OCULUS Myopia Master®

INSTRUCTION MANUAL

OCULUS®

Notes on this instruction manual

The Myopia Master® has been manufactured and tested according to strict quality criteria. To ensure safe operation, it is essential that you use the device correctly. For this reason you should familiarise yourself thoroughly with the contents of this instruction manual before operating the device. In particular, pay attention to the safety instructions.

- This instruction manual describes the measuring procedure, how to manage the patient data, and the settings in the Myopia Master®program.

Due to ongoing development, the diagrams shown may depict minor changes to the actual device delivered.

If you have any queries or would like additional information about your device, do not hesitate to call or send us an email or a fax. Our service team will gladly assist.

OCULUS Optikgeräte GmbH

OCULUS is certified according to DIN EN ISO 13485, setting high standards of quality for the development, manufacture, quality assurance and service of the entire range of products.

Table of Contents

1 Scope of Delivery

Products and accessories	Order number
Version ■ Myopia Master® Advanced, with chin and head rest, with Scheimpflug camera (fully equipped) ■ Myopia Master® Advanced, without chin and head rest, with Scheimpflug camera ■ Myopia Master® Basic, with chin and head rest, without Scheimpflug camera ■ Myopia Master® Basic, without chin and head rest, without Scheimpflug camera	68100 68110 68120 68130
Eye shield black	076500001028
Dust protection cover	026010005001
Paper for chin support	65313
Printing paper roll (3 rolls)	65311
USB mini cable	05200600
USB FS MED-Isolator	015692000010
Power adapter	05150725
Cable, EU	5200905
Cable, GB (optional)	5200915
Cable, USA (optional)	5200910
Cable, AU (optional)	5200920
Cable, Argentinia (optional)	5200925
Testeye	68105
Software-Installation	SI/50000/.../en
Instruction Manual	G/68100/EN Rev04 0820

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

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

➔ Keep the packaging. Keep the packaging in order to ship or transport the device properly if service or repairs are needed. You will thus avoid incurring unnecessary damage and costs.

Note

We reserve the right to change the scope of delivery in line with ongoing technical development.

Software versions

The instruction manuals describe the following Software Set version: 1.1r2

2 Graphic Symbols

Symbols equipment				Symbols packaging	
	Manufacturer		Protection class		Keep dry
	Date of manufacturing	IP XX	Type of protection		This way up
CE	Conformité européenne	REF	Article number		Fragile
	Follow instruction for use	SN	Serial number	Transport	Limit of temperature for transport
	Disposal in household trash is prohibited		Caution	Lagerung	Limit of temperature for storage
	Applied part Type B		Do not re-use		Limit of humidity
		MD	Medical device		Limit of air pressure
(21) ABCDEFG123456789 Matrix (01) 04049584000040		Example: UDI number, consisting UDI-DI (Device-Identification) UDI-PI (Product Identifier) machine-readable matrix code			

Additional Symbols and abbreviations on power adapter					
	Indoor use only		Testing center		Aquivalent to RoHS
	Conform to US and Canadian standards		Nemkos symbol		Chinese Standard Sign
	Meets German safety requirements		Polarity of DC connector		

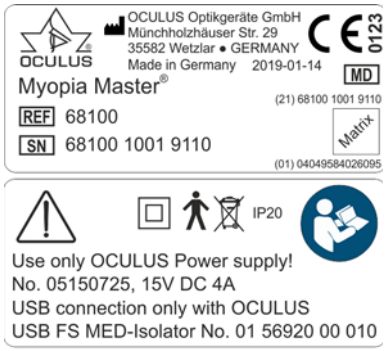


Fig. 2-1: Name plate (example)

There are no temporarily fixed markings on the device.

3 Structure of the Documentation

A folder containing documentation is supplied with your Myopia Master®:

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

  This manual describes the basic operation and the different features of the Myopia Master® versions.
- **Software Installation:** The introduction to the Software Installation describes how to install the Myopia Master® software and the associated drivers.

4 Safety Instructions

4.1 About this Manual

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

4.1.1 Pictograms Used in this Manual

	**Warning** Identifies a potentially dangerous situation which may cause irreversible injury.
	**Caution** Identifies a potentially dangerous situation which may cause minor injury or damage to property.
	**Note** Denotes situations which could result in incorrect findings, denotes user instructions and useful or other important information.
	Identifies important information about the product and its use which require special attention.

4.2 Safety Instructions for Use

Caution

Personal injury or property damage due to improper operation

➔ Observe the following safety instructions.

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

➔ No modifications may be made to this device without the permission of the manufacturer or authorized dealers.

Instructions for Operating Personnel

➔ Make sure that the Myopia Master® is used only by clinical persons or eye specialists

- who can guarantee proper handling due to their knowledge, training and practical experience.
- who have been instructed by OCULUS staff or an authorized dealer before the initial operation.

Transport and Storage Instructions

Refer to the notes in *sec. 20, page 74*.

Instructions for Setup and Connection

➔ Do not use or store the Myopia Master® in rooms that are humid.

➔ Keep the Myopia Master® away from water that may drip, splash or spray on it, and make sure that no liquids can get into the Myopia Master®. Do not place any containers holding liquids in the vicinity of the Myopia Master®.

➔ Only operate the Myopia Master® in rooms used for medical purposes after they have been set up according to the VDE Regulation 0100-710.

➔ Do not operate the devices included in the delivery in areas where explosions may occur, or in proximity to flammable anesthetics or volatile substances such as alcohol, benzine or similar products.

➔ Only use a power cord which meets the requirements of IEC 60227-1, type H05VVH2-F (type 53), minimum 0,75 m² and IEC 60320-1, type C7.

➔ Set up the Myopia Master® so that the power plug is easy to access. That way, you can easily disconnect it from the power supply for any repairs or maintenance work.

- Do not use excessive force when connecting the electrical plug.
  If a connection is not possible, check whether the plug fits the socket.
  If you find damage to the plug connector, have the damage corrected by our service department.
- Establish an USB connection only with the OCULUS USB FS MED-Isolator (Nr. 01 56920 00 010).
- Note that an output voltage of maximum 5.5 V DC is supplied by a device connected via USB.
- Do not use the Myopia Master® with wireless technology, for example with wireless USB.
- **Data responsibility:** The device itself is not designed to connect with the internet, but only to a PC. It does not require the internet to function.
  Do not connect with the internet while using the device. It is considered misuse.
  If you elect to connect the PC to the internet for other purposes you are responsible for ensuring data security.
- Only use a Myopia Master® which is mounted properly.

Patient environment information

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

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

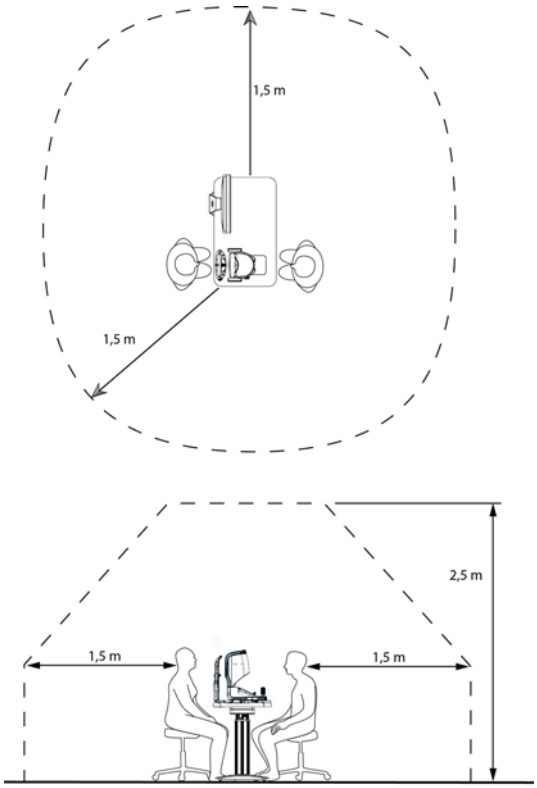


Fig. 4-1: Patient environment

Information about the operation of an ME system

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

- ➔ Make sure that all devices of the ME system meet the requirements of IEC 60601-1, IEC 60950-1 or 62368-1.
- ➔ Note that an output voltage of maximum 5.5 V DC is supplied by a device connected via USB.

Instructions for Operation

- ➔ Never operate a damaged Myopia Master®.
- ➔ Only operate the Myopia Master® with the original accessories supplied by us and only when the unit is in technically perfect condition.
- ➔ Before first use: Let OCULUS or an authorized dealer train you in the operation of the Myopia Master®.
- ➔ Only operate the device if you have understood the operating instructions.

- Do not put any heavy objects onto the unit or the cables.
- Do not put the Myopia Master® down onto devices that produce heat, heaters (e.g. radiators), microwaves or similar.
- Make sure that the device cannot tip over by leaning against it or sitting on it.

Instructions for Maintenance

Caution

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

The Myopia Master® contains a Class 1 laser according to DIN EN 60825-1:2015 and DIN EN 60825-1: 2001. It is an encapsulated laser system. When the Myopia Master® cover is opened, you may be exposed to invisible, Class 3R (5 mW) laser radiation.

- Never open the unit.
- For authorized service personnel only: When doing maintenance jobs, avoid looking directly into the laser beam.

To ensure satisfactory and reliable operation, we recommend that you have the Myopia Master® checked every two years by our service department or an authorized dealer. If an error occurs which you cannot correct, label the Myopia Master® as being "out-of-order" and contact our service department.

Instructions for Disassembly and Disposal

- When disconnecting electrical connections, pull on the respective plug and not on the cable itself.
- Dispose of the device according to legal regulations.

Instructions on Electrical Safety

Caution

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

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

- Ensure that connections with non-medical devices are made correctly.
- Only use the power adapter listed in the packing list.
- Establish an USB connection only with the OCULUS USB FS MED-Isolator (Nr. 01 56920 00 010).
- Use only a computer that meets the specifications given in this instruction manual, *sec. 23, page 78*.
- Note that an output voltage of maximum 5.5 V DC is supplied by a device connected via USB.

Caution

Use of a multiple socket outlet

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

If you use a multiple socket outlet to connect the Myopia Master® to the power supply, you must heed the following information:

- Use an extension cord that complies with the requirements of IEC 60601-1: 2005, section 16.
- Do not place the multiple socket outlet on the floor.
- Do not use more than one multiple socket outlet.
- Plug only the Myopia Master® and the computer that is being used with the unit (if applicable) into the multiple socket outlet.

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

If you are using a new computer for the Myopia Master®, you must have the electrical safety checked. Call OCULUS Service for this purpose.

Electromagnetic Compatibility (EMC) / Cables

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

Portable and mobile RF communications equipment can affect medical electrical equipment *sec. 24, page 82*.

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

Cybersecurity

Do not use the Myopia Master® with wireless technology, for example with wireless USB

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

Precautions for access control of the computer

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

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

- Prefer wired connections of the computer to the network.
- If you are using Wi-Fi connections nevertheless, please ensure the usage of adequate security methods (for example WPA2/AES – Wi-Fi Protected Access / Advanced Encryption Standard – with a strong network key).
- The usage of a firewall (software or hardware) is recommended.

Recommendation: Use anti-malware tools with up to date malware definitions.

Note

Also observe the regulations, notes and recommendations of the *Bundesamt für Sicherheit in der Informationstechnik* for the protection of critical infrastructures.

5 Intended Use

The Myopia Master® is designed to photograph the eye and take Scheimpflug images of the anterior segment to evaluate the thickness of the cornea. The integrated keratometer measures the central radii of the cornea. The integrated ophthalmic refractometer measures the refractive power of the eye. The integrated interferometer measures the axial length of the eye.

The Myopia Master® can be used by physicians, opticians and optometrists to support myopia management.

The Myopia Master® may only be used for the purpose described in this instruction manual.

➔ Heed the safety instructions listed above.

Contraindications

None known

6 Transport to Installation Location

The transport and storage conditions see *sec. 20, page 74*.

➔ Wait approx. 3-4 hours after transport before operating the Myopia Master®. Extreme temperature changes from cold areas to warm rooms can cause condensation on the optical components.

Note

Equipment damage due to incorrect transport and improper storage

➔ Avoid shocks and vibration.

➔ Avoid contamination, high temperatures and humidity.

➔ Transport the Myopia Master® professionally.

➔ Store the Myopia Master® according to the storage conditions.

➔ Avoid placing near radiators and moisture.

Note

➔ Keep the packing material. You can then ship or transport the unit in the proper manner for any servicing or repairs that may arise. You can thus avoid unnecessary damage and costs.

7 Device Description

7.1 Overview of Device Components

1	*Gauge head*	*4*	*Control Wheel*	*7*	*Function keys*
2	*Printout slot*	*5*	*Sliding plate*		
3	*Display*	*6*	*Joystick*		

Fig. 7-1: Device components

8	*Head rest*	11	*On/Off Switch*	14	*USB port*
9	*Marking for the eye height*	12	*Control LED*	15	*Chin rest*
10	*Pachycam camera glass cover*	13	*Mains connection*	16	*Measuring ocular / Patient eyepiece with Keratometer ring*

Fig. 7-2: Device components

7.2 Mode of Operation of the Myopia Master®

The Myopia Master® combines different measuring functions in one unit.

Auto-Refractometer

An infrared light source projects measuring light onto the retina of the eye from where it is reflected back to the shutter location. Sensitive sensor chips, or CCD cameras now register the deviation of the reflected light from the shutter location. The deviation depends on the ametropia. From that, an integrated microcomputer calculates the ametropia in D, based on the sphere, cylinder and cylinder axis position.

Keratometer

To determine the curvature of the cornea, a reflected image of the cornea is captured by a camera sensor and is measured.

The reflection of test marks and of a ring is used as the reflected image.

This allows the central radii of the cornea to be determined.

Pachymeter (optional)

The pachymetry principle uses Scheimpflug images of the cornea, which are analysed by a built-in computer.

600 Absolute data points are evaluated with the Scheimpflug images. The measuring range lies on a 4 mm slit through the apex.

The slit light illuminates a sectional plane from the front surface of the cornea to the back surface. The transparent cells of the cornea scatter the slit light such that the sectional plane appears as if it were self-luminous.

This is captured at an angle of 45° through the pupil by a camera, whereby the image plane of the camera is also tilted 45° to the optical axis of the camera lens, in order to sharply focus the light-scattering cornea plane onto the image plane of the camera (Scheimpflug image).

Due to this arrangement, sharp sectional images of the cornea can be attained.

Axial length

The axial length of the eye is measured and displayed by interferometry. The Myopia Master® measures six times the axial length of the patient's eye.

Applied parts

1 Head rest
2 Chin rest
Fig. 7-3: Applied parts

8 Set up and Connection

Caution

Risk of incorrect measurements/equipment damage due to improper set-up

- ➔ Before first use, make sure the installation and connection of the "Myopia Master®" examination station are completed by our service team or by a professional authorized by OCULUS.

Note

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

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

8.1 Electrical Connection

Caution

Electrical safety hazard

- ➔ Do not use the Myopia Master® adjacent to or stacked with other equipment.
- ➔ If you have to use the Myopia Master® adjacent to or stacked with other equipment, verify the correct operation of the Myopia Master®.
- ➔ Only use the power adapter listed in the list, *sec. 24.1, page 82*.
- ➔ Only use a power cord which meets the requirements of IEC 60227-1, type H05VVH2-F (type 53), minimum 0,75 m² and IEC 60320-1, type C7.

- If you use a multiple socket outlet to connect the Myopia Master®: Use a multiple socket outlet that complies with the requirements of IEC 60601-1.
- Do not place the multiple socket outlet on the floor.
- Do not use more than one multiple socket outlet.
- Plug only the Myopia Master® and the computer that is being used with the unit (if applicable) into the multiple socket outlet.

Fig. 8-1: Connection

- Connect the device to the power supply using the power cable provided, see *sec. 24.1, page 82*.

Note

Risk of equipment damage due to incorrect connection

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

- Do not use excessive force when connecting the electrical plug.
- Pay attention to the specifications on the nameplate.

If the electrical plug is damaged, contact our service department or an authorized dealer to repair the damage.

8.2 Integrate into IT Network for Service Purposes

An authorized person is allowed to connect the Myopia Master® to a computer via a USB connection for maintenance and service purposes. For example to update firmware or calibrate the device. You need an USB port for the connection.

It is possible to connect the Myopia Master® to a computer which is integrated in an IT network. Do not use wireless technology.

Each connection of the Myopia Master® to a computer creates an IT network or an existing network will be changed. The changes could introduce new risks for patients and operators. Changes to the IT network include:

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

If your computer is already integrated into an IT network, the following information will apply.

Caution

Risk of incorrect measurements/equipment damage due to unauthorized personal

➔ Ensure that only an expert, authorized by OCULUS
  - connects the computer.
  - updates the firmware.

Risk of incorrect measurements/equipment damage due to incorrect connection

Each connection of a Myopia Master® with a computer could introduce risks for patients and operators, which are not described in this manual.

➔ Ensure the safety of the patient and the operator and ensure the functionality of the Myopia Master® and the connected computer.

➔ Connect the device to your computer/laptop using the USB port, with a USB cable with an USB FS MED-Isolator for maintenance and service purposes only.

9 Operation

➔ Wait approx. 3-4 hours after transport before operating the Myopia Master® for the first time. Extreme temperature changes from cold areas to warm rooms can cause condensation on the optical components.

