OCULUS
Myopia Master®

Instruction for Use

OCULUS®

Preface

The Myopia Master® was manufactured and tested based on strict quality criteria. Proper use of the device is essential for ensuring safe operation. For this reason, please thoroughly familiarize yourself with the content of this instruction manual prior to commissioning. In particular, observe the safety instructions.

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

- **Instruction for Use:** Describes the layout of the device, contains all safety-related instructions for handling the device and guides you through the measuring procedure. Contains basic instructions for handling patient data management.

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

- **User Guide:** Contains information that goes beyond the operating concept and describes all options in the examination and evaluation software. Contains further instructions for patient data management.
- **Interpretation Guide:** Intended to assist with interpreting measurement results and graphic illustrations that are created using the device.
- **Software Installation:** Describes how to install the software and the relevant drivers.
- **Floating License Key:** Informs you of how you can use the device within a network.

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

OCULUS Optikgeräte GmbH

Article number: G/68100/EN
Revision: Rev12
Release: 04/05/2026

Table of contents

1 Scope of Delivery

Product and accessories
Version:
■ Myopia Master® Advanced with chin and forehead rest (not available) including automatic refractometer, keratometer, axis length, pachymetry
■ Myopia Master® Advanced without chin and forehead rest (not available) including automatic refractometer, keratometer, axis length, pachymetry
■ Myopia Master® Basic with chin and forehead rest including automatic refractometer, keratometer, axis length
■ Myopia Master® Basic without chin and forehead rest including automatic refractometer, keratometer, axis length
■ Myopia Master® Optiswiss with chin and forehead rest (only available from Optiswiss AG) including automatic refractometer, keratometer, axis length
■ Black eye patch
■ Dust cover
■ Chin rest paper
■ Printer paper (3 rolls)
■ USB-mini cable
■ USB FS MED isolator
■ Power adapter
■ Cable, EU
■ Cable, GB (optional)
■ Cable, USA (optional)
■ Cable, AU (optional)
■ Cable, Argentina (optional)
■ Test eye
■ Software installation
■ Instruction for Use

➔ If you discover any transport damage on delivery, submit a complaint to the transport company immediately.

➔ Have the driver confirm the damage on the delivery note to ensure that proper claims can be settled.

➔ Retain the packaging. You can use it to send or transport the device properly in the event of service or repair situations. You can avoid unnecessary damage and costs in this way.

Note

We reserve the right to change the scope of delivery during the course of technical development.

2 Safety

- ➔ Read the Instruction for Use carefully.
- ➔ Store the Instruction for Use carefully near the device.
- ➔ Observe the legally applicable accident prevention regulations.
- ➔ If standards are specified without a date of publication, the current version applies.

2.1 Symbols

2.1.1 On the Device and the Nameplate

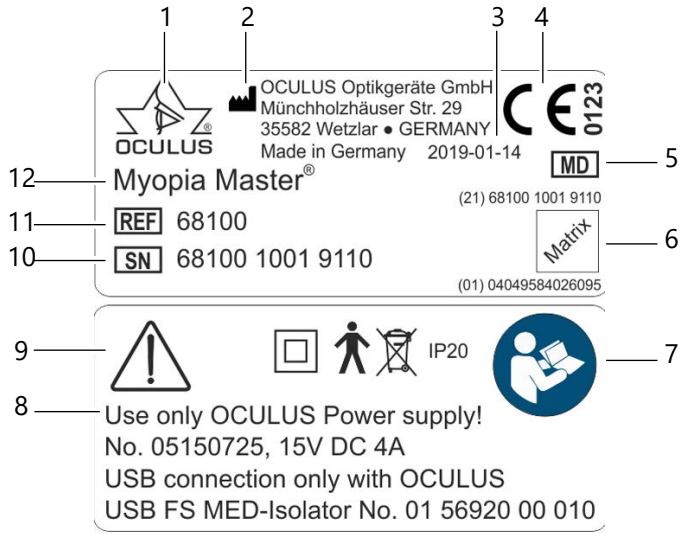


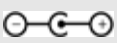
Fig. 2-1: Nameplate (example)

No.	Description	No.	Description
1	Manufacturer logo	7	Observe Instruction for Use
2	Manufacturer's name and address	8	Power adapter details
3	Date of manufacture	9	Attention
4	CE mark and number of the notified body	10	Serial number
5	Medical device	11	Reference number
6	UDI number: Top: UDI PI (product identifier) Center: machine-readable matrix code Bottom: UDI DI (device identifier)	12	Device name

Symbol	Description	Symbol	Description
	Protection class		Do not dispose of in household trash
	Application part B	IP 20	Degree of protection

No temporary labels are attached to the device.

2.1.2 On the Power Adapter

Symbol	Description	Symbol	Description
	For indoor use only		NEMKO symbol
	Complies with US and Canadian standards		Chinese standard mark
	Complies with German quality requirements		Recycling code
	Notified body		Polarity of the DC connection

2.1.3 On the Packaging

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

2.1.4 In this Manual

Caution

Identifies a potentially dangerous situation that may cause minor injuries or damage to property.

Note

Identifies situations that could lead to incorrect examination results, usage instructions, and useful or important information.

Information

Identifies further information about the product or its manual, to which particular attention should be paid.

> Menu paths are marked with >.
Example of calling a new examination:
Myopia Master® > Examination > New
Which means:
➔ Select the menu [Examination] from the menu bar.
➔ Select the menu item [Scan].

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

2.2 Safety Instructions for Use

Caution
Personal injury or property damage due to incorrect operation
➔ Observe the following safety instructions.

Caution
Personal injury or property damage due to unsafe device modifications
➔ This device may not be modified without the manufacturer's approval.
Any changes or modifications may only be carried out by OCULUS Service.

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

2.2.1 Instructions for Operating an ME System

The device and a connected computer form a medical electrical system (ME system) in accordance with IEC 60601-1. If you connect other devices such as a printer, this device will become a part of the ME system.
Ensure that all devices belonging to the ME system meet IEC 60601-1 or IEC 60950-1/IEC 62368-1 requirements.

2.2.2 Instructions for Laser Use

Caution
Risk of personal injury or property damage due to invisible laser beams
The device contains a laser in class 1 in accordance with 60825-1: 2014. This is an enclosed laser system. If the device cover is opened, you may be exposed to laser beams in class 3R (5 mW).
➔ Never open the device.
➔ Only for authorized service staff: do not look directly into the laser beam during maintenance.

2.2.3 Instructions on Electrical Safety

Caution

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

Connecting the device with non-medical electrical devices (such as data processing devices) to a medical electrical system must not result in a safety level for the patient that is less than IEC 60601-1 . If the leakage current threshold is exceeded as a result of this connection, protective measures including a circuit breaker must be in place.

- ➔ Make sure that connections with non-medical devices are made correctly.
- ➔ Only use the power adapter listed in the scope of delivery.
- ➔ Only use a computer that meets the specifications that are listed in this Instruction for Use → Chapter “Computer” (page 75).

Caution

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

If you are using a multiple socket outlet to connect the device, observe the following instructions:

- ➔ Use the multiple socket outlet in accordance with IEC 60601-1, section 16 requirements.
- ➔ Do not place the multiple socket outlet on the floor.
- ➔ Use no more than one multiple socket outlet.
- ➔ Only use this multiple socket outlet to connect the device and, where applicable, the corresponding computer.

If you are using a multiple socket outlet, it must be supplied with an isolating transformer.

If your are using a new computer for the device, have the electrical safety inspected. To do this, call OCULUS Service or an authorized dealer.

Caution

Personal injury and/or property damage due to electromagnetic interference

Portable and mobile HF communication devices (high frequency) may interfere with medical electrical devices → Chapter 16 (page 83).

- ➔ Make sure that portable and mobile HF communication devices are not causing any interference emissions.
- ➔ Recommendation: Maintain a minimum distance of 4m. If the distance is less, you must make sure that the device is working properly.

2.3 Instructions for Cybersecurity

Note

The regulations, guidelines and recommendations of the authority responsible for information security and protection of critical infrastructures in the applicable country must be observed.

The device is designed so that a network or Internet connection is not required. The device works exclusively via a connected computer.

Users who connect the computer connected to the device to the Internet or another network for other purposes are responsible for ensuring that this is done securely and in a controlled manner.

2.3.1 Precautionary Measures Against Unauthorized Access

To increase the cybersecurity of the device:

➔ Secure the device against unauthorized access by unauthorized people.

Take the following precautions:

- Secure the computer with a strong password (e.g. when starting Windows).
- Select a complex password consisting of at least twelve characters and containing letters, numbers and special characters. Avoid dictionary words.
- Do not select names or device names as a password (such as “Pentacam”).
- Change the default password after logging in for the first time.
- Change the password regularly.
- Do not write down the password at an accessible location.
- Use unique passwords for different user accounts.
- Do not give colleagues or other people any user names or passwords, even if authorized by law and employer policy to view the same type of information (e.g., two users reviewing the same patient samples).
- Set up a screensaver that required the password to be entered again when deactivating.
- Define an appropriate time for the screensaver (e.g. 10 minutes), which depends on the operating conditions such as the examination duration and the patient flow.
- Ensure that the device is locked (keyboard shortcut: Windows logo button + ‘L’) or secured in another way when not in use, in order to prevent unauthorized access to electronically-protected patient data (ePHI).
- Train users regarding data protection and handling personal data.
- Contact the health facility’s IT department if necessary.

2.3.2 Precautions when Connecting to a Local or Internet Network

- Do not establish an Internet connection while the device is in use. This is deemed misuse!
- If the computer is connected to the Internet for a different purpose, data security must be ensured.

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

- Preferably connect the computer to the network via a cable connection and not via a wireless connection.
- Also use robust security methods including the Advanced Encryption Standard with a strong network key for cable connections. Use of a firewall (software or hardware) is recommended.
- Observe the instructions for integration into an IT network → Chapter 16.7 (page 92).

Note

The IT department at the health facility should implement a risk management framework in accordance with IEC 80001-1 in order to support secure integration of medical IT networks. This includes evaluating risks, implementing access controls, securing networks, applying software updates, monitoring incidents, protecting data, managing device lifecycles and training employees in order to guarantee patient safety and data integrity.

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

2.3.3 Device Security

- ➔ Ensure that the device is protected against unauthorized access → Chapter 2.3.1 (page 15).
- ➔ Protect the device and connected systems from malware.
- ➔ Implement new software versions as soon as they are available.
- ➔ Implement operating staff access on a needs basis.

The IT department at the health facility is responsible for implementing controls for handling and disposing of media and assets.

2.3.4 Responsibility for Data

The users should avoid entering unnecessary identifying data. Wherever possible, data should be anonymized and linked to the sample ID rather than the patient. Only use the input data that is required for the intended purpose.

The users have access to sensitive patient data (ePHI).

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

The data must be deleted regularly in accordance with the deletion guidelines at the health facility if applicable data is processed on the device.

The IT department at the health facility is responsible for deleting unused user accounts.

Only authorized staff are permitted to create backup copies. The IT department at the health facility manages the storage location for every backup in order to be able to react to queries from data subjects. Backups and archive data must be transmitted and stored securely.

2.3.5 Reporting and Handling Security Incidents

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

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

3 Device Description

3.1 Overview of the Device Components

Fig. 3-1: Device components

No.	Description	No.	Description
1	Measuring head	5	Sliding plate
2	Print output	6	Joystick
3	Display	7	Function buttons
4	Rotating wheel		

Fig. 3-2: Device components

No.	Description	No.	Description
1	Forehead rest	5	Mains connection
2	Eye height mark	6	USB port
3	On/off switch	7	Chin rest
4	Check LED	8	Measuring window/patient viewer with keratometer ring

3.2 Functionality of the Device

The device combines several measuring functions in one device.

3.2.1 Automatic Refractometer

The measuring light enters the eye's retina from an infrared source and is reflected back to the glare location. Sensitive sensor chips or CCD cameras now register the deviating reflected light from the glare location, which depends on the applicable ametropia. An integrated microcomputer calculates the ametropia in dpt from this by sphere, cylinder and axis length of the cylinder.

3.2.2 Keratometer

The curvature of the cornea is determined by taking a reflective image of the cornea using a camera sensor and measuring it.

The reflection from test marks and a ring is used as the reflective image.

This enables the cornea central radii to be determined.

3.2.3 Pachymeter (optional)

Pachymetry works using Scheimpflug images of the cornea, which are evaluated in the computer integrated into the device.

The Scheimpflug image is used to determine 600 absolute height values. The measuring range is on a horizontal 4 mm slit through the apex.

The slit light illuminates the sectional plane from the cornea front surface to the rear surface. The transparent cells of the cornea scatter the slit light so that the sectional plane appears to be self-illuminating.

This is recorded by a camera at a 45° angle through the pupil and the image plane of the camera is also inclined at 45° to the optical axis of the camera lens in order to depict the light-scattering cornea plane in focus on the camera's image plane (Scheimpflug image).

This arrangement provides you with focused sectional views of the cornea.

3.2.4 Axis Length

The eye's axis length is measured by an interferometer and displayed. The device measures the six-fold axial length of the patient's eye.

3.2.5 Application Parts

Fig. 3-3: Application parts

No.	Description	No.	Description
1	Forehead rest	2	Chin rest

3.3 Intended Use

The Myopia Master® has been developed to photograph the eye and to take Scheimpflug images of the front section of the eye in order to be able to evaluate the thickness of the cornea. The integrated keratometer measures the central radii of the cornea. The integrated opthalmic refractometer measures the eye's refraction power. The integrated interferometer measures the eye's axial length.

The Myopia Master® may only be used for the purpose described in this Instruction for Use.

➔ Observe the aforementioned safety instructions.

3.3.1 Intended Medical Indication

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

3.3.2 Contraindication

None known

3.3.3 Potential Side Effects

None known

3.3.4 Intended Users

The device is intended exclusively for use in:

- Eye specialists practices
- Clinics
- At opticians or optometrists

The device is intended for use by trained staff:

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

3.3.5 Patient Group

Children ages 3 and older up to unlimited. No restrictions on weight and health condition. The patient must be awake and able to understand and to look into a fixation target.

