OCULUS
Pentacam® AXL Wave



Instructions for Use

OCULUS®

Preface

The Pentacam® AXL Wave has been manufactured and tested according to strict quality criteria.
To ensure safe operation, it is essential that you use the device correctly. For this reason you should familiarize yourself thoroughly with the contents of this Instructions for Use before operating the device. In particular, pay attention to the safety instructions in the Instructions for Use.

The following user information is included with the device in printed form:

- **Instructions for Use:** Describes the device's design, contains all safety-related instructions for using the device, and guides you through the measurement process. Includes basic instructions on how to use the patient data management system.

Further user information is available on the OCULUS website or via the QR code provided:

- **User Guide:** Contains information supplementing the description of the operating concept. All features of the examination and analysis software are described in the User Guide, along with detailed information about the Patient Data Management system.
- **Interpretation Guide:** Serves as a support for interpreting measurement results and graphical representations generated with the device.
- **Software Installation:** Describes how to install the device software and the associated drivers.
- **Manual Floating License Key:** Information on the use of the device within networks.

Due to ongoing development, the figures shown may depict minor changes to the actual device delivered.
If you have any queries or would like additional information about your device, do not hesitate to call or send us an email or a fax. Our service team will gladly assist.

OCULUS Optikgeräte GmbH

Item number: G/70020/US
Revision: Rev13
Release: 07/10/2026

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1 Scope of Delivery

Standard Components
Pentacam® AXL Wave
■ x-y base with cograils
■ Support plate
■ Sliding plate
■ Head and chin rest with chin rest paper
■ Pentacam® AXL Wave
■ User information
■ Pentacam® Basic Software
■ Y-cable with Med. secure isolator + USB connection
■ Country specific power supply
■ Dark sheet with washing manual
■ Accessories Package

Optional Software Packages
■ Screening Package
■ Cataract Package
■ Refractive Package
■ Contact Lens Fitting Package
■ Myopia Package incl. GRAS Module

Single Licenses
■ Holladay Report and Holladay EKR Detail Report
■ 3D pIOL Simulation and Aging Prediction
■ IOL Caluclator
■ DICOM
■ Visual Performance

We reserve the right to make changes to the scope of delivery in the course of technical development.

➔ If you find transport damage upon delivery, immediately file a claim with the transport company.

➔ Have the damages noted on the bill of lading, so that your claim for damages can be handled properly.

For more information regarding shipping and handling, see → Chap. 10 (Page 81).

2 Safety

All safety-related instructions of the device are given in the Instructions for Use only.

- ➔ Read and follow the Instructions for Use.
- ➔ Keep the Instructions for Use in good condition near the device.
- ➔ Observe the legal regulations with regard to accident prevention.

Any serious-incident that has occurred in relation to the device should be reported to the manufacturer (vigilance@oculus.de) and the competent authority of the region in which the user and/or patient is established.

2.1 Symbols

2.1.1 On the Device / Name Plate

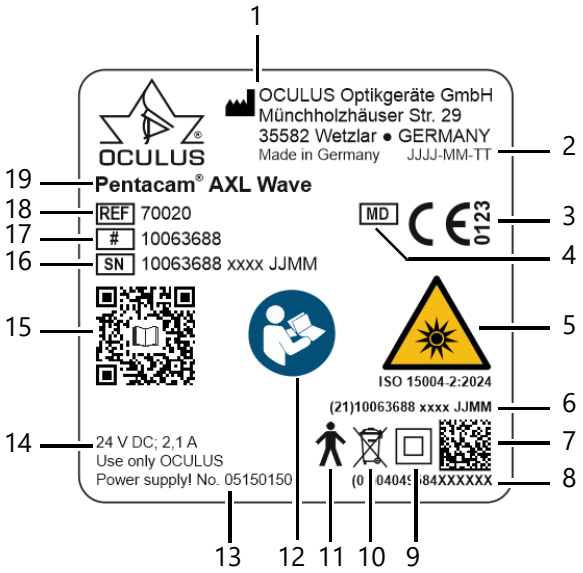


Fig. 2-1: Name plate (example)

No.	Description	No.	Description
1	Name and address of manufacturer	11	Applied part type B
2	Date of manufacture	12	Follow instructions for use
3	CE mark and number of notified body	13	Power supply unit to be used
4	Medical device	14	Power supply
5	Warning regarding optical radiation	15	QR-Code to user information (other languages, user guides etc.)
6	UDI-DI (Device Identifier)	16	Serial number
7	Machine-readable matrix-code	17	Model number
8	UDI-PI (Product Identifier)	18	REF number
9	Protection class	19	Device name
10	Disposal in household trash is prohibited		

2.1.2 On the Packaging

Symbol	Description
	Protect from moisture
	Transport upright
	Fragile
	Permissible temperature range for transport
	Permissible temperature range for storage
	Permissible range for humidity
	Permissible range for air pressure

2.1.3 In this Manual



Warning
Identifies a potentially dangerous situation which may cause serious injury.



Caution
Identifies a potentially dangerous situation which may cause minor injury.



Note
Identifies situations which may cause damage to the device or incorrect test results.



Information
Indicates important instructions for use and important information about the device.

> This symbol denotes menu paths and screen shots. Example for starting a new examination:
Pentacam® AXL Wave > Examination > Scan
which means:
➔ Select the "Examination" menu from the menu bar.
➔ Select the menu item "Scan".

[ ] Marks buttons.

→ Cross reference

2.2 Safety Instructions for Use



Caution

Personal injury or property damage due to improper operation

➔ Observe the following safety instructions.



Caution

Personal injury or property damage due to equipment modifications that could jeopardize safety

➔ No modifications may be made to this device without the permission of the manufacturer. Only the OCULUS service are allowed
- to modify the device or the associated lifting table.
- to install software and software updates.

2.2.1 Information for the Operation of an ME System

The device and a connected computer form a medical electrical system (ME system) according to IEC 60601-1. If you connect additional devices, such as, for example a printer, those devices become part of the ME system.

➔ Make sure that all devices of the ME system meet the requirements of IEC 60601-1 or IEC 60950-1/IEC 62368-1.

2.2.2 Instructions for Laser Use



Warning

Risk of personal injury or material damage due to invisible laser radiation

The device contains a Class 1 laser according to IEC 60825-1: 2014. It is an encapsulated laser system. When the device cover is opened, you may be exposed to invisible, Class 3R (5 mW) laser radiation.

➔ Never open the unit.

➔ For authorized service personnel only: When doing maintenance jobs, avoid looking directly into the laser beam.

2.2.3 Instructions on Electrical Safety



Warning

Risk of personal injury or damage to property due to an incorrect level of safety

Connecting the device with its non-medical electrical equipment (e.g. data processing equipment) to a medical electrical system must not result in a patient safety level below that prescribed by IEC 60601-1. If making this connection leads to the leakage current threshold being exceeded, protective measures including a circuit breaker must be in place.

- ➔ Ensure that connections with non-medical devices are made correctly.
- ➔ Only use the power adapter listed in the packing list.
- ➔ Use only a computer that meets the specifications given in this instructions for use → Chap. 12 (Page 84).



Warning

Risk of personal injury or material damage caused by unsafe multiple socket extension cord

If you use a multiple socket extension cord to connect the device to the power supply, you must heed the following information:

- ➔ Use an extension cord that complies with the requirements of IEC 60601-1, section 16.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the device and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.
- ➔ If you are using a multiple socket extension chord it has to be supplied with a isolation transformer.
- ➔ If you are using a new computer for the device, you must have the electrical safety checked. Call OCULUS Service for this purpose.



Warning

Risk of personal injury or damage to property due to electromagnetic interference

Portable and mobile RF communications equipment can affect medical electrical equipment → Chap. 13 (Page 86).

- ➔ Make sure that portable and mobile RF communications equipment do not cause interference.
- ➔ Recommendation: Maintain a minimum distance of 4 m. If the distance is shorter, you must ensure that the device functions correctly.

2.3 Instructions on Cyber Security



Note

Please also follow the regulations, guidelines, and recommendations of the relevant authorities responsible for information security and the protection of critical infrastructure in your country.



Information

The device is designed to operate independently without requiring an internet connection, network access, or portable media. It functions solely through a connected computer.

If you choose to connect the computer to the internet or another network for unrelated purposes, you are responsible for ensuring that the connection is secure and controlled.

2.3.1 Precautionary Measures Against Unauthorized Access

To increase the cybersecurity of the device:

➔ Secure the device against unauthorized access by unauthorized persons.

Observe all precautionary measures:

- Secure the computer with a strong password (e.g. during Windows startup).
- Choose a complex password of at least twelve characters that includes letters, numbers and special characters. Avoid dictionary words.
- Do not select a name or a device name as a password (such as “Pentacam”).
- Change the default password after the first authentication.
- Change the password regularly.
- Do not write down the password at an accessible location.
- Use unique passwords for different user accounts.
- Do not share user names or passwords with colleagues or anyone else, even if authorized by law and employer policy to view the same type of information (e.g. two users reviewing the same patient samples).
- Enable a screen saver that requires re-entry of the password upon deactivation.
- Set an appropriate screen saver timeout (e.g. 10 minutes) based on operational conditions such as examination duration and patient flow.
- Ensure that the device is locked (keyboard shortcut: Windows logo button + ‘L’) or otherwise secured when not in use to prevent unauthorized access to electronic Protected Health Information (ePHI).
- Operators are required to be trained according to privacy awareness and handling personal data.
- If necessary, contact your Healthcare Organization’s IT Department.

2.3.2 Precautionary Measures if the Computer is Connected to a Local or Internet Network

- Do not establish an internet connection while using the device. This is considered misuse!
- If you connect the computer to the internet for any other purpose, you are responsible for ensuring data security.

If you connect your computer to a local network, you are responsible for ensuring data security and must observe at least the following precautionary measures:

- Preferably connect the computer to the network using a cable connection over wireless connection.
- Use robust security methods incl. advanced Encryption Standards with a strong network key also for wired connections (not only for Wi-Fi connections).
- Use of a firewall (software or hardware) is recommended.
- Observe the instructions for integration into an IT network → Chap. “Precautionary Measures if the Computer is Connected to a Local or Internet Network” (Page 15).



Note

The Healthcare Organization’s IT Department should implement a risk management framework in alignment with IEC 80001-1 to support the secure and safe integration of medical IT networks. This includes assessing risks, enforcing access control, securing networks, applying software updates, monitoring incidents, protecting data, managing device life cycles, and training staff to help safeguard patient safety and data integrity.

The Manufacturer Disclosure Statement for Medical Device Security (MDS2) is available upon request for detailed security information.

2.3.3 Device Security

Ensure that the device is secured against unauthorized access → Chap. 2.3.1 “Precautionary Measures Against Unauthorized Access” (Page 14).

➔ Protect the device and attached systems from malicious software.
➔ Implement new software versions when available.
➔ Implement operators access only on a need-to-know-basis.

The Healthcare Organization’s IT Department is responsible for implementing controls for the handling and disposal of media and assets.

2.3.4 Data Responsibility

Operators should avoid entering unnecessary identifying data. Whenever possible, data should be de-identified and linked to the sample ID instead of the patient. Use only the input data essential for the intended purpose.

Operators have access to sensitive patient data (ePHI).

➔ Do not take any snapshots, screenshots, or images (e.g. using another device) of the information displayed on the device.

Data shall be deleted on a regular basis according to the Healthcare Organization's deletion policy, if respective data are processed by the device.

The Healthcare Organization's IT Department is responsible for deleting unused user accounts.

Only authorized personal is allowed to take backups. The Healthcare Organization's IT Department shall manage the location of each backup in order to respond to potential data subject requests. Backups and archive files are required to be transmitted and stored securely.

2.3.5 Reporting and Handling of Security Incidents

Operators must inform their Healthcare Organization's IT Department about any suspected or confirmed privacy or security breaches, including suspected or compromised user accounts, and report any service outages or access issues.

If accounts are deemed compromised, devices are lost, or unauthorized access has been discovered or assumed, the Healthcare Organization's IT Department locks or changes the user login criteria and issues new login information so that the user can safely access his or her account.

3 Device Description

3.1 Device Components



Fig. 3-1: Device components

No.	Description	No.	Description
1	Ventilation opening	5	On/Off Switch with indicator light
2	Measuring window	6	Y-cable connector
3	Camera opening	7	Cross slide
4	Name plate	8	Joystick

3.2 Applied Parts

The chin and forehead rest are apllied parts of type B.



Fig. 3-2: Applied parts

No.	Description
1	Forehead rest
2	Chin rest

3.3 Functionality of the Device

While rotating around the eye, the device captures Scheimpflug images of the anterior eye segment through varying axes. The Scheimpflug images created during an examination are transmitted to the connected PC.

The axial length of the eye is measured and displayed by partial interferometry.

Scheimpflug images can be captured at two seconds.

Up to 138,000 genuine height values are measured and analysed from the Scheimpflug images.

The Scheimpflug images are the basis for the height data which are used to calculate a mathematical 3D model of the anterior eye segment. At same time any eye movements are recorded and taken into account.

A quality specification (QS) lets you gauge the quality of the measurement taken.

The mathematical 3D model, corrected for eye movements, provides the basis for all subsequent analysis.

The topography of the front and back surfaces of the cornea, the pachymetry and the densitometry are calculated and displayed from limbus to limbus for the entire surface of the cornea.

An analysis of the anterior chamber provides the basis for calculating the chamber angle, chamber volume and chamber depth.

Densitometry of the cornea and lens automatically produces quantified values.

Colour images displayed on the screen show the results of the measurement.

A rotatable 3D model displays the front and back surfaces of the cornea, the iris and the lens.

Wavefront measurement uses a Hartmann Shack aberrometer to detect the low and high order aberrations of the entire eye. The aberrations of the cornea, the crystalline lens and the objective refraction are calculated from this measurement.

Retroillumination can be used to show opacities of the eye. Furthermore post-op check up of IOL inclination and centration can be performed.

3.4 Intended Purpose



Information

The device is intended exclusively for the use specified in this manual and in compliance with the safety instructions.

3.4.1 Intended Use

The Pentacam® AXL Wave is intended to image the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens. It is indicated for the evaluation of

- corneal shape,
- condition of the lens (opaque crystalline lens),
- the anterior chamber angle,
- anterior chamber depth,
- the volume of the anterior chamber,
- anterior or posterior cortical opacity,
- the location of cataracts using cross slit imaging with densitometry,
- corneal thickness,
- axial length,
- white-to-white distance,
- optical aberrations of the eye,
- and retroillumination imaging.

The Pentacam® AXL Wave also performs calculations to assist physicians in determining the power of the intraocular lens for implantation.

3.4.2 Contraindication

none known

3.4.3 Possible Side Effects

none known

3.4.4 Intended Users

The Pentacam® AXL Wave is intended exclusively for use in:

- ophthalmology practices
- clinics
- opticians or optometrists

The Pentacam® AXL Wave is intended for use by trained personnel:

- Who can ensure proper handling based on their knowledge, training and practical experience.
- Who have been instructed by OCULUS personnel or an authorized dealer prior to commissioning.

3.4.5 Patient Group

- Children from 3 years up to not limited.
- No restrictions on weight.
- Patient is awake.
- Patient is able to understand and to look into a fixation target.

4 Setup and Installation

- ➔ Only OCULUS or an authorized dealer is allowed to set up and to connect the device.
- ➔ Do not use or store the device in rooms that are humid.
- ➔ Keep the device away from water that may drip, splash or spray on it, and make sure that no liquids can get into the device. Do not place any containers holding liquids in the vicinity of the device.
- ➔ Germany: Only operate the device in rooms used for medical purposes after they have been set up according to the VDE Regulation 0100-710.
- ➔ Do not operate the devices included in the delivery in areas where explosions may occur, or in proximity to flammable anesthetics or volatile substances such as alcohol, benzine or similar products.
- ➔ Set up the device so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.
- ➔ Do not force any plug connections.
  If you are unable to make a plug connection, check whether the plug fits the socket.
  If you detect damage to the connection, you should let authorized dealer repair the damage.
- ➔ Only use a device which is mounted at the lifting table properly.

4.1 Setup



Note

Incorrect installation may result in incorrect measurements or even damage to the device.

- ➔ Have the device set up and connected by our service department or by a specialist authorized by OCULUS.
- ➔ Set up the device so that it cannot fall over. Mount the device on an examination table.
- ➔ Set up the device so that it is protected from dripping, splashing or spray water.



Note

Damage to the device due to incorrect handling

- ➔ Do not expose the device to any vibrations, shocks, contaminants, moisture, or high temperatures.
- ➔ Handle the device with care.

- ➔ Set up the device so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.
- ➔ Place the device so that direct light cannot affect the measurement.
- ➔ Make sure the examination is free from light reflections. To achieve this, darken the examination room.

4.2 Installation and Ambient Operating Conditions

Temperatute	+10 – +35 °C
Air humidity	30 – 90%
Air pressure	800 – 1060 hPa

- Before installation, compare the transport and storage temperature with the temperature in the intended installation room.
- The difference between the transport and storage temperature and the installation room should not be more than 10°C to prevent the internal optics from misting up.

4.3 Patient Environment Information

Patient environment is the area where patients can come into contact with any part of a medical electrical equipment (ME equipment) or with another person being in contact with the ME equipment.

➔ Only use devices that are compliant with IEC 60601-1 in the patient environment.

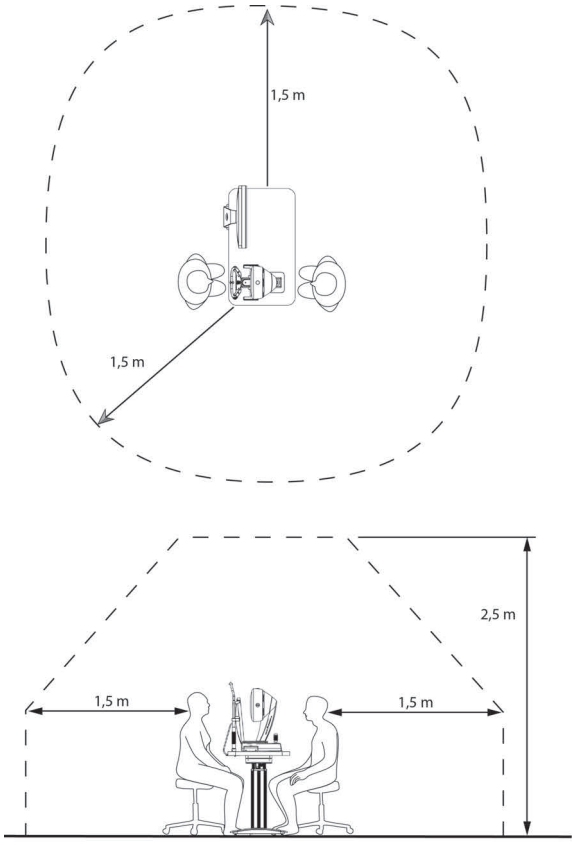


Fig. 4-1: Patient environment

4.4 Electrical Connection

Note

If there are temperature differences between the transport and storage temperature and the installation room, especially if the temperature exceeds 10°C, the optics may fog up and/or condensation may form.

➔ Leave the device unused in the installation room for at least 6 hours before connecting it so that the device can adjust to the ambient temperature.

Caution

Electrical safety hazard

➔ Do not use the device adjacent to or stacked with other equipment.

➔ If you have to use the device adjacent to or stacked with other equipment, verify the correct operation of the device.

➔ Only use the power adapter listed in the list, → Chap. "Electromagnetic Compatibility (EMC)" (Page 86).

➔ If you use a multiple socket to connect the device: Use a multiple socket that complies with the requirements of IEC 60601-1.

➔ Do not place the multiple socket extension cord on the floor.

➔ Do not use more than one multiple socket extension cord.

➔ Plug only the device and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.

➔ Use a socket with a protective earth connection which is fully operating.



Fig. 4-2: Connecting

1. Plug the connector of the Y cable into the jack and tighten the connection. Make sure that the plug is inserted in the correct position.

Note

If the device is not connected correctly and voltage is applied, the device may be damaged after a short time.

- ➔ Do not use excessive force to connect electrical connections.
- ➔ Observe the specifications on the name plate.
- ➔ If the plug is defective, contact OCULUS Service or an authorized dealer to repair the damage.

