OCULUS Keratograph 5M

INSTRUCTION MANUAL

System for measuring and analyzing the cornea topography

OCULUS®

Foreword

The Keratograph 5M was manufactured and tested under strict quality criteria. To ensure safe operation, it is essential that you use the device correctly. For this reason, you should thoroughly familiarize yourself with the contents of this instruction manual before operating the device. In particular, pay attention to the safety instructions!

This instruction manual describes how to manage the patient data and the procedures for conducting the following measuring operations with the Keratograph 5M:
Additional information that goes beyond the scope of this manual can be found in the Keratograph 5M user manual.

Due to ongoing development, the diagrams shown here may vary slightly from the actual software delivered.

If you have any questions or would like additional information about your device, please do not hesitate to contact us by mail or fax. Our team will be happy to assist you.

OCULUS Optikgeräte GmbH

Article number: G/77000/XXXX/EN
Release: 24.05.2023
Revision 05

Table of contents

1 Delivery and Deliverables

Products and accessories	Article number
Keratograph 5M (measuring device) multiple versions	77000
Imaging software	77130
OCULUS Wireless Joystick	18200
Keratograph 5M accessories ■ Table-top power pack 24 V ■ Dust protection cover	77701 05150150 02 60100 05 001
■ Reference sphere	77007
■ Contact lens holder	70512
Keratograph 5M User Package ■ Instruction Manual ■ User Manual ■ Software Installation	77002 G/77000/XXXX/EN UG/77000/XXXX/EN SI/50000/XXXX/EN
■ Mains cable: USA England Australia EU Switzerland Argentina	 05200210 05200211 05200212 05200320 05200322 05200323
■ Connection cable Med. secure Isolator + USB Connection acc. Extension cable for Med. secure Isolator 4 m	 70002 10002173
■ Floating License Key incl. instructions	77900 SI/77900/XXXX/EN
Optional:	
■ JENVIS Pro Dry Eye Report - R scan - TF scan - Meibo scan	77250 77110 77120 77140
■ Pupillometry	70542
■ DICOM/PACS Interface	70681
■ OxiMap	70679
■ Hard drive package	70005
■ Foot-operated switch	77006
■ Retaining plate (size: 360 mm)	78060
■ Retaining plate, long (size: 490 mm)	78030
■ Long support plate adjustable for OCULUS rack wheels (size 360 – 460 mm) without chin rest	78070

Products and accessories	Article number
■ Long support plate adjustable for OCULUS rack wheels (size 360 – 460 mm) with chin rest	78080

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 *Chap. 23, page 88*.

2 Symbols

2.1 On the device/nameplate

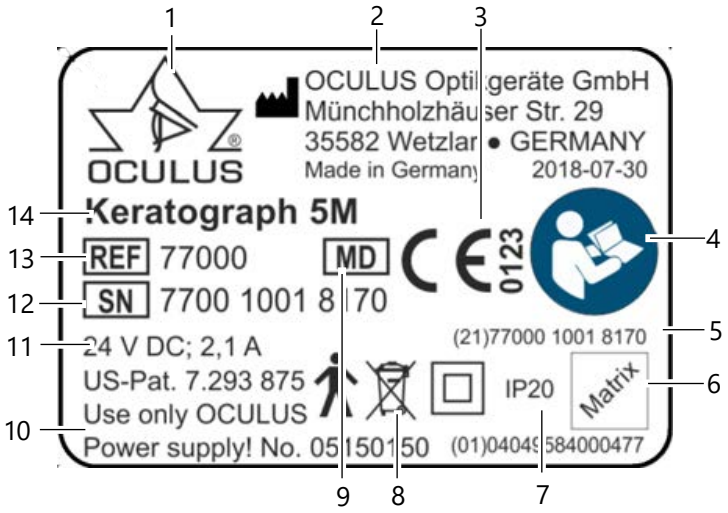


Fig. 2-1: Name plate (example)

1 Manufacturer's logo
2 Manufacturer's address
3 CE mark
4 Read the instruction manual
5 UDI number
6 Matrix for device identification
7 Protection class
8 Disposal in household trash is prohibited
9 Medical device
10 Power adapter
11 Power supply
12 Serial number of the device
13 Device type
14 Name of device

2.2 On the packaging

Symbols	Notes	Symbols	Notes
Transport 	Permitted temperature range for transport	**Storage** 	Permitted temperature range for storage
	Keep dry		Limit of humidity
	This way up		Limit of air pressure
	Fragile		

3 Structure of the Documentation

A folder containing a set of documentation is supplied with your Keratograph 5M:

- **Instruction Manual:** The design of the unit is described in detail in this document. The instruction manual also gives you general information about working with the Patient Data Management system and all safety-related instructions for use of the Keratograph 5M.

Attention

All safety-related instructions for use of the Keratograph 5M are given in the Instruction Manual for the unit. It is therefore imperative that you read and understand the whole Instruction Manual before you use the Keratograph 5M.

- **User Manual:** All features of the examination and analysis software are described in the User Guide, along detailed information about the Patient Data Management system.
- **Software Installation:** The introduction to the Software Installation describes how to install the Keratograph 5M software and the associated drivers.

If you work with a floating license key, the respective instruction manual explains how you can use the Keratograph 5M within a network.
For external software: „Description of external Software data interface“ describes settings and data formats.

4 Safety Instructions

➔ Carefully read through the Instruction Manual.
➔ Keep the Instruction Manual in good condition near the device.
➔ Observe the legal regulations with regard to accident prevention.

If standards are named without an issue date, the current version always applies.

4.1 Pictograms in this manual

Attention
Identifies a potentially dangerous situation which may cause minor injury or damage to property.

Note
Denotes situations which could result in incorrect findings, denotes user instructions and useful or other important information.

Identifies important information about the product and its use which require special attention.

> This symbol denotes menu paths and screenshots.
For example, in order to open a new examination:
Keratograph 5M > Examination > New
which means:
➔ Select the “Examination” menu from the menu bar.
➔ Select the menu item “New”.

4.2 Safety Instructions for Use

Attention
Personal injury or property damage due to improper operation
➔ Observe the following safety instructions.

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

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

4.3 Instructions for Operating Personnel

➔ Make certain that the Keratograph 5M is used exclusively in clinics and by eye specialists and opticians (trained staff etc.).
For this reason the Keratograph 5M may only be operated by personnel instructed to do so, who, with appropriate training, knowledge and practical experience, are able to ensure proper handling of the device.

4.4 Transport and Storage Instructions

Refer to the notes in *Chap. 23, page 88*.

4.5 Instructions for Setup and Connection

➔ Only OCULUS or an authorized dealer is allowed to set up and to connect the Keratograph 5M.
➔ Do not use or store the Keratograph 5M in rooms that are humid, *Chap. 23, page 88*.
➔ Keep the Keratograph 5M away from water that may drip, splash or spray on it, and make sure that no liquids can get into the Keratograph 5M. Do not place any containers holding liquids in the vicinity of the Keratograph 5M.
➔ Only operate the Keratograph 5M in rooms used for medical purposes after they have been set up according to the VDE Regulations 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 Keratograph 5M 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 use excessive force when connecting the electrical plug.
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 Keratograph 5M which is mounted at the lifting table properly.

4.6 Patient environment information

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

Attention

In the patient environment, use only devices that conform to IEC 60601-1. If a multiple power socket is to be used, or if a device is to be used that does not meet the IEC 60601-1 standard, use an isolating transformer.

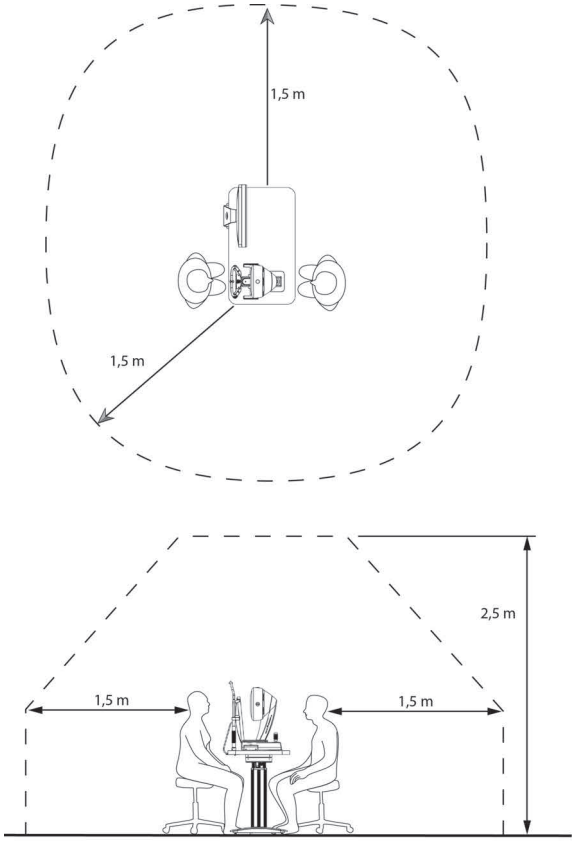


Fig. 4-1: Patient environment

4.7 Information about the operation of an ME system

The Keratograph 5M and a connected computer form a medical electrical system (ME system) according to IEC 60601-1. If you connect additional devices, such as, for example a printer, those devices become part of the ME system.

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

4.8 Instructions for Operation

➔ Before first use: Let OCULUS or an authorized dealer train you in the operation of the Keratograph 5M.

➔ Never operate a damaged Keratograph 5M.

➔ Only operate the Keratograph 5M with the original accessories supplied by us and only when the unit is in technically perfect condition. Use only the power supply unit specified in the scope of delivery.

➔ 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, e.g. if it is leaned against or sat on.

➔ Do not put the Keratograph 5M including rechargeable battery or cable, down onto devices that produce heat, heaters, microwaves or similar.

➔ Only operate the device if you have understood the instruction manual.

4.9 Instructions for Maintenance

The Keratograph 5M is designed so that no special maintenance is necessary. To keep the device functioning properly, we recommend performing the tasks specified under “maintenance” on a regular basis.
If an error occurs which you cannot correct, label the Keratograph 5M as being “out-of-order” and contact our service department, see contact data, *Chap. 25, page 90*.

4.10 Instructions for Disassembly and Disposal

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

➔ Dispose of the device according to legal regulations.

4.11 Instructions on Electrical Safety

Attention

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

Connecting the Keratograph 5M with non-medical electrical equipment (e.g. data processing equipment) to a medical electrical system must not result in a patient safety level below that prescribed by IEC 60601-1. If making this connection leads to the leakage current threshold being exceeded, protective measures including a circuit breaker must be in place.

- ➔ Ensure that connections with non-medical devices are made correctly.
- ➔ Only use the power adapter listed in the packing list.
- ➔ Use only a computer that meets the specifications given in this instruction manual, *Chap. 26, page 92*.

Attention

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

If you use a multiple socket extension cord to connect the Keratograph 5M to the power supply, you must heed the following information:

- ➔ Use an extension cord that complies with the requirements of IEC 60601-1, section 16.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the Keratograph 5M and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.

If you are using a multiple socket extension cord it has to be supplied with a isolation transformer.

If you are using a new computer for the Keratograph 5M, you must have the electrical safety checked. Call OCULUS Service for this purpose.

Attention

Electromagnetic compatibility (EMC/cable) hazard

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

Portable and mobile RF communications equipment can affect medical electrical equipment, *Chap. 27, page 95*.

- ➔ Make sure that portable and mobile RF communications equipment do not cause interference.
- ➔ Recommendation: Maintain a minimum distance of 4 m. If the distance is shorter, you must ensure that the Keratograph 5M functions correctly.

4.12 Cybersecurity Instructions

The device itself was not designed to connect via a coupled computer to the internet or other network, or to portable media, as the device does not require a network or internet connection to function.

User who elect to connect the device coupled computer to the internet or other network for other purposes are responsible for ensuring that it is done so in a controlled manner.

Data responsibility

The device itself is not designed to connect with the internet, but only with a computer. It does not require the internet to function.
Do not connect with the internet while using the device. It is considered misuse.
If you elect to connect the computer to the internet for other purposes you are responsible for ensuring data security.

Device Security

It is the responsibility of the authorized user to ensure that the Keratograph 5M device is not left unlocked, or otherwise unsecured when not in use, to ensure that non-authorized medical, professional, or otherwise unapproved personnel are not exposed to, or gain access to, ePHI.

User Responsibility

User names or passwords must not be shared with colleagues or others, even if they are permitted by law and provider policy to view the same type of information (e.g. two operators reviewing the same examinations).
Operators have access to patients' ePHI and must not take snap-shots, screenshots or pictures (e.g. using another device) of any information viewed through the device.
Operators should not enter identifying data into the device. All the data on the device should be de-identified and relate to the Examinations ID and not to the patient.

Reporting Device Security or Privacy Breaches

Operators must contact their local IT department and disclose any suspected or confirmed compromised user accounts, and any other privacy or security breaches.

Recovering from Compromised Accounts or Devices

When accounts are considered compromised, devices are lost, or unauthorized access is discovered or suspected, the Healthcare Organization's IT network administrators suspend and modify the user login criteria and issue new login credentials for the user to access their account securely.

Unavailable Service

Users should report unavailable service or prohibited access to information to their local Healthcare Organization's IT department.

Precautions

➔ To ensure cyber security in order to the usage of the device, the following security measures should be considered. Contact your computer administrator:

Precautions for access control of the computer

- ➔ Secure the computer with a password (for example at Windows start up).
- ➔ Choose a complex password: A good password should be at least eight characters long and are not in the dictionary. In addition to letters, it should also include numbers and special characters.
- ➔ Do not choose a name or device name for a password (for example “Keratograph”).
- ➔ Change the password regularly.
- ➔ Do not note the password in an accessible location.
- ➔ Use different passwords for different users.
- ➔ Enable the screen saver and use the option for the necessity of re-entering the password when exit the screen saver.
- ➔ Choose an adequate time setting for starting the screen saver if software session is inactive (e.g. 10 minutes).
  Adequate time setting should consider duration of examination, number of patients, time between examinations, use of other devices in the examination room, several user, etc.
- ➔ Lock the computer if you are leaving the workstation (shortcut: ‘windows logo key’ + ‘L’).

Precautions if the computer is connected to a LAN or internet network

- ➔ If you elect to connect the computer to the LAN or internet, you are responsible for ensuring data security.
- ➔ Prefer wired connections of the computer to the network.
- ➔ If you are using Wi-Fi connections nevertheless, please ensure the usage of adequate security methods (for example WPA2/AES – Wi-Fi Protected Access / Advanced Encryption Standard – with a strong network key).
- ➔ The usage of a firewall (software or hardware) is recommended.
- ➔ Heed the instructions for integration into an IT-network, *Chap. 27.5, page 104*

Note

For authorized service personnel only:

Always use a wired connection to transfer examination data from the unit to the PC. Do not use wireless technologies.

5 Purpose

The Keratograph 5M is a measuring device for eye examinations. It measures the surface of the cornea (corneal topography). The Keratograph 5M is thus intended for use in individual contact lens fitting.
The Keratograph 5M is also intended for use in dry eye screenings.
The Keratograph 5M must be used with the examination station intended for that purpose, or with an examination unit.
The Keratograph 5M should only be used in accordance with the purpose specified in this instruction manual and especially in accordance with the safety instructions.

5.1 Intended Medical Indication

The Keratograph 5M can be used by physicians, ophthalmic opticians and optometrists in order to examine the following:

- ➔ corneal topography for contact lens fitting
- ➔ Tear film analysis (dry eye)

5.2 Contraindication

None known

5.3 Side effects

None known

5.4 Intended users

The Keratograph 5M is only intended for use in optometrist practices, in clinics and by opticians.
The Keratograph 5M is intended for use by trained personnel:

- Make sure that the device is only be used by personnel, who, due to their training or their knowledge and practical experience, can guarantee proper handling of the device.
- instructed by OCULUS personnel or an authorized dealer prior to use.

5.5 Patient Group

Children from 3 years up to not limited. No limitations with regard to weight and health condition: Patient must be awake and able to understand.

6 Device Description

6.1 Components

Fig. 6-1: Equipment overview of the Keratograph 5M

1 Housing
2 Joystick
3 Adjusting base
4 Med. Secure Isolator cable connector plug
5 On/Off switch
6 Rating plate (partly visible)
7 Locking screw
8 Camera aperture and fixation mark
9 Placido bowl
10 Test marks

Applied parts

Fig. 6-2: Applied parts

1 Forehead rest
2 Chin rest

6.2 Functionality

The OCULUS Keratograph 5M combines the keratometric measuring process with topographic mapping.
Measurement of the corneal surface is done by means of a Placido ring system that is reflected off the cornea. These data are analyzed by the computer.

Note

Data misuse

OCULUS Optikgeräte GmbH shall not be liable in any form for further use of the data recorded with the Keratograph 5M or for any calculations based thereon.

Technical Principle

An illumination system with a special reflector illuminates a transparent Placido bowl from the rear which contains a series of concentric rings.
The image of this Placido bowl is reflected off the patient's eye.
This virtual image is captured by a precision objective and a connected high-resolution color camera.
All distortions due to the different radii of curvature of the patient's eye that become visible are available for the measuring process.

The analog image is first prepared for analysis in the measuring unit, i. e. it is digitized and compressed for processing in the computer.
When the computer has received the respective dataset for the measurement image, it develops a topographic map of the cornea based on that data.
It displays the measurement results on the monitor as a color map, a graph and as a spatial image.

7 Set up and Connection

Attention

Improper measurements/equipment damage due to improper set-up

- ➔ Before first use, make sure the installation and connection of the "Keratograph 5M" examination station are completed by our service or by a professional authorized by OCULUS.
- ➔ Let OCULUS or an authorized dealer train you in the operation of the Keratograph 5M.

Note

Risk of damage to the devices if not handled properly

- ➔ Do not expose the Keratograph 5M to any vibrations, shocks, contaminants, moisture, or high temperatures.
- ➔ Handle the optical device with care.

The ambient conditions for operation are given in *Chap. 26, page 92*.

- ➔ Set up the Keratograph 5M so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.
- ➔ Place the device so that direct light cannot affect the measurement.
- ➔ Make sure the examination is free from reflections. To achieve this, darken the examination room.

7.1 Connect Foot Switch

If needed, you can connect a foot switch. With this, you can trigger the image capture. For a video, you can start and stop the recording by pressing this foot switch, *Chap. 17.5, page 59*.

Prerequisite: USB port

- ➔ Plug the USB connector of the foot switch into a USB port at your computer.
  The foot switch is active.

7.2 Electrical connection

Caution

Impairment of electrical safety

- ➔ Do not use the Keratograph 5M directly next to other devices and do not stack it on top of other devices.
- ➔ If you have to use the Keratograph 5M adjacent to or stacked with other equipment, verify the correct operation of the Keratograph 5M.
- ➔ Only use the power adapter listed in the packing list, *Chap. 27.1, page 95*.
- ➔ Use only a mains cable that meets the requirements of IEC 60227-1, Type H05V V-F, min. 0.75 mm^2 and of IEC 60320-1, Type C7.

- ➔ If you use a multiple socket extension cord to connect the Keratograph 5M: Use an extension cord that complies with the requirements of IEC 60601-1.
- ➔ Do not place the multiple socket extension cord on the floor.
- ➔ Do not use more than one multiple socket extension cord.
- ➔ Plug only the Keratograph 5M and the computer that is being used with the unit (if applicable) into the multiple socket extension cord.
- ➔ Use a power socket that has a flawless earth conductor connection.

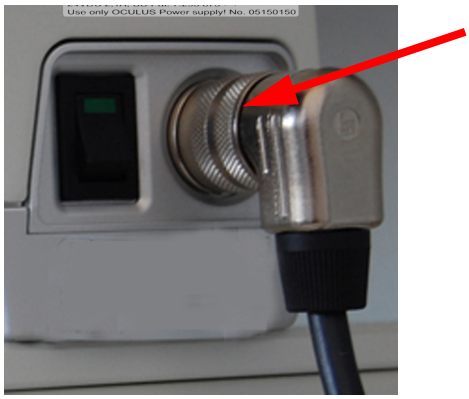


Fig. 7-1: Connecting

- ➔ Plug the connector of the Med. Secure Isolator cable into the jack and tighten the connection. Make sure that the plug is inserted in the correct position.

Note

Risk of equipment damage due to incorrect connection

If you do not connect the Keratograph 5M properly, and the connection is live, the unit can be damaged within a short period of time.

- ➔ Do not force any plug connections.
- ➔ Please pay attention to the specifications on the nameplate.

If the plug is faulty, contact OCULUS Service or an authorized dealer to repair the damage.

- ➔ Firmly tighten the connection.
- ➔ Connect the Med. Secure Isolator cable to the computer/laptop and the power adapter.

8 Putting Back Into Operation

➔ After transport, allow the Keratograph 5M to rest for approx. 3-4 hours in its new location so that the device can adjust to the ambient conditions. Drastic temperature changes from cold to warm can cause the optical components to fog up.

8.1 Turning On

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

➔ Then turn on the Keratograph 5M with the on/off switch (position ON). The LED on the switch lights up green.

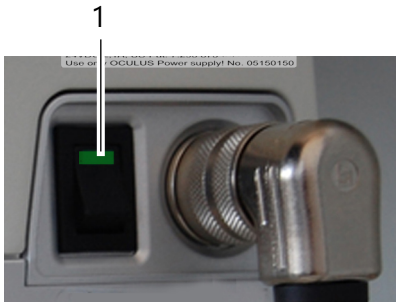


Fig. 8-1: On/Off switch

8.2 Turning Off

➔ Close the Keratograph 5M program and the Patient data management.
➔ Shut down the Windows operating system.
➔ Turn the Keratograph 5M off with the on/off switch (OFF position).

Attention

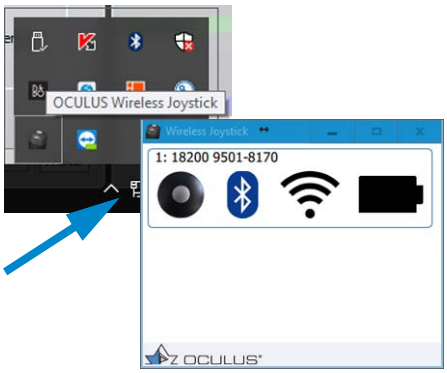
Risk of electric shock if the Keratograph 5M is not completely disconnected from the mains for transport, cleaning, maintenance, disinfection and repair.

➔ Pull the power plug before cleaning and maintenance. Take hold of the power plug for this purpose; do not pull on the cable.

8.3 Using the wireless joystick

If your device is equipped with a wireless joystick, you can use the joystick to trigger different images.

This is the joystick icon that appears on the screen.



➔ Make sure that the wireless joystick has been selected.
To do so, open the hidden icons in the task bar.
In the system tray, you should see the icon for the OCULUS wireless joystick. Click it to see the joystick status, e.g. battery charge level.

➔ Touch the joystick to activate it.
Within 2 seconds, it will establish communication with the computer and the examination software. The LED on the Bluetooth USB adapter will be red.

Fig. 8-2: Joystick with trigger button (arrow)

Initiate a measurement	Press the capture button on the joystick
Record a video	Keep the capture button on the joystick pressed.

If the joystick is left idle for 90 seconds, the connection to the Bluetooth USB adapter will be dropped in order to conserve battery power. The red LED on the Bluetooth USB adapter will then turn off.

