OCULUS PENTACAM® AXL

Measurement and evaluation system
for the anterior segment of the eye

INSTRUCTIONS FOR USE

OCULUS®

Preface

The Pentacam® AXL was manufactured and tested based on strict quality criteria. Proper use of the device is essential for ensuring safe operation. For this reason, please thoroughly familiarize yourself with the content of the user information prior to commissioning. In particular, observe the safety instructions.
With the device, you receive the following user information:

- **Instructions for Use:** Description of patient data management, default settings in the Pentacam® program and the measurement process
- **User Guide:** Description of all functions of the examination and evaluation software as well as further information on patient data management
- **Software Installation:** Description of the installation of the Pentacam® software and the corresponding drivers
- **Floating License Key:** Description of how to use the device within a network
- **Interpretation Guide:** Presentation of real-life use cases

Minor deviations in the figures illustrated here to the device that was in fact delivered are possible for development reasons.
If you have any additional questions or require further information about your device, please feel free to call, email, or fax us. The OCULUS Service Team will be happy to assist you.

OCULUS Optikgeräte GmbH

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Revision: Rev06

Table of Contents

1 Scope of Delivery

Product and Accessoires
Pentacam® AXL
■ x-y base ■ Cograil ■ Cover ■ Sliding plate ■ Chinrest paper ■ Head and chin rest ■ Test eye
Pentacam® AXL accessories: ■ Power supply ■ Dark sheet ■ Washing manual ■ Wire clip ■ Hexagon screwdriver
■ Instructions for Use ■ User Guide ■ Software Installation
Additional accessories: ■ Dustcover ■ Hard drive, package ■ Y cable with galvanic isolation 2m ■ Extension cable for Y cable 4m ■ Electric cable EU ■ Electric cable Switzerland ■ Electric cable Argentina ■ Electric cable US ■ Electric cable GB ■ Electric cable Australia

Standard Software
Pentacam® AXL Standard Software
■ Fast Screening Report ■ 1 Large Color Map ■ Virtual Eye ■ Tomography ■ 4 Maps Refractive ■ General Overview ■ Anterior Segment Tomography ■ Topometric / KC Staging (Belin ABCD Keratoconus Staging) ■ Belin ABCD Progression Display ■ Iris Camera and Automatic HWTW Measurement ■ 3D Anterior Chamber Analysis ■ Compare 2 Exams ■ Compare 2 Exams Scheimpflug Images ■ Scheimpflug Image Overview

Optional Software Module
Screening Package
■ Belin/Ambrósio Enhanced Ectasia Display ■ Corneal Optical Densitometry ■ Show 2 Exams ■ 4 Maps Selectable
Refractive Package
■ Corneal Optical Densitometry ■ Refractive Display ■ Pachymetric Display ■ 4 Maps Selectable ■ Compare 4 Exams ■ 2 Exams Topometric ■ 2 Exams Pachymetric ■ Corneal Rings
Cataract Package
■ PNS and 3D Cataract Analysis ■ Cataract Pre-OP Display ■ Aberrometry Cornea ■ Corneal Power Distribution ■ Compare 4 Exams ■ Show 2 Exams Topometric ■ Show 2 Exams Pachymetric ■ 4 Maps Topometric ■ 4 Maps Anterior Chamber ■ Total Corneal Refractive Power (TCRP) ■ True Net Power (TNP) ■ Anterior Chamber Depth ■ Anterior Chamber Angle at Scheimpflug Images

Optional Software-Single License
Holladay Report und Holladay EKR Detail Report
3D pIOL Simulation and Aging Prediction
IOL Calculator
DICOM
Belin/Ambrosio Enhanced Ectasia Display
Corneal Optical Densitometry
Contact Lens Fitting Software incl. Fourier Analysis

We reserve the right to change the scope of delivery in line with ongoing 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 → Chapter 12 (page 69).

- The software version of the Patient Data Management appears in the settings of the Patient Data Management software.
- The software version of the Pentacam® program appears in the settings.
- The minimum screen resolution of the Pentacam® displays is 1280x720 with a text size of 100%.

2 Safety Instructions

All safety-relevant instructions on the use of the device are only provided in the Instructions for Usefor the device. This is why it is mandatory that you have fully read and understood the Instructions for Use prior to using the device.

- ➔ Carefully read through the Instructions for Use.
- ➔ Keep the Instructions for Use in good condition near the device.
- ➔ Observe the legal regulations with regard to accident prevention.

2.1 Symbols

2.1.1 On the Device / Type Plate

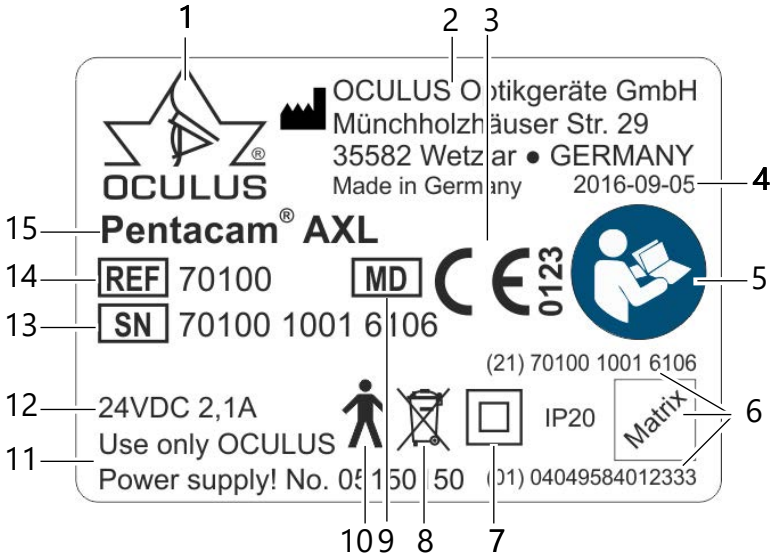


Fig. 2-1: Type Plate (example)

No.	Description	No.	Description
1	Manufacturer logo	8	Do not dispose of in household trash
2	Name and address of the manufacture	9	Medical device
3	CE mark and no. of notified body	10	Application part type B
4	Date of manufacture	11	Power adapter details
5	Observe the Instructions for Use	12	Power supply
6	UDI number consisting of: top: UDI PI (production identifier) middle: machine-readable matrix code bottom: UDI DI (device identifier)	13	Serial number
		14	Article number
		15	Device name
7	Protection class		

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 that may cause severe injuries.

Caution
Identifies a potentially dangerous situation that may cause minor injuries.

Note
Identifies situations that may cause damage to the device or result in false examination results.

Identifies important application instructions and important information about the product.

> This symbol denotes menu paths.
For example, to start a new examination:
Pentacam® > Examination > New
Which means:
➔ Select the menu “Examination” from the menu bar.
➔ Select the menu item “Scan”.

[...] Menu items and buttons are shown in brackets

2.2 Safety Instructions for Use

Caution

Operating the device incorrectly may cause injuries to a person or damage the device.

➔ Observe and follow the safety instructions in this Instructions for Use.

Caution

Unapproved modifications to the device may cause injuries to a person or damage the device.

➔ This device and the corresponding lifting table must not be modified without the prior consent from the manufacturer.

➔ Any changes or modifications must only be carried out by OCULUS Service and/or an authorized dealer.

Report any severe incidents that occur in connection with the product to the manufacturer (vigilance@oculus.de) and the competent authority of the Member State where you and/or your patient are located.

2.2.1 Instruction for the Operation of an ME System

The device and a connected computer form a medical electrical system (ME system) in accordance with IEC 60601-1. Any other device, such as a printer, that you connect will become a part of the ME system.
All devices belonging to the ME system must meet IEC 60601-1 or IEC 62368-1 requirements.

2.2.2 Instructions on Electrical Safety

Warning

Personal injury and/or property damage due to an incorrect level of safety

Connecting the device with its non-medical electrical equipment (such as data processing equipment) to a medical electrical system must not result in a safety level for the patient that is less than IEC 60601-1. If as a result of this connection the leakage current threshold is 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 scope of delivery.
- ➔ The computer used in connection with the device must meet the specifications that are listed in → Chapter 12 "Technical Data" (page 69).

Warning

Personal injury and/or property damage due to unsafe multiple socket outlet

When using a multiple socket outlet to connect the device, observe the following instructions:

- ➔ Use an multiple socket outlet in accordance with IEC 60601-1, section 16 requirements.
- ➔ Do not place the multiple socket outlet on the floor.
- ➔ Use no more than one multiple socket outlet.
- ➔ Only use this multiple socket outlet to connect the device and, where applicable, the corresponding computer.
- ➔ When using a multiple socket outlet, it must be supplied with an isolating transformer.
- ➔ If using a new computer for the device, have the electrical safety inspected. Call OCULUS Service to do this.

Warning

Personal injury and/or property damage due to electromagnetic interference

Portable and mobile HF communication devices (high frequency) may interfere with medical electrical devices → Chapter 2.2.1 "Instruction for the Operation of an ME System" (page 12).

- ➔ Make sure that portable and mobile HF communication devices are not causing any interference emissions.
- ➔ Recommendation: Keep a minimum distance, please observe → Chapter 15.1 "Electromagnetic Compatibility" (page 74). If the distance is less, you must make sure that the device is working properly.

2.2.3 Instructions for Laser Use

Caution

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

The Pentacam® AXL contains a Class 1 laser according to IEC 60825-1: 2014. It is an encapsulated laser system. When the Pentacam® AXL 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.

2.3 Instructions for Cybersecurity

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.

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 → Chapter 15.5 "Instructions for Integration into an IT-Network" (page 82).

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 Siehe “Precautionary Measures Against Unauthorized Access” auf Seite 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 Overview of the Device Components

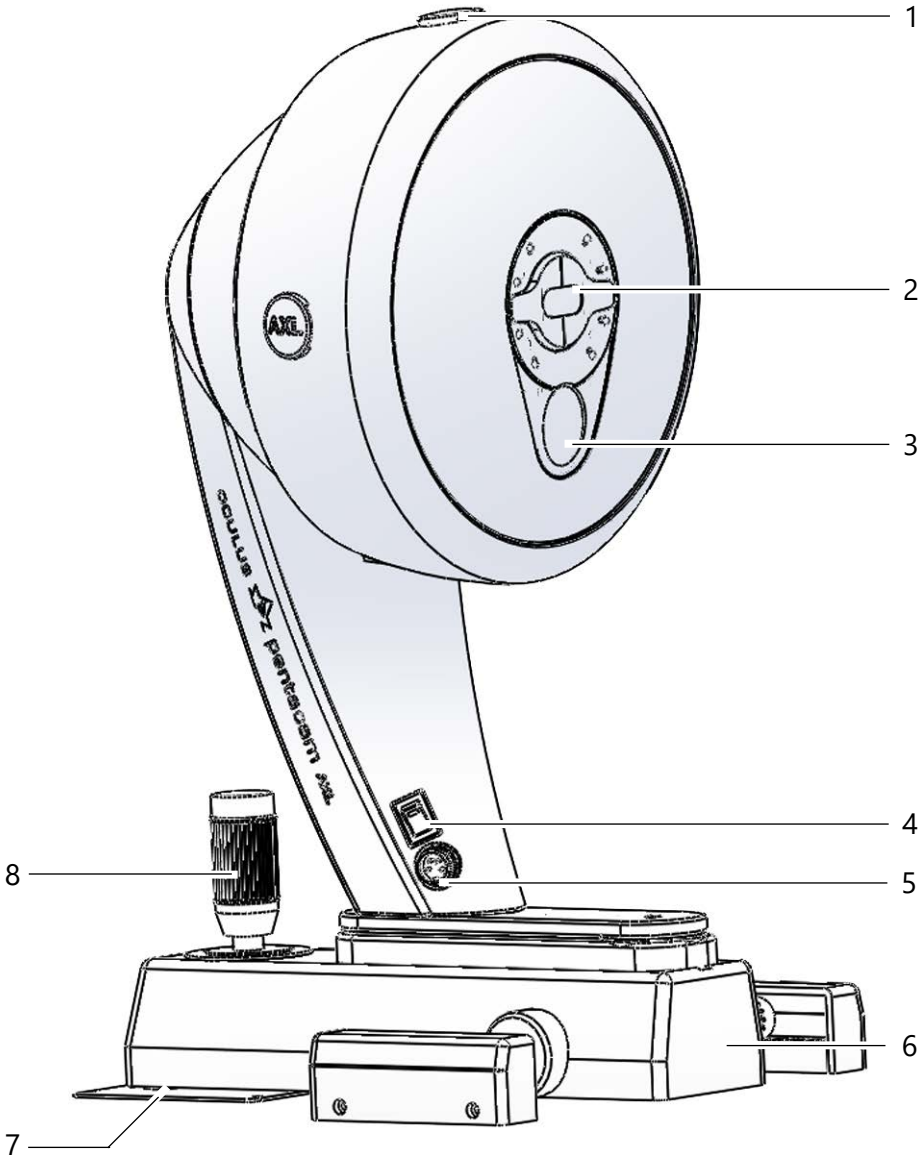


Fig. 3-1: Device Components

No.	Description
1	Ventilation opening
2	Measuring window
3	Camera opening
4	On/off switch with indicator light
5	Y-cable connector
6	Cross slide
7	Sliding plate with circular markings
8	Joystick

3.2 How the Device Works

While rotating around the eye, the Pentacam® 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 interferometry.
Scheimpflug images can be captured at two seconds.
Up to 138000 genuine height values are measured and analyzed 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 rear surfaces of the cornea and the pachymetry 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.
Color images displayed on the screen show the results of the measurement.
A rotatable 3D model displays the front and rear surfaces of the cornea, the iris and the lens.

OCULUS shall not be liable in any form for further use of the data recorded by a Pentacam® and for the evaluations it has calculated.

