Harmonic distortion	IEC 61000-3-2	Class A
Voltage fluctuations and flicker emissions	IEC 61000-3-3	Complies

Immunity

Phenomenon	Standard	IEC 60601-1-2 test level	IEC TR 60601-4-2 test level
Electrostatic discharge (ESD)	IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air (housing, connector panel, patient interface, monitor, keyboard, mouse)	±4 kV contact ±2 kV, ±4 kV, ±8 kV air (housing, connector panel, patient interface, monitor, keyboard, mouse)
Radiated RF EM fields	IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz (housing)	3 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz (housing)
Electrical fast transient / burst	IEC 61000-4-4	±2 kV, 100 kHz repetition rate (power cable) ±1 kV, 100 kHz repetition rate (data cable*)	±1 kV, 100 kHz repetition rate (power cable) ±0.5 kV, 100 kHz repetition rate (data cable*)
Surge voltage / surges line to line	IEC 61000-4-5	±0.5 kV, ±1 kV (power cable)	±0.5 kV, ±1 kV (power cable)
Surge voltage / surges line to earth		±0.5 kV, ±1 kV, ±2 kV (power cable)	±0.5 kV, ±1 kV, ±2 kV (power cable)
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM frequency bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz (power and data cable*)	3 V 0.15 MHz - 80 MHz 80% AM at 1 kHz (power and data cable*)
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m, 50 Hz and 60 Hz (housing)	3 A/m, 50 Hz and 60 Hz (housing)

Phenomenon	Standard	IEC 60601-1-2 test level	IEC TR 60601-4-2 test level
Voltage dips	IEC 61000-4-11	0% U_T ; 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% U_T ; 1 cycle and 70% U_T ; 25 cycles at 50 Hz / 30 cycles at 60 Hz single-phase: at 0° (power cable)	0% U_T ; 0.5 cycles at 0° and 180° 0% U_T ; 1 cycle and 70% U_T ; 25 cycles at 50 Hz / 30 cycles at 60 Hz single-phase: at 0° (power cable)
Voltage interruptions		0% U_T ; 250 cycles at 50 Hz / 300 cycles at 60 Hz (power cable)	0% U_T ; 250 cycles at 50 Hz / 300 cycles at 60 Hz (power cable)
Magnetic fields at close range	IEC 61000-4-39	65 A/m 134.2 kHz Pulse modulation 2.1 kHz 7.5 A/m 13.56 MHz Pulse modulation 50 kHz	

*including data cables with a maximum length of less than 3 m

Phenomenon	Standard	Frequency band [MHz]	Radio service	IEC 60601-1-2 test level [V/m]	IEC TR 60601-4-2 test level [V/m]
Immunity to radiated radio frequencies, caused by wireless communications equipment, in accordance with IEC 60601-1-2: 2014, table 9 and/or IEC TR 60601-4-2:2016, table 7	IEC 61000-4-3	380-390	TETRA 400	27	6
		430-470	GMRS 460, FRS 460	28	9
		704-787	LTE Band 13.17	9	3
		800-960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	28	9
		1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	28	9
		2400-2570	Bluetooth; WLAN 802.11b/g/n; RFID 2450; LTE Band 7	28	9
		5100-5800	WLAN 802.11 a/n	9	6

13 Optional accessories

- Instrument table
- Keyboard and mouse
- Printer
- Network isolator

In these instructions for use, accessories are described which are not necessarily part of the individual delivery. An up-to-date list of accessories can be obtained from your ZEISS contact.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

Use only accessories and spare parts which are approved by ZEISS for this device. If accessories and spare parts are used that are not approved by ZEISS, safe operation of the device cannot be guaranteed.

13.1 Instrument table

WARNING!

Electrical hazard due to improper electrical connection

Improper electrical installation may cause an electric shock.

- ▶ Connect the device via an instrument table qualified by Carl Zeiss Meditec. If another table is used, the user is solely responsible for ensuring the electrical safety of the device.

CAUTION!

Mechanical hazard due to instability

Injury may be caused by falling parts.

- ▶ When selecting a suitable table, ensure that the combination of table and device is stable up to a tilt angle of 10°. The table must be designed for 4 times the weight of the device configuration.
- ▶ When using a mobile table, ensure that the casters have locking devices.

13.2 Mouse and keyboard

The device can be operated using the touch screen monitor or a keyboard and mouse. The keyboard and mouse are connected to the USB ports of the device.

13.3 Connecting a printer to IOLMaster 700

The IOLMaster 700 supports PostScript® printers that can be connected via the Ethernet or a printer server. A network-capable PostScript printer can be connected to the IOLMaster 700 directly (peer to peer) or via an existing network.

WARNING!