The battery lasts approx. one year on average. Once the battery has been used up, a battery change notification is displayed in the examination software.

9 Preparing for Measurements

9.1 Starting Patient Data Management

You must enter patient data in the patient data management and then use it.
After you have switched on the computer, it first loads the operating system.

➔ If necessary, click on the Keratograph 5M icon .
The user interface for the Patient Data Management appears.

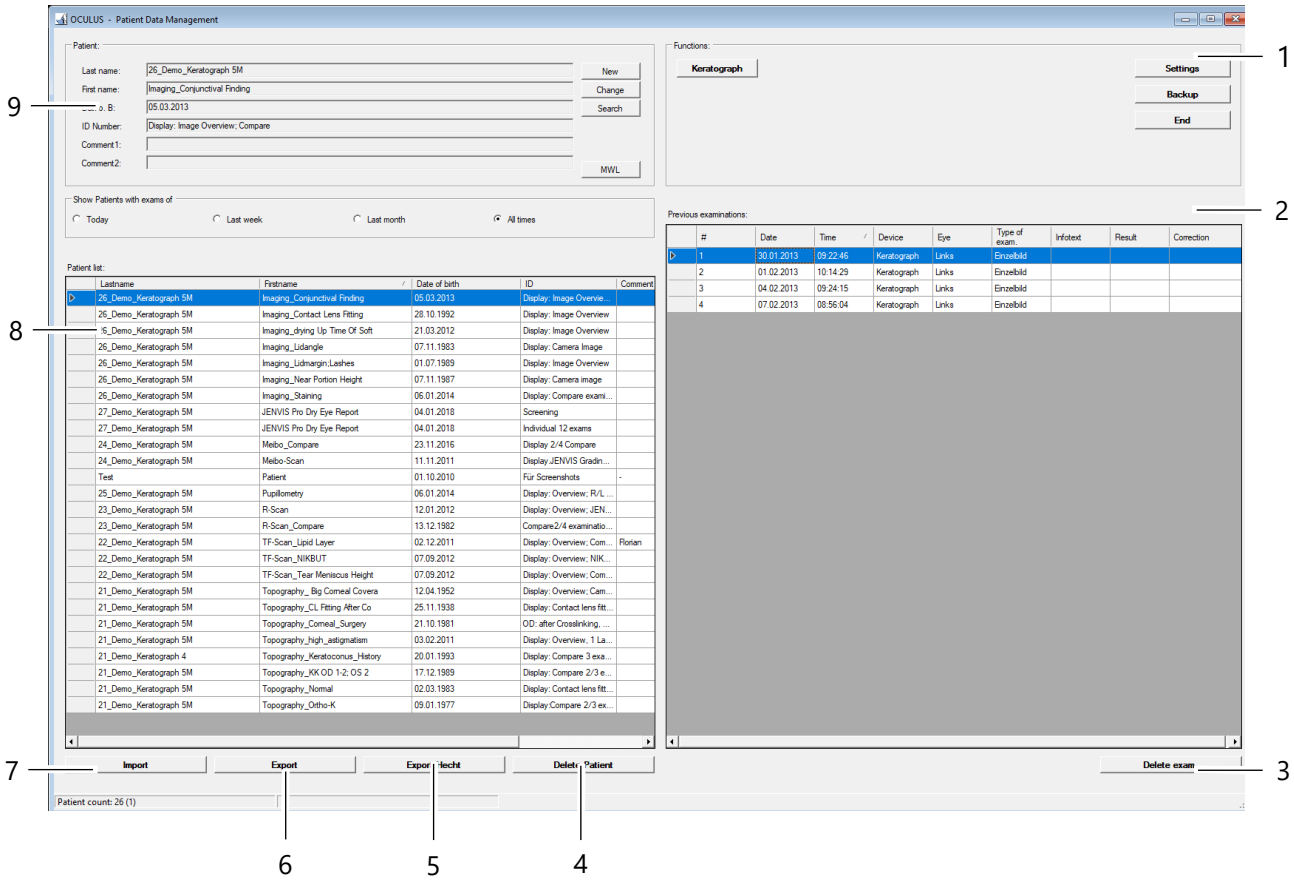


Fig. 9-1: User interface for Patient Data Management

1 “Functions” box
2 Examination list
3 [Delete exam.] button
4 [Delete Patient] button
5 [Export Hecht] button (optional)
6 [Export] button
7 [Import] button
8 Patient list
9 “Patient” group box

To get to the Keratograph 5M program, you must first enter a new patient (8) or select an existing patient from the examination list. For more information on patient data management, refer to the *Chap. 20, page 76*.

9.2 Entering a New Patient

➔ Press the [New] button to enter a new patient in the patient data management system.

➔ Enter the patient's last name, first name and date of birth in the patient window.

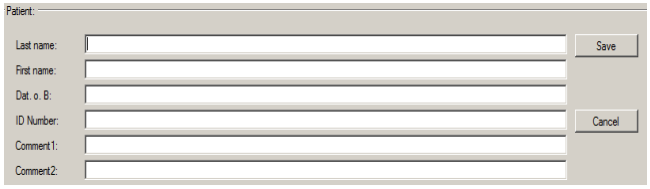


Fig. 9-2: Entering patients

Optionally you can enter an ID number for the patient.

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

9.3 Selecting an Existing Patient

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

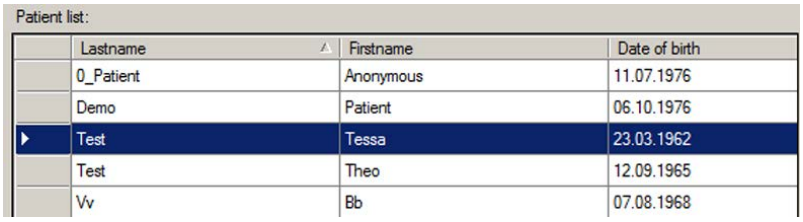


Fig. 9-3: Patient list

➔ Choose [Search] to quickly find the patient you are looking for in the list.

➔ 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.

➔ 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).

9.4 Extended Patient Search: [Extended] check box

➔ Click on the [Extended] checkbox.

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

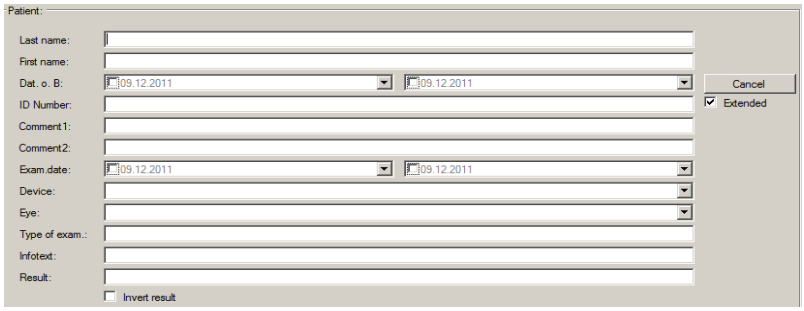


Fig. 9-4: Extended search

9.5 Use Hecht E-Mail Function

If you have enabled it in the Patient Data Management system preferences, you can use the [Hecht] button. Please also refer to the *User Guide*.

➔ Select the desired patient or examination in the patient data management.

➔ Click the button [Export Hecht].

➔ You can optionally enter your own message in the text field.

➔ Confirm the message with the [OK] button.

■ After you have selected your Hecht supplier (which only needs to be done once) and you have decided on a consultation method, the data, including your personal message, is sent to the “Hecht MailCenter”.

10 Fundamentals of working with the Keratograph

The Instruction Manual concentrates on how to operate the Keratograph 5M and describes

- the measurement process and
- loading previous examinations

For detailed information about measurement evaluations, please refer to the User Guide.

10.1 Starting the Keratograph 5M Software

You have the following options for starting the Keratograph 5M software:

➔ Select a patient in the Patient Data Management view, and double-click on an examination in the list of existing examinations.

or

➔ Select a patient in the Patient Data Management view, and click the [Keratograph] button.

or

➔ Double-click the desired patient name.

10.2 Performing a Reference Measurement

Before the first measurement you need to perform a reference measurement.

➔ Select the menu item [Settings].
➔ Choose [Reference Measure].
For how to perform a reference measurement see *Chap. 21.5, page 85*.

10.3 Loading an Existing Examination

➔ Select the menu item [Examination] and click [Load].
The "Examination Explorer" screen opens.

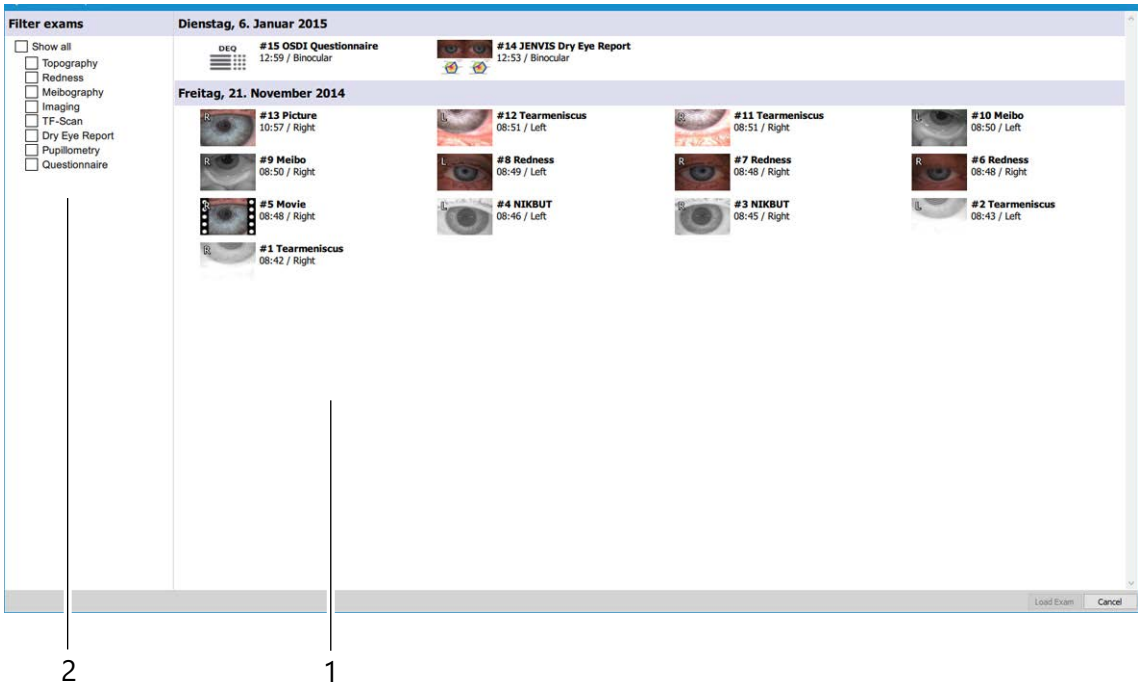


Fig. 10-1: Choose examination and load it.

1 Filter exams 2 Preview of examinations

➔ If necessary, select an examination filter, for example "Topography". Only the topography examinations will appear in the preview.
➔ Select the desired examination by clicking on it.
➔ Confirm your selection by clicking [Load examination], or by double clicking.
The Keratograph 5M program will load the examination you have selected.

When performing certain measurements e.g. tear meniscus height measurement, you are led directly to the evaluation menu by pressing the [Image] button.

10.4 Print Screen

➔ Select the menu item [Print].
The Print menu appears:
➔ Select the desired printer and enter the settings.
➔ Press the [Seen] button.
The currently displayed screen is printed.

10.5 Preparing the Examination

Attention

Erroneous measurements due to incorrect operation

Before first use:

- ➔ Make sure the installation and connection of the "Keratograph 5M" examination station are completed by our service or by a professional authorized by OCULUS.
- ➔ Let OCULUS or an authorized dealer train you in the operation of the Keratograph.

Recommended for beginners: First practice the entire measurement process a few times using the supplied reference sphere, *(Chap. 21.5, page 85)*.

- ➔ Make sure that no interfering light gets into the viewer of the Keratograph 5M.
  If necessary, darken the room.
- ➔ Check that
  - fresh paper has been placed on the chin rest, or, if necessary, the chin rest has been cleaned and disinfected
  - the forehead rest has been cleaned and disinfected, see also *Chap. 21, page 81*
- ➔ Ask the patient to place his chin on the chin rest.
- ➔ Do not touch the patient and the device at the same time.
- ➔ Adjust the table height so that the patient's head rests comfortably on the head-chin rest.
- ➔ Adjust the chin rest so that the patient's eyes are approximately at the level of the black ring on the chin-forehead rest.

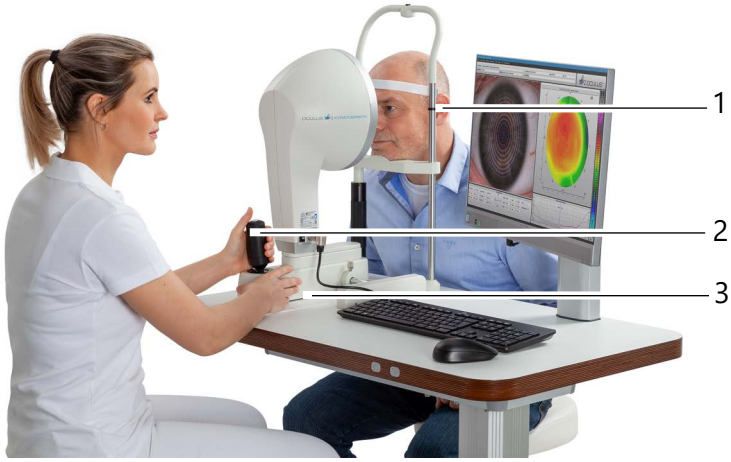


Fig. 10-2: Patient positioning

1 Chin-forehead rest with marking
2 Joystick with twist handle
3 Adjusting base

➔ Example of preliminary adjustment for the right eye: To do this, move the adjusting base. The marking on the back of the adjusting base must roughly coincide with the circle R.

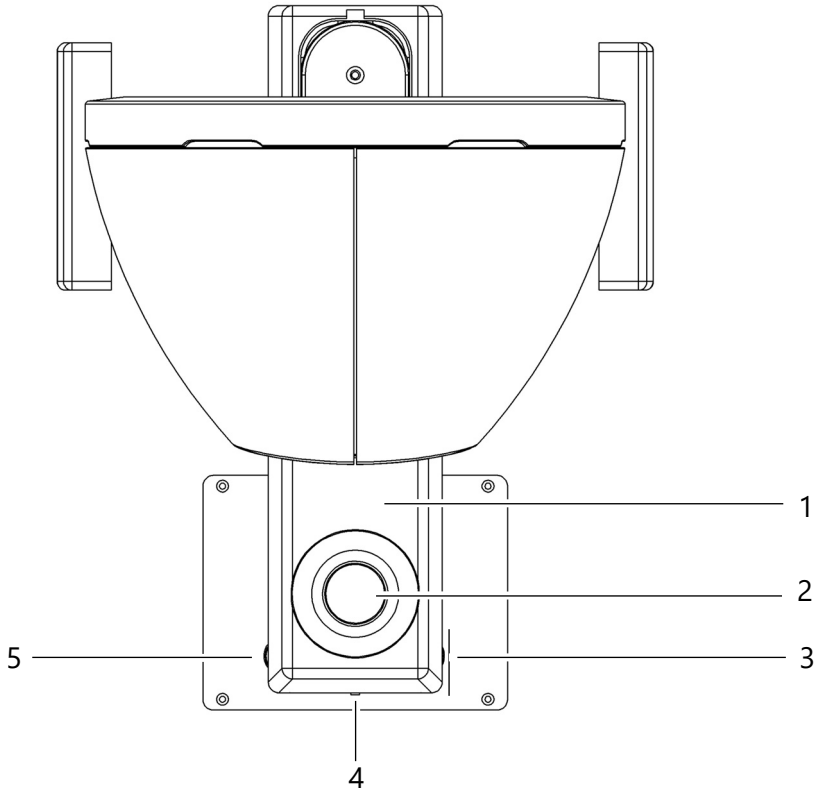


Fig. 10-3: Preliminary Adjustment

1 Adjusting base
2 Joystick
3 Circular mark left (hidden)
4 Marking on the adjusting base
5 Circular mark right (hidden)

➔ If necessary, correct the position of the adjusting base.
➔ Instruct the patient to focus on the red light in the center of the rings during the entire measurement.

10.6 Start screen

The following screen is always displayed at the start of the examination:

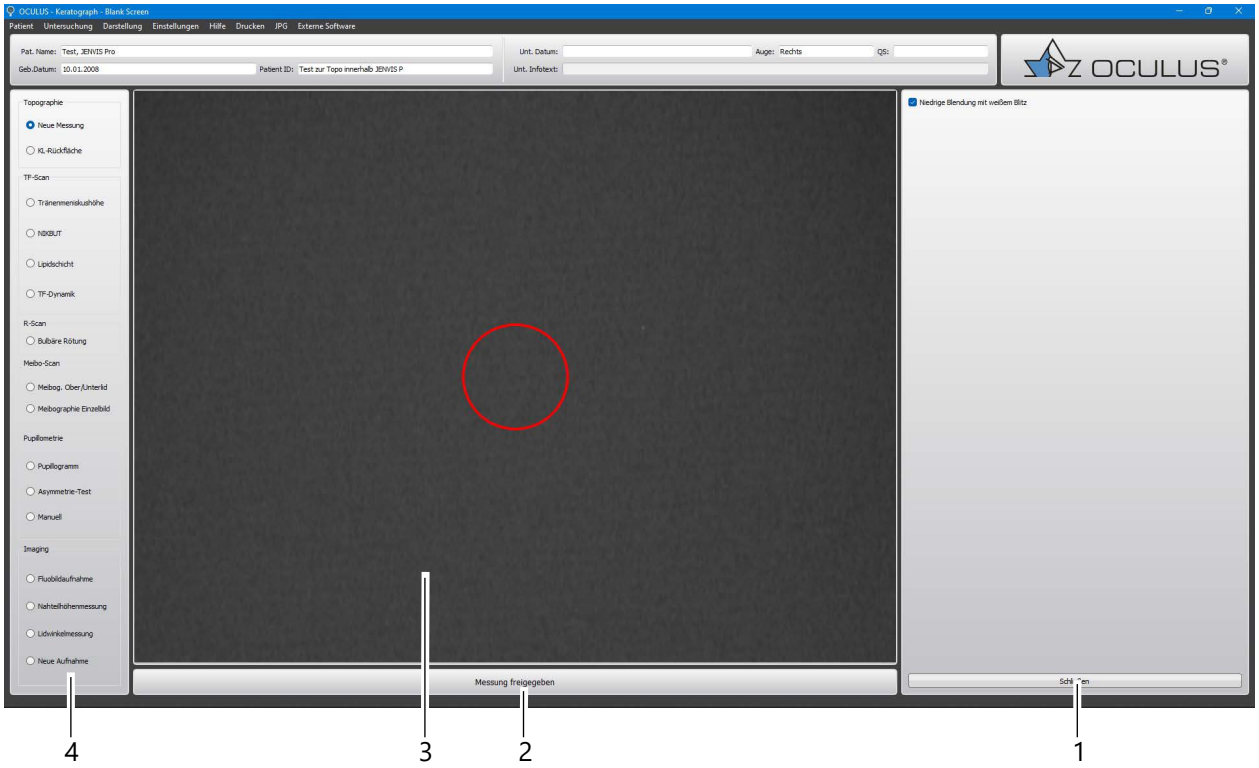


Fig. 10-4: Start screen

1 [Close] button
2 [Measuring released] button
3 Current camera image with cross hair
4 Examination bar

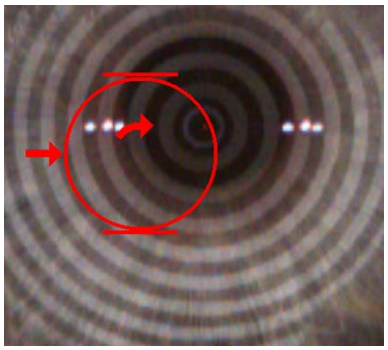
The examination list shows the examinations which can be performed with the Keratograph.
Examinations which are not enabled are grayed out.

10.7 Aligning the camera with the joystick

In the measuring functions “Topography” and “NIKBUT”, the measurements are triggered automatically. The camera must be accurately aligned for this purpose.

➔ Position the measuring head in front of the eye so that the keratometry marks are in focus (see figure).

➔ Align the camera exactly. Move or rotate the joystick in the directions indicated.

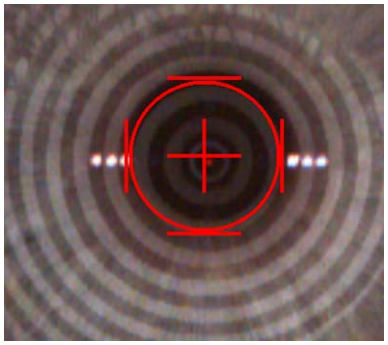


Example:

➔ Move the joystick to the right.

➔ Turn the joystick clockwise.

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 the position has been approximately reached, a cross appears in the center of the ring that is bordered by four bars.
The Keratograph 5M will automatically begin measuring.

For some measurements, the “Illumination“, “Magnification Changer“ and “Camera” groupboxes appear. You can set values for illumination, magnification changer and camera. You can save the settings as a program.

Proceed as described in *Chap. 17.5, page 59*.

10.8 Manual measurement

In rare cases, for example when highly irregular corneas are present, the measurement cannot be triggered automatically.

➔ Press the spacer bar to disable the automatic triggered measurement.

➔ Press the Enter key to trigger the measurement manually.

or

➔ Press the spacer bar and then the foot switch.
The measurement is triggered manually.
A manually initiated measurement may not be reproducible in some circumstances.

10.9 Image Capture with the Foot Switch

For measuring functions in which a single image is to be captured (snap shot), or a video is to be recorded (e.g. measurement of the tear meniscus height, R-Scan, Meibo-Scan, etc.) for the purpose of documenting the findings, you can simplify the process by using the foot switch.

➔ Capture (Grab) Image: Briefly press the foot switch.

➔ Record a video: Press the foot switch and hold it down for the duration you want to record the video.
To end the video recording, take your foot off the foot switch.

10.10 Finishing the Exam

➔ Ask the patient to remove his or her head from the chin-forehead rest.

➔ In the menu bar select the “Patient” menu and click on [New Patient/End].

➔ If necessary, make preparations to examine another patient (see “10.5 Preparing the Examination” on page 32).