2. Firmly tighten the connection.
3. Connect the Y-cable to the PC/laptop and the power adapter.

4.5 Switching On

Note

Risk of incorrect measurements due to improper setup

Before taking measurements, the device has to be switched on, at least for one hour.

1. Switch on the PC or laptop.
2. Then turn on the device with the on/off switch (position ON).
   The LED on the switch lights up green.

4.6 Switching Off

1. Close the Pentacam® program and close the Patient Data Management.
2. Shut down the Windows operating system.
3. Turn the device off with the on/off switch (OFF position).

4.7 Software Installation on Separate PCs

The Pentacam® Software is network compatible. This makes it possible to install the Pentacam® Software on several PCs, connected in a local network.

Make sure, that all PC in a network do have the same Pentacam® Software Version installed.

A Floating License Key is part of every device shipment. Please ensure a proper installation based on the Manual for the Floating License Key.

This allows an interactive parallel evaluation of the Pentacam® exams based on the released optional software packages and modules.

The demo examinations included can be viewed on every computer having the Pentacam® Software installed.

For more detailed information contact your authorized dealer or our service department.

5 Pentacam® Software

The device is safe to use if no error message is displayed after starting the software when the device is connected and switched on (e.g. component failure, camera not recognized, missing reference data etc.).

After starting, the Patient Data Management opens → Chap. 7 (Page 62).

Information

The Pentacam® Program is not to be used to dictate therapy without professional correlation with other clinical findings and diagnostic tests.

Information

As this instructions for use focuses on the device operating concept, the description of Pentacam® Software functions is limited to starting the measuring process and loading previous examinations. The user guide contains detailed information on the functions of the Pentacam® Software.

5.1 Start Screen: Blank General Overview Display

To open the Pentacam® Software

1. choose a patient from the patient list
2. and click on the [Pentacam] button in the Patient Data Management.

The Software starts with the blank General Overview display:

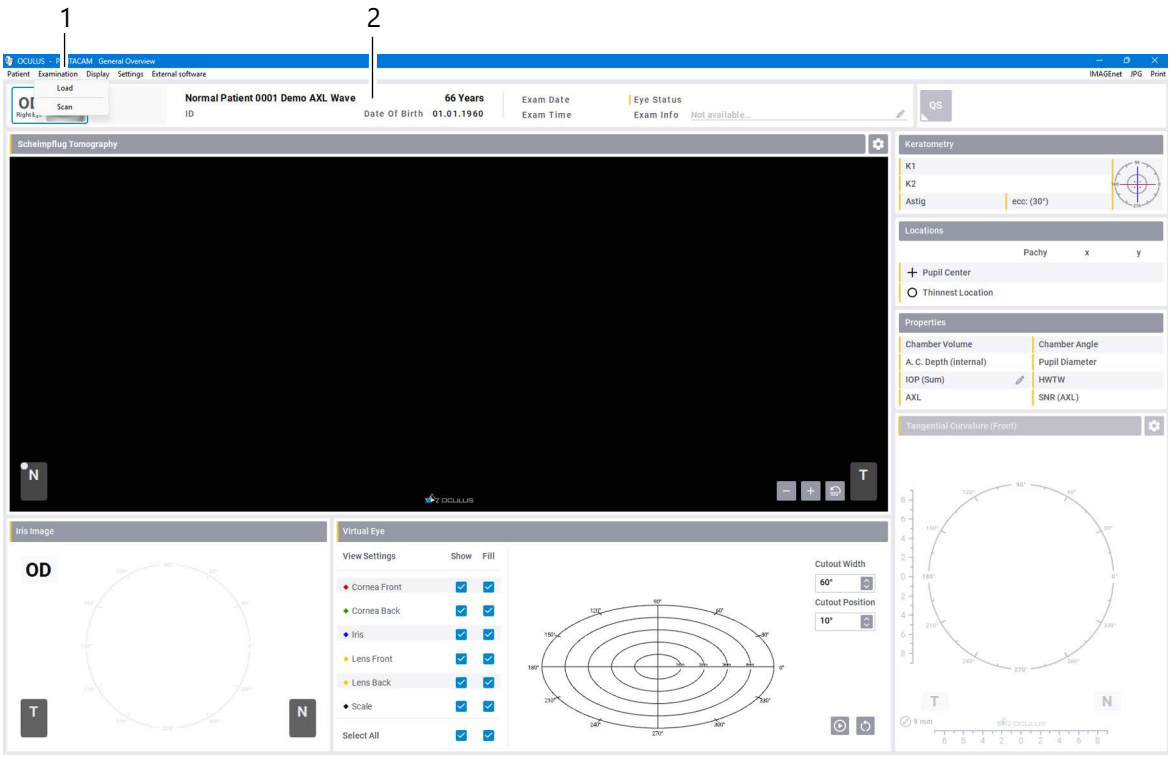


Fig. 5-1: Blank General Overview display

No.	Description	No.	Description
1	Examination menu	2	Patient data

5.2 Scan Screen

After starting the full sequence program this display appears:

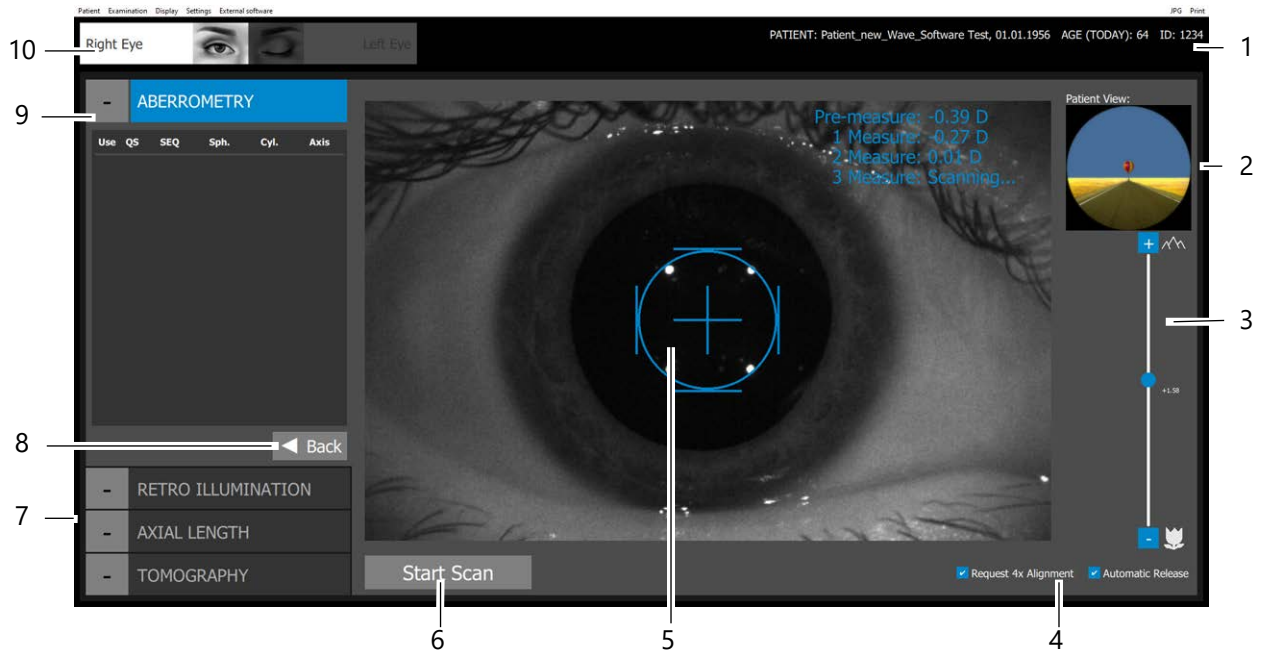


Fig. 5-2: Scan screen (example "Wavefront")

No.	Description	Explanation
1	Patient data	
2	Patient view	The patient view shows the respective image or fixation target, where the patient has to look where the patient has to look at during the measurement.
3	Slider for fixation target	The slider of the fixation target adjusts itself automatically based on the objective refraction to the respective distance.
4	Checkboxes for respective measurement	It depends on the measurement mode which checkboxes are displayed.
5	Overview image with adjusting aid	The overview image with a cross hair as an adjusting aid supports the examiner to align the device correctly to the patients eye. After the alignment is finished the device releases the measurement automatically.
6	[Start Scan] button	In cases where no automatic measurement release is possible for example unstable fixation, click the [Start Scan] button to activate the manual measurement. You can also use the Return key.
7	Overview examination modes	You can change the mode of the examination. → Chap. "Information on Examination Modes" (Page 28) Click the [Back] button to go to the prior examination mode.
8	[Back] button	
9	Current examination mode	The current examination mode shows the information whether the data can be used to analyze the data, the QS value and measurement specific results such as axial length.
10	Display of currently examined eye (R\L)	The eye currently being examined is detected automatically and displayed.

5.2.1 Information on the Single Measurements

Each measurement is listed and rated.



Fig. 5-3: Example Aberrometry: Objectiv erefraction parameter

No.	Description	Explanation
1	"Use" column	Choose one measurement for the full sequence examination. If you don't select a measurement, no results will be displayed.
2	"QS" column	If the QS value is marked with a green check mark, it can be used for the evaluation in the full sequence analysis. The full sequence analysis is a comprehensive summary display which includes the data from all four measurements/pictures which where done in one full sequence routine. If the QS value is yellow, you may want to repeat the measurement. If the QS value is red, you have to repeat the measurement.
3	Values, depending on current mode	

5.2.2 Information on Examination Modes

Information

The User Guide contains detailed information on the settings and default settings of the device.

Aberrometry Mode

Wavefront aberrometry of the entire eye enables an objective assessment of the total refractive error of an eye before and after cataract and refractive surgery.

Retroillumination Mode

Implemented retroillumination enables a check of the inclination and centration of IOLs, especially toric IOLs.

Axial Length Mode

Contact-free optical biometry from the corneal surface to the retina is performed for IOL power calculation:

Type of examination	Examination mode	Images	Automatic measurement	Notes
Axial length	AXL	6	Yes	Take care of the correct eye status.

Tomography Mode

Based on 25 or 50 captured Scheimpflug images and resulting 3D model, the anterior eye segment can be measured, displayed and analyzed for different applications.

Type of examination	Examination mode	Images	Automatic measurement	Notes
Topography	3D scan	25 – 50	Yes	
Pachymetry	3D scan	25 – 50	Yes	
Anterior chamber analysis	3D scan	25 – 50	Yes	Do not apply mydriatic drops.
Densitometry	3D scan	25 – 50	Yes	Use the same number of images to enable a progress check, apply mydriatic drops.

5.3 Loading Previous Examinations

1. Select the menu item [Examination] and click [Load].
   The dialog box “Load Examination” appears.
2. Make a selection by clicking the required examination.
3. Confirm your selection by clicking [OK], or by double clicking.
   The Pentacam® Program will load the examination you have selected.

5.4 Direct Help



The Pentacam® Sofware provides helpful assistance. This can be found by clicking on the yellow mark.



This symbol is displayed for some measurements.

➔ Click on this symbol to display the corresponding message.

You must check the corresponding measured value.

6 Measuring Procedure

This section describes the procedure how to

- prepare a measurement
- measure the wavefront aberration
- use the retroillumination mode
- measure the axial length
- perform a tomography scan of the anterior segment of the eye
- perform a single scan of each examination mode



Caution

Hazardous optical radiation can cause eye damage (retina)

The device emits high-intensity light that may exceed permissible exposure limits during prolonged exposure.

Exposure at maximum intensity for more than 41 minutes may exceed the limit of 2.2 J/cm^2 and cause damage to the retina.

Exposure exceeding the recommended maximum exposure (RME) of 10 J/cm^2 (equivalent to more than 189 minutes) can pose a significant risk of eye damage.

There is an increased risk for particularly sensitive individuals.

➔ Keep exposure time as short as possible.
➔ Use the device only within the operating parameters.
➔ Follow the instructions regarding the measuring procedure.



Note

Risk of incorrect measurement due to incorrect use

➔ Before first use: Let OCULUS or an authorized dealer train you in the operation of the device.



Note

Risk of incorrect measurements due to improper setup

➔ Before taking measurements, the device has to be switched on, at least for one hour.



Note

Due to small movements of the patient or caused by a wheelchair, the patient is no longer positioned appropriately to the device, which can lead to incorrect measurements.

➔ Perform a scan only if the patient sits in a stationary chair.
➔ In cases of wheel chairs lock the brakes.

Group 2 instrument according to ISO 15004-2

A graph showing the relative spectral output of the instrument between 305 nm and 1100 nm when the instrument is operating at maximum light intensity and maximum aperture will be provided by OCULUS on request. The spectral output will be shown for the beam after it exits the instrument.

Information

OCULUS Optikgeräte GmbH is not liable for the evaluation and interpretation of measurements taken with the Pentacam® AXL Wave. The user manual and interpretation guide can provide assistance in this regard.

An full examination sequence with the device combines the following modi:

- total wavefront aberrometry
- retroillumination
- axial length
- Scheimpflug tomography

The program automatically guides you through the examination routine.

6.1 Preparations

Before taking a measurement, make sure that:

- The device is in technically perfect condition.
- The device is operated with the original accessories supplied by OCULUS.
- The ventilation openings are not covered.
- The device is stable and cannot tip over.
- You have read and understood the instructions for use.

1. Start the examination in the Pentacam® Program:
   Menu [Examination] > [New Full Sequence]
   The blue slit light is activated and the Scan menu opens.
2. Make sure that the desired measurement mode is activated.
3. Adjust the table height.
4. Check that
   - ➔ fresh paper has been put onto the chin rest or the chin rest has been cleaned and disinfected → Chap. 8 (Page 70).
   - ➔ the forehead rest has been cleaned and disinfected → Chap. 8 (Page 70).
   - ➔ the lens in front of the camera and the acrylic glass are clean.
5. Ask the patient to place his or her head on the chin and forehead rest.
   - ➔ Do not touch the patient and the device simultaneously.

6.2 Darken the Room

6. Dim the lights in the room.
   If the lighting in the examination room cannot not be dimmed or switched off, use the dark sheet supplied to cover the patient and the device.



Fig. 6-1: Patient and device with cover sheet

6.3 Rough Adjustment

7. Advice the patient to look at the respective fixation target/picture.
8. Adjust the chin rest so that the patient's eyes are approximately at the level of the black ring on the chin-forehead rest.

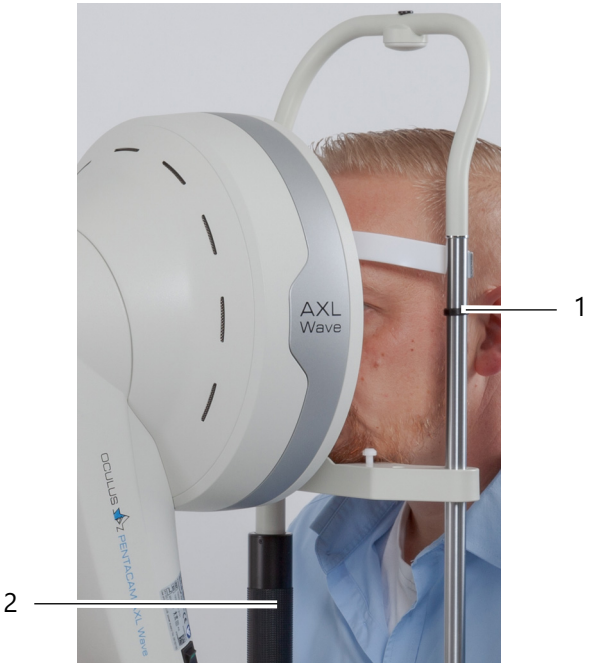


Fig. 6-2: Rough adjustment of the chin and forehead rest

No.	Description
1	Black ring for eye level orientation
2	Twist grip for adjusting the height of the chin rest

9. Adjust the patient's eye level using the twist grip.
The patient is positioned correctly when chin and forehead touch the rests and the eyes are levelled with the marking.

Information

If you adjust the chin rest for a small head (for example: a child's head), the test eye will stop the chin rest. Swing the test eye to the side and then adjust the chin rest.

10. Move the cross slide (example for the right eye) until the marking at the end of the cross slide roughly coincides with the circle R on the sliding plate.

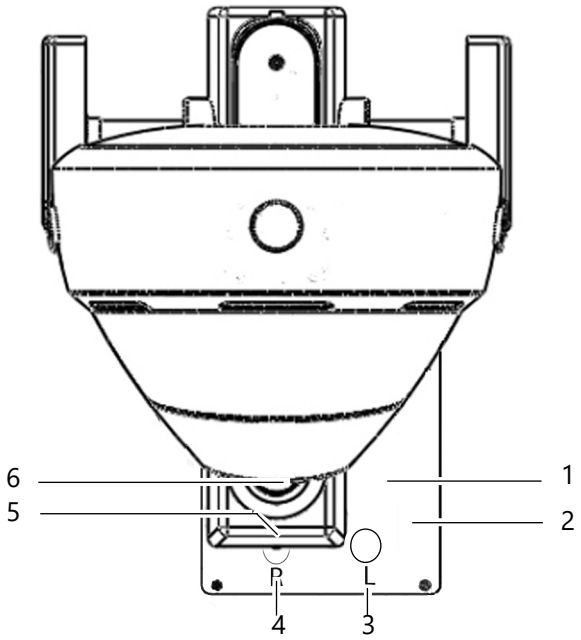


Fig. 6-3: Markings on the cross slide

No.	Description	No.	Description
1	Cross slide	4	Right marking
2	Sliding plate	5	Marking on the cross slide
3	Left marking	6	Joystick

11. Look at the patient's eye you are examining from one side and make sure that the blue slit light illuminates the cornea.
12. If necessary, adjust the position of the cross slide to the left or right.

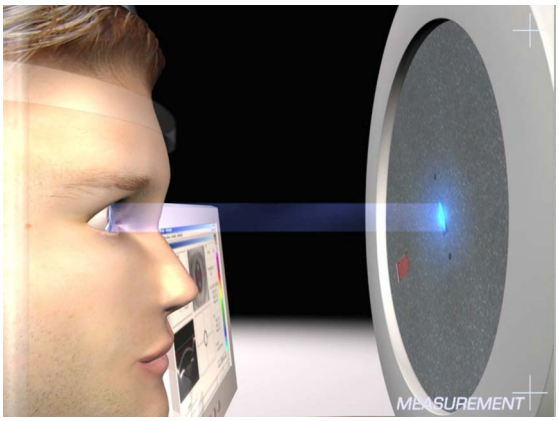


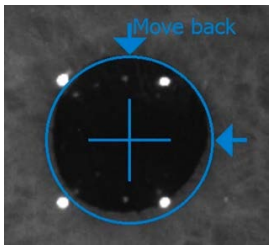
Fig. 6-4: Slit light on the cornea

Information

If the blue slit light is not visible, ensure that you have activated the [Slit Light] checkbox on the "Scan" screen.

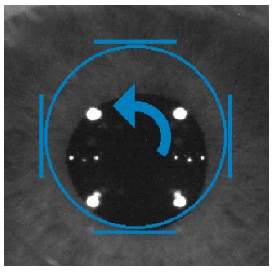
6.4 Fine Adjustment

➔ Make any fine adjustments required based on the information in the adjustment window.



Example (with blue arrows): distance and position to patient's eye is not correct.

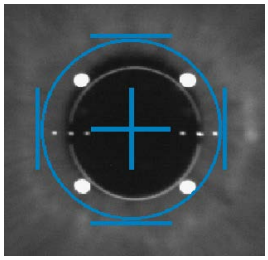
➔ Move the joystick backwards and to the left.



Example (with blue arrows): Move or rotate the joystick in the specified direction.

➔ Turn the joystick counter clockwise.

Arrow	Camera movement	Joystick movement
	Right	Move the joystick to the right
	Left	Move the joystick to the left
	Forwards	Move the joystick toward the patient
	Backwars	Move the joystick away from the patient
	Up	Rotate the joystick clockwise
	Down	Rotate the joystick counter-clockwise



When you have achieved the expected position, a blue cross will appear in the centre of the ring, surrounded by four blue lines.
The device will automatically start with the measurement.

➔ For measuring manually: Start measuring by clicking [Start Scan] or by pressing the return key.

6.5 Measure the Wavefront Aberration of the Total Eye

➔ Prepare the measurement and adjust the patient → Chap. 6.2 (Page 32).