9.1 Switching On

➔ Turn on the Myopia Master® with the On/Off Switch (position I). The LED lights up green.

9.2 Switching Off

➔ End the current session.

➔ Turn the Myopia Master® off with the on/off Switch (position 0).

Caution

Risk of electric shock if the Myopia Master® is not completely disconnected from the mains for transport, cleaning, maintenance, disinfection and repair.

➔ Turn the Myopia Master® off.

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

9.3 Daily Operation

If you move the Myopia Master® to another location, you must position the Myopia Master® so that direct light cannot influence measurements.

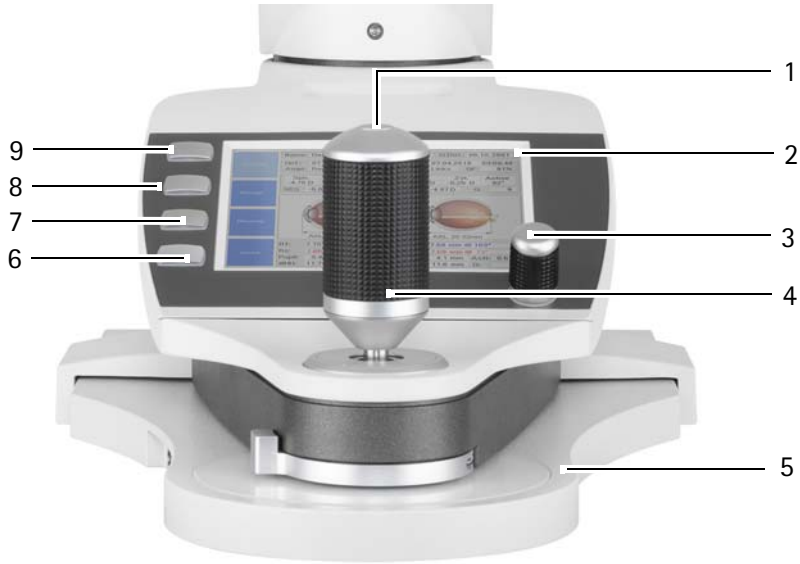
➔ Place the Myopia Master® on a level surface.

➔ Connect the unit to the mains with the supplied power cable.

➔ Make sure that the mains voltage is the same as the voltage specified on the rating plate.

➔ Switch on the Myopia Master® at the On/Off Switch, see *sec. 9.1, page 20*.

10 Functions of the Control Pad



1	*Joystick button*	*4*	*Joystick with turning handle*
2	*Display*	*5*	*Compound slide*
3	*Control wheel*	*6-9*	*Functions assigned to buttons*

Fig. 10-1: Functions on the control pad

Component	Function	Operation
Functions assigned to buttons (6 – 9)	Activates the adjacent keypad, depending on the active screen	➔ Press the desired button.
Control wheel (3) 	Changes the respective parameter. Activates the selected parameter	➔ Turn the knob to the left or to the right. The selected parameter is highlighted in blue. ➔ Press the knob downwards. The selected parameter is activated or deactivated.
Joystick (4)	Adjusts the height, distance and alignment to the left and to the right	➔ Move the joystick up, down and to either side, turn it, *"Fine Adjustment", page 30*.
Joystick button (1)	Manually triggers the measurement (when the auto measurement release function is switched off)	➔ Press the button.
Display (2)	Shows the program screens and acts as a touch screen	➔ Lightly press on the desired button
Compound slide (5)	Used for rough adjustment	➔ Move the adjusting base until you can see the patient's eye clearly on the screen.

10.1 Touch Screen

If the function is not activated:

➔ Enable the checkbox in "Setting 2/5" *(sec. 15.2, page 54)*,

In addition to the function keys, you can now also use the buttons on the screen, for example you can enable the respective button by gently pressing it on the touch screen.

10.1.1 Function Keys on the Touch Screen

Use these function keys to work with the patient data management system.

Button	Function	Button	Function
	Change keyboard	↵	Enter
←	Delete character	↑↑	Return to upper line
ESC	Escape		

11 Preparing Patients Data

Use the patient data management if you want to assign the examinations to a patient or want to save them long-term.

➔ In that case, enter the patient's name and date of birth before you conduct the measurement.

11.1 Entering new Patients (touch screen)

➔ To input a new patient, press the button [Patient] in the patient data menu.

The following screen appears:

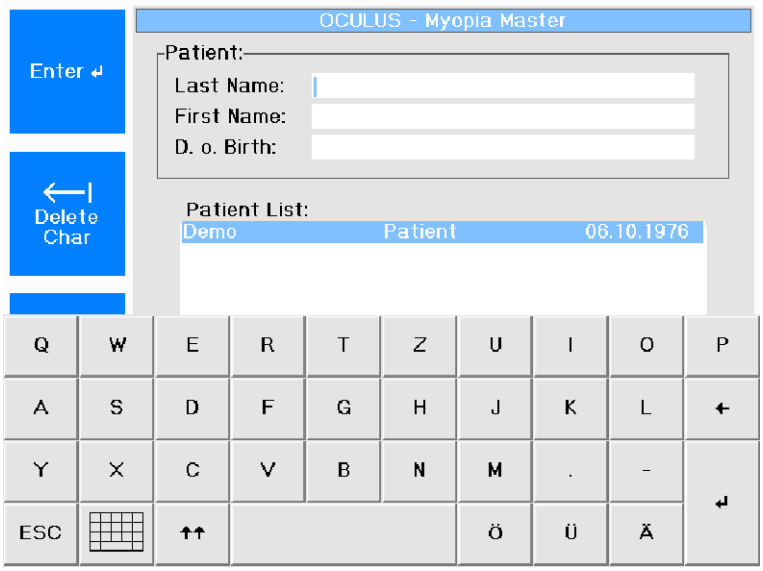


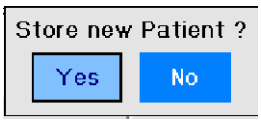
Fig. 11-1: Touch screen keyboard, enter patient data

➔ Use the touch screen as described in *(sec. 10.1, page 22)*.

➔ Enter the patient's last name and first name and confirm.

In the "D. o. Birth" field, the keyboard changes to a numeric keypad.

➔ Enter the date of birth and confirm.



A confirmation dialog box appears.

➔ Select the option "Yes".

The name of the patient appears in the list.

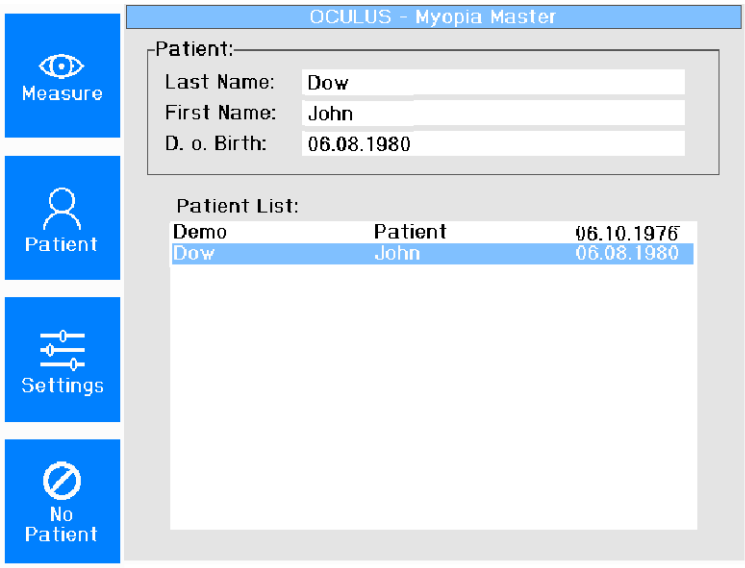


Fig. 11-2: Patient list

➔ Press the [Measure] button to switch to measuring mode.

11.2 Entering new Patients (touch screen deactivated)

➔ To input a new patient, press the button [Patient] in the patient data menu.

The following screen appears:

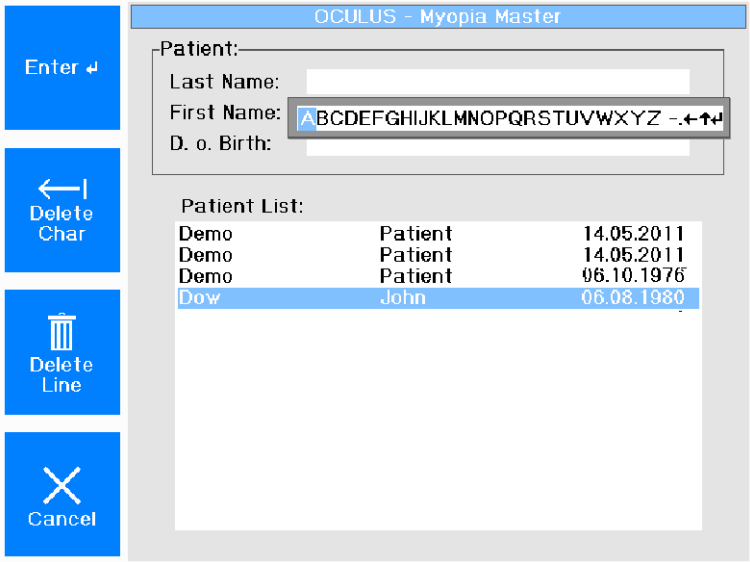


Fig. 11-3: Touch screen deactivated

➔ Select each individual letter by turning the control wheel accordingly.

Confirm each letter by pressing the control wheel.

➔ Enter the patient's last name.

- To correct an incorrect entry:
  Press the [Delete Char] button to delete one character.
  Press the [Delete Line] button to delete the whole entry in the field.
  Alternatively, you can delete the entered text with the control wheel by selecting the symbol "←".
- After you have entered the full last name, press the [Enter] button.
- Alternatively, you scroll up to the previous line or down to the next line by activating the symbols " ↑" and "↵" accordingly.
- Enter the patient's first name and date of birth in the same manner.
- After you have entered the date of birth, confirm by pressing [Enter].
- You will now be asked whether you want to save the new patient data.
- Select the option "Yes".
  The name of the patient appears in the list.
- Press the [Measure] button to switch to measuring mode.

11.2.1 Selecting existing Patients

Select patients whose data have already been saved.

- In the Patient Data Management menu, press the button [Patient].
- Turn the control wheel to get to the desired entry in the list.
  The following screen appears:

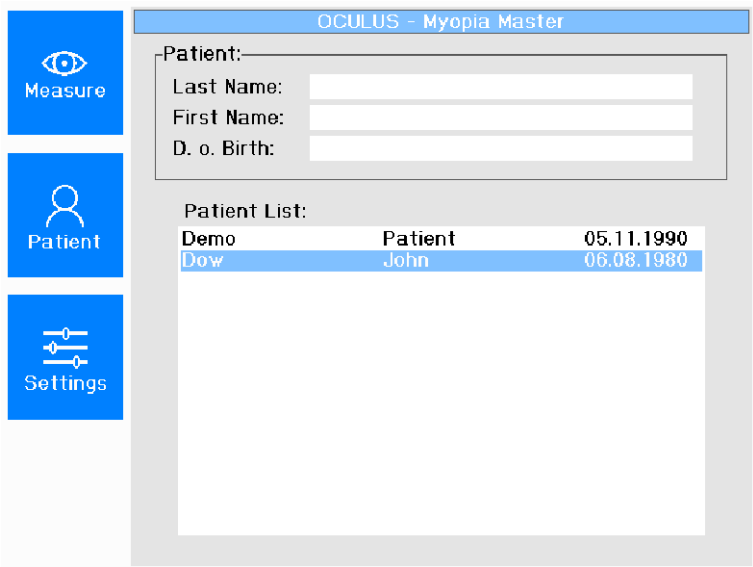


Fig. 11-4: Select a patient

- Press the [New Exam] button to switch to measuring mode.

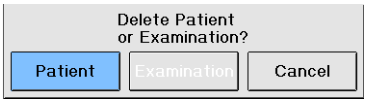
11.2.2 Rename a Patient

- Select the patient that you want to rename.
- Press the button.
- Enter the new name in the field "New Name", or enter a new date of birth.
- Confirm your input.

11.2.3 Delete a Patient or an Examination

If you want to delete a patient or an examination:

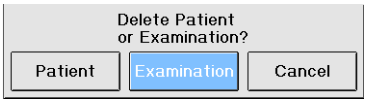
- Select the patient in question.
- Press the button.



To delete a patient:

- Select with the control wheel the button [Patient].
- Press the control wheel.

  The data of the patient is deleted.



To delete an examination:

- Select with the control wheel the button [Examination].
- Select the examination that is to be deleted.

  The line for the selected examination appears highlighted in blue.
- Press the control wheel.

  The examination is deleted.

11.2.4 Load an Examination

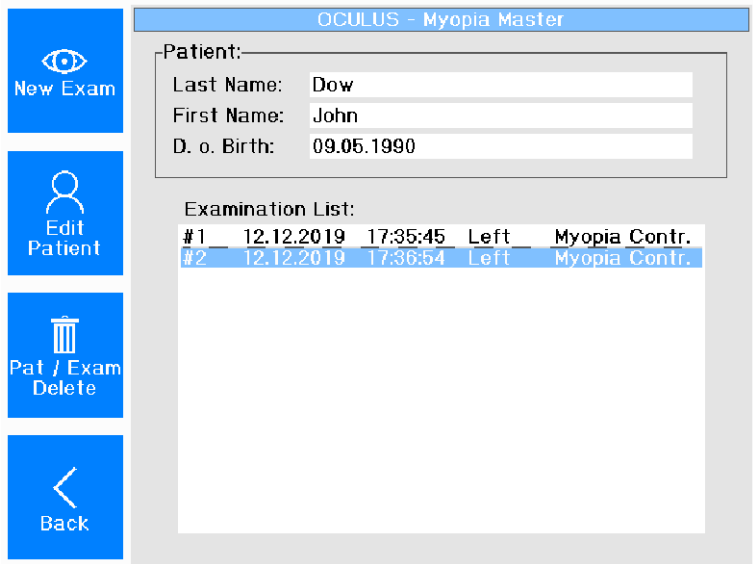


Fig. 11-5: Load an Examination

All examinations can be reloaded and print out at a later date.
If two examinations have already been printed out together, these are also automatically saved together (R+L) and in turn, they are also reloaded together.
If the measurements were not printed out together, the examinations are listed individually (right, left).
The measurements must then be loaded separately, one after the other.
Generally, two measurements can only be displayed together when they belong to a single measuring operation.

12 Measuring Procedure

Caution

Risk of incorrect measurement due to incorrect use

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

A measuring procedure consists of the following steps:

➔ Selecting a measuring mode
➔ Preparing a measurement
➔ Performing a measurement
➔ Saving data
➔ Completing the measurement

12.1 Selecting a Measurement Mode

The measuring procedure depends on the selected mode:

- Myopia, more information *sec. 12.3, page 32*
- AR + K, more information *sec. 12.4, page 37*
- AXL (axial length), more information, *sec. 12.6, page 41*

Measuring mode display:

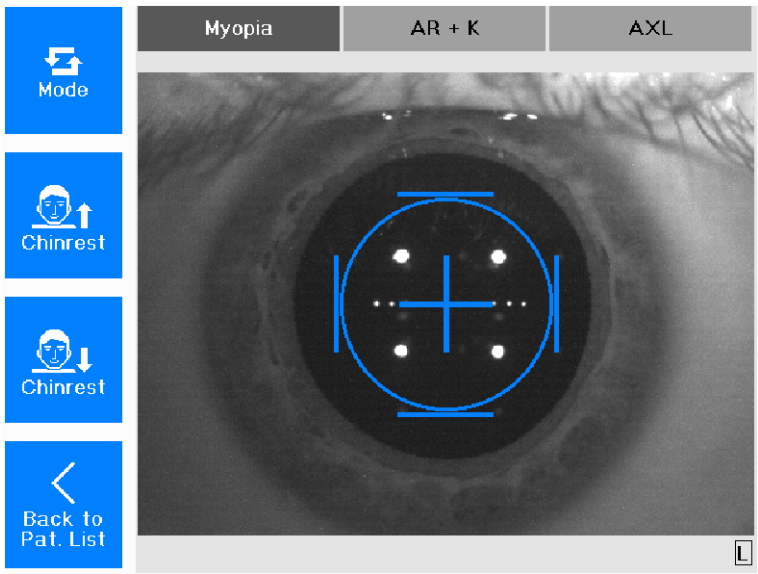


Fig. 12-1: Measuring mode display

➔ Press the [Mode] button to change the combination of measuring functions for the individual measurement.
The other parameters that have been selected in "Settings" remain active *(sec. 15, page 52)*.
The eye that is being measured is shown at the bottom right, [R] for right or [L] for left.

12.2 Preparing a Measurement

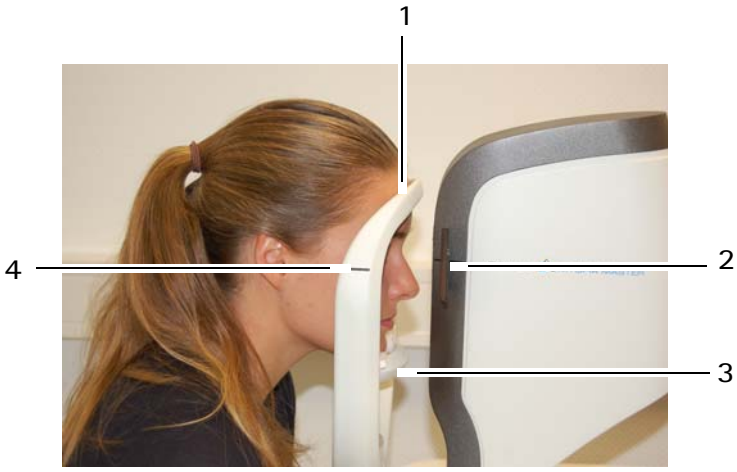
Position the patient and adjust the device before the measurement.