11 Performing a “Topography” Examination

➔ Start the Keratograph 5M software (see “10.1 Starting the Keratograph 5M Software” on page 30).
➔ In the [Examination] menu, select [New].
The following screen is displayed:

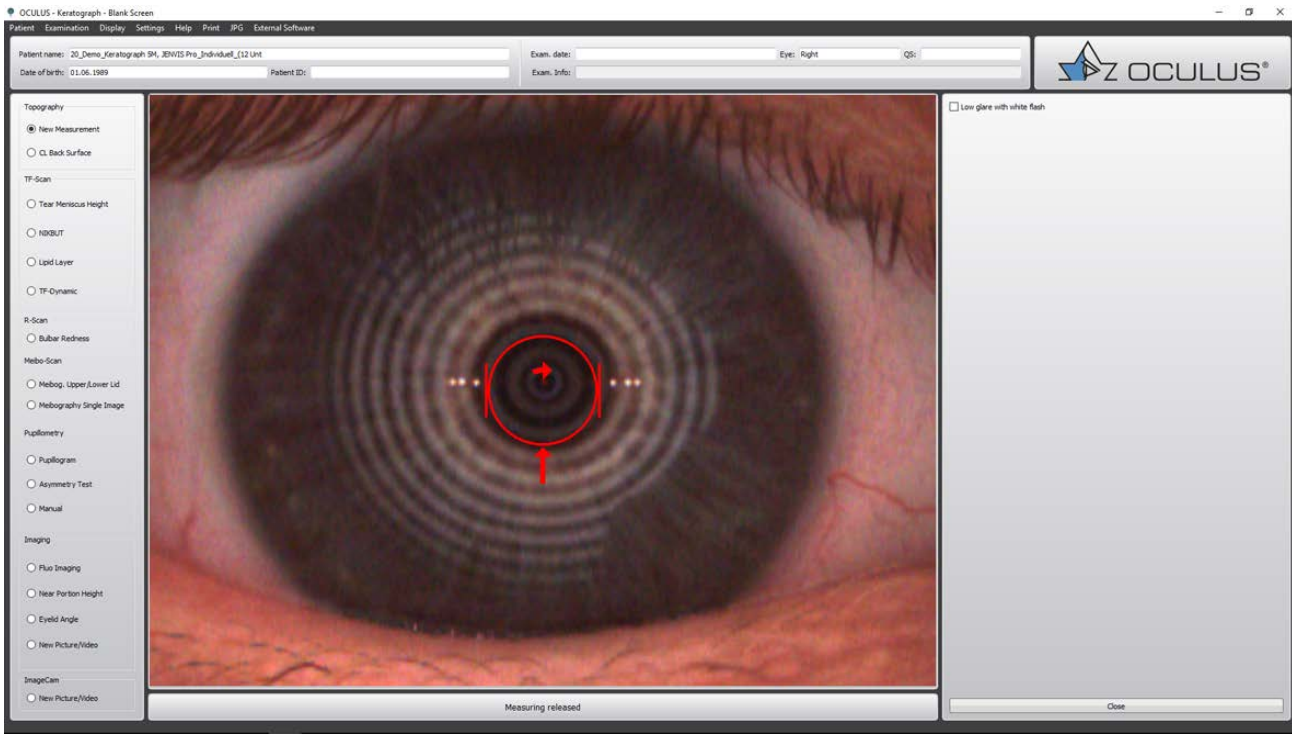


Fig. 11-1: Topography examination

➔ Position the patient and have them look at the red light in the middle of the device with their eyes wide open.
➔ When examining particularly light-sensitive patients, disable the [Low glare with white flash] (see “11.1 Patients who are sensitive to light: Low glare with white flash” on page 38) button if necessary.
➔ Activate the radio button [New Measurement].
➔ Align the camera using the joystick (see “10.7 Aligning the camera with the joystick” on page 34).

Once the cross-hairs are precisely aligned, the Keratograph automatically starts measuring. This opens the “Overview” screen”.

If the measurement does not start automatically, which can happen in case of severe corneal irregularities (e.g. severe keratoconus),

- you can initiante the measurement manually (see “10.8 Manual measurement” on page 36).

or

- you will be prompted in a pop-up window to manually mark the centre of the Placido rings (see “11.2 Manually marking the center of the Placido rings” on page 38)

A manually initiated measurement may not be reproducible in some circumstances.

11.1 Patients who are sensitive to light: Low glare with white flash

When examining particularly light-sensitive patients, it may be necessary to reduce the light intensity of the Keratograph.

➔ Low glare with white flash.

The aligning process between the device and the patient`s eye is performed under infrared light. Just the capturing process itself is conducted with white light. This will allow the patient to open their eye wider, enlarging the measured area.

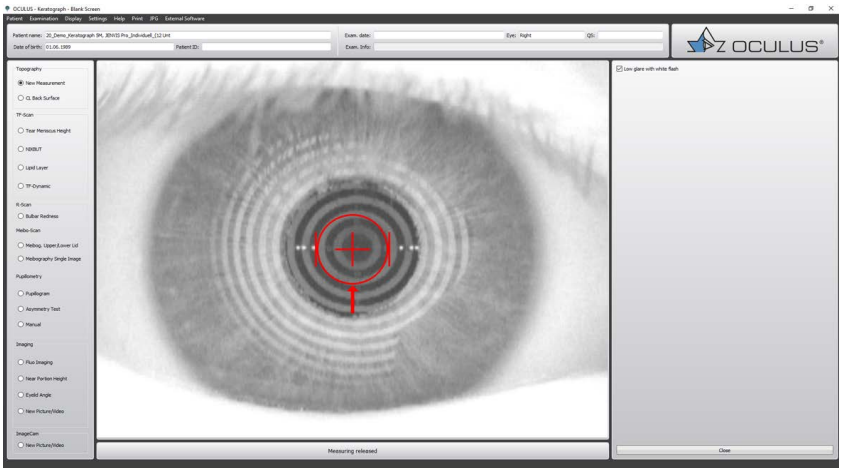


Fig. 11-2: Topography examination with white flash

11.2 Manually marking the center of the Placido rings

If considerable corneal irregularities are present, the keratometry marks may not be on a plane with the center point of the Placido rings. Automatic analysis of the topography data is then not possible. In that case, you will be prompted to manually mark the center of the Placido rings *(“Manual measurement” on page 36)*.

➔ Click with the left mouse button on the center point of the rings projected on the cornea.
The topography of the cornea is then calculated.

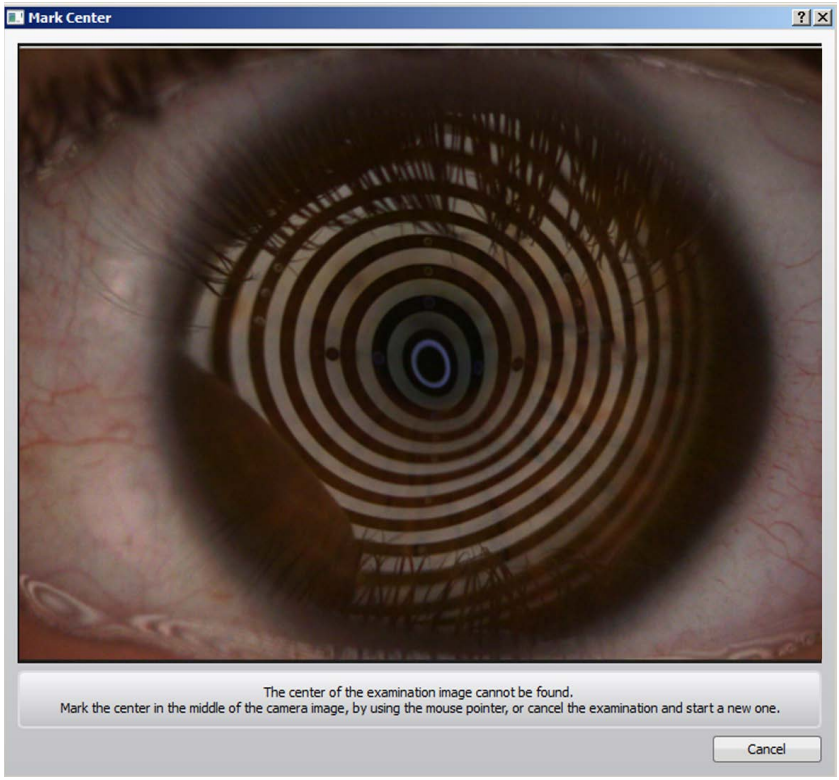


Fig. 11-3: Pop Up: Manually marking the center of the Placido rings

12 Contact lens back side measurement

Measuring of the back surface of contact lenses works similarly to measuring corneas.
After the contact lens has been secured into place in the contact lens holder, the latter can be put onto the fixation clip (see below).

12.1 Parts for Measuring the Back Surfaces of Contact Lenses

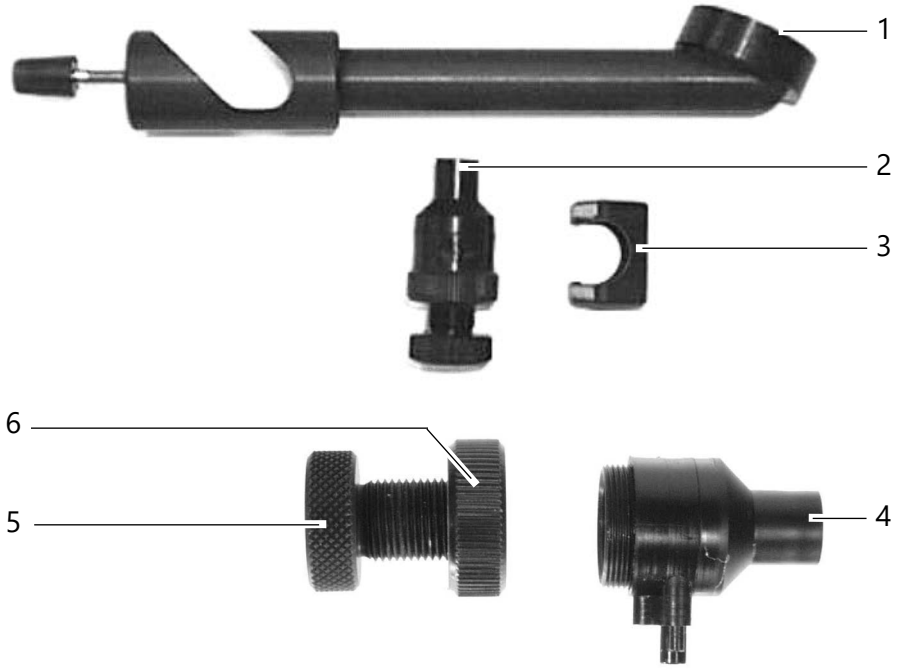


Fig. 12-1: Mounting Parts for Measuring the Back Surfaces of Contact Lenses

1 Reference sphere holder
2 Contact lens holder
3 Mounting clip
4 Contact lens holder, enlarged view (top part)
5 Contact lens holder, enlarged view (lock nut)
6 Contact lens holder, enlarged view (adjusting screw)

12.2 Fill the Contact Lens Holder with Water

- ➔ Unscrew the union nut to open the contact lens holder.
- ➔ Pour in the water and close the contact lens holder again by screwing the lock nut back on. Make sure that as little air as possible gets trapped inside.
- ➔ Hold the contact lens holder so that the adjusting screw points downwards.
- ➔ Screw the adjusting screw further into the contact lens holder until the top part of the contact lens holder is fully wet with water.
- ➔ Then screw out the adjusting screw again until the surface of the water takes on a slightly concave curvature.

12.3 Measure the Back Surface of the Dry Contact Lens

- ➔ Clean and dry the contact lens that is to be measured with a soft cloth.
- ➔ Make sure that there is no moisture, dust or fingerprints on the concave inner surface.

12.4 Fixating the Contact Lens

- ➔ Place the contact lens between your thumb and index finger and carefully lay it on the surface of the water on the contact lens holder.
- ➔ Screw the adjusting screw of the contact lens holder out until the contact lens sits securely in the holder.
  Take care to ensure that no air bubbles are produced and that no water gets onto the back surface that is to be measured.

12.5 Fasten the Mounted Contact Lens Holder into Place

- ➔ Screw the reference sphere holder to the chin rest
- ➔ Plug the contact lens holder onto the mounting clip.
- ➔ Adjust the mounting arm so that the optical axes of the contact lens roughly coincide with those of the keratograph.

12.6 Fully assembled contact lens holder

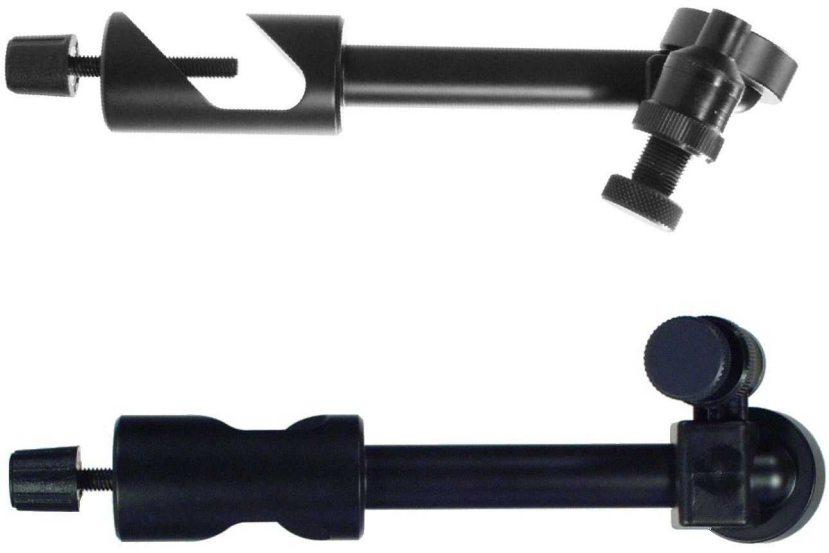
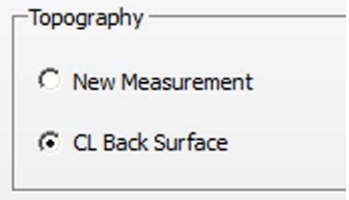


Fig. 12-2: Assembled contact lens holder

12.7 CL Back Surface

➔ Start the Keratograph 5M software (see "10.1 Starting the Keratograph 5M Software" on page 30).
➔ In the [Examination] menu, select [New].

➔ Enable the radio button [CL Back Surface].
Measurement now takes place in the same way as the topography measurement *(Chap. 11, page 37)*.



13 Performing a “TF Scan” Examination

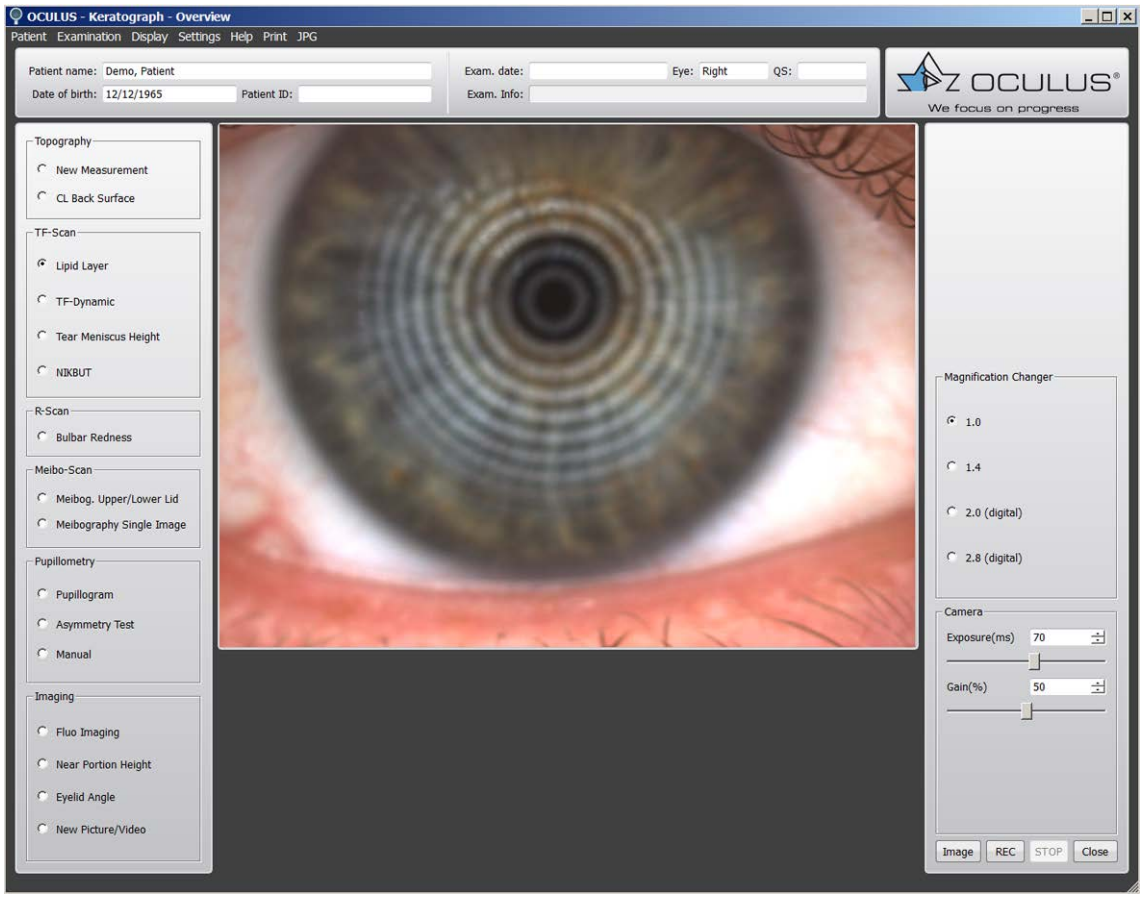


Fig. 13-1: TF scan examination , lipid layer example

The TF scan offers the following possibilities, with which you can examine the tear film:

- Lipid layer, *Chap. 13, page 43*
- TF dynamic, *Chap. 13.2, page 45*
- Tear meniscus height, *Chap. 13.3, page 46*
- NIKBUT, *Chap. 13.4, page 47*

You can find instructions on the magnification changer in *Chap. 17.5, page 59*

13.1 Examination of the Lipid Layer

The interference colors of the lipid layer and its structure are visible and can be recorded.

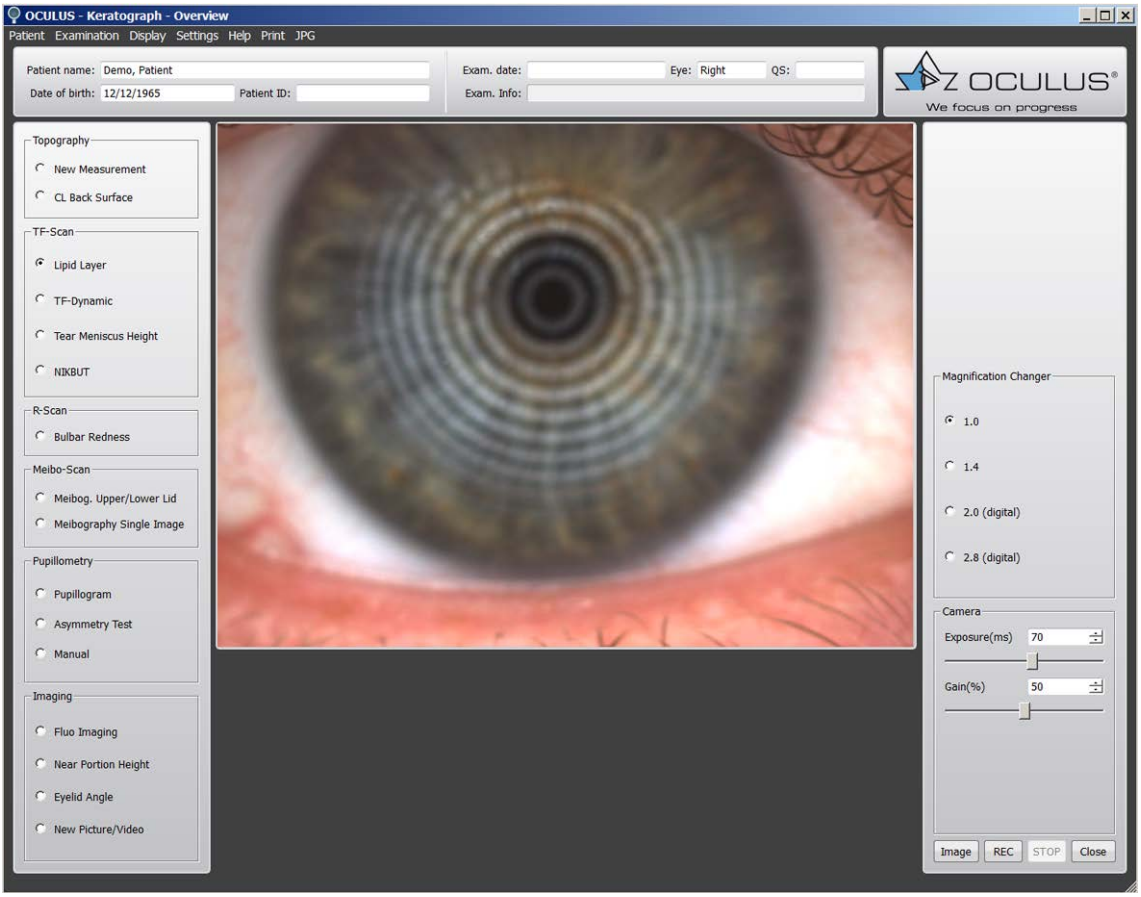


Fig. 13-2: Lipid Layer Measurement

- ➔ Activate the [Lipid Layer] radio button.
- ➔ Move the Keratograph 5M in small increments toward the patient’s eye. Now properly focus the Placido rings.
- ➔ Slightly pull back the camera and focus the lipid layer in the recording.
- ➔ Press the [Image] button to take a snap shot of the lipid layer, or press the [REC] button to record a video. To stop recording, click on the [STOP] button.
  Use the foot switch alternatively, *(Chap. 10.10, page 36)*.

Recommendation: A video recording is the best way to optimally document the lipid layer.

- ➔ To be able to optimally assess the distribution of the lipid on the surface of the tear film, record the lipid layer for the duration of two to three eyelid blinks.

You can find instructions on the magnification changer in *Chap. 17.5, page 59*

13.2 TF Dynamics Examination

With the video recording (up to 32 frames per second), you can observe the distribution of the particles in the tear film. Based on the flow properties, inferences can be made regarding the viscosity.