3.3 Intended Purpose

3.3.1 Intended Use

The Pentacam® AXL is designed to take photos of the anterior segment of the eye which includes the cornea, pupil, anterior chamber and lens of the eye. To evaluate:

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

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

3.3.2 Contraindication

None known

3.3.3 Possible Side Effects

- After-image
- Headache
- Vertigo
- Tearing eyes

3.3.4 Intended Users

The Pentacam® AXL is intended exclusively for professional use:

- In Eye specialists practices
- In Clinics
- At optician or optometrist shots

The Pentacam® AXL is intended for use by trained staff:

- Who, based on their knowledge, training and practical experience, can ensure professional handling.
- Who have been instructed by OCULUS personnel or an authorized dealer prior to putting the device into operation.

3.3.5 Patient Group

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

4 Setup and Connection

4.1 Setup and Operating Conditions

Temperature	+10°C to+35°C
Air humidity	30% to 90%
Air pressure	800hPa to 1060hPa

- Before installing the device, consider the transport, storage and current room temperature, where the device is to be installed.
- The difference between the temperature of the installation room and the storage and transport temperature should not be more than 10°C to avoid fogging of the internal optics.
  - If the difference in temperature is greater than 10° C, leave the system at least for 6 hours until the temperature of the instrument has adapted to room temperature.

4.2 Instructions for Setup and Connection

- ➔ Only OCULUS or an authorized dealer is allowed to set up and to connect the device.
- ➔ Place the device so that direct light cannot affect the measurement.
- ➔ 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.
- ➔ Do not expose the device to any vibrations, shocks, contaminants, moisture, or high temperatures.
- ➔ 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 Pentacam® AXL 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.

4.3 Patient Environment Information

The patient environment is the area in which patients may come into contact with any part of the system or where the patient may come into contact with another person that was in contact with the system.

➔ Only use devices in the patient environment that conform to IEC 60601-1.

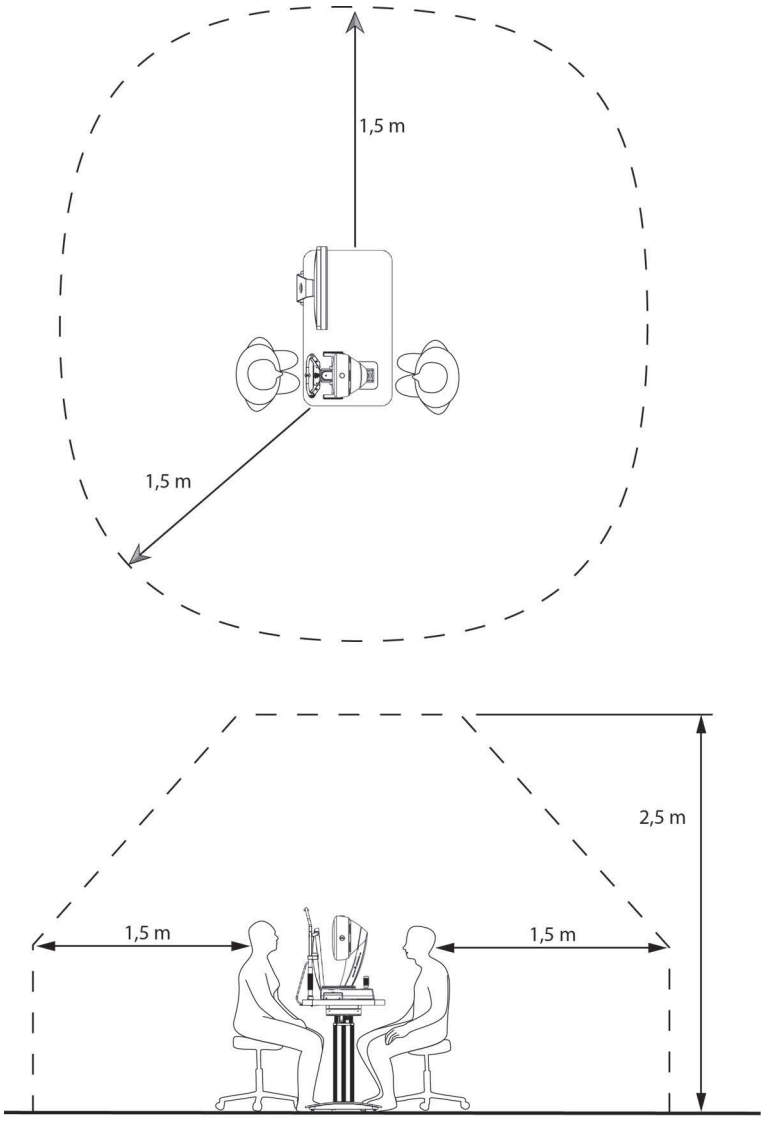


Fig. 4-1: Patient Environment

4.4 Electrical Connection

Caution

Electrical safety hazard

- ➔ Do not use the device in the direct proximity of other devices.
- ➔ Do not stack the device with other devices.
- ➔ If you use the device near or stacked with other devices, you must ensure that the device functions properly.
- ➔ Only use the power adapter listed in → Chapter 12 (page 69).
- ➔ When using a multiple socket outlet to connect the device, the multiple socket outlet must meet IEC 60601-1 requirements.
- ➔ Do not place the multiple socket outlet on the floor.
- ➔ Only use this multiple socket outlet to connect the device and, where applicable, the corresponding computer.

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 you do not connect the device properly, and the connection is live, the unit can be damaged within a short period of time.

- ➔ Do not use excessive force when connecting the electrical plug.
- ➔ Pay attention to the specifications on the nameplate.
- ➔ If the electrical plug is damaged, contact our service department or an authorized distributor 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.

➔ The first step is to switch on the PC or laptop.

➔ Then turn on the Pentacam® AXL with the on/off switch (position ON). The LED on the switch lights up green → fig. 4-2 (page 23).

4.6 Switching Off

➔ Close the Pentacam® program and close the Patient Data Management.

➔ Shut down the Windows operating system.

➔ 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 Pentacam® 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 distributor or our service department.

5 Patient Data Management

5.1 Starting Patient Data Management

You can enter and use the patient data by the patient data management.
After you have switched on the PC, it first loads the operating system.

➔ Click the [Pentacam] symbol. The user interface for the Patient Data Management appears.

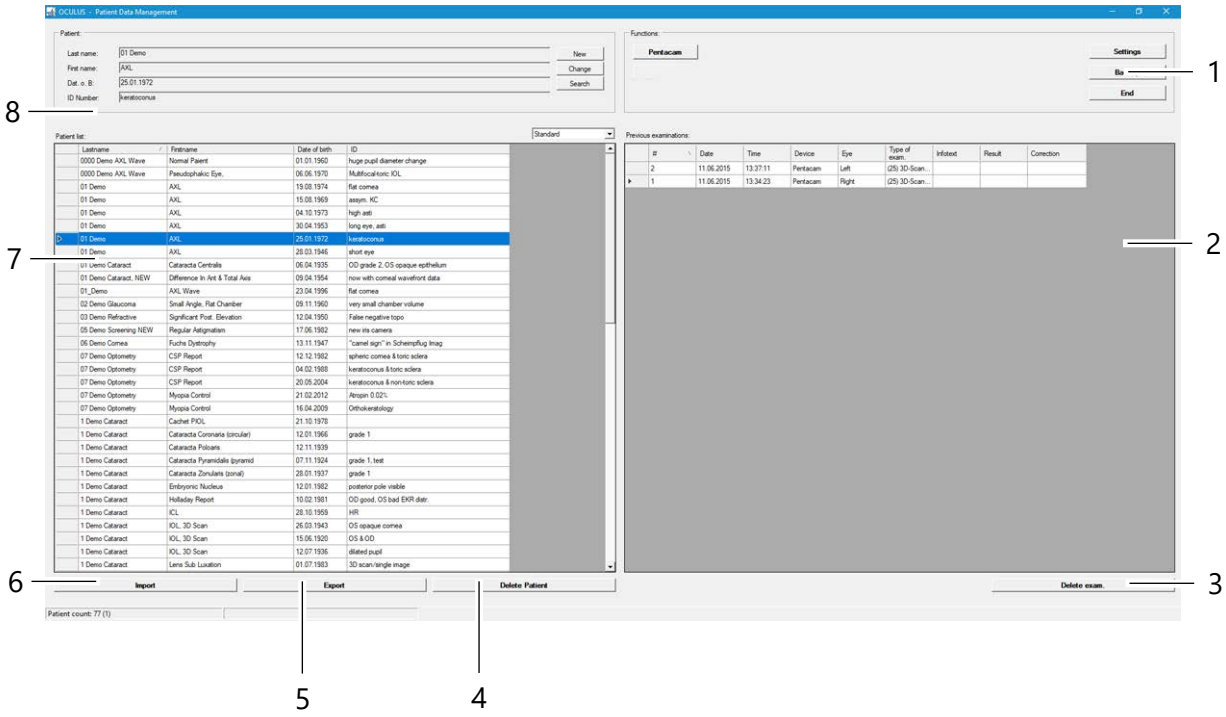


Fig. 5-1: Patient Data Management user interface

Nr.	Beschreibung
1	“Functions” group box
2	Previous examinations
3	[Delete exam.] button
4	[Delete Patient] button
5	[Export] button
6	[Import] button
7	Patient list
8	“Patient” group box

To get to the Pentacam® program, you must first enter a new patient or select an existing patient from the patient list.
For more information on Patient Data Management, refer to → Chapter 8 (page 52).

5.1.1 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.

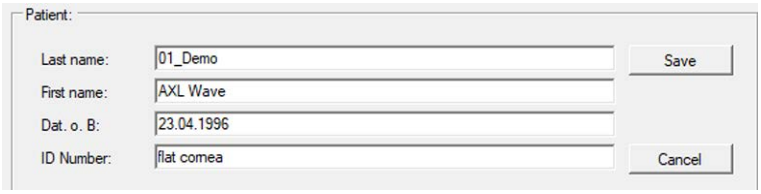


Fig. 5-2: Entering Patients

Optionally you can enter an ID number for the patient.

3. To save the data you entered, click [Save].
   The patient you have just entered now appears in the patient list.

5.1.2 Selecting an Existing Patient

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

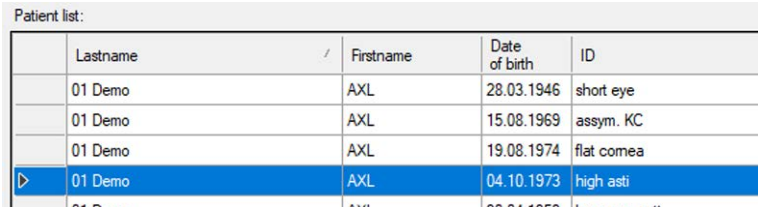


Fig. 5-3: Patient list

1. Choose [Search] to quickly find the patient you are looking for in the list.
2. Enter the patient's name or the first letter of the name in the “Last name” field. Alternatively, you can search for the patient using an ID number, first name or date of birth, assuming that one was assigned when the patient was first recorded.
3. In the list that appears, click the entry you were searching for to transfer the patient's name to the patient window. This also brings up a list of any previous examinations for that patient in the examination window (bottom right side).
4. Click on “End Search” to finish that process. The respective patient is still highlighted in blue.

Extended Patient Search: [Extended] Checkbox

➔ Click on the [Extended] checkbox.

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

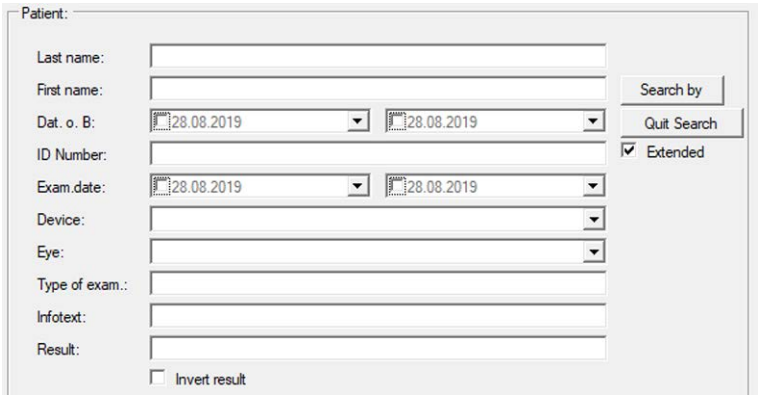


Fig. 5-4: Extended Search

5.2 Starting the Pentacam® Software

Switching from Patient Data Management to the Pentacam® program:

➔ After selecting a patient: Press the [Pentacam] button to start the Pentacam® program → fig. 5-1 (page 25).

or

➔ Double-click the selected patient name or an examination to start the Pentacam® program.

Proceed a test measurement if a message appears → Chapter 9 (page 58). If you do not proceed a test measurement, it will be stored in the Pentacam® program.

6 Pentacam® Program

As this instruction manual focuses on the device operating concept, the description of Pentacam® program functions is limited to starting the measuring process and loading previous examinations. The Reference manual contains detailed information on the functions of the Pentacam® program.

If no error message appears after starting the software with the device connected and switched on (for example component failure, camera not detected, missing references data, etc.), the device is safely ready for operation.

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

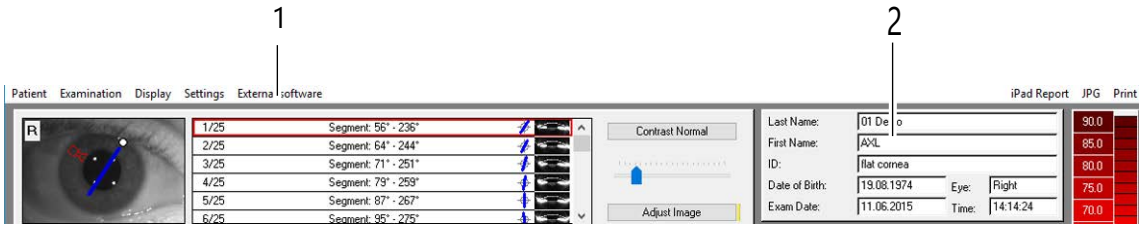


Fig. 6-1: Pentacam® program menu (upper section)

No.	Description
1	Menu bar
2	Examination and Patient data

Loading previous examinations

➔ Select the menu item [Examination] and click [Load].
The dialog box "Load Examination" appears.
➔ Make a selection by clicking the required examination.
➔ Confirm your selection by clicking [OK], or by double clicking.
The Pentacam® program will load the examination you have selected.