Rough adjustment

➔ Check that
- fresh paper has been put onto the chin rest or that the chin rest has been disinfected
- the head rest has been cleaned and disinfected after each examination, *sec. 18, page 67*.

➔ Do not touch the device and the patient simultaneously.

➔ Ask the patient to place his or her head on the chin and head rest.
The eye height marking between the chin rest and the headrest should be located roughly at the centerline of the patient's eye.



1 Head rest
2 Mark on device
3 Chin rest
4 Mark eye height
Fig. 12-2: Patient position

➔ Adjust the chin rest.
In addition, you can also adjust the height of the gauge head by turning the joystick: Turn it clockwise to move the gauge head upwards.
Turn it counter-clockwise to move it downwards.[1]

1.If you turn the joystick to the limit stop, the measuring head and the chin rest move in the opposite direction.

Note

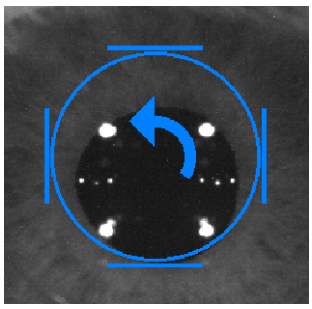
When "Eye-tracking" is active, height adjustment takes place automatically.

- ➔ What to say to the patient: "Look into the eyepiece. You will see a balloon. Relax and look at its center".
- ➔ Adjust the compound slide until the image of the patient's eye is sharply focussed on the display.

  If necessary: Adjust the height by adjusting the chin rest or the gauge head accordingly.

Fine Adjustment

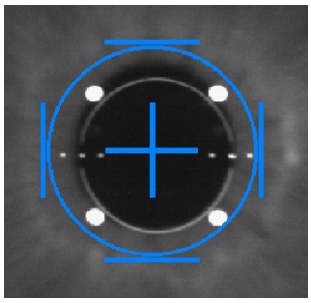
- ➔ Make any fine adjustments required based on the information in the adjustment window. To do this, move or turn the joystick in the specified directions:



Example:

- ➔ Turn the joystick counter clockwise.

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



When the position has been reached accurately enough, a cross appears in the center of the ring that is bordered by four bars.

The Myopia Master® will automatically begin measuring. Alternately you can start the measuring procedure manually.

Manual measurement:

- ➔ Initiate the measurement by pressing the joystick button.

Note

In the measuring procedure described here, the relative measuring functions „Myopia“ are activated.

First the central corneal radii are measured, then the refraction is performed followed by the axial length measurement.

Furthermore, "Eye-tracking" and "Auto-release" are standardly activated.

At the bottom of the screen, you can see whether measurements have already been taken and saved for the respective eye.

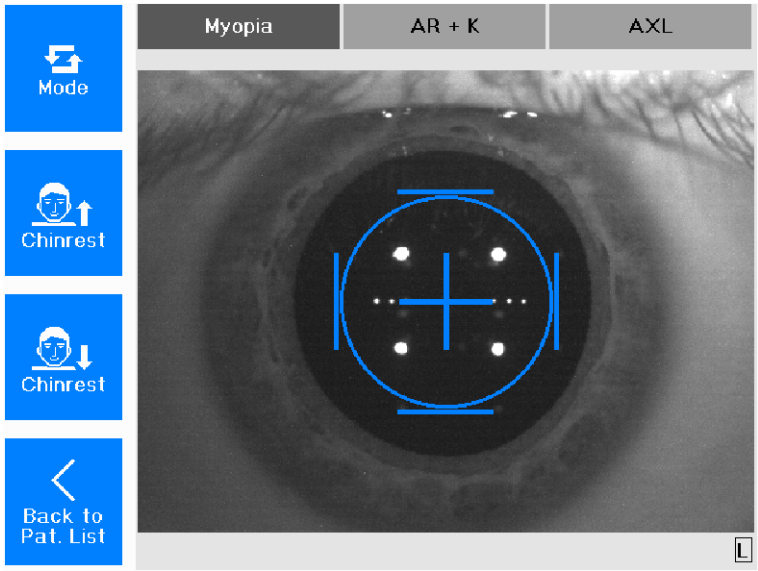


Fig. 12-3: Measuring mode

If the symbol appears at the bottom right or left  :

The right or the left eye has already been measured.

The respective measurement can be found in the memory.

➔ Select the appropriate eye to load the examination that was just conducted.

Clear — To delete the existing examinations from the memory, press this button.

12.3 Myopia measurement and results

The measurement mode is preset to "Myopia".

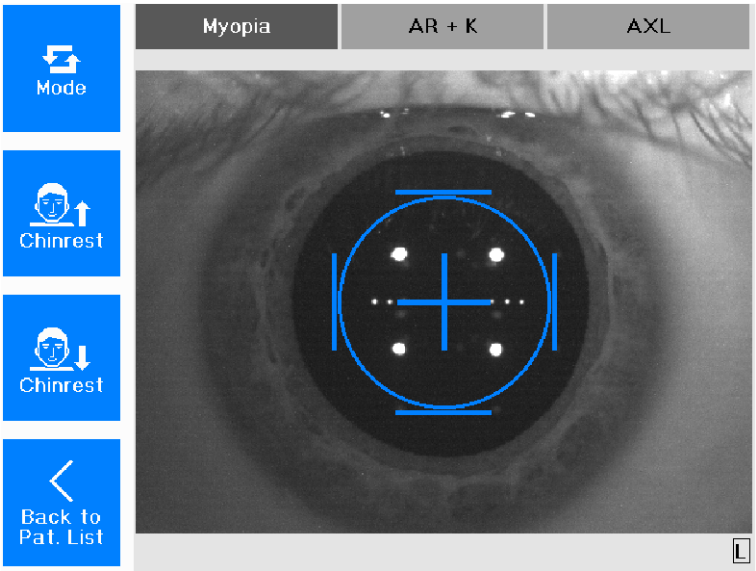


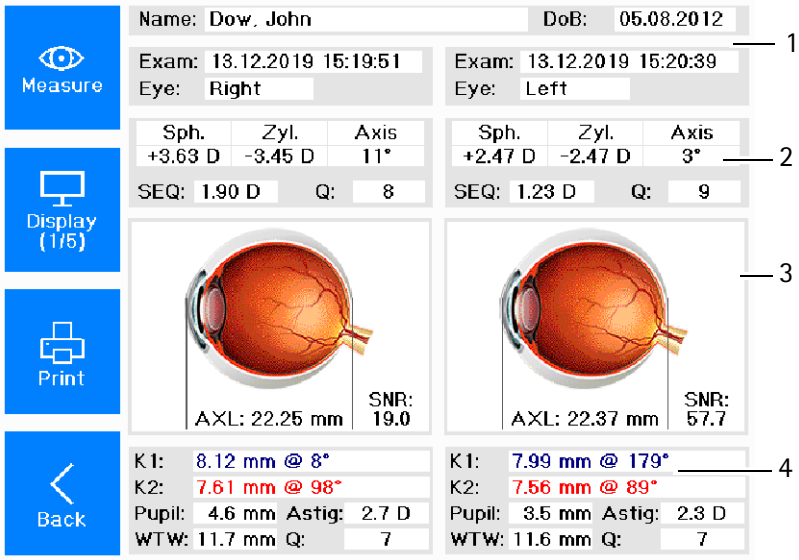
Fig. 12-4: Measuring mode

These steps belong to a complete myopia measurement

- central cornea radii (K)
- objective refraction (ARK)
- axial length (AXL)

12.3.1 Myopia Overview Display

The measured values of the myopia examination are displayed in the overview display.



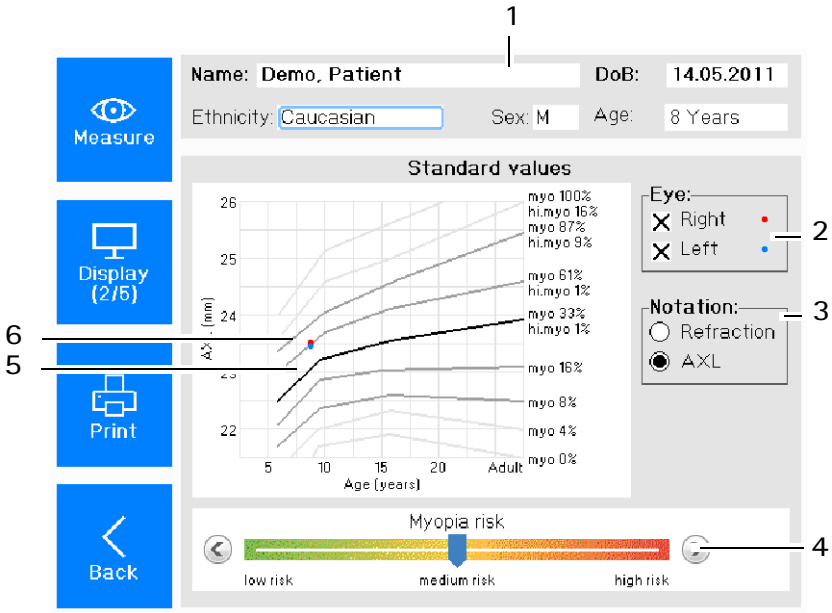
1 *Patient and examination data*
2 *Refraction values*
3 *AXL images*
4 *Pachymeter values*

Fig. 12-5: Myopia overview display

➔ Press the button to change to the prognosis display.

12.3.2 Myopia Results

After performing the measurement the following display appears.



1 *Patient and examination data*
2 *Colour for examined eye*
3 *Type of notation*
4 *Risk assesment*
5 *Measurement values of the patients age*
6 *Progressive representation of axial lengths and objective refraction values*

Fig. 12-6: Progression display

The display shows the measurement values of either a single or both eyes. They are colour coded.

You can select the values of axial length or the refraction.

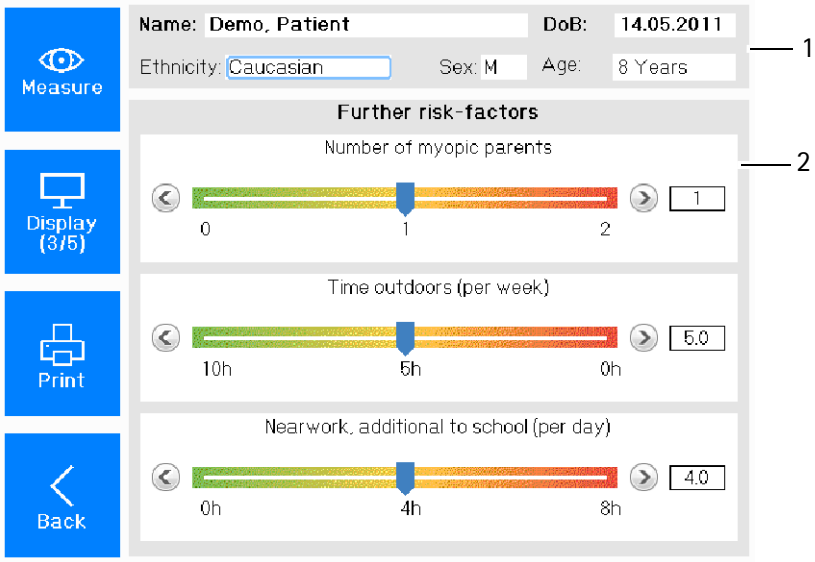
The graph displays the axial length measurement values in accordance to the age of the patient.

The grey lines reflect the percentile curves.

You can set the risk of the Myopia in the colour bar manually.

➔ Press the button to change to the risk factors display.

The following display appears.



1 Patient and examination data
2 Further risk factors
Fig. 12-7: Risk factors display

The questionnaire gives you a brief risk assessment. The risk is classified according to scientific studies.

➔ Ask the patient about his/her:
- ethnicity
- number of myopic parents
- gender
- time outdoors (per week)
- near work, additional to school (per day)

➔ Answer the respective question by adjusting the slider to the corresponding value.

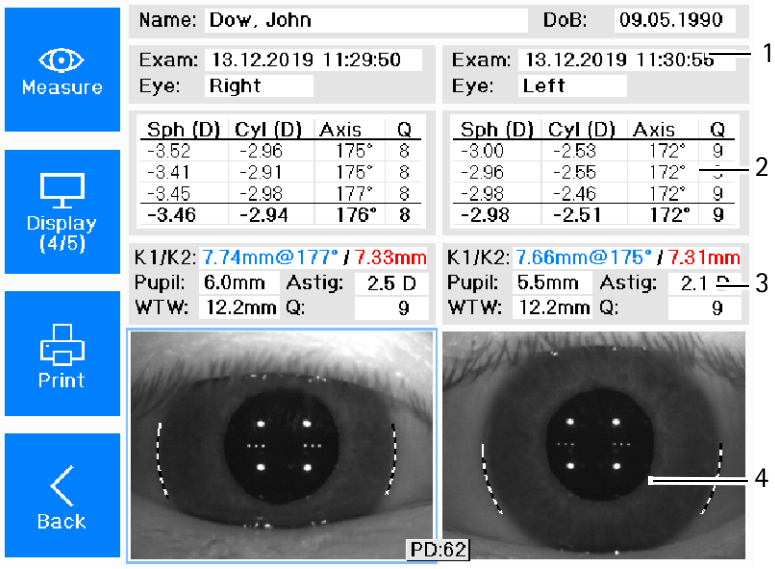
You can therefore use the control wheel and confirm by pushing.

Alternatively use the arrow button to the right for increasing or to the left for decreasing the values.

➔ Press the button to change to the AR + K display.

12.3.3 Refraction Results

After performing the measurement the following display appears..



1 Patient and examination data
2 Refraction values
3 Keratometer
4 Scheimpflug images

Fig. 12-8: AR + K overview display

Refraction Values (2)

The sphere, cylinder, axis position and quality values are displayed in this field.

The refraction values are measured three times. The mean value is displayed in the fourth line.

Q-value:
If the field has a white background (9-8) - the measuring results are good.
If the field has a yellow background (7-6) - the measuring results are critical; repeat the measurement, if necessary.
If the field has a red background (≤6) - repeat the measurement.

Keratometer Values (3)

- K1/K2: Horizontal/vertical radius of curvature in the center
  blue: flat meridian
  red: steep meridian
- Pupil: Size of pupil
- Astig: Astigmatism of cornea in the center
- WTW: (white-to-white) Cornea diameter or iris diameter.
- Q-value:
  If the field has a white background (9-8) - the measuring results are good.
  If the field has a yellow background (7-6) - the measuring results are

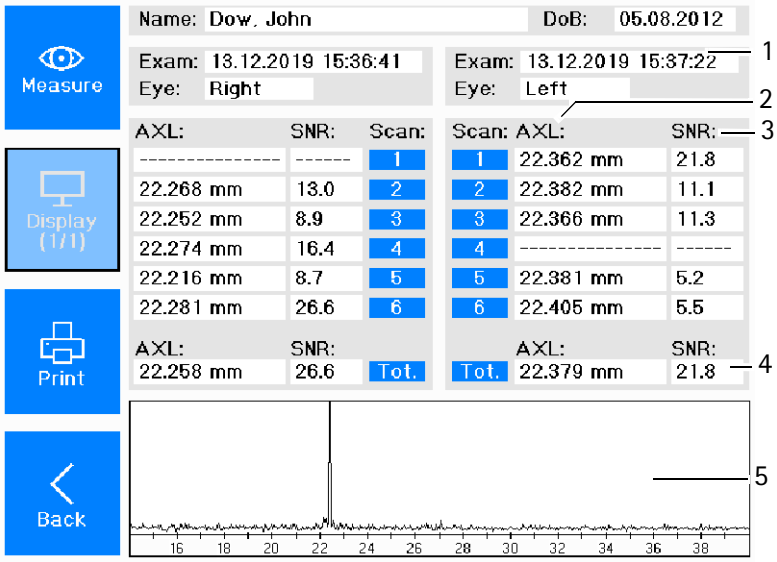
critical; repeat the measurement, if necessary.
If the field has a red background (≤6) - repeat the measurement.

Camera image (4)

The cornea or the edge of the iris is marked in the camera image.

12.3.4 Axial length results

After performing the measurement the following display appears.



1 Patient and examination data
2 AXL values
3 SNR values
4 Highest SNR value
5 Signal to noise ratio graph

Fig. 12-9: AXL overview display

The axial length values for one or both eyes are shown in the table (2).

The corresponding signal to noise ration (SNR) (3) is listed. The axial length with the highest SNR (4) is shown in a single line.

Furthermore the SNR is shown in a graph (5).

12.3.5 Ending the measurements

➔ Print and/or save the data, *sec. 12.8, page 44*.

12.4 AR + K measurement and results

The AR + K values can be measured independently.

➔ Select the mode AR + K.