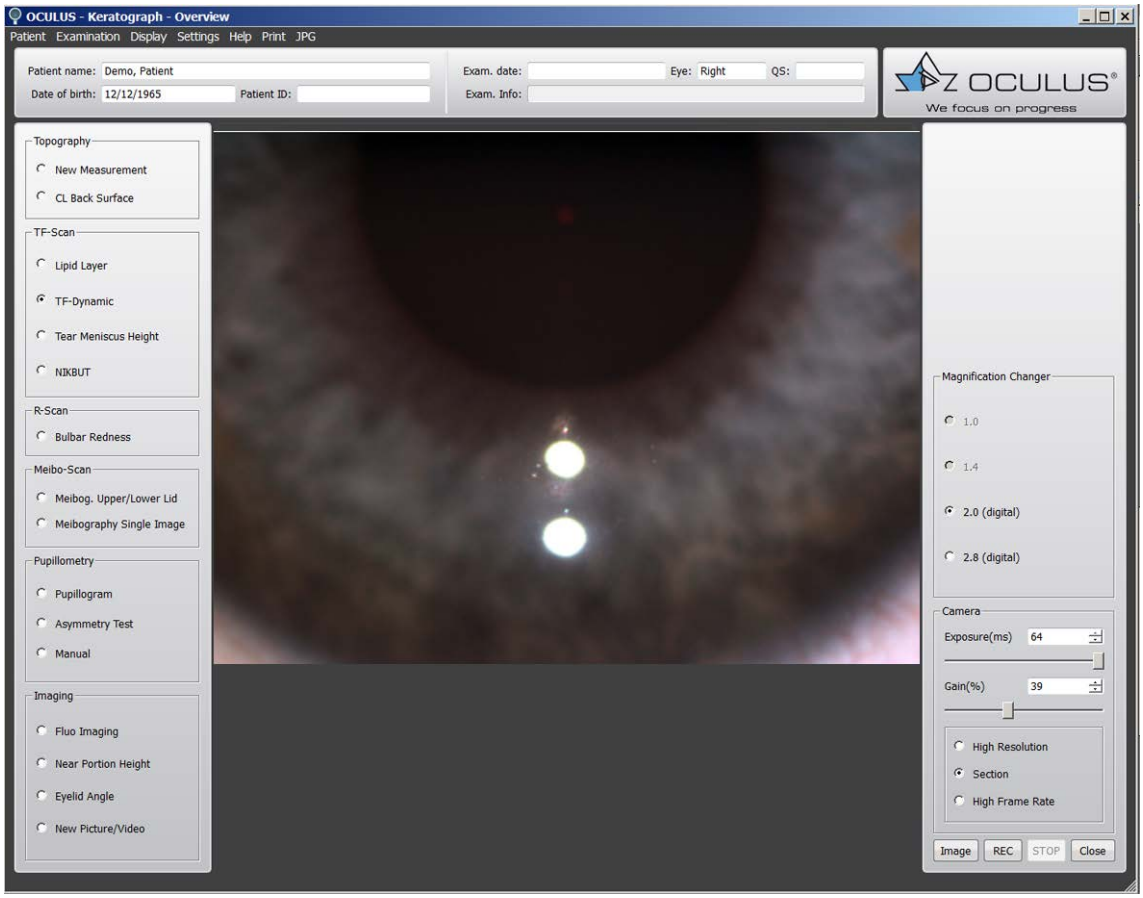


Fig. 13-3: TF Dynamics Measurement

- ➔ Activate the [TF-Dynamic] radio button.
- ➔ Adjust the camera if necessary, *Chap. 17.5, page 59*.
- ➔ Focus the light spots. The tear film must be clearly focused.
- ➔ Press the [Image] button to take a snap shot of the particles in the tear film, or press the [REC] button to record a video. To stop recording, press the [STOP] button.
  Use the foot switch alternatively, *(Chap. 10.10, page 36)*.

Recommendation: A video recording is the best way to document the tear film dynamic.

- ➔ To be able to assess the flow rate and flow properties of the tear film, as well as the number of particles, record the video for the duration of two to three eyelid blinks.

You can find instructions on the magnification changer in *Chap. 17.5, page 59*

13.3 Measuring the Tear Meniscus Height

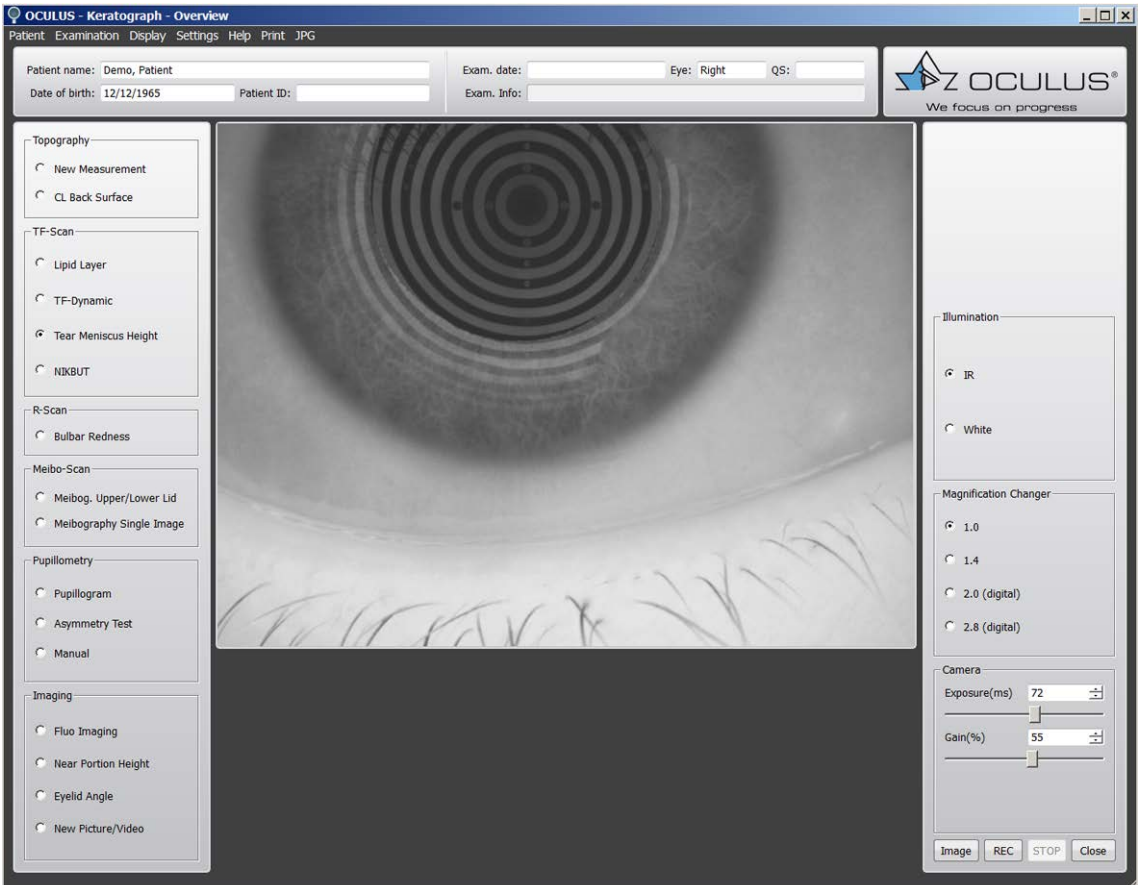


Fig. 13-4: Measurement of tear meniscus

To determine the amount of tear film, it is necessary to measure the tear meniscus height.

➔ Activate the [TF-Dynamic] radio button.

➔ Select [IR] or [White] lighting in the group box on the right.

Infrared light (IR) is not visible to the human eye. The use of this type of illumination for measuring purposes prevents the patient’s eye from being dazzled. This, in turn avoids falsification of the measuring results caused by an irritation secretion, which could occur in patients who are sensitive to light.

➔ Adjust the camera if necessary, *Chap. 17.5, page 59*.

➔ Adjust the camera image so that the tear meniscus is centrally displayed.

➔ Focus the reflected rings of the tear meniscus height.

➔ Press the [Image] button.

You can use the foot switch alternatively, *(Chap. 10.10, page 36)*.

You can find instructions on the magnification changer in *Chap. 17.5, page 59*

13.4 Measuring NIKBUT

With the NIKBUT measurement (Non Invasive Keratograph Break-Up Time), the dissolution period of the tear film is determined. Infrared light or white light is used for illumination in this case.

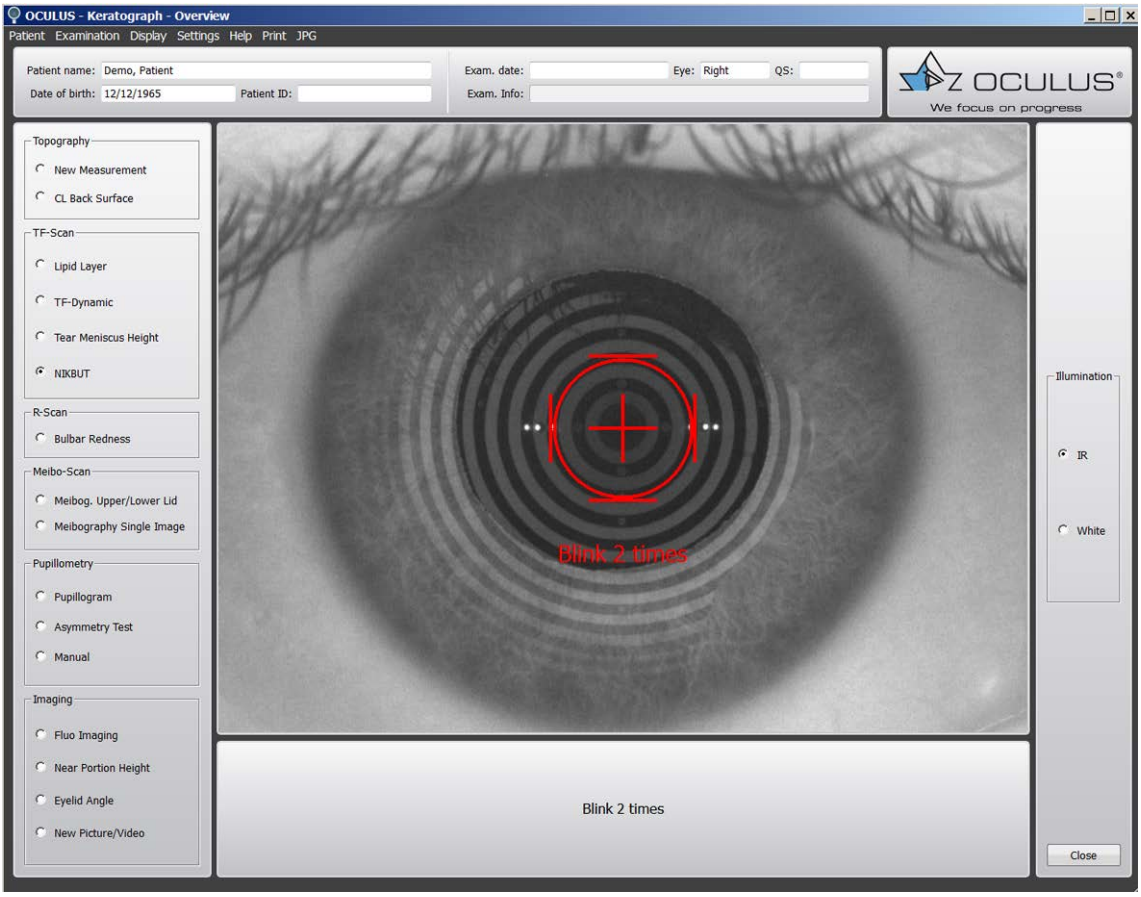


Fig. 13-5: NIKBUT IR examination

- ➔ Activate the [NIKBUT] radio button on the left in the examination bar.
- ➔ Select [IR] or [White] lighting in the group box on the right.

Infrared light (IR) is not visible to the human eye. The use of this type of illumination for measuring purposes prevents the patient’s eye from being dazzled. This, in turn avoids falsification of the measuring results caused by an irritation secretion, which could occur in patients who are sensitive to light.

- ➔ Adjust the camera if necessary, *Chap. 17.5, page 59*.
  After successful positioning and adjustment this prompt appears: „Blink 2 times“.
- ➔ Ask the patient to blink twice.
  The measurement is performed.
- ➔ Please tell the patient to keep his eye open as long as it is comfortable.

Note

The measurement is automatically terminated if the patient blinks, moves strongly, or the tear film significantly breaks up.

14 Performing an “R Scan” Examination

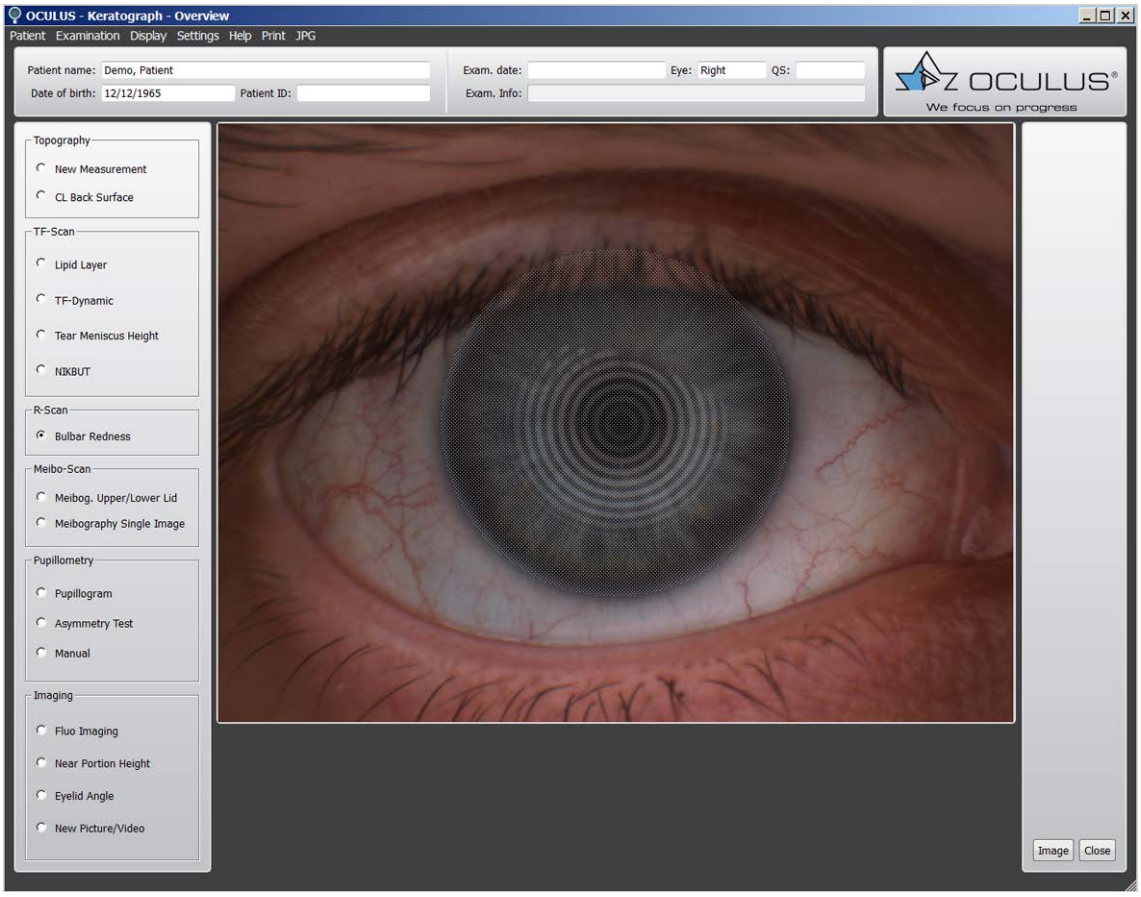
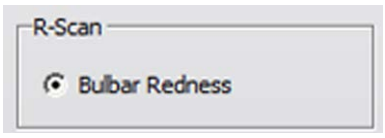


Fig. 14-1: R-Scan examination



With this examination, you can classify levels of redness.

➔ Activate the [Bulbar Redness] radio button.

➔ Align the camera so that the grey “disc” covers the iris and .

➔ Press the [Image] button.
Use the foot switch alternatively, *(Chap. 10.10, page 36)*.

15 Performing a “Meibo Scan” Examination

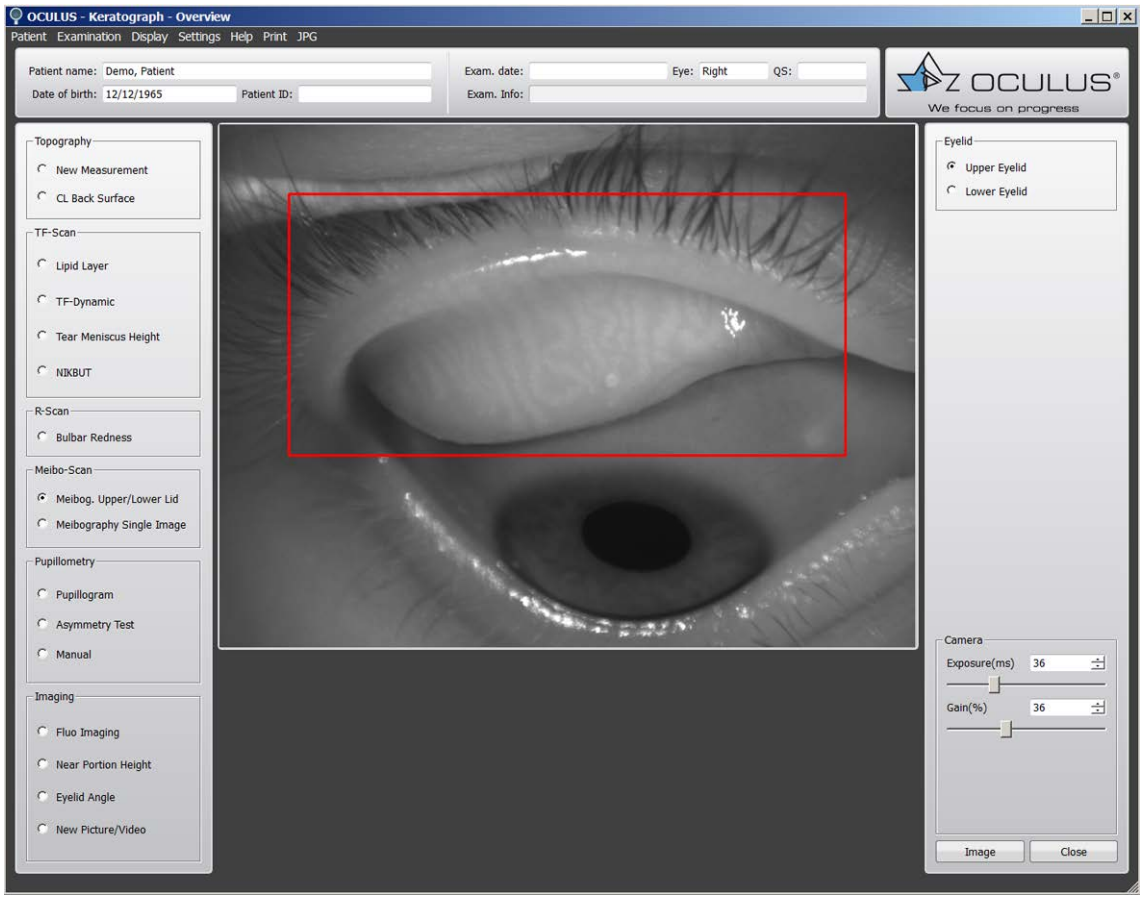
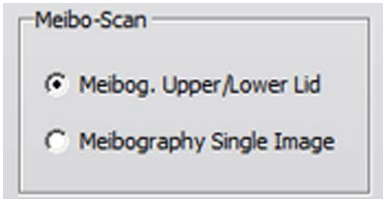


Fig. 15-1: Meibo-Scan examinations

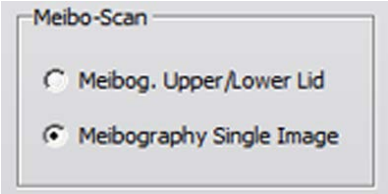
This examination visualizes the meibomian glands. They are displayed three-dimensionally. You can make images of the upper and lower eyelid as well as individual images. Changes can be viewed and classified.

15.1 Upper and Lower Eyelid Image



- ➔ Enable the [Meibog. Upper/Lower Lid] radio button in the right group box [Meibo-Scan].
- ➔ Ectropionize the upper eyelid first.
- ➔ Adjust the camera if necessary, *Chap. 17.5, page 59*.
- ➔ Position the camera so that the upper eyelid fits in the red-framed recording box.
- ➔ Focus on the Meibom glands.
- ➔ Start the recording of the upper eyelid. To do this, press the [Image] button.
  Use the foot switch alternatively, *(Chap. 10.10, page 36)*.
- ➔ Repeat the steps for the lower eyelid.

15.2 Recording a Single Image



- ➔ Activate the [Meibography Single Image] radio button.
- ➔ Ectropionize the upper or lower eyelid.
- ➔ Position the camera so that the upper or the lower eyelid fits in the red-framed recording box.
- ➔ Focus on the Meibom glands.
- ➔ Start the recording. For this, press the [Image] button.
  Use the foot switch alternatively, *(Chap. 10.10, page 36)*.

16 Performing a “Pupillometry” Examination

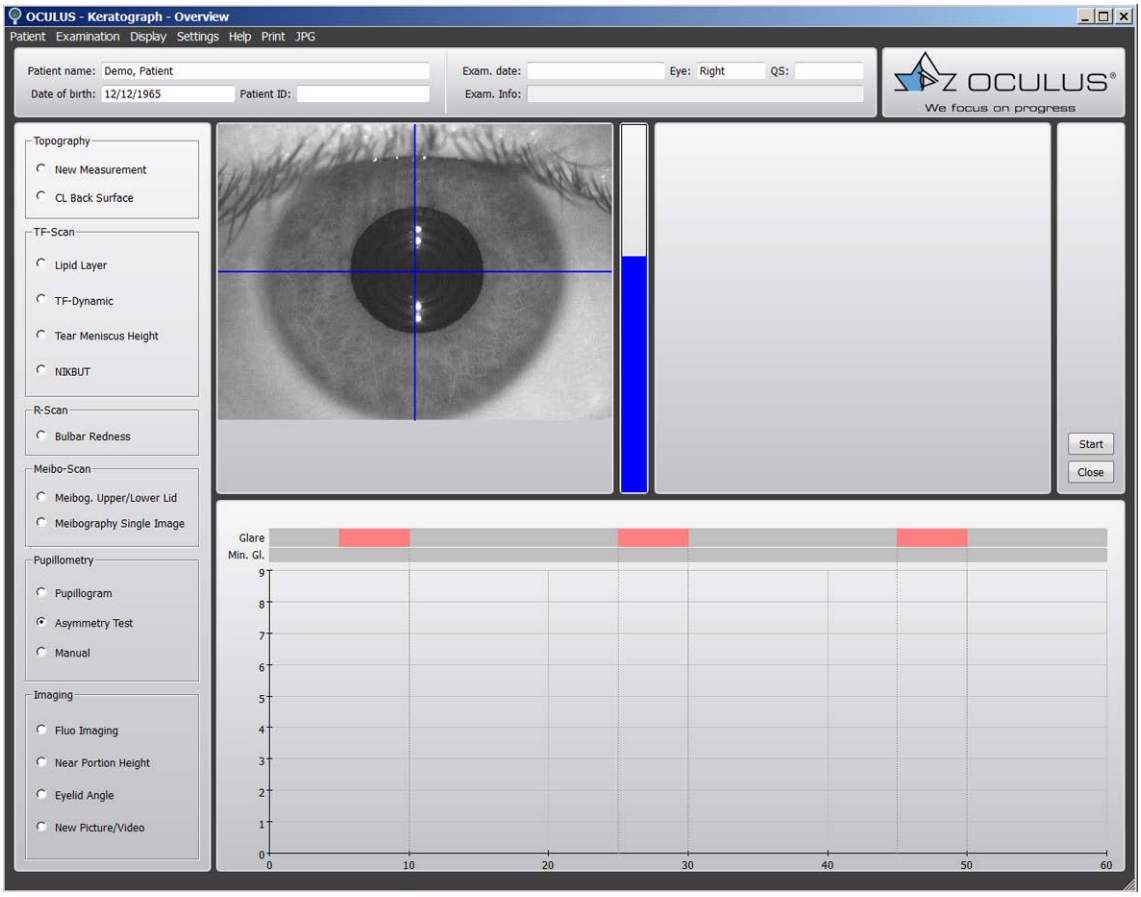
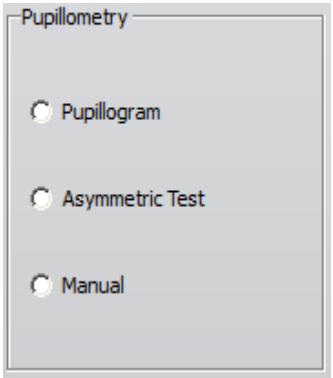


Fig. 16-1: Pupillometry Examination



With this function, you continuously examine the pupil size dependent on different glare states.