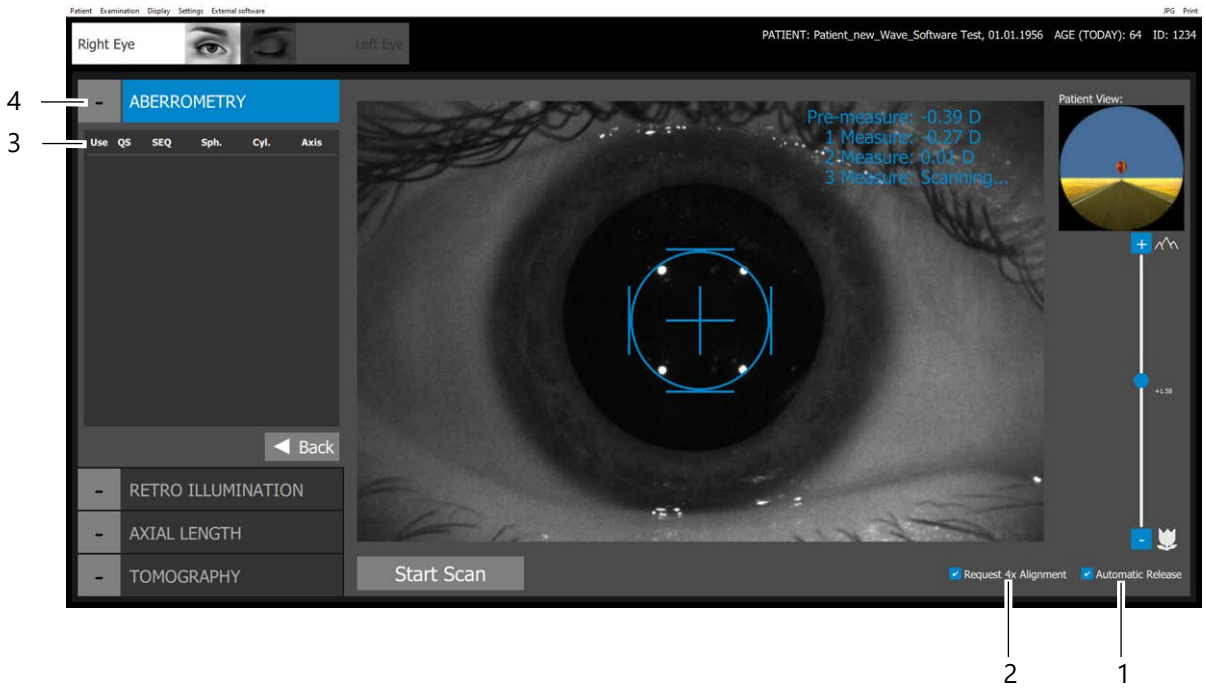
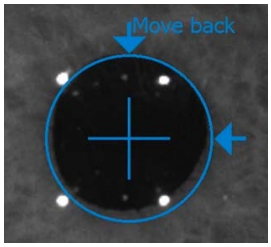


Fig. 6-5: Scan screen “Aberrometry”

No.	Description	No.	Description
1	[Automatic Release] checkbox	3	Objective refraction parameter
2	[Request 4x alignment] check-box	4	Current examination mode

1. Ask the patient to blink normally, take a short break and proceed with the aberrometry scan.
2. Make sure that the [Automatic Release] checkbox is selected, to activate the automatic measurement release. The option should be activated per default.
3. Make sure that the button “Request 4x Alignment” is activated.
   If “Request 4x Alignment” is activated, the aberrometry measurements starts only if the patient is fixating correctly. The measurement starts automatically. “Request 4x Alignment” deactivated means: The measurements are performed without any interruptions.
   “Request 4x Alignment” is activated by default. Only deactivate “Request 4x Alignment” if the patient cannot fixate properly.



4. Move the image with the cross towards the patient until the four infrared LEDs are clearly seen.

You can use the adjusting aid of the fine adjustment alternatively → Chap. “Fine Adjustment” (Page 34).

5. Shortly before you have reached the final position ask the patient to widen his or her eye and not to blink.
   The tentative final position of the camera is reached when the four bars frame the blue circle.
   The device triggers the measurement of the aberrometry and the retroillumionation automatically.
6. Follow the instructions on the screen and then continue with the measurement of the axis length.

Objective refraction parameter



Fig. 6-6: Objective refraction parameter

Use	Activate this checkbox to use the data for the full sequence analysis. Use only one exam of each exam mode for the full sequence examination → Chap. "Information on the Single Measurements" (Page 28)
QS	Quality Specification value → Chap. "Quality Specifications and Parameter for Wavefront Aberrometry" (Page 38)
SEQ	Spherical equivalent based on the wavefront aberrometry
Sph.	Spherical power based on the wavefront aberrometry
Cyl.	Cylindrical power based on the wavefront aberrometry
Axis	Position of the axis based on the wavefront aberrometry

6.5.1 Quality Specifications and Parameter for Wavefront Aberrometry

After you have begun measuring either automatically or manually, the Pentacam® Program opens. The "QS" value appears in a separate field.

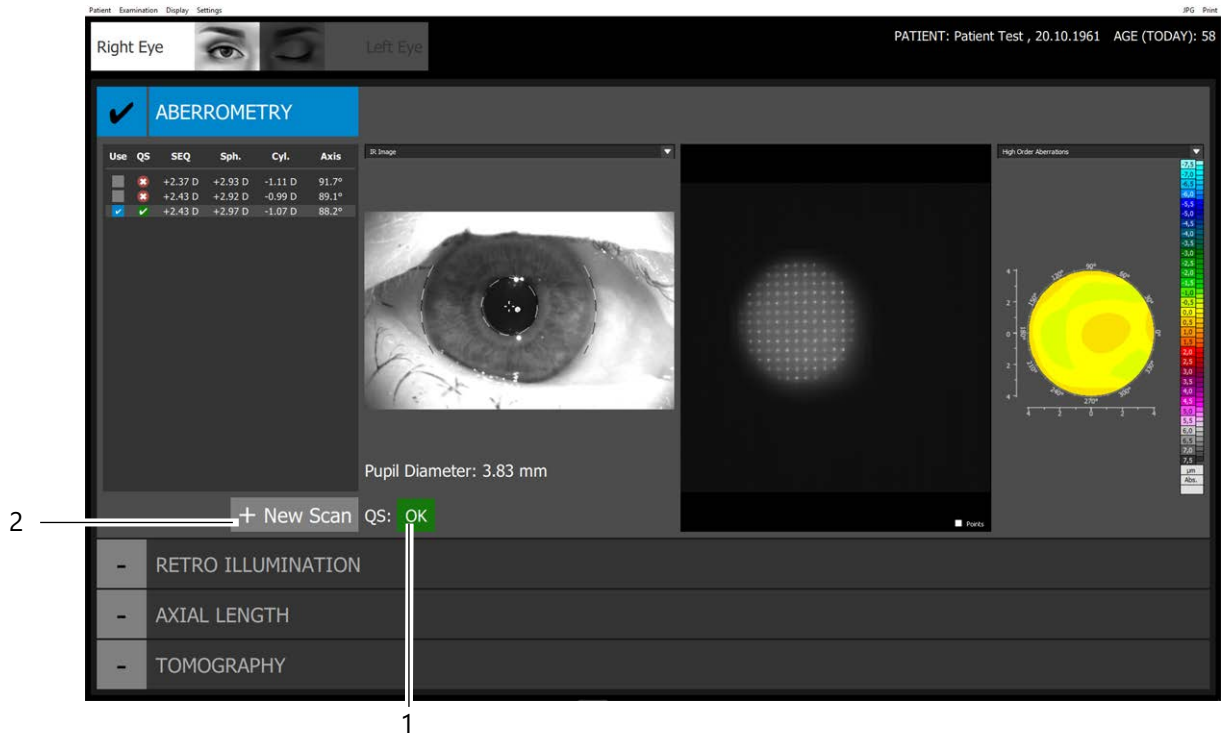


Fig. 6-7: Aberrometry result display

No.	Description	No.	Description
1	If the QS field is ■ green and reads OK, the measurement is correct and can be used for the evaluation of the examination. ■ yellow, you may want to repeat the measurement. ■ red, you have to repeat the measurement.	2	[+New Scan] button

Note

All examinations are automatically saved, regardless of the quality of the measurement taken.

➔ If you click on the “QS” button, the following dialog box appears:

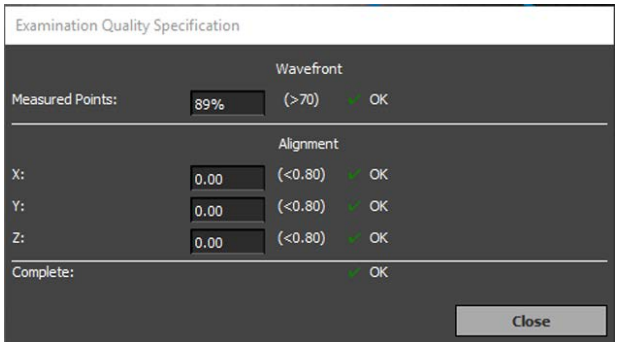


Fig. 6-8: Examination Quality Specification

➔ Check the measurement results.
➔ If you have any doubts, repeat the measurement.

Parameters	Description
Measured Points	If analyzed data is less than the permissible threshold
Alignment X, Y and Z	If one of these values exceeds the permissible threshold, you may have moved the cross slide at the moment you began measuring
Complete	The worst value of the of the QS parameters is displayed.

Terminating “QS”

➔ Click [Close] to return to the Pentacam® Software.
➔ Terminate the current examination which has been saved.
➔ If required, click the [+New Scan] button for a new measurement. Otherwise click on the next exam mode [RETRO ILLUMINATION].

6.6 Capturing Procedure for the Retro Illumination

Immediately after measuring the wavefront aberration, a single retroillumination exposure is automatically carried out. Use this measurement mode for further retroillumination exposures.

Information

You have to carry out an image capture with manual release.

➔ Prepare the measurement and adjust the patient → Chap. 6.2 (Page 32).

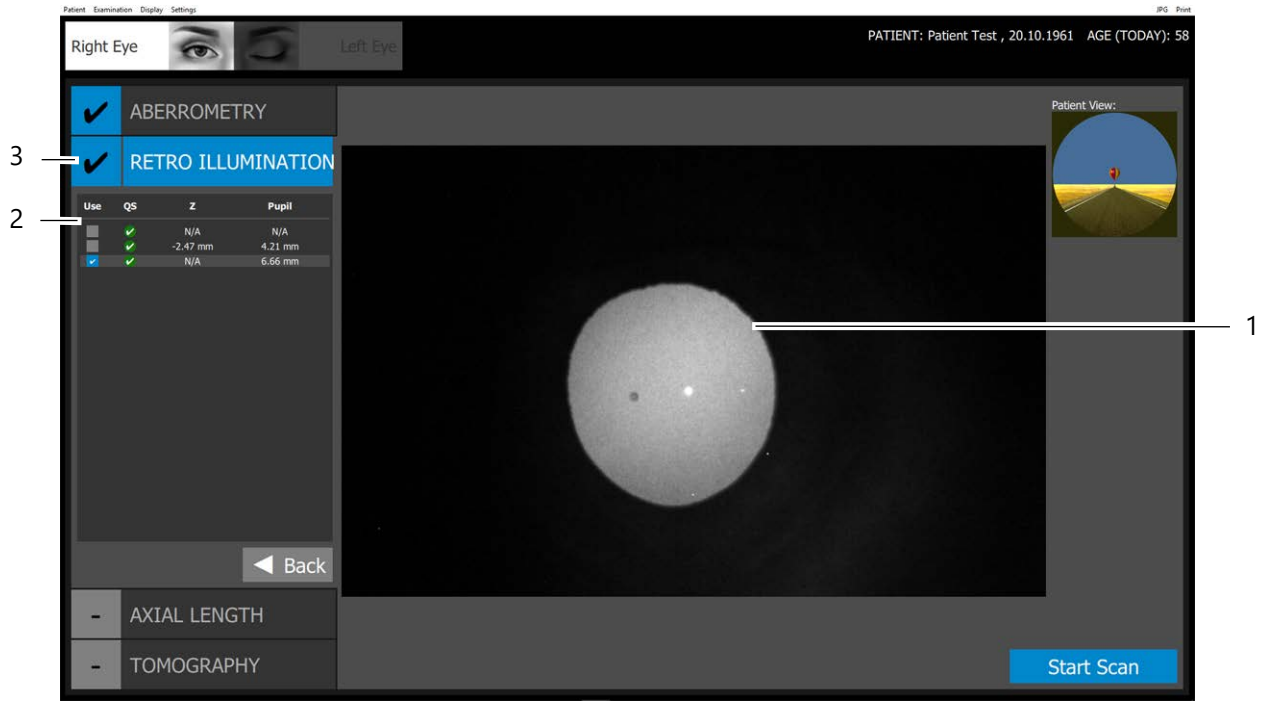


Fig. 6-9: Scan screen “Retroillumination”

No.	Description	No.	Description
1	Pupil image during retroillumination	2	Retroillumination parameter
		3	Current examination mode

1. Click on the [RETRO ILLUMINATION] button.
2. Focus the pupil image by moving the joystick → Chap. “Fine Adjustment” (Page 34).
   The tentative final position of the camera is reached when you find your point of interest.
3. Shortly before you have reached the final position ask the patient to widen his or her eye and not to blink.
4. Click on [Start Scan] button to capture the image of interest – for example opacities of the crystalline lens.

Retroillumination parameters

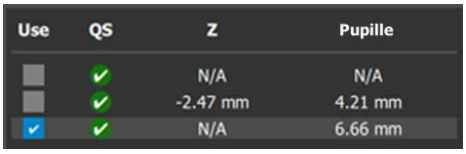


Fig. 6-10: Objective Retroillumination parameter

- **Use**: Activate this checkbox to use the data for the full sequence analysis. Use only one exam of each exam mode for the full sequence examination.
- **Z:** Distance of the device to the focus level
- **Pupil**: Diameter of the pupil

6.7 Measure the Axial Length

➔ Make sure that the [Automatic release] checkbox is activated.

➔ Ensure that the "Request 6x Alignment" button is activated.
If "Request 6x Alignment" is activated, the measurement of the axial length only starts when the patient is correctly immobilised. The measurement starts automatically. If "Request 6x Alignment" is deactivated, this means that the axial length measurements are performed without interruption.
"Request 6x Alignment" is activated by default. Only deactivate "Request 6x Alignment" if the patient cannot fixate correctly.

Note

It is mandatory to select the correct eye status before every axial length measurement. Different eye status lead to different results for the axial length measurement, hence influence the IOL power calculation. The eye status has to be selected by the user before every AXL-Scan.

➔ To select the eye status click on button “Eye status” in the axial length scan mode of the full sequence measurement mode.

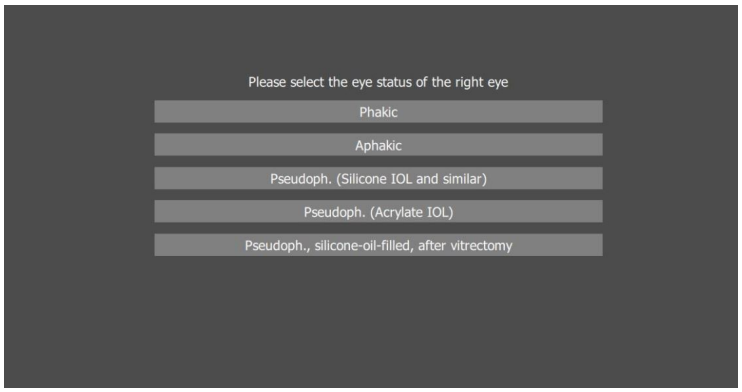


Fig. 6-11: Eye status selection

- **Phakic**: Default status. Presence of crystalline lens.
- **Aphakic**: Absence of the crystalline lens.
  Correction of measured axial length by +0.200 mm
- **Pseudophakic (Silicone IOL or similar)**: IOL of silicone or similar material implanted.
  Correction of axial length by +0.120 mm.
- **Pseudophakic (Acrylate)**: Acrylat/Metaacrylate IOL implanted.
  Correction of axial length by +0.110 mm.
- **Pseudophakic, silicon-oil filled, after vitrectomy**: previous vitrectomy with a silicon-oil-filled vitreous.
  Correction of axial length by -0,692 mm.

Note

Risk of incorrect measurement caused by unchecked plausibility

➔ Check both eyes on plausibility.

Recommended differences between both eyes

Axial length AXL:	< 0,3 mm
Curvature:	< 0,18 mm. This equals approximately in 1 dpt (based on a refractive index of 1,3375)

Difference of IOL power to reach emmetropia by same target refraction:

< 1 dpt

The following conditions may influence the readings of the measurement respectively make it impossible:

- Mature cataracts,
- opaque corneas in the optical center,
- severe fixation problems.

In **pseudophakic eyes the anterior chamber depth is not calculated correctly** but it is possible to measure the anterior chamber depth in the Scheimpflug image manually.

➔ Prepare the measurement and adjust the patient → Chap. 6.2 (Page 32).

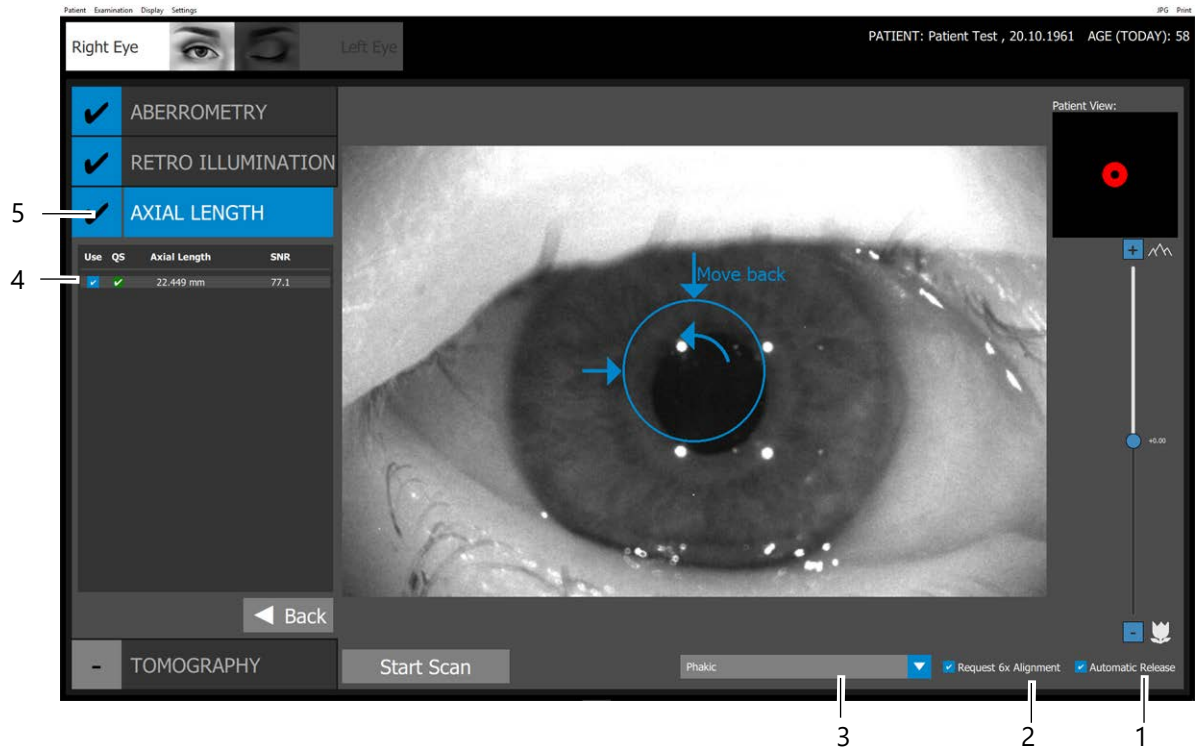
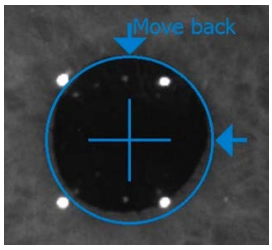


Fig. 6-12: Scan screen “Axial length”

No.	Description	No.	Description
1	[Automatic Release] checkbox	4	Axial Length parameter
2	[Request 6x alignment] checkbox	5	Current examination mode
3	Dropdown list for eye status		



➔ Move the image with the cross towards the patient until the four infrared LED are clear.