4 Setup and Connection

4.1 Instructions for Setup and Connection

- ➔ The device may only be set up and connected by OCULUS or an authorized dealer.
- ➔ Do not use the device in moist locations and never set the device down there.
- ➔ Avoid areas dripping, splashing or spraying water near the device and make sure that no liquid can penetrate the device. Therefore, do not place any containers filled with liquids near the device.
- ➔ Avoid shock, vibrations, contamination, high temperatures and humidity.
- ➔ Only operate the device in rooms used for medical purposes provided that they have been set up in accordance with VDE regulations 0100-710.
- ➔ Do not operate the devices included in the scope of delivery in explosive areas, or in proximity to flammable anesthetics or volatile substances such as alcohol, benzine or similar products.
- ➔ Set up the device so that the power plug can be easily accessed. This way, you can easily disconnect it from the power supply for any repairs.
- ➔ Do not apply excessive force when connecting electrical plug connections.
  If you are unable to make a connection, check whether the plug fits the socket.
  If you detect damage to the plug connection, have our Service repair the damage.
- ➔ Only use a device that is properly mounted to a suitable lifting table.
- ➔ Handle the optical device with care.

4.2 Patient Environment Information

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

Caution

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

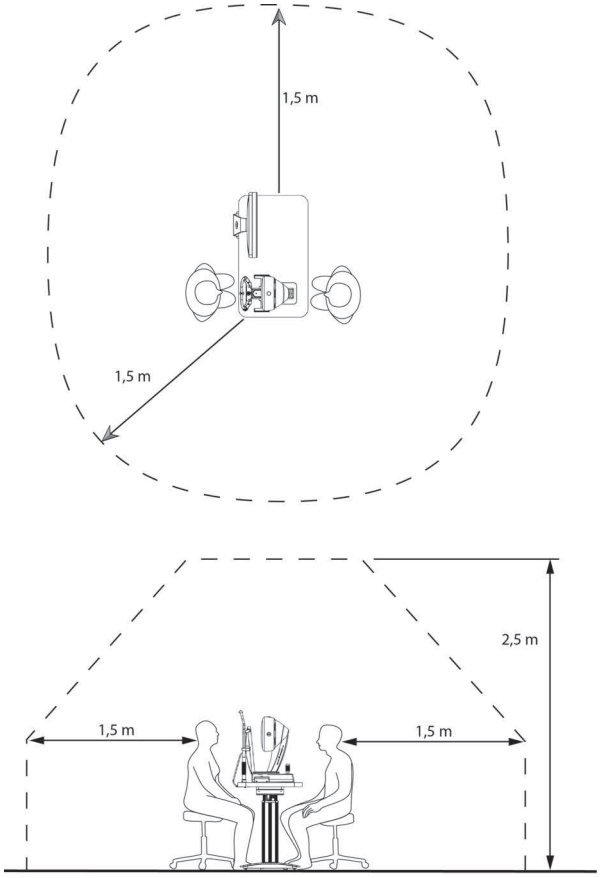


Fig. 4-1: Patient environment

4.3 Transporting to the Setup Location

For information on the transport and storage conditions, see → Chapter 14.1 (page 77) and → Chapter 14.2 (page 77).

➔ Only start up the device around 3-4 hours after transport or storage. The severe temperature change from cold areas to warm rooms can cause the optical components to mist up.

Note

Risk of device damage due to improper transport and storage

➔ Avoid shock and vibrations.

➔ Avoid contamination, high temperatures and humidity.

➔ Transport the device properly.

➔ Store the device in accordance with the storage conditions.

➔ Avoid placing near heaters and moisture.

Note

➔ Retain the packaging. You can use it to send or transport the device properly in the event of service or repair situations. You can avoid unnecessary damage and costs in this way.

4.4 First Start-Up

Before starting the device up for the first time, you must

- Put it up and have it set up
- Receive instruction

Note

Faulty measurements/device damage if instruction is not received

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

Note

Faulty measurements/device damage due to putting the device up incorrectly

➔ Note that before first use, setup and connection of the examination location must have been performed by our service department or by a specialist authorized by OCULUS.

4.5 Setup Work when Starting for the First Time

- ➔ Only start up the device around 3-4 hours after transport. If the device has been stored in a cold room or in a vehicle during cold weather, the optical components on the device may mist up due to severe temperature differences from cold to warm areas.
- ➔ Check whether the transport lock is unlocked → Chapter 4.6.2 (page 27).

4.6 Setup Work After Internal Transport

Note

Device damage caused by lifting incorrectly

If you lift the device by the measuring head, it may break off.

- ➔ Hold the device from below and on the forehead rest to lift it.

4.6.1 Setting up the Device

- ➔ Place the device on a flat surface.
- ➔ Position the device to ensure that no direct light can affect the measurement.
- ➔ Set up the device so that the power plug can be easily accessed. This way, you can easily disconnect it from the power supply for any repairs.
- ➔ Ensure a reflection-free examination. To do this, darken the examination room.
- ➔ Avoid shock and vibrations.
- ➔ Avoid contamination, high temperatures and humidity.

4.6.2 Unlocking the Transport Lock

The device is secured with a transport lock for transport. This must be unlocked before use.

➔ Open the cover with the display.

Fig. 4-2: Open the cover with the display

➔ Unlock the transport lock if it is locked.

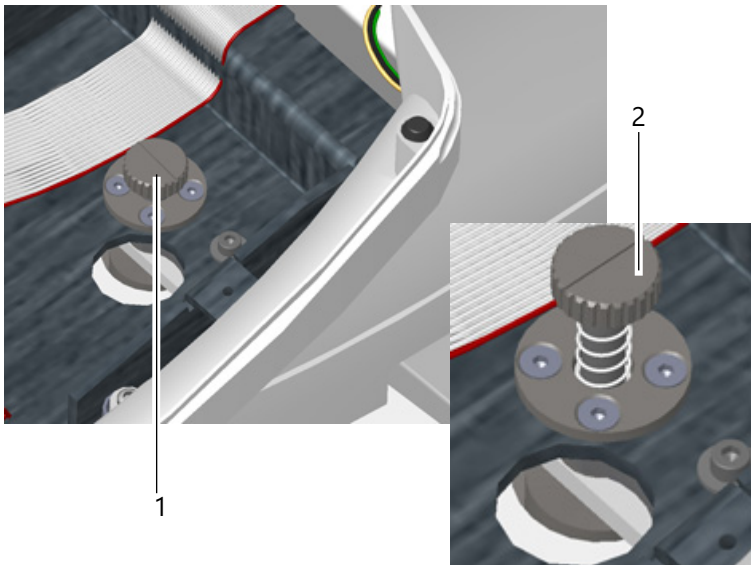


Fig. 4-3: Transport lock

No.	Description
1	“Locked” position
2	“Unlocked” position

➔ Push the transport lock down slightly and turn it counterclockwise into the “Unlocked” position. The spring then pushes the transport lock up.

➔ Close the cover with the display → Fig. 4-2 (page 27).

4.7 Electrical Connection

Caution

Electrical safety hazard

- ➔ Do not use the device in the immediate vicinity of other devices and do not stack it with other devices.
- ➔ If you use the device in the vicinity of other devices or stack it with other devices, you must ensure that the device functions correctly.
- ➔ Only use the power adapter listed in the scope of delivery → Chapter 1 (page 9).
- ➔ Only use a cable that meets the requirements of IEC 60227-1, type H05VVH2-F (type 53), minimum 0.75 m^2 and IEC 60320-1, type C7.
- ➔ If you are using a multiple socket outlet to connect the device: Use the multiple socket outlet in accordance with the IEC 60601-1 requirements.
- ➔ Do not place the multiple socket outlet on the floor.
- ➔ Use no more than one multiple socket outlet.
- ➔ Only use this multiple socket outlet to connect the device and, where applicable, the corresponding computer.

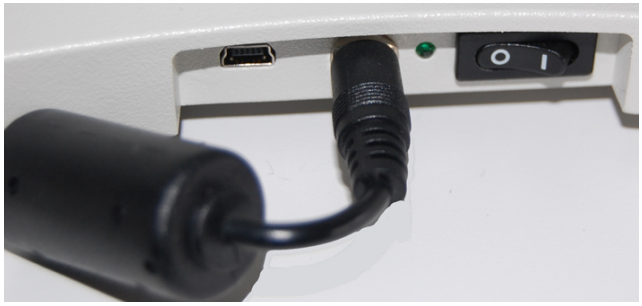


Fig. 4-4: Connecting

- ➔ Use the supplied mains cable to connect the device to the mains → Chapter 1 (page 9).

Note

Device damage due to incorrect connection

If you do not connect the device properly and it is live, the device may be damaged after a short period of time.

- ➔ Do not apply excessive force when connecting electrical plug connections.
- ➔ Observe the information on the nameplate.

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

Caution

Faulty measurements/device damage due to unauthorized staff

➔ Ensure that only a specialist authorized by OCULUS
- establishes the connection to a computer.
- Software updates performed.

Note

Faulty measurements/device damage due to incorrect device connection

Each time a Instruction for Use is connected to a computer, this can pos risks for patients or users, which go beyond the risks described in this Instruction for Use.

➔ Ensure that patient and operator safety, as well as functionality on the Instruction for Use and the connected computer are guaranteed.

➔ Connect the device to a USB cable only via the USB FS MED isolator to your computer/laptop.

5 Start-Up

➔ Only start up the device around 3-4 hours after transport. If the device has been stored in a cold room or in a vehicle during cold weather, the optical components on the device may mist up due to severe temperature differences from cold to warm areas.

5.1 Instructions for Operation

➔ Before first-time use: Allow OCULUS or an authorized dealer to instruct you in the operation of the device.
➔ Never put a damaged device into operation.
➔ Only operate the device using the original accessories supplied by OCULUS and only if in perfect technical condition. Use the power adapter listed in the scope of delivery only.
➔ Do not cover the ventilation openings.h.
➔ Do not touch the patient and the device at the same time.
➔ Make sure that the device cannot tip over by leaning against it or sitting on it.
➔ Do not set the device, including the battery pack or cable, down on devices that produce heat, heating units (such as radiators), microwaves or similar.
➔ Only operate the device if you have fully understood the Instruction for Use.

5.2 Switching On

➔ Switch the device on at the on/off switch (position I). The LED then illuminates green.

5.3 Switching Off

➔ Terminate the current session.
➔ Switch the device off at the on/off switch (position 0).

Caution

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

➔ Switch the device off.
➔ Pull out the mains plug before cleaning and maintenance. To do this, hold the mains plug. Do not pull on the cable.

5.4 Daily Start-Up

If you are transporting the device to a different location, you must position it to ensure that no direct light can affect the measurements.

- ➔ Place the device on a flat surface.
- ➔ Use the supplied mains cable to connect the device to the mains.
- ➔ Observe the information on the nameplate.
- ➔ Switch the device on at the on/off switch → Chapter 5.2 (page 30).

6 Operating Panel Functions

Fig. 6-1: Operating panel functions

No.	Description	No.	Description
1	Joystick button	4	Joystick with twist grip
2	Display	5	Adjustment base
3	Rotating wheel	6	Screen-dependent buttons

Component	Function	Operation
Screen-dependent buttons	Activates the adjacent button field depending on the corresponding screen	➔ Press the required button.
Rotating wheel 	Changes the corresponding parameter Activates the selected parameter	➔ Turn the wheel to the left or right. The selected parameter is highlighted in blue. ➔ Press the rotating wheel down. The selected parameter is activated or deactivated.
Joystick	Adjusts the height, distance and alignment to the left and right	➔ Move the joystick forwards, backwards and to the sides, turn it → Chapter 8.2.2 (page 43).
Joystick button	Triggers the measurement manually (if the automatic trigger function is switched off)	➔ Press the button.
Display	Displays program screens Used as a touchscreen	➔ Press the required button gently.

Component	Function	Operation
Adjustment base	Used for rough adjustment	➔ Move the adjustment base until you can see the eye of the person to be examined well on the screen.

6.1 Touchscreen

If the function is deactivated:

➔ Activate the checkbox in “Settings 2/5” → Chapter 10.2 (page 61)

In addition to the screen-dependent buttons, you can also use buttons on the touchscreen as buttons. The buttons change depending on the display function.

6.1.1 Function Buttons on the Touchscreen

You can use the following buttons to work in patient data management.

Button	Function	Button	Function
	Change keyboard		Input
	Delete characters		Switch to the higher line
	Abort the process		

7 Preparing Patient Data

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

➔ In this case, enter the patient name and date of birth before performing the measurement if possible.

7.1 Entering a new Patient (Touchscreen)

➔ In the patient data management menu, press the [Patient] button to enter a new patient.

The following screen is displayed:

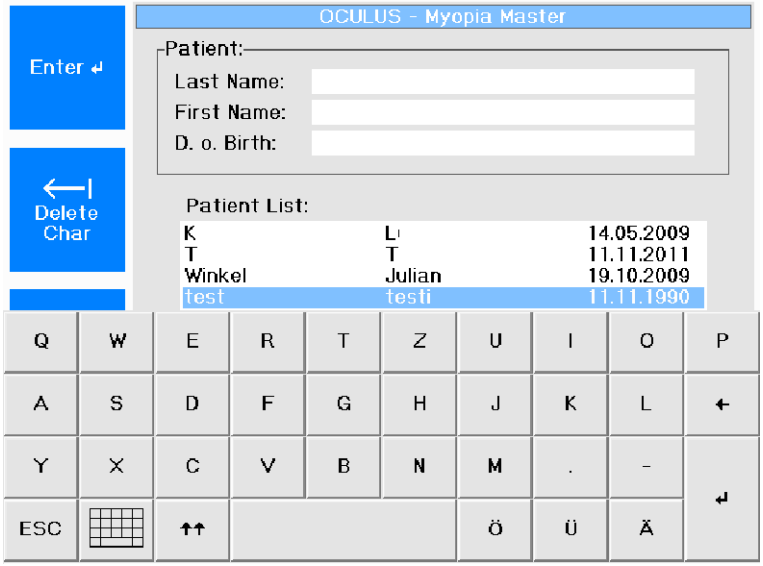


Fig. 7-1: Touchscreen keyboard, enter patient data

➔ Use the touchscreen as described in → Chapter 6.1 (page 33).

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

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

➔ Enter the date of birth and confirm.

➔

A confirmation dialog box is displayed.