➔ Select the desired measuring program by enabling the corresponding radio button:

- Pupillogram (*page 54*)
- Asymmetric test (*page 54*)
- Manual (*page 54*)

16.1 Adjustment

To use the pupillometry function, you must first focus the image.

➔ Use the adjusting base and the joystick to focus on the center of the pupil (see “10.7 Aligning the camera with the joystick” on page 34).

➔ Use the image sharpness to adjust the distance.
To do so, sharply focus the image of the pupil by moving the x-y stage or the joystick towards the Keratograph or away from the Keratograph.

The blue bar indicates the degree of sharpness of the camera image. The higher the blue bar is, the sharper the camera image.

16.2 Measuring values display

The measured values are displayed as a diagram:

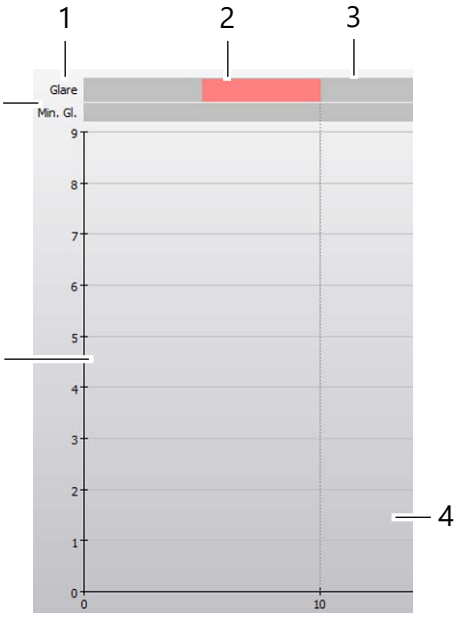


Fig. 16-2: Diagram

1	“Glare” bar	4	x axis
2	Red marker	5	y axis
3	Gray marker	6	“Min. Gl.” bar

Glare	Indicates the status of the ring illumination (Placido system).
Red markers	“Glare on”
Grey markers	“Glare off”
x axis	Measuring time in s
y axis	Size of pupil in mm

Min. Gl.	indicates the status of the inner ring. The glare intensity is much weaker.

16.3 Pupillogram

Automatic, standard pupillometry program.
0.2s Glare, then 9.8s intermission (5 times).

➔ Enable the radio button [Pupillogram].
➔ Focus the image.
➔ Press the [Start] button to start the measurement.
The measurement automatically comes to an end after 60 seconds.
You can end the measurement manually by pressing the [Stop] button. The measurement is saved and the next screen appears automatically, refer to the *User Guide*.

16.4 Asymmetric Test

Automatic pupillometry program for detection of unequal pupils.
5s Glare, then 15s intermission (3 times).

➔ Enable the radio button [Asymmetric Test].
➔ Focus the image.
➔ Press the [Start] button to start the measurement.
The measurement automatically comes to an end after 60 seconds.
You can end the measurement manually by pressing the [Stop] button.
The measurement is saved and the next screen appears automatically, refer to the *User Guide*.

16.5 Manually

The glare states are set manually.

➔ Adjust the glare intensity by pressing the [Glare] and [Min. glare] buttons accordingly.
In this program, you set the glare manually (in contrast to the automatic programs).
[Glare] button: Switches the entire ring system on or off.
[Min. glare] button: Switches the inner ring of the ring system on or off.
The stimulus intensity of [Min. glare] is much lower than that of [Glare].

The measurement ends automatically when the measurement reaches the right side of the diagram.
Alternatively, you can end the measurement by pressing the [Stop] button.
When the measurement has ended, the Overview screen automatically opens (*(Fig. 10-4, page 34)*).

17 Imaging

With the imaging software and the high-resolution color camera, you can record videos and create image files to document clinical findings of the eye, or you can conduct special measurements for the adaptation of contact lenses and for checking their proper fit, with or without fluorescine.

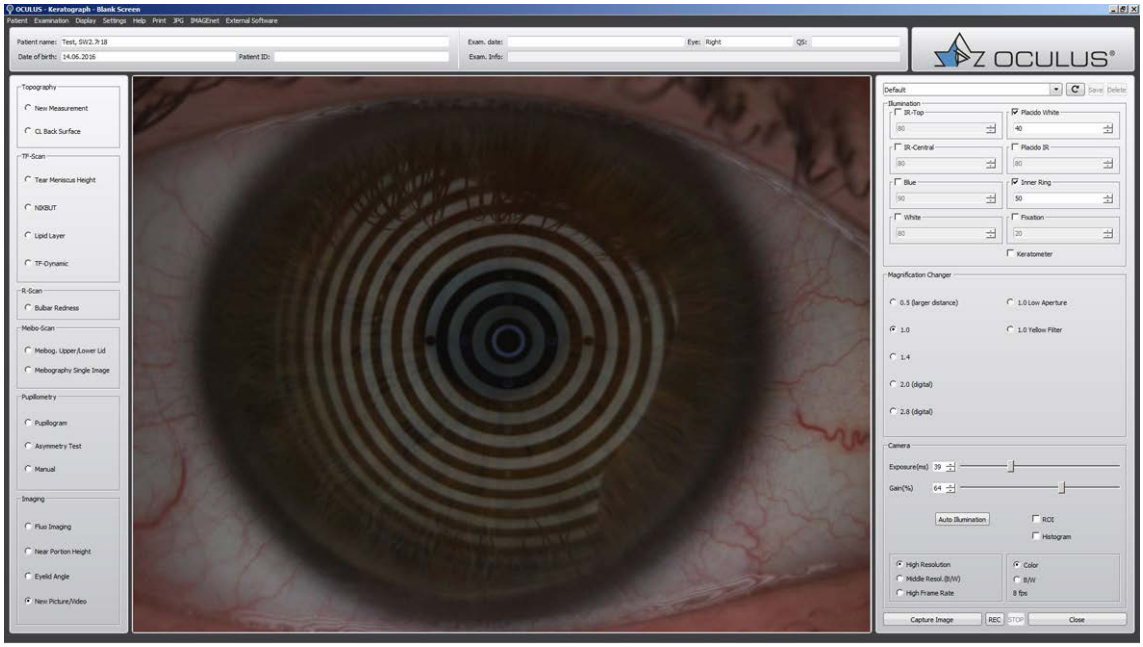
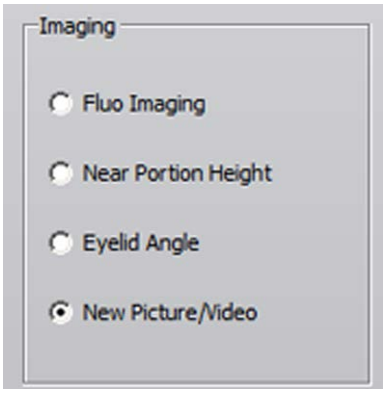


Fig. 17-1: Examinations with “Imaging”



➔ Select the desired recording type.
To do this, activate the appropriate radio button:

- Record Fluo Imaging, *Chap. 17.1, page 56*
- Measure near portion height, *Chap. 17.2, page 57*
- Eyelid angle measure, *Chap. 17.3, page 58*
- New recording, *Chap. 17.4, page 59*

17.1 Recording a Fluo Image

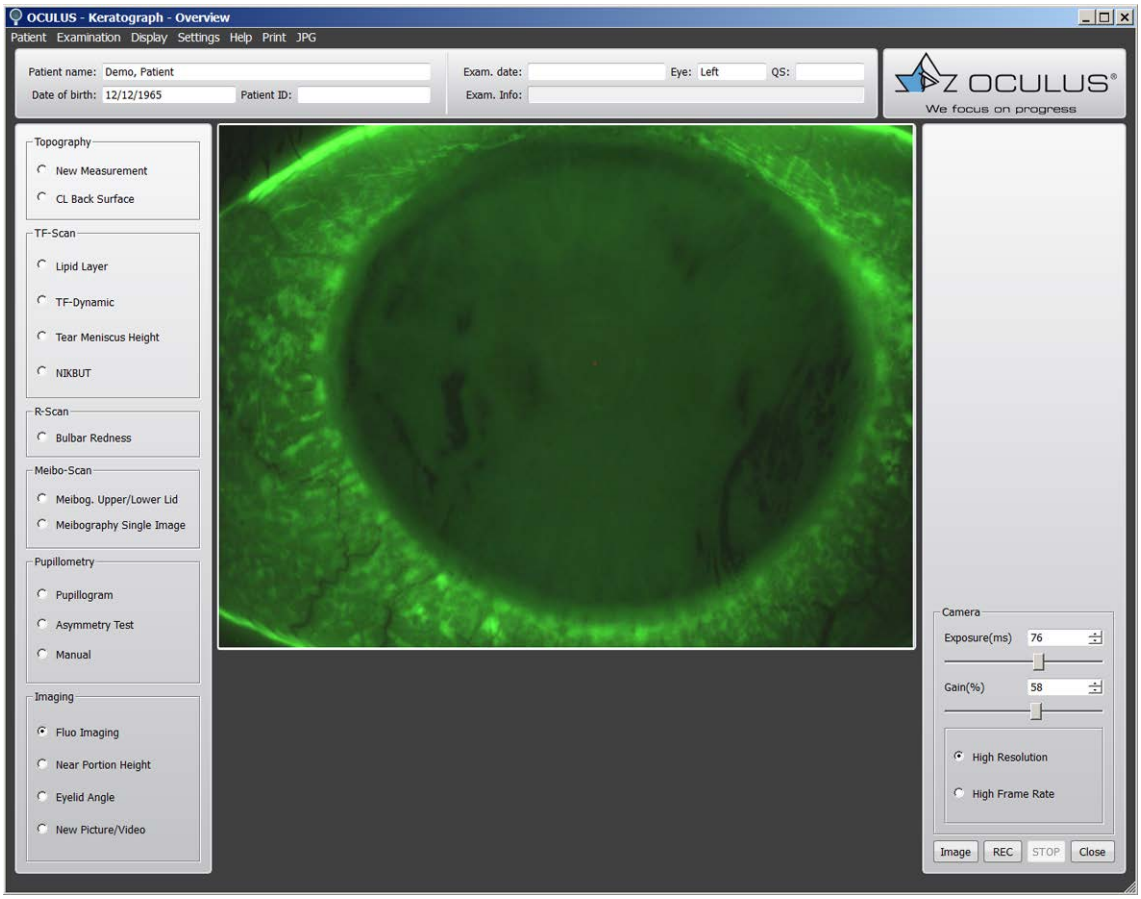


Fig. 17-2: "Fluo imaging" function

- ➔ Activate the [Fluo Imaging] radio button.
- ➔ Adjust the camera if necessary, *Chap. 17.5, page 59*.
- ➔ Align the camera to the center of the contact lens.
- ➔ Press the [Image] button for a static image.
  Now you can use the fluo image for contact lens fitting, see *User Guide*.
- ➔ Press the [REC] button to record a video, for example, to dynamically check the fit of the contact lens.
  Click the [STOP] button to stop or pause the recording.
  You can use the foot switch alternatively, *(Chap. 10.10, page 36)*.

The video recordings and single images are saved automatically.

- ➔ Press the [Close] button and you will reach the overview display.

You can find more information in the *User Guide*.

17.2 Near Portion Height Measurement

The near portion height measurement is used to determine separator positions for bifocals and rigid contact lenses.

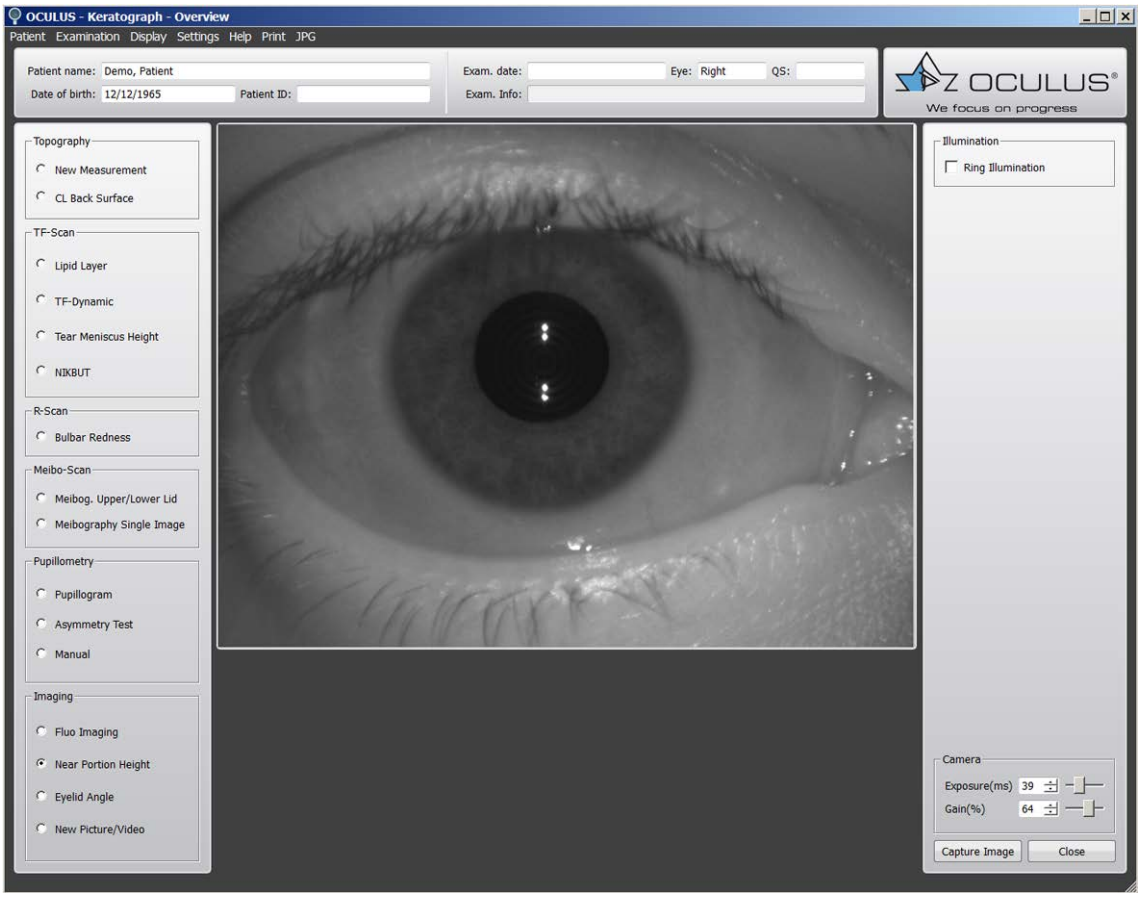


Fig. 17-3: "Near portion height measurement" imaging function

- ➔ Activate the [Near Portion Height] radio button.
- ➔ Adjust the camera if necessary, *Chap. 17.5, page 59*.
- ➔ Center and focus on the eye in the camera image.
- ➔ Enable the [ring illumination] radio button to make the illumination brighter. This will dazzle the eye, making the pupil diameter as small as possible.
- ➔ Press the [Image] button to trigger the recording.
  Use the foot switch alternatively, *(Chap. 10.10, page 36)*.

The image is stored automatically.
Press the [Close] button and you will reach the next display.
Perform the near part height measurement and evaluation, see *User Guide*.

17.3 Eyelid Angle Measurement

The measurement of the nasal lower lid angle is required for the fitting and accurate calculation of toric soft lenses.

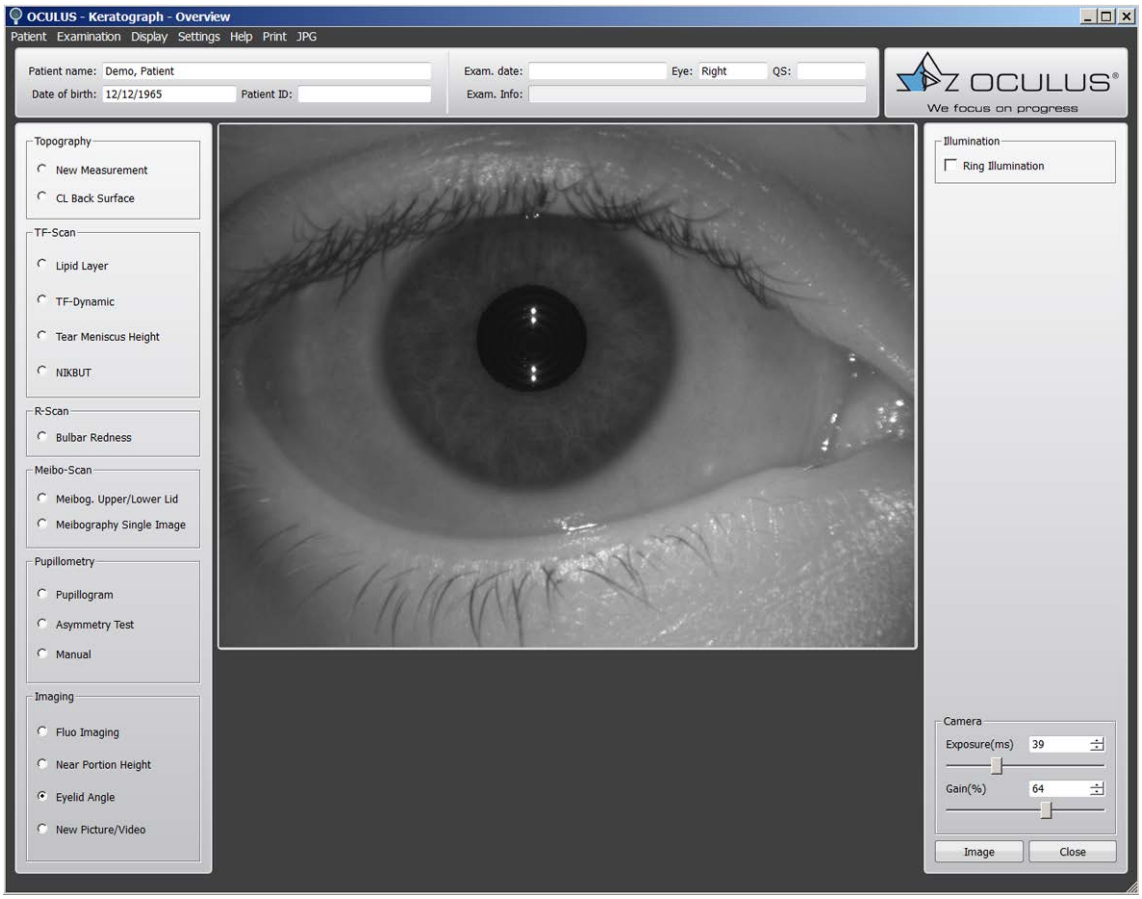


Fig. 17-4: "Eyelid angle measurement" imaging function

- ➔ Activate the [Eyelid Angle] radio button.
- ➔ Adjust the camera if necessary, *Chap. 17.5, page 59*.
- ➔ Center the eye in the camera image.
- ➔ Press the [Image] button to trigger the recording.
  Use the foot switch alternatively, *(Chap. 10.10, page 36)*.

The image is stored automatically and you will reach the next display.
Now you can perform the eyelid angle measurement, see *User Guide*.

17.4 New Recording

This allows you to make additional photos and videos for image documentation.

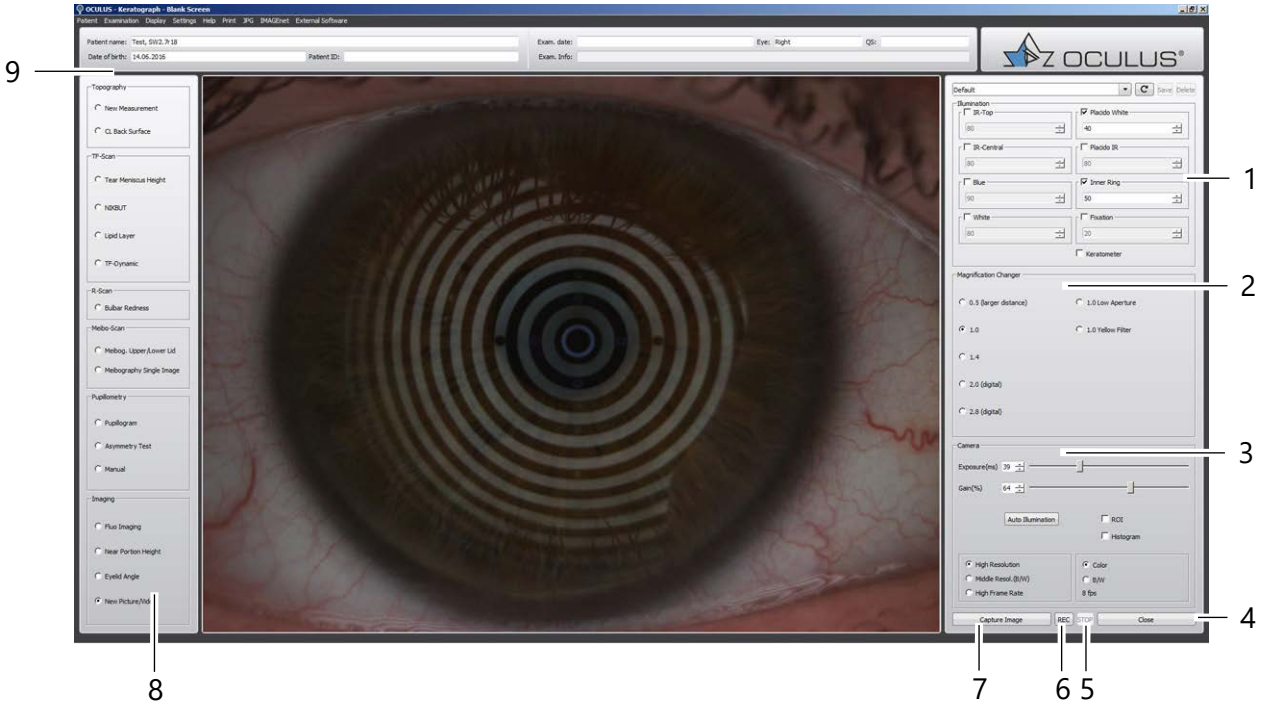


Fig. 17-5: "New recording" overview

1 Illumination settings
2 Magnification changer
3 Camera settings
4 [Close] button
5 [STOP] button
6 [REC] button
7 [Image] button
8 Previous examinations
9 Examination and patient data

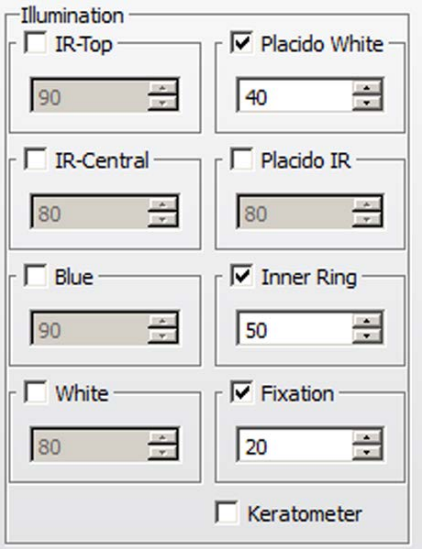
How to adjust the camera can be found in *Chap. 17.5, page 59*.