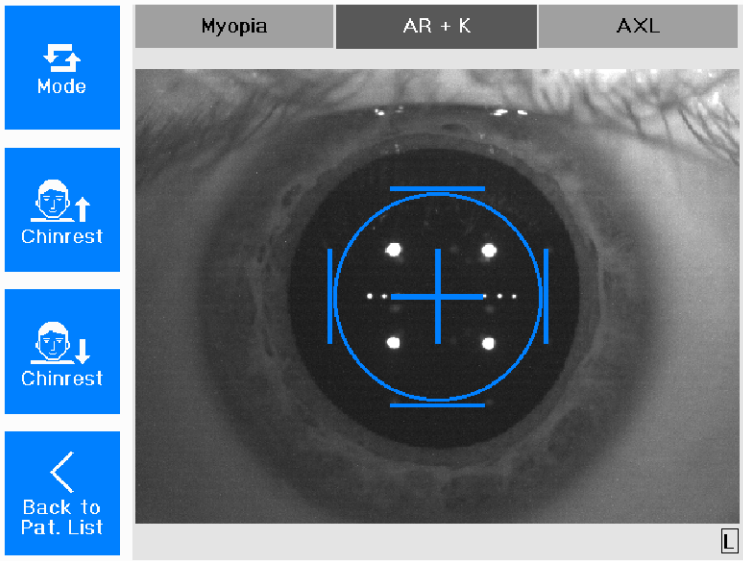
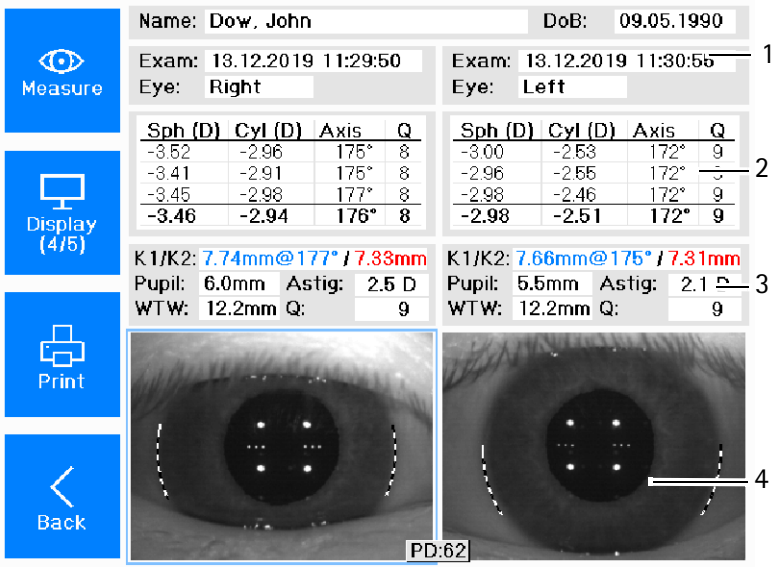


Fig. 12-10: Measuring mode AR + K

The measurement AR + K is executed for both eyes. The following screen appears.



1 Patient and examination data
2 Refraction values
3 Keratometer
4 Camera images

Fig. 12-11: AR + K display (if both eyes are measured)

➔ Print and/or save the data, *sec. 12.8, page 44*.

Refraction Values (2)

The sphere, cylinder, axis position an quality values are displayed in this field.

The refraction values are measured three times. The mean value is displayed in the fourth line.

Q-value:
If the field has a white background (9-8) - the measuring results are good.
If the field has a yellow background (7-6) - the measuring results are critical; repeat the measurement, if necessary.
If the field has a red background (≤6) - repeat the measurement.

Keratometer Values (3)

- K1/K2: Horizontal/vertical radius of curvature in the center
  blue: flat meridian
  red: steep meridian
- Pupil: Size of pupil
- Astig: Astigmatism of cornea in the center
- WTW: (white-to-white) Cornea diameter or iris diameter.
- Q-value:
  If the field has a white background (9-8) - the measuring results are good.
  If the field has a yellow background (7-6) - the measuring results are critical; repeat the measurement, if necessary.
  If the field has a red background (≤6) - repeat the measurement.

Camera image (4)

The cornea or the edge of the iris is marked in the camera image.

12.5 P + AR + K measurement and results

If your device is equipped with a pachymeter the corneal thickness can be measured additionally.

➔ Select the mode P + AR + K.

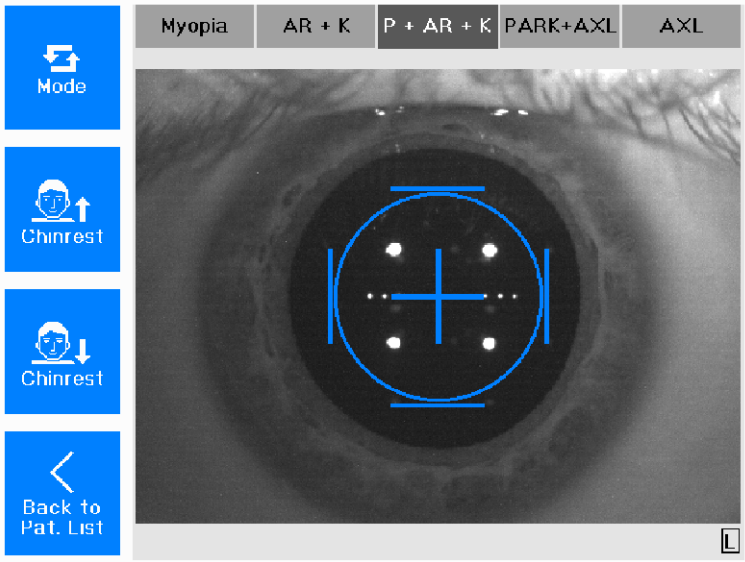
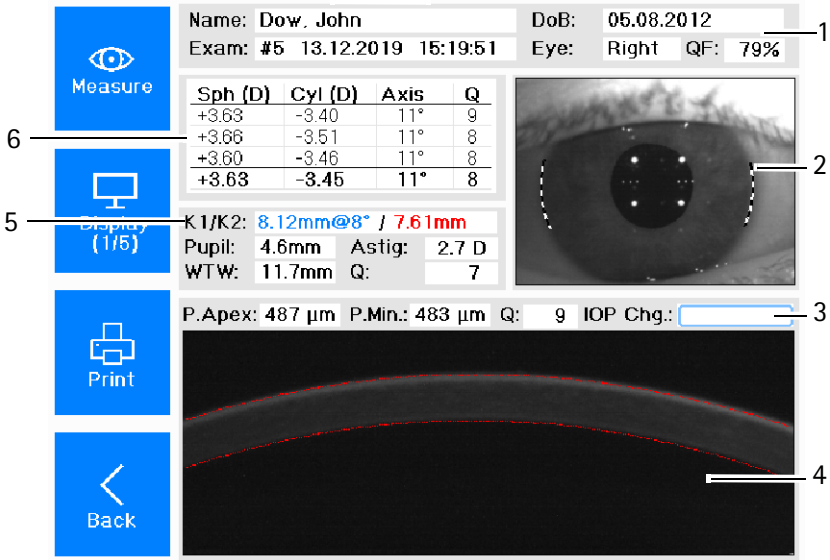


Fig. 12-12: Measuring mode P + AR + K

If the measurement mode was executed, the following overview screen appears for the examination of the right eye.



1 *Patient and examination data*
2 *Camera image*
3 *Pachymeter values*
4 *Scheimpflug image*
5 *Keratometer values*
6 *Refraction values*

Fig. 12-13: P + AR + K display (if both eyes are measured)

➔ Print and/or save the data, *sec. 12.8, page 44*.

Pachymeter values (3)

- P. Apex: Corneal thickness at the apex
- P. Min: Corneal thickness at the thinnest point
- Q-value:
  If the field has a white background (9-8) - the measuring results are good.
  If the field has a yellow background (7-6) - the measuring results are critical; repeat the measurement, if necessary.
  If the field has a red background (≤6) - repeat the measurement.
- IOP Chg.: Correction of the intraocular pressure dependent on the corneal thickness in the apex *(sec. 17, page 62)*.
  Correction is done based on the selected correction table. The type of correction table can be selected in the settings.

Scheimpflug (4)

The Scheimpflug image shows the cornea between the red doted lines.

Keratometer Values (5)

- Rh/Rv: Horizontal/vertical radius of curvature in the center
  blue: flat meridian
  red: steep meridian
- Pupil: Size of pupil
- Astig: Astigmatism of cornea in the center
- WTW: (white-to-white) Cornea diameter or iris diameter.
- Q-value:
  If the field has a white background (9-8) - the measuring results are good.
  If the field has a yellow background (7-6) - the measuring results are critical; repeat the measurement, if necessary.
  If the field has a red background (≤6) - repeat the measurement.

Refraction Values (6)

The sphere, cylinder, axis position and quality values are displayed in this field.

The refraction values are measured three times. The mean value is displayed in the fourth line.

Q-value:
If the field has a white background (9-8) - the measuring results are good.
If the field has a yellow background (7-6) - the measuring results are critical; repeat the measurement, if necessary.
If the field has a red background (≤6) - repeat the measurement.

12.6 PARK + AXL and results

If your device is equipped with a pachymeter the corneal thickness can be measured additionally.

➔ Select the PARK + AXL mode.

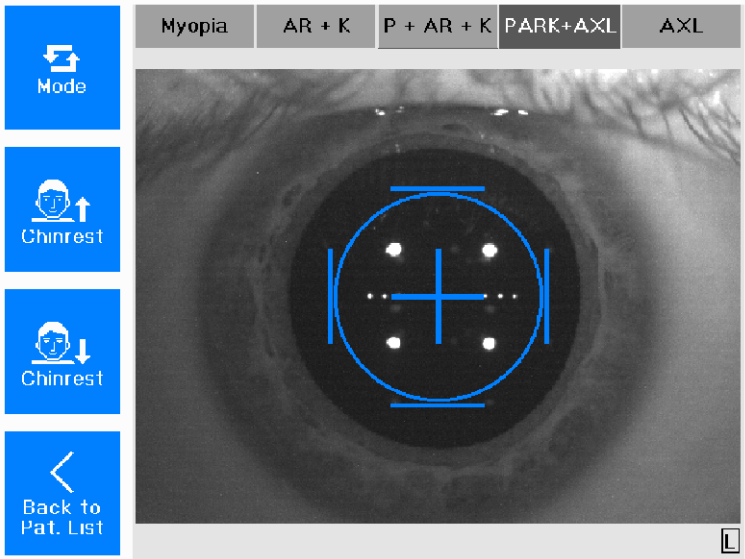
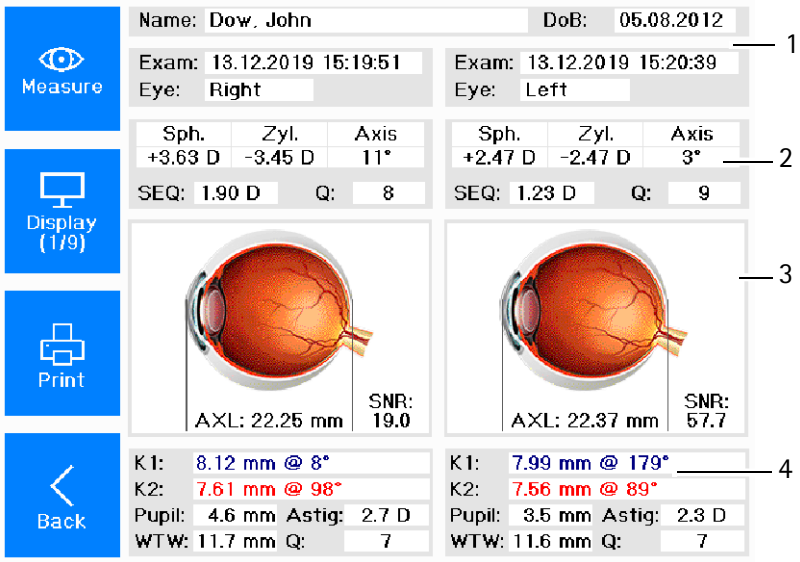


Fig. 12-14: Measuring mode PARK + AXL

If the measurement mode were executed, the following overview screen appears for the examination of the right eye:



1 *Patient and examination data*
2 *Refraction values*
3 *AXL images and values*
4 *Keratometer values*

Fig. 12-15: Overview AXL with images

➔ Print and/or save the data, *sec. 12.8, page 44*.

Refraction Values (2)

The sphere, cylinder, axis position and quality values are displayed in this field.

SEQ: Spherical equivalent

Q-value:
If the field has a white background (9-8) - the measuring results are good.
If the field has a yellow background (7-6) - the measuring results are critical; repeat the measurement, if necessary.
If the field has a red background (≤6) - repeat the measurement.

AXL values (3)

The axial length values for one or both eyes are shown.

The corresponding signal to noise ration (SNR) is listed.

Keratometer Values (6)

- K1/K2: Horizontal/vertical radius of curvature in the center
  blue: flat meridian
  red: steep meridian
- Pupil: Size of pupil
- Astig: Astigmatism of cornea in the center
- WTW: (white-to-white) Cornea diameter or iris diameter.
- Q-value:
  If the field has a white background (9-8) - the measuring results are good.
  If the field has a yellow background (7-6) - the measuring results are critical; repeat the measurement, if necessary.
  If the field has a red background (≤6) - repeat the measurement.

12.7 Axial length and results

To measure the axial length of the eye only select the AXL mode.

➔ Select the AXL mode.

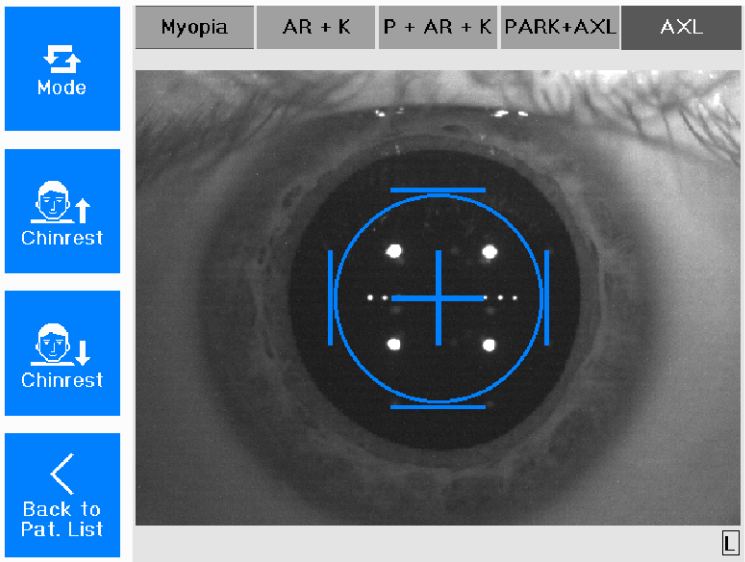
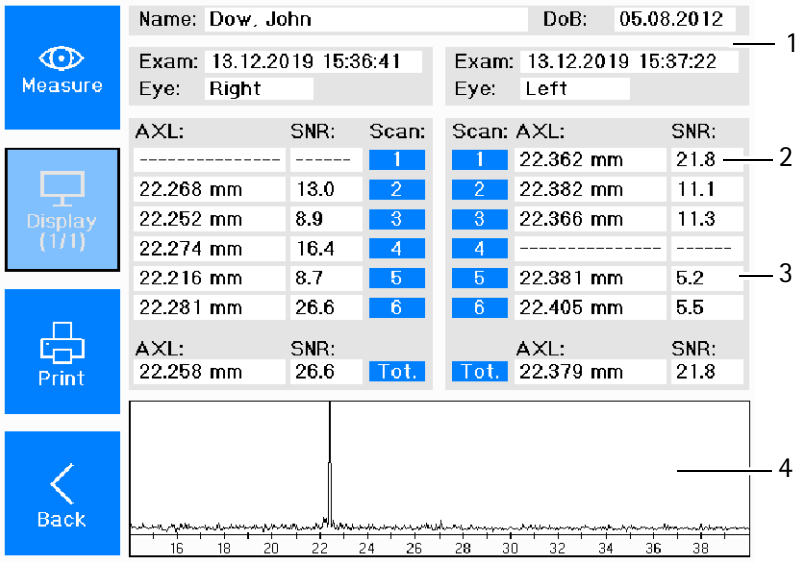


Fig. 12-16: Measuring mode AXL

If the measurement mode were executed, the following overview screen appears for the examination of the right eye:



1 Patient and examination data
2 AXL values
3 SNR values
4 Graph axial length measurement

Fig. 12-17: Overview AXL measurement display

➔ Print and/or save the data, *sec. 12.8, page 44*.

- AXL: Axial length measurement value. The final result of the axial length is calculated just only from all feasible SNR peaks.