Starting a measurement

➔ Select the [Examination] tab and click [Scan].
The blue slit light is activated and the Scan menu → Chapter 6.1 (page 29) appears.

Helpful information

The Pentacam® program provides you a direct help. You can recognize that by a yellow mark.

This symbol appears for some measured values.
➔ Click on this symbol to show the corresponding message.
You must check the corresponding measured value.

6.1 Scan Menu

Switching from the Pentacam® program to the Scan menu:

➔ In the Pentacam® program → fig. 6-1 (page 28) select the menu item [Examination] and click [Scan].

6.2 Screen Layout

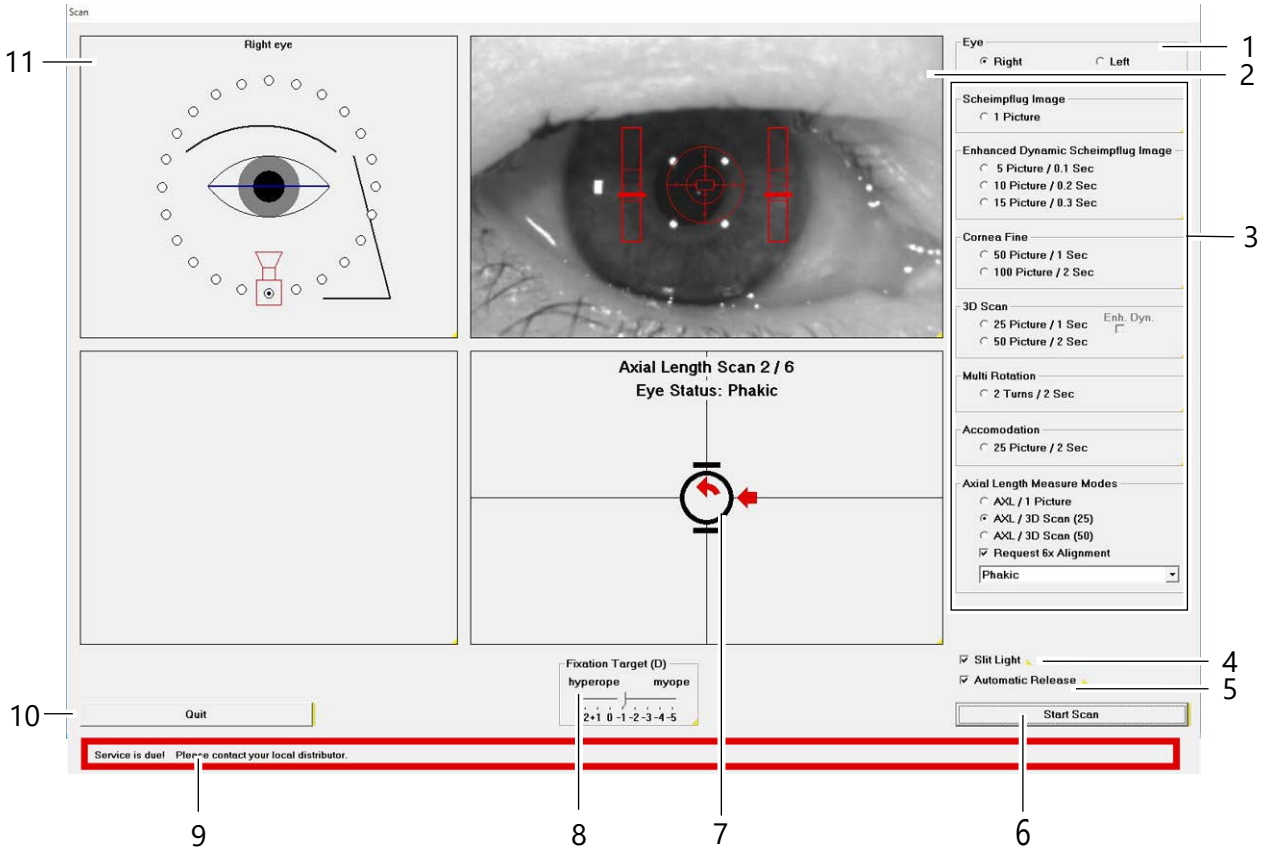


Fig. 6-2: "Scan" screen

Nr.	Beschreibung	Nr.	Beschreibung
1	"Eye" field	7	Adjustment window
2	Overview image with adjusting aid	8	Fixation Target
3	"Image Options" area	9	Message about device
4	[Slit Light] checkbox	10	[Quit] button
5	[Automatic Release] checkbox	11	"Orientation" field
6	[Start Scan] button		

- The eye currently being examined is detected automatically and is displayed in the "Eye" field.
- The Overview Image shows the pupil and a cross hair as an adjusting aid.
- You can set the type of image required for the respective examination in the "Image Options" area → Chapter 6.2.1 (page 30) and → Chapter (page 31).
  "Axis Length Measure Modes": Click a button to enable a measurement of the axial length. Select the eye status in the corresponding dropdown list.
  Eye Status:
  - Phakic: Default status. Presence of crystalline lens.
  - Aphakic: Absence of the crystalline lens.
  - Pseudophakic (Silicone IOL or similar): IOL of silicone or similar material implanted.
  - Pseudophakic (Acrylate): Intraocular lens made of Acrylat/Meatacrylate.
  - Pseudophakic, silicon-oil filled, after vitrectomy:
    previous vitrectomy with a silicon-oil-filled vitreous.
- 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.
- This line shows messages about the device, for example if a service is due.
- 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.

6.2.1 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 minimize 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. This type of image is suitable for a purely densitometric assessment of the lens.

"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 50 images takes longer of the patient provides the highest amount on measured elevation data. This type of examination is used for evaluating the cornea and anterior chamber.

"Cornea Fine" group box

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

"Multi Rotation" group box

- If you select this option, the camera will record Scheimpflug images from 50 different positions while performing a full rotation twice around the eye.

"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 -5D to +2D. The camera records the Scheimpflug images from a preselected camera position.

"Axial Length Measure modes" group box

1. Select this option for measuring the axial length.
   If you select this option, the desired mode for the axial length measurement is enabled.
2. 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 patients eye.
3. Read the message on the screen and give the patient a break for blinking.
4. Advise the patient to watch on the red blinking light. Click on the OK button to proceed with the 3D scan.
5. Follow the instructions on the screen to align the patients 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 interrupt.
"Request 6x Alignment" is activated by default and should just deactivated if the patient has problems to fixate the red blinking light.

[Enh. Dyn.] checkbox in the "3D Scan" group box

- Activating the "Enh. Dyn." function prolongs the exposure time per Scheimpflug image. The advantage is an accurate representation of phakic IOLs. If you select this recording mode, colors and evaluations are neither calculated nor displayed.

"Fixation Target" slider

- Use of the "Fixation Target" enables a better fixation of the patient. For this, the active "Fixation Target", i.e. the LED blinking red in the middle of the blue slit, can be shifted in steps of 0.5D. The object is to offset defects in the patient's vision and ensure a simpler method of fixation.

6.3 Information for recording Scheimpflug images

Type of examination	Examination mode	Images	Automatic measurement	Notes
Topography	3D scan	25-50	Yes	
Pachymetry	3D scan	25-50	Yes	
Analysis of the anterior chamber	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.
Axial length	AXL	6	Yes	Pay attention to eye status.

7 Measuring Procedure

Note

Improper setup may cause faulty measurements.

➔ Before first-time use: Allow OCULUS or an authorized dealer instruct you in the operation of the device.

Note

Faulty measurements if the device is not ready for operation.

➔ The device must have been switched on for at least an hour before taking measurements.

Note

Faulty measurements caused by slight movements by the patient.

Slight movements that may occur naturally may cause the patient to no longer be positioned adequately to the device.

➔ Only take measurements with the device if the patient is seated in a stationary chair. If the patient is seated in a rolling chair, lock the brake.

7.1 Instructions for Operation

➔ Before first use: Let OCULUS or an authorized dealer train you in the operation of the device.
➔ Never operate a damaged device.
➔ Only operate the device with the original accessories supplied by us and only when the unit is in technically perfect condition.
➔ Do not cover the ventilation openings.
➔ Do not touch the patient and the device at the same time.
➔ Make sure that the device cannot tip over by leaning against it or sitting on it.
➔ Do not put the device, including rechargeable battery or cable, down onto devices that produce heat, heaters (for example radiators), microwaves or similar.
➔ Only operate the device if you have understood the operating instructions.

Caution

The light emitted from this instrument is potentially hazardous. The longer the duration of exposure and the greater the number of pulses, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum output will exceed the safety guideline after 48 treatments.

7.2 Measuring Procedure to Measure the Axial Length

7.2.1 Before the Measurement

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 examiner has to select the eye status before every axial length scan.

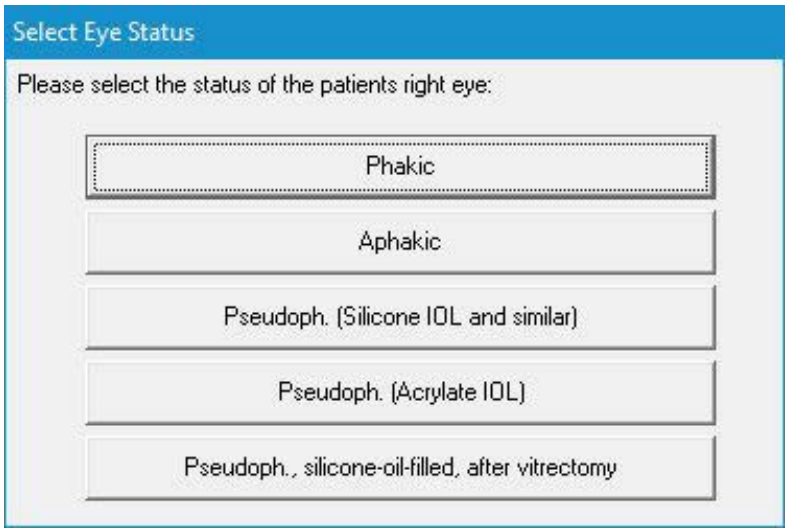


Fig. 7-1: Selection of Eye Status

1. To select the eye status open the scan menu and click on "Eye status"
   - Phakic: Default status. Presence of crystalline lens.
   - Aphakic: Absence of the crystalline lens. Correction of measured axial length by +0.200mm
   - Pseudophakic (Silicone IOL or similar): IOL of silicone or similar material implanted. Correction of axial length by +0.120mm.
   - Pseudophakic (Acrylate): Acrylat/Metaacrylate IOL implanted. Correction of axial length by +0.110mm.
   - Pseudophakic, silicon-oil filled, after vitrectomy: previous vitrectomy with a silicon-oil-filled vitreous. Correction of axial length by -0,692mm

Caution

Risk of incorrect measurement caused by unchecked plausibility

➔ Check both eyes on plausibility.

Recommended differences between both eyes should be below:

- Axial length AXL <0,3 mm
- Curvature <0,18 mm equals approximately in 1D (based on a refractive index of 1,3375)
- Difference of IOL power to reach emmetropia by same target refraction <1 D

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

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

Note: In pseudophakic eyes the anterior chamber depth is not declared but it is possible to measure the anterior chamber depth in the Scheimpflug images manually.

2. Start the Scan menu → Chapter 6.1 (page 29).
3. Make sure that the button "Automatic Release" is activated.
4. Make sure that the button "Request 6x Alignment" is activated.
   If "Request 6x Alignment" is activated, the axial length measurement starts only if the patient is fixating correctly. The measurement starts automatically.
   "Request 6x Alignment" deactivated means: The axial length measurements are performed without any interrupt.
   "Request 6x Alignment" is activated by default. Just deactivate "Request 6x Alignment" if the patient has strong problems with fixation.
5. Adjust the table height.
6. Check that
   - fresh paper has been put onto the chin rest or the chin rest has been cleaned and disinfected → Chapter 10 (page 64).
   - the forehead rest has been cleaned and disinfected after each examination, → Chapter 10 (page 64).
   - the optical window is clean.
7. Ask the patient to place his or her head on the chin and forehead rest.
8. Do not touch the patient and the device simultaneously.

7.2.2 Rough Adjustment

9. The black ring marking between the chin rest and the forehead rest should be used for gauging the required height of the patient's eyes.

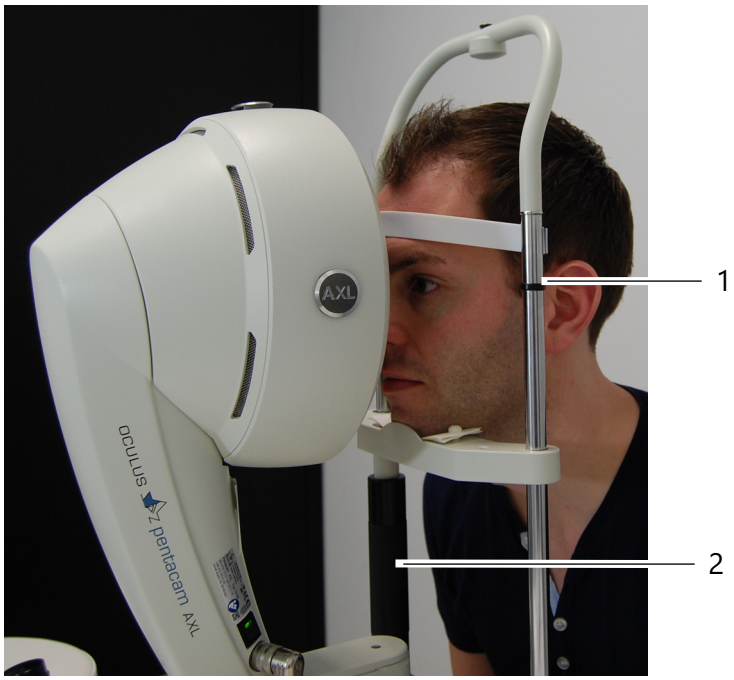


Fig. 7-2: Rough adjustment of the chin and forehead rest

No.	Description
1	Marking (black ring)
2	Twist grip

10. 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 level with the marking.