➔ Select "Yes".

The patient name is displayed in the list.

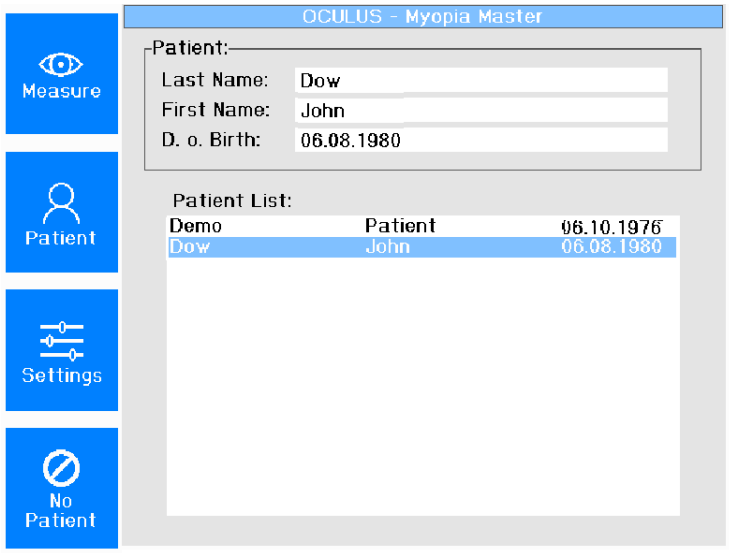


Fig. 7-2: Patient list

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

7.2 Entering a new Patient (Touchscreen Deactivated)

➔ In the patient data management menu, press the [Patient] button to enter a new patient.
The following screen is displayed:

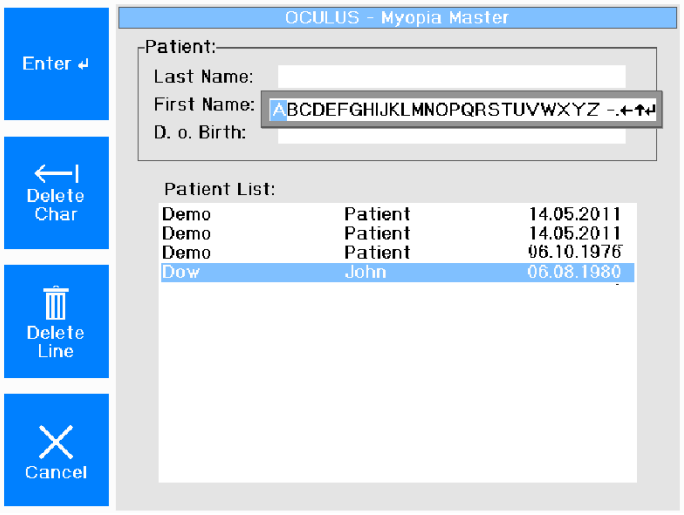


Fig. 7-3: Enter a patient

➔ Use the rotating wheel to select each individual letter.
Confirm each of these by pressing the rotating wheel.
➔ Enter the last name of the patient to be examined.

- ➔ Correcting an incorrect entry:
  You can delete a letter by pressing the [Delete Char] button.
  You can delete the entire field by pressing the [Delete Line] button.
  Alternatively, you can delete the input level using the rotating wheel by selecting the "← ιχον.
- ➔ After entering the last name completely, press the [Enter] button.
  Alternatively, you can use the "↑" and "↵" icons to go to the next line up or down.
- ➔ Enter the first name and the date of birth in the same way.
- ➔ After entering the date of birth, press [Enter] to confirm.
- ➔ You are now asked whether you want to save the new patient.
- ➔ Select "Yes".
  The patient name is displayed in the list.
- ➔ Use the [Start] button to access measuring mode.

7.2.1 Selecting a Saved Patient

Select patients whose data is already saved.

- ➔ In the patient data management menu, press the [Patient] button.
- ➔ Use the rotating wheel to navigate to the required list entry.
  The following screen is displayed:

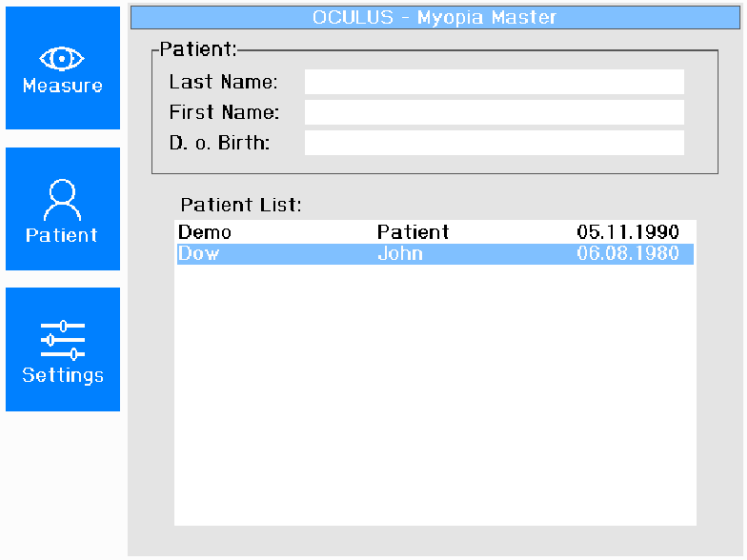


Fig. 7-4: Selecting a patient

- ➔ Press the [New measurement] button to access measuring mode.

7.2.2 Renaming a Patient

- ➔ Select the patient that you want to rename.
- ➔ Press the button.
- ➔ Enter the new name or a new date of birth in the “New name” field.
- ➔ Confirm the entry.

7.2.3 Deleting a Patient or an Examination

If you want to delete a patient or an examination:

- ➔ Select the applicable patient.
- ➔ Press the button.

Deleting a patient

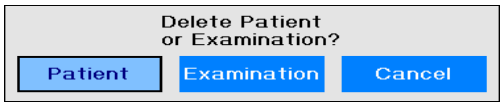


Fig. 7-5: Deleting a patient

- ➔ Use the rotating wheel to select the [Patient] button.
- ➔ Press the rotating wheel down.
  The patient is deleted.

Deleting an examination

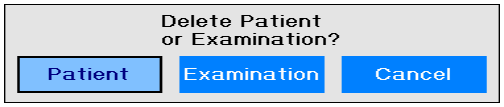


Fig. 7-6: Deleting an examination

- ➔ Use the rotating wheel to select the [Examination] button.
- ➔ Select the examination to be deleted.
  The line with the selected examination is highlighted in blue.
- ➔ Press the rotating wheel down.
  The examination is deleted.

7.2.4 Loading an Examination

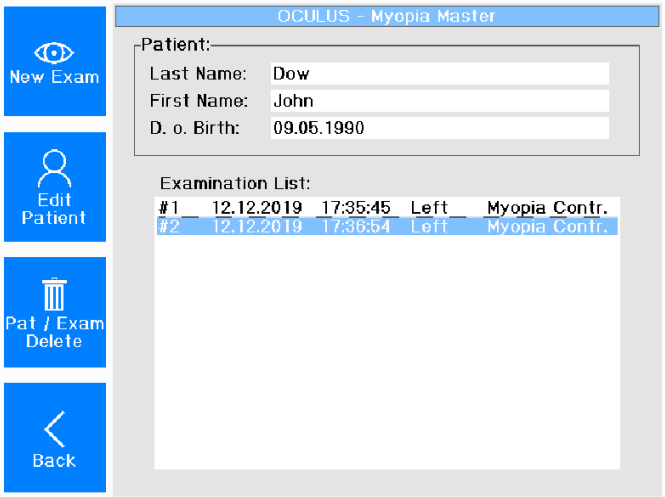


Fig. 7-7: Loading an examination

You can also load and print existing examinations at a later time in patient data management.

If two examinations have already been printed together once, they are also saved together automatically (R+L) and also loaded again simultaneously.

If the measurements were not printed together, the examinations are listed separately (right, left).

You must then load the measurements separately, one after the other.

Two measurements can then only be displayed together if they belong to one measurement process.

8 Measuring Procedure

Note

Faulty measurements due to incorrect operation

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

A measuring procedure consists of the following steps:

➔ Selecting measuring mode
➔ Preparing the measurement
➔ Performing the measurement
➔ Saving the data
➔ Ending the measurement

8.1 Selecting Measuring Mode

The measuring procedure depends on the selected mode:

		Measuring function			
		Keratometry measurement	**Refraction measurement**	**Axis length measurement**	**Pachymetry measurement**
Measuring mode	**Myopia**	X	X	X	
	AR + K	X	X		
	AXL			X	
	P + AR + K (optional)	X	X		X
	PARK + AXL (optional)	X	X	X	X

Measuring mode display:

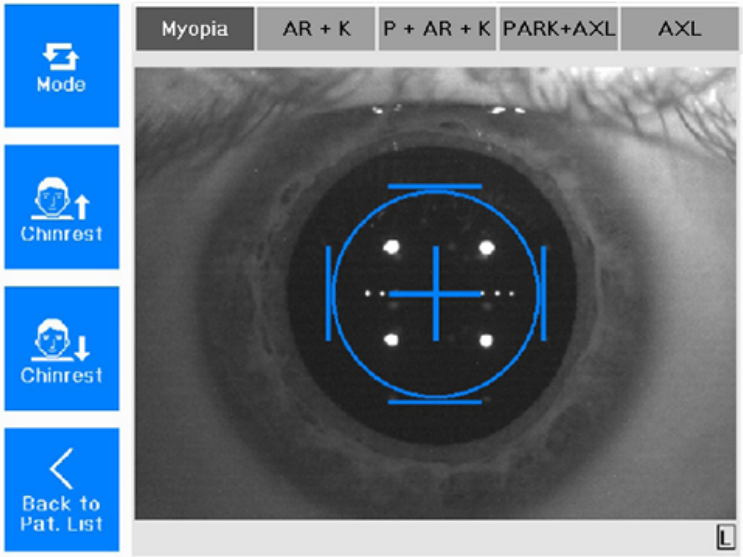


Fig. 8-1: Measuring mode display

➔ Press the [Mode] button to change the combination of measuring functions for the individual measurement.
The other presettings selected in “Settings” are retained → Chapter 10.1 (page 59).
Right [R] or Left [L] indicates which eye is being measured.

8.2 Preparing the Measurement

Position the patient and adjust the device before the measurement.

8.2.1 Rough Adjustment

➔ Check whether
- Fresh paper has been placed on the chin rest or the chin rest has been cleaned and disinfected if necessary.
- The forehead rest has been cleaned and disinfected → Chapter 11 (page 66).

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

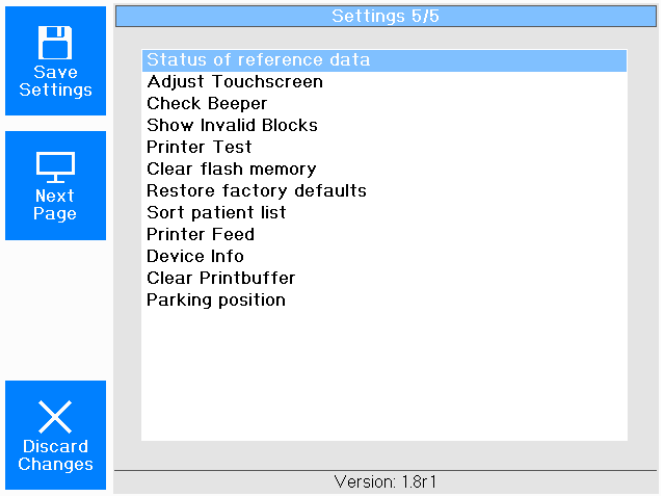


Fig. 8-2: Settings 5

➔ Ask the patient to place their head in the chin and forehead rests.
The eye height marking between the chin and forehead rests should be aligned roughly in the center of the patient's eye.

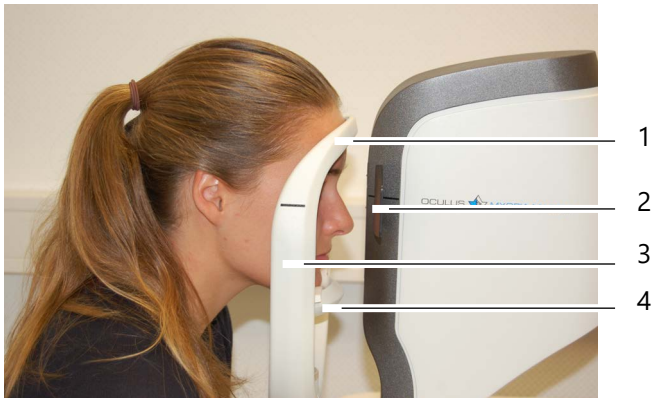


Fig. 8-3: Patient position

No.	Description	No.	Description
1	Forehead rest	3	Chin rest
2	Mark on the device	4	Eye height mark

➔ Adjust the chin rest.
Turn the joystick to control the measuring head height: Clockwise moves the measuring head upwards. Counterclockwise moves it downwards.
If you turn the joystick to the stop, the measuring head and the chin support move in the opposite direction.

Information

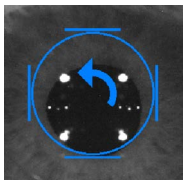
If "Eye-tracking" is activated, the height is aligned automatically.

➔ Patient instruction: "Look through the measurement window. You will see an image of a balloon. Relax and look into the center of it".
➔ Move the cross slide until the patient's eye is in focus on the display.
If necessary: Use the chin rest or the measuring head to readjust the height.

8.2.2 Fine Adjustment

➔ Use the joystick to perform file adjustment according to the specifications on the display. Move or turn the joystick in the specified directions to do this:

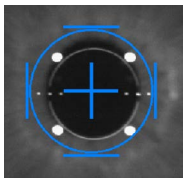
➔



Example:

➔ Turn the joystick counterclockwise.

Ar-row	Camera movement	Joystick movement
→	Right	Push the joystick to the right
←	Left	Push the joystick to the left
↑	Forw	Push the joystick towards the patient
↓	Back	Push the joystick away from the patient
↱	Top	Turn the joystick clockwise
↰	Bottom	Turn the joystick counterclockwise



Once the sufficiently accurate position is reached, a cross appears in the center of the ring, which is surrounded by four bars.

