OCULUS
Keratograph 5M

INSTRUCTIONS FOR USE

OCULUS®

Preface

The Keratograph 5M has been manufactured and tested in accordance with the strictest quality criteria.
Using the device correctly is essential for safe operation.

➔ Familiarise yourself with the contents of these instructions for use before use. Pay particular attention to the safety instructions!

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

- **Instructions for use**: Describes the layout of the device, contains all safety information for handling the device and guides you through the processes of the various measurements. Contains basic information on handling patient data management.

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

- **User manual:** contains all information beyond pure measurement. It describes all of the options in the examination and evaluation software, as well as advanced instructions for patient data management.
- **Software installation manual:** describes installing the Keratograph 5M software and the corresponding drivers.
- **Floating licence key:** describes how you can use the Keratograph 5M within a network if you are working with a floating licence key.
- **Description of external software data interface:** describes the settings and data formats for external software.

The illustrations shown here may deviate slightly from the actual device delivered.

If you have any queries or require further information regarding your device, phone us, send us an e-mail or fax us. Our team is happy to help.

OCULUS Optikgeräte GmbH

Item number: G/77000/XXXX/EN
Released: 21/05/2026
Revision: 06

Table of contents

1 Scope of Delivery

Standard scope of delivery
Keratograph 5M
■ Imaging software
■ OCULUS wireless joystick
■ Mains cable (depending on the country of use)
■ Connection cable Med. secure isolator + USB connection acc. Extension cable for Med. secure isolator 4 m
■ Floating licence key incl. instructions

Optional equipment
■ JENVIS Pro Dry Eye Report - R scan - TF scan - Meibo Scan
■ Pupillometry
■ DICOM/PACS Interface
■ OxiMap
■ Hard drive package
■ Foot switch
■ Mounting plate, for OCULUS gear racks, adjustable (size: 360 mm – 460 mm), with/without chin and forehead rest
■ Mounting plate, for OCULUS gear racks, adjustable (size: 360 mm – 460 mm), with chin and forehead rest

Accessories
■ 24 V desktop power supply
■ Dust protection cover
■ Reference sphere
■ Contact lens holder
■ User information

We reserve the right to change the supplied contents as part of technical developments.

➔ If you discover transport damage upon delivery, report this to the transport company immediately.

➔ Confirm the damage on the delivery note in order to ensure that claims can be settled properly.

Further information on transport is provided in → Chap. 18 (page 80)

2 Safety

All safety-relevant instructions for using the device are only described in the instructions for use.

- ➔ Read the instructions for use carefully.
- ➔ Keep the instructions for use near the device.
- ➔ Observe the local accident prevention regulations.

Report all serious incidents that occurred in conjunction with the product to the manufacturer (vigilance@oculus.de) and the authority responsible in the Member State in which you and/or your patient reside.

2.1 Symbols

2.1.1 On the Device and Type Plate

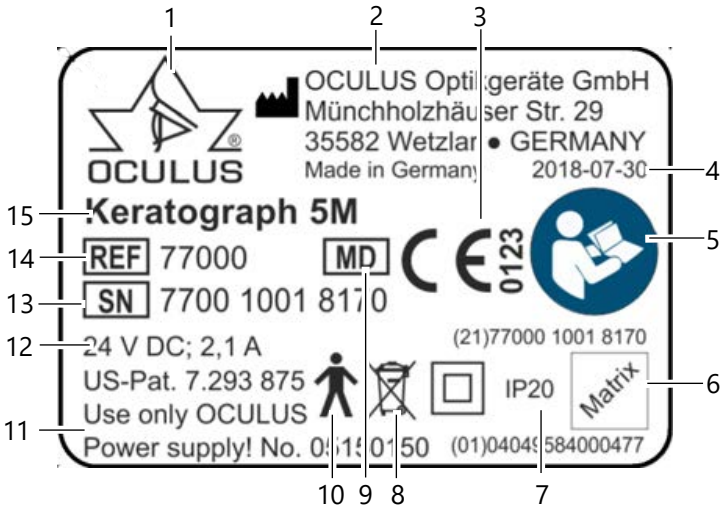


Fig. 2-1: Type plate (example)

No.	Description	No.	Description
1	Manufacturer's logo	8	Disposing with household waste prohibited
2	Name and address of the manufacturer	9	Application part type B
3	CE marking and number of the notified body	10	Medical device (Medical device)
4	Date of manufacture	11	Information on the power supply
5	Observe the instructions for use	12	Voltage supply
6	UDI number consisting of: UDI-DI (device identification) UDI-PI (product identifier) and Machine-readable matrix code	13	Serial number
		14	Item number
		15	Device designation
7	Protection class		

2.1.2 On the Packaging

Symbol	Explanation
Transport 	Permissible temperature range for transport
	Protect from moisture
	Transport upright
	Fragile
Storage 	Permissible temperature range for storage
	Humidity limit
	Air pressure, limit

2.1.3 In this Manual

Caution

Indicates a potentially dangerous situation that can cause minor bodily injury or damage to property.

Note

Indicates situations that can cause incorrect examination results, usage instructions and useful or important information.

Indicates further information regarding the product or handling, to which special attention must be paid.

> describes menu paths.
> Example for calling a new examination:
> Pentacam® > Examination > New
> Specifically:
> ➔ Select the “Examination” menu from the menu bar.
> ➔ Select the "Scan" menu item.

[...] marks buttons

→ Cross-reference

2.2 Safety Instructions for Use

Caution

Incorrect operation can injure people or damage the device.

➔ Observe and follow the safety instructions in these instructions for use.

Caution

Unauthorised modifications to the device may result in personal injury or damage to the device.

➔ Do not modify this device or the corresponding lift table without the manufacturer's permission.

➔ Changes or modifications may only be made by OCULUS customer service and authorised dealers.

2.2.1 Information Regarding Operating 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 a printer, those devices become part of the ME system.

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

2.2.2 Information Regarding Electrical Safety

Caution

Personal injury or damage to property due to incorrect level of safety

Connecting the Keratograph 5M to 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 this connection leads to the leakage current threshold being exceeded, protective measures including a circuit breaker must be in place.

➔ Ensure that connections to non-medical devices are established correctly.

➔ Only use the power supply that is supplied as standard.

➔ Use only a computer that meets the specifications in these instructions for use (see the technical data)

Caution

Personal injury or damage to property due to unsafe multi-sockets

If you are using a multi-socket to connect the Keratograph 5M, you must adhere to the following instructions:

➔ Use a multi-socket that complies with the requirements of IEC 60601-1, section 16.

- ➔ Do not place the multi-socket on the floor.
- ➔ Do not use more that one multi-socket.
- ➔ Only plug the Keratograph 5M and the computer that is being used, if applicable, into the multi-socket.
- ➔ The multi-socket must be supplied via an isolating transformer.
- ➔ If you are using a new computer for the Keratograph 5M, you must have the electrical safety checked. Phone OCULUS customer service for this.

Caution
Impairment of electromagnetic compatibility (EMC/cables)
Personal injury or damage to property due to electromagnetic interference

Portable and mobile HF (high frequency) communications equipment can affect medical electrical equipment, *Chap. , page 83*.

- ➔ Ensure that portable and mobile HF communications equipment does not cause interference.
- ➔ Recommendation: Maintain a minimum distance of 4 m. If the distance is less, you must ensure that the Keratograph 5M functions correctly.

2.3 Information Regarding Cyber Security

Note

Observe the regulations, guidelines and recommendations of the competent authorities responsible for information security and the protection of critical infrastructures in the applicable country.

The device is designed to work without the need for a network or an internet connection. The device works exclusively via a connected computer.

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

2.3.1 Precautions against Unauthorised Access

To increase the cyber security of the device:

➔ Secure the device against unauthorised access by unauthorised people.

Take the following precautions:

- Secure the computer with a strong password (e.g. at Windows startup).
- Choose a complex password of at least twelve characters, which contains letters, numbers and special characters. Avoid words from the dictionary.
- Do not choose a name or device name for a password (for example, "Pentacam").
- Change the default password after the first login.
- Change the password regularly.
- Do not write down the password in an accessible place.
- Use unique passwords for different user accounts.
- Do not share usernames or passwords with colleagues or others, even if permitted by law and employer policy to view the same type of information (e.g. two operators reviewing the same patient sample).
- Set up a screen saver that requires the password to be re-entered when deactivated.
- Set an appropriate time setting for starting the screensaver (e.g. 10 minutes), taking into account operating conditions such as the duration of the examination and patient flow.
- Ensure that the device is locked (shortcut: Windows logo key + 'L') or secured in another way when not in use, in order to prevent unauthorised access to electronic protected health information (ePHI).
- Train operators in data protection and the handling of personal data.
- If necessary, contact the IT department of your healthcare facility.

2.3.2 Precautions when Connecting to a Local or Internet Network

- Do not connect to the internet while the device is in use. This is considered misuse!
- If the computer is connected to the internet for any other purpose, data security must be ensured.

If the computer is connected to a local network, data security must be ensured. The following precautions must be taken:

- Preferably connect the computer to the network via a cable connection and not via a wireless connection.
- Use robust security methods, including advanced encryption standards, with a strong network key, even for wired connections. Using a firewall (software or hardware) is recommended.
- Observe the instructions for integration into an IT network → Chap. Appendix G "Instructions for Integration into an IT Network" (page 91).

Note

The IT department of the healthcare facility should implement a risk management framework in accordance with IEC 80001-1 to support the secure integration of medical IT networks. This includes evaluating risk, enforcement of access controls, securing networks, application of software updates, monitoring incidents, protecting data, managing device life cycles and employee training in order to guarantee

patient security and data integrity.
The Manufacturer Disclosure Statement for Medical Device Security (MDS2) is available on request for detailed security information.

2.3.3 Device Security

- ➔ Ensure that the device is secured against unauthorised access See "2.3.1 Precautions against Unauthorised Access" on page 14.
- ➔ Protect the device and connected systems from malware.
- ➔ Implement new software versions as soon as they are available.
- ➔ Implement operating staff access based on necessity.

The IT department of the healthcare facility is responsible for implementing checks for handling and disposing of media and assets.

2.3.4 Responsibility for Data

The user should avoid entering unnecessary identifying data. Whenever possible, data should be anonymised and linked to the sample ID instead of the patient. Only use the input data required for the intended purpose.

Users have access to sensitive patient data (ePHI).

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

The data must be deleted regularly according to the deletion guidelines at the healthcare facility if corresponding data is processed on the device.

The IT department of the healthcare facility is responsible for deleting unused user data.

Only authorised staff are authorised to create backup copies. The IT department of the healthcare facility manages the storage location of each backup in order to be able to react to potential queries by data subjects. Backups and archive data must be transmitted and stored securely.

2.3.5 Reporting and Handling Security Incidents

Operators must contact the IT department at their health organisation about any suspected or confirmed data protection or security breaches including suspected or compromised user accounts. The operators must report all service downtimes or access problems.

- If accounts are considered compromised, devices have been lost or unauthorised access is discovered or suspected, the healthcare organisation's IT department will suspend the user account or modify the login criteria and issue new login credentials for the user to access their account securely.

3 Device Description

3.1 Parts of the Device

Fig. 3-1: K5 without chin/forehead rest (left) and with chin/forehead rest (right)

No.	Description	No.	Description
1	Calotte with Placido rings	7	Locking screw
2	Camera opening with focus mark	8	Gear racks
3	Type plate	9	Forehead rest
4	On/off switch	10	Chin rest
5	Power connection	11	Joystick
6	Cross slide	12	Rotary knob to adjust the height of the chin rest

3.2 Wireless Joystick

If your device is equipped with a wireless joystick, the icon shown to the side will be displayed on the screen. The joystick can be used to trigger various images.

➔ Ensure that the wireless joystick is selected.
To check, open the hidden icons in the taskbar.
The icon for the OCULUS wireless joystick is displayed in the system tray. You can check the joystick status here, e.g. the battery charge level.

➔ Touch the joystick to activate it.
Communication with the computer or the examination software is established within 2 seconds. The LED on the Bluetooth USB adapter illuminates red.

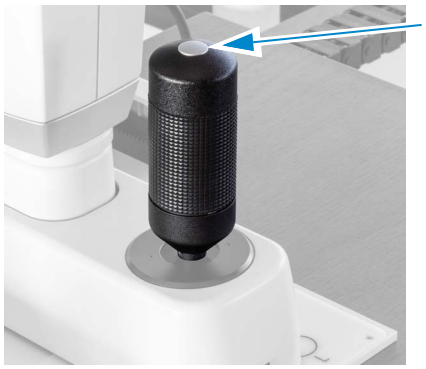


Fig. 3-2: Joystick with trigger (top)

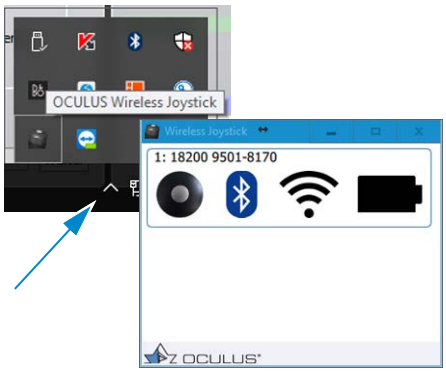


Fig. 3-3: Checking the status and settings of the joystick

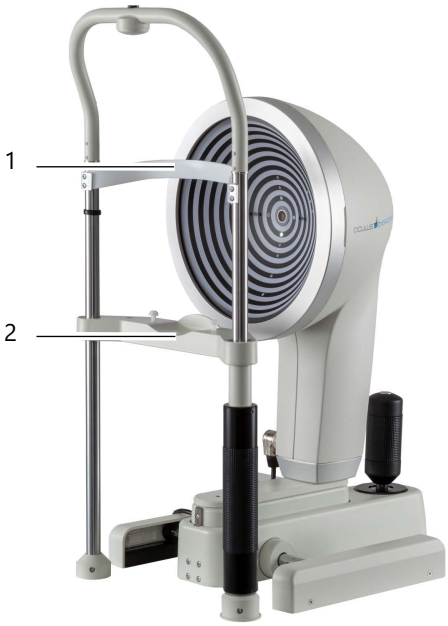
Triggering measurement	Press the trigger
Record a video	Press and hold the trigger

If you do not use the joystick for 90 seconds, communication with the Bluetooth USB adapter is interrupted to save the battery. The red LED on the Bluetooth USB adapter extinguishes.

The battery lasts for around 1 year under average usage conditions.

Once the battery has worn out, a message to change the battery is displayed in the examination software.

3.3 Application Parts



No.	Description
1	Forehead rest
2	Chin rest

Fig. 3-4: Application parts

The chin and forehead rest are type B application parts.

3.4 Functionality

The OCULUS Keratograph 5M combines the keratometric measuring procedure with the topographical.

The cornea surface is measured by a ring system that reflects on the cornea. The computer evaluates this data.

Technical principle

A lighting system with a special reflector illuminates a transparent calotte that is equipped with concentric circles from behind.

The image of this calotte is reflected by the test subject's eye that is placed opposite.

This virtual image is taken by a precision lens and a downstream, high-resolution colour camera.

All distortions that are visible due to deviating curvature radii of the test subject's eye are therefore available for the measurement procedure.

The image that was initially analogue is prepared for evaluation in the measuring equipment, i.e. it is available for processing in the computer in digitised and compressed form.

If the computer has received the corresponding data record of a measurement image, it develops a topographical image of the cornea from this.

It shows the measurement result on the monitor as a colour illustration, as a diagram and as a spatial image.

3.5 Intended Use

3.5.1 Intended Purpose

The Keratograph 5M is a measuring device for eye examinations and measures the surface of the cornea (cornea topography). The Keratograph 5M is therefore designed for use for individual contact lens adjustment.

Furthermore, the Keratograph 5M is intended for screening dry eyes.

The Keratograph 5M must be used in conjunction with the intended examination station or on an examination unit.

The Keratograph 5M may only be used for the purpose specified in these instructions for use, which particularly includes complying with the safety instructions.

3.5.2 Intended Medical Indication

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

- ➔ Cornea topography for contact lens adjustment
- ➔ Tear film analysis (dry eye)

3.5.3 Contraindications

None known

3.5.4 Possible Side Effects

None known

3.5.5 Intended Users

The Keratograph 5M is intended exclusively for professional use in:

- Ophthalmology practices
- Clinics
- With opticians or optometrists

The Keratograph 5M is intended for use by trained personnel:

- Who can guarantee proper handling due to their knowledge, training and practical experience.
- Who have been instructed by OCULUS staff or an authorised dealer prior to using for the first time.

3.5.6 Patient Group

Children from age 3. No upper limit. No restrictions regarding weight and state of health: The patient must be awake and able to understand and to look into a fixation target.

4 Setup and Connection

- The device may only be set up and connected by OCULUS or an authorised dealer.
- Do not use the device in damp rooms and do not leave the device there.
- Prevent dripping, splashing and spattering water in the vicinity of the device and ensure that no moisture can penetrate the device. Therefore, do not place any containers filled with liquid in the vicinity of the device.
- Only operate the device in spaces used for medical purposes if they are installed in accordance with VDE regulations 0100-710.
- Do not operate the devices supplied as standard in explosive areas, in the presence of inflammable anaesthetics or volatile solvents such as alcohol, benzine or similar.
- Set the device up so that the mains plug is easily accessible. You can therefore disconnect it from the mains easier for maintenance work.
- Do not force the electrical plug connections.
- If connection is not possible, check whether the plug fits the socket.
- If you discover damage to the plug connection, have it repaired by our customer service department.
- Only use a device that is correctly installed on a suitable lifting table.

Device damage due to improper transport or storage

➔ Do not expose the Keratograph 5M to vibrations, impacts, contamination, moisture and/or high temperatures.

➔ Handle the device with care.

Incorrect measurements/device damage due to improper setup

➔ Prior to first use, note that installation and connection of the "Keratograph 5M" examination station must have been completed by our customer service department or by a professional authorised by OCULUS.

➔ Obtain training from OCULUS or an authorised dealer on how to use the Keratograph 5M.

4.1 Setup and Operating Conditions

Device damage due to condensation caused by large temperature differences

➔ After transport or storage, let the device rest for about 3-4 hours at the place of installation so that the device can adapt to the ambient conditions. The optical components can mist up due to severe temperature differences from cold to warm areas.

Temperature	+10 – +35°C
Air humidity	30 – 75%
Air pressure	800 – 1060 hPa

➔ Set the Keratograph 5M up so that the mains plug is easily accessible. You can therefore disconnect it from the mains easier for maintenance work.
➔ Position the device so that no direct light can influence the measurement.

4.2 Information Regarding the Patient Environment

Patient environment is the area in which patients can come into contact with any part of the system or with another person who is in contact with the system.

Use only devices that comply with IEC 60601-1 in the patient environment. If a multi-socket is to be used or if a device that does not comply with the IEC 60601-1 standard is to be used, use an isolating transformer.