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

11. Example of a rough adjustment for the right eye: Move the cross slide until the marking at the end of the cross slide roughly coincides with the circle R on the sliding plate.

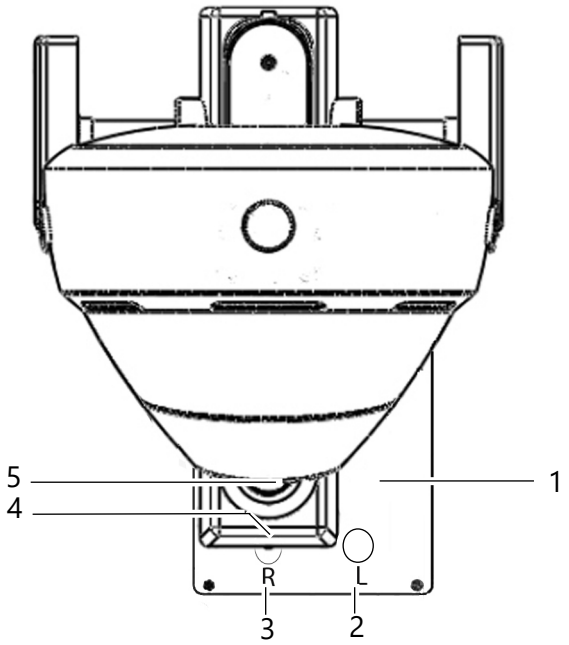


Fig. 7-3: Markings on the cross slide

Nr.	Beschreibung	Nr.	Beschreibung
1	Cross slide	4	Marking on the cross slide
2	Left marking	5	Joystick
3	Right marking		

12. Look at the patient's eye you are examining from one side and make sure that his/her eye is in front of the measuring window.
13. If necessary, adjust the position of the cross slide to the left or right.

7.2.3 Darkening the Room

14. 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 Pentacam®.
15. Advice the patient to look at the red fixation target/point.

7.2.4 Adjustment

16. Move the image with the cross towards the patient until the four infrared LED are clearly to see.

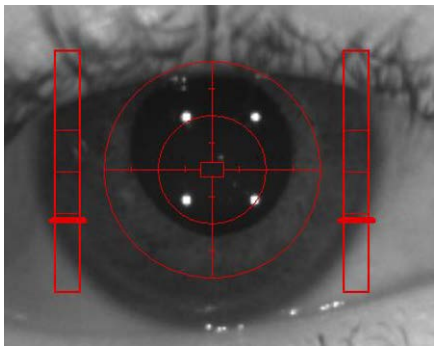


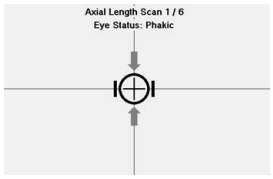
Fig. 7-4: Overview image

17. Focus the pupil image by moving the joystick towards the device or away from it.
    The bars on the right and left of the pupil will support you to find the correct position. The closer the marks to the middle of the bars are the better is the adjustment.
18. 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 anti-clockwise.
    The tentative final position of the camera is reached when the central corneal reflex is in the center of the box of the red cross hair.
19. 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.

You can use the adjusting aid of the fine adjustment alternatively, see
→ Chapter 7.2.5 “Fine adjustment” (page 39).

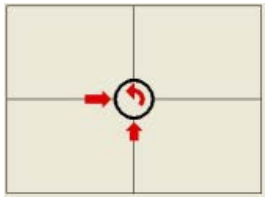
7.2.5 Fine adjustment

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



Example (with grey arrows): distance to patients eye is not correct.

21. Move the device towards or away from the patient.



Example (with red arrows): Move or rotate the joystick in the specified directions.

22. Move the joystick to the right.

23. Turn the joystick counter clockwise.

24. Move the joystick forwards.

Arrow	Camera movement	Joystick movement
→	right	Move the joystick to the right
←	left	Move the joystick to the left
↑	forward	Move the joystick toward the patient
↓	back	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 black cross will appear in the center of the ring, surrounded by four black lines. The device will automatically begin measuring, alternately you can start the measuring procedure manually.

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

It may not be possible to carry out a measurement with manual release.

26. Ask the patient to blink normally, take a short break and proceed with the 3D Pentacam® scan.

27. Follow the instructions on the screen and then continue with the 3D scan.

28. Go to measurement → Chapter 7.2.4 "Adjustment" (page 38).

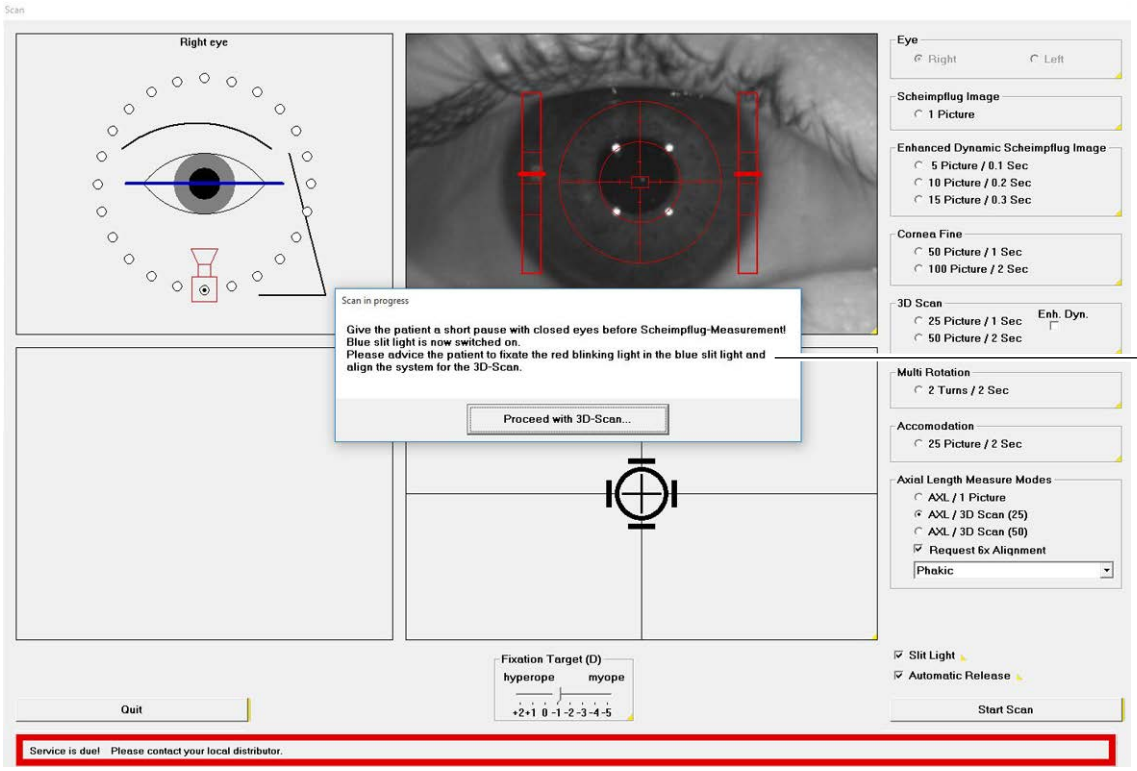


Fig. 7-5: Proceed with 3D-Scan

No.	Description
1	Message with instructions

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

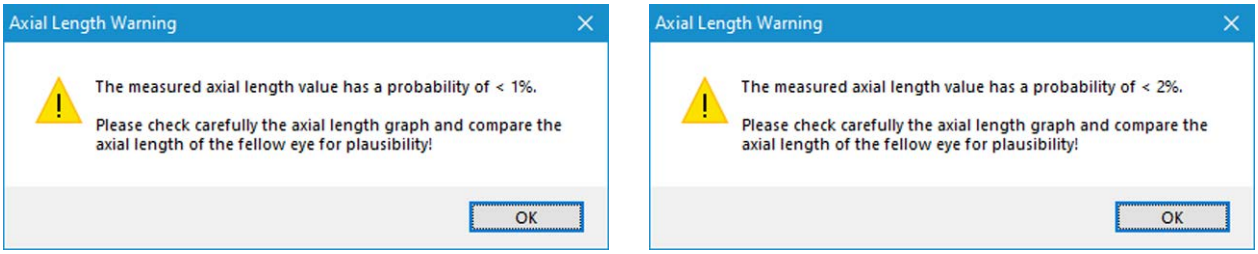


Fig. 7-6: Message: Plausibility check

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.

29. 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.

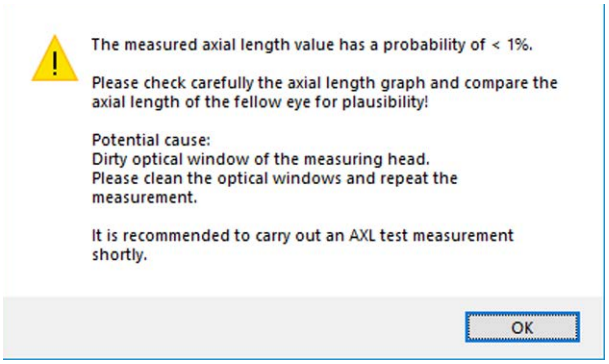


Fig. 7-7: Message: dirty optical window

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.

30. Repeat the measurement.

You must check the corresponding measured value.

7.3 Measuring Procedure for the Anterior Segment of the Eye

7.3.1 Default Settings

1. Start the Scan menu → Chapter 6.1 (page 29).
2. If necessary make changes to the image options for the particular part of the front of the eye that is to be examined.
   The default settings in the "3D Scan" options are "25 images/1 second".
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 → Chapter 10 (page 64).
   - the forehead rest has been cleaned and disinfected after each examination → Chapter 10 (page 64).
   - the illuminated slit with, 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.
6. Do not touch the patient and the device simultaneously.

7.3.2 Rough Adjustment

7. The black ring marking between the chin rest and the forehead rest should be used for gauging the required height of the patient's eyes.

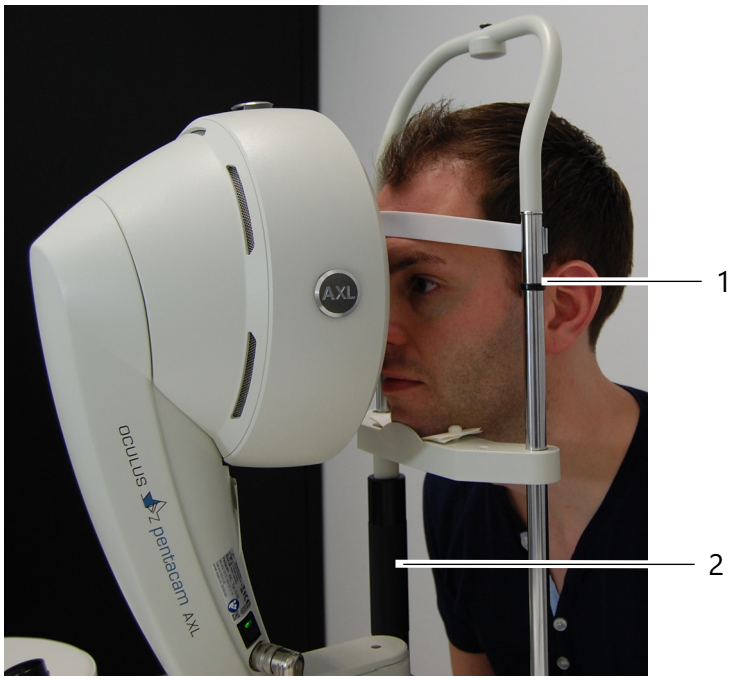


Fig. 7-8: Rough adjustment of the chin and forehead rest

No.	Description
1	Marking (black ring)
2	Twist grip

8. Adjust the patient's eye level using the twist grip → fig. 7-8 (page 42), item 2. The patient is positioned correctly when chin and forehead touch the rests and the eyes are level with the marking.

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

9. Example of a rough adjustment for the right eye: Move the cross slide until the marking at the end of the cross slide roughly coincides with the circle R on the sliding plate.

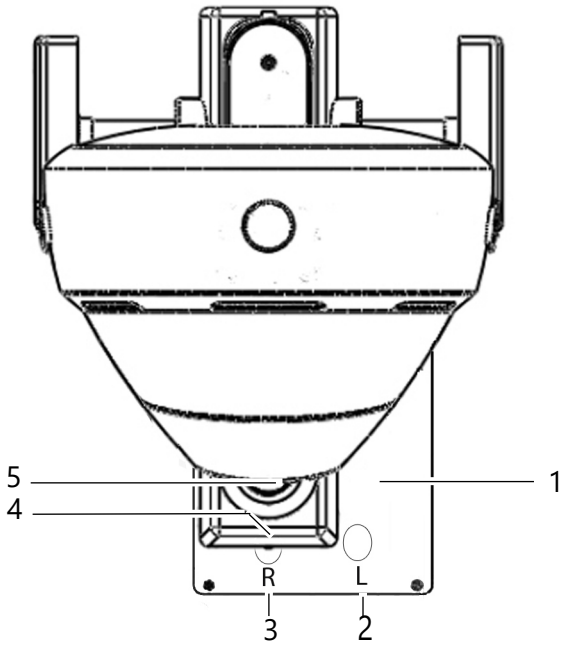


Fig. 7-9: Markings on the cross slide

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

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

Fig. 7-10: Slit light on the cornea

Note

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

7.3.3 Darkening the Room

12. 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.