➔ Focus the pupil image by moving the joystick → Chap. “Fine Adjustment” (Page 34).

➔ Shortly before you have reached the final position ask the patient to widen his or her eye and not to blink.
The tentative final position of the camera is reached when the four bars frame the blue circle.
The device triggers the measurement automatically.

➔ Follow the instructions on the screen

➔ Ask the patient to blink normally, take a short break and then continue with the examination of the anterior segment of the eye (tomography scan).

During the measurement of both eyes the following messages may occur:

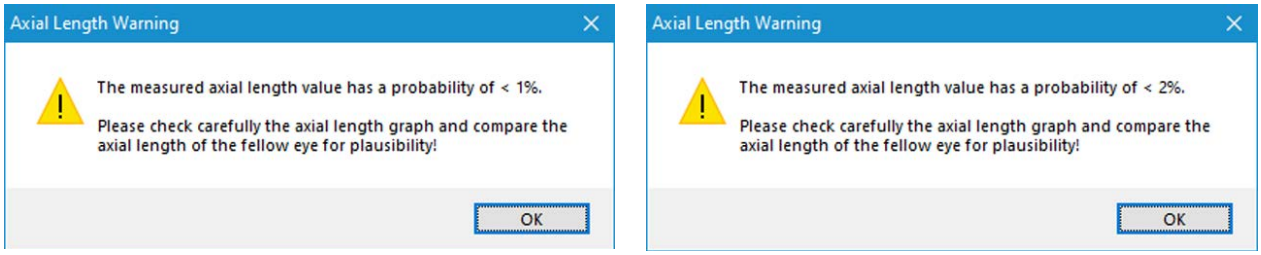


Fig. 6-13: Message: Plausibility check

Note

The axial length values do not correspond to the values of the normal population.

➔ Check the axial length values of both eyes.

The plausibility is marked by a yellow flagged QS value. This will be stored in the Pentacam® Program accordingly.



This symbol, related to the messages appears for example in the IOL calculator.

➔ Click on this symbol to show the corresponding message.

You must check the corresponding measured value.

If the measured axial length value has a probability of < 1 %, the following message may occur.

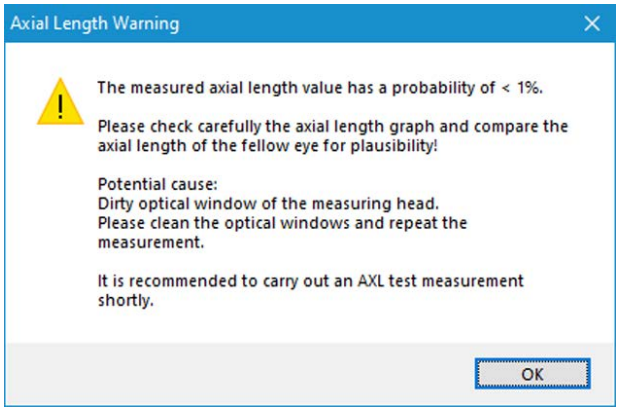


Fig. 6-14: Message: dirty optical window

Note

Faulty measurements due to dirty window

➔ Clean the optical window.

➔ Carry out a test measurement.

If you do not carry out the test measurement, then this message will be stored in the Pentacam® Program accordingly marked by a red flagged QS value, for example in the IOL calculator.

➔ Repeat the measurement.

You must check the corresponding measured value.

Axial length parameters

- **Use:** Activate this checkbox to use the data for the full sequence analysis. Use only one measurement of each exam mode for the full sequence examination.
- **QS:** Quality Specification value → Chap. 6.5.1 (Page 38)
- **Axial Length:** Measured axial length
- **SNR:** Signal to noise ratio

6.7.1 Quality Specifications for Biometry

After you have measured one examination either automatically or manually, the Pentacam® Program opens. The "QS" value appears in field.



Fig. 6-15: "QS" display

No.	Description	No.	Description
1	Single scans with SNR values	3	If the QS field is ■ green and reads OK, the measurement is correct and can be reproduced. SNR >=6.3. ■ yellow, you may want to repeat the measurement. SNR >=5.0 ■ red, you have to repeat the measurement. SNR < 5.0 The QS field is also displayed in red if only one of six measurements is valid, as this is not sufficient for a final result.
2	Signal to noise ratio of the axial length measurement	4	[+New Scan] button

Note

All examinations are automatically saved, regardless of the quality of the measurement taken.

➔ Check the axial length measurements in the display AXL Scan carefully for possible double-peaks and a valid SNR.

Information

If the "QS" display is highlighted in yellow or red, check the QS values.

➔ Click the "QS" button.
The following dialog box appears:

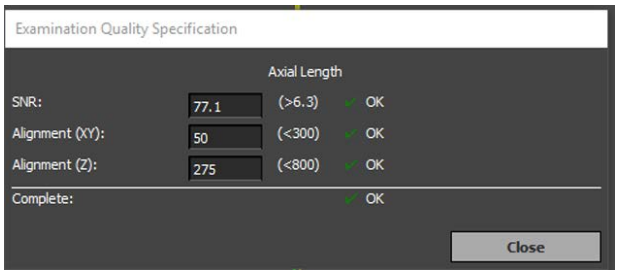


Fig. 6-16: Examination Quality Specification

SNR:	Signal to noise ratio of the axial length measurement
Axial length:	The final result of the axial length is calculated only of all feasible SNR peaks. The signal to noise ratio graph of the best scan is displayed.
Alignment (XY): Alignment (Z):	If one of these values exceeds the permissible threshold, you may have moved the cross slide at the moment you began measuring.
Complete:	The worst value of the QS parameters is displayed

➔ Check the measurement results.
➔ If you have any doubts, repeat the measurement.

Terminating "QS"

➔ Click [Close] to return to the Pentacam® Program.
➔ Terminate the current examination which has been saved.
➔ If required, click the [+New Scan] button for a new measurement. Otherwise click on the next measurement mode [Tomography].

6.8 Measuring Procedure for Tomography

➔ Prepare the measurement and adjust the patient → Chap. 6.2 (Page 32).

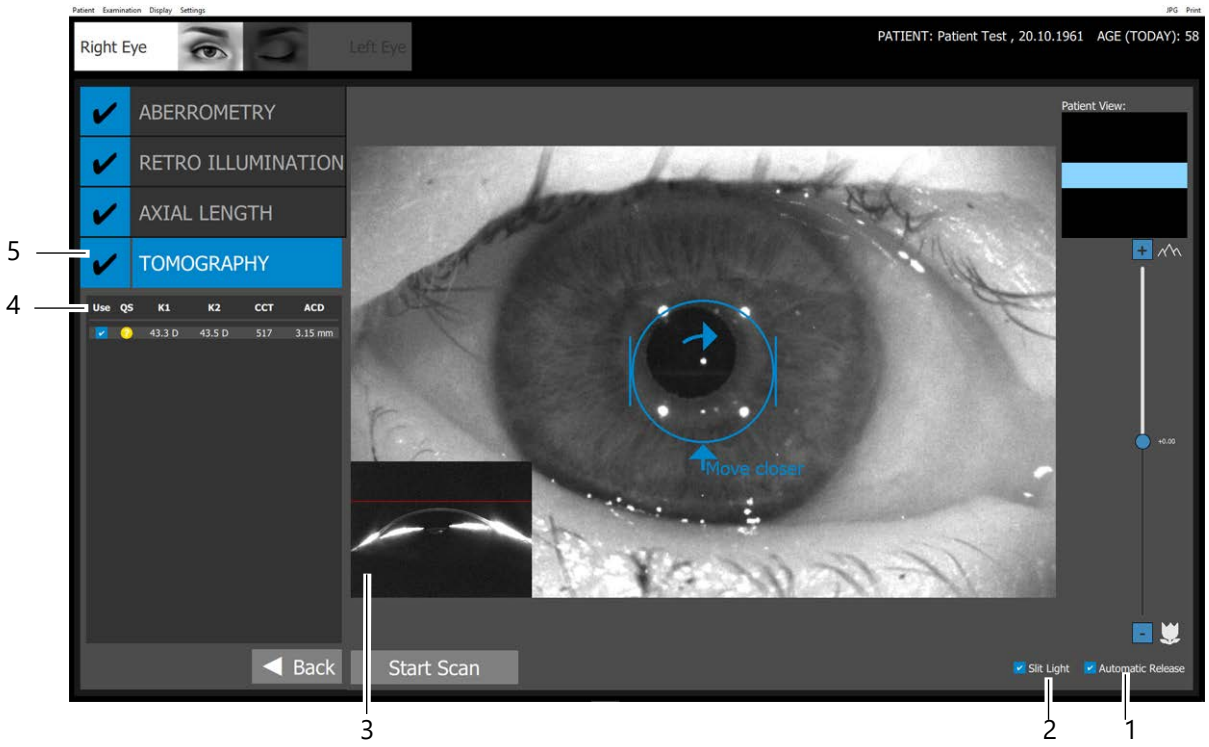


Fig. 6-17: Scan screen "Tomography"

No.	Description	No.	Description
1	[Automatic Release] checkbox	4	Tomography parameter
2	[Slit light] checkbox	5	Current examination mode
3	Live Scheimpflug image		

➔ Move the cross slide towards the patient until the live Scheimpflug image shows the cornea of the eye that you are examining.

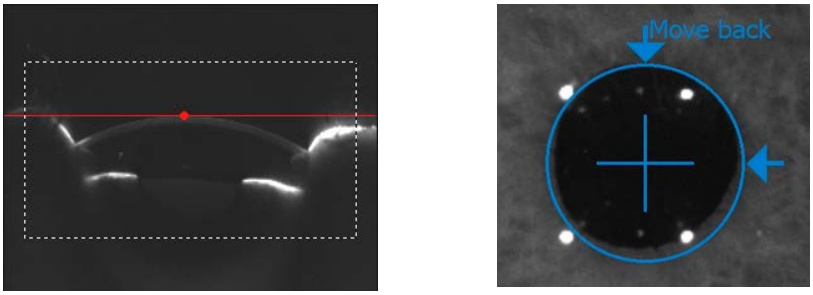


Fig. 6-18: Scheimpflug image (left) and overview image (right)

The image is sharpest when the red dot coincides with the red line in the Scheimpflug image.

➔ Focus the pupil image by moving the joystick towards the device or away from it.
➔ Ask the patient to widen his or her eye and not to blink.
➔ Adjust the left/right position of the device and its height setting.
Move the joystick to the left or right and rotate the joystick clockwise or anticlockwise.
The tentative final position of the camera is reached when the four bars frame the blue circle.
The device triggers the measurement automatically.
➔ Ask the patient to remove his or her head from the rest.
➔ Check the measurement results by referring to the quality specifications → Chap. 6.8 (Page 47).

Tomography parameters

- **Use:** Examination can be used for the evaluation.
Click the checkbox of the respective measurement to use it for the evaluation.
Use only one measurement for the full sequence examination.
- **QS:** Quality Specification value → Chap. 6.5.1 (Page 38)
- **K1:** Flat radius of the corneal curvature
- **K2:** Steep radius of the corneal curvature
- **CCT:** Central corneal thickness
- **ACD:** Anterior chamber depth

6.8.1 Quality Specifications for the Tomography

After measuring either automatically or manually, the Pentacam® Program opens. The "QS" value appears in a field.

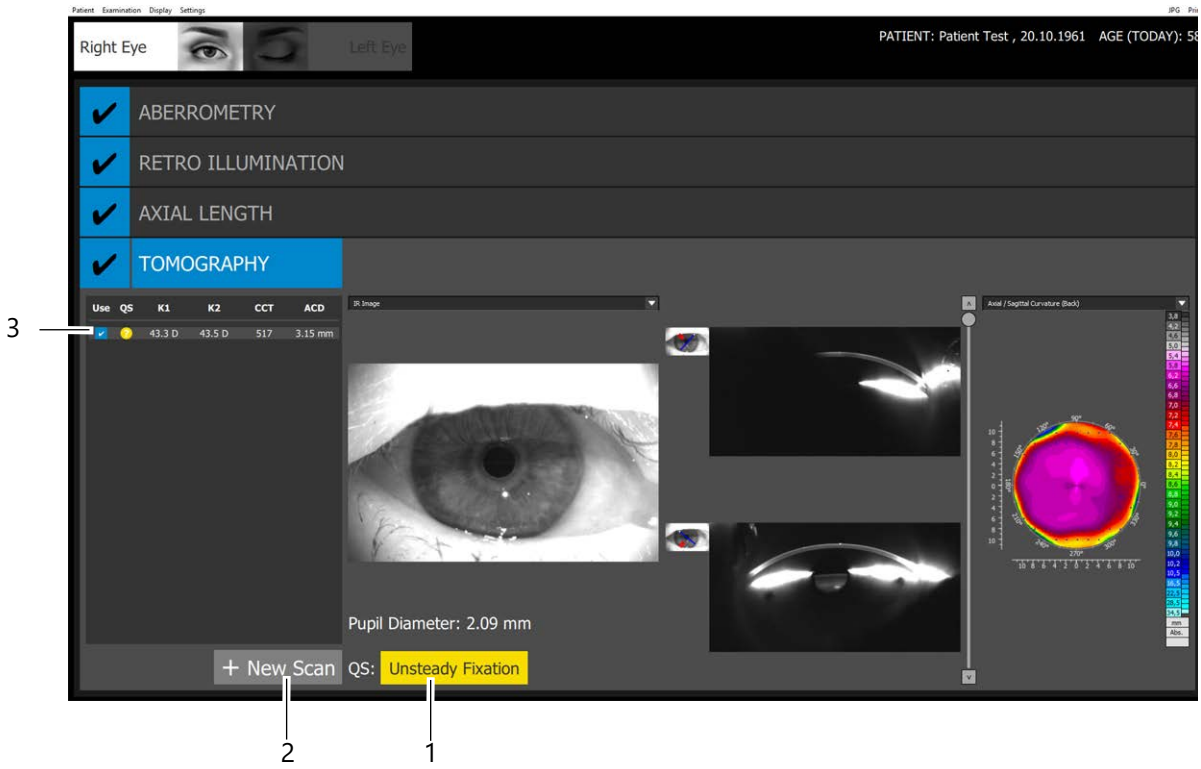


Fig. 6-19: "QS" display

No.	Description
1	If the QS field ■ is green and reads OK, the measurement is correct and can be reproduced ■ is yellow, you may want to repeat the measurement ■ is red, you must repeat the measurement
2	[+New Scan] button
3	[Use] checkbox

Note

All examinations are automatically saved, regardless of the quality of the measurement taken.

➔ Click the "QS" button.
The following dialog box appears:

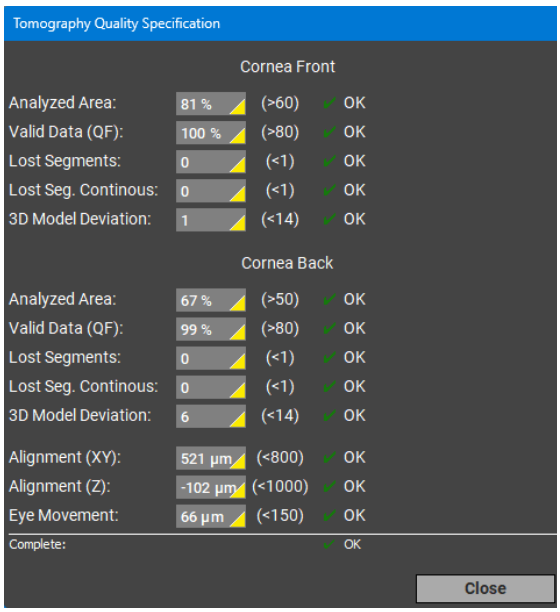


Fig. 6-20: Examination Quality Specification

➔ Check the measurement results.
➔ If you have any doubts, repeat the measurement.

QS Parameter	If an error occurs here, ...
Analysed Area	... the measured area of the cornea is too small. ➔ The patient must open their eye wider. If necessary, assist the patient by holding their upper eyelid.
Valid Data	... no continuous data points could be determined in the Scheimpflug images, which can sometimes be the case with irregular or very cloudy corneas. In such cases, even repeated measurements will yield values highlighted in yellow at most. Or an ambient light source interfered with the recording. ➔ Completely darken the room.
Lost Segments Lost Seg. Continuous	... the patient blinked or the shadow cast by the nose is too large. ➔ Before the measurement process begins, the patient should blink again and then, without blinking, focus on the red LED or black ring on the device during the measurement process. ➔ If the error was caused by the nose covering the camera line, you must slightly turn the patient's head so that the nose is positioned away from the camera.
3D Model Deviation	... there is a deviation of measured cornea from calculated 3D model
Alignment (XY) and Alignment (Z)	... the device/cross slide was moved during the measurement trigger. ➔ Repeat the measurement.
Eye Movement	... the patient has not focused correctly on the target. ➔ Before the measurement process begins, the patient should blink once more and then, without blinking, focus on the red LED or black ring on the device during the measurement process.

Terminating "QS"

➔ If required, delete the measurement if the image is inadequate.
➔ If required, click the [+New Scan] button for a new measurement.
➔ Click [Close] to return to the Pentacam® Program.

6.9 CSP Pro Measurement

In a CSP Pro measurement, not only the cornea, but also parts of the sclera are measured. This means larger diameter contact lenses such as scleral lenses can be fitted.

Before the measurement

By default, a tomography measurement is carried out after the axial length measurement → Chap. 6.8 (Page 47).

➔ Move the CSP Pro slider to the right position to activate the CSP Pro measurement.
The "Tomography" entry is hidden and the "CSP Pro" entry is displayed instead.
➔ Make sure that the checkbox [Slit Light] is activated.
➔ Make sure that the [Automatic Release] checkbox is selected.
➔ Prepare the measurement and adjust the patient → Chap. 6.2 (Page 32).

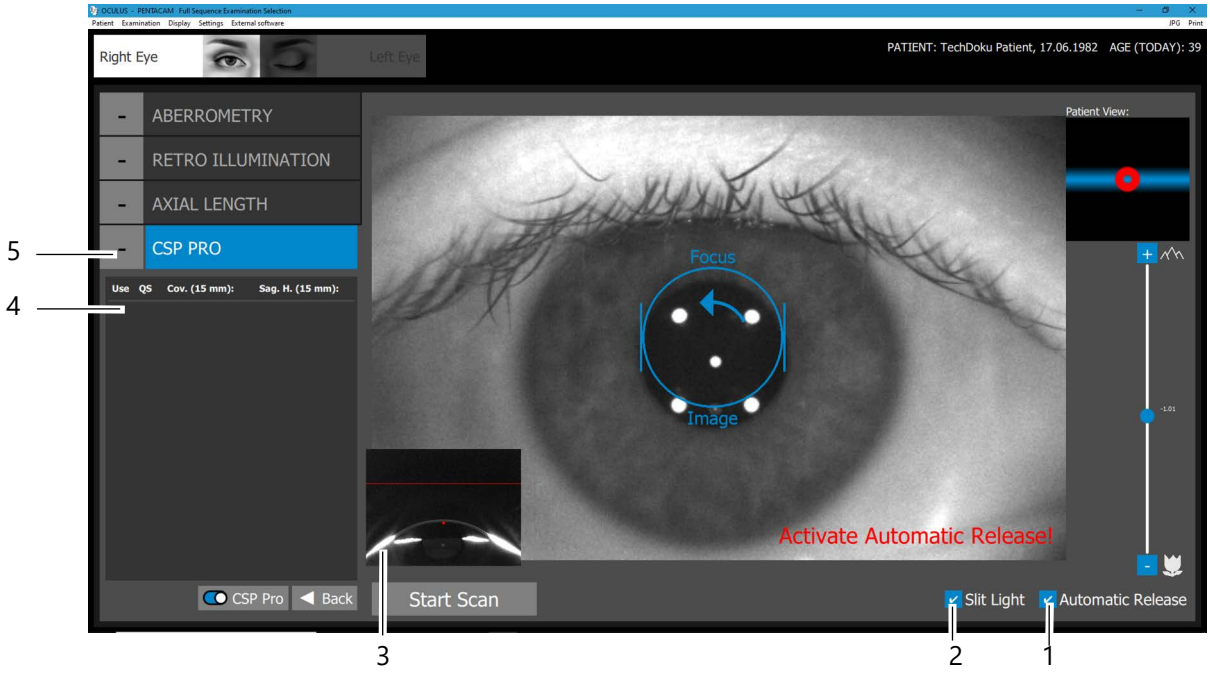


Fig. 6-21: "CSP Pro" examination screen

No.	Description	No.	Description
1	[Automatic Release] checkbox	4	Tomography parameter
2	[Slit Light] checkbox	5	Current examination mode
3	Live Scheimpflug images		

Perform CSP Pro measurement

➔ Move the cross slide towards the patient until the live Scheimpflug image shows the cornea of the eye that you are examining.