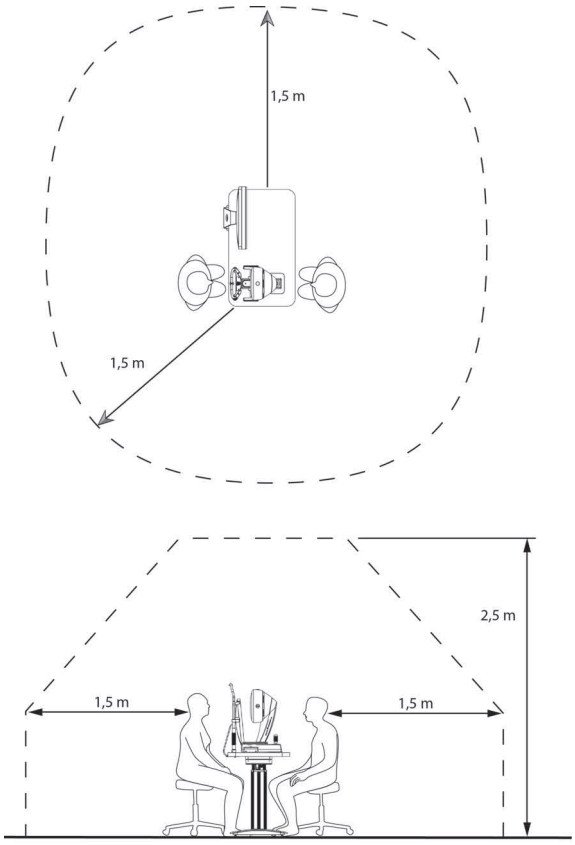


Fig. 4-1: Patient environment

4.3 Connecting the Foot Switch

You can connect a foot switch if required (prerequisite: USB connection on the PC). You can use the foot switch to trigger an image. You can use the foot switch to start and stop recording a video → Chap. 12.5 (page 54).

➔ Connect the foot switch's USB connector to a USB socket on your PC.
The foot switch is active.

4.4 Connecting the Power Supply

Caution
Risk to electrical safety

Note the following to ensure electrical safety:

- ➔ Do not use the device in the immediate vicinity of other devices.
- ➔ Do not stack the device with other devices.
- ➔ Only use the power supply that is supplied as standard, Chap. Appendix A, page 83.
- ➔ Only use a mains cable that meets the requirements of IEC 60227-1, type H05VV-F, 0.75 mm^2 min. and IEC 60320-1, type C7.
- ➔ If you are using a multi-socket to connect the Keratograph 5M: Use a multi-socket that complies with the requirements of IEC 60601-1.
- ➔ Do not place the multi-socket on the floor.
- ➔ Do not use more that one multi-socket.
- ➔ Only plug the Keratograph 5M and the computer that is being used, if applicable, into the multi-socket.
- ➔ Use a socket outlet that has a flawless protective conductor connection.

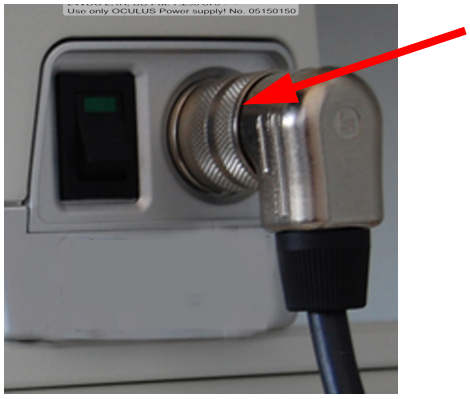


Fig. 4-2: Connection

1. Insert the plug for the Med. secure isolator cable into the socket and screw the connection tight. Ensure that the plug is inserted in the correct position.

Note
Device damage due to improper connection

If you do not connect the device properly and voltage is present, the device can get damaged.

- ➔ Do not force the electrical plug connections.
- ➔ Pay attention to the specifications on the type plate.
- ➔ If the plug is damaged, contact our customer service department or an authorised dealer to repair the damage.

2. Screw the connection tight.
3. Connect the Med. secure isolator cable to the computer/laptop and the power supply.

4.5 Switching on

1. First switch the computer/laptop on.
2. Then switch the Keratograph 5M on at the on/off switch (ON position).

The LED in the switch illuminates.

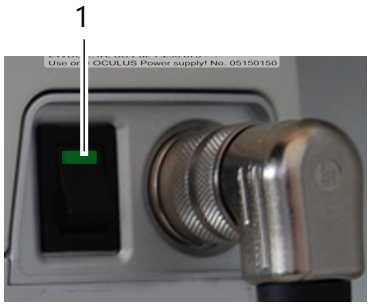


Fig. 4-3: On/off switch

4.6 Switching off

1. Close the Keratograph 5M program and patient data management.
2. Shut down the Windows operating system.
3. Switch the Keratograph 5M off at the on/off switch (OFF position).

Warning

Risk of electric shock if the Keratograph 5M is not disconnected from the power supply at all poles for transport, cleaning, maintenance, disinfection and repair.

➔ Remove the mains plug prior to cleaning or maintenance. Hold the plug to do this. Do not pull the cable.

5 Keratograph Software and Operation

The following descriptions relate to software version V 2.18r0 and higher.

5.1 Measurement Screen

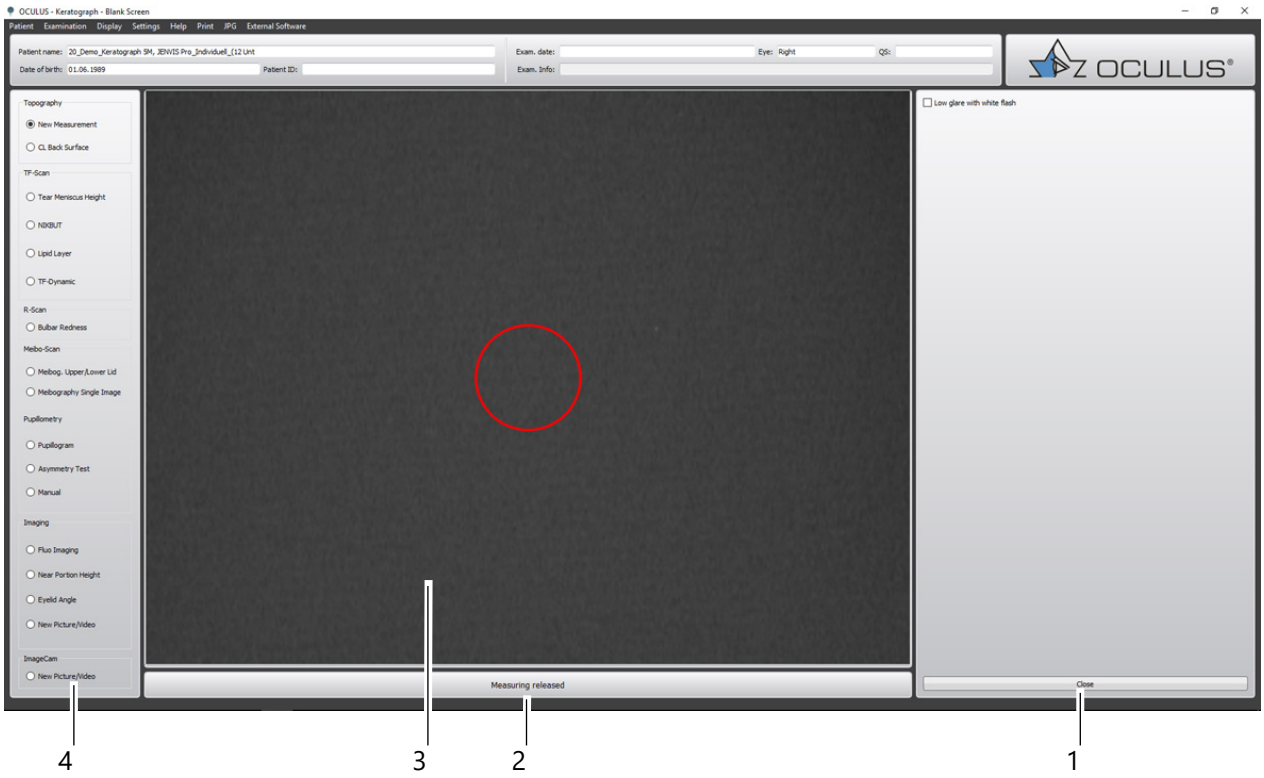


Fig. 5-1: Measurement screen

No.	Field name	Description
1	[Close] button	
2	[Enable measurement] button	
3	Current camera image with crosshair	
4	Examination bar	The examination bar displays the examinations that can be performed using the Keratograph. The examinations that are not enabled are greyed out.

5.2 Loading an Existing Examination

➔ Select the [Examination] menu item and press [Load].
The “Examination explorer” screen opens.

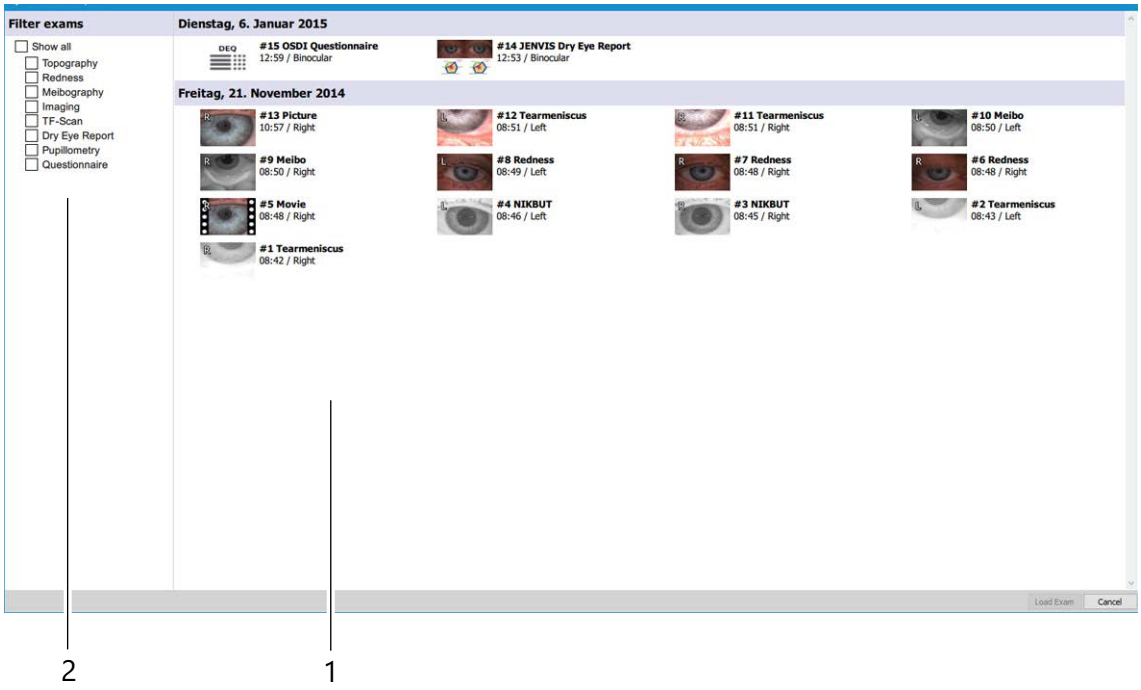


Fig. 5-2: Selecting and loading an examination

No.	Description
1	Examination filter
2	Preview of the examinations

1. Activate an examination filter if necessary, e.g. “Topography”. Only the topography examinations are then displayed in the preview.
2. Click the required examination to select it.
3. Press [Load examination] or double-click to confirm.
   The required examination is loaded into the Keratograph 5M program.

For some measurements such as measuring the eyelid angle, you are taken directly to the evaluation menu once you have pressed the [Single image] button.

5.3 Printing the Screen

1. Select the [Print] menu item.
   The print menu opens.
2. Enter the required printer and settings.
3. Press the [Print] button.
   The current screen is printed.

5.4 Images Using the Foot Switch

For measurement functions in which a single image is to be taken or a video recorded to document the result (e.g. image of the tear meniscus height, R scan, Meibo Scan, etc.), you can use the foot switch for easier operation.

Take an image	Press the foot switch briefly
Record a video	Press and hold the foot switch until the required end of the recording

5.5 Finishing the Examination

1. Ask the patient to remove their head from the chin and forehead rest.
2. Stop the measurement or prepare to measure a new patient.
   [Patient] menu > [New patient / End]

6 Measurement preparations

The instructions for use concentrate on the device's operating concept and describe the process of the various measurements.

Detailed information on evaluating the measurements is provided in the user manual.

Caution

Incorrect measurements due to incorrect operation

Before first use:

➔ Let OCULUS or an authorised dealer train you in operating the device.

OCULUS Optikgeräte GmbH is not liable in any way for further use of the data recorded by the device and calculated analyses.

Note the following when operating the device:

- ➔ Never start a damaged device up.
- ➔ Only operate the device with the original accessories supplied by OCULUS and only when the device is in technically perfect condition. Only use the power supply that is supplied as standard.
- ➔ Do not cover the ventilation openings.
- ➔ Do not touch the patient and the device at the same time.
- ➔ Ensure that the device cannot fall over, e.g. by leaning or sitting on it.
- ➔ Do not place the device and battery or cables on devices that generate heat, radiators, microwaves or similar.
- ➔ Only operate the device if you have understood the instructions for use.

6.1 Starting the Keratograph Program

1. Start the Keratograph by doing the following in patient data management
   - Select a patient or
   - Create a new patient

   Then click the [Keratograph] button.
2. Check whether
   - There is clean paper on the chin rest or the chin rest has been cleaned and disinfected
   - the forehead rest has been cleaned and disinfected
3. Before the first measurement: Perform a reference measurement.
   How to perform a reference measurement is specified in Chap. 15.6, page 74.

➔ For beginners, we recommend performing the measurement procedure several times using the reference sphere *(Chap. 15.6, page 74)* to practice.

4. Darken the room to ensure that no interfering light falls into the device's field of view.

6.2 Positioning the Patient and the Table

5. Adjust the table height so that the patient can place their head comfortably on the chin/forehead rest.
6. Ask the patient to place their chin on the chin rest.

➔ Do not touch the patient and the device at the same time.

7. Use the rotary knob to adjust the height of the chin rest.
   The patient is sitting correctly if their forehead and chin are touching the rests and their eye are at the height of the marking (black ring).

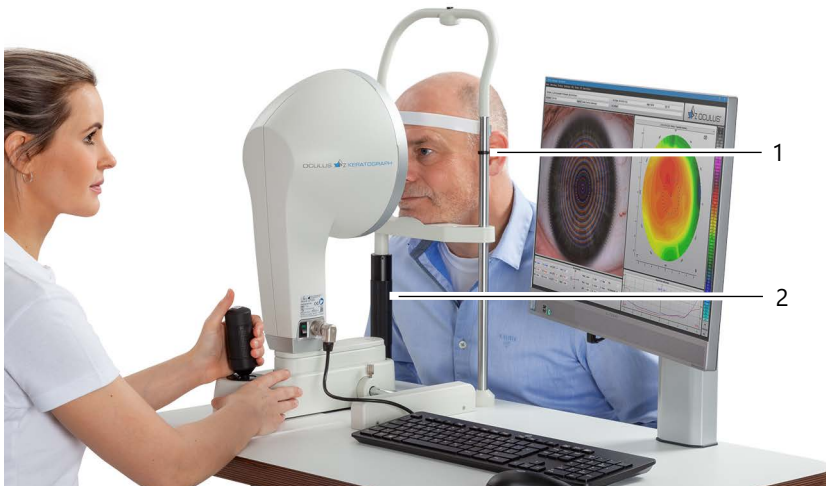
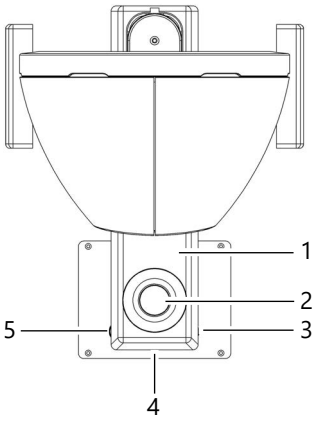


Fig. 6-1: Adjusting the chin/forehead rest

No.	Description
1	Black ring for guidance for the eye height
2	Rotary knob to adjust the height of the chin rest

8. For rough adjustment (e.g. for the right eye), move the adjustment base until the marking on the rear of the adjustment base is roughly superimposed on circle 'R'.



No.	Description
1	Adjustment base
2	Joystick
3	“L” marking = left
4	Marking on the adjustment base
5	“R” marking = right

Fig. 6-2: Pre-adjustment

9. Correct the position of the adjustment base if necessary.
10. Advise the patient to focus on the red light in the middle of the ring system for the entire duration of the measurement.

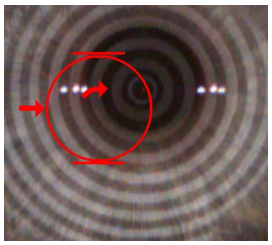
6.3 Selecting the Measurement

11. Select the required measurement and proceed as described in the corresponding chapter.
    → Chap. 7 “Topography Measurements” (page 32)
    → Chap. 8 “Tear Film Measurements (TF Scan)” (page 37)
    → Chap. 9 “Degree of Redness Measurements (R Scan)” (page 42)
    → Chap. 10 “Photographs of the Meibomian Glands (Meibo-Scan)” (page 43)
    → Chap. 11 “Photographs of the Pupil (Pupillometry)” (page 45)
    → Chap. 12 “Imaging Measurements” (page 48)

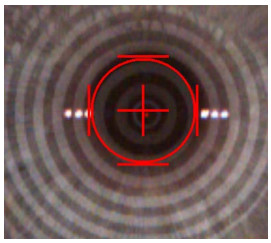
6.4 Aligning the Camera

The “Topography” and “NIKBUT” measurement functions are performed via an automatic measurement trigger. The camera must be aligned precisely for this.

1. Position the measuring head in front of the eye so that the Keratometer marks are sharp (see the illustration).
2. Align the camera precisely by turning or tilting the joystick in the specified directions.



Arrow	Camera movement	Joystick movement
→	Right	Tilt the joystick to the right
←	Left	Tilt the joystick to the left
↑	Forward	Tilt the joystick towards the patient
↓	Back	Tilt the joystick away from the patient
↱	Up	Turn the joystick clockwise
↰	Down	Turn the joystick anticlockwise



As soon as the position is sufficiently precise, a cross appears in the middle of the ring, which is surrounded by four bars.

The Keratograph 5M triggers the measurement automatically.

The [Lighting], [Magnification changer] and [Camera] group fields are displayed for some measurements. In these group fields, you can adjust the camera and the lighting, and save the settings as a program.

Proceed as described in Chap. 12.5, page 54.

6.5 Manual Measurement

In rare cases, such as in the event of highly irregular corneas, triggering an automatic measurement is not possible. In this case, you can trigger the measurement as follows:

1. Press the space bar to block the automatic measurement trigger.
2. Press the Enter button,
   or
   first press the space bar and then the foot switch to trigger the measurement manually.

A measurement that was triggered manually is sometimes not reproducible.

7 Topography Measurements

7.1 New Measurement

1. Prepare the measurement and position the table and test subject.
2. In the [Examination] menu, select the [New] menu item.
3. Activate the [New measurement] selection in the 'Topography' field.