  It´s display in a single line.
- SNR: Signal to noise Ratio of the axial length value

12.8 Printing and Saving Examinations

After performing the measurement of the myopia the following display appears.:

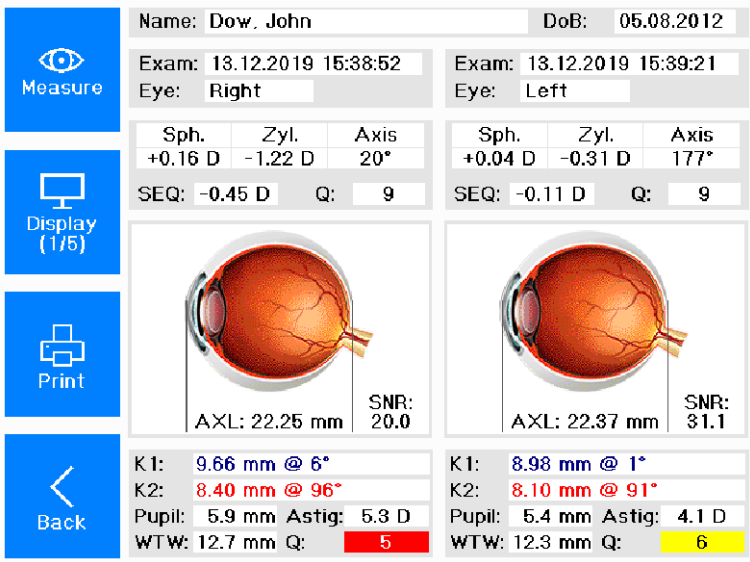


Fig. 12-18: Display with print button

12.8.1 Printing

➔ Press the [Print] button to print out the examination results.

Note

The measurement is automatically saved if you entered a new patient *(sec. 11.1, page 23)* prior to starting the measuring process.
When printed out, each measurement is automatically temporarily saved to the exam nr. memory *("Saving data by Exam no. memory", page 46)*.

The **different measuring processes** are outlined briefly in the chapter "Chronology of Different Measuring Processes" *(sec. 13, page 47)*.

Save the examination retroactively if you did not set up a new patient *(sec. 13.2, page 48)* prior to executing the measuring process.

12.8.2 Saving an examination

There are two different ways of saving an examination:

- Exam nr. memory
- Patient Data Management

Saving data by Exam no. memory


#8

OCULUS
Myopia Master

Patient: Dow, John
D. o. Birth: 05.08.2012 (7)

Date: 13.12.2019
Time: 15:42:11
QF: 87%

R

Refraction (VD=12 mm):

S	C	A	Q
-0.71	-0.25	18°	9
-0.66	-0.06	8°	8
-0.52	-0.02	42°	8
-0.63	-0.10	18°	8

Keratometry:

Rh: 6.55 mm / 51.5 D @ 29 °
Rv: 6.64 mm / 50.8 D @ 119 °
Rm: 6.60 mm / 51.2 D
Astig: 0.7 D
WTW: 11.9 mm
Pupil: 6.0 mm
Q: 9

Achslaenge:

AXL	SNR
25.197 mm	9.1
25.252 mm	6.8
25.201 mm	13.9
25.038 mm	6.8
25.172 mm	13.9

After printing, each examination is automatically saved in the exam no. memory and can be retrieved from there later.
A maximum of 100 examinations can be stored in the exam nr. memory, after which the first measurement that was saved is overwritten again. If you want to save examinations long-term, use the patient data management.

If you want to retrieve a measurement again later, you will find the examination in the exam nr. memory under the exam number that was assigned to it and can thus reload it.

You can retrieve the measurement at a later time using the number [15].

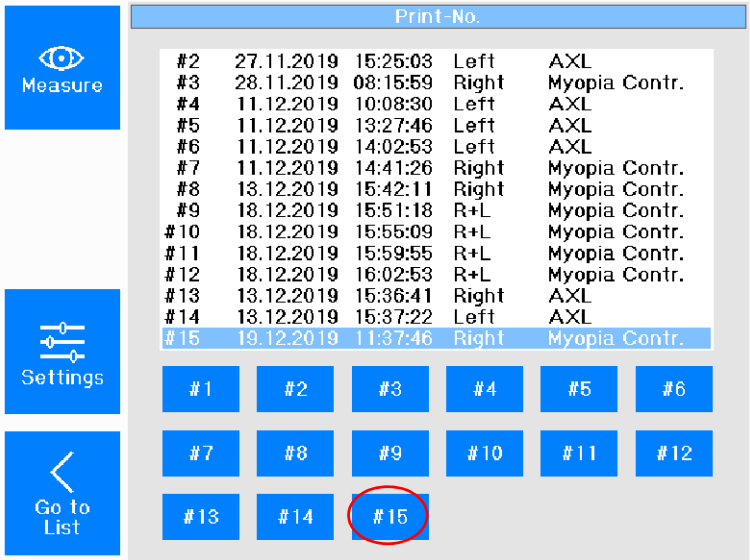


Fig. 12-19: Exam nr. Memory

12.9 Complete measurement

This button is displayed after a measurement has been conducted.

- ➔ Press this button to save the examination data to the patient's record.
- ➔ After each patient remove one of the paper sheets from the chin rest. See also *sec. 18.4, page 71*.
- ➔ Disinfect the head rest and, if neccessary, the chin rest after each patient, *sec. 18.2, page 69*.

13 Chronology of Different Measuring Processes

The chronology of three different measuring processes is outlined briefly below.

1 You enter a patient in the patient data management and then conduct the measurement.

The examination data are automatically saved under the newly entered patient's name *(sec. 13.1, page 47)*.

2 You start directly with the measuring operation and then subsequently save the examination under an existing patient's name. Alternatively, you can also enter a new patient after performing the measuring operation *(sec. 13.2, page 48)*.

3 You perform a measuring operation without saving the examination under a patient's name *(sec. 13.3, page 49)*.

13.1 Enter Patient + Measure

➔ Press the button [Patient] in the patient data management.

➔ Create a new patient, as described in *sec. 11.1, page 23*.

The newly entered patient appears in the list of patients and is highlighted in blue.

➔ Start the measuring operation by pressing the [Measure] button.

Press the optional joystick button.

➔ Conduct the measurement *(sec. 12, page 28)*.

When the measuring operation has been completed, the overview screen appears *(fig. 12-5, page 32)*.

The conducted examinations are automatically saved in the patient data management.

The saved examinations can be viewed again at any time *(sec. 12.8, page 44)*.

13.2 Saving an Examination Retroactively

- Start the measuring operation directly.
- The following screen appears:

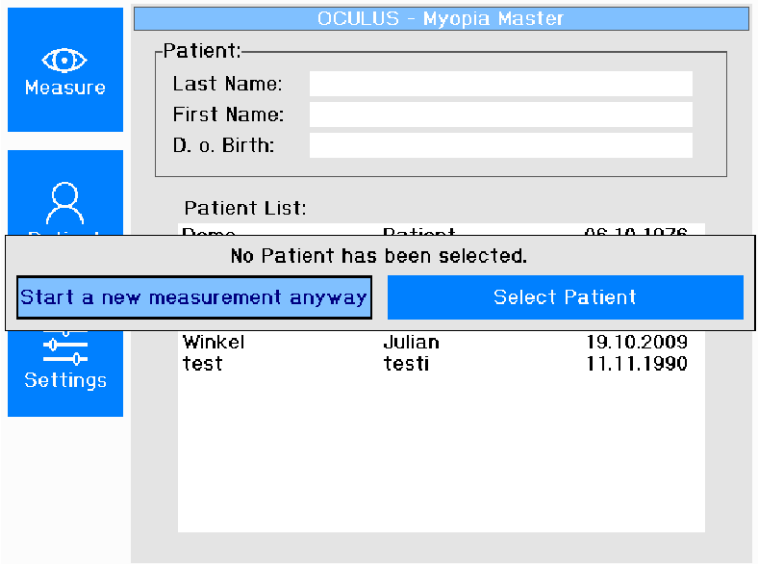


Fig. 13-1: Start a new measurement

- Select "Start a new measurement anyway".
- Conduct the measurement *(sec. 12, page 28)*.

  When the measuring operation has been completed, the overview screen appears *(fig. 12-5, page 32)*.
- In the overview screen, press the button [Save to Patient].

  The "Patient List" display opens.

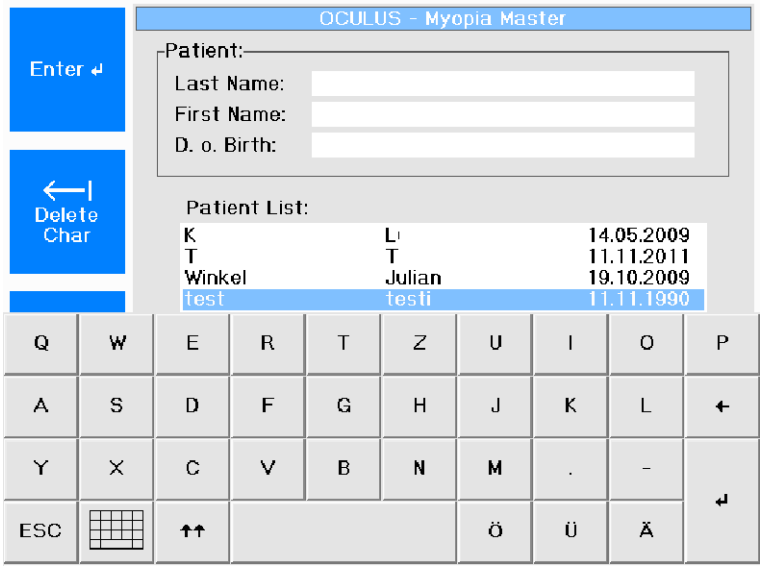


Fig. 13-2: Patient list

1 **You can enter a new a patient and save the conducted measurement under that patient's name. You must first exit the patient list.**

The patient data management is already opened *(fig. 11-1, page 23)*.

➔ Create a new patient, as described in *sec. 11.1, page 23* .

The newly entered patient appears in the list of patients and is highlighted in blue.

The conducted examinations are saved in the patient data management.

You can retrieve the saved examinations at any time *(sec. 12.8, page 44).*

2 **You can select a patient** and save the conducted measurement under that patient's name

➔ Exit the character box for entering the patient's data.

➔ Press the "ESC" button on the keyboard.

➔ Select the patient and confirm by pressing the control wheel.

➔ Alternatively use the button "Save to Patient"

The examination data are saved under the selected patient's name.

The saved examinations can be viewed again at any time *(sec. 12.8, page 44)*.

13.3 Measuring Without Saving the Patient Data

➔ Start the measuring operation directly.

➔ Conduct the measurement *(sec. 12, page 28)*.

When the measuring operation has been completed, the overview screen appears *(fig. 12-5, page 32)*.

Print out the measurement(s) *(sec. 12.8, page 44)*.

When printed out, each measurement is automatically temporarily saved to the exam nr. memory *("Saving data by Exam no. memory", page 46)*.

14 Reference Measurement

To achieve a high measuring accuracy, the Myopia Master® must be set up

- before conducting the first examination on a patient
- after changing the position of the Myopia Master®

The first reference measurement is performed during setup by OCULUS or an authorized dealer. OCULUS recommends performing a reference measurement once each month.

The reference measurement can be performed easily and quickly using the reference tool.

Required materials

- reference tool, provided
- cleaning agent, see *sec. 18, page 67*

Measuring with the reference tool

Prerequisite: the Myopia Master® must be turned on for at least 15 minutes. For the reference measurement, proceed as follows:

➔ Remove the cover cap.

➔ Thoroughly clean the reference tool before saving reference values with the cleaning agent.

➔ Place the reference tool on the chin rest.

Fig. 14-1: Installation of the reference tool

➔ Add a new patient, named "reference test" and select "Myopia" or "ARK + AXL".

➔ Perform a measuring operation with the reference tool *(sec. 12.3, page 32)*.

➔ Compare the results with the results on the reference tool.

Fig. 14-2: Example: Result on reference tool

The system is now ready for operation.

15 Settings

Choose the default settings for your individual measuring mode.

15.1 Settings 1

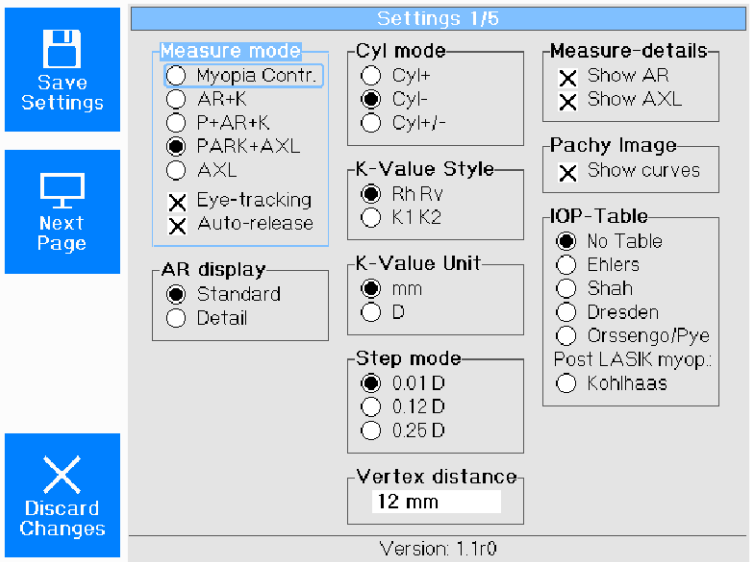


Fig. 15-1: Settings 1

Measuring Mode

You can preset the measuring function combinations here.

Myopia Contr.: Myopia measurement

AR + K: Refraction+Keratometry

P + AR + K: Pachymetry+Refraction+Keratometry

PARK + AXL: Pachymetry+Refraction+Keratometry+axial length

AXL: axial length measurement

You also activate or deactivate the functions "Eye-tracking" and "Auto-release" here.

Eye-tracking: Automatic adjustment of the measuring head in y-direction (height).

Auto-release: Automatic triggering of the measuring operation

AR display

In "Standard" mode, the calculated mean refraction is displayed.

"Detail" mode additionally displays the values of the individual measuring steps.

Cyl mode

Select whether plus or minus cylinders are to be used.

When the program is started, this preselected cylinder type is then always active.

K-Value Style

Select the mode for determining how the central radii are to be displayed.

Rh Rv: horizontal / vertical radius

K1 K2: Flat radius / Steep radius

K-Value Unit

The measured curvature of the cornea can either be shown as a radius of curvature in mm, or as the curvature equivalent in diopters.

Step mode

Select the increments in which the diopters of the refraction values are to be rounded.

Vertex distance

Set the cornea vertex distance to which the displayed refraction values are to relate.

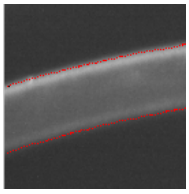
Measure-details:

Show AR: Activates the refaction display *(fig. 12-8, page 35)*

Show AXL: Activates the axial length display *(fig. 12-9, page 36)*

Pachy Image

If the checkbox "Show curves" is activated, the pachymetric curves are displayed in red:



IOP Table

Here, you select the formula for correction of the tonometrically measured IOP to estimate the actual IOP value *(fig. 17-1, page 63)*.

15.2 Settings 2

➔ On the "Settings 1" screen, press the button [Next Page].

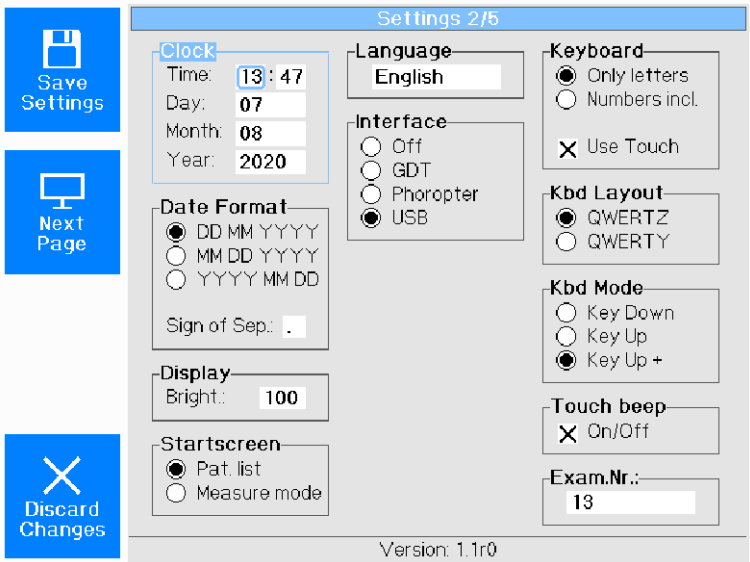


Fig. 15-2: Settings 2

Clock - Date Format

In these two fields, you set the time and the date by turning and pressing the rotary knob.

Display

You can adjust the brightness of the display here.

Startscreen

When the option "Measure mode" is active, you start with the measuring operation directly after switch-on.

When the option "Pat. list" is active, you start with the patient data management directly after switch-on.

Language

Select the on-screen language.

Interface

You can deactivate the interfaces.

With the GDT interface, you can link the Myopia Master® to an existing office software and can thus import and export data.

If you want to connect a phoropter that is supported by PARK *(fig. 15-5, page 56)*, then activate the option "Phoropter".

If the Myopia Master® is connected to a computer via USB, you need to set the interface settings to "USB".

Keyboard / touch screen / Kbd Layout / Kbd Mode

- In the "Keyboard" field, select the keyboard interface of the touch screen for input of patient data, for example.
  You activate or deactivate the touch screen function in the "Use Touch" checkbox
- In the "Kbd Layout" field, you select the keyboard layout.
  QWERTZ stands for the German keyboard layout.
  QWERTY stands for the American keyboard layout.
- In the field "Kbd Mode", you select the contact control of the touch screen.
  In "Key Down" mode, the characters are input as soon as you make contact with the touch screen
  In "Key Up" ,mode, the characters are input when you stop pressing the touch screen.
  This is the case in "Key Up+" mode too. However, the entered character is also displayed on the screen:

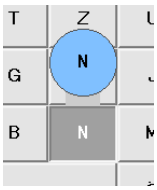


Fig. 15-3: Kbd Mode "Key Up+", Example: The letter N

Touch beep

If the Checkbox is activated, then a “peep tone” will sound- when the touch screen is operated.