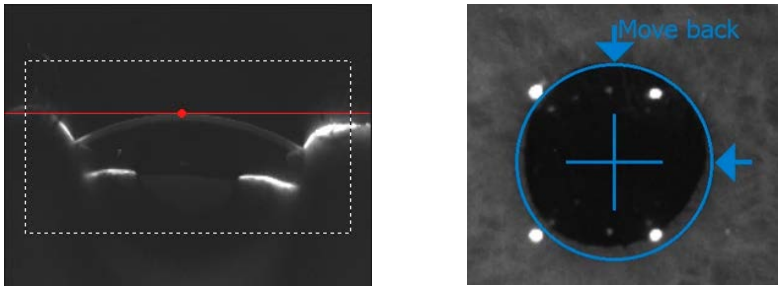


Fig. 6-22: Scheimpflug image (left) and overview image (right)

The image is sharpest when the red dot coincides with the red line in the Scheimpflug image.

➔ Focus the pupil image by moving the joystick towards the device or away from it.
➔ Ask the patient to widen his or her eye and not to blink.
➔ Adjust the left/right position of the device and its height setting.
Move the joystick to the left or right and rotate the joystick clockwise or anticlockwise.
The tentative final position of the camera is reached when the four bars frame the blue circle.
The device triggers the measurement automatically.
➔ Ask the patient to remove his or her head from the rest.
➔ Check the measurement results by referring to the quality specifications → Chap. 6.9.1 (Page 53).

6.9.1 Quality Specification for CSP Pro Measurement

After measuring either automatically or manually, the Pentacam® Program opens. The “QS” value appears in field.

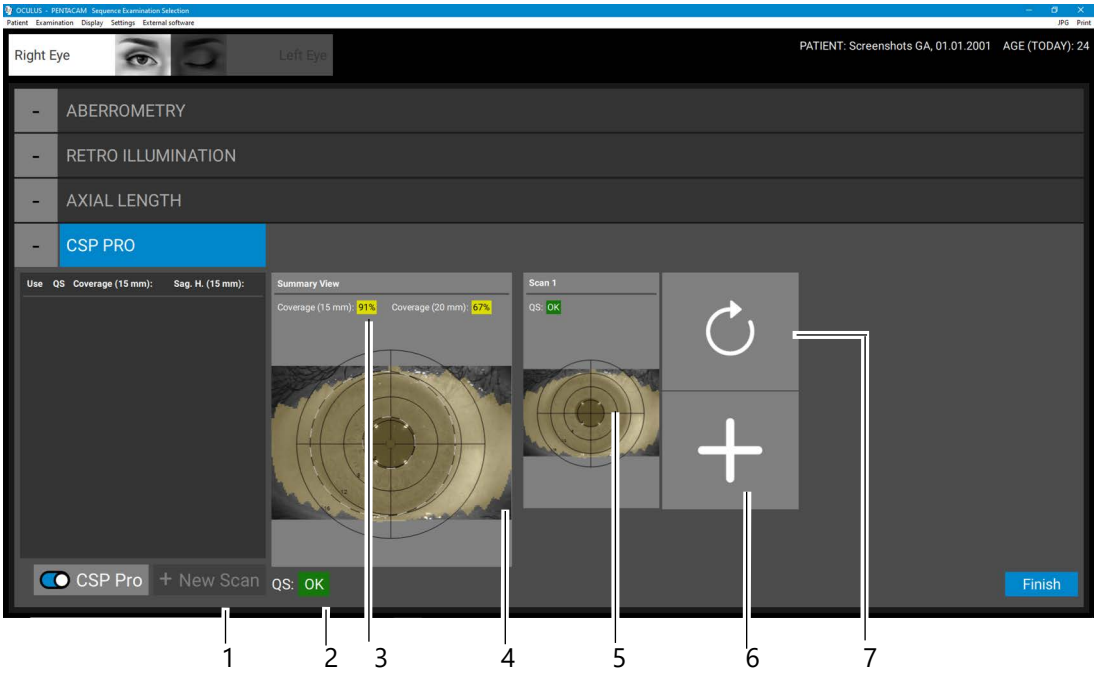


Fig. 6-23: Results display for a CSP Pro measurement

No.	Description	No.	Description
1	[+New Scan] button	3	Value for the overall coverage
2	If the “QS” field ■ is green and reads OK, the measurement is correct and can be reproduced. ■ is yellow, you may want to repeat the measurement. ■ is red, you must repeat the measurement.	4	Display sum of all individual measurements
		5	Individual measurements
		6	[Add measurment] button
		7	[Repeat measurement] button

Note

All examinations are automatically saved, regardless of the quality of the measurement taken.

If an error message is displayed in the "QS" field, the measurement must also be repeated.

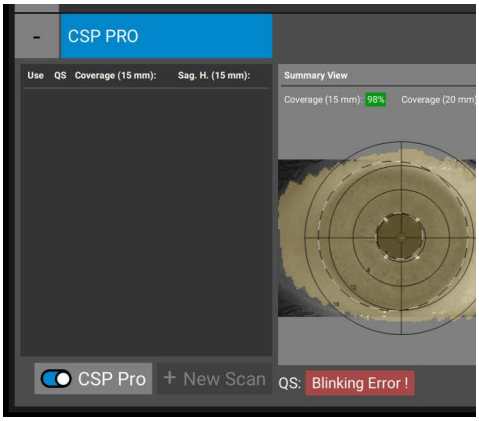


Fig. 6-24: Error message after a CSP Pro measurement

6.9.2 Repeat or Delete Measurement

If the QS value of the first measurement is not sufficient to use this for evaluation, repeat the measurement:

➔ Click on the [Repeat measurement] button.
The measurement is repeated and the previous measured values automatically get deleted.

Note

The eye needs to be held open wide enough for the desired measurement area not to be covered by the eyelids to achieve good coverage of the cornea and sclera. We recommend holding up the upper eyelid with the LidStick® or alternatively a long cotton swab. The patient can carefully pull down his or her lower eyelid with a finger.

➔ Click the [+] button to the right of the last measurement taken to add a measurement.
The coverage area of each measurement is shown in a different color in the corresponding display.
The coverage of all individual measurements is displayed summed up in the coverage map.

➔ Carry out additional examinations until the required measurement area is achieved i.e. a complete corneal scleral profile.

➔ If necessary, delete measurements with yellow or red QS.
This is also necessary if more than 4 individual measurements have to be carried out in order to obtain coverage >95%.

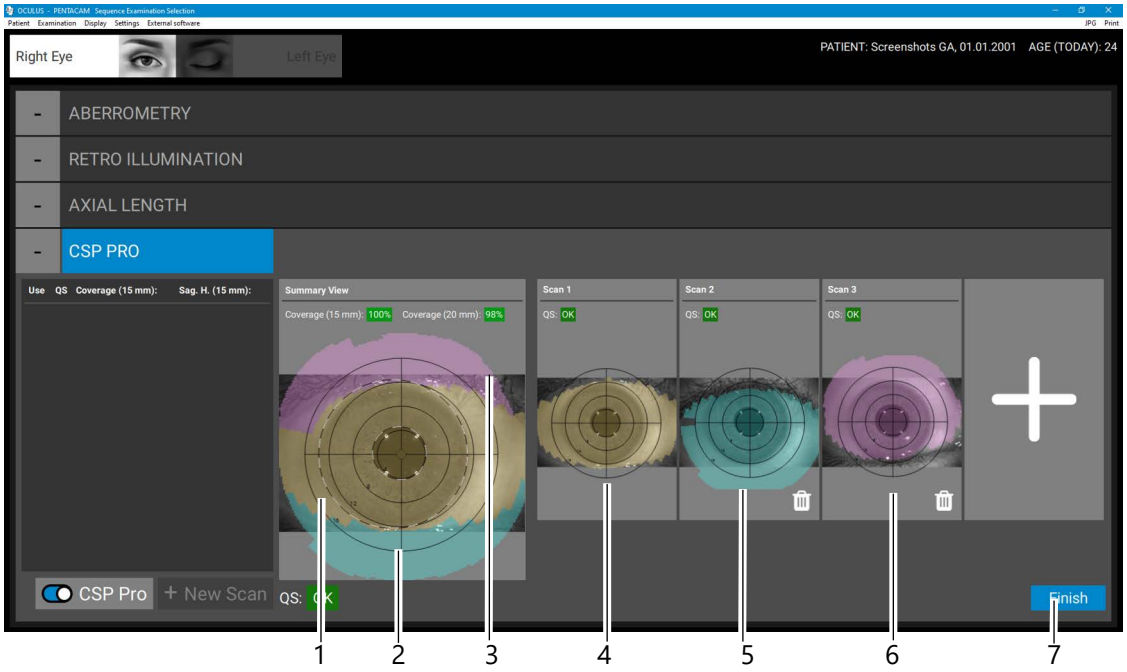


Fig. 6-25: Coverages of individual measurements and total coverage

No.	Description	No.	Description
1	Coverage by measurement 1	5	Coverage by single measurement 2
2	Additional coverage by measurement 2	6	Coverage by single measurement 3
3	Additional coverage by measurement 3	7	[Finish] button
4	Coverage by single measurement 1		

➔ Click the [Finish] button to complete the CSP Pro measurement.

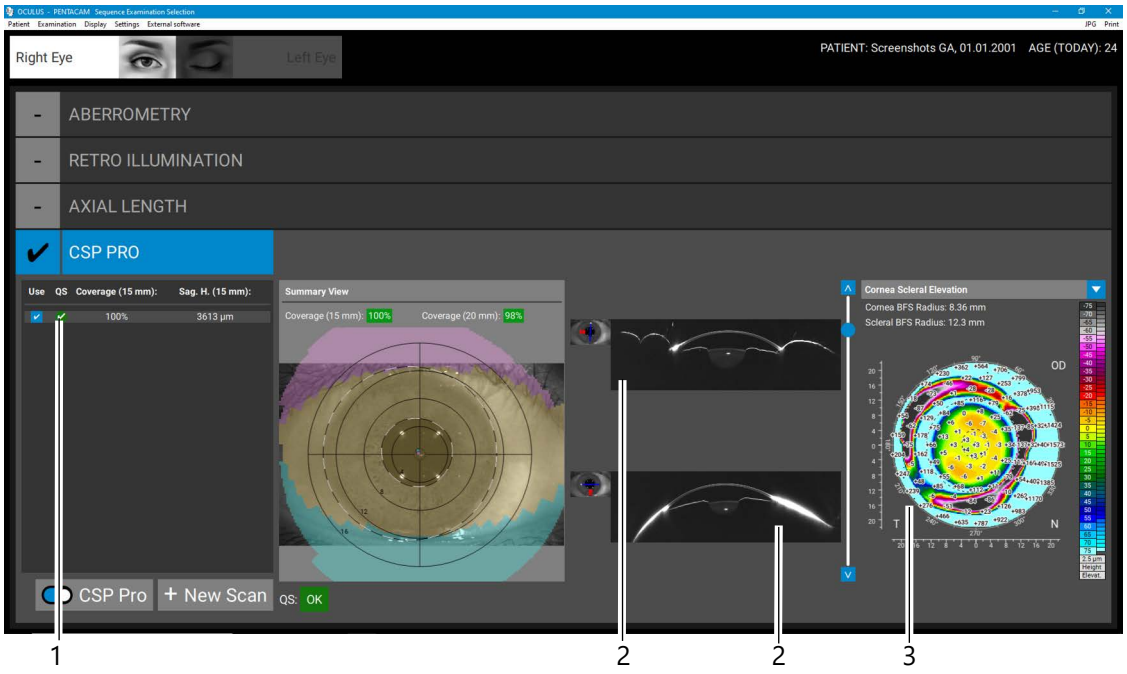


Fig. 6-26: Completed CSP Pro measurement

No.	Description	Explanation
1	Parameters of the CSP Pro measurement	■ **Use:** Click the checkbox of the respective measurement to use it for the evaluation. Use only one measurement for the full sequence examination. ■ **QS:** Quality Specification value ■ **Cov. (15 mm):** Coverage of the cornea and sclera in percent. ■ **Sag. H. (15 mm):** Sagittal height of the cornea for a diameter of 15 mm.
2	Scheimpflug images	
3	Elevation map	

6.10 Perform a Single Scan for an Examination Mode

You can perform single scans for each examination mode, for example to check values after a surgery.

➔ Adjust the table height.

➔ Check that

- fresh paper has been put onto the chin rest or the chin rest has been cleaned and disinfected → Chap. 8 (Page 70).
- the forehead rest has been cleaned and disinfected after each examination → Chap. 8 (Page 70).
- the lens in front of the camera and the acrylic glass are clean.

- ➔ Ask the patient to place his or her head on the chin and forehead rest.
- ➔ Do not touch the patient and the device simultaneously.
- ➔ If the lighting in the examination room has not been turned down or switched off, use the dark sheet supplied to cover the patient and the device.
- ➔ Select the [Examination] tab and click [Scan].

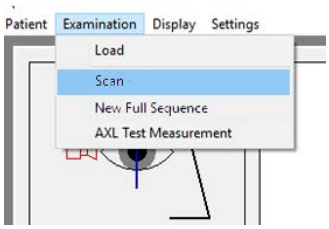


Fig. 6-27: Single scan start

The screen for a single scan is displayed.

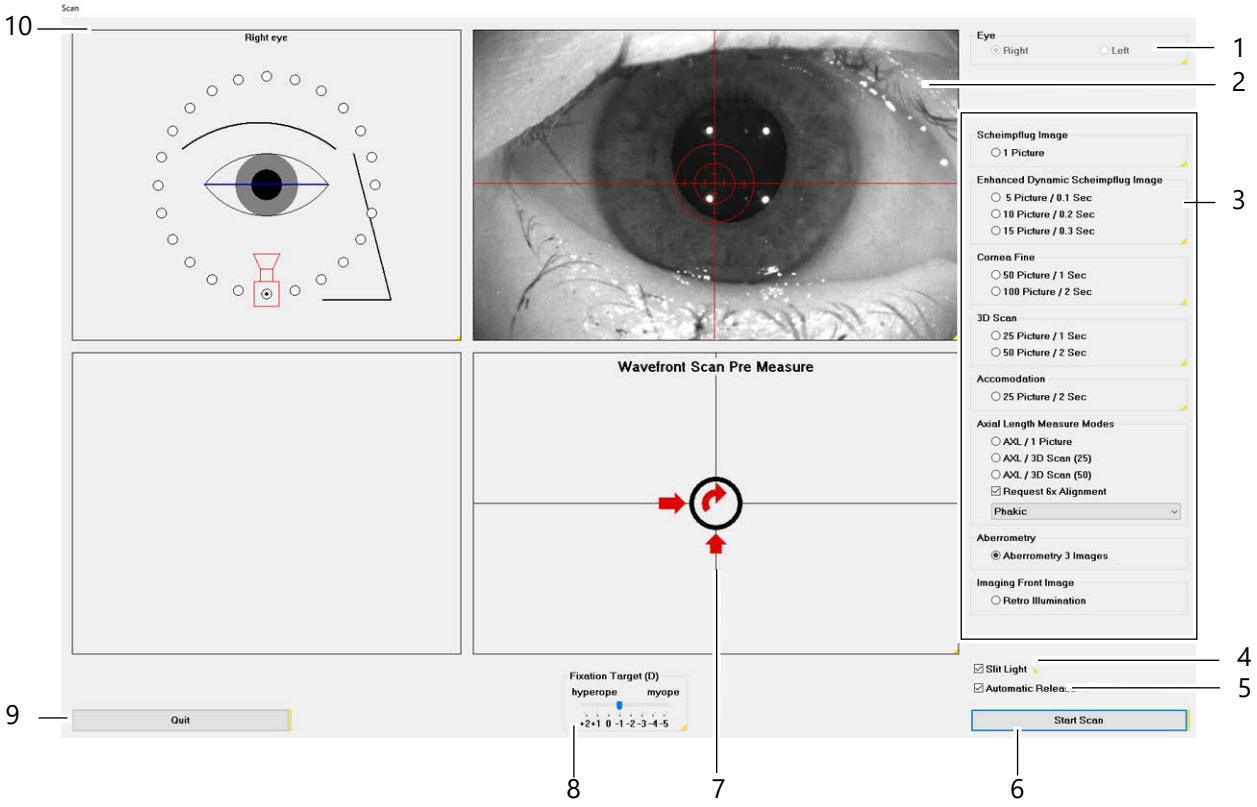


Fig. 6-28: Screen for single scans (example: aberrometry)

No.	Description	No.	Description
1	Display of currently examined eye	6	[Start Scan] button
2	Overview image with adjusting aid	7	Adjustment window
3	Examination mode area	8	Fixation Target
4	[Slit Light] checkbox	9	[Quit] button
5	[Automatic Release] checkbox	10	“Orientation” field

6.10.1 Procedure to Take a Single Scan

➔ Select the examination mode → Chap. 6.10.3 (Page 58).
Enable the depending radio buttons and checkboxes.
➔ Advice the patient to look at the fixation target/point.
The eye currently being examined is detected automatically and is displayed in the display of currently examined eye.
➔ Adjust the camera → Chap. "Darken the Room" (Page 32) and → Chap. "Fine Adjustment" (Page 34).
The Overview Image shows the pupil and a cross hair as an adjusting aid.
➔ Shortly before you have reached the final position ask the patient to widen his or her eye and not to blink.
The device triggers the measurement automatically.

6.10.2 General Settings

- Click the [Slit Light] checkbox to activate/deactivate the blue light for illuminating the eye.
- Click the [Automatic Release] checkbox to activate automatic measurement.
- Clicking the [Start Scan] button activates manual measurement. You can also use the Return key.
- Inside the adjustment window, there are arrows showing you the direction in which you have to move the device to activate automatic measurement (Automatic Release).
- The "Fixation Target" setting is a parameter to optimize the fixation of the patient. For this, the active "Fixation Target", for example the LED blinking red in the middle of the blue slit, can be shifted in steps of 0.5 D. The objective is to offset defects in the patient's vision and ensure a simpler method of fixation.
- Click the [Quit] button to abort the measurement.
- The "Orientation" field shows the respective position of the camera and the eye, which is currently being examined.

6.10.3 Scheimpflug Image Settings

You can set the number and type of images required for the respective examination in the "Image Options" box.

"Scheimpflug Image" group box

- If you activate this option, the camera records only one Scheimpflug image. You can freely select the camera position you require by clicking the white rings in the "Orientation" field.

"Enhanced Dynamic Scheimpflug Image" group box

- Use this option to make the camera record either 5, 10 or 15 Scheimpflug images, with the camera remaining in the same position. Image averaging is carried out on the recorded images to minimise background noise. Only one Scheimpflug image is displayed. You can freely select the camera position you require by clicking the white rings in the "Orientation" field (10). This type of image is suitable for a densitometric assessment of the lens.

"Cornea Fine" group box

- Select this option for a more detailed image of the cornea.
  The camera does not capture the deeper-lying layers. You can select 50 Scheimpflug images with a recording time of one second, or 100 Scheimpflug images with a recording time of two seconds.

"3D Scan" group box

- Use this option to select how many images you want the camera to record per scan. The difference is in the duration of the examination and the number of measuring points that are evaluated. A scan comprising of 50 images takes longer, but it provides the highest amount of measured elevation data.
- This type of examination is used for evaluating the cornea and anterior chamber.

"Accommodation" group box

- If you select this option, the camera will take a total of 50 Scheimpflug images. While the camera is recording the images, the "Fixation Target" shifts constantly from -5 D to +2 D. The camera records the Scheimpflug images from a pre-selected camera position.

"Axial Length Measure Modes" group box

➔ Select this option for measuring the axial length.
  If you select this option, the desired mode for the axial length measurement is enabled.
➔ Follow the instructions on the screen to align the patients eye to the device. If the patients eye is aligned to the device properly the device measures six times the axial length of the patient's eye.
➔ Read the message on the screen and give the patient a break for blinking.
➔ Advise the patient to fixate on the red blinking light. Click on the OK button to proceed with the 3D scan.
➔ Follow the instructions on the screen to align the patient's eye to the device properly.