The device triggers the measurement automatically or the measurement can be triggered manually.

Manual measurement:

➔ Press the joystick button to trigger the measurement.

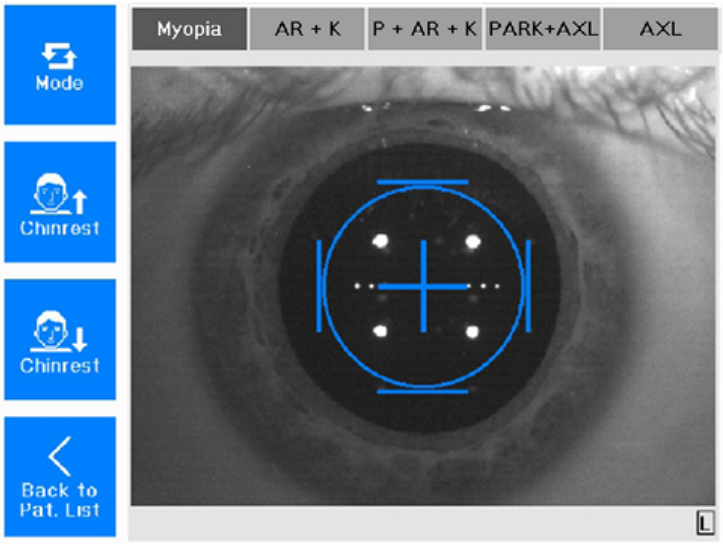
Note

In the measuring procedure described here, the “Myopia” measurement functions are activated.

The central cornea radii are first measured, then refraction takes place, followed by the axis length measurement.

Furthermore, “Eye-tracking” and “Auto-release” are activated by default.

At the bottom screen edge, you can see whether measurements were already performed on the applicable eye.



If the  icon appears on the right or the left at the bottom:

The right or left eye has already been measured.

You can find the corresponding measurement in the memory.

➔ Select the eye to load the examination that was just performed.

To delete the examinations that were already measured from the memory, press the [Clear] button.

8.3 Measurement and Results

The measuring mode is preset to “Myopia”.

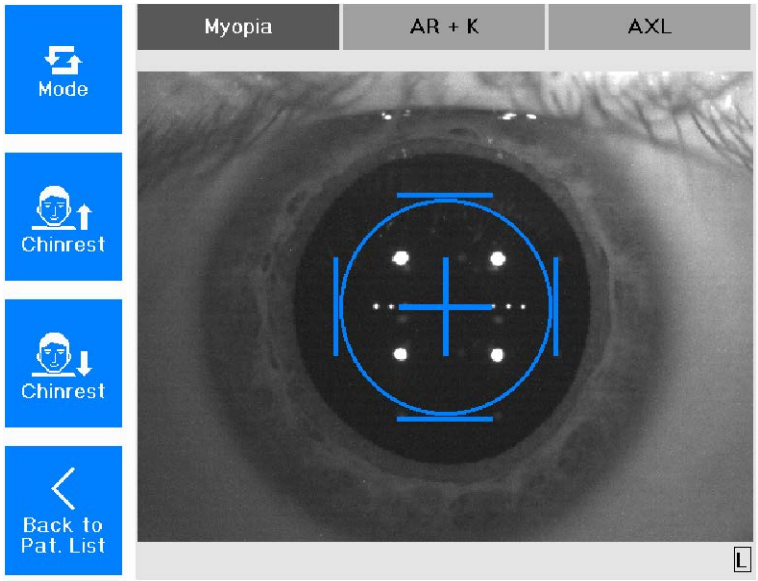


Fig. 8-4: Measuring mode

A complete myopia measurement consists of the following steps:

- Central cornea radii (K)
- Objective refraction (AR)
- Axis length (AXL)

8.3.1 Myopia Overview Illustration

The values measured in a myopia examination are displayed in an overview.

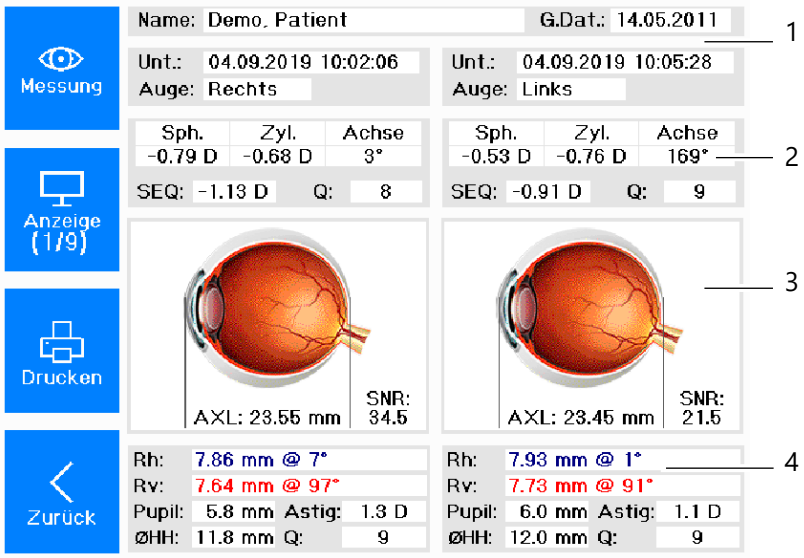


Fig. 8-5: Myopia overview illustration

No.	Description	No.	Description
1	Patient and examination data	3	Axis length settings
2	Refraction values	4	Keratometer values

➔ Press the button to access the progress display.

8.3.2 Myopia Results

After the measurement is complete, the following screen is displayed:

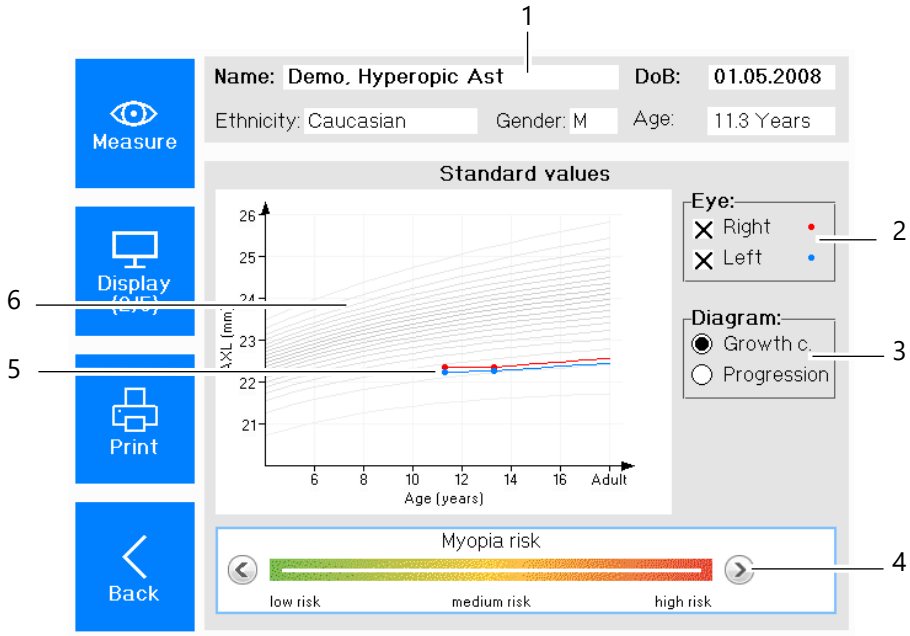


Fig. 8-6: Diagram (here: growth curves)

No.	Description	No.	Description
1	Patient and examination data	4	Risk assessment
2	Color for the examined eye	5	Measured values according to the patient's age
3	Select to switch the display between growth curves and progression	6	Progressive display of axis lengths and objective refraction values

The display shows the measured values either for one single eye or for both eyes. They are highlighted in color.

You can choose between the growth curves and the progression, i.e. the development over time.

Growth curves

If you select the “Growth curves” display, the graphic shows the measured values for the axis length depending on the patient's age. The gray lines reflect the percentile curves.

Progression

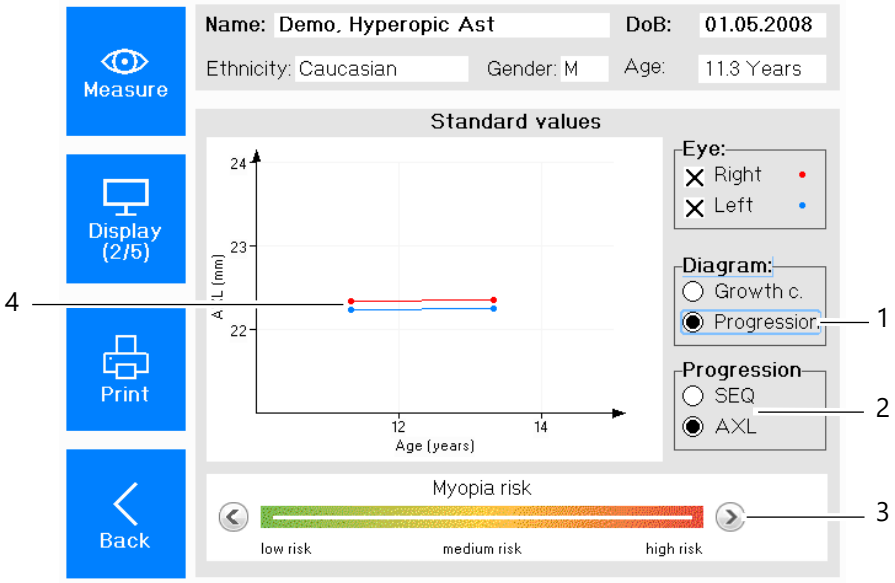


Fig. 8-7: Diagram (here: progression)

No.	Description	No.	Description
1	Select the progression display	3	Risk assessment
2	Select the displayed measured value	4	Measured values according to the patient's age

If you select the “Progression” display, the graphic shows the development over time for the selected measured values depending on the patient's age. You can choose between displaying the following measured values:

- Spherical equivalent (SEQ)
- Axis length (without percentile curves)

Regardless of the selected display, you can adjust the risk of myopia in the color bar manually.

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

The following screen is displayed.

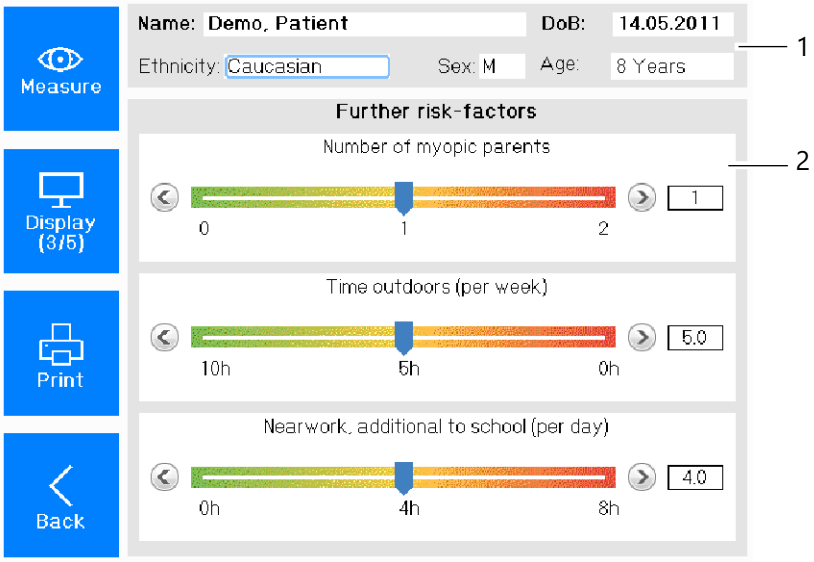


Fig. 8-8: Risk factors display

No.	Description
1	Patient and examination data
2	Other risk factors

The questionnaire provides you with a short risk assessment. The risk is classified according to scientific studies.

➔ Ask your patient about their:
- Ethnicity
- Number of myopic parents
- Gender
- Time outdoors (per week)
- Near work, additional to school (per day)

➔ Answer the applicable question by setting the slider to the corresponding value. You can also use the rotating wheel and confirm by pressing.
Alternatively, use the right arrow to increase the values or the left arrow to decrease the values.

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

8.3.3 Refraction Results

After the measurement has been performed, the following is displayed.

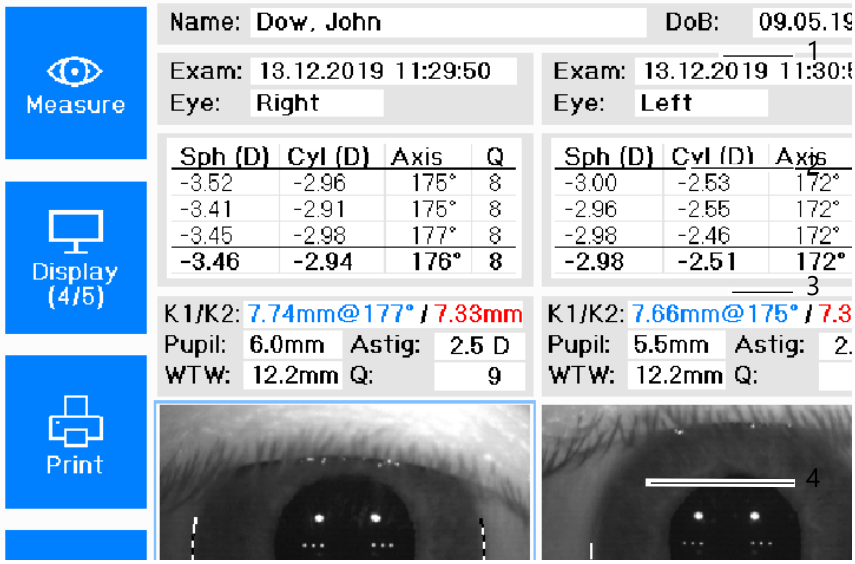


Fig. 8-9: AR+K overview display

No.	Description	No.	Description
1	Patient and examination data	3	Keratometer
2	Refraction values	4	Iris images

Refraction values

This field displays the values for sphere, cylinder, axis position and quality.

The refraction values are measured three times. The average value is displayed in the fourth row.

Q value:

If the field has a white background (9-7), the measurement results are good.

If the field has a yellow background (6), the measurement results are critical; repeat the measurement if necessary.