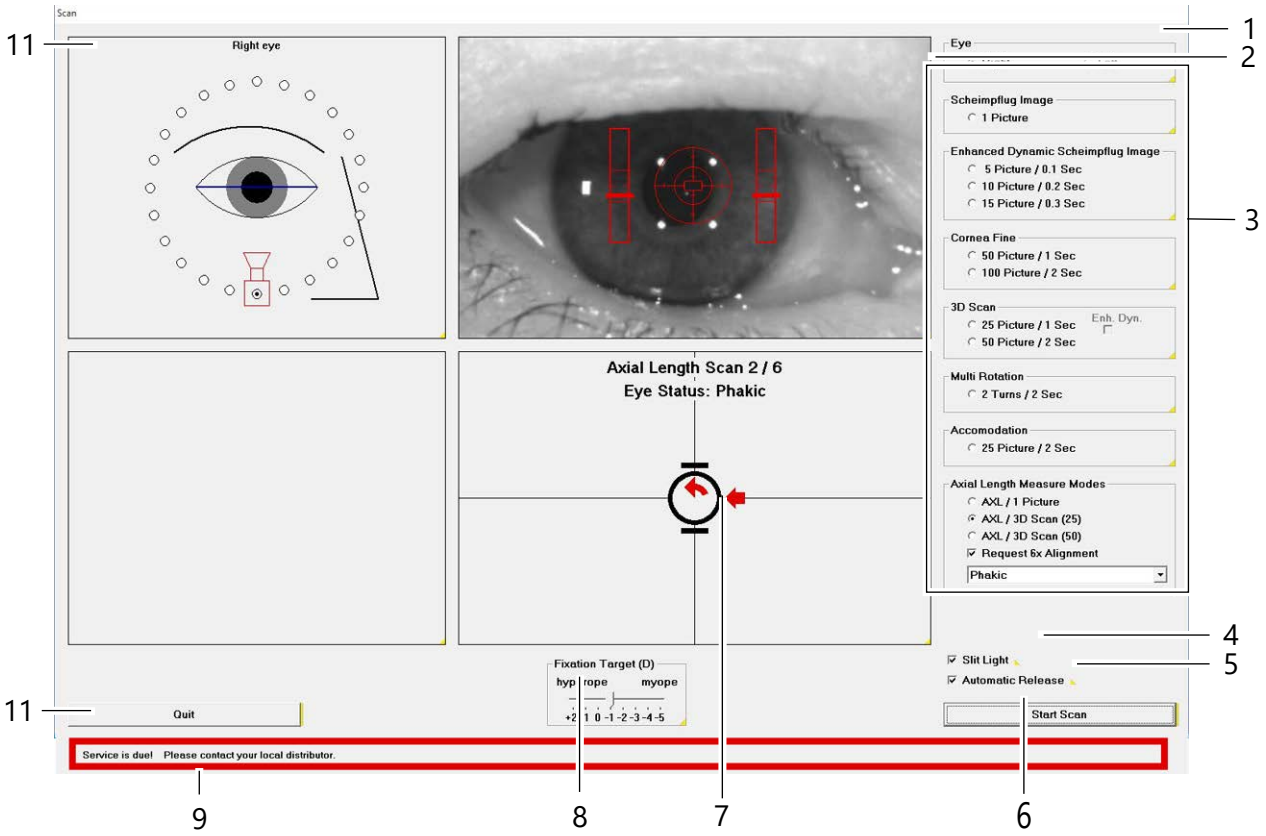


Fig. 7-11: "Scan" screen

No.	Description	No.	Description
1	"Eye" field	7	Adjustment window
2	Overview image	8	Fixation Target
3	"Image Options" area	9	Message about device
4	[Slit Light] checkbox	10	[Quit] button
5	[Automatic Release] checkbox	11	"Orientation" field
6	[Start Scan] button		

7.3.4 Adjustment

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

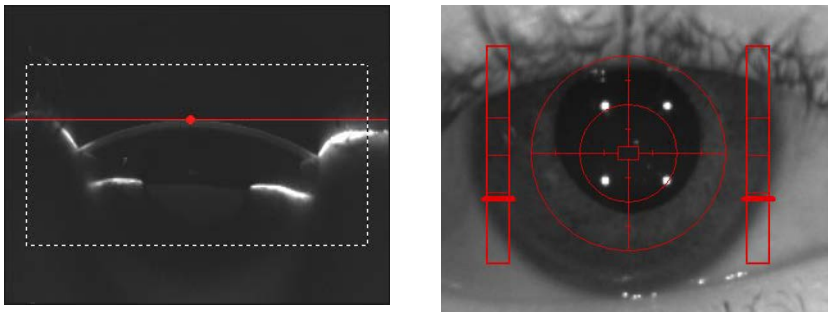


Fig. 7-12: Scheimpflug image (left)[aa] and overview image (right)

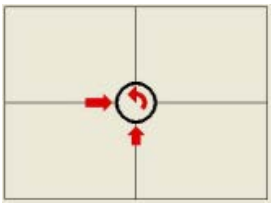
a. This screen is only available with a Pentacam® AXL image without an axial length measurement

The image is sharpest when the red dot coincides with the red line in the Scheimpflug image (relevant for Pentacam® AXL without an axial length measurement).

14. Focus the pupil image by moving the joystick towards the device or away from it.
15. Adjust the left/right position of the Pentacam® AXL and its height setting.
    Move the joystick to the left or right and rotate the joystick clockwise or anti-clockwise.
    The tentative final position of the camera is reached when the four infrared LEDs are sharp and the red cross hair is in the center of the pupil.
16. Ask the patient to widen his or her eye and not to blink.

The device triggers the measurement automatically.

7.3.5 Fine Adjustment

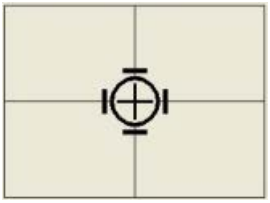


17. Make any fine adjustments required based on the information in the adjustment window. To do so, move the joystick in the specified directions.

Example:

18. Move the joystick to the right.
19. Turn the joystick counter clockwise.
20. Move the joystick forwards.

Arrow	Camera movement	Joystick movement
→	right	Move the joystick to the right
←	left	Move the joystick to the left
↑	forward	Move the joystick toward the patient
↓	back	Move the joystick away from the patient
↷	up	Rotate the joystick clockwise
↶	down	Rotate the joystick counter-clockwise



21. When you have achieved the expected position, a black cross will appear in the center of the ring, surrounded by four black lines.

The device will automatically begin measuring.

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

It may not be possible to carry out a measurement with manual release.

23. Ask the patient to remove his or her head from the rest.
24. Check the measurement results by referring to the quality specifications → Chapter 7.4 (page 48).

7.4 Quality Specifications in the Pentacam® Program

After you have measured either automatically or manually, the Pentacam® program opens. The “QS” value appears in field.

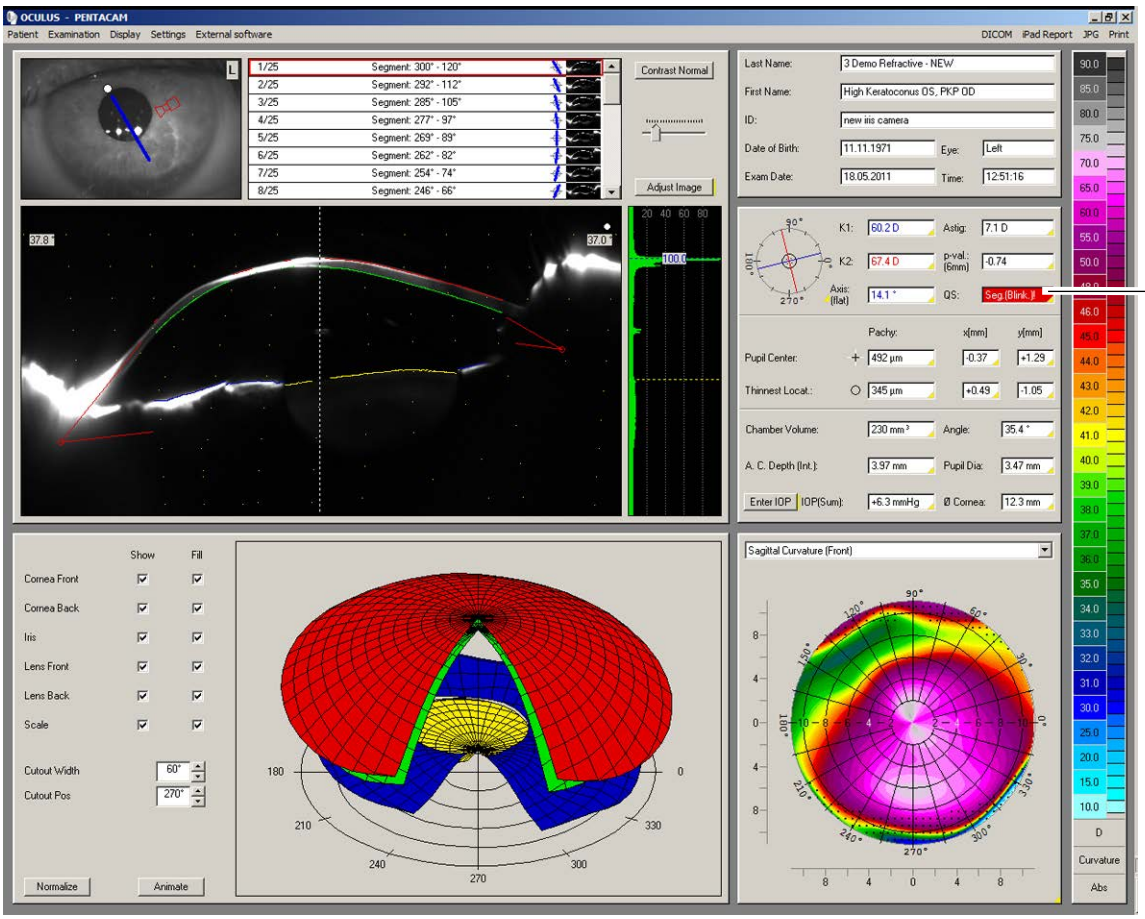


Fig. 7-13: Pentacam® program with “QS” display

No.	Description
1	“QS” Display

Note

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

If the “QS” display

- reads OK, the measurement is correct and can be reproduced.
- is red, you must repeat the measurement.
- is highlighted in yellow, click on the “QS” button.

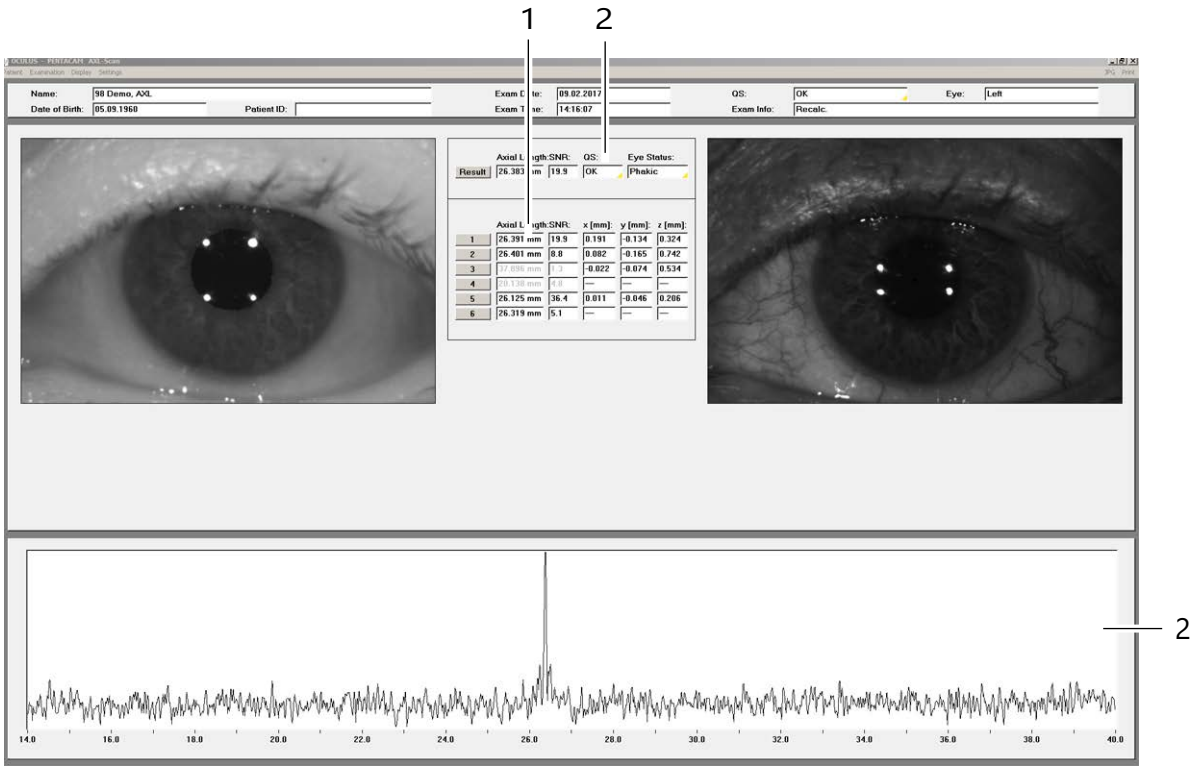


Fig. 7-14: Result display for axial length measurement

No.	Description
1	Single scans with grey colored values
2	"QS" Display
3	Signal to noise ratio of the axial length measurement

AXL scan data

- **Axial length:** The final result of the axial length is calculated just of all feasible SNR peaks. If you push the button "Result" the signal curve of the best scan is displayed.
- **SNR:** Signal to noise ratio
  - reads OK, the measurement is correct and can be reproduced. SNR >= 6.3
  - is yellow, you may want to repeat the measurement. SNR >= 5.0
  - is red, must repeat the measurement. SNR < 5.0

If only one of six SNR values is valid, it will only be displayed as an red single value, even though the SNR value is above the limit.