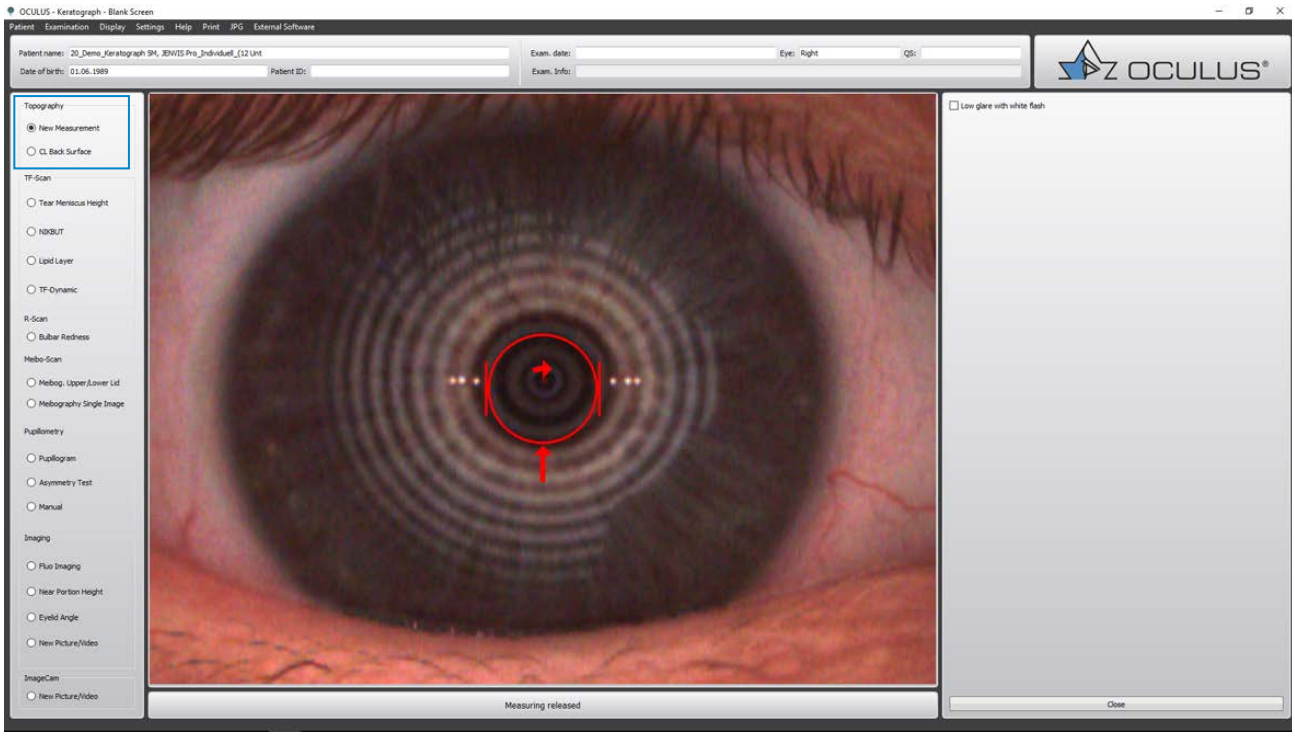


Fig. 7-1: Topography measurements

4. Ask the patient to look at the red light in the middle of the device with their eyes wide open.
5. If the test subject is particularly sensitive to light, deactivate the [Low glare with white flash] button (→ Chap. 7.1.1 (page 33)).
6. Use the joystick to align the camera.

As soon as the crosshair is aligned precisely, the device triggers the measurement automatically. The "Overview" screen opens.

If the measurement is not triggered automatically, which may occur if there are large irregularities on the cornea (e.g if there is a severe Keratokonus),

- you can trigger the measurement manually (→ Chap. 6.5 (page 31)).

or

- A dialogue box requests that you mark the centre point of the Placido rings manually (→ Chap. 7.1.2 (page 33))

A measurement that was triggered manually is sometimes not reproducible.

7.1.1 Patients who are Sensitive to Light: Low Glare with White Flash

If a patient is particularly sensitive to light, it may be necessary to reduce the brightness of the Keratograph.

➔ Activate the “Low glare with white flash” function.

The device is centred to the eye under infrared light. Only the image itself is taken using white light. The test subject can therefore open their eye wider, which causes the area to be measured to be enlarged.

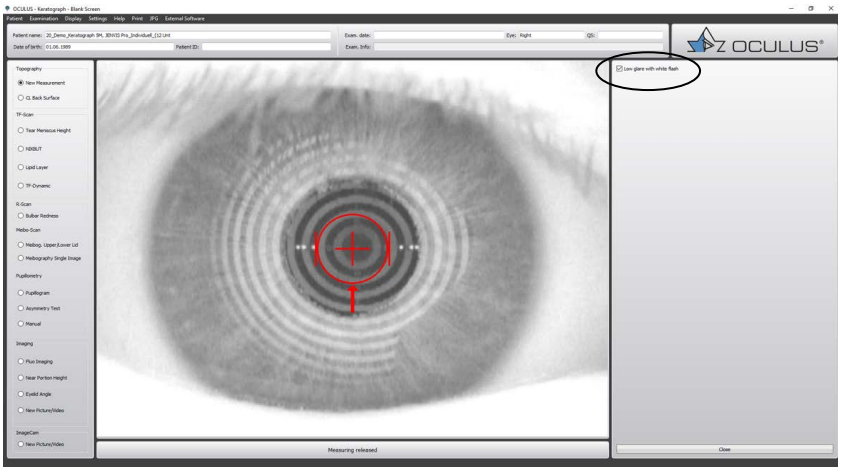


Fig. 7-2: Topography examination with low glare

7.1.2 Marking the Centre Point of the Placido Rings Manually

In the event of severe cornea irregularities, the Keratometer marks may not be on the same level as the centre point of the Placido rings. Automatic evaluation of the topography data is then not possible. In this case, you are requested to mark the centre point of the Placido rings manually *(<XRef>“Manual Measurement” on page 31)*.

➔ Left-click the centre point of the rings projected onto the cornea.
The cornea topography is calculated.

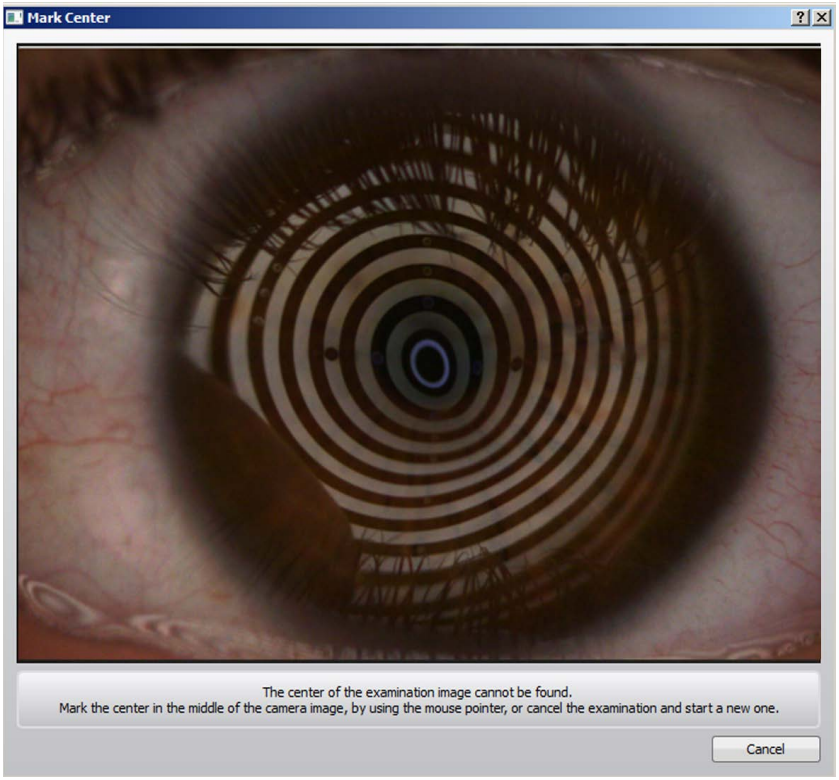
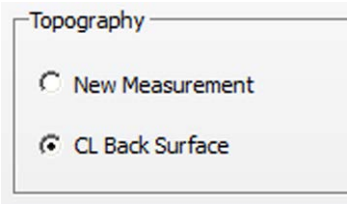


Fig. 7-3: Dialogue box: Marking the centre point of the Placido rings manually

7.2 CL rear Surface

Contact lens rear surfaces are measured in a similar way to corneas.

1. Start the Keratograph 5M software.
2. In the [Examination] menu, select the [New] menu item.
3. Select the [CL rear surface] button. Measurement now takes place in a similar way to the topography measurement → Chap. 7 (page 32).



The contact lens holder can be put onto a fastening clip if the contact lens was first secured in the CL holder (see below).

7.2.1 Parts for Contact Lens Rear Surface Measurement

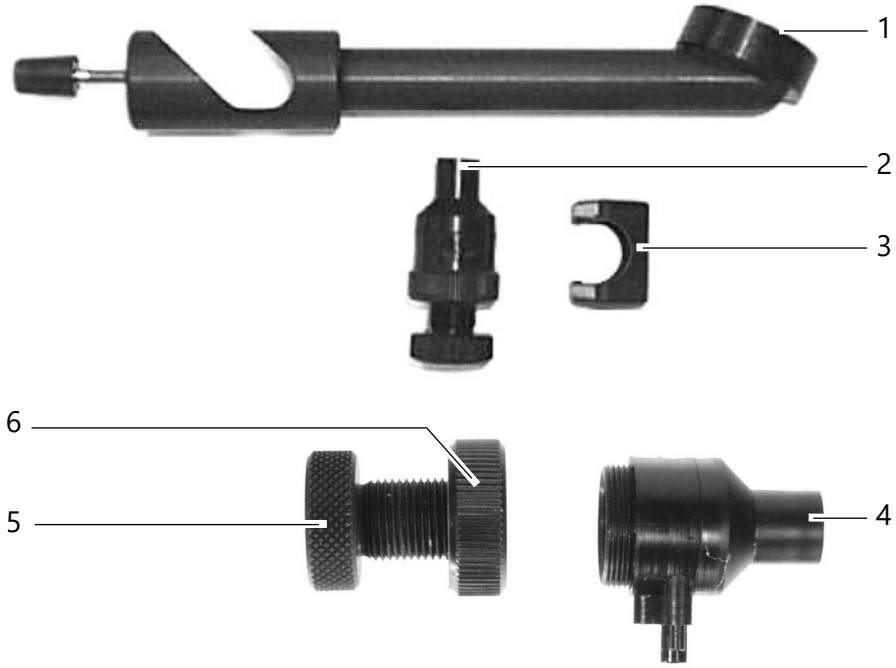


Fig. 7-4: Parts required for the contact lens rear surface measurement

No.	Description	No.	Description
1	Reference sphere holder	4	Top part of the CL holder (zoomed in)
2	Contact lens holder	5	CL holder cap nut (zoomed in)
3	Fastening clip	6	CL holder adjustment screw (zoomed in)

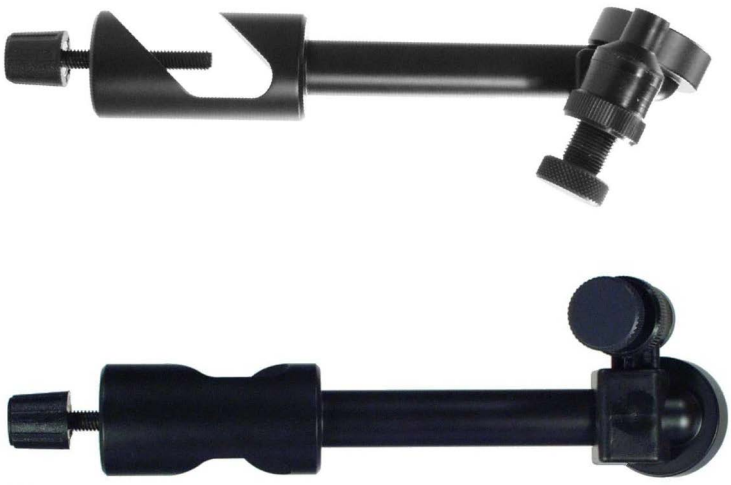


Fig. 7-5: Fully assembled contact lens holder

7.2.2 Filling the Contact Lens Holder with Water

1. Unscrew the cap nut to open the contact lens holder.
2. Fill with water and use the cap nut to re-close the contact lens holder. Ensure that as little air as possible is trapped inside.
3. Hold the contact lens holder with the adjustment screw at the bottom.
4. Screw the adjustment screw further into the contact lens holder until the top part of the contact lens holder is covered completely with water.
5. Then unscrew the adjustment screw again until the water surface has a slightly concave curvature.

7.2.3 Measuring the Contact Lens Rear Surface dry

6. Clean and dry the contact lens to be measured with a soft cloth.
   Ensure that there is no moisture, dust residues or fingerprints on the concave inner surface.

7.2.4 Securing the Contact Lens

7. Take the contact lens between your thumb and index finger, and place it carefully on the contact lens holder's water surface.
8. Unscrew the contact lens holder adjustment screw until the contact lens is secured in the holder.
   No air bubbles may be formed and no water may get onto the rear surface to be measured.

7.2.5 Securing the Fitted Contact Lens Holder

9. Screw the reference sphere holder onto the chin rest
10. Put the contact lens holder onto the fastening clip.
11. Align the fastening arm so that the optical axes for the contact lens and the Keratograph 5M roughly match.

8 Tear Film Measurements (TF Scan)

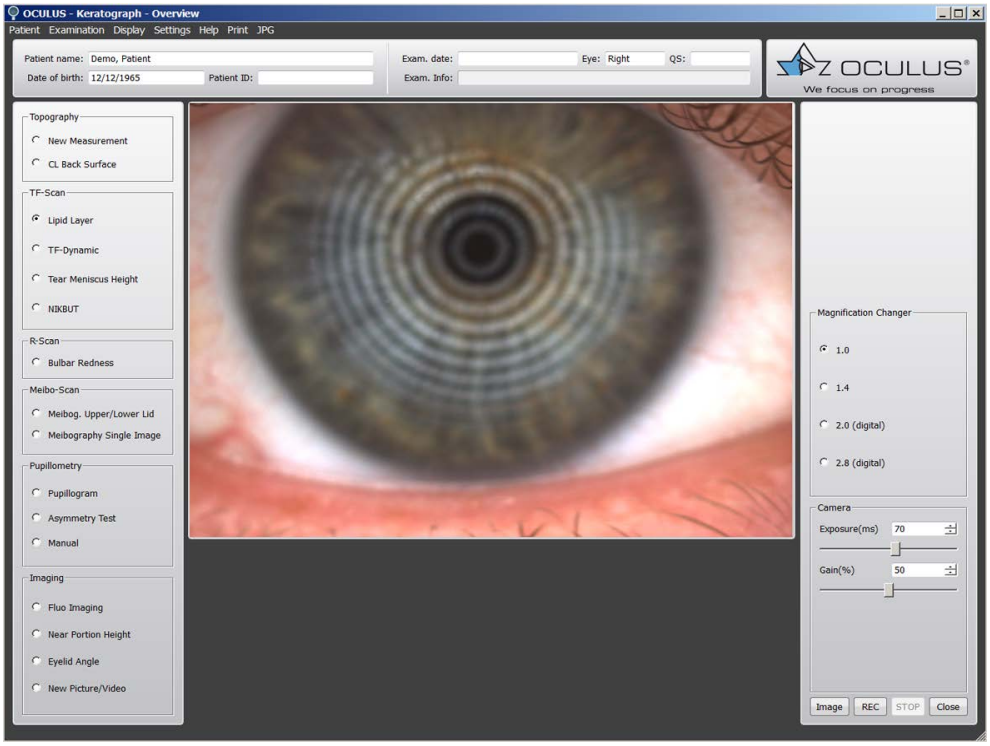


Fig. 8-1: TF scan examinations, e.g. lipid layer

The TF scan provides the following options that you can use to examine the tear film:

- Lipid layer, → Chap. 8.1 (page 38)
- TF dynamics, → Chap. 8.2 (page 39)
- Tear meniscus height, → Chap. 8.3 (page 40)
- NIKBUT, → Chap. 8.4 (page 40)

Information about the magnification changer is provided in → Chap. 12.5 “Adjusting the Lighting, Magnification Changer and Camera” (page 54).

8.1 Examining the Lipid Layer

The interference colours of the lipid layer and their structure become visible and can be photographed.

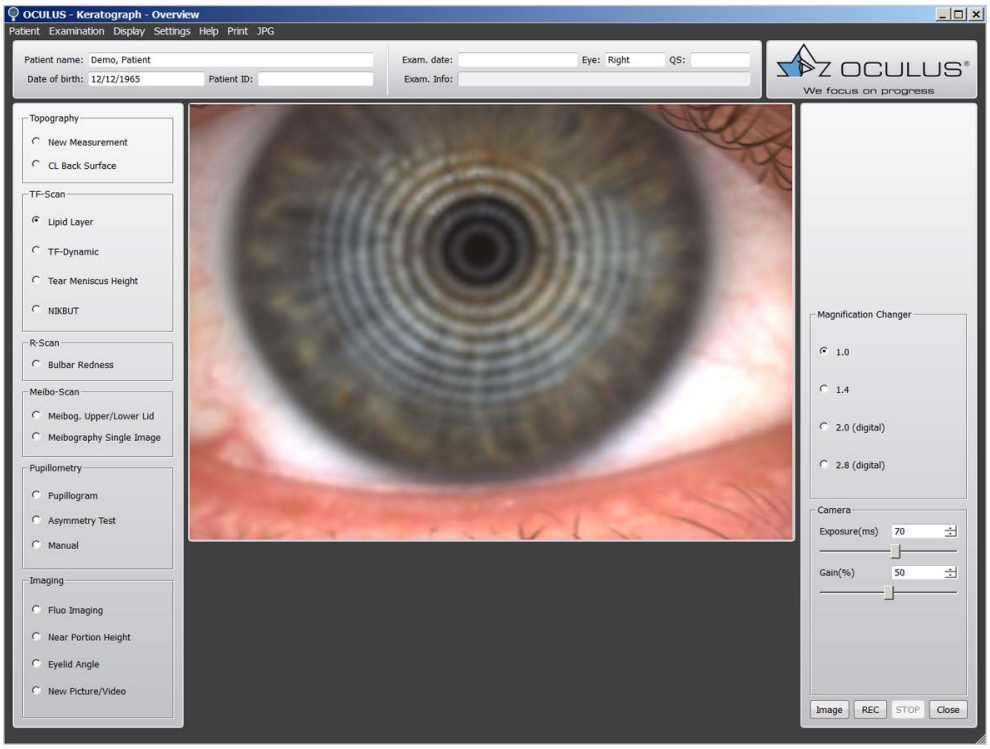


Fig. 8-2: Lipid layer measurement

1. Select the [Lipid layer] button.
2. Move the Keratograph 5M in small increments towards the patient's eye. First focus the Placido rings.
3. Pull the camera back slightly and focus when photographing the lipid layer.
4. Press
   - [Image] to obtain a snapshot of the lipid layer or
   - [REC] to record a video. Use [STOP] to stop the video recording.