If "Request 6x Alignment" is activated, the axial length measurement starts only if the patient is fixating correctly during the complete scan. After the device is aligned properly, the measurement starts automatically.

"Request 6x Alignment" deactivated means: The axial length measurements are performed without any interruptions.

"Request 6x Alignment" is activated by default and should only deactivated if the patient has problems to fixate on the red blinking light.

➔ Select the "Eye Status":
  - Phakic: Default status. Presence of crystalline lens.
  - Aphakic: Absence of the crystalline lens. Correction of measured axial length by +0.200 mm
  - Pseudophakic (Silicone IOL or similar): IOL of silicone or similar material implanted. Correction of axial length by +0.120 mm.
  - Pseudophakic (Acrylate): Acrylat/Metaacrylate IOL implanted. Correction of axial length by +0.110 mm.

Plausibility of axial length

During the measurement of both eyes the following messages may occur.

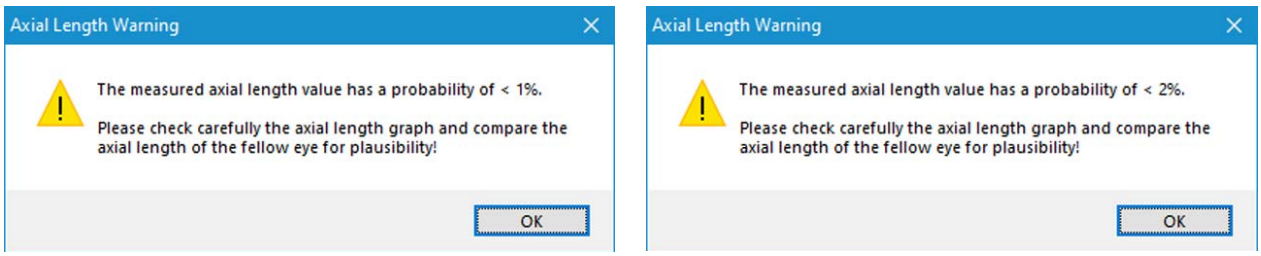


Fig. 6-29: Message: Plausibility check

Note

The axial length values do not correspond to the values of the normal population.

➔ Check the axial length values of both eyes.

The plausibility is marked by a yellow flagged QS value. This will be stored in the Pentacam® Program accordingly.



This symbol, related to the messages appears for example in the IOL calculator.

➔ Click on this symbol to show the corresponding message.

You must check the corresponding measured value.

If the measured axial length value has a probability of < 1%, the following message may occur.

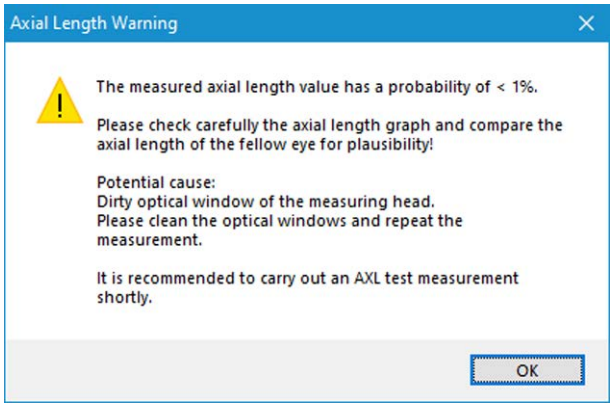


Fig. 6-30: Message: Dirty optical window

Note

Faulty measurements due to dirty window

➔ Clean the optical window.

➔ Carry out a test measurement.

If you do not carry out the test measurement, then this message will be stored in the Pentacam® Program accordingly marked by a red flagged QS value, for example in the IOL calculator.

➔ Repeat the measurement.

You must check the corresponding measured value.

"Aberrometry" group box

- Enables the wavefront aberrometry measurement.

"Imaging Front Image" group box

- Enables the retro illumination.

Further information on the capturing process → Chap. "Capturing Procedure for the Retro Illumination" (Page 40).

6.11 Manual Measurement Function in the Scheimpflug Image

➔ Select the button in the extended Scheimpflug image display.
➔ Click with the left mouse button on the Scheimpflug image and define the start point of the measurement.
➔ Now move the cursor and the distance between the start point and the current mouse position will be displayed in µm.
➔ To cancel the current measurement, press the right mouse button.
➔ Once you have reached the end point for the measurement, click the left mouse button again.

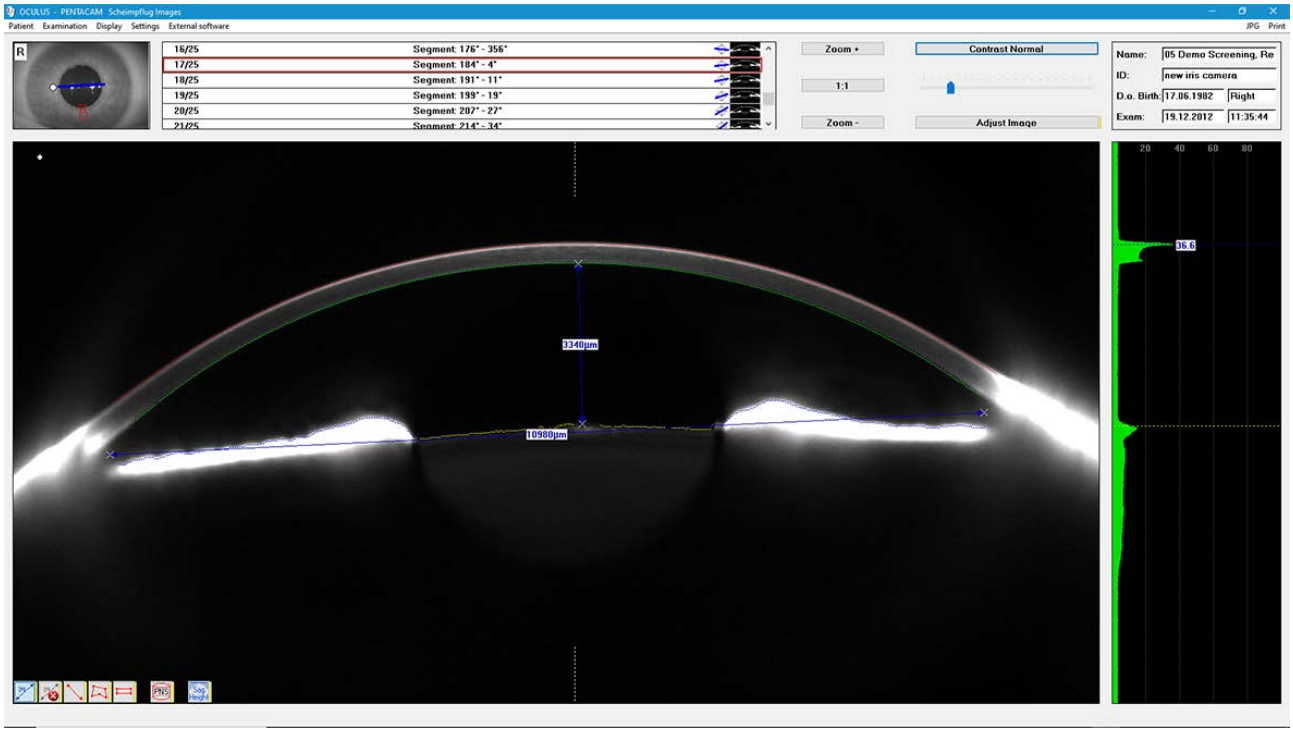


Fig. 6-31: Measurement function in the Scheimpflug image

The arrow head and the associate distance will now be permanently displayed.

➔ Click on the button . The last measuring line is deleted.

7 Patient Data Management

Information

For more information on Patient Data Management → User Guide.

Information

The myopia package for the device can only be used in conjunction with the GO Patient Data Management system, version V7.5r12 or later.

7.1 Starting Patient Data Management

After you have switched on the PC, it first loads the operating system.

1. Click the [Pentacam] icon at the desktop.

The user interface for the Patient Data Management appears.

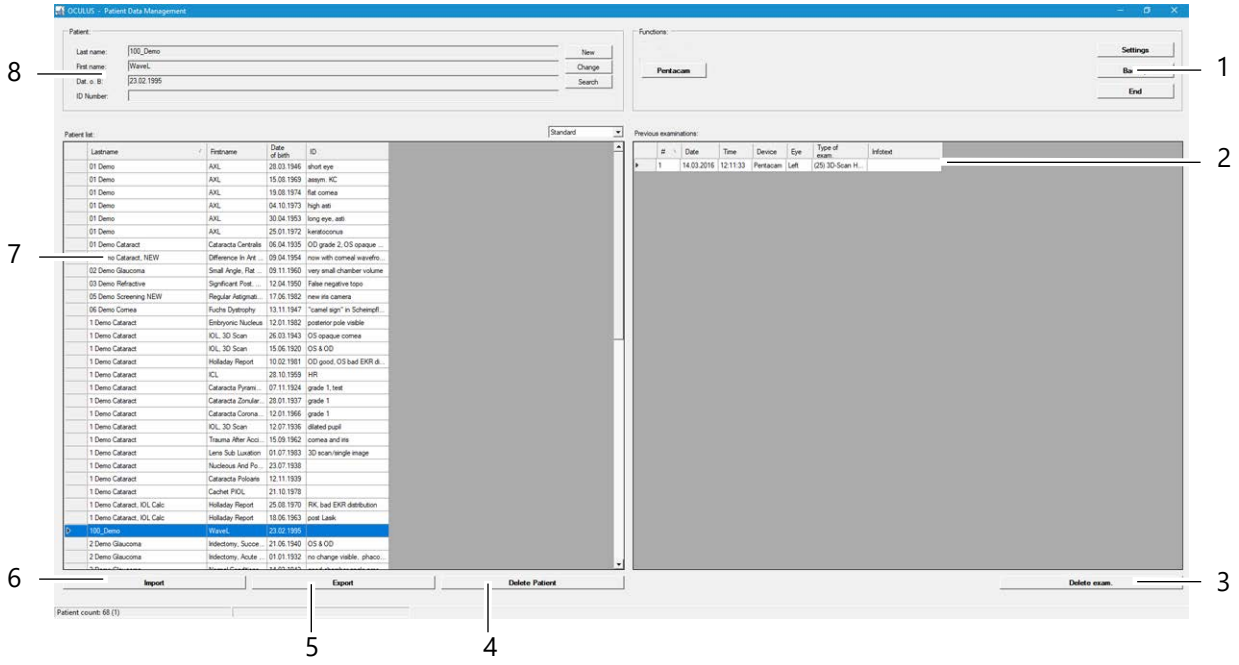


Fig. 7-1: Patient Data Management user interface

Nr.	Designation	Description
1	"Functions" area	■ List of available devices ■ Settings ■ Backup: → Chap. 7.7 (Page 67) ■ End
2	Previous examinations	all existing test results for the selected patient
3	[Delete exam.] button	
4	[Delete Patient] button	
5	[Export] button	→ Chap. 7.5 (Page 65)
6	[Import] button	→ Chap. 7.6 (Page 66)
7	Patient list	
8	„Patient" area	Patient data ■ New: → Chap. 7.2 (Page 63) ■ Change ■ Search

Information

To open the device software, you must first select an existing patient or enter a new patient.

7.2 Entering a New Patient

1. Press the [New] button to enter a new patient in the Patient Data Management system.
2. Enter the patient's last name, first name and date of birth in the patient window.

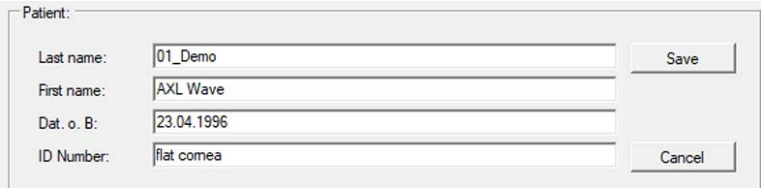


Fig. 7-2: Entering patient

Optionally you can enter an ID number for the patient.

3. To save your entries use the [Save] button.
The patient you have just entered now appears in the patient list and is automatically selected.

7.3 Selecting an Existing Patient

The patient data list on the left-hand side of the screen displays all previously examined patients in alphabetical order.

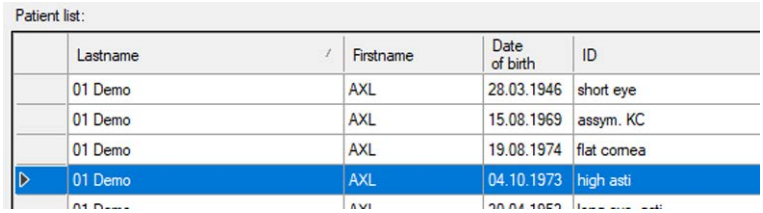


Fig. 7-3: Patient liste

1. Select the patient from the patient list.
   or
   Click the [Search] button and enter the last name, first name, ID number, or date of birth of the patient you are looking for.
2. Click the patient's name to transfer the data to the "Patient" window.
   The window on the right will display a list of all existing examinations for this patient.

7.3.1 Extended Patient Search: [Extended] Checkbox

1. Mark the [Extended] checkbox.

The screen displays additional search parameters which reference previous examinations. Proceed as for the input of a patient name.

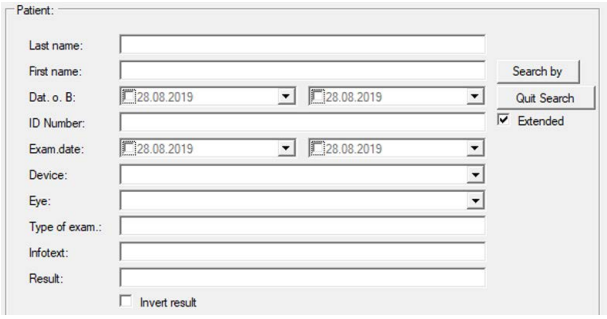


Fig. 7-4: Extended search

2. To exit the extended patient search click [Quit Search].

7.4 Rename Patient Data

After creating of the patient data, you can edit it.

1. Press the [Change] button.
   The input boxes for patient data are now enabled, and the cursor jumps to the "Last name" field.
2. Change the entries in the individual boxes.
3. Press the [Save] button.

7.5 Exporting Patient Data

Patient and examination data can be exported, for example, for forwarding to another clinic.

1. Select the patient and also one of the examinations in the respective list as required.
2. Click [Export] button below the patient list. The following dialogue appears:

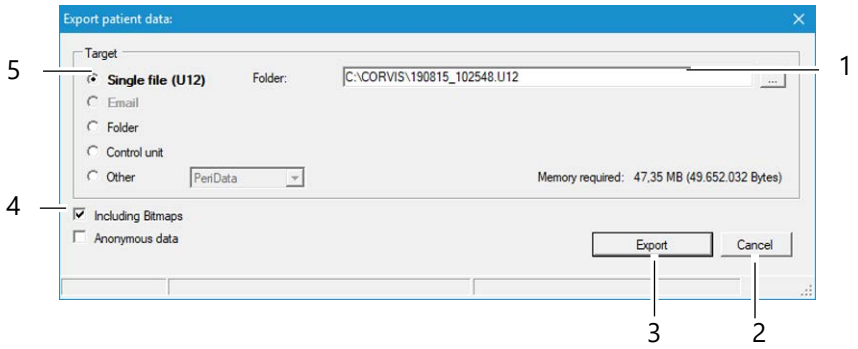


Fig. 7-5: "Export patient data" dialog

No.	Description	No.	Description
1	Saving destination selection	4	[Export] button
2	[...] button	5	Options for data export
3	[Cancel] button		

Information

The default options for import and export of data are configured in the "Settings" field → User Guide.

Depending on the settings, you may not have to perform all of the following steps (e.g. selection of the directory).

3. Select the "Target" where you would like to export the data.

Information

Recommendation: Export the patient data using the "Single file (U12)" option.

4. Press the [...] button.
5. In the dialog that appears, select the folder or the file to which the patient data should be exported.
6. Specify the name and destination of the file you are saving.
7. Make sure you have selected [Including Bitmaps].
8. Click [Export].
9. The patient and examination data have now been saved at the destination specified.

You can send data stored on the hard drive as an e-mail attachment.

Information

Requirements for transferring data to another PC:

- The Pentacam® Program must be installed on the other PC. If the program is updated on the device PC (sender), the program on the other PC (recipient) must also be updated.
- Make sure, that the PC is connected to a local network controlled by the Floating License Key or that a single license key is connected to the PC in order to interactively evaluate the exams.

7.6 Importing Patient Data

If you receive patient data, for example, on a USB stick, you can import these data.

Note

Risk of loss of data due to computer viruses

Computer viruses can cause loss of data.

➔ Run a virus check before importing data from the USB flash drive.

1. Press the [Import] button. The following dialog appears:

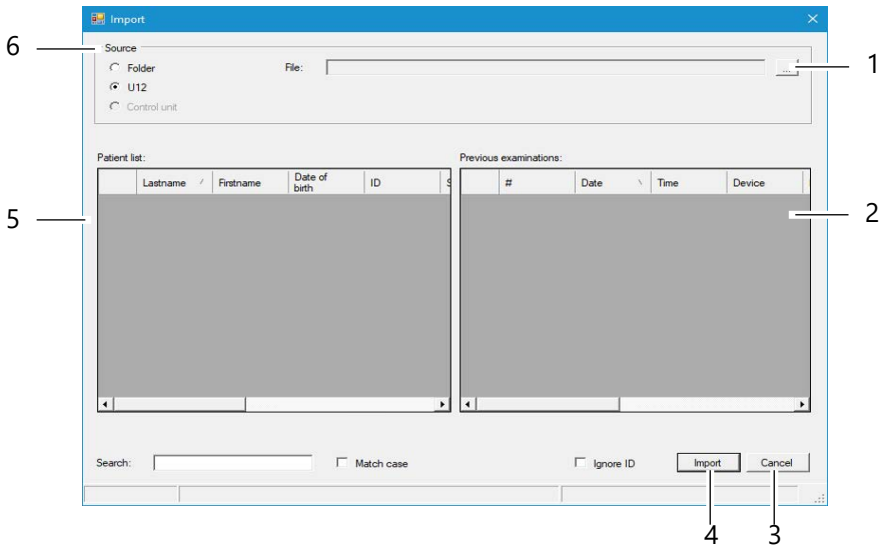


Fig. 7-6: "Import" dialog

No.	Description	No.	Description
1	Saving destination selection	4	[Import] button
2	Previous examinations	5	Patient list
3	[Cancel] button	6	Select data source

Information

The default options for import and export of data are configured in the “Settings” field → User Guide.

➔ Depending on the settings, you may not have to perform all of the following steps (e.g. selection of the directory).

2. Select the option where the source data are contained (“Folder” or “U12” (single file)).

Information

Recommendation: Import the patient data using the “Single file (U12)” option.

3. Press the [...] button.
4. In the dialog box, select the directory or the file where the patient data are located.
5. Confirm your selection with [OK] or [Open].
   The patients and the associated examinations that are found are displayed in the lower part of the dialog.
6. To import the data, press the [Import] button.
   The data will then be available in the Patient Data Management system.

7.7 Data Backup

You should make a backup copy of patient and examination data at regular intervals. In case of loss of data, you can reconstruct the data from a previously created backup with the help of this function. Since data backup takes several minutes, depending on the scope of the database and the data to be backed up, a backup should be carried out when the PC and the device will not be needed.

Note

Risk of loss of data due to computer viruses

Computer viruses can cause loss of data.

➔ Run a virus check before making a backup to a USB flash drive.

Information

The general rules for security backups apply to the creation of backup copies created with the help of the Patient Data Management system. Storage of backup files should always be done on a separate system (e.g. on a USB flash drive with adequate capacity).