- **1 – 6, x (mm), y (mm), z (mm):** Display of all six single scans with results. Via clicking on the numbered buttons the respective signal curves can be viewed. Grey colored values: In order to enhance the quality of measurements all single scans are screened to remove invalid signal peaks. These are displayed in grey color and are not considered in the final result, see → fig. 7-14 (page 49).
- **QS:** If the AXL scan data
  - reads OK, the measurement is correct and can be reproduced. SNR >= 6.3
  - is yellow, you may want to repeat the measurement. SNR >= 5.0
  - is red, must repeat the measurement. SNR < 5.0

1. If the "QS" display is highlighted in yellow, click on the "QS" button. The following dialog box appears:

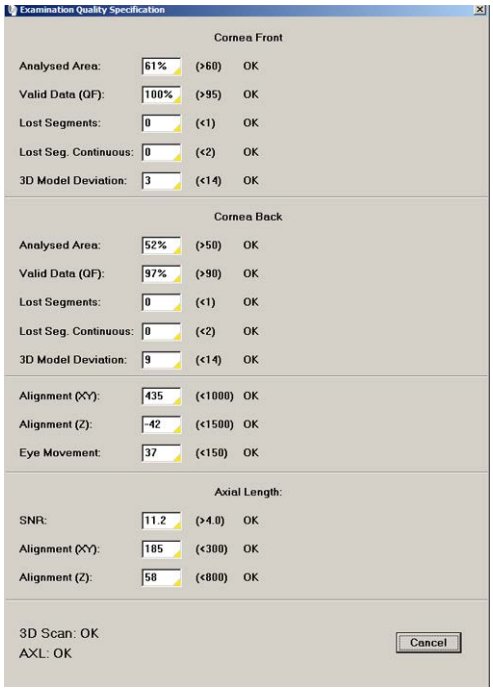


Fig. 7-15: Examination Quality Specification

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

Notes on individual parameters

- **Analyzed Area**
  If this value is less than the permissible threshold, the patient must widen his or her eye.
- **Valid Data**
  If this value is less than the permissible threshold, you must darken the room.
- **Lost Segments** and **Lost Segments Continuous**
  If one of these values exceeds the permissible threshold, you must ask the patient not to blink while you are measuring.
- **3D Model Deviation:** deviation of measured cornea from calculated 3D model
- **Alignment (XY)** and **Alignment (Z)**
  If one of these values exceeds the permissible threshold, you may have moved the cross slide at the moment you began measuring.
- **Eye Movement**
  If this value exceeds the permissible threshold, the fixation of the patient is inadequate.
- **SNR**
  Signal to noise ratio

Terminating "QS"

1. Click [Cancel] to return to the Pentacam® program.
2. If required, delete the measurement if the image is inadequate.
3. Terminate the current examination which has been saved.
4. If required, make preparations to examine another patient. In the "Pentacam" overview, select the "Examination" menu and click [New Patient/End].

8 Managing Patient Data

Once you have completed an examination, you can do the following with the patient data:

- Rename it → Chapter 8.1 (page 52)
- Export it → Chapter 8.2 (page 52)
- Import it → Chapter 8.3 (page 54)
- Back up → Chapter 8.4 (page 55)

For more information on Patient Data Management, refer to the User Guide.

8.1 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.

8.2 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 dialog appears:

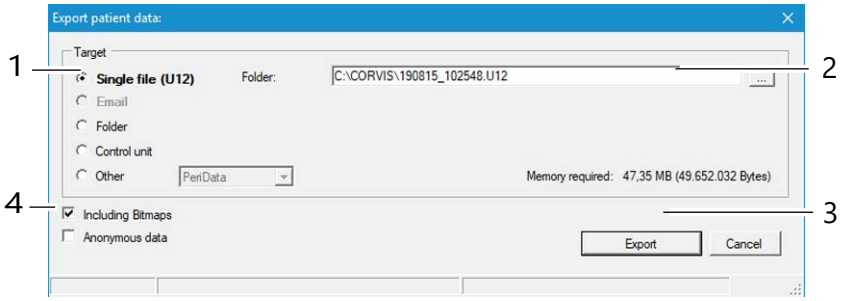


Fig. 8-1: "Export patient data" dialog

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

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

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

➔ Select the “Target” where you would like to export the data.

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

3. Press the [...] button.
4. In the dialog that appears, select the folder or the file to which the patient data should be exported.
5. Confirm your selection with [OK] or [Save].
6. Select whether the data with or without camera images and possibly to be exported anonymously.
7. Click [Export] to export the data.
   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.

Note

Requirements for transferring data to another PC:

- The Pentacam® program must be installed on the other PC. If the program is updated on the Pentacam® 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.

8.3 Importing Patient Data

Import received patient and examination data in the Pentacam® software. In case you keep patient data on a USB stick, you can import this 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:

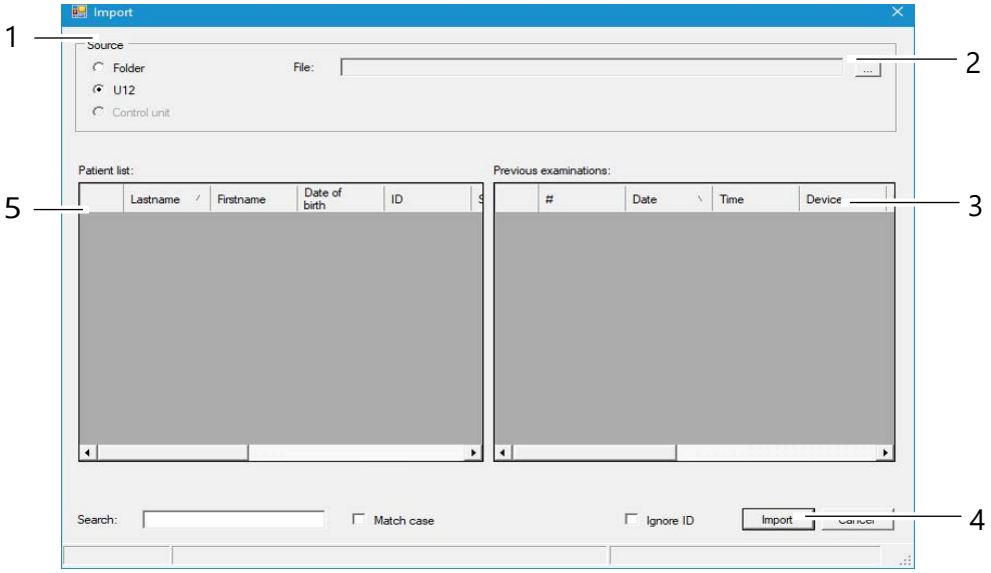


Fig. 8-2: "Import" dialog

No.	Description	No.	Description
1	Select data source	4	[Import] button
2	[...] button	5	Patient list
3	Previous examinations		

The default options for import and export of data are configured in the "Settings" field, see also the 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)).

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.

8.4 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.

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 (for example on the delivered external hard drive on a USB flash drive with adequate capacity).

8.4.1 Backup Data

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

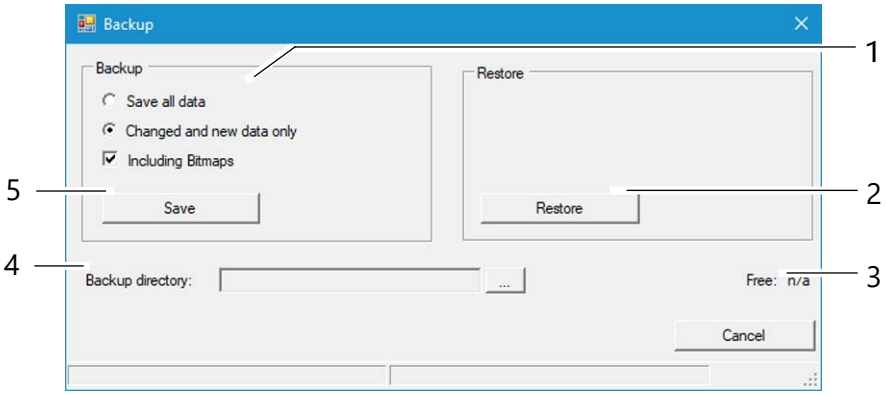


Fig. 8-3: "Backup" dialog

Nr.	Beschreibung	Nr	Beschreibung
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.

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.

8.4.2 Reconstructing Data

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

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

8.4.3 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, see User Guide.

9 Test Measurement with the Pentacam®

9.1 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 dpt
Pachymetry	+/- 10 µm

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

9.2 Test Measurement: Axial Length

9.2.1 Attach the Test Eye

Tool and material

- Test eye (70108)
- 1.5mm Allen key

Procedure

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.

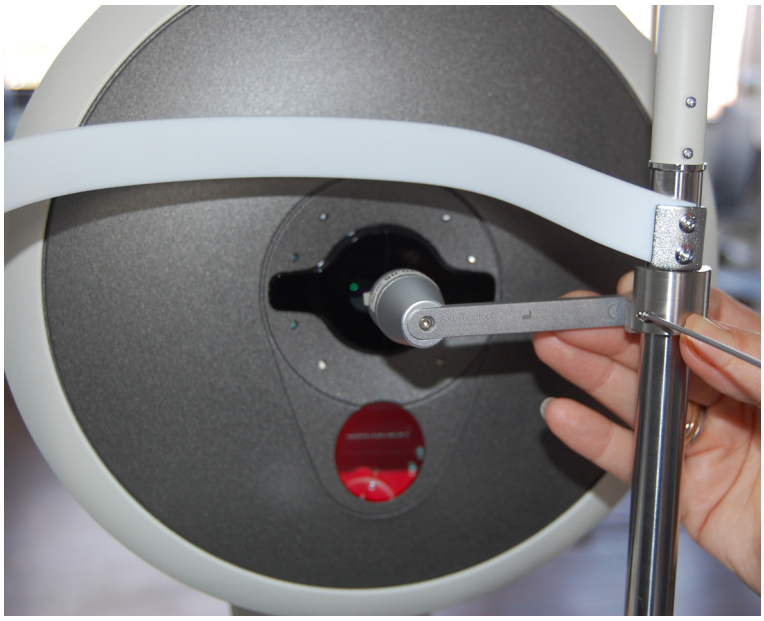


Fig. 9-1: Attach the test eye

3. Make sure that the test eye is in park/home position when it is not being used.

Fig. 9-2: Test eye in park/home position

9.2.2 Carrying out the Test Measurement

The axial length test measurement routine has to be performed daily before the first "Full Sequence Examination". After the Full Sequence Mode is selected the following screen appears:

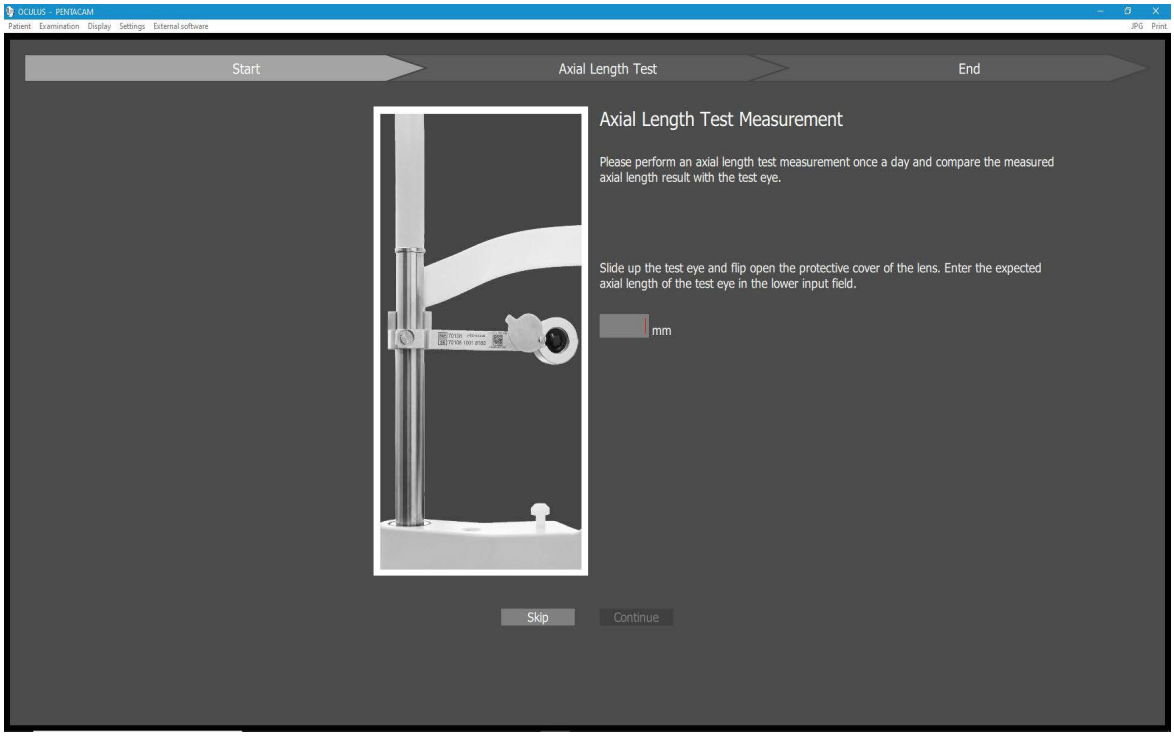


Fig. 9-3: "Start" Screen

Follow the instructions on the screen, type in the axial length of the test eye and click on "Continue". For the case the test measurement is skipped it is saved in the software and all following AXL scans recieve a bad QS value including the message "Missing test measurement".