   Alternatively, you can also use the foot switch for the images *(→ Chap. 5.5 (page 27))*.

Recommendation: A video is best suited for optimum documentation of the lipid layer.

➔ Record the lipid layer for two to three blinks in order to be able to appraise the distribution of the lipid on the tear film surface as well as possible.

Information about the magnification changer is provided in → Chap. 12.5 (page 54).

8.2 Examining the TF Dynamics

You can use the video recording (up to 32 images per second) to observe the distribution of particles in the tear film. Conclusions can be drawn about the viscosity based on the flow behaviour.

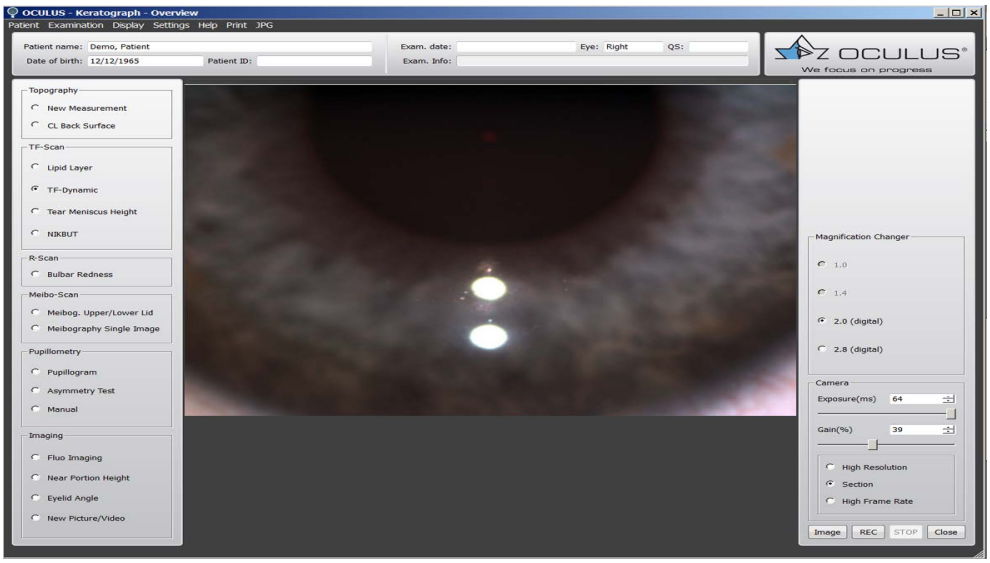


Fig. 8-3: TF dynamics measurement

1. Select the [TF dynamics] button.
2. Adjust the camera if necessary → Chap. 13.3.2 (page 61).
3. Focus the bright spots. The tear film must be focussed.
4. Press
   - [Image] to obtain a snapshot of the particles in the tear film or
   - [REC] to record a video. Use [STOP] to stop the video recording.

   Alternatively, you can also use the foot switch for the images → Chap. 5.5 (page 27).

Recommendation: A video is best suited for documenting the tear film dynamics.

➔ Record the video for two to three blinks in order to be able to appraise the flow speed and the flow behaviour of the tear film, as well as the number of particles.

Information about the magnification changer is provided in → Chap. 12.5 (page 54).

8.3 Measuring the Tear Meniscus Height

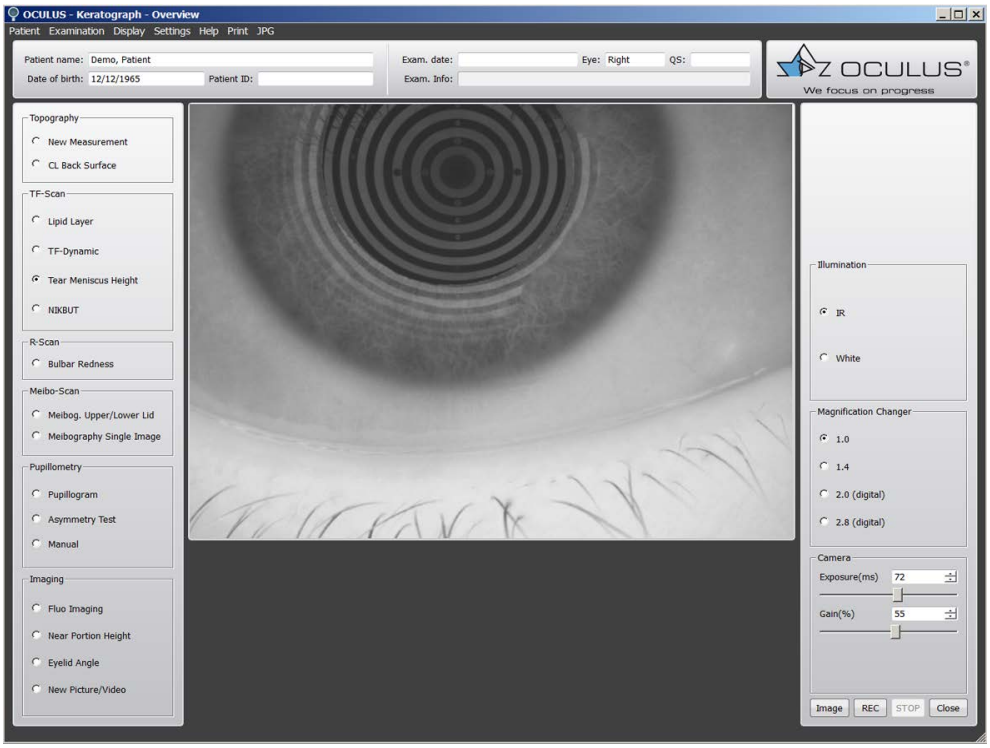


Fig. 8-4: Tear meniscus measurement

The tear meniscus height must be measured in order to be able to determine the tear film quantity.

1. Select the [Tear meniscus height] button.
2. Select the lighting [IR] or [White] on the right in the group field.

Infrared light (IR) is not visible to the human eye. Using this light for measurement prevents dazzling the patient's eye. You can therefore avoid a falsification of the measurements result due to stimulated secretion in patients who are sensitive to light

3. Adjust the camera if necessary → Chap. 12.5 (page 54).
4. Adjust the camera so that the tear meniscus is shown in the centre.
5. Focus the reflected rings of the tear meniscus.
6. Press [Image].
   Alternatively, you can also use the foot switch for the images → Chap. 5.5 (page 27).

Information about the magnification changer is provided in Chap. 12.5, page 54.

8.4 Measuring NIKBUT

The NIKBUT measurement (Non Invasive Keratograph Break-Up Time) determines the break-up time of the tear film. Infrared light or white light is used as the lighting here.

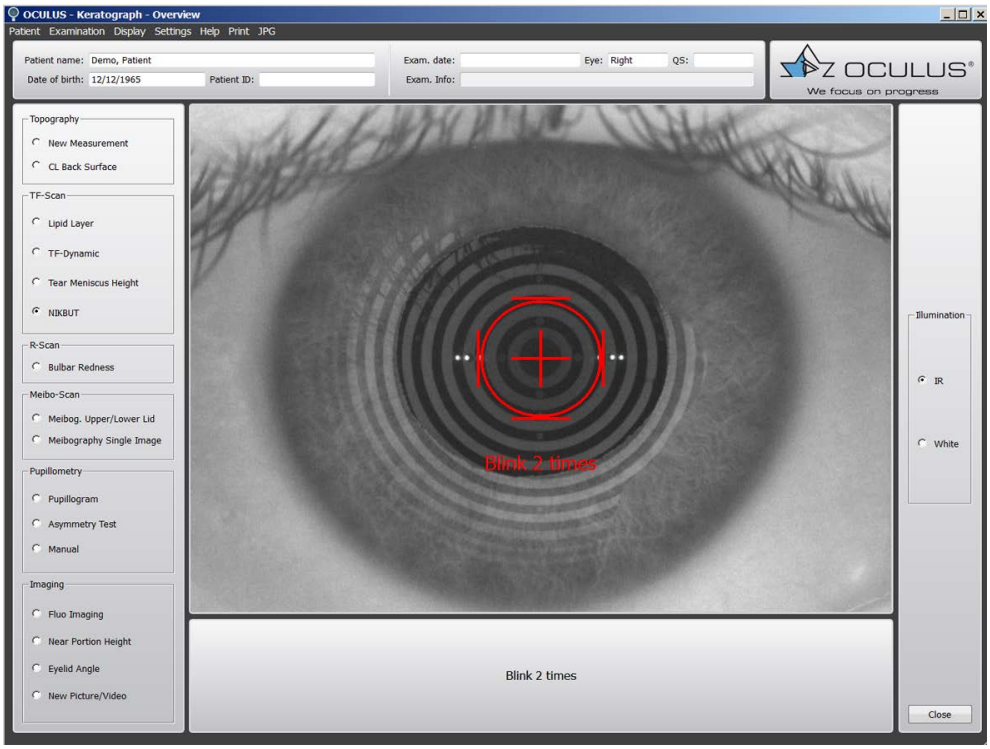


Fig. 8-5: NIKBUT examination

1. Select the [NIKBUT] button on the left in the examination bar.
2. Select the lighting [IR] or [White] on the right in the group field.

Infrared light (IR) is not visible to the human eye. Using this light for measurement prevents dazzling the patient's eye. You can therefore avoid a falsification of the measurements result due to stimulated secretion in patients who are sensitive to light

3. Adjust the camera if necessary → Chap. 12.5 (page 54).
   Request that the patient blinks twice more as soon as the notice appears on the screen. The patient should then keep their eye open for as long as it is possible and comfortable.

➔ The measurement is performed automatically.

The measurement stops if the patient blinks, moves or the tear film breaks up significantly.

9 Degree of Redness Measurements (R Scan)

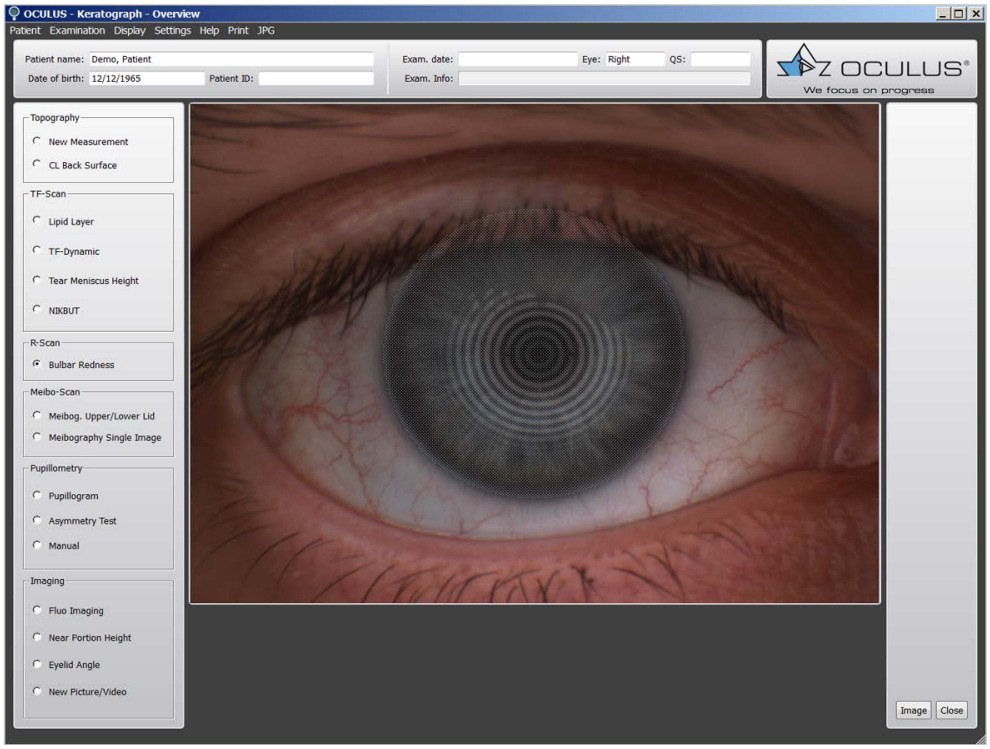
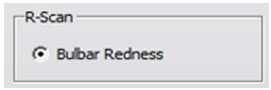


Fig. 9-1: R scan examination



You can use this function to classify the degree of redness.

1. Select the [Bulbar degree of redness] button.
2. Align the camera so that the grey grid covers the iris and that the visible vessels of the conjunctiva are in focus.
3. Press [Image].
   Alternatively, you can also use the foot switch for the images *(Chap. 5.5, page 27)*.

10 Photographs of the Meibomian Glands (Meibo-Scan)

In the Meibo Scan, images can be taken of the upper eyelid and the lower eyelid, and single images can be taken in order to see and classify changes to the Meibomian glands. These images can be used to visualise the Meibomian glands and to display them in three dimensions.

For the automated analysis and classification of the condition of the Meibomian glands the software uses an **AI-powered method** (= Meibo Analytics). The results are used to assist the user but they do not replace the specialist evaluation by a doctor.

For more detailed information, do not hesitate to contact OCULUS (sales@oculus.de).

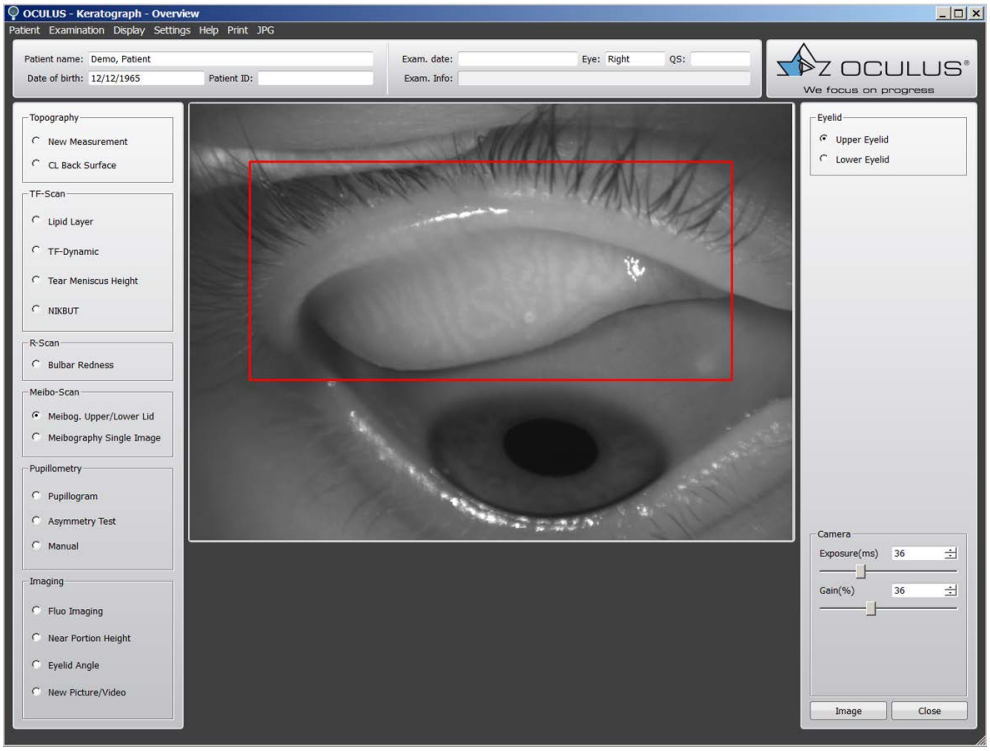


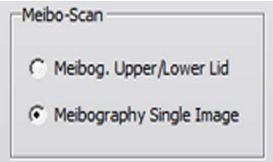
Fig. 10-1: Meibo Scan examination

10.1 Photographing the Upper Eyelid and the Lower Eyelid

1. Select the [Meibog. upper eyelid/lower eyelid] button on the right in the group field [Meibo Scan].
2. Adjust the camera if necessary → Chap. 12.5 (page 54).
3. Position the camera so that first the upper eyelid fits into the imaging field with a red frame.
4. Ectropionise the upper eyelid.
   To fold the upper eyelid over, have the patient look down, place the round end of the LidStick® in the centre on the upper eyelid (roughly at the end of the tarsal plate) and pull gently with the other hand to fold over the upper eyelid.
5. Focus the Meibomian glands.

6. Press [Image] to trigger the image for the upper eyelid.
   Alternatively, you can also use the foot switch for the images → Chap. 5.5 (page 27).
7. Repeat the steps for the lower eyelid.
8. To fold over the lower eyelid, place the end of the LidStick® in the centre under the eyelid edge and pull it down. Exert gentle pressure on the eye to fold over the eyelid.

10.2 Photographing a Single Image



1. Select [Meibography single image].
2. Ectropionise the upper or lower eyelid.
3. Position the camera so that the upper eyelid or the lower eyelid fits into the imaging field with a red frame.
4. Focus the Meibomian glands.
5. Press [Image] to trigger the image.
   Alternatively, you can also use the foot switch for the images → Chap. 5.5 (page 27).

11 Photographs of the Pupil (Pupillometry)

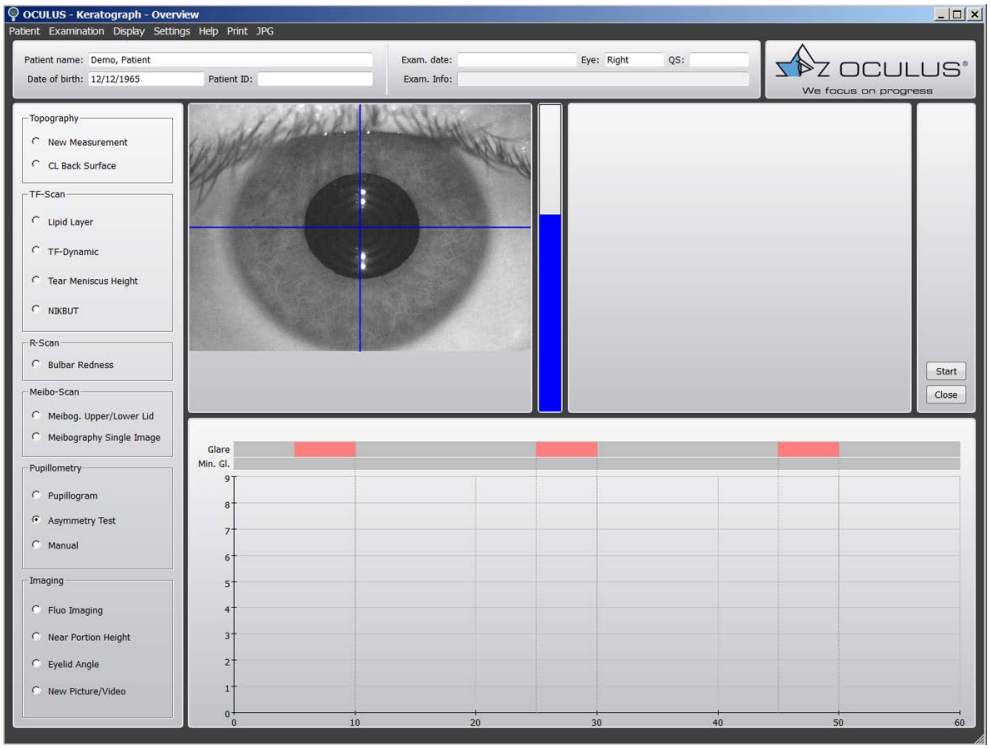
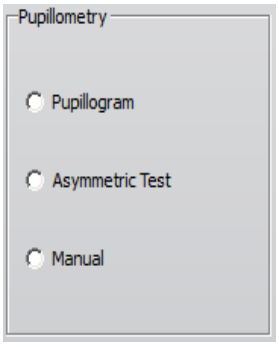


Fig. 11-1: Pupillometry examination



You can use this function to continuously examine the pupil size depending on various glare statuses.