17.5 Adjusting Illumination, Magnification Changer and Camera

For some measurements, the "Illumination", "Magnification Changer" and "Camera" groupboxes appear. You can set values for illumination, magnification changer and camera. You can save the settings as a program.

The optimal camera and illumination settings have already been preset for the selectable measuring functions.

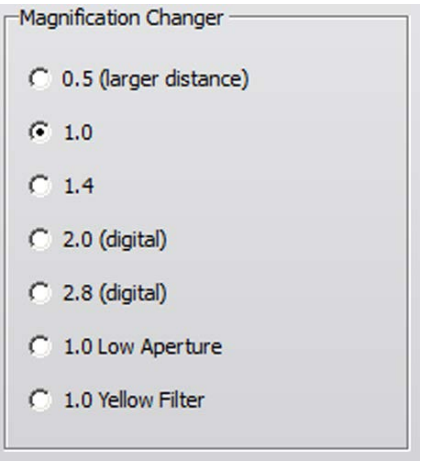
17.5.1 Adjust Illumination: [Illumination] groupbox



➔ Activate the desired radio button.

IR-Top/IR-Central: If only the "IR-Top" and "IR-Central" checkboxes are enabled (in a darkened room):
The fit of the contact lens can be evaluated with the pupil dilated (e.g. for fitting multi-focal lenses).
Blue: The blue light is used for excitation of the fluorescine to fluorescence.
White: TF-Dynamic: Two spots in the bottom segment of the Placido bowl are set to white.
Placido White: Topography and NIKBUT examination: The illumination of the Placido bowl is set to white.
Placido IR: The lighting of the Placido bowl is set to infrared.
Inner Ring: The patient's eye is subjected to minimal glare.
Fixation Used to assist the patient's fixation.
Checkbox: [Keratometer]: Keratometry marks for aligning the topography

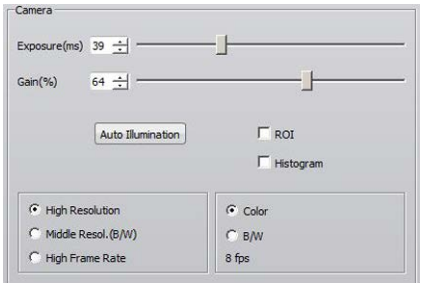
17.5.2 Magnification changer



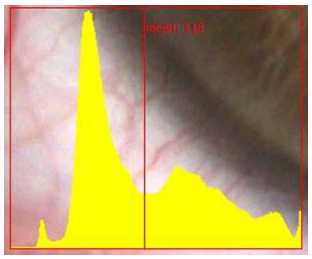
You can set the magnification in this group box. You have a choice of three optical and two digital zooms.

- **0.5 to 1.4**
- **2.0 (digital)**
- **2.8 (digital)**
- **1.0 Low Aperture**, for greater depth of field
- **1.0 Yellow Filter**, for images taken with fluorescine

17.5.3 Adjusting the Camera: Camera groupbox



Exposure time: The longer the exposure time is, the brighter the image will be. The image can, however, become less sharp as a result.
➔ Change the exposure time using the slider control.
Gain: If you increase the gain value, the picture brightens. However, the image quality suffers as a result; too much gain results in grainy images.
➔ Change the gain setting on the slider control.
Auto Illumination: You can adjust the illumination with this function, e.g. so as not to overexpose an image.
➔ Press the button [Auto Illumination].
You can now adjust the illumination for the entire image capture.



ROI: (Region of Interest); the illumination for a defined region of the image is adjusted.

➔ Activate the checkbox [ROI].

➔ Move the cursor to the desired position and click on the left mouse button.

You can now adjust the illumination for the selected region.

Histogram: Depending on what has been selected, a histogram is displayed for the entire image or just for the ROI.
The illumination is properly adjusted when the peak on the graphic lies on the red center line.

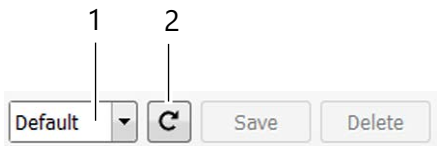
High Resolution, Middle R. (B/W) or High Frame Rate: Details will be more visible at a higher resolution, high frame rates provide "smooth" videos.
Color or B/W: You can choose color or black and white display.

17.5.4 Buttons

REC/STOP: You start or stop the video recording with these buttons. Limit the duration of the recordings to maximum one minute. otherwise the volume of data on your computer will become too extensive.
Image: With this button you start an individual recording. You can, for example, record static fluo images.

Note
The video recordings and single images are saved automatically.

17.5.5 Selecting and saving settings



You can use default settings and you can save your own settings as an image program.
Using default settings:

➔ In the drop down list select the "Default" program.
default settings
"XXX": your own saved settings

17.5.6 Using your own settings for an image program

➔ Select the settings.

➔ Enter the name of the program.

➔ Press the [Save] button.

If you press the button, the image program uses the saved settings.
If you press the [Delete] button, you delete the image program. You cannot delete the manufacturer "default" settings.

18 Performing Dry Eye Examinations: JENVIS Dry Eye Report

You can perform Dry Eye examinations in the JENVIS Dry Eye Report. The results are summarized in a clear and understandable manner. You can also print a report with the results and explanations for the patient.

➔ Select the [New JENVIS Dry Eye Report] menu in the "Examination" menu bar.
The following screen will appear:

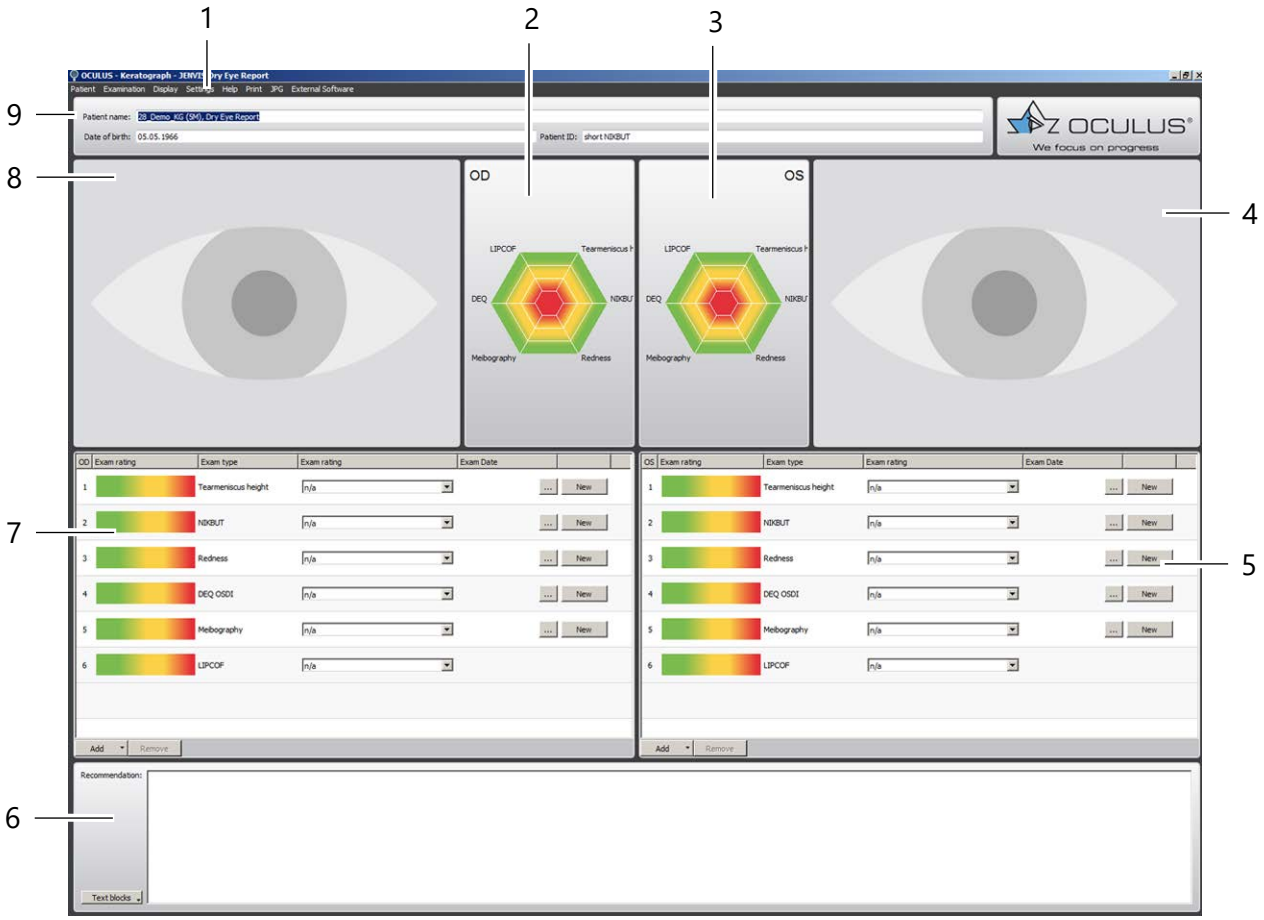
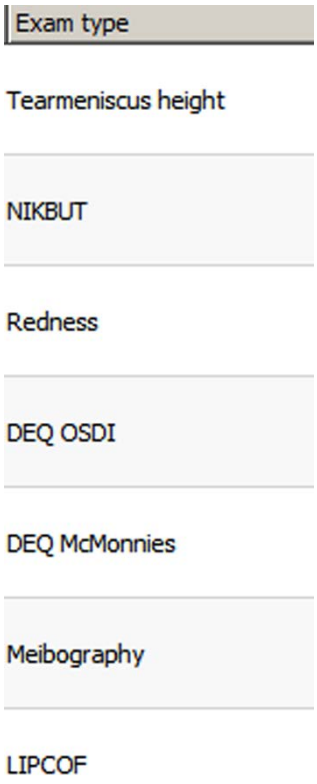


Fig. 18-1: Overview of Dry Eye Examinations

1 JENVIS Dry Eye Report menu bar
2 Result diagram for right eye
3 Result diagram for left eye
4 Camera image for left eye (if available)
5 Exam types for left eye
6 "Recommendation" field
7 Exam types for right eye
8 Camera image for right eye (if available)
9 Patient and examination data

18.1 Selecting the Exam Type



You can choose from six standard exam types for the right and left eye respectively. Load the required examination or enter a value.

➔ Select the desired exam type by clicking on the [New] button or choosing a value from the drop down menu.

You can select further exam types. For more information, refer to the *User Guide*.

18.2 Performing the selected examination

➔ Perform the selected examination. The respective examination is performed similar to the examinations already described.

- Tear meniscus height, *Chap. 13.3, page 46*
- NIKBUT, *Chap. 13.4, page 47*
- Redness, *Chap. 14, page 49*
- DEQ OSDI, *Chap. 18.5, page 65*
- Meibo-Scan, *Chap. 15, page 50*
- LIPCOF, *Chap. 18.6, page 66*

The latest measurement result is shown as a blue dot in the menu bar.

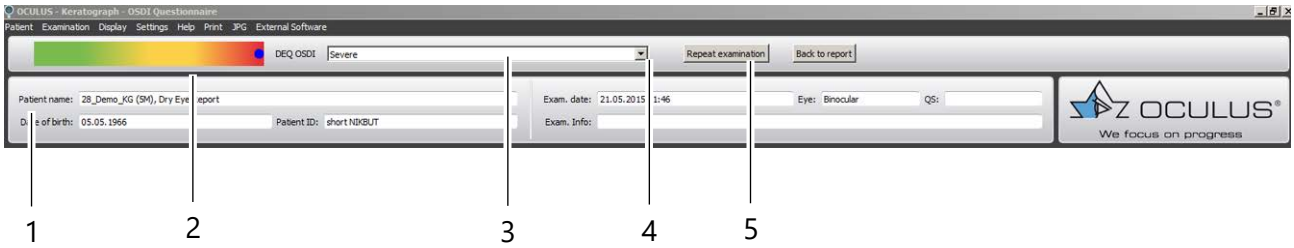


Fig. 18-2: JENVIS Dry Eye Report menu bar

1 Patient and Examination Data
2 Color bar for measurement result
3 Drop down list for measurement result
4 [Repeat examination] button
5 [Back to report] button

➔ If measurement was correct: Click on the [Back to report] button to return to the overview display.
After performing a redness examination, the image of the eye is shown in the overview display.
➔ If measurement has to be repeated: Press the [Repeat examination] button.

Recommendation:
- Always perform all given examinations to receive a complete hexagram.
- Fill in the "Recommendation" field so that the patient receives the respective information, *Fig. 18.3, page 64*.

For further information on the JENVIS Dry Eye Report and the examinations, refer to the *User Guide*.

18.3 Filling in the "Recommendation" field

In this field you can insert details which are later shown on the printout. You can use text components.
For more information, refer to the *User Guide*.

18.3.1 Using Text Blocks

➔ Click the [Text blocks] button.
➔ Select the desired text component. This text will be added to the "Recommendation" field.
➔ Select further text components, if required.

18.3.2 Entering own Texts

➔ Move the cursor to the "Recommendation" field and enter your own text.

18.3.3 Deleting Texts

➔ Mark the text which should be deleted with the cursor.
➔ Press "Del" on the keyboard.
The text will be deleted permanently.

18.4 Printing the JENVIS Dry Eye Report

➔ Select the [Print] menu item.
The print dialog opens.
Select the desired printer.
➔ Press the [Print] button.
The results of the dry eye examinations will be printed in the JENVIS Dry Eye Report.
After printing, the JENVIS Dry Eye Report is in read-only mode.

For more detailed information on the printout, refer to the *User Guide*.

18.5 DEQ OSDI

The DEQ OSDI (Dry Eye Questionnaire Ocular Surface Disease Index) is a standardized medical history form. The patient is asked about his/her subjective symptoms. The 12 answers result in an OSDI value.
You can find more information in the *User Guide*.

➔ Press the [New] button. The DEQ OSDI is displayed.

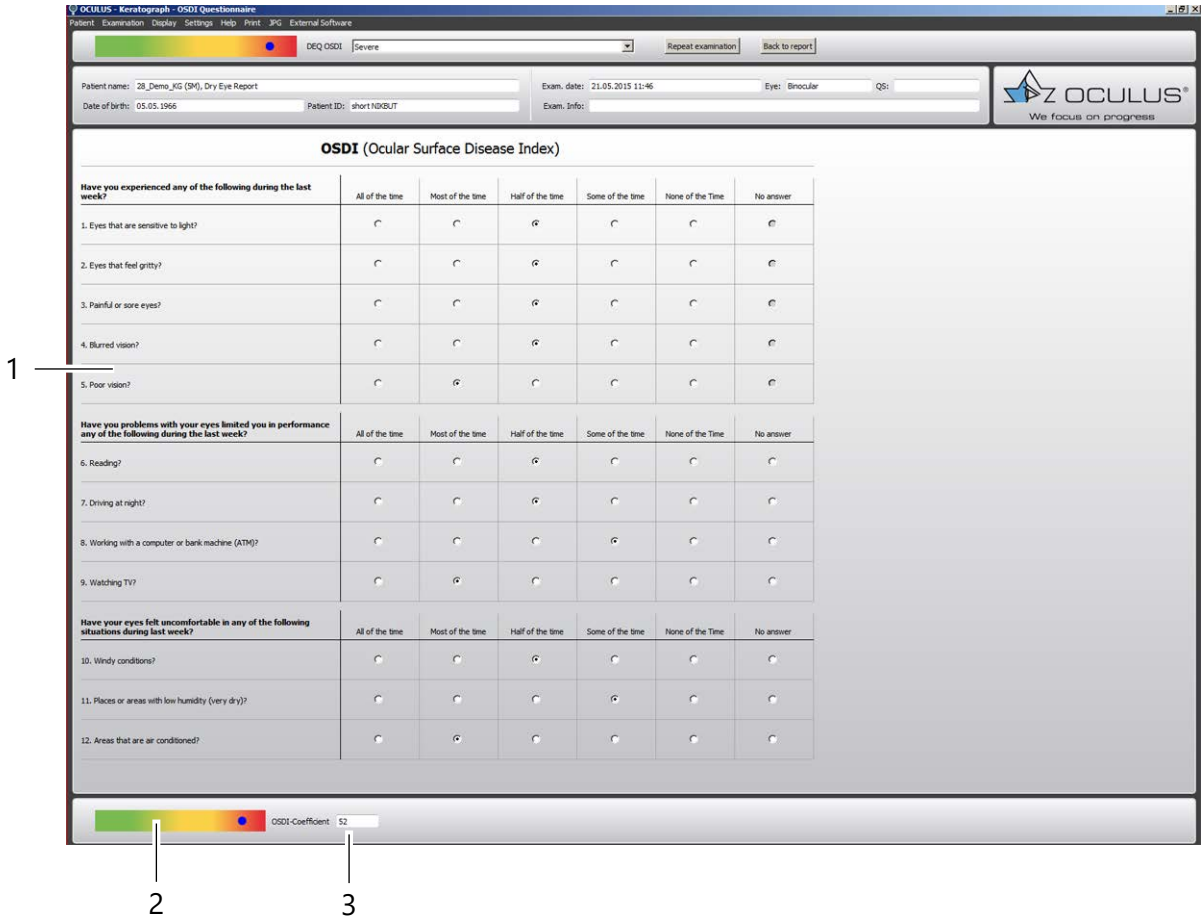


Fig. 18-3: DEQ OSDI screen

1 Questions
2 Diagram for measurement result
3 OSDI coefficient

➔ Go through the questions and ask the patient to select the respective answers. The results apply for both eyes.

➔ Go back to the overview display by pressing the [Back to report] button.
The OSDI value is shown in the assessment field and the diagram.

You can also use the McMonnies Questionnaire instead of the DEQ OSDI. For this, change settings as shown in the *User Guide*.

18.6 LIPCOF

If lid-parallel conjunctival folds (LIPCOF) are present, they can be seen in the vertical slit when examining the temporal lower lid area of the conjunctiva using a slit lamp. Please enter the results here. These results are a further parameter in the assessment of the Dry Eye.

➔ Open the drop down list in the Exam rating column.

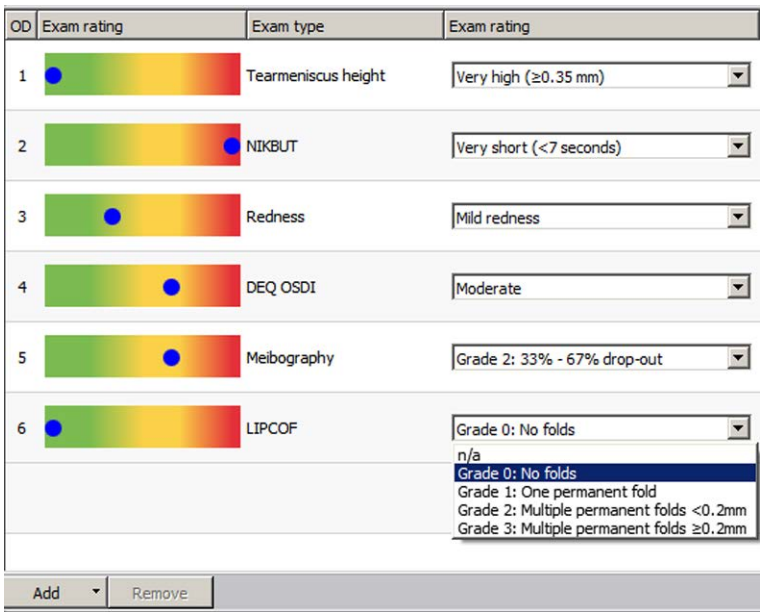


Fig. 18-4: Entering the examination result

➔ Select the grade or text which corresponds to the result.

➔ Go back to the overview display by pressing the [Back to report] button.

For more information on LIPCOF, refer to the *User Guide*.

19 Performing extended examinations: JENVIS Pro Dry Eye Report (optional)

With the JENVIS Pro Dry Eye Report you perform a complete dry eye workup. It is possible to choose from different worklists like:

- Screening
- Individualized
- Follow-Up
- by DEWS

In every worklist you have a structured workflow which saves time and lets you work more efficiently. You have the liberty however to skip to any position within the worklist.
For each examination the software provides to you additional, supportive information regarding the capturing process (on which area to focus, light adjustment, camera settings etc.).
After you have conducted dry eye workup with a capture worklist, for example "Individualized", you can evaluate the results in the assessment worklist. In the assessment display the causes of dry eye disease are sorted in sub-categories. You can evaluate every single picture/examination separately, or if you click on a sub headline for example "Lid/ Margin", all respective examinations pop up on the screen.
Based on the assessments which were made it is possible to create a treatment plan with different options to cure the causes of the dry eye disease.
Finally you can create a comprehensive print out (JENVIS Pro Dry Eye Report) which contains all results of the tests, the treatment options and extensive glossary, where all examinations are explained.

➔ Select in the menu bar "Examination" the entry [New Dry Eye Report] Individualized.

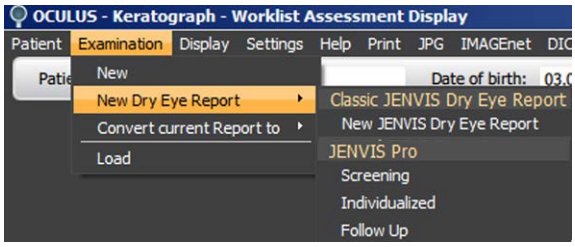


Fig. 19-1: Select Dry Eye Report

The following screen appears:

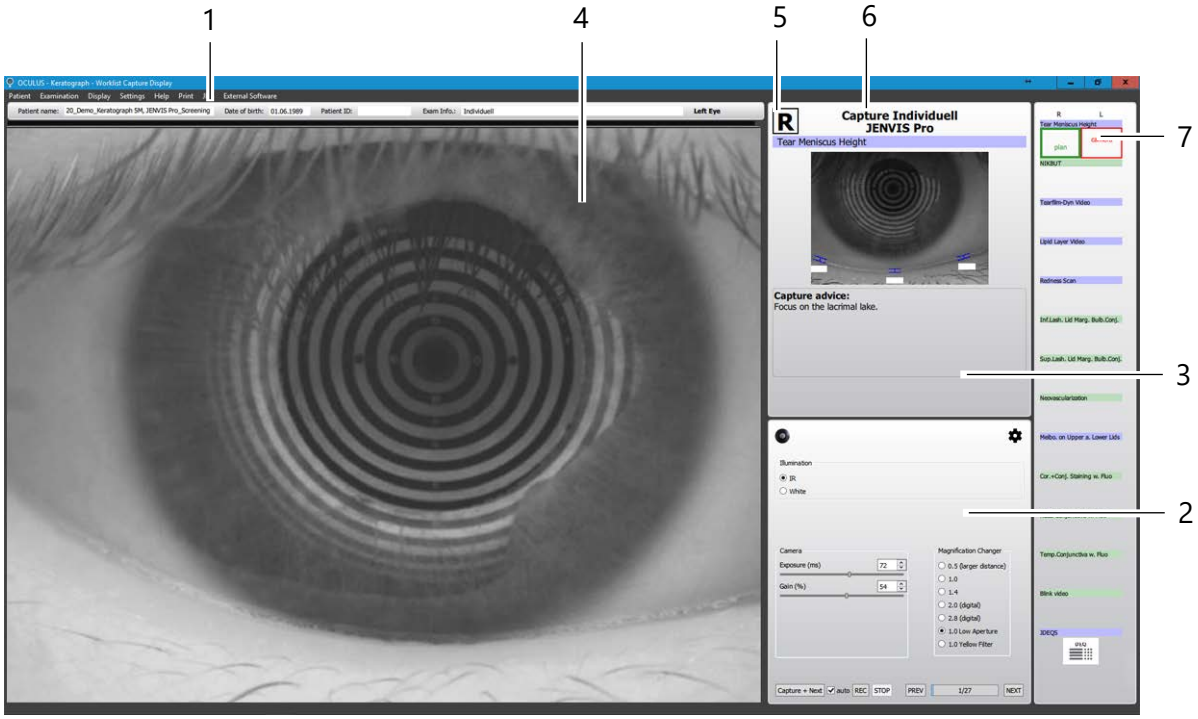


Fig. 19-2: Overview of the Dry Eye examinations

1 Patient and Examination Data
2 Camera live image
3 Currently examined eye (here: left eye)
4 Additional supportive information for capturing process
5 Pre-defined examinations
6 Information on measurement
7 Camera/illumination settings

19.1 Perform the capture plan based on the worklist

The worklist shows you the first step of the capture plan with the aid of a green and red box.
The red box shows the actual camera position and requests you to capture a photo or video.