Fig. 9-4: Axial Length Test Eye

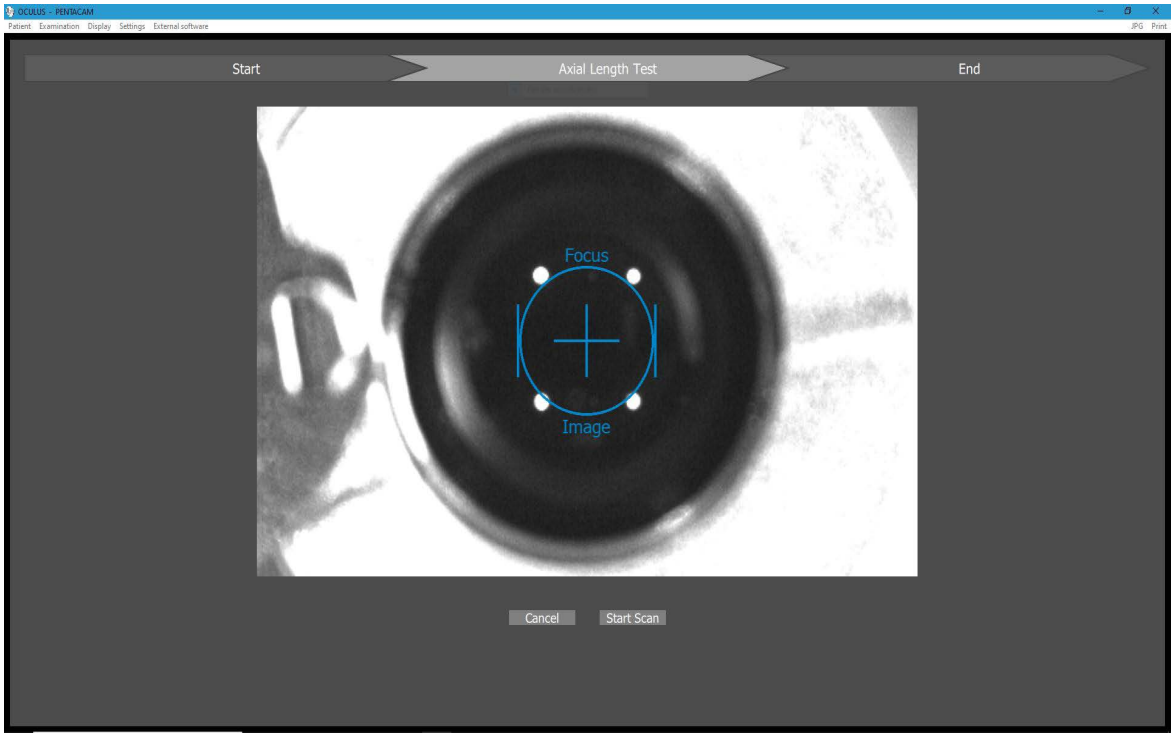


Fig. 9-5: Axial Lengths Test Screen

1. Align the device to the test eye → Chapter 7.2.5 (page 39).
2. Press [Start Scan] or press the return button to start the test measurement manually.

In case the test measurement is successful, the following message appears:

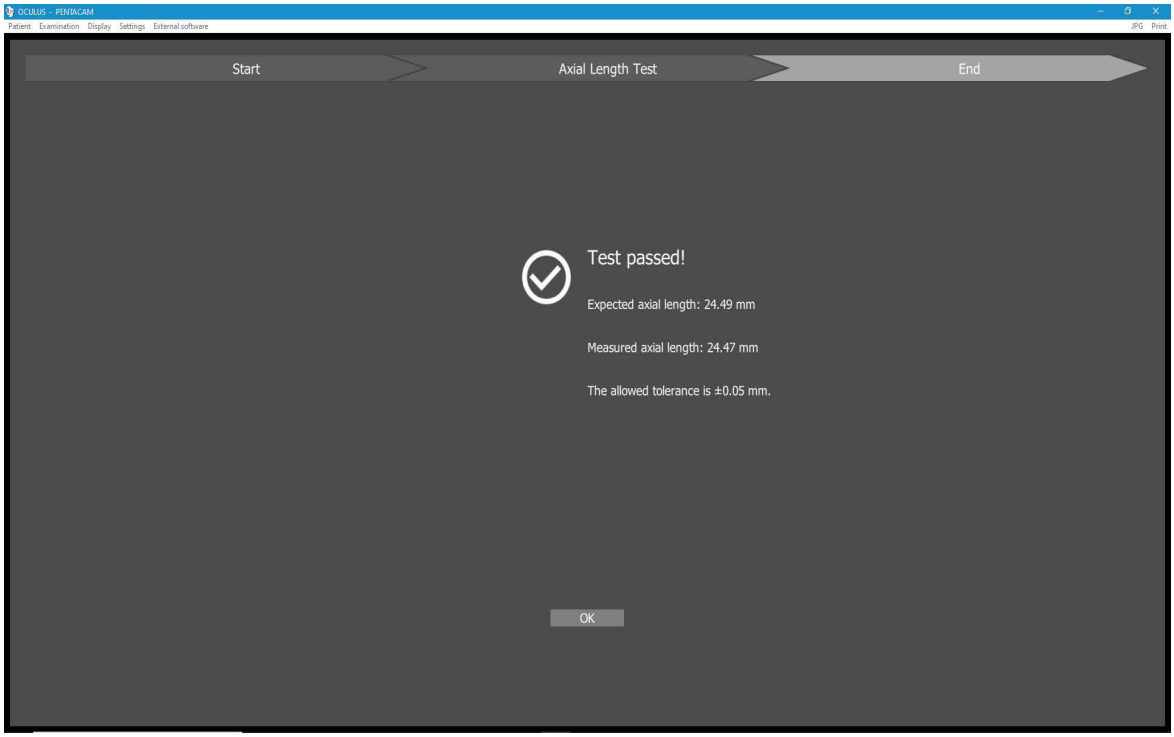


Fig. 9-6: Notification after Successful Test Measurement

3. To finish the process click “OK”.

In case the test measurement failed the following message appears:

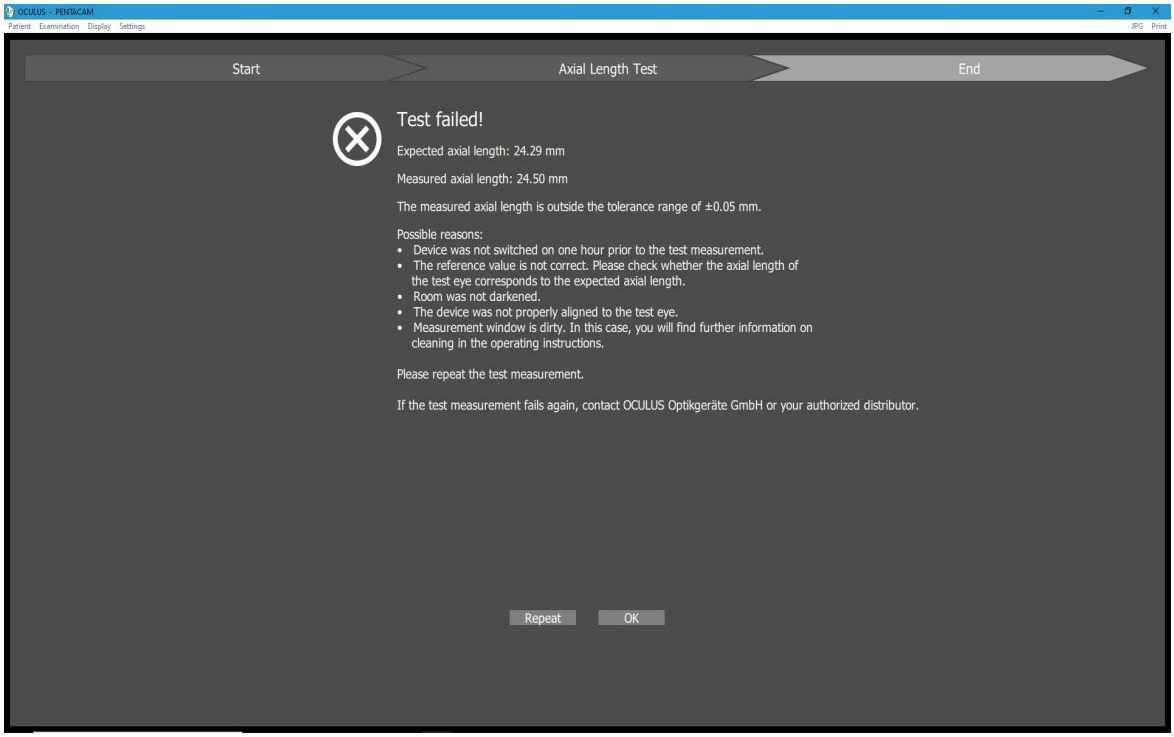


Fig. 9-7: Notification of Failed Test Measurement

4. Exclude all possible reasons for a fail test measurement (see screen).
5. Repeat the test measurement again.
6. If also this test measurement is not successful, finish this process by clicking [OK] and contact OCULUS.
7. Follow the instructions on the screen.

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.

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

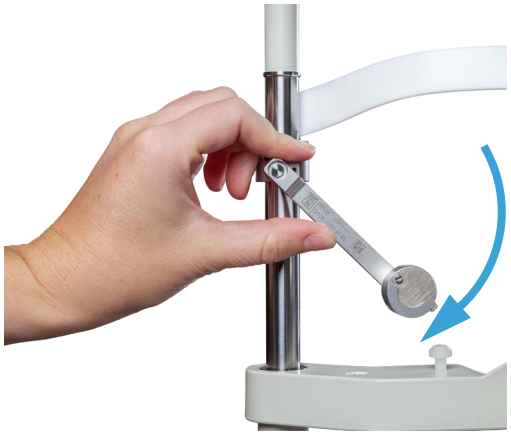


Fig. 9-8: Sliding Down the Test Eye

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

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.

10 Maintenance, Cleaning and Disinfection

Sterilization is not required.

➔ Heed the product descriptions and instruction manuals of products and equipment you use to care for, clean, and disinfect the unit and/or its accessories.

➔ Do not clean the device with aggressive, chlorine containing, abrasive or sharp cleaning agents.

Clean the cover glass from time to time to retain the high measurement accuracy of the device and to avoid malfunctions. If the test measurement shows a peak at 39 mm, a corresponding message will occur → Chapter 9 (page 58).

10.1 Maintenance

In order to retain the high measurement accuracy of the device OCULUS Optikgeräte GmbH recommends to perform a maintenance service every two years or after 25000 scans. A corresponding message appears.
By daily pop up window:

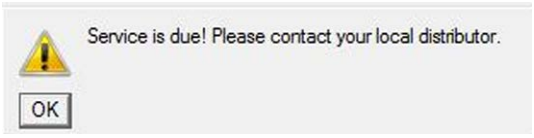


Fig. 10-1: Daily pop up window

In the settings, see User Guide:

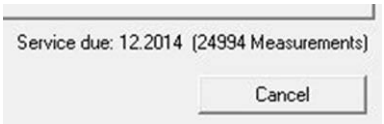


Fig. 10-2: Date of next service and number of performed examinations

In the scan menu → Chapter 6.1 (page 29):

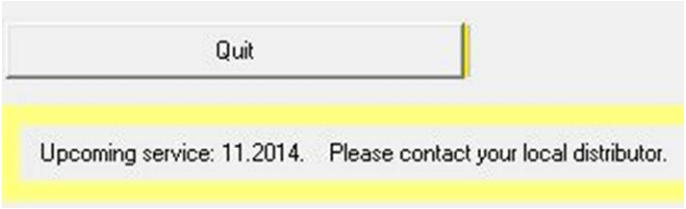


Fig. 10-3: Preliminary information (3 month before)

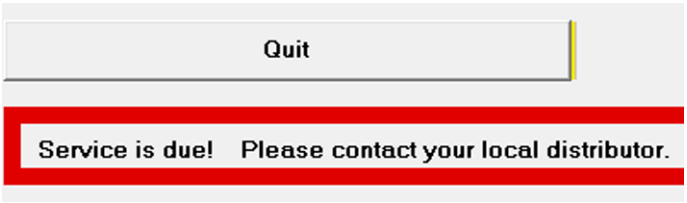


Fig. 10-4: Information when service is due

In examinations (it will be stored):

Fig. 10-5: Sign to perform maintenance

Let the device checked by our service department or an authorized distributor.

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 Pentacam® AXL cover is opened, you may be exposed to invisible, Class 3R (5mW) laser radiation.

➔ Never open the unit.

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

10.2 Cleaning

Caution

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

➔ Turn the device off → Chapter 4.6 (page 24).

➔ Pull the power plug before cleaning. When disconnecting electrical connections, pull on the respective plug and not on the cable itself.

Required materials:

- Anti-static 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

Cleaning intervals

➔ Clean the components of the device once a month or if necessary.

Cleaning the Housing

1. It is best to clean the housing surfaces with a soft cloth and an anti-static cleaning agent.
2. Wipe off any residue from painted surfaces with the mixture for painted surfaces.

Cleaning the Chin-Forehead Rest

1. Make sure that no liquid gets into any of the openings of the device.
   Do not use liquid from aerosol cans.
2. Clean the chin-forehead rest with a soap solution (or with alcohol, if very dirty).
3. Use a lint-free, damp cloth.

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

Damage to the optics

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

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

10.3 Disinfection

1. Use disinfection wipes suitable for medical devices, for example:
   Mikrozid sensitive wipes premium
   Fa. Schülke & Mayr
   Softpack 48 pieces
   Art.-No.: 165711
   Schülke & Mayr GmbH
   Tel: +4940521000
   Fax: +494052100318
   E-Mail@schuelke.com
   www.schuelke.com

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.

2. Disinfect the forehead rest after each examination.
3. If you do not use paper for the chinrest, disinfect the chinrest after each examination.

10.4 Attaching Paper to the Chin Rest

If you want to attach new chin rest paper, follow these instructions:

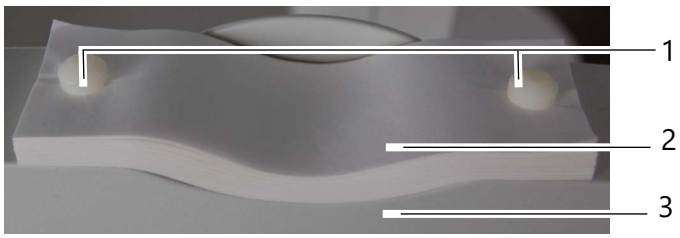


Fig. 10-6: Fasten chin rest paper

No.	Description	No.	Description
1	Pins	3	Chin rest
2	Paper for chin support		

1. Pull the two pins out of the chin rest.
2. Place the chin rest paper in such a way that the holes of the paper and those in the chin rest are aligned.
3. Insert the two pins in the chin rest.

11 Troubleshooting

Caution

If an error occurs which you are unable to correct by following the instructions below, label the device as "out-of-order" and contact our service department or an authorized distributor.