➔ Select the required measurement program by clicking the corresponding button:
- Pupillogram (→ Page 46)
- Asymmetry test (→ Page 46)
- Manual (→ Page 47)

11.1 Adjusting

To use pupillometry, you must adjust the focus.

➔ Use the adjustment base and the joystick to focus the pupillometry (→ Chap. 3.2 (page 18)).

➔ Use the focus to adjust the gap.
To do this, focus the pupil image by moving the cross slide or the joystick towards the Keratograph or away from it.

The blue bar is used as orientation for the focus of the camera image. The higher the blue bar, the sharper the camera image.

11.2 Displaying the Measured Values

The measured value are displayed as a diagram:

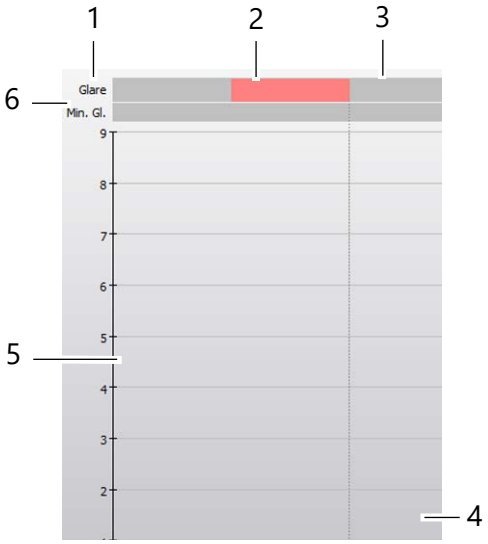


Fig. 11-2: Diagram

No.	Name	Description
1	Glare	Displays the status of the ring lighting (Placido system) depending on the measurement time.
2	Red markings	"Glare on"
3	Grey markings	"Glare off"
4	X-axis	Measurement time in s
5	Y-axis	Pupil size in mm
6	Min. glare	Displays the status of the inner ring depending on the measurement time. The degree of glare is significantly weaker.

11.3 Pupillogram

Automatic standard pupillometry program.
0.2s glare then 9.8s break (5 times).

1. Select the [Pupillogram] button.
2. Focus the image.
3. Press the [Start] button to start the measurement.
   Measurement stops automatically after 60 seconds.
   You can press the [Stop] button to stop the measurement manually.
   The applicable measurement is saved and you go to the subsequent screen automatically, see the *User manual*.

11.4 Asymmetry Test

Automatic pupillomety program to detect a pupil difference.
5s glare then 15s break (3 times).

1. Select the [Asymmetry test] button.
2. Focus the image.

3. Press the [Start] button to start the measurement.
   Measurement stops automatically after 60 seconds.
   You can press the [Stop] button to stop the measurement manually.
   The applicable measurement is saved and you go to the subsequent screen automatically, see the *User manual*.

11.5 Manual

The glare statuses are set manually.

➔ Use the [Glare] and [Min. glare] buttons to control the degree of glare.
Set the glare manually in this program (during the measuring process, in contrast to the automatic programs).
[Glare] button: switch the entire ring system on or off
[Min. glare] button: switch the inner ring of the ring system on or off
The stimulation intensity of [Min. glare] is significantly lower than that of [Glare].

Measurement stops automatically after 60 seconds once the measurement reaches the right side of the diagram

Alternatively, use the [Stop] button to stop the measurement manually.

Once the measurement is complete, the overview illustration opens automatically *(Fig. 5-1, page 25)*.

12 Imaging Measurements

You can use the imaging software and the high resolution colour camera to record video and image files to document results on the eye or you can perform special measurements for contact lens adjustment and checks for how the contact lenses sit both with and without fluorescein.

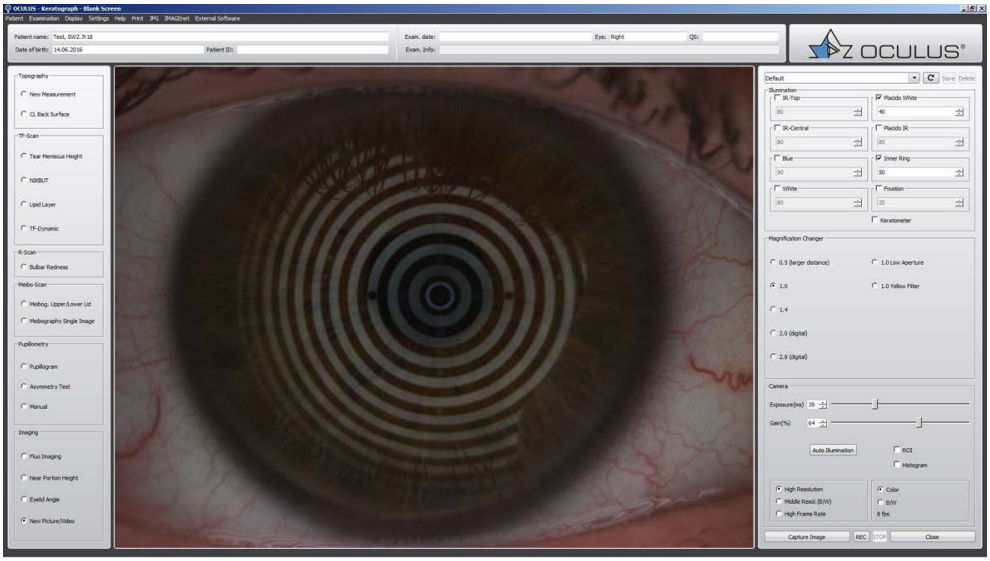
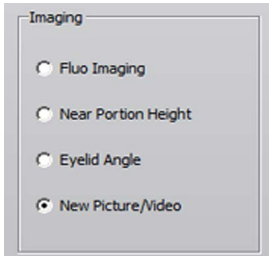


Fig. 12-1: Examinations with “Imaging”



➔ Select the type of image by clicking the corresponding button:
- Fluorescein image→ Chap. 12.1 (page 49)
- Near vision height measurement→ Chap. 12.2 (page 50)
- Eyelid angle measurement→ Chap. 12.3 (page 51)
- New image→ Chap. 12.4 (page 52)

12.1 Fluorescein Image

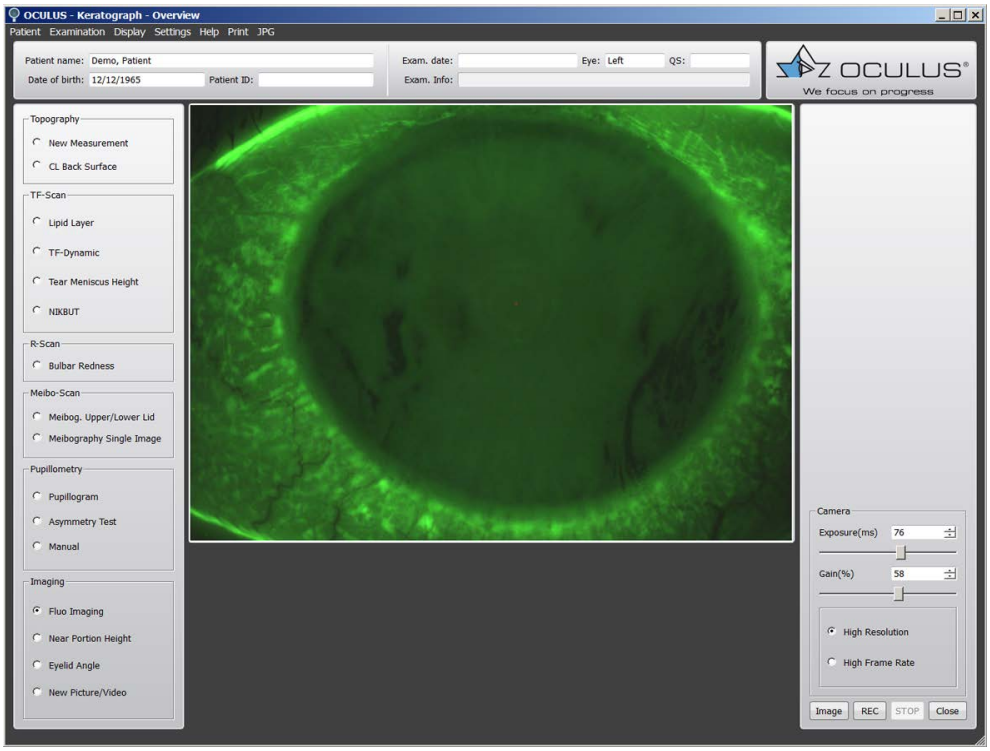


Fig. 12-2: "Fluorescein image" imaging function

1. Select the [Fluorescein image] button.
2. Adjust the camera if necessary → Chap. 12.5 (page 54).
3. Align the camera to the centre of the contact lens.
4. Press
   - [Image] for a static image or
   - [Rec] to record a video that can be used, for example, to appraise how the contact lens sits dynamically. You can press the [Stop] button to pause/stop the video recording.

   Alternatively, you can also use the foot switch for the images *(→ Chap. 5.4 "Images Using the Foot Switch" (page 27))*.

The video and single images are saved automatically.

You can use the fluorescein image to adjust the contact lenses, see the *User manual*.

➔ Use the [Close] button to go directly to the overview of images.
For more information about this, see the *User manual*.

12.2 Near Vision Height Measurement

The near vision height measurement can be used to determine the dividing line position for bifocal, inherently stable contact lenses.

Fig. 12-3: “Near vision height measurement“ imaging function

1. Select the [Near vision height measurement] button.
2. Adjust the camera if necessary → Chap. 12.5 (page 54).
3. Centre and focus the eye in the camera image.
4. Select the [Ring lighting] button to increase the illumination. This dazzles the eye and makes the pupil diameter as small as possible.
5. Press the [Single image] to trigger the image.
   Alternatively, you can also use the foot switch for the images *(→ Chap. 5.4 (page 27))*.

The image is saved automatically.

Press [Close] to go to the subsequent screen.

You can now perform the near vision height measurement and evaluation, see the *User manual*.

12.3 Eyelid Angle Measurement

The nasal lower eyelid measurement is required to adjust and precisely calculate soft toric contact lenses.

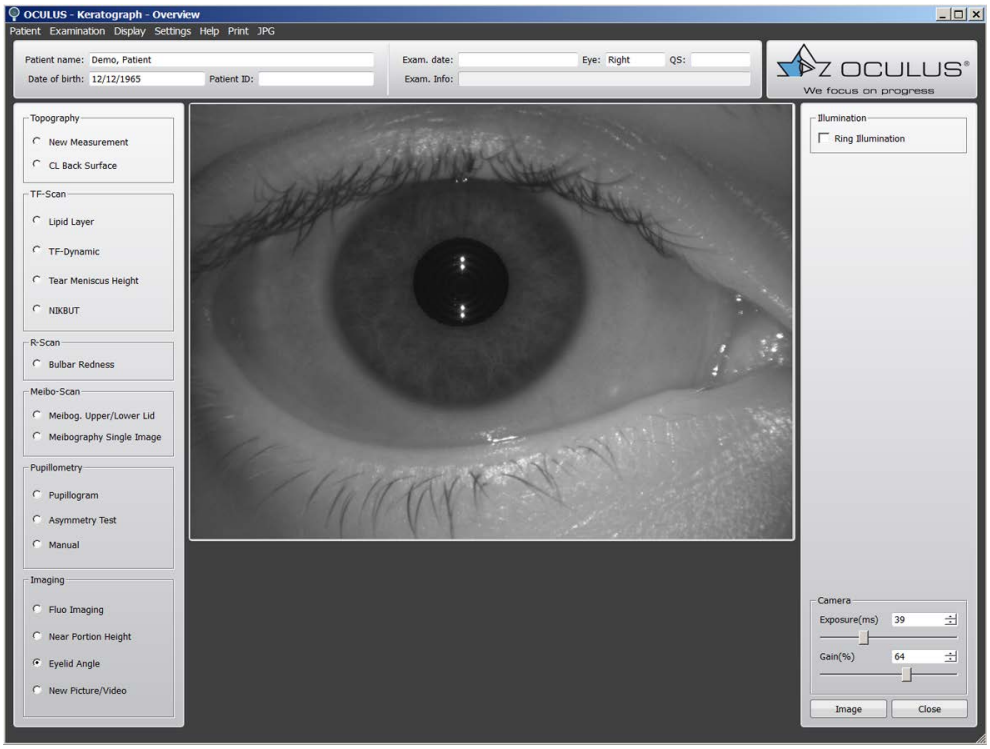


Fig. 12-4: “Eyelid angle measurement” imaging function

1. Select the [Eyelid angle measurement] button.
2. Adjust the camera if necessary → Chap. 12.5 (page 54).
3. Centre the eye in the camera image.
4. Press [Image] to trigger the image.
   Alternatively, you can also use the foot switch for the images *(→ Chap. 5.4 (page 27))*.

The image is saved and you go to the subsequent screen automatically.

You can now perform the eyelid angle measurement, see the *User manual*.

12.4 New Image

You can use [New image] to create new photos and videos for image documentation and make special settings for these.

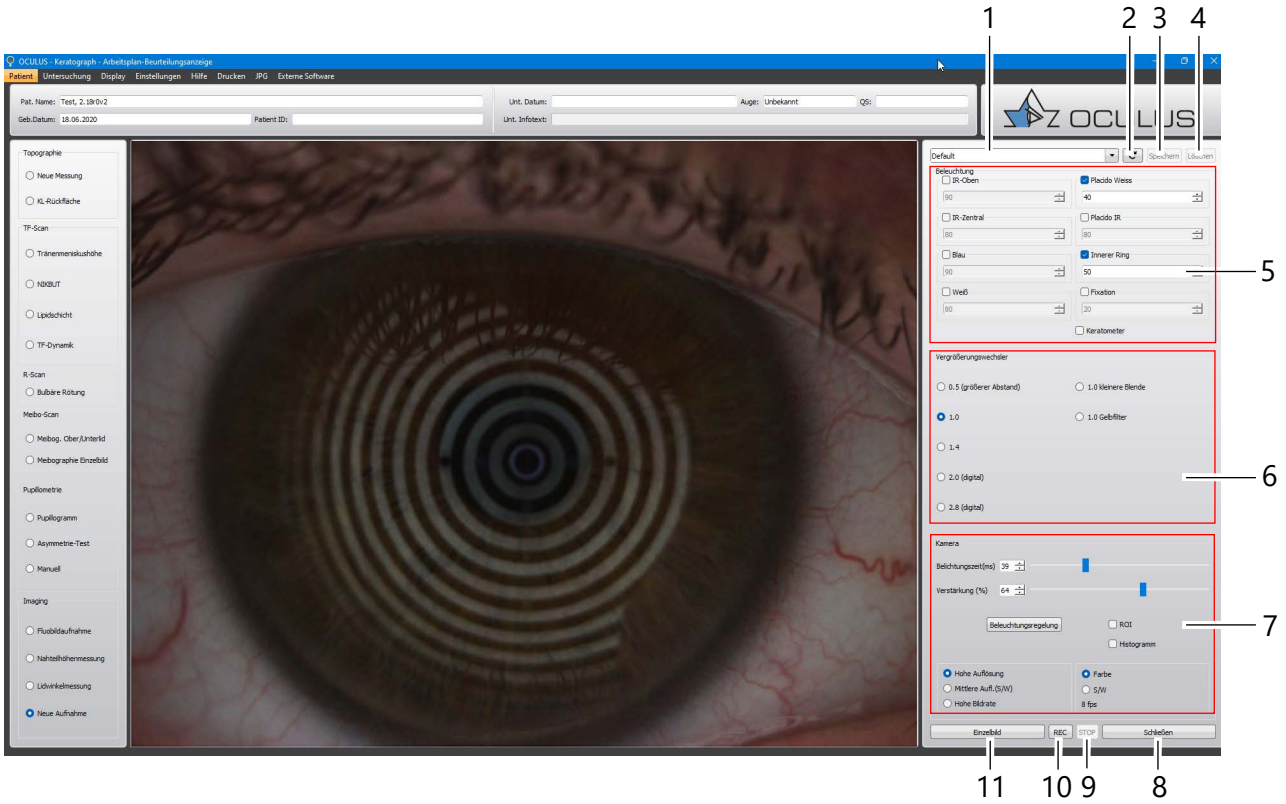


Fig. 12-5: “New image” overview illustration

No.	Name	Description
1	Selection list	Dropdown list You can use preset image values (default) or select your own image settings.
2	Update	The values for the selected image program are inserted into the fields.
3	[Save]	➔ Make image settings. ➔ Enter the name for the new image program. ➔ Press [Save].
4	[Delete]	The selected image program is deleted. The manufacturer’s “Default” settings cannot be deleted.
5	Lighting	→ Chap. 12.5.1 (page 54)
6	Magnification changer	→ Chap. 12.5.2 (page 54)
7	Camera	→ Chap. 12.5.3 (page 54)
8	[Close]	
9	[Stop]	Stop the video recording.

No.	Name	Description
10	[REC]	Start the video recording. Limit the duration of the videos to no more than 1 minute, as otherwise, the data quantity will become very large.
11	[Single image]	Trigger a single image, e.g. to take static fluorescein images.

Note

Videos and single images are saved automatically.

12.5 Adjusting the Lighting, Magnification Changer and Camera

The [Lighting], [Magnification changer] and [Camera] fields are displayed for some measurements. In these fields, you can set the applicable values and save the settings as a program.

The optimum camera settings are already preset for certain measurement functions.

12.5.1 Lighting

I**R top/IR central:** If only the "IR top" and "IR central" checkboxes are activated (when the room is darkened):

How the contact lens sits can be evaluated when the pupil is dilated (for example, when adjusting multi-strength lenses).

Blue: The blue light is used to stimulate the fluorescein to become fluorescent.

White: TF dynamics: Two spots in the lower part of the calotte are set to white.

Placido white: Topography and NIKBUT examination: The calotte lighting is set to white.

Placido IR: The calotte lighting is set to infrared.

Inner ring: The patient's eye is dazzled to a minimum.

Fixation Used to support that patent's fixation.

Checkbox: [Keratometer]: Keratometer marks for centring during topography

12.5.2 Magnification Changer

In the magnification changer field, you have the option of choosing between three optical and two digital magnifications.

- 0.5 to 1.4
- 2.0 (digital)
- 2.8 (digital)
- **1.0 less glare,** for better depth sharpness
- **1.0 yellow filter,** for images with fluorescein

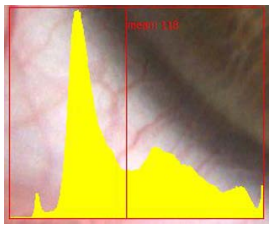
If your device is equipped with a wireless joystick, you can use the joystick to trigger various images.