If the field has a red background (≤5), repeat the measurement

Keratometer values

- K1/K2: Horizontal/vertical curvature radius in the center,
  Blue: flat meridian
  Red: steep meridian
- Pupil: Pupil size
- Astig: Astigmatism of the cornea in the center
- ∅WTW: Cornea or iris diameter
- Q value:
  If the field has a white background (9-7), the measurement results are good.
  If the field has a yellow background (6), the measurement results are critical; repeat the measurement if necessary.
  If the field has a red background (≤5), repeat the measurement.

Camera image

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

8.3.4 Axis Length Results

After the measurement has been performed, the following is displayed.

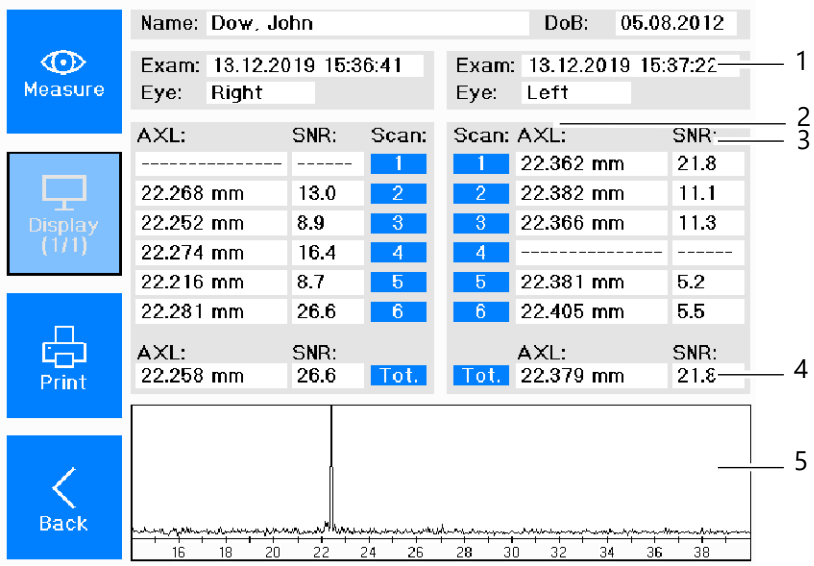


Fig. 8-10: AXL overview display

No.	Description	No.	Description
1	Patient and examination data	3	Signal-to-noise ratio (SNR)
		4	Highest SNR value
2	AXL values	5	SNR graphic

The axis length values for one or both eyes are displayed in the table.

The corresponding signal-to-noise ratio (SNR) is listed. A specially averaged axis length and the highest SNR are displayed.

Furthermore, the SNR is displayed as a graphic.

8.3.5 Pachymetry Results (optional)

➔ After the measurement has been performed, the following is displayed: Tap the touchscreen in the "Progression of the cornea thickness" field.
The device shows you the exact cornea position at the selected point.

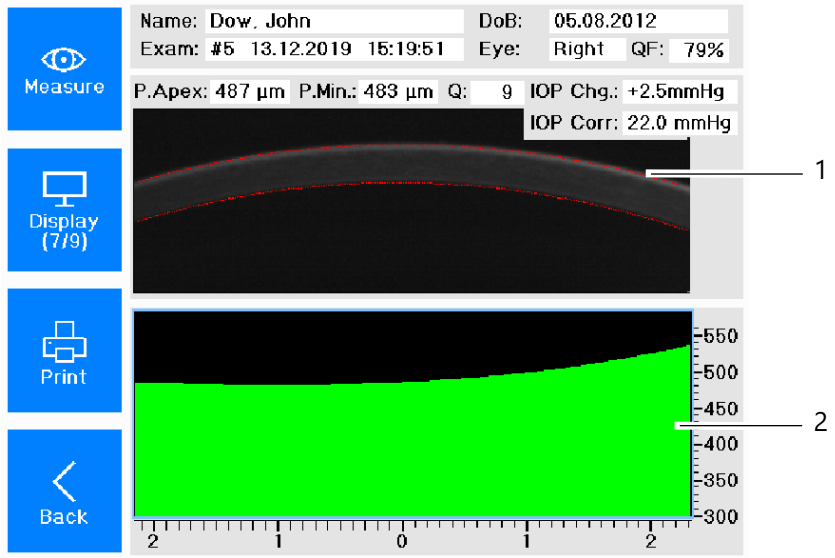


Fig. 8-11: Pachymetry measurement results overview

No.	Description
1	Scheimpflug image
2	Progression of the cornea thicknesses (Measuring range: horizontal 4mm slit through the apex)

You can use the touchscreen or the rotating wheel to move the pointer to the left or the right.

8.3.6 Ending Measurements

➔ Print and/or save the data → Chapter 8.4 (page 53).

8.4 Printing and Saving the Examinations

Once the myopia measurement has been performed on both eyes, the following screen is displayed:

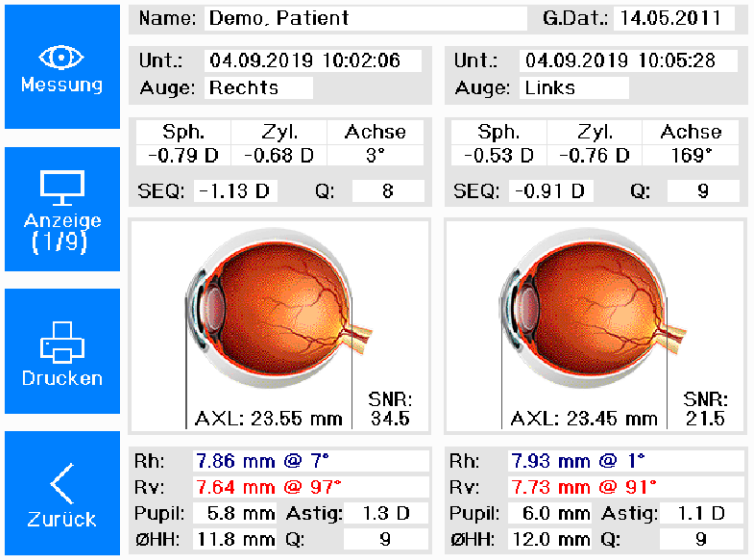


Fig. 8-12: Display with pushbutton

8.4.1 Printing

➔ Press the button to print the examination results.

Note

The measurement is saved automatically if you have entered a new patient → Chapter 7.1 (page 34) before the measuring procedure.
Printing automatically saves each measurement intermediately in the print number memory → Chapter "Saving the data in the print number memory" (page 54).

The "Chronology of different measuring procedures" section → Chapter 9 (page 55) outlines the different measuring procedures briefly.

Save the examination retrospectively if you have not created a new patient → Chapter 9.2 (page 56) before the measuring procedure.

8.4.2 Saving an Examination

There are two different options for saving an examination:

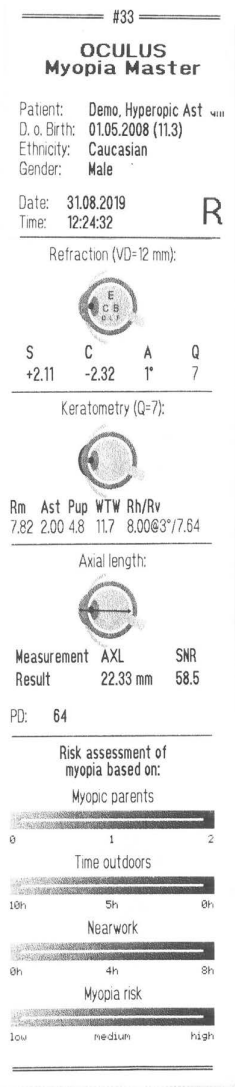
- Print number memory
- Patient data management

Saving the data in the print number memory

If the print number memory is activated in the settings, each examination is saved to the print number memory automatically after printing and can be called again at a later time.

A maximum of 100 examinations can be saved in the print number memory. After this, the first saved measurement is overwritten. If you would like to save the examinations for the long term, use patient data management.

You can call the measurement at a later time using its number [24].



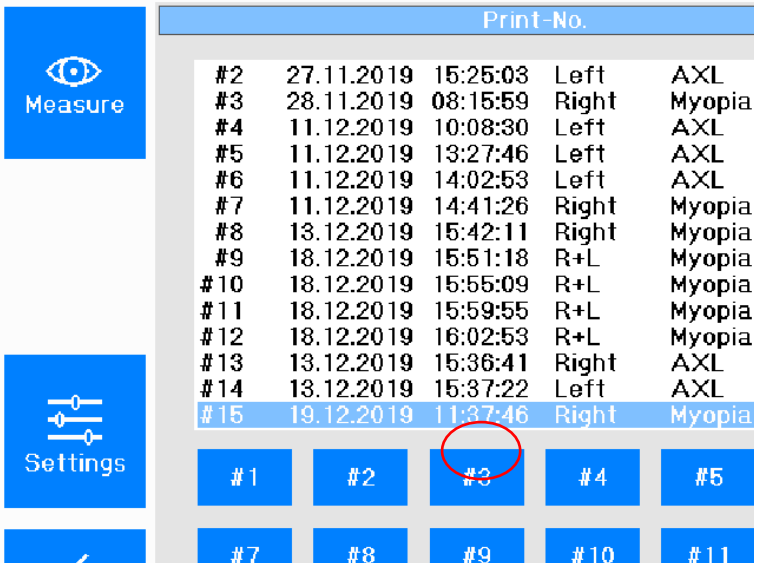


Fig. 8-13: Print number memory

8.5 Ending the Measurement

This button is displayed after performing a measurement.

➔ Press this button to save the examination data to the patient.

➔ Remove one of the sheets of paper from the chin rest after each patient, also see → Chapter 11.5 (page 70).

➔ Disinfect the forehead rest and, if necessary, the chin rest after each patient, → Chapter 11.3 (page 69).

9 Chronology of Different Measuring Procedures

The following outlines three different measuring procedures briefly.

1. You enter a patient into patient data management and then perform the measurement.
   The examination data is saved automatically to the newly-entered patient → Chapter 9.1 (page 55).
2. You start measurement directly and save the examination retrospectively to an existing patient. Alternatively, you can enter a new patient after the measurement → Chapter 9.2 (page 56).
3. You perform a measurement without saving the examination to a patient → Chapter 9.3 (page 57).

9.1 Entering a New Patient and Measuring

➔ Press the [New patient] button in patient data management.
➔ Create a new patient → Chapter 7.1 (page 34).
The newly-entered patient is displayed in the patient list and has a blue background.
➔ Press the [Start] button to start the measurement.
You also have the option of pressing the joystick button.
➔ Perform the measurement → Chapter 8 (page 39).
The overview display is shown when the measurement is complete → Fig. 8-6 (page 47).
The examinations that were performed are saved automatically in patient data management.
You can call the saved examinations again at any time → Chapter 8.4 (page 53).

9.2 Saving an Examination Retrospectively

➔ Start the measurement directly.
The following screen is displayed:

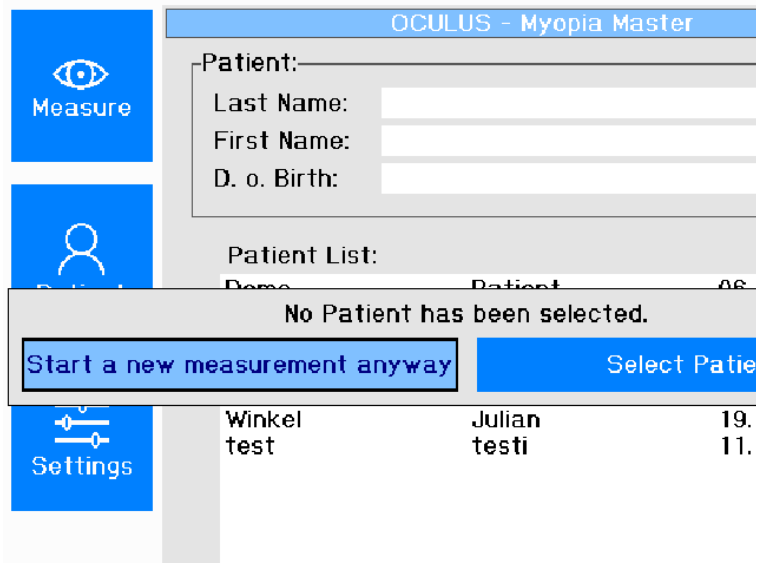


Fig. 9-1: Starting a new measurement

➔ Select [Start a new measurement anyway].
➔ Perform the measurement → Chapter 8 (page 39).
The overview display is shown when the measurement is complete → Fig. 8-6 (page 47).
➔ In the overview display: Press the [Save to patient] button.
The [Patient list] display opens.

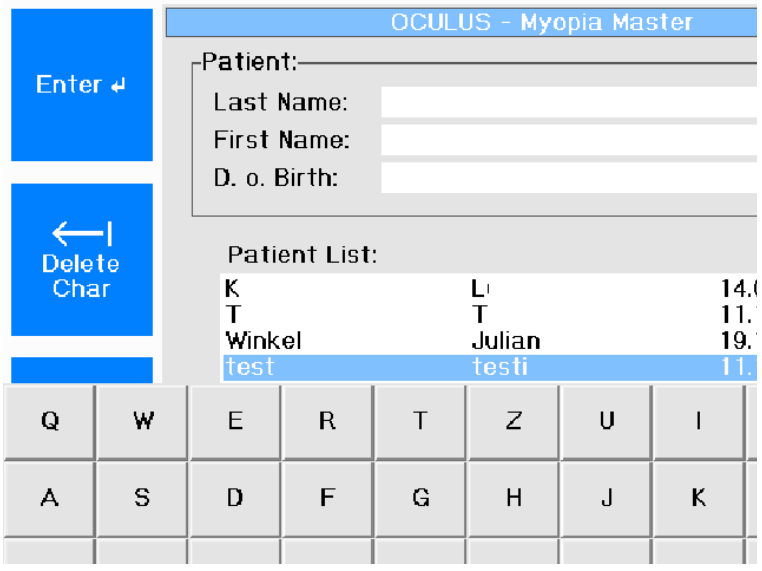


Fig. 9-2: Patient list

4. You can select a patient and save the measurement that was performed to this patient. First exit the patient list.
   Patient data management is already open.
   ➔ Create a new patient as described in → Chapter 7.1 (page 34).
   The newly-entered patient is displayed in the patient list and has a blue background.
   The examinations that were performed are saved in patient data management.
   You can call the saved examinations again at any time → Chapter 8.4 (page 53).
5. You can select a patient and save the measurement that was performed to this patient.
   ➔ Leave the character area to enter the patient data.
   ➔ Press the Escape button on the keyboard.
   ➔ Select the patient and press the rotating wheel to confirm.
   ➔ Alternatively, use the [Save to patient] button.
   The examination data is saved to the selected patient.
   You can call the saved examinations again at any time → Chapter 8.4 (page 53).