Error	Possible cause	Remedy
After you have started the Pentacam® program → Chapter 6 (page 28), the following dialog box appears: "No communication with Pentacam!".	No power to the power adapter	➔ Check whether the indicator light on the power supply is on. ➔ If not, connect the power supply to the mains.
	Connection cable of the device is not plugged properly.	Check whether ➔ the power supply cable is correctly attached to the device. ➔ the blue slit light is visible in the Scan menu → Chapter 6.1 (page 29). ➔ the USB connector is properly inserted.
	Software/hardware problems	➔ Switch the device off. ➔ Restart the PC. ➔ Switch the device on as soon as Patient Data Management becomes active. When you start the Pentacam® program, the message, "Load Bootloader" must appear. ➔ Contact the service department or your authorized distributor.

12 Technical Data

Measuring Equipment

Camera	Digital CCD camera
Light source	Blue LEDs (475 nm, UV-free)
Speed	100 images in 2 seconds, 2760 measuring points per recorded image
Number of evaluated measuring points	max. 138000
Dimensions W x D x H (measuring head)	275 x 320 – 400 x 500 – 530 mm (10.8 x 12.6 – 15.7 x 19.7 – 20.9 in)
Weight Pentacam® AXL (measuring head)	8.4 kg (18.5 lbs)

Measuring Range

Corneal topographer according ISO 19980	Type A
Curvature:	3 – 38 mm 9 – 99 D
Accuracy	± 0.1 D
Reproducibility	± 0.1 D
Working distance	80 mm
Axial length Reproducibility	14 – 40 mm ± 30 µm

Power Adapter

Power adapter	HEMG 49 (05150150)
Mains connection	90 – 264 VtAC
Frequency	47 – 63 Hz
Power input, max.	85 VA
Output voltage	24 V DC
Fuses	Integrated over-current shut-off

Power supply Pentacam® AXL

Output voltage	24 V DC
Max. power consumption	42 W

Other information

Contraindications	None noted
Lifecycle expectancy	Up to 10 years

Classification according to IEC 60601 - 1

Type of protection against electrical shock: protection class	2
Level of protection against electrical shock: type	B
Level of protection against damaging water entry	IP20

Computer

Use a computer which is in conformity with the DIN EN 60950 or IEC 62368 standard.

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

CE Marking

CE in accordance with Regulation (EU) 2017/745 on Medical Devices (MDR)
The unit is a Class IIa product.

CE 0123

Conformity assessment procedure: (EU) 2017/745 MDR, Annex IX excluding chapter II.

Classification according to IEC 60825-1: 2014

The unit contains a Class 1 laser.	
Maximum output of the laser radiation	0.7 mW
Single pulse duration Pulse count per examination	520 ms 6x
Wavelength	880 nm

13 Transport, Storage and Disposal

The device must be properly dismantled and packed before being transported or stored.

13.1 Disassembly

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

Fig. 13-1: Disassembly

4. Loosen the screw connection of the Y cable and pull it out.
   When disconnecting electrical connections, pull on the respective plug and not on the cable itself.

13.2 Storage Conditions

- Avoid proximity to radiators and moisture.

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

13.3 Transport Conditions

Ambient temperature	-40°C – +70°C
Relative humidity including condensation	10% – 95%
Air pressure	500 hPa – 1060 hPa

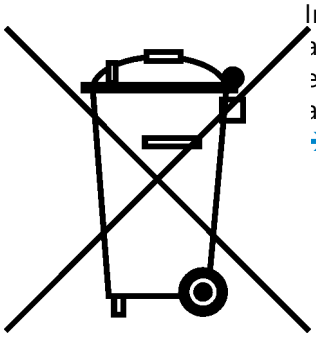
13.4 Transport and Storage

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.

13.5 Disposal



In accordance with Directive 2012/19/EC of the European Parliament and the Council 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 disposed of as household waste.

- ➔ Dispose the device in a compliant manner.

14 Terms of Warranty and Servicing

14.1 Terms of Warranty

- Prior to and while operating the device it is important that you heed the instruction manual and safety instructions.
- In accordance with legal regulations, you are entitled to a warranty for the device.
- If modifications are made to the device by unauthorized persons, all warranty claims shall be voided. Improper modifications and repairs may result in considerable hazards to users and patients.
- Any entitlement to a warranty shall also be void if unauthorized persons interfere with the supplied computer hardware and software.
- Any transport damage must be reported immediately to the shipping company. Have the transport damage noted on the bill of lading so that complaint handling and compensation of damages can proceed in an orderly manner.
- In general, our Business and Shipping Terms on the date of purchase apply.

14.2 Assumption of Liability for Functions and Damage

OCULUS will only accept responsibility for the safety, reliability and serviceability of the device if the unit is used in compliance with the following terms:

- Only use the equipment in conformance with this instruction manual.
- There are no parts either on or inside the device that require maintenance or repair by the user. If assembly work, modifications, adjustments, repairs, changes or service are performed by unauthorized personnel, or if the device is improperly maintained or handled, then any liability by OCULUS is voided.
- If the above-referenced work is performed by authorized persons, request a certification of the scope and type of repair, and, if necessary, the changes to the standard values or to the operating range from the service technician. This certification must contain the date of performance and statement of the performing firm, with signature.
- If requested, OCULUS will provide the service technician with a list of spare parts and additional descriptive material for this purpose.
- Make certain that only original OCULUS parts are used.

15 Annex

15.1 Electromagnetic Compatibility

Medical electrical equipment is subject to special preary requirements with respect to EMC, and must be installed and operated according to the EMC-Instructions contained in the accompanying paperwork.
No special measures need be observed in respect of OCULUS devices and systems.
Portable and mobile RF-communications devices can interfere with electrically operated medical devices.
The device is intended to be used in a professional health care facility environment. Manufactured under consideration of permitted degradations during or as a consequence of the EMC test without affecting the basic safety:

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

Caution
The use of accessories, transducers and cables not specified by OCULUS (for example as replacement parts) may result in increased emissions or decreased immunity of the Pentacam® AXL.

➔ Use only the original accessories, transducers and cables specified by OCULUS.

The use of accessories, transducers and cables specified by OCULUS with devices other then the Pentacam® AXL may result in increased emissions or decreased immunity of the other device.

➔ Do not use the accessories, transducers and cables specified by OCULUS with devices other then the Pentacam® AXL.

To be in compliance with the requirements of the IEC 60601-1-2 the following types of equipment, accessories, power adapters and cables must be used.

Order number	Description	
70100	Pentacam® AXL	
05200320	Cable with connector plug, EU standard	2.5m (98.4 in)
05200210 (110 Volt)	Cable with connector plug, US standard	2.5m (98.4 in)
05150150	Power adapter HMEG 49	24V, 2,1A
70002	Y cable with galvanic isolation	2m

15.2 Guidance and Manufacturer's Declaration: Electromagnetic Emissions

Electromagnetic emissions		
The OCULUS Pentacam® AXL is intended for operation in the electromagnetic environment specified below. The user of the Pentacam® AXL should ensure that it is being used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Pentacam® AXL 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	

Electromagnetic immunity			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	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%.
Electrical Fast transient/bursts IEC 61000-4-4	± 2kV for power supply lines ± 1kV for input/ output lines	± 2kV for power supply lines ± 1kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 6100-4-5	± 1kV kine(s) to line(s) ± 2kV line(s) to earth	± 1kV differential mode ± 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Electromagnetic immunity			
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_τ (> 95% dip in U_τ) for 0,5 cycle 40% U_τ (60% dip in U_τ) for 5 cycles 70% U_τ (30% dip in U_τ) for 25 cycles <5% U_τ (> 95% dip in U_τ) for 5 s	< 5% U_τ (> 95% dip in U_τ) for 0,5 cycle 40% U_τ (60% dip in U_τ) for 5 cycles 70% U_τ (30% dip in U_τ) for 25 cycles <5% U_τ (> 95% dip in U_τ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Pentacam® AXL requires continued operation during power mains interruptions, it is recommended that the Pentacam® AXL be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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 – guidelines**
Conducted RF IEC 61000-4-6	3Vrms 150KHz to 80Mhz	V_{rms}= 3V	Portable and mobile RF communications equipment should be used no closer to any part of Pentacam® AXL, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	3V/m 80MHz to 2.5GHz	E = 3V/m	$d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 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: 
Note 1: Note 2:	At 80Hz and 800MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
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 is used exceeds the applicable RF compliance level above, the Pentacam® AXL 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. b. Over the frequency range 150KHz to 80MHz, field strengths should be less than 3V/m.			

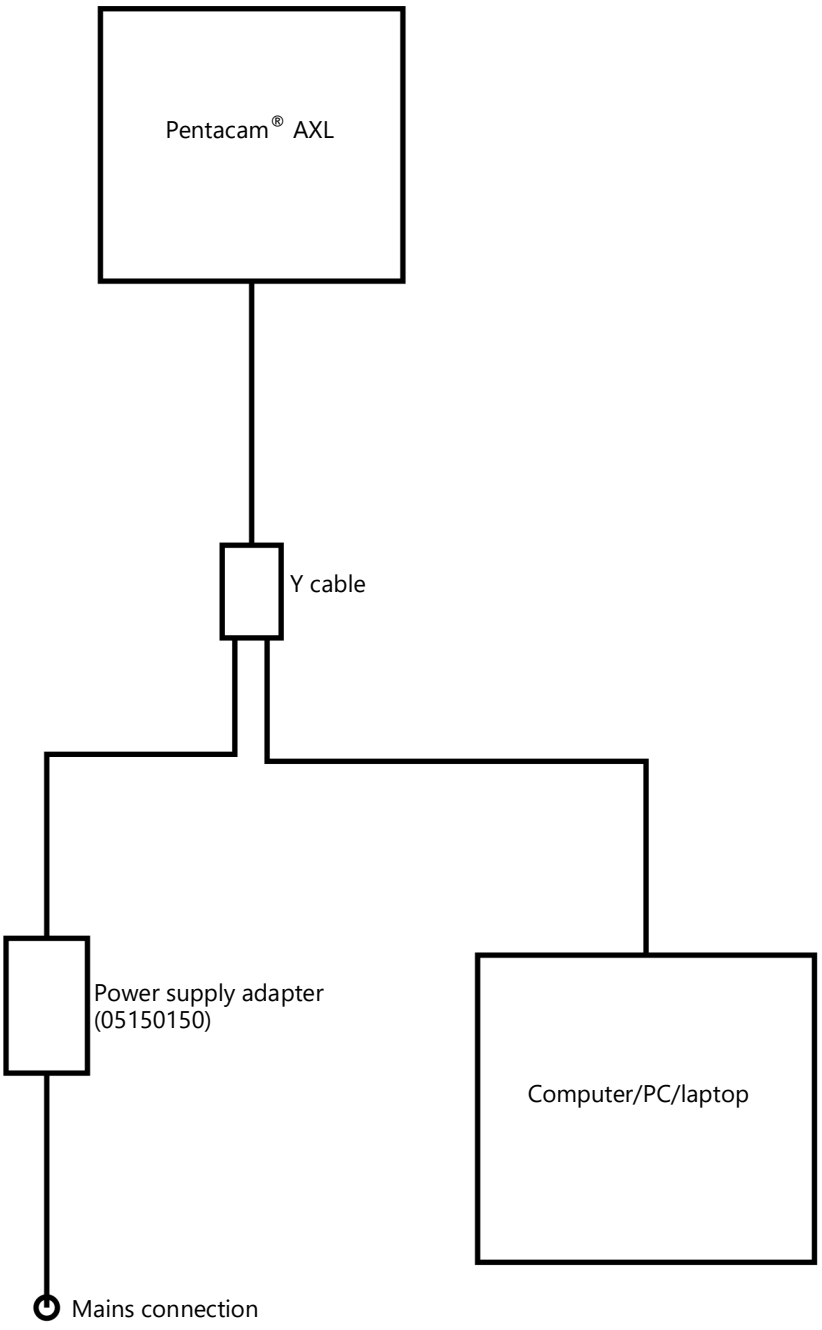
Recommended separation distances between portable and mobile RF communications equipment and the Pentacam® AXL

The Pentacam® AXL in intended for us e in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Pentacam® AXL can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Pentacam® AXL 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	150 KHz to 80 Mhz d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz 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 80 MHz and 800 MHz, 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.

15.3 Description of the Connection



15.4 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.

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

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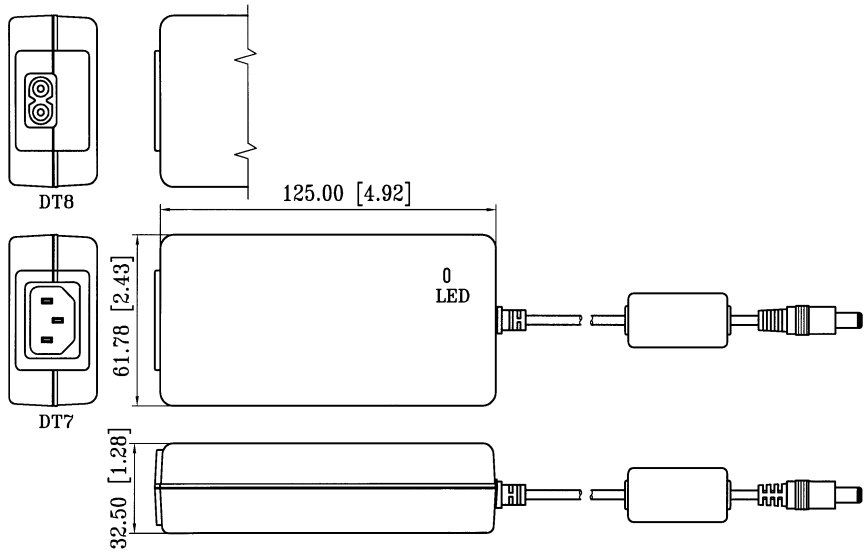
OUTPUT VOLTAGE / CURRENT RATINGS CHART

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.)



15.5 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 cybersecurity instructions section of "Safety Instructions" in the device instruction manual.
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 cybersecurity section of "Safety Instructions" in the device instruction manual.
- Refer to the "Floating License Key - License management for software options" instruction manual (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

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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