Electrical hazard due to improper printer installation

Incorrect printer installation may cause an electric shock.

- ▶ Position the printer outside the patient's range (1.5 m from the patient's seat at the device).
- ▶ Operate the printer with a network isolator (cut-off voltage of at least 4 kV).
- ▶ Connect the printer to a separate socket.
- ▶ Do not touch the printer and the patient at the same time.
- ▶ If the printer is to be operated in the patient environment, connect the printer additionally via an isolating transformer.

Action

- ▶ Keep the user manual for your printer or printer server at hand. The printer must be configured according to the instructions contained in the user manual for the printer or printer server.

13.3.1 Peer-to-peer connection of printer with IOLMaster 700

Action

1. Connect the network printer or printer server to the IOLMaster 700 via a network isolator and the supplied network cables.
2. Switch on the IOLMaster 700 and printer or printer server.
3. Configure the network printer or printer server with the aid of the user manual provided with the instrument as follows:
IP address: 192.168.100.6
Subnet mask: 255.255.255.0

13.3.2 Connection of printer via an existing network

Action

- The administrator responsible for your local network must first of all set up a network printer or printer server in the network. The procedure for printer configuration is described in the user manual for the network printer or printer server. The IP address and subnet mask to be used will be assigned by the administrator of the network.
- By default the IOLMaster 700 is pre-configured to the static network address 192.168.100.1.
- ▶ Indications on the use of the installation of the printer are to be found in section "Software description / Settings / General settings [▶ 145]".

13.4 Network isolator

The purpose of the galvanic network isolator is to provide a galvanic separation of the network supply (main cable) between the device and a printer/printer server.

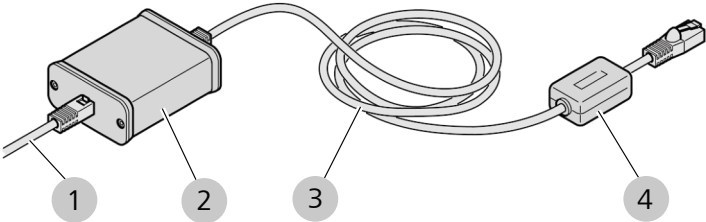


Figure 96: Network isolator

1	Network cable to LAN	2	Network isolator
3	Network cable to device	4	Ferrite (with rectangular body)

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14 Disposal of the device

- ▶ Retain packaging materials for future relocation or repair.
- ▶ If you wish to dispose of the packaging material: Submit the packaging material to a recognized collection system for recycling.

The device contains electronic components with built-in batteries.

- ▶ Dispose of the device and the built-in batteries properly and in accordance with national regulations.



In accordance with applicable EU guidelines and national regulations at the time at which the device was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities.

- ▶ For further information on disposing of the device, contact the ZEISS contact person for your country.

You can find the ZEISS representative for your country online on the following website: www.zeiss.com/med

- ▶ If you resell the device or its components: Inform the buyer that the device is to be disposed of in accordance with the currently applicable regulations.

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Glossary

ACD

Anterior chamber depth

AE

AE (Application Entity) is the name of a DICOM node

AL

Axial length

CCT

Central corneal thickness

D

Diopter (unit of measurement of the refractive power of optical systems)

DICOM

Digital Imaging and Communications in Medicine (open standard for the archiving and exchange of information within medical image management)

DVI

DVI (Digital Visual Interface) is an electronic interface for the transfer of digital and analog video content.

ID

Identification

IEC

International Electrotechnical Commission

IOL

Intraocular lens (artificial lens for the eye)

IP

Internet Protocol (communications protocol to transfer data in the Internet or a network)

LASEK

Laser-epithelial keratomileusis

LASIK

Laser-in-situ keratomileusis

LED

Light emitting diode

LT

Lens thickness

LVC

Refractive corneal surgery (laser vision correction), e.g. LASIK

LVC mode

Settings for IOL calculation considering prior refractive corneal surgery

LVC state

State of the cornea with reference to prior refractive surgery

Modality Worklist

Service for automatic transfer of jobs including relevant patient data to information systems

OCT

Optical coherence tomography

OD

Oculus dexter (right eye)

OS

Oculus sinister (left eye)

PCI

Partial coherence interferometry

PCS

PCS (posterior corneal surface) is the curvature of the posterior corneal surface.

PRK

Photorefractive keratectomy

RK

Radial keratectomy

SD

Standard deviation

SE

The spherical equivalent is the sum of the sphere and half cylinder and is used as a measure of the refractive error.

SNR

Signal-to-noise ratio

TK

Total Keratometry

USB

Universal serial bus (standard connector to connect peripheral devices)

VD

Vertex distance

WTW

White-to-white distance

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