9.3 Measuring Without Saving Patient Data

➔ Start the measurement directly.
➔ Perform the measurement → Chapter 8 (page 39).
The overview display is shown when the measurement is complete → Fig. 8-6 (page 47).
Print the measurement(s) → Chapter 8.4 (page 53).
Printing automatically saves each measurement intermediately in the print number memory .

10 Reference Measurement

In order to ensure high measurement precision, the device must be set up

- Before performing the first examination on a patient
- After changing the device position

The first reference measurement is performed by OCULUS or an authorized dealer when setting up. OCULUS recommends performing a reference measurement once per month.

The reference measurement can be performed quickly and easily using a test eye.

Required materials

- Test eye, supplied
- Cleaning agent → Chapter 11 (page 66)

Using the test eye for measurement

Prerequisite: The device has been switched on for around 15 minutes.

Proceed as follows for the reference measurement:

➔ Remove the cap.

➔ Clean the test eye thoroughly with the cleaning agent before saving reference values.

➔ Fasten the test eye holder to the chin/forehead rest.

Fig. 10-1: Installed test eye

➔ Enter a new patient named “Reference test” and select “Myopia” or “ARK + AXL”.

➔ Perform a measurement with the test eye → Chapter 8.3 (page 45).

➔ Compare the results with the results on the test eye.

Fig. 10-2: Example: Results on the test eye

The system is now ready for operation.

10.1 Settings 1

Define the default settings for your individual measuring mode.

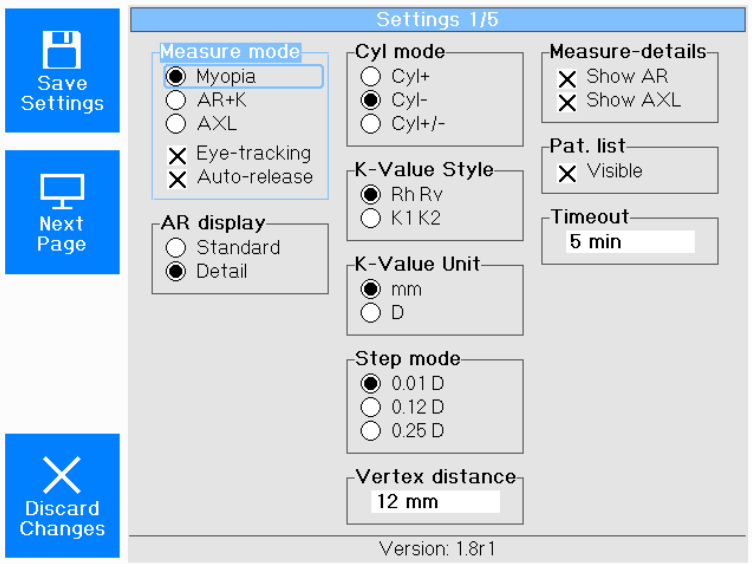


Fig. 10-3: Settings 1

Measuring mode

You can preset the combination method of the measuring functions here.

- Myopia: Myopia measurement
- AR+K: Refraction + Keratometry
- AXL: Axis length measurement
  Furthermore, you can activate or deactivate the “Eye-tracking” or “Auto-release” function.
- Eye-tracking: Automatic alignment of the measuring head in the Y direction (height)
- Auto-release: Automatic measurement release.

AR display

In “Standard” mode, the calculated average value of the refraction is displayed.
In “Detail” mode, the values of the individual measurement steps are also displayed.

Cyl. mode

Choose whether you want to work with plus or minus cylinders.
This preselected cylinder type is then always active when starting the program.

K-Value Style

Define the mode for determining the central radii display.
Rh Rv: horizontal / vertical radius
K1 K2: flat radius / steep radius

K-Value Unit

The measured curvature of the cornea can either be displayed as a curvature radius in mm or as a curvature equivalent in diopter.

Step mode

Select the steps in which the diopter values for the refraction values are to be rounded.

Vertex distance

Set the cornea vertex distance to which the displayed refraction values should refer.

Measure details

Show AR: Activates the refraction display → Fig. 8-9 (page 50)

Show AXL: Activates the axis length display → Fig. 8-10 (page 51)

Pat. list

If the "Visible" checkbox is activated, all patients are displayed with their last name, first name and date of birth. You can deactivate the checkbox, e.g. for data protection reasons. The patient list is then empty.

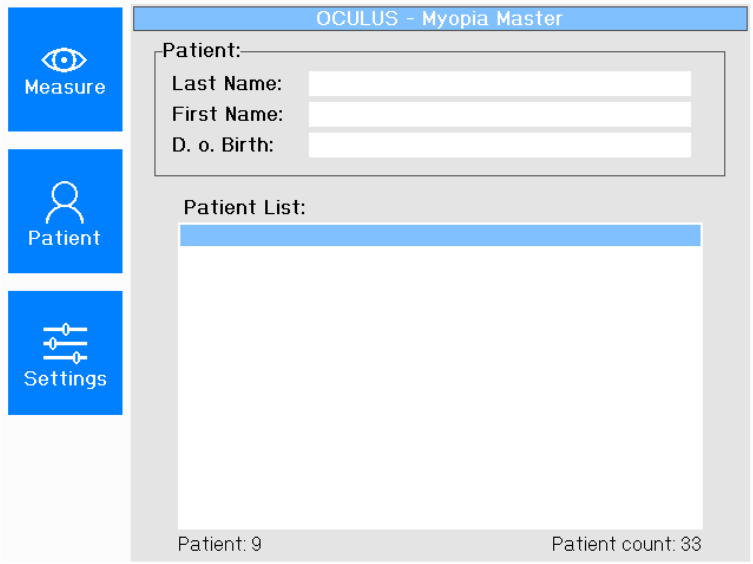


Fig. 10-4: Empty patient list when the checkbox is deactivated

Timeout

Enter the required value in the field in order to define when the screensaver is activated when the device is inactive. You can select time values between 5 and 120 minutes.

10.2 Settings 2

➔ Press the [Next page] button in [Settings 1].

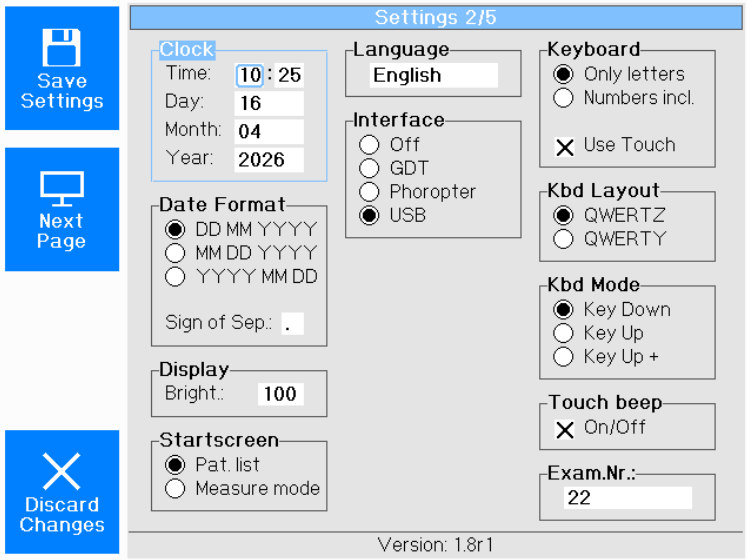


Fig. 10-5: Settings 2

Clock – Date format

Set the time and date in these two fields by turning and pressing the rotating wheel.

Display

Control the screen brightness.

Start screen

If the “Measure mode” button is activated, you start the measurement directly after switching on.

If the “Pat. list” button is activated, you start patient data management after switching on.

Language

Select the screen language.

Interface

You can deactivate the interface.

If the device is operated via a USB connection to a computer, you must set the interface settings to “USB”.

Keyboard / Use Touch / Kbd Layout / Kbd Mode

- Select the keyboard interface for entering patient data, for example, in the "Keyboard" field.
  Use the "Use Touch" checkbox to activate or deactivate the touchscreen function.
- Select the keyboard layout in the "Kbd Layout" field.
  QWERTZ is for the German keyboard layout.
  QWERTY is for the American keyboard layout.
- Select the contact control for the touchscreen in the "Kbd Mode" field.
  In "Key down" mode, characters are entered via direct contact with the touchscreen.
  In "Key up" mode, characters are entered when letting go of the touchscreen.
  The same applies in "Key Up+". However, the character is also shown on the display:

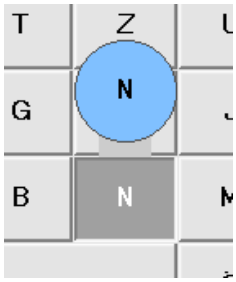


Fig. 10-6: Kbd Mode "Key Up+", example: Letter N

Touch beep

If this checkbox is activated, touching the touchscreen is accompanied by a beep.

Exam.Nr.:

You can set the "Exam.Nr." that you can also see on the printout for identification to zero as required. However, the consequence of this is that different patients may receive the same examination number when counting starts again from zero.

10.3 Settings 3

In [Settings 3] the growth curve displays can be enabled in the lower [Licensing options] area with the "Growth Curve" device license.

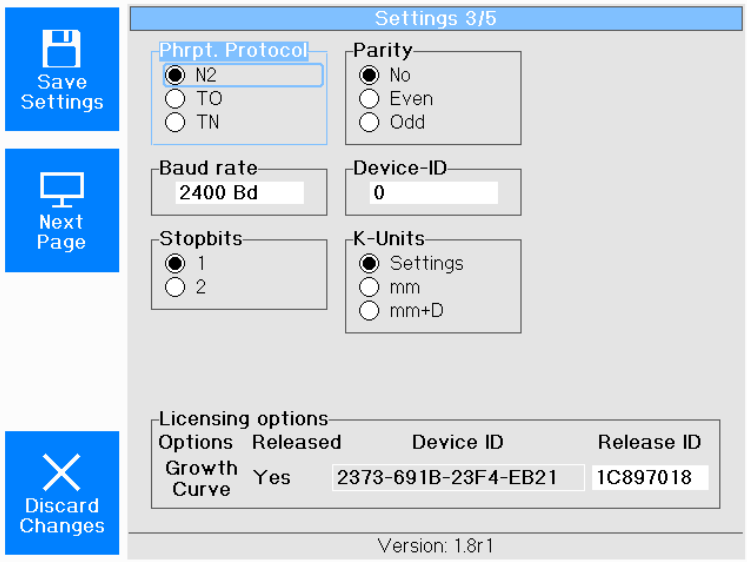


Fig. 10-7: Settings 3

➔ Contact your OCULUS point of contact to acquire the corresponding license.
➔ Enter the release ID into the field provided to enable the growth curves.

10.4 Settings 4

You can configure the printout individually in [Settings 4].

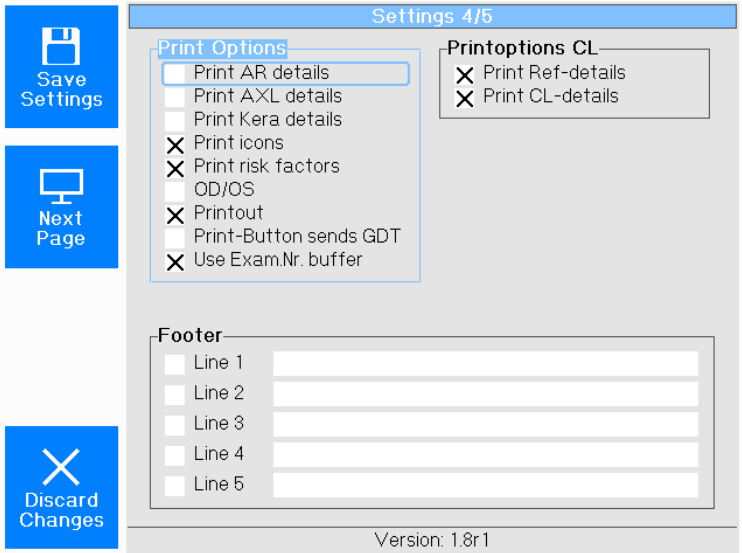


Fig. 10-8: Settings 4

Print AR details

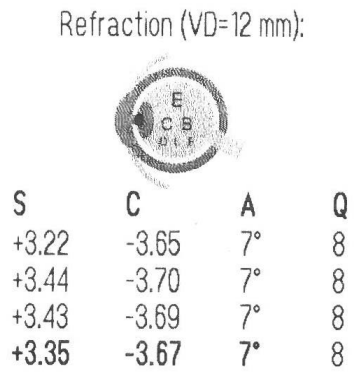


Fig. 10-9: Print AR details: activated

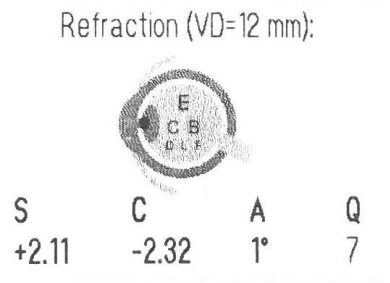


Fig. 10-10: Print AR details: deactivated

Print Kera details

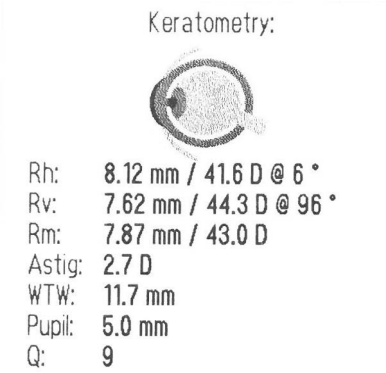


Fig. 10-11: Print Kera details: activated

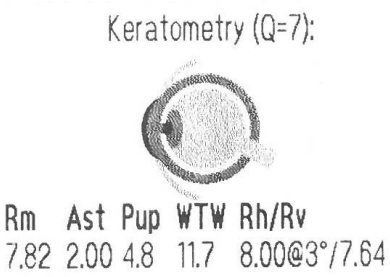


Fig. 10-12: Print Kera details: deactivated

Print AXL details

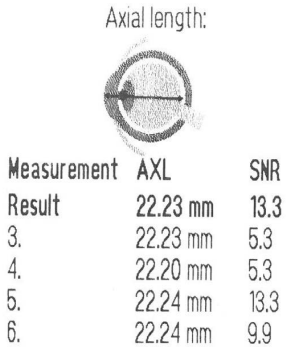


Fig. 10-13: Print AXL details: activated

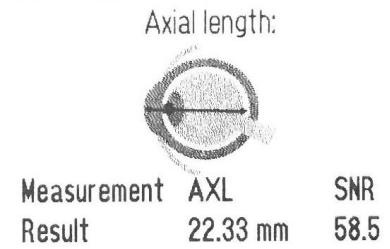


Fig. 10-14: Print AXL details: deactivated

- Print icons: The associated icons for the different measurements are also printed.
- Print risk factors: Risk factors are also printed