➔ Click on the [Capture] button to perform the requested examination.

If the [auto] button is enabled then the [Capture] button is transformed to [Capture + Next]. This means, that after the capturing, the software moves automatically to the next step in the worklist.

If you do not want to capture the image you have to click on [Next]. The green box indicates which type of examination will be administered and which of either eyes will be tested.

To work most efficiently the software recommends in which order to capture/examine the right and the left eye consecutively.
It is suggested to start for the Tear Meniscus Height with the right eye and switch then to the left eye. For the NIKBUT the software recommends to start with the left eye and follow with the right eye.

For the next three exams you are advised to do all captures of the right eye and switch then to the left eye. If vital dyes like fluorecine have to be instilled contribute all capture items first for one eye and then for the other eye.

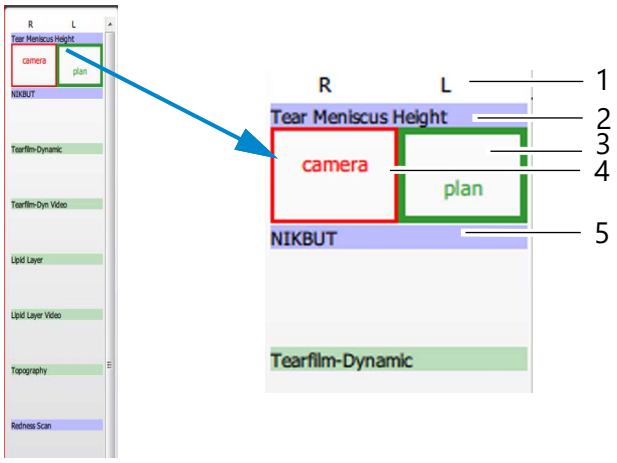


Fig. 19-3: Software recommendations

1 Right eye/left eye
2 Examination
3 Current camera position
4 Next camera position
5 Following examination

19.2 Additional supporting information

This part of the screen supports you in getting the best images for your assessment. The preview picture shows the area of interest for the respective examination. In the field below some capture advices are given for example where to focus the camera, if to use vital dyes or not, how to position the eyelid etc .

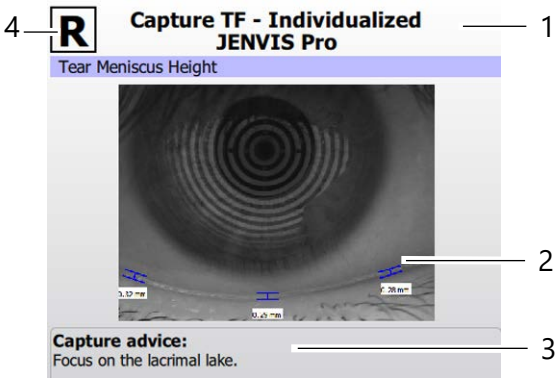


Fig. 19-4: Additional supporting information

1 Capture element of the examination (area of interest)
2 Preview
3 Capture advices
4 Right eye/left eye

19.3 Adjusting Illumination, Magnification Changer and Camera

For some measurements, the [Illumination], [Magnification Changer] and [Camera] groupboxes appear. You can set values for illumination, magnification changer and camera. You can save the settings as a program.

The optimal camera and illumination settings have already been preset for the selectable measuring functions.

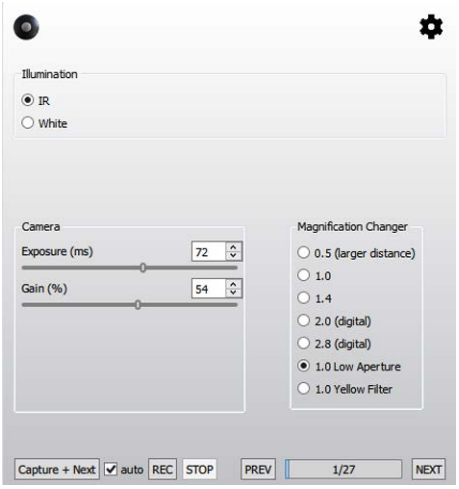
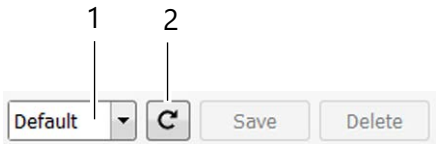


Fig. 19-5: Camera settings

19.3.1 Selecting and saving settings



You can use default settings and you can save your own settings as an image program.

Using default settings

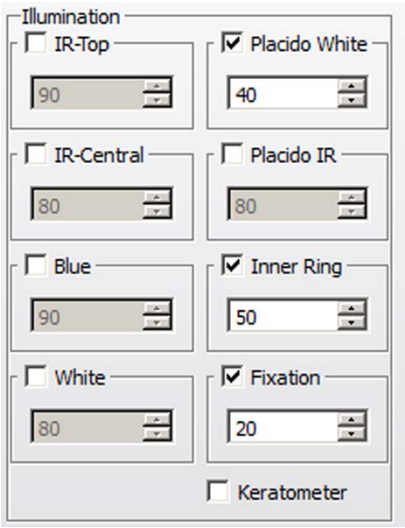
➔ In the drop down list select the program.
"Default": default settings
"XXX": your own saved settings

Using your own settings for an image program

➔ Select the settings.
➔ Enter the name of the program.
➔ Press the [Save] button.

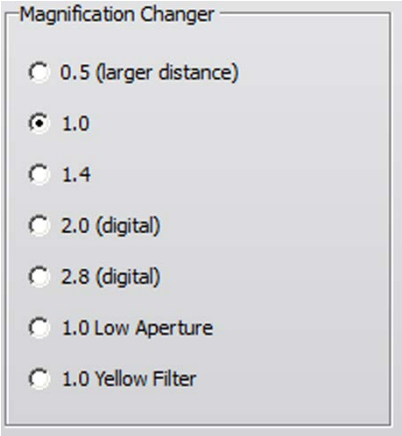
If you press the button, the image program uses the saved settings.
If you press the [Delete] button, you delete the image program. You cannot delete the default settings.

19.3.2 Adjust Illumination: [Illumination] groupbox



➔ Activate the desired radio button.
IR-Top/IR-Central: If only the "IR-Top" and "IR-Central" checkboxes are enabled (in a darkened room):
The fit of the contact lens can be evaluated with the pupil dilated (e.g. for fitting multi-focal lenses).
Blue: The blue light is used for excitation of the fluorescine to fluorescence.
White: TF-Dynamic: Two spots in the bottom segment of the Placido bowl are set to white.
Placido White: Topography and NIKBUT examination: The illumination of the Placido bowl is set to white.
Placido IR: The lighting of the Placido bowl is set to infrared.
Inner Ring: The patient's eye is subjected to minimal glare.
Fixation Used to assist the patient's fixation.
[Keratometer] checkbox: Keratometry marks for aligning the topography

19.3.3 Adjusting magnification: Magnification Changer groupbox



You can set the magnification in this groupbox. You have a choice of three optical and two digital zooms.

- **0.5 to 1.4**
- **2.0 (digital)**
- **2.8 (digital)**
- **1.0 low aperture**, for greater depth of field
- **1.0 yellow filter**, for images taken with fluorescine

If your device is equipped with a wireless joystick, you can use the joystick to trigger different images.

19.3.4 Modifying Dry Eye Report capture settings: cog icon groupbox

Click this icon to open the "Dry Eye Report Capture Settings" window.

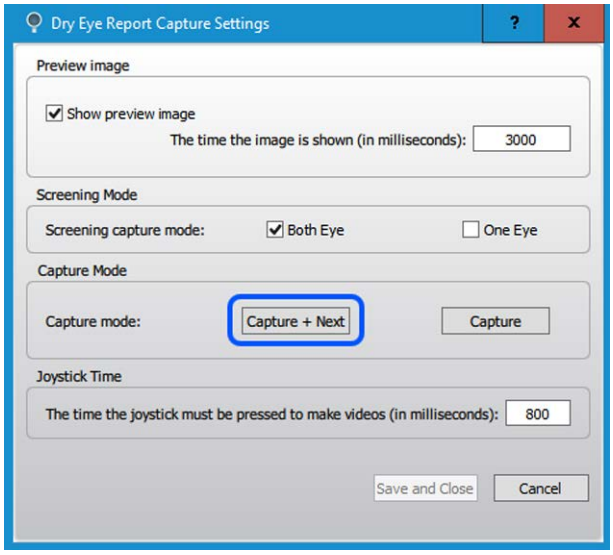
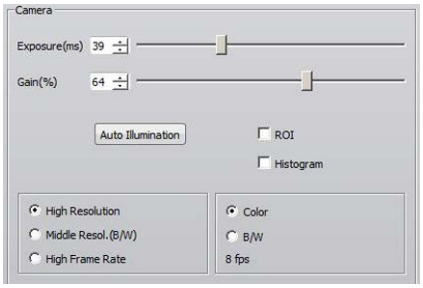


Fig. 19-6: Dry Eye Report capture settings

Preview: Click to enable or disable the preview image and set the display duration time.
Screening mode: Click to determine if both eyes or just one eye should be examined in screening mode. If you select "one eye", the screening will be done on the eye that the Keratograph 5M is currently facing.
Capture mode: Click to decide if the software should automatically go on to the next examination step (other eye or next examination) after completing a measurement/image.
Joystick time: Define the length of time that the joystick button must be held down to initiate video recording.

19.4 Adjusting the Camera: Camera groupbox



Exposure time: The longer the exposure time is, the brighter the image will be. The image can, however, become less sharp as a result.

➔ Change the exposure time using the slider control.

Gain: If you increase the gain value, the picture brightens. However, the image quality suffers as a result; too much gain results in grainy images.

➔ Change the gain setting on the slider control.

Auto Illumination: You can adjust the illumination with this function, e.g. so as not to overexpose an image.

➔ Press the button [Auto Illumination].
You can now adjust the illumination for the entire image capture.

High Resolution, Middle R. (B/W) or High Frame Rate: Details will be more visible at a higher resolution, high frame rates provide "smooth" videos.
Color or B/W: You can choose color or black and white display.
fps: frames per second

19.4.1 Buttons and Checkboxes

Start, stop or save your images or skip to the next examination step with the following buttons.

Fig. 19-7: Example: Displayed buttons during an examination

[auto] checkbox: Changes the [Capture] button into [Capture+Next] button.
Capture + Next: Checkbox "auto" is enabled. If you click this button the image is captured. The software then skips to the next step in the work-list automatically.
Image: Checkbox "auto" is disabled. Capture an image or video.
REC/STOP: You start or stop the video recording with these buttons. Limit the duration of the recordings to maximum one minute. otherwise the volume of data on your computer will become too extensive.
Back: With this button you start an individual recording. You can, for example, record static fluo images.
0/50: Progress bar of the worklist
Next: Use these buttons to move on to the next step in the worklist. You are not recording any image or video.

19.4.2 Check quality of images

Show preview

If the checkbox is enabled after every captured image the user sees a little preview of the captured image. He can decide if he/she wants to keep or delete the image.

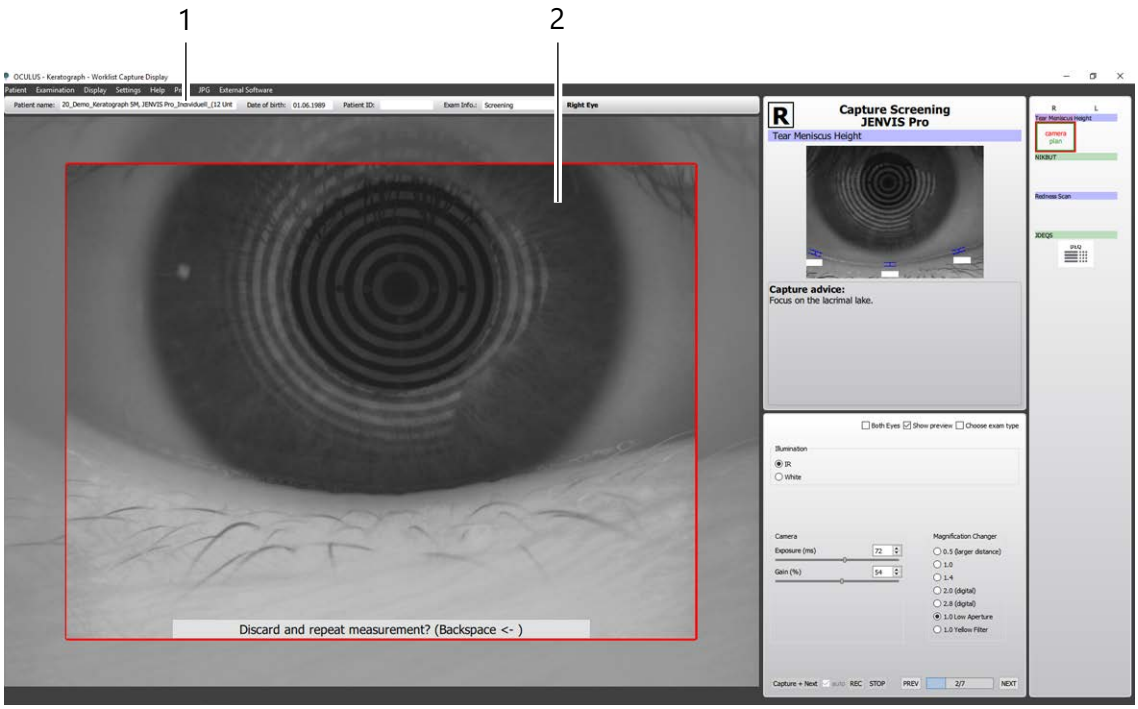


Fig. 19-8: Overview with preview

1 Patient and Examination Data

2 Preview

19.5 Printing a JENVIS Pro Dry Eye Report

Depending which type of the JENVIS Pro Dry Eye Report is used two layouts are available. You can print

- JENVIS Pro Dry Eye Screening
  The Screening printout contains the results and description of the three screening tests.
- JENVIS Pro Dry Eye Report
  The Report print out shows all assessed categories.

Using the Print button in the menu bar, the corresponding type can be send to a printer or printed as a PDF file.

➔ Select the [Print] menu item.

Fig. 19-9: [Print] menu item

1 [Print] button 2 [Print to PDF] button

Using the first entry you can physically print the JENVIS Pro Dry Eye Report.
The second entry enables to print the report as a PDF file.
The results of the dry eye examinations are shown on the printout of the JENVIS Pro Dry Eye Report. The JENVIS Pro Dry Eye Report includes a glossary of relevant terms for the patient.

20 Patient Data Management

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

- Rename it, *Chap. 20.1, page 76*
- Export it, *Chap. 20.2, page 76*
- Import it, *Chap. 20.3, page 77*
- Save it, *Chap. 20.4, page 79*

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

20.1 Rename Patient Data

After creation of the patient data you can edit it.

➔ Press the [Change] button.
The input boxes for patient data are now enabled, and the cursor jumps to the “Last name” field.

➔ Change the entries in the individual boxes.

➔ Press the [Save] button.

20.2 Exporting Patient Data

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

➔ Select the patient and also one of the examinations in the respective list as required.

➔ Press the [Export] button below the patient list. The following dialog is displayed:

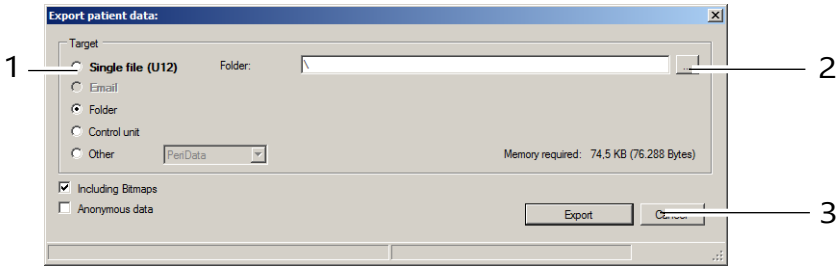


Fig. 20-1: “Export patient data” dialog

1 Saving destination selection
2 [...] button
3 [Cancel] and [Export] buttons

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.

➔ Press the [...] button.
➔ In the dialog that appears, select the folder or the file to which the patient data should be exported.
➔ Confirm your selection with [OK] or [Open].
➔ To export the data, press the [Export] button.

20.3 Import Patient Data

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

Note
Risk of loss of data due to computer viruses
Computer viruses can cause loss of data.
➔ Run a virus check before importing data from the USB flash drive.

➔ Press the [Import] button. The following dialog is displayed:

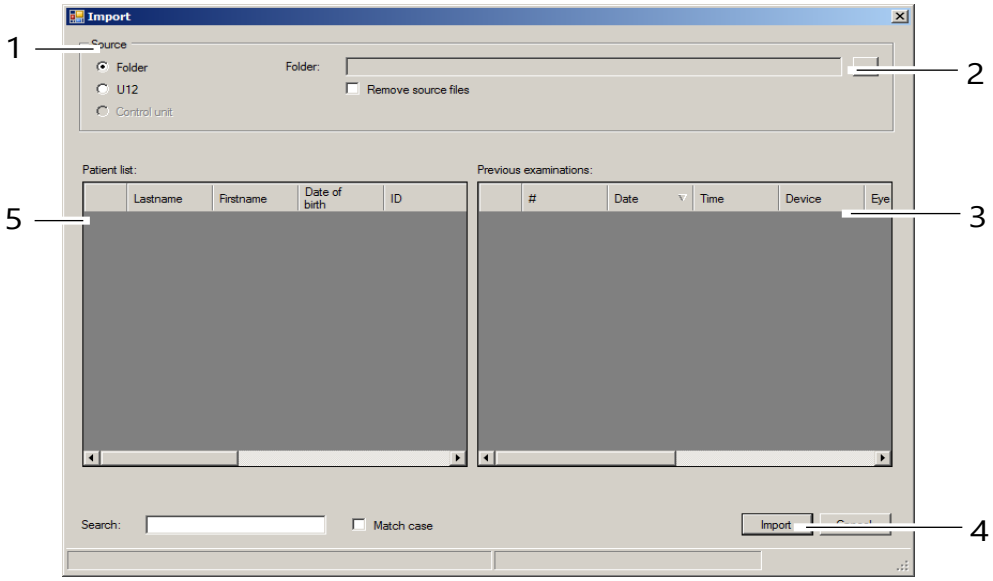


Fig. 20-2: "Import" dialog

1 Select data source
2 [...] button
3 Previous examinations
4 [Import] button
5 Patient list

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 option where the source data are contained ("Folder" or "U12").

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

➔ Press the [...] button.
➔ In the dialog box, select the directory or the file where the patient data are located.
➔ 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.
➔ To import the data, press the [Import] button.
The data is then available in the user interface for "Patient Data Management".

20.4 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 computer and the device are not in use.

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 (e.g. on a USB flash drive with adequate capacity).

20.4.1 Backup Data

➔ In the upper right part of the patient data management user interface, press the [Backup] button. The following dialog is displayed:

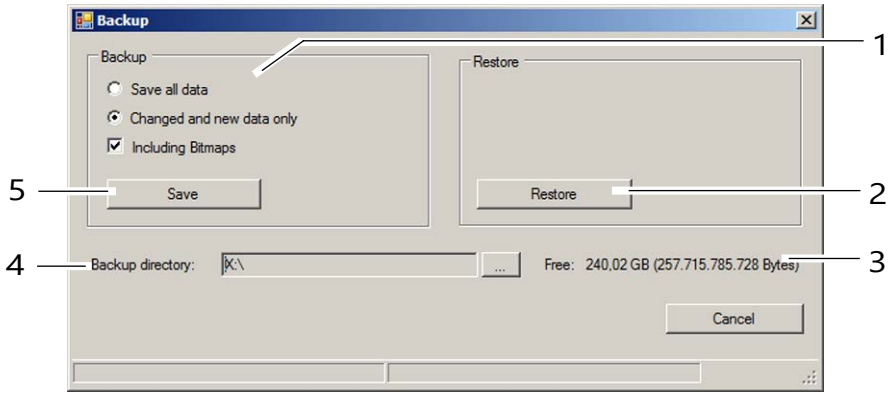


Fig. 20-3: "Backup" dialog

1 Backup data selection
2 [Restore] button
3 Display free storage space
4 Backup directory and [...] button
5 [Save] button

➔ 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.

➔ Press the [...] button to the right of the "Backup directory" field.

➔ In the dialog that appears, select the folder to which the data should be backed up.
➔ Confirm your selection with [OK].
➔ To back up the data, press the [Save] button. The previously selected data will then be backed up to the corresponding folder.

20.4.2 Restoring Data

If a loss of data occurs, the data from a previous backup can be imported again into the patient data management user interface.

➔ Press the [...] button.
➔ In the dialog that appears, select the folder which contains the backup data.
➔ Confirm your selection with [OK].
➔ To import the data, press the [Restore] button. All data in the corresponding folder will be transferred to the patient data management user interface.

20.4.3 Automatic Backup

Besides the manually executed backup, there is also the option to carry out a backup when the patient data management user interface is closed. The settings required for this can be made in the "Settings" area, see *User Guide*.

21 Cleaning, disinfection and maintenance

Cleaning of the Keratograph 5M is described in this chapter.
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 Keratograph 5M with aggressive, chlorine-containing, abrasive or sharp cleaning agents.

Note

Equipment damage due to penetration of moisture

➔ Ensure that no moisture gets into the Keratograph 5M during cleaning and disinfection.