7.7.1 Backup Data

1. Press the [Backup] button at the top right of the Patient Data Management system. The following dialog is displayed:

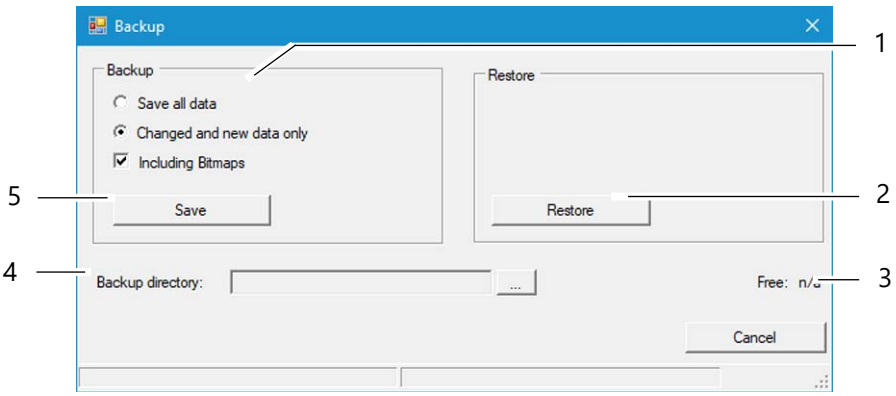


Fig. 7-7: "Backup" dialog

No.	Description	No.	Description
1	Backup data selection	4	Backup directory and button [...]
2	[Restore] button	5	[Save] button
3	Display free storage space		

2. Select whether all of the data or only changed data should be backed up.

Information

The Patient Data Management system internally tags all saved data records.

If you select the option "Changed and new data only", only the data records that were not saved during a previous backup will be backed up.

3. Press the [...] button to the right of the "Backup directory" box.
4. In the dialog that appears, select the folder to which the data should be backed up.
5. Confirm your selection with [OK].
6. To back up the data, press the [Save] button. The previously selected data will then be backed up to the corresponding folder.

7.7.2 Reconstructing Data

If a loss of data occurs, the data from a previous backup can be re-imported into the Patient Data Management system.

➔ Press the [...] button.
➔ In the dialog that appears, select the folder which contains the backup data.
➔ Confirm your selection with [OK].
➔ To import the data, press the [Restore] button. All data in the appropriate directory are copied to the Patient Data Management system.

7.7.3 Automatic Backup

In addition to the manually performed backup, it is also possible to automatically run a backup when exiting the Patient Data Management system. The settings required for this can be made in the “Settings” area → User Guide.

8 Cleaning, Disinfection and Maintenance

Caution

Risk of personal injury or material damage due to invisible laser radiation

The device contains a Class 1 laser according to IEC 60825-1: 2014. It is an encapsulated laser system. When the device cover is opened, you may be exposed to invisible, Class 3R (5 mW) laser radiation.

➔ Never open the unit.

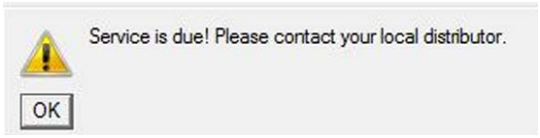
➔ For authorized service personnel only: When doing maintenance jobs, avoid looking directly into the laser beam.

To ensure a high degree of measurement accuracy of the device, OCULUS Optikgeräte GmbH recommends conducting maintenance every year or every 25000 scans.

➔ If an error occurs that you cannot alleviate, label the device as out-of-order and notify our service.

The device will inform you of the upcoming maintenance in various ways:

- In the daily display window



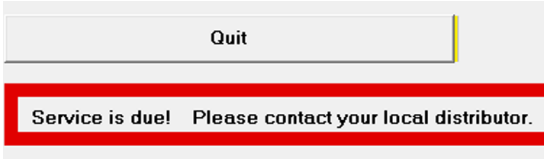
- In the settings → refer to the User Guide:
  Date of next service or number of examinations conducted



- In the scan menu → chap. 5.2 (page 27)
  as preliminary information
  (3 months before)



- or when service is due.



- During an examination (this is saved), a symbol appears next to the QA field.



➔ Please contact OCULUS service or your local dealer to arrange a maintenance appointment.

Sterilization is not required.

➔ Observe the product descriptions or instructions for use of the agents and devices that you use for the care and cleaning of the appliance or accessories.

➔ Do not clean the device with aggressive, chlorinated, abrasive, or harsh cleaning agents.

8.1 Intervals for Cleaning, Disinfection and Maintenance

Interval	Activity
Before first daily use	➔ Perform the test measurement of axial length.
Beafore each use	➔ Place fresh paper on the chin rest. ➔ Disinfect the chin rest if it is used without paper.
Before each use	➔ Disinfect the forehead rest.
Monthly	➔ Clean device (housing, illuminated slit).
Monthly	➔ Perform tomography test measurement.
every 2 years or after 25000 measure-ments	➔ Maintenance by OCULUS Service or an authorized dealer.
As needed (peak during test measure-ment at 39mm)	➔ Clean the glass cover.

8.2 Consumables

Chinrest paper	400 sheets, Art.-No. 65313
LidStick®	2 rolls of 100 each, Art.-No. 77502
Disinfection wipes	SONO® Disinfecting wipes EPA Reg.No. 6836-340-89018 www.sonowipes.comPDI Sani-Cloth® AF3 Germicidal Disposable Wipe EPA Reg.No. 9480-9 www.pdihc.com

8.3 Cleaning



Caution

Risk of electric shock if the device is not completely disconnected from the mains for the cleaning.

➔ Turn the device off → Chap. 4.6 (Page 24).

➔ Pull the power plug before cleaning.

⚠ **Pull on the respective plug and not on the cable itself.**

Required materials:

- Antistatic cleaning agent
- Cleaner for painted surfaces: Mixture of equal parts of alcohol and distilled water, possibly with a few drops of household detergent
- Soft, lint-free cloth
- Purified compressed air
- commercial clean agent for the acrylic glass

8.3.1 Cleaning the Housing

➔ It is best to clean the housing surfaces with a soft cloth and an anti-static cleaning agent.

➔ Wipe off any residue from painted surfaces with the mixture for painted surfaces.

8.3.2 Cleaning the Chin-Forehead Rest

➔ Make sure that no liquid gets into any of the openings of the device.
Do not use liquid from aerosol cans.

➔ Clean the chin-forehead rest with a soap solution (or with alcohol, if very dirty).

➔ Use a lint-free, damp cloth.

8.3.3 Cleaning the Illuminated Slit

The optical components illuminating the slit, and the lens in front of the camera are precision parts and sensitive to pressure. The surfaces of these components are susceptible to scratching.

Note

When cleaning the illuminated slit, do not use a cloth or other cleaning agents.

- ➔ Carefully clean the centre of the illuminated slit with purified compressed air.
- ➔ Clean the lens in front of the camera using a dry, lint-free cloth.
- ➔ Clean the acrylic glass with a commercial clean agent.

8.3.4 Cleaning the Cover Glass

- ➔ Clean the cover glass if a peak at 39 mm is visible during the test measurement → Chap. 8.6 (Page 74).

8.4 Disinfection

- ➔ Use disinfection wipes suitable for medical devices, recommendation see → Chap. 8.2 (Page 71).

Note

Equipment damage caused by disinfectant solution

The disinfectant solution may damage the surface of the device if it is sprayed directly on it.

- ➔ Spray the disinfectant solution onto a cleaning cloth, do not spray it directly on the device.

- ➔ Disinfect the forehead rest after each examination.
- ➔ If you do not use paper for the chin rest, disinfect the chin rest after each examination.

8.5 Attaching Paper to the Chin Rest

Take the following steps to place the chin rest paper:

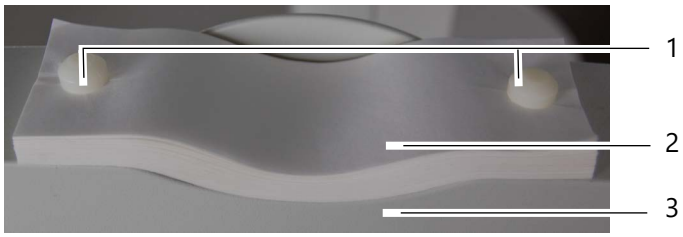


Fig. 8-1: Attaching the chin rest paper

No.	Description
1	Fastening pins
2	Chin rest paper
3	Chin rest

1. Pull the two fastening pins out of the chin rest.
2. Place a new sheet of chin rest paper. The holes in the paper and the chin rest must align.
3. Insert the two fastening pins through the paper and the chin rest.

8.6 Test Measurements

The device is tested and calibrated in the OCULUS factory. OCULUS Optikgeräte GmbH recommends to perform regular test measurements of the device.
The Pentacam® Software prompts the user to perform a test measurement every day.

8.6.1 Test Measurement: Axial Length

The axial length test measurement routine has to be performed daily before the first "Full Sequence Examination".

Required Tools and Materials

- Pentacam® AXL Test eye (Art.-No.: 70108)
- 1.5mm Allen key

Information

Make sure the test eye is in the park position when it is not in use.



Fig. 8-2: Parking position

How to Proceed

1. Turn off the device.
2. Use the Allen key to attach the test eye to the chin and head rest, directly underneath the retainer for the head rest.
3. Slide it up in front of the device.

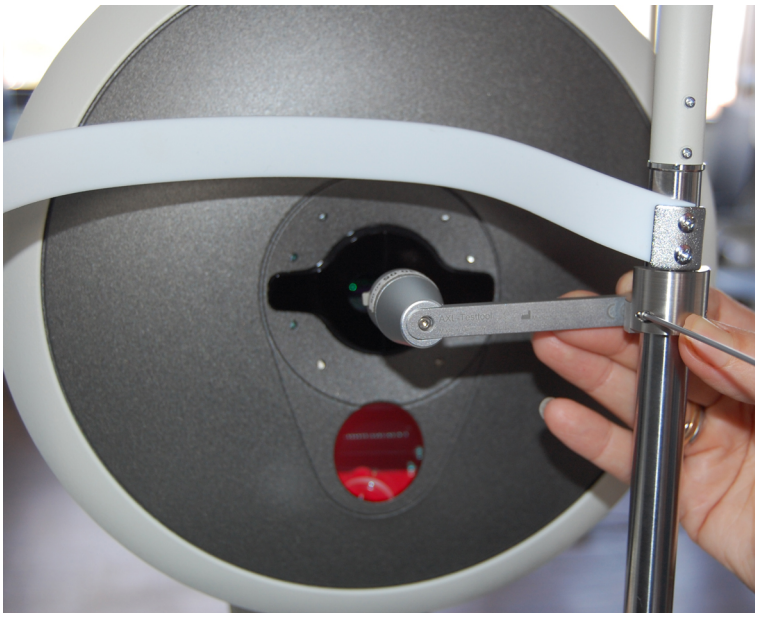


Fig. 8-3: Attach the test eye

4. After the Full Sequence Mode is selected the following screen appears:

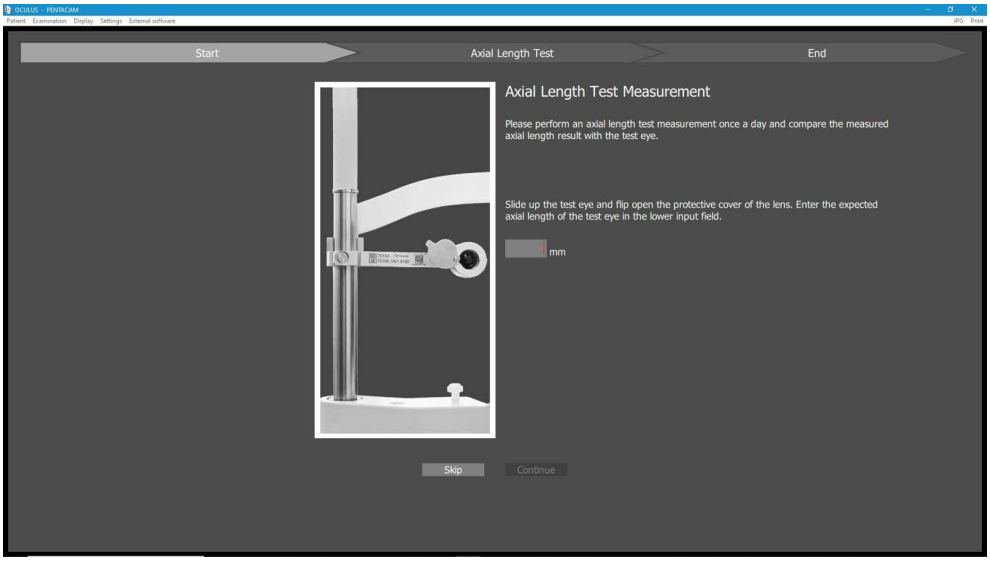


Fig. 8-4: Axial Length Test Measurement start screen

5. Follow the instructions on the screen.

Information

If you skip the test measurement all following AXL scans receive a bad QS value including the message “Missing test measurement”.

6. Type in the axial length of the test eye and click on “Continue”.



Fig. 8-5: Axial length of the test eye

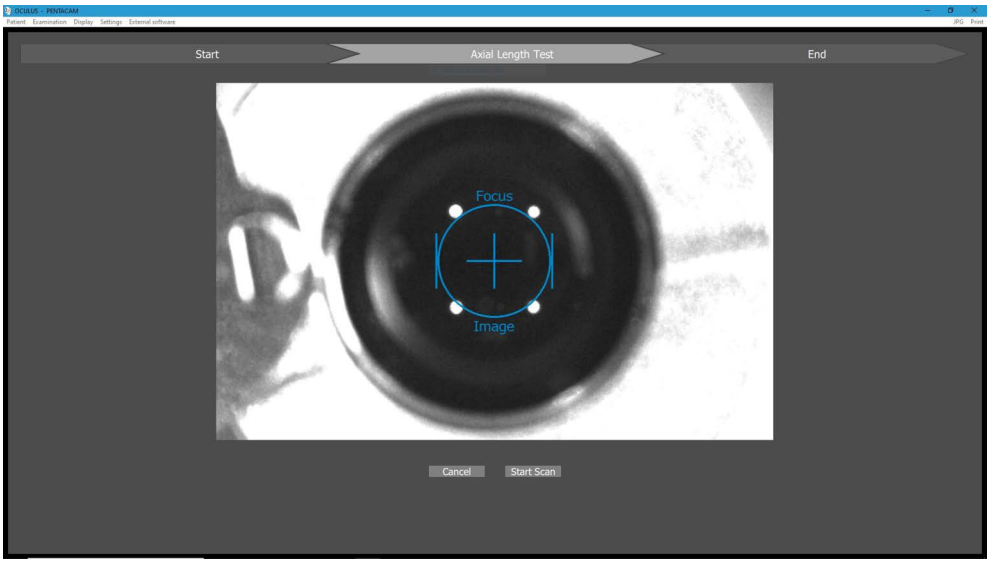


Fig. 8-6: Axial length test

7. Align the device to the test eye → Chap. “Fine Adjustment” (Page 34).
8. Press [Start Scan] or press the return button to start the test measurement manually.
9. If the test measurement is **successfully** passed, press “OK” on the upcoming screen.

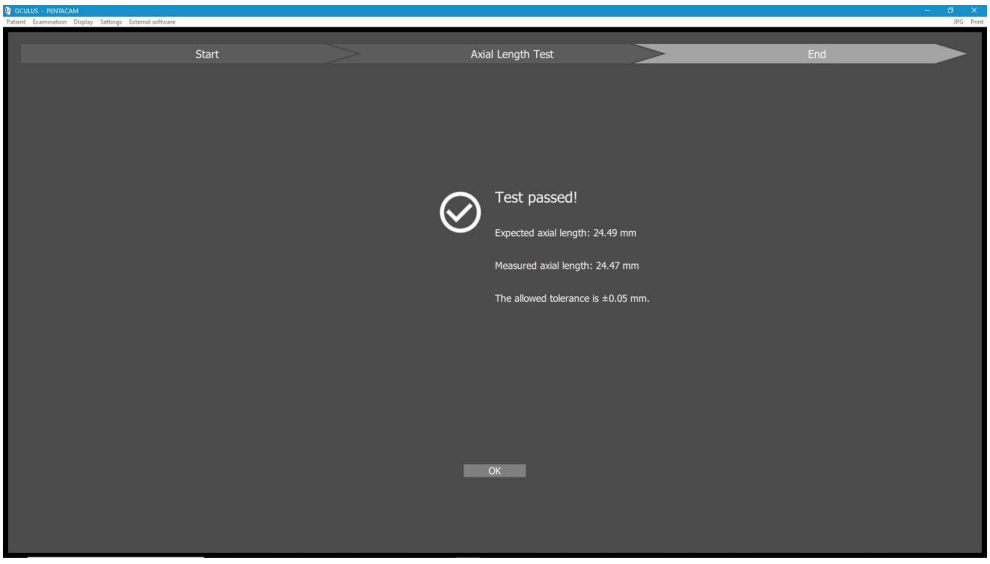


Fig. 8-7: Test passed screen

10. If the test measurement **failed**, you have to repeat the test measurement.
    ➔ Exclude all possible reasons (see screen) for a fail test measurement.

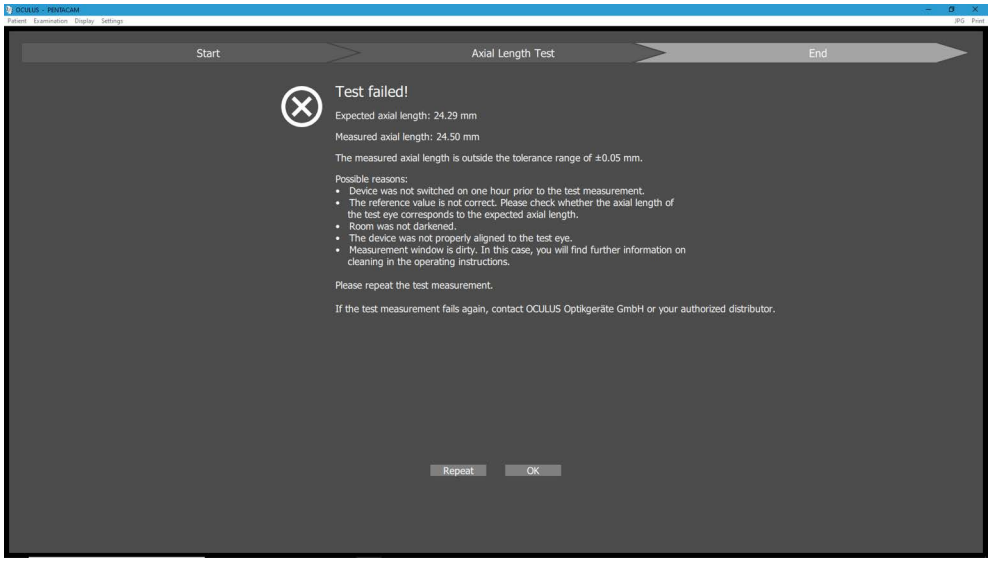


Fig. 8-8: Test failed screen

➔ If this test measurement also failed please call your authorized dealer.
➔ To finish this process click “OK”.

Information

In case you had to replace the test eye because of any reason you have to type in the axial length of the new test eye into the input field before you do a new test measurement.

11. After the test measurement process is finished you can slide down the test eye.

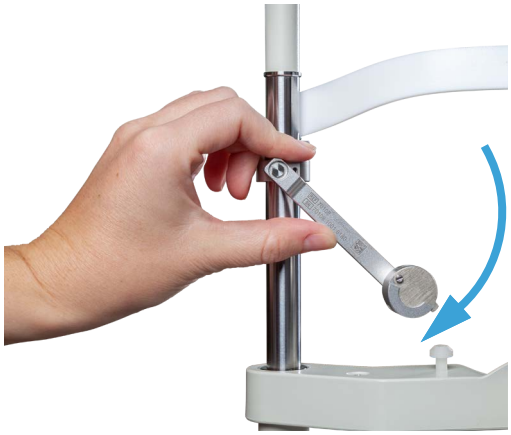


Fig. 8-9: Sliding down the test eye

The protective cover closes automatically. You can proceed with the measurements.

Information

During an examination: If you adjust the chin rest for a smaller head (the head of a child, for example), the test eye may be in the way. Slide the test eye to the side and then adjust the chin rest.

8.6.2 Test Measurement: Tomography (3D Scan)

The device is tested and calibrated at OCULUS.

OCULUS Optikgeräte GmbH recommends to carry out additional regular test measurements with the device.

Start the test with a measurement of a human eye. Carry out at least five successive measurements on each eye. Calculate the arithmetic mean and log the results.

Once a month, this measurement sequence should be carried out on the same eye as described above.

Compare the arithmetic mean from the initial measurement with the current measurement.