Exam.Nr.

The "Exam Nr." that appears on every printout for identifications purposes can be reset to zero at any time.

15.3 Settings 3

On the "Settings 3" screen, you set the communication parameters for the respective phoropter:

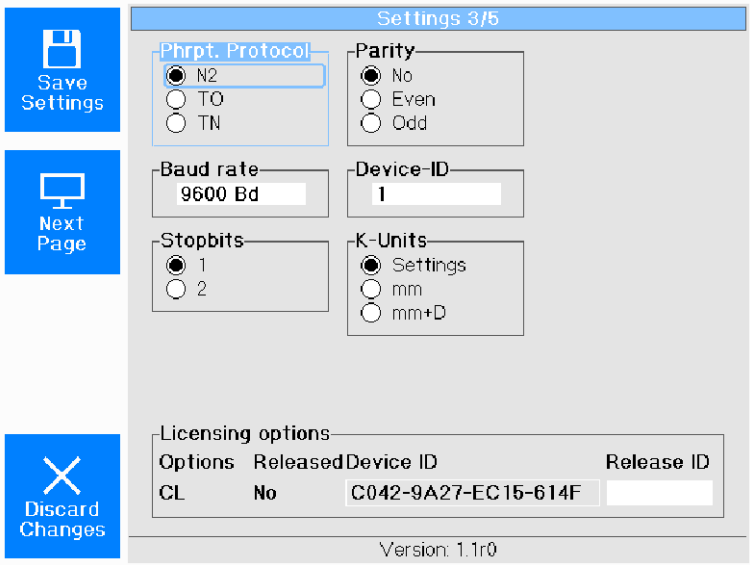


Fig. 15-4: Settings 3

Examples of communication parameters of phoropters that are supported by Myopia Master® (Status: December 2019):

Manufacturer	Phoropter	Baud rate	Parity	Stop bits	Phrpt.protocol
Nidek	RT-5100 RT-2100 RT-1200S	9600	uneven	1	N2
Topcon	CV-5000	9600/2400	none	2	TN

Fig. 15-5: Parameters for phoropters supported by Myopia Master®

In the "Device-ID" field, you identify the Myopia Master® that is connected to a phoropter. Assign a Device-ID, e.g. when multiple devices are connected to a phoropter.

15.4 Settings 4

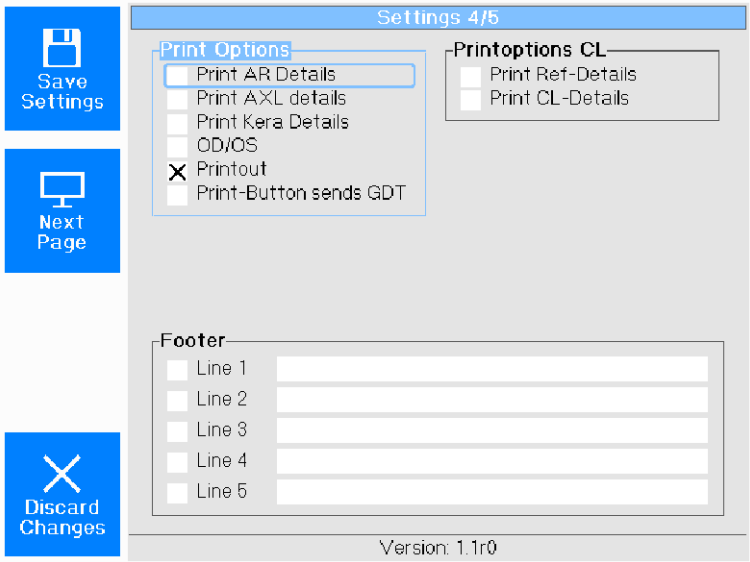


Fig. 15-6: Settings 4

On the "Settings 4" screen, you can individually configure the printout.

Print AR Details

Refraction (VD=12 mm):

S	C	A	Q
-0.71	-0.25	18°	9
-0.66	-0.06	8°	8
-0.52	-0.02	42°	8
-0.63	-0.10	18°	8

Print AR Details: activated

Refraction (VD=12 mm):

S	C	A	Q
-0.71	-0.25	18°	9

Print AR Details: activated

Print Keratometer Details

Keratometry:

Rh:	6.55 mm / 51.5 D @ 29 °
Rv:	6.64 mm / 50.8 D @ 119 °
Rm:	6.60 mm / 51.2 D
Astig:	0.7 D
WTW:	11.9 mm
Pupil:	6.0 mm
Q:	9

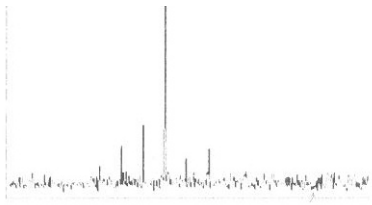
Print single line K-Values: activated

Print AXL Details

Achslaenge:

AXL	SNR
25.197 mm	9.1
25.252 mm	6.8
25.201 mm	13.9
25.038 mm	6.8
25.172 mm	13.9

Print AXL Details: activated



SNR graph: activated

- Print Ref Details
  Refraction details (objective / subjective / corrected measurement are also printed out).
- Footer in the printout
  If you want to include your business or office name on the printout: Enter the appropriate information in the lines provided for that purpose and activate the checkboxes in front of each line.

OD/OS

According to the settings R (right) and L (left) is printed out or OD (oculus dexter) and OS (oculus sinister).

15.5 Settings 5

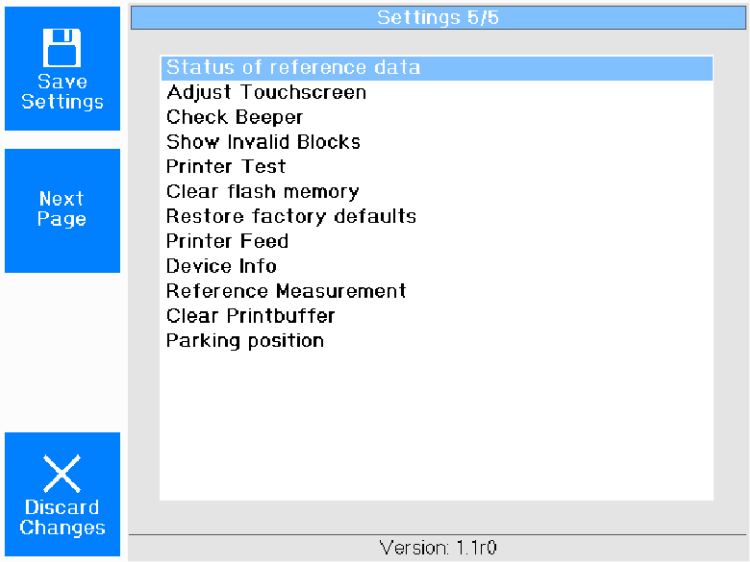


Fig. 15-7: Settings 5

16 Display Options

In addition to the overview of the measuring results for an eye *(fig. 12-5, page 32)*, you can also select other display settings.

➔ To access the available, press the [Display] button repeatedly.

Examination results for both eyes: Refraction and Keratometry

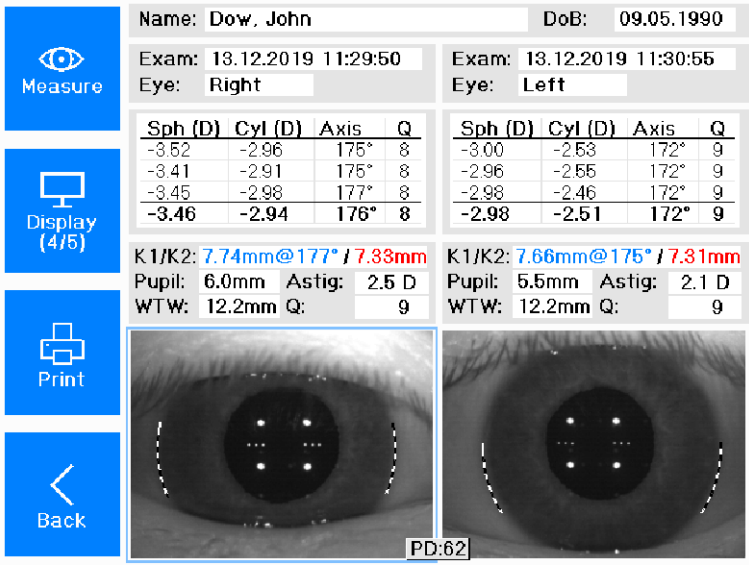
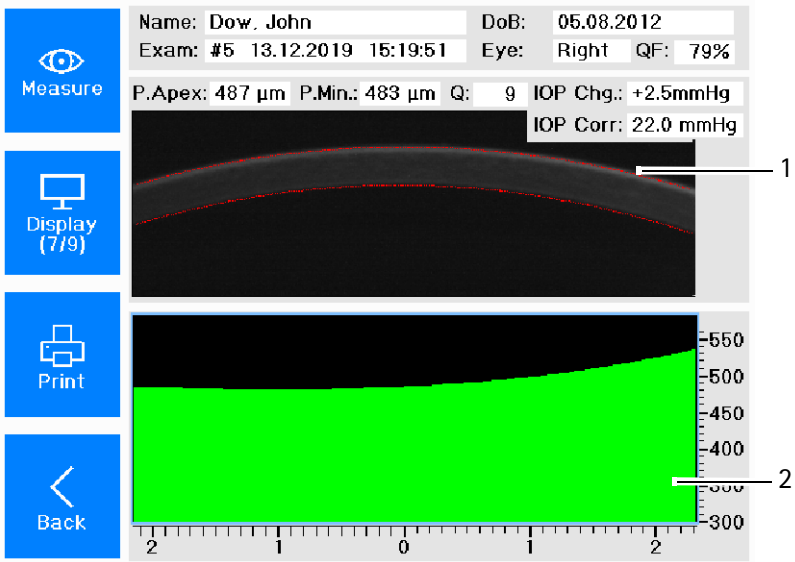
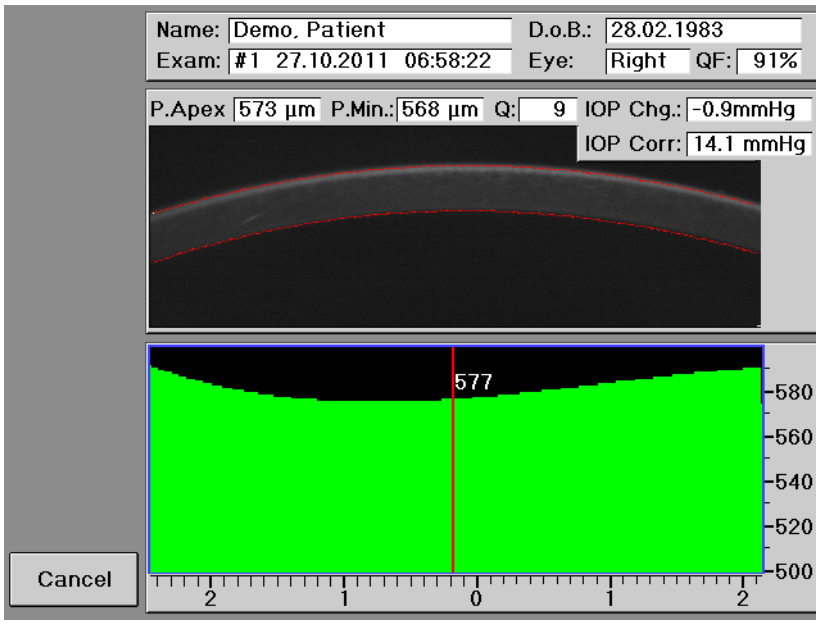


Fig. 16-1: Standard - Right and Left

Display of Pachymetry



1 Scheimpflug image
2 Corneal thickness range
(Measuring range: horizontal 4mm section through the apex)
Fig. 16-2: Overview Pachymetry



➔ Press in the "Corneal thickness progression" field on the touch screen.

The device shows you the exact location of the cornea at the selected spot.

You can move the pointer to the left or to the right on the touch screen with the rotary knob.

17 Calculated correction of tonometrically measured IOP

Independent studies have shown that tonometric measurements of intraocular pressure (IOP) are influenced by the thickness and curvature of the cornea in its center. This systematic measurement error can only be eliminated by calculation. This holds regardless of whether measurements have been performed with an applanation tonometer or a noncontact tonometer.

The Myopia Master® software provides a means of saving a tonometrically measured IOP value obtained in a seperate examination and correcting the value on the basis of the corneal thickness of that eye as measured with the Myopia Master®. This can be done using any of the various correction formulas available for this purpose. These formulas are described further below, and some are illustrated with diagrams.

17.1 IOP correction based on central corneal thickness

The correction formulas of Shah and Ehlers as well as the Dresden correction formula are estimates of the true IOP based on measured IOP and corneal thickness.

Correction is achieved by adding a correction summand, which is referred to as IOP change and is a function of corneal thickness, to the measured IOP:

$$IOP_{corrected} = IOP_{measured} + IOP - change$$

The calculation of this summand is based on a mean thickness value for which the summand assumes the value zero, i.e. where the measured pressure need not to be corrected. Within a range of approx. ±70µm around this thickness value the correction summand changes linearly with corneal thickness, while for thicknesses above or below this range a linear relationship has not been confirmed.

The diagram below shows the progression of the correction summand over a range of corneal thickness as given by the three formula:

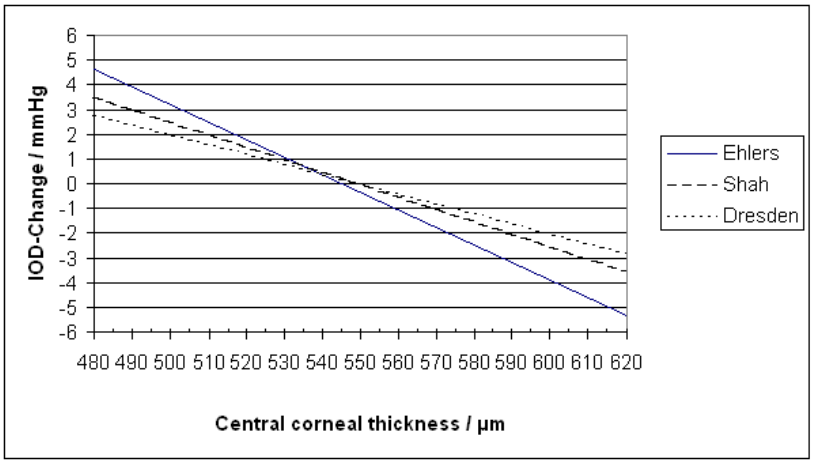


Fig. 17-1: Progression-diagram

Each formula gives a different way of calculating the IOP correction summand, as follows:

- Ehlers: IOP change = 0.071 * (545 µm - corneal thickness$_{measured}$)
- Shah: IOP change = 0.050 * (550 µm - corneal thickness$_{measured}$)
- Dresden: IOP change = 0.040 * (550 µm - corneal thickness$_{measured}$)

17.2 Post-LASIK IOP correction

The Kohlhaas-formula estimates the true IOP concerning post-LASIK, myopic patients.

17.3 IOP correction based on central corneal thickness and corneal curvature

The formula developed by Orssengo and Pye considers not only the corneal thickness but also the corneal curvature in calculating the corrected IOP.

This yields a factor with which the true IOP can be estimated from the measured IOP. In contrast to those quoted above this formula includes the measured IOP as a parameter in calculating the corrected IOP.

It thus involves a larger number of input variables, which according to its originators permits a more precise estimate of IOP regardless of corneal thickness.

With this formula the correction factor, or IOP change, is calculated as follows:

$$IOD_{corrected} = IOD_{corrected} \cdot k$$

$$k = \frac{B}{B_c - C_c + C} = \textit{correction factor} \quad (IOD - \textit{change})$$

$$B_c = \frac{0.6\pi R_c\left(R_c - \frac{t_c}{2}\right)\sqrt{1-\nu_c^2}}{t_c^2} = 324.8117$$

R_c =7.8 mm mean apical radius of curvature

t_c = 0.545 mm mean corneal thickness

ν_c = 0.49 = Poisson number

$$C_c = \frac{\pi R_c\left(R_c - \frac{t_c}{2}\right)^2(1-\nu_c)}{A \cdot t_c} = 176.7797$$

A = 7.35 mm² (flattened corneal surface)

$$B = \frac{0.6\pi R\left(R - \frac{t}{2}\right)\sqrt{1-\nu^2}}{t^2}$$

R = measured corneal radius of curvature in mm

t = measured corneal thickness

$\nu = \nu_c$ =Poisson number

$$C = \frac{\pi R\left(R - \frac{t}{2}\right)^2(1-\nu)}{A \cdot t}$$

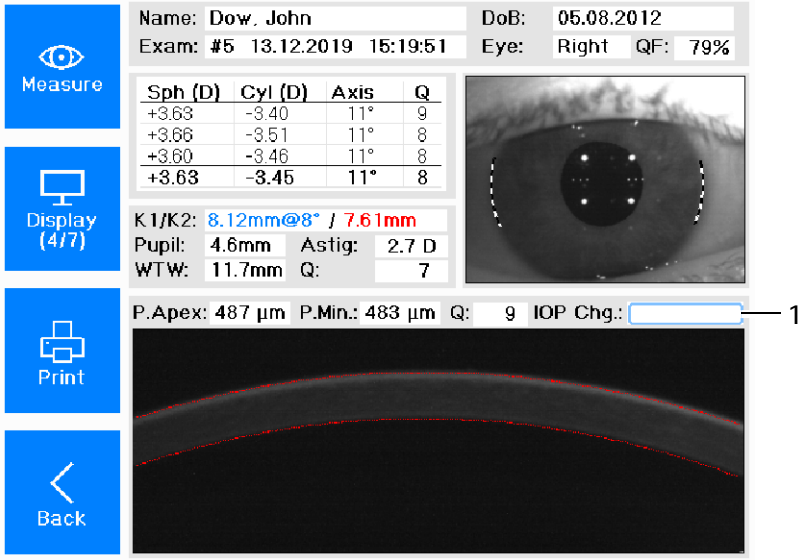
Fig. 17-2: Correction formula

17.4 Performing IOP correction with the Myopia Master®

➔ Select an IOP-Table in the menu "Settings 1" *(sec. 15.1, page 52)*.