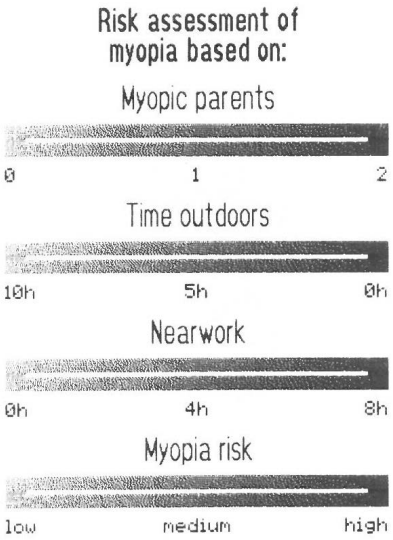


Fig. 10-15: Print risk factors: activated

- Print Ref-details: Refraction details (subjective / objective measurement) are also printed
- Footer: If you want to apply your business or practice name to the printout, enter the name in the lines provided and activate the checkbox in front of them.
- OD/OS: The printout corresponds to the settings: R (right) and L (left) or OD (OCULUS dexter) and OS (OCULUS sinister).

10.5 Settings 5

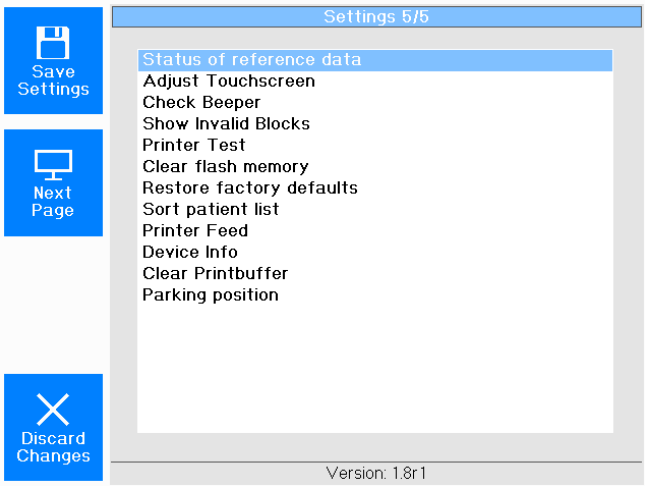


Fig. 10-16: Settings 5

11 Cleaning, Disinfection and Maintenance

To ensure a high degree of device measurement accuracy, OCULUS Optikgeräte GmbH recommends conducting maintenance every 2 years.

➔ If an error occurs, which you cannot rectify , label the device as out-of-order and notify OCULUS Service.

This section describes cleaning the device.

No sterilization is necessary.

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

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

Note

Device damage due to penetrating moisture

➔ Ensure that no liquids can penetrate the device.

11.1 Cleaning, Disinfection, and Servicing Intervals

Interval	Task
Prior to each use	➔ Place fresh paper onto the chin rest or disinfect the chest rest if no paper is used.
Prior to each use	➔ Disinfect the forehead rest.
Monthly Or as required	➔ Clean the housing.
Every 2 years	➔ Maintenance by OCULUS Service or by an authorized dealer

11.2 Cleaning

Caution

Risk of electric shock if the device is not disconnected from the power supply at all poles for these tasks.

➔ Switch the device off → Chapter 5.3 (page 30).

➔ Pull the power plug before cleaning. To do this, pull on the power plug, not on the cable itself.

Required materials:

- Antistatic cleaner for plastic surfaces
- Cleaner for painted surfaces: Mixture of equal parts alcohol and distilled water, possibly with a few drops of household detergent
- Soft, lint-free cloth
- Methanol or pure alcohol or lens cleaning agent
- Gauze moistened with cleaning alcohol
- Soapy solution

Fig. 11-1: Cleaning

No.	Description
1	Forehead rest
2	Lens protection glass
3	Chin rest

11.2.1 Cleaning the Chin and Forehead Rests

Information

The device can remain switched on for this cleaning step.

- ➔ Ensure that no liquids penetrate into one of the openings of the device.
- ➔ Clean the parts before examining the next patient. Use a soft, lint-free cloth for this.
- ➔ Use cleaning alcohol for persistent dirt.

11.2.2 Cleaning the Lens Protection Glass

The housing openings for the lenses are covered by protection glass that must be kept free of dust and dirt.

- ➔ If the lens protection glass is dirty, clean it with a soft, lint-free cloth that is moistened with alcohol.

11.2.3 Cleaning the Housing

Clean the housing once per month or as required.

- ➔ Switch the device off → Chapter 5.3 (page 30).
- ➔ Clean the plastic surfaces on the housing with a soft cloth and a cleaner with an anti-static effect if soiled.
- ➔ When cleaning with a damp cloth, ensure that no liquid penetrates the device.
- ➔ Wipe any residues off painted surfaces using the cleaner for painted surfaces.

11.2.4 Cleaning the Display

- ➔ Use a dry, soft, lint-free cloth to clean the display.

11.3 Disinfection

Recommended material:

- mikrozid® sensitive wipes premium
  Schülke & Mayr
  Various pack sizes, e.g. 2x soft pack of 50/Art. no. 59882

Note

Device damage due to disinfectant solution

The disinfectant solution may damage the surface of the equipment if it is sprayed onto it directly.

➔ Spray the disinfectant solution onto a cloth; do not spray it directly onto the device

➔ Disinfect the forehead rest after each examination.

➔ If you do not use paper on the chin rest, disinfect the chin rest after each examination.

11.4 Maintenance

The device is designed so that regular maintenance is not required. For safety reasons, we recommend inspecting the light-related and electrical values at intervals of two years.

➔ Contact OCULUS Service for this.

Caution

Personal injury or property damage due to invisible laser beams

The device contains a laser in class 1 in accordance with IEC 60825-1:2015 und IEC 60825-1: 2001. This is an enclosed laser system. If the device cover is opened, you may be exposed to invisible laser beams in class 3R (5 mW).

➔ Never open the device.

➔ Only for authorized service staff: avoid looking directly into the laser beam during maintenance.

11.5 Attaching Paper to the Chin Rest

Take the following steps to place the chin rest paper:

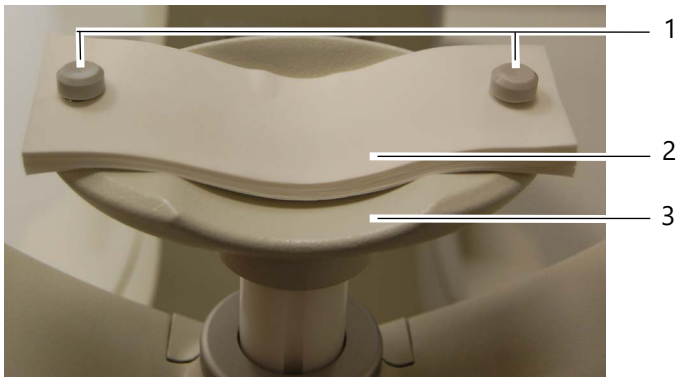


Fig. 11-2: Attaching the chin rest paper

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

➔ Pull the two fastening pins out of the chin rest.
➔ Put the new chin rest paper on so that the holes in the paper and on the chin rest are on top of each other.
➔ Insert both fixing pins into the chin rest.

11.6 Inserting a New Printer Paper Roll

➔ Fold up the display unit

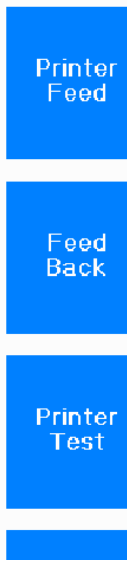


Fig. 11-3: Display to move the printer roll forwards and back

You can move the printer paper forwards and back by pressing the [Printer Feed] and [Feed Back] buttons.

Replacing the printer paper:

- ➔ Press [Feed Back] to move the printer paper back.
- ➔ Take the printer paper out of the holder and pull the metal pin in the center out.
- ➔ Push the metal pin into the a new printer roll and place the printer roll into the holder.
- ➔ Push the paper that is coming from the bottom through the paper guide.

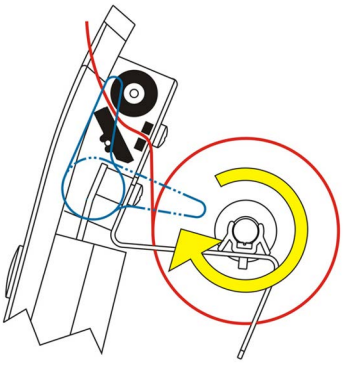


Fig. 11-4: Correct paper guidance

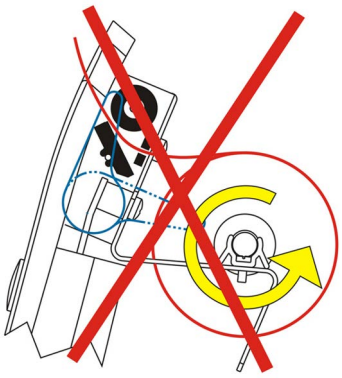


Fig. 11-5: Incorrect paper guidance

- ➔ Press “Printer Feed” so that the printer paper is pulled through the opening.
- ➔ Close the opened display unit.

12 Troubleshooting

Caution

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

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

Contact options:

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

12.1 Basic Troubleshooting Measures

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

12.2 Device-specific Troubleshooting Measures

Fault	Possible cause	Remedy
No function when pressing the on/off switch	■ No device connection to the power supply ■ Mains failure or the socket is not active	➔ Insert the mains cable into the socket or the connection port on the device. ➔ Notify the in-house electrician. ➔ Check that the plug is connected correctly.
Printer does not print	■ No paper	➔ Insert a new paper roll.
Printout contains red stripes	■ End of the paper roll	➔ Insert a new paper roll.

13 Technical Data

Measuring modes

Myopia, AR + K, P + AR + K (optional), PARK + AXL (optional), AXL

Measuring range

Remote PD	20 – 80 mm (in 1 mm steps)
Cornea diameter measuring range	10 – 14 mm (in 0.1 mm steps)
Pupil diameter measuring range	1 – 8 mm (0.1 steps)
Eye-tracking	Automatic alignment of the height (Y direction)
Auto-release	Automatic measurement release

Pachymeter (optional)

Measuring range	200 – 1200 µm)
Measuring points	600
Measuring duration	approx. 1 s
Light source	Blue LED (455 nm UV-free)

Automatic refractometer

Cornea vertex distance (Vertex distance)	0; 10,5; 12; 13.75; 15; 16.5 mm
Sphere	-20 – +22 dpt (VD = 12 mm) (Increments: 0.01; 01.2; 0.25 dpt)
Cylinder	10 D (VD = 12 mm) (Increments: 0.01; 0.12; 0.25 dpt)
Axis	1 – 180° (increments: 1°)
Minimum measurable pupil diameter	2.5 mm

Axis length

Axis length	14 – 40 mm

Classification (in accordance with IEC 60601-1)

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

Power adapter

Power adapter	GSM60B15-P1J (05150725)
Mains connection	80 – 264 V AC
Frequency	47 – 63 Hz
Output voltage	15 V DC/4 A, 60 W max.
Fuses	Integrated overcurrent protection

Other

Dimensions W x D x H	266 x 538 x 493 – 523 mm
Weight	12 kg
Voltage	15 V DC/4 A
Power input, max.	25 W
Printer	Thermal printer
Display	TFT - LCD 5.7" (touchscreen)
Interface(s)	USB
Contraindications	None known
Expected service life	Up to 10 years

Computer

The IT equipment must meet the requirements defined in IEC 62368-1 or IEC 60950.

Recommended computer specifications	Intel® Core™ i5, 500 GB SSD, 8 GB RAM, Windows® 10, Intel® HD Graphics
Recommended monitor size	24“
Recommended monitor resolution	1920 x 1280 pixels
Minimum monitor resolution	1366 x 768 pixels

CE in accordance with the EU Medical Devices Regulation (2017/745)

The device is a category IIa product.

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

Classification in accordance with DIN EN 60825-1:2015 and DIN EN 60825-1: 2001

The device contains a laser in class 1.	
Maximum output value for the laser beam	0.7 mW
Single pulse duration Number of pulses per examination	510 – 760 ms 6x
Wavelength	880 nm

14 Dismantling, Transport and Disposal

The device must be properly dismantled and packed before transporting and storing it. To avoid transport damage, perform the following steps in the subsection.

14.1 Storage Conditions

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

14.2 Transport Conditions

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

14.3 Parking Position

- ➔ Switch the device on at the on/off switch.
- ➔ Select [Settings].
- ➔ Navigate to settings page 5/5.
- ➔ Select the parking position.