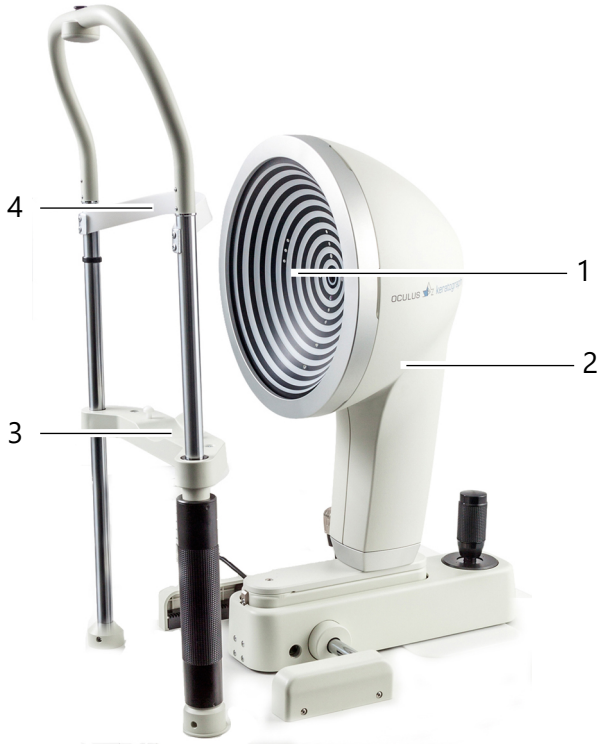


Fig. 21-1: Components for cleaning and disinfection

1 Placido bowl
2 Housing
3 Chin rest
4 Headrest

21.1 Cleaning, disinfection and maintenance schedule

Cleaning	
Activities	Period
Clean the housing, chin rest, forehead support and skullcap	1 x month or as needed

Disinfection	
Activities	Period
Disinfect the forehead support	After every examination
Disinfect the chin support (if using without paper)	After every examination
Disinfect the housing	Whenever necessary

Care and Maintenance	
Activities	Period
Reference Measurement	once a month
Have the lighting and electrical values checked by OCULUS Service	every 2 years (recommended)

The Keratograph 5M is designed so that no special maintenance is necessary. To keep the device functioning properly, we recommend performing the tasks specified under "maintenance" on a regular basis.
If an error occurs which you cannot correct, label the Keratograph 5M as being "out-of-order" and contact our service department, see contact data *Chap. 25, page 90*.

21.2 Cleaning

Attention

Risk of electric shock if the Keratograph 5M is not completely disconnected from the mains for these jobs.

➔ Turn the Keratograph 5M off, *Chap. 8.2, page 25*.

➔ Pull out the power plug before performing any cleaning work. Take hold of the power plug for this purpose; do not pull on the cable.

Materials needed:

- Cleaner for plastic surfaces with anti-static effect
- 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

21.2.1 Cleaning the Housing

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

21.2.2 Cleaning the Chin-Forehead Rest

- ➔ Make sure that no liquid gets into any of the openings of the Keratograph 5M.
- ➔ Clean the chin-forehead rest with a soap solution (or with alcohol, if very dirty).
- ➔ Use a lint-free, damp cloth.

21.2.3 Cleaning the Placido Bowl

The Placido bowl is a precision component and is pressure-sensitive. The surfaces of these components are susceptible to scratching.

- ➔ Take special care when cleaning the surface of the Placido bowl. Use a lint-free, dry cloth.
- ➔ Make sure that no dust gets into the little holes.
- ➔ If necessary, you can also carefully clean the Placido bowl with a barely damp cloth.

21.3 Disinfection

Attention

Risk of electric shock if the Keratograph 5M is not completely disconnected from the mains for these jobs.

➔ Turn the Keratograph 5M off, *Chap. 8.2, page 25*.

➔ Pull the power plug before cleaning. Take hold of the power plug for this purpose; do not pull on the cable.

- Mikrozid sensitive wipes premium
  Fa. Schülke & Mayr
  Softpack 48 pcs
  Art. no. 165711
  Schülke & Mayr GmbH
  Phone: +4940521000
  Fax. +494052100318
  E-Mail@schuelke.com
  www.schuelke.com

Note

Equipment damage caused by disinfectant solution

The disinfectant solution may damage the finish if it is sprayed directly on it.

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

➔ Disinfect the forehead rest after each examination, disinfect the housing if necessary.

➔ If you do not use chin rest paper: Disinfect the chin rest after each examination.

21.4 Attaching Paper to the Chin Rest

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

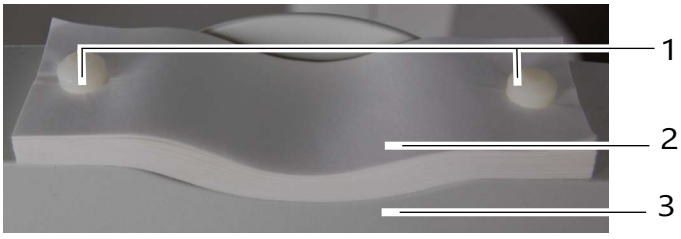


Fig. 21-2: Fasten chin rest paper

1 Pins
2 Paper for chin support
3 Chin rest

➔ Pull the two pins out of the chin rest.

➔ Place the chin rest paper in such a way that the holes of the paper and those in the chin rest are aligned.

➔ Insert the two pins in the chin rest.

21.5 Reference Measurement

To achieve a high measuring accuracy, the Keratograph must be set up before conducting the first examination on a patient.
The first reference measurement is performed during setup by OCULUS or an authorized dealer.
OCULUS recommends performing a reference measurement once each month. The reference measurement can be performed easily and quickly using the reference sphere (r = 8.000 mm).
A reference measurement should also be performed after the device is set up in a new location.

Required Materials

- Reference sphere (r=8.000 mm), provided
- Cleaning alcohol

Measuring With The Reference Sphere

Prerequisite: the Keratograph 5M has been turned on for at least 15 minutes.
For the reference measurement proceed as follows:

➔ Thoroughly clean the reference sphere before saving reference values (e.g. with cleaning alcohol).

Fig. 21-3: Sphere holder with reference sphere

➔ Fasten the sphere holder on the right vertical brace of the head-chin rest.

Fig. 21-4: Align the reference sphere in parallel (device as seen from above)

Rotate the sphere holder so that the reference sphere is aligned parallel to the device.

➔ Align the sphere holder vertically so that the reference sphere is at the same height as the black marking (ring) on the left vertical brace of the head-chin rest.

Fig. 21-5: Align the height of the reference sphere

1 Marking for height alignment

Ensure that the reference sphere is still aligned parallel to the device.

➔ In the [Settings] menu, select the [Reference Measure] menu item.
➔ Perform a measuring operation with the reference sphere *(Chap. 10.6, page 34)*.
➔ Confirm the question "Calibration ok" with [OK].

Note

If the error message "Reference sphere not completely measured!" appears, the sphere must be carefully cleaned and the measuring operation repeated.

The system is now ready for operation. The reference data is stored directly on the device, so that the measuring head is not dependent on a particular computer or laptop.

22 Troubleshooting

Attention

Risk of personal injury or equipment damage due to improper troubleshooting

➔ 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 dealer.

Error	Possible Cause	Remedy
After starting the Keratograph 5M program the dialog box opens: “No communication with the Keratograph 5M!”.	No power to the power adapter.	Check whether the indicator light on the power adapter is on. If not, connect the power adapter to the mains.
	Connection cable (Med. Secure Isolator cable) Keratograph 5M/ Power Adapter/computer/Laptop are not plugged in properly.	Check that ■ the connector is properly plugged into the Keratograph 5M ■ the USB connector is correctly plugged into the computer/laptop ■ the connector for the low voltage side of the power adapter is plugged in
	Software/Hardware problems.	Switch off the Keratograph 5M and restart the computer. Switch on the Keratograph 5M as soon as the patient data management becomes active. When you start the Keratograph 5M program, the message “Load Bootloader” must be displayed.

23 Transport and Storage

➔ Observe the transport an storage conditions, refer to *"Technical Data" on page 92*.

The Keratograph 5M, must be properly dismantled and packed before the device is being transported or stored.

After storage and/or transport

➔ After transport, allow the Keratograph 5M to rest for approx. 3-4 hours in its new location so that the device can adjust to the ambient conditions. Drastic temperature changes from cold to warm can cause the optical components to fog up.

23.1 Disassembly

➔ End the current session.
➔ Turn the device off.
➔ Disconnect the cable from the computer/laptop and the power adapter.
➔ Loosen the screw connection of the Med. Secure Isolator cable and pull it out.
Pull only on the plugs and not on the cables.

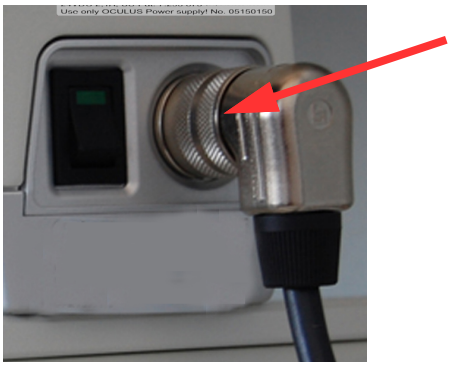


Fig. 23-1: Loosen the screw connection of the Med. Secure Isolator cable

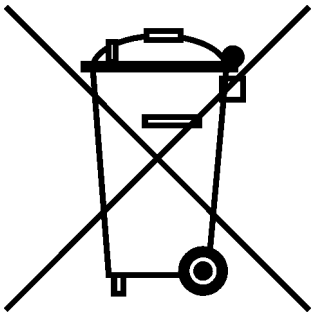
23.2 Transport and Storage

➔ Observe the transport an storage conditions, refer to *"Technical Data" on page 92*.

Attention
Equipment damage due to improper transport and storage
➔ Avoid shocks, vibration and dust.
➔ Avoid high temperatures and moisture.

➔ Transport the Keratograph 5M carefully.
➔ Do not hold the device by the joystick to carry it.
➔ Avoid placing near heaters and moisture.

24 Disposal



In accordance with Guideline 2012/19/EG of the European Parliament and of the Council, and also the Law of the Federal Republic of Germany on the Commercialization, Recall and Environmentally Compatible Disposal of Electrical and Electronic Equipment, old electrical and electronic equipment must be sent out for recycling and may not be disposed in household trash.

➔ Dispose the Keratograph 5M in a compliant manner.

25 Terms of Guarantee and Servicing

25.1 Terms of Guarantee

Please note the following guarantee provisions:

- 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 Keratograph 5M.
- If modifications are made to the Keratograph 5M 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 guarantee 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.

25.2 Assumption of Liability for Functions and Damage

OCULUS will only accept responsibility for the safety, reliability and serviceability of the Keratograph 5M 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 Keratograph 5M 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 Keratograph 5M 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.

25.3 Manufacturer- and Service address

Additional information is available from our Service Department or from our authorized representatives.
Manufacturer- and Service address:

Germany:

OCULUS Optikgeräte GmbH
Münchholzhäuser Str. 29
35582 Wetzlar
GERMANY
Phone: +49 641 2005-0
Fax: +49 641 2005-255
E-mail: sales@oculus.de
www.oculus.de

USA:

OCULUS, Inc.
17721 59th Avenue NE
Arlington
WA 98223-1337
Phone: +1 425-670-9977
Fax: +1 425-670-0742
E-mail: sales@oculususa.com
www.oculususa.com

26 Technical Data

Gauge head

Measuring range	3 to 38 mm 9 to 99 dpt
Accuracy	± 0.1 dpt
Reproducibility	± 0.1 dpt
Number of rings	22
Working distance	78 – 100 mm
Number of analyzed data points	22000
Camera	Digital CCD color camera
Dimensions H x W x D	275 x 320 – 400 x 480 – 510 mm
Weight	3.2 kg (measuring equipment only) 6.1 kg (with X-Y stage)
Interface	USB
Power supply	24 V DC; 2.1 A
Voltage	90-264 V AC
max. Electric energy consumption	18 W
Serviceable life expectancy	10 Years

LED illumination

Illumination	Color	Wavelength
Fluo	blue	465 nm
Ring Illumination	infra red	880 nm
Meibo	infra red	840 nm
Fixation	red	660 nm
Glare ring	white	-
Tear Film	white	-
Ring Illumination	white	-

Power adapter

Power adapter HMEG49-S240210-7 (05150150)	
AC input	90-264 V AC
Frequency	47-63 Hz
DC output	24 V 2.1 A max. 50.5 W
Electric energy consumption	131.1 VA
Fuses	Integrated over current shut-off

Classification according to IEC 60601 - 1

Type of protection against electric shock	Protection class 2
Degree of protection against electric shock	Type B
Level of protection against harmful penetration of water	IP20

Operating Conditions

Temperature	+10 — +35°C
Humidity	30 — 75%
Air pressure	800 — 1060 hPa

Storage conditions

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

Transport

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

Computer

Use a computer which is in conformity with the DIN EN 62368-1 and DIN EN 60950 standard

Recommended Computer Requirements	Intel® Core™ i5, 500 GB SSD, 8 GB RAM, Windows® 10, Intel® HD Graphics
The IT equipment (computer, monitor, etc.) must meet the requirements of IEC 62368-1 or IEC 60950	
Recommended screen size	24"
Recommended screen resolution	1920 x 1080 Pixel (Full HD)

CE in accordance with EC Directive 93/42/EEC for Medical Devices

CE 0123

The unit is a Class IIa product. Conformity assessment procedure as per (EU) 93/42/EEC (MDD), Annex II without Section 4

27 Appendices

27.1 Electromagnetic compatibility

Medical electrical equipment is subject to special pre-attentionary requirements with respect to EMC, and must be installed and operated according to the EMC-Instructions contained in the accompanying paperwork. OCULUS devices and systems are suitable for use in professional healthcare establishments, e.g. doctor's practices or clinics; however, they may not be used in proximity to HF surgical units or inside of the HF shielded room of an ME system for magnetic resonance imaging. Portable and mobile HF communications appliances can affect medical, electric equipment.

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.
- Minor picture noise in the analogue camera of the device (slightly snowy display image) during the examination is permissible, since this does not affect diagnostics, treatment or monitoring.
- Brief flickering of the device's illumination during the examination is permissible, as it does not affect the diagnosis, treatment and monitoring.

Attention

The use of accessories, converters, and cables that do not meet OCULUS specifications can result in increased emissions or a reduced interference immunity of the Keratograph 5M.

➔ Only use accessories, converters and cables that meet OCULUS specifications.

The use of OCULUS-specified accessories, converters and cable with any devices other than the Keratograph 5M can result in increased emissions or a reduced interference immunity of the other devices.

➔ Do not use the OCULUS-specified accessories, converters and cables for any device other than the Keratograph 5M.

Attention

Recommended separation distances between portable and mobile RF communication devices and the device.

The Keratograph 5M is intended for use in an electromagnetic environment in which the radiated RF interference is uncontrolled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance, based on the maximum output of the communication equipment, between portable and mobile RF communication devices (transmitters) and the Keratograph 5M as recommended below. Portable RF communication devices (including peripheral devices such as antenna cables and external antennas) should not be any closer than 30 cm (12 inches) to any part of the Keratograph 5M device. Otherwise, the device performance may be affected.

To ensure compliance with the requirements of IEC 60601-1-2 6.1 and 6.2, the following devices, accessories, converters and cables must be used:

Order Number	Description	
77000	Keratograph 5M	
05200320	Cable with plug, EU Standard	2.5m
05200210 (110 Volt)	Cable with plug, US Standard	2.5m
05150150	Power adapter HEMG 49	24 V, 2.1A
70002	Med. secure Isolator + USB Connection acc.	2 m

27.2 Guidance and manufacturer´s declaration Electromagnetic interference emission and interference immunity of the Keratograph 5M

Guidance and manufacturer´s declaration: Electromagnetic emissions of the Keratograph 5M, IEC 60601-1-2, based to table 1		
The OCULUS Keratograph 5M is intended for operation in the electromagnetic environment specified below. The user of the Keratograph 5M should ensure that it is being used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - Guidelines**
HF emissions CISPR 11	Group 1	The device 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, IEC 60601-1-2, based on table 4			
Immunity test	**test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air discharge	± 8 kV ± 15 kV	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electromagnetic immunity, IEC 60601-1-2, based on table 5, 8			
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/ output lines	± 2 kV ---------- ± 1 kV	The quality of the supply voltage should correspond to that of a typical business- or hospital environment.

Surges per IEC 6100-4-5	± 2 kV line(s) to earth ± 2 kV Common mode voltage	± 1 kV ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Keratograph 5M requires continued operation during power mains interruptions, it is recommended that the Keratograph 5M be powered from an uninterruptible power supply or battery.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity, IEC 60601-1-2, based on table 4, 5			
Interference resistance tests	**Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Directed RF interference per IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 V_{eff} 150 KHz to 80 Mhz 6 V in ISM- and amateur radio frequency bands between 150 kHz and 80 MHz 80% AM to 1 kHz 3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	V_{eff} = 3 V	Portable and mobile radio equipment should not be used any closer to the Keratograph 5M including the lines, than the recommended shield distance calculated according to the applicable equation for the transmission frequency. Recommended separation distance: $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ for 80MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ for 800 MHz to 2.5 GHz with P being the power rating of the transmitter in watts (W) in accordance with the transmitter manufacturer's specifications, and d being the recommended separation distance in meters (m). The field strength from fixed RF transmitters, as determined by an on-site test (a), should be less than the compliance level (b) in each frequency range. Interference is possible in the vicinity of devices that bear the following pictogram: 
Note 1:	At 80 Hz and 800 MHz, the higher frequency range applies.		
Note 2:	These guidelines may not be applicable in all cases. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and humans.		
a. The field strengths of stationary senders, such as base stations of radio telephones and mobile terrestrial radio equipment, amateur radio stations, AM- and FM-radio and TV transmitters in theory cannot be accurately predicted. 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 Keratograph 5M is used exceeds the applicable RF compliance level above, the Keratograph 5M should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Keratograph 5M. b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the Keratograph 5M

The Keratograph 5M in intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Keratograph 5M can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

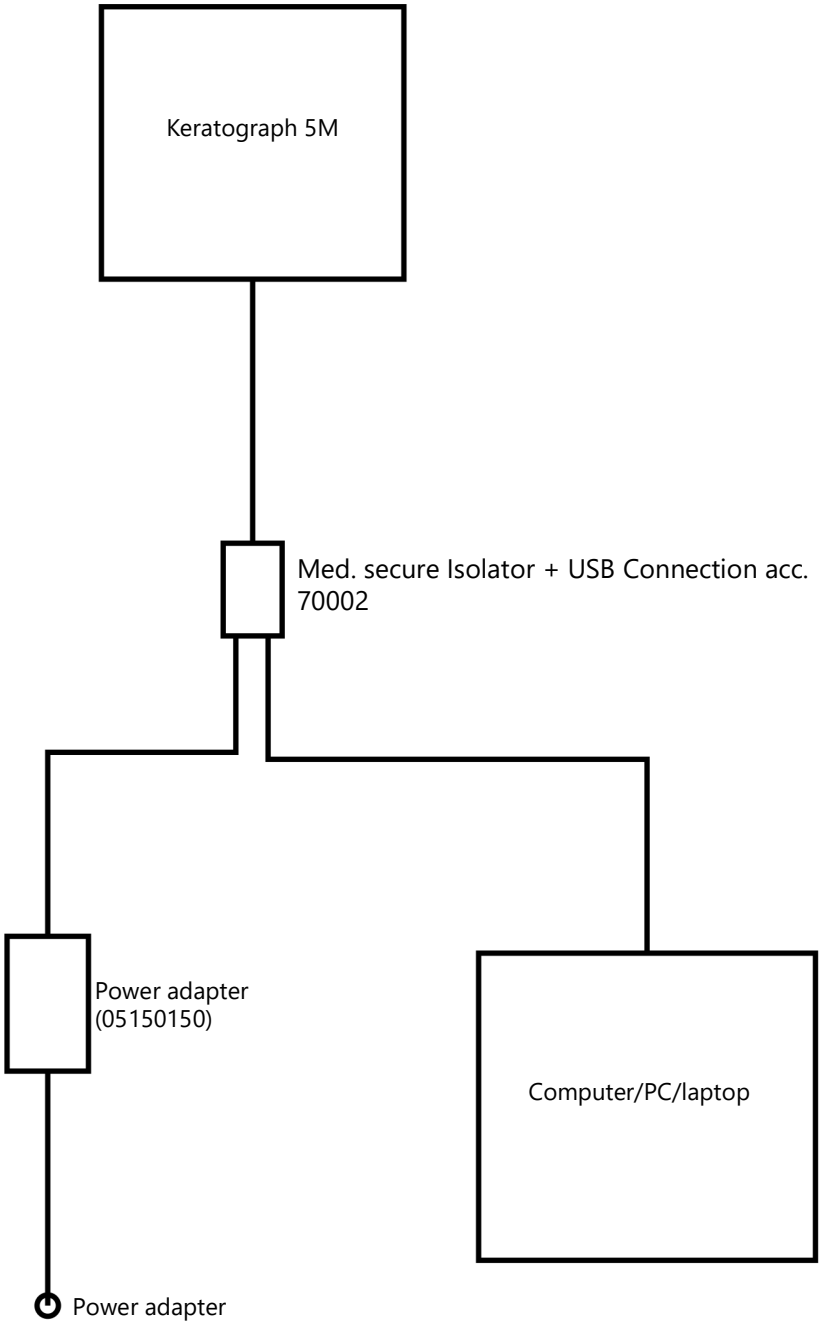
	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	150 KHz to 80 Mhz d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23

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. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, objects and humans.

27.3 Connection Diagram



27.4 Data sheet HEMG 49-S240210-7 (05150150)

H HiTRON

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

FEATURES:

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

SPECIFICATION

INPUT SPECIFICATION

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

OUTPUT SPECIFICATION

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

GENERAL SPECIFICATION

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

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

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

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

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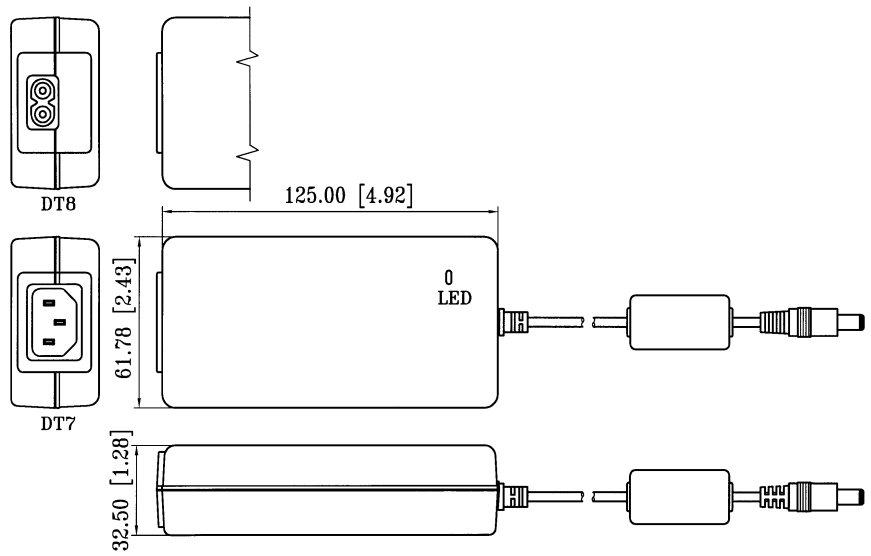
OUTPUT VOLTAGE / CURRENT RATINGS CHART

SINGLE OUTPUT

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

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



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27.5 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 (*"Cybersecurity Instructions" on page 17*) of "Safety Instructions" (*page 12*) 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 (*page 17*) of "Safety Instructions" (*page 12*) 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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