➔ Perform a P+AR+K or a PARK + AXL measurement *(sec. 12, page 28)*.

The results screen appears for the examined eye:



1 IOP change field

Fig. 17-3: IOP change

The IOP change value is displayed in the IOP change field (1). Depending on the formula which is used, the IOP change value is either a summand or a factor.

➔ Turn the control wheel until the "IOP Chg." field is activated.

➔ Press the control wheel.

The field for entering the tonometrically measured IOP value appears:

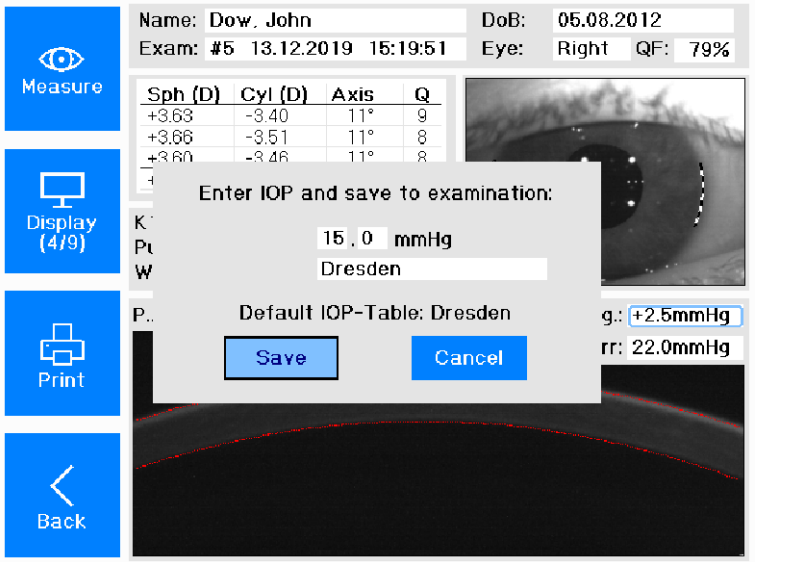


Fig. 17-4: Entering tonometrically measured IOP manually

Note

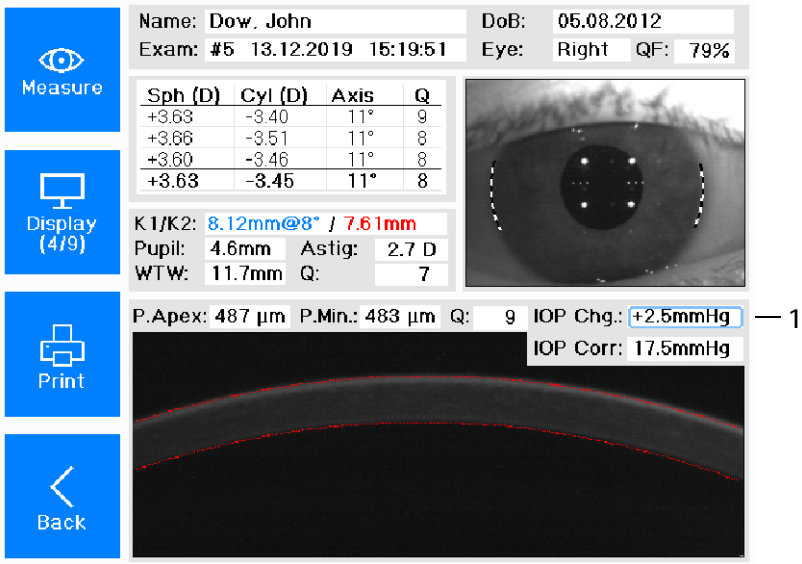
By default, the IOP correction is calculated by the correction formula, which was selected in the settings.

If another formula should be used (for example myopic post-LASIK), you can select it on the screen of the IOP correction.

➔ Enter the IOP value by pressing and turning the control wheel.

➔ Confirm the IOP value with the button [Save].

The corrected IOP value appears:



1 Corrected IOP value

Fig. 17-5: Corrected IOP

17.4.1 Save the IOP data

➔ Store the patient data of the examination *(fig. 12-5, page 32)*.

➔ Printout the data.

On the printout you can find the following IOP values:

- IOP-Table
- IOP Change
- IOP Measured
- IOP corrected

18 Cleaning, Disinfection and Maintenance

This chapter describes how to clean, disinfect, and maintain the Myopia Master®.

Sterilization is not required.

➔ Always pay attention to the product descriptions and instruction manuals of any materials or products that you use to care for, clean, and disinfect the device and/or its accessories.

Note

Equipment damage due to moisture

➔ Make sure that no liquid can get into the Myopia Master®.

18.1 Cleaning

Caution

Risk of electric shock if the Myopia Master® is not completely disconnected from the mains for the cleaning.

➔ Turn the Myopia Master® off, *sec. 9.2, page 20*.

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

➔ Do not clean the Myopia Master® with aggressive, chlorinated, abrasive or harsh cleansers.

Required materials:

- Cleaner for plastic surfaces with anti-static effect
- Cleaner for painted surfaces: Mixture of equal parts of alcohol and distilled water, possibly with a few drops of commercial detergent
- Soft, lint-free cloth
- Methanol or pure alcohol or lens cleaner
- Gauze moistened with rubbing alcohol
- Soap solution

Cleaning intervalls

➔ Clean the chin rest an head reat after each examination, clean the housing once a month or if necessary.

1 Head rest
2 Protective glass covers
3 Chin rest
Abb. 18-1: Cleaning

Cleaning head rest and chin rests

The Myopia Master®can be switched on for cleaning the head rest and chin rest.

During the measuring process, sweat, cosmetics, etc. from the patient can get on the head and chin rest.

➔ Clean these parts before examining the next patient. Use a lint-free, damp cloth.

Do not wipe more difficult spots repeatedly with a dry cloth. Instead moisten it with rubbing alcohol.

Protective glass covers for the optics

The openings in the housing for the optics are covered by protective glass covers which must be kept dust- and dirt-free.

➔ If they are dirty, clean the lens protection glass with a lint-free cloth moistened with alcohol.

Cleaning the Housing

➔ Clean the housing once a month or if necessary.

➔ Turn the Myopia Master® off, *sec. 9.2, page 20*.

➔ If it is dirty, it is best to clean the housing plastic surfaces with a soft cloth and an anti-static cleaning agent.

➔ Make sure that no liquid gets into any of the openings of the Myopia Master®.

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

Cleaning the Touch Screen

➔ Clean the touch screen using a dry, lint-free cloth.

18.2 Disinfection

Caution

Risk of electric shock if the Myopia Master® is not completely disconnected from the mains for the disinfection.

➔ Turn the Myopia Master® off, *sec. 9.2, page 20*.

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

Required material:

- Mikrozid sensitive wipes premium
  Fa. Schülke & Mayr
  Softpack 48 pieces
  Art.Nr. 165711
  Schülke & Mayr GmbH
  Telefon: +4940521000
  Telefax: +494052100318
  mail@schuelke.com
  www.schuelke.com

Caution

Risk of infection after conducting a measurement on a sick patient.

If you have conducted a measurement on a sick patient, the headrest, chin rest or the housing could be contaminated.

- ➔ Disinfect the headrest after every examination and the housing whenever necessary.
- ➔ If you do not use a paper liner for the chin rest: Disinfect the chin rest after every examination.

Note

Equipment damage caused by disinfectant solution

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

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

18.3 Maintenance

The Myopia Master® is designed so that no special maintenance is necessary. For safety reasons, we recommend that the illumination and electrical values be checked every two years.

- ➔ Please contact OCULUS Service for this.

Note

Incorrect examination results due to a damaged device

If you use a damaged device, your examination results may be incorrect.

If a fault occurs that you cannot rectify:

- ➔ Label a damaged Myopia Master® as non-operational.
- ➔ Report the damage to OCULUS Service or to your authorised dealer.
- ➔ Only use an undamaged Myopia Master®.

Additional measures are not required during preventive maintenance.

Caution

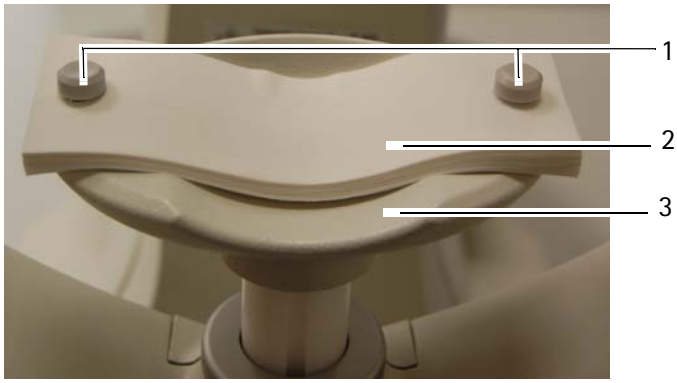
Risk of personal injury or material damage due to invisible laser radiation

The Myopia Master® contains a Class 1 laser according to DIN EN 60825-1:2015 and DIN EN 60825-1: 2001. It is an encapsulated laser system. When the Myopia Master® cover is opened, you may be exposed to invisible, Class 3R (5 mW) laser radiation.

- ➔ Never open the unit.
- ➔ For authorized service personnel only: When doing maintenance jobs, avoid looking directly into the laser beam.

18.4 Attaching Paper to the Chin Rest

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



1 Pins
2 Chin rest paper
3 Chin rest

Fig. 18-2: Attaching chin rest paper

- ➔ Pull the two pins (1) out of the chin rest.
- ➔ Put the chin rest paper (2) in such a way that the holes of the paper and the chin rest (3) are aligned.
- ➔ Insert the two pins (1) in the chin rest.

18.5 Inserting a New Roll of Printer Paper

Caution

Risk of electric shock if the Myopia Master® is not completely disconnected from the mains

- ➔ Turn the Myopia Master® off, *sec. 9.2, page 20*.
- ➔ Pull the power plug before inserting a printer paper. When disconnecting electrical connections, pull on the respective plug and not on the cable itself.

➔ Flip up the display

Fig. 18-3: Display for advancing and reversing the feed roller

You can advance and reverse the printer paper by pressing the buttons "Printer Feed" and "Feed Back" accordingly.

- To change the printer paper:

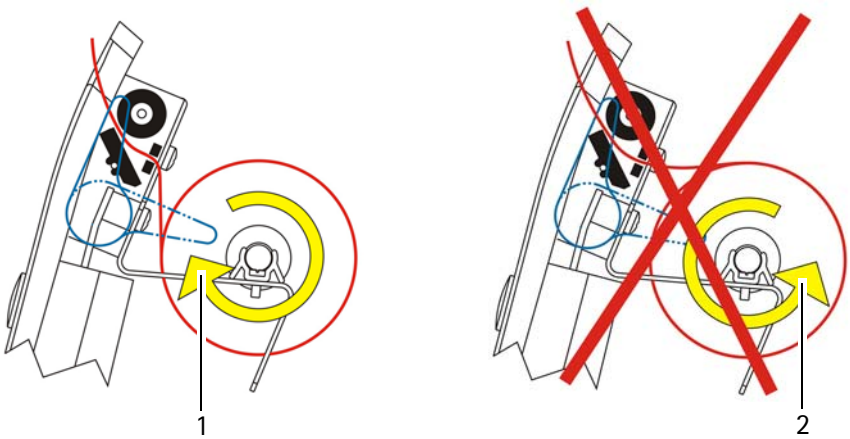
➔ Press "Feed Back" to reverse, or roll back the printer paper.

➔ Remove the feed roller from the holder and pull out the middle metal pin.

➔ Push the metal pin into a new feed roller and insert the feed roller into the holder.

➔ Slide the paper from below through the paper guide.

➔ Make sure the paper (1) is correctly aligned.



1 Proper paper guide

2 Wrong paper guide

Fig. 18-4: Inserting the paper

➔ Press the button "Printer Feed" so that the printer paper is pulled through the opening.

➔ Close the opened display unit.

19 Troubleshooting

Caution

Risk of personal injury or equipment damage due to improper troubleshooting

- ➔ Do not plug in or pull out any cables while the Myopia Master® is switched on.
- ➔ If an error occurs which you are unable to correct by following the instructions below, label the device as "out-of-order" and contact our service department or an authorized dealer.

Damage to the device cause by improper operation

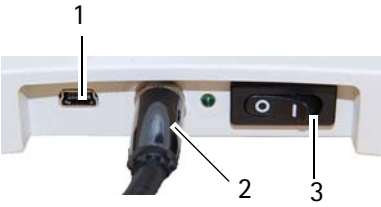
- ➔ Never plug in or unplug the cable or plug while the PC and/or the Myopia Master® are switched on. This could destroy the individual units.

Error	Possible Cause	Remedy
No function when the On/Off Switch is pressed	The Myopia Master® is not connected to the power supply.	Plug the power cable into the power outlet, or into the port at the Myopia Master®. Inform the in-house electrician.
	Power failure or power outlet is not active.	Check that the connector is plugged in properly.
The printer is not printing.	No paper.	Insert a new roll of paper.
Printout has red stripes on it.	End of the paper roll.	Insert a new roll of paper.

20 Dismantling, Transport and Storage

The Myopia Master®, must be properly dismantled and packed before being transported or stored.

20.1 Disassembly



- ➔ End the current session.
- ➔ Switch off the Myopia Master® with the On/Off Switch.
- ➔ Unplug the power cord.
  When disconnecting electrical connections, pull on the respective plug and not on the cable itself.
- ➔ Pack the Myopia Master® with the original packaging.

20.2 Transport and Storage Information

This device cannot withstand the temperature conditions for storage and transport specified in ISO 15004-1.

Storage

Ambient temperature range	-10°C to +55°C
Relative humidity, including condensation	10% to 95%
Air pressure range	700 hPa to1060 hPa

Transport

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

20.3 Transport and Storage

Caution

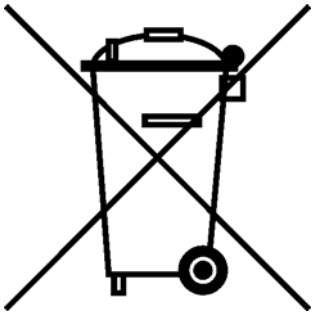
Risk of equipment damage due to incorrect shipment or from improper storage

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

- ➔ Transport the Myopia Master® carefully.

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

21 Disposal



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

- Dispose the Myopia Master® in a compliant manner.

22 Terms of Warranty and Servicing

22.1 Terms of Warranty

Please note the following warranty provisions:

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

22.2 Assumption of Liability for Functions and Damage

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

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

22.3 Manufacturer and Service Address

Supplemental information is available from our Service Department or from our authorized representatives.

Manufacturer and Service address:

OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29
35582 Wetzlar
GERMANY
Tel. +49 641 2005-0
Fax +49 641 2005-295
E-Mail: export@oculus.de
www.oculus.de

USA:

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

23 Technical Data

Measuring modes

Myopia, AR + K, P + AR + K, PARK + AXL, AXL	

Measuring range

Distance-pD	20 up to 80 mm (in 1mm steps)
Measuring range Cornea diameter	10 up to 14 mm (in 0,1 steps)
Measuring range pupil diameter	1 up to 8 mm (in 0,1 steps)
Auto-Position	Positioning the height automatically (y direction)
Auto-Release	Automatic release

Pachymeter

Measuring range	200 – 1200 µm
Measured points	600
Measuring time	approx. 1 s
Light source	blue LED (455 nm, UV free)

Autorefractometer

Corneal vertex distance (VD)	0; 10,5; 12; 13,75; 15; 16,5 mm
Sphere	-20 — +22 D (VD = 12 mm) (increments: 0.01; 012; 0.25 D)
Cylinder	10 D (VD = 12 mm) (increments: 0,01; 0,12; 0,25 D)
Axis	1 — 180° (increments: 1°)
Minimum pupil diameter	2.5 mm

Axial length

Axial length	14 – 40 mm

Classification according to IEC 60601 - 1

Protection against electric shock: Protection class	2
Insulation of applied parts: Type	Type B
Protection against foreign objects, contact and water	IP20

Ambient operating requirements

Temperature	+10 – +35 °C
Humidity	30 – 90%
Air pressure	800 – 1060 hPa

Storage requirements

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

Transport requirements

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

Power adapter

Netzteil	GSM60B15-P1J (05150725)
AC input	80 – 264 VAC
Frequency	47 – 63 Hz
DC output	15 V DC/4 A, 60 W max.
Fuses	Integrated overcurrent shut-off

General

Dimensions height x width x depth	266 x 538 x 493 – 523 mm
Weight	12 kg
Voltage	15 V DC/4 A
Max. power consumption	25 W
Printer	thermal-printer
Display	TFT - LCD 5.7" (touch screen)
Interface (s)	USB
Contraindications	None Noted
Lifecycle expectancy	Up to ten years

Computer

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

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

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

The unit is a Class IIa product.