12.5.3 Camera

Illumination time: The longer the illumination time, the brighter the image. However, the focus can reduce by moving the slider.

Amplification: If you increase the amplification value, the image becomes brighter. However, this reduces the image quality. Too great an amplification causes noisy images.

Lighting regulation: You can use this function to regulate the lighting for the entire image, e.g. to avoid excessively illuminating an image.



For JENVIS PRO Dry Eye and Chrystal Tear, 2 additional checkboxes are displayed here:

- ROI (Region of Interest): Select [ROI] and move the cursor to the required position. Press the left mouse button.
  You can now regulate the lighting for the selected area.
- Histogram: Depending on the presetting, a histogram is displayed for the entire image or for the ROI image section.

If the tip of the graphic is on the red centre line, the lighting is set well.

High resolution, medium resolution (black and white) or high image rate: At a higher resolution, details are more visible and a higher image rate provides "non-jerky" videos.

Colour or black and white: You can choose between a colour or a black and white image.

fps (frames per second): Images per second

12.6 DEQ OSDI

The DEQ OSDI (Dry Eye Questionnaire Ocular Surface Disease Index) is a standardised medical history form. Questions are asked about the patient's subjective symptoms. You receive an OSDI value as the result of the 12 questions.

For more information, see the *User manual*.

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

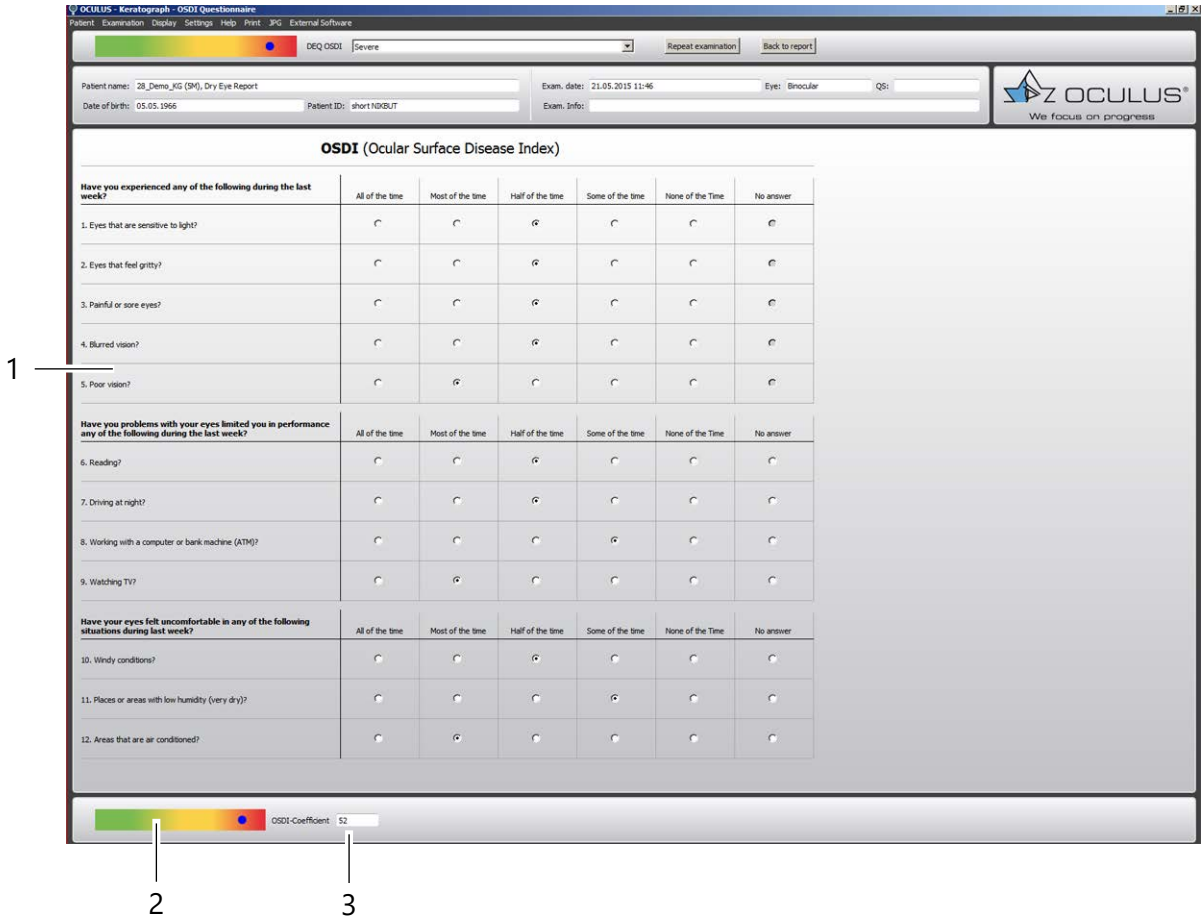


Fig. 12-6: Screen for the DEQ OSDI

No.	Description
1	Medical history questions
2	Diagram for the measurement result
3	OSDI coefficient

➔ Go through the questions with the patient and select the appropriate answers. The results apply to both eyes.

➔ Go back to the overview. Press the [Back to report] button to do this. The OSDI value is entered into the evaluation field and the diagram.

You can also use the McMonnies questionnaire instead of the DEQ OSDI. To do this, you must change the settings, see the *User manual*.

12.7 LIPCOF

If lid-parallel conjunctival folds (LIPCOF) are present, you can use an SL examination in the vertical optical slit in the temporal lower eyelid area to see this. You can enter the result of your evaluation here. These results represent a further parameter when evaluating the dry eye.

1. Open the dropdown list in the evaluation column.

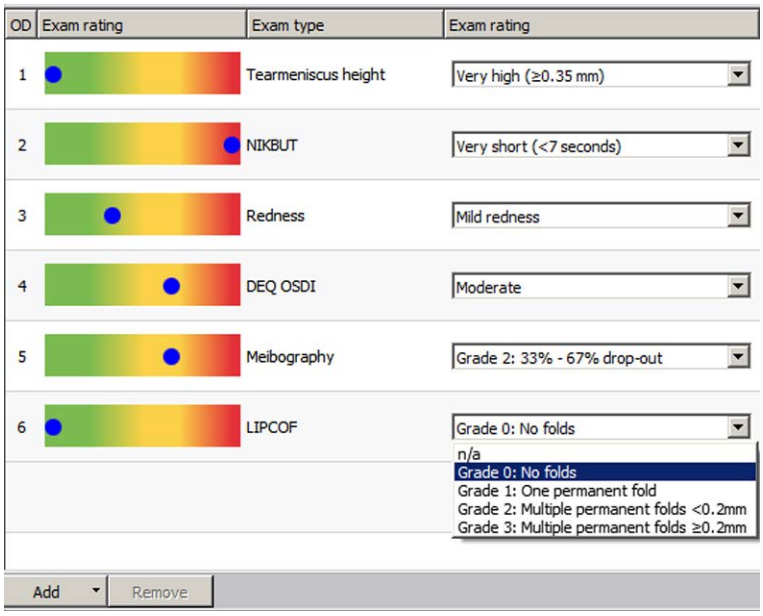


Fig. 12-7: Entering the examination result

2. Select the LIPCOF degree that corresponds to your evaluation.
3. Press [Back to report] to return to the overview.

For more information regarding LIPCOF, see the *User manual*.

13 JENVIS Pro Dry Eye Report

You can use the JENVIS Pro Dry Eye Report to perform a complete diagnostic assessment of the dry eye. You can choose between several comprehensive worklists, such as:

- Screening
- Individualised
- Aftercare
- By DEWS

Each worklist provides you with a structured workflow that saves time and enables you to work efficiently. You can jump to any item in the worklist.

For each examination, the software provides you with additional supporting information on the photography process (focal area, lighting settings, camera settings, etc.).

After you have completed the diagnostic assessment of the dry eye using a worklist, for example, "Individualised", you can evaluate the results in the evaluation worklist. The causes of the dry eye are sorted into subcategories on the evaluation screen. You can evaluate each individual image/each individual examination separately or, if you click a subtitle such as "Eyelid edge", all applicable examinations are displayed on the screen.

A treatment plan with various options can be compiled based on the evaluations performed, in order to treat the causes of the dry eye disease.

Finally, you can produce a comprehensive printout (JENVIS Pro Dry Eye Report) that contains all test results, the treatment options and a comprehensive glossary in which all examinations are explained.

➔ Select [Examination] > [New Dry Eye Report] > [Individual].

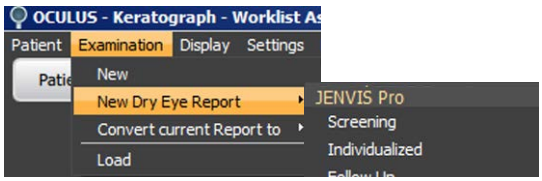


Fig. 13-1: Selecting the Dry Eye Report

The following screen is displayed:

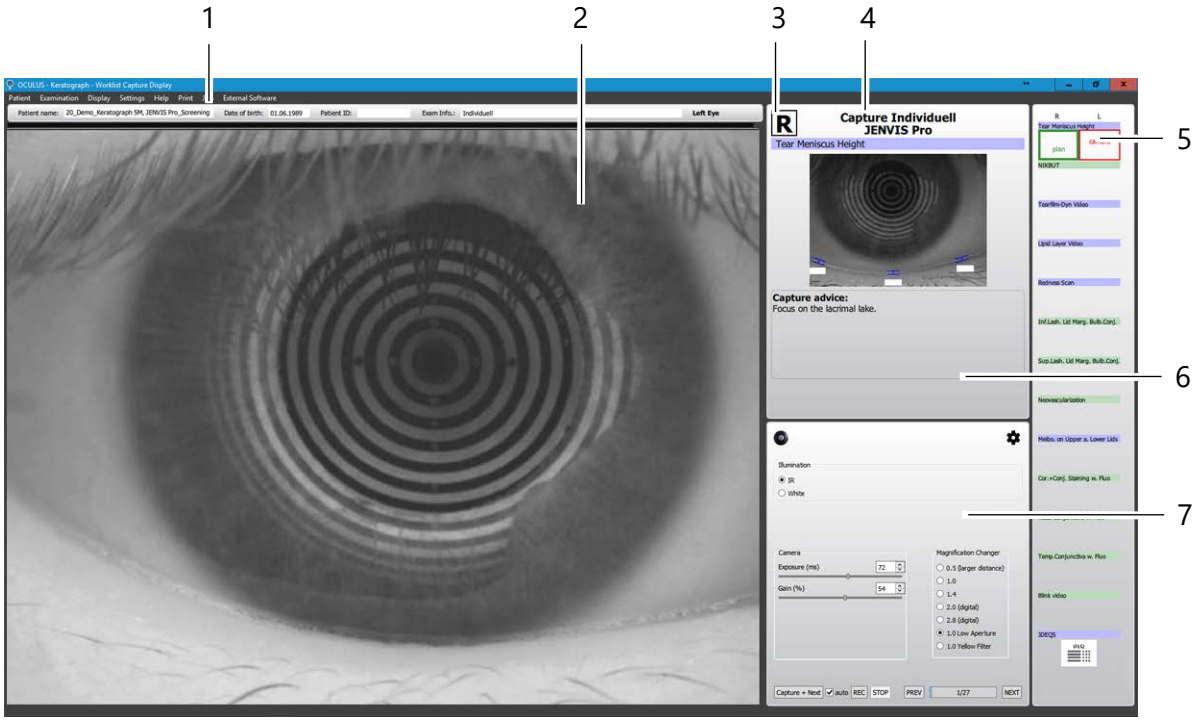


Fig. 13-2: Overview of the dry eye examinations

No.	Description	No.	Description
1	Patient and examination data	5	Predefined examinations
2	Single image of the eye	6	Notes on the measurement
3	Current examined eye (left eye here)	7	Camera/lighting settings
4	Support for the current examination		

13.1 Procedure with an Examination Plan Based on a Worklist

The worklist shows you the first step of the examination plan using a red and a green box.

The red box prompts you to create an image (single image or video) for the examination.

➔ Carry out examination displayed (red box).
If the [Auto] checkbox is selected, the [Image] button becomes the [Image + next] button. This means that the software switches to the next step in the worklist automatically after the image has been taken.
If you do not wish to create this image, press the [Next] button. The green box displays the next examination step and which eye is being tested.

In order to work as effectively as possible, the software recommends the sequence in which the images/examinations for the right and left eye should be performed.

The suggestion is to start with the tear meniscus height for the right eye and then to change to the left eye. For the NIKBUT examination, the software recommends starting with the left eye, followed by the right eye. For the next three examinations, you are instructed to take all images for the right eye and then to change to the left eye. If you are instilling vital dyes such as fluorescein, take all images for the one eye first and then for the other eye.

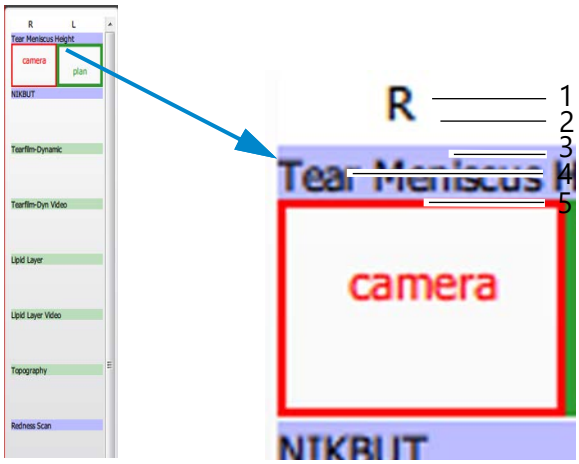


Fig. 13-3: Steps for the examinations

No.	Description	No.	Description
1	Right or left eye	4	Display the next camera position
2	Current examination	5	Display the next examination
3	Current camera position		

13.2 Further Supporting Information

This field assists you in obtaining the best possible image. The preview image shows the area of interest for the corresponding information. In the field below, you obtain image information such as the camera focus, whether vital dyes should be used, eyelid position, etc.

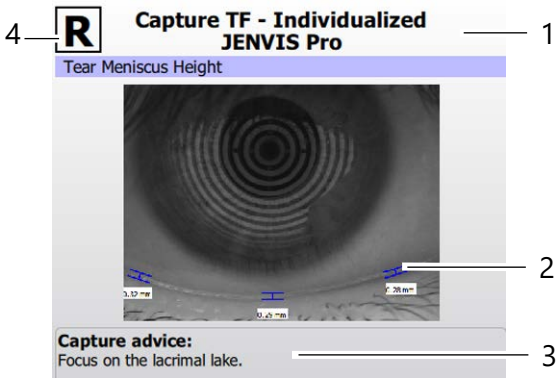


Fig. 13-4: Further supporting information

No.	Description
1	Image element for the examination (area of interest)
2	Preview image
3	Image information
4	Right eye/left eye

13.3 Adjusting the Lighting, Magnification Changer and Camera

→ Chap. 12.5 “Adjusting the Lighting, Magnification Changer and Camera” (page 54)

13.3.1 Changing the Dry Eye Report image settings

If you press this icon, the “Dry Eye Report image settings” display opens.

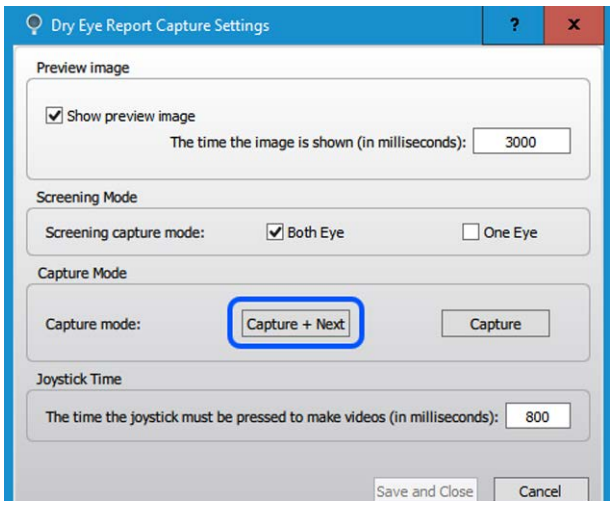


Fig. 13-5: Dry Eye Report image settings

Preview image: Define whether and for how long the preview image should be displayed.

Screening mode: Define whether you wish to examine both eyes or just one eye in screening mode. If “One eye” is selected. the screening is performed with the eye that is current in front of the Keratograph 5M.

Image mode: Decide whether the software should jump to the next examination step (other eye or next examination) automatically after the measurement/image is complete.

Joystick time: Define the duration that the joystick trigger must be pressed to record a video.

13.3.2 Buttons and Checkbox

You can use the following buttons to start, stop and save an image, and to continue to the next examination step.

Fig. 13-6: Example: Buttons for an image of the tear meniscus height

“Auto” checkbox: Changes the display of the [Image] button to [Image + next].

Image + next: The “Auto” checkbox is selected. You can use this button to start taking an image and continue to the next step in the worklist.

Image: The “Auto” checkbox is deselected. You can use this button to start taking an image.

REC/STOP: You can use this button to start or stop recording a video.

Limit the duration of the videos to no more than one minute. Otherwise, the data quantity on your computer will become too large.

Back: You can use this button to trigger a single image. For example, you can take static fluorescein images.

0/50: Progress indicator

Next: You can use this button to go to the next step in the worklist. You do not take an image or record a video.

13.3.3 Checking the Image Quality

Show preview image

If this function is selected, the image is shown briefly each time after taking a single image. You can use this function to decide whether the image has high image quality (sharpness) or whether it can be discarded.

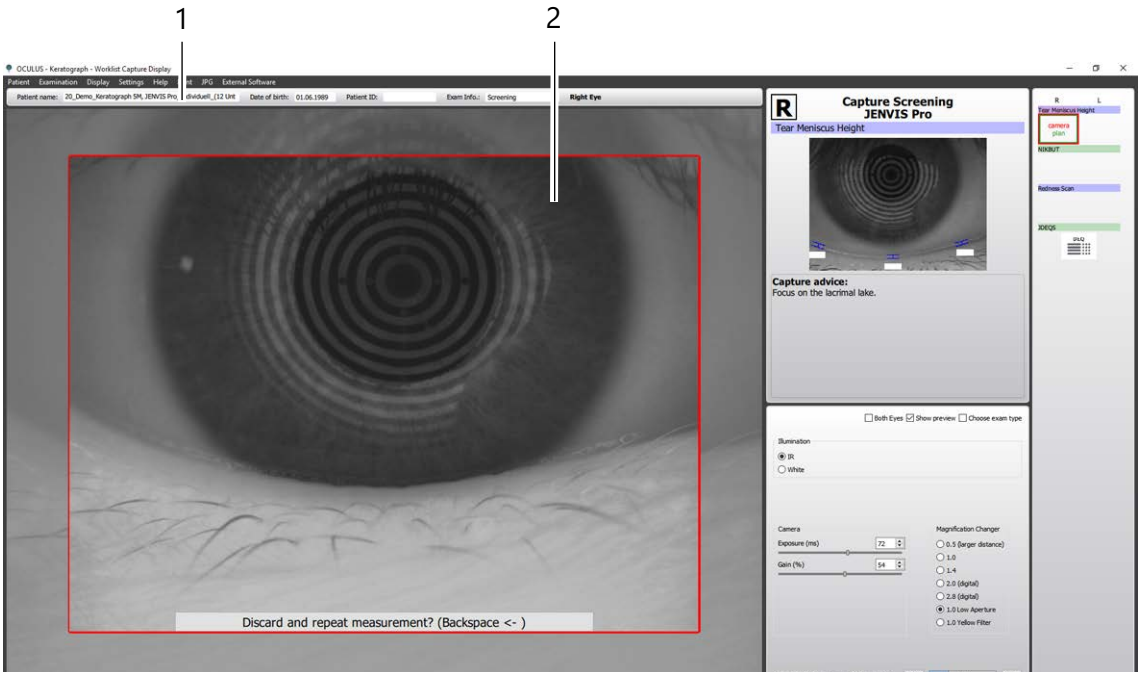


Fig. 13-7: Overview with preview image

No.	Description
1	Patient and examination data
2	Preview image

13.4 Printing the JENVIS Pro Dry Eye Report

Two layouts are possible depending on the type of the JENVIS Pro Dry Eye Report. You can print the following:

- JENVIS Pro Dry Eye Screening
  The screening printout contains the results and descriptions of three screening tests.
- JENVIS Pro Dry Eye Report
  The report printout shows all evaluated categories.