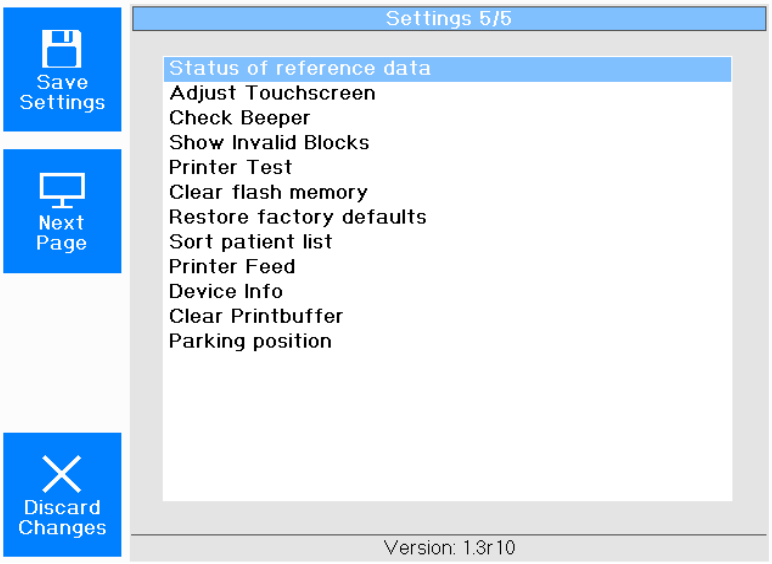


Fig. 14-1: Menu window [Settings 5/5]

The device now returns to the parking position.

14.4 Inserting the Transport Lock

- ➔ Switch the device off at the on/off switch.
- ➔ Remove the mains plug.
- ➔ Pull the mains cable out of the device.
- ➔ Pull the USB cable to the computer/laptop out of the USB port.
- ➔ Open the cover with the display.

Fig. 14-2: Open the cover with the display

- ➔ Move the device over the transport lock receptacle to the adjustment base.

➔ Lock the transport lock.
To do this, push the transport lock down slightly and turn it clockwise into the "Locked" position. The transport lock must engage.

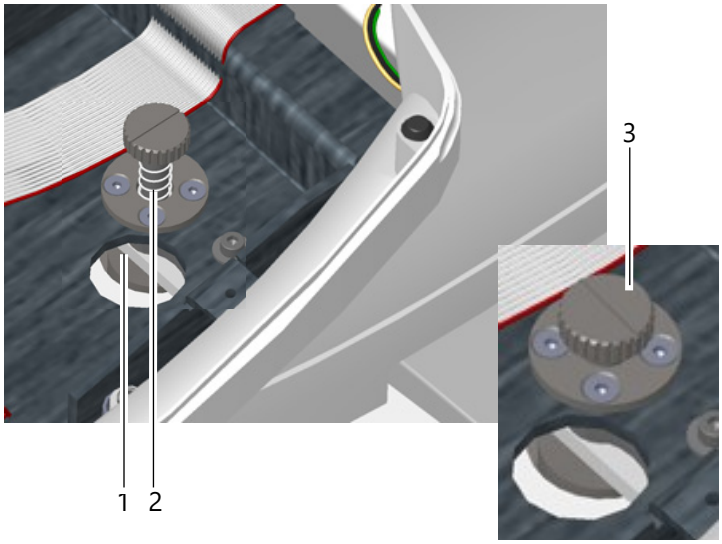


Fig. 14-3: Locking the transport lock

No.	Description
1	Transport lock receptacle
2	Spring
3	"Locked" position

Close the cover with the display → Fig. 14-2 (page 78).

14.5 Joystick Lock

➔ Turn the lever to the right into the limit position.

Fig. 14-4: Joystick lock

No.	Description
1	Lever

The device is now fully prepared and can be packed.

14.6 Transport and Storage

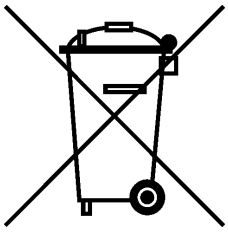
Note

Risk of device damage due to improper transport and storage

If you lift the device by the forehead rest, it may break off.

- ➔ Hold the device from below to lift it.
- ➔ Avoid shock, vibrations, and contamination.
- ➔ Avoid high temperatures and humidity.
- ➔ Check the device for damage each time after transporting.
- ➔ Do not hold the device by the joystick when transporting.
- ➔ Only start up the device around 3-4 hours after transport or storage.
- ➔ The severe temperature change from cold areas to warm rooms can cause the optical components to mist up.

14.7 Disposal



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

➔ Dispose of the device properly.

15 Warranty Terms and Service

15.1 Warranty Terms

Observe the following warranty terms:

- Prior to or while operating the device, it is important that you observe the Instruction for Use and safety instructions.
- According to legal regulations, you are entitled to a warranty for the device.
- Any attempt by unauthorized people to tamper with the device will void all warranty entitlements. This is because improper alterations and repairs can pose considerable risks to the user and the patient.
- Warranty entitlements also expire if unauthorized persons tamper with the supplied computer hardware and software.
- Please report any transport damage to the transport company immediately on or after delivery and have the damage confirmed on the consignment note so that proper claims can be settled.
- In general, our general terms and conditions of business and delivery apply in the version of the date of purchase.

15.2 Assumption of Liability for Functions and/or Damage

OCULUS will only accept responsibility for the safety, reliability and suitability for use of the device if you observe the following provisions:

- Use the device in conformance with this Instruction for Use.
- There are no parts on or in the device that must be maintained or repaired by the user. If assembly work, upgrades, adjustments, servicing (apart from the work mentioned above), modifications or repairs are performed by unauthorized personnel, or if the device is improperly maintained or handled, this will void any liability on the part of OCULUS.
- If the work described above is performed by authorized persons, they are required to provide a certificate stating the type and scope of the repair, including any changes to the nominal data or the work area. The certificate must include the date and execution as well as company details with signature.
- Upon request, OCULUS will provide the authorized person with lists of spare parts and additional descriptive material for this purpose.
- Please be sure to use only original OCULUS parts for repairs.

16 Appendices

16.1 Electromagnetic Compatibility (EMC)

Medical electrical equipment is subject to special precautionary requirements with respect to EMC, and must be installed and operated according to the EMC-Instructions contained in the accompanying paperwork.

OCULUS devices and systems are suitable for use in professional healthcare establishments, e.g. doctor's practices or clinics; however, they may not be used in proximity to HF surgical units or inside of the HF shielded room of an ME system for magnetic resonance imaging. Portable and mobile HF communications appliances can affect medical, electric equipment.

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

Note

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

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

➔ Portable RF communication devices (including peripheral devices such as antenna cables and external antennas) should not be any closer than 30 cm (12 inches) to any part of the device.

Minimal performance quality and essential performance criteria:

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

Caution

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

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

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

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

Article Number	Description	
68100	Myopia Master® Advanced with chin and forehead rest (optional)	
68110	Myopia Master® Advanced without chin and forehead rest (optional)	
68120	Myopia Master® Basic with chin and forehead rest	
68130	Myopia Master® Basic without chin and forehead rest	
10010848	Myopia Master® Optiswiss with chin and forehead rest	
5200905	EU cable	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, Argentina (optional)	1.8 m
05150725	Power adapter GSM60B15-P1J	
015692000010	USB FS Med isolator	
05200600	USB-mini cable	1 m

16.2 Guidelines and Manufacturer's Declaration – Electromagnetic Emissions

Electromagnetic Emissions		
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.		
Emission 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	

16.3 Guidelines and Manufacturer's Declaration – Electromagnetic Immunity

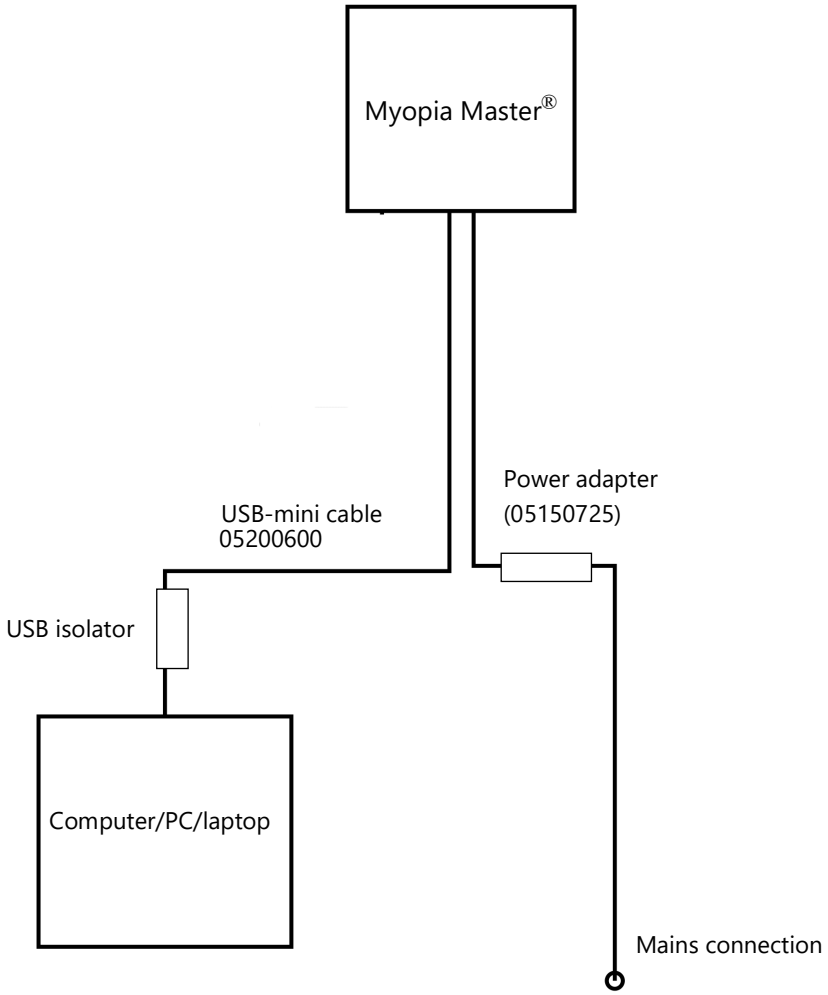
Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	± 8kV ± 15kV	Floors should be made of wood or concrete or covered with ceramic tiles. If the floor is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

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

16.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the Myopia Master®			
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.			
	Separation distance according to frequency of transmitter m		
Rated maximum output power of transmitter W	150KHz to 80Mhz d = 1.2 √P	80MHz to 800MHz d = 1.2 √P	800MHz to 2.5GHz d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.80	3.80	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1:	At 80MHz and 800MHz, the separation distance for the higher frequency range applies.		
Note 2:	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		

16.5 Connection Diagram



16.6 GSM60B15-P1J (05150725) Data Sheet

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,2.1φ x5.5φ 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

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

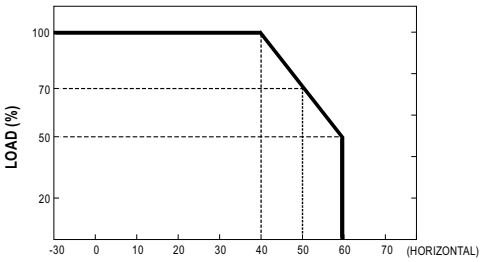
SPECIFICATION

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)								

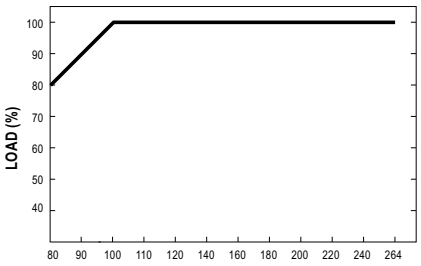
File Name:GSM60B-SPEC 2016-03-16

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

■ Derating Curve

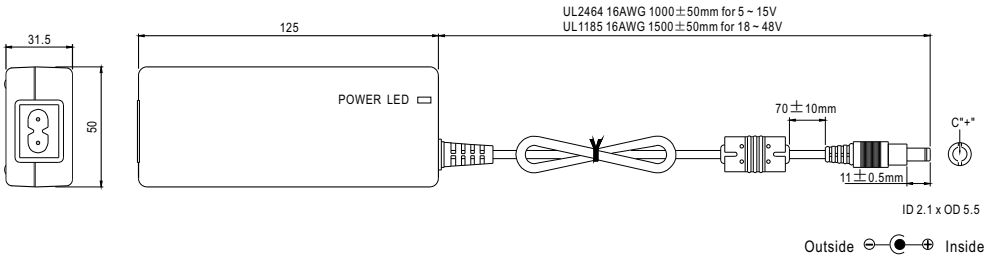


■ Static Characteristics



■ 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

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16.7 Instructions for Integration into an IT Network

The device in combination with the connected computer and the device software that runs on it form a programmable medical electrical system (PEMS system) in accordance with IEC 60601-1.

It is essential to observe the section → Chapter "Device Description" (page 18) in the "Safety Instructions" → Page 10 section in the device's Instruction for Use.

Please observe the instructions for integrating the PEMS in an IT network:

The purpose of integrating the PEMS into an IT network may be:

- Licensing by the local license server
- Storing and pulling up examination data on a local network drive
- Printing
- Data export

Required characteristics of the IT network that the PEMS is to be integrated:

- Give preference to a wired LAN connection
- Ipv4 network
- Fast Ethernet (100 Mbit/s minimum)

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

- License: Required open ports: 3968 TCP; 51371 - 51372 UDP
- Storing, printing, data export: File and printer sharing for Microsoft networks (SMB 3.0 or higher – required open port: 445]

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

- Read the section on cybersecurity → Page 18 under "Safety Instructions" → Page 10 in the device's Instruction for Use.
- See Instruction for Use "Floating License Key – License management for software options"

The intended flow of information between PEMS, the IT network and other devices in the IT network and the intended routing by the IT network

- License handling from the local license service to PEMS and vice versa
- Storage and data export to local network storage and loading from local network storage
- Printing on local printer

List of potential risks resulting from the IT network being unable to provide the functions required to meet the purpose of integrating the PEMS into the IT network:

- Loss of data
- Unsuitable data exchange
- Data corruption
- Unsuitable time-based data allocation
- Unexpected data reception
- Unauthorized access to data

Connecting the PEMS to an IT network that includes other devices may result in risks for patients, operators, and third parties that have not yet been identified.

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

Any changes to the IT network later on may involve new risks and require additional analyses.

Changes in the IT network may include:

- Changes in IT network configuration
- Connecting additional items to the IT network
- Disconnecting elements from the IT network
- Updating the devices connected to the IT network

G/68100/EN
Rev12

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