CE 0123

Conformity assessment: Directive 93/42 / EEC: Annex II without section 4.

Classification according to DIN EN 60825-1:2015 and DIN EN 60825-1: 2001

The unit contains a Class 1 laser.	
Maximum output of the laser radiation	0.7 mW
Single pulse duration Pulse count per examination	510 – 760 ms 6x
Wavelength	880 nm

24 Annex

24.1 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.

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

Portable and mobile RF-communications devices can interfere with electrically operated medical devices.

Produced in the consideration of permissible deterioration during or caused by t7he EMC testing without affecting the essential performance criteria.

Caution

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

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

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

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

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

Order number	Description	
68100	Myopia Master® Advanced, with chin and head rest, with Scheimpflug camera (fully equipped)	
68110	Myopia Master® Advanced, without chin and head rest, with Scheimpflug camera	
68120	Myopia Master® Basic, with chin and head rest, without Scheimpflug camera	
68130	Myopia Master® Basic, without chin and head rest, without Scheimpflug camera	
5200905	Cable, EU	1.8 m
5200915	Cable, GB (optional)	1.8 m
5200910	Cable, USA (optional)	1.8 m
5200920	Cable, AU (optional)	1.8 m
5200925	Cable, Argentinia (optional)	1.8 m
05150725	Power adapter GSM60B15-P1J	
015692000010	USB FS MED-Isolator	
05200600	USB mini cable	1 m (39.4 in)

24.2 Guidance and Manufacturer's Declaration - Electromagnetic Emmisssions and Immunity for the Myopia Master®

Guidance and manufacturer´s declaration electromagentic emmissions IEC 60601-1-2: 2015, based to table 1		
The OCULUS Myopia Master® is intended for operation in the electromagnetic environment specified below. The user of the Myopia Master® should ensure that it is being used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The Myopia Master® 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	

Electromagentic immunity, IEC 60601-1-2: 2015, based on table 4			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV ± 15 kV	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30%.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Electromagentic immunity, IEC 60601-1-2: 2015, based on table 5, 8			
Electrical Fast transient/bursts IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	± 2 kV ---------- ± 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV kine(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	0% U_τ; 1/2 period at 0, 45, 90, 135, 180, 225, 270 and 315 degree 0% U_τ; 1 period and 70% U_τ; 25/30 periods Single-phase: at 0 degree 0% U_τ; 250/300 periods	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Myopia Master® requires continued operation during power mains interruptions, it is recommended that the Myopia Master® be powered from an uninterruptible power supply or battery.
Note: U_τ is the a.c. mains voltage prior to application of the test level.			

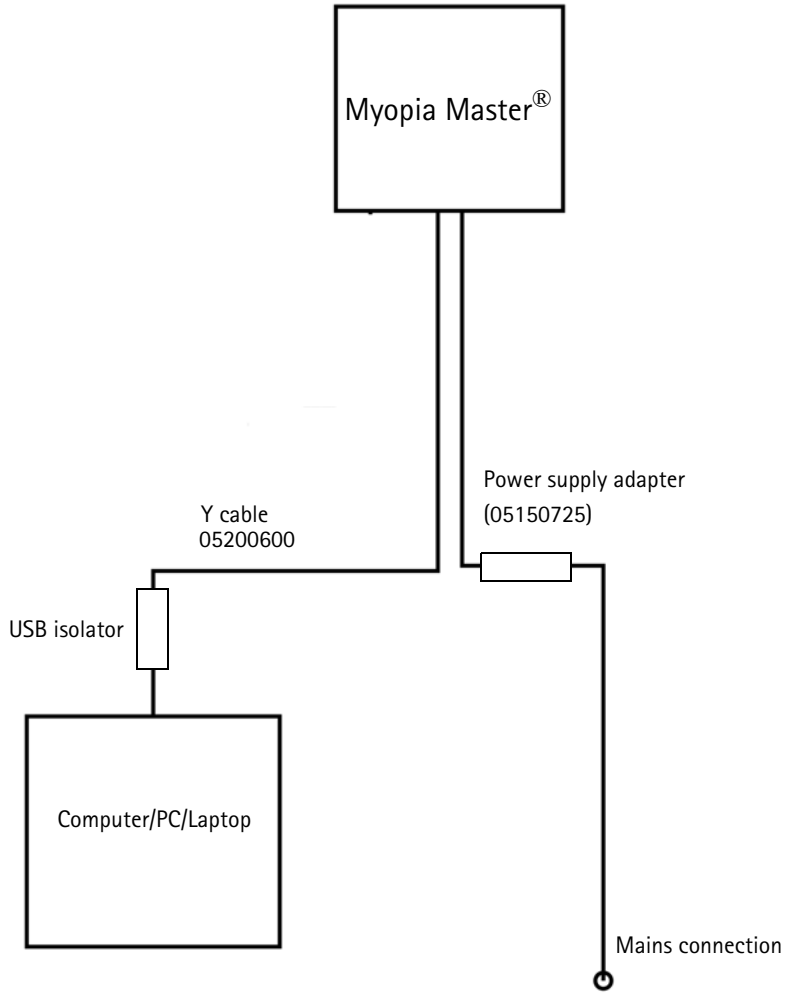
Electromagentic immunity, IEC 60601-1-2: 2015, based on table 4, 5			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidelines**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	$3\ V_{eff}$ 150 KHz to 80 Mhz 6 V in ISM- and amateur radio frequency bands between 150 kHz and 80 MHz 80% AM to 1 kHz 3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	$V_{eff} = 3\ V$	Portable and mobile RF communications equipment should be used no closer to any part of Myopia Master®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{(V_1)}\right]\sqrt{P}$ $d = \left[\frac{3,5}{(E_1)}\right]\sqrt{P}$ 80MHz to 800 MHz $d = \left[\frac{7}{(E_1)}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interferences may occur in the vicinity of equipment marked with the following symbol: 
Note 1: Note 2:	At 80 Hz and 800 MHz, the higher frequency range applies. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength in the location in which the Myopia Master® is used exceeds the applicable RF compliance level above, the Myopia Master® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Myopia Master®.

b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Myopia Master®, IEC 60601-1-2:2007, table 6			
The Myopia Master® in intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Myopia Master® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Myopia Master® as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 KHz to 80 Mhz d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHz to 2.5 GHz d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

24.3 Description of the Connection



24.4 Data Sheet GSM60B15-P1J (05150725)

MEAN WELL

60W AC-DC High Reliability Medical Adaptor **GSM60B series**

(V for 5~9V)

Features

- Universal AC input / Full range
- 2 pole AC inlet IEC320-C8
- Medical safety approved (2 x MOPP between primary to secondary)
- Suitable for BF application with appropriate system consideration
- Low leakage current <50uA
- No load power consumption<0.1W
- Energy efficiency level VI(Except 5~9V for Level V)
- Comply with EISA 2007/DoE,NRCan, AU/NZ MEPS, EU ErP and meet CoC Version 5
- Built-in active PFC function
- High efficiency up to 91.5%
- Fanless design with -30~+60℃ working temperature
- Class Ⅱ power (without earth pin)
- Protections: Short circuit / Overload / Over voltage / Over temperature
- Fully enclosed plastic case
- LED indicator for power on
- 100% full load burn-in test
- Optional lock type DC plug
- 3 years warranty

Applications

- Mobile clinical workstation
- Oral irrigator
- Portable hemodialysis machine
- Breath Machine
- Medical computer monitor

Description

GSM60B is a highly reliable, 60W desktop style single-output green medical adaptor series. This product is equipped with a 2-pin (no FG) standard IEC320-C8 power plug, adopting the input range from 80VAC to 264VAC. The entire series supplies different output voltages between 5VDC and 48VDC that can satisfy the demands for various kinds of medical electrical devices. The circuitry design meets the international medical standards (2*MOPP), having an ultra low leakage current (<50 uA), fitting the medical devices in direct electrical contact with the patients.

With the efficiency up to 91.5% and the extremely low no-load power consumption below 0.1W, GSM60B is compliant with USA EISA 2007/DoE, Canada NRCan, Australia and New Zealand MEPS, EU ErP,and meet Code of Conduct (CoC) Version 5. The supreme feature allows the adaptor to save the energy when it is either under the operating mode or the standby mode. The entire series utilizes the 94V-0 flame retardant plastic case, providing the double insulation that effectively prevents electrical shock. GSM60B is approved with the international medical safety certificates.

Model Encoding

GSM60 B 05 - P1J

- DC plug type: P1J: Plug for standard model,2.1ψ x5.5ψ x11mm,c+,tuning fork type; Optional plug type available by customer requested
- Output voltage
- IEC320-C8 AC inlet
- Output wattage
- Series name

File Name:GSM60B-SPEC 2016-03-16

MEAN WELL

60W AC-DC High Reliability Medical Adaptor **GSM60B series**

SPECIFICATION

ORDER NO.		GSM60B05-P1J	GSM60B07-P1J	GSM60B09-P1J	GSM60B12-P1J	GSM60B15-P1J	GSM60B18-P1J	GSM60B24-P1J	GSM60B48-P1J
OUTPUT	SAFETY MODEL NO.	GSM60B05	GSM60B07	GSM60B09	GSM60B12	GSM60B15	GSM60B18	GSM60B24	GSM60B48
	DC VOLTAGE Note.2	5V	7.5V	9V	12V	15V	18V	24V	48V
	RATED CURRENT	6A	6A	6A	5A	4A	3.33A	2.5A	1.25A
	CURRENT RANGE	0 ~ 6A	0 ~ 6A	0 ~ 6A	0 ~ 5A	0 ~ 4A	0 ~ 3.33A	0 ~ 2.5A	0 ~ 1.25A
	RATED POWER (max.)	30W	45W	54W	60W	60W	60W	60W	60W
	RIPPLE & NOISE (max.) Note.3	100mVp-p	100mVp-p	100mVp-p	100mVp-p	100mVp-p	150mVp-p	180mVp-p	240mVp-p
	VOLTAGE TOLERANCE Note.4	±5.0%	±5.0%	±5.0%	±3.0%	±3.0%	±3.0%	±3.0%	±2.5%
	LINE REGULATION Note.5	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%	±1.0%
	LOAD REGULATION	±5.0%	±5.0%	±5.0%	±3.0%	±3.0%	±3.0%	±3.0%	±2.5%
	SETUP, RISE TIME Note.6	1000ms, 30ms / 230VAC 1500ms, 30ms / 115VAC at full load							
	HOLD UP TIME (Typ.)	50ms / 230VAC 15ms / 115VAC at full load							
INPUT	VOLTAGE RANGE Note.7	80 ~ 264VAC 120 ~ 370VDC							
	FREQUENCY RANGE	47 ~ 63Hz							
	EFFICIENCY (Typ.)	81.5%	86%	87.5%	88%	88.5%	89%	90%	91.5%
	AC CURRENT (Typ.)	1.4A / 115VAC 1A / 230VAC							
	INRUSH CURRENT (Typ.)	30A / 115VAC 65A / 230VAC							
	LEAKAGE CURRENT(max.)	Touch current < 50μA/264VAC							
PROTECTION	OVERLOAD	105 ~ 160% rated output power							
		Protection type : Hiccup mode, recovers automatically after fault condition is removed							
	OVER VOLTAGE	5.25 ~ 6.75V	7.88 ~ 10.13V	9.45 ~ 12.15V	12.6 ~ 16.2V	15.75 ~ 20.25V	18.9 ~ 24.3V	25.2 ~ 32.4V	50.4 ~ 64.8V
		Protection type : Shut down o/p voltage, re-power on to recover							
	OVER TEMPERATURE	Shut down o/p voltage, re-power on to recover							
ENVIRONMENT	WORKING TEMP.	-30 ~ +60℃ (Refer to "Derating Curve")							
	WORKING HUMIDITY	20% ~ 90% RH non-condensing							
	STORAGE TEMP., HUMIDITY	-40 ~ +85℃, 10 ~ 95% RH							
	TEMP. COEFFICIENT	±0.03% / ℃ (0 ~ 40℃)							
	VIBRATION	10 ~ 500Hz, 2G 10min./1cycle, period for 60min. each along X, Y, Z axes							
SAFETY & EMC (Note. 8)	SAFETY STANDARDS	ANSI/AAMI ES60601-1 / ES60601-1-11, TUV EN60601-1 / 60601-1-11 approved							
	ISOLATION LEVEL	Primary-Secondary: 2xMOPP							
	WITHSTAND VOLTAGE	I/P-O/P:4KVAC							
	ISOLATION RESISTANCE	I/P-O/P:100M Ohms / 500VDC / 25℃/ 70% RH							
	EMC EMISSION	Compliance to EN55011(CISPR11) class B, EN61000-3-2,3, FCC PART 15 class B,CAN ICES-3(B)/NMB-3(B)							
	EMC IMMUNITY	Compliance to EN61000-4-2,3,4,5,6,8,11, EN55024, EN60601-1-2, EN61204-3 medical level, criteria A							
OTHERS	MTBF	720K hrs min. MIL-HDBK-217F(25℃)							
	DIMENSION	125*50*31.5mm (L*W*H)							
	PACKING	0.32Kg; 40pcs/13.8Kg/1.05CUFT							
CONNECTOR	PLUG	See page 3 ; Other type available by customer requested							
	CABLE	See page 3 ; Other type available by customer requested							

NOTE

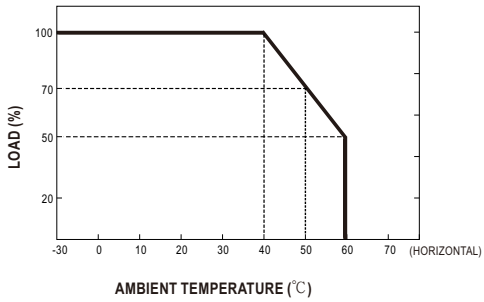
1. All parameters are specified at 230VAC input, rated load, 25℃ 70% RH ambient.
2. DC voltage: The output voltage set at point measure by plug terminal & 50% load.
3. Ripple & noise are measured at 20MHz by using a 12" twisted pair terminated with a 0.1uf & 47uf capacitor.
4. Tolerance: includes set up tolerance, line regulation, load regulation.
5. Line regulation is measured from low line to high line at rated load.
6. Length of set up time is measured at first cold start. Turning ON/OFF the power supply may lead to increase of the set up time.
7. Derating may be needed under low input voltages. Pleas check the derating curve for more details.
8. The power supply is considered as an independent unit, but the final equipment still need to re-confirm that the whole system complies with the EMC directives. For guidance on how to perform these EMC tests, please refer to "EMI testing of component power supplies." (as available on http://www.meanwell.com)

File Name:GSM60B-SPEC 2016-03-16

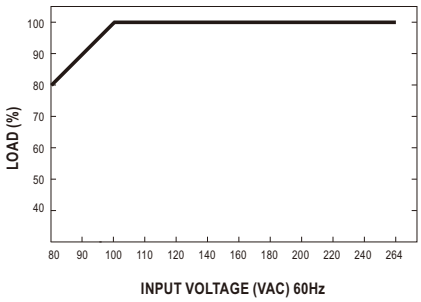
MEAN WELL

60W AC-DC High Reliability Medical Adaptor **GSM60B series**

■ Derating Curve

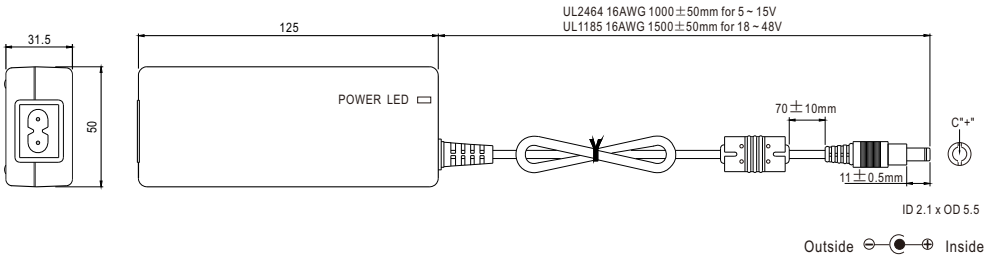


■ Static Characteristics



■ Mechanical Specification

Case No. GSM60B Unit:mm



■ Plug Assignment

Standard plug: P1J

P1J	
P/N	OUTPUT
CENTER	+

Optional lock type plug: P2S
SWITCHCRAFT S761K plug equivalent

■ Installation Manual

Please refer to : http://www.meanwell.com/webnet/search/InstallationSearch.html

File Name:GSM60B-SPEC 2016-03-16

Manufacturer and Service Address

Headquarters:
OCULUS Optikgeräte GmbH
Münchholzhäuser Straße 29 • 35582 Wetzlar • GERMANY
Tel. +49 641 2005-0 • Fax +49 641 2005-295
E-Mail: export@oculus.de • www.oculus.de

USA:
OCULUS, Inc.
17721 59th Avenue NE • Arlington • WA 98223
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