You can use the "Print" button in the menu bar to send the applicable type to a printer or print it to a PDF file.

➔ Select the [Print] menu item.

Fig. 13-8: [Print] menu item

No.	Description
1	[Print] button
2	[Print as PDF] button

If you use the first entry, you can print the JENVIS Pro Dry Eye Report.

The second entry enables it to be printed as a PDF.

The results of the examinations are shown on the JENVIS Pro Dry Eye Report printout. The JENVIS Pro Dry Eye Report contains a glossary of the most important terms for the customer/patient.

14 Patient Data Management

If you are working with patient data management GO Version 2.70 or higher, the instructions for use are available on our website or using the QR code.

14.1 Starting Patient Data Management

You can enter and use patient data via patient data management.
The computer first loads the operating system after switching on.

➔ Press the Keratograph 5M icon if necessary .
The patient data management user interface is displayed

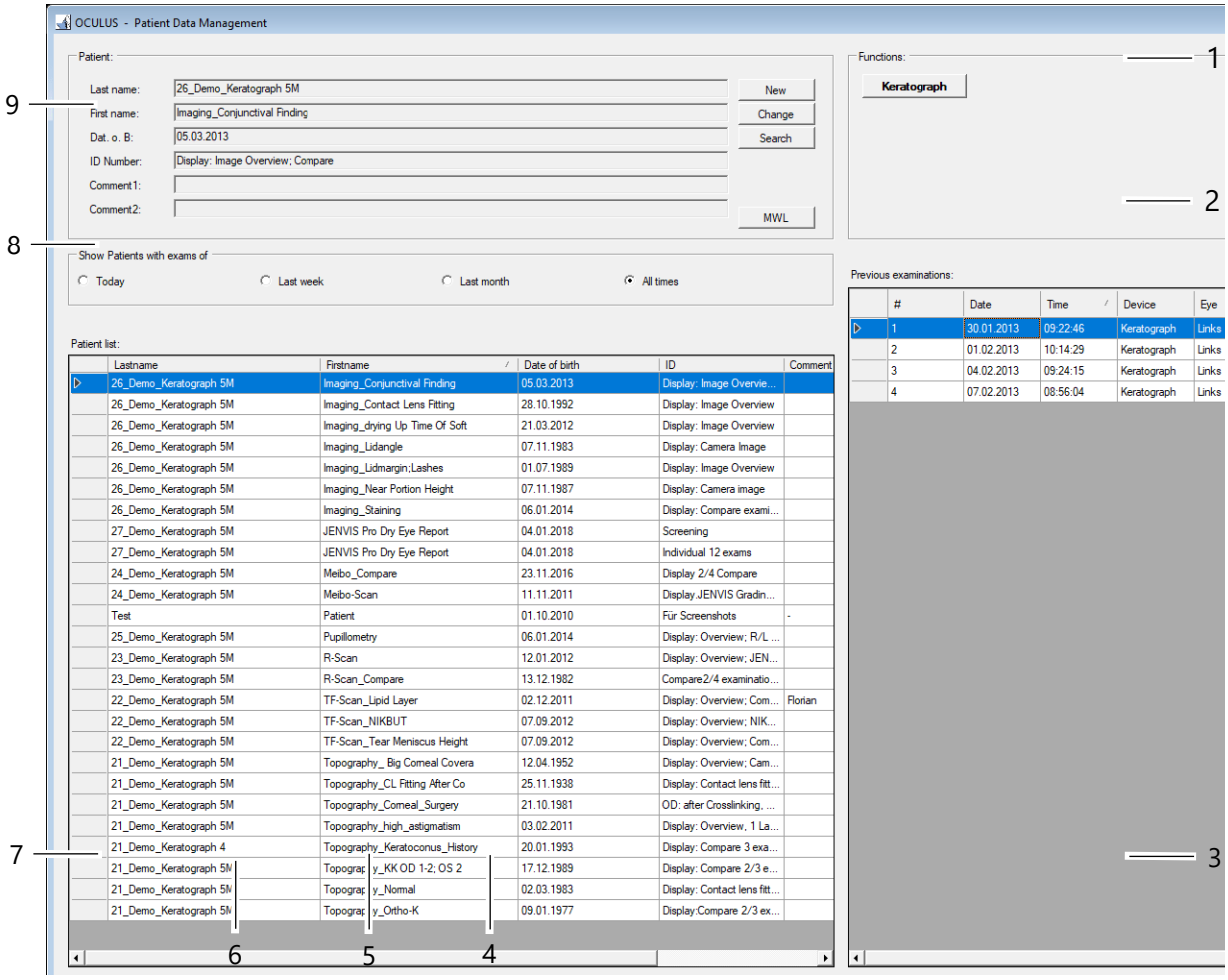


Fig. 14-1: Patient data management user interface

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

In order to be able to access the Keratograph 5M program later, you must first enter a new patient or select an existing patient from the examination list. For more information regarding patient data management, see Chap. 14, page 64.

14.2 Entering a New Patient

➔ Press the [New] button to enter a new patient into patient data management.
➔ Enter the patient's surname, forename and date of birth into the patient window.

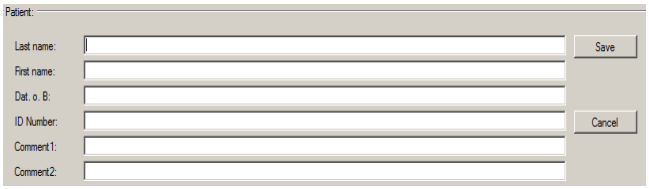


Fig. 14-2: Entering a patient

You can also enter an optional ID number for the patient.
➔ Press [Save] to save your entries.
The new patient is displayed in the patient list and selected automatically.

14.3 Selecting an Existing Patient

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

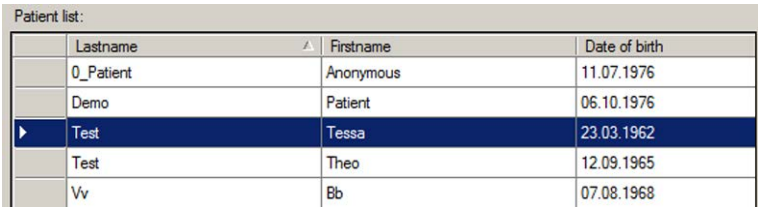


Fig. 14-3: Patient list

➔ Press the [Search] button to find the required patient quickly in the list.
➔ Enter the patient's name or the first letter of the name in the "Last name" field.
Optionally, you can search for the patient using their ID number, forename or date of birth, if this was assigned when the patient was first entered.
➔ Click the required list entry to transfer the patient name to the patient window.
This also brings up a list of any previous examinations for that patient in the examination window (bottom right).

14.4 Extended Patient Search: [Extended] Checkbox

➔ Select the [Extended] checkbox.

The screen displays additional search parameters which reference previous examinations, for example. Proceed as described for entering a patient name.

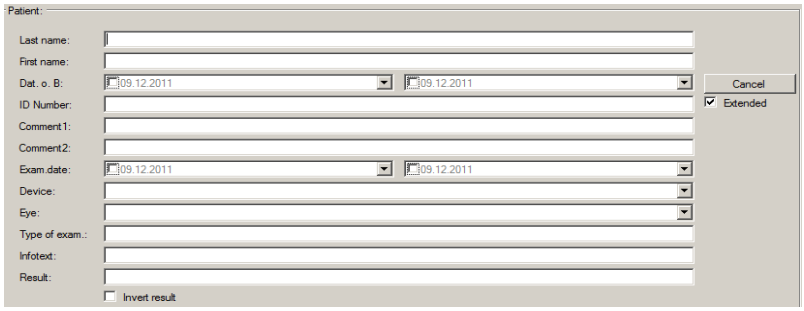


Fig. 14-4: Extended search

14.5 Using the Hecht E-Mail Function

If you have activated the Hecht e-mail function in the patient data management settings, you can use the [Hecht] button to use this, also see the *User manual*.

➔ Select the required patient or the required examination in patient data management.
➔ Press the [Hecht Export] button.
➔ Enter an optional individual message into the text field.
➔ Press [OK] to confirm that the message is to be sent.
- After you have selected your Hecht supplier (once) and decided on a form of consultation, the data including the individual message will be sent to the "Hecht MailCenter".

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

- Rename, Chap. 14.6, page 66
- Export, Chap. 14.7, page 67
- Import, Chap. 14.8, page 67
- Save, Chap. 14.9, page 68

For more information regarding patient data management, see the *User manual*.

14.6 Renaming Patient Data

You can change patient data retrospectively after creating it.

➔ Press the [Change] button.
The input fields for the patient data are now enabled and the cursor jumps to the "Last name" field.
➔ Change the entries in the individual fields.
➔ Press the [Save] button.

14.7 Exporting Patient Data

In order to transfer patient and examination data to a different surgery, for example, you can export this data.

➔ Select the patient and, if necessary, one of the examinations in the relevant list.

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

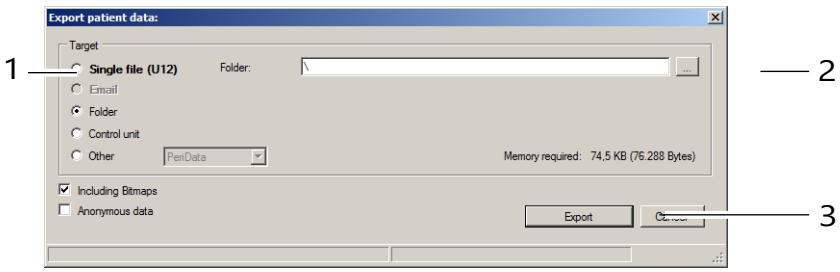


Fig. 14-5: "Export patient data" dialogue box

1 Selecting the save target
2 Button [...]
3 [Cancel] and [Export] buttons

The import and export options are pre-set in the "Settings" area, also see the *User manual*.

You may not need to perform all of the following steps (e.g. selecting a directory) depending on the settings.

➔ In "Target", select how you wish to export the data.

Recommendation: Use the "Single file (U12)" option to export the patient data.

➔ Press the [...] button.

➔ In the dialogue box, select the directory or file into which the patient data is to be exported.

➔ Press [OK] or [Open] to confirm.

➔ Press the [Export] button to export the data.

14.8 Importing Patient Data

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

Note

Loss of data due to computer viruses

Computer viruses can cause a loss of data.

➔ Check that the USB stick is free of viruses before importing.

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

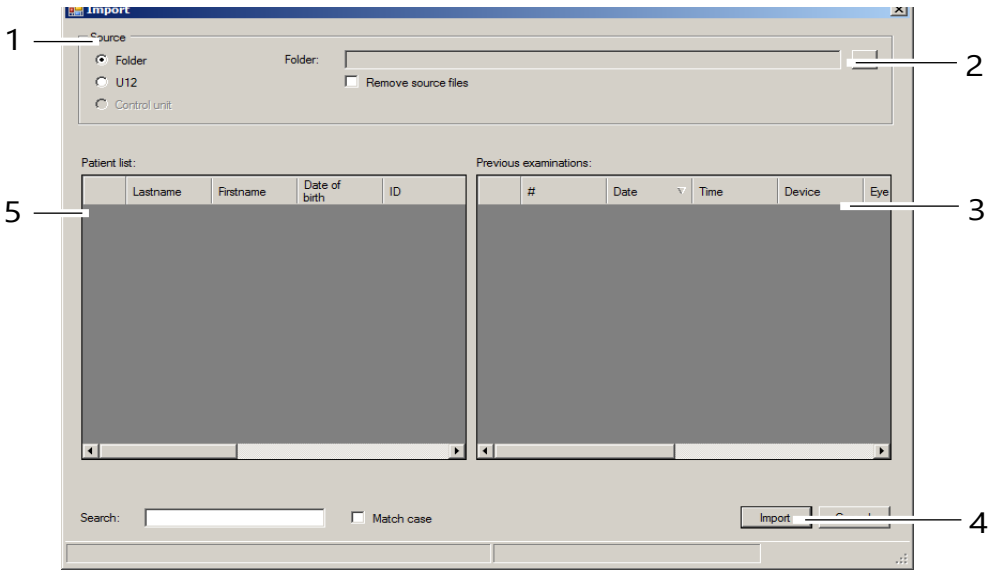


Fig. 14-6: "Import" dialogue box

1 Select the data source
2 Button [...]
3 Examination list
4 [Import] button
5 Patient list

The import and export options are pre-set in the "Settings" area, also see the *User manual*.

➔ You may not need to perform all of the following steps (e.g. selecting a directory) depending on the settings.

➔ Select the option in which the source data is available ("Folder" or "U12").

Recommendation: Use the "U12" option to import the patient data.

➔ Press the [...] button.
➔ In the dialogue box, select the directory or file in which the patient data is available.
➔ Press [OK] or [Open] to confirm.
The patients that were found and the corresponding examinations are displayed in the bottom part of the dialogue box.
➔ Press the [Import] button to import the data.
The data is then available in patient data maintenance.

14.9 Storing Data (Backup)

You should back up all patient and examination data at regular intervals. If data loss occurs, you can use this function to restore the data from a previous backup. As the data backup required some time depending on the size of the database and the data to be backed up, perform a backup when the computer and the device are not required for some time.

Note

Computer viruses can cause a loss of data.

➔ Check that the storage medium (external hard drive, USB stick, etc.) is free of viruses before backing the data up.

The generally applicable rules for creating backup copies apply to a data backup using patient data management. The backup files must always be stored on a separate system (e.g. a USB stick with sufficient capacity).

14.9.1 Storing Data

1. Press the [Backup] button in the upper right part of patient data management. The following dialogue box is displayed:

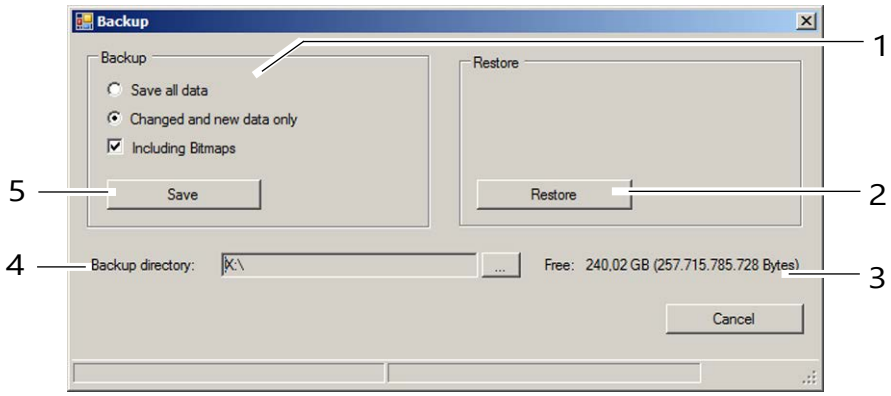


Fig. 14-7: "Backup" dialogue box

1 Select the data to be backed up
2 [Restore] button
3 Free storage space indication
4 Backup directory and [...] button
5 [Save] button

2. Select whether all data or only changed data is to be backed up.

Patient data management selects all backed up data records internally.

If you select the "Changed and new data only" option, only the data records that have not already been saved during a previous backup are saved.

3. Press the [...] button to the right of the "Backup directory" field.
4. In the dialogue box, select the directory to which the data is to be backed up.
5. Press [OK] to confirm your selection.
6. Press the [Backup] button to save the data. The data that you selected previously is then saved to the relevant directory.

14.9.2 Restoring Data

After data loss, the data from a previous backup can be read back into patient data management.

1. Press the [...] button.
2. In the dialogue box, select the directory in which the backed up data is stored.
3. Press [OK] to confirm your selection.
4. Press the [Restore] button to read the data in again. All data in the selected directory is transferred to patient data management.

14.9.3 Automatic Backup

In addition to the manual backup, you can also execute the backup automatically when closing patient data management.

You can make the settings required for this in the "Settings" area, see the *User manual*.

15 Cleaning, Disinfection and Maintenance

Device sterilisation is not required.

The Keratograph 5M is designed so that regular maintenance is not required. In order to ensure that the device functions perfectly, we recommend performing the work described in the maintenance section regularly.

15.1 Intervals for Cleaning, Disinfection and Maintenance

Cleaning	
Activity	**Time period**
Cleaning the housing, chin rest, forehead rest and calotte	Once a month or as required

Disinfection	
Activity	**Time period**
Disinfecting the forehead rest	After each examination
Disinfect the chin rest (when used without paper)	After each examination
Disinfect the housing	As required

Maintenance	
Activity	**Time period**
Reference measurement	1 x per month or when setting up the device in a new location
OCULUS customer service	Every 2 years (recommended) to check the photometric and electrical values

15.2 Consumables

Chin rest paper	400 sheets, item no. 65313
LidStick®	2 rolls of 100 units each, item no. 77502
Disinfectant wipes	mikrozid® sensitive wipes premium Schülke & Mayr GmbH Various pack sizes: e.g. 2x 50 pieces in a soft pack, item no. 59882

15.3 Cleaning

Caution

There is a risk of electric shock if the Keratograph 5M is not disconnected from the mains power supply at all poles for these tasks.

➔ Switch the Keratograph 5M off → Chap. 4.6 (page 24).

➔ Remove the mains plug prior to cleaning. Hold the plug to do this. Do not pull the cable.

Note

Device damage due to improper cleaning

➔ Ensure that no moisture can penetrate the device.

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

➔ Do not use aggressive, chlorinated, abrasive or caustic cleaning agents to clean the device.