The following table depicts the tolerance range between the result of the initial measurement and the result of the current measurement:

	Tolerance range
Curvature	+/- 0,1 D
Pachymetry	+/- 10 µm

If the difference between the initial value and the current value lies outside the tolerance range, contact our service or your marketing authorisation holder. The values are shown in the overview display, for example; please refer to the User Manual.

9 Troubleshooting



Caution

Incorrect troubleshooting may result in personal injury or damage to the device.

➔ If a fault cannot be rectified, label the device as “out of order” and contact the service department or an authorized dealer.

Contact details:

- Telephone (urgent cases): +49 641 2005-800
  Have TeamViewer ready and provide the following information:
  - Customer number
  - Serial number
  - Software version
  - Description of the fault
  - Steps already taken
- E-Mail: service@oculus.de
  Provide the same information.
  - If necessary, include: U12 files, images
  - Large files can be sent via WeTransfer

Action	Description
Restart	1. Switch off the device using the on/off switch. 2. Wait 15 seconds. 3. Switch on the device using the on/off switch.
Check connections	Check ➔ that all cables are properly connected. ➔ the connection between the Y-cable and the power supply. ➔ the connection between the Y-cable and the PC. ➔ whether a USB extension cable is being used. This must be a repeater cable. ➔ whether an active USB hub (with its own power supply) is being used.
Check energy options	1. Go to Power System Settings. 2. Deselect the [Turn on fast startup (recommended)] option. 3. Go to Device Manager. 4. Click the [Power Management] tab. 5. Deselect the [Allow the computer to turn off this device to save power] option.
Check USB ports	➔ Replace the USB ports on the PC.
Check XY base	➔ Check whether the device is positioned parallel to the XY axis.

10 Transport, Storage and Disposal

The device must be properly uninstalled and packed before transport or storage. Use the original packaging and foam inserts for packing.

Note

Risk of equipment damage due to incorrect shipment or from improper storage

- ➔ Avoid shocks, vibrations, and contamination.
- ➔ Avoid high temperatures and humidity.

- ➔ Transport the device carefully.
- ➔ Do not hold the device by the joystick to carry it.
- ➔ Store the device in compliance with the storage conditions.
- ➔ Avoid placing near heaters and moisture.

10.1 Disassembly

1. End the current session.
2. Switch off the device.
3. Disconnect the cable from the computer/laptop and the power adapter.



Fig. 10-1: Disassembly

4. Loosen the screw connection of the Y cable and pull it out.
   ⚠ **Only pull on the plugs, not on the cables itself.**

10.2 Storage Conditions

Ambient temperature range	-10 – +55 °C
Relative humidity, including condensation	10 – 95 %
Air pressure range	700 – 1060 hPa

10.3 Transport Conditions

Ambient temperature range	-40 – +55 °C
Relative humidity, including condensation	10 – 95 %
Air pressure range	500 – 1060 hPa

10.4 Disposal



In accordance with Directive 2012/19/EC of the European Parliament and the Council of 4th of July 2012, and in accordance with German law governing the marketing, return and environmentally compatible disposal of used electrical and electronic devices, such appliances must be recycled and may not be discarded as household waste.

➔ Dispose the device in a compliant manner.

11 Terms of Warranty and Service

Please note our General Terms and Conditions (GTC) on our website www.oculus.com.

12 Technical Data

Measuring Head

Camera	digital CMOS camera
Light source	blue LEDs (475 nm, UV-free)
Processor	DSP with 2746 million floating point operations/s
Speed	100 recordings in 2 seconds (Cornea Fine Scan)
Dimensions W x D x H (measuring head)	278 x 320 – 400 x 502 – 532 mm 10.9 x 12.6 – 15.7 x 19.8 – 21.0 in
Weight (measuring head)	9.0 kg / 20.2 lbs

Measuring Range

Corneal topographer according ISO 19980	Type A
Curvature	3 – 38 mm 9 – 99 dpt
Accuracy	± 0.1 dpt
Reproducibility	± 0.1 dpt
Working distance	55 mm
Axial length	14 – 40 mm
Reproducibility	± 30 µm
Refraction	
Spherical measurement range	-10 D – +6 D (7 mm pupil)
Cylindrical measurement range	0 D – +6 D
Number of measurement points (Abberometer lenslets)	420 (7 mm pupil)

Power Adapter

Type	HEMG 49 (05150150)
Main conection	100 – 240 V AC
Frequency	50/60 Hz
Power input, max.	85 VA
Output voltage	24 V DC
Fuses	Integrated overcurrent shutoff

Power Supply

Output voltage	24V DC
Max. power consumption	35W

Lifecycle Expectancy

Lifecycle Expectancy	Up to 10 years

IT Specifications

The IT equipment (computer, monitor etc.) must meet the requirements defined in IEC 60950 or IEC 62368-1.

Recommended computer specifications	Intel® Core™ i5, 500 GB HDD, 8 GB RAM, Windows® 10, Intel® HD Graphics

Classification

According to IEC 60601-1	
Type of protection against electrical shock	Protection class 2
Level of protection against electrical shock	Type B

According to IEC 60825-1	
The unit contains a class 1 laser classified SLED	
Maximum output of the laser radiation	0.7mW
Single pulse duration Pulse count per examination	520ms 6x
Wavelength	880nm

CE Conformity

The device is a category IIa product.

CE 0123

Conformity assessment procedure according to (EU) 2017/745 MDR, Annex IX, Section I and III.

13 Annex

13.1 Electromagnetic Compatibility (EMC)

Electrical medical devices are subject to special precautionary requirements with respect to EMC, and must be installed and operated according to the EMC instructions provided in the accompanying documents.

OCULUS devices and systems are suitable for use in environment in professional health care facilities, such as doctors' offices or clinics; however, they must not be used in proximity to HF surgical units or inside of the HF shielded room of an ME system for magnetic resonance imaging.

No special measures must be observed for OCULUS devices and systems.



Note

Portable and mobile HF communication devices may interfere with medical electrical devices and potentially interfere with their performance.

The device is intended for use in an electromagnetic environment with uncontrolled radiated RF interference. The user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment:

➔ Portable RF communications equipment (including peripherals such as antenna cables and external antennas) may not be used closer than 30 cm (12 inches) to any part of the device.

Definition of the minimum operating quality or essential performance criteria:

- A short interruption of the USB connection during the examination is permissible because it will not affect the diagnosis, treatment and observation.



Caution

Use of accessories, transducers, and lines not specified by OCULUS may result in increased emissions or decreased immunity of the device.

➔ In connection with the device only use accessories, transducers, and lines that are specified by OCULUS.

➔ Do not use accessories, transducers, and line that are specified by OCULUS with other devices.

To achieve conformance with IEC 60601-1-2 requirements, use the following devices, accessories, transducers, and lines:

Description	
Pentacam® AXL Wave	
Cable with connector plug, EU standard	2.5 m (98.4 in)
Cable with connector plug, US standard	2.5 m (98.4 in)
Power adapter HMEG 49	24 V, 2,1 A
Y cable with galvanic isolation	2 m

13.2 Guidance and Manufacturer's Declaration: Electromagnetic Emissions

Electromagnetic Emissions		
The OCULUS Pentacam® AXL Wave is intended for operation in the electromagnetic environment specified below. The user of the Pentacam® AXL Wave should ensure that it is being used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Pentacam® AXL Wave uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF-emissions CISPR 11	Class B	
Harmonics emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	complies	

13.3 Guidelines and Manufacturer's Declaration – Electromagnetic Immunity

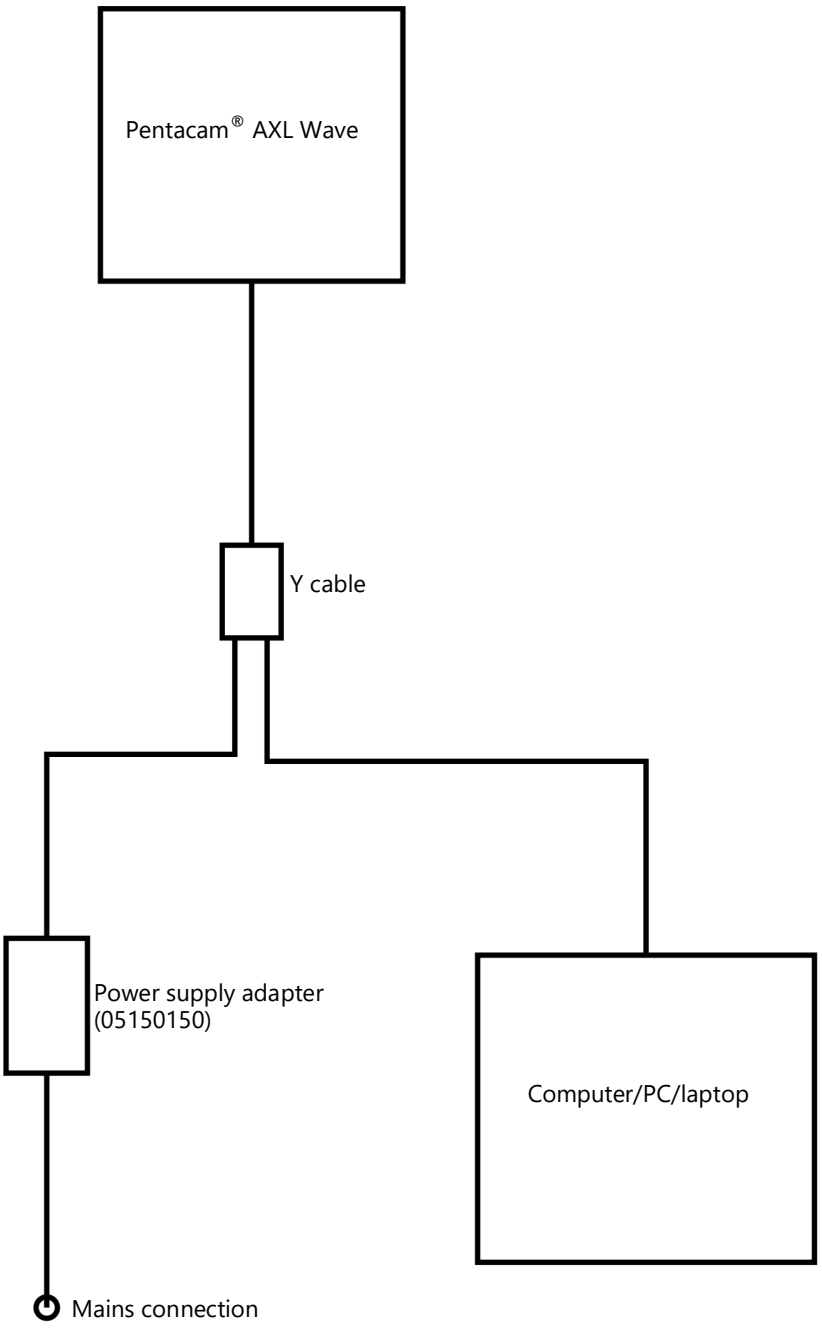
Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	± 8kV ± 15kV	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electrical fast transient/bursts IEC 61000-4-4	± 2kV for power supply lines 100kHz repetition frequency ± 1kV for input/output lines	± 2kV ± 1kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pentacam® AXL Wave requires continued operation during power mains interruptions, it is recommended that the Pentacam® AXL Wave be powered from an uninterruptible power supply or battery.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	$3V_{eff}$ 150KHz to 80Mhz 6V in ISM- and amateur radio frequency bands between 150kHz and 80MHz 80% AM to 1kHz	V_{eff} = 3V	Portable and mobile RF communications equipment should be used no closer to any part of Pentacam® AXL Wave, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 80MHz to 800MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interferences may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2,7GHz 80% AM at 1kHz		
Note 1:	At 80Hz and 800MHz, the higher frequency range applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Pentacam® AXL Wave is used exceeds the applicable RF compliance level above, the Pentacam® AXL Wave HR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Pentacam® AXL Wave. b. Over the frequency range 15KHz to 80MHz, field strengths should be less than 3V/m.			

13.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Pentacam® AXL Wave			
The Pentacam® AXL Wave in intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pentacam® AXL Wave can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pentacam® AXL Wave as recommended below, according to the maximum output power of the communications equipment.			
	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	150KHz to 80Mhz d = 1.2 √P	80MHz to 800MHz d = 1.2 √P	800MHz to 2.5GHz d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1:	At 80MHz and 800MHz, the separation distance for the higher frequency range applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

13.5 Description of the Connection



13.6 Data Sheet HEMG 49-S240210-7 (05150150)

HiTRON

UNIVERSAL INPUT AC-DC MEDICAL & ITE APPLICATION EXTERNAL DESKTOP SWITCHING ADAPTER 48-50 WATTS GREEN POWER SINGLE OUTPUT HEMG49 SERIES



FEATURES:

- **ACCOMMODATE UNIVERSAL AC INPUT**
- **MEET MEDICAL STANDARDS IEC60601-1 & ITE STANDARDS IEC60950-1**
- **EMI MEET EN 55011 & EN55022 / FCC CLASS B**
- **MEET ENERGY STAR LEVEL V & CEC LEVEL IV**
- **CE MARKING COMPLIANCE**

SPECIFICATION

INPUT SPECIFICATION

Input Voltage: Typical 90-264Vac.
Input Connector: 3 pole AC inlet IEC320-C14(DT7) / 2 pole AC inlet IEC320-C8(DT8).
Input Frequency: 47-63Hz.
Inrush Current: 12Arms (52Apk) at 230Vac.
Input Current: Typical 0.91A at 115Vac/ 0.57A at 230Vac.
Dielectric Withstand: Meet IEC60601-1 & IEC60950-1.
EMI: Meet EN55011 & EN55022 / FCC Class B.
Hold-up Time: Typical 12mS at 115Vac. Typical 70mS at 230Vac.
Over Temp. Protection: Optional (NTC circuit).
Earth Leakage Current (Class I) : Less than 0.3 mA.
Touch Leakage Current (Class I & II) : Less than 0.1mA.
No Load Power: Less than 0.3W at 230Vac

OUTPUT SPECIFICATION

Output Voltage: See Ratings Chart.
Output Current: See Ratings Chart.
Output Wattage: Typical 48-50Watts.
Output Connector & Cord: Optional.
Line Regulation: Typical 0.1%.
Load Regulation: Typical ±1.5-3.0%.
Noise & Ripple: 1.0% peak to peak.
OVP: Built-in by latch circuit.
Adjustability: Factory set.
Over Current Protection (OCP):
Fully protected against output overload and short circuit.
The PSU will shut down after OCP is activated.
Consult the factory for OCP setting.

GENERAL SPECIFICATION

Efficiency: Typical 87%-88% (various with the output voltage)
Switching Frequency: Typical 65KHz.
Circuit Topology: Fixed Frequency Flyback circuit.
Transient Response: Output voltage returns in less than 5.5mS following a 50% load change.
Safety Standard: Meet Medical IEC60601-1 & ITE IEC60950-1, Class I for DT7(C14) or Class II for DT8(C8)

Operating Temperature: 0°C to +40°C.
Storage Temperature: -20 to +85°C.
Cooling: Free air convection.
Construction: Impact resistant thermo-plastic enclosure case.
Power Density: 3.14-3.27Watts. / Cubic inch.
Desktop Format.

NOTE: (1) All measurements are at nominal input, full load, and +25°C unless otherwise specified.
(2) Load regulation is measured at 115Vac or 230Vac in percentage to indicate the change in output voltage as the load varied from half load to full load (±%).
(3) The exact obtainable load regulation depends upon the output cord selected and load current.
(4) Due to requests in market and advances in technology, specifications subject to change without notice.

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For the details of safety approval, please consult the factory.

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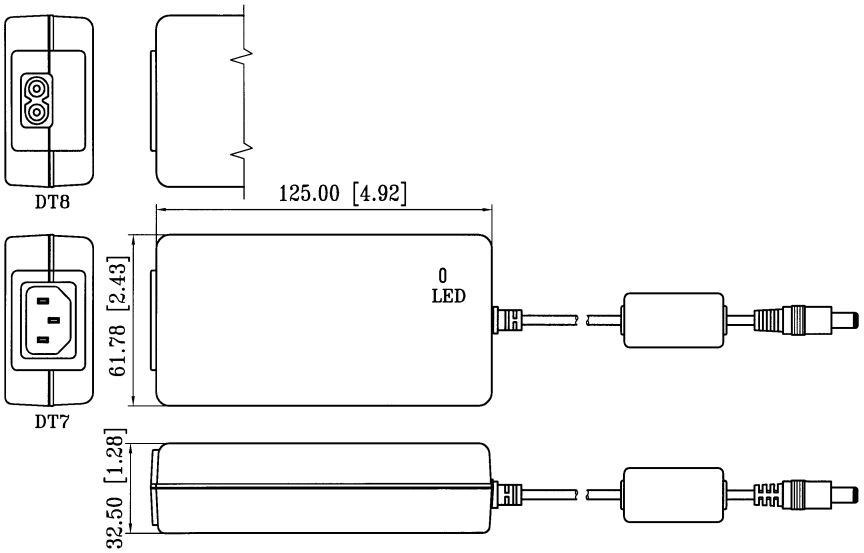
OUTPUT VOLTAGE / CURRENT RATINGS CHART

SINGLE OUTPUT

MODEL NO.	AC INLET	O/P VOLTAGE	O/P CURRENT
HEMG49-S120400-7	IEC320-C14(DT7)	**12.0Vdc**	4.0A
HEMG49-S120400-8	IEC320-C8(DT8)	**12.0Vdc**	4.0A
HEMG49-S150330-7	IEC320-C14(DT7)	**15.0Vdc**	3.3A
HEMG49-S150330-8	IEC320-C8(DT8)	**15.0Vdc**	3.3A
HEMG49-S240210-7	IEC320-C14(DT7)	**24.0Vdc**	2.1A
HEMG49-S240210-8	IEC320-C8(DT8)	**24.0Vdc**	2.1A

MECHANICAL DIMENSIONS: MM [INCHES] **WEIGHT:** 373.0g (13.2 Oz.)



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13.7 Instructions for Integration into an IT-Network

The device, in conjunction with the connected computer and the device software running on it, forms a programmable electrical medical system (PEMS) according to IEC 60601-1.

It is essential that you follow the section → Chap. "Instructions on Cyber Security" (Page 14) of → Chap. "Safety" (Page 10) in the device instructions for use.

Please note the following information for implementing an integration of the PEMS into an IT-Network:

The purpose of integrating the PEMS into an IT-Network can be:

- Licensing by local license server
- Storage and retrieval of the examination data on a local network drive
- Printing
- Data export
- DICOM workflow

Required characteristics of the IT-Network into which the PEMS is to be integrated:

- Prefer wired LAN connection
- IPv4 network
- Fast-Ethernet (100 Mbit/s minimum)

Required configuration of the IT-Network into which the PEMS is to be integrated:

- Licensing: required opened ports: 3968 TCP; 51371 - 51372 UDP
- Storage, printing, data export: File and Printer Sharing for Microsoft Networks (SMB 3.0 or higher - required opened port: 445)
- DICOM Storage Service Class = PACS
- DICOM Worklist Management Service Class (Modality Worklist Server)

Technical specifications of the network connection with the PEMS, including the specifications of data security:

- Refer to the section → Chap. "Instructions on Cyber Security" (Page 14) of → Chap. "Safety" (Page 10) in the device instructions for use.
- Refer to the "Floating License Key - License management for software options" instructions for use (if applicable)
- Refer to device specific DICOM interface description (if applicable)

The intended flow of information between PEMS, the IT-Network and other devices in the IT-Network and the intended routing through the IT-Network

- License handling from local license server to PEMS and vice versa
- Storage and data export to local network storage and loading from local network storage
- Printout to local printer

List of hazard situations that result from the IT-Network being unable to provide the features that are required to fulfill the purpose of integrating the PEMS into to meet the IT-Network:

- Loss of data
- unsuitable data exchange
- Data corruption
- unsuitable temporal data allocation
- unexpected data reception
- unauthorized access to data

Information

Connection of the PEMS to an IT-Network that includes other equipment could result in previously unidentified risks to patients, operators or third parties.

The responsible organization should identify, analyze, evaluate and control these risks.

Subsequent changes to the IT-Network could introduce new risks and require additional analysis.

Changes to the IT-Network include:

- changes in IT-Network configuration
- connection of additional items to the IT-Network
- disconnecting items from the IT-Network
- update of equipment connected to the IT-Network

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