Fig. 15-1: Device parts that must be cleaned or disinfected

No.	Description	No.	Description
1	Calotte	3	Chin rest
2	Housing	4	Forehead rest

Required materials:

- Cleaning agent for plastic surfaces with anti-static effect
- Cleaning agent for painted surfaces: Mixture of even parts methylated spirit and distilled water, with a few drops of normal washing-up liquid if necessary
- A soft, lint-free cloth

15.3.1 Cleaning the Housing

➔ Clean the housing surfaces with a soft cloth and an antistatic cleaning agent.
➔ Wipe any residues off painted surfaces using the aforementioned mixture for painted surfaces.

15.3.2 Cleaning the Chin Rest and Forehead Rest

➔ Use a soap solution to clean the chin rest and forehead rest (use alcohol if heavily contaminated).
➔ Use a lint-free, damp cloth.

15.3.3 Cleaning the Calotte

The calotte is a precision piece and sensitive to pressure. The surface of the calotte is prone to scratches.

➔ Clean the calotte surface particularly carefully.
Use a lint-free, dry cloth.
➔ Ensure that no dust can penetrate the small holes.
➔ You can also clean the calotte carefully with a very slightly damp cloth.

15.4 Disinfection

Caution

There is a risk of electric shock if the Keratograph 5M is not disconnected from the mains power supply at all poles for these tasks.

➔ Switch the Keratograph 5M off → Chap. 4.6 (page 24).
➔ Remove the mains plug prior to disinfection. Hold the plug to do this. Do not pull the cable.

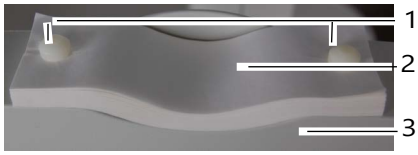
Note

The disinfectant solution can damage the device surface if it sprayed directly onto it.

➔ Only spray disinfectant solution onto a cleaning cloth and not directly onto the device.

15.5 Replacing the Chin Rest Paper

Proceed as follows to put on new chin rest paper:



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

Fig. 15-1: Securing the chin rest paper

1. Remove both fixing pins from the chin rest.
2. Put the new chin rest paper on. The holes in the paper and on the chin rest must be aligned.
3. Insert both fixing pins through the paper and the chin rest.

15.6 Reference Measurement

In order to ensure high measurement precision, the Keratograph must be set up before examining the first patient.

The first reference measurement is performed by OCULUS or an authorised dealer when setting up.

Required materials
■ Reference sphere (r=8,000 mm), supplied as standard
■ Cleaning alcohol

The Keratograph 5M must have been switched on for around 15 minutes before performing the measurement.

Proceed as follows to perform the reference measurement:

1. Clean the reference sphere thoroughly before saving the reference values (e.g. using cleaning alcohol).

Fig. 15-2: Sphere holder with reference sphere

2. Attach the sphere holder to the right vertical strut on the chin/forehead rest.
3. Turn the sphere holder so that the reference sphere is aligned parallel to the device.

Fig. 15-3: Aligning the reference sphere parallel (Top-down view of the device)

4. Align the sphere holder height so that the reference sphere is at the same height as the black marking (ring) on the left vertical strut on the chin/forehead support.

Fig. 15-4: Aligning the reference sphere height

When doing so, ensure that the reference sphere remains aligned parallel to the device.

5. In the [Settings] menu, select the [Reference measurement] menu item.
6. Perform a measurement using the reference sphere *(→ Chap. 7.1 "New Measurement" (page 32))*.
7. Press [OK] to confirm the "Calibration OK" prompt.

Note

If the "Reference sphere was not completely measured" error message appears, the sphere must be cleaned again carefully and a new measurement performed.

The system has been set up again once the reference measurement is complete.

The reference data is saved directly in the device and therefore, the measuring head does not depend on a specific computer or laptop.

16 Technical Data

Measuring head

Measuring range	3 to 38 mm 9 to 99 dpt
Precision	± 0.1 dpt
Reproducibility	± 0.1 dpt
Number of rings	22
Working gap	78 to 100 mm
Number of evaluated data points	22,000
Camera	Digital CCD colour camera
Dimensions H x W x D	275 x 320 – 400 x 480 – 510 mm
Weight	3.2 kg (only the measuring equipment) 6,1 kg (with X-Y table)
Interface	USB
Power supply	24 V DC; 2.1 A
Voltage	90 — 264 V AC
Max. power consumption	18 W
Expected service life	10 years

LED lighting

Lighting	Colour	Wavelength
Fluo	Blue	465 nm
Ring lighting	Infrared	880 nm
Meibo	Infrared	840 nm
Fixation	Red	660 nm
Glare ring	White	-
Tear film	White	-
Ring lighting	White	-

Power supply

HMEG49-S240210-7 power supply (05150150)	
AC input	90 – 264 V AC
Frequency	47 – 63 Hz
DC output	24 V 2.1 A max. 50.5 W
Power consumption	131.1 VA
Fuses	Integrated overload protection

Classification in accordance with IEC 60601 - 1

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

IT equipment

The IT equipment (PC, monitor, etc.) must meet the requirements of IEC 62368-1 or IEC 60950.

Recommended computer specifications	Intel® Core™ i5, 500 GB SSD, 8 GB RAM, Windows® 10, Intel® HD Graphics
Recommended screen size	24"
Recommended screen resolution	1920 x 1080 pixels (Full HD)

CE marking

In accordance with Regulation (EU) 93/42 on medical devices.

CE

The device is a product in product class IIa.

Conformity evaluation procedure in accordance with (EU) 93/42/EEC (MDD), Annex II without section 4

17 Troubleshooting

Caution

Improper troubleshooting can cause personal injury or damage to the device.

➔ If a fault cannot be rectified, mark the device as "Out of order" and contact customer service or an authorised specialist dealer.

Contact options:

- Phone (urgent cases): +49 641 2005-800
  Have TeamViewer ready and specify the following information:
  - Customer number
  - Serial number
  - Software version
  - Error description
  - Measures already taken
- E-mail: service@oculus.de
  Send the aforementioned information.
  - If necessary, supplemented by: U12 files, images
  - Large files can be sent using WeTransfer.

Measure	Description
Restart	➔ Switch the device off at the on/off switch. ➔ Wait for 15 seconds. ➔ Switch the device on at the on/off switch.
Check the plug connections	➔ Check whether all cables are plugged in correctly. ➔ Check the plug connection between the Y cable and the power supply. ➔ Check the plug connection between the Y cable and the PC. ➔ Check whether a USB extension cable is used. This must be a repeater cable. ➔ Check whether an active USB hub (with its own power supply) is used.
Check the energy settings	➔ Navigate to the system settings. ➔ Deselect the [Activate quick start (recommended)] option. ➔ Navigate to the device manager. ➔ Click the [Energy management] tab. ➔ Deselect the [Computer can switch off the device to save energy] option.
Check the USB ports	➔ Replace the USB ports on the PC.
Check the XY base	➔ Check whether the device is parallel to the XY base.

Fault	Possible cause	Remedy
After starting the Keratograph 5Mprogram, the dialogue box opens: "No communication with the Keratograph 5M!".	Power supply has no power.	Check whether the control lamp on the power supply is illuminated. If not, power up the power supply.
	Connection cable (Med. secure isolator cable) Keratograph 5M/ power supply/computer/laptop not plugged in correctly.	Check whether ■ the plug connection is plugged into the Keratograph 5M correctly ■ the USB plug is plugged into the computer/laptop correctly ■ the plug connection on the low-voltage side of the power supply is plugged in
	Software/hardware problems.	Switch off the Keratograph 5M, restart the computer. As soon as patient data management is active, switch on the Keratograph 5M. When starting the Keratograph 5M program, the "Load Bootloader" message must be displayed.

18 Transport, Packaging and Disposal

Before you transport and store the device, you must dismantle and pack the device properly.

18.1 Transport and Storage Conditions

Caution

Device damage due to improper transport and storage

- ➔ Avoid impacts, shaking and contamination.
- ➔ Avoid high temperatures and moisture.
- ➔ Transport the device carefully.
- ➔ Do not hold the device by the joystick to carry it.
- ➔ Avoid being close to radiators and moisture.

	Storage	Transport
Ambient temperature	-10°C — +55°C	-40°C — +70°C
Relative humidity including condensation	10 – 95%	10% — 95%
Air pressure	700 – 1060 hPa	500 hPa — 1060 hPa

18.2 Dismantling

- ➔ Do not pull the cable when disconnecting electrical connections. Pull the relevant plugs.

1. End the current session.
2. Switch the device off.
3. Pull the cable out of the computer/laptop and the power supply.
4. Undo the screw connection for the Med. secure isolator cable and pull it off.
   Only pull by the plug. Do not pull the cable.

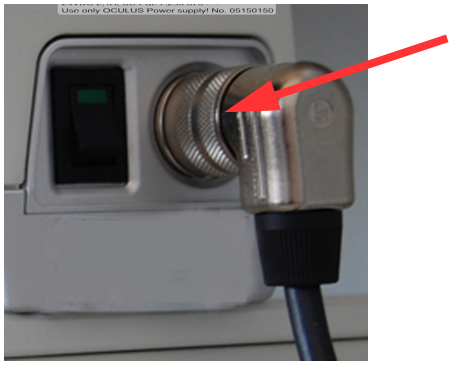


Fig. 18-1: Undo the screw connection for the Med. secure isolator cable

18.3 Packaging

- ➔ Only use the original packaging with the foam parts for safe transport.

➔ Observe the device's weight and dimensions → Chap. 16 "Technical Data" (page 76).

➔ Avoid impacts, shaking and contamination.
➔ Avoid high temperatures and moisture.
➔ Do not hold the device by the joystick to lift or carry it
➔ Lash the device securely to a pallet.

18.4 Disposal

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

➔ Dispose of the Keratograph 5M properly and according to the legal regulations.

19 Warranty Conditions

Please note our General Terms and Conditions (GTC) on our website at www.oculus.de/imprint

Appendices

Appendix A Electromagnetic Compatibility

Medical electrical equipment is subject to special precautionary 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.

No special measures need be observed in respect of OCULUS devices and systems.

Note

Portable and mobile RF-communications devices can interfere with electrically operated medical devices and affect the performance of the device.

The device is intended for use in an electromagnetic environment in which the radiated RF interference is uncontrolled. The user can help prevent electromagnetic interference by maintaining the following minimum distance, based on the maximum output of the communication equipment, between portable and mobile RF communication devices (transmitters) and the device:

➔ 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 device.

Minimal performance quality and essential performance criteria:

- A slightly disturbance of the camera of the device (slightly image noise on screen) during the examination is permissible because it will not affect the diagnosis, treatment and observation.
- A short flicker of the illumination of the device during the examination is permissible because it will not affect the diagnosis, treatment and observation.
- A short interruption of the USB connection during the examination is permissible because it will not affect the diagnosis, treatment and observation.

Caution

The use of accessories, adapters and cables not specified by OCULUS may result in increased emissions or reduced immunity of the device.

➔ Use only accessories, converters and cables specified by OCULUS.

➔ Do not use accessories, adapters and cables specified by OCULUS with other devices.

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

Article number	Description	
77000	Keratograph 5M	
05200320	Cable with plug, EU standard	2.5m
05200210 (110 Volt)	Cable with plug, US standard	2.5m
05150150	HEMG 49 power supply	24 V, 2.1A
70002	Med. secure isolator + USB connection acc.	2m

Appendix B Guidelines and Manufacturer's Declaration – Electromagnetic Emissions

Electromagnetic Emissions		
The OCULUS Device Name® is intended for operation in the electromagnetic environment specified below. The user of the Device Name® should ensure that it is being used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The Device Name® 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	

Appendix C Guidelines and Manufacturer's Declaration – Electromagnetic Immunity

Electromagnetic immunity			
Immunity tests	**IEC 60601Test level**	**Compliance level**	**Electromagnetic environment - guidelines**
Electrostatic discharge (ESD) in accordance with IEC 61000-4-2	± 8 kV contact discharge ± 15kV air discharge	± 8kV ± 15kV	Floors should be made of wood or concrete, or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Power frequency (50/60 Hz) magnetic field in accordance with 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 commercial or hospital environment.
Electromagnetic immunity, IEC 60601-1-2, according to table 5, 8			
Electrical fast transients/bursts in accordance with IEC 61000-4-4	± 2 kV for mains cables 100 kHz repetition frequency ± 1 kV for signal input and signal output components	± 2kV ---------- ± 1kV	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 6100-4-5	± 1 kV symmetrical voltage ± 2 kV common mode voltage	± 1kV ± 2kV	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 in accordance with IEC 61000-4-11	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degrees 0% U_τ; 250/300 periods	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degrees 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degrees 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 cuts, we recommend powering the Keratograph 5M from an uninterruptible power supply or battery.
Note: U_τ is the A.C. mains voltage prior to applying the test level			

Electromagnetic immunity, IEC 60601-1-2, according to table 4, 5			
Immunity tests	**Test level**	**Compliance level**	**Electromagnetic environment - guidelines**
Conducted HF transients in accordance with IEC 61000-4-6	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 at 1 kHz	V_{eff} = 3 V	Portable and mobile HF communications equipment should be used no closer to any part of the Keratograph 5M, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ for 80 MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ for 800 MHz to 2.5 GHz where P is the rated output of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). The field strength for fixed radio transmitters should be less than the compliance level in each frequency range (b) as determined by an electromagnetic site survey (a). Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated HF transients in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz		
Note 1:	The higher frequency range applies at 80 Hz and 800 MHz.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

a. Field strengths from fixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radios, AM and FM radio broadcasts, and TV broadcasts cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, a site survey should be considered. If the measured field strength in the location in which the Keratograph 5M is used exceeds the aforementioned compliance level, 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 of 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Appendix D Recommended Separation Distances

Recommended separation distances between portable and mobile HF telecommunication equipment and the Keratograph 5M

The Keratograph 5M is intended for use in an electromagnetic environment in which RF transients are controlled. The Keratograph 5M user can make a significant contribution to avoiding electromagnetic interference by keeping a minimum distance of between the portable and mobile HF telecommunication devices (transmitters) and the device, depending on the communication device's output power as specified below.

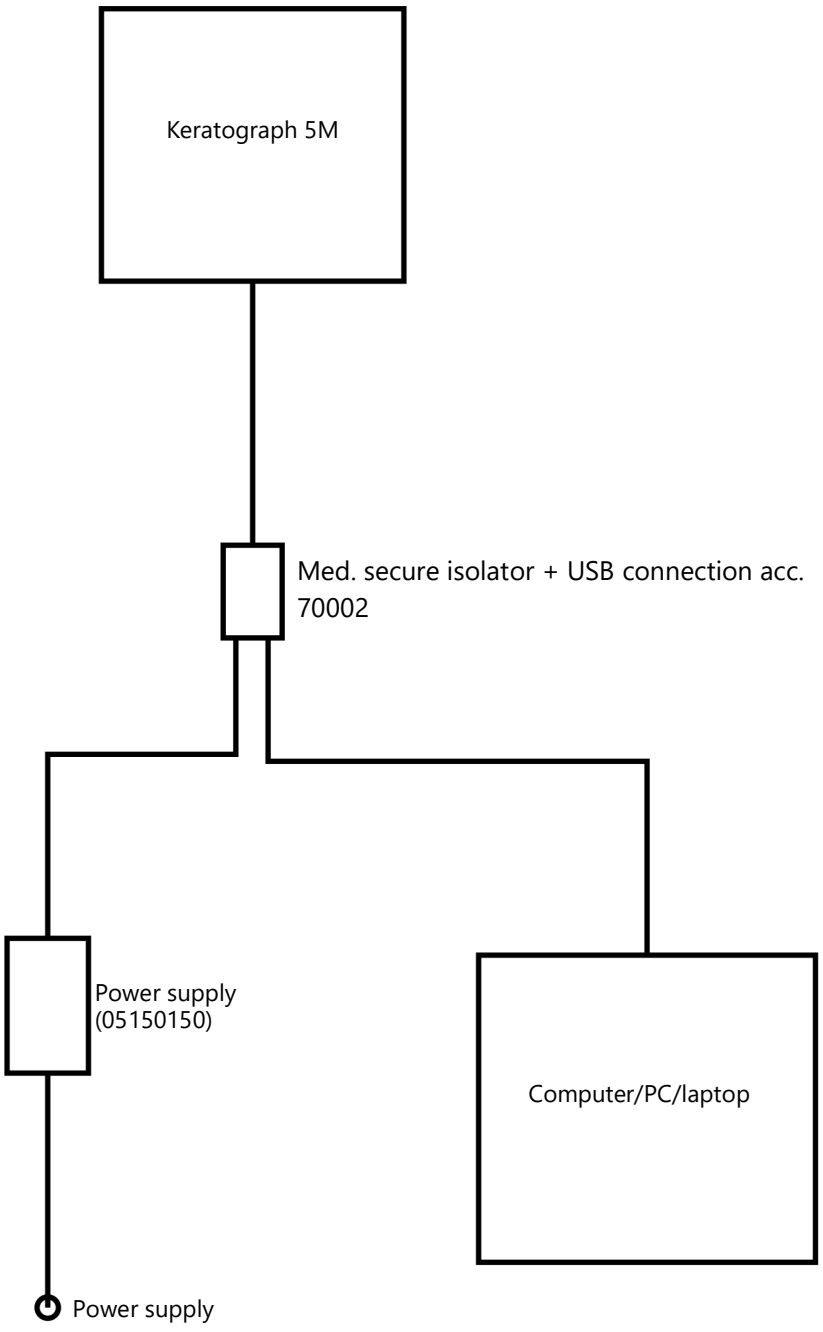
	Separation distance according to the transmission frequency in m		
Transmitter rated output W	150 kHz to 80 MHz d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23

For transmitters with a maximum rated output not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the relevant column, where P is the maximum transmitter rated output in watts (W) according to the transmitter manufacturer's specifications.

Note 1: The higher frequency range applies at 80 MHz and 800 MHz.

Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Appendix E Connection Diagram



Appendix F Data Sheet for HEMG 49-S240210-7 (05150150)

HiTRON

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

FEATURES:

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

SPECIFICATION

INPUT SPECIFICATION

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

OUTPUT SPECIFICATION

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

GENERAL SPECIFICATION

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

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

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

c UL us LISTED

CE

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

-7-

HiTRON

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

FEATURES:

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

SPECIFICATION

INPUT SPECIFICATION

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

OUTPUT SPECIFICATION

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

GENERAL SPECIFICATION

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

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

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

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

Appendix G 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.

Always observe → Chap. 2.3 “Information Regarding Cyber Security” (page 13) in these instructions for use.

Observe the following instructions for integrating 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:

- Favour a wired LAN connection
- IPv4 network
- Fast Ethernet (at least 100 Mbit/s)

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

- Licensing: Required open 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 for data security:

- Read the section on cyber security (page → Page 13) in the 'Security' chapter in the device's operating manual.
- See the “Floating License Key - License management for software options” operating manual
- See the device specific DICOM interface description

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

- Licence handling from the local licence server to PEMS and vice versa
- Storage and data export to local network storage and loading from local network storage
- Printing on the local printer

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

- Data loss
- Unsuitable data exchange
- Data corruption
- Unsuitable temporal data allocation
- Unexpected data reception
- Unauthorised 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 organisation should identify, analyse, 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 to the IT network configuration
- Connecting additional items to the IT network
- Disconnecting items from the IT network
- Updating equipment connected to